



OPERATING MANUAL

Smartdop 45

OPERATING MANUAL

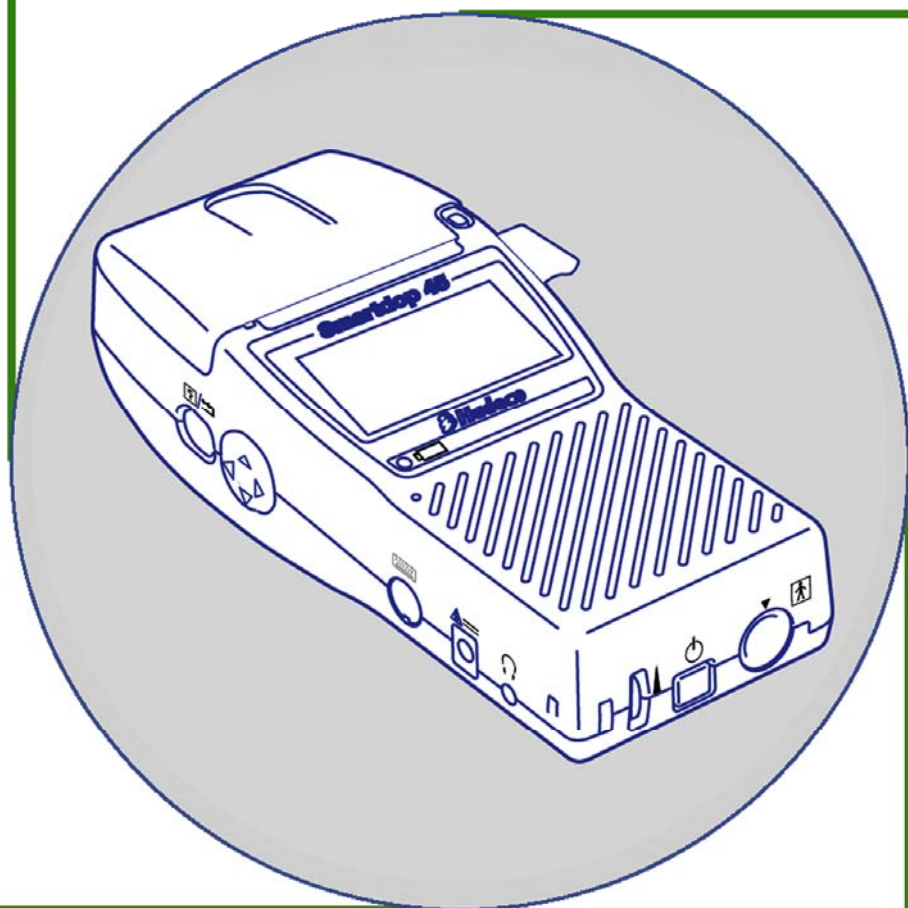


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CAUTIONS

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
 - (1) Follow the requirements for storage and operating environments.
 - (2) Do not place it near water.
 - (3) Do not place it where atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salt, sulfur and so forth will affect the unit adversely.
 - (4) Pay attention to the stability conditions to avoid too much inclination, vibration, shock and so on during transportation and installation of the unit.
 - (5) Do not place it where chemicals are stored or gas may be generated.
 - (6) Do not place it where the unit tends to fall.
5. Before use:
 - (1) Make sure that the unit operates safely and correctly by implementing performance check mentioned in "§ 4-1. 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 by gas, autoclave or so on to prevent any damage.
 - (6) Sterilizable probes should be sterilized before use.
6. Operation
 - (1) Do not use the unit simultaneously with either electric cautery, cardioverter, other ultrasonic device or mobile phone.
 - (2) Be cautious not to exceed too much time and volume required for the measurement.
 - (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) Do not let the patient touch the unit.
 - (6) Use the designated components only.
 - (7) Do not use the components for other devices.
 - (8) Use the unit under the operating environments specified on the specifications.
 - (9) Use the unit as specified in the operation manual.

(10) Do not use the unit in a strong electromagnetic field or it may cause incorrect measurements.

7. After use:

- (1) 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 (2) to (6) of section #4 Device placement in the previous page.
- (2) When using the unit next time, perform the maintenance to make sure it works properly and safety.

9. Maintenance and inspection

- (1) Do the periodical maintenance by following the procedures mentioned in "§ 4-1. 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.
- (3) Optional sterilizable probe (reusable & disposable) can be sterilized in the manner described in § 5-2. Sterilizable Doppler probes. However, only one time sterilization is possible for disposable probe, and do not reuse it. Except optional ACP probe, do not sterilize probes by steam autoclave.

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 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

- * **CONVENIENT PROBE ACTIVATION BUTTON**
Freezes and prints waveform and numerical data for notation.
Button function can be changed on probe key mode setting, PRB-KEY.

- * **MULTIPROBE SELECTION of 2, 4, 5, 8, 10 and 20 MHz.**
(When connecting 20 MHz probe, only **kHz** (Doppler frequency shift) is available in Unit mode. See "§ 3-2-3. I. Others - Unit" for the details)

- * **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.


1-4. Contents of package

Main unit	1
Probe	1
AC adaptor	1
Ultrasonic gel	1
Paper	1
Carrying case	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.

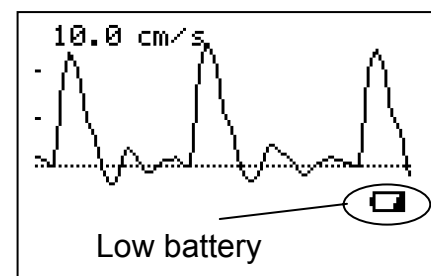
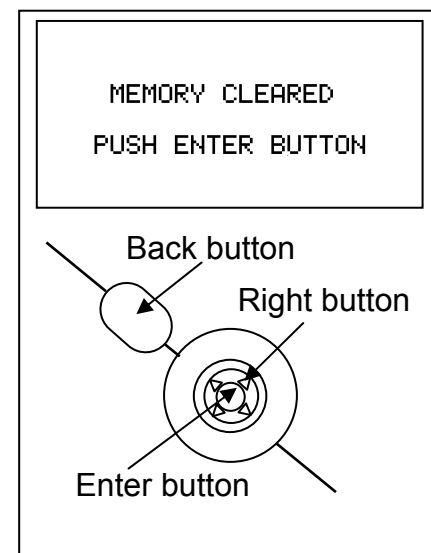
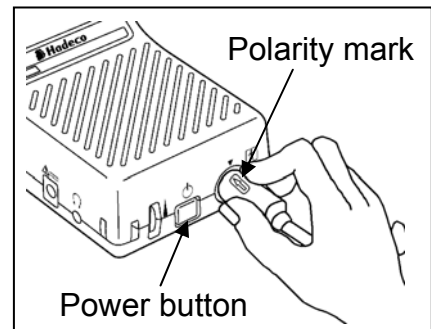
2-1. Turning the unit ON / OFF

(1) Connect the probe to the probe connector so that the polarity mark  will be placed under ▼ mark as shown in the right (12 o'clock).

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

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

(4) When battery is low, low battery indicator appears as shown in the right. Smartdop can be used for a few more minutes. Recharge the 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) 35 minutes when in measurement. (Only Fetal Heart Rate WAVE mode)
- (b) 15 minutes when in measurement. (Except Fetal Heart Rate WAVE mode)
- (c) 5 minutes when no signal.
- (d) 10 minutes when on freeze mode.

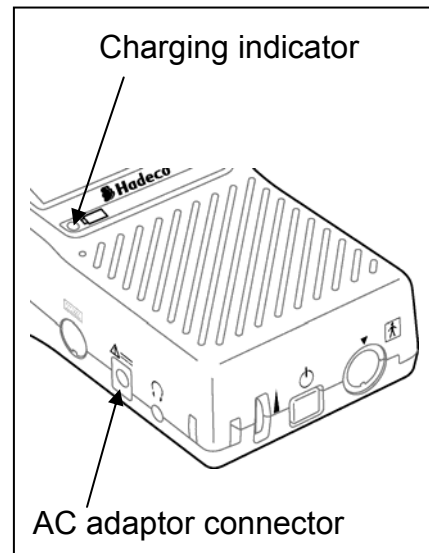
Note: If Automatic shut-off functions while on Freeze mode, Smartdop will revert to Freeze mode and display the frozen waveform on LCD by turning the unit on.

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, see "§ 6-3.Specifications".

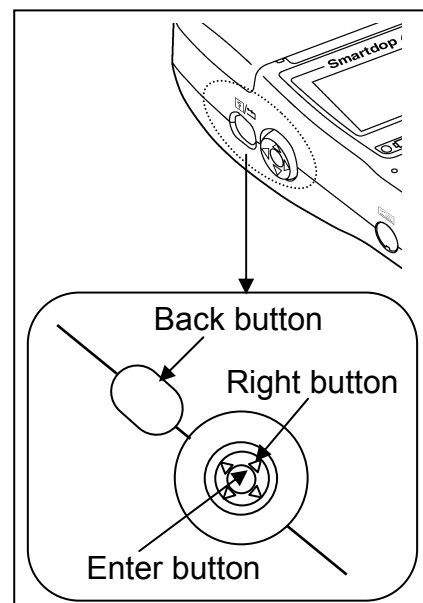
- (2) When the battery is fully charged, the charging indicator will go solid green. Unplug the AC adaptor.



- (3) 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 as follows:

- 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.

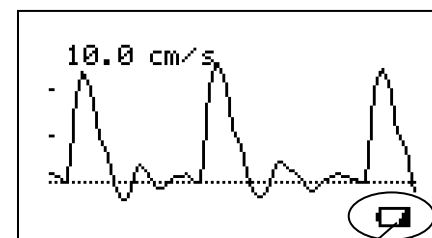
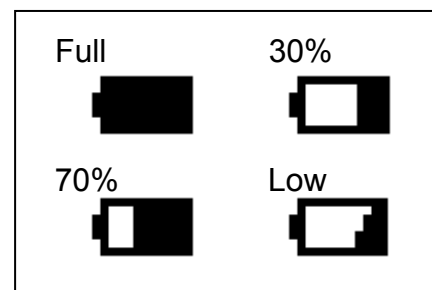
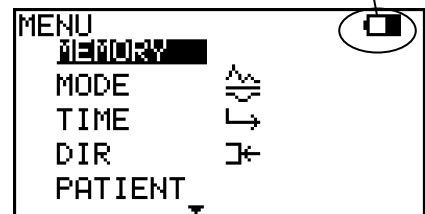
Low battery indicator

When the battery is low, the low battery indicator will be shown on bottom right of LCD. Recharge the battery.

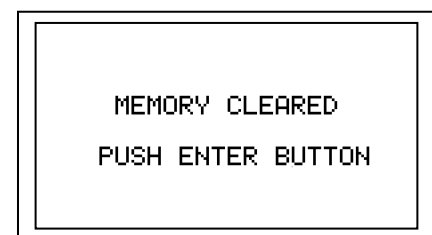
See "2-2. Charging / Discharging Battery"

If battery gets extremely low, the message shown right will appear upon turning it on to indicate memory data have been cleared for waveform data,

Battery level indicator



Low battery indicator

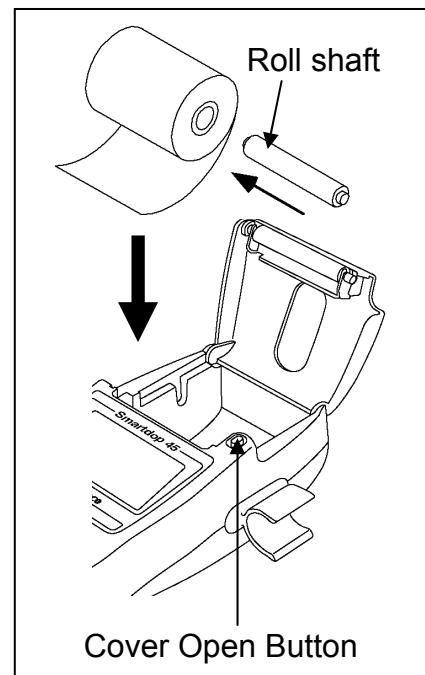


Date setting, and Patient data excluding other Menu mode settings.

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


2-4. Setting printer paper

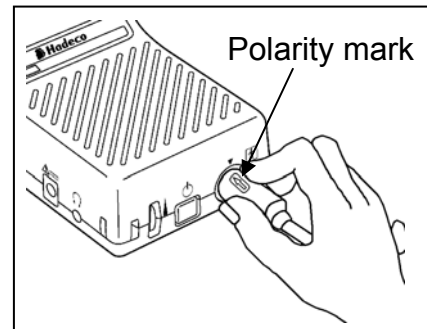
- (1) Press Cover Open Button to open the paper cover and remove the roll shaft.
- (2) Insert the roll shaft into the paper roll.
- (3) Set them in the paper compartment as shown in the right. Pull the paper edge out a few inches and close the paper cover tightly.



2-5. Measuring blood velocity

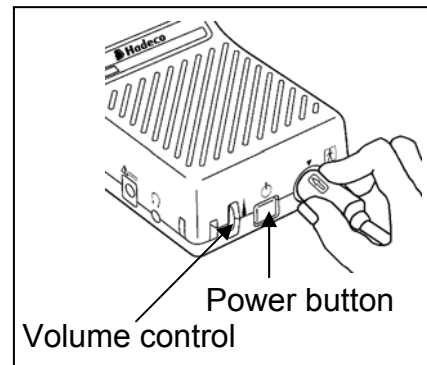
This section explains the fundamental use of measuring blood velocity. Refer to “3. Appearance and Mode Settings” for various uses.

(1) Connect the probe to the probe connector so that the polarity mark  will be placed under ▼ mark as shown in the right (12 o'clock).



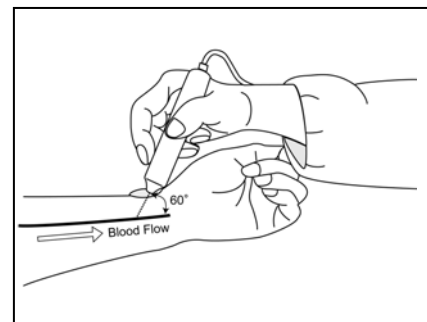
(2) Put ultra ultrasonic gel on the probe top or patient skin.

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

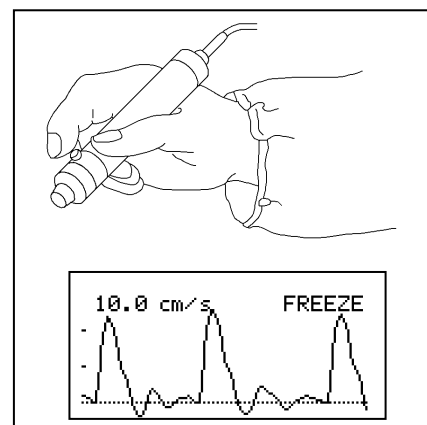


If you wish to enter the patient data, see “3-2-3-j. Patient Data Input”.

(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 45 to 60 degrees.

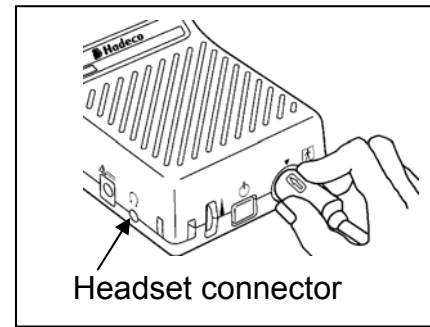


(5) When the waveform becomes rhythmical and stable, wait more than 5 sec without moving the probe, and then press the probe button to freeze the waveform. Press Print Button to print the waveform of last 5 sec. if necessary.




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

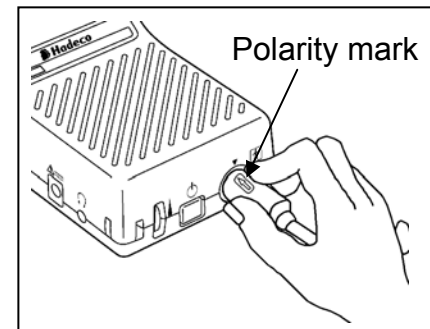
- (6) Headset (Option) can be used to listen to Doppler sounds. It will cut off the speaker.



2-6. Measuring fetal heart rate (2 MHz only)

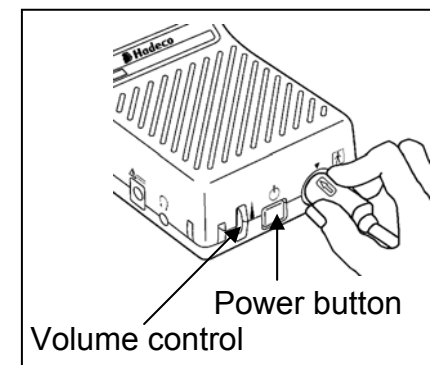
This section explains the fundamental use of measuring fetal heart rate. Refer to “3. Appearance and Mode Settings” for various uses.

- (1) Connect the probe to the probe connector so that the polarity mark  will be placed under ▼ mark as shown in the right (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.

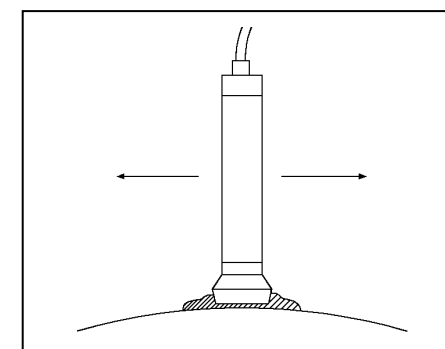


- (4) If you wish to monitor heart rate waveform, see “3-2-3-g. DISP (Waveform / Data)” to change the mode.

- (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.

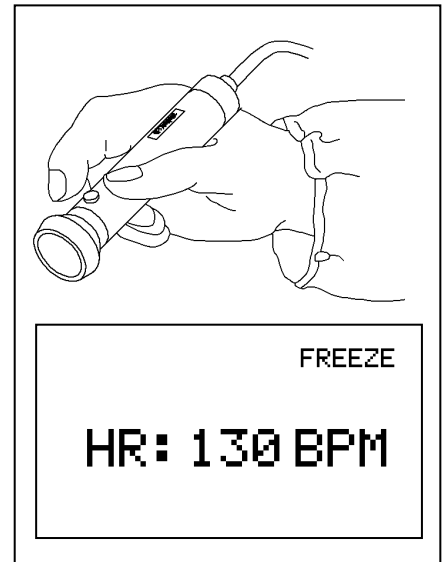
(Maternal heart rates match the maternal pulse rates.)



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

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

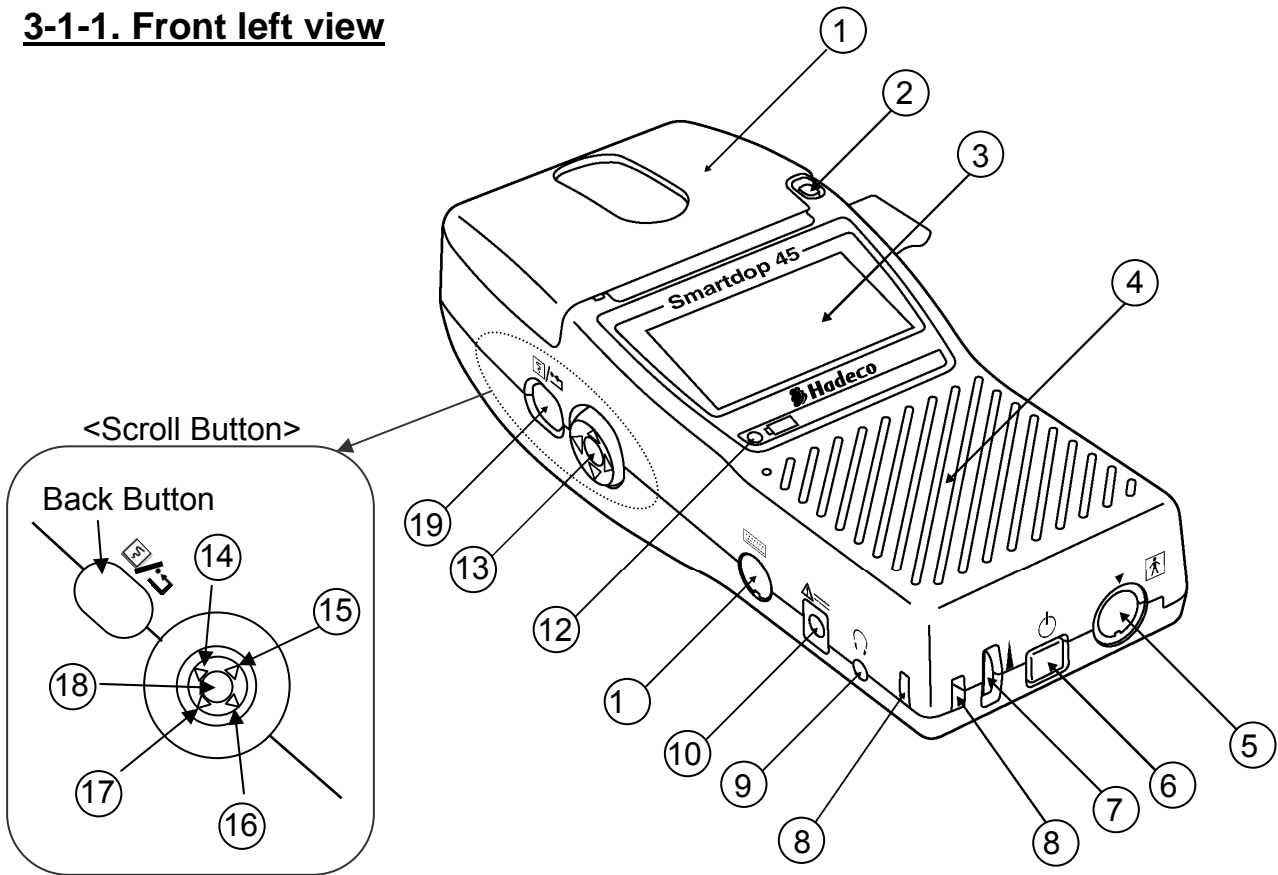
(7) Headset (Option) can be used to listen to Doppler sounds. It will cut off the speaker.







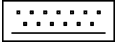


3. Appearance and mode settings

3-1. Operating controls

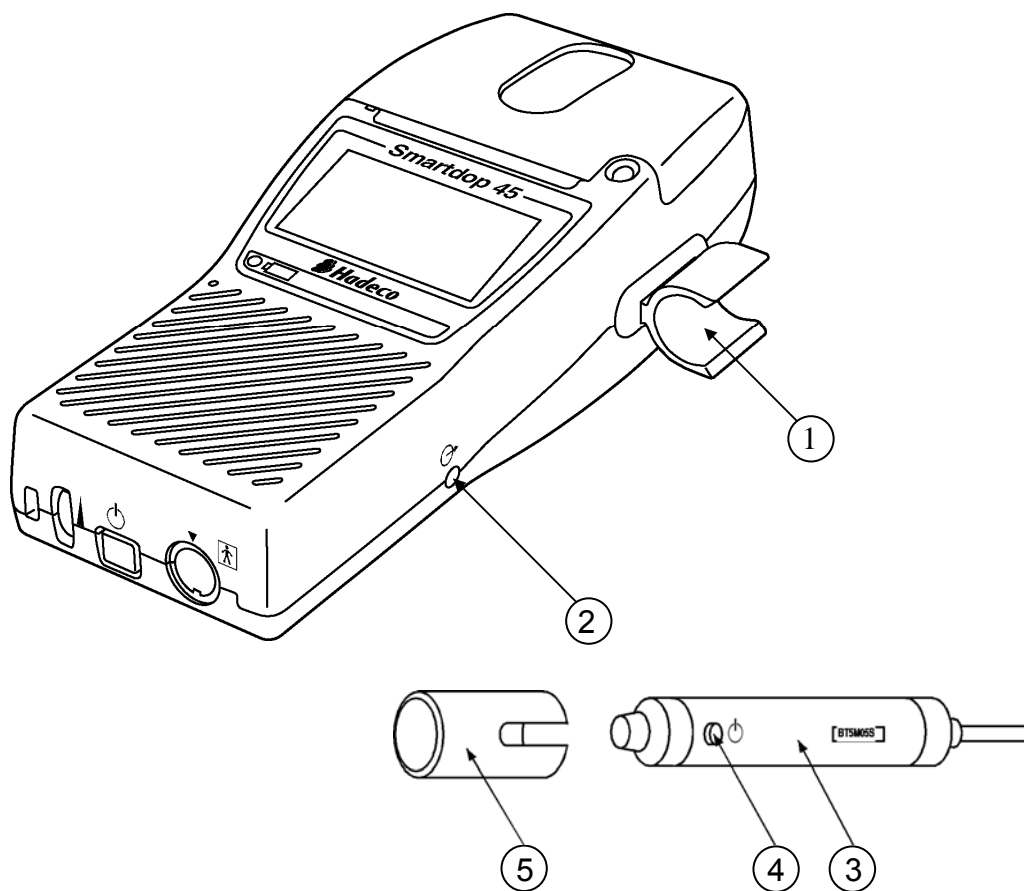
3-1-1. Front left view



- | | | |
|----------------------|---|---|
| 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, optional.
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

Note: For the mode settings for options, see “§ 5-2-5. Menu for PPG” and “§ 5-3-5. Menu for PV”.

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)

Connecting 4, 5, 8 or 10 MHz probe sets on Blood Velocity mode automatically.

Connecting 2 MHz probe sets on Fetal Heart Rate mode automatically.

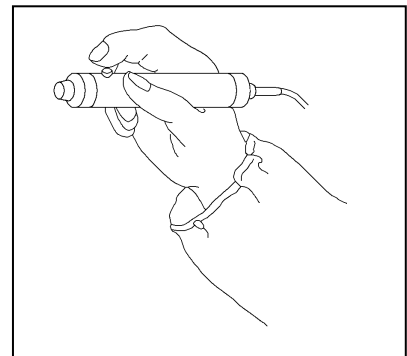
Optional operation modes are available by connecting optional PPG and PV probes. See " 5. Options".

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.

(When PRB-KEY is Freeze mode.)

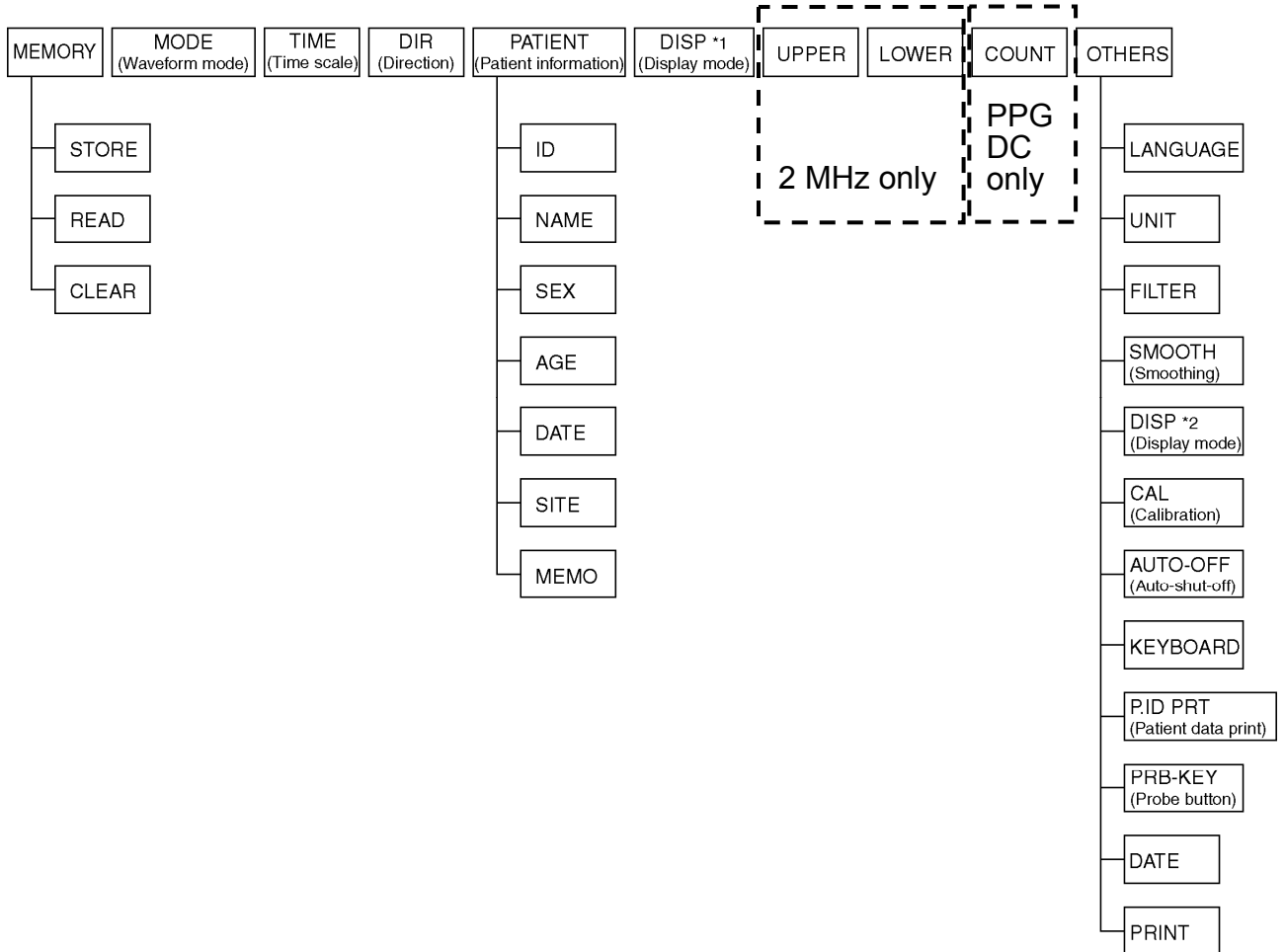
With 2 MHz probe, Fetal Heart Rate mode, pressing Right button also changes the mode alternatively.



3-2-2. Menu

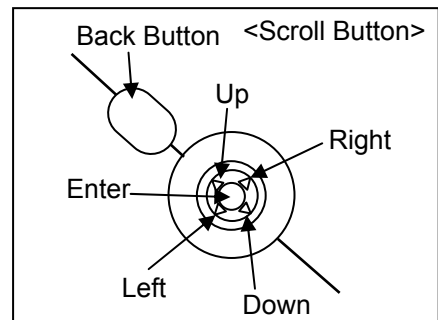
Using Scroll Button, various mode settings are changeable on Menu mode. Some menus have sub menus. Refer to following **Menu structure** and **Menu operation** first.

a. Menu structure



b. Menu operation

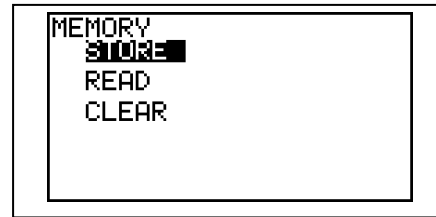
(1) Press Enter to show MENU depending on Basic Mode.



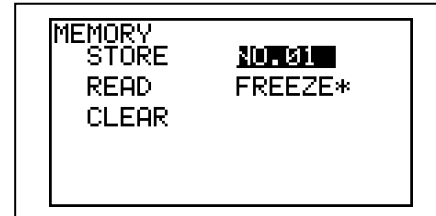
(2) Select the mode by pressing Up and Down buttons and selected mode will be highlighted. Press Enter once or twice to change the mode setting.



- (3) For MEMORY, PATIENT and OTHERS in MENU, pressing Enter or Right button shows sub menu for further mode settings.









- (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	Reference in §3-2-3.
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
MODE (waveform)		Compound  Separate 	d. Mode
TIME scale		Normal  Slow 	e. Time
DIR, direction		Forward  Reverse 	f. DIR
PATIENT data	ID, NAME, SEX, AGE, DATE, SITE, MEMO		j. Patient
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	UNIT	cm/s , kHz	l. Others - Unit
	FILTER	80Hz, 200Hz	m. Others - Filter
	SMOOTHING	5Hz, 10Hz	n. Others - Smooth
	DISP, display mode	WAVE , DATA	g. Others - DISP
	CALibration	ON, OFF	o. Others - CAL
	AUTO-OFF	ON , OFF	p. Others - Auto- off
	KEYBOARD	ENGLISH , JAPANESE	q. Others - keyboard
	P.ID PRT (Patient data print)	ON , OFF	r. Others - P.ID PRT
	PRB-KEY (Probe button)	PRT & FRZ, PRINT, FREEZE	s. Others - PRB - KEY
	DATA	MMM.DD,YYYY HH:MM:SS	t. Others - Date

Note: Selections in bold face in the table above are default settings.

d. Menu for Blood Velocity Freeze mode

Menu	Sub Menu	Selections	Reference in §3-2-3.
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
MODE (waveform)		Compound  Separate 	d. Mode
DIR, direction		Forward  Reverse 	f. DIR
DISP, display mode		WAVE , DATE	g. DISP
PATIENT date	ID, NAME, SEX, AGE, DATE, SITE, MEMO		j. Patient
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	AUTO-OFF	ON , OFF	p. Others - Auto- off
	KEYBOARD	ENGLISH , JAPANESE	q. Others - keyboard
	P.ID PRT (Patient data print)	ON , OFF	r. Others - P.ID PRT
	PRB-KEY (Probe button)	PRT & FRZ, PRINT, FREEZE	s. Others - PRB - KEY
	DATA	MMM.DD,YYYY HH:MM:SS	t. Others - Date
	PRINT		u. Others - Print

Note: Selections in bold face in the table above are default settings.

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

Menu	Sub Menu	Selections	Reference in §3-2-3.
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
DISP, display mode		WAVE , DATE	g. DISP
UPPER limit		60 to 220 (every 5 BPM)	h. Upper
LOWER limit		60 to 220 (every 5 BPM)	i. Lower
PATIENT date	ID, NAME, SEX, AGE, DATE, SITE, MEMO		j. Patient
OTHERS	LANGUAGE	ENGLISH , DEUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	AUTO-OFF	ON , OFF	p. Others - Auto- off
	KEYBOARD	ENGLISH , JAPANESE	q. Others - keyboard
	P.ID PRT (Patient data print)	ON , OFF	r. Others - P.ID PRT
	PRB-KEY (Probe button)	PRT & FRZ, PRINT, FREEZE	Others - PRB - KEY
	DATA	MMM.DD,YYYY HH:MM:SS	t. Others - Date
	PRINT		u. Others - Print

Note: PRINT is only available when in WAVE & Freeze mode. DISP mode is not changeable when on freeze mode. Selections in bold face in the table above are default settings.

Button functions limited to Fetal Heart Rate mode

- 1 Right To freeze and unfreeze the waveform & heart rate.
- 2 Up / Down To restart waveform monitoring when on WAVE mode.
- 3 Left To show next page of monitoring waveform when on Freeze mode.

3-2-3. Mode Setting Details

See "§ 3-2-2-b. Menu operation" for button operation on Menu mode.

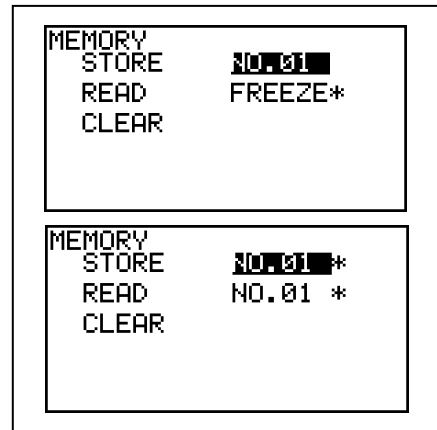
Do the mode setting once and subsequent Smartdop use will revert to this mode.

However, if battery gets extremely low, memory data will be cleared for waveform data, Date setting, and Patient data excluding other Menu mode settings.

a. MEMORY - STORE

- (1) The first memory number available will be selected automatically on STORE. If necessary, change the number where to store waveform data and patient data by pressing Up and Down.

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

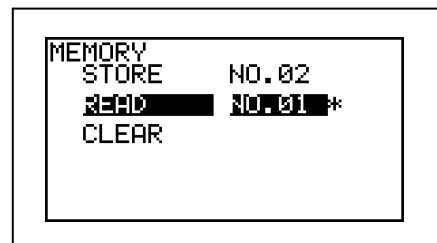


- (2) Press Enter to store the data into the memory and it will go back to waveform display.

Note: If other data have been already stored in memory number storing, a confirmation of "OVERWRITE?" will be shown. Press Enter to overwrite, or Left to cancel for selecting other memory number available.

b. MEMORY - READ

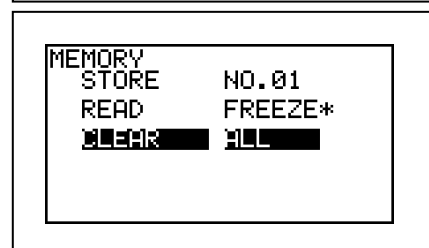
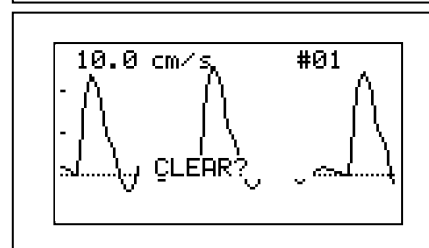
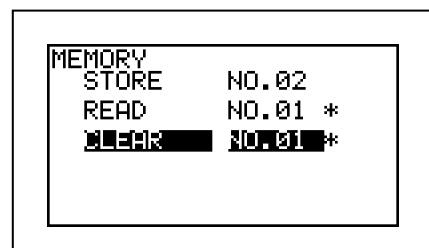
- (1) Select the memory number where you wish to read waveform data and patient data from by pressing Up and Down.
- (2) Press Enter button to show the waveform.
- (3) Press Up and Down to show next waveform if necessary.



Note: Any frozen waveform is stored temporarily in memory area of FREEZE separated from regular 30 memory. 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

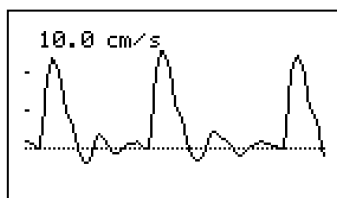
- (1) Select the memory number you wish to clear the data. The memory number with "*" indicates memory area where data have been already stored.
- (2) Press Enter and then the confirmation screen with waveform data will be displayed as shown in the right. Press Enter to clear the memory, or press Left to cancel.
- (3) To clear all the data except FREEZE in the memory at once, select and press on ALL and follow the instruction.



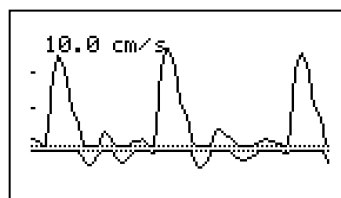
d. MODE (Baseline mode)

- (1) Press Enter to change the baseline mode as follows:

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 as follows:

Normal:  For arteries (2.56 sec/screen)

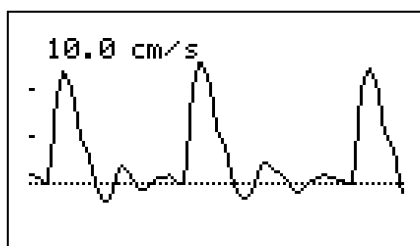
Slow:  For veins (12.8 sec/screen)

f. DIR (Flow direction)

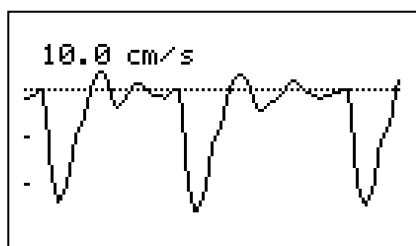
(1) Press Enter button to change waveform polarity as follows:

Forward:  Flow toward probe is processed as positive component.

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



Forward mode



Reverse mode

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

(1) Press Enter to change the Display mode as follows:

Blood Velocity mode

WAVE: Displays waveforms.

DATA: Displays numerical data

See "3-3-1. Blood Velocity mode" for more details.

Fetal Heart Rate mode

WAVE: Monitoring waveform

DATA: Numerical data

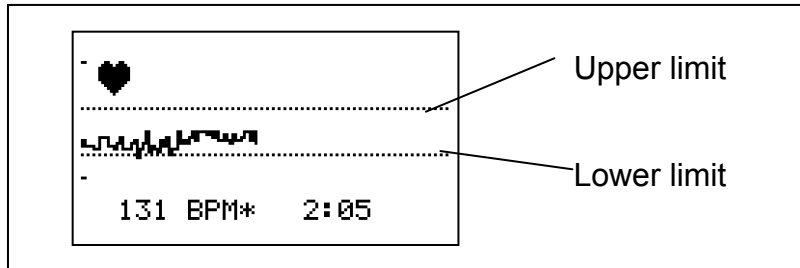
See "3-3-2. Fetal Heart Rate mode" for more details.

Note: Display mode cannot be changed when on Freeze mode. When on measurement mode with WAVE mode, pressing Up or Down restarts the monitoring.

h. UPPER (Upper limit for FHR)

If heart rate exceeds the upper limit for more than 30 sec, LCD will start flashing for warning.

- (1) Press Up and Down to select the upper limit in 5 BPM steps and press the button to fix it.



i. LOWER (Lower limit for FHR)

If heart rate gets below lower limit for more than 30 sec, LCD will start flashing for warning.

- (1) Press Up and Down to select the lower limit in 5 BPM steps and press the button to fix it.

j. 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.

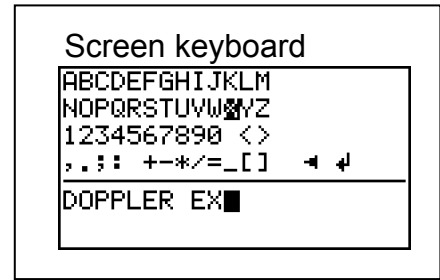
- (1) Prior to the patient data input, go to OTHERS-DATE menu and set the date and time for an initial setting.

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.

The screenshot shows a patient data input screen with the following text:
ID: 1234567890
NAME: TARO HADECO
SEX: MALE AGE: 31
DATE: Jan, 31, 2005
SITE: RADIAL-RIGHT
MEMO: DOPPLER EXAMINAT
ION

- (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.



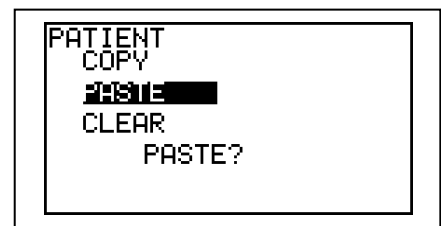
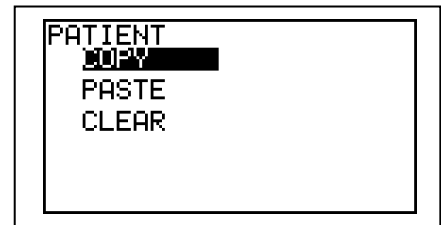
When using external PS2 keyboard:

- (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.



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 as follows:

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

m. OTHERS - FILTER (Arterial / Venous filter)

The high-pass filter cuts off Doppler signals with lower frequencies than filtering frequency (200 or 80 Hz) for optimal audibility.

- (1) Press Enter to change the filter as follows:

200 Hz: For arteries
80 Hz: For veins

n. OTHERS - SMOOTH (Smoothing filter)

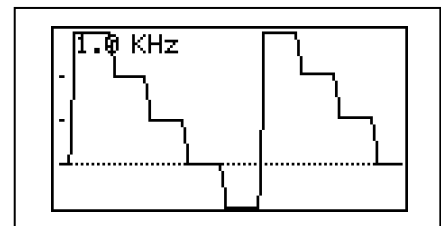
- (1) Press Enter to change smoothing frequency as follows:

10 Hz: For normal signals
5 Hz: For noisy signals

o. OTHERS - CAL (Calibration)

- (1) Press Enter to change CAL mode as follows:

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 as follows:

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 as follows:

PRT&FRZ: Freezes and prints.

PRINT: Prints and goes to Monitoring mode as follows:

FREEZE: Freezes

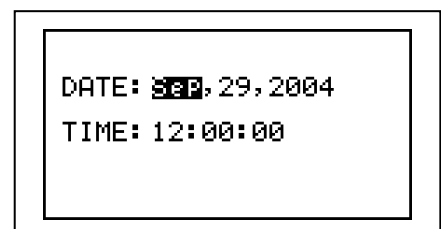
Note: When on FHR - DATA mode, only FREEZE is functional no matter what is selected on the PRB-KEY mode.

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.

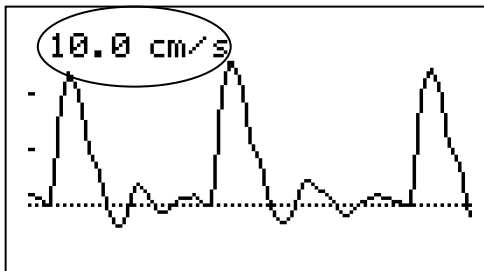
Note: Pressing Print Button also activates printer. Press Print the second time to deactivate printer.

3-3. LCD display

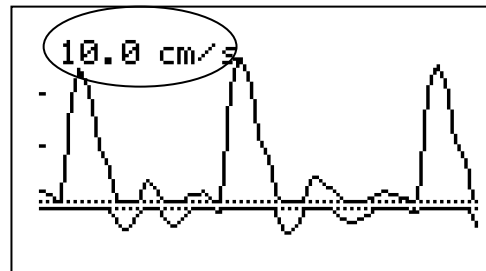
3-3-1. Blood Velocity Mode

Waveforms

- (1) The base line is automatically located at optimal position for each waveform.
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 on top left of LCD.

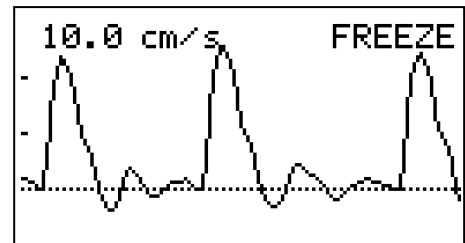


Compound mode

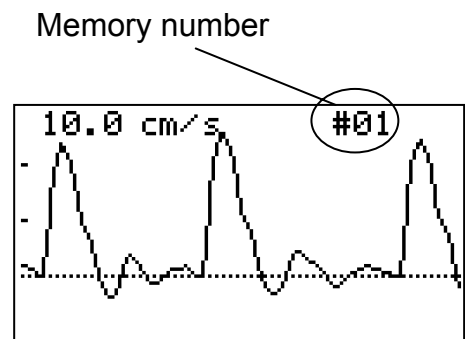


Separate mode

- (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" on top right of LCD.



Numerical data

Following numerical parameters are displayed on DATA mode.

```
S: 30.6 cm/s
MN: 15.6 cm/s
D: 10.2 cm/s
MIN: 8.3 cm/s
RP: 0.66 SD: 3.00
PI: 1.42 HR: 85BPM
```

Unit: cm/s

```
S: 1.12 kHz
MN: 0.11 kHz
D: 0.00 kHz
MIN: -0.17 kHz
RP: 1.00 SD: **. **
PI: 11.72 HR: 73BPM
```

Unit: kHz

See “3-5. Numerical Data” for the meaning of abbreviations and the definitions of parameters.

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

Displaying heart rate at the moment (DATA mode)

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

(2) The heart mark " ♥ " tracks heart beat while in measurement. The heart mark also indicates the speed of heart movements in 3 different sizes as follows:

Fast



Medium



Slow

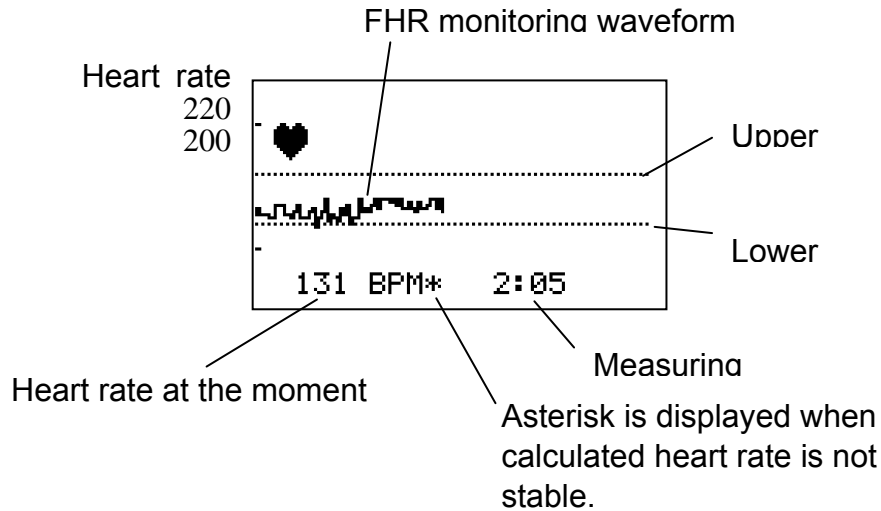


```
♥ *
HR: 61 BPM
```

(3) When calculated heart rate is not stable, the asterisk (*) will show above “HR”.

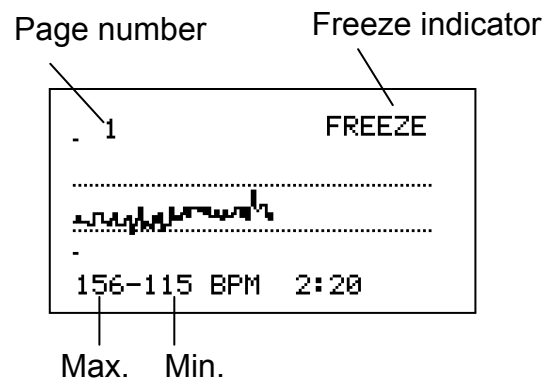
Monitoring heart rate in graph (WAVE mode, Monitoring mode)

- (1) The measurement range of heart rate is 60 to 220 BPM.
- (2) Heart rate at the moment is displayed on bottom left of LCD.

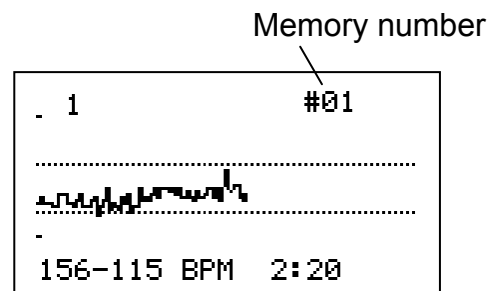


- (3) Heart mark indicates the same way as DATA mode. See previous page.
- (4) Two dotted lines indicate Upper and Lower limits of heart rate. If it gets out of limits for more than 30 sec, LCD will start flashing for warning.

- (5) When on freeze mode by pressing probe or Right button, the latest monitoring waveform of up to 33 minutes can be shown over 4 pages on LCD with FREEZE indicator. Turn Shuttle Button down to show next page. (Approx. 8 minutes a page)



- (6) The read out waveform from memories is displayed with memory number, e.g. "#01" on top right LCD.



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.

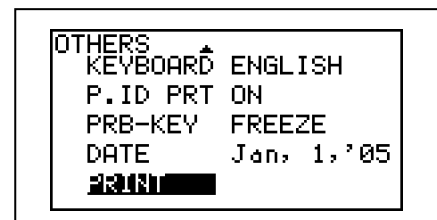
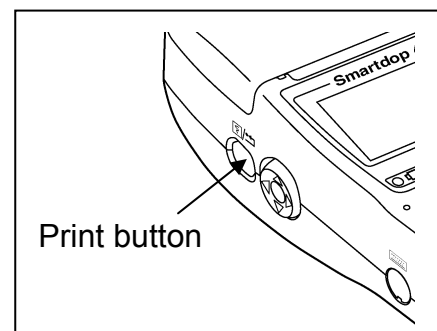
Note: Refer to the description of each mode in “ 3-2-3. Mode Setting Details”.

<u>Mode</u>	<u>Abbrev.</u>	<u>Selection</u>
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/s, kHz
f. Filter	FILTER	80Hz, 200Hz
g. Smoothing filter	SMOOTH	5 Hz, 10 Hz
h. Waveform / Data	DISP	Wave, Data
i. 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.



Blood Velocity mode

TIME is Normal: Waveform of the 5 sec before freezing

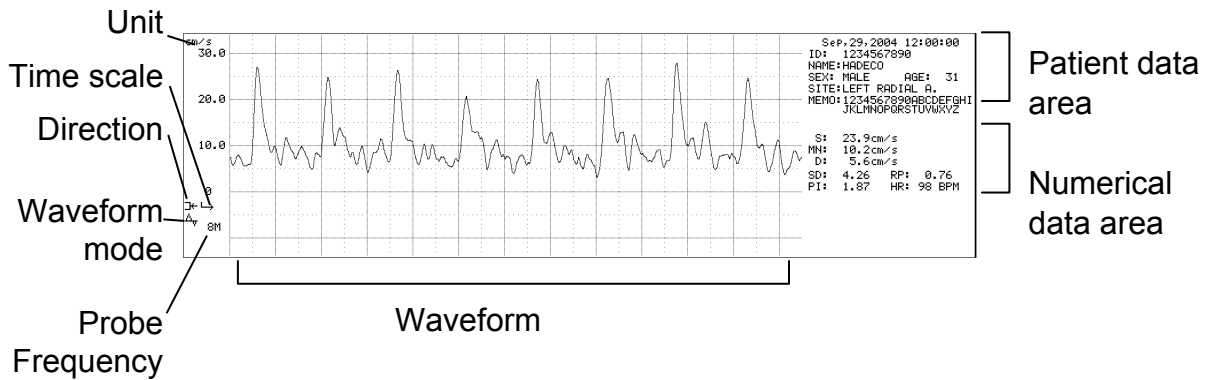
TIME is Slow: Waveform of the 25 sec before freezing

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.

3-4-3. 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	
Minimum velocity [cm/s] or minimum Doppler shift [kHz]	MIN	
Resistance Parameter	RP	$RP = (S - D) / S$ RP=1 if waveform goes below base line.
Pulsatility Index	PI	$PI = (\text{Peak-to-peak}) / MN$ $PI \leq 99.99$
S/D ratio	SD	$SD = S / D$
Heart rate [BPM]	HR	

Samples displayed on LCD

S:	30.6	cm/s
MN:	15.6	cm/s
D:	10.2	cm/s
MIN:	8.3	cm/s
RP:	0.66	SD: 3.00
PI:	1.42	HR: 85BPM

Unit: cm/s

S:	1.12	kHz
MN:	0.11	kHz
D:	0.00	kHz
MIN:	-0.17	kHz
RP:	1.00	SD: **, **
PI:	11.72	HR: 73BPM

Unit: kHz

3-6. External outputs

3-6-1. Headset

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

See 3-1. Operating Controls.


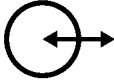





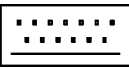





3-6-2. Communication port (3.5 mm jack)

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 an entire report for 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	Description	Symbol	Description
	Type BF applied part		USB connector
	Headset		Volume control
	Print button		Charging indicator
	AC adaptor connector		Keyboard connector
	Caution*1		Back button
	Power button		Manufacturer
	Authorized representative in Europe		

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

4. Maintenance

4-1. Performance check by user

Perform the following performance checks at least once a year:

- (1) Make sure if there is no damage and/or crack on the 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.

Check the unit by maintenance procedures mentioned in "§ 4-1. Performance check by user" before using the unit.

4-3. Warranty

Guarantee period:

*: Frequency

Main unit		Two(2) years
Probe	BT*M05S8C(A), BF8M15S8A, BP*M05S8A, VRP-*, LRP-*, FDP-08, ACP-08* ¹ , BDP-*	One(1) year
	CRP-*H, NRP-*H	Six(6) months
	NRP-*HF	Three(3) months

The guarantee period is after the date of purchase when used under normal condition. In the event of any trouble during the warranty period, please contact the dealer from who

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

*1: Guarantee period of ACP-08: either one year from the date of purchase or within 5 times of autoclave sterilization.

5. Options

5-1. Probe selection

Standard Doppler probes: 2, 4, 5, 8 and 10 MHz (with curled or straight cable)

Flat type Doppler probes: 2, 8 MHz

Sterilizable Doppler probes: 8, 10, & 20 MHz (Amplifier required)

Vascular, lapaloscopic, neurovascular, cardiovascular

Amplifier Model BDP*MS8 (*: Frequency 8, 10, & 20 MHz)

PPG probe: Model PG-21

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

Headset

5-2. Sterilizable doppler probes

VRP: Vascular, LRP: Lapaloscopic, NRP: Neurovascular,

CRP: Cardiovascular, FDP: Flat, ACP: Autoclavable (up to 5 times)

5-2-1. Sterilization

Only sterilizable probes can be sterilized. Do not sterilize other type of probes including amplifiers as well as main unit.

Warnings

Sterilizable probes are not sterilized before shipment.

They must be sterilized before use as follows:

Sterilization limits

1. All sterilizable probes except ACP probe: Up to 50 times
2. ACP probe: Up to 5 times (steam autoclave)

Note. Do not exceed sterilization limits or it may cause damage to probes.

Caution

1. Except ACP probe, do not sterilize probes by steam autoclave nor put them in washer disinfectant or it will damage probes.
2. ACP probe should be sterilized by steam autoclave as described in section "Sterilization" below.

Instructions for sterilization

Point of preparation: No particular requirements.

Preparation for cleaning:

No particular requirements.

Cleaning:

Automated

Do not do automated cleaning of probes other than ACP probe.

Manual

Do not soak probes into medicinal solution. Wipe any contamination from probes with damp cloth.

Disinfection:

Not applicable

Sterilization:

Sterilizable probes except ACP probe

Low temperature plasma sterilization (Hydrogen peroxide low temperature plasma sterilization), under 60 degrees (C).

Do not put liquid, powder & cellulose inside sterilization equipment or it may reduce effectiveness of sterilization because these substances absorb hydrogen peroxide.

Eliminate water on surface of probe because it may reduce effectiveness of sterilization.

Sterilization should be performed in accordance with instructions of the sterilization equipment.

ACP probe

Steam autoclave;
30 minutes under 115 degrees (C)
20 minutes under 121 degrees (C)
10 minutes under 134 degrees (C)
Do not expose the instrument to temperatures exceeding 134 degrees (C).
Sterilization should be performed in accordance with instructions of the sterilization equipment.

Drying:

Sterilizable probes except ACP probe
No particular requirements.

ACP probe
Dry it well after the sterilization.

Maintenance: No particular requirements.

Inspection and Function Testing:

No cracks nor contaminations in appearance.
Connect the probe to main unit and make sure if you hear Doppler sounds properly when you rub probe tip.

Packaging: No particular requirements.

Storage: No particular requirements.

Manufacturer contact:

Hadeco, Inc.
2-7-11 Arima, Miyamae-ku, Kawasaki, 216-0003, Japan
Tel: +81-44-877-4361
Fax: +81-44-855-7301

The instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personal in the processing facility achieve the desired result. This requires validation and routine monitoring of process. Likewise any deviation by the processor from the instruction provided should be evaluated for effectiveness and potential adverse consequences.

5-3. Photoplethysmograph

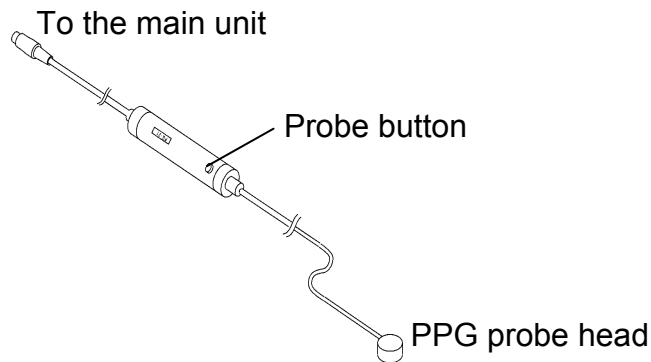
With the PG-21 and PGV-20 (PPG mode), Smartdop senses the reflection of light from the hemoglobin of the red blood cells in surface vessels by utilizing infrared light.

Basically, “How to use photoplethysmograph” is described in this section. For other matters such as Cautions, Technical information and Interpretations of test result, refer to the Operating Manual that comes with your PPG probe.

5-3-1. PPG (Photoplethysmography) Probe Assemblies

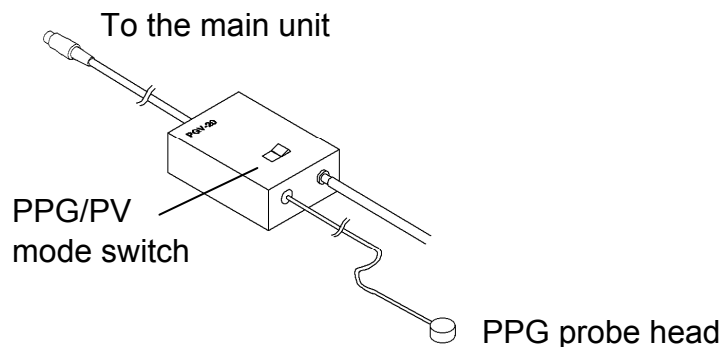
Single-channel photoplethysmography (PPG) probe

Model PG-21



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

Model PGV-20



5-3-2. Clinical Applications

AC Coupling: Arterial pulse waveform studies, Toe pressure

DC Coupling: Venous reflux study

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

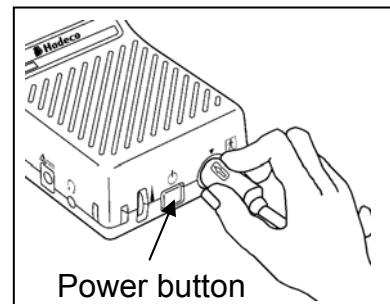
Purpose

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.

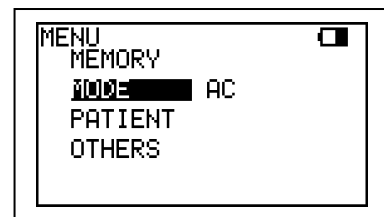
Preparation

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

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



- (2) Press Enter button to display MENU and make sure MODE is on AC mode. If it's been set for DC mode, press Enter on MODE to change to AC.



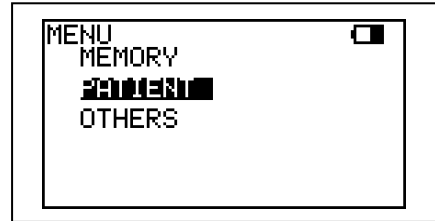
Press Left to get out of the MENU mode.

- (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.

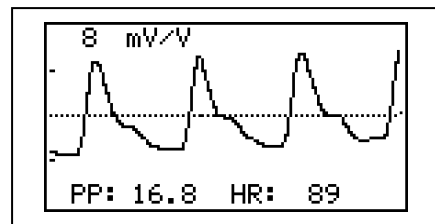
Examination Procedure

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

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

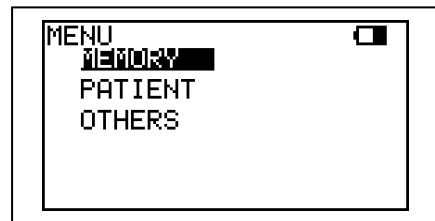


(3) The gain is automatically adjusted and the PPG waveform is shown on the LCD.



(4) When the waveform gets stable and rhythmic, press Right or probe button to freeze the waveform. Press Print Button to print the waveform of last 5 sec. if necessary.

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



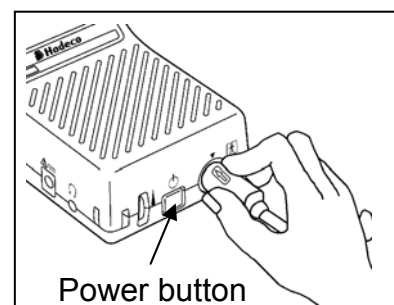
5-3-4. PPG - Venous Reflux Study

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.

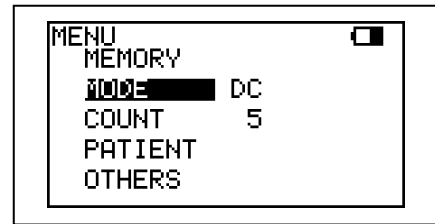
Preparation

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



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

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



- (3) COUNT represents number of foot exercise during study and if desired, press Enter on COUNT and press Up and Down to change the number.

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 limb is warm. Cold constricts superficial blood vessels and thus jeopardizes the accuracy of PPG measurements.

Examination Procedure

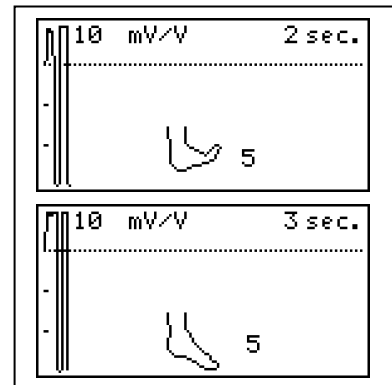
- (1) Have the patient sit on an examination table so that the feet are off the floor.
- (2) Apply the sensor, with the clear side against the skin surface, to the medial malleolus over the posterior tibial vein.
Fix the sensor in place with double-sided clear tape.

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



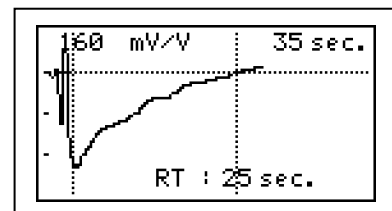
(4) Press Right or probe button to begin the measurement process.

(5) Ask the patient to flex the foot specified number 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 completed when the waveform returns to the baseline and Smartdop will automatically freeze the waveform. Press Print Button to print the waveform if necessary.



(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.



5-3-5. Menu for PPG

Menu	Sub Menu	Selections	Reference in §3-2-3
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
MODE(Coupling)		AC , DC	5-3-6. Mode
COUNT		1 to 20	5-3-6. Count
PATIENT data	ID, NAME, SEX, AGE, DATE, SITE, MEMO		j. Patient
OTHERS	LANGUAGE	ENGLISH , EUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	AUTO-OFF	ON , OFF	p. Others – Auto-off
	KEYBOARD	ENGLISH , JAPANESE	q. Others – Keyboard
	P.ID PRT (Patient data print)	ON , OFF	r. Others – P.ID PRT
	PRB-KEY (Probe button)	PRT & FRZ, PRINT, FREEZE	s. Others – PRB-KEY
	DATE	MMM. DD, YYYY HH:MM:SS	t. Others – Date
	PRINT		u. Others – 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.

5-3-6. PPG Mode settings

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

(1) Press Enter to change mode as follows:

AC: For arterial testing

DC: For venous reflux study

COUNT (Only available in DC - Measurement mode)

Set the number for foot exercise.

(1) Press Enter on COUNT and press Up and Down to change the number. Press Enter to fix it.

5-4. Pneumoplethysmograph

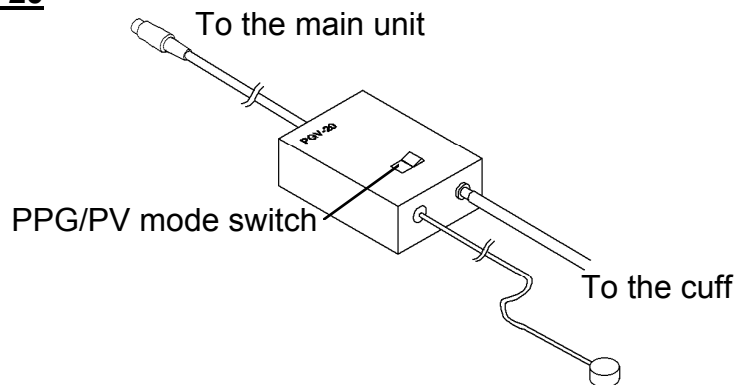
With the PPG-20 (PV mode), Smartdop senses volume changes in a limb or digit by measuring the pressure changes in a recording cuff.

Basically, “How to use pneumoplethysmograph” is described in this section. For other matters such as Cautions, Technical information and Interpretations of test result, refer to the Operating Manual comes with your PV probe assembly.

5-4-1. PV (Pneumoplethysmography) Probe Assemblies

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

Model PPG-20



5-4-2. Clinical Applications

AC Coupling: PV Arterial studies

DC Coupling: Measurement of maximum venous outflow

5-4-3. PV - Arterial Studies

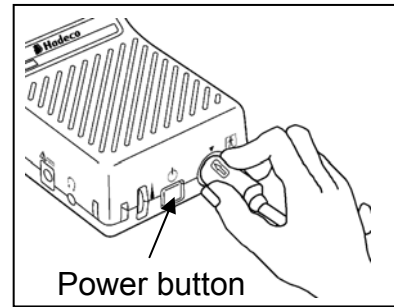
Purpose

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.

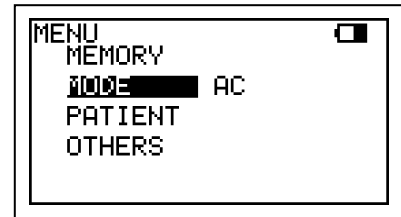
Preparation

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

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

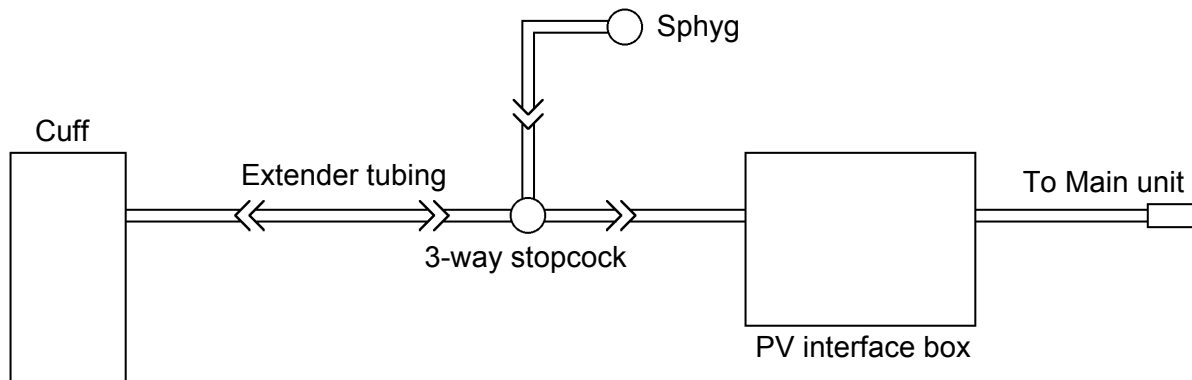


- (2) Press Enter button to display MENU and make sure MODE is on AC mode. If it's been set for DC mode, press Enter on MODE to change to AC. Press Left to get out of the MENU mode.

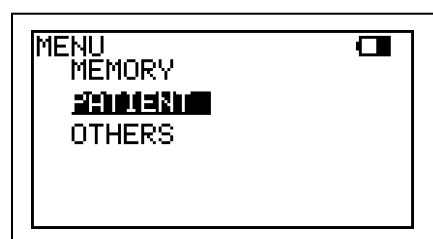


Examination Procedure

- (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.

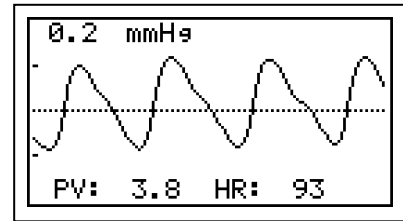


- (4) Turn the stopcock so that air is routed from the sphygmomanometer to the cuff.
- (5) If you wish to input patient data, see "3-2-3-j . PATIENT".



(6) Inflate the cuff to 60 mmHg. Then, turn the stopcock so that it blocks the sphyg and routes 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 the waveform. Press Print Button to print the waveform of last 5 sec. if necessary.

(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.

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

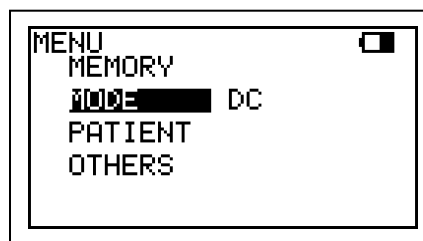
Purpose

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

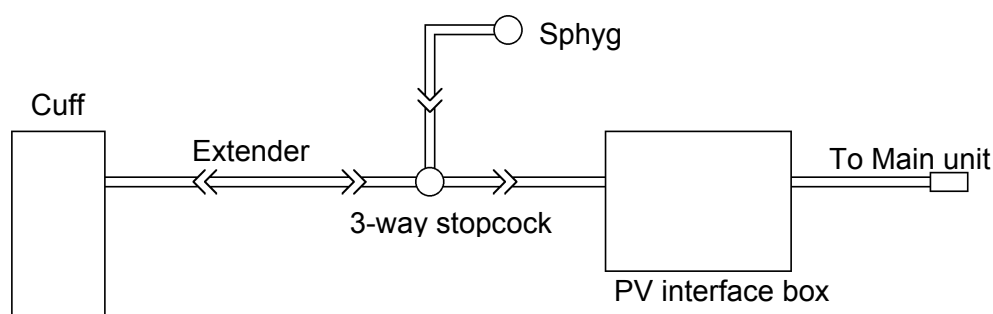
(1) Connect the PV probe to the main unit, and turn the unit on.

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



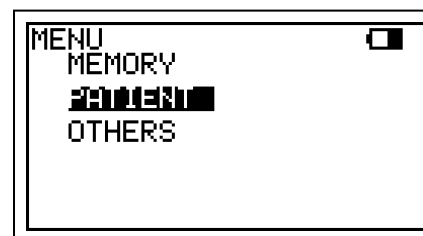
Examination Procedure

- (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- j . PATIENT”.



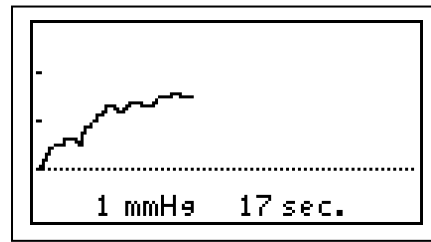
- (6) Inflate the sensing cuff to 40 mmHg. Wait 10 seconds to allow time for settling and deflate the cuff to 15 mmHg.

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

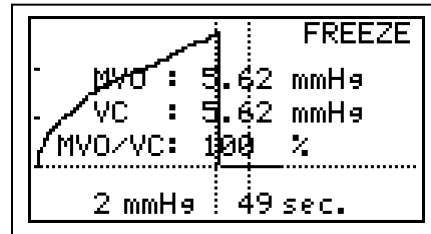
- (8) Disconnect the sphyg from the stopcock and attach it to the occluding cuff at the thigh.

- (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.

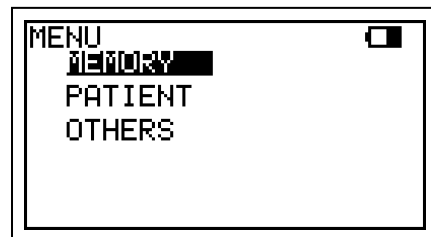


(11) After 90 seconds, disconnect the sphyg from the occluding cuff. The pressures on the screen will drop back to the baseline.



(12) Smartdop will automatically stop the measurement process, and then freeze the waveform. Press Print Button to print the waveform if necessary.

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



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

5-4-5. Menu for PV

Menu	Sub Menu	Selections	Reference in §3-2-3
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
MODE(Coupling)		AC, DC	5-3-6. Mode
PATIENT data	ID, NAME, SEX, AGE, DATE, SITE, MEMO		j. Patient
OTHERS	LANGUAGE	ENGLISH, EUTSCH, ITALIANO, ESPANOL, FRANCAIS	k. Others - Language
	AUTO-OFF	ON, OFF	p. Others – Auto-off
	KEYBOARD	ENGLISH, JAPANESE	q. Others – Keyboard
	P.ID PRT (Patient data print)	ON, OFF	r. Others – P.ID PRT
	PRB-KEY (Probe button)	PRT & FRZ, PRINT, FREEZE	s. Others – PRB-KEY
	DATE	MMM. DD, YYYY HH:MM:SS	t. Others – Date
	PRINT		u. Others – Print

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

5-4-6. PV Mode setting

MODE (AC / DC) (Only Measurement mode)

(1) Press Enter to change mode as follows:

AC: For arterial testing

DC: For measurement of maximum venous outflow

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.).

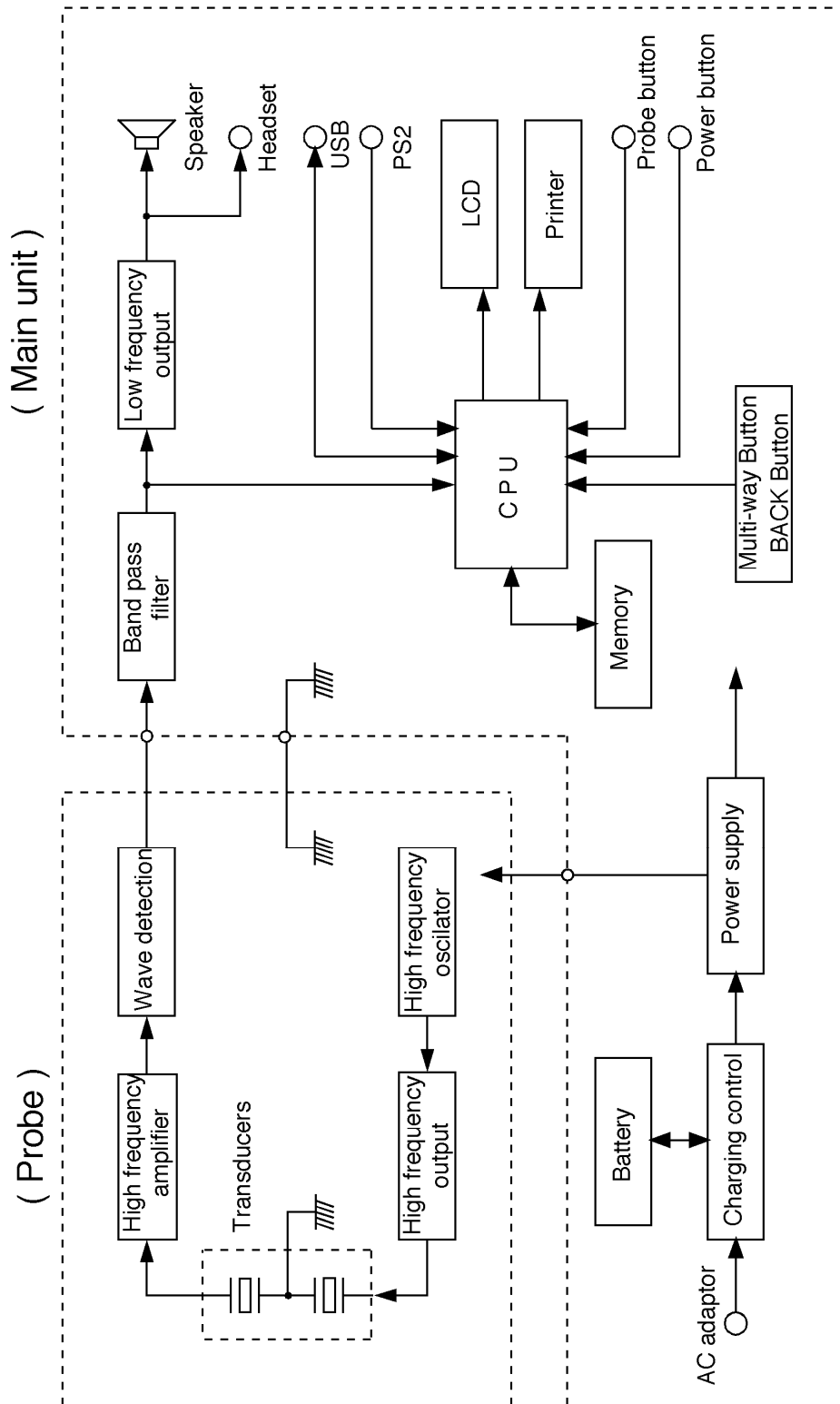
The unit amplifies the high frequency oscillation output and then supplies it to the transmitter transducer. It is converted to ultrasound by the transducer and the ultrasound is transmitted to external objects. The ultrasound moves straight through biophysical object, and is reflected by the moving 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 waveform signals which can be displayed and printed.

6-2. Block diagram



6-3. 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
	<i>*Ispta : Spatial Peak - Temporal Average Intensity</i>		
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	
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: 5 min.	Freeze: 10 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 waveform (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
85% humidity or less with no condensation

Dimensions: Main unit: 92 (W) x 210 (D) x 60 (H) mm
(Probe holder not included)
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 “SN”.

Examples:

03020001: Feb/2003
0401: Jan/2004

* Specifications subject to change

6-4. Safety standards

The unit conforms 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) Guidance and manufacturer's declaration - electromagnetic emissions and immunity

Guidance and manufacturer's declaration – electromagnetic emissions		
The Smartdop 45 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop 45 should assume that it is used in such an environment.		
Emissions test	compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Smartdop 45 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 45 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 45 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 45 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop 45 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% U_T (> 95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) 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 U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Smartdop 45 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartdop 45 should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC61000-4-6</p> <p>Radiated RF IEC61000-4-3</p>	<p>3Vrms 150 kHz to 80 MHz</p> <p>3V/m 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Smartdop 45, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80 to 800 MHz</p> <p>$d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>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).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of the equipment marked with the following symbol:</p> 

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smartdop 45 is used exceeds the applicable RF compliance level above, the Smartdop 45 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Smartdop 45.

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



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SD45 OM E-24
June, 2013
Printed in Japan
080-00095-2.4