Test Solutions for
Medical Device Manufacturers

WHALETEQ

【From Theory to Practice】A Comprehensive Guide to Conducting Accurate Tests for ECG, PPG, PWTT, and Respiration Rate

Speaker: Richard Ding

Verify and Validate Your Product Design with Ease

Time	Contents
30 min.	• ECG test methods according to international standards • Heart rate (HR) and SpO_2 testing using PPG technology • PWTT testing using ECG and PPG signals
20 min.	• Respiration rate measurement using impedance and modulation test methods • Introduction of WhaleTeq's test equipment – SECG 5.0 AIO
10 min.	• Conclusions • Q&A

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ECG Test Methods
According to International Standards

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ECG Standards

Three ECG Standards for Three Kinds of ECG

- **Diagnostic ECG: IEC60601-2-25:2011**.

  A device intends to obtain, record and/or display a set of conventional or orthogonal ECG signatures, and provide a diagnostic ECG report. The tests include Performance and database testing.

- **ECG in patient monitor: IEC60601-2-27:2011**.

  A monitor that obtains heart rate and waveform by ECG, is used to display the heart rate and/or heart rate waveform of the monitored patient, as well as an alarm for arrhythmia. The tests include Performance testing only.

- **Ambulatory ECG: IEC60601-2-47:2012**.

  A system is capable of continuous recording and analysis or continuous analysis and partial or limited recording of an ECG, which records and stores the ECG and then analyzes it in a stand-alone unit, or records and analyzes simultaneously. The tests include Performance and database testing.

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Performance Test Items

IEC60601-2-47

- Test ambulatory ECG electrical performance
- Five major performances for all ECG standards, i.e. Amplitude-related, Input Impedance, Noise-related, Frequency Response-related, and Pacing Pulse-related.
- Noise includes mains frequency common mode noise and system (internal) noise.
- Frequency response includes low/high cutoff frequency response and pass band response.

201.12.4.4.101	Linearity and dynamic range	← Amplitude-related
201.12.4.4.102	Input impedance	← Input Impedance
201.12.4.4.103	Common mode rejection	← Noise-related
201.12.4.4.104	GAIN accuracy	
201.12.4.4.105	GAIN stability	
201.12.4.4.106	System noise	← Noise-related
201.12.4.4.107	Multichannel crosstalk	
201.12.4.4.108	Frequency response	← Frequency Response-related
201.12.4.4.109	Function in the presence of pacemaker pulses	← Pacing Pulse-related
201.12.4.4.110	Timing accuracy	
201.12.4.4.111	GAIN settings and switching	
201.12.4.4.112	Temporal alignment	

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Linearity and Dynamic Range – 201.12.4.4.101

Digital ECG

PURPOSE (DIGITAL ECG)

- Digital ambulatory recorders shall be capable of responding to and displaying an input signal of 10mV peak-to-valley (p-v) in amplitude in the presence of a DC offset voltage of ± 300mV.

METHOD

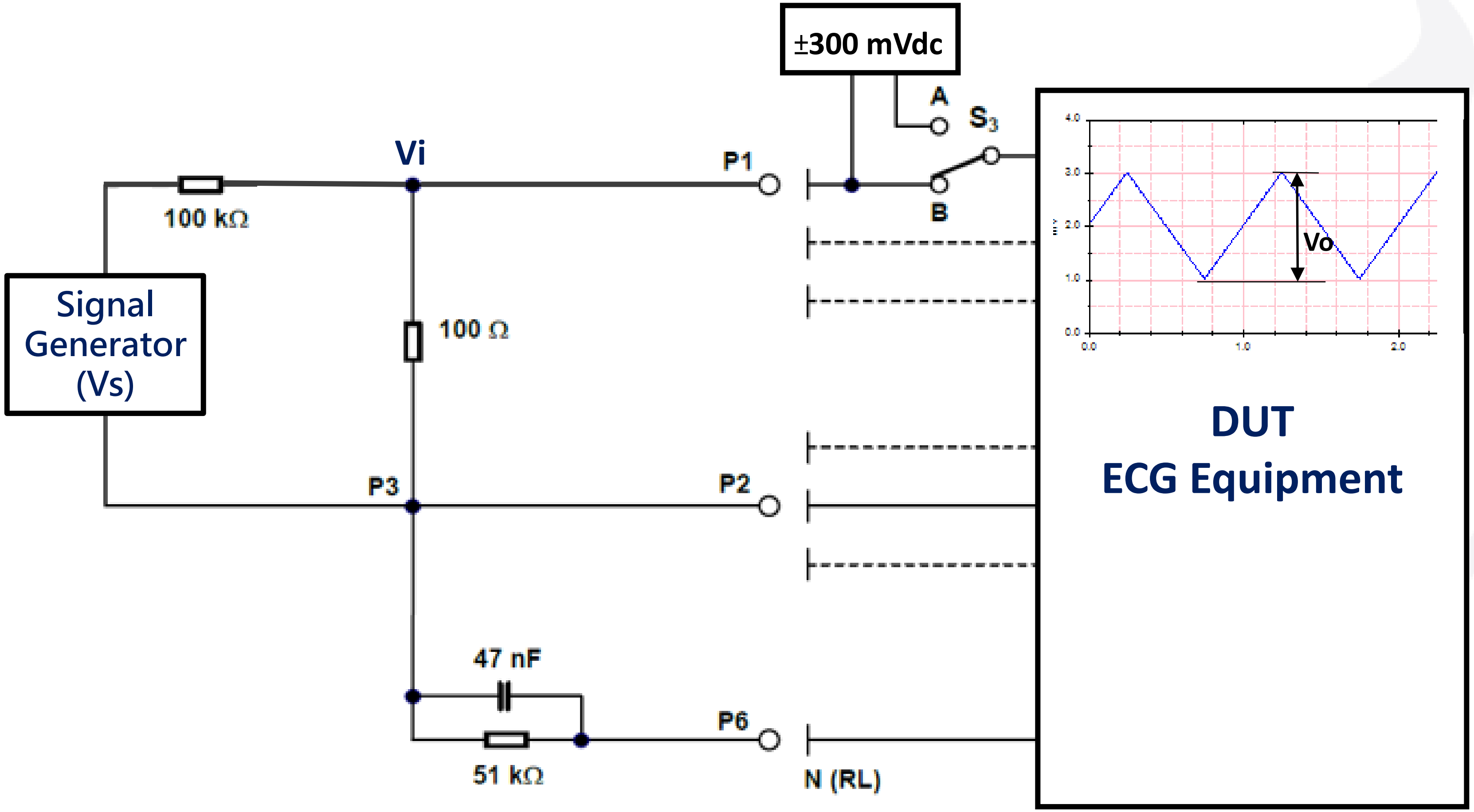
- Feed a 6.25Hz triangular wave, 0.5mV, 1mV, 2mV, and 10mV p-v into the test circuit.
- Set switch S3 to position A to superimpose an offset voltage of ±300mV.

• Alternatively:

- 4Hz sine wave, with the same amplitudes as above, either continuous or consisting of isolated cycles repeated once a second.

RESULTS

✓ Output signal amplitude referred to input shall not change by more than 10% or 50μV, whichever is greater.



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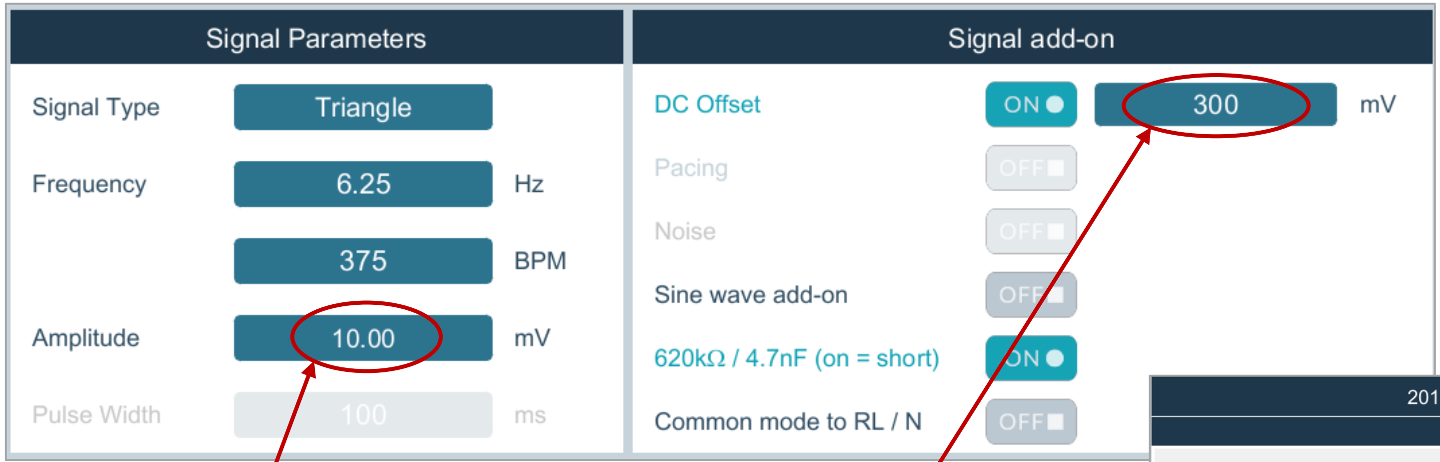
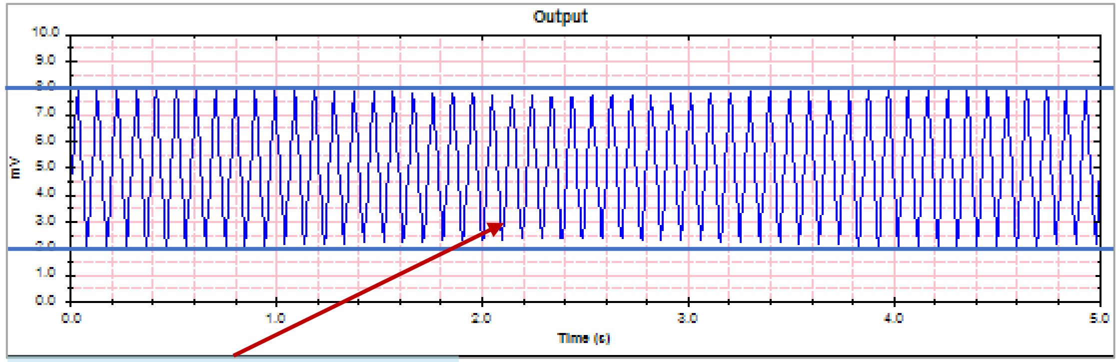
Linearity and Dynamic Range Test

SECG 5.0 AIO Setup and Standard Assistant – Digital ECG



0.5mV, 1mV, 2mV, 10mV

±300 mV



Vp-v ≤10% or 50µV whichever is greater

201.12.4.4.101 - Linearity and dynamic range Digital AMBULATORY RECORDERS

Lead : Channel 1

(mV)	DC Offset		
Amplitude	0 mV	300 mV	-300 mV
0.5 mV	0.50	0.50	0.50
1 mV	1.20	1.00	1.00
2 mV	2.00	2.00	2.00
10 mV	10.00	10.00	10.00

Report | Description | Procedure | Pass Criterion

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Input Impedance - 201.12.4.4.102

With a 620KΩ//4.7nF Parallel Circuit

PURPOSE

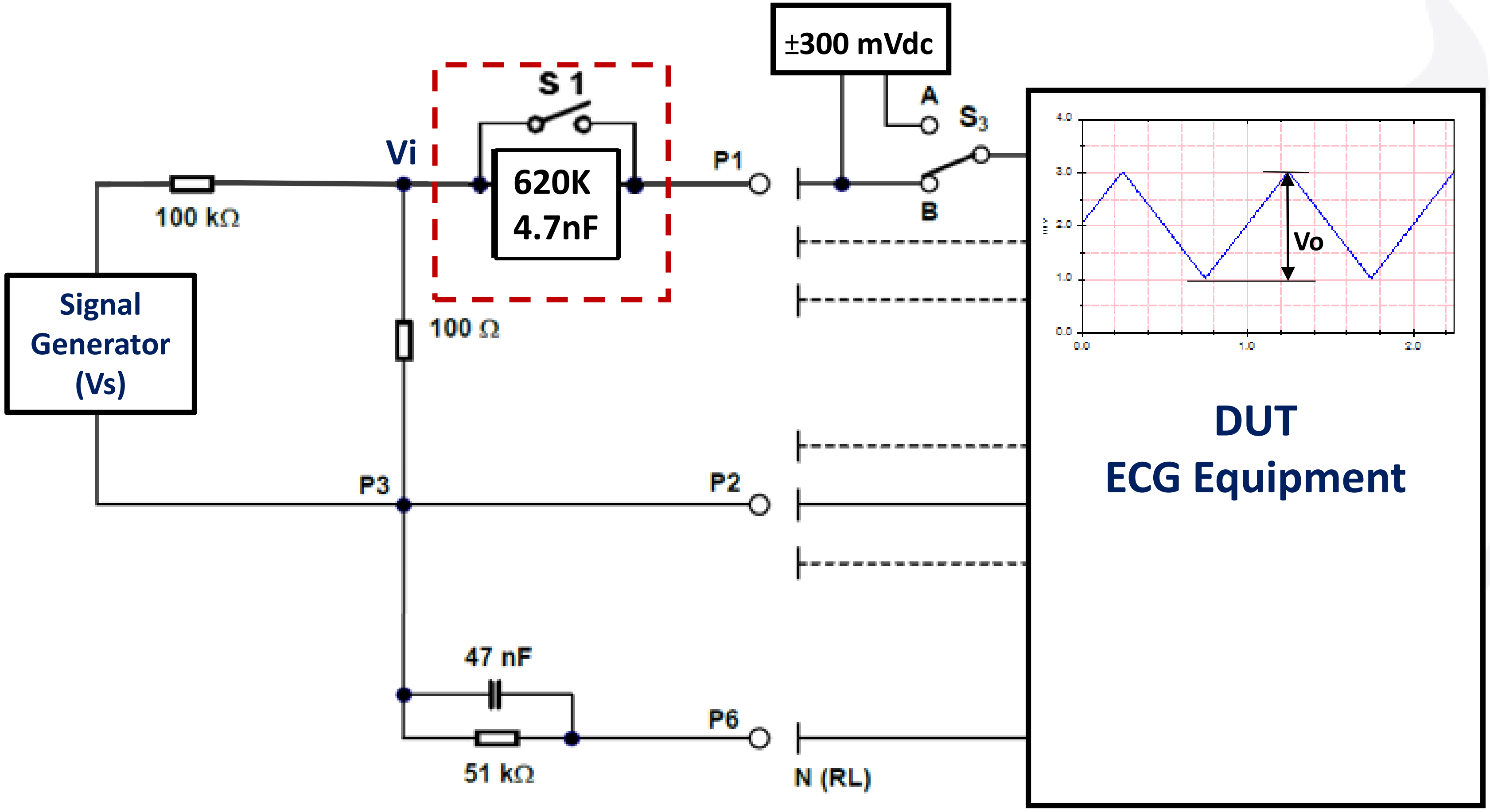
- The input impedance shall be greater than 10MΩ for the frequency specified in the test and for all input channels. This requirement shall be met across the total required DC offset voltage of ± 300mV capabilities.

METHOD

- Apply a 10Hz sinusoidal, 5mV amplitude.
- Connect the patient electrode connections of the first channel to P1 and P2. Connect all other patient electrode connections to P6.
- Open S1 (620KΩ//4.7nF) and measure the output amplitude change.
- Repeat the test with offset voltages of 300mV and -300mV respectively.
- Repeat all these tests for all other ECG channels.

RESULTS

- The steady-state output amplitude shall not decrease by more than 6%.



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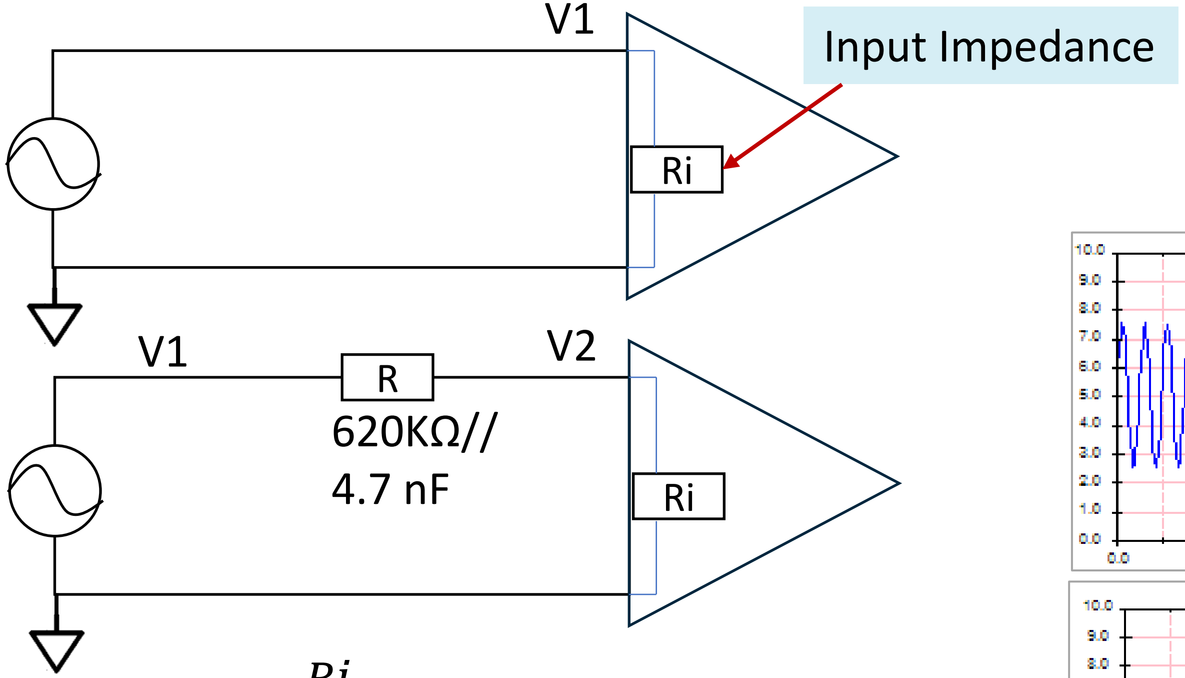
Input Impedance

Calculate by Voltage Divider Concept

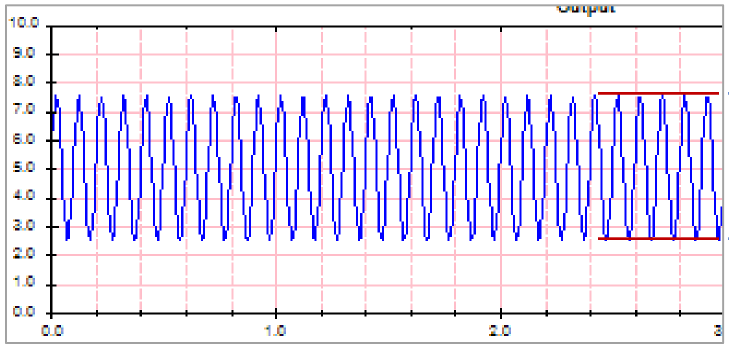


$$V2 = \frac{Ri}{R+Ri} * v1$$

$$Ri = \frac{V2}{V1-V2} * R\ (620K\Omega)$$

If V2 = 0.8V1, Ri = 4R ~ 2.5MΩ

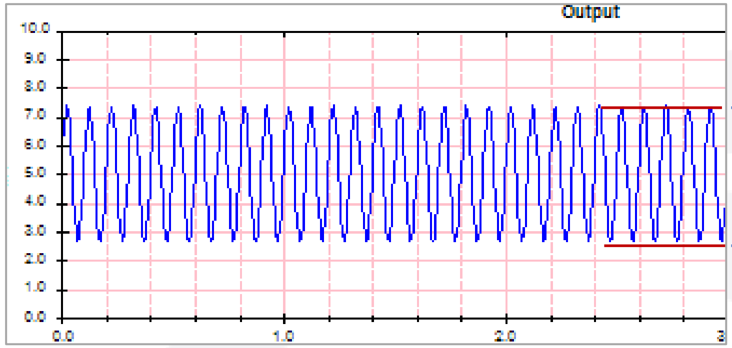
If V2 = 0.94V1, Ri ~ 16R ~ 10 MΩ



V1

= without 620KΩ/4.7nF

V2/V1 ≥ 94%



V2

= with 620KΩ/4.7nF and ±300 mV DC

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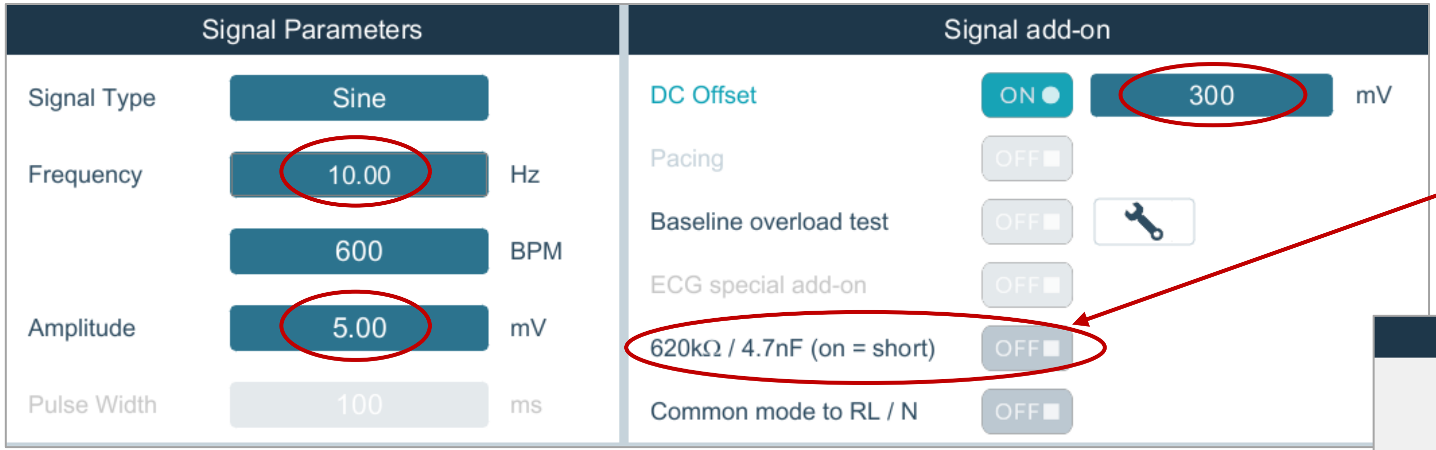
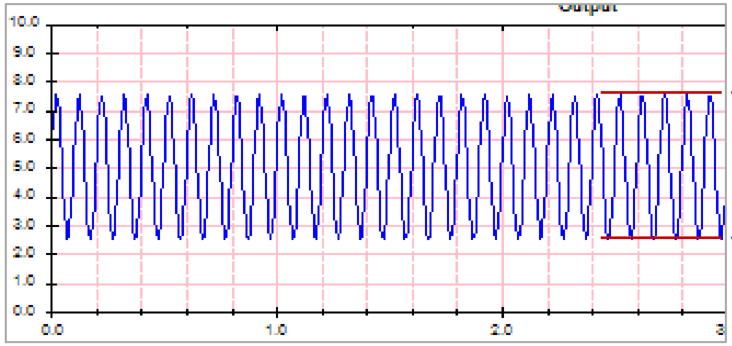
Input Impedance

SECG 5.0 Setup and Standard Assistant



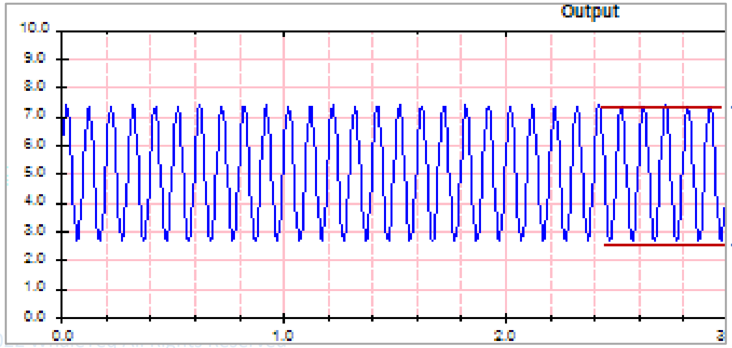
S1 OFF: with 620KΩ
ON: without 620KΩ



V1

= without 620KΩ/4.7nF

V2/V1 ≥ 94%



V2

= with 620KΩ/4.7nF
and ±300 mV DC

201.12.4.4.102 - Input impedance

(mV)	Patient Electrode
DC Offset	Channel 1
0mV(Vref)	4.90
0mV+620KΩ	4.70
300mV+620KΩ	4.60
-300mV+620KΩ	4.71

Report | Description | Procedure | Pass Criterion

Heart Rate (HR) and SpO_2 Testing Using PPG Technology

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Green LED and PD to Measure HR

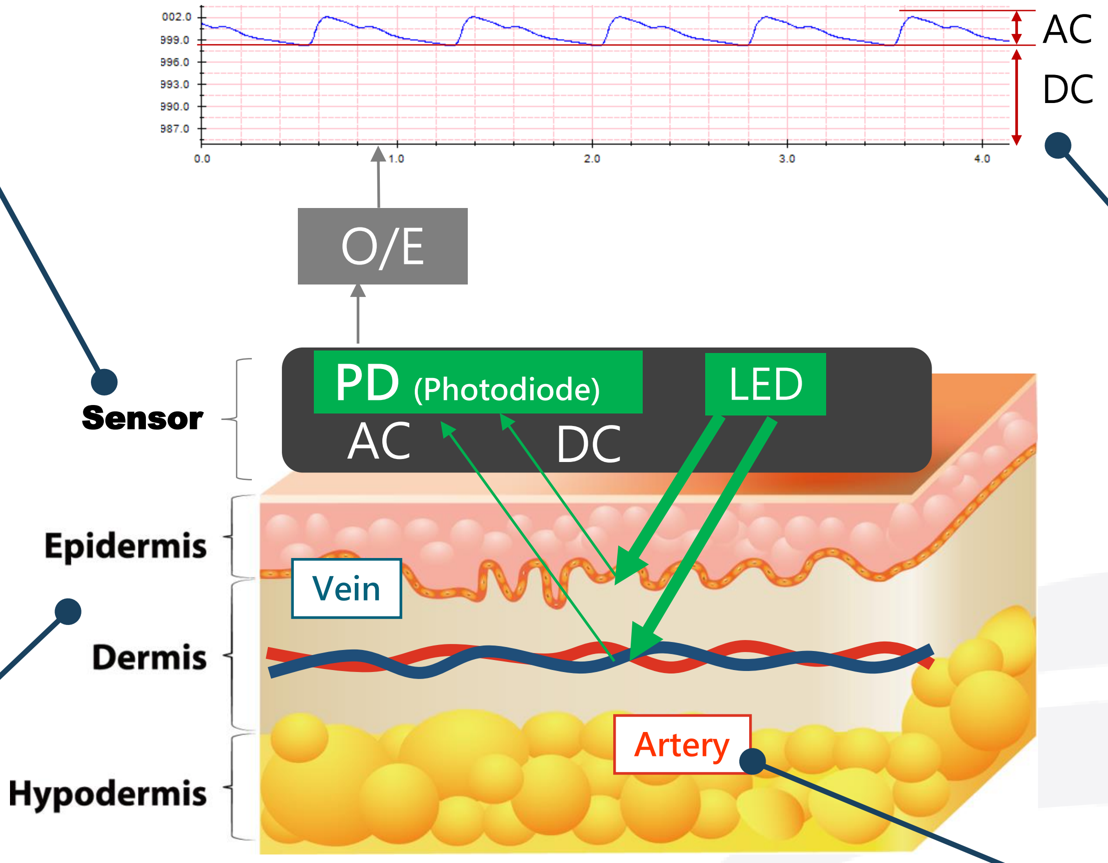
PPG: Photoplethysmography

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.
- The more elastic the artery is, the larger amplitude changes the reflected AC signal has. So the AC level represents the artery's elastic range.

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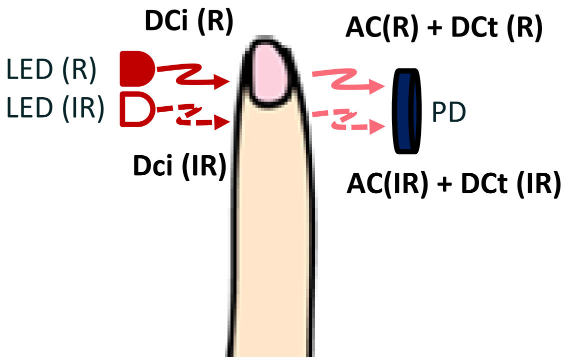
R & IR LED and PD

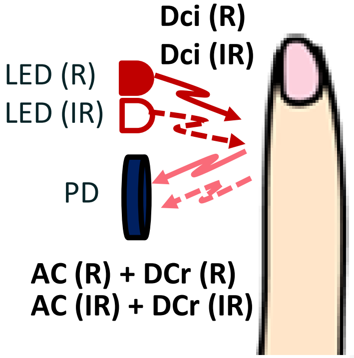
For R Value and SpO_2 Value of Pulse Oximetry

- 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.

Transmittance



Reflectance



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

$$R = \frac{(AC/DC)_R}{(AC/DC)_{IR}} \Rightarrow SpO_2 = K1 + K2R$$

R curve

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

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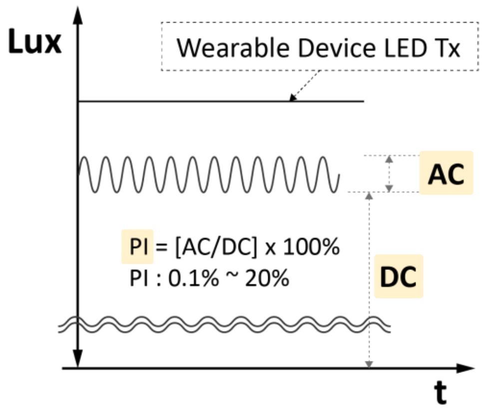
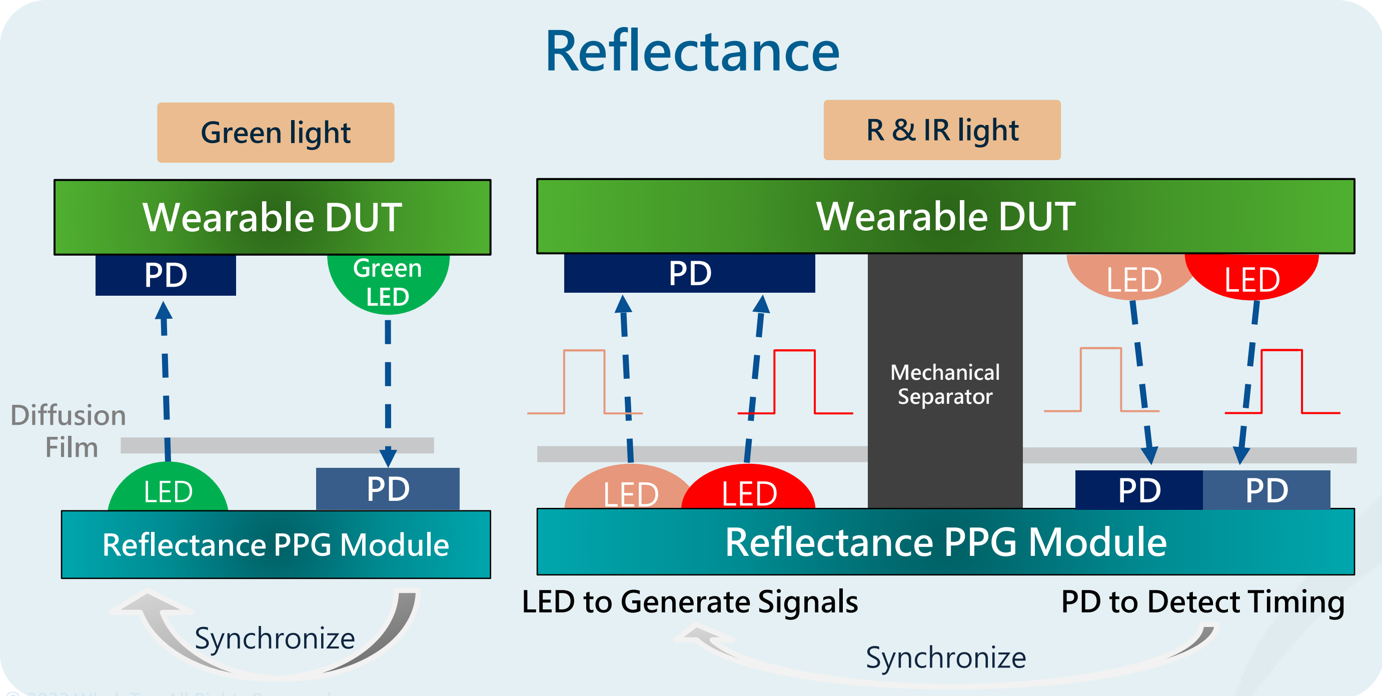
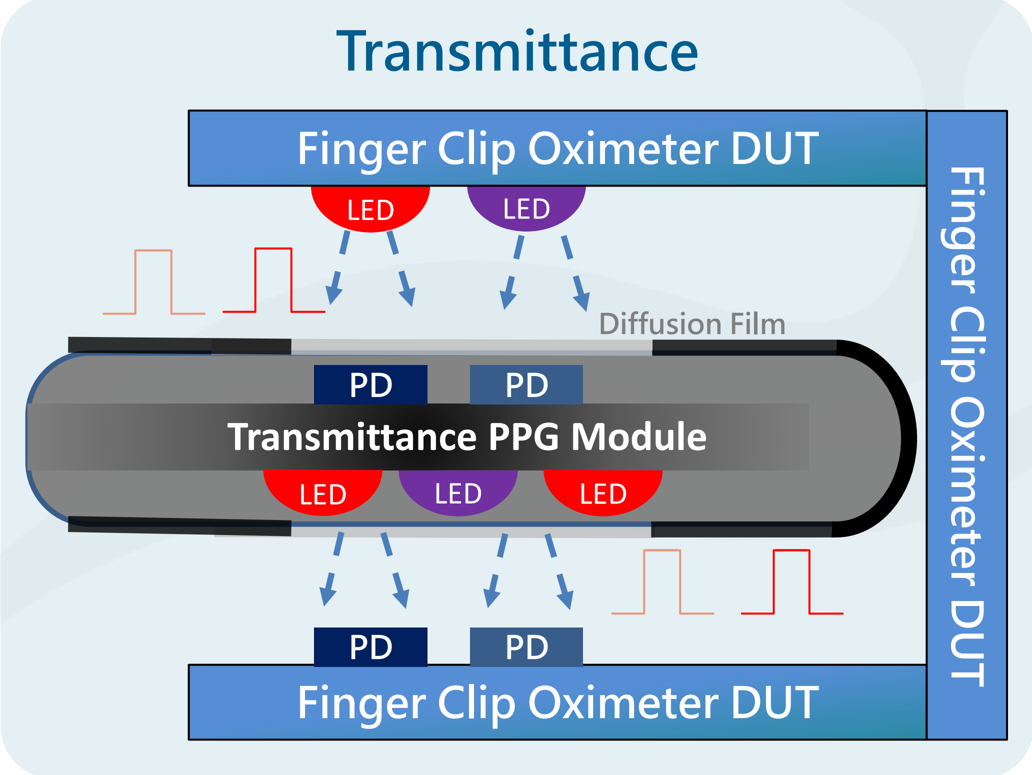
Heart Rate (HR) and SpO_2 Testing – Reflectance & Transmittance

Synchronization & 3 Major Parameters AC, DC, BPM, Effectively Simulating Reflection and Transmission Light



- BPM (Beat Per Minute) – AC signal's frequency for simulating 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%





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PWTT Testing

Using ECG and PPG Signals

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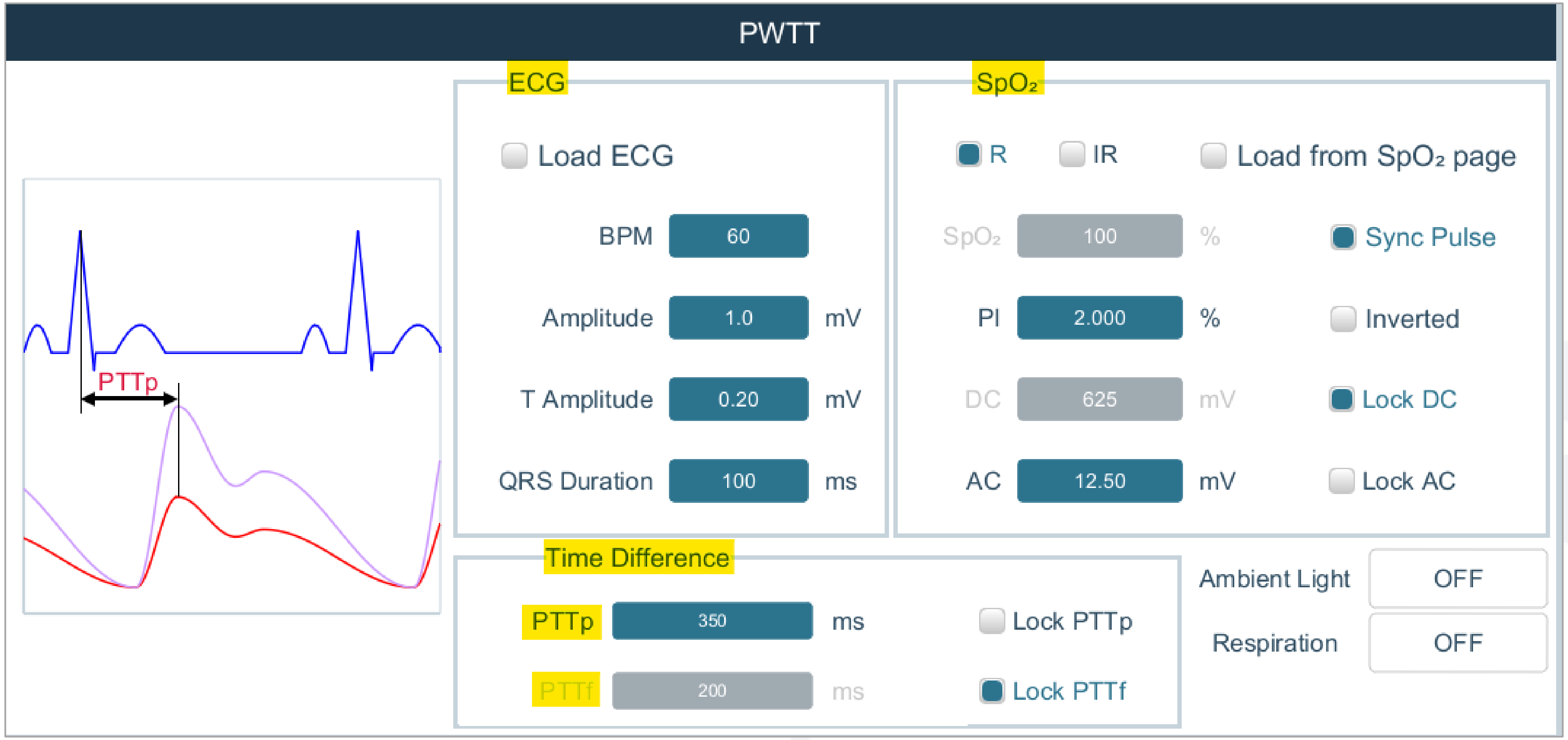
Pulse Wave Transit Time (PWTT)

Simultaneously Play ECG and PPG Waveforms

- Simultaneously play ECG and PPG waveforms, and the time difference–PTTp (PTT peak) and PTTf (foot)–of ECG and PPG waveforms is adjustable.
- The estimated continuous blood pressure (BP) value can be calculated by measuring the PTTp or PTTf.



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Respiration Rate Measurement Using Impedance and Modulation Test Methods

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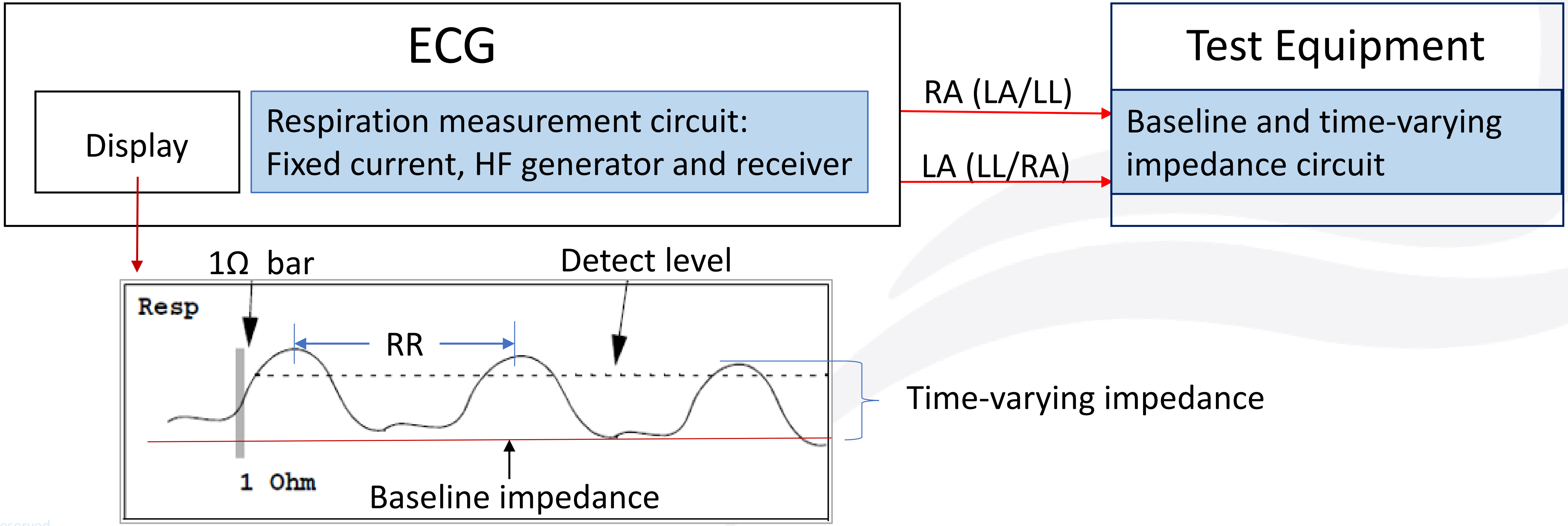
Respiration Rate (RR) Measurement

Impedance Test Methods

- RR is defined as the measurement of a person's breathing rate per minute (BrPM) at rest.
- When the thoracic cavity expands/reduces (inspiration/expiration), the chest impedance increases/decreases.
- The ECG leads (Lead I, II, or III) can measure the transthoracic impedance changes through a fixed current, high frequency signal source generated from ECG internal respiration circuit.
- Test equipment uses baseline and time-varying impedance circuits to simulate the transthoracic impedance changes.
- The similar baseline and time-varying impedance circuit (with different impedance ranges) can be used to take the ICG (Impedance Cardiography) measurement.



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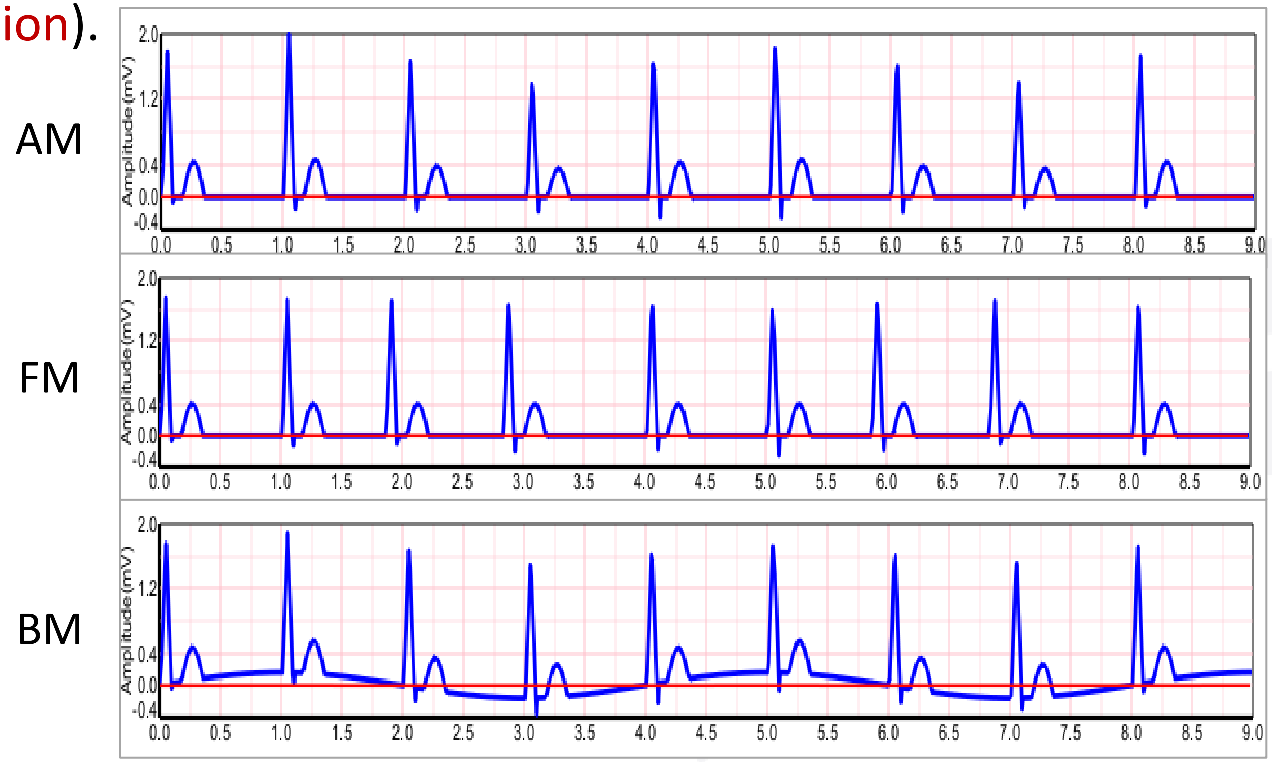
Respiration Rate Measurement

Modulation Test Methods – EDR

- The method extracting respiratory signals via ECG or PPG technology is called EDR (ECG-derived Respiration), and the other one using PPG technology is called PDR (PPG-derived Respiration).
- Three types of EDR analysis to detect changes in respiration rate when breathing:
  1) The heart axis deviates and causes ECG amplitude to change (AM: Amplitude Modulation).
  2) The heart beating rate changes (FM: Frequency Modulation).
  3) The ribs and diaphragm position changes, which leads Electromyography (EMG) to change the ECG (BM: Baseline Modulation).



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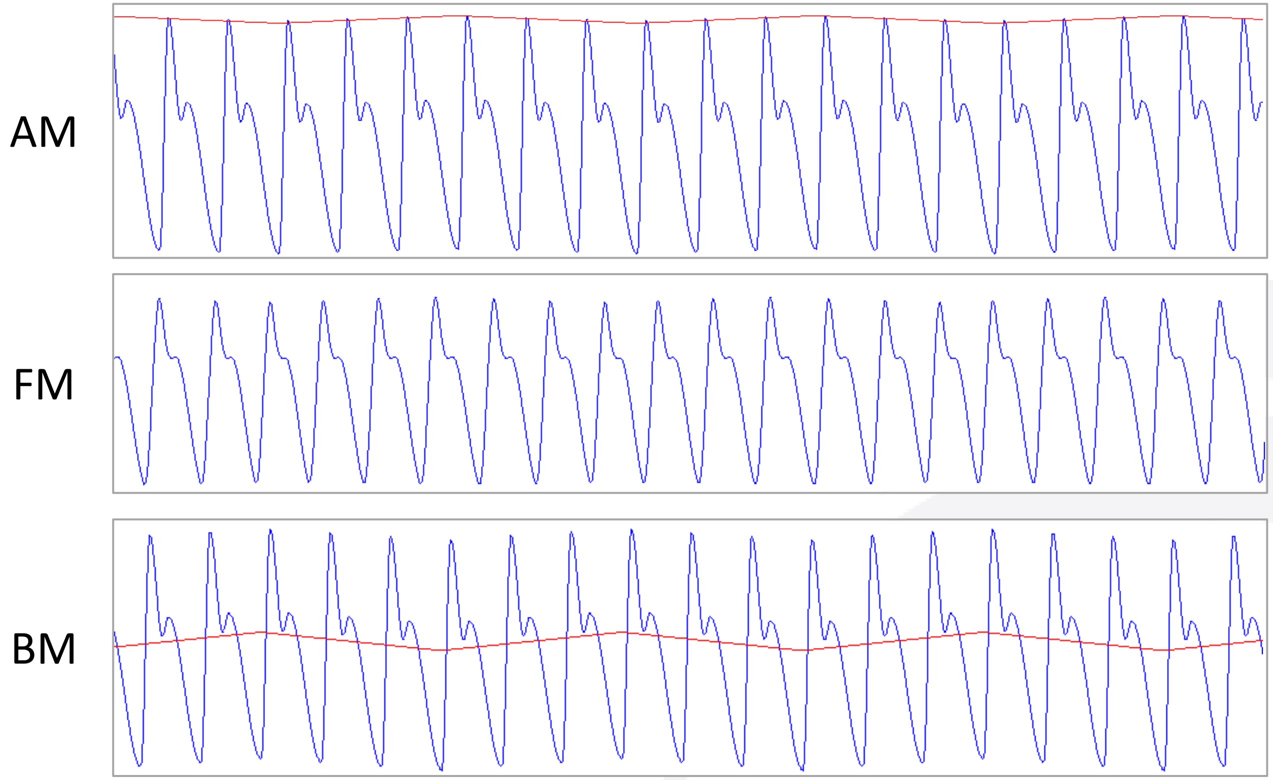
Respiration Rate Measurement

Modulation Test Methods – PDR

- Three types of PDR analysis to detect changes in respiration rate when breathing:
  1) The heart volume changes and causes the PPG amplitude to change (AM: Amplitude Modulation).
  2) The heart beating rate changes (FM: Frequency Modulation).
  3) The change in thoracic pressure causes changes in blood flow and affects the baseline change of PPG (BM: Baseline Modulation).



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Introduction of WhaleTeq's Test Equipment – SECG 5.0 AIO

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SECG 5.0 AIO

ECG & PPG Simulator for Performance Testing

- ECG performance test — built-in test circuits per defined in ECG standards and standard assistant
- Heart Rate (HR) and SpO_2 testing — Reflectance & Transmittance PPG modules
- PWTT testing — time difference between ECG and PPG signals
- Respiration rate measurement — Impedance Type, Wave Modulation Type (Baseline/Amplitude/Frequency)
- Auto Sequence function — assists in conducting preferred tests in sequence
- Play raw data — loading recorded or programmed waveform files facilitates verifying DUT algorithms
- Software Development Kit (SDK) — allows users to develop customized or automated test software

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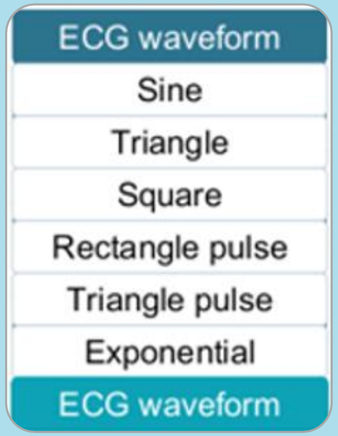
SECG 5.0 AIO

User Interface Introduction



Special Functions

- IEC standard waveform
- File playback
- Add NST noise
- Auto Pacing / Heart Rate / Frequency Scan
- Lead Off
- Auto Sequence

Standard Assistant

- IEC 60601-2-25 / 27 / 47
- YY0782 / 0885 / 1079 / 1139
- GB9706.225 / 227
- YY9706.247

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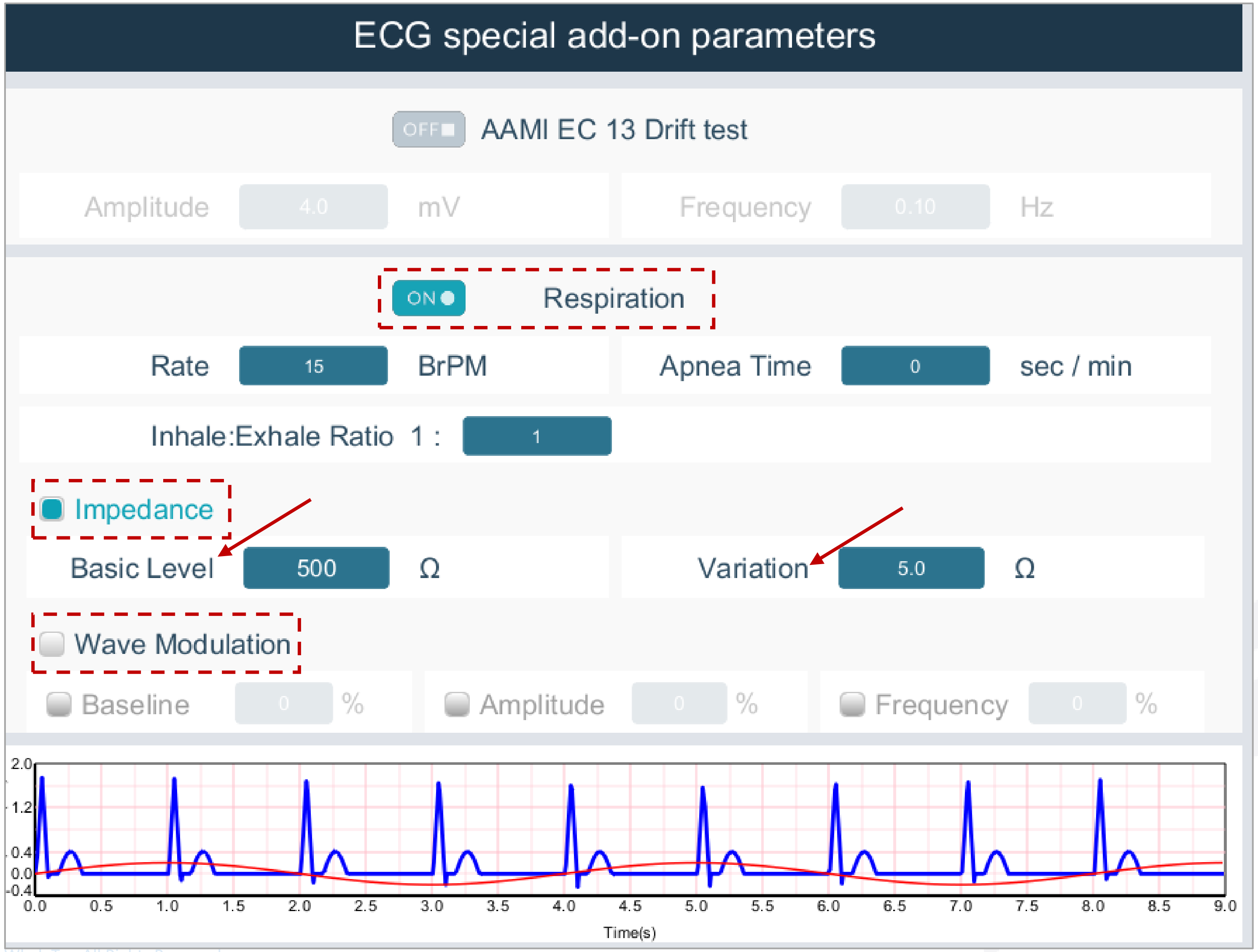
SECG 5.0 AIO

Respiration Rate Test



Respiration rate test spec.	
BrPM Rate	0-170 BrPM in 1 BrPM step
Impedance Baseline	100Ω,200Ω,500Ω-4500Ω in 500Ω step
Impedance Variation	0.0Ω-5.0Ω in 0.05Ω step 5.0Ω-10.0 in 0.1Ω step

ICG test spec.	
Impedance Baseline	20Ω-100Ω in 20Ω step
Impedance Variation	0.0Ω-1.0Ω in 0.05Ω step 1.0Ω-5.0 in 0.1Ω step

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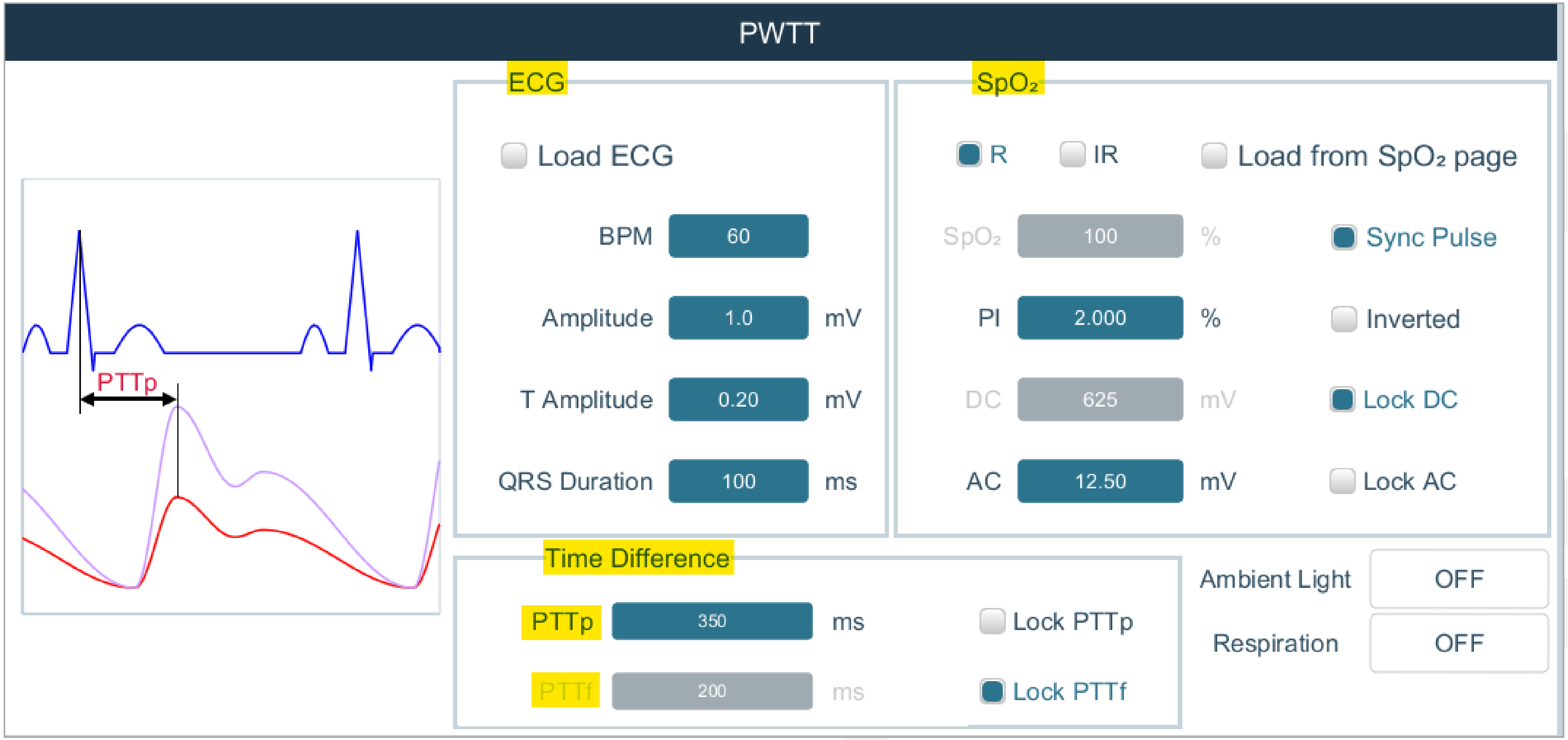
SECG 5.0 AIO

PWTT Test



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Conclusions

ECG, PPG, PWTT, RR, ICG and Test Equipment

- There are three ECG standards for three kinds of ECG performance and database tests.
- Five major performances for all ECG standards, i.e. Amplitude-related, Input Impedance, Noise-related, Frequency Response-related, and Pacing Pulse-related.
- PPG technology is currently applied mainly to Heart Rate (HR) and SpO_2 measurements.
- Three major parameters: BPM as HR, AC level represents the artery's elastic range, and DC level represents the skin color range.
- The PWTT can be adjusted to effectively verify the accuracy of the blood pressure measurement algorithm.
- RR and ICG (Impedance Cardiography) measure skin impedance changes to get BrPM and CO (Cardiac Output).
- Test equipment simulates the impedance changes with baseline and time-varying impedance circuits.
- SECG5.0 AIO can support ECG, PPG, PWTT, RR, and ICG applications.

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