Ultrasound Bone Sonometer

MSLBD09、MSLBD10 Models

Use of Instructions

★Please read the instruction manual before installing and using this product

Before use

1. Thank you for choosing "MSL" brand products. In order to make the product work better, please read this instruction manual carefully.
2. Please make sure to preserve this instruction manual. The instruction manual provides detailed information about the system function, operation principle, product installation, software operation and maintenance of the product. It is convenient for you to use and maintain the product when finish reading this instruction manual.
3. The ultrasound bone sonometer (the following abbreviation is the product) trademark used by Medsinglong Global Group Co.,Ltd (the following abbreviation is the company) is a registered trademark and protect by relevant laws. Any company or individual are strictly prohibiting using the “MSL” trademark, the violator shall be investigated further for legal responsibility.
4. Ultrasound bone sonometer software is developed based on Windows XP/7/8/10 platform. The operation steps are described in detail in this instruction manual. Our company has full intellectual property right of the software. User are strictly prohibited to copy the software and install to other devices.
5. This instruction manual content includes two models of ultrasound bone sonometer (MSLBD09，MSLBD10). Please read the relevant specific model instruction according to the specific of the product which you are using.
6. Production date see product label, design operation life is eight years.

Thank you for purchasing ultrasound bone sonometer.

For the safety of using this product, please read this instruction manual and fully grasp the operation methods and important notice before using.

Warning, symbols and graphical signs

For the safe and correct using of this product, we have provided the following warnings, symbols and graphical signs in this instruction manual.

1. Warning

Danger！

"**Danger**" Ignoring this item may cause personal injury or accident.

Caution！

"**Caution**" Ignoring this item may cause the product working unproperly, damaged or inaccurate when measuring.

2. Symbols

Important note, it must be kept in mind when operating.

Please be attention and read the specific sections of the instruction manual or other documentation.

3. Graphical Signs

1) On the packing box

Up, suggesting that when storing, transporting and delivering, the product should be placed up.

Fragile product, suggesting that when moving the product, please be careful.

Keep dry, suggesting that when storing, transporting and delivering, please pay attention to rain and moisture.

Prohibit rolling, suggesting that when transporting the product, it cannot be

rolling. 

Stacking layer, suggest that the stacking layer should be no more than 4 layers.

2) On the Host

I Indicate that the product is Class I product according to security category classification which is located on the label of the host.

Indicate that the product is Type B product according to safety category classification which is located on the label of the host.

IPXO The host machine protection classification (IP code) is located on the label of the host.

开关 This is the power switch, is off, is on, which is located near the main power switch.

USB interface is located near the main power switch and the tablet connection interface.

注意！查阅随机文件 The label reminds users to read the instruction manual, which is located on the back of the host.

POWER The indicator light is located on the top of the host.

3） On the probe

IPX7 The probe protection class (IP code) is located on the probe label.

160501 Represent the probe number

PW-1MHz Represent the probe model

Catalog

Chapter 1 Introduction

Osteoporosis is one of the most serious diseases in 21st century. This product uses ultrasound method to measure Radius and Tibia. It will cost about 75 seconds to complete the measurement, during the measurement process, the waveform will display analog waves on the screen.

For the safe and correct use of this product, you must read the instruction manual before using. Prohibit operating the product use in other ways, except the way from the instruction manual.

Important information for product use

- This product is a medical device and can be used after people have trained well.
- Indications: Ultrasound measure Radius and Tibia density values.
- Contraindications：The people who allergy ultrasound transmission gel, or have disease in Radius and Tibia, or measurement position has fractures, skin lesions and open trauma.
- Users should know the danger of electronic medical equipment, when face the emergency situation, users should know how to solve problems.
- Please do not open the product without authorization.
- Please choose qualified external equipment (read the instruction manual Chapter 2.2), install the software correctly to ensure the ultrasound bone sonometer work properly.
- When this product software damage, it may not affect the safety of users, and will not cause significant damage or social loss.
- Please do not move the sonometer when it is working.
- Do not apply too much pressure to the subject when using the probe. Do not forget using ultrasound transmission gel to ensure signal transmission.
- Please keep the probe interface clean, when each subject finishes measurement, use 75% alcohol to wipe disinfection.
- After using phantom please clean the ultrasound transmission gel.
- Ultrasonic probe immersion depth does not exceed 1.5cm.
- Use the product as instruction require, avoid mechanical damage to the transducer part of the ultrasonic probe.
- You had better to remove the power or turn off the power when you not use. It can avoid causing interference to other devices.

- If interference occurs during use of this product, please check the surrounding environment of electromagnetic interference, including computer equipment, charging equipment, communications equipment.
- This product cannot be used with high-frequency equipment.
- Only use qualified and recommended peripheral equipment and accessories (meet the requirements of GB9706.1-2007 standard). Otherwise it may cause this product EMC performance decrease significantly. The added devices must be used for their intended purpose and have compatible interfaces.
- The company can provide the circuit diagram, list of components, etc., however we recommend users do not open equipment for repair. When the equipment has some problems, please contact the company for maintenance. If the users repair the equipment by their own, the company will cancel the warrant.
- This product needs to use ultrasound transmission gel, cleaning the probe need to use tissue, alcohol and water, etc., these wastes should be treated as medical waste to prevent cross-infection.
- This product contains electronic components, circuit boards and other materials, when need to scrap the product, please according to local environmental protection and other regulatory requirements for disposal, the company can also recycle the product. Do not dispose of it so as not to affect the environment.
- Portable and mobile communication equipment may affect this product.
- Do not connect to the connector which marked with the electrostatic discharge warning symbol, unless electrostatic discharge precautions are used.
- Provisions on precautionary measures for electrostatic discharge:

➢ The body brings different electrostatic voltage; due to the electrostatic discharge is in ns or μs to complete the time, the peak voltage may up to tens of amps, instantaneous power is very large, and the pulse energy is sufficient to damage the sensitive components in the electronic components. Since the rise time of the current waveform is very short, that is, the rate of change (di / dt) of the current is large, so that a high potential of several hundred volts or even kilovolts can produce a strong electric field to penetrate the sensitive element. In order to prevent damage to the instrument, the following measures should be taken:

1) To ensure environmental humidity

2) Laying anti-static flooring or carpet

3） Operators should wear the anti-static strap wrist

We recommend the user need to accept the interpretation of electrostatic discharge warning signs and electrostatic discharge precautions training.

We recommend to use the probes and cables which sold by the company, the use of specified accessories and cables can result in increased equipment or system emission or reduced immunity.

- The following cable types must be used to ensure compliance and compliance with interference radiation and immunity standards.

Cable	Length (m)
Power cable	2.5
USB cable	1.5
Probe cable	1.6

- This equipment cannot be used in close or stacked with other equipment, if it must be close or stacked, please check whether it can work properly or not.

➢ EMC Basic performance description： a）SOS Repeatability error≤0.4%；b）SOS accuracy CV≤0.15%。

- Pay attention to the electromagnetic environment, because the equipment may be affected by the field of electromagnetic fields. The equipment should be installed and used far away from the facilities which have strong magnetic wave emission, such as radio signal transmitting tower, high frequency electric knife, and nuclear magnetic resonance equipment.

The equipment may also produce some electromagnetic interference that may affect some electric equipment, but this product satisfied the electromagnetic compatibility standards, the following table shows instruction under electromagnetic environment.

Electromagnetic radiation

Guidance and Manufacturer declaration ------- Electromagnetic emission		
MSLBD10Ultrasound bone sonometer can be used under the following electromagnetic environment, the user should ensure that it used in this electromagnetic environment.		
Emission test	Conformity	Electromagnetic environment ----- guide
Radio frequency emission GB 4824	1 Group	MSLBD10 Ultrasound bone sonometer uses RF energy only for its internal functions. So, its radio frequency emission is very low, and has low possible to affect nearby electronic equipment.

Radio frequency emission GB 4824	A Type	MSLBD10 Ultrasound bone sonometer can be used in non-domestic and residential low-voltage power supply network.
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation / flicker emission GB 17625.1	Not applicable	

Electromagnetic immunity 1

Guidance and manufacturer's declaration -------- electromagnetic immunity			
MSLBD10Ultrasound bone sonometer can be used under the following electromagnetic environment, the user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC 60601 Test	Voltage	Electromagnetic environment --- guide
Electrostatic discharge GB/T 176626.2	±6kV Contact discharge ±8kV Air discharge	±6kV Contact discharge ±8kV Air discharge	The floor should be wood, concrete or tile, if the ground is covered with synthetic material, the humidity should be at least 30%
EFT GB/T 17626.4	±2kV power cable ±1kV in/out cable	±2kV power cable Not suitable	The power supply should have the quality that is used in a commercial or hospital environment.
Wave GB/T 17626.5	±1kV Line to line ±2kV Line to ground	±1kV Line to line ±2kV Line to ground	The power supply should have the quality that is used in a commercial or hospital environment.
Power input line voltage decrease, Short interruptions and voltage changes GB/T 17626.11	< 5%UT, last 0.5 week (On UT, >95% Temporary decline) 40% UT, last 5 week (On UT, 60% Temporary decline) 70% UT, last 25 week (On UT 上, 30%	< 5%UT , last 0.5 week (On UT, >95% Temporary decline) 40% UT, last 5 weeks (On UT 上 , 60% Temporary decline) 70% UT, Last 25 weeks (On UT 上, 30%	The power supply should have the quality that is used in a commercial or hospital environment. If users need to use the equipment during a power outage. we recommended that it should powered by an uninterruptible power

	Temporary decline) < 5%UT, last 5 s (On UT, >95% Temporary decline)	Temporary decline) < 5%UT, Last 5 s (On UT, >95% Temporary decline)	supply or battery.
Magnetic field (50Hz) GB/T 17626.8	3A/m	3A/m	Magnetic field should have quality to used in a commercial or hospital environment.
Note：UT ---- AC voltage applied before the test voltage			

Electromagnetic immunity 2

Guidance and manufacturer's declaration -------- electromagnetic immunity			
MSLBD10Ultrasound bone sonometer can be used under the following electromagnetic environment, the user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC 60601Test	Voltage	Electromagnetic environment --- guide
Radio frequency conduction GB/T 17626.6 Radio frequency radiation GB/T 17626.3	3V (Valid values) 150kHz~80MHz 3V/m 80MHz~2.5GHz	3V (Valid values) 3V/m	Portable and mobile RF communication equipment should not be closer than the recommended isolation distance. Please according to the formula to calculate the correct distance. Recommend distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz~800MHz $d=2.3\sqrt{P}$ 800MHz~2.5GHz Formula： P——Maximum transmitter output power, in watts (W) d——Recommended distance in meters (m). The strength of a fixed RF transmitter is determined by measure electromagnetic field A, each frequency should be lower than the composite level at each frequency B.

			Interference may occur when see the following symbol. 
Note 1：In the 80MHz and 800MHz frequency, using the higher frequency band formula. Note 2：These guidelines may not appropriate for all situations. Electromagnetic transmission affects by the building, objects and human body absorption and reflection effects.			
A Fixed transmitter, such as: Wireless (cellular / cordless) phones and terrestrial mobile radio base stations, amateur radio, AM and FM radio broadcasting and television broadcasting, the field strength cannot be accurately predicted in theory. In order to determine the electromagnetic environment of fixed RF transmitters, we should consider the electromagnetic fields. If the field strength is higher than the RF compliance level, we need to observe whether the ultrasound bone sonometer work well. If abnormal performance is observed, supplemental measures are necessary, such as adjusting the direction and position of the ultrasound bone sonometer. B In the whole frequency range of 150kHz ~ 80MHz, the field strength should be lower than 3V / m.			

Safety Distance

Recommend isolation distance between the Portable, mobile RF communication equipment and ultrasound bone sonometer			
MSLBD10 Ultrasound bone sonometer is expected to use under the radio frequency radiation and electromagnetic environment. According to the maximum output power of communication equipment, MSLBD10 users can be maintained by portable and mobile radio frequency communication equipment (transmitter)and MSLBD09S+ minimum distance to prevent electromagnetic interference.			
Transmitter maximum output power W	The isolation of different frequencies/m		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

This table not listed the transmitter maximum output power, the recommended isolation distance “d” in meters (m) can be determined using the formula to calculate, where “P” is provided by the transmitter manufacturer Transmitter maximum output power in watts (W).

Note 1: In the 80MHz and 800MHz frequency, using the higher frequency band formula.

Note 2: These guidelines may not appropriate for all situations. Electromagnetic transmission affects by the building, objects and human body absorption and reflection effects.

Chapter 2 Product Overview

2.1 Working principle and scope

Principle of operation: Ultrasonic velocity measurements of ultrasonic waves along the Tibia or Radius direction of the ultrasonic velocity (SOS), and calculating a set of parameters to reflect the bone condition. When the ultrasonic wave from a sparse medium into the wave dense media, it will be in the two kinds of media interface to produce reflected and refracted wave phenomenon. As the angle of incidence increases, the angle of refraction increases gradually. When the angle of incidence reaches a certain value, its refraction direction is parallel to the direction of the bone surface, and after the distance from the surface of the bone, the same angle Bone surface shot. The propagation time of the first arrival signal can be measured and used to calculate the speed. The speed can directly reflect the size of bone density, bone density decreased, the ultrasonic conduction velocity decreased.

Scope of application: Ultrasound detection of Tibia or Radius site of bone density.

2.2 Product model

- Product model
  MSLBD09、MSLBD10
- Model contrast

Project \ Model		MSLBD09	MSLBD10
1	Measure Site	Radius	Tibia or Radius
2	Software	Tibia /Radius software V1.0a	Tibia /Radius software V1.0b

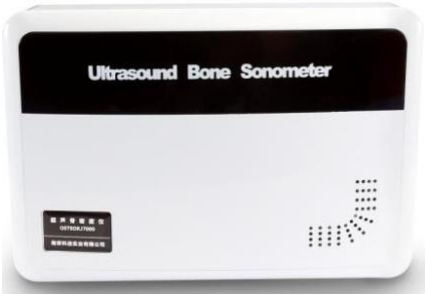
2.3 Product component

Ultrasound bone sonometer consists of host, ultrasound probe, USB cable, power cable, power adapter, phantom, positioning ruler, host holder and program discs

2.3.1 Host Machine

2.3.1.1 Host machine component

Host front side appearance



Host right side appearance

Host back side appearance

Host left side appearance

MSLBD09、MSLBD10 Appearance

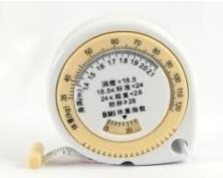
2.3.1.2 Port description

NO.	Name	Function
1	Probe interface	Ultrasound probe interface
2	Power light	Light on, product working
3	USB interface	Connect to computer
4	Power switch	“ ”is on, “ ”is off
5	Power interface	+12V Power interface

2.3.2 Accessories

Before using the product, confirm the following accessories, if have any problem, please contact the company.

Accessories composition table

Product Name	Quantity	The main application
 Probe	1	Connect to host
 Phantom	1	Calibration
 USB cable	1	Connect to host and computer
 Power cable	1	To supply power
 Power Adapter	1	To supply power
 Position ruler	1	To confirm the measure position

 Host bracket	1	To fix host
 Program disc	1	**Software name: Tibia /Radius ultrasound bone sonometer software.** Version: V1.0 With set the date, time, enter the subject information, measurement steps, print preview and print diagnostic reports, T-score, Z-score, T-ratio, Z-ratio, bone age, BQI, RRF, EOI, calibration, PACS, print review, touch screen, language, recover, search, delete, back up.

2.3.3 About consumables

Consumables (ultrasound transmission gel, alcohol) are not the part of this product, user need to buy it by themselves.

4.2.2 Replacement of consumables

Name	Quantity	Instruction
Ultrasound Transmission Gel	——	Ultrasound is difficult to through the air, so we should use ultrasound transmission gel when measuring. User should purchase and use qualified ultrasound transmission gel.
Alcohol	——	Use 75% medical alcohol, cleaning the equipment after each subject measurement.

2.3.4 Recommended computer configuration

The sonometer need to link computer, monitor, printer, keyboard, mouse, and install software correctly that can run correctly. Users must purchase the regular manufacturers branded products. External device configuration requirements:

Operating system: Windows XP or higher

CPU: Intel P4 1.7Gor higher

RAM: ≥1G

Hard disk: ≥80G（The minimum disk space required for installation is 100M）

Monitor: Resolution 1024×768 or higher

Color printer: 300DPI or higher

It is recommended to use a solid table (mounting table) for the placement of external devices.

Connect the USB interface of the product with the USB interface of the host machine reliably with USB cable. Firstly, turn on the computer and then turn on this product. When first time operate the product, please install the software use the program CD. After installation, you can run the software to operate the equipment. (Chapter 3 Product use).

2.4 Product connection and external printer settings

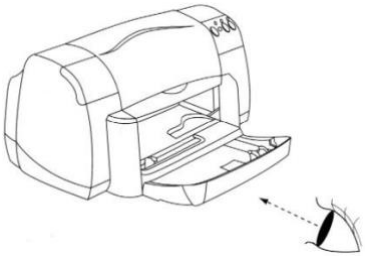
1）connect the USB cable to the product

The plug needs to align with the port.

When pull out the USB cable from the host, do not pull the cable directly and pull it out at the interface position. The USB cable should be plugged in.

Cable connection diagram 2）

Make sure that the paper is supplied to the printer as required.



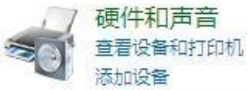
External printer

External printer setting:

If you set up an external printer to print the report, you need to enter the Windows system control panel, change the printer settings. For example, the following is windows 7 operation system to set the external printer steps:

Click "Start" in the lower-left corner of the desktop and then enter the Control

Panel (or open "My Computer" and then click "Control Panel" on the left):

Click 

" next "View devices and printers", and you will see:

Under "Printers and faxes", right-click the external printer which you need:

Choose“Set as the default printer (A)”, and then finished.

Chapter 3 Product use

3.1 The use of hardware

3.1.1 Use the phantom

3.3.2.3 Calibration

Scribble Ultrasound Transmission Gel on phantom

Put the probe on the phantom

3.1.2 Measurement

According to demand choose right position

Measure Radius BMD
Locate Radius 1/3 position
Wipe the subject's arm with alcohol

Measure Tibia BMD
Locate Tibia half position
Wipe the subject's leg with alcohol

Apply ultrasound transmission gel

Measure like these two pictures

Measure Radius BMD methods:

1) In general, choose the rarely used side arm of the subject, if the rarely used side of the body deformity or injury, please choose the other side of the arm.
2) The subject sits towards to doctor and close to the work table. The rarely used side arm rests on the work table, and the palm of the subject should be stretched vertically and the fingers close together.
3) Use the position ruler to measure the arm to the top of the middle finger (not including the length of the nail), marked in half the length of the position, this position is Radius distal 1/3.

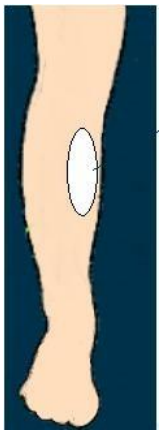
After determining the position between the probe and the test site of the subject, then start measuring.

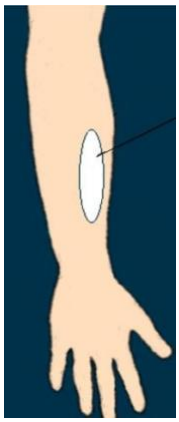
When the measurement is started, the test site of the subject cannot be moved and should remain stationary. After each measurement, use tissue to clean the probe, and then use 75% concentration of alcohol cotton cleaning the probe and the body where may touch the probe.

3.1.3 Location and dosage of Ultrasound Transmission Gel

Apply ultrasound transmission gel on the calcaneus

In order to remove residual air between the probe and measurement position, please apply sufficient ultrasound transmission gel.



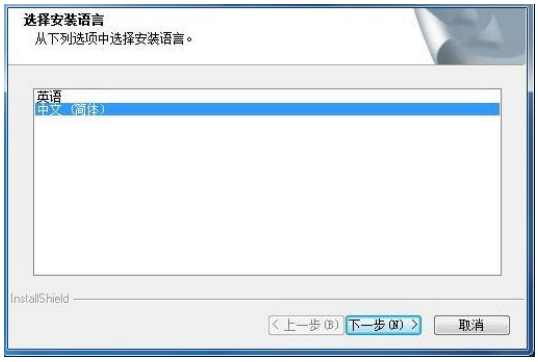


3.2 Software installation

3.2.1 Initial installation

When first installing ultrasound bone sonometer Software V1.0, please insert the program CD into the CD-ROM drive and double-click setup.exe in the installation file. The software installation dialog box will appear, select the required language (English) and click "Next (N)" when popped up ultrasound bone sonometer software installation dialog box, as shown below:

Click "Next" (N) when popped up license agreement dialog box, as shown below:



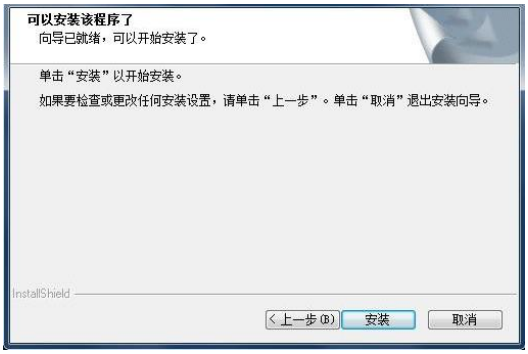
Click "Next" (N) when popped up license agreement dialog box, as shown below:

Select "I accept the terms of the license agreement (A)", and then click "Next (N)" when popped up the installation selection dialog box, as shown below:

Select the installation path and click "Next (N)" when popped up installation

confirmation dialog box, as shown below:

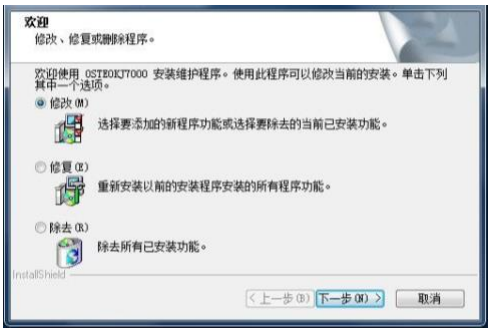
Click "Install", the software starts to install, as shown below:



After the installation has completed, the following dialog box will pop up. At this time, click "Finish (F)" to complete the installation of the software.

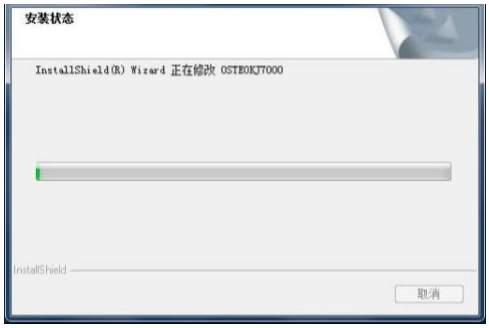
3.2.2 Software alterations and deletions

During the use of this product, if the software have problems, you can choose software repair or software removal. Double-click the installer setup.exe, enter the program maintenance dialog box, as shown:

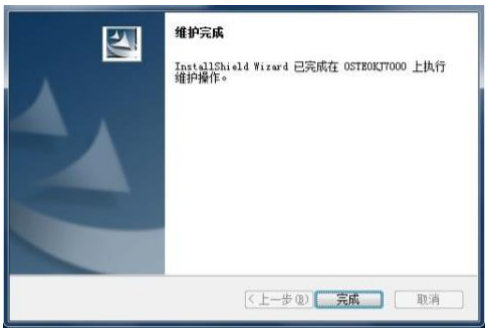


Select "modify (M)", click the button "next (N), as shown below:

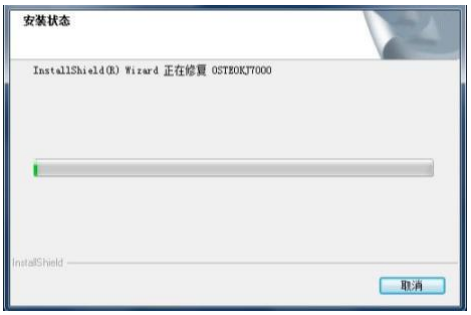
Set the custom option, click "Next (N)", the software began to install, display the installation progress:



Click "Finish" to complete the installation of the software.



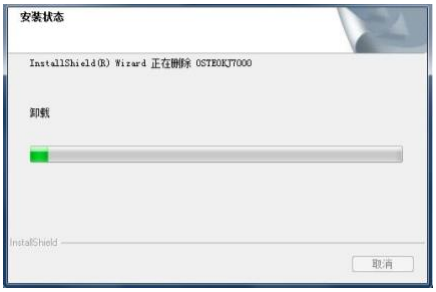
Select "Repair (E)", click "Next (N)", the software starts to repair, show the progress:



Click "Finish" to complete the installation of the software.

In the program maintenance dialog box, select "Remove (R)", click "Next (N)", the pop-up confirmation dialog box appears, as shown:

Click "yes (Y)", the software automatically uninstall, as shown:

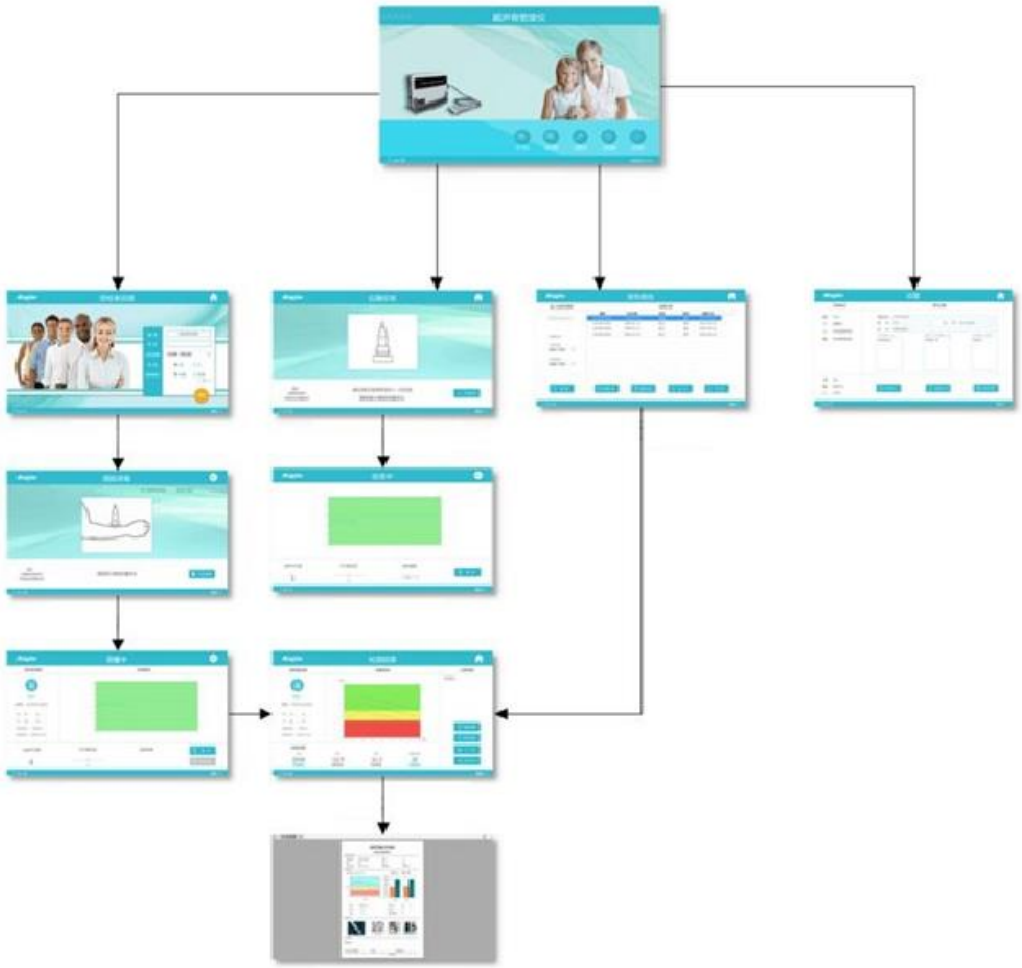


Click "Finish" to complete the process.

3.3 Software operation method

Ultrasound bone sonometer software V1.0 is based on Windows XP or higher platform to operate, so it requires the users have some computer knowledge, also know the computer hardware and software knowledge. So the users can get maintain the equipment better and avoid a variety of failures.

3.3.1 Software flow chart



3.3.2 Program operation method

3.3.2.1 Program operation and initial procedure setting

Turn on the main power switch.

Make sure the ultrasound bone sonometer software V1.0 has been installed. Double click the software icon to enter the software, the main interface as shown below:

In the main interface, there are "Login", "Search", "Calibration", "Settings", "Exit" button. These buttons are described below.

Login: Enter into subject information.

Search: Search the specific subject information.

Calibration: Calibrate by a fixed module to ensure the machine can operate accurately.

Settings: To set the report information and report comments.

Exit: Exit the software.

Software version: V1.0.

3.3.2.2 Bone density measurement

Daily calibration should be done before subject measurement.

3.3.2.3 Calibration

3.3.2.2.1 Subject login

In the main interface, click the "Login" button to enter the "Subject’s info" interface, and the subject's age default is more than 20 years old, as shown below:

If subject's age is less than 20 years old, the interface will jump to the following login screen:

1) Adult login interface（Age ≥ 20 years old）

ID: The system will automatically set the number according to the computer system date, such as the number "201707310001". The first 4 numbers represent the year, the 5 and 6 numbers indicate the month, the 7 and 8 number indicate the date, and the last four number indicate the number of today's test. The doctor can change the subject number as necessary, but must be a number, and cannot exceed 11 numbers.

Name: You can enter any character, but not more than 12 bytes.

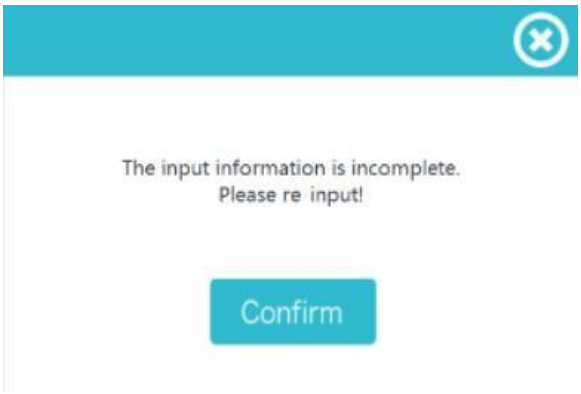
Birth Date: Drop-down list, choose the subject date of birth, and the subject age must less than 100 years old.

Gender: Can choose "male" or "female". The default value is Male.

Measurement position: can choose “Radius” or “Tibia”. The default position is Radius. MSLBD09 model only can measure Radius, can choose left or right, the default value is left.

These data will be reflected in the report.

If the information input is not complete, the system will pop up the following dialog box, click "Confirm" button, and enter the missing subject information.



2) Children or teenager login interface (Age <20 years old)

After entering the correct age, the subject information interface will jump automatically, this interface is slightly different from the previous interface, the difference is that there are no database option. But you will find the subject height (cm), weight (kg), father and mother height (cm). These four items can only enter numbers, and cannot exceed 3 bytes. These data will also be reflected in the report.

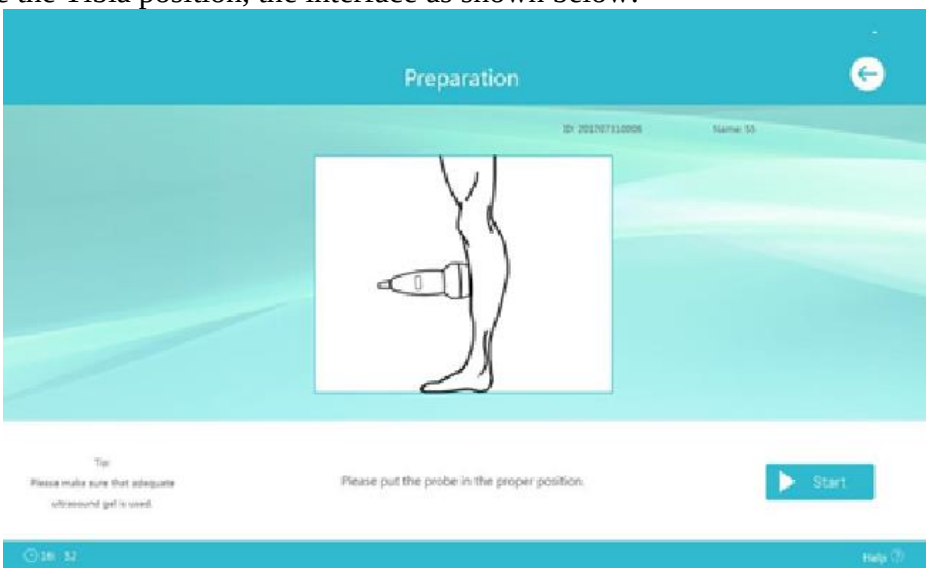
Height range: 50 ~ 200cm, Weight range: 5 ~ 100kg, if height or weight out of range, click "Confirm" button when popped up the following dialog box, as shown below:

3.3.2.2.2 Subject measurement

1) Prepare to measure

After the subject information input has completed, click the "confirm" button and enter the "Prepare to measurement" interface, as shown below:

If choose to measure the Tibia position, the interface as shown below:



This two interface show the measurement position. When the subject has been placed correctly, you can click on "Measure", jump to the measurement interface, begin to measure bone density. If the doctor wants to return to the subject information

interface, click "Back" button.

2) Measuring

When the subject age over than 20 years old, "Measuring" interface as shown below:

“Measuring” interface left side is subject’s information, the right side shows the real-time measurement curve.

The “Depth of parallelism” is to adjust the data acquisition, the smaller the value, the higher the accuracy of the probe parallelism, the more accurate the data, but the more difficult to collect data; and the greater the value, the lower parallel requirements, the greater the data fluctuations, but the acquisition of data easier. It is recommended that the parallelism be set between 15 and 25.

After enter the interface, the product will start the bone density measurement automatically, click the "pause" button to stop the measurement, click "continue" will continue to measure bone density. As shown below:

Click“ ”button, back to previous interface.

3） Measurement result

When “View result” button light, click “View result” will enter into measurement result interface.

When the subject age over than 20 years old, result interface as shown below:

The upper left part of the interface shows the subject information, followed by name, ID, gender, age, position and date. The lower left shows the measurement results: SOS, T-score, Z-score and bone age. The middle of the interface shows the T value obtained from the subject with the standard value of the corresponding age. The horizontal axis indicates the age of the subject (age range 20 to 100 years old), and the vertical axis represents the corresponding value of the T value for different ages. In the three curves, the middle red line represents the average T-score of the different ages. The upper and lower black lines represent the highest and lowest values of the normal range of different ages T-score value. There are three areas (green, yellow and red), the measurement point falls in the green area, that is, high T-score, mean the bone condition is relatively healthy; fall in the yellow area, said T-score of bone condition is normal; if it falls in the red area, that is, the lower T-score of bone condition is bad, there is the risk of osteoporosis.

In the Measurement Result interface can analysis the result and add the information in the diagnostic information.

When the subject age less than 20 years old, result interface as shown below:

The upper left part of the interface shows the subject information and the lower left shows the measurement result. In the Z-value chart, the measurement point is located in the green area, then the bone development is better; if the measurement point falls in the red area, then the Z value is low, the bone development is bad; when the Z value in the area of -1 ~ 1 means the bone develop normally, and the higher the value means bone development better. In the height chart, if the measurement point falls in the white area, indicating that the height is higher than average height; if the measurement point falls in the blue, green or yellow area, indicating that the height is under the normal range; if the measurement point falls in the red area, then the height is lower than average standard height.

Under diagnostic information, some button as shown below:

- Re-Scan, will re-scan the subject and get new result.
- Report: Enter into “Report” interface.

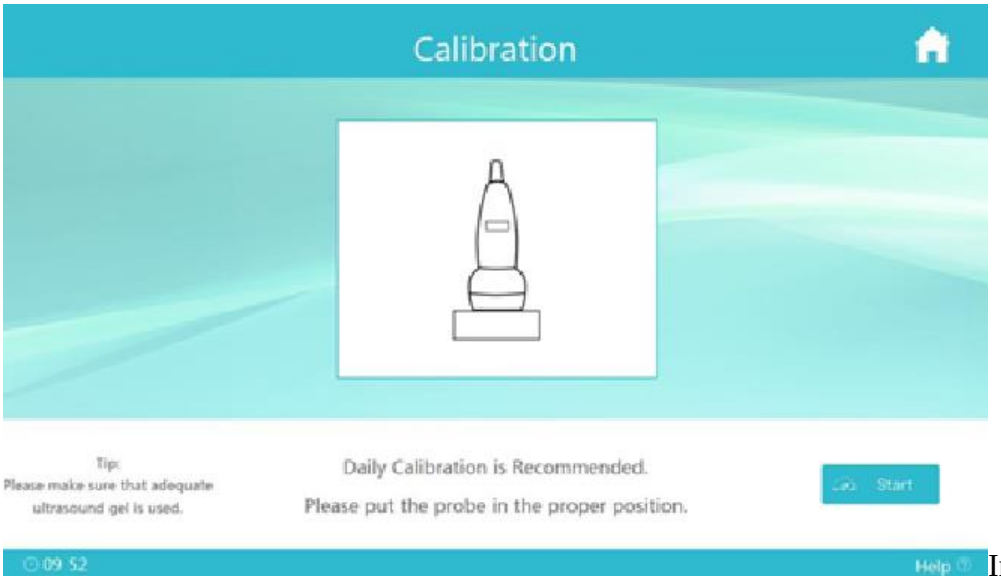
  3.3.2.5 Report
- Send to PACS: click “Send to PACS”.

  3.3.2.6 PACS

- Print: Can view report preview.

  ☞ 3.3.2.4 Report output

3.3.2.3 Calibration



In the main interface click “Calibration”, as shown below

Apply the ultrasound transmission gel on the probe and place it upon the phantom, click “start”, will start calibration, ”, back to main interface.

Enter the current environment temperature, click "Start" to enter the calibration state, as shown below:

When the calibration is completed, a dialog box indicating the calibration is successful, as shown below:

Click “confirm, back to main interface.

When the phantom is not properly placed or there is no phantom at calibration, the calibration interface background color is red. Click "Pause" to pause the calibration progress and click " to return to the "Calibration" interface.

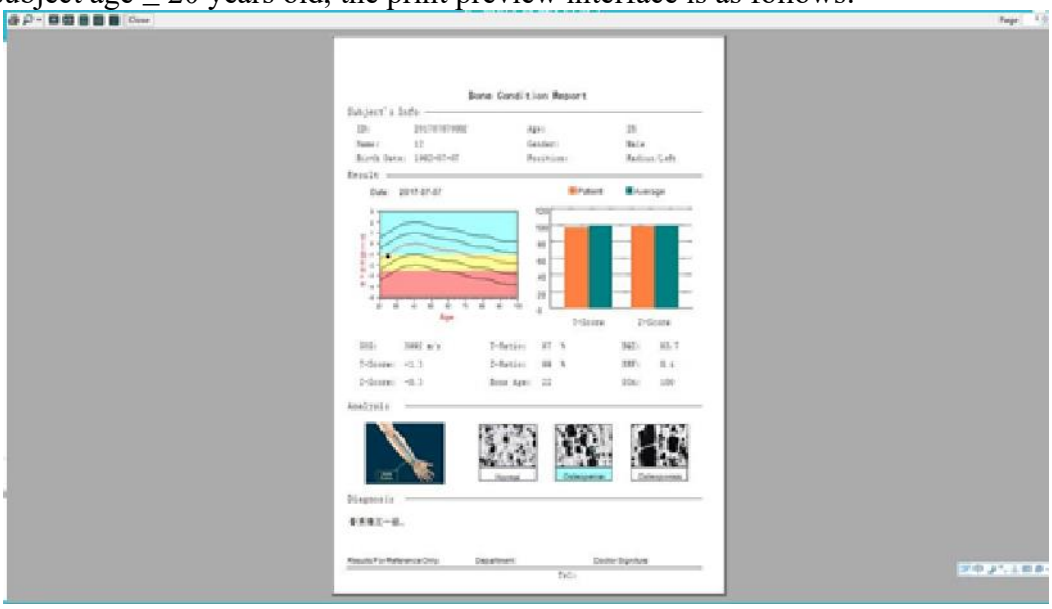
3.3.2.4 Report output

Measurement data can only be output via an external computer and an external printer.

2.4 Product connect and external printer setting

3.3.2.6 Function setting

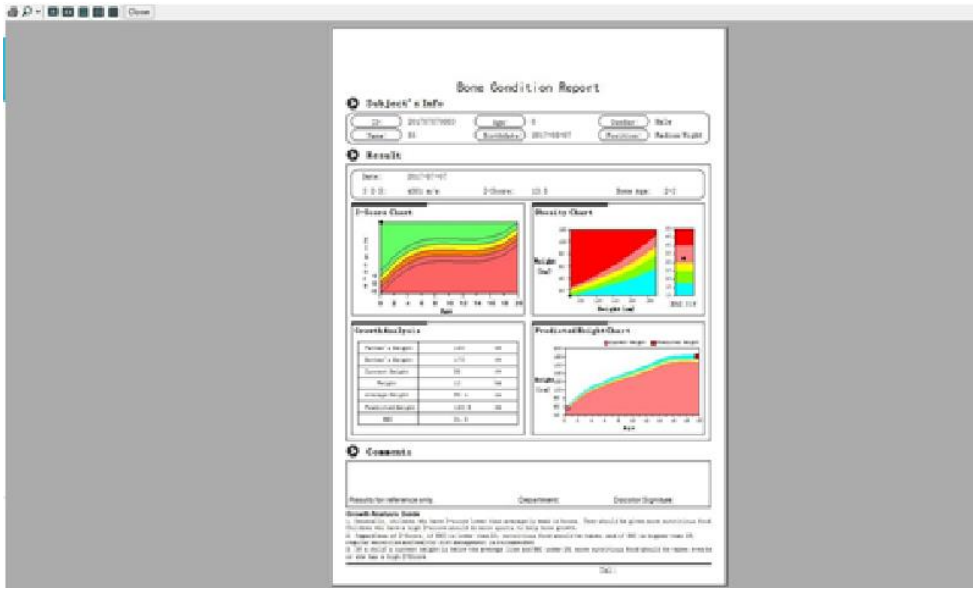
For subject age ≥ 20 years old, the print preview interface is as follows:



Click "Print", the report will print automatically

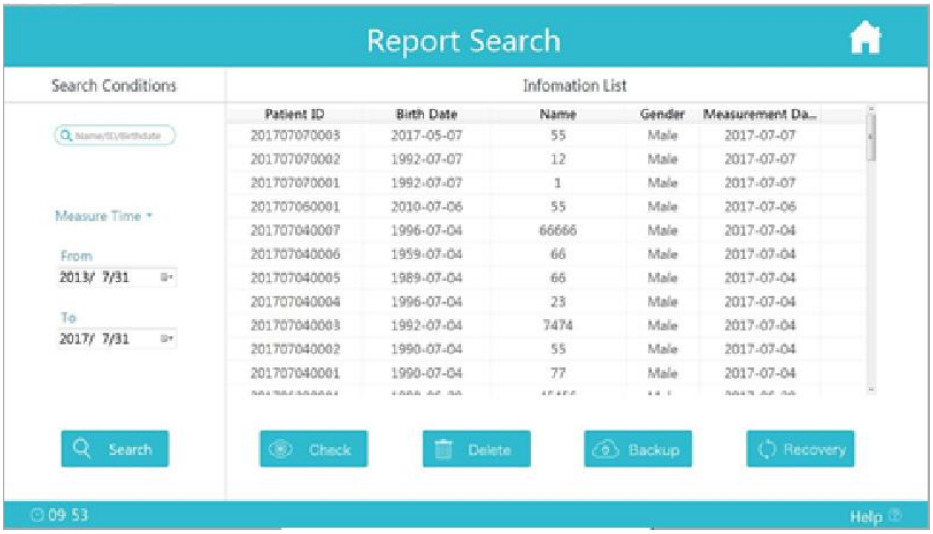
The subject information shows patient ID, name, age, gender, and birth date and measurement position, the measurement time. The results show the measurement date, the two orange bars shows the subject's T-score and Z-Score, the two green bar charts shows the standard results, SOS, T-score, Z-score, T-ratio, Z-ratio, bone age, BQI, RRF and EOA. The results show the software determine in the subject's bone situation (including normal, osteopenia, osteoporosis).

When subject age <20 years old, if use the built-in printer, the print preview interface as shown below:



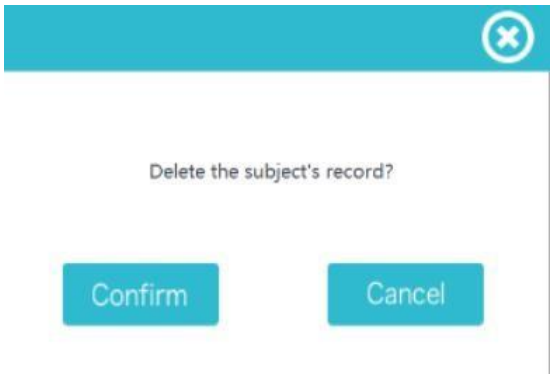
The subject information shows the patient ID, name, age, gender, birth date and measurement position; the results show the measurement date, SOS, Z-score, bone age, Z-score chart and obesity chart and the predicted height chart. In the growth analysis list, the values shown are BMI, father's height, mother's height, average height, current height and predict height and weight.

3.3.2.5 Search



In the main interface click "search" :

- You can input the name in the search Settings (no more than 12 characters), ID (only number cannot exceed 11 bytes), Birth Year (only number, cannot exceed 4 bytes) and the Measure Time, when the search conditions are completed, click the "Search" button, you can search out all the meet condition subject records, and the subject information will display in the list.
- Delete: After selecting a subject in the list, click "Delete" when popped up dialog box will ask whether delete or not. Click "Confirm" and you can delete the subject. Click "Cancel", you can return to Report Settings.



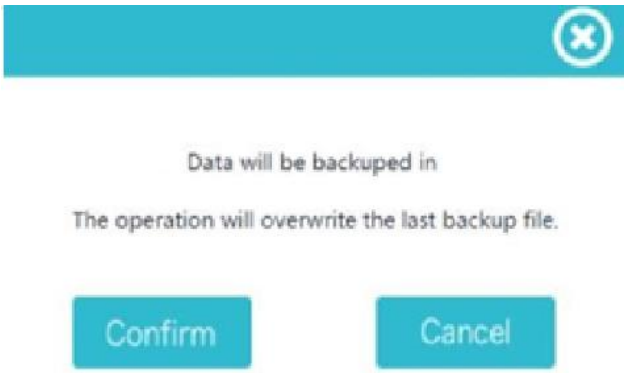
- View Record

After selecting a subject in the list, click "View Record", the system will jump to the "Record" interface of the subject.

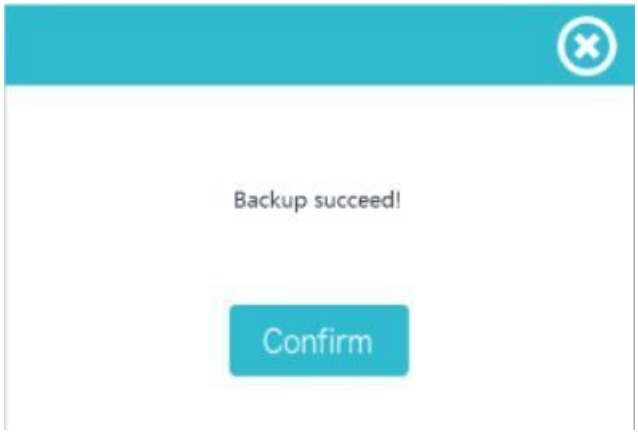
3.3.2.2.2 Subject measurement

- Backup

Click the "Backup" button, the following interface will pop up and ask whether confirm or not, as shown below:

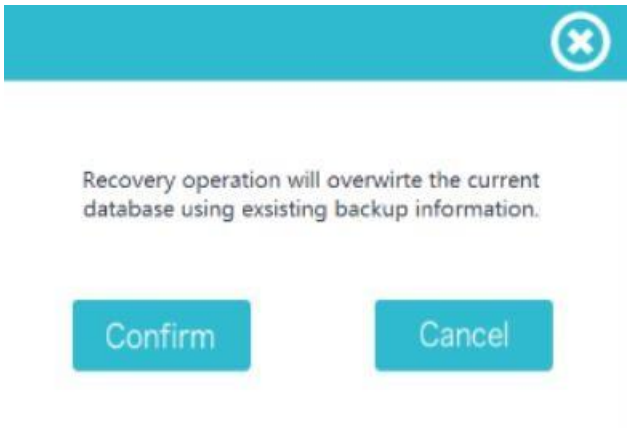


Click "Confirm" to back up in this folder. After backup has finished, the following dialog box will pop up and let you know the backup has been completed; click "Cancel" to return to the Report inquiry interface.

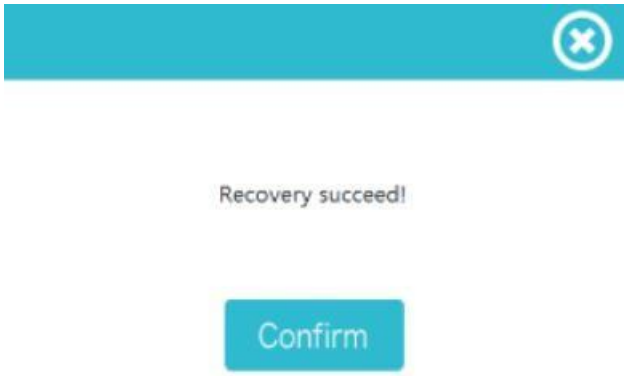


- **Recovery**

Click the "Recovery" button, the dialog box will pop up and ask whether recovery the backup file or not, as shown below:



Click "Confirm" to restore the data from the backup file. After the recovery is complete, the “Recovery succeed” dialog box will pop up.



3.3.2.6 Configuration

In the main interface click “Configuration”. User can set hospital information, language, PACS, report preview.

- Hospital information

The user can enter the hospital name, the doctor, or any character, and cannot

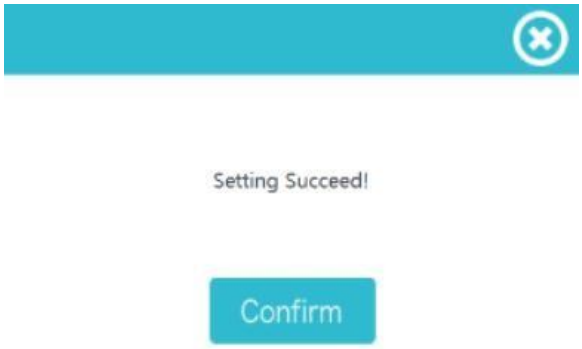
exceed 30 bytes. The address can be entered in any character and cannot exceed 60 bytes. Phone numbers can only enter numbers and cannot exceed 25 bytes.

In the report comments, there are three T-score range, with different intervals corresponding to different comments. Users can use the default comments, or modify it according to their needs. You can also enter any character, but no more than 200 bytes. The diagnostic information of the "Report Settings" interface will automatic display the comment corresponding to the T-Score interval set here when the subject's measured T-score is within a certain interval.

- PACS Setting

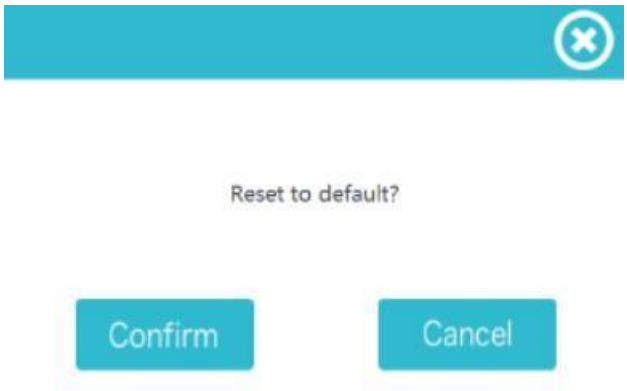
Choose "PACS" to open the PACS sending function. Click "PACS Settings", the PACS dialog box will pop up, as shown below:

When finish input, click "Cancel" to return to the report information setting interface. Click "Confirm"when popped up the “Setting Succeed” dialog box, then click "Confirm" to return to the settings interface.



- Restore the default settings

Click "Reset to default", the following interface will pop up and ask whether restore the default settings or not dialog box, as shown below:



Click "Confirm" to restore all parameters to the default settings. Click "Cancel" to return to the setting interface.

- Advanced settings

Click "Advanced Settings", the dialog box will pop up as shown below:

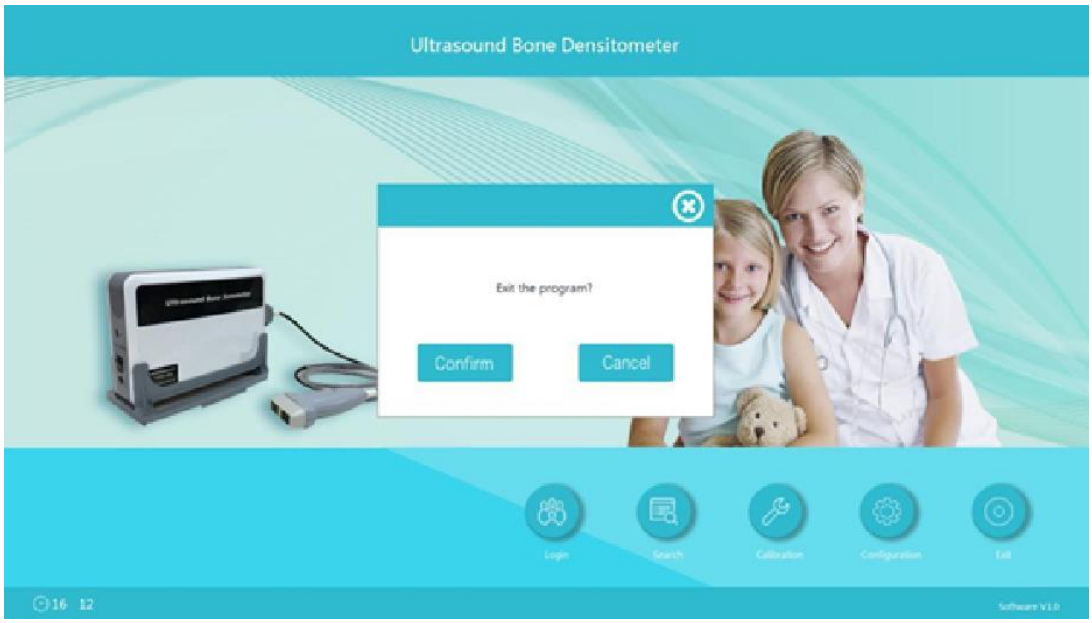
This item is the manufacturer needs to set when adjusting the software. If user uses equipment correctly, the user does not need to operate this item. If the product fails, it may need to open this maintenance, please contact the company and ask for the code, please do the operation under the guidance of the manufacturers.

- Language: can choose “简体中文” or “English”
- Function: can choose “PACS”, “touch input”, “start with windows” and “print preview”, click the function what you want.

  If install the software in win8/10system, can choose “touch input”, after click it, the product can operate with tablet. Under win7 or XP system, this function cannot use.

3.3.2.7 Exit the program

If click "Exit" button in the main interface, you can see the "Exit the Program" dialog box, then click "Confirm" button to exit the program. Click "Cancel" to return



to the main interface.

Attention！
In the above instructions, the description of "unlimited number of characters" or "unlimited number of words" input box, said the input box cannot enter more than 32,767 characters.

3.4 Software maintenance

The company is responsible for software tracking and maintenance. If the user find the abnormal function or software BUG, our company manufacturer will solve the problem free. The company can provide update software CD-ROM free, and guide the user to install in one year. Users can also contact the manufacturer and through the website to download software.

Chapter 4 Product maintenance

4.1 Solve problem

Only the professional maintenance staff can open the product for maintenance.

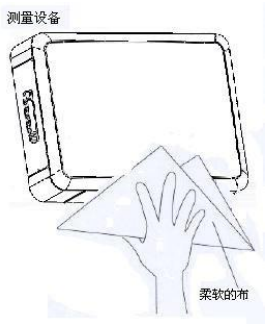
If happened the following problem, please follow the list items to check the equipment.

Problem	Check items
Turn on the power switch but the ultrasound bone sonometer does not work properly.	Is the power supply connecting properly?
	Is the power cable broken?
Open software, enter into “log in” or “Calibration” interface , pop up”No device found, try again!”	Whether the power switch is turned on
	Is the power supply connects properly?
	Is the USB cable connects properly?
	Is the software driver damaged or not properly installed?
When the power switch has turned on, but the screen operate abnormal.	Is the screen switch on? Read the screen instruction manual.
The brightness of the screen is not sufficient.	Adjust the brightness of the monitor. Read the screen instruction manual.
The results are abnormal	3.3.2.2 Bone measurement 3.3.2.3 Calibration
	Is the measure location correct?
	Is the oil balloon installing properly?
	Is the surface of the oil balloon stained with a dry ultrasound transmission gel? 4.2.1 Cleaning, disinfection
	Check ultrasound transmission gel dosage.
During measuring:"No device found"	Whether the power switch is turned on and USB cable connects properly.
During measuring: "Calibration Required"	Calibration must be performed before the subject measurement.

Caution！
If you still cannot solve the problem, please contact the Medsinglong Global Group Co.,Ltd.

4.2 Repair and maintenance

4.2.1 Cleaning, disinfection, sterilization

Caution！		
Turn off the power switch before cleaning the product.		
Product	**Example**	**Instruction**
Product		Keep the product appearance cleaning. Please wipe with a soft tissue. Do not allow put water or neutral lotion on products directly. If the water come into the product inside may cause damage to electronic circuits.
Probe		After daily diagnosis, need to wipe with a soft paper, and then use the 75% medical alcohol disinfection.

4.2.2 Replacement of consumables

Always equip the following consumables.

2.3.3 About the consumables

Consumable	Content
Printer paper	The external printer uses A4 white paper; the built-in printer uses the specific printing paper. When using an external printer, please refer to the specific printer instruction manual.
Ultrasound Transmission Gel	Ultrasound Transmission Gel is consumables, so you should purchase new Ultrasound Transmission Gel before use out.

4.2.3 Storage

Daily storage	1） Remove the power cable from the power supply socket. 2） The dust may cause the precision structure of the product damage, so it should cover dust cloth after using. 3） If the product inside remain the residual solidified ultrasound transmission gel or other debris, please clean it immediately 4.2.1 Cleaning, disinfection
Long time storage	1） Remove the power cable from the power socket and remove the USB cable from the USB port. 2） Storage the power and USB cables.

4.3 Product transportation and storage

Ultrasound bone sonometer is precision equipment, it cannot be stored in the outdoors. The product should be stored in the temperature: -10 ℃ ~ +40 ℃, the humidity should not more than 80%, non-corrosive gases and well-ventilated room. If store in over cold or hot location may affect the equipment using life.

The products should transport by ordinary traffic. During handling, please be careful. It cannot roll. During transportation and storage, rain, snow, violent bumps and mechanical impacts should be avoided.

Please open the package carefully, we suggest keep the original package for future handling, the box of the relevant documents (instruction manual, etc.) should be collected and properly preserved.

4.4 Product operation method

4.4.1 Safety precautions

Download the safety precautions when using the product.

Always following the precautions when turn on the equipment. Please also refer to "4.4.2 Precautions when using medical device products".

⚠ **Danger！**	➢ High voltage in the host, please do not open it. Not follow the instruction may cause danger situation. ➢ To prevent electrical shock and leakage, check the cable before turning on the power. If there is damage or rupture, please contact the company or authorized agent. ➢ Plug the power cable into a power outlet. If you share a power outlet with another product, the product may be affected.
Caution！	➢ Before using this equipment, please read the instruction first. ➢ In order to read at any time, please put this instruction manual in the specified location. ➢ If an abnormal sound occur when the power turn on or an abnormal condition occur on the screen, please contact Medsinglong Global Group Co.,Ltd.Make sure have turned off the power switch before cleaning the product.

4.4.2 Attention when using medical devices

4.4.1 Safety Precautions

1. **Only doctor can use, someone who do not have the permissions are not allowed to use.**

   Excessive ultrasound can cause harm to the human body, do not take a long time or repeated measuring.

2. **When installing the equipment, please following the list instruction. Avoid the following places and note the following:**

   1) Place where the equipment may be exposed to moisture.
   2) Place where water is spraying.
   3) Place where have high density water vapor.
   4) Place where may occur excessive shock and vibration.
   5) Place where the ground is inclined more than 10 degrees.
   6) Place where the pressure, temperature and humidity change immediately.
   7) Places where have direct sunlight or dust, salt, sulfur and other substances.

8) Place where storage chemical material or gas.
9) Place where AC voltage instability.
10) Badly ventilated place.
11) Do not tilt the device, oscillate or crash the product during transport.
12) Frequency, voltage or current shall be suitable for the product.

3. Before using the product, please confirm the following:

1) Check the power switch has turned off before insert the power cable into the outlet.
2) Whether the power supply is suitable for (AC220V,50Hz).
3) Whether ground properly.
4) Whether power and devices are connecting properly to the system?

2.5 Before turn on the power

5) The product has been adjusted into the best condition. Do not attempt to adjust any control or switch unless follow the instruction manual for the professional operation.
6) If an abnormal phenomenon occurs when the power has turned on, please turn off the power switch and contact our company immediately.
7) Confirm all wires are connected correctly. Please follow the instruction manual to connect the ultrasound bone sonometer to other devices.
8) When using this equipment with other products at the same time, please do not operate wrong.
9) The equipment and the various components should be placed more than 20cm from the wall.

4. Please confirm the following conditions before running the equipment.

1) Whether the equipment and the subject are in a correct state.
2) Whether there is sufficient space between different devices.
3) When the equipment and the subject are found abnormal, please stop operating and confirm that the subject is in danger or not.
4) This product uses ultrasound to measure. Ultrasound in the atmosphere will be reflected, thus will affect the accuracy of the test. Therefore, before the measurement of the subject, full ultrasound transmission gel should be applied between the oil balloon and the subject heel.

5. Confirm the following after using equipment.

1) Stop the program follow the standard steps, and turn off the power.
2) Please remove the power plug and do not pull the power cable directly.
3) Comply with the following steps when handling the product.

①Do not place the equipment in a moisture location

②Avoid the instantaneous pressure, temperature and humidity changes, and avoid placing the product in direct sunlight, dust, salt, sulfur and other substances exist place.

③Do not tilt the product or crash the product during handling.

4) Please clean the accessory after use.
5) The equipment should be kept clean for reuse.

6. Please do not repair or open the product when the product has problems.

7. Please do not change the equipment structure. If need repair, please send the company or designated maintenance agent.

8. Inspection and maintenance

After daily measurement, please clean the oil balloon. If you do not wipe ultrasound transmission gel and residue three to four days or more, the solidification will make the equipment difficult to maintain. If do not use the equipment for a long period, please check the equipment before using.

9. Workbench attention

The product placed on the workbench may slide when they are moved at an incline, so the display and the printer should be separated before moving.

10. Environmental protection

The life of this equipment is eight years, the production date is on the product label. When the product use five years it should be normally scrapped. If you want continue use, it should be re-testing by the manufacturer. Disuse should be disinfected before disposal, and according to the requirements of environmental protection regulations crapped products or give it to environmental organizations.

11. Others

Read this instruction manual firstly, after understand the details of the product and then use the product correctly.

Chapter 5 Main technical parameters and software download

5.1 Parameter

5.1.1 Main technical parameters

Item		Characteristics or parameters
Security features	Anti-shock type	I type device
	Application Part	BF type application part
	Operate mode	Intermittent loading, continuous operation
	Use in air mix gas	Cannot be used in combustible anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide.
Performance parameters	Ultrasound operating frequency	1MHz, error: ±15%。
	Ultrasound velocity error	≤±0.4%
	Accuracy	≤0.15%
	Measuring time	Single≤25S、Repeat≤75S
Main function	Information input	Subject name, age, gender and so on
	Parameter measurement, calculation and display	SOS, T-score, Z-score, T-Ratio, Z-ratio, Bone age, BQI, RRF, EOA
	Confirm	Calibration
	Report output	Display, search, settings, preview, print
Host	Size	245mm×165mm×70mm
	Weight	1.2kg
	Input voltage	Single - phase alternating current AC 220V±10%
	Input power	＜60VA
	Continuous working time	＞8 hours
	Liquid protection	IPX0
Ultrasound probe	Center frequency	1MHz±15%
	Ultrasound output	See Chapter 6: Sound Output Data
	Liquid protection	IPX7
	Connector type	D-sub(9w4)

Environmental requirements	Operate temperature	5 ～ 40 ℃
	Transport / storage temperature	-10 ～ 55 ℃
	Humidity	Relative humidity≤80%
	Transport / storage humidity	Relative humidity 0 ～ 80%, Non-condensing
	Atmospheric pressure	860 ～ 1060 hPa
	Shock wave	Do not exceed 2 g in 6 microseconds
	Environmental hygiene	Install and use this equipment in a clean, well ventilated room, avoiding dust and fumes. Clean the equipment with soft cloth when you have finished using.

The equipment electrical safety meets the GB9706.1-2007《Medical electrical equipment Part I: General requirement for safety》. The profession electrical safety requirements meet the GB9706.9-2008《Safety requirements for medical Ultrasound diagnostic and monitoring equipment for medical electrical equipment》, Electromagnetic compatibility Requirements meet theYY0505-2005《Medical electrical equipment Part 1-2: safety requirements for the common side-by-side standards: EMC requirements and testing》, environmental testing are meeting the GB / T14710-2009《medical electrical environmental requirements and test methods" of the relevant requirements》.

5.1.2 Description of each item

Parameter	Meaning	Range
Birth date	The subject's birth year, month, and day	1752-9-14 to now
Height	The subject's current height cm	20-200 cm
Weight	The subject's current weight kg	2-100 kg
Father height	<20 subject’s father height	50-200 cm
Mother height	<20 subject’s mother height	50-200 cm

5.1.3 Description of each displays the parameter

Symbol	Meaning	Range

SOS	Speed of sound	Calculations
T-score	The standard deviation of mean value of subject and the same sex teenager group bone condition.	Calculations
Z-score	The standard deviation of mean value of subject and the same sex group bone condition.	Calculations
T-Ratio	The percentage of subject compare with the same sex teenager group bone condition.	Calculations
Z-Ratio	The percentage of subject compare with the same sex group bone condition.	Calculations
Bone age	Comparison of subject bone condition with average bone condition in all age groups.	Calculations
BQI	Bone quality index, higher the value means higher the bone density	Calculations
RRF	Relative risk of fracture. Smaller the value means the lower the risk of fracture.	Calculations
EOA	Estimate osteoporosis age	Calculations

Chapter 6 Sound output data

Index name			MI	TIS			TIB	TIC
				scanning	Non-scanning		Non-scanning	
					A_{aprt}≤1cm²	A_{aprt}＞1cm²		
Maximum value			0.08	-	-	＜0.002	＜0.002	-
Related Sound parameters	p_{ra}（MPa）		0.058	/	/	/	/	/
	P（mW）		/	-	-	/	＜1.0	-
	$P_{\alpha}(z_S)$ and $I_{ta\cdot\alpha}(z_S)$ Minimum		/	/	/	＜1.0	/	/
	Z_s（mm）		/	/	/	55.2	/	/
	Z_{hp}（mm）		/	/	/	55.2	/	/
	z_b（mm）		/	/	/	/	66.12	/
	Maximum $I_{pi\cdot\alpha}$ z（mm）		66.12	/	/	/	/	/
	d_{eq}（cm）		/	/	/	/	30.15	/
	f_{awf}（MHz）		0.524	-	-	0.524	0.524	-
	A_{aprt} diameter (mm)	X	/	-	-	30.12	30.12	-
		Y	/	-	-	30.15	30.15	-
Other information	t_d（μs）		1.71	/	/	/	/	/
	Prr（kHz）		1.00	/	/	/	/	/
	Maximum $p_r$in $I_{pi,}$（MPa）		0.063	/	/	/	/	/
	Maximum d_{eq}in$I_{pi,}$（cm）		/	/	/	/	30.15	/
	Maximum $I_{pa\cdot\alpha}$ in MI（mW/cm²）		0.13	/	/	/	/	/
Operate control condition	Control 1		-	-	-	-	-	-
	Control 2		-	-	-	-	-	-
	Control 3		-	-	-	-	-	-

Chapter 7 Product warranty and maintenance tips

1. Product Warranty Statement

1) If there are product quality problems, the company can provide free warranty within one year, start from install date, during the warranty period will be free to repair and replace accessories, the warranty way is sending the equipment to the company to repair. If you need to provide on site warranty service, you must sign a separate door warranty contract.
2) Warranty is valid only when operate is according to the instruction book.
3) The following example: MSL Industrial Co., Ltd. will not give warranty
   - Equipment beyond the warranty period.
   - Equipment due to natural disasters lead to damage.
   - The equipment does not work properly due to improper transportation and use.
   - Repair and update by unauthorized staff or agent lead to does not work properly.
4) Change the product structure randomly does not give warranty.
5) Man-made damage is not given warranty
6) MSL Industrial Co., Ltd. can provide paid maintenance service for the accessories which has no warranty.

2. Attention!

1) If there is something wrong with the equipment, please turn off the power immediately, and carefully read the instruction book.
2) If you need repair service, before contact the manufacturer or dealer, please turn off the power, and obtain the device model, product number and other relevant information.
3) You need to pay the shipping fee and insurance premium when you ship the equipment to the company.
4) We will try our best to assist you if you want to repair equipment by yourself.

3. The above items apply to all our users, but no other agency or authorized individual may make any commitment beyond the above items on behalf of MSL Industrial Co., Ltd. Hereby declare.

Appendix： Product Acceptance

Product acceptance

Dear user：

Thank you for using the Medsinglong Global Group Co.,Ltd. Ultrasound bone sonometer, After install the equipment, please check the following items one by one according to the below list, sign "√" to check, after the completion of this acceptance by the user, The Product acceptance will send back to the company as a user file, so that the company can provide Warranty, Thank you for your cooperation.

Medsinglong Global Group Co.,Ltd.

（Stamp）

Hospital Name		president of a hospital	
Contact number		Doctor	
Model	MSL_____	Host Number	
Installer		Install date	

Item Name	Quantity Check	Function check	Note
Host			
Foot auxiliary desk			
Module			
USB cable			
Power cable			
Program CD			
Printer paper			

Working condition:

Signature ： Date：