Test Solutions for
Medical Device Manufacturers

How to Test the Performance of Pulse Oximeters and ECG Equipment?

- Applications of the Vital Sign Multifunction Tester

Speaker: Richard Ding

Verify and Validate Your Product Design with Ease

Time	Contents
30 min.	• Basics of testing PPG optical Heart Rate (HR) and SpO_2 functions • Introduction of the Multifunction Tester • How to use the Multifunction Tester to test optical heart rate and SpO_2 functions
15 min.	How to use the Multifunction Tester to: • Test ECG equipment according to ECG standards • Test Pulse Wave Transit Time (PWTT)
15 min.	• Conclusions • Q&A

© 2022 WhaleTeq All Rights Reserved

Basics of testing PPG optical Heart Rate (HR) and SpO_2 functions

© 2022 WhaleTeq All Rights Reserved

Green LED and PD to Measure HR

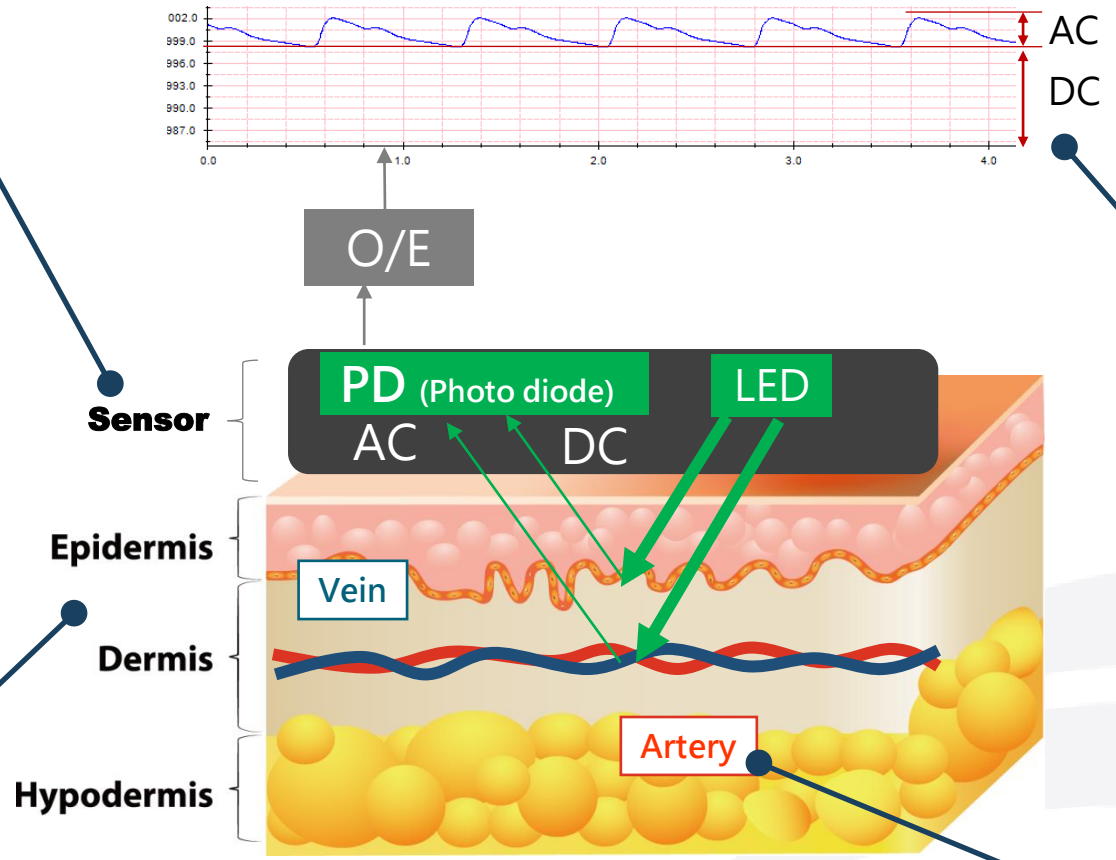
PPG: Photoplethysmography

LED emits green light to the skin

- Partially absorbed by skin tissue, arteries, and veins
- Partially reflected back to the PD of the sensor

Skin tissue and veins

- In a static state, the volume does not change with each heartbeat, and the intensity of absorbed light and reflected light is stable. It is converted into direct current (DC) by the PD.
- Darker skin color will absorb more incident light, so the reflected light will be weaker, and vice versa. So the DC level represents the skin color range.



- The converted electrical signal consists of two parts, DC and AC.
- The AC signal comes with HR variation parameters.

Artery

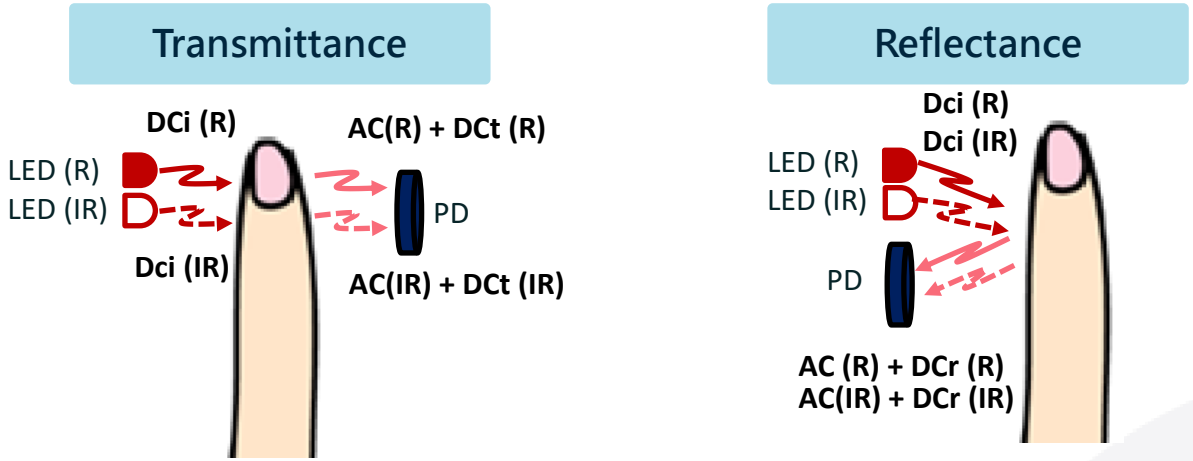
- The blood volume changes with each heartbeat and the heart rate, so it is converted into alternating current (AC) through PD.
- People with more elastic arteries, meaning the reflected AC signal has larger amplitude changes, so the AC level represents the artery elastic range.

© 2022 WhaleTeq All Rights Reserved

R & IR LED and PD

For R value and SpO_2 value of Pulse Oximetry

- Pulse oximetry determines SpO_2 value by illuminating vascular tissue with rapid switching between Red and IR light.
- AC signals of Red and IR PPG are sensitive to changes in SpO_2 value because of the variance in the light absorption of O2Hb (Oxyhaemoglobin) and HHb (Deoxyhaemoglobin) at these two wavelengths.



- R value: using the amplitude ratio of AC/DC signals for both Red and IR wavelengths

$$R = \frac{(AC/DC)_R}{(AC/DC)_{IR}} \Rightarrow Sp02 = K1 + K2R$$ R curve

Note: SpO_2 value can be calculated as a linear function of R, where K1 and K2 are constants.

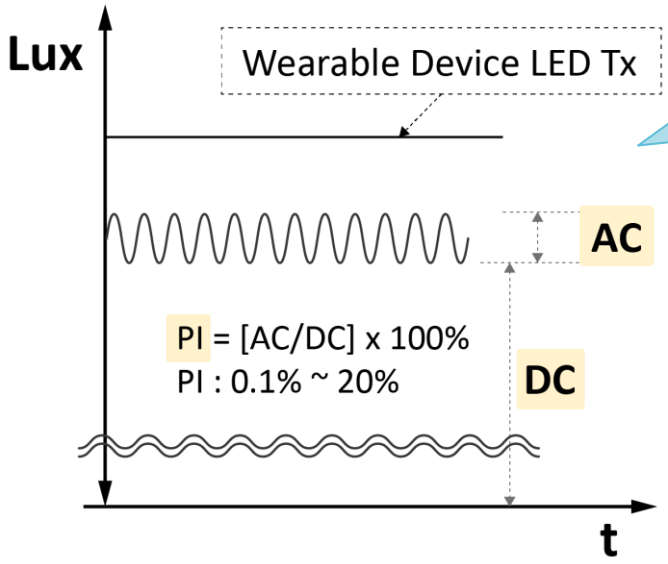
© 2022 WhaleTeq All Rights Reserved

Introduction of the Multifunction Tester & how to use it to test optical heart rate and SpO_2 functions

© 2022 WhaleTeq All Rights Reserved

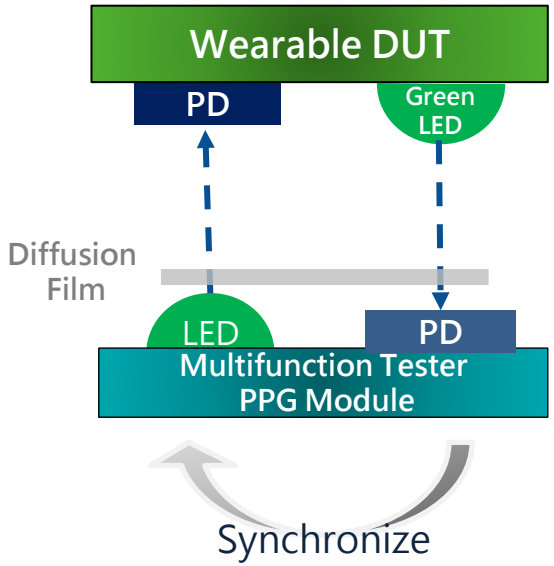
Synchronization & Three Major Parameters AC, DC, BPM

Variable parameters, effective simulation of reflection light

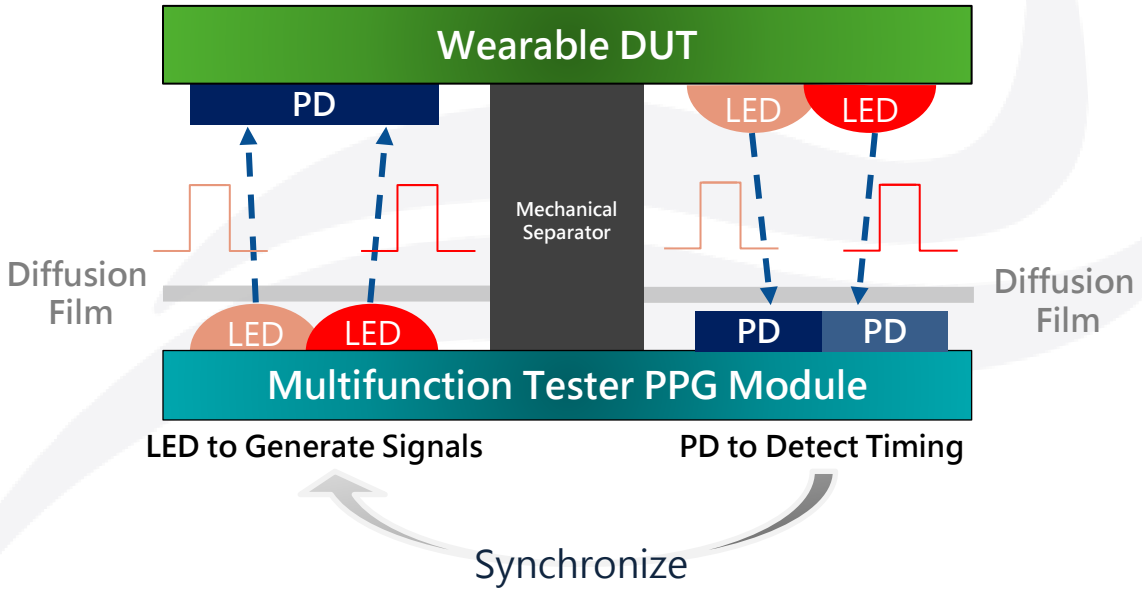


- BPM (Beat Per Minute) – adjusts the frequency of the AC signal to simulate different heart rates.
- DC – simulates brightness reflected of different skin colors.
- AC – simulates PPG waveforms changing in arterial blood volume within the skin.
- PI (Perfusion Index) – (AC/DC) x 100%

Green light



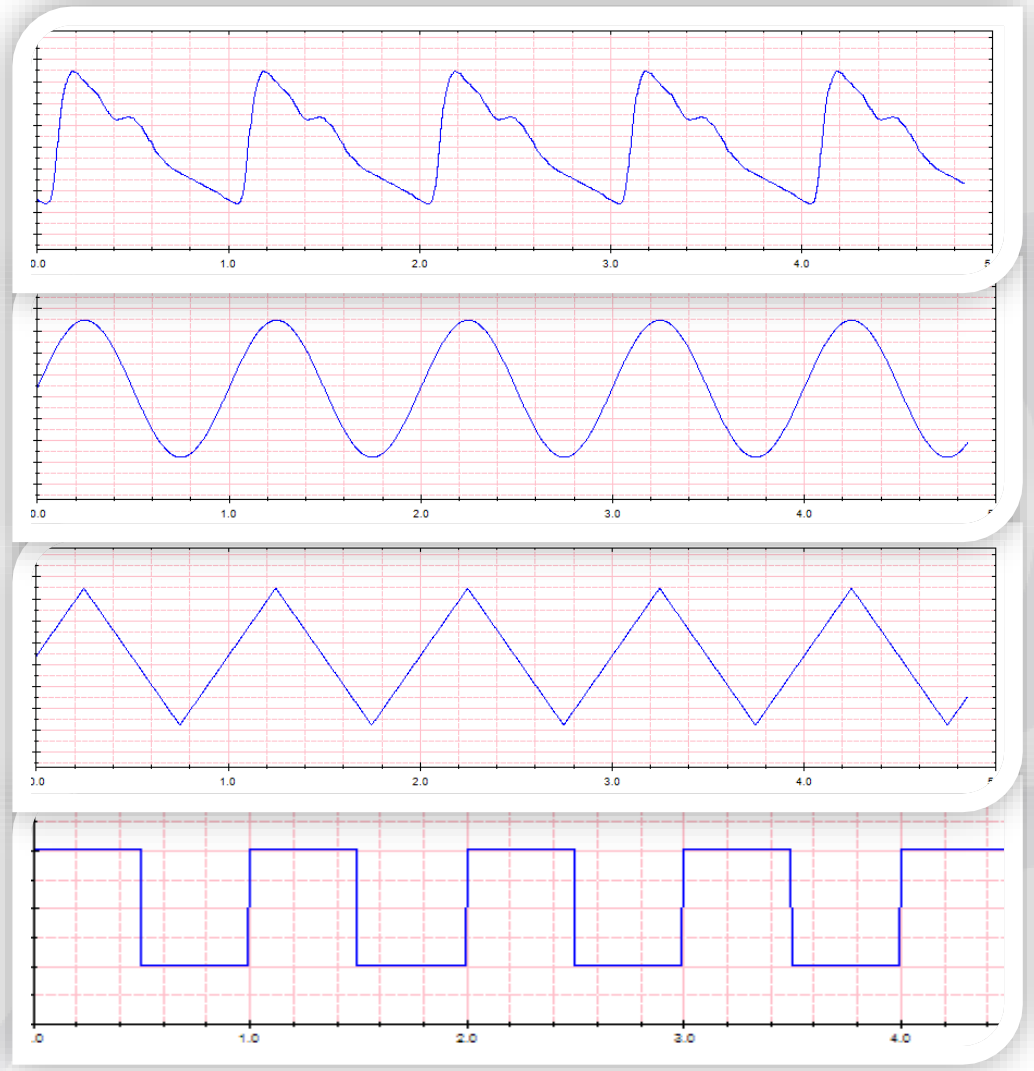
R & IR light



© 2022 WhaleTeq All Rights Reserved

Functional Signal and Parameter Range

- The standard AC source generates a frequency-accurate standard function waveform
  - Sine, Triangle, Square, or PPG waveform
  - Range: 10 bpm ~ 300 bpm
  - HR accuracy: ±1 bpm
- Adjustable AC/DC amplitude
  - Range of AC amplitude: 0.75 ~ 30 mV
  - Range of DC amplitude: 100 ~ 3000 mV
  - PI (AC/DC * 100%) range: 0.025% ~ 30%

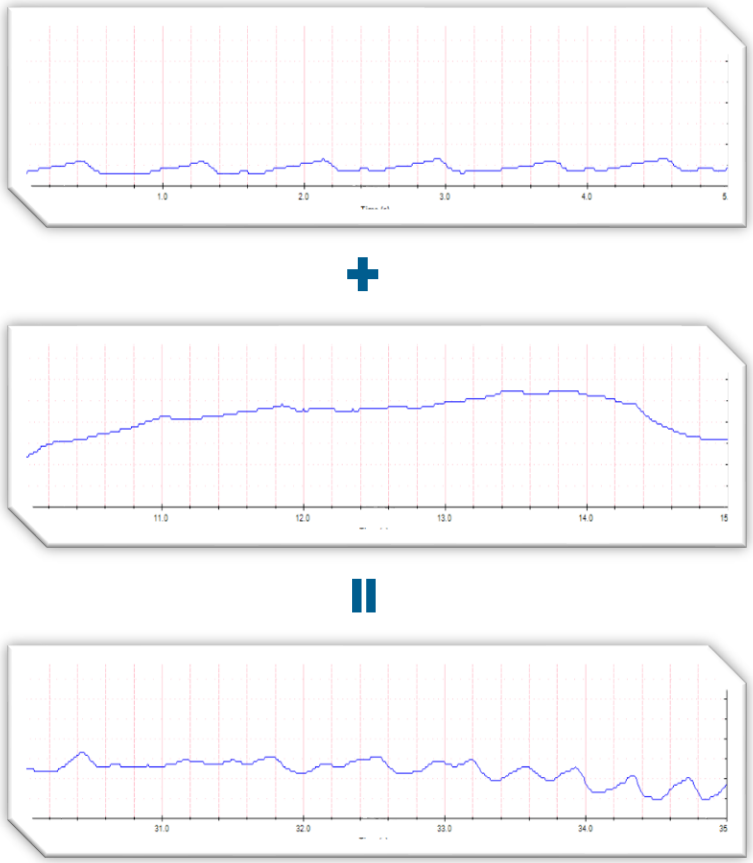


© 2022 WhaleTeq All Rights Reserved

Optical Noise

The biggest technical obstacle to digitizing PPG signals is to separate the arterial blood volume signals and noise

- The noise is divided into：



◆ Motion noise

(1) Non-pulsating physiological tissue movement such as during exercise or daily activities will lead to reflected light intensity changes with the movement.

(2) If the frequency of movement is close to the heart rate, it is difficult to differentiate it from arterial blood volume changes.

◆ Ambient light noise

(1) Ambient light, such as sunlight and lamp light.

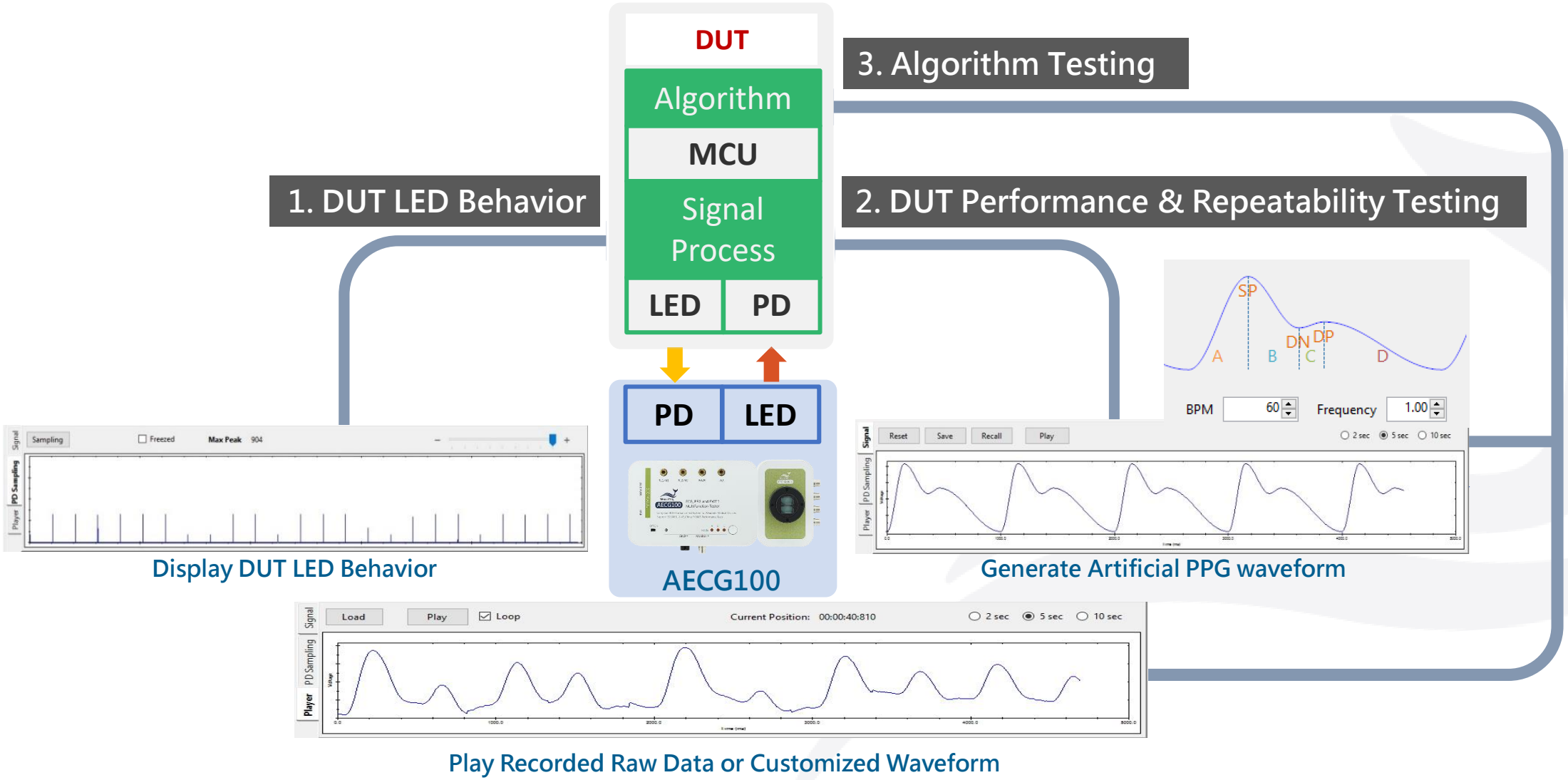
(2) It's also absorbed by the PD in the sensor and generates a physiological-like signal that interferes in measurements of changes in arterial blood volume.

◆ Motion noise and Ambient light noise

Note: The waveforms are for reference only and do not represent actual superimposed results.

© 2022 WhaleTeq All Rights Reserved

Three Major Testing Function



Display DUT LED Behavior

Generate Artificial PPG waveform

Play Recorded Raw Data or Customized Waveform

© 2022 WhaleTeq All Rights Reserved

AECG100 + PPG Module

AECG 100 main unit

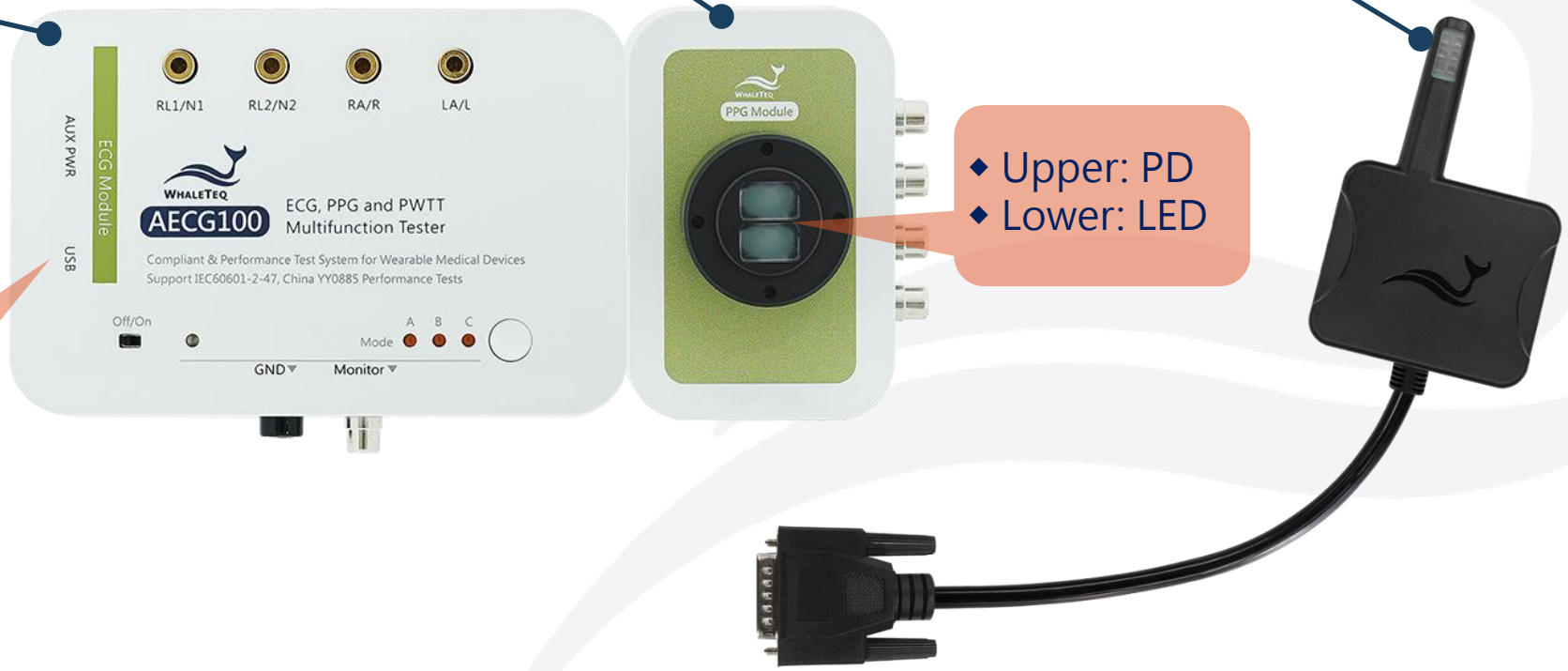
- A single-channel ECG device tester
- Designed for ECG standard (IEC 60601-2-47, YY0885)

Reflectance PPG module

- R & IR
- Green

Transmittance PPG module

- R & IR



- Upper: PD
- Lower: LED

USB port

- Used for connecting to a laptop/PC to control the AECG100 through its software

© 2022 WhaleTeq All Rights Reserved

SpO_2 Testing Example

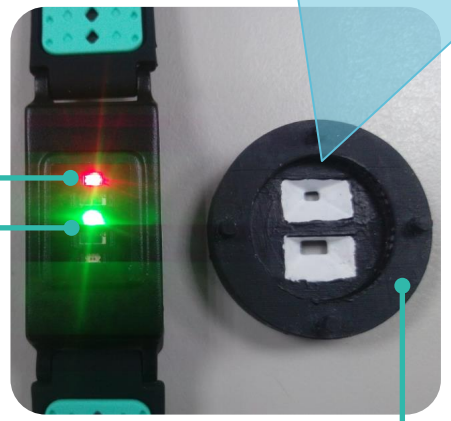
Testing MAXREFDES103 SpO_2 Function

1 2 3

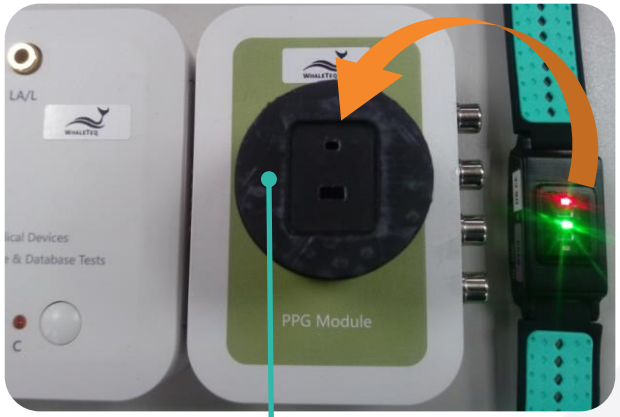
- Upper opening: matches DUT R & IR LEDs
- Lower opening: matches DUT PD, and blocks DUT green light to facilitate SpO_2 testing

R & IR LED

Green LED



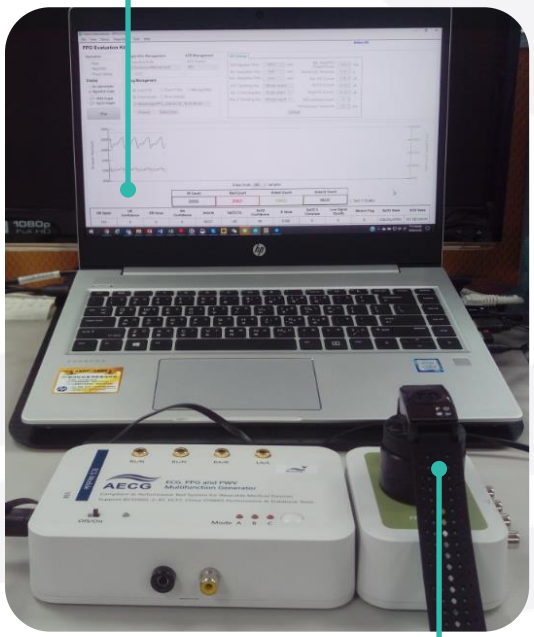
3D test fixture to match the DUT and AECG100 PPG module



Mount the other side of the 3D test fixture onto the PPG module and then put the DUT onto it

Align the LED and PD on DUT to the PD and LED on the module respectively

Control the AECG100 and the DUT



DUT (MAXREFDES103) put on the 3D test fixture using Bluetooth communication with the PC

© 2022 WhaleTeq All Rights Reserved

AECG100 SW Parameters & MAXREFDES103 SpO_2 Measurement

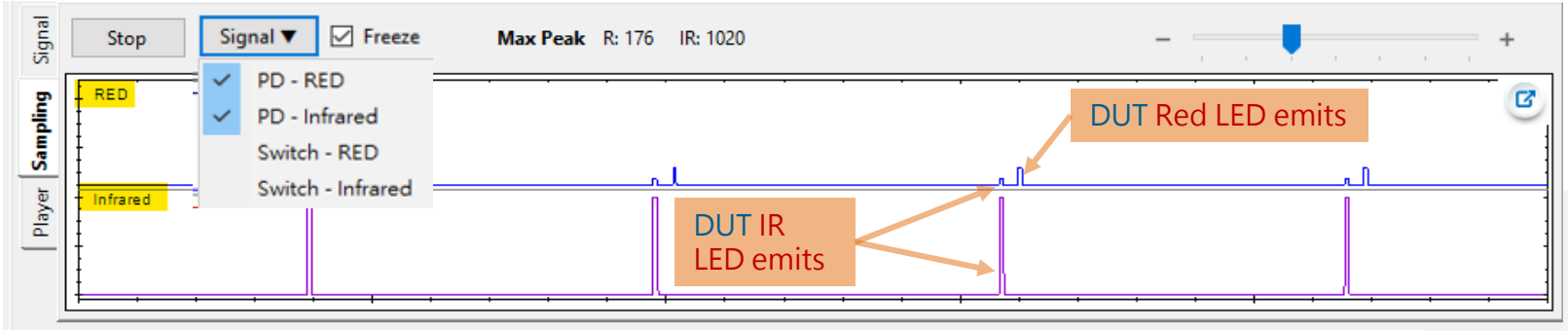
MAXREFDES103 PPG Evaluation Kit SW controls the DUT through Bluetooth or USB

© 2022 WhaleTeq All Rights Reserved

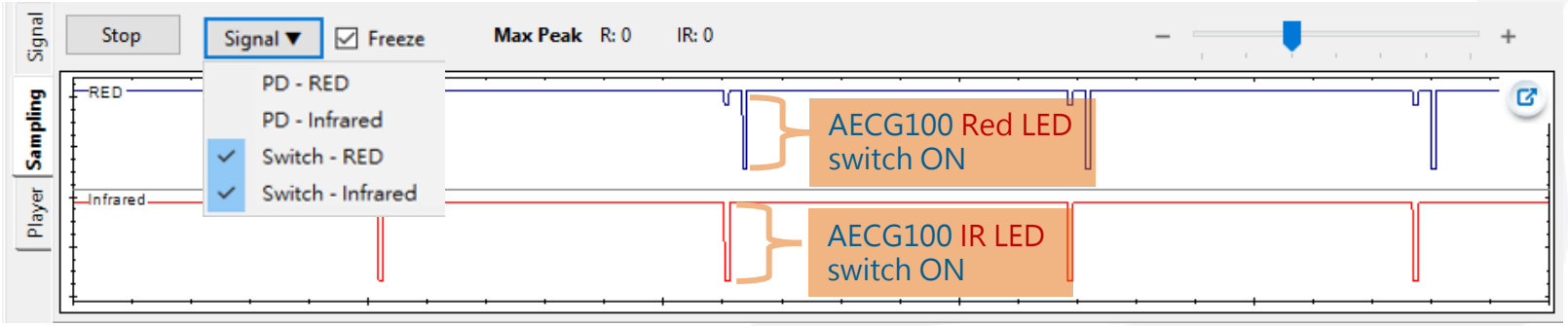
AECG100 LED Synchronizes With DUT LED Lighting Timing

Sampling tab – AECG 100 PD sampling and LED switch on/off function

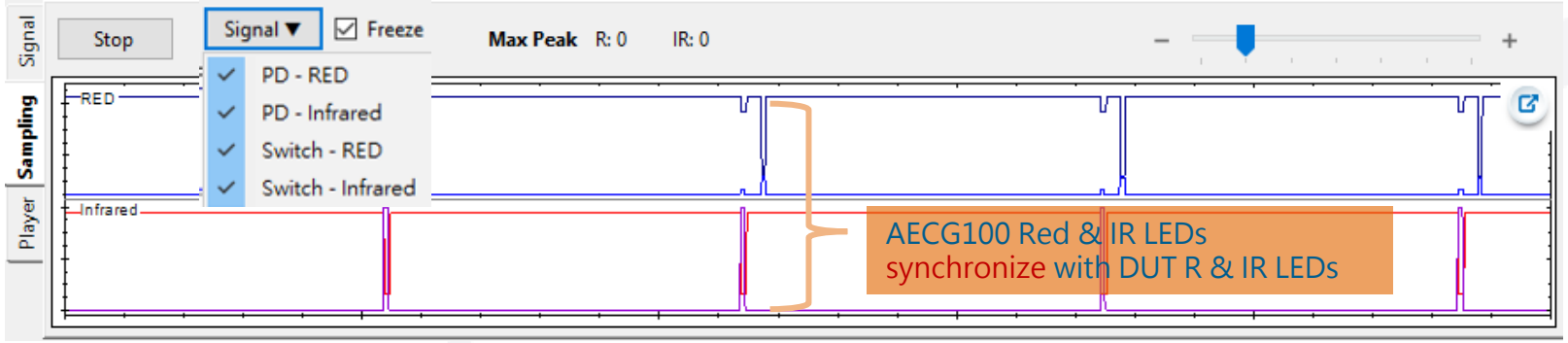
- AECG100 PDs detect DUT LEDs lighting timing & intensity



- AECG100 LED switches' on-off timing synchronizes with DUT LEDs

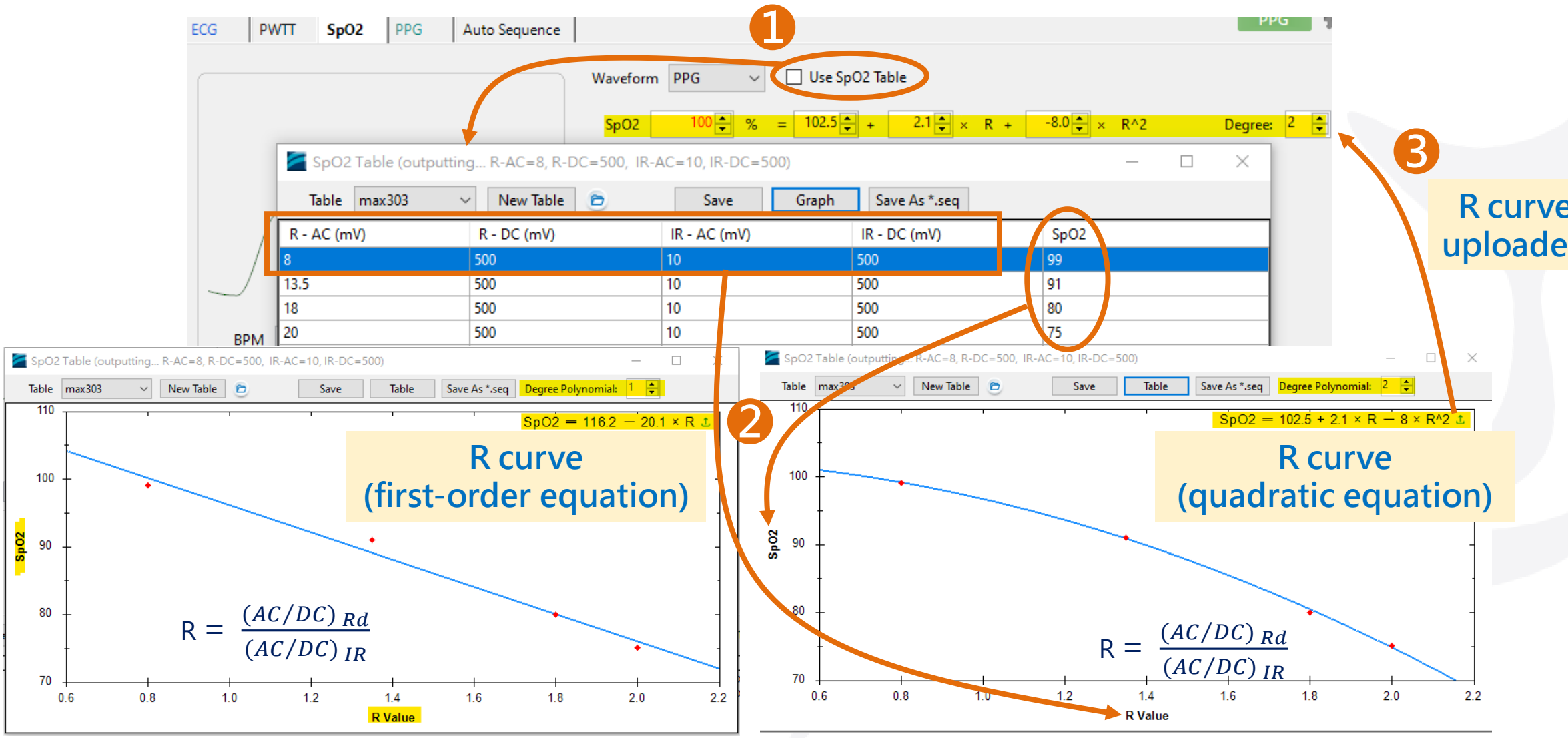


- DUT LEDs synchronize with AECG100 LED switches



© 2022 WhaleTeq All Rights Reserved

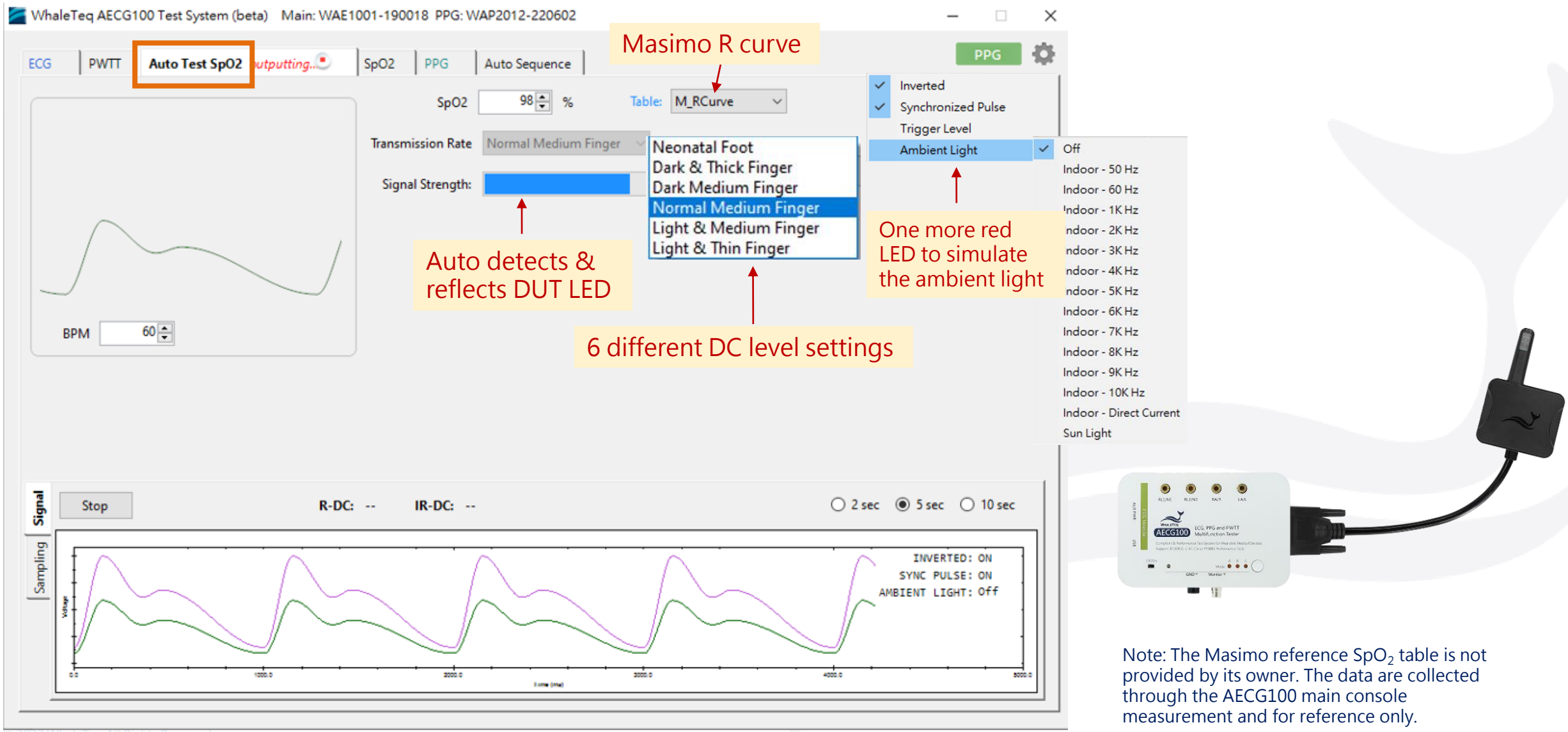
Establish a SpO_2 table & build an R curve via the SpO_2 table



© 2022 WhaleTeq All Rights Reserved

Auto Test SpO_2 Function

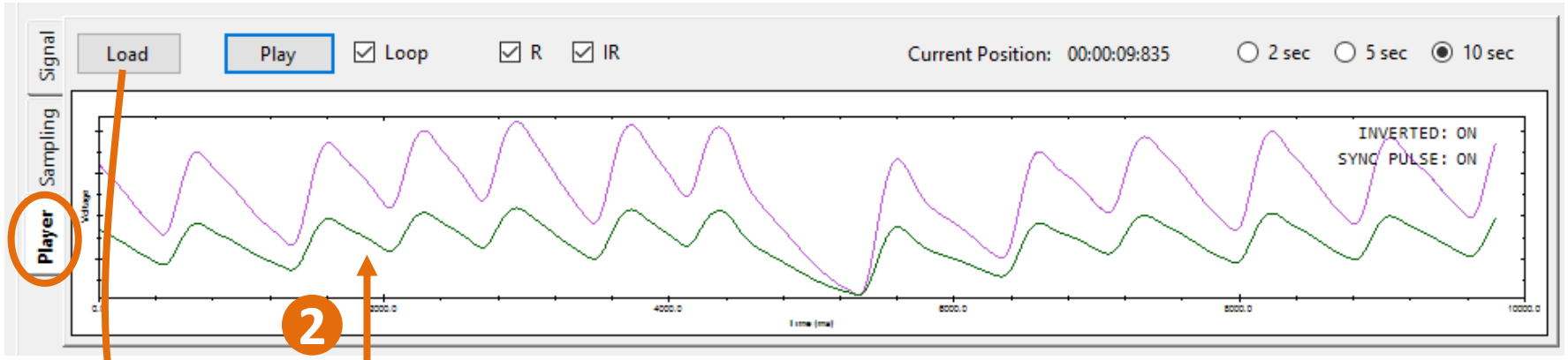
Transmittance PPG Module – Extra Test Fixture Is Not Required



Note: The Masimo reference SpO_2 table is not provided by its owner. The data are collected through the AECG100 main console measurement and for reference only.

© 2022 WhaleTeq All Rights Reserved

Player tab – Replay raw data file



A01P.txt: raw data file

A01P.txt

檔案(F) 編

```
250
25000
1
PPG_70
1.126240
1.130298
1.134806
1.138864
1.142922
1.146528
1.150586
1.154193
1.158251
1.161858
1.165464
1.169071
1.172678
```

Help - WhaleTeq format

File Format

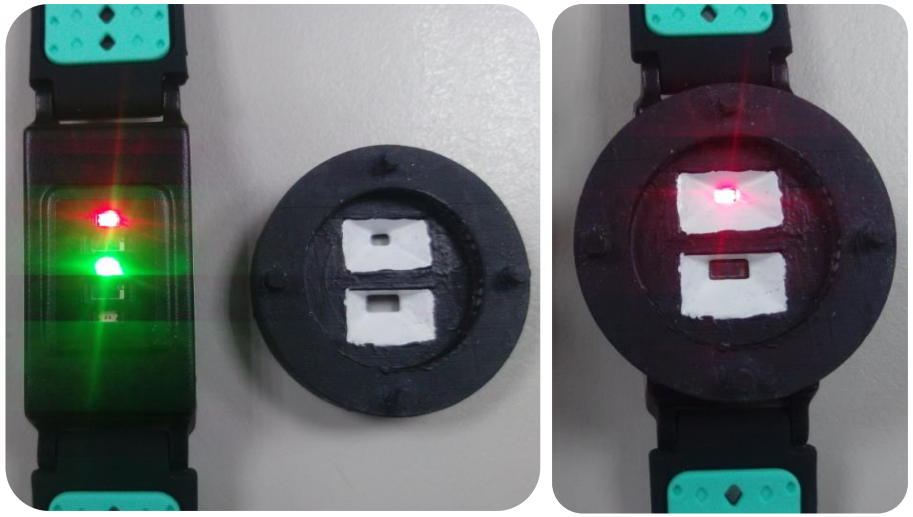
[sampling frequency]
[number of samples per signal]
[number of signals]
[signal description (signal-1)],[signal description (signal-2)], ...
[sample data-1 (signal-1)],[sample data-1 (signal-2)], ...
[sample data-2 (signal-1)],[sample data-2 (signal-2)], ...
...
[sample data-N (signal-1)],[sample data-N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

Description

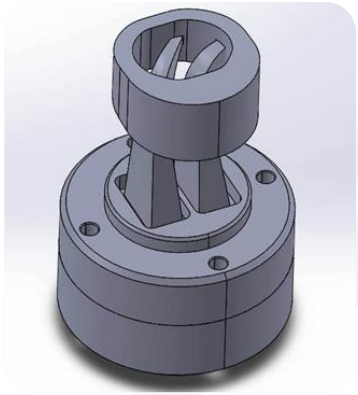
© 2022 WhaleTeq All Rights Reserved

Test Fixture Examples

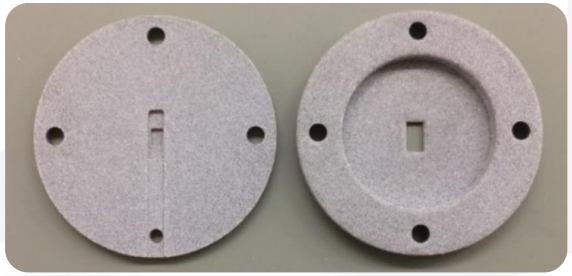
Watch

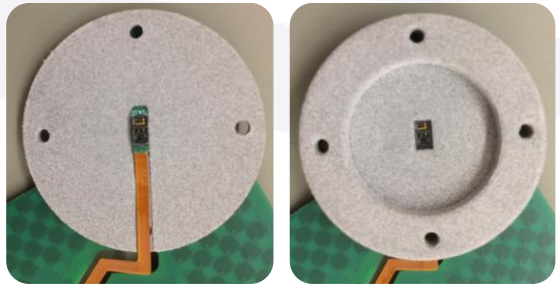


Ring



Earphone



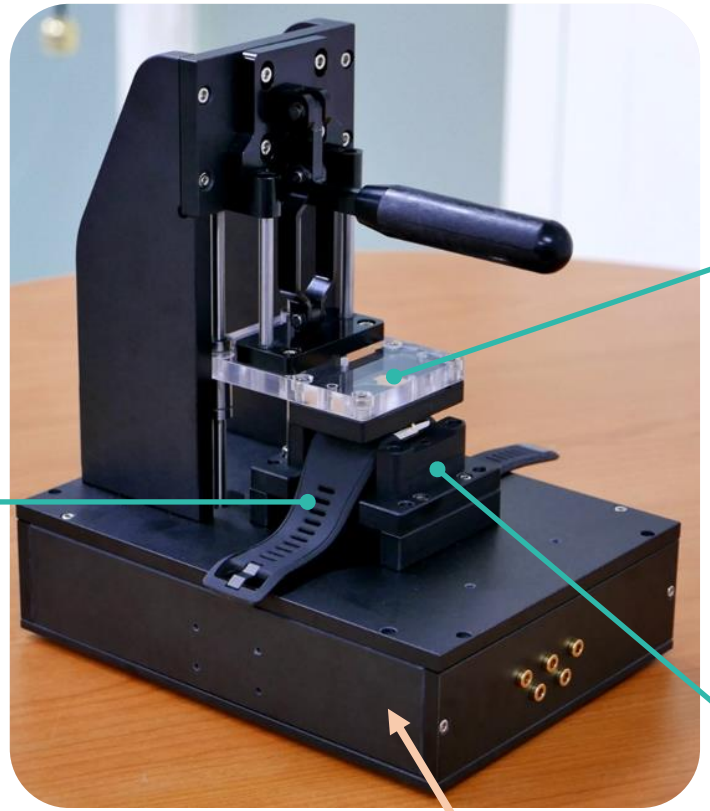


© 2022 WhaleTeq All Rights Reserved

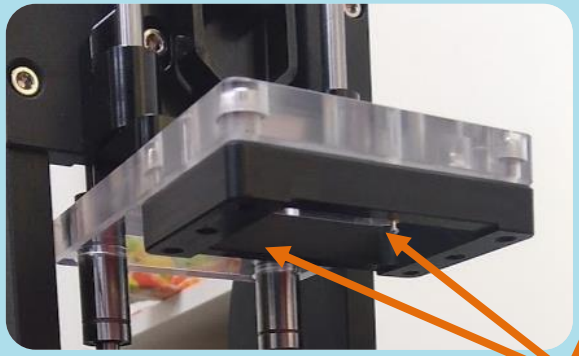
Test Fixture Examples

The smartwatch G69 adopted MediaTek MT2511 provides ECG, PPG, and Blood Pressure measurement functions

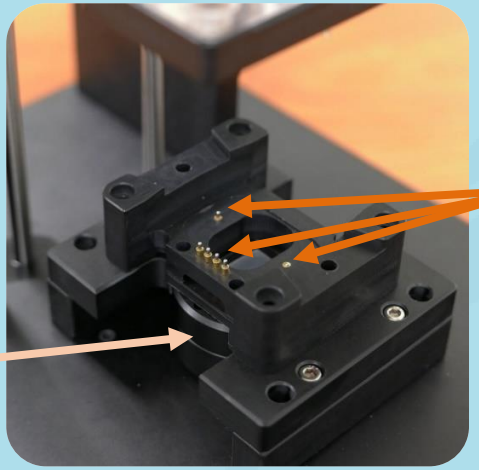
- WhaleTeq successfully developed exclusive test solutions for MediaTek MT2511.



DUT



Flexible probes on the upper fixture mounting base
(electric module matched)



Flexible probes on the lower
fixture mounting base
(electric module matched)

Multifunction tester PPG base
(optical module matched) and ECG connections

G69-related news and photos for reference:
https://kknews.cc/digital/4qa3k6g.html

© 2022 WhaleTeq All Rights Reserved

Conclusions

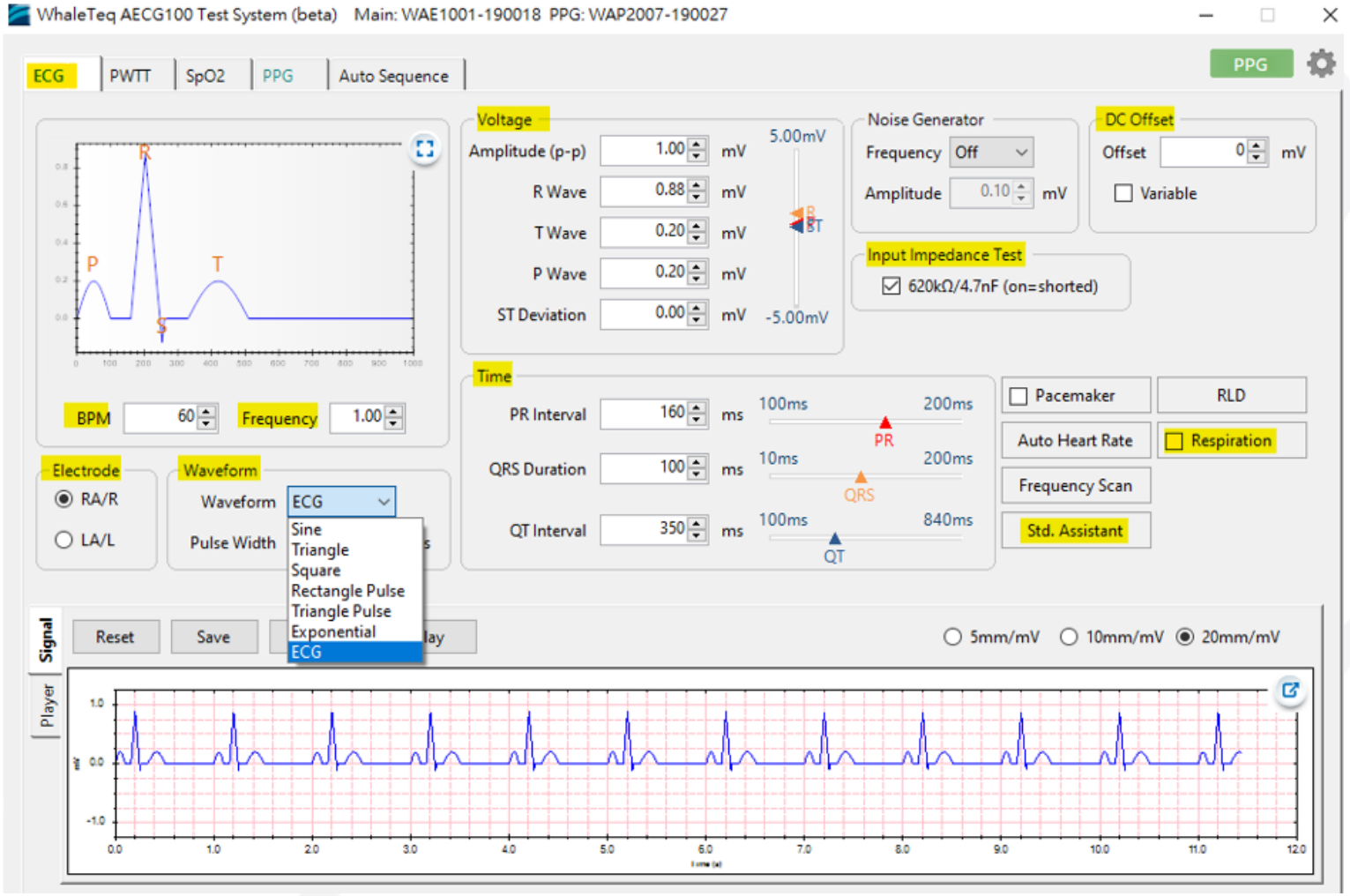
- The multifunction tester is mainly used to determine the performance, measurement range, and stability of pulse oximeters.
- The described method changes the parameter AC, then PI, and the R value, and finally the SpO_2 value changes according to the R curve.
- The R curve can be directly input or established through testing.
  - This method can be used to acquire stable measured values before clinical trials by avoiding directly conducting the clinical trials and having test results at great risk.
- Reference R curve: using the Multifunction tester to test and it is different from the R curve after having clinical trials.
- The above test takes the reflectance wearable device as an example. The transmittance pulse oximeter is also tested similarly.
  - The reflectance one has LED and PD on the same side while the transmittance one has them on the opposite sides.
  - In general, the transmittance one doesn't need a test fixture.

© 2022 WhaleTeq All Rights Reserved

How to use the Multifunction Tester to test ECG equipment according to ECG standards

© 2022 WhaleTeq All Rights Reserved

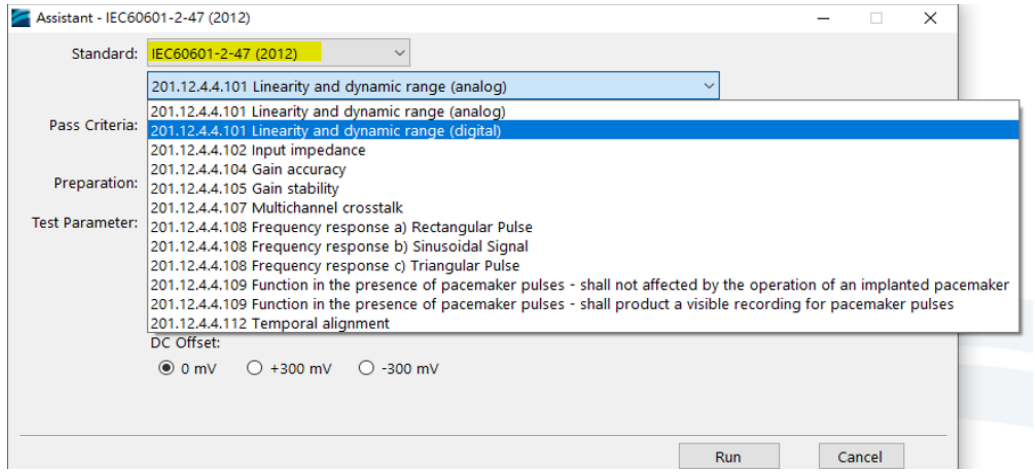
AECG100 Main Unit

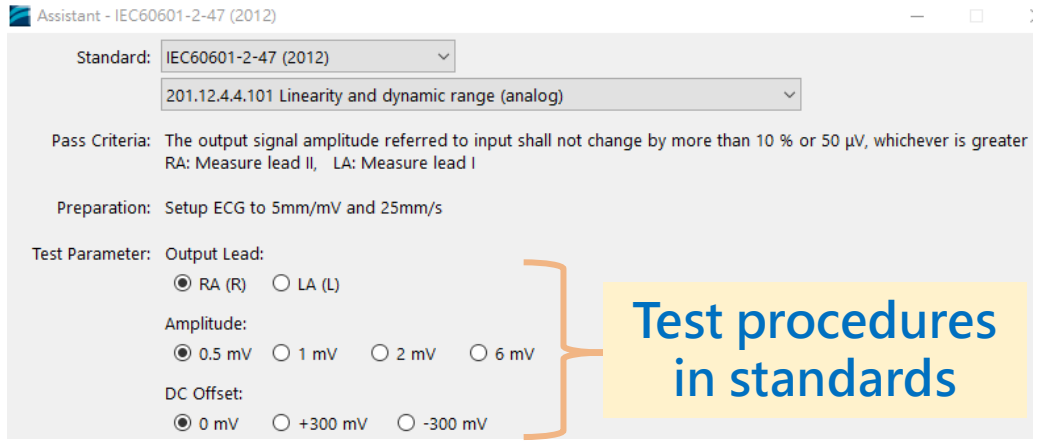


© 2022 WhaleTeq All Rights Reserved

IEC 60601-2-47:2012 & YY0885-2013

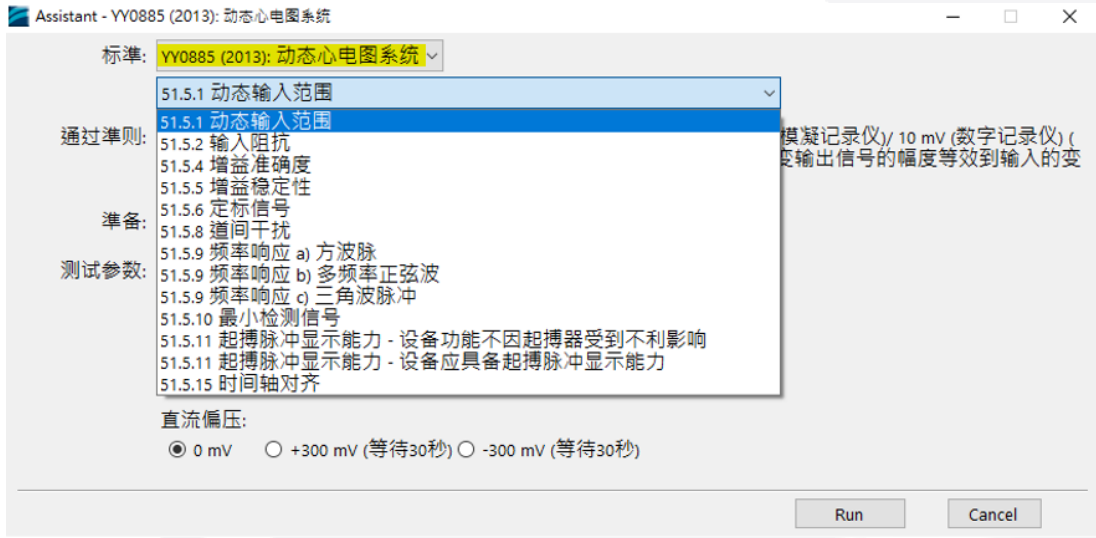
IEC 60601-2-47:2012





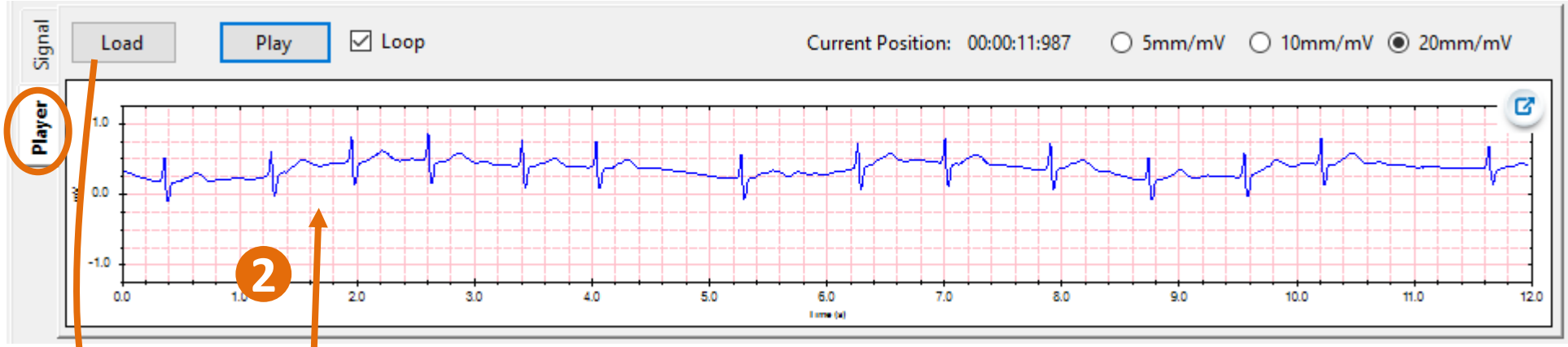
Test procedures in standards

YY0885-2013



© 2022 WhaleTeq All Rights Reserved

Player tab – Replay raw data file



A01P.txt: raw data file

A01E.txt -
檔案(F) 編輯

```
250
25000
1
ECG_70
0.324519
0.319712
0.319712
0.319712
0.320913
0.320913
0.320913
0.319712
0.314904
0.313702
0.312500
```

Help - WhaleTeq format

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

© 2022 WhaleTeq All Rights Reserved

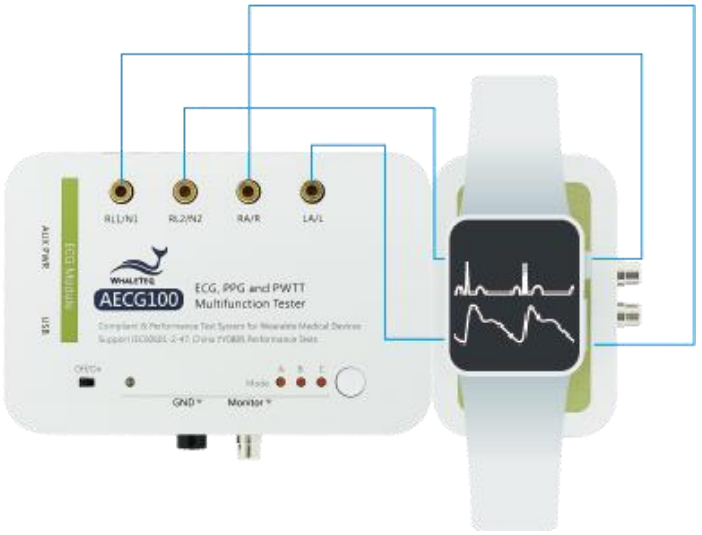
How to use the Multifunction Tester to test Pulse Wave Transit Time (PWTT)

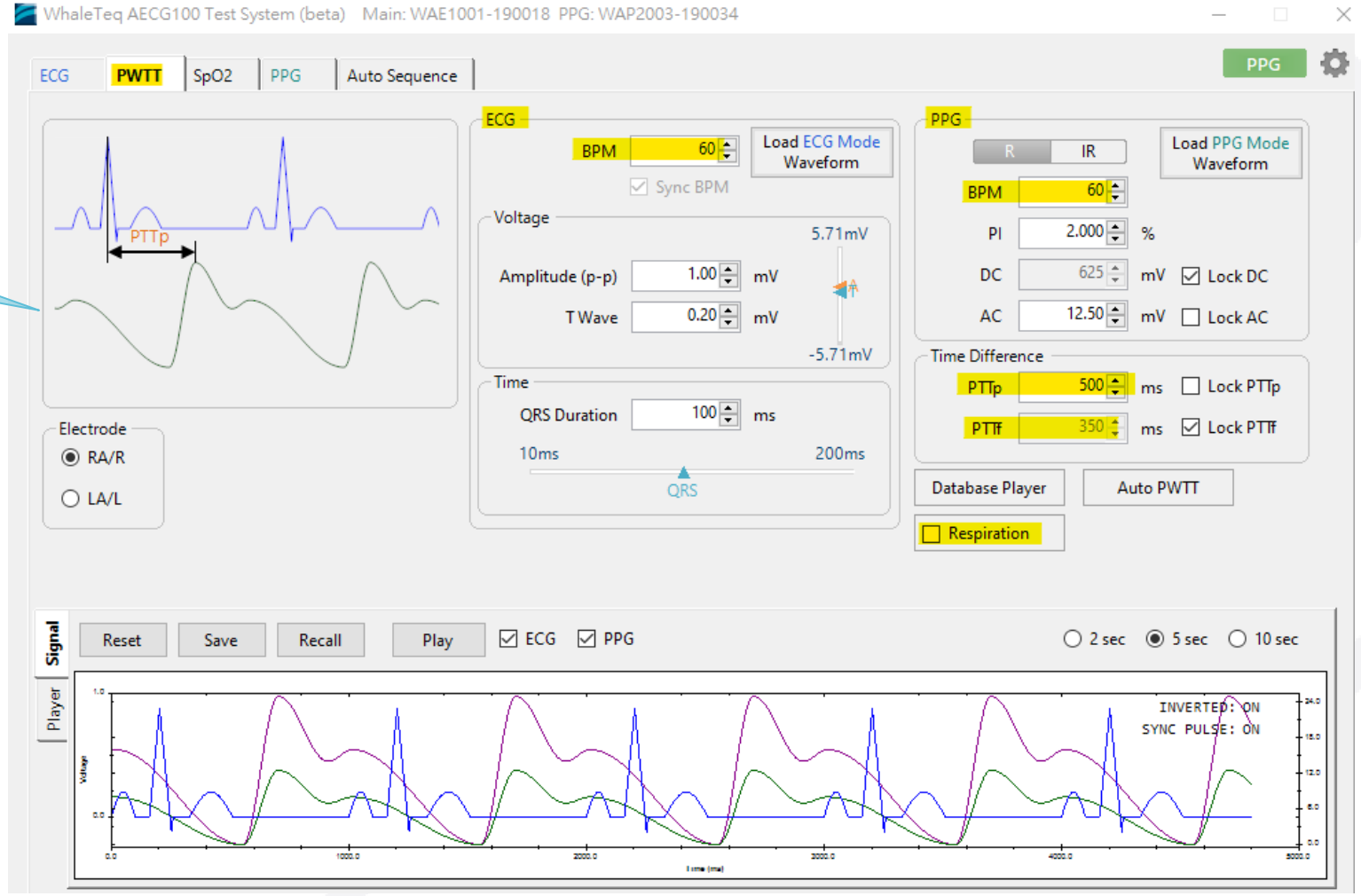
© 2022 WhaleTeq All Rights Reserved

Simultaneously play ECG and PPG waveforms

The estimated BP value can be calculated by measuring the time delay of ECG and PPG waveforms

- Simultaneously play ECG and PPG waveforms, and the time delay of ECG and PPG waveforms is adjustable.





© 2022 WhaleTeq All Rights Reserved

Conclusions

© 2022 WhaleTeq All Rights Reserved

Conclusions

Multifunction Tester

- The multifunction tester optical PPG modules provide PPG heart rate and SpO_2 testing
- DUT R curves can be established to provide algorithm verification and validation of pulse oximeters
- The ECG tester in the multifunction tester is designed according to the requirements of the standard test circuit, and the output signals fully comply with the medical standard
- The PWTT can be adjusted to effectively verify the accuracy of the blood pressure measurement algorithm
- Play raw data waveforms to reproduce clinical recordings or user-defined waveforms
- Standard assistant software organizes test steps and processes required test items of medical standards
- Provide SDK (Software Development Kit) for users to flexibly develop automated testing programs

© 2022 WhaleTeq All Rights Reserved

Verify and Validate Your Product Design with Ease

www.whaleteq.com service@whaleteq.com +886-2-2517-6255

WHALETEQ Web

WHALETEQ Facebook

WHALETEQ Youtube

WHALETEQ Linkedin