

# WHALETEQ AECG100

# User Manual



Revision 2024-04-30
AECG100 PC Software Version 1.0.7.3



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# 1 Product Introduction

WhaleTeq's AECG100 is a multifunction testing unit, which could function as ECG (Electrocardiogram) tester, PPG (Photoplethysmography) tester, PWTT (Pulse Wave Transit Time) tester, and SpO<sub>2</sub> (Peripheral Oxyhemoglobin Saturation) tester parameter adjustment control. The main ECG module is a single-lead ECG tester that could produce signals according to IEC standards for medical equipment. The users can use it with the single-channel or dual-channel PPG module of their choice. The single-channel PPG module provides a green LED, offering simulated PPG heart rate signals; besides, the dual-channel PPG module provides red LED and infrared LED, simulating different SpO<sub>2</sub> blood oxygen levels. This tester also supports "4.3.1 PPG simulator test" of IEC 63203-402-3:2024.

When the ECG module and the PPG module work at the same time, the users can get the pulse wave transit time (PWTT) by adjusting the time difference (PTTp or PTTf) between the peak value of ECG to the peak or the valley of the PPG wave. The parameters can be used for improving the wearable devices on measuring blood pressure and calculating the degree of arteriosclerosis. This method can significantly increase the accuracy of the blood pressure measurement.



# 2 System Setup

## 2.1 Product Appearance (AECG100 + Reflectance Modules)

The left figure shows the AECG100 main console, the upper right figure shows the reflectance single-light module, and the lower right figure shows the reflectance SpO<sub>2</sub> module.



Figure 1: Product Appearance (1)

- (1) **AECG100 Main Console:** The ECG test module of the AECG100 Test System.
- (2) **PPG Fixture Mounting Base:** The fixture mounting base is provided for the user to develop the fixture to fasten DUT onto PPG modules of AECG100.
- (3) **LA/L Electrode:** Connect to DUT's matching electrode to output ECG signal.
- (4) **RA/R Electrode:** Connect to DUT's matching electrode to output ECG signal.
- (5) **RL2/N2 Electrode:** Connect to DUT's matching electrode.
- (6) **RL1/N1 Electrode:** Connect to DUT's matching electrode.
- (7) AUX PWR Port: Connect to a computer's USB port or a USB hub for power supply, and this USB port is not for data transferring. We strongly suggest connecting this USB port to prevent the



- power supply shortage.
- (8) **USB Port:** Connect to the computer's USB port for data transferring and power supply. If connect this USB port to a USB hub, AECG100 will operate in the standalone mode.
  - Note: Please refer to "2.5.2 Standalone Operation" for more information.
- (9) **Power Switch:** To control power on and power off.
- (10) Power Indicator:
  - Red LED remains on or no LED display: The AECG100 system is crashed and needs further troubleshooting. Please see Chapter 7 Troubleshooting for further details.
  - Red LED flashing: AECG100 is in standalone operation mode.
     The flash frequency is 1 time per second.
  - Green LED flashing: AECG100 is in PC software operation mode. The flash frequency is 1 time per second.
- (11) **GND Terminal:** In ECG test mode, we suggest putting a metal plate under AECG100 and DUT. Then, connect the AECG100 GND terminal and DUT ground to the metal plate to lower the noise. Please see section 2.3 for the set-up illustration.
- (12) **Monitor Port:** The ECG output monitor port to enlarge the ECG signal for 1,000 times so that the user can measure via an oscilloscope.
- (13) **Mode A/B/C LEDs:** To switch among 3 saved modes under standalone operations to output different signals. The LEDs light with corresponding modes.
  - When AECG100 is connected to a computer, Mode A/B/C parameters can be saved via the Signal tab Standalone option of AECG100 PC software (see below figure).



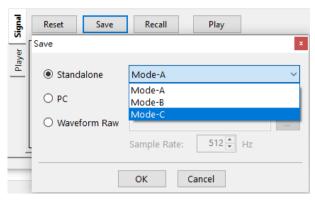


Figure 2: Set Mode A/B/C

- Under standalone operation, the user can press the button to switch among the modes. There is a total of 3 modes to choose from, and only the LED light of the chosen mode will be on. The default mode is Mode A.
- Under standalone operation mode, switching modes require loading the restored parameters while LED flashes 4 times per second. The LED remains on when the restored parameters are loaded successfully.
- Mode A/B/C: The default parameters are for PWTT tests.

Note: When testing AECG100 main console with different PPG modules, re-saving Mode A/B/C is required in order to obtain desired test results.

- (14) Mode Selection Button: To select amongst Mode A/B/C.
- (15) **DB15 Port (Female):** The port on the AECG100 main console to be connected with various PPG modules.
- (16) **DB15 Port (Male):** The port on the PPG module to be connected with that of (1)AECG100 main console.
- (17) **LED & Photodiode (PD):** Receiving the LED signal of DUT and emitting the LED signal to DUT.
- (18) LED Monitor Port: This is for the PPG-1R-525 PPG module to connect to the oscilloscope and measure the output voltage of the green LED AC signal. The output voltage is 100 times of



original voltage.

- (19) PD Monitor Port: This is for the PPG-1R-525 PPG module to connect to the oscilloscope to measure electrical signal transferred by AECG100 PD. This port is for monitoring the optical signal of DUT's green LED.
- (20) **LED1 Monitor Port:** This is for the PPG-2R-880 or the PPG-2R-940 PPG module to connect to the oscilloscope and measure the output voltage of the red LED AC signal. The output voltage is 100 times of original voltage.
- (21) **PD1 Monitor Port:** This is for the PPG-2R-880 or the PPG-2R-940 PPG module to connect to the oscilloscope to measure electrical signal transferred by AECG100 PD. This port is for monitoring the optical signal of DUT's red LED.
- (22) **LED2 Monitor Port:** This is for the PPG-2R-880 or the PPG-2R-940 PPG module to connect to the oscilloscope and measure the output voltage of the infrared LED AC signal. The output voltage is 100 times of original voltage.
- (23) **PD2 Monitor Port:** This is for the PPG-2R-880 or the PPG-2R-940 PPG module to connect to the oscilloscope to measure electrical signal transferred by AECG100 PD. This port is for monitoring the optical signal of DUT's infrared LED.



# 2.2 Transmittance SpO<sub>2</sub> module (PPG-2TF-660)



Figure 3: Product Appearance (2)

- (1) **Index Finger Simulation**: To simulate the scenario of an index finger using an oximeter.
- (2) **EXT DB15 Connector**: To connect with AECG100.
- (3) **PD Monitor Port**: With MCX to BNC port, PPG-2TF-660 can be connected to an oscilloscope to measure the optical signal sent by the red LED of the DUT to the PD.
- (4) LED Monitor Port: With MCX to BNC port, PPG-2TF-660 can be connected to an oscilloscope to measure the voltage of the AC analog signal driving the red LED and the switch status of DUT R/IR LED. This voltage is 100 times higher than the original driving voltage.
- (5) **Standard Accessory**: MCX (RF) male to BNC cable \* 2 (K29-0300601)
  - Note: The "2TF660" represents the "PPG-2TF-660" in the following contents and figures.



# 2.3 Product Wiring Diagram

- Main Console and PPG Module Connection:
  - Directly connect with PPG module



Figure 4: Direct Connection between AECG100 and PPG Module

Connect with PPG module with DB15



Figure 5: Connection through DB15



Figure 6: Direct Connection between AECG100 and PPG-2TF-660



ECG Test Mode



Figure 7: ECG Test Mode Product Wiring Diagram

Note: When testing ECG only, the system will not be forced to connect with the reflectance module.

ECG Test Mode with Noise Reduction Suggestion (see 2.1 (11) GND)

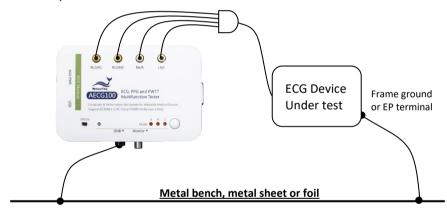


Figure 8: ECG Test Mode with Noise Reduction Product Wiring Diagram

PPG Heart Rate Test Mode



Figure 9: PPG Heart Rate Test Mode Product Wiring Diagram



Pulse Wave Transit Time Test Mode



Figure 10: Pulse Wave Transit Time Test Mode Product Wiring Diagram

SpO<sub>2</sub> Test Mode



Figure 11: SpO₂ Test Mode Product Wiring Diagram

• Auto Sequence Test Mode



Figure 12: Auto Sequence Test Mode Product Wiring Diagram



## 2.4 DUT Best Position Adjustment

# 2.4.1 Reflectance SpO<sub>2</sub> Testing Device



Figure 13: Reflectance PPG-1R-525 Module (as example)

- Step 1: Line up the DUT's LED with the PD of AECG100.
- **Step 2:** Confirm the position of the DUT's LED and AECG100's PD are lined up: Connect AECG100 to the computer and power on AECG100. Download, install and execute the AECG100 software on the computer, and see if the pulse signals are visible on the PD's sampling tab. If so, the LED of the DUT is lined up with AECG100's PD.
- **Step 3:** Confirm the positions of the DUT's PD and AECG100's LED: Execute the AECG100 software, and under PPG test mode, set DC=500mV AC=30mV BPM=60, and check if DUT can get the heart rate of 60 BPM.
  - If so, then the relative positions of DUT's PD and AECG100's LED are correct.
  - If not, try to modify the DC value by adding or reducing 50mV and check again to see if DUT can get the heart rate of 60. If the heart rate is still not found,



reposition DUT and repeat Step 2 and Step 3 until DUT can get the heart rate.

# 2.4.2 Transmittance SpO<sub>2</sub> Testing Device



Figure 14: Transmittance SpO<sub>2</sub> Module (PPG-2TF-660)

**Step 1:** Clamp the DUT to the index finger simulation on the PPG-2TF-660, and plug the DB15 connector on the PPG-2TF-660 into the DB15 port on the AECG100 main console. Plug the USB Type-B connectors of the USB cables provided to the AUX PWR port and USB port on the AECG100 main console; at the other end of the USB cables, plug the USB Type-A connectors into a laptop or a PC. Switch the power switch located at the lower-left corner on the top of the AECG100 main console to "On" to power on it.

Note: Align the LED and PD on DUT to the PD and LED on the PPG-2TF-660 respectively.

**Step 2:** Go to the <u>official AECG100 webpage</u> to download and install the AECG100 software. Complete the installation and click the AECG icon to start the test. Select the Auto Test SpO<sub>2</sub> tab and check the "signal strength" on the software interface. It shows the optical signal intensity detected.





Figure 15: Signal Detection

Note: Because the light intensity of the DUT varies, the "signal strength" may not be filled. Please adjust the position and find a relatively large signal value.

#### 2.5 Operation Modes

AECG100 can be controlled through PC software operation or standalone operation.

#### 2.5.1 PC Software Operation

AECG100 must be connected to the computer and the PC software should be installed properly. AECG100 offers a total of 4 test modes, including ECG test mode, PPG test mode, PWTT test mode, and SpO<sub>2</sub> test mode. Auto Sequence test mode can combine any of the 4. Please see chapter 4 Software Interface for a detailed operation description.

 ECG Test Mode: AECG100 can conduct single-lead ECG testing under this test mode. All the ECG-related standards are supported including a series of single-channel testing, such as sensitivity, frequency response, input impedance, and so on. This test mode is compliant with international standards of IEC 60601-2-47, YY 0885, and YY 9706.247.



- PPG Mode: Users can choose different testing waveforms and adjust waveform parameters under this test mode. To test the PPG heart rate accuracy of the DUT, AECG100 can simulate human skin reflection signals and noise. Moreover, users can record or program a set of signals, and play the signals using this test mode. It is a very useful tool when developing the algorithm.
- PWTT Mode: The device can send ECG and PPG signals simultaneously under this test mode. By adjusting the time difference of the two signals, users can improve the blood measurement algorithm of wearable devices or calculate the degree of arteriosclerosis.
- Auto Test SpO<sub>2</sub> Mode: Apply only to PPG-2TF-660 module. When PPG-2TF-660 detects the signals from the DUT, the system will identify the parameter settings such as Trigger Level and DC value of R/IR, and record Trigger Level to SpO<sub>2</sub> and PPG tabs. Users can adjust the pulse amplitude, transmission rate, ambient light value and quick verification.
   Note:
  - 1. This mode is mainly for developers to quickly test for reference, not for after-sales calibration and testing on oximeters. If users require development tests on  $SpO_2$  parameters and specifications, please use the  $SpO_2$  mode.
  - 2. If the DUT can't measure the  $SpO_2$  value or its  $SpO_2$  measured value fluctuates, please adjust the measuring position or select another transmission rate to test. At the same time, checking the human body detection algorithm of the DUT is suggested.
  - If further assistance is needed, please contact WhaleTeq.
- SpO<sub>2</sub> Mode: Under this test mode, users can individually



adjust the AC/DC ratio of R and IR LED. This is to simulate the light absorption degree so that DUT can determine the  $SpO_2$  value after receiving AECG100's optical signals.

 Auto Sequence Mode: User can program a playlist including play time and sequence of different waveforms. The playlist can be saved as a file for repeated playback. Users can save a significant testing time of switching among different waveforms and parameters.

# 2.5.2 Standalone Operation

Up to 3 quick test modes can be stored in AECG100. This is designed for quick testing without opening AECG100's PC software. A USB hub can be used as a power source.

## 2.6 Reflectance PPG Module Fixture Mounting Base Dimensions

Below are the dimensions of PPG module fixture mounting base. User can develop a fixture to fasten DUT onto the PPG module fixture mounting base. AECG100 3D Model can be downloaded here.

 Mechanical Drawing (Fixture mounting base of PPG-1R Module)

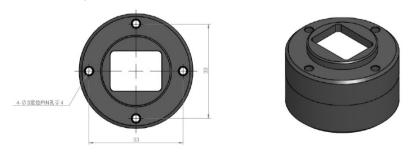


Figure 16: Fixture Mounting Base of PPG-1R Module



Mechanical Drawing (Fixture mounting base of PPG-2R modules)

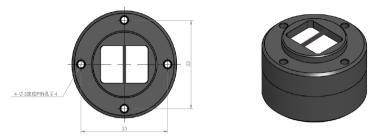


Figure 17: Fixture Mounting Base of PPG-2R modules

## Sectional View:

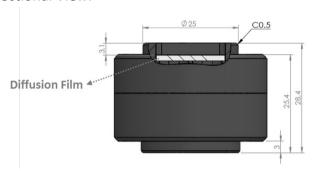


Figure 18: Sectional View

# 3 Software Installation

# 3.1 System Requirements

AECG100 Test System uses a Windows PC to connect and control the USB module of AECG100 unit.

# PC requirements:

- Windows PC (Windows 7 or later, suggest to use the genuine version)
- Microsoft .NET 4.0 or higher



- Administrator access (essential for installing software, driver, and Microsoft .Net Framework)
- 1.5 GHz CPU or higher
- 1GB RAM or higher<sup>1</sup>
- USB port

Note: If this is the first time using WhaleTeq's product, please refer to the two sections below (3.2 and 3.3) to confirm that the USB driver and Microsoft .Net Framework 4.0 are both installed.

#### 3.2 USB Driver Installation

If Windows device manager can't recognize WhaleTeq's product, please follow the below instructions to Install Microchip® USB driver.

## Microsoft Windows 10

 As Windows 10 has built-in Microchip® USB Driver, there are no needs to install any drivers. It just takes a while for Windows Device manager to recognize and install the driver.

#### Microsoft Windows 8 and Windows 8.1

 If Windows 8 and Windows 8.1 can't recognize AECG unit, please download "mchpcdc.inf" from WhaleTeq website. This driver is provided by Microchip® to be used with PIC microprocessors having built-in USB function.

<sup>&</sup>lt;sup>1</sup> Relative to normal PC processing, there is no special use of PC speed. However, there has been noted a slow increase in system RAM usage over long periods of time up to 30-40MB (related to MS Windows "garbage collection"). PCs with only 512MB or less installed and are running several other programs (in particular, Internet Explorer), may exceed the available RAM, requiring access to the hard drive and dramatically impacting speed. In this case, streaming interruptions and other problems may occur.



- As mchpcdc.inf provided by Microchip® does not contain digital signature, please disable driver signature enforcement in Windows 8 and Windows 8.1. Please click <u>here</u> to watch the tutorial video.
- When the USB module is connected for the first time, select manual installation, and point to the folder containing the above file. Then continue to follow the instructions to finish the installation. There may be a warning that the driver is not recognized by Windows®, and this can be ignored. Please click here to watch the tutorial video.

# Microsoft Windows 7

- If Windows 7 can't recognize AECG100 unit, please download "mchpcdc.inf" from WhaleTeq website. This driver is provided by Microchip® to be used with PIC microprocessors having built-in USB function.
- When the USB module is connected for the first time, select manual installation, and point to the folder containing the above file. Then continue to follow the instructions to finish the installation. There may be a warning that the driver is not recognized by Windows®, and this can be ignored. Please click here to watch the tutorial video.

#### 3.3 Microsoft .Net Framework 4.0 Installation

WhaleTeq software is developed based on Microsoft .Net Framework 4.0. If AECG software fails to execute properly, please check whether Microsoft .Net Framework 4.0 or higher versions was installed in the operation system.



If your PC hasn't installed Microsoft .Net Framework 4.0 or higher versions, please download from Microsoft website. Please click <a href="here">here</a> to watch the tutorial video (from 2:03).



## 4 Software Interface

# 

Figure 19: Button Functions in General Mode

## 4.1.1 PPG Configuration

This function belongs to the PPG module and configures PWTT, SpO<sub>2</sub>, PPG, and Auto Sequence (where applicable) tabs. Different DUTs might have different signal processing, so AECG100 provides the "Inverted" function to output the inverted waveform, which can be confirmed on an oscilloscope. Check "Synchronized Pulse" to enable the synchronization behavior between AECG100 LED and DUT LED.

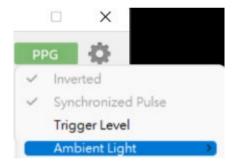


Figure 20: PPG Configuration

Trigger level: Set the trigger level that drives the AECG100 LED to turn on after the AECG100 PD detects the value of the LED brightness of the DUT.

Ambient light: Available when connecting the transmittance  $SpO_2$  module PPG-2TF-660 to the AECG100 main console to superimpose 14 types of simulated indoor/outdoor ambient light signals to the output waveform.



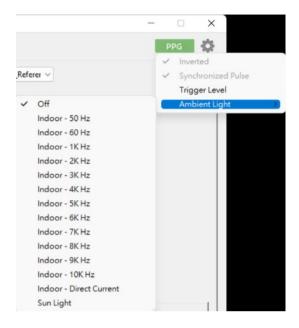


Figure 21: Trigger level and Ambient light

## **4.1.2** Settings

Applies to all tabs unless specified otherwise.

- Select "Check for Updates" to ensure whether there are software or firmware updates.
- Select "Help" to see the instruction of the SpO<sub>2</sub> table and WhaleTeq file format.
- Select "Language" to switch among English, simplified Chinese, and traditional Chinese.
- Select "Restore Factory Settings" to reset the following back to default settings: LED Level of PWTT, SpO<sub>2</sub>, and PPG tabs, and Trigger level from *Sampling* of SpO<sub>2</sub> and PPG tabs.
- Select "Device Information" to check the device serial number.
- Select "License" to confirm AECG100 device ID and check the activation status of ECG standard assistant software and PPG/ PWTT database player.
- Select "About" to check the software version and device function introduction.



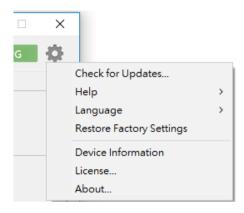


Figure 22: Settings Function List

# 4.1.3 Firmware/FPGA Update

The steps for updating firmware and FPGA are identical except that the file they need for updating is different.

**Step 1:** Click the setting button in the upper-right corner and select "About".

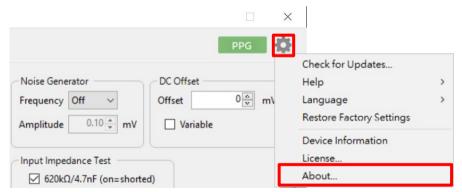
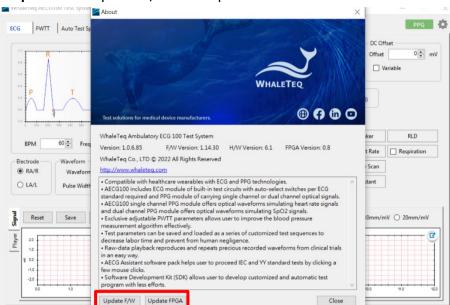


Figure 23: Firmware/FPGA Update (Step 1)





Step 2: Click "Update F/W" or "Update FPGA".

Figure 24: Firmware/FPGA Update (Step 2)

**Step 3:** Select the file for updating firmware or FPGA, then click "Open". Note: The screenshot below shows a file for updating FPGA.

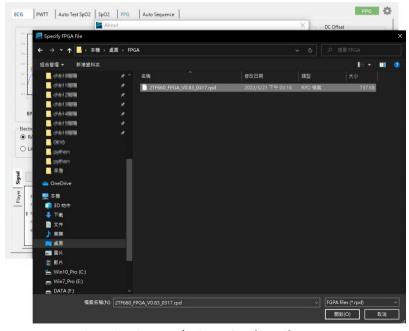
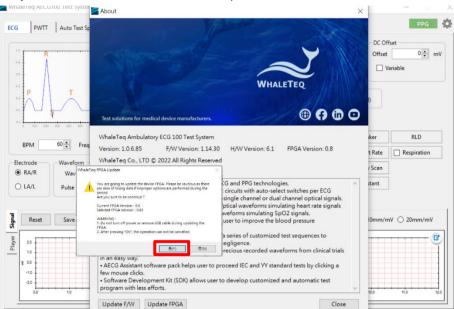


Figure 25: Firmware/FPGA Update (Step 3)





Step 4: Click "Yes" to activate the update.

Figure 26: Firmware/FPGA Update (Step 4)

# **Step 5:** The update is processing. After it's complete, please reboot the AECG100 for use.



Figure 27: Firmware/FPGA Update (Step 5)



#### 4.2 ECG Mode

ECG Mode can be separated into 2 sections. The upper section is for waveform selection and test parameter setting; the lower section is for waveform playback display and setting.

# Upper section:

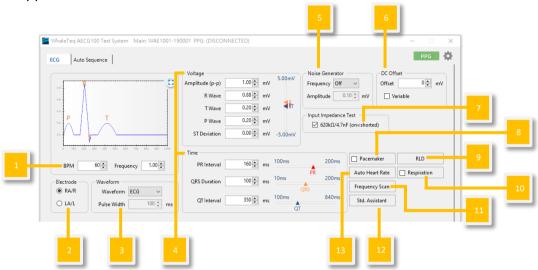


Figure 28: ECG Mode Interface Buttons

- (1) **BPM:** Adjust for different BPM (Beat-Per-Minute).
- (2) Output Electrode Selection: Choose the output electrode.
  - RA/R: Right Arm Electrode
  - LA/L: Left Arm Electrode
- (3) **Output Waveform Selection:** Select to output different waveform types (ex. Sine, Triangle, Square...).
- (4) **Output Waveform Parameter:** Adjust voltage and time parameters of standard waveforms and pulse waveforms.
- (5) **Noise Simulation:** To simulate noise with different frequency and amplitude.
- (6) DC Offset (DC Fine-tune): To add a DC offset of +300mV, 0 or -300mV to the output signal.
- (7) **Input Impedance Test:** To add  $620k\Omega/4.7nF$  to the output signal.



This is for ECG DUT to measure the amplitude and evaluate the input impedance of ECG DUT.

(8) Pacemaker: Output simulated ECG pacemaker signal to ECG DUT.

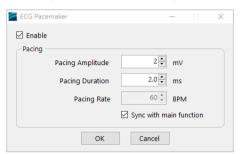


Figure 29: Pacemaker Simulation Setting

- (9) **RLD:** Right Leg Detection for measurement of reference voltage difference of DUT.
- (10) **Respiration:** AECG100 uses the impedance pneumography method to simulate the impedance changes of human skin when breathing. "Respiration Rate" is the number of breaths taken during 60 seconds intervals. "Basic Level" refers to the impedance of human skin, and "Variations" refers to the impedance changes while breathing. Respiration "Ratio" is the ratio of inhalation to exhalation. The "Apnea Selection" consists of "Duration" (apnea length) and "Cycle" (regular breathing time). Please note that "Duration" (apnea length) is not included in "Cycle" (regular breathing time).



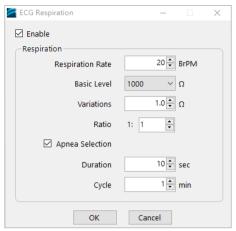


Figure 30: ECG Respiration Setting

(11) **Frequency Scan:** Users can set the amplitude, start frequency, stop frequency, and duration. This function is for testing the frequency response of ECG DUT by using the sine wave.

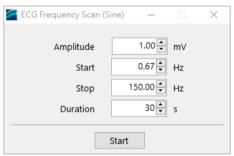


Figure 31: ECG Frequency Scan Setting

(12) **Std. Assistant software:** Standard assistant software supports international medical standards of IEC 60601-2-47, YY 0885, and YY 9706.247. It simplifies the standards into test parameters, test criteria, and test sequences. This is an optional function, please contact WhaleTeq for detailed information and purchase.



(13) **Auto Heart Rate:** By using the ECG waveform, the auto heart rate function can set different test combinations of BPM, QRS Amplitude, QRS duration, and interval.



Figure 32: ECG Auto Heart Rate Testing Setting

#### Lower section:

- \* The UI is illustration only. For detailed display please check on oscilloscope.
- (1) **Signal tab:** Users can reset/ save/ recall/ play waveform with preset parameters.



Figure 33: Signal tab

(2) Player tab: Users can load/ play/ loop raw data file.



Figure 34: Player Tab



- (3) **Reset:** Resume the default setting in the upper section.
- (4) **Save:** Save the preset test parameters from the upper section into Standalone (device Mode A/B/C), PC file (in \*.ecg), or Waveform Raw (in \*.txt) format.

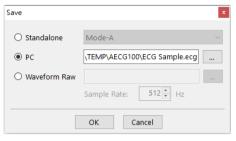


Figure 35: Save Function

Note: Standalone (device Mode A/B/C) and PC file can be used in (1) Signal tab "Recall" and Auto Sequence Mode. Only Waveform Raw can be played in (2) Player tab.

- (5) Recall: Load the previously saved test parameters stored in Standalone (device Mode A/B/C) or as a PC file (\*.ecg format).
- (6) Play/ Stop: Play the selected waveform with preset parameters.
  Once stopped, play from the beginning.
- (7) **Waveform Display Scale**: Adjust the display scale for 5mm/mV, 10mm/mV, or 20mm/mV.
- (8) **Display Window Enlargement:** Click to enlarge the display window.
- (9) Load: User can load and play raw data via selecting the raw data file either saved from (1) Signal tab "Waveform Raw" or selfconstructed according to WhaleTeq rule (click "Help" for more details). The total length shows the total playback time of raw data.

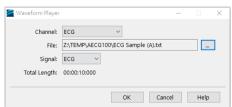


Figure 36: Load and Play Settings



- (10) **Play/ Stop:** Play the selected raw data file in \*.txt format. Once stopped, play from beginning.
- (11) Loop: Check to replay the raw data file repeatedly.
- (12) Current Position: Display the timing of the played raw data.

#### 4.3 PPG Mode

It requires to connect PPG-1R-525, PPG-2R-880, PPG-2R-940 or PPG-2TF-660 module to initiate PPG test mode. PPG Mode can be separated into 2 sections. The upper section is for waveform selection and test parameter setting; the lower section is for waveform playback display and setting.

## Upper section:

The software UI is for AECG100 main console unit with PPG-1R-525

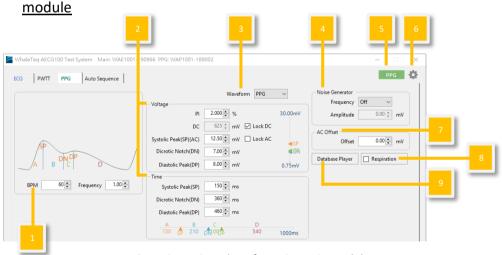


Figure 37: PPG mode UI for PPG-1R-525 module



# <u>The PPG mode UI is for AECG100 main console unit with reflectance SpO<sub>2</sub> module (PPG-2R-880/PPG-2R-940)/transmittance SpO<sub>2</sub> module (PPG-2R-880/PPG-2R-940)/transmittance SpO<sub>2</sub> module</u>

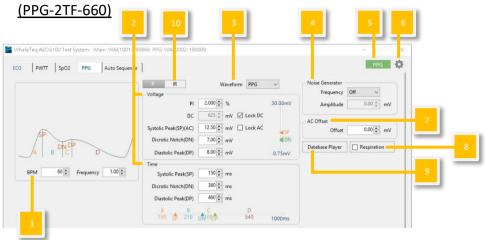


Figure 38: PPG mode UI for reflectance SpO<sub>2</sub> module and transmittance SpO<sub>2</sub> module

- BPM: Adjust for different heart rates. The value is from 10 BPM to 300 BPM.
- (2) Output Waveform Parameter: Adjust voltage and time parameters of standard waveforms and pulse waveforms.
- (3) **Output Waveform Selection:** Select to output different waveform types (ex. PPG, Sine, Triangle, Square...).
- (4) **Noise Simulation:** To simulate noise with different frequency and amplitude.
- (5) **PPG Config:** Refer to 4.1 General 4.1.1 PPG Configuration.
- (6) Setting: Refer to 4.1 General 4.1.2 Settings.
- (7) AC Offset: Shift the signal upwards by the value of AC offset.
- (8) **Respiration:** Add respiration modulation to the PPG function. Baseline Modulation (BM), Pulse Amplitude Modulation (AM), and Frequency Modulation (FM) are the available signals for breath modulation.
  - i. **Baseline Modulation (BM)**: Change in intrathoracic pressure when breathing causes changes in venous blood return, which changes the baseline of PPG <sup>[1]</sup>. Also called DC modulation.
  - ii. Pulse Amplitude Modulation (AM): The heart axis deviates when

Addison, P.S., Watson, J.N., Mestek, M.L. et al. Developing an algorithm for pulse oximetry derived respiratory rate (RRoxi): a healthy volunteer study. J Clin Monit Comput 26, 45–51 (2012). https://doi.org/10.1007/s10877-011-9332-y



- breathing. Inspiration corresponds to decreased left ventricular (the main pumping chamber) stroke volume, which leads to decreased pulse amplitude [1].
- iii. **Frequency Modulation (FM)**: As a result of autonomic nervous system activity fluctuation, breathing leads to changes in heartbeats <sup>[1]</sup>. Pulse period varies over the respiratory cycle: Heart rate increases during inspiration; decreases, expiration. Also known as RSA (respiratory sinus arrhythmia) <sup>[2]</sup>.

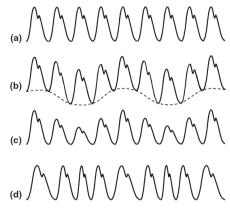


Figure 39: PPG Respiration and Modulation [1]

a) Unmodulated waveform; b) Baseline; c) Amplitude; d) Frequency

Users can choose the appropriate modulation signal with different parameters (respiration rate, inhale/ exhale ratio, and variation range) to conduct the signal simulation.

- "Respiration Rate" is the number of breaths taken during 60 seconds intervals, ranging from 1 to 150 BrPM.
- Respiration "Ratio" is the ratio of inhalation to exhalation, up to 1:5.
- "Variation" adjustment ranges -16  $^{\sim}$  16%. BM refers to the baseline drift of the PPG amplitude during one breathing cycle, with baseline drift ranging from -16 to 16%. In the contrast, AM

Addison, P.S., Watson, J.N., Mestek, M.L. et al. Pulse oximetry-derived respiratory rate in general care floor patients. *J Clin Monit Comput* 29, 113–120 (2015). https://doi.org/10.1007/s10877-014-9575-5

Paul S. Addison. Respiratory effort from the photoplethysmogram. *Medical Engineering & Physics* 41, 9-18 (2017). https://doi.org/10.1016/j.medengphy.2016.12.010.



means that the amplitude itself of the PPG wave changes -16  $^{\sim}$  16% of the original amplitude during one breathing cycle. FM shifts the pulse duration instead of amplitude: in one breathing cycle, the interval change between the heartbeat is -16  $^{\sim}$  16% of the original set heartbeat.

The adjustment method is shown in the figures below.

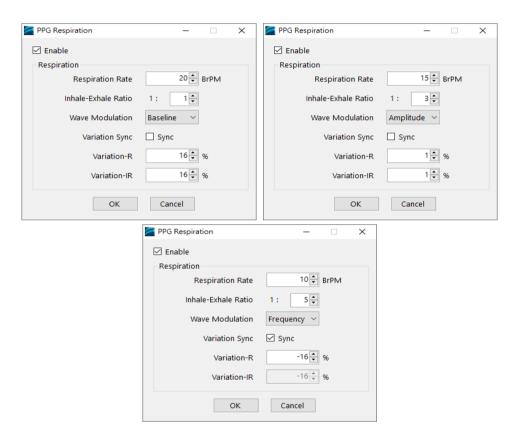


Figure 40: PPG Respiration Setting



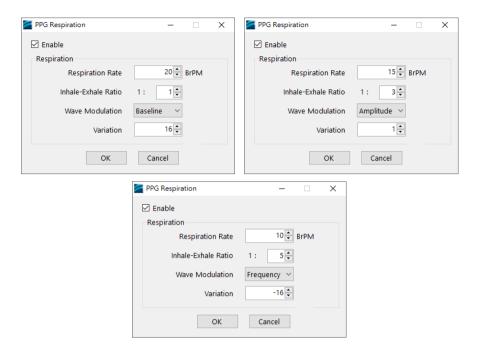


Figure 41: PPG Respiration Setting

(9) Database Player: The WhaleTeq database includes 30 records of PPG waveforms recorded in clinical trials to be used in PPG test mode and 10 records of PPG and ECG waveforms recorded in clinical trials to use in PWTT test mode. The recorded disease waveforms, including AF (Atrial Fibrillation), APC (Atrial Premature Complexes), VPC (Ventricular Premature Contraction), and first-degree AV block. The first record is available for trial purpose and illustrated in Player tab from the lower section. Please contact WhaleTeq to purchase the completed database playback function.



Figure 42: PPG Database Player



(10) **R/IR Test Parameter Selection:** Click to see settings of Red LED or Infrared LED.

#### Lower section:

<u>The software UI is for AECG100 main console unit with PPG-1R-525</u> module

\* The UI is illustration only. For detailed display please check on oscilloscope.

# Signal Tab



Figure 43: Signal Tab

## Sampling Tab: Sampling PD

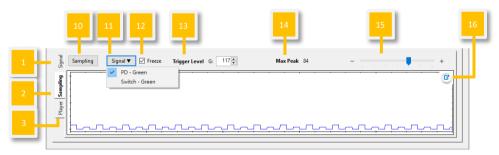


Figure 44: Sampling PD

# Sampling Tab: Sampling LED Switch

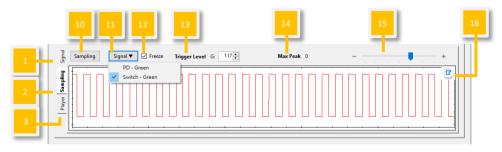


Figure 45: Sampling LED Switch



#### Player Tab

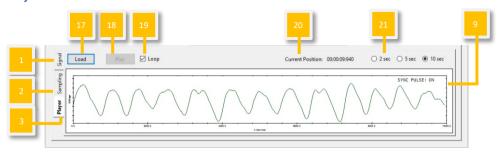


Figure 46: Player Tab

<u>The PPG mode UI is for AECG100 main console unit with reflectance SpO<sub>2</sub> module (PPG-2R-880/PPG-2R-940)/transmittance SpO<sub>2</sub> module (PPG-2TF-660)</u>

\* The UI is illustration only. For detailed display please check on oscilloscope.

# Signal Tab



Figure 47: Signal Tab

## Sampling Tab: Sampling PD

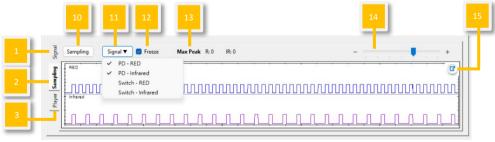


Figure 48: Sampling Tab: Sampling PD



#### Sampling Tab: Sampling LED Switch

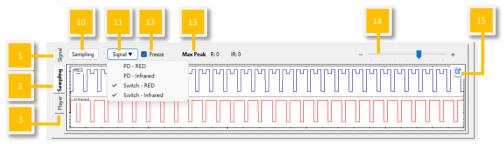


Figure 49: Sampling Tab: Sampling LED Switch

## Player Tab

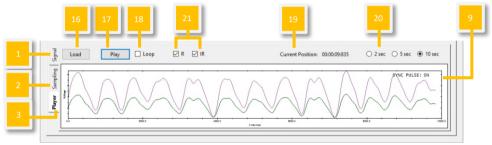


Figure 50: Player Tab

- (1) **Signal tab:** Users can reset/ save/ recall/ play waveform with preset parameters.
- (2) **Sampling tab for PD/LED Switch:** Users can observe DUT LED brightness and AECG100 LED switch status.
- (3) Player tab: Users can load/ play/ loop raw data file.
- (4) **Reset:** Resume the default setting in the upper section.
- (5) **Save:** Save the preset test parameters from the upper section into Standalone (device Mode A/B/C), PC file (in \*.ppg), or Waveform Raw (in \*.txt) format.

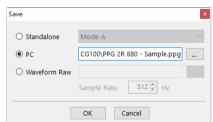


Figure 51: Save Test Parameters



Note: Standalone (device Mode A/B/C) and PC file can be used in (1) Signal tab "Recall" and Auto Sequence Mode. Only Waveform Raw can be played in (3) Player tab.

- (6) **Recall:** Load the previously saved test parameters stored in Standalone (device Mode A/B/C) or as a PC file (\*.ppg format).
- (7) **Play/Stop:** Play the selected waveform with preset parameters. Once stopped, play from the beginning.
- (8) **Waveform Display Scale:** Adjust the display scale for 2 sec, 5 sec, or 10 sec time frames.
- (9) Inverted/Sync Pulse:

Table 1: Inverted/ Sync Pulse Function Description

Inverted: On	AECG100 outputs PPG waveform upside down.
Inverted: Off	AECG100 output PPG waveform as per the window display.
Sync Pulse: On	LED behaviors of AECG100 synchronize with
	DUT LED.
Sync Pulse: Off	AECG100 LED remains on.

- (10) **Sampling:** To sample and measure the DUT LED brightness.
- (11) Signal:

PD-Green/PD-RED/PD-Infrared:

It shows the intensity and behaviors of DUT LED sampled by AECG100's PD. Displayed in **Blue** and **Purple** curves.

Switch-Green/ Switch-RED/ Switch-Infrared:

It shows the timing AECG100 switches LED on or off. Waveform displays low means AECG100 turn on LED. Waveform displays high means AECG100 turns off LED. Displayed in **Blue** and **Red** curves.

PD/ Switch selection is memorized.

- (12) **Freeze:** Once checked, the display of PD/ LED switch sampling would stay as it is.
- (13) Max Peak: Display the peak value of DUT LED, which is sampled by



AECG100 PD, during the selected time interval.

- (14) **Time axis:** Adjust to change the unit of the time axis.
- (15) **Enlarge:** Click to better view the sampling details.
- (16) **Load:** It requires loading PPG raw data separately by different "Channels" (PPG Green/ PPG RED/ PPG Infrared). The raw data file can be loaded by clicking the "File" section. The raw data file is either saved from (1) Signal tab "Waveform Raw" or self-constructed according to the WhaleTeq rule (click "Help" for more details). The "Signal" number corresponds to channel types. The "Total Length" displays the total playback time. Users have to manually adjust "Output Setting" to ensure the AECG100 output signal properly.



Figure 52: Waveform Player

- (17) **Play/Stop:** Play the selected raw data file in \*.txt format. Once stopped, play from the beginning.
- (18) **Loop:** Check to replay the raw data file repeatedly.
- (19) **Current Position:** Display the timing of the played raw data.
- (20) **Waveform Display Scale:** Adjust the display scale for 2 sec, 5 sec, or 10 sec time frames.
- (21) Output Selection: Users can select to play signals via RED LED (waveform displayed in Grey-green) and Infrared LED (waveform displayed in Purple), or via either one of them.



#### 4.4 PWTT Mode

It requires to connect Green LED PPG module (PPG-1R-525) or reflectance  $SpO_2$  module (PPG-2R-840/PPG-2R-940) or transmittance  $SpO_2$  module (PPG-2TF-660) to initiate PWTT test mode. PWTT Mode can be separated into 2 sections. The upper section is for waveform selection and test parameter setting; the lower section is for waveform playback display and setting.

Upper section:

The software UI is for AECG100 main console unit with PPG-1R-525 module

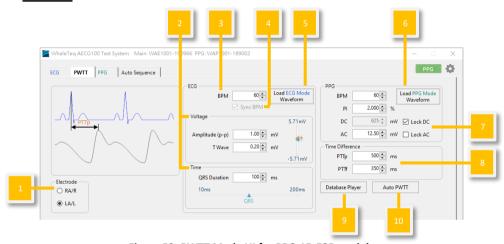


Figure 53: PWTT Mode UI for PPG-1R-525 module

<u>The PWTT mode UI is for AECG100 main console unit with reflectance SpO<sub>2</sub> module (PPG-2R-880/PPG-2R-940)/transmittance SpO<sub>2</sub> module</u>



Figure 54: PWTT mode UI for reflectance SpO<sub>2</sub> module and transmittance SpO<sub>2</sub> module



- (1) **Electrode:** Select the output electrode to RA/R or LA/L.
- (2) **ECG Waveform Parameter:** Set test parameters of voltage and time.
- (3) **BPM:** Adjust different heart rates for testing.
- (4) Sync BPM: BPM values of ECG wave and PPG wave are locked to be synchronized.
- (5) **Load ECG Mode Waveform:** Load and display ECG mode preset waveform.
- (6) Load PPG Mode Waveform: Load and display PPG mode preset waveform. Not allowed when PPG BPM differs from that of ECG's.
- (7) **PPG Waveform Parameters:** PPG waveform can be adjusted via PI (Perfusion Index) = AC/DC. Select "Lock AC" to adjust DC and PI values. Select "Lock DC" to adjust AC and PI values.
- (8) Time Difference: Adjust the time difference between ECG (R wave peak) and PPG waveform (peak or trough). PTTp is the time to peak and PTTf is the time to trough.
- (9) Database Player: In PWTT test mode, AECG100 can download and play PhysioNet MIMIC database (mimicdb). Furthermore, the WhaleTeq database includes 30 records of PPG waveforms recorded in clinical trials to use in PPG test mode and 10 records of PPG and ECG waveforms recorded in clinical trials to use in PWTT test mode. The recorded PPG disease waveforms include AF (Atrial Fibrillation), APC (Atrial Premature Complexes), VPC (Ventricular **Premature** Contraction), and first-degree AV block. Additional 5 records of AF (Atrial Fibrillation) are provided for PWTT test mode. The first record is available for trial purposes and illustrated in the Player tab from the lower Section. Please contact WhaleTeg to purchase the completed database playback function.
- (10) **Auto PWTT:** Set time difference, PTTp range, PTTp step, and intervals for PWTT automation.
- (11) **R/IR Selection:** Click to switch between RED and IR LED test parameters page.



#### Lower section:

# <u>The software UI is for AECG100 main console unit with PPG-1R-525</u> module

\* The UI is illustration only. For detailed display please check on oscilloscope.



Figure 55: PWTT mode UI for PPG-1R-525 module

<u>The PWTT mode UI is for AECG100 main console unit with reflectance SpO<sub>2</sub> module (PPG-2R-880/PPG-2R-940)/transmittance SpO<sub>2</sub> module (PPG-2TF-660)</u>

\* The UI is illustration only. For detailed display please check on oscilloscope.







Figure 56: PWTT mode UI for reflectance SpO<sub>2</sub> module and transmittance SpO<sub>2</sub> module

- (1) **Signal tab:** Users can reset/ save/ recall/ play waveform with preset parameters.
- (2) Player tab: Users can load/ play/ loop raw data file.
- (3) **Reset:** Resume the default setting in the upper section.
- (4) **Save:** Save the preset test parameters from the upper section into Standalone (device Mode A/B/C), PC file (in \*.pwv), or Waveform Raw (in \*.txt) format.

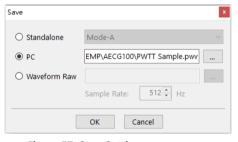


Figure 57: Save Setting

Note: Standalone (device Mode A/B/C) and PC file can be used in (1) Signal tab "Recall" and Auto Sequence Mode. Only Waveform Raw can be played in (2) Player tab.

- (5) **Recall:** Load the previously saved test parameters stored in Standalone (device Mode A/B/C) or as a PC file (\*.pwv format).
- (6) Play/ Stop: Play the selected waveform with preset parameters.
  Once stopped, play from the beginning.
- (7) Output waveform selection: Select to play ECG waveform (displayed in Blue) and/ or PPG waveform.
- (8) **Waveform Display Scale:** Adjust the display scale for 2 sec, 5 sec, or 10 sec time frames.



(9) Load: It is required to load PPG/ ECG raw data separately by different "Channels" (ECG/ PPG Green/ PPG RED/ PPG Infrared). Either saved from (1) Signal tab "Waveform Raw" or self-constructed according to WhaleTeq rule (click "Help" for more details), the raw data file can be loaded by clicking the "File" section. The "Signal" number corresponds to channel types. The "Total Length" displays the total playback time. Users have to manually adjust "Output Setting" to ensure AECG100 outputs signal properly.

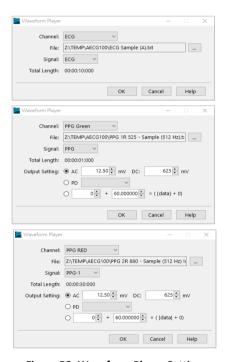


Figure 58: Waveform Player Setting

- (10) **Play/Stop:** Play the selected raw data file in \*.txt format. Once stopped, play from the beginning.
- (11) Loop: Check to replay the raw data file repeatedly.
- (12) Current Position: Display the timing of the played raw data.

Note: If the transmittance SpO<sub>2</sub> module has ECG function, the PWTT mode operation is the same as the above.



#### 4.5 Auto Test SpO<sub>2</sub> Mode (will show after connecting the PPG-2TF-660)

This mode can automatically identify the parameter settings such as Trigger Level and the DC values of R/IR (the AC value of IR can be displayed when using the "Table" function on this tab to create an R curve).

The Trigger Level will be recorded to  $SpO_2$  and PPG tabs to help users quickly perform tests; the DC values of R/IR provide the light intensity information of themselves emitted by the DUT.

#### Note:

- 1. This mode is mainly for developers to quickly test for reference, not for after-sales calibration and testing on oximeters. If users require development tests on SpO<sub>2</sub> parameters and specifications, please use the SpO<sub>2</sub> mode.
- 2. If the DUT can't measure the  $SpO_2$  value or its  $SpO_2$  measured value fluctuates, please adjust the measuring position or select another transmission rate to test. At the same time, checking the human body detection algorithm of the DUT is suggested.

If further assistance is needed, please contact WhaleTeq.

The Auto Test SpO<sub>2</sub> Mode is only applicable to the PPG-2TF-660. The PPG-2TF-660 can be used only after it is connected to the AECG100.

If the Auto Trigger Level reminder shows, please check the IR status, or whether the DUT connects to the PPG-2TF-660 and is in a proper measuring position. After confirming the aforementioned situations, click "OK" to continue.



Figure 59: Auto Trigger Level reminder

Auto Test  $SpO_2$  Mode tab can be separated into 2 sections. The upper section is for waveform selection and test parameter setting; the lower section is for waveform playback display and setting. This mode can detect the dynamic



light intensity function of the DUT, so the PPG-2TF-660 can send corresponding signals as the same intensity to the DUT according to the change in light intensity.

#### Upper section:

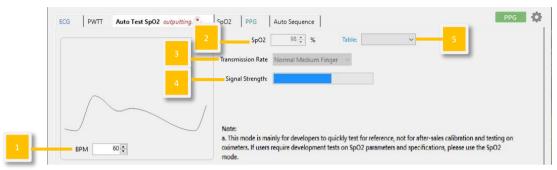


Figure 60: Auto Test SpO₂ Interface

- (1) **BPM:** Adjust for different heart rates. The value is from 10 BPM to 300 BPM.
- (2) **SpO<sub>2</sub>:** Adjust for different heart rates. The value is from 1% to 100%.
- (3) **Transmission Rate:** The user can choose to simulate 6 different transmission rates (Light & Thin Finger, Light & Medium Finger, Normal Medium Finger, Dark Medium Finger, Dark & Thick Finger and Neonatal Foot).
- (4) **Signal Strength:** Detect the signal strength of the DUT to set up a proper measuring position for test.
- (5) **Table:** The dropdown list provides 4 reference SpO<sub>2</sub> tables (Masimo, Nellcor, GE, and Philips) for users to compare. To create the DUT's SpO<sub>2</sub> table for verification, please click the "Table" and refer to the instructions below.

If users already have self-defined  $SpO_2$  tables with the same names as the reference  $SpO_2$  tables (G\_R-curve, M\_R-curve, N\_R-curve, and P\_R-curve), the dropdown list would not show the Masimo, Nellcor, GE, and Philips reference  $SpO_2$  tables.

To load the 4 reference  $SpO_2$  tables, first, please go to the user's  $SpO_2$  folder "C:\Users\admin\AppData\Local\WhaleTeq\AECG\SpO2" and move the original file of the user-defined  $SpO_2$  table to the desktop, then rename it.



Second, delete the entire user's  $SpO_2$  folder and restart the AECG100 software, so the system will automatically create a new user's  $SpO_2$  folder with imported Masimo, Nellcor, GE, and Philips reference  $SpO_2$  tables. Finally, move the renamed user-defined  $SpO_2$  table into the new user's  $SpO_2$  folder, then users can return to the dropdown list to select from the 4 reference  $SpO_2$  tables and the user-defined  $SpO_2$  table.

Note: The Masimo, Nellcor, GE, and Philips reference SpO<sub>2</sub> tables are not provided by their respective owners. The data are collected through the AECG100 main console measurement and for reference only.

\*The UI is illustration only. For detailed display please check on your software UI.

Set up the  $SpO_2$  parameter and transmission rate, then click "Play" at the lower section of the Auto Test  $SpO_2$  tab to send signals to the DUT as figure 61 shows.

Note: If the DUT can't measure the  $SpO_2$  value or its  $SpO_2$  measured value fluctuates greatly, please adjust the measuring position or select another transmission rate to test.

If the optical signals emitted by the DUT is in the critical range of PD recognition of the PPG-2TF-660, it may affect the stability of the LED output signals of the PPG-2TF-660, and lead to the DUT continuously calculating the  $SpO_2$  value and failing to display it.

If further assistance is needed, please contact WhaleTeq.



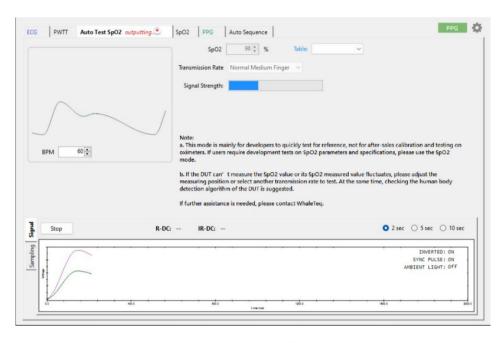


Figure 61: Auto Test SpO<sub>2</sub> mode is operating

# Click "Stop" to show the DUT's DC values of R and IR, as the figure 62.

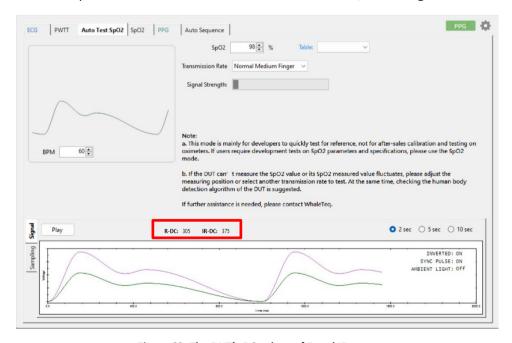


Figure 62: The DUT's DC values of R and IR appears



Click "Table" to bring up the SpO<sub>2</sub> Table window, then click "New Table" and create a name for a new table. The DC value of R and AC and DC values of IR are automatically filled in, as the figure 63.

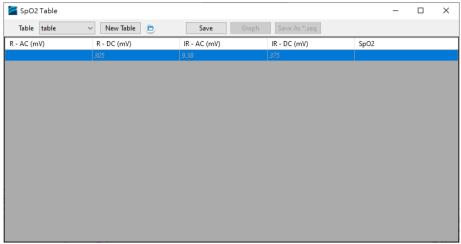


Figure 63: The DC value of R and AC and DC values of IR are automatically filled in

Fill in a designated AC value of R, then the DUT shows the SpO<sub>2</sub> value. Fill in the SpO<sub>2</sub> value in the table and click "Save" as the figure 64.

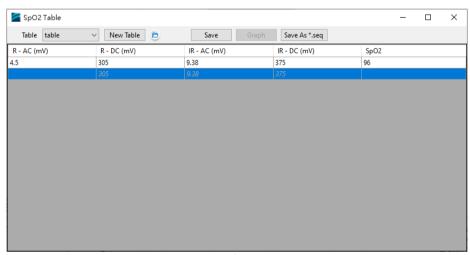


Figure 64: Fill in the AC value of R and the SpO<sub>2</sub> value and save



Repeat the above steps to gather enough information, then click "Graph" to bring up the DUT's R curve.

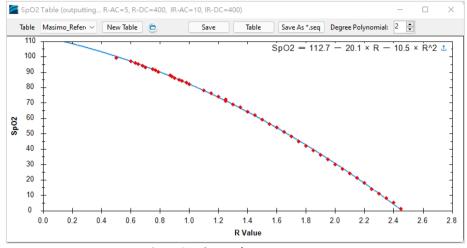


Figure 65: The DUT's R curve

#### Lower Section:

\* The UI is illustration only. For detailed display please check on oscilloscope.

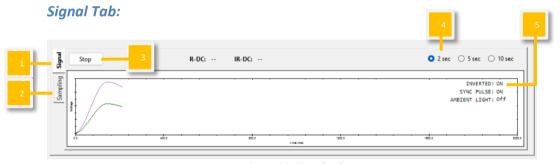


Figure 66: Signal Tab



#### Sampling Tab: Sampling PD

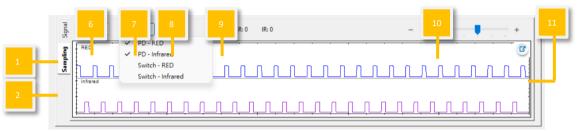


Figure 67: Sampling PD

## Sampling Tab: Sampling LED Switch



Figure 68: Sampling LED Switch

- (1) **Signal tab:** Users can play waveform with preset parameters.
- (2) **Sampling tab for PD/LED Switch**: Users can observe the DUT LED brightness and AECG100 LED switch status.
- (3) **Play/Stop:** Play the selected waveform with preset parameters. Once stopped, play from the beginning.
- (4) **Waveform Display Scale:** Adjust the display scale for 2 sec, 5 sec, or 10 sec.
- (5) Inverted/Sync Pulse/Ambient Light:

Table 2: Inverted/Sync Pulse/Ambient Light Function Description

Inverted: On	AECG100 outputs PPG waveform upside
	down.
Inverted: Off	AECG100 output PPG waveform as per the



	window display.
Sync Pulse: On	LED behaviors of AECG100 synchronize with
	DUT LED.
Sync Pulse: Off	AECG100 LED remains on.
Ambient Light: On	The selected ambient light is activated and
	shown here. Please refer to figure 21 to see
	the 14 options of ambient light signals.
Ambient Light: Off	The ambient light function is turned off.

(6) **Sampling:** Use PD of AECG100 to measure intensities of DUT LED.

#### (7) Signal:

PD-RED/ PD-Infrared:

It shows the intensity and behaviors of DUT LED sampled by AECG100's PD. Displayed in **Blue** and **Purple** curves.

## Switch-RED/ Switch-Infrared:

It shows the timing AECG100 switches LED on or off. Waveform displays low means AECG100 turn on LED. Waveform displays high means AECG100 turns off LED. Displayed in **Blue** and **Red** curves.

PD/ Switch selection is memorized.

- (8) **Freeze:** After enabling this function, the display of PD/ LED switch sampling would stay as it is.
- (9) **Max Peak:** Display the peak value of DUT LED, sampled by AECG100 PD.
- (10) **Time Axis:** Adjust the time axis of PD sampling and switch.
- (11) **Enlarge:** Click to better view the sampling details.

#### 4.6 SpO<sub>2</sub> Mode

It requires connecting the PPG-2R-940, PPG-2R-880 or PPG-2TF-660 module to initiate  $SpO_2$  test mode.  $SpO_2$  test mode can be separated into 2 sections. The upper section is for waveform selection and test parameter setting; the lower section is for waveform playback display and setting.



## Upper section:

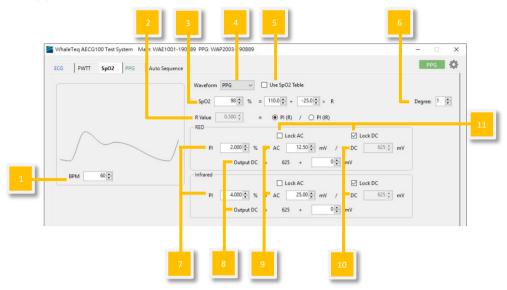


Figure 69: SpO<sub>2</sub> mode UI for reflectance SpO<sub>2</sub> module and transmittance SpO<sub>2</sub> module

- (1) **BPM:** Adjust for different heart rates. The value is from 10 BPM to 300 BPM.
- (2) **R Value:** The R Value is the ratio of RED LED PI percentage and Infrared LED PI percentage. Selecting PI (R) means changing the SpO<sub>2</sub> value by altering the PI of the red LED; selecting PI (IR) means changing the SpO<sub>2</sub> value by altering the PI of the infrared LED.
- (3) R curve, the SpO<sub>2</sub> Level Equation Adjustment: Default equation is the Webster linear empirical calibration formula: SpO<sub>2</sub> level (%) = 110.0 25.0\*R, where R is the R value from (2).
  - For known R curve, users simply adjust the  $SpO_2$  value (by indirectly changing the RED or Infrared parameters) to ensure the DUT  $SpO_2$  value changes along with that of AECG's. Key-in the desired  $SpO_2$  level (%) without modifying the intercept and slope, the R value will be generated in accordance with R-Curve equation. The same R Value is used to display the corresponding RED/Infrared parameters.



For unknown R curve, users may obtain the intercept and slope of the R-Curve equation by using the SpO<sub>2</sub> Table (Please refer to the description of (12) Table).

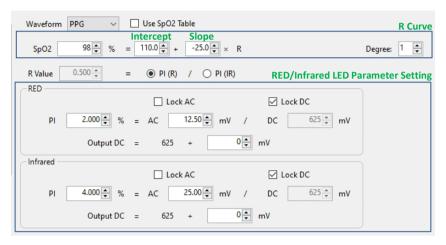


Figure 70: Setting R Curve

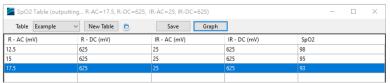
- (4) **Output Waveform Selection:** Select to output different waveform types (ex. Sine, Triangle, or PPG).
- (5) Use SpO<sub>2</sub> Table:

Option 1. User can click "Table" to build SpO<sub>2</sub> table with specified parameters of R/IR LED.



Figure 71: Using SpO<sub>2</sub> Table

After completing the  $SpO_2$  table, click "Graph" to obtain the R curve equation.





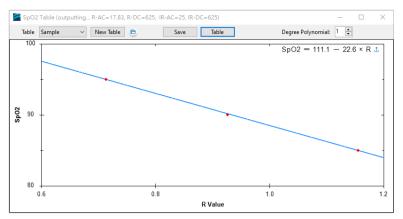


Figure 72: Equation for Obtaining the R Curve

Click distribution at the upper-right corner to copy the R curve to the main screen. Users can directly set designated SpO<sub>2</sub> level (%), and AECG100 will output optical signals accordingly. Please notice that the SpO<sub>2</sub> level can only be set in accordance with the SpO<sub>2</sub> values stored in (12) Table. AECG100 automatically outputs optical signals.

Option 2. Select already-created table from the drop-down menu, the function "Use Calibration Curve" appears.



Figure 73: Use Calibration Curve Function

When checking "Use Calibration Curve" and select "Degree" (of Polynomial), a R-Curve equation is generated based on the data points entered in the table. Any SpO<sub>2</sub> level (in integer) can be set with displayed equation.



Figure 74: Use Calibration Curve Interface



After adjusting parameters of RED or Infrared LED, R value and  $SpO_2$  level are changed simultaneously. Press "Play" to have AECG100 output optical signals.

- (6) **Degree:** Change the degree of polynomial between linear and quadratic when not using the SpO<sub>2</sub> table.
- (7) **PI value:** PI refers to the Perfusion Index (PI). Fix AC value to adjust DC and PI values, or fix DC value to adjust AC and PI values.
- (8) Output DC (Fine-Tune): As ambient light and inner electrical circuit offset of DUT would affect the DC value received by DUT, users can fine-tune the Output DC to minimize the influence. The default value is 0.

Note: Due to the following reasons, the PI measured value may not match the setting value: the existence of dark current in the LED making it require a certain driving current to light, the luminous power of the LED, and the difference in calculations from the PI formula. When the PI measured value doesn't match the setting value, please adjust the Output DC compensation value to calibrate the PI measured value.

The PI formula of WhaleTeq is "PI= AC/DC", and the figure below shows the AC and DC ratio.

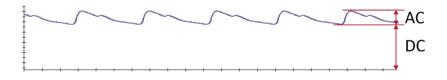


Figure 75: AC and DC Ratio

#### Note:

a. Adjusting the DC compensation value will indirectly affect the  $SpO_2$  value.



b. When using the R curve from Table, changing the DC compensation value will also affect the SpO<sub>2</sub> value of the R curve.

To adjust the DC compensation value, for example:

Set PI=3, AC=15, DC=500, compensation value=10.

If the PI measured value is 4, which is higher than the setting value, the compensation value should be increased to 15 to lower the measured value near 3.

If the PI measured value is 2, which is lower than the setting value, the compensation value should be decreased to 5 to raise the measured value near 3.

Adjust the compensation value until the PI measured value is the same as the setting value. According to the actual situation, the compensation value can be adjusted to a negative number. If further assistance is needed, please contact WhaleTeq.

- (9) **AC value:** To simulate the artery volume change of artery diastolic phase and systolic phases.
- (10) **DC value:** To simulate reflected optical signal of the average artery and vein volume change from skin tissue, bone, and muscle.
- (11) **Parameter Lock and Adjustment:** Lock AC value to adjust PI and DC value or lock DC value to adjust PI and AC value.
- (12) **Table** (Upon clicking "Use SpO<sub>2</sub> Table"): An SpO<sub>2</sub> level matching table is built by entering AC and DC values of RED and Infrared LEDs, along with the SpO<sub>2</sub> values resulted from DUT. These parameters are used to adjust the intercept and slope of the linear (Degree 1) or quadratic (Degree 2) equations.



Figure 76: Using SpO₂ Table



Click "New Table" button to add a SpO<sub>2</sub> table, and DUT shall be put onto AECG100 to test. As shown in the following figure 77, users may set PPG R-AC (12.5), R-DC (625), IR-AC (25), and IR-DC (625). AECG100 automatically output optical signal. Users shall observe the SpO<sub>2</sub> value from DUT, and fill this SpO<sub>2</sub> value into the table.



Figure 77: Build SpO<sub>2</sub> Table (1)

As shown in the following figure 78, user can change the AC values of R or IR (one at a time) to conduct a series of tests to get SpO<sub>2</sub> values and fill them into the SpO<sub>2</sub> table. Press "Save" button to save the table as a file.

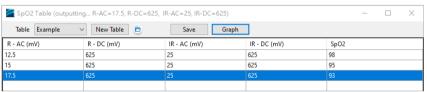


Figure 78: Build SpO<sub>2</sub> Table (2)

After completing the  $SpO_2$  table, press "Graph" button to obtain a R-curve based on the  $SpO_2$  table, and users may adjust the degree of polynomial. When selecting simple equation, AECG100 software will determine the equation with intercept and slope. Press upload  $\ ^{\ }$  at the upper-right corner to adjust the R-Curve equation for DUT.

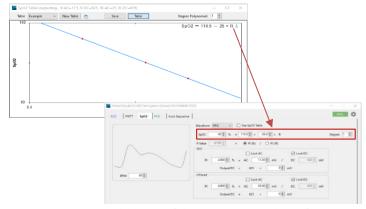


Figure 79: Automatic Calculation of the Intercept and Slope of the SpO<sub>2</sub>



#### Lower Section:

\* The UI is illustration only. For detailed display please check on oscilloscope.

# Signal Tab

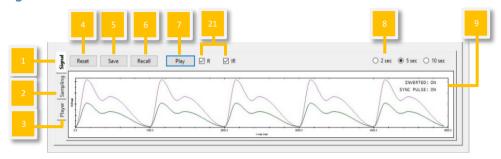


Figure 80: Signal Tab

# Sampling Tab: Sampling PD

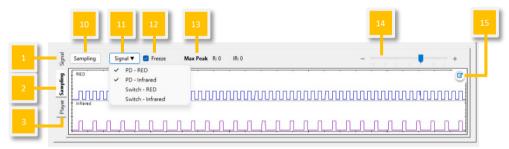


Figure 81: Sampling PD

# Sampling Tab: Sampling LED Switch



Figure 82: Sampling LED Switch



#### **Player Tab**

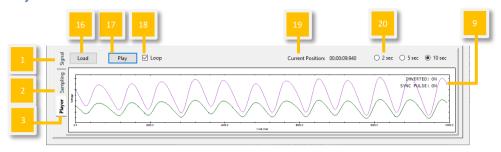


Figure 83: Player Tab

- (1) **Signal tab:** Users can reset/ save/ recall/ play waveform with preset parameters.
- (2) Sampling tab for PD/ LED Switch: Users can observe the DUT LED brightness and AECG100 LED switch status.
- (3) Player tab: Users can load/ play/ loop raw data file.
- (4) **Reset:** Resume the default setting in the upper section.
- (5) **Save:** Save the preset test parameters from the upper section into Standalone (device Mode A/B/C), PC file (in \*.spo), or Waveform Raw (in \*.txt) format.

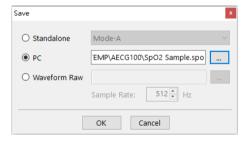


Figure 84: Save Setting

Note: Standalone (device Mode A/B/C) and PC file can be used in (1) Signal tab "Recall" and Auto Sequence Mode. Only Waveform Raw can be played in (2) Player tab.

Saving in Waveform Raw requires license purchase. Please send the "AECG ID" to WhaleTeq to purchase and obtain the "Activation Key" to access the software.



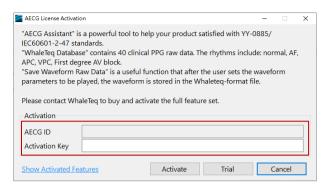


Figure 85: Enter Activation Key Screen Display

- (6) **Recall:** Load the previously saved test parameters stored in Standalone (device Mode A/B/C) or as a PC file (\*.spo format).
- (7) **Play/Stop:** Play the selected waveform with preset parameters. Once stopped, play from the beginning.
- (8) Waveform Display Scale: Adjust the display scale for 2 sec, 5 sec, or 10 sec.
- (9) Inverted/Sync Pulse:

Table 3: Inverted/ Sync Pulse Function Description

Inverted: On	AECG100 outputs PPG waveform upside down.
Inverted: Off	AECG100 output PPG waveform as per the
	window display.
Sync Pulse: On	LED behaviors of AECG100 synchronize with DUT
	LED.
Sync Pulse: Off	AECG100 LED remains on.

- (10) Sampling: Use PD of AECG100 to measure intensities of DUT LED.
- (11) Signal:

PD-RED/ PD-Infrared:

It shows the intensity and behaviors of DUT LED sampled by AECG100's PD. Displayed in **Blue** and **Purple** curves.

Switch-RED/ Switch-Infrared:

It shows the timing AECG100 switches LED on or off. Waveform displays



low means AECG100 turn on LED. Waveform displays high means AECG100 turns off LED. Displayed in **Blue** and **Red** curves. PD/ Switch selection is memorized.

- (12) **Freeze:** After enabling this function, the display of PD/ LED switch sampling would stay as it is.
- (13) **Max Peak:** Display the peak value of DUT LED, sampled by AECG100 PD.
- (14) Time Axis: Adjust the time axis of PD sampling and switch.
- (15) Enlarge: Click to better view the sampling details.
- (16) **Load:** To load PPG raw data for each channel (PPG RED/ PPG Infrared). Select channel first, and then load PPG RED or PPG Infrared raw data in the "File" section accordingly. Raw data file is either saved from (1) Signal tab "Waveform Raw" or self-constructed according to WhaleTeq rule (click "Help" for more details). "Total Length" indicates the total waveform playback time. User has to manually adjust "Output Setting" to assure AECG100 output signal with suitable parameters.

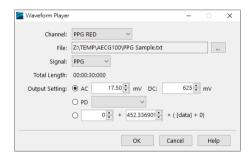


Figure 86: Waveform Player

- (17) Play/Stop: Play the selected raw data file in \*.txt format. Once stopped, play from the beginning.
- (18) **Loop:** Play the loaded waveform repeatedly.
- (19) **Current Position:** Display the timing of the played raw data.
- (20) **Display Scale:** Adjust the display scale for 2 sec, 5 sec, or 10 sec time frames of AECG100 PD sampling windows.
- (21) Output waveform selection: Select to play R and IR signals together or separately.



#### 4.7 Auto Sequence Mode

Auto Sequence mode allows users to use the saved waveform file from ECG/PWTT/SpO<sub>2</sub>/PPG tabs to edit the sequence and testing time as an auto-test file. This auto-test file can be programmed to repeat.

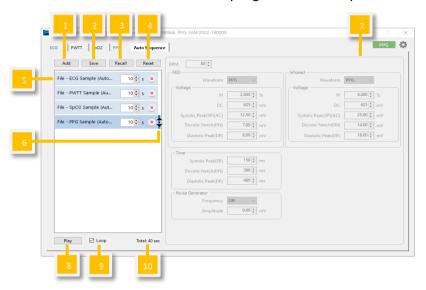


Figure 87: Auto Sequence Mode

(1) Add: To add new waveform file of ECG/SpO<sub>2</sub>/PWTT/PPG to auto sequence combination. Files must be saved from Standalone option or as PC file.

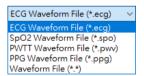


Figure 88: Add Waveform Files

- (2) **Save:** To save auto sequence combination as an automatic testing sequence (in \*.seq format).
- (3) **Recall**: To load the saved auto sequence.
- (4) **Reset:** To remove all the loaded waveform files.
- (5) **Testing Combination:** Test combinations displayed in an assigned sequence.



- (6) **Sequence Cursor:** Drag the file to change the order of the sequence played.
- (7) **Waveform Parameter Display:** To display the test parameters of selected test sequences. **Unable** to modify the test parameters.
- (8) **Play/ Stop:** Play the selected test sequence. Once stopped, play from the beginning.
- (9) **Loop:** To replay the selected test sequence repeatedly.
- (10) **Total:** Show the total playback time of the set sequence.

## 4.8 Supported Raw Data File Format

AECG100 support Text file (\*.txt) only and file content describes as below:

#### File Format:

```
[sampling frequency]
[number of samples per signal]
[number of signals]
[signal description (signal-1)],[signal description (signal-2)], ...
[sample data-1 (signal-1)],[sample data-1 (signal-2)], ...
[sample data-2 (signal-1)],[sample data-2 (signal-2)], ...
[sample data-N (signal-1)],[sample data-N (signal-2)], ...
```

#### **Description:**

```
sample frequency
Input the frequency of sample data
```

## number of samples per signal

The limitation is related to the available memory size of PC system. If PC system has available memory for 1Gb, the maximum number of single channel sample data would be 131,072.

#### number of signals

This number must be greater than 1.



signal description
The description text for the signal.

sample data
The raw data unit is mV.

For ECG, the data range is [-5, 5] mV.

For PPG, there are no limits for the range of the raw data, but you can scale the range to [0, AC], which can be adjusted in AECG100 PC software. If we set AC level for 10mV in AECG100 PC software, this means the [0, AC] becomes [0,10]. Then AECG100 PC software will automatically calculate the sample data value to a specific AC value by the following formula:

[Data Value / (Maximum Data Value – Minimum Data Value)] \* Maximum AC Level

For example, if we setup AC level = 10mV while the maximum data value is 12.500 and the minimum data value is 0.000, the sample data 0.021 will become [0.021/(12.500-0.000)]\*10 = 0.0168 mV.

#### **Example:**

1000

1000

2

sine wave-5, sine wave-10

0.000,0.000

0.031,0.063

0.063, 0.126

0.094,0.188

0.126,0.251

0.157,0.314

0.188,0.377

0.220,0.440

0.251,0.502

0.283,0.565

0.314,0.628

0.345,0.691



- 0.377,0.753
- 0.408,0.816
- 0.439,0.879
- 0.471,0.941
- 0.502,1.004
- 0.533,1.066
- 0.564,1.129
- 0.595,1.191
- 0.627,1.253
- 0.658,1.316
- 0.689,1.378
- 0.720,1.440
- 0.751,1.502
- 0.782,1.564
- 0.813,1.626
- 0.844,1.688

#### .....

- -1.029,-2.059
- -0.999,-1.997
- -0.968,-1.935
- -0.937,-1.874
- -0.906,-1.812
- -0.875,-1.750
- -0.844,-1.688
- -0.813,-1.626
- -0.782,-1.564
- -0.751,-1.502
- -0.720,-1.440
- -0.689,-1.378
- -0.658,-1.316
- -0.627,-1.253
- -0.595,-1.191
- -0.564,-1.129
- -0.533,-1.066
- -0.502,-1.004
- -0.471,-0.941
- -0.439,-0.879
- -0.408,-0.816
- -0.377,-0.753



- -0.345,-0.691
- -0.314,-0.628
- -0.283,-0.565
- -0.251,-0.502
- -0.220,-0.440
- -0.188,-0.377
- -0.157,-0.314
- -0.126,-0.251
- -0.094,-0.188
- -0.063,-0.126
- -0.031,-0.063

## 5 Software Development Kit (SDK)

WhaleTeq provides the software development kit (SDK) for AECG100. All test parameters correspond to specific SDK commands and DLL (Dynamic-link library) shared library can be used for efficient program binding and version upgrade. Support C/C++ header, C# interface, third-party tools, and script language integration.

#### 6 Calibration and Validation

WhaleTeq original calibration service is equipped with calibration equipment specially designed for physiological simulator to ensure the accuracy of calibration, and can calibrate the offset value of the device within the original specification of WhaleTeq. Under normal use, the device is recommended to be calibrated once a year.

There are three kinds of calibration/validation methods for AECG100: calibrated by Masimo Radical-7 Pulse CO-Oximeter, calibrated by "Covidien" Nellcor Portable SpO<sub>2</sub> Patient Monitoring System, or measuring electrical and LED/PD parameters including output voltage, frequency, LED intensity, and PD ability to detect light. Any of the above methods require traceable equipment. Steps for Calibration/Validation methods are also available upon request. Please contact WhaleTeq for more information (see section 13).



Note: If WhaleTeq detects that the components of the device are damaged and makes it impossible to adjust, it shall be sent back for maintenance.

#### 6.1 Self-calibration

Self-calibration assists the user calibrates the AECG100 to quickly confirm the signal quality before testing, not to replace the original calibration service recommended every year. Please follow the steps below to conduct self-calibration.

1. Set up the parameters of the AECG100 AP to "Square, 5 mV, 0.1 Hz" and output to the RA lead electrode as the figure shown below:

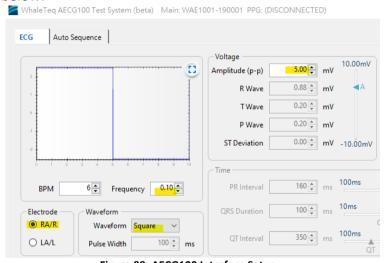


Figure 89: AECG100 Interface Setup

2. Connect the multimeter to RA and LA of the AECG100, and measure the DC mV. The value should be in 1% of 5 mV because the output amplitude of the AECG100 gives alternating 5s (0.1 Hz square wave) phases at -2.5mV and +2.5mV, which the multimeter is zeroed (delta function) at one phase (e.g., -2.5mV), with reading taken from the other phase (e.g., +2.5mV) to obtain the 5mV peak-peak value.

Note: Please use the multimeter which is 6 1/2 (6 1/2 digits) or more.





Figure 90: Self-Calibration Setup

3. The AECG100  $\pm$ 300 mV DC offset check is shown as the red square in the figure below. The AECG100 connects DC in series with electrode wire (in the case, RA).

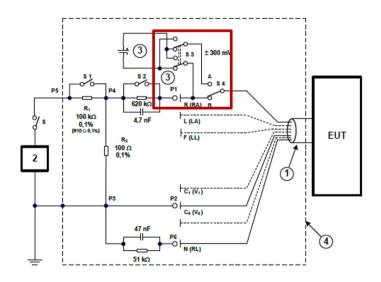


Figure 91: AECG100 ±300 mV DC offset

4. The user can verify the DC voltage by setting up the parameters of the AECG100 AP to "Square, 0 mV, 0.1 Hz and DC Offset Setting to 300 mV".



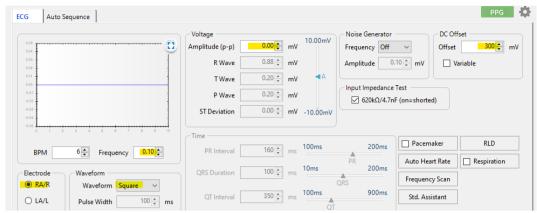


Figure 92: DC Voltage Verification (300mV)

5. Connect the multimeter to RA and LA of the AECG100 and measure the DC voltage. The value should be in 1% of 300 mV. The setup is shown in the below figure.



Figure 93: Self-Calibration Setup

6. If the user wants to check the DC voltage other than 300 mV, set the DC voltage from -1000 mV to +1000 mV with 5% accuracy. Please look at the figure below for details.

Note: This extra DC voltage can support some other than 300 mV testing.



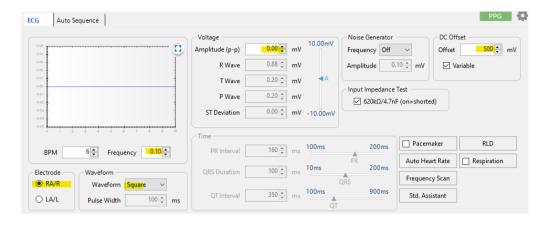


Figure 94: DC Voltage Verification (>300mV)

## 7 Troubleshooting

- If the PPG module is accidentally separated from AECG100 main console unit in operation, please follow the below steps to have the test system work properly.
  - Step1: Turn off the power switch on AECG100 main console unit and assure the power indicator is off.
  - Step2: Re-connect the PPG module to the AECG100 main console.Step3: Turn on the power switch on AECG100 main console unit
    - and assure the power indicator is on.
- (2) When Red LED of the power indicator remains on:

  If Red LED remains on, the AECG100 system is crashed. Please try
  turning off and then turning on the AECG100 test system.
- (3) No LED display at the power indicator: For no LED display, either the system is crashed or no power is supplied to the test system. Please try to unplug and re-plug in the USB cable, or try turning off and then turning on the AECG100 test system.



#### 8 Cautions

- (1) Mode A/B/C is saved in AECG100 main console, while info stored within Mode A/B/C may correspond to different variable values for different PPG modules connected. Therefore, when testing AECG100 main console with different PPG modules, re-saving Mode A/B/C is required to obtain desired test results.
- (2) When a stable and firm connection between AECG100 main console and PPG modules is desired (e.g., moving the entire system around), it is recommended to fasten with a DB15 cable in between. The cable spec is DB15 male to female.
- (3) It is suggested to warm up AECG100 Test System for at least 30 minutes before testing.
- (4) Before using PPG-related functions, please assure the distance between the PPG module head and DUT PPG sensor is fixed.
- (5) During testing, it is essential to minimize the ambient light, as it would influence the test result as well.
- (6) LED luminous decay occurs as time goes on. It is recommended to send the AECG100 units to WhaleTeq for calibration every year to replace the LED base if needed (depends on usage frequency) to ensure LED brightness is qualified. Please contact WhaleTeq Co, Ltd for more details.
- (7) When upgrading AECG100 firmware, DO NOT disconnect the USB cable or close the software during the process.
- (8) Warranty voids if QC PASS label is removed or tampered with.
- (9) This is a professional testing instrument instead of a medical device. It is for testing only and will not be used on human or clinical use.



# 9 Specification

## 9.1 ECG Test Mode

**Table 4: ECG Test Mode Specification** 

Parameters		Specifications
	Resolution	2.5μV (DAC resolution)
Main Output Voltage	Accuracy	±1% for amplitudes of 0.5mVpp or higher
Frequency/Pulse Repetition Rate	Accuracy	±1 %
Pulse Duration/Timing	Accuracy	±1ms
	Setting Range	-1000mV ~ +1000mV
Pacing Pulse Amplitude		±2mV pulse: ±1%
r deling r disc / implicade	Accuracy	>2mV or <-2mV pulse: ± 10%
	Setting Range	0.1ms ~ 2ms
Pacing Pulse Width	Minimum Step Size	0.1ms
	Accuracy	±5μs
Pacing Pulse	Rise / fall time	5μs
Characteristics	Overshoot	<1%
	Settling time	<1%
Sample Rate	Rate	50 ~ 40kHz (Normal mode/ Standalone mode); 40kHz (Raw data mode)
	Accuracy	Depend on system clock accuracy
DC Offset	Range	-300mV, +300mV
(fixed, noise free, sourced from internal super capacitor)	Accuracy	±1%



Parameters		Specifications
DC Offset (variable, may include up	Setting Range	-500mV ~ +500mV
to 50µVpp noise)	Accuracy	±1%
DCA O La LA validada	Range	ECG electrode output x1000, max 10V
RCA Output Amplitude	Accuracy	±1% for amplitudes of 0.5Vpp or higher
S/N Ratio		>51dB (with USB isolator)

### 9.2 PPG Test Mode

**Table 5: PPG Test Mode Specification** 

Parameters		Specifications
	Setting Range	10 ~ 300 BPM
Heart Rate	Minimum Step Size	1 BPM
	Accuracy	±1 BPM
LED DC Level Reference	Setting Range	100 ~ 3000mV
Output	Minimum Step Size	1mV
LED AC Level Reference	Setting Range	0.75 ~ 30mV
Output	Minimum Step Size	0.01mV
	Setting Range	50 ~ 925 Lux (full range) (5mm from diffusion film)
Lumen <sup>§</sup>	Resolution	(1/3000) full range
	Accuracy	±6%
Light Wavelength	Range	525 / 660 / 880 / 940nm
	Accuracy	±10nm
LED Scan Rate	Rate	50 ~ 40kHz (Normal mode/ Standalone mode);



Parameters		Specifications
		10kHz (Raw data mode)
	Accuracy	±5μs
PD Sample Rate	Rate	250kHz (single channel)
	Accuracy	±5μs
DD Dooroon Time	Rising	1μs Typical*
PD Response Time	Falling	1μs Typical*

<sup>§</sup> The data is for PPG-1R-525 module.

#### 9.3 PWTT Test Mode

**Table 6: PWTT Test Mode Specification** 

Paramete	rs	Specifications
Time Difference (PTTp, PTTf)	Setting Range	0 ~ 5999ms (for the heart rate setting as 10BPM. As the heart rate value increases, the setting range of time difference will decrease accordingly.)
	Minimum Step Size	1ms
	Accuracy	±1ms

# 9.4 Reflectance PPG Module + SpO<sub>2</sub> Test Mode

Table 7: Reflectance PPG Module + SpO<sub>2</sub> Test Mode Specification

Parameters		Specifications
	Setting Range	10 ~ 300 BPM
Heart Rate	Minimum Step Size	1 BPM
	Accuracy	±1 BPM

<sup>\*</sup> The PD response time will vary with the light intensity of the DUT.



Parameters		Specifications
LED DC Level Reference	Setting Range	100 ~ 3000mV
Output	Minimum Step Size	1mV
LED AC Level Reference	Setting Range	0.75 ~ 30mV
Output	Minimum Step Size	0.01mV
PI (AC level/DC level)	Setting Range	0.025% ~ 30% (AC/DC, varies with AC or DC level)
	Accuracy	NA
	Range	Red: 660nm; Infrared: 940nm/880nm
LED Light Wavelength	A	Red:±10nm;
	Accuracy	Infrared: ±10nm
Red Light Absolute	Intensity	3.55 mW/m^2
Irradiance (100%)§	Accuracy	±15%
Infrared Light Absolute	Intensity	6.65 mW/m^2
Irradiance (100%)§	Accuracy	±15%
LED Scan Rate	Rate	50 ~ 40kHz (Normal mode/ Standalone mode); 10kHz (Raw data mode)
	Accuracy	±5μs
DD Commis Data	Rate	250kHz (single channel)
PD Sample Rate	Accuracy	±5μs
DD Dospones Times	Rising	1μs Typical*
PD Response Time	Falling	1μs Typical*
	Setting Range	1~100 (%)
SpO <sub>2</sub> (%)	Minimum Step Size	1 (%)



Parameters		Specifications
	Accuracy	±1% + specified accuracy of the DUT (using Masimo Radical-7 Pulse CO- Oximeter or "Covidien" Nellcor Portable SpO <sub>2</sub> Patient Monitoring System)

Data Collection Method: To connect the spectrometer with a 2-inch integrating sphere, and fix the integrating sphere on the DUT to measure the absolute irradiance of the LED of the DUT.

## 9.5 Transmittance PPG Module + SpO<sub>2</sub> Test Mode

Table 8: Transmittance PPG Module + SpO<sub>2</sub> Test Mode Specification

Parameters		Specifications
	Setting Range	10 ~ 300 BPM
Heart Rate	Minimum Step Size	1 BPM
	Accuracy	±1 BPM
LED DC Level Reference	Setting Range <sup>1</sup>	30 ~ 3000 mV
Output	Minimum Step Size	1 mV
LED AC Level Reference Output	Setting Range <sup>1</sup>	0.75 ~ 30 mV
	Minimum Step Size	0.01mV
PI (AC level/DC level) <sup>2</sup>	Setting Range	0.025% ~ 30% (AC / DC, varies with AC or DC level)
Triple levely be levely	Accuracy	NA
LED1 Absolute Irradiance	Intensity	2.36mW / m^2
(100%) §	Accuracy	±15%
	Intensity	0.25mW / m^2

<sup>\*</sup> PD response time varies with the light intensity of the DUT.



Parameters		Specifications
LED2 Absolute Irradiance (ambient light) §	Accuracy	±15%
LED Scan Rate	Rate	50 ~ 40kHz (Normal mode/ Standalone mode) 10kHz (Raw data mode)
	Accuracy	±5μs
DD Cample Date	Rate	250kHz (single channel)
PD Sample Rate	Accuracy	±5μs
PD Response Time	Rising	1μs Typical <sup>3</sup>
	Falling	1μs Typical <sup>3</sup>
	Setting Range	1% ~ 100%
	Minimum Step Size	1%
SpO <sub>2</sub> (%) SpO <sub>2</sub> parameter specifications <sup>4</sup>	Accuracy	91 % ~ 100%: ±1% +specified accuracy of the DUT 81 % ~ 90%: ±2% +specified accuracy of the DUT 71 % ~ 80%: ±3% +specified accuracy of the DUT Below 70%: with unspecified accuracy
MCY LED Voltage	Amplitude	AC Level x 100
MCX LED Voltage	Accuracy	±5%

Data Collection Method: To connect the spectrometer with a 2-inch integrating sphere, and fix the integrating sphere on the DUT to measure the absolute irradiance of the LED of the DUT.

#### Note:

- 1. The AECG100 test system adjusts AC/DC output according to the linearity of LED electrooptical conversion.
- 2. The PI value may vary according to the different calculation methods of each manufacturer.
- 3. PD response time varies with the light intensity of the DUT.
- 4. The SpO<sub>2</sub> parameter specifications apply to SpO<sub>2</sub> Test Mode.



## 9.6 General Specification

### **AECG100 Main Console Unit**

Table 9: AECG100 Main Console Unit General Specification

	Operating Temp.	10°C ~ 40°C
Environment	Storage Temp.	0°C ~50°C
	Humidity	0 – 80% RH, Non-condensing
	Housing	Plastic
Physical Properties	Weight	241g
rroperties	Dimensions (L x W x H)	150mm x 98mm x 33mm

### **Reflectance & Transmittance PPG Module**

**Table 10: PPG Module General Specification** 

	Operating Temp.	<b>10</b> °C ~40°C
Environment	Storage Temp.	0°℃~50°℃
	Humidity	0–80% RH, Non-condensing
	Housing	Plastic
	Weight	Reflectance Module: 165g
Physical	Dimensions (L x W x H)	Transmittance Module: 122g
Properties		Reflectance Module:
op oo		70mm x 98mm x 60mm
		Transmittance Module:
		132mm x 85mm x 14mm



# **10** Ordering Information

## **AECG100 Main Console Unit**

**Table 11: AECG100 Main Console Unit Ordering Information** 

Part No.	Description	Quantity
100-AE00001	Model No.: AECG100 The main console unit for ECG testing. Supports ECG and Auto Sequence test modes.	1

## **PPG Modules**

**Table 12: PPG Module Ordering Information** 

Part No.	Description	Quantity
100-AE00002	Model No.: PPG-1R-525 Model Name: Reflectance Green Light Heart Rate Module The reflectance PPG module of 525nm green LED. Supports PWTT / PPG / Auto Sequence test modes.	1
	Model No.: PPG-2R-880	1
	Model Name: Reflectance SpO <sub>2</sub> Module	
100-AE00004	The reflectance PPG module of 880nm IR	
100-AE00004	LED and 660nm Red LED.	1
	Supports PWTT / SpO <sub>2</sub> / PPG / Auto	
	Sequence test modes.	
100-AE00005	Model No.: PPG-2R-940	
	Model Name: Reflectance SpO <sub>2</sub> Module	1
	The reflectance PPG module of 940nm IR	1
	LED and 660nm Red LED.	



Part No.	Description	Quantity
	Supports PWTT / SpO <sub>2</sub> / PPG / Auto	
	Sequence test modes.	
	Model No.: PPG-2TF-660	
	Model Name: Transmittance SpO <sub>2</sub>	1
	module	
100 1500007	The transmittance PPG module.	
100-AE00007	Supports PWTT / Auto Test SpO <sub>2</sub> / SpO <sub>2</sub> /	
	PPG / Auto Sequence test modes.	
	(two MCX (RF) male to BNC cables	
	included)	

Note: Connect the AECG100 main console with the reflectance and transmittance PPG modules PPG-2R-940, PPG-2R-880 and PPG-2TF-660 can conduct SpO<sub>2</sub> testing as the reflectance and transmittance SpO<sub>2</sub> testing device.

## **Optional Software Add-on Pack**

**Table 13: Optional Software Add-on Pack Ordering Information** 

Part No.	Description
HA0-AE01001	Auto setup for IEC 60601-2-47:2012 performance tests.
HA0-AE01002	Auto setup for YY0885-2013 performance tests.
HA0-AE01003	Auto setup for YY 9706.247-2021 performance tests.
HC0-AE01001	To have wearables to perform more closely to medical grade device and to decrease the time and cost of clinical trials, AECG100 has built-in clinical database waveforms. All those PPG database waveforms are recorded simultaneously with ECG



Part No.	Description	
	signals and have physicians determined the	
	arrhythmia marks via ECG signals.	
	The WhaleTeq database includes 30 records of PPG	
	waveforms recorded in clinical trials to use in PPG	
	test mode and 10 records of PPG and ECG	
	waveforms recorded in clinical trials to use in PWTT	
	test mode. The 25 recorded disease waveforms	
	include symptoms such as AF (Atrial Fibrillation),	
	APC (Atrial Premature Complexes), VPC (Ventricular	
	Premature Contraction) and first degree AV block.	
	Save Waveform Raw Data	
LICO AF04003	Standard waveforms in ECG, PPG, SpO₂ and PWTT	
HC0-AE01002	test modes can be saved in raw data formats for	
	further modification	

# **Optional Calibration Service and Warranty Extension**

**Table 14: Optional Calibration Service and Warranty Extension Ordering Information** 

Part No.	Description
	Model No.: C3
VV0007	Provides (3) years of calibration service coverage.
YY0007	WhaleTeq equipment can be calibrated to original
	performance on the basis of (1) year interval.
	Model No.: R3
YY0008	Extends the limited warranty from (1) year to (3)
	years.



# **11 Package Contents**

# **AECG100 Test Systems**

Table 15: AECG100 + PPG-1R-525 Package Contents

Part No.	Item	Quantity
	AECG100 Main Console Unit	1
	PPG-1R-525 Module	1
	USB Type-A to Type-B Cable (Male to Male),	2
100-AE00001 + 100-AE00002	1.8m	2
	Grounding Cable (1m)	1
	RCA to BNC Cable (74cm)	2
	Compound Terminal	4
	DB15 Cable (Male to Female), 30cm	1

Table 16: AECG100 + PPG-2R-940 Package Contents

Part No.	ltem	Quantity
	AECG100 Main Console Unit	1
	PPG-2R-940 Module	1
	USB Type-A to Type-B Cable (Male to Male),	2
100 / 1200001	1.8m	2
	Grounding Cable (1m)	1
	RCA to BNC Cable (74cm)	2
	Compound Terminal	4
	DB15 Cable (Male to Female), 30cm	1

Table 17: AECG100 + PPG-2R-880 Package Contents

Part No.	Item	Quantity
	AECG100 Main Console Unit	1
	PPG-2R-880 Module	1
	USB Type-A to Type-B Cable (Male to Male),	2
100 / 1200001	1.8m	۷
	Grounding Cable (1m)	1
	RCA to BNC Cable (74cm)	2
	Compound Terminal	4
	DB15 Cable (Male to Female), 30cm	1



Table 18: AECG100 + PPG-2TF-660 Package Contents

Part No.	Item	Quantity
	AECG100 Main Console Unit	1
	PPG-2TF-660 Module	1
100-AE00001 + 100-AE00007	USB Type-A to Type-B Cable (Male to Male),	2
	1.8m	۷
	Grounding Cable (1m)	1
	MCX (RF) Male to BNC Cable (30cm)	2
	Compound Terminal	4

## **AECG100 Main Console Unit and PPG Modules**

**Table 19: AECG100 Package Contents** 

Part No.	Item	Quantity
100-AE00001	AECG100 Main Console Unit	1
	USB Type-A to Type-B Cable (Male to Male),	2
	1.8m	2
	Grounding Cable (1m)	1
	RCA to BNC Cable (74cm)	1
	Compound Terminal	4

Table 20: PPG-1R-525 Package Contents

Part No.	Item	Quantity
100-AE00002	PPG-1R-525 Module	1
	RCA to BNC Cable (74cm)	1

Table 21: PPG-2R-940 Package Contents

Part No.	Item	Quantity
100-AE00005	PPG-2R-940 Module	1
	RCA to BNC Cable (74cm)	1



Table 22: PPG-2R-880 Package Contents

Part No.	Item	Quantity
100-ΔF0000Δ	PPG-2R-880 Module	1
	RCA to BNC Cable (74cm)	1

Table 23: PPG-2TF-660 Package Contents

Part No.	Item	Quantity
100-AE00007	PPG-2TF-660 Module	1
	MCX (RF) Male to BNC Cable (30cm)	2

#### Note:

- PPG module is required to connect to AECG100 main console unit to enable PWTT / SpO<sub>2</sub> / PPG test modes.
- 2.  $SpO_2$  test mode is only available when the reflectance PPG module or transmittance  $SpO_2$  module is connected to AECG100 main console.

# **12** Revision History

**Table 24: Revision History** 

Version	Revision Description	
2019-07-24	First version	
2020-07-02	<ul> <li>Updated cover photo</li> <li>Added details to Output DC of SpO<sub>2</sub> mode</li> <li>Added Absolute Irradiance (for PPG R/IR) under Spec Chapter</li> <li>Specified file types saved for Waveform Raw/ PC file and loaded for Recall/ Player/ Auto Sequence</li> <li>Added ECG ground illustration</li> <li>Moved description of Setting &amp; PPG config to a general section</li> <li>SpO<sub>2</sub> &amp; PPG parts: Demo figures of Sampling tab to include PD and LED switch separately</li> </ul>	



Version	Revision Description
	Added PPG Respiration function
2020 00 00	Added Calibration section
2020-09-08	Included SAVE RAW-AECG as optional add-on
	software
	∘ Updated SpO <sub>2</sub> spec (with reference DUT)
2020-10-13	Updated PPG spec LED AC level
	<ul> <li>Moved "Resume Operation" from System Setup to</li> </ul>
2021-01-11	Troubleshooting Chapters.
	<ul> <li>Added Cautions and Revision History chapters</li> </ul>
	Update
2021-10-01	<ul><li>Chapter 8 (point (9))</li></ul>
2021 10 01	<ul> <li>Chapter 2.3 Product Wiring Diagram</li> </ul>
	<ul> <li>Chapter 6.1 Self-calibration</li> </ul>
	Updated
	<ul> <li>2.3 Product Wiring Diagram</li> </ul>
	<ul> <li>2.4 DUT Best Position Adjustment</li> </ul>
	<ul> <li>2.5 Operation Modes</li> </ul>
2022-06-10	6.1 Self-calibration
2022-00-10	<ul> <li>Chapter 10 Ordering Information</li> </ul>
	<ul> <li>Chapter 11 Package Contents</li> </ul>
	Added
	<ul> <li>4.5 Auto Test SpO<sub>2</sub> Mode</li> </ul>
	<ul> <li>9.5 Transmittance PPG Module + SpO<sub>2</sub> Test Mode</li> </ul>
	Updated
2022-06-16	<ul> <li>4.5 Auto Test SpO<sub>2</sub> Mode</li> </ul>
2022-06-16	<ul> <li>9.4 Reflectance PPG Module + SpO<sub>2</sub> Test Mode</li> </ul>
	<ul> <li>9.5 Transmittance PPG Module + SpO₂ Test Mode</li> </ul>
	Updated
	<ul> <li>4.5 Auto Test SpO<sub>2</sub> Mode</li> </ul>
2022-07-27	∘ 4.6 SpO₂ Mode
	9.1 ECG Test Mode
	9.2 PPG Test Mode
	<ul> <li>9.4 Reflectance PPG Module + SpO<sub>2</sub> Test Mode</li> </ul>



Version	Revision Description
2022-09-12	Updated  • 4.6 SpO₂ Mode  • product name  - Transmission SpO₂ Module → Transmittance SpO₂  Module  - Reflective SpO₂ Module → Reflectance SpO₂ Module
2023-02-23	Updated
2023-07-05	Updated  2.5.1 PC Software Operation  4.2 ECG Mode  9 Specification  10 Ordering Information  11 Package Contents  Added  Subsection 4.1.1, 4.1.2, and 4.1.3
2024-01-17	Updated
2024-04-30	Updated  ∘ 1 Product Introduction

# 13 Contact WhaleTeq

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