

SONOST 3000

User' Manual

Model: **SONOST 3000**

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 3000

User Manual

Manufacturer and EC Authorized Representative Information

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 **CAUTION!**

- 1. You must be well acquainted with this manual before using it.**
- 2. This manual should be placed where the user could read it whenever necessary.**

User's Manual (Confidential)

OsteoSys Co., Ltd.

Model Designation : SONOST 3000

DOC. No. : OT-IFU-S3K

Thank you for purchasing SONOST 3000 Ultrasound Bone Densitometer. To ensure safe operation and long-term performance stability, it is essential that you fully understand the functions and operating, 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 3000

NOTE !
Check the symbol before using the SONOST 3000.

	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.

	<p>User Manual User of the equipment to check how to check the product.</p>
	<p>Communication Status It indicates communication status of the equipment.</p>

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 equipment from electromagnetic waves.

Disposal of device



This symbol which is printed on the user manual or box means you do not regard 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°C
- 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(Cytotoxicity), 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 3000 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	<p>All women 65 years and older and men 70 years and older for asymptomatic screening.</p> <p>Women younger than 65 years old at risk for osteoporosis:</p> <ul style="list-style-type: none"> • 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 <p>Women younger than 65 years old or men younger than 70 years old with the following risk factors:</p> <p>Current cigarette smoker</p> <ul style="list-style-type: none"> • Loss of height • Thoracic Kyphosis <p>Individuals at any age with bone mass osteopenia or fragility fractures on imaging studies</p> <p>Individuals 50 years and older who developed wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, excluding pathologic fractures.</p> <p>People of any age who developed one or more insufficiency fractures.</p> <p>Individuals receiving (or expected to receive) glucocorticoid therapy equivalent to > or = to 5 mg of prednisone or equivalent per day for > or = 3 months.</p> <p>Individuals beginning or receiving long-term therapy with medications known to affect BMD adversely:</p> <ul style="list-style-type: none"> • Anticonvulsants • Androgen deprivation therapy • Aromatase inhibitor therapy • Chronic heparin <p>Individuals with an endocrine disorder known to affect BMD adversely</p> <ul style="list-style-type: none"> • Hyperparathyroidism • Hyperthyroidism • Cushing's syndrome <p>Hypogonadal men 18 years and older and men with surgically or chemotherapeutically induced castration</p> <p>Individuals with medical conditions that could alter BMD:</p> <ul style="list-style-type: none"> • Chronic renal failure • Rheumatoid arthritis and other inflammatory arthritis • Eating disorders, including anorexia nervosa and bulimia

			<ul style="list-style-type: none"> • 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 <p>Individuals considering pharmacologic therapy for osteoporosis.</p> <p>Individuals monitored for:</p> <ul style="list-style-type: none"> • Assess the effectiveness of osteoporosis drug therapy • Follow-up medical conditions associated with abnormal BMD. <p>Children or adolescents with medical conditions associated with abnormal BMD including but not limited to:</p> <ul style="list-style-type: none"> • 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 dysplasia known to have excessive fracture risk (osteogenesis imperfecta, osteopetrosis) or high bone density • Individuals with medical conditions that could change BMD, for example: <ol style="list-style-type: none"> 1. Chronic renal failure 2. Rheumatoid arthritis and other inflammatory arthritis 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, malnutrition, osteomalacia, vitamin D deficiency, acromegaly, cirrhosis, HIV infection, prolonged exposure to fluorides <p>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.</p>
4	Contraindications	A	<p>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:</p> <ul style="list-style-type: none"> - Try to measure the other side of heel if a patient had some surgery like implant which is placed by calcaneus bone.

5	Target group	User	A	<p>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)</p>
		Patient	A	<p>a) Ages: 20 – 100 years old b) The patient condition: Osteopenia, Osteoporosis or Normal healthy bone</p>
6	Disposable device	N/A	SONOST 3000 is not a disposable device.	
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	<p>BMD measurement is performed once a year or once every two years (It depends on the patient's situation). Contact with body: SONOST-2000: there are contact point between calcaneus part and balloon as below image.</p>  <p>SONOST 3000: It als same as SONOST-2000</p>  <p>Need to apply ultrasound gel in between skin and probe in order to get</p>	


			proper contact for path of ultrasound waves.
10	Contacting with body fluids or others	N/A	There is no contact between any body fluids or people during the examination process.
11	Measurement site	A	<p>The correct position for measurement for calcaneus bone on the heel is as the below.</p> <p>It's just below the area of the ankle, where you should apply enough amount of ultrasound gel just like the below instructions. (need to apply to both sides of feet)</p> <p>*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 Os-calcis (Richard D. Wasinch, Philip D. Ross, Lance K. Heilbrun, and John M. Vogel)</p> <p>*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 for patients with pre-existing risk of osteoporosis and patients with mild osteoporosis to reduce the risk of fracture. (Changzhou Li, Jifeng Sun, Li Yu)</p>

Guidance and manufacturer's declaration – electromagnetic emissions		
The model SONOST 3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the model SONOST 3000 should make sure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model SONOST 3000 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.
RF emissions CISPR 11	Class A	
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 3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the model SONOST 3000 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 3000 requires continued operation during power mains interruptions, it is recommended that the model SONOST 3000 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The model SONOST 3000 is intended for use in the electromagnetic environment specified below. The customer or the user of model SONOST 3000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms s 150 kHz to 80 MH z	3 Vrms 150 kHz to 80M Hz	Portable and mobile RF communications equipment should be used no closer to any part of the model SONOST 3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. $d=[3.5/V1] \sqrt{P}$ $d=[3.5/E1] \sqrt{P}$ 80MHz to 800MHz $d=[7/E1] \sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and-d is the recommended separation distance in meters(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC61000-4-3	10 V/ m 80 MH z to 2.5 GHz	10 V/m 80M Hz to 2.5 GHz	
Note 1 At 80MHz and 800MHz, the higher frequency range applies. Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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	
probe	C2MR-004	10 years	
QC Phantom	C3ES-002	10 years	
Power Cable	250VAC 10A	10 years	

Input and output parts which are using for operate device.

Number	Name	Detailed specification
1	Paper for printing	Thermal paper, Thickness is over : 0.07mm
2	External printer	It requires WindowsXP driver
3	External monitor	It requires 800x600 of resolution with a VGA port
4	USB memory stick	It requires above USB 1.1
5	External mouse	USB or PS/2 supplied
6	External mouse	USB port supplied



6) Input and output parts which are using for operation of device.
(IEC60601-1 contents of test 6.8.2. Requirement

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1 Introduction



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

The measurement site is the calcaneus. It takes about 1 minute 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 precision error as follows. (Estimated index in vivo)

T-score -0.5 or more

T-score -0.5 or less

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

- When you give the appropriate commands in SONOST 3000 software, ultrasonic waves are generated. The generated ultrasonic waves pass through the Patient's calcaneus and the electric signal is treated by SONOST 3000 algorithm.

- 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.

- Never remove any system covers.

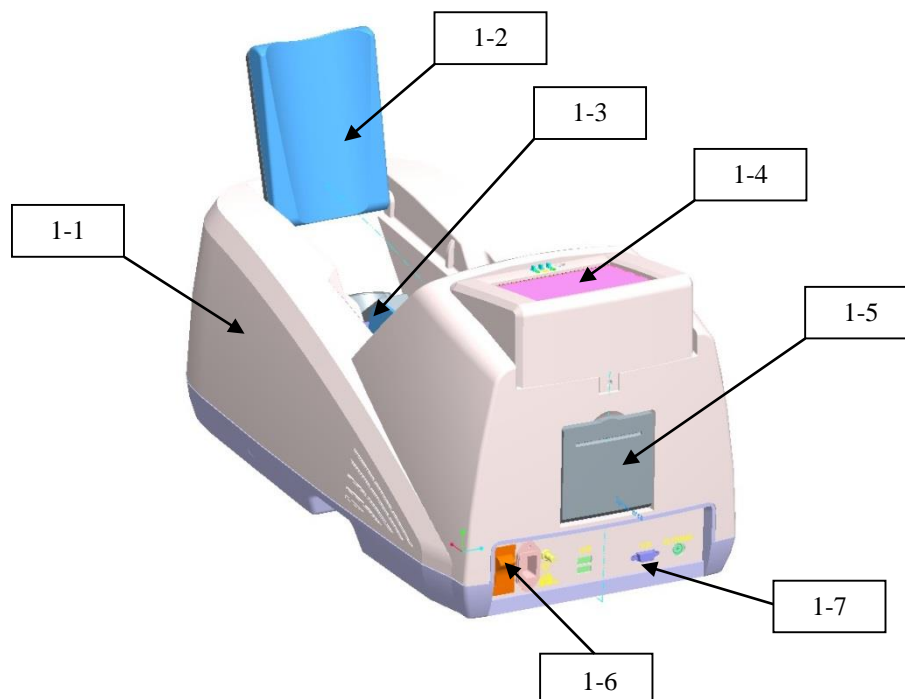
- In case of changing the printer for other products, check them according to IEC/EN60601-1-1.

- Unplug the power cord after using.

2 Configuration of Device

2.1 Composition of Device

2.1.1 Shape and components of SONOST 3000



NO	Name	Function
1-1	Top cover	Protection for internal circuit
1-2	Calf supporter	Leg fixation for diagnosing
1-3	Probe	Generation of ultrasound
1-4	LCD	Display for measuring status
1-5	Thermal printer	Thermal printing for the measurement report
1-6	Switch panel	Connection for the power cord and power ON/OFF switch
1-7	External connector	USB Port for printer, keyboard and mouse

 **NOTE !**

Use external device certificated by standard (IEC-60601-1).



 **NOTE !**

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

2.1.2 Accessories list



Check the following accessories before installing the system.
If they are not in good condition, contact to OsteoSys or your local authorized dealer for this 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. (base, 0, 1, 2, 3(P))
QC Phantom	1	<p>It is used to calibrate the system.</p>  <p>Keep it in the specified place and protect it against deformation by heat or pressure.</p>
Power Cable	1	<p>It is used to connect to the source of electric power with the main body of SONOST 3000</p>  <p>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.</p>

 **NOTE !**

**Use accessories which are defined in the user's manual.
Check the following accessories before installing the system**

2.1.3 Articles list

Check the following accessories before installing the system.

If they are not in good condition, contact OsteoSys or local authorized dealer for service.

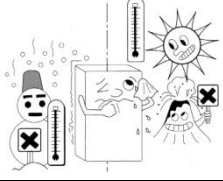
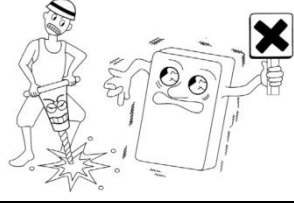
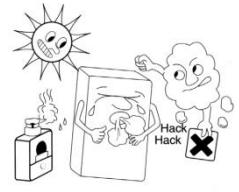


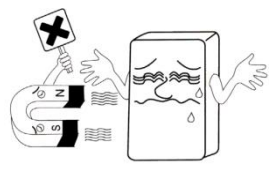
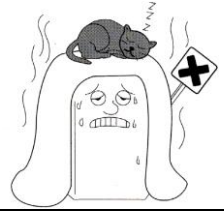
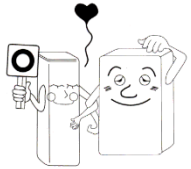
**4.2.2 Stockpiles and Replacement of Articles**

Names of Products	Number	Uses
Alcohol	1 box	It removes some materials which prevents ultrasound from progressing.
Printer Paper	2 rolls	Result paper is printed using printer paper. Minimum paper thickness : 0.07mm

2.2 Installation of SONOST 3000

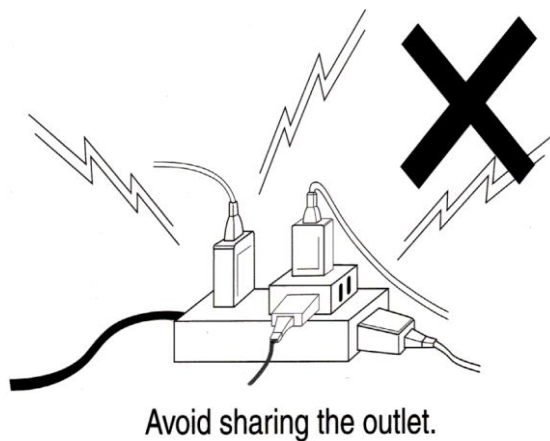
NOTE !

Since SONOST 3000 is made up of sensitive components, you should install the product according to instructions below.

NOTE!	
<p>Do not install and keep SONOST 3000 at excessively high or low temperatures.</p> <p>Proper temperature: 18~27 °C</p> 	<p>Do not install or keep SONOST 3000 in a place where the machine can be rocked or shaken. Make sure to place the system parallel to the floor.</p> 
<p>Do not install the system in a place exposed to polluted air and high humidity, and do not expose the machine to direct ray sunlight. It is advised to use SONOST 3000 in a place equipped with air conditioning or heating.</p> <p>Proper humidity: 20~80%</p> 	<p>Install SONOST 3000 at a place where it is free from water or chemicals.</p> 
<p>Do not share the power outlet with other products through an extension cord.</p> 	<p>For escaping from electronic noise, do not install near an electronic generator, X-ray equipment, or broadcasting equipment. It affects the device to produce inaccurate results.</p> 
<p>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.</p> 	<p>100-240V is usable. When SONOST 3000 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 product, you should install SONOST 3000 at a place where power supply is stable.</p> 

2.3 Before Turning on Power

Connection of power & USB Cable (with the device)



CAUTION !

- 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 the power outlet in order to prevent SONOST 3000 from being affected.

3 Using SONOST 3000

3.1 Daily test

The system of SONOST 3000 can be maintained by running Daily Test on a daily basis.

The daily test should be performed at least once a day, before patient's measurements.

3.1.1 Preparation

SONOST 3000 device, Phantom, and ultrasound transmission gel

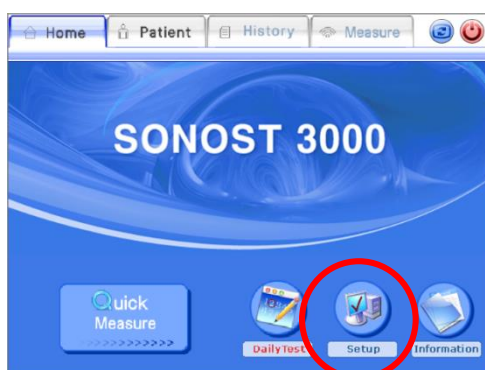
NOTE! Daily Test Recommendation

- The daily test should be performed within operating temperature. (Recommended temperature: 18 ~ 27 °C)
- 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.

3.1.2 daily test procedure

- Phantom's value checking

Switch on the device and the main screen appears after booting up. Select "setup" button to check the value of phantom.



When you see the bottom of the phantom, you can find a label which has two different kinds of label. You should check the contents on the label and below two clauses.

- 1) The values of SOS and the range of BUA are correctly written on Phantom info.
- 2) If you can see 'V0.2' on the right side of label, you have to tick on the '0.2Ver'

check box. If no, you must not check the box. The box should be left blank. (If the values and check box are on the UI are different from what's written on the Phantom, you have to revise it to match the UI with what's on the Phantom.)

Check the Bottom part of label

Label Type	S/N	SOS	BUA	0.2Ver / V0.2
type 1	PxxxxxxxS	1638	34	
type 2	PxxxxxxxS	1638	23	V0.2

□ Phantom's setting

Apply the ultrasound transmission to the phantom to the area which will be in contact with both probes when the phantom is on the foot rest. The amount of gel should be enough to cover the area of the phantom that comes in contact with the probes.



Put the phantom on the foot supporter 1 (don't use foot supporter 2 for Daily Test) in the measuring position of device.

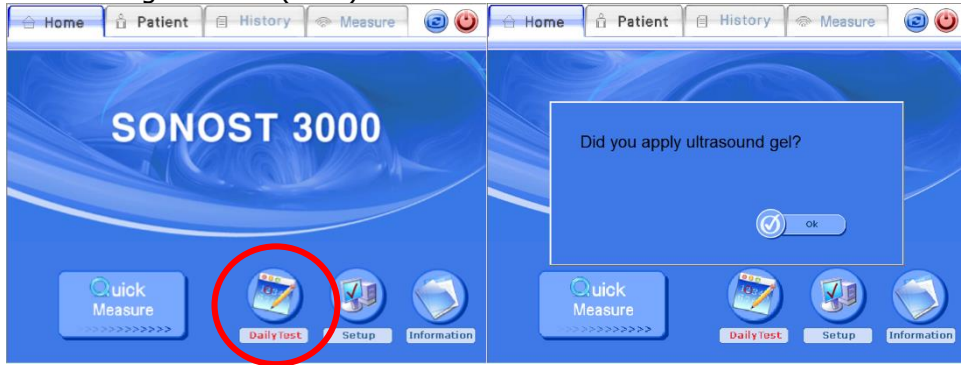


❑ Perform the Daily Test

Press the Daily Test button

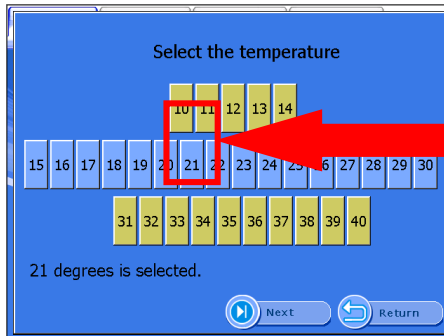
The Daily test should be done if the color of the button is red.

When the daily test is finished, the color of the button will turn back to its original color(blue).



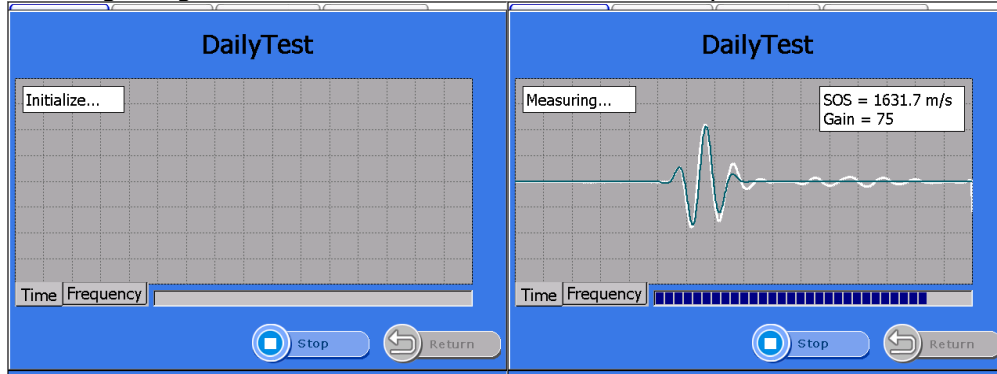
After clicking the daily test button, you will see a message "Did you apply ultrasound gel?" If you have already done so, click "OK".

Select the temperature from the UI after checking the thermo label on the surface of the phantom. Among the two numbers that are highlighted in colors, choose the higher number.

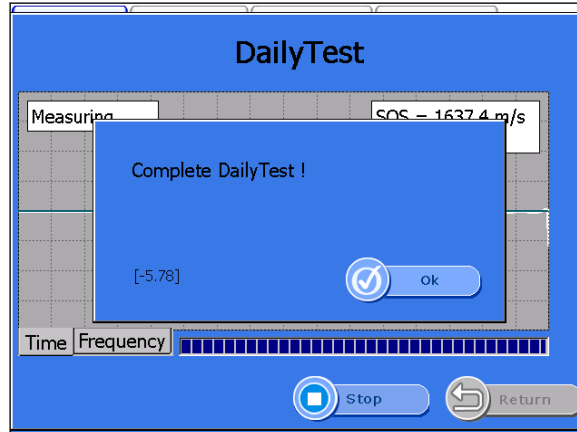


Perform Daily Test by clicking the 'Next' button.

The following images are the execution screen of the daily test.




"Complete Daily Test" appears when the daily test is done. Complete the process of <the daily test> by pushing the "OK" button. You are now able to enter BMD measurement mode and perform a patient test.



3.2 Shutting down processing

The following is the instruction for Shutdown function of the system

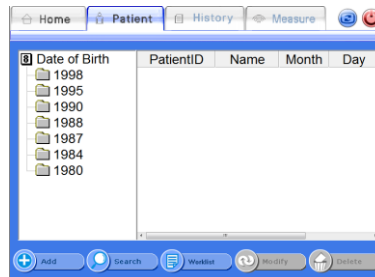
 NOTE !
To avoiding losing data, you should follow our instructions to correctly shut down system.

3.2.1 Position of shutdown

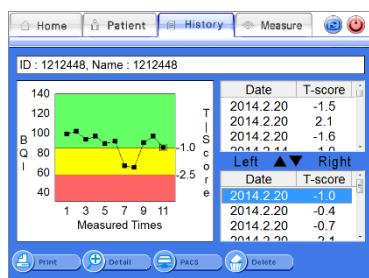
The shutdown button can be found at four different screens.



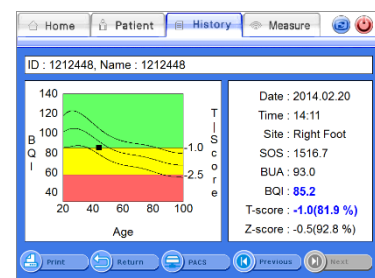
① Main screen



② Patient screen



③ History screen

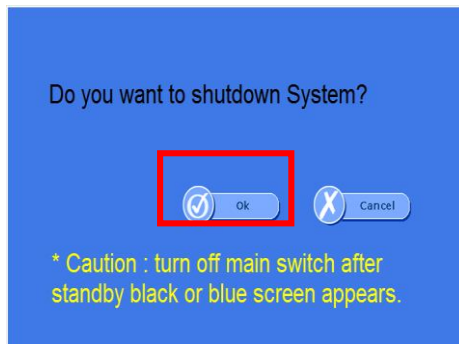


④ History detail screen

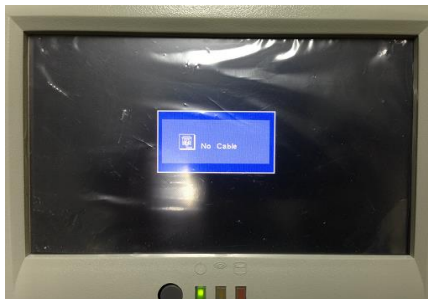
3.2.2 Shutting down processing



Click shutdown button




Click [OK]



Waiting until the black or blue screen appear



Turning off the main switch of the system

	NOTE !
Push the power switch to "0" to power off the machine.	

3.3 The analysis of how to rotate the screen

The procedure of rotate the screen is as below

! NOTE !

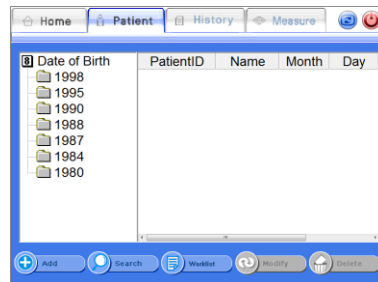
This function is NOT applied to all Sonost 3000 devices. The adopted device will have its serial number starting with AC1TA.

3.3.1 The locations of screen rotation button

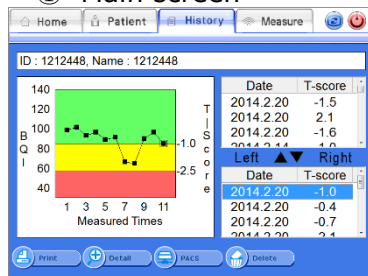
The screen rotation button can be found at four different four different screens



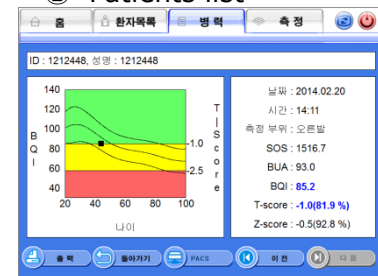
① Main screen



② Patients list



③ Disease history
- standard screen

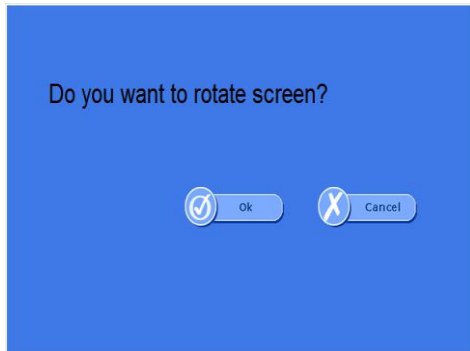


④ Disease history
- detailed screen

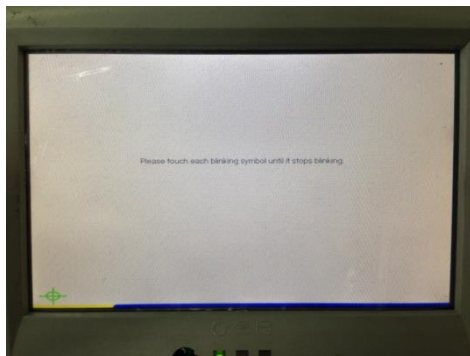
3.3.2 The method and sequence order of the screen rotation button



Press the screen rotation button on the top right side of the screen



Press the "Ok" button



Touch calibration program will be running. And then it will start the calibration. After calibration, the screen will rotate 180 degrees.



If the graphic card does not support, the screen does not rotate and you can see message like left picture.

3.3.3 Patient measurement procedure



Clean the surface of the Coupling Pad with an alcohol pad and apply sufficient gel to probes.

! NOTE !

To remove debris from the probe, clean the surface of the probe with an alcohol pad before use.



Clean both sides of patient's heel with an alcohol pad and apply gel.



Insert patient's foot.

Let a patient move his foot up and down just like this picture.

Start a measurement after insertion and positioning of the patient's foot. Ensure correct Foot Positioner 1 or 2 is used depending on the patient's foot size.

! NOTE !

Insert patient's foot only if the gap between probes is wide enough, because probe pad is made from soft silicon.

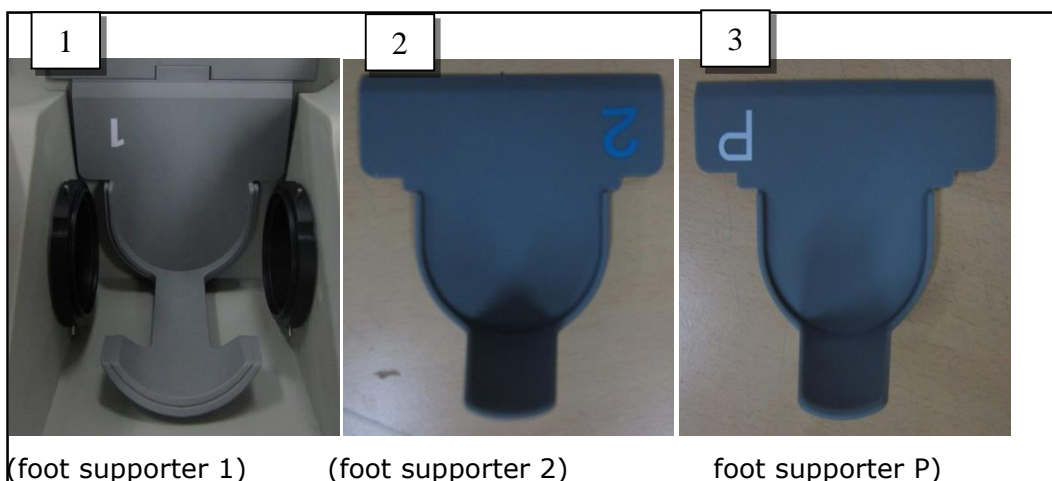
3.3.4 Selection of the foot supporter



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

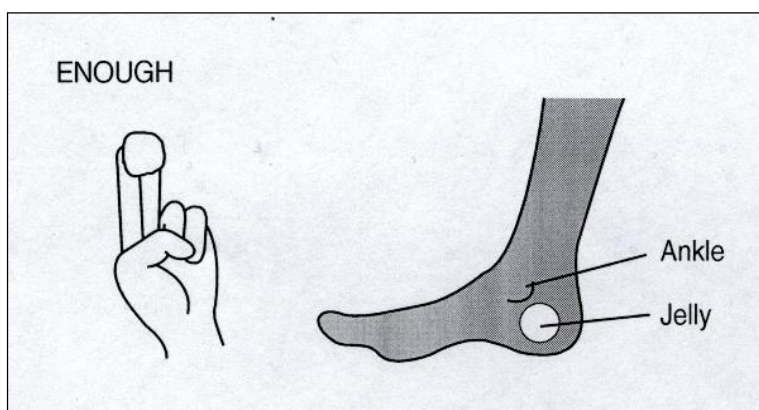
If the foot of patient is belong to

- * Section 1 : use only foot supporter 1.
- * Section 2 : use foot supporter 1 and 2 together.
- * Section P: use foot supporter1, 2and P together.

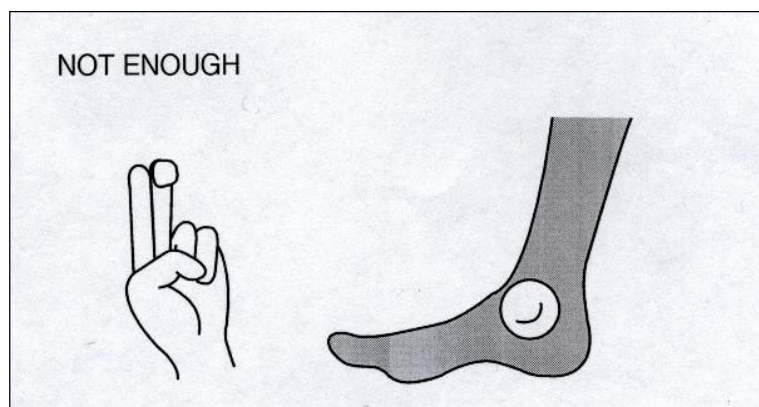


3.3.5 Where and how much to apply to the patient's heel

Before measuring, use alcohol to rub patient's heel. This provides 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

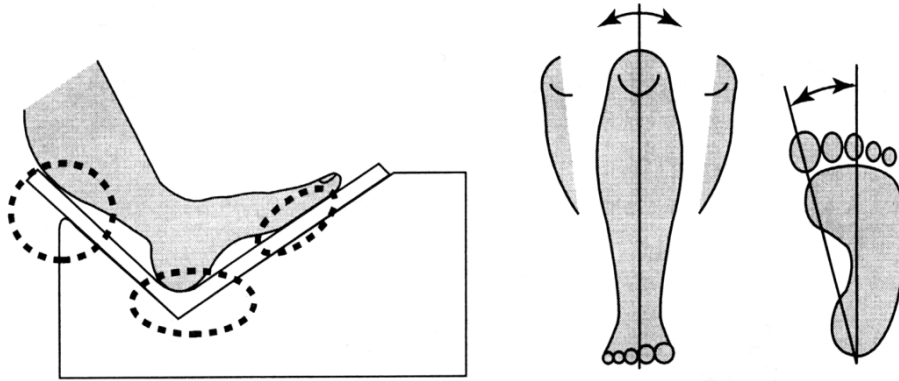
CAUTION !

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

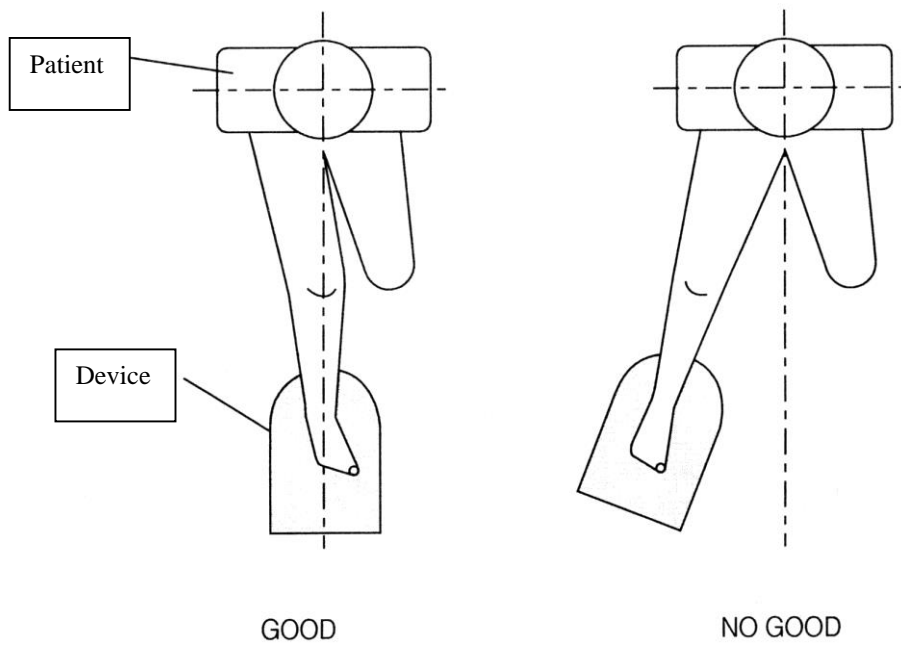
Do not forget to apply the gel before measuring.

3.3.6 Correct position for patient's foot&body

Place heel in the unit as shown in the 3 points below.

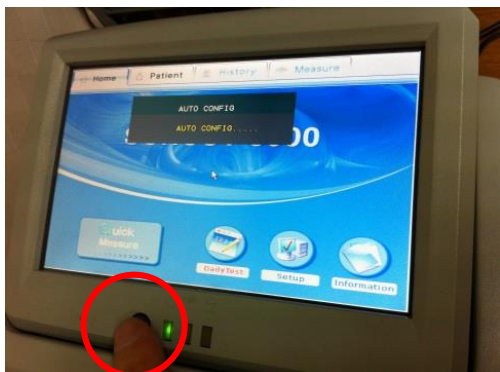


Make sure measuring device and body should be one line as shown below.



3.3.7 OSD (Auto screen alignment)

The size and position of LCD screen is adjusted automatically by pushing the button on the LCD cover.



3.3.8 Setting of internal printer

- Paper type: Thermal paper with 58mm width, and minimum thickness of 0.07mm (About 80 reports are printable with one roll)
- Paper character: Only printable in the outer surface
- Purchasing: Purchase from the manufacturer or from a local agency.

<Paper inserting>

- ① Cover opening: Pull-down and open the dark gray cover on the device's backside



- ② Paper inserting: Insert the paper as shown below. Outer surface of paper should face to the inside of the device. Paper will scroll in




automatically.

- ③ Cover shutting: Put the paper to the gap on the cover, and then shut the cover up.



- ④ Paper cutting: For a sharp outline of report printing, cut off the remained paper once by a saw tooth in the cover.

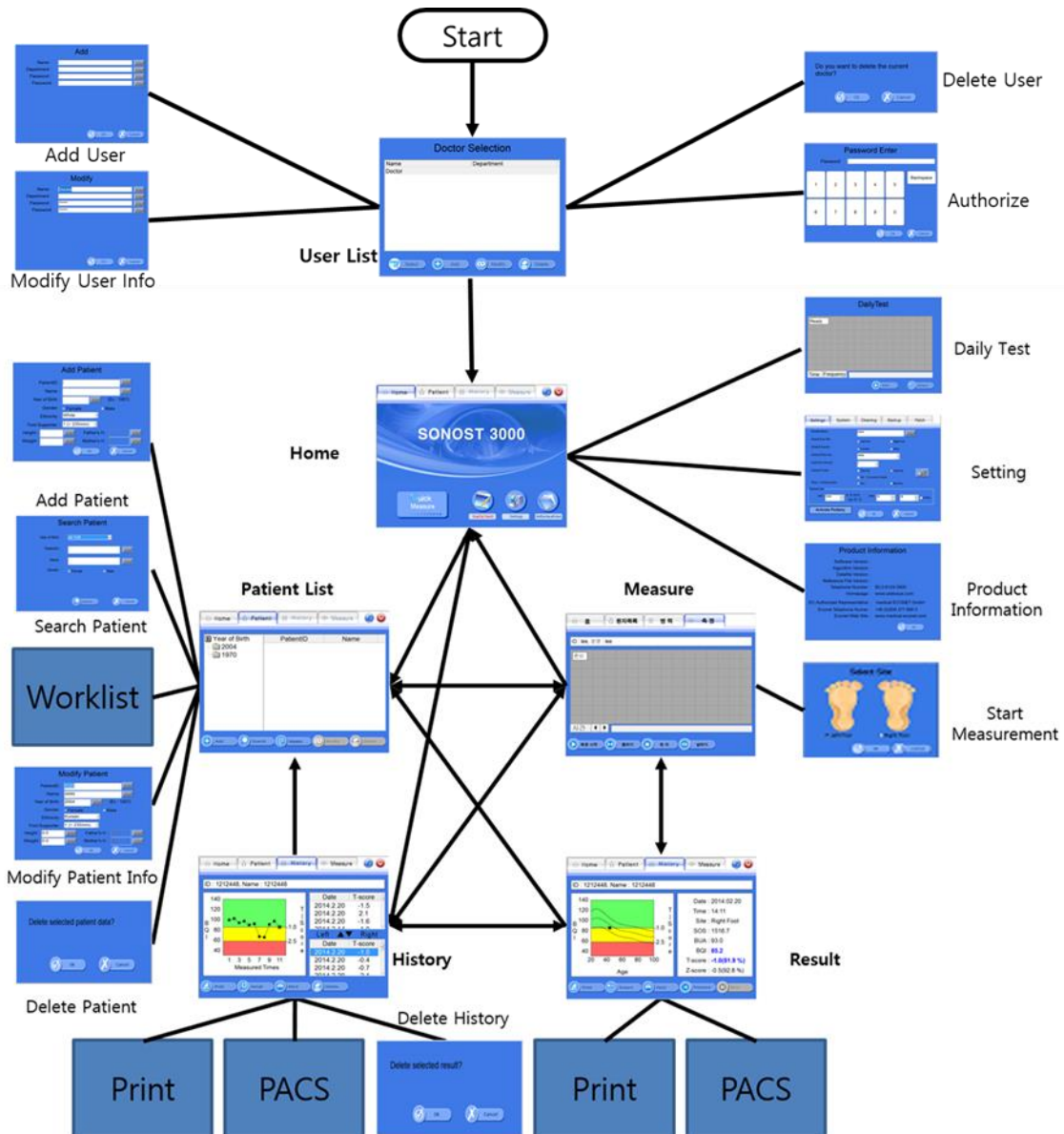



CAUTION !

Do not touch the metal part of the thermal printer head. The hot surface may cause to burn.

3.4 Using S/W

3.4.1 Program Table of program



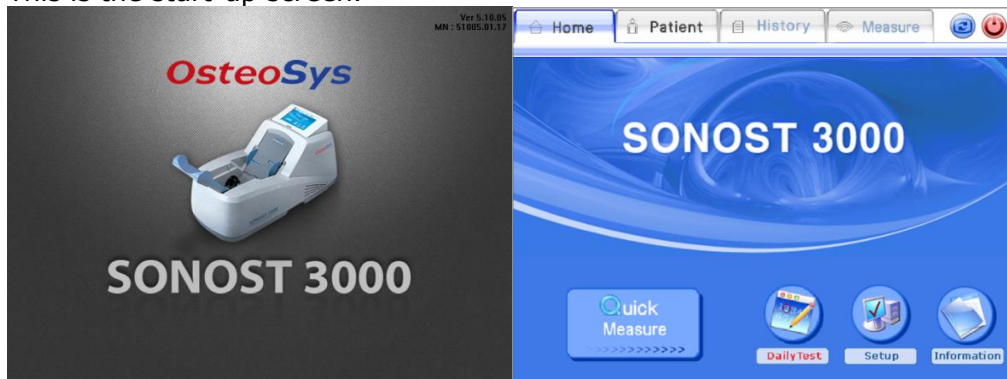
3.4.2 Execution of program

⚠ CAUTION !
If you hear any strange noise from the screen, switch it off and contact to OsteoSys or your local authorized dealer.
NOTE !
<u>When the device is powered on, the power LED turns green.</u>

Turn on the power switch and power LED is turn on green.

15 seconds after splash screen that checks functions of the system and memory device, the program is automatically activated and you should configure the settings.

This is the start-up screen.



Home of the startup screen

The four main menus sits on the top of the home screen. Use them to switch between differ modes.

The bottom line consists of sub-menus. They are for sub-functions

- Quick Measure : Direct measuring function without patient registration process.
- DailyTest : Daily test function.
When the daily test is required, the color of button turns red.
When not needed, the color of button stays as it is in blue.
- Setup : Consists of functions which are related to program settings.

- Information : Display information about the program and device.

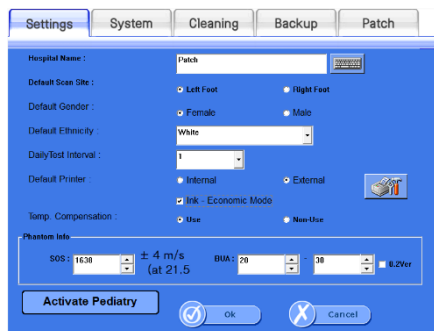
3.4.3 Setting of the incipient environment

Click the <Setup> button on the Home Screen, then environment window appears.

<'Set up' Window>


- <Settings> : Fundamental settings related to the software.
- <System> : Settings related to Operating System.
- <Cleaning> : Manually set the probes to move for the user's to clean the probes.
- <Backup> : Control of measured data.
- <Patch> : Software upgrade.

- ① Settings: Change fundamental settings related to the software.



<Setup>Settings Window


- Hospital Name : Insert the hospital name which will be printed on the report.
- Default Scan Site : Select the default scan site when performing a measurement.
- Default Gender : Choose the default gender when registering a new patient.
- Default Ethnicity : Choose the default ethnicity when registering a new patient.
- DailyTestInterval : Fix the interval of Daily Test
- Default Printer : Choose the default between the internal thermal printer or an externally connected printer.
- Print Graph : Choose whether or not to print the graph when printing using the internal printer
- Ink-Economic : Choose the Ink-Economic mode when using an external printer.

-  : Setup printer.
- Temp. Compensation: To choose the temperature compensation function when Performing Daily Test.
- Phantom Info : the values on the bottom label on the phantom.
- Check version of phantom whether it is 0.2ver or not.
- Activate Peditry(Activate BMD) : To switch the mode of BMD and Peditry.
- ② System: It makes settings related to the Operating System.



<Setup>System Window

- System Date/ Time: Present time setting. It becomes the standard time for all patients registered date, measured date and printed date. Set the time and click the <Save> icon on the right.
- Language : The language can be changed in the language settings.
- Touch Panel calibration: It is used when the touch panel is out of order.
Read the screen message carefully, then press the arrow indicated points precisely.
- Storage Server: If you would like to send images through PACS, you should input information. You have to get your own IP address and port from the hospital to connect to a storage server to fill in the information. (You should request for server information to a person in charge at your hospital.)
- Worklist Server: The Worklist input field is used to import subjects registered in the server. You have to get own IP address and port from the hospital to connect worklist server and then input these things exactly. Moreover, in terms of Worklist, you must input correctly due to patients are classified by Modality.

you can find 3.4.1  e explained more detail things.

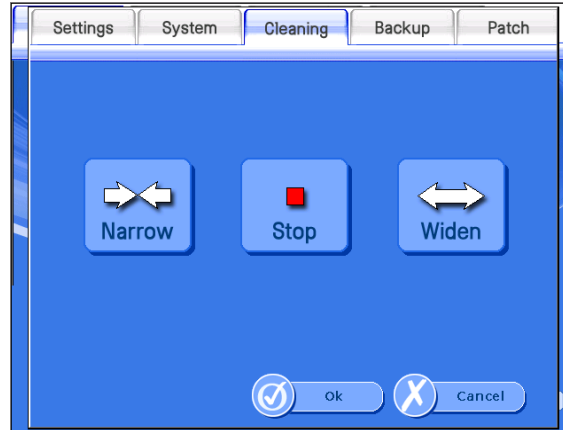
- Query: You should input some conditions from which you can get information about patients from the worklist server. When you input modality in Query it should be the same as the modality in worklist server. You can choose which is today, week(7days before), weeks(14days before), month(30days before) from Query .It is based on the system date server. It can show person's information which is someone checking through this device.

 **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.

We support several languages. Contact Osteosys if you need to make changes or select your language using language option.

- ③ **Cleaning:** It makes probes to manually move for the user to clean them.



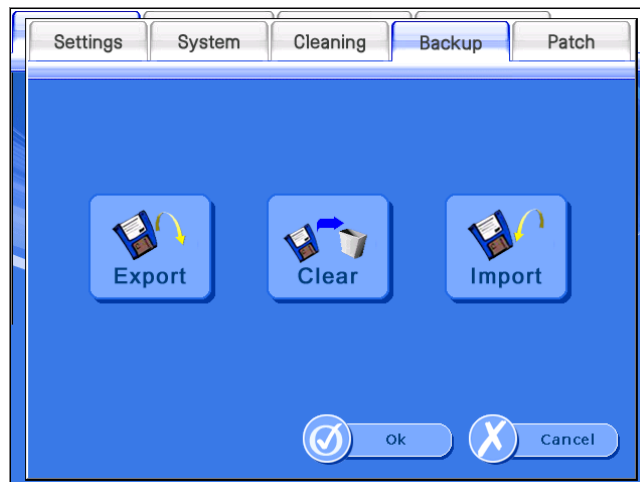
<Setup>Cleaning Window

- Narrow : the interval between the two probes becomes narrow.
- Stop : the probes stop moving
- Widen : the interval between the two probes widens.

- ④ Backup.

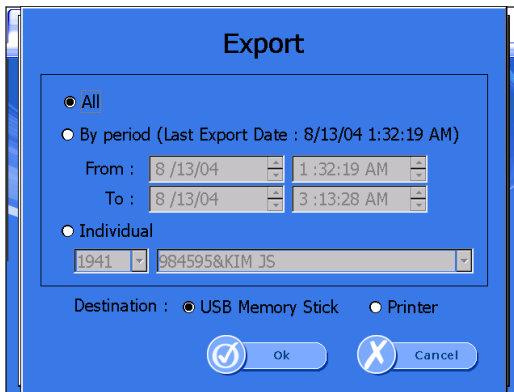
It controls the measured data.

※ If a USB memory has many files and folders inside, the speed of recognition of the USB memory can be slow. Connect an empty USB memory.



<Setup>Backup Window

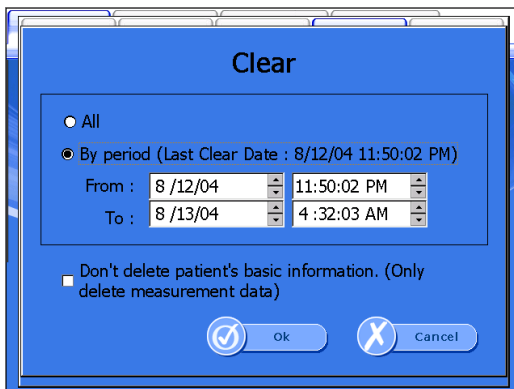
- **Export** : If you click this button, you can export data to a USB memory stick or an external printer.



<Setup>Backup>Export Window

- All : Export all data.
- By period : Export data within a selected period of time.
- Individual : Export selected patient's data.
- Destination : You can select USB Memory Stick or Printer.
(But, If you select 'Individual', Printer cannot be selected.)

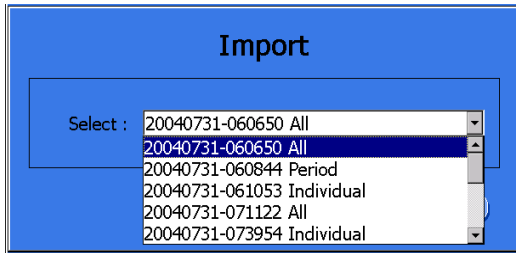
- Clear : If you click this button, you can clear data.



Setup>Backup>Clear Window

- All : Clear all data.
- By period : Clear data within a selected period of time.

- Import : If you click this button, you can import the once exported data.



Setup>Backup>Import Window

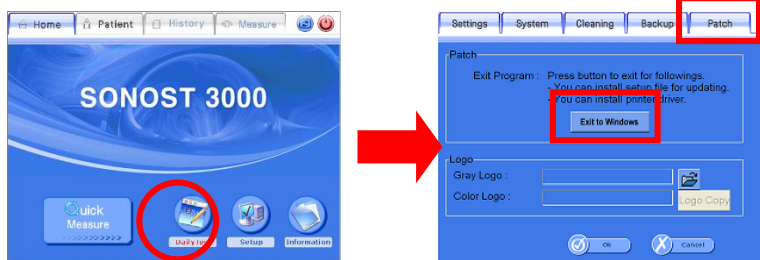
⑤ Patch

It is an upgrade of the Software.

First, Prepare a USB removable disk which supports USB 2.0. You can use mp3 player or digital camera as well. Copy the setup file (file name : setup.exe) to USB removable disk.

Insert USB removable disk into SONOST 3000 device's USB port.

Select [Setup>Patch>Exit to Windows] to close the program.



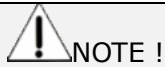
Execute the setup.exe in the setup folder of the USB memory stick.

Choose remove to delete former installed program.

After removing, execute the setup.exe file for installation again.

Restart SONOST 3000.


You can confirm by seeing software information at Home>Information.



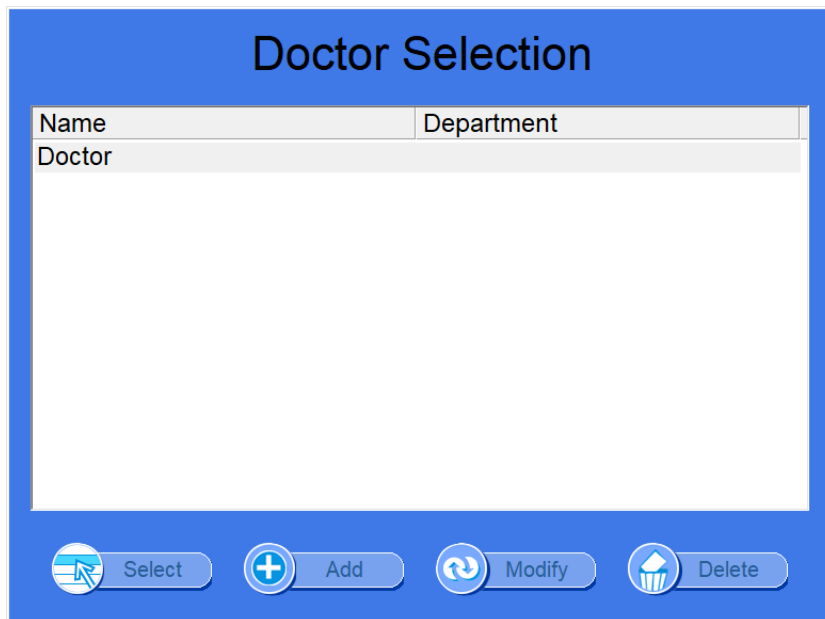
NOTE !

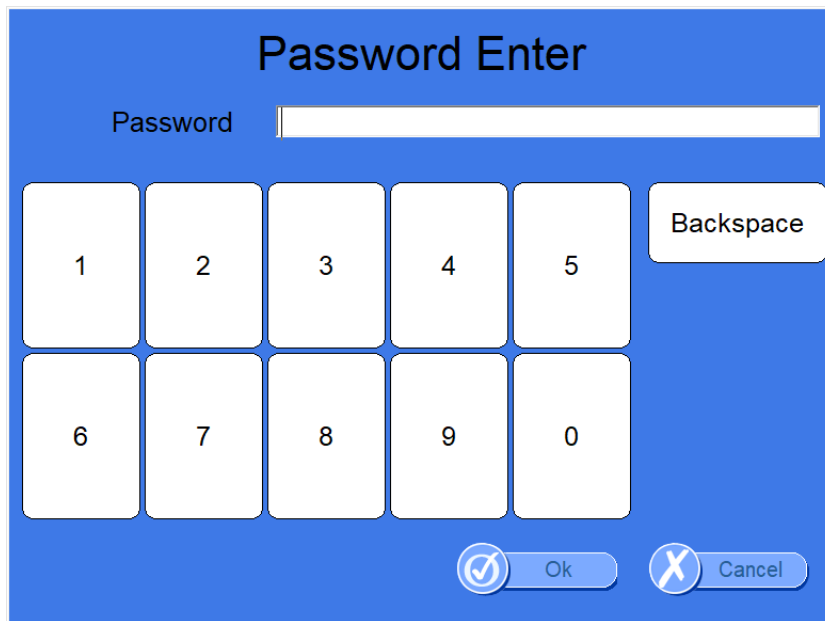
During patch, if you turn off device or take out the USB removable, There may be critical problem to the system.

3.4.4 Registration, Modification & Deletion of users


 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 "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.



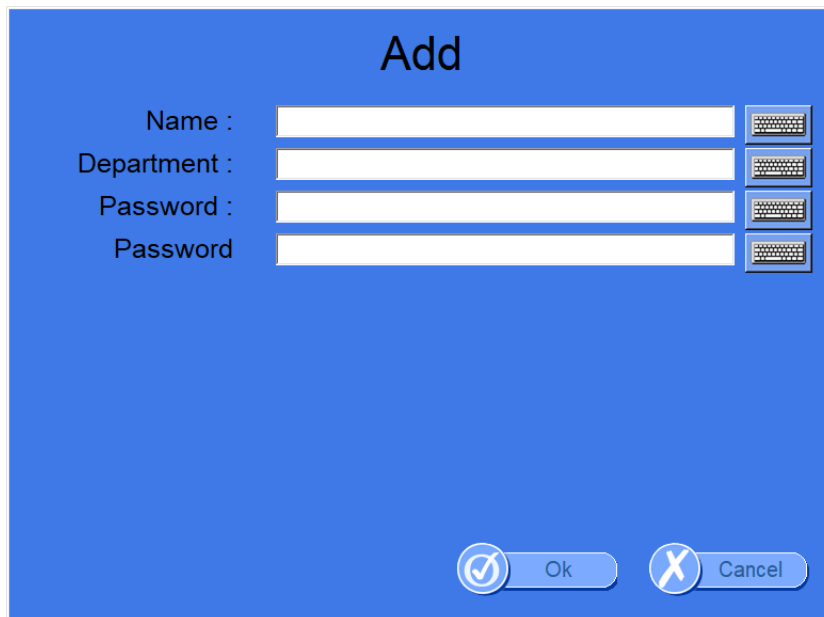


The image shows a blue rectangular dialog box titled "Password Enter". At the top, the text "Password" is followed by a white input field. Below the input field is a numeric keypad with two rows of buttons: the first row contains buttons for digits 1, 2, 3, 4, and 5; the second row contains buttons for digits 6, 7, 8, 9, and 0. To the right of the keypad is a "Backspace" button. At the bottom right of the dialog box are two buttons: "Ok" with a checkmark icon and "Cancel" with an 'X' icon.

 NOTE !

After login, it is automatically locked for 15 minutes after the last touch.

- (2) If you are a new user(doctor), click the "Add" button in the "Doctor Selection" window, and then the "Add" window appears. If you enter your information(name, department and password) and click the "OK" button, the registration process is completed. The log-in process is same as the description "(1)"



The image shows a blue dialog box titled "Add". It contains four input fields: "Name", "Department", "Password", and "Password". Each field has a small keyboard icon to its right. At the bottom of the dialog box, there are two buttons: "Ok" with a checkmark icon and "Cancel" with an 'X' icon.

- (3) If you want to modify registered users, select a desired user and click "Modify" from the "Doctor Selection" window. Enter the password in the edit box from "Password Enter" window and click "OK" to modify details of the user.

Password Enter

Password

1 2 3 4 5

6 7 8 9 0

Backspace

Ok Cancel

Modify

Name :

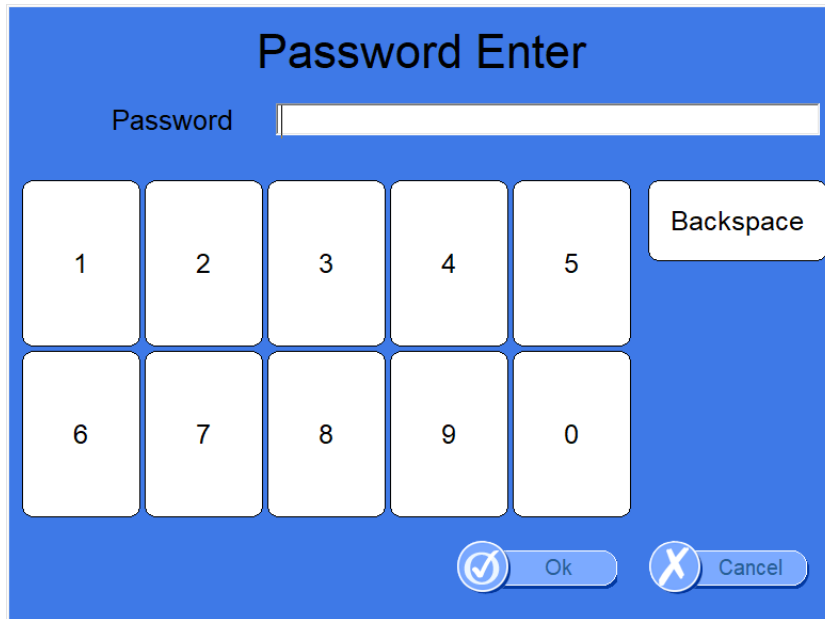
Department :

Password :

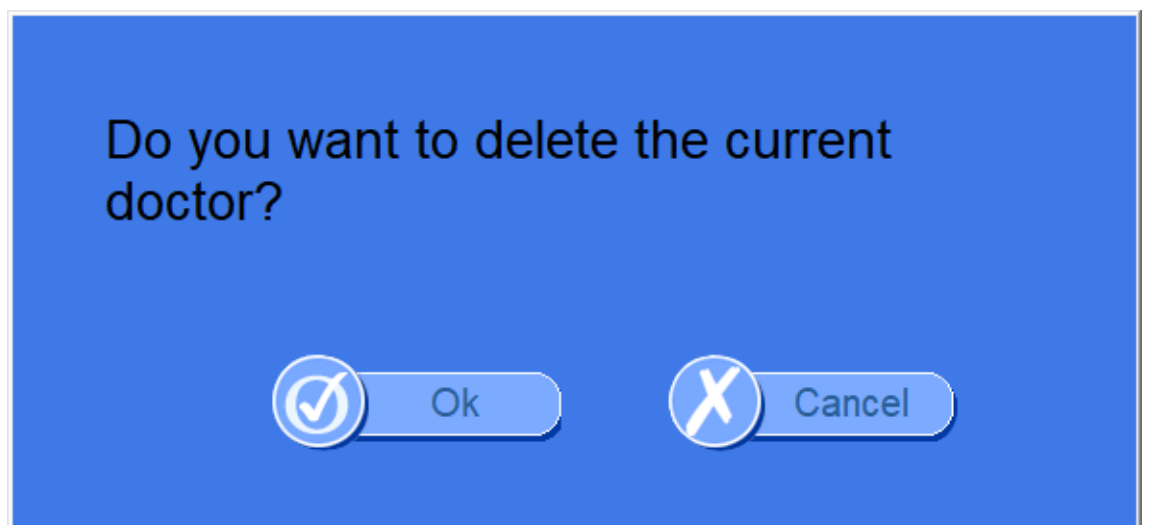
Password :

Ok Cancel


- (4) If you want to delete registered users, select a desired user and click "Delete" from the "Doctor Selection" window. Enter the password in the edit box from the "Password Enter" window and click "OK" to delete the user.



- (5) Upon clicking "OK" you will be asked to again if you want to delete the selected user. Select "OK" or "Cancel", and choosing "OK" will delete the user and its information.



3.4.5 Measurement of Bone Mineral Density

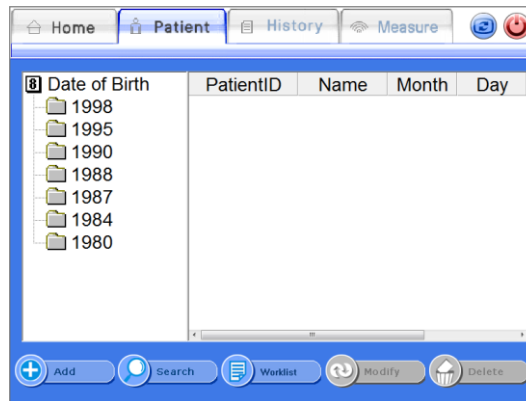
 **NOTE !**

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

<Patient Registration>

If you click <patient> from the top menu, you will be directed to "Patient List" which displays and allows you to manage all the registered patients.

The list on the left indicates the year of birth for registered patients. If you click a year, you can see the patients IDs and names who belong to the selected year of birth.



Patient List Window

If you want to register a new patient, click <Add> from the bottom menu. Then "Add Patient" window is displayed for you to insert the patient's information.

If you insert and click <Ok>, then the patient is registered and displayed on the screen.

Add Patient

PatientID :

Name :

Year of Birth : (Ex : 1957)

Gender : Female Male

Ethnicity :

Foot Supporter :

Height : Father's H. :

Weight : Mother's H. :

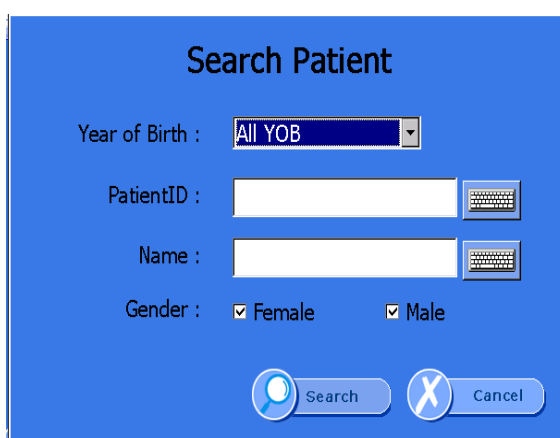
Add Patient Window

- PatientID : Insert the ID which can identify the patient.(64 characters are MAX)

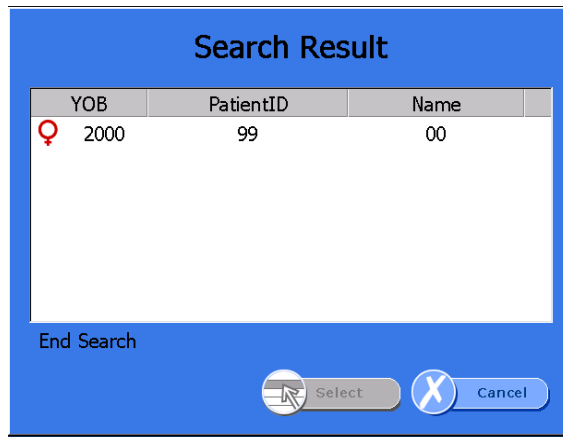
- Name : Insert the patient's name. (64 characters are MAX)
- Year of Birth : Insert the patient's year of birth.
- Gender : Insert the patient's gender.
- Ethnicity : Insert the patient's ethnicity.
- Foot Supporter : Choose the Foot Supporter according to the foot size of the patient.
- Height : Input the height of the patient.
- Weight : Input the weight of the patient.
- Father's H. : Input the height of the patient's father. (It is disabled on BMD mode)
- Mother's H. : Input the height of the patient's mother.(It is disabled on BMD mode)

<Patient Search>

If you want to search for a registered patient, click <Search> from the bottom menu. On the "Search Patient" window, you can use patient's ID, name, gender and the year of birth to find a patient. Click <Ok> to find results searched.



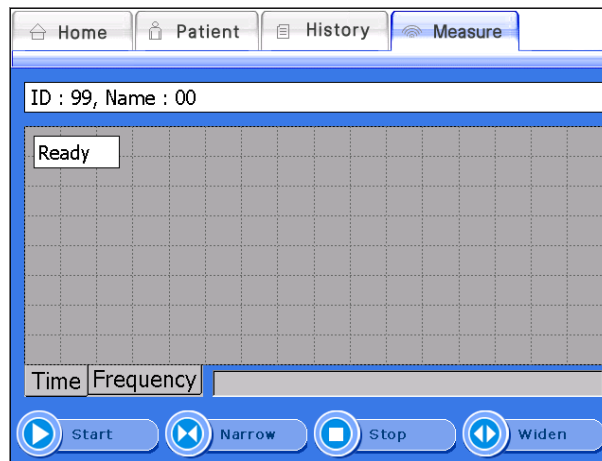
Search Patient Window



Search Result Window

<Measurement of Patients>

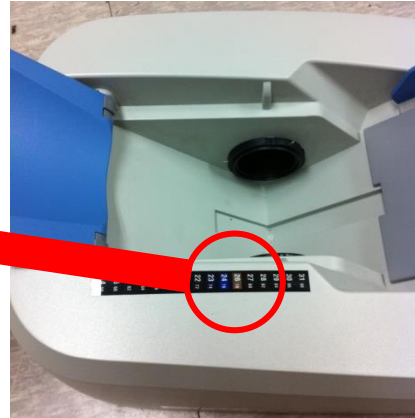
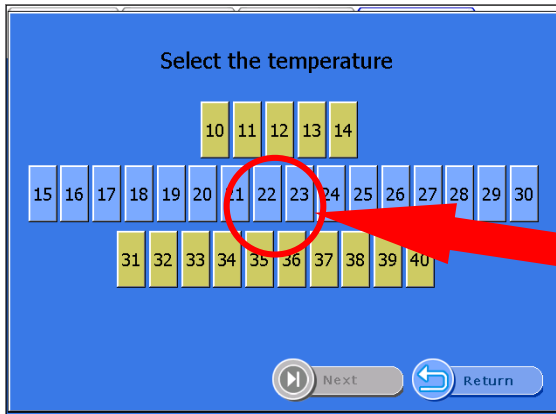
If you want to measure the patient's Bone Density, select a desired patient in the Patient List screen and click <Measure>. Then the "Measure" screen appears as shown below.



Measure Screen

Click <Start> from the bottom menus and you will find a chart for selecting the temperature. Select the temperature that matches temperature on the thermos label attached to the surface of the device. (Choose the highest number among those colored on the thermo label)

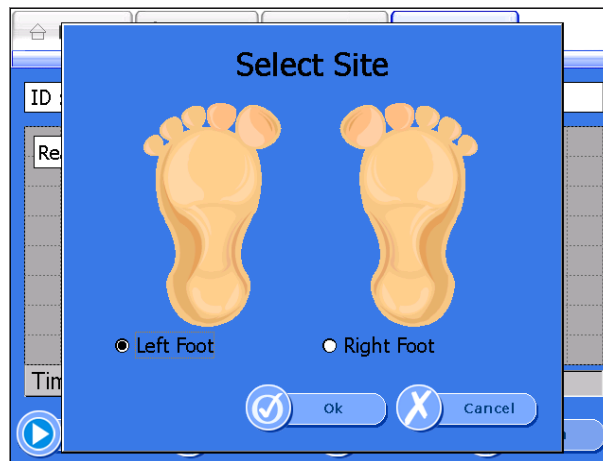
※If you select the option of non-use Temperature Compensation, the temperature dialog box will not be displayed.



Temperature screen

Click <Next> to select the scan site of the foot and click <OK>.

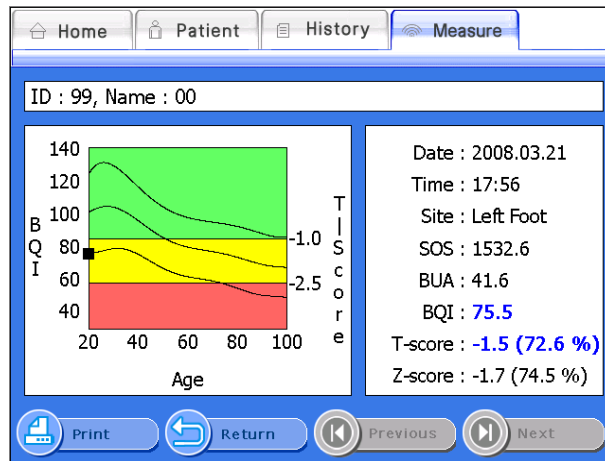
Ultrasound waves are generated from the probes.



Select Site Window

When ultrasound waves are being generated, the <Start>button will change to <Stop>button. In case of emergency, click <Stop>, and you can stop the measurement in progress. In normal conditions, the generation of ultrasound waves is finished in about 15 seconds, then the "Measure Complete" window will be displayed with a notification sound.

When you click <Ok>, the detailed results are displayed as shown below.



Detailed results screen.

Click <Print> on the bottom of results screen, then the report is printed.



3.4.8 Printing of clinical history and Result

3.4.6 Modification and Deletion of patient's information

① Modification of patient's information

If you want to edit registered patients' information, select a desired patient and click <Modify> from the bottom menu.

Then the "Modify Patient" screen appears as shown below. Change details of the patient followed by clicking <OK> to save the changes.

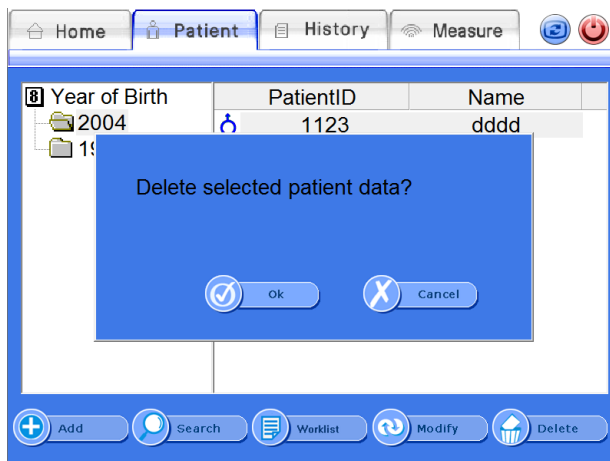
The screenshot shows a 'Modify Patient' window with a blue background. It contains several input fields and controls: 'PatientID' (08141009), 'Name' (cymls), 'Date of Birth' (1998/08/14) with an example '(Ex:1980/09/07)', 'Gender' (radio buttons for Female and Male), 'Ethnicity' (dropdown menu showing Korean), 'Foot Supporter' (dropdown menu showing 1 (> 235mm)), 'Height' (167.0), 'Weight' (45.0), 'Father's H.' (0.0), and 'Mother's H.' (0.0). At the bottom are 'ok' and 'Cancel' buttons.

Modify Patient Window

② Deletion of patient's information

If you want to delete registered patients' information, select a desired patient in the "Patient List" screen and click <Delete> from the bottom menus.

You will then be asked again "Delete selected patient data?", and selecting <OK> will delete the selected patient.



Delete Patient Window

③ Worklist

If you click <Worklist> from the bottom menus of the Patient list, the list will be updated to the latest, depending on patients that are already registered on the worklist server. Once selecting <worklist> button, the remaining four buttons will be greyed and become inactive status aside from the <worklist> button. If you click <worklist> again, it will go back to the previous <worklist> status.

Date of Birth	PatientID	Name	Month	Day
1998	♀ 14082701	140827...	9	7
1995	♀ 14082702	dykim	9	12
1990	♂ 14082703	140827...	50	21
1988	♀ 14082704	140827...	6	23
1987	♀ 14082705	140827...	5	24
1984				
1980				

The result of requested worklist from system

Worklist - Giving a test to someone who is already registered on the system. After selection of a patient from the list, you can take a test or see the disease history

From <Disease history> or <Test> tab. (If someone already registered on the system

And yet they do not have any disease history, the system will show an error message).

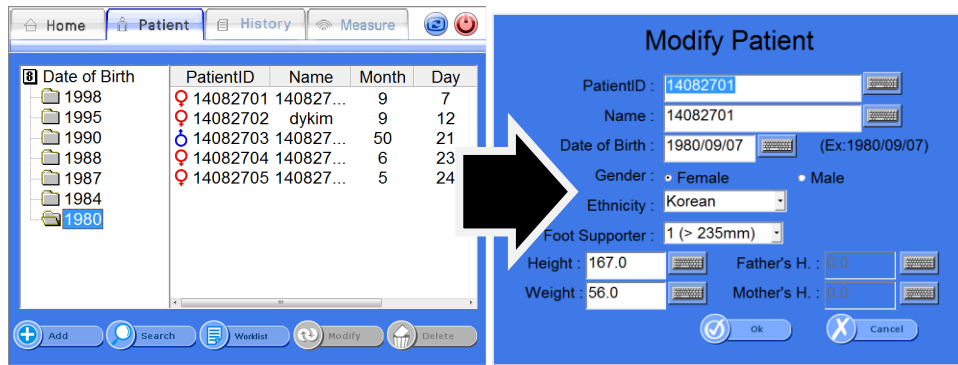
Worklist - Giving a test to someone who is not registered yet on the system. If someone is not registered yet, you can list on the system after clicking <Test> button.

※When worklist server is active, other buttons such as <save>, <find>, <modifi-

cation> and <Deletion>, will be greyed out and turn inactive. Therefore, if you would

like to give a test to a patient, you should select the person who will have a test,

and then click the <test> button on the screen. The device will start the test.

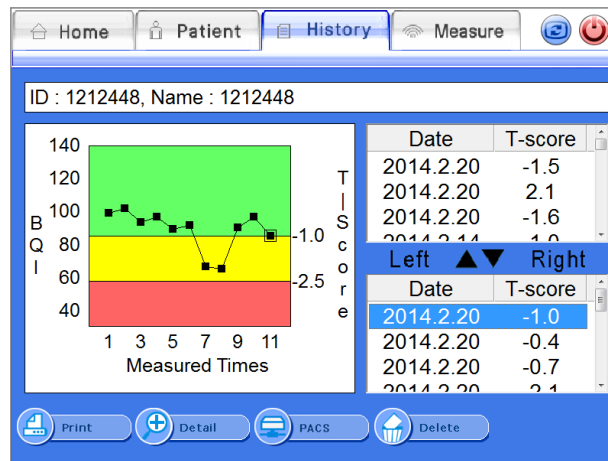


3.4.7 Inquiry and deletion of clinical history of existing patients

① Inquiry of Clinical History of Existing Patients

If you want to retrieve the clinical history of existing patients, select a desired patient and click <History> from the top menus on the "Patient List" screen.

Then "History List" screen appears that contains the patient's clinical history as shown below. On the right side, the list of results of left and right foot's measurement is displayed. If you select a measurement result from the list, the relevant clinical history will be displayed with a graph on the left side of the window.



History List Screen

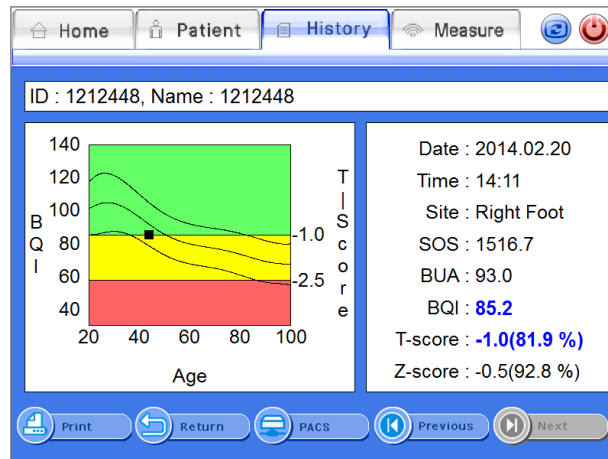
On the lower part of screen, you can see <PACS> button. When you press the <PACS> button, the result will be sent to the server.

② Detailed Representation of Clinical History of Existing Patients

If you click the <Detail>button on the "History List" screen, the detailed result of the selected patient appears in the full screen.

NOTE !

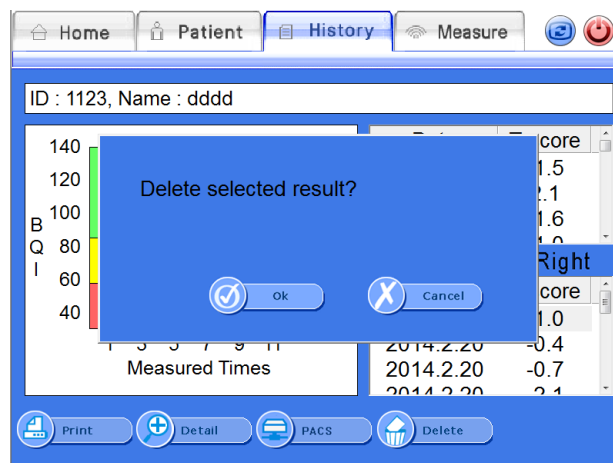
Click the History icon to view patient information.



Detailed Result Screen

③ Deletion of Clinical History of Existing Patients

If you want to delete the clinical result of patients, select a desired result and click the <Delete>button on the bottom of the result screen. Then the message box "Delete History?" will be displayed to confirm the deletion. Click <OK> to delete.



Delete Patient Window

3.4.8 Daily test of SONOST 3000

Daily test

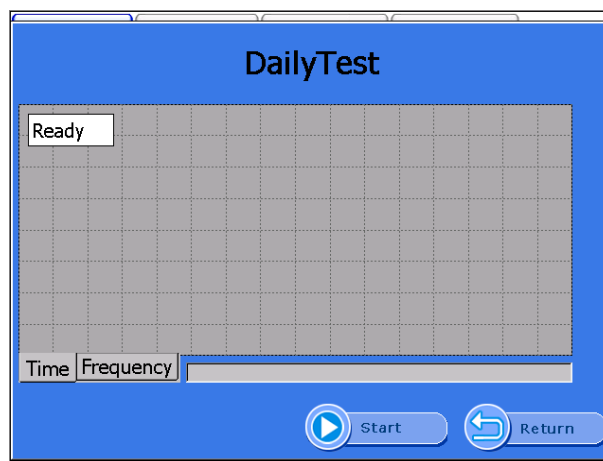
Make sure to calibrate the system to reduce a margin of error and to get accurate value in times of examining bone density. It is to raise credibility of examination results through checking of system reliability on a daily basis.

To calibrate the system, click the <DailyTest>button in the "Home" screen.

Then the "DailyTest" screen appears as shown below. When you click the <Start DailyTest>button, DailyTest is started. If the DailyTest is successful, the message box "Complete Dailytest" appears. Press "OK" to return to "Home" screen.

If you select the "Time" tap, a graph appears in the time domain.

If you select the "Frequency" tap, graph appears in the frequency domain.

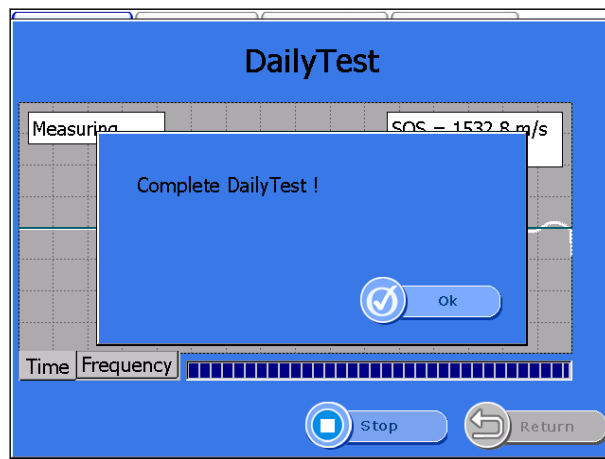


DailyTest Screen



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

If you input the temperature and then click the <Start>button on the bottom, ultrasonic waves are generated and the <Start> button will be changed to <Stop>. In case of emergency, click this button and you can stop the daily test in progress. In normal conditions, the message box "Complete Daily Test" appears as shown below with an alarm sound after progressing calibration of the system and if you click<OK>button, the calibration is complete.



 **NOTE !**

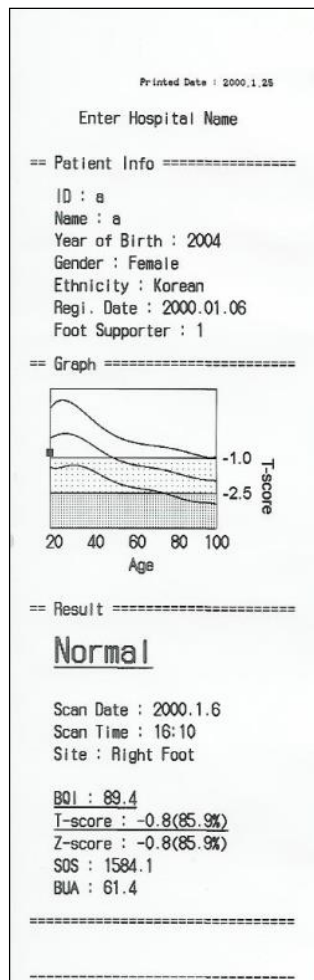
In case of Daily Test failure, do not use the system and execute "DailyTest" once again. If calibration fails continuously, contact to OsteoSys or your local authorized dealer.

3.4.9 Printing of clinical history result

SONOST 3000 supports using the inner printer (thermal printer) and external printer (normal USB printer). (If the selected model is exclusive use of external printer. The inner printer will not be provided.)

Inner Printer (Thermal Printer)

Inner printer is affixed to the rear of the system inside. You can use the inner printer without any software settings.

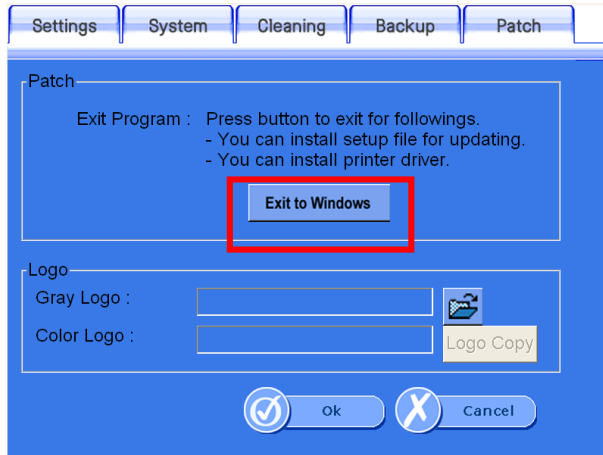


Printed result paper

<External Printer (Normal Printer)>

Available printer : All USB printer supporting Windows XP driver.

For the installation of printer driver, exit program (Setup > Patch > Exit to Windows)

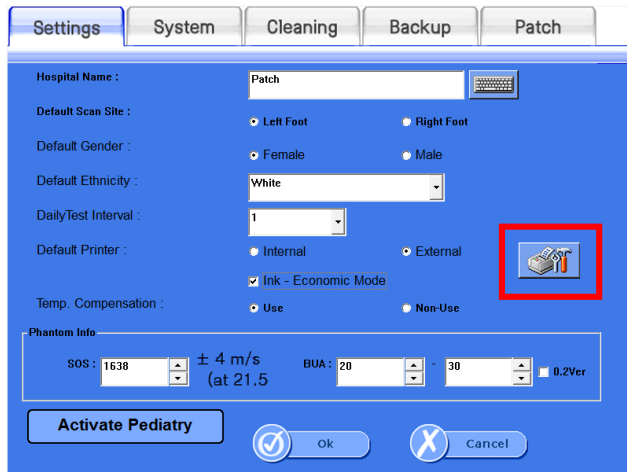


Copy the printer driver to USB memory stick.

Connect the USB memory stick to USB port on the back of device.

Execute the setup file of driver on the memory stick.

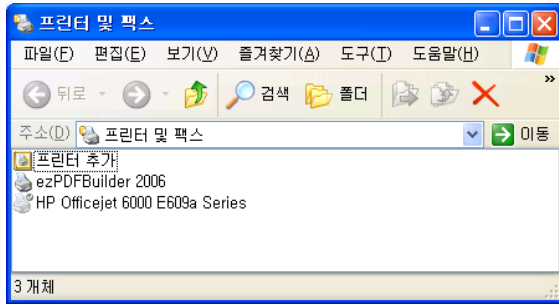
After installation is complete, reboot device.



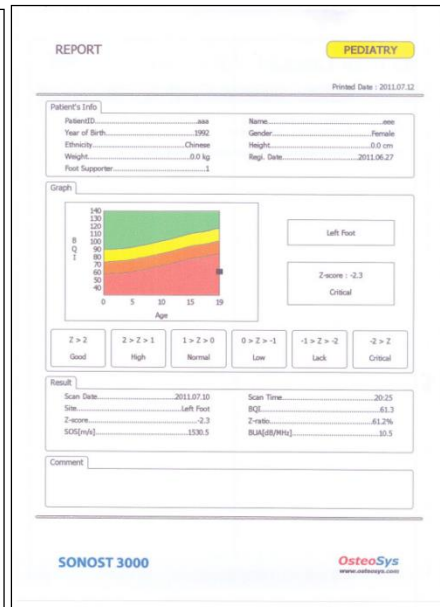
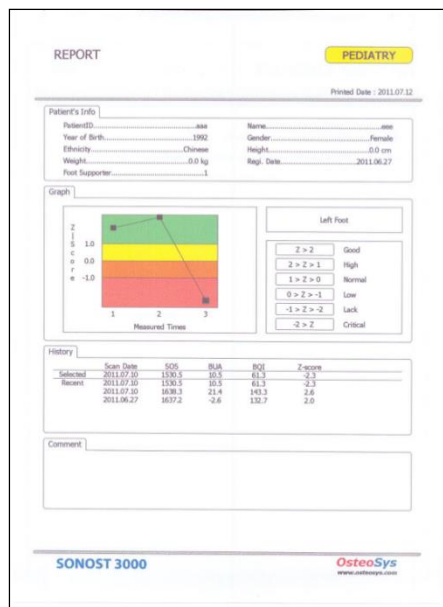
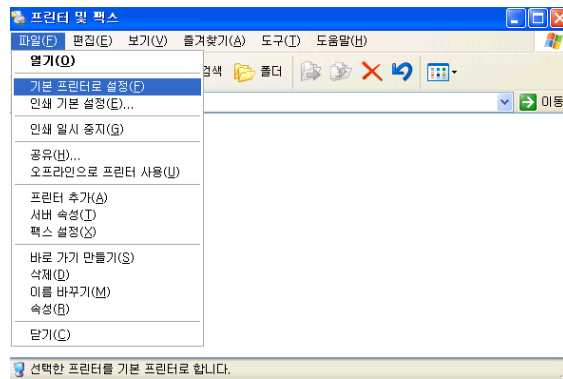
Select External and then click the icon of printer setting.

You can find the installed printer above and check if it's set as a default printer

(default printer : printer with checked mark)



If you want to change the default printer, select the printer and then choose [File] – [default printer] on the top menu.



Printed Paper

3.4.10 Customize the logo

Make the bitmap files for the color printing and gray printing as 272 px X 70 px X 24 bit.



Give the name and extension name to bmp (ex: NHIC_C.bmp, NHIC_G.bmp)

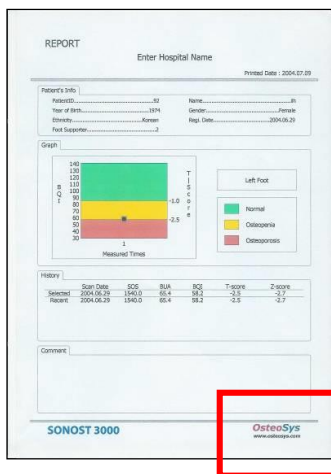
Copy the files to the USB memory stick and connect to the device.

Push the folder shaped button and select the image file for color and gray sequentially.

Push the button of Logo Copy



The logo on the bottom of printed paper is changed.



3.4.11 Setup the worklist

Connect to worklist

In terms of Worklist, it makes database from people who checked BMD using the device. This database is saved in the hospital server. Later, you can get this information from the PC connected to the server. The information cannot be changed on a local PC.

Set up User Interface in Worklist

At the beginning of SONOST 3000 program, you should press the <set up> button, and then navigate to <System>

Storage Server	Worklist Server	Query
IP 192.168.20.174	IP 1 192.168.20.174	Modality DX
Port 3000	Port 2 3000	Date <input type="radio"/> Today <input checked="" type="radio"/> A week <input type="radio"/> Weeks <input type="radio"/> A month
Remote ATitle DX	Remote ATitle 3 PACSSERVER	
Local ATitle PACSSERVER	Local ATitle 4 SONOST3000	
	Modality 5 DX	

You should get information from someone in charge of the server, the manager of OCS in hospital.

- Worklist IP → 1
 - Port number → 2
 - Remote ATitle → 3
 - Local ATitle → 4
 - Modality → 5
- Local A-title in SONOST 3000 means SONOST 3000, you should tell the manager of OCS. It cannot be changed.
 - Modality is basically "DX", it can be changed.

- You should input modality in Query which is next to set up of Worklist server. Next, you should choose date on the person.
- When you finish input server and Query, press the "confirm" button.
- Move on to "List of patients", you can use worklist which reference from '3.4.6'

3.4.12 Setup and sending function of PACS

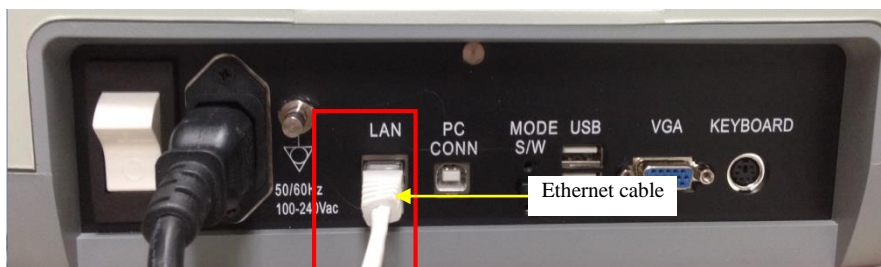
PACS requirements

- USB Ethernet Adapter
- You should get specification IP, Serve net mask, basic gateway from hospital network.
- PACS server IP and Port (Hospital already has information about PACS server)
- Remote A-Title(You should ask the manager of PACS in hospital)

How to connect to PACS

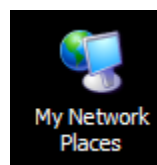
- Connect of Device

Connect the Ethernet cable to the LAN port on the back of the device.



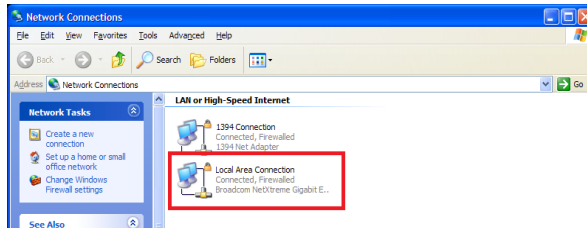
- Network set up

You can see 'My Network Places' on the screen. Select this item and right click your mouse and select "properties".

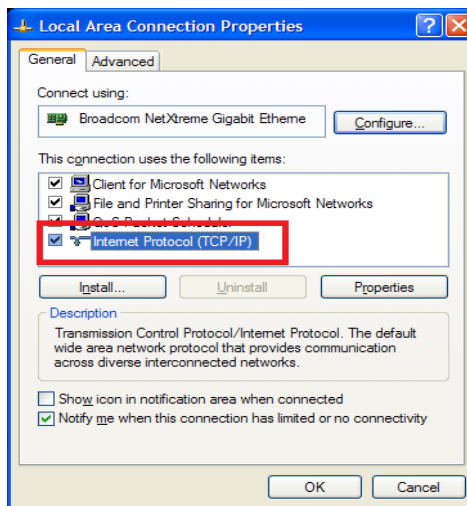


- Setup of the LAN Card

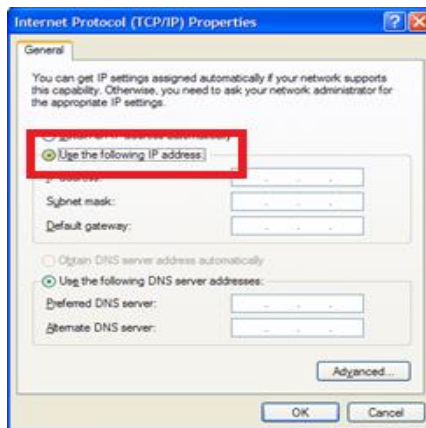
When you set up LAN card, you should turn on the device.



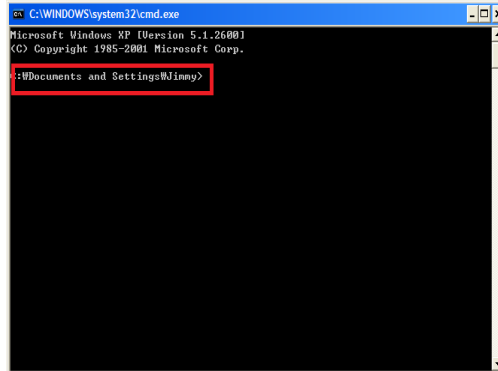
When you connect to PACS network in hospital, you should choose Local area. Next, right click your mouse and select 'properties'. From the Properties, you should choose Internet Protocol(TCP/IP) and click the 'properties' underneath.



You should input IP address, serve net mask, gateway for connect PACS server. After that, press the 'confirm' button.



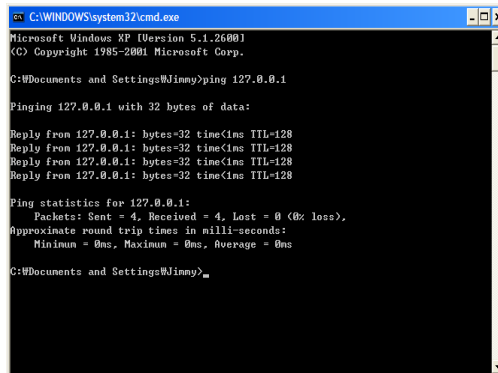
You should press the start and command button for connect to PACS server in the hospital. When Command board appeared, you should input CMD. Next, you can see DOS mode.



You should input IP address for connect to PACS

For instance) C:\>ping 192.168.20.3

You should input IP address(192.168.20.3) which you get from the hospital.



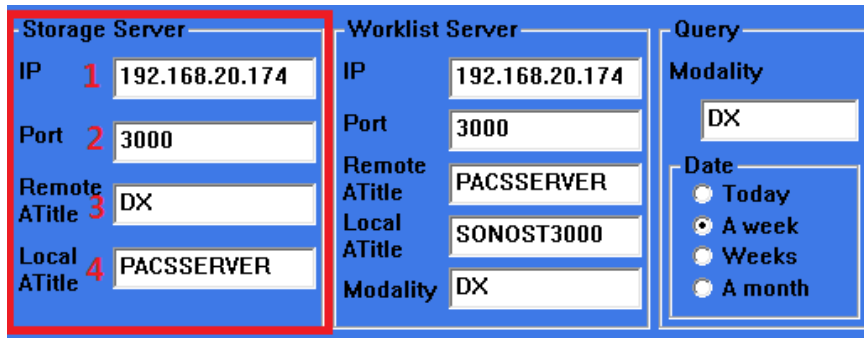
When you input command, you can see information which related to connection

You can see 'Reply from (IP address): byte=32 time=128' message 4times and

If you get 'Packet : Send = 4, Receive = 4' message, it is a normal sign.

Running SONOST 3000 user program

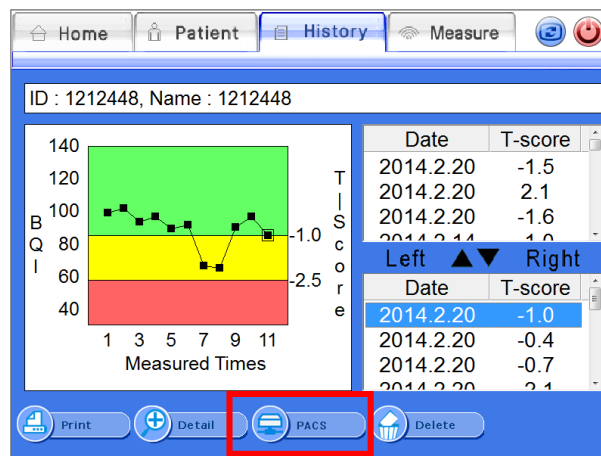
At the beginning of SONOST 3000 program, you should press the <control> button, and move on to <System>



This pictures figure the same as Worklist server control, when you input IP, Port, Atitle which can be available from the server manager in hospital.

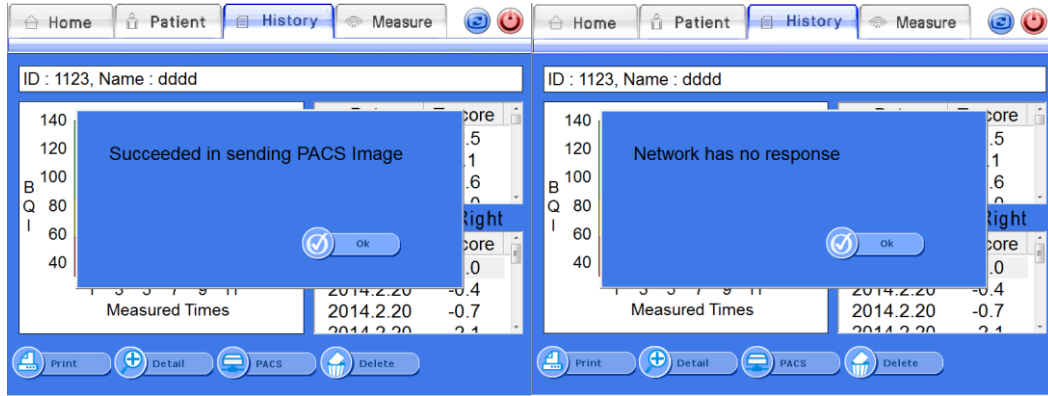
- Sending PACS

After move on to 'list of patients', you can see 'disease history' or 'result' screen. you should select 'disease history' you would like to send to PACS, then press the <PACS> button.



<PACS> button on disease history

The message showing whether sending the disease history to the server is successful or not.



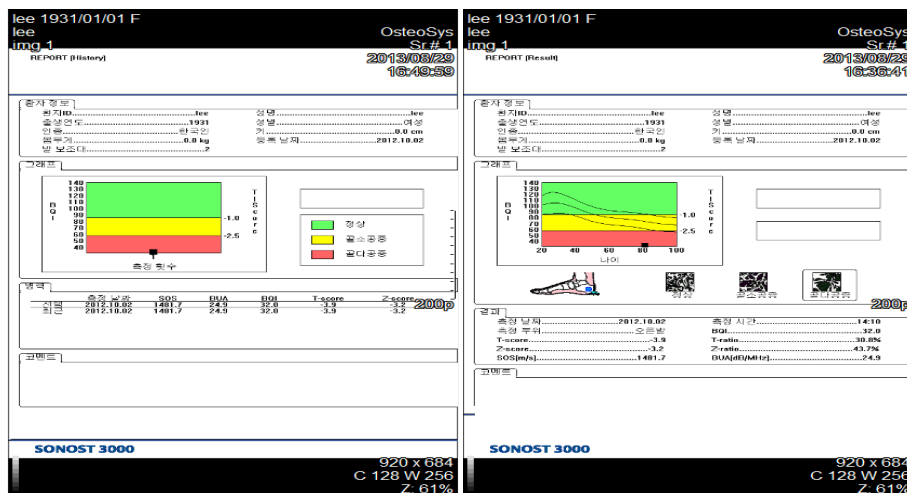
Sending successful

Sending failure

When it comes to receiving a failure message, you should check below parts.

- 1) The Network line is connected properly
- 2) The contents of storage server in system are correct.
- 3) Storage server is running properly. (You should ask the server manager)

Send result sheet to PACS server



The report of disease history

The report of result

3.4.13 FRAX

FRAX Mode predicts the risk of fracture within the next 10 years using the patient's lifestyle and medication use.

The FRAX results predict the risk of femoral fractures and major osteoporotic fractures (vertebral, wrist, femur, and shoulder fractures) within 10 years.

This function was developed by the World Health Organization (WHO) to assess the risk of patient fracture. Since the agency has provided the relevant functions, 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.

When entering from the Patient List screen

- In the Patient List window, select the Add Patient or Modify Patient menu.



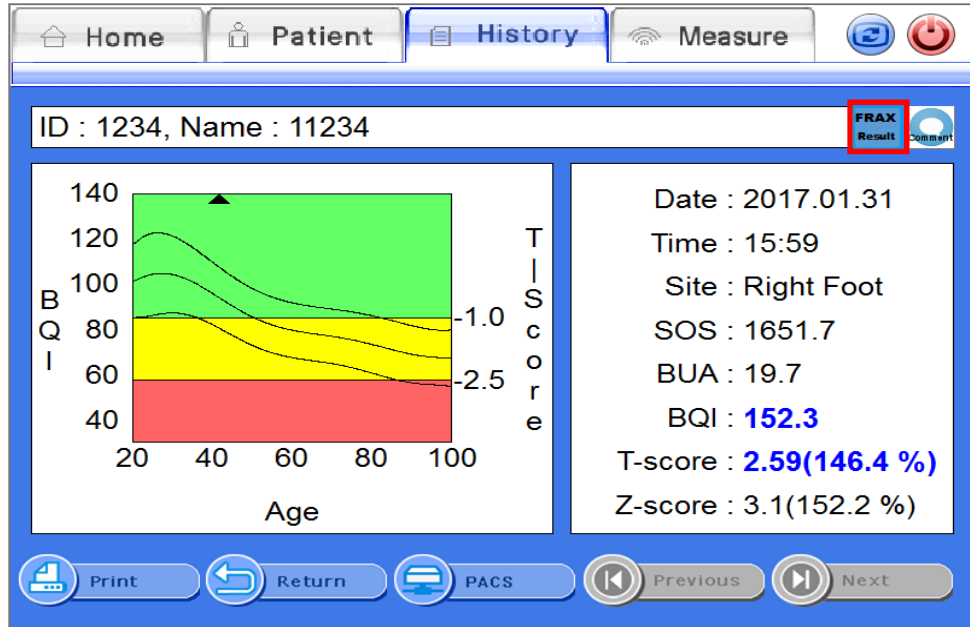
[the Patient List Window]

If your patient is over 40 years old and below 90 years old, the FRAX button will be activated and you can fill in the FRAX information.

Two side-by-side screenshots of software forms. The left form is titled 'Add Patient' and contains fields for PatientID (patID2018-01-01), Name (Kim Do Yeon), Date of Birth (1975/09/07), Gender (Female selected), Ethnicity (Korean), Foot Supporter (1), Height (180), Weight (84), and parental heights. A 'Frax' button is visible. The right form is titled 'FRAX' and contains a dropdown for Ethnicity (South Korea), several checkboxes for risk factors (Alcohol 3 or more units/day, Current Smoking, Previous fracture, Parent Fractured Hip, Glucocorticoids, Rheumatoid arthritis, Secondary osteoporosis), and input fields for T-Score, Z-Score, and a 'None' radio button. Both forms have 'OK' and 'Cancel' buttons at the bottom.

- Input on Detailed History Screen.

On the Detailed History screen, select FRAX Button and enter the FRAX information.



- The screen configuration is shown as below.

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-

sized beer (285ml), a cup of distilled liquor (30ml), a medium-sized wine (120ml), or a pre-drinking glass (60ml).

ii. Currently smoking

Check the box if you are currently smoking.

iii. Previous fracture

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.



CAUTION !




Before calculating the FRAX value, check that the questionnaire items are correct.

4 Maintenance and Repair of SONOST 3000

4.1 Resolution to problems



If SONOST 3000 shows following symptoms, check the system as follows.

Problems	Checking Points
SONOST 3000 is not activated with the power on.	Is the device properly plugged?
	Isn't the power cord damaged?
Result of calibration of the system turns out to be abnormal	 3.4.7 DailyTest of SONOST 3000
Result of measurement turns out to be abnormal	 3.3.1 Patient Measurement Procedure 3.4.7 DailyTest of SONOST 3000
Despite measurement according to the instructions, its result turns out to be abnormal	 Is the desired part of the body properly placed? 4.2.1. Cleaning, Disinfection, Sterilization





CAUTION !

If you cannot resolve the problem, contact OsteoSys or your local authorized dealer.

4.2 Maintenance and repair

4.2.1 Cleaning



 CAUTION !
Turn off the power before cleaning the device.

Product	Instructions
Device	<p>After using the device, wash with Alcohol swap.</p> <p>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.</p> <p style="text-align: center;">Probe endurance condition</p> <p style="text-align: center;">Temperature range : -40°C~70°C</p> <p style="text-align: center;">Humidity 0~90%</p> <p style="text-align: center;">Atmospheric pressure : 50~106kPa</p> <p style="text-align: center;">External force 0~1N</p> <p>  Make sure not to put water or detergent on the device directly because it can cause fatal damage in the electric circuit contained inside. </p>

4.2.2 Product's life

This product's life is 10 years. (Except Accesory)

4.2.3 Storage

Daily Storage	<ul style="list-style-type: none"> - Unplug the power cord. - Dust on the product can damage the system. After use, make sure to cover it with a vinyl cover. <ul style="list-style-type: none"> - If the hardened gel remains in the device, it can affect BMD results. Please clean the device everyday. <div style="text-align: center; margin-top: 10px;">  4.2.1 Cleaning, Disinfection, Sterilization </div>
Storage for a long time period	<ul style="list-style-type: none"> - Unplug the power cord. - Put cover on the product to avoid dust. - Keep the product according to instructions described in “2.2 Installation of SONOST 3000” <div style="text-align: center; margin-top: 10px;">  2.2 Installation of SONOST 3000 </div>

4.3 Safe use of SONOST 3000

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 !	<ul style="list-style-type: none">➤ 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 instructions carefully before using the product. ➤ Place the user's instructions 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 LCD screen after turning on the product, OsteoSys or your local authorized distributor.
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	<ul style="list-style-type: none">➤ 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.
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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 3000 except for doctors and authorized personnel
- 2) Comply with followings in times of installation of SONOST 3000. 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.



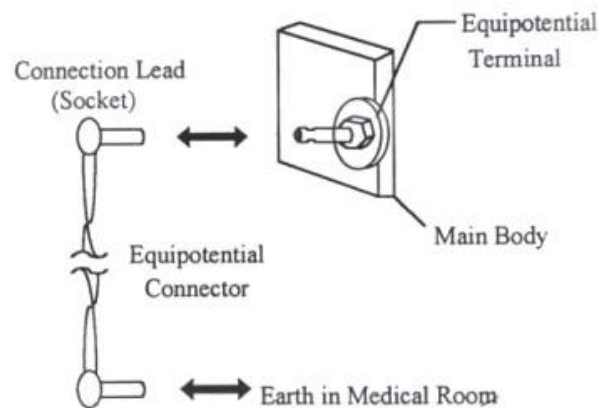
2.3 Before Turning on Power

- 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 3000, 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 20cm 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 3000. 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 lifecycles, do not dispose them at your own discretion. Contact OsteoSys or its authorized dealer for 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)	615(W) × 310(D) × 312(H) (Calf supporter folded) 615(W) × 310(D) × 387(H)
Weight	12.6 Kg
Input Voltage	AC 100V ~ 240V, Free Voltage (Single Phase)
Frequency	50/60Hz
Power consumption	300VA
Performance (Reproducibility)	$0 \leq \text{SOS cv} \leq 1 \%$ $0 \leq \text{BUA cv} \leq 2 \%$
Ultrasonic Probe Diameter	Ø25mm
Ultrasonic Center Frequency	0.5MHz
Ultrasound Output	4uW/cm ²
Focus Type	Flat
MI	<0.2

Ultrasonic Probe Position Setting	Variable Measurement 12~136mm
Patient's Measurement Posture	In a sitting posture
Accessory	QC Phantom













***Environmental**

Operating Temperature	10 ~ 40°C
Transport / Storage Temperature	-5 ~ 50°C
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 3000 software are irregular, we will inform you through your email whenever SONOST 3000 software needs to be updated
- 2) For details, call the OsteoSys Co., Ltd Customer Service Department, or your OsteoSys Co., Ltd distributor.


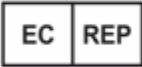



5.3 Labels

OsteoSys Co.,Ltd MADE IN KOREA	901~914, 9F, JnK Digitaltower, 111 Digital-ro 26, Guro-gu, Seoul, REPUBLIC OF KOREA  TEL: +82 26124 5900 Fax : +82 26124 5958
European Representative() : CMC Medical Devices & Drugs S.L. C/Horacio Lengo N° 18, CP 29006, Málaga, Spain TEL: +34 951 214 054 FAX: +34 952 330 100	
 {01}08800008400046{11}221100{21}S3K220038Q	
Ultrasound Bone Densitometer MODEL() : SONOST 3000 S/N() : Manufactured() :	Power rating 100-240 VAC~, 50/60 Hz, 200 VA      
WARNING	To avoid electrical shock, do not open the cabinet Refer serving to qualification personnel only.
CAUTION	Federal Law restricts this device to sale by or on the order of physician.

<product label>

 <p>SONOST 3000 Ultrasound Bone Densitometer OsteoSys Co., Ltd</p>	 <p>SONOST 3000 Ultrasound Bone Densitometer OsteoSys Co., Ltd</p>	 <p>SONOST 3000 Ultrasound Bone Densitometer OsteoSys Co., Ltd</p>	 <p>SONOST 3000 Ultrasound Bone Densitometer OsteoSys Co., Ltd</p>
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Operating temperature range	10 ~ 40 °C
Operating humidity range	20 ~ 80 %
Operating atmospheric	800 ~ 1060 hPa
Storage temperature range	-5 ~ 50 °C
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
	CMC Medical Devices & Drugs S.L. C/Horacio Lengo N° 18, CP 29006, Málaga, Spain. Tel) +34-951-214-054 Fax) +34-952-330-100
	
	
	

<packing label>

6 Reference

6.1 Definition of parameter terminology

- BUA(Broadband Ultrasound Attenuation)

Parameter which reflect bone density and structure by reduction analysis of ultrasound pulse intensity which through the bone.

- SOS(Speed Of Sound)

Velocity of ultrasound wave through the bone which reflect bone mineral density

- BQI(Bone Quality Index)

Generally SOS is in proportion to the temperature, and BUA is in inverse proportion to the temperature. These correlation coefficients are (α , β) combined for as shown below. This Parameter which is represented constant number compensates the precision error from the temperature.

- ✱ The relation between age and BQI (Refer to the picture)

$$BQI = \alpha \times SOS + \beta \times BUA$$

- T-Score

Average BQI in twenties(Young adult), that is BQI standard deviation in twenties.

- ① More than -1 : Normal
- ② -1 ~ -2.5 : Osteopenia
- ③ -2.5 and below : Osteoporosis

- ✱ T- Score's meaning in the view of probability

T-Score represents the patient's BQI above or below a reference "Young adult" mean and is expressed in standard deviation(SD) units.

Therefore, If patient's BMD value makes normal distribution shape, then T-Score means in the view of probability as below.

- ① $T < -6, T > +6$: 2 of 1,000,000,000 persons
- ② $T < -5, T > +5$: 3.8 of 100,000,000 persons
- ③ $T < -4, T > +4$: 6.3 of 10,000 persons

- ④ T < -3, T > +3 : 2.7 of 1,000 persons
- ⑤ T < -2, T > +2 : 4.6 of 100 persons

For example, Person in T<-3 exist 1.35 ratio of 1,000 persons in whole population.

- Z-Score

Average BQI in the same age, that is BQI standard deviation in the same age.

- ① More than 0 : BMD is higher than the average of the same age.
- ② 0: Average value of the same age.
- ③ 0 and below : BMD is lower than the average of the same age.

- Explanations of BUA Measurement MODE Terminology

- ① PEAK : Maximum value of signal in the frequency domain.
- ② Center Frequency : Value of center frequency.
- ③ Percent : % Bandwidth(3dB bandwidth ÷ Center Frequency × 100)
- ✱ Generally, as these values are lower, BUA values is higher.

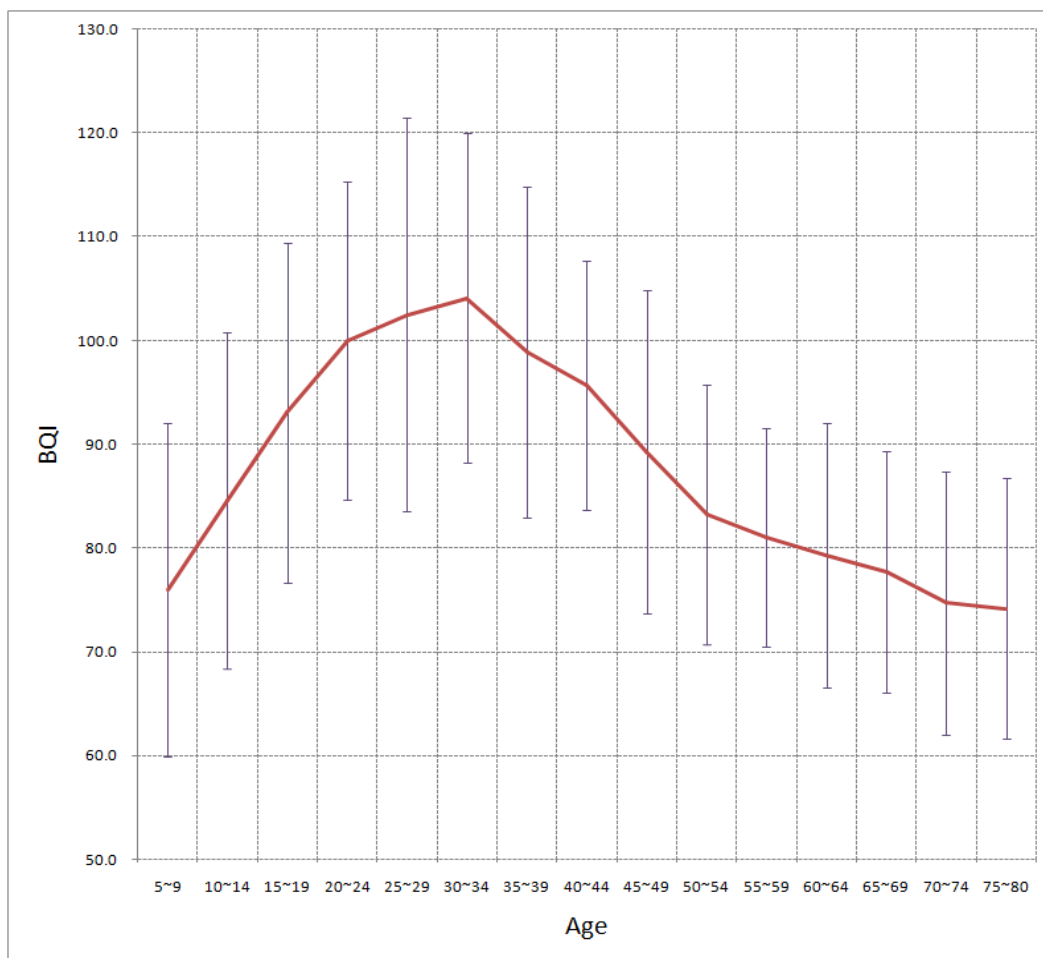
- Explanations of SOS Measurement MODE Terminology

- ① Zero Point : Cross point of the time Ox which is used for acquiring the signal's position.
- ② Gain : Amplification degree of ultrasonic signal which is controlled automatically.
- ③ Peak : Maximum value of signal in the time domain.
- ④ TOF(Time Of Flight) : Elapsed time of ultrasonic signal from transmission to reception. It is used for SOS calculation.

6.2 Reference data

- Reference data

We achieved reference data from several group with different environment in Korea. And the data is analyzed by statistical method



Ages	5~9	10~14	15~19	20~24	25~29	30~34	35~39	40~44	45~49	50~54	55~59	60~64	65~69	70~74	75~80
Mean	76.0	84.6	93.0	100	103	104	98.9	95.7	89.3	83.2	81	79.3	77.7	74.7	74.2
SD	16.0	16.2	16.4	15.3	19	15.9	15.9	12	15.6	12.5	10.5	12.7	11.6	12.7	12.5
N	36	41	39	40	38	35	38	40	42	37	41	35	37	38	35

✱ Where we make the BQI(Bone Quality Index) by weighting sum of SOS, BUA

7 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 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.**

8 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,	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

	numbers, and special characters.	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 could not 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.

WARNING !

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.

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.