



OPERATING MANUAL

Smartdop 30EX

OPERATING MANUAL

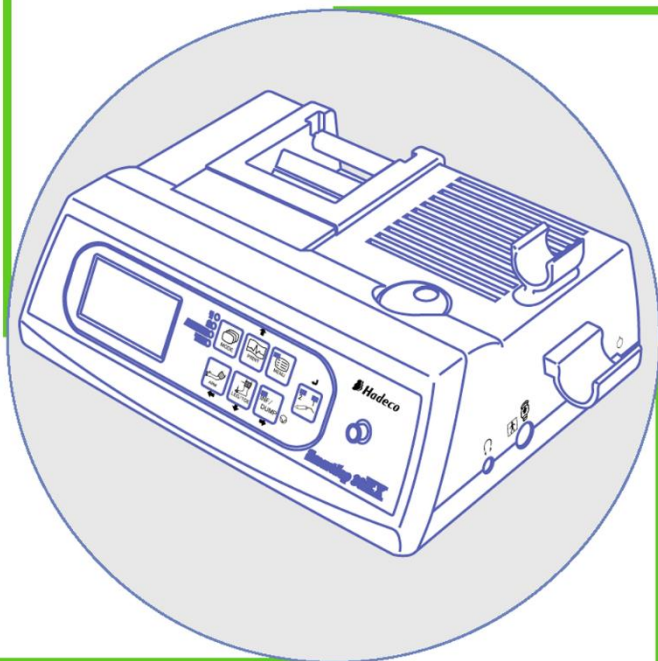


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Cautions

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

1. Only skilled persons should operate the unit.
2. Use the unit for measuring blood flow.
3. Do not apply any modification to the unit.
4. Device placement

Follow the requirements for storage and operating environments.

- (1) Do not place it near water.
- (2) Do not place it where atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salt, sulfur and so forth will affect the unit adversely.
- (3) Pay attention to the stability conditions to avoid too much inclination, vibration, shock and so on during transportation and installation of the unit.
- (4) Do not place it where chemicals are stored or gas may be generated.
- (5) Do not place it where the unit tends to fall.
- (6) Do not place it on or adjacent other electronic devices.

5. Before use

- (1) Make sure that the unit operates safely and correctly by implementing performance check mentioned in "§ 6-1. Performance check by User".
- (2) Make sure that all cables are connected correctly and safely.
- (3) Using it with other equipment together may cause a misdiagnosis or danger to patient due to a malfunction.
- (4) Double-check that all the cables do not obstruct any external connection to the patient.
- (5) Do not sterilize the main unit and non-sterilizable probe 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 make sure 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 cuff:
 - Press INF/DUMP button to dump the pressure.
 - Disconnect the tubing 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 operation manual.
- (11) Do not use the unit in a strong electromagnetic field or it may cause incorrect measurements.

7. After use

- (1) Return all switches to the conditions before use and turn the unit off the way specified.
- (2) Do not pull the cable(s) too much while disconnecting or it may cause damage.
- (3) Clean the unit, AC adaptor, cables and probes and place them in right place for the next use.

8. Storage

- (1) Follow the caution (1) to (5) of section #4 Device placement in the previous page.
- (2) Clean the unit, AC adaptor, 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 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 any allergic reaction occurs.

12. Battery

- (1) When battery is extremely low, the LCD display will not operate. Also there will be no speaker sounds. Charge the battery.
- (2) Battery life is 300 full charges. When full charging life is 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 persons 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 place battery in a fire or it may cause an explosion and injury.

17. Any connected computer is not allowed to be in the patient area according to IEC60601-1.

1. Introduction

Thank you very much for choosing the Smartdop 30EX.

The Hadeco Smartdop 30EX is a uniquely designed bi-directional Doppler with backlit LCD display and Doppler blood pressure monitor capability. It detects arterial and venous blood flows in extremities as well as blood pressures of brachial, ankle and toe, calculates ABI and TBI and fetal heart sounds.

Please read this manual carefully to acquaint yourself with the unit operation.

This medical device can be used by doctor for the purposes mentioned in "§ 1-2. Clinical applications" for patient in hospital and clinic.

For the use with computer, refer to the operating manual for Windows linking software optional.

1-1. Features

✧ BI-DIRECTIONAL DOPPLER WITH BACKLIT LCD and PRINTER

Displays and prints velocity waveforms in bi-directional & dual separation channel and numerical data.

✧ DOPPLER BLOOD PRESSURE RECORDER

Full auto system with built-in cuff inflator

Shows instructions on LCD for measuring pressures if desired.

Calculates and prints ABI /TBI and velocity/pressure documentation.

✧ TWO PROBE COMBINATIONS (for 2, 4, 5, 8, 10 MHz, PPG and PV)

The unit has dual probe connectors and selection switch.

Convenient for measuring pressures for TBI using with PPG.

✧ Hadeco DESIGNED SMART MICROPROCESSOR

Various mode settings are available for optimal measurement with the menu displayed on the LCD. 30 waveform memory.

✧ BUILT-IN PULSE VOLUME with automatic cuff inflator.

✧ CONVENIENT PROBE ACTIVATION BUTTON

Freezes waveform as well as FREEZE button.

Inflates and dump cuff as well as INF/DUMP button.

Button function can be changed on probe key mode setting, PRB-KEY.

✧ USB COMPUTER INTERFACE

Transfers waveforms and numerical data to computer for data storage.

Communication cable and Windows software are optional.

- ✧ PPG and PV-MVO PROBES optionally available
Expands arterial & venous testing.

1-2. Clinical applications

Detections of fetal heart rate

Evaluation of fetal heart rate and sounds throughout pregnancy except where fetal heart is not developed sufficiently during the first trimester.

Detections of arterial and venous blood flow velocity and pressures for vascular disease

- ◆ ABI and TBI studies
- ◆ Bi-directional lower extremity studies.
- ◆ PEAK & MEAN blood velocity determinations.
- ◆ Peripheral vascular procedures.
- ◆ Blood pressure segmental studies.
- ◆ Venous compressions.
- ◆ Penile & digit systolic pressures.
- ◆ Toe pressure & venous reflux studies (PPG).
- ◆ PV - Arterial studies

Note: The Smartdop 30EX and associated Doppler probes, inflatable cuffs, and optional photoplethysmography probe are not intended for use in contact with blood or mucous membrane.

CONTRAINDICATIONS

Do not use the Smartdop 30EX for ophthalmic or periordical studies as the acoustic intensity is higher than the level recommended by authorities for use on and around the eye.

1-3. Probe selection

The frequency of diagnostic ultrasound is inversely proportional to depth of penetration. The Smartdop has 5 interchangeable probes with different frequencies. Use those probes depending on your applications.

BT2M20S8C (2MHz):	Fetal heart rate
BT4M05S8C (4 MHz):	Deep peripheral blood velocity and flow
BT5M05S8C (5 MHz):	Deep peripheral blood velocity and flow
BT8M05S8C (8 MHz):	Superficial blood velocity and flow
BT10M5S8C (10 MHz):	Superficial blood velocity and flow

Note: One of these probes comes with Smartdop as a standard component. Other probes are available as optional components.

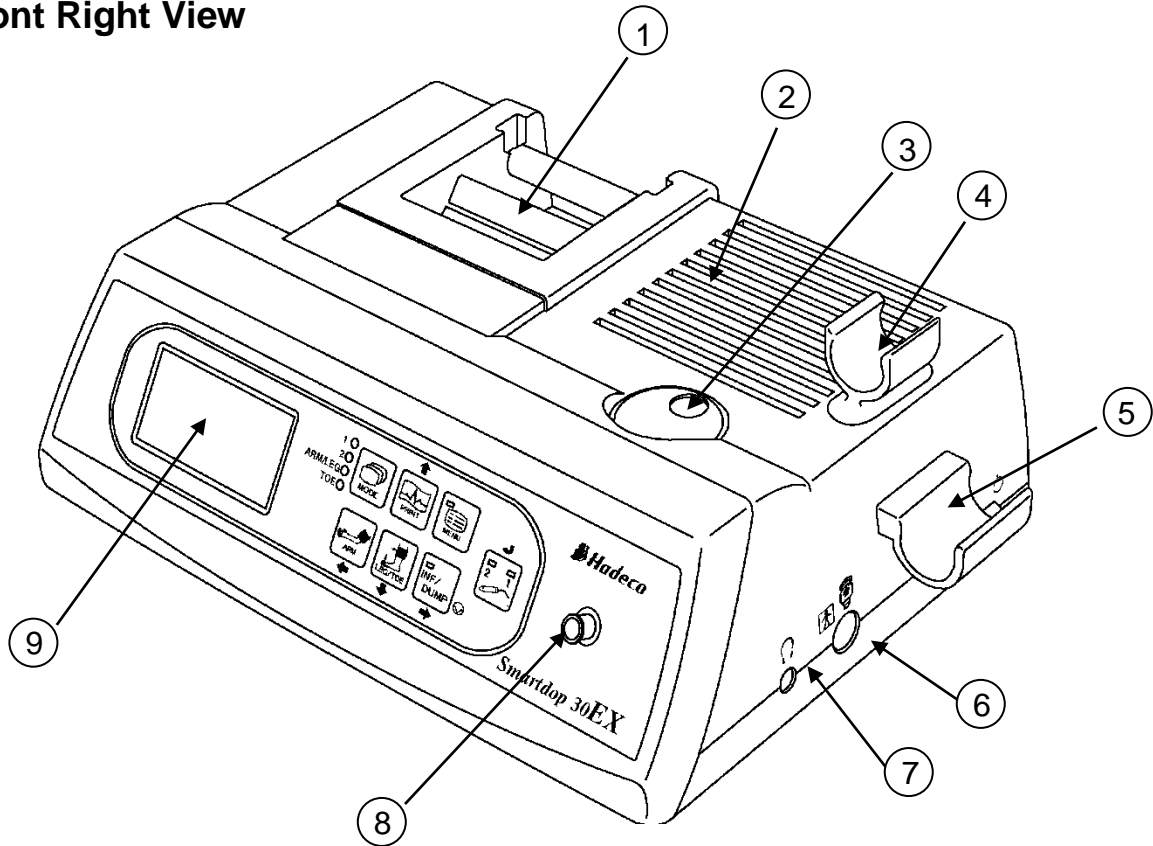
1-4. Contents in package



Main unit	1
Probe.....	1
AC adaptor (GMPU18UI-3)	1
Ultrasonic gel (AQUAULTRA BASIC).....	1
Paper.....	1
Blood pressure cuff (VC-12).....	1
Tubing	1

2. Appearance

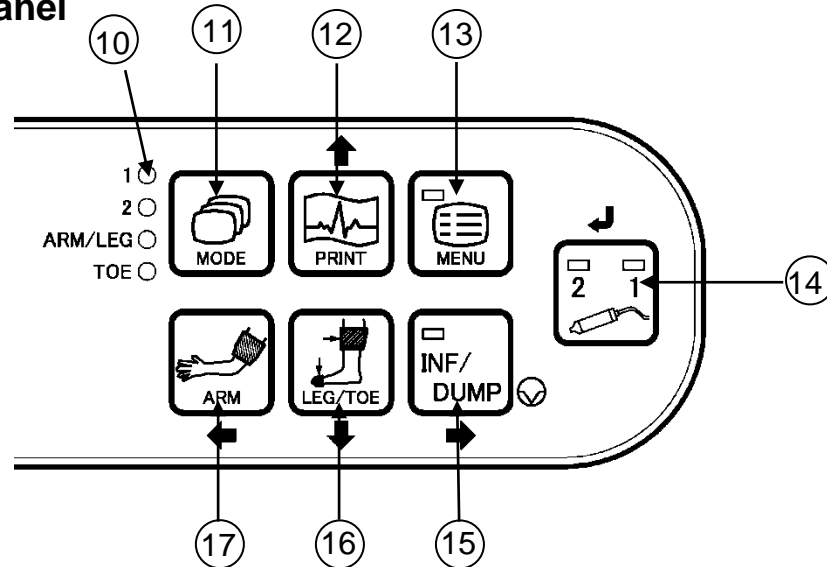
2-1. View





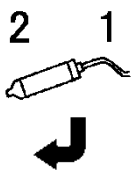

Front Right View



- | | | |
|------------------------|---|---|
| 1. Printer: | | To print velocity wave forms, systolic pressures, ABI / TBIs and velocity / pressure documentations and PPG / PV waveforms. |
| 2. Speaker: | | Outputs Doppler sounds. |
| 3. Volume control: | | To adjust sound volume. |
| 4. Probe holder #2: | | For probe placement when not in use.
Probe holder #2 can be removed by removing the 2 screws. Fix them to the unit. |
| 5. Probe holder #1: | | For probe placement when not in use. |
| 6. Probe connector #1: |  | To connect probe #1. |
| 7. Headset: |  | To connect headset. It cuts off the speaker. |
| 8. Inflation inlet: | | To connect the tubing for the blood pressure cuff. |
| 9. LCD display: | | Displays waveform, numerical data, and menu for mode settings. |

Operating Panel



10. **Mode LEDs:** Indicate the mode selected. (Mode 1, Mode 2, ARM/LEG, TOE) illuminate sequentially while charging battery.
11. **MODE** button:  To select the mode of either the arterial Mode 1, venous Mode 2, ARM/LEG pressure or TOE pressure mode. See “§ 4-1-1. Basic Modes” for details.
When optional PPG/PV probe is connected, Mode 1 and Mode 2 correspond to AC and DC modes respectively.
12. **PRINT** button:  To activate and deactivate the printer.
Up  **Menu mode**
To move the cursor up.
13. **MENU** button:  To go to menu mode. See “§ 4-2. Menu Mode” for details.
MODE+ To turn backlight on/off.
14. **Probe selection** button:  To select the probe intended to use from the connected probes. The LED corresponding to the probe number will illuminate.
Enter  To select PV Arterial mode and both of LED will illuminate.
When displaying stored waveforms on Freeze mode:
To increase memory #.
MODE+ To decreases memory #
Menu mode
To fix the mode or value.
To change the mode or setting.

15. **INF/DUMP** button:
Freeze
Right



To freeze / unfreeze the waveform.

Measuring pressure

To inflate / dump the blood pressure cuff.



To move cursor (systolic pressure point) to the right.

Menu mode

To move the cursor right.

To change the mode or setting.

16. **LEG/TOE** button
Down



Measuring pressure

To store and display the measured pressure value as a leg or toe pressure. (Freeze mode)

To display ABI or TBI (Measurement mode)

To erase measured pressure data by pressing longer than 2 sec. (Measurement mode)



To magnify the view of waveform.

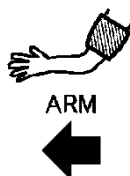
Measuring blood velocity

To change the Display mode. (Waveform / Numerical data)

Menu mode

To move the cursor down.

17. **ARM** button:
Left



Measuring pressure

To store and display the measured pressure value as an arm (brachial) pressure. (Freeze mode)

To display ABI or TBI. (Measurement mode)

To erase measured pressure data by pressing longer than 2 sec. (Measurement mode)



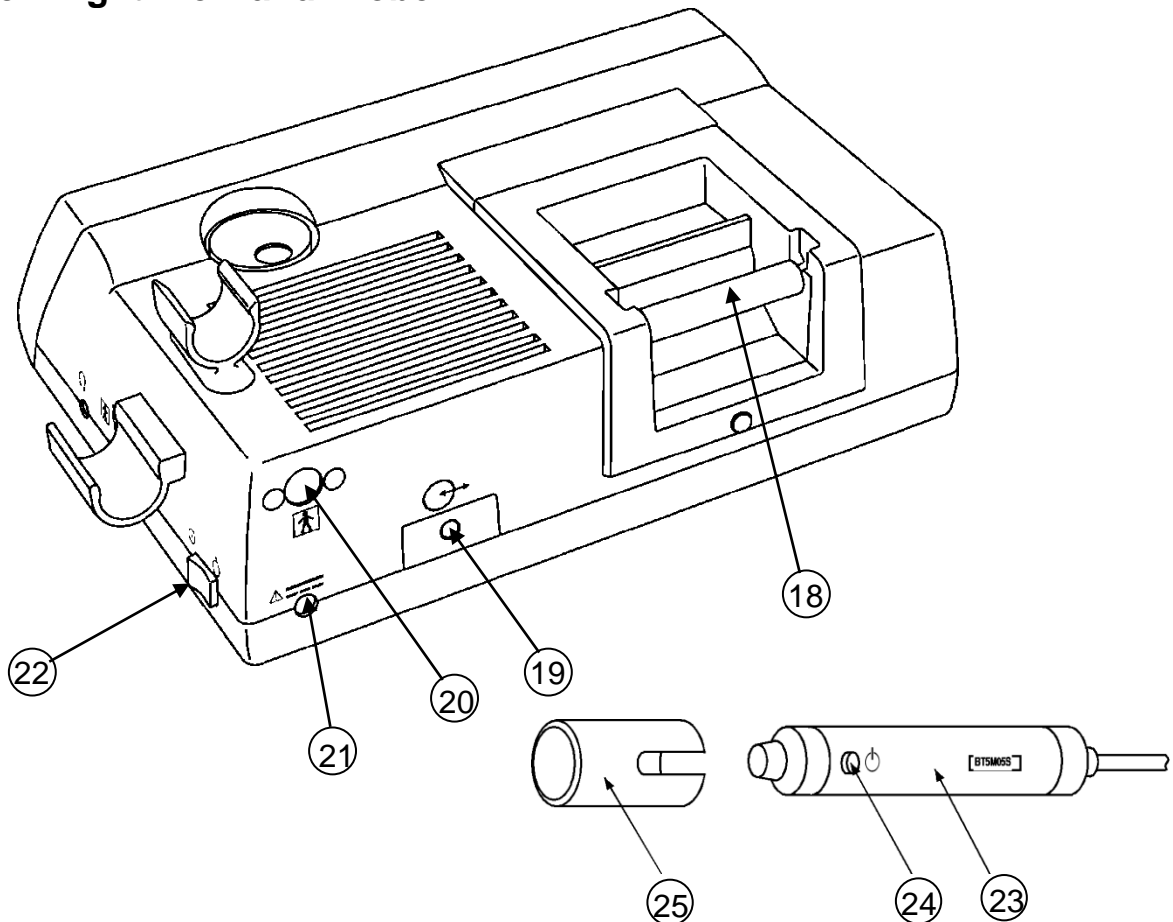
To move cursor (systolic pressure point) to the left






Menu mode

To go back to previous menu or to get out of menu mode.

MODE+ means to press and hold MODE button before pressing each button.

Back Right View and Probe



18. Roll shaft: To set paper roll.
19. Communication port:  To connect computer. (USB)
20. Probe connector #2:  To connect probe #2.
21. AC adaptor connector:  To connect the designated AC adaptor.
22. Power switch:  To turn on/off the unit.
ON OFF
23. Probe: Multi-probe selection of 2, 4, 5, 8 and 10 MHz
24. Probe button:  To freeze and unfreeze the waveform.
To activate and deactivate cuff inflator.



Note: The function is defined in the menu PRB-KEY. See § 4-2-7-1. OTHERS -PRB-KEY” for details.

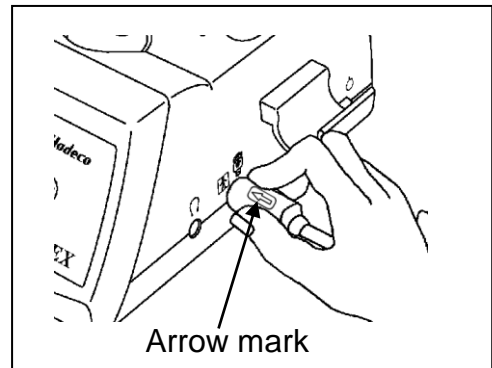
25. Probe cap: To protect the probe transducer tip when probe is not in use.

3. Quick start

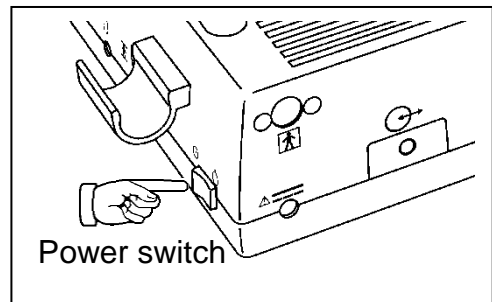
For the first time of use and in case the unit has not been used for a while, fully charge the internal battery.

3-1. Turning the unit ON

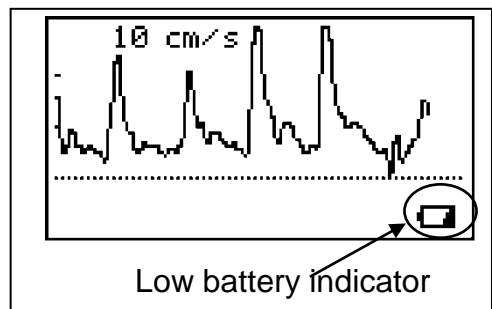
- (1) Connect the probe to the probe connector so that the arrow mark  will be placed under the Probe connector mark .



- (2) Press the power switch to turn the unit ON.



Note: When battery is low, low battery indicator appears as shown right. The unit can be used for a few more minutes however, we recommend recharging battery as soon as possible for further use.



AUTOMATIC SHUT-OFF:

When the AUTO-OFF is ON, if the unit is left on without AC adaptor connected, the power is automatically shut off after following time passes:

- (a) 5 minutes when no signal.
- (b) 15 minutes when on measurement.
- (c) 10 minutes when on freeze mode.

Note: If automatic shut-off functions while on freeze mode, the unit will resume the waveform on freeze mode by turning the unit on.

3-2. Charging / Discharging battery

Charging battery:

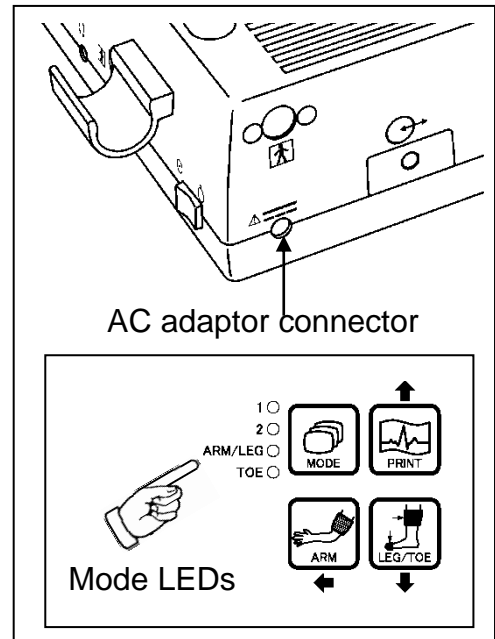
- (1) Turn the unit off and plug the AC adaptor to the unit to charge battery. The Mode LEDs will illuminate sequentially (one after another) while charging is in progress.

Note1: Use the designated AC adaptor.

Model name: GMPU18UI-3

Note2: Charging battery with AC adaptor while in use may cause unnecessary power-supply noise.

When the battery is fully charged, the Mode LEDs will be turned off. Unplug the AC adaptor.



Discharging battery:

Using and charging the battery repeatedly without fully discharging may cause a shorter full charge battery life. Fully discharge battery before charging every once in a while. See “§ 4-2-7-q. OTHERS -DISCHARGE” how to do it.

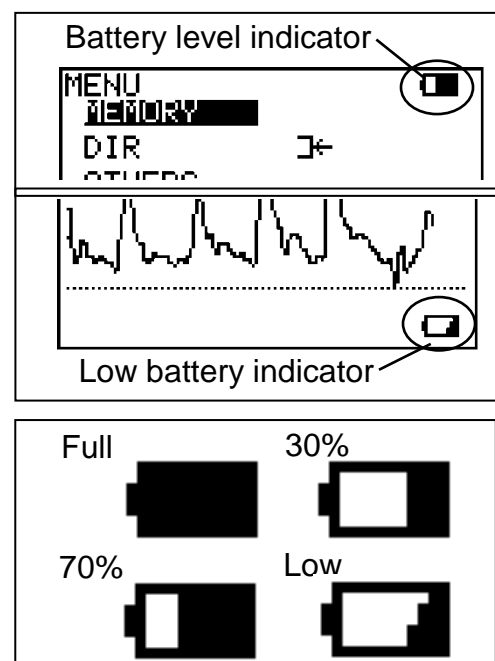
3-3. Checking battery level

Battery level indicator shows upper right of the menu screen.

- (1) Turn the unit on and press MENU button to display the menu.

When battery is low, low battery indicator will be shown on bottom right of LCD as shown in the right. Charge the battery when in low.

Note: Battery level indicator shows the battery level in 4 steps as shown right.



3-4. Setting printer paper

(1) Remove the roll shaft and set it into the paper roll. Insert and hold the paper edge into the paper entry under the printer and press the PRINT button.

(2) Press the button again when sufficient paper comes out. Pull the paper edge out a few inches and cut it at the paper guide. Put the roll shaft with the paper back on the roller guide.

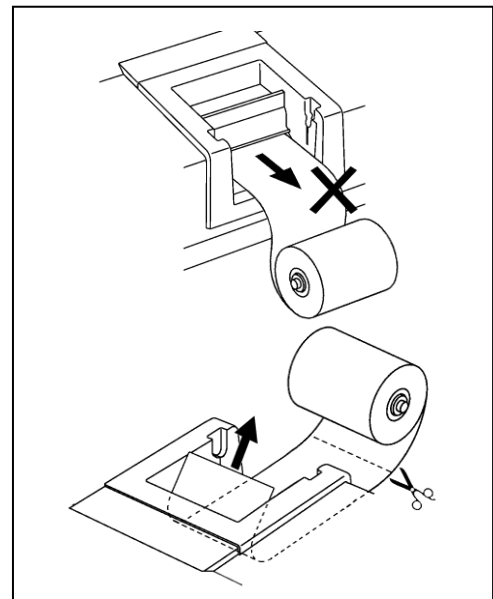
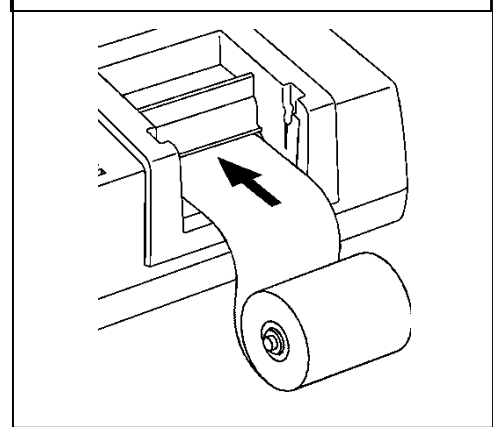
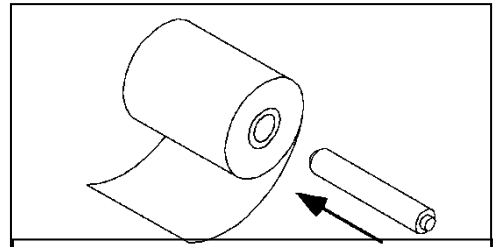
Note: Cut the paper straight before inserting the paper for loading it easily. Apply slight fingertip pressure to the paper at beginning of insertion.

Caution:

Do not pull paper in a direction opposite to the direction of paper feed (printing and auto loading). It may cause malfunction of the printer.

In cases removing paper from printer, cut the paper at the roll side and pull the remaining paper out in the direction of paper feed.

Also paper feed problems like paper jam or wrinkled paper hit by printer head or something may cause malfunction of the printer. Insert the paper correctly by following the steps mentioned above.



3-5. Measuring Blood Velocity

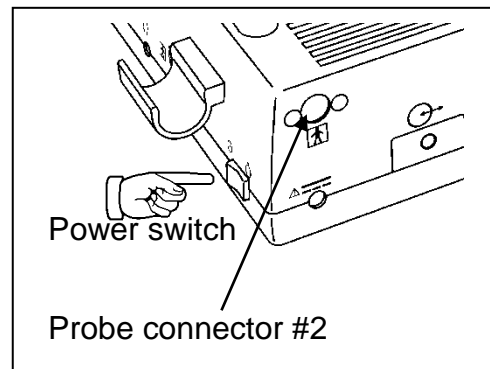
This section explains typical operation of measuring blood velocity. Refer to “§ 5-1. Arterial and venous blood velocity modes” and “§ 4-2. Menu Mode” for mode settings of various uses.

- (1) Connect the probe to the probe connector.

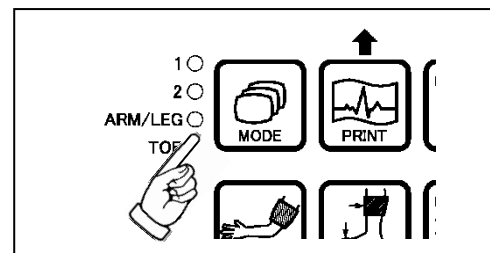
See the step# (1) in the “§.3-1. Turning the unit ON” for the details.

- (2) Put ultrasonic gel on tip of probe or patient skin.

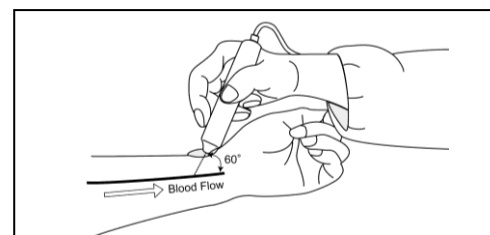
- (3) Turn the unit on and turn the volume control to maximum. Make sure the probe selection LED illuminating corresponds to the connector you connected probe. If not, press probe selection button to change it.



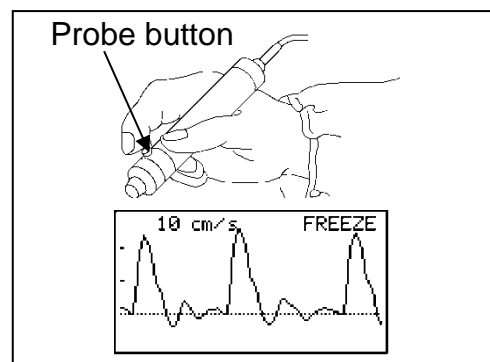
- (4) Press MODE button to select Mode 1 for arteries or Mode 2 for veins.



- (5) Put the probe on the measurement area and move it slowly to locate the point where the maximum Doppler sounds are heard. An ideal probe angle to the vessel is approximately 45 to 60 degrees.



Wait more than 5 sec for MODE 1 (OR up to 25 sec for MODE 2) without moving probe after the maximum Doppler sounds, press probe button (or INF/DUMP button) to freeze the waveform. Press PRINT button to print the waveform, if necessary.

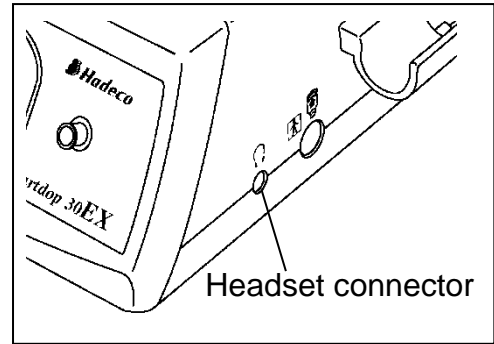


Note: Function of the probe button can be selected from Freeze, Print, and Freeze & Print on PRB-Key mode settings. See “§4-2-7-1.OTHERS - PRB-KEY (Probe button function)”.

- (6) Headset can be used to listen to Doppler sounds. It will cut off the speaker.

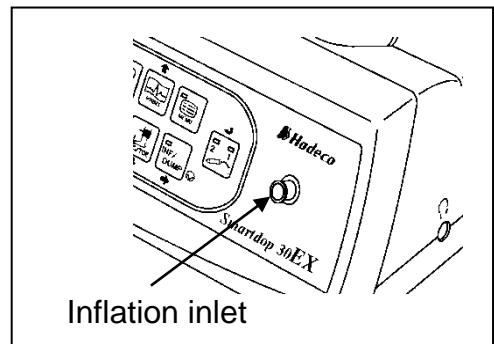
If you wish to save the waveform and numerical data on the memory, see “§ 4-2-7-a. MEMORY - STORE”.

If you retry the measurement, press INF/DUMP button or probe button to get out of the freeze mode.



3-6. Ankle brachial pressure index (ABI)

- (1) Connect the cuff VC-12 to the tubing and other end of tubing to the inflation inlet as shown in the right.

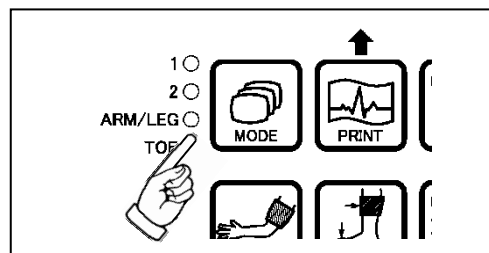


- (2) Connect the probe to the probe connector #1 or #2.

See the step# (1) in the “§.3-1. Turning the unit ON” for the details.

- (3) Turn the unit on and make sure the probe selection LED illuminating corresponds to the connector you connected probe. If not, press probe selection button to change it.

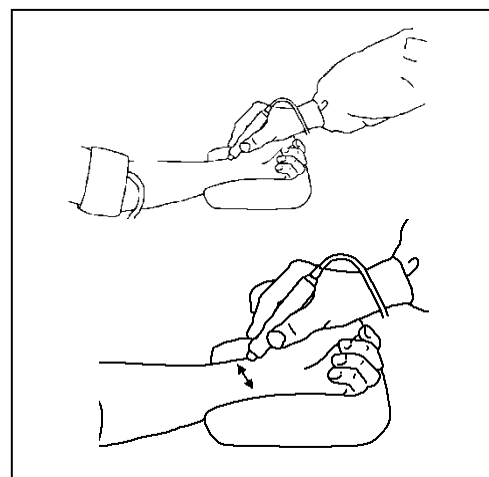
Press MODE button to select ARM/LEG pressure mode. (ARM/LEG LED will illuminate.)



Taking Arm pressure:

- (4) Wrap the cuff above the elbow and apply the probe to the radial or brachial artery at an angle of approximately 45 to 60 degrees.

- (5) Move the probe slowly to locate the point where the maximum Doppler sounds are heard and the INF/DUMP LED will blink after a few seconds.

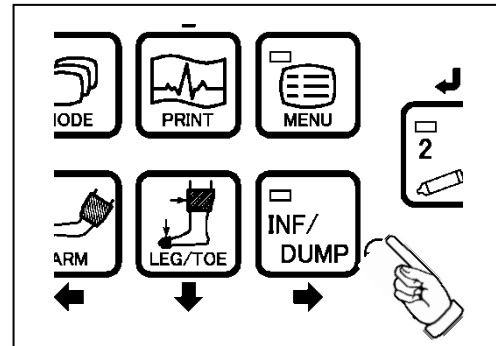


Note1: Once you locate the point, please keep the probe there until blood pressure is taken.

Note2: In case INF/DUMP LED doesn't blink due to low flow or arrhythmia, press INF/DUMP button longer than 2 sec to activate cuff inflator manually in the next step #6.

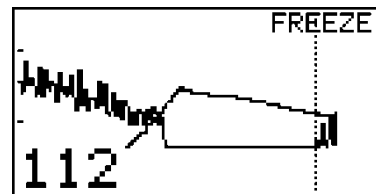
(6) Press INF/DUMP or probe button to inflate the cuff. The unit will stop the inflation at estimated 30 mmHg above the sound cessation and deflate the cuff at 3 to 4 mmHg/sec automatically.

Note: In case the inflation doesn't stop automatically, press INF/DUMP or Probe button to stop the inflation.

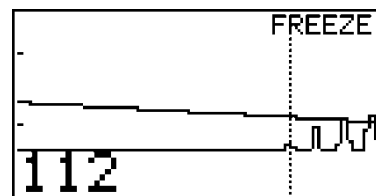


If an error message is displayed in the inflation and deflation processes, press any button other than probe selection button to delete the error message and go back to step #5.

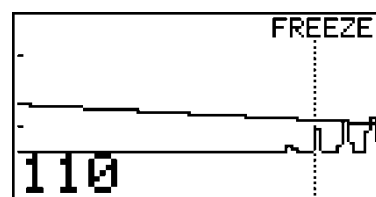
The LCD will show the systolic pressure when the first Doppler sound is heard and then the cuff pressure will be dumped automatically.



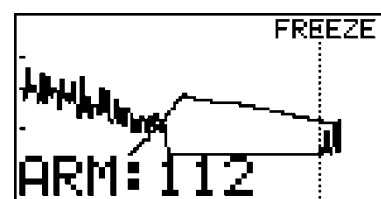
Press and hold MODE button and press Down (LEG/TOE) to get on MAGNIFIED waveform mode if desired. Do it again to go back to FULL waveform mode.



If the systolic pressure is not satisfied, press and hold MODE and press Right / Left to move the cursor (vertical dotted line) to get it adjusted.



(7) Press ARM button to store it as the brachial pressure and the LCD will show it as shown in the right.

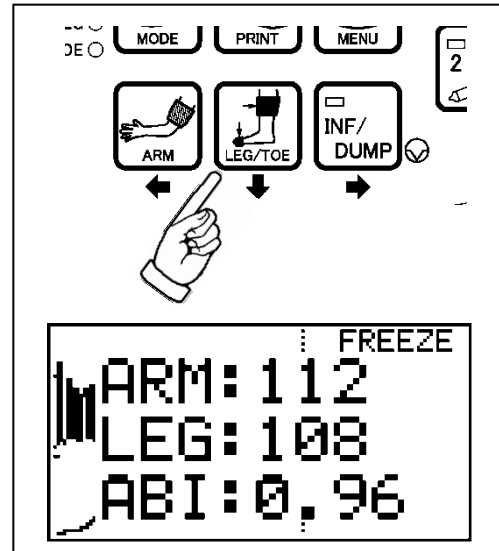


(8) Press INF/DUMP button to go back to the measurement mode for ankle pressure.

(9) Wrap the cuff above the ankle and apply the probe to the posterior tibial artery at an angle of approximately 45 to 60 degrees.

Taking Ankle pressure:

(10) Take the ankle pressure the same way for the brachial. (Steps #5 to #6 of this section) Press the LEG/TOE button to store it as the ankle pressure and the ABI will be displayed as shown in the right.



(11) Go to the next ankle pressure on the other side.

Note: Press the ARM or LEG / TOE button more than 2 sec to clear the pressure data for the next patient.

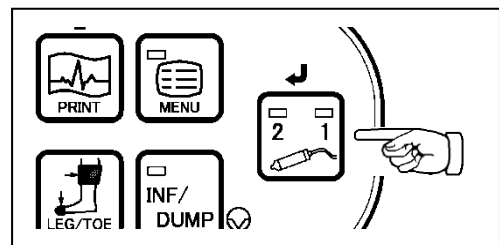
3-7. Toe brachial pressure index (TBI)

Optional PPG probe (PG-21) is required for this testing.

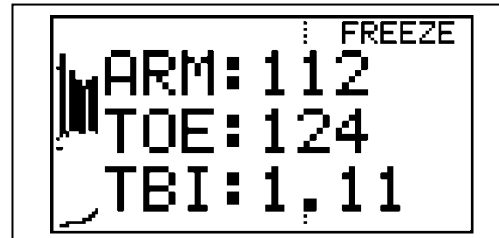
- (1) Take the brachial pressure in the same way as ABI. Follow steps #1 to 7 of "§ 3-6 Ankle brachial pressure index (ABI)".
- (2) Remove arm cuff from tubing and replace with toe cuff, DVC-1.9 or DPC-2.5 for toe pressures.
- (3) Press MODE button to select toe pressure mode. (TOE LED will illuminate.)
- (4) Connect PPG probe to the probe connector # 2 with the round polarity mark up on the probe connector (12 o'clock).

(5) Press probe selection button to select probe #2.

(6) Wrap the cuff around the base of the big toe and affix the PPG probe to the pad of the toe with Velcro strap.



(7) Take the toe pressure the same way for the brachial. Press the LEG/TOE button to store it as the toe pressure and the TBI will be displayed as shown right.

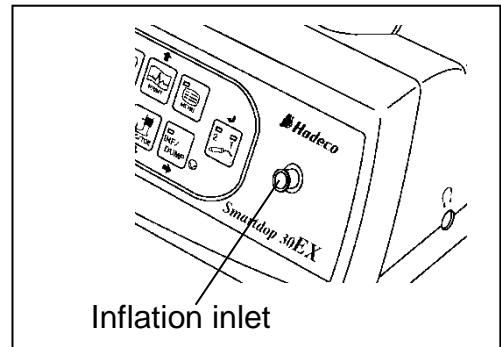


(8) Go to the next toe pressure on the other side.

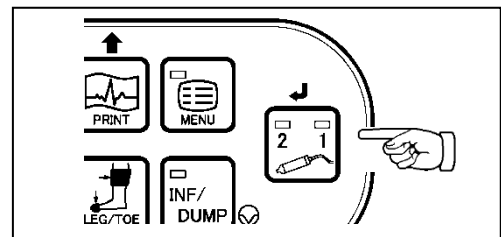
Note: Press the ARM or LEG/TOE button more than 2 sec to clear the pressure data for the next patient.

3-8. PV – Arterial studies

- (1) Wrap VC-12 cuff around patient's leg, thigh at groin, above knee, below knee, or ankle.
- (2) Connect the cuff to the tubing and other end of tubing to the inflation inlet as shown in the right.

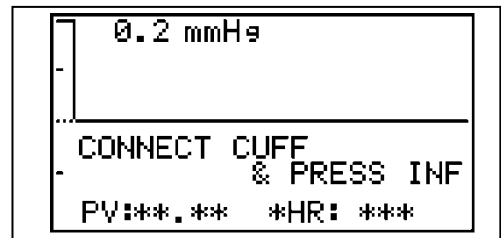


- (3) Turn the unit on and press Probe Selection button a few times until both #1 and #2 LEDs on the button illuminate to go to PV-AC mode.



LCD will display as shown right below.

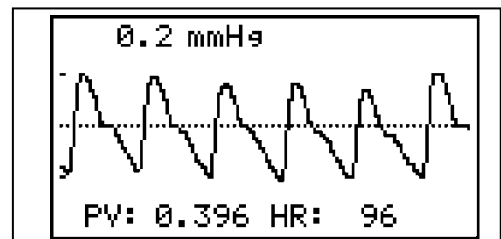
- (4) Press INF/DUMP button to inflate the cuff up to 60 mmHg automatically.



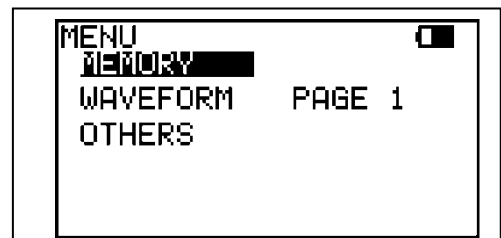
Note: Press INF/DUMP button to stop the inflation and dump cuff while inflation is in progress if desired.

The gain is automatically adjusted and the PV waveform is shown on the LCD.

- (5) When the waveform gets stable and rhythmic, press INF/DUMP (Freeze) to freeze the waveform and to dump the cuff. Press PRINT button to print the waveform of last 5 sec, if necessary.



- (6) If you wish to save the data on the memory, see “§ 4-2-7-a. MEMORY - STORE”.



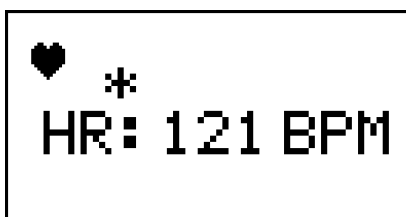
- (7) Remove the cuff and wrap it to the next site. Press INF/DUMP or probe button to unfreeze waveform and repeat steps #5 to #7 for next site.

3-9. Measuring Fetal Heart Rate

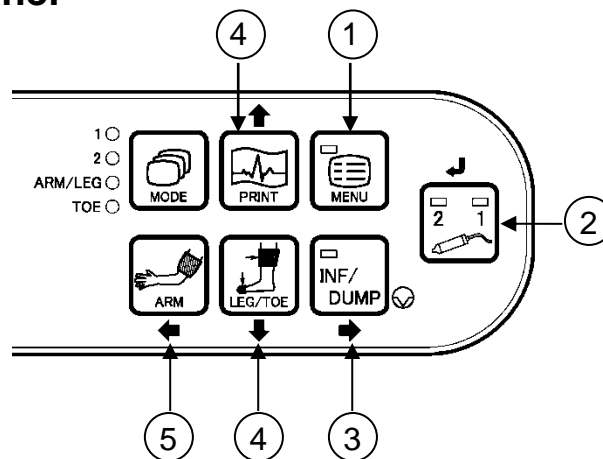
Evaluation of fetal heart rate and sounds throughout pregnancy except where fetal heart is not developed sufficiently during the first trimester.

3-9-1. Functions

- * Connect 2 MHz probe to the unit to go to fetal heart rate mode.
- * The unit display heart rate calculated every 2 sec.
- * Heart rate range is 30 to 240 BPM.
- * Heart mark “♥” tracks heart beat while in measurement.
- * When calculated heart rate is not stable, the asterisk (*) will show above “HR”.



3-9-2. Operating panel



- | | |
|----------------------------|---|
| 1. MENU: | To go to menu mode. |
| 2. Probe selection button: | To select the probe intended to use from the connected probes. |
| 3. FREEZE / RIGHT: | To freeze heart rate. Pressing probe button also freezes it.
To fix the mode or change the setting on menu mode. |
| 4. UP / DOWN: | To move the cursor up / down on menu mode. |
| 5. LEFT: | To get out of menu mode. |
- Other buttons are not available on fetal heart rate mode.

Note1: Fetal heart rate can't be stored in memory and printed out.

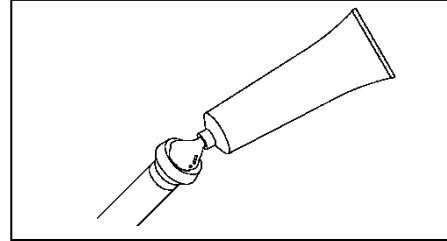
Note2: Using with Smart-V-Link and Smart-Fetal-Link on connected computer are not available.

3-9-3. OPERATION

- (1) Connect the probe to the probe connector.

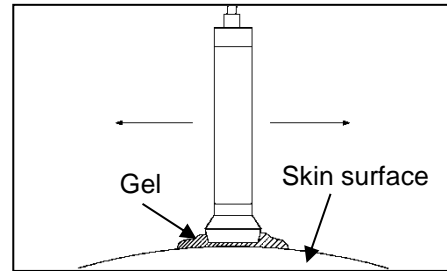
See the step# (1) in the “§.3-1. Turning the unit ON” for the details.

- (2) Put ultrasonic gel on the probe top or patient skin.



- (3) Turn the unit on and make sure the probe selection LED illuminating corresponds to the connector you connected probe. If not, press probe selection button to change it.

- (4) Put the probe on the middle of the abdomen at right angle to the skin surface, and move it slowly to locate the point where the maximum heart beat Doppler sounds are heard.



Caution:

Verify the fetal heart rate. (Maternal heart rates match the maternal pulse rates)

- (5) When the heart rate becomes stable, press the probe button or FREEZE button to freeze it.



4. Mode settings

Note: For the mode and menu for PPG probe and PV probe, see “§ 7-3-4. Menu for PPG” and “§ 7-4-3. Menu for PV”.

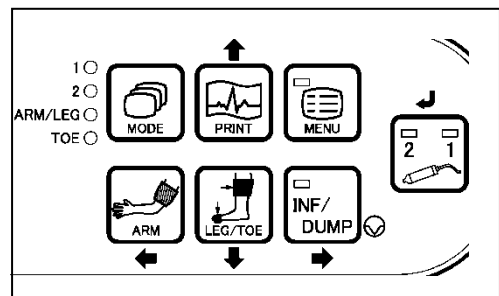
4-1-1. Basic Modes

Smartdop has following six Basic Modes:

- 1. Arterial Blood Velocity: Mode 1
- 2. Venous Blood Velocity: Mode 2
- 3. Arm and Leg Pressure: ARM/LEG
- 4. Toe Pressure: TOE
- 5. PV-Arterial: PV-AC
- 6. Menu: For other functions and settings

Pressing MODE button changes basic mode for mode #1 through 4 and each mode LED selected will illuminate. (Basic mode can be changed only when on measurement mode.)

To go to PV-Arterial mode, press Probe Selection button a few times until both LEDs on the button illuminate. Press MENU button to go to menu mode and MENU LED on the button will illuminate.



4-1-2. Measurement / Freeze Mode

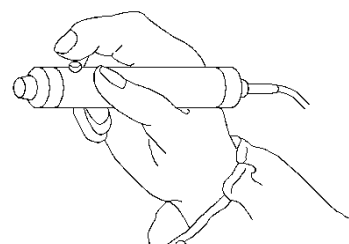
Press Freeze button or probe button to freeze or unfreeze the waveform.

- Measurement mode: For measurement (Unfreeze)
- Freeze mode: For observing waveforms and numerical data

Note1: On Freeze mode, following waveforms are temporarily stored in the memory Freeze.

- Mode 1: Waveform of the 5 sec before freezing
- Mode 2: Waveform of the 25 sec before freezing
- PV-AC: Waveform of the 5 sec before freezing

Note2: Pressing probe button also freezes and unfreezes waveform. Probe button can be set for other function upon PRB-KEY on menu mode.



4-2. Menu mode

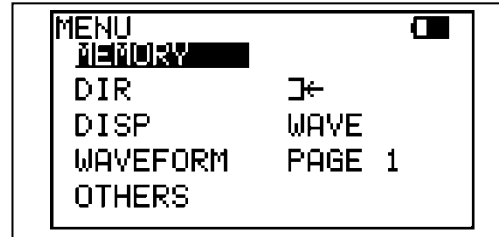
Various mode settings are changeable in Menu mode. Some menus have sub menus. Refer to following Menus and Menu operation first.

4-2-1. Menus

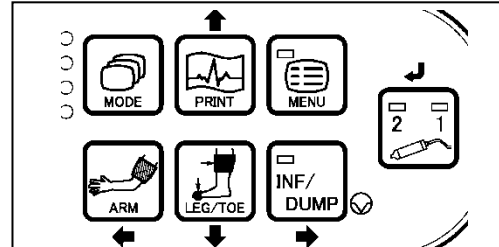
	Menu:	Submenu:	
Blood Velocity measurement mode	<pre> MENU MEMORY DIR ← OTHERS </pre>	<pre> MEMORY READ CLEAR </pre>	<pre> OTHERS LANGUAGE ENGLISH DISP WAVE PRB-KEY FREEZE CAL OFF CAL PRINT OFF </pre>
Blood Velocity freeze mode	<pre> MENU MEMORY DIR ← DISP WAVE WAVEFORM PAGE 1 OTHERS </pre>	<pre> MEMORY STORE READ CLEAR </pre>	<pre> OTHERS LANGUAGE ENGLISH PRB-KEY FREEZE CAL PRINT OFF BACKLIGHT OFF </pre>
ARM/LEG/TOE measurement mode	<pre> MENU MEMORY GUIDANCE OFF P. CLEAR OTHERS </pre>	<pre> MEMORY READ CLEAR </pre>	<pre> OTHERS LANGUAGE ENGLISH PRB-KEY FREEZE BACKLIGHT OFF AUTO-OFF ON </pre>
ARM/LEG/TOE freeze mode	<pre> MENU MEMORY WAVEFORM FULL CURSOR P. DISP ON P. CLEAR </pre>	<pre> MEMORY STORE READ CLEAR </pre>	<pre> OTHERS LANGUAGE ENGLISH PRB-KEY FREEZE BACKLIGHT OFF AUTO-OFF ON </pre>
PV AC measurement mode	<pre> MENU MEMORY OTHERS </pre>	<pre> MEMORY READ CLEAR </pre>	<pre> OTHERS LANGUAGE ENGLISH PRB-KEY FREEZE BACKLIGHT OFF AUTO-OFF ON </pre>
PV AC freeze mode	<pre> MENU MEMORY WAVEFORM PAGE 1 OTHERS </pre>	<pre> MEMORY STORE READ CLEAR </pre>	<pre> OTHERS LANGUAGE ENGLISH PRB-KEY FREEZE BACKLIGHT OFF AUTO-OFF ON </pre>

4-2-2. Menu Operation

(1) Press MENU button to go to Menu mode. The unit will display the menu depending on Basic Mode.



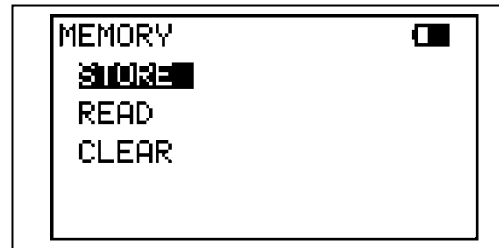
(2) Select the menu by pressing Up (PRINT) or Down (LEG/TOE) buttons and selected mode will be highlighted. Press Right (INF/DUMP) button to change the setting.



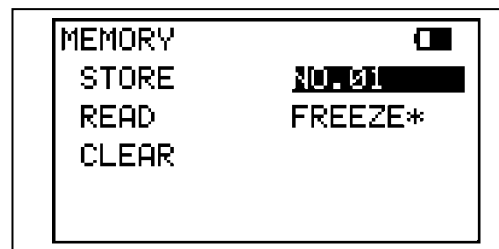
Note: On menu mode, some of the buttons on operation panel work as cursor buttons as follows:

PRINT:	Up
ARM:	Left
LEG / TOE:	Down
INF / DUMP:	Right
Probe selection:	Enter

(3) For MEMORY and OTHERS modes, press Enter (or Right) to display sub menu and Up and Down to select each sub menu.





(4) For MEMORY submenu, press Enter (or Right) to show the memory number, and press Up and Down to change the number.





(5) Press Left to go back to previous menu or press MENU to get out of menu mode.

4-2-3. Menu for Blood Velocity Measurement Mode

Menu	Sub Menu	Selections	Reference in §3-3-7.
MEMORY	READ	1 to 30, FREEZE	b. Memory - Read
	CLEAR	1 to 30, ALL	c. Memory - Clear
DIR, direction		Forward  , Reverse 	d. DIR
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	DISP, display mode	WAVE , DATA	e. Others - DISP
	PRB-KEY (Probe button)	FREEZE , PRINT, PRT&FRZ	l. Others - PRB-KEY
	CALibration	ON, OFF	m. Others - CAL
	CAL PRINT	ON, OFF	n. Others - CAL PRINT
	BACKLIGHT	ON, OFF , 10 to 60 (10-sec steps)	o. Others - Backlight
	AUTO-OFF	ON , OFF	p. Others - AUTO-OFF
	DISCHARGE *1		q. Others - Discharge

Note: *1 DISCHARGE is available when AC adaptor is connected to the main unit.

4-2-4. Menu for Blood Velocity Freeze Mode

Menu	Sub Menu	Selections	Reference in §3-3-7.
MEMORY	STORE	1 to 30, FREEZE	a. Memory - Store
	READ	1 to 30, FREEZE	b. Memory - Read
	CLEAR	1 to 30, ALL	c. Memory - Clear
DIR, direction		Forward  , Reverse 	d. DIR
DISP, display mode		WAVE , DATA	e. DISP
WAVEFORM		PAGE 1 , PAGE 2	f. Waveform
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	PRB-KEY (Probe button)	FREEZE , PRINT, PRT&FRZ	l. Others - PRB-KEY
	CAL PRINT	ON, OFF	n. Others - CAL PRINT
	BACKLIGHT	ON, OFF , 10 to 60 (10-sec steps)	o. Others - Backlight
	AUTO-OFF	ON , OFF	p. Others - AUTO-OFF
		DISCHARGE *1	

Note: *1 DISCHARGE is available when AC adaptor is connected to the main unit.

4-2-5. Menu for Pressure Mode

Menu	Sub Menu	Selections	Reference in §3-3-7.
MEMORY	STORE *3	1 to 30, FREEZE	a. Memory - Store
	READ	1 to 30, FREEZE	b. Memory - Read
	CLEAR	1 to 30, ALL	c. Memory - Clear
GUIDANCE *1		ON, OFF	g. GUIDANCE
P.CLEAR			h. P.CLEAR
WAVEFORM *2		FULL, MAGNIFIED	f. WAVEFORM
CURSOR *2			i. CURSOR
P.DISPlay *2		ON, OFF	j. P.DISP
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	PRB-KEY (Probe button)	FREEZE , PRINT, PRT&FRZ	l. Others - PRB-KEY
	BACKLIGHT	ON, OFF , 10 to 60 (10-sec steps)	o. Others - Backlight
	AUTO-OFF	ON, OFF	p. Others - AUTO-OFF
	DISCHARGE *4		q. Others - Discharge

Note: *1 GUIDANCE is available only on Measurement mode.

*2 WAVEFORM, CURSOR and P.DISP are available only on Freeze mode.

*3 STORE is available only when on Freeze mode and pressure(s) has been assigned to ARM or LEG/TOE.

*4 DISCHARGE is available when AC adaptor is connected to the main unit.

4-2-6. Menu for PV-AC Mode

Menu	Sub Menu	Selections	Reference in §3-3-7.
MEMORY	STORE *2	1 to 30, FREEZE	a. Memory - Store
	READ	1 to 30, FREEZE	b. Memory - Read
	CLEAR	1 to 30, ALL	c. Memory - Clear
WAVEFORM *1		PAGE 1 , PAGE 2	f. Waveform
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	PRB-KEY (Probe button)	FREEZE , PRINT, PRT&FRZ	l. Others - PRB-KEY
	BACKLIGHT	ON, OFF , 10 to 60 (10-sec steps)	o. Others - Backlight
	AUTO-OFF	ON, OFF	p. Others - AUTO-OFF
	DISCHARGE *3		q. Others - Discharge

Note: *1 WAVEFORM is available only on Freeze mode.

*2 STORE is available only on Freeze mode.

*3 DISCHARGE is available when AC adaptor is connected to the main unit.

4-2-7. Menu Mode Details

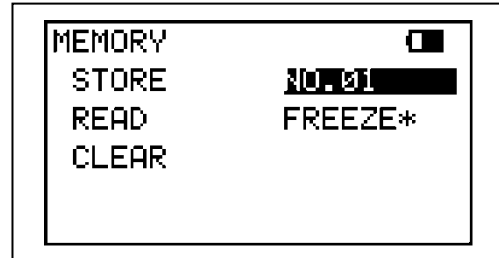
See “§ 4-2-2. Menu Operation” how to show each menu item.

Do the mode setting once and subsequent Smartdop use will revert to this mode.

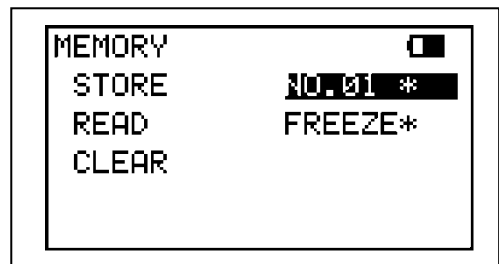
a. MEMORY - STORE

(1) STORE sub menu is available when on freeze mode only.

Press Enter (or Right) on STORE sub menu and the first memory number available will be shown automatically on STORE sub menu. If necessary, change the number where to store waveform data by pressing Up and Down.

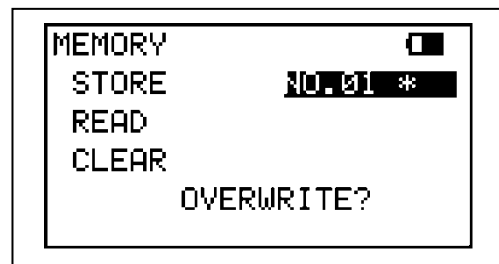


Note: The memory number with "*" indicates memory area where other data have been already stored.



(2) Press Enter to store the data into the memory and it will go back to waveform display automatically.

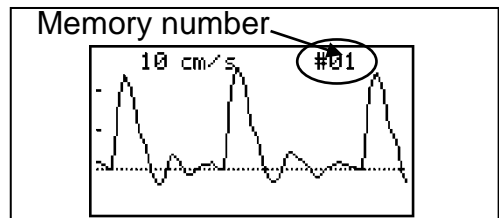
Note: If other data have been already stored in memory number storing, a confirmation of "OVERWRITE?" will be shown. Press Enter to overwrite, or press any one of cursor buttons to cancel for selecting other memory number available. STORE sub menu is not available if pressure has not been assigned to ARM or LEG/TOE.



b. MEMORY - READ

(1) Select the memory number where to read waveform data from by pressing Up and Down.

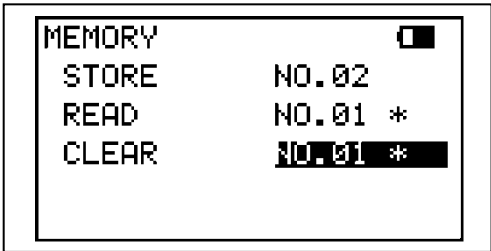
(2) Press Enter button to show the waveform. If desired, press Enter again or MODE + Enter to show next or previous waveform stored, respectively.



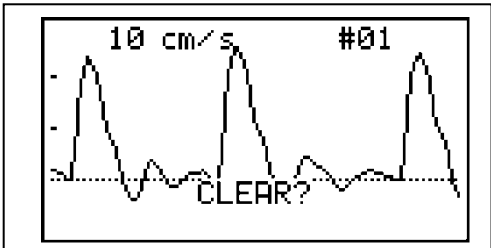
Note: Any frozen waveform is stored temporarily in memory area of FREEZE separated from regular 30 memories. It can be re-shown by reading from memory FREEZE and won't be erased until next waveform is frozen or unit is turned off.

c. MEMORY - CLEAR

(1) Select the memory number, in which you wish to clear the data. The memory number with "*" indicates memory area where data have been already stored.



(2) Press Enter and then the confirmation screen with waveform stored will be displayed as shown in the picture right. Press Enter to clear the data, or press Left to cancel.



Note: If the waveform selected is not the one you wish to clear, press Up and Down to select other memory #.

(3) To clear all the data at once except FREEZE, select and press on ALL and follow the instruction.

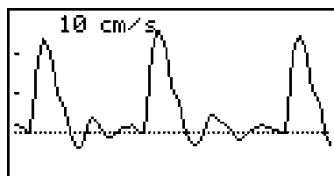


d. DIR (Flow direction)

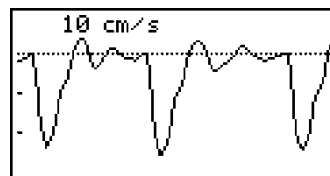
Press Right to change waveform polarity as follows:

Forward: Flow toward probe is processed as positive component.

Reverse: Flow away from probe is processed as positive component.



Forward



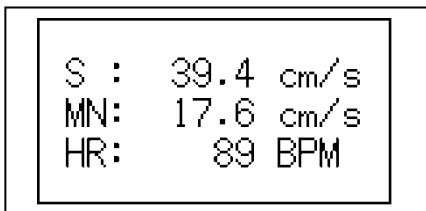
Reverse

e. DISP / OTHERS - DISP (Waveform / Data)

Press Right to change the Display mode as follows:

WAVE: Displays waveforms.

DATA: Displays numerical data



Note: Changing Display mode can be also done by pressing LEG/TOE.

f. WAVEFORM (Freeze mode only)

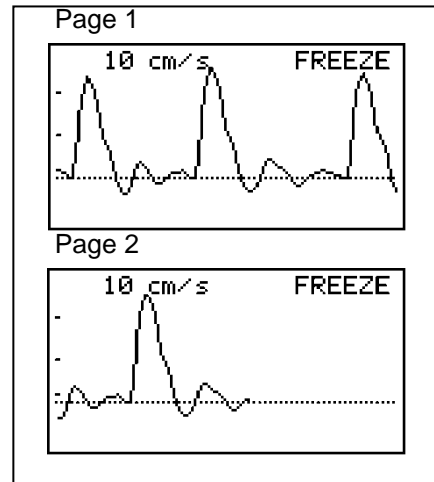
- ◆ Blood velocity and PV Arterial modes (Changing viewing area of waveform);

Press Right to change viewing area of waveform.

Page 1: First half of waveform

Page 2: Second half of waveform

Note: The pages can be also switched by pressing a shortcut key of MODE when on freeze mode of velocity and PV arterial.

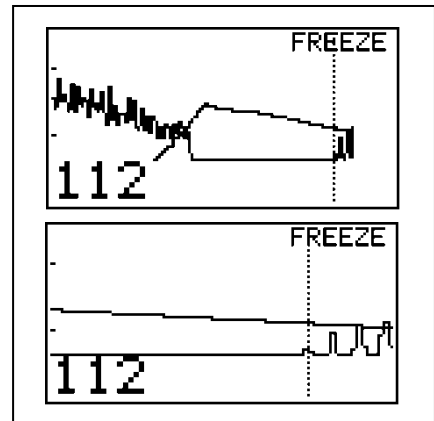


- ◆ ARM/LEG and TOE pressure mode;
(Magnifying/ demagnifying viewing area of waveform)

Press Right to change viewing area of waveform.

FULL: Full waveform is displayed on LCD

MAGNIFIED: Magnified waveform where systolic pressure has been determined is displayed on LCD.



Note: FULL/MAGNIFIED mode can be also changed by pressing a key combination of MODE + Down when on pressure freeze mode.

g. GUIDANCE

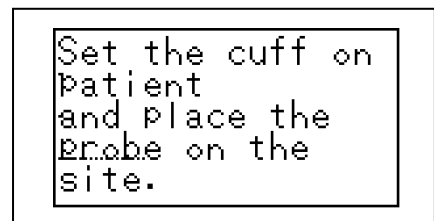
This setting enables or disables the function of displaying guidance on the LCD while on ARM/LEG and Toe pressure modes.

Press Enter or Right to change the guidance mode;

ON: Displays guidance

OFF: Not display guidance

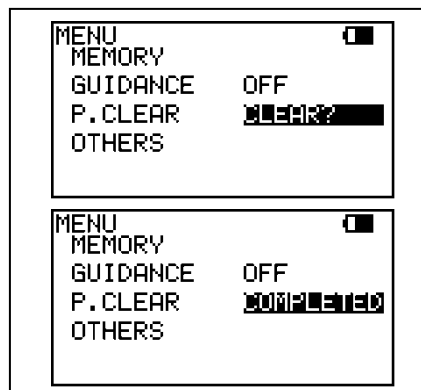
Note: GUIDANCE mode can be changed only when on measurement mode.



h. P.CLEAR (Clearing blood Pressure data)

- (1) Press Enter and a confirmation of "CLEAR?" will be shown.
- (2) Press Enter again to clear the pressure data in RAM and "COMPLETED" will be shown for 5 sec.

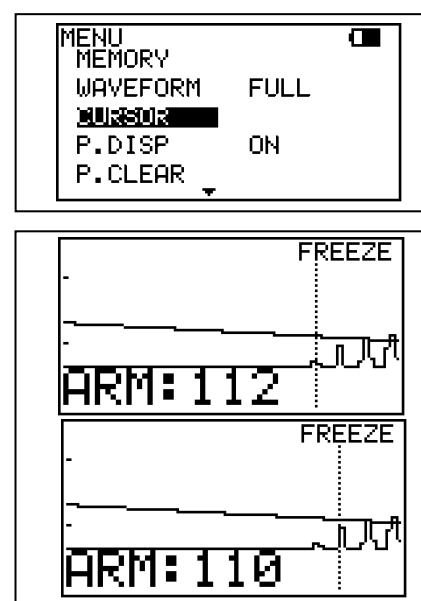
Note: This function can be also done by turning unit off and on OR pressing a shortcut key of ARM or LEG/TOE longer than 2 sec.



i. CURSOR (Mode for adjusting systolic pressure point)

- (1) Press Enter to go to Cursor mode.
- (2) Press Right / Left to move cursor to the right and the left for locating the true systolic pressure point.
- (3) Press Enter to fix it or press Menu to cancel.

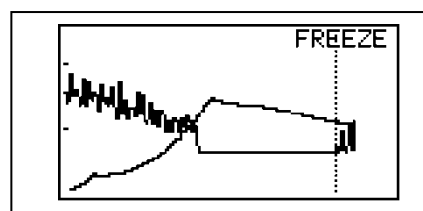
Note: Adjusting systolic point can be also done by pressing a key combination of MODE + Right / Left.



j. P.DISP (Displaying/erasing Pressure value)

Press Enter (or Right) to display pressure waveform WITH or WITHOUT pressure value(s).

Note: The Pressure Display mode can be also switched by pressing a shortcut key of MODE.



Without pressure value(s)

k. OTHERS - LANGUAGE

Press Enter or Right to select the language desired in which menus and messages are written.

Languages: English, Deutsch, Italiano, Español, Français

I. OTHERS - PRB-KEY (Probe button function)

Press Enter or Right to change the probe button function.

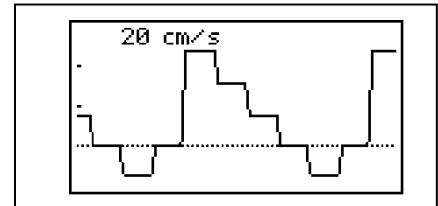
- FREEZE: Freezes/unfreezes waveform
- PRINT: Activates/deactivates printer
- FRZ&PRINT: Freeze and Print

Note: When on ARM/LEG and TOE modes, probe button works the same way as INF/DUMP button no matter what is selected on the PRB-KEY mode.

m. OTHERS - CALibration

Press Enter or Right to change the mode.

- ON: Displays 4 step (3, 2, 1, 0, - 1kHz) calibration waveform on the LCD.
- OFF: Measurement mode

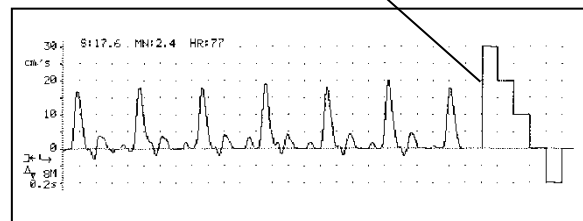


n. OTHERS - CAL PRINT (Printing Calibration)

Press Enter or Right to change the mode.

- ON: Prints 4 step (3, 2, 1, 0, - 1kHz) calibration after velocity waveform on the chart.
- OFF: Prints no calibration waveform.

4 Step Calibration



o. OTHERS - BACKLIGHT

LCD backlighting time can be adjusted on BACKLIGHT setting and the longer time gives you shorter battery life.

Press Up and Down to select the time and press Enter to fix it.

- ON: Turns backlight always on.
- OFF: Turns backlight always off.
- 10 ... 60: Auto-off time with 10 sec steps

Note: BACKLIGHT ON / OFF can be also done by pressing a key combination of MODE + MENU.

When on the Auto-Off mode, backlight goes off if unit is left with no operation for more than auto-off time and next any button operation will turn the light on as well as doing function associated with the button however, light is always on while on measurement mode.

p. OTHERS - AUTO-OFF (Automatic shut-off)

Press Enter or Right to change the mode.

ON: Enables Automatic shut-off.

OFF: Disables Automatic shut-off.

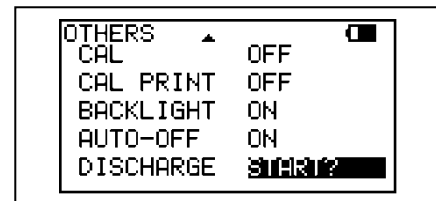
See “§ 3-1. Turning the Unit On” for the details.

q. OTHERS - DISCHARGE

DISCHARGE is available when AC adaptor is connected to Smartdop.

(1) Press Enter and confirmation “START?” will be shown.

(2) Press Enter again to start discharging and then charging.

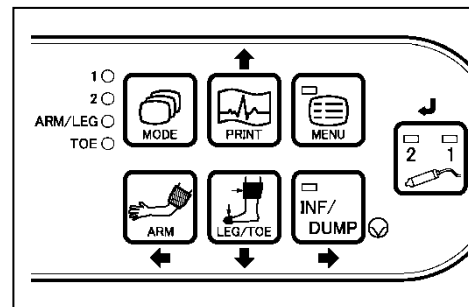


Note: It takes a few extra hours to fully discharge a fully charged battery prior to full charging hours.

4-3. Shortcut keys

Shortcut keys	Functions	Modes	Reference in § 4-2-7
MODE + MENU	Backlight On / Off	All modes	o. Others - Backlight
MODE + RIGHT	Right Cursor	Pressure	i. Cursor
MODE + LEFT	Left Cursor	Pressure	i. Cursor
MODE + DOWN	Zoom In / Out	Pressure	f. Waveform
ENTER	Next waveform	Freeze	b. Memory - Read
MODE + ENTER	Previous waveform	Freeze	b. Memory - Read
ARM / LEG long press	BP clear	Pressure	h. P. Clear
MODE	BP display On / Off	Pressure	j. P.DISP
MODE	Change Page 1/2 or 2/2	Velocity & PV - AC	f. Waveform

Note: “MODE +” means to press and hold MODE button before pressing 2nd combination button.



4-4. External outputs

4-4-1. Headset

Connect the headset when necessary. The headset cuts off the speaker.


















4-4-2. Communication Port

To observe the waveform in high resolution on a PC monitor or to store the waveform and numerical data into a computer for future reference as well as a report of standardized testing modules.

- (1) Install the communication software Smart-V-Link, option, on your computer.
- (2) Connect Smartdop to the computer with dedicated communication cable that comes with Smart-V-Link.
- (3) Turn the unit on and start Smart-V-Link on your computer.

Note: Refer to the operating manual for Smart-V-Link for details.

4-5. Symbol list

Symbol	Description	Symbol	Description
	Type BF applied part		Freeze
	Headset		Mode button
	USB connector		Print button
	AC adaptor connector		Menu button
	Probe connector		Arm button
	Caution* Refer to the Operating manual		Leg / Toe button
	Power ON		Probe selection button
	Power OFF		Probe button
	Manufacturer		

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

5. Display and Printing

5-1. Arterial and venous blood velocity modes

Arterial and venous blood velocity can be measured on these modes by Doppler technique. Smartdop displays and prints waveform as follows:

Mode 1:

Displays approx. 2.56 sec of waveform per screen of LCD

Prints waveform in time scale of approx. 25 mm/sec.

Forward and reverse components are combined.

Mode 2:

Displays approx. 12.8 sec of waveforms per screen of LCD

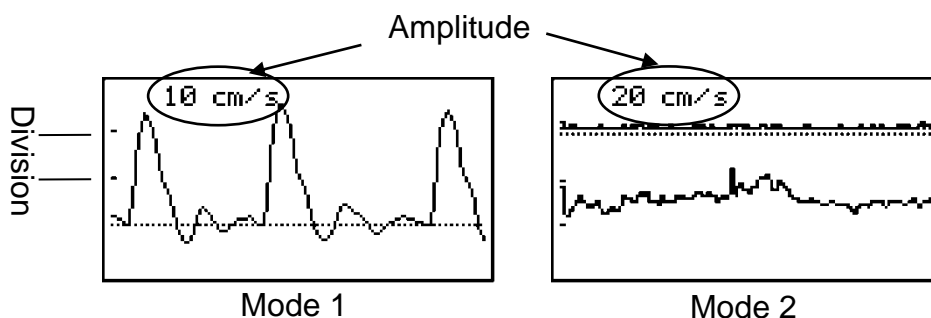
Prints waveforms in time scale of approx. 5 mm/sec.

Forward component (arterial) is separated from reverse component (venous).

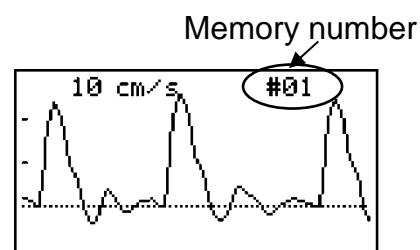
For typical operation for blood velocity modes, see "§ 3-5. Measuring Blood Velocity".

5-1-1. Waveforms on LCD

- ◆ The base line is automatically located at best position depending on how big the reverse component is. Smartdop has 4 base lines, the bottom, 1/4 from the bottom, the center, and 3/4 from the bottom.
- ◆ The waveform amplitude is automatically adjusted for optimal observation.
- ◆ The velocity amplitude scale per division is shown at top left of LCD.



- ◆ Memory number is shown at top right of LCD for waveform read on MEMORY mode. e.g. "#01"



5-1-2. Parameters

Mode 1:		Abbrs.
Systolic velocity	[cm/s]	S
Mean velocity	[cm/s]	MN
Heart rate	[BPM]	HR

Mode 2:		Abbrs.
Systolic velocity	[cm/s]	S
Mean velocity	[cm/s]	MN

Note: All computations are based on as follows:

Mode1: Latest 3 beat average on measurement mode

First 3 beat average on freeze mode

Mode2: Latest 10 sec average on measurement mode

First 10 sec average on freeze mode

If the heart rate can't be calculated because of an over +/-25% irregularity due to an Arrhythmia or venous waveform, "HR:****" will be printed out as an error indicator.

5-1-3. Printing Waveform and Numerical Data

(1) Press PRINT button to print waveforms.

Also, pressing probe button controls printer when PRB-KEY in the menu is set for PRINT or FRZ&PRINT mode.

(2) Smartdop prints waveforms and numerical data as follows and then stops printing automatically.

Measurement mode

Mode 1: Waveform of the last 5 sec before pressing PRINT button

Mode 2: Waveform of the last 25 sec before pressing PRINT button

Freeze mode

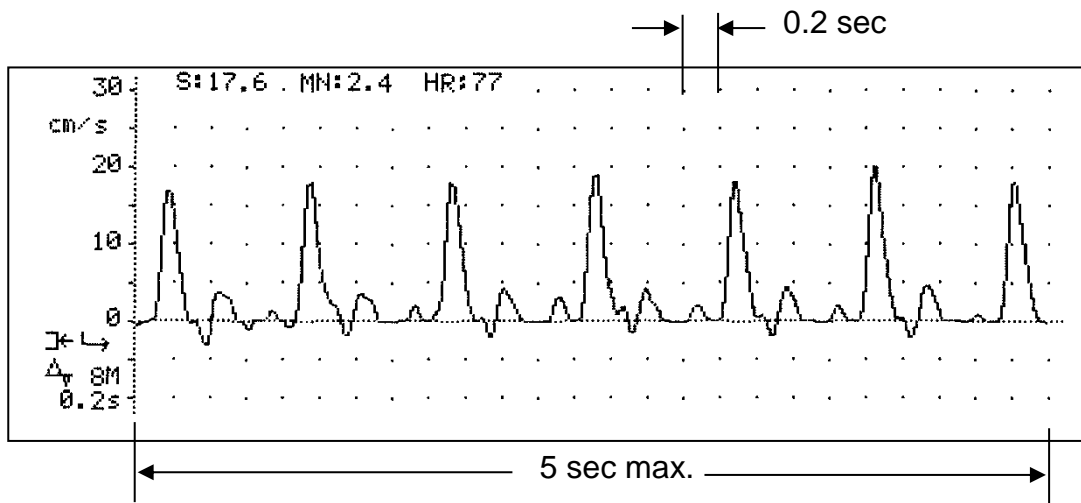
Mode 1: Waveform of the last 5 sec before freezing

Mode 2: Waveform of the last 25 sec before freezing

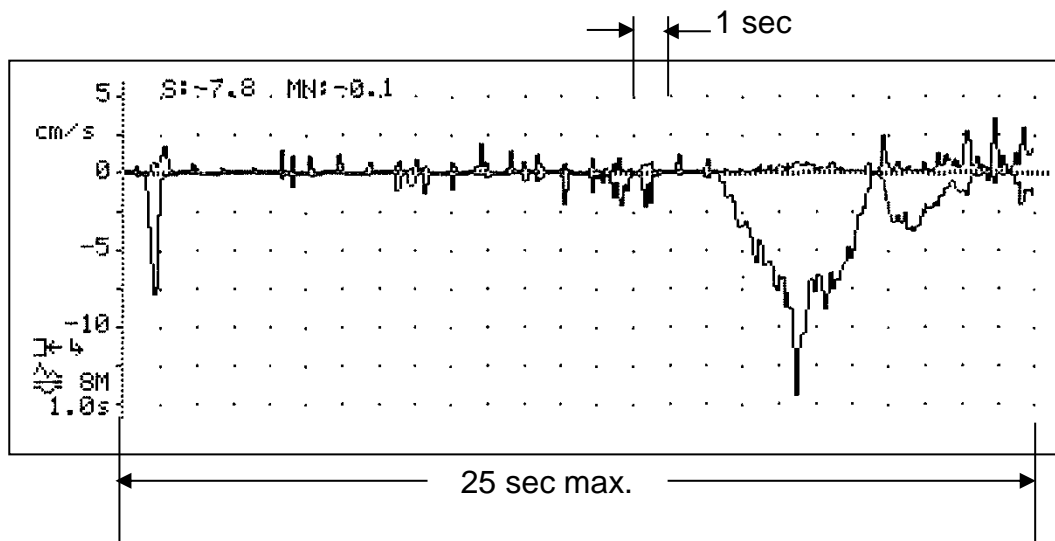
(3) If necessary, press PRINT button the second time to deactivate printer while the printing is in progress.

5-1-4. Print Samples

Mode 1 (Artery): *Time scale 0.2 sec/div. (approx. 25 mm/sec)



Mode 2 (Vein): *Time scale 1 sec/div. (approx. 5 mm/sec)



5-2. ARM / LEG and TOE pressure modes

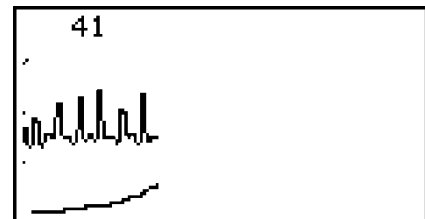
Systolic blood pressures of Arm, Leg and Toe can be measured automatically on these modes and displayed them with velocity/pressure documentation.

Also, Smartdop calculates ABI / TBI and prints them.

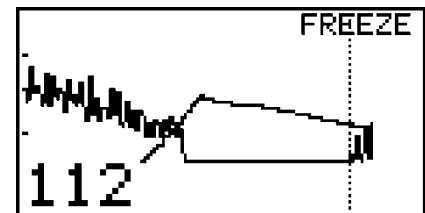
For typical operation for Pressure modes, see “§ 3-6. Ankle brachial pressure index (ABI)” and “§ 3-7. Toe brachial pressure index (TBI)”.

5-2-1. Display Samples in Pressure Measurement Process

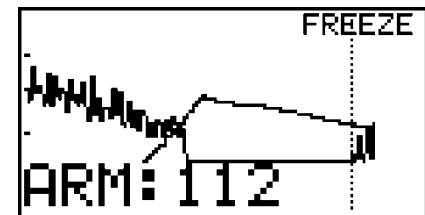
(1) During measurement for blood pressure of arm



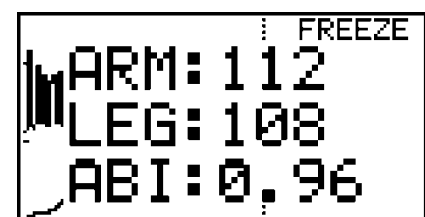
(2) End of the measurement for arm pressure (Freeze mode)



(3) After pressing ARM button



(4) After measurement of leg pressure and pressing LEG button



5-2-2. Optional Functions

Press ARM or LEG/TOE button to recalculate ABI/TBI for the 2 stored pressure data read from the memory.

5-2-3. Error Messages

When error occurs while measuring blood pressure, the following error messages will be displayed on the LCD:

- E1: (Reserved)
- E2: Waveform error.
- E3: Pressure exceed 300 mmHg.
- E4: Systolic pressure not found.
- E5: Time out.
- E6: Cuff pressure don't go up.
- E7: Cuff pressure don't go down
- E9: Cuff pressure go up very fast

Press any button other than probe selection button to delete the error message and proceed to next step.

5-2-4. Print Samples

(1) Pressing PRINT button less than 1 sec.

ARM only

```
ARM: 103mmHg (SM)
HR: 76BPM
```

LEG only

```
LEG: 106mmHg (SM)
HR: 66BPM
```

TOE only

```
TOE: 100mmHg (PPG)
HR: 66BPM
```

ARM and LEG

```
ARM: 89mmHg (SM)
LEG: 106mmHg (SM)
ABI: 1.19
```

ARM and TOE

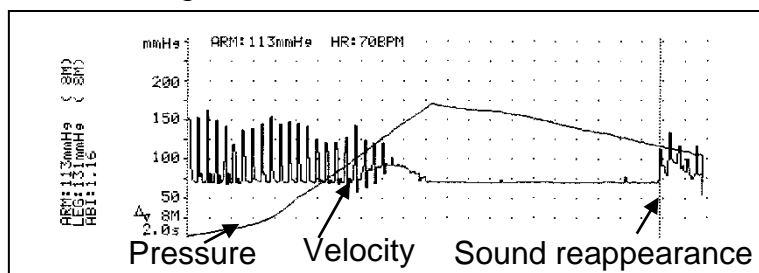
```
ARM: 89mmHg (SM)
TOE: 100mmHg (PPG)
TBI: 1.12
```

Arm, Leg and Toe (Arm should be saved at the end.)

```
ARM: 89mmHg (SM)
LEG: 106mmHg (SM)
ABI: 1.19

ARM: 89mmHg (SM)
TOE: 100mmHg (PPG)
TBI: 1.12
```

(2) Pressing PRINT button longer than 2 sec.



5-3. PV arterial mode (PV-AC)

PV Arterial Studies (PV-AC mode) can be performed on this mode without any optional probes. (PV-DC needs optional PV probe.)

Smartdop displays and prints waveform as follows:

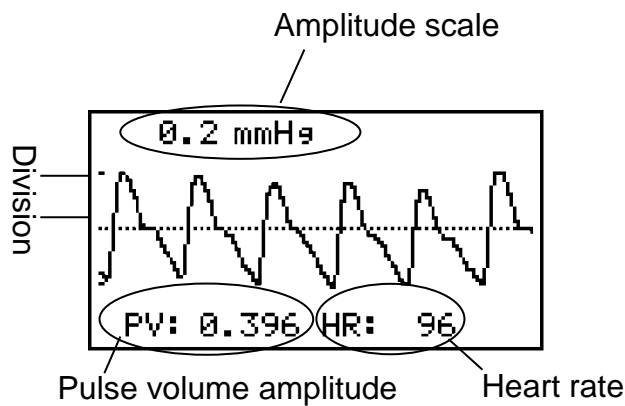
Displays approx. 2.56 sec of waveform per screen of LCD

Prints waveform in time scale of approx. 25 mm/sec.

For typical operation for PV-AC mode, see “§ 3-8. PV - Arterial Studies”.

5-3-1. Waveforms on LCD

- ◆ The waveform amplitude is automatically adjusted for optimal observation.
- ◆ The pressure amplitude scale per division is shown at top left of LCD.



- ◆ Pulse volume amplitude and heart rate are shown at bottom of LCD.

6. Maintenance

6-1. Performance check by user

Please perform the maintenance in case the unit is not in use for a while.

Preparation

- (1) Make sure if there is no damage and / or crack on the main unit and probe.
- (2) Check if wall voltage is good for rating input voltage of AC adaptor.
- (3) Turn the unit off.
- (4) Connect AC adaptor to the unit.
- (5) Connect the probe, suitable for intended clinical application, to the unit.

Checking

- (1) Connect AC adaptor.
- (2) Turn the unit on.
- (3) Check if LCD works properly.
- (4) Set printing paper to the unit and check if it prints waveform properly.
- (5) Rub the probe tip and check if sounds come out from speaker and LCD shows the waveform.
- (6) Check if sound volume can be adjusted.
- (7) Check if battery level is sufficient for battery operation.

6-2. Cleaning

Probe

Remove the Doppler gel from the probe head after use.

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.

If using disinfectant, consult in advance with the manufacturer.

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. Check the unit by maintenance procedures mentioned in "6-1. § Performance check by user".

Blood pressure cuffs

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

6-3. Warranty

The guarantee period is two years for this equipment and one year for probe after the date of purchase when used under normal conditions.

In the event of a problem during the warranty period, please contact your dealer.

In case the warranty period is over, please consult your dealer for a charged service.

7. Options

7-1. Probe selection:

The frequency of diagnostic ultrasound is inversely proportional to depth of penetration. Use those probes depending on your applications.

Standard Doppler probe:

Standard:



- 2MHz: BT2M20S8C(A)*
- 4MHz: BT4M05S8C(A)*
- 5MHz: BT5M05S8C(A)*
- 8MHz: BT8M05S8C(A)*
- 10MHz: BT10M5S8C(A)*

Flat:



- 8MHz: BF8M15S8A

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

PPG probe:

PG-21



PV probe:

PV-21



7-2. Others:

- Sphygmomanometer
- 3-way stopcock
- Smart-V-Link software with communication cable
- Cuffs: DVC-1.9, DPC-2.5, VC-10, VC-12
- PPG probe clip

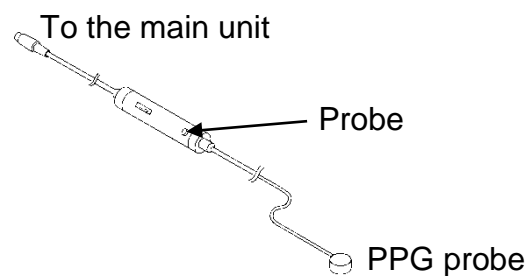
7-3. Photoplethysmograph

With the PG-21, Smartdop senses the reflection of light from the hemoglobin of the red blood cells in surface vessels by utilizing infrared light.

“How to use photoplethysmograph” is described in this section.

7-3-1. PPG (Photoplethysmography) Probe Assemblies

Model PG-21



AC Coupling: Arterial pulse waveform studies, Toe pressure

DC Coupling: Venous reflux study

7-3-2. PPG - Arterial Pulse Waveform Studies

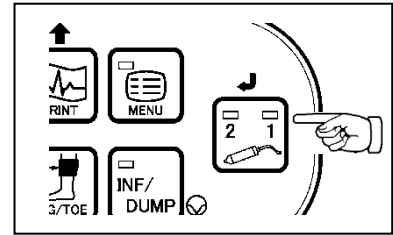
Purpose

Arterial pulse waveform studies by photoplethysmography are performed to determine the presence or absence of pulsatile flow and to assess the state of perfusion in the tissue area immediately beneath the sensor site. When used with a suitable cuff and manometer, the method permits the measurement of systolic blood pressure in the fingers and toes.

Preparation

(1) Connect the PPG probe assembly to the probe connector #1 or #2.

(2) Make sure Mode 1 LED (AC mode) illuminates. If not, press MODE button to select Mode 1 for AC mode.



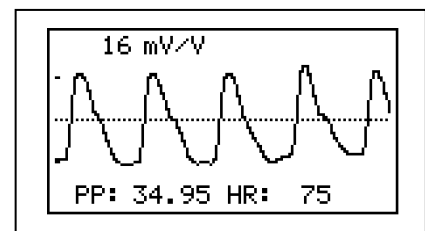
(3) Check that the face of the PPG sensor is free of stains. Clean it if necessary.

(4) Make certain that room temperature is comfortable and, especially, that the skin surface where the probe is to be mounted is warm. Cold constricts superficial blood vessels and thus jeopardizes the accuracy of PPG measurements.

Examination Procedure

(1) Apply the sensor with the clear side against the skin surface, and fix it in place using Velcro strap or double-sided clear tape or PPG probe clip (Option).

(2) The gain is automatically adjusted and the PPG waveform is shown on the LCD.

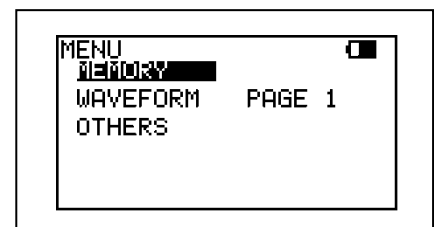


(3) When the waveform gets stable and rhythmic, press INF/DUMP or probe button* to freeze the waveform.

Press PRINT button to print the waveform of last 5 sec., if necessary.

Note: *When PRB-KEY is on Freeze mode.

(4) If you wish to save the data on the memory, see "§ 4-2-7-a. MEMORY - STORE".



7-3-3. PPG - Venous Reflux Study

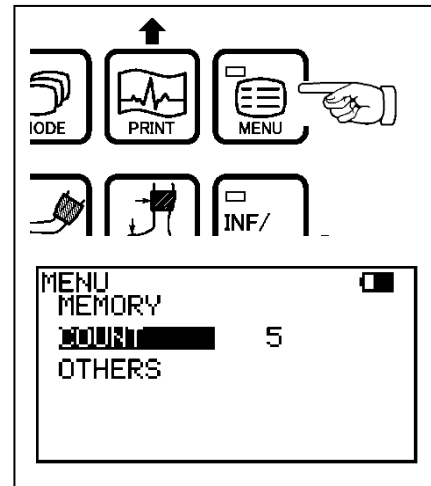
Purpose

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

Preparation

- (1) Connect the PPG probe assembly to the probe connector #1 or #2.
- (2) Make Sure Mode 2 LED (DC mode) illuminates. If not, press MODE button to select Mode 2 for DC mode.
- (3) To change the counting number for patient dorsiflexes, go to the menu and select COUNT and then press Enter (or Right) until the number becomes the one desired.

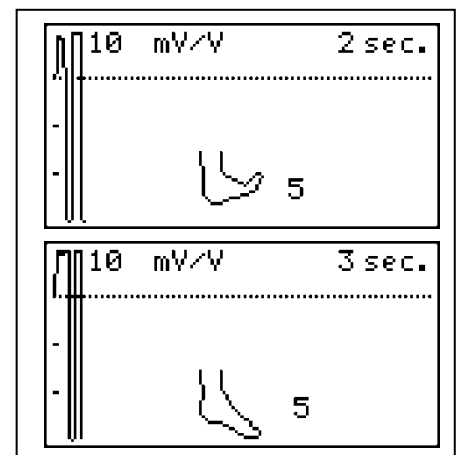
Press MENU button to get out of the MENU mode.



- (4) Check that the face of the PPG sensor is free of stains. Clean it if necessary.
- (5) Make certain that room temperature is comfortable and that the skin surface of the lower limb is warm. Cold constricts superficial blood vessels and thus jeopardizes the accuracy of PPG measurements.

Examination Procedure

- (1) Have the patient sit on an examination table so that the feet are off the floor.
- (2) Apply the sensor, with the clear side against the skin surface, to the medial malleolus over the posterior tibial vein. Fix the sensor in place with double-sided clear tape.
- (3) Press PRINT or probe button to begin the measurement process.
- (4) Ask the patient to flex the foot specified number of times on COUNT following the foot animation on LCD. The exercise should be forceful, especially when lifting the foot upward.
- (5) After flexing, instruct the patient to relax the foot and avoid all movement.



- (6) The test is complete when the waveform on the LCD returns to the baseline amplitude. Smartdop will automatically freeze the waveform and calculate recovery times.

Note: "1/2" is the half recovery time for returning to 50% of refilling amplitude where middle vertical dotted line is shown.

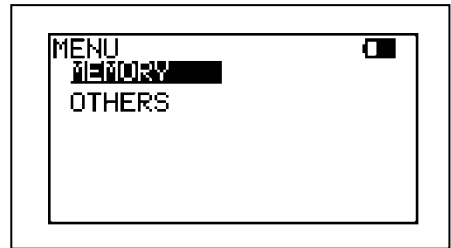
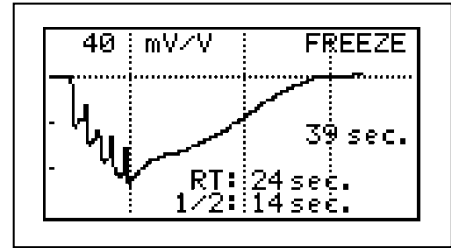
Interpretation

Normal: RT > 20 sec
 1/2RT > 7 sec

- (7) If you wish to save the data on the memory, see "§ 4-2-7-a. MEMORY - STORE".

- (8) Press the INF/DUMP or probe button* to get out of the freeze mode.

Note: *When PRB-KEY is on Freeze mode.



7-3-4. Menu for PPG

Menu	Sub Menu	Selections	Reference in §4-2-7
MEMORY	STORE ^{*3}	1 to 30, FREEZE	a. Memory - Store
	READ	1 to 30, FREEZE	b, Memory - Read
	CLEAR	1 to 30, ALLE	c, Memory - Clear
WAVEFORM ^{*1}		PAGE 1, PAGE 2	f. Waveform
COUNT ^{*2}		1 to 20 (5)	6-1-6. Count
OTHER	LANGUAGE	ENGLISH, DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	PRB-KEY (Probe button)	FREEZE, PRINT, PRT&FRZ	l. Others - PRB-KEY
	BACKLIGHT	ON, OFF, 10 to 60 (10-sec steps)	o. Others - Backlight
	AUTO-OFF	ON, OFF	p. Others – AUTO-OFF
	DISCHARGE ^{*4}		q. Others - Discharge

Note ^{*1}: WAVEFORM is available only on PPG-AC and Freeze mode.

^{*2}: COUNT is used for DC mode when in Measurement mode.

^{*3}: MEMORY - STORE is available only on Freeze mode.

^{*4}: DISCHARGE is available when AC adaptor is connected to the main unit.

7-3-5. PPG Mode Settings

MODE (AC / DC) (Only available in Measurement mode);

(1) Press MODE button to select the mode. Mode LED corresponding to the mode will illuminate.

Mode 1: AC coupling mode for arterial pulse waveform studies

Mode 2: DC coupling mode for venous reflux study

COUNT (Only available in DC - Measurement mode);

(1) Go to COUNT on MENU and number for patient dorsiflexes will be shown.

(2) Press Right (or Enter) to change the number and press MENU to get out of MENU mode.

WAVEFORM;

(1) Go to WAVEFORM on MENU when on PPG-AC and freeze mode and press Right to show 1st/2nd half of waveform on LCD.

Note: Switching 1st/2nd half can be also done by pressing MODE. See “§ 4-2-7-f. WAVEFORM”.

7-4. Pneumoplethysmograph

With the PV-21, Smartdop senses volume changes in a limb or digit by measuring the pressure changes in a recording cuff.

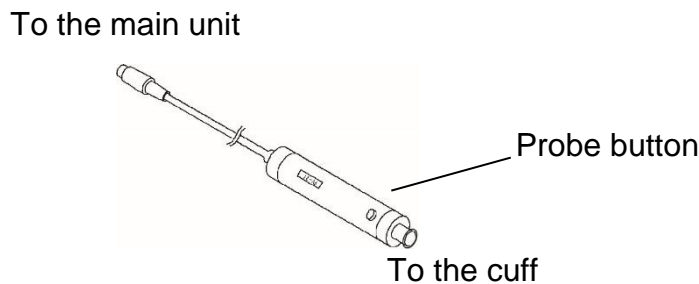
“How to use pneumoplethysmograph” is described in this section.

Built-in cuff inflator works when INFLATOR in menu mode is ON to inflate cuff.

See “§ 7-4-4. PV Mode Setting - INFLATOR” for details.

7-4-1. PV (Pneumoplethysmography) Probe Assemblies

Model PV-21



DC Coupling: Measurement of maximum venous outflow

7-4-2. PV - Measurement of Maximum Venous Outflow

Purpose

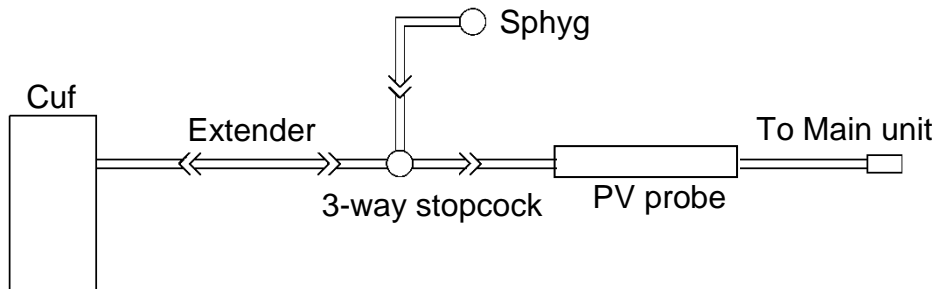
Because deep venous occlusion cannot be diagnosed reliably on the basis of presenting signs and symptoms, pain and swelling being frequently due to other causes, objective screening tests are of value in confirming or ruling out suspected venous obstructions in the lower extremities. The test consists of first inducing temporary venous pooling by means of a constricting thigh cuff followed by measurement of the rapidity of emptying when the constricting cuff is suddenly vented. Measurement of maximum venous outflow is frequently employed as an adjunct to Doppler venous compression studies.

Preparation

- (1) Connect the PV probe assembly (PV-21) the probe connector #1 or #2 of the main unit, and turn it on.
- (2) Make sure Mode 2 LED (DC mode) illuminates. If not, press MODE button to select Mode 2 for DC mode.

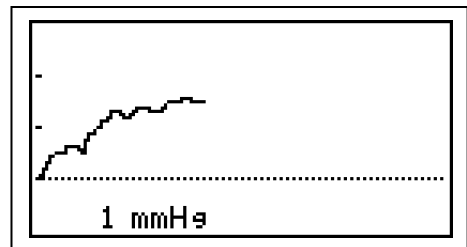
Examination Procedure

- (1) Place the patient in supine position with the leg and hip rotated outward. Use pillows to support the leg and hip. It is important that the patient is comfortable and relaxed.
- (2) Wrap a wide occluding cuff at mid-thigh and a sensing cuff at mid-calf.
- (3) Connect a 3-way stopcock to the inlet of PV probe. Interconnect the stopcock, tubing, cuff and sphygmomanometer as shown below.

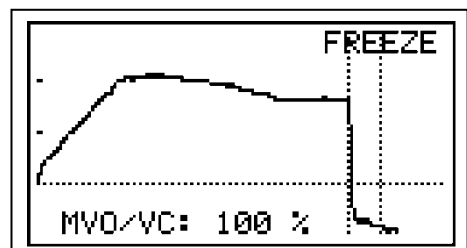


- (4) Turn the stopcock so that air is routed from the sphygmomanometer to the sensing cuff at mid-calf.
- (5) Inflate the sensing cuff to 40 mmHg. Wait 10 seconds to allow time for settling and deflate the cuff to 15 mmHg.
- (6) Turn the stopcock so that it blocks sphyg and routes cuff pressure to the PV probe.
- (7) Disconnect the sphyg from the stopcock and attach it to the occluding cuff at the thigh. If INFLATOR is ON, connect occluding cuff to inflation inlet of Smartdop instead of sphyg with a tubing.
- (8) Press PRINT button to begin the measurement process.

- (9) Inflate the occluding cuff at the thigh to at least 60 mmHg. If INFLATOR is ON, press INF instead to inflate cuff. Pressures in sensing cuff are plotted on the screen. The graph will indicate a gradual increase in waveform amplitude signifying that venous outflow is blocked by the occluding cuff.



- (10) After 90 seconds, disconnect the sphyg from the occluding cuff. The pressures on the screen will drop back to the baseline.



(11) Smartdop will automatically stop the measurement process, and then freeze the waveform. Press PRINT button to print the waveform, if necessary.

(12) If you wish to save the data on the memory, see “§ 4-2-7-a. MEMORY - STORE”.

(13) Press the INF/DUMP button to get out of the freeze mode.



7-4-3. Menu for PV

Menu	Sub Menu	Selections	Reference in § 4-2-7
MEMORY	STORE*2	1 to 30, FREEZE	a. Memory - Store
	READ	1 to 30, FREEZE	b. Memory - Read
	CLEAR	1 to 30, ALL	c. Memory - Clear
IINFLATOR*1		ON , OFF	6-3-5. Inflator
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	PRB – KEY (Probe button)	FREEZE, PRINT, PRT & FRZ	l. Others - PRB-KEY
	AUTO-OFF	ON , OFF	p. Others - AUTO-OFF
	DISCHARGE*3		q. Others - Discharge

Note *1: INFLATOR is available only on Measurement mode.

*2: MEMORY - STORE is available only on Freeze mode.

*3: DISCHARGE is available when AC adaptor is connected to the main unit.

7-4-4. PV Mode Setting

MODE (AC / DC) (Only Measurement mode);

(1) Press MODE button to select the mode. Mode LED corresponding to the mode will illuminate.

Mode 1: AC coupling mode for arterial pulse waveform studies

Mode 2: DC coupling mode for measurement of maximum venous outflow

INFLATOR;

(1) Go to INFLATOR on MENU and press Enter or Right to change the mode as follows:

ON: Inflator ON when used with PV-21 without sphyg.

OFF: Inflator OFF when used with PV-21 with sphyg.

(2) When INFLATOR is ON, connect 3-way stop cock to inflation inlet of Smartdop instead of sphyg with a tubing and Smartdop will inflate the cuff to 60 mmHg automatically.

8. Technical Information

8-1. Principles

Model Smartdop 30EX is designed to obtain various blood flow velocity 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 or a headset.

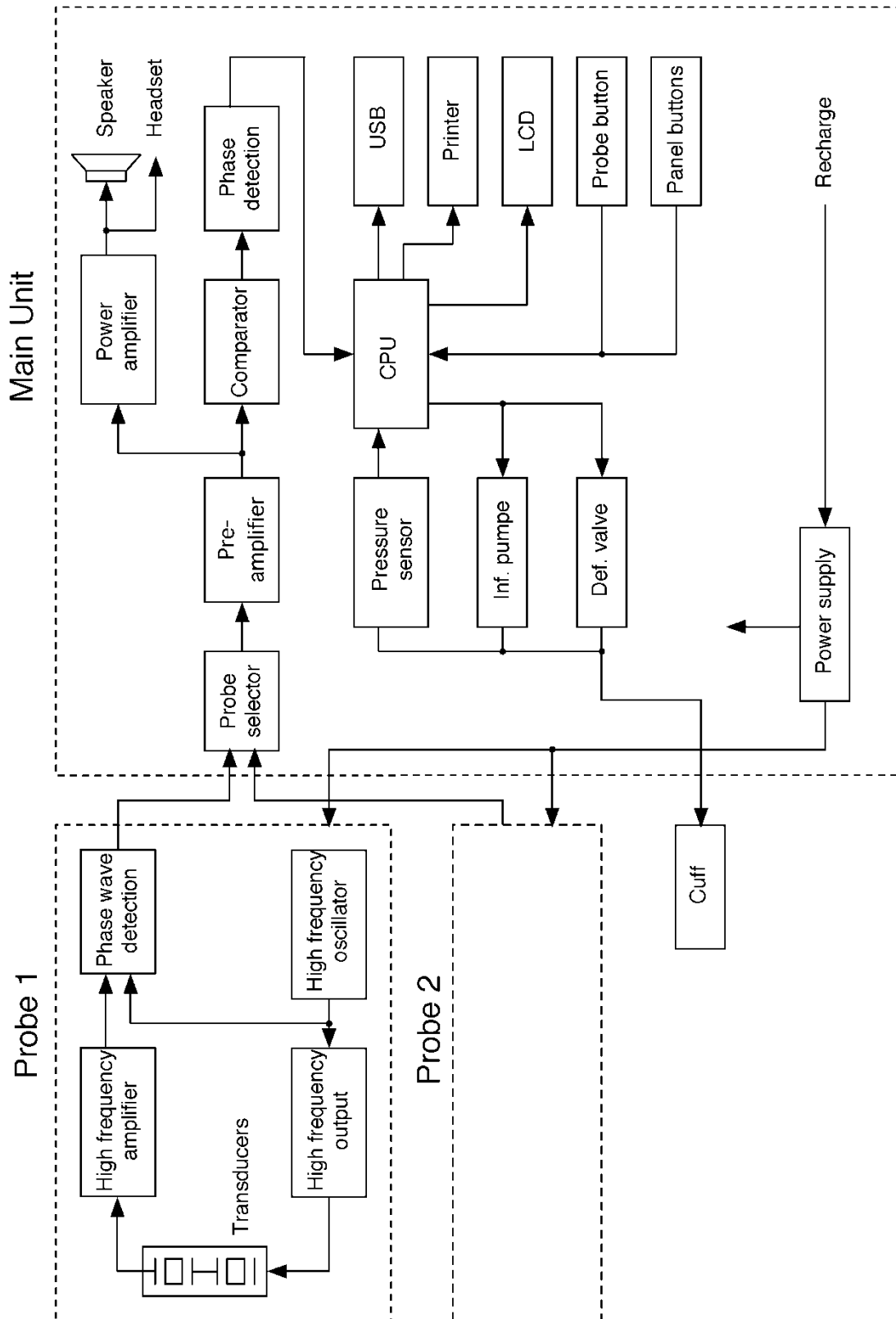
Simultaneously, the Doppler shift signals are applied to the CPU and converted to blood flow velocity waveform signals which can be displayed and printed.

On the ARM / LEG and TOE pressure modes, the blood pressure cuff is wrapped where the blood pressure is taken and the probe is put on the lower extremity 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 30 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 displays the systolic blood pressure on the LCD.

8-2. Block diagram



8-3. Specifications

Probes:	Model	Freq.	Ispta* (in situ) [mW/cm ²]
	BT2M20S8C	2 MHz	80 mW/cm ² or less
	BT4M05S8C	4 MHz	390 mW/cm ² or less
	BT5M05S8C	5 MHz	390 mW/cm ² or less
	BT8M05S8C	8 MHz	390 mW/cm ² or less
	BT10M5S8C	10 MHz	390 mW/cm ² or less

**Ispta: Spatial Peak - Temporal Average Intensity*

Power: Ni-MH rechargeable battery pack or AC adaptor
Input: AC 100-240V- 0.3A (max), 50/60 Hz
Output: DC 12V, 500mA or more

AC Adaptor: Model name: GMPU18UI-3
Consumption: DC 12 V, 500 mA
Recharge: Approx. 4 hours by the AC adaptor
Full charge life: 7 hours or more with printing
Battery life: Approx. 2 years, 300 full charges
Automatic shut-off: No signal: 5 min. Freeze: 10 min. Others: 15 min.
Frequency range: 200 Hz to 5 kHz
Mode settings: Operation, Display, Direction, Memory, Others
Waveform memory: 30 waveforms
LCD display: 128 x 64 dots, STN LCD
Bi-directional blood velocity waveform
Numerical data (Systolic & mean velocities, HR)
Heart rate: 30 to 240 BPM
Blood pressure data (pressure profile, ABI, TBI)
PV-Arterial waveform
Battery level and low battery indicators

Printer: Paper: 58 mm (W) x 25 m/roll (L), Thermal
Resolution: 332 dots/line
Print speed: Approx. 2.5 mm/sec

Accuracy: Velocity: +/-10% or less comparing with internal phantom testing.
Heart rate: +/-5%
Pressure: +/-5 mmHg

Speaker output: 250 mW or more
Inflation rate: 10 - 20 mmHg/sec

Deflation rate: 2 - 5 mmHg/sec
External outputs: Headset, USB port
Electrical safety: Conform to IEC60601-1
Internally powered equipment
Type BF applied part.



Operating environment: 10 to 37 degrees Centigrade
85% humidity or less with no condensation

Storage and transport environment:
0 to 50 degrees Centigrade
85% humidity or less with no condensation

Dimensions: Main unit: 252 (W) x 192 (D) x 91 (H) mm
(Probe holders not included)
Probe: 20 (Diam.) x 105 (L) mm

Weight: Approx. 1.6 kg (including 1 probe)

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

Examples:

03020001: Feb/2003

0401: Jan/2004

* 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 device
 : Internally powered equipment
 Protection grade against electric shock : Type BF applied part

- (2) Electromagnetic emission and electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic emissions		
The Smartdop 30EX is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop 30EX should assume that it is used in such an environment.		
Emissions test	compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Smartdop 30EX 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 30EX 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 30EX 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 30EX is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop 30EX 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.

Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV 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	< 5% UT (> 95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 s	< 5% UT (> 95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 s	Mains power should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Smartdop 30EX is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop 30EX should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Smartdop 30EX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80 MHz to 2,5 GHz	3V/m	$d = 1,2\sqrt{P}$ 80 - 800 MHz $d = 2,3\sqrt{P}$ 800 MHz - 2,5 GHz 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

			<p>determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b</p> <p>Interference may occur in the vicinity of the equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 30EX is used exceeds the applicable RF compliance level above, the Smartdop 30EX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Smartdop 30EX.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			



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