

WHALETEQ

NIBP Simulator & Analyzer (BPA700)

User Manual



Version 2024-11-15

Software Version 1.1.0.0

(Due to the function optimization, some operating interfaces should be based on the latest software version.)

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Contents

1	Introduction	8
1.1	Basic Concept	8
1.2	Standard/Application	9
1.3	BPA700 Hardware Overview	10
1.4	Main Specifications	10
1.5	Product Label	12
1.6	Cleaning Method	12
2	Set Up.....	13
2.1	Software Installation	13
2.1.1	<i>System Requirements</i>	<i>13</i>
2.1.2	<i>BPA700 PC Software Installation</i>	<i>13</i>
2.2	Connecting to the NIBP Monitor	15
2.3	Main Screen	17
2.4	Language Selection	19
2.5	Pressure Unit	20
2.6	Auto Sequence	21
2.6.1	<i>Basic Function</i>	<i>21</i>
2.6.2	<i>Operation</i>	<i>22</i>
2.7	Static Pressure	25
2.8	Blood Pressure	28
2.8.1	<i>Rules for Pressure Value Setting</i>	<i>28</i>
2.8.2	<i>Default Method</i>	<i>31</i>
2.8.3	<i>Customized Method</i>	<i>32</i>
2.9	Leak Test	37
2.10	Overpressure Test	39
2.11	Play and Record Data	41
2.11.1	<i>Basic Concept</i>	<i>41</i>
2.11.2	<i>Operation settings</i>	<i>43</i>
2.12	Standalone Mode	49
2.13	Standard Assistant	54
2.13.1	<i>Import License Key</i>	<i>54</i>
2.13.2	<i>Standard Assistant Software</i>	<i>56</i>
3	Software Development Kit (SDK).....	59
4	Calibration and Validation.....	59

5	Troubleshooting	59
6	Caution	60
7	Ordering Information	60
7.1	Standard Package	60
7.2	Optional Accessories, Software and Services	61
	· <i>Optional Software Add-on Pack</i>	<i>61</i>
	· <i>Optional Accessories</i>	<i>61</i>
	· <i>Optional Calibration Service and Warranty Extension</i>	<i>61</i>
8	Revision History	62
9	Contact WhaleTeq	62

List of Table

Table 1: Standard / Application.....	9
Table 2: BPA700 Specifications	10
Table 3: BPA700 Standard Package.....	60
Table 4: Optional Software.....	61
Table 5: Optional Accessory	61
Table 6: Optional Calibration Service and Warranty Extension	61
Table 7: Revision History	61

List of Figure

- Figure 1: BPA700 Hardware Overview 10
- Figure 2: Product Label..... 12
- Figure 3: Update Notice 14
- Figure 4: The Configuration of Wrist BP Monitor 15
- Figure 5: The Configuration of Arm BP Monitor 16
- Figure 6: The Configuration with Air Reservoir 16
- Figure 7: Main Screen..... 17
- Figure 8: Graph Tabs 18
- Figure 9: Graph Tabs Details 18
- Figure 10: Setup Chart..... 19
- Figure 11: Setting Button 19
- Figure 12: Language Selection..... 20
- Figure 13: Pressure Unit Selection 20
- Figure 14: Auto Sequence Basic Introduction 21
- Figure 15: Choose Auto Sequence 22
- Figure 16: Choose Test Item and Start to Test 22
- Figure 17: Stop to End the Test 23
- Figure 18: Export Auto Sequence List 23
- Figure 19: Import Auto Sequence List 24
- Figure 20: Save Auto Sequence List..... 24
- Figure 21: Pre-setting of Static Pressure Test 25
- Figure 22: Start Static Pressure Test 26
- Figure 23: Test Value- 30 mmHg 26
- Figure 24: Test Value- 60 mmHg 27
- Figure 25: Test Value- 90 mmHg 27
- Figure 26: Drag the Cursors for Details 28
- Figure 27: Different Ways to Set Test Values..... 29
- Figure 28: Default Setting..... 31
- Figure 29: Waiting for the Test Result..... 31
- Figure 30: Showing Test Result 32
- Figure 31: Envelope Adjustment 32
- Figure 32: Customized Setting..... 33
- Figure 33: Adjustable Envelope..... 34
- Figure 34: Adjust Envelope in Different Ways..... 35
- Figure 35: Export the Result 35
- Figure 36: Import the Result 36
- Figure 37: Reset Data 36
- Figure 38: Save to Device 37
- Figure 39: Leak Test Setting 38
- Figure 40: Set Calibration Value 38

Figure 41: Leak Test Result..... 39

Figure 42: Overpressure Test Setting 40

Figure 43: Run Overpressure Test 40

Figure 44: Overpressure Test Result 41

Figure 45: Setup of Play and Record Data 42

Figure 46: Record Data Trial Rules 42

Figure 47: Software installation 43

Figure 48: Record Data 43

Figure 49: Edit recorded blood pressure data..... 44

Figure 50: Blood pressure data storage path 44

Figure 51: Play Data..... 45

Figure 52: Convert Tool 45

Figure 53: Click Start to Play Data 46

Figure 54: Play Self-recorded Data..... 47

Figure 55: The Format of the Data 47

Figure 56: Standalone Mode Interface..... 49

Figure 57: Static Pressure Setup..... 50

Figure 58: Static Pressure Result 50

Figure 59: Blood Pressure Setup 51

Figure 60: Blood Pressure Result..... 51

Figure 61: Leak Test Setup 52

Figure 62: Leak Test Pressurizing 52

Figure 63: Overpressure Test Setup..... 53

Figure 64: Overpressure Test Result 53

Figure 65: Auto Sequence Setup 54

Figure 66: Enter Activation Key 55

Figure 67: Import Activation Key Successfully 55

Figure 68: Select Medical Standard and Test Clause..... 56

Figure 69: Click “Run” button 56

Figure 70: Click “Finish” to See the Test Result..... 57

Figure 71: Test Result Shown on the Table 57

Figure 72: Different Function Tabs..... 58

Figure 73: Export Test Report..... 58

1 Introduction

1.1 Basic Concept

The WhaleTeq NIBP Simulator & Analyzer (BPA700) is a performance analyzer designed for electronic non-invasive (NIBP) blood pressure monitor and physiological monitors with blood pressure measurement. Built-in high-precision sensors and inflatable pumps provide static pressure testing, dynamic pressure testing, leak testing and overpressure testing, for ISO/IEC/YY particular standards.

- Measure blood pressure with oscillometric method

The principle of the oscillometric method used in blood pressure measurement is based on the generation and propagation of the pulse wave. When the heart contracts, blood is pushed into the arteries, creating a pressure wave. This pressure wave gradually travels through the blood vessels with each heartbeat.

A blood pressure monitor utilizes an inflatable cuff (typically a sleeve or wristband) wrapped around the upper arm or wrist, which is connected to a pressure sensor via tubing. As the cuff inflates, the pressure increases gradually until it is sufficient to temporarily obstruct arterial blood flow. Then, the pressure is gradually released, allowing the arterial blood flow to resume.

During this process, the pressure sensor detects changes in arterial pressure. These pressure variations are converted into electrical signals and transmitted through the circuit connected to the blood pressure monitor to the display. The waveform displayed on the monitor represents the changes in blood pressure over time, typically in the form of a pulse waveform.

- Adjust blood pressure envelope flexibly

The blood pressure envelope typically represents the acceptable range of blood pressure values for a particular individual based on factors such as age, sex, and medical condition. It consists of an upper limit (systolic pressure) and a lower limit (diastolic pressure), within which the blood pressure readings are considered normal or acceptable.

With an adjustable blood pressure envelope, the user can modify or set the upper and lower limits according to specific requirements or medical guidelines. This feature can be particularly useful when monitoring individuals with specific health conditions or those who require customized blood pressure management.

By adjusting the blood pressure envelope, healthcare professionals or individuals can ensure that the blood pressure measurements are evaluated within the desired range, allowing for more accurate monitoring and management of blood pressure levels.

For a full list of tests, please refer to the standard together with Section 1.2.

1.2 Standard/Application

The following table shows the NIBP standards for which the BPA700 has been designed for:

Table 1: Standard / Application

Standard	Clause(s)
IEC 80601-2-30	201.11.8 Interruption of the power supply/supply mains to ME Equipment
	201.12.1.101 Measuring and display ranges
	201.12.1.102 Limits of the error of the manometer from environmental
	201.12.1.103 Internal electrical power source
	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
	201.101.2 Pressurization
	201.104 Maximum inflating time
	201.105.1 Automatic cycling modes for LONG-TERM
	201.105.2 Automatic cycling modes for SHORT-TERM

1.3 BPA700 Hardware Overview



Figure 1: BPA700 Hardware Overview

- (1) **Air reservoir port** (500mL/100mL/Cuff)
- (2) **DUT:** Blood pressure monitor connection
- (3) **User Interface:** Operate BPA700 with the touchscreen (Please refer to [2.11 Standalone Mode](#) Section)
- (4) **Null:** Turn on/off pressure offset to zero
- (5) **USB Type-B port:** To connect with PC and allow PC software to control BPA700

1.4 Main Specifications

In general, the system has been designed to the standards above, taking into account Clause 201.11.8/ 201.12.1 in IEC 80601-2-30. The table below shows the specifications of BPA700:

Table 2: BPA700 Specifications

Parameters		Specifications
Pressure Unit		mmHg, kPa
Manometer	Range	0 to 400 mmHg

	Resolution	0.1mmHg
	Accuracy	\pm (0.3% of reading + 0.5 mmHg)
Pressure Source	Target Pressure	20 to 400 mmHg
	Settle time	5 seconds
	Resolution	1 mmHg
	Accuracy	\pm 0.5 mmHg
Pulse Rate	Range	30-300 bpm
	Accuracy	\pm 1 bpm
	Pulse Amplitude	2 mmHg max (500 ml air reservoir)
	Pulse Volume	0.1 to 2 ml
Waveform		Oscillometric
Leak Test	Leak Test Time	0 to 999 seconds
	Target Pressure	20 to 400 mmHg
	Range	0 to 300 mmHg/min
Overpressure Test	Release Time	0 to 999 seconds
	Range	Automatic inflation Instantaneous: 0 to 400 mmHg
BP Envelope Shift	Systolic Range	\pm 20 mmHg
	Diastolic Range	\pm 20 mmHg
BP Dynamic Range	Diastolic Range	10 to 250 mmHg
	Systolic Range	25 to 300 mmHg
Dynamic NIBP Simulation Repeatability		\pm 2 mmHg 0.05 mmHg standard deviation
Self-Leakage		<1 mmHg /min (500 ml air r�servoir volume)
Environment	Operating Temperature	10°C to 40°C
	Storage Temperature	0°C to 50°C
	Humidity	0–90% RH, Non-condensing

Shape	Dimensions (Lx W x H)	(326.4 x 315 x 88) mm
	Display	Graphic LCD Resolution: 320 x 240 pixels
	Weight	4.5 kg
Communication		USB
Power		AC 100-240V, 50/60 Hz

1.5 Product Label



Figure 2: Product Label

1.6 Cleaning Method

Please keep the surface of the product clean and dry. Please remove the input signal before cleaning the product. Please check the instrument frequently as required by the operating conditions. To clean the external surface, follow these steps:

1. Use a lint-free cloth to wipe the dust on the outside of the instrument. Pay attention to avoid scratching the display filter made of plastic.
2. Use a soft cloth dampened with water to clean the instrument. The cleaning effect is better with 75% isopropyl alcohol aqueous solution.

***Note:** When cleaning the exterior, avoid wetting the inside of the device. Only moisten a dry cloth or cotton swab with an appropriate amount of cleaning solution. To avoid damage to the instrument, please do not expose it to various sprays, liquids, or solvents, and do not use any corrosive or chemical cleaning products.

2 Set Up

2.1 Software Installation

2.1.1 System Requirements

The NIBP Simulator & Analyzer BPA700 can be operated via the touch screen or PC software via USB connection.

PC Requirements :

- Windows PC (Windows 7 or later, suggest using the genuine version)
- Microsoft .NET 4.0 or higher
- Administrator access (essential for installing software, driver, and Microsoft .Net Framework)
- 1.5 GHz CPU or higher
- 1GB RAM or higher
- USB port

2.1.2 BPA700 PC Software Installation

Here are the steps to download and execute the BPA700 software:

1. Go to the [WhaleTeq Official Website](#)
2. Click on "Software" and then click "AP" to start the download
3. Open File Explorer and choose a location to save the file
4. Extract the file to the designated folder
5. Open the folder and ensure all files are extracted to the same folder
6. Double-click on BPA700.exe to execute the software
7. Run WhaleTeqBPA700.exe installer to install the BPA700 PC software

If the BPA700 software cannot run properly, or if you are using WhaleTeq products for the first time, please ensure the USB driver and Microsoft .Net Framework 4.0 are installed.

***Note 1:** To enable the PlayData function, it is necessary to purchase and download the "Kit" separately from the same page on the Official Website.

***Note 2:** To check if the software version needs updating, click "Check for Updates." Two kinds of pop-up windows will appear: click "Yes" (right image) if an update is needed, or click "OK" (left image) if no update is needed.

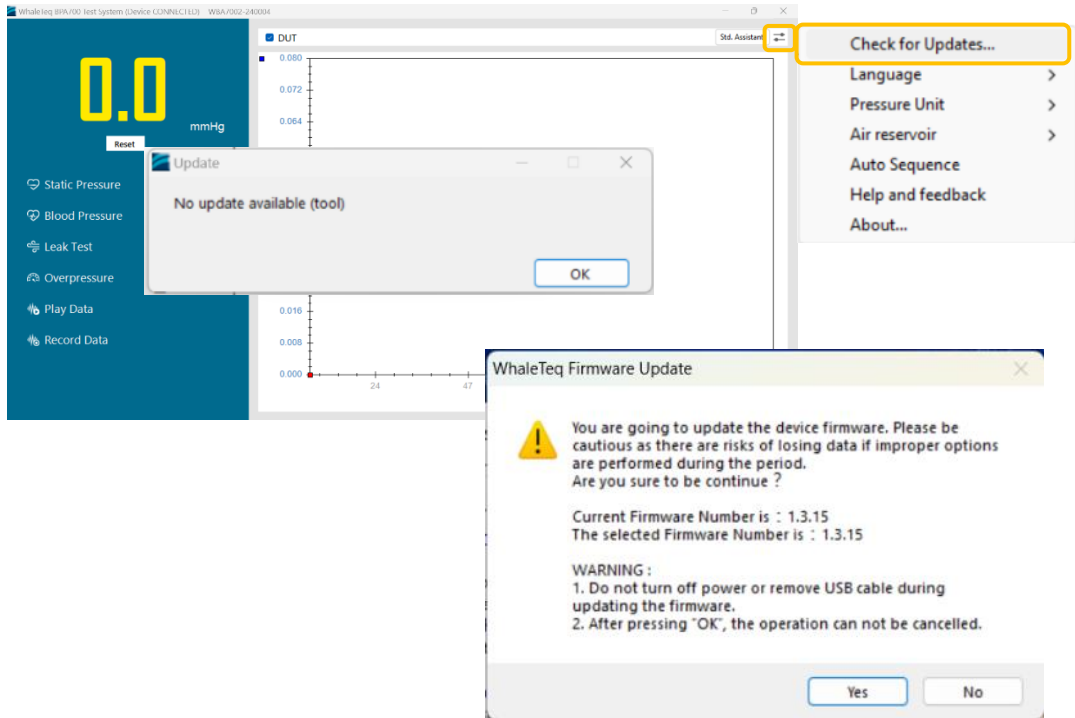


Figure 3: Update Notice

2.2 Connecting to the NIBP Monitor

To connect the NIBP device easily, BPA700 is equipped with correspondent accessories:

1. Optional Accessories
Two 14cm long tubes, the user can adjust the desired length by themselves.
2. Recommended Length of the Tube
(1) For air reservoir: 14 cm
(2) For cuff: the same as its original manufacturer
3. The Configuration of Wrist Blood Pressure Monitor

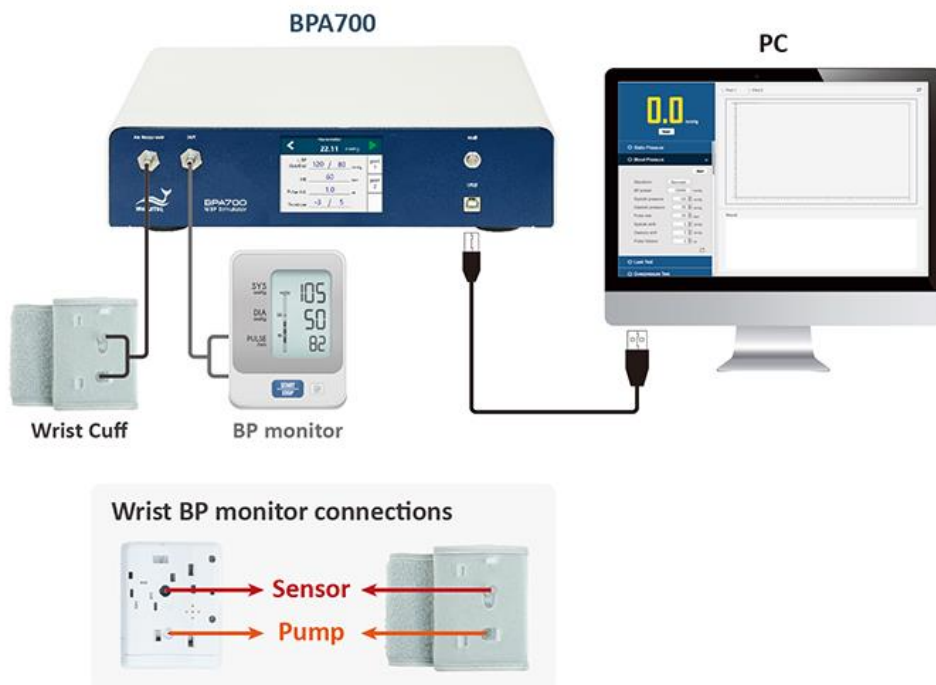


Figure 4: The Configuration of Wrist BP Monitor

- To display the pressure waveform on a computer, BPA700 is connected to the computer via a USB cable, as shown in the dark black line.
- The connection of the tubing is indicated by black and gray lines.
- The wrist cuff and the blood pressure monitor itself are separated, and each is externally connected to BPA700 using the tubing, as shown in the diagram above.



Figure 5: The Configuration of Arm BP Monitor

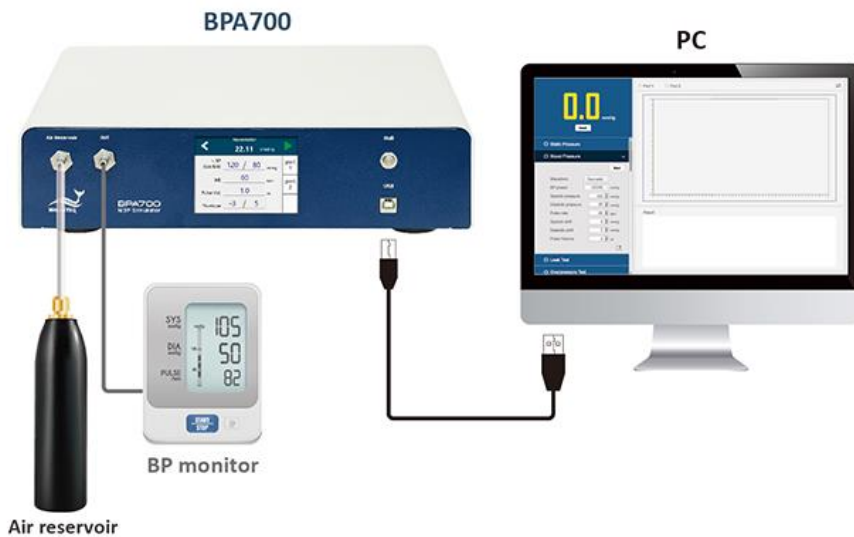


Figure 6: The Configuration with Air Reservoir

2.3 Main Screen



Figure 7: Main Screen

- (1) Select DUT
- (2) Select Standard Assistant
- (3) Other settings
- (4) The real-time display of blood pressure
- (5) Function tab (static pressure, blood pressure, leak test, overpressure test, play data and record data)
- (6) The display of pressure-time graph
- (7) Display test result

On the graph, right-click anywhere to make use of the function tabs.

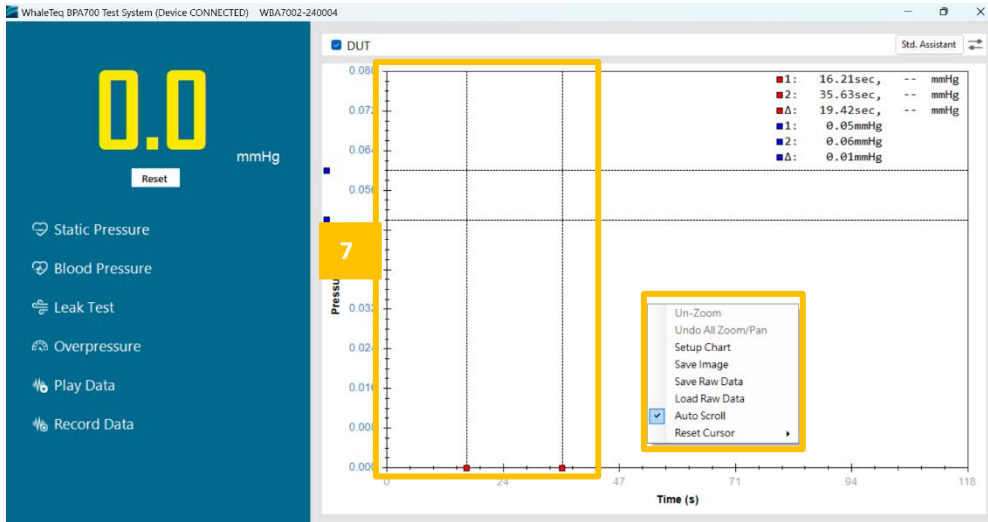


Figure 8: Graph Tabs

- (1) Un-Zoom: cancel or revert a zoomed-in view, returning the graph to its original size.
- (2) Undo All Zoom/Pan: revert or reset the zoom level of the graph to its default or original state
- (3) Setup Chart: set X/Y axis value (See Figure 10: Setup Chart)
- (4) Save Image: Waveforms are saved to a PC or laptop as a jpg. file
- (5) Save Raw Data: save the graph as csv file to PC or laptop
- (6) Load Raw Data: load the graph saved from last time
- (7) Auto Scroll: Automatically scale down the proportion to display the entire pressure waveform
- (8) Reset Cursor: there are 4 cursors in total, the user can drag out the cursor from the point beside the graph, and see details of time- pressure relation

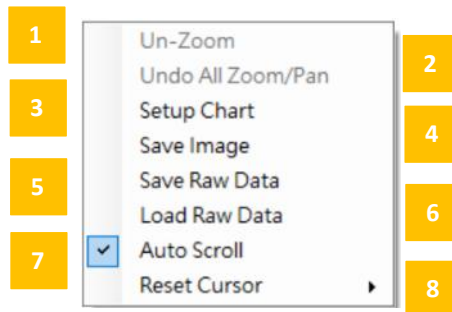


Figure 9: Graph Tabs Details

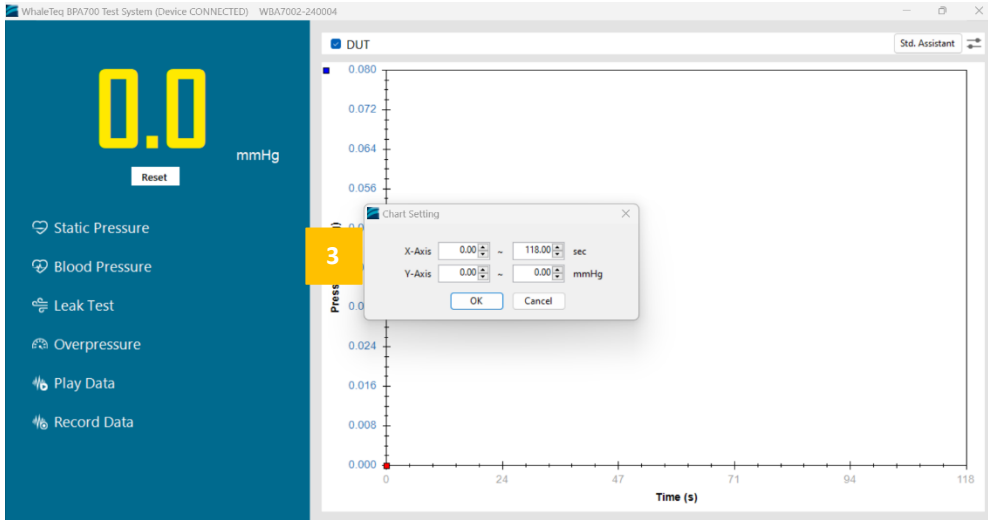


Figure 10: Setup Chart

2.4 Language Selection

The BPA700 provides 3 different languages for selection. Click the setting button and select the desired language.

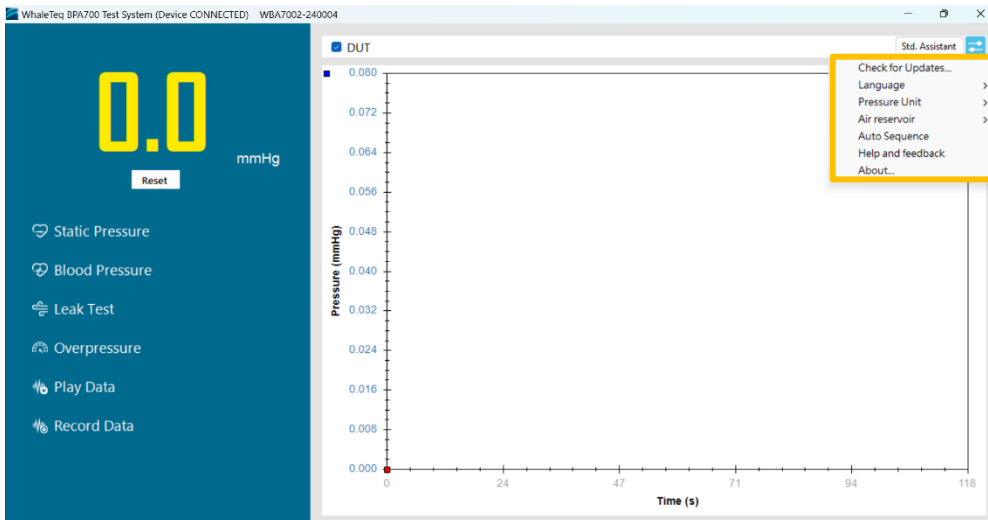


Figure 11: Setting Button

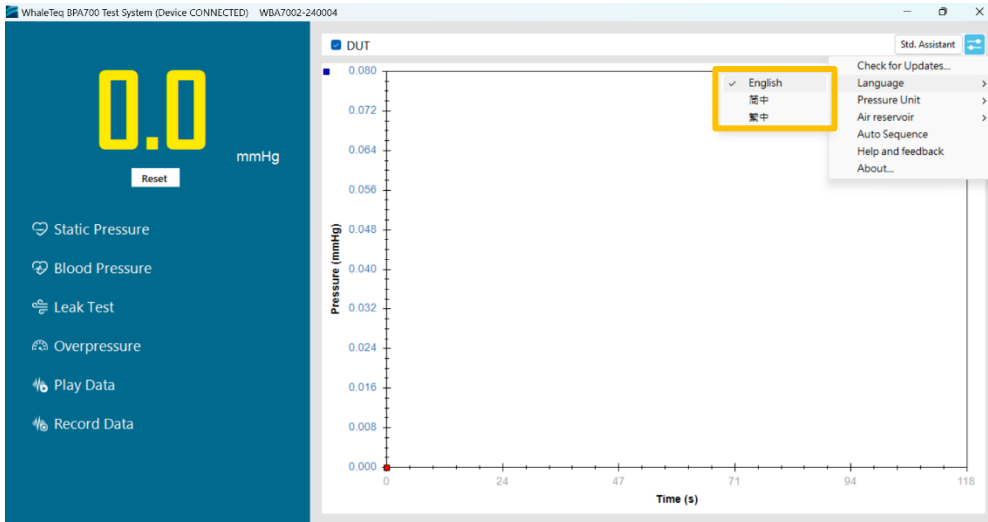


Figure 12: Language Selection

2.5 Pressure Unit

The user can either choose mmHg or kPa to conduct the pressure test.

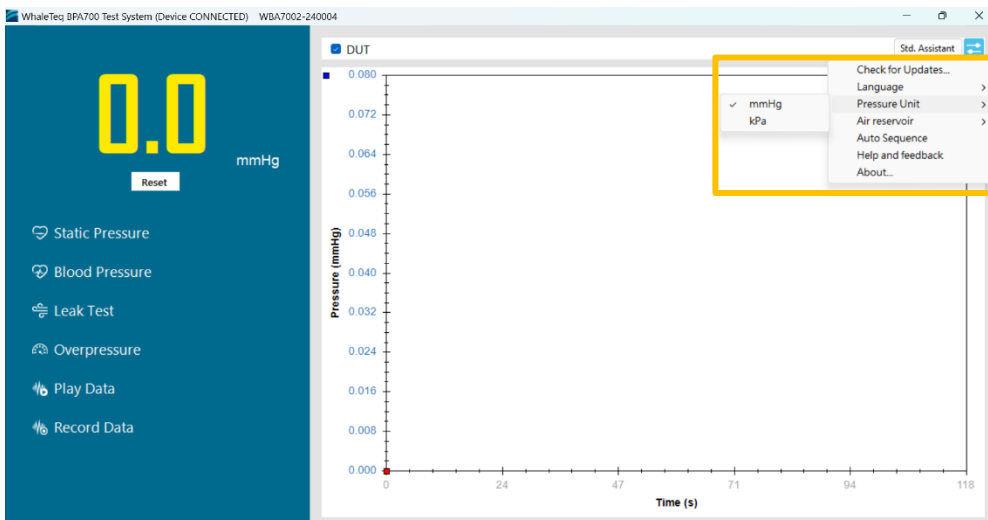


Figure 13: Pressure Unit Selection

2.6 Auto Sequence

2.6.1 Basic Function

The user can set test items, and save the sequences as a file for repeated testing. There are two different ways to conduct auto sequence testing:

- Standalone Mode**
 The standalone mode is only available when the user sets up the test conditions on AP first. The maximal test groups are 5 (a test group is shown as a block as the figure below), and the order is unable to change.
- PC-connected AP Mode**
 The maximal test group are 50, and the order can be adjusted arbitrarily.



Figure 14: Auto Sequence Basic Introduction

- (1) Return to homepage
- (2) A test group block, the user can move the block freely to change the order in AP mode.
- (3) “X” button to delete the test group
- (4) Import and Export: Import test group set up from AP mode. Export test group list as a file for standalone mode to use
- (5) Save: Save the list to BPA700

(6) Stop: Stop the testing

2.6.2 Operation

(1) Click “Auto Sequence” on the upper right column.

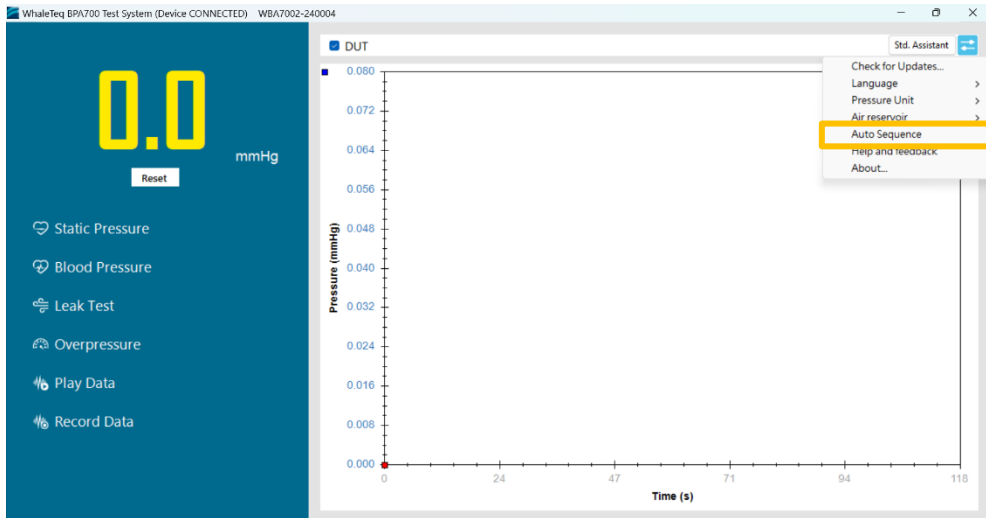


Figure 15: Choose Auto Sequence

(2) Choose “Testing Functions” and add to function list. Click “Start”.

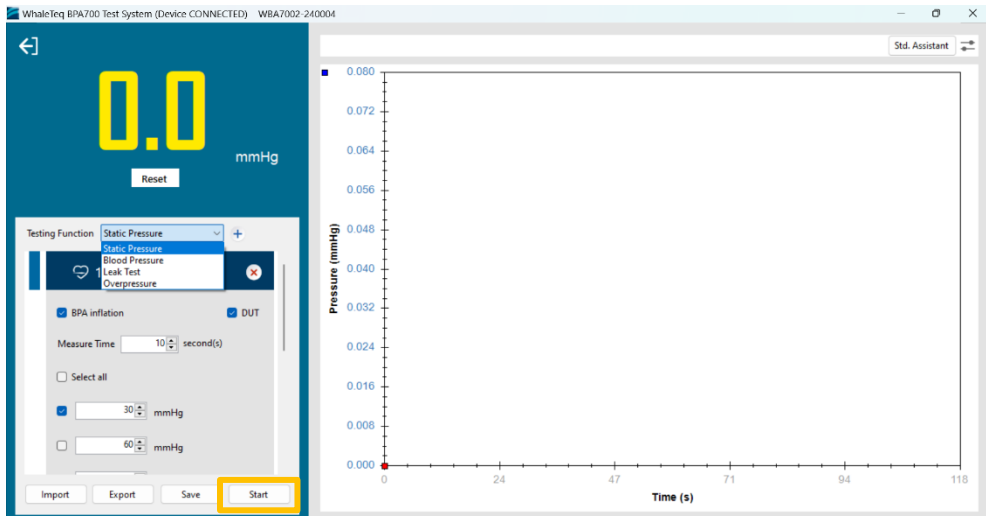


Figure 16: Choose Test Item and Start to Test

(3) Click “Stop” to end the test.

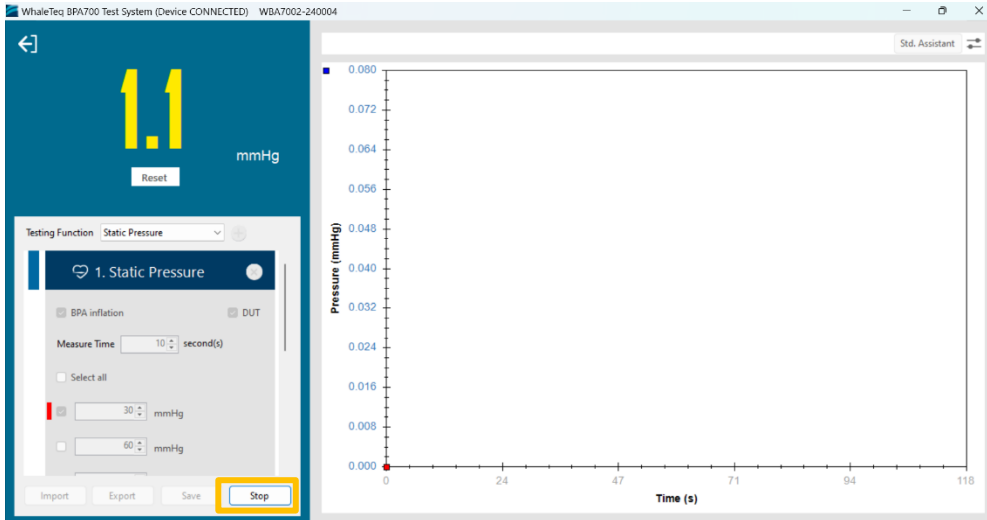


Figure 17: Stop to End the Test

(4) Click “Export” to export auto sequence list as a file, so you can import next time. (As Figure 18 shown.)

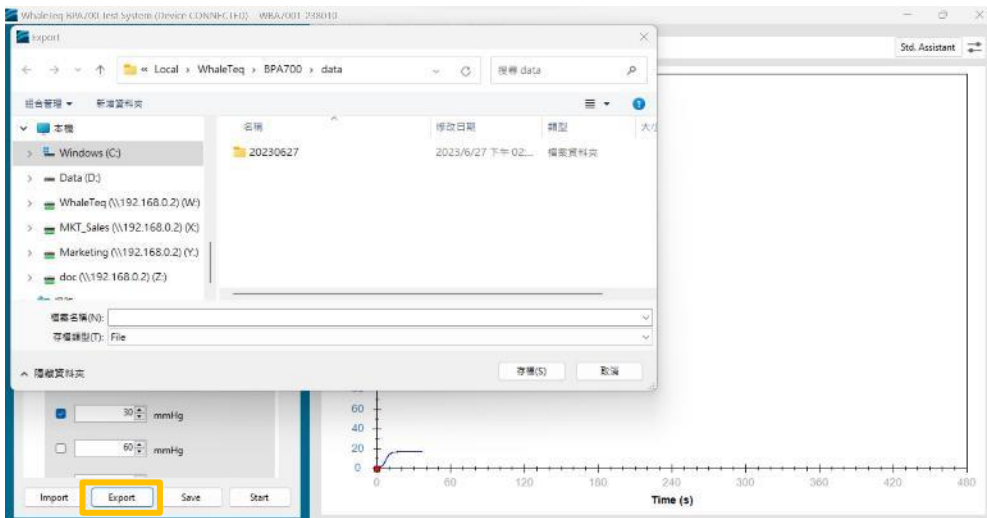


Figure 18: Export Auto Sequence List

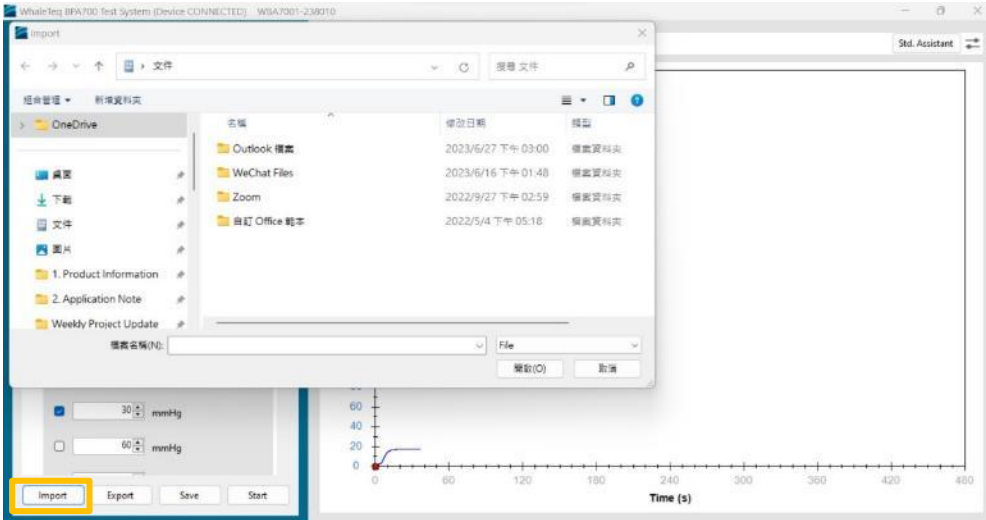


Figure 19: Import Auto Sequence List

(5) Click save to save testing list to BPA700, click the check box you want to save and save your auto sequence list to the BPA device (for standalone mode). Click the question mark box in the upper right corner to view the parameter setting rules.

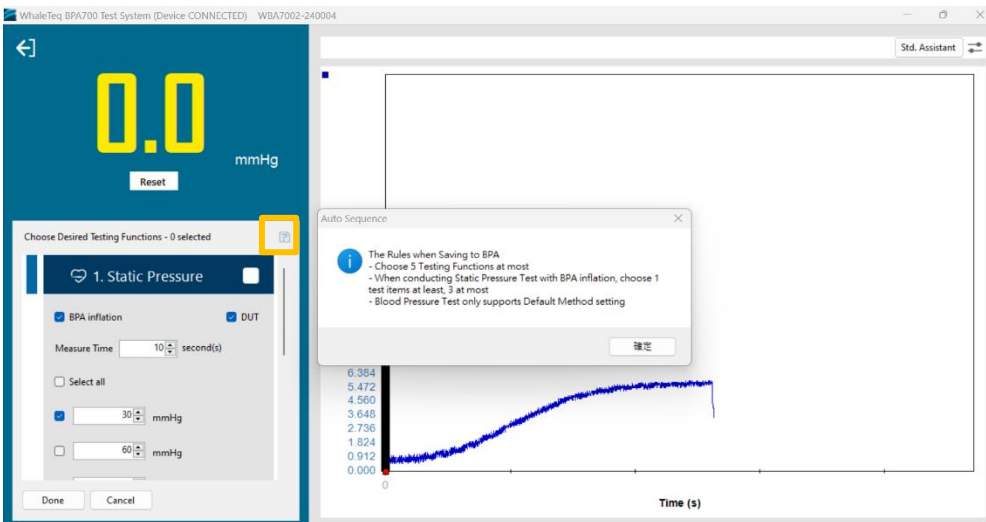


Figure 20: Save Auto Sequence List

***Note: When the user is in standalone mode, there are several limitations when saving test groups to BPA700:**

- Choose 5 Testing Functions at most
- When conducting Static Pressure Test with BPA inflation, choose 1 test items at least, 3 at most
- Blood Pressure Test only supports Default setting

2.7 Static Pressure

A pressure gauge (Manometer) measures externally generated static pressures ranging from 0 to 400 mmHg (0 to 53.3 kPa).

(1) Click “Static Pressure”. Before starting the test, there are 3 pre-setting needed:

- make sure BPA inflation checked
- check DUT
- choose pressure value

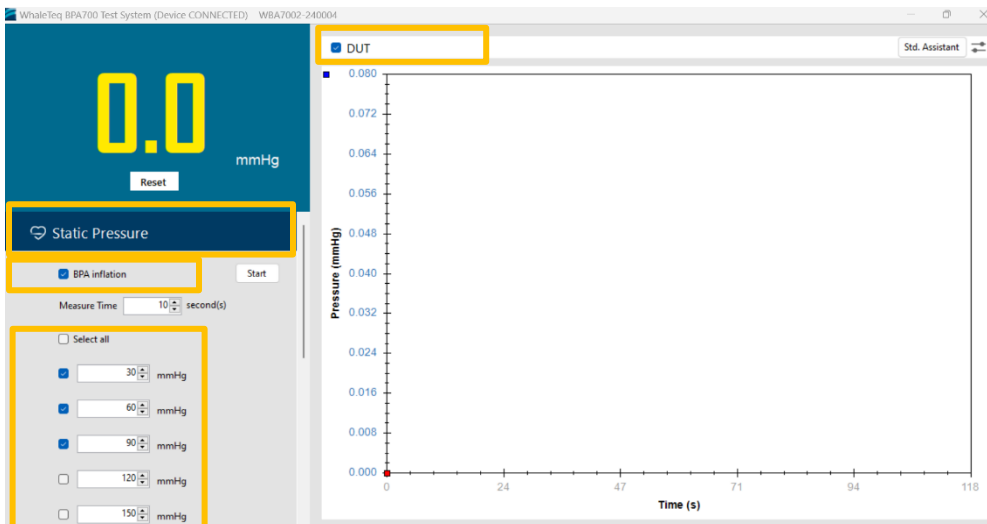


Figure 21: Pre-setting of Static Pressure Test

(2) Click “Start”. You can test up to 10 values consecutively.

***Note 1:** Standalone mode allows only 3 consecutive values.

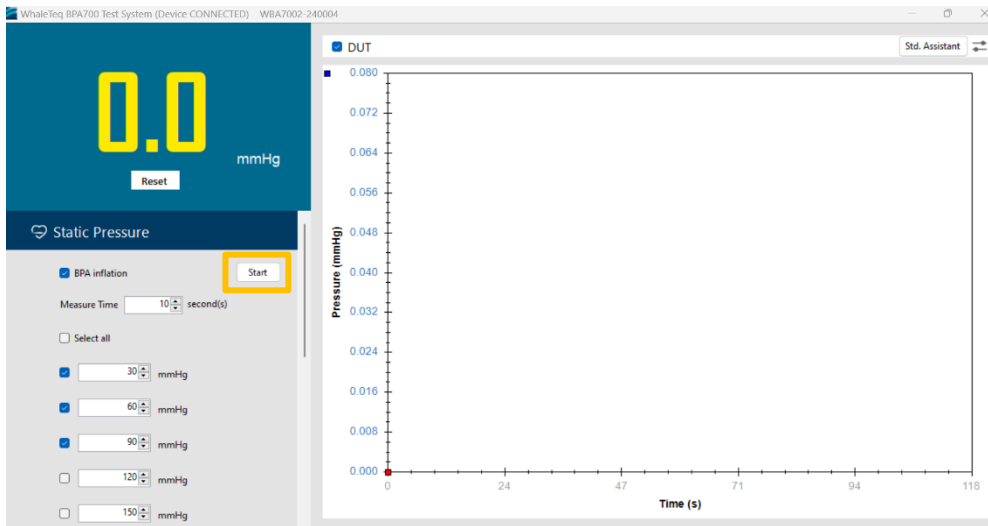


Figure 22: Start Static Pressure Test

***Note 2:** When testing each section of pressure, it takes 5 seconds to stabilize, if the setting time is 10s, the test time should be 15s.

(2) You will see a red block in front of the test values. In this case, we set 30, 60, and 90 mmHg in a row.

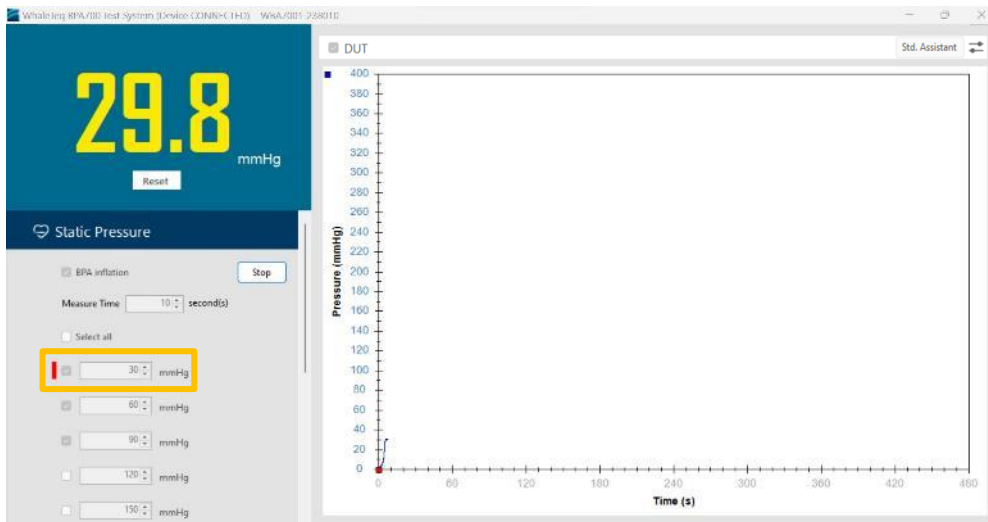


Figure 23: Test Value- 30 mmHg

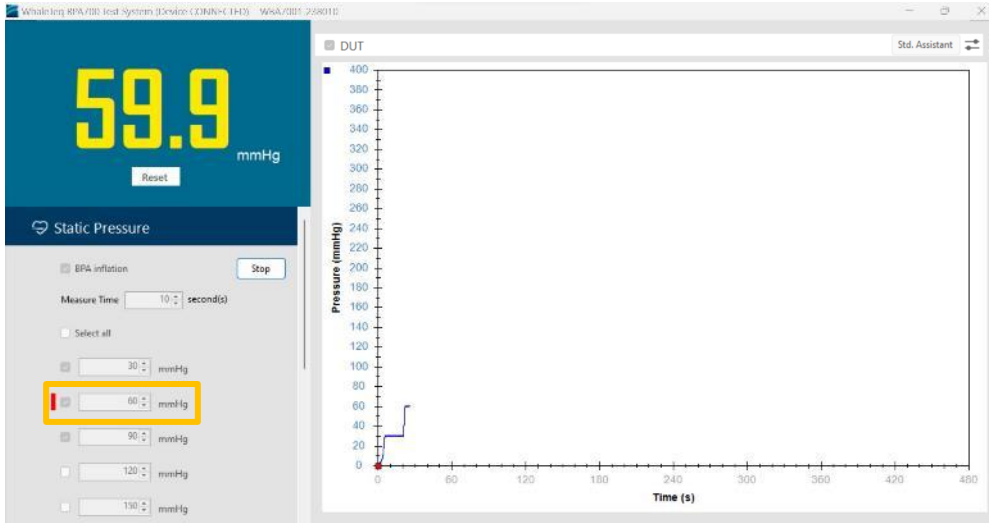


Figure 24: Test Value- 60 mmHg

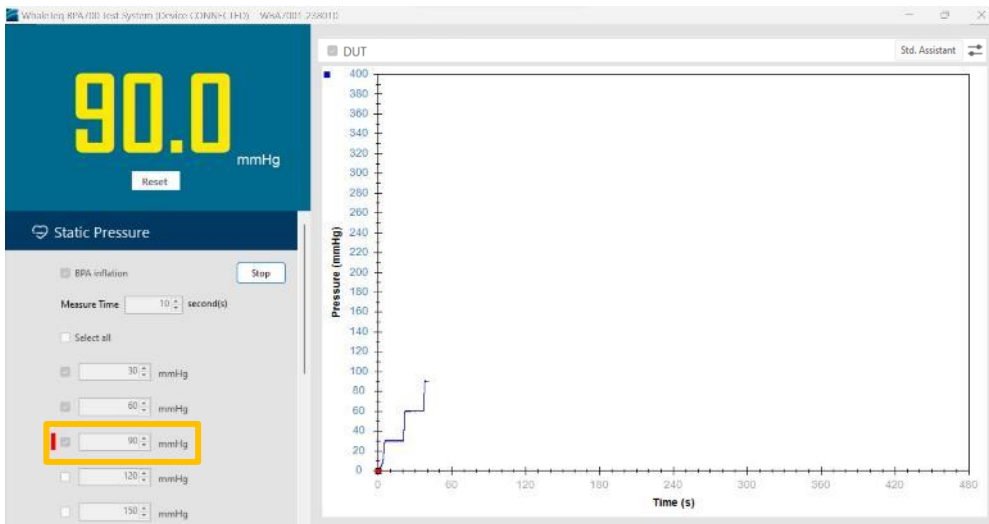


Figure 25: Test Value- 90 mmHg

(3) Drag the cursors on the graph for more details. You can drag four at most at the same time.



Figure 26: Drag the Cursors for Details

***Note:** X axis and Y axis introduction

- X axis: Display the corresponding time of the pressure measurement
- Y axis: pressure
- X-X cursors: shows the difference of the time
- Y-Y cursors: shows the difference of the pressure

2.8 Blood Pressure

Simulate pulse pressure band to set blood pressure and test the efficacy and repeatability of non-invasive blood pressure monitor.

2.8.1 Rules for Pressure Value Setting

There are 2 kinds of method to set the test value: Default and Customized. For Default method, there are several preset values prepared for the user.

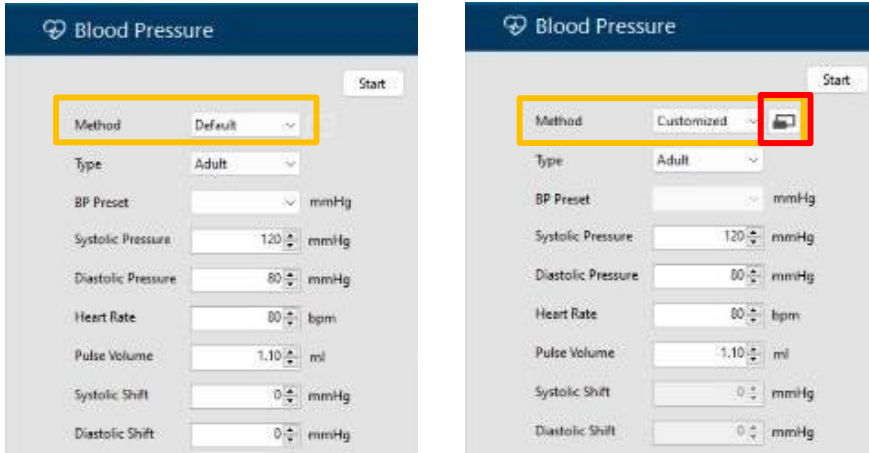


Figure 27: Different Ways to Set Test Values

For Customized method, you can set all values by yourself, please refer to the following rules.

A. Heart Rate

Select the HR number field to set the number of heartbeats and enter the target heartbeat value. Increase or decrease the heartbeat in units of 1bpm. The heartbeat ranges from 30 bpm to 300 bpm.

B. Pulse Volume

The user can change the magnitude of blood pressure amplitude.

Select the Pulse Volume number field to set the pulse volume.

Adjust for each DUT. Increase or decrease the pulse volume in units of 0.05 ml. The pulse volume ranges from 0.1 ml to 2 ml.

- Pulse volume adjustment principle:
The pulse volume refers to the amplitude or intensity of the simulated pulse signal (the pressure changes of the artery) of an NIBP simulator. The setting of this has to be done correctly if the NIBP monitors are to be tested to get the correct blood pressure values under the respective physiological conditions.
- How to Adjust the Volume:
Step 1: Set the pulse volume
Increase or decrease the pulse volume in units of 0.05 ml. The pulse volume ranges from 0.1 ml to 2 ml.

Step 2: Making the Observations

Observe the correlated change on the simulator display when you adjust the pulse volume. Ensure the pulse volume is not set too low (which could result in weak or undetectable pulses) or too high (which could create unrealistically strong pulses).

Step 3: Confirm with the NIBP Monitor

1. Start a Test Measurement

Start a blood pressure measurement on the NIBP monitor with the simulator running. Check whether the monitor correctly detects the simulated pulse.

**Note: Adjust if Necessary*

If the monitor cannot sense the pulse or senses wild values, go back to the simulator, adjust a tiny bit lower or higher, and try the measurement again on the NIBP monitor. Use this procedure a few times to determine if the measurement improved.

2. Repeatability Check:

Be sure that the NIBP monitor can read the blood pressure simulation correctly, using a consistent method, for several repeat measurements. The pulse volume setting is adjusted correctly once the recordings are stable.

C. Envelope

There are two ways to adjust the envelope:

1. Envelope shift: Adjust the position of the envelope's systolic and diastolic pressures forward or backward.
2. Envelope customized waveform: Allow arbitrary adjustments to the waveform within the envelope.

Click the square next to Customized to adjust. (See Figure 27) Increase or decrease in 1 mmHg units. Envelope ranges from minus 20 mmHg to 20 mmHg.

***Please refer to [2.8.3 Customized Method](#) for more details.*

2.8.2 Default Method

(1) Click “Blood Pressure”, and check DUT. Set the pressure value of the test. Click “Start”.

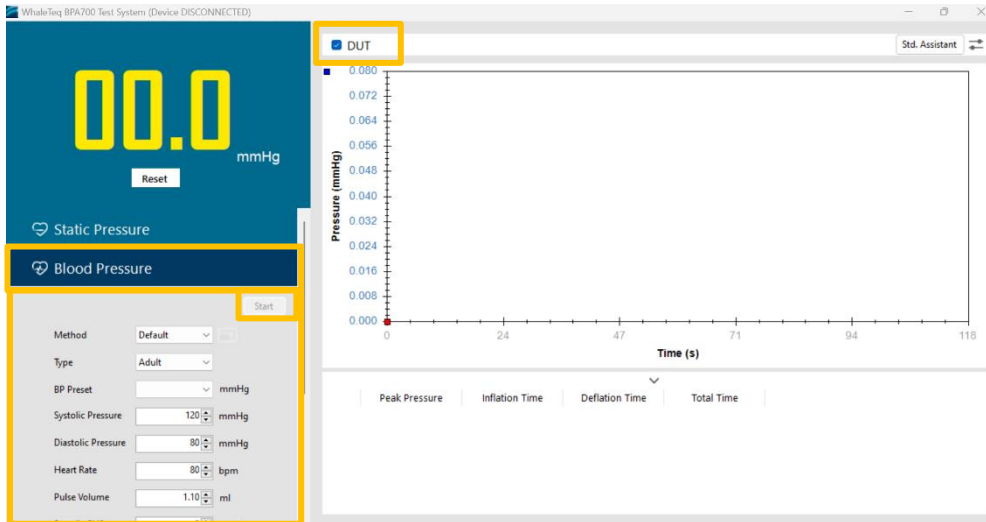


Figure 28: Default Setting

(2) You will see the graph is showing the change of the blood pressure. Please wait for seconds until the result comes out.

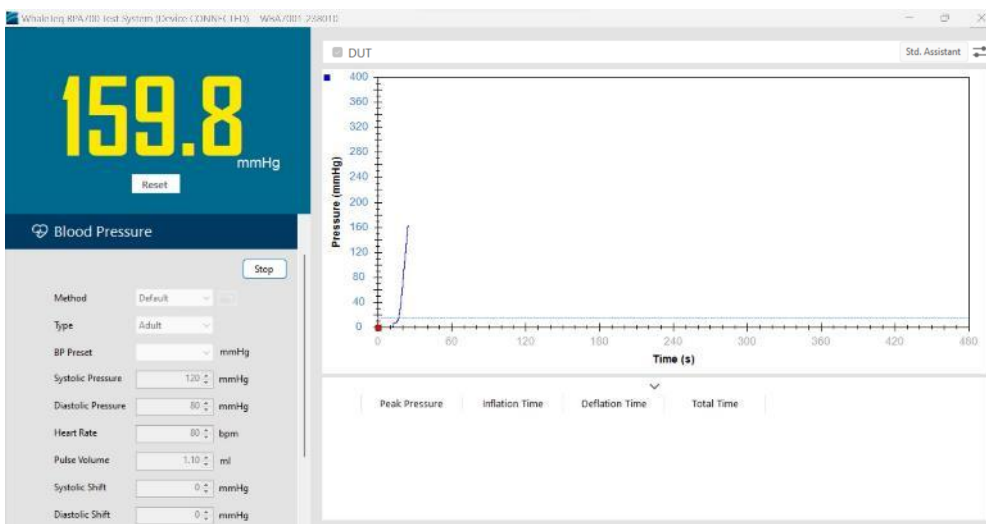


Figure 29: Waiting for the Test Result

(3) The result is shown below the graph. The user can test consecutively, getting test results in a row.

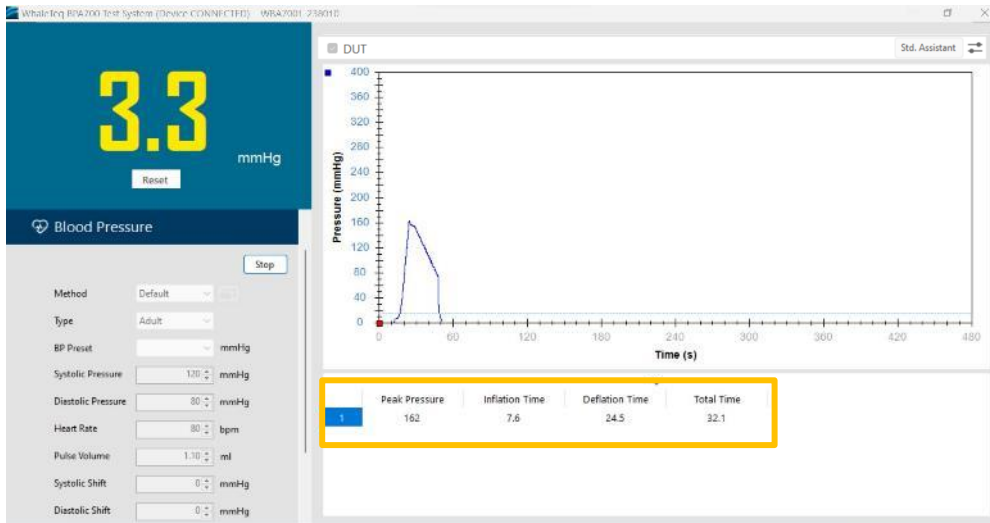


Figure 30: Showing Test Result

2.8.3 Customized Method

Introduction of the pulse envelope

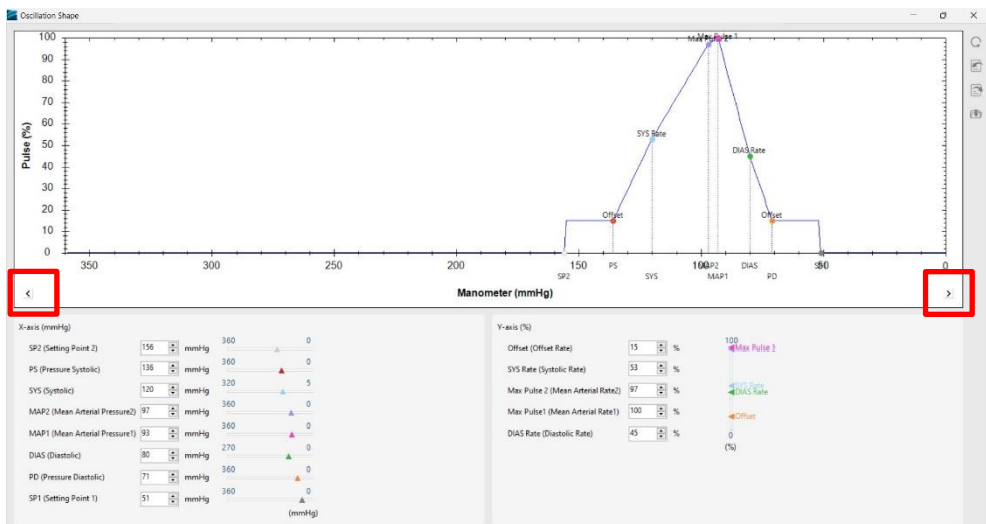


Figure 31: Envelope Adjustment

*Arrows on the right and left side: able to pan-shift the entire pulse envelope

X-axis: the pressure of the cuff

1. Setting Point 2: The blood pressure starts to oscillate in the cuff.
2. Start Pressure: The pulse oscillate starts to measure.
3. Systolic Pressure: the systolic pressure set.
4. Mean Arterial Pressure 2 (MAP 2): The highest point of pulse.
5. Mean Arterial Pressure 1 (MAP 1): The highest point of pulse.
6. Diastolic Pressure: The diastolic pressure set.
7. End Pressure: The pulse oscillates stops measuring.
8. Setting Point 1: The blood pressure stops oscillating in the cuff.

Y-axis: the amplitude of the pressure pulses in the cuff

1. Offset Rate: The starting point of amplitude change.
2. Systolic Rate: The systolic point of amplitude change.
3. Mean Arterial Rate2: The highest point of amplitude change.
4. Mean Arterial Rate 1: The highest point of amplitude change.
5. Diastolic Rate: The diastolic point of amplitude change.

- ①. Click “Blood Pressure”, and check DUT. Set the pressure value of the test. Click “Start”.

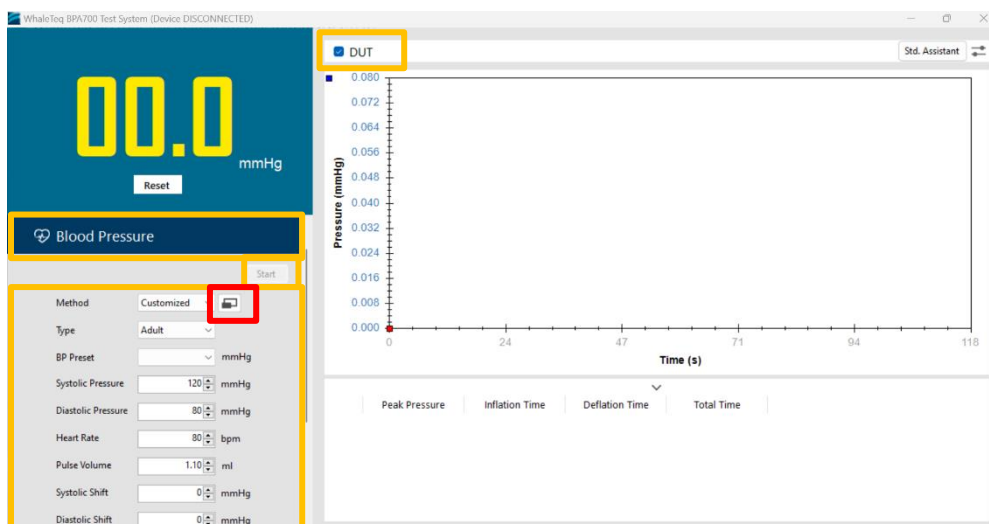
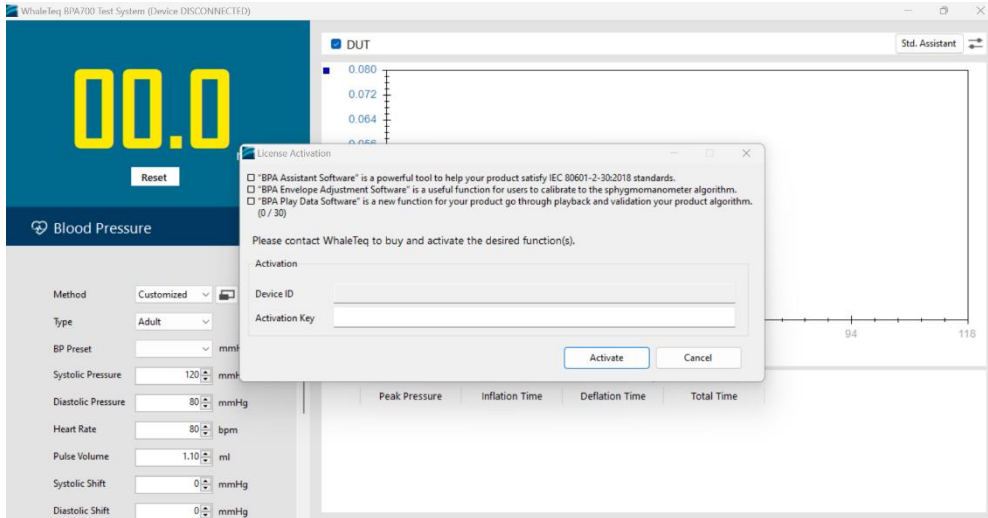


Figure 32: Customized Setting

(2) If there are deviations from the actual values, click the square next to the Customized (See red mark in Figure 32), and enter a pop-up window of envelope setting. All turning point can be customized based on user's need.



*After connecting the BPA700, enter the activation key and click "Activate."

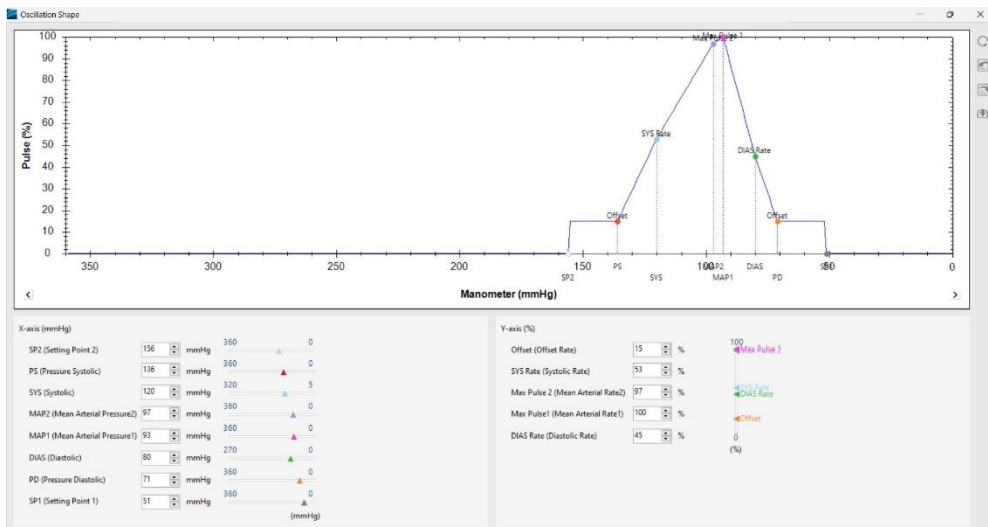


Figure 33: Adjustable Envelope

(3) You can either adjust the values directly on the graph, or using two different kinds of cursors below.

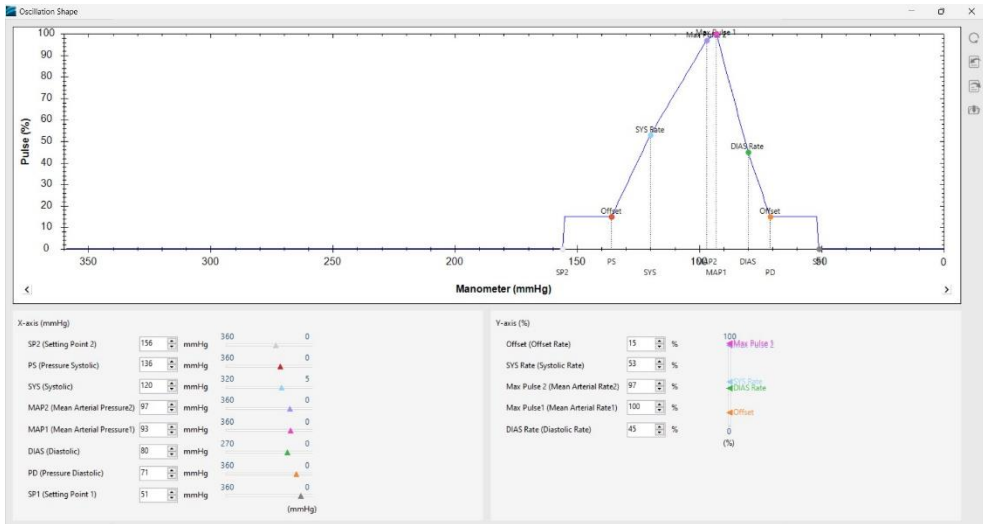


Figure 34: Adjust Envelope in Different Ways

(4) Export your test result by clicking the right-side button.

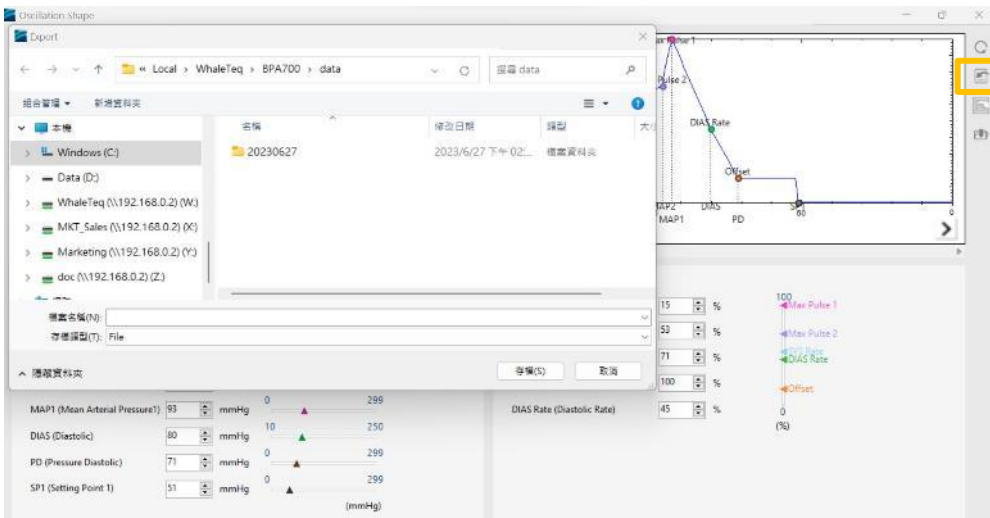


Figure 35: Export the Result

(5) Import your test result by clicking the right-side button.

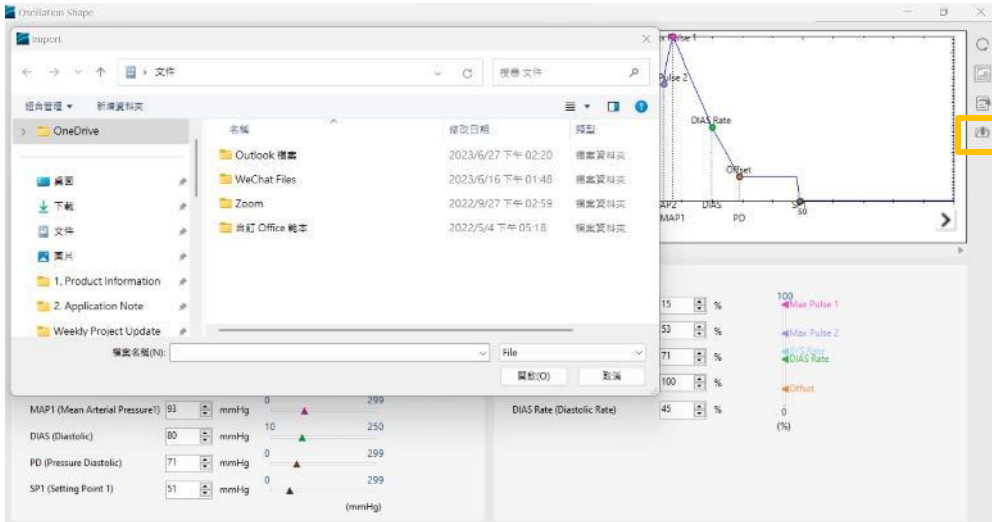


Figure 36: Import the Result

(6) Reset button at the right-side button
 Reset to default. Once the data is saved, the reset button will reset to the previous data.

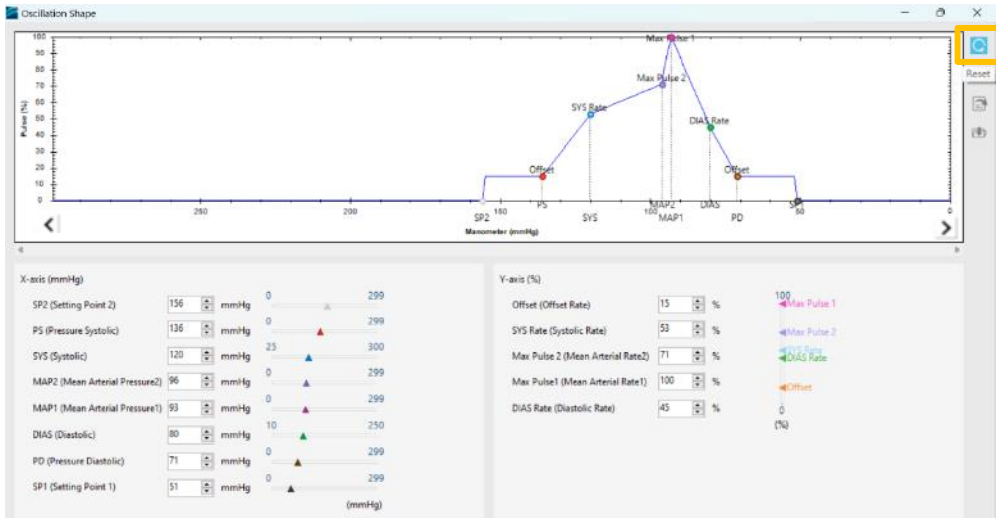


Figure 37: Reset Data

(7) Saved to device (BPA700)

The user can save the data when connect to device

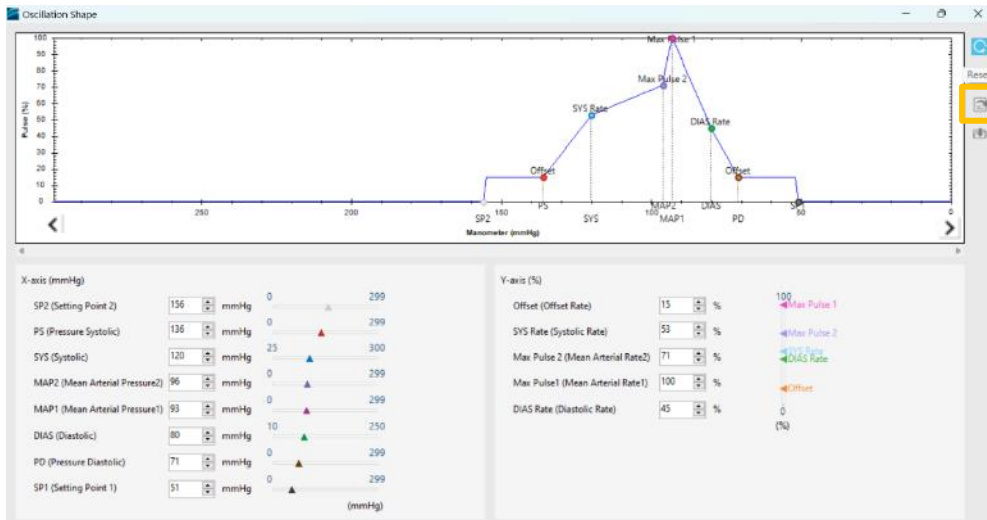


Figure 38: Save to Device

2.9 Leak Test

The pressure leak test tests pneumatic systems by pressurizing them to a target pressure defined by the user (marked as a set point). Up to 400 mmHg (53.3 kPa) for final measurement of pressure loss over time.

(1) Click "Leak Test". Set "Calibration" for deducting the self-test leakage rate of the BPA700 itself, and the self-test leakage rate during the actual measurement.

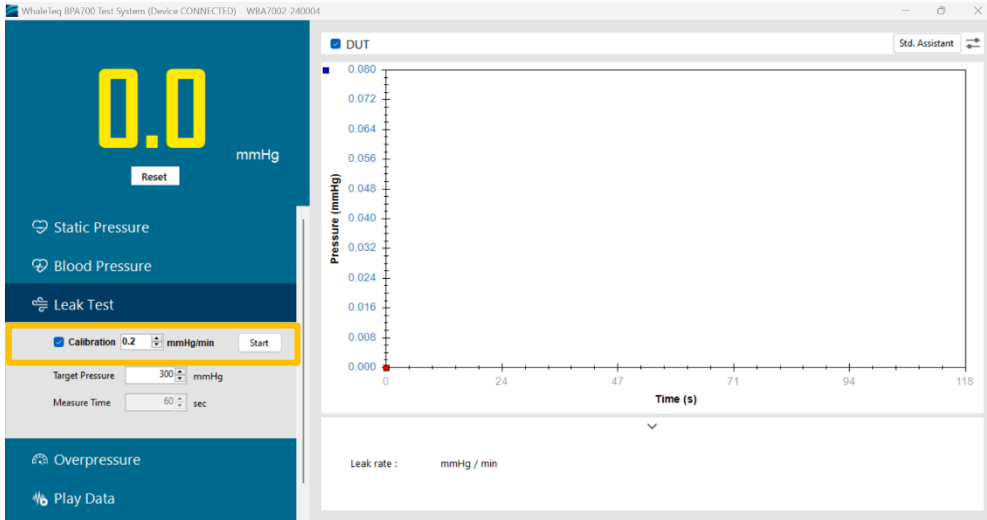


Figure 39: Leak Test Setting

(2) Enter the target pressure and test time. Click “Start”.

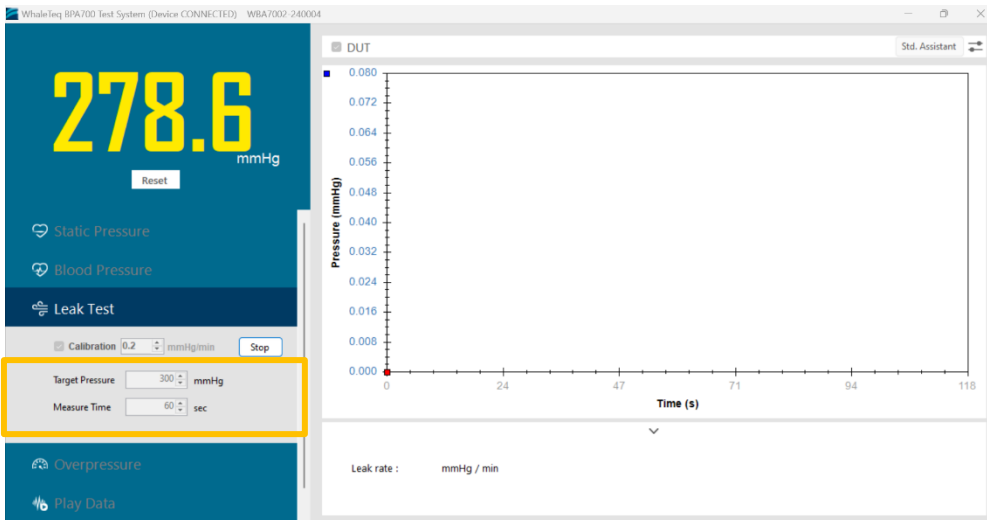


Figure 40: Set Calibration Value

(3) The result is shown as the graph.

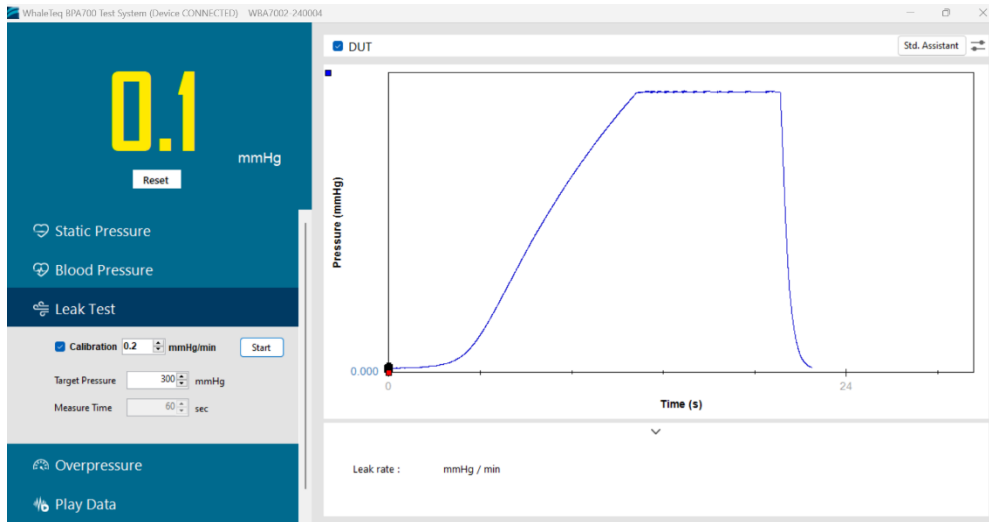


Figure 41: Leak Test Result

2.10 Overpressure Test

Overpressure testing is performed by pressurizing to a user-defined target pressure (marked as the set point). Threshold 1 is the starting pressure; Threshold 2 is the threshold where the pressure reaches its peak. When the measured blood pressure exceeds this threshold, the software will automatically calculate the deflation time according to ISO 81060-2-30 and trigger a deflation alarm.

(1) Click “Overpressure”, and check DUT. Enter the target pressure (only needs to be set when BPA inflation is checked), standard minimum pressure, and maximum pressure point. Click “Start”.

*Check BPA700 Inflation to refer to the supply of air by BPA700. To read the pressure of the blood pressure monitor, uncheck the checkbox.

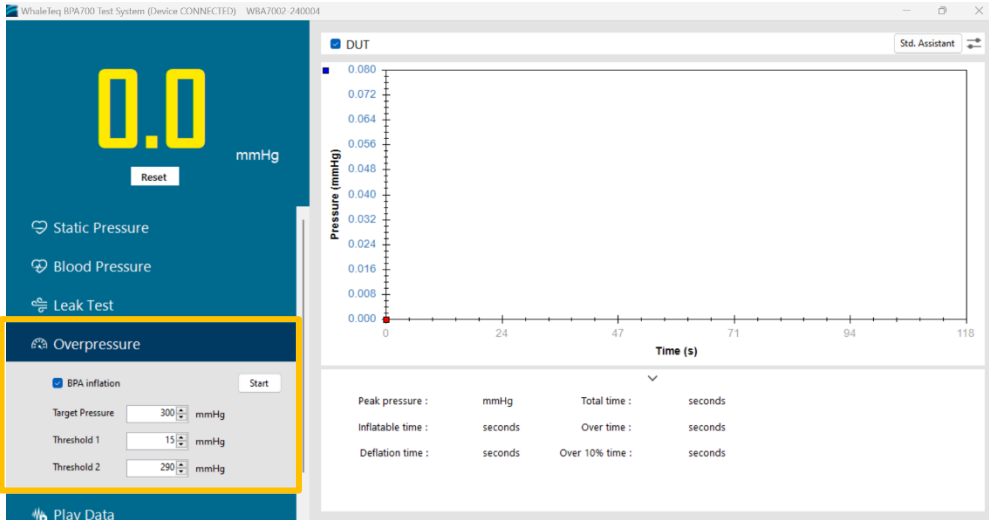


Figure 42: Overpressure Test Setting

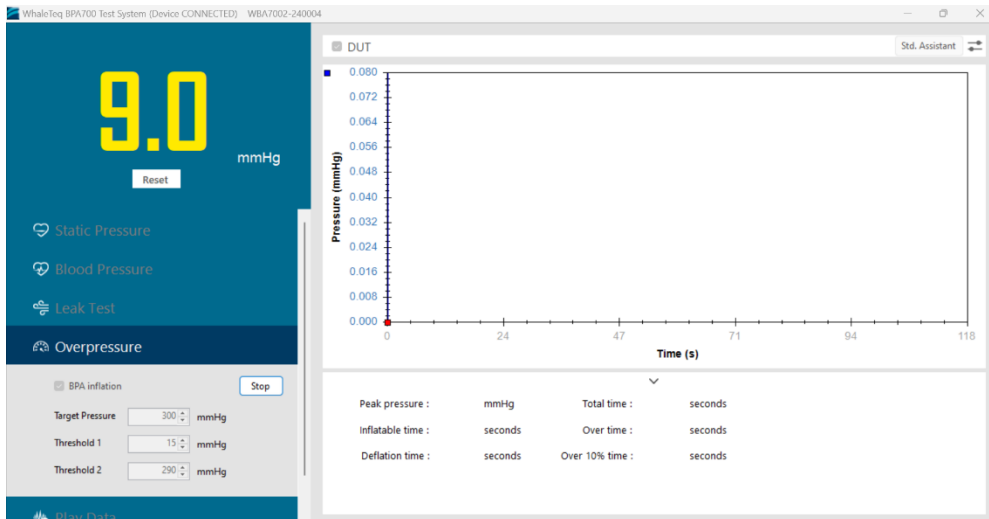


Figure 43: Run Overpressure Test

(2) Check whether test result correspondent to the setting.

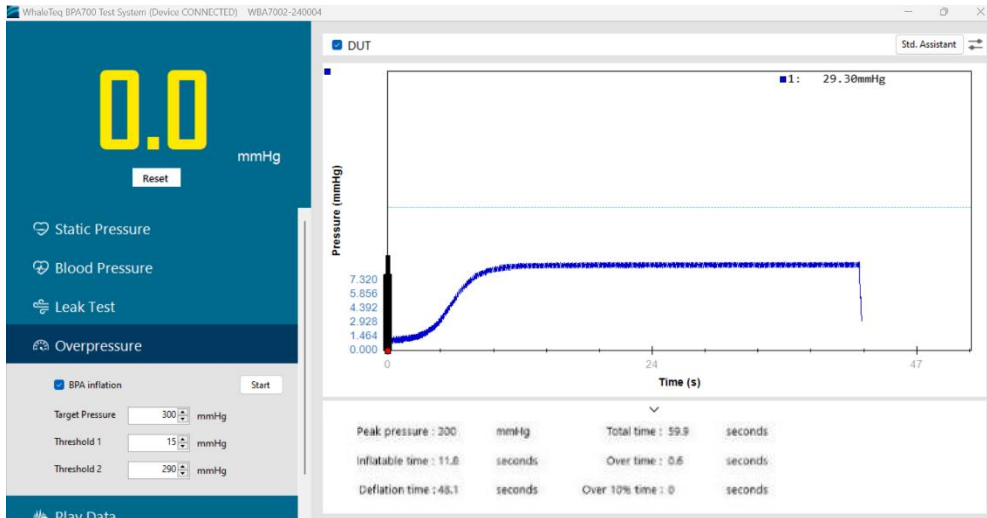


Figure 44: Overpressure Test Result

2.11 Play and Record Data

2.11.1 Basic Concept

In clinical practice, diastolic and systolic values are determined using the Korotkoff sound method. However, over 90% of commercially available electronic blood pressure monitors use the oscillometric method, with manufacturers developing their own algorithms to estimate blood pressure values.

To improve the potential inaccuracies of these estimates, medical device regulations require manufacturers to conduct clinical trials involving 85 subjects and 255 measurements before a blood pressure monitor can be marketed to ensure accuracy validation. Regardless of whether data from just 85 subjects can encompass all human blood pressure models, it is foreseeable that collecting these clinical data involves significant time and expense for manufacturers.

To address the challenges of preclinical validation, the BPA700 offers data playback and recording functions. It can record real blood pressure data and

convert it into files for repeated playback, thereby reducing the burden of clinical trials and effectively validating algorithms.

Below are the basic settings for play and record data:

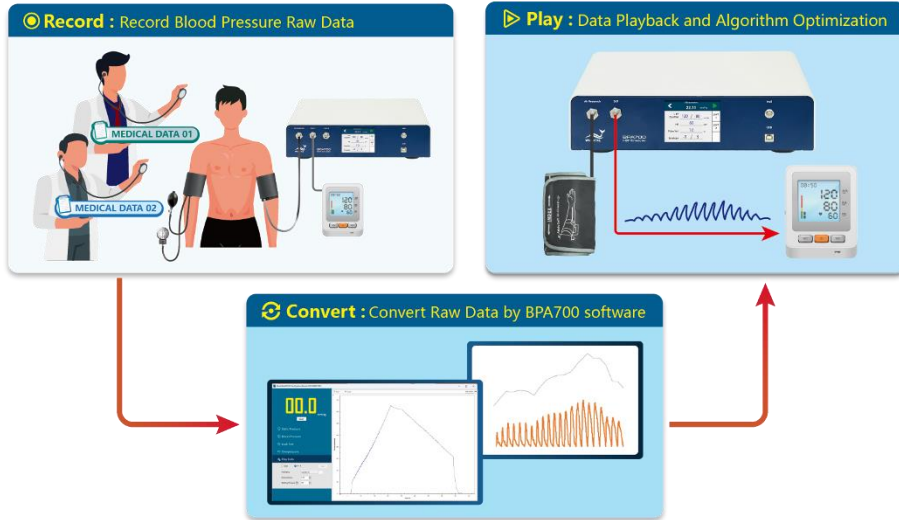


Figure 45: Setup of Play and Record Data

*Note: A free trial of 30 uses is available. Please contact WhaleTeq for full features and services after the trial period.

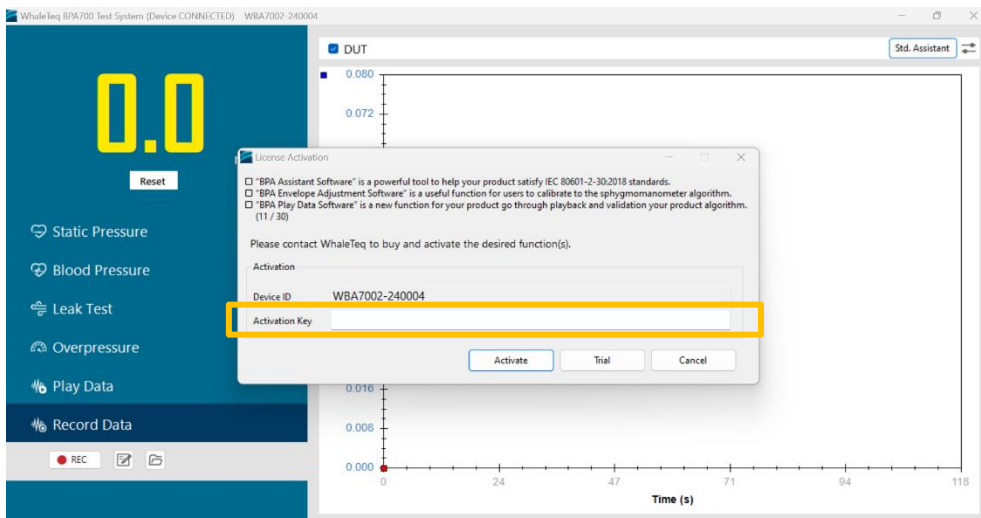


Figure 46: Record Data Trial Rules

2.11.2 Operation settings

- **Software installation**

Please refer to [Chapter 2.1.2 BPA700 PC software installation](#), go to WhaleTeq’s official website to download and execute the "AP" and "Kit" at the same time to activate the PlayData function. (optional)

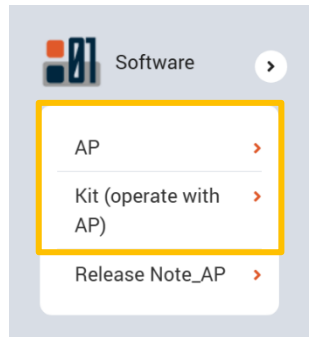



Figure 47: Software installation

- **Record Data**

- ① Select **Record Data** on the feature bar. Select  to start recording blood pressure data.

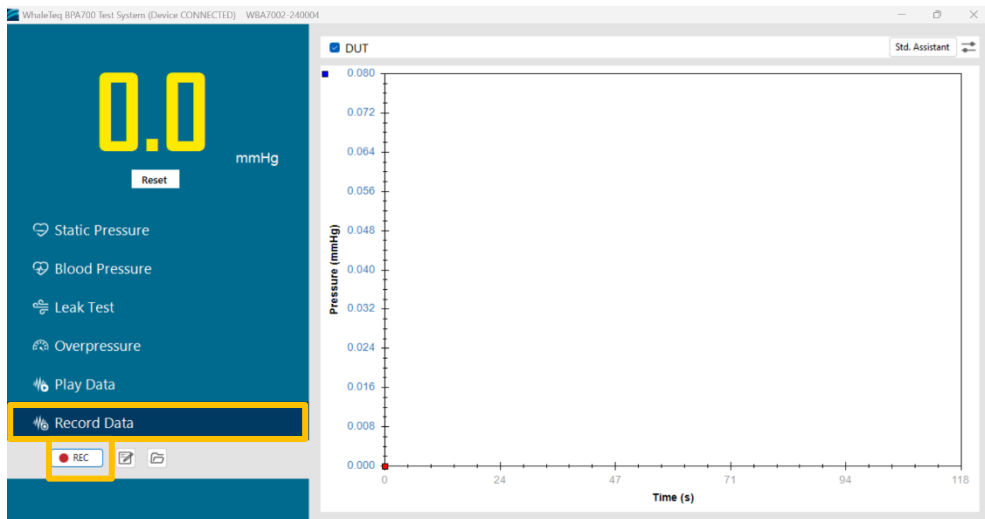


Figure 48: Record Data

- ②. Enter the actual readings on BP monitor as annotation.

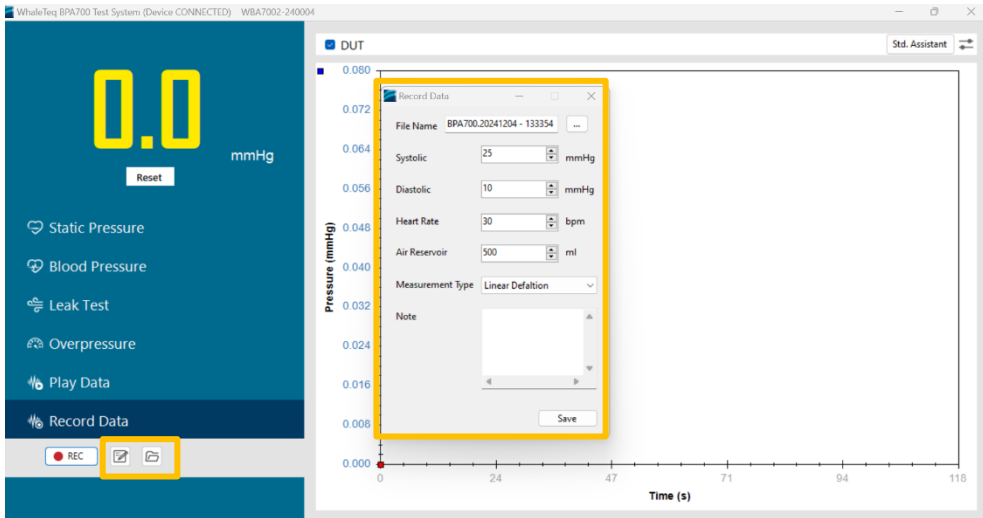


Figure 49: Edit recorded blood pressure data

- ③. File storage path
Open the file box. There are two file formats in the file.

Name	Date modified	Type
BPA700.20240227 - 104938.ann	2/27/2024 10:50 AM	ANN File
BPA700.20240227 - 104938	2/27/2024 10:54 AM	Text Document

Figure 50: Blood pressure data storage path

- (1) .ann file: parameter data
- (2) .txt file: blood pressure raw data

- **Play Data**
Use the Data Recorded by BPA700

- ①. Click " Play Data" and select the box on the right column of the file name to open the file.

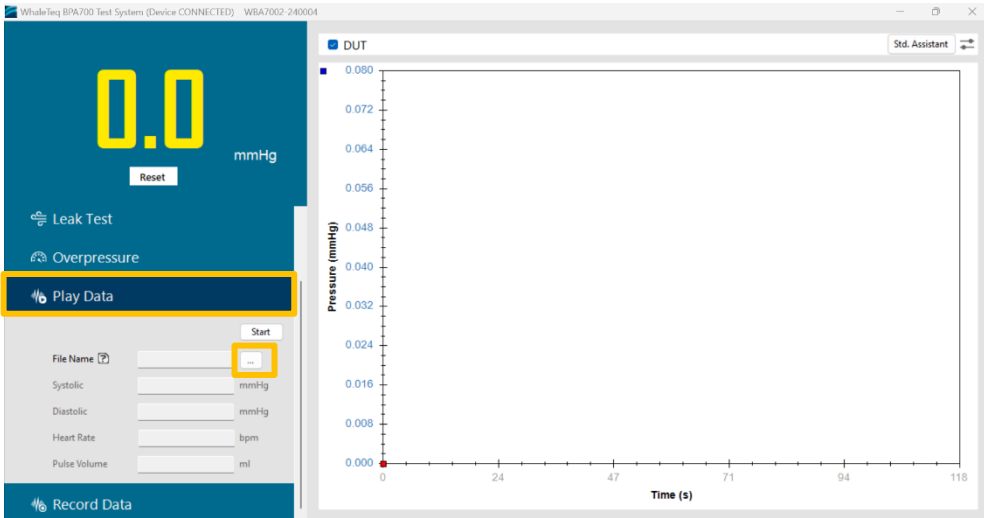


Figure 51: Play Data

- ②. After selecting the file and opening it, enter the Convert Tool to convert the blood pressure data and confirm whether the data needs to be adjusted.

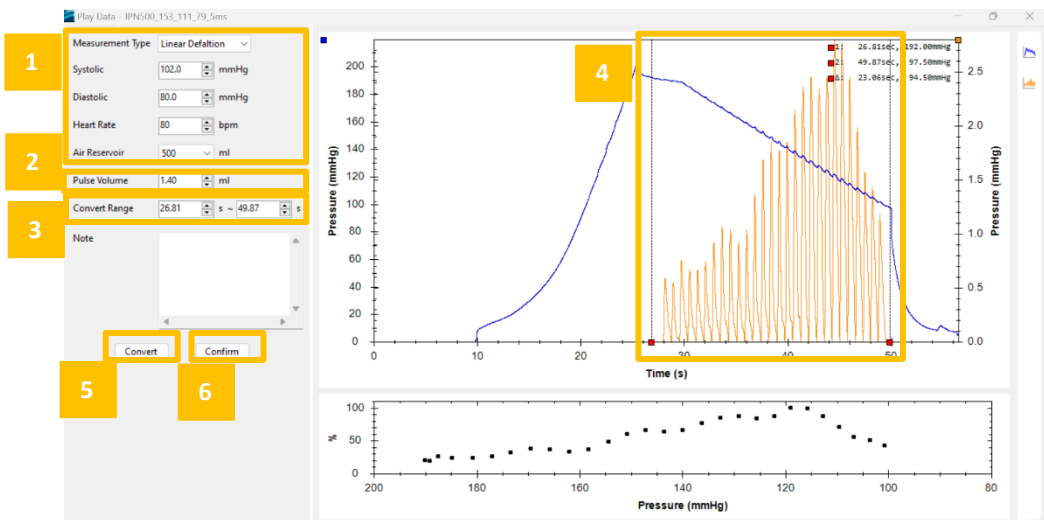


Figure 52: Convert Tool

- (1) Store parameters (systolic blood pressure/diastolic blood pressure/heart rate) and select testing air reservoir volume. (500/100 ml).
- (2) Pulse volume: The pulse volume converted by the software is adjusted based on the actual measurement value and MAP (Mean Arterial Pressure).
- (3) Convert range: Select the required conversion range through the indicators on the chart, and the software converts the cuff pressure data into pulse. After adjustment, you need to click "Convert"

***Note:** The convert range supports a 40-second interval, otherwise playback will fail.

- (4) Chart area: adjust the range to be converted.
 - (5) Convert: Click "Convert" to convert the data into pulse amplitude and oscillation waveform.
 - (6) Confirm: Click "Confirm" and the convert tool will automatically jump out and return to the main page.
- ④. After returning to the main page, check DUT and click "Start" to execute the test. At the same time, turn on the blood pressure monitor and check whether the data is consistent.

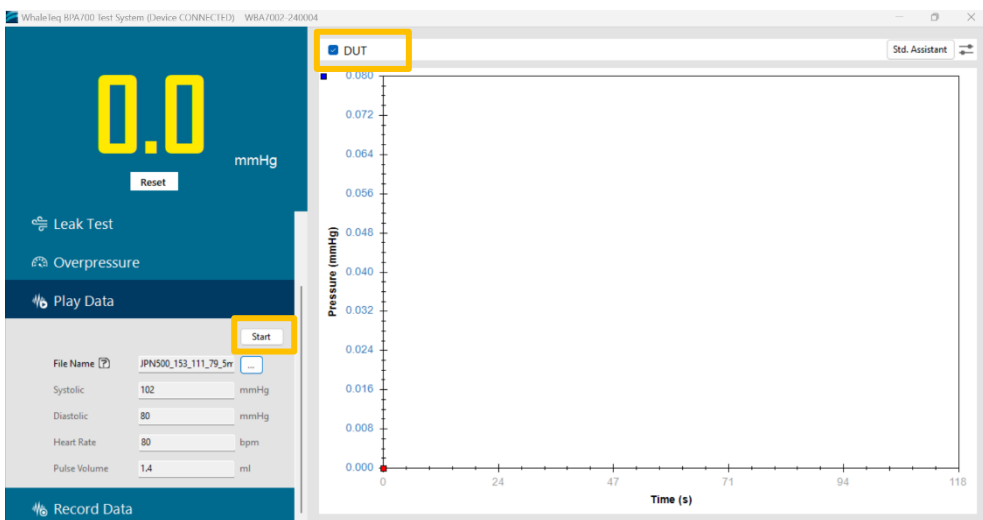



Figure 53: Click Start to Play Data

Use Self-recorded Data

- Convert the existing data to the format required by the software and click  next to the file name to learn about the file format.

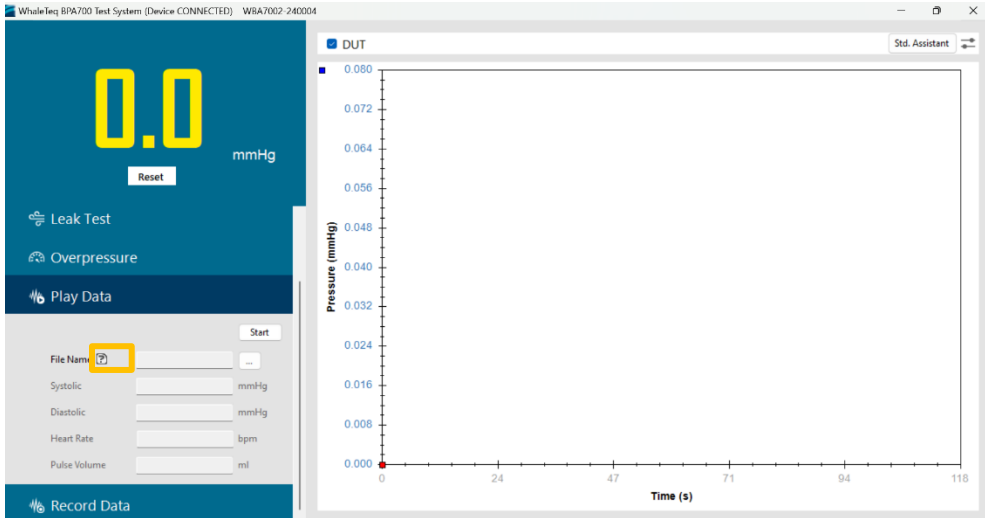


Figure 54: Play Self-recorded Data

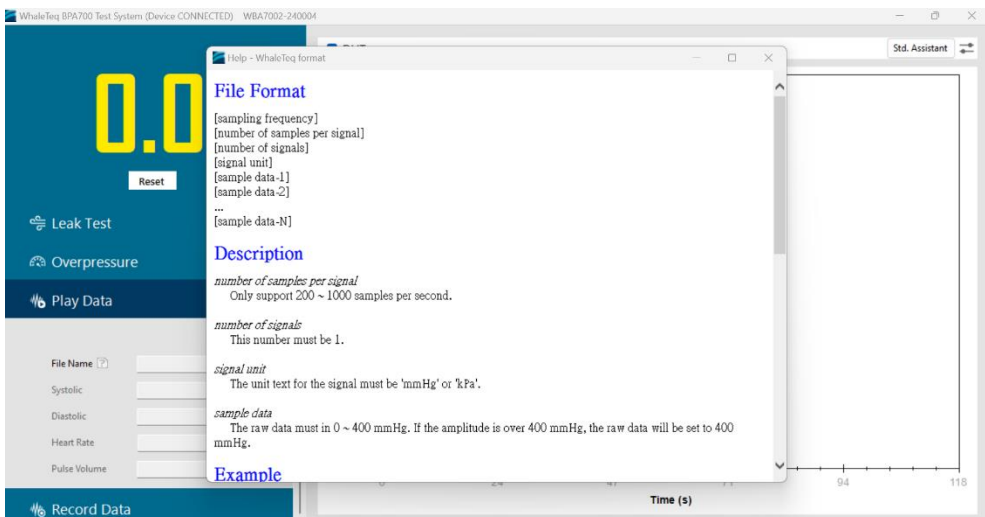


Figure 55: The Format of the Data

The remaining steps are the same as " Use the Data Recorded by BPA700 ":

- ②. Select the box in the right column of the file name to open the file.
- ③. After selecting the file and opening it, enter the convert tool to convert the blood pressure data. You can fill in the parameters (measurement method/systolic blood pressure/diastolic blood pressure/heart rate) and select testing air reservoir volume. (500/100 ml/others).
- ④. After clicking to confirm, the data parameters will be updated to the .ann file simultaneously (the parameters will be saved the next time it is opened)
- ⑤. After returning to the main page, check DUT and click "Start" to execute the test. At the same time, turn on the blood pressure monitor and check whether the data is consistent.

2.12 Standalone Mode

BPA700 offers the user a convenient way to test without connecting to PC. To make sure standalone mode can conduct smoothly, setting on PC mode is necessary.

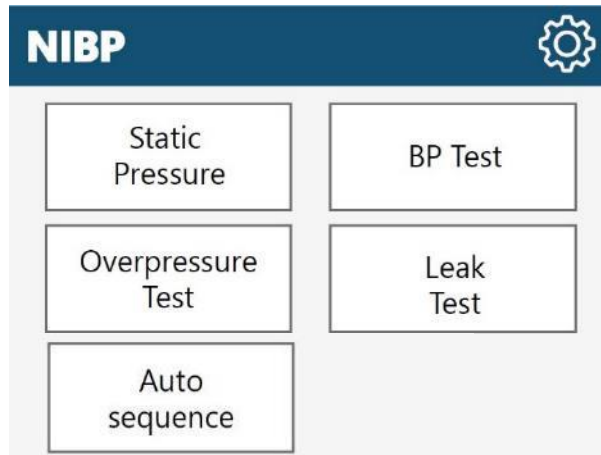


Figure 56: Standalone Mode Interface

There are 4 differences between these two modes:

- The test group of auto sequence (Please refer to [2.6.1 Basic Function](#))
- Edit auto sequence details
- Pressure value setting limits (Please refer to [2.7 Static Pressure](#))
- Adjustable envelope (Please refer to [2.8.3 Customized Method](#))

Here, we only show the illustrations of each testing, please refer to the correspondent chapter for the details.

1. Static Pressure: Refer to [2.7 Static Pressure](#)



Figure 57: Static Pressure Setup

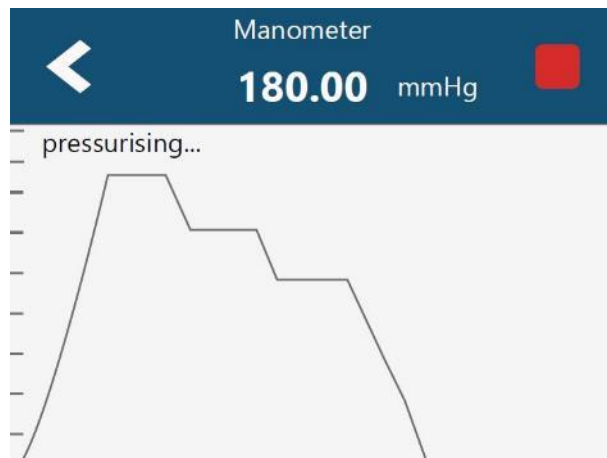


Figure 58: Static Pressure Result

2. BP Test: Refer to [2.8 Blood Pressure](#)



Figure 59: Blood Pressure Setup

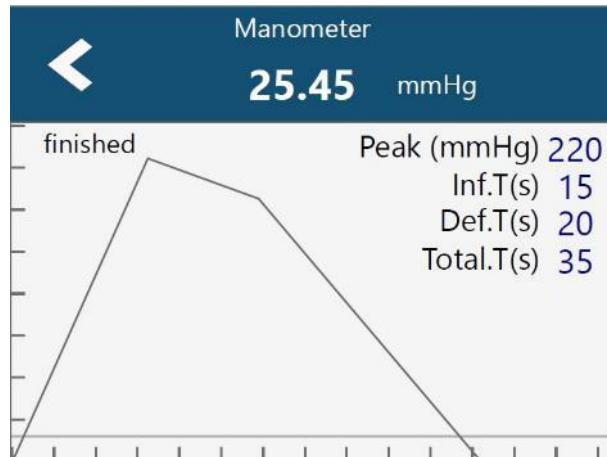


Figure 60: Blood Pressure Result

3. Leak Test: Refer to [2.9 Leak Test](#)

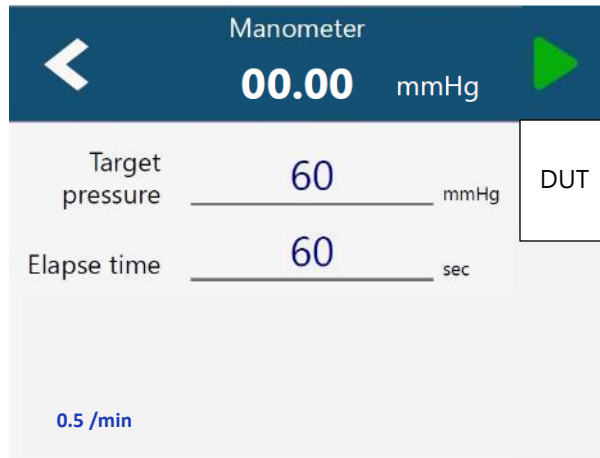


Figure 61: Leak Test Setup

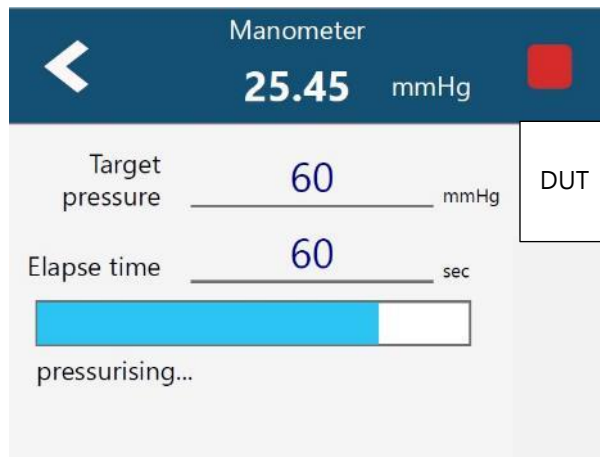


Figure 62: Leak Test Pressurizing

4. Overpressure Test: Refer to [2.10 Overpressure Test](#)



Figure 63: Overpressure Test Setup

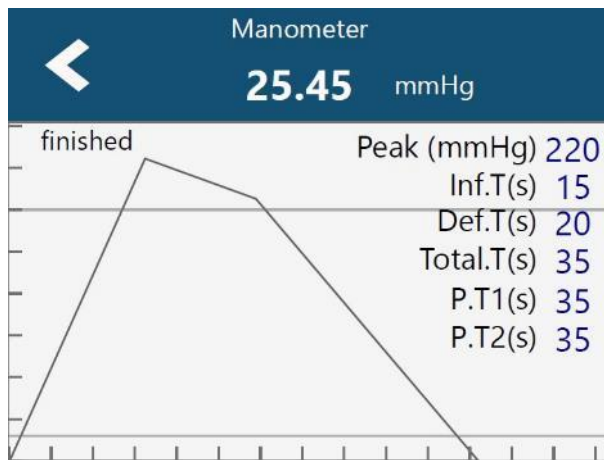
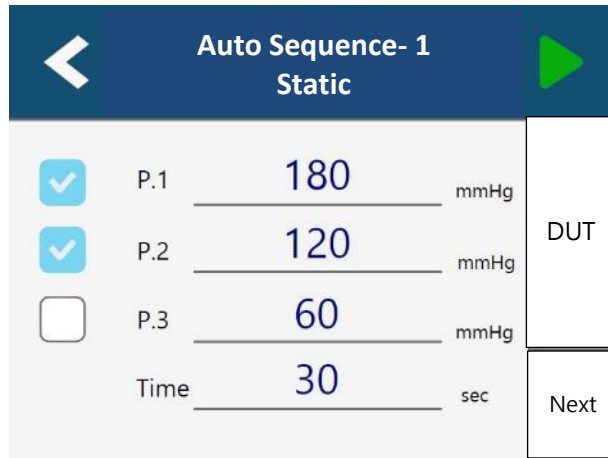


Figure 64: Overpressure Test Result

5. Auto sequence: Refer to [2.6 Auto Sequence](#)



Auto Sequence- 1 Static		
<input checked="" type="checkbox"/>	P.1	180 mmHg
<input checked="" type="checkbox"/>	P.2	120 mmHg
<input type="checkbox"/>	P.3	60 mmHg
	Time	30 sec
		DUT
		Next

Figure 65: Auto Sequence Setup

2.13 Standard Assistant

BPA700 is equipped with the new medical standard assistant software supporting IEC 80601-2-30 and YY9706.230. The testing parameters, options, procedures, and pass criteria are exclusively programmed for test clauses in different medical standards. This is to assist users to simplify the test.

The new medical standard assistant software shall be purchased separately from BPA700.

2.13.1 Import License Key

For the first-time user, the system requires the user to import the Activation Key.

(1) Please contact WhaleTeq and choose the desired medical standards. An email will be sent to your mailbox after the purchase.

(2) Key in your Activation Key in the box below, click “Activate”.

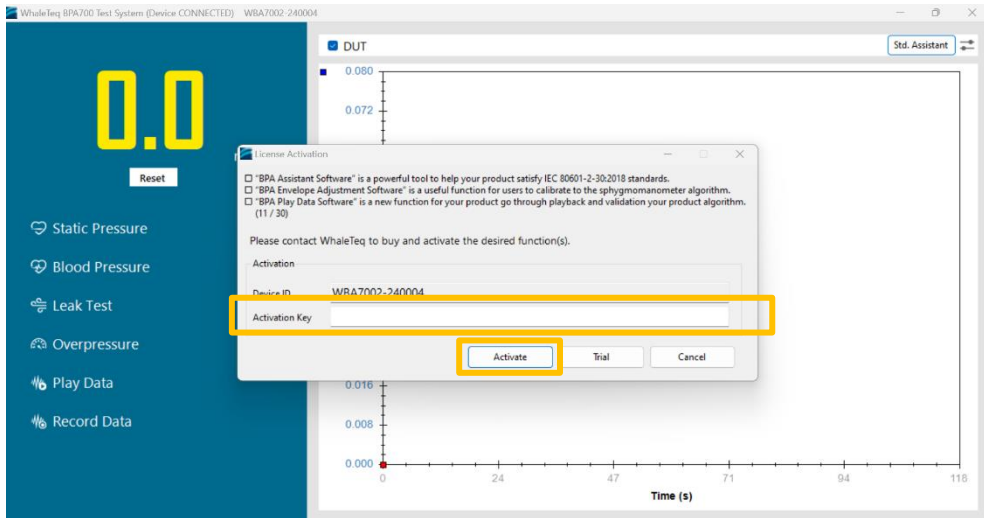


Figure 66: Enter Activation Key

(3) You will see 2 pop-up windows showing test item lists and pressure-time graph separately after entering the key.

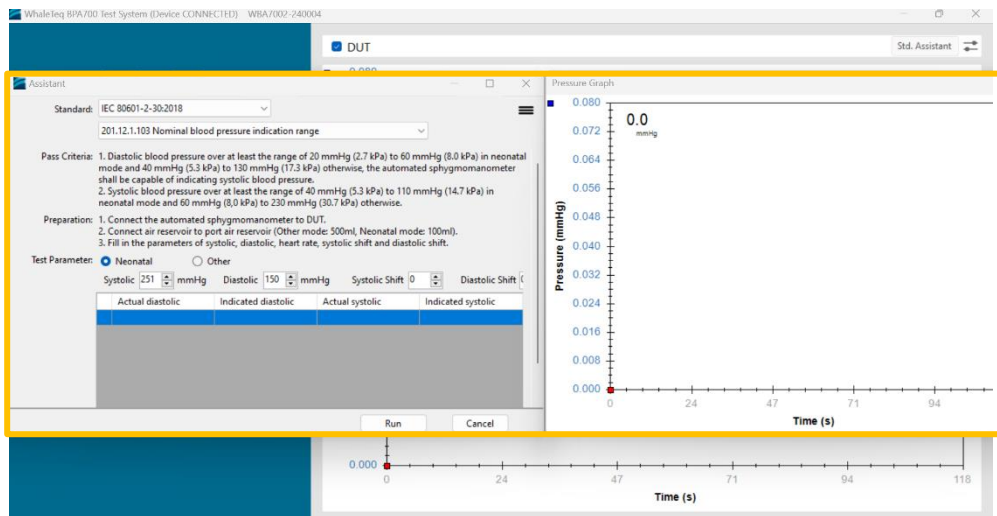


Figure 67: Import Activation Key Successfully

2.13.2 Standard Assistant Software

Please follow the operation instruction:

(1) Select the required medical standard and test clause.

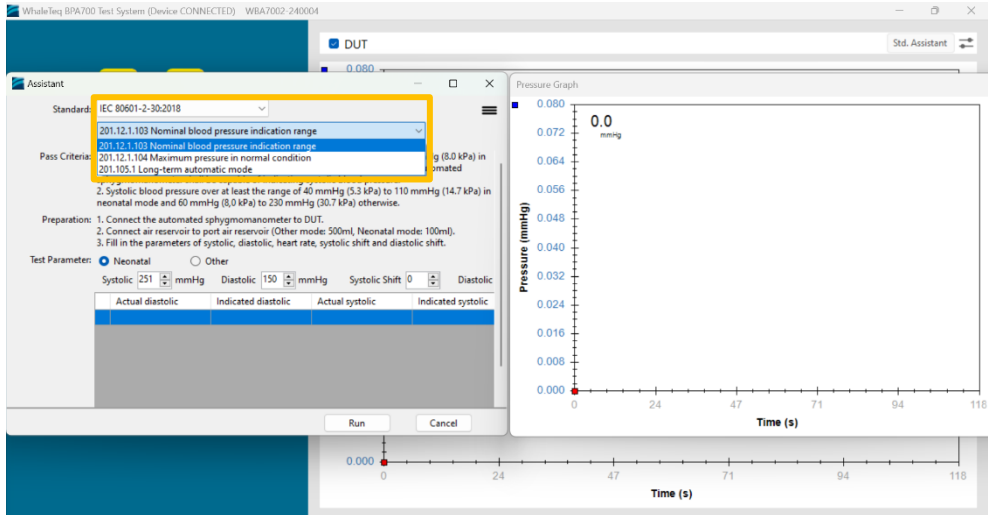


Figure 68: Select Medical Standard and Test Clause

(2) Click “Run” to start the test.

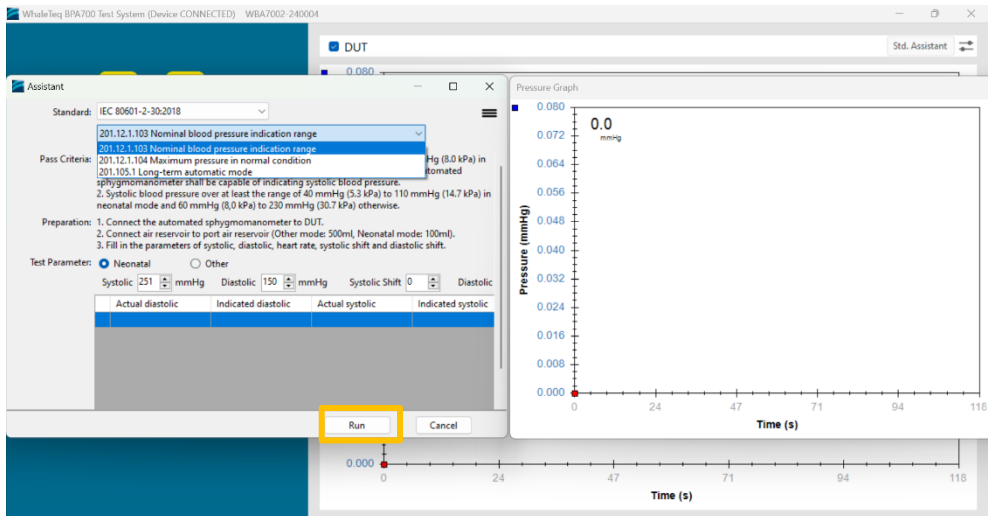


Figure 69: Click “Run” button

(3) Click “Finish” and the result will show on the table automatically.

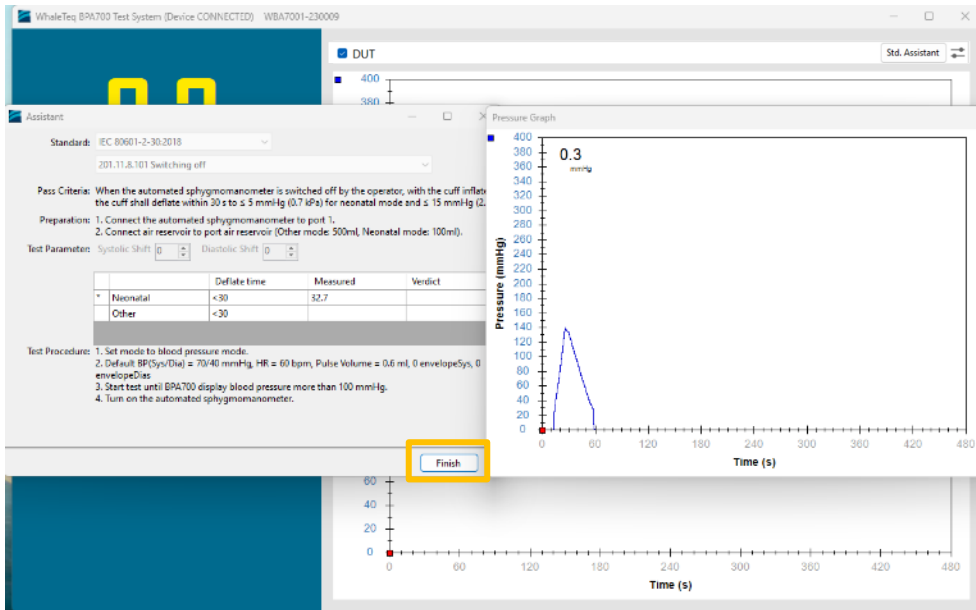


Figure 70: Click “Finish” to See the Test Result

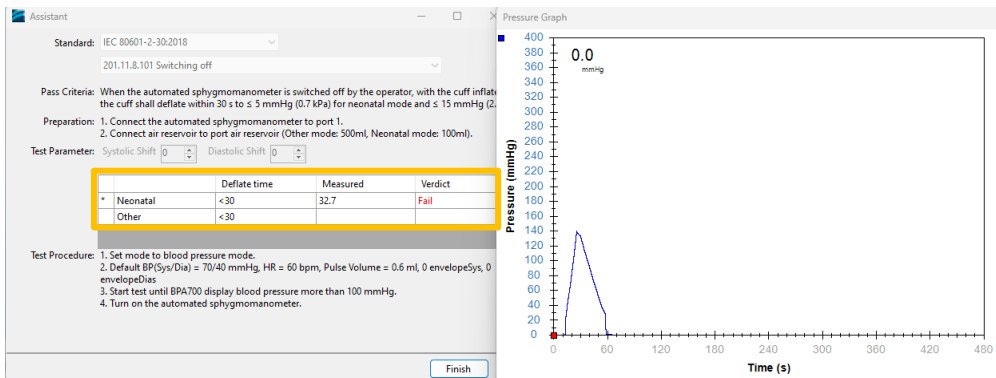


Figure 71: Test Result Shown on the Table

(4) You can either Load, Save, Export test report as HTML file, or Clear test results by clicking the right column.

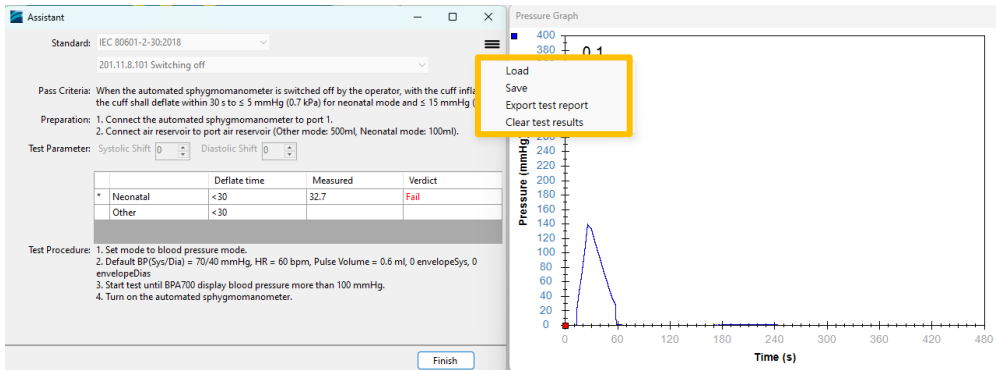


Figure 72: Different Function Tabs

Test Solutions Medical Device Manufacturers

IEC 80601-2-30:2018

201.11.8.101 Switching off

PASS CRITERIA:
When the automated sphygmomanometer is switched off by the operator, with the cuff inflated, the cuff shall deflate within 30 seconds to ≤ 5 mmHg (0,7 kPa) for neonatal mode and ≤ 15 mmHg (2,0 kPa) for other mode.

RESULTS:

	Deflate Time	Measured	Verdict
Neonatal	<30	23.1	Pass
Other	<30	56	Fail

201.11.8.102 Interruption of the supply mains

PASS CRITERIA:
When the supply mains to the automated sphygmomanometer is interrupted, the cuff shall deflate within 30 s to ≤ 5 mmHg (0,7 kPa) for neonatal mode and ≤ 15 mmHg (2,0 kPa) for other mode.
When the supply mains is restored, the automated sphygmomanometer:
a) shall continue in the same mode of operation and with all operator settings unchanged, or
b) shall
 1) remain Inoperative, and
 2) remain Inoperative, and

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Figure 73: Export Test Report

3 Software Development Kit (SDK)

WhaleTeq provides Windows SDK (Software Development Kit) for BPA700 test system. All test parameters correspond to specific SDK commands and DLL (Dynamic-link library) shared library can be used for efficient program binding and version upgrade. Support C/C++ header, C# interface, third-party tools, and script language integration such as Python.

4 Calibration and Validation

Both WhaleTeq BPA700 and software have been system verified, and reports can be provided according to user's needs.

Prior to shipping, each unit is tested for component values and output voltages, using a calibrated precision multi-meter. As WhaleTeq cannot provide ISO 17025 accredited calibration, laboratories which are required to follow ISO 17025 should perform calibration either periodically or on a before use basis, following normal procedures and practice. The extent of calibration may be limited depending on the needs of the laboratory.

It is recommended to calibrate BPA700 annually. Calibration and validation both require traceable equipment. Steps for Calibration/ Validation methods are available upon request. Please contact WhaleTeq for more details.

5 Troubleshooting

1. If the AP is not connected to the BPA700, check whether the cables are firmly connected.
2. If the dynamic pressure motor is not detected within 10s when power on, please contact WhaleTeq's service team.
3. If the BPA700 detects a pressure value of 440mmHg or more, stop the test and open all solenoid valves for venting and a warning screen will pop up.
4. If the test starts (test with pumping function) and the pressure does not exceed 2mmHg after 15s, the warning screen will appear.

6 Caution

1. Please warm up the BPA700 for 30 minutes before confirming that it has been turned on again.
2. Before using products, use a grounded wrist strap or touch a grounded safely object or a metal object, such as the power supply case, to avoid damaging them due to static electricity.
3. WhaleTeq does not recommend connecting test equipment with DUT to conduct an Electrostatic Discharge (ESD) test. This may cause unexpected damages to test equipment.
4. When operating the “Firmware Update”, there are risks of losing data if improper options are performed during the Firmware Update period.
5. Warranty void if QC PASS label is removed or tampered with.
6. Do not place the device where it is difficult to disconnect the power cord. It must be ensured that the user can operate the power cord at any time to quickly disconnect it when needed.
7. Connect properly and disconnect properly.

7 Ordering Information

7.1 Standard Package

Table 3: BPA700 Standard Package

Part No.	Description
100-BP00001	<p>Model No.: BPA700 Model Name: NIBP Simulator and Analyzer</p> <p>Package contents:</p> <ul style="list-style-type: none"> • USB Transfer Cable: Type-A to Type-B (Male to Male), 1.8m x1 • Tube (14cm) x2 • T-connector x1

7.2 Optional Accessories, Software and Services

- **Optional Software Add-on Pack**

Table 4: Optional Software

Part No.	Description
HA0-BP18001	Assistant Software
HE0-BP00001	Envelope Adjustment Software

- **Optional Accessories**

Table 5: Optional Accessory

Part No.	Description
S21-0500201	500ml Air Reservoir
S21-0100301	100ml Air Reservoir
5HA-BP18012	Tube (14cm)
E18-UN0Q060	T-connector

- **Optional Calibration Service and Warranty Extension**

Table 6: Optional Calibration Service and Warranty Extension

Part No.	Description
YY0007	Model No.: C3 Provides (3) years of calibration service coverage. WhaleTeq equipment can be calibrated to original performance on the basis of (1) year interval.

YY0008	Model No.: R3 Extends the limited warranty from (1) year to (3) years.
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8 Revision History

Table 7: Revision History

Version	Modified Contents	Issued Date
2023-06-15	First release	2023-06-15
2024-01-10	Update <ul style="list-style-type: none"> • 1.3 Hardware Overview • 1.5 Product Label • 2.12 Standard Assistant • 7 Ordering Information 	2024-01-31
2024-06-18	Update <ul style="list-style-type: none"> • BPA700 PC Software Installation • 2.8.1 Pressure Value Setting Rules • 2.10 Overpressure Test • 2.11 Play and Record Data 	2024-06-28
2024-11-15	Update <ul style="list-style-type: none"> • Software Interface Port 1 & 2 change to DUT • Hardware Change • 2.8.3 Customize method Shift Botton 2.11 Play Data Operation Settings	2024-12-04

9 Contact WhaleTeq

WHALETEQ Co., LTD

service@whaleteq.com | (O)+886 2 2517 6255

8F., No. 125, Songjiang Rd., Zhongshan Dist., Taipei City 104474, Taiwan