BeeTLe

User's Manual

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BeeTLe APP

OsteoSys

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

BeeTLe

User's Manual

Manufacturer and EC Authorized Representative Information

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CAUTION !

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

Thank you for purchasing BeeTLe Ultrasound Bone Densitometer.

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

Marks and symbols used in this manual

1) Hazard warning signal

Several hazard warning signals are provided for safe use of this product.
Depending on its degree, it is labeled " WARNING ", " CAUTION " and " NOTE ".

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.

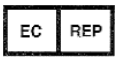
CAUTION !
"Caution" is used to indicate the presence of hazard that will or can cause minor personal injury and property damage if the caution is ignored.

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

2) Information and reference symbols

	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 date of manufacture
	This symbol indicates "caution" for the hot surface.
	User Manual Refer to manual
	Communication Status It indicates communication status of the equipment.
	Mark of prohibition
	Mark of obligation
	European Conformity

	Manufacturer
	Serial Number
	Authorized representative in the EUROPEAN COMMUNITY
	Indicates the item is a medical device

3) Protecting the equipment from external electromagnetic waves

This device's accuracy and normal operation can be affected by external electromagnetic waves. Use the equipment in a location where the equipment can be protected from any wireless electromagnetic waves generated by other products or mobile phones.

4) Disposal of equipment

This symbol marked in the product manual or on the packaging indicates the equipment should not be handled as household waste. To dispose the equipment, send the electric/electronic equipment or electric medical devices to waste collecting locations for recycling. Proper disposal of the product prevents any possibilities that can negatively affect environment or human health.

Material recycling can help saving natural resources. Please contact the store from which you purchased the product or service agencies for more details on product disposal.

5) Cautionary Notes

(1) Environmental Condition

To prevent possible performance loss or malfunction of device components caused by sudden and excessive environmental changes, as well as the resultant shortening of their life cycle, the environmental conditions below must be met.

- Working Temperature : Within 10 ~ 40℃
- Working Humidity : Within 30~ 75%
- Air Pressure : Within 700 ~ 1060hPa

(2) Pre-operation Checklist

- Check the switch connection and polarity indicator status, and verify the device works properly.
- Check all cable connections for their accuracy and safety.
- Double-check the areas that make direct contact with the patient.
- Check the device and the patient for any anomaly.
- If anomaly is found with the device or the patient, take appropriate actions including suspending device operation under safe conditions.
- Fully apply gel between probe and patient heel for accurate measurement.

(3) Cautions regarding specialist prescription

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

(4) Do not expose ultrasound to the fetus except for unnecessary ultrasound exposure and use during pregnancy.

(5) The FRAX function should be used according to the prescription and management of the specialist.

(6) Biocompatibility - Ultrasound gel, etc.

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

(7) Cautions for Storage

- Do not apply excessive force when connecting or disconnecting cables.

- Auxiliary devices should be maintained clean, and in working conditions.
- Equipment should be positioned in their proper positions, so as not to interfere with operator's or patient's movement.

6) Guidance and manufacturer's declaration

Guidance and manufacturer's declaration – Clinical information				
No	**Contents**		**A or N/A**	**Description**
1	Intended Use		A	The BeeTLe system supports the doctor's activities for the diagnosis of osteoporosis and the prevention of future fractures to the patient through the measured BMD results. The measurement sites is calcaneus/ Heel bone.
2	Name of Disease or Condition		A	Osteoporosis, Osteopenia, Normal healthy bone
3	Indications		A	• Provides an estimate of bone mineral density at Calcaneus. • Provides an assessment of relative fracture risk based on the patient's T-score value using the categories of fracture risk defined by the World Health Organization (WHO).
4	Contraindications		A	There are no absolute contraindications to performing QUS. Possibly of limited value or require modification of the technique or rescheduling of the examination in some situations, including: - Try to measure the other side of heel if a patient had some surgery like implant which is placed in calcaneus bone.
5	Target group	User	A	Education: Bachelor or higher. Physician or trained medical personnel located in hospitals and clinics Knowledge: Educated or trained for BMD (Bone Mineral Density) under the relevant majors such as orthopedics, internal medicine, obstetrics & gynecology, etc.

				Language Understanding: English Experience: More than 2 years of work experience in hospital as a doctor, a sonographer and etc. (Patient does not operate the BMD device)
		Patient	A	a) Ages: 20 – 100 years old b) The patient condition: Osteopenia, Osteoporosis or Normal healthy bone
6	Disposable device		N/A	BeeTLe is not a disposable device.
7	Invasive device		N/A	Not intended to be invasive
8	Implantable device		N/A	Not intended to be implantable
9	Duration of use or contact with body		A	BMD measurement is performed once a year or once every two years (It depends on the patient's situation). Contact with body:  There are contact point between calcaneus part and balloon as image above. Need to apply ultrasound gel in between skin and probe in order to get proper contact for path of ultrasound waves.
10	Contacting with body fluids or others		N/A	There is no contact between any body fluids or people during the examination process.
11	Measurement site		A	The correct position for measurement for calcaneus bone on the heel is as the below.

			It's just below the area of the ankle, where you should apply enough amount of ultrasound gel just like the below instructions. (need to apply to both sides of feet) *According to the article Selection of the optimal skeletal site for fracture risk prediction, the most significant relationships of BMC to fracture risk were observed for the Os-calcis (Richard D. Wasinch, Philip D. Ross, Lance K. Heilbrun, and John M. Vogel)

7) Electromagnetic Emission

This equipment is manufactured to operate in the electromagnetic environment described below

The customer or user should verify if this equipment is operated in such environment

Radiated disturbance according to CISPR 11	Group 1 Class B	The EMISSIONS characteristics of this equipment make it suitable for use in home healthcare environment.
Mains terminal disturbance voltage according to CISPR 11	Group 1 Class B	
Harmonic current emission IEC 61000-3-2	Class A	The BeeTLe is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building s used for domestic purposes.
Voltage Fluctuation/Flicker IEC 61000-3-3	Complied	

8) Electromagnetic susceptibility

- This equipment is manufactured to operate in the electromagnetic environment described below
- The customer or user should verify if this equipment is operated in such environment.

Test of Electronic Interference Resistance	IEC60601-1-1-2 Test Level	Standard Compliance Level	Electromagnetic Environment Guideline

Electrostatic Discharge (ESD) according to IEC 61000-4-2	Discharge by 8 kV direct contact 15 kV of Air-gap discharge	Discharge by 8 kV direct contact 15 kV of Air-gap discharge	The floor should be wooden or cemented floor or ceramic tile floor. In case that the floor is made of chemical compound materials, the relative humidity should be at least 30%
Radiated RF Electromagnetic Field immunity according to IEC 61000-4-3	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	The BeeTLe is suitable to use in home healthcare environment.
Immunity to Proximity Fields from RF wireless Communications Equipment according to Table 9 in IEC 60601-1-2	28 V/m Max. 385-5785 MHz in according to table 9	28 V/m Max. 385-5785 MHz in according to table 9	RF communication equipment is used on closer than 30 cm to any part of the BeeTLe
Electrical Fast Transient/Burst according to IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency	± 2 kV for power supply lines 100 kHz repetition frequency	The quality of supplied power should be suitable for home healthcare environment.
Surge according to IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	The quality of supplied power should be suitable for home healthcare environment.
Immunity to conducted disturbances induced	3 V 0.15-80 MHz	3 V 0.15-80 MHz	The strength of RF field in the frequency range higher than 150 kHz~80

by RF fields according to IEC 61000-4-6	6 V in ISM & Amaterur bands between 0.15 and 80 MHz 80% AM at 1kHz Power supply line & I/O lines	6 V in ISM & Amaterur bands between 0.15 and 80 MHz 80% AM at 1kHz Power supply line & I/O lines	MHz, the strength of the RF field is smaller than 3 V
Voltage dips/ Voltage interruption according to IEC 61000-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 Cycles Single phase: at 0º 0 % U_T; 250/300 cycle	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 Cycles Single phase: at 0º 0 % U_T; 250/300 cycle	The quality of supplied power should be suitable for home healthcare environment.
Magnetic field of supply frequency (50/60Hz) according to IEC 61000-4-8	30 A/m	30 A/m	The magnetic field of power frequency should be coincided with the general value found in the home healthcare environment
Immunity to Proximity magnetic fields according to	65 A/m Max. 30 kHz, 134.2 kHz, 13.56 MHz in according to table 11	65 A/m Max. 30 kHz, 134.2 kHz, 13.56 MHz in according to table 11	RFID communication equipment is used on closer than 5 cm to any part of the BeeTLe

Table 11 in IEC 60601-1-2			
Note: U_T is the AC voltage of the power before using test level			

WARNING !

Protective Distance

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BeeTLe, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

7) Safety considerations about part of device and compartment

For safe use, you must use part of device supplied or approved by Osteosys

NOTE !

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

WARNING !

A warning regarding stacking and location close to other EQUIPMENT

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

8) RF Exposure

This appliance and its antenna must not be co-located or operation in conjunction with any other antenna or transmitter. A minimum separation distance of 20cm must be maintained between the antenna and the person for this appliance to satisfy the RF exposure requirements.

9) Environmental protection

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

The exchange and usage period of consumable goods

Name	Part number	The period for exchange	The method of exchange expandable products
Foot supporter	FOOT SUPPORTER 1 : S3MM-108A	10 years	You should request the manufacturer or distributor to have these replaced.
	FOOT SUPPORTER 2 : S3MR-005A	10 years	
	FOOT SUPPORTER 3 : S3MR-006A	10 years	
	FOOT SUPPORTER 4 : S3MR-007A	10 years	
probe	C2MR-004	10 years	
QC Phantom	C3ES-002	10 years	
AC adapter	S3EB-004A	10 years	

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Chapter 1. Introduction

BeeTLe is a bone densitometry device to measure and prevent osteoporosis by measuring the bone mineral density of Calcaneus using ultrasound.

This device measures SOS (Speed Of Sound) and BUA (Broadband Ultrasound Attenuation) using ultrasound with a center frequency of 0.5 MHz and calculates the BQI to show the degree of bone density by Z-Score and T-Score.

It is easy to move and install in a stand-alone mode that does not require a separate accessory equipment, and powerful software functions enable convenient measurement and patient management.

This device is a precision equipment. For accurate results and safe and correct service, it is absolutely necessary to educate the proper use and service method by the right technician.

※ Features and Cautions

Intended user profile

Consideration	Description
Education	Bachelor or higher Physician or trained medical personnel located in hospitals and clinics.
Knowledge	Educated or trained for BMD(Bone Mineral Density) under the relevant majors such as orthopedics, internal medicine, obstetrics & gynecology, etc.
Language Understanding	English, offered in the User manual
Experience	More than 2 years of work experience in hospital as a doctor, a sonographer and etc (Patient is not operator: not relevant, unless patient is agitated)

This device is an ultrasound bone densitometer which has precision error as follows;
T-score ±0.2

Because it is a medical device, a physician who is trained by a salesperson or an A / S employee needs to make a measurement to get accurate data.
When you give the appropriate commands in BeeTLe software, ultrasonic waves are generated. The generated ultrasound passes through the calcaneus of the human body and measures bone density. The BeeTLe operating program uses a unique algorithm and calculates and displays the patient's various bone density values to the user.

The user of this device must understand the hazards of electronic medical devices and be aware of the precautions to be taken when an emergency occurs.
BeeTLe should be located more than 20cm away from the wall when measuring the patient.
In any case, do not disassemble the device at your discretion.

Chapter 2. Configuration of Device

2.1 Composition of Device

2.1.1 Shape and Components of Device

NO	Name	Function
1	CALF SUPPORTER	It functions as the top cover of the device when not in use and as the calf supporter when in use.
2	PROBE	Generation of ultrasound
3	Power button	ON / OFF the device
4	External power connector	Connect the AC adapter to power the unit and charge the battery.
5	Smart device holder	You can put the smart device through which the results are shown
6	Handle	You can grab and move the device by hand.

NOTE !
Check the location and contents of the label attached to the device. Check the location of the device power switch.

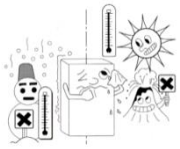
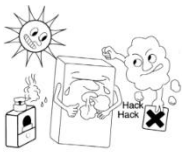
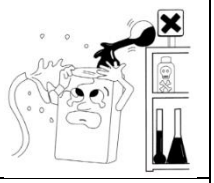
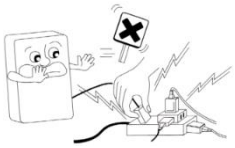
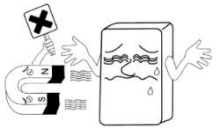
2.1.2 Accessories List

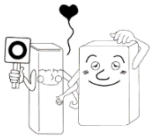
Check the following accessories before installing the system. If they are not in good condition, contact to OsteoSys or its authorized dealer for this service.

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 calibrate the system.
		Keep it in the specified place and protect it against deformation by heat or pressure.
AC adapter	1	It is used to connect to the source of electric power with the main body of the device.

2.2 Installation of BeeTLe

⚠ **NOTE !**
Since BeeTLe is made up of precise components, you should install the device according to instructions below.

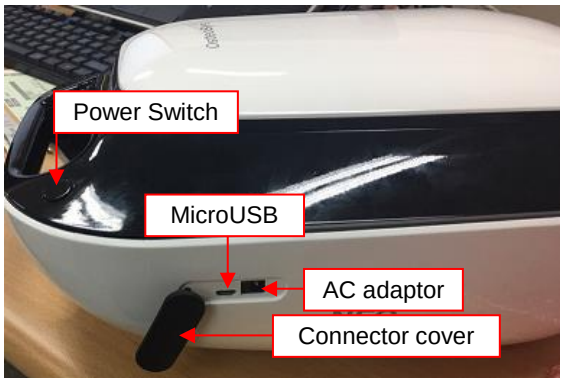
Do not install and keep BeeTLe at excessively high or low temperatures. Proper temperature: 10~35 ℃ 	Do not install or keep BeeTLe in the place where the device can be rocked or shaken. Make sure to place the device parallel to the floor. 
Do not install the device in the place with polluted air and high humidity and do not expose the device to direct sunlight. It is advisable to use BeeTLe in the place equipped with air conditioning or heating. Proper humidity: 30~75% 	Install BeeTLe 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 an electronic generator, X-ray equipment, broadcasting equipment. It causes an inaccurate results. 

Do not cover ventilation of the device or place it near the wall. High internal temperature of the device might cause a fire. 	100-240V is usable. Since sudden power outage can remove all data saved in the device, you should install BeeTLe in the place where a power supply is stabilized. 

2.3 Before Turning on Power

2.3.1 Connection of AC adaptor

Simply plug in the included AC adapter to charge and power your equipment immediately.



NOTE !

Before you start up the BeeTLe for the first time, fully charge BeeTLe's battery so that the battery performance can be used effectively.

※ Check the power switch is off when charging the battery.

NOTE !

If the battery is completely drained, it should be charged for at least 20 minutes.

NOTE !

Please use the AC adapter that is provided when you purchase the device.

Otherwise, it can cause device malfunctions and failures.

NOTE !

The AC adapter and MicroUSB port cannot be used simultaneously.

It can cause device malfunctions and failures.

CAUTION !

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

Chapter 3. Using BeeTLe

3.1 Daily Test

When using the device, daily check is performed to check the validity of the device measurement value. Daily check is performed once every day before starting the first measurement.

Preparation of the Daily test

1) Items to be prepared

BeeTLe, daily check phantom, ultrasound gel

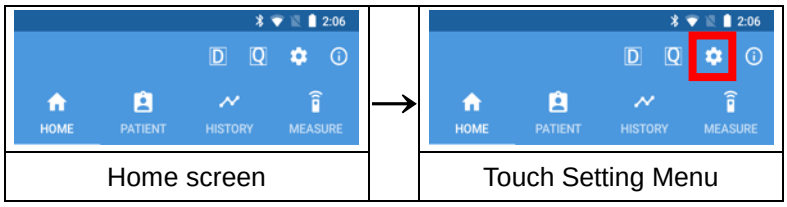
Perform the Daily test

1) Device Connection

[Using App] – [Device Connection]

2) Check the phantom value

When you turn on the app, press the Settings button ( ) and Setting Menu on the screen that appears.



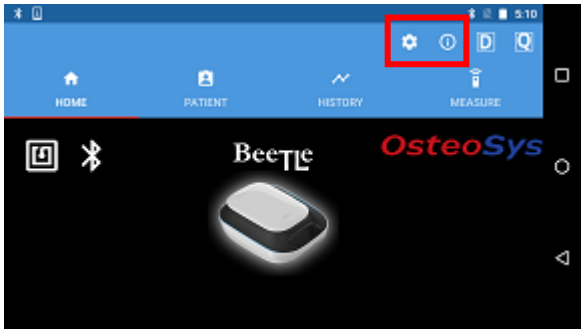
Home screen | Touch Setting Menu

NOTE !

If you're using a tablet or smart device, The 'Settings' and 'Info' icons will appear right away.

Settings icon

Information icon



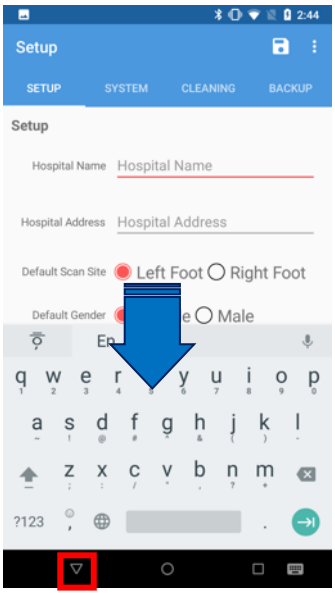
On the bottom of the phantom, one of two types of labels is shown below.

Confirm the contents listed below and confirm the following two items.

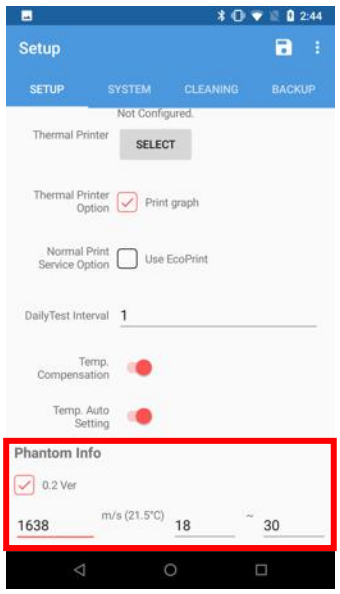
1. Make sure that the SOS value and the BUA range that are listed in the phantom label to be correctly shown in the Phantom Info section of Settings.

(If you find any mismatch, modify it according to phantom value.)

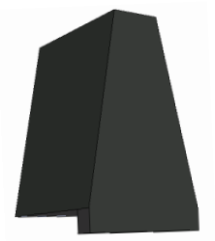
2. If there is 'V0.2' in the upper right corner of the label, make sure to check '0.2Ver' in the checkbox in Settings. If not, make sure not to select it.

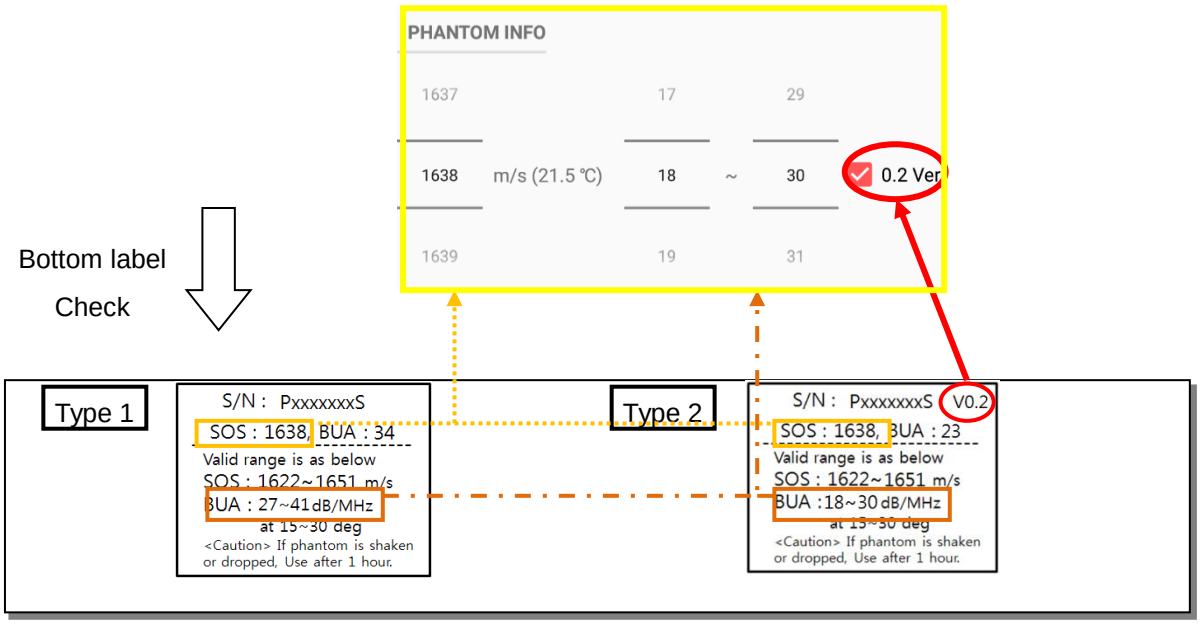


Lower the keyboard and down the screen.



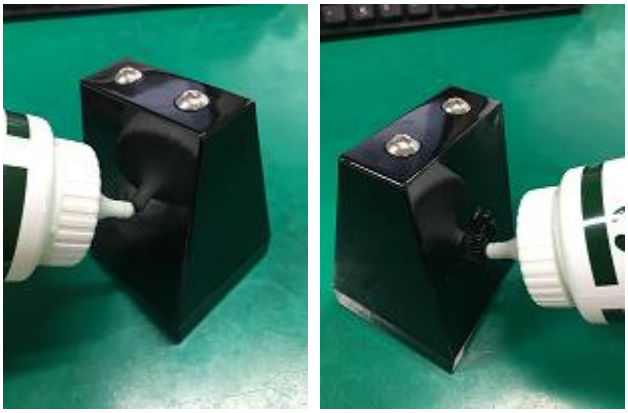
Check and modify phantom information.





3) Phantom Installation

Apply ultrasound gel to the phantom. The position to apply the gel is the position on both sides of the phantom where the probe touches the phantom, that is, the contact area of the probe. The amount of gel should be as large as possible so that the area is the same as the contact area of the probe.



Place the phantom on the Foot Supporter 1 in the measuring position of the device. (The phantom must be on the edge of the Foot Supporter as shown below.)

The Foot Supporter 2 is not used for Daily test.



Start Daily test, lightly push down the foot supporter as shown in the picture below.

⚠ **NOTE !**
It is required to press foot support to have proper daily test with Phantom.

4) Execution of Daily test

[Using App] – [System check of product (Daily test)]

⚠ **NOTE !**
Daily Test Recommendation

Daily test should be performed at an operating temperature conditions of the unit.

(Recommended operating temperature: 15 to 30 degrees Celsius).

Phantom should always be kept close to the device.

Daily test should be done immediately after turning on the device.

Turn off the device after a day's work is finished.

As soon as the device is turned on at the beginning of the day's work, the Daily test needs to be performed immediately before the temperature rises due to the heat inside the device.

3.2 Shutting down the product

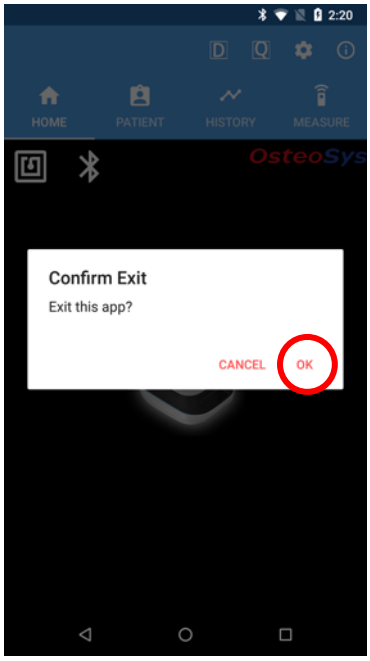
To shut down the device, proceed as follows.

 NOTE !

When turning off the device, proceed as follows to avoid data loss.

3.2.1 Shut down sequence

On the Home screen, press the Android Back button to exit the Android app by selecting the <OK> button marked with a red circle.



Once you exit the App, press the power button on the BeeTLe to shut down the device.

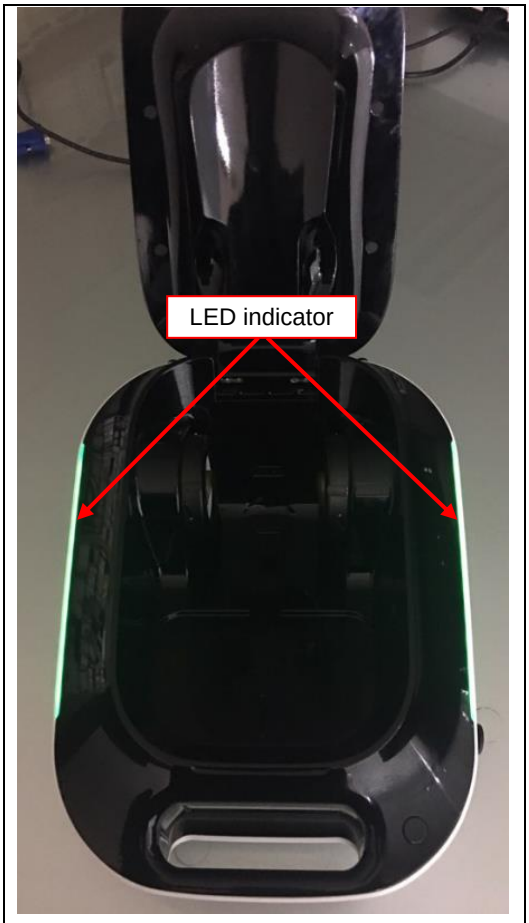
NOTE !
In iOS, you can exit BeeTLe app with iOS home button method. Press home button twice, and swipe to remove app from the list. Then app will shutdown immediately.

3.3 Using H/W

3.3.1 LED indicator

The LED display on both sides of the device shows different colors according to each operation.

The contents are as follows.



LED indicator on both sides

LED indicator	
Status	**Color**
Standby(Waiting)	Green
Measure	White
Power save(Sleep)	Black (Light off)
Low battery	Red
Charging	Flashing Green and Black (light off)
Charging complete	Flashing Green and Blue

3.3.2 Power saving mode

When the battery is not used for a long time, you can use the power saving mode to increase the usage time.

The power saving mode and standby mode can be switched by simple operation of cover closing/openinng.

Standby(waiting) mode		Power saving mode
		
Open the cover		Close the cover

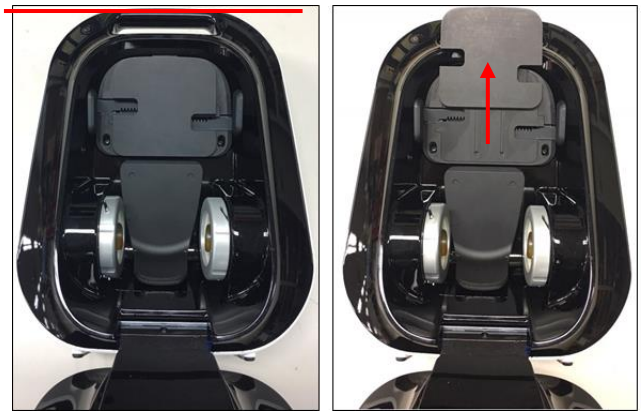
⚠ NOTE !
※ Bluetooth connection will remain in power saving mode. ※ Bluetooth connection is feasible in power saving mode.

3.3.3 Patient Measurement Procedure

	Clean the surface of the Coupling Pad with an alcohol pad.
	Clean the both side of patient's heel with an alcohol pad and apply gel.
	Place patient's foot like this picture. Start measuring after the positioning.

⚠NOTE !
If the probe spacing made of soft material is not sufficient, it may cause harm to the patient or cause problems with the measured values. Therefore, if your feet are large, make sure that the probe spacing is wide enough before inserting your feet.

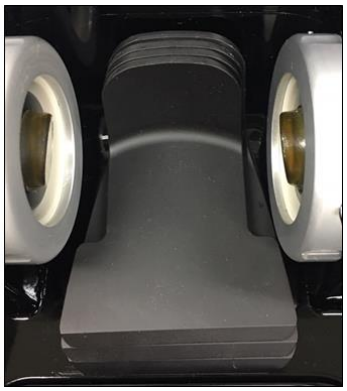
3.3.4 How to use the toe holder

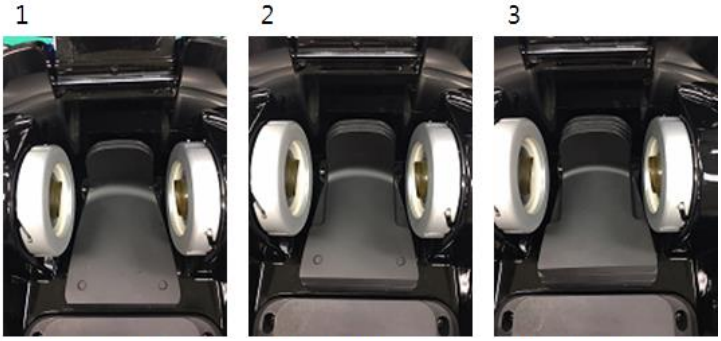


When the toe crosses the handle of the device (red line), push forward the toe folder as shown in the image on the right.

Put patient's foot on the BeeTLe and fix the foot by adjusting both wings.

3.3.5 Selection of Foot Supporter





(Foot Supporter 1) (Foot Supporter 2) (Foot Supporter P)

Put the foot supporter according to the size of patient's foot as below.

If patient's foot is over 260cm

: Use foot supporter 1 (overlapping two sheets).

If patient's foot is 250 cm or less

: Use foot supporter 1 and 2 together (overlapping three sheets).

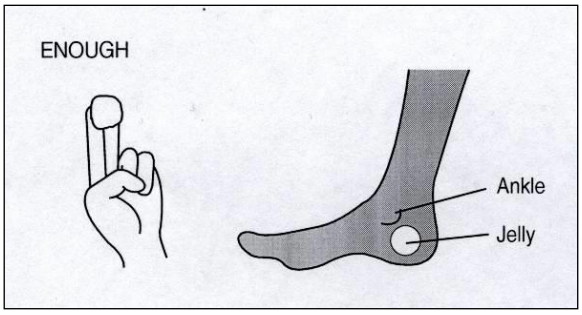
If patient's foot is 240 cm or less

: Use foot supporter 1, 2 and P together (overlapping four sheets).

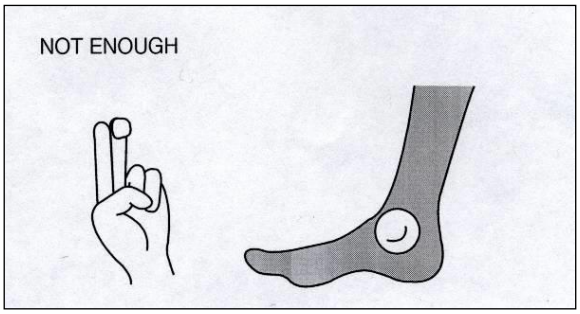
3.3.6 Where and How to Apply Gel to the Patient's Heel

Swipe patient's heel with alchol pad and apply gel.

Apply sufficient amount of gel to the heel to remove air remaining between the probe and the patient's heel.



Good



Not Good

NOTE !

Apply sufficient amount of gel for accurate measurement. Do not make a thin apply.

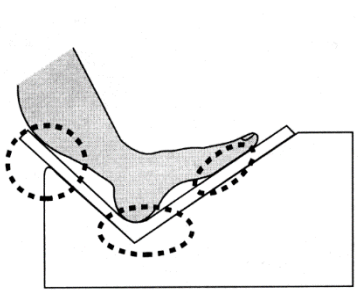
Caution !

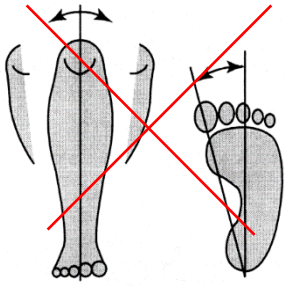
To prevent damage to skin and cells, use commercially available ultrasound gels that have passed ISO 10993-5(Cytoxicity), ISO 10993-10(Skin sensitization), and ISO 10993-23(Skin irritation) tests.

Do not forget to apply the gel before measuring.

3.3.7 Position of foot and body

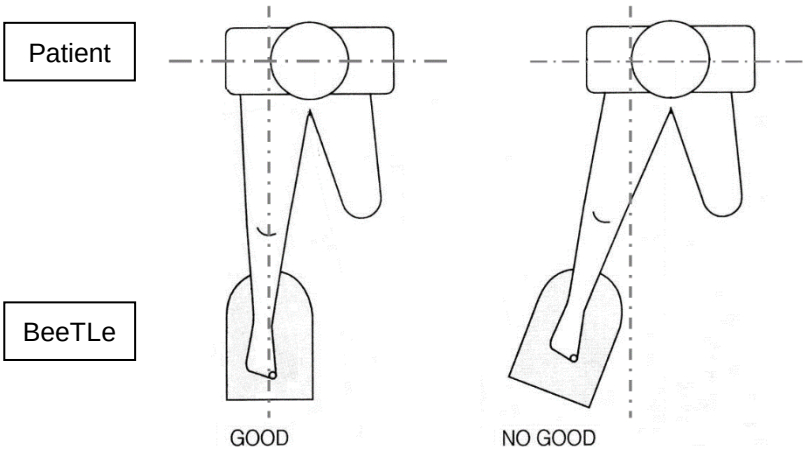
Place heel in the device and make sure that the 3 points of the foot are attached to the device as below.





GOOD : Not tilted(Straight) NOT GOOD : Tilted

With both legs widened to the shoulder width, make sure that the measuring device and the axis of the foot you want to measure are aligned with the axis of the ear.
(In the figure, it is an example of measuring the right foot.)

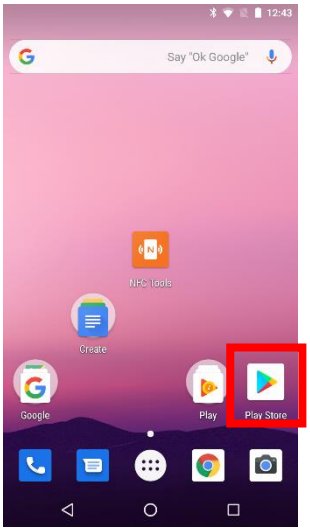


3.4 Using App

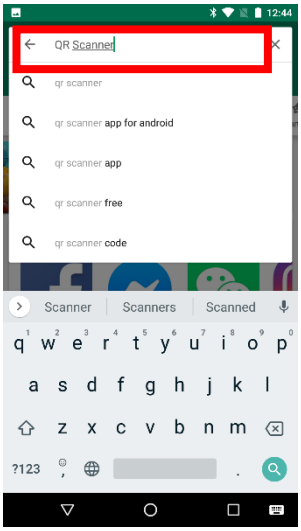
3.4.1 Install the program

⚠ NOTE !
BeeTLe APP installation can be done in two ways as follows. 1) Install using QR code 2) Install using Play store search

1) How to install using QR code.

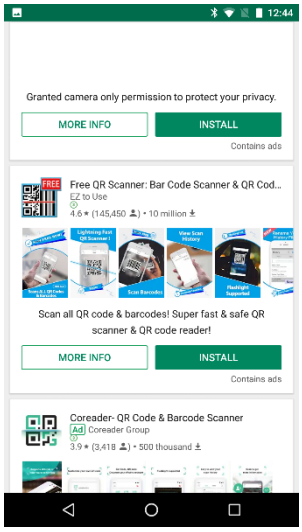


→

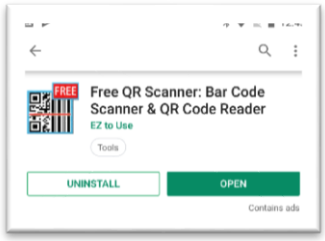


(1) Start the Play store. (2) Search for 'QR scanner'

→

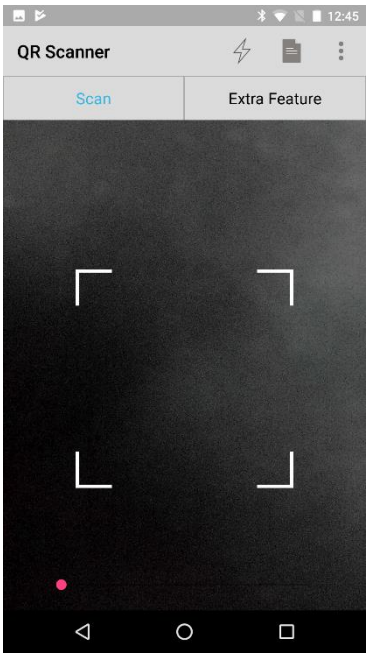


→



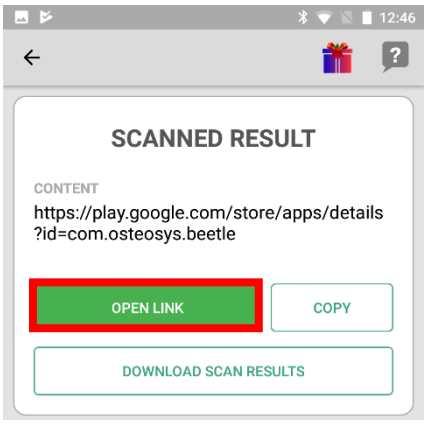
(3) Install APP after search (4) This manual uses the QR -scanner of <EZ to Use>

(5) Start the QR scanner APP.

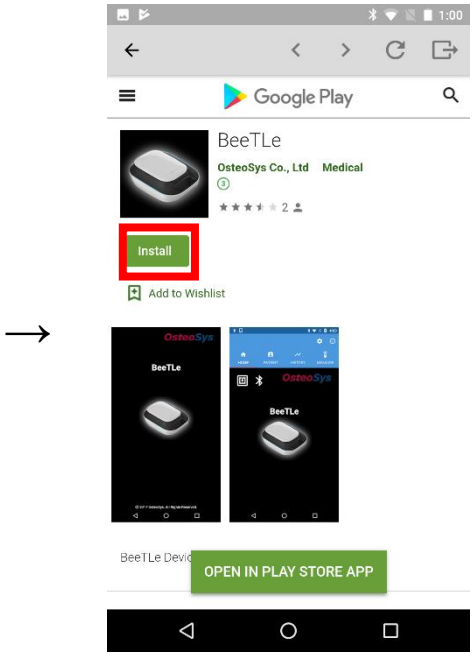


(6) Scan the QR Code of (7) Smartphone screen

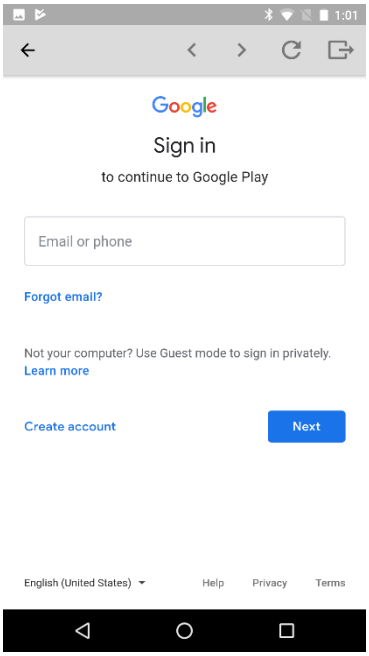
(7) QR code of BeeTLe APP



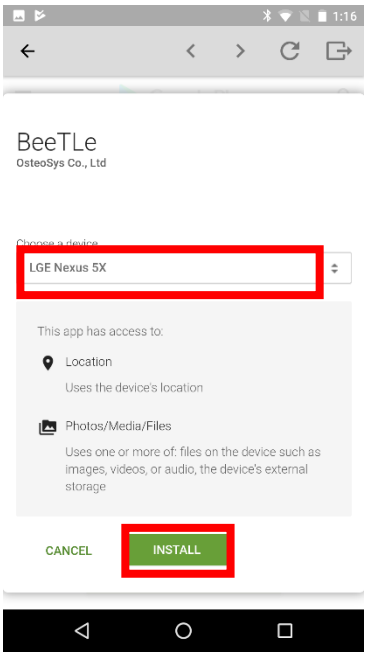
(8) When the scan is completed, Touch "Open Link".



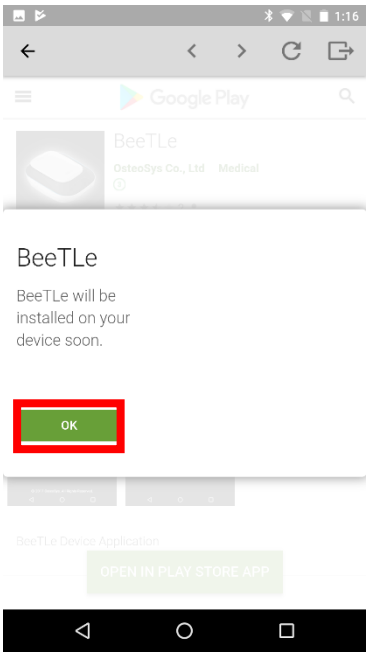
(9) When the BeeTLe APP screen appears, touch the 'Install' button.



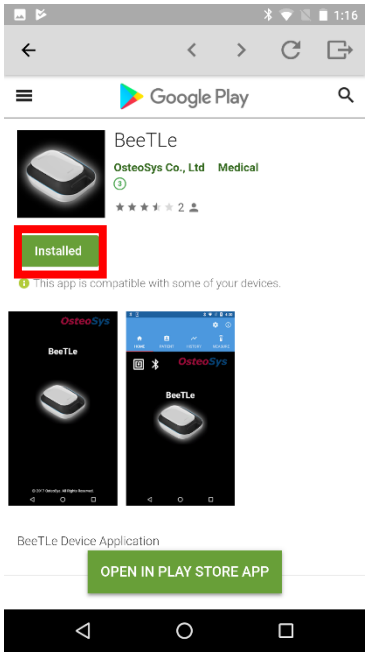
(10) If login screen appears, touch 'Install' button again after login.



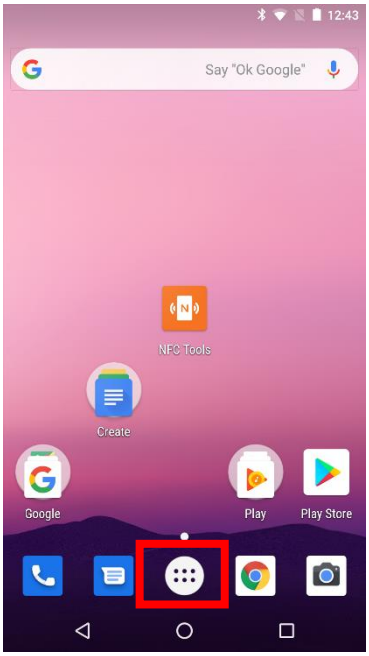
(11) When the device selection screen appears, select the device you are using and then touch the 'Install' button



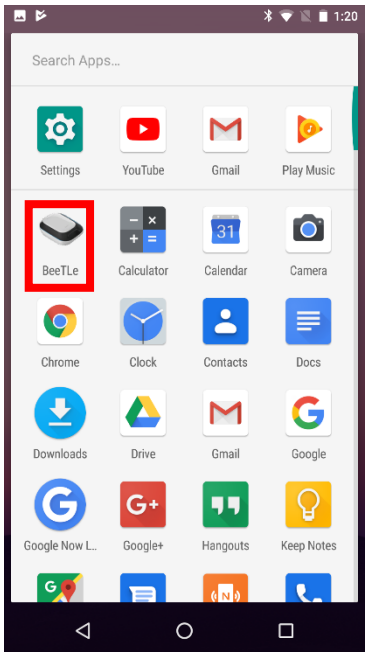
(12) Touch the OK button.



(13) When installation is completed, exit to the home screen.



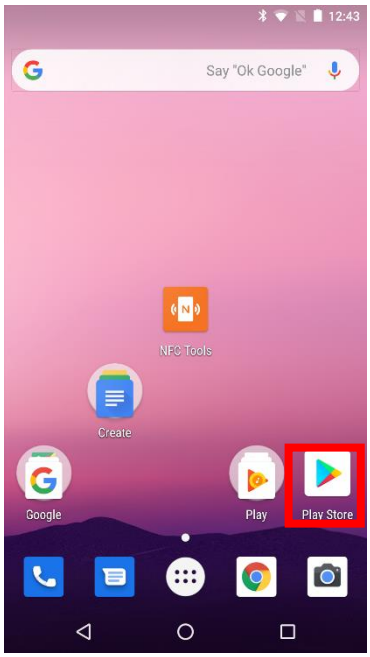
(14) On the home screen, touch the Install APP List icon.



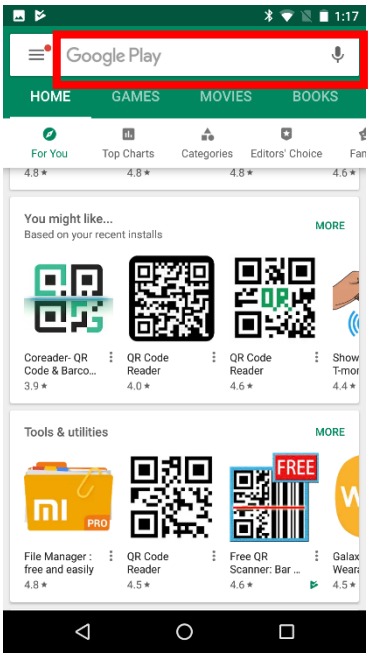
(15) Check the BeeTLe APP icon and touch.

(16) Once the installation is completed successfully, you can see the home screen of BeeTLe APP.

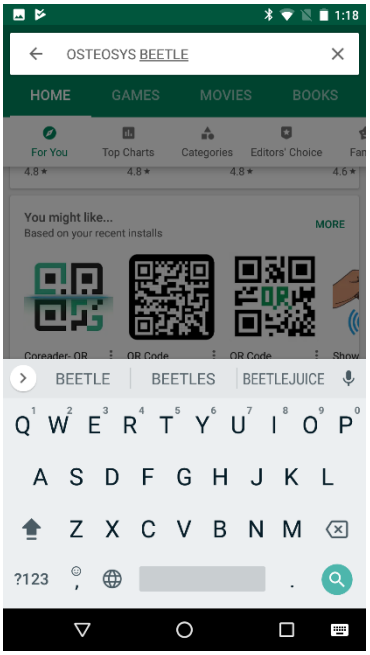
2) How to install Play store search



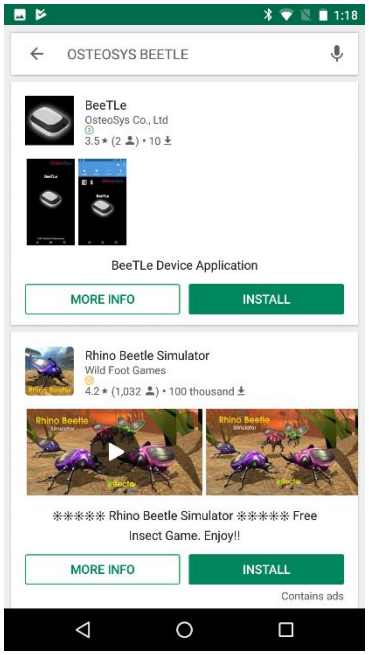
(1) Start the Play store.



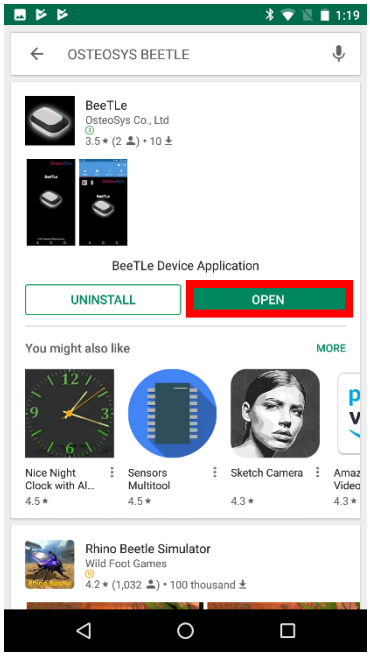
(2) When the Play store screen appears, touch the search box.



(3) Enter 'OSTEOSYS BEETLE' in the search box and touch the search icon[ ]



(4) Check the APP name and developer name and touch the 'Install' button.



(5) When installation is completed, touch 'Open' button.

(6) Once the installation is completed successfully, you can see the home screen of BeeTLe APP.

3.4.2 Execution of the program

Select the BeeTLe icon on the app selection screen to run the program. After about 5 ~ 15 seconds of preparation, the start screen appears. A description of each icon is shown below.

Home

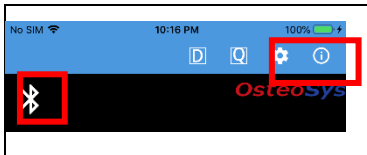
Status	Status icons	
	NFC	Bluetooth
Unavailable		
Available		
BeeTLe connection	·	

※ When NFC & Blue tooth are not available, refer to the user manual of smart device to turn on this function

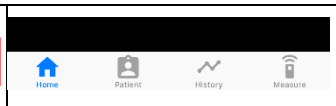
Icons		Description
Icons	Function	
D	Daily test	Start daily test
Q	Quick Measure	Start immediate measurement without patient registration.

Setting & Info Menu

Details of additional menu		
Icons	Function	Description
	Setting	You can see the settings and other functions related to the program.
	Information	You can see information about programs and device.



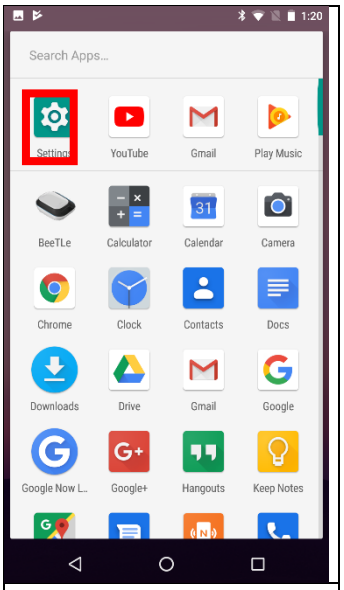
In iOS, there is no NFC.



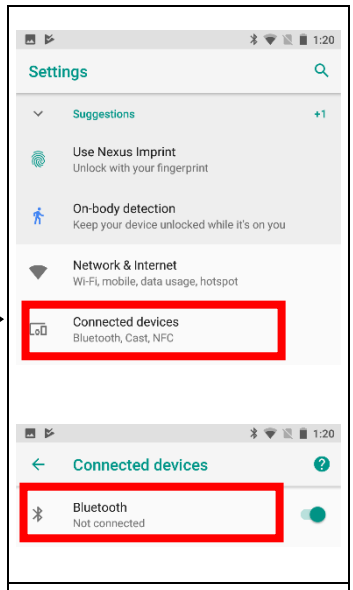
In iOS, TAB bar is located at bottom of the iOS device.

3.4.3 Registration of BeeTLe (Bluetooth)

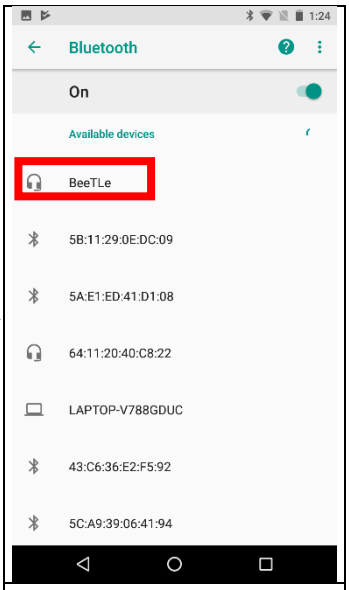
Register your Bluetooth device on your smart device for seamless connection with BeeTLe.



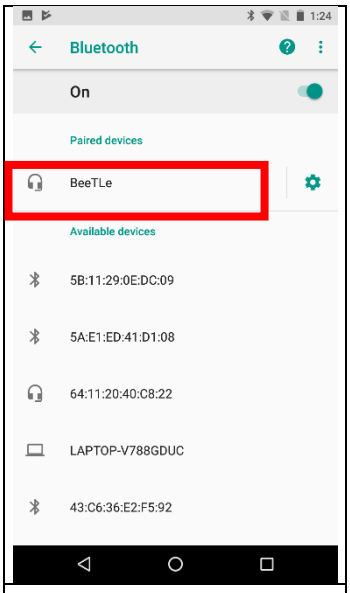
(1) Touch Setting icons



(2) Touch the Bluetooth entry



(3) Touch BeeTLe



(4) Device registered.

Device (BeeTLe) Connection

Once the device registration is complete, run APP and proceed to connect the device.

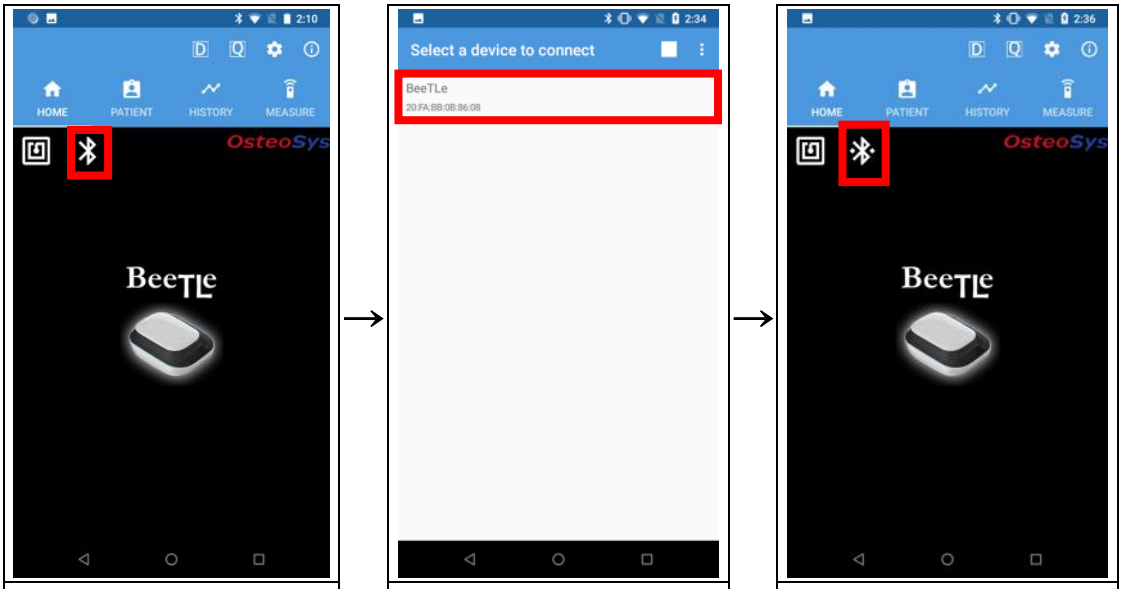
NOTE !

For Android phone, proceed with 'Registration of BeeTLe' first and then with the connection.
For iOS(iPhone), registation process is not required.

NOTE !

The distance that BeeTLe can be connected with Bluetooth is as follows.
※ Transmissible distance in space without obstruction: 5M.
- Transmission range in households may vary depending on environment conditions(existence of any obstruction) and smart device specifications.

1) How to search and connect



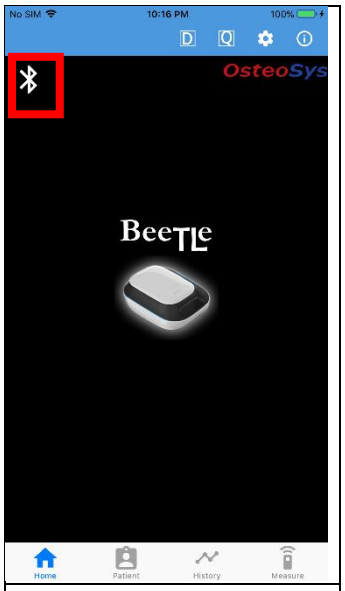
(1) Touch the Bluetooth icon

(2) Touch BeeTLe

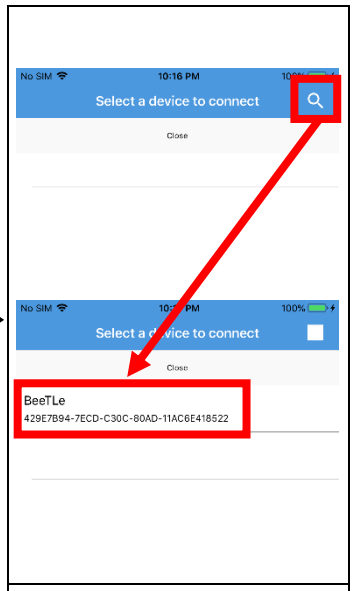
(3) Check the connection Notification window.

NOTE !

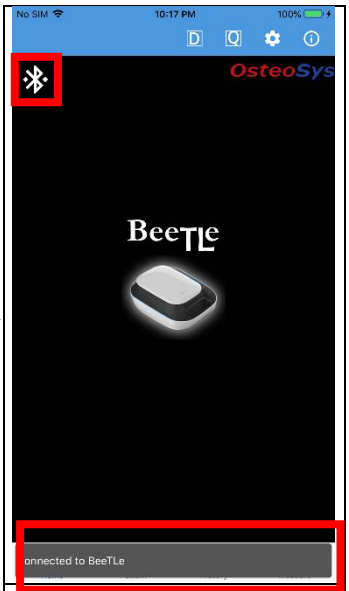
In case of iOS, proceed as below.



(1) Touch the Bluetooth icon



(2) Touch BeeTLe



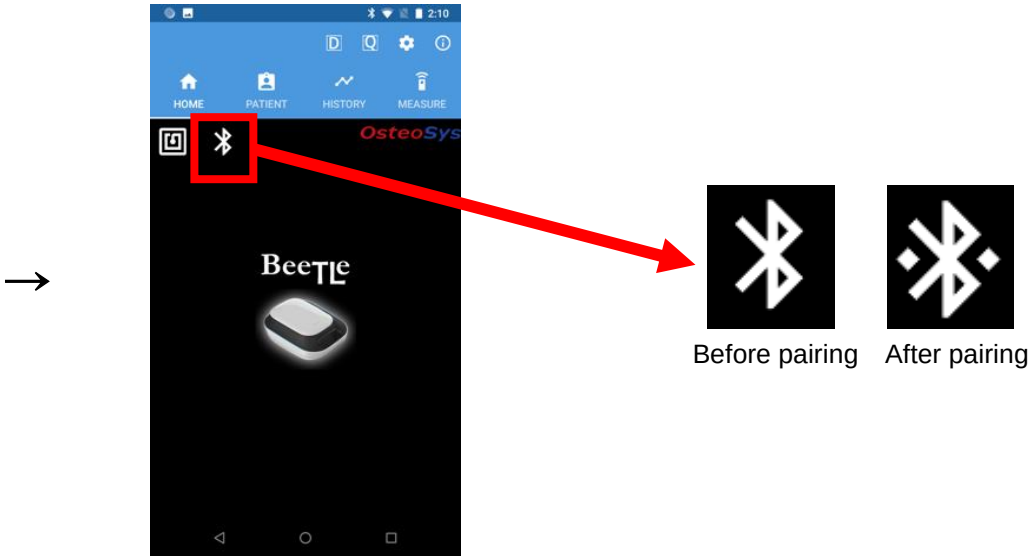
(3) Check the connection Notification window.

2) How to connect by NFC tagging.

⚠ **NOTE !**
In iOS, BeeTLe App does NOT provide NFC connect method.

After launching the BeeTLe APP, proceed as follows.

(1) Place your smart device near the NFC mark on the BeeTLe



Before pairing After pairing

(2) When pairing is completed, the icon changes.

Sometimes when you try to connect your device, you may be requested to enter your PIN code. If this happens, enter "1234" as the PIN code to connect.

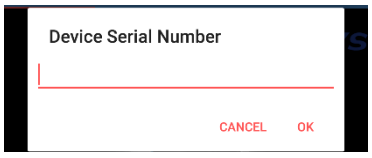
When you connect the device, the Bluetooth button will be displayed as shown on the right.

⚠ NOTE !
Your smart device must support Bluetooth 4.0 or higher. If Bluetooth is disabled, enable Bluetooth. Bluetooth activation is also required when connected via NFC.

⚠ NOTE !
Make sure to Connect the device before using the BeeTLe.(Bluetooth pairing) If the device is not connected, you might experience malfucntioning.

⚠ NOTE !
The app that has been previously connected to BeeTLe dwill attempt to connect automatically when they launch the BeeTLe app.

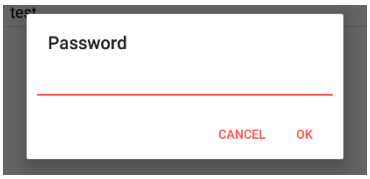
3.4.4 Device Serial Number Verification



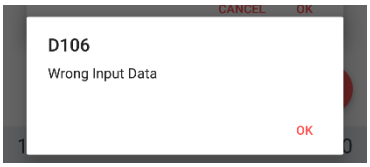
When you connect to the device, a window appears for you to enter the serial number of the device. If you enter the serial number, proceed to the next step. If the device serial number is not the same, the following error message window appears. If the device serial number is not verified, the app disconnects the device connection. If the device is not connected, you will not be able to use most of the features of the BeeTLe app.

3.4.5 Inspector Selection

When the device serial number is verified, the inspector selection window appears.

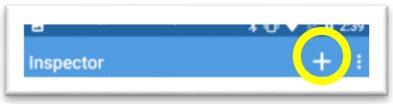


Touch the inspector and a password entry window will appear.

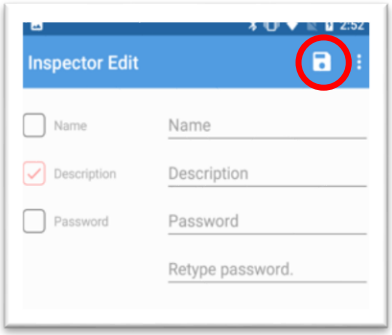


If an incorrect password is entered, an error dialog which is like the picture will be displayed. If the correct password is entered, the home screen will be displayed.

3.4.6 Adding an Inspector



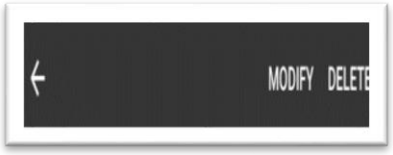
In the inspector selection window, you can add an inspector by pressing the button marked with a yellow circle.



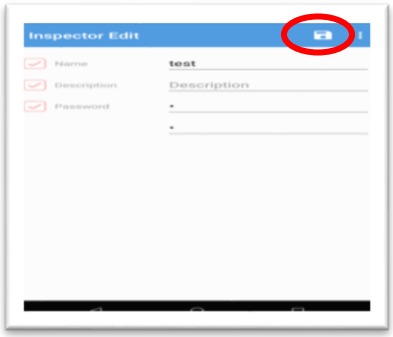
After filling the contents, press the Save button marked with a red circle to save and move back to the inspector selection screen.

NOTE !
Enter user information accurately.

3.4.7 Modifying an Inspector

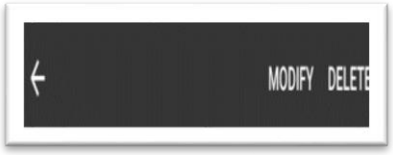


If you long click(on Android) or swipe(on iOS) the inspector you want to modify, you can choose to modify the inspector.



After modifying the contents, press the Save button marked with a red circle to save and move back to the inspector selection screen.

3.4.8 Deleting an Inspector



If you long click(on Android) or swipe(on iOS) the inspector you want to delete, you can choose to delete the inspector.

NOTE !
You must reconnect to the device to reset the inspector selection. In addition, the inspector selection is automatically reset (deselect) when the device is disconnected.

3.4.9 Setting

Click the <Setting> button on the <Home> screen to display the Setting window.

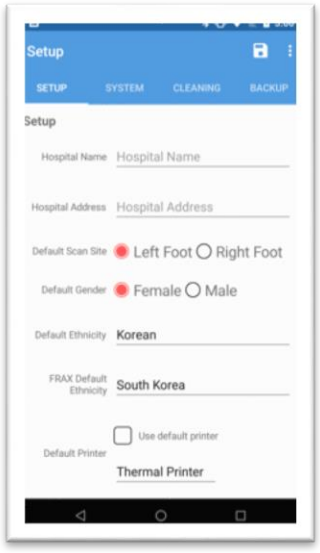
<Settings> window

- Setup: Set the default settings related to the software.
- System: Make OS related settings.
- Cleaning: Clean the probe. Use with the connected device only.
- Backup: Manage measurement data.

1) Setup

Make default settings related to the software.

Setting > Setup tab



- Hospital Name: Enter the hospital name to be displayed in the printout.
- Hospital Address: Enter the hospital address to be displayed on the printout.
- Default Scan Site: Select the default site for measurement.
- Default Gender: Select the default gender when adding a user.
- Default Ethnicity: Select the default ethinicity when adding the user.
- FRAX Default Ethinicity: Choose the default ethnicity of FRAX.
- Printer selection: Select whether to select the printer type when printing.
- Default printer: Choose whether to use a thermal printer or a regular printer for output. You can even set the printer to be output every time you print.
- Thermal printer setting: Connect the thermal printer.
- Graph printing: Select whether to print the graph when using thermal printer.
- Ink-saving mode: When you use an external printer, you can change the graph output method to save ink.
- DailyTest interval: Set the interval of DailyTest.
- Temperature compensation: Select whether to perform DailyTest and temperature compensation for patient measurement.
- Auto temperature setting: Select whether to set temperature value automatically.
- Phantom Info: Change the information of the phantom used for the DailyTest.
- You have to check or uncheck the version according to Phantom version.

2) System

Make operating system related settings.

Setting > System

- Language: Change your app's language setting. The app will not take effect until you restart it.

- Device Location Tracking: Show the locations of the BeeTLe device. A location map window is popped out when the button is clicked.

[Using App] - [Battery check]

- Storage Server: Input the relevant information if you want to transfer images through PACS. The hospital must provide a unique IP address and port for accessing the Storage Server, and then enter capital letters and lower case letters correctly (you must request server information from the hospital server administrator).

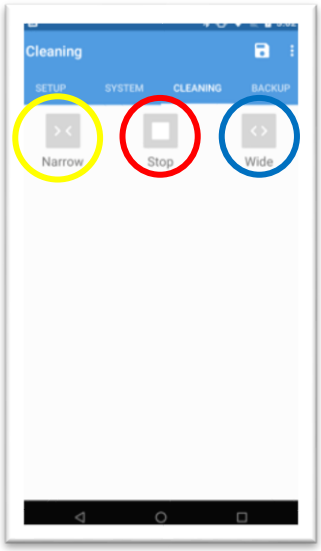
- Worklist Server: The Worklist input field is used to import the subjects registered in the server. The hospital must be provided with a unique IP address and port for connecting to the Worklist Server and then enter capital letters and lower case letters correctly.
In addition, the worklist must be entered correctly because the patients are classified according to the modality.

- Query: Enter conditions to import the subjects registered in Worklist server. The input value of modality entered in the query should the same with that of modality of the worklist server. The dates that are available in Query can be calculated based on the system date to obtain the subjects registered before today, week (7 days), weeks (14 days), and month (30 days).

⚠ NOTE !
The IP Address, Port, Modality of the Storage / Worklist Server using DICOM can be attained from hospital server administrator. You need to ask the administrator for information. For server information, make sure that you enter capital letters and lower case letters correctly.

3) Cleaning

Move the probe of the device to an easy-to-clean position.



Setting > Cleaning tab

- Narrow: This is a button marked with a yellow circle. Pressing this button while the deviced is connected, the gap between the probes get narrowed, and exposes the probe. Press the button before cleaning the probe.

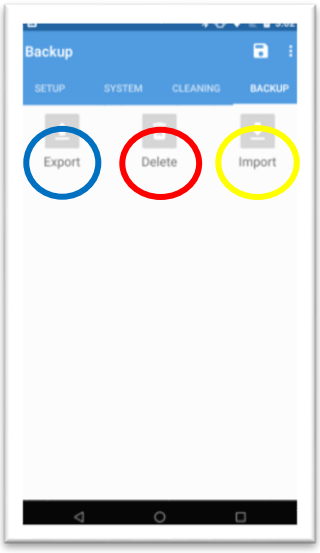
- Stop: This is a button marked with a red circle. Pressing this button
while the instrument is connected stops the movement of the probe.

- Widen: This is a button marked with a blue circle. When this button is pressed while the device is connected, the gap between the probes widens and the probe gets into the device. After cleaning the probe, press it.

⚠ NOTE !
Noise may occur due to the characteristics of the motor during cleaning, but it is not a malfunction of the device.

4) Backup

Manage your data. Be sure to restart the app when using the Erase or Import feature.



Settings> Backup tab

- Export: This is a blue circled button. Patient data and measurement data can be exported in DB format or exported in CSV format (UTF-8 encoding). If you export to CSV format and send data to your computer by Bluetooth or e-mail, you can check the data through a spreadsheet program such as Excel or a text editor.

- Delete: A button marked with a red circle. It initializes measurement data.

- Import: A button marked with a yellow circle. It imports DB that has been exported.

⚠ NOTE !
Import function is available between Android and iOS. Import function supports importing database from BeeTLe beta app. However, BeeTLe beta app can not import the database of BeeTLe app.

3.4.10 Measurement

NOTE !

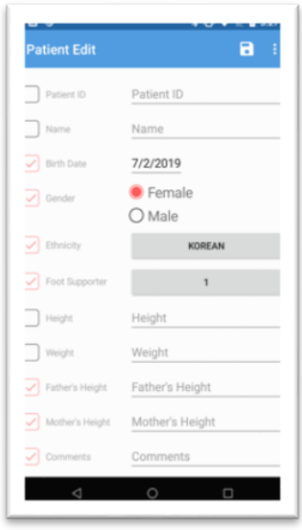
Measurements may not be accurate if patient information is entered incorrectly.

Patient registration

From the initial screen, select the <Patient List> tab at the top to go to the "Patient List" screen, which displays and manages registered patients.

To register a new patient, click the <Add> button marked with a red circle. The "Add Patient" window will appear. Enter the patient information and click the <OK> button. The patient will be registered and displayed on the screen.

[Patient List Screen]



- Patient ID: Enter the ID that can distinguish the patient.
- Name: Enter the name of the patient.
- Date of Birth: Enter the patient's date of birth. Press the button marked with the date to enter the date of birth on the calendar.
- Gender: Select the gender of the patient.
- Ethnicity: Choose the ethnicity of the patient.
- Foot Supporter: Select the foot supporter according to the patient's foot size.

- Height: Enter the patient's height in cm.
- Weight: Enter the patient's weight in kg.

- Father's Height: Enter the patient's father's height in cm.
- Mother's Height: Enter the patient's mother's height in cm.

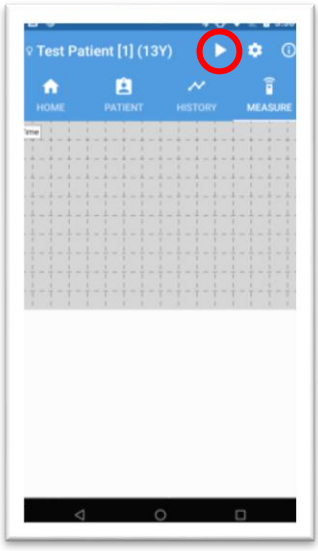
(Father's and Mother's Height appears only when the patient is not an adult. Registration process can be done without Father's/Mother's Height, but this will disable height prediction function.)

- Comments: Enter the comments of the patient.

Patient measurement

To measure the patient's bone density, select the patient to be measured on the patient list screen and click the <Measurement> tab at the top. The "Measurement" screen appears as shown below.

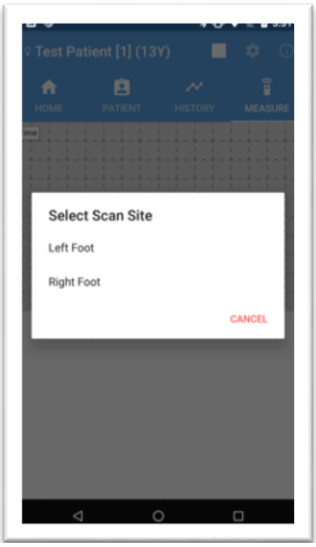
Then, when you click the <start measurement> button marked with a red circle, a message box asks the measurement area as follows. After selecting the measurement site, BeeTLe device will start measurement. If you disable the <Temperature Auto Adjustment> function with <Temperature Compensation> enabled, the temperature selection window may appear.



[Measurement screen]

Measure the temperature and select the temperature closest to the value. The temperature is reflected in the temperature compensation.

If the <Temperature compensation> function is activated and the <Temperature automatic setting> function is also activated, the temperature selection window will not appear. The temperature unit is in degrees Celsius (° C).



Scan Site selection window

[Measuring foot selection screen]

When you start measurement, the <Start> button changes to the <Stop> button. If an emergency occurs during the ultrasonic emission, clicking this button will stop the ultrasonic emission. After a certain period of time (about 10 seconds), the result of the measurement of bone density is shown as below.

[Detailed measurement result screen]

Press the <Print> button marked with a red circle at the top of the screen to print the results.
Press the PACS <image transfer> button marked with a yellow circle to transfer the results to the Storage server.
Press the <Share Image> button marked with a purple circle and the results will be shared via email or instant messaging.
Press the <Result Comment> button marked with a brown circle and you can edit result comments.

 [Using App] - [Printing History/Result]

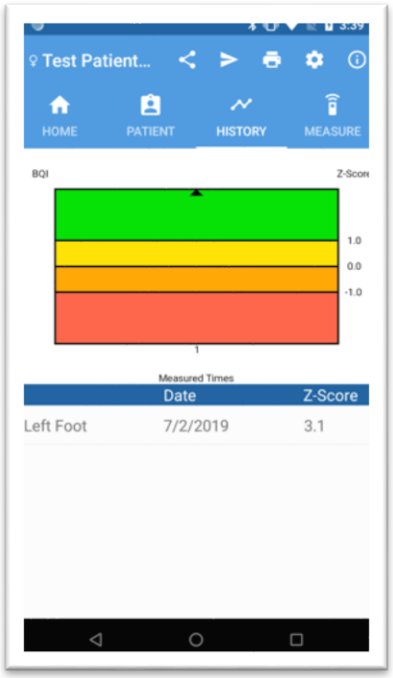
⚠ **NOTE !**
If the image transfer is successful, the corresponding measurement data is deleted. If the measurement data are the only measurement data from the patient, the patient information is also deleted.

Pediatric mode

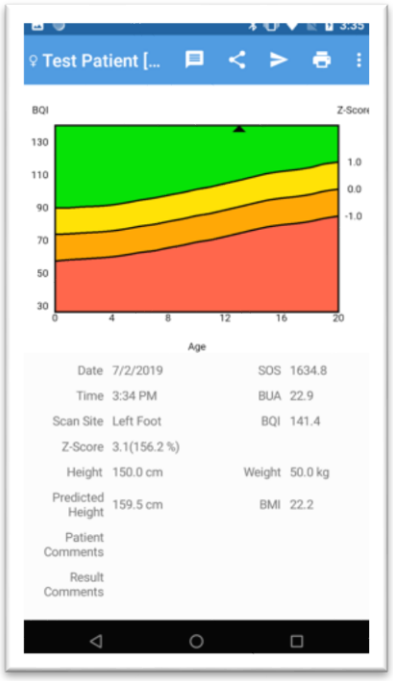
If patient's age is under adult age, the following screen is displayed. Each screen can be changed by tapping the graph.

- Pediatric bone density results and graphs
- Current height and predicted height and graphs (Predicted Height is displayed as hollowed points.)
- Current weight and graphs
- BMI results and graphs

※ **Pediatric Bone Density Results**

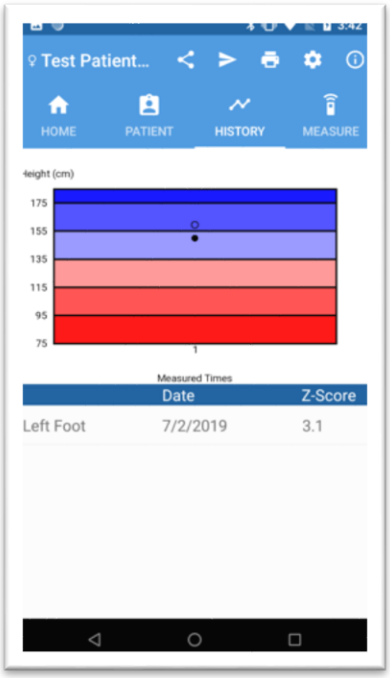


[History]

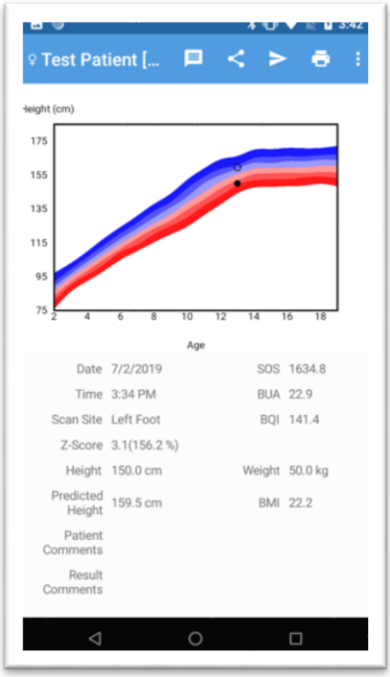


[Detail]

※ **Current Height and Predicted Height Results**

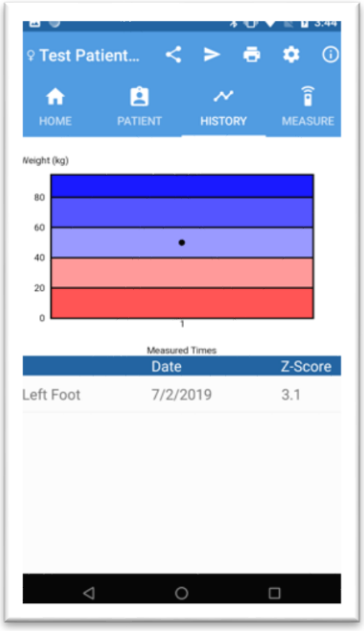


[History]

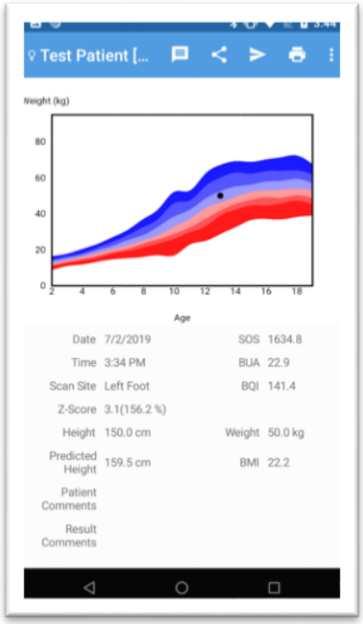


[Detail]

※ **Current Weight Results**

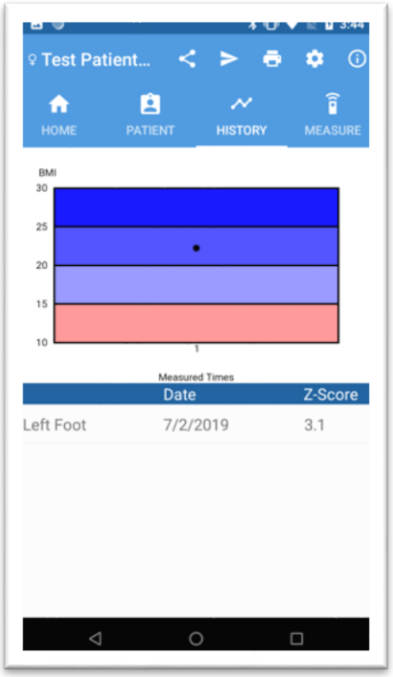


[History]

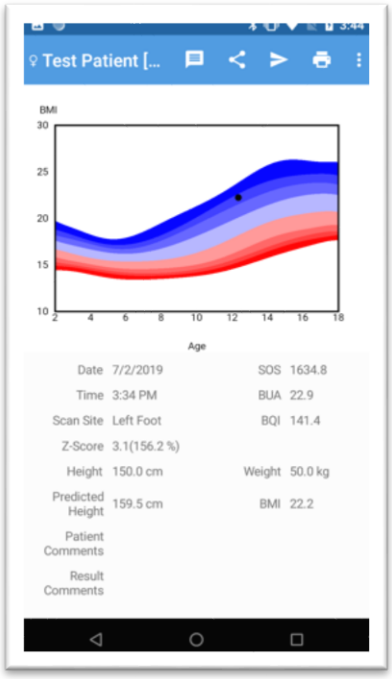


[Detail]

※ **BMI Results**

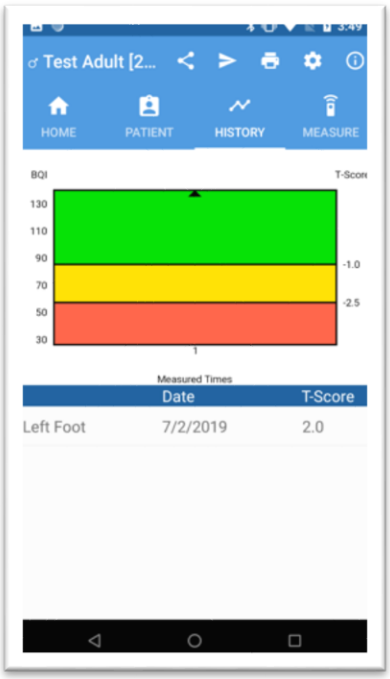


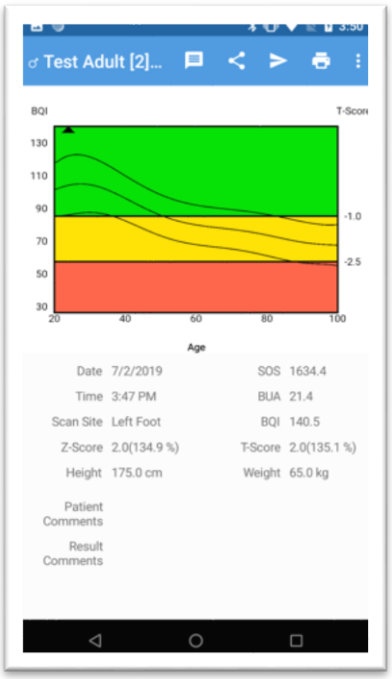
[History]



[Detail]

※ If you select an adult patient, you will see the following screen.



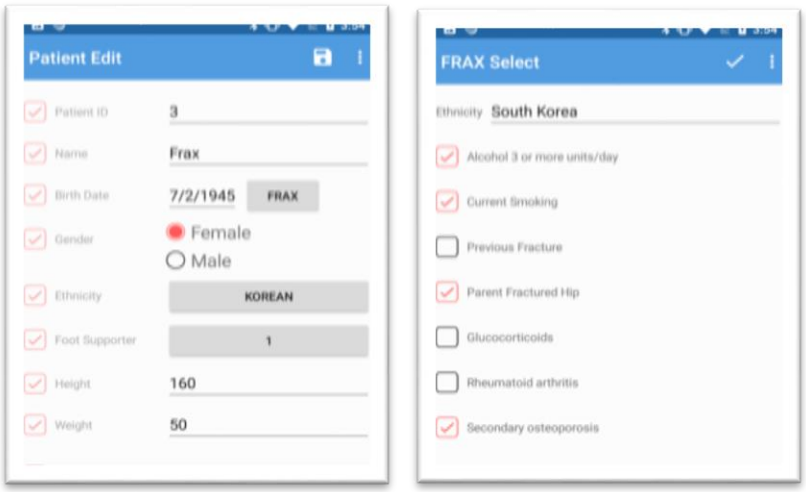


[History] [Detail]

3.4.11 FRAX

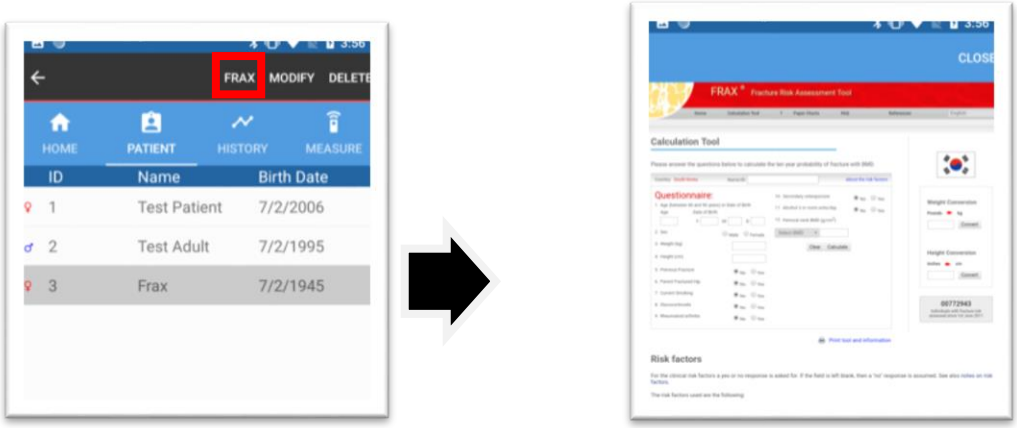
If the patient is between 40 and 90 years old, the FRAX is available. FRAX is a function that predicts fracture risk developed by WHO. If you know the femoral neck BMD, you can calculate more accurate fracture risk.

On the patient add / modify screen, if the patient's age is FRAX age (40 to 90), the FRAX button is activated. Click the button to register patient information.



[FRAX Seelction]

After registering a patient, you can use the FRAX function by selecting the <FRAX> button in the window that appears by long-pressing (on Android) or swiping (on iOS) the patient on the "Patient List" screen.



[FRAX Menu] [FRAX Result]

⚠ NOTE !

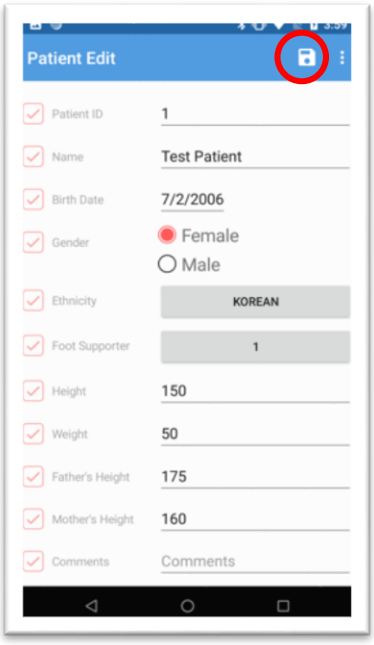
You can see FRAX Menu button with each patient. But FRAX Menu button works only when the patient's age belong to FRAX available age (40 ~ 90).

Modifying and deleting patient information

1) Modifying patient information

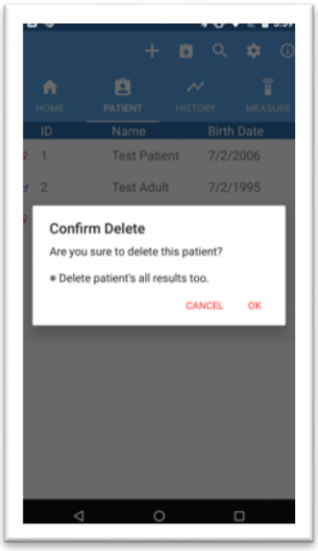
If you want to modify the information of an existing patient, tap and hold the patient(on Android) or swipe the patient(on iOS) on the "Patient List" screen and select the <Modify> button in the window that appears.

The "Modify Patient Information" window will appear as shown below, where you can enter the new value of the patient's information and click the <Save> button to modify the patient's information.



[Modify Patient Information window]

2) Deleting patient information



To delete patient information, select the patient to be deleted from the "Patient List" screen and click the <Delete> button at the bottom(on Android). In iOS, swipe the patient to delete and touch the <Delete> button. The "Delete patient information" message box appears as follows. If you click <OK> button, patient information will be deleted.

[Delete patient information window]

3) Worklist

You can use it after registering Worklist server information in Setting. On the "Patient List" screen, click the <worklist> button shown below. If there is a subject registered in the worklist server, the updated window of the subjects registered in the worklist appears. You can exit the Worklist window by tapping the Android back button or by clicking close button.

Worklist button

[Worklist request result]

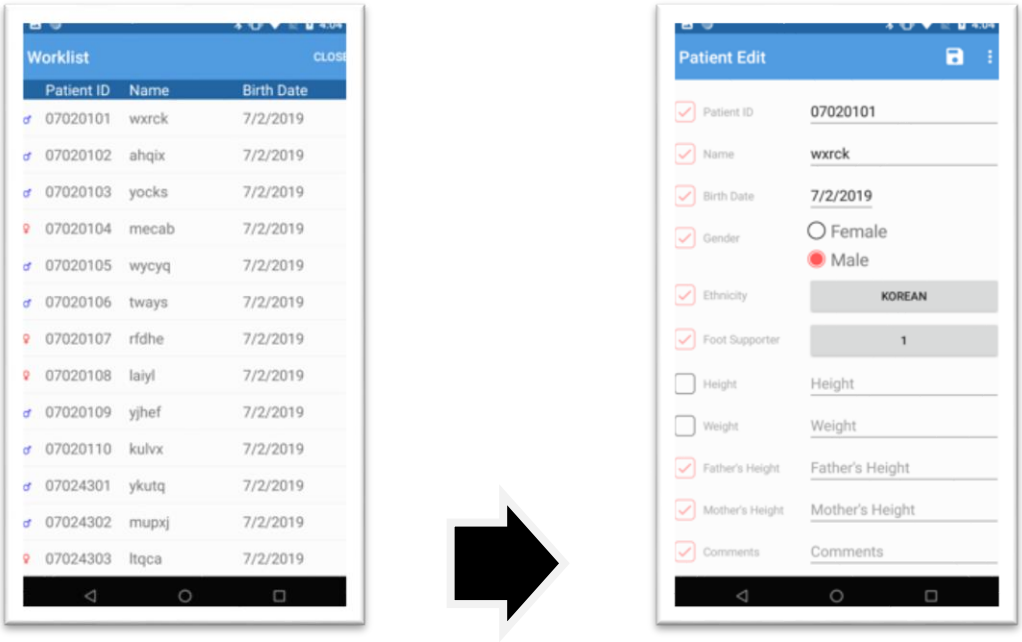
Worklist - Measurement of registered patients

Updating the worklist: If you select the subject you want to measure from the subject list, you will be able to carry out measurements or show patient's medical history.

Worklist - Measurement of unregistered patients

If you select an unregistered patient, you can register the patient.

After registering the patient, select the registered patient and press the <Measurement> tab to start the measurement.



4) Searching patient

If you want to search for a patient, click the <Search> button at the top of the "Patient List" screen and the "Search" window will appear as shown below.

Search requirement

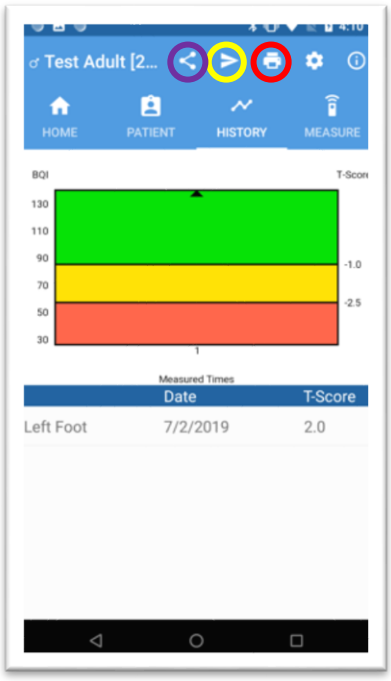
- Year of birth: You can search for patients who were born in a certain year, or for all years.
- Patient ID: You can search for the letters contained in the ID. If you do not enter it, it will find all IDs.
- Name: You can search for the letters contained in the name. If you do not type, all names are searched.
- Gender: You can search only for a specific gender, or for all genders. If you do not select any genders at all, search will not proceed.

When the search is completed, the window shown on the left appears. When a patient is selected, the patient is selected and moved to the patient's "History" screen.

Listing and deleting patient history

1) Listing Patient History

If you want to view the history of the patient, select the patient in the "Patient List" screen and click on the <History> tab at the top. The history of the patient will appear on the "History" screen as shown below.



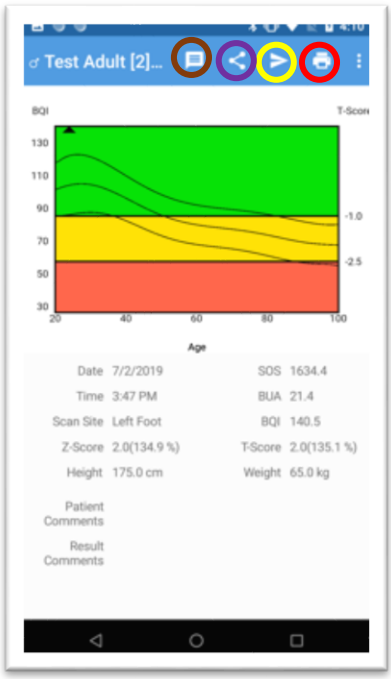
[History Screen]

Press the <Print> button marked with a red circle at the top of the screen to print the results. Pressing the PACS <image transfer> button marked with a yellow circle transfers the results to the Storage server. Press the <Share image> button marked with a purple circle and the results will be shared via email or Bluetooth.

[Using App] - [Printing History/Result]

⚠ **NOTE !**
The History image transfer **DOES NOT** delete measurement data.

2) Detailed Patient History Result



[Detail Result Screen]

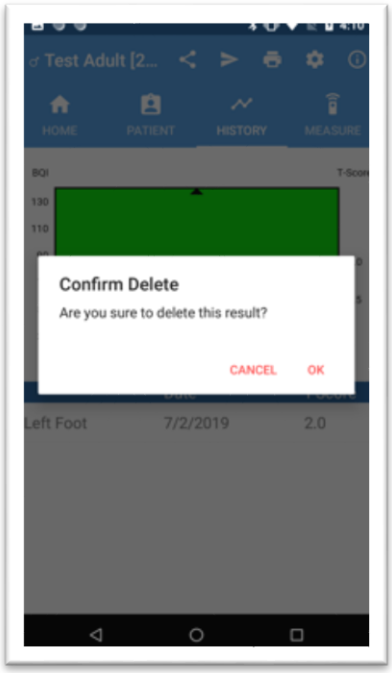
It appears when you select a result from a list on the History screen. Full details of the result selected on the History screen are shown in full screen.

Press the <Print> button marked with a red circle at the top of the screen to print the result. Pressing the PACS <image transfer> button marked with a yellow circle transfers the result to the Storage server. Press the <Share image> button marked with a purple circle and the result will be shared via email or Bluetooth. Press the <result comment> button marked with a brown circle and you can edit result comments.

⚠ NOTE !

If the image transfer is successful, the corresponding measurement data is deleted. If the measurement data are the only measurement data from the patient, the patient information is also deleted.

3) Deleting Patient History Result



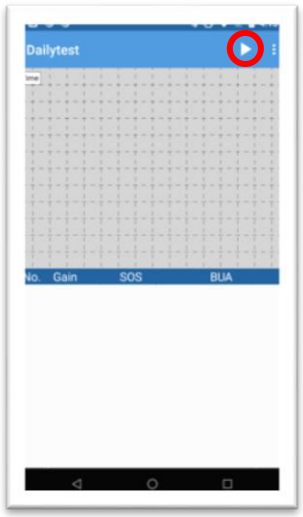
[Deleting patient result Screen]

If you want to delete a patient's history, press and hold the result you want to delete from the list of history screen, the delete button will appear. If you click the Delete button, the following message box will appear asking you whether you want to delete it. If you click the <OK> button, the result you selected from patient history will be deleted.

3.4.12 System check of device (Daily test)

To reduce the error in measuring the patient's bone density and to obtain accurate values, a DailyTest of a system should be performed. This is to increase the reliability of the measurement results by checking the stability of the system on a daily basis.

Touch the icon[D] at the top of the home screen and the measurement window will appear. Clicking the red circled <Start measurement> button to start daily check. If successful, a success message is printed.
Each time you select a graph, the time and frequency graphs are displayed alternately.



[Daily test Screen]

Whenever you calibrate the system, you should use the QC Phantom included in the accessories list.
To check the system, click the <Measurement start> button at the bottom and the ultrasonic wave will start to fire.

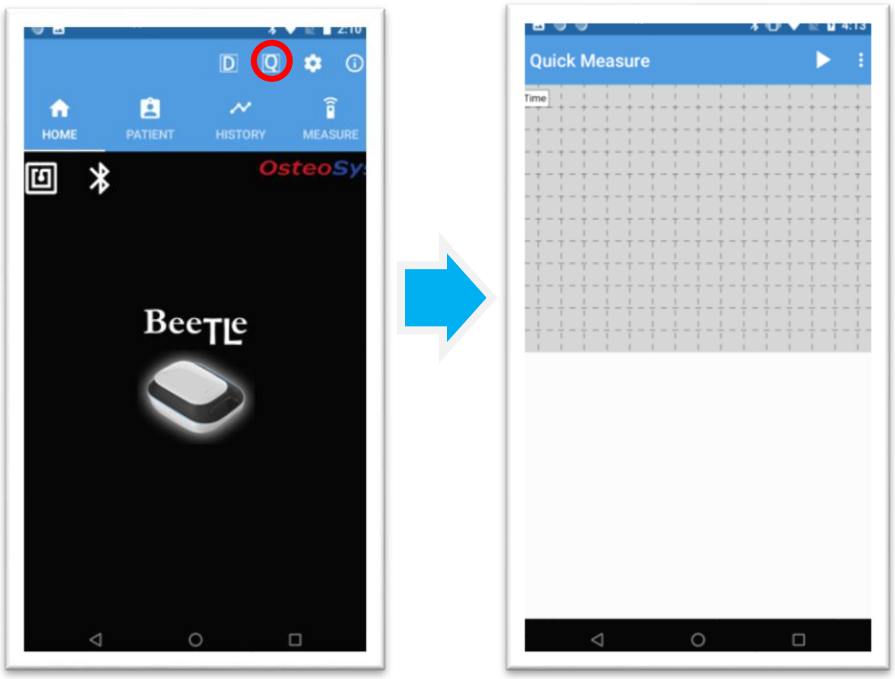
At this time, the <Measurement start> button changes to the <Stop> button. If an emergency occurs during an ultrasonic emission, clicking this button will stop the ultrasonic emission. When the Daily test routine is normally completed, a "Daily test OK" message box will appear. Click the <OK> button to complete the Daily test routine.

⚠ NOTE !

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

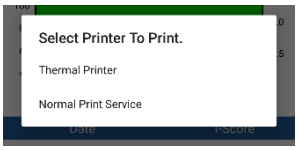
3.4.13 Quick Measure

Touch the icon[Q] at the top of the home screen and the measurement window will appear. The measurement screen will be displayed first. After entering the patient data, the result screen will appear. The value from Quick Measure is not stored.



3.4.14 `Printing History/Result

BeeTLe supports thermal printers and normal printers.



The printer settings can be set in the Setup tab of the Setting Screen. If you have not set the default printer, the printer selection window will appear as shown below. If you select the printer you want to use, the result will be printed. If you set the default printer, it will be prompted to print by a default printer as soon as you press the print button.

[Using App] - [Setting]

Thermal Printer

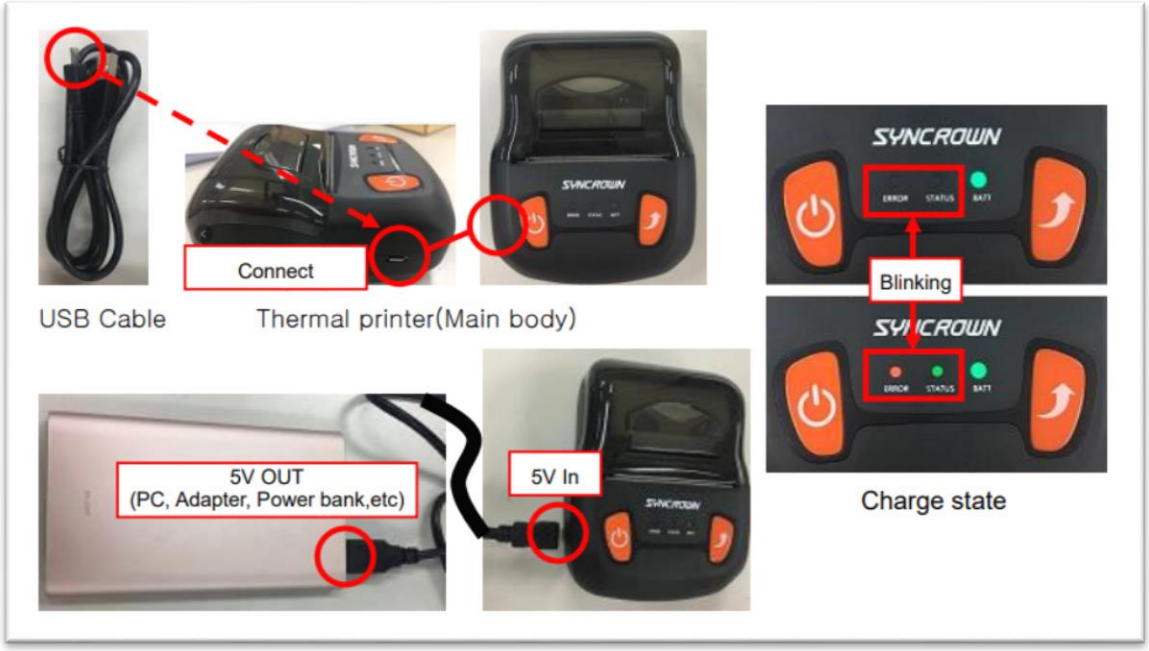
A mobile thermal printer can be purchased separately. Instead of plain paper, thermal printer uses thermal printing paper.

You can use the mobile thermal printer after connecting it through the thermal printer setting in <Settings>. Before printing, make sure that the thermal printer is turned on and set up properly.

How to charge a Thermal printer

Connect printer to USB port or recharger with USB cable.(5V)

When the charging starts, status LED and error will blinking.

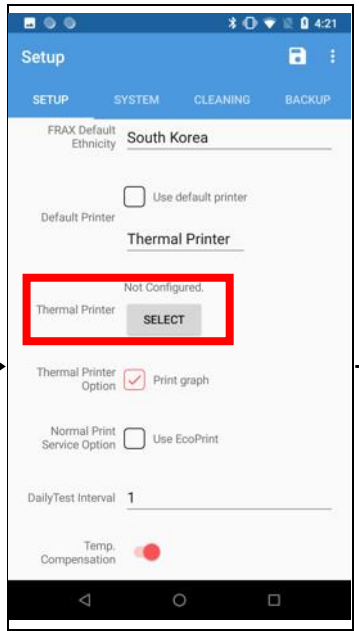


How to connect a Thermal printer

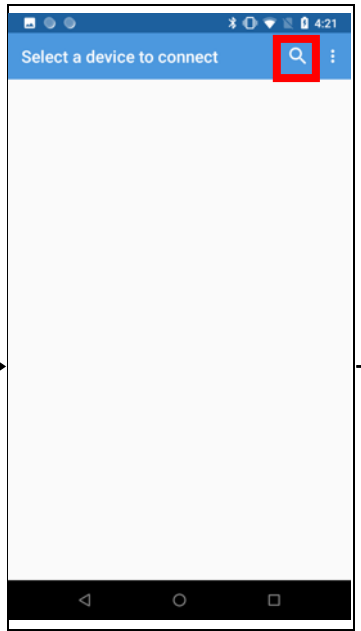
(1) Find the icon [ ]

(2) Touch 'Setting icon'

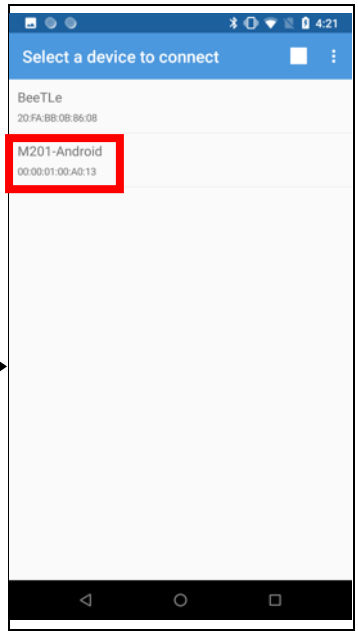
(3) Touch tab SETUP



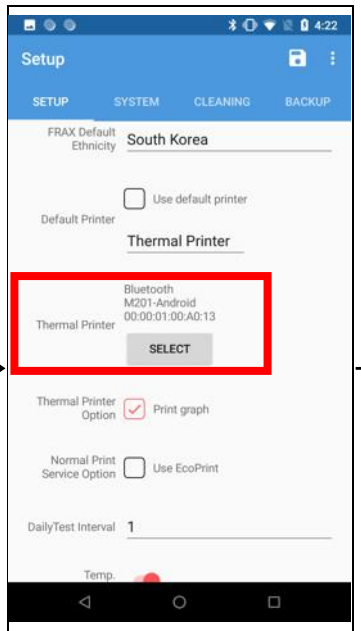
(4) Touch SELECT



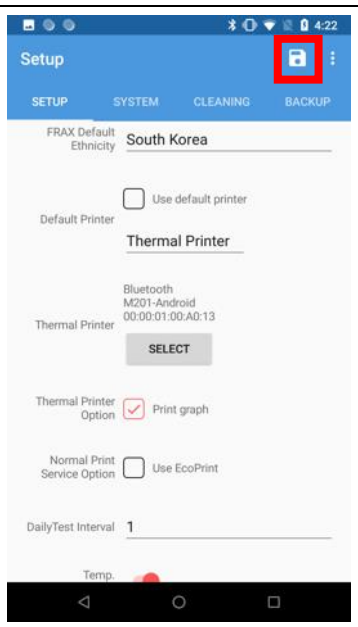
(5) Touch icon [ ]



(6) Touch 'M201-Android'.
In iOS, Touch 'M201-iOS'.

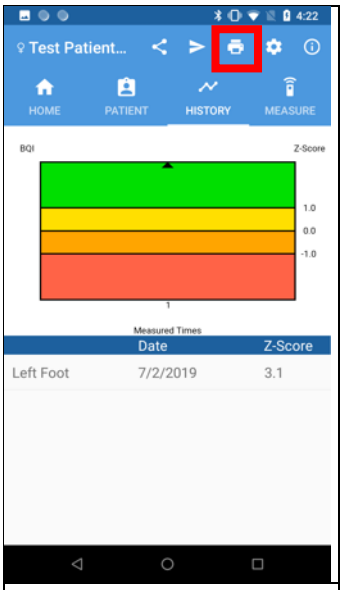


(7) Registered thermal printer

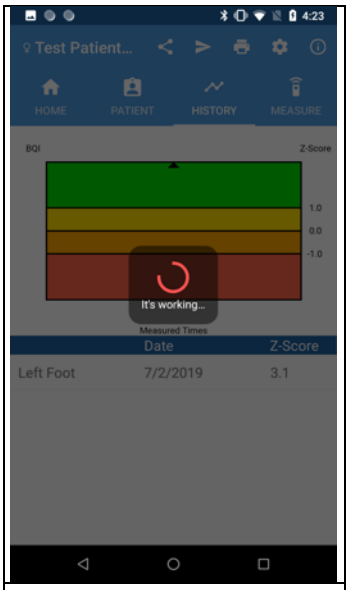


(8). Touch save icon[ ]

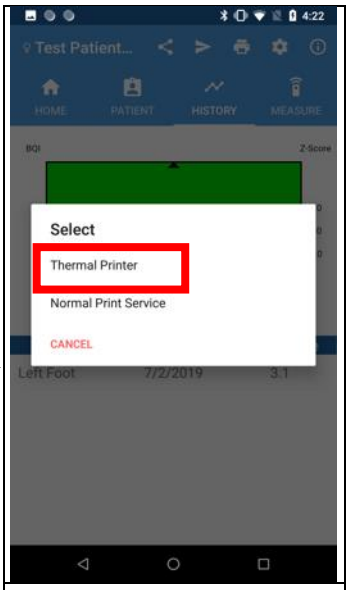
Thermal printer output method.



(1) Touch the print icon [ ] on the result screen.

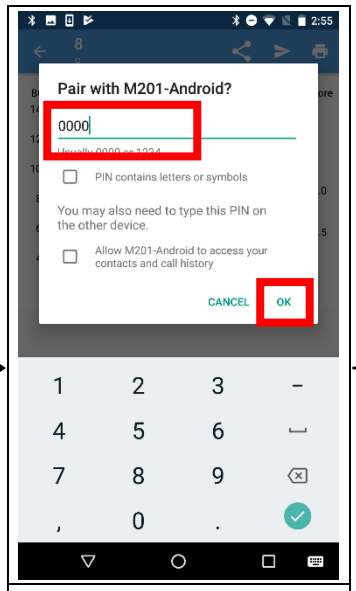


(2) If you set it as the def -ault printer, it prints imme -diately.

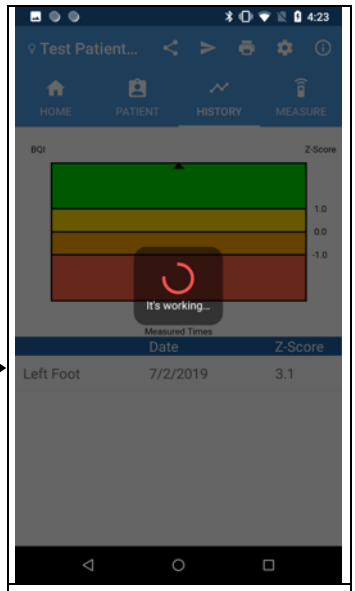


(3) When the selection window appears, select the thermal printer

Thermal Printer Result (ex, Graph print off mode)



(4) When the pairing window appears, enter '0000' and touch [OK].



(5) Output printer.

Printed Date : Nov 1, 2017

Hospital Name 001

== Patient's Info ==========
Patient ID : T01
Name : Test Patient
Date of Birth : Dec 22, 1990
Sex : Male
Ethnicity : Korean
Height(cm) : 180.0 (cm)
Weight(kg) : 80.0 (kg)
Reg. Date : Dec 27, 2016
Foot Supporter : 1

== History ==========

Left Foot

No.	Date	BQI	T-score
4	Jul 7, 2017	163.0	3.2
3	Dec 27, 2016	24.6	-4.3
2	Dec 22, 2016	153.4	2.6
1	Dec 22, 2016	152.5	2.6

Right Foot

No.	Date	BQI	T-score

== Comment ==========

Print of History

Printed Date : Nov 1, 2017

Hospital Name 001

== Patient's Info ==========
Patient ID : T01
Name : Test Patient
Date of Birth : Dec 22, 1990
Sex : Male
Ethnicity : Korean
Height(cm) : 180.0 (cm)
Weight(kg) : 80.0 (kg)
Reg. Date : Dec 27, 2016
Foot Supporter : 1

== Result ==========

Normal

Scan Date : Dec 22, 2016
Scan Time : 9:52 PM
Scan Site : Left Foot

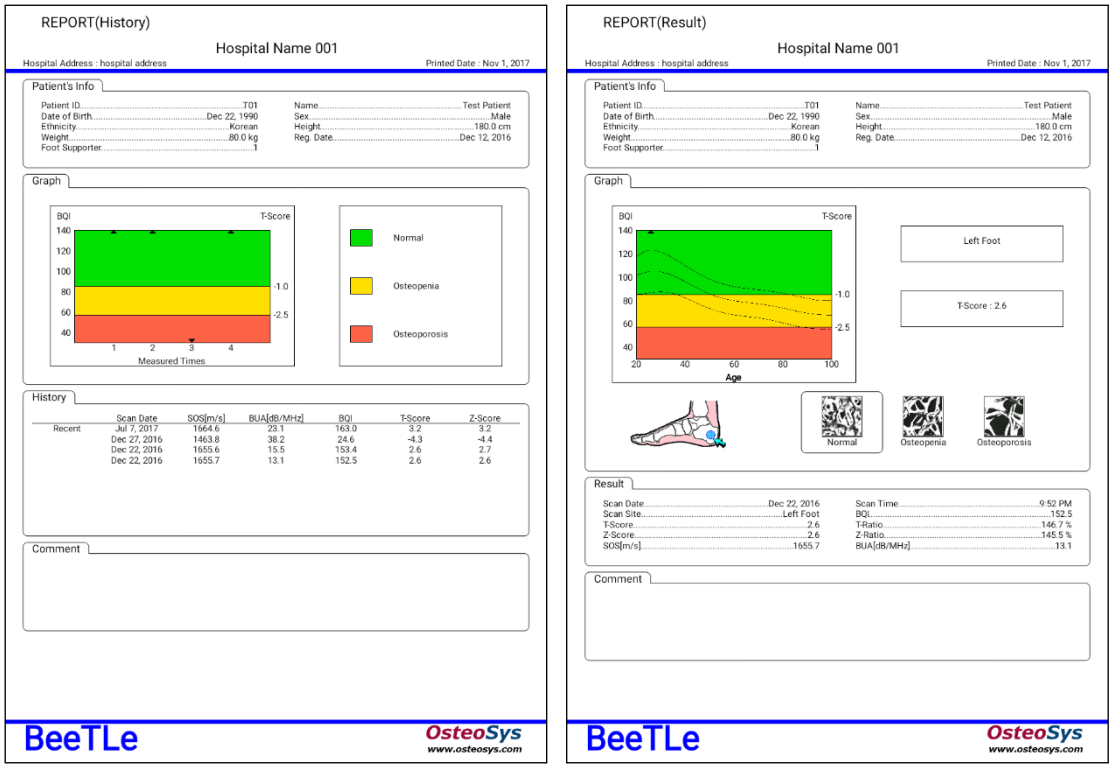
BQI : 152.5
T-Score : 2.6 (146.7 %)
Z-Score : 2.6 (145.5 %)
SOS[m/s] : 1655.7
BUA[dB/MHz] : 13.1

== Comment ==========

Print of Detail

Normal Printer

Before using a regular printer, make sure that the printer service you want to print is installed on smart device. To use regular printer output, the printer service for that printer must be installed on smart device. Please check with your printer manufacturer for installation information.



Normal Printer Result

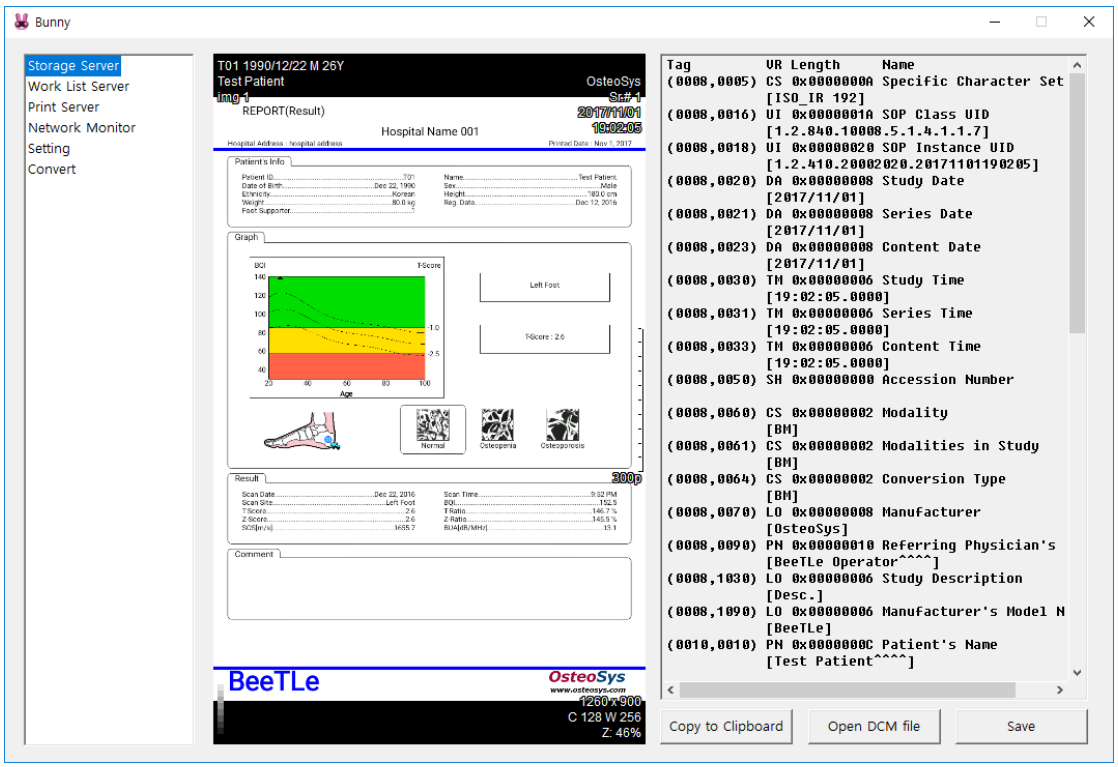
Share Image

The image sharing feature uses App standard features to send report images through apps that share images. The transfer image is the same as the normal printer result above.

PACS image transfer

The PACS image transfer function can be used after setting in the system tab of Setting.
Pressing the PACS image transfer button will send the report image to the Storage server.

PACS image transfer result



Standby(waiting) mode	Power save mode

Open the cover

Close the cover
(in power button ON state)

Battery check

You can check the remaining amount of batteries through the BeeTLe app.

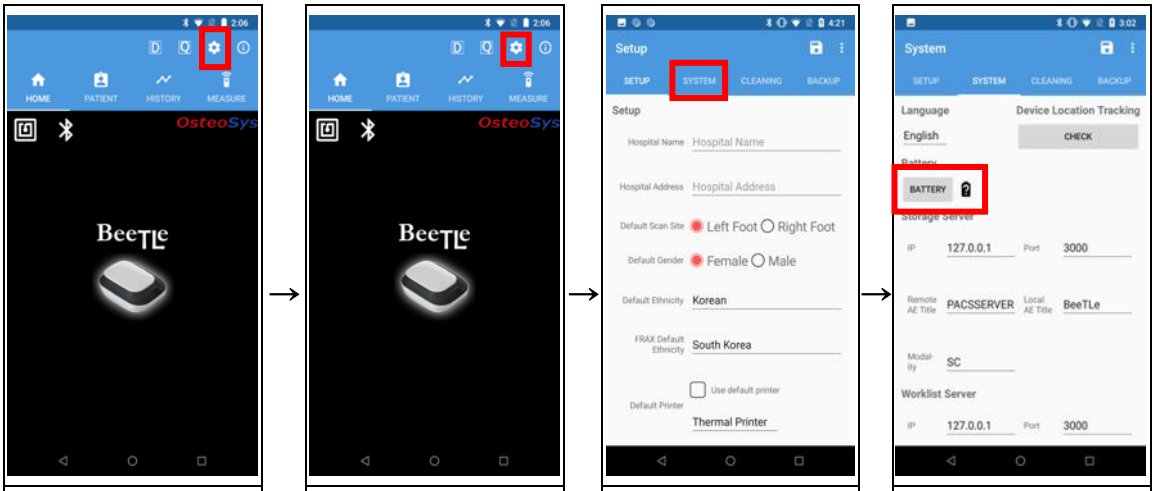
(1) How to check on the System tab. (Check with touch to battery button.)

⚠ NOTE !
You can check the remaining battery charge only when BeeTLe is connected to Bluetooth.

Battery markings and the meaning of each shape are as follows.

Markings					
Meaning	Unknown (Unchecked status)	100%	<75%	<50%	<25% (Charge required)

(1) How to check on the System tab (Check with touch to battery button)



(1) Find the Setting Icon | (2) Touch 'Setting Icon' | (3) Touch tab 'SYSTEM' | (4) Touch 'BATTERY' button

3.4.15 Setting of the incipient environment

Language : The language can be changed in the language settings.

NOTE !
Contact Osteosys or its authorized dealer if you need to make changes or select your language using language option.

Chapter 4. Maintenance and Repair of BeeTLe

4

4.1 Resolution to Problems

If BeeTLe shows following symptoms, check the system as follows.

Problems	Checking Points
BeeTLe is not activated with the power on.	Is the battery fully charged?
	Isn't the AC adapter damaged?
	Is the AC adapter properly connected?
Result of calibration of the system turns out to be abnormal	3.1 Daily Test
Result of measurement turns out to be abnormal	3.1 Daily Test 3.3 Using H/W
Despite measurement according to the instructions, its result turns out to be abnormal	Is the desired part of the body properly placed? 24~25 page : Where and How Much Apply to the Patient's Heel

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	The device should be cleaned with clean soft cloth wrung a water every day, 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 Storage

Daily Storage	Unplug the AC adapter. If the hardened gel remains in the device, it can affect BMD results. Please clean the device every day.  4.2 Maintenance and Repair
Storage for a long time period	Unplug the AC adapter. Press the power button to completely shut down the device if the device is not in power saving mode. Put cover on the product to avoid dust.

4.3 Safe Use of BeeTLe

4.3.1 Safety Rules

The followings are instructions for safe use of the device.
Make sure to comply with the instructions when you activate the system.

4.3.2 Cautions Related to Use Electronic Medical Equipment

 **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 consistent equipotential bonding. Medical device needs to be connected with connecting leads made up with angle sockets to the equipotential bonding network in medical rooms.
 **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 devices. If you share the outlet it will affect the device. Read user's manual carefully before using the device. Place the user's manual at a designated place so that users can read it whenever necessary.

	If you hear a strange noise or if you find any abnormality on the screen after turning on the device, contact OsteoSys or an authorized distributor. If damage is visible on the exterior, do not operate and contact OsteoSys or an authorized distributor. Make sure to turn off the power switch before cleaning the device. Make sure to use the device to intact skins only. Do not use the device for subjects on their foot or heel with breached skin, open sores, bleeding.

Chapter 5. Specifications & S/W Update

5.1 Specifications

Grade and type		Internal Power, Class II, Type B
Input voltage		AC 100-240 V, Free Voltage(Single Phase), 50 Hz/60 Hz
Max power consumption		25VA
Product Dimension (Unit: mm)		250(W) × 145(D) × 337(H) (Calf supporter folded)
Product weight		3.9 kg
Display		None
Software version		1.0.10
Firmware version		1.0
Ultrasound gel		Ultrasonic gel must be biocompatibility guaranteed for ISO 10993-5(Cytoxicity), ISO 10993-10(Skin sensitization) and ISO 10993-23(Skin irritation) tests.
Performance	Reproducibility	0 ≤ SOS cv ≤ 1% 0 ≤ BUA cv ≤ 2 %
Transducer (Ultrasonic probe)	Center frequency	0.5 MHz ± 10%
	Bandwidth	> 30%
	Diameter	Ø 25.00 mm
	Focus type	Flat

Bluetooth

Manufacturer	IOT747
Model name	IDC747
Standard	Bluetooth 5.2 Class2
Frequency used and data rate	2.4GHz / 3Mbps (typical 1.6Mbps)
Sensitivity	0.1% BER at -96dBm (Typical)
Operating voltage	3.3V ~ 4.7V DC
Dimensions	11.8mm x 18mm x 3.2mm
Weight	1.1g

Adapter

Manufacturer	Meanwell
Input voltage	AC 100-240 V, Free Voltage(Single Phase), 50 Hz/60 Hz
Output	5 Vdc, 6.0 A

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

5.2 Environmental

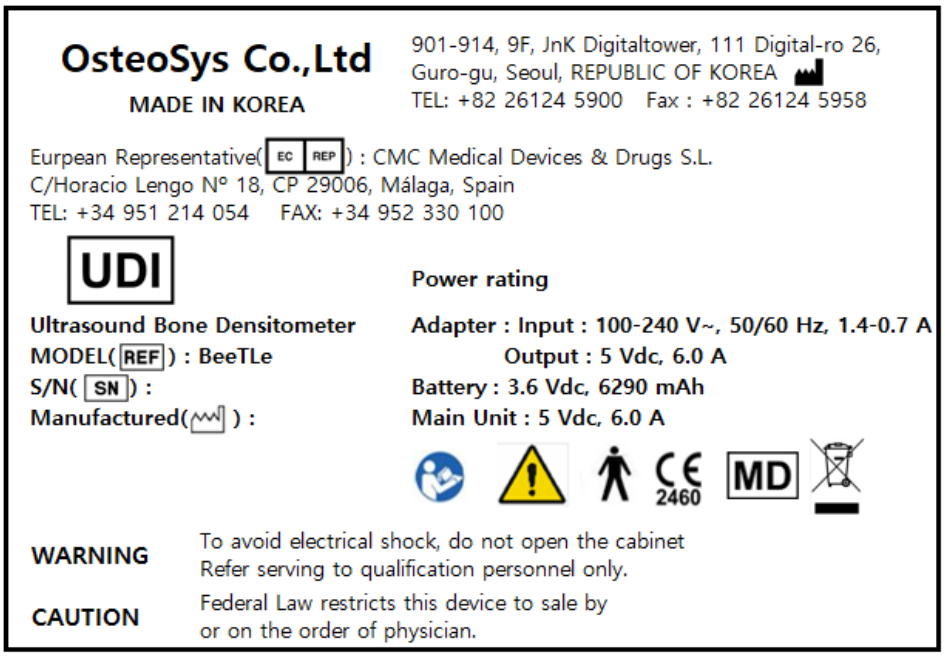
Operating Temperature	10 ~ 35℃
Transport / Storage Temperature	-20 ~ 50℃
Operating Humidity	30 ~ 75% relative humidity
Transport / Storage Humidity	0 ~ 90% relative humidity, non-condensing
Atmosphere	700 ~ 1060 hPa
Shock	Not to exceed 2G in six millisecond
Dust, Fumes, Airborne debris	Install system in a clean, well-ventilated area. Excessive dust and other airborne debris contaminants can impair sensitive parts.

5.3 S/W Update

Updates to BeeTLe software are irregular

For software update, please contact your Osteosys office or an authorized distributor.

5.4 Label


OsteoSys Co.,Ltd
MADE IN KOREA
901-914, 9F, JnK Digitaltower, 111 Digital-ro 26,
Guro-gu, Seoul, REPUBLIC OF KOREA
TEL: +82 26124 5900 Fax : +82 26124 5958
Eurpean Representative(EC REP) : CMC Medical Devices & Drugs S.L.
C/Horacio Lengo N° 18, CP 29006, Málaga, Spain
TEL: +34 951 214 054 FAX: +34 952 330 100
UDI
Power rating
Ultrasound Bone Densitometer
MODEL(REF) : BeeTLe
S/N(SN) :
Manufactured( ) :
Adapter : Input : 100-240 V~, 50/60 Hz, 1.4-0.7 A
Output : 5 Vdc, 6.0 A
Battery : 3.6 Vdc, 6290 mAh
Main Unit : 5 Vdc, 6.0 A
CE 2460
MD
WARNING
To avoid electrical shock, do not open the cabinet
Refer serving to qualification personnel only.
CAUTION
Federal Law restricts this device to sale by
or on the order of physician.

Chapter 6. Reference

6.1 Definition of Parameter Terminology

- **BUA(Broadband Ultrasound Attenuation)**

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

- **SOS(Speed Of Sound)**

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

- **BQI(Bone Quality Index)**

BQI = α x SOS + β x BUA

Generally, SOS is in proportion to the temperature, and BUA is in inverse proportion to the temperature. The correlation coefficients are (α, β) combined as shown below. These coefficients compensate the precision error from the temperature.

- **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

-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.

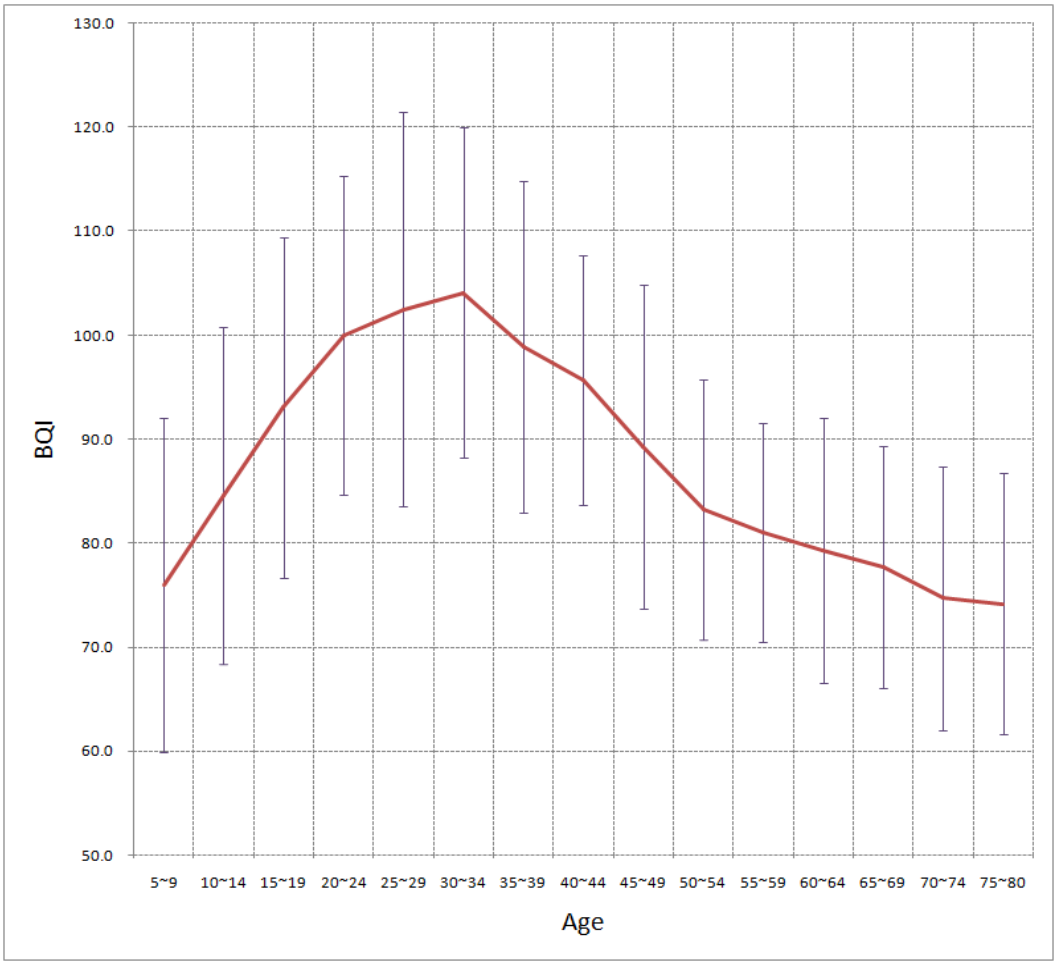
4) TOF(Time Of Flight) : Elapsed time of ultrasonic signal from transmission to reception. It is used for SOS calculation.

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

Chapter 7. Product Warranty

● Scope and Period of Warranty

- All OsteoSys products can benefit from free warranty repair for failure and defects caused in normal transportation/operation environment for 1 year from the purchase
- For the following cases, a certain amount of service fee will be billed
(1) Product failure after warranty period
(2) Failure due to natural disasters including fire, earthquake, lightning, flood, etc.
(3) Failure due to inappropriate moving or negligence in use
(4) Failure due to service provided by other than OsteoSys, agencies not designated by OsteoSys and engineers or persons not approved by OsteoSys
- Any defects or damage to the product that are not related to the main functions of this product are not eligible for free repair.

● Necessary for repair

- If the product is out of order, stop using it and read the manual carefully
- 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.
- Defective equipment shipped from you to OsteoSys Co., Ltd. must be packed in the replacement cartons.
- If you request the product information to repair the defective product yourself, OsteoSys provides you with the proper information.

Chapter 8. Security

SEC.1. Introduction

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

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

SEC.2. Security features

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

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

SEC.3. Access control

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

- Access subject
- How to secure access
- When to grant access
- Access information

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

- A person who accesses a smartphone
- Resources for which the user is authorized to use on the smartphone

NOTE !
Without any configuration, every user uses this device needs to be authorized.

SEC.4. Audit Control

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

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

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

SEC.5. Certification

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

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

SEC.6. Password management

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

Password	Recommended use pattern	Contents
minimum length	4-16 characters	Short passwords are easy to remember, but are easily at risk. Long passwords are secure, but easy to forget or write down. Long passwords increase resistance to brute force attacks.
Expires	30 – 360 days	When the expiration date comes, the user must change their password regularly. A common rule of expiration period is to balance the length of the expiration authority with the password so that it expires before the password is cracked.
Character composition	You must mix uppercase and lowercase letters, numbers, and special characters.	This is a set of attributes used to increase the number of possible password combinations, prevent dictionary attacks, and mitigate brute force attacks. It also makes password guessing difficult.

Password reuse	Do not reuse password	To avoid password prediction, you should not use previously used passwords.
Incremental password	Disable Incremental Passwords	Users should avoid creating passwords that are not significantly different from their previous passwords, such as password1, password2 and password3 or trick, track and truck.

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

SEC.7. Permission

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

SEC.8. Malicious Software Protection

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

SEC.9. Customer's Responsibilities

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

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

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

SEC.10. Product features

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

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

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

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

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

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

Information security requirements should also consider:

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

And OsteoSys provides Cyber security product upgrades.

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

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

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

SEC.12. Software and Application Hardening

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

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

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

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

SEC.13. Unauthorized network access

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

SEC.14. Virus protection software

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

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

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

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

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

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

SEC.15. System security

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

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

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

SEC.16. Data protection

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

SEC.17. HEALTH DATA Integrity and Authenticity

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

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

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

SEC.18. HEALTH DATA Storage and Confidentiality

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

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

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

SEC.19. Security operations

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

SEC.20. Health Data De-Identification

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

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

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

SEC.21. Network security

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

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

SEC.22. Business continuity

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

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

SEC.23. Data Backup and Disaster Recovery

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

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

SEC.24. Media access control point

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

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

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

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

SEC.25. Remote service

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

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

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

SEC.26. Network Interface Specification and Risk Management

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

• DICOM connection to other DICOM devices

• Remote service connection via TeamViewer

SEC.27. Network Interface Technical Specification

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

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

SEC.28. Network information flow

Flow name	DICOM connection
Device network connection	Motherboard NIC
Type of use, function, purpose	Connection to other DICOM devices
Optional / required	options
Communication server	PACS, RIS
Intermediate protocol	TCP

Application protocol and encoding	DICOM
Traffic Characteristics and Bandwidth Requirements	On demand, the local user receives the DICOM Worklist query results from RIS, performs the checks, and sends the report to PACS.

SEC.29. Transmission Integrity

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

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

SEC.30. Required Characteristics

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

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

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

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

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