

# **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) Dot 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.
  - (7) Do not place it on or adjacent other electronic device.
- 5. Before use
  - (1) Make sure that the unit operates safely and correctly by implementing performance check mentioned in "§ 5-1. 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, non-sterilizable probes and amplifiers to prevent any damage.
  - (6) Sterilizable probes should be sterilized before use. (See §5-3. Probe sterilization)
- 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 "§ 5-1. 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) can be sterilized in the manner described in § 5-3.Probe sterilization.
  - (4) 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.
- (3) When the battery life is over, it may cause the following defect(s) even though battery is fully charged:
  - It turns on only when AC adaptor is connected.
  - It doesn't turn on even though AC adaptor is connected.
  - Battery only works for a short time.
  - Printer doesn't work with or without AC adaptor.
- 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. The Smartdop displays velocity waveforms and numerical data. 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 BACKLIT LCD DISPLAY and FAST PRINTER

Displays real-time velocity waveforms and numerical data. Prints frozen waveform and numerical data 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 20MHz.

#### • USB COMPUTER INTERFACE

Stores waveforms and numerical data in your computer for data analyzing and filing. Communication cable and Smart-V-Link Windows software are optional.

#### • PHOTOPLETHYSMOGRAPH (PPG) PROBE OPTIONAL

Venous testing

## 1-2. Clinical applications

## Detection of arterial and venous blood flow velocity for vascular disease

 Probes to be used:
 BT2M20S8C (2MHz)

 BT4M05S8C (4 MHz)
 BT5M05S8C (5 MHz)

 BT8M05S8C (8 MHz)
 BT10M5S8C (10 MHz)

- \* PEAK & MEAN blood velocity determinations.
- \* Detection of arterial and venous blood flow velocity for vascular disease.

## 2. Appearance

#### 2-1. Front left view



- 1. Paper cover:
- 2. Cover Open Button
- 3. LCD display:
- 4. Speaker:
- 5. Probe connector #1:
- 6. Power button: (
- 7. Volume control:
- 8. Strap holes:
- 9. Headset:
- À É
- 10. AC adaptor connector:
- 11. Probe connector #2:



- For printer paper
- To open the paper cover
- Displays waveform, numerical data, heart rate and menu for mode settings
- **Outputs Doppler sounds**
- To connect probe
- To turn the unit on / off
- To adjust sound volume
- To attach hand strap
- To connect headset. It cuts off the speaker
- To connect the designated AC adaptor
- To connect probe

See §7-2. Others for 2<sup>nd</sup> probe holder option.

12. Charging indicator:	Indicates battery status.
	Orange: Charging
	Green: Fully charged
13. Scroll Button:	
Consists of 5 internal buttons and h	nas 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 sub-menu.
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 sub-menu or get out
	from menu.
	To turn backlight on/off.
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.
	To get out of Site guidance mode.

#### 2-2. Front right view and Probe



- 1. Probe holder:
- 2. Communication port: ( -
- 3. Probe:
- 4. Probe button:
- 5. Probe cap:

For probe placement when not in use. To connect computer. (USB) Multi-probe selection of 2, 4, 5, 8, 10 and 20 MHz To freeze and unfreeze the waveform. To activate and deactivate the printer.

Note: The function is defined in the menu PRB-KEY.

See "§4-2-t, OTHERS - PRB-KEY" for the details. To protect the probe transducer tip when probe is not in use.

## 3. Quick start

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

## 3-1. Turning the unit ON / OFF

Press the power button to turn the unit ON. Smartdop will show a moment what probe is connected as shown in the right.

In case no probe is connected, it will show "NC" for no connection as shown in the right.



#### 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) 15 minutes when in measurement. (35 min. for FHR waveform mode)
- (b) 5 minutes when no signal.
- (c) 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.

## 3-2. Charging / Discharging battery

#### Charging battery:

 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 AC adaptor. Model name: **GMPU18EI-3** 

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

#### Discharging battery:

Using and charging the battery repeatedly without fully discharging may cause a shorter full charge battery life. Fully discharge battery before charging every once in a while as follows:

- (1) Turn the unit off and plug the AC adaptor.
- (2) Press and hold Back button and press Enter and then Right to start discharging the battery.
   "DISCHARGE" will appear on LCD while discharging and disappear when completed. Charging process will start automatically and charging indicator will go solid ORANGE.

Note1: It takes about 3 hours to fully charge battery.

- Note2: Battery life is 300 full charges. When full charging life is obviously short, contact your dealer for replacing battery. When battery life is over, it may cause the following defect(s) even though battery is fully charged:
  1) It turns on only when AC adaptor is connected.
  2) It doesn't turn on even though AC adaptor is connected.
  - 3) Battery only works for a short time.
  - 4) Printer doesn't work with or without AC adaptor.





Note3: The AC adaptor is designed for charging the battery only however, it may provide enough power for the unit operation except printing while charging the battery.

## 3-3. Checking battery level

- (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.





## 3-4. Setting printer paper

- 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 over LCD and close the paper cover completely.



## 3-5. Measuring blood velocity

#### 3-5-1. Normal mode

This section explains the fundamental use of testing blood velocity. Refer to "4. Menu and Mode Settings" for various uses.

 Put ultrasonic gel on the probe top or patient skin.



Put the probe on the testing 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.

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

Note1: Probe button function can be selected from **PRINT, FRZ & PRINT** or **FREEZE** on **PRB- KEY** mode setting. See "§.4-2-t. OTHERS-PBR-KEY" for details.

Note2: If **FREEZE** mode is set for **AUTO**, Smartdop will freeze the waveform automatically when the waveform becomes stable. See "§.4-2-k. OTHERS-FREEZE" for details.







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



#### LCD Backlighting time:

LCD backlighting time can be adjusted on BACKLIGHT mode setting. See the section "§.4-2-q. OTHERS - BACKLIGHT" for details. Press **LEFT** button to turn it ON / OFF instantly during testing.

#### 3-5-2. Site guidance mode

This mode allows you to easily proceed multiple Smart-V-Link testing by just pressing probe button without connecting Smart-V-Link.

Register **Abbreviated site & test names** on the unit through Smart-V-Link to activate this mode. Once the names are registered, the unit will show each of names at the beginning of each testing to let you know where to test next.

#### Preparation for site guidance mode:

- Connect the unit to the computer with the USB cable and start Smart-V-Link.
- (2) Go to Site Screen and input abbreviated site & test name for each waveform memory and then store the names on the unit.
- (3) Go to MEMORY menu and clear ALL memory data on the unit before newly starting the site guidance mode.

See the section "§ 4-1-4. Site" on Smart-V-Link, V4.1 or over, operating manual for more details.



<Site Screen of Smart-V-Link>

#### Site guidance mode procedures:

- (4) Turn the unit off and on and the 1<sup>st</sup> guidance with memory number and abbreviated site & test name will appear as shown in the right.
- Note: The first memory number available will be selected automatically.
- (5) Press the probe button to start monitoring waveform.Press **Back** button to get out of "Site guidance"

mode" for normal mode operation.

- (6) Press probe button the 2<sup>nd</sup> time to freeze the waveform when it becomes stable and the 2<sup>nd</sup> guidance "STORE?" as shown in the right will appear.
- (7) Press probe button the 3<sup>rd</sup> time to store the frozen waveform data on the designated memory number.
- (8) The 1<sup>st</sup> guidance for the next testing will appear as shown in the right. Repeat steps #(5) to #(8) until all testing is completed.



Abbreviated site & test name









#### 12

### 3-6. Measuring heart rate (2 MHz only)

This section explains the fundamental use of measuring heart rate. Refer to "4. Menu and Mode Settings" for various uses.

- (1) Connect the 2MHz probe to the unit and turn the unit ON.
- (2) Press Enter to display MENU and set DISP mode for WAVE or DATA.
  If necessary, change the upper and lower limits by pressing UP & Down between 60 and 220 BPM at 5 BPM intervals and press Enter to set them. See "§4-2- w. UPPER" and "§4-2-x. LOWER" for details.
- (3) Put ultrasonic gel on the probe top or the skin surface.
- (4) Put the probe on the middle of the abdomen, as shown in the right, and move it slowly to locate the point where the maximum Doppler sounds are heard.
- (5) When the heart rate becomes stable, press the probe button or **Right** button to freeze it. In case FHR exceeds the upper and lower limits, LCD will start flashing and also, beep sounds will be heard if SOUND mode is set for ON. See "§4-2- v. SOUND" for details.
- (6) Headset can be used to listen to Doppler sounds. It will cut off the speaker.







## 3-7. 2 MHz BEEP mode

2 MHz BEEP mode is available when 2 MHz probe is connected and it displays blood velocity waveform and beeps when velocity exceeds the limit.

- Connect the 2MHz probe to the unit and turn the unit ON.
- Press Enter to display MENU and set DISP mode for BEEP.
   LIMIT-1 and LIMIT-2 menu will be shown as shown in the right.
- (3) Change the LIMIT-1 by pressing Up & Down between 0 and 120 cm/s at 1 cm/s intervals and press Enter to set it.follows;
  - MAX: To beep when max velocity exceeds upper limit AVE: To beep when average velocity exceeds upper limit
- (4) Put ultrasonic gel on the probe top or the skin surface.
- (5) Put the probe on the measurement area, as shown in the right, and move it slowly to locate the point where the maximum Doppler sounds are heard.
- (6) When velocity exceeds the limit, beep sounds will be heard.



	5.0	cm∕s	2M	FRE	EZE
	λл	AM	A	Л	Λ
/	÷	v,	٧	\g	<i>۳۰-</i> ۰
Limit	LIMI	T:5cm/	s	MAX	

MENU MEMORY DISP BEEP WAVE 23cm/s MAX

## 4. MENU and Mode settings

Note: For the mode settings for options, see "§ 7-3-5. Menu for PPG".

## <u>4-1. Menu</u>

By using Scroll buttons, various mode settings can be selected on Menu mode. Some of the menus consist of sub-menu(s).

#### 4-1-1. Menu operation

• To show MENU:

Press Enter to show MENU.



<Buttons on left side of Smartdop 45>

#### • To select the mode:

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

MODE	A	
DIR	⊒←	
TIME	$\mapsto$	
FLOW	↓ ON	

#### To go to sub-menus:

**MEMORY**, **PATIENT** and **OTHERS** consist of sub-menus. Press **Enter** to go to sub-menus.

Press **Right** to show lower sub-menus.

On lower sub-menu of either **MEMORY** or **LANGUAGE**, press **Up & Down** to select memory number or language, respectively. Press **Left** once or twice to go back to main menu or to get out of menu mode.



Setting **FLOW** for **ON** activates **DIAMETER** menu for volume flow calculations. See "§4-2-g. FLOW / 4-2- h. DIAMETER" for details.

MEMORY Sidda READ CLEAR	<b>↓</b>
Su	ub-menus





DIAMETER menu

### 4-1-2. Menu for Blood Velocity Measurement mode

Menu	Sub-menu	Selections	Reference in §4-2
	STORE	1 to 30, FREEZE	a. MEMORY - STORE
MEMORY	READ	1 to 30, FREEZE	b. MEMORY - READ
	CLEAR	1 to 30, ALL	c. MEMORY - CLEAR
MODE		Compound 🛆 Separate 🔶	d. MODE
DIR		Forward _← Reverse _→	e. DIR
TIME		Normal $\longrightarrow$ Slow $\hookrightarrow$	f. TIME
FLOW		ON, <b>OFF</b>	g. FLOW
DIAMETER		0.1mm – 20.0mm	h. DIAMETER
PATIENT	ID, NAME, SEX, AGE	E, DATE, SITE, MEMO	i. PATIENT
	LANGUAGE	ENGLISH, DEUTSCH, ITALIANO,	
		ESPANOL, FRANCAIS	J. OTTIERS - LANGUAGE
	FREEZE	MANUAL, AUTO	k. OTHERS - FREEZE
	UNIT	<b>cm/s</b> , kHz	I. OTHERS - UNIT
	FILTER	ARTERIAL, VENOUS	m. OTHERS - FILTER
	SMOOTH	NORMAL, LOW-PASS	n. OTHERS - SMOOTH
	DISP	WAVE, DATA	o. OTHERS - DISP
OTHERS	CAL	ON, <b>OFF</b>	p. OTHERS - CAL
	BACKLIGHT	ON, <b>OFF,</b> 60sec, 50sec, 40sec,	q. OTHERS - BACKLIGHT
		30sec, 20sec, 10sec	
	AUTO-OFF	<b>ON</b> , OFF	r. OTHERS - AUTO-OFF
	P.ID PRT	ON, <b>OFF</b>	s. OTHERS - P.ID-PRT
	PRB-KEY	FRZ&PRINT, PRINT, FREEZE	t. OTHERS - PRB - KEY
	DATE	MMM.DD,YYYY HH:MM:SS	u. OTHERS - DATE
	PRB20MHz	ON, <b>OFF</b>	x. PRB20MHz

Note1: Selections in bold face in the table above are default settings.

Note2: PRB20MHz menu is only available when either a 20MHz probe or no probe is connected.

### 4-1-3. Menu for Blood Velocity Freeze mode

Menu	Sub-menu	Selections	Reference in §4-2
	STORE	1 to 30, FREEZE	a. MEMORY - STORE
MEMORY	READ	1 to 30, FREEZE	b. MEMORY - READ
	CLEAR	1 to 30, ALL	c. MEMORY - CLEAR
MODE		Compound 🛆 Separate 🔶	d. MODE
DIR		Forward _← Reverse _>	e. DIR
DISP		WAVE, DATA	v. DISP
FLOW		ON, <b>OFF</b>	g. FLOW
DIAMETER		0.1mm – 20.0mm	h. DIAMETER
PATIENT	ID, NAME, SEX, AGE	, DATE, SITE, MEMO	i. PATIENT
	LANGUAGE	ENGLISH, DEUTSCH, ITALIANO,	
		ESPANOL, FRANCAIS	J. OTHERS - LANGUAGE
	FREEZE	MANUAL, AUTO	k. OTHERS - FREEZE
	BACKLIGHT	ON, <b>OFF,</b> 60sec, 50sec, 40sec,	q. OTHERS - BACKLIGHT
OTHERS		30sec, 20sec, 10sec	
	AUTO-OFF	ON, OFF	r. OTHERS - AUTO-OFF
	P.ID PRT	ON, <b>OFF</b>	s. OTHERS - P.ID-PRT
	PRB-KEY	PRT & FRZ, PRINT, FREEZE	t. OTHERS - PRB - KEY
	DATE	MMM.DD,YYYY HH:MM:SS	u. OTHERS - DATE

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

Menu	Sub-menu	Selections	Reference in §4-2
	STORE	1 to 30, FREEZE	a. MEMORY - STORE
MEMORY	READ	1 to 30, FREEZE	b. MEMORY - READ
	CLEAR	1 to 30, ALL	c. MEMORY - CLEAR
DISP		WAVE, <b>DATA,</b> BEEP	g. DISP
SOUND		ON, <b>OFF</b>	v. SOUND
UPPER		60 to 220 (every 5 BPM)	w. UPPER
LOWER		60 to 220 (every 5 BPM)	x. LOWER
PATIENT	ID, NAME, SEX, AGE	, DATE, SITE, MEMO	i. PATIENT
	LANGUAGE	ENGLISH, DEUTSCH, ITALIANO,	j. OTHERS - LANGUAGE
		ESPANOL, FRANCAIS	
	BACKLIGHT	ON, <b>OFF,</b> 60sec, 50sec, 40sec,	q. OTHERS - BACKLIGHT
		30sec, 20sec, 10sec	
UTHERS	AUTO-OFF	<b>ON</b> , OFF	r. OTHERS - AUTO-OFF
	P.ID PRT	ON, <b>OFF</b>	s. OTHERS - P.ID-PRT
	PRB-KEY	PRT & FRZ, PRINT, FREEZE	t. OTHERS - PRB - KEY
	DATE	MMM.DD,YYYY HH:MM:SS	u. OTHERS - DATE

### 4-1-4. Menu for Heart Rate mode (Measurement and Freeze)

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

#### 4-1-5. MENU for 2MHz BEEP Measurement mode

Menu	Sub Menu	Selections	Reference in §4-2
	READ	1 to 30, FREEZE	b. MEMORY - READ
MEMORY	CLEAR	1 to 30, ALL	c. MEMORY - CLEAR
DISP		WAVE, DATA, BEEP	o. DISP
DISP/BEEP		WAVE, DATA	o. DISP
LIMIT-1		0 – 120cm/s or 0.0kHz – 12.0kHz	z. LIMIT-1
LIMIT-2		MAX, AVE	aa. LIMIT-2
		ENGLISH, DEUTSCH, ITALIANO,	
	LANGUAGE	ESPANOL, FRANCAIS, TURKCE,	j. OTHERS - LANGUAGE
OTHERS		POLSKI	
	UNIT	<b>cm/s</b> , kHz	I. OTHERS - UNIT
	BACKLIGHT	ON, <b>OFF</b> , 10 to 60 (10 sec. steps)	q. OTHERS - BACKLIGHT
	AUTO-OFF	ON, OFF	r. OTHERS - AUTO-OFF

Menu	Sub Menu	Selections	Reference in §4-2
	STORE	1 to 30, FREEZE	a MEMORY - STORE
MEMORY	READ	1 to 30, FREEZE	b. MEMORY - READ
	CLEAR	1 to 30, ALL	c. MEMORY - CLEAR
DISP		WAVE, DATA, BEEP	o. DISP
DISP/BEEP		WAVE, DATA	o. DISP
		ENGLISH, DEUTSCH, ITALIANO,	
	LANGUAGE	ESPANOL, FRANCAIS, TURKCE,	j. OTHERS - LANGUAGE
OTHERS		POLSKI	
	BACKLIGHT	ON, <b>OFF</b> , 10 to 60 (10 sec. steps)	q. OTHERS - BACKLIGHT
	AUTO-OFF	ON, OFF	r. OTHERS - AUTO-OFF

### 4-1-6. MENU for 2MHz BEEP Freeze mode

#### Button operation for Heart Rate mode only

- 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.

## 4-2. Mode Setting Details

#### 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.

MEMORY STORE READ CLEAR	NO.01 FREEZE*
< On r	ormal mode>
MEMORY STORE READ CLEAR ABI	R DP

< On site guidance mode>

- (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

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

MEMURY Store <b>Maing</b>	NO.02 No.01 *
CLEAR	

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

- Select the memory number you wish to clear (1) the data for. The 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: 4 Combined forward and reverse components Separation of forward from reverse component Separate mode:



Compound mode



e. DIR (Flow Direction)

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

Flow toward probe is processed as positive component.  $\leftarrow$ 

Reverse:

Forward:

Flow away from probe is processed as positive component.



Þ



Reverse

REHD MEERS	NU.01 * NU.01 *
10.0 cm/ 	s #01
MEMORY STORE READ MEMORIA	NO.01 FREEZE*

NO.02

MEMORY STORE

#### f. TIME (Time scale)

(1) Press Enter to change the time scale as follows:

Normal:  $\longrightarrow$  For arteries (2.56 sec/screen)

Slow: For veins (12.8 sec/screen)

#### g. FLOW (Blood volume flow) / h. DIAMETER (Estimated vessel diameter)

Blood volume flow will be calculated on blood velocity measurement & freeze modes when **FLOW** is set for **ON**.

(1) Press Enter to set FLOW mode for ON and

**DIAMETER** menu will be shown as shown below.



Set FLOW ON

(2) Set the estimated vessel diameter by pressing Up & Down for anywhere between 0.1 and 20.0 mm at 0.1 mm intervals and Smartdop will calculate and show blood volume flow of numerical data MAX (Maximum) and MN (Mean) on DATA display.

Note: Set **DISP** mode for **DATA** to display numerical data and press **Right** to show flow **MAX** and **MN** on 2<sup>nd</sup> page of numerical data as shown below.



i. PATIENT (Patient data input)

Patient data contains ID, NAME, SEX, AGE, examination DATE, test SITE and MEMO. 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. 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 / Female.

DATE can be changed on PATIENT menu when on FREEZE mode only.

- (3) After entering the data, scroll to 4 (Enter) and press Enter to save the data.
- (4) Press Left to 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.

- Press **Back** Button while Patient Data screen is displayed.
- (2) Scroll to the edit command and press **Enter**.
  - **COPY** will copy all items of the patient data to clipboard.
  - 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.
  - **CLEAR** will delete the patient data.
  - **PASTE** and **CLEAR** commands require the confirmation as shown in the right.

MCEHD-1234567890 NAME: TARO HADECO SEX: MALE AGE: 31 DATE:Jan,31,2005 SITE:RADIAL-RIGHT MEMO:DOPPLER EXAMINAT ΙŌΝ







- Press Enter to proceed or press Left to cancel.
- Press **Back** Button to go back to Patient Data.

#### j. OTHERS - LANGUAGE

 Press Up & Down to select the language you wish for menus and messages and press Enter to set it.

#### k. OTHERS – FREEZE

 Set FREEZE for AUTO to freeze the waveform automatically when it becomes stable. Set it for MANUAL for freezing waveform manually.

#### I. OTHERS - UNIT (cm/s / kHz)

- (1) Press **Enter** to change the unit of blood flow as follows:
  - cm/s: Blood flow velocity
  - kHz: Doppler-shifted frequency

#### 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:

ARTERIAL: For arteries

VENOUS: For veins

#### n. OTHERS - SMOOTH (Smoothing filter)

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

NORMAL: For normal signals

LOW-PASS: For noisy signals

#### o. DISP (DISP, OTHERS – DISP, DISP/BEEP)

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

<DISP>

- WAVE: Waveform
- DATA: Numerical data
- BEEP: 2MHz BEEP mode

#### <DISP/BEEP>

WAVE: Waveform for 2MHz BEEP mode

DATA: Numerical data for 2MHz BEEP mode

Note: On Heart rate mode, display mode cannot be changed when on Freeze mode. When on Heart rate measurement mode with WAVE mode, pressing **Up & Down** restarts the monitoring.

#### p. 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	



#### q. OTHERS - BACKLIGHT

LCD backlighting time can be adjusted on BACKLIGHT mode.

(1) Press **Up & Down** to select the time and press **Enter** to set it.

ON:	Turns backlight always on.
-----	----------------------------

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

BACKLIGHT can be also turned ON / OFF by pressing **Left** button on the unit. When BACKLIGHT is set for **Auto-off**, backlight goes off in auto-off time of no operation and any button operation will turn the light on again.



#### r. OTHERS - AUTO-OFF (Automatic shut-off)

Set it for ON / OFF for auto-off on / off.
 See "§3-1. Turning the unit ON / OFF for more details.

#### s. 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.

#### t. OTHERS - PRB-KEY (Probe button function)

(1) Press **Enter** to change the probe button function as follows:

PRT&FRZ: Freezes and prints.

PRINT: Prints

FREEZE: Freezes

Note: When on FHR - DATA mode, printing is not functional even though **PRB-KEY** mode is set for either **PRT&FRZ** or **PRINT**.

#### u. 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 & Down.
- (3) Press Enter to set it or press Back Button to cancel.

DATE: 300,29,2004 TIME: 12:00:00

#### v. SOUND (Beep sound for FHR mode)

Set SOUND mode for ON to activate beep sounds when heart rate gets out of upper and lower limits during the test except 1<sup>st</sup> 30 sec.

(1) Press Enter to change beep sound ON / OFF.

#### w. UPPER (Upper limit for FHR)

In case heart rate exceeds the upper limit during the test except 1<sup>st</sup> 30 sec, LCD will start flashing.

(1) Press Up and Down to select the upper limit in 5 BPM steps and press the

button to set it.



#### x. LOWER (Lower limit for FHR)

In case heart rate gets below lower limit during the test except 1<sup>st</sup> 30 sec, LCD will start flashing.

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

#### y. PBR20MHz

For 20MHz probe, set 20MHz mode for ON before connecting the probe.

#### z. LIMIT-1 (For 2MHz BEEP mode)

In case maximum or average blood velocity exceeds the limit, beep sound will be heard.

#### aa. LIMIT-2 (For 2MHz BEEP mode)

Press Enter to select the mode as follows;

- MAX: Beeps when maximum velocity exceeds limit.
- AVE: Beeps when average velocity exceeds limit.


## 5. Maintenance

## 5-1. 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 being come off.
- (3) Turn the unit on and make sure if the LCD displays normally.

## 5-2. 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 "§ 5-1.Performance check by user" before using the unit.

## 5-3. Probe sterilization

#### 5-3-1. Sterilizable probes: (Amplifier required)

Small pencil	8MHz:	VRP-08
	10MHz:	VRP-10
	20MHz:	VRP-20
Long	8MHz:	LRP-08
	10MHz:	LRP-10
Flat	8MHz:	FDP-08
Autoclavable	8MHz:	ACP-08
Curved pencil	10MHz:	CRP-10H*
	20MHz:	CRP-20H*
	20MHz:	CRP-20H1N*

Bayonet	10MHz:	NRP-10H*
	20MHz:	NRP-20H*
Flexible	10MHz:	NRP-10HF*
	20MHz:	NRP-20H1NF*
Single use	10MHz:	NDP-10H*
	20MHz:	NDP-20H*
		*: Except European Union Countries.

#### 5-3-2. 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 and FDP probe: Up to 50 times
- 2. ACP probe: Up to 5 times by steam autoclave
- 3. FDP probe: Up to 5 times

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 disinfector or it will damage probes.
- 2. ACP probe should be sterilized by steam autoclave as described in section

"Instructions for sterilization" below.

#### Instructions for sterilization:

Point of preparation: No particular requirements.

Preparation for cleaning:

No particular requirements.

Cleaning:	

Do not do automated cleaning of probes other than ACP probe.
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°C.
	Sterilization system is compatible with only the STERRAD® by
	Johnson & Johnson, K.K. sterilization system as follows:
	• STERRAD <sup>®</sup> 50
	<ul> <li>STERRAD<sup>®</sup>100S (only short cycle)</li> </ul>
	<ul> <li>STERRAD<sup>®</sup>200 (only short cycle)</li> </ul>
	<ul> <li>STERRAD<sup>®</sup>NX (only standard cycle)</li> </ul>
	<ul> <li>STERRAD<sup>®</sup>100NX (only standard cycle)</li> </ul>
	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 121 °C
	4 minutes under 134 °C
	Do not expose the instrument to temperatures exceeding
	134 °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 Functi	on 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.

## 5-4. Warranty

Guarantee period:

\*: Frequency

Main unit	-	Two(2) years
Probe	BT*M05S8C(A), BF8M15S8A,	One(1) year
	BP*M05S8A, VRP-*, LRP-*,	
	BDP*MS8, PG-21,	
	ACP-08	Either one year from the date of purchase or
		within 5 times of autoclave sterilization.
	FDP-08	Either 3 months from the date of purchase or
		within 5 times of sterilization.
Probe	PV-21, TP-01	One(1) year
Except	CRP-*H, CRP-20H1N, NRP-*H	Six(6) months
European	NRP-10HF,NRP-20H1NF	Three(3) months
Union	Single use probe	Either one year from the date of purchase or
Countries		out of box failure

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.

# 6. Supplemental information

## 6-1. Basic mode

Eight Basic Operation Modes:

- Blood Velocity Measurement
- Blood Velocity Freeze
- Heart Rate Measurement
- Heart Rate Freeze
- 2 MHz BEEP- Measurement
- 2 MHz BEEP- Freeze

For measuring blood velocity For observing waveforms and numerical data For measuring heart rate For observing heart rate and graph For precordial blood velocity For observing waveforms and numerical data For changing other mode settings

• Menu

#### Changing mode with probe button (Measurement / Freeze)

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

Note: If the probe button is pressed longer than 2 sec., the unit will turn OFF.

With 2 MHz probe, you can also change mode (Measurement / Freeze) by pressing BACK button of the unit.



## 6-2. 2 Probe connections:

2 probes can be connected at the same time, and select the one you wish to use by pressing each probe button.

Connect probes to the probe connectors as shown in the right.





Note1: Second probe is available as an option.

Note2: Next use will revert to the previous probe selection.

## 6-3. LCD display

#### 6-3-1. Blood Velocity Mode

#### Waveforms:

- The base line is automatically placed 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.
- The waveform amplitude is automatically adjusted for optimal observation.
- The amplitude scale (velocity or frequency per division) is displayed on top left of LCD.





Separate mode

• When on freeze mode, "FREEZE" will be displayed on top right of LCD.



34

• Memory number is shown on top right of LCD for waveform read from MEMORY.



#### Numerical data:

Following numerical parameters are displayed on DATA mode.

ABI R	: PT		#06		ABI R	DP		#05
S:	32.8	cm/s			S:	1.83	kHz	
MN :	16.0	Cm∕s			MN:	1.04	kHz	
D:	8.4	cm⁄s	۰.		D:	0.69	kHz	I
MIN:	8.2	_cm∕s			MIN:	0.67	kHz	
RP:	0.74	SD:	3.90		RP:	0.62	SD:	2.65
PI:	1.54	HR:	72 BPM		PI:	1.12	HR:	71 BPM
Unit:	cm/s			-	Unit:	kHz		

See "§6-5. Numerical Data" for the meaning of abbreviations and the definitions of parameters.

#### 6-3-2. Heart Rate mode (Only for 2 MHz probe)

#### Numerical heart rate (DATA mode):

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



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

#### Monitoring heart rate in graph (WAVE monitoring mode):

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



- (3) Heart mark indicates the same way as DATA mode.
- (4) Two dotted lines indicate Upper and Lower limits of heart rate. If it gets out of limits during the test except 1<sup>st</sup> 30 sec, LCD will start flashing.
- (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)
   Page number



(6) Memory # is shown on top right of LCD for waveform read from MEMORY as shown in the right.

			\ Í
-	1		#01
 	naaka <sup>ka</sup>	<sub>¶₽₽</sub> лą <sup>Į</sup> 'ų	
1	56-115	BPM	2:20

Memory number

#### 6-3-3. 2 MHz BEEP mode

#### Waveforms (DISP/ BEEP: WAVE):

- (1) The base line is fixed 1/4 from the bottom.
- (2) The waveform amplitude is automatically adjusted depending on limit.
- (3) The amplitude scale (velocity or frequency per division) is displayed on top left of LCD.



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

## 6-4. Printing waveforms and data

#### 6-4-1. How to print

Printing waveform with numerical data is available when on Freeze mode.

- Freeze the waveform and press **Print** button to print it out.
   Also, pressing probe button makes print when PRB-KEY is set for **PRT&FRZ** or **PRINT** mode.
   Smartdop prints following waveforms and then
- (2) Smartdop prints following waveforms and then stops printing automatically.



Normal TIME scale:	Waveform of the 5	sec before	e freezing
_			

Slow TIME scale: Waveform of the 25 sec before freezing

#### FHR mode;

Monitoring mode: Waveform of up to 33 minutes before freezing

Press **Print** button the 2<sup>nd</sup> time to stop printing.



#### 6-4-2. Print sample

Note: See "§4-2. Mode Setting Details" and "§6-5. Numerical Data" for the meaning of icons, abbreviations and the definitions on the printed data.



## 6-5. Numerical data

Parameters	Abbrs.	Definitions
Systolic velocity [cm/s] or	S	
Systolic Doppler shift [kHz]		
Mean velocity [cm/s] or	MN	
Mean Doppler shift [kHz]		
Diastolic velocity [cm/s] or	D	
Diastolic Doppler shift [kHz]		
Minimum velocity [cm/s] or	MIN	
Minimum Doppler shift [kHz]		
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	
Max volume flow	MAX	
Mean volume flow	MN	
Vessel diameter	DIAM	

## 6-6. Extrernal outputs

6-6-1.Headset

Connect the optional headset when necessary and it cuts off the speaker.

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

It is for Smart-V-Link for Windows for comprehensive vascular testing and data storage.

- (1) Connect a computer with designated communication cable (option).
- (2) Press the Power Button to turn the unit on.
- (3) Run Smart-V-Link (option) on your computer.

Note: For software operation, refer to the Smart-V-Link software operating manual.

## 6-7. Symbol list

Symbols	Description	Symbol	Description
<b>†</b>	Type BF applied part	¢	USB connector
$\bigcap$	Headset		Volume control
ş	Print button		Charging indicator
	AC adaptor connector	•+	Back button
$\triangle$	Caution*1		Manufacturer
$\bigcirc$	Power button	EC REP	Authorized representative in Europe

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

## 6-8. Contents in package

Main unit	1
Probe	1
AC adaptor	1
Ultrasonic gel (AQUAULTRA BASIC)	1
Paper	1
Carrying case	1

# 7. Options

## 7-1. 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.

#### Standard Doppler probe:

Standard:

ereases y	2MHz:	BT2M20S8C
	4MHz:	BT4M05S8C
	5MHz:	BT5M05S8C
	8MHz:	BT8M05S8C
	10MHz:	BT10M5S8C
Flat:		
8 MHz #Hadeca	2MHz:	BF2M20S8A
	8MHz:	BF8M15S8A
Pencil:		
	8MHz:	BP8M05S8A*
	10MHz:	BP10M5S8A*
Sterilizable probe:		
Small Pencil:		
	8MHz:	VRP-08
	10MHz:	VRP-10
Long:		
	8MHz:	LRP-08
	10MHz:	LRP-10
Flat:		
8		
L Internet	8MHz:	FDP-08
Autoclavable:		
- T	8MHz:	ACP-08



## 7-2. Others

Smart-V-Link software with communication cable

## 7-3. Photoplethysmograph

With the PG-21 (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.

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

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

Single-channel photoplethysmography (PPG) probe



#### 7-3-2. PPG – AC mode: 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:**

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

- 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 "4-2-i.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 "4-2-a. MEMORY - STORE".



#### 7-3-3. PPG – DC mode: 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:**

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

MENU MEMORY IUU: DC COUNT 5 PATIENT OTHERS	
---	--

#### **Examination Procedure:**

- 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 "4-2-i.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 "§4-2-a. MEMORY - STORE".
- (9) Press the Right to get out of the freeze mode.









#### 7-3-4. Menu for PPG

Menu	Sub-menu	Selections	Reference in §.4-2
	STORE	1 to 30, FREEZE	a. MEMORY- STORE
MEMORY	READ	1 to 30, FREEZE	b. MEMORY- READ
	CLEAR	1 to 30, ALL	c. MEMORY- CLEAR
MODE(Coupling)		AC, DC	7-3-6. Mode
COUNT		1 to 20	7-3-6. Count
PATIENT data	ID, NAME, SEX, A	ID, NAME, SEX, AGE, DATE, SITE, MEMO	
		ENGLISH, EUTSCH, ITALIANO,	j. OTHERS - LANGUAGE
	LANGUAGE	ESPANOL, FRANCAIS	
	FREEZE	MANUAL, AUTO	k. OTHERS - FREEZE
	BACKLIGHT	ON, <b>OFF</b> , 60sec, 50sec, 40sec,	q. OTHERS - BACKLIGHT
OTHERS		30sec, 20sec, 10sec	
	AUTO-OFF	ON, OFF	r. OTHERS - AUTO-OFF
	P.ID PRT	ON, <b>OFF</b>	s. Others – P.ID PRT
	PRB-KEY	PRT & FRZ, PRINT, FREEZE	t. Others – PRB-KEY
	DATE	MMM. DD, YYYY HH:MM:SS	u. Others – DATE

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.

#### 7-3-5. 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.

 Press Enter on COUNT and press Up & Down to change the number. Press Enter to set it.

## **7-4.** Pneumoplethysmograph \*Except European Union Countries.

With the PV-21 (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.

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

#### Model PV-21



#### 7-4-2. 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:**

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

# Power button

#### **Examination Procedure:**

- 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) Inflate the cuff to 60 mmHg. Then, turn the stopcock so that it blocks the sphyg and routs cuff pressure to the PV probe.
- (6) The gain is automatically adjusted and the PV waveform is shown on the LCD.



- (7) When the waveform gets stable and rhythmic, press the **Right** or probe button to freeze the waveform. Press Print Button to print the waveform of last 5 sec if necessary.
- (8) If you wish to save the data on the memory, see"§4-2-a. MEMORY STORE".



(9) Deflate the cuff and repeat steps #3 through #7 of this section for each cuff on each limb.

#### 7-4-3. 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 probe. Interconnect the stopcock, tubing, cuff and sphygmomanometer as shown below.



- (4) Turn the stopcock so that air is routed from the sphygmomanometer to the sensing cuff at mid-calf.
- (5) Inflate the sensing cuff to 40 mmHg. Wait 10 seconds to allow time for settling and deflate the cuff to 15 mmHg.
- (6) Turn the stopcock so that it blocks sphyg and routes cuff pressure to the PV interface box.
- (7) Disconnect the sphyg from the stopcock and attach it to the occluding cuff at the thigh.
- (8) Press **Right** or probe button to begin the measurement process.
- (9) 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.
- (10) After 90 seconds, disconnect the sphyg from the occluding cuff. The pressures on the screen will drop back to the baseline.



1	FREEZE
JW0 5.62	mmHe
VC : 5.62	eHmm
/MVO/VC: 1900	7
2 mmH9 49	sec.

(11) Smartdop will automatically stop the measurement process, and then freeze the waveform. Press Print Button to print the waveform if necessary. (12) If you wish to save the data on the memory,see "§4-2-a. MEMORY - STORE".



(13) Press **Right** or probe button to get out of the freeze mode.

#### 7-4-4.Menu for PV

Menu	Sub-menu	Selections	Reference in §.4-2
	STORE	1 to 30, FREEZE	a. MEMORY - STORE
MEMORY	READ	1 to 30, FREEZE	b. MEMORY - READ
	CLEAR	1 to 30, ALL	c. MEMORY - CLEAR
MODE		<b>AC</b> , DC	7-4-7. Mode
PATIENT	ID, NAME, SEX, A	GE, DATE, SITE, MEMO	i. PATIENT
		ENGLISH, EUTSCH,ITALIANO,	j. OTHERS - LANGUAGE
	LANGUAGE	ESPANOL, FRANCAIS	
	FREEZE	MANUAL, AUTO	k. OTHERS - FREEZE
	BACKLIGHT	ON, <b>OFF</b> , 60sec, 50sec, 40sec,	q. OTHERS - BACKLIGHT
OTHERS		30sec, 20sec, 10sec	
	AUTO-OFF	<b>ON</b> , OFF	r. OTHERS - AUTO-OFF
	P.ID PRT	ON, <b>OFF</b>	s. Others – P.ID PRT
	PRB-KEY	PRT & FRZ, PRINT, FREEZE	t. Others – PRB-KEY
	DATE	MMM. DD, YYYY HH:MM:SS	u. Others – DATE

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

#### 7-4-5. 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

## **<u>7-5. Foot Temperature</u>** \**Except European Union Countries.*

With optional temperature probe (TP-02), Smartdop can detect foot temperature.

#### 7-5-1. Foot temperature study



Note: Comprehensive foot temp. study can be organized with Smart-V-Link for Windows, optional. 33.1

°C

Menu	Sub-menu	Selections	Reference in §.4-2
UNIT		°C, °F	7-5-1-(2)
LANGUAGE		ENGLISH, EUTSCH,ITALIANO, ESPANOL,	j. OTHERS - LANGUAGE
		FRANCAIS	
	BACKLIGHT	ON, <b>OFF</b> , 60sec, 50sec, 40sec, 30sec, 20sec,	q. OTHERS - BACKLIGHT
UTHERS		10sec	
	AUTO-OFF	ON, OFF	r. OTHERS - AUTO-OFF
	DATE	MMM. DD, YYYY HH:MM:SS	u. Others – DATE

## 7-5-2. Menu for Foot temperature

## Specifications:

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



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# 8. Technical information

## 8-1. 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 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.

## 8-2. Block diagram



## 8-3. Specifications

Probes:	Model	Freq.	Ispta* (in situ) [mW/cm2]	
	BT2M20S8C	2 MHz	80 mW/cm <sup>2</sup> or less	
	BT4M05S8C	4 MHz	390 mW/cm <sup>2</sup> or less	
	BT5M05S8C	5 MHz	390 mW/cm <sup>2</sup> or less	
	BT8M05S8C	8 MHz	390 mW/cm <sup>2</sup> or less	
	BT10M5S8C *lspta : Spatial Peal	10 MHz k - Temporal A	390 mW/cm <sup>2</sup> or less verage Intensity	
Power:	Input: Output:	AC 100-240\ DC 12V, 500	/- 0.3A (max), 50/60 Hz mA or more	
AC adaptor	Model name: GMP	U18EI-3		
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 free:	ze mode.	
Battery life:	Approx. 2 years, 30	0 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 Bi-directional wavef Numerical data (Sys HR) Heart rate:	LCD orm (normal & stolic, diastolic 30 to 300 BP	slow mode) & mean velocities, RP, PI, SD, M, accuracy of ±5%	
	Battery level and low	w battery indica	ators	
Printer:	Paper: Resolution: Print speed:	58 mm (W) x 384 dots/line 25 mm/s	25 m/roll (L), Thermal	
Velocity accuracy:	±10% or less compa	aring with interr	nal phantom testing.	
Speaker output:	250 mW or more			
External outputs:	Headset, USB port			
Electrical safety:	Conform to IEC6060 Class II device Internally powered e Type BF applied par	01-1 equipment rt.		

Operating environmer	nt:		
	10 to 37 °C		
	85% humidity or less	with no condensation	
Storage and transport	environment: 0 to 50 °C 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:	440 grams (without paper & 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: 0401:	Feb/2003 Jan/2004	

\* Specifications subject to change

## 8-4. Safety standards

The unit confirms to the following standards:

Manufacturing standard: IEC60601-1

- (1) Protection class against electric shock
- : Class II device

Protection grade against electric shock

: Internally powered equipment : Type BF applied part

(2) Guidance and manufacturer's declaration - electromagnetic emissions and immunity:

#### IEC60601-1-2:2007(3rd Edition)

Guidance ar	nd manufacture	r'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 4	5 should assume that it is used in such an environment.
Emissions test	compliance	Electromagnetic environment - guidance
RF emissions	Group 1	The Smartdop 45 use RF energy only for its internal
		function. Therefore, its RF emissions are very low and are
CISPR 11		not likely to cause any interference in nearby electronic
		equipment.
RF emissions	Class A	The Smartdop 45 is suitable for use in all establishments
		other than domestic, and may be used connected to the
CISPR 11		public low-voltage power supply network that supplies
Harmonic	Class A	buildings used for domestic purposes provided the
emissions		following warning in needed:
IEC61000-3-2		Warning: This equipment/system is intended for use by
Voltage	Complies	healthcare professions only. This equipment/system may
fluctuations/		cause radio interference or may be necessary to take
flicker emissions		mitigation measures, such as re-orienting or relocating the
IEC61000-3-3		Smartdop 45 or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity					
The Smartdop 45 is	The Smartdop 45 is intended for use in the electromagnetic environment specified below. The customer				
or the user of the Sr	martdop 45 should assure t	that it is used in such an e	nvironment.		
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment		
			- guidance		
Electrostatic	±6 kV contact	±6 kV contact	Floors should be wood,		
discharge(ESD)			concrete or ceramic tile. If		
	±8 kV air	±8 kV air	floors are converted with		
IEC61000-4-2			synthetic material, the relative		
			humidity should be at least		
			30%.		
Electrical fast	±2 kV for power supply	±2 kV for power supply	Mains power should be that		

transient/burst	lines	lines	of a typical commercial or
			hospital environment.
IEC61000-4-4	±1 kV for input/output	±1 kV for input/output	
	lines	lines	
Surge	±1 kV differential mode	±1 kV differential mode	Mains power should be that
			of a typical commercial or
IEC61000-4-5	±2 kV common mode	±2 kV common mode	hospital environment.
Voltage dips, short	< 5% U <sub>T</sub>	< 5% U⊤	Mains power should be that
interruptions and	(> 95% dip in U⊤)	(> 95% dip in U⊤)	of a typical commercial or
voltage variations	for 0,5 cycles	for 0,5 cycles	hospital environment.
on power supply			
input lines	40% U <sub>T</sub>	40% U⊤	
	(60% dip in U⊤)	(60% dip in U⊤)	
IEC61000-4-11	for 5 cycles	for 5 cycles	
	70% U⊤	70% U⊤	
	(30% dip in U⊤)	(30% dip in U⊤)	
	for 25 cycles	for 25 cycles	
	< 5% U⊤	< 5% U⊤	
	(> 95% dip in U⊤)	(> 95% dip in U⊤)	
	for 5 s	for 5 s	
Power frequency	3 A/m	3 A/m	Power frequency magnetic
(50/60Hz)			fields should be at levels
magnetic field			characteristic of a typical
IEC61000-4-8			location in a typical
			commercial or hospital
			environment.
NOTE $U_{T}$ is the a.c. mains voltage prior to application of the test revel.			

Guidance and manufacturer's declaration – electromagnetic immunity					
The Smartdop 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	Compliance level	Electromagnetic environment - guidance		
	test level				

			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.
			Recommended separation distance
Conducted RF IEC61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms 150 kHz to 80 MHz	<i>d</i> = 1,2 √ <i>P</i>
Radiated RF			$d = 1,2 \sqrt{P}$ 80 to 800 MHz
IEC61000-4-3	3V/m 80 MHz to 2,5	3V/m 80 MHz to 2,5	<i>d</i> = 2,3 √ <i>P</i> 800 MHz to 2,5 GHz
			where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).
			Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>
			Interference may occur in the vicinity of the equipment marked with the following symbol:
			$(((\bullet)))$

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.

For European Union Countries:

EC REP European Authorized Representative ICHIYAMA GmbH Benderstraße 130, 40625 Düsseldorf, Germany Tel: 0211-298538 Fax: 0211-299257



Manufactured by Hadeco, Inc. 2-7-11 Arima, Miyamae-ku, Kawasaki, Kanagawa, 216-0003 Japan

