SONOST 3000

User's Manual

Model: SONOST 3000

Council Directive 93/42/EEC Concerning Medical Device

OsteoSys

http://www.osteosys.com

OsteoSys Co., Ltd.

SONOST 3000

User's Manual

Software Version :   5.10 (Windows XP)

DataManager Version :   1.07.02

Document Version :   9.1

Manufacturer and EC Authorized Representative Information

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

  903, 9F, JnK Digital Tower Building, 111 Digital-Ro 26, Guro-Gu,

  Seoul, Korea

  Tel : 82-2-6124-5900   Fax : 82-2-6124-5958

♣ **EC Authorized Representative : Ecornet Medical GmbH**

  High-t' Part Mainstr. 6c-d,D-45768, Marl,Germany

  Tel : 49-2365-92-437-0   Fax : 49-2365-92-437-55

⚠ **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.
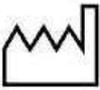
⚠ CAUTION !

"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.

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 ±0.2(T-score)precision error.**

- **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
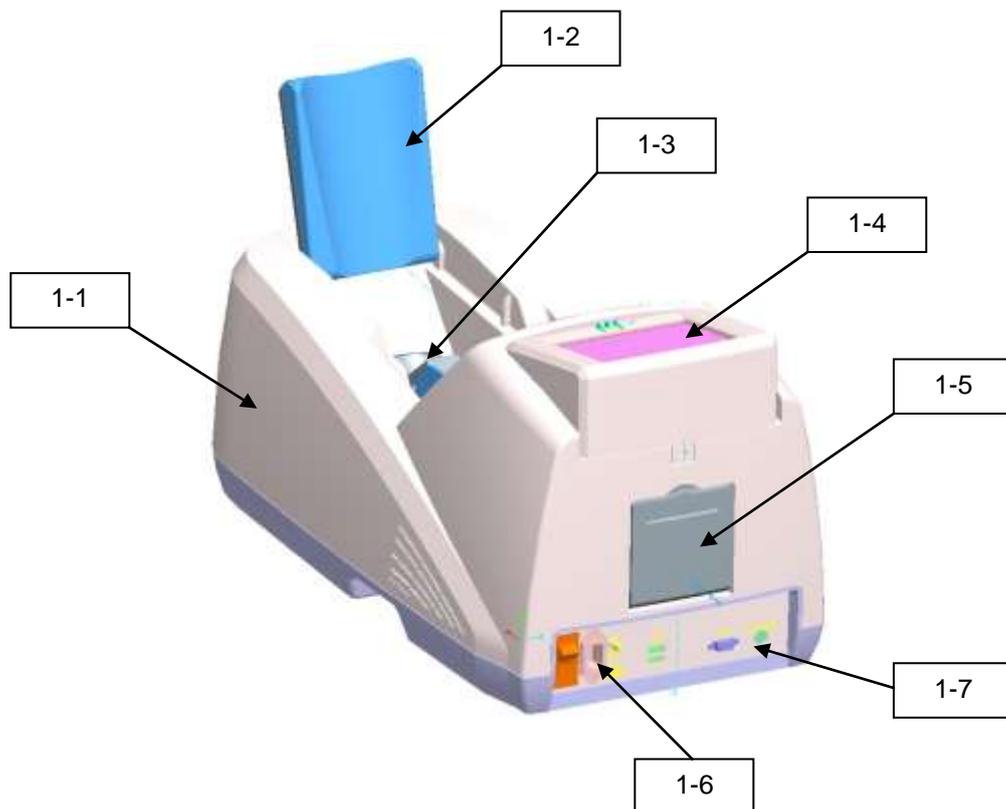
N O	Name	Function
1-1	TOP COVER	Protection for internal circuit
1-2	CALF SUPPORTER	Leg fixation for diagnosing
1-3	PROBE	Generation of ultrasound
1-4	LCD	Display for measuring status
1-5	THERMAL PRINTER	Thermal printing for the measurement report
1-6	SWITCH PANEL	Connection for the power cord and power 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

4.2.2 Stockpiles and Replacement of Articles

Names of Products	Number	Uses
Ultrasound Gel	**2 bottles**	**It helps ultrasound to progress between a probe and patient's heel.**
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.**
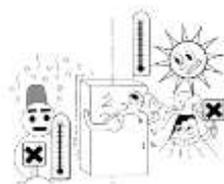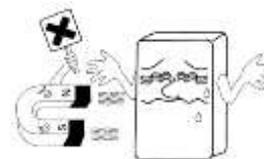
Do not cover ventilation of the system or place it near the wall. High inside temperature of the machine might cause a fire.	**100-240V is usable. When SONOST3000 is taken out of a warehouse, insulating transformers should be set to 100-240V. Since sudden power outage can remove all data saved in the product, you should install SONOST3000 in the place where a power supply is stabilized.**
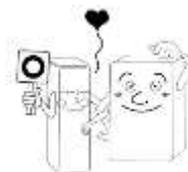
2.3 Before Turning on Power

Connection of Power Cable(with the outlet)

Avoid sharing the outlet.
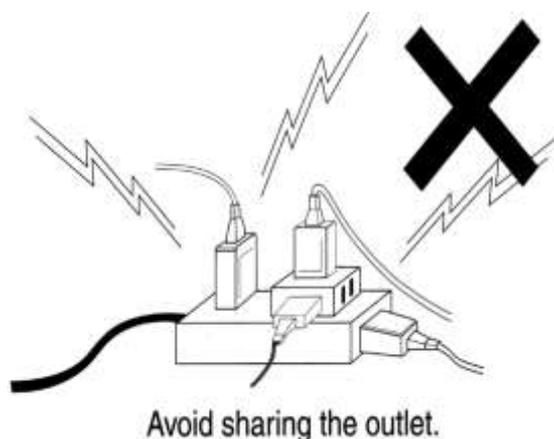
⚠ **CAUTION !**

> ➤ 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, Phantomand ultrasound transmission gel

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Dailytest Recommendation

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

</div>

3.1.2. Daily Test Procedure

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

❑ **Phantom's value checking**

Check the value of the SOS and range of the BUA on the Phantom Info of setting menu comparing to the bottom of the user phantom.

Bottom label
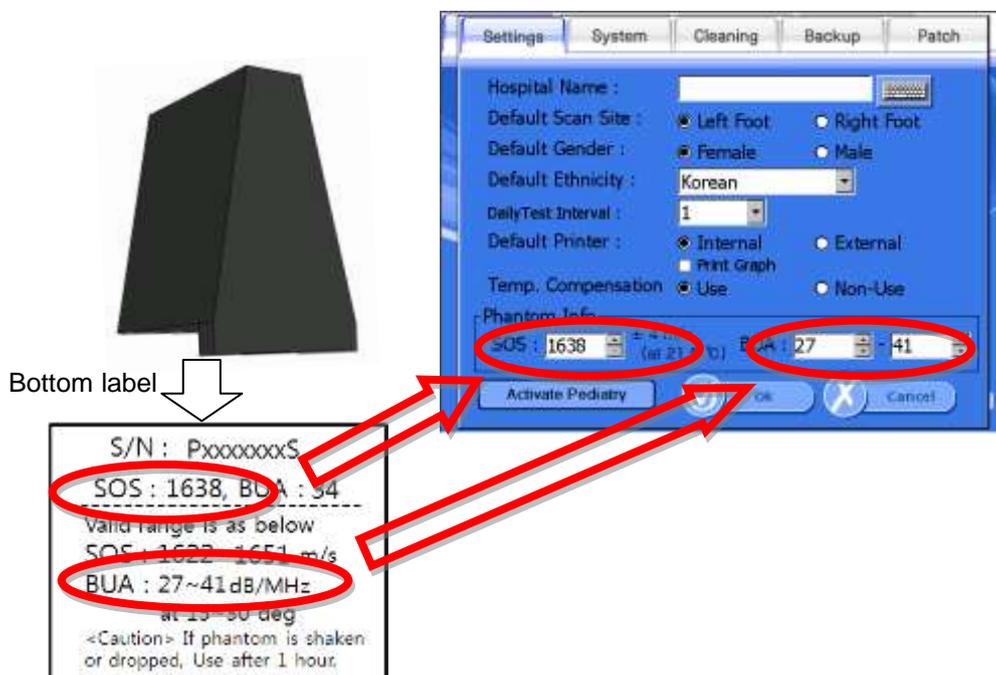
❑ **Phantom's setting**

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**

Push the DailyTest button

The Daily test should be done if the color of button is red.
The color is changed after daily test is completed.

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.
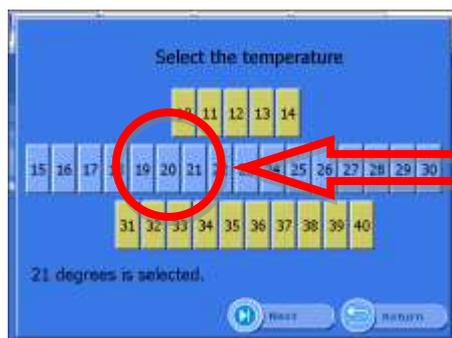
Execute <the daily test> by pushing the 'start' button.
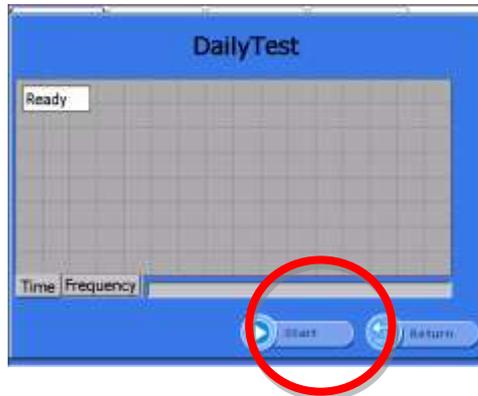
The following images are the execution screen of <the daily test>.
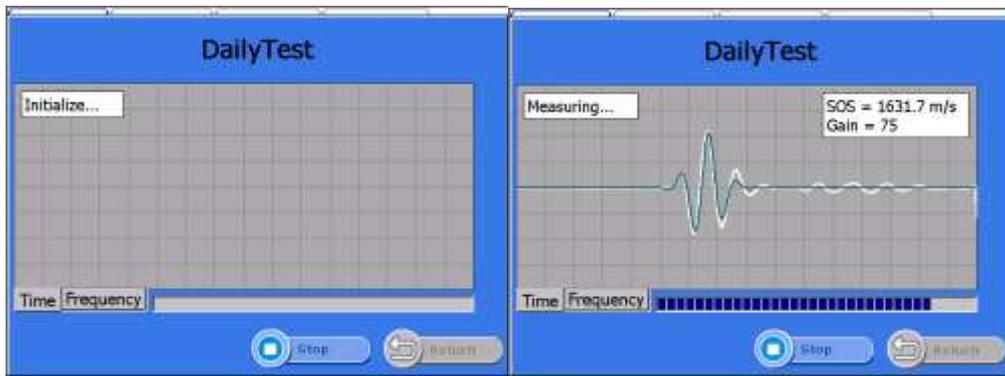
"Complete Daily Test" appears when the daily test is done.

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 Tab

②   Patient Tab

③   History Tab

④   History Detail Tab

3.2.2 Shutting down processing

Click shutdown Button [Power off button]
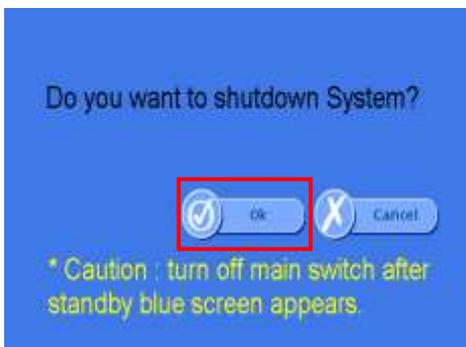
Click [OK]

Waiting until the blue screen appear

Turning off the main switch of the system

3.3 Using H/W

3.2.1 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

3.3.2 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 (lower section2) : use foot supporter 1 , 2 and P together.

①	②	③
(foot supporter 1)	(foot supporter 2)	(foot supporter P)

3.3.3 OSD (Auto screen alignment)

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

3.3.4 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
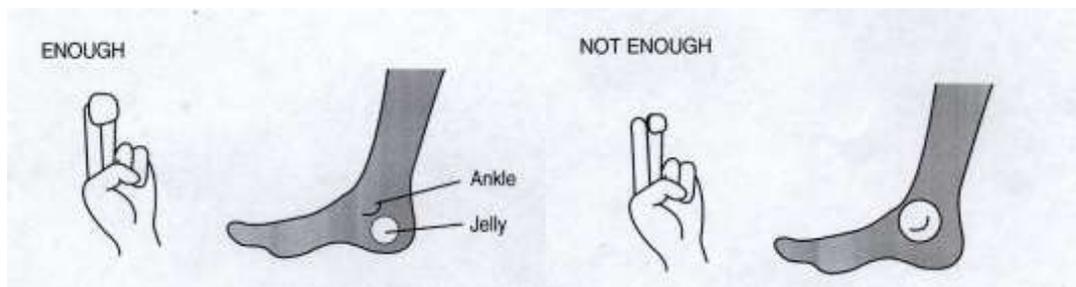
GoodNo Good

3.3.5 Correct position for Patient's foot & body

⚠ **NOTE !**

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

Place heel in the unit as shown in the 3 points below.
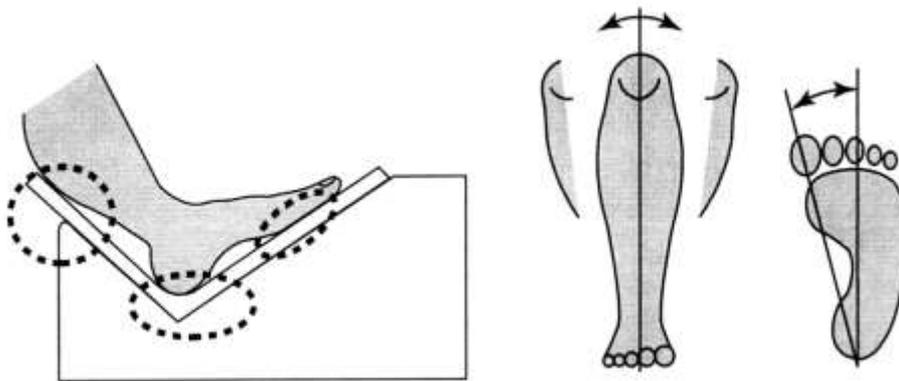
Make sure measuring device and body should be one line as shown below.

GOOD   NO GOOD
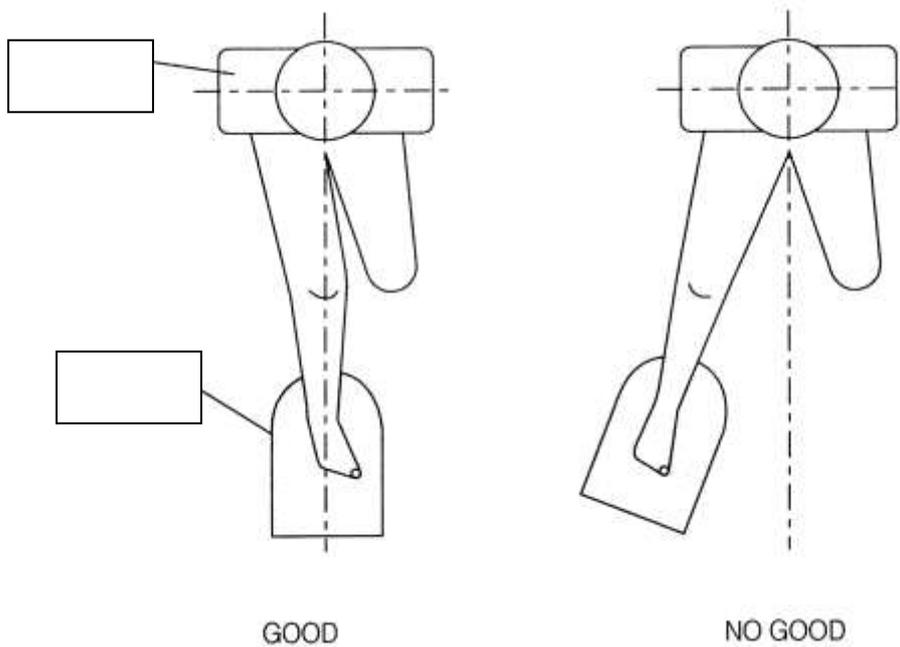
3.3.6 Setting of Internal Printer

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

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

② Paper inserting : Insert the paper as shown below.

  Outer surface of paper should face to the inside of the device.

Paper is scrolled in automatically.

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

⑥ 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 Progress Table of Program
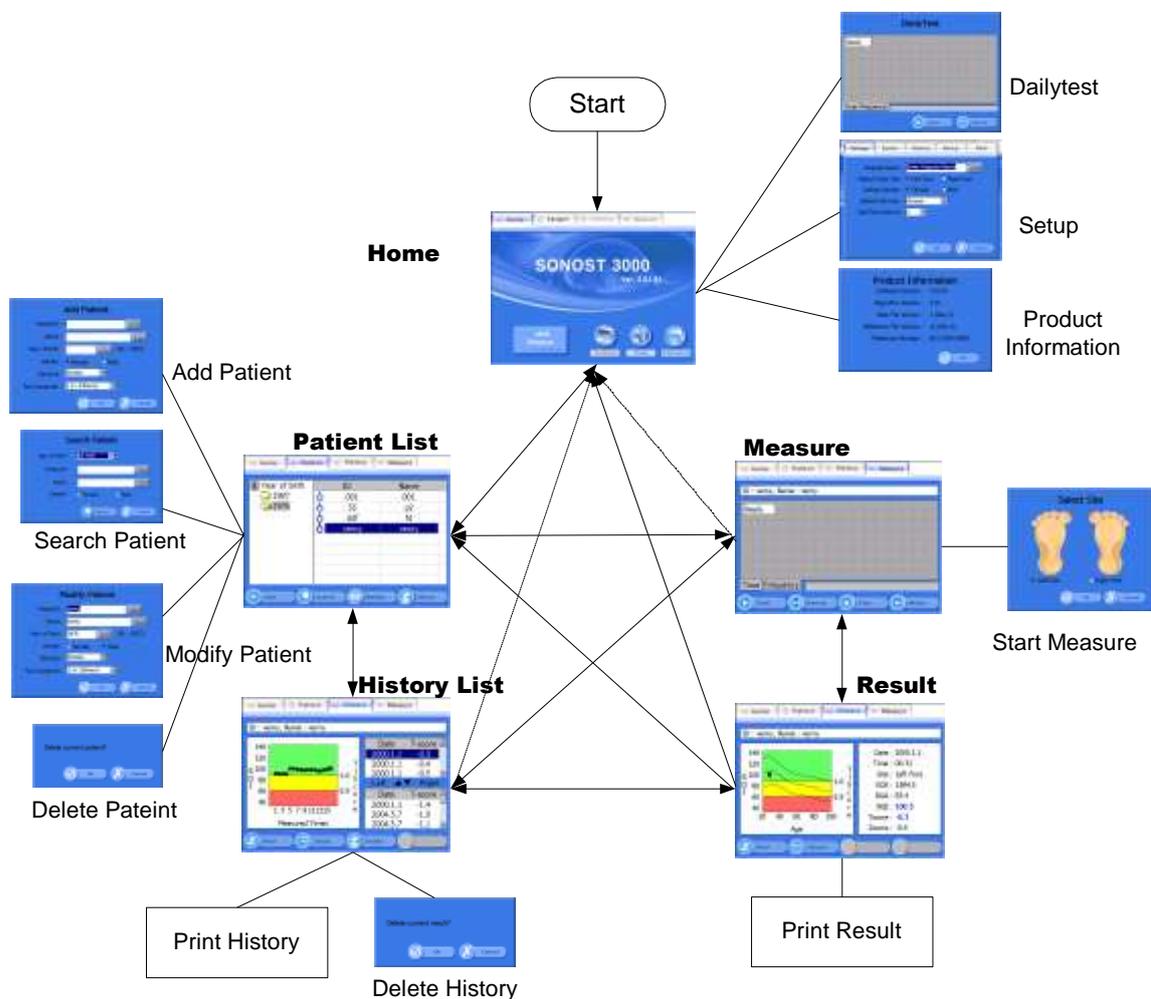
3.4.2 Execution of Program

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⚠ **CAUTION !**

If you hear any strange noise from the screen, switch it off and contact to OsteoSys or its Authorized dealer.

</div>

Turn on the power switch.

10 seconds after calibration that checks functions of the system and memory device, the program is automatically activated and you should configure the incipient environment.

This is the start up screen.

Home of the start up 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.
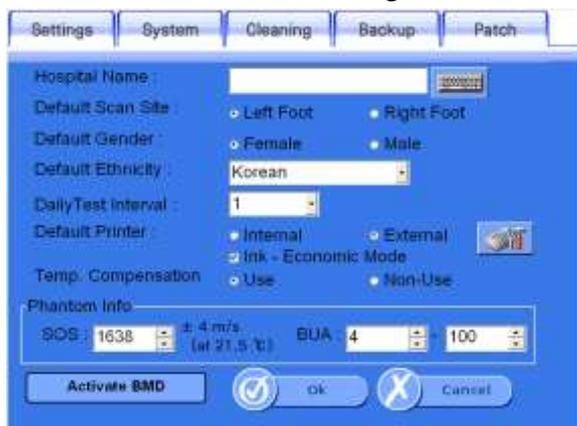
Setup>Settings Window

   - 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.
   - DailyTest Interval : 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.

- 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.

Cleaning

It makes probe is moved of user's own accord for cleaning.
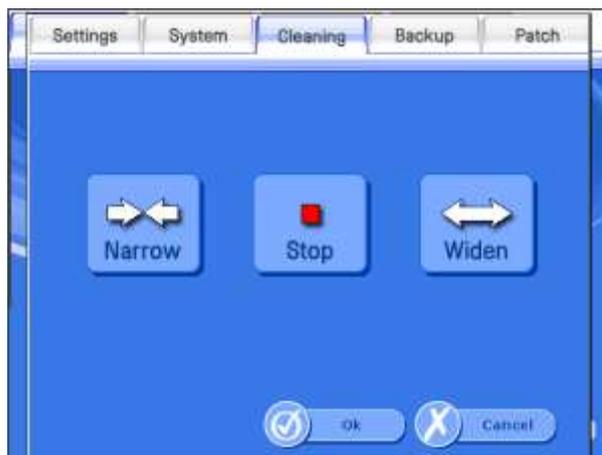
Setup>Cleaning Window

- 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.
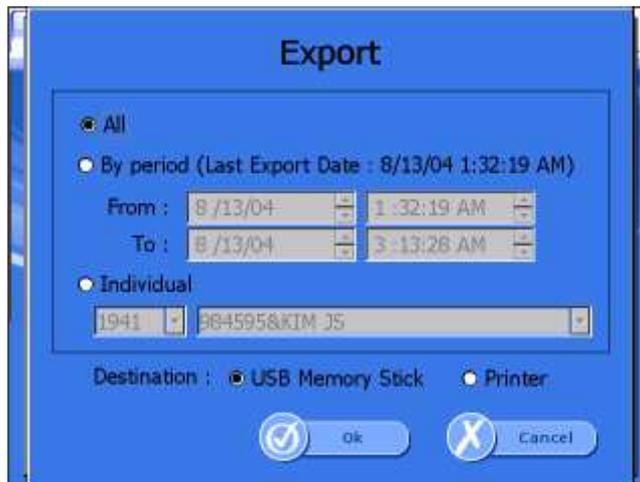
Setup>Backup>Export Window

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.
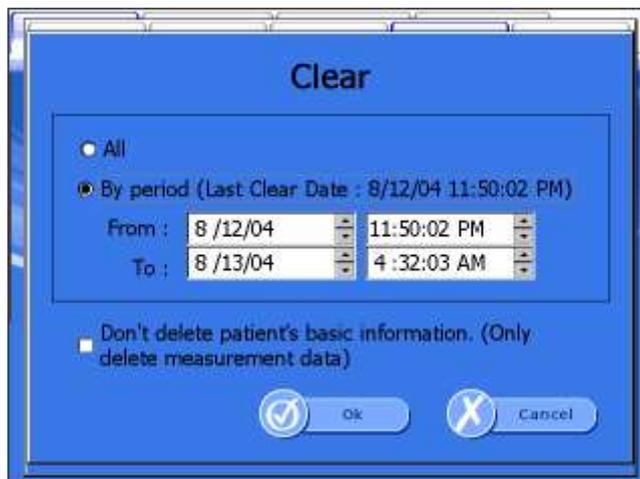
Setup>Backup>Clear Window

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.
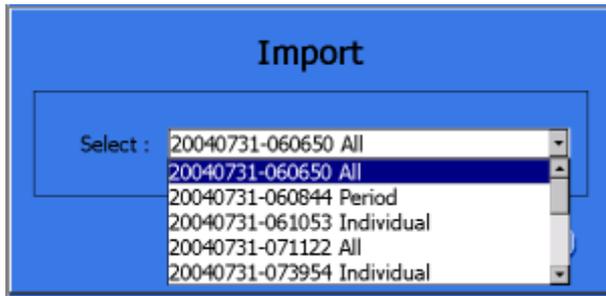
Setup>Backup>Import Window

Patch

It is upgrade the Software.

At first, Prepare a USB removable disk which support USB 1.1.   You can use mp3
player or digital camera too.

Copy the setupfolder including setup file(file name : setup.exe) to USB removable
disk.
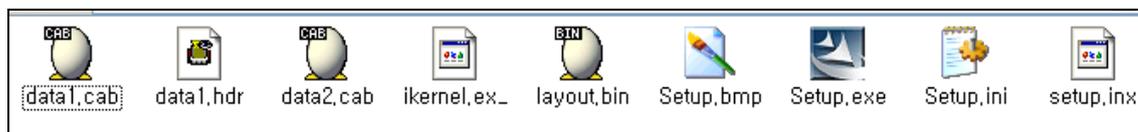
Insert USB removable disk into SONOST 3000 device's USB port.

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

Selection of BMD and GDP

Pediatry mode : 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]
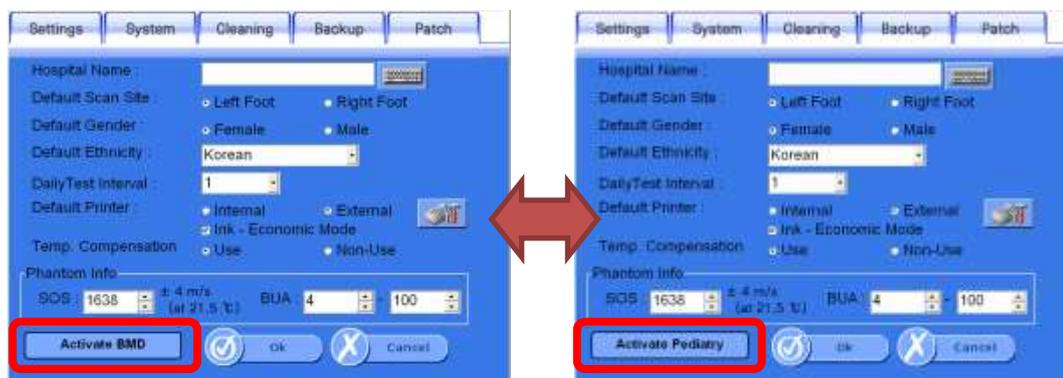
Patient Registration

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.
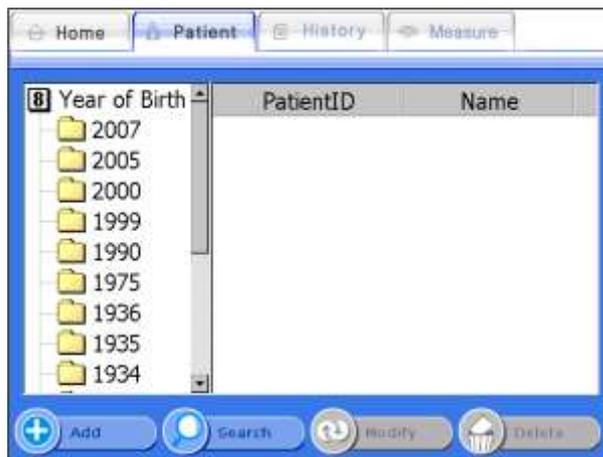
Patient List Window

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.
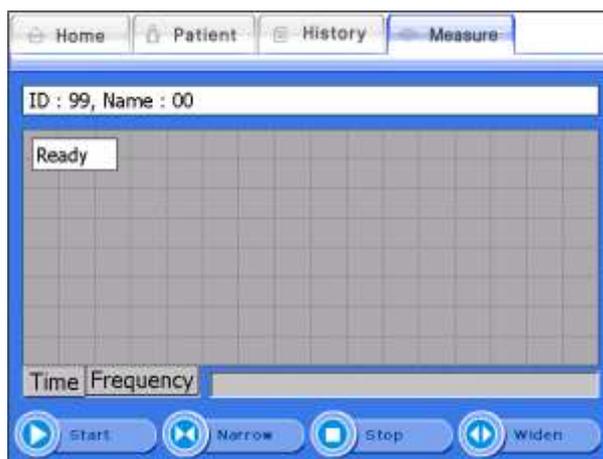
Measure Screen

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.
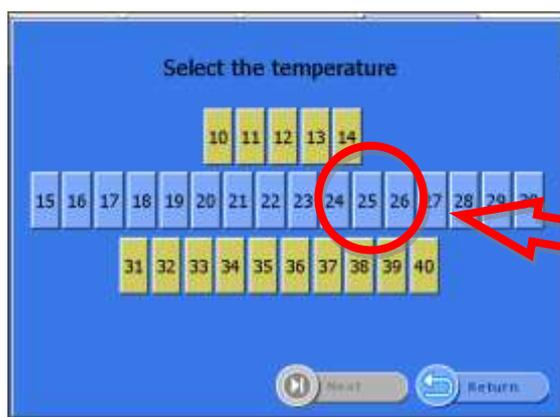
Temperature screen
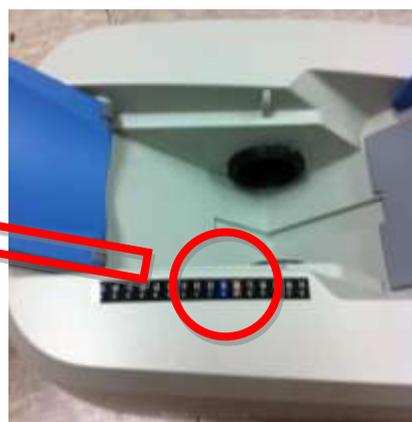
Click the next button.And Select the site of the foot and push the OK button.

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.
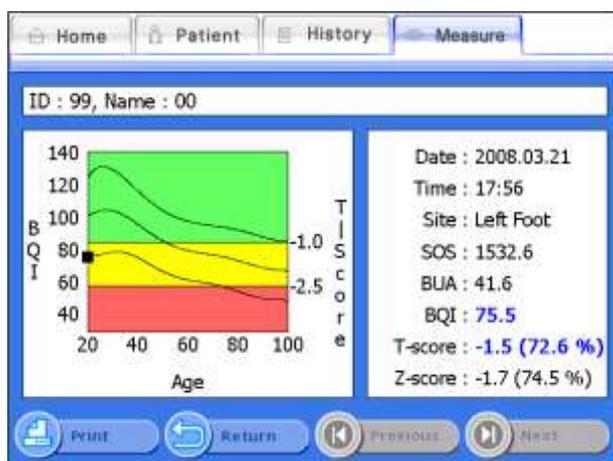
Detailed results screen.

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

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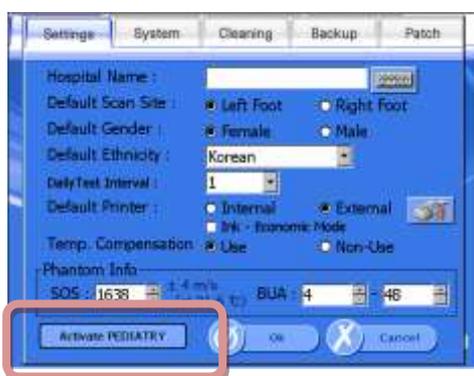
The button of Activate is used to toggle between PEDIATRY mode to BMD mode.

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.(supported from version 5.00)
- the result and graph of BMI. (supported from version 5.00)

※ Pediatric BMD
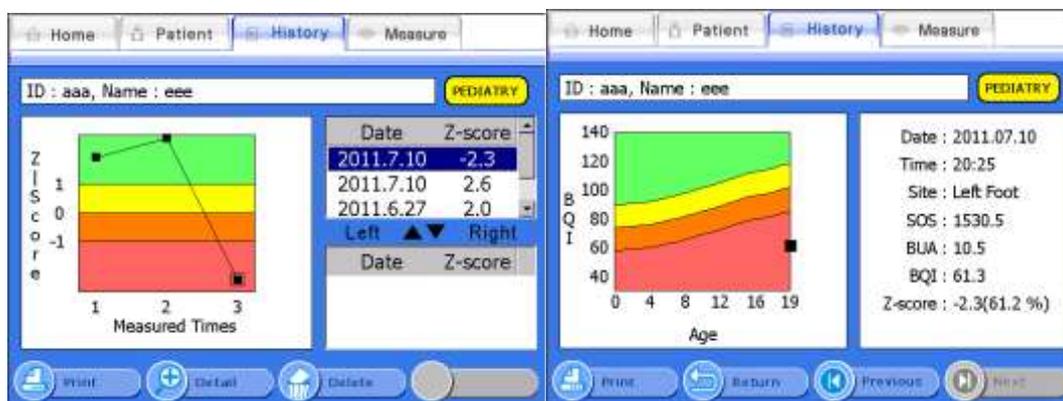
[History View]   [Detailed Result View]

※ 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.
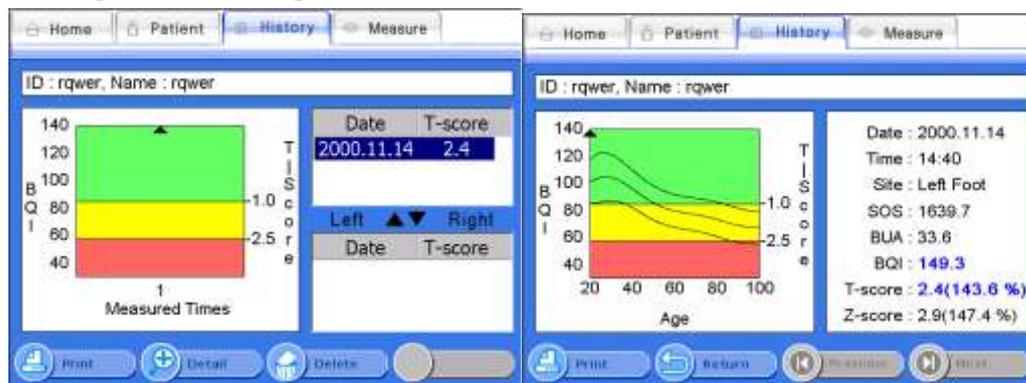
[History View]   [Detailed Result View]

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.
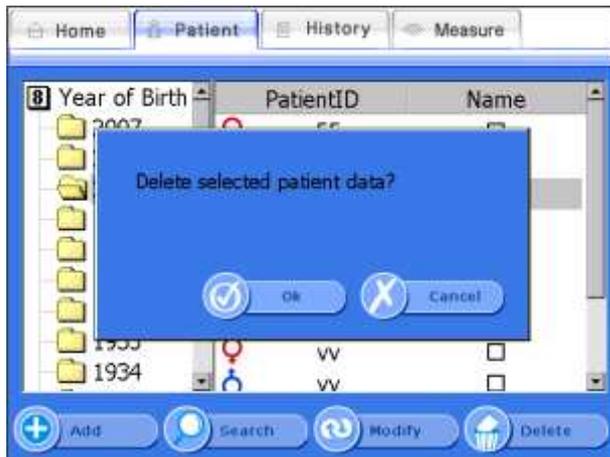
Delete Patient Window

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.
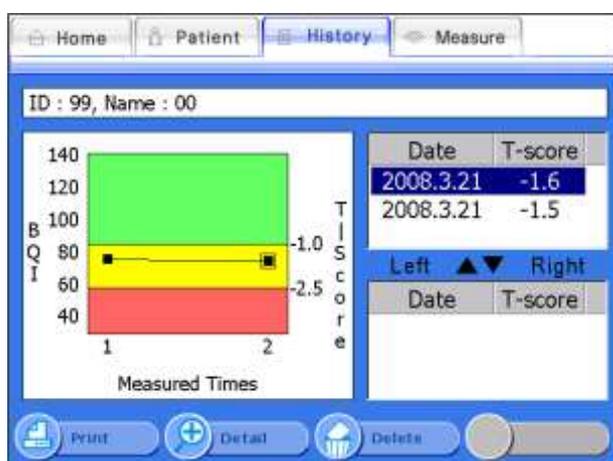
History List Screen

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.
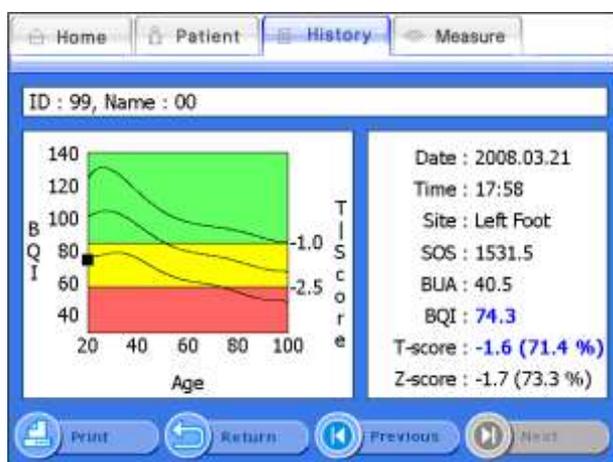
Detailed Result Screen

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.
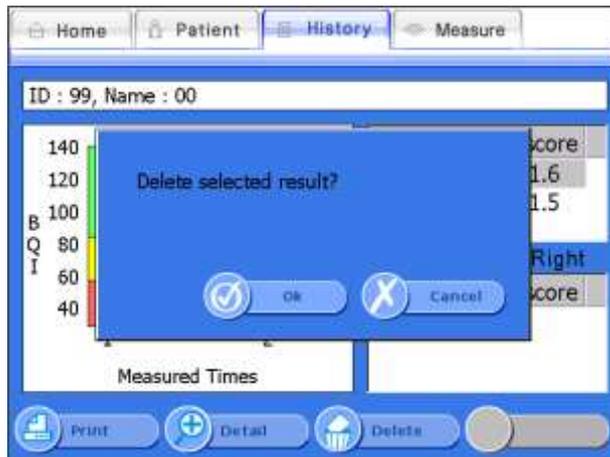
Delete Patient Window

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 DailyTest is 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.
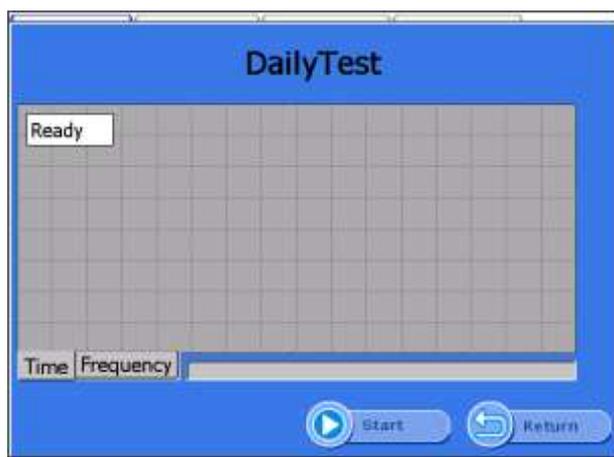
DailyTest Screen

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.
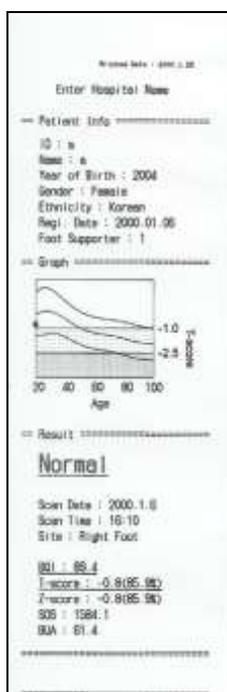
Printed result paper

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)
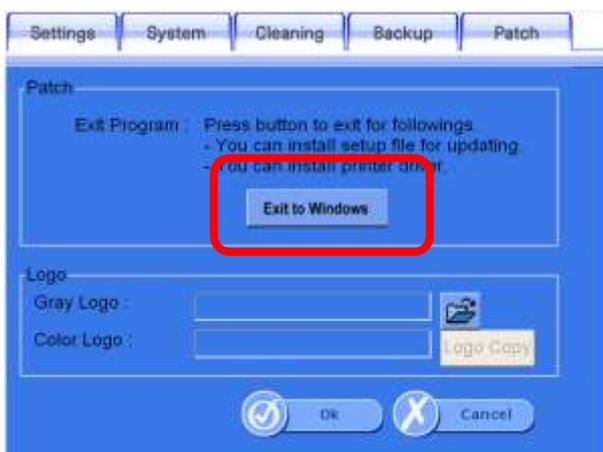
Copy the printer driver to USB memory stick.

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.
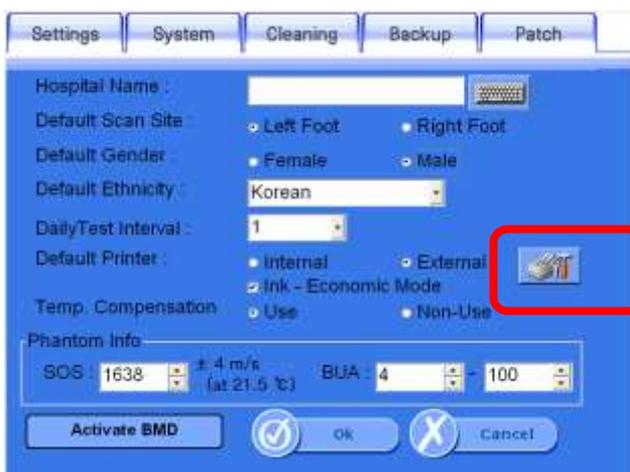
Select External and then click the icon of printer setting.

You can find the installed printer above and check it default printer (default printer : printer with checked mark)
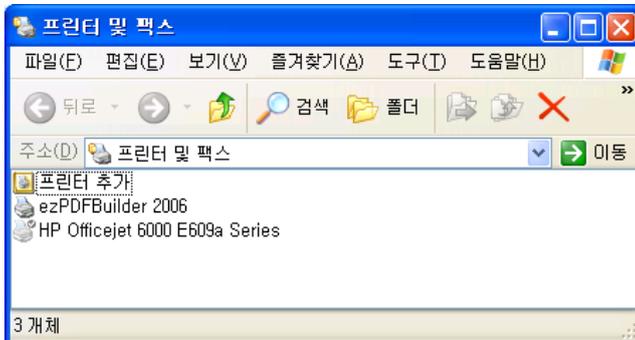
If you want to change the default printer, select the printer and then choose [File] – [default printer] on the top menu.

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.

70px

272px

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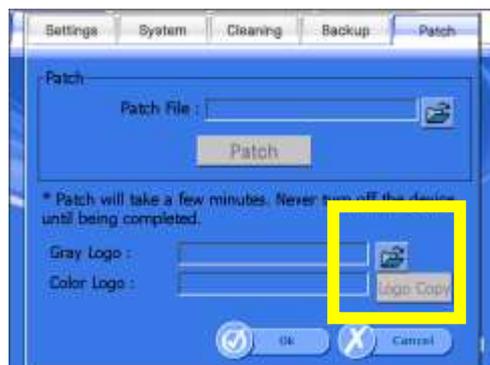
Push the button looks like folder shaped and select the image file for color and gray sequentially.

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.

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.

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	**3.2.6 Calibration of SONOST3000**
Result of measurement turns out to be abnormal	**3.2.4 BMD Measurement** **3.2.7 Calibration 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 7 years. (Except Accessory)

4.2.3 Stockpile and Replacement of Articles

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

2.1.3 Articles List

Articles	Specifications
Gel	Gel is a necessary article when measuring BMD. Please purchase new one before it being out of stock.

4.2.4 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.**

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.
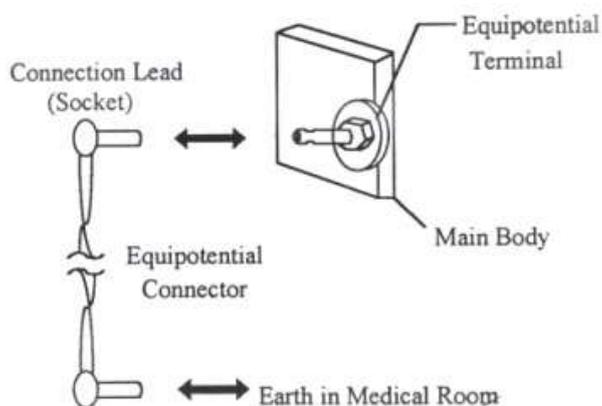
⚠ **NOTE !**

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**

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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 BF Applied part

*Device

Dimensions	615mm× 293mm× 310mm
Weight	12Kg
Input Voltage	AC 100V ~ 240V, Free Voltage (Single Phase)
Input Current	1A, Class I
Frequency	50/60Hz
Power	220W max.
Ultrasonic Probe Diameter	Ø25mm
Ultrasonic Center Frequency	0.55MHz
Ultrasonic Probe Position Setting	Variable Measurement 25~100mm
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 ～ 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 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.

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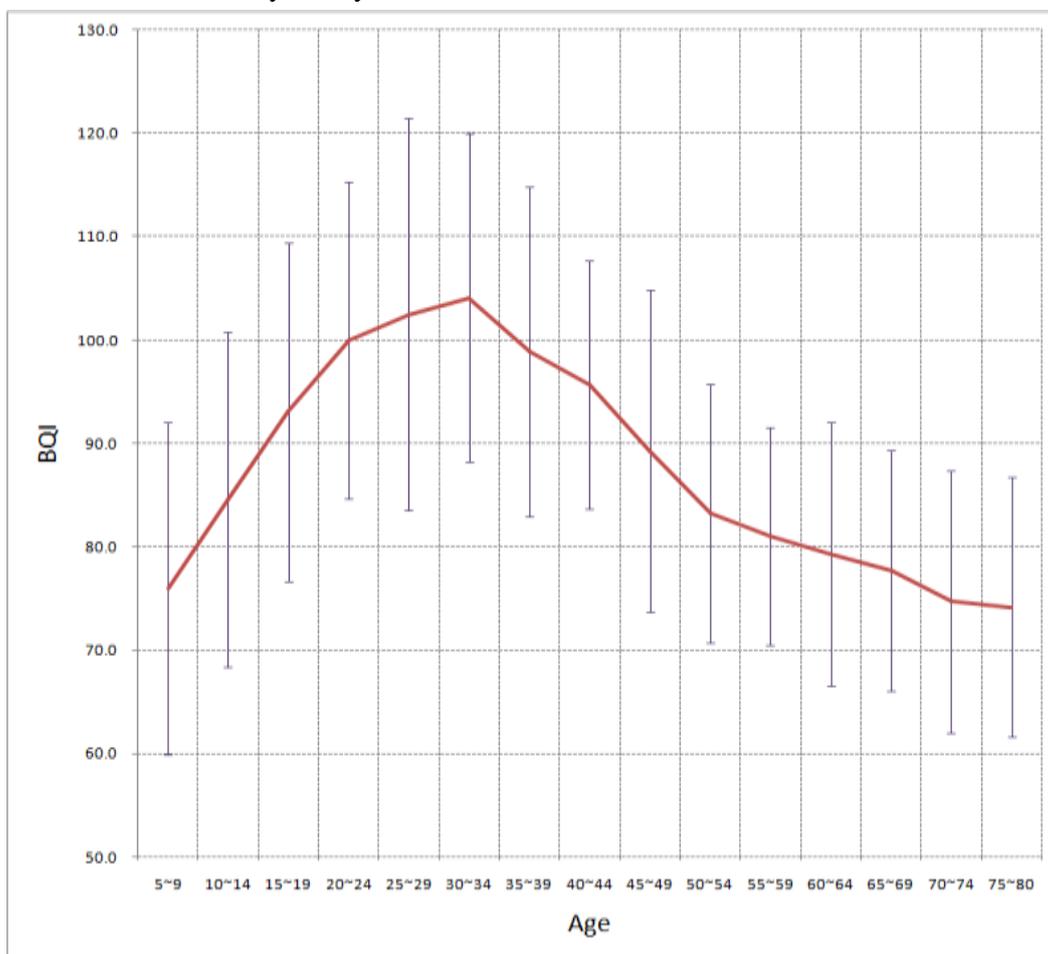
Ages	5~9	10~14	15~19	20~24	25~29	30~34	35~39	40~44	45~49	50~54	55~59	60~64	65~69	70~74	75~80
Mean	76.0	84.6	93.0	100	103	104	98.9	95.7	89.3	83.2	81	79.3	77.7	74.7	74.2
SD	16.0	16.2	16.4	15.3	19	15.9	15.9	12	15.6	12.5	10.5	12.7	11.6	12.7	12.5
N	36	41	39	40	38	35	38	40	42	37	41	35	37	38	35

✳ 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.