SONOST 3000

User's Manual

Model: SONOST 3000

Council Directive 93/42/EEC Concerning Medical Device

Doc Version: 12.2.3 (2023.12.15)

$C\epsilon$
2460

OsteoSys

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

SONOST 3000

User's Manual

Manufacturer and EC Authorized Representative Information

♣ **Manufacturer: OsteoSys Co., Ltd.**

901~914, 9F, JnK Digitaltower, 111 Digital-ro 26, Guro-gu, Seoul, REPUBLIC OF KOREA

info@osteosys.com

Tel: +82 26124 5900 Fax：+82 26124 5958

♣ **European Representative: CMC Medical Devices & Drugs S.L.**

C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Tel: +34 951 214 054

Fax: +34 952 330 100

⚠ **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.

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 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

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

The protecting device from external electromagnetic wave. 1)

This device can be affect from external electromagnetic wave which is related to precision and operation. When you using this device, we strongly recommend you, avoid from other device from protect electromagnetic wave.

Disposal of device.2)

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

Cautionary Notes

(1) Environmental Condition

To prevent possible performance loss or malfunction of device components caused by sudden and excessive environmental changes, as well as the resultant shortening of their life cycle, the environmental conditions below must be met.
- Working Temperature : Within 10 ~ 40℃
- Working Humidity :Within 30~ 75%
- Air Pressure :Within 700 ~ 1060hPa

(2) Pre-operation Checklist
- Check the switch connection and polarity indicator status, and verify the device works properly.
- Check all cable connections for their accuracy and safety.
- Double-check the areas that make direct contact with the patient.
- Check the device and the patient for any anomaly.
- If anomaly is found 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, in working conditions.
- Devices should be positioned in their proper positions, so as not to interfere with
worker or patient movement.

(4) Cautions regarding specialist prescription
This device is designedfor osteoporosis diagnosis, and therefore should be used for
the purpose of diagnosis performed by doctors. Its use must be prescribed and
managed by specialists.

Guidance and manufacturer's declaration

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 assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model SONOST-3000 uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The model SONOST-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.
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	Mains 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	Mains 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	Mains 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.			
Immunityt est	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	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 meteres(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 80MHz to 2.5 GHz	10 V/m 80MHz 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 considerations about part of device and compartment. 3)

For use safely, you must use part of device which supplied or approved from Osteosys.

⚠ **NOTE !**

If you use part of device which is not approved from Osteosys, we do not guarantee safety to user.

Moreover, it become dangerous and errors and wrong results to users or patients. In this case, user has 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 using period of expandable goods

Name	Part number	The period for exchange	The method of exchange expandable products
Foot supporter	FOOT SUPPORTER 0 : A3MM-013	10years	You should require to manufacturer or distributor where can repair this device.
	FOOT SUPPORTER 1 : A3MM-014	10years	
	FOOT SUPPORTER 2 : A3MR-005	10years	
	FOOT SUPPORTER P : A3MR-105	10years	
QC Phantom	C3MR-004	10years	
Power Cable	250VAC 10A	10years	

Input and output parts which are using for operate device.4)

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

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

Table of Contents

Chapter 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 wave 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 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 : BQI(C.V.%) 5

  T-score   -0.5 or less : BQI(C.V.%) 2

- 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 the wall.

- Never remove any system covers.
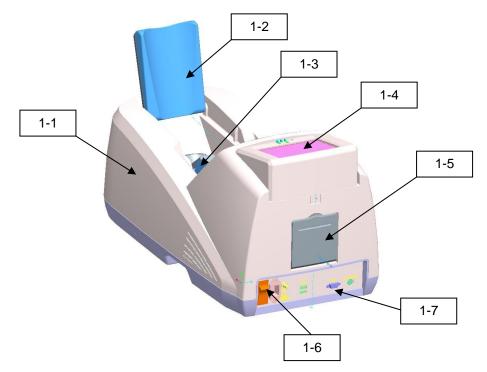
- In case of changing the printer for other products, check them according to IEC/EN60601-1-1.

- Unplug the power cord after using.

Chapter 2. Configuration of Device

2.1 Composition of Device

2.1.1 Shape and Components of Device

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 which certificated by standard (IEC-60601-1).

⚠️ **NOTE !**

Use Accessory which defined at user's manual.

2.1.2 Accessories List

Check the following accessories before installing the system.
If they are not in good condition, contact to OsteoSys or its
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 supporter	4	Use them in accordance with patients' foot size. (base, 0, 1, 2, 3(P))
QC Phantom	1	It is used to calibration the system. Keep it in the specified place and protect it against deformation by heat or pressure.
Power Cable	1	It is used to connect to the source of electric power with the main body of SONOST 3000. Make sure to connect it with a grounded electric outlet.

2.1.3   Articles List

Check the following accessories before installing the system.
**If they are not in good condition, contact to OsteoSys or its authorized
dealer for this service**
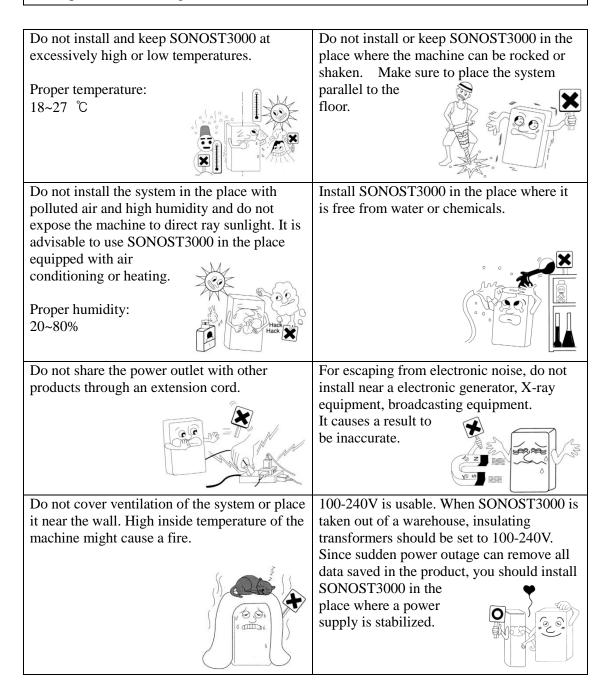
4.2.3 Stockpiles and Replacement of Articles

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

2.2 Installation of SONOST 3000
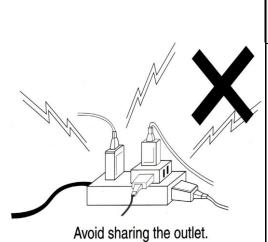
> ⚠ **NOTE !**
>
> Since SONOST3000is made up of precise components, you should install
> the product according to instructions below.

Do not install and keep SONOST3000 at excessively high or low temperatures. Proper temperature: 18~27 ℃	Do not install or keep SONOST3000 in the place where the machine can be rocked or shaken. Make sure to place the system parallel to the floor.
Do not install the system in the place with polluted air and high humidity and do not expose the machine to direct ray sunlight. It is advisable to use SONOST3000 in the place equipped with air conditioning or heating. Proper humidity: 20~80%	Install SONOST3000 in the place where it is free from water or chemicals.
Do not share the power outlet with other products through an extension cord.	For escaping from electronic noise, do not install near a electronic generator, X-ray equipment, broadcasting equipment. It causes a result to be inaccurate.
Do not cover ventilation of the system or place it near the wall. High inside temperature of the machine might cause a fire.	100-240V is usable. When SONOST3000 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 SONOST3000 in the place where a power supply is stabilized.

2.3 Before Turning on Power

Connection of Power Cable(with the outlet)

Avoid sharing the outlet.

⚠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 it,
immediately contact an agency.
- Put the Power cord into only oneplug.
- Make sure not to share the power outlet
to prevent SONOST 3000 from being
affected.

Chapter 3. Using SONOST 3000

3.1. Daily Test

The SONOST 3000 system is checkedusing the daily test.

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

3.1.1. Preparation

SONOST 3000 device, Phantomandultrasound transmission gel

Dailytest Recommendation

- The daily test should be performedwithin operating temperature.
  (Recommended temperature : 18 ~ 27 ℃)
- The phantom should be kept beside of device closely.
- Daily test should be done just after turning on the device.
- Turn on the device and then do Dailytest immediately at beginning time
  of day before warming up the device.
- Turn off the device after using at closing time of day.

3.1.2. Daily Test Procedure
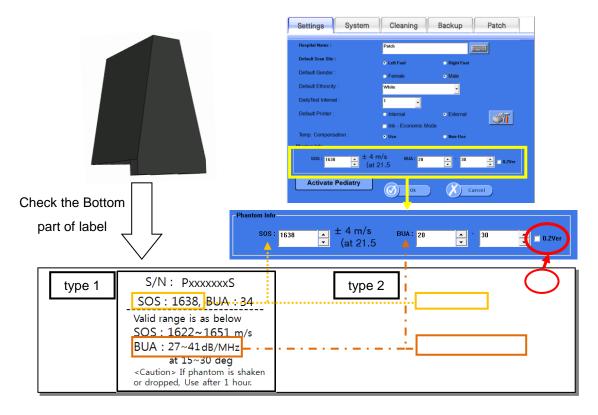
❑ **Phantom's value checking**

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 is two kind of different label. You should check contents on the label and below two clauses.

1. the value of SOS and the range of BUA are correctly write on Phantom info.

2.If you can see 'V0.2' on the right side of label, you have to tick on the '0.2Ver' radio box, if no, you must check the radio box. The box should be blank.

(If it is wrong with the information which comes from the label, you have to revise it.)

Check the Bottom part of label
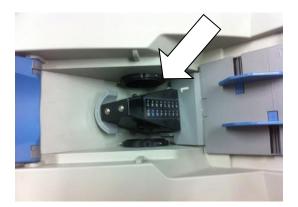
❑ Phantom's setting

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 the gel should be same as the area of the phantom in contact with the probe.

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

❑ **Perform the dailytest**

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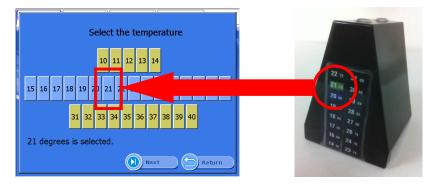
The Daily test should be done if the color of button is red.

When the daily test is finished, red colored character will be disappear.
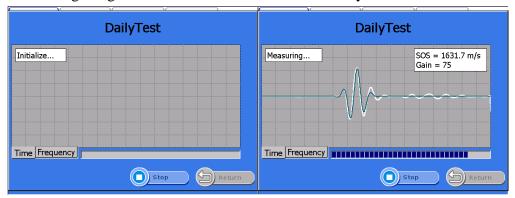
After click the daily test button, you can see the message. If you put the ultrasound transmission on the phantom, press "YES"button.Input the temperature referring to the thermo label on the surface of the device.

The correct temperature is the highest digit between appeared with color on the thermo label.

Execute <the daily test> by pushing the 'start' button.

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

"Complete Daily Test" appears when the daily test is done.
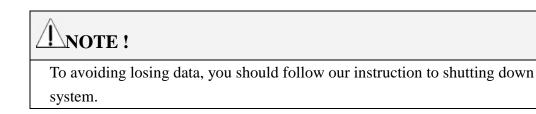
Complete the process of <the daily test> by pushing the "OK" button.

Youare 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 instruction to shutting down system.

3.2.1 Position of Shutdown button
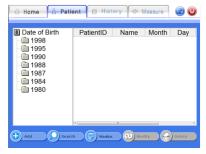
The shutdown button is located as below 4 screens.

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
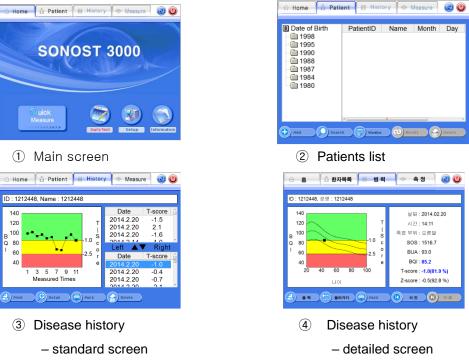
3.3 The analysis of how to rotate the screen

The procedure of rotate the screen is as below

> ## ⚠NOTE !
>
> This function is applicated some devices. The adopted device's serial number is start from AC1TA.

3.3.1 The location of screen rotation button
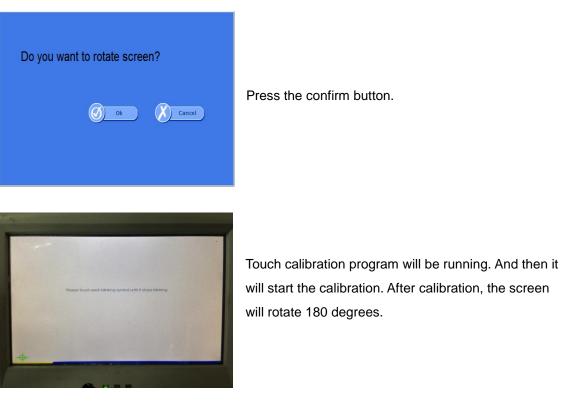
The screen rotation button is located in 4part of the screen as below images.

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 confirm 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.

Clean the both side of patient's heelwith an alcohol pad and apply gel.

Insert patient's foot.
Let a patient move his foot up to down just like this picture.

Start measure after insertion and positioning. Ensure correct Foot Positioner 1 or 2 is used depending on patients foot size

⚠ NOTE !

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

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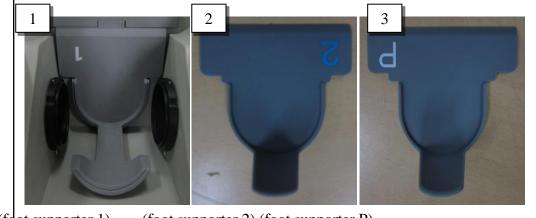
Put the foot supporter according to the below guide.
The section is arranged for each size of the foot.

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.
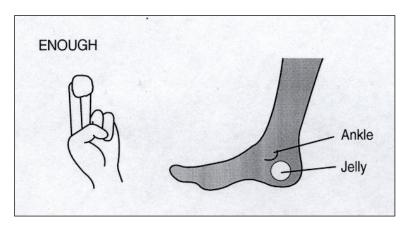
(foot supporter 1)   (foot supporter 2) (foot supporter P)
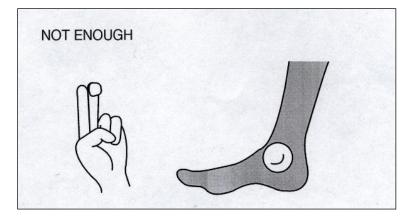
3.3.5 Where and How Much Apply to the Patient's Heel

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 side of patient's heel
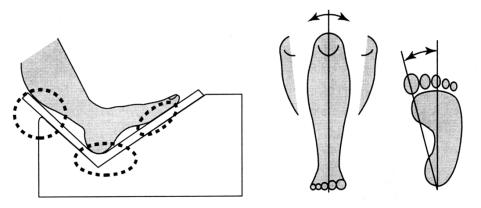
Good
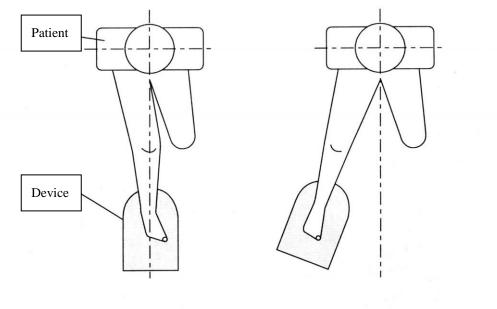
No Good

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.

Patient

Device

GOOD   NO GOOD

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 width 58mm. thickness : MIN 0.07mm

(About 80 reports are printable by one roll)

- Paper character : Only printable in the outer surface

- Purchasing : Purchase from the headquarters or an agency.

Paper inserting

1)Cover opening : Pull-down open the dark gray cover on the device'sback

side

2) Paper inserting : Insert the paper as shown below.Outer surface ofpaper
shouldface to the inside of the device. Paper isscrolled
inautomatically.

3) Cover shutting : Put the paper to the gap in the cover, then shut thecoverup.

4) Paper cutting : For a sharp outline of report printing, cut off the remained
paperonce by a saw tooth in the cover.
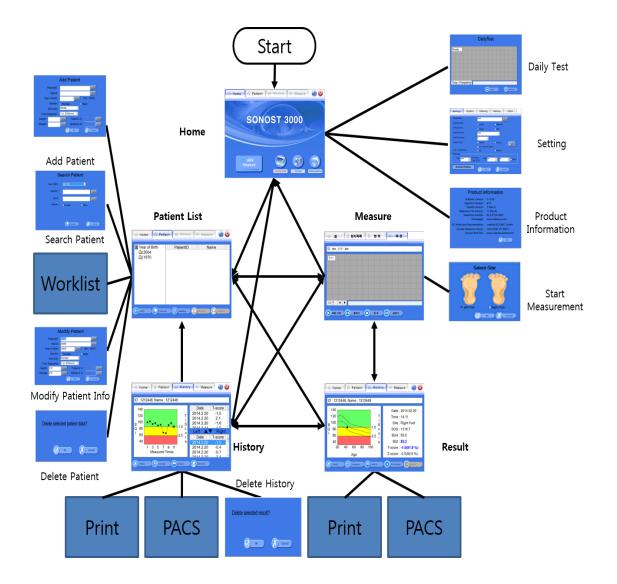
⚠ CAUTION !

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 Progress 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 its Authorized dealer.

Turn on the power switch.

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

This is the start up screen.

of the startup screen

There are Main buttons on the top line, It is used when the screen is moved.
The bottom line is consisted of Sub buttons, it is used for sub function.
Other screens are similar formation.

- QuickMeasure : Direct measuring function without patient's registration process.
- DailyTest   : Daily test function.
                   When the daily test is needed, the color of button is red.
                   When not needed, the color of button is the same as the others.
- Setup   : Consists of functions which are related with program setting.
- 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 is appeared.

'Setup' Window
- <Settings> : Fundamental settings related Software.
- <System> : Settings related Operating System.
- <Cleaning> : It makes probe is moved of user's own accord for cleaning.
- <Backup> : Control of measured data.
- <Patch> : Software upgrade.

Settings

It makes fundamental settings related Software.

 Setup>Settings Window

 - Hospital Name : Insert the hospital name which will be on the report.
- Default Scan Site : Select the default scan site when measure.
- Default Gender : Choose the gender when insert the patient's information.
- Default Ethnicity : Choose the ethnicity when insert the patient'sinformation.
- DailyTestInterval : Fix the interval of daily test
- Default Printer : Choose the internal thermal printer or external general printer.
- Print Graph : Choose the Graph included when use the internal printer
- Ink-Economic : Choose the Ink-Economic mode when use the external printer.
- : Setup printer.
- Temp. Compensation : To choose the temperature compensation function when
                        Dailytest and measuring.
   - Phantom Info : the value of the user phantom.
   - Check version of phantom whether it is 02ver or not.
- Activate Pediatry(Activate BMD) : To switch the mode of BMD and Pediatry.

System

It makes settings related Operating System.

 Setup>System Window

- System Date/ Time: Present time setting. It becomes standard for patient's
                registered date, measured date and printed date.
                Fix the time and click the <Save>button.
- Touch Panel calibration : It is used when the touch panel is out of order.
                Read the screen message carefully, then press the arrow
                indicated point exactly.
- Storage Server :If you would like to send images through PACS, you should
                inputinformation.
You have to get own IP address and port from the hospital to
connect storage server and then input these things exactly. (You
should request for server information from the manager who is
working at hospital.)
-Worklist Server :The form of Worklist, using for when you get information
from server which is people checked through device,You
have to get own IP address and port from the hospital to
connect storage 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 3.4.12, we explained more detail things.

- Query :You should input some conditions which are get information about patients from the worklist server.When you input modality in Query should be the same as the modality in worklist server.

You can choice which is today, week(7days before), weeks(14days before), month(30days before) from Query.It is based on the system date fromserver.It can show person's information which is someone checked through this device.

⚠ NOTE !

Using DICOM, which related to storage/worklist server IP, Port, Modality should be request from the server manager in the hospital.Youmust input server information exactly which is get from the hospital.

Cleaning

It makes probe is moved of user's own accord for cleaning.

Setup>Cleaning Window

- Narrow : It makes narrow the probe's interval
- Stop : It makes the probe stop.
- Widen : It widen the space of two probes.

Backup

It controls the measured data.

※ If a USB memory has many files and folders , the speed of recognition of the
USB memory could be lower. Connect a USB memory after empty.

Setup>Backup Window

- Export : If you click this button, you can export data to USB memory stick or
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 are select 'Individual', you can't select printer)

- 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 exported data.

Setup>Backup>Import Window

Patch

It is upgrade the Software.

At first, Prepare a USB removable disk which support USB 2.0. You can use mp3 player or digital camera too.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] for close the program.

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

Choose the 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.
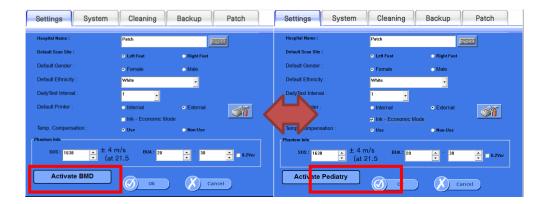
⚠ **NOTE !**
During patch, if you turn off device or take USB removable disk off, Critical problem will occur.

3.4.4 Measurement of Bone Mineral Density

Selection of BMD and GDP

- Pediatrymode :when you want to get the result and graph of Pediatry BMD and
GDP (growth rate factor) for under 20 years old.
Click the [Activate Pediatry] which is changed to [Activate BMD]

- BMD mode :when you want to get the result and graph of adult BMD for over 20
years old.
Click the [Activate BMD] which is changed to [Activate Pediatry]
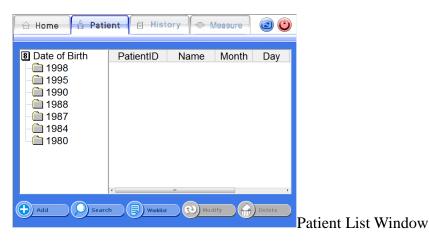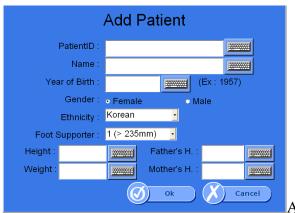
Patient Registration

If you click the <patient>button on the top line at the incipient screen, you can move to "Patient List" which display and control the registered patient

Left list mean registered patient's birth year. If you click the year, you can see the patient's ID and name list were bone in the same year.

Patient List Window

If you want to register a new patient, then click the <Add>button on the bottom line. Then "Add Patient" window is appeared which insert the patient's information.

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

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.

- Height : Input the height of patient.

- Weight : Input the weight of patient.

- Father's H. : Input the height of patient's father. (it is disabled on BMD mode)

- Mother's H. : Input the height of patient's mother.(it is disabled on BMD mode)

Patient Search

If you want to search the registered patient, click the <Search>button on the bottom line and make it appear the "Search Patient" window. It apply search condition of the patient's ID, name, gender and year of birth.
If you insert the related information and click the <Ok>button, then the result is displayed on the screen.

Search Patient Window

Search Result Window
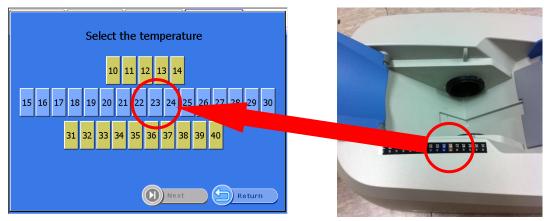
Measurement of Patients

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

Measure Screen

Click the <Start>button on the bottom of left.You could find the dialog box for the temperature. Input the temperature referring to the attached thermo label on the surface of the device. (choose the highest digit for the temperature among the colored digit on the thermo label)
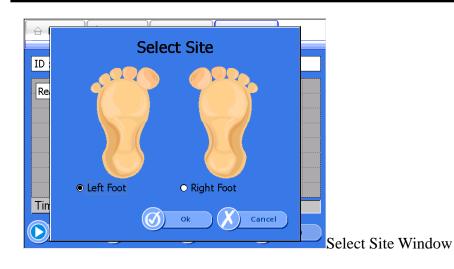
※ If you select the option of non-use Temperature Compensation, the temperature dialog box is not appeared.
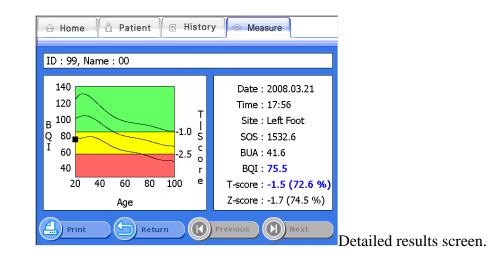
Temperature screen

Click the next button.AndSelect the site of the foot and push the OK button. Ultrasound waves are generated from the probe.

 Select Site Window

When ultrasound waves are generated, the <Start>button is changed into <Stop>button. In case of emergency, click this button, and you can stop measuring. In the normal condition, ultrasound waves generation is finished about 15 seconds after, then the "Measure Complete" window is appeared with the alarm sound.
If you click the <Ok> button, the detailed results   is displayed as shown below.

 Detailed results screen.

If you click the <Print>button on the bottom of results screen, then the report is printed.

☞ 3.4.8Printing of clinical history and Result

Pediatricfunction

Accessory is arranged for more convenience of pediatric measurement.

If you want to purchase below item, contact to Osteosys.

   - Top cover for Pediatry

   - Foot supporter for Pediatry

If you want to view the graph of pediatry for children, select Activate Pediatry button in setup window.

The button of Activate is used to toggle between PEDIATRY mode to BMD mode.

When you choose the Activate Pediatry, you can see the followings.

- Pediatric BMD result and graph
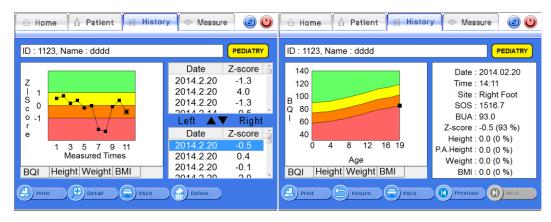
- the result and graph of Current height and predicted adult height.

(supported from version 5.00)

·the graph of current weight.

·the result and graph of BMI.
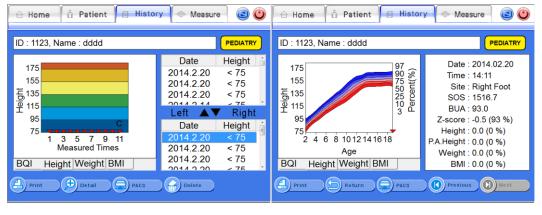
※Pediatric BMD

[History View]   [Detailed Result View]
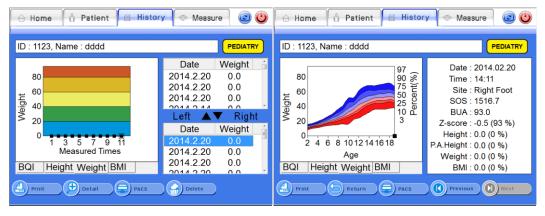
※Current Height and Predicted adult height

[History View]   [Detailed Result View]
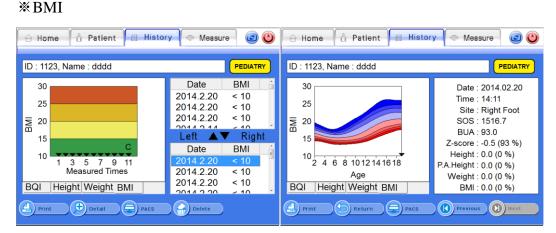
※Weight

[History View]   [Detailed Result View]

※BMI
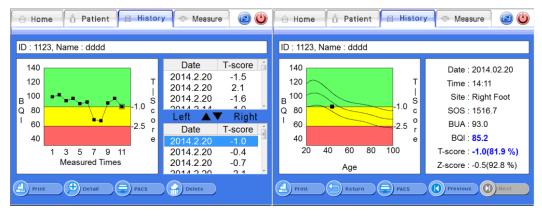
[History View]   [Detailed Result View]

※When [Activate BMD] is selected.

[History View]   [Detailed Result View]
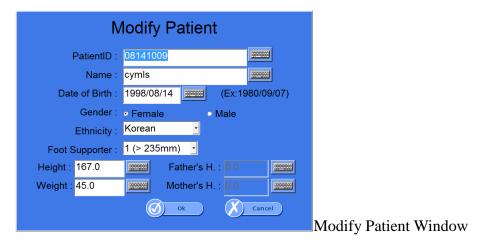
3.4.5 Revision and Deletion of Patient's Information

Revision of Patient's Information

If you want to revise the registered patients' information, select a desired patient and click the <Modify>button on the bottom.
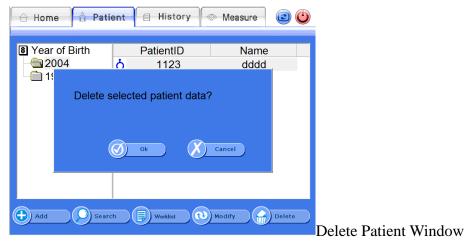
Then the "Modify Patient" screen appears as shown below, in this condition, if you enter a new value to make desired changes in the patient's information and click the <OK>button, the patient's information is revised.

Modify Patient Window

Deletion of Patient's Information

If you want to delete the registered patients' information, select a desired patient in the "Patient List" screen and click the <Delete>button on the bottom.
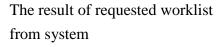
Then the message box "Delete Patient" inquiring about the whether to delete the information surely appears and if you click the <OK> button, the information is deleted.

 Delete Patient Window

Worklist

If you click <Worklist> button on the lower part of patient list, it will updated to latest patient list, however it depends on patients are already registered on worklist server.
After press the <worklist> button, 4buttons will turned to non-active status aside from <worklist>button.If you click the <worklist> button,　it will go back to previous <worklist> status.
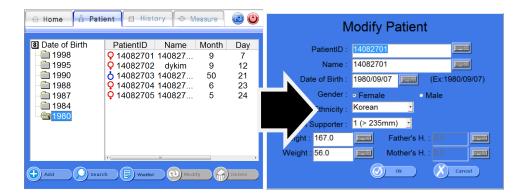
 The result of requested worklist from system

Worklist - Giving a test to someone who is already registered on the system.
After selection of 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 but, they do not have any disease history, the system will show you error message).

Worklist - Giving a test to someone who is not registered yet on the system.
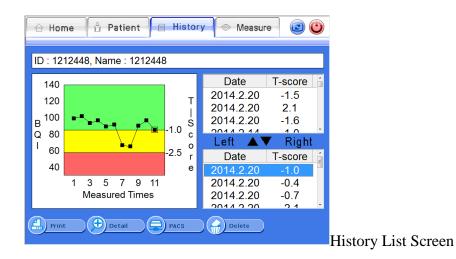If someone is not registered yet, you can listed on the system when you after click <Test> button.
※When worklist server is active, other buttons such as <save>, <find>,<modification> and <Deletion>, will turned to non-active status. Therefore, if you would like to give a test to patient, you should select the person who will have a test, and then click the <test> button on the screen. The device will start to the test.

3.4.6 Inquiry and Deletion of Clinical History of Existing Patients

Inquiry of Clinical History of Existing Patients

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

Then "History List" screen appears that contains the patient's clinical history as shown below. On the right side, the left and right foot's measurement results list shows. If you select a measurement result in the list, the relevant clinical history represented by a graph on the left side.

 History List Screen

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

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.

Detailed Result Screen

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?" that inquiring about whether to delete the result or not appears. If you click the <OK>button, the result is deleted.

Delete Patient Window

3.4.7 DailyTest of SONOST 3000

DailyTest

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 <StartDailyTest>button, DailyTest is started. If the DailyTestis successful, the message box "Complete Dailytest" appears press "OK" and return to "Home" screen. If you select the "Time" tap, graph appears in the time domain. If you selectthe"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 word on the <Start> button is changed into <Stop>. In case of emergency, click this button and you can stop daily testing. In the normal condition, the message box "Complete Dailytest" appears as shown below with an alarm sound after progressing calibration of the system and if you click<OK>button, the progress of calibration is completed.
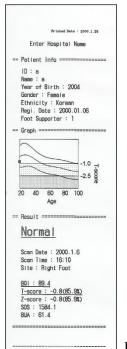
⚠ NOTE !

In case of the screen shows the calibration has failed, do not use the system and execute "DailyTest" once again. If calibration fails continually, contact to OsteoSys or its authorized dealer.

3.4.8 Printing of clinical history and Result

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

Inner Printer (Thermal Printer)

Inner printer is affixed on the device back inside. It will be able to use without software setting.

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 completed, reboot device.

Select External and then click the icon of printer setting.

 You can find the installed printer above and check it 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

3.4.9 Customize the logo in printing

Make the bitmap filesfor 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 button looks like folder shaped and select the image file for color and gray sequentially.

Push the button of Logo Copy
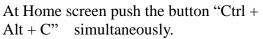
The logo on the bottom of printed paper is changed.

3.4.10 The function of Shot Count

Connect USB keyboard or PS/2 keyboardto the device.

F

At Home screen push the button "Ctrl + Alt + C"   simultaneously.

Push the number 1686.

The total number of measurement is shown at shot count.

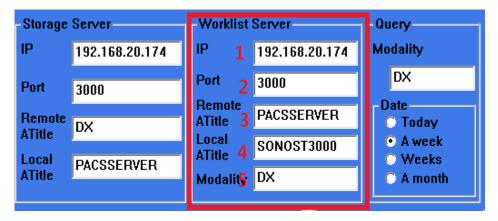If Reset button is selected the shot count is set to default value of 0.

3.4.11 Setup the worklist

Connect to worklist

In terms of Worklist, it makes database from people who checked through this device. This database saved in the hospital server. Later, you can get this information from the PC which is connecting to server. It cannot change information on the local PC

Set up User Interface in Worklist

At the beginning of SONOST3000 program, you should press the <set up> button, and then move on to <System>

You should get information from someone who work in hospital or manager of OCS in hospital.

- Worklist IP →1
- Port number → 2
- Remote ATitle → 3
- Local ATitle→ 4
- Modality → 5

  - Local A-title in SONOST300 means SONOST3000, you should tell to a manager of OCS. It cannot change

  - Modality is basically "DX", it can be change

  - You should input modality in Query which is next to set up of Worklist server. Next, you should choice 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'3.4.5'

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 get information about PACS server)
- Remote A-Title(You should ask to a manager of PACS in hospital)

The method connect to PACS

- Connect ofDevice

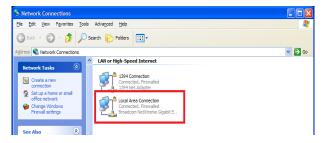Connect the Ethernet cable to the LAN port on the back of the device.

- Network set up

You can see 'My Network Places' on the screen. Select this item and press the right side of mouse. You should select "properties"

- Setup of the LAN Card

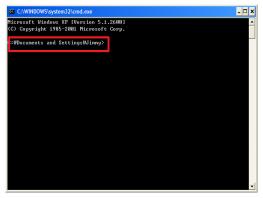When you set up LAN card, you should turn on the device.

When you connect to PACS network in hospital, you should choice Local area. Next, click the right side of mouse on 'properties'. If you see message, you should choice Internet Protocol(TCP/IP) and click the 'properties'

You should input IP address, serve net mask, gateway for connect PACS server. After that, press the 'confirm' button.
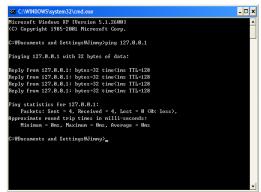
You should press the start and command button for connect to PACS server in hospital. When Command board appeared, you should input CMD. Next, you can see DOS mode.

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 is get from 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 SONOST3000 user program
At the beginning of SONOST3000 program, you should press the <control> button, move on to <System>
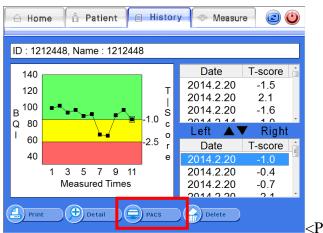
This pictures figure the same as Worklist server control, when you input IP, Port, Atitle which are bring from server manager in hospital.

- Sending PACS

After move on to 'list of patients', you can see 'disease history' or 'result' screen.

you should select 'disease history' which is you would like to send to PACS. After, press the <PACS> button.

<PACS> button on disease history

The alarming message whether when sending disease history to server
success or not.

Sending successfulSending failure

When it comes to sending 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 require to server manager)

Send result sheet to PACS server

The report of disease historyThe 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.

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, the FRAX button will be activated and you can fill in the FRAX information.

• Input on Detailed HistoryScreen.

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

• The screen configuration is shownas 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 ifyou 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 boxif 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 race of the patient to be measured.If you cannot find the race of your patient in the list of the reference, you should select the race which is the most akin to your patient's race from the list.

.

3.4.14 Card Reader

The Patient information file is received in an arbitrary directory, and registration, deletion or modification is automatically performed.

It is a function to generate a file in an arbitrary directory of measurement information by using the selected patient information.

It is called Card Reader function because it can be linked to card reader.

The Card Reader function provides a solution for interlocking patient information that the system should provide to S3K and the result information that S3K provides to the system.

- Patient information file

   It is INI file format for patient registration / modification / deletion and supports the following format.

   ● Insert.ini Format

[INSERT]

ID=dykim80

Name=kimdoyeon

Birthdate=1980-09-07

; SEX 0 : female, 1 : male

SEX=1

Height=180

Weight=86

; Ethnicity = Korean, European, Asian, Chinese, Hispanic

Nation=Korean

   ● Modify.ini 포멧

[Modify]

ID=dykim80

Name=kimdoyeon

Birthdate=1980-09-07

   ● Delete.ini 포멧

[Modify]

ID=dykim80

Name=kimdoyeon

Birthdate=1980-09-07

   ● Patient registration

   The procedure for registering a patient is shown below.

1. Insert the Insert.ini file into the PatientInputDir directory.

   (The default PatienttInputDataDir directory is the same as "C: \ Program Files \ Osteosys \ Sonost3000 \ PatientInputDir".)

   Recognize the Insert.ini file, and the patient registration dialogue box appears.

2. Enter the patient information and click the OK button.

3. You can see registered patients in the patient list.

● Edit patient information

   The procedure for correcting patient information is as follows.

1. Put the Modify.ini file in the PatientInputDir directory.

   (The default PatienttInputDataDir directory is the same as "C: \ Program Files \ Osteosys \ Sonost3000 \ PatientInputDir".)

2. The Modify.ini file is recognized, and a patient information modification dialog window appears.

3. Confirm the contents of the patient information and click the OK button.

4. You can see the modified patient in the patient list.

● Delete patient information

The procedure for deleting patient information is as follows.

1. Put the Delete.ini file in the PatientInputDir directory.

   (The default PatienttInputDataDir directory is the same as "C: \ Program Files \ Osteosys \ Sonost3000 \ PatientInputDir".)

2. The Delete.ini file is recognized and a message window appears asking you to delete the patient.

3. Click the OK button to delete the patient

4. You can confirm that the patient information is deleted from the patient list.

- File format of Measurement result information

After the measurement is completed, the measurement result file will be created in

MeasureResultDir (Default: C: \ {Program Files \ Osteosys \ Sonost 3000

\ MeasureResultDir}).

1. INI Format

[Result]
id=dykim80
name=kimdoyeon
yearofbirth=1980-09-07
sex=1
enthnicity=Korean
height=180
weight=86
dadheight=173
momheight=164
measuretime=20150327_173518
site=LEFT_FOOT
sos=1893.1
bua=-0.0968459
bqi=154.006
tscore=2.51907
zscore=3.14366
tscoreRatio=143.931
zscoreRatio=146.403
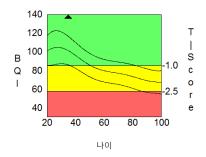
2.   TEXT Format

id:dykim80

name:kimdoyeon

birthdate:1980-09-07

sex:1

enthnicity:Korean

height:180

weight:86

dadheight:173

momheight:164

measuretime:20150327_175907

site:LEFT_FOOT

sos:1893.54

bua:-0.551017

bqi:153.832

tscore:2.50973

zscore:3.13244

tscoreRatio:143.768

zscoreRatio:146.238

● File format of Measurement result image

After the measurement is completed, a measurement result image file is created in MeasureResultDir (default: C: \ Program Files \ Osteosys \ Sonost 3000 \ MeasureResultDir). The format is as follows.

1.   Graph BMP File

This is generated when the ResultImageType registry value is set to "Graph".

2.   Report.JPG File

ResultImageType is a measurement result image file created when the registry value is set to "Report" or as "Default"

- Option setting of Card Reader function

You can register the Key in the Registry section and set the value for the Card Reader function.

(Registry path : "MY COMPUTER\HKEY_CURRENT_USER\Software\OsteoSys\sonost-2000\Settings")

1. File creation setting of Patient measurement result
   - Key : CreateResultFileMode
   - Value :   "1" ->Activate generation of result file, "0" ->Disable generation of result file
   - Default Value: "1" -> Result file creation activation status

2. Set the patient information request file directory
   - Patient information request file (Patient.ini) This is the directory setting that receives the file.
   - Key : " PatientInputDataDirPath"
   - Default Value : " C:\Program Files\OsteoSys\SONOST 2000\PatientInputDir"

3. Setting the Patient Measurement Results File Directory
   - This is the directory path setting where the result file will be generated after patient measurement.
   - Key : "MeasureResultDirPath"
   - Default Value : "C:\Program Files\OsteoSys\SONOST 2000\MeasureResultDir"

4. File setting of Patient measurement result information

- Set the format in patient measurement result file.

- Key : " ResultFileType"

- Value : "INI" -> INI File, "TEXT" -> TEXT File

- Default Value : "INI" ->The INI file is the default Value.

- EX) ID_NAME.ini

5. File setting of Patient measurement result image

- Set the format in patient measurement result file.

- Key : " ResultFileType"

- Value : "Graph" -> Graph bmp File, "Report" -> Report format jpg File

- DefaultValue : "Graph" ->Graph bmp file is the default Value.

- EX) ID_NAME.bmp

6. F ile name setting of Patient measurement result information

- Set the file name in the patient measurement result file.

- Key : " ResultFileName"

- **Default Value : "" -> ID_NAME.txt or ID_NAME.ini (ResultFileType Related)**

- **If a value other than "" is entered as a value, the name is assigned to the value.**

- **EX) Value = "custom" => custom.ini or custom.txt**

7. N ame setting of Patient measurement result image file

- Set the file name in the image file of patient measurement result..

- Key : " ResultImageName"

- **Default Value : "" -> ID_NAME.jpg or ID_NAME.bmp (ResultImageTypeRelated)**

- **If a value other than "" is entered as a value, the name is assigned to the value.**

- **EX) Value = "custom" => custom.bmp or custom.jpg**

8. F ile witdh size setting of Reference Graph image

- Set the width size in Graph Bmp image file.

- Key : " ResultImageWidthSize"

- **Default Value : 452 (452 if no value is set   )**

- **When you set Value value, it has Width Size of set numerical value.**

9. F ile height size setting of Reference Graph image

7 7

- ■ Set the height size in the Graph Bmp image file.

- ■ Key : " ResultImageHeightSize"

- ■ **Default Value: 342 (342 if no value is set)**

- ■ **When you set Value value, it will have the Height Size of the set numeric value.**

10. F ile font size setting of Reference Graph image

- ■ Set the font size in the Graph Bmp image file.

- ■ Key : " ResultImageFontSize"

- ■ **Default Value : 15 (15 if the value is not set   )**

- ■ **When setting the value, the font size of the numeric value is set.**

11. H idden menu of Card Reader function option setting

Hidden menus for 1 to 10 registry settings are provided.
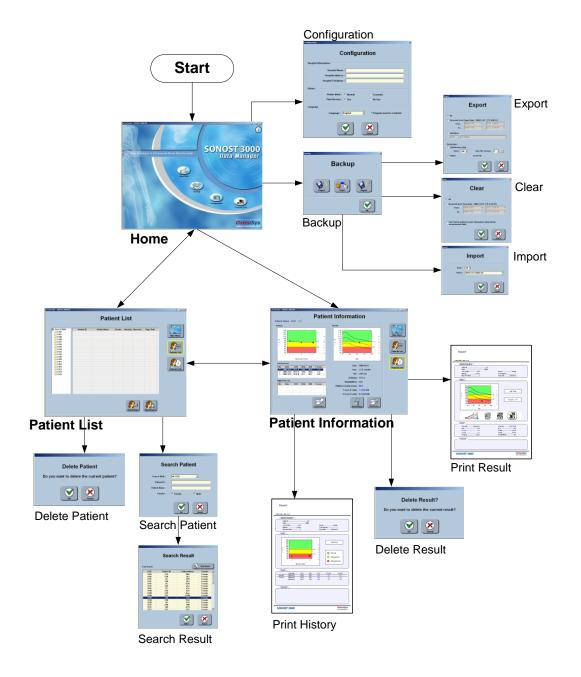
You can set the options from 1 to 10 in the following dialog window.

The hidden dialog window appears on the main screen with the Ctrl + Alt + S key combination.

3.5 The Method of Data manager S/W

3.5.1 Program operation process

Configuration

Export

Clear

Backup

Import

Home

Patient List

Patient Information

Print Result

Delete Patient

Search Patient

Delete Result

Print History

Search Result

3.5.2 Start to program

You can operate the program, when you click "SONOSTO 3000 DM" on the screen or on the srart button.

Home screen
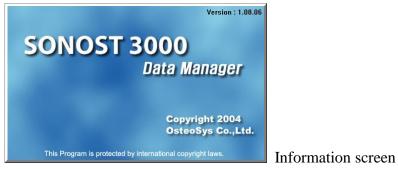
Screen is consist of 4 buttons and <Information> button which is you can show software information.

- view data : You can search results and print the report.
- Backup : you can get the data from other device or from this device and turn to at the beginning of status.
- configuration : you can set up this device which relate to program.
- program exit : you can close this program
- information : you can print the information of program which is on the right side of screen.

Information screen

3.5.3 Program Setup

You can setup this program

- Hospital name : you can input name. This information, when you printer you port, you can see it.

-Hospital Address : you can input address. This information, when you print report, you can see it.

-Hospital Telephone: you can input telephone number. This information, when you print report, you can see it

-Printer mode: This set up is for the saving Ink. If you choice 'Economic', you can save the ink.

-Print preview: when you print a report, you can choice preview of print

-Language: You can choice language. When you change the language, you should restart the OS. If not, the language will not change.

3.5.4 Backup

This function is if you send data to others such as USB memory stick, Printer and MS Excel file or get from USB memory stick, or delete the data.

Backup window

-Export: When you send data in PC to USB memory stick, or print data or make
       a file via MS Excel.
-Clear: You can delete data according as the condition.
-Import: you can get data to data manager from Software in PC or before exported
data from data manager

Export

This function is data saved in PC and export to other device.

You can export to USB memory stick, it can be send data to other PC and device.

Also, you can print. Out. Moreover, you can make excel file.

Export window

Export window are divided by two. You can set up the range and target.

Range set up is setting up the range of data for export. There are three way of methods.

-All : It can process data which are saved in PC.

- By period : It can process data when you set up the period which is 'From' and ' To'

- Individual: It is processed only chosen patients
(It can export via only USB memory stick)

Target set up is setting up the range of data for export. There are three way of methods..
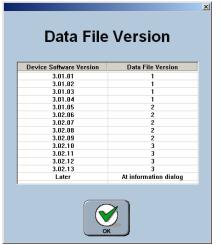
-USB Memory Stick: It is export via USB memory stick

-Printer : It is print out the result list.

-Excel File : It is make a excel file which is the result list

* When you export data to USB memory stick, you should choice the version correctly. If it is transfer data between data manager, it will be no problem. However, if it is transfer data between device, you must check and make the same version.
* When you click <?> button on the right side of screen, you can see data file's version.
* When you export to USB memory stick, it makes folder which is included the information of date and method of range set up. These data will save in this folder. Therefore, If you want to import data, you have to remember the date of export and method of range set up.

Data File Version

Device Software Version	Data File Version
3.01.01	1
3.01.02	1
3.01.03	1
3.01.04	1
3.01.05	2
3.02.06	2
3.02.07	2
3.02.08	2
3.02.09	2
3.02.10	3
3.02.11	3
3.02.12	3
3.02.13	3
Later	At information dialog

OK

Data File Version window

Clear

This is delete data in PC

   Clear window

Clear window are divided by two which are range set up and delete the patients' information set up.

Range set up is setting up the range of data for delete. There are two way of methods.
-All : It can process data which are saved in PC
- By period : It can process data when you set up the period which is 'From' and ' To'

Delete the patients' information set up mode can be delete basic information such as patients' ID, name and birth date

Import

This function is get data from USB memory stick to PC.

Import window

You can choice the data from SELECT and then click <OK> button. The contents in list of SELECT are when it exported on time and range. You should remember when you exported data.

3.5.5 Patient search and delete

When you click <View Data> button on the screen, you can see patients' list as below picture. On the left side of folders show patients' birth date and central part of screen, you can see patients' list which are lined up by birth date.

Patient List window

Search the Patient

If you click <Patient Search> on "Patient List" window, you can see "Search Patient" window
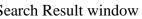
Search Patient window

You should input information correctly, and click <OK> button. It can show you Search Result window and then find the patient

Doing search, if you find the result, you can stop search through click <Stop Search> button.

Search Result window

After, select the patient, click <OK> button, you can choice the patient on the "Patient List" window

Delete the patient's info

If you want to delete patient, you should click <Patient Delete> button on "Patient List" window. Then it will show you "Delete Patient" window, when you press <OK> button, patient will be delete.

Delete Patient window
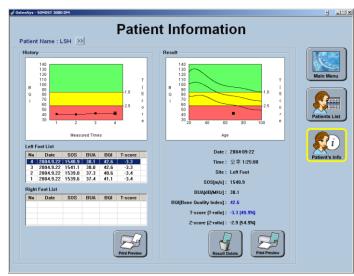
3.5.6 Searching, erasing and printing the result about patients' Disease history

Searching Patients' disease history

When you search about patients' disease history, you should choice patient on the
'Patient List' screen. Next to click <Patient Info> button, it will show you patient's
disease history and result on the 'Patient Information' window.
You can see disease on the left side of screen, on the right side, you can see detailed
information which are chosen by user. On the lower part of left side screen, you can
see disease history on each foot.   If you choice disease history on the list, you can

Patient Information window

Delete the patient's disease history

When you click <Delete Result> button, it will show you 'Delete Result?' window
which means whether delete this data or not. If you would like to delete this result,
you should click <OK> button.
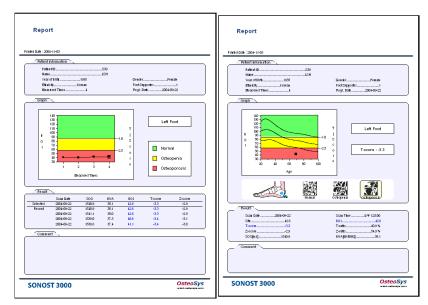
Delete result window

Print out the result sheet

There are two type of result sheet. One of them is disease history result sheet.

   The other one is normal result sheet. If you click <Print> button in the left side, you will get disease history result. And If you click on the right side of <print> button, you will get normal result sheet.

The report of disease historyThe report of result

Chapter 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 SONOST3000
Result of measurement turns out to be abnormal	3.3.1 Patient Measurement Procedure 3.4.7 DailyTest of SONOST3000
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 to OsteoSys or its authorized dealer.

4.2 Maintenance and Repair
4.2.1 Cleaning, Disinfection, Sterilization.

⚠ CAUTION !
Turn off the power before cleaning the device.
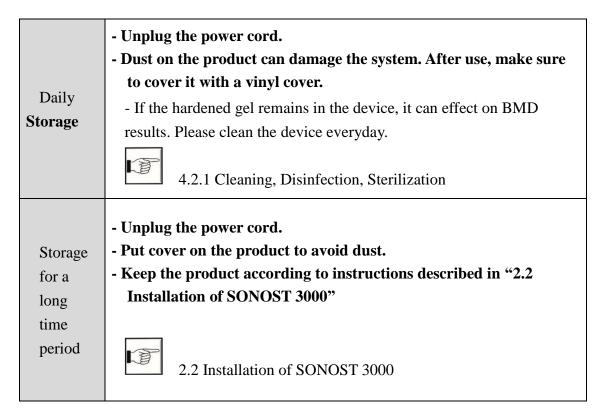
Product	Instructions
Device	**After using the device, wash with Alcohol swap.** The device should be cleaned with clean soft cloth wrung a water everyday, because gel remains around the probe or below the device. Especially, gel stained on the probe should be removed. After this procedure, clean the stained area with a dry piece of cloth. Probe endurance condition Temperature range : -40℃~70℃ Humidity 0~90% Atmospheric pressure : 50~106kPa External force 0~1N **Make sure not to put water or detergent on the device directly because it can cause fatal damage in the electric circuit contained inside.**

4.2.2 Product's life

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

4.2.3 Storage

Daily **Storage**	**- Unplug the power cord.** **- Dust on the product can damage the system. After use, make sure to cover it with a vinyl cover.** - If the hardened gel remains in the device, it can effect on BMD results. Please clean the device everyday. 4.2.1 Cleaning, Disinfection, Sterilization
Storage for a long time period	**- 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"** 2.2 Installation of SONOST 3000

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 !**	➢ **Do not open it because there are some high-tension components inside. It might cause serious danger.** ➢ **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.**
⚠ **CAUTION !**	➢ **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, contact the headquarters or an agency.** ➢ **Make sure to turn off the power switch before cleaning the product.A**

4.3.2   Cautions Related to Use Electronic Medical Equipment

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 "4.3.1Safety 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.
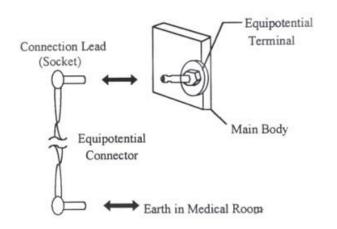
   👉   **2.3 Before Turning on Power**

   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 connection any other manufactures' 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 avoids electrical noise during scanning. Otherwise, abnormal images may 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.

D) If the fuses are gone, exchange the same type (250V T315AL). Otherwise a fire may occur or you may receive electric shock.

5　**Checking points after use of product**

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

B) Do not pull the power cord forcibly.

C) Comply with followings to keep the product properly.

① Avoid places that can wet the product.

② Avoid places where air pressure, temperature and humidity drastically change 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 modify use the product. 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 incline 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 useful lives, do not dispose them at your option. Contact OsteoSys or its authorized dealer for this service.

１１　**Others**

Read the user's instructions carefully and use the product properly.

Chapter 5.   Specifications & Software Updates

5.1   Specifications

*General

Classification	Class Ⅰ, Type B Applied part

*Device

Dimensions	615mm× 293mm× 310mm
Weight	12.6 Kg
Input Voltage	AC 100V ~ 240V, Free Voltage (Single Phase)
Input Current	1A, Class I
Frequency	50/60Hz
Power consumption	300VA
Ultrasonic Probe Diameter	Ø25mm
Ultrasonic Center Frequency	0.5MHz
Ultrasonic Probe Position Setting	Variable Measurement 12~136mm
Patient's Measurement Posture	In a sitting posture
Accessory	QC Phantom

*Environmental

Operating Temperature	15~ 30℃
Transport / Storage Temperature	-10~ 70℃
Operating Humidity	30 ~ 75% relative humidity
Transport / Storage Humidity	0 ~ 90% relative humidity, non-condensing
Atmosphere	700 ~ 1060hPa
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 debriscontaminants 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 Label

Osteosys Co.,Ltd   901-914, 9F, JnK Digitaltower 111 Digital-ro 26, Guro-gu Seoul 152-848 REPUBLIC OF KOREA
MADE IN KOREA   TEL: +82 2 6124 5900   Fax : +82 2 6124 5958

Eurpean Representative(EC REP) : CMC Medical Devices & Drugs S.L.
C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
TEL: +34 951 214 054   FAX: +34 952 330 100

Ultrasound Bone Densitometer   **Power rating**
MODEL(REF) : SONOST 3000   100-240VAC~, 50/60Hz, 300VA
S/N(SN) :

CE 2460

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.

Chapter 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.
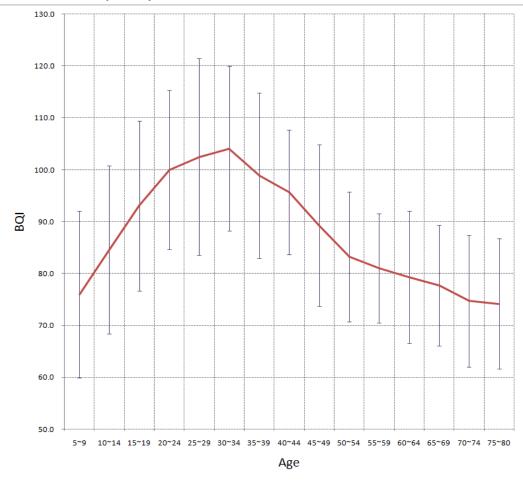
2) Gain : Amplification degree of ultrasonic signal which is controlled automatically.

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

Chapter 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 responsible to you for incidental or consequential damages of any kind arising from or connected with the use of its equipment.

●**What Should be Noted in Times of Request of Repair**

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

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

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

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

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