Test Solutions for
Medical Device Manufacturers

Mastering Verification and Validation for Multi-Vital Sign Testing in R&D

Speaker: Stephan Syue

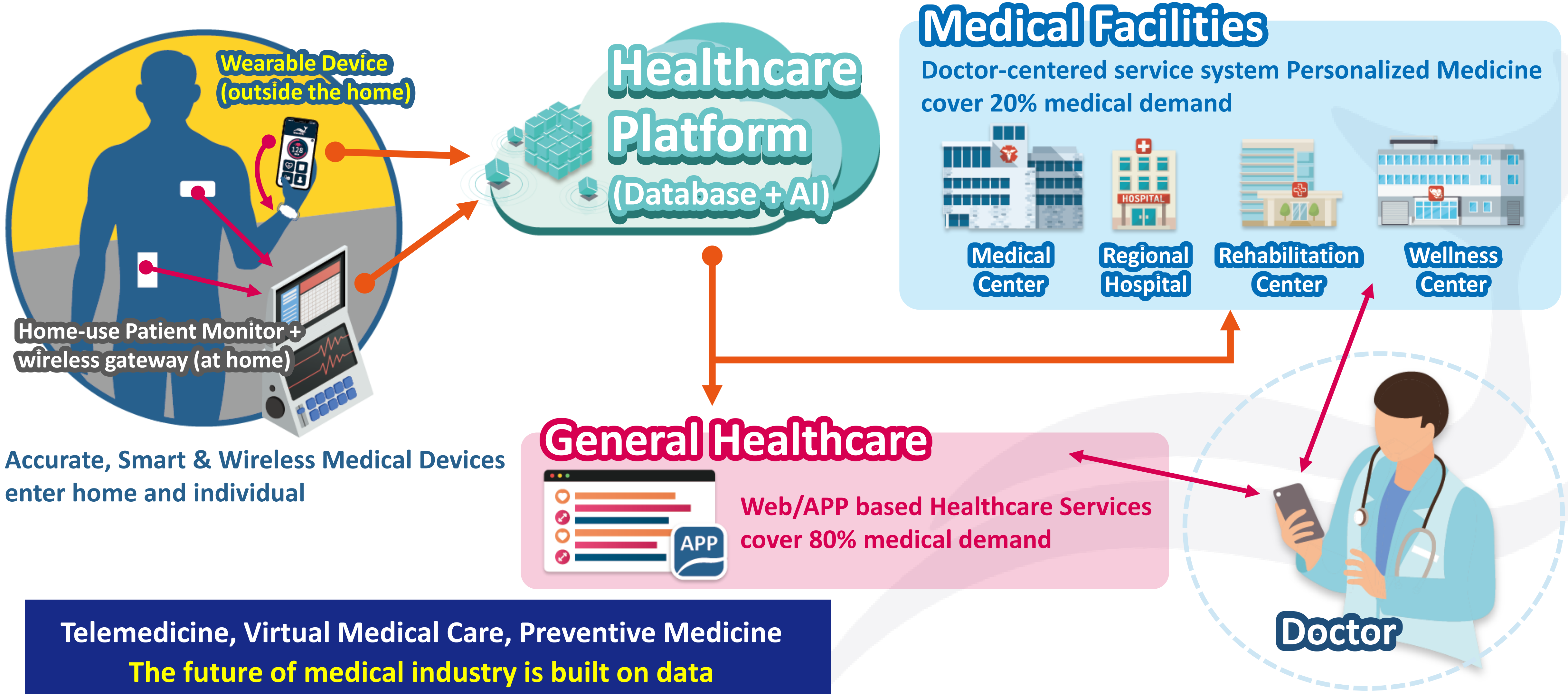
Outline

Time	Contents
2.5 min.	**Vital Sign Testing Concepts** • The Correlation between Vital Signs — Taking Patient Monitors as An Example • Multiparameter Simulation Demonstration — ECG, PPG, Impedance Respiration, and NIBP Signals
23 min.	**ECG & PPG Testing** • Brief Introduction of ECG Compliance Tests • PPG Principle for SpO_2 Measurement • Transmittance SpO_2 Module PPG-2TF-660 Demonstration
18 min.	**Respiration & NIBP Testing** • Optimized Respiration Simulation and Raw Data Playback • Brief Introduction of NIBP Compliance Tests • NIBP Simulator BPA700 Demonstration
4.5 min.	**Automated Testing Solution** • Sample Code of ECG and NIBP Compliance Tests • User Testimonial — ECG Automated Testing
10 min.	**Conclusions and Q&A**

(1) Vital Sign Testing Concepts

Vital Sign Correlation Powered By Multiparameter Simulation

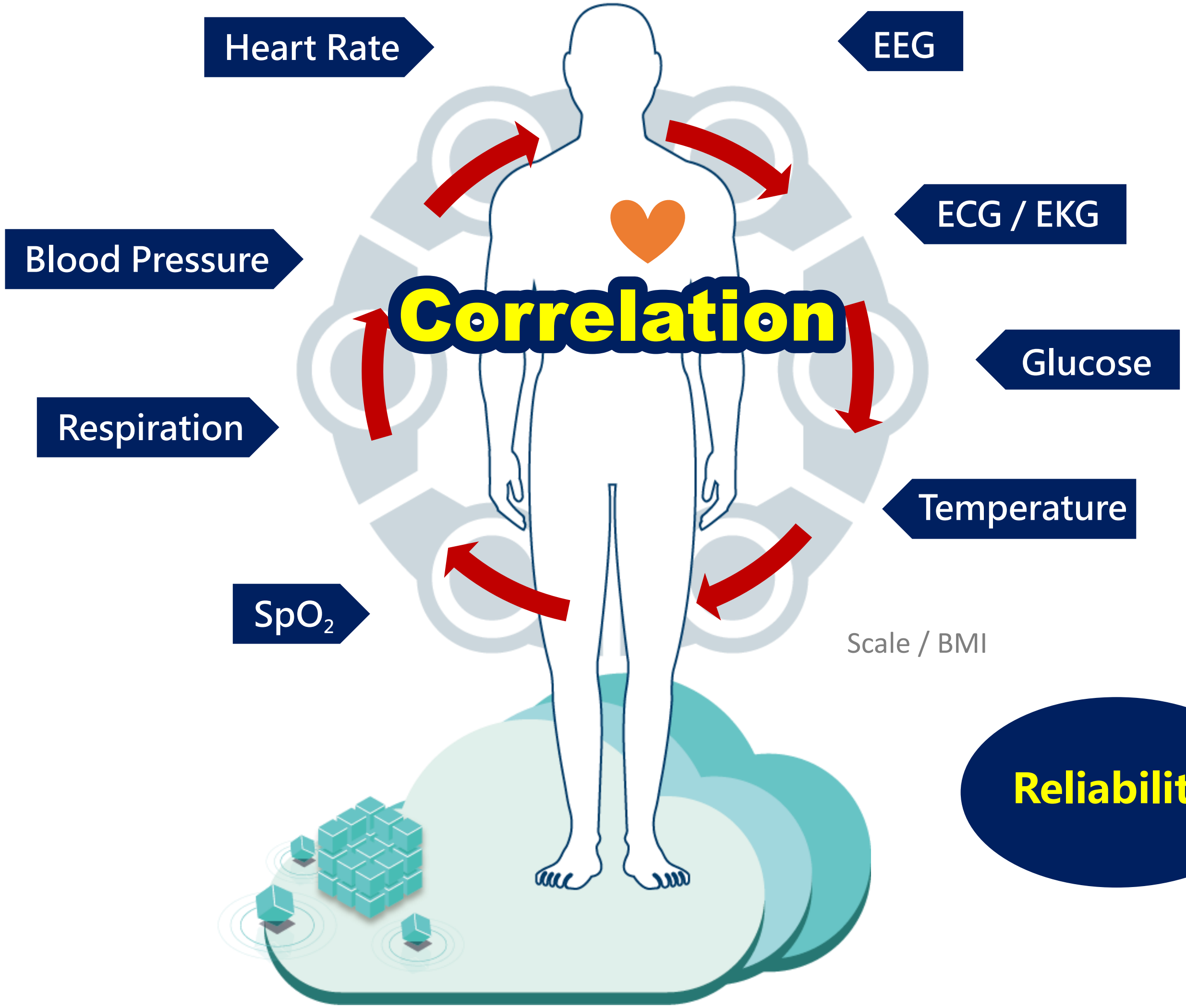
Next-generation Medical System



Telemedicine, Virtual Medical Care, Preventive Medicine
The future of medical industry is built on data

More Accurate and Effortless Diagnosis : Vitals Correlation+AI

Data-says-it-all Medical Future



Reliability **Accuracy** **Compliance**

(2) ECG & PPG Testing

(2-1) ECG Testing

SECG 5.0 AIO

Multi Vital Sign Simulator

- 2-1-1 IEC 60601-2-27 Test Requirements
- 2-1-2 Test Method
- 2-1-3 Test Example

Six Essentials of ECG Standard Test Items

For example: IEC 60601-2-27:2011 Patient Monitoring ECG

201.7.9.2.9.101 Additional instructions for use

- 201.7.9.2.9.101 b) 4) Heart rate meter accuracy and response to irregular rhythm
- 201.7.9.2.9.101 b) 5) Response time of heart rate meter to change in heart rate
- 201.7.9.2.9.101 B) 6) Time to alarm for tachycardia

ALGORITHM PERFORMANCE

Verify with PQRST Complex, Clinical Database, etc.

201.12.1.101 ESSENTIAL PERFORMANCE of ME EQUIPMENT

- 201.12.1.101.1 Accuracy of signal reproduction
- 201.12.1.101.2 Input dynamic range and differential offset voltage
- 201.12.1.101.3 Input impedance
- 201.12.1.101.4 Input NOISE
- 201.12.1.101.5 Multichannel crosstalk
- 201.12.1.101.6 GAIN control and stability
- 201.12.1.101.7 Sweep speed
- 201.12.1.101.8 Frequency and impulse response
- 201.12.1.101.9 GAIN INDICATOR
- 201.12.1.101.10 Common mode rejection
- 201.12.1.101.11 Baseline reset
- 201.12.1.101.12 Pacemaker pulse display capability
- 201.12.1.101.13 Rejection of pacemaker pulses
- 201.12.1.101.14 Synchronizing pulse for cardioversion
- 201.12.1.101.15 Heart rate range, accuracy, and QRS detection range
- 201.12.1.101.16 Channel height and aspect ratio
- 201.12.1.101.17 Tall T-wave rejection capability

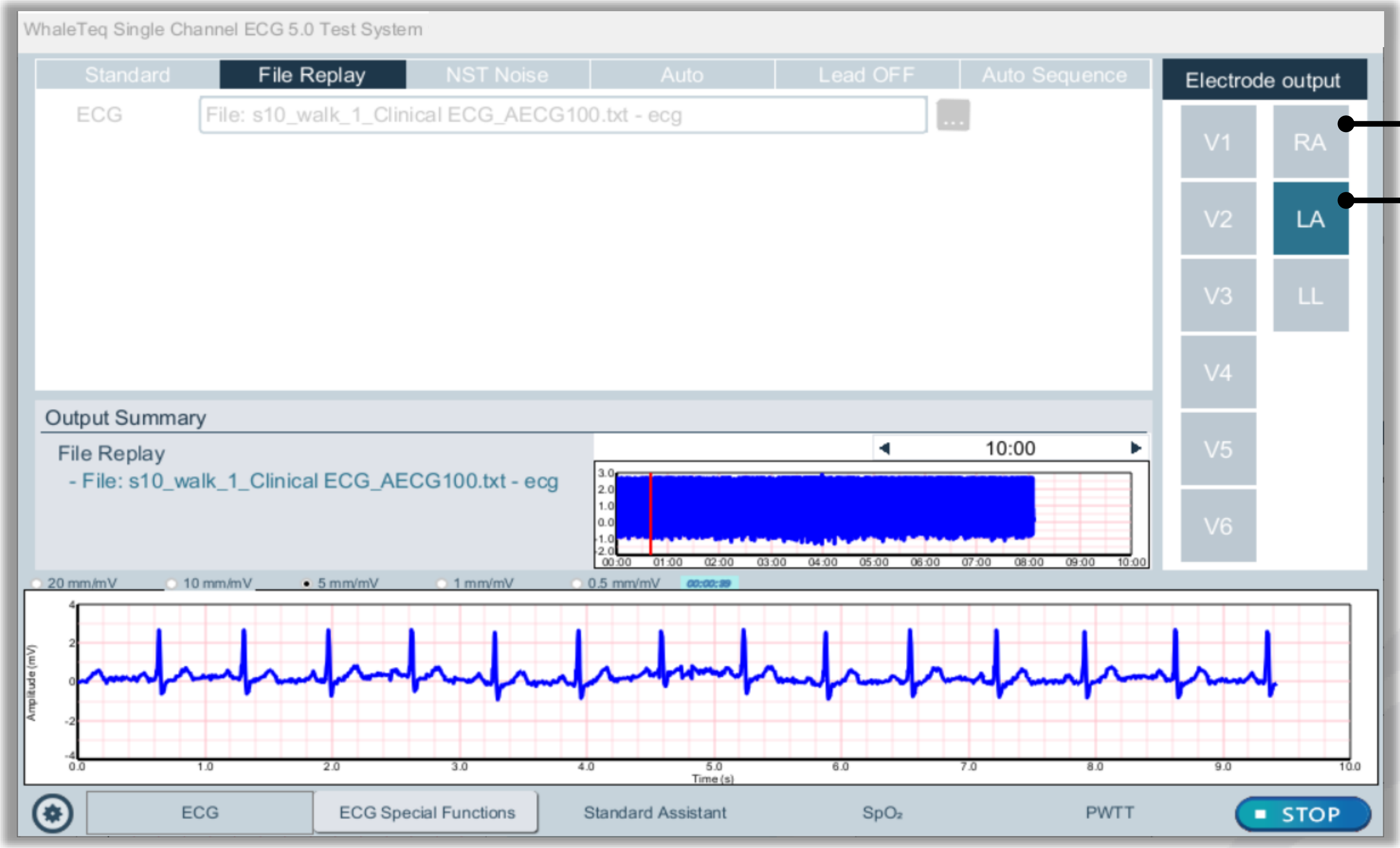
ELECTRICAL PERFORMANCE

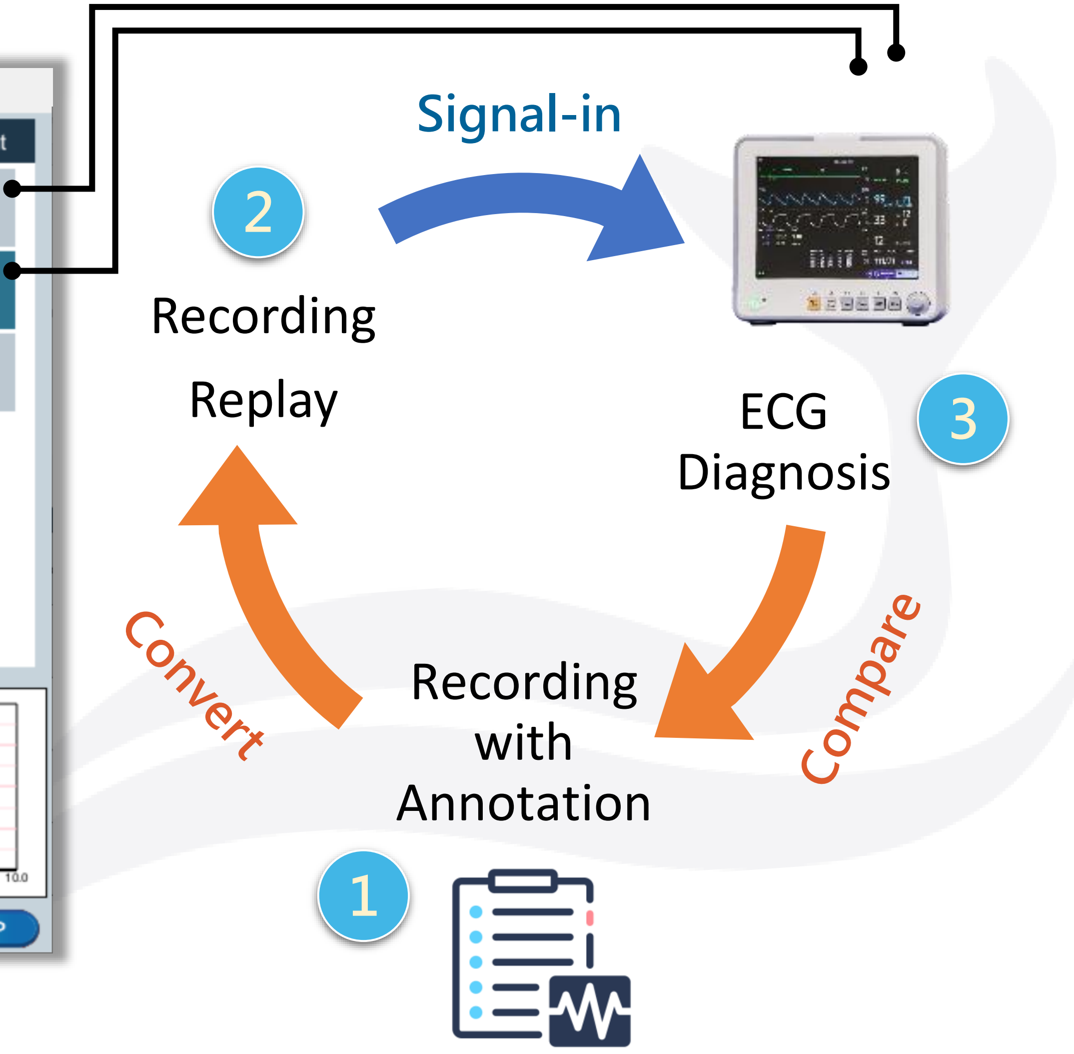
- ◆ Amplitude Accuracy
- ◆ Dynamic Range
- ◆ Input Impedance
- ◆ Frequency Response
- ◆ Noise

Verify with Basic Waveforms

Advanced Algorithm Testing

Machine Learning as Looking up to Annotation





ECG Test Capabilities powered by Hassle-free HW and GUI

2-1-2
Test Method

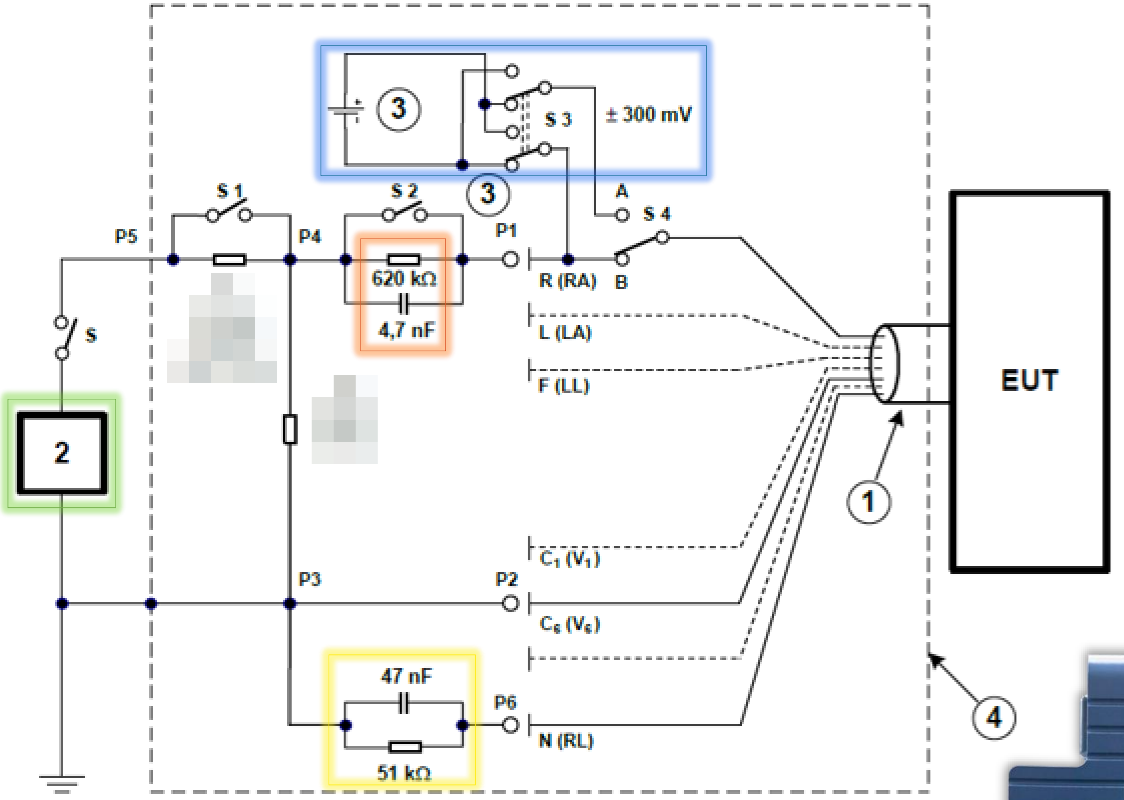


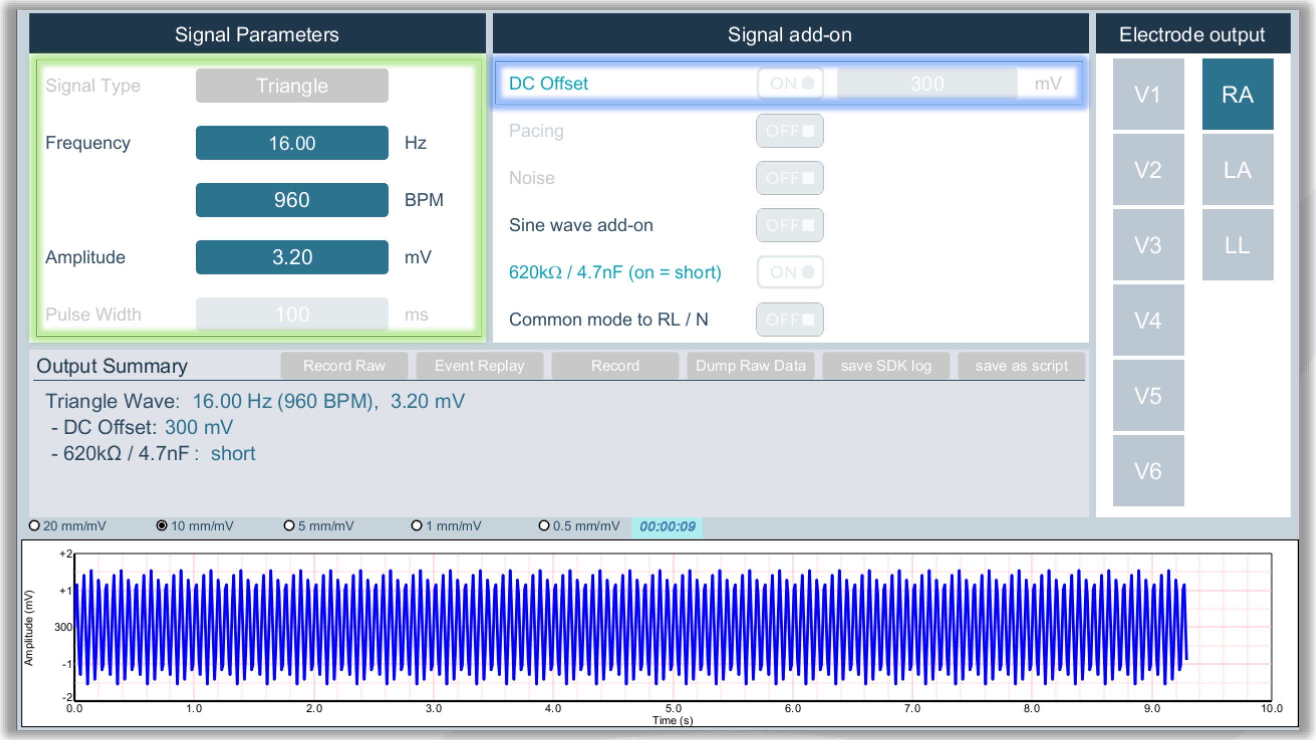
Figure 201.105 – General test circuit

Test Example

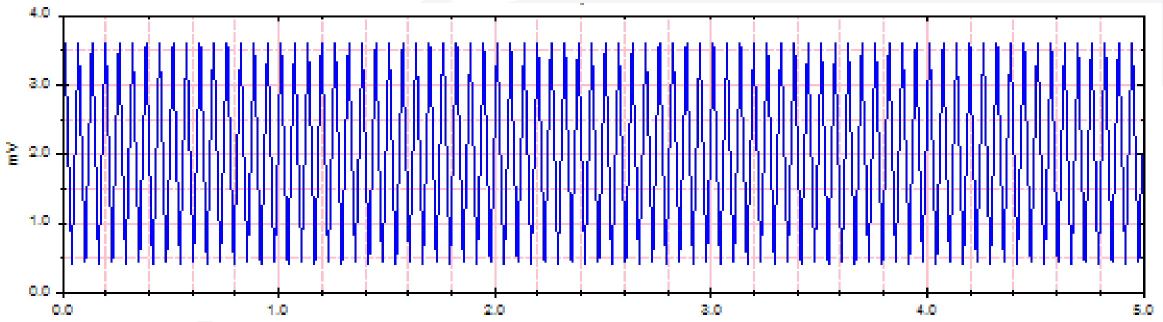
201.12.1.101.2 Input dynamic range and differential offset voltage

- Purpose
  - With a d.c. offset voltage in the range of ±300 mV and differential input signal voltages of ±5 mV that vary at rates up to 320 mV/s, when applied to any LEAD WIRE, the time-varying output signal amplitude shall not change by more than ±10 % over the specified range of d.c. offset.
- METHOD
  - Open S1, close S and S2 and S4 at position B (no DC).
  - Apply a 16 Hz triangular or sinusoidal signal to any LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P2)as defined in Table 201.103.
  - Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s.
  - Adjust the signal generator so that the applied input signal produces an output amplitude of 80% of the full scale channel height. Record the amplitude of this output signal.
  - Set S4 to position A (with DC)to apply a d.c. offset voltage of +300 mV.
  - Repeat this test for a d.c. offset voltage of -300 mV by changing the position of S3.
  - Repeat the test for each LEAD WIRE until all combinations of LEAD WIRES have been tested as defined in Table 201.103.
  - Repeat the test for each PERMANENT DISPLAY and NON-PERMANENT DISPLAY.
- RESULTS
  - Verify that the output signal amplitude is within ±10% of the previously recorded amplitude

    (Triangle wave: SR=4fVp=4x 16 x 5 mV=320 mV/s)

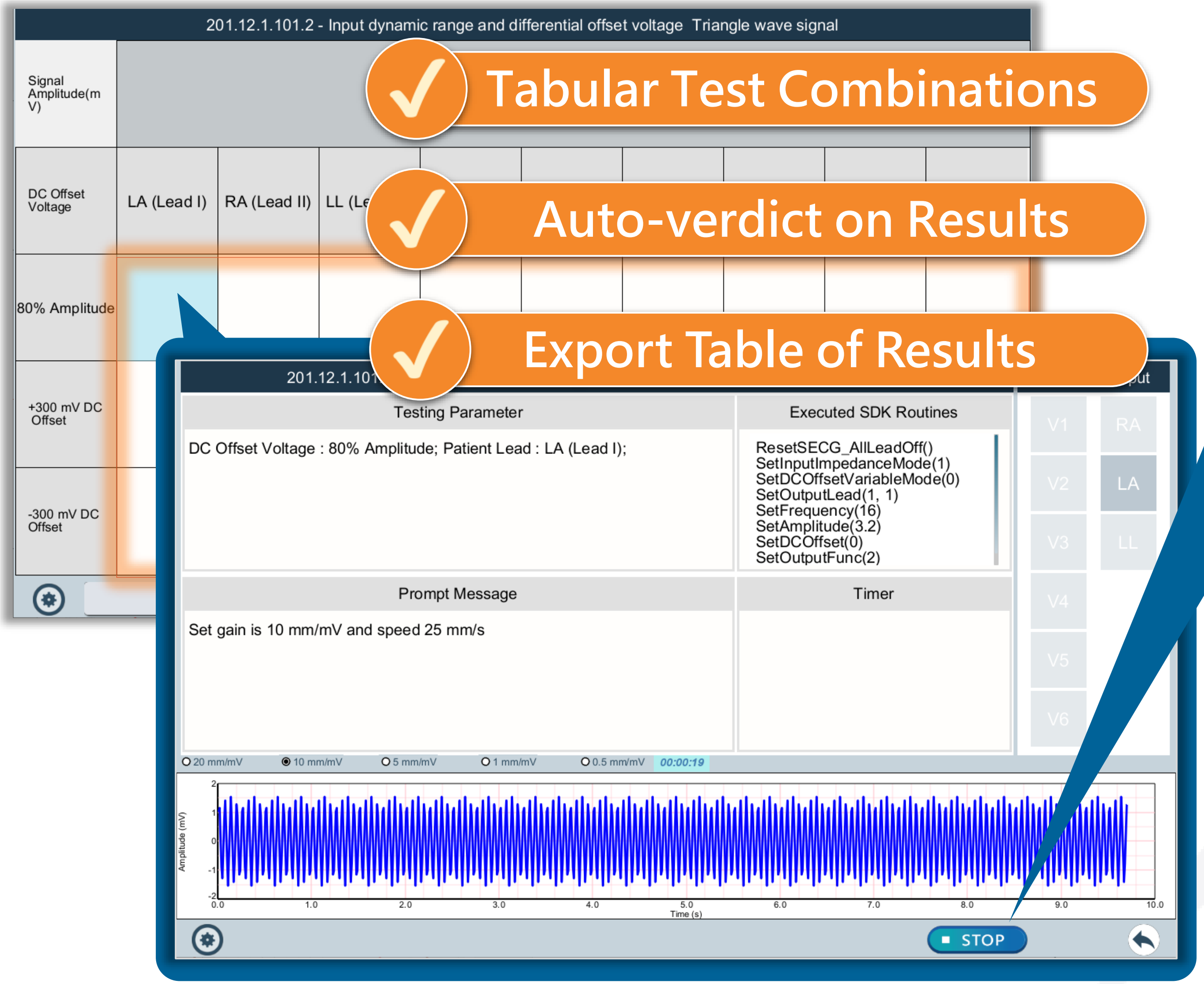


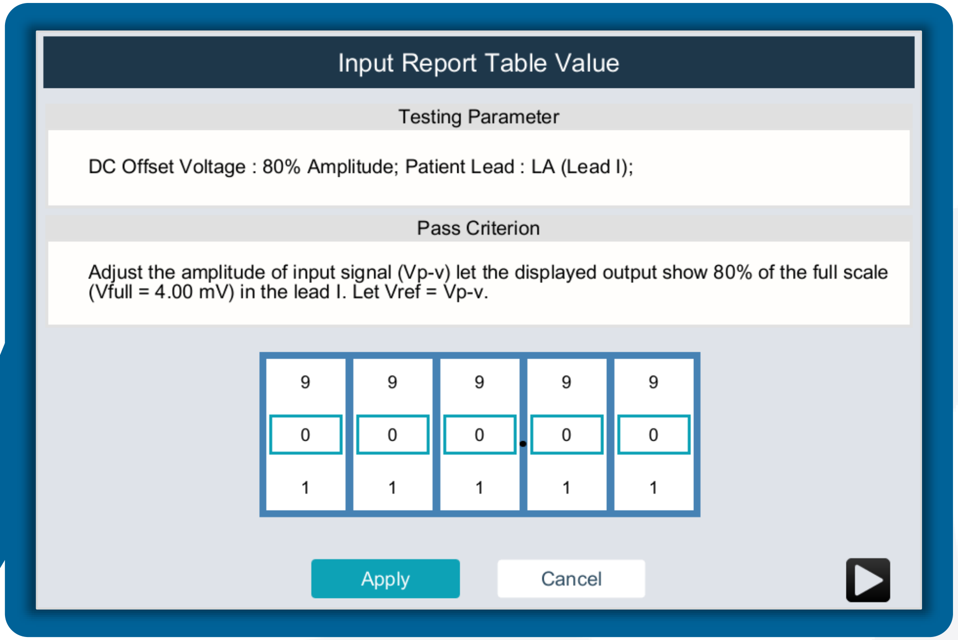
EUT Display & Measurement :



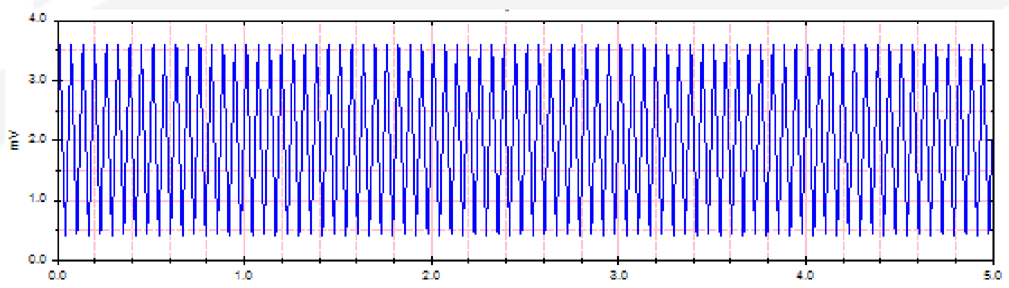
Test Example

201.12.1.101.2 Input dynamic range and differential offset voltage



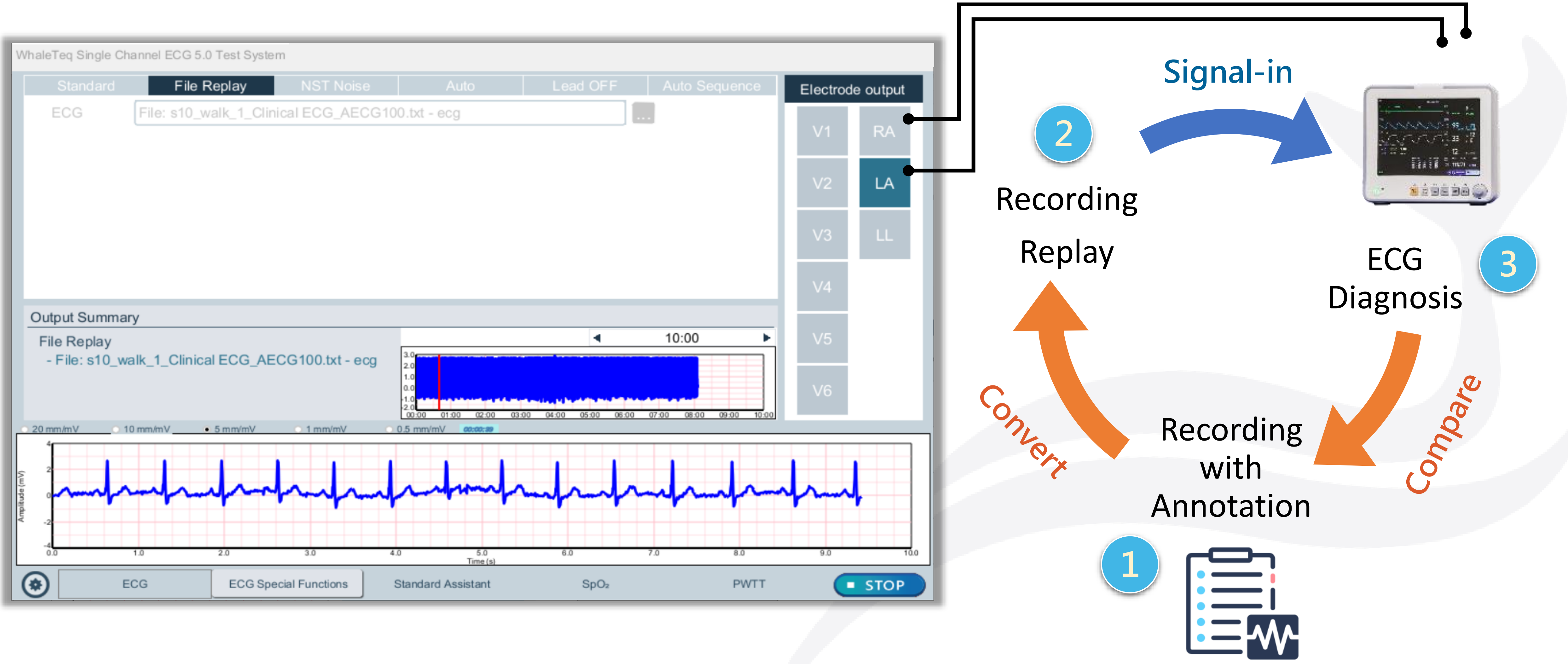


EUT Display & Measurement:



Advanced Algorithm Testing

Machine Learning as Looking up to Annotation



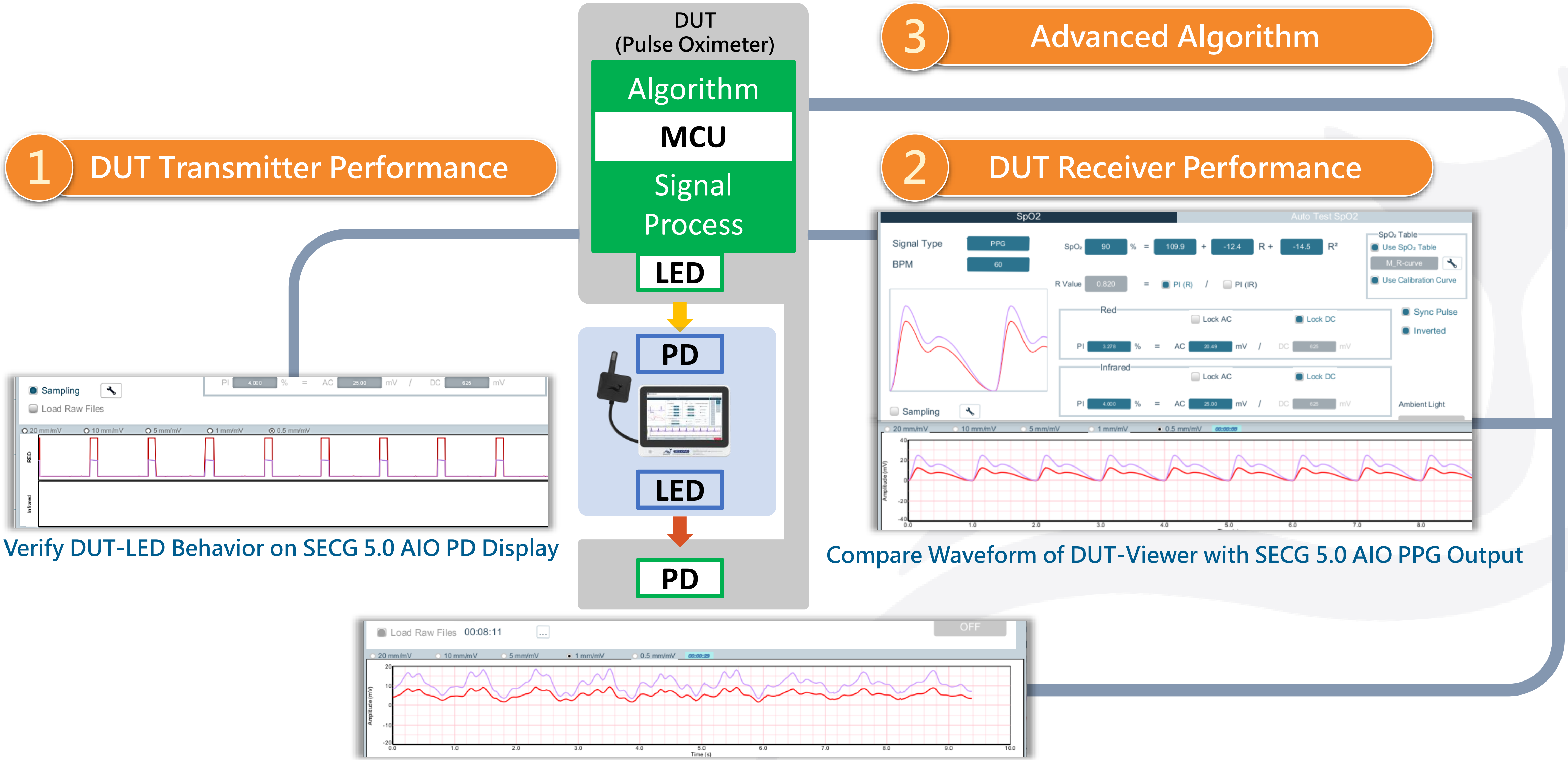
(2-2) PPG Testing

PPG-2TF-660

Transmittance SpO_2 Module

- ▶ 2-2-1 PPG Technology for SpO_2 Measurement
- ▶ 2-2-2 Test Method
- ▶ 2-2-3 Operational Principle
- ▶ 2-2-4 Test Method

Three Essentials of PPG for SpO_2



Verify DUT-LED Behavior on SECG 5.0 AIO PD Display

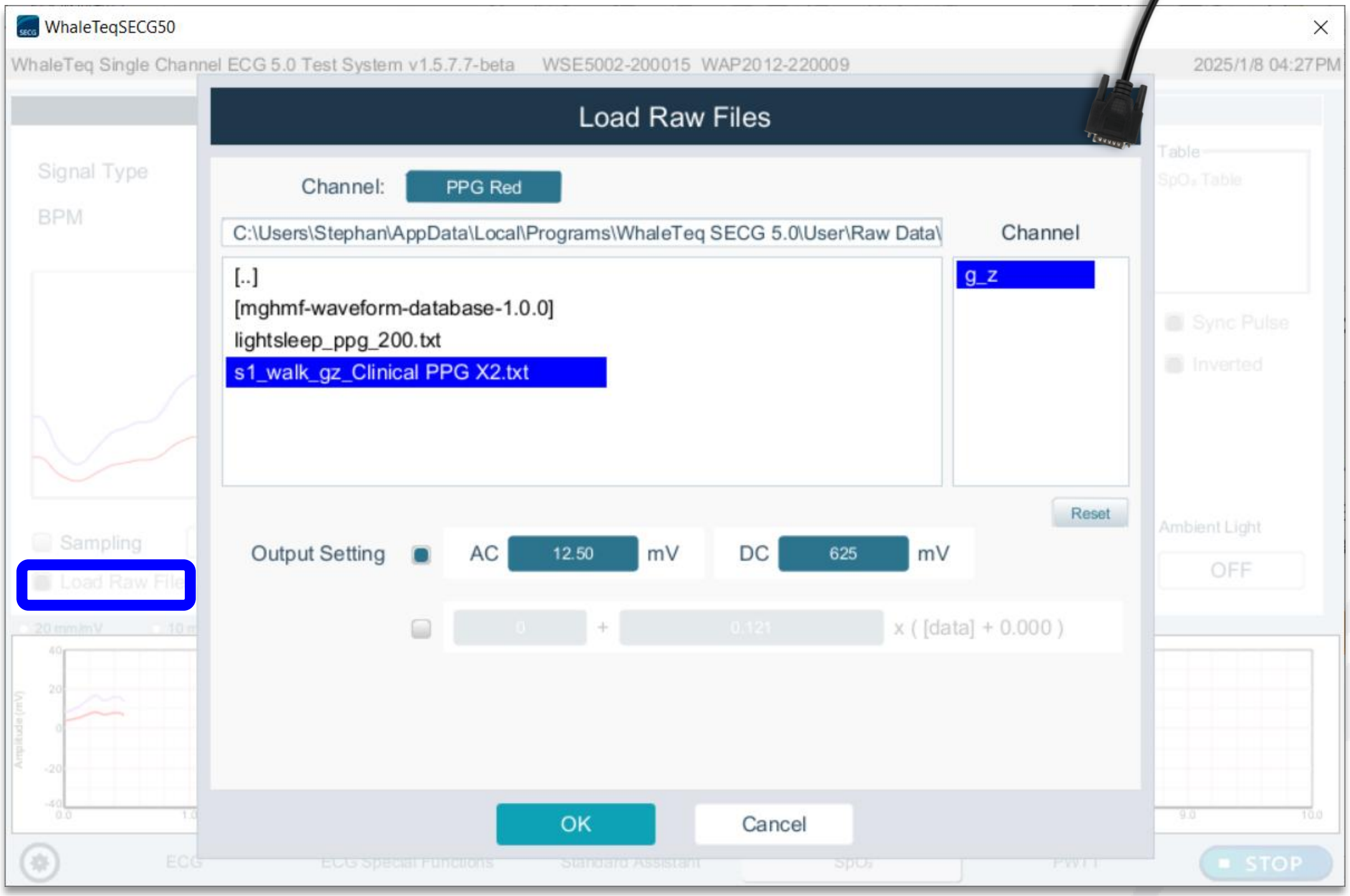
Compare Waveform of DUT-Viewer with SECG 5.0 AIO PPG Output

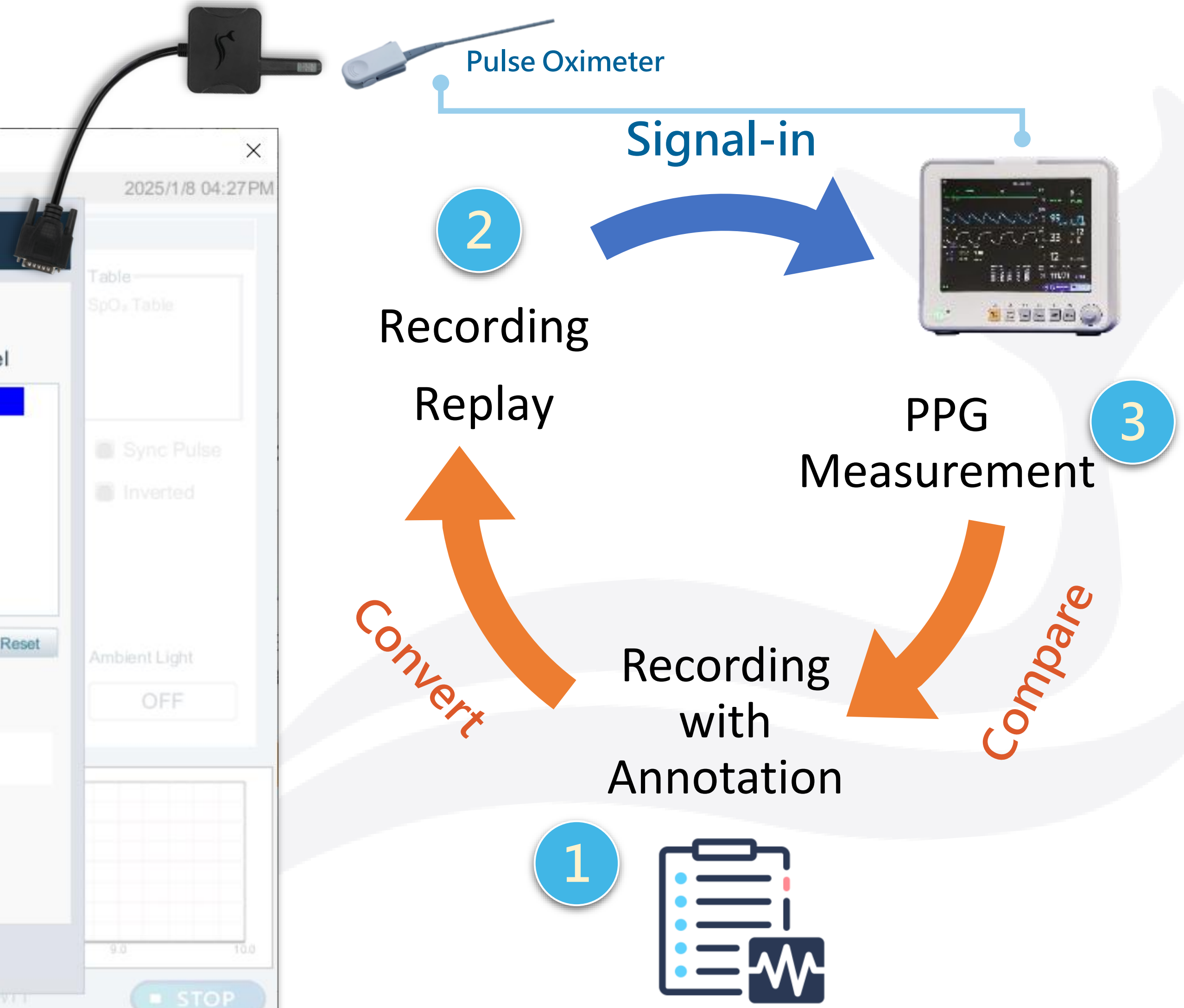
Verify Readings with Recorded Raw Data or Customized Waveform Replayed by SECG 5.0 AIO

Advanced Algorithm Testing

Machine Learning as Looking up to Annotation

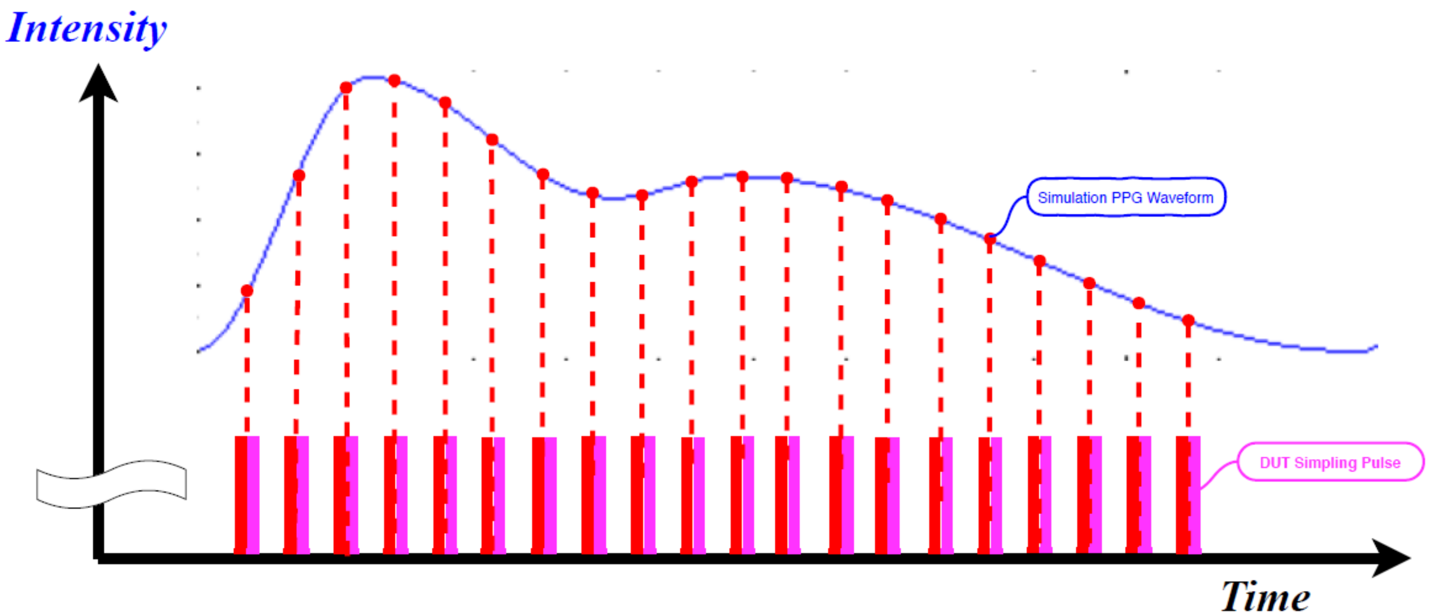
2-2-2
Test Method

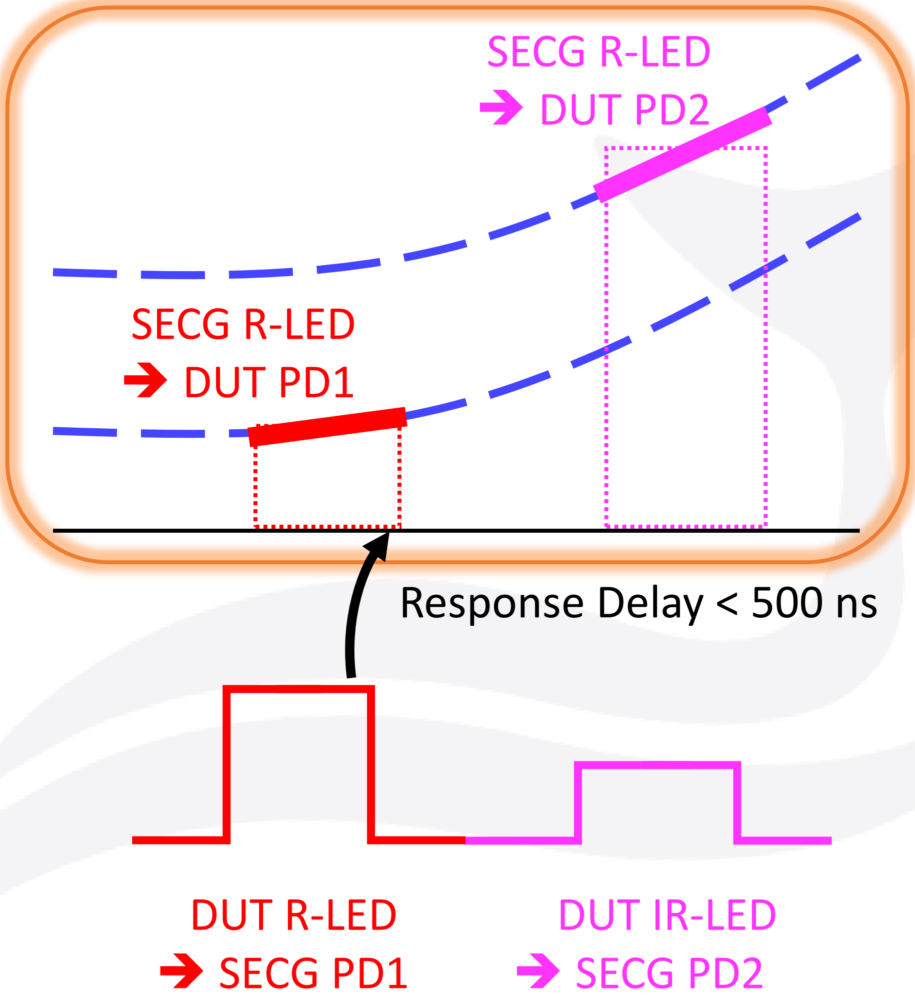


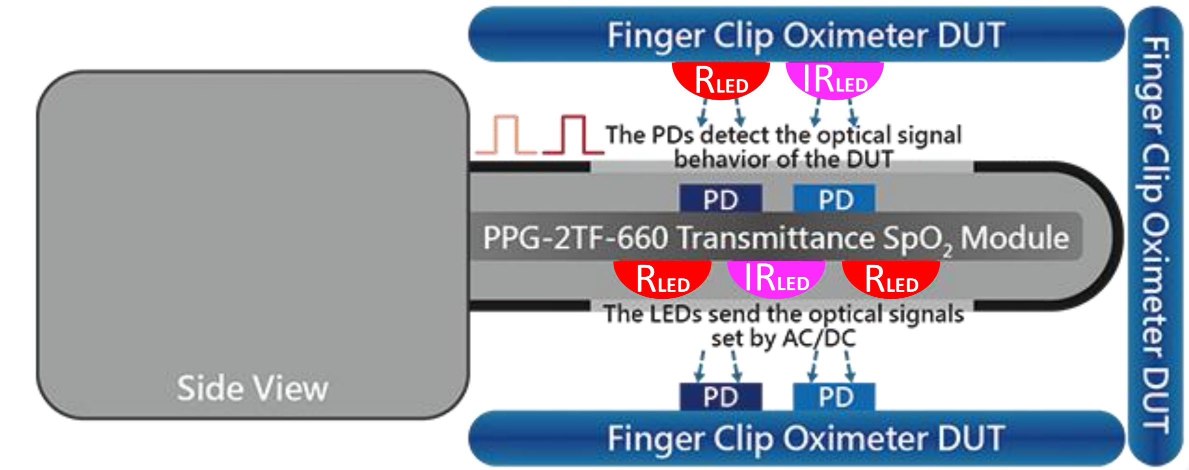


Operational Principle

Synchronize DUT Sampling Frequency



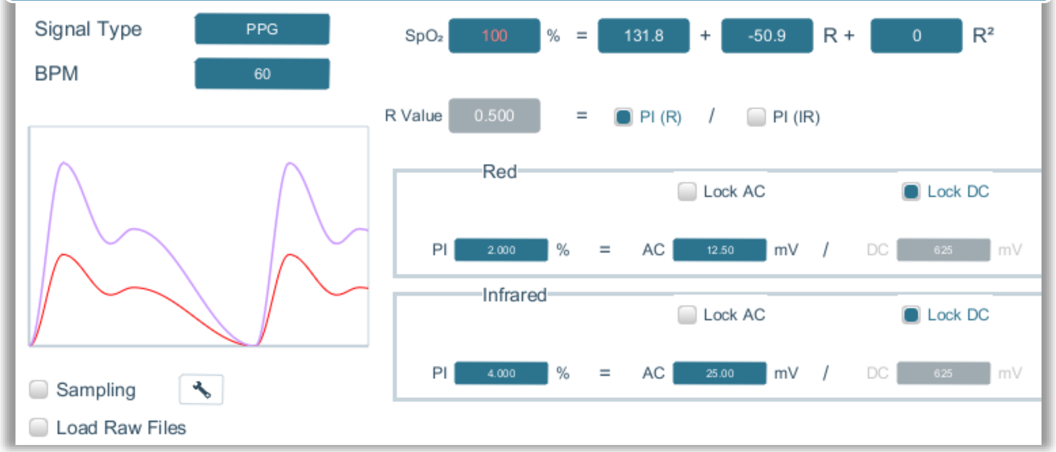




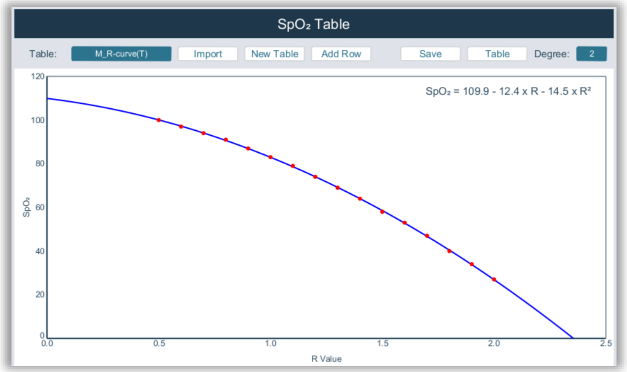
PPG-2TF-660 Functions

R&D-purposed Transmittance PPG Simulator

1 Adjust Separate R/IR-AC and R/IR-DC to Simulate Various Patient Conditions

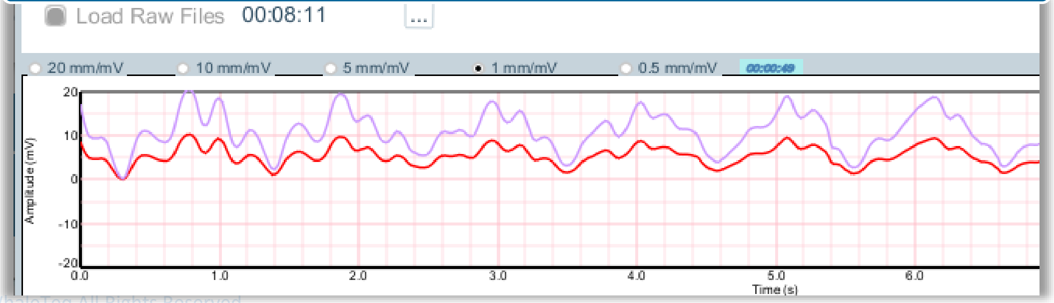


2 Derive DUT-tailored Reference R Curve to Check Repeatability and Reproducibility

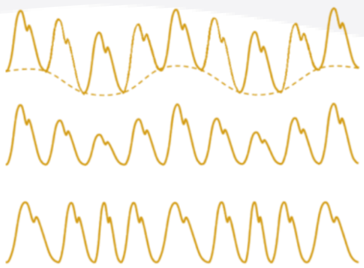


SpO_2 (%)	SN 1 Golden	SN 2	SN 3	SN 4
95	95 95	94	95	96
90	89			
85	85			
80	81			

3 Load User-defined Waveform to Replay for Algorithm Enhancement



4 Add-on Signals: Ambient Noises, Finger type-specific Transmission Rates & Respiration



Brief Conclusion

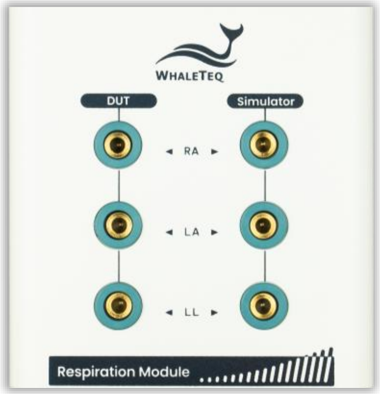
Brief Conclusion

- **Flexible ECG, PPG, Impedance RESP and NIBP Simulations At Once** enhances analysis of vital sign correlation by patient monitors.
- **Standard Assistant Software** breaks down and streamlines ECG medical standard tests into Pass Criteria, Preparation, Test Parameter per Condition and Auto-verdict.
- **Independent R/IR-AC and R/IR-DC Settings of PPG Simulation** portrays various patient conditions.
- **DUT-tailored R Curve** helps benchmark new product with the existing one and also assures repeatability and reproducibility.
- **Replaying clinical ECG and / or PPG database the analogue way** cost-effectively enhances algorithm testing.

(3) Respiration & NIBP Testing

(3-1) Respiration Testing

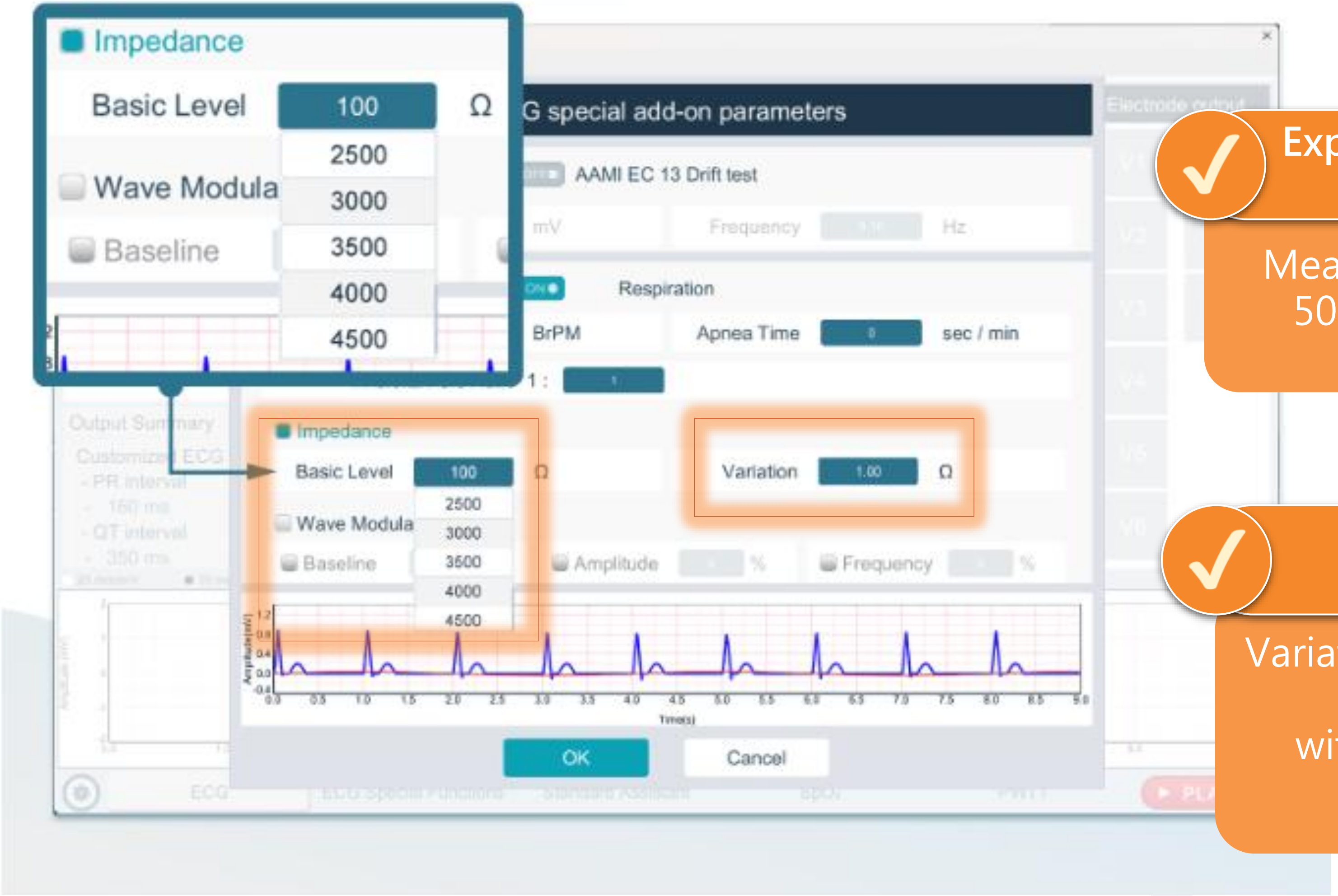
Respiration Module



- ▶ 3-1-1 Respiration Module Introduction
- ▶ 3-1-2 Test Method

Advanced Respiration Parameters

Both Impedance and Modulation Methods Available



Expands the respiratory measurement range of impedance basic level

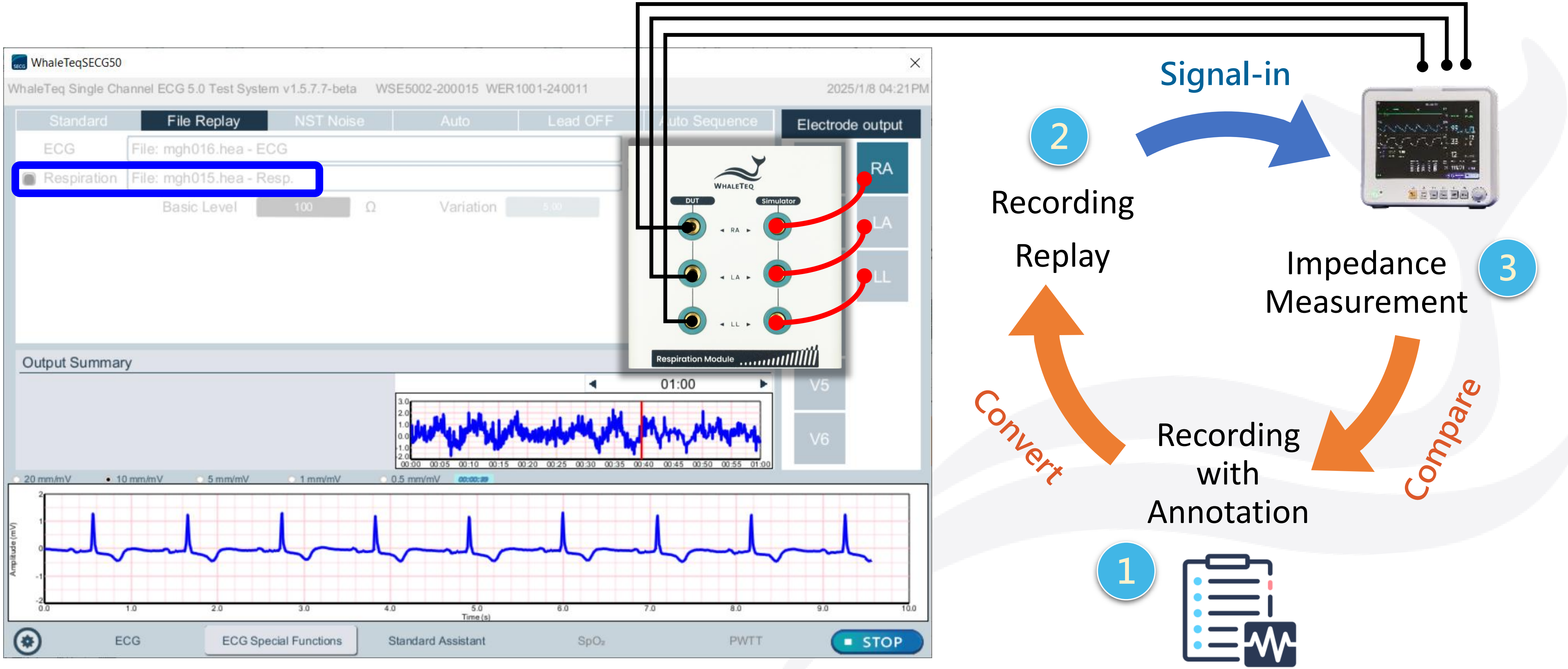
Measurement range expanded from the original 500Ω to 2500Ω to a range of **100Ω to 4500Ω**

Optimizes variation resolution

Variation range expanded from the original 1.0Ω to 5.0Ω to a range of **0.0Ω to 10.0Ω** with **a minimum step size of 0.05Ω** within the range of 0.0Ω to 5Ω

Advanced Algorithm Testing

Machine Learning as Looking up to Annotation



(3-2) NIBP Testing

BPA700

NIBP Simulator & Analyzer

- ▶ 3-2-1 IEC 80601-2-30 Test Requirements
- ▶ 3-2-2 Test Method
- ▶ 3-2-3 IEC 80601-2-30 Test Requirements
- ▶ 3-2-4 Test Example
- ▶ 3-2-5 IEC 80601-2-30 Test Requirements
- ▶ 3-2-6 Test Example
- ▶ 3-2-7 BPA700 Specifications

Six Essentials of NIBP Standard Test Items

IEC 80601-2-30

① **201.11.8: Interruption of the power supply/supply mains to the equipment**.

201.11.8.101 Switching off
201.11.8.102 Interruption of the supply mains

② **201.12.1: Accuracy of controls and instruments**.

201.12.1.101 Measuring and display ranges
201.12.1.102 Limits of the error of the manometer from environmental conditions
201.12.1.103 Nominal blood pressure indication range
201.12.1.104 Maximum pressure in normal condition
201.12.1.105 Maximum pressure in single fault condition
201.12.1.106 Manometer test mode
201.12.1.107 Reproducibility of the blood pressure determination

③ **201.101.2: Pressurization**.

④ **201.104: Maximum inflating time**.

⑤ **201.105: Automatic cycling mode**.

201.105.1 Long-term automatic mode
201.105.2 Short-term automatic mode
201.105.3 Self-measurement automatic mode
201.105.3.1 General
201.105.3.2 Normal condition
201.105.3.3 Single fault condition

① Deflation Time

② Manometer Accuracy & Sys/Dia Repeatability

③ Protection Mechanism at Max. Pressure

④ Cuff and Bladder Robustness

⑤ Max. Inflating Time

⑥ Sys/Dia Accuracy

Compliance ≠ Competence

Friendly GUI

BPA700

Instant Pressure Display

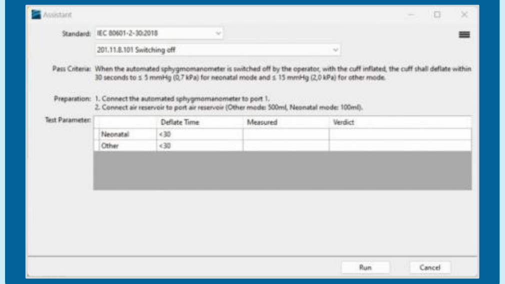
BP monitor

00.0 mmHg

Reset

- Static Pressure
- Blood Pressure
- Leak Test
- Overpressure
- Play Data
- Record Data

Standard Assistant Software



3-2-2 Test Method

DUT

① Deflation Time

② Manometer Accuracy & Sys/Dia Repeatability

③ Protection Mechanism at Max. Pressure

④ Cuff and Bladder Robustness

⑤ Max. Inflating Time

⑥ Sys/Dia Accuracy

201.12.1.106 Manometer Test Mode

201.12.1.106 * Manometer test mode

The AUTOMATED SPHYGMOMANOMETER shall have a manometer test mode that permits static pressure measurement over at least the NOMINAL BLOOD PRESSURE indication range (see 201.12.1.103). This mode shall not be available in NORMAL USE but restricted to SERVICE PERSONNEL.

EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

Manometer of NIBP Monitor

EXAMPLE 2 A port for connection to a reference manometer that can be pressurized by the AUTOMATED SPHYGMOMANOMETER in a test mode.

Pressure Source of NIBP Monitor

NOTE This mode can be used to verify manometer pressure accuracy.

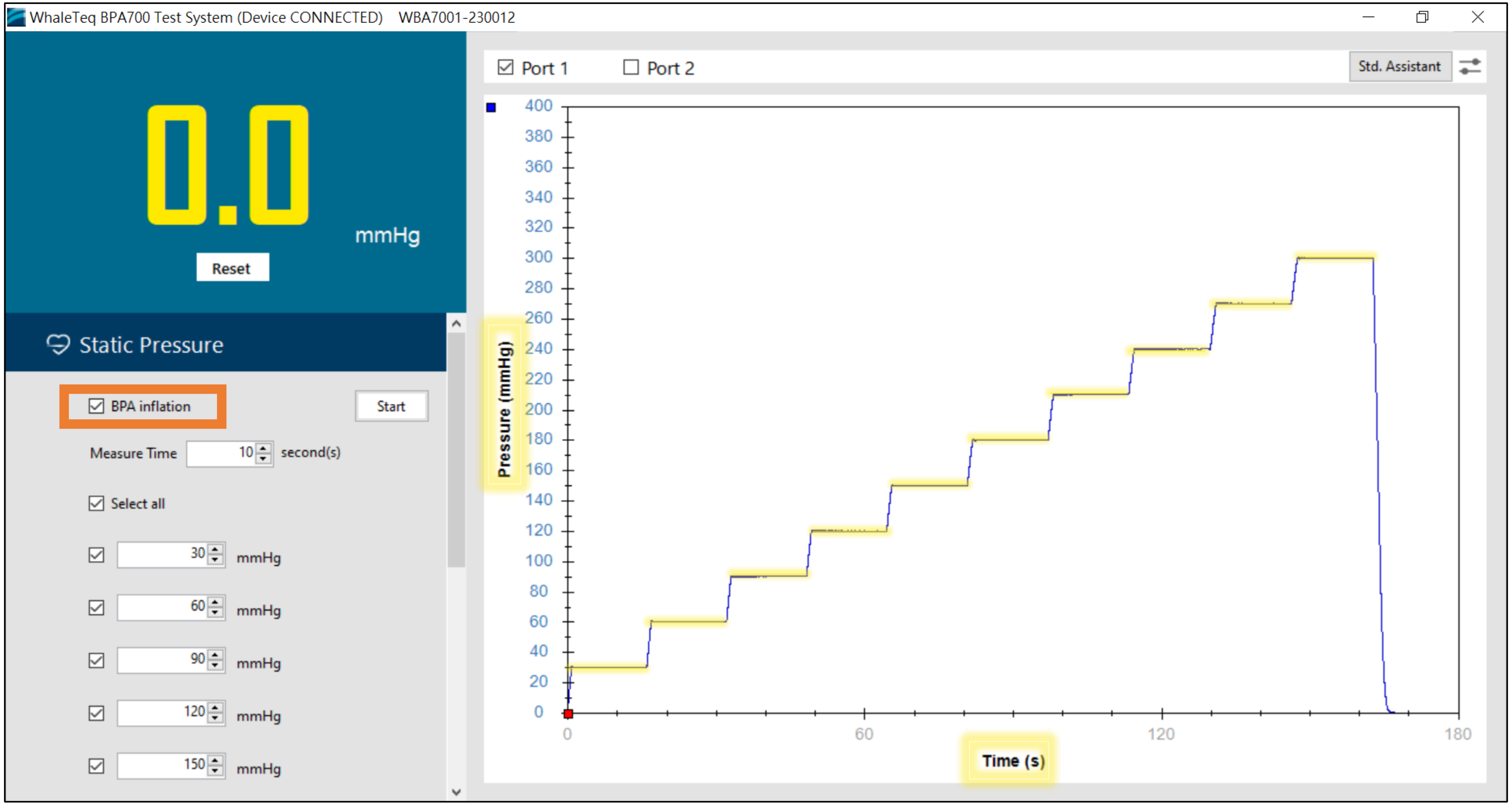
The technical description shall include a test method that can be used to verify the calibration of the AUTOMATED SPHYGMOMANOMETER.

Compliance is checked by inspection and functional testing.

Static Pressure Test

against Manometer of NIBP Monitor

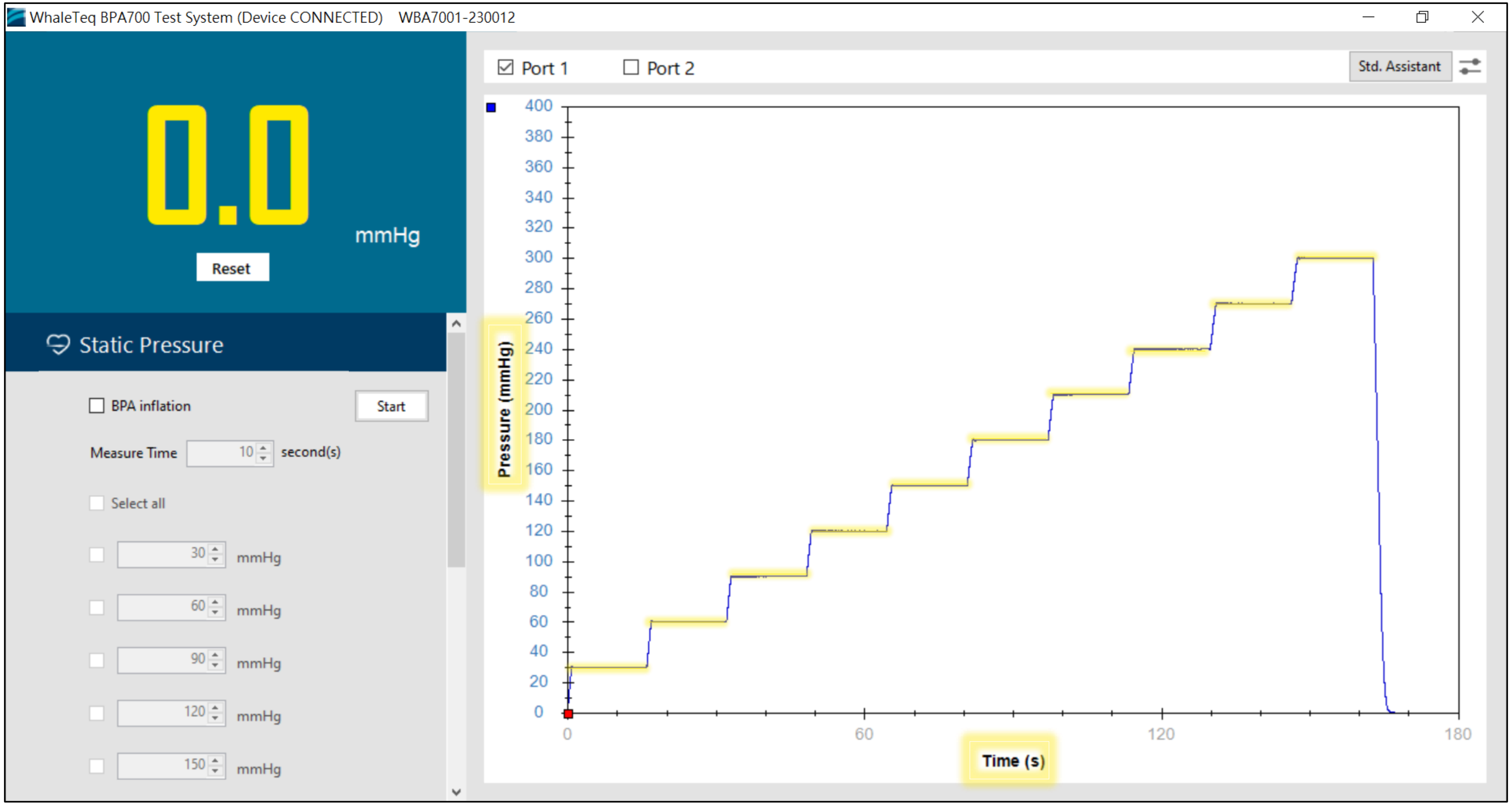
3-2-4
Test Example



Static Pressure Test

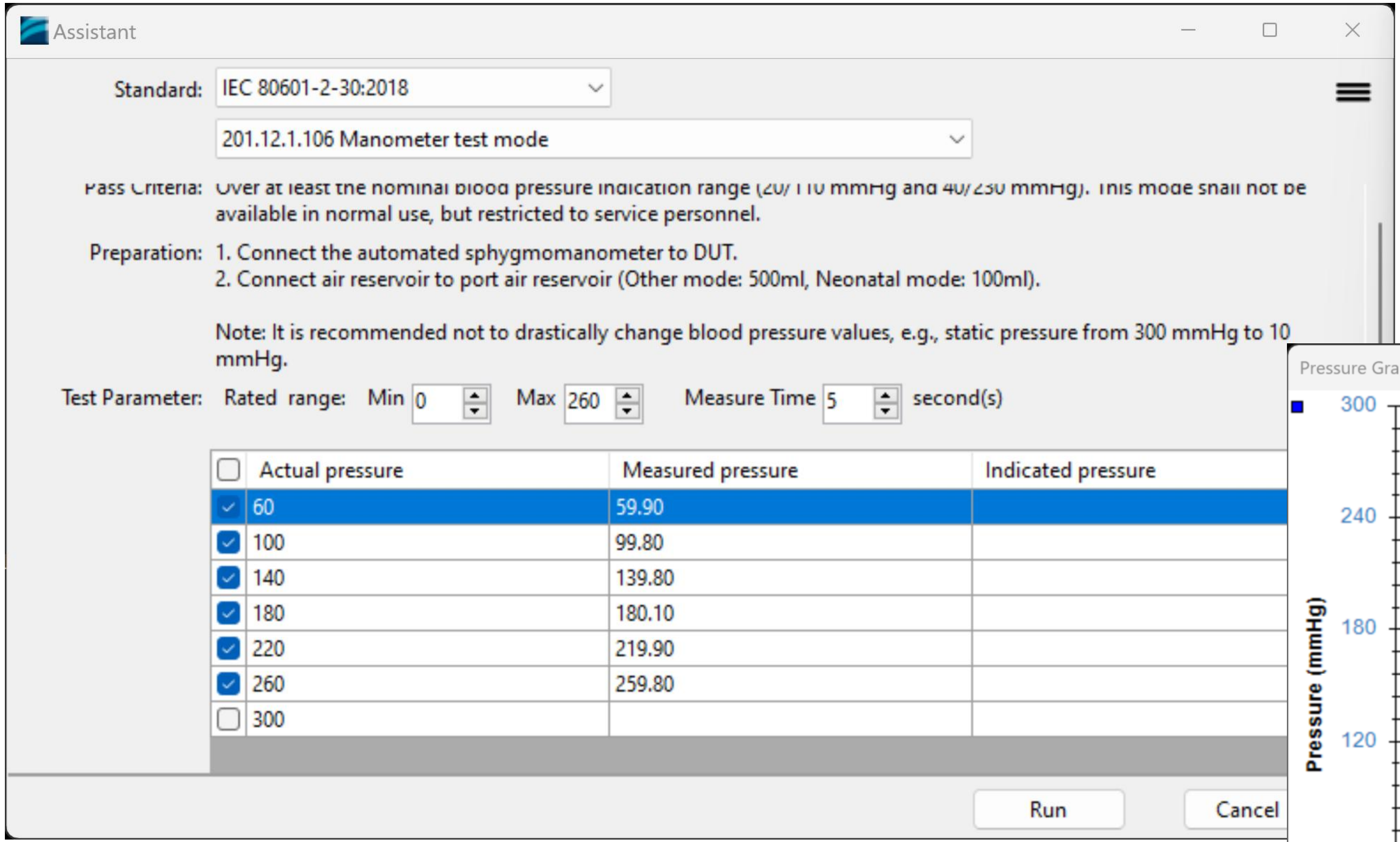
against Pressure Source of NIBP Monitor

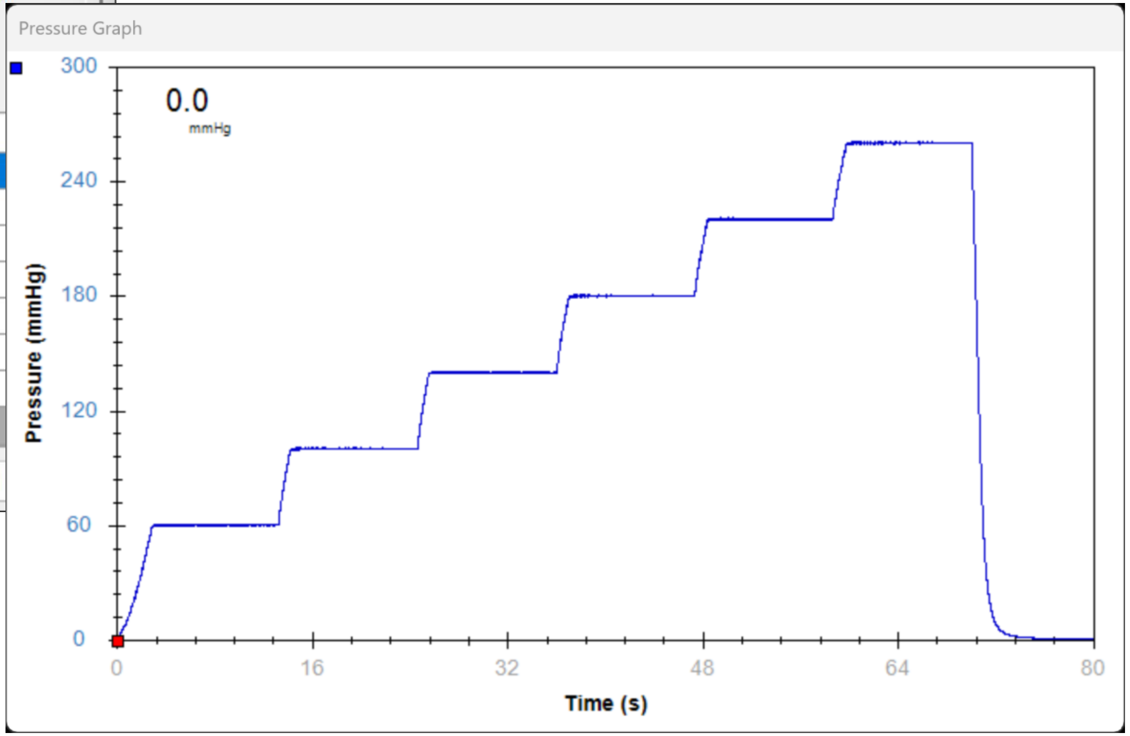
3-2-4
Test Example



BPA700 Standard Assistant

201.12.1.106 Manometer test mode





201.105.1 Long-term Automatic Mode

3-2-5
IEC 80601-2-30
Test Requirements

201.105 * Automatic cycling modes

201.105.1 LONG-TERM AUTOMATIC MODE

If an AUTOMATED SPHYGMOMANOMETER is equipped with a LONG-TERM AUTOMATIC MODE, a PROTECTION DEVICE shall be provided to ensure that:

a) in NORMAL CONDITION:

– the total duration of the alternating inflation/deflation periods in an unsuccessful DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation time specified in 201.104; and

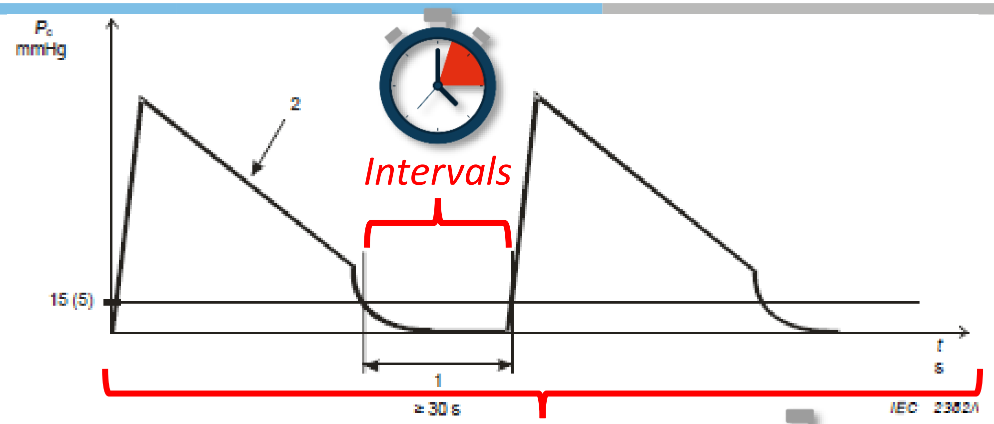
– after each successful DETERMINATION;

the CUFF pressure shall be released and shall remain below the values in Table 201.102 for at least 30 s (see Figure 201.104); and

b) in SINGLE FAULT CONDITION:

if the duration of deflation below the values in Table 201.102 is less than 30 s (see Figure 201.105), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall release the CUFF pressure to the values in Table 201.102.

Compliance is checked by functional testing.



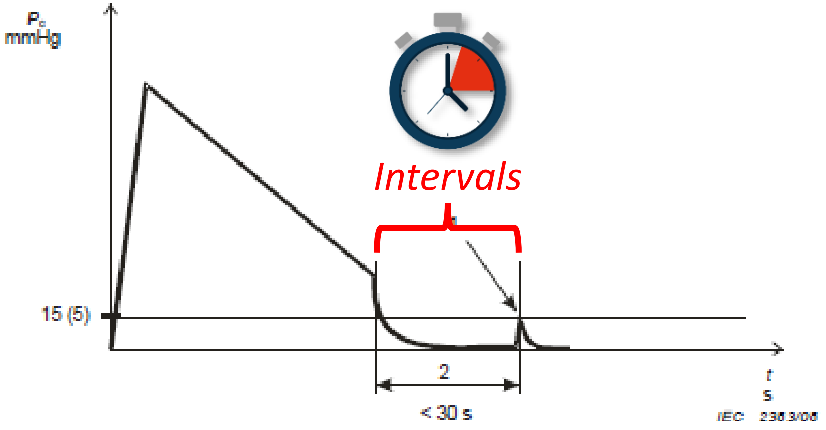
1 Deflated time

2 Linear CUFF deflation shown

NOTE Stepwise, exponential or other waveforms can be used for CUFF deflation.

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.104 – LONG-TERM AUTOMATIC MODE CUFF pressure in NORMAL CONDITION



1 Pressure relief PROTECTION DEVICE activates

2 Deflated time

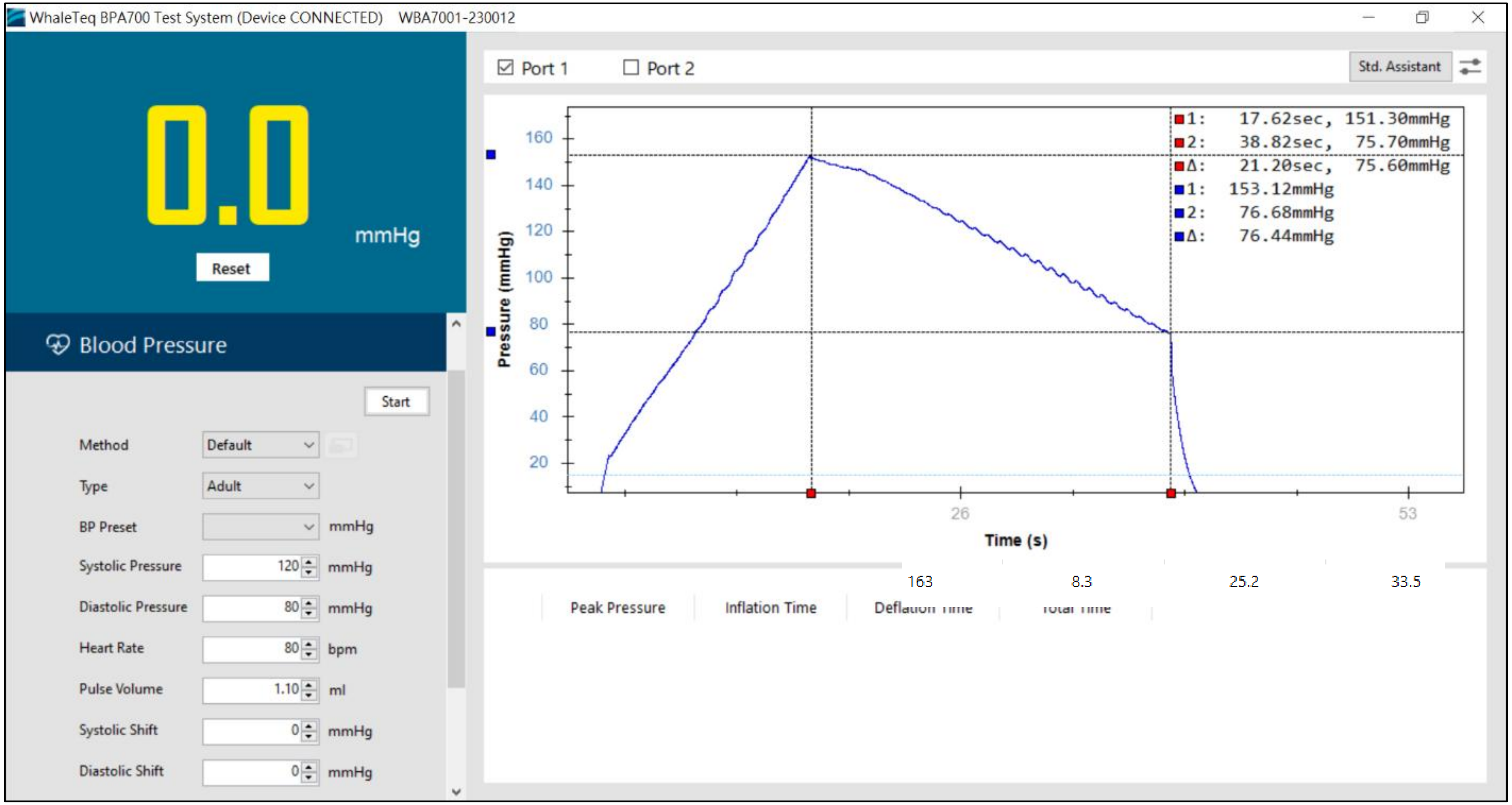
CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.105 – LONG-TERM AUTOMATIC MODE CUFF pressure in SINGLE FAULT CONDITION

Blood Pressure Test

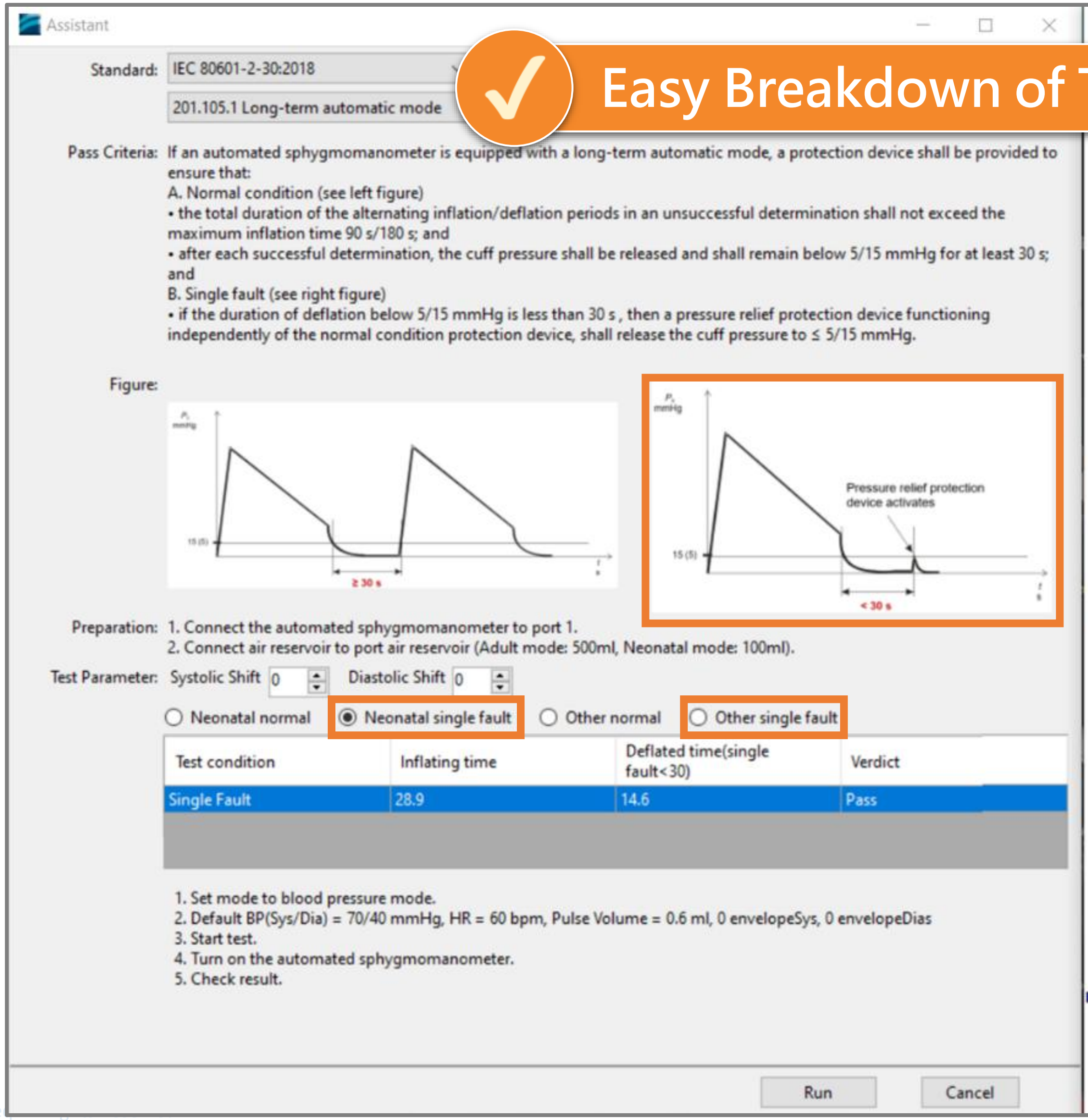
with Sys, Dias, HR and Two-end Sys/Dias Shift

3-2-6
Test Example



BPA700 Standard Assistant

201.105.1 Long-term automatic mode—Single Fault


Assistant

Standard: IEC 80601-2-30:2018

201.105.1 Long-term automatic mode

Pass Criteria: If an automated sphygmomanometer is equipped with a long-term automatic mode, a protection device shall be provided to ensure that:
A. Normal condition (see left figure)
• the total duration of the alternating inflation/deflation periods in an unsuccessful determination shall not exceed the maximum inflation time 90 s/180 s; and
• after each successful determination, the cuff pressure shall be released and shall remain below 5/15 mmHg for at least 30 s; and
B. Single fault (see right figure)
• if the duration of deflation below 5/15 mmHg is less than 30 s, then a pressure relief protection device functioning independently of the normal condition protection device, shall release the cuff pressure to ≤ 5/15 mmHg.

Figure:

Preparation: 1. Connect the automated sphygmomanometer to port 1.
2. Connect air reservoir to port air reservoir (Adult mode: 500ml, Neonatal mode: 100ml).

Test Parameter: Systolic Shift 0 Diastolic Shift 0

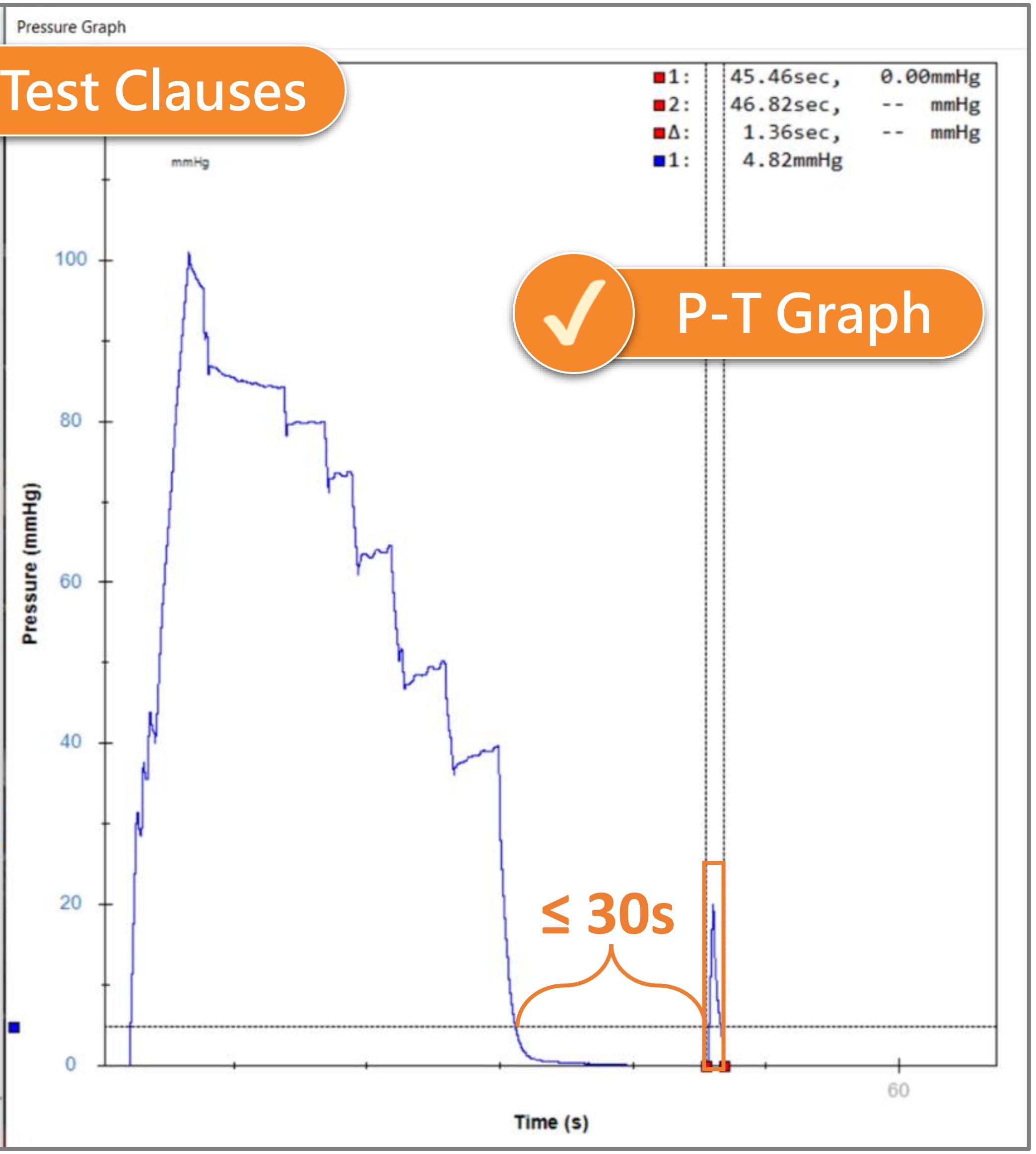
○ Neonatal normal ◉ Neonatal single fault ○ Other normal ○ Other single fault

Test condition	Inflating time	Deflated time(single fault<30)	Verdict
Single Fault	28.9	14.6	Pass

1. Set mode to blood pressure mode.
2. Default BP(Sys/Dia) = 70/40 mmHg, HR = 60 bpm, Pulse Volume = 0.6 ml, 0 envelopeSys, 0 envelopeDias
3. Start test.
4. Turn on the automated sphygmomanometer.
5. Check result.

Run Cancel

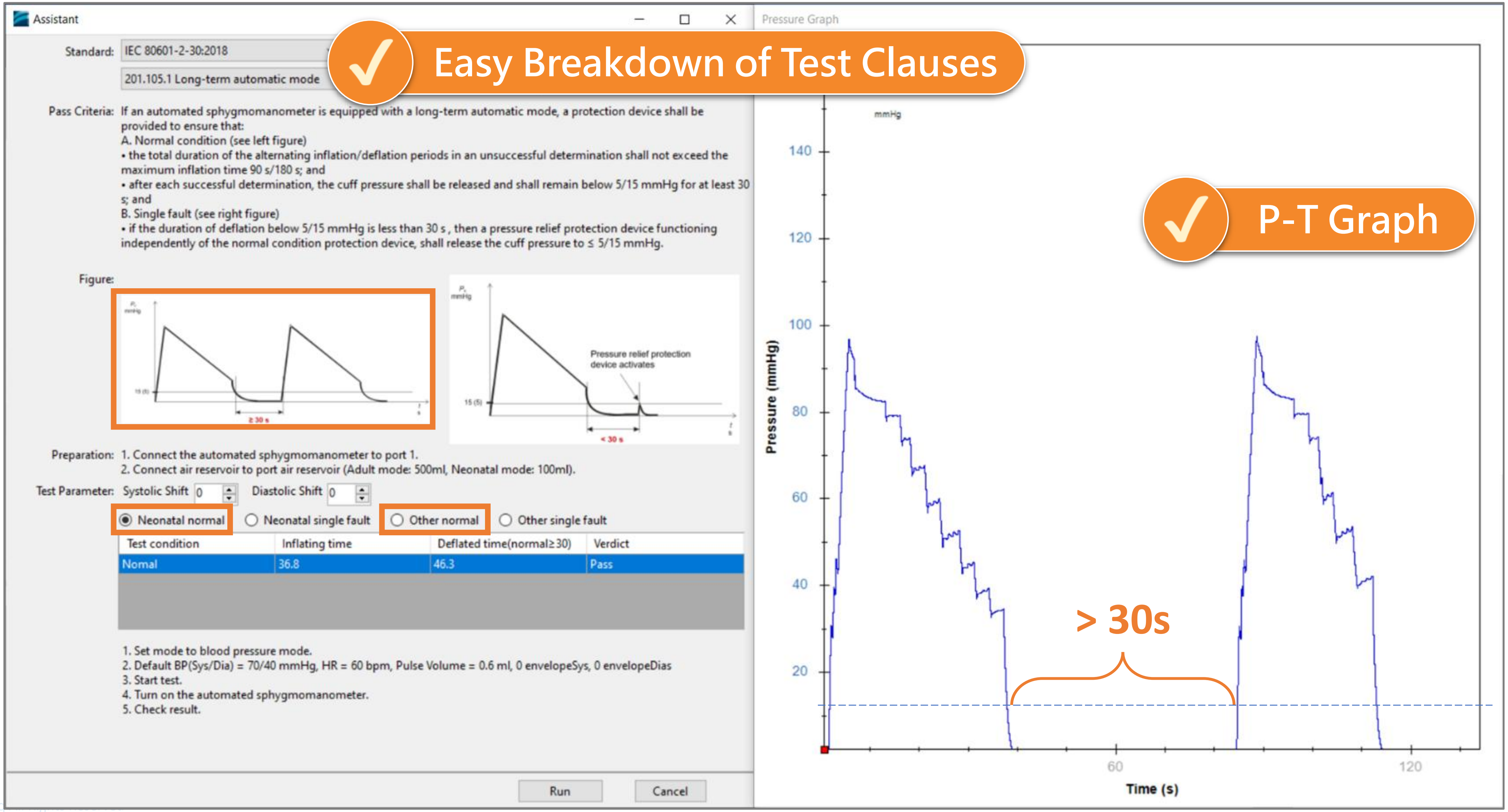
✓ Easy Breakdown of Test Clauses



✓ P-T Graph

BPA700 Standard Assistant

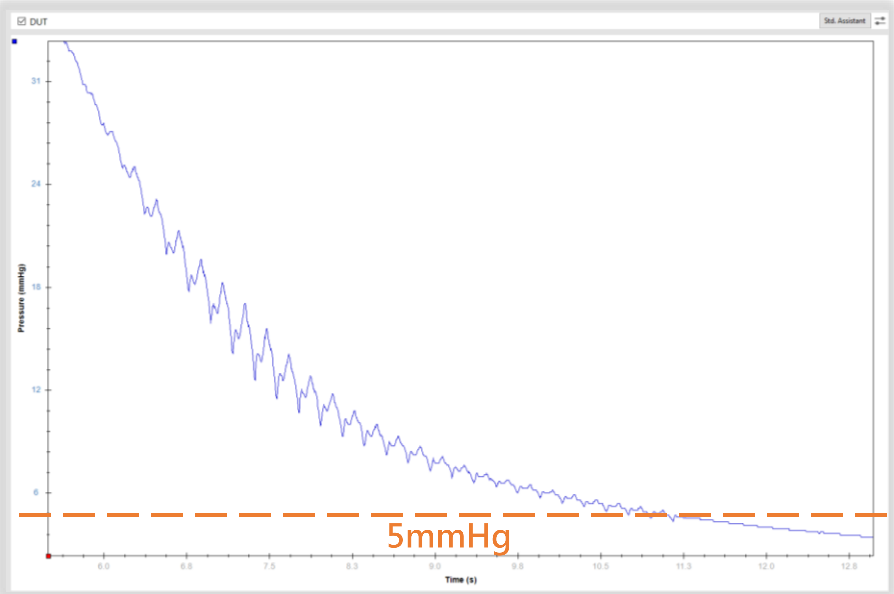
201.105.1 Long-term automatic mode—Normal Condition

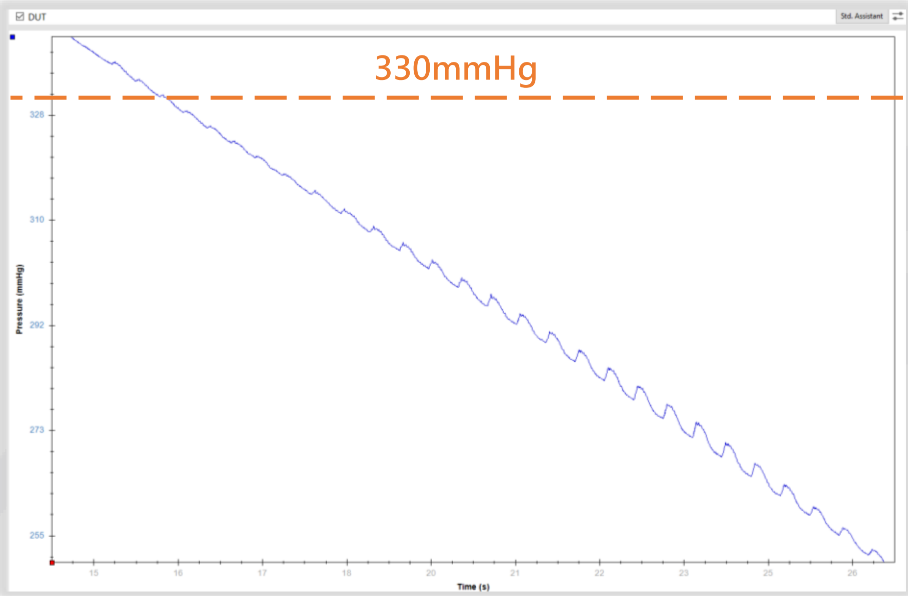


Advanced Specifications

Widen patient spectrum

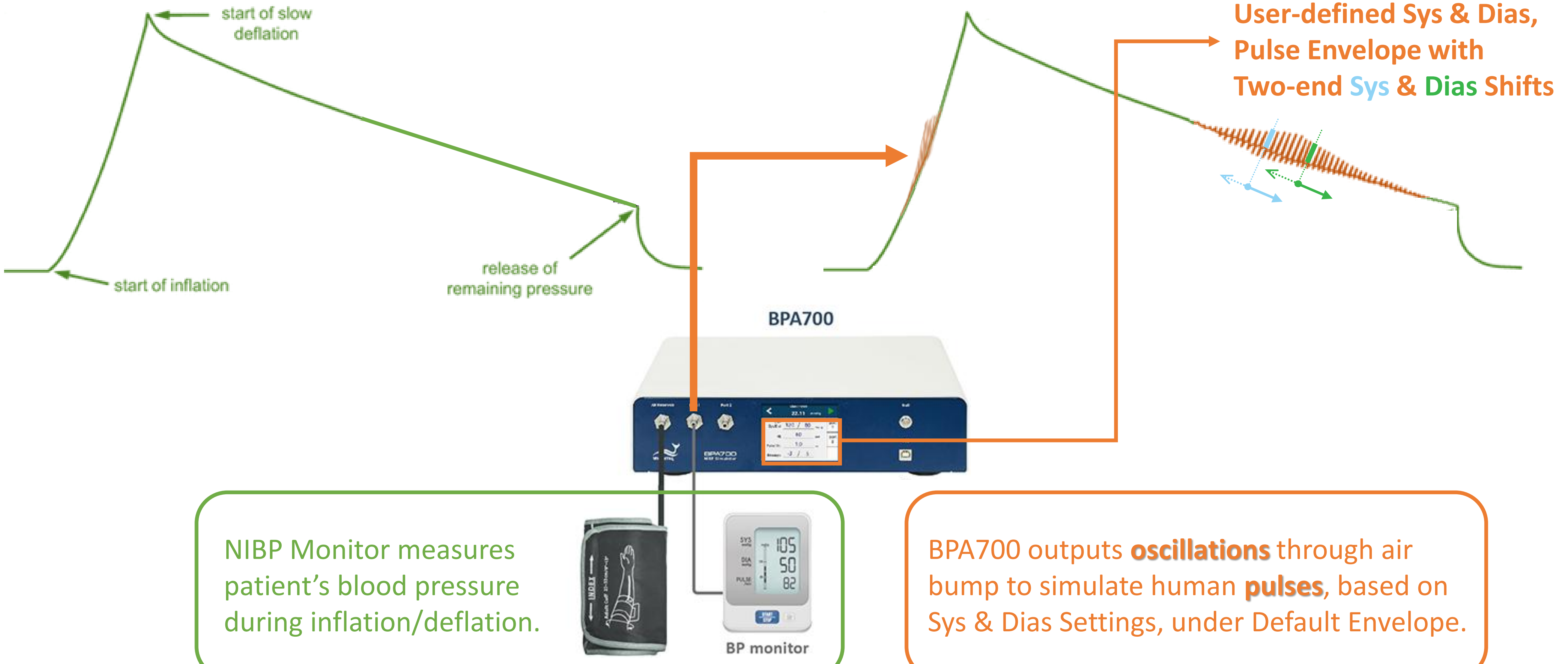
Sphygmomanometer	Specs	BPA700
0-300	Manometer (mmHg)	0-400 ± (0.3% of reading + 0.5mmHg)
0-300	Pressure Source (mmHg)	20 to 400 ± 0.5mmHg
40-200(BPM), 40-290(PM)	Systolic range (mmHg)	25-300
40-195(BPM), 30-245(PM)	Diastolic range (mmHg)	10-250
± 3	BP Accuracy (mmHg)	± 1
40-200	Pulse rate (bpm)	30-300
±4% of reading	Pulse accuracy (bpm)	±1





Advanced Specifications

Widen patient spectrum



NIBP Monitor measures patient's blood pressure during inflation/deflation.

BPA700 outputs **oscillations** through air bump to simulate human **pulses**, based on Sys & Dias Settings, under Default Envelope.

BPA700

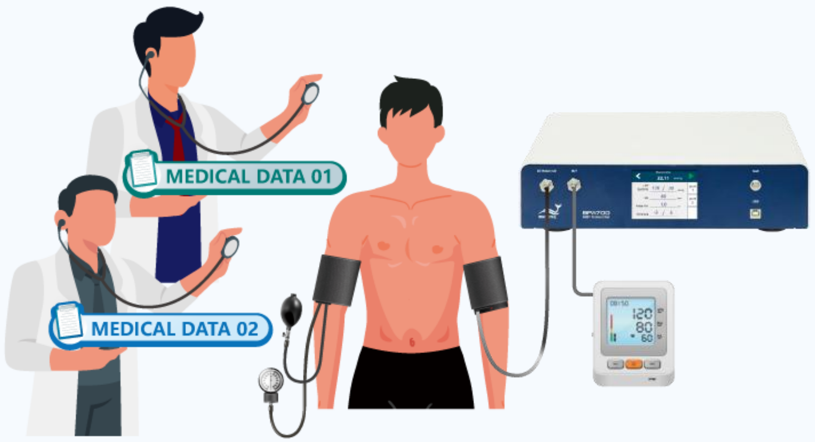
Data Recording and Playback

- ▶ 3-2-8 Data Recording and Playback Process
- ▶ 3-2-9 Data Recording
- ▶ 3-2-10 Data Conversion
- ▶ 3-2-11 Data Playback

Blood Pressure Database Recorder and Player

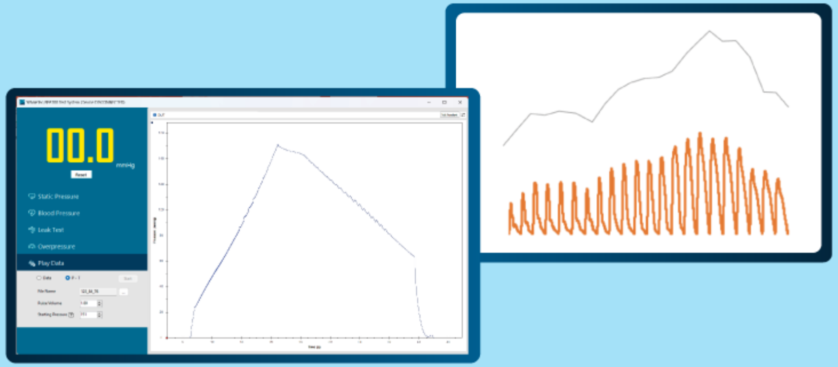
ISO 81060-2_5.2.3 REFERENCE DETERMINATION

Record : Record Blood Pressure Raw Data



Play : Data Playback and Algorithm Optimization

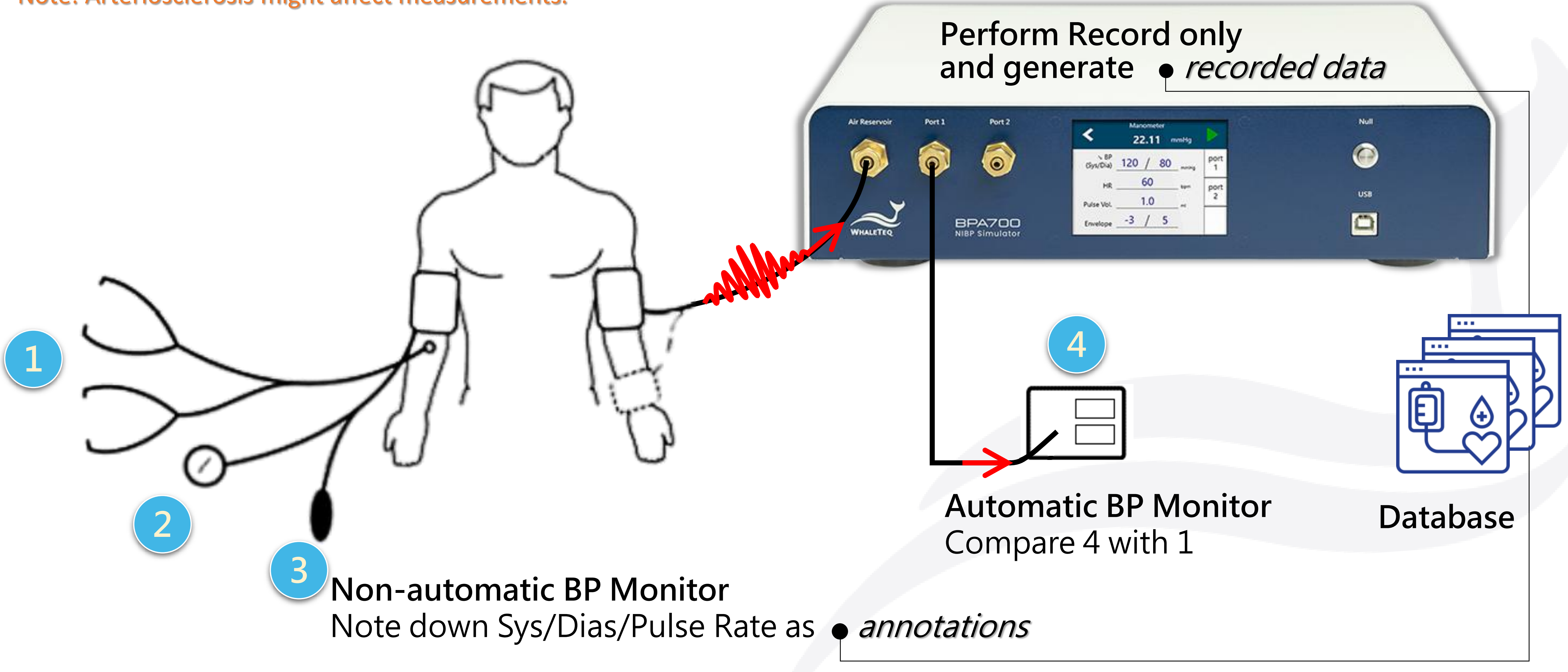
Convert : Convert Raw Data by BPA700 software



Record a Person's BP Raw Data

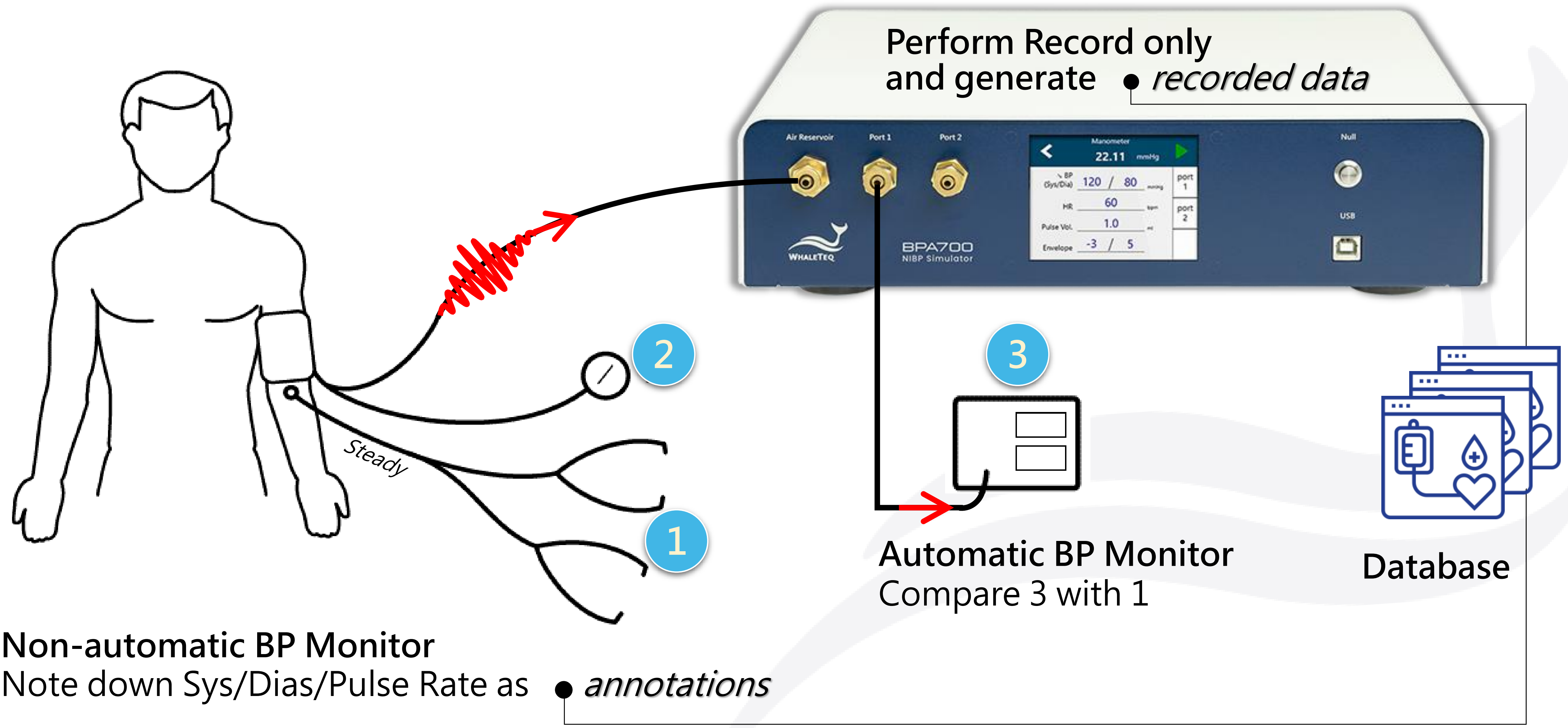
ISO 81060-2_5.2.4.3 Opposite arm simultaneous method

Note: Arteriosclerosis might affect measurements.

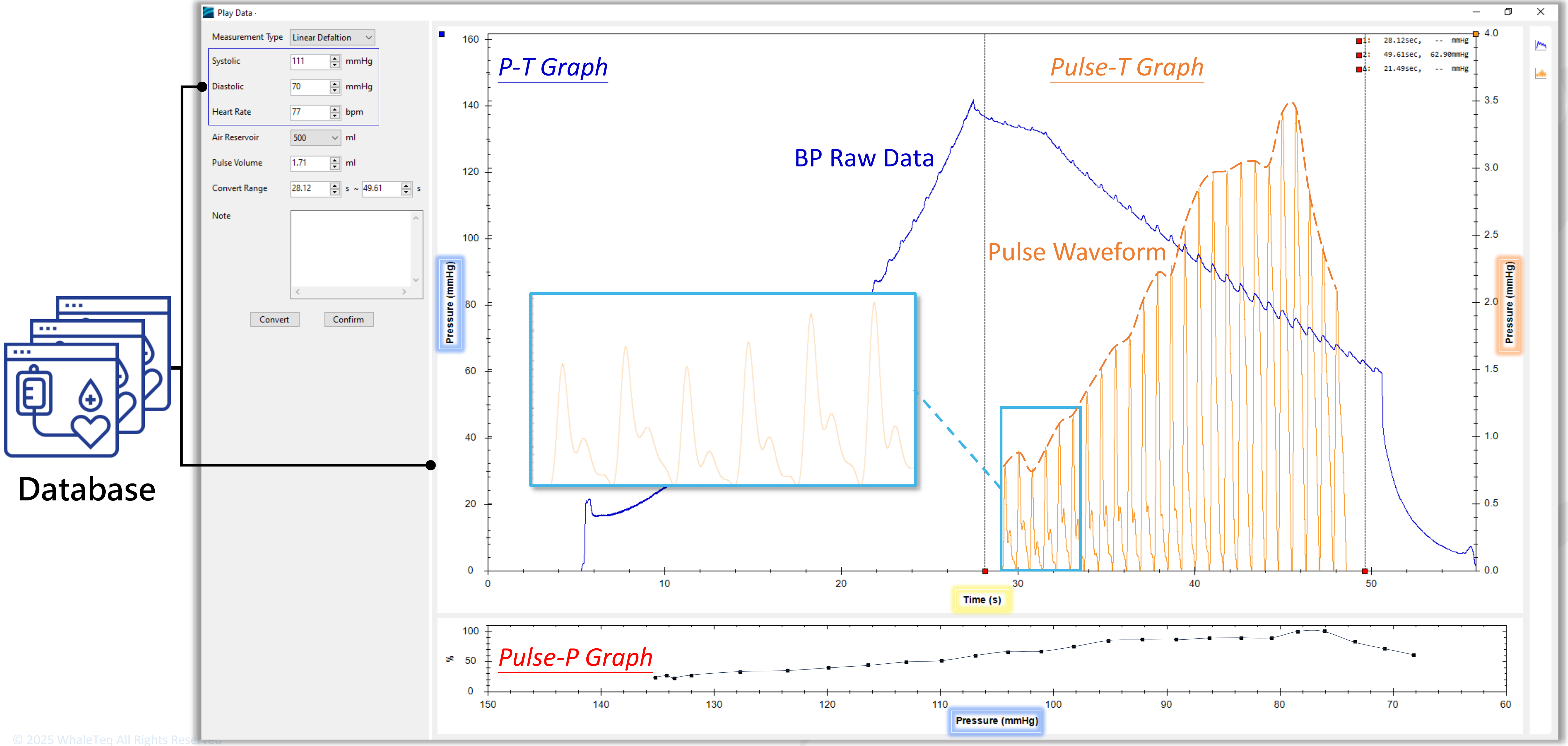


Record a Person's BP Raw Data

ISO 81060-2_5.2.4.1 Same arm simultaneous method



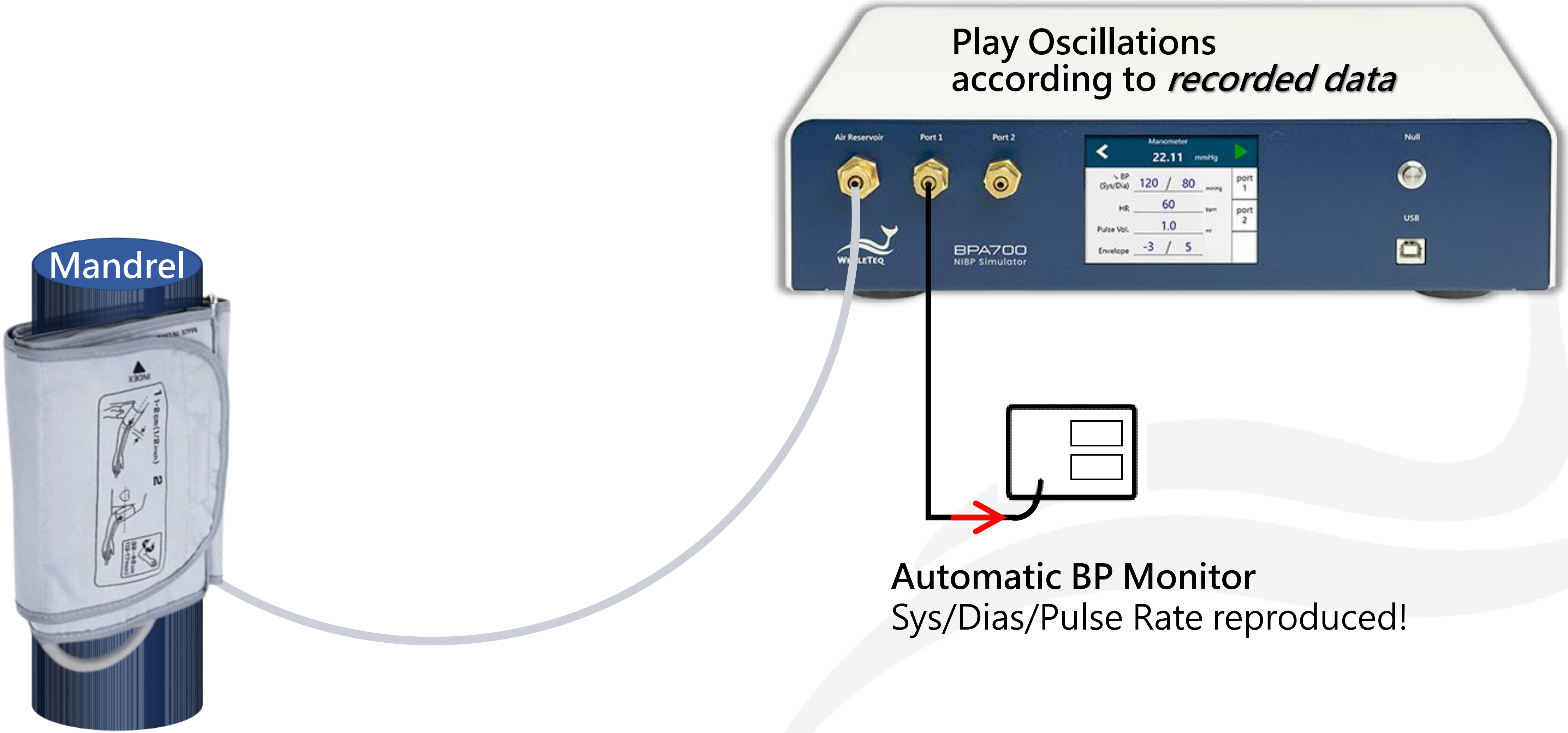
Convert BP Raw Data into Pulse Waveform



Play Oscillation Waveform of the Person

at Algorithm Development

3-2-11
Data Playback



Brief Conclusion

Brief Conclusion

Respiration Testing

- Respiration Module, paired with SECG 5.0 AIO, allows developers verifying BrPM in wider ranges and finer adjustments.

- Respiration Module, paired with SECG 5.0 AIO, makes possible RESP. Database Playback and cost-effectively enhances algorithms.

Brief Conclusion

NIBP Testing

- **P-T Graph** of BPA700 GUI displays **instant pressure changes** over time by DUT.
- The **Widest Ranges** of SYS/DIAS(10-300mmHg) and Pressure Source (20-400mmHg).
- BPA700, **also functioning as a BP Database Recorder and Player**, cost-effectively enhances algorithm testing to ensure NIBP monitor cover a broader patient spectrum.
- **Standard Assistant Software** breaks down Test Requirements of Medical Standard into Pass Criteria, Preparation, Test Parameter per Condition, Auto-Verdict and P-T Graph, and also helps users **keep records**.

(4) Automated Testing Solution

Powered by WhaleTeq SDK

WhaleTeq SDK

Key Features

✓ **Free of Charge**

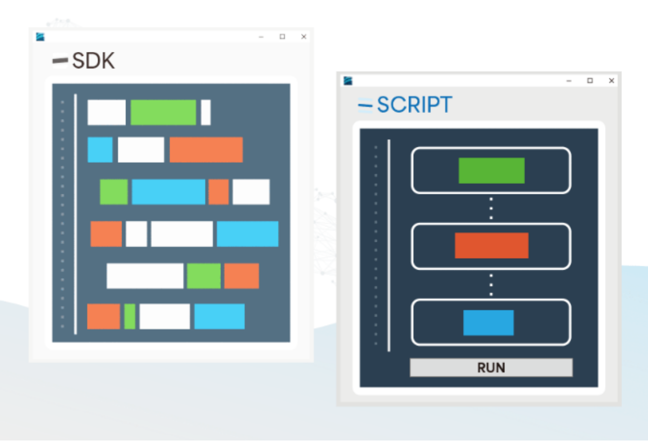
Downloadable on the website, helping ramp up throughput for developers.

✓ **User-Friendly**

Well-documented APIs and Python sample codes available.

✓ **Cross-Platform Compatibility**

Supported OS: Windows, Linux and Raspberry Pi.



Example: IEC 60601-2-27 Test Sequence

Powered by SECG 5.0 AIO SDK

```
# Test 201.12.1.101.11: Baseline Reset
print("Performing Baseline Reset test...")
secg.set_output_function(OutputFunction.Output_Sine)
secg.set_frequency(10)  # 10Hz
secg.set_amplitude(1)  # 1V
time.sleep(10)
print("Turning baseline reset off and measuring signal...")

# Test 201.12.1.101.12: Pacemaker Pulse Display Capability
print("Performing Pacemaker Pulse Display Capability test...")
secg.set_output_function(OutputFunction.Output_Sine)
secg.set_frequency(1.5)  # 1.5Hz
secg.set_amplitude(0)  # 0mV
secg.set_pacing_rate(90)  # 90bpm
secg.set_pacing_amplitude(700)  # 700mV
secg.set_pacing_duration(2)  # 2ms
time.sleep(10)
print("Measuring pacemaker pulse display...")
```

201.12.1.101.11
Baseline Reset

Signal Type, Frequency, and Amplitude Settings

201.12.1.101.12
Pacemaker Pulse Display Capability

Signal Type, Frequency, Amplitude, and Pacing Signal Settings

Example: IEC 80601-2-30 Test Sequence

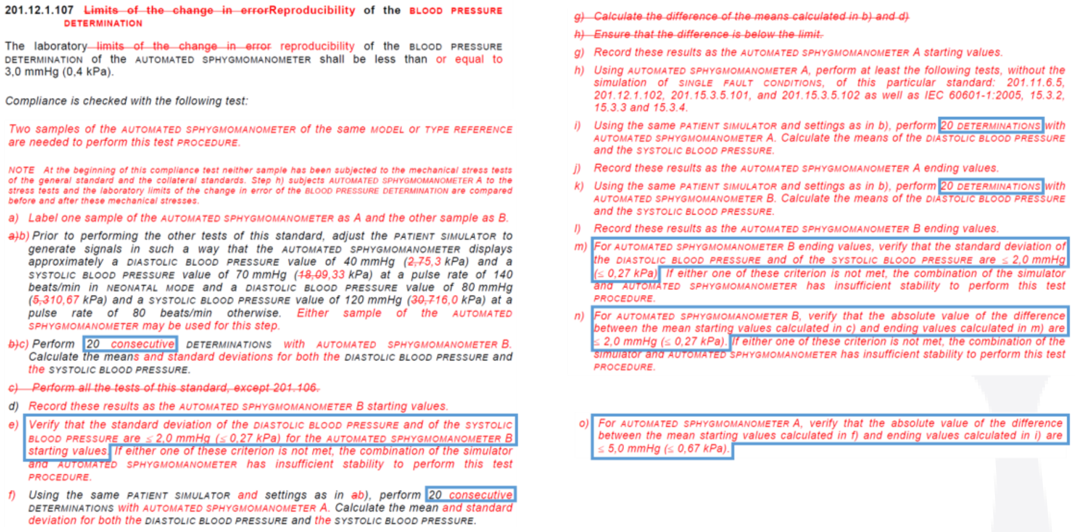
Powered by BPA700 SDK

201.12.1.107

Reproducibility of Blood Pressure Determination

```python
# Test 201.12.1.107: Reproducibility of Blood Pressure Determination
print("Performing Reproducibility of Blood Pressure Determination test...")
for sample in ['A', 'B']:
    test_params.Systolic = 70
    test_params.Diastolic = 40
    test_params.HeartRate = 140
    for i in range(20):
        bpa.run_blood_pressure_test(test_params, None)
        time.sleep(10)
        print(f"Test {i + 1}/20 for sample {sample} completed.")
```

Systolic, Diastolic, and Heart Rate Settings for 20 Required Tests



201.12.1.107 ~~Limits of the change in error~~Reproducibility of the BLOOD PRESSURE DETERMINATION

The laboratory ~~limits of the change in error~~ reproducibility of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than or equal to 3,0 mmHg (0,4 kPa).

Compliance is checked with the following test:

Two samples of the AUTOMATED SPHYGMOMANOMETER of the same MODEL or TYPE REFERENCE are needed to perform this test PROCEDURE.

NOTE At the beginning of this compliance test neither sample has been subjected to the mechanical stress tests of the general standard and the collateral standards. Step h) subjects AUTOMATED SPHYGMOMANOMETER A to the stress tests and the laboratory limits of the change in error of the BLOOD PRESSURE DETERMINATION are compared before and after these mechanical stresses.

a) *Label one sample of the AUTOMATED SPHYGMOMANOMETER as A and the other sample as B.*

~~a)~~b) *Prior to performing the other tests of this standard, adjust the PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays approximately a DIASTOLIC BLOOD PRESSURE value of 40 mmHg (~~2,7~~5,3 kPa) and a SYSTOLIC BLOOD PRESSURE value of 70 mmHg (~~18,0~~9,33 kPa) at a pulse rate of 140 beats/min in NEONATAL MODE and a DIASTOLIC BLOOD PRESSURE value of 80 mmHg (~~5,3~~10,67 kPa) and a SYSTOLIC BLOOD PRESSURE value of 120 mmHg (~~30,7~~16,0 kPa) at a pulse rate of 80 beats/min otherwise. Either sample of the AUTOMATED SPHYGMOMANOMETER may be used for this step.*

~~b)~~c) *Perform 20 consecutive DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER B. Calculate the means and standard deviations for both the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

~~c) Perform all the tests of this standard, except 201.106.~~

d) *Record these results as the AUTOMATED SPHYGMOMANOMETER B starting values.*

e) *Verify that the standard deviation of the DIASTOLIC BLOOD PRESSURE and of the SYSTOLIC BLOOD PRESSURE are ≤ 2,0 mmHg (≤ 0,27 kPa) for the AUTOMATED SPHYGMOMANOMETER B starting values. If either one of these criterion is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.*

f) *Using the same PATIENT SIMULATOR and settings as in ~~a~~b), perform 20 consecutive DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER A. Calculate the mean and standard deviation for both the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

~~g) Calculate the difference of the means calculated in b) and d)~~

~~h) Ensure that the difference is below the limit.~~

g) *Record these results as the AUTOMATED SPHYGMOMANOMETER A starting values.*

h) *Using AUTOMATED SPHYGMOMANOMETER A, perform at least the following tests, without the simulation of SINGLE FAULT CONDITIONS, of this particular standard: 201.11.6.5, 201.12.1.102, 201.15.3.5.101, and 201.15.3.5.102 as well as IEC 60601-1:2005, 15.3.2, 15.3.3 and 15.3.4.*

i) *Using the same PATIENT SIMULATOR and settings as in b), perform 20 DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER A. Calculate the means of the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

j) *Record these results as the AUTOMATED SPHYGMOMANOMETER A ending values.*

k) *Using the same PATIENT SIMULATOR and settings as in b), perform 20 DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER B. Calculate the means of the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

l) *Record these results as the AUTOMATED SPHYGMOMANOMETER B ending values.*

m) *For AUTOMATED SPHYGMOMANOMETER B ending values, verify that the standard deviation of the DIASTOLIC BLOOD PRESSURE and of the SYSTOLIC BLOOD PRESSURE are ≤ 2,0 mmHg (≤ 0,27 kPa). If either one of these criterion is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.*

n) *For AUTOMATED SPHYGMOMANOMETER B, verify that the absolute value of the difference between the mean starting values calculated in c) and ending values calculated in m) are ≤ 2,0 mmHg (≤ 0,27 kPa). If either one of these criterion is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.*

o) *For AUTOMATED SPHYGMOMANOMETER A, verify that the absolute value of the difference between the mean starting values calculated in f) and ending values calculated in i) are ≤ 5,0 mmHg (≤ 0,67 kPa).*

① Prepare Sample A and Sample B of the same DUT model.

② B: 20* BP determinations → means & SD (B starting values)

③ A: 20* BP determinations → means & SD (A starting values)

④ Sample A alone goes thru mechanical stress test as per 201.12.1.102 & 201.15.3.5.101

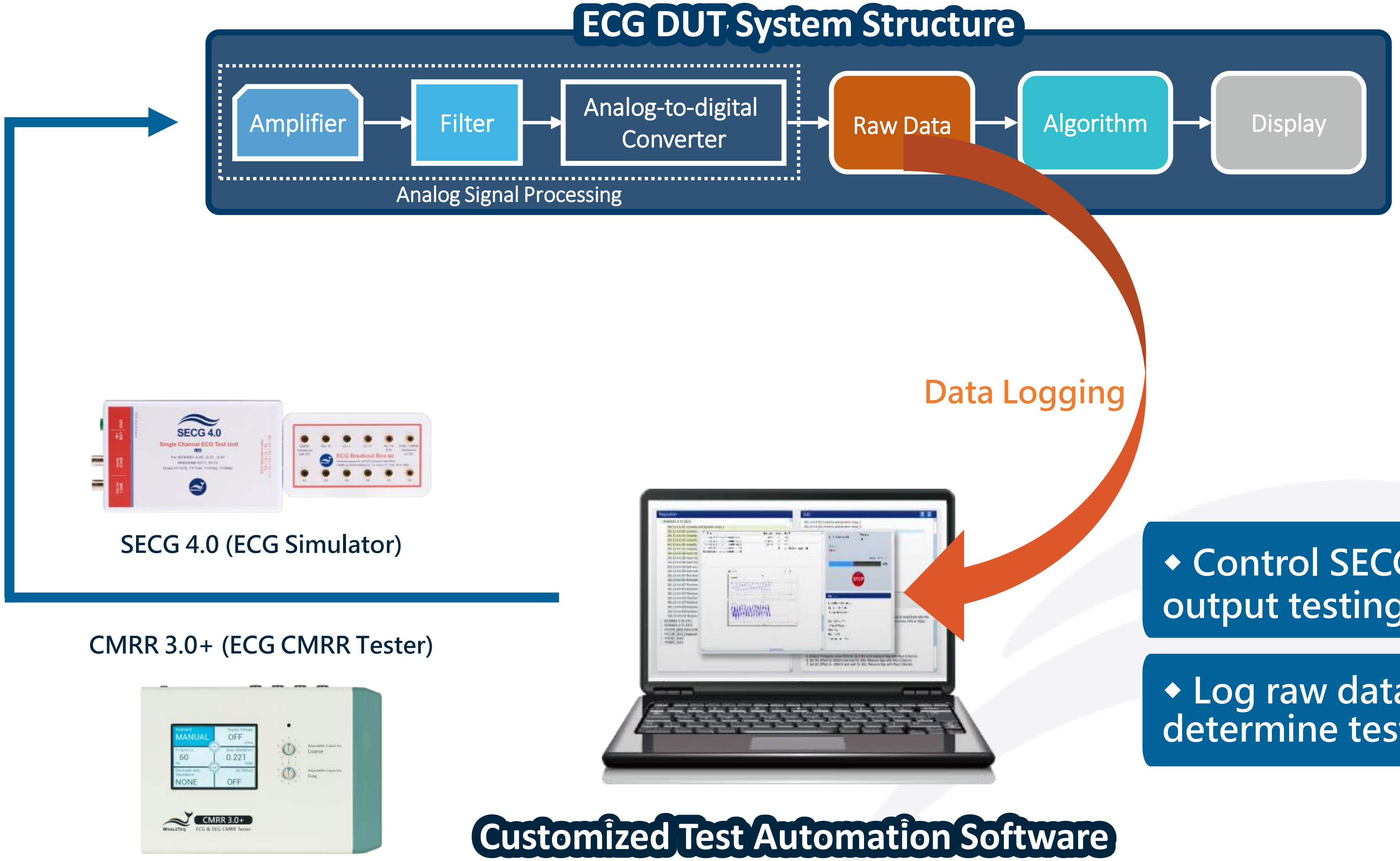
⑤ A: 20* BP determinations → **means (A ending values)**

⑥ B: 20* BP determinations → **means & *SD* (B ending values)**

⑦ Give verdicts as per criteria

- B ending standard deviation value: ***SD*** ≤ 2.0 mmHg (≤ 0.27 kPa)
- B abs. mean difference : |③ - ⑤| ≤ 2.0 mmHg (≤ 0.27 kPa)
- A abs. mean difference : |② - ⑥| ≤ 5.0 mmHg (≤ 0.67 kPa)

Automated Testing Framework

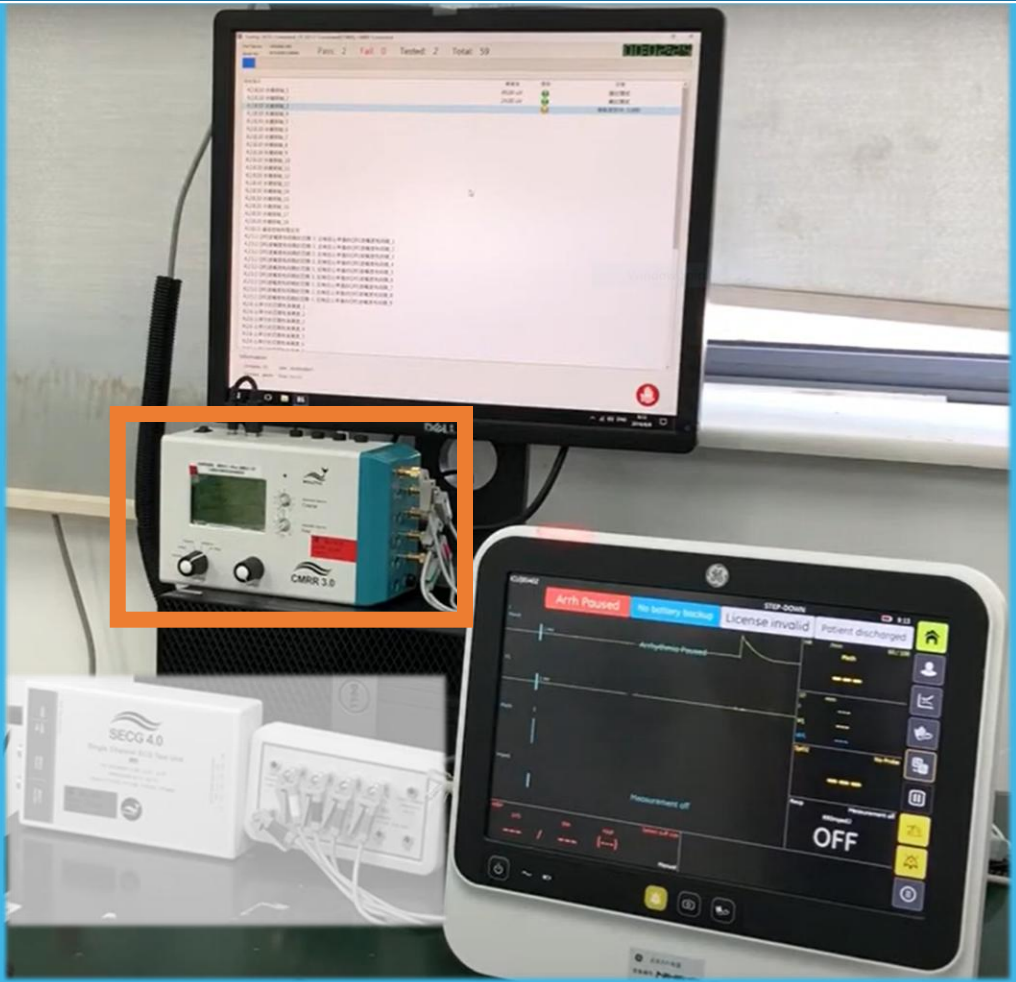


- Control SECG 4.0 and CMRR 3.0+ to output testing signals
- Log raw data from DUT and determine test results

Case Study

https://www.youtube.com/watch?v=LfxOEm_0n4o

ECG CMRR Test



ECG Performance Test

(5) Overall Conclusions

- **Flexible ECG, PPG, Impedance RESP and NIBP Simulations At Once** enhances analysis of vital sign correlation by patient monitors and verify exceptional spec. of developers.
- **Replaying clinical databases and recorded raw data** cost-effectively enhances algorithm testing.
- **Standard Assistant Software** breaks down and streamlines medical standard tests into Pass Criteria, Preparation, Test Parameter per Condition and Auto-verdict.
- **SDK** makes all WhaleTeq Products automatable for end-of-line testing.


Q
A

Questions from Attendees

#	Questions
1	How can one evaluate the impact of changing the emitter brightness on the PPG signal quality?
2	Can BPA700 test smartwatches with inflatable strap?
3	Can PPG, coming from transflective sensor, also be tested?
4	Is ECG and IBP waveform synchronized? e.g. Change in ECG signal reflects change in IBP?

Q1: How can one evaluate the impact of changing the emitter brightness on the PPG signal quality?

TX Testing By SECG 5.0 AIO's PD

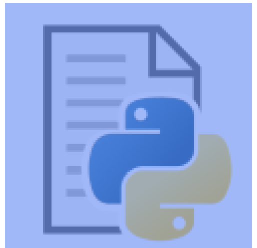
Equivalent to Sampling function on SECG SW

- - Suggested steps - -

1 Use **SECGEnableSampling** with **SamplingCallback** to extract **ADC counts** of SECG 5.0 AIO's R&IR-PD.

2 Based on Developer's criteria, give verdict on DUT's LED performance.

Note: Developer may refer to the sample code in SDK available below.

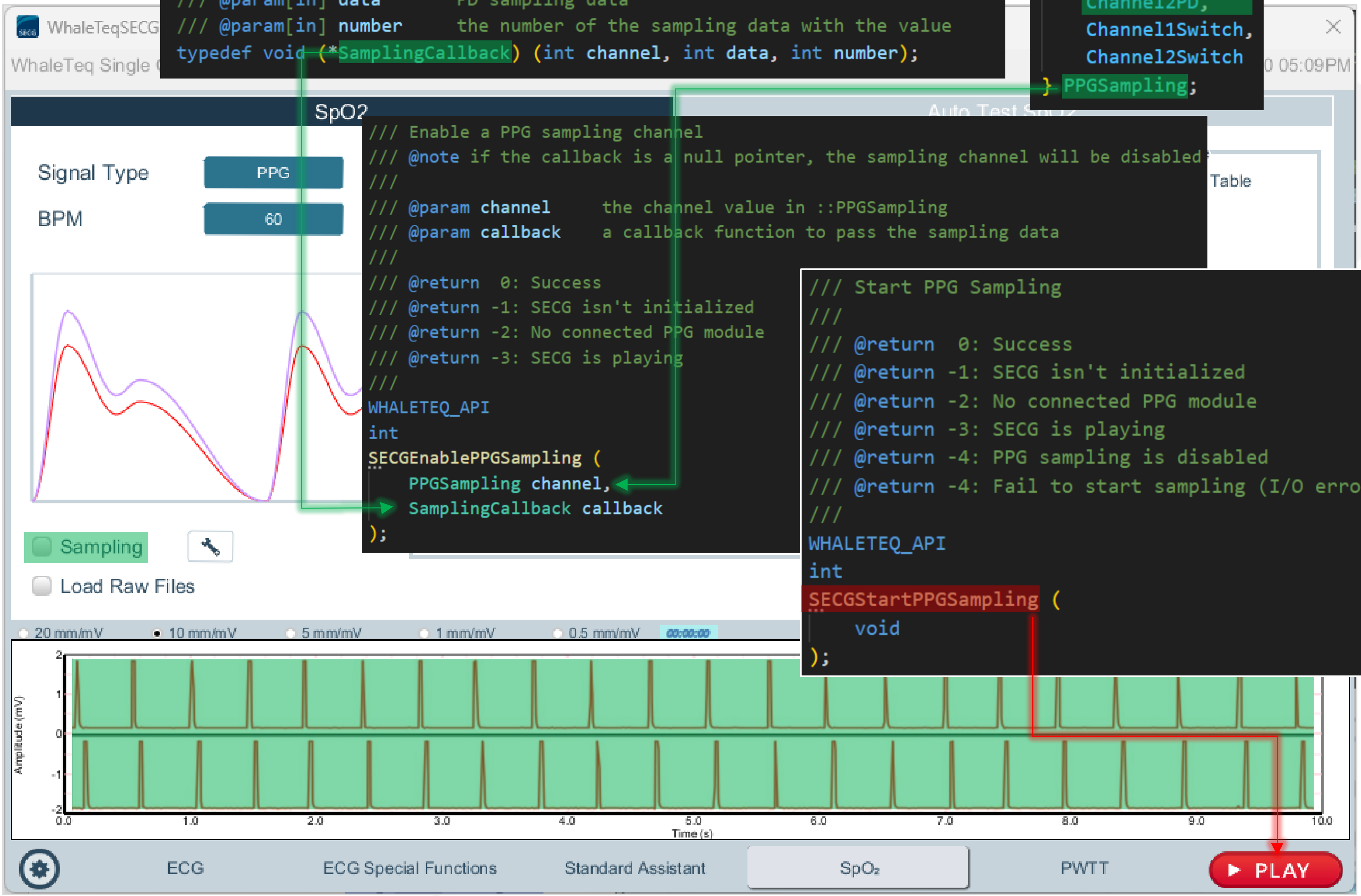



```
/// @fn SamplingCallback
/// @brief Called back with sampling data; the PD sampling data is [0, 1023]
///
/// @param[in] channel    ::PPGSampling
/// @param[in] data       PD sampling data
/// @param[in] number     the number of the sampling data with the value
typedef void (*SamplingCallback) (int channel, int data, int number);
```

```
typedef enum {
    Channel1PD = 0,
    Channel2PD,
    Channel1Switch,
    Channel2Switch
} PPGSampling;
```

```
/// Enable a PPG sampling channel
/// @note if the callback is a null pointer, the sampling channel will be disabled
///
/// @param channel     the channel value in ::PPGSampling
/// @param callback    a callback function to pass the sampling data
///
/// @return  0: Success
/// @return -1: SECG isn't initialized
/// @return -2: No connected PPG module
/// @return -3: SECG is playing
///
WHALETEQ_API
int
SECGEnablePPGSampling (
    PPGSampling channel,
    SamplingCallback callback
);
```

```
/// Start PPG Sampling
///
/// @return  0: Success
/// @return -1: SECG isn't initialized
/// @return -2: No connected PPG module
/// @return -3: SECG is playing
/// @return -4: PPG sampling is disabled
/// @return -4: Fail to start sampling (I/O error)
///
WHALETEQ_API
int
SECGStartPPGSampling (
    void
);
```



Q1: How can one evaluate the impact of changing the emitter brightness on the PPG signal quality?

RX Testing By SECG 5.0 AIO's LED

Equivalent to Unsynced PPG output on SECG SW

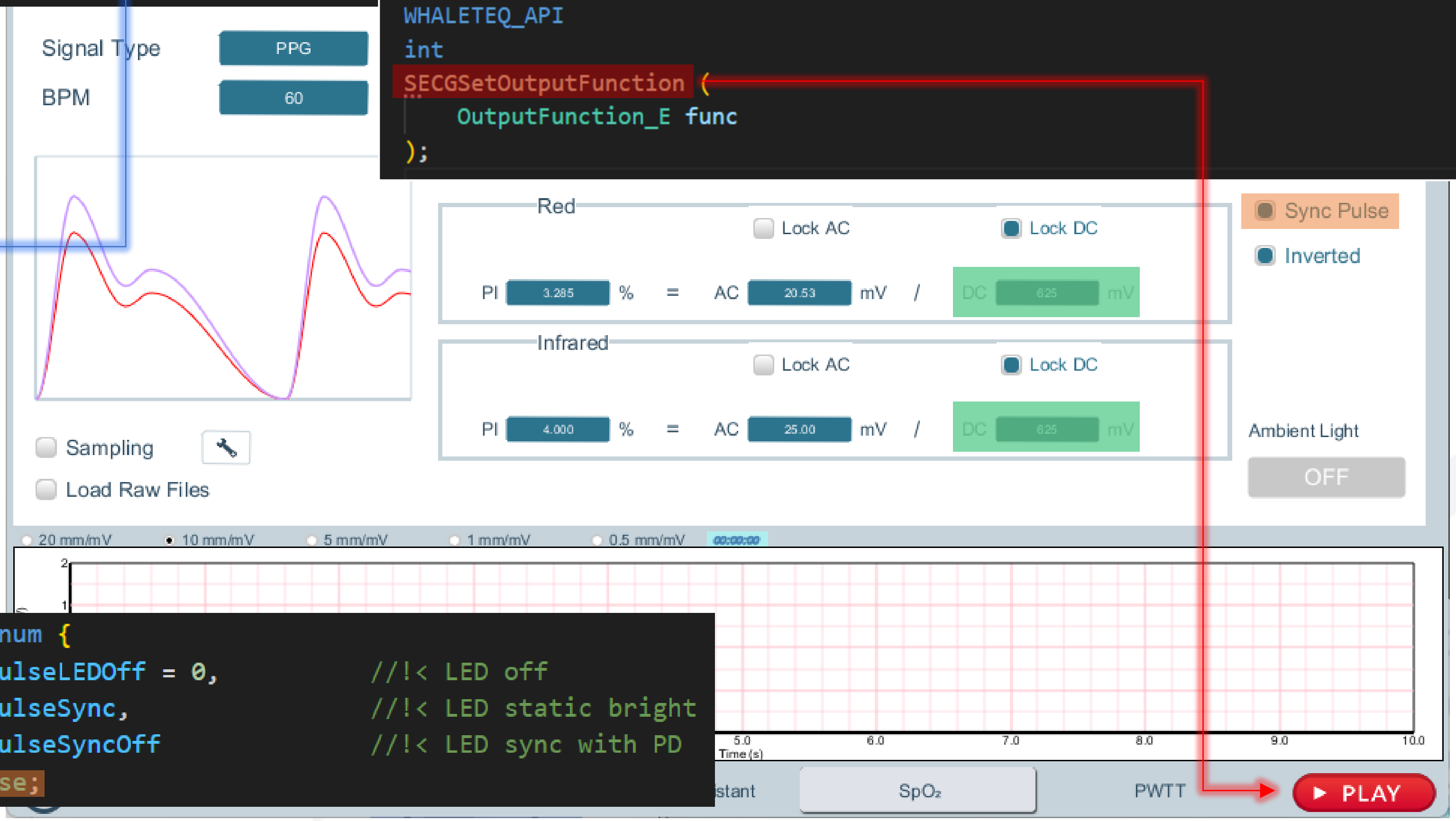
- - Suggested steps - -

1 Output signal with proper DC only (no AC) and **SyncPulseSyncOff** to keep SECG 5.0 AIO's LED always on.

2 Based on Developer's criteria, give verdict on DUT's PD performance.

```
/// Switch the PPG channel output
///
/// @param type  the LED type of channel to config
/// @param onOff true to enabled the PPG channel, or false to disable it
///
/// @return  0: Success
/// @return -1: SECG is playing
/// @return -2: Invalid LED type
///
WHALETEQ_API
int
SECGEnablePPGOutput (
    LEDType type,
    bool onOff
);
```

```
///
/// Set output function
/// @note if the parameter is not ::Output_Off, the device will start outputting
/// @param func output function type
///
/// @return 0 if success, or -1 if fail
///
WHALETEQ_API
int
SECGSetOutputFunction (
    OutputFunction_E func
);
```




```
WHALETEQ_API
int
SECGSetPPGStandardWaveform (
    LEDType type,
    PPGWaveformType waveformType,
    SyncPulse syncPulse,     Set to Unsynced
    PPGInverted inverted,
    double frequency,
    double dc,               DC set to proper level
    double ac                AC set to zero
);
```

```
typedef enum {
    SyncPulseLEDOff = 0,          //!< LED off
    SyncPulseSync,                //!< LED static bright
    SyncPulseSyncOff              //!< LED sync with PD
} SyncPulse;
```

Q2: Can BPA700 test smartwatches with inflatable strap?

Yes, but it would take one extra watch sample as an interface, which is illustrated as **Watch A**

Remove **Upper Cover of Watch A.**
No electronics is required to pass the pressure.

Keep **Lower Cover**, the strap and the airbag to transfer pressure via BPA700 from **Watch B**

Watch A

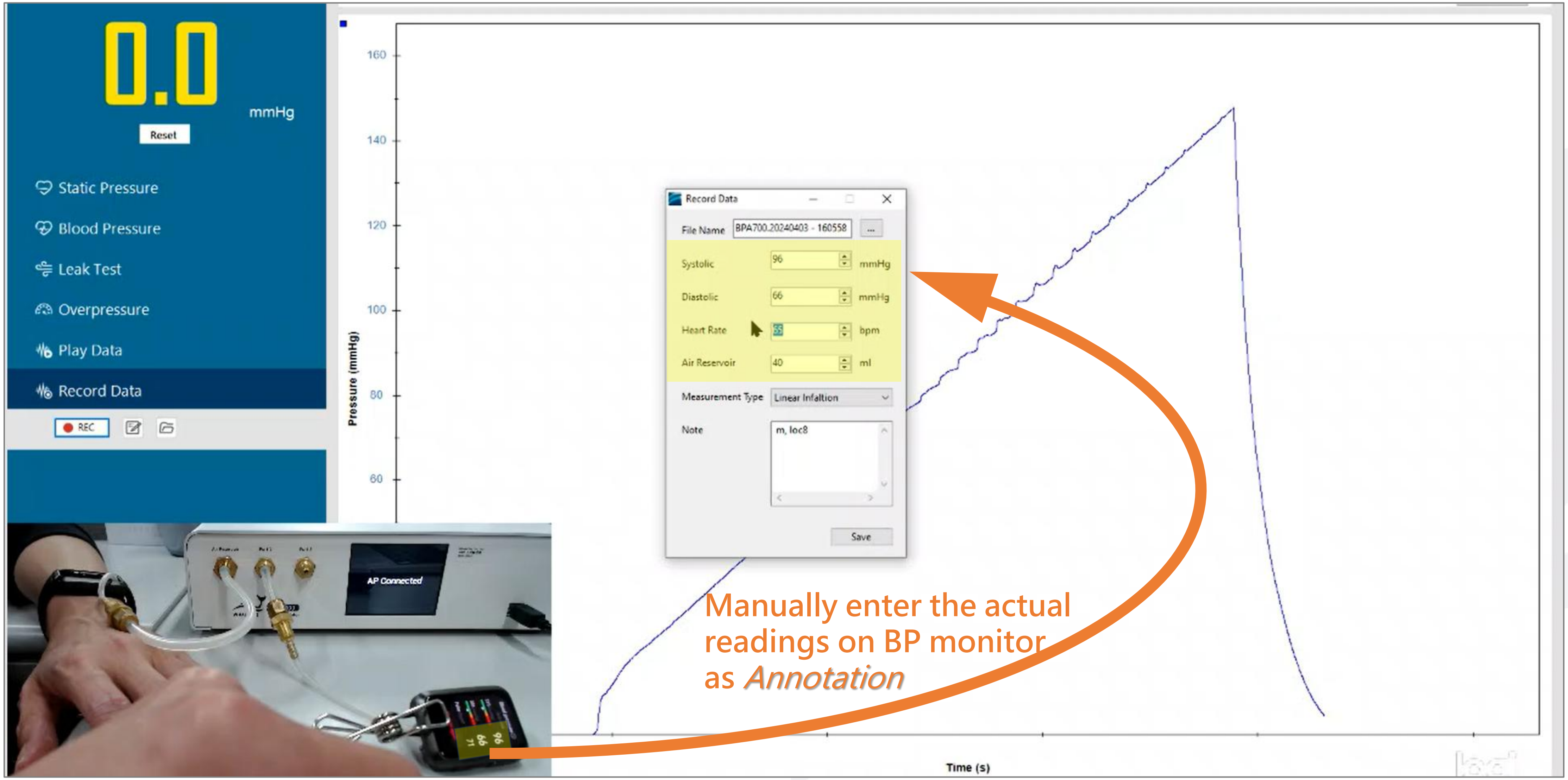
Perform Record only and generate ● *recorded data*

Watch B
Note down Sys/Dias

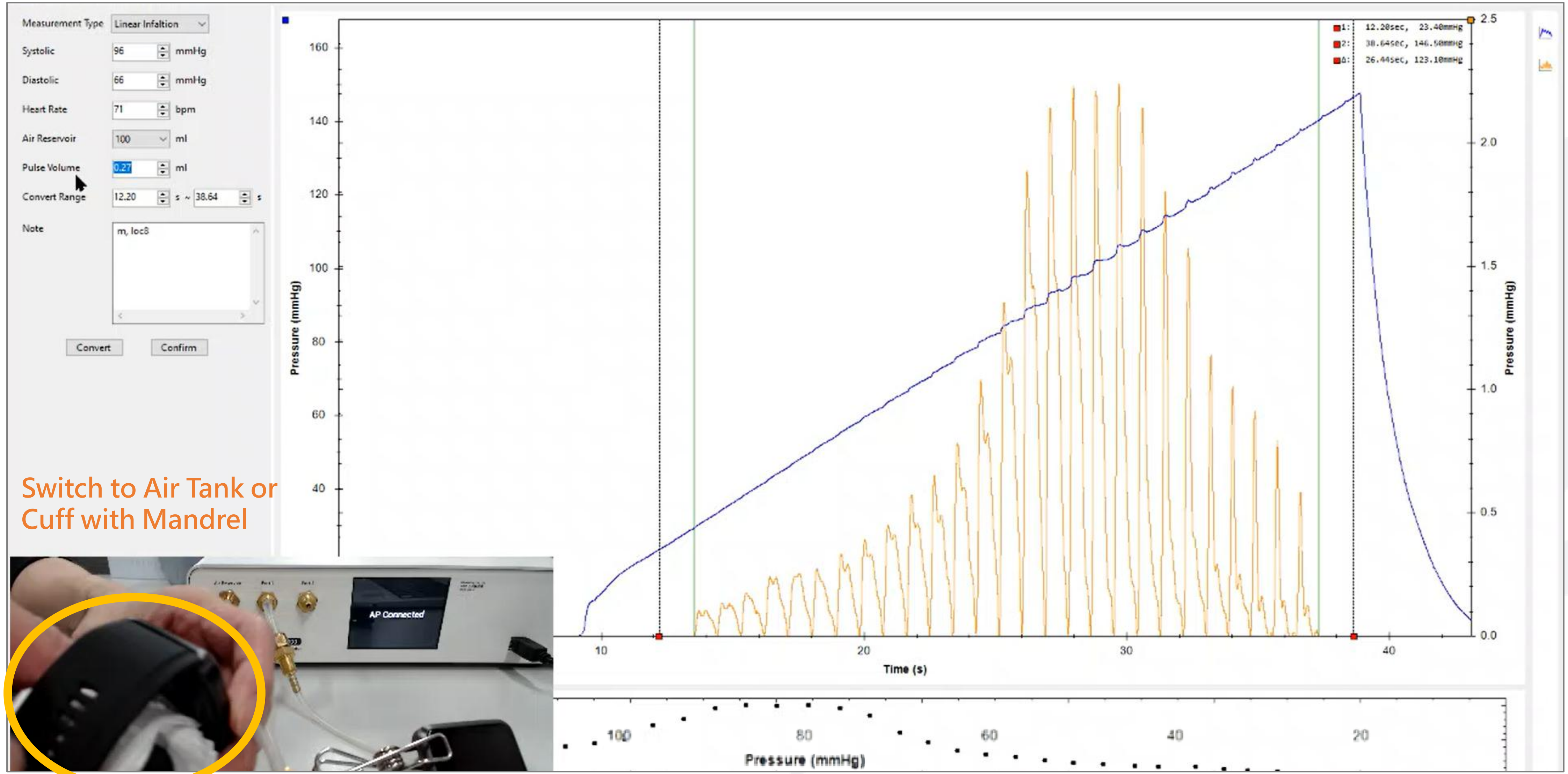
Q2: Can BPA700 test smartwatches with inflatable strap?

Yes, but it would take one extra watch sample as an interface, which is illustrated as **Watch A**

a. Record

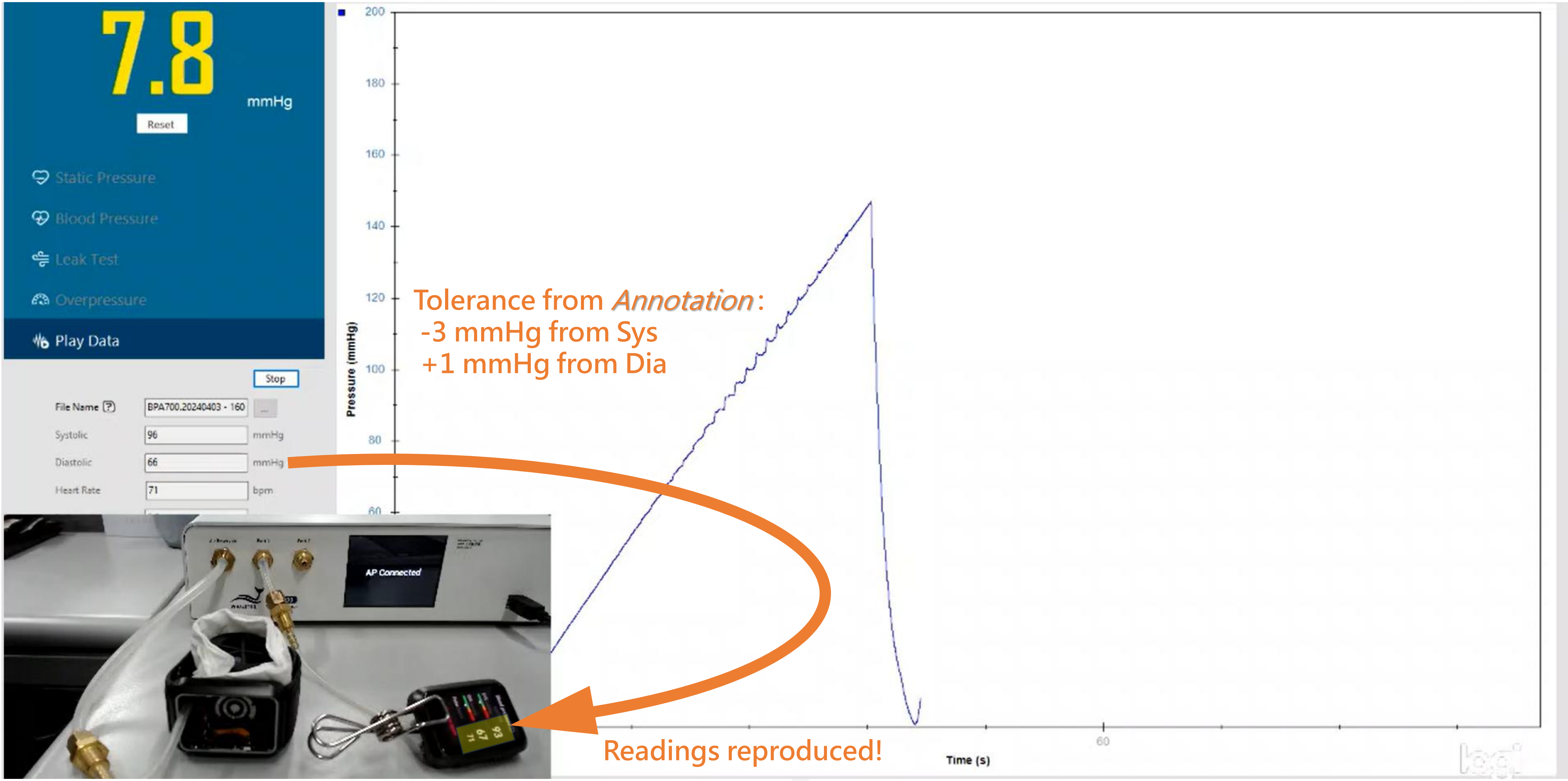

0.0
mmHg
Reset
Static Pressure
Blood Pressure
Leak Test
Overpressure
Play Data
Record Data
REC
AP Connected
160
140
120
100
80
60
Pressure (mmHg)
Time (s)
Record Data
File Name
BPA700.20240403 - 160558
Systolic
96
mmHg
Diastolic
66
mmHg
Heart Rate
bpm
Air Reservoir
40
ml
Measurement Type
Linear Infaltion
Note
m, loc8
Save
Manually enter the actual readings on BP monitor as *Annotation*

b. Convert



Switch to Air Tank or Cuff with Mandrel

c. Replay


7.8
mmHg
Reset
Static Pressure
Blood Pressure
Leak Test
Overpressure
Play Data
Stop
File Name
BPA700.20240403 - 160
Systolic
96
mmHg
Diastolic
66
mmHg
Heart Rate
71
bpm
AP Connected
Pressure (mmHg)
Time (s)
Tolerance from *Annotation*:
-3 mmHg from Sys
+1 mmHg from Dia
Readings reproduced!

Q3: Can PPG, coming from transflective sensor, also be tested?

Yes, the PPG-2TF-660 can test it.

It's a transmittance PPG simulator, so it works for transmittance sensors.

PPG-2TF-660
(Transmittance SpO_2 Module)

PPG-2TF-660 with the Multi Vital Sign Simulator SECG 5.0 AIO for ECG, PPG, Respiration, and PWTT Testing

Q4: Is ECG and IBP waveform synchronized? e.g. Change in ECG signal reflects change in IBP?

Actually IBP is not supported. We support NIBP testing.

Regarding IBP, we have a partner we've been working with for a long time and if you're interested, please let us know and we will direct you to the person.

Thank you for your time

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