SONOST-2000

User' Manual

Model: SONOST-2000

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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OsteoSys

http://www.osteosys.com
OsteoSys Co., Ltd.

SONOST-2000

User' Manual

CAUTION !
You must be well acquainted with this manual before using it. This manual should be placed where the user could read it whenever necessary.

Manufacturer and EC Authorized Representative Information

♣ **Manufacturer: OsteoSys Co., Ltd.**
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Tel: +82 26124 5900 Fax：+82 26124 5958

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Thank you for purchasing SONOST-2000 Ultrasound Bone Densitometer. To ensure safe operation and long-term performance stability, it is essential that you fully understand the functions and operating, and maintenance instructions by reading this manual before operating the equipment.

Particular attention must be paid to all warnings, cautions and notes incorporated herein.

Incorrect operation, or failure of the user to maintain the equipment relieves the manufacturer or his agent of the system's noncompliance with specifications or of responsibility for any damage or injury.

The following conventions are used throughout the manual to denote information of special emphasis.

WARNING !
"Warning" is used to indicate the presence of a hazard that can cause severe personal injury, death or substantial property damage if the warning is ignored.

CAUTION !
"Caution" is used to indicate the presence of hazard that will or can minor personal injury and property damage if the caution is ignored.

NOTE !
"Note" is used to notify the user of installation, operation or maintenance information that is important but not hazard related.

The symbols which are shown in this manual or SONOST-2000

NOTE !
Check the symbol before using the SONOST-2000.

	The noticed information should be concerned with explanation in this manual.
	The noticed information when the device is operated.
	The reference page or section.
	Applied Part Type B.
	I and O on power switch represent ON and OFF, respectively.
	The Attention symbol that marks warning and important information in the user's manual.
	The conductor provides a connection between equipment and the potential equalization bus-bar of the electrical installation.
	The date of manufacture.
	This symbol indicates "caution" for the hot surface.

	User Manual **User of the equipment to check how to check the product.**
	Communication Status **It indicates communication status of the equipment.**

The protecting device from external electromagnetic wave

This equipment can be affected from external electromagnetic waves which is related to precision and operation. When you are using this equipment, we strongly recommend that you refrain from using other devices to protect the euipment from electromagnetic waves.

Disposal of device

This symbol which is printed on the user manual or box means you do not regret as just waste from home. If you would like to dispose this device, you should send to a place for reuse of electrical device. It will help environment and human's healthy life. Reuse of this equipment contributes to saving natural resources. If you want to more detail things about disposal of device, ask to manufacturer or distributor.

Cautionary Notes

(1) Environmental Condition

The environmental conditions below must be met to prevent possible performance loss or malfunction of some components which can be caused by sudden and excessive environmental changes, which may then lead to shortening of life cycle of the equipment, the environmental conditions below must be met.

- Working Temperature: Within 10 ~ 40℃

- Working Humidity: Within 20~ 80%
- Air Pressure: Within 800 ~ 1060hPa

(2) Pre-operation Checklist

- Check the switch connection and polarity indicator status to ensure the device works properly.
- Check all cable connections for correct and safe operation of the device.
- Double-check the areas that make direct contact with the patient.
- Check the device and the patient for any abnormal conditions.
- If any uncertainty is witnessed with the device or the patient, take appropriate actions including suspending device operation under safe conditions.

(3) Cautions for Storage

- Do not apply excessive force when connecting or disconnecting cables.
- Auxiliary devices should be maintained clean, and in working conditions.
- Devices should be positioned in their proper positions, so as not to interfere with operator's or patient's movement.

(4) Cautions regarding specialist prescription

This device is designed for the diagnosis of osteoporosis and therefore should only be used for diagnosis performed by doctors. Its use must be prescribed and managed by specialists.

(5) Biocompatibility - Ultrasound gel, etc.

To prevent damage to skin and cells, use commercially available ultrasound gels that have passed ISO 10993-5(Cytoxicity), ISO 10993-10(Skin sensitization), and ISO 10993-23(Skin irritation) tests.

Guidance and manufacturer′s declaration

Guidance and manufacturer′s declaration – Clinical information			
No	Contents	A or N/A	Description
1	Intended Use	A	The SONOST-2000 system supports the doctor's activities for the diagnosis of osteoporosis and the prevention of future fractures to the patient through the measured BMD results. The measurement sites is calcaneus/ Heel bone.
2	Name of Disease or Condition	A	Osteoporosis, Osteopenia, Normal healthy bone
3	Indications	A	All women 65 years and older and men 70 years and older for asymptomatic screening. Women younger than 65 years old at risk for osteoporosis: • Estrogen deficiency • History of maternal hip fracture before the age of 50 • Low body mass (less than 57.6kg/127 pounds) • History of amenorrhea more than 1 year before the age of 42. Women younger than 65 years old or men younger than 70 years old with the following risk factors: Current cigarette smoker • Loss of height • Thoracic Kyphosis Individuals at any age with bone mass osteopenia or fragility fractures on imaging studies. Individuals 50 years and older who developed wrist, hip, spine, or proximal humerus fractures with minimal or no trauma, excluding pathologic fractures. People of any age who developed one or more insufficiency fractures. Individuals receiving (or expected to receive) glucocorticoid therapy equivalent to > or = to 5 mg of prednisone or equivalent per day for > or = 3 months. Individuals beginning or receiving long-term therapy with medications known to affect BMD adversely: • Anticonvulsants • Androgen deprivation therapy • Aromatase inhibitor therapy • Chronic heparin Individuals with an endocrine disorder known to affect BMD adversely • Hyperparathyroidism • Hyperthyroidism • Cushing's syndrome Hypogonadal men 18 years and older and men with surgically or

| | | | chemotherapeutically induced castration
Individuals with medical conditions that could alter BMD:
 • Chronic renal failure
 • Rheumatoid arthritis and other inflammatory arthritis
 • Eating disorders, including anorexia nervosa and bulimia
 • Organ transplantation
 • Prolonged immobilization
 • Conditions associated with secondary osteoporosis, such as gastrointestinal malabsorption or malnutrition, sprue, osteomalacia, vitamin D deficiency, endometriosis, acromegaly, chronic alcoholism or established cirrhosis, and multiple myeloma
 • Individuals who have had a gastric bypass for obesity
Individuals considering pharmacologic therapy for osteoporosis.
Individuals monitored for:
 • Assess the effectiveness of osteoporosis drug therapy
 • Follow-up medical conditions associated with abnormal BMD.
Children or adolescents with medical conditions associated with abnormal BMD including but not limited to:
 • Individuals receiving (or expected to receive) glucocorticoid therapy for more than 3 months
 • Individuals receiving radiation or chemotherapy for malignancies
 • Individuals with an endocrine disorder known to adversely affect BMD (e.g., hyperparathyroidism, hyperthyroidism, growth hormone deficiency or Cushing's syndrome)
 • Individuals with bone dysplasias known to have excessive fracture risk (osteogenesis imperfecta, osteopetrosis) or high bone density
 • Individuals with medical conditions that could change BMD, for example:
  1. Chronic renal failure
  2. Rheumatoid arthritis and other inflammatory arthritides
  3. Eating disorders, including anorexia nervosa and bulimia
  4. Organ transplantation
  5. Prolonged immobilization
  6. Conditions associated with secondary osteoporosis, such as; gastrointestinal malabsorption, sprue, inflammatory bowel disease, malnKKutrition, osteomalacia, vitamin D deficiency, acromegaly, cirrhosis, HIV infection, prolonged exposure to fluorides
QUS may be indicated in the diagnosis, staging, and follow-up of individuals with conditions that result in pathologically increased BMD, such as osteopetrosis or prolonged exposure to fluoride. |
| 4 | Contraindications | A | There are no absolute contraindications to performing QUS.
Possibly of limited value or require modification of the technique or rescheduling of the examination in some situations, including:
- Try to measure the other side of heel if patient had some surgery like implant which is placed by calcaneus bone. |

5	Target group	User	A	Education: Bachelor or higher. Physician or trained medical personnel located in hospitals and clinics Knowledge: Educated or trained for BMD (Bone Mineral Density) under the relevant majors such as orthopedics, internal medicine, obstetrics & gynecology, etc. Language Understanding: English/Korean. Experience: More than 2 years of work experience in hospital as a doctor, a sonographer and etc. (Patient does not operate the BMD device)
		Patient	A	a) Ages: 20 – 100 years old b) The patient condition: Osteopenia, Osteoporosis or Normal healthy bone
6	Disposable device		A	SONOST-2000 has silicon balloon on the probe part which can keep the water inside of balloon as media for path of ultrasound wave more efficiently.
7	Invasive device		N/A	Not intended to be invasive
8	Implantable device		N/A	Not intended to be implantable
9	Duration of use or contact with body		A	BMD measurement is performed once a year or once every two years (it's depending on the patient's situation). Contact with body: SONOST-2000: there are contact point between calcaneus part and balloon as below image. SONOST 3000: It also same as SONOST-2000

			Need to apply ultrasound gel in between skin and probe in order to get proper contact for path of ultrasound waves.
10	Contacting with body fluids or others	N/A	There are no contact between anybody fluid of human during the examination process.
11	Measurement site	A	Correct position for measurement for calcaneus bone on heel as below That point is just below area of ankle and then apply ultrasound gel with enough amount just like below instruction. (need to apply to both side of feet) *According to the article Selection of the optimal skeletal site for fracture risk prediction, the most significant relationships of BMC to fracture risk were observed for the Oscalcis (Richard D. Wasinch, Philip D. Ross, Lance K. Heilbrun and John M. Vogel) *According to the article Diagnostic value of calcaneal quantitative ultrasound in the evaluation of osteoporosis in middle-aged and elderly patients, the study assessed calcaneal QUS and DXA in senile osteoporosis diagnosis performance, as osteoporosis screening not only has good specific degrees, and with the lumbar spine and proximal femur DXA has good correlation, in screening for large-scale people play the role of more convenient, economic, Therefore, calcaneal QUS can be recommended as a pre-screening tool to determine whether DXA screening should be performed and timely treatment should be performed I patients with pre-existing risk of osteoporosis and patients with mild osteoporosis to reduce the risk of fracture. (Changzhou Li, Jifeng Sun, Li Yu)

Guidance and manufacturer's declaration – electromagnetic emissions		
The model SONOST-2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the model SONOST-2000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model SONOST-2000 uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The model SONOST-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.
Harmonic emissions IEC 61000-3-2	Class A	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) < 5 % U_T (> 95 % dip in U_T) for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the model SONOST-2000 requires continued operation during power interruptions, it is recommended that the model SONOST-2000 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note : U_T is the a.c. mains voltage prior to application of the test level.

Safety consideration about parts of device and compartment

For use safely, you must use parts of device which are supplied or approved from OsteoSys.

NOTE !

If you use parts of device which are not approved from OsteoSys, we do not guarantee safety to user. Moreover, it become dangerous and prone to producing errors and wrong results to users or patients. In this case, the user has the sole responsibility.

1) Protect device from external electromagnetic wave (IEC60601-1, 6.8.2 Requirement) 2) Disposal of device (IEC60601-1, 6.8.2 Requirement) 3) Safety considerations about part of device and compartment (IEC60601-1,6.8.2 Requirement)

The exchange and usage period of consumable goods

Name	Part number	The period for exchange	The method of exchange expandable products
Foot supporter	FOOT SUPPORTER 0 : A3MM-013	10 years	You should request the manufacturer or distributor to have these replaced.
	FOOT SUPPORTER 1 : A3MM-014	10 years	
	FOOT SUPPORTER 2 : A3MR-005	10 years	
QC Phantom	A3MR-009	10 years	
Probe	A3ES-001	10 years	
Power Cable	250VAC 10A	10 years	

Table of Contents

1   Introduction

1.1 General product information

Osteoporosis is one of the serious diseases. This device is a bone densitometer which estimates bone mineral density of the calcaneus by using ultrasound

It takes about 15 seconds to measure the density and to display the shape of ultrasonic waves by computing simulation on the monitor.

To ensure safe operation and long-term performance stability, it is essential that you fully understand the functions, operating and maintenance instructions by reading this manual before operating the equipment.

※ Features and Cautions !

- This device is an ultrasound bone densitometer which has ±0.2(T-score) precision error.

- The equipment must be operated only by, or under supervision of a qualified person.

- When you give appropriate commands in SONOST-2000 software, ultrasonic waves are generated. The generated ultrasonic waves pass through the patient's calcaneus and the electric signals are treated by SONOST-2000 algorithm.

- SONOST-2000 measures speed of sound(SOS) and the frequency-dependent attenuation of the sound waves(BUA), and combines them to form a clinical measure called Bone Quality Index(BQI)

- All operators must understand the potential hazards in the use of medical electronic devices. They must be able to recognize hazards and protect themselves and others from injury.

- The system should be placed at least 20cm from any wall. However the USB cable length should not be longer than 3.0m.

- Never remove any system covers.

- In case of changing the PC or the printer for other products, check them according to IEC/EN60601-1-1.

- Unplug the power cord before you move or clean the device and after using SONOST-2000

- For installation and operation of this equipment, national regulations shall be considered.

2   Configuration of SONOST-2000

2.1 Composition of SONOST-2000

2.1.1 Shape and componennts of SONOST-2000
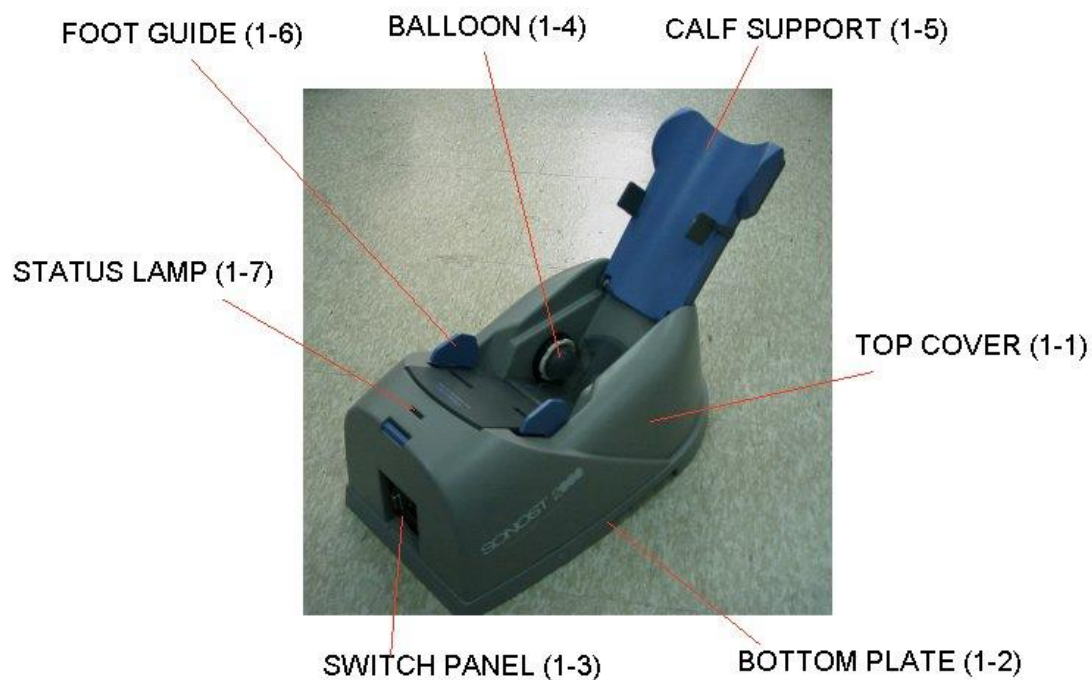
NO	Name	Function
1-1	TOP COVER	Protection for internal circuit
1-2	BOTTOM PLATE	Fixation for device position & top cover
1-3	SWITCH PANEL	Switch, Power cord, RS-232 Connector
1-4	BALLOON	Connect between heel and ultrasound probe
1-5	CALF SUPPORT	Leg fixation for diagnosing
1-6	FOOT GUIDE	Foot fixation for diagnosing
1-7	STATUS LAMP	Present status of the Device

OBJ NOTE !

**Check the location and contents of the label attached to the product.
Check the location of the product power switch.**

2.1.2 Keyboard
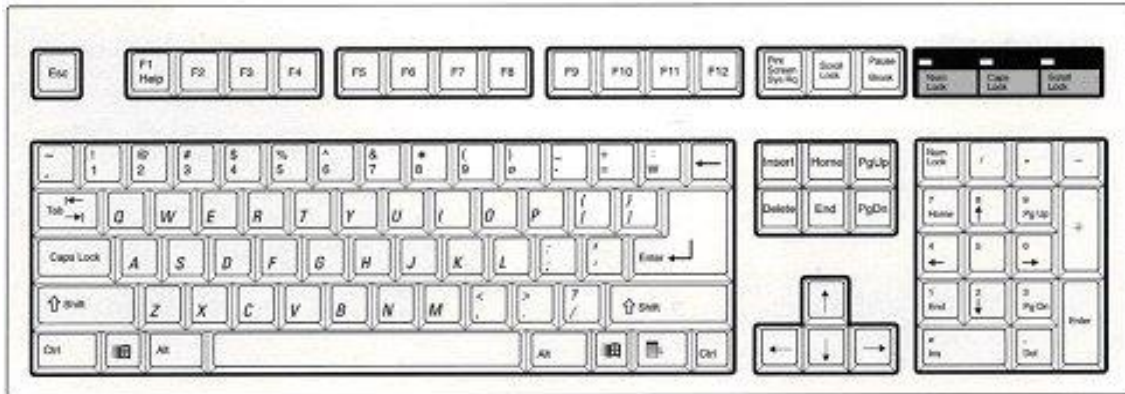
Keyboard

Activate SONOST-2000 by pressing a key on the keyboard according to the instructions shown on the monitor.

The manual shows keys required to activate SONOST-2000 are as shown below.

Enter key

Space key
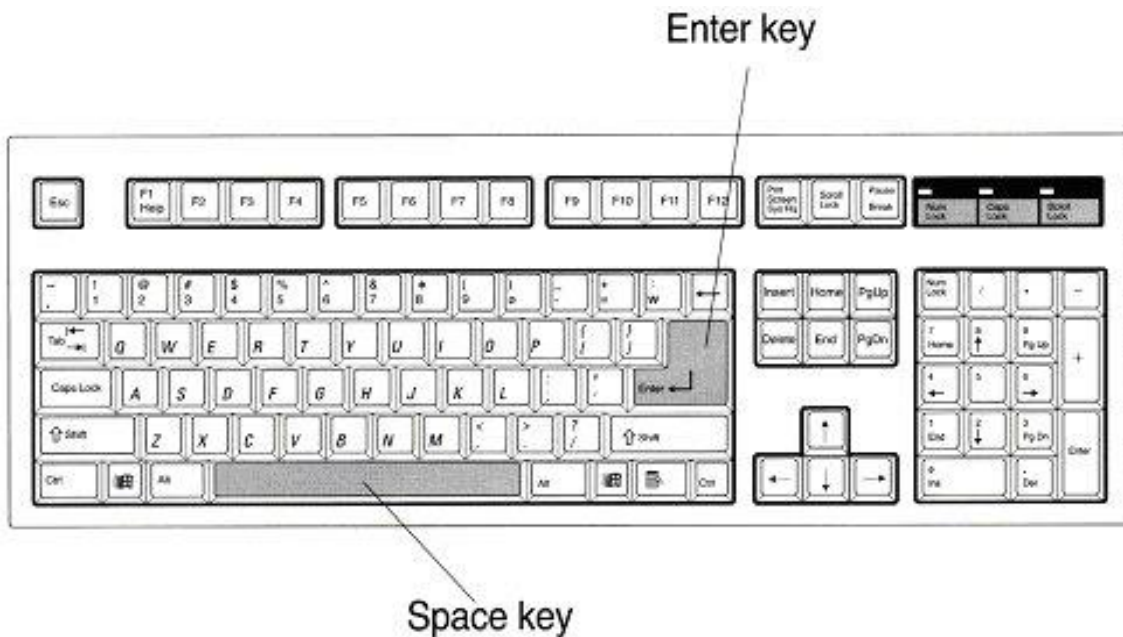
▣NOTE !
Use accessories which are defined in the user's manual. **Check the following accessories before installing the system**

2.1.3 Accessories list

Check the following accessories before installing the system.
If they are not in good condition, contact OsteoSys or local authorized dealer for service.

Names of Products	Number	Uses
User's Manual	1	Make sure to keep it at a designated place so that users can read it anytime they need to.
Foot Positioner	3	Use them in accordance with patients' foot size.
QC Phantom	1	It is used to calibrate the system. Keep it in the specified place and protect it against deformation by heat or pressure.
Injector	1	It helps to take water into the balloon easily.
Guide	5	It helps to take water into the balloon easily.
USB Cable	1	It is used to connect the computer to the main body of SONOST-2000.
Power Cable	1	It is used to connect to the source of electric power with the main body of SONOST-2000 Make sure to connect it with a grounded electric outlet. If you want to change a power cord, then you must use a power cord stronger than Appendix A of KS C IEC60227-1:2007.
Program CD	1	It is used to install the software program on the computer.(The program is factory installed on the computer before being delivered).

2.1.4 Articles list

Check the following accessories before installing the system.
If they are not in good condition, contact ~~to~~ OsteoSys or local authorized dealer for ~~this~~ service.

4.2.2 Stockpiles and Replacement of Articles

Names of Products	Number	Uses
Balloon / Housing	Balloon : 8 Housing : 1	It connects a foot with the ultrasound probes and helps ultrasound to progress between them. Keep the spare balloons and housings in a cool place.
Alcohol	1 box	It removes some material which prevents ultrasound from progressing.

2.2 Installation of SONOST-2000

NOTE !
Since SONOST-2000 is made up of sensitive components, you should install the product according to instructions below.

NOTE !

Do not install and keep SONOST-2000 at excessively high or low temperatures.

Proper temperature: 18~27 ℃

Do not install the system in the place with polluted air and high humidity and do not expose the machine to direct ray sunlight. It is advised to use SONOST-2000 in the place equipped with air conditioning or heating.

Proper humidity: 20~80%

Do not share the power outlet with other products using an extension cord.

Do not install or keep SONOST-2000 in a place where the machine can be rocked or shaken. Make sure to place the system parallel to the floor.
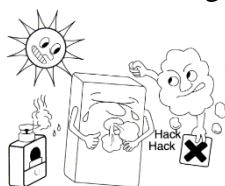
Install SONOST-2000 at a place where it is free from water or chemicals.
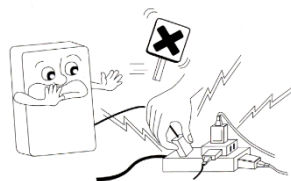
Do not use the system near a device that generates strong magnetic fields.
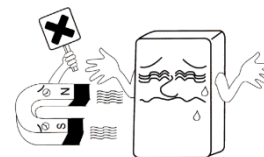
Do not cover ventilation of the system or place it near or against a wall. If the temperatures of the inside of the system rise too high, it can be a cause of the fire.

100-240V is usable. When SONOST-2000 is taken out of a warehouse, insulating transformers should be set to 100-240V. Since sudden power outage can remove all data saved in the system, you should install SONOST-2000 at a place where power supply is stable.
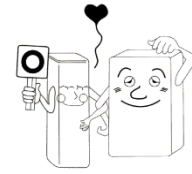
2.3 Before Turning on Power

(1) Connection of power &USB Cable (with the device)

Plug in the cable.

Plug into the connector.
When you disconnect the any cable from the main body of SONOST-2000, do not hold the cable, instead hold the connector. Otherwise the cable can break.

(2) Connection of power cable (with the oulet)
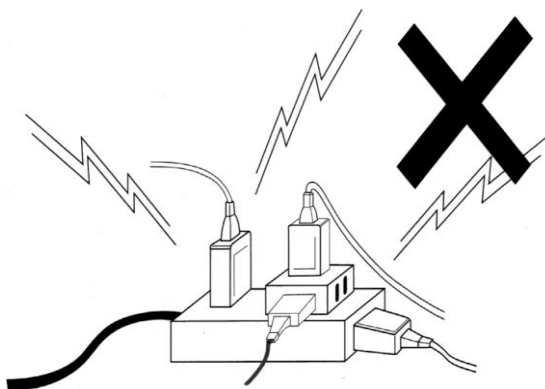
Avoid sharing the outlet.

CAUTION !

(3)   Adjust the balloons in the device

4.2.2   Stockpile   and Replacement of Articles

> ➢ Make sure that the covering of cable is not damaged to prevent electric shock or short circuit.
> ➢ If you find any damage or any sign of potential damage, immediately contact a local dealer.
> ➢ Put the Power cord into only one plug.
> ➢ Make sure not to share a power outlet in order to prevent SONOST-2000 from being affected.
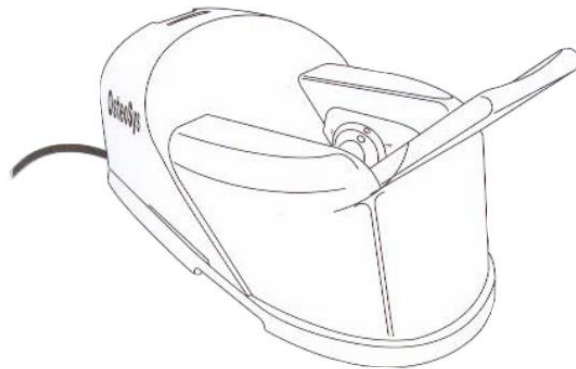
3   Using SONOST-2000

3.1 Using H/W

3.1.1 Applying the Balloon to the Measuring Device

Clean the surface of the probe with an alcohol pad.

┌─────────────────────────────┐
│ ⚠ **NOTE !** │
├─────────────────────────────┤
│ **To remove debris from the** │
│ **probe, clean the surface of** │
│ **the probe with an alcohol pad** │
│ **before use.** │
└─────────────────────────────┘

Attach the balloon to the probe holder.

Adjust the balloon housing to the probe holder.

Fill water into the balloon using an injector until it is full (65~70cc)..

Close it with the stopper.

Tap the balloon to remove bubbles inside of the balloon.

3.1.2 Using the QC phantom

3.2.2.8   Daily Test of SONOST-2000

Insert the standard block positioner.

Apply gel on ~~the~~ both sides of the QC Phantom.

Put the QC Phantom between the balloons and press the phantom until the phantom touches the bottom.

Attach the QC phantom to the ankle of the foot supporter 1.

3.1.3 Patient Measurement procedure

Put the foot positioner in accordance with a patient's foot size

- Ex) Using the #1foot positioner

- Ex) Using the #2 foot positioner

If you use the #2 foot positioner,
Make sure you place it on top of   #1 foot positioner.

System Setup Complete

Clean ~~the~~ both sides of the patient's heel with an alcohol pad.

Apply plenty of gel on both sides of patient's heel.

Insert patient's foot

Let a patient move his foot up and down for the balloons to be covered with ultrasound gel sufficiently.

CompleteComplete and ready for a measurement.

CompleteComplete and ready for a measurement.

Start a measurement after adhering patient's calf to the calf supporter.

3.1.4 Disposing water

Dispose water inside the device.

▶ Replacement period : 1 ~ 3(week)
▶ If there is air in the balloons, fill up water promptly. Otherwise it causes an error when you measure patients' BMD.

3.1.5 Where and how much apply to the patient's heel

Before measuring, use alcohol to rub patient's heel : protection for removing air bubbles surface of patient's skin and other infections.
Apply plenty of ultrasound gel to both sides of patient's heel

Good

Not good
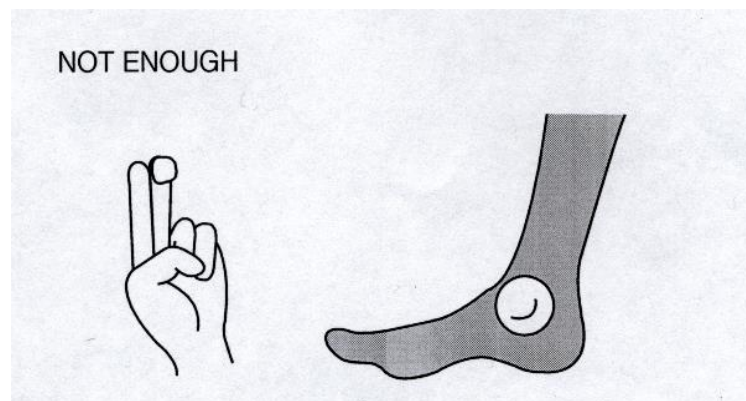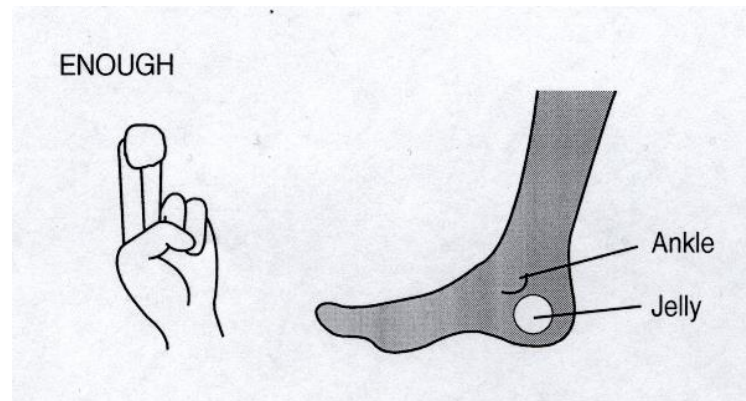
CAUTION !
To prevent damage to skin and cells, the gel used with Sonost-2000 must be commercially available ultrasound gels that have passed ISO 10993-5(Cytoxicity), ISO 10993-10(Skin sensitization) and ISO 10993-23(Skin irritation) tests. Do not forget to apply the gel before measuring.

3.1.6 Correct position for patient's foot & body

Adhere a heel to the measuring device closely as shown below.
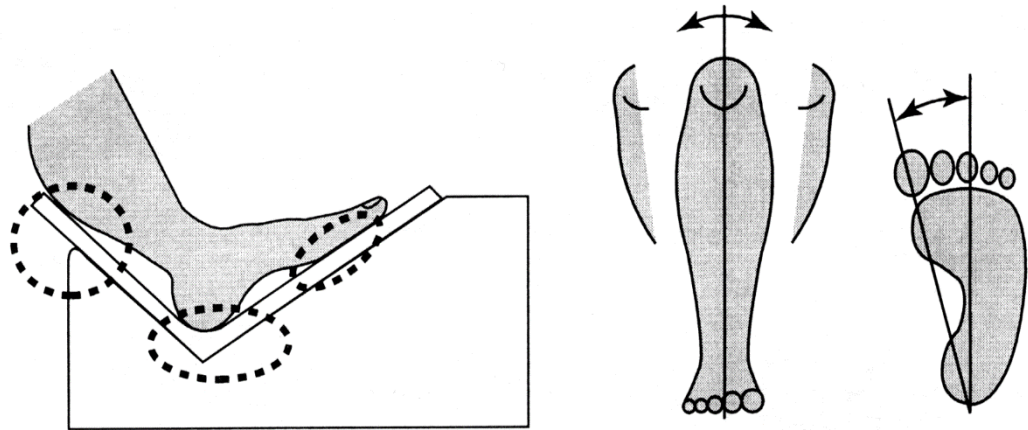
Make sure measuring device and body should be one line as shown below.
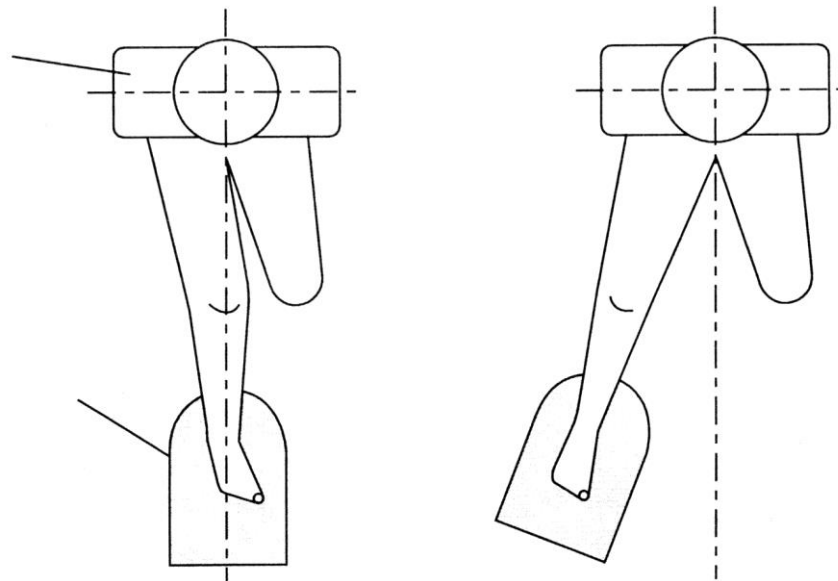
GOOD   NO GOOD

3.1.7 Seection of the foot supporter

Put the foot supporter according to the below guide.
The section is arranged for each size of the foot.

If the foot of patient is belongs to
* Section 1: use only foot supporter 1.
* Section 2 under: use foot supporter 1, 2 and P together.
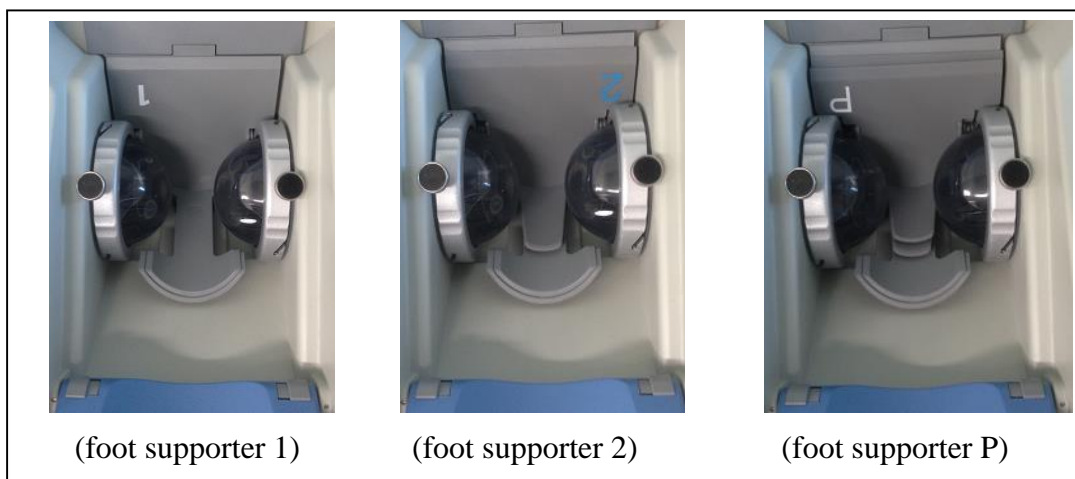
(foot supporter 1)   (foot supporter 2)   (foot supporter P)

3.1.8　Shutting down processing

Turning off the main switch of the system

[OBJ]**NOTE !**
Push the power switch to "0" to power off the machine.

3.2 Using S/W

3.2.1 Progress table of program
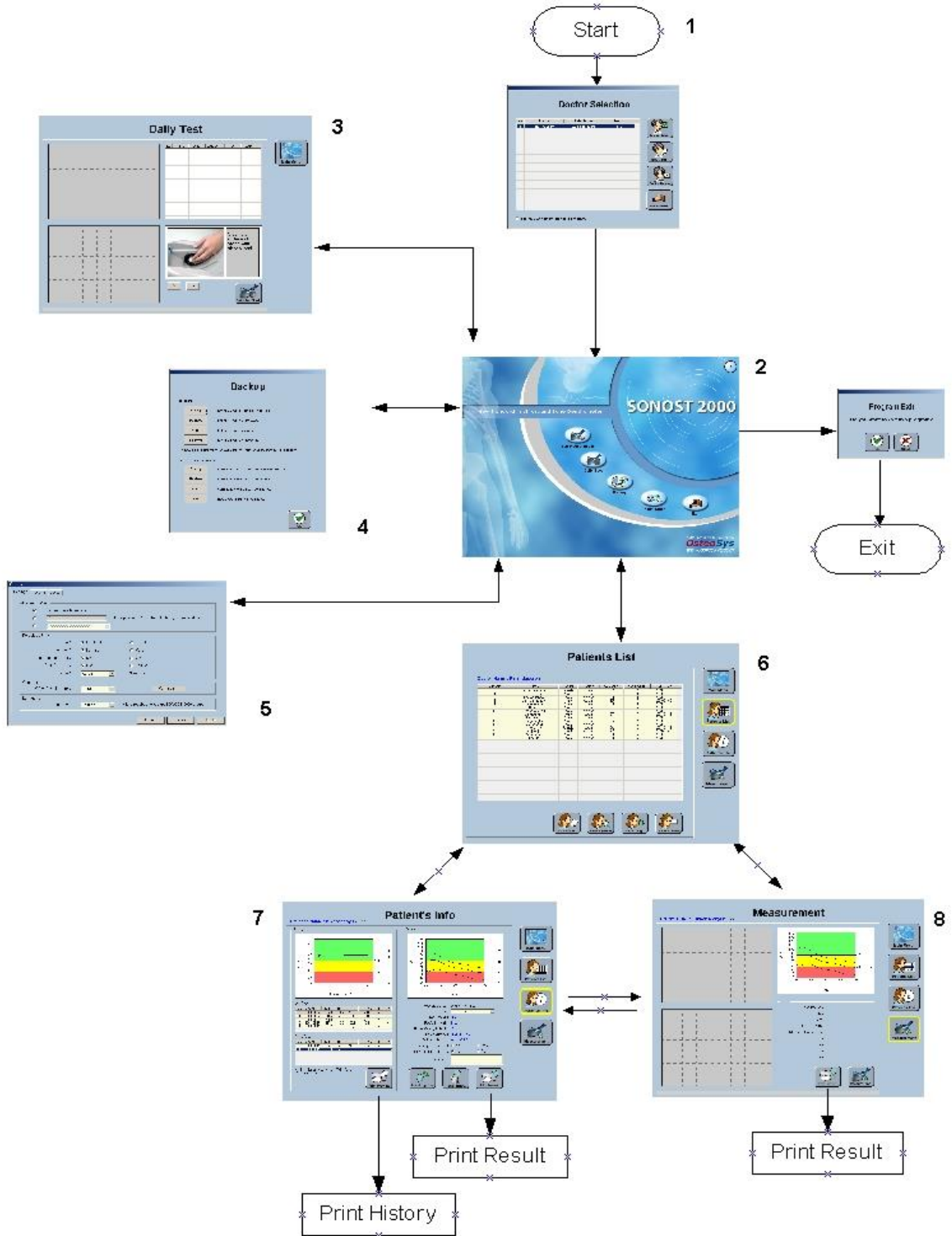
3.2.2 Using program

3.2.2.1 Setup program

(1) Execute the Setup.exe file for installation
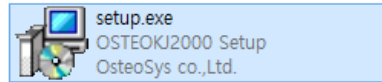
(2) Click [Next]
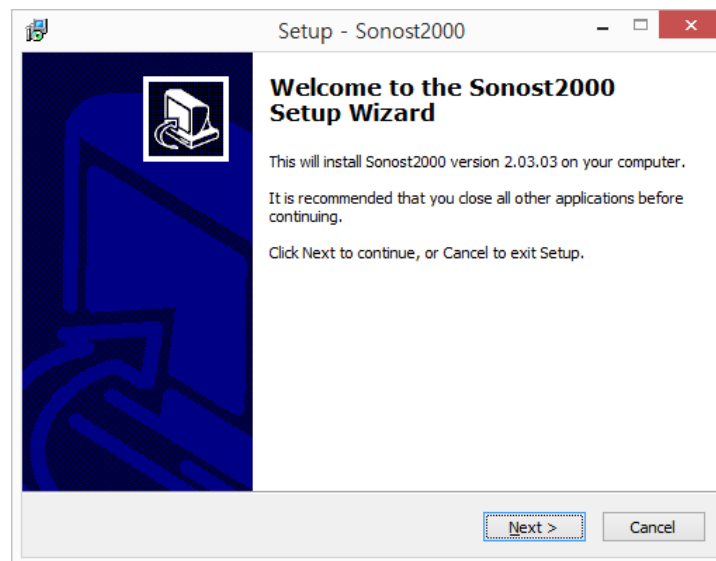
(3) Click [Next]
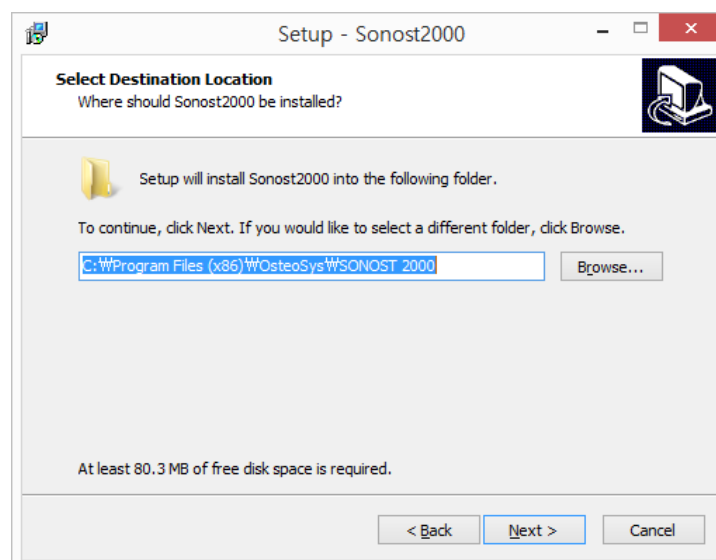
(4) Click [Next]
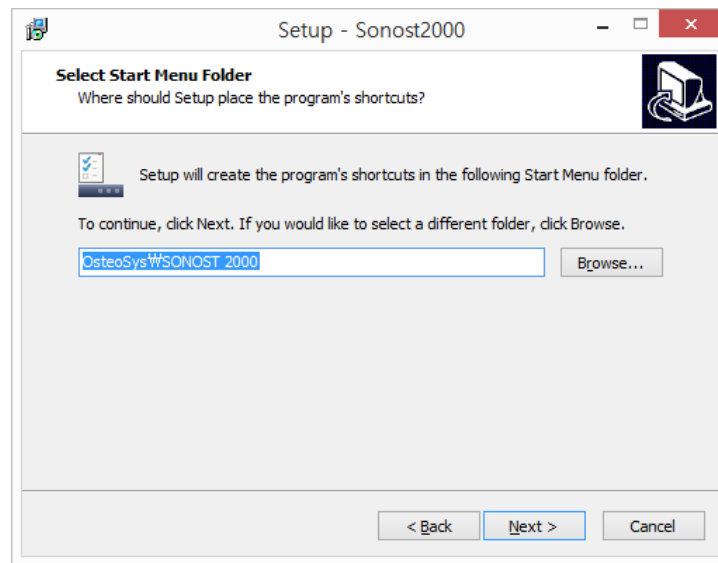
(5) Click [Next]
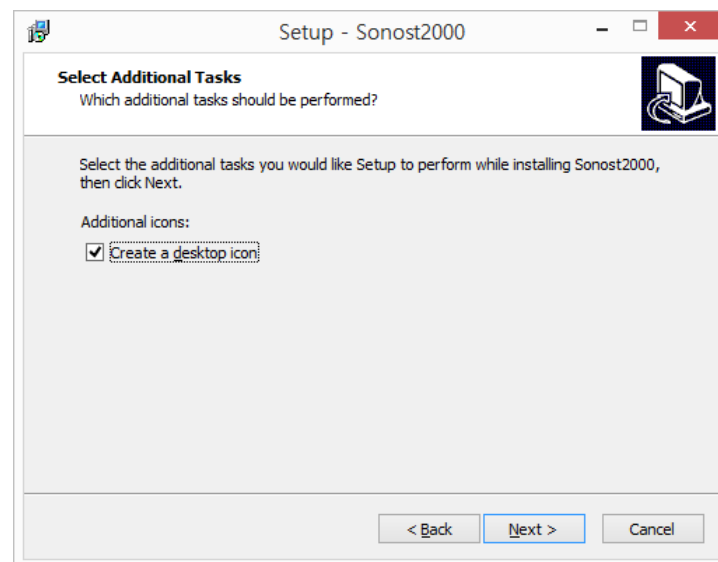
(6) Click [Next]
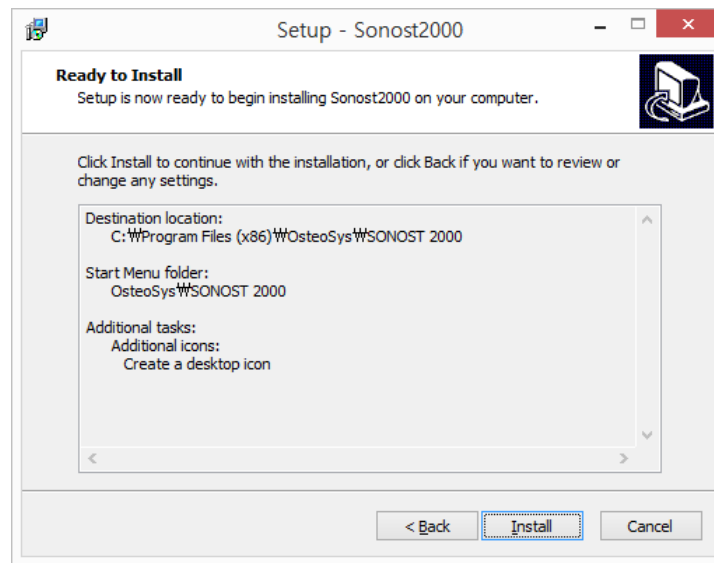
(7) Click [Finish], Program installation is finished
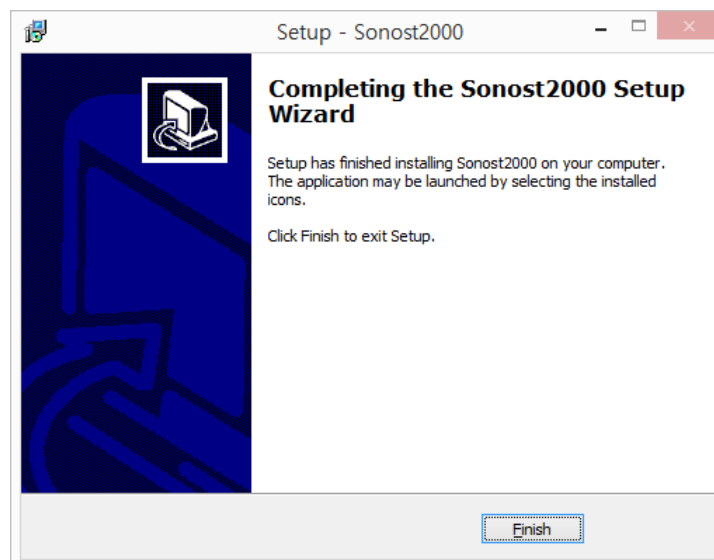
3.2.2.2 Setup USB Driver

※ The following is the instruction for Windows XP driver

(1) Connect the USB cable from PC to SONOST-2000, Hardware Wizard will start.

(2) Select [Install from a list or specific location(Advanced)] and Click [Next]

(3) Select [Include the location in the search] and Click [Browse].

(4) Select the folder that contains the driver files and Click [Next]
' My computer > C > Program Files > OsteoSys > SONOST-

2000 > USB Driver > WinXP'
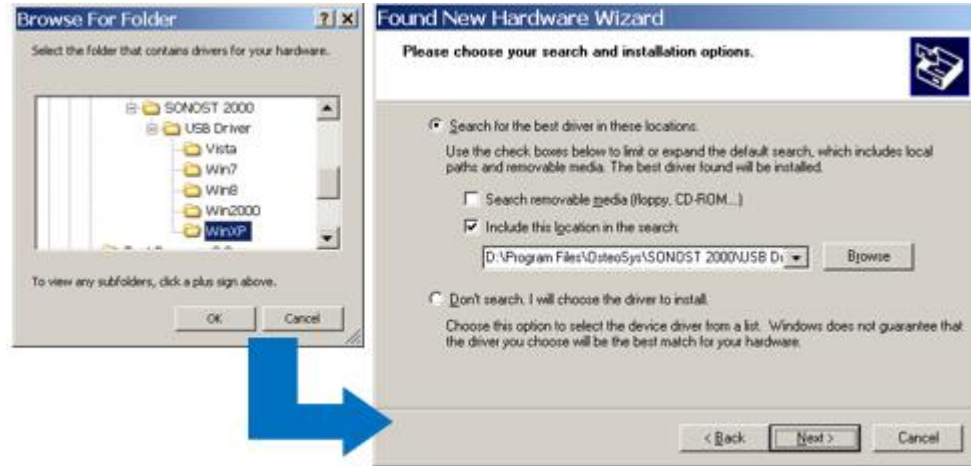
(5) Select [SONOST-2000+XP] and Click [Next]
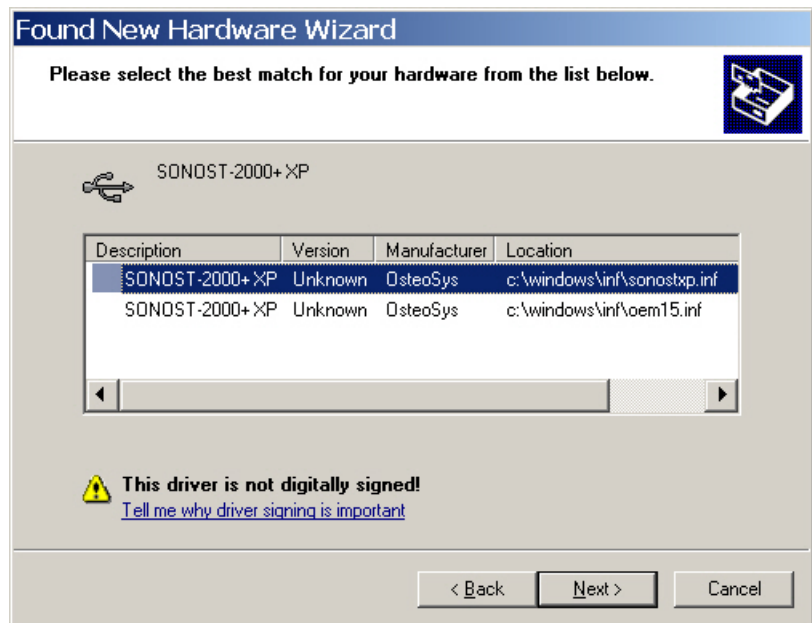
(6) Click [Continue Anyway]

(7) Click [Browse]

(8) Go to the folder indicated below, select a SonostXP.sys
    file and click [OK].

' My computer > C > Program Files > OsteoSys > SONOST-
2000 > USB Driver > WinXP '
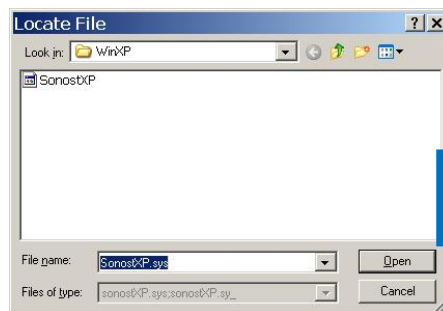
(9) Click [Finish]
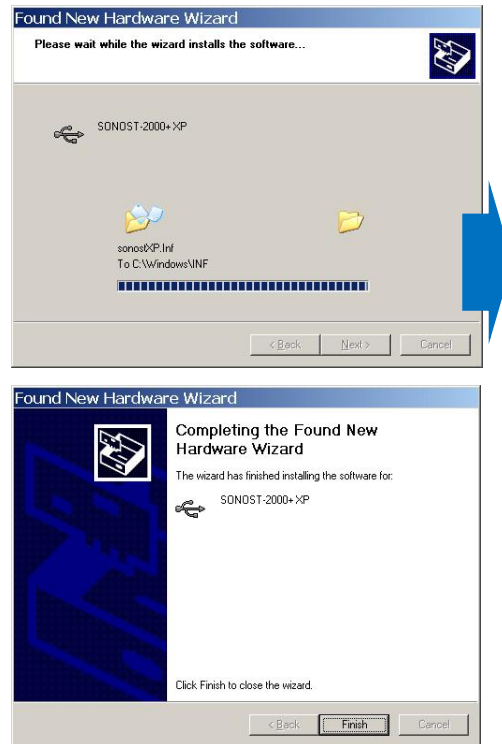
(10)   You must check if [SONOST-2000+XP] appears under
Universal serial bus controller. (Exclamation mark[!]
must be removed)
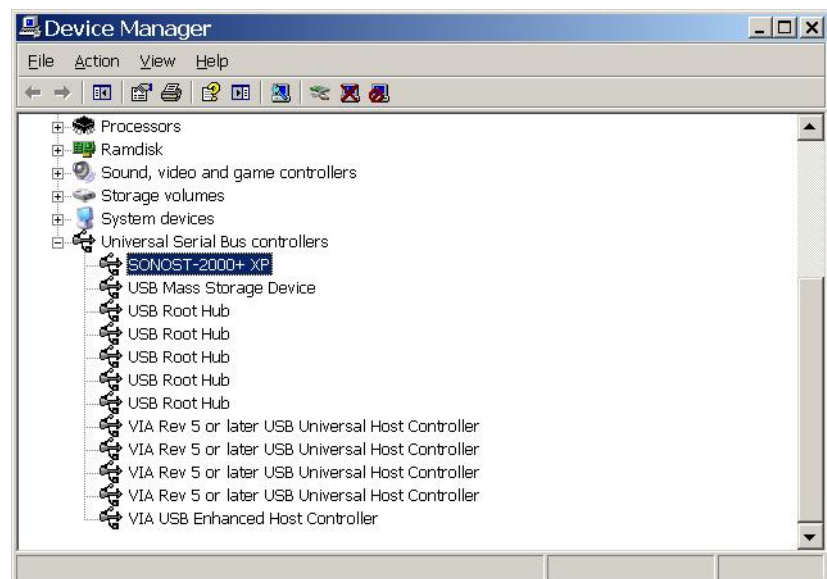
※ **For Windows 7 and Windows 10, the driver is installed automatically during Install.**

※ **If not installed properly, you can refer to the instructions below.**

※ **The following is the instruction for Windows 7 driver**

How to install the SONOST-2000 driver for Windows 10 in next chapter.

※ **The following is the instruction for Windows 10 driver**

(1) Insert the SONOST-2000 driver CD

(2) Go to the folder in which the SONOST-2000 program is installed.

32bit OS : C:\Program Files\OsteoSys\SONOST-2000\USB Driver

64bit OS : C:\Program Files (x86)\OsteoSys\SONOST-2000\USB Driver

(3) Go to the OS folder and double click file below.

32bit OS : \Win7+\x86\sono2K_x86.exe

64bit OS : \Win7+\x64\Sono2K_x64.exe
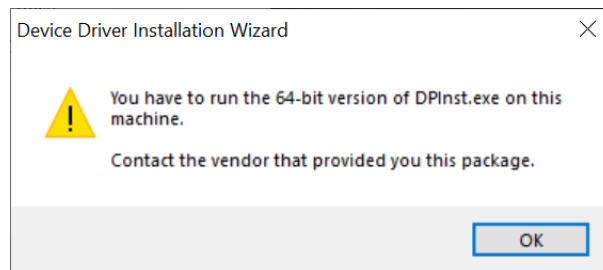
If you are using a different executable file of the OS version, an alert windows appears.

(4) Click [Next].

42
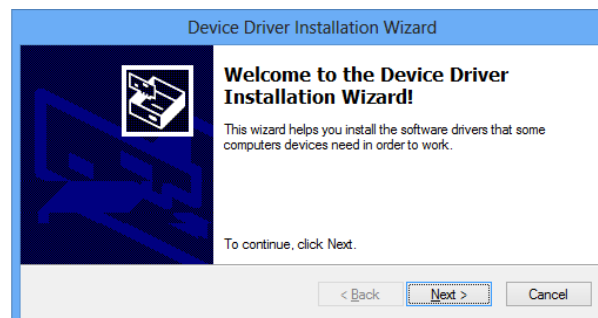
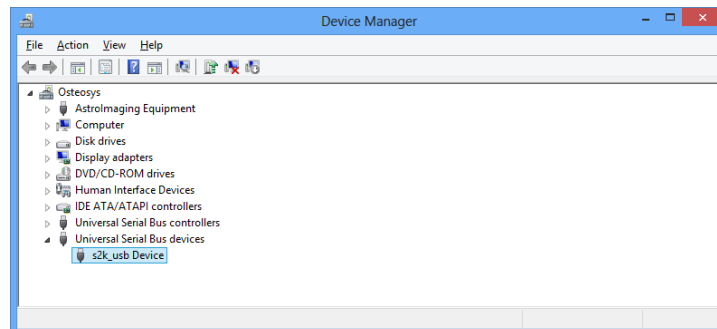(5) Click [Finish] and installation is complete.
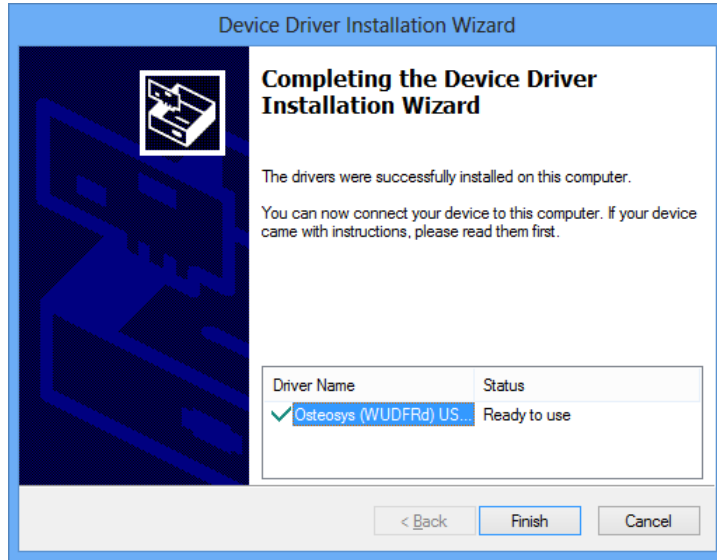
(6) Connect the USB cable from PC to SONOST-2000.

(7) The drivers are installed automatically and the following window appears, click Close.

(8) You must check whether [s2k_usb Device] is shown under Universal Serial Bus devices. (Exclamation mark[!] should not appear)


(9) Driver installation is finished.

3.2.2.3 Execution of Program and Configuration of the Incipient Environment

CAUTION !
If you hear any strange noise from the screen, switch it off and contact ~~to~~ OsteoSys or your local authorized dealer.

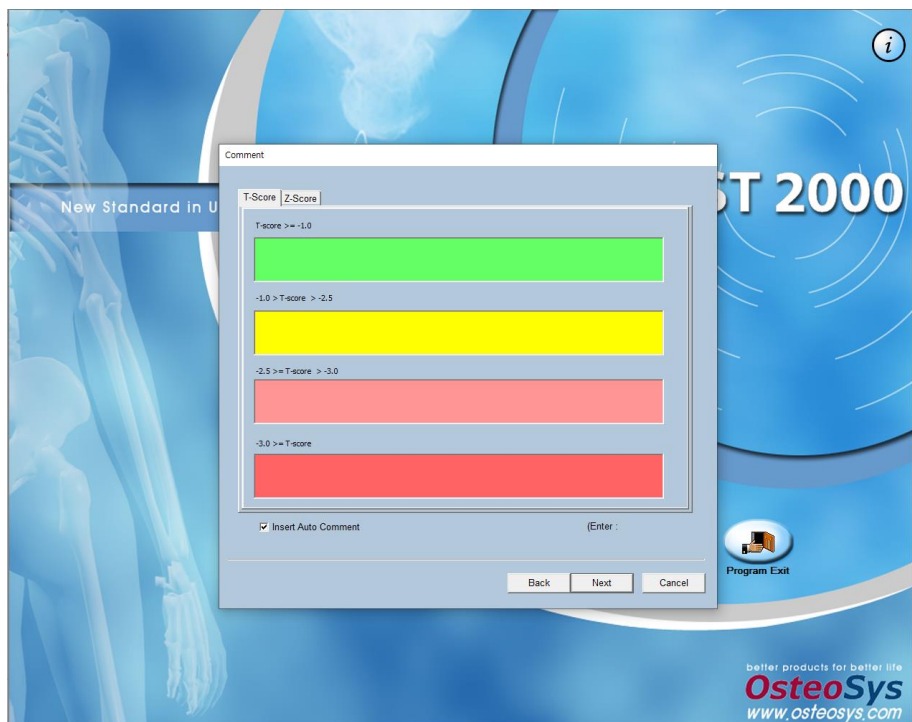| NOTE ! |
|---|
| When the device is powered on, the power LED turns green. |

(1) Turn on the power switch and power LED is turned on green light.

(2) 10 seconds after Daily Test that checks functions of the system and memory device, the program is automatically activated and you should configure the incipient environment.

(3) Settings :

- Patient ID Mask : Set the type of patients' ID.

- Default Settings : Set the default measurement site, Patients' gender, menopause state, ethnicity, the function "Print Preview", etc.

- Language : Select your own language to use the program.
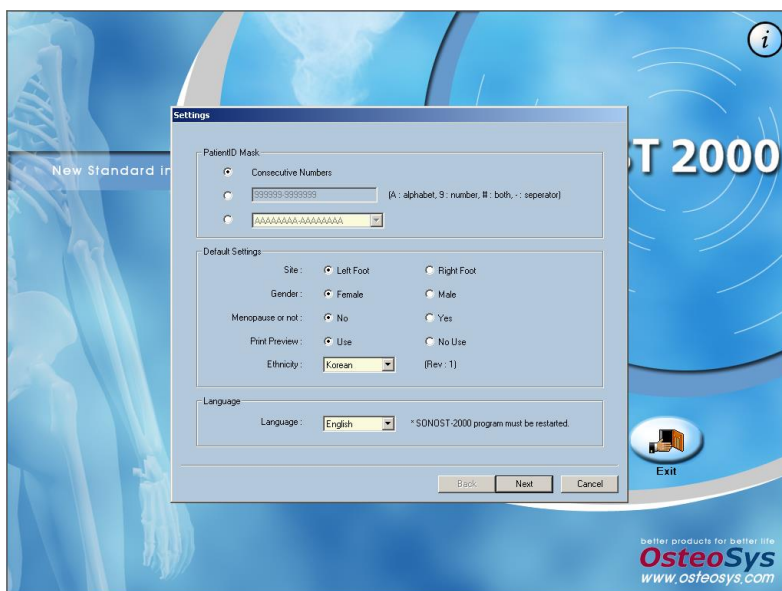
(4) Hospital : Set the name, address and phone number of your
hospital.
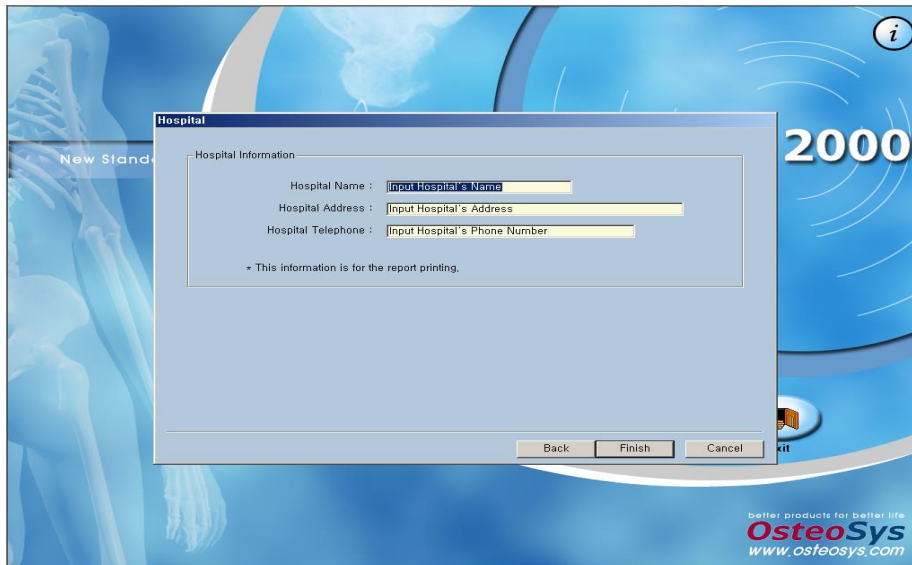
(5) Comment: Enter the comment information to be displayed
according to the T-score in the patient measurement result.

(6) DICOM

| [OBJ]**NOTE !** |
|---|
| Using DICOM, which related to storage/worklist server IP, Port, Modality should be requested to the server manager in the hospital. You must input server information exactly which can be only obtained from the hospital. |

- Storage Sever : Set the server information to transmit measurement results.
- Worklist Sever : Set the server information to retrieve patient information.

3.2.2.4 Registration & Deletion of Users

| [OBJ]**NOTE !** |
|---|
| Enter user information accurately. |

(1) As soon as you configure the user environment, the "Doctor Selection" window appears as shown below. If you are a registered user(doctor), click the "Doctor Select" button after selecting your name in the "Doctor Selection" window using the mouse. And then if you enter the password in the edit box "Password Enter" and click the "OK" button, you can log in the program.
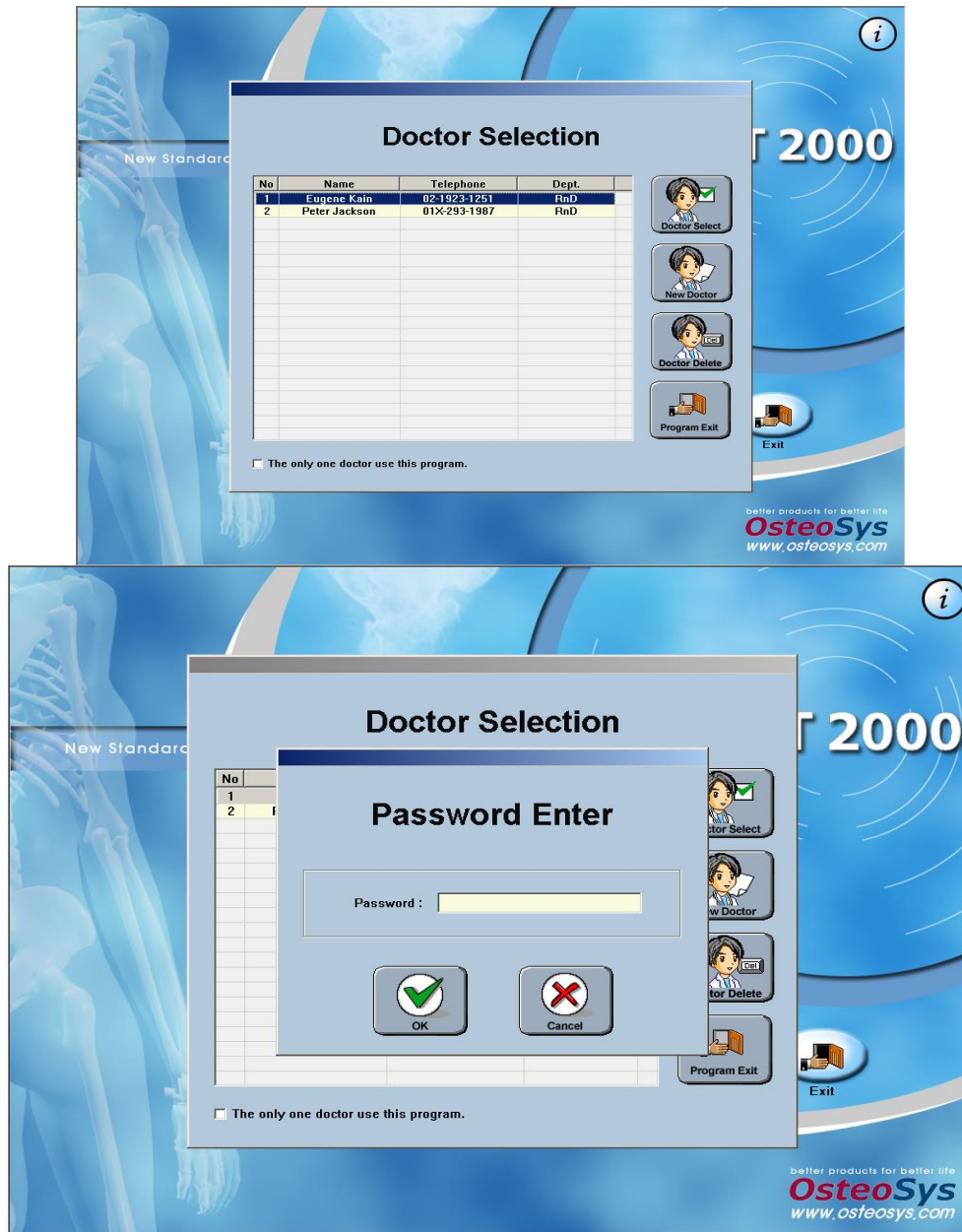
(2) If you are a new user(doctor), click the "New Doctor" button in the "Doctor Selection" window, and then the "New Doctor" window appears. If you enter your information (name, phone number, department and password) and click "OK" button, the registration process is complete. The log-in process is same as the description "(1)"
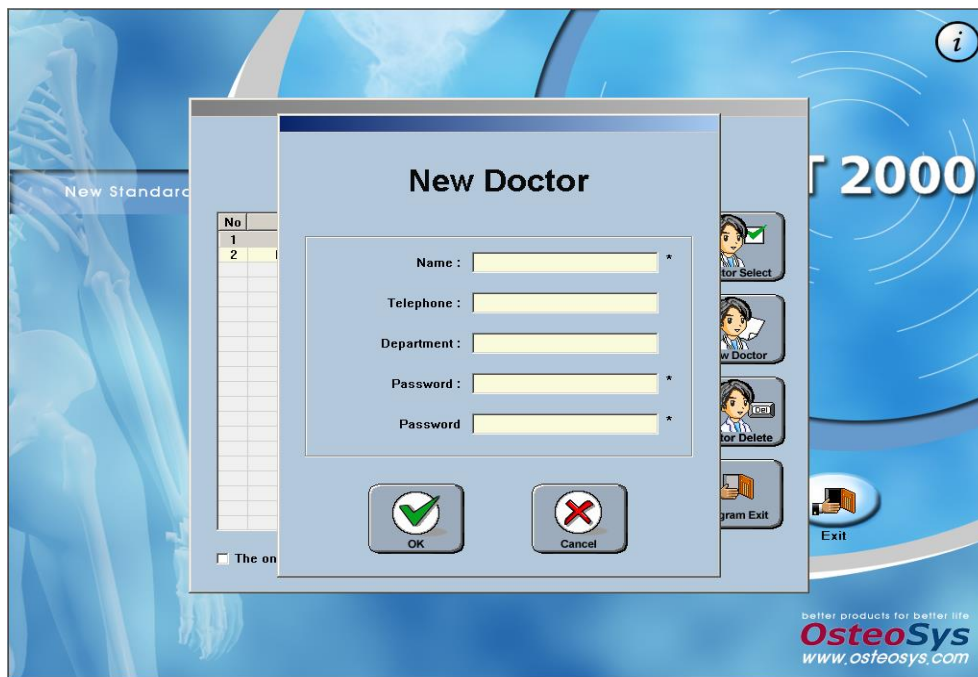
(3) If you want to delete registered users, select a user to delete and click "Doctor Delete" button of the "Doctor Selection" window. If there are two or more registered users, the message box "Patients Shifting" inquiring your intention appears as shown below.

- "OK" All registered users, except the user you selected to delete, are displayed on the left side of "OK" button. If you wish to back up the measurement data saved inside a user before you delete it from Doctor Selection, select another user to which you would like the data relocated. Click "OK' then the data transfers to the selected user's DB and the user of your choice for deletion will be removed from the Doctor Selection window.

- "NO" : If you click this button, the user you want to delete including the patients' data saved inside are deleted together.

- "Cancel" : If you click this button, you can cancel the deletion process.
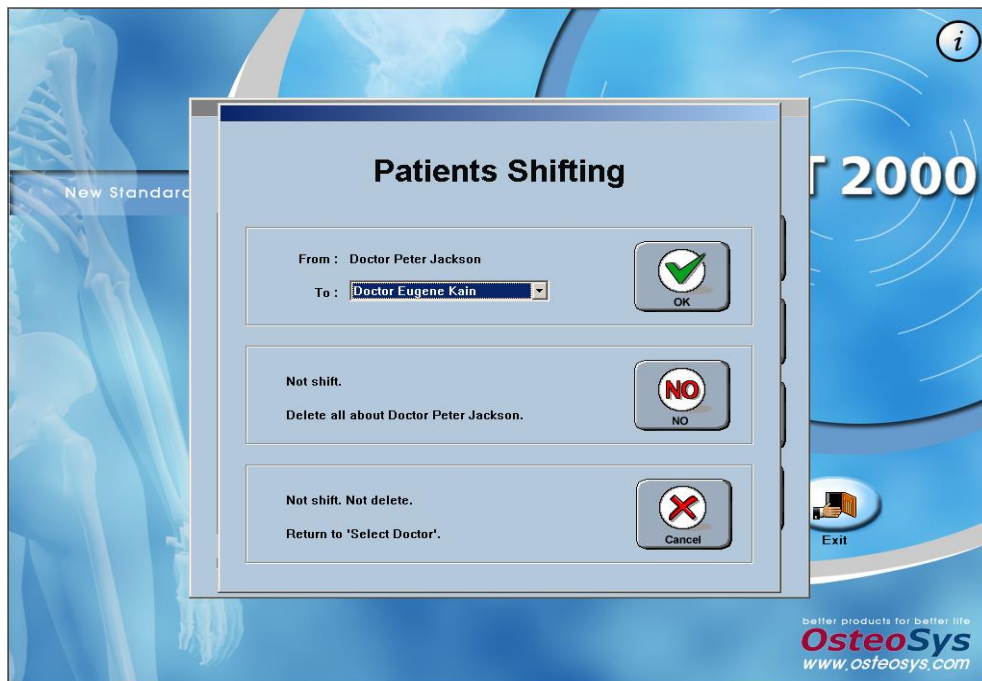
(4) If you click the "OK" or "NO" button, the message box "Surely delete doctor?" appears to reconfirm your intention to delete the selected doctor. If you click "OK" button the user information is deleted.
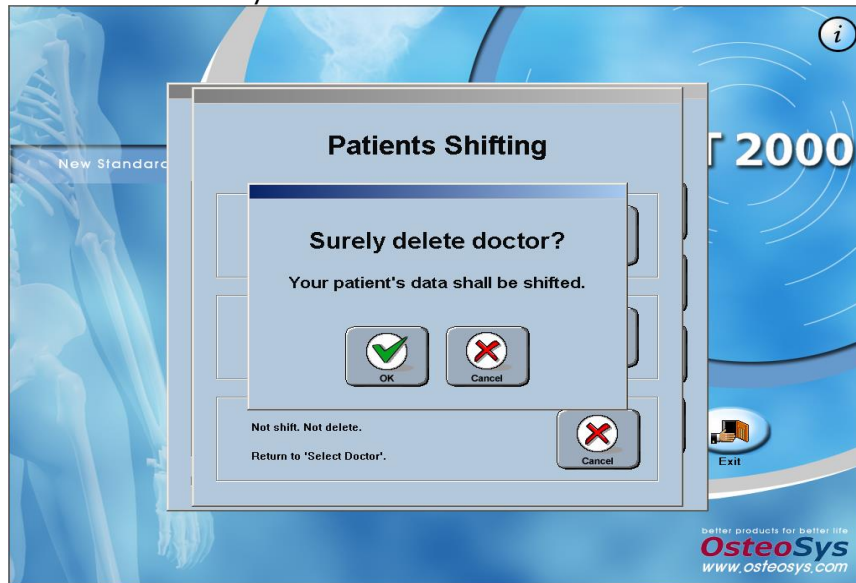
(5) If there is only one registered user when you click the "Doctor Delete" button in the "Doctor Selection" window, the message box "The Last Doctor" appears to ask for data backup. If you click "OK", the deletion process starts. If you are the only one user, check the checkbox "The only one doctor use this program"50on the bottom of the "Doctor Selection" window. Then you can use the system without entering password.
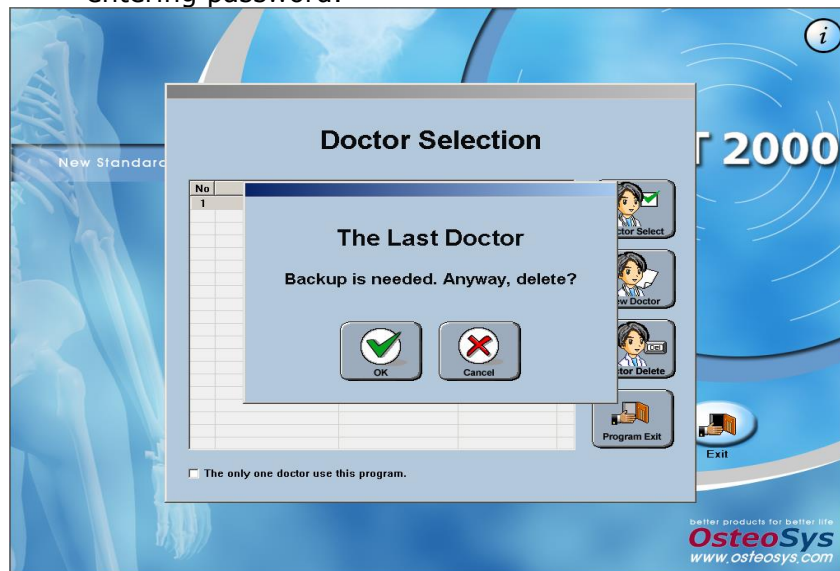
3.2.2.5 BQI Measurement

<Registration & Retrieval of Patients>

(1) If you click the "BQI Measurement" button in the default screen, you can move to the "Patient List" screen that contains all information of the registered patients.
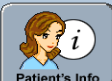

NOTE !
This "Patients List" screen displays only 200 patients for improving the system speed. If you need to find patients that are not on the list, use the "Patient Search" menu.

⬚NOTE !
Measurements may not be accurate if patient information is entered incorrectly.

(2) If you want to register new patients, click "New Patient" button on the bottom of the "Patient List" screen. Then on the "New Patient" window, you can enter information of a new patient and click "OK" to save. Then the patient is registered.
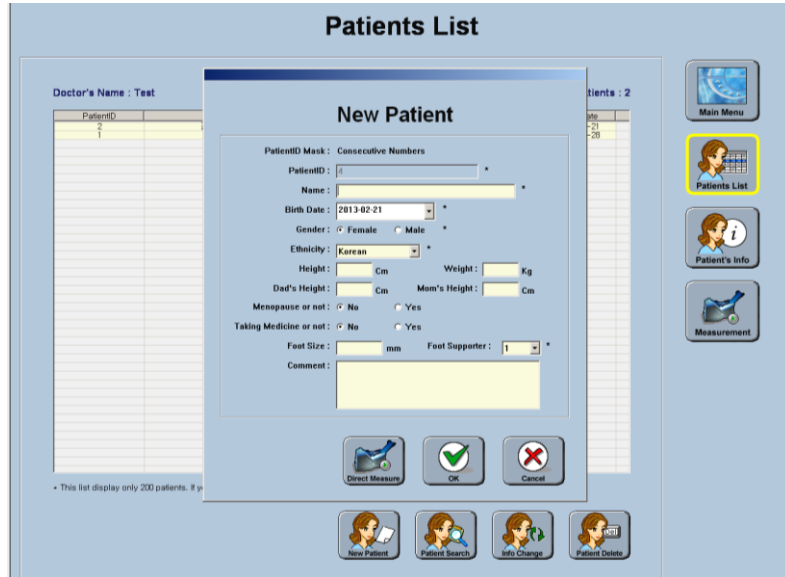
(3) If you want to retrieve registered patients, click "Patient Search" button, and then "Patient Search" window will ask you to fill in search keys (name, ID, gender and year of month, then the result appears on the screen.

<Worklist Usage and Searching Patient>
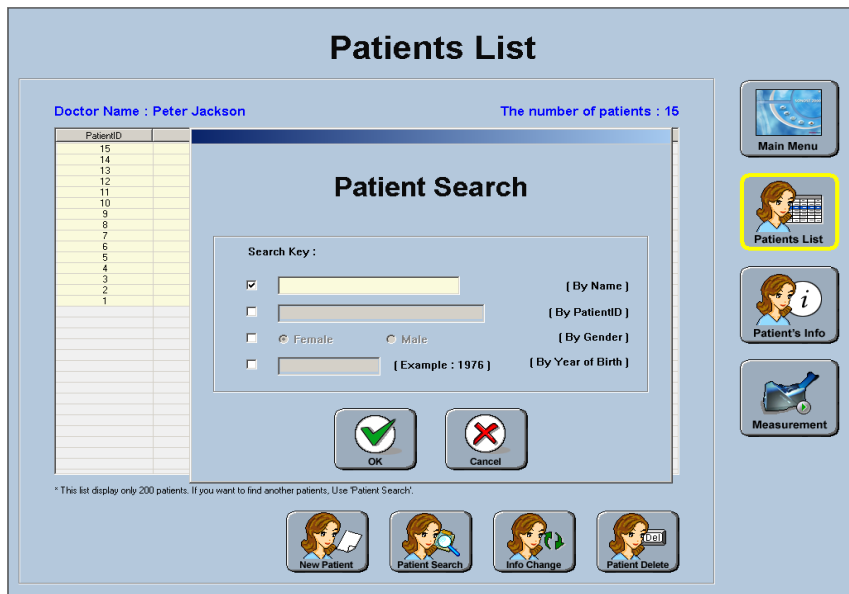
(1) If you press the "Worklist" button to use Worklist, the screen is converted while the patient registration, patient information change, and patient deletion buttons are deactivated.

(2) Click "Search", enter the search date (based on the registered date) and click the OK button.

(3) If the Worklist is set normally, the registered patient list appears as shown on the screen.
- For Worklist-related settings, you can set Worklist Server in DICOM Settings in the settings window of the initial screen.
- If importing Worklist repeatedly fails, contact the PACS management company for the information.

<Measurement of patients>
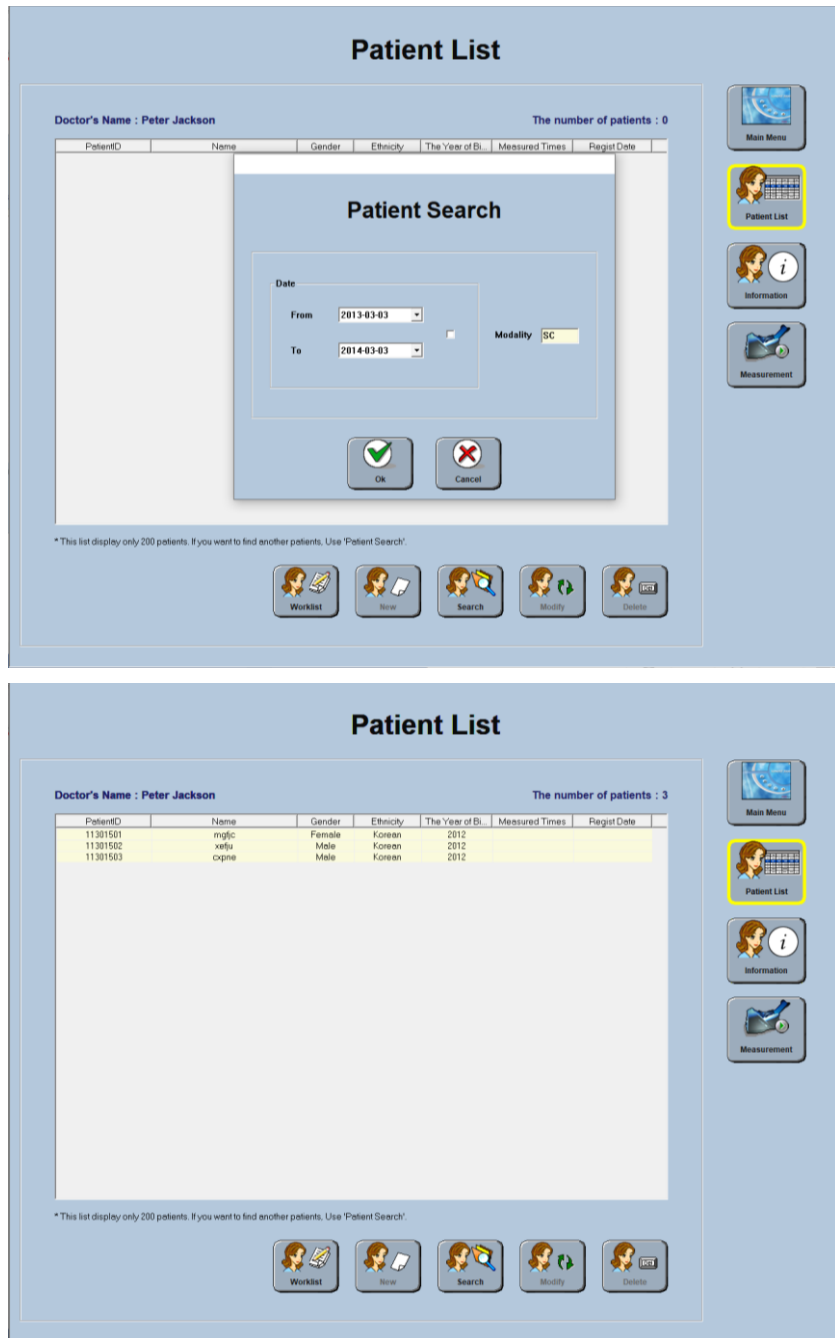
(1) If you want to measure BQI, select a desired patient from "Patients List", Click "Measurement" on the right side of the screen. Then the "Measurement" screen appears as shown below.
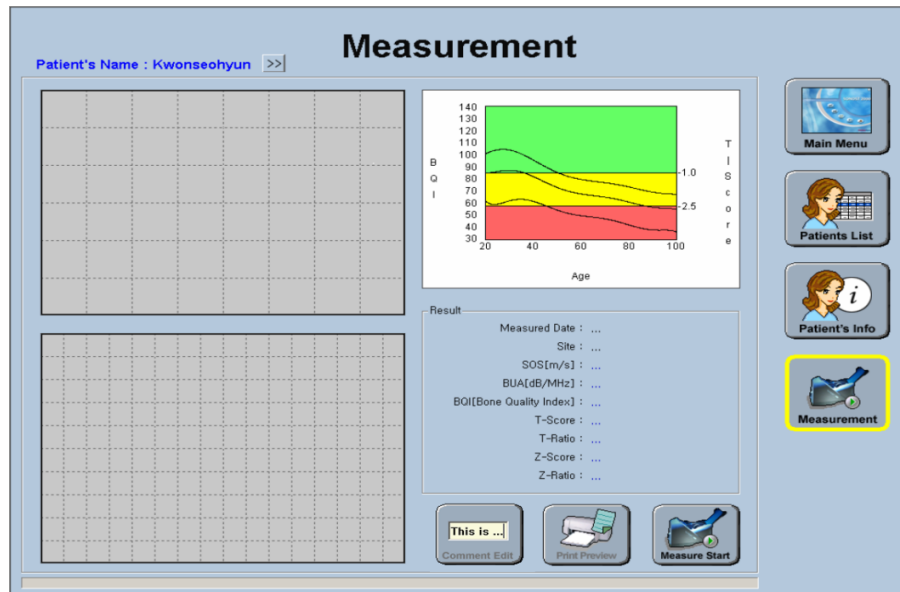
(2) Click "Measurement Start" on the bottom of the "Measurement" window. Then the "Measurement Start" window appears and you are asked to select measuring site and some basic information on the patient. When you are ready to measure your patient, click "Measurement Start", and the ultrasonic waves are generated from the probe.
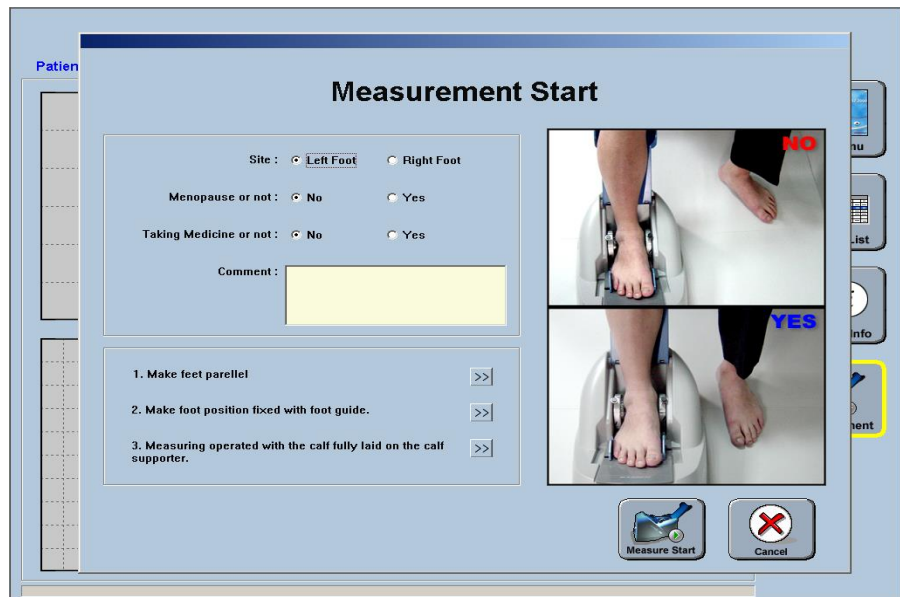
(3) When ultrasonic waves are generated, the "Measurement Start" button will change to "Measurement Stop" for you to click this button when in case of emergency. Click this button to stop an ongoing measurement. In normal conditions, the message box "Measurement Completion" appears upon finishing the measurement with a sound, asking whether to restart measurement of BQI.
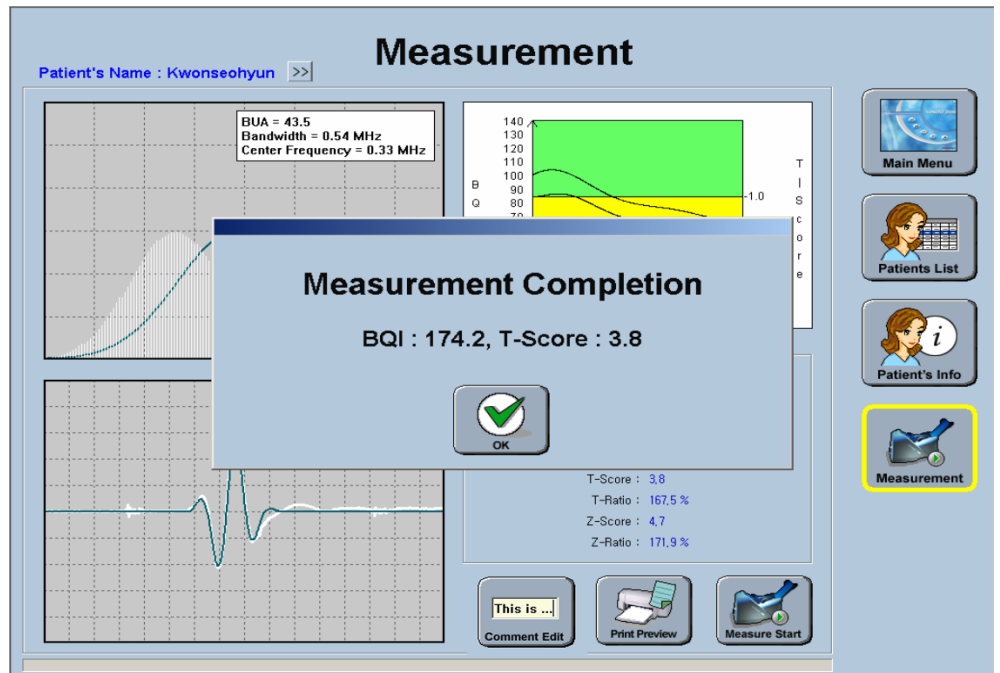
(4) If you click ~~the~~ "OK", the results appears in the screen as shown
below.
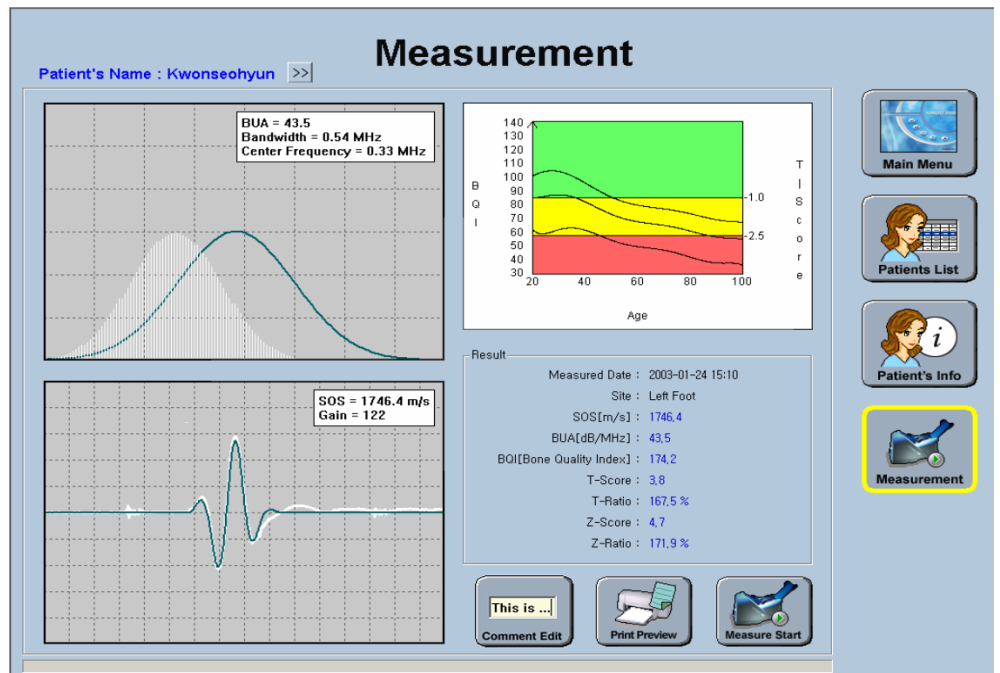
(5) If you need to write or modify comment, click "Comment Edit" on the bottom of the screen. Then the "Comment Edit" window will appear and you can write or modify comments.
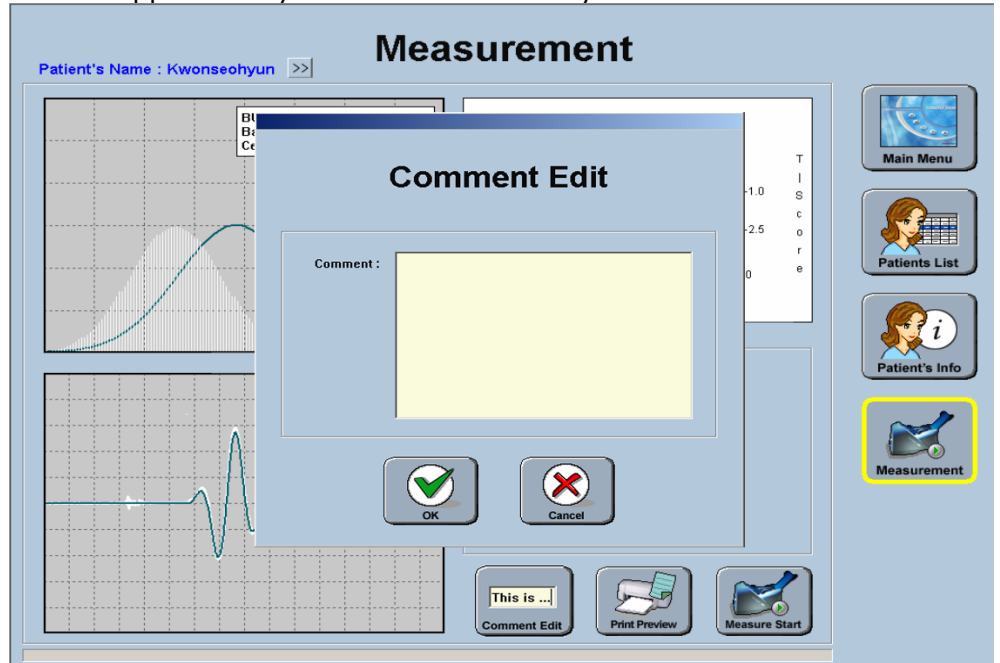
(6) If you click "Print Preview" on the bottom of the screen after a successful measurement of BQI, you can preview the results that will be printed out in the form of a report as shown below. If you click "Print" in the upper left corner of the window, the report will be printed. The "Print Preview" function can be set in the "Configuration" menu.
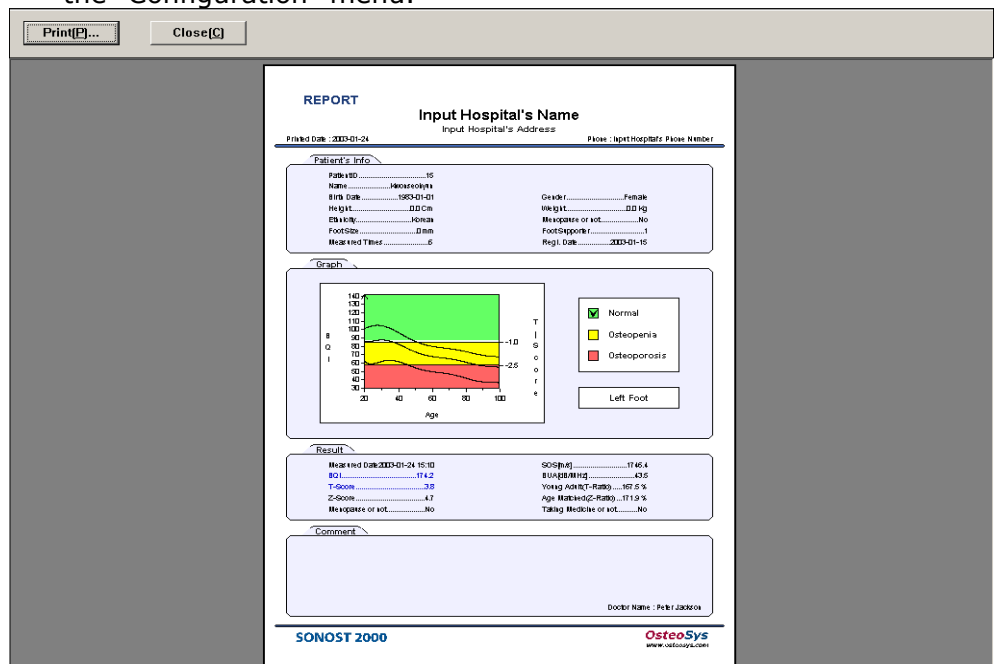
< Send PACS >

(1) Measurement results can be transmitted to the PACS Server.
- PACS transmission can transmit results and troop transmission respectively.

- Bone density mode and pediatric bone density mode are supported.

- PACS transmission setting can be changed in DICOM setting in the setting window of the initial screen.
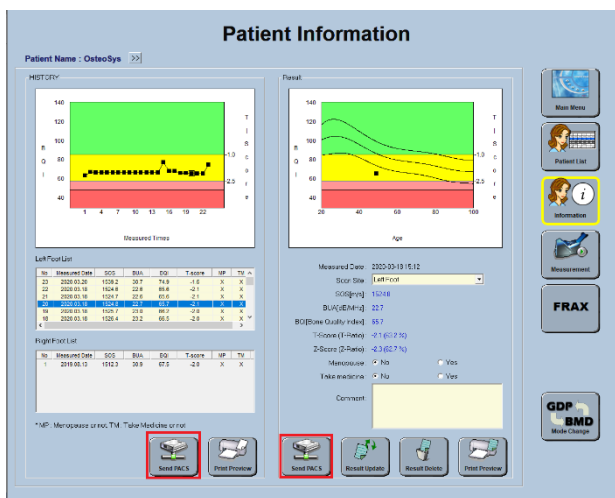
(2) If transmission is successful, a window like the one on the screen appears.
- If transmission fails, try again after changing Storage Server settings in DICOM settings in the settings window of the initial screen.

- In case of repeated failure, you can contact the PACS management company for the information.
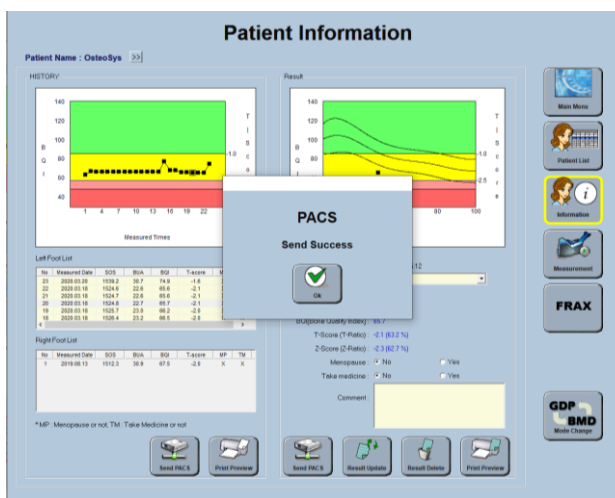
3.2.2.6 Revision & Deletion of patient's information

(1) If you want to revise the registered patients' information, select a desired patient using the mouse and click "Info Change" ~~button~~ on the bottom of "Patients List" window.

(2) Then the "Patient's Info Change" screen appears. Edit information of the selected patient and click "OK" to save changes. The changes you can make about a patient are name, date of birth, gender, height, weight, Ethnicity, menopause state, foot size and etc
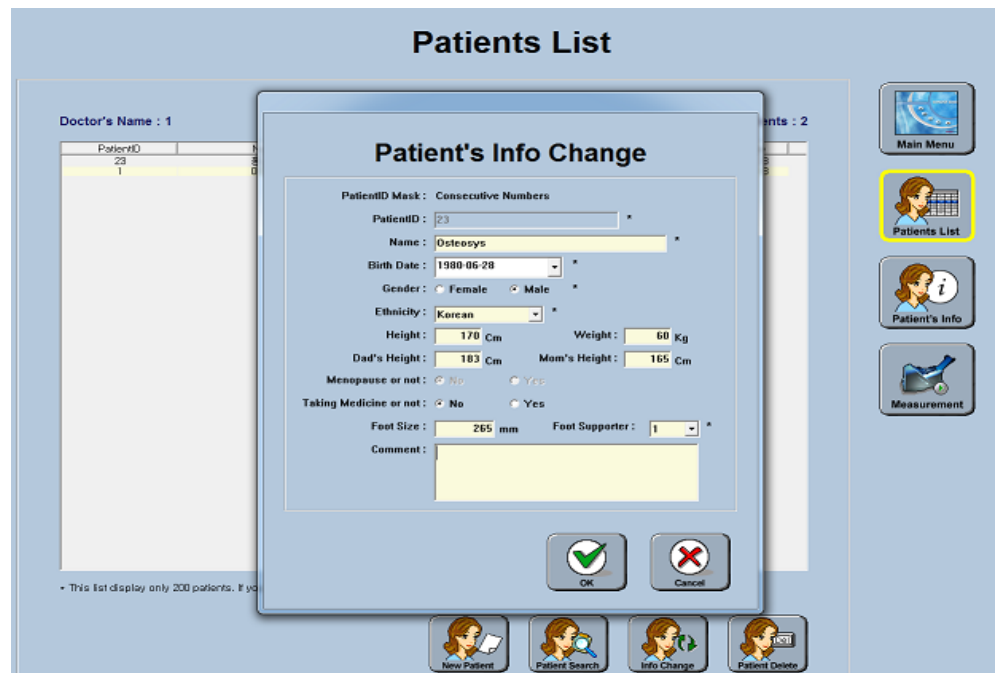
(3) If you want to delete a registered patient, select from the "Patients List". You can select multiple patients to delete at once. To do so, click those patients while pressing the Ctrl key or if you want to select all patients from a certain point of the list to another, click the first and the last line from the list while pressing the Shift key.

(4) After selecting a desired patient, click ~~the~~ "Patient Delete" on
the bottom of the screen. Then the message box "Patient
Deletion" appears to confirm whether or not to delete
completely. If you click ~~the~~ "OK", the information is deleted.
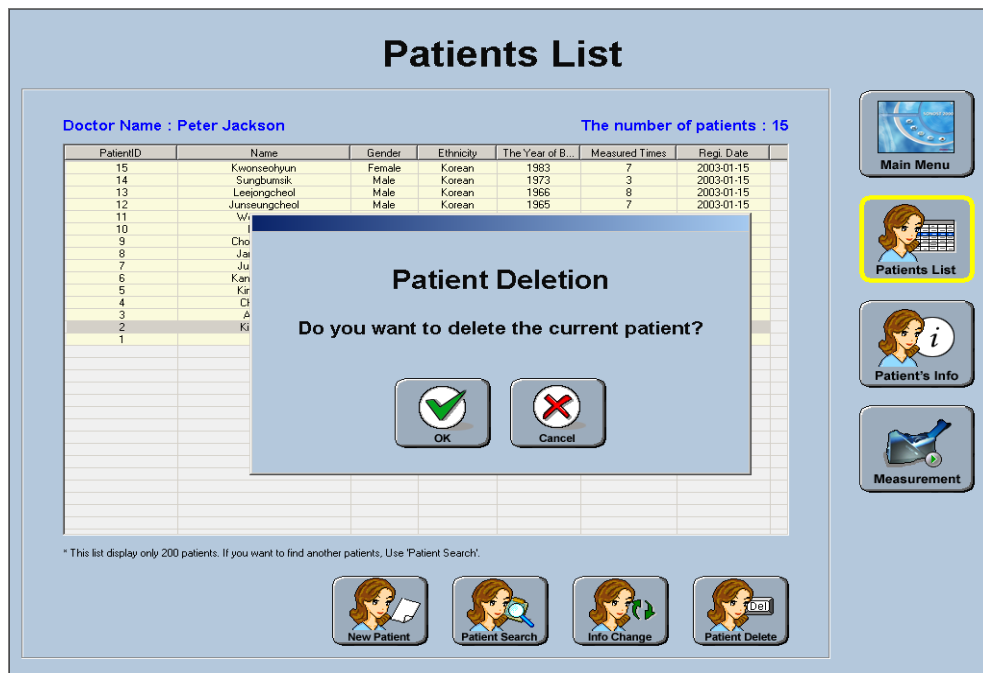
3.2.2.7 Inquiry & Deletion of clinical history of existing patients

(1) If you want to retrieve the clinical history of existing patients, select a desired patient and click "Patient Info" on the right side of the "Patients List" screen. Then "Patient's Info" screen appears that contains the patient's clinical history as shown below. On the left side of the window, you will see results of selected measurement and the list of entire measurements for the patient. If you select a different measurement from the list, the selected results and data will be displayed.
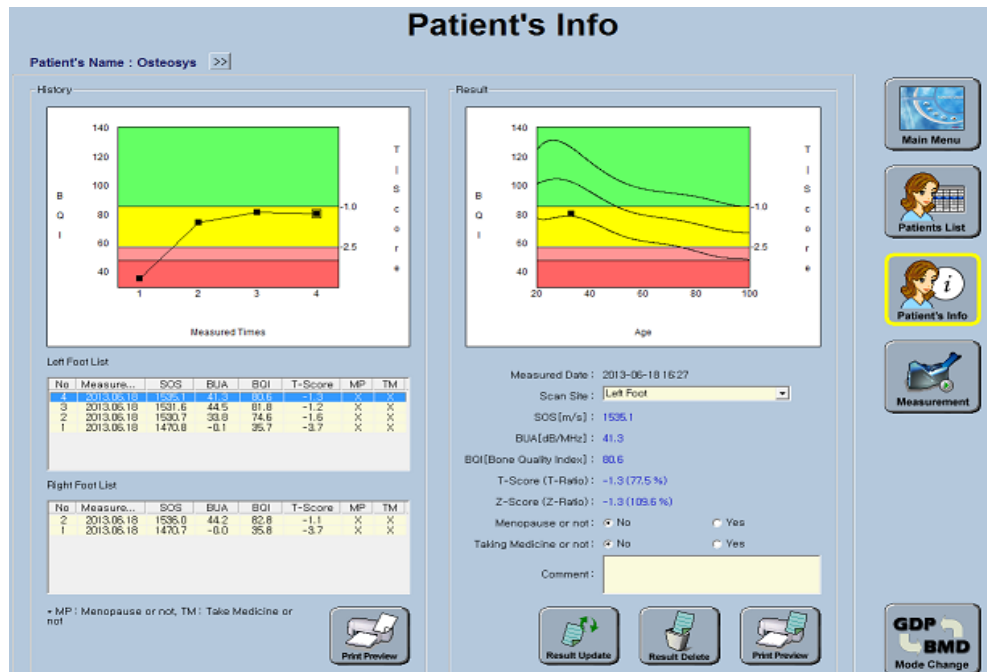
NOTE !
There are two "Print Preview" buttons in the "Patient's Info" screen comparing to the "Measurement" screen, and each button has the different functions.
Click the Patient Information icon to view patient information.

① If you click "Print Preview" on the right side, the result you
selected appears in the "Patient's Info" screen.
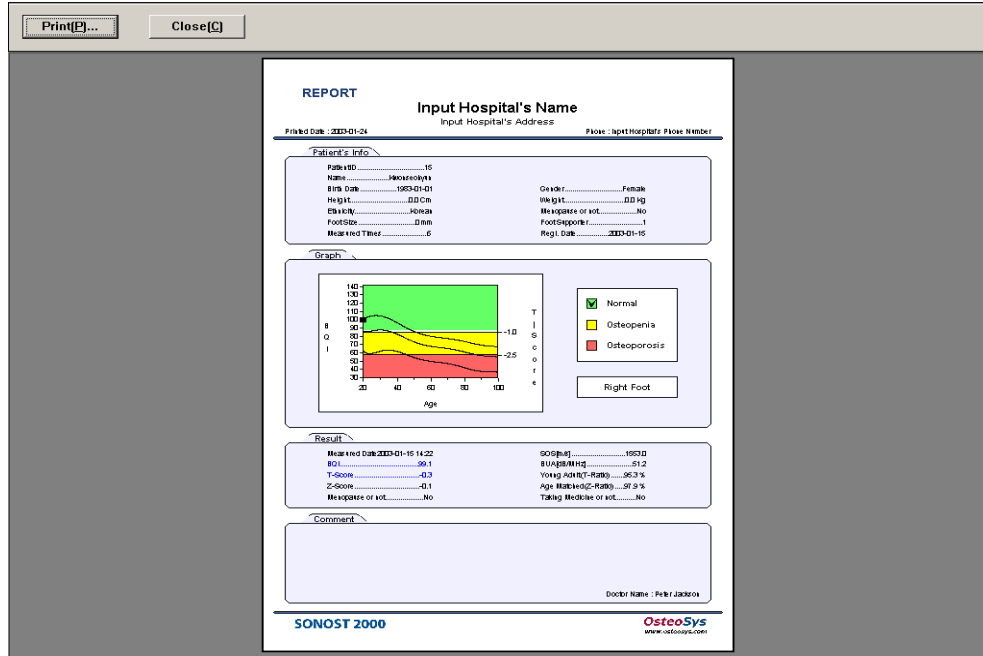
② If you click "Print Preview" on the left side, all results of the
selected patient appears in the "Patient Info" screen.

[Print Sample ①]

REPORT

OsteoSys
2F, DAVIT Tower, 551-1, Sungnae-Dong, Kangdong-Ku, Seoul, Korea
Printed Date : 2003-02-14   Phone : +82-2-2041-5600

Patient's Info

PatientID..2		
Name.............................kimminsoo		
Birth Date....................1976-10-31	Gender.....................................Male	
Height................................0.0 Cm	Weight................................0.0 Kg	
Ethnicity..............................Korean	Menopause or not.....................No	
Foot Size...............................0 mm	Foot Supporter.............................1	
Measured Times..........................6	Regi. Date...................2003-01-15	

Graph
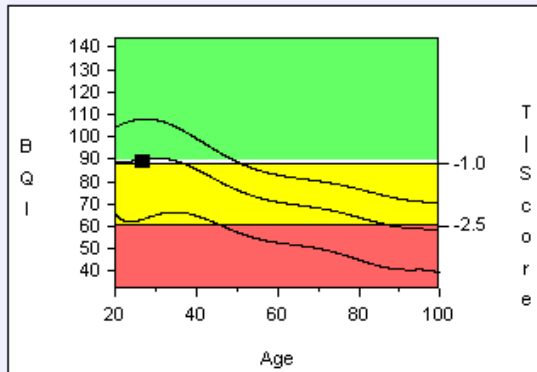
Left Foot

- Normal
- Osteopenia
- Osteoporosis

(Graph: BQI vs Measurement Times, T I Score)

Result

	Measured Date	SOS	BUA	BQI	T-Score	Z-Score
Selected	2003-01-15	1528.6	55.0	90.5	-0.9	-1.0
Recent	2003-01-15	1528.6	55.0	90.5	-0.9	-1.0
	2003-01-15	1526.0	52.8	88.8	-1.0	-1.1
	2003-01-15	1527.1	57.5	90.7	-0.9	-1.0

Comment

Doctor Name : 2003-01-15 Test

SONOST 2000   **OsteoSys**
                                                    www.osteosys.com

[Print Sample ②]

(2) After revising patients' information(menopause state, taking drug, etc.), if you click "Result Update" on the Patient's Info window, the message box "Result Updating" appears to confirm whether or not to apply the changes. Click "OK" to update the changes.
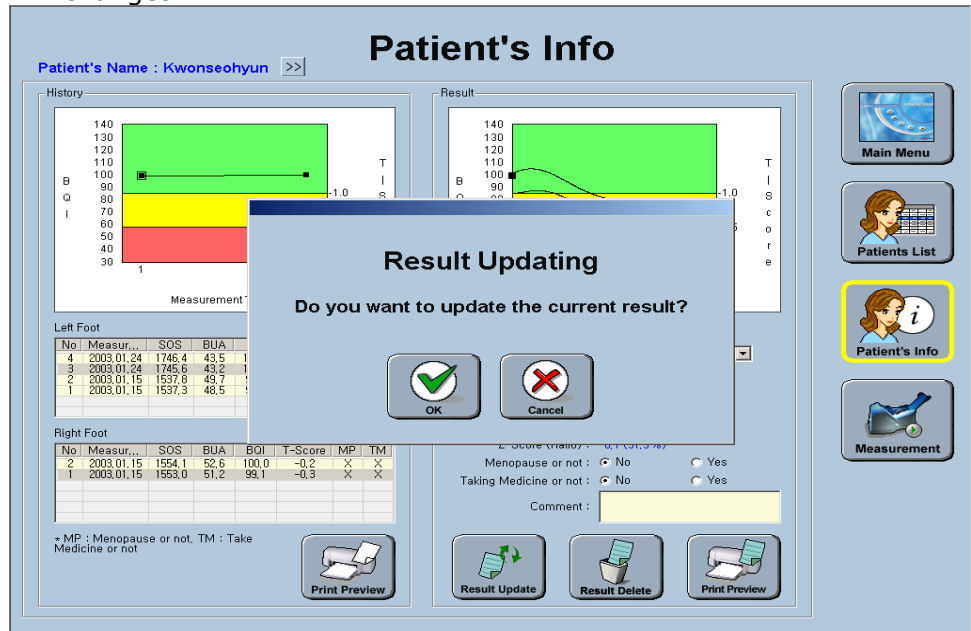
(3) If you want to delete the clinical result of a patient, select a desired result and click the button "Result Delete" in the "Patient's Info" screen. Then the message "Result Deletion" appears to confirm whether or not to delete the result you have selected. Click "OK" to delete.
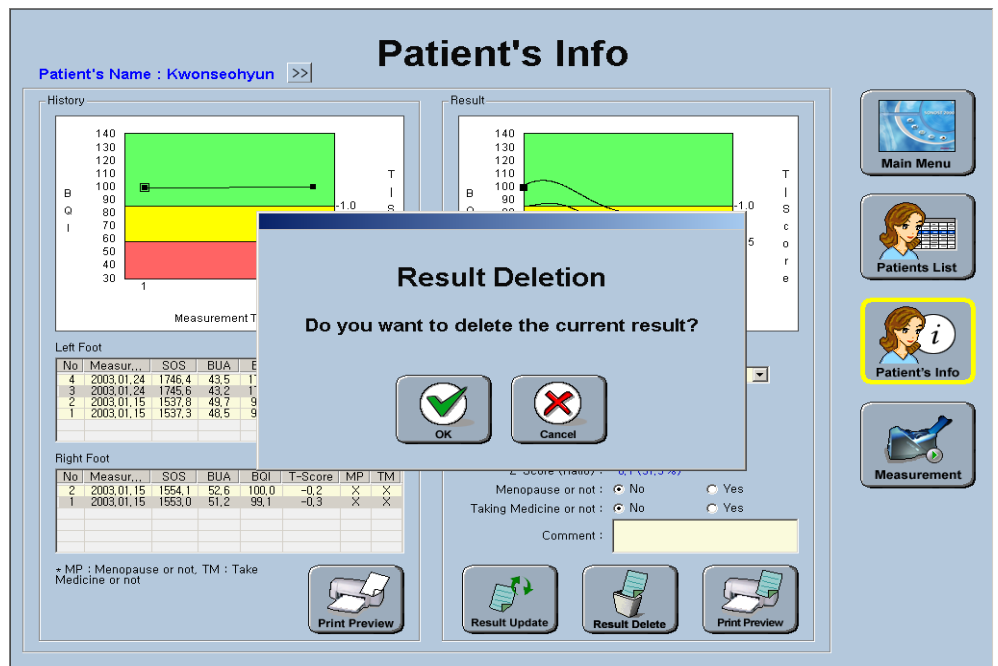
3.2.2.8 Daily test of SONOST-2000

NOTE! Daily Test Recommendation

- The daily test should be performed within operating temperature. (Recommended temperature: 18 ~ 27 ℃)
- The phantom should be kept beside of device closely.
- Daily test should be done just after turning on the device.
- After turning on the device for the first time of the day, immediately perform Daily Test immediately before warming up the device.
- Turn off the device after using at closing time of the day.

(1) Make sure to run Daily Test for the system to reduce a margin of error and to get accurate values in times of examining a patient's bone density. It is to raise credibility of examination results through checking of system reliability on a daily basis.

Whenever you calibrate the system, you should use the QC Phantom included in the accessory list.

☞ **3.1.2   Using the QC Phantom**

(2) To calibrate the system, click the "Daily Test" button from the main menu. Then the "Daily Test" screen appears as shown below. When you click the "Daily Test Start" button in this screen, ultrasonic waves are generated from the probe.
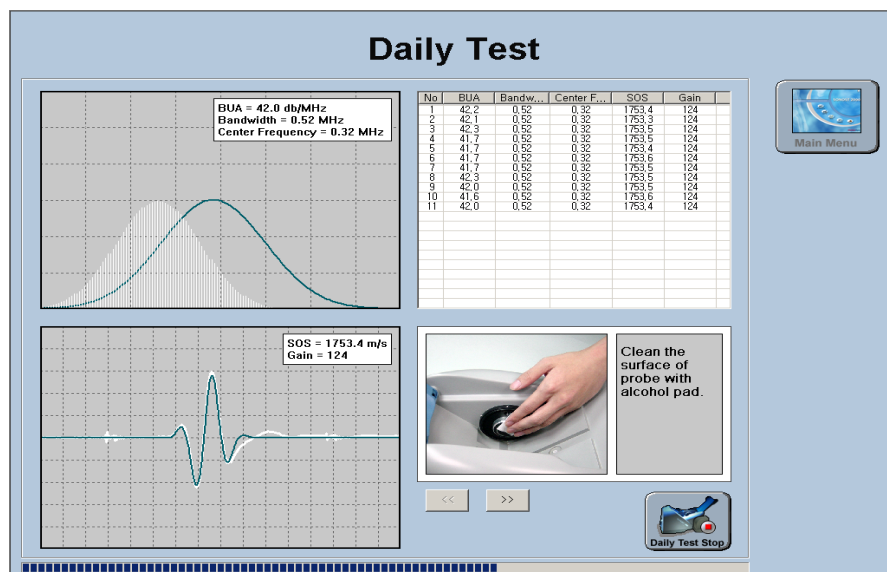
(3) When ultrasonic waves are generated, the "Daily Test Start" button changes to "Daily Test Stop". In case of emergency, click this button and you can stop Daily Test

(4) in progress. In normal conditions, the message box "Daily Test Success" appears as shown below with an alarm sound after completion of Daily Test. Click "OK" to finish the Daily Test.
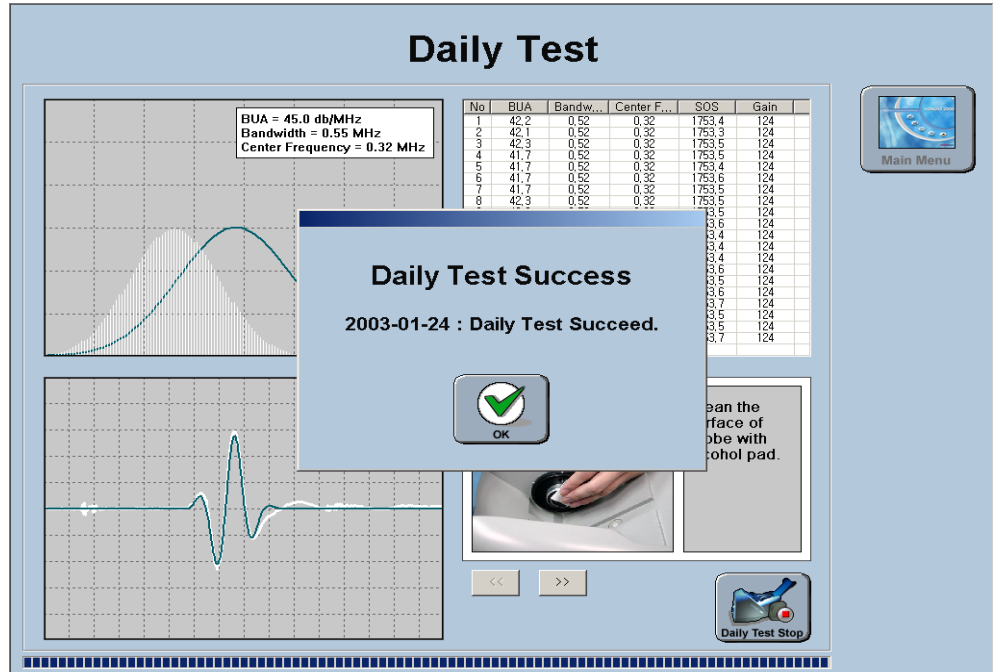
NOTE !
In case of Daily Test failure, do not use the system and execute "Daily Test" once again. If Daily Test fails continuously contact ~~to~~ OsteoSys or your local authorized dealer.

3.2.2.9 Data Backup

(1) If you need to save the data, click "Backup" from the main menu. When clicked, the default screen of "Backup" menu appears as shown below.
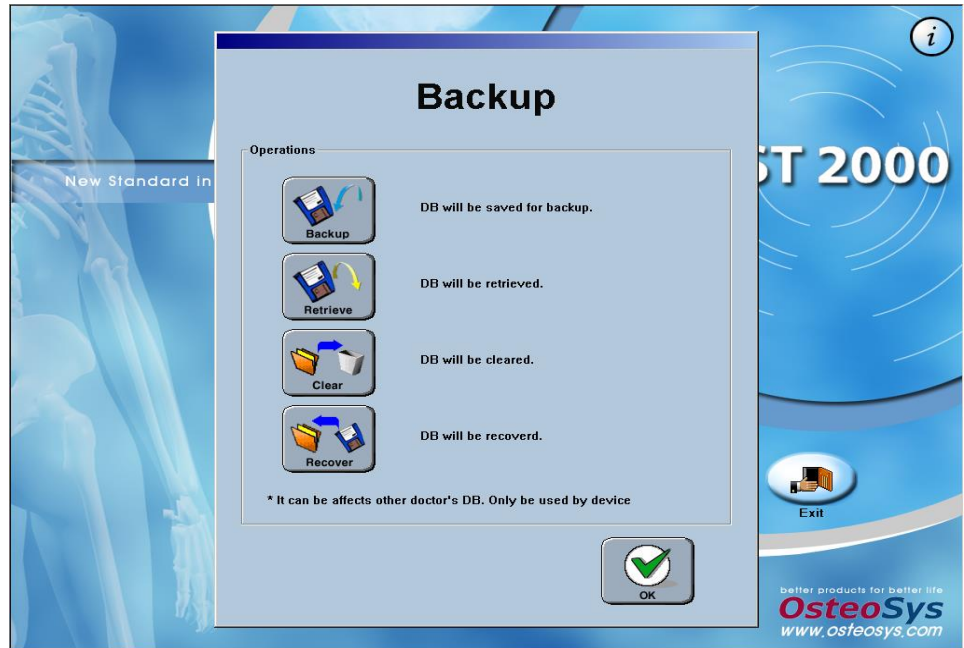
(2) Backup : If you click this button, you can save all users' DB in the PC.
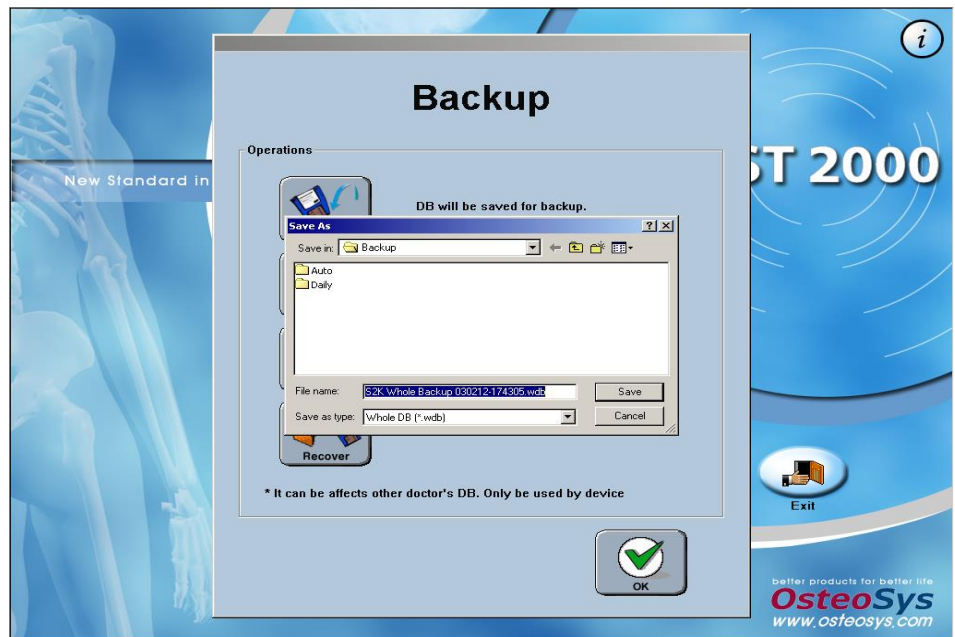
(3) Retrieve : If you click this button, you can exchange all users'
DB into others
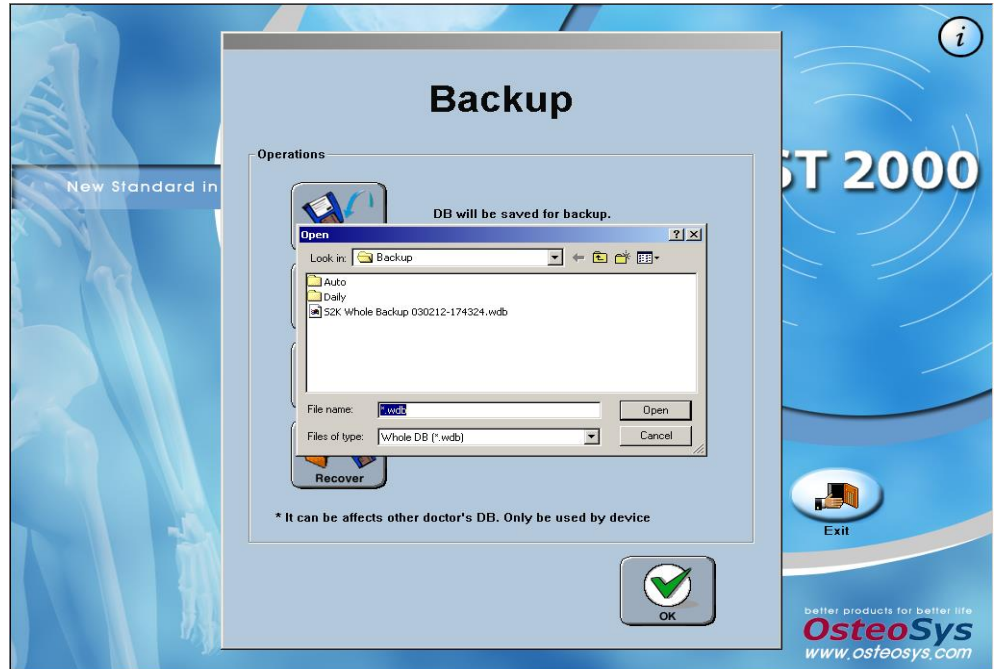
(4) Clear : If you click this button, the message box "Surely clear
doctor?" appears for your confirmation. If you click the "OK",
you can clear all users' DB.
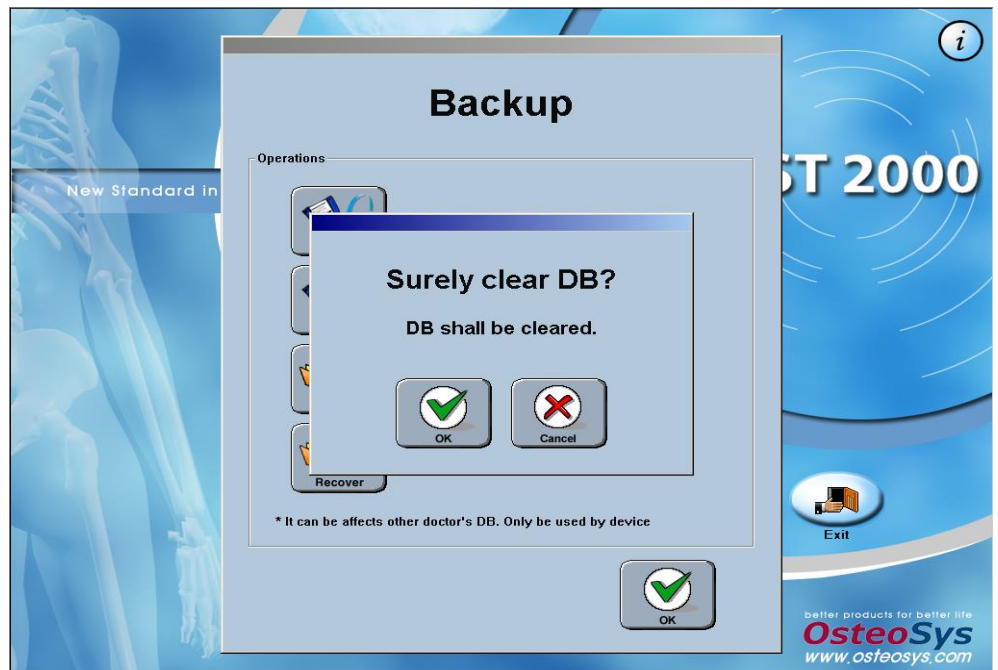
(5) Recover : If you click this button, you can recover all users' DB.
All records related to the DB are written in this field.
After selecting the record and clicking the "OK" button in this
screen, the DB is recovered.
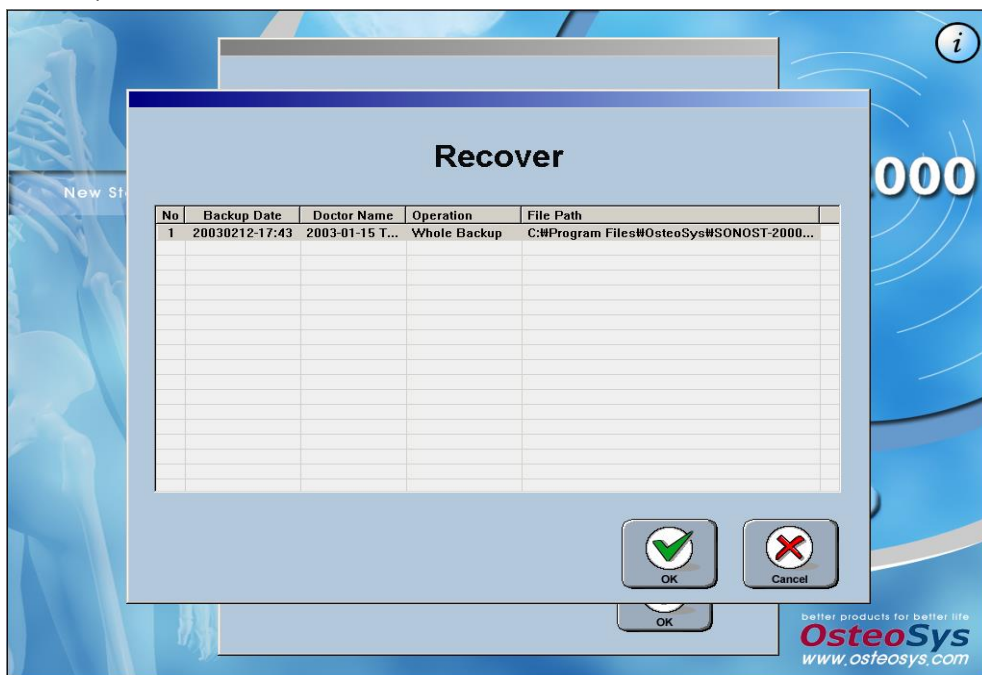
3.2.2.10 Configuration of environment

(1) If you want to configure the user environment again, click the "Configuration" button from the main menu. There are three sub-menus from "Settings" to "Doctor".

(2) Settings :

☞ **3.2.2.3 Execution of Program and Configuration of the Incipient Environment**
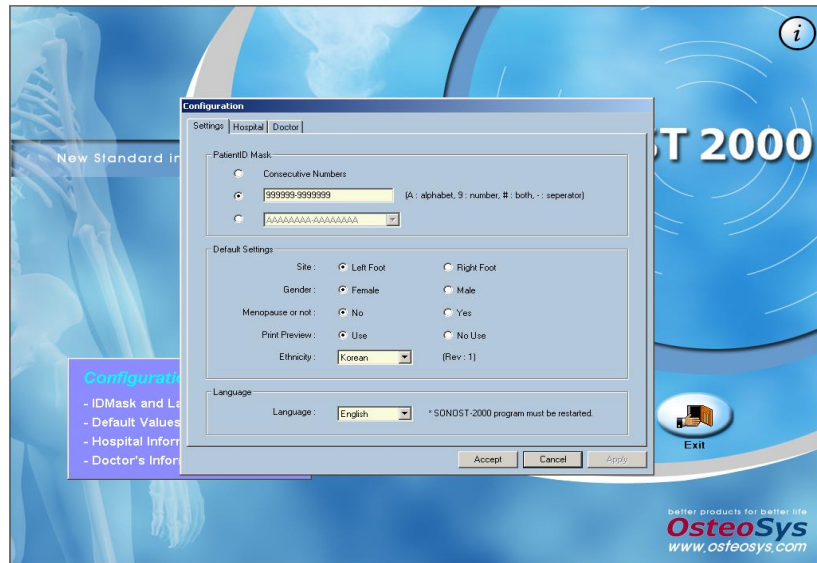
(3) Hospital

☞ **3.2.2.3 Execution of Program and Configuration of the Incipient Environment**
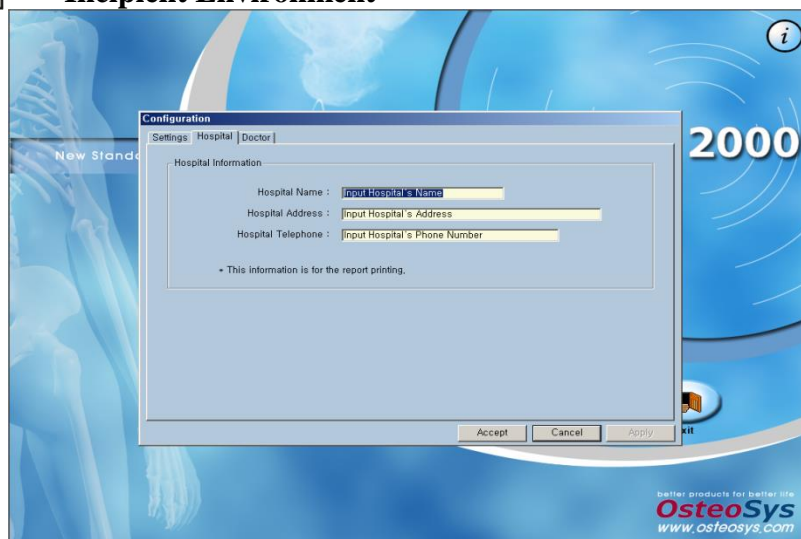
(4) Comment: Enter the comment information to be displayed according to the T-Score in the patient measurement result.

(5) DICOM : Set the storage server and worklist server information.

(6) Doctor: You can set your name, phone number and department. If you click the "PW Change" button, you can change your password.
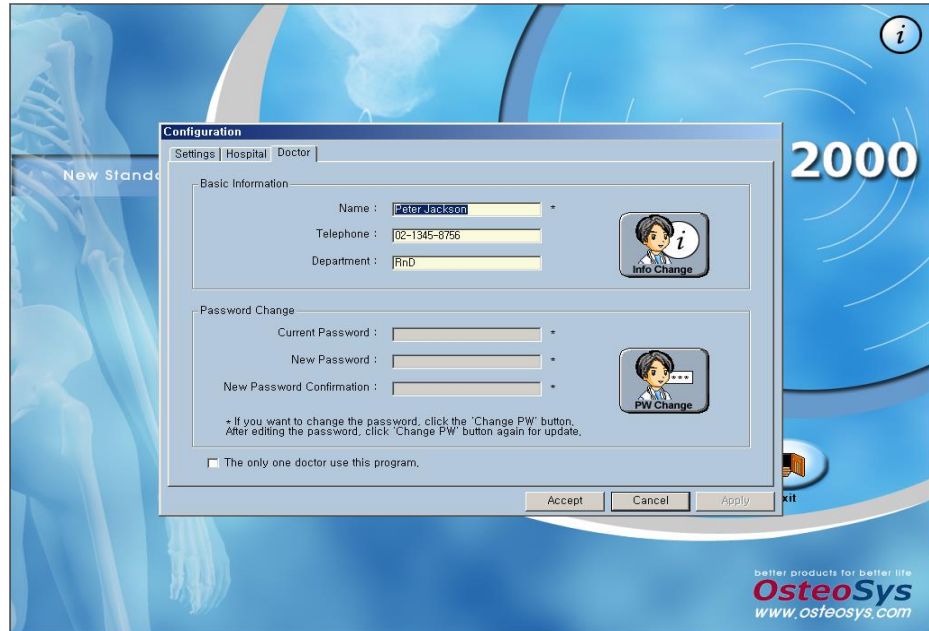
3.2.2.11 Inactivation of SONOST-2000

If you click the "**Exit**" button from the main menu, the message box "Program Exit" appears. Click **"Ok"** to terminate the program.

3.2.2.12 FRAX

FRAX Mode predicts the risk of fractures within the next ten years using the patient's lifestyle and use of medication. The FRAX results predict the risk of femoral fractures and major osteoporotic fractures (vertebral, wrist, femur, and shoulder fractures) within ten years. This function is developed by the World Health Organization (WHO) to assess a patient's fracture risk. Since the agency has provided the relevant function, the following site provides the details and the same results.

 http://www.shef.ac.uk/FRAX/

※ This function offers FRAX result by using patient's medical questionnaire about fracture-related risk factors.

NOTE: This function is only available for patients aged 40 years or older, and 90 years or below.

> (1) Entering from the Patient List
>
> In the Patient List window, select the Patient Registration(New Patient) or Change Patient Information(Patient's Info Change) menu.

If your patient is over 40 years old and below 90 years old, the FRAX button becomes activated and you can enter FRAX information.

(2) Entering from Patient Info

In the Patient Info screen, select FRAX button and input FRAX information.
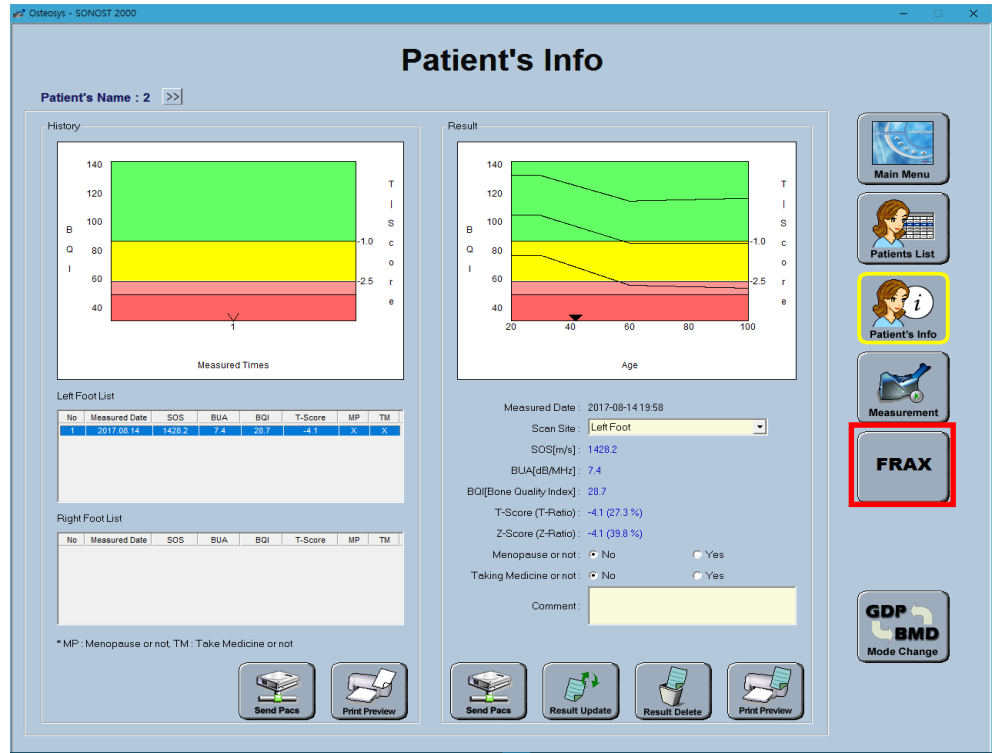
(3) Frax Screen configuration is as follows.

Frax Screen
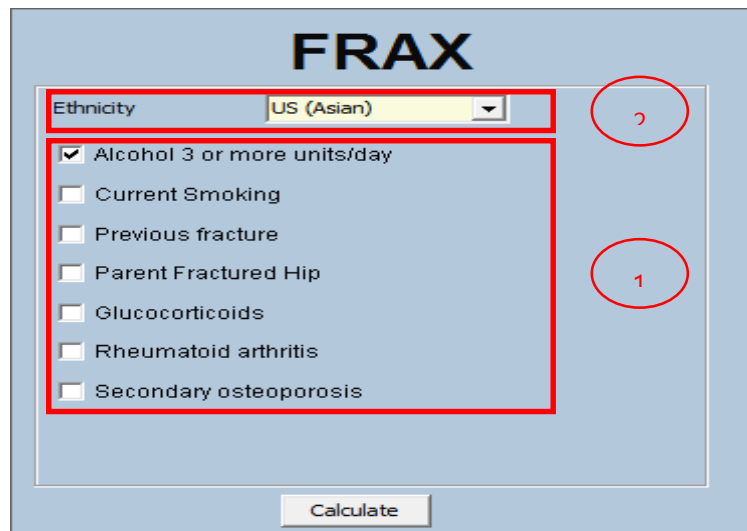
⚇**CAUTION !**
Before calculating the FRAX value, check that the questionnaire items are correct.

① You can select the risk factor value of each individual patient to predict the risk of fracture

I. More than 3 drinks a day

If you drink more than three drinks a day, please check the box.

The amount of one cup varies slightly from country to country, but corresponds to 8-10 grams of alcohol. This is equivalent to a standard size beer (285ml), a cup of distilled liquor (30ml), a medium-sized wine (120ml), or a pre-drinking glass (60ml).

II. Currently smoking

Please check the box if you are currently smoking.

III. Previous fracture history

To be accurate, a previous fracture refers to a fracture resulting from a mild trauma that cannot cause a fracture for a healthy person, or to a fracture that occurs after adulthood.

IV. Parent Hip Fracture

Check the box if there is a history of mother's or father's hip fracture.

V. Steroid agent

Check the box if you had taken or are now taking oral glucocorticoids or prednisolone 5 mg or more per day (or other glucocorticoids of equivalent volume) for 3 months or more.

VI. Rheumatoid arthritis

Check the box if you have been diagnosed with rheumatoid arthritis

VII. Secondary osteoporosis

Check the box if you have a disease that is strongly associated with osteoporosis.

These include: Type 1 (insulin dependent) diabetes

mellitus, adult osteogenesis imperfecta, untreated long-term hyperthyroidism, hypogonadism or premature menopause (before age 45), chronic malnutrition or absorption disorders, chronic liver disease.

② You can select the Ethnicity of the patient to be measured. If you cannot find the Ethnicity of your patient in the list of the reference, you should select the Ethnicity which is the most akin to your patient's Ethnicity from the list.

<Frax Report>

#The report contents are for reference purposes only.

4 Maintenance and Repair of SONOST-2000

4.1 Resolution to problems

If SONOST-2000 shows following symptoms, check the system as follows.

Problems	Checking points
SONOST-2000 is not activated with the power on.	**Is the device properly plugged?**
	Isn't the power cord damaged?
	Aren't the fuses gone?
Computer is not activated with the power on.	**Is the device properly plugged?**
	Isn't the power cord damaged?
Result of Daily Test of the system turns out to be abnormal.	**3.2.2.8 Daily Test of SONOST-2000**
Result of measurement turns out to be abnormal	**3.2.2.5 BQI Measurement** **3.2.2.8 Daily Test of SONOST-2000**
Despite measurement according to the instructions, its result turns out to be abnormal	**Is the desired part of the body properly placed?**
	Are the balloons adjusted properly?
	Are there bubbles in the balloon?
	Is the hardened gel stuck on the surface of the balloons **4.2.1 Cleaning**
The balloons tears easily	**Is there any material on the surface of QC phantom?**
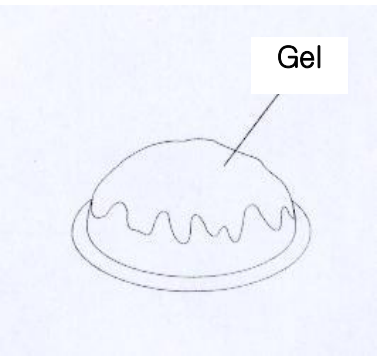
CAUTION !
If you cannot resolve the problem, contact ~~to~~ OsteoSys or your local authorized dealer.

4.2 Maintenance and Repair

4.2.1 Cleaning

CAUTION !
Turn off the power before cleaning the system.

Product	Example	Instructions
Device	Measuring device Soft Cloth	After using the device, remove the balloons from the device and wash with water. The device should be cleaned with a clean soft cloth with water every day, because gel remains around the probe or below the device. Specially, gel stained on the balloons should be moved. After this procedure, clean the stained area with a dry piece of cloth. Make sure not to put water or detergent on the device directly because it can cause fatal damage in the electric circuit contained inside.
Product	Example	Instructions
Balloon	Gel	After using the device, remove the balloons from the device and wash them with water.

4.2.2 Stock pile and replacement of articles

Make sure to keep following articles of consumption all the time.

2.1.5 Articles List

Articles	Specifications
Balloon	Purchase ones at our authorized dealer when it needs to be used. **< Replacement procedure of the balloon >** 1. Remove the hardened gel from the probe. 2. Clean the surface of the probe with an alcohol pad. 3. After attaching the balloon to the probe holder, Adjust the balloon housing to the probe holder. 4. After filling water into the balloon, close it with the stopper. 5. Check the surface of the probe through the balloon. Tap the balloon to remove bubbles inside of the balloon.

4.2.3 Storage

Daily storage	1) Unplug the power cord. 2) Dust on the product can damage the system. After use, make sure to cover it with a vinyl cover. 3) If the hardened gel remains in the device, it can negatively affect BMD results. Please clean the device every day. ☞ **4.2.1 Cleaning**
Storage for a long time of period	1) Unplug the power cord. 2) Do not disconnect the cable of the device connected to the plug to prevent dust from coming in. Place cable near the product or at an empty area in its front. 3) Put cover on the product to avoid dust. 4) Keep the product according to instructions described in **"2.2 Installation of SONOST-2000"** ☞ **2.2 Installation of SONOST-2000**

4.3 Safe use of SONOST-2000

4.3.1 Safety rules

The followings are instructions for safe use of the product

Make sure to comply with the instructions when you activate the system.

Refer to "4.3.2 Caution related to electronic medical equipment"

☞ **4.3.2 Cautions Related to Use of Electronic Medical Equipment**

CAUTION !	➢ Do not open it because there are some high-tension components inside. It might cause serious danger. ➢ Do not assemble or disassemble the product arbitrarily. ➢ Check if the cable coating is not damaged before turning on the system to prevent electric shock or leakage of electricity. If it is damaged or broken, immediately contact an agency. ➢ Do not share the power outlet with other products. If you share the outlet it will affect the product. ➢ Read user's manual carefully before using the product. ➢ Place the user's manual at a designated place so that users can read it anytime they need it. ➢ If you hear a strange noise or if you find any abnormality on the screen after turning on the product, contact OsteoSys or your local authorized distributor. ➢ If damage is visible on the exterior, do not operate and contact OsteoSys or your local authorized distributor. ➢ Make sure to turn off the power switch before cleaning the product. ➢ Make sure to use the Systems to intact skins only. Do not use the Systems for subjects with breached skin, open sores, bleeding, infection or skin diseases on the foot or heel.

4.3.2 Cautions related to use of electronic medical device

Safety rules described below are based on Paragraphs 495 of laws and ordinances promulgated by Ministry of Welfare of Japan. The safety rules pertain to use of electric medical equipment. Read them carefully for safe use of the product and make sure to refer to **"4.3.1 Safety rules"**

4.3.1 Safety Rules

1) **Nobody can handle SONOST-2000 except for doctors and authorized personnel**

2) Comply with followings in times of installation of SONOST-2000. Do not install it in following places.

   A) Places where the product is exposed to water vapor.

   B) Places where the product is exposed to spray or splashing water.

   C) Places where the product is exposed to high density oil vapor

   D) Places where the product is subject to excessive shocks or vibrations.

   E) Places where the angle of inclination of the mounting surface exceeds 10 degrees.

   F) Places where air pressure, temperature or humidity drastically changes.

   G) Places exposed to direct sunlight or places where air is polluted due to dirt, salt and sulfur.

   H) Places where chemicals are kept or toxic gas is leaked.

   I) Places where the AC power line voltage fluctuates heavily.

   J) Places where the AC power line voltage fluctuates heavily while this product is operating.

   K) Places where there is a ventilation problem.

   L) Do not lean, shake or rock the product during transportation.

   M) Adjust frequency, voltage or current to the product.

   N) The product is portable but make sure to put a brake on it when you stop the product.

   O) Ground the product by using ground wire.

   P) Do not share the power outlet.

3) **Check followings before using the product.**

   A) Whether power is off before putting a plug in the socket.

B) Whether the power supply line is suitable with that of the system (AC 100~240 V)

C) Whether the system is fully grounded.

D) Whether all the connection parts(power and optional equipment) are connected with the system properly.

☞ 2.3 Before Turning on Power

E) The product has been factory-set for optimum performance. Do not attempt to adjust any preset controls or switches except for operation as specified in this manual.

F) If you experience any trouble with the product, turn it off immediately and contact OsteoSys or its authorized dealer for assistance.

G) Before electrically or mechanically connecting a third party devices to SONOST-2000, contact OsteoSys or its authorized dealer for instructions.

H) Do not operate the product improperly when you use it with other products.

I) Make sure to check whether external parts of the device directly touches the   patient.

J) Make sure to check whether the products keep distances at least 10cm from walls.

CAUTION !

Equipotential Bonding
In hospital, doctors and patients are subjected to dangerous, uncontrollable compensating currents. These currents are due to the potential differences between connected equipment and touchable conducting parts as found in medical rooms. The safest solution to the problem is accomplished is consistent equipotential bonding. Medical equipment is connected with connecting leads made up with angle sockets to the equipotential bonding network in medical rooms.
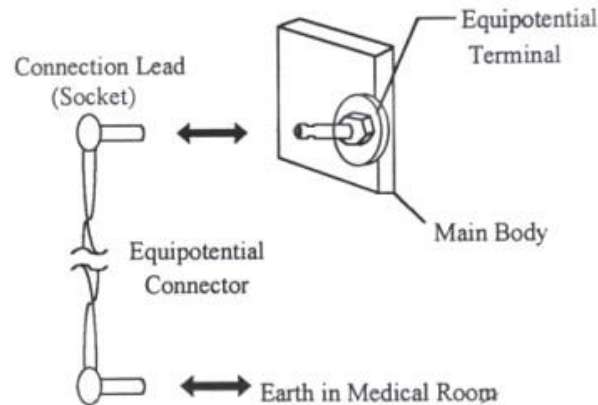
> **NOTE !**
>
> Try to place the system far from power generators, X-ray machines, broadcasting stations, and transmission lines to avoid electrical noise during scanning. Otherwise, it may lead to abnormal result. An independent circuit and a-safely grounded outlets are strongly recommended for SONOST-2000. Poor or abnormal images may occur if the system shares a power source with other electrical or electronic equipment.

> **NOTE !**
>
> **The classification according to standard IEC/EN 60601-I**
> Type of protection against electric shock : Class I
> Degree of protection against electric shock : Type B
> Degree of protection against harmful ingress of water : IPX 0
> Methods of sterilization or disinfection : See Chapter 4.2.1
> Not suitable for use in the pressure of flammable anesthetic mixtures.

4) **Check followings while the device is in operation.**

   A) Whether the product and the patient are normal.

   B) Whether the products keep distances with one another.

   C) If you find any abnormality related to the product or patient, stop its operation and check if it can cause any danger to the patient.

5) **Checking points after use of product**

   A) Make sure to clean the product. Deactivate the product and turn the power off in order.

   B) Do not pull the power cord with an excessive force.

C) Comply with followings to keep the product properly.

① Avoid places that can wet the product.

② Avoid places where air pressure, temperatures and humidity change drastically and where there are direct ray of sun, dirt, salt and sulfur.

③ Do not lean, shake or rock the product.

D) Clean accessories after use.

E) Make sure to clean the product so that users can use it immediately

6) If the product is out of order, do not try to repair it for yourself.

7) Do not attempt to modify product yourself. If any modification is desired, ask OsteoSys or its authorized dealer for ~~this~~ service.

8) Check, maintenance and repair

9) Cautions in times of transportation of cart
If you have to move the cart on inclined floor, you should detach the product from the cart so that the product does not slip to the ground.

10) Environmental protection

If the products are at the end of their lifecyles, do not dispose them at your own discretion. Contact OsteoSys or its authorized dealer for ~~this~~ service.

11) Others
Read the user's manual carefully and use the product accordingly.

5 Specification & Software Updates

5.1 Specifications

*General

Classification	Class I, Type B Applied part

*Device

Dimensions (W x D x H)	523(W) × 286(D) × 254(H) (Calf supporter folded) 523(W) × 286(D) × 358(H)
Weight	7.8 Kg
Input Voltage	AC 100V ~ 240V, Free Voltage (Single Phase)
Frequency	50/60Hz
Power	200W max.
Performance (Reproducibility)	0 ≤ SOS cv ≤ 1 % 0 ≤ BUA cv ≤ 2 %

*Transducer & Balloon

Center Frequency	0.5MHz ± 10%
Ultrasound Output	$4uW/cm^2$
Bandwidth	> 30%
Diameter	31.75mm
MI	<0.2

Focus Type	Flat
Connector Type	UHF

*Measuring Circuit

Input Analogue signal	Ultrasound Transducer, 2 channel, Bandwidth : 0.3 ~ 1MHz
Output Analogue signal	Amplitude : 200Vp-p, Pulse width : 4 usec
A/D Converting	8 bit, 32MHz
Measurement of Electric signal	The number of Data : 1024

*Environmental

Operating Temperature	10 ~ 40℃
Transport / Storage Temperature	-5 ~ 50℃
Operating Humidity	20 ~ 80% relative humidity
Transport / Storage Humidity	0 ~ 90% relative humidity, non-condensing
Atmosphere	700 ~ 1060 hPa
Shock	Not to exceed 2G in six millisecond
Dust, Fumes, Airborne debris	Install system in a clean, well-ventilated area. Excessive dust and other airborne debris and contaminants can impair sensitive parts. We recommend instituting a "No Smoking" policy in system area.

5.2 Software updates

1) Updates to SONOST-2000 software are available at our homepage (http://www.osteosys.com).

2) Updates to SONOST-2000 software are free, regardless of the product warranty.

3) Updates to SONOST-2000 software are irregular, we will inform you through your email whenever SONOST-2000 software needs to be updated.

4) For details, call the OsteoSys Co., Ltd Customer Service Department, or your OsteoSys Co., Ltd distributor.

5.3 Labels

Operating temperature range	10 ~ 40 ℃
Operating humidity range	20 ~ 80 %
Operating atmospheric	800 ~ 1060 hPa
Storage temperature range	-5 ~ 50 ℃
Storage humidity range	0 ~ 90%

Product	Ultrasound Bone Densitometer
Model	SONOST-2000
🏭	Osteosys Co., Ltd. 901~914, 9F, JnK Digitaltower, 111 Digital-ro 26, Guro-gu, Seoul, REPUBLIC OF KOREA Tel)+82-2-6124-5900 Fax)+82-2-6124-5958
EC REP	CMC Medical Devices & Drugs S.L. C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain. Tel) +34-951-214-054 Fax) +34-952-330-100
⚒	
SN	
CE 2460	

6 Product warranty

● **Scope and Period of Warranty**

(1) OsteoSys Co., Ltd. guarantees all new product against faults in materials or workmanship for a period of one year from date of shipment to purchaser. OsteoSys Co., Ltd. will, as sole and exclusive remedy, at no charge, replace any such defective unit returned to its service designated warranty period.

(2) This warranty applies only to failures from operating the product under conditions for which it was designed. Warranted product is to be used only for the intended and labeled indications presented in the literature accompanying the product.

(3) OsteoSys Co., Ltd. will charge service fees in following cases.

- If the product is out of order after the warranty period expires.

- If the product is out of order due to natural disasters such as fire, flood, windstorm, hail, lightning and earthquake.

- If the product is out of order due to improper transportation after installation and careless use.

- If the product is out of order due to improper repair or renovation by someone other than service personnel of the company.

(4) Cosmetic defects or deterioration will not be refinished or replaced. The costs of replacement of fuses are not covered.

(5) OsteoSys Co., Ltd. will not be responsible for any loss, damage, or injury resulting from delay in rendering service under this warranty.

(6) OsteoSys Co., Ltd. will not be held responsible ~~to you~~ for incidental or consequential damages of any kind arising from or connected with the use of its equipment.

● **What Should be Noted in times of Request of repair**

(1) If the product is out of order, stop using it and read the manual carefully.

(2) Before you request for repair, switch off the product and contact a designated service agency after checking the name of model, serial number and date of purchase. OsteoSys Co., Ltd. will replace the defective product at no cost to

you. OsteoSys Co., Ltd. will pay the shipping and insurance costs of product sent to you.

(3) Defective equipment shipped from you to OsteoSys Co., Ltd. must be packed in the replacement cartons. Shipping and insurance costs for the return of the defective product must be pre-paid by you.

(4) If you request the product information to repair the defective product yourself, we provide you with the proper information.

● **This limited is in lieu of all other warranties expressed or implied, including warranties of merchant ability or fitness for any particular use. No representative or other person is authorized to represent or assume for OsteoSys Co., Ltd. any warranty liability beyond that set forth herein.**

7 Security

SEC.1. Introduction

This section describes the security features, functionality and management requirements of OsteoSys software. The manual is intended to assist medical facilities in using the system in a manner that protects the privacy and security of patients and to perform their work in accordance with national regulatory requirements. This section also covers the expected software usage environment.

Software users should use risk management procedures to assess and prioritize security and privacy risks. Based on your risk assessment, you can make the most of the software's performance. Risk assessments should be closely compared to compliance and patient safety as well as security. If security mitigation is inconsistent with patient safety, patient safety is considered a high priority.

SEC.2. Security features

The software includes security features designed to allow flexible access to safety and security implementations, with a focus on the principles of confidentiality, integrity and availability. Throughout this document, information about the performance and use of these features is described.

NOTE !
A user can change system security function in configuration menu.

SEC.3. Access control

Access control is a comprehensive mechanism used to determine and enforce the following:

• Access subject

• How to secure access

• When to grant access

• access information

Access control includes electronic as well as physical aspects, and includes authentication and authorization. You can use Windows to set security policies that control access to software and patient files. Windows user accounts define the activities that can be performed in Windows as follows:

• A person who accesses a computer

• Resources for which the user is authorized to use on the computer

NOTE !
Without any configuration, every user use this device need to be authorized.

SEC.4. Audit Control

Capability to record and examine system activity by creating audit trails on a device to track system and HEALTH DATA access, modification, or deletion.

Securing of audit data as appropriate (especially if they contain personal data themselves).

NOTE !
Audit Log will be added every data handling action.

SEC.5. Certification

Authentication is the process of providing an individual's identity and is a key component of an access control system.

A password inspector account is required to restrict access to patient health information to authorized personnel.

SEC.6. Password management

There is a risk of losing or hacking passwords. To create and use secure passwords, you can apply various rules to password generation. The following checklist is determined by the user.

Password	Recommended use pattern	Contents
minimum length	4-16 characters	Short passwords are easy to remember, but are easily at risk. Long passwords are secure, but easy to forget or write down. Long passwords increase resistance to brute force attacks.
Expires	30 – 360 days	When the expiration date comes, the user must change their password regularly. A common rule of expiration period is to balance the length of the expiration authority with the password so that it expires before the password is cracked.
Character composition	You must mix uppercase and lowercase letters, numbers, and special characters.	This is a set of attributes used to increase the number of possible password combinations, prevent dictionary attacks, and mitigate brute force attacks. It also makes password guessing difficult.
Password reuse	Do not reuse password	To avoid password prediction, you should not use previously used passwords.
Incremental password	Disable Incremental Passwords	Users should avoid creating passwords that are not significantly different from their previous passwords, such as password1, password2 and password3 or trick, track and truck.

Risk level assessment is important for the setting of appropriate properties. Password attribute combinations do not have a single "accurate". Increasing the security settings of a category often allows mitigation of other categories to achieve the same level of protection. Closely evaluate and evaluate password strength rules to mitigate the need for users to write down or forget passwords.

SEC.7. Permission

Authorization is the process of issuing and withdrawing an individual's right to access information, functions, or services and is another important component of an access control system. Although an administrative process that operates primarily in accordance with an organization's policies and procedures, software includes the ability to execute and enforce an organization's methods. The software can run using a limited user account.

SEC.8. Malicious Software Protection

The computing environment is increasingly hostile, and threats from malicious software, including computer viruses, worms, Trojan horses, denial of service attacks, and other malware, continue to grow. Various levels of careful defense are necessary to prevent system damage from malicious software. Effective protection requires the cooperation and partnership of OsteoSys and its customers.

SEC.9. Customer's Responsibilities

Customers should visit the OsteoSys website for up-to-date information about vulnerability information and the impact on software. Customers need to install validated Microsoft security software patches.

1. OsteoSys software computing system holders must apply a validated Microsoft security software patch for their Windows operating system version.

2. The patch can be downloaded from Microsoft's website (https://support.microsoft.com).

SEC.10. Product features

The product's features to help defend against malware include:

• Instrument design and configuration: System computers are shipped with only the minimum services and protocols required for operation. Unnecessary operating system services and protocols have been disabled by default. This helps to prevent unauthorized access.

• Security update and patch process: Install critical operating system security patches on your system when you release the product. In addition, new security patches load automatically each time you update your software.

NOTE !

When the user wants to update the system, please contact OsteoSys to receive appropriate service.

SEC.11. Third-Party Components in Product Lifecycle Roadmap

OsteoSys provides information security throughout the entire life cycle of the product from its launch to discontinuation.

Information security requirements should also consider:

a) the level of confidence required towards the claimed identity of users, in order to derive user authentication requirements;
b) access provisioning and authorization processes, for business users as well as for privileged or technical users;
c) informing users and operators of their duties and responsibilities;
d) the required protection needs of the assets involved, in particular regarding availability, confidentiality, integrity;
e) requirements derived from business processes, such as transaction logging and monitoring, non-repudiation requirements;
f) requirements mandated by other security controls, e.g. interfaces to logging and monitoring or data leakage detection systems.

And OsteoSys provides Cyber security product upgrades.

As soon as possible, third-party security patches need to be installed in medical products in accordance with regulations requiring.

OsteoSys Provides product security patch upgrades in a unified working manner by installation/field service personnel.

NOTE !

Third party component updates will proceed with the distribution of patch files from OsteoSys during product warranty.

SEC.12. Software and Application Hardening

Prohibit the use of unauthorized programs while using the UI program.

Users should not use unauthorized programs while using the UI program, but should only use the program in an approved manner.

CAUTION !
The user needs to stop unneeded system services to protect the whole system.

CAUTION !
The user needs to close unneeded network ports via a firewall to protect the whole system.

SEC.13. Unauthorized network access

Patient health care today relies heavily on IT to electronically collect, process, distribute, display and store patient data. Every computer connected to the network can be affected by network viruses and other bad attacks. Owners and operators of networked medical devices are responsible for protecting their computers from these malicious attacks.

SEC.14. Virus protection software

You can protect your computer by following the standard computer running procedures. Antivirus programs are an appropriate way to make sure that your electronic media and files are free of viruses before they are introduced to your network. You must also install the latest validated operating system update patch.

You must install and run a virus protection program on the computer that uses the BMD. However, virus protection programs have the following disadvantages:

• Do not start a virus scan while using the device. Certain files are marked read-only.

• Your virus protection program may be false positive. Double check the isolation status before taking permanent action. Virus protection programs may incorrectly recognize medical image files as viruses and can damage them.

• If a virus protection program uses too much memory or system resources, the software may not work properly.

CAUTION !
The user needs to use anti-malware software to protect the whole system.

SEC.15. System security

You can set up a screensaver with password protection to block access to the system after a period of inactivity.

CAUTION !
Without appropriate logoff, leaving the work spot could be dangerous.

NOTE !
The database connection will be disconnected after 8 hours from no actions to database or at 0 AM.

SEC.16. Data protection

Data protection and privacy are often based on customer management policies and procedures. The software includes features to help implement data protection measures. It supports device-to-device authentication of AE Title and IP addresses for network services such as DICOM.

SEC.17. HEALTH DATA Integrity and Authenticity

HEALTH DATA will be destroyed if it is changed in an unauthorized manner.

To ensure the integrity and authenticity of HEALTH DATA, authorized users must access and modify the health information in an approved manner.

NOTE !
A doctor who has access to health information must use the correct password to modify health information.

SEC.18. HEALTH DATA Storage and Confidentiality

To provide security of health data stored in products or media, OsteoSys uses a database and a specific file system.

In order to access, view, and modify patient health data, it is necessary to obtain access to the database and to interpret the specific file system.

By applying these multiple security policies, we maintain the security of health data stored in products or media.

SEC.19. Security operations

Security operations are best implemented as part of an overall "depth defense" information assurance strategy used through information technology systems that address personal, physical security, and technology. The hierarchical approach to defense in depth limits the risk that a system can be compromised by the failure of a single security safeguard.

SEC.20. Health Data De-Identification

Patient health data is provided non-identifiable by unauthorized users by default.

Authorized users may use dedicated software to access and identify patient health data.

CAUTION !
Please check the health data is de-identified when sharing with third parties.

SEC.21. Network security

Ideally, medical devices operate in a secure network environment that is separate from your organization's general-purpose computing network. Effective techniques, including firewall protection, DMZ and VLAN implementation, can be used to isolate medical devices to secure subnetworks.

CAUTION !
The user needs to set up a closed network system to use DICOM without leaking data.

SEC.22. Business continuity

Support for patient data backup to prevent hardware failures and other disasters. The use of an uninterruptible power supply is recommended to mitigate the risk of data loss due to an unexpected power outage of the system.

CAUTION !
Do data backup at least every week. OsteoSys is unable to recover the data not performed latest data backup when the disaster occurred.

SEC.23. Data Backup and Disaster Recovery

The UI Program backs up data and database once a week.

The user can recover after damage or destruction of device data, hardware, software, or site configuration information.

SEC.24. Media access control point

Removable media without security features and ports for media access represent a risk of data loss and theft. Restrict archive media and computer access to stakeholders.

Removable media is used for common backup options. Store media in a safe, locked place.

Secure the same terminal as the USB port and follow the computer security measures.

CAUTION !
The user needs to lock up the workstation's physical communication port and the device's to protect unauthorized access through a physical port.

SEC.25. Remote service

Often, the most efficient and effective way to service OsteoSys is to access the system remotely. Every effort is made to ensure the security of these connections.

OsteoSys software requires separate TeamViewer remote access. In no case is the instrument activated remotely.

Unless you use the system or have a site visit, you will not be able to connect to your system.

SEC.26. Network Interface Specification and Risk Management

When properly connected to the network, the product supports the following functionality:

• DICOM connection to other DICOM devices

• Remote service connection via TeamViewer

SEC.27. Network Interface Technical Specification

Connection name	PC Motherboard NIC
Physical network connection type	IEEE 802.3 10/100 / 1000BASE-T Ethernet
Speed and dual mode support	10 Mbps Half and Full Duplex 100 Mbps Half and Full Duplex 1000 Mbps Half and Full Duplex Auto configuration (default)
Default IP Settings (Factory Defaults)	DHCP
IP Address	IPv4 DHCP

The network interface used to connect the device is pre-configured with an IP for use. Incorrect connection between the network interface used to connect the equipment and the network interface for network connection may not work.

SEC.28. Network information flow

Flow name	DICOM connection
Device network connection	Motherboard NIC
Type of use, function, purpose	Connection to other DICOM devices
Optional / required	options
Communication server	PACS, RIS
Intermediate protocol	TCP
Application protocol and encoding	DICOM
Traffic Characteristics and Bandwidth Requirements	On demand, the local user receives the DICOM Worklist query results from RIS, performs the checks, and sends the report to PACS.

SEC.29. Transmission Integrity

Since the TCP/IP used by the DICOM Upper Layer guarantees the integrity, DICOM communication also guarantees transmission integrity.

<table>
<tr><td>WARNING !</td></tr>
<tr><td>When DICOM transmission is succeeded but transmitted data is malformed, first contact the network manager and the DICOM server provider. OsteoSys has verified DICOM features with other DICOM systems.</td></tr>
</table>

SEC.30. Required Characteristics

The network must meet the specific requirements for a subset of the functions, use cases required by users in the responsible organization, and all of the above flows related to the workflow.

SEC.31. Potential risks of safety, effectiveness or security

• Delayed or degraded access to images, examination information, or patient data.

• Permanent loss or damage of images, examination information or patient data.

• Responsible organizations must continue to identify, analyze, assess, and control risk.