OPERATING MANUAL

Minidop ES-100VX
POCKET DOPPLER

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Excellence in Human Service and Technology

Hadeco, Inc.

Thank you very much for choosing the Minidop ES-100VX.

The POCKET DOPPLER Minidop ES-100VX can be used with interchangeable probes having different frequencies of 2, 4, 5, 8, 10 and 20 MHz, to detect arterial and venous blood flows in the extremities.

Please read this manual carefully.

Features

ES-100VX is designed for the use to detect arterial & venous blood flows in the extremities, and has the following features.

- POCKETABLE, HAND-HELD SIZE
- GREAT SENSITIVITY
- WIDE PROBE SELECTION (2, 4, 5, 8, 10 and 20 MHz) for user flexibility.
- CONVENIENT PROBE ACTIVATION BUTTON turns ES-100VX ON and OFF.

Cautions

1. General

Non-conformability with expendables / components / other device

Please use designated battery, ultrasonic gel, probe and headset. Do not use those components for other devices.

Only skilled persons should operate the unit.

1-1. Probe

(1) The standard probe is for transcutaneous use only.

(2) Optional sterilizable probe (reusable & disposable) can be sterilized in the manner described in the page 14, Sterilization. However, only one time sterilization is possible for disposable probe, and do not reuse it.

(3) Except optional ACP probe, do not sterilize probes by steam autoclave.

(4) The probe transducer is a very thin and delicate. Please handle with great care and use the probe cap when not in use.

(5) The probe cover also prevents against switching ON when storing the unit after use.

1-2. Ultrasound gel

(1) Do not apply ultrasound gel to the probe body other than the tip of probe.

(2) Always use an ultrasound gel. Using other materials such as baby oil and cream may damage the probe.

(3) The ultrasound gel enclosed is non-sterile and do not use it for surgeries.

(4) Incidence of allergy: Discontinue the use of gel if any allergic reaction occurs.

1-3. Battery

(1) When battery is low, the power indicator flashes. Replace the battery.

(2) Use a 9 volt alkaline square type battery. A non-alkaline may cause a shortage of power.

(3) When not using the unit for a long time, remove the battery.

2. Before using the unit

(1) Make sure that the unit operates safely and correctly by implementing performance check mentioned in “Cautions 7. Periodical safety check by user”.

(2) Do not place near water or other liquid.

(3) Do not place where atmospheric pressure, ventilation, sunlight, dust, salt, sulfur and so forth will not affect the unit adversely.

(4) Do not place it on or adjacent other electronic device.

(5) Use only on conditions of temperature between 10 °C and 37 °C and humidity less than 85 %.

(6) Pay attention to the stability conditions to avoid too much inclination, vibration, shock, and so on during transportation and installation of the unit.

(7) Do not place it where chemicals are stored or gas may be generated.

(8) Keep the unit and the patient from a computer more than 1.5 m apart.

(9) When using the unit after a long time, do not forget to check whether the unit operates normally and safely.

(10) Make sure that there are no damages on the unit and probe.

(11) Clean the probe using damp cloth or a recommended probe cleaner before use. Using alcohol or thinner may damage the probe.

(12) Sterilizable probes (optional) should be sterilized before use. (See Page 12,

Sterilization)

(13) Do not sterilize the main unit, non-sterilizable probes and amplifier to prevent any damage.

(14) Using it with other equipment together may cause a misdiagnosis or danger to patient due to a malfunction.

3. When operating the unit

(1) Do not use the unit simultaneously with either electric cautery, cardioverter, other ultrasonic device or mobile phone.

(2) 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.

(3) Possibility of operation under unexpected environments

(4) Please do not use the Doppler continuously for more than 1 hour to avoid a rash of the skin.

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

(6) Be cautious not to exceed too much time and volume required for the measurement.

4. After using the unit

(1) Turn the unit off, and disconnect all cables.

(2) Clean the unit, components, cables and probes. (See Page 18, Cleaning)

5. When the unit gets out of order, contact the dealer for repair from who you purchased the unit.

6. Do not disassemble the equipment.

7. Periodical safety checks by user

Please perform the following safety checks at least once a year:

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

(2) Shake the main unit and make sure if there are no sounds inside from internal components coming out.

(3) Turn the unit on and make sure if the pilot lamp goes on.

8. 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.

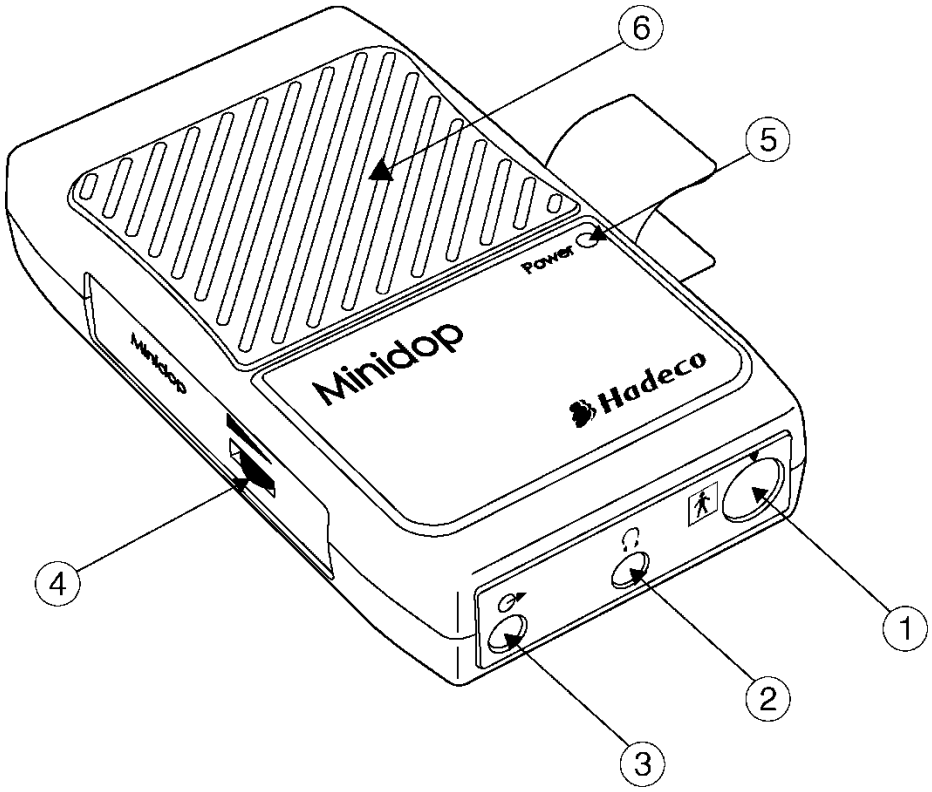
Clinical applications

Use the unit for the following clinical applications only:

- Blood flow detection

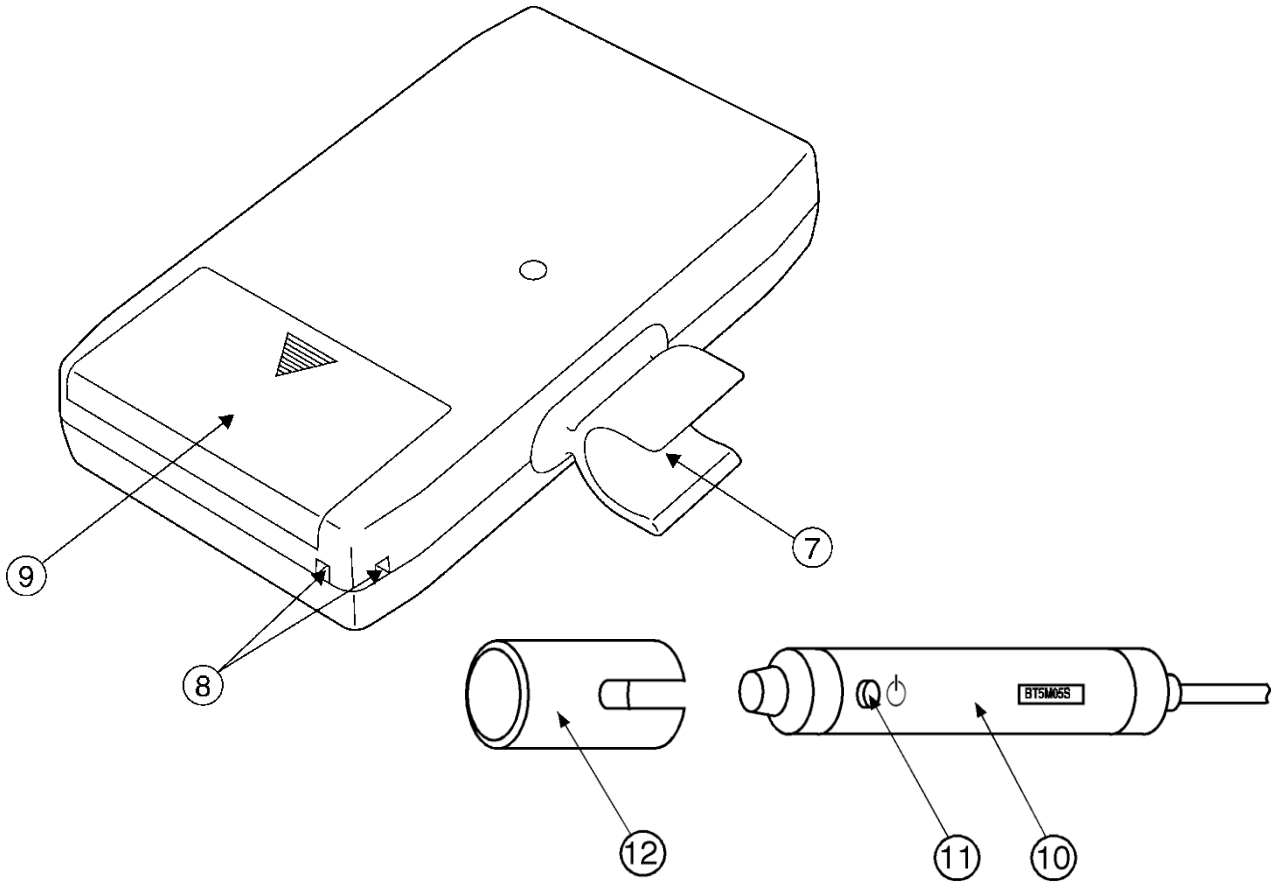
Operating controls

Front panel



1. Probe connector : To connect probe.
2. Headset : To connect headset.
3. Connector for : Not allowed to use it. Only for service purpose.
4. Volume control : To adjust sound volume.
5. Power indicator : Indicates power ON/OFF and Low Battery Charge with flashing.
6. Speaker : Outputs Doppler sounds.

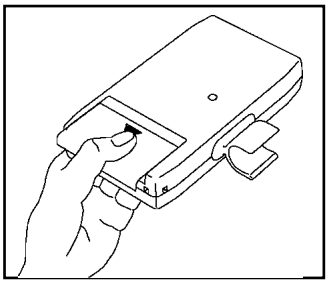
Rear panel



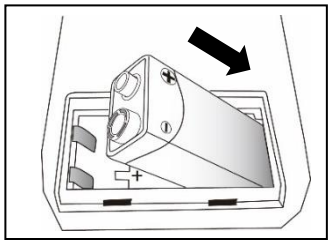
7. Probe holder : For probe placement when not in use.
8. Strap holes : To connect neck strap.
9. Battery cover : For battery placement.
10. Probe : Multi-probe selection of 2, 4, 5, 8, 10 and 20 MHz.
11. Probe button : To turn the unit ON / OFF.
12. Probe cap : To protect the probe transducer tip when probe is not in use.

How to turn the unit ON and OFF

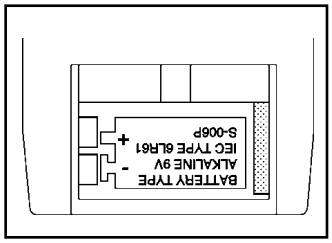
(1) Open the battery cover as pictured on the right.



To prevent any damage to the battery terminal, please insert the battery to battery box as shown right.

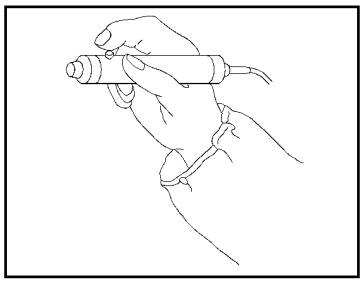


(2) Set an alkaline square type battery in the unit ensuring that the positive and negative electrodes correspond to the + and - marks on the label in the battery box.



(3) Connect the probe to the Minidop so that the arrow mark ⇧ will be placed under ▼mark, and press the probe button to turn the unit ON.

To start the measurement, turn the volume control to maximum.



(4) Press the probe button again to turn the unit OFF.

AUTOMATIC SHUT-OFF

If the unit is left on with no signal input, the power is automatically shut off in about 3 minutes.

REPLACING BATTERY

Replace the battery with new one if the power indicator flashes. Use a 9 volt ALKALINE square type battery. A non-alkaline may cause a shortage of power.

Note: Use the battery composed in the package as a standard component for performing operation check only.

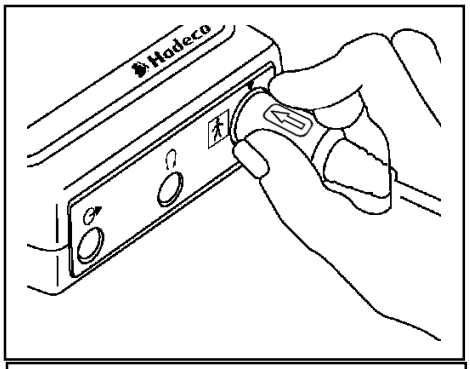
External outputs

HEADSET

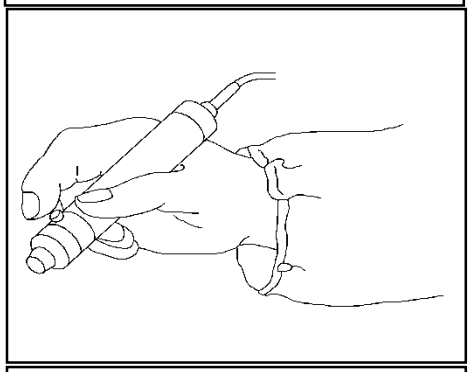
Connect the headset when necessary. The headset cuts off the speaker.

Operation

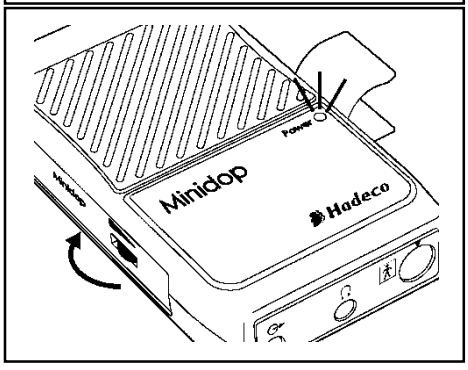
(1) Connect the probe to the Minidop so that the arrow mark ⇧ will be placed under ▼ mark, as shown on the right.



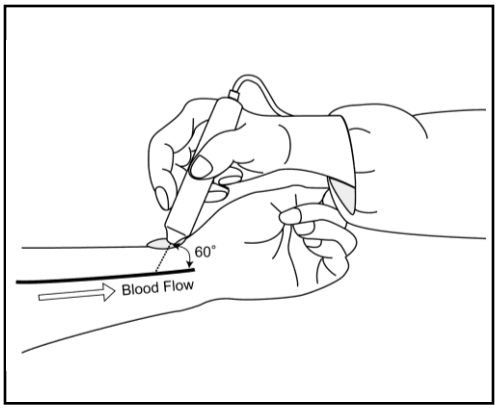
(2) Put ultrasonic gel on the probe top or patient skin. Press the probe button to turn the unit on.



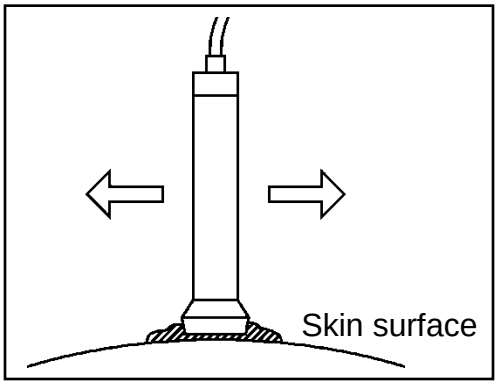
(3) Make sure the power indicator on the unit is on. Turn the volume control to maximum.



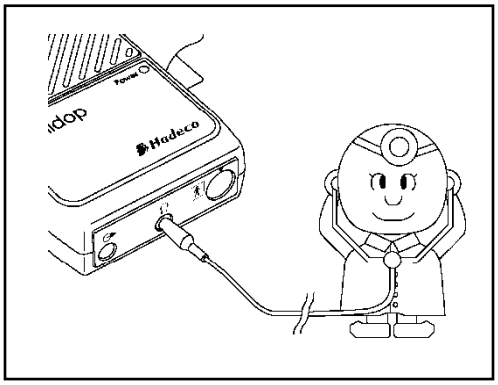
(4) Put the probe on the measurement area and move it slowly to locate the point where the maximum Doppler sounds are heard. An ideal probe angle to the vessel is approximately 45° to 60°.



(5) If you are using the 2 MHz probe, put the probe on the measurement area and move it slowly to locate the point where the maximum sounds are heard.



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



Probe selection

The frequency of diagnostic ultrasound is inversely proportional to depth of penetration. The Minidop has 5 interchangeable probes with different frequencies.

Use those probes depending on your applications.

BT2M20S8C (2 MHz):	Deep peripheral blood flow
BT4M05S8C (4 MHz):	Deep peripheral blood flow
BT5M05S8C (5 MHz):	Deep peripheral blood flow
BT8M05S8C (8 MHz):	Superficial blood flow
BT10M5S8C (10MHz):	Superficial blood flow

Clinical applications

- **Detection of Arterial and Venous Blood Flow Velocity for vascular disease.**

Probes to be used: BT2M20S8C (2 MHz)
BT4M05S8C (4 MHz)
BT5M05S8C (5 MHz)
BT8M05S8C (8 MHz)
BT10M5S8C (10MHz)

Options

Probe selection

Standard Doppler probe:

Standard:

2MHz: BT2M20S8C
4MHz: BT4M05S8C
5MHz: BT5M05S8C
8MHz: BT8M05S8C
10MHz: BT10M5S8C

Pencil:

8MHz: BP8M05S8A
10MHz: BP10M5S8A

Flat:

2MHz: BF2M20S8A
8MHz: BF8M15S8A

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

Bayonet*:

10MHz: NRP-10H

20MHz: NRP-20H

Flexible*:

10MHz: NRP-10HF

20MHz: NRP-20H1NF

Curved pencil*:

10MHz: CRP-10H

20MHz: CRP-20H

20MHz: CRP-20H1N

Single use*:

10MHz: NDP-10H

20MHz: NDP-20H

**: Except European Union Countries*

Amplifiers:

8MHz: BDP08MS8

10MHz: BDP10MS8

20MHz: BDP20MS8

-- Sterilizable probes --

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

All sterilizable probes except ACP and FDP probe: Up to 50 times

FDP probe: Up to 5 times

ACP probe: Up to 5 times (steam autoclave)

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

Caution

Except ACP probe, do not sterilize probes by steam autoclave nor put them in washer disinfector or it will damage probes.

ACP probe should be sterilized by steam autoclave as described in section "Sterilization" below.

Instructions for sterilization

Point of preparation: No particular requirements.

Preparation for cleaning: No particular requirements.

Cleaning:

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

Manual Do not soak it 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®50
・STERRAD®100S (only short cycle)
・STERRAD®200 (only short cycle)
・STERRAD®NX (only standard cycle)
・STERRAD®100NX (only standard cycle)

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 at 121 °C
4 minutes at 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 Function Testing:

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

Packaging: No particular requirements.

Storage: No particular requirements.

Manufacturer contact

Hadeco, Inc.

2-7-11 Arima, Miyamae-ku, Kawasaki, 216-0003, Japan

Tel: +81-44-877-4361 Fax: +81-44-855-7301

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

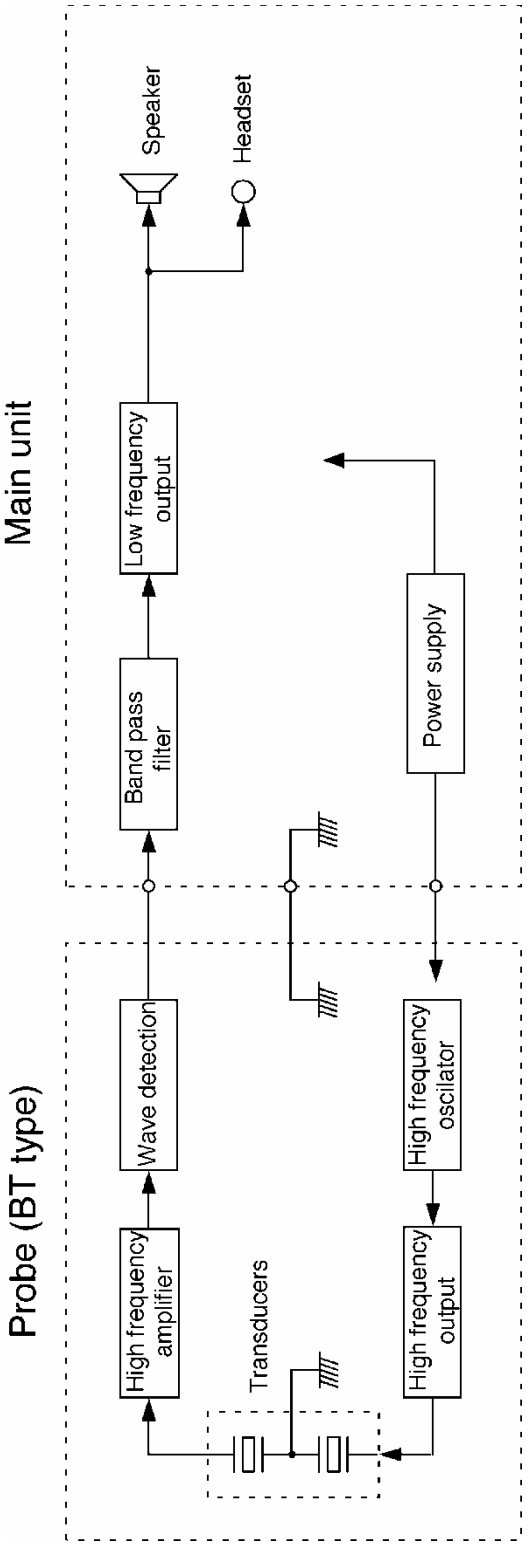
Principles

Model ES-100VX Minidop is designed to receive blood flow velocity information by ultrasound. A specific frequency is transmitted from the probe to the patient.

Technically the transceiver amplifies a high frequency oscillation output for transmission to the transducer. The voltage is converted by a piezoelectric crystal (transducer) to ultrasound. The ultrasound beam is transmitted to blood cells flowing through arteries. The ultrasound beam is reflected by the red blood cells or by moving structures and received by the crystal in the transducer which converts the ultrasound into a voltage. A Doppler shift occurs between the emission and reception of the ultrasound beam.

The voltage is amplified. The electronics amplifies the signal, filters out noise and improves the S/N ratio. The Doppler shift signals are amplified further and converted to audible sound via a speaker.

Block diagram



Specifications

Probes:	Model:	Freq.	Ispta* (in situ) [mW/cm²]
	BT2M20S8C	2 MHz	80 or less
	BT4M05S8C	4 MHz	390 or less
	BT5M05S8C	5 MHz	390 or less
	BT8M05S8C	8 MHz	390 or less
	BT10M5S8C	10 MHz	390 or less

**Ispta: Spatial Peak - Temporal Average Intensity*

Battery:	DC 9 volts, Alkaline square type battery
Battery life:	Approx. 3 hours (Alkaline)
Automatic shut-off:	No signal: 3 min.
Probe button:	Power ON/OFF
Speaker output:	300 mW or more
External outputs:	
Headset:	Cuts off the speaker. (3.5 mm jack)
Dimensions:	Main unit: 78(W) x 141(L) x 27(H) mm
	(not including probe holder)
	Probe: 20(Diam.) x 105(L) mm
Weight:	Approx. 240 grams (including battery & probe)
Electrical safety:	Conform to IEC60601-1
	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
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

< Contents in package >

Standard:	Main unit
	Probe
	Carrying case
	Ultrasonic gel (AQUAULTRA BASIC)
	Battery
Option:	Neck strap (Except European Union Countries)

Cleaning

1. 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.

2. 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 “Cautions 7. Periodical safety checks by users” before using the unit.

Warranty

Guarantee period: **Frequency*

Main unit		Two(2) years
Probe	BT*M05S8C(A), BF8M15S8A, BP*M05S8A, VRP-*, LRP-*, BDP*MS8,	One(1) year
	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 *Except European Union Countries*	CRP-*H, CRP-20H1N, NRP-*H	Six(6) months
	NRP-10HF,NRP-20H1NF	Three(3) months
	Single use probe	Either one year from the date of purchase or 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.

Safety standards

The unit confirms to the following standards: IEC60601-1

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

Protection grade against electric shock : Type BF applied part

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The ES-100VX is intended for use in the electromagnetic environment specified below. The customer or the user of the ES-100VX should assume that it is used in such an environment.		
Emissions test	compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ES-100VX 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 B	The ES-100VX 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.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ES-100VX is intended for use in the electromagnetic environment specified below. The customer or the user of the ES-100VX 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	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8 kV 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	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	
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 100% for 250/300	Not applicable	

	cycles		
Power frequency (50Hz) Magnetic field Immunity 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 UT is the a.c. mains voltage prior to application of the test revel.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ES-100VX is intended for use in the electromagnetic environment specified below. The customer or the user of the ES-100VX 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	3Vrms 150 kHz to 80 MHz 1kHz 80%AM modulation 6Vrms in ISM bands(I/O cables < 3m excluded) Patient coupled ports tested with current clamp	3Vrms 150 kHz to 80 MHz 1kHz 80%AM modulation 6Vrms in ISM bands(I/O cables < 3m excluded) Patient coupled ports tested with current clamp	Portable and mobile RF communications equipment should be used no closer to any part of the ES-100VX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80MHz to 2,7GHz, 1kHz 80%AM modulation Table-9 (IEC60601-1-2:2014)	3 V/m 80MHz to 2,7GHz, 1kHz 80%AM modulation Table-9 (IEC60601-1-2:2014)	$d = 1,2\sqrt{P}$ 80 to 800 MHz $d = 2,3\sqrt{P}$ 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, 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 ES-100VX is used exceeds the applicable RF compliance level above, the ES-100VX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ES-100VX. 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

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CE 0123

May, 2018
Printed in Japan
080-00142-2. 4