Hadeco

OPERATING MANUAL

Bidop 7

OPERATING MANUAL

TABLE OF CONTENTS

Cautions

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 not affect the unit adversely.
   (4) Pay attention to the stability conditions such as inclination, vibration, and shock during transportation and installation work.
   (5) Do not place it where chemicals are stored, or where gas may be generated.
   (6) Do not place it where the unit tends to fall.
   (7) Do not place it on or adjacent other electronic device.

5. Before use:
   (1) Make sure that the unit operates safely and correctly by following the maintenance procedures 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. Operation
   (1) Do not use the unit simultaneously with an electric cautery, cardioverter, other ultrasonic device or mobile phone.
   (2) Be careful not to exceed time and volume of diagnosis treatment required.

(3) Always make sure the unit and patient are not under abnormal conditions.
(4) When any abnormality is found on the unit or the patient, take proper action such as stopping operating the unit in a manner safe to the patient.
(5) Do not let the patient touch the unit.
(6) Use the designated components only such as the probe.
(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 Operating manual.
(10) Do not use the unit in a strong electromagnetic field or it may cause incorrect measurement.

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, 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) Clean the unit, probes and place them in right place for the next use.
(3) When using the unit next time, perform the maintenance to make sure it works properly and safety.

9. Maintenance
(1) Do the periodical maintenance by following the procedures mentioned in "§ 5-1. Performance Check by user".
(2) The maintenance must be done at least once a year.

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

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

12. Battery
    (1) When battery is extremity low, the LCD display will not operate. Also there will be no speaker sounds. Charge the battery.
    (2) Battery life is 500 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.
        - Battery indicator will not indicated correctly when AC adaptor is connected.
        - It doesn’t turn on even though AC adaptor is connected.

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

14. Do not disassemble the unit.

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

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

1. Introduction

Thank you very much for choosing the Bidop 7.

The Hadeco Bidop 7 is a uniquely designed bi-directional Doppler with color LCD display. It detects arterial and venous blood flow in extremities.

The Bidop 7 displays velocity waveform and numerical data.
Please read this manual carefully to acquaint yourself with the Bidop 7 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, please refer to the operating manual for Windows linking software optional.

1-1. Features

- **BI-DIRECTIONAL DOPPLER WITH LARGE COLOR LCD DISPLAY**
  - ✓ Displays real-time waveforms, numerical data on color LCD.

- **NEWLY ADVANCED GREAT SOUNDS**
  - ✓ Highly sensitive “ST” probes enhance the Hadeco sensitivity with wider Doppler beam for 4, 5, 8, & 10 MHz
  - ✓ Optimized volume control for a whole range of low to high flow.

- **SNAP-LOCK CONNECTOR for easy insertion and removal**

- **ADVANCED MENU SCREEN for easy operation**

- **USB COMPUTER INTERFACE**
  - ✓ Transfers waveforms and numerical data to computer for data storage.
  - ✓ FFT waveforms available when connecting with Smart-V-Link software.

- **OPTIONAL PPG PROBE**
  - ✓ Available for expanding arterial & venous testing.

1-2. Clinical applications

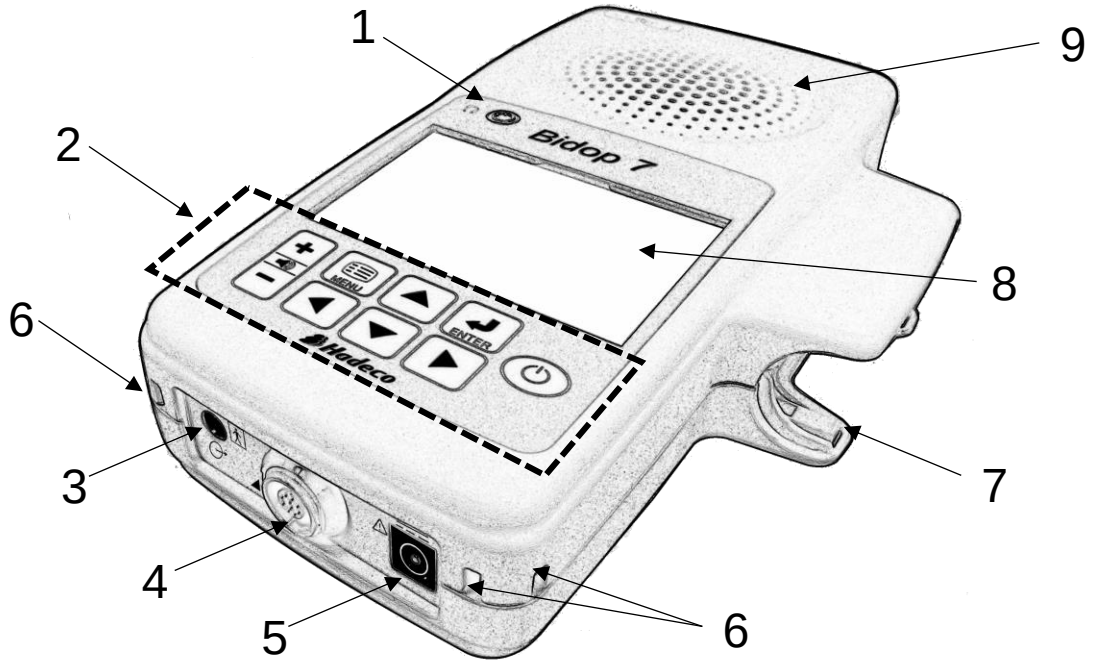
- **Detections of arterial and venous blood flow velocity for vascular disease**

  Probe to be used: ST8M05S8C (8MHz)
  Probes to be available in near future:
  ST2M20S8C (2 MHz)
  ST4M05S8C (4 MHz)
  ST5M05S8C (5 MHz)
  ST10M5S8C (10 MHz)

- **PEAK & MEAN blood velocity determinations**

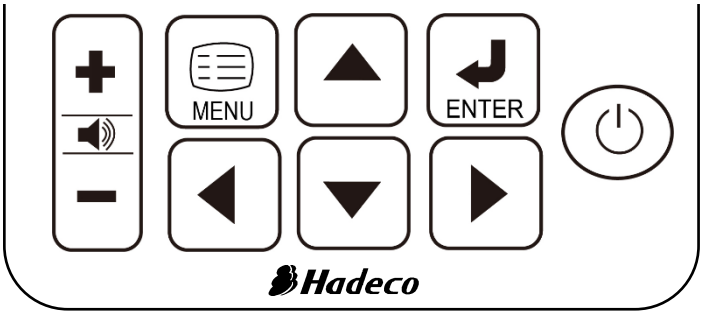
2. Appearance

2-1. Front view



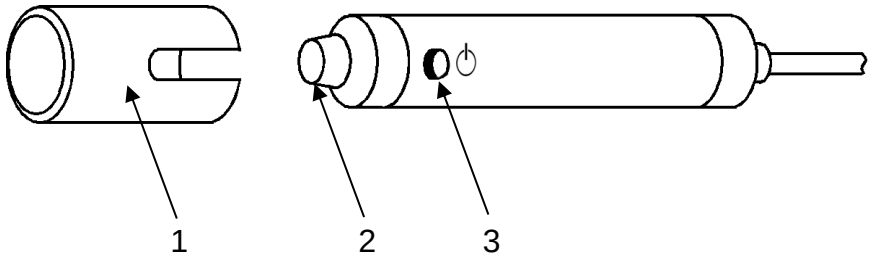
1	Headset connector		To connect your own headset. It cuts off the speaker
2	Operating panel		To operate the unit See “§2.2 Operating panel” for the details.
3	Serial port		To connect computer (USB)
4	Probe connector		To connect probe
5	AC adaptor connector		To connect AC adaptor
6	Strap holes		To connect your own strap
7	Probe holder		For probe placement when not in use
8	LCD display		Displays waveform, numerical data, heart rate and menu for mode settings
9	Speaker		Outputs Doppler sounds

2-2. Operating panel



Volume control button		To adjust sound volume; : To turn the volume UP. : To turn the volume DOWN. Press it longer than 1 sec to mute the unit.
Menu button	MENU	To get to and get out of MENU mode.
Up / Down button		To select menu item. (MENU mode) To display next memory data. (Freeze mode)
Right / Left button		: To go to sub-menu when on MENU mode. To change display mode from waveform to numerical data when on Measurement or Freeze mode. : To get back to previous menu when on MENU mode. To change display mode from numerical data to waveform when on Measurement or Freeze mode.
Enter button	ENTER	To go to sub-menu and implement mode setting / command when on MENU mode.
Power button		To turn the unit ON/ OFF.

2-3. Probe



1	Probe cap		To protect the transducer tip when not in use.
2	Doppler transducer		To detect blood flow.
3	Probe button	⏻	To freeze and unfreeze the waveform & numerical data.

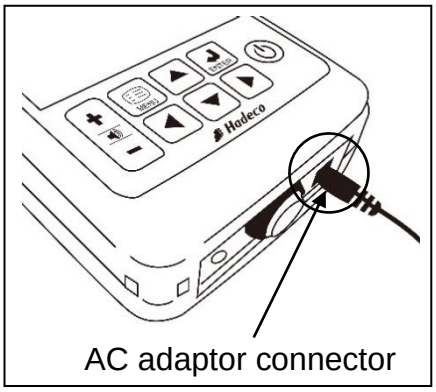
3. How to use

3-1. Preparation

3-1-1. Charging the battery

(1) Press Power button to turn the unit OFF.

(2) Plug the AC adaptor to the unit to charge the battery.



AC adaptor connector

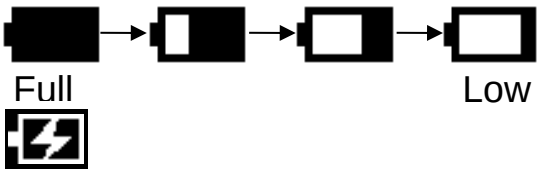
Note: Use the designated AC adaptor.
Model name: **GMPU18EI-3**

"**CHARGING**" will be shown on LCD during charging and it will disappear when battery is fully charged.

(3) Unplug the AC adaptor from the Bidop after charging.

3-1-2. Checking battery level

Battery level indicator shows the battery in 5 steps as shown below.


Full Low

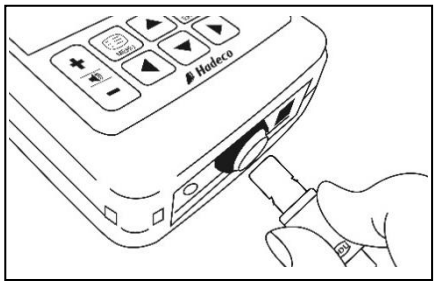
Charging

Charge the battery when it's low.

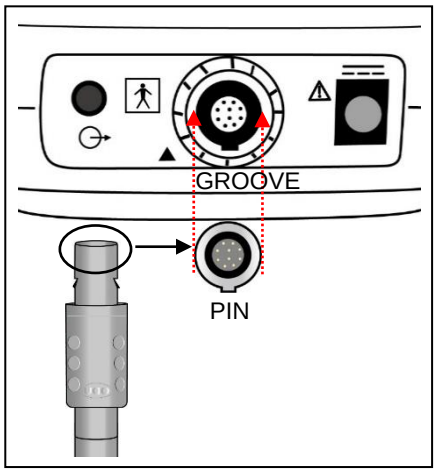
Battery level indicator

3-1-3. Connecting probe

Connect the probe to the Bidop so that the PIN key of probe connector goes into the GROOVE key at 6 o'clock of the Bidop connector.

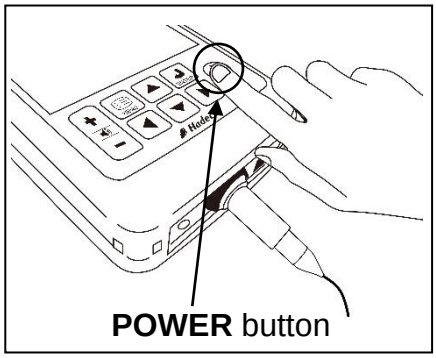


Note: Make sure to push the connector all the way until it clicks for connection.
Hold the Bidop and straight pull the base of connector for disconnection.

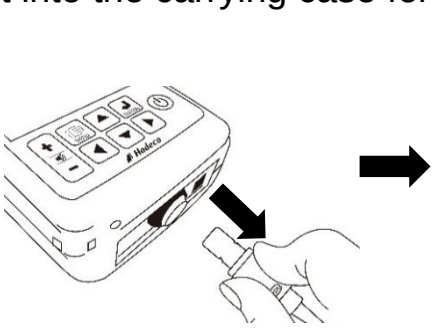


3-1-4. Turning the unit ON

Press ⏻ to turn the unit ON.



After the measurement, press ⏻ to turn it off. Disconnect the probe from the Bidop so that the unit will fit into the carrying case for storage.

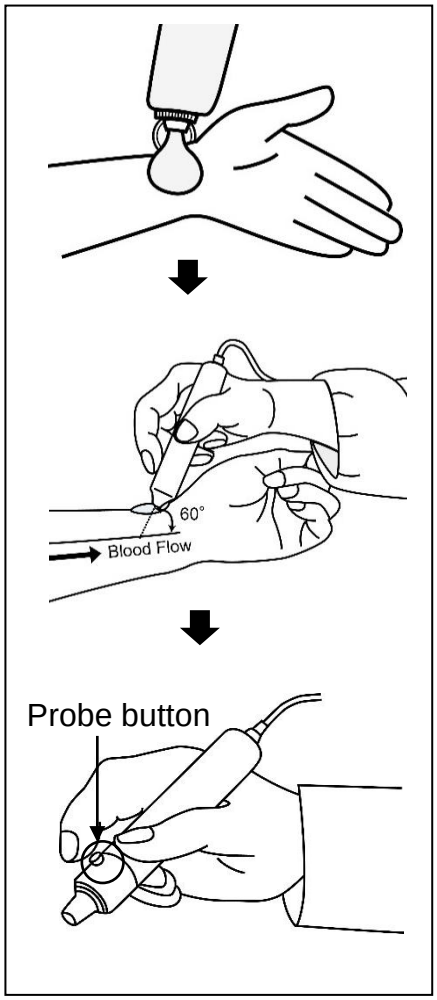


3-2. Measurement

3-2-1. Blood velocity mode

This section explains the fundamental use of measuring blood velocity.

(1) Put ultrasonic gel on the patient skin.

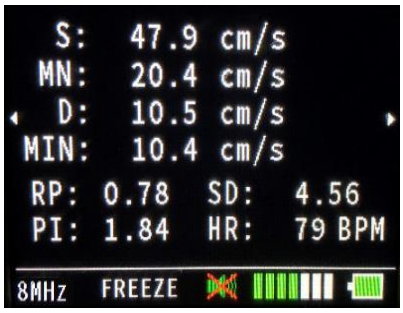


(2) Put the probe on the measurement area and move it slowly to locate the point where the maximum Doppler sounds are heard. An ideal probe angle to the vessel is approximately 45° to 60°.

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

To get numerical data, press ▶.

Waveform data



Numerical data

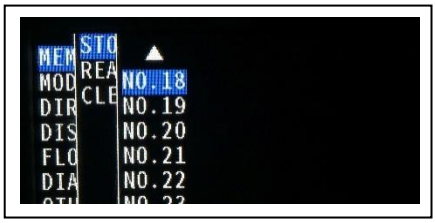
Note: See “§6-1. Numerical data” for meaning of abbreviations and the definition of each parameter.

◆ To store the data

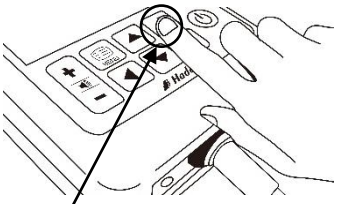
If you wish to store the waveform and numerical data on the memory, do the following procedures.

(1) Press MENU and go to **MEMORY** menu.

(2) Select **STORE** and next memory number available for storage will be displayed as shown in the right.
Press ▲ and ▼ to change the memory number, if necessary.



(3) Press ENTER to store the data.



ENTER **ENTER**

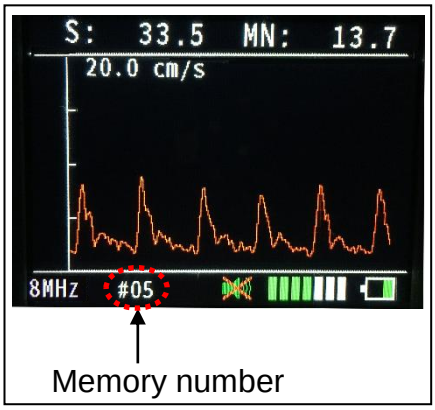
Note: The memory number(s) with asterisk "*" indicates where other data have been already stored.

◆ To display stored data

(1) Press MENU and go to **MEMORY** menu.

(2) Select **READ** and the memory number with "*" you wish to read by pressing ▲ and ▼.

(3) Press ENTER or ▶ to show the waveform.
To show the next waveform, press ▲ and ▼.



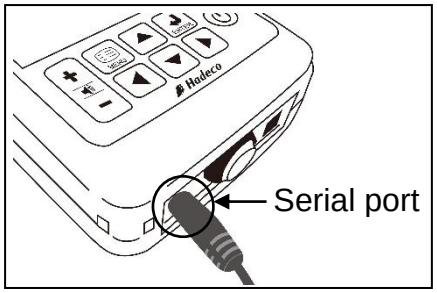
3-2-2. Site guidance mode

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.

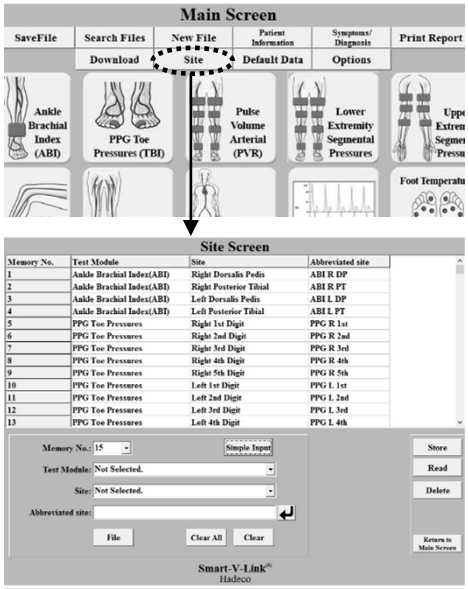
◆ Preparation for site guidance mode

(1) Connect the unit to the computer with the USB cable and start Smart-V-Link.



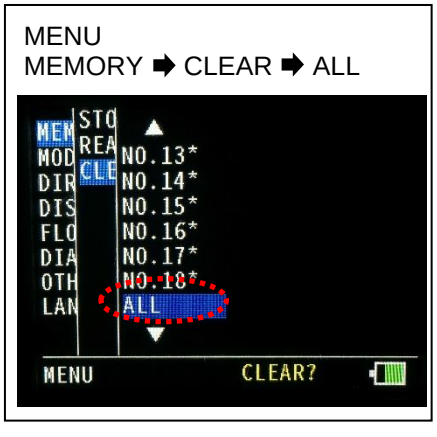
(2) Go to **Site Screen** and input abbreviated site & test name for each waveform memory and then store the names on the Bidop.

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



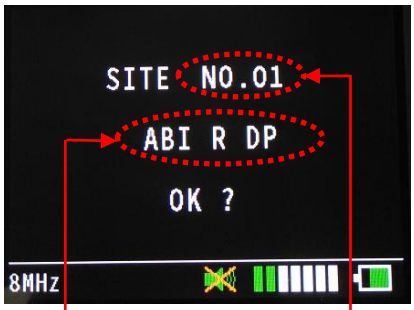
Site Screen of Smart-V-Link

(3) Go to **MEMORY** on the Bidop and clear all memory data before newly starting the site guidance mode.



◆ Site guidance mode procedures

(1) Turn the unit off and on and the 1st guidance with memory number and abbreviated site & test name will appear as shown in the right.

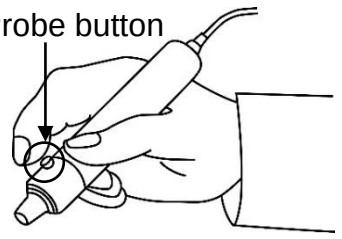


Memory number

Abbreviated site & test name

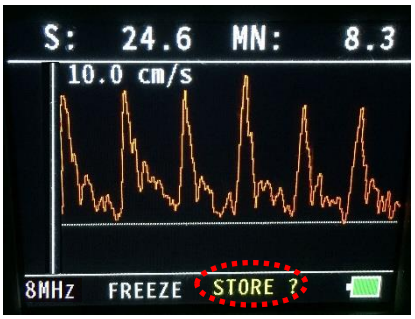
Note: The first memory number available will be selected automatically.

(2) Press the probe button to start monitoring waveform.



Note: To get out of "Site guidance mode", press ◀ for normal mode operation.

Press the probe button the 2nd time to freeze the waveform when it becomes stable and the 2nd guidance "**STORE?**" as shown in the right will appear.



(3) Press the probe button the 3rd time to store the frozen waveform data on the designated memory number.

(4) The 1st guidance for the next testing will appear as shown in the right.
Repeat steps (2) to (3) until all testing is completed.

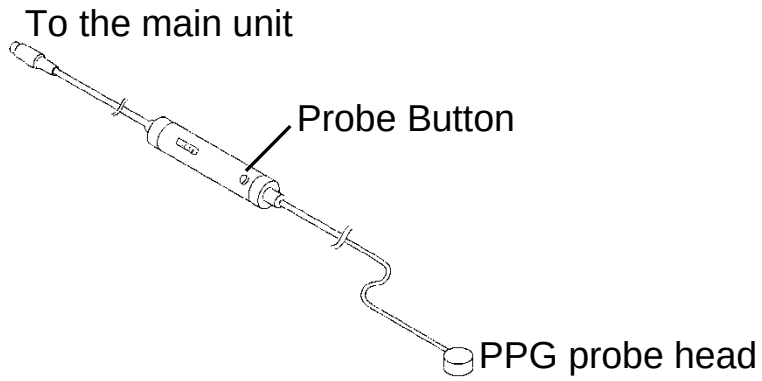
(5) Press the probe button when the message shown right is displayed upon completion of all testing and the unit will get out of site guidance mode.

3-2-3. PPG waveform studies

With the PPG probe, PG-30 (Option), the Bidop senses the reflection of light from the hemoglobin of the red blood cells in surface vessels by utilizing infrared light. This section explains the fundamental use of measuring PPG, photoplethysmograph.

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

Model PG-30



◆ 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.

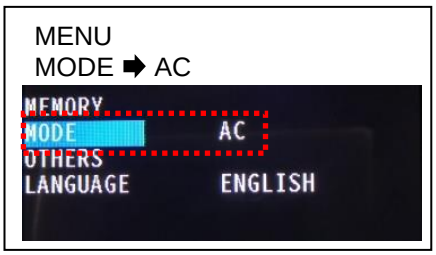
Note: Make certain that room temperature is comfortable and, especially, that the skin surface where the probe is to be mounted is warm. Cold constricts superficial blood vessels and thus jeopardizes the accuracy of PPG measurements.

Preparation:

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

(2) Go to **MODE** menu and set it for **AC**.

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



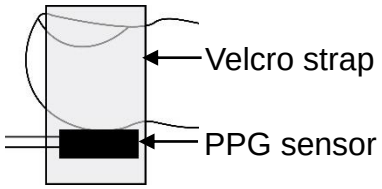
Examination Procedure:

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

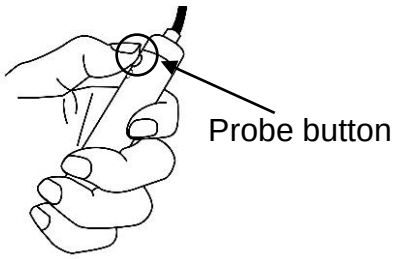
(2) The gain is automatically adjusted and the PPG waveform is shown on the LCD. High-pitched sounds following heartbeats can be heard from the speaker.

(3) When the waveform gets stable and rhythmic, press probe button to freeze the waveform.

If you wish to store the data, go to MEMORY menu and store it.



PPG AC waveform



◆ 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.

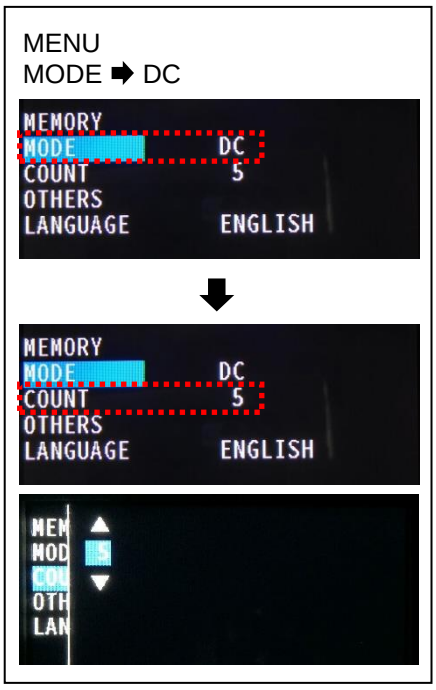
Preparation:

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

(2) Press MENU to go to **MODE** menu and set it for **DC**.

(3) **COUNT** represents number of foot exercise during study. If desired, go to **COUNT** menu and press ▲ and ▼ to change the number.
Press ENTER to set it.

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

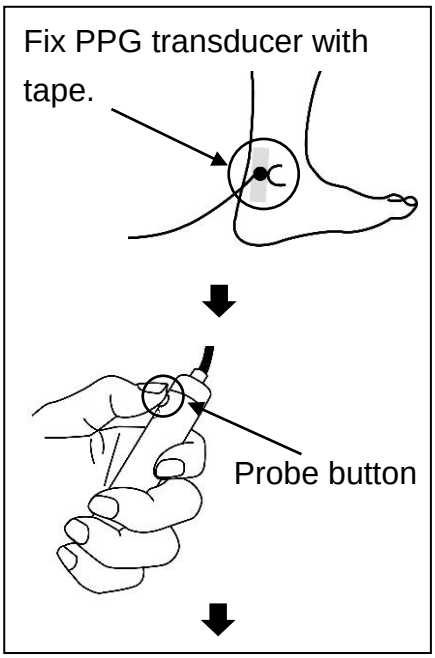


Examination Procedure:

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

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

(3) Press the probe button to begin the measurement process.



(4) Ask the patient to flex the foot specified number on **COUNT** following the foot animation and beep on Bidop. The exercise should be forceful, especially when lifting the foot upward.

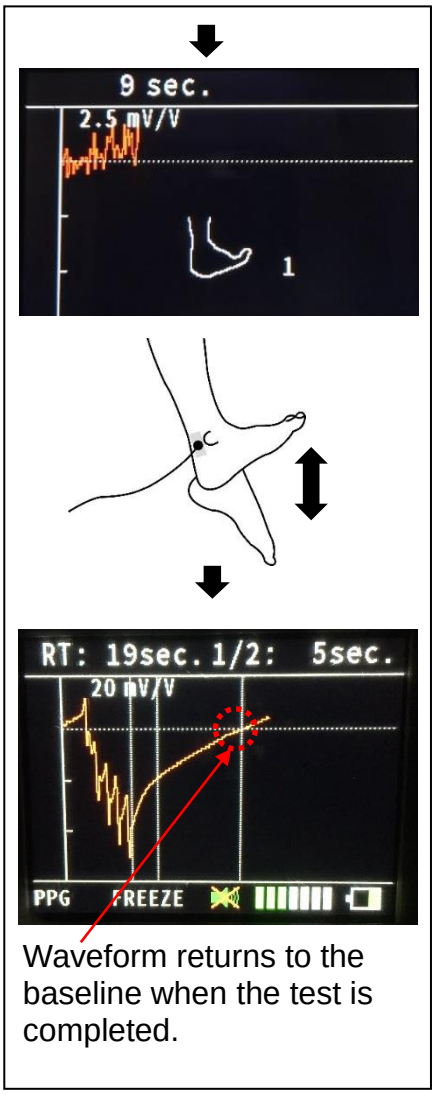
(5) After flexing, instruct the patient to relax the foot and avoid all movement.

(6) The test is completed when the waveform returns to the baseline and Bidop will automatically freeze the waveform and calculate recovery times.

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

If you wish to store the data, go to MEMORY menu and store it.

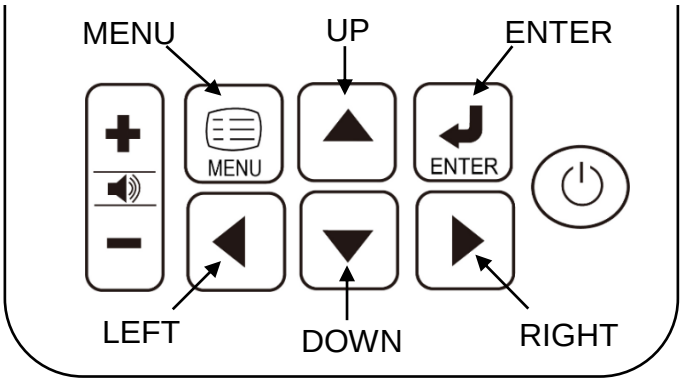
Press the probe button to get out of the freeze mode.



Waveform returns to the baseline when the test is completed.

4. Menu and Mode settings

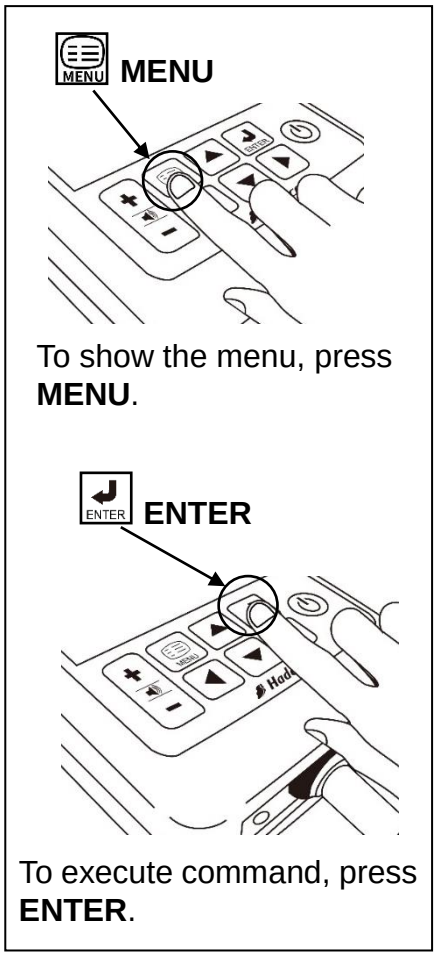
Various mode settings can be selected on **MENU** mode. Some of the menus consist of sub-menu(s).



< Operating panel >

4-1. Menu operation

- Press MENU to show the **MENU** depending on Basic mode.
- Select the menu by ▲ and ▼ **.** Selected menu will be highlighted.
- Press ENTER or ▶ to change the menu setting.
- Press ENTER to execute command.
- For **MEMORY** and **OTHERS** menu, pressing ENTER or ▶ to show the sub menu for further mode settings.
- Press ◀ to go back to main menu from the sub menu.
- To get out of the menu mode, press MENU .



To show the menu, press **MENU**.

To execute command, press **ENTER**.

4-2. MENU for Blood Velocity mode

Selections in bold face in the table are default settings.

Menu	Sub Menu	Selections	M/F*	Reference Section#.
MEMORY	STORE	1 to 30, FREEZE	F	§3-2-1
	READ	1 to 30, FREEZE		
	CLEAR	1 to 30, ALL		
MODE		**COMPOUND**  SEPARATION 		§4-4
DIR		**FORWARD**  REVERSE 		
DISP		**WAVE**, DATA	F	
TIME		**NORMAL**  , SLOW 	M	
FLOW		ON, **OFF**		
DIAMETER		0.1 – 20.0 mm (**2.0 mm**) (Set **FLOW** for **ON** to enable it**)**		
OTHERS	FREEZE	**MANUAL**, AUTO		
	UNIT	**cm/s**, kHz	M	§4-4
	FILTER	**ARTERIAL**, VENOUS	M	
	SMOOTH	**NORMAL**, LOW-PASS	M	
	DISP	**WAVE**, DATA	M	
	CAL	ON, **OFF**	M	
	DATA1	**S**, MN, D, MIN, RP, PI, SD, HR		
	DATA2	S, MN, D, MIN, RP, PI, SD, **HR**		
	AUTO-OFF	**ON**, OFF		
LANGUAGE		**ENGLISH**, DEUTSCH, ESPANOL, FRANCAIS		

* M/F (For all the MENUs, §4-2 and §4-3)

- M: Available on Measurement mode only
- F: Available on Freeze mode only
- Blank: Available on both Measurement and Freeze modes

4-3. Menu for PPG AC/DC mode

Menu	Sub Menu	Selections	M/F*	Reference Section#.
MEMORY	STORE	1 to 30, FREEZE	F	§3-2-1
	READ	1 to 30, FREEZE		
	CLEAR	1 to 30, ALL		
MODE		**AC**, DC	M	§3-2-3
COUNT		1 to 20 (DC mode only)	M	
OTHERS	FREEZE	**MANUAL**, AUTO		
	AUTO-OFF	**ON**, OFF		§4-4
LANGUAGE		**ENGLISH**, DEUTSCH, ESPANOL, FRANCAIS		

Note: **COUNT** is available on **DC** mode only.

4-4. MENU and Mode settings details

Menu	Symbol/ Selections		Description
MODE (Waveform mode)		Compound	Combined forward and reverse components
		Separation	Separation of forward from reverse component
DIR (Flow direction)		Forward	Flow toward probe is processed as positive component.
		Reverse	Flow away from probe is processed as positive component.
DISP (Display mode)	WAVE		Blood velocity waveform data
	DATA		Blood velocity numerical data
TIME		Normal	Time scale for arteries (5.8 sec./ screen)
		Slow	Time scale for veins (29 sec./ screen)
FLOW (Blood volume flow)	ON/ OFF		To show the blood volume flow
DIAMETER	0.1 mm – 20.0 mm		To set the estimated vessel diameter for calculation of blood volume flow Note: Set **FLOW** for **ON** to enable **DIAMETER**.
OTHERS-UNIT	cm/s		Unit for blood flow velocity
	kHz		Unit for Doppler-shifted frequency
OTHERS-FILTER	VENOUS		High-pass filter for veins (80 Hz)
	ARTERIAL		High-pass filter for arteries (200 Hz)
OTHERS-SMOOTH	NORMAL		Smoothing filter for normal signals (10 Hz)
	LOW-PASS		Smoothing filter for noisy signals (5 Hz)
OTHERS-CAL (CAL mode)	ON		Displays 5 steps (3, 2, 1, 0, 1 kHz) calibration waveform
	OFF		Normal waveform
OTHERS-DATA1/ DATA2 (Numerical parameter to show on LCD)	S, MN, D, MIN, RP, PI, PI, SD, HR		DATA1: To show on upper left side of LCD DATA2: To show on upper right side of LCD
OTHERS-AUTO-OFF (Automatic shut-off)	ON/ OFF		AUTO-OFF works after following time passed: • 15 minutes when in measurement (35 minutes for FHR waveform mode) • 2 minutes when no signal • 5 minutes when on freeze mode

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 coming off.

(3) Turn the unit on and make sure if the color 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, please 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”.

5-3. Warranty

Guarantee period:

- **Main unit**: Two (2) years
- **Probe**: One(1) year

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. Numerical data

Parameters	Abbr.	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 blow base line.
Pulsatility Index	PI	PI = (S - MIN) / MN PI ≤ 99.99
S/D ratio	SD	SD = S / D
Heart rate [BPM]	HR	
Max volume flow [ml/minute]	MAX	
Mean volume flow [ml/minute]	MN	
Vessel diameter [mm]	DIAM	

6-2. Symbol list

Symbols	Descriptions	Symbols	Descriptions
	Type BF applied part		Caution*
	Headset		Manufacturer
	Power button		Authorized representative in Europe
	Serial port		AC adaptor connector

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

6-3. Contents in package

- Main unit ····· 1
- Probe ····· 1
- Carrying case ····· 1
- Ultrasonic gel ····· 1 (Model name: AQUAULTRA BASIC)
- AC adaptor ····· 1

7. Options

7-1. Probe selection

Standard Doppler probe:

ST8M05S8C (8MHz)

PPG probe:

PG-30

7-2. Others

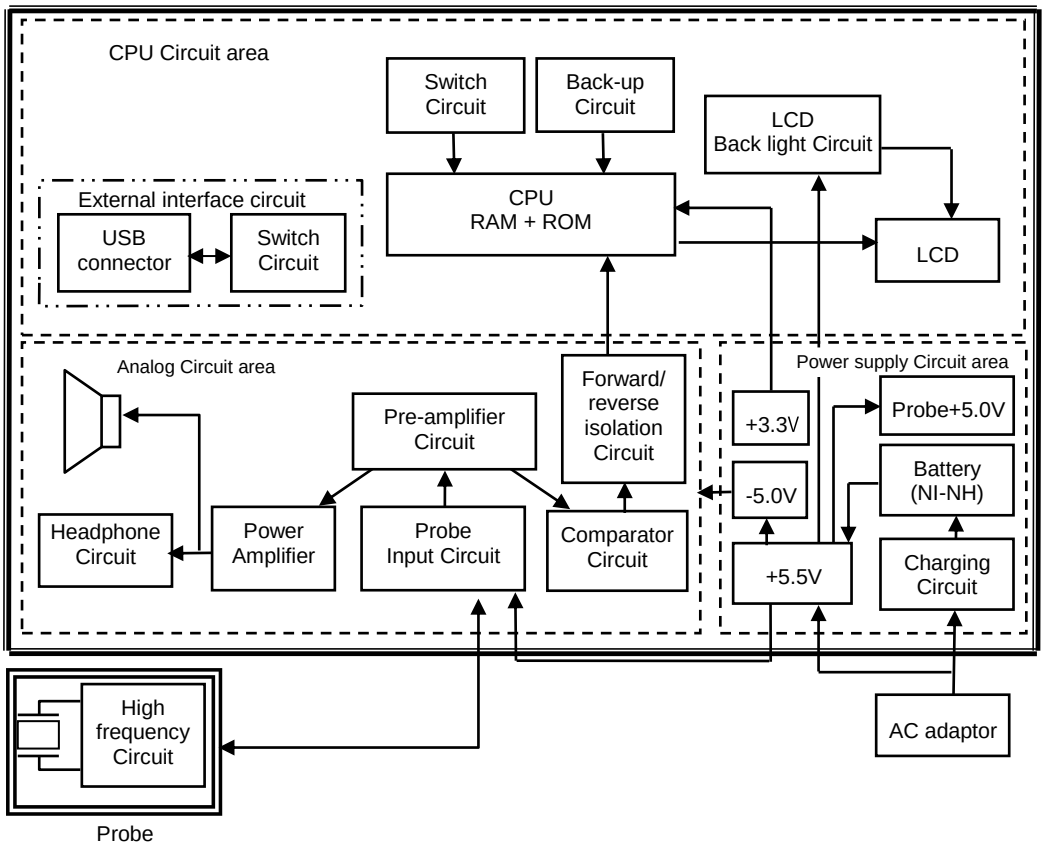
Smart-V-Link software with communication cable

8. Technical information

8-1. Principles

Model Bidop 7 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.

8-2. Block diagram



8-3. Specifications

Probes: Frequency: Acoustic power Ispta* (in situ):
4, 5, 8 and 10MHz 720 [mW/cm²] or less
** Ispta: Special Peak-Temporal Average Intensity.*

AC adaptor: Model name: GMPU18EI-3

Power: Input: AC 100-240V, 50/60Hz
Output: DC 12V, 1A or more

Consumption: DC 12 V, 550 mA MAX.

Recharge: Approx. 5 hours by the AC adaptor

Full charge life: Approx. 2.5 hours

Battery life: Approx. 2 years, 500 full charges

Automatic shut-off: No signal: 2 minutes

Frequency range: 80/ 200 Hz to 5 kHz

Waveform memory: 30 waveforms

LCD display: 320 x 240 dots, Color LCD
Bi-directional waveform, Numerical data,
Heart rate: 30 to 300 BPM, accuracy of ±5%

Velocity accuracy: ±10% or less comparing with internal phantom testing.

Waveform Scale & Baseline: Auto-Gain & Baseline Control
Bottom, 1/4, Center, 3/4

Speaker output: 1.25W or less

External outputs: Headset, serial port (USB)

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

Operating environment:
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: 93 (W) x 214 (L) x 60.5 (H) mm (Probe holder not included)
Probe: 20 (Diam.) x 105 (L) mm

Weight: 570 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 battery 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

8-4. Safety standards

The unit confirms to the following standards: IEC60601-1

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

(2) Protection grade against electric shock: Type BF applied part

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The Bidop 7 is intended for use in the electromagnetic environment specified below. The customer or the user of the Bidop 7 should assume that it is used in such an environment.		
Emissions test	compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Bidop 7 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 Bidop 7 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Bidop 7 is intended for use in the electromagnetic environment specified below. The customer or the user of the Bidop 7 should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are converted with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines(100KHz) ±1kV for input/output lines	±2kV for power supply lines(100KHz) ±1kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±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	Dip to 0% for 0.5cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°&315° Dropout to 0% for 1 cycles @ 0°phase angle Dropout to 70% for 25/30 cycles @ 0°phase angle Interrupts 0% for 250/300 cycles	Dip to 0% for 0.5cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 70°&315° Dropout to 0% for 1 cycles @ 0°phase angle Dropout to 70% for 25/30 cycles @ 0°phase angle Interrupts 0% for 250/300 cycles	Mains power should be that of a typical commercial or hospital environment.
Power frequency (50Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test revel.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Bidop 7 is intended for use in the electromagnetic environment specified below. The customer or the user of the Bidop 7 should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150kHz to 80MHz, 1kHZ 80%AM Modulation 6Vrms in ISM bands(I/O cables< 3m excluded) Patient coupled ports tested with current clamp 3V/m, 80Mhz to 2,7GHz, 1kHz 80%AM modulation Table-9 (IEC60601-1-2:2014)	3Vrms 150kHz to 80MHz, 1kHZ 80%AM Modulation 6Vrms in ISM bands(I/O cables< 3m excluded) Patient coupled ports tested with current clamp 3V/m, 80Mhz to 2,7GHz, 1kHz 80%AM modulation Table-9 (IEC60601-1-2:2014)	Portable and mobile RF communications equipment should be used no closer to any part of the Bidop 7, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 to 800MHz $d = 2,3\sqrt{P}$ 800MHz to 2,5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of the equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Bidop 7 is used exceeds the applicable RF compliance level above, the Bidop 7 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Bidop 7. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

For European Union Countries:

EC REP European Authorized Representative

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