# Sphygmomanometer and Sphygmograph

# VaSera VS-2000 Series

Ver. 03

# **Operation Manual**



- \* Before using the product, please read this manual thoroughly.
- \* Store this manual where it can be always referred to.





**A** CAUTION

Federal Law restricts this device to sale by or on the order of a physician.

#### **CAUTION**

- Only physician or persons instructed by physicians are allowed to use the equipment.
- The information contained in this document is subject to change without notice due to improvement in the equipment.

© 2015 Fukuda Denshi Co., Ltd.

No part of this document may be reproduced or transmitted in any form without the prior written permission of Fukuda Denshi Co., Ltd.

If this manual has pages missing or out of order, contact Fukuda Denshi for replacement.

#### **Preface**

This operation manual is a guide to the correct and safe use of the VaSera VS-2000 series.

Thank you for purchasing our product.

For details on this product or this manual, please contact your local Fukuda Denshi service representative.
This is an operation manual for the following device:  • VS-2000
A mark is used to indicate explanations of the functions of the toe blood pressure option.

# **Safety Notations**

The following safety notations are used throughout this manual. Each of these notations has a different meaning, as shown below.

Read the following information thoroughly to ensure proper, correct and safe use of the product.

<b>↑</b> DANGER	Failure to follow this message may result in death or serious injury to the patient or operator, damage the device, or create a fire hazard.
<b>↑</b> WARNING	Failure to follow this message may result in death or serious injury to the patient or operator or create a fire hazard.
<u> </u>	Failure to follow this message may cause injury or failure to the device.
$\triangle$	The mark is displayed on the main unit of the device to protect the device from damage, and is used throughout the explanations in this operation manual.
NOTE	A note is not related to product safety, but provides information about the proper usage methods to prevent incorrect operation and malfunction.

# An Example of Safety Symbol

$\Diamond$	Indicates prohibited actions. Refer to the instruction.
A	Indicates a matter of Danger, Warning, or Caution that calls attention for safety. Refer to the instruction.
0	Indicates mandatory or instructed actions. Refer to the instruction.

#### **Precaution from Fukuda Denshi**

Fukuda Denshi is liable for the safety, reliability, and performance of its medical devices only if: Maintenance, modifications, and repairs are carried out by authorized personnel. Components are used in accordance with Fukuda Denshi operating instructions.

If the device is used incorrectly and becomes unusable as a result, Fukuda Denshi is not liable for the malfunction. Use the device only for the purposes specified in this manual.

# **Safety Labels**

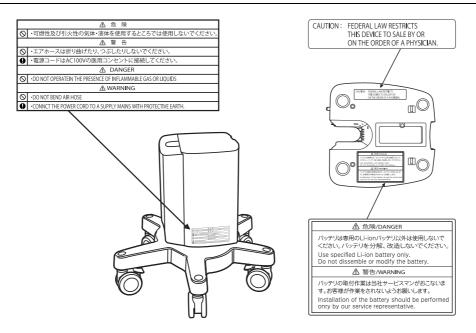
Warning (safety) labels are attached to this device to indicate precautions that need to be followed to ensure proper and safe use of the device. Make sure to follow the instructions of the warning labels attached to this device when operating the device. The positions of the labels attached to this device are indicated below.

#### **⚠** CAUTION



• Do not damage or erase the warning labels attached to the device.

These warning labels contain important information for handling and operating the device properly and safely. If any of these labels are damaged, it may not be able to ensure safety when using the device.



# Symbols on the Device

Below is a list of symbols used on this device.

A	Caution: Explained in this manual.
$\Diamond$	Indicates the potential equalization terminal.
$\sim$	Indicates the alternating current (AC) power supply.
모	Indicates the LAN connector.
S> M	Indicates the SD card slot.
<b>ورث</b>	Indicates the USB port.
I WI	Indicates a defibrillation-proof type CF applied part.
I	Indicates an operation explained in this operating manual.
<b>(3)</b>	Refer to this operating manual.

### Safety

#### Design Specifications

This device complies with ANSI/AAMI ES 60601-1: "Medical Electrical Equipment - Part1: General Requirements for Basic Safety and Essential Performance" and is classified as follows:

#### 1. Protection against electrical shock

Class I, Internally Powered Device.

#### 2. Degree of protection against electrical shock

Type CF applied part.

#### 3. Degree of protection against ingress of water

No special protection against ingress of water. (IPX0)

# 4. Degree of safety when using in air, flammable anesthetic gas, or in areas where oxygen, nitrous oxide or flammable anesthetic gas are used

To be used in environments without flammable anesthetic gas or other flammable substances.

#### 5. Operation Mode

Can be used continuously.

#### Preventive Maintenance

Preventive maintenance should be performed to ensure that the device can be used safely at all times and prevent various problems from occurring in future.

This maintenance needs to be performed at least once every 12 months.

Inspect the mainframe and all connectors and cables for any external damage.

If any of the following events occurs, perform maintenance immediately.

The device receives a strong impact due to dropping, etc.

Liquid is spilled on or into the device

The device does not function normally

The enclosure of the device is cracked, broken or damaged

Cables such as the power cable and lead wires have deteriorated in performance

Check all cables, devices and accessories for damage, leakage current and accuracy.

# **Non-Explosion Proof**

# **⚠** DANGER ■

 $\bigcirc$ 

 Never operate the equipment where flammable gas or fluid such as anesthetic, oxygen and hydrogen are used.

Explosion or fire may result.

0

 Never operate the equipment in the presence of flammable anesthetics, high concentration of oxygen.

This may cause an explosion or fire.

0

• Never operate the equipment inside a hyperbaric chamber.

This may cause an explosion or fire.

0

• Do not ground with a gas pipe.

Explosion or fire may result.

# **Using with MRI**

#### | ∕ NARNING



• Do not use this product with a magnetic resonance imaging (MRI) device.

This device may be pulled towards the MRI device. The local heating caused by the induced electromotive force may also cause burns to the patient or cause the performance of this product to deteriorate.

# **Using with Defibrillators**

# MARNING |



- · Use only the supplied lead cable when defibrillating.
- Do not touch this device during defibrillation.
- This device will return to standard operating mode within 10 seconds. The measurement accuracy will temporarily decrease during defibrillation, but it will not compromise the safety of patient and the device.

# **Application to Heart**

# **⚠** CAUTION



 Although this device has a type CF applied part, it is not designed to be applied directly to the heart.

# **Using with High Frequency Surgical Devices**

# **№** WARNING



 When using this devices with a high frequency surgical device (electrical scalpel), make sure the contact between the patient and the ground plate is secured.

If the connection is incomplete, the patient may suffer a burn at the electrode site.



• When using with electrical scalpels, make sure the contact between the patient and the ground plate can be sufficiently secured.

If the connection is incomplete, the current from the electrical scalpel may run into the electrodes of this device and the patient may suffer a burn at the electrode site.



Plug the electrical scalpel into a hospital grade outlet as far away as possible from the outlet
of this device. This will reduce interference from the electrical scalpel.

# **Using Accessories and Optional Accessories**

#### /N WARNING ■



- Use only the cables specified by Fukuda Denshi.
- Use of other cables may result in increase in emission or decrease in immunity.
- Contact your local Fukuda Denshi service representative for more information on connecting the cables.

#### **Device and Accessories**

### 



• Do not bend, crush or twist the air hose of the cuff.

The blockage of the hose will stop the cuff deflation, resulting in obstruction of the blood flow.



Connect the power cable to a hospital grade outlet.

Use the battery when operating in areas with no hospital grade outlet.

Use an outlet with a power supply sufficient for the power consumption of this device.



Use the battery when operating in areas with no hospital grade outlet.

Use an outlet with a power supply sufficient for the power consumption of this device.



• Never disassemble or modify the device.

Disassembly may cause a fire hazard or electric shock.



• Do not touch this device during defibrillation.

This may cause an electric shock.



Use only the specified lead cable.

The device may be damaged or become unsafe if a lead cable without a defibrillation protection function is used instead of the specified lead cable when using this device with a defibrillator.



• Make sure to use the specified PCG microphone (MA-310HDS(V)).

The device may become unsafe if an unspecified microphone is used.



• Contact your local Fukuda Denshi service representative when connecting other equipment to the device.

It is necessary to determine whether the device to be connected complies with IEC or ISO standards, related JIS safety standards or technology standards stipulated in the Electrical Appliance and Material Safety Act. If it does not, it must be of an equivalent safety level. Otherwise, danger such as electric shock may result to the patient and operator.

#### **Connection to Other Devices**

#### **№** WARNING



• Do not connect any unauthorized devices.

# **Disposal**

# **| MARNING** |



 When disposing of this product and accessories, contact a specialized waste disposal company

# **Connecting the Power Cable**

### MARNING ■



• When operating this device using an AC power supply, make sure to connect the power cable to a hospital grade outlet.

Use the battery when operating in areas with no hospital grade outlet.

• Multi-tap power outlets cannot be used as they may make the device unsafe for the patient and operator.

# Leakage Current

# **⚠** CAUTION |



• If the power cables of multiple devices are plugged into the same outlet, increase in leakage current may cause danger to the patient.



• A danger may occur if the patient is using a pacemaker or other electrical stimulator.

Follow the instructions in the operation manual of the pacemaker or other electrical stimulator.



• When using this device with other devices, perform equipotential grounding to prevent potential difference between the devices.

If potential difference occurs between the devices, danger may result to the patient and operator.



- Do not touch the electrodes of this device or the conductive part of the attached connectors. Touching these may cause danger to the patient.
- Do not touch the metal part of this device or the conductive part of the connector and the patient at the same time.

# **Precautions for Safe Operation of Medical Electrical Equipment**

#### **⚠** CAUTION |



 Although this device is a transportable equipment that is designed to be used in different areas, safe operation may be compromised if it is subjected to strong impact such as being dropped or getting caught in elevator doors during transportation.



• Do not use or store the device in an area where it will be subject to splashing water.

Otherwise, danger such as electric shock may result to the patient and operator.



• Do not drop the device or subject it to strong impact or vibration.

This may result in electric shock or a fire hazard.

Contact your local Fukuda Denshi service representative if this device is dropped or otherwise damaged.



• Do not subject the LCD screen to strong impact.

Doing so may cause damage.



 Do not allow the patient to come in contact with this device, other electrical devices or metals.

This may increase leakage current, which may result in danger to the patient.



 Do not insert the SD card or USB memory in reverse direction or use excessive force when inserting them.

This may damage this device and the media.



 Always hold the plug when removing cables. Do not pull on the cable. Do not insert or remove cables with wet hands.

This may cause electric shocks, short circuiting or injury.



Always use your fingers to operate the touch panel or keys.
 Using other items may cause damage such as scratching the surface of the touch panel.



• Do not use the touch panel with film or adhesive tape attached to it. It may cause malfunction or damage the touch panel.



• Remove dirt from the surfaces by wiping with ethanol on a soft cloth.



• Make sure to use the specified battery pack (BTE-001) when operating the device on battery power.

Otherwise, leakage, overheating or explosion may occur.



• If using the stand, do not use or store it where it will be subject to an inclination of 5 degrees or more.

The device and trolley may fall down, resulting in injury to the operator or damage to the device. Make sure that all 5 casters are locked when the device is in use or in a storage position. Otherwise, the trolley may move or fall down, resulting in injury to the operator or damage to the device.

#### [Inspections]



Perform daily checks to maintain safety.



Perform periodic inspections every 12 months to maintain safety.



• Check all cables, devices and accessories for damage, leakage current and accuracy.

To operate the device correctly, read the following precautions carefully.

- User should have a thorough knowledge of the operation before using this device.
- Pay attention to the following when installing or storing the device.





• Do not install or store in an area where the environmental conditions, such as atmospheric pressure, temperature, sunlight, dust, sodium, sulfur, will adversely affect the system.



• Take care to ensure stability with no inclination, vibration, or impact (including during transportation). Do not install on an unstable surface.



• Place the device with the base side downward. Do not allow other surfaces (such as the back or sides) to touch the floor.



• Do not install or store in an area where chemicals are stored or gases are evolved.



 Do not subject the device to excessive vibration or impact when moving to a new installation location.



Verify the power frequency, voltage and allowable current (or power consumption).



• Ensure proper grounding by connecting the accompanying power cable to the hospital grade outlet.



• To ensure the safety of medical devices, do not keep standard electrical devices in areas with patients.

Before operating the system, verify the following items:



· Verify the power voltage.



• Multi-tap power outlets cannot be used as they may make the device unsafe for the patient and operator.



• Check the cable connection and polarity of the device and its connectors to ensure proper operation of the equipment.



• Make sure the power system has adequate earth ground.



• Ensure that all cables and air hoses are correctly and safely connected.



• Pay special attention when the equipment is used in conjunction with other equipment as it may cause erroneous diagnosis and danger.



• Ensure that all cables directly connected to patients are correctly connected.

During operation of the system, verify the following items:



 Make sure that the electrodes and lead cord tips do not touch metal areas of the bed or other conductive items.



• Always observe the device and patient to ensure safe operation of the device.



• If you notice any abnormalities in the device or the patient, stop the device or take other appropriate measures to ensure the safety of the patient.



• Do not allow the patient to come in contact with the device.



Do not block the vents.

This may result in overheating or a fire hazard.



Do not drop the device or subject it to strong impact or vibration.
 This may result in electric shock or a fire hazard. Contact your local Fukuda Denshi service representative if this device is dropped or damaged.

# 



• Do not pull strongly on cables such as the lead cable and sensor cable.

After using the system, verify the following items:



• Unplug all the cables from the patient before turning OFF the power.



 When unplugging the cables, do not apply excessive force by pulling on the cord. Pull by the connector part of the cable.



• Keep the accessories and cables together in one place after cleaning.



Keep the device clean to ensure proper operation for the next use.



• If the device is damaged, stop the examination, label the unit "OUT OF ORDER" and contact our service representative.



· Do not remodel the device.



 If using a defibrillator while using this device, check the paste volume, output energy, etc. to prevent the risk of burning the patient. Also, verify that each equipment is properly grounded.

[Precautions when Using the SD card and USB memory]



• Turn OFF the power when inserting/removing the media.

An error may occur if the media is inserted or removed during operation. If the media needs to be inserted or removed while the power is ON, make sure that the icon indicating the media status has changed before operating the device.



• Use only the media specified by Fukuda Denshi.

Using unspecified media may cause failure to the device, such as damage or loss of waveform data.

The warranty does not cover data retrieval or repair that is required when problems such as these are caused by using unspecified devices.

Various icons are displayed in the device status display area when inserting specified media.



• Do not remove the media while data is being saved to the media.

The data may become unreadable. This may include the data that was already saved in addition to the data that was being saved at the time.



 If connecting an extension cable to the USB port, use an extension cable that is no longer than 2m. Do not supply power via the USB port.

The device may not work properly if a cable longer than 2m is used.

Other precautions specific to each media can be found on the pages concerning these media. Make sure to read these precautions in addition to those on this page.

# **Precautions Concerning the PCG Microphone**

# **⚠** CAUTION |



• Take measurements in a quiet room with no noise or vibration in the surrounding area.



• Do not drop the PCG microphone, subject it to strong impact or pull strongly on the cable.

# **Precautions Concerning the Cuffs**

### **⚠** CAUTION |



Wash only the cuff cover in water, and clean only the surface of the cuff. Washing the cuff
in water may cause water to get inside the cuff, which may damage the cuff or cause
deterioration in performance.



• Select the appropriate cuff size according to the patient's brachial/ankle circumference.

# **Precautions Concerning the Toe Cuffs**

#### 

#### <CUF-139>



• This product is made of synthetic rubber and does not contain natural rubber. Synthetic rubber is unlikely to cause allergic reactions such as itchiness, redness, hives, swelling, fever, breathing difficulties, asthma-like symptoms, low blood pressure or shock, but if such symptoms do occur, stop using the device immediately and consult a doctor.



• Do not pressurize toe cuffs before wrapping them around toes. Otherwise, they may burst.



• Do not wrap the toe cuffs too loosely or at an angle. Otherwise, they may burst.

#### **Precautions for Storage**



• Store this product in a cool area. Avoid areas with direct sunlight, UV rays, high temperatures and high humidity.



• Do not store this device together with volatile chemicals.

#### **Precautions for Disinfection**



• Disinfect the cuffs by wiping gently with water or alcohol. Do not place in an area with direct sunlight, UV rays or high temperatures when drying.



• Do not use disinfection methods such as high-pressure steam disinfection, gas disinfection or radiation disinfection.

#### **Usage Count**



• Even when these precautions are followed, the cuffs cannot be used more than 200 times.

# **Precautions Concerning the Limb Cushion (Optional)**

# ♠ CAUTION



• The inner part under the cover cannot be washed.



• Do not open the fastener of the inner part under the cover. This will scatter the filling.



The cover cannot be ironed.





· Do not wash the cover with chlorine detergent.



Dry the cover by hanging it in the shade.



Avoid leaving the cover folded for long periods of time as this will leave creases.



• The length, width and height of the cushion (and cover) differ. Make sure to put the cover on the right way after washing.

# **Precautions Concerning the LAN**

#### ♠ CAUTION |



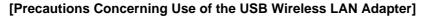
• The devices to be connected to the network must be located outside the patient environment. (IEC 60601-1-1: 2000 / EN 60601-1-1: 2001)



 Use only Ethernet hubs specified by Fukuda Denshi when connecting this device to the network (LAN).



Do not use a LAN cable longer than 50m when connecting this device to the network (LAN).





 Turn OFF the power of this device before inserting the USB wireless LAN adapter. Never remove the wireless LAN adapter during wireless LAN communication.
 An error may occur if the wireless LAN adapter is inserted or removed during operation.



 Do not use this device in areas with static electricity or electromagnetic interference, in rooms insulated with a metal door or near devices that emit radio waves (microwaves, thermotherapy devices, etc.) The device may not be able to receive a signal in some operating environments.



• Due to the characteristics of radio waves, the communication range and communication speed vary depending on the installation location and operating environment.

[Precautions Concerning Use With Other Devices when Using the Wireless LAN Adapter]



 When using a wireless LAN, make sure to check the operation of any medical devices nearby. Stop using the wireless LAN immediately if unexpected waveform noise occurs or interference occurs in surrounding equipment.

[Precautions Concerning the Wireless LAN Adapter]



Use the wireless LAN adapter specified by Fukuda Denshi.

If an unspecified wireless LAN adapter is used, it may not be possible to communicate with the DMS, and the main unit of the device may even be damaged. The warranty does not cover data retrieval or repair that is required when problems such as these are caused by using unspecified devices.

#### [Prior Precautions Concerning Static Electricity]



- The wireless LAN adapter is extremely delicate and is very vulnerable to damage from electrostatic discharge. If the human body comes into contact with the metal part of the wireless LAN adapter, static electricity may be discharged onto the parts or into the circuit of the wireless LAN adapter, which may damage the wireless LAN adapter. Make sure to follow the precautions below to protect the wireless LAN adapter and this device from damage from static electricity.
  - Remove static electricity from the body before using.
  - Hold the end of the wireless LAN adapter when handling it. Never touch the metal part of the wireless LAN adapter.

# Storage and Cleaning

# **⚠** CAUTION



· Do not open the housing.



· Remove dirt from the surfaces of the housing by wiping with ethanol on a soft cloth.



• Perform daily inspection to maintain safety.



• Perform periodic inspection every 12 months to maintain safety.



• Check all cables, devices and accessories for earth impedance and accuracy.



• If the device has not been used for a while, make sure to check that the device operates properly and safely before using it.



• Do not allow alcohol or other liquids to enter the device.



• If the optional software is installed, make sure to keep the software (SD card). If the main unit needs to be repaired, send the optional software (SD card) to Fukuda Denshi along with the main unit.

# **Transportation**

#### **!** CAUTION |



• Pack this device in packaging specified by Fukuda Denshi when transporting.



• This device has no handle. Carry it with both hands when transporting.

# **Cleaning and Disinfecting the Device**

Use the following procedures to clean and disinfect the enclosure of the device.

#### Cleaning

# **⚠** CAUTION



 Immerse a cloth in a solution of domestic neutral detergent and water, wring it out thoroughly and then wipe the main unit.



. Do not use ether or benzine as they may damage the enclosure.

# Disinfecting

### **⚠** CAUTION



• Wipe the device with a cloth that has been thoroughly wrung out after being sprayed with a solution of alcohol and water or glutaraldehyde. Then, wipe with a soft lint cloth.

# **Cleaning the System Devices**

### **⚠** CAUTION ■



• Clean the connected devices according to the instructions in their respective manuals.

# **Precautions for Safe Operation under Electromagnetic Interference (EMC)**

#### **♠** CAUTION

#### ■ Malfunctions Due to EMC

While this device complies with the IEC 60601-1-2 (2004) and JIS T 0601-2-25 (2006) safety standards, malfunctions may occur if there are strong electromagnetic (radio) waves nearby that exceed the limit. Please take the necessary countermeasures in such cases.

#### ■ Effects of Emitted Electromagnetic Interference

- The use of mobile phones may cause malfunction.

  Mobile phones and radio sets should be turned OFF in the facility where the medical device is located.
- The use of microwave therapy devices nearby or in an adjacent room may affect the waveform. Keep these devices a sufficient distance apart according to the Guidance on Electromagnetic Compatibility.

#### ■ Effects of Burst and Conducted Electromagnetic Interference

High frequency noise interference may occur from other devices through the power outlet. Check the source of the noise and stop the device that is causing the noise if it is possible to do so. If it cannot be stopped, take countermeasures to change the path of the noise, such as using a filtering device.

#### ■ Effects of Static Electricity

Malfunctions may be caused by the discharge of static electricity in dry environments (rooms), such as in winter. Measures such as humidifying the room should be taken, and both the operator and the patient should remove any static electricity before the device is used.

#### ■ Effects of Surges (Lightning)

A lightning nearby may induce excessive voltage to the equipment. Unplug the power cable from the AC outlet in such situation.

Use an uninterruptible power supply system if available.

# **Precautions Concerning Printing of Interpretation**

# **⚠** CAUTION

The interpretations printed from this device may indicate possible arterial stenosis or occlusion, possible arteriosclerosis or high blood pressure based on measurements such as the ankle-brachial index (ABI), cardio-ankle vascular index (CAVI) and brachial blood pressure. However, please note that some patients with latent diseases may have measurements within the normal range, and some patients with no diseases may have abnormal measurements.

Clinical diagnoses of diseases such as arteriosclerosis or arteriosclerosis obliterans should therefore combine measurements from this device with other interpretations.

Other precautions specific to each media can be found on the pages concerning these media. Make sure to read these precautions in addition to those on this page.

### • EMC Guidance

This device complies with the Safety Standard IEC 60601-1-2 (2004). However, if portable transmitter or wireless LAN equipment is used extremely nearby, the electromagnetic influence may largely exceed the compliance level and may cause unexpected phenomenon such as noise interference on the waveform, etc.

This device should be used in a location specified by each medical institution.

If any unexpected noise interference on the waveform or failure to the peripheral device occurs, stop using the device and follow the instruction of the technical engineer.

The following is the information relating to EMC (Electromagnetic Compatibility). (When using this device, verify that it is used within the environment specified below.)

#### • Compliance to the Electromagnetic Emissions

The VS-2000 is intended for use in the electromagnetic environment specified below.

Emission Test	Compliance	Electromagnetic Environment/Guidance
RF emissions: CISPR 11	Group 1	The VS-2000 uses 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 VS-2000 is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

# • Compliance to the Electromagnetic Immunity (1)

The VS-2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the VS-2000 should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment/Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±2, 4, 6 kV: contact ±2, 4, 8 kV: air	±2, 4, 6 kV: contact ±2, 4, 8 kV: air	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2kV: power supply lines ±1kV: input/output lines	±2kV: power supply lines ±1kV: input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge: IEC 61000-4-5	±0.5, 1kV: differential mode ±0.5, 1, 2kV: common mode	±0.5, 1kV: differential mode ±0.5, 1, 2kV: common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycles 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub> (95% dip in U <sub>T</sub> ) for 5 sec.	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycles 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub> (95% dip in U <sub>T</sub> ) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment.  If it is required to continuously operate the VS-2000 during power failure, it is recommended to operate on an uninterrupted power supply or a battery (optional).
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3A/m	3A/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 AC mains voltage prior to application of the test level.

#### Compliance to the Electromagnetic Immunity (2)

The VS-2000 is intended for use in the electromagnetic environments specified below. The customer or the user of the VS-2000 should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment/Guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz 3 V/m	3Vrms	PPortable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the
Radiated RF IEC 61000-4-3	80MHz to 2.5GHz	3 V/m	recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended Separation Distance: $d = 1.2 \sqrt{\textbf{P}} \qquad 26 \text{MHz to } 80 \text{MHz}$ $d = 1.2 \sqrt{\textbf{P}} \qquad 80 \text{MHz to } 800 \text{MHz}$ $d = 2.3 \sqrt{\textbf{P}} \qquad 800 \text{MHz to } 2.5 \text{GHz}$ 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 strengths from fixed RF transmitters, as determined by an electromagnetic site survey *1, should be less than the compliance level in each frequency range *2.  Interference may occur in the vicinity of 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.

- 1 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 can not 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 VS-2000 is used exceeds the applicable RF compliance level above, the VS-2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VS-2000.
- 2 Over the frequency range 150kHz to 80MHz, field strength should be less than 3V/m.

# Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the VS-2000

The VS-2000 is intended for use in electromagnetic environments where radiated RF interference is controlled. The customer or the user of the VS-2000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VS-2000 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum	Separation Distance (m) based on Transmitter Frequency			
Output Power of Transmitter (W)	26 to 80MHz d = 1.2 √ <b>P</b>	80 to 800MHz d = 1.2 √ <b>P</b>	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80MHz and 800MHz, 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.

#### •Interference generated by electrical scalpels

When used with an electrical scalpel having the specifications described below, this device is protected against any malfunctions that the resulting interference could produce.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment/Guidance
Incision mode	Output power 300W	Output power 300W	When an electrical scalpel generates high-frequency
Coagulation mode	Output power 100W	Output power 100W	energy the waveform noise level that is indicated and recorded by the instrument increases. However, it returns to normal levels less in 10 seconds or less after the high frequency energy ends.
			Usable analysis results may not be obtainable for analyses made of waveforms during periods when high-frequency energy is generated.

# **Messages and Countermeasures**

The displayed error messages along with the countermeasures are listed below.



If the error message is still displayed even after trying the countermeasure, stop the examination and contact your local Fukuda Denshi service representative.

#### Α

Message	Cause	Countermeasure
Abnorm BP Meas.	The BP measurement failed.	Make sure that the cuff is properly attached, patient is relaxed, and start the measurement again.
Air Leak Error	During the pulse wave acquisition, the cuff pressure decreased to 5mmHg and below.	Inspect the cuff and air hose for damage or breakage.
	The inflation time to reach the target value has exceeded the specified time.	<ul> <li>After the cuff deflates, press the [START] key to start the measurement again.</li> <li>Inspect the cuff and air hose for damage or breakage.</li> </ul>
	Air is leaking due to loose air connector.	Reconnect the air connector correctly.

#### В

Message	Cause	Countermeasure
Battery is running low. Please recharge the battery.	During battery operation, the power will automatically turn OFF when the battery capacity becomes low.	Connect the power cable and operate the device on AC power, or charge the battery.
Battery operating. Please switch to the AC power supply.	During battery operation, series examination was started.	Series examination cannot be performed during battery operation to avoid measurement interruption caused by the low battery. Connect the power cable and switch to AC power operation.
Because re-inflation is set to OFF, re-inflation cannot be done.	The cuff did not re-inflate when necessary as "BP Re-Inflation" was set to OFF.	Set the "BP Re-Inflation" to ON, or raise the pressure value.

#### C

Message	Cause	Countermeasure
Cannot send to host.	The data could not be sent to the DMS (Data Management System).	When this message is displayed, the data is not sent to the DMS (Data Management System). Check the communication settings. If no problem can be found on the communication settings, contact your local Fukuda Denshi service representative.
Cannot write due to insufficient space on SD card.	The data could not be saved on the SD card as the maximum number of recordable data has been reached.	When this message is displayed, the data is not recorded. Replace with a new SD card and write the data again.
Cannot write due to insufficient space on USB mem.	The data could not be saved on the USB memory as the maximum number of recordable data has been reached.	When this message is displayed, the data is not saved. Replace with a new USB memory and save the data again.
Check BP zero	An abnormality has occurred in the pressure sensor unit.	<ul><li> Check whether there is air in the cuff.</li><li> Turn the power OFF and then turn it back ON.</li></ul>
Communication error has occurred.	An error occurred during communication with the DMS (Data Management System).	When this message is displayed, the device is not connected to the DMS (Data Management System). Contact your local Fukuda Denshi service representative.
Cuff Error	An error occurred during inflation.	Inspect the cuff and air hose for damage or breakage.

# Ε

Message	Cause	Countermeasure
Enter the AF distance.	The AF value is not entered.	<ul> <li>Enter the AF value.</li> <li>To enter this value by using the patient's height, select [Height] for "Distance Input Method" (PW/BP Examination Settings).</li> </ul>
Exc. Infl. Time	The BP measurement timed out and activated the safety device.	Inspect the cuff and air hose for damages or breakage.
Exceeded Max P.	Due to abnormal increase of cuff pressure during the measurement, the safety device activated.	Inspect the cuff and air hose for damage or breakage.

#### F

Message	Cause	Countermeasure
Failed to connect.	Initial connection to the DMS (Data Management System) failed.	Check the DMS status and connection to the DMS. Also check the communication settings with the DMS.
Failed to delete data.	Failed to delete the examination data.	There may be a problem with the external media. Contact your local Fukuda Denshi service representative.
Failed to format SD card.	The device failed to format the SD card.	SD card failure can be considered. Contact your local Fukuda Denshi service representative.
Failed to format USB mem.	The device failed to format the USB memory.	USB memory failure can be considered. Contact your local Fukuda Denshi service representative.
Failed to load settings.	Failed to load the settings from the SD card.	Make sure that the correct SD card is used which the settings are saved.  If the correct SD card is used, a failure of the SD card can be considered. Contact your local Fukuda Denshi service representative.
Failed to retrieve patient information.	The patient information could not be retrieved.	Make sure that the correct media is used.
Failed to save the settings.	Failed to save the settings to the SD card.	There may be a problem with the SD card. Contact your local Fukuda Denshi service representative.
Failed to save to SD card.	The device failed to save the data to the SD card.	SD card failure can be considered. Write down the error code at the end of the message and contact your local Fukuda Denshi service representative.
Failed to save to Shar. Folder.	The file could not be saved to the shared folder.	<ul><li> Check if the network connection is correct.</li><li> Check if the shared folder settings are correct.</li></ul>
Failed to save to USB mem.	The device failed to save the data to the USB memory.	USB memory failure can be considered. Write down the error code at the end of the message and contact your local Fukuda Denshi service representative.

#### ı

Message	Cause	Countermeasure
Input height.	The height has not been entered.	Enter the height.
Input L as vascular length.	The vascular length value L is not entered.	Enter the vascular length value L.     To enter this value automatically by calculating from the patient's height, select [Height] for "Distance Input Method" (PW/BP Examination Settings).

Message	Cause	Countermeasure
Low BP Error	The BP value is below the measurable limit.	Make sure that the cuff is properly attached. If the error is not caused by the cuff, use other means to perform the measurement.
Low PW Ampl.	The blood pressure could not be measured because the pulse wave was too small.	Make sure that the cuff is properly attached. If the error is not caused by the cuff, use other means to perform the measurement.

# N

Message	Cause	Countermeasure
No data selected.	A process was attempted without selecting a data.	Select a data before performing the process.

# 

Message	Cause	Countermeasure
Operation has timed out.	The time limit for communication with the DMS (Data Management System) was exceeded.	Check the connection and start the connection again.  If this message appears frequently, contact your local Fukuda Denshi service representative.

# P

Message	Cause	Countermeasure
Please set DMS.	DMS is not set.	Set the DMS.
Please set SD card.	SD card is not inserted.	Insert an SD card.
Please set USB mem.	USB memory is not inserted.	Insert a USB memory.

# R

Message	Cause	Countermeasure
Replace the backup	The backup battery for the clock is running	The backup battery needs to be replaced. For
battery. The clock will be	out.	details, refer to "Chapter 12 Maintenance and
initialized. (Contact your		Inspection".
dealer for details.)		

# S

Message	Cause	Countermeasure
Safety Operat.	Due to abnormal increase of cuff pressure	Inspect the cuff and air hose for damage or
	during the measurement, or due to	breakage.
	measurement time-out, the safety device	
	activated.	

# T

Message	Cause	Countermeasure
The analysis range contains some calibration waves. Analysis cancelled.	Some calibration waves are included in the specified analysis range.	Specify a range that does not contain calibration waves.
The battery voltage is too low. Cannot access Media.	During battery operation, the device could not access the media due to low battery level.	Connect the power cable and operate the device on AC power, or charge the battery.
The examination data was not saved.	The examination data was not saved when proceeding to the next examination.	Save the examination data before proceeding to the next examination.
There is no relevant data.	There was no data found on the DMS (Data Management System).	Check the details of the data requested to the DMS (Data Management System).
There is not enough space on SD card. Please replace the media with another one.	There is not enough space on the SD card to save the data.	Replace with an SD card with enough capacity.

Message	Cause	Countermeasure
There is not enough space on USB mem. Please replace the media with another one.	There is not enough space on the USB memory to save the data.	Replace with a USB memory with enough capacity.
To not run out of battery, the power supply will be switched off automatically.	During battery operation, the power will automatically turn OFF if the operation is not performed within the specified duration.	Turn ON the power again.

#### V

Message	Cause	Countermeasure
Valve error	Cuff depressurization or deflation took too	Inspect the cuff and air hose for damage or
	long.	breakage.

# **Table of Contents**

An Example of Safety Symbol	
Safety Labels	
Symbols on the Device	
Safety	
Non-Explosion Proof	
Using with MRI	
Using with Defibrillators	
Application to Heart	
Using with High Frequency Surgical Devices	
Using Accessories and Optional Accessories	
Device and Accessories	
Connection to Other Devices	
Disposal	
Connecting the Power Cable	
Leakage Current	
Precautions for Safe Operation of Medical Electrical Equipment	
Precautions Concerning the PCG Microphone	
Precautions Concerning the Cuffs	
Precautions Concerning the Toe Cuffs	
Precautions Concerning the Limb Cushion (Optional)	10
Precautions Concerning the LAN	11
Storage and Cleaning	12
Transportation	12
Cleaning and Disinfecting the Device	12
Cleaning the System Devices	
Precautions for Safe Operation under Electromagnetic Interference (EMC)	13
Precautions Concerning Printing of Interpretation	13
●EMC Guidance	
Messages and Countermeasures	19
A	19
В	19
C	
E	
F	
l	
L	
N	
O	
P	23
R	
S	
T	_
V	_
Table of Contents	
er 1 Preface	1-1
Function of This Device	
Main Features	
Product Configuration of the VS-2000	
Accessories	
Accessory Package	1-5
	25

Safety Notations ......1

	PCG Microphone	
	BPU-100 NIBP/Pulse Wave Unit (Optional)	
	ASV-05U Four-Limb Blood Pressure Package (Optional)	
	ASV-06 Toe Blood Pressure Package (Optional)	
	Names of Parts and Their Functions	
	Main Unit	
	Display Unit	
	BPU-100 NIBP/Pulse Wave Unit	
	Description of the Screen	
	How to View the Icons	1-12
Chap	oter $2$ Installation	2-1
	Cautions when Selecting the Installation Location	2-1
	Installing the Battery (Optional)	2-2
	Installation	2-2
	Cautions When Using the Battery	
	Charging	
	Operating the Device on Battery Power	
	Installing the Main Unit and Display Unit on a Stand	2-5
	Connecting the Cables, Hoses, Cuffs and PCG Microphone	2-8
	Connecting the Power Cable	
	Connecting the Cuffs (2-Channel Examination)	
	Connecting the PCG Microphone	
	Storing the Cuff Holders and PCG Microphone	
	Installing Optional Devices	
	Connecting the Cuffs (4-Channel Examination)	
	Turning the Power ON and OFF	2-12
	To Turn ON the Power	2-12
	To Turn OFF the Power	
	Acquiring the Date and Time	2-14
	Basic Operations	2-15
	Changing the Examination Type	
	Displaying the Menu	
	Connecting to the Network	
	Example of Network Configuration	
	Network Settings (Wired LAN)	
	Settings for External Printer Output	
	When Using a Network Printer	
	Settings for Saving PDF Files	
	Network Settings (If Using a Shared Folder)	
	Auto Output Selection	
	Manual Output	2-22
Chap	oter $oldsymbol{3}$ Pre-Examination Preparations	3-1
•	Attaching the Cuffs	
	Attaching the Cuffs (Standard 2-Channel Examination)	
	Using the Limb Cushion (Optional, 2-Channel/4-Channel Examination)	
	Attaching the PCG Microphone	
	Attaching the Fog Microphone	
Cha <u>r</u>	oter $4$ Entering Patient Information	A 4
unap		4-1
	Patient Data Categories	4-1

	Entering the Basic Information	4-3
	Loading Information from the DMS (Master ID)	4-8
	Using Patient Information Registered to an SD Card (Patient File Selection)	
	Registering the Patient Information	
	Loading the Patient Information Using the ID Number	
	Loading the Patient Information by Specifying the Patient	
	Searching the Patient Information Using Search Condition	
	Deleting the Unnecessary Patient Information	
	Using Patient Information from Examination Data Saved to the SD Card (Load Pas	
Chap	oter $5$ Blood Pressure and Pulse Wave Examinations (CAVI/A	
Stand	dard Mode	5-1
	Measurement Preparations	5-2
	Home Display	5-3
	Function Buttons Used in Examinations	
	Measuring CAVI/ABI	
	(Standard 2-Channel Examination)	5-5
	Measuring CAVI/ABI/TBI	
	(4-Channel/6-Channel Examination)	5-8
	Attachment Site Guide	
	Waveform Length of Pulse Wave	
	Real Time CAVI Check	
	Auto Extension	
	CAVI Check Result Display	
	Examination Result Display	
	Changing the Measurement Content	
	Checking and Changing the Measurement Items and Sites	
	Setting Blood Pressure Measurements Manually	
	Setting Sensitivity Manually	
	Entering Blood Vessel Length	
	To Ensure Accurate Measurement	
	Measuring CAVI (Manually)	
	Manually Capturing and Measuring Waveforms	
	Simple CAVI Measurement	
	Description of the Reports	
	Types of Reports Color Reports	
Chap	oter $6$ Blood Pressure and Pulse Wave Examination: Simple M	lode 6-1
	Measurement Content	
	Measurement Procedure	6-2
	Examination Result Display	6-5
	How to Interpret Reports	6-7
	Color Reports	6-7
Chap 7-1	oter $7$ Blood Pressure and Pulse Wave Examinations: Other F	unctions
	Correcting the Patient Information	7-1
	Correcting the Boundaries for CAVI Measurement	
	Using the Compare Waveforms Function	
	<del>-</del>	

Recalculating the ABI/TBI	7-4
Series Examination	7-5
About the Series Examination	7-5
Setting the Examination Type	7-5
Measurement Procedure	
Charter & Brackiel Blood Bracerra Eversinations	0.4
Chapter 8 Brachial Blood Pressure Examinations	
Measurement Preparations	
Home Display	8-2
Function Buttons Used in Examinations	8-4
Measuring Blood Pressure	8-5
Examination Result Display	8-6
How to Interpret Reports	8-8
Entering the BP Examination Result in the Patient Information	
Convenient Functions	
Chapter 9 File Transfers	9-1
Functions	
Handling Media	9-1
Precautions when Using the SD Card and USB Memory	
Files and Folders	
Inserting the SD Card	
Function Buttons Used in These Operations	9-3
Initialization	9-4
Saving Examination Data	9-5
Methods for Saving Data	
Media that can be Used for This Operation	
Saving	
Loading Examination Data	9-8
Loading	9-8
Searching for Data	
Printing Reports	
Changing the Media	
Printing the Data List	
Clearing All Data Selections	
Deleting Examination Data	
Deleting Data from the List	
Restoring Deleted Data	
Correcting Examination Data	
Copying Examination Data	
Copying	
Naming Folders	
Naming	
Printing the Folder List	
Changing the Folder	
Changing the Folder	
Communication History	
Printing the Communication History  Selecting Communication History Data	
Erasing the Communication History	
Reports	9-21

Chapt	er $10$ Recording Daily Reports	10-1
	Content of Daily Reports	10-1
	Function Buttons Used in These Operations	10-2
	Recording a Daily Report	10-2
Chapt	er 11 Settings of This Device	11-1
-	Overview of Settings	
	Function Buttons Used in These Operations	
	Operations Used to Configure Settings	
	Performing Operations in the Settings Display	
	Selecting Setting Values	
	Selecting Items by Touching Buttons	
	Specifying Settings by Using Sliders	11-3
	Entering Numbers	
	Entering Text	
	Setting the Examination Method	
	Equipment Control Settings	
	General/Power	
	Buzzer Control	
	Print	
	PDF/XML	
	Localization	
	Patient Information Settings	
	General/ID-A.C.	
	Department  Medicine - Technician	
	File Settings	
	General	
	Printing	
	Communication Settings	
	General	
	DMS Settings	
	Printer	
	Settings for Blood Pressure and Pulse Wave Examinations	
	Pulse Wave: General	
	File	11-17
	Pulse Wave Examination	11-18
	BP Examination	
	Print	
	Settings for Brachial Blood Pressure Examinations	
	Brachial BP: General	
	File	
	Brachial BP Settings	
	Registering Examinations	
	Changing the Examination Order	
	Selecting the Examination on Startup	
	Adding a New Examination	
	Deleting an Examination Copying an Examination	
	Registering a Series Examination	
	Saving and Initializing the Settings	
	Saving Settings to an SD Card	
	Saving Codes to an SD Card	
	Initializing Common Settings	
	5	. — -

Initializing Each Setting	11-26
Chapter 12 Maintenance and Inspection	12-1
Daily Inspection	12-1
Daily Inspection Procedure	12-1
Periodic Inspection	12-2
Periodic Inspection Procedure	12-2
Electrical Safety Inspection Methods	12-6
About the Consumable Parts	12-9
Replacement Period of Consumable Parts	12-9
Cleaning and Disinfection	
Cleaning and Disinfecting the Device	12-9
Cleaning the Accessories	
Replacing the Built-in Battery	
Replacing the Clock Battery	
When error messages are displayed	
Chapter 13 Appendix	13-1
Main Specifications	
Measurements	
Blood Pressure and Pulse Wave Examinations	
Printed Messages	
Optional Accessories	
Example of Combinations of Medical Devices and Non-Medical Devices	
Index	
Inspection List	13-13 12 <sub>-</sub> 15

# **Chapter 1 Preface**

This chapter provides basic information to be aware of before using the device, such as the merits of the device and the names of the parts.

# **Function of This Device**

#### VS-2000 (Intended Use)

The device measures the non-invasive blood pressure in all four limbs to simultaneously obtain measurements such as PCG and four limb pulse waves. This makes it possible to examine arterial extensibility and the degree of blood flow disorders in blood vessels in the lower limbs of a patient.

The device includes a PCG and BPU-100 NIBP/Pulse Wave Unit as standard features and can measure blood pressure in all four limbs with two channels. Another BPU-100 can be added to measure blood pressure in all four limbs with four channels. It is also possible to measure blood pressure in the toes by connecting another BPU-100 to the IB connector.

#### BPU-100 NIBP/Pulse Wave Unit (Optional)

A unit for measuring non-invasive blood pressure and pulse wave with two channels. Adding this makes it possible to simultaneously measure the left and right brachium and ankle blood pressure on both sides or measure blood pressure in the toes.

#### Main Features

#### CAVI (Cardio-Ankle Vascular Index)

Independent of blood pressure, the Cardio-Ankle Vascular Index calculates the specific stiffness of arterial walls. The CAVI is also useful for time-serial observation of medication effects.

This device measures the following 2 types of CAVI.

(1)R-CAVI: CAVI between the heart valve and right ankle artery, calculated from measurements of PCG (heart sound II) and plethysmograms taken using cuffs applied to the right brachium and right ankle.

(2)L-CAVI: CAVI between the heart valve and left ankle artery, calculated from measurements of PCG (heart sound II) and plethysmograms taken using cuffs applied to the right brachium and left ankle.

#### Four-Limb Blood Pressure

The device measures non-invasive blood pressures of brachia and ankles simultaneously. It also allows selection of any brachium and ankle for measurement.

#### BPB (BP Balance)

The BPB is a 2D graph showing the blood pressure measured in the ankles and that measured in the brachialis muscles. It allows the balance between the blood pressure in the upper and lower limbs to be seen at a glance, making it easy to detect stenosis and occlusion in the limb arteries.

#### • ABI (Ankle-Brachial Pressure Index)

The ABI is an index indicating the degree of stenosis or occlusion of the lower limb artery due to peripheral arterial disease (PAD). A value of 0.90 or less indicates the probable presence of occlusion or stenosis.

# • TBI (Toe Brachial Index) T

TBI is an index to evaluate blood flow disorders from the ankles to the peripheral arteries.

#### CAVI measurement without ECG

CAVI is calculated from the PCG and pulse wave, meaning that ECG electrodes do not need to be attached.

#### Register Examination/Series Examination

Unique examinations can be created and recorded based on pulse wave examinations. This makes it possible to tailor examinations to the conditions of the facility. It is also possible to create series examinations, in which up to three examinations selected by the user can be performed successively. This series examination will speed up the testing.

#### Color LCD Monitor

A color LCD monitor with a wide viewing angle is used to display the waveforms clearly. The direction of the monitor can be changed so that the waveforms can be viewed on the screen during tasks such as attaching the sensors. The display also makes it possible to easily check patient information, examination results and device statuses.

#### • Capacitive Touch Panel

The device has a capacitive touch panel. This can be operated with a lighter touch than conventional touch panels.

#### Color Printing

Examination reports can be printed in color using a printer on the network.

# Simple Examination Mode (Only for 2-channel blood pressure and pulse wave examination)

First-time users of the VS-2000 are guided through operations by the machine.

The Simple Examination Mode is available only when English is selected as the language.

#### CAVI Indicator

An indicator is displayed, showing the CAVI waveform quality in real time.

#### Freeze

During CAVI examinations, it is possible to obtain up to 100 seconds of waveform data and select and measure any continuous heart rate from the screen while viewing the CAVI indicator.

In the event of arrhythmia or abnormal heart rate caused by movement of the body, this can be viewed and normal heart rate can be selected.

#### Auto Extension

The PCG and pulse wave quality necessary for CAVI measurement are checked in real time and the optimum waveform is obtained automatically.

#### Wavelength

The waveform acquisition time can now be extended from the standard 5 seconds to 8 or 16 seconds and CAVI is now calculated for a larger number of beats to improve the accuracy of the measurements.

#### • Time Series Waveform Comparison of Plethysmogram (PVR) Waveform

The device can print PVR waveforms together in a single report to make it easy to view changes to the PVR waveform over time.

#### Edit Waveform Division Points

The positions of the division points in the waveforms can be edited.

#### Brachial BP Examination

It is possible to perform simultaneous blood pressure measurements of both brachialis muscles, measure blood pressure multiple times and calculate averages.

#### Long-term Trends

Changes to CAVI values over an extended period (up to 50 measurements) can be printed in a report.

#### Filing and Report Preview

Pulse wave examinations with waveforms and measurement values can be stored in the SD card or USB memory set in the device. The stored data can be searched and printed at any time, and examination results or a color report preview can be displayed on the screen.

#### Network

In addition to the wired network, the optional wireless LAN adapter can be attached to connect to the network without worrying about cables.

#### PDF File

A PDF file of the examination report can be filed on the SD card or USB memory. Pulse wave examination reports can also be stored in a shared folder on the network.

#### Computer-based Data Management

Measurement data from multiple VS-2000 can be managed on a computer by connecting the devices and the computer to the network. Data can be registered, searched, displayed and printed.



This requires optional Data Management System (DMS) (VSS).

#### Battery (Optional)

A battery can be mounted to perform up to 70 minutes of pulse wave examinations in areas where the device cannot be powered by a hospital grade outlet.

#### Stand (Optional)

A new design of stand is used to prevent the cables and hoses from becoming tangled, allowing easy operation.

# **Product Configuration of the VS-2000**

Below are the product configuration of the VS-2000 and the measurements that can be performed by adding the optional items.

	Optional		Measuring Items		
	BPU-100 + Four-Limb BP Package (ASV-05U	BPU-100 + Toe BP unit Package (ASV-06)	CAVI	Four-Limb Blood Pressure ABI	Toe Blood Pressure TBI
VS-2000 (Standard Set)	No		Yes	*	No
	Yes	No	Yes	Yes	No
VS-2000 +	Yes	Yes	Yes	Yes	Yes
Optional	Yes	No	Yes	Yes	No
	Yes	Yes	Yes	Yes	Yes

<sup>•</sup> BPU-100 + Four-Limb Blood Pressure Measurement Package (ASV-05U)

A package containing a 2-channel blood pressure and pulse wave measurement unit and cuffs and hoses for all four limbs.

A package containing a 2-channel blood pressure and pulse wave measurement unit, connection cable and toe cuffs.

<sup>•</sup> BPU-100 + Toe Blood Pressure Measurement Package (ASV-06)

<sup>\*:</sup> In a simple examination mode of VS-2000 standard set, the ABI cannot be measured. In the standard examination mode, the ABI can be measured one side at a time.

# **Accessories**

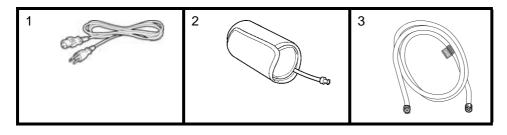
#### Accessories of the VS-2000

No.	Accessory	Model	Quantity	Remarks
1	Operation Manual (this manual)		1	

# **Accessory Package**

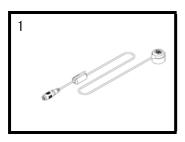
The following is a list of accessories for the VS-2000. No. 1-3 are included in the ASV-04U accessory package.

No.	Accessory		Model	Quantity	Remarks
1	Power Cable (3 m)		CS-24	1	
2	NIBP Cuffs	(Brachium)	CUF-142MH	1	
		(Ankle)	CUF-143MH	1	
3	Air Hose (2.7 m)	(Brachium)	OA-20APL2.7-BH	1	
		(Ankle)	OA-20APL2.7-AH	1	



# **PCG Microphone**

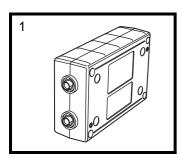
1	PCG microphone	MA-310HDS(V)	1	



# **BPU-100 NIBP/Pulse Wave Unit (Optional)**

An additional unit for measuring non-invasive blood pressure and pulse wave with two channels.

No.	Accessory	Model	Quantity	Remarks
1	NIBP/Pulse Wave Unit	BPU-100	1	



# **ASV-05U Four-Limb Blood Pressure Package (Optional)**

No.	Access	Accessory		Quantity	Remarks
1	NIBP Cuffs (Right Brachium)		CUF-129MRU	1	
		(Left Brachium)	CUF-129MLU	1	
		(Right Ankle)	CUF-138MRU	1	
		(Left Ankle)	CUF-138MLU	1	
2	Air Hose (2.7 m)	(Upper limbs)	OA-30APL2.7-BH	1	
		(Lower limbs)	OA-30APL2.7-AH	1	
3	Installation Manual			1	
4	NIBP Label		R-B, L-B	1	
5	NIBP Label		R-A, L-A	1	

# **ASV-06 Toe Blood Pressure Package (Optional)**

No.	Accessory	Model	Quantity	Remarks
1	Connection Cable (2.5m)	CJV-03SS2.5	1	
2	Toe Cuffs	CUF-139M2	2	
3	Toe Cuff Cover	OA-459M	1	
4	Installation Manual		1	

# **Names of Parts and Their Functions**

#### **Main Unit**

This section explains the names and functions of the parts of the VS-2000.

#### CAUTION



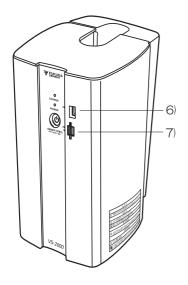
- Do not bend or drop the SD card or USB memory or subject them to impact.
- Do not subject the device to impact while the SD card or USB memory are in operation.

  This may damage the recorded data or break the card.
- Do not touch the terminal parts of the SD card or USB memory with your hands or metal objects.

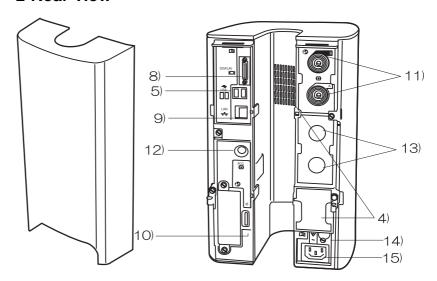
Caution about the warning labels attached to the device

- These warning labels contain important descriptions for handling and operating the device properly and safely.
- Do not damage or erase the warning labels attached to the device.

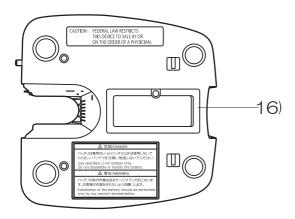
#### **■** Front view



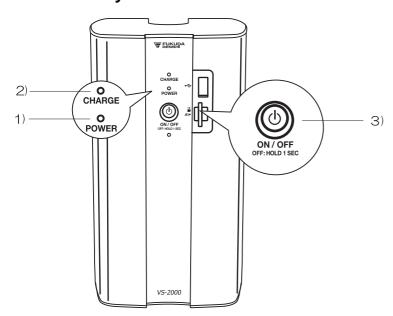
#### ■ Rear view



#### **■** Bottom view



#### **■** Control keys



The following is an outline of the functions of each part.

#### 1) AC Power Indicator (Blue)

When the device is connected to an AC outlet, the LED is lit faintly. When the device is turned ON, the LED is lit brightly.

#### 2) Charge Lamp (Blue/Yellow)

During charging, the LED lights in blue. When charging is completed, the LED turns OFF. If an error occurs during charging, the LED lights in yellow. (Refer to "Charging" (P2-3))

#### 3) POWER Key

Turns the device ON and OFF. Hold down the button 1 second or longer to turn OFF. The device can also be turned ON and OFF using the power switch on the display unit. When the power is turned OFF, the device will enter into standby mode and the AC power indicator will light faintly.

#### 4) Vents

Air inlets and outlets for the cooling fan in the device.

## NOTE

To ensure the necessary air flow, do not block these vents. A minimum space of 5 cm is also required between the rear and side of the device and the wall.

#### 5) USB1 and 2 ports

Insert a USB memory (optional).

#### 6) USB3 ports

Insert a USB memory (optional). Use this to store or read data.

#### 7) SD Card Slot

Insert an SD card (optional). Use this to store or read data.

#### NOTE

Do not remove the SD card or USB memory or turn off the device during operation of the SD card or USB memory.

#### 8) DISPLAY Connector

Connects the cable from the display unit.

#### 9) LAN connector

Connects the device to the DMS (data management system) via LAN. (Refer to "Connecting to the Network" (P2-16))

#### 10) IB connector

Connects the connection cable of the BPU-100 for measuring blood pressure in the toes.

#### 11) Air Connectors

Connect the limb cuff air hoses.

#### 12) PCG Connector

Connects the PCG microphone.

#### 13) Slot for Additional Pulse Wave Unit

A slot for adding an additional BPU-100.

#### 14) Potential Equalization Terminal

Connects the optional ground cable for equipotential connection.

#### 15) AC Power Supply Connector

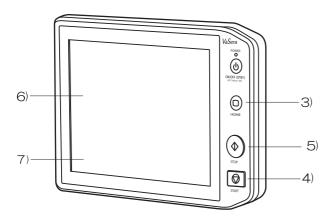
Connects the AC power cable. (Refer to "Connecting the Power Cable" (P2-8) )

#### 16) Battery Compartment

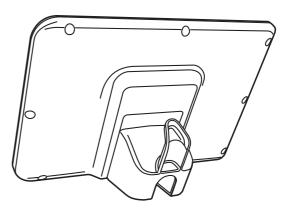
An optional battery (BTE-001) can be inserted here.

# **Display Unit**

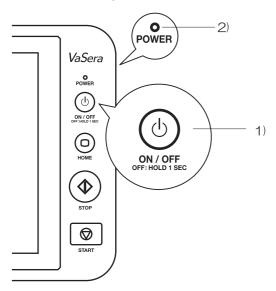
#### **■** Front view



#### ■ Rear view



#### ■ Control keys



#### 1) POWER Key

Turns the device ON and OFF. Hold down the button for 1 second or longer to turn OFF. The device can also be turned ON and OFF using the power switch on the main unit. When the power is turned OFF, the device will enter into standby mode and the AC power indicator will light faintly.

- AC Power Indicator (Blue)
   This is lit when the device is turned ON.
- HOME KeyDisplays the home display.
- 4) START Key
  Starts measurements.
- 5) STOP Key
  Stops measurements.
- 6) Touch panel A capacitive touch panel.
- 7) LCD Monitor

Displays information such as waveform information and patient information. (Refer to "Description of the Screen" (P1-11))

#### NOTE

Although the LCD utilizes highly accurate picture elements, occasionally, there may be a few pixels which do not light or constantly light. The temperature changes may also cause some irregularities in the LCD monitor due to its characteristics. Please note that this is not a failure.

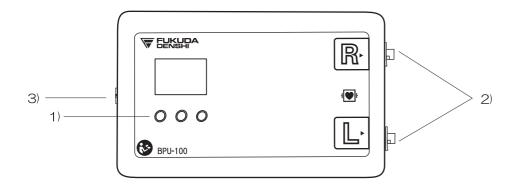
#### NOTE

Remove dust and stains from the LCD screen by wiping with ethanol on a soft cloth.

#### NOTE

The capacitive touch panel does not respond to thick gloves or a standard pen tip. Use a dedicated touch pen for capacitive touch panels.

# **BPU-100 NIBP/Pulse Wave Unit**



#### 1) Function Keys

Keys for performing maintenance operations.

#### NOTE

These control keys are for maintenance and cannot be used during normal examinations.

#### 2) Air Connectors

Connect the air hoses connected to the cuffs.

#### 3) BPU Connector

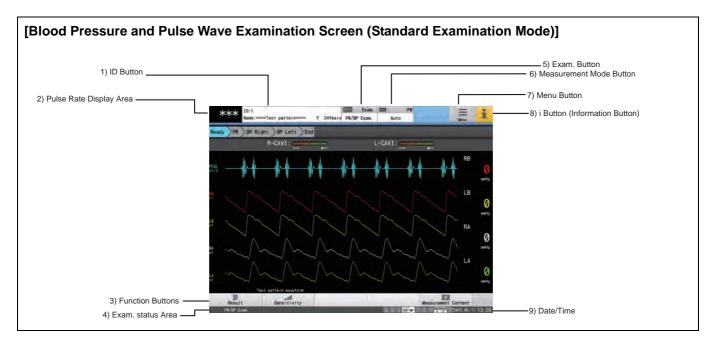
Connects the cable to the main unit.

# **Description of the Screen**

This section explains the screens for blood pressure and pulse wave examinations.

#### NOTE

This is an example of the screen shown during a 4-channel blood pressure and pulse wave examination.



#### 1) ID Button (Patient Information Display Area)

Touch this to display a window for entering patient information.

Information such as the ID, name and age of the patient are displayed, and patient information can be added or edited.

- Pulse Rate Display Area
   The pulse rate is displayed.
- Function Buttons
   Buttons for controlling the main unit are available.
- Examination Status Area
   Displays the status of the examination.
- 5) Examination Button

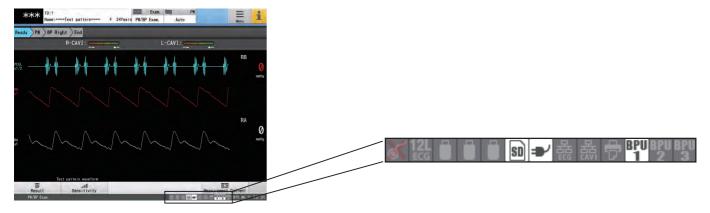
The currently selected examination is displayed. Touching this button displays the "Select Examination" window for selecting an examination.

- Measurement Mode Button
   Switch the mode for obtaining waveforms (Auto or Manual).
- Menu Button
   Touch this to display the Menu screen.
- 8) i Button (Information Button) Touch this to display a screen indicating the status of the device.
- Date/Time Display Area
   Displays the current date and time.

# How to View the Icons

# **Home Display**

The icons indicating the status of external device are displayed at the bottom of the screen.



The following information on devices, etc. is displayed

USB	SD	Power	VaSera	External	BPU1	BPU2	BPU3
Memory	Card	Supply/	LAN	Printer			
		Battery					

#### • Icon List

Item	Icon	Description
Normal Mode/ Offline Mode		Normal Mode
	<b>-</b> /-	Offline Mode
USB memory 1-3		Normal USB connection
	***	USB connection error
		ID reader connection
		When unused
SD Card	SD	Normal SD card connection
	80	SD card connection error
	SD	When unused

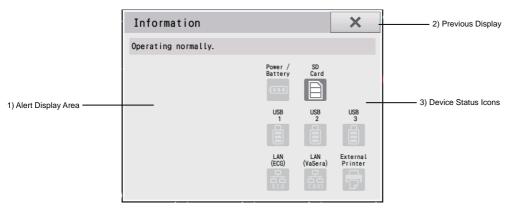
Item	Icon	Description
Battery		Power cable connected
		Remaining battery power 30-0%
	mm mm	Remaining battery power 60-30%
		Remaining battery power 100-60%
	×	Battery error
VaSera (CAVI) LAN	뭖	VaSera LAN connection
	器	VaSera LAN connection error
	(((†1)) CAVI	VaSera wireless LAN connection
	0+0	VaSera wireless LAN connection error
	몷	When unused

Item	Icon	Description
External Printer	<b>-</b>	Connected
	<b>**</b>	Error
		When unused
BPU1	BPU 1	Normal connection
	BPU	Error
	BPU 1	When unused

Item	Icon	Description
BPU2	BPU 2	Normal connection
	BPU	Error
	BPU 2	When not connected
BPU3	BPU 3	Normal connection
	BBU	Error
	BPU 3	When not connected

#### **Information Window**

The following window is displayed when the Information button is touched.



#### 1) Alert Display Area

An image indicating the type of error is displayed when the following two types of errors occur.

- •Device errors
- •Examination errors
- 2) Previous Display

This button closes the Information window.

3) Device Status Icons

The following information is displayed to indicate the device status.

Power Supply/Battery	SD Card	
USB1	USB2	USB3
	VaSera LAN	External Printer

#### • Icon List (Alert Display Area)

Item	Icon	Description
Noise	www	Noise
Battery		Battery 30-0%
	•	Battery 60-30%
	<b>(11)</b>	Battery 100-60%
Battery	œ	Battery error
USB		USB1 connection error
	02	USB2 connection error
	8	USB3 connection error

Item	Icon	Description
SD Card		SD card connection error

Item	Icon	Description
VaSera (CAVI) LAN	<b>%</b>	VaSera LAN connection error
	((sp))	VaSera wireless LAN connection error
External Printer	*	External printer error
	X	External printer out of paper

Item	Icon	Description
External Printer	海	Paper jam in external printer
	$\Diamond$	Low toner in external printer
	Ø.	External printer out of toner

# • Icon List (Device Status Display Icons)

Item	Icon	Description
Battery		Remaining battery power 30-0%
		Remaining battery power 60-30%
		Remaining battery power 100-60%
	œ	Battery error
USB1/2/3		USB capacity level 3
		USB capacity level 2
		USB capacity level 1
	8	USB connection error
		When unused

Item	Icon	Description
SD		SD card capacity level 3
		SD card capacity level 2
		SD card capacity level 1
	X	SD card connection error
		When unused
VaSera (CAVI) LAN	묪	VaSera LAN connection
	<b>2</b> 6 €	VaSera LAN connection error
	(( • ))) CAVI	VaSera wireless LAN connection
		VaSera wireless LAN connection error
	뫎	When unused

#### **Chapter 1 Preface**

Item	Icon	Description
External Printer	P	External printer connection
	X	External printer error
	X	External printer out of paper
	海	Paper jam in external printer
	4	Low toner in external printer
	Ø.	External printer out of toner
		When unused

# Icons displayed in other windows

Display area	Icon	Description
During file operations	SD	SD Card
	1	USB1
	2	USB2
	3	USB3
		DMS
	١٩	Internal memory
		Folder
		Trash
Message Display time	<u> </u>	CAUTION
	<u> </u>	WARNING

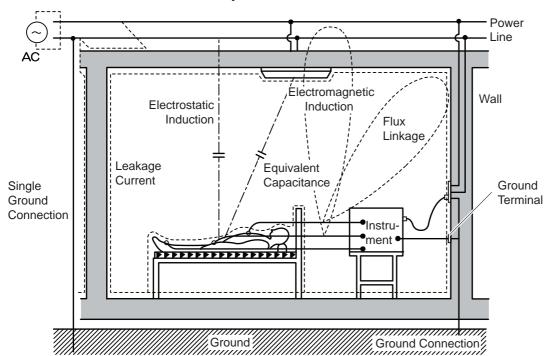
# Chapter 2 Installation

Install the device in preparation to conduct measurements.

# Cautions when Selecting the Installation Location

Take the following precautions when selecting the installation location.

- Radio interference occurs if there are strong radiated radio waves nearby (leakage currents, static
  induction and electromagnetic induction enter by the path shown in the figure).
   Select a location where no high-voltage power cables or power lines with a high load will pass by the device or the
  patient's bed.
- Equipment such as X-ray devices, ultrasound devices, radio devices, stands and fluorescent lighting also causes interference.
- Select a location where the room temperature will remain at 20-25°C.
- · Select a location with low humidity.





Select a location with minimal noise in the surrounding area.

PCG and pulse waves will not be measured correctly if there is noise or vibration from an air conditioning machine or vehicles driving past, or if there is noise such as compressor noise, engine noise or generator noise.

# **Installing the Battery (Optional)**

This section explains how to install and charge the optional internal battery (BTE-001 battery).

#### **№** WARNING



- Make sure to remove the power cable before installing or replacing the battery.
   Otherwise, the device will be damaged and an electric shock may occur.
- Contact Fukuda Denshi before installing or replacing the battery.
   Incorrect handling may result in danger such as electric shock to the patient and operator.



- Do not throw the battery into fire.
  - If the battery is placed in fire, it may explode.
- The battery should be charged only with this device.

Otherwise, leakage, overheating or explosion may occur.

. Do not disassemble or remodel the battery.

If the battery breaks and the acid leaks onto the skin or clothing, wash it off with water immediately. If the acid gets into the eyes, rinse with clean water and consult a doctor immediately.

• Do not use the battery in any other device.

Otherwise, leakage, overheating or explosion may occur.

- · Do not short-circuit the terminal.
  - Otherwise, leakage, overheating or explosion may occur.
- If charging is not completed after the prescribed charging time, stop charging the battery.
   Otherwise, leakage, overheating or explosion may occur.
- Do not drop the battery or subject it to strong impact.
- · Contact a specialist when disposing of the battery.

#### **!** CAUTION ■



• Make sure to use the specified internal battery (BTE-001 battery).

Leakage, overheating or explosion may occur if a battery other than the specified battery is used.

#### Installation

Installation of the battery should be performed by a Fukuda Denshi service representative. Contact your nearest service representative to install the battery.

#### **Cautions When Using the Battery**

Take the following precautions when using the battery.

#### **Battery Life**

The battery can be charged and discharged (used) around 300 times. However, the battery life varies depending on how frequently the battery is used and the charging and discharging pattern. If the battery runs out shortly after being charged, this means that it has reached the end of its life and needs to be replaced with a new battery.

#### **Storing the Battery**

If the device will not be used for a long period of time, remove the battery from the device and store it. Make sure to install the battery in the device and fully charge it once every three months. If left for a long period of time, the battery may self-discharge to the point where it can no longer be used.

Avoid storing the battery in an area below 0°C or above 35°C.

#### Charging

The battery of this device is charged in the device.

## 1 Turn OFF the power.

(Refer to "Turning the Power ON and OFF" (P2-12) )



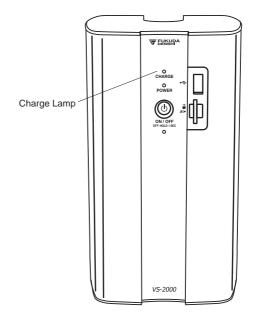
The battery is not charged while the device is operating.

# 2 Connect the power cable to the device.

(Refer to "Connecting the Power Cable" (P2-8) ) The AC power indicator and charge lamp are lit and charging starts. The charge lamp indicates the charging status. (When the optional battery (BTE-001) is installed)

Lit in blue: Charging Unlit: Charging completed

Lit in yellow: An error occurred during charging



#### NOTE

The charge lamp may light in yellow during charging for the following reasons:

- The battery temperature is too high or too low.
- · An error occurred in the main unit or battery.

Remove the power cable, wait a while and then charge the battery again.

If the charge lamp still lights in yellow when charging the battery again, contact Fukuda Denshi.

The battery charges from a completely empty state within 2 hours and 30 minutes. The charging time varies depending on factors such as the level from which the battery is charged and the ambient temperature.

Charging does not start if the battery is nearly full, to prevent overcharging.

It is recommended to charge the battery at or near a normal room temperature (10-30°C).



To ensure that the battery can be used at any time, do not unplug the power cable immediately after turning off the device when operating the device on AC power. Allow the battery to charge until the charge lamp goes out.

The battery does not charge while the device is being operated.



Below are examples of charging times.

- When the battery temperature is 10°C or above, charging will complete within 2 hours and 30 minutes.
- When the battery temperature is between 0°C and 10°C, charging will complete within 4 hours and 30 minutes.
- When the battery temperature is 0°C or below, or 60°C or above, charging will not be performed.

#### **Operating the Device on Battery Power**

Turn on the device by pressing the [POWER] key on the display unit while the power cable is unplugged. (Refer to "Turning the Power ON and OFF" (P2-12))



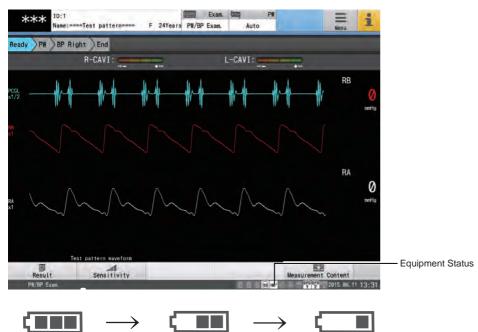
The device automatically switches to battery power if the power cable is removed or a power outage occurs while operating the device on AC power.

#### **Checking the Remaining Battery Power**

The device can be used continuously for around 70 minutes from a fully charged state each time it is charged. (CAVI/ABI measurements, 5-minute intervals, room temperature 20°C, standard LCD brightness).

However, the length of time for which it can be used will depend on the usage and storage condition of the battery.

An icon indicating the remaining battery power is displayed in the device status display area of the screen when the device is operating on battery power.



The icon changes as shown above as the remaining battery power decreases.

When the icon indicating the remaining battery power changes to \_\_\_\_\_, the battery needs to be charged.

The following message may be displayed on the screen when the battery is low. Switch to AC power or charge the battery.

#### NOTE

- If the device continues to be operated when a message indicating low battery voltage is displayed, the device automatically switches off. Connect the power cable immediately and charge the device, as this means that the battery has run out. If left in this state, the battery may self-discharge to the point where it can no longer be used.
- Avoid using the battery in a room temperature 0°C or below, or 40°C or above.

<sup>&</sup>quot;To not run out of battery, the power supply will be switched off automatically."

<sup>&</sup>quot;Battery is running low. Please recharge the battery."

<sup>&</sup>quot;Battery operating. Please switch to the AC power supply."

<sup>&</sup>quot;The battery voltage is too low. Cannot access media."

<sup>&</sup>quot;The battery voltage is too low. Cannot measure."

<sup>&</sup>quot;The battery voltage is too low. Measurement aborted."

# Installing the Main Unit and Display Unit on a Stand

When using the optional stand (OTV-03), install the device as follows.

#### **⚠** WARNING



- Use the specified stand (OTV-03).
- Make sure to secure the device to the stand using the specified screws.
   If the device is not secured, it may fall off the stand, resulting in injury to the operator or damage to the device.
- Make sure to lock all casters when using or storing the device.
   If the casters are not locked, the device may move or tip over, resulting in injury to the operator or damage to the device.
- When moving the stand, make sure to hold the handle.



- Do not use with any unauthorized devices.

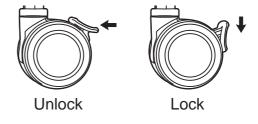
  The device and stand may tip over, resulting in injury to the operator or damage to the device.
- Do not use or store the stand where it will be subject to an inclination of 5 degrees or more.

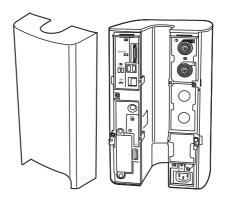
  The device and stand may tip over, resulting in injury to the operator or damage to the device.
- · Do not alter or customize the stand.
- 1 Lock the casters of the stand (five casters).

#### NOTE

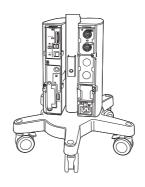
Make sure to lock the casters before working with the device. If work is carried out while the casters are not locked, the stand may move unexpectedly and the device may fall, resulting in injury to the operator or damage to the device.

2 Remove the cover located on the rear side.

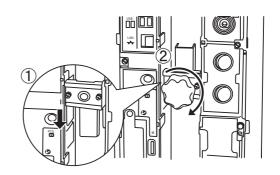




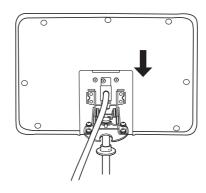
3 Place the main unit on the stand so that the column of the stand fits into the depression of the main unit.



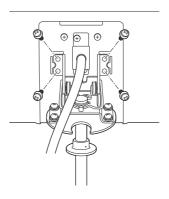
- 4 1) Insert the fixing bracket into the slits of the main unit.
  - 2) Lock with the knobbed bolt.



5 Insert the display unit into the fixing bracket at the top of the stand.



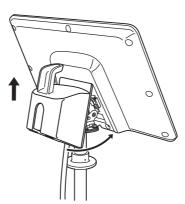
6 Secure with the four M4 screws.



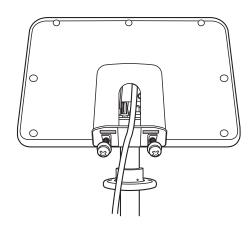
7 Tilt the screen around 30° and attach the hinged cover.

#### NOTE

The hinged cover can only be attached if the screen is tilted.



8 Secure the hinged cover with the two screws.

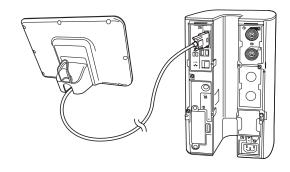


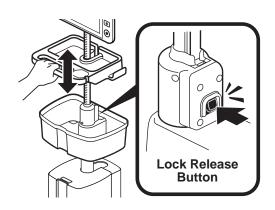
**9** Connect the cable of the display unit to the DISPLAY connector on the rear side of the main unit.

#### NOTE

Securely tighten the screws at either end of the DISPLAY connector.

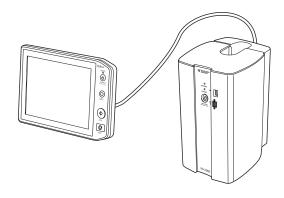






#### ■Installing Without the Stand

The main unit and display unit can be placed on a table, etc. instead of using the stand.



#### NOTE

The power turns ON when the cable of the display unit is connected to the main unit. The power automatically turns OFF when the cable is removed.

# Connecting the Cables, Hoses, Cuffs and PCG Microphone

#### **№** WARNING



• Connect the power cable to a hospital grade outlet.

Grounding is only guaranteed if the device is plugged in by connecting the supplied power cable to a hospital-grade three prong grounded outlet.



• Do not bend, crush or twist the air hose of the cuff.

The blockage of the hose will stop the cuff deflation, resulting in obstruction of the blood flow.



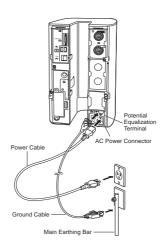
• Make sure to use the specified PCG microphone (MA-310HDS(V)).

#### **Connecting the Power Cable**

Connect the power cable to the device.

1 Connect the supplied three-prong power cable to the power supply connector. Connect the other end to a hospital-grade outlet.

Connect the three-prong power cable to a hospital grade power outlet (three-prong grounded AC power outlet). This will automatically ground the instrument. Use only the supplied AC power cable. If this device is connected with a different cable, danger such as electric shock may result to the patient and operator.

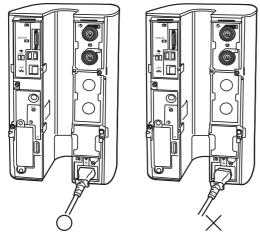




Do not use with on-board inverters such as those in an ambulance, as the device is not intended for this use.

#### NOTE

- Operate this device using the optional internal battery (BTE-001 battery) if the grounding conditions cannot be confirmed. If this device is used with improper grounding, danger such as electric shock may result to the patient and operator.
- · Insert the power cable all the way in.
- Do not install the device in a location where it is difficult to plug/unplug the power cable.



The cable is properly connnected.

The cable is not properly connnected.

2 To equalize the potential, connect the optional potential equalization cable to the potential equalization terminal of the device and the potential equalization terminal of another device.



When connecting multiple devices, electrical potential difference may be generated between the devices. This may result in electric shock to the patient connected to these devices. To avoid such electrical potential difference, use the ground cable to connect each device's potential equalization terminal to the same ground terminal. This is called equipotential grounding.



When using with other medical devices, perform equipotential grounding to prevent potential difference between the devices. If potential difference occurs between the devices, danger such as electric shock may result to the patient and operator. Pay special attention for use in Operating Room, ICU, CCU, Cardiac Catheter Laboratory and Cardiovascular X-ray room.

#### **⚠** CAUTION

• Equipotential Grounding

When connecting multiple devices, electrical potential difference may be generated between the devices. This may result in electric shock to the patient connected to these devices. Pay special attention for use in Operating Room, ICU, CCU, Cardiac Catheter Laboratory and Cardiovascular X-ray room. To avoid such electrical potential difference, use the ground cable to connect each device's potential equalization terminal to the same ground terminal. This is called equipotential grounding.

#### **⚠** DANGER



Do not ground with a gas pipe. This is dangerous.
 Explosion or fire may result.

#### **⚠** CAUTION



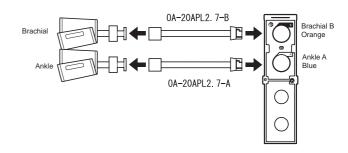
- Check that the ground cable is not loose or disconnected.
- Attach the clip of the ground cable securely to the ground bus.
- If there is no ground bus, insert the metal rod into the ground. This is more effective if the surrounding area is sufficiently wet with water.
- Do not connect to ungrounded items. (metal window frames, plastic water pipes, ground terminals of other devices, etc.)
- Avoid using water pipes as a ground conductor as they may not provide stable grounding.

#### **Connecting the Cuffs (2-Channel Examination)**

- 1 Insert the connector of the air hose into the air connector on the device and rotate the connector to secure it.
- 2 Connect the connector of the air hose to the air connector of the cuff in the same way.

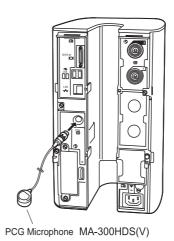
Secure the connectors properly to prevent air from leaking. Connect them according to the text and colors on each label.

Position	Model	Cuff color
Brachium	CUF-142M	Orange
Ankle	CUF-143M	Blue



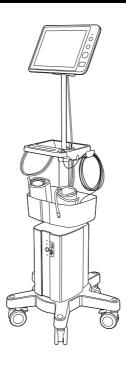
# **Connecting the PCG Microphone**

1 Connect the PCG microphone.



**Storing the Cuff Holders and PCG Microphone** 

1 The cuffs and PCG microphone can be stored in the storage case on the stand.



# **Installing Optional Devices**

Installation of the BPU-100 NIBP/Pulse Wave Unit should be performed by Fukuda Denshi service representative. When installing, contact your nearest service representative

#### **Connecting the Cuffs (4-Channel Examination)**

- 1 Insert the connector of the air hose into the air connector on the device and rotate the connector to secure it.
- 2 Connect the connector of the air hose to the air connector of the cuff in the same way.

Secure the connectors properly to prevent air from leaking. Connect them according to the text and colors on each label.

Position	Model	Cuff color
Right brachium	CUF-129MRU	White
Left brachium	CUF-129MLU	Black
Right ankle	CUF-138MRU	Green
Left ankle	CUF-138MLU	Red

#### NOTE

- Do not use the cuffs and hoses that were used before adding the BPU-100. Use the cuffs and hoses marked with the area for use (right brachium, left brachium, right ankle, left ankle).
- The air hoses are connected differently. Connect according to the hose color, cuff color and position name.

#### NOTE

 When the device is turned ON after adding the BPU-100, the device automatically recognizes the BPU-100 and operates in 4-channel mode.

#### **■**Connecting the Toe Cuffs

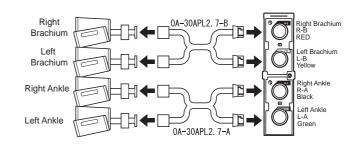
- 1 Insert the connector of the toe cuff into the air connector on the BPU-100 and rotate the connector to secure it.
  - The position of the right toe cuff is indicated in black, and the position of the left toe cuff is indicated in green.
  - 2) Secure the connectors properly to prevent air from leaking. The toe cuffs are interchangeable.

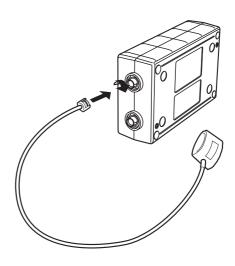
#### **Toe Cuff Sizes and Colors**

Position	Model	Cuff color
Big toe	CUF-139M2	Blue
Second toe	CUF-139S2	Brown

#### NOTE

- When the device is turned ON after adding the BPU-100, the device automatically recognizes the BPU-100 and operates in 6-channel mode.
- The BPU-100 will not operate in 6-channel mode if is connected without adding the BPU-100 (refer to "Installing Optional Devices" (P2-10)).





# **Turning the Power ON and OFF**

#### To Turn ON the Power



Check that the AC power indicator is lit faintly in blue.

#### Press the [POWER] key on either the display unit or the main unit.

Check that a beep sounds when the POWER key is

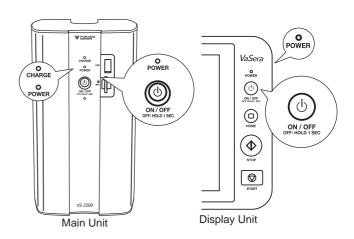
If no sound is heard when the AC power is turned ON, the power cable may not be connected properly. Reconnect the power cable.



A crackling sound is heard after the power is turned ON. This is the operation sound of the valve. It occurs during the preparation operations of the device and is not a malfunction.



The device may take longer to start up after the power is turned ON when the temperature in the room (or other area where the device is being used) is below 10°C. This is not a malfunction. Use the device in temperatures within the specified range (10-40°C).



An initial display appears on the screen after the power is turned ON, followed by the home display.

#### **Initial Display**

# FUKUDA **VaSera**

#### **Home Display**



The examination set in "Exam. on Startup" is displayed.

#### To Turn OFF the Power

- 1 Check that all measurement operations on the device and transmissions to the computer have been completed (the icons should no longer be blinking).
- **2** Remove all cables from the patient.
- 3 Press and hold the [POWER] key on the display unit or the main unit for one second.
- 4 When turning OFF the power of the main unit, unplug the power cable from the main unit. When the power is turned OFF, the device will enter into standby mode and the AC power indicator will light faintly.



If the device will not be used for a long time, remove the power cable from the main unit for safety \Lambda purposes.

If the device does not turn OFF after pressing and holding the [POWER] key on the display unit, keep pressing the [POWER] key. After pressing and holding for around 10 seconds, operations will stop and the device will turn OFF.



The AC power indicator may stay lit for around 10 seconds after the power cable is removed. This is not a malfunction.

# **Acquiring the Date and Time**

Check the date and time at the bottom right of the home display and set the correct date and time if they are not correct.



If the date/time becomes incorrect although the correct date/time is set, the built-in battery may have reached the expiration date. Replace the battery as soon as possible. (Refer to "Replacing the Clock Battery" (P12-10).)

- 1 Touch the [Menu] button on the touch panel.
- 2 When the "Menu" display appears, touch [Maintenance].
- 3 When the "Maintenance" display appears, touch [Set Time/Date].
- 4 Check that the date and time are correct.

If correct, proceed to step 9, and if incorrect, proceed to step 5.



If the device is already connected to the network and the date and time can be obtained from the NTP server, the date and time can be set automatically by touching [Acquire Time/Date from NTP Server].

It is possible to automatically obtain the date and time from the NTP server each time the device is turned ON by placing a check mark for [Acquire Automatically on Power On].

5 Set the time difference between UTC.

Touch the box for "UTC+".

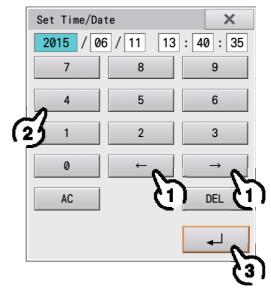


Enter the time difference between UTC. Touch  $[\pm]$  to switch between [+] and [-].



The default setting is "+9:00".

6 Set the current date and time.



- 1) Touch [←] and [→] to select the item to be changed.
- 2) Enter the current date and time.
  - [0] [9]:
  - Enters the numbers.
     [AC]:
  - Clears all entered numbers
  - [DEL]:

Clears the number immediately before (to the left of) the cursor.

- [←]/[→]:
  Changes the item to be entered.
- 3) Touch [ ].
  Touching [x] will close the "Set Time/Date" window without saving the changes.

7 After the settings have been configured, press [Back] twice and then press the [HOME] on the display unit.

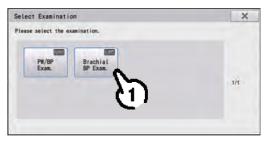
# **Basic Operations**

# **Changing the Examination Type**

1 Touch [Examination].



2 Touch the desired examination.



Touch [V] to display the next page.

Touch [x] to close the "Select Examination" window without switching the examination.



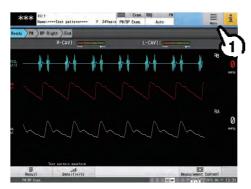
Types of examination icons

Blue border: Blood Pressure and Pulse Wave

**Green border: Series examination** 

# **Displaying the Menu**

1 Touch the [Menu] button on the touch panel.



2 Touch the desired item.



Touch [To exam] or press [HOME] on the display unit.

The screen returns to the examination display.

# **Connecting to the Network**

Follow the steps below to connect to the network to send examination results from the device to a computer.

#### **Example of Network Configuration**

Connect the devices as shown in the figure below.

An Ethernet hub and LAN cable are required. Connect the LAN cable to the LAN connector of the main unit and connect the other end to the Ethernet hub. Connect the PC in the same way.

#### **Required Items**

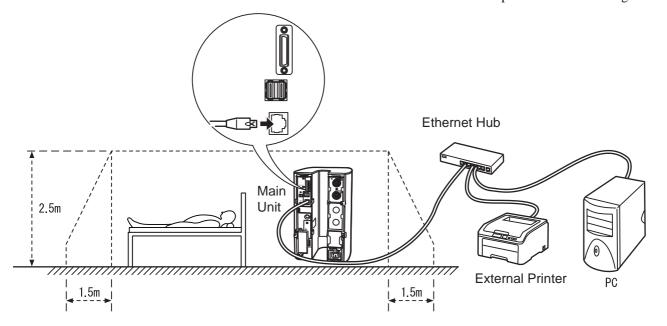
- Ethernet hub
- LAN cable (straight) x 2

If the settings need to be changed according to an existing network environment, refer to "Network Settings (Wired LAN)" (P2-17) and change the settings.

#### **№** WARNING



- . Configure and connect to the network as specified by Fukuda Denshi.
- Use an external printer and Ethernet hub specified by Fukuda Denshi.
- The devices connected to the network, such as the external printer, Ethernet hub and computer, need to be installed 1.5m away from the patient (IEC 60601-1-1: 2000/EN 60601-1-1: 2001).
- The devices connected to the network, such as the external printer, Ethernet hub and computer, need to be grounded.
- · Use a network cable with no damage to areas such as the covering.
- Do not place devices such as the printer, Ethernet hub or computer on the trolley.
- The devices can also be connected by wireless LAN. If connecting by wireless LAN, factors such as obstructions may prevent correct communication in some installation locations. Check that correct communication is possible when installing the device.





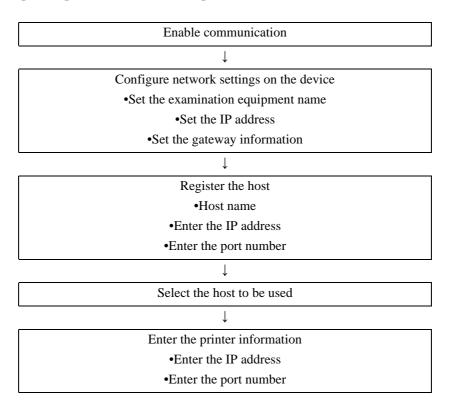
- The network must be used only for this device and must be separate from other hospital networks.
- If two or more of this device are connected to the same network, a separate IP address must be assigned
  to each device. (Set the IP address in the network settings of the device in "Network and Master ID
  Settings".)
- Software such as VSS is required to connect the device to a computer.

#### NOTE

The list of optional products in the appendix indicates the printers that can be connected.

#### **Network Settings (Wired LAN)**

#### **■**Steps for Configuring Network Settings





- Consult the network administrator to confirm the IP addresses (e.g. 192.168.0.3) and port numbers that can be assigned to the device, computer and printer.
- · Contact Fukuda Denshi for more information on configuring the wireless LAN settings.

#### **■**Configuring the Settings

# 1 Touch the [Menu] button.



## 2 Touch [Setting].



# 3 Touch [Communication].



# 4 Select [ON] for [Communication] in the [General] tab.

Check that [Method] is set to [Wired LAN].

#### 5 Set the IP address of the device.

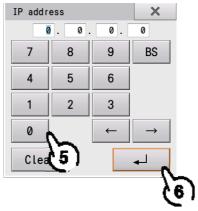
- 1) Touch [DMS Settings].
- 2) Touch the [Examination Equipment Info] tab.
- 3) Touch "Examination Equipment Name" and enter the examination equipment name.
  - The examination equipment name is entered in the same way as the patient name in "Chapter 4 Entering Patient Information" (P4-1).
  - The default setting for the examination equipment name is "VASERA". An examination equipment name does not need to be entered if using this name.
- 4) Touch [IP address].



5) Enter the IP address.

Refer to "Example Setting: For "Example of Network Configuration" (P2-16)" (P2-19) for details on the settings.

6) Touch [ ← ].



- 7) Touch the [DMS Settings] tab.
- 8) Enter the subnet mask and default gateway in <Gateway>.

Refer to "Example Setting: For "Example of Network Configuration" (P2-16)" (P2-19) for details on the settings.

# **6** Register the host.

- 1) Touch the [Host Info] tab.
- 2) Enter the host name, IP address and port number in <Host Info X>.

"Host" refers to information about the computer to connect. Set the host name, IP address and port number. Up to 6 hosts can be registered.

Refer to "Example Setting: For "Example of Network Configuration" (P2-16)" (P2-19) for details on the settings.

# 7 Select the host to be used.s

- 1) Touch [DMS Settings].
- 2) Touch the host to be used ([Recording&Playback Host], [PW/BP Host], [Patient Info Host]).
- 3) Enter the host number set in step 6 (the "X" part of "Host Info X", 1-6).
  - VSS can be used as pulse wave hosts or patient information hosts.
- 4) Touch [Enter].

## **8** Configure the network printer settings.

Network printers that can print without a computer (laser printers) can be connected.

1) Touch [Printer].

- Set [Network Printer] to [ON] if using a network printer.
- 3) Enter the IP address and port number.
- 4) Touch [Enter] after configuring the settings.
- 5) Select [Equipment Control] [Print on Normal Paper] [Output Target] and then select [Network Printer] or [PC Printer].

#### ■Example Setting: For "Example of Network Configuration" (P2-16)

Example network settings on the device

Item	Description
IP Address	192.168.0.1
Sub-Network Mask	255.255.255.0
Default Gateway	192.168.0.3



If connecting two or more of this device to the same network, set a different IP address for each device ("192.168.0.1" and "192.168.0.2", etc.)

Example host device information settings

Item		Description
Host name		VSS
IP Address		192.168.0.3
Port No.	Pulse wave host	8192
	Patient information host	



- If installing multiple host programs on the same PC, set a different port number for each program.
- A pulse wave host is a host for recording and reading examination data for pulse wave examinations.
- A patient information host is the master ID communication host if "VS-PC" is selected as the location from which to load patient information.
- Select [Communication]-[DMS Settings]-[Read Patient Info From] and then select [VS-PC] if using VSS as the master ID communication host.

#### **Chapter 2 Installation**

#### Example of network printer settings

Item	Description
IP Address	192.168.0.6
Port No.	9100

#### Network settings of shared folder

Item	Description
IP Address	The IP address of the Windows computer on which the shared folder
	was created.

#### Shared folder settings

Item	Description
Mounted Directory	The folder name of the shared folder created on the Windows computer.
Login name	The login name used to access the shared folder (usually the user name of the Windows computer).
Password	The login password.
Domain	The domain name if the computer is in a Windows domain.



- If using a shared folder, set the IP address, port number and domain of the computer in [Communication]-[DMS Settings] after creating the shared folder on the computer.
- In [Communication]-[DMS Settings]-[Shared Folder], set the login name and password of the user with access permission to the shared folder and set the folder name of the shared folder on the computer as the mounted directory.
- The folder name, login name and password of the shared folder can only contain alphanumeric characters and the following symbols: = (equals sign), @ (at sign), " (double quotation mark), / (slash) (hyphen), \_ (underscore), (comma), . (period), # (number sign) \, ? (question mark), { } (curly brackets), [ ] (square brackets), ( ) (parentheses).
- Refer to "Configuring Sharing Settings on the Computer" (separate manual) for details on configuring the sharing settings.

# **Settings for External Printer Output**

Network printers that can print without a computer (laser printers) can be connected as external printers.

#### NOTE

The entire process for printing via an external printer takes around 1-2 minutes per page. It may take a long time to complete a print job if a large volume of printing is requested at once. (The time required depends on the usage environment.)

#### When Using a Network Printer

- 1 Install the network printer.

  Refer to "Connecting to the Network" (P2-16).
- 2 Check the IP address of the network printer.

Refer to the operation manual of the printer.

- 3 In the Settings, select [Communication] [Printer] [Network Printer] and set the IP address of the network printer in the "IP address" field.
- 4 Select [Communication] [Printer] [Network Printer] in the Settings and set [Yes].
- 5 Select [Equipment Control] [Print] [Output Target] in the Settings and set [Network Printer].

# **Settings for Saving PDF Files**

PDF files of examination reports can be saved on the SD card or USB memory. Pulse wave examination reports can also be stored in a shared folder on the network.

#### **Network Settings (If Using a Shared Folder)**

Configure the following settings.

- Create a shared folder on the computer. Refer to "Configuring Sharing Settings on the Computer" (separate manual) for details on configuring the sharing settings.
- Follow the instructions in "Connecting to the Network" (P2-16) to configure the network settings of the VS-2000.
- Use the example settings as a reference to configure the network settings of the shared folder for the VS-2000.

#### **Auto Output Selection**

- 1 In the Settings, select [Equipment Control] [PDF/XML] [Save as PDF/XML File] and set "Yes" for "Auto Save".
- 2 Select "SD card", "USB memory" or "Shared Folder" for "Save Media".

#### **■**Examination

When examination results are displayed for pulse wave examinations and brachial blood pressure examinations, a PDF file containing the report is written to the storage media according to the report output settings.

#### NOTE

- PDF files can only be written to the shared folder for pulse wave examinations and brachial blood pressure examinations.
- It may take a while to save the output PDF files if a large number are output at once.



- Examination results can also be output to XML files.
- If PDF files are saved to the same media as the examination data, this means that less examination data can be stored. It is therefore recommended to save the PDF files to a separate media from the examination data.

#### **Manual Output**

- 1 Touch [Print] in the examination result screen.
- 2 Select the report to be saved and touch [Save].

The Storage Media window will be displayed. Select the storage media to save the PDF file.



Files are stored in the "IMAGE" folder on the card.

## **Chapter 3 Pre-Examination Preparations**

This section explains how to attach the cuffs, sensors and to set the date and time.

## **Attaching the Cuffs**

The cuffs can be attached to the brachium, ankle, or toe.

## Attaching the Cuffs (Standard 2-Channel Examination)

• There are brachial and ankle cuffs. The edge colors of the cuffs indicate the measurement site as follows.:

Brachial: Orange Ankle: Blue

Attach to the correct site according to the edge color of the cuff.

The brachial and ankle cuffs can be used on either right or left side of the corresponding measurement site.

The cuff size is applicable if the INDEX (A) mark is within the RANGE when attached to the patient. The
applicable circumference range is indicated on each cuff. The size range applies to the circumference
measured at the center part of the cuff.

The cuff size and applicable size range are listed below.

No.	Model	Usage, Size	Applicable Circumference Range
1	CUF-142S	Brachium, S	17-22cm (6.7"-8.7")
2	CUF-142M	Brachium, M	22-30cm (8.7"-11.8")
3	CUF-142L	Brachium, L	30-39cm (11.8"-15.4")
4	CUF-143S	Ankle, S	17-22cm (6.7"-8.7")
5	CUF-143M	Ankle, M	20-30cm (7.9"-11.8")
6	CUF-143L	Ankle, L	30-42cm (11.8"-16.5")

- Make sure that the air hose are not bent and that no object has been placed on them.
- Make sure that the cuffs and air hoses exhibit no cracks or other damage.



- Select the appropriate cuff size according to the patient's brachial/ankle circumference.
- It is recommended to use a cuff cover (optional) so that it can be removed and washed after use, as the cuff can get dirty from sweat, etc.
- The examination is not intended for neonates, infants, and adults outside the applicable brachial/ ankle circumference range.

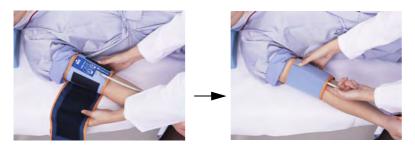
#### **Attaching the Cuff to the Brachium**

1 Attach a brachial cuff (orange edge) to the right or left brachium.

Wrap the cuff on the brachium with its center (where the air hose is connected) going along the center of the inside of the brachium and with the lower side of the cuff just above the elbow joint.



**2** Wrap the cuff around the brachium securely but <u>not too tightly</u>. Make sure there is no gap between the cuff and the brachium.



#### Attaching the Cuff to the Ankle

1 Attach an ankle cuff (blue edge) to the right or left ankle.

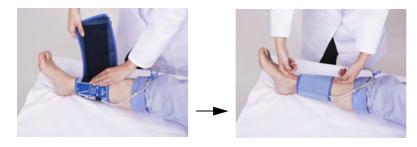
Place the cuff so that the bottom is 1cm above the ankle and the label with the arrow is on the inside of the ankle.



Bending the knees of the patient will facilitate the cuff application.



**2** Wrap the cuff around the ankle securely but <u>not too tightly</u>. Make sure there is no gap between the cuff and the ankle.



## **Attaching the Limb Cuffs (4-Channel Examination)**

There are right brachial, left brachial, right ankle and left ankle cuffs. Attach to the correct site according
to the edge color of the cuff.

The edge colors of the cuffs indicate the measurement site as follows.

Right Brachium: Red, Left Brachium: Yellow, Right Ankle: Black, Left Ankle: Green

• The cuff size is applicable if the INDEX (▲) mark is within the RANGE when attached to the patient. The applicable circumference range is indicated on each cuff. The size range applies to the circumference measured at the center part of the cuff.

The toe cuff can be used on either right or left side.

The cuff size and applicable size range are listed below.

No.	Model	Usage, Size	Applicable Circumference Range
1	CUF-129SRU	Right brachium, S	17-22cm
2	CUF-129SLU	Left brachium, S	(6.7"-8.7")
3	CUF-138SRU	Right ankle, S	17-22cm
4	CUF-138SLU	Left ankle, S	(6.7"-8.7")
5	CUF-129MRU	Right brachium, M	22-30cm
6	CUF-129MLU	Left brachium, M	(8.7"-11.8")
7	CUF-138MRU	Right ankle, M	20-30cm
8	CUF-138MLU	Left ankle, M	(7.9"-11.8")
9	CUF-129LRU	Right brachium, L	30-39cm
10	CUF-129LLU	Left brachium, L	(11.8"-15.4")
11	CUF-138LRU	Right ankle, L	30-42cm
12	CUF-138LLU	Left ankle, L	(11.8"-16.5")

- Make sure that the air hose are not bent and that no object has been placed on them.
- Make sure that the cuffs and air hoses exhibit no cracks or other damage.



- Do not conduct 4-channel examination with the cuffs and hoses used for 2-channel examination.
- Select the appropriate cuff size according to the patient's brachial/ankle circumference.
- It is recommended to use a cuff cover (optional) so that it can be removed and washed after use, as the cuff can get dirty from sweat, etc.

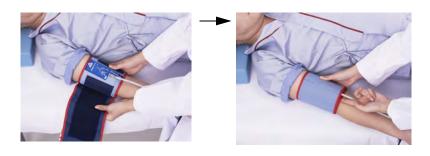
#### Attaching the Cuff to the Brachium

1 Select the red-edged cuff for the right brachium and the yellow-edged cuff for the left brachium.

Wrap the cuff on the brachium with its center (where the air hose is connected) going along the center of the inside of the brachium and with the lower side of the cuff just above the elbow joint.



**2** Wrap the cuff around the brachium securely but <u>not too tightly</u>. Make sure there is no gap between the cuff and the brachium.



#### Attaching the Cuff to the Ankle

1 Select the black-edged cuff for the right ankle and the green-edged cuff for the left ankle.

Place the cuff so that the bottom is 1cm above the ankle and the label with the arrow is on the inside of the ankle.



Bending the knees of the patient will facilitate the cuff application.



2 Wrap the cuff around the ankle securely but <u>not too tightly</u>. Make sure there is no gap between the cuff and the ankle.



# Using the Limb Cushion (Optional, 2-Channel/4-Channel Examination)

Use a limb cushion when the pulse is weak, the rise of the pulse wave is unstable or if it is difficult to find the notch of the pulse wave.





Place the limb cushion below the elbow or heel to obtain a stable pulse wave.

The limb cushion can be used in horizontal or vertical direction. Use it in a suitable direction so that the cuff will not touch the bed.



The limb cushion is an optional accessory.



- If the limb cushion is too high, or if it causes pain to the patient, use a towel instead of the limb cushion. Fold the towel 2 or 3 times, place it under the heel, and adjust the height so that the cuff does not touch the bed.
- If the cuff touches the bed even when using the longest side of the limb cushion, place a towel folded 2 or 3 times under the limb cushion to adjust the height.
- If the patient's limb is not placed stably on the limb cushion, the tension caused by the patient's effort to keep the limb on the limb cushion may cause a faint shake. As this will affect the pulse wave recording, make sure to place the limb at the center of the limb cushion.

## **⚠** CAUTION ■

• If there is a risk of bone fracture due to osteoporosis, etc, be particularly careful when raising the patient's arm or leg to place it on the limb cushion. Special care must also be taken when attaching cuffs to these patients.

## **Attaching the PCG Microphone**

Attach the PCG microphone.

1 Attach the dual-side adhesive tape to the adhesion surface of the PCG microphone.

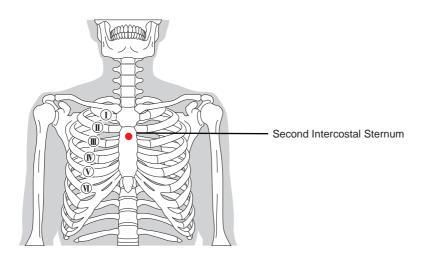
Use the dual-side adhesive tape designed for the PCG microphones (DA-30, optional).

The microphones can also be secured with tape such as surgical tape.

2 Attach the PCG microphone to the second intercostal sternum.







## **⚠** CAUTION ■

- The dual-side adhesive tape cannot be reused.
- Take measurements in a quiet room with no noise or vibration in the surrounding area.
- Do not drop the PCG microphone, subject it to strong impact or pull strongly on the cable.

## Attaching the Toe Cuff (6-Channel Examination) T

## ⚠ CAUTION

- Be careful not to wrap the toe cuff around the toe too hard. The cuff may restrict the blood flow resulting in hemostasis.
- Do not wrap the toe cuffs too loosely or at an angle. Otherwise, the cuff may burst or give inaccurate measurements.
- Do not reuse the same toe covers for more than one patient.

This device incorporates a function for avoiding too much pressure on the toe during toe cuff attachment (toe cuff attachment assist function).



The toe cuff attachment guide is activated by touching the [TOE GUIDE] function button on the display. This function operates while "Cuff assistant function running" is displayed.

1 Use the correct toe cuff and toe cover for the measuring site.

Apply the toe cover to the big or index toe.



2 Switch the display to the [PW/BP Exam.] display and touch [Assist Toe Cuff]. The cuff should be attached such that the hose faces towards the heel of the foot. The cuff is fan-shaped. Its shorter end should be positioned at the base of the toe. Wrap the cuff along the root of the toe above the toe cover.



If the toe cuff assist function is used, the air bag will contain a small amount of air before it is wrapped around the toe. Firmly wrap the cuff around the toe in this condition. When wrapped, the air is exhausted from the air bag to provide an adequate wrapping.

Finally, check that there is no gap between the cuff and the toe.



Set "Toe Cuff Attachment Guide" to "No" in the BP Exam. Setting if not using the toe cuff attachment guide. The toe cuffs and toe cuff covers are optional and need to be purchased separately.

Position	Model	Cuff color	Toe circumference (mm)	Toe cover
Big toe	CUF-139M2	Blue	65-90	OA-459M
Second toe	CUF-139S2	Brown	50-65	OA-459S

## **Chapter 4 Entering Patient Information**

Enter the name, age and gender of the patient.

There are following 6 methods to enter the information.

Input Method	Description	Reference
Basic information input	Enter items such as the ID, age, gender and height manually.	"Entering the Basic Information" (P4-3)
Master ID	Load information from the DMS.	"Loading Information from the DMS (Master ID)" (P4-8)
Patient file selection	Use patient information registered to an SD card.	"Using Patient Information Registered to an SD Card (Patient File Selection)" (P4-9)
Load past information	Use patient information from examination data saved to the media (including internal memory).	"Using Patient Information from Examination Data Saved to the Media (Load Past Information)" (P4-12)
External input	Read information from a magnetic card, barcode, etc.	"Connecting an ID Reader and Displaying Order Information" (P10-8)

Select an appropriate method depending on the situation.



The Difference between Patient File Selection and Loading Past Information

- Patient file selection allows to select patient information from a patient information list.
- Loading past information allows to load patient information from examination data saved to a media (including internal memory) by entering the patient's ID. The patient's height can be loaded from previous examination data, which is convenient when measuring CAVI in pulse wave examinations. (This is the same as the "Load ID" function of the VS-1500 series.)

#### NOTE

When using the device for the first time, set whether to assign the ID in the patient information with or without zero padding (adding zeros to the ID). If using zero padding, set the number of digits to be used for ID. (Refer to "Patient Information Settings" (P11-9).)

## **Patient Data Categories**

The following information can be entered.

Display	Description	Setting Range	Note
ID	Patient code	3-20 digits	Can be entered in alphanumeric characters
Age	Age	3 digits (0-150)	Separate input fields are used for the year, month, week and day. (Do not enter months, weeks or days for CAVI measurements.) A date of birth can also be entered.
Gender	Gender	Male/Female	
Name	Name	24 single-byte characters	Alphanumeric characters and symbols can be entered.
Dept.	Department information such as the ward (Dept. 1) and department (Dept. 2)	Up to 4 items can be entered in Dept. 1-4. Code: 4-8 digits 16 single-byte characters	4-8 digits, can be changed A total of up to 400 items can be registered for Dept. 1-4.
Height	Height	3-digit integer + 1 decimal place	Unit: cm, inch Max. 300cm
Weight	Weight	3-digit integer + 1 decimal place	Unit: kg, lb Max. 300kg

#### **Chapter 4 Entering Patient Information**

Display	Description	Setting Range	Note
Abdominal Circumfere nce	Abdominal Circumference	3-digit integer + 1 decimal place	Unit: cm, inch Max. 300cm
Blood Vessel Length	Blood vessel length (Displayed when the blood vessel length input format is set to Section or Segment in the settings.)	3-digit integer + 1 decimal place	Unit: cm, inch Max. 300cm
Med.	Medicine code or medicine information	Code: 2-4 digits 16 single-byte characters	Up to 20 items can be registered
Symp.	Subjective symptoms	Code: 2-4 digits 16 single-byte characters	Up to 20 items can be registered
Comment	Comment	Code: 2-4 digits 100 single-byte characters	Alphanumeric characters and symbols can be entered. Up to 20 items can be registered
BP	Systolic/diastolic blood pressure	3 digits each	Unit: mmHg, kPa
Body position	The position being measured	Supine, sitting or standing	
Respiration Rate	Respiration rate	3 digits	
Inquiry	Inquiry	Hypertension, Hyperlipidemia, Diabetic, Beta Blocker	Hypertension, Hyperlipidemia, Diabetic, Beta Blocker: Y/N
		Therapeutic exercise application	Therapeutic exercise application/ Application with condition/ Contraindication/Unfilled: Y/N
Doctor	The doctor in charge	Code: 2-12 digits Dr. Nm1-2 can be used to enter a total of 2 items 24 single-byte characters	Alphanumeric characters and symbols can be entered. A total of up to 100 items can be registered for Dr. Nm1 and 2.
Technician	The name of the technician in charge	Code: 2-12 digits 24 single-byte characters	Alphanumeric characters and symbols can be entered. Up to 100 items can be registered



It is possible to set whether to display entered information, whether to record the entered information even after the power is turned OFF, the number of digits in ID numbers, the position of the hyphen (-) in ID numbers, prefix of ID, ID Auto Increment and the unit of each item. Set these beforehand. (Refer to "Patient Information Settings" (P11-9).)

Items for "Dept.", "Med.", "Symp.", "Comment", "Doctor" and "Technician" can be registered in advance. (Refer to "Patient Information Settings" (P11-9).)

It is possible to set whether to display the entry for Dept. after the entry for Name or after the entry for BP. (Refer to "Patient Information Settings" (P11-9).)

## **Entering the Basic Information**

1 Turn ON the power.

(Refer to "Turning the Power ON and OFF" (P2-12).)

2 Touch the patient information display area.



3 Enter the ID number.

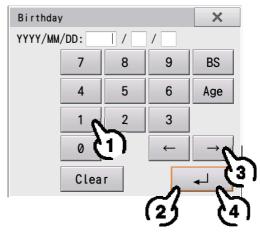


- 1) Enter the ID number.
  - [Clear]: All entered numbers are cleared.
  - [BS]: The number to the left of the cursor is cleared.
  - [+1]: 1 is added to the current ID number.
  - [-1]: 1 is subtracted from the current ID number.
  - [x]: Closes the "Input ID" window.
- **2)** Touch [ ← ].
  - The entered ID is reflected in the "Patient Information" window.



This window is not displayed if [Patient Info.] - [General/ID-A.C.] - [ID number] - [Input ID Number] is set to [No] in the Settings.

4 Enter the patient's birth date.

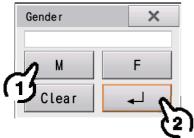


- 1) Touch the number buttons to enter the patient's year of birth.
  - [Clear]: All entered numbers are cleared.
  - [BS]: The number to the left of the cursor is cleared.
  - [Years], [Mths], [Weeks], [Days]: Switches the age unit when entering the age.
  - [Age]: Age input window will be displayed.
  - [D.O.B.]: Date of birth input window will be displayed.
  - [x]: Closes the "Date of birth" window.
- 2) Press the number buttons to enter the month.
  - Touch [←] to return the cursor to the Year input field.
- Touch [→] to move the cursor to the Day input field and press the number buttons to enter the day.
  - Touch [←] to return the cursor to the Month input field.
- **4)** Touch [ **↓** ].
  - The age is calculated from the entered date of birth and reflected in the "Patient Information" window.



The age can also be entered directly. Touch [Age] to switch to the "Enter age" window and enter the age using the number buttons.

## 5 Select the patient's gender.



- 1) Touch "Male" or "Female".
  - [Clear]: The entered gender is cleared.
  - [x]: Closes the "Gender" window.
- 2) Touch [ \_ ].
  - The entered gender is reflected in the "Patient Information" window.

## **6** Enter the name of the patient.



- 1) Enter the name of the patient.
  - [A→a] [a→A]: Switches between capital and lower case English letters.
  - [Symbol]: Switches to symbols.
  - [BS]: The character to the left of the cursor is cleared.
  - [Clr All]: All entered characters are cleared.
  - [←]: Moves the cursor to the left.
  - $[\rightarrow]$ : Moves the cursor to the right.
  - [Space]: Makes a space.
  - [x]: Closes the "Name" window.

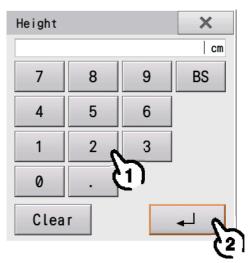
#### 2) Touch [ \_ ].

• The entered name is reflected in the "Patient Information" window.



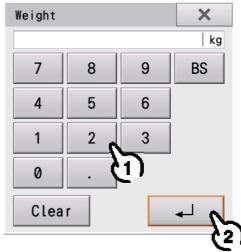
If Clear All IDs is not set to "Yes", "Test pattern" remains in the Name field if a test pattern is measured immediately beforehand. In this case, enter the correct name or clear the name.

## 7 Enter the height.



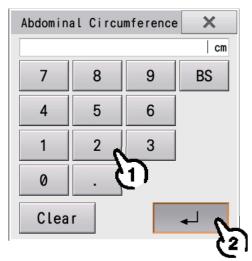
- 1) Touch the number buttons to enter the patient's height.
  - [x]: Closes the "Height" window.
- 2) Touch [ \_ ].
  - The entered height is reflected in the "Patient Information" window.

## 8 Enter the weight.



- 1) Touch the number buttons to enter the patient's weight.
  - [x]: Closes the "Weight" window.
- **2)** Touch [ **↓** ].
  - The entered weight is reflected in the "Patient Information" window.

### 9 Enter the abdominal circumference.



- 1) Touch the number buttons to enter the patient's abdominal circumference.
  - [x]: Closes the "Abdominal Circumference" window.
- 2) Touch [ \_\_ ].
  - The entered abdominal circumference is reflected in the "Patient Information" window.

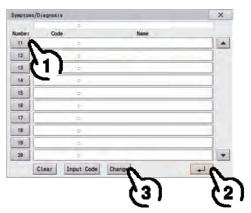
## 10 Enter Med.1 and 2.



- 1) Touch the applicable medicine.
  - [Clear]: All entered numbers are cleared.
  - [x]: Closes the window.
- 2) Touch [ \_ ].
  - The selected medicine is reflected in the "Patient Information" window.
- 3) The code and medicine name can be changed by touching the applicable medicine and then touching [Change].

(The medicines with codes 1 to 10 cannot be changed.)

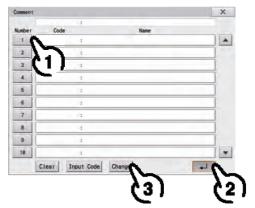
## 11 Enter the symptoms.



- 1) Touch the applicable symptom.
  - [Clear]: All entered numbers are cleared.
  - [x]: Closes the window.
- 2) Touch [ \_\_ ].
  - The selected symptoms are reflected in the "Patient Information" window.
- The code and symptom name can be changed by touching the applicable symptom and then touching [Change].

(The symptoms with codes 1 to 10 cannot be changed.)

## 12 Enter a comment.



- 1) Touch the applicable comment.
  - [Clear]: All entered numbers are cleared.
  - [x]: Closes the window.
- 2) Touch [ \_\_ ].
  - The selected comment is reflected in the "Patient Information" window.
- 3) The code and comment can be changed by touching the applicable comment and then touching [Change].

## 13 Enter the blood pressure (BP).

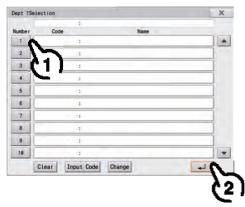


- Touch the number buttons to enter the patient's systolic blood pressure.
  - [x]: Closes the "Input BP" window.
- 2) Touch [DIA].
- 3) Enter the patient's diastolic blood pressure in the same way.
- **4)** Touch [ **↓** ].
  - The entered blood pressure is reflected in the "Patient Information" window.
- 5) Touch [BP mon.] to switch to brachial blood pressure measurement mode and measure the blood pressure.

(Refer to "Chapter 8 Brachial Blood Pressure Examinations" (P8-1) .)

Touch [Back] to return to the patient information entry window.

## 14 Select Dept. 1.

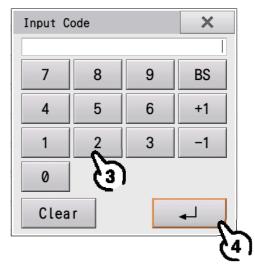


- 1) Touch the applicable department code.
  - [Clear]: All entered numbers are cleared.
  - [x]: Closes the "Select Dept. 1." window.
- **2)** Touch [ **↓** ].
  - The selected department classification is reflected in the "Patient Information" window.

#### **■** Entering the Department Code Directly

Department codes can be directly entered by the following process:

- 1) Touch [Input Code].
- 2) Touch the number buttons to enter the code.
  - [Clear]: All entered numbers are cleared.
  - [BS]: The number to the left of the cursor is cleared.
  - [+1]: 1 is added to the current code.
  - [-1]: 1 is subtracted from the current code.
  - [x]: Closes the "Input Code" window.

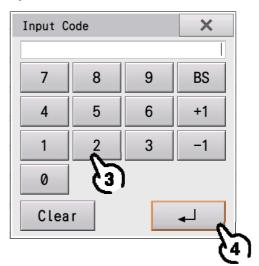


- 3) Touch [Enter].
  - The entered code is reflected in the "Select Dept. 1." window.

## Creating/Editing a Department

Create or edit a department code and department name. Change the information by the following process.

- 1) To create a new department, touch a blank department classification. To edit an existing department, touch the department classification to be edited.
- 2) Touch [Change].
- 3) Enter the code.

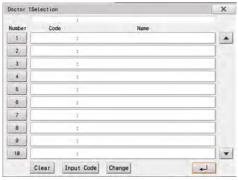


**4)** Touch [ **↓** ].

5) Enter the name of the department.

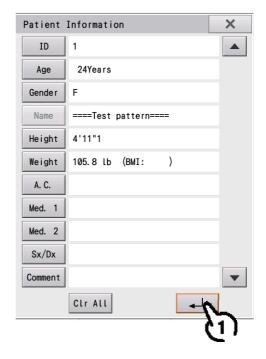


- **6)** Touch [ **↓** ].
- 15 Enter Dept. 2, 3 and 4 in the same way.
- 16 Enter the body position.
  - 1) Touch Supine, Sitting or Standing.
    - [Clear]: The selected body position is cleared.
  - 2) Touch [ \_ ].
    - The selected body position is reflected in the "Patient Information" window.
- 17 Enter the respiration rate.
  - 1) Touch the number buttons to enter the patient's respiration rate.
    - [x]: Closes the "Respiration Rate" window.
  - 2) Touch [ 🚚 ].
    - The entered value is reflected in the "Patient Information" window.
- 18 Enter the doctor and technician.



- 1) Touch the applicable code.
  - [Clear]: All entered numbers are cleared.
  - [x]: Closes the window.

- 2) Touch [ \_\_ ].
  - The selected content is reflected in the "Patient Information" window.
- The code and doctor/technician name can be changed by touching the applicable doctor/ technician name and then touching [Change].
- 19 Check the entered information and touch [ \_ ].



- The display will return to home display.
- The entered information will be displayed in the patient information display area.
- [Clr All]: All entered information is cleared.
- [x] Saves the entered information and returns to the home display.



If any information needs to be changed, touch the item to display the input window and correct the information.

# Loading Information from the DMS (Master ID)

Turn the ID number into a button and search for and load the patient information from the DMS.



For patient information settings, select [Extended] under [General/ID-A.C.] - [Input ID], and [Master ID] under [General/ID-A.C.] - [Patient Information Reference] beforehand. (Refer to "General/ID-A.C." (P11-9).) Also, configure the communication settings.

1 Touch the patient Information display area.



2 Enter the ID number.



- 1) Touch the number buttons to enter the ID number.
  - [x]: Closes the "Input ID" window.
- 2) Touch [ \_\_ ].
  - The entered ID is reflected in the "Patient Information" window.

The entered ID number is turned into a button and the patient information is loaded from the DMS and displayed in the "Patient Information" window.



- The message "No patient information was found for the entered ID number" is displayed if there is no patient information corresponding to the specified ID number.
- The following information can be loaded using Master ID.

Items that can be loaded
Name1 (maximum length: 10 double-byte characters)
Birth Date
Age
Gender
Height
Weight
SYS
DIA
Department 1
Department 2
Med.1
Subjective symptoms
Comment
(maximum length: 22 single-byte characters)

# Using Patient Information Registered to an SD Card (Patient File Selection)

Patient information entered when conducting an examination can be registered to an SD card and then called and used again for the next examination.



- Set [General/ID-A.C.] [Patient Information Reference] to "Patient file selection" to use the function for registering patient information.
- The following patient information can be registered: ID number, name, date of birth, gender, height, weight and Dept. 1-4. Enter a date of birth, not an age, as the patient's age will be different at each examination. (Refer to "Entering the Basic Information" (P4-3).)
- Insert an SD card in the SD card slot and format it beforehand. (Refer to "Initialization" (P9-4).)
- A maximum of 5,000 patient data can be registered to the SD card, but this number may vary depending on the capacity
  of the SD card that is used and the content that is recorded. Use only an SD card specified by Fukuda Denshi.

### **Registering the Patient Information**

Enter the patient information, perform the examination and then save the patient information to the SD card.

- 1 Insert a formatted SD card in the SD card slot.
- 2 Enter the patient information and perform the examination.



When the examination is completed, the patient information used in the examination is automatically registered to the SD card.

The message "There is no patient information registration environment on the SD card. Create a registration environment?" is displayed when registering patient information for the first time. Touch [Yes].

#### NOTE

- The patient information is registered to the SD card immediately after the examination is completed.
   Removing the SD card or turning OFF the power too soon may damage the SD card.
- The examination result will not be saved if the power is turned OFF with the examination screen displayed.
   Make sure to touch [Back] before turning OFF the power.

## Loading the Patient Information Using the ID Number

Use the ID number to load the patient information from the SD card.

1 Touch the patient information display area.



 ${f 2}$  Enter the ID number.



- 1) Touch the number buttons to enter the ID number.
- **2)** Touch [ **↓** ].

- The entered ID is reflected in the "Patient Information" window.
- 3) The patient information will be searched on the SD card from the entered ID, and the searched information will be displayed in the patient information display area.



The message "No patient information was found for the entered ID number" is displayed if there is no patient information corresponding to the specified ID number.

## Loading the Patient Information by Specifying the Patient

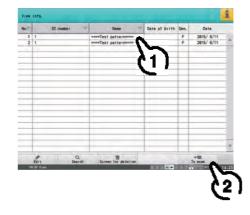
Load the patient information from the SD card before performing an examination.

## 1 Touch [Selection].



The patient information list is displayed.

## 2 Select a patient.



1) If the applicable patient information is not displayed, use the scroll bar to scroll up and down the list.

Press the title area to sort the list in ascending or descending order.

[No.]: Sorts the list in number order.

[ID number]: Sorts the list in order of ID number.

[Name]: Sorts the list in name order.

2) Selecting a patient on the list will highlight the corresponding row in black. Touch [To exam] to display the selected information on the patient information display area.

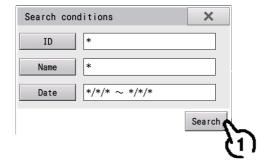


Only the following patient information is registered: examination date, ID number, name, date of birth, gender, height, weight and Dept. 1-4. Enter other patient information separately as needed.

## **Searching the Patient Information Using Search Condition**

The patient information can be searched using the search condition.

- 1 Specify search conditions and search the patient information.
  - 1) Touch [Search] to display the "Search conditions" window.



[ID]: Specify an ID number.

[Name]: Specify a name.

[Exam. Date]: Specify an examination date.

2) Touch the [Search] button to display a list of items that match the entered ID number, name or examination date.

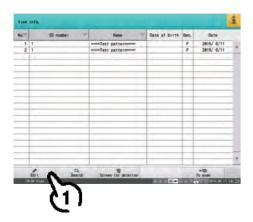


- Wild cards can be specified with a "\*". For example, "123\*" will retrieve items such as "12345" and "1234567890" in addition to "123".
- Omit the start number to retrieve all items up to the end number or omit the end number to retrieve all items from the start number onward.
- When searching for character strings, all items containing that character string are retrieved. For example, if "Ab" is entered, names such as "Abel", "Abraham" and "Fabian" will be retrieved.

## **Deleting the Unnecessary Patient Information**

Unnecessary patient information can be deleted from the SD card.

## 1 Touch [Edit].

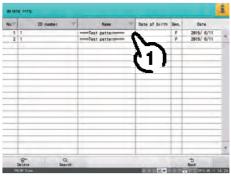




On a confirmation window, touch [Yes].

# 2 Touch the patient information to be deleted.

The selected patient information is highlighted.



1) Select the patient to be deleted, and touch [Delete].

A confirmation window will be displayed.

2) Touch [Execute].

The specified patient information is deleted from the SD card.



More than one patient information can be selected for deletion.

3) Touch [Back] to return to the patient information list.

# Using Patient Information from Examination Data Saved to the Media (Load Past Information)

The examination data saved on the media (internal memory, SD card, USB memory) can be loaded and used on the next examination.

To use this function, set [General/ID-A.C.] - [Input ID] to "Extension" and set [General/ID-A.C.] - [Patient Information Reference] to [Load past information] under the patient information setting.

All the entered patient information can be loaded. Make sure to enter a date of birth, not an age, as the patient's age will be different depending on the examination date.

## MEMO

- This function is the same as the "Load from CF Card" function of the previous models such as the VS-1500 series.
- The data will be searched in the media selected under [File] [General] [Read from This Media].
- 1 Touch the patient information display area.



2 Enter the ID number.



- 1) Touch the number buttons to enter the ID number.
- 2) Touch [ \_\_ ].
  - The entered ID is reflected in the "Patient Information" window.
- 3) The patient information will be searched on the SD card from the entered ID, and the searched information will be displayed in the patient information display area.



 The message "No patient information was found for the entered ID number" is displayed if there is no patient information corresponding to the specified ID number.

# Chapter 5 Blood Pressure and Pulse Wave Examinations (CAVI/ABI/TBI): Standard Mode

Limb blood pressure, CAVI, ABI and TBI can be measured.

#### Take care when applying to the following patients.

- · Patients with swelling or who bleed easily
- Patients with blood congestion that may cause a thrombus
- Patients with blood congestion that may cause peripheral circulation obstruction
- Patients who experience inflammation, suppurative disease, external wounds, etc. in the area where the cuff is attached

#### **Important Basic Precautions**

- Do not attach the cuff in the following areas.
  - · Limbs with an artificial dialysis shunt
  - Limbs receiving IV drips, blood transfusions, etc.
  - · Limbs to which a catheter, etc. is attached
  - · Arm on the side of a mastectomy
- Blood pressure and pulse waves are measured by applying pressure to the limbs. If the patient reports any pain or physical abnormalities, press the [STOP] key immediately to abort the examination.

#### 



- Let the patient rest for 10 minutes before the examination.
- Frequent measurements will result in blood flow disorder. When repeating the measurement, wait until the blood flow is fully recovered. (5 minutes interval is recommended.)
- Do not connect other medical devices to the limb which a cuff is attached.
- When the cuff is removed after the examination, check the condition of the limbs.
- When examining, make sure to let the patient lie on his/her back so that the cuffs are at the same level as the heart.
- During the examination, let the patient maintain a relaxed posture free from tension and instruct him/her not to speak, apply pressure to or hit the cuffs or move the limbs. Otherwise, correct measurements may not be obtained, or the measurement may fail due to prolonged measurement by the cuff re-inflation.
- Always observe the patient and device to ensure safe operation of the device, and if any abnormality is found, take appropriate measures such as ceasing operation of the device in the safest way for the patient.
- If cuff inflation does not stop, takes a long time to deflate or any other malfunction occurs, press the [STOP] button immediately and remove the cuffs.
- Measurements such as BP values, ABI values and CAVI values should be considered only as reference values when examining a patient with fluctuating respiration rate due to extrasystole, etc.
- Arterial stenosis or occlusion in the lower limbs may cause a lower CAVI value.
- Make sure to comply with the environmental condition during operation/storage/transportation specified on "Main Specifications" (P13-1).

## **Measurement Preparations**



Check the following again before measuring.

Two modes can be used for blood pressure and pulse wave examinations: Simple Examination Mode and Standard Examination Mode. This section explains Standard Examination Mode.

The mode can be switched by configuring the setting in [Menu] - [Setting] - [Equipment Control] - [Examination Mode]. (Refer to "Equipment Control Settings" (P11-6).)

#### Is the place of examination appropriate?

- Check for noise generating electrical devices such as x-ray equipment or ultrasonic instruments nearby.

  If any, turn them OFF or change the place of examination to avoid adverse influence from such instruments.
- Select a location with low humidity.
- Make sure the selected location is quiet and not exposed to engine noise, noise from air conditioners, vibrations from railroads, passing cars or treadmills.

#### How is the condition of the patient?

- Check if the patient is nervous.
   If nervous, his/her blood pressure may be higher than normal. Reassure the patient by briefly explaining the examination method to the patient.
- Also, instruct the patient not to move or speak.

#### Are the cuffs and sensors connected to the device and applied to the patient correctly?

• If not, it may not be possible to perform the examination or the results may be incorrect.

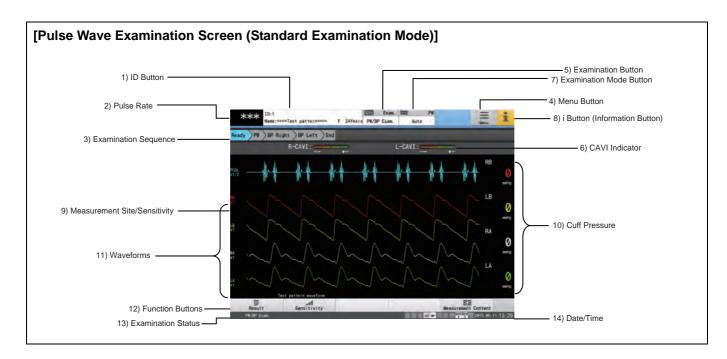
#### Is the air hose bent, or is there any object placed on the air hose?

• It may affect the accuracy of the examination and cause incorrect examination results.



Let the patient lie down and rest for 10 minutes or more before starting the measurements.

## **Home Display**



#### 1) Pulse Rate Display Area

The pulse rate is displayed.

#### 2) ID Button (Patient Information Display Area)

Touch this to display a window for entering patient information.

Information such as the ID, name and age of the patient are displayed, and patient information can be added or edited.

#### 3) Examination Sequence Area

Displays the examination procedure and current progress status.

#### 4) Menu Button

Touch this to display the Menu screen.

#### 5) Examination Button

Touch this to display the "Select Examination" window to select an examination. The currently selected examination will be displayed.

#### 6) CAVI Indicator

Displays the quality of the pulse wave signal.

#### 7) Examination Mode Button

Switches the mode for obtaining waveforms (Auto or Manual).

#### 8) i Button (Information Button)

Touch this to display a screen indicating the status of the device.

#### 9) Measurement Site/Sensitivity Display

Displays the measurement site and waveform sensitivity.

#### 10) Cuff Pressure Display

Displays the current cuff pressure.

#### 11) Waveform Display

Displays the PCG and the pulse waves for the brachial, ankle and toe cuffs.

#### 12) Function Buttons

Displays the function buttons for this device.

#### 13) Examination Status Display Area

Displays the examination status.

#### 14) Date/Time Display Area

Displays the current date and time.

## **Function Buttons Used in Examinations**

#### **Before Examination**

Result	Sensitivity	Blood Vessel Length	Previous Measurement	Measurement Content	1/2
		Touch [1/2] to switch	displays		
File List		Assist Toe Cuff	Normal Md. Offline Md.	Comm.Inp.	2/2

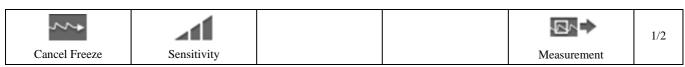
#### **During Examination**

Sensitivity	Up/Down Pressure		Freeze	1/2	
Touch [1/2] to switch displays					
	1,00			2/2	
	Addition Pressure				

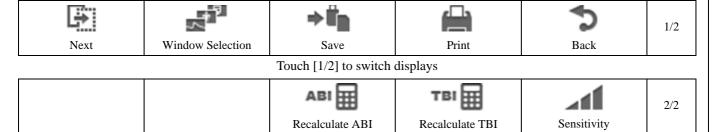
#### **During CAVI Check**

		Pause	1/2
			1/2
		Cancel	

### **During Freeze Condition**



## **During Examination Results Display**



[Result]: Switches to the examination result display. [Sensitivity]: Displays the window for adjusting the sensitivity.

[Blood Vessel Length]: Displays the window for setting the blood vessel length.

[Previous Measurement]: Displays previous examination data for the same ID.

[Measurement Content]: Displays the window for setting the measurement sites, interval period, and measurement count. [File List]: Displays the file list.

[Assist Toe Cuff]: Turns ON/OFF the Assist Toe Cuff function. This is displayed when TBI measurement is available.

[Normal Md./Offline Md.]: Switches between normal mode and offline mode. During normal mode, data will be saved to the DMS. During offline mode, online operation such as master ID, auto saving to DMS, report output will not be performed.

[Comm. Inp.]: Displays the comment input window.

[Up/Down Pressure]: Displays the window for increasing or decreasing the cuff.

[Freeze]: Switches to the Freeze display. This is displayed in manual mode.

[Pause (Cancel)]: Stops counting the remaining time to allow more time for the CAVI check. Touch Cancel while paused to start counting the remaining time again.

[Cancel Freeze]: Cancels freezing and returns to the home display.

[Measure]: Sets the selected area as a target for measurement, cancels freezing and proceeds to the next measurement.

[Next]: Proceeds to the next data if multiple items are selected from the file list in the result display.

[Window Selection]: Displays the windows that can be selected in the result display.

[Save]: Saves the examination data to media.

[Print]: Prints an examination report.

[Recalculate ABI], [Recalculate TBI]: Reselects the brachial site and recalculates ABI/TBI.

[Back]: Switches from the examination result display to the home display.

[ $\downarrow 1/2$ ]: Displayed when the function buttons consist of 2 pages.



"Blood Vessel Length" is not displayed if "Height" is set for [PW/BP Exam.] - [Pulse Exam. Set.] - [Distance Input Method] in the Settings.

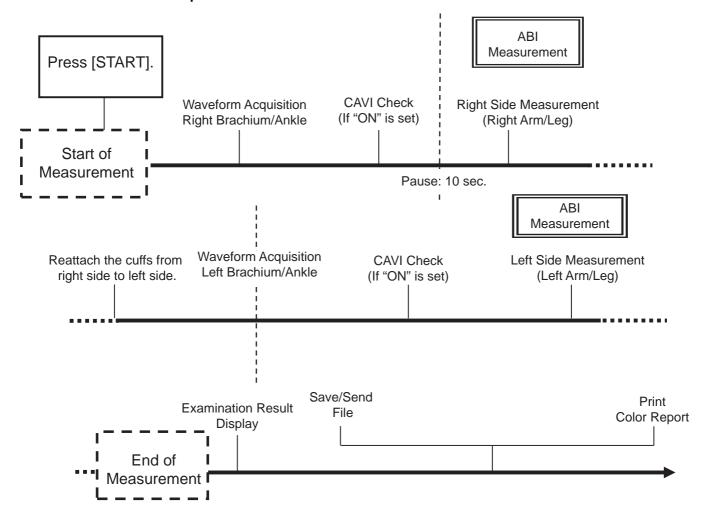
"Result" is displayed only if measurement results exist.

"Return to Freeze" is displayed only if the user proceeded to this display from the Freeze display.

"Next" is displayed only if subsequent examination results exist.

# Measuring CAVI/ABI (Standard 2-Channel Examination)

Below is the measurement procedure for standard 2-channel examination. This section describes the procedures for each mode.



### 1 Touch [Examination].



## 2 Touch [PW/BP Exam.].

The preset examination mode will be displayed when the power is turned ON.



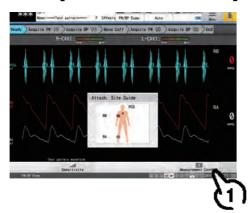
## 3 Enter patient information.

(Refer to "Chapter 4 Entering Patient Information" (P4-1))

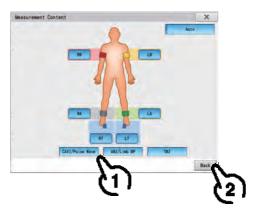


If "Section" or "Segment" is set for [PW/BP Exam.] - [Pulse Exam. Set.] - [Distance Input Method] in the Settings, enter the measurement sites according to "Entering Blood Vessel Length" (P5-20).

## 4 Touch [Measurement Content].



**5** Check the measurement items and measurement sites.



- 1) Check the measurement items.
  Select from CAVI/Pulse Wave or ABI/Limb BP.
- 2) Check the measurement sites.
  Check the measurement sites.
  (Refer to "Checking and Changing the Measurement Items and Sites" (P5-19))
- 3) Touch [Back].

## 6 Attach the cuffs to the right brachium and ankle.

A measurement site guide is displayed. Attach the cuffs in the indicated position. (Refer to "Attaching the Limb Cuffs (4-Channel Examination)" (P3-2) .)

# 7 Attach the PCG microphone and check that a PCG appears in the display.

• (Refer to "Attaching the PCG Microphone" (P3-5) .)

## **8** Check the waveform sensitivity.

Check whether the waveform sensitivity on the home display is appropriate or not. Usually, the sensitivity is set to "Auto" to enable automatic selection of proper sensitivity for each waveform. If the sensitivity is not appropriate, you can manually select the sensitivity. (Refer to "Setting Sensitivity Manually" (P5-20).)

## **9** Press the [START] key on the display unit.

- Inflate the cuffs to acquire a pulse wave.
- If "Manual" is set as the method for acquiring waveform, refer to "Manually Capturing and Measuring Waveforms" (P5-24).
- To suspend the measurement, press the [STOP] key.



If the cuff pulse wave is unstable, reattach the cuffs or touch [Up/Down Pressure].

If the current pressure is 30mmHg or 50 mmHg, it will be pressurized to 50mmHg or 65 mmHg, respectively.

- The pulse wave will be acquired after the cuff inflation.
- During waveform acquisition, the boundaries will be displayed. If the boundaries are in the incorrect position, press the [STOP] key to stop the measurement and reattach the cuffs and PCG microphone.
- Press the [START] key to perform a real-time CAVI check and display a CAVI indicator to check the

reliability of the waveform. A red display indicates low reliability and a green display indicates high reliability. If the display remains red, press the [STOP] key to stop the measurement and check whether the cuffs or PCG microphone are attached correctly and whether the patient is calm.

(Refer to "Real Time CAVI Check" (P5-12).)



10 If "ON" is set for [PW/BP Exam.] - [Pulse Exam. Set.] - [CAVI Check], the CAVI Check display will appear after the CAVI measurement is completed.

(Refer to "CAVI Check Result Display" (P5-12))



If CAVI cannot be measured due to 🗥 causes such as noise interference, the message "Cannot measure CAVI..." appears in the CAVI Check display and the measurement will be suspended. To stop the measurement and perform the measurement again, press the [STOP] key. To continue measuring, touch [Cancel] or press the [START] key. The blood pressure measurement will proceed.

11 Measure the right brachial and right ankle blood pressure.



The pause duration can be set between 5 and 120 seconds in "Meas Pause Right to Left" in the BP Exam. Settings.

## 12 Change the cuff sites. Remove the cuffs from the right brachium/ankle and attach them to the left brachium/ankle.

A measurement site guide is displayed. Attach the cuffs in the indicated position. (Refer to "Attachment Site Guide" (P5-11).)

- 13 After the cuffs have been attached, press the [START] key.
  - Inflate the cuffs on the left brachium/ankle to acquire a pulse wave.
  - The CAVI Check display appears. (Refer to "CAVI Check Result Display" (P5-12))
- 14 Measure the left brachial and left ankle blood pressure.
- 15 Upon completion, the examination result will be displayed. (Refer to "Examination Result Display" (P5-14) .)

If the color printer is set to automatic printing, the results are automatically printed after the measurements are completed.



■ If "ON" is set for [File] - [General] -[Auto Save] in the Settings:

The data is automatically saved to the media set for [Save Media].

16 Press the [Back] button.

The display will return to the home display.



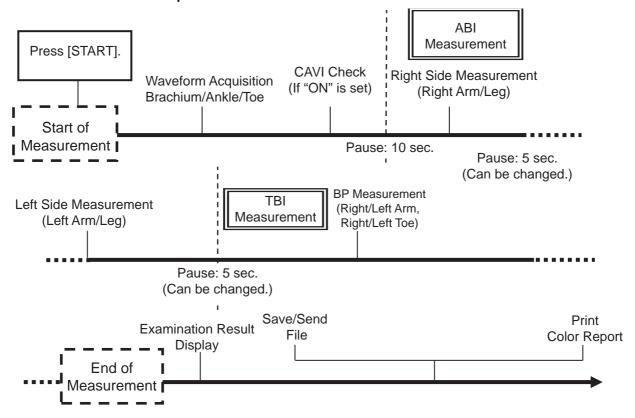
The results can be checked before they are automatically saved or sent. This mode is enabled if "ON" is set for [PW/ BP Exam.] - [Pulse Wave: Gen] - [Confirm results] in the Settings. Touch [Back] in the result display to return to the home display without saving or sending. (In this case, the measurement results will not be saved.)

# Measuring CAVI/ABI/TBI (4-Channel/6-Channel Examination)

Below is the measurement procedure for a 4-channel or 6-channel examination.

If one BPU-100 NIBP/Pulse Wave Unit is added, measurements can be performed on the left and right sides without switching the cuffs.

Adding two BPU-100 NIBP/Pulse Wave Units makes it possible to measure the toe blood pressure and TBI. This section describes the procedure for each mode.



### NOTE

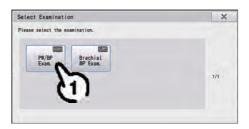
• TBI can be measured in 6-channel examination. A toe waveform is displayed in the waveform display and TBI is displayed in the measurement content and measurement results.

## 1 Touch [Examination].



## 2 Touch [PW/BP Exam.].

The preset examination mode will be displayed when the power is turned ON.



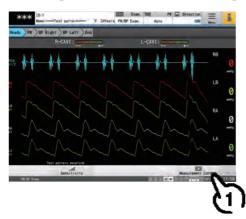
## 3 Enter patient information.

(Refer to "Chapter 4 Entering Patient Information" (P4-1))

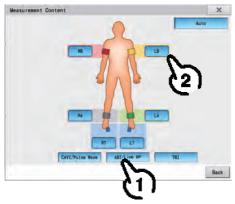


If "Section" or "Segment" is set for [PW/BP Exam.] - [Pulse Exam. Set.] - [Distance Input Method] in the Settings, enter the measurement sites according to "Entering Blood Vessel Length" (P5-20).

## 4 Touch [Measurement Content].



## 5 Check the measurement items and measurement sites.



- 1) Check the measurement items.

  Select from CAVI/Pulse Wave, ABI/Limb BP or TBI.
- 2) Check the measurement sites.
- 3) Touch [Back].

## **6** Attach the brachial, ankle and toe cuffs.

(Refer to "Attaching the Cuffs (Standard 2-Channel Examination)" (P3-1), "Attaching the Limb Cuffs (4-Channel Examination)" (P3-2) and "Attaching the Toe Cuff (6-Channel Examination)" (P3-6))

- 7 Attach the PCG microphone and check that PCG waveform appears in the display.
  - (Refer to "Attaching the PCG Microphone" (P3-5) .)

## 8 Check the waveform sensitivity.

Check whether the waveform sensitivity on the home display is appropriate or not. Usually, the sensitivity is set to "Auto" to enable automatic selection of proper sensitivity for each waveform. If the sensitivity is not appropriate, you can manually select the sensitivity. (Refer to "Setting Sensitivity Manually" (P5-20).)

## **9** Press the [START] key on the display unit.

- Inflate the cuffs to acquire a pulse wave.
- If "Manual" is set as the method for acquiring a waveform, refer to "Manually Capturing and Measuring Waveforms" (P5-24).
- To suspend the measurement, press the [STOP] key.



If the cuff pulse wave is unstable, reattach the cuffs or touch [Up/down Pressure].

If the current pressure is 30mmHg or 50 mmHg, it will be pressurized to 50mmHg or 65 mmHg respectively.

- The pulse wave will be acquired after the cuff inflation.
- During waveform acquisition, the boundaries will be displayed. If the boundaries are in the incorrect position, press the [STOP] key to stop the measurement and reattach the cuffs and PCG microphone.
- Press the [START] key to perform a real-time CAVI check and display a CAVI indicator to check the reliability of the waveform. A red display indicates low reliability and a green display indicates high reliability. If the display remains red, press the [STOP] key to stop the measurement and check whether the cuffs or PCG microphone are attached correctly and whether the patient is calm. (Refer to "Real Time CAVI Check" (P5-12).)



10 If "ON" is set for [PW/BP Exam.] - [Pulse Exam. Set.] - [CAVI Check], the CAVI Check display will appear after the CAVI measurement is completed.

(Refer to "CAVI Check Result Display" (P5-12))



 $\triangle$ 

If CAVI cannot be measured due to causes such as noise interference, the message "Cannot measure CAVI..." appears in the CAVI Check display and the measurement will be suspended. To stop the measurement and perform the measurement again, press the [STOP] key. To continue measuring, touch [Cancel] or press the [START] key. The blood pressure measurement will proceed.

11 The right brachial and right ankle blood pressure will be measured. After the set pause duration, the left brachial and left ankle blood pressure will be measured.



The pause duration can be set between 5 and 120 seconds in "Meas Pause Right to Left" in the BP Exam. Settings.

12 After the set pause duration, the toe blood pressure will be measured.



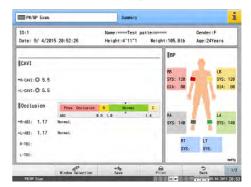
The pause duration can be set between 5 and 120 seconds in "Measurement Pause for Toe BP" in the BP Exam. Settings.

The brachial blood pressure can be remeasured during the toe blood pressure measurement depending on the setting.

Set "ON" for [PW/BP Exam.] - [BP Exam. Setting] - [Inflate Brachial Cuff for TBI] in the Settings.

# 13 Upon completion, the examination result will be displayed. (Refer to "Examination Result Display" (P5-14).)

If the color printer is set to automatic printing, the results are automatically printed after the measurements are completed.



If "ON" is set for [File] - [General] -[Auto Save] in the Settings:

The data is automatically saved to the media set for [Save Media].

14 Press the [Back] button.

The display will return to the home display.



The results can be checked before they are automatically saved or sent. This mode is enabled if "ON" is set for [PW/BP Exam.] - [Pulse Wave: Gen] - [Confirm results] in the Settings. Touch [Back] in the result display to return to the home display without saving or sending. (In this case, the measurement results will not be saved.)

### **Attachment Site Guide**

When measuring both the left and right CAVI and ABI for standard 2-channel examination, the cuff attachment site guide will be displayed.

It will be displayed at the timing when the cuffs and PCG microphone needs to be attached. The corresponding cuff and PCG microphone will be indicated by blinking.

The guide disappears when the examination starts after cuffs and PCG microphone are attached.



## **Waveform Length of Pulse Wave**

Select a waveform length for the pulse wave to be obtained in the CAVI examination from 5 seconds, 8 seconds or 16 seconds. A longer waveform length means that measurement takes longer, but it improves the accuracy as a larger number of pulse waves can be used for the CAVI calculation. Even if pulse waves that are unreliable for reasons such as arrhythmia are excluded, there will still be sufficient pulse waves that can be used for CAVI calculation.

Set the waveform length by selecting [PW/BP Exam.] - [Pulse Exam. Set.] - [Pulse Wave Measurement Time] in the Settings. (Default: 8 sec.)



This function is common to 2-channel, 4-channel and 6-channel examinations.

#### **Real Time CAVI Check**

During waveform acquisition, press the [START] key to display a real time pulse wave check (CAVI check).



This function is common to 2-channel, 4-channel and 6-channel examinations. The example shown below is 2-channel examination.



The CAVI indicator displays the number of usable beats to measure CAVI with a reliable quality. Measure until it turns green.

Red : - - <24% usable beats Orange : - 25-49% usable beats
Yellow : + 50-74% usable beats Green : ++ >75% usable beats

#### **Auto Extension**

If "Auto" is set for [Pulse Exam. Set.] - [Wave Recording Method] or "ON" is set for [Pulse Exam. Set.] - [Auto Extension], pulse wave acquisition is automatically extended if the waveform consists of less than 50% of usable beats due to arrhythmia or other irregular pulse.

Waveform acquisition completes when the waveform consists of 50% or more usable beats.



Auto extension is possible for up to 60 seconds. If a proper waveform cannot be acquired after 60 seconds, auto extension will cease. In such case, perform the examination again.

## **CAVI Check Result Display**

If "ON" is set for [PW/BP Exam.] - [Pulse Exam. Set.] - [CAVI Check], the CAVI Check display will appear after the CAVI measurement is completed.



This function is common to 2-channel, 4-channel and 6-channel examinations.

#### [2-Channel Examination]



#### [4 or 6-Channel Examination]



#### 1) Waveform Area

Displays the waveform.

For 2-channel examination, the upper area displays the waveform of the first measurement and the lower area displays the waveform of the second measurement.

#### 2) CAVI Indicator

Displays the number of usable beats that can be used to measure CAVI with a reliable quality. Measure until this turns green. For 2-channel examination, the upper area displays the waveform of the first measurement and the lower area displays the waveform of the second measurement.

Red: - <24% usable beats
Orange: - 25-49% usable beats
Yellow: + 50-74% usable beats
Green: ++ >75% usable beats

#### 3) Remaining Time

Counts down the remaining time of the CAVI check.

#### 4) Measured Beats

Displays the number of measured beats.

#### 5) Comment

Displays any comments about the measurement.

#### 6) Measured Data

The measured data will be displayed.



The symbols displayed in the representative value column indicate the selected beats for the corresponding item.

#### If the measurement duration is 8 or 16 seconds

×: <24% usable beats

 $\triangle$  : 25-49% usable beats

○: 50-74% usable beats

⊚ : >75% usable beats

#### If the measurement duration is 5 seconds

×:1 usable beat

 $\triangle$ : 2 usable beats

O: 3 usable beats

⊚ : 4-6 usable beats

#### • [Pause]

Touch this to pause the countdown.

#### • [Cancel]

Touch this to resume the countdown.

## **Examination Result Display**

When the examination is completed, the examination result will be displayed.

Flick left or right on the screen (slide your finger quickly across the screen) to switch between the examination result displays.

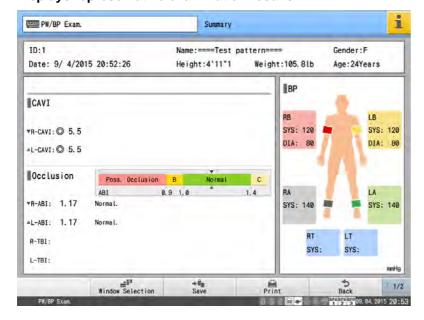
Touch the [Window Selection] button to display a window for switching the display. Touch the [Summary], [BP], [Wave+Meas.] or [Trend] button to switch the display.



This function is common to 2-channel, 4-channel and 6-channel examinations. The example shown below is 4-channel examination.

#### • [Summary]

Displays representative examination results.

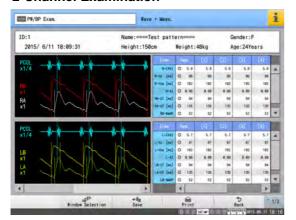


- The patient information (ID, name, gender, age, height and weight) and the date/time of the examination are displayed.
- R/L-CAVI, R/L-ABI, R/L-TBI and ABI bar graph are displayed.
- The left and right brachial, ankle and toe blood pressure (SYS and DIA) are displayed.
- The items that are not measured are left blank.
- The threshold level of the ABI bar graph is either 1.4 or 1.3 depending on the TASCII/ACC AHA settings.

#### • [Wave+Meas.]

The waveform and the measurement for each beat can be checked.

#### 2-Channel Examination



#### **4-Channel Examination**



- The patient information (ID, name, gender, age, height and weight) and the date/time of the examination are displayed.
- The acquired waveform, average value and detailed measurements for each beat are displayed.
- Double-touching the waveform area will allow to edit the boundaries.
- Slide the waveform display area or detailed values to navigate left, right, up or down through the waveform or measurements.
- When measuring CAVI on both sides in 2-channel examination;

The waveform and measurement displays are divided vertically.

Upper display: PCG, right brachial and right ankle pulse wave measurements for the first measurement will be displayed.

Lower display: PCG, left brachial and left ankle pulse wave measurements for the second measurement will be displayed.

- When measuring CAVI on both sides in 4-channel examination;
  Displays PCG, the right brachial, left brachial, right ankle and left ankle pulse wave measurements.
- Detailed measurements are shown for the following measurements.

  R-CAVI, L-CAVI, R-tb, L-tb, R-tba, L-tba, RB-UT, LB-UT, RA-UT, LA-UT, RT-UT, LT-UT

  RB-%MAP, LB-%MAP, RA-%MAP, LA-%MAP, RT-%MAP, LT-%MAP

#### • [BP]

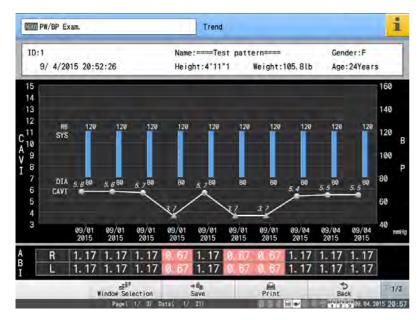
The blood pressure and pulse amplitude graph can be seen.



- The patient information (ID, name, gender, age, height and weight) and the date/time of the examination are displayed.
- The SYS/DIA, UT and %MAP values are shown for the left and right brachia, left and right ankles and left and right toes.

- A pulse amplitude graph is shown for the left and right brachia, left and right ankles and left and right toes.
- If "ON" is set for Inflate Brachial Cuff for TBI, the SYS/DIA, UT and %MAP values and a pulse amplitude graph of the left and right brachia when measuring TBI will be also displayed.

#### • [Trend]



- The patient information (ID, name, gender, age, height and weight) and the date/time of the examination are displayed.
- Representative CAVI values (higher value of left and right CAVI) and right brachial blood pressure values (SYS and DIA) are displayed in a trend graph.

If no right brachial blood pressure values exist, left brachial blood pressure values are displayed instead.

- : Normal measurement  $\blacktriangle$  : CAVI (reference value) O : Converted CAVI  $\vartriangle$  : Converted CAVI (reference value) Reference values: Refer to P5-33 Converted CAVI: CAVI value converted from the VS-1000
- Up to 10 items are displayed in trend graphs.
- The Y axis range of the blood pressure is calculated based on the maximum and minimum displayed SYS/DIA values. Unit per segment: 10mmHg, 1.5kPa
- Up to 10 previous left and right ABI values are displayed in a table. Values of 0.9 or lower are displayed with a red background.

#### • [Save]

Touch this to display the "Storage Media" window. Touch the desired storage media to manually save the data.



#### • [Print]

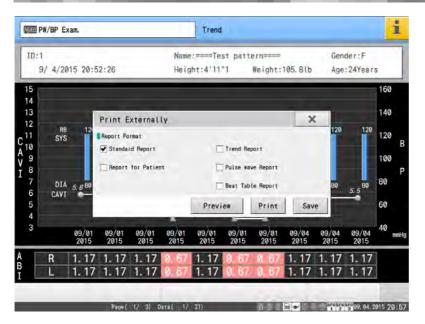
Examination results can be manually output to an external color printer, etc.

Touch [Print] to print on the set printer.

Touch [Preview] to display the report image.

Touch [Save] to display the "Storage Media" window. Touch the desired storage media to save the PDF file.

Refer to "Description of the Reports" (P5-26) for description of the reports.



#### Report Preview

When printing, touch "Preview" to check the preview of the report before printing.



[Zoom In]: Enlarges the display.

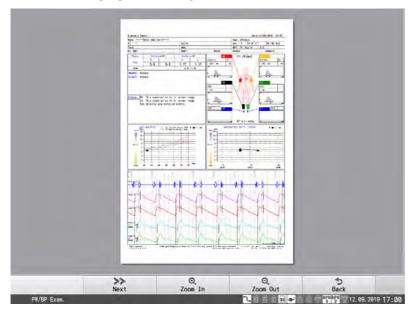
[Zoom Out]: Reduces the display.

[Next]: Preview of the next report will be displayed.

This is not displayed if no report exists.

[Back]: Preview of the previous report will be displayed.

This is not displayed if no report exists.





The PDF files are stored in the "IMAGE" folder on the card.

The shared folder can only be saved during blood pressure and pulse wave examinations.

Refer to "Network settings of shared folder" (P2-20) for instructions on configuring shared file settings.

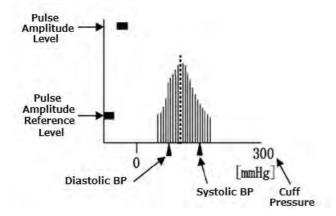


**BP-pulse Wave Amplitude Graph** 

The BP-pulse wave amplitude graph of right brachial, left brachial, right ankle and left ankle will be recorded. The pulse

amplitude graph shows the pulse wave amplitude and the blood pressure value measured by the oscillometric method. The amplitude is adjusted at recording for easy viewing.

The highest level of pulse wave amplitude obtained while measuring the blood pressure will be indicated. A pulse wave amplitude level that is higher above the reference level indicates a more stable measurement. If it is below the reference level, the blood pressure cannot be measured.



### NOTE

The Y axis scale differs between the amplitude graph and the pulse wave amplitude level.



- The shape of the pulse wave amplitude graph may be affected by R-R changes caused by pacemaker/arrhythmia or body movement.
- It is recommended to perform the examination again if the shape of the pulse wave amplitude graph is irregular or the pulse and blood pressure values are unreliable.

# **Changing the Measurement Content**

## **Checking and Changing the Measurement Items and Sites**

## 1 Touch [Measurement Content].

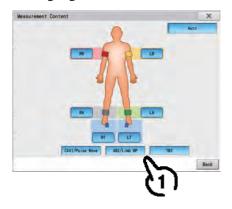


MEMO

The default measurement items are the items set in [PW/BP Exam.] - [Pulse Wave: Gen] - [Default Measurements].

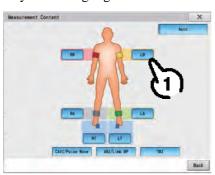
## 2 Touch measurement items to be enabled.

The highlighted items are enabled.



## **3** Touch the measurement sites.

The blood pressure or pulse wave can be measured only for the highlighted sites.



MEMO

The default measurement sites are the sites set in [PW/BP Exam.] - [Pulse Wave: Gen] - [Default Measurement Site].

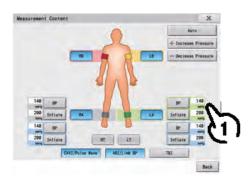
If [TBI] is not enabled as a parameter, toe blood pressure is not measured even if [RT] and [LT] are enabled as measurement sites, and therefore toe blood pressure measurement results will not be displayed.

## NOTE

- If CAVI, ABI or TBI is selected as a measurement item, the relevant measurement sites are selected automatically.
- TBI is displayed only for 6-channel examination.

## **Setting Blood Pressure Measurements Manually**

## 1 Set the inflation value.



The inflation value can be set manually. The sites that can be set are the left and right ankles and left and right toes.

Touch [Auto] to switch to manual inflation mode and display the operation buttons.

[BP]: Enter the systolic blood pressure for the ankle. [Inflate]: Enter the inflation value of the cuff.

\*The values are set as follows:

(Blood Pressure Value) + 60 = (Inflation Value) [Increase Pressure]:

Increases the inflation value by 20mmHg at all sites.

[Decrease Pressure]:

Decreases the inflation value by 20mmHg at all sites



The inflation value of blood pressure measurement is usually set to "Auto". Refer to P11-19 for information on settings.

## $oldsymbol{2}$ Touch [Back] after configuring the settings.

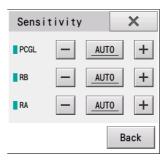
## **Setting Sensitivity Manually**

## 1 Touch [Sensitivity].



## 2 Touch [+] or [-] to change the sensitivity.

- Touching [+] changes the sensitivity in the following order: x1 → x2 → x4 → x8 → x16.
- Touching [-] changes the sensitivity in the following order:  $x1 \rightarrow x1/2 \rightarrow x1/4 \rightarrow x1/8 \rightarrow x1/16$ .





Touch the button displaying the sensitivity ([x4], [x1/16], etc.) to set the sensitivity to "AUTO" (automatic sensitivity).

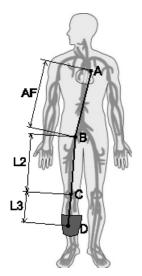
3 Touch [Back] after configuring the settings.

## **Entering Blood Vessel Length**

If "Section" or "Segment" is set as the distance input method, enter the distance between the measurement sites with the following procedure. This procedure is not required if "Height" is set as the distance input method as it will be calculated automatically from the height.

## • Entering Section Values

# 1 Measure the distance between the measurement sites.



Measure the distance using a PWV measurement scale (OA-35, optional) or a tape measure.

#### AF Distance

The distance (cm) from the left side of the left second intercostal sternum (point A in the diagram) to the pulse position of the right femoral artery (point B in the diagram).

## L2 Distance

The distance (cm) from the pulse position of the right femoral artery (point B in the diagram) to the center of the right knee joint (point C in the diagram).

## L3 Distance

The distance (cm) from the center of the right knee joint (point C in the diagram) to the center of the cuff applied to the right ankle (point D in the diagram).

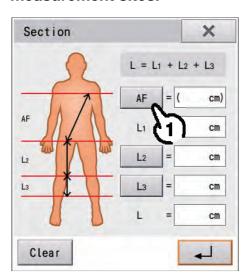


Make sure to enter the distance between each site when measuring CAVI. The measurement cannot be performed if the distance is not entered.

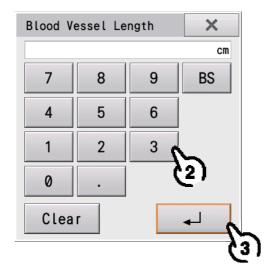
## 2 Touch [Blood Vessel Length].



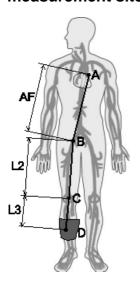
# 3 Enter the distance between the measurement sites.



1) Touch the button corresponding to the site to enter a value.



- Entering Segment Values
- 1 Measure the distance between the measurement sites.



- 2) Enter the value.
- 3) Touch [ \_\_ ].
  - The L1 distance is automatically calculated and entered when the AF distance is entered.
  - The total L distance is calculated when all values are entered.
- 4) Repeat steps 1) 3) to enter all necessary values.
- 5) When all values have been entered, touch [ ] in the "Section" window.

Place the tape measure with the "0" point (starting point) at the center of the right ankle cuff (point D in the diagram) and measure the distances from there to the center of the right knee joint (point C in the diagram), the pulse position of the right femoral artery (point B in the diagram) and the left side of the left second intercostal sternum (point A in the diagram).

#### **Knee Joint**

Scale reading (cm) at point C.

#### **Femoral Artery**

Scale reading (cm) at point B.

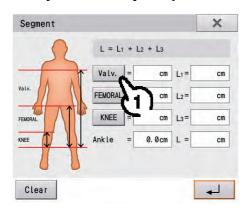
#### **Aortic Valve**

Scale reading (cm) at point A.

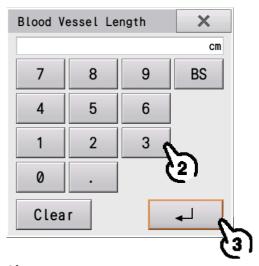
2 Touch [Blood Vessel Length].



3 Enter the distances to the aortic valve, artery and knee joint positions.



1) Touch the button for the corresponding value.



- 2) Enter the value.
- 3) Touch [ ← ].

  The distances between the entered positions (L1, L2 and L3) are calculated automatically.
- 4) Repeat steps 1) 3) to enter all necessary values.
- 5) When all values have been entered, touch [ ₄ □ ] in the "Segment" window.

## To Ensure Accurate Measurement

Pay attention to the following points to ensure accurate measurement.

**Note: Points for Checking Waveforms** 

PCG waveform: Check that there is a primary radical wave in the second heart sound.

O Good Waveform



× Bad Waveform



Brachial pulse wave: Check that the pulse wave rises smoothly and that there is a notch on the downward slope.

O Good Waveform

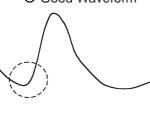


× Bad Waveform

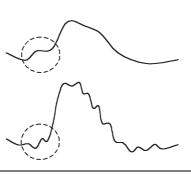


Ankle pulse wave, knee pulse wave: Check that the pulse wave rises smoothly.

O Good Waveform



× Bad Waveform





- Make sure that there are no ambient vibrations or noise.
- Check whether the bed is large enough and does not cause tension by not properly accommodating the limbs.
- Check that limbs are located on the limb cushions correctly so that the patient does not become tense from the effort of keeping them in position.
- Check that the cuffs are not too loose.

# **Measuring CAVI (Manually)**

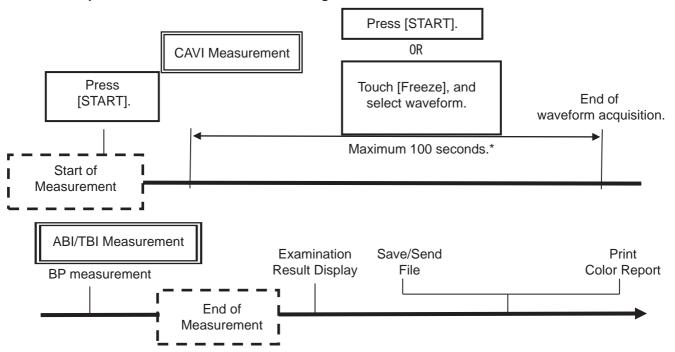
During CAVI examinations, it is possible to obtain up to 100 seconds of waveform data and select and measure any continuous heart rate from the screen while viewing the CAVI indicator.



This function is common to 2-channel, 4-channel and 6-channel examinations.

Below is the procedure for taking measurements.

When performing 2-channel examination on both sides, the measurement process needs to be performed twice with separate measurements taken for the right and left side.



<sup>\*</sup>The device returns to the standby status if it is paused for maximum of 100 seconds.

## **Manually Capturing and Measuring Waveforms**

- 1 Touch the [Auto/Manual] button at the top of the display to switch to manual capture mode.
  - "Auto/Manual" is displayed at the top of the home display when the device is in the waveform capture mode.
- **2** Perform steps 3 to 9 of "Measuring CAVI/ABI/TBI" (P5-9).
- 3 Press the [START] key on the display unit.
- 4 "Press the START button to acquire the waveforms" is displayed when measurements can be taken.
- **5** Touch the [Freeze] button after the boundaries of the waveform have been displayed.



The acquired waveforms will be displayed. Scroll through the displayed waveforms and select a continuous waveform with no irregularities such as arrhythmia by surrounding it with a white box. The quality of the selected waveform will be displayed in real time by the CAVI indicator.



The maximum waveform length that can be acquired during freeze status is 100 seconds.

6 After selecting the waveform, touch [Measure].

After the CAVI check display, measurement will start.

7 The waveforms can be also acquired by pressing the [START] key at step 4, after the boundaries are displayed, and when the waveform is stable.

Check the points mentioned in "To Ensure Accurate Measurement".

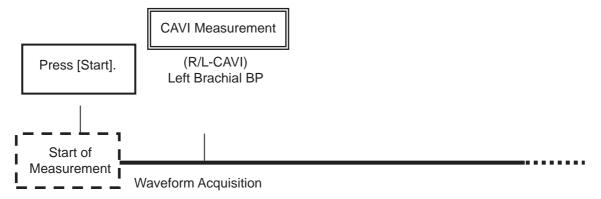
The blood pressure measurement starts after the CAVI check display.

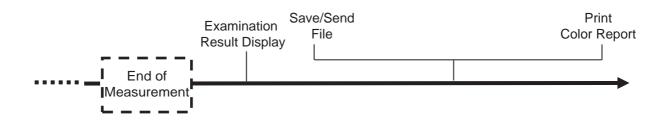


- Measurement will automatically complete after 100 seconds.
- It is also possible to set "Manual" for [PW/BP Exam.] - [Pulse Exam. Set.] - [Wave Recording Method] in the Settings.

# Simple CAVI Measurement

If measuring only CAVI, the overall examination time can be reduced by setting "ON" for [PW/BP Exam.] -[Pulse Exam. Set.] - [Simple CAVI Measurement]. Use this function for examinations with 4 channels or more. Below is the procedure for taking measurements.







If this measurement mode is configured so that ABI is not measured, the blood pressure is measured without recording the left brachial pulse wave during the pulse wave measurement to reduce the time of CAVI measurement. As a result, the waveform of the left brachial pulse wave will not be recorded for the color report.

The measurement procedure is the same as the standard measurement (P5-6). Attach the brachial and ankle cuffs and PCG microphone. Check the waveform and press the [START] key to start the measurement. The left brachial blood pressure is measured at the same time as the pulse wave.



- CAVI can be measured in a shorter time if ABI and TBI are not measured.
- If ABI and TBI are also measured, the left brachial blood pressure is measured only once when acquiring the pulse wave, even if "ON" is set for Inflate Brachial Cuff for TBI.

# **Description of the Reports**

## **Types of Reports**

The following reports can be printed.

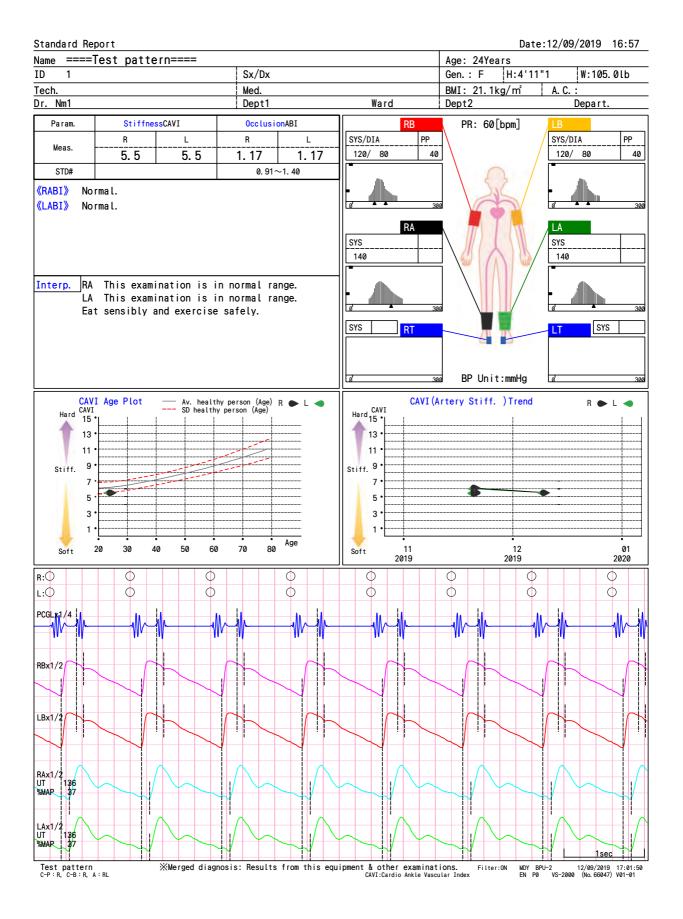
Report Name	Printed Items
Standard Report	A 5, 8 or 16-second PCG, limb and toe pulse waves, CAVI, ABI, TBI, blood pressure, pulse amplitude graph, patient body illustration, trend graph, age graph and comments are printed.
Report for Patient	A report for the patient containing CAVI, ABI, blood pressure, CAVI, blood pressure, weight trend graph and age graph.
Trend Report	A report containing a trend graph of CAVI, ABI, TBI, blood pressure, weight, BMI and abdominal circumference.
Pulse Wave Report	A PCG and limb pulse wave and toe pulse wave are printed as full disclosure waveforms according to the 5, 8 or 16-second setting.
Beat Table Report	Detailed measurements for up to 20 beats are printed.

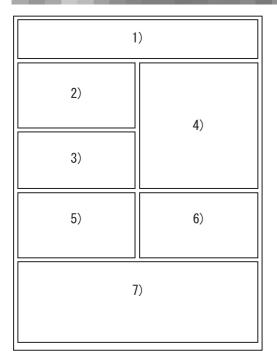
## NOTE

Pulse Wave Reports and Beat Table Reports can be printed for examination of 4 or more channels.

## **Color Reports**

## Standard Report





#### 1) Patient information

The patient information and the examination date/time are recorded.

#### 2) Numeric Data Table

CAVI, ABI and TBI values, the standard range and comments are recorded.

An ABI value of 0.90 or less is shown with a yellow background.



() are used if there is a possibility that the R-CAVI and L-CAVI values may not have been correctly measured. In this case, check the waveforms.

() are used in the following cases:

- 1. When ABI is 0.90 or less
- 2. When the pulse waves of 2 beats or less are usable (the values differ for each beat)

## 3) Observation Field

Comments of the results are printed, such as an age corresponding to the blood vessel or occlusion.

#### **Blood Pressure Value**

The blood pressure values and a pulse wave amplitude graph are recorded for the brachia, ankles and toes.

#### 5) Left Side of Standard Graph

The content to be printed can be selected by configuring the settings.

6) Right Side of Standard Graph

The content to be printed can be selected by configuring the settings.

#### 7) Waveform

PCG and cuff pulse wave (for the brachia, ankles and toes) are recorded. UT and %MAP values for the ankles and toes are also recorded.

## ■ Printed Items in the Right and Left Sides of the Standard Graph

The items to be printed can be selected from the following.

## Vascular Age Graph

A graph of the standard R/L-CAVI values for each age group is displayed. The black line indicates the average values. The red lines indicate  $\pm 1$  standard deviation. The circle marks the position of the patient's actual age (X axis) and R/L-CAVI value.

#### **CAVI Trend**

Previously measured CAVI values are marked on the graph. The numbers by the marks indicate the measured values.

(black): R-CAVI ▲ (black): Converted R-CAVI ● (green): L-CAVI ▲ (green): Converted L-CAVI

## **BP Balance**

The blood pressure of each limb is indicated by the distance from the origin. If the BP value of the right (left) brachium is not available, the BP of left (right) brachium will be printed. The same applies to the ankle blood pressure.

- +: Indicates the median point of the systolic blood pressure of the limbs.
- †: The length of the arrow indicates the degree of ischemia at the applicable site when ischemia is suspected.

#### **ABI Trend**

A trend graph of R/L-ABI is displayed.

#### **TBI Trend**

A trend graph of R/L-TBI is displayed.

#### **Brachial BP Trend**

A trend graph of the brachial blood pressure (SYS, DIA) is displayed.

## **Weight Trend**

A trend graph of the patient's weight is displayed.

#### **BMI Trend**

A trend graph of the patient's BMI is displayed.

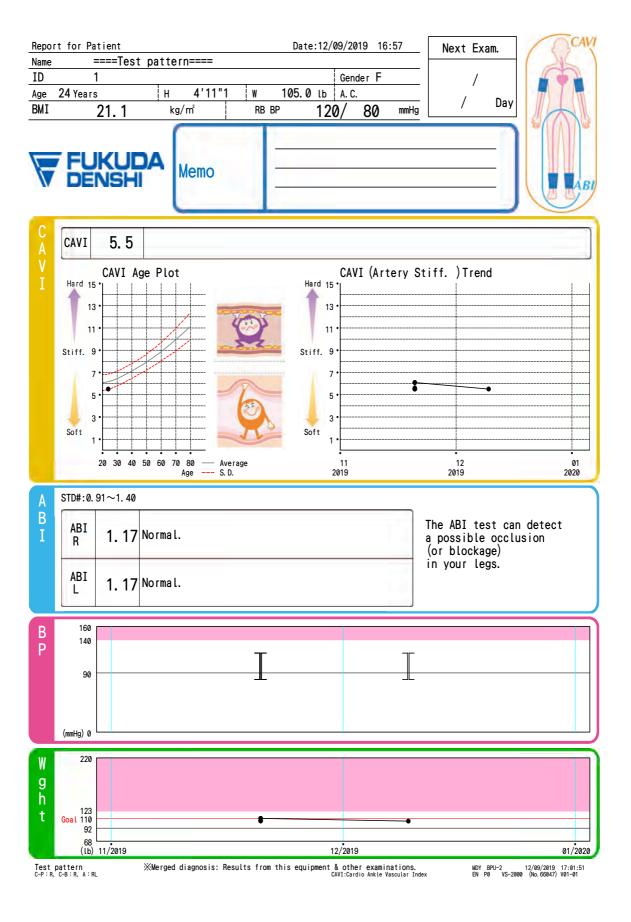
#### **Abdominal Circumference Trend**

A trend graph of the patient's abdominal circumference is displayed.



The items to be printed can be selected in [PW/BP Exam.] - [Print] - [Print2] -[Print Settings] in the Settings.

## • Report for Patient



1)
2)
3)
4)
5)

## 1) Patient information

The patient information and the examination date/time are recorded.

## 2) Memo

## 3) CAVI

The CAVI value is recorded.

A graph showing the CAVI progress in time series is printed. The black line indicates the average values. The red lines indicate  $\pm 1$  standard deviation.

## 4) Occlusion of Artery

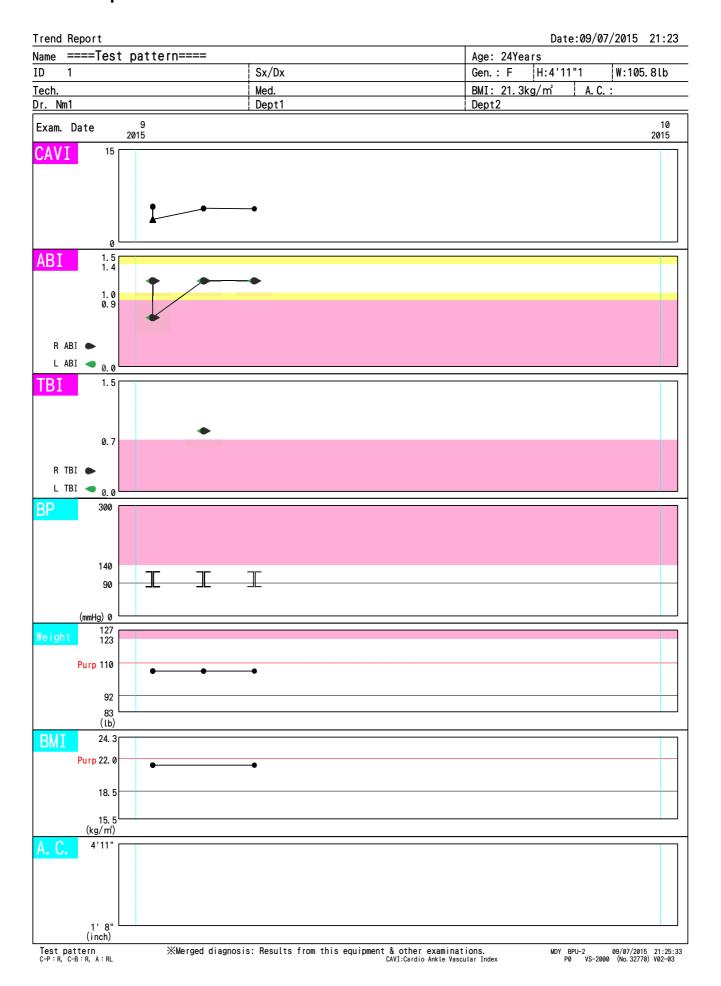
ABI value, the standard range and comments are recorded.

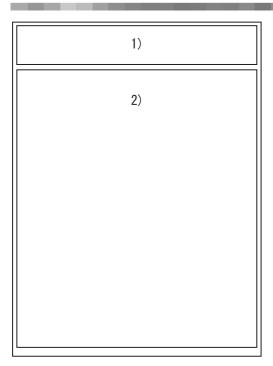
An ABI value of 0.90 or less is shown with a yellow background.

## 5) Trend Graph

A trend graph of the right brachial blood pressure and weight is printed.

## • Trend Report





## 1) Patient information

The patient information and the examination date/time are recorded.

## 2) Trend Display

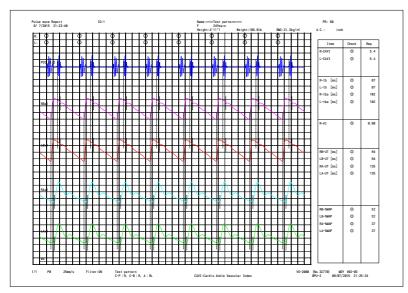
The following trend graphs are recorded.

- · CAVI Trend
- · ABI Trend
- · TBI Trend
- · BP Trend
- · Weight Trend
- · BMI Trend
- · Abdominal Circumference Trend

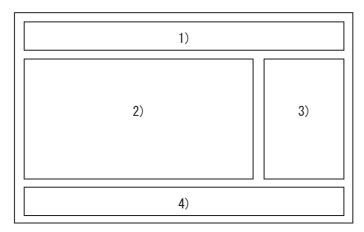


The target BMI is set as 22 which is the standard value. The target weight is calculated from the standard BMI of 22 and the patient's height.

## • Pulse Wave Report



(The above example is a pulse wave report of "5 seconds" measurement.)



#### 1) Header Information Area

The examination date, patient information and pulse rate are recorded.

## 2) Waveform Area

PCG, pulse wave and toe pulse waves are recorded.



The symbol O at the top of the waveform indicates which pulse(s) are used. A larger number of circles indicates a higher quality of waveform and more stable measurement of CAVI.

#### 3) Measurement Information Area

The following values are recorded: R-CAVI, L-CAVI, R-tb, L-tb, R-tba, L-tba, R-Tha, L-Tha, R-AI and UT and %MAP for each site.

## 4) Footer Area

Information such as hospital name is recorded.

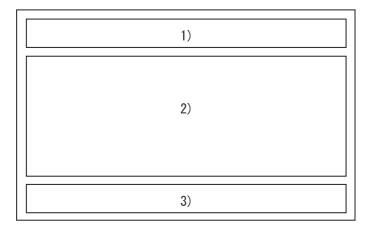
## NOTE

R-CAVI and L-CAVI values are marked with ( ) and designated as reference values if there is a possibility that the values may not have been correctly measured. In this case, check the waveforms.

- ( ) are used in the following cases:
- 1. When ABI is 0.90 or less
- 2. When the usable beats are 50% or less (the values of the beats are irregular)

## • Beat Table Report

eat Table Rep 9/ 7/2015 21			ID:1					F	24Y		 Weight: 185.	PR: 60 5.8Lb BMI:21.3kg/m' A.C.: inch
Item	Rep.	1st B	2nd B	3rd B	4th B	5th B	6th B	7th B	8th B	9th B	10th B	1
R-CAVI L-CAVI	O 5.4	5.4 5.4	5. 4 5. 4	5. 4 5. 4	5.4 5.4	5. 4 5. 4	5.4 5.4	5. 4 5. 4	5.4 5.4			1
R-tb [ms]	Q 87	87	87	87	87	87	87	87	87			†
L-tb [ms]	O 87	87	87	87	87	87	87	87	87			
R-tba [ms] L-tba [ms]	O 182	182 182	102	102	102 102	102 102	182 182	102 102	182 182			
R-AI	O 8.88	0.88	0.88	0.88	0.88	0.88	0.88	0.88	0.88			-
RB-UT [ms]	O 94 O 94	94 94	94 94	94 94	94 94	94 94	94 94	94 94	94 94			1
RA-UT [ms]	O 135	135	135	135	135	135	135	135	135		l	
LA-UT [ms]	O 135	135	135	135	135	135	135	135	135			
RB-1MAP	O 52	52	52	52	52	52	52	52	52	-		+
LB-1MAP	O 52	52	52	52	52	52	52	52	52			
RA-MMAP	O 37	37 37	37 37	37 37	37 37	37 37	37 37	37 37	37 37			
LA-SMAP	0 3/	3/	3/	3/	37	37	37	37	37			
Item	11th B	12th B	13th B	14th B	15th B	16th B	17th B	18th B	19th B	20th B	]	
R-CAVI L-CAVI												
R-tb [ms]											1	
L-tb [ms] R-tba [ms]												
L-tha [ms]												
R-AI											1	
RB-UT [ms] LB-UT [ms]			l	l							l	
RA-UT [ms]				l							l	
LA-UT [ms]												
RB-1MAP			_								-	
			l	l							l	
LB-1MAP			l	l							l	
RA-SMAP				l							l	
		1										



## 1) Header Information Area

The examination date and time, patient information and pulse rate are recorded.

## 2) Details Area

The following information is recorded: Detailed values for each beat (tb, tba, CAVI, UT,%MAP and AI) Waveform quality

## 3) Footer Area

Information such as hospital name is recorded.

# **Chapter 6 Blood Pressure and Pulse Wave Examination: Simple Mode**

## Take care when applying equipment to the following patients.

- · Patients with swelling or who bleed easily
- Patients with blood congestion that may cause a thrombus
- Patients with blood congestion that may cause peripheral circulation obstruction
- Patients who experience inflammation, suppurative disease, external wounds, etc. in the area where the cuff is attached

## **Important Basic Precautions**

- . Do not attach the cuff in the following areas.
  - · Limbs with an artificial dialysis shunt
  - Limbs receiving IV drips, blood transfusions, etc.
  - · Limbs to which a catheter, etc. is attached
  - · Arm on the side of a mastectomy
- Blood pressure and pulse waves are measured by applying pressure to the limbs. If the patient reports any pain or physical abnormalities, press the [STOP] key immediately to abort the examination.

## CAUTION



- Let the patient rest for 10 minutes before the examination.
- Frequent measurements will result in blood flow disorder. When repeating the measurement, wait until the blood flow is fully recovered. (5 minutes interval is recommended.)
- Do not connect other medical devices to the limb which a cuff is attached.
- · When the cuff is removed after the examination, check the condition of the limbs.
- When examining, make sure to let the patient lie on his/her back so that the cuffs are at the same level as the heart.
- During the examination, let the patient maintain a relaxed posture free from tension and instruct him/her not to speak, apply pressure to or hit the cuffs or move the limbs. Otherwise, correct measurements may not be obtained, or the measurement may fail due to prolonged measurement by the cuff re-inflation.
- Always observe the patient and device to ensure safe operation of the device, and if any abnormality is found, take appropriate measures such as ceasing operation of the device in the safest way for the patient.
- If cuff inflation does not stop, takes a long time to deflate or any other malfunction occurs, press the [STOP] button immediately and remove the cuffs.
- Measurements such as BP measurement values, ABI values and CAVI values should be considered only
  as reference values when examining a patient with fluctuating respiration rate due to extrasystole, etc.
- · Arterial stenosis or occlusion in the lower limbs may cause a lower CAVI value.

The simple mode examination navigates new users with on-screen operation instructions through each process. This mode is available only for 2-channel blood pressure and pulse wave examinations.



Two modes can be used for blood pressure and pulse wave examinations: Simple Mode and Standard Mode. This section explains the procedure for Simple Mode.

The mode can be switched by configuring the setting in [Menu] - [Equipment Control] - [Examination Mode]. (Refer to "Equipment Control Settings" (P11-6))



This function cannot be used if BPU-100 NIBP/Pulse Wave Units are added.

This function cannot be used if a language other than Japanese or English is selected in the language selection screen when the device is started for the first time.

## **Measurement Content**

The following items can be measured in this mode.

- CAVI on one side (right or left)
- · Brachial and ankle blood pressure on one side

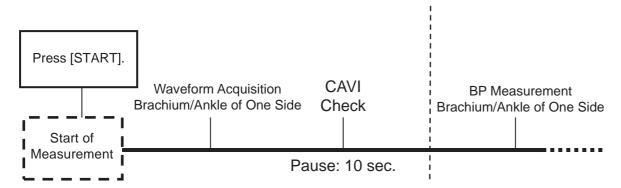
## NOTE

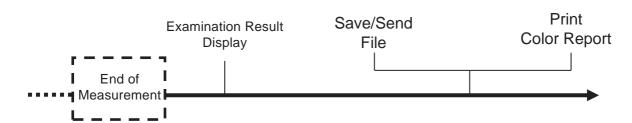
As Simple Examination Mode only measures one side, ABI is not measured and blood pressure is displayed for one ankle only.

The Simple Examination Mode is available only when English is selected as the language.

# **Measurement Procedure**

Below is the measurement procedure.





## 1 Touch [Examination].



## 2 Touch [CAVI/BP].

When the power is turned ON, the registered examination for startup will be displayed.



- **3** 1) Enter the patient information.
  - 2) Touch [Next].

(Refer to "Chapter 4 Entering Patient Information" (P4-1))

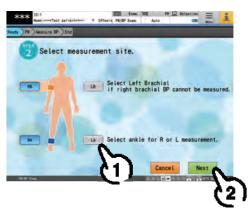


## **4** 1) Select a measurement site.

For standard use, select RB. Select LB if the right brachial blood pressure cannot be measured. Select either the right or the left ankle.

## 2) Touch [Next].

Touch [Cancel] to return to step 3.



5 Attach the cuffs to the brachium and ankle according to the displayed instructions and then touch [Next].

(Refer to "Attaching the Cuffs (Standard 2-Channel Examination)" (P3-1) )



- **6** 1) Attach the PCG microphone according to the displayed instructions.
  - 2) Check that a PCG waveform is displayed.
  - 3) Touch [Next].

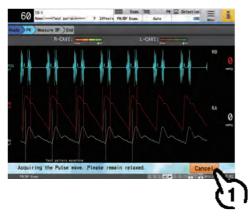
(Refer to "Attaching the PCG Microphone" (P3-5))



# 7 Read the displayed precautions, then touch [Start].



- Pulse wave acquisition starts.
- Touch [Cancel] to abort the examination. The display will return to step 3.



## NOTE

Make sure to keep the patient at rest during the pulse wave acquisition.

## 8 Touch [Next].

When the pulse wave acquisition is completed, the next display appears.

If the pulse wave is obtained correctly



The device proceeds to the blood pressure examination after 10 seconds.

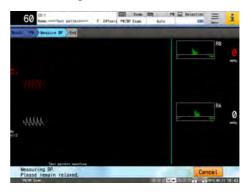


The following display appears if the CAVI check is not completed correctly.

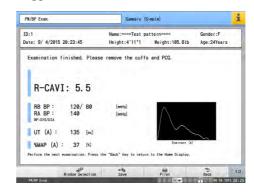


Touch [Cancel] to perform the examination again. To proceed to the blood pressure measurement, touch [Next].

• The blood pressure is measured.



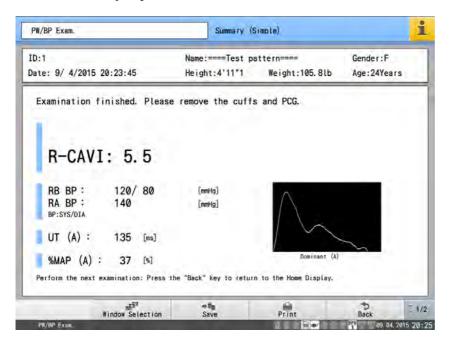
• When the examination is completed, the result display appears.



# **Examination Result Display**

When the examination is completed, the result display appears. Flick the screen (slide your finger quickly across the screen) to switch between displays.

## Result Display



#### 1) Patient Information Display

Displays the patient information and the examination date/time.

2) CAVI

Displays the CAVI values.

3) Brachial BP (SYS/DIA)

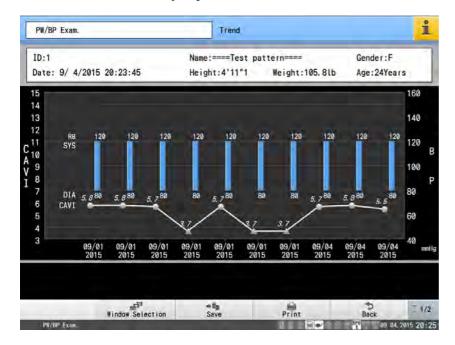
Displays the brachial blood pressure measurements.

## 4) Ankle BP (SYS)

Displays the ankle blood pressure measurements.

5) Dominant Wave of Ankle Pulse Wave: UT, %MAP Displays the UT and %MAP value of the dominant ankle waveform.

## • Trend Result Display



## 1) Patient Information Display

Displays the patient information and the examination date and time.

#### 2) Trend Graph

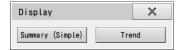
Displays the right or left CAVI value and right brachial blood pressure (SYS/DIA) in graph format.

## • [Next Result]

Proceeds to the results for the next data if multiple items are selected from the file list in the result display.

## • [Window Selection]

Displays a window for selecting a result display.



## • [Save]

Displays the "Storage Media" window. Select a media to save the data.

## • [Print]

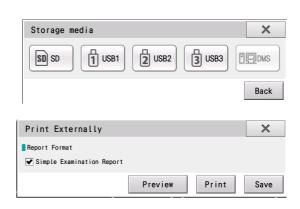
Examination results can be manually output to an external color printer, etc.

Touch [Print] to display the window for printing setup. Select a report, and touch [Print] to output to the set destination.

Touch [Preview] to display the report to be printed.

(Refer to "Report Preview" (P6-9))

(Refer to "Report Preview" (P6-9) for instructions on how to interpret reports.) Touch [Save] to save the PDF file. (Refer to "● [Save]" (P5-15))

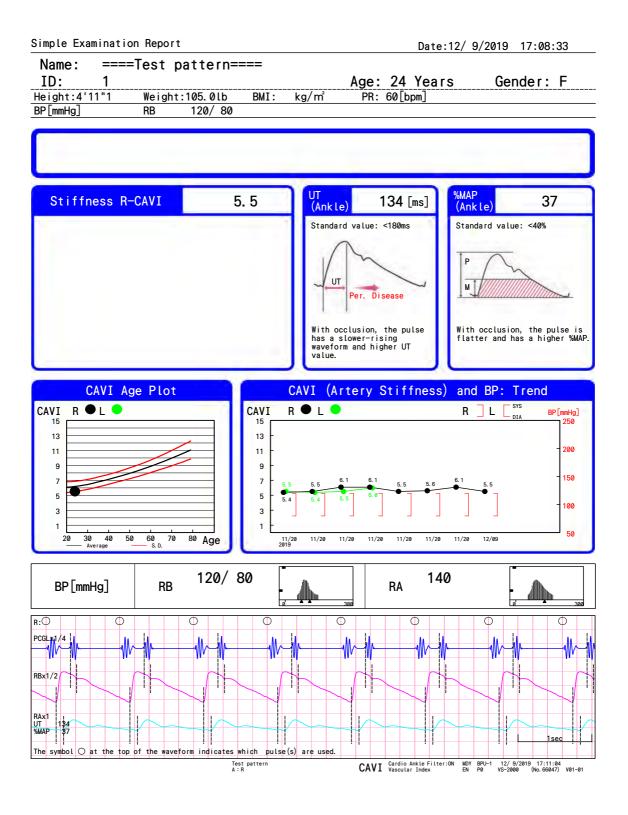


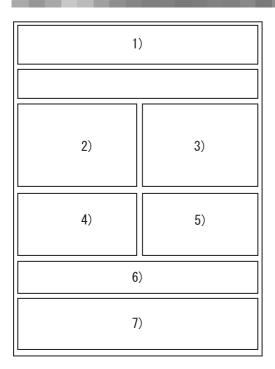
# **How to Interpret Reports**

## **Color Reports**

The following report is output from color printers.

## Simple Examination Report





## 1) Patient information

Records the patient information and the date/time of measurement.

#### 2) CAVI

Records the R(L)-CAVI measurement.

## 3) %MAP and UT for Ankle

Records the %MAP and UT measurements.

Displays the explanatory drawings for %MAP and UT.

#### 4) CAVI- Age Graph

A circle mark indicates the CAVI value (Y axis) at the patient's actual age (X axis). The black line indicates the average values. The red lines indicate  $\pm 1$  standard deviation.

#### 5) Trend Graph

Records the trend graph of the R(L)-CAVI and the right (left) brachial blood pressure.

## 6) Blood Pressure

Records the systolic, diastolic and pulse wave amplitude graph for the right (left) brachium and right (left) ankle.

## 7) Waveform

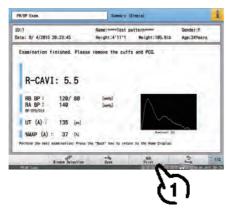
Records the PCG, right (left) brachial and right (left) ankle pulse waves.

Usable beats are marked with a circle at the top.

## **Report Preview**

Examination reports can be checked on the display before printing.

- 1 Conduct the examination.
- 2 Touch [Print] in the examination result display.



3 Touch [Preview].



4 Check the report.



[Back]: Displays a preview of the previous report. [Next]: Displays a preview of the next report.

[Zoom In]: Zooms in the report display. [Zoom Out]: Zooms out the report display.

5 Touch [Back] to return to the print display.

# Chapter 7 Blood Pressure and Pulse Wave Examinations: Other Functions

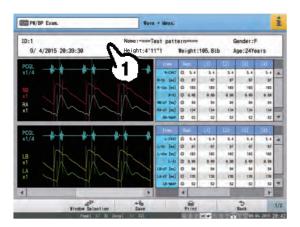
# **Correcting the Patient Information**

In the examination result display, patient information can be corrected.

1 Conduct the examination.

After the examination, examination result will be displayed.

2 Touch the patient information display area.



**3** Correct the patient information.



Refer to "Chapter 4 Entering Patient Information" (P4-1) for procedures.

4 After editing the patient information, print and save it manually.



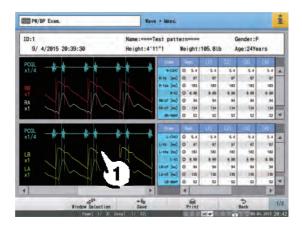
- The examination result is displayed after the examination is completed. It can be also displayed from the files. (Refer to "Loading Examination Data" (P9-8))
- The examination result will be saved as new data when it is saved immediately after the examination. When the examination result loaded from the file is saved, the original data will be overwritten.
- Make sure to save the data in order to enable the correction.

# Correcting the Boundaries for CAVI Measurement

The boundaries for calculating CAVI can be manually corrected.

The boundaries that can be edited in each examination are as follows.

- CAVI: Second heart sound, right brachial rise, left brachial rise, right brachial notch, left brachial notch, right ankle rise, left ankle rise
- 1 Display the waveforms on the examination result display
- 2 Double touch the pulse wave to be changed.



A window for correcting the boundaries is displayed.

**3** Change the line marker positions.



- 1) Touch the following cursor buttons to move the line marker positions.
  - $[\rightarrow\rightarrow]$ : Moves the cursor a long distance to the right.
  - $[\rightarrow]$ : Moves the cursor a short distance to the right.
  - $[\leftarrow\leftarrow]$ : Moves the cursor a long distance to the left.
  - $[\leftarrow]$ : Moves the cursor a short distance to the left.
  - $[ \Box ]$ : Shows the zoomed in display

Touch this again to return to the normal display. The zoomed in display can also be shown by touching a line marker.

Boundaries: If there are two boundaries, one can be selected by touching it. The selected line marker changes color.

- 2) Touch [ \_\_ ].
- 4 CAVI, UT, %MAP are recalculated according to the new positions of the boundaries and the results are updated.
- **5** After editing the boundaries, print and save the data manually.



The CAVI boundaries can also be edited for the examination result loaded from the files. (Refer to "Correcting Examination Data" (P9-14))

# **Using the Compare Waveforms Function**

If the past examination results of the same ID are saved, the previous results of dominant waveform, ABI, TBI, CAVI, tb, tba values can be loaded and displayed.

## NOTE

This function is not available for 2-channel mode examination.

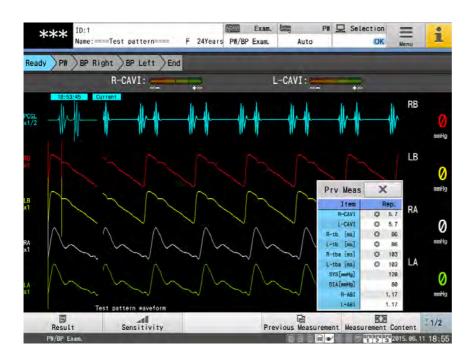
The following settings need to be configured in order to use this function.

- Set "Yes" for [PW/BP Exam.] [File] [Compare Waveforms].
- Select the media to load the previous data under [File] [General] [Read from This Media].
- 1 Select [PW/BP Exam.].
- 2 Enter the ID in the Patient Information.
- 3 If the past examination results of the same ID are saved, the date/time and dominant waveform of the previous examination will be displayed on the left side of the display.

4 Touch [Previous Measurement] to display the R/L-CAVI, R/L-ABI, tb, and tba value.



If there is no previous data, this area is blank, with no dominant waveform.



# Recalculating the ABI/TBI

To eliminate influences such as subclavian stenosis, ABI/TBI can be recalculated by changing the measurement site on the brachium.

- 1 Select [PW/BP Exam.].
- **2** Display the examination result.

Refer to "Loading Examination Data" (P9-8) for procedure to load and display the examination result from a file.

- 3 Touch [2/2] on the examination result display.
- 4 Perform the recalculation.
- To Recalculate the ABI
  - 1) Slide the display to the BP display.
  - 2) Touch [Recalculate. ABI.]
  - 3) Touch [LB], [RB] or [BB]. ABI will be recalculated with the BP of the selected arm.
  - 4) Touch [ \_\_ ].



## ■ To Recalculate the TBI

- 1) Slide the display to the BP display.
- 2) Touch [Recalculate. TBI.]
- 3) Touch [LB], [RB] or [BB]. TBI will be recalculated with the systolic blood pressure (SYS) of the selected arm.
- 4) Touch [ \_\_ ].



**5** After recalculating, print and save the data manually.



ABI and TBI are calculated according to the setting under [PW/BP Exam.] - [BP Exam. Setting] - [ABI Brachial BP Usage Method].

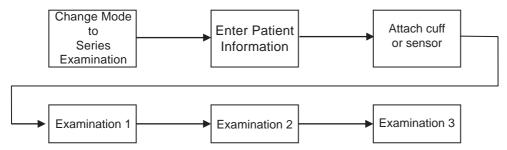
## **Series Examination**

Maximum of three types of examinations can be performed continuously on the same patient.

## **About the Series Examination**

A series examination allows to perform maximum of 3 examinations continuously, which can be selected from PW/BP or other newly registered examination.

Below is the examination procedure.



## Setting the Examination Type

To use this function, examination types for series examination needs to be registered under [Setting] - [Register Examination] - [Series Examination]. Refer to "Registering a Series Examination" (P11-25) for procedures.

## **Measurement Procedure**

The following explains the procedure using an example of Examination 1 -> Examination 2.

- 1 Switch to the registered series examination.
  - Examination 1 will be displayed.
- 2 Enter patient information. (Refer to "Chapter 4 Entering Patient Information"(P4-1))
- 3 Attach the cuffs, PCG microphone or sensors. (Refer to "Chapter 3 Pre-Examination Preparation" (P3-1)
- 4 Check that the waveform is displayed, and press the [START] key.

The set items will be printed on the report. The printing will automatically stop when the examination is completed. Also, the data can be saved on an external media or automatically sent to a PC depending on the setting.

If the examination result is displayed, touch [Back].

- 5 When the Examination 1 is completed, the display will automatically switch to the Examination 2.
- **6** Check that the waveform is displayed.
- **7** Press the [START] key.
- 8 When the measurement is completed, the examination result will be displayed.

(Refer to "Examination Result Display" (P5-14)) The examination results can be automatically printed on an external color printer depending on the setting. Also, the data can be saved on an external media or automatically sent to a PC depending on the setting.

9 Touch [Back].

# **Chapter 8 Brachial Blood Pressure Examinations**

Brachial blood pressure examinations measure the blood pressure in the right, left or both brachia. The measurement count can be selected from 1, 2, or 3 (default: 1), interval time can be selected from 1 to 5 minutes, and simultaneous measurement on both brachia, multiple measurements, average calculation is possible.

## Take care when applying equipment to the following patients.

- · Patients with swelling or who bleed easily
- · Patients with blood congestion that may cause a thrombus
- · Patients with blood congestion that may cause peripheral circulation obstruction
- Patients who experience inflammation, suppurative disease, external wounds, etc. in the area where the cuff is attached

## **Important Basic Precautions**

- · Do not attach the cuff in the following areas.
  - · Brachia with an artificial dialysis shunt
  - Brachia receiving IV drips, blood transfusions, etc.
  - · Brachia to which a catheter, etc. is attached
  - · Arm on the side of a mastectomy
- Blood pressure is measured by applying pressure to the brachium. If the patient reports any pain or physical abnormalities, press the [STOP] key immediately to abort the examination.

## **⚠** CAUTION



- Let the patient rest for 10 minutes before the examination.
- Frequent measurements will result in blood flow disorder. When repeating the measurement, wait until the blood flow is fully recovered. (5 minutes interval is recommended.)
- Do not connect other medical devices to the limb which a cuff is attached.
- · When the cuff is removed after the examination, check the condition of the limbs.
- During the examination, let the patient maintain a relaxed posture free from tension and instruct him/her not to speak, apply pressure to or hit the cuffs or move the limbs. When the patient is in a sitting posture, both legs should be on a floor and not cross-legged. Otherwise, correct measurements may not be obtained, or the measurement may fail due to prolonged measurement by the cuff re-inflation.
- Always observe the patient and device to ensure safe operation of the device, and if any abnormality is found, take appropriate measures such as ceasing operation of the device in the safest way for the patient.
- If cuff inflation does not stop, takes a long time to deflate or any other malfunction occurs, press the [STOP] button immediately and remove the cuffs.

## **Measurement Preparations**



Check the following again before measuring.

#### Is the place of examination appropriate?

- Check for noise generating electrical devices such as x-ray equipment or ultrasonic instruments nearby.

  If any, turn them OFF or change the place of examination to avoid adverse influence from such instruments.
- Select a location with low humidity.
- Make sure the selected location is quiet and not exposed to engine noise, noise from air conditioners, vibrations from railroads, passing cars or treadmills.

#### How is the condition of the patient?

- Check if the patient is nervous.
  - If nervous, his/her blood pressure may be higher than normal. Reassure the patient by briefly explaining the examination method to the patient.
- Also, instruct the patient not to move or speak.

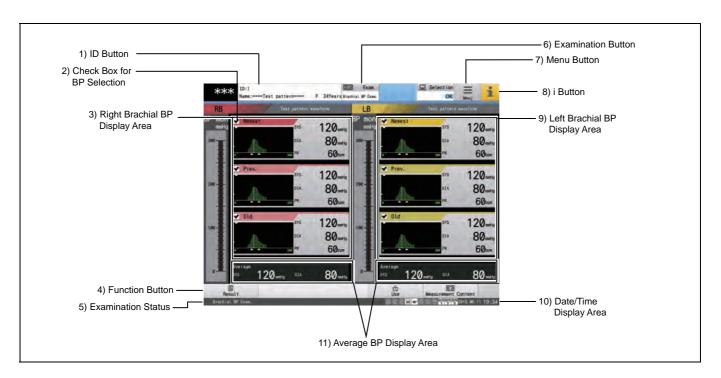
#### Are the cuffs correctly attached to the patient?

Is the air hose of any cuff bent and are objects placed on any of the air hoses?



Let the patient rest for ten minutes or more before taking measurements.

# **Home Display**



## 1) ID Button (Patient Information Display Area)

Tap this to display a window for entering patient information.

Information such as the ID, name and age of the patient are displayed, and patient information can be added or edited.

2) Check Box for BP Selection

Use these to select whether to use each blood pressure type when calculating the average blood pressure from multiple measurements.

#### 3) Right Brachial BP Display Area

Displays up to three blood pressure measurements for the right brachium.

Displayed content: Current cuff pressure, systolic blood pressure, diastolic blood pressure, pulse rate, pulse amplitude graph

#### 4) Function Button

Buttons for controlling the main unit are available.

#### 5) Examination Status

Displays the status of the examination.

#### 6) Examination Button

Tapping this button displays the "Select Examination" window for selecting an examination.

The currently selected examination is displayed.

#### 7) Menu Button

Tap this to display the Menu screen.

#### 8) i Button (Information Button)

Tap this to display a screen indicating the status of the device.

## 9) Left Brachial BP Display Area

Displays up to three blood pressure measurements for the left brachium.

Displayed content: Current cuff pressure, systolic blood pressure, diastolic blood pressure, pulse rate, pulse amplitude graph

#### 10) Date/Time Display Area

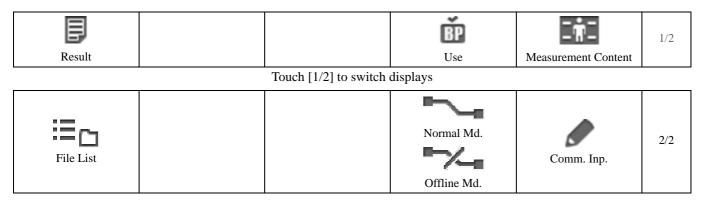
Displays the current date and time.

#### 11) Average BP Display Area

Displays the average blood pressure taken from the systolic and diastolic blood pressure of the types of blood pressure selected using the check boxes (right brachial or left brachial blood pressure).

## **Function Buttons Used in Examinations**

## **Before Examinations**



## **During Examination Results Display**



[Measurement Content]: Set the measurement site, interval period and measurement count.

[Use]: Calculates the average blood pressure according to the selected blood pressure types and proceeds to the result display. If this display was accessed from [BP] in the patient information, the blood pressure of the measurement sites selected for use is reflected.

(Displayed if results exist.)

[File List]: Displays the file list.

[Normal Md./Offline Md.]: Switches between normal mode and offline mode. During normal mode, data will be saved to the DMS. During offline mode, online operation such as master ID, auto saving to DMS, report output will not be performed.

[Comm. Inp.]: Displays the comment input window. [Next]: Proceeds to the next data if multiple items are selected from the file list in the result display.

[Save]: Saves the examination data to media. (Displayed if results exist.)

[Print]: Prints an examination report. (Displayed only if results exist.)

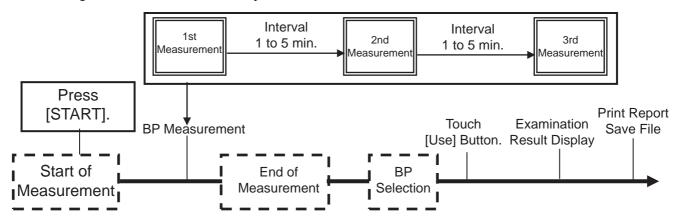
[Back]: Switches to the home display.

## NOTE

- [Save] and [Print] are displayed only if measurement results exist.
- [Next] is displayed only if subsequent examination results exist.

## **Measuring Blood Pressure**

The following is an outline of measurement operations.



#### NOTE

For 2-channel examination, only one side (right or left brachium) can be measured. For 4-channel and 6-channel examinations, both sides (right and left brachia) can be measured.



The measurement site can be selected from right brachium (RB), left brachium (LB) or both brachia (BB). There are two measurement methods: manual and automatic. Manual measurements can be taken the desired number of times at the desired intervals. Automatic measurements are taken at preset intervals.

#### 1 Touch [Examination].



## 2 Touch [BP Exam.].

When the power is turned ON, the registered examination for startup will be displayed.



# 3 Touch [Measurement Content] and select the measurement site, interval period and measurement count.

The measurement site can be selected from the right brachium (RB), the left brachium (LB) and both brachia (BB).



# 4 Attach a cuff to the right and/or left brachium depending on the site(s) to be measured.

• (Refer to "Attaching the Cuffs (Standard 2-Channel Examination)" (P3-1) )

## **5** Take the measurement.

#### [Manual Measurement]

Press the [START] key on the display unit to measure the blood pressure. The blood pressure is only measured once. The blood pressure value(s) are displayed in the Newest area when the measurement is completed. Press the [START] key again to take a second or third measurement.

#### [Interval Measurement]

In Measurement Content, select "2 times" or "3 times" as the measurement count and select an interval period between 1 minute and 5 minutes. Press the "START" key on the display unit to measure the blood pressure. The blood pressure value(s) are displayed in the Newest area when the first measurement is completed. The second and third measurements start automatically when the specified time has elapsed after the start time of the previous measurement. To stop a measurement, press the [STOP] key. The blood pressure measurement is aborted immediately.

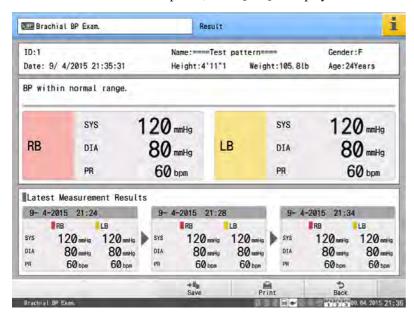
**6** When the measurement is completed, the examination result will be displayed.



- The results of the last three blood pressure measurements are displayed.
- The average of the last three blood pressure measurements is displayed at the bottom of the display.
- If there are any blood pressure measurement results that should not be used to calculate the average blood pressure, remove the check from the check box. The average blood pressure is calculated from the checked results.

## **Examination Result Display**

When the examination is completed, touch [Use] to display the examination result.



- The brachial blood pressure measurement(s) and comments are shown at the top of the display.
- Average systolic blood pressures, diastolic blood pressures and pulse rates for the right and left brachia are shown at the center of the display.
- The last three right and left systolic blood pressures, diastolic blood pressures and pulse rates for this ID are shown at the bottom of the display.

#### Printing Conditions of Observation

• High blood pressure.

The systolic blood pressure for the left/right brachium is above the high blood pressure threshold (SYS 2)

The diastolic blood pressure for the left/right brachium is above the high blood pressure threshold (DIA 2)

Difference between both side of BP.
 The difference between the left and right systolic blood pressures is above the left and right blood pressure difference threshold

• The blood pressure is at the high end of the normal range.

The systolic blood pressure for the left/right brachium is above the high blood pressure threshold (SYS 1)

The diastolic blood pressure for the left/right brachium is above the high blood pressure threshold (DIA 1)

#### • [Save]

Touch this to display the "Storage Media" window. Select a media to save the data.



#### • [Print]

Examination results can be manually output to an external color printer, etc.

Touch [Print] to print to the set output destination.

Touch [Preview] to display the report to be printed on the screen

(Refer to "Report Preview" (P8-9))



The desired values for the SYS2, DIA2, SYS1 and DIA1 thresholds can be set in the Settings.

Set the latest values for each type of high blood pressure.

Refer to "How to Interpret Reports" (P8-8) for instructions on how to interpret reports.

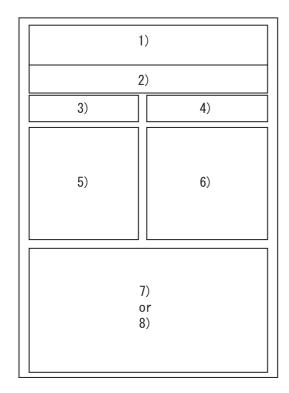


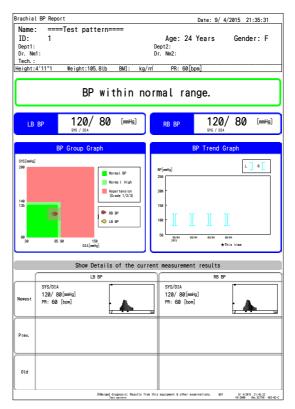
## **How to Interpret Reports**

#### Brachial BP Report



When a comment area is printed





When a blood pressure and pulse wave graph is printed

#### 1) Patient information

The patient information and the measurement date and time are printed.

#### 2) Blood Pressure Observation

Comments of the blood pressure measurement are printed.

Comments:

High blood pressure.

Difference between both sides of BP.

The blood pressure is at the high end of the normal range.

#### 3) and 4) Blood Pressure Value

Systolic and diastolic blood pressure values are printed for the left and right brachia.

Each of the latest three systolic and diastolic blood pressures, pulse rates and pulse amplitude graphs are recorded

#### 5) Blood Pressure Group Graph

A graph showing the blood pressure value group is printed, with the left and right brachial blood pressure plotted on the graph. The graph is divided into three areas (blood pressure groups). These are determined by blood pressure thresholds specified in the Settings.

- Green area: Normal BP
- Yellow area: Normal High
- Red area: Hypertension (Grade 1/2/3)

The blood pressure groups are set using the SYS2, DIA2, SYS1 and DIA1 hypertension thresholds to comply with various guidelines.

#### 6) Blood Pressure Trend Graph

A trend graph of the systolic and diastolic blood pressure for the left and right brachia is recorded. Previous brachial blood pressure examination data for the same ID can be loaded and printed from an SD card. Up to 6 items can be printed.

#### 7) Blood Pressure and Pulse Wave Graph

A graph of the blood pressure and pulse amplitude at the time of the blood pressure measurement is printed. Graphs for up to three measurements can be printed.

#### 8) Comment

A field for entering comments.



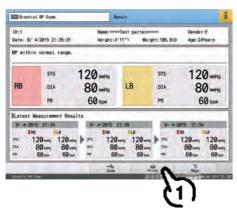
Set whether to print 7) or 8) in the Settings.

#### **Report Preview**

Examination reports can be checked in the display before printing to an external printer.

1 Conduct the examination.

# 2 Touch [Print] in the examination result display.



## 3 Touch [Preview].



## 4 Check the report.



[Back]: Displays a preview of the previous report.

[Next]: Displays a preview of the next report.

[Zoom In]: Zooms in on the report.

[Zoom Out]: Zooms out of the report.

# 5 Touch [Back] to return to the print display.

# **Entering the BP Examination Result in the Patient Information**

On the patient information setting window for each examination, selecting [BP mon] for entering BP value will proceed to the brachial blood pressure examination. This examination result can be automatically entered in the patient information.

#### 1 Touch [Use].

The selected examination result is entered for "BP" in the Patient Information.



## **Convenient Functions**



#### Graphic simulation of mercurial sphygmomanometer

During blood pressure measurement, a graphic representation of a mercurial sphygmomanometer is shown in the display.

#### Pulse amplitude graph display

A pulse amplitude graph is displayed to confirm whether blood pressure is being measured correctly.

## **Chapter 9 File Transfers**

This section explains how to transfer files by connecting a memory device to this device or using a LAN.

## **Functions**

Measurement data and examination results can be saved to external media such as a USB memory(\*) or SD card. Data can also be sent to other devices via a LAN. Saved data can be loaded when needed and then compared with other data, modified, copied, or deleted if it is no longer needed.

- Below are the formats and capacities of external media supported by this device. (Refer to "Saving Examination Data" (P9-5).)
  - SD card: SD-2G (2GB)
  - USB memory(\*): TS16GJF600 (16GB), TS8GJF600 (8GB)
  - DMS (Data Management System)
     This device is compatible with DMS from Fukuda Denshi (VSS).
- The device can receive or read data saved to other devices. (Refer to "Loading Examination Data" (P9-8).)
- \*Use a USB memory to move and store files. Use an SD card for ordinary operations.

## **Handling Media**

This section explains precautions that need to be taken when handling the SD card and USB memory.

#### Precautions when Using the SD Card and USB Memory

Take the following precautions when handling the SD card and USB memory.

#### /!\ CAUTION ■



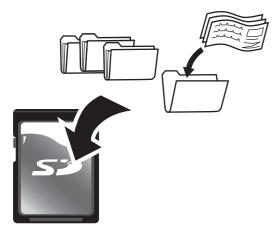
- Use only SD cards and USB memory devices specified by Fukuda Denshi
- If an external media that is not specified by Fukuda Denshi is used, examination data may not be saved correctly and it may not be possible to load recorded data.
- Make sure to format the media before using it for the first time.
- Do not bend the media, drop it or subject it to impact.
- Do not remove the media or turn off the power during operation. Also, do not subject this device to impact or vibration.

This may damage the recorded data or break the card.

- Do not allow any dust to enter the connectors. Also, do not touch the connectors or the terminals of the SD card with your hands or with metal items. Doing so may cause damage.
- Keep the card in the case supplied with the card and store it in an area without high temperatures, high humidity, dust or magnets. Do not subject the media to strong impact during storage.
- Make sure to back up any important data, as data may be damaged as a result of improper handling.
- Other Precautions (Failure to observe these precautions may cause damage.)
  - Do not place the media in areas with high temperatures or high humidity, such as near a heater or in direct sunlight.
  - Avoid using or storing media in areas with extreme changes in temperature.
  - Do not allow media to get wet.
  - Do not disassemble media.
  - Avoid using or storing media near magnets or devices with a magnetic field.
  - · Insert the media in a correct direction.

#### Files and Folders

It is difficult to organize and manage data if a large number of data items (files) are recorded. Folders are therefore used to organize files in a functional way by keeping multiple files together.



Folder1 is the first folder to be created. Data is saved to Folder1 until Folder1 becomes full. Data is then saved to Folder2. The maximum number of folders depends on the capacity of the media.



- A folder is created when the SD card or USB memory is formatted.
- The folder to save the data can be changed. (Refer to "Changing the Folder to Save the Data" (P9-17).)

## Inserting the SD Card

Insert the optional card in the SD card slot of this device.



Make sure to insert the SD card in a correct direction.

The SD card needs to be formatted before it can be used.

(Refer to "Initialization" (P9-4).)

## **Function Buttons Used in These Operations**

#### **File List Display**

		Q	ů,	\$	1/3
Display	Report	Search	Media	Back	
			<b>=</b>		2/3
	Delete	Copy	Select All	Clear All	
≔⊟	$\overline{\overline{\mathbf{w}}}$				3/3
List	Trash Box				

#### **Trash Box List Display**

	ď	ů,		₽	1/2
Recover	Search	Media		Back	
			<b>=</b>		2/2
			Select All	Clear All	

#### **Folder Management Display**

≔≞		<b>▶</b>	\$	
List	Chang	e Name Folder	Back	

#### **Communication History**



[Display]: Displays the results of the selected file.

[Report] Prints the report.

[Search]: Searches the data.

[Media]: Changes the target media.

[Copy]: Copies the selected data.

[Back]: Returns to the menu display.

[ $\downarrow$ 1/2]: The function keys can be used to display the

second page if there is one.

[List]: Prints the data list.

[Trash Box]: Switches to the Trash Box List Display.

[Delete]: Deletes the selected data.

[Select All]: Selects all data in the file list.

[Clear All]: Clears all data selections.

[Recover]: Recovers the deleted data.

[Change Name]: Changes the name of the folder.

[Folder to Save]: Sets the folder to save the data.

## **Initialization**

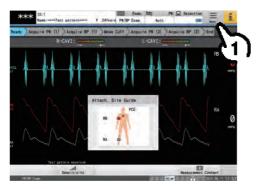
Newly purchased SD cards and USB memory devices need to be formatted (initialized) first. Examination data can be saved after the media has been formatted.

Below are the differences between the types of media and formats.

Media	Format	Examination data that can be saved	Maximum number of examination data items that can be saved to one folder.
SD Card	Standard	All examinations	1,000
USB Memory	Standard	All examinations	10,000

#### NOTE

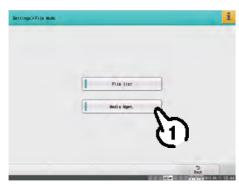
- DMS (Data Management Systems) connected by LAN cannot be formatted.
- Formatting these will clear all data recorded on the media. Check that there is no necessary data on the media before formatting. (Refer to "Loading Examination Data" (P9-8).)
- Use only SD cards and USB memory devices specified by Fukuda Denshi.
- USB memory devices can only be initialized via USB Connector 3.
- Insert the storage media into this device.
- **2** Touch [Menu] on the touch panel.



3 Touch [File/Communication].



4 Touch [Media Mgmt.].



5 Touch [Format].

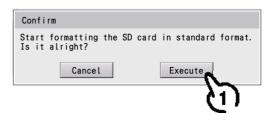


6 Touch the button corresponding to the type and purpose of the media to be formatted.



7 Check that the correct media and purpose has been selected and touch [Execute].

The media is formatted.



## **Saving Examination Data**

Examination data recorded on the device can be saved to media or sent to another device for storage.

#### **Methods for Saving Data**

The following methods can be used to save data to the SD card, USB memory(\*) or DMS.

• Automatically save examination data immediately after each examination

The recorded examination data is automatically saved immediately after each examination according to the Settings. (Refer to "Auto Save" (P9-6).)

Manually save examination data during the next examination (Simple Operation)

The user uses the function buttons to save the examination data during the next examination. (Refer to "Saving Manually (Simple Operation)" (P9-6).)

 Manually save examination data during the next examination (File Utility Operation)

The user uses the file utility to save the examination data during the next examination. (Refer to "Saving Manually (File Utility Operation)" (P9-6).)

#### Media that can be Used for This Operation

The following media can be used.

- SD card, USB memory(\*)
- DMS (Data Management System)



The DMS can also be used as media for saving, loading and copying data.

#### Saving

Data can be saved by the following 3 methods.

- Auto Save: The data is saved automatically after the examination is finished.
- Save manually (simple operation): The data is saved manually after the examination is finished.
- Save manually (file utility operation): Desired data items recorded to the memory of the device are saved.
- \*Use a USB memory to move and store files. Use an SD card for ordinary operations.

#### **Auto Save**

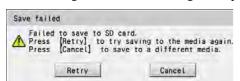
Examination data is automatically saved to a specified media after each examination is finished.



Configure the following items in the Settings.

- Set [File] [General] [Auto Save] to "Yes".
- Specify the desired media in [File] [General] [Save Media].
   If [Auto Save] is set to "Each Exam. Mode", the [Auto Save] settings need to be configured for each examination setting.

If auto saving fails, a check message is displayed.



[Retry]:

Tries saving the data to the media again.

[Cancel]:

Does not save the data to the media. If there is another storage media, the device saves the data to the other media.



The settings can be configured to display the save error message without needing to press a button to confirm it.

#### **Saving Manually (Simple Operation)**

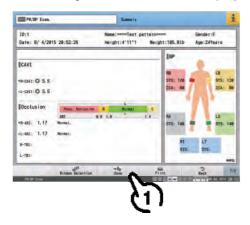
Manually save examination data to a specified media after each examination is finished.

- 1 Conduct the examination.
- 2 Insert the storage media into this device.

If the media is not formatted, format it first. (Refer to "Initialization" (P9-4).)

3 Touch [Save] after the examination is finished.

The "Storage Media" window is displayed.



4 Touch the media to save the data.

The data is recorded to the media corresponding to the button that was touched.



5 When saving is complete, touch [Back] in the "Storage Media" window.

The screen returns to the result display.

#### **Saving Manually (File Utility Operation)**

Desired data items recorded to the memory of the device can be saved to the media. The storage media can also be selected.

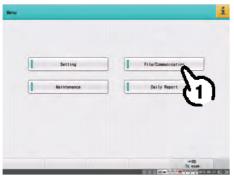
- 1 Conduct the examination.
- 2 Insert the storage media into this device.

If the media is not formatted, format it first. (Refer to "Initialization" (P9-4).)

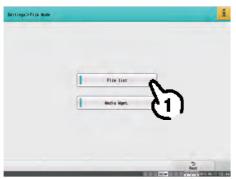
3 Press [Menu] on the touch panel.



4 Touch [File/Communication].



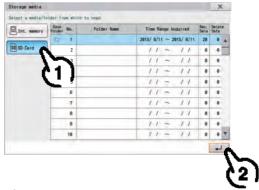
5 Touch [File list].



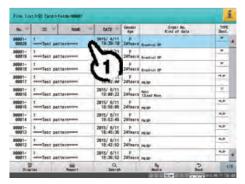
6 Touch [Media].



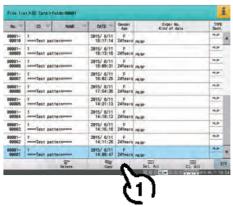
7 Specify the internal memory as the location of the data to be copied (Copy From).



- 1) Touch [Int. memory].
- 2) Touch [ 🚚 ].
- 8 Touch the data to be saved. The data is highlighted.



**9** Touch [1/3] - [Copy].



**10**Touch [ **↓** ].

The selected data is copied.





To change the media to copy the data, touch [Change] and specify a media.

## **Loading Examination Data**

The examination data can be read from the media to review on this device.

#### Loading

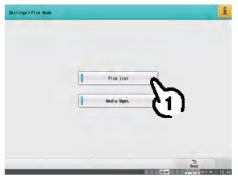
- 1 Insert the media containing the desired data into this device.
- 2 Touch [Menu] on the touch panel.



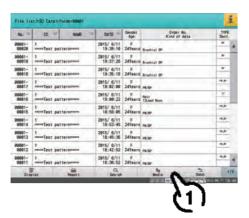
3 Touch [File/Communication].



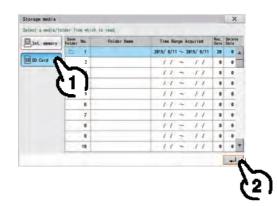
4 Touch [File list].



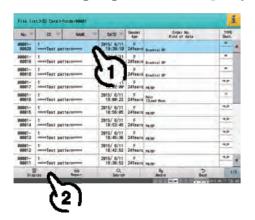
5 Touch [Media].



6 Specify the location of the data to be loaded.



- 1) Touch the location of the data to be loaded.
- 2) Touch [ \_\_\_ ].
- 7 Touch the data to be loaded. When the data is highlighted, touch [Display].





The "Search" function needs to be used to display the examination data when loading examination data from the DMS. (Refer to "Searching for Data" (P9-9).)

- The selected data is played and the Exam. Results display appears. Examination results can be displayed and printed from this display.
- · Touch [Back] to return to the File list display.
- If multiple data items are selected, they are played in succession before the result display appears. Touch [Next] in the result display to display the

examination results of the next data item.



An analysis guide and commentary are not printed if the data was analyzed on a different version of this device.

#### **Searching for Data**

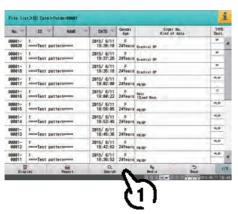
Data can be searched from the media if any of the following information is known:

ID number, name of the patient, examination date and/or folder number

#### 1 Follow steps 1-6 in "Loading" (P9-8).

#### 2 Touch [Search].

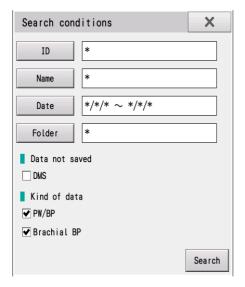
A window for entering search conditions is displayed.



# 3 Touch the item to be used as a search condition and enter the condition.

Parts of the display indicating the search conditions that can be entered differ depending on the media being searched.

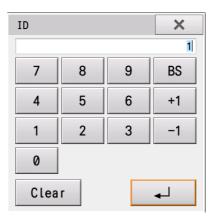
- SD card, USB memory:
   [ID], [Name], [Date], [Folder], [Data not saved] and [
   Kind of data] are displayed.
- DMS: [ID], [Name], [Date], [Media Code] and [Kind of data] are displayed.



#### ■ Searching by ID Number

Touch [ID]. A window for entering an ID number is displayed.

Enter the ID number of the desired data.





- · All ID numbers are set as search targets by default.
- Wild cards can be specified with a "\*".

#### ■ Searching by Patient Name

Touch [Name]. A window for entering a patient name is displayed.

Enter the patient name for the desired data.



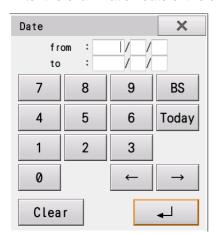


All patients are set as search targets by default.

#### Searching by Examination Date

Touch [Date]. A window for entering an examination date range is displayed.

Enter the examination date of the desired data.





- All examination dates are set as search targets by default.
- An examination start date and end date can be entered.

If no start date is entered, all data items before the end date are search targets. If no end date is entered, all data items from the start date onward are search targets.

#### Searching by Folder Number

Touch [Folder]. A window for entering a folder number is displayed.

Enter the number of the desired folder.





- All folder numbers are set as search targets by default.
- A start number and end number can be entered. If no start number is entered, all data items below the end number are search targets. If no end number is entered, all data items above the start number are search targets.
- Media numbers are displayed in place of folder numbers when searching the DMS.

#### 4 Touch [Search].

The time search will start.

#### **Printing Reports**

1 Follow steps 1-7 of "Loading" (P9-8) to select data to be printed.

#### 2 Touch [Report].

A report for the selected examination data is printed.

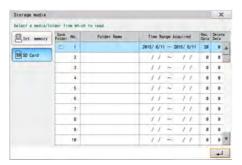


The report format for playback can be selected in the playback format settings in [File] in the Settings.

#### **Changing the Media**

#### 1 Touch [Media].

The "Storage media" window is displayed.



Specify the media and folder to load the data and touch [ 🔟 ].

#### **Printing the Data List**

## 1 Touch [1/3] - [2/3] - [LIST].

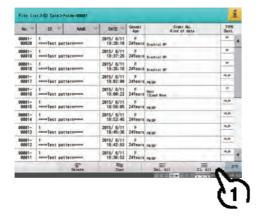
The data list is printed.



#### **Clearing All Data Selections**

#### 1 Touch [1/3] - [Cl. All].

All of the data selections are cleared.



## **Deleting Examination Data**

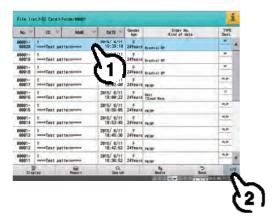
#### **Deleting Data from the List**

Deleting data from the list simply means that it is no longer displayed in the list. The data is still stored on the media.

#### NOTE

Data stored on the DMS cannot be deleted.

- 1 Follow steps 1-6 in "Loading" (P9-8).
- 2 Touch the data to be deleted. The data is highlighted.

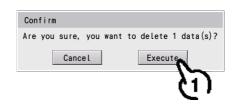


**3** Touch [1/3] - [Delete].



#### 4 Touch [Execute].

The data is deleted from the list.



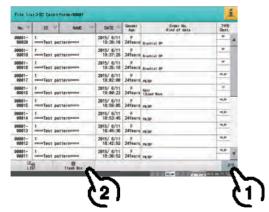


To restore the deleted data, follow the steps in "Restoring Deleted Data" (P9-13).

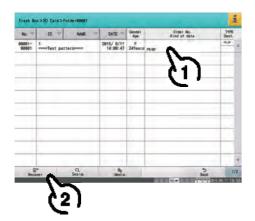
## **Restoring Deleted Data**

Data deleted from the list is moved to the [Trash Box]. Data in the Trash Box can be restored.

1 Touch [1/3] - [2/3] - [Trash Box].



2 Select the data to be restored.



1) Touch the data to be restored,

Alternatively, touch [Search] to search for data and then select data from the results.

- 2) Touch [Recover].
- 3 Touch [Yes].

The data is restored.



#### NOTE

Data cannot be deleted from the Trash Box.

## **Correcting Examination Data**

The height, age and boundaries in examination data files can be edited to correct the CAVI values.

- 1 Follow steps 1-7 in "Loading" (P9-8).
- 2 Touch [Save] and then touch the storage media to save the corrected data.



#### NOTE

- Touch [Back] in the Exam. Results display to return to the "File list" display without saving the corrected data.
- The file is overwritten with the corrected data.

#### ■ Correcting Patient Information

Refer to "Correcting the Patient Information" (P7-1).

#### ■ Editing Boundaries

Refer to "Correcting the Boundaries for CAVI Measurement" (P7-2).

#### ■ Recalculating ABI/TBI

Refer to "Recalculating the ABI/TBI" (P7-4).

## **Copying Examination Data**

Examination data can be copied between different media.

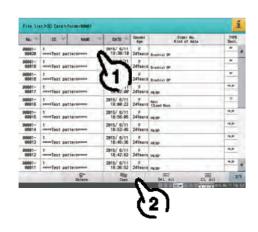


"SD card", "USB memory", "DMS" or "Int. memory" can be selected as the media of copy source.

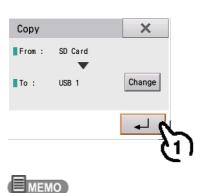
A different media from the copy source ("SD card", "USB memory", "DMS" or "Int. memory") can be selected as the media to copy the data from the copy source.

#### Copying

- 1 Insert the media of copy source and the media to save the data from the copy source.
- 2 Follow steps 1-6 in "Loading" (P9-8).
- 3 Touch the data to be copied and touch [1/3] [Copy].



4 Check the media to copy the data and touch [ ₄ ... ].



To change the media to copy the data, press [Change].

5 When data is copied from media to the DMS, the PC icon is displayed in the "Storage media" field.

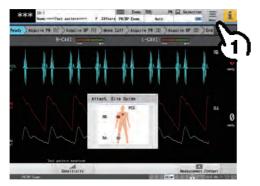


## **Naming Folders**

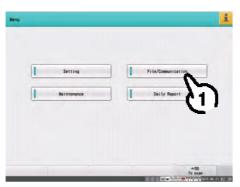
Folders on SD cards and USB memory devices can be named to organize the saved data clearly.

#### **Naming**

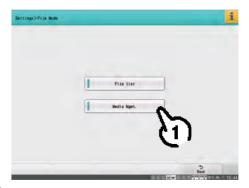
- 1 Insert the SD card or USB memory into this device.
- 2 Touch [Menu] on the touch panel.



3 Touch [File/Communication].



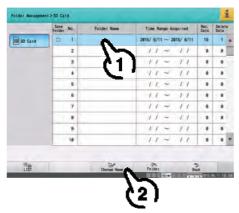
4 Touch [Media Mgmt.].



**5** Touch [Folder Management].



6 Select the folder for which to change the name.



- 1) Touch the folder.
- 2) Touch [Change Name].
- 7 Enter the new name.



#### 1) Enter the name of the department.

This is entered in the same way as the name in Patient Information. (Refer to "Chapter 4 Entering Patient Information" (P4-1))



Only alphanumeric characters can be used for folder names.

#### 2) Touch [ 山 ].

The name of the folder is registered.



If [x] is touched, the entered folder name is not registered.

#### **Printing the Folder List**

#### 1 Touch [LIST].

The folder list is printed.



## Changing the Folder to Save the Data

When saving data to an SD card or USB memory(\*), the folder to save the data can be changed.

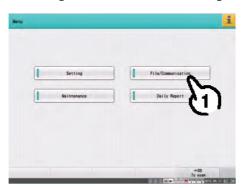
The folder can also be changed at the timing of saving the data. (Refer to "Saving Manually (File Utility Operation)" (P9-6).) \*Use a USB memory to transfer and store files. Use an SD card for ordinary operations.

#### **Changing the Folder**

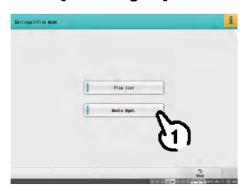
- 1 Insert the SD card or USB memory.
- 2 Touch the [Menu] button on the touch panel.



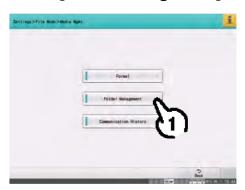
3 Touch [File/Communication].



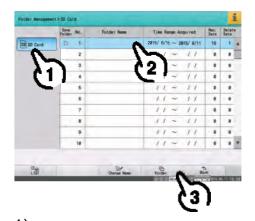
4 Touch [Media Mgmt.].



5 Touch [Folder Management].



6 Select the folder to save the data.



- 1) Touch the media to save the data.
- 2) Touch the folder to save the data.
- 3) Touch [Folder].

## **Communication History**

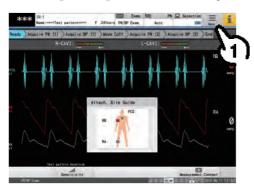
Print the history of communication between the device and the DMS and/or media.



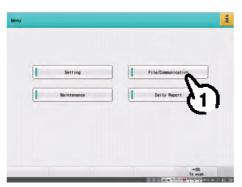
The latest 500 communication data items are recorded.

## **Printing the Communication History**

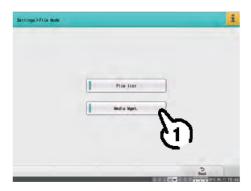
- 1 Insert the SD card or USB memory to be named into this device.
- **2** Touch [Menu] on the touch panel.



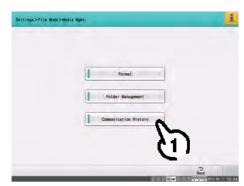
3 Touch [File/Communication].



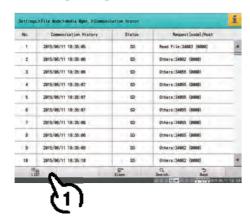
4 Touch [Media Mgmt.].



**5** Touch [Communication History].



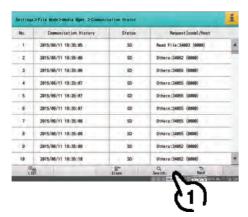
6 Touch [LIST].



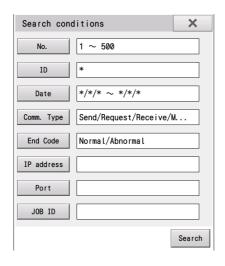
## **Selecting Communication History Data**

Communication history items can be selected for printing by specifying conditions.

#### 1 Touch [Search].



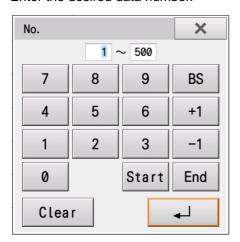
2 Touch the item to be used as a search condition and enter the condition.



#### ■ Searching by Data Number

Touch [No.]. A window for entering a data number range is displayed.

Enter the desired data number.





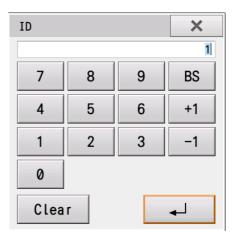
- · All numbers are set as search targets by default.
- · A start number and end number can be entered. If no

start number is entered, all data items below the end number are search targets. If no end number is entered, all data items above the start number are search targets.

#### ■ Searching by ID Number

Touch [ID]. A window for entering an ID number is displayed.

Enter the desired ID number.





- · All ID numbers are set as search targets by default.
- Wild cards can be specified with a "\*".

#### Searching by Examination Date

Touch [Date]. A window for entering an examination date range is displayed.

Enter the desired examination date.





All access dates are set as search targets by default.

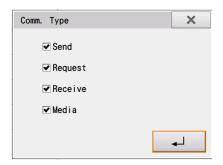


A start date and end date can be entered. If no start date is entered, all data items before the end date are search targets. If no end date is entered, all data items from the start date onward are search targets.

#### ■ Searching by Communication Type

Touch [Comm. Type]. A window for entering a history type is displayed.

Select the desired type.



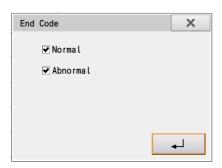


All communication types are set as search targets by default.

#### ■ Searching by End Code

Touch [End Code]. A window for entering an end code is displayed.

Select the desired end code.





All end codes are set as search targets by default.

#### ■ Searching by IP Address

Touch [IP address]. A window for entering an IP address is displayed.

Enter the desired IP address.



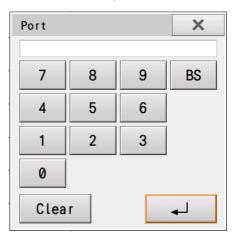


All IP addresses are set as search targets by default.

#### ■ Searching by Port Number

Touch [Port]. A window for entering a port number is displayed.

Enter the desired port number.



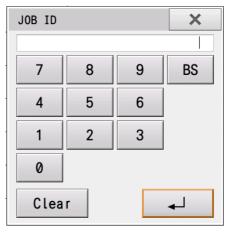


All port numbers are set as search targets by default.

#### ■ Searching by Job ID

Touch [JOB ID]. A window for entering a job ID is displayed.

Enter the desired job ID.





All job ID numbers are set as search targets by default.

## 3 Touch [Search].

The time search will start.

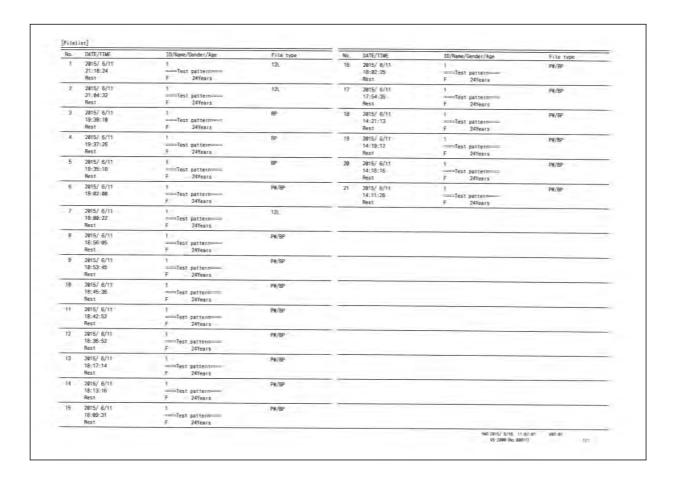
## **Erasing the Communication History**



Touch [Erase]. The communication history is erased.

#### Reports

#### •File List



#### •Communication History

Mix.	File/Communication Info	Status	Request (Code)	No.	File/Communication Info	Status	Request (Code)
5	2815/86/11 19:55:56	50	Read Fi (e:34004 (0000)	21	2015/06/11 19:57:20	sn	Others:34028 (0000)
2	2015/06/11 19:55:56	SD	Others:34031 (8000)	72	2015/06/11 19:57:21	SO.	Ochers: 34027 (8606)
3	•	50	Search; 34899 (8609)	23	2015/06/11 19:58:28	\$3	Read File:34004 (0000)
4	2015/06/11 19:55:57	50	Uniters:34674 (8809)	24	2015/06/11 19:58:33	\$3	Others:34028 (8000)
0	2015/06/11 19:35:57	50	Read Fi (e: 34004 (2000)	25		ŞD	Others:34027 (8080)
6	2015/86/11 19:56:28	50	Others: 34031 (0000)	26	2015/05/11 19:50:34	50	Others:34028 (6000)
7	2015/06/11 19:56:20 ×	50	Search:34009 (0000)	27	2015/06/11 19:58:50	SD	0"hers:34027 (6000)
8	2015/06/11 19:56:21	50	(trhers:34074 (8000)	28	2015/86/11 19:58:51	SD	Others:34028 (6808)
9	2015/06/11 19:56:21 00000000000000000000001	50	Read Fi Le: 34003 (0000)	29	2815/86/11 19:59:69	50	Others:34027 (0800)
	2015/06/11 19:56:34	50	Others:34862 (8888)	30	2815/96/11 19:59:86	50	Read File:34004(0000)
18	2015/06/11 19:56:35			31	2015/06/11 19:59:20	SD	(https://dexa.com/
38.	2015/96/11 19:56:35	S0	Others:34055 (0000)		2015/06/11 19:59:27		
12	99999999999999999999999999999999999999	SD	Others:34062 (0000)	32	2015/06/11 19:59:28	50	(hthers:34827 (6088)
13	0000000000000000000001 2015/06/11 19:56:37	20	Others:34062 (8000)	33	2015/06/11 19:59:45	50:	Others(34828 (8088))
14	90000000000000000000000000000000000000	50	Others:34855 (8000)	- 34	2015/05/11 19:59:45	20	Others:34027 (1000)
15	96000000000000000000000000000000000000	SD	Read File:34803 (8000)	35	2015/05/11 19:59:56	50	Others:34228 (8980)
16	9009090000000000000001 2015/86/11 19:56-58	- 50	Others:34962 (9888)	- 36	2015/06/11 19:59:57	50	0:hers:34077 (6900)
17		50	Others:34055 (8000)	37	2015/06/11 20:00:06	50	Onhers:34028 (0800)
18	00000000000000000000000000000000000000	50	Others: 34862 (0000)	- 38	2015/05/11 20:00:07	50	Others:34027 (0000)
19	00000000000000000000000000000000000000	\$0	Others:34862 (8888)	36	2015/06/11 20:00:20	20	Onhers:34928 (8998)
28	90690000000000000000000000000000000000	50	Others; 34855 (8880)	4	2015/05/11 20:00:21	50	Others:34027 (0000)
	SELVERGE II 12-10-50						780 2015/ E/16 11:15:80 80:41: (5-200 (No. 8001)) 1/12

## **Chapter 10 Recording Daily Reports**

This chapter explains how to record daily reports of examinations.

## **Content of Daily Reports**

It is possible to confirm the execution status of examinations that have been conducted by printing the recorded information in daily reports.

The following information is printed in the daily report list in the order in which the examinations were conducted.

- · Examination date and time
- Examination information
- Patient information (ID number, name, age, gender)





- Up to 500 daily reports can be saved. When another daily report is saved after this, the oldest daily report is deleted.
- If more than the maximum number of daily reports are saved in one day, a message saying "Daily report data is full" is displayed after the examination is completed. This message is displayed only once.
- Daily reports can only be saved to an SD card.

## **Function Buttons Used in These Operations**

#### "Specify Daily Report" Display



[Print]: Prints the daily report.

[Save]: Saves the daily report data to the SD card in CSV format.

[To exam]: Proceeds to the examination.

[Back]: Returns to the menu display.

 $[\rightarrow]$ : The function keys can be used to display the second page if there is one.

## **Recording a Daily Report**

1 Touch the [Menu] button on the touch panel.



## 2 Touch [Daily Report].



## 3 Touch the desired recording method.

The content recorded by each recording method is as follows.

- Today: Prints a daily report for the current day.
- Date: Prints a daily report for the data specified by the user.
- All: Prints all daily reports recorded in the device.



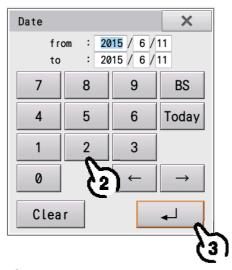
#### ■ If [Today] is Touched

A daily report for the current day is printed.

#### ■ If [Date] is Touched



1) Touch [Enter].



- 2) Specify a date.
- 3) Touch [ \_\_ ].

#### ■ If [All] is Touched

All registered daily reports are printed.

#### 4 Touch [Print].

• Daily reports for the selected period are printed.



## 5 Touch [Save].

The daily report data is saved to the SD card in CSV format.



Daily reports can only be saved to an SD card.

## **Chapter 11 Settings of This Device**

Detailed settings relating to the operations of this device can be configured to suit your purpose. This chapter explains how to configure the settings.

## **Overview of Settings**

Settings relating to the operations of this device and each examination method can be configured as necessary.

Item	Description	Reference
Equipment Control	Configure general settings relating to the equipment.	P11-6
Patient information	Set whether to enter items as patient information.	P11-9
File	Configure settings such as the methods for saving and loading examination data.	P11-14
Communication	Configure settings for communication methods with other devices.	P11-15
External device	Configure settings for connections with external devices.	P11-17
PW/BP Exam.	Configure settings concerning examination methods and recorded content for blood pressure and pulse wave examinations.	P11-17
Brachial BP Exam.	Configure settings concerning examination methods and recorded content for brachial blood pressure examinations.	P11-21

## **Function Buttons Used in These Operations**

#### **Settings**

Initialize Settings	Save settings	Load settings	To exam	Back	↓1/2
⊕ <sub>D</sub>	D	⇒P <sub>1</sub> 2 <sub>3</sub>	[# <sub>123</sub>		↓2/2
Read Fixed message	Clear Fixed comment	Save Code.	Read Code.		

#### **Registering Examinations**

	<b>→</b> <u>&lt;</u>	\$	
	To exam	Back	

#### **Operations Other than Registering Examinations**

Enter		<b>→</b> To exam	Back	↓1/2
	Initialize			↓2/2

[Initialize Settings]: Initializes the settings.

[Save settings]: Saves the settings to the SD card.

[Load settings]: Loads settings from the SD card.

[To exam]: Proceeds to the examination.

[Read Fixed message]: Loads the text of a fixed message  $\,$ 

from the SD card.

[Clear Fixed comment]: Clears the fixed message text

that was loaded.

[Save Code.]: Saves the code to the SD card.

[Read Code.]: Loads the code from the SD card.

[Back]: Returns to the menu display.

[ $\downarrow 1/2$ ]: The function keys can be used to display the

second page if there is one.

[Enter]: Saves the settings and returns to the settings

menu.

[Init.]: Initializes the settings.

## **Operations Used to Configure Settings**

The settings are configured by selecting setting values, entering text, entering numbers and using sliders.

#### **Performing Operations in the Settings Display**



- 1 Select the setup item to be configured by touching it.
- 2 Touch the desired setting value to change the setting of the item.

Repeat these steps to configure other setup items.

#### **Selecting Setting Values**

Below are instructions on selecting one or multiple items from multiple displayed setting values.

#### 1 Press the desired setting value.

The display changes as shown below.

	Unselected	Selected
When only one item can be selected	○ 0FF	OFF
When multiple items can be selected	ABI/Limb BP	✓ ABI/Limb BP

#### **Selecting Items by Touching Buttons**

Below are instructions on selecting items by touching the desired button in a set of multiple displayed buttons.

1 Touch the button corresponding to the desired item.

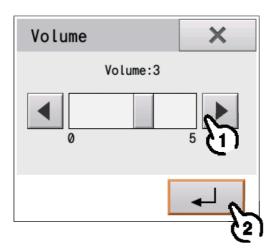
More detailed setup items are displayed.



## **Specifying Settings by Using Sliders**

This method is used to specify colors from a color palette or the volume and tone of the buzzers.

1 Move the slider.

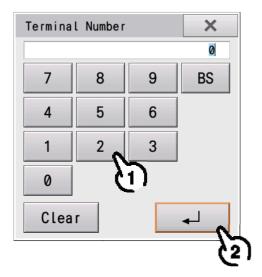


- 1) Touch [◄] or [▶] to move the slider.
- 2) Touch [ \_\_ ].

#### **Entering Numbers**

Below are instructions on how to enter numbers. Numbers are entered in the same way as values such as the patient's height and weight.

1 Use the numeric keys to enter the numbers.



- 1) Enter the desired number using the number keys.
- 2) Touch [ 🚚 ].

Touch [BS] to clear one digit of the entered number. Touch [Clear] to clear the whole of the entered number.

Touch [x] to discard the entered number and close the input window.

#### **Entering Text**

Below are instructions on how to enter the hospital name, doctor name, technician name, department, medicine, symptoms and comments. This is entered in the same way as the name in Patient Information. (Refer to "Chapter 4 Entering Patient Information" (P4-1))

1 Enter alphanumeric characters or symbols.



#### 1) Touch the characters to be entered.

•  $[A \rightarrow a][a \rightarrow A]$ :

Switches between capital and lower case English letters.

• [Alphanum.]:

Switches to alphanumeric characters.

• [Symbol]:

Switches to symbols.

• [BS]:

The character to the left of the cursor is cleared.

• [Clr All]:

All entered characters are cleared.

• [←]:

Moves the cursor to the left.

• [→]:

Moves the cursor to the right.

• [Space]:

Enters the space.

• [x]:

Closes the "Input ID" window.

## 2) Touch [ 山 ].

• The entered name is reflected in the "Patient Information" window.

# **Setting the Examination Method**

### NOTE

Contact Fukuda Denshi for more information on connecting and configuring the settings of ID readers.

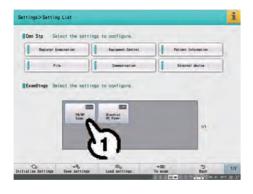
1 Touch [Menu] on the touch panel.



2 Touch [Setting].



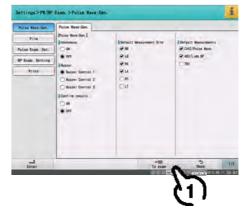
3 Touch the desired examination.



# **4** Change the settings.

Refer to the items below for information on the settings and setting values for each item.

5 Touch [To exam] after configuring the settings.



# 6 To enable the new settings, touch [Yes].

- Touching [No] will discard the changes and return to the examination display.
- Pressing [Cancel] will return to the settings display.



This completes the changing of the settings.

# **Equipment Control Settings**



The text in [] indicates the factory default setting.

### **General/Power**

Setup Item	Description	Setting Range
Examination mode	Specifies the examination mode. (Displayed only during 2-channel examination.) The Simple Examination Mode is available only when English is selected as the language.	[Standard Examination Mode], Simple Examination Mode
Terminal Number	Specifies the terminal number of the device. This is useful when creating system configurations.	[0]-255
Auto power-off	Turns the power off automatically if no operations are performed for the prescribed period of time when using the battery.	OFF, [5 minutes], 10 minutes
Power Frequency	Specifies the frequency of the AC power supply to which the device is connected.	50Hz, [60Hz]
Password*	A password for entering the settings function (maximum of 4 digits) can be set.	Not set

### **Buzzer Control**

#### **Buzzer Control 1, 2, 3**

Setup Item	Description	Setting Range
<buzzer> Volume Setting</buzzer>	All: Set all volumes at once. Individual: Set each volume individually.	[All], Individual
<buzzer> Set All Volumes</buzzer>	Set all volumes.  0: Sound will be silenced.  1-5: The volume will increase with the value respectively.	0, 1, 2, [3], 4, 5
<voice guidance=""> Voice Guidance</voice>	Set whether to use voice guidance.	ON, [OFF]
<pre-exam. guidance=""> Volume</pre-exam.>	Set the volume of the pre-examination guidance. 0: Sound will be silenced. 1-5: The volume will increase with the value respectively.	0, 1, 2, [3], 4, 5
<post-exam. guidance=""> Volume</post-exam.>	Set the volume of the post-examination guidance.  0: Sound will be silenced.  1-5: The volume will increase with the value respectively.	0, 1, 2, [3], 4, 5
<key sound=""> Volume*</key>	Set the volume of the tone that sounds when a key is pressed.  0: Sound will be silenced.  1-5: The volume will increase with the value respectively.	0, 1, 2, [3], 4, 5
<process end="" tone=""> Volume*</process>	Set the volume of the tone that sounds when a process such as auto record is finished.  0: Sound will be silenced.  1-5: The volume will increase with the value respectively.	0, 1, 2, [3], 4, 5
<warning tone=""> Volume*</warning>	Set the volume of the warning tone. 0: Sound will be silenced. 1-5: The volume will increase with the value respectively.	1, 2, [3], 4, 5
<abnormality tone=""> Volume*</abnormality>	Set the volume of the tone that sounds when an abnormality occurs in the device.  0: Sound will be silenced.  1-5: The volume will increase with the value respectively.	1, 2, [3], 4, 5
<file save="" tone=""> Volume*</file>	Set the volume of the tone that sounds when file saving is completed normally.  0: Sound will be silenced.  1-5: The volume will increase with the value respectively.	0, 1, 2, [3], 4, 5
<prohibited tone=""> Volume*</prohibited>	Set the volume of the tone that sounds when key operations are prohibited.  0: Sound will be silenced.  1-5: The volume will increase with the value respectively.	1, 2, [3], 4, 5



- The detailed buzzer control settings can be selected when "Individual" is set as the <Buzzer> volume setting.
- The key touch tone volume set in Buzzer Control 1 is applied for each volume throughout the settings display.

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Individual] key.

### **Print**

#### **General**

Setup Item	Description	Setting Range
Paper Size for Normal Paper	Specify the paper size for printing on normal paper. B5 can only be used when printing blood pressure and waveform reports.	[A4], B5, LETTER
Output Target	Specify the output target type. Multiple items can be selected.	PC Printer, [Network Printer]
Register Facility Name	Register the facility name to be printed in the report. (30 single-byte characters.)	Not set

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Details] key.

# PDF/XML

Setup Item	Description	Setting Range
Auto Save PDF	Automatically saves data as a PDF after taking a measurement.	ON, [OFF]
XML Output	Saves the PDF as XML file.	ON, [OFF]
Save Media	Specifies the media to save PDF.  Multiple items can be selected.  Caution: If a shared folder is selected, only reports from PW/BP examinations and brachial blood pressure examinations are saved.	[SD Card] USB1, 2, 3 Shared Folder

# Localization

Setup Item	Description	Setting Range
Language	Sets the displayed language.	[ENGLISH], 日本語, FRANÇAIS, ITALIANO, ESPAÑOL, DEUTSCH, русский
Length Unit	Sets the measurement unit of length.	m, [inch]
Weight Unit	Sets the measurement unit of weight.	kg, [lb]
Pressure Unit	Sets the measurement unit of pressure.	[mmHg], kPa
Date Format	Sets the date format.	YYYY/MM/DD, [MM/DD/ YYYY], DD/MM/YYYY
UTC +/-	Sets the time difference between the UTC (Coordinated Universal Time).	[+09:00]

# **Patient Information Settings**

### General/ID-A.C.

Configure general settings relating to input of patient information.

#### General

Setup Item	Description	Setting Range
Input ID	Extension (2 Levels): Specified items other than ID, gender and age are displayed in 2 levels.  Extension (3 Levels): Specified items other than the information in Extension (2 Levels) are displayed in the third level.	[Extension (2 Levels)] Extension (3 Levels)
Patient Information Reference	Specifies the source from which to refer to patient information.	Master ID Patient file selection Load past information [NO]
Department Input Order	Set whether to display the entry for Dept. after the entry for Name or after the entry for BP.	After the name, [After BP]
Auto Window (for ID Card Reader)	Specifies the input window to be opened when patient information is entered by means other than an ID card or bar code.	[ID number], Age, Gender, Name, Department Code 1-4, Height, Weight, Inquiry, Medicine Info, Subjective Symptoms, Comment, BP, Doctor, Technician
Auto Window (Others)	Specifies the input window to be opened when patient information is entered by means other than an ID card or bar code.	[ID number], Age, Gender, Name, Department Code 1-4, Height, Weight, Inquiry, Medicine Info, Subjective Symptoms, Comment, BP, Doctor, Technician
Clear All IDs	Specifies whether to clear the previous patient information after entering the ID number.	[ON], OFF
Display Stng (2 Lvls)*	Items other than the ID and age can be specified to appear in the patient information display area of the examination display when "Extension (2 Levels)" is set as the ID input method.	[Name], Department Code 1-4, Height, Weight, BP, Doctor Name 1 and/or 2, Technician
Display Stng (3 Lvls)*	Items other than the ID and age can be specified to appear in the patient information display area of the examination display when "Extension (3 Levels)" is set as the ID input method.	Name, Department Code 1-4, Height, Weight, BP, Doctor Name 1 and/or 2, [Technician]
Auto Window Display*	Specifies whether to display the input window when a patient information is entered for ID card or bar code.	ON, [OFF]

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Details] key.

#### **ID Number**

Setup Item	Description	Setting Range
Enter	Specifies whether to enter, display and print ID numbers.	[ON], OFF
Number of digits	Specifies the number of digits to be used in ID numbers.	[20], 3-20
ID Auto Increment	Automatically generates ID numbers by adding 1 after using automatic recording.	ON, [OFF]
Prefix*	Desired alphanumeric characters can be added as a prefix to ID numbers.	Desired alphanumeric characters
Hyphen position*	Specifies the position (how many digits from the right) in which to place hyphens in ID numbers. Up to 3 hyphen positions can be specified.	Not set
ID Input*	Numeric only: Allows input only from the number keys. Alphanum. Allows numbers to be input using the number keys and alphabetical characters to be input using the full keyboard.	Numeric only, [Alphanum.]
Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily
ID number zero padding*	ON: Uses zero padding (adds zeros).  OFF: Does not use zero padding (does not add zeros).  *Zero padding adds zeros to numbers below the set number of digits. If 12 is set as the number of digits for ID numbers and "123" is entered as the ID in the Patient Information window, this becomes "000000000123" if zero padding is set to "ON".	ON, [OFF]

#### Age (\*When this setting is changed, the device needs to be restarted before the new setting is enabled.)

Setup Item	Description	Setting Range
Input Method	Birthday: The patient's age will be automatically calculated when their birth date is entered.  Age: Enter the patient's age.	[Birthday], Age
Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily

#### Name

Setup Item	Description	Setting Range
<name> Enter</name>	Specifies whether to enter, display and print names.	[ON], OFF
<name> Backup*</name>	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily
<gender> Backup*</gender>	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Details] key.

### Height, Weight, BMI, Abdominal Circumference

Setup Item	Description	Setting Range
<height> Enter</height>	Specifies whether to enter, display and print the patient's height.	[ON], OFF
<height> Backup*</height>	ON: Data is backed up. The content before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily
<weight> Enter</weight>	Specifies whether to enter, display and print the patient's weight.	[ON], OFF
<bmi> Display</bmi>	Specifies whether to display and print the patient's BMI.  BMI = Weight [kg] / (Height [m] x Height [m])	[ON], OFF
<a.c.> Enter</a.c.>	Specifies whether to enter, display and print the patient's abdominal circumference.	[ON], OFF

# **Department**

Setup Item	Description	Setting Range
<department code<br="">1-4&gt;</department>		
Enter	Specifies whether to enter, display and print the department code.	[ON (Department Code 1 and 2)], [OFF (Department Code 3 and 4)]
Input Length Setting	Specifies the input length of department codes.	4-8 digits [4 digits]
Regist Code	Register a department code. A total of up to 100 codes can be registered. (16 single-byte characters)	-
Input Prohibited*	Sets the current content so that it cannot be changed.	ON, [OFF]
Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on.  OFF: Data is not backed up.  Content is erased when the power is turned off.  Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Details] key.

### **Medicine - Technician**

Configure settings relating to input of the medicine, subjective symptoms, comments, blood pressure measurements, body position, respiration rate, inquiry, doctor and technician.

#### **Medicine Info-Comment**

Setup Item	Description	Setting Range
<medicine info=""></medicine>		
Medicine Info1 Input Info	Specifies whether to enter medicine information.	ON, [OFF]
Medicine Info2 Input Info	Specifies whether to enter medicine information.	ON, [OFF]
Input Length Setting	Specifies the input length of medicine codes.	2-4 [2]
Regist Code	Register a medicine code. Up to 20 codes can be registered. (16 single-byte characters)	-
Medicine Info1 Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily
Medicine Info2 Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily
<subjective symptoms=""></subjective>		
Enter	Specifies whether to enter, display and print subjective symptoms.	ON, [OFF]
Input Length Setting	Specifies the input length of subjective symptom codes.	2-4 [2]
Regist Code	Register a subjective symptom code. Up to 20 codes can be registered. (16 single-byte characters)	-
Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily
<comment></comment>		
Enter	Specifies whether to enter, display and print comments.	ON, [OFF]
Input Length Setting	Specifies the input length of comment codes.	2-4 [2]
Regist Code	Register a comment code. Up to 20 codes can be registered. (16 single-byte characters)	-

#### **BP Measurement-Body**

Setup Item	Description	Setting Range
Input BP	Specifies whether to enter, display and print the patient's blood pressure.	[ON], OFF
Input body position	Specifies whether to enter, display and print the patient's body position.	ON, [OFF]

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Details] key.

#### **Doctor Name-Technician Name**

Setup Item	Description	Setting Range
<dr. nm1-2=""></dr.>		
Enter	Specifies whether to enter, display and print doctor names.	ON, [OFF]
Input Length Setting	Specifies the input length of doctor codes.	2-12 [4]
Regist Code	Register a doctor name. (100 items each, 24 single-byte characters)	-
Input Prohibited*	Sets the current content so that it cannot be changed.	ON, [OFF]
Clear All*	Specifies whether to keep the doctor names when clearing all other information.	[Delete], Keep
Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on.  OFF: Data is not backed up.  Content is erased when the power is turned off.  Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily
<technician></technician>		
Enter	Specifies whether to enter, display and print technician names.	ON, [OFF]
Input Length Setting	Specifies the input length of technician codes.	2-12 [4]
Regist Code	Register a technician name. (100 items, 24 single-byte characters/)	-
Input Prohibited*	Sets the current content so that it cannot be changed.	ON, [OFF]
Clear All*	Specifies whether to keep the technician names when clearing all other information.	[Erase], Keep
Backup*	ON: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. OFF: Data is not backed up. Content is erased when the power is turned off. Daily: Recorded data is erased at the end of each day.	ON, [OFF], Daily

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Details] key.

# **File Settings**

#### **General**

Configure settings relating to saving and loading data and communication with other devices.

Setup Item	Description	Setting Range
Save Media	Specifies the media to save the data. Multiple items can be specified.	[SD Card], USB1, 2, 3, DMS
Read from This Media	Specifies the media to load the data.	[SD Card], USB1, 2, 3, DMS, Int. memory
Auto Save	Specifies whether to automatically save the data. ON: Saves all savable data. OFF: Does not automatically save data. Each Exam. Mode: Follows the setting for each examination mode.	ON [OFF] Each Exam. Mode
ID Confirm.	Displays a confirmation window when ID is not entered.	ON [OFF]
Check Storage	Checks whether the previous examination result data has been saved before starting the examination.  A message is displayed if the data has not been saved.  Specifies the media to be checked.	SD Card USB1, 2, 3, DMS
Display List	Select the display format of the file list. Date Order: Displays the files starting from the newest date. Index Order: Displays the oldest page of the file list. Index (Newest): Displays the newest page of the file list.	[Date Order], Index Order, Index (Newest)

# **Printing**

#### **Playback Format Stng**

Setup Item	Description	Setting Range
Print PW/BP	Specifies the blood pressure and pulse wave printing format for file playback.	[PW/BP Exam.], Registered Exam.
Print Brachial BP Exam.	Specifies the brachial blood pressure printing format for file playback.	[Brachial BP Exam.], Registered Exam.

<sup>\*:</sup> Can be configured on the detailed settings window which will be displayed by pressing the [Details] key.

# **Communication Settings**

#### **General**

Setup Item	Description	Setting Range
Communication	Specifies whether to communicate with other devices.	ON, [OFF]
Communication method	Specifies whether to use wired LAN or wireless LAN.	[Wired LAN], Wireless LAN
Retry Count on Comm. Timeout	Specifies the number of retries when a timeout occurs during communication.	0-5 [1]
Response Time from DMS	Specifies the time after which a timeout occurs during communication with the DMS.	10 seconds-180 seconds [30 seconds]

# **DMS Settings**

#### **DMS Settings**

Setup Item	Description	Setting Range
<dms settings=""></dms>		
Recording & Playback Host	Specifies the recording and playback host to connect.	[1], 2, 3, 4, 5, 6
PW/BP Host	Specifies the host to send PW/BP examination results.	1, 2, 3, [4], 5, 6
Patient Info Host	Specifies the master ID communication host.	1, 2, 3, [4], 5, 6
Shared Folder	Specifies the shared folder host.	1, 2, 3, 4, [5], 6
<gateway></gateway>		
Sub-Network Mask	Set the subnet mask of the gateway.	[0.0.0.0]
Default Gateway	Set the IP address of the gateway.	[0.0.0.0]
<dns></dns>		
Priority DNS Server	Set the IP address of the priority DNS server.	[0.0.0.0]
Alternate DNS Server	Set the IP address of the alternate DNS server.	[0.0.0.0]
<ntp></ntp>		
NTP Server	Set the IP address of the NTP server.	[0.0.0.0]

#### **Host Information**

Setup Item	Description	Setting Range
Host Info1-6 Host name	Specifies the host name.	[DMS (Host Info 1 Only)] No default settings for Host Info 2-6
Host Info1-6 IP Address	Specifies the IP address of the host.	[0.0.0.0]
Host Info1-6 Port No.	Specifies the port number.	[0], 5 digits

### **Examination Equipment Information**

Setup Item	Description	Setting Range
Examination Equipment Name	Specifies the name of the equipment.	[VASERA]
IP Address	Specifies the IP address of the equipment.	[0.0.0.0]

#### **Wireless LAN**

Setup Item	Description	Setting Range
SSID	Specifies the SSID.	Up to 32 single-byte alphanumeric characters and symbols.
Authentication	Specifies the authentication method.	[WEP64Bit], WEP128Bit, WPA, WPA2
Network key	Specifies the network key.	Up to 64 single-byte alphanumeric characters and symbols.

#### **Shared Folder**

Item	Description	Setting Range
Mounted Directory	Specifies the name of the shared folder set on the Windows computer. If a hierarchical file structure is used, the path can be set using "/".	Up to 32 single-byte alphanumeric characters and symbols.
Login name	Specify the user name of the user who will access the shared folder.	Up to 32 single-byte alphanumeric characters and symbols.
Password	Specify the password of the user who will access the shared folder.	Up to 32 single-byte alphanumeric characters and symbols.
Domain	If the user who will access the shared folder belongs to a domain, specify the domain. This does not need to be specified if the user does not belong to a domain.	Up to 32 single-byte alphanumeric characters and symbols.

#### **Printer**

Setup Item	Description	Setting Range
<network printer=""></network>		
Network Printer	Specifies whether a printer is connected via the wired LAN or wireless LAN.	ON, [OFF]
IP Address	If "Network Printer" is set to "ON", specify the IP address of the printer.	[0.0.0.0]
Port No.	Specifies the port number.	[9100] Maximum 5 digits
<pc printer=""></pc>		
PC Printer	Specifies whether a printer is connected via the wired LAN or wireless LAN.	ON, [OFF]
IP Address	If "PC Printer" is set to "ON", specify the IP address of the printer.	[0.0.0.0]
Port No.	Specifies the port number.	[18200] Maximum 5 digits

# **Settings for Blood Pressure and Pulse Wave Examinations**

**Pulse Wave: General** 

Setup Item	Description	Setting Range
Anonymous	Specifies whether to make patient information anonymous. ON: The name, age and gender are not displayed or printed. OFF: The information is not made anonymous.	ON, [OFF]
Buzzer	Specifies the buzzer setting.	[Buzzer Control 1], Buzzer Control 2, Buzzer Control 3
Confirm results	Specifies whether to confirm the result display before performing actions such as saving after taking measurements.	ON, [OFF]
Default Measurement Site	Set the default measurement site. The site set here is set as the measurement site when the power is turned on or when switching to a new patient. Multiple items can be selected.	[RB], [LB], [RA], [LA], RT, LT <b>7</b>
Default Measurements	Set the default measurement item. The item set here is set as the measurement item when the power is turned on or when switching to a new patient. Multiple items can be selected.	[CAVI/Pulse Wave], [ABI/Limb BP], TBI 7

#### **File**

Setup Item	Description	Setting Range
Auto Save	Specifies whether to automatically save blood pressure and pulse wave data after taking measurements.  This is enabled when [File] - [General] - [Auto Save] is set to "Each Exam. Mode".	ON, [OFF]
Storage Media S	Specifies the media to save the data.  Multiple items can be specified.	[SD Card], USB1,2,3, DMS
Trend Count	Specifies the maximum number of trends to be printed in reports.	10, [50]
Compatible with VS-1500 Series	Saves data in the same format as the VS-1500 Series.	ON, [OFF]
Compare Waveforms	Specifies whether to automatically obtain data when conducting trend examinations.	ON, [OFF]

S: Indicates settings that are displayed in Simple Examination Mode.

# **Pulse Wave Examination**

Setup Item	Setup Item Description		
PCG Characteristic	Specifies the PCG characteristic. L: Displays the standard PCG waveform. PWV: Uses a special waveform for detecting the second heart sound.  "L" should usually be used as the PCG characteristic. Use "PWV" to check the position of the PWV boundaries. CAVI (PWV) measurements are not affected by the item selected for this setting.		
PCG Noise Filter	Set whether to remove noise from the PCG signal.	[ON], OFF	
Pulse Wave Measurement Time	Change the measurement time if the patient has a low heart rate and only a small number of beats are expected to be detected during a five-second period.	5 seconds, [8 seconds], 16 seconds	
Distance Input Method	Select the method for obtaining the blood vessel length to be entered for CAVI examinations.  Height: This method automatically calculates the blood vessel length from the patient's height.  Section: In this method, the distances between each of the measurement sites are entered.  Segment: In this method, the distances to each measurement site from the center of the ankle cuff are entered in segments.  This is enabled if "CAVI" is selected as the measurement item.		
Wave Recording Method	Wave Recording Method Select whether to manually check the measured waveform that is recorded during CAVI examinations or perform the process automatically. Auto: The measured waveform is automatically recorded as soon as it can be measured. Manual: The measured waveform is recorded manually after the cuff is pressurized.		
Wave Sensitivity	Set the print sensitivity of the pulse wave. Individual: The sensitivity at which each pulse wave waveform reaches its maximum is set individually. Unify: The sensitivity of each pulse wave is unified.	Individual, [Unify]	
CAVI Check  Specifies whether to perform a CAVI check.  This is enabled if "CAVI" is selected as the measurement item.		[ON], OFF	
Simple CAVI Measurement  Specifies whether to perform a simple CAVI measurement.  MEMO  This is enabled if "CAVI" is selected as the measurement item.		ON, [OFF]	
Cuff Pressure for CAVI	Set the cuff pressure for pulse wave measurements.	30mmHg, [50mmHg]	
Auto Extension			

# **BP Examination**

Setup Item	Description	Setting Range
BP Re-Inflation	Select whether to use the re-inflation function when measuring blood pressure.	[ON], OFF
Meas Pause Right to Left	Set the pause to occur between measuring the right side and measuring the left side.  This is enabled if "ABI" is selected as the measurement item.	[5 seconds] 5-120 seconds
Measurement Pause for Toe BP $\boxed{T}$	Set the pause to occur before proceeding to the toe blood pressure measurement.  This is enabled if "TBI" is selected as the measurement item.	[5 seconds] 5-120 seconds
ABI Judgment Reference	Select the criteria to be applied to ABI measurements.  ACC/AHA Standard: Complies with the 2005 ACC/AHA Standard.  TASCII Standard: Complies with the TASCII (ACC/AHA 2011) Standard.  This is enabled if "ABI" is selected as the measurement item.	ACC/AHA Standard, [TASCII Standard]
ABI Brachial BP Usage Method	Specifies the brachial blood pressure usage method to be used in ABI calculations. L/R Average: Complies with the 2000 AHA Standard. L/R Maximum: Complies with the TASCII (2011 and 2005 ACC/AHA) Standard.  This is enabled if "ABI" is selected as the measurement item.	L/R Average, [L/R Maximum]
BP Measurement Method	Measurement Method  Select whether to measure blood pressure on the left and right side separately or in all four limbs at once.  Simultaneous Inflation: Inflates the cuffs of all four limbs at once.  Right to Left Inflation: The blood pressure on the left side is measured after the blood pressure measurements on the right side are completed.  This is enabled if "ABI" is selected as the measurement item.	
Calc auto Pressure Increment	Set whether to automatically calculate the pressurization when measuring blood pressure.	[ON], OFF
Toe Cuff Attachment Guide <b>7</b>	Select whether to enable the function for avoiding too much pressure on the toe during toe cuff attachment (toe cuff attachment assist function).	[ON], OFF
TBI Judgment Reference	Select the TBI criteria for outputting an interpretation in the case of possible peripheral arterial disease.  An interpretation is output when TBI<0.61 or when TBI<0.70.    MEMO   This is enabled if "TBI" is selected as the measurement item.	
Inflate Brachial Cuff for TBI 7		
Default Ankle Pressure	Specifies the default pressurization to be used when measuring ankle blood pressure.	[200mmHg], 100mmHg-295mmHg
Default Toe Pressure		

### **Print**

#### Print 1

Setup Item	Description	Setting Range
Printing Item Setting	Set whether to print each item in color when conducting each blood pressure and pulse wave examination.	[ID], [Name], [Age], [Height], [Weight], [A.C.], [Med.], [Symp.], [Dept. 1], [Dept. 2], [Dr. Nm1], [Dr. Nm2], [Tech.], [ABI Result Comment], [TBI Result Comment], [UT], [%MAP]
Paper speed	Specifies the printing speed of pulse wave reports.	[25mm/s], 50mm/s

#### Print 2

Setup Item	Description	Setting Range
<print settings=""></print>		
Standard Graph (L)	Specifies the content to be printed in the left graph of the Standard Report.	[Age Graph], BP Balance, CAVI Trend, ABI Trend, TBI Trend, Tend, Brachial BP Trend, Weight Trend, BMI Trend, Abdominal Circumference Trend
Standard Graph (R)	Specifies the content to be printed in the right graph of the Standard Report.	Age Graph, BP Balance, [CAVI Trend], ABI Trend, TBI Trend, T Brachial BP Trend, Weight Trend, BMI Trend, Abdominal Circumference Trend
BPB Arrow	Specifies whether to output a BPB arrow in the Standard A Color Report.	[ON], OFF

# **Auto Print Copies**

Setup Item	Description	Setting Range	
<automatic (copies)="" 1="" print=""></automatic>			
Simple Examination Report			
Standard Report	Standard Report Specifies the number of color copies of the Standard Report to be printed.		
Report for Patient Specifies the number of color copies of the Patient Report to be printed.		[None], 1, 2, 3, Priority	
<automatic print<br="">(Copies) 2&gt;</automatic>			
Trend Report	Specifies the number of color copies of the Trend Report to be printed.	[None], 1, 2, 3, Priority	
Pulse Wave Report Specifies the number of color copies of the Pulse Wave Report to be printed.		[None], 1, 2, 3, Priority	
Beat Table Report Specifies the number of color copies of the Beat Table Report to be printed. [N		[None], 1, 2, 3, Priority	

S: Indicates settings that are displayed in Simple Examination Mode.

# **Settings for Brachial Blood Pressure Examinations**

# **Brachial BP: General**

Setup Item	Description	Setting Range
Anonymous	Specifies whether to make patient information anonymous.	ON, [OFF]
Buzzer	Specifies the buzzer setting.	[Buzzer Control 1], Buzzer Control 2 Buzzer Control 3

# File s

Setup Item	Description	Setting Range
Auto Save	Specifies whether to automatically save brachial blood pressure data after taking measurements.  This is enabled when [File] - [General] - [Auto Save] is set to "Each Exam. Mode".	ON, [OFF]
Storage Media	Specifies the media to save the data. Multiple items can be specified.	[SD Card] USB1,2,3, DMS

# **Brachial BP Settings**

#### **Brachial BP Settings** S

Setup Item	Description	Setting Range
Default Measurement Site	Set the default blood pressure measurement site.	[RB], LB, RB/LB
Default Interval Period	Automatically starts recording in intervals of the set time. Pause periods are ignored while capturing and recording waveforms.	OFF, [1 minute], 2 minutes, 3 minutes, 4 minutes, 5 minutes
Default Measurement Count	Default Measurement Count Set the default measurement count.	
Hypertension Threshold (SYS1)	Hypertension Threshold (SYS1) The SYS threshold between the green and yellow areas of the blood pressure value group graph.	
Hypertension Threshold (SYS2)	Hypertension Threshold (SYS2) The SYS threshold between the yellow and red areas of the blood pressure value group graph.	
Hypertension Threshold (DIA1)	Hypertension Threshold (DIA1) The DIA threshold between the green and yellow areas of the blood pressure value group graph.	
Hypertension Threshold (DIA2) The DIA threshold between the yellow and red areas of the blood pressure value group graph.		[90] 30-280
BP threshold (L and R) Specifies the value for indicating a difference between the left and right systolic blood pressure.		[15] 1-100

#### NOTE

This can be entered as a SYS2>SYS1>DIA2>DIA1 relationship.

#### Print settings S

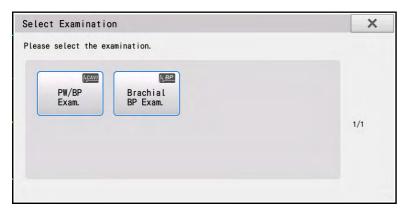
Setup Item	Description	Setting Range
Printing Item Setting	Set whether to print each item when conducting brachial blood pressure examinations.	[ID], [Name], [Age], [Height], [Weight], [A.C.], [Med.], [Symp.], [Dept. 1], [Dept. 2], [Dr. Nm1], [Dr. Nm2], [Tech.]
Brachial BP Report: Print Copies	Specifies the number of color copies of the Brachial BP Report to be printed.	None, [1], 2, 3, [Priority]
Print Settings for Bottom of Report	Set the content to be printed at the bottom of the color Brachial BP Report.	Details, [Comment]

S: Indicates settings that are displayed in Simple Examination Mode.

# **Registering Examinations**

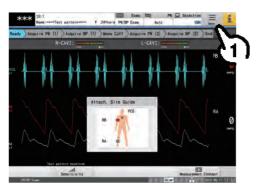
Touch [Examination] to display the "Select Examination" window. It is possible to change the display order and positions of the examinations in this window.

It is also possible to register new examinations based on existing examinations and register a series examination in which multiple examinations are conducted in a series. Up to 16 examinations can be registered, including the initially registered examination.



# **Changing the Examination Order**

1 Touch [Menu] on the touch panel.



2 Touch [Setting].



3 Touch [Register Examination].



4 Change the examination order.



- 1) Touch the [Change Exam. Pos.] tab.
- 2) Touch the examination to change the order.
- 3) Touch the direction keys to change the position.

Up to eight examinations can be shown in one display. To perform operations for an examination in a different display, touch [V] to switch the display.

5 Touch the [Back] button.

The new setting is reflected.

# Selecting the Examination on Startup

The examination to be displayed on startup can be selected.

- 1 Perform steps 1-3 in "Changing the Examination Order" (P11-22).
- 2 Touch the [Exam. on Startup] tab.



# 1) Select the examination to be displayed on startup.

The icon of the selected examination is displayed in "Exam. on Startup".

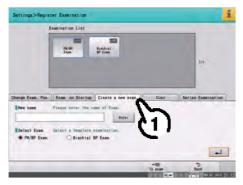
The selected examination is registered as the examination to be displayed on startup.

# **Adding a New Examination**

New examinations can be set.

Newly registered examinations can be selected in the "Select Examination" window in the same way as other examinations.

- 1 Perform steps 1-3 in "Changing the Examination Order" (P11-22).
- **2** Touch the [Create a new exam.] tab.



3 Touch the [New name] input area or touch [Enter].



- 1) Enter the name of the new examination.
- 2) Touch [ 🚚 ].

4 Select an examination on which to base the examination.



Touch the examination on which to base the examination.

5 Touch [→] after the settings have been configured.

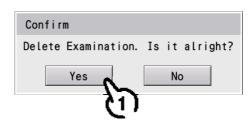
### **Deleting an Examination**

Examinations that are no longer needed can be removed from the "Select Examination" window.

- 1 Perform steps 1-3 in "Changing the Examination Order" (P11-22).
- **2** Touch the [Change Exam. Pos.] tab.



- 1) Touch the examination to be deleted.
- 2) Touch [Delete].
- 3 Touch [Yes].



The selected examination is removed from the Examination List.

## **Copying an Examination**

- 1 Perform steps 1-3 in "Changing the Examination Order" (P11-22).
- 2 Touch the [Copy] tab.

  Touch the [ExamName] input area or touch [ ← ].



- 1) Enter the name.
- **2)** Touch [ **↓** ].

3 Touch the examination to be copied.



**4** Touch [ **↓** ].

The copy of the examination is registered in the Examination List.

### **Registering a Series Examination**

It is possible to register a series examination on this device to conduct up to three types of examinations in a series. Series examinations need to be registered in advance in order to perform them.

Registered series examinations can be selected in the "Select Examination" window in the same way as other examinations.



- Simple blood pressure examinations cannot be conducted in a series examination.
- 1 Perform steps 1-3 in "Changing the Examination Order" (P11-22).
- **2** Touch the [Series Examination] tab.



3 Touch the SerExamName input area. Enter the name of the series examination.



- 1) Enter the name.
- **2)** Touch [ **↓** ].

4 Specify the examinations to be conducted in a series.



- 1) Touch the examination to be conducted first.
- 2) Touch [Examination 2].
- 3) Touch the examination to be conducted second.
- 4) Touch [Examination 3].
- 5) Touch the examination to be conducted third.
- **6)** Touch [ **↓** ].

The series examination is registered in the Series Examination List.

7) To delete an examination from a series examination, touch the examination and touch [Delete].

# Saving and Initializing the Settings

The current settings can be saved to the SD card or printed as a report. The settings can also be initialized.

### Saving Settings to an SD Card

- 1 Insert the SD card into the device.
- 2 Touch [Menu] on the touch panel.
- 3 Touch [Setting].
- 4 Touch [Save settings].
  - The current settings are saved to the SD card.

 The settings saved to the SD card can be loaded later using [Load settings]. This is useful in situations such as when the same settings need to be configured on multiple devices.



Network settings (device name, IP address, etc.) are not saved.

## Saving Codes to an SD Card

- 1 Insert the SD card into the device.
- **2** Touch [Menu] on the touch panel.
- 3 Touch [Setting].
- 4 Touch [1/2].
- 5 Touch [Save Code.].

- The codes registered for Dept. 1-4, Med., Symp., Dr. Nm1-2 and Tech., along with the names and facility name, are saved to a file called "TABLE.INI" in the "ETC" folder on the SD card.
- The codes saved to the SD card can be loaded later using [Read Code.]. This is useful in situations such as when the same settings need to be configured on multiple devices.

### **Initializing Common Settings**

- 1 Touch [Menu] on the touch panel.
- 2 Touch [Setting].

3 Touch [Initialize Settings].

All of the common settings are initialized. The settings for each examination are not initialized.

### **Initializing Each Setting**

- 1 Touch [Menu] on the touch panel.
- 2 Touch [Setting].
- 3 Touch the applicable setting.

- 4 Touch [1/2].
- 5 Touch [Reset].

The applicable setting is initialized.

# **Chapter 12 Maintenance and Inspection**

To ensure the long-term safety of the device, the device needs to be inspected and accessories need to be replaced periodically.

This chapter describes the maintenance and inspection procedures for this device.

Make sure to perform daily inspections and periodic inspections to maintain functionality, performance and reliability. Fukuda Denshi shall not be liable for accidents arising from failure to perform maintenance and inspections.

#### 



Never disassemble or modify the device.
 It may result in fire hazard or electric shock.

### **♠** CAUTION



• Do not perform the Maintenance menu procedure which is not described in this manual. It may result in malfunction.

# **Daily Inspection**

Perform daily inspections according to the Daily Inspection Procedure described below.

- If the device fails any inspection on the daily inspection list, the overall judgment will be "Fail". Take actions for all failed items.
- Use the device only when it has passed all the inspection items.

# **Daily Inspection Procedure**

#### Visual Inspection

Item	Inspection Item	Procedure	Criteria
Main Unit	1) Enclosure	Verify that there are no scratches, cracks, deformation or rust	No scratch, crack, deformation and rust should be found.
	2) Labels and panels	Verify that labels and panels are not peeled off or stained.	No peeling or stain should be found.
	3) Keys	Verify that the keys are not damaged	No damage should be found.

#### Accessories, Cables

Item	Inspection Item	Procedure	Criteria
Accessories	Sensors (*)	Verify that there is no scratch or damage.	No scratch or damage should be found.
		Verify the connection status of the cables and hoses.	Should be connected properly.
	Operation manual	Verify that the operation manual is kept in specified location.	Should be kept in specified location.

Item	Inspection Item	Procedure	Criteria
Cables	Power supply cable	Verify that there is no scratch or damage.	No scratch or damage should be found.
	LAN cable BPU cable	Verify the connection status of the cables.	Should be connected properly.

<sup>\*</sup> Cuffs, air hoses, PCG microphone, etc.

#### **Operation**

Item	Inspection Item	Procedure	Criteria
Operation			The screen should be displayed at power ON.
	Display	Check the screen.	No abnormality or flickering should be found.
		Check for errors on the screen.	No errors should be displayed on the screen.
	Icon display (At power on)	Check the status of the icons	The device connection status should be displayed correctly.
	Keys and Buttons	Press and check the keys and buttons.	Operation should be smooth.
OmmHg check Check the pressure value dispower on.		Check the pressure value displayed at power on.	Should be within ±1 mmHg.
	Clock	Check the date/time displayed at the lower right of the display.	The current date/time should be displayed correctly.

# **Periodic Inspection**

Perform periodic inspections according to the Periodic Inspection Procedure described below.

- Perform the inspections described in the Periodic Inspection Procedure once a year.
- If the device fails any inspection on the periodic inspection list, the general assessment must be "failed". Fix all failed items.
- Use the device only when it has passed all the inspection items.

# **Periodic Inspection Procedure**

#### • Visual Inspection

Item	Inspection Item	Procedure	Criteria	
Main Unit	1) Enclosure	Verify that there are no scratches, cracks, deformation or rust	No scratch, crack, deformation and rust	
	2) Labels and panels	Verify that labels and panels are not peeled off or stained.	No peeling or stain should be found.	
	3) Keys	Verify that the keys are not damaged	No damage should be found.	

# • Accessories, Cables

Item	Inspection Item	Procedure	Criteria	
Accessories	Sensors (*)	Verify that there is no scratch or damage.	No scratch or damage should be found.	
		Verify the connection status of the cables and hoses.	Should be connected properly.	
	Operation manual	Verify that the operation manual is kept in specified location.	Should be kept in specified location.	
Cables	Power supply cable LAN cable	Verify that there are no scratches or damage.	No scratches or damage should be found.	
	BPU cable	Verify the connection status of the cables.	Should be connected properly.	

<sup>\*</sup> Cuffs, air hoses, PCG microphone, etc.

#### **Operation**

Item	Inspection Item	Procedure	Criteria	
Operation	Power Supply	Check the startup screen at power ON.	Verify that the screen is displayed at power ON.	
	Display	Check the screen.	No abnormality or flickering should be found.	
		Check for errors on the screen.	No errors should be displayed on the screen.	
	Icon display (At power on)	Check the status of the icons	The device connection status should be displayed correctly.	
	Keys and Buttons	Press and check the keys and buttons.	Operation should be smooth.	
	power ON.  Clock Check the date/time displayed at the lower T		Should be within ±1 mmHg.	
			The current date/time should be displayed correctly.	

#### • Maintenance Test

Item	Inspection Item	Criteria		
Status display	Check the voltage of backup battery.	Should be 2.5V or above.		
Touch Panel Test	Touch the "+" marks in [Touch Panel Test].	Each key should have good tactile response.		
LCD Test	Touch [LCD Test] and then press the [START] key.	All dots should appear. The colors must be correct.		
Display Unit Test	Touch [Key/LED Test] and then touch a button on the display unit.	The symbol of the touched button should be highlighted.		
Sound Test	Touch [Sound Test] and then touch each test button.	The sound of the touched button should be heard. The volume should change.		



To enter maintenance mode, touch the [Menu] - [Maintenance] function buttons.

#### Performance

Item	Inspection Item	Procedure	Criteria		
Four-Limb Blood Pressure	Zero point	Read the pressure value at the atmospheric pressure when no connection is made to the air connectors.	Should be within 0±1mmHg.		
	Pressure accuracy	Perform this inspection in Maintenance - "Test Mode" (see the VS-2000 Service Manual).	Should be within ±3 mmHg.		
	Maximum pressure	Perform this inspection in Maintenance -	Should be 320±10mmHg.		
	Inflation time	"Pressure Test" (see the VS-2000 Service Manual).	Should be 20 sec. or less.		
	Air leakage	Transau).	Should be 4mmHg/min or less.		
	Quick exhaust		Should be 10 sec. or less.		
	100% open		Should be within 100 to 250mmHg/sec		
	75% open		Should be within 20 to 190mmHg/sec		
	Time Limit		Should be 130±10 sec. Should be 8±1 sec. at high speed.		
PCG	PCG filter characteristics (PWV)	Input sine-wave signals to the PCG connector to measure the amplitude at 165 Hz and 280 Hz when the amplitude at 200 Hz is 100%.	Should be 70% or above.		
	PCG filter characteristics (L)	Input sine-wave signals to the PCG connector to measure the amplitude at 30Hz, 50Hz and 80Hz when the amplitude at 100Hz is 100%.	50% or above at 30Hz 70% or above at 50 Hz 90% or above at 80 Hz		



Inspect the PCG function using the Manufacturer maintenance - [A/D Waveform] display.

#### Others

Item	Inspection Item	Criteria
Power Supply	Check that the power can be turned ON and OFF when operating the device on AC and battery power.	Should be able to turn the power ON and OFF when operating the device on AC and battery power.
Power Supply Cable	Perform continuity test using a tester and check that continuity occurs.	Should maintain continuity.

# • Electrical Safety

Refer to "Electrical Safety Inspection Methods" (P12-6).

# **Electrical Safety Inspection Methods**

Electrical safety-related testing methods and measurement equipment are prescribed in safety test standards. Specialist safety testing and measurement equipment are required for this measurement. Check that the measurement results do not exceed the allowable values and record the numerical values.

#### Safety Testing and Measurement Equipment

The descriptions of these testing and examination items presume that quality-controlled specialized electrical safety testing equipment will be used. It is recommended to use specialized safety testing and measurement equipment to simplify the testing and ensure accuracy.

For details on safety testing and measurement equipment, contact your local Fukuda Denshi service representative.

#### • Inspection Items

The following types of electrical safety inspections should be conducted.

(1)	Earth leakage current	Leakage current that flows along the protective earth wire
(2)	Touch current	Leakage current that flows from the enclosure of the device to the earth
(3)	Patient leakage current (From Patient Connection to Earth)	Leakage current that flows from the applied parts to the earth through the patient. There are two ways to measure, DC and AC.
(4)	Patient leakage current (External Voltage)	Leakage current that flows from the device to the earth by the power supply voltage on the patient in the type F applied parts.
(5)	Patient auxiliary current	Current that flows through the patient between applied parts. There are two ways to measure, DC and AC.

There are following two measurement conditions.

(1)	Normal condition	Measurement in normal usage conditions
(2)	Single fault condition	Measurement in single fault condition

#### • Allowable Leakage Current Values

Leakage Current (Unit: mA)		Type B		Type BF Type CF			
		Normal Condition	Single fault Condition	Normal Condition	Single fault Condition	Normal Condition	Single fault Condition
Earth leakage current		5	10	5	10	5	10
Touch current		0.1	0.5	0.1	0.5	0.1	0.5
Patient leakage current	DC	0.01	0.05	0.01	0.05	0.01	0.05
(From Patient Connection to Earth)	AC	0.1	0.5	0.1	0.5	0.01	0.05
Patient leakage current (External Voltage)		_	_	_	5	_	0.05
Patient auxiliary current	DC	0.01	0.05	0.01	0.05	0.01	0.05
	AC	0.1	0.5	0.1	0.5	0.01	0.05

<sup>\*:</sup> indicates the values that apply to this device.





If a value exceeds the allowable limit during safety inspection, immediately stop using the device, and replace or repair the defective part properly.

If the device is used without repairing, it may cause serious accident.

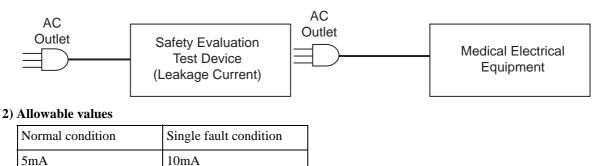
#### 1. Safety specifications of this device

Classification by protection type: Class I equipment

Classification of applied part by degree of protection: Type CF applied part

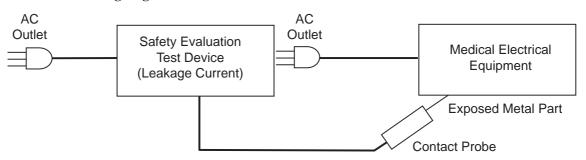
#### 2. Earth leakage current inspection

#### 1) Measurement wiring diagram



#### 3. Touch current inspection

#### 1) Measurement wiring diagram



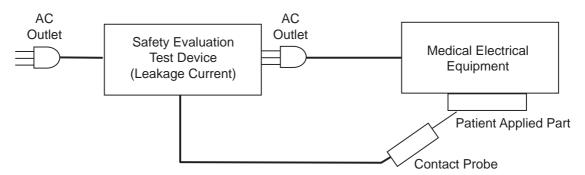
Exposed Metal: Potential equalization terminal, etc.

#### 2) Allowable values

Normal condition	Single fault condition
0.1mA	0.5mA

#### 4. Patient leakage current (from patient connection to earth) inspection

#### 1) Measurement wiring diagram



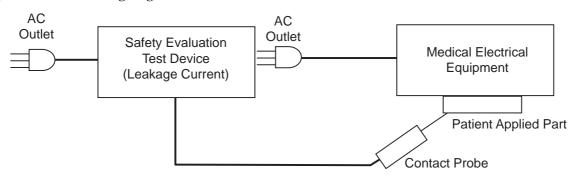
Patient Applied Part: Cuffs, PCG microphone chip, etc.

#### 2) Allowable values

	Normal condition	Single fault condition
Direct Current	0.01mA	0.05mA
Alternating Current 0.01mA 0.05mA		0.05mA

#### 5. Patient leakage current (external voltage) inspection

#### 1) Measurement wiring diagram



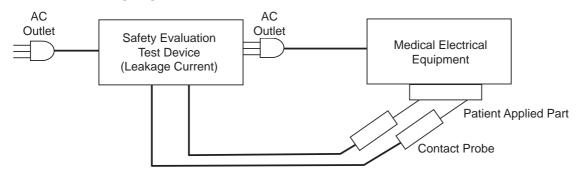
Patient Applied Part: Cuffs, PCG microphone chip, etc.

#### 2) Allowable values

Single fault condition	
0.05mA	

#### 6. Patient auxiliary current inspection

#### 1) Measurement wiring diagram



Patient Applied Part: Cuffs, PCG microphone chip, etc.

#### 2) Allowable values

	Normal condition	Single fault condition
Direct Current	0.01mA	0.05mA
Alternating Current	0.01mA	0.05mA

# **About the Consumable Parts**

### **Replacement Period of Consumable Parts**

The following parts and accessories are consumable parts. The indication of replacement period for each item is as follows. Some items may need to be replaced sooner than the time mentioned here depending on factors such as the usage environment. Please replace the item immediately if an abnormality or deterioration in performance is noticed during usage or inspection.

#### • Battery pack: 300 charge/discharge cycles

When the battery deteriorates, the operating time is short even after sufficiently charging the battery.

- Limb cuffs: 30,000 times of usage
- Toe cuffs: 200 times of usage

A worn cuff cannot measure blood pressure accurately.

LCD backlight: 80,000 hours

A worn LCD backlight lowers the LCD brightness and may prevent the LCD from illuminating.

#### • Battery for the clock: 6 years (if stored at a temperature of 25°C)

The battery powers the internal clock. When the battery is depleted, the date and time cannot be correctly recorded. The service life may be shortened depending on the operating environment, or if used in a temperature, humidity range specified for transport/storage. Replace the battery as soon as possible when the battery is depleted, and a message "Replace the backup battery. The clock will be initialized." is displayed.

#### Cooling fan: Approximately 70,000 hours (if continuously used)

If the fan stops moving, the internal temperature of the device increases and the power will automatically turn OFF. If the power repeatedly turns OFF automatically during AC power operation, the cooling fan may be damaged or the vents may be clogged. Contact your local Fukuda Denshi service representative.

# **Cleaning and Disinfection**

# **Cleaning and Disinfecting the Device**

#### ■ Cleaning and Disinfecting the Enclosure

Use the following procedures to clean and disinfect the enclosure of the device.

#### Cleaning

Immerse a cloth in a solution of domestic neutral detergent and water, wring it out thoroughly and then wipe the main unit. Do not use ether and benzine as they may damage the enclosure.

#### Disinfection

Wipe the device with a cloth that has been thoroughly wrung out after being sprayed with a solution of alcohol and water or glutaraldehyde disinfectant. Then, wipe with a soft lint cloth.

#### ■ Cleaning the Display

Remove dust and stains from the display by wiping with a cloth that has been thoroughly wrung out after being soaked in alcohol such as ethanol.

### **Cleaning the Accessories**

#### • Toe cuff

Wipe the cuffs gently using water or alcohol for disinfection. Do not use organic solvents such as thinner or toluene.

#### • Cuffs and Air Hoses

Clean using neutral detergent or 70% isopropyl alcohol. Do not pull the cable from the connector part when cleaning. Do not use organic solvents or cresol liquid soap as these will cause the hoses to deteriorate.

#### • PCG microphone

Clean using neutral detergent or 70% isopropyl alcohol. Do not pull the cable from the connector part when cleaning. Do not use organic solvents or cresol liquid soap as these will cause the cable covers to deteriorate.

#### • Connection Cables

Wipe gently with domestic neutral detergent or 70% isopropyl alcohol for cleaning. Do not use organic solvents such as thinner or toluene.

# Replacing the Built-in Battery

If the battery operating time becomes extremely short even if it is fully charged, purchase a new battery. Contact your local Fukuda Denshi service representative when installing or replacing the battery.



Contact your local Fukuda Denshi service representative to purchase a battery.

# Replacing the Clock Battery

This device is equipped with a built-in battery to power the clock.

If incorrect time is shown shortly after setting the correct time, the service life of the clock battery may have been depleted. The replacement period of the battery is also indicated by a message, "Replace the backup battery. The clock will be initialized." Contact your local Fukuda Denshi service representative.



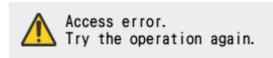


The device needs to be disassembled to replace the battery. Contact your local Fukuda Denshi service representative.

# When error messages are displayed

The following two types of system error messages are displayed when an unexpected failure occurs in the system. Take appropriate action by following the message.

#### If continuous operation is possible



Processing was **suspended** due to a failure occurring in the system. The suspended process can be continued by performing the previous operation again.

#### If continuous operation is not possible



Access error.

Press and hold the POWER button for 10 seconds to shutdown the system.

Processing was **aborted** due to a failure occurring in the system. An error in the device settings or a failure in the built-in software may have occurred. Press and hold the POWER button for 10 seconds to turn OFF the power and then contact your local Fukuda Denshi service representative.

#### If the BPU-100\* Pulse Wave Unit is defective



A communication timeout occurred with BPU1.

The BPU-100 Pulse Wave Unit may be defective. Contact your nearest service representative.

\* BPU1: Indicates the BPU-100 inserted in the upper slot of the VS-2000.

BPU2: Indicates the BPU-100 inserted in the lower slot of the VS-2000.

BPU3: Indicates the BPU-100 connected to the IB connector of the VS-2000.

# Chapter 13 Appendix

# **Main Specifications**

Display		Color LCD, 1024x768 dots (with LED backlight)	
PCG	Frequency characteristic	L filter: 50 Hz (-6 dB/oct)	
		PWV filter: 165 - 280Hz within -3 dB	
Non-Invasive Blood Pressure Measurement (BPU-100)	Maximum Measuring range	0 to 300 mmHg	
	Scale interval	1 mmHg	
	Pressure accuracy	±3 mmHg	
	Pressure detection	Semiconductor pressure sensor	
	Zero balancing	Automatic balancing	
	Measurement	Oscillometric method	
	NIBP measurement range	20 to 280 mmHg	
	Inflation	Automatic inflation by pump	
	Deflation	Automatic deflation by electromagnetic valve	
	Safety mechanism	Activates when 330 mmHg or above, or 10 mmHg or above lasts for 130 sec. or longer	
SD Card Slot		Compatible with SD Card Specification 2.0	
LAN connector		Complies with IEEE802.3u 100BASE-TX (cable must be 50m or below)	
USB ports		Compatible with USB2.0 Full Speed, 3 channels	
Safety standard		ANSI/AAMI ES 60601-1:2005	
Type of protection against electrical shock		Class I Equipment and Internally Powered Equipment	
Degree of protection against electrical shock		NIBP: Type CF applied part, defibrillation-proof applied part	
		PCG input: Type CF applied part, defibrillation-proof applied part	
Power Supply		AC 100 to 240V, 50/60 Hz, 80 VA DC11.1V (During battery operation)	
Dimensions	Main Unit	Approx. 178mm (W) x 181mm (D) x 315mm (H) 4.5kg (weight, excluding battery pack)	
	Display Unit	Approx. 297mm (W) x 210mm (H) x 95.5mm (thickness) (excluding protrusions) 1.6kg (weight)	
	BPU-100	Approx. 90mm (W) x 140mm (D) x 43mm (H) 0.40kg (weight)	
Operating environment	Temperature	10 to 40°C	
	Humidity	15 to 95% (non-condensing)	
Storage environment	Temperature	-10 to +60°C	
	Humidity	10 to 95% (absolute humidity in conditions below 40°C and 95%RH, excluding conditions with condensation)	
	Atmospheric Pressure	800 to 1060hPa	
Service life		6 years, provided that periodic maintenance and inspection is made (based on company standard)	

# **Measurements**

#### **Blood Pressure and Pulse Wave Examinations**

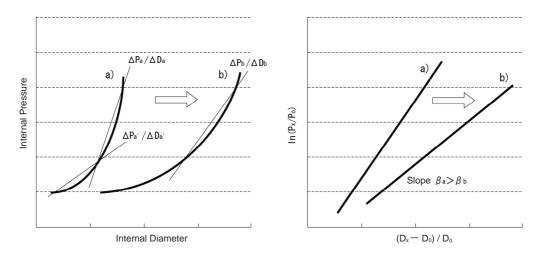
#### [1] CAVI (Cardio-Ankle Vascular Index)

A new index based on stiffness parameter  $\beta$ , CAVI is a pressure-independent index indicating the natural stiffness of the blood vessels. While compliant with Hasegawa PWV method, the Cardio-Ankle Vascular Index calculates the specific stiffness of arterial walls independent of blood pressure. A larger CAVI implies greater stiffness of the arterial walls.

#### (1) Stiffness Parameter β

As shown in the diagrams below, the relationship between internal pressure and inner diameter is nonlinear. b) has greater extensibility than a) and at the same pressure  $\Delta Pa/\Delta Da > \Delta Pb/\Delta Db$ . However, a comparison of low pressure regions with high pressure regions show that the relationship between inner diameter and inner pressure is not constant even for a).

As shown in the diagram on the right, plotting the relationship between natural logarithm for the pressure ratio ln (Px/Po) and the rate of change in inner diameter (Dx-Do)/Do shows a linear relationship. This oblique straight line is called stiffness parameter  $\beta$ . It is known that this parameter is independent of internal pressure and that a larger  $\beta$  indicates lower extensibility (greater vascular stiffness).



Assessment of carotid arterial distensibility using β stiffness index - Nippon Rinsho Vol 62, Suppl 3, 2004

The stiffness parameter  $\beta$  is calculated as shown below.

$$\beta = \left(\ln \frac{Ps}{Pd}\right) \cdot \frac{D}{\Delta D} \quad \dots \qquad \boxed{1}$$

ln(Ps/Pd): Logarithmic pulse pressure (Ps: systolic pressure, Pd: diastolic pressure)

 $D/\Delta D$ : Reciprocal of radius percentage change (D: Vascular radius,  $\Delta D$ : Beat-initiated change in the vascular radius)

#### (2) Bramwell-Hill Equation

The Bramwell-Hill equation produces the following formula.

$$\text{PWV}^2 = \left(\frac{\Delta P}{\rho}\right) \cdot \left(\frac{V}{\Delta V}\right) = \left(\frac{\Delta P}{\rho}\right) \cdot \left(\frac{D}{2\Delta D}\right)$$

$$\frac{D}{\Delta D} = \frac{2\rho \cdot PWV^2}{Ps - Pd} \qquad \cdots \qquad 2$$

 $\rho$ : Blood density, V: Volume,  $\Delta$ V: Change to volume

PWV: Pulse wave transmission speed (refer to "(4) PWV (Pulse Wave Velocity)" (P13-3))

#### (3) CAVI Equation

By substituting equation (1) into equation (2), we obtain the following CAVI equation.

$$CAVI = \beta = \left(\ln \frac{P_S}{Pd}\right) \cdot \left(\frac{D}{\Delta D}\right) = \left(\ln \frac{P_S}{Pd}\right) \cdot \left(\frac{2\rho \cdot PWV^2}{P_S - Pd}\right)$$

The actual CAVI is coordinate-transformed to correspond to aortic PWV.

$$CAVI = a \cdot \left( \ln \frac{Ps}{Pd} \right) \cdot \left( \frac{2\rho \cdot PWV^2}{Ps - Pd} \right) + b$$
 (a, b: Conversion Constant)

Brachial blood pressure is used as the average systolic pressure (Ps) and diastolic pressure (Pd) of the body.

#### (4) PWV (Pulse Wave Velocity)

Pulse wave traveling through the blood vessels is recorded at two blood vessel locations. Then by dividing the distance between the two locations with the pulse wave time difference between the two locations produces PWV, a speed value and an index that assesses the stiffness of the arteries. The higher the PWV, the stiffer the arterial wall is.

$$PWV = \frac{L}{\Delta T}$$

L: Distance between two blood vessel locations,  $\Delta T$ : Pulse wave time difference between the two blood vessel locations

The following two PWV are used to calculate CAVI.

• Heart valve - right (left) ankle artery PWV

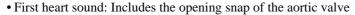
#### (5) Time measurement of pulse waves

To calculate PWV, we need to obtain pulse transmission time T from the heart valve to the ankle.

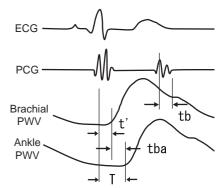
To establish T = t'b + tba

t'b = tb,

T = tb + tba is obtained.



- Second heart sound: Closing snap of the aortic valve
- Notch of the brachial pulse wave: Pulse wave at the closing the aortic valve
- t'b: Time between the first heart sound and the rise of the brachial pulse wave
- tb: Time between precomponents of the second heart sound and the notch of the brachial pulse wave
- tba: Time difference between the rise of the brachial pulse wave and that of ankle pulse wave



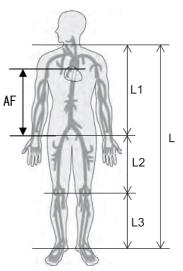
#### (6) Vascular length

Obtain the vascular length to calculate PWV.

- AF: Direct distance between the sternal border in the second intercostal space and the femoral artery pulsating site.
- L1: Vascular length between the heart valve and the femoral artery pulsating site  $(=1.3 \times AF)$
- L2: Direct distance between the femoral artery pulsating site to the center of AF the knee joint
- L3: Direct distance between the center of the knee joint to the center of the cuff applied to the ankle.
- L: Vascular length between the heart valve and ankle artery (= L1 + L2 + L3)

The PWV is obtained using the following formula.

• Heart valve - right (left) ankle artery PWV =  $\frac{L1 + L2 + L3}{tb + tba}$ 



#### (7) CAVI Measurement Value

There are following types of CAVI depending on the measurement locations.

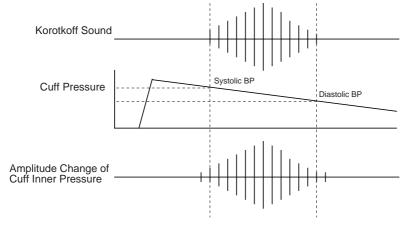
R-CAVI: CAVI between the heart valve and the right ankle artery.

L-CAVI: CAVI between the heart valve and the left ankle artery.

R/L-CAVI are calculated from the brachial pulse wave obtained from the right brachial cuff and pulse waves obtained from the right and left ankle cuffs.

#### [2] Oscillometric Method

This is an indirect blood pressure measurement method. Attach the cuff to the brachium, apply the pressure to the blood vessels and gradually reduce the pressure. The blood pressure values are determined by analyzing the shape of the pulse waves obtained during this process. The cuff pressure at the point where the pulse pressure wave sharply increases is generally referred to as the systolic blood pressure, and the cuff pressure at the point where the pulse pressure wave sharply decreases is referred to as the diastolic blood pressure.



#### [3] ABI (Ankle-Brachial Index)

The ABI (ankle brachial index) is a quotient obtained by dividing the ankle systolic blood pressure by the brachial systolic blood pressure. It is an index used to evaluate the degree of stenosis and occlusion resulting from atherosclerosis in the lower limbs. It is also called ABPI (ankle-brachial pressure index) or API (ankle pressure index).

R-ABI and L-ABI are obtained through the following formulas:

$$R-ABI = \frac{\text{Right ankle systolic blood pressure}}{\text{Typical brachial systolic blood pressure}}$$

$$L-ABI = \frac{Left \text{ ankle systolic blood pressure}}{Typical \text{ brachial systolic blood pressure}}$$

The typical brachial blood pressure is determined according to the following conditions:

- When ABI Brachial BP Usage Method is set to "Average"
  - When the difference between the right and left brachial systolic blood pressures is 10 mmHg or above : Typical brachial blood pressure = the higher of the right or left brachial systolic blood pressure
  - If the difference between the right and left brachial systolic blood pressures is 10 mmHg or below:
  - Typical brachial blood pressure = average of both the right and left brachial systolic blood pressure

■ When ABI Brachial BP Usage Method is set to "Highest"

Typical brachial blood pressure = the higher of the right or left brachial systolic blood pressure

The device examination results comply with the ACC/AHA and TASC II standards.

The applied standard of the output result depends on the setting.

#### [4] TBI (Toe Brachial Index)

The TBI (toe brachial index) is a quotient obtained by dividing the toe systolic blood pressure by the brachial systolic blood pressure. It is effective in detecting advanced arteriosteogenesis in the ankle joints and peripheral stenosis or occlusion beyond the ankle joint.

It is also called TBPI (toe-brachial pressure index) or TPI (toe pressure index).

R-TBI and L-TBI are obtained from the following formulas.

$$R-TBI = \frac{\text{Right toe systolic blood pressure}}{\text{Typical brachial systolic blood pressure}}$$

For details on typical brachial systolic blood pressure, refer to the section on ABI.

#### [5] BMI (Body Mass Index)

BMI is a measure of obesity and is obtained using the following formula.

$$BMI = \frac{Weight (kg)}{Height (m) \times Height (m)}$$

#### [6] UT (Upstroke Time)

The UT is utilized as a risk marker of stenosis resulting from arteriosclerosis. Stenosis or occlusion causes the pulse wave to rise gently leading to an increase in the UT value.

It measures the time from the rise of brachial and ankle pulse waves to the pulse wave peak.

RB-UT: UT of right brachial pulse wave

RA-UT: UT of left brachial pulse wave

LB-UT: UT of left brachial pulse wave

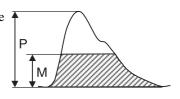
LA-UT: UT of left ankle pulse wave

#### [7] %MAP (Percent Mean Arterial Pressure)

As shown in the following formula, %MAP is a quotient obtained by dividing the mean pulse pressure by the pulse pressure - assuming the cuff-induced pulse waves as blood pressure waveform - and expressed as a percentage.

waveform - and expressed as a percentage.

The mean pulse pressure is a quotient obtained by dividing the area of the pressure pulse wave by the time.



$$%MAP = \frac{Mean Pulse Pressure (M)}{Pulse Pressure (P)} \times 100$$

The %MAP is an index that expresses pulse wave acuteness. The presence of arterial stenosis or occlusion increases %MAP.

RB-%MAP: %MAP of right brachial pulse waveLB-%MAP: %MAP of left brachial pulse wave RA-%MAP: %MAP of right ankle pulse waveLA-%MAP: %MAP of left ankle pulse wave

#### [8] AI (Augmentation Index)

AI expresses the ratio of the percussion wave generated by a pressure increase of the aorta to the tidal wave at the systole in brachial pulse waves. It is obtained through the following formula:

$$AI = \frac{P2}{P1}$$

P1: Pressure at the peak of percussion wave

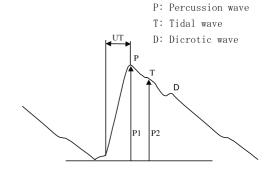
P2: Pressure at the peak of tidal wave

AI is an index indicating vascular extensibility. It has a positive correlation with the resistance of the aortic vessel and increases with age and arteriosclerosis.

R-AI: Measurement obtained from the right brachial pulse wave

L-AI: Measurement obtained from the left brachial pulse wave

The values are printed in the following priority order: R-AI, L-AI.





All may also be expressed as a ratio of the pressure difference  $\Delta P$  (= P2 - P1) to the pulse pressure. With the VS-2000, however, a ratio of P1 to P2 is calculated.

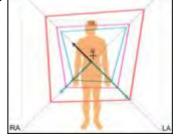
#### [9] BPB (Blood Pressure Balance)

This graph shows the direction of blood pressure reduction in the limbs.

This shows the blood pressure of each limb with the distance from the starting point. The BP of each limb is shown at an angle of 45°; the right brachium at upper left, the left brachium at upper right, the right ankle at lower left and the left ankle at lower right.

If the BP value for the right (left) brachium is not available, the BP value for the left (right) brachium will appear instead.

Similarly, if the BP value for the right (left) ankle is not available, the BP value for the left (right) ankle will appear instead.



+ The gravity point of the systolic BP of the limbs

Angle: The clockwise angle starting from 0, which is between the third and fourth quadrant.

Distance: The BP distance from the starting point to the gravity point.

The length of the arrow indicates the degree of ischemia at the applicable site.

Arrow indication: An arrow appears when lower limb ABI is below 1.00 and the systolic BP difference of left and right upper limbs is 20mmHg or above.

Arrow length:

Corresponds to the ABI value for the lower limbs and the value of the following equation for the upper limbs.

Systolic BP of Corresponding Site Higher Systolic BP of Left/Right Brachial

An arrow is drawn as far as the inner line when the ABI of the lower limbs or the value from the above equation for the upper limbs is 0.90, and as far as the outermost line when the value is 0.50.

Arrow color:

Upper limbs: Black; Right ankle: Blue; Left ankle: Green



↑ The ↑ arrow will only appear if ischemia is suspected.

#### **Measurement Unit for Each Parameter**

Value	Unit	Value	Unit
Blood pressure	mmHg (kPa)	UT	ms
ABI	None	%MAP	None
CAVI	None	AI	None
BMI	kg/m <sup>2</sup>		

## **Printed Messages**

<b>Print Location</b>	Message	Printout Conditions				
Degree of arterial occlusion	■ If 2005 ACC/AHA standard is selected					
(ABI)	Noncompressible.	• 1.30 ≤ R/L-ABI				
Test result (interpretation)(*1)	Normal.	• $1.00 \le R/L\text{-ABI} \le 1.29$				
	Borderline (equivocal).	• $0.91 \le R/L$ -ABI $\le 0.99$				
	Possible mild-to-moderate Peripheral Arterial Disease.	• $0.41 \le R/L$ -ABI $\le 0.90$				
	Possible severe Peripheral Arterial Disease.	• $0.00 \le R/L\text{-ABI} \le 0.40$				
	Suspicion of Peripheral Arterial Disease.	When the pulse wave height is too small for blood pressure measurement				
	■ If TASC II (ACC/AHA 2011) standard is selected					
	Noncompressible.	• 1.41 ≤ R/L-ABI				
	Normal.	• $1.00 \le R/L\text{-ABI} \le 1.40$				
	Borderline (equivocal).	• $0.91 \le R/L$ -ABI $\le 0.99$				
	Suspicion of Peripheral Arterial Disease.	• $0.00 \le R/L$ -ABI $\le 0.90$				
		When the pulse wave height is too small for blood pressure measurement				
Degree of arterial occlusion (TBI) (*2)	Suspicion of Peripheral Arterial Disease.	• When TBI < 0.61 or TBI < 0.70 (depending on the judgment criteria.)				
Blood pressure [mmHg] (*1)	High blood pressure.	A systolic blood pressure of 140 or above or a diastolic pressure of 90 or above				
	Normal.	• Others				

<sup>\*1</sup> Set whether to print ABI and blood pressure interpretations in "BP/PW Result Comment" in [Record] - [Record: Common] - [BP/PW Print Item Settings].

\*2 Set whether to print TBI interpretations in "TBI Result Comment" in [Record] - [Record: Common] - [BP/PW Print Item Settings].

#### NOTE

The normal range for TSAC II is  $0.91 \le R/L$ -ABI  $\le 1.40$ .

<b>Print Location</b>	Message	Printout Conditions
Interpretation (*1)	RA/LA: This examination is in normal range.	
	■ If 2005 ACC/AHA standard is selected	• $0.91 \le R/L$ -ABI $\le 1.29$ and $R/L$ -CAVI $< 9.0$
	■ If TASC II (ACC/AHA 2011) standard is selected	• $0.91 \le R/L$ -ABI $\le 1.40$ and $R/L$ -CAVI $< 9.0$
	RA/LA: Possible arterial stenosis, occlusion.	<ul> <li>When R/L-ABI ≤ 0.90</li> <li>R/L-TBI ≤ 0.60, 0.69 (*3)</li> </ul>
	• R/L-ABI is 0.90 or lower	• When R/L-ABI $\leq 0.90$
	• Low PW Ampl. (*2)	When the pulse wave amplitude is low
	• RA/LA-UT is 180ms or higher (*2)	• When RA/LA-UT $\geq$ 180ms
	• RA/LA-%MAP is 40% or higher (*2)	• When RA/LA-%MAP $\geq 40\%$
	RA/LA: Noncompressible	
	■ If 2005 ACC/AHA standard is selected	• When R/L-ABI $\geq 1.30$
	■ If TASC II (ACC/AHA 2011) standard is selected	• When R/L-ABI $\geq 1.41$
	Brachial pressure seems high.	When either the right or left brachial blood pressure includes:     Systolic blood pressure ≥ 140mmHg or Diastolic blood pressure ≥ 90mmHg
	Difference between R and L arm BP.	When the difference between the right brachial and left brachial systolic blood pressure is greater than 15mmHg.
	Doctor's instructions.	• Examination result shows values outside the standard range.
	Keep doing proper exercise/meal.	Examination results show values within standard range.

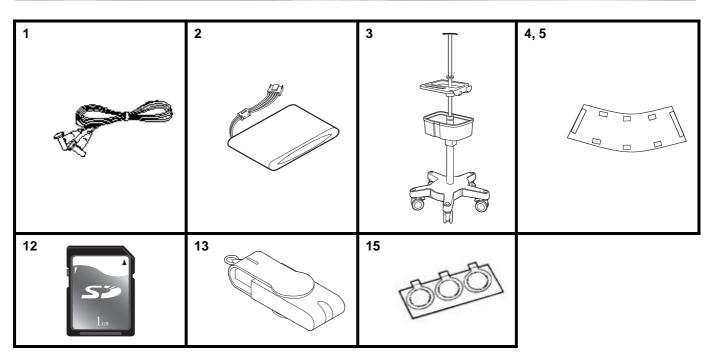
<sup>\*1</sup> Set whether to print general interpretations in "BP/PW Result Comment" in [Record] - [Record: Common] - [BP/PW Print Item Settings] in the settings for each examination.

<sup>\*2</sup> No report is printed when R/L-ABI  $\geq 0.91$ .

<sup>\*3</sup> This printing condition is added when "TBI Result Comment" is selected for [Record] - [Record: Common] - [BP/PW Print Item Settings] in the settings for each examination.

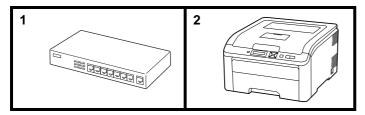
# **Optional Accessories**

No.	Accessory	Model	Remarks
1	Equipotential lead	CE-11	
2	Built-in battery	BTE-001	Lithium-ion Battery
3	Stand	OTV-03	
4	Cuff cover (for upper limb)	OA-1129M	
5	Cuff cover (for lower limb)	OA-1130M	
6	NIBP cuffs		
	(for right brachium, S)	CUF-129SRU	
	(for left brachium, S)	CUF-129SLU	
	(for brachium, S)	CUF-142SHU	
	(for brachium, L)	CUF-142LHU	
	(for right brachium, L)	CUF-129LRU	
	(for left brachium, L)	CUF-129LLU	
	(for right ankle, L)	CUF-138LRU	
	(for left ankle, L)	CUF-138LLU	
	(for right ankle, S)	CUF-138SRU	
	(for left ankle, S)	CUF-138SLU	
	(for ankle, S)	CUF-143SHU	
	(for ankle, L)	CUF-143LHU	
7	Air hose for upper limbs	OA-30APL2.7-BU	
	Air hose for lower limbs	OA-30APL2.7-AU	
8	Toe cuff, M	CUF-139M2	
	Toe cuff, S	CUF-139S2	
9	Toe cover	OA-459M	50 pieces per box
10	Limb cushion	OA-461	
11	Limb cushion cover	OA-463	
12	SD Card	SD-2G	2GB
13	USB Memory	TS16GJF600	16GB
		TS8GJF600	8GB
14	Wireless LAN adapter	GW-USEco300A	USB type
15	Dual-side adhesive tape	DA-30	Dual-side adhesive tape for PCG microphone 150 pieces per box
16	NIBP/ pulse wave unit	BPU-100	
	Four-limb blood pressure package	ASV-05U	
	Toe blood pressure package	ASV-06	



#### **Peripheral Devices**

No.	Accessory	Model	Remarks
1	Ethernet hub	IEC 60950 and RoHS compliant Switching Hub	
2		Manufacturer: Brother HL-3170CDW duplex color laser printer	



#### NOTE

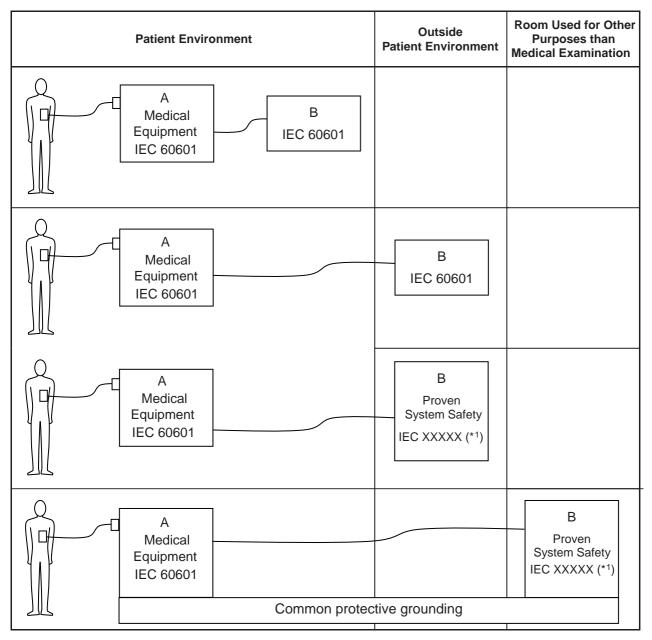
Please note that specifications are subject to change without prior notice for quality improvement.

# **Example of Combinations of Medical Devices and Non-Medical Devices**

Below is an overview of situations that may be created when combinations of different devices described in IEC 60601-1: "General Requirements for Medical Electrical Systems" are used in different medical environments.

Systems used in patient environment must contain safety features equivalent to medical devices that comply with IEC 60601-1. Systems used outside the patient environment must contain safety features equivalent to non-medical devices that comply with other IEC standards. IEC 60601-1 states that in the case of non-medical devices outside the patient environment, it is sufficient to ensure that the safety features comply with the applicable technical standard under IEC or the Electrical Appliance and Material Safety Act, or are equivalent to such features. (\*1).

When building a medical electrical system, assuming that this device is device A, device B should be installed as shown below.



### Index

Symbols	Description of the Reports 5-2
%MAP 13-6	Description of the Screen 1-1
A	Displaying the Menu 2-1
ABI 5-1, 13-4, 13-5, 13-6, 13-7, 13-8	DMS 4-1, 4-
AC Power Supply Connector 1-8	Dual-Side Adhesive Tape 3-
Accessories 1-5	E
Adding a New Examination 11-23	Electrical scalpel1
AF	Electromagnetic Emissions1
AF Distance 5-19	Electromagnetic Immunity1
Al	EMC13, -1
Air Connectors	Entering Blood Vessel Length 5-1
Appendix	Entering Patient Information 4-1, 5-6, 5-8, 6-3, 7-1,
Attaching the Cuffs	5, 9-16, 11-3
Auto Extension 5-11	Entering Section Values 5-1
	Entering Segment Values 5-2
В	Entering the BP Examination Result in the Patient
Battery Level Message 2-4	Information 8-1
Battery Life 2-2	Equalizing the Potential2
Beat Table Report 5-33	Equipment Control Settings 11-
Blood Pressure and Pulse Wave Examination 6-1, 7-	Equipotential Grounding 2-
1	Ethernet Hub 2-1
Blood Pressure and Pulse Wave Examination Screen	Examination Result Display 5-13, 8-
1-11	Examination Sequence Area 5-
Blood Pressure Balance	Example of Network Configuration 2-1
BMI 13-5	F
Brachial Blood Pressure Examinations 8-1	<del>-</del>
Bramwell-Hill Equation 13-2	File List
C	File Settings
Capturing Waveforms 5-23	File Transfers
Caution1	Formats 9- Function of This Device 1-
Cautions When Using the Battery 2-2	Function of this Device
CAVI 5-1, 13-2	Н
CAVI Check 5-7, 5-9, 5-11	Home Display 8-
CAVI Indicator 1-2, 5-6, 5-9, 5-11, 5-12, 5-23	How to View the Icons 1-1
CAVI Measurements 13-4	
Changing the Examination Order 11-22	i Button 1-11, 5
Changing the Examination Type 2-15	Initialization
Changing the Folder to Save the Data 9-17	Installation
Charge Lamp 2-3	Installation Location
Charging 2-3	Installing the Battery (Optional) 2-
Charging Time 2-3	
Cleaning and Disinfection 12-9	L
Communication History 9-18, 9-22	L
Communication Settings 11-15	L1
Connecting to the Network 2-21	L2
Consumable Parts 12-9	L2 Distance 5-1
Copying an Examination 11-24	L3
Copying Examination Data 9-14	L3 Distance 5-1
Correcting Patient Information 7-1	LAN Cable (Straight) 2-1
Cuff 3-2, 3-3	Limb Cushion
Cuff Pressure Display 5-3	Loading Examination Data 9-
D	M
Daily Inspection 12-1	Main Features 1-
Danger1	Main Specifications 13
Data Management System 1-3	Maintenance and Inspection 12-
Date and Time2-14	Measurement Items 5-1
Deleting an Examination	Measurement Sites 5-6, 5-1
Deleting Examination Data 9-12	Measurements
J	

#### **Chapter 13 Appendix**

Measuring Blood Pressure Messages and Countermeasures Methods for Saving Data	19
N	
Names of Parts and Their Functions Naming Folders Network Settings	9-15
0	
Optional Accessories Oscillometric Method	
P	
Patient A Report	11-9 1-8
PCG Microphone 2-10, 3-5, 5	
Periodic Inspection Peripheral Devices	
Potential Equalization Terminal	
Power Cable	
Precautions when Using the SD Card and USE	
Memory	
Printed Messages	
Printing of Interpretation	
Product Configuration	
Pulse Wave Examination Screen	5-3
Pulse Wave Time Measurement	
PWV	13-3
R	
Real Time CAVI Check	5-11
Recalculating the ABI/TBI	
Recording a Daily Report	
Recording Daily Reports	
Registering a Series Examination	
Remaining Battery Power	
Replacement Period Replacing the Clock Battery	
Restoring Deleted Data	
Result Display	
_	0 0
Section	2
SafetySafety Labels	
Safety Notations	
Saving and Initializing the Settings	11-26
Saving Examination Data	
SD Card	
Selecting the Examination to be Conducted on 11-23	
Series Examination	
Setting Sensitivity	5-19
Settings for Blood Pressure and Pulse Wave	44.47
Examinations Settings for Brachial Blood Pressure Examinat	
11-21	
Settings for External Printer Output  Settings of This Device	
Simple CAVI Measurement	
Slot for Additional Pulse Wave Unit	1-8
Stand	
Standard A Report (w/o BPB)	
Standard B Report	

Stiffness Parameter	13-2
Storing the Battery	2-2
Symbols on the Device	
Г	
tb	13-3
tba	13-3
TBI	
To Ensure Accurate Measurement	5-22
Toe Cover	3-6
Toe Cuffs	
Trend Report	5-30
Trend Result Display	6-6
Troubleshooting	14
Turning the Power ON and OFF	
J	
Using the Compare Waveforms Function	on 7-3
UT	
<i>I</i>	
Vascular Length	13-4
N	
Warning	-1
Waveform Display	
wavololili biopiay	0

# **Inspection List**

#### **Daily Inspection List**

Conduct inspections according to the Daily Inspection Procedure.

Management No.

Item		Ins	spection Item	Procedure a	Procedure and Criteria		Judgment	Remarks (Repair Needed)
Visual	Main Unit	1	Enclosure	No scratch, c	crack, deformat	on and rust	Pass / Fail	
Inspection (Visual		2	Labels and panels	No peeling o	r staining		Pass / Fail	
check)		3	Keys and Buttons	No damage			Pass / Fail	
	BPU-100	1	Enclosure	No scratch, o	crack, deformat	on and rust	Pass / Fail	
	(For toes)	2	Label and panel	No peeling o	r staining		Pass / Fail	
Accessories,	Accessories	1	Cuffs, Sensors	No scratch o	r damage		Pass / Fail	
Cables				Cables and h	noses are conn	ected properly.	Pass / Fail	
		2	Operation manual	Kept in a spe	cified location		Pass / Fail	
	Cables	1	Power supply cable	No scratch o	r damage		Pass / Fail	
			Connector cables	Cables and h	Cables and hoses are connected properly.		Pass / Fail	
Operation	Operation	1	Power	Display turns ON at power ON.			Pass / Fail	
		2	Display	No abnormal	No abnormality or flickering.			
				Verify that no screen.	Verify that no errors are displayed on the screen.			
		3	Icon display (At power on)	Verify that the status of the connected device is displayed correctly.			Pass / Fail	
		4	Keys and Buttons	Smooth operation.  Verify that the pressure value displayed at power on is within ±1 mmHg.  Verify that there are no abnormalities in the display.			Pass / Fail	
		5	0mmHg check				Pass / Fail	
		6	BPU-100 (For toes)				Pass / Fail	
		7	Clock	Verify that the present date/time is displayed in the Clock Setting window and is correct.			Pass / Fail	
Overall judgment			1				Pass / Fail	
Model Nar	ne	Va	Sera VS-2000 Series	Model		Serial number		1
Location						Date of Purchase		
Date of Ins	spection			Checked by		Approval		

<sup>•</sup> Copy this sheet for use.

#### **Periodic Inspection List**

Conduct inspections according to the Periodic Inspection Procedure. <u>Management No.</u>

Item			spection Item	Procedure and Criteria	Judgment	Remarks (Repair Needed)	
Visual	Main Unit	1	Enclosure	No scratch, crack, deformation and rust	Pass / Fail		
Inspection (Visual check)		2	Labels and panels	No peeling or staining	Pass / Fail		
		3	Keys and Buttons	No damage	Pass / Fail		
	BPU-100 (For toes)	1	Enclosure	No scratch, crack, deformation and rust	Pass / Fail		
	<u> </u>	2	Label and panel	No peeling or staining	Pass / Fail		
Accessories, Cables	Accessories	1	Cuffs, Sensors	No scratch or damage	Pass / Fail		
				Cables and hoses are connected properly.	Pass / Fail		
		2	Operation manual	Kept in a specified location	Pass / Fail		
	Cables	1	Power supply cable	No scratch or damage	Pass / Fail		
			Connector cables	Cables and hoses are connected properly.	Pass / Fail		
Operation	Operation	1	Power	Display turns ON at power ON.	Pass / Fail		
		2	Display	No abnormality or flickering.	Pass / Fail		
				Verify that no errors are displayed on the screen.	at no errors are displayed on the Pass / Fail		
		3	Icon display (At power on)	Verify that the status of the connected device is displayed correctly.	Pass / Fail		
		4	Keys and Buttons	Smooth operation.	Pass / Fail		
		5	0mmHg check	Verify that the pressure value displayed at power on is within ±1 mmHg.	Pass / Fail		
		6	BPU-100 (For toes)	Verify that there are no abnormalities in the display.	Pass / Fail		
		7	Clock	Verify that the present date/time is displayed in the Clock Setting window and is correct.	Pass / Fail		
Mainte- nance	Status	1	Backup battery	The battery should have a voltage of 2.5V or greater.	Pass / Fail		
	Touch panel	1	Touch Panel Test	Each key should have good tactile response.	Pass / Fail		
	Display	1	Screen Test	All dots should appear. The colors must be correct.	Pass / Fail		
	Display Unit	1	Key/LED Test	The symbol of the touched key should be highlighted. The LED should light and go out correctly.	Pass / Fail		
	Sound	1	Sound Test	The sound of the touched button should be heard. The volume should change.	Pass / Fail		

Item		Ins	spection Item	1	Procedure and Criteria	Judgmen	t			Remarks (Repair Needed)		
Perfor-	Blood				1	R-B	L-B	R-A	L-A			
mance	pressure	1 Zero point			Within 0±1mmHg	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		2	Pressure accuracy	50 mmHg	Within ±3mmHg	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
				100 mmHg	Within ±3mmHg	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
				150 mmHg	Within ±3mmHg	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
				250 mmHg	Within ±3mmHg	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
				300 mmHg	Within ±3mmHg	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		3	Maximum pr	essure	320±10mmHg	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		4 Inflation time			20 sec. or less	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		5	Air leakage		6mmHg/min or less	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		6	Quick exhau	st	10 sec. or less	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		7	100% open		100 to 250mmHg/sec.	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		8	75% open		20 to 190mmHg/sec.	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
		9	Time Limit		130 ±10sec., 8±1sec. at high speed	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail			
	BPU-				•	Right toe	Right toe Left toe					
	100 (Toes)	1	Zero point		Within 0±1mmHg	Pass/Fail		Pass/Fail				
	(1000)	2	Pressure accuracy	50 mmHg	Within ±3mmHg	Pass/Fail		Pass/Fail				
				100 mmHg	Within ±3mmHg	Pass/Fail		Pass/Fail				
						150 mmHg	Within ±3mmHg	Pass/Fail		Pass/Fail		
				250 mmHg	Within ±3mmHg	Pass/Fail		Pass/Fail				
						300 mmHg	Within ±3mmHg	Pass/Fail		Pass/Fail		
		3	Maximum pr	essure	Should be 320±10mmHg.	Pass/Fail		Pass/Fail				
		4	Inflation time		20 sec. or less	Pass/Fail		Pass/Fail				
		5	Air leakage		6mmHg/min or less	Pass/Fail		Pass/Fail				
		6	Quick exhau	st	10 sec. or less	Pass/Fail		Pass/Fail				
		7	100% open		100 to 250mmHg/sec	Pass/Fail		Pass/Fail				
		8	75% open		20 to 190mmHg/sec	Pass/Fail		Pass/Fail				
		9	Time Limit		130 ±10sec., 8±1sec. at high speed:	Pass/Fail		Pass/Fail				

Item		Ins	spection Item		Procedure and Criteria	Judgment	Remarks (Repair Needed)														
Perfor- mance	PCG	1	PCG filter characteristics (PWV)	165Hz	70% or above	Pass/Fail															
				PCG filter characteristics	280Hz	70% or above	Pass/Fail														
	2		_	30Hz	50% or above	Pass/Fail															
																	L characteristics	50Hz	70% or above	Pass/Fail	
				80Hz	90% or above	Pass/Fail															

#### **Chapter 13 Appendix**

Item		Inspection Item		Procedure and Criteria	Judgment	Remarks (Repair Needed)	
Others	Others	1	Power	The power should turn ON and OFF when operating on AC and battery.	Pass/Fail		
		2	Power supply cable	Should maintain continuity.	Pass/Fail		

Item	Inspection Item			Procedure and Measurement Value Judgment Criteria			Judgment	Remarks (Repair Needed)	
Electrical Safety	1	Earth leakage current	Normal condition	5mA or le	ess		mA	Pass/Fail	
			Single fault condition	10mA or			mA	Pass/Fail	
	2	Touch current	Normal condition	0.1mA oi			mA	Pass/Fail	
			Single fault condition	0.5mA oi	less		mA	Pass/Fail	
	3	Patient leakage current (from patient connection to earth) (DC)	Normal condition	0.01mA	or less	mA		Pass/Fail	
			Single fault condition	0.05mA	or less		mA	Pass/Fail	
		Patient leakage current (from patient connection to earth) (AC)	Normal condition	0.01mA	or less		mA	Pass/Fail	
			Single fault condition	0.05mA	or less		mA	Pass/Fail	
	4	Patient leakage current (external voltage)	Single fault condition	0.05mA	or less		mA	Pass/Fail	
	5	Patient auxiliary current (DC)	Normal condition	0.01mA or less			mA	Pass/Fail	
			Single fault condition	0.05mA or less			mA	Pass/Fail	
		Patient auxiliary current (AC)	Normal condition	0.01mA or less			mA	Pass/Fail	
			Single fault condition	0.05mA or less			mA	Pass/Fail	
Cleaning	Cleaning			Should be clean.			Pass/Fail		
Final judgment								Pass/Fail	
Model Name	VaSera VS-2000 Series			Model			Serial number		
Location							Date of Purchase		
Date of Inspection				Checked by			Approval		

<sup>•</sup> Copy this sheet for use.



# FUKUDA DENSHI CO.,LTD. 3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan Tel: +81-3-5684-1455 Fax: +81-3-3814-1222 http://www.fukuda.com Printed in Japan 4L011364D 202001