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How to Test Wearable Device with Reflectance-based Pulse Oximeter Function

Foreword

According to ISO80601-2-61:2011 standard –

Every PULSE OXIMETER EQUIPMENT tester intended to generate simulated signals on the market at the time of writing is a FUNCTIONAL TESTER. An appropriate FUNCTIONAL TESTER allows the RESPONSIBLE ORGANIZATION to determine whether the PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE is performing as the MANUFACTURER designed it to perform, without in any way determining whether the design was correct. To obtain the accurate SpO2 value, a clinical calibration using CO-oximeter or secondary standard PULSE OXIMETER EQUIPMENT is required.

A FUNCTIONAL TESTER presents the PULSE OXIMETER EQUIPMENT with a signal having a predictable value of R, so that the RESPONSIBLE ORGANIZATION can observe the resulting displayed value of SpO2, and evaluate it in comparison to expectations for that particular PULSE OXIMETER MONITOR model. If the tester MANUFACTURER knows the calibration curve that has been designed into a particular PULSE OXIMETER MONITOR, the MANUFACTURER can accurately produce the R value which ought to lead to a particular value of SpO2, e.g. 85 %. Then the PULSE OXIMETER EQUIPMENT can be evaluated for its ability to reproduce the calibration curve that was designed into it.

An accurate reading of SpO2 on a FUNCTIONAL TESTER never implies that the PULSE OXIMETER EQUIPMENT is accurate on human beings. All that is being evaluated by the tester is the PULSE OXIMETER MONITOR'S ability to reproduce the calibration curve that the MANUFACTURER designed into it; this calibration curve might not be accurate.

Based on these descriptions, the functional tester tests the pulse oximeter device with a signal of a predictable R value, verifies its function, and evaluates its ability to reproduce the calibration curve designed in it. The calibration curve is proportional to the R values and we can call it "R curves". In the standard of ISO80601-2-61: 2011, mainly regulates clinical testing methods. There are no detailed procedures for how to use the functional tester. Therefore, the method for testing reflectance-based pulse oximeter described below is based on the test spirit for the transmissive pulse oximeter described in the standard. AECG100 can be the functional tester, providing a pre-clinical test method to determine the performance, measurement range, and stability. Otherwise, the test results will be at great risk if manufacturer enters the stage of clinical trials without any performance testing.

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Here we will introduce how to test wearable device with reflectance-based pulse oximeter function by using the AECG100 test system. The Maxim wearable device MAXREFDES103 is used as the test object. The test steps are described as following:

Test Wearable Device with Reflectance-based Pulse Oximeter Function

- **Test Setup Requirements**

(1) A PC installed with AECG100 PC software and connected with AECG100 test system

(2) Maxim MAXREFDES103 wearable device

(3) Test fixture for MAXREFDES103 wearable device

- **Introduction of Maxim MAXREFDES103 wearable device and test fixture**

(1) The MAXREFDES103 platform uses high-sensitivity green / red / infrared PPG biosensors, power management ICs (PMICs) and microcontrollers with algorithms, Bluetooth wireless transmission, three axis accelerometer, etc., and uses a wrist-worn design to capture biometric signals that are vital to healthcare. The platform also contains algorithms for calculating heart health based on the results of biosensor measurements. The vital signs collected by this wearable device are HR, SpO2, HRV, etc.

(2) Figure 1 shows the detailed hardware description of MAXREFDES103, and Figure 2 shows a 3D-printing fixture that tightly connects AECG 100 PPG module and MAXREFDES103 for properly testing pulse oximeter function. Since only R / IR LED light is used when testing SpO2, the upper opening on the 3D-printing fixture is matched with the red / infrared LED light emitted by the DUT, and the green light is blocked to facilitate the test. The lower opening fits the DUT PD. After the 3D-printing fixture is tightly fastened to AECG 100 PPG fixture base, the other side of the 3D-printing fixture will be matched with the PD and LED light of the DUT (i.e., PPG LED vs. DUT PD, PPG PD vs. DUT LED).

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Fig. 1 MAXREFDES103 Detailed Hardware Description

Fig. 2 The 3D-printing fixture is tightly fastened onto AECG 100 PPG fixture base

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- **Test procedures**

(1) Figure 3 is the test setup for testing the reflectance-based pulse oximeter. The DUT is MAXREFDES103, and the PC is used to control the AECG 100 test system and DUT through USB connection and wireless Bluetooth, respectively. The DUT is fastened onto AECG100 PPG module via a 3D-printing fixture.

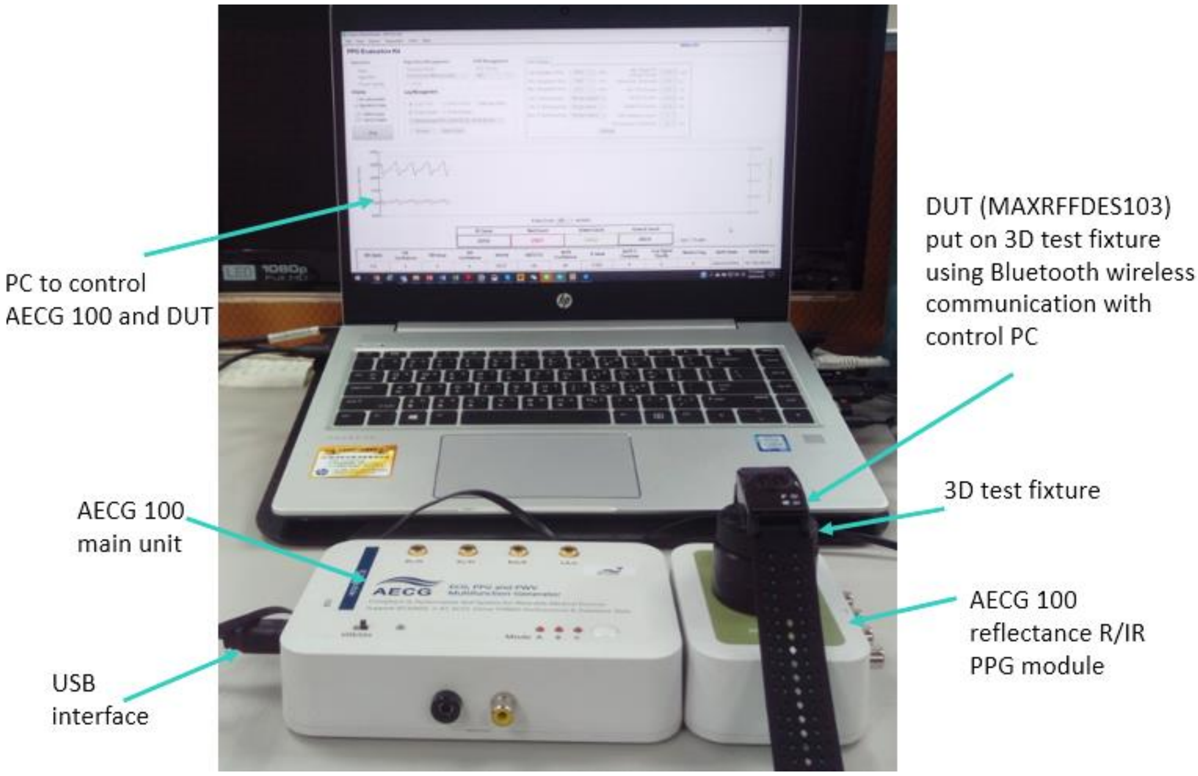

Fig. 3 Test setup

(2) Figure 4 is the display screen of the PPG Evaluation Kit control software of the device under test MAXREFDES103. This software controls the DUT through wireless Bluetooth. The two sets of waveforms in the middle are the waveforms after PD detection of red light and infrared light, and the bottom SpO2 (%) is the measured SpO2 value. The leftmost HR (bpm) is the measured heart rate value, but because the HR value is measured by reflected green light, and this test only uses red and infrared light, the displayed HR value is meaningless.

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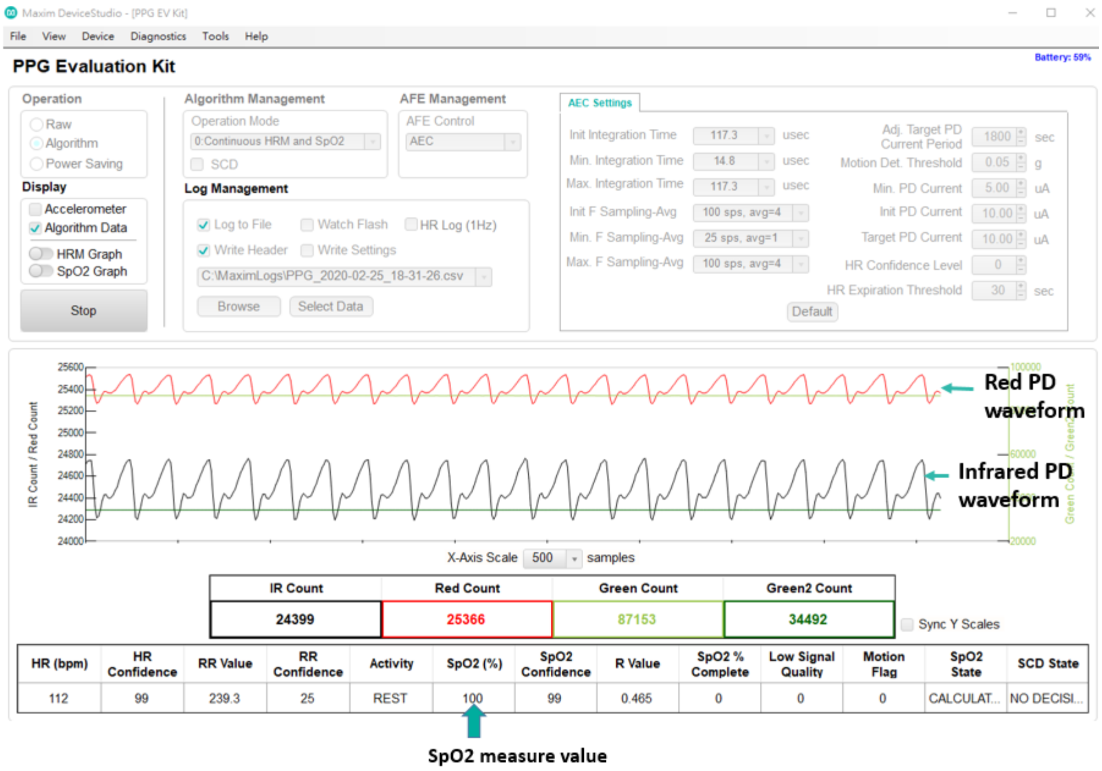

Fig. 4 The display screen of the PPG Evaluation Kit control software of the DUT MAXREFDES103

(3) Before the test, see how the pulse oximeter measures the SpO2 value:

- **The SpO2 value is calculated from the R curve**. At the beginning, the Webster linear empirical calibration formula can be used: **SpO2 = 110-25R**, where the R value is defined as PI (R) / PI (IR), PI (R) and PI (IR) is the perfusion index of red light and infrared light.
- **PI(R) = AC(R)/DC(R)， PI(IR) = AC(IR)/DC(IR)，** AC(R)/AC(IR) and DC(R)/DC(IR) are AC and DC components of red / infrared light intensity, respectively.
- **The AC component** reflects changes in the arterial blood volume of the human body. People with large changes in arterial blood volume also absorb more incident light, so the difference in the intensity of reflected light is also larger, that is, the AC changes more, the AC value is higher.
- **The DC part** reflects the change of human skin color. People with darker skin will absorb more incident light, so the reflected light is weaker, that is, the DC value is lower.

(4) **SpO2 test mode Default setting of AECG100 test system**: As shown in Figure 5, firstly use the SpO2 test mode default setting. The R curve equation is 110-25R, PI (R) = 2%, AC (R) = 12.5 mV, DC (R) = 625 mV, PI (IR) = 4%, AC (IR) = 25 mV, DC (IR) = 625 mV, and SpO2 = 98%. After playing this set signal, first press the “Sampling” button on the lower left. The function of this button is to display the optical signal waveform

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of the PD detection DUT LED on the AECG 100 test system. It can be known from the waveform in Figure 5 that the intensity of the detected infrared light is higher than the intensity of red light. This indicates that the intensity of the infrared light emitted by the DUT LED is higher than the intensity of red light. Therefore, reset the AECG 100 DC value of R / IR making that the intensity of IR is greater than R. In addition, the LED light emitting behavior of the DUT detected by AECG 100 test system can be known respectively the R / IR LED light intensity and delay, light pulse repetition period, and whether the light intensity is stable. The raw signals detected by AECG 100 test system can be output to the oscilloscope from another connector on the right side of the PPG module. Using the higher sampling rate and resolution in the oscilloscope, this signal information can be analyzed more accurately.

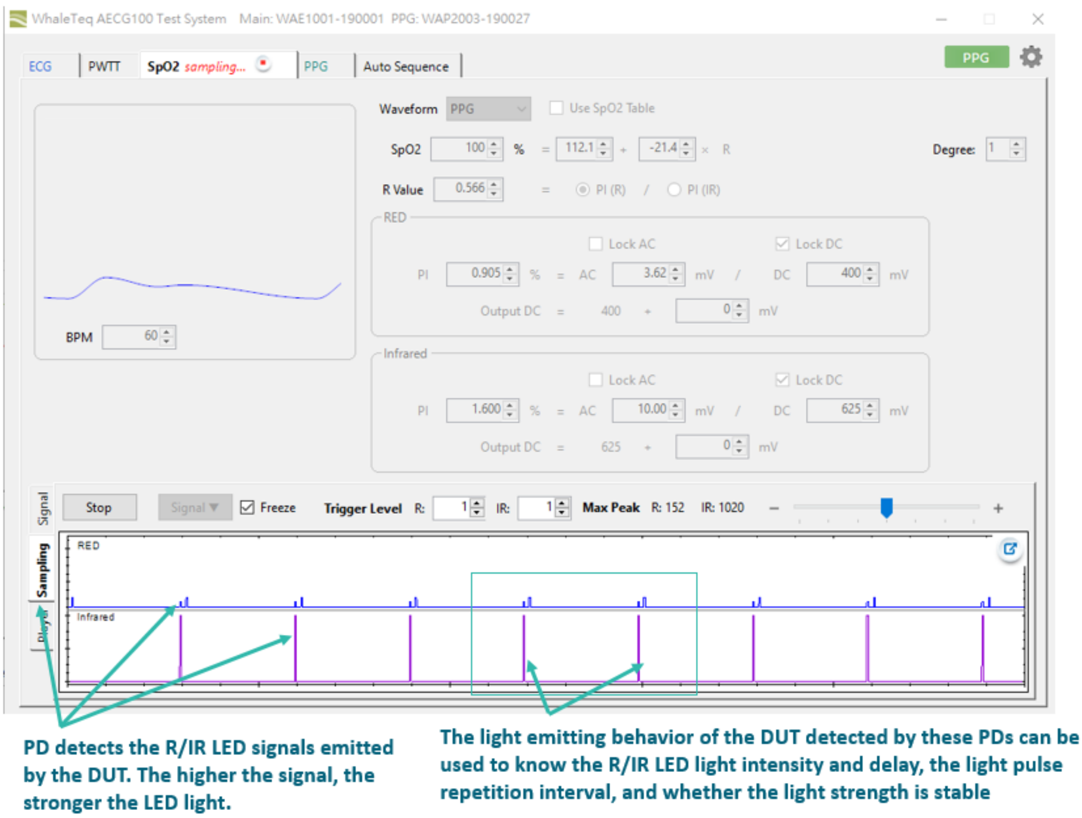

Fig. 5 AECG 100 test system detects the R/IR signals emitted by the DUT LED

(5) **Change SpO2 test mode setting**: As shown in Figure 6, firstly adjust the DC (R) to 400 mV to make the intensity of the red light weaker than the intensity of the infrared light DC (IR) = 625 mV, then lock the two DCs value. Adjust AC (IR) to 10 mV, at this time PI (IR) is fixed at 2.5% (10/625 = 0.025), and PI (R) = AC (R) / 400, so when adjust the AC (R), the value of PI (R) shall change, and the R value shall change with the change of PI (R), then the value of SpO2 will change. (This setting is also in line with the actual

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test conditions of the human body. Since the change in the absorbance of red light by oxyhemoglobin and reduced hemoglobin is greater than that of infrared light, the intensity of reflected red light changes greatly and the infrared light is small.)

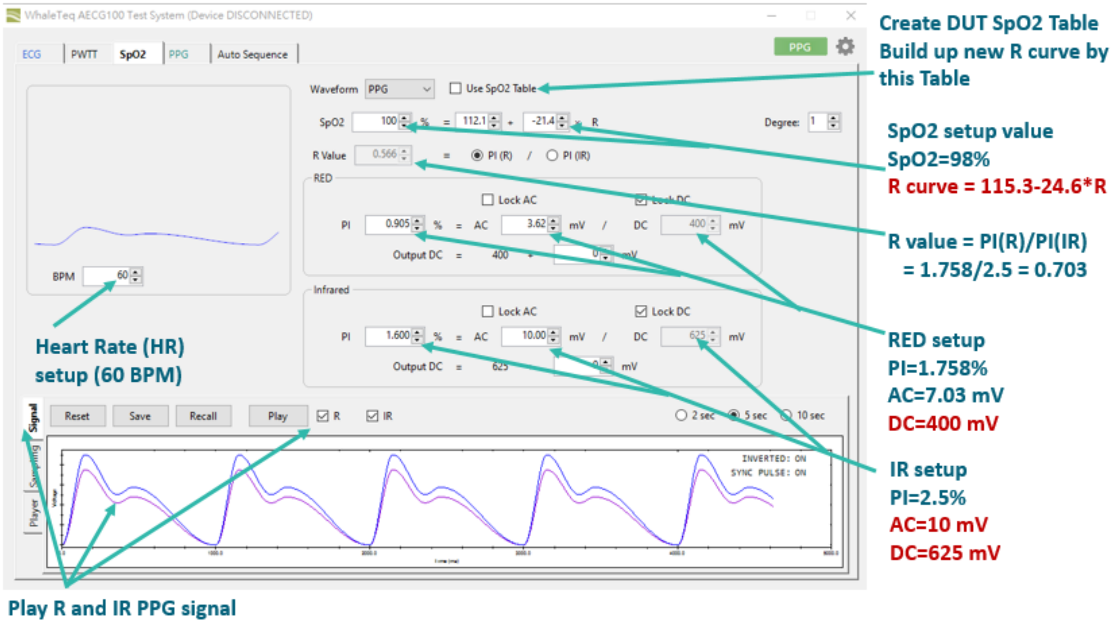

Fig. 6 Adjust the parameters of AC/DC/PI/R/SpO2

(6) **Find R curve of the DUT from SpO2 Table function**: The next step is to find the R curve of the DUT by using the function of changing the R value of the AECG 100. At the beginning, the default setting of the R curve is 110 – 25R, but this R curve may be inconsistent with the R curve of the DUT, so although the same R value is set, the SpO2 value measured by the DUT will be different from the SpO2 setting value of the AECG 100. To obtain the R curve that conforms to the DUT, the R curve equation can be derived from the SpO2 value actually measured by the DUT and the changed R value. The first row "Use SpO2 Table" in the middle of Figure 6 is to create a table of SpO2 and R values, and then use the parameters in the table to derive the R curve equation of the DUT.

(7) Figure 7 is the SpO2 value of the DUT (MAXREFDES103) tested by adjusting the R value of AECG 100. Take the value in the second row of the table as an example, AC (R) = 3.6 mV, DC (R) = 400 mV (PI (R) = 3.6 / 400 = 0.9%), AC (IR) = 10 mV, DC (IR) = 625 mV (PI (IR) = 10/625 = 1.6%), the SpO2 value displayed by the DUT is 100%, next step, change only AC (R) = 4.2 mV and keep the other parameters unchanged. At this time, the SpO2 value displayed by the DUT is 98%. Then gradually increase the AC (R) value. As the AC (R) value increases, the R value will increase, the SpO2 value will gradually decrease. Therefore, a series of

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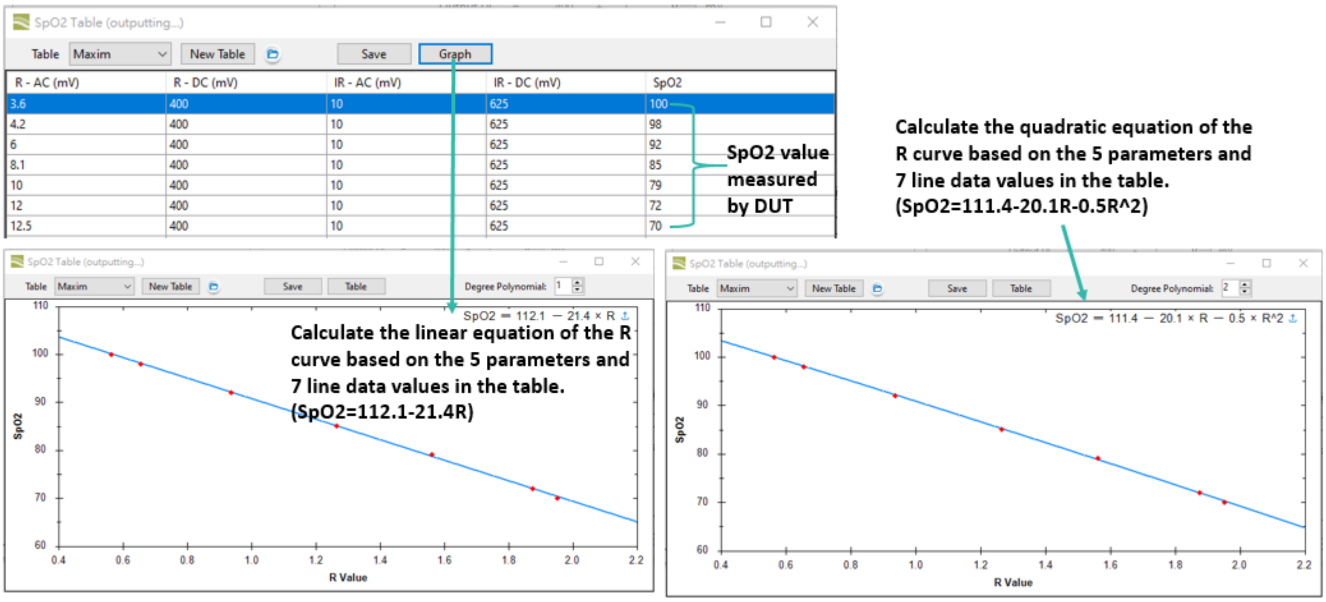
changed R values and SpO2 values measured by the DUT can be obtained. The table in Figure 7 lists 7 sets of measured data, and the SpO2 values are from 100% to 70%. From these data, one Linear/Quadratic equation of R curve can be derived, because these equations are the SpO2 value measured by the DUT according to the R value changed by the AECG 100, so the measured DUT R curve can be obtained.



R - AC (mV)	R - DC (mV)	IR - AC (mV)	IR - DC (mV)	SpO2
3.6	400	10	625	100
4.2	400	10	625	98
6	400	10	625	92
8.1	400	10	625	85
10	400	10	625	79
12	400	10	625	72
12.5	400	10	625	70

Fig. 7 SpO2 Table is established and the R curve of DUT is derived based on Table data

(8) **Use the new DUT R curve to test other SpO2 values**: As shown in Figure 8, change the SpO2 to 80% of the AECG 100, the DUT also changes the SpO2 measurement value to 80%, and then change the SpO2 value to 90%, 70%, the DUT can be accurately changed according to the SpO2 value set by the AECG 100, and the error is less than 1%. It can be confirmed that under such test conditions, the DUT can follow the R curve of the linear equation of SpO2 = 112.1-21.4R or the R curve of the quadratic equation of SpO2 = 111.4-20.1R-0.5R ^ 2 to test the DUT hardware and whether the algorithm is consistent, it is able to use a R curve to measure a wide range of SpO2 values.

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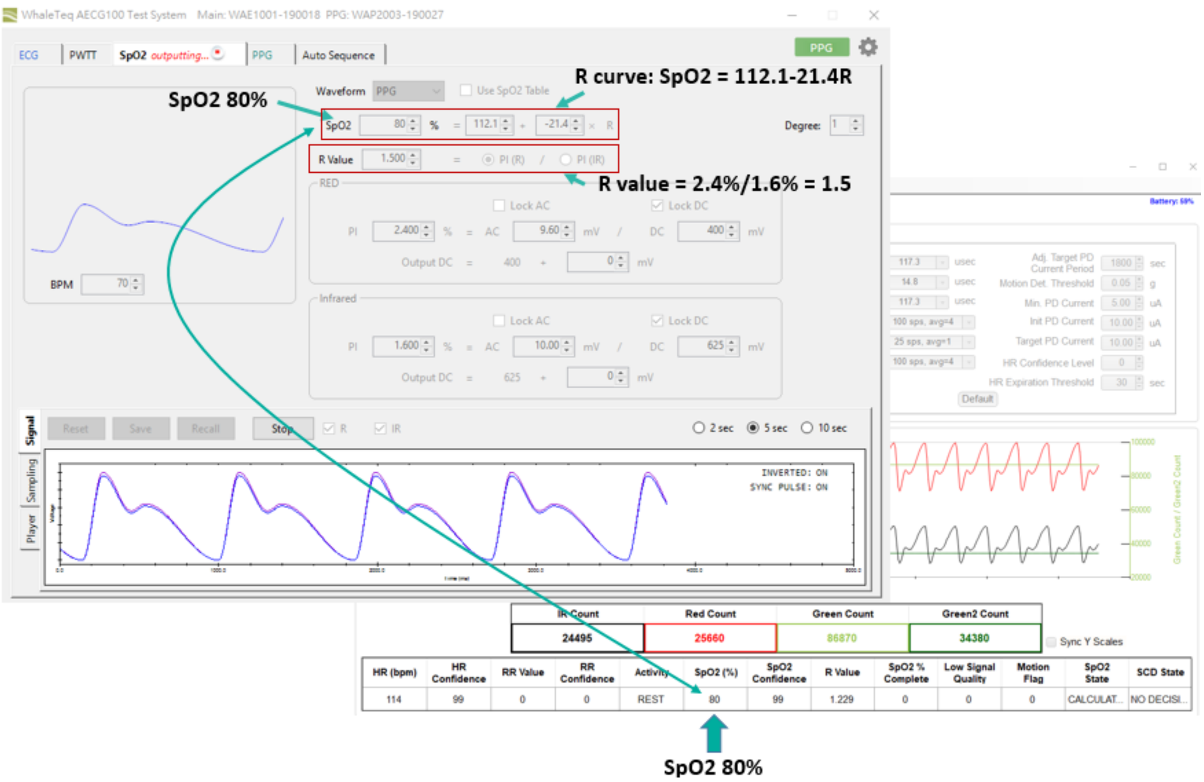

Fig. 8 When the new DUT R curve is used for testing SpO2 = 80%, the DUT also changes the SpO2 measurement value to 80%.

Conclusions

SpO2 functional tester is mainly used to determine the performance, measurement range and stability of pulse oximeter equipment. The method described above adjusts AC parameter, which shall lead to PI changes, the R value changes, and eventually the SpO2 value changes according to the R curve. The R curve can be directly input or obtained through testing. Before clinical testing, this method can be used to obtain stable measurement values when doing the clinical testing. This R curve is obtained as a reference R curve because it was obtained before clinical testing. After clinical testing, the original R curve may be modified, at this time, a new set of R curves can be obtained using the same test steps. This new R curve can be defined as the correct R curve. In the future, the quality control and production of the same product can be measured using this correct R curve.

The above test is based on the reflectance-based pulse oximeter wearable device. The transmissive pulse oximeter device is also tested in a similar way. The difference is that the PPG module structure of the SpO2 functional tester is

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different. The reflective type is LED and PD on the same side, transmissive is on different sides. Therefore, different PPG modules or test fixtures are needed, but the test methods and steps are the same.

Reference

1. IEC medical standard ISO80601-2-61:2011.
2. User manual of WhaleTeq AECG 100 test system

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