❀Hadeco

OPERATING MANUAL

Smartdop XT
(6 ports)
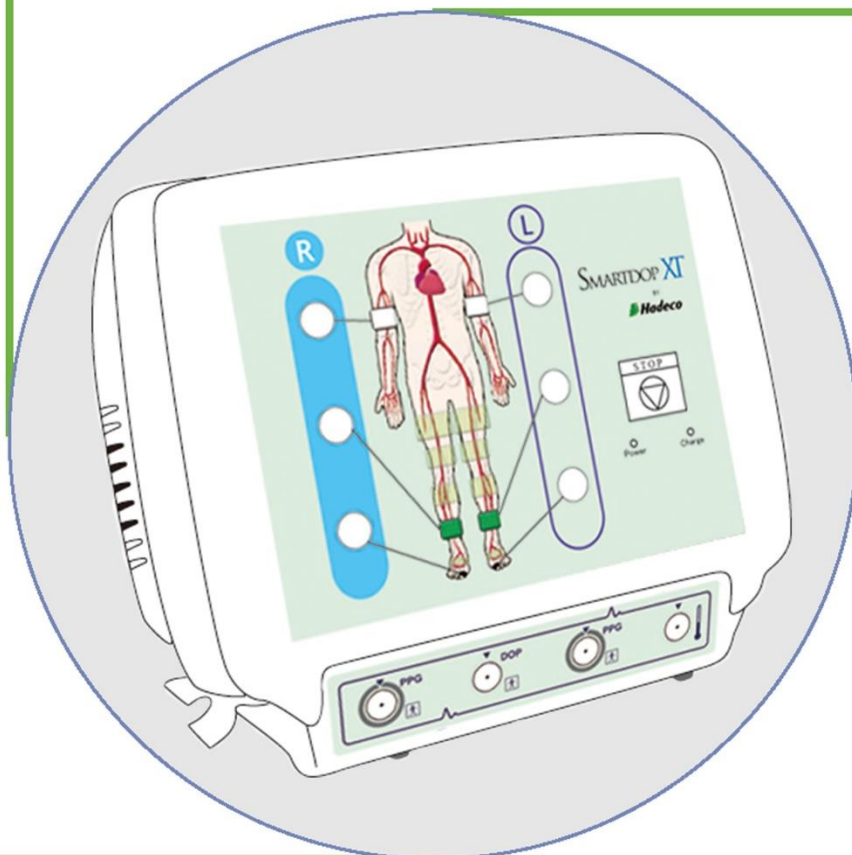## with Smart-XT-Link

Table of Contents

Cautions

Please read the following important points carefully before you operate the unit.

1. Only skilled people should operate the unit.

2. Use the unit for intended use described in "§1-2. Clinical applications".

3. Do not modify the unit.

4. Device placement:
   Take care of storage and operating environments.
   (1) Do not place it near water.
   (2) Do not put anything where disconnecting power supply of the unit could be obstructed.
   (3) Do not place it where atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salt, sulfur and so forth will affect the unit adversely.
   (4) Pay attention to the stability conditions to avoid too much inclination, vibration, shock and so on during transportation and installation of the unit.
   (5) Do not place it where chemicals are stored or where gas may be generated.
   (6) Do not place it where the unit tends to fall.
   (7) Do not place it on or adjacent other electronic device.

5. Before use:
   (1) Make sure that the computer works properly for Smart-XT-Link.
   (2) Make sure that the unit operates safely and correctly by implementing simple check before use mentioned in "§ 6-1. Performance check by user".
   (3) Make sure that all cables and components are connected correctly and safely.
   (4) Using it with other equipment together may cause a misdiagnosis or danger to patient due to a malfunction.
   (5) Double-check that all the cables and components do not obstruct any external connection to the patient.
   (6) Do not sterilize the main unit by gas, autoclave or so on to prevent any damage.

6. Operation:
   (1) Do not use the unit simultaneously with either electric cautery, cardioverter, other ultrasonic device or mobile phone.
   (2) Be careful not to exceed time and volume of diagnosis treatment required.
   (3) Always watch so the unit and patient are not under abnormal conditions.
   (4) When any abnormality is found on the unit or the patient, take proper action such as stopping use of the unit in a manner safe for the patient.
   (5) In case of emergency or unexpected situations, take the following action(s) to stop the inflation of the cuffs:
       • Press STOP button on the front panel of the unit.
       • Disconnect the tubing of cuff from the unit.
       • Turn the unit off.
   (6) Do not let the patient touch the unit.
   (7) Use the designated components only.

(8) Do not use the components for other devices.
(9) Use the unit under the operating environments specified on the specifications.
(10) Use the unit as specified in the operating manual.
(11) Do not use the unit in a strong electromagnetic field or it may cause incorrect measurements.

7. After use:
   (1) Do not extensively pull the cable(s) while disconnecting or it may cause damage.
   (2) Clean the unit, tubing, probes and AC adaptor and place them in right place for the next use.

8. Storage:
   (1) Follow the caution (1) to (5) of section #4 in the previous page.
   (2) Clean the unit, components, cables and probes and place them in right place for the next use.
   (3) When using the unit next time, perform the maintenance to make sure it works properly and safety.

9. Maintenance:
   (1) Do the periodical maintenance by following the procedures mentioned in "§6-1. Performance check by user".
   (2) The maintenance must be done at least once a year.

10. Probes:
   (1) Clean the probe using damp cloth before use. Using alcohol or thinner may damage the probe.
   (2) The probe transducer tip is very thin and delicate. Please handle with great care and use the probe cap when not in use.

11. Ultrasonic gel:
   (1) Do not apply ultrasonic gel to the Doppler probe body other than the tip of probe
   (2) Using other materials such as baby oil and cream may damage the probe.
   (3) The ultrasonic gel enclosed is non-sterile and do not use it for surgeries.
   (4) Incidence of allergy: Discontinue use of gel if an allergic reaction occurs.

12. Battery:
   (1) When battery is low, the power indicator blinks in green. If it's extremely low, the unit will not operate. Charge the battery.
   (2) Battery life is 300 full charges. When full charged life becomes obviously short, contact your dealer for replacing battery.

13. For transportation of the unit, it should be packed properly to protect against shock.

14. Repair services:
   (1) When the unit gets out of order, contact the dealer for repair from whom you purchased the unit.
   (2) Only authorized people should perform the repair services.

15. Do not disassemble the unit.

16. Destruction:
    (1) In case of destruction of the unit, follow the instructions for disposal of the destruction appointed by each country or local government.
    (2) Do not throw battery in a fire or it may cause an explosion and injury.

17. Connection to computer:
    (1) Any connected computer is not allowed to be in the patient area according to IEC60601-1.
    (2) Use the computer confirming with IEC60601-1 to connect to the unit.
    (3) Connection of the connected computer to a network that includes other equipment such as network printer could result in previously unidentified risks to patients, or operators and the user of the unit should identify, analyze, and control such risks.
    (4) Subsequent changes to network could introduce new risks and require new analysis; and changes to network include:
        (a) Connection of additional items to network
        (b) Disconnecting items from network
        (c) Update of equipment connected to network
        (d) Upgrade of equipment connected to network

1. Introduction

Thank you very much for choosing the Smartdop XT.

The Hadeco Smartdop XT is a fully automatic total vascular testing system for ABI and TBI studies that works with a Windows software Smart-XT-Link including automated blood pressure & pulse volume measurement capabilities for up to 6 sites with simple one-button operation as well as up to 14 sites with rolling basis segmental testing.
Please read this manual carefully to acquaint yourself with the unit operation.
This medical device can be used for the purposes mentioned in "Clinical Applications" for patients in hospitals and clinics.

1-1. Features
◆ One button operation for up to 6-site automatic blood pressure measurements by oscillometry & PPG for ABI, TBI.
◆ Up to 6-site semi-automatic blood pressure measurements by Doppler & PPG for ABI & TBI along with Doppler.
◆ Segmental blood pressures for up to 14 sites with rolling basis operation
◆ PPG Venous reflux study with dual PPG probes.
◆ All tests controlled & stored by computer with Smart-XT-Link for Windows that includes capabilities to print waveform data and export to DICOM.

1-2. Clinical applications
◆ ABI and TBI studies
◆ PEAK & MEAN blood velocity determinations
◆ Detection of arterial and venous blood flow velocity for vascular disease

1-3. System requirements
MAIN UNIT: Smartdop XT
SOFTWARE: Smart-XT-Link for 6 ports for Windows
COMPUTER

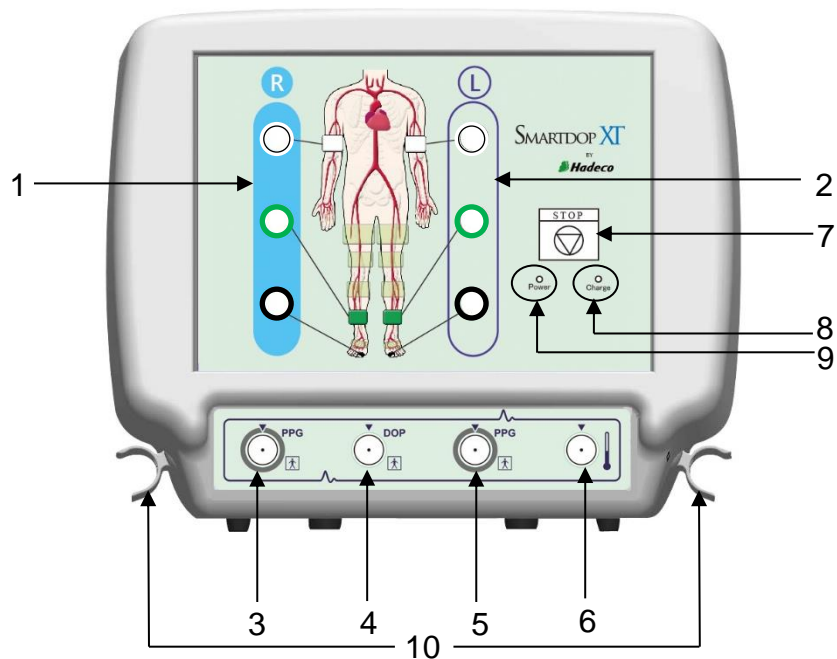|	OS:	Windows 7/ 8.1/ 10 (Except Tablet PC)
	Display:	800 x 600 dots or more
		256 colors or more
	USB:	USB2.0

2. Appearance

2-1. Smartdop XT

Front view

| 1	Inflation ports for right side	To connect extender tubes for right side cuffs
2	Inflation ports for left side	To connect extender tubes for left side cuffs
3	PPG probe connector for right side	To connect right PPG probe
4	Doppler probe connector	To connect Doppler probe, option
5	PPG probe connector for left side	To connect left PPG probe
6	Foot temperature probe connector	To connect foot temperature probe, option
7	Stop button	To stop testing and dump all cuffs immediately while in measurement
8	Charge indicator	To indicate battery charging status as follows; ● Orange LED: Charging battery with AC adaptor ● LED turns off: When battery fully charged (See "§3-1. Charging battery" for details.)
9	Power indicator	To indicate the power status as follows; ● Green LED: Unit turned on ● Green LED blinking: Low battery ● LED turned off: Unit turned off
10	Probe holder	To place optional Doppler/ temperature probe when not in use

Side view
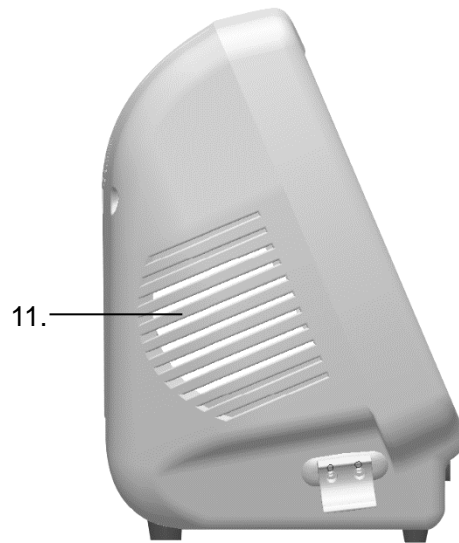
11	Speaker	To output sounds

Note: Sound volume can be adjusted on each testing screen of Smart-XT-Link software.
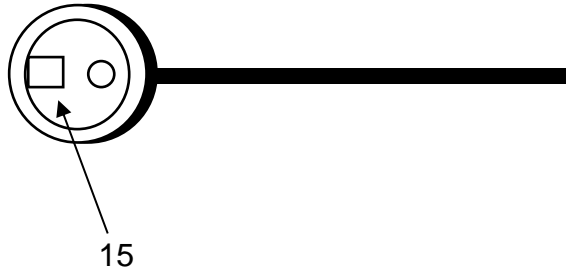
Rear view

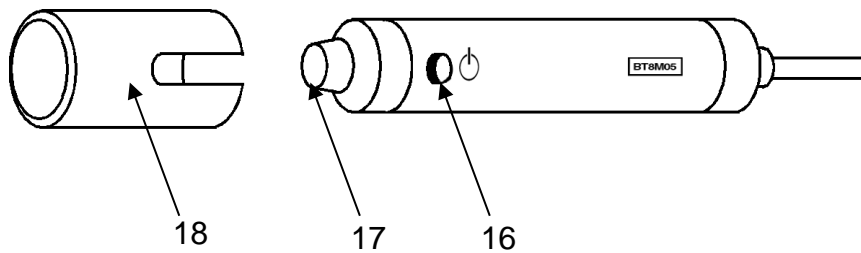| 12	Power switch ON: OFF:	To turn the unit ON and OFF
13	AC adaptor connector ---	To connect designated AC adaptor
14	Serial port	To connect computer with designated USB cable

2-2. Probes

PPG probe

Model: PG-01

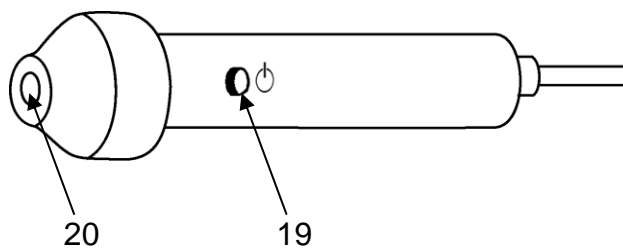

15

Doppler probe (Option)

Model: BT*M05S8C (A)   *Frequency

18   17   16

## Temperature probe (Option) *Except European Union Countries

Model: TP-01

20   19

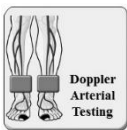| 15	PPG transducer	To detect toe PPG waveforms for toe and transmetatarsal pressures
16	Doppler probe button	To freeze and unfreeze the waveform
17	Doppler transducer	To detect blood velocity
18	Probe cap	To protect the transducer tip when not in use
19	Temperature probe button	To record the temperature
20	Temperature transducer	To detect temperature

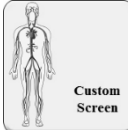# 2-3. Smart-XT-Link for 6 ports for Windows
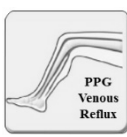
Main screen

Menu bar

Launcher icons
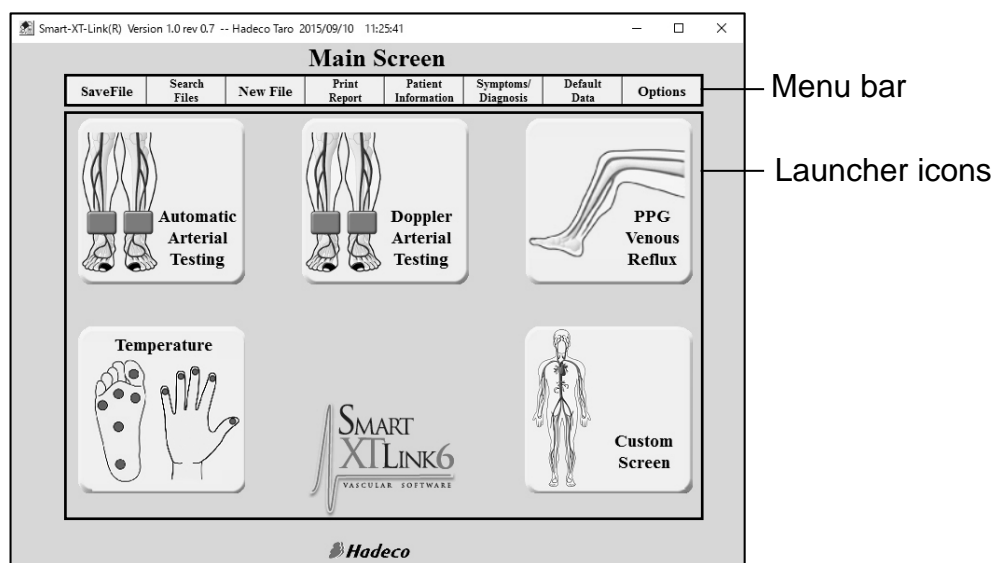
Menu bar

Save File	To save data file
Search Files	To search data files to open
New File	To create new patient file
Print Report	To print report or export it to PDF file
Patient Information	To input patient data
Symptoms/Diagnosis	To input symptoms and diagnosis for patient
Default Data	To input and/or revise Default Data: Facility data, Performing Studies and Requesting Physician
Options	To set optional settings for CommPort, Language, DICOM®, data folder and others

Launcher icons

	Automatic Arterial Testing		Temperature
	Doppler Arterial Testing		Custom Screen
	PPG Venous Reflux		

3. Getting started

3-1. Charging battery

(1) Turn the unit off and plug the AC adaptor to it to charge the battery.
  The Charge indicator will turn to orange while charging is in progress.
(2) When the battery is fully charged, the orange Charge indicator will be turned
  off. Unplug the AC adaptor.

Note: When the battery is low, the green Power indicator blinks. Use the designated AC
    adaptor for charging.

3-2. Software installation

3-2-1. Installing Smart-XT-Link

(1) Connect the **Smart-XT-Link for 6 ports USB stick** to the USB port of
  your computer.
(2) Double-click Setup.exe in the USB device in which Smart-XT-Link USB is
  connected, to install Smart-XT-Link software. Follow the instructions of
  the installer.
(3) When installation process is completed, Smart-XT-Link will start
  automatically with Default Data screen.

3-2-2. Installing USB Cable Driver

(1) Connect the **Smart-XT-Link for 6 ports USB stick** to the USB port of
  your computer.
(2) If automatic installer **Smart-XT-Link for 6 ports Ver1.0 installation**
  pops up, click on **Cancel**.
(3) Connect the Smartdop XT to your computer by using the USB cable
  enclosed.
  The following procedures depend on your Windows version as follows:

Windows 7 and 8.1
(4) A shortcut for "Windows 7 and 8 Driver Installation" will be created
  automatically on the desktop when Smart-XT-Link installation is
  completed. Click it and follow the instructions.

Windows 10
 (4) USB Driver will be installed automatically.

3-2-3. Uninstalling Smart-XT-Link

(1) Before uninstalling Smart-XT-Link, copy all the waveform data saved on
  the **WaveData** folder for future reference.
  The initial **WaveData** is located in **C: \Hadeco \SXTLink6_1.0**. (Default)

Windows 7 and 8.1
(2) Select **Hadeco\Smart-XT-Link6 Ver1.0\Uninstall Smart-XT-Link6
  Ver1.0** on Program menu to uninstall Smart-XT-Link.

Windows 10
 (2) Select **Hadeco\Uninstall** on All apps to uninstall Smart-XT-Link.

4. Testing

4-1. Starting operation

(1) Connect the USB cable to the unit.

Note: Use the designated USB cable, attached as the standard accessory.

(2) Connect the other side of the cable to USB port of the computer.

(3) Turn the unit on.

(4) Start Smart-XT-Link and **Patient Information** screen will appear.

(5) Type the patient information or you may do it later.

Note: Click the pull-down menu next to "Date of Birth" and select the date format you desire for Patient Information screen and it will be used for both "Date of Birth" and "Test Date" of all patient information. Default setting is MM/DD/YYYY.

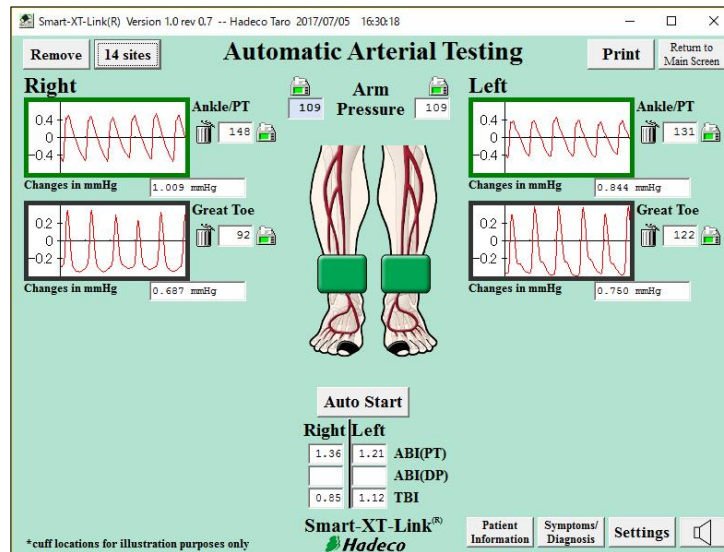(6) Click **Save** to save the information and it will go to Main Screen.

(7) Click **Options** and do **Search Comm** once to search for COM port where the unit is connected and Smart-XT-Link will show the COM port #. Do the other settings desired on Option Screen. (See section "§5-8. Option Screen" for more details.)

(8) Click **Return to Main Screen**.

Note: Smart-XT-Link does not support both Windows power options of Sleep and Suspend and thus disable the options while using the software.

4-2. Automatic Arterial Testing (Oscillometry)

Automatic Arterial Testing includes ABI, TBI and PV-Arterial studies for up to 6 sites with simple one-button operation. PPG and oscillometry are used for taking blood pressures on great toes, ankles and Arms, respectively.


4-2-1. Preparations

(1) Get the necessary components ready as the following example for 6 sites:

Cuffs (Option)	VC-10H: 4 pcs.	For brachia and ankles
	DVC-1.9H: 2 pcs.	For great toes
Tubing	2 tubing each color x 3 sets; White for Arm, Green for Ankle/PT, Black for Great toe (Tubing with blue mark at both ends are for the right side)	
PPG probe	PG-01 x 2 pcs.	
PPG clip	PPG Clip x 2 pcs.	

(2) Click **Automatic Arterial Testing** launcher icon on Main Screen.

(3) **Settings**
Click **Settings** button on Automatic Arterial Testing screen and set each setting as follows.

8
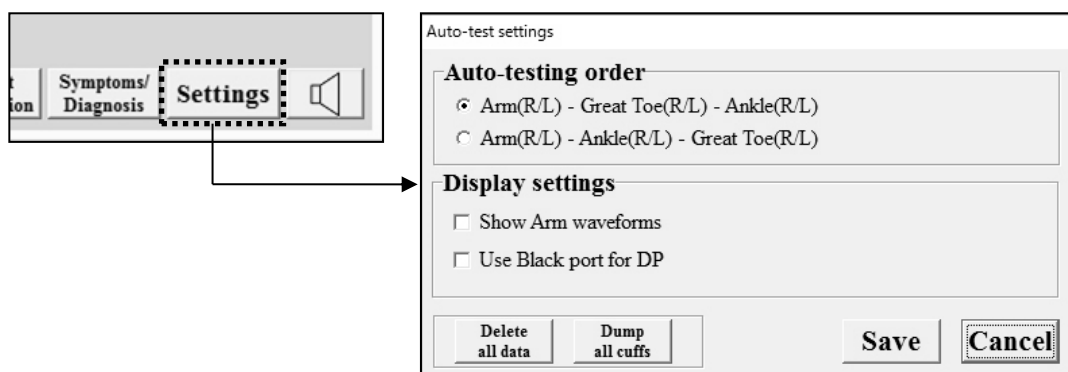
Auto-testing order:
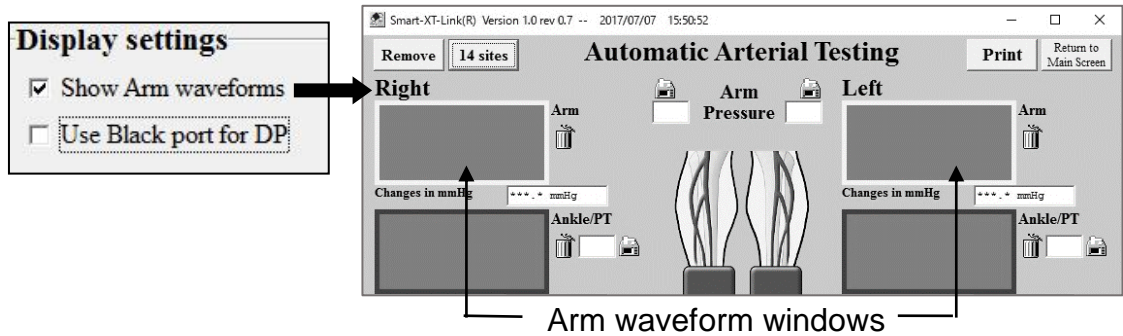No.1: Arm (R/L) - Great Toe (R/L) - Ankle (R/L)
No.2: Arm (R/L) - Ankle (R/L) - Great Toe (R/L)
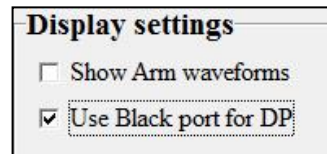Default setting is No.1.

Display settings:
■ **Show Arm waveforms:**
Check it to show arm waveform windows on the screen.

Arm waveform windows

■ **Use black port for DP:**
Check it when you wish to use the black ports for taking transmetatarsal
waveforms and DP pressures instead of toe measurements.

Click **Save** to set the settings.

Delete all data:
Click **Delete all data** to delete all waveform data on the screen.

Dump all cuffs:
Click **Dump all cuffs** to dump all cuff.

(4) **Sound adjustment**
Click Sound button and select **R** or **L** side from where waveform sounds
come out from the speaker and move the slider to adjust the sound volume.
Check the Mute check box to mute the sound volume.

Select **R** or **L**.

Slider
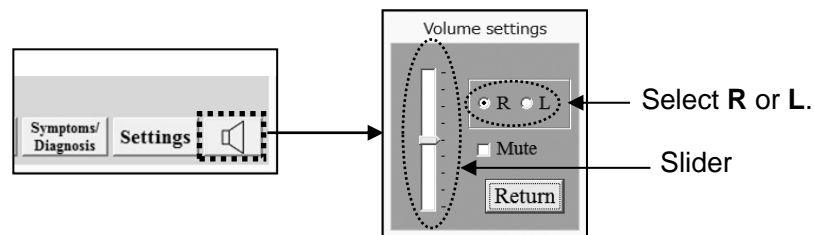
Note: No sounds during oscillometry testing.

(5) **Removing waveform window(s)**
To remove waveform window(s) you do not use, click each trash can 🗑 next to the window, clicked can becomes f⬤ , and then click **Remove** button to proceed.

┌─ Remove button

Trash can
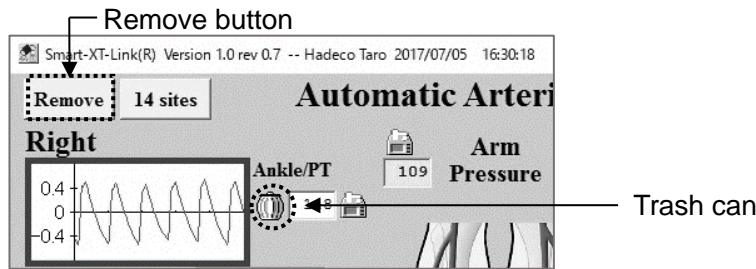
Note: Click [14 sites] & [6 sites] buttons to get the removed window(s) back.

4-2-2. Starting Automatic Arterial Testing

(1) Wrap cuffs snugly on each side of brachium, ankle, and great toe.

Note: Use appropriately sized cuffs for each patient.

(2) Hook up each color coded tubing between cuff and the inflation port with the same color as tubing's for each site.

Toe cuff

(3) Connect 2 PPG probes to the unit and affix each PPG transducer with clear side against the pad of each great toe with PPG probe clip.

Clip PPG probe
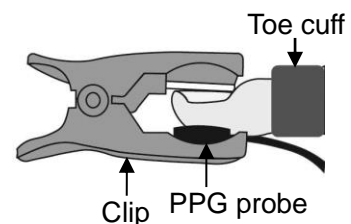
Note: PPG probe is used for taking great toe and transmetatarsal/DP pressures.

(4) Click **Auto Start** button and auto-testing will start on both sides simultaneously in the order selected in Auto-testing order.

Red star mark(s) ⭐ appears to let you know for which site(s) will be taken.

When each testing is completed, the blood pressure value and waveform will be shown in blood pressure box and waveform window, respectively, as shown below.

Blood pressure

Waveform
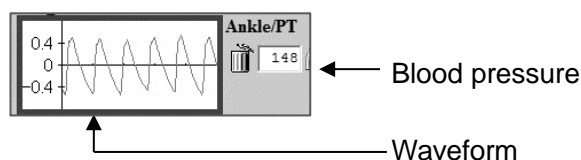
Note: **Auto start** button will change to **Stop** button while in testing. Click **Stop** button to stop the testing.

Note: For legs, PV testing is performed prior to each blood pressure testing.

(5) When all tests are completed, the dialog box as shown below will appear.

Click **OK** to close it and ABI and TBI will be calculated automatically during the tests. After all testing is completed, Smartdop will dump all cuffs with beeping automatically.
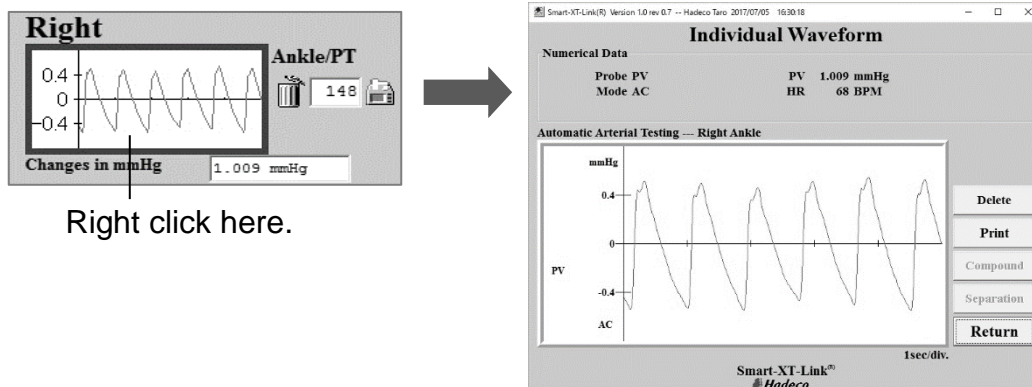
Note: ABI = (Ankle pressure) / (Brachial pressure)
     TBI = (Toe pressure) / (Brachial pressure)

Enlarging waveform

Right click one of waveform windows to enlarge it and the Individual waveform screen will appear for waveform analysis.
- Click **Delete** to delete the waveform.
- Click **Print** to print out the waveform data.
- Click **Return** to go back to previous screen.

Right click here.

Manual testing

Each site can be manually tested as follows:

Manual testing of PV waveform:
(1) Click the PV waveform window where you wish to test manually and Smartdop will start PV testing.

Manual testing of blood pressure testing:
(1) Click the pressure icon 🗐 where you wish to test manually.
(2) Select **Take pressure** in pull-down menu to start testing.


Select **Take pressure**

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4-3. Further segmental studies

If desired, further blood pressure segmental studies can be performed with the Smartdop on rolling basis operation for up to 14 sites on both Automatic Arterial Testing and Doppler Arterial Testing screens.

4-3-1. Preparations

(1) Click 14 sites button on the testing screen to show 14 each of blood pressure box and waveform window.

14 sites button
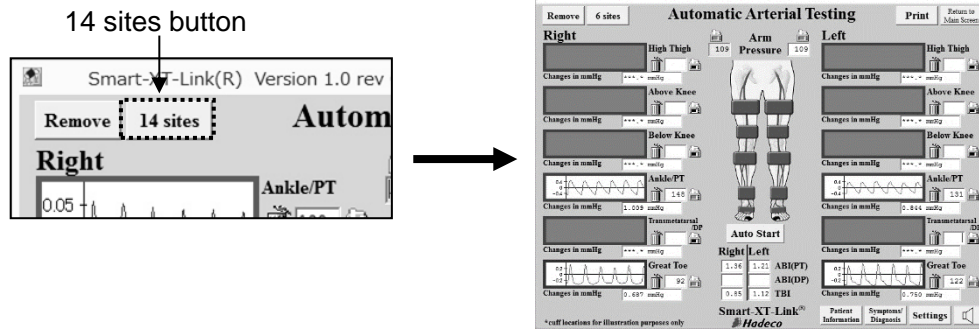
Note: The green inflation ports for ankles will be used for the segmental testing at high thigh, above knee, below knee, and transmetatarsal/DP as well as ankle/PT.
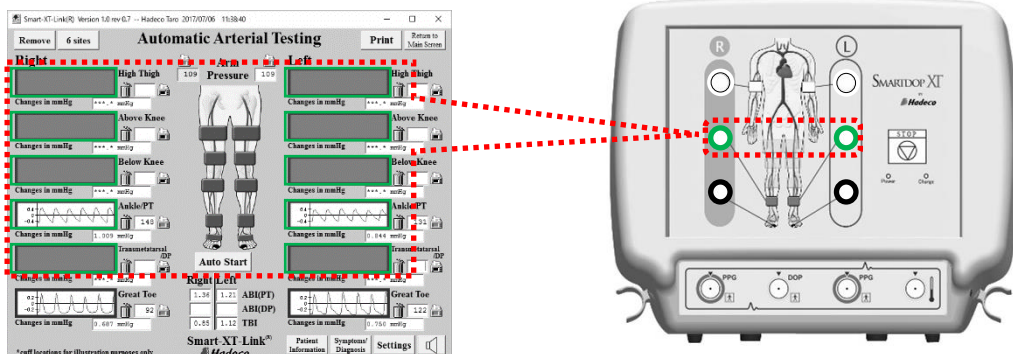
Note: Even if the check box "Use Black port for DP" is being checked on "Settings", the black inflation ports will still have to be used for great toes for segmental testing.

(2) Click **Settings** button and set the Auto-testing order and click **Save** to set the settings.

(3) **Sound adjustment**
    See the step# (4) in the "§4-2-1. Preparations" for sound adjustment.

(4) **Removing waveform window(s)**
    See the step# (5) in the "§4-2-1. Preparations" for removing the window(s).

4-3-2. Starting segmental studies

(1) Wrap cuffs, tubing and PPG probes
ready for the testing sites.

(2) Click **Auto Start** button to start
auto-testing and follow the guidance to
proceed.
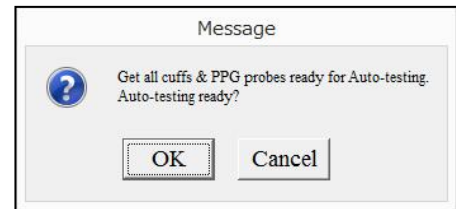
Red star mark(s) ⭐ appears to let you
know for which site(s) you should get the
cuff(s) ready.
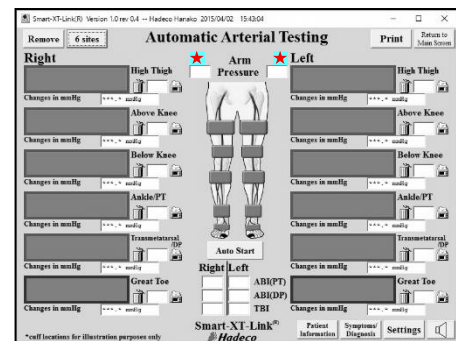
Note: PPG probe must be used for taking great toe and transmetatarsal pressures.

Note: **Auto start** button changes to **Stop** button while in testing. Click **Stop** button to stop
the testing.

Note: On Doppler Arterial Testing, ankle cuff is used
for taking transmetatarsal/DP pressure as
shown in the right.
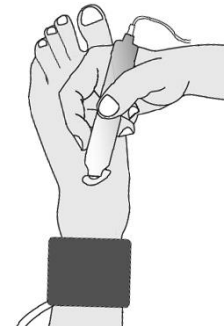
(3) When all tests are completed, the dialog
box as shown right will appear. Click **OK**
to close it.
Smartdop will dump all cuffs
automatically while beeping.

4-4. Doppler Arterial Testing

Doppler Arterial Testing includes ABI, TBI and PV-Arterial studies for up to 6 sites with semi-automatic simple operation. PPG and Doppler probes are used for taking blood pressures on great toes, ankles and Arms, respectively.

<Doppler Arterial Testing screen>

4-4-1. Preparations

(1) Get the necessary components ready as the following example for 6 sites:

Cuffs (Option)	VC-10H: 4 pcs.	For brachia and ankles
	DVC-1.9H: 2 pcs.	For great toes
Tubing	2 tubing each color x 3 sets; White for Arm, Green for Ankle/PT, Black for Great toe (Tubing with blue mark at both ends are for the right side)	
PPG probe	PG-01 x 2 pcs.	
PPG clip	PPG Clip x 2 pcs.	
Doppler probe (Option)	8MHz Doppler probe x 1pc. See "§7-3. Options"	
Ultrasonic gel (AQUA ULTRA BASIC) for Doppler testing (Option)		

(2) Click **Doppler Arterial Testing** launcher icon on Main Screen.

(3) **Settings**
Click **Settings** button on Doppler Arterial Testing screen and set Doppler-test settings as follows.
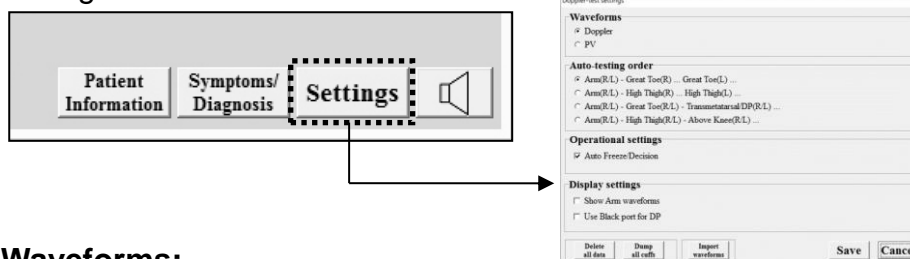
Waveforms:
Select **Doppler** or **PV** which is used for waveform testing.

14

Auto-testing order:
Select the Auto-testing order desired from following 4 orders:

No	Auto-testing order for Doppler Arterial Testing
1	Arm (R/L) – Great toe (R) - Ankle/PT (R) - Great toe (L) - Ankle/PT (L)
2	Arm (R/L) - Ankle/PT (R) - Great toe (R) - Ankle/PT (L) - Great toe (L)
3	Arm (R/L) - Great Toe (R/L) – Ankle/PT (R/L)
4	Arm (R/L) - Ankle/PT (R/L) – Great Toe (R/L)

It setting differs depending on which **Doppler** or **PV** is used for waveform testing as follows;
- When **Doppler** is used for waveform testing: No.1
- When **PV** is used for waveform testing: No.3

Operational settings:
■ **Auto Freeze / Decision**
Check the check box to freeze the waveform and save the testing data automatically when waveform becomes stable.

Display settings:
■ **Show Arm waveforms:**
Check it to show arm waveform windows on the screen.

■ **Use black port for DP:**
Check it when you wish to use the black ports for taking transmetatarsal waveforms and DP pressures instead of toe measurements.

Click **Save** to set the settings.

Delete all data:
Click **Delete all data** to delete all waveform data on the screen.

Dump all cuffs;
Click **Dump all cuffs** to dump all cuffs.

Import waveforms:
When you click **Import waveforms**, the dialog box as shown right will appear.
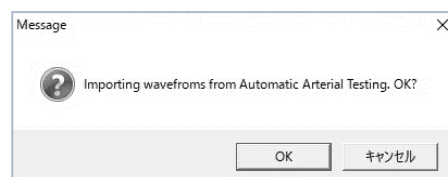
Click **OK** to copy and import stored PV waveforms from **Automatic Arterial testing**.

(4) **Sound adjustment**
See the step# (4) in the "§4-2-1. Preparations" for the details.

(5) **Removing waveform window(s)**
See the step# (5) in the "§4-2-1. Preparations" for removing the window(s).

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4-4-2. Starting Doppler Arterial Testing

(1) Wrap cuffs snugly on each site of brachium, ankle and great toe.

Note: Use appropriately sized cuffs for each patient.

(2) Hook up each color coded tubing between cuff and the inflation port with the same color as tubing's for each site.

Toe cuff

Clip   PPG probe

(3) Connect 1 Doppler and 2 PPG probes to the unit and affix each PPG transducer with clear side against the pad of each great toe with PPG probe clip.

(4) Click **Auto Start** button to start Auto-testing and dialog box as shown in the right will appear.
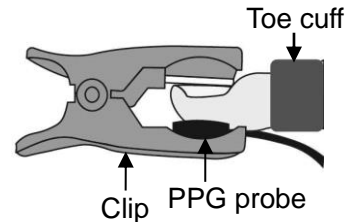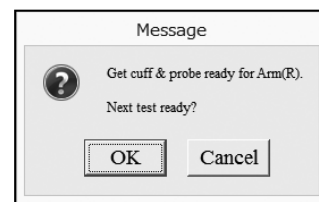
Red star mark(s) ★ appears to let you know for which site(s) you should get the cuff(s) and (or) probe ready.

Message

Get cuff & probe ready for Arm(R).

Next test ready?

OK   Cancel

(5) Click **OK,** hit Space bar or press the probe button to start auto-testing.

Note: **Auto start** button changes to **Stop** button while in testing. Click **Stop** button to stop the testing.

(6) When taking blood pressures except great toe, follow the guidance with site name shown on upper left of monitoring screen to perform the testing.

Smart-XT-Link(R) Version 1.0 rev 0.4 -- Hadeco Hanako 2016/01/28   16:26:34

Pressure Monito

Right Arm

Place Doppler or PPG probe at testing site.
Get waveform stable and cuff inflation will start automatically for taking blood pressure.
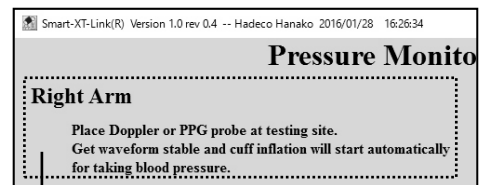
Guidance

Note: All the PV testing is performed prior to blood pressure testing.

Note: For Doppler testing, put ultrasonic gel on tip of Doppler probe. Place the probe to the artery with an angle of 45 to 60 degrees and move it slowly to locate the point where the maximum sounds are heard. Adjust sound volume if necessary.

60°

Blood Flow
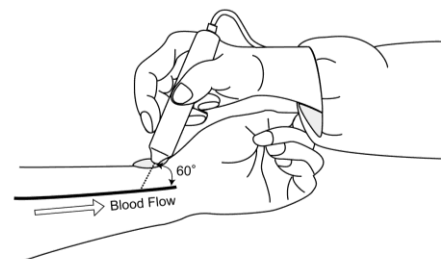
Note: Smartdop always restart Auto-testing by re-clicking **Auto Start** from where any testing has been cancelled.

(7) When all tests are completed on Doppler
    Arterial Testing screen, the dialog box as
    shown right will appear. Click **OK** to close
    it
    and ABI and TBI will be calculated
    automatically during tests.
    After all testing is completed, Smartdop will dump all cuffs automatically while
    beeping.

Note: ABI = (Ankle pressure) / (Brachial pressure)
      TBI = (Toe pressure) / (Brachial pressure)

Enlarging waveform

PV/ blood velocity waveforms: Right click one of waveform windows. See
                              "Enlarging waveform" of "§4-2-2. Starting Automatic
                              Arterial Testing".

Blood pressure waveforms: Right click one of pressure icons and click **Show
                              Waveform** to enlarge the waveform.

Click **Show Waveform**
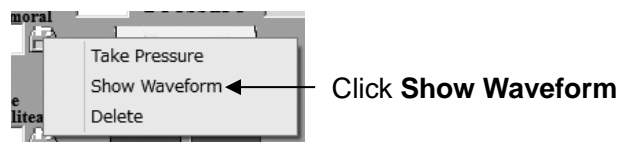
Manual testing

Each site can be manually tested in the same manner as other testing.
See "Manual testing" in the "§4-2-2. Starting Automatic Arterial Testing" for
more details.

4-4-3. Further segmental studies

If desired, further blood pressure segmental studies can be performed with the
Smartdop on rolling basis operation for up to 14 sites on both Automatic Arterial
Testing and Doppler Arterial Testing screens.
See "§4-3. Further segmental studies" for Automatic Arterial Testing.

4-4-4. Monitoring screen

Each of monitoring screens will show up while performing Doppler blood pressure testing or individual waveform testing of blood velocity, PV and PPG on Doppler Arterial Testing screen as follows:

<Pressure Monitor for Doppler>

<Velocity, PV, and PPG waveforms>
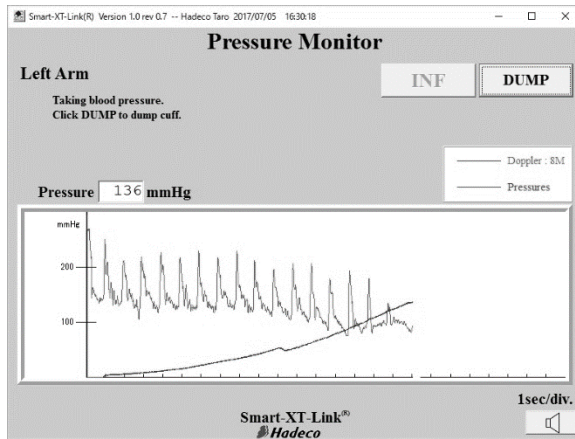
4-5. PPG Venous Reflux

PPG Venous reflux study is performed to assess valvular competence by measuring the time required for venous refilling after calf veins have been emptied through exercise.

<PPG Venous Reflux screen>
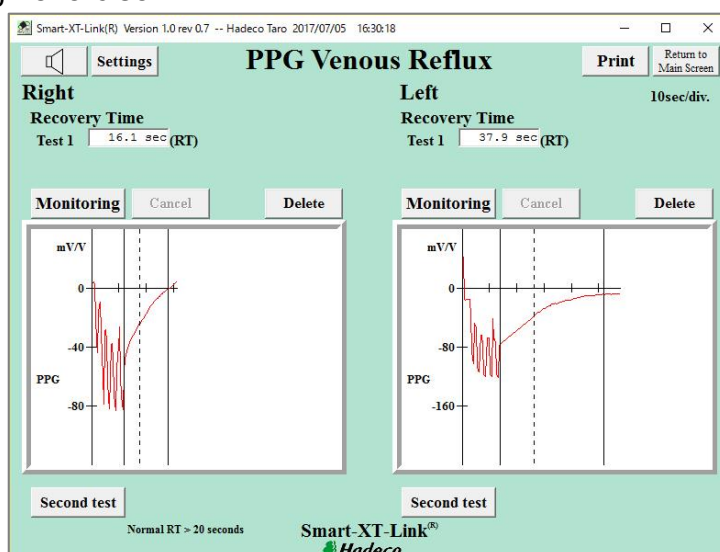
4-5-1. Preparations

(1) Prepare the following components;
- PPG probe: PG-01 x 2 pcs.

(2) Click **PPG Venous Reflux** launcher icon on main screen to go to PPG Venous Reflux screen.

(3) Click **Settings** button on the screen and set PPG Venous Reflux settings as follows.
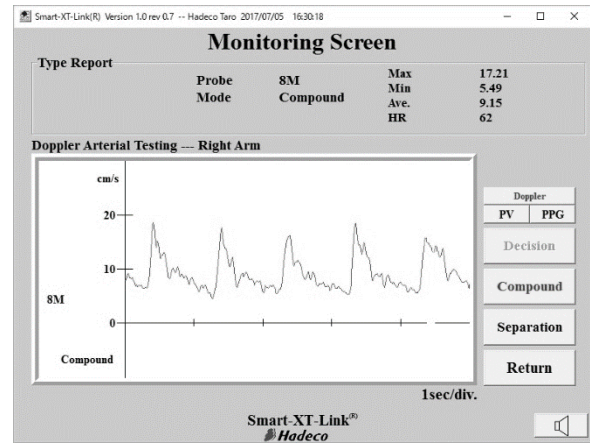
Test mode:
Select either "**Single test**" or "**Dual test**" for testing right and left legs separately or simultaneously, respectively.

Count:
Type the number of times for patient dorsiflexes.

1/2RT:
Check the checkbox to show the 1/2RT half recovery time values on the screen, returning to 50% of refilling amplitude where vertical dotted line is shown.

Click **Save** to set all the settings.

Delete all data:
Click it to delete all waveform data on the screen.

(4) **Sound adjustment** 🔲
See the step# (7) in the "§4-2-1. Preparations" for sound adjustment.

4-5-2. Starting PPG Venous Reflux study

(1) Connect 2 PPG probes to the unit.

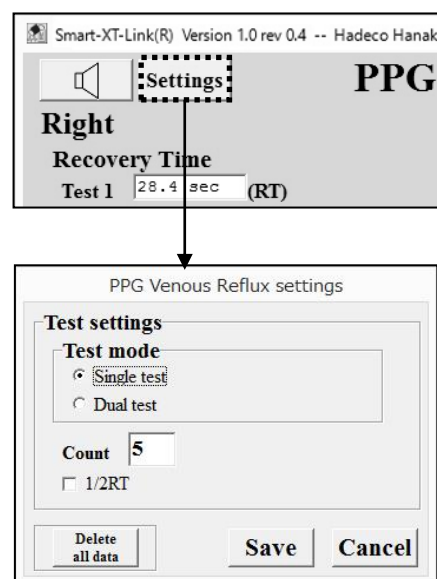(2) Have the patient sit on an examination
table so that feet are off floor.

(3) Apply the PPG transducer with the clear
side against the skin surface to the
medal malleolus over the posterior tibial
vein. Fix the PPG transducer in place
with tape.

Fix PPG transducer
with tape.

(4) Click one of **Monitoring** buttons or
waveform windows to start monitoring
the waveform.

(5) When patient is ready, click **Start Test**
button to start venous reflux study.

(6) Ask patient to flex his foot synchronizing
with beep sound as many as count
number being set on the settings.
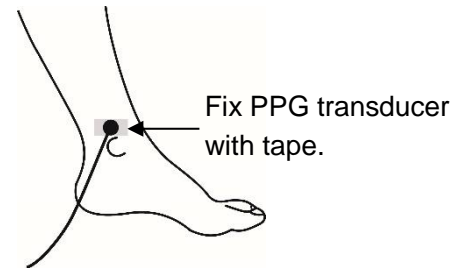
Click **Cancel** to cancel testing if
necessary.
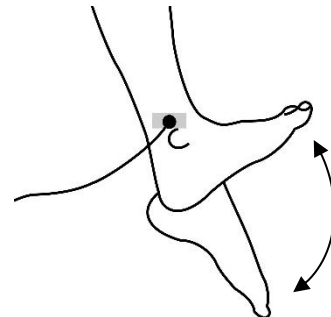
When an appropriate waveform returns
to the base-line amplitude, it will
automatically freeze and save the
waveform and show **Recovery Time**.

(7) Repeat steps # (4) to (5) on the other
side or on the second test.

Note: Beep sound is heard from the speaker of computer.

Note: Click **Second test** to add second test
window(s) on the screen if necessary.
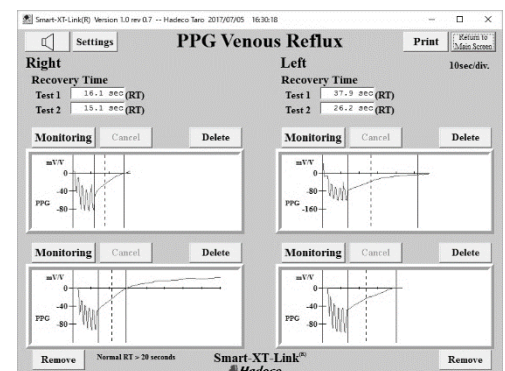
4-6. Temperature (Except European Union Countries)

This screen is to record several temperatures on each foot or finger through temperature probe as well as typing in manually through keyboard. Extra temperature boxes are available for other sites.

<Foot temperature screen>
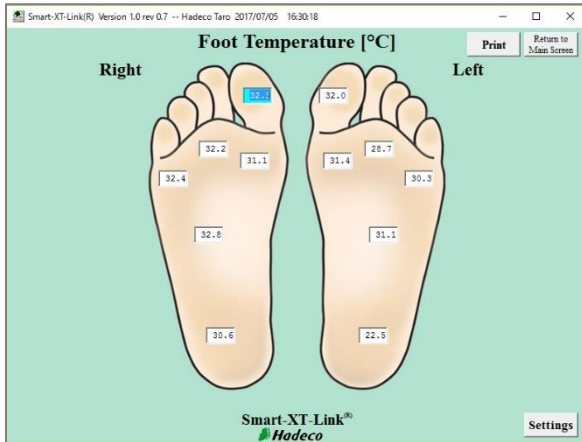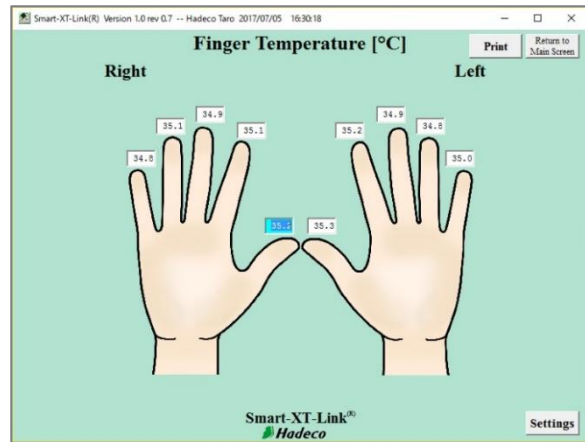
< Finger temperature screen>

4-6-1. Preparations

(1) Prepare 1 temperature probe, optional, for foot temperature testing.

(2) Click **Foot Temperature** launcher icon on Main Screen.

(3) Click **Settings** button on Foot Temperature screen and set the settings as follows.

Unit:
Select either **Celsius (°C)** or **Fahrenheit (°F)** for temperature unit.
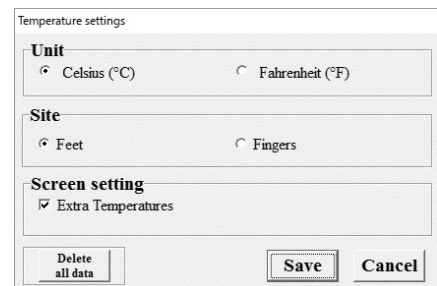
Site:
Select either **Feet** or **Fingers** for measurement site.

Extra temperatures:
Check the checkbox to show extra temperature boxes on the screen.
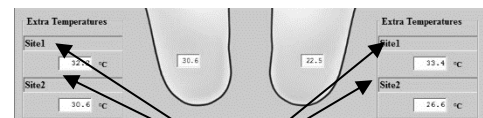
Type the site name here.

Note: Site name for each extra temperature box can be changed by typing in.
Click **Save** to set all the settings.

Delete all data:
Click it to delete all temperature data on the screen.

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4-6-2. Operation

Measuring foot temperatures:

(1) Connect temperature probe, optional, to the unit

(2) Go to Foot Temperature screen and temperature box for right toe will be selected and turn to light blue automatically.

(3) Get the probe tip close to the measuring site less than 4 cm as shown in the right.

(4) Press the probe button to measure and show the temperature in the box and it will automatically go to the next temperature box turning into light blue.
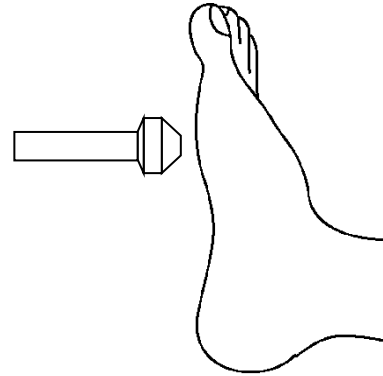
Note: Hit space bar or Enter to skip to the next box without taking temperature OR click the box where you wish to measure for.

(5) Repeat steps # (3) to (4) for the next site until all testing is completed.

Note: After using temperature probe, wipe the probe using with a soft dry cloth. Take great care that any water may not penetrate into the probe.

Typing foot temperatures:

(1) Click the temperature box where you wish to type one in taken by an external thermometer and it will turn into light blue.
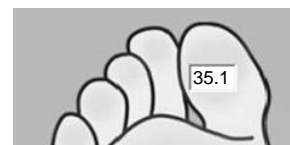
(2) Type the foot temperature in the box and press Enter.

Specifications:

Temperature measuring method: non-contact
Accuracy: ± 0.5°C (measurement range 10 to 40 °C), when operating temperature is 0 to 40°C
Display Resolution: 0.1°C
FOV: 4:1 (object distance: measuring range)
Emissivity: 0.98

Less than 4cm

Object 1cm
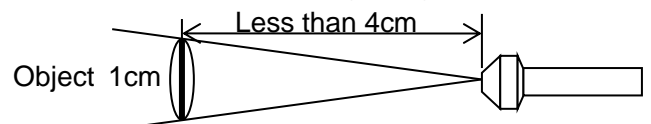
4-7. Custom Screen

Custom Screen allows you to create your own test module with favorable site names up to 14 sites

<Custom screen>
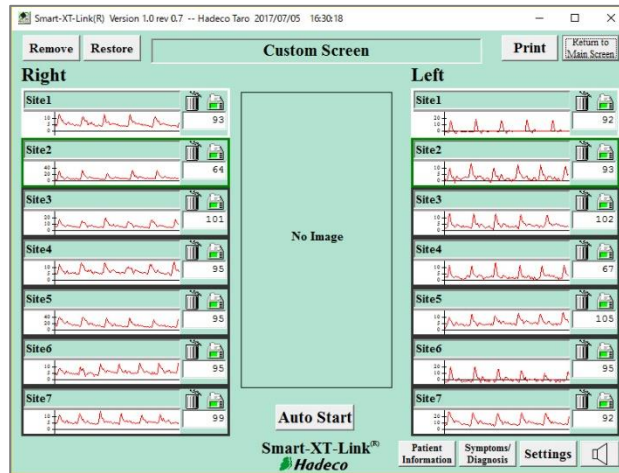
4-7-1. Preparations

(1) Prepare cuffs, tubing and probe for the testing.
(2) Click **Custom Screen** launcher icon on Main Screen.
(3) Overtype the name of screen and site you wish to test on each of name boxes.

Name of screen

Name of site
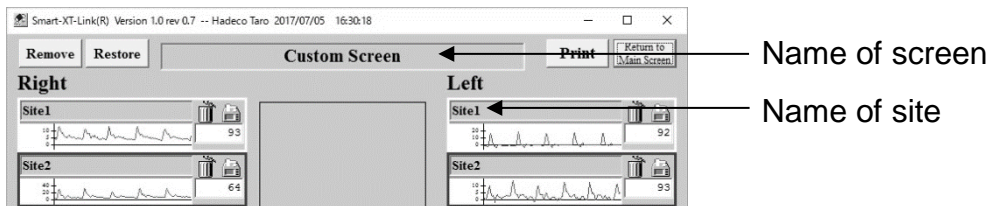
(4) Click **No image** and select **Open** to put a desired image on center of the screen.
(5) Click **Settings** button and set the settings as follows.

Waveforms:

Select either **Doppler**, **PV** or **PPG** for waveform test module.
Uncheck the check box for Waveforms windows if waveform is not necessary.

Pressures:

Select pressure test module depending on waveform test module as follows:

Waveforms \ Pressures	Doppler	PPG
Doppler	✓	
PV	✓	✓
PPG		✓
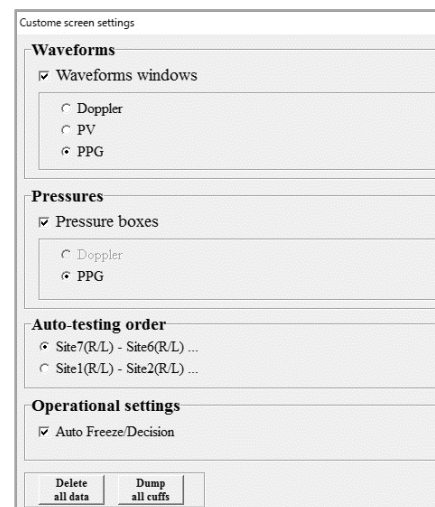
Uncheck the check box for Pressure boxes if pressure is not necessary.

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Auto-testing order:

Select the Auto-testing order as follows:

No.	Auto-testing order for Custom testing	Default setting: No.1
1	Right side (From site# 7 to site# 1) => Left side (From site# 7 to site# 1)	
2	Right side (From site# 1 to site# 7) => Left side (From site# 1 to site# 7)	

Operational settings:

◆ **Auto Freeze / Decision**
Check the check box to freeze and save waveform automatically when it becomes stable.

Delete all data;
Click **Delete all data** to delete all waveform data on the screen.

Dump all cuffs;
Click **Dump all cuffs** to dump all cuffs.

(6) **Sound adjustment:** 🔲
Click the sound button and adjust sound volume by moving the slider.

(7) **Removing waveform window(s) not using:** 🗑
Click the trash can next to any waveform window you do not use and click **Remove** to remove the window(s). Click **Restore** to get them back.

4-7-2. Starting Auto - testing

(1) Wrap a cuff snugly on each site.

(2) Hook up each color coded tubing between cuff and the inflation port with the same color as tubing's for each site.

(3) Connect Doppler or/and PPG probe(s) to the unit for the testing.

(4) Click **Auto Start** button to start Auto-testing and follow the guidance to proceed.

(5) When all tests are completed, the dialog box as shown right will appear. Click **OK** to close it.

After all testing is completed, Smartdop will dump all cuffs automatically while beeping.

Message
ⓘ All testing completed. Dumping cuffs while beeping.
OK

5. Menu
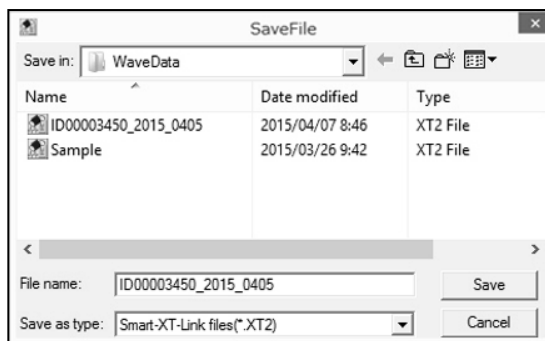
5-1. SaveFile

(1) Click **SaveFile** on Main Screen to open SaveFile window with a file name of Patient ID, or name if ID is not typed, along with extension "XT2".

Note: Default data folder can be specified on Option Screen.

(2) Change the file name if necessary and click **Save** to save testing data.

Note: If the check box of **Export to DICOM** on Option Screen is being checked, Smart-XT-Link will automatically export all the report images of each test module to DICOM.

5-2. Search Files

Folders pane — Files pane
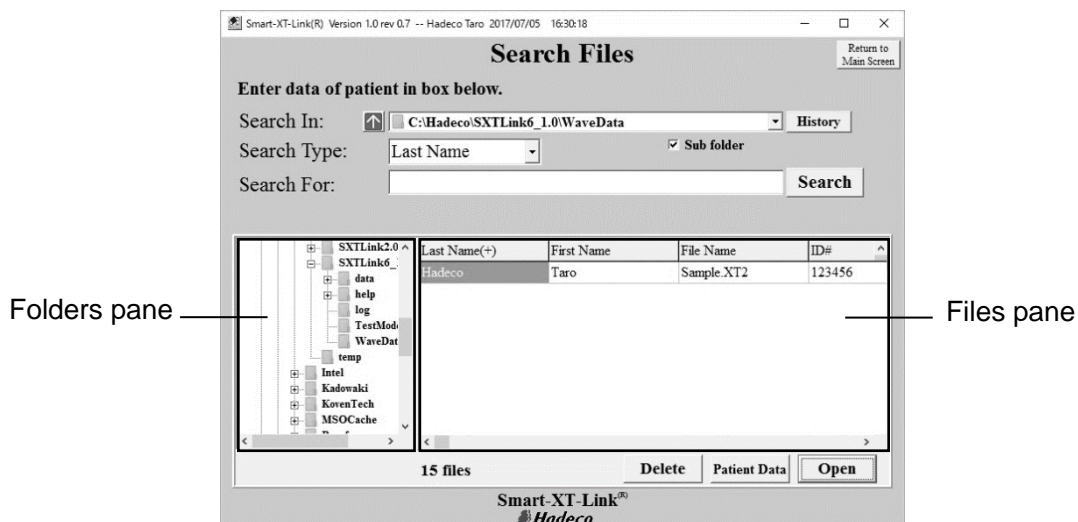
(1) Click **Search Files** on Main Screen to open Search Files screen and it will show Smart-XT-Link data files stored on the data folder specified on Option Screen. (Default: C\Hadeco\SXTLink6_1.0\WaveData)

(2) Select the file you wish to use and click either **Open** to open it or **Patient Data** to start a new testing with the same "Patient information" and "Symptom/ Diagnosis" on the existing file.

Folder selection:
(a) Click other folder on folders pane where you wish to search files and the folder path and Smart-XT-Link files found will be shown on "**Search In**" path box and files pane, respectively.
(b) Click the up arrow ⬆ to go to upper folder.
(c) Check **Sub folder** check box to include sub folders for searching.
(d) Click **History** to show a list of folder paths you have searched before.

Search options:
(a) Select **Search Type** from pull-down menu, and type a search word in the **Search For** text box.

Note: **Search Type** includes **patient name**, **ID**, **file name**, **requesting physician**, and **test date**.

(b) Select a file you wish to delete and click **Delete** to proceed.

Advanced operation:
(a) Folders pane and files pane can be resized by dragging the splitter bar between the 2 panes. Columns in files pane can also be resized.
(b) Click the column name to sort files alphabetically and click it the second time to sort anti-alphabetically.

Click here

Last Name(+)	First Name	File Name	ID#
Hadeco	Hanako	Sample2.XT2	1234567
Hadeco	Hanako	Sample3.XT2	1234567

(c) Right-click on folder in folders pane to show a context menu of **Rename**, **Delete folder** and **New folder** and select the one you wish to proceed.

Right click here

			First Nam
Hade	Rename	)	
D	Delete folder		sample1
S	New folder		Taro
S			
SXTLink1.0		Hadeco	Hanako
SXTLink2.0		Hadeco	Hanako
SXTLink6_		Hadeco	Hanako
data		Hadeco	Taro
help			
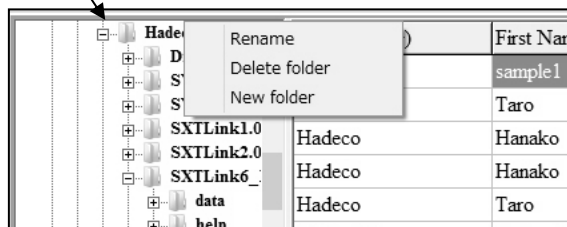
5-3. New File

Click **New File** to create a new patient file and **Patient Information** screen will open. Type all the patient data and click **Save** to save the information.
If previous data has not been saved when **New File** is clicked, a confirmation dialog box as shown below will appear. Click **Yes** to save the previous data, **No** to erase it or **Cancel** to cancel New File process.
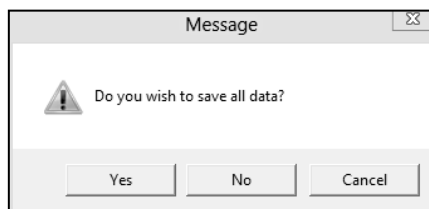
5-4. Print Report

(1) Click **Print Report** on Main Screen to open the Print Report screen.
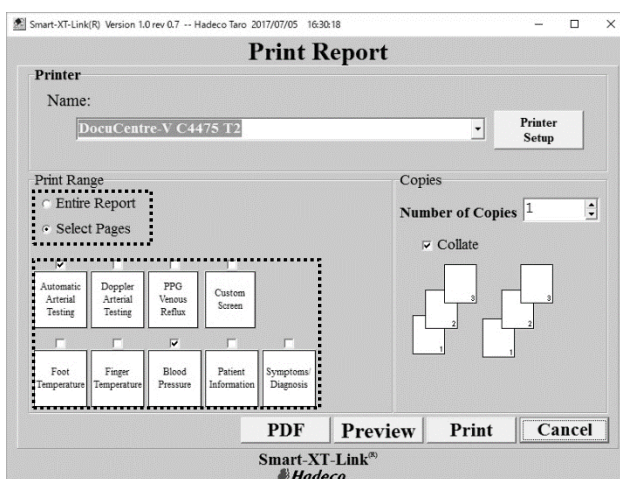
(2) Choose the printer and check each check box of the reports you wish to print out. Select **Entire Report** if you wish to print all the reports.
(3) Click **Print** to print out report(s), **Preview** to see print preview, or **PDF** to create PDF report file.

5-5. Patient Information*1

See the section "§4-1. Starting operation".

5-6. Symptoms/ Diagnosis*1

(1) Check the appropriate check boxes and type information in text boxes and then click **Save** to proceed.

Note: "Other 1" to "Other 3" can be overtyped with your own word for Diagnosed Conditions if desired.

Note: Type the year and month, YYYY/MM, on each "since" boxes when patient was first diagnosed with it and the years elapsed will be automatically calculated.

*1: To open these screens on the testing screen, click **Patient information**, **Symptoms/ Diagnosis** buttons on bottom of Automatic Arterial Testing, Doppler Arterial Testing screen and Custom screen.
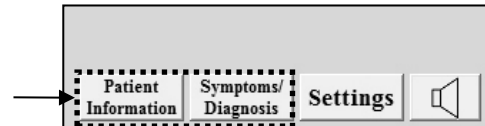
5-7. Default Data

Default data saved on this screen can be used in the pull-down menus on Patient Information screen.

(1) Type each default data for **Facility**, **Address**, **Telephone number**, **Performing Studies** and **Requesting Physician**.
Select the data and overtype other word and then click **Change** to revise.
Select the data and click **Delete** to delete it.

(2) Click **Sav**e to proceed when the data have been typed.

5-8. Option Screen
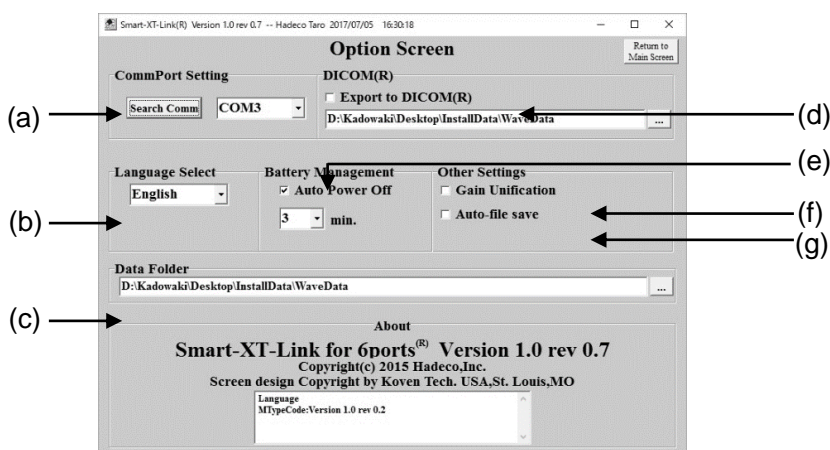
(a) **CommPort Setting**
   Turn on the unit and connect it to computer. Go to Option Screen and click **Search Comm** to search COM port connected to the unit. COM port number will be shown next to **Search Comm** when it's been found.

(b) **Language Select**
   Select your language from the pull-down menu and restart Smart-XT-Link to activate the new language.

(c) **Data Folder**
   Click the button "..." and select the folder where you wish to save Smart-XT-Link files regularly and then click OK. The folder path will be shown in the path box and it will be used on Search Files and Save File as a default folder.

(d) **Export to DICOM**
   Check it to export the report images to DICOM when data file is saved. Set the DICOM folder under the check box where DICOM files should be exported.

(e) **Auto Power Off**
   To activate the auto-power-off capability and the unit will be automatically shut off when it is left on without AC adaptor connected and the auto-off-time selected from pull-down menu passes. This box is checked as default settings.

(f) **Gain Unification**
   Check it to unify all the amplitude scales of waveforms in each testing module.

(g) **Auto-file save**
   Check it to overwrite the data automatically every time any testing is completed. A message "Do **SaveFile** and Auto-file overwriting will start for each testing" will be displayed as shown below.
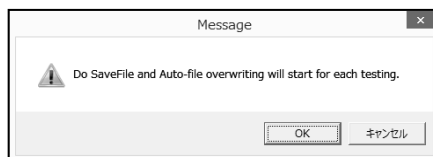
Note: This function is not available for DICOM file. If you wish to save DICOM file, please go to Main Screen to do it. (See "§5-1. Save file" for details)

6. Maintenance

6-1.Performance check by user

Perform the following performance checks at least once a year:
(1) Make sure if there is no damage and/or crack on the unit including all components.
(2) Perform entire tests on either Automatic or Doppler Arterial Testing and make sure the unit works properly and provides appropriate test results.

Simple check before use:
(1) Connect the unit to your computer and open Smart-XT-Link.
(2) Turn the unit on and make sure the Power LED goes green.

6-2.Cleaning

PROBE:
Remove any dust, stain, and gel from the probe.
Clean the probe using damp cloth and then wipe with a soft dry cloth, but take great care that any water may not penetrate into the probe.

MAIN UNIT:
To clean the main unit, use a damp cloth and then wipe with a soft dry cloth, but take great care that any water may not penetrate into the unit.

CUFFS:
The cuffs are intended for use only on intact skin. To clean them, wipe away any dirt or stain using alcohol.

6-3.Warranty

The guarantee period is two years for the main unit and one year for the probe after the date of purchase when used under normal conditions. In the event of a problem during the warranty period, please contact your agent.
In case the warranty period is over, please consult the dealer for a charged service.

7. Supplemental information

7-1. Symbol List

Symbol	Description	Symbol	Description
⊙	Power ON	⃝	Power OFF
▬ ▬ ▬	AC adaptor Connector	⊖→	Serial port
▽	Stop button	🌡	Temperature probe connector
⚠	Caution*	🧍	Type BF applied part
🏭	Manufacturer		

* Caution must be observed to avoid damage to the unit. Refer the operating manual carefully.

7-2. Contents of package

- Main unit ····································· 1
- Smart-XT-Link for 6 ports (USB stick) 1
- USB cable ···································· 1
- Operating manual ························· 1
- Tubing ··· 6
- AC adaptor (DPS54-M) ················· 1
- Power cable ································· 1
- PPG probe (PG-01) ······················ 2
- PPG probe holder ························· 2
- PPG probe clip ····························· 2

How to use the PPG probe holder

1. Attach the holder to the flat place on the main unit with double-sided tape.

2. Put PPG transducer to the holder as shown below.
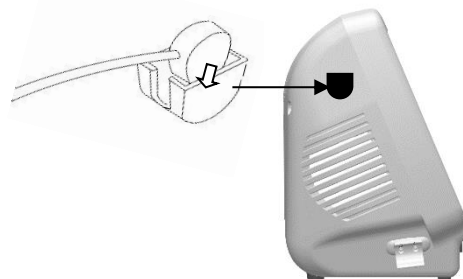
How to use the blue band for PPG probe

1. 2 snap-on blue bands are included in the white box of a PG-01 probe.
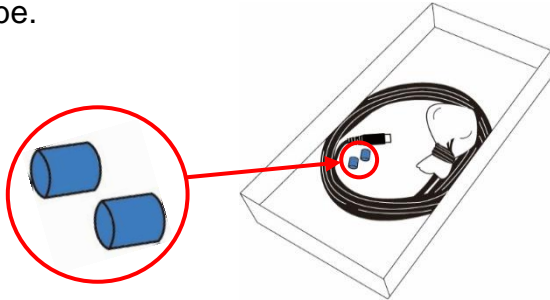
2. Snap on the blue band on each side of the PPG probe for right side indication as shown below.

The blue bands on Tubing is for right side indication as shown below.
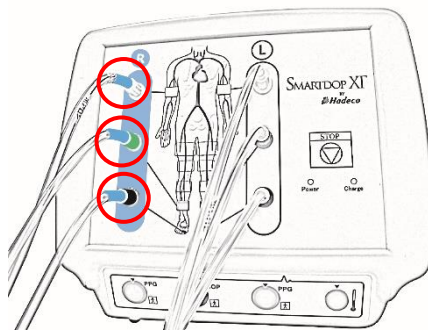
7-3. Options

- **Cuffs:** Refer the following cuff size as example;

Cuff	Site name
VC-10H, VC-12H	Brachia, above knees, below knees, ankles and high thighs
DVC-1.9H	Great toes
VC-7.5H	Transmetatarsi

- **Probe**

Standard Doppler probe:

4MHz: BT4M05S8C (A)*
5MHz: BT5M05S8C (A)*
8MHz: BT8M05S8C (A)*

*The end word "C" indicates curl type cable, "A" indicates straight type cable.

Flat type:

8MHz: BF8M15S8A

Pencil Type:

8MHz: BP8M05S8A

Temperature probe: TP-01
Except European Union Countries

- **Ultrasonic gel** AQUA ULTRA BASIC

8. Technical information

8-1.Principles

Doppler blood velocity measurement:
While performing Doppler waveform test on Doppler Arterial Testing, blood flow velocity is detected through the ultrasound which is transmitted from probe to patient body and is reflected by the blood (hemocyte, etc.).
The unit amplifies the high frequency oscillation output and then supplies it to the transmitter transducer. It is converted to ultrasound by the transducer and the ultrasound is transmitted to external objects. The ultrasound moves straight through biophysical object, and is reflected by the moving object (blood flow, fetal heartbeat etc.).
The reflected ultrasound is received by the receiving transducer and is converted into electric signals again.
The converted signals are amplified and then detected. After removing unnecessary noise from the signals and improving S/N ratio at the filter circuit, the Doppler shift signals are amplified and are converted to audible sounds through a speaker.
Simultaneously, the Doppler shift signals are applied to the CPU and converted to blood flow velocity waveform signals which can be displayed.

Doppler blood pressure measurement:
While taking blood pressures on Doppler Arterial Testing, the blood pressure cuff is wrapped where the blood pressure is taken and the probe is put on the arm/leg artery by the operator.
Before the inflation, the peak amplitudes of the blood flow signals should be stable. As the cuff pressure goes up by activating the inflation pump, the blood vessel is being pressed and the peak amplitudes become lower. The CPU finds the point where the peak amplitudes are below the threshold and waits until the cuff pressure is inflated an estimated 20 mmHg above the point. Then the CPU deactivates the inflation pump and lets the cuff pressure go down at a moderate rate until the first blood flow signal that exceeds the threshold is detected.
The cuff pressure at the first signal is the systolic pressure. After confirming a return of the rhythmical blood flow signals, the CPU opens the air valve to dump the cuff pressure and converted to systolic pressure waveform signals which can be displayed.

Oscillometry:
While taking blood pressure on Automatic Arterial Testing screen and deflating cuff for arm or leg after the inflation, the unit detects oscillations of the blood vessel synchronizing with each heart beat and determines the systolic pressure based on oscillometry algorithm.

Photoplethysmography:

While taking toe pressure with PPG probe as well as performing PPG venous reflux study, the unit senses the reflection of light from the hemoglobin of the red blood cells in surface vessels by utilizing infrared light with the probe.

Pneumoplethysmography (PV): (Except European Union Countries)
While performing PV waveform test for toes and legs on either Automatic or Doppler Arterial Testing, the unit assesses changes in blood volume in the tissues beneath an inflated cuff. Alterations in pressure are transmitted to a pressure transducer that records the volume changes through the cardiac cycle to produce a waveform.

8-2.Block diagram
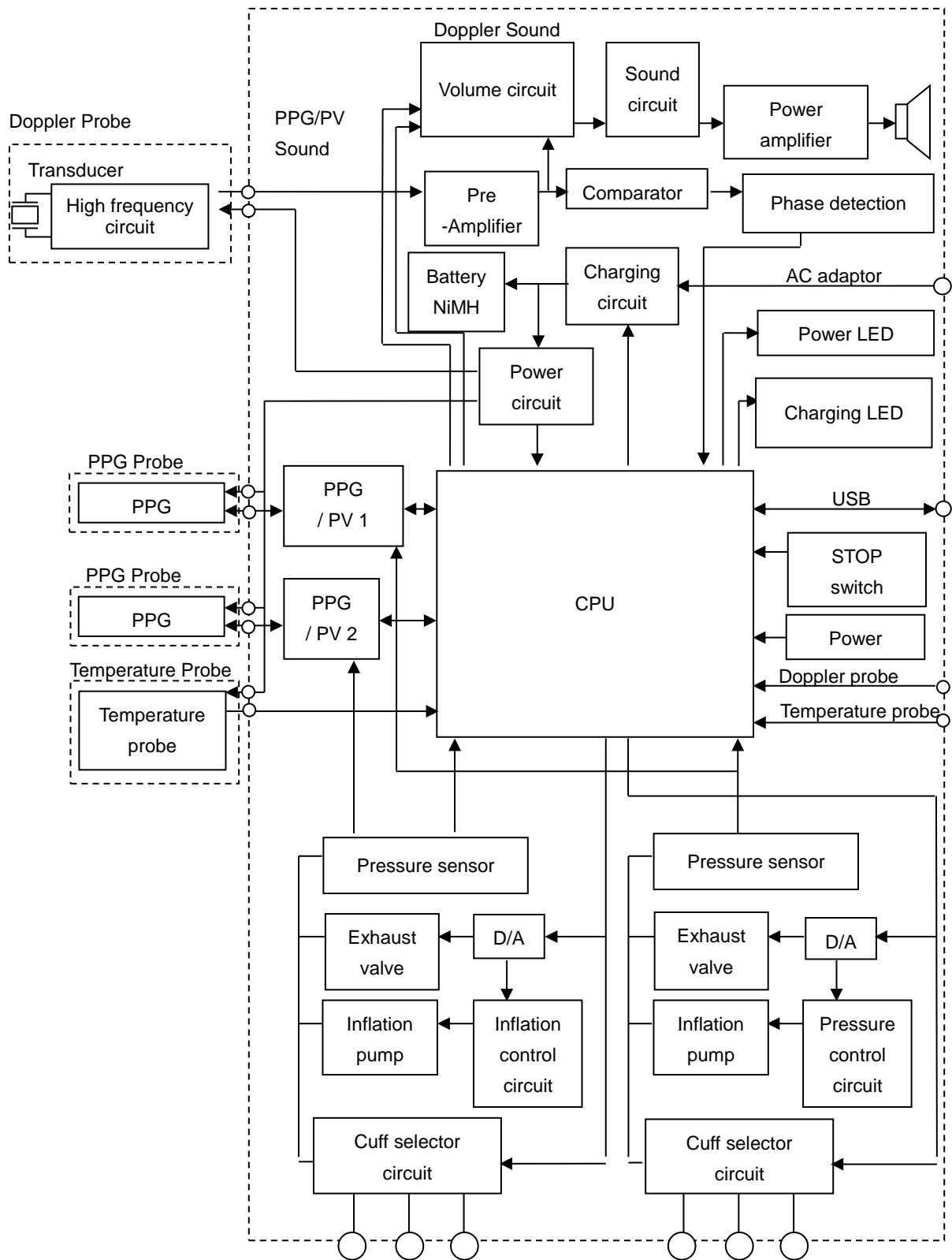
8-3.Specifications

Power: Ni-MH rechargeable battery pack or AC adaptor

AC adaptor: Model #: DPS54-M
                                 Input: AC 100-240V, 50Hz/ 60Hz
                                 Output: DC 15V, 4A or more

Consumption: DC 15V, 1.75 A

Recharge time   Approx. 4 hours by the AC adaptor

Full charge life: Approx. 2 hours, approx. 10 times of automatic testing

Battery life: Approx. 2 years

Measurement range;
   Blood pressure: Oscillometry: 50 to 260 mmHg
                                 Doppler: 30 to 260 mmHg
   Heart rate: Oscillometry: 30 to 200 BPM
                                 Doppler: 30 to 240 BPM

Accuracy;
   Blood pressure: Oscillometry: ± 5 mmHg
                                 PPG/Doppler: ± 5 mmHg
   Heart rate: ± 5%
   Temperature: ± 0.5°C
   Velocity: ± 10%

Doppler probe, option: Frequency   Acoustic power Ispta* (In situ)
                                 8MHz   720 mW/cm² or less
                                 Ispta: Spatial Peak – Temporal Average Intesity

Speaker output: 250 mW

External output: USB port

Electrical safety: Conform to IEC60601-1
                                 Class II
                                 Internally powered equipment
                                 Type BF applied part.

Operating environment: 10 to 37°C
                                 85% humidity or less with no condensation

Storage environment: 0 to 50°C
                                 85% humidity or less with no condensation

Transportation environment:

        0 to 50°C

        85% humidity or less with no condensation

Dimensions: Main unit: 300 (W) x 244 (H) x 167 (D) mm

Weight: Approx. 3.5kg (Without AC adaptor and components)

Manufacturing date: The first 2 digits and following 2 digits of the serial number represent the year and month of manufacturing, respectively.

        Examples:

        14010001:   Jan/ 2014

        1401001:   Jan/ 2014

* Specifications subject to change

8-4.Safety standards

The unit confirms to the following standards:

Manufacturing standard: IEC60601-1

(1) Protection class against electric shock: Class II, Internally powered equipment

    Protection grade against electric shock: Type BF applied part

(2) Guidance and manufacturer's declaration - electromagnetic emissions and immunity:
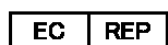
    IEC60601-1-2:2014(4th Edition)

Guidance and manufacturer's declaration – electromagnetic emissions		
The Smartdop XT is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop XT should assume that it is used in such an environment.		
Emissions test	compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Smartdop XT use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Smartdop XT is suitable for use in all establishments other than domestic, and may be used connected to the public low-voltage power supply network that supplies buildings used for domestic purposes provided the following warning in needed: Warning: This equipment/system is intended for use by healthcare professions only. This equipment/system may cause radio interference or may be necessary to take mitigation measures, such as re-orienting or relocating the Smartdop XT or shielding the location.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Smartdop XT is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop XT should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are converted with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% U_T （100% dip in U_T） for 0,5 cycles 0% U_T （100% dip in U_T） for 1 cycle 70% U_T （30% dip in U_T） for 25 cycles 0% U_T （100% dip in U_T） for 250 s	0% U_T （100% dip in U_T） for 0,5 cycles 0% U_T （100% dip in U_T） for 1 cycle 70% U_T （30% dip in U_T） for 25 cycles 0% U_T （100% dip in U_T） for 250 s	Mains power should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test revel.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Smartdop XT is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop XT should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance

			Portable and mobile RF communications equipment should be used no closer to any part of the Smartdop XT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz 6Vms ISM bands 150kHz and 80MHz	3Vrms 150kHz to 80MHz 6Vms ISM bands 150kHz and 80MHz	$d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 to 800MHz
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.7GHz	3V/m 80MHz to 2.7GHz	$d = 2{,}3\sqrt{P}$ 800MHz to 2,5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of the equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smartdop XT is used exceeds the applicable RF compliance level above, the Smartdop XT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Smartdop XT.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

For European Union Countries:

| EC | REP | European Authorized Representative

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Hadeco