OPERATING MANUAL

Smartdop 45

BI-DIRECTIONAL BLOOD FLOWMETER
With
Waveform Display and Printer

Excellence in Human Service and Technology

Hadeco, Inc.

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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 blood flow measurement purposes only.

3. Do not apply any modification to the unit.

4. Unit installation:
   (1) Take care of storage and operating environments.
   (2) Do not place near water.
   (3) Dot not place where atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salt, sulfur and so forth will not affect the unit adversely.
   (4) Take care of the stability conditions such as inclination, vibration, and shock during transportation and installation works.
   (5) Do not place where chemicals are stored, or where gas may be generated.
   (6) Do not place where the unit tends to fall.

5. Before use:
   (1) Make sure that the unit operates safely and correctly by following the maintenance procedures mentioned in " 4-1. Performance Check Procedures by User".
   (2) Make sure that all cables are connected correctly and safely.
   (3) Using more then one equipment together may result in erroneous diagnosis from malfunction or cause a danger.
   (4) Recheck external connections to the patient carefully.
   (5) 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 an electric cautery, cardioverter, other ultrasonic device or mobile phone.
(2) Be careful not to exceed time and volume which is necessary for diagnosis treatment.
(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 operating the unit in a manner safe to the patient.
(5) Do not let the patient touch the unit.
(6) Use the designated accessories only such as the probe.
(7) Do not use the accessories with other devices.
(8) Use the unit under the operating environments specified on the specifications.
(9) Use the Smartdop as specified in the operation manual.

7. After use:

(1) Return all switches to the conditions before use and turn off the power supply following the prescribed procedures.
(2) Do not apply excessive force to disconnect the cables such as pulling them too strongly.
(3) Clean the unit, accessories, cables and probes and place in right place for the next use.

8. Storage:

(1) Take care of (1) to (5) of section #4 in the previous page.
(2) Clean the unit, accessories, cables and probes and place in right place for the next use.
(3) When using the unit next time, follow the maintenance procedures to make sure it works properly and safely.

9. Do the periodical inspection by following the procedures mentioned in " 4-1. Performance Check Procedures by User".

(1) Inspection must be done once a year.

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

11. Ultrasonic gel:
    (1) Use ultrasonic gel only for non-invasive use. Using other materials such as baby oil and cream may cause incorrect Doppler sounds.
    (2) Using other materials 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 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. 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.

14. Do not disassemble the Smartdop.

15. Destruction:
    (1) In case of destruction of the unit, follow the instructions for disposition of the destruction appointed by each country or local government.

16. 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 45.

The Hadeco Smartdop 45 is a uniquely designed bi-directional handheld Doppler with LCD display and fast printer. It detects arterial and venous blood flows in extremities as well as fetal heart sounds.
The Smartdop displays velocity waveforms, numerical data and fetal heart rate. Also it prints them out.

Please read this manual carefully to acquaint yourself with the Smartdop 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 HANDHELD DOPPLER WITH LCD DISPLAY and FAST PRINTER
  Displays real-time velocity waveforms, numerical data and heart rate.
  Prints frozen waveform, numerical data and monitored heart rate as well as patient data.

* HADECO DESIGNED SMART MICROPROCESSOR
  Various mode settings are available for optimal measurement with the menu displayed on the LCD and unique Scroll Button.
  30 waveform memory for waveform, numerical data, heart rate and patient data.

* CONVENIENT PROBE ACTIVATION BUTTON
  Freezes & prints waveform and numerical data for notation.

* MULTIPROBE SELECTION of 2, 4, 5, 8 and 10 MHz.

* AUTOMATIC POWER "OFF"

* USB COMPUTER INTERFACE
  Stores waveforms and numerical data in your computer for data analyzing and filing. Communication cable and Windows software are optional.

* Photoplethysmograph (PPG) and Pneumoplethysmograph (PV) PROBES OPTIONAL
  Expands arterial & venous testing.

1-2. CLINICAL APPLICATIONS

1-2-1. Detections of fetal heart rate

Probe to be used BT2M20S8C (2 MHz)

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

1-2-2. Detections of arterial and venous blood flow velocity

Probes to be used	BT4M05S8C	(4 MHz)
	BT5M05S8C	(5 MHz)
	BT8M05S8C	(8 MHz)
	BT10M5S8C	(10 MHz)

* ABI studies
* PEAK & MEAN blood velocity determinations.
* Peripheral vascular procedures.
* Blood pressure segmental studies.
* Venous compressions.
* Penile & digit systolic pressures.
* Flow velocities in recovery room.

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.

Note: One of these probes comes with Smartdop 45 as a standard accessory. Other probes are available as optional accessories.

BT2M20S8C (2 MHz):	Fetal heart rate and sounds
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

1-4. ACCESSORIES

Carrying case	1
AC adaptor	1
Ultrasonic gel	1
Paper	1
Headset	1

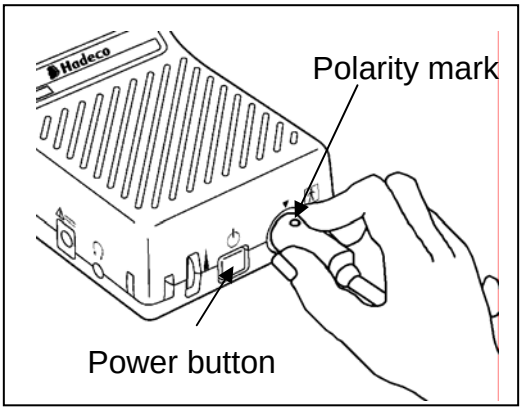
2. QUICK START

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

2-1. TURNING THE UNIT ON / OFF

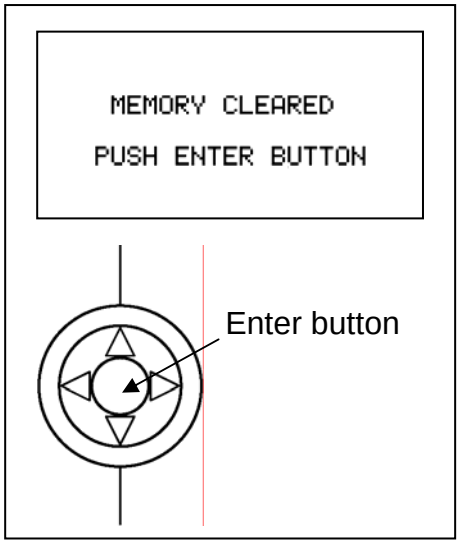
(1) Connect the probe with round polarity mark up (12 o'clock) on the probe connector and press the power button to turn the unit ON.

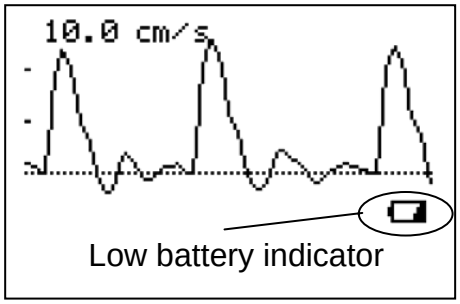
(2) Press the power button again to turn the unit OFF.



(3) When Smartdop is turned ON first time, the message as shown in picture right will appear, press Enter button to proceed.

(4) When battery is low, low battery indicator appears as shown right. You can use Smartdop for some time though, we strongly recommend recharging battery as soon as possible for further use.





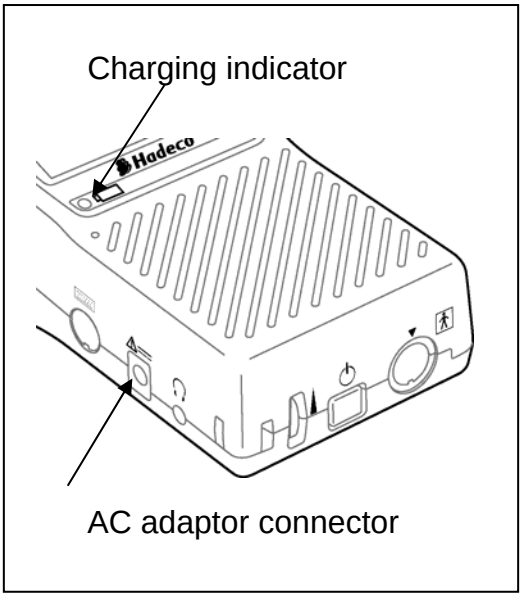
(5) AUTOMATIC POWER OFF

When the AUTO-OFF mode is ON, if the unit is left on, the power is automatically shut off after following time passes:

(a) 35minutes when in measurement. (Only Fetal Heart Rate WAVE mode)
(b) 15minutes when in measurement. (Except Fetal Heart Rate WAVE mode)
(c) 2 minutes when no signal.
(d) 5 minutes when on freeze mode.

2-2. CHARGING / DISCHARGING BATTERY

(1) Turn the unit off and plug the AC adaptor to the unit to charge battery. The charging indicator will go solid orange while charging is in progress.



Note: Use the designated adaptor, **FRIWO Model #: FW 3299/15.0974 for Europe**.

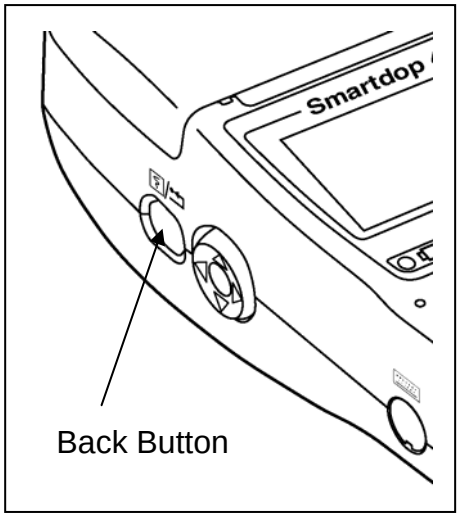
(2) When the battery is fully charged, the charging indicator will go solid green. Unplug the AC adaptor.

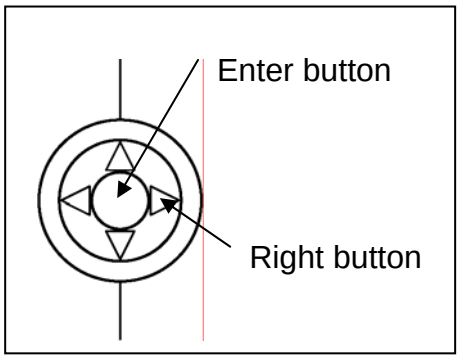
(3) **Discharging battery**

When the battery is not fully discharged, charging battery may cause the short charge life of the battery. In this case, we recommend discharging the battery before charging.

• Turn the unit off and plug the AC adaptor.

• Press Back Button and hold it, and press Enter button to display battery level.
• While holding Back Button, press Right button to discharge the battery.
• The “DISCHARGE” will be displayed on the LCD.
• After the discharging completed, charge process will start automatically and the “DISCHARGE” will disappear, then charging indicator will go solid orange.

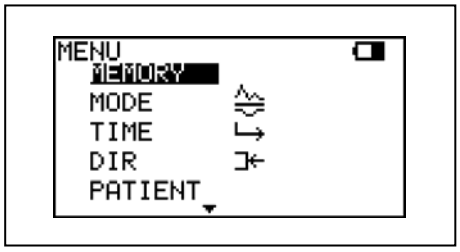




Note: It takes about 3 hours to fully charge battery. Battery life is 300 full charges. Contact your dealer for replacing battery.

2-3. CHECKING BATTERY LEVEL

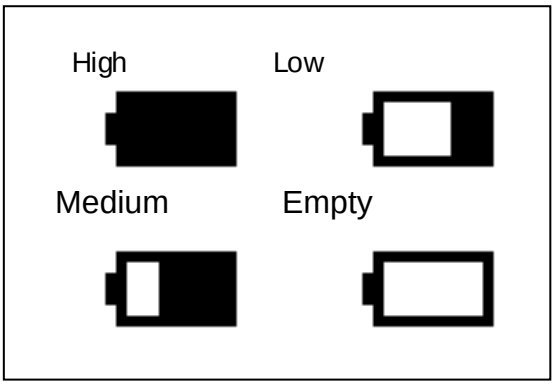
Battery level indicator shows upper right of the menu screen.



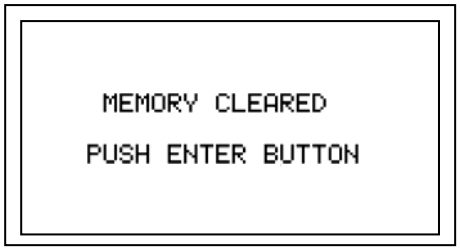
(1) Turn the unit on and press Enter button to display the menu.

(2) Battery level indicator shows the battery level in 4 steps as shown right.

(3) Charge the battery when in low.



When turning the unit on in case battery is extremely low, the message shown right appears, and all data such as waveform memories and mode settings have been cleared.



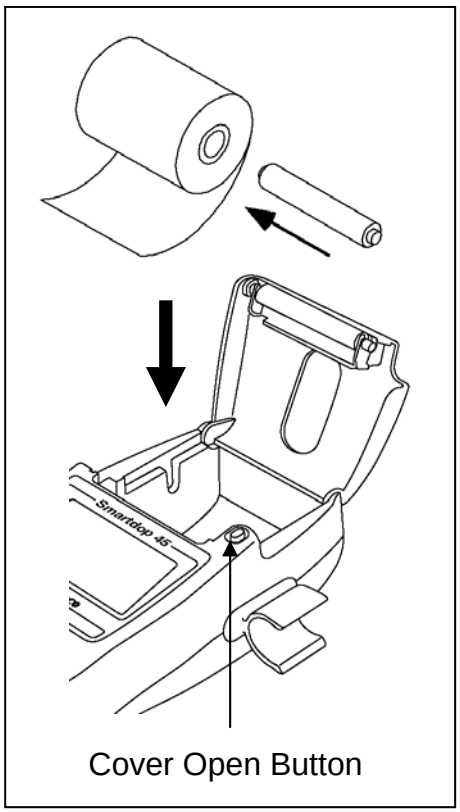
(1) Press Enter button to go to Measurement mode and charge the battery.

2-4. SETTING PRINTER PAPER

(1) Press Cover Open Button to open the paper cover and remove the roll shaft.

(2) Insert the roll shaft into the paper roll.

(3) Set them in the paper compartment as shown right. Pull the paper edge out a few inches and close the paper cover.

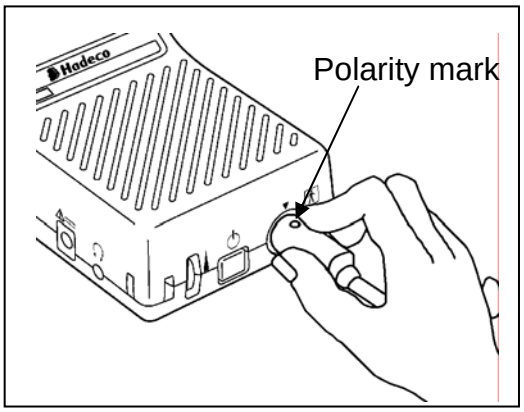


Cover Open Button

2-5. MEASURING BLOOD VELOCITY

This section explains the fundamental use of measuring blood velocity. Refer to “ 3. Appearance and Mode Settings” for various uses.

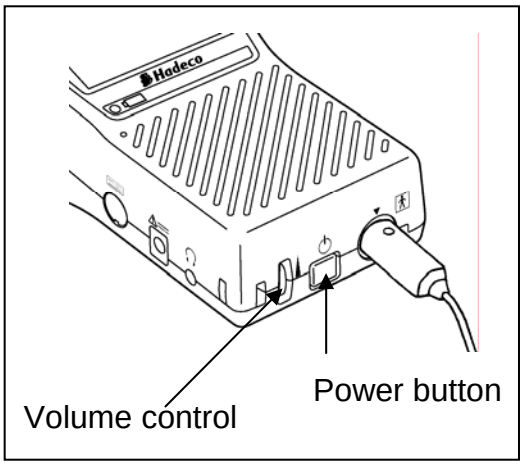
(1) Connect the probe to the Smartdop with the round polarity mark up on the probe connector (12 o'clock).



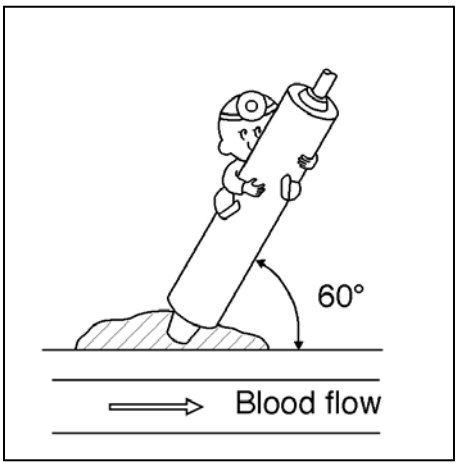
(2) Put ultrasonic gel on the probe top or patient skin.

(3) Press the power button to turn the unit on. Turn the volume control to maximum.

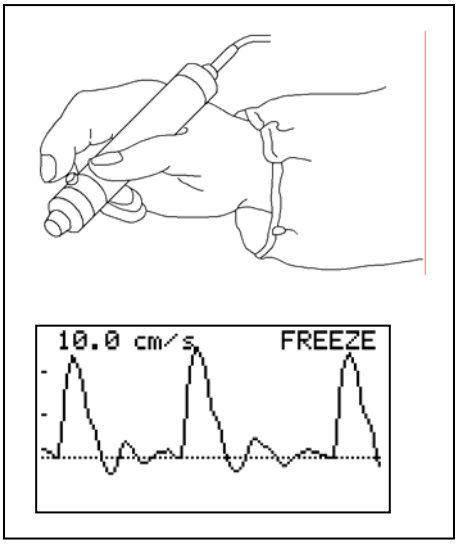
If you wish to enter the patient data, see “ 3-2-3-g. Patient Data Input”.



(4) 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 60 degrees.

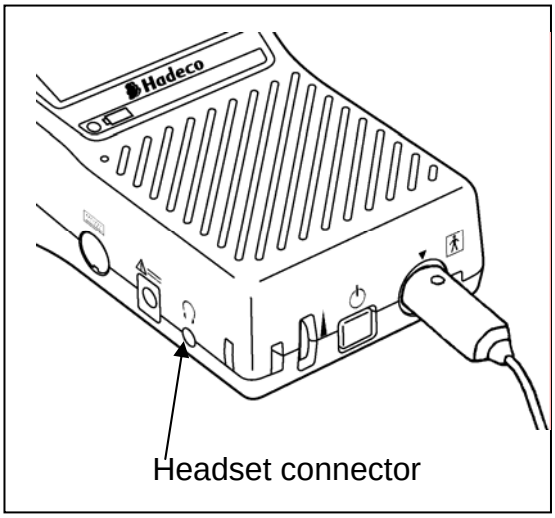


(5) When the waveform becomes rhythmical and stable, wait more than 5 sec without moving the probe, and then press the probe button to freeze and print the waveform of last 5 sec.



Note: Probe button function can be selected from Freeze & Print, Freeze, and Print on PRB-KEY mode setting.

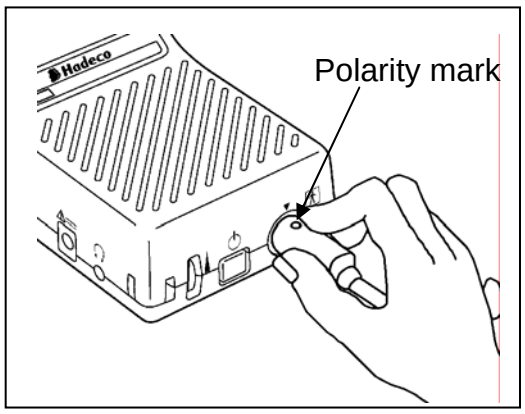
(6) Headset can be used to listen to Doppler sounds. It will cut off the speaker.



2-6. MEASURING FETAL HEART RATE (2 MHz only)

This section explains the fundamental use of measuring fetal heart rate. Refer to “ 3. Appearance and Mode Settings” for various uses.

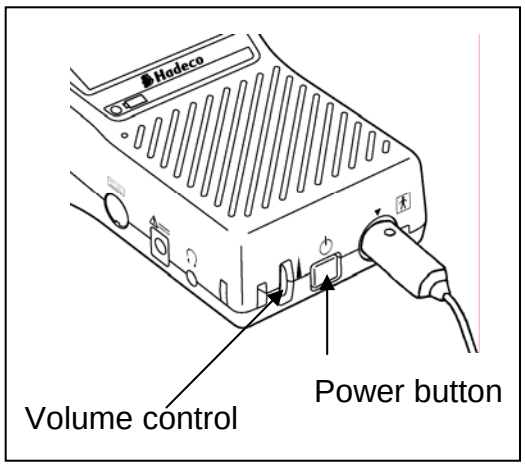
(1) Connect the 2 MHz probe to the Smartdop with the round polarity mark up on the probe connector (12 o'clock).



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

(3) Press Power button to turn the unit on. Turn the volume control to maximum.

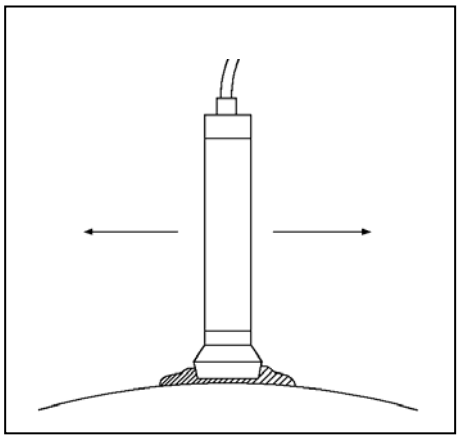
(4) If you wish to monitor heart rate waveform, see “ 3-2-3-h. DISP (Waveform / Data)” to change the mode.



(5) 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.

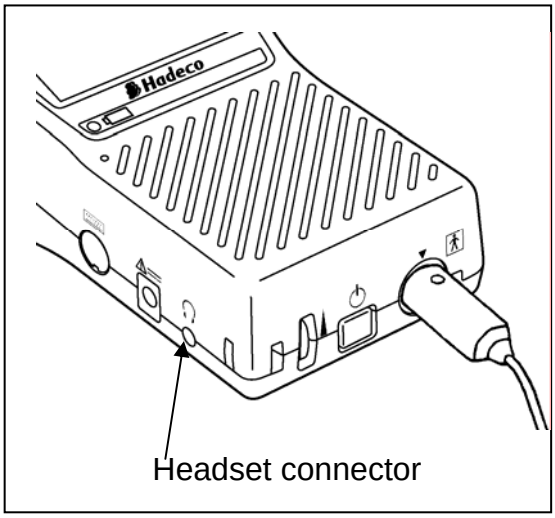
(Maternal heart rates match the maternal pulse rates.)



(6) When the heart rate becomes stable, press the probe or Right button to freeze it.

Note: If the stable signals are not being detected, the "*" mark will be shown above "HR".

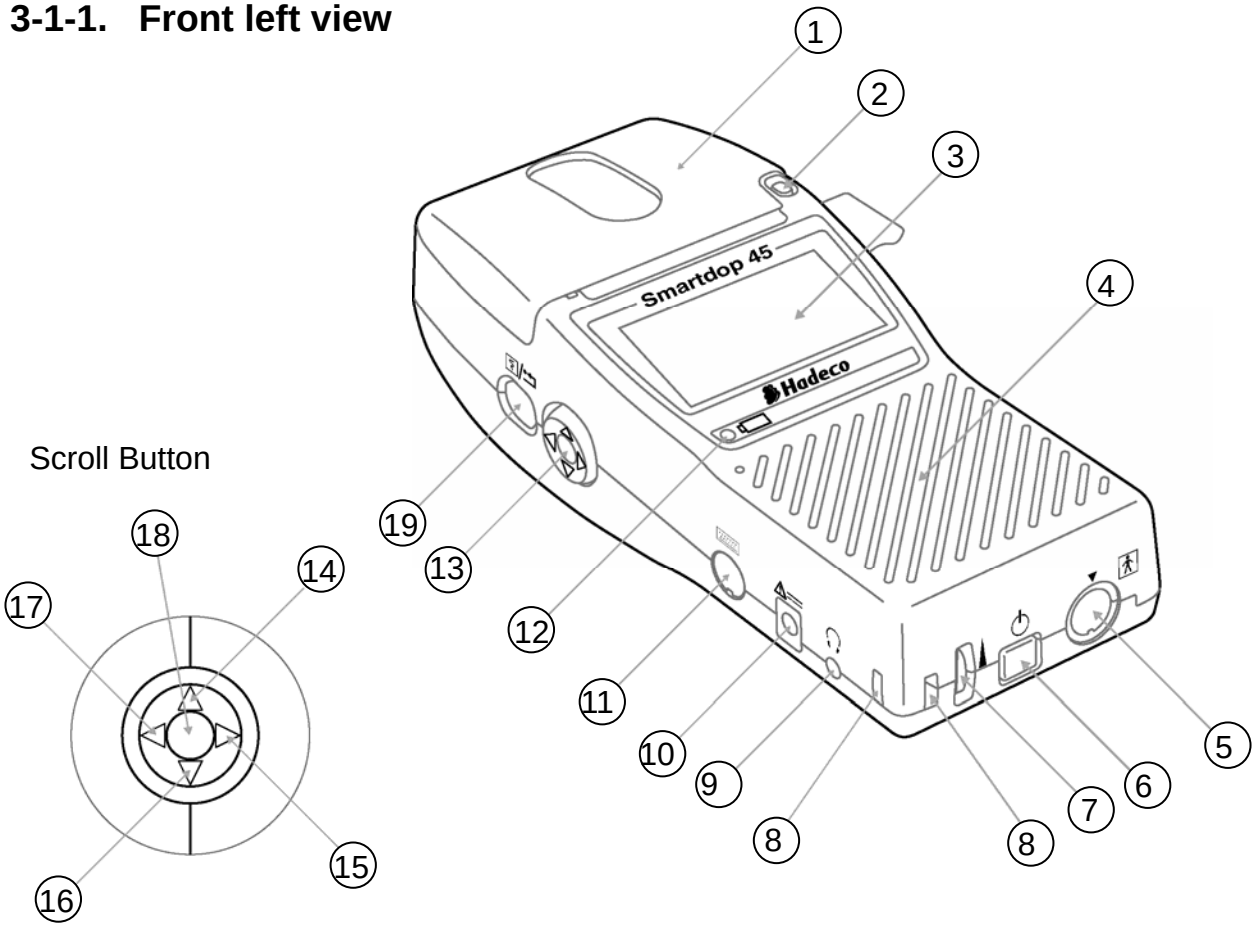
(7) Headset can be used to listen to Doppler sounds. It will cut off the speaker.



3. APPEARANCE AND MODE SETTINGS

3-1. OPERATING CONTROLS

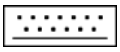
3-1-1. Front left view



1. Paper cover: For printer paper.
2. Cover Open Button To open the paper cover.
3. LCD display: Displays waveform, numerical data, heart rate and menu for mode settings.
4. Speaker: Outputs Doppler sounds.
5. Probe connector: To connect probe
6. Power button: To turn the unit on / off.
7. Volume control: To adjust sound volume.
8. Strap hole: To attach hand strap.

9. Headset:  To connect headset. It cuts off the speaker.

10. AC adaptor connector: To connect the designated AC adaptor.

11. Keyboard connector:  To connect PS2 keyboard.

12. Charging indicator:  Indicates battery status.

    Orange : Charging
    Green : Fully charged

13. Scroll Button: Consists of 5 internal buttons and has following functions.

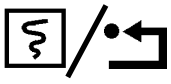
    14. Up: To select upper menu item.
    To increase waveform memory number in Freeze mode.
    To move cursor up on the on-screen keyboard.

    15. Right: To move cursor right on the on-screen keyboard.
    To go to submenu.

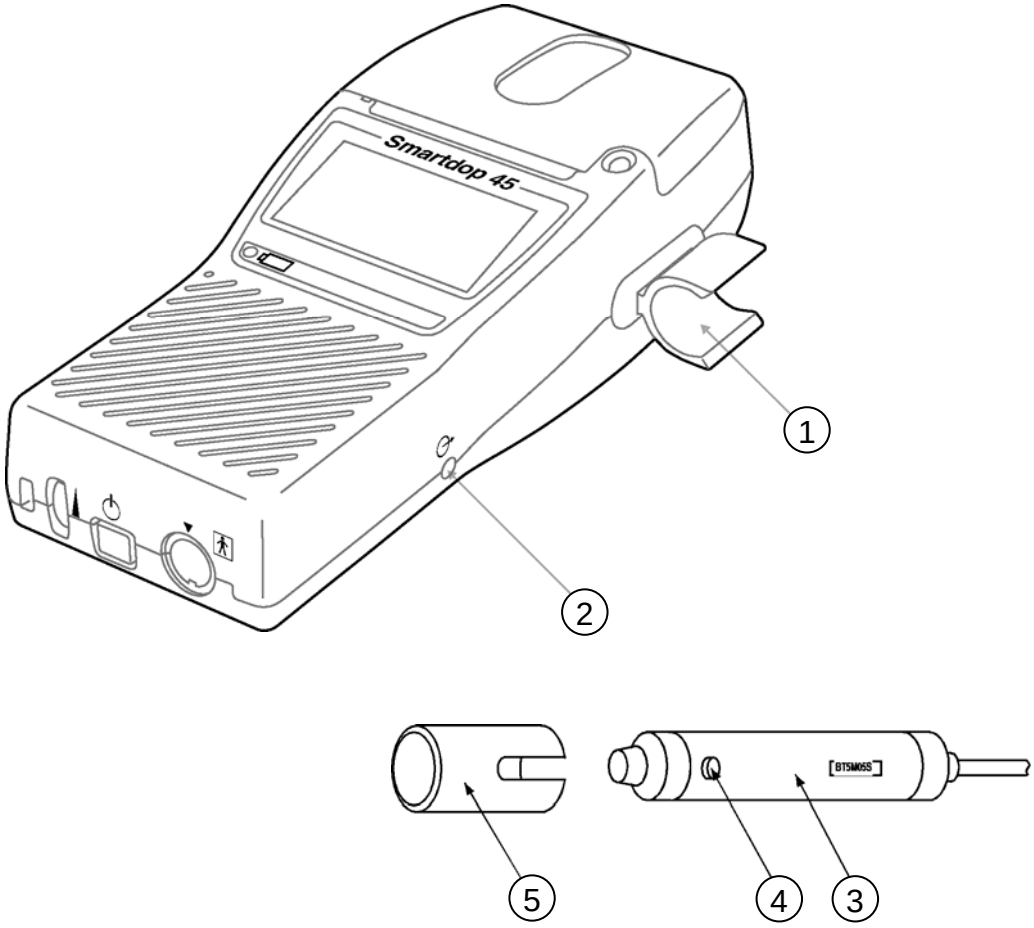
    16. Down: To select lower menu item.
    To decrease waveform memory number in Freeze mode.
    To move cursor down on the on-screen keyboard.

    17. Left: To move cursor left on the on-screen keyboard.
    To go back to main menu from submenu or get out from menu.

    18. Enter: To go to menu mode.
    To perform the selected command on the menu.

19. Print / Back Button:  To activate / deactivate the printer.
    To go back to previous screen.

3-1-2. Front right view and Probe



1. Probe holder: For probe placement when not in use.
2. Communication port: To connect computer. (USB)
3. Probe: Multi-probe selection of 2, 4, 5, 8 and 10 MHz
4. Probe button: To freeze and unfreeze the waveform.
   To activate and deactivate the printer.

Note : The function is defined in the menu PRB-KEY. See “ 3-2-3-s. OTHERS - PRB-KEY” for the details.

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

3-2. MODE SETTINGS

3-2-1. Basic Modes

Smartdop has following five Basic Operation Modes:

- Blood Velocity - Measurement — For measuring blood velocity
- Blood Velocity - Freeze — For observing waveforms and numerical data
- Fetal Heart Rate - Measurement — For measuring fetal heart rate
- Fetal Heart Rate - Freeze — For observing heart rate and graph
- Menu — For changing Other Mode Settings

Changing Basic Mode with probe connection (Blood Velocity / Fetal Heart Rate)

Connect 4, 5, 8 or 10 MHz probe to the probe connector and turn the unit on for Blood Velocity mode.

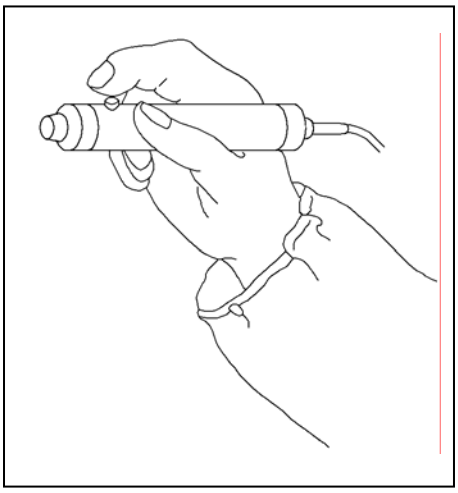
Connect 2 MHz probe to the probe connector and turn the unit on for Fetal Heart Rate mode.

Optional operation modes are available by connecting optional PPG and PV probes. See " 5. Options".

Changing mode with probe button (Measurement / Freeze)

Press the probe button to go to freeze mode and press again to get back to measurement mode.

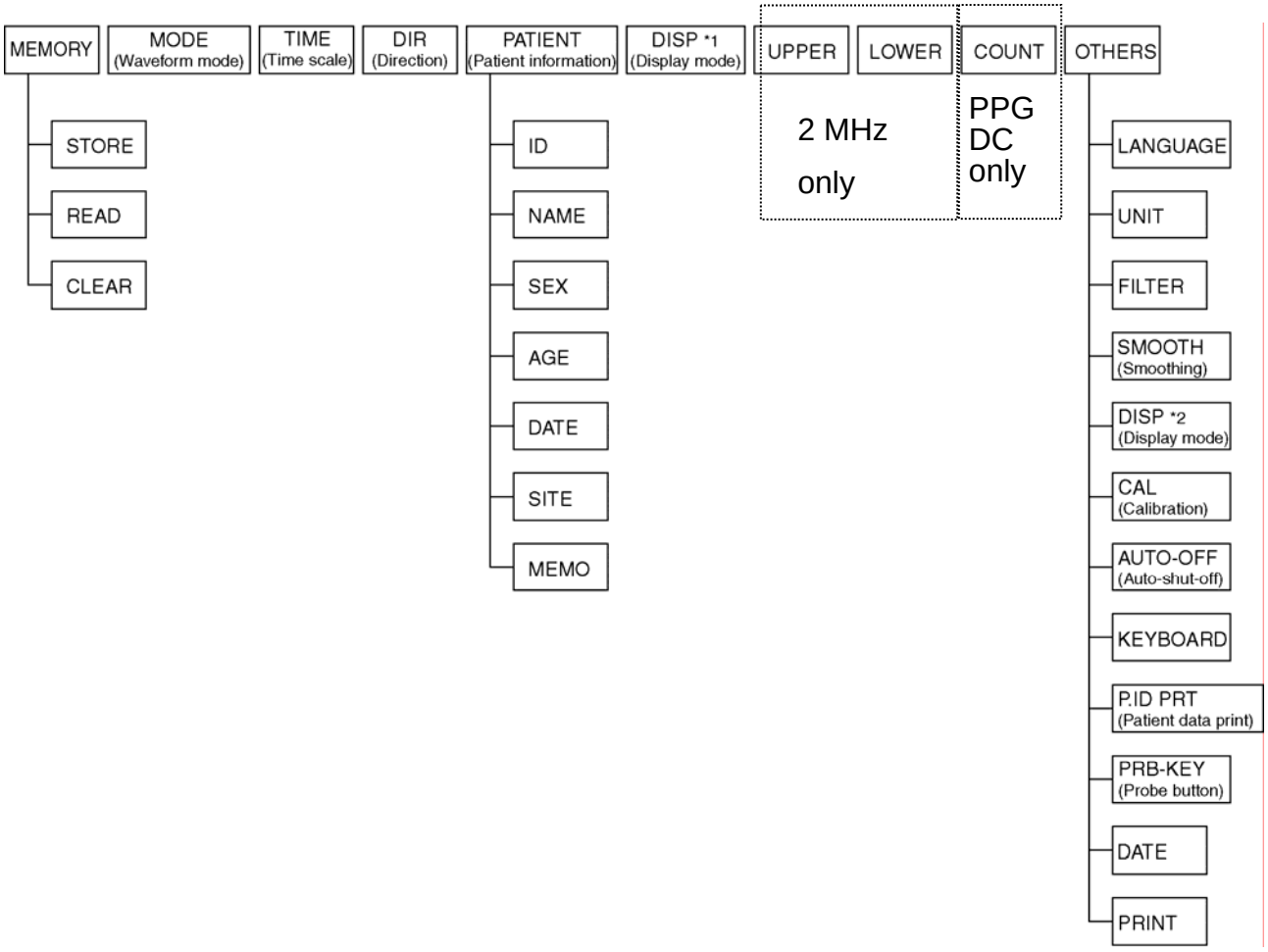
With 2 MHz probe, Fetal Heart Rate mode, pressing Right button also changes this mode.



3-2-2. Menu

Using Scroll Button, various mode settings are changeable on Menu mode. Some menus have sub menus. Refer to following **Menu structure** and **Selecting mode setting from menu** first.

a. Menu structure

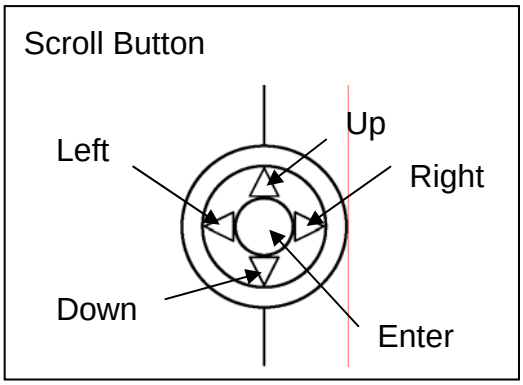


"DISP" menu placement depends on basic mode:

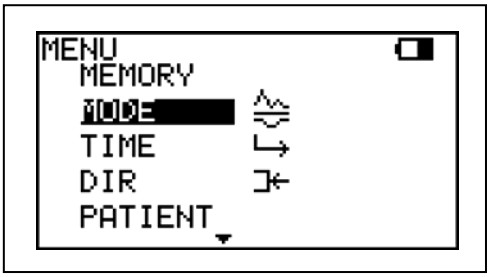
	Measurement	Freeze
Blood velocity	*2	*1
Fetal heart rate	*1	*1

b. Menu operation

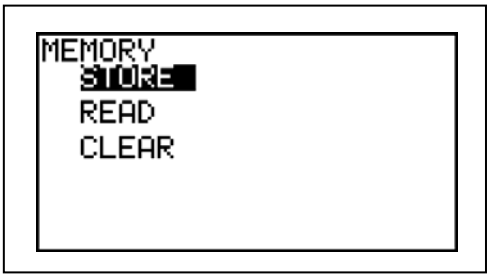
(1) Press Enter to go to Menu mode. Smartdop will display the menu depending on Basic Mode.

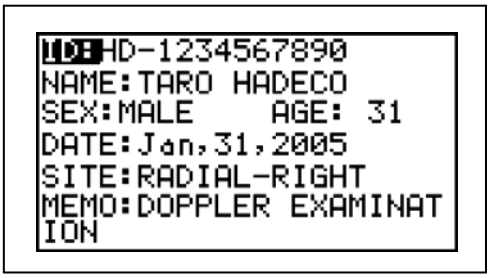


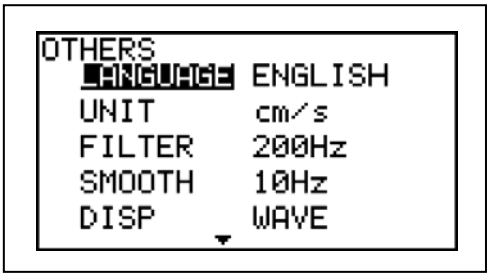
(2) Select the mode by pressing Up button or Down button and selected mode will be highlighted. Press Enter button once or twice to change the mode.



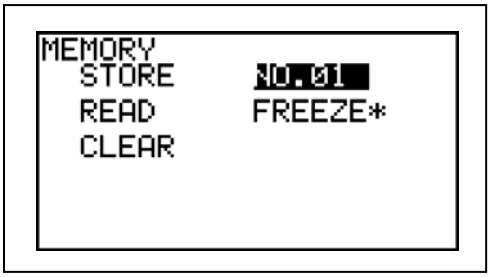
(3) For MEMORY, PATIENT and OTHERS, press Enter button or Right button to display sub menu. Press Up button or Down button for the selection of sub menu.







(4) For MEMORY sub menus and LANGUAGE, press Up or Down button again for the selection of memory number or language.



(5) Press Left button to go back to main menu from submenu or get out of the menu mode.

c. Menu for Blood Velocity Measurement mode

Menu	Sub Menu	Selections
MEMORY	STORE	1 to 30, FREEZE
	READ	1 to 30, FREEZE
	CLEAR	1 to 30, ALL
MODE		Compound , Separate
TIME		Normal , Slow
DIR		Forward , Reverse
PATIENT		ID, NAME, SEX, AGE, DATE, SITE, MEMO
OTHERS	LANGUAGE	ENGLISH, DEUTSCH, ITALIANO, ESPANOL, FRANCAIS
	UNIT	cm/s, kHz
	FILTER	80Hz, 200Hz
	SMOOTH	5Hz, 10Hz
	DISP	WAVE, DATA
	CAL	ON, OFF
	AUTO-OFF	ON, OFF
	KEYBOARD	ENGLISH, JAPANESE
	PRT-SEL	+PATIENT, PRMONLY
	PRB-KEY	PRT&FRZ, PRINT, FREEZE
	DATE	YY/MM/DD HH:MM:SS

Note : Selections in bold face in the table above are defaults.

d. Menu for Blood Velocity Freeze mode

Menu	Sub Menu	Selections
MEMORY	STORE	1 to 30, FREEZE
	READ	1 to 30, FREEZE
	CLEAR	1 to 30, ALL
MODE		Compound  , Separate 
DIR		Forward  , Reverse 
DISP		WAVE, DATA
PATIENT		ID, NAME, SEX, AGE, DATE, SITE, MEMO
OTHERS	LANGUAGE	ENGLISH, DEUTSCH, ITALIANO, ESPANOL, FRANCAIS
	AUTO-OFF	ON, OFF
	KEYBOARD	ENGLISH, JAPANESE
	PRT-SEL	+PATIENT, PRMONLY
	PRB-KEY	PRT&FRZ, PRINT, FREEZE
	DATE	YY/MM/DD HH:MM:SS
	PRINT	

Note : Selections in bold face in the table above are defaults.

e. Menu for Fetal Heart Rate mode (Measurement and Freeze)

Menu	Sub Menu	Selections
MEMORY	STORE	1 to 30, FREEZE
	READ	1 to 30, FREEZE
	CLEAR	1 to 30, ALL
DISP, display mode		WAVE, **DATA**
UPPER limit		60 to 220 (every 5 bpm)
LOWER limit		60 to 220 (every 5 bpm)
PATIENT data	ID, NAME, SEX, AGE, DATE, SITE, MEMO	
OTHERS	LANGUAGE	**ENGLISH**, DEUTSCH, ITALIANO, ESPANOL, FRANCAIS
	AUTO-OFF	**ON**, OFF
	KEYBOARD	**ENGLISH**, JAPANESE
	P.ID PRT (Patient data print)	**ON**, OFF
	PRB-KEY (Probe button)	**PRT&FRZ**, PRINT, FREEZE
	DATE	MMM.DD,YYYY HH:MM:SS
	PRINT	

Note : When in Freeze mode, PRINT is available, and only WAVE is selectable on DISP mode.

Selections in bold face in the table above are defaults.

Button functions limited to Fetal Heart Rate mode

1 Right — To freeze the waveform & numerical data.

2 Up / Down — To cancel and restart the measurement on Monitoring mode.

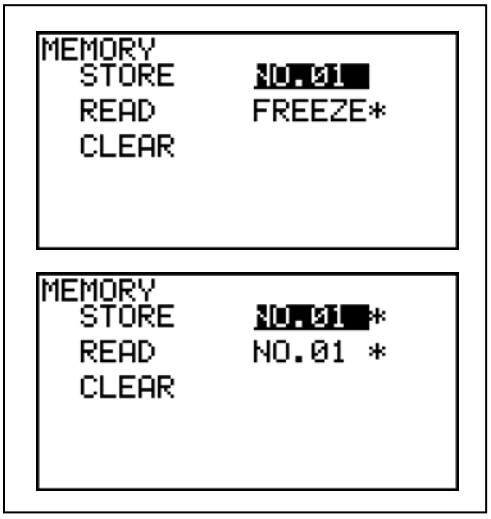
3 Left — To go to next page on Freeze mode.

3-2-3. Mode Setting Details

To get to following menu items, see “ 3-2-2-b. Menu Operation”.
Do the mode setting once and subsequent Smartdop use will revert to this mode. However, when battery gets extremely low, the settings will get back to default settings.

a. MEMORY - STORE

(1) The first memory number available will be selected automatically and displayed right side of STORE on the menu. If necessary, change the memory number in which you wish to store the waveform including numerical data and patient data by pressing Up and Down.



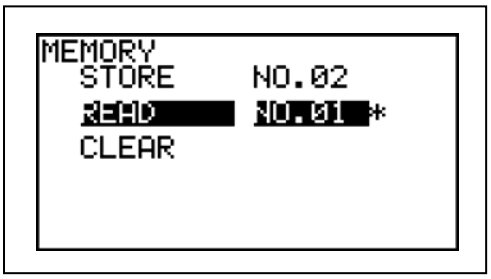
Note: The memory number with "*****" indicates in which data is being stored.

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

Note: When storing the data into data existing memory, the confirmation "OVERWRITE?" will be displayed. Press Enter to overwrite, or press Left to cancel.
When on measurement mode, the data have been frozen before executing STORE command.

b. MEMORY - READ

(1) Select the memory number from which you wish to read the data (waveform, numerical data and patient data) by pressing Up and Down.



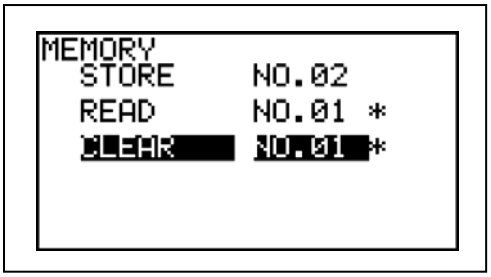
(2) Press Enter button to read the data from the memory.

(3) Press Up and Down to display next waveform if necessary.

Note: When going into freeze mode, the frozen data will be stored automatically into memory # of FREEZE. If you need to see the frozen data after reading other data from the memory, read FREEZE on the LCD.

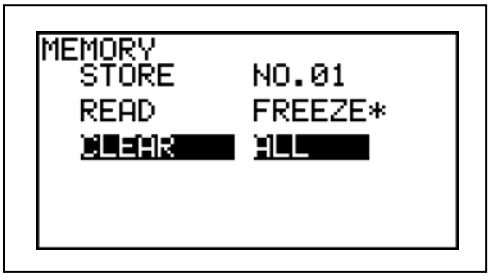
c. MEMORY - CLEAR

(1) Select the memory number in which data you wish to clear by pressing Up and Down. The memory number with "*****" indicates in which data is being stored.



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

(3) If you choose ALL and press Enter , all data in the memories will be cleared except FREEZE, frozen data.

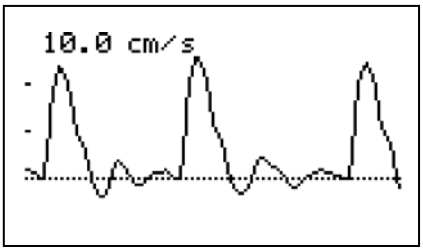


d. MODE (Baseline mode)

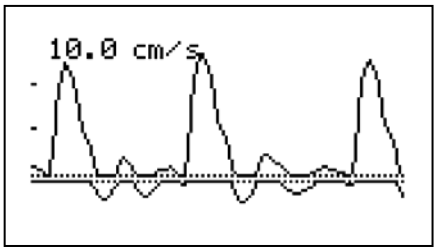
(1) Press Enter to change the mode.

Compound mode: Combined forward and reverse components

Separate mode: Separation of forward from reverse component



Compound mode



Separate mode

e. TIME (Time scale)

(1) Press Enter to change the time scale.

Normal: 2.56 sec/screen
Intended use : Examinations for artery

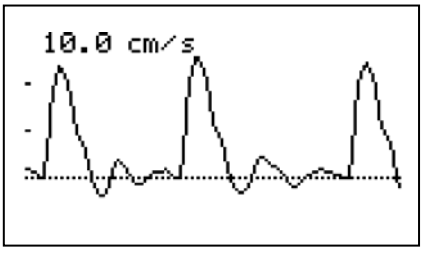
Slow: 12.8 sec/screen
Intended use : Examinations for vein

f. DIR (Flow direction)

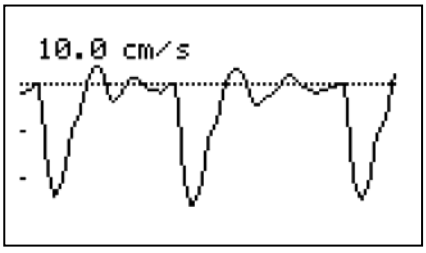
(1) Press Enter button to change the direction of waveform.

Forward: Flow toward probe is processed as positive component.

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



Forward mode



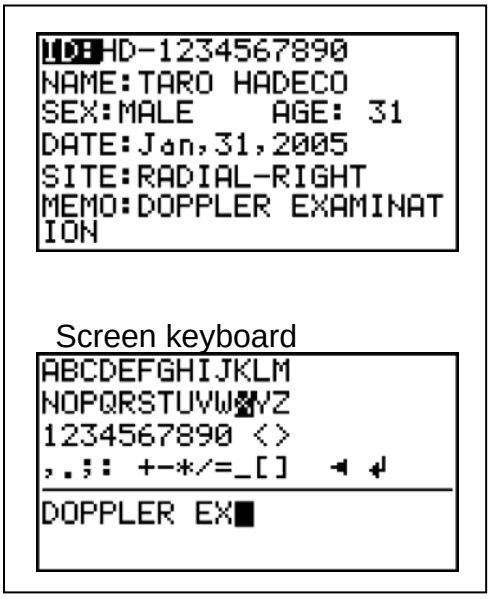
Reverse mode

g. PATIENT (Patient data input)

The patient data can be input. This setting contains ID, NAME, SEX, AGE, examination DATE, anatomical SITE and MEMOrandum.

Save the patient data on Measurement mode and it will apply to all of future measurement data until it's changed so that you won't have to input the same data for the same patient again. If it is done on Freeze mode, the patient data will apply only to the stored/FREEZE data selected.

(1) Prior to the patient data input, go to OTHERS-DATE menu and set the date and time for an initial setting.
Scroll to the item where you wish to input and press Enter to display data input screen. With SEX, pressing Enter changes Male to Female or vice versa. DATE data can be changed on PATIENT menu when on FREEZE mode only.



(2) Scroll to the letter you wish and press Enter to type it. Pressing Back Button or entering Backspace (⇤) deletes the letter you typed previously.

(3) After entering the data, press and hold Print/Back for longer than 1 sec to save the data or scroll to ↵ (Back) and press Enter to do it.

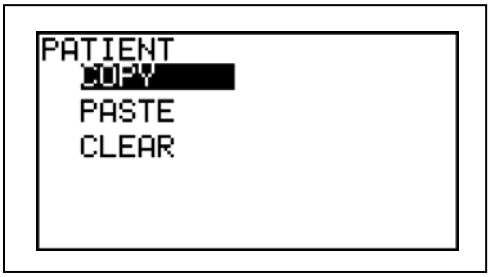
(4) Press Left to get out of Patient Data screen.

When using external PS2 keyboard:

(1) Press any key on the keyboard to open Patient Data screen.
(2) Use cursor keys to select item and input the data by typing letters
(3) Press Esc or End to save the data and get out of Patient Data screen.

Copy / Paste / Clear of the data

You can copy and paste the patient data to the other patient data area when on FREEZE mode mainly for your convenience.



(1) Press Back Button while Patient Data screen is displayed.
(2) Scroll to the edit command and press Enter.
(3) COPY will copy all items of the patient data to clipboard.
(4) PASTE will paste the clipboard data to the other patient data area. It overwrites the existing data. All items except DATE will be pasted at once.
(5) CLEAR will delete the patient data.
(6) PASTE and CLEAR commands require the confirmation as shown right. Press Enter to proceed or press Left to cancel.
(7) Press Back Button to go back to Patient Data screen.

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

(1) Press Enter to change the Display mode.

Blood Velocity mode

WAVE: Displays waveforms.

DATA: Displays numerical data

See “ 3-3-1. Blood Velocity mode” for the details.

Fetal Heart Rate mode

WAVE: Monitors heart rate in graph. (Monitoring mode)

DATA: Displays heart rate every moment.

See ” 3-3-2. Fetal Heart Rate mode” for the details.

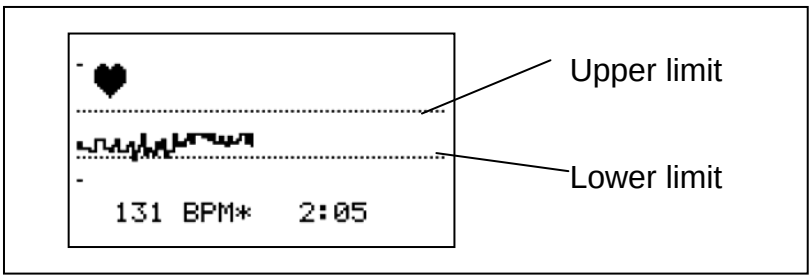
Note: Display mode cannot be changed on Freeze mode.

When Display mode is WAVE in measurement mode, pressing Up or Down resets monitoring data and restarts measurement.

i. UPPER (Upper limit for FHR)

When the heart rate exceeds the upper limit, the LCD flushes. (After more than 30 seconds have passed since the start.)

(1) Press Up and Down to select the upper limit of heart rate and press Enter to fix it. The heart rate is selectable every 5 bpm.



j. LOWER (Lower limit for FHR)

When the heart rate is blow the lower limit, the LCD flushes. (After more than 30 seconds have passed since the start.)

(1) Press Up and Down to select the lower limit of heart rate and press Enter to fix it. The heart rate is selectable every 5 bpm.

k. OTHERS - LANGUAGE

(1) Press Up and Down to select the language in which menus and messages are written. And press Enter to fix it.

l. OTHERS - UNIT (cm/s / kHz)

(1) Press Enter to change the unit of blood flow.

cm/s: Blood flow velocity
kHz: Doppler frequency shift

m. OTHERS - FILTER (Arterial / Venous filter)

The high-pass filter cuts low frequency components of the Doppler signal to reduce noise. Choosing 200 Hz for artery or 80 Hz for vein is recommended.

(1) Press Enter to change the frequency of filter.

n. OTHERS - SMOOTH (Smoothing filter)

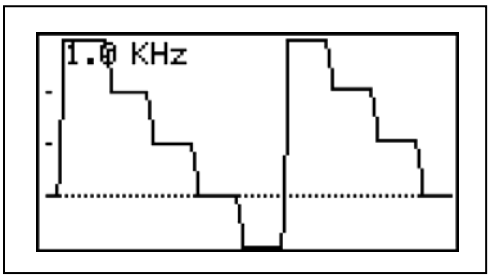
(1) Press Enter to change the smoothing frequency.

o. OTHERS - CAL (Calibration)

(1) Press Enter to change the mode.

ON: Displays 4 step (3, 2, 1, 0, -1 kHz) calibration waveform.

OFF: Measurement mode



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

(1) Press Enter to change the mode.

For the explanation of Automatic shut-off, refer to 2-1. Turning the unit ON / OFF.

q. OTHERS - KEYBOARD (External)

(1) Press Enter to change the keyboard.

ENGLISH: 104 English keyboard PS2

JAPANESE: 109 Japanese keyboard PS2

Note : Only PS2 keyboard is available.

r. OTHERS - P.ID PRT (Patient data print)

(1) Press Enter to change the mode.

ON: Prints with patient data.
OFF: Prints without patient data.

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

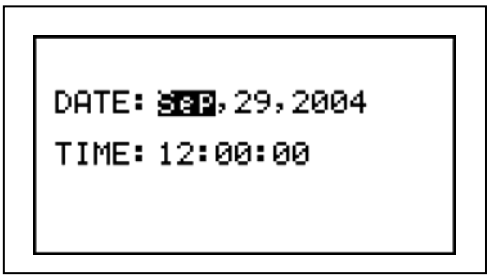
(1) Press Enter to change the probe button function.

PRT&FRZ:	Freezes and prints.
PRINT:	Prints and goes to Monitoring mode.
FREEZE:	Freezes

Note : When on FHR - DATA mode, only FREEZE is functional no matter what is selected on the PRB-KEY mode.

t. OTHERS - DATE (Date and time setting)

(1) Press Enter to go to Date Setting screen.



(2) Scroll item with Right and Left, and adjust it with Up and Down.

(3) Press Enter to fix it or press Back Button to cancel.

u. OTHERS - PRINT (Printer activation)

(1) Press Enter to activate the printer.

Note: Pressing Print Button also activates printer. Press Print the second time to deactivate printer.

3-3. LCD DISPLAY

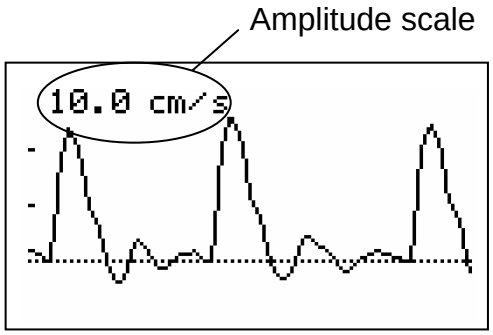
3-3-1. Blood Velocity Mode

Waveforms

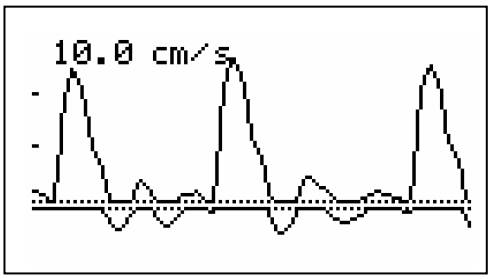
(1) The base line is automatically located at best position. Smartdop has 4 base lines, the bottom, 1/4 from the bottom, the center, and 3/4 from the bottom.

(2) The waveform amplitude is automatically adjusted for optimal observation.

(3) The amplitude scale (velocity or frequency per division) is displayed at the upper left of the LCD.

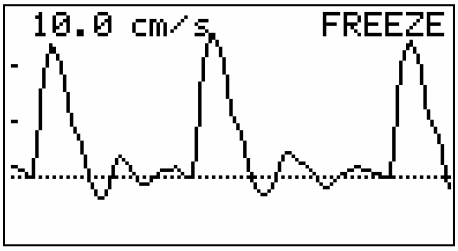


Compound mode

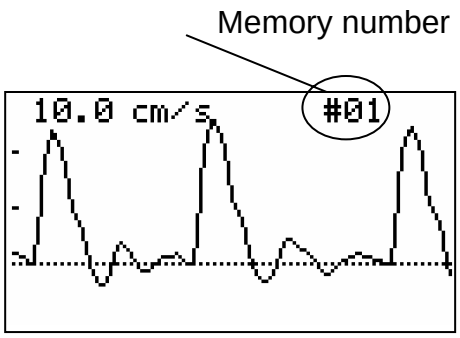


Separate mode

(4) When pressing probe button to freeze the waveform, Smartdop will stop monitoring sequence and will display frozen waveform with “FREEZE”.

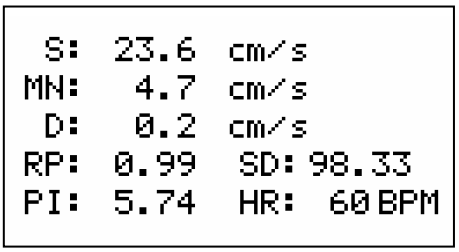


(5) The read out waveform is displayed with memory number, e.g. "#01" at the upper right of the LCD

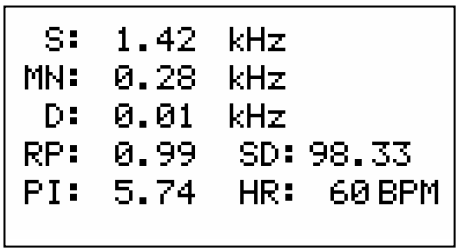


Numerical data

Following numerical parameters are displayed on DATA mode.



Unit: cm/s



Unit: kHz

See " 3-5. Numerical Data" for the meaning of abbreviations and the definitions of parameter.

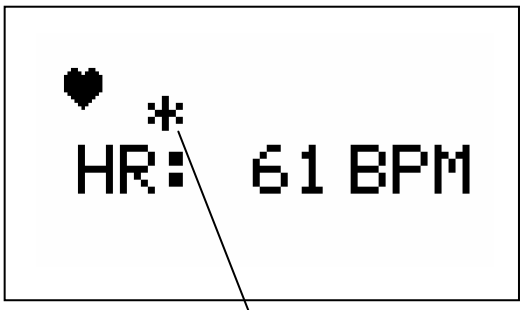
3-3-2. Fetal Heart Rate (FHR) mode (Only 2 MHz probe)

Displaying heart rate at the moment (DATA mode)

Heart rate is displayed based on a 4 beat average once the Smartdop gets sufficient data to calculate.

The heart mark "♥" tracks heart beat while in measurement.

When calculated heart rate is not stable, the asterisk (*****) is displayed.



Asterisk is displayed when calculated heart rate is not stable.

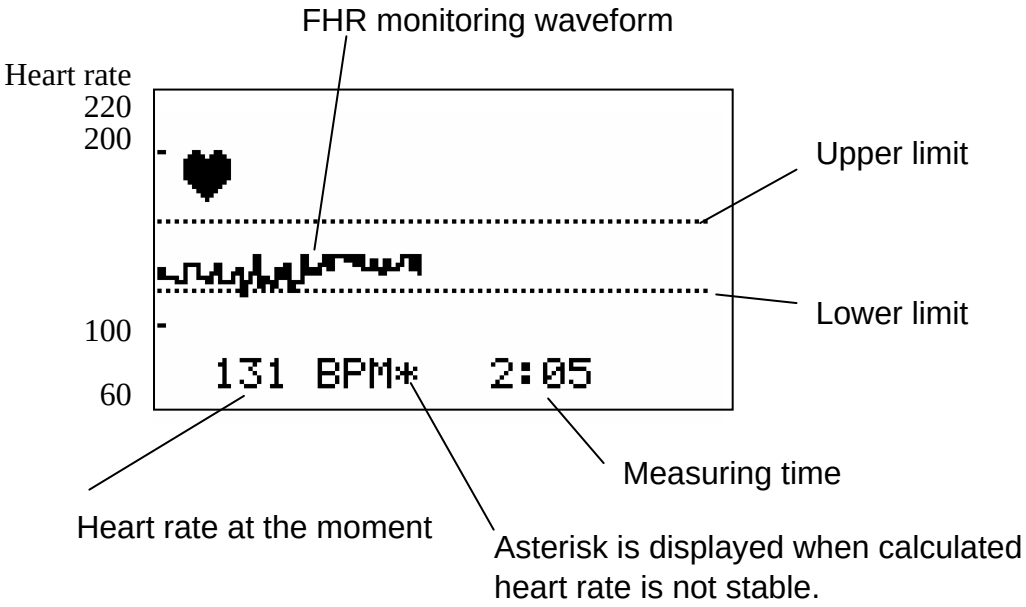
Note: The heart mark also indicates the speed of heart movements in 3 different size of heart marks.

Fast Medium Slow

Monitoring heart rate in graph (WAVE mode, Monitoring mode)

(1) The measurement range of heart rate is 60 to 220 bpm.

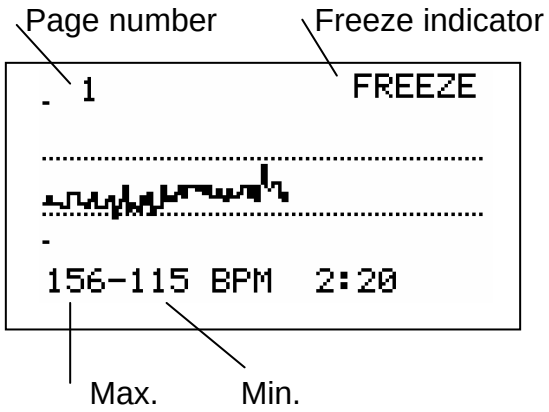
(2) The heart rate at the moment is displayed on the bottom left of the screen.



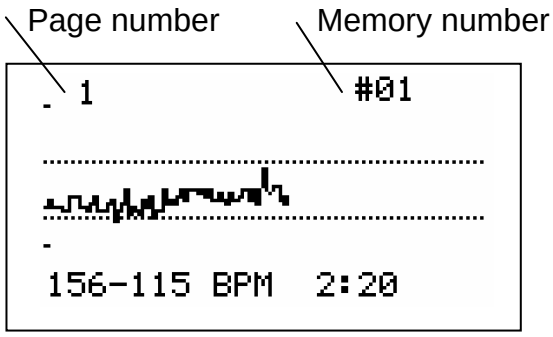
(3) Heart mark indicates the same as in DATA mode.

(4) Two dotted lines indicate Upper and Lower limits of heart rate. When the heart rate is out of limits, LCD will flash. (After more than 30 seconds have passed since the start.)

(5) When pressing probe button or Right button to freeze the waveform, Smartdop will stop monitoring sequence and will display the monitoring waveform of up to the last 33 minutes within 4 pages with “FREEZE” indicator. (Approx. 8 minutes a page)
Press Left button to go to next page.



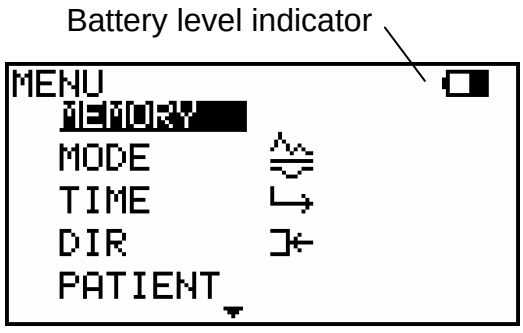
(6) The read out waveform from memories is displayed with memory number, e.g. "#01" at the upper right of the screen.



3-3-3. Battery Indicators

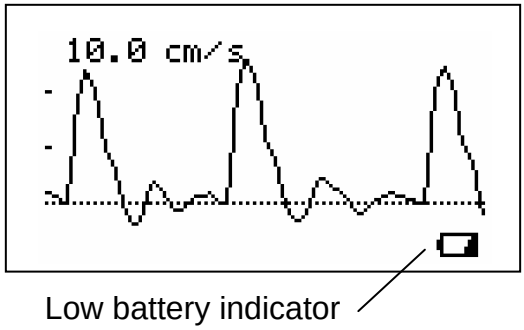
Battery level indicator

Battery level indicator shows upper right of the menu screen.
See “ 2-3. Checking Battery Level” for the details.



Low battery indicator

When the battery is low, the low battery indicator will be shown on bottom right of LCD. Recharge the battery.
See " 2-2. Charging / Discharging Battery"



3-4. PRINTING WAVEFORMS and DATA

3-4-1. The mode settings influencing printed chart

The following mode settings influence the printed waveform and data. Smartdop prints depending on the present mode settings. Change modes before printing if desired.

Note: Refer to the description of each mode in " 3-2-3. Mode Setting Details".

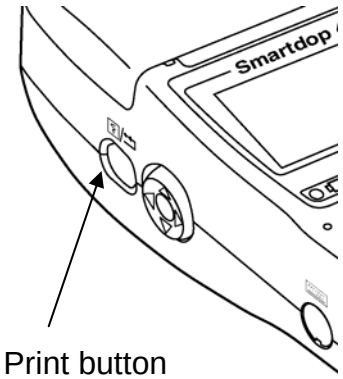
Mode	Abbrev.	Selection
a. Baseline mode	MODE	Compound, Separate
b. Time scale	TIME	Normal, Slow
c. Flow direction	DIR	Forward, Reverse
d. Language	LANGUAGE	English, Deutsch, Italiano, Español, Français
e. Unit	UNIT	cm/sec, kHz
f. Smoothing filter	SMOOTH	5 Hz, 10 Hz
g. Waveform / Data	DISP	Wave, Data
h. Patient data print	P.ID PRT	ON, OFF

3-4-2. How to print

Printing waveform and data is available on Freeze mode and Patient Data Input mode.

(1) Press Print button or execute PRINT command on the menu mode to print waveforms.
Also, pressing probe button makes print when PRB-KEY is on PRT&FRZ or PRINT mode.

(2) Smartdop prints following waveforms and then stops printing automatically.



Print button

Blood Velocity mode

TIME is Normal : Waveform of the 5 sec before freezing

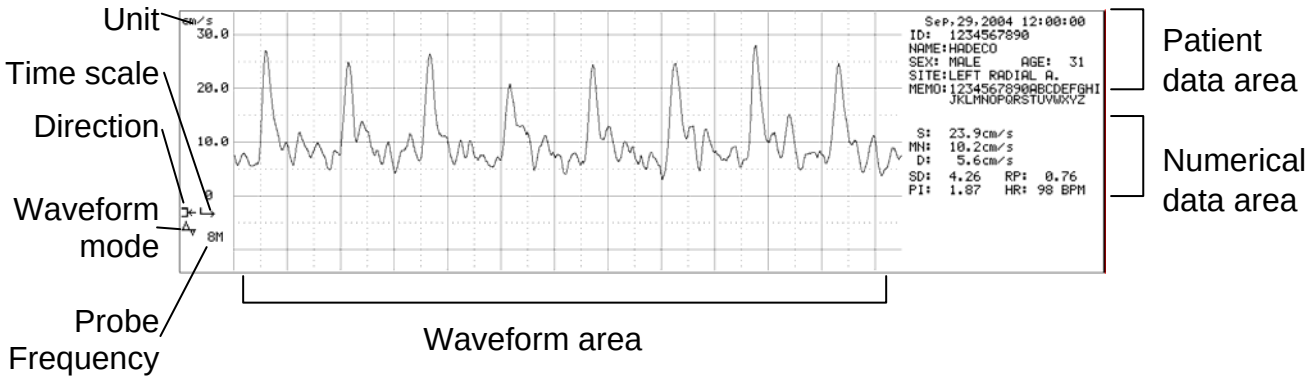
TIME is Slow : Waveform of the 25 sec before freezing

FHR mode

Monitoring mode : Waveform of up to the 33 minutes before freezing

(3) Press Print button or execute PRINT command the second time to deactivate the printer.

3-4-2. Print sample

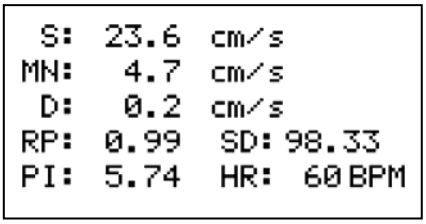


Note: See " 3-5. Numerical Data" for the meaning of abbreviations and the definitions of Numerical data.

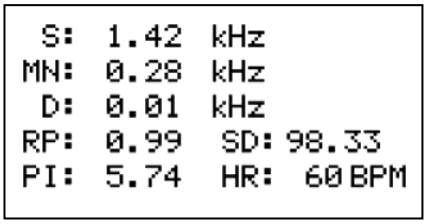
3-5. NUMERICAL DATA

Parameters	Abbrs.	Definitions
Systolic velocity [cm/s] or systolic Doppler shift [kHz]	S	
Mean velocity [cm/s] or mean Doppler shift [kHz]	MN	
Diastolic velocity [cm/s] or diastolic Doppler shift [kHz]	D	
Resistance Parameter	RP	RP = (S - D) / S RP = 1 if waveform goes below base line.
Pulsatility Index	PI	PI = (Peak-to-peak) / MN PI ≤ 99.99
S/D ratio	SD	SD = S / D
Heart rate [bpm]	HR	

Samples displayed on LCD



Unit: cm/s



Unit: kHz

3-6. EXTERNAL OUTPUTS

3-6-1. Headset 

Connect the headset when necessary. The headset cuts off the speaker.
See 3-1. Controls and Functions.

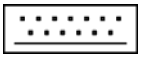
3-6-2. Communication port (3.5 mm jack) 

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) Connect a computer with dedicated communication cable (option).
(2) Press the Power Button to turn the unit on.
(3) Run the communication software (option) on your computer.

Note: For software operation, refer to the software operating manual.

3-7. SYMBOL LIST

	Symbols	Descriptions			Symbols	Descriptions
1		Type BF applied part		7		USB connector
2		Headset		8		Volume control
3		Print Button		9		Charging indicator
4		AC adaptor connector		10		Keyboard connector
5		Caution		11		Back Button
6		Power button				

4. MAINTENANCE

4-1. PERFORMANCE CHECK PROCEDURES BY USER

Perform the following performance checks once a year:

(1) Make sure if there is no damage and/or crack on the main unit and probe.
(2) Shake the main unit and make sure if there are no sounds inside from internal components coming out.
(3) Turn the unit on and make sure if the LCD displays normally.

4-2. 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.

4-3. WARRANTY

This equipment is guaranteed for the period of one year 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 the dealer for a charged service.

5. OPTIONS

5-1. OPTIONAL ACCESSORIES

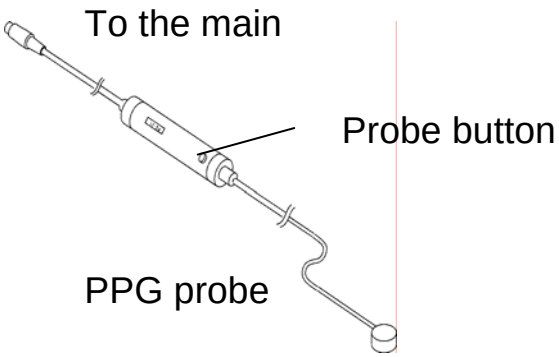
Doppler probes:	2, 4, 5, 8 and 10 MHz (with curled or straight cable)
PPG probe :	Model PG-21
PV probe :	Model PV-20
PPG/PV probe :	Model PGV-20 (switchable single channel)
Cuffs :	DVC-1.9, DPC-2.5, VC-10, VC-12
Sphyg	
Tubing:	120 cm
3-way stopcock	
Smart-V-Link software with communication cable	
Smart-Fetal-Link software with communication cable	

5-2. PHOTOPLETHYSMOGRAPH

With the PG-21 and PGV-20 (PPG mode), Smartdop senses the reflection of light from the hemoglobin of the red blood cells in surface vessels by utilizing infrared light.
Basically, “How to use photoplethysmograph” is described in this manual. For other matters such as Cautions, Technical information and Interpretations of test result, refer to the Operating Manual comes with your PPG probe assembly.

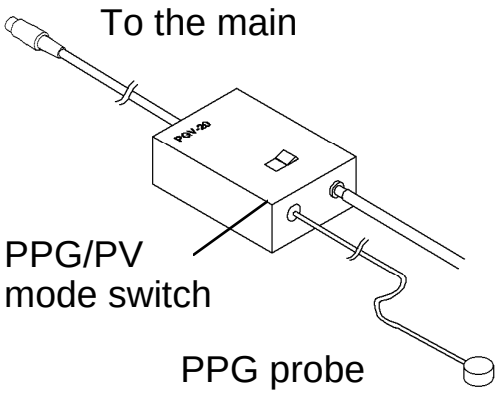
5-2-1. PPG (Photoplethysmography) Probe Assemblies

Single-channel photoplethysmography (PPG) probe



Model PG-21

Switchable dual-modality (PPG/PV) single-channel probe



Model PGV-20

5-2-2. Clinical Applications

AC Coupling: Arterial pulse waveform studies, Toe pressure
DC Coupling: Venous reflux study

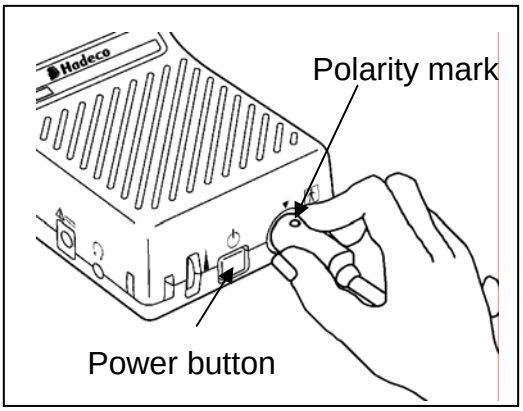
5-2-3. PPG - Arterial Pulse Waveform Studies

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.

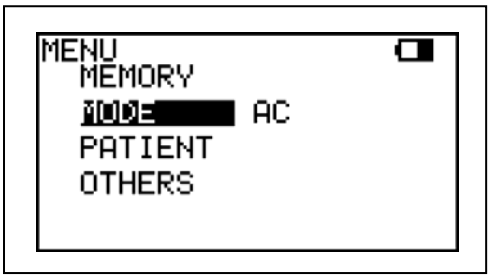
Preparation

(1) Connect the PPG probe assembly to the main unit, and turn it on.



Note: With the PGV-20 probe, set the probe switch to the PPG mode beforehand.

(2) Press Enter button to display MENU and make sure MODE is on AC mode. If necessary, change to AC by pressing Enter on MODE.
Press Left to get out of the MENU mode.



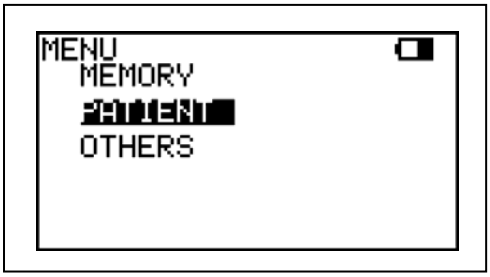
(3) Check that the face of the PPG sensor is free of stains. Clean it if necessary.

(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

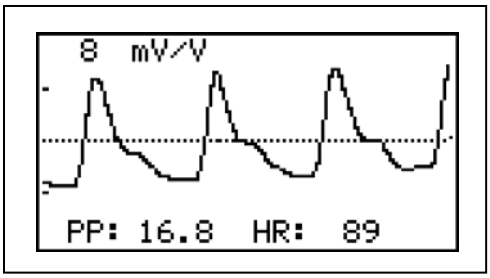
(1) Apply the sensor with the clear side against the skin surface, and fix it in place using Velcro strips or double-sided clear tape.

(2) If you wish to input patient data, see " 3-2-3-g. PATIENT".

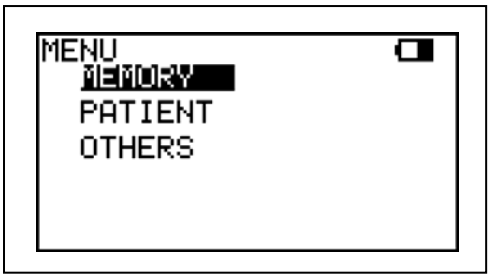


(3) The gain is automatically adjusted and the PPG waveform is shown on the LCD.

(4) When the waveform gets stable and rhythmic, press Right or probe button to freeze and print the waveform.



(5) If you wish to save the data on the memory, see " 3-2-3-a. MEMORY - STORE".



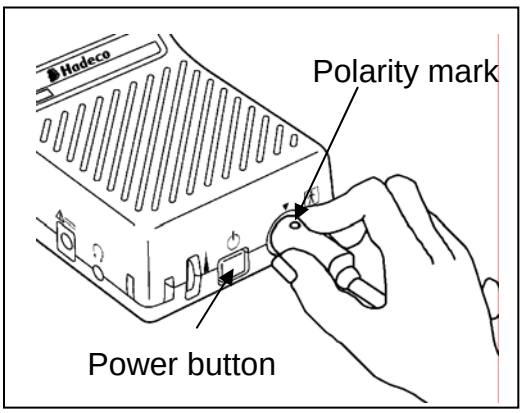
5-2-4. PPG - Venous Reflux Study

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.

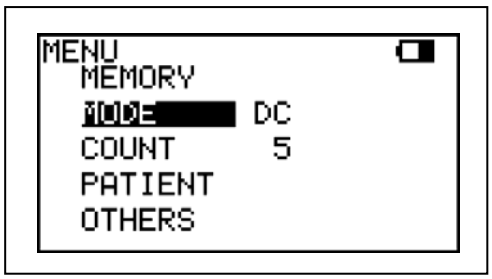
Preparation

(1) Connect the PPG probe assembly to the main unit, and turn it on.



Note: With the PGV-20 probe, set the probe switch to the PPG mode beforehand.

(2) Press Enter button to display MENU. Scroll to MODE and press Enter to change to DC mode.



(3) If desired, scroll to COUNT and press Enter and then change the number of times for patient dorsiflexes. Press Left to get out of the MENU mode.

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

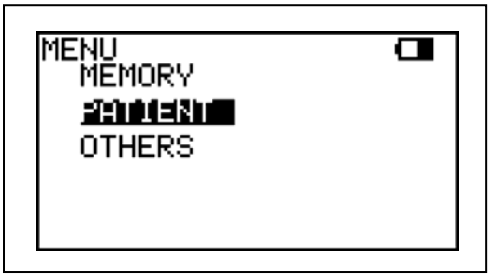
(5) Make certain that room temperature is comfortable and that the skin surface of the lower lime is warm. Cold constricts superficial blood vessels and thus jeopardizes the accuracy of PPG measurements.

Examination Procedure

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

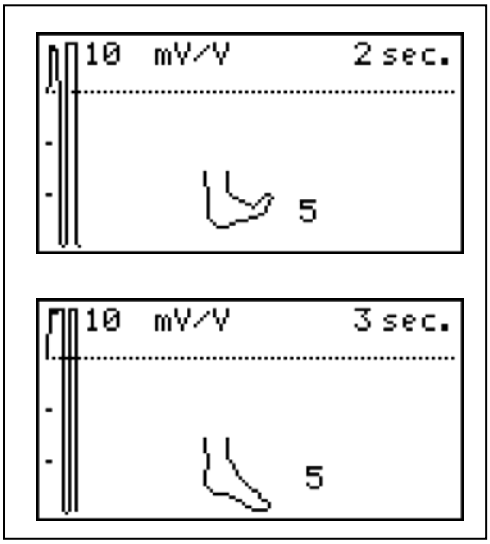
(2) Apply the sensor, with the clear side against the skin surface, to the medial malleolus over the posterior tibial vein. Fix the probe in place with double-sided clear tape.

(3) If you wish to input patient data, see " 3-2-3-g. PATIENT".



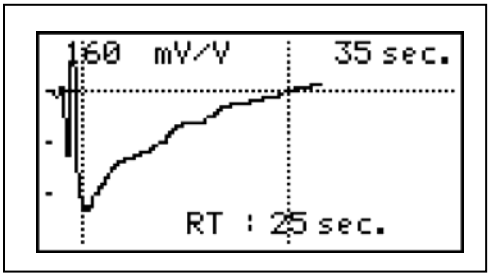
(4) Press Right or probe button to begin the measurement process.

(5) 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.

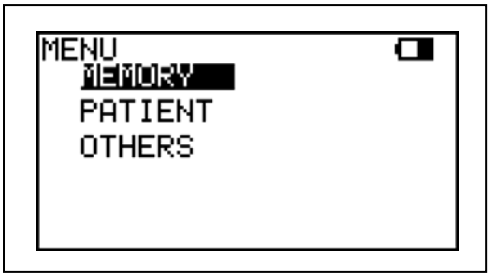


(6) After flexing, instruct the patient to relax the foot and avoid all movement.

(7) The test is complete when the waveform on the LCD returns to the baseline amplitude.
Smartdop will automatically freeze and print the venous reflux study waveform.



(8) If you wish to save the data on the memory, see “ 3-2-3-a. MEMORY - STORE”.



(9) Press the Right to get out of the freeze mode.

5-2-5. Menu for PPG

Menu	Sub Menu	Selections
MEMORY	STORE	1 to 30, FREEZE
	READ	1 to 30, FREEZE
	CLEAR	1 to 30, ALL
MODE (Coupling)		**AC**, DC
COUNT		1 to 20
PATIENT data	ID, NAME, SEX, AGE, DATE, SITE, MEMO	
OTHERS	LANGUAGE	**ENGLISH**, DEUTSCH, ITALIANO, ESPANOL, FRANCAIS
	AUTO-OFF	**ON**, OFF
	KEYBOARD	**ENGLISH**, JAPANESE
	P.ID PRT (Patient data print)	**ON**, OFF
	PRB-KEY (Probe button)	**PRT&FRZ**, PRINT, FREEZE
	DATE	MMM.DD,YYYY HH:MM:SS
	PRINT	

Note : MODE is selectable when in Measurement mode, and PRINT is available when in Freeze mode.

COUNT is used for DC mode when in Measurement mode.

5-2-6. PPG Mode settings

MODE (AC / DC) (Only Measurement mode)

(1) Press Enter to change the mode.

AC: AC coupling mode for arterial pulse waveform studies

DC: DC coupling mode for venous reflux study

COUNT (Only DC - Measurement mode)

Set the number of times for patient dorsiflexes.

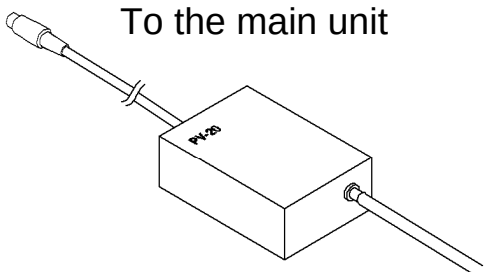
(1) Press Up and Down to select number of times and press Enter to fix it.

5-3. PNEUMOPLETHYSMOGRAPH

With the PV-20 and PGV-20 (PV mode), Smartdop senses volume changes in a limb or digit by measuring the pressure changes in a recording cuff. Basically, “How to use pneumoplethysmograph” is described in this manual. For other matters such as Cautions, Technical informations and Interpretations of test result, refer to the Operating Manual comes with your PV probe assembly.

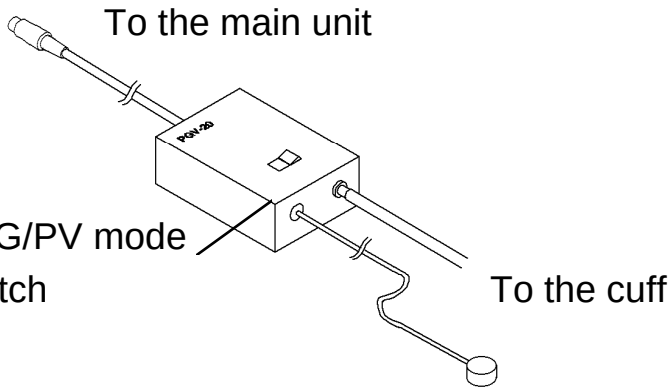
5-3-1. PV (Pneumoplethysmography) Probe Assemblies

Single-channel pneumoplethysmography (PV) probe



Model PV-20

Switchable dual-modality (PPG/PV) single-channel probe



Model PGV-20

5-3-2. Clinical Applications

AC Coupling: Arterial pulse waveform studies
DC Coupling: Measurement of maximum venous outflow

5-3-3. PV - Arterial Pulse Waveform Studies

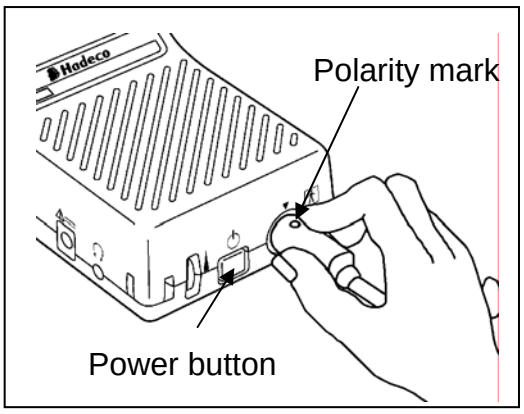
Purpose

Pneumoplethysmography is useful in detecting arterial occlusive conditions in the lower limbs through analysis of waveform patterns. The method is sufficiently sensitive for digital studies. PV also offers an alternative to Doppler techniques for segmental blood pressure studies. Pneumoplethysmography is particularly useful for patients in whom vessel calcification prevents accurate Doppler signal processing and occlusion-cuff pressure measurements.

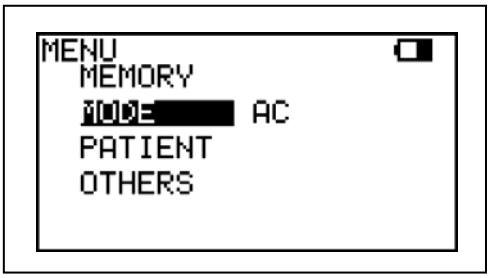
Preparation

(1) Connect the PV probe assembly to the main unit, and turn it on.

Note: With the PGV-20 probe, set the probe switch to the PV mode beforehand.



(2) Press Enter button to display MENU and make sure MODE is on AC mode. If necessary, change to AC mode. Press Left to get out of the MENU mode.

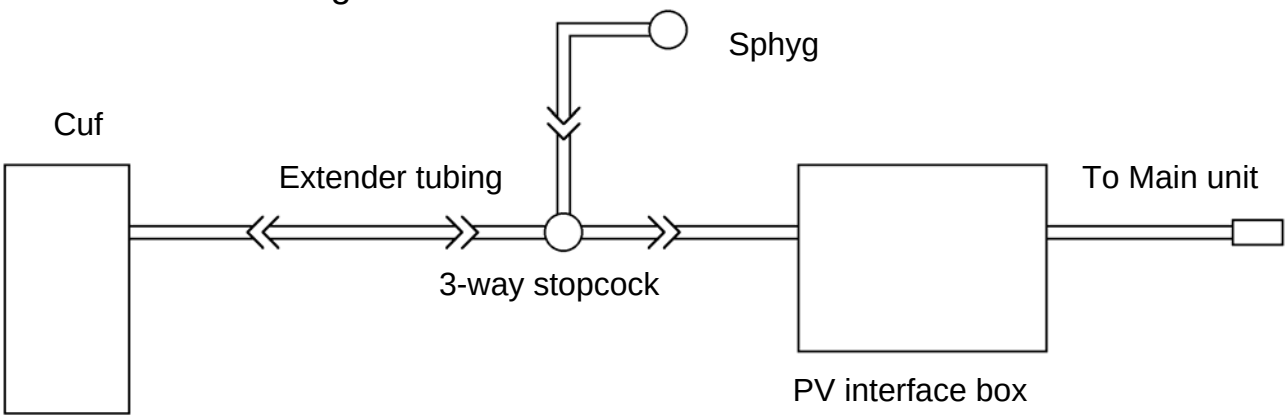


Examination Procedure

(1) Place the patient in supine position with the leg and hip rotated outward. Use pillows to support the leg and hip comfortably.

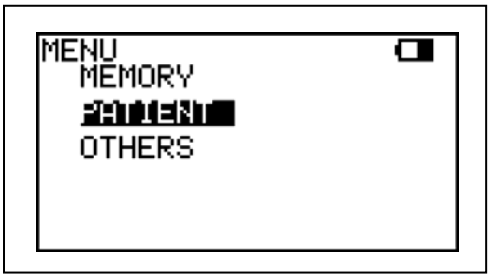
(2) Wrap cuffs of appropriate width around the thigh at the groin, above the knee, below the knee, and at the ankle on both limbs. Avoid wrapping cuffs tightly. The fit should be snug but comfortable.

(3) Connect a 3-way stopcock to the inlet of the PV interface box. Interconnect the stopcock, tubing, cuff, and sphygmomanometer as shown in the diagram below.



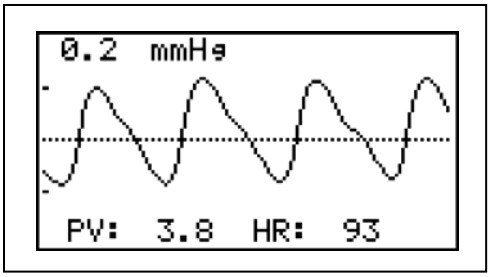
(4) Turn the stopcock so that air is routed from the sphygmomanometer to the cuff.

(5) If you wish to input patient data, see “ 3-2-3-g. PATIENT”.



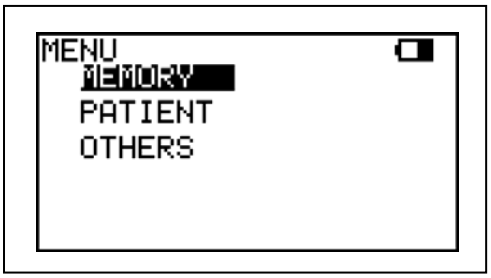
(6) Inflate the cuff to 60 mmHg. Then, turn the stopcock so that it blocks the sphyg and routs cuff pressure to the PV interface box.

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



(8) When the waveform gets stable and rhythmic, press the Right to freeze and print the waveform.

(9) If you wish to save the data on the memory, see “ 3-2-3-a. MEMORY - STORE”.



(10) Deflate the cuff and repeat steps #3 through #10 of this section for each cuff on each limb.

5-3-4. PV - Measurement of Maximum Venous Outflow

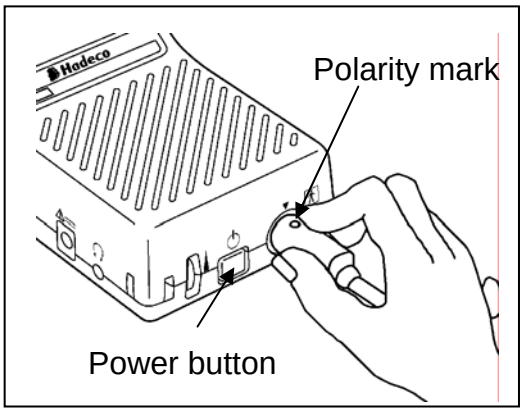
Purpose

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.

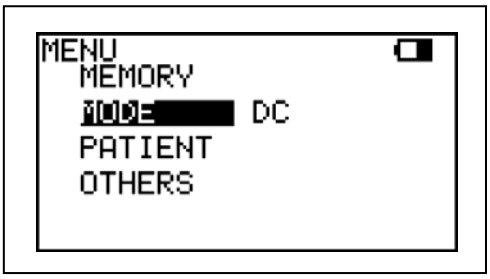
Preparation

(1) Connect the PV probe assembly to the main unit, and turn the it on.

Note: With the PGV-20 probe, set the probe switch to the PV mode beforehand.



(2) Press Enter button to display MENU. Scroll to MODE and press Enter to change to DC mode.

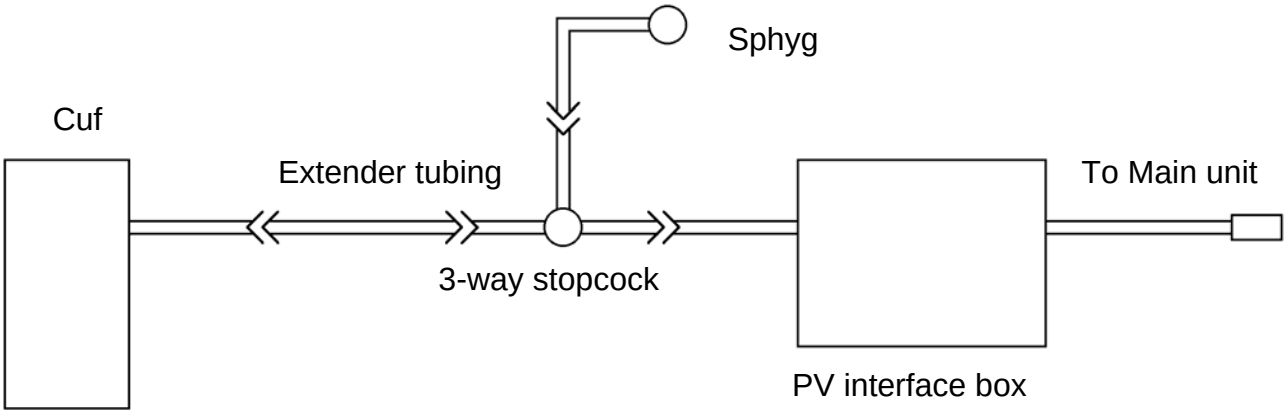


Examination Procedure

(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.

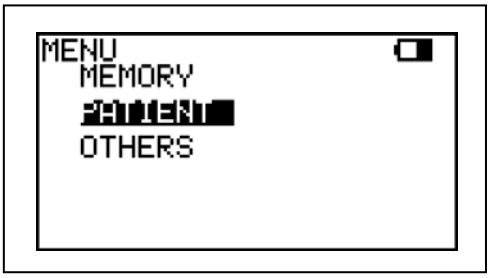
(2) Wrap a wide occluding cuff at mid-thigh and a sensing cuff at mid-calf.

(3) Connect a 3-way stopcock to the inlet of PV interface box. 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) If you wish to input patient data, see " 3-2-3-g. PATIENT".



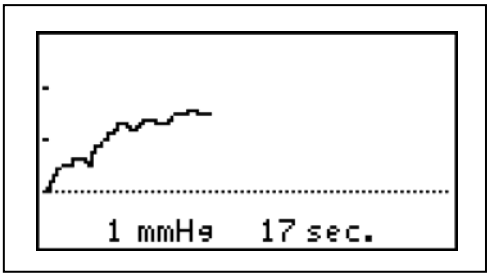
(6) Inflate the sensing cuff to 40 mmHg. Wait 10 seconds to allow time for settling and deflate the cuff to 15 mmHg.

(7) Turn the stopcock so that it blocks sphyg and routes cuff pressure to the PV interface box.

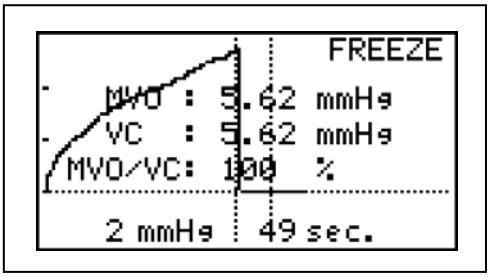
(8) Disconnect the sphyg from the stopcock and attach it to the occluding cuff at the thigh.

(9) Press Right to begin the measurement process.

(10) Inflate the occluding cuff at the thigh to at least 60 mmHg. Pressures in the 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.

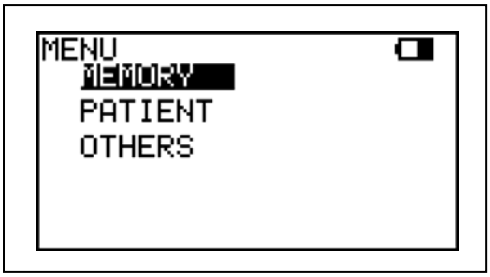


(11) After 90 seconds, disconnect the sphyg from the occluding cuff. The pressures on the screen will drop back to the baseline.



(12) Smartdop will automatically stop the measurement process, and then freeze and print the waveform.

(13) If you wish to save the data on the memory, see “ 3-2-3-a. MEMORY - STORE”.



(15) Press the Right to get out of the freeze mode.

5-3-5. Menu for PV

Menu	Sub Menu	Selections
MEMORY	STORE	1 to 30, FREEZE
	READ	1 to 30, FREEZE
	CLEAR	1 to 30, ALL
MODE (Coupling)		**AC**, DC
PATIENT data	ID, NAME, SEX, AGE, DATE, SITE, MEMO	
OTHERS	LANGUAGE	**ENGLISH**, DEUTSCH, ITALIANO, ESPANOL, FRANCAIS
	AUTO-OFF	**ON**, OFF
	KEYBOARD	**ENGLISH**, JAPANESE
	P.ID PRT (Patient data print)	**ON**, OFF
	PRB-KEY (Probe button)	**PRT&FRZ**, PRINT, FREEZE
	DATE	MMM.DD,YYYY HH:MM:SS
	PRINT	

Note : MODE is selectable when in Measurement mode, and PRINT is available when in Freeze mode.

5-3-6. PV Mode setting

MODE (AC / DC) (Only Measurement mode)

(1) Press Enter to change the mode.

AC: AC coupling mode for arterial pulse waveform studies

DC: DC coupling mode for venous reflux study

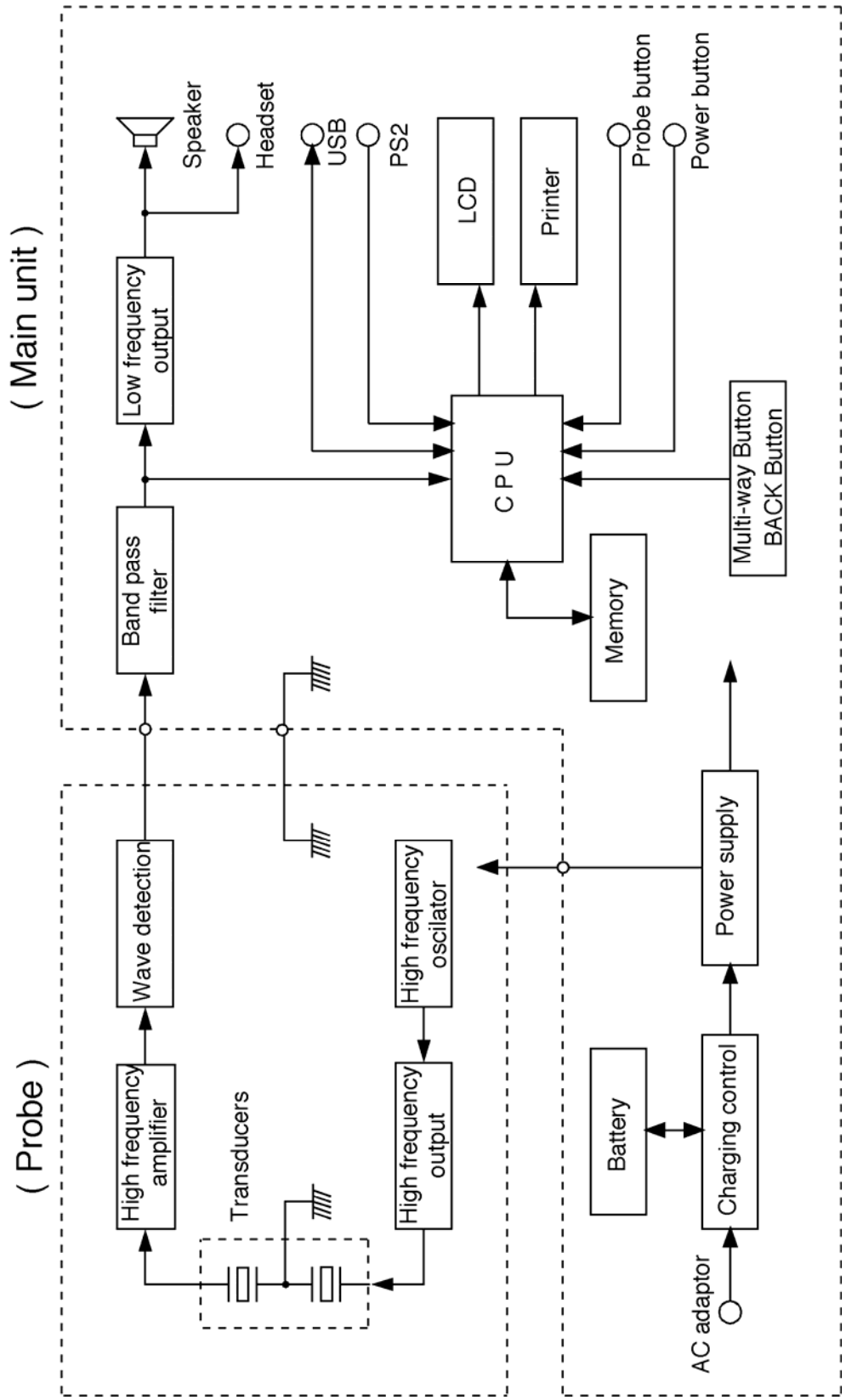
6. TECHNICAL INFORMATION

6-1. PRINCIPLES

Model Smartdop 45 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 wave form signals which can be displayed and printed.

6-2. BLOCK DIAGRAM



6-3. SPECIFICATIONS

Probes:	Model (multi freq.)	Freq.	Probe power
	BT2M20S8C	2 MHz	80 mW/cm^2 or less
	BT4M05S8C	4 MHz	180 mW/cm^2 or less
	BT5M05S8C	5 MHz	180 mW/cm^2 or less
	BT8M05S8C	8 MHz	180 mW/cm^2 or less
	BT10M5S8C	10 MHz	180 mW/cm^2 or less
Power:	Ni-MH rechargeable battery pack or AC adaptor, FRIWO model #: FW 3299/15.0974		
	Input:	230 V AC, 50 Hz	
	Output:	12 V DC, 580 mA	
	Fuse:	250 V, 80 mA	
	Or 120 V AC, 12 V DC, 580 mA for US and Canada		
Consumption:	DC 12 V, 300 mA		
Recharge:	Approx. 3 hours by the AC adaptor		
Full charge life:	2.5 hours or more if used with freeze mode.		
Battery life:	Approx. 2 years, 300 full charges		
Automatic shut-off	No signal: 2 min. Freeze: 5 min. Others: 15 min. (only FHR WAVE mode: 35 min.)		
Frequency range:	80 / 200 Hz to 5 kHz		
Mode settings:	Memory, Waveform, Direction, Time scale, Others		
Waveform memory:	30 waveforms		
LCD display:	128 x 64 dots, STN LCD Bi-directional wave form (normal & slow mode) Numerical data (Systolic, diastolic & mean velocities, RP, PI, SD, HR) Heart rate: 30 to 300 BPM, accuracy of ±5% Battery level and low battery indicators		
Printer:	Paper:	58 mm (W) x 25 m/roll (L), Thermal	

	Resolution:	384 dots/line
	Print speed:	25 mm/s
Velocity accuracy:	±10% or less comparing with internal phantom testing.	
Speaker output:	250 mW or more	
External outputs:	Headset, USB port	
Electrical safety:	Conform to IEC60601-1 Internally powered equipment Type BF applied part. 	

Operating environment:

10 to 40 degrees Centigrade

85% humidity or less with no condensation

Storage and transport environment:

0 to 50 degrees Centigrade

Dimensions:	Main unit:	115 (W) x 210 (D) x 60 (H) mm
	Probe:	20 (Diam.) x 105 (L) mm
Weight:	560 grams (including battery & probe)	

Manufacturing date :

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

The serial number is located inside of the printer paper compartment and it consists of 4 to 8 digits and may start with “Serial number” or “S/N”.

Examples:

03020001:	Feb/2003
0401:	Jan/2004

* Specifications subject to change

6-4. 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) Leak current:
Based upon IEC60601-1

Items	Normal	Single fault
Housing leak current	0.1 mA or less	0.5 mA or less
Patient leak current	0.1 mA or less	0.5 mA or less

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