



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

- Applications of the Vital Sign Multifunction Tester

Speaker: Richard Ding

Time	Contents
30 min.	<ul style="list-style-type: none">• Basics of testing PPG optical Heart Rate (HR) and SpO₂ functions• Introduction of the Multifunction Tester• How to use the Multifunction Tester to test optical heart rate and SpO₂ functions
15 min.	<p>How to use the Multifunction Tester to:</p> <ul style="list-style-type: none">• Test ECG equipment according to ECG standards• Test Pulse Wave Transit Time (PWTT)
15 min.	<ul style="list-style-type: none">• Conclusions• Q&A

Basics of testing PPG optical Heart Rate (HR) and SpO₂ functions

Green LED and PD to Measure HR

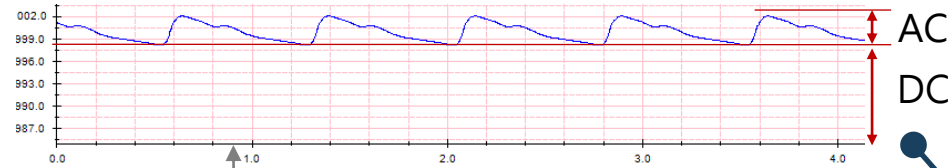
PPG: Photoplethysmography

LED emits green light to the skin

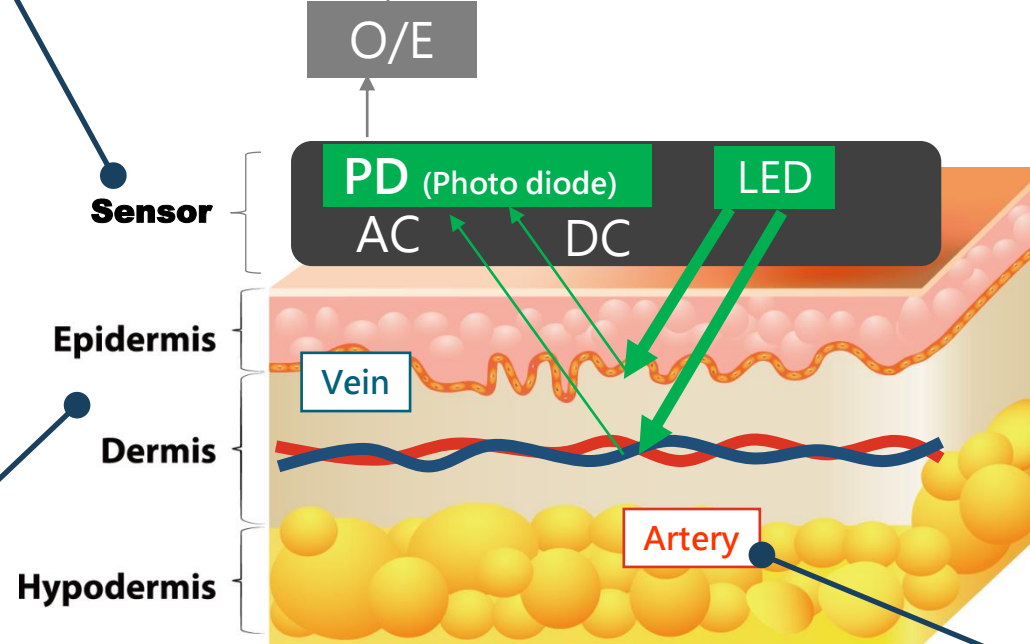
- ◆ **Partially absorbed** by skin tissue, arteries, and veins
- ◆ **Partially reflected** back to the PD of the sensor

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**.



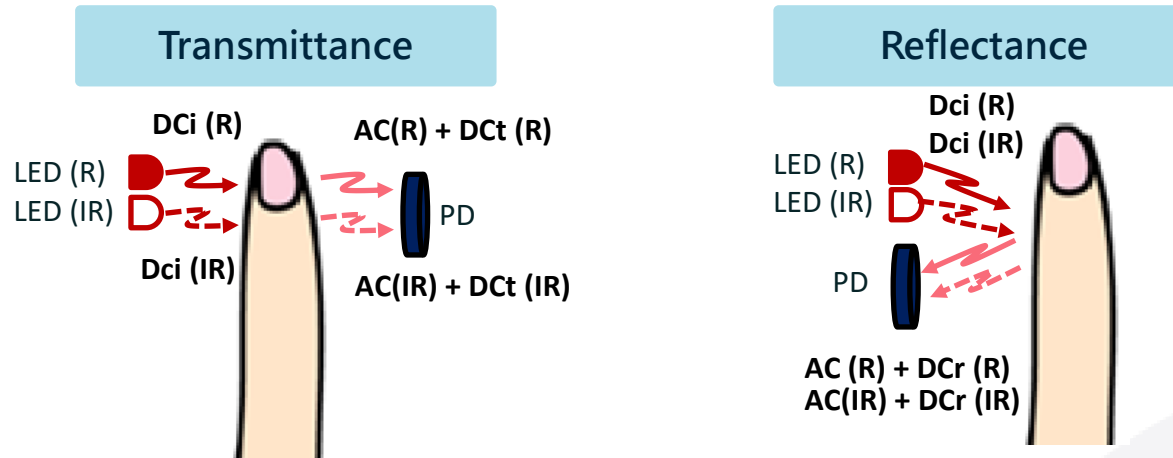
Artery

- ◆ **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**.

R & IR LED and PD

For R value and SpO₂ value of Pulse Oximetry

- **Pulse oximetry** determines SpO₂ 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 SpO₂ 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

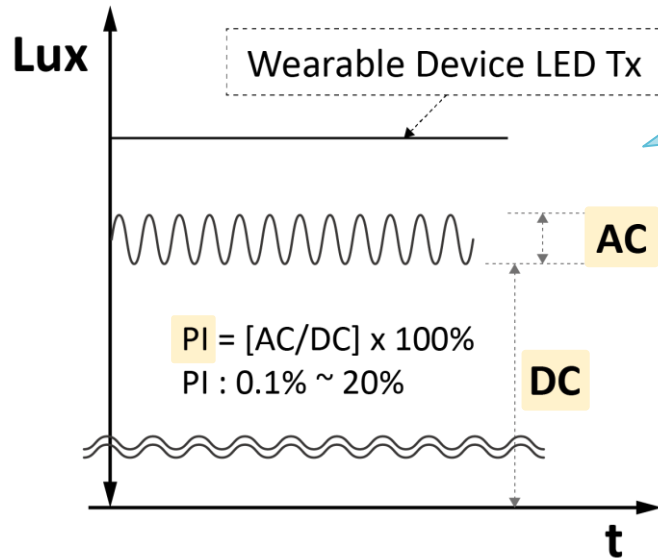
$$R = \frac{(AC/DC)_R}{(AC/DC)_{IR}} \rightarrow SpO_2 = K_1 + K_2 R \quad \text{R curve}$$

Note: SpO₂ value can be calculated as a linear function of R, where K₁ and K₂ are constants.

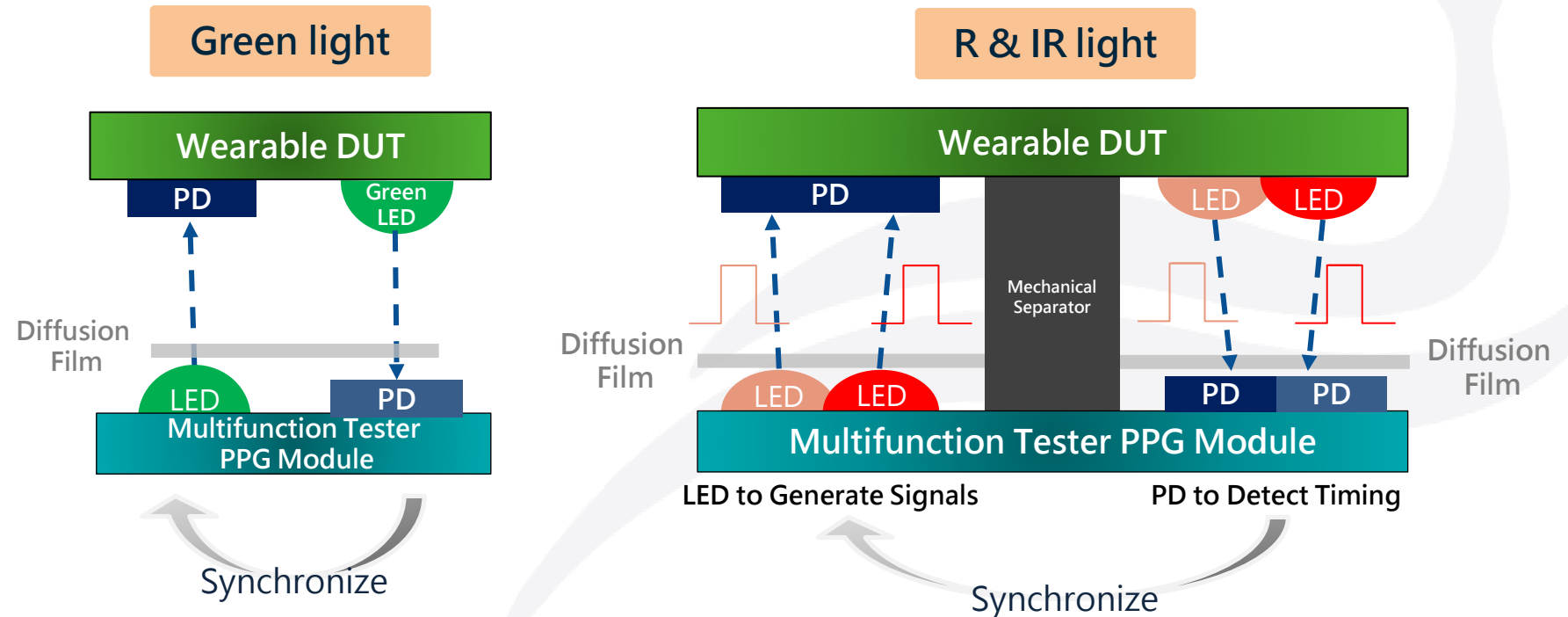
Introduction of the Multifunction Tester & how to use it to test optical heart rate and SpO₂ functions

Synchronization & Three Major Parameters AC, DC, BPM

Variable parameters, effective simulation of reflection light

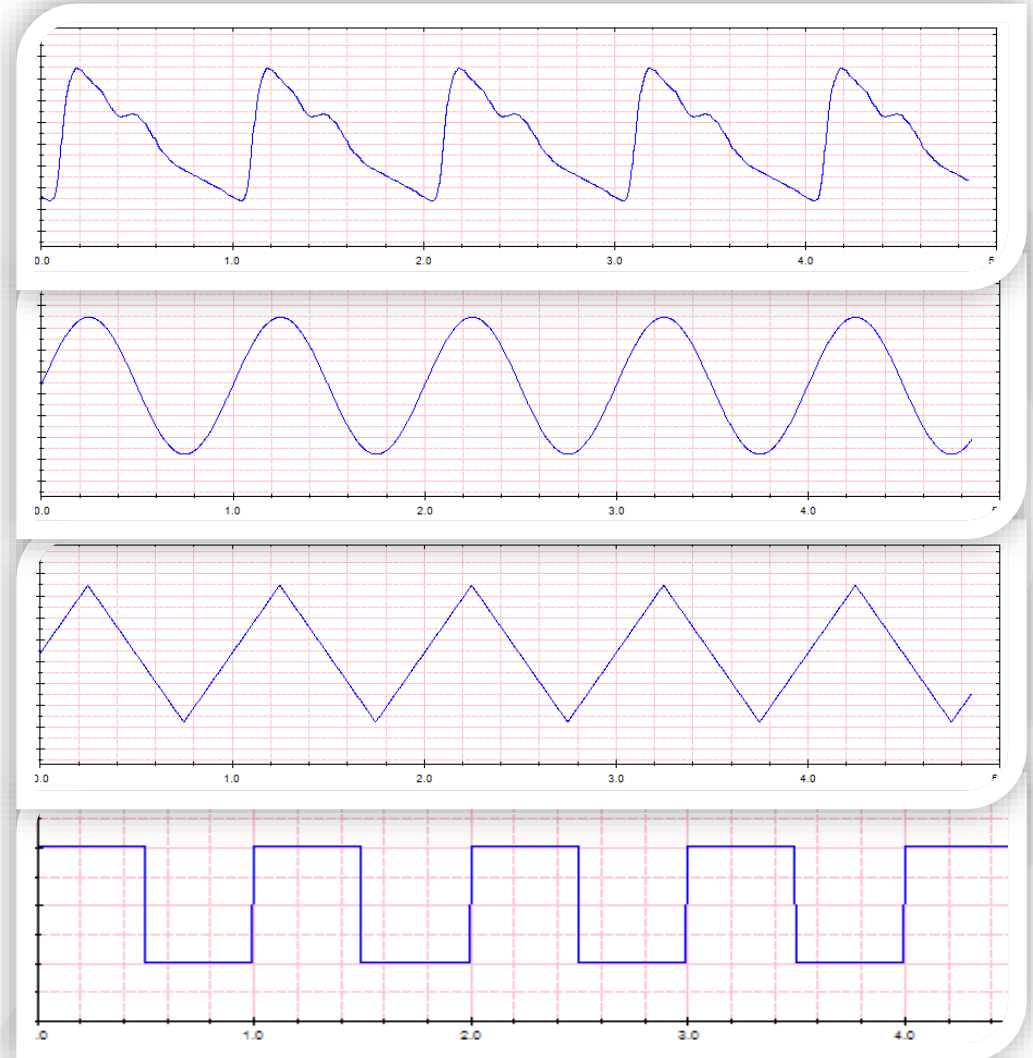


- **BPM** (Beat Per Minute) – adjusts the frequency of the AC signal to simulate different **heart rates**.
- **DC** – simulates brightness reflected of different **skin colors**.
- **AC** – simulates PPG waveforms changing in **arterial blood volume** within the skin.
- **PI (Perfusion Index)** – $(AC/DC)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



Functional Signal and Parameter Range

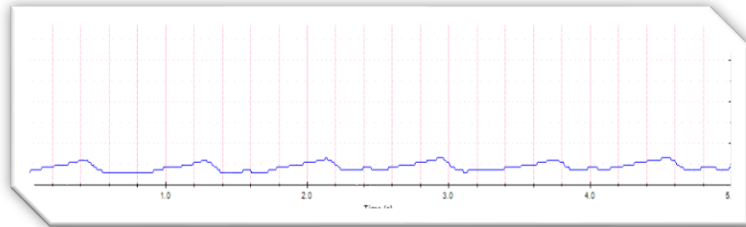
- The standard AC source generates a **frequency-accurate standard function waveform**
 - ◆ Sine, Triangle, Square, or PPG waveform
 - ◆ Range: **10 bpm ~ 300 bpm**
 - ◆ HR accuracy: **± 1 bpm**
- Adjustable AC/DC amplitude
 - ◆ Range of **AC amplitude**: **0.75 ~ 30 mV**
 - ◆ Range of **DC amplitude**: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



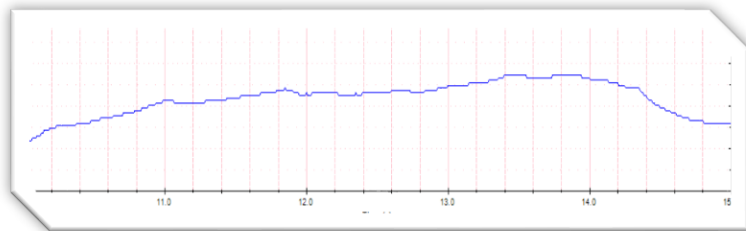
Optical Noise

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

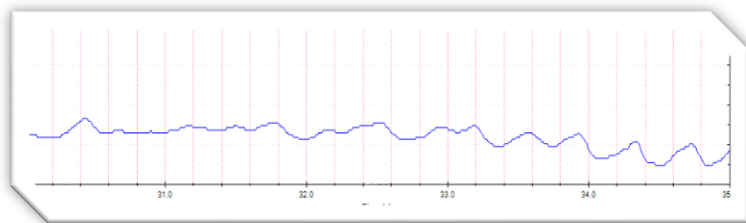
- The noise is divided into :



+



||



- ◆ **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.

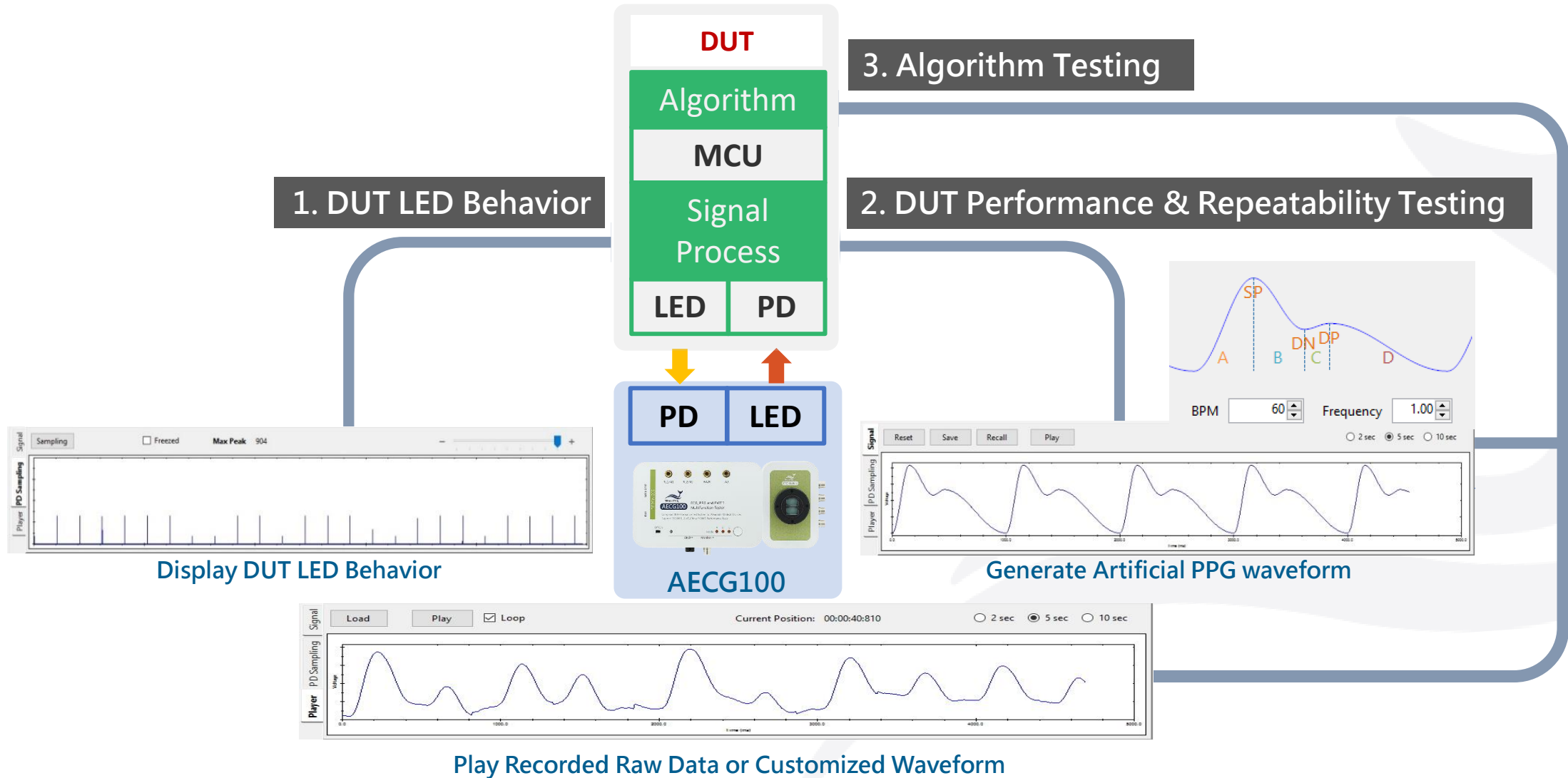
- ◆ **Ambient light noise**

- (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.

Three Major Testing Function



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

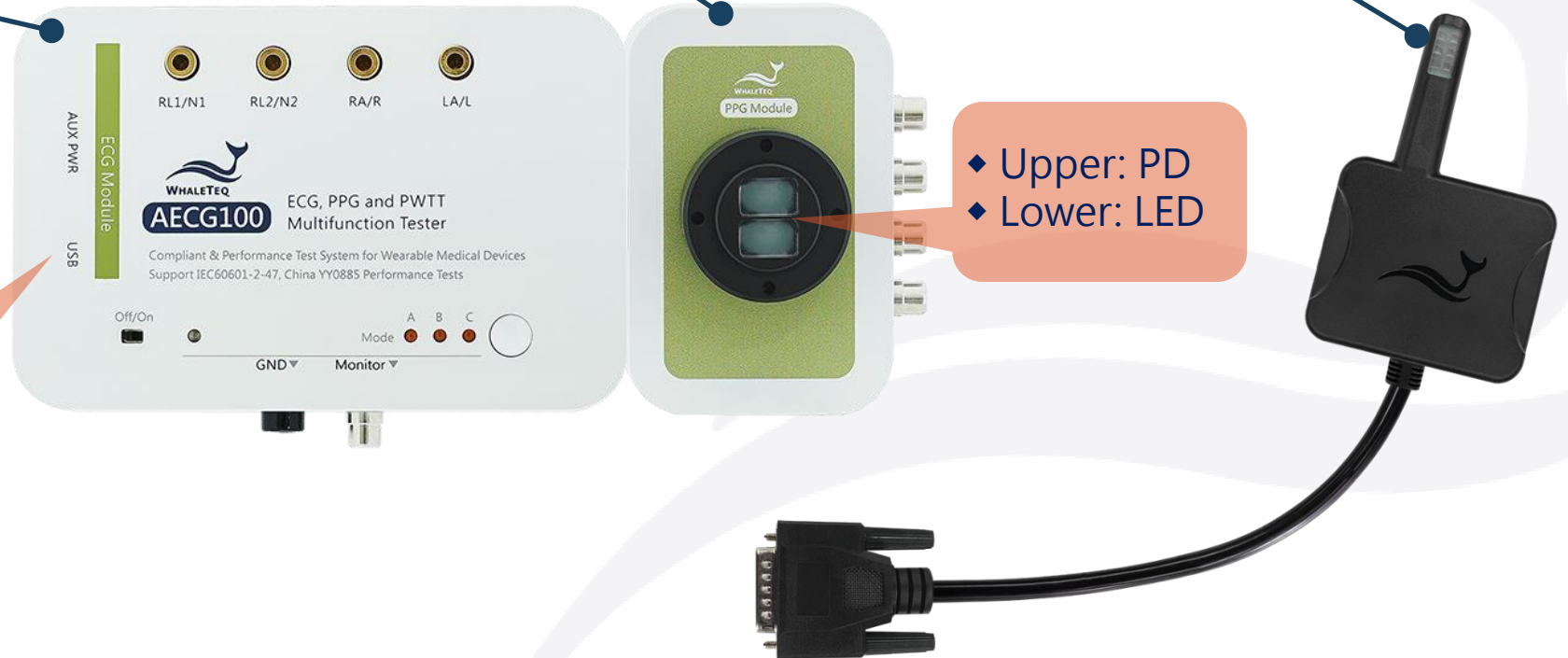
Transmittance PPG module

- ◆ R & IR

USB port

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

- ◆ Upper: PD
- ◆ Lower: LED



SpO₂ Testing Example

Testing MAXREFDES103 SpO₂ Function

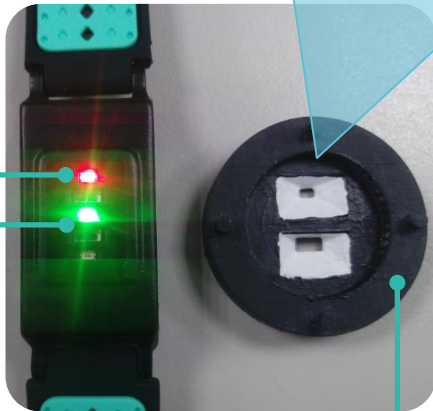
1

2

3

- ◆ Upper opening: matches DUT R & IR LEDs
- ◆ Lower opening: matches DUT PD, and blocks DUT green light to facilitate SpO₂ 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

AECG100 SW Parameters & MAXREFDES103 SpO₂ Measurement

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

Maxim DeviceStudio - [PPG EV Kit]

File View Device Diagnostics Tools Help

PPG Evaluation Kit

Operation

Raw
 Algorithm
 Power Saving

Display

Accelerometer
 Algorithm Data
 HRM Graph
 SpO2 Graph

Stop

Algorithm Management

Operation Mode: 0: Continuous HRM and SpO2

SCD

Log Management

Log to File Watch Flash HR Log (1Hz)

Write Header Write Settings

C:\MaximLogs\PPG_2022-09-05_14-18-20.csv

Browse Select Data

AFE Management

AFE Control: AEC

AEC Settings

Init Integration Time: 117.3
Min. Integration Time: 14.8
Max. Integration Time: 117.3
Init F Sampling-Avg: 100 sps, av
Min. F Sampling-Avg: 25 sps, av
Max. F Sampling-Avg: 100 sps, av

Red PD waveform

IR PD waveform

IR Count	Red Count	Green Count
8145	9434	3606

HR (bpm)	HR Confidence	RR Value	RR Confidence	Activity	SpO2 (%)	SpO2 confidence	R Value	SpO2 % Complete	Low Signal Quality	Motion Flag	SpO2 State	SCD State
115	99	0	0	REST	97.9	98	0.678	0	0	0	CALCULAT...	OFF SKIN

WhaleTeq AECG100 Test System (beta) Main: WAE1001-190018 PPG: WAP2003-190034

ECG PWTT SpO2 PPG Auto Sequence

Waveform PPG Use SpO2 Table

R curve

SpO2 98 % = 102.5 + 2.1 x R + -8.0 x R^2 Degree: 2

R Value 0.893 = PI (R) / PI (IR)

R curve

RED Lock AC Lock DC

PI 1.786 % = AC 8.93 mV / DC 500 mV

Output DC = 500 + 0 mV **R: PI = AC/DC**

Infrared Lock AC Lock DC

PI 2.000 % = AC 10.00 mV / DC 500 mV

Output DC = 500 + 0 mV **IR: PI = AC/DC**

BPM 60

Signal [Reset] [Save] [Recall] [Play] R IR 2 sec 5 sec 10 sec

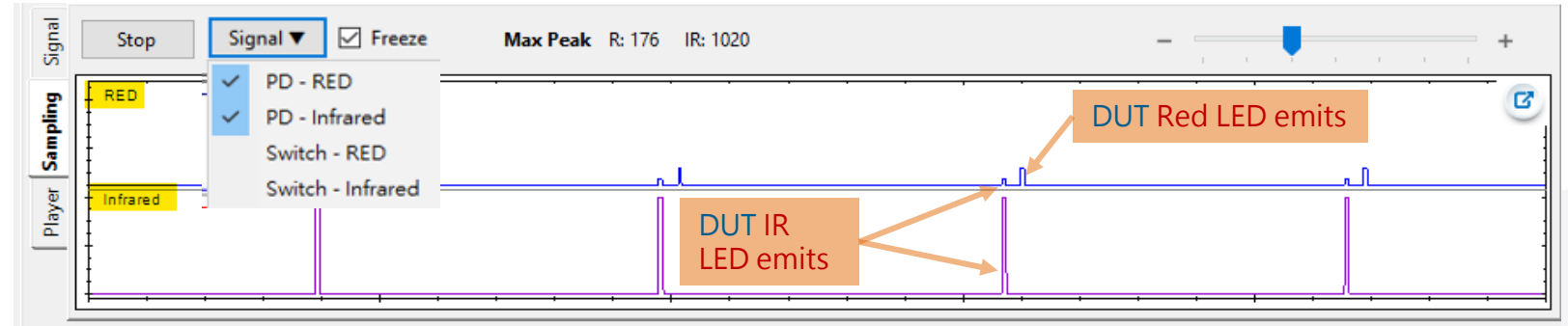
Player [Sampling] [Waveform]

INVERTED: ON
SYNC PULSE: ON

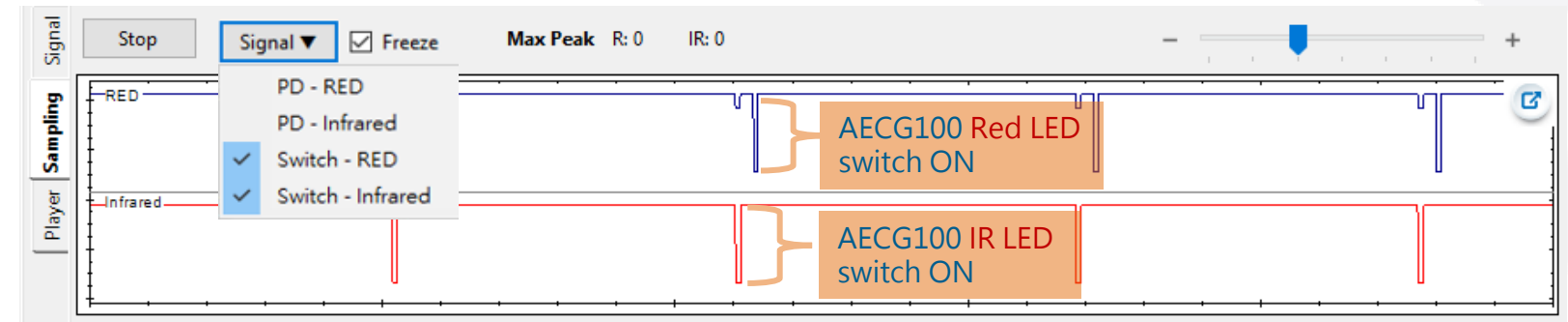
AECG100 LED Synchronizes With DUT LED Lighting Timing

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

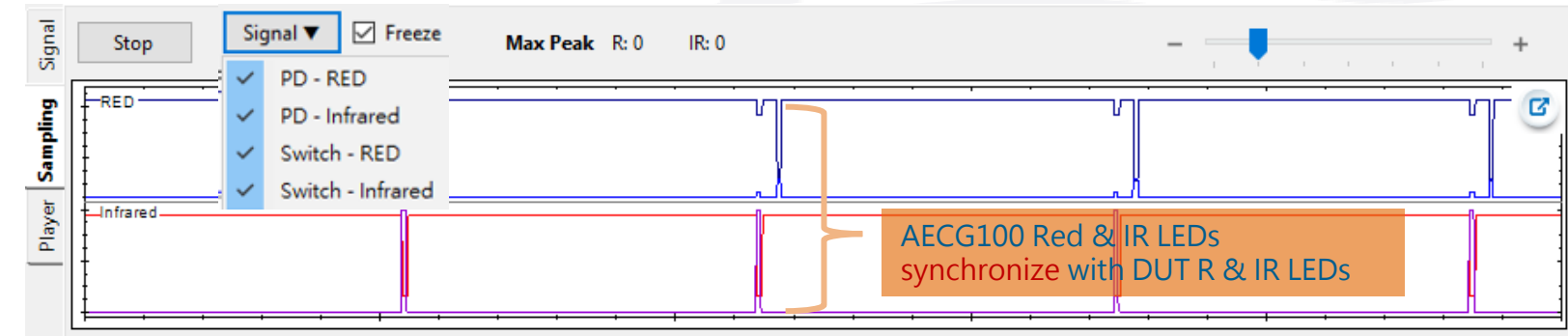
- ◆ AECG100 PDs detect **DUT LEDs** lighting timing & intensity



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



- ◆ DUT LEDs synchronize with AECG100 LED switches



Establish a SpO₂ table & build an R curve via the SpO₂ table

1 Use SpO₂ Table

SpO₂ = 100 % = 102.5 + 2.1 × R + -8.0 × R² Degree: 2

R - AC (mV)	R - DC (mV)	IR - AC (mV)	IR - DC (mV)	SpO ₂
8	500	10	500	99
13.5	500	10	500	91
18	500	10	500	80
20	500	10	500	75

2 R curve (first-order equation)

$$R = \frac{(AC/DC) Rd}{(AC/DC) IR}$$

SpO₂ = 116.2 - 20.1 × R

3 R curve (quadratic equation)

$$R = \frac{(AC/DC) Rd}{(AC/DC) IR}$$

SpO₂ = 102.5 + 2.1 × R - 8 × R²

R curve uploaded

Auto Test SpO₂ Function

Transmittance PPG Module – Extra Test Fixture Is Not Required

WhaleTeq AECG100 Test System (beta) Main: WAE1001-190018 PPG: WAP2012-220602

ECG | PWTT | **Auto Test SpO2** | SpO2 | PPG | Auto Sequence

SpO2: 98 % Table: M_RCurve

Transmission Rate: Normal Medium Finger

Signal Strength: [Bar]

Table: Neonatal Foot, Dark & Thick Finger, Dark Medium Finger, Normal Medium Finger, Light & Medium Finger, Light & Thin Finger

PPG Settings: Inverted, Synchronized Pulse, Trigger Level: Ambient Light

BPM: 60

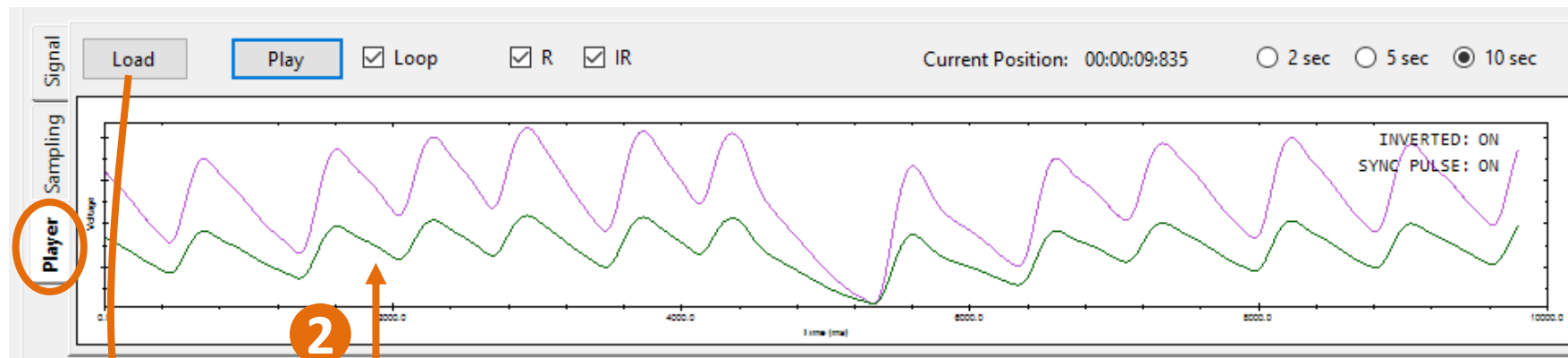
Signal Graph: R-DC: --, IR-DC: --, 2 sec, 5 sec, 10 sec. INVERTED: ON, SYNC PULSE: ON, AMBIENT LIGHT: Off

Annotations:
- Masimo R curve (points to Table dropdown)
- Auto detects & reflects DUT LED (points to Signal Strength bar)
- 6 different DC level settings (points to Table dropdown)
- One more red LED to simulate the ambient light (points to Ambient Light dropdown)



Note: The Masimo reference SpO₂ table is not provided by its owner. The data are collected through the AECG100 main console measurement and for reference only.

Player tab – Replay raw data file



1

A01P.txt: raw data file

```
A01P.txt
檔案(F) 編輯
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

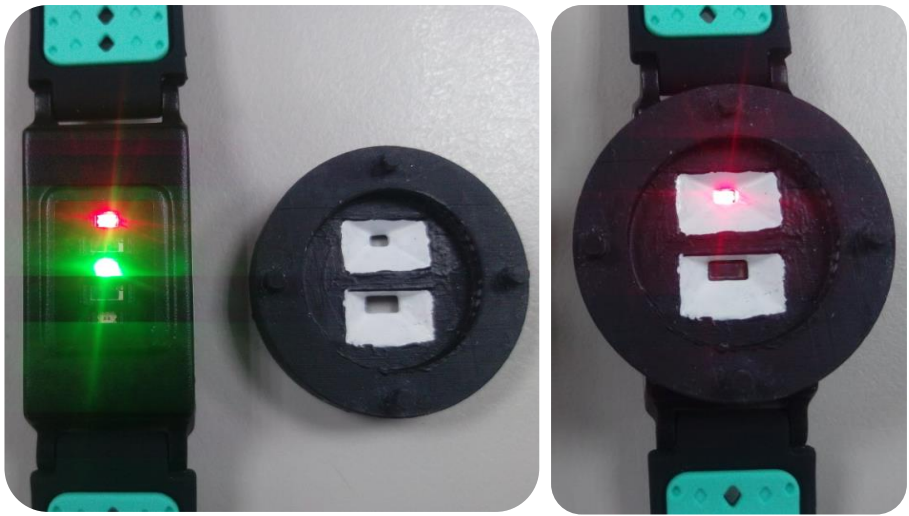
File Format

[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)], ...

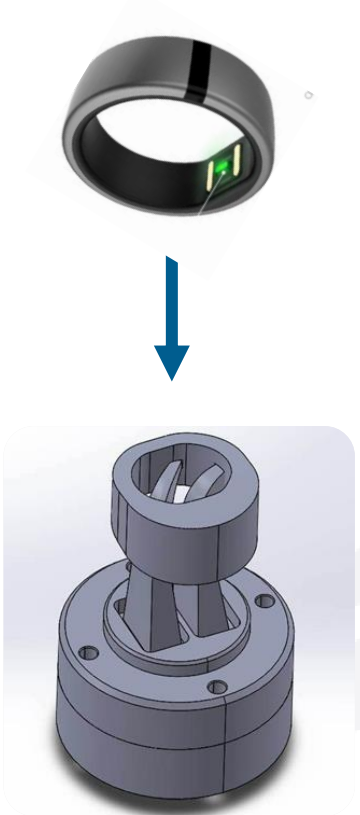
Description

Test Fixture Examples

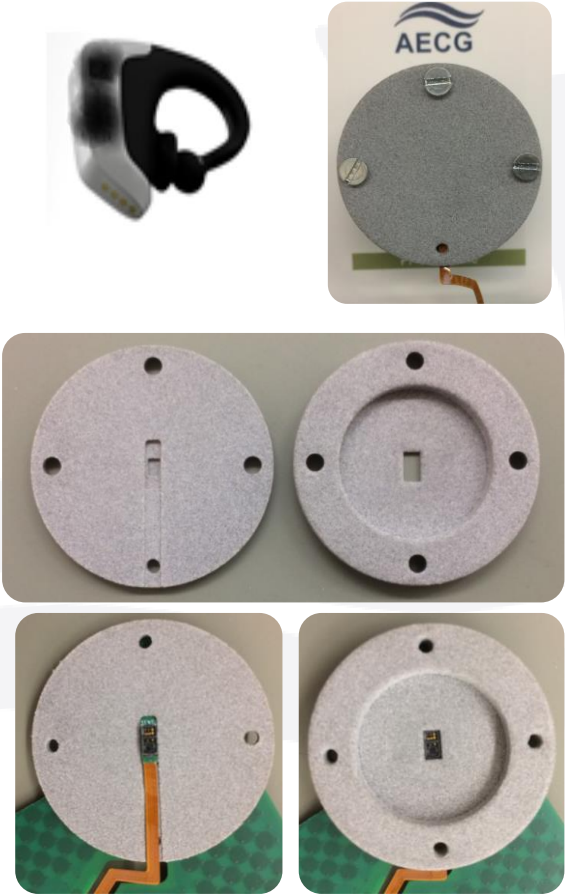
Watch



Ring



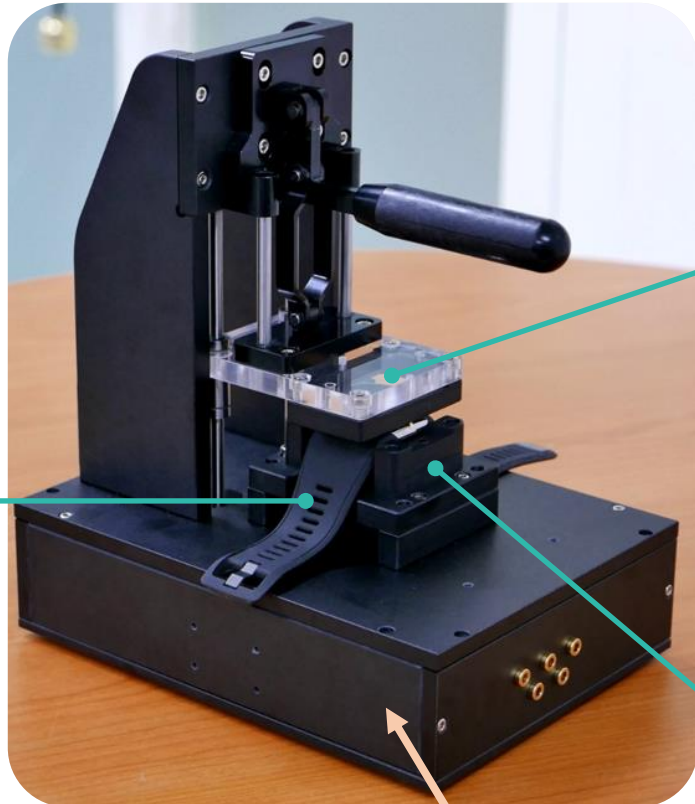
Earphone



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.

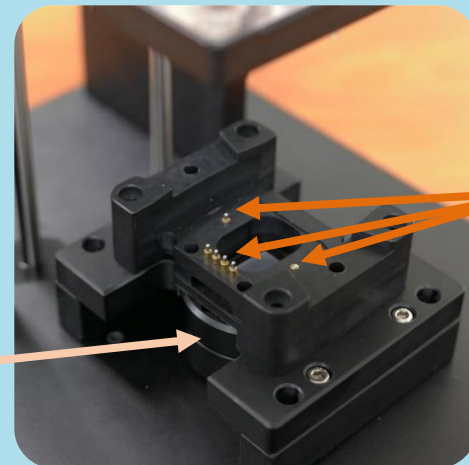


DUT

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



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



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

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

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 SpO₂ 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.



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

AECG100 Main Unit



WhaleTeq AECG100 Test System (beta) Main: WAE1001-190018 PPG: WAP2007-190027

ECG | PWTT | SpO2 | PPG | Auto Sequence | PPG

ECG

Amplitude (p-p) 1.00 mV
 R Wave 0.88 mV
 T Wave 0.20 mV
 P Wave 0.20 mV
 ST Deviation 0.00 mV

5.00mV
 -5.00mV

Noise Generator
 Frequency Off
 Amplitude 0.10 mV

DC Offset
 Offset 0 mV
 Variable

Input Impedance Test
 620kΩ/4.7nF (on=shorted)

BPM 60 Frequency 1.00

Time
 PR Interval 160 ms 100ms 200ms
 QRS Duration 100 ms 10ms 200ms
 QT Interval 350 ms 100ms 840ms

Electrode
 RA/R
 LA/L

Waveform
 Waveform ECG
 Pulse Width

Pacemaker
 RLD
 Auto Heart Rate
 Respiration
 Frequency Scan

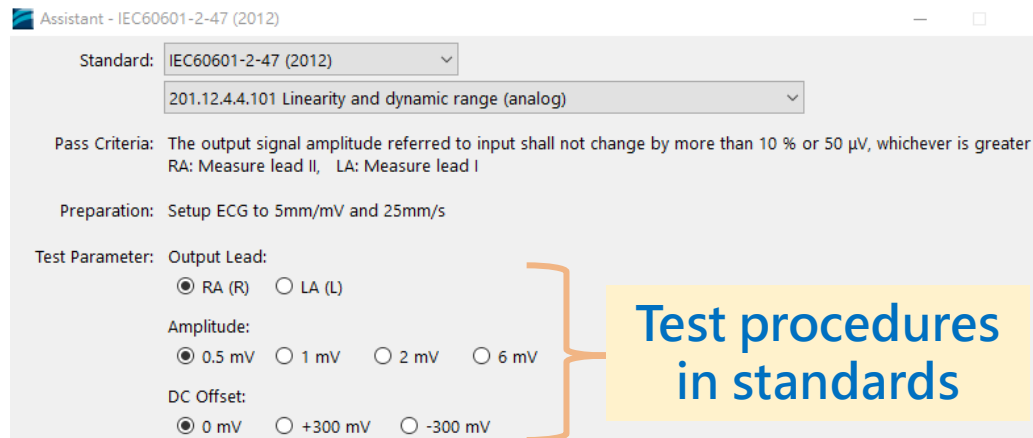
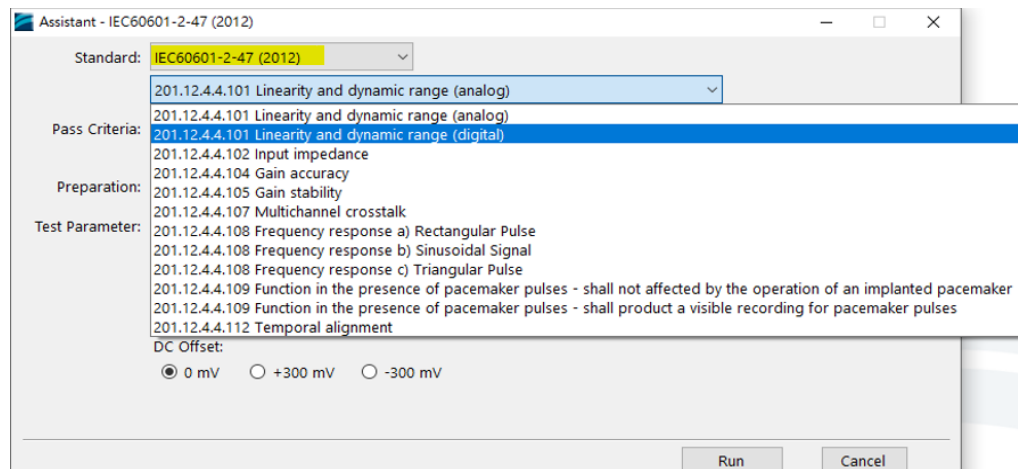
Signal

5mm/mV 10mm/mV 20mm/mV

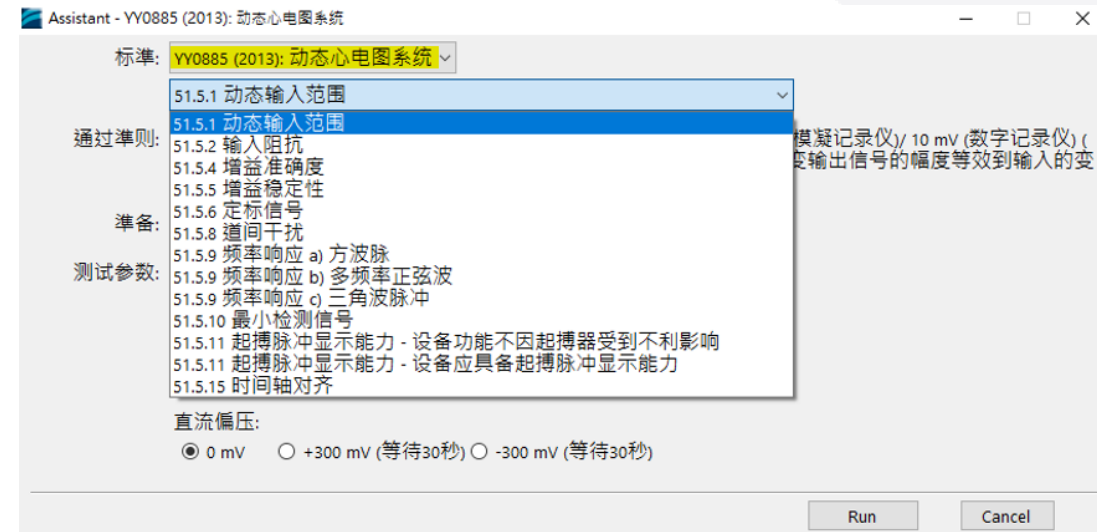
Player
 1.0
 0.0
 -1.0
 0.0 1.0 2.0 3.0 4.0 5.0 6.0 7.0 8.0 9.0 10.0 11.0 12.0
 Time (s)

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

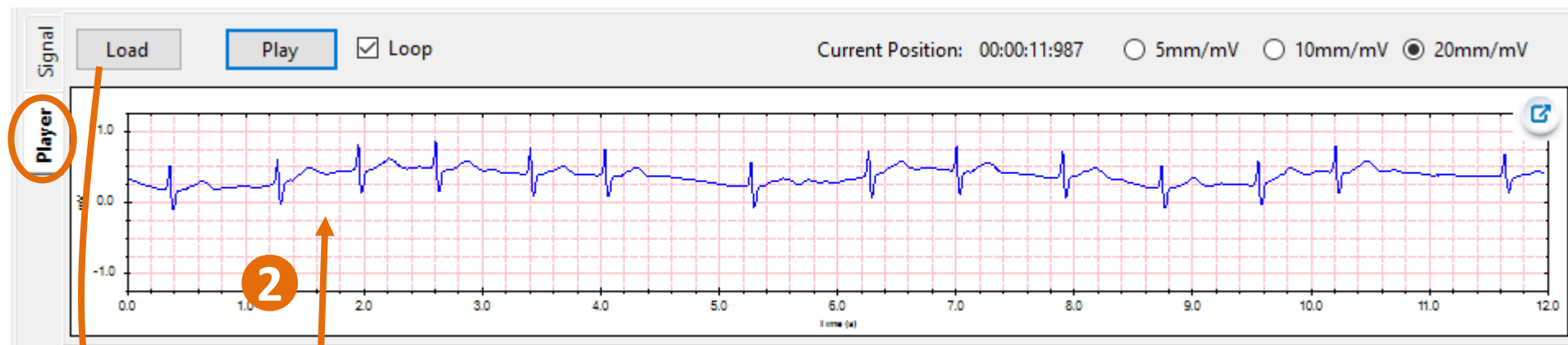
IEC 60601-2-47:2012



YY0885-2013



Player tab – Replay raw data file



1 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
0.319712
0.320913
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)], ...
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...
[sample data-N (signal-1)],[sample data-N (signal-2)], ...

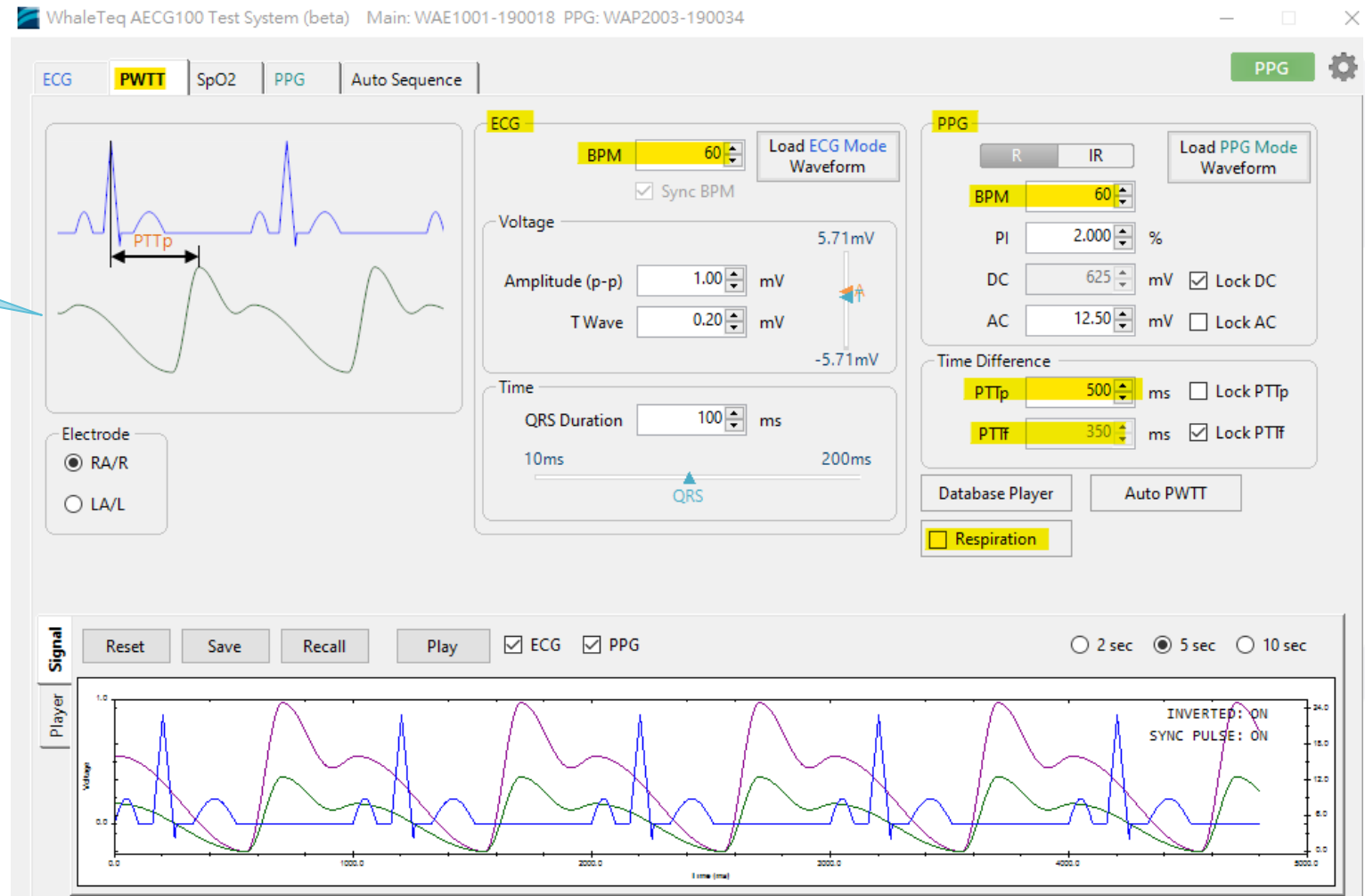
Description

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

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.



Conclusions

Conclusions

Multifunction Tester

- The multifunction tester **optical PPG modules** provide PPG heart rate and SpO₂ 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



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