EXCELLUS

User Manual

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OsteoSys

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OsteoSys Co., Ltd.

EXCELLUS

User Manual

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1 General Use

1.1 Guidance of Manual

1) Marking

Guidance of Manual is written and organized as follows:

- Order, marking signs/symbols and icons.

Description of a process follows alphabetical order.

a. No. 1 in description
b. No. 2 in description
c. No. 3 in description

Examples to explain about Manual will be in boxes marked with 'Example)'.

Example)

a. Have a patient on the bed of the measuring equipment. b. Check whether the site to be measured is within the measuring range and locate the site correctly. c. Select Yes/No in the window of User program asking, 'Do you want to move to the default position?'.

Additional explanation will be in single quotation marks (") to add supplementary information.

Information and symbols for attention on description or important issues in Manual:

 : Warning sign

 : Mark of prohibition

 : Mark of obligation

 : Caution in using the equipment

 : Description in using the equipment

 : Pages for reference

2) Labels

Label 1.

'CAUTION! 'Label for laser radiation

- Eyes can be damaged when staring at the laser in the front without any protective gear when the laser is ON.

Label 2.

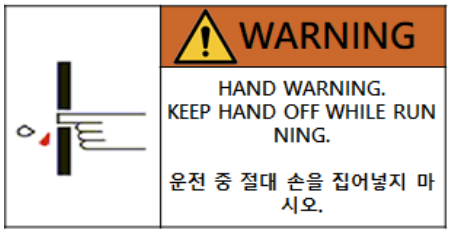
'CAUTION 'Label for high voltage

- A user can be exposed to the danger of high voltage equipment.

Label 3.

'WARNING 'Label for movement of the equipment

It can cause accidents when fingers are stuck in between the moving measuring ARM and the patient's table.



3) Symbols

: X-ray ON

It indicates the X-ray is turned ON. It displays in the controller of the equipment and the display monitor when measuring a patient or conducting a daily test.

: X-ray OFF

It indicates that the X-ray is turned OFF. It displays in the monitor screen when the equipment is on standby for measuring or finished measuring.

: X-ray radiation

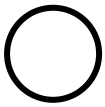
It indicates X-ray is radiated; it could be dangerous for patients and users when exposed to a large amount of radiation.

: Pointer

It displays the danger of laser pointers.

: Power ON

It indicates the power is ON. (Power ON)



: Power OFF

It indicates the power is OFF. (Power OFF)

: Start

It indicates X-ray is being ready.

: Communication Status

It indicates the communication status of the equipment.

: Caution

It indicates safety caution or referring to User Manual is needed.

: Equipotential grounding

It indicates equipotential circuit which should be connected to earth of the doctor's office and the equipment.

: Date of manufacturing

 : Protecting the equipment from external electromagnetic waves

 : Disuse of the equipment

 : European Conformity

 : Manufacturer

 : Serial Number

 : Authorized representative in the EUROPEAN COMMUNITY

 : TYPE B APPLIED PART

 : Refer to manual

1.2 How to use the product

A user should learn knowledge about the equipment and how to use it properly. Please read Manual carefully before Operation of the equipment.

Be aware of the 'caution' symbols for cautions or warnings.

 The person who installs/uses the equipment is responsible for operation of the equipment according to the related regulations of the location in which the equipment is installed and used.

A user should be properly trained in using the equipment properly and fully understand the procedure of using the equipment by reading/studying Manual on a regular/irregular basis.

It is recommended that a user continuously practices using the equipment and takes simulation sessions for emergency situations.

 The communication can be automatically stopped depending on the network card of the laptop manufacturer when using a laptop. When using a separately purchased desktop, communication can be interrupted depending on the integrated board network card; therefore, buy a separate LAN card designated by the company and connect it to the equipment.

1.3 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 18℃ ~ 27℃
- Working Humidity : Within 20~ 80%
- Air Pressure : Within 800 ~ 1060hPa

2) Protection against Radiation

To prevent users or patients from contracting diseases due to excessive exposure to X-ray, the following protective measures should be taken.

- Refrain from generating unnecessary X-ray, and perform measurements only when required for clinical purposes.
- Evacuate all non-essential personnel – other than the operator and patient - when performing measurement.
- Personnel performing measurement in the measurement room should wear protective clothing, gloves and goggle (if required), to minimize exposure to X-ray.
- To avoid scatter radiation, the operator should remain at least 1 meter away from the center of the scanner.

3) Pre-operation Checklist

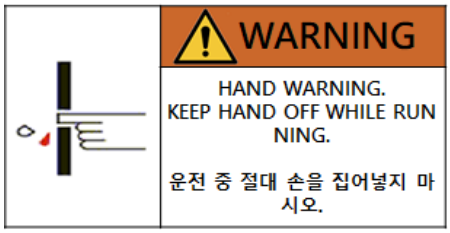
- Check the switch connection and polarity indicator status, and verify the device works properly.
- Check all cable connections for their accuracy and safety.
- Double-check the areas that make direct contact with the patient.
- The patient must wear socks and gloves to prevent the patient skin from directly touching the device
- 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.
- Be aware that patients with sensitive skin may experience biocompatible reactions.

4) Cautions for Storage

- Do not apply excessive force when connecting or disconnecting cables.
- Auxiliary devices should be maintained clean, in working conditions.
- Devices should be positioned in their proper positions, so as not to interfere with worker or patient movement.

5) Warning Indication

When the device performs measurement on the patient, the scanner arm moves left and right to scan the patient. During this process, the patient's hand may be caught between the scanner arm and the table, causing injury. For this reason, the following indication is attached to the said arm.



6) Cautions regarding specific age group, gender and physical conditions

This device measures bone density and mineral content by projecting X-ray through bones or adjacent tissues. Using this device, the doctor performs measurement on people of the age group and gender who the doctor regards as requiring osteoporosis diagnosis.

Since this device uses X-ray and thus may affect fetuses, it should not be used on pregnant women.

In addition, patients deemed as having physical conditions unsuitable for use of this device by a specialist must consult a specialist before use of this device.

7) 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.

8) Cautions regarding possible side effects and accidents caused by negligent use of the device.

This device uses X-ray, and its excessive use may cause side effects. Therefore, all personnel using the device must comply with all regulations regarding radiation safety.

Since this device uses laser pointer to set scanner position for measurement, the laser beam from the pointer may damage the patient's sight when looked at directly. To prevent such injury, the following indication is attached to the device.

This device uses high voltage. Therefore, the following high-voltage indication is attached to the device.

9) Continuous irradiation of pulse-type X-ray on implantable cardiac pacemaker or implantable defibrillator may cause device malfunction. Avoid direct X-ray irradiation on X-ray implantable cardiac pacemaker or implantable defibrillator, and limit X-ray output to a minimum.

1.4 Software

User programs and the application programs for using the device are protected by the copyrights.

Only users approved by OsteoSys are authorized to use the company's software.

Warning

-The company is not responsible for any injuries/damages due to the equipment caused by those who are not authorized to use the software/programs and use the software or manipulate/modify/illegally change the programs without the company's permission.

1.5 Protecting personal data

Patients' personal information and measurements should be protected by the related regulations/laws.

1.6 Installing and driving the equipment

Installation and changing the installation location should be based on the related regulations/laws.

OsteoSys and the manufacturer/sellers/installers/importers are not responsible for any abnormal operation or measurement issues of the equipment.

* When the equipment was not used as Manual instructs.
* When a person who was not authorized by the company conducted software installation, upgrade, modification or A/S.
* When the parts that affect safety of the equipment are not the genuine items for the company services.
* When the equipment was used in a location that does not follow the installation/operation standards for the equipment.

1.7 Maintenance

For safety of the user/operator, patients and a third party, inspection/maintenance/ repair of the equipment and regular inspection on the safety devices/equipment are recommended.

You can find information on inspection and maintenance of the equipment in 'Contents' of Manual in using the equipment. Regular inspection and maintenance are recommended.

When service is needed, contact OsteoSys AS team or an authorized local dealer in your area.
Osteosys A/S department contact number: +82-2-6124-5900

According to the related regulations/law, specific inspection that requires regular inspection may be added.

1.8 Protecting the equipment from external electromagnetic waves

This equipment's measurement 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.

1.9 Disuse of the equipment(NOTE)

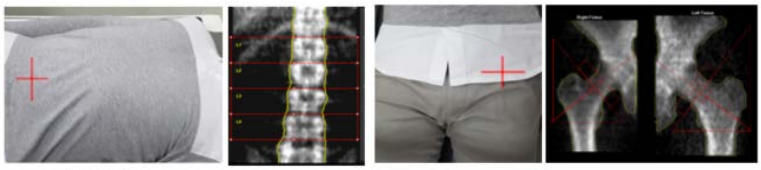
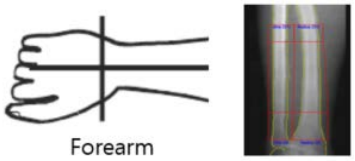
This symbol marked in the equipment manual or on the packaging indicates the equipment should not be handled as household waste. To dispose the equipment, send the electric/electronic equipment or electric medical devices to waste collecting locations for recycling. Proper disposal of the equipment prevents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

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

1.10 Guidance and manufacturer's declaration

Clinical information			
No	**Contents**	**A or N/A**	**Description**
1	Intended Use	A	The EXCELLUS 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 are the spine, femur, and forearm.
2	Name of Disease or Condition	A	Osteoporosis, Osteopenia, Normal healthy bone
3	Indications	A	Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, and Forearm). 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 DXA.

				Possibly of limited value or require modification of the technique or rescheduling of the examination in some situations, including: - Recently administered gastrointestinal contrast or radionuclides; - Pregnancy; - Severe degenerative changes or fracture deformity in the measurements area; The patient's inability to attain correct position and/or remain motionless for the measurement. Extremes of high or low body mass index (BMI) which may adversely affect the ability to obtain accurate and precise measurements. Quantitative computed tomography (QCT) may be a desirable alternative in these individuals.
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 radiologist and etc. (Patient does not operate the BMD device)
		Patient	A	a) Ages: 20 – 100 years old. b) The patient condition: Osteoporosis, Osteopenia or Normal healthy bone
6	Disposable device		N/A	No disposable component or accessory.
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		N/A	BMD measurement is performed once a year or once every two years (it's depending on the patient's situation). In general, there are no contact area when a patient has worn patient's uniform. However, when a patient wearing short pants or a shirt without wearing a patient's uniform, some part of skin may contact with the bed leather of BMD device.

10	Contacting with body fluids or others	N/A	There are no contact between any organ or tissue or body fluid of human body with BMD device during the examination process.
11	Measurement site	A	According to ISCD official positions (in 2019) / 2019-Official-Positions-Adult-1.pdf (iscd.org) the anatomic sites commonly measured in clinical practice are spine and proximal femur(s). and here is more detailed below. Skeletal sites to measure: *Measure BMD at both the AP spine and hip(femur) in all patients  AP Spine Femur *Forearm BMD should be measured under the following circumstances: -Hip and/or spine cannot be measured or interpreted -Hyperparathyroidism -Very obese patients(over the weight limit for DXA table)  Forearm The measurement sites in EXCELLUS are the spine, femur and forearm.

Guidance and manufacturer's declaration – electromagnetic emissions		
EXCELLUS is intended for use in the electromagnetic environment specified below. The customer or the user of EXCELLUS should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	EXCELLUS uses RF energy only for its internal functions. Therefore, its RF emissions are very low+ and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	EXCELLUS is suitable for use in all establishments including domestic and those directly connected

Harmonic emissions IEC 61000-3-2	Class A	to the public low-voltage power supply network for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Note : EXCELLUS with radiation protection in accordance with IEC 60601-1-3:2008, where EXCELLUS represents the object (X-ray equipment) for which complicance is to be stated.		

Guidance and manufacturer's declaration – electromagnetic immunity			
EXCELLUS is intended for use in the electromagnetic environment specified below. The customer or the user of EXCELLUS should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 60601-4-11	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cyclesa 0% U_T (100% dip in U_T) for 250/300 cyclesa	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cyclesa 0% U_T (100% dip in U_T) for 250/300 cyclesa	Main power quality should be that of a typical commercial or hospital environment. If the user of EXCELLUS requires continued operation during power mains interruptions, it is recommended that EXCELLUS be powered from an uninterruptible power supply or battery.

Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note : *U*T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
EXCELLUS is intended for use in the electromagnetic environment specified below. The customer or the user of EXCELLUS should assure that it is used in such an environment.			
Immunityt est	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz Outside ISM Bandsc amateur radio bands Bandsd 6 Vrms 150 kHz – 80 MHz In ISM bandsc amateur radio bands Bandsd	3 Vrms 6Vrms, 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of EXCELLUS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2√P d=1.2√P 80MHz to 800MHz d=2.3√P 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment

Radiated RF IEC61000-4-3	3 V/m 80MHz to 2.7 GHz 10 V/m Home Health	3 V/m 80MHz to 2.7 GHz	marked with the following symbol: 

Note 1 At 80MHz and 800MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy

b assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HGN1 is used exceeds the applicable RF compliance level above, the HGN1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HGN1b

When the frequency range exceeds 150 kHz – 80 MHz, the electric field strength should be not higher than 3 V/m.

c The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to6.795MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

d The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Guidance and manufacturer's declaration - electromagnetic immunity					
The HGN1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30cm (12 inches) to any part of the HGN1. Otherwise, degradation of the performance of this equipment could result.					
Immunity test	Band [a]	Service [a]	Modulation	IEC 60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28V/m
	1700 – 1990 MHz	GSM 1800 CDMA1900 GSM 1900 DECT LTE Band 1,2,4,25 UMTS	Pulse modulation 217 Hz	28 V/m	28V/m
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450	Pulse modulation 217 Hz	28V/m	28V/m

		LTE Band 7			
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m
NOTE : If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.					
For some services, only the uplink frequences are included. The carrier shall be modulated using a 50% duty cycle square wave signal. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.					

2 Safety and handling problems

2.1 Operating the equipment

EXCELLUS is equipment that generates X-ray and measures patient's spine and the femur region by motor-driven movement. A caution is needed for safety of patients/users regarding motor-driven movement.

 Understand fully how to operate the equipment.

- It is not safe for a user/patient to lean against the equipment ARM or touch the moving equipment when the equipment is on standby or measuring mode.

- Patients must not stand up when measuring.

- With the power ON, the equipment moves to the initial position automatically; do not go near the moving ARM when the power is turned ON from OFF.

- When the equipment is ON, press the Emergency Switch for an abnormal movement or noise, and contact an authorized dealer or OsteoSys AS team.

- When power is applied to the equipment, check whether the software is installed by turning on the power LED. If not, contact the manufacturer.

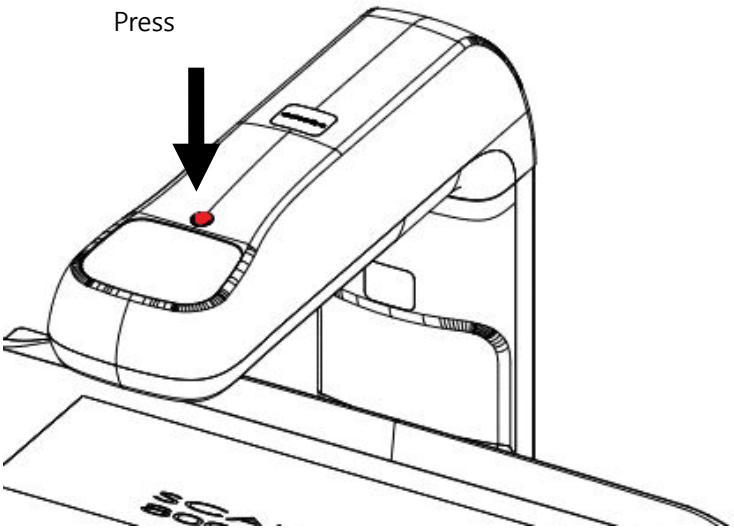
- Check the location of the emergency switch in case of an emergency.

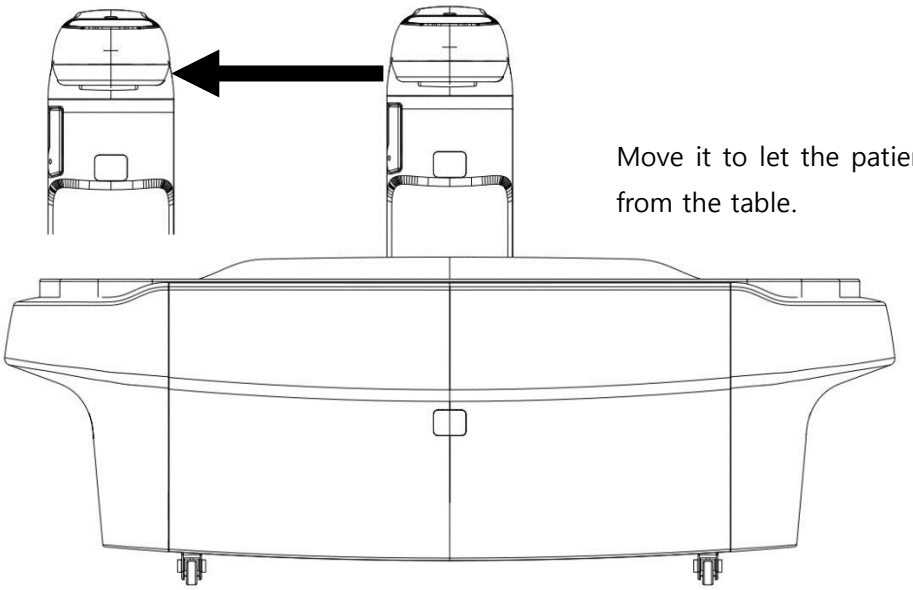
- If the plug is incorrectly connected, check the fuse condition. If the fuse is burnt out, contact OsteoSys AS team.

2.2 Using the emergency switch

Follow the procedure below when using the emergency switch due to unexpected situations.

a. Press the emergency switch when emergency or abnormal movement of the equipment.
b. Push the arm in one direction to let the patient come down from the table.
c. Let the patient come down from the equipment, turn the main switch OFF.
d. Press the emergency switch again to return to the initial status.
e. Perform any necessary actions and turn the main switch ON.
f. Check the equipment's movement.





Move it to let the patient come down from the table.

2.3 Stopping the equipment in case of emergency evacuation

Follow the procedure below for evacuation when there is fire in the building or natural disasters.

a. Press the emergency switch and push the arm in one direction to evacuate the patient.
b. Turn OFF the main switch or remove the power supply to evacuate the patient immediately.

2.4 Stopping the equipment when there is fire

a. Turn OFF the main switch, remove the power supply connected to the equipment when there is fire.
b. Let the patient come down from the table to evacuate immediately.

⚠ Poison gas may be released if the equipment is blackened or burnt due to fire. Please have proper measures/actions against fire established.

2.5 Safety related to the measuring auxiliaries

For safe use of the equipment, use the measuring auxiliaries made by or approved by OsteoSys.

⚠ The user is fully responsible for measurement errors of the equipment due to use of unapproved auxiliaries.

3 Cleaning and maintenance

3.1 Cleaning the equipment

 Warning
Turn the main switch OFF before cleaning.

Remove the AC cable from the power supply.

 Caution
Do not spray any cleaning solution in a spray bottle onto the equipment.

Spray type cleaning solution is likely to damage any electronic devices/parts within the equipment.

Make sure the cleaning solution does not flow in the equipment.

- Keep the contact part of the patient/equipment clean at all times.
- Clean the equipment cover with a soft cloth smeared with diluted cleaning solution or light neutral detergent.

  Spraying water directly on the equipment or water smeared in may damage the equipment.
- Do not use solvents or paint removers.

3.2 Cleaning the monitor

 Caution
Do not use acidic or alkali detergents to clean the monitor.
It may damage the monitor surface.

- To clean the monitor, dust off with a soft brush first or wipe with a soft cloth using light neutral detergent when necessary.

- Wipe the monitor screen surface with a soft cloth or use a detergent exclusively for monitor screens.

3.3 Cleaning the keyboard

- Dust off with a soft brush or wipe with a soft cloth using light neutral detergent when necessary.

4 EXCELLUS product

4.1 About the product

EXCELLUS is a medical device for the diagnosis of osteoporosis using Dual X-ray Absorptiometry (DXA) with high energy and low energy. It calculates the value of bone mineral density by analyzing images acquired from scanning of spine, femur and forearm by fan beam technology. It analyzes essential bone density and regional body composition including fat mass, lean mass and fat%

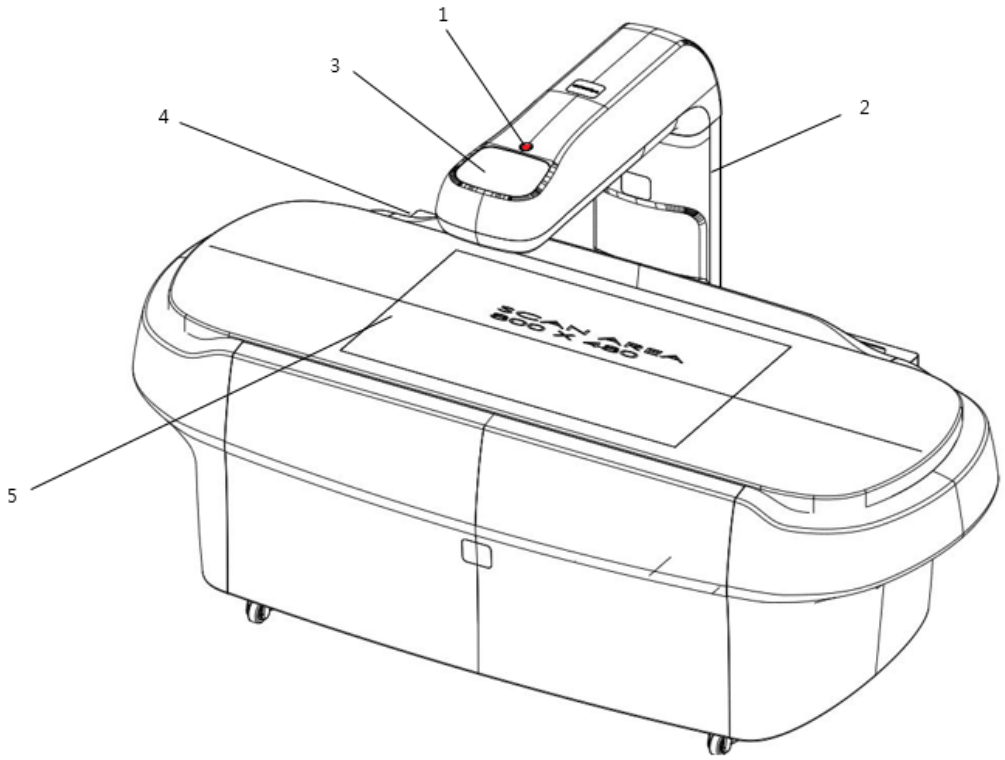
- Type: Central DXA (with regional body composition)
- Method: Narrow fast Fan-beam
- Scan method : Rectilinear scan
- Scan site: AP spine
  Femur
  Forearm
- Measuring method: One Scan (Simultaneous measuring 3sites of AP Spine and Dual Femur)
  Ergonomic Scan
  Rescan
- Measuring information :
  BMD(g/cm^2), BMC(g), BMI, T-score, Z-score, Area(cm^2), HA(Hip Analysis)
  composition(Fat(g)/Lean(g)/BMC(g)/Fat(%)/BMD%/
  Color coding image trend)
  in the unit of % and gram,
  HA(Hip Analysis), Orthopedics
- Reference data: Total 23 types of standard data
  (Midleast, Asian, White, Black, Hispanic, Italian, Chinese, Australia, Korean, Spain, European, USA_White, USA_Asian, USA_Hispanic, USA_Black, NHANES_Asian, NHANES_Black, NHANES_Hispanic, NHANES_White, Turkey_Asian, Turkey_Black, Turkey_Hispanic, Turkey_White)
- Clinical parameters : 20 – 100 years old. Patient weight capacity 150kg
- Modifying specific site : A user can add/delete bone and Tissue to reduce errors in calculating BMD for fracture, implant, and

surgery area.

- Automatic Calibration : Available with Daily calibration phantom
- Auto ROI : Automatic ROI(region of interest) classification after measuring.
- Radiation dose : Less than 10mRem per 1 time. (0.005~0.083mGy/h) (Scan time and X-ray dose value are mentioned on the patient report)
- System interlock : DICOM 3.0& PACS, Data compatibility with GE, DB Back Up / Restore, Archive system for patient data.
- Multiple output feature : Fat information, trend output
- Trend report and Comparison function
- Software : AP spine Measurement and Analysis
  Femur M&A
  Orthopedics M&A
  Half body M&A
  Forearm M&A
  Lateral Spine M&A
  LVA M&A
  Hand M&A
  Half body composition
  Hip Analysis
  Color Mapping
  Trend Analysis (BMD, composition, Image)
  B-Scope (Body Scope)
  FRAX
  Ergonomic Scan
  Choice of the Zone of interest
  Auto ROI
  Angle ROI (Manual)
  Angle adjustment
  Brush function
  Edge auto detection
  Implant Auto detection
  Automatic Real One Scan
  Rescan (Automatic positioning and repositioning)
  Dual energy image inspection (Low & High)

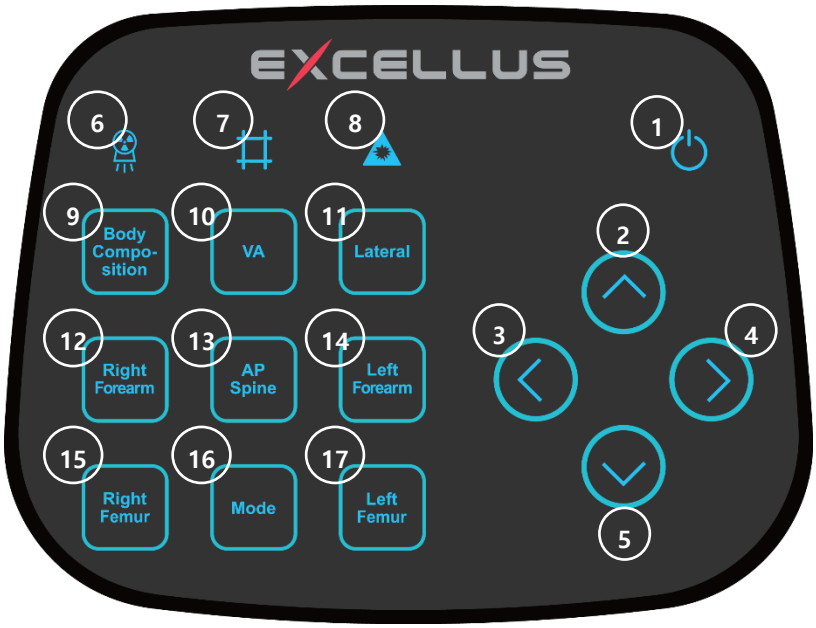
Compare function
Archive system
Data Back Up & Restore (with GE, DB Back Up/Restore)
Reference Population
DICOM 3.0 capability
Multi language
Skin Entrance Dose indication

4.2 EXCELLUS exterior



1. Emergency switch.
2. Carriage.
3. User operation switch
4. Power switch
5. Patient table

4.3 User operation switch exterior



1) Power'ON' LED : Green light is ON when the power is applied.
2) Move 'Top' : Direction key to move to the patient's head.
3) Move 'Left' : Direction key to move to the patient's left hand.
4) Move 'Right' : Direction key to move to the patient's right hand.
5) Move 'Bottom' : Direction key to move to the patient's feet.
6) X-ray ON : Yellow LED is ON when X-ray is being emitted.
7) Shutter OPEN : Yellow LED is ON when the shutter opens.
8) Laser pointer LED : Red light is ON when the laser pointer is ON.
9) Half body : Select the patient's spine. Blue LED is ON.
10) LVA : Select the patient's VA. Blue LED is ON.
11) Lateral Spine : Select the patient's lateral spine. Blue LED is ON.
12) Right Forearm : Select the patient's right forearm. Blue LED is ON.
13) AP Spine : Select the patient's spine. Blue LED is ON.
14) Left Forearm : Select the patient's left forearm. Blue LED is ON.
15) Right Femur : Select the patient's right femur. Blue LED is ON.
16) User mode : Additional function key
(If you select Mode key after clicking Femur/LVA, it changes into Orthopedic/APVA)
17) Left Femur : Select the patient's left femur. Blue LED is ON.

4.4 EXCELLUS system

Main Body		
No.	product	note
1	Main Body(EXCELLUS)	
Accessory		
No.	product	note
1	Computer	
2	LCD Monitor	
3	Supporter set (Foot supporter, Lateral positioner, Lateral cushion)	
4	Daily inspection Phantom	
5	User manual	
6	Power cable	
7	Communication LAN cable	
8	Software installation CD	

 If the items in the accessory or component list are not included, contact the manufacturer.

5 EXCELLUS basic installation

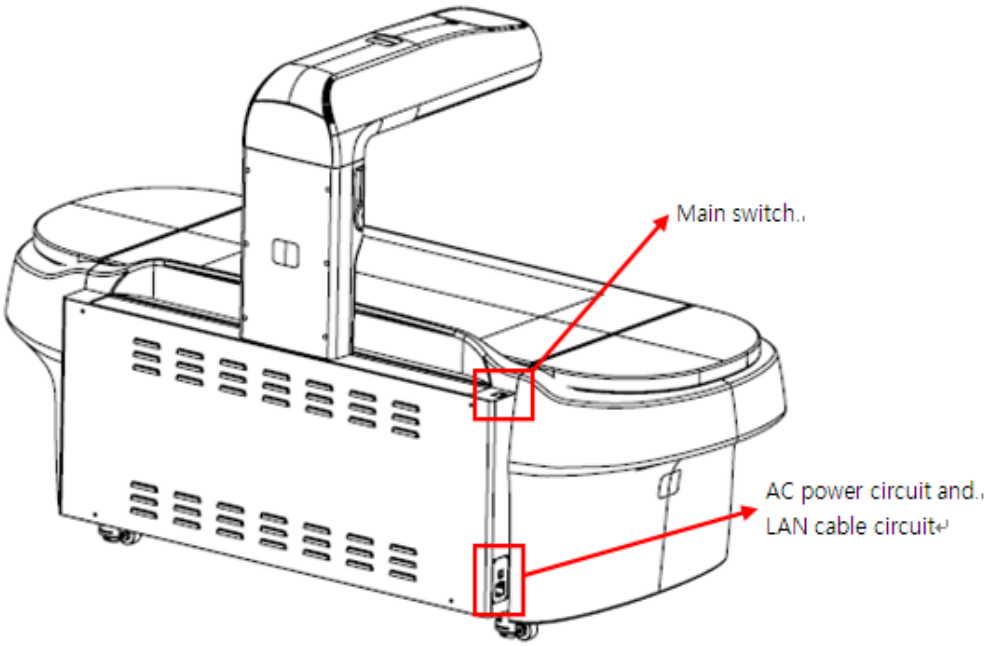
5.1 Moving the equipment

- EXCELLUS has 4 fixing supports for 4 wheels and 2 support fixtures at the bottom of the equipment.
- Move the equipment as follows:

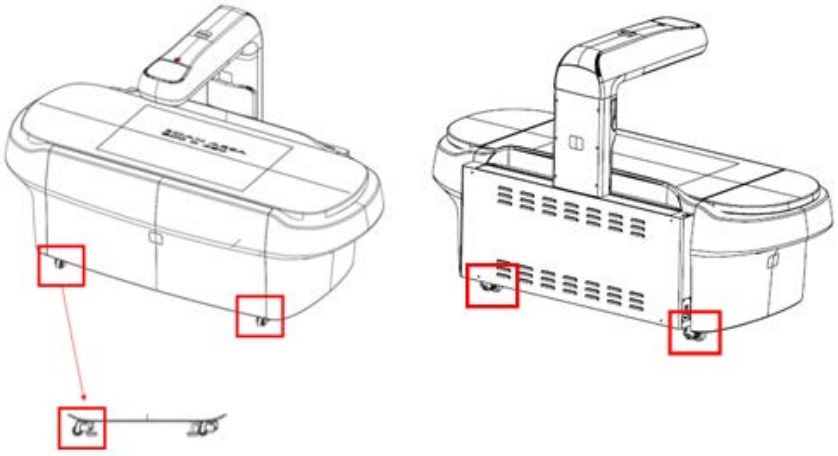
a. Turn the main power OFF.
b. Remove AC power connection and PC LAN cable from the equipment.
c. Turn the fixing supports and support fixtures counterclockwise to lift the supports up from the ground.
d. Push the equipment to move it using the wheels.

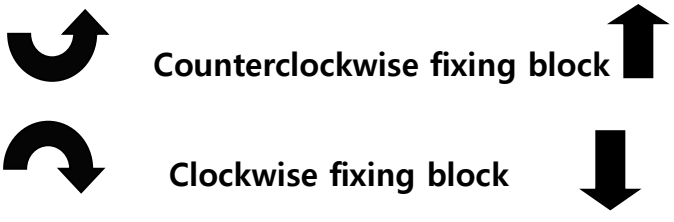
 When tilting or moving EXCELLUS, the carriage should be protected to protect the equipment; please contact our AS team or an agency.

 When moving the equipment, unfixed carriage might cause injuries therefore handle the equipment very carefully.



Main switch location and power supply/LAN cable circuit location.





Fixing and releasing the blocks.

5.2 Installation of the equipment.

- Installation is done in the reversed order of moving the equipment.
- Installation is done as follows:
  a. Open the box packaging, remove the carriage and HFG fixing blocks (red colored) in the box.
  b. Push the equipment to place it in the installation space.
  c. Turn the fixing blocks clockwise so that the blocks touch the 4 points on the ground.
  d. Lift both wings of EXCELLUS bed and push and fix them to the equipment.
  e. Connect the AC power cable and connect LAN cable to the PC.
  f. Turn the main power ON.


Installation and storing of the equipment in an improper location may cause performance deterioration, damage or malfunctioning.

Examples of improper installation and storing location:
1) Too much humidity.
2) Direct sunlight.
3) Higher temperature than the proper temperature for the equipment (18 ~ 27 ℃)
4) Physical impact or vibration that can affect the equipment.
5) Severe slope.
6) Storage place for chemicals.
7) Near equipment that generates magnetic field.


When reinstalling the equipment and applying AC power, check before connecting if the main power is turned OFF. Otherwise it could damage the equipment.

Install the equipment on a flat/horizontal ground. Otherwise the carriage or HFG may move towards the slope when the power is OFF.

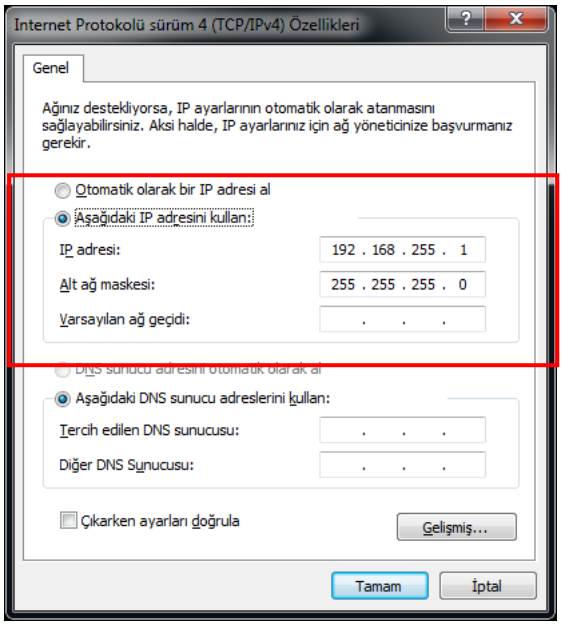
You must use a bed with proven biocompatibility. If you need a replacement, contact the manufacturer.

5.3 Software installation.

1) PC LANCARD Network IP setting.

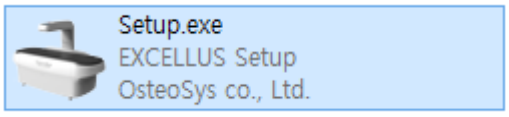
- EXCELLUS communicates with PC through LAN. Specific IP address should be set on regular PC for communication.

a. Right-click on Network Setting icon on the wallpaper.
b. Click 'Properties'.
c. In 'Properties' tab, click 'internet protocol (TCP/IP)' at the bottom and click 'Properties'.
d. When a window pops up as shown, fill the following in the IP address box and click OK.
e. Click OK to complete the setting.

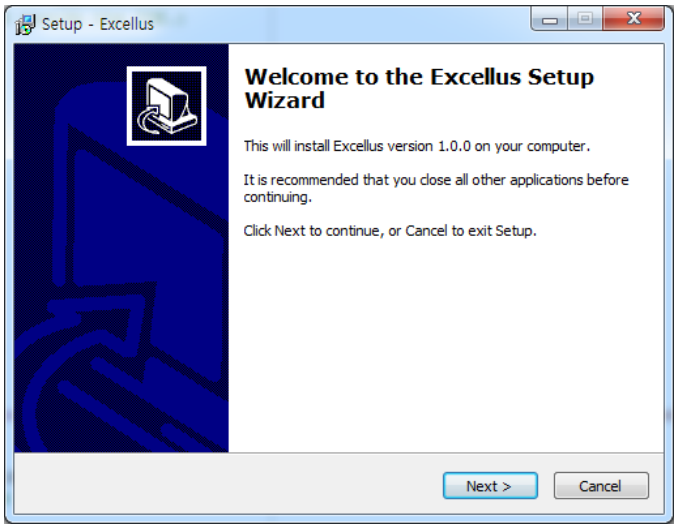


2) Use program installation.

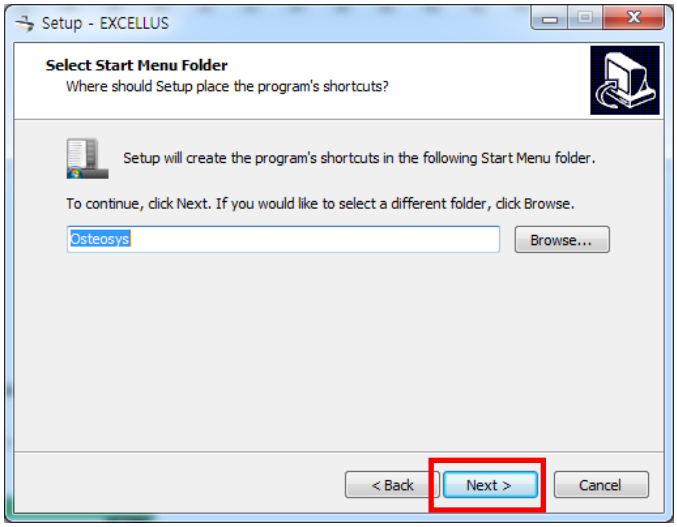
a. Insert the CD into the PC.
b. Click 'My Computer' icon and right-click the drive where the CD is inserted.
c. Click 'Search'; when the window pops up, find and click 'Setup.exe'.



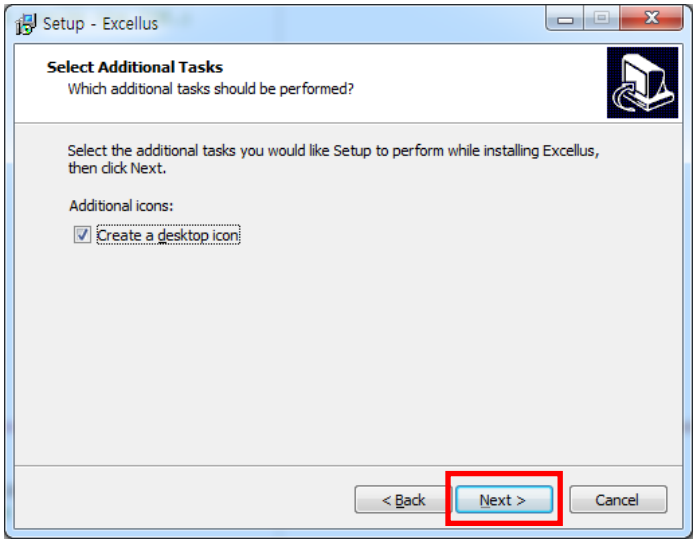
d. Wizard will start for EXCELLUS installation.



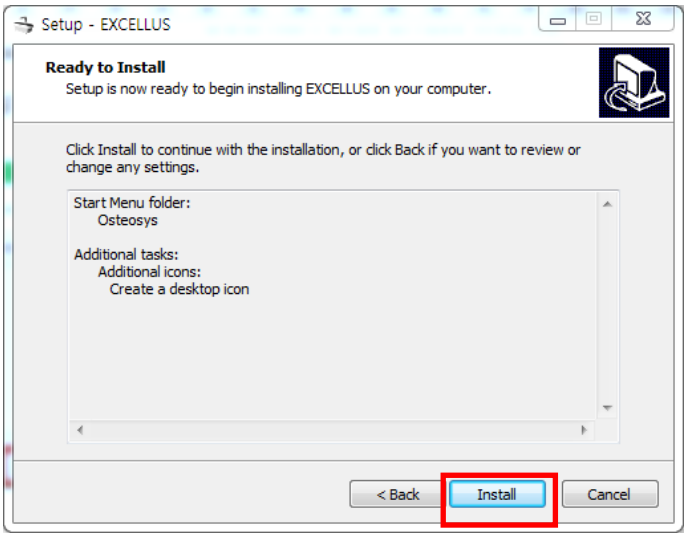
e. Press 'Next' button.



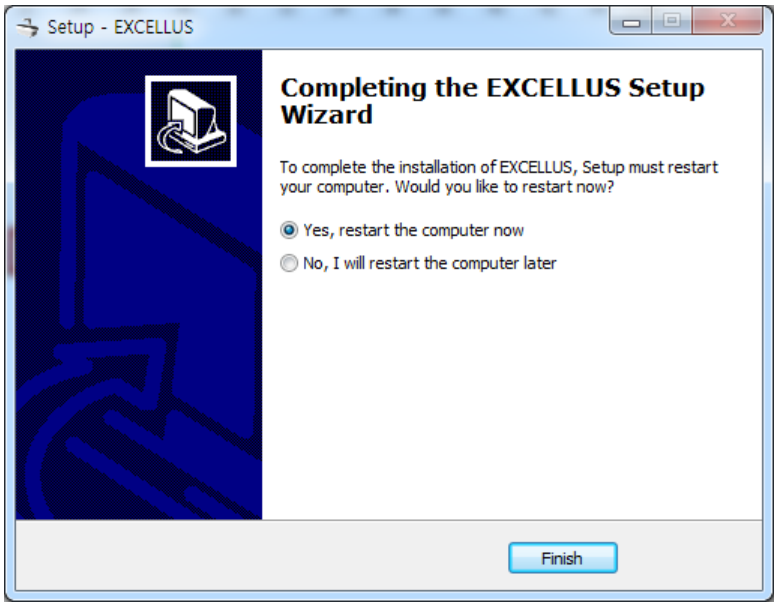
f. If you would like to install an icon on desktop screen, check the box and click "Next' button.



g. Click 'Install' button to start installation.



h. EXCELLUS Program installation is completed.



For the normal execution of the program, make sure to reboot the computer.

i. After rebooting, press {Win Key+R} to enter [%appdata%] in the window, followed by pressing the enter key.

j. Make sure that EXCELLUS folder is created in Application Data folder.

k. Move to EXCELLUS folder, and check whether Calibration Files folder, Bin folder and Config.xml file is copied.

6 Using EXCELLUS Program

6.1 Starting the program.

Turn ON the equipment and click EXCELLUS icon to start the user program. Power LED of the user operation switch will be ON and ARM will move to the initial position if it is not already in the initial position. Perform configuration at the beginning of installation and daily inspection everyday.

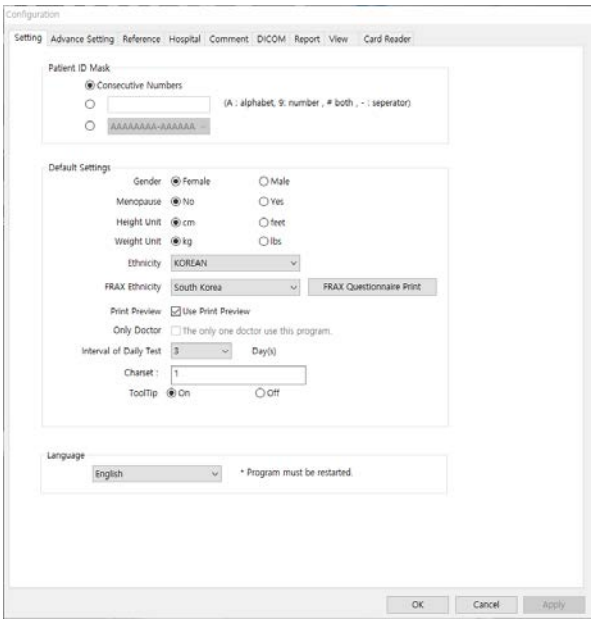
6.2 User program configuration.

Configuration is required one time after installation.

Perform configuration for using the equipment in the user program.

Check or select the check boxes according to the description of each item.

1) Settings tab.



a. Patient ID Mask

- Consecutive number: ID number is given starting from1, as a serial number.
- User setting box: Type A (You can type A-Z– Cannot type other characters)
  Type 9 (You can type 0-9 – Cannot type other than numbers)
  Type # (You can type alphabet characters and numbers together, no limit on digits)

- Designated ID Type
  * AAAAAAAA – AAAAAAAA
  * 999999 – 9999999
  * ######## – ########
  * A#9A#9A#9A#9

 When you need to type 8AD123 for ID
' 9AA999 ' or' ##### 'or'##########'
You can use # without any limit on digits.
• When using a designated ID type, it should be the same as the type to register examinee's ID.

b. Default Settings

- Gender : It selects basic setting for patients' gender.
- Menopause: It selects basic setting for menopause of female patients.
- Height Unit : It selects basic setting for height unit.
- Weight Unit : It selects basic setting for weight unit.
- Ethnicity : It selects basic setting for patients' ethnicity.
- FRAX Ethnicity : It selects basic setting for FRAX ethnicity.
- Print Preview: Basic setting for print preview.
- Only Doctor : Select this if one user uses the equipment and it won't request PW when starting the program.
- Interval of Daily Test : Select daily test cycle.
- Tool tip : You can choose whether to have a small window for explanation of each function.

c. Language

- Various languages are available and the change will apply when restarting the program. Check available languages by selecting the combo boxes.

(The change will apply only after restarting the program.)

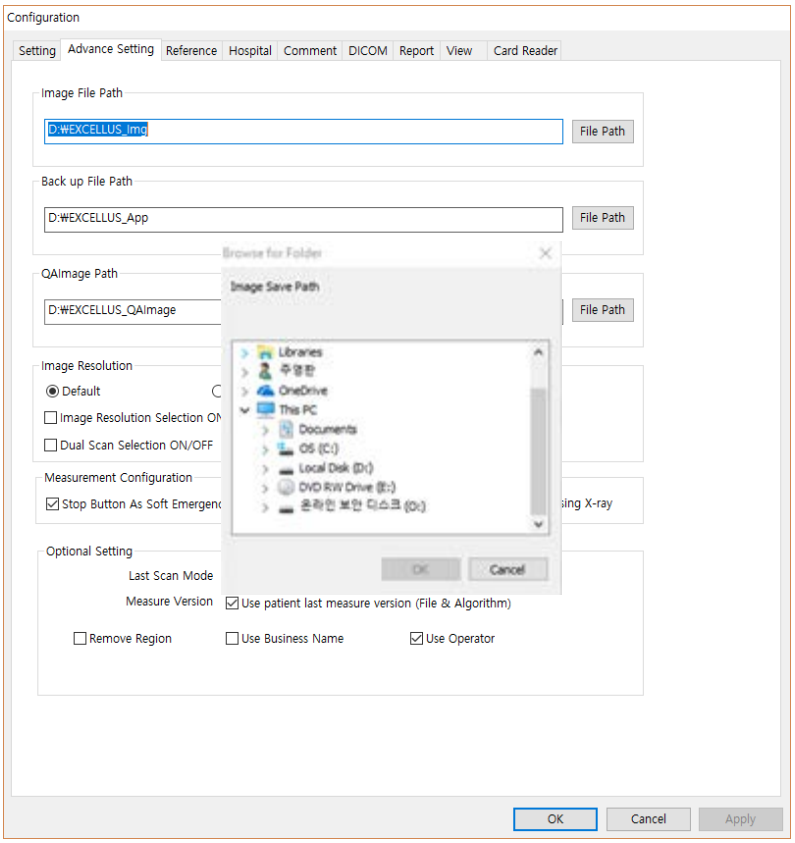
NOTE : If additional language changes are required, contact the manufacturer.

2) Advanced setting

- Set a value of graph to be drawn on analysis screen.
- Set a path to store the result image.
- Set a file path for backup.
- Set Measurement Configuration.

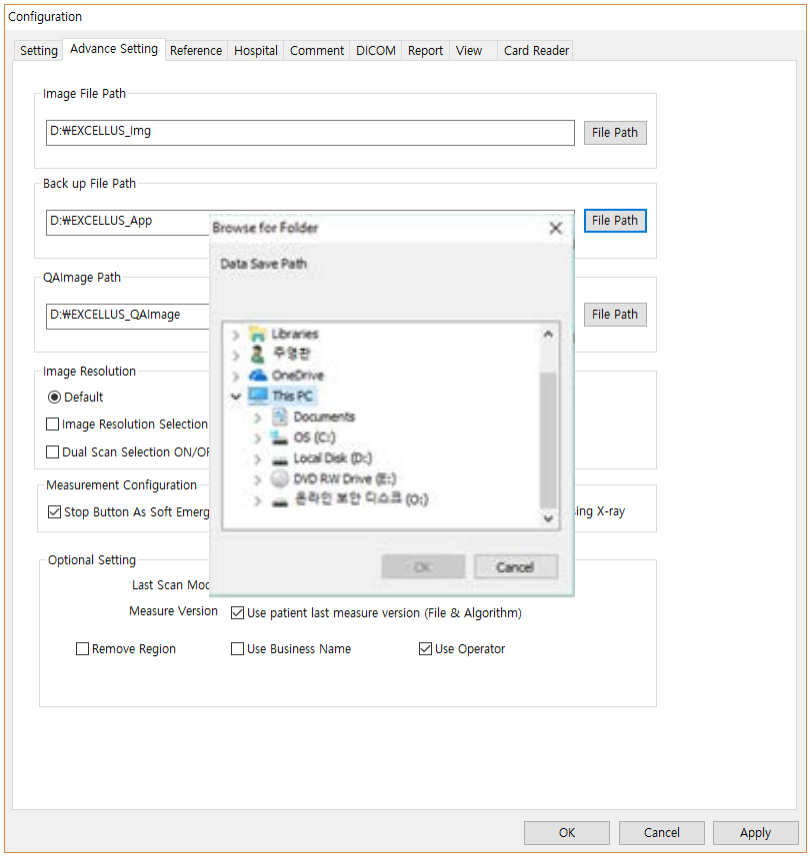
a. Path for Image Files.

- Set a path to store the result image.
  Press file path button to select a folder in a path to be stored, and then click to confirm.

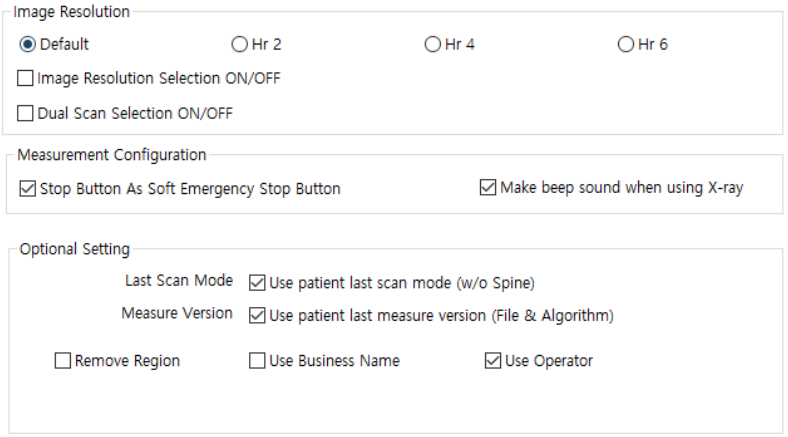


b. Backup File Path.

- Select a path of backup file.
  Press file path button to select a folder in a path to be stored, and then click to confirm.



c. Image resolution



- Setting for high resolution mode which is available in Dual Scan and Spine

d. Measure Configuration

- Stop Button As Soft Emergency Stop Button : This option is the same as the Emergency Button when the Stop button is clicked on the measurement screen.
- Make beep sound when using X-ray : This option sets beep sound when X-ray

is shot during measurement.

e. Operation setting

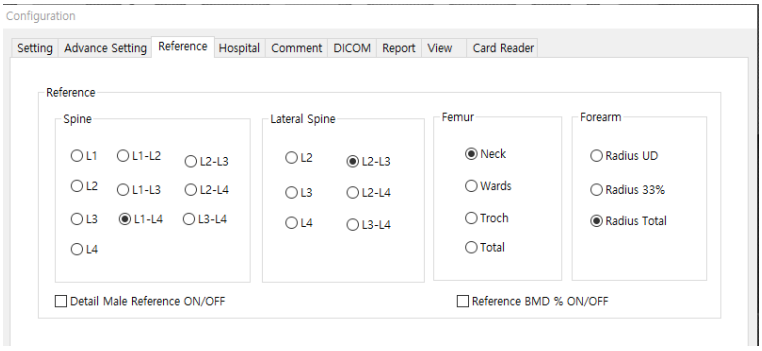
- Last Scan Mode : Use patient's last scan mode.
- Measure Version : Use patient's last measure version
- Remove Region : Set the T-Score notation change when removing a region.
- Use Business Name : Use patient's company name. You can check the company name in the Report.
- Use Operator : You can check the operator in the PatientList and the Report.

3) Reference

Set a value of graph to be drawn on anlaysis screen

a. Reference setting

- AP Spine : Select a standard graph to be used for AP Spine analysis result.
- Lateral Spine : Select a standard graph to be used for Lateral Spine analysis result.
- Femur : Select a standard graph to be used for Femur analysis result.
- Forearm : Select a standard graph to be used for Forearm analysis result.



Details Male Reference ON/Off

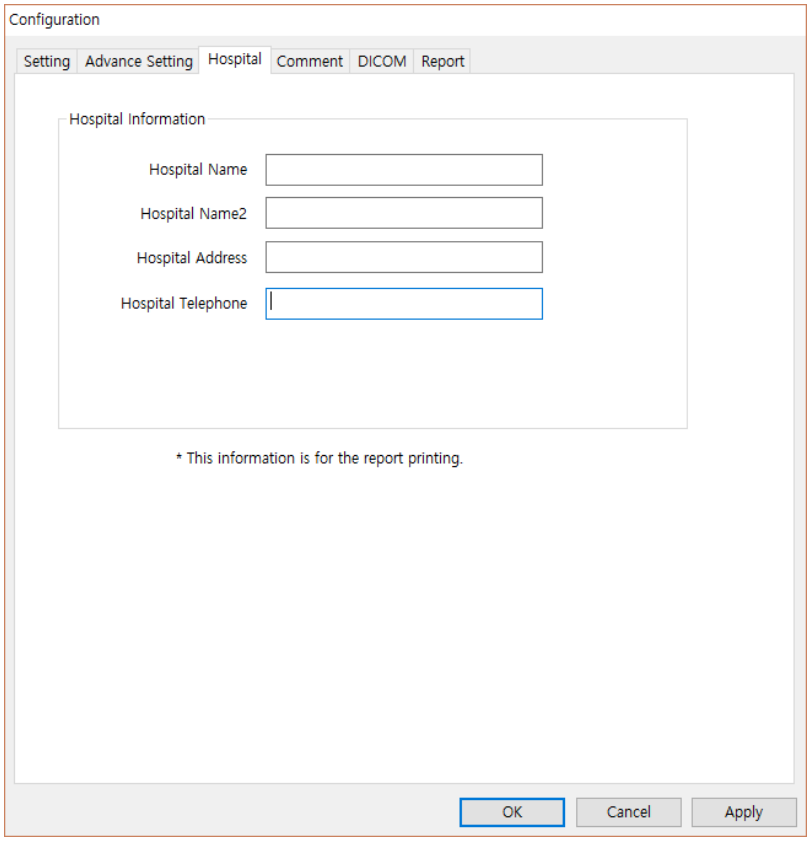
- It shows Male Reference graph in to 3 (off) or 5 (on) grades.

Reference BMD % ON/Off

- It shows T-Score & Z-Score % value

4) Hospital

- Fill in the hospital information.
- Hospital information appears on top in the patient report.



a. Hospital information

- Hospital Name : Fill in the hospital name.
- Hospital Name2 : Fill in the sub name of hospital.
- Hospital Address : Fill in the hospital address.
- Hospital Telephone : Fill in the hospital telephone number.

5) Comment

It sets up automatic comments appropriate for BMD value.

- T ≥ -1.0 : Automatic comments for normal group
- -1.0 > T > -2.5 : Automatic comments for osteopenia group
- T ≤ -2.5 : Automatic comments for osteoporosis group

6) DICOM

It sets up the information of Storage Server and Worklist Server

a. Storage Server
   - It sets up the information of PACS (IP, Port, andATitle)

b. Worklist Server
   - It sets up the information of Worklist Server(IP, Port, ATitle)

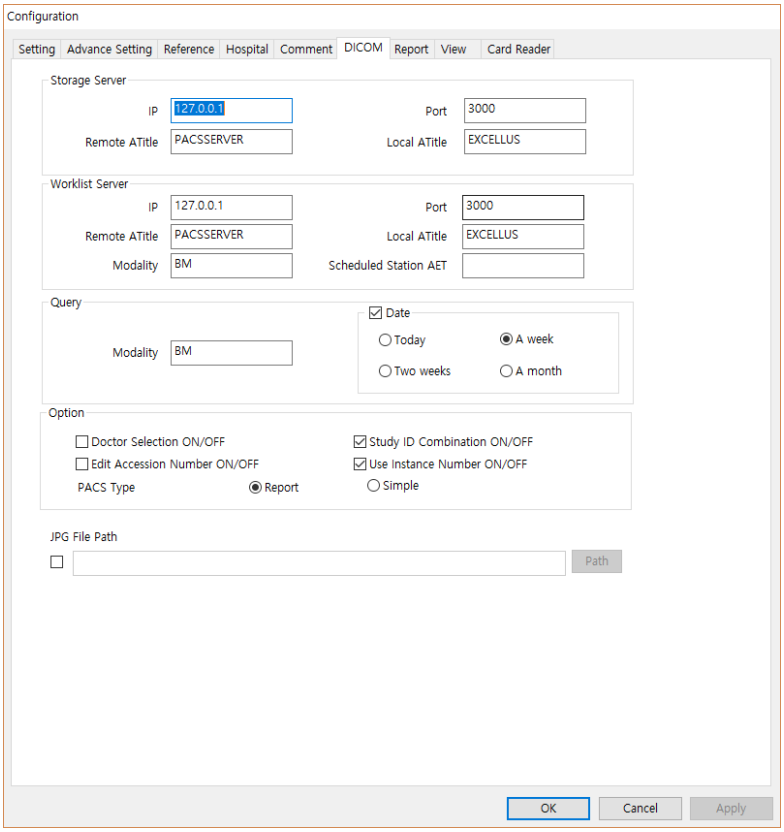
c. Query
   - It sets up a basic modality and period

d. Option
   - Docotr Selection ON/OFF : It sets up the window of selecting Doctor for DICOM.
   - Study ID Combination ON/OFF : Send report to one StudyID.
   - Edit Accession Number ON/OFF : Set Accession Number when sending PACS
   - Use Instance Number ON/OFF : Set Instance Number when sending PACS. It

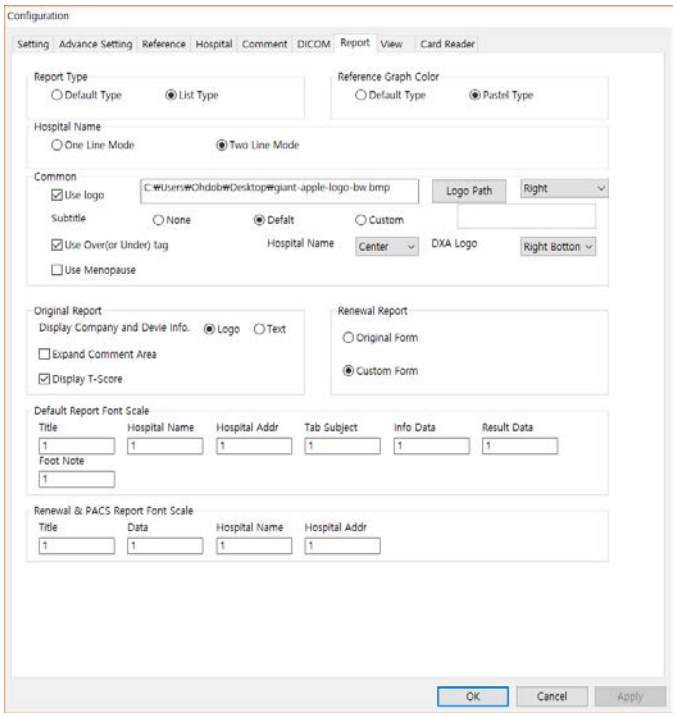
selects Report Type and Simple Type for PACS transmission

e. JPG File Path

- You can save PCAS image with JPG file into the path that you set for PACS transmission



7) Report

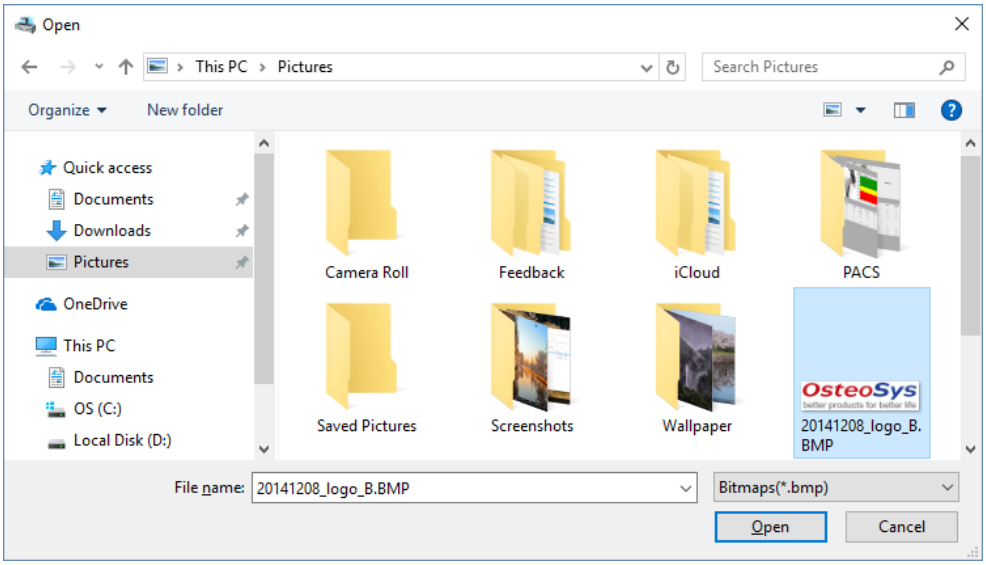


a. Report Type
   - Select between Default Type (Default Report) and List Type (Default Report + Renewal Report).

b. Reference Graph Color
   - Select between Default and Pastel Report Type.

c. Hospital Name
   - Choose one or two hospital names.

d. Common Settings
   - Use LOGO : Set to show/not to show the hospital logo image file in the report. To add the logo, type the path of the logo image file in the Path box. The set file path is displayed on the box, left of the button.



Adding the logo

Logo format

- Logo file format *.bmp file
- File size (recommended) : 390 * 140 (pixel)
- Saving the logo

Create a file and save it in [C:₩Program Files₩Osteosys₩EXCELLUS₩Resource] folder. You can save it in a folder you want.

Example: (C:₩Program Files₩ Osteosys₩EXCELLUS₩Resource ₩OsteoSys.bmp

- Hospital Name, DXA Logo
  - Set the hospital name and DXA Logo location
- SubTitle
  - Default (Report Type) is the default SubTitle. If you select Custom, you can enter your own text.
- Use Over (or Under) tag
  - If the T-Score and Z-Score values exceed a certain level, set the options displayed as Over or Under.
- Use Menopause
  - In the report, you can set whether to print the patient information in the menopause.
- Use Referrring Physician
  - This option displays the name of the doctor in the Referring Physician position in the report.

e. Default Report

- Company, Device Info
  - Select company or equipment information from Logo or Text.
- Expand Comment Area
  - The comment area the report is expanded.
- Display T-Score
  - The T-Score value is displayed below the Reference Graph

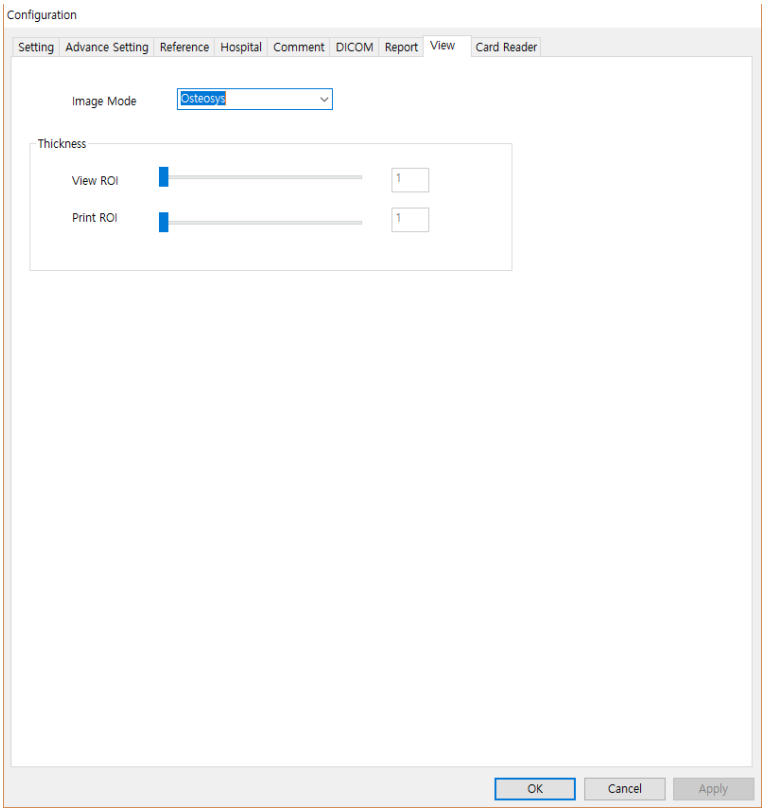
f. Renewal Report

- Select Report Type between Original and Custom Form.

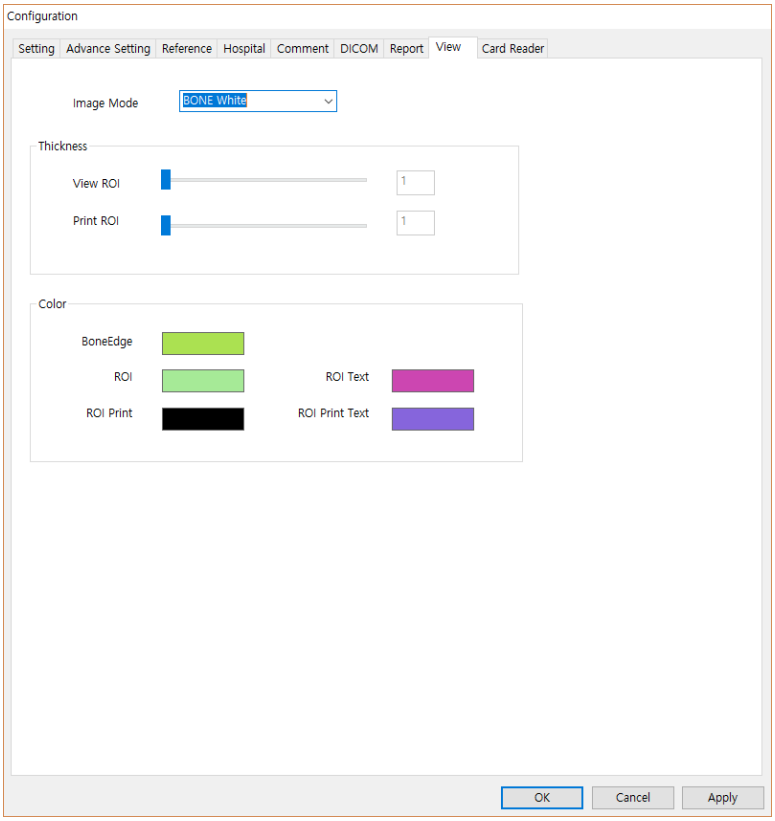
g. Default Report Font Scale, Renewal & PACS Report Font Scale

- Set Font Scale in Report

8) View

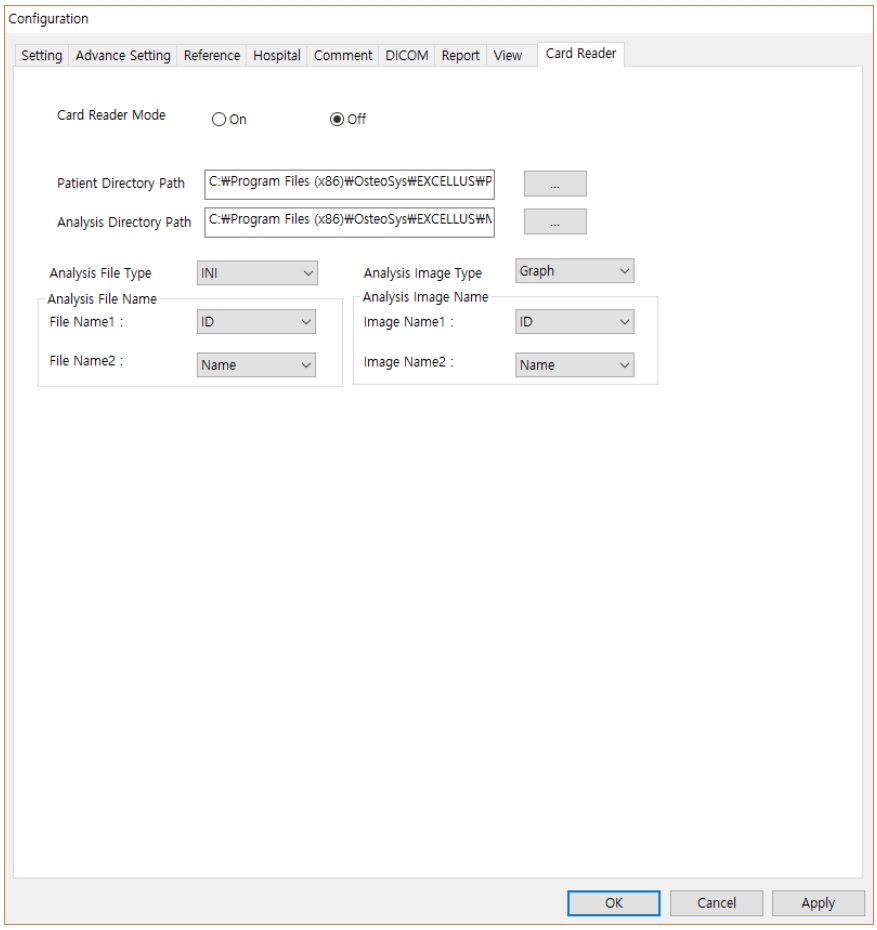


- It sets up image mode, color and ROI thickness
- Image mode: Osteosys, GE, Hologic, Bone Black, Bone White



- In case of BONE White and Bone Black, it is possible to select color of bone edge, ROI, ROI Text, ROI Print and ROI Print Text.

9) Card reader



- It is to receive patient information through a card reader and perform registration, modification, and deletion automatically. This transfers the measured result data to the system according to the specified format.

a. Card Reader Mode On/Off

b. Setting patient information file directory

- It sets up patient information file directory like Patient.ini file.
- Default Value : " C:₩Program Files₩OsteoSys₩EXCELLUS₩PatientInputDir"

c. Setting patient analysis file directory

- It sets up patient analysis file directory.
- Default Value : "C:₩Program Files₩OsteoSys₩EXCELLUS₩MeasureResultDir"

d. Setting patient anlaysis file name

- It sets up patient analysis file name.
- Type : None, ID, Name, BirthDate, Gender
- Default Value : FileName1 - PatientID, FileName2 - PatientName
- EX) FileName1 = ID, FileName2 = Name
  file name : #ID_#NAME_#SITE.ini or #ID_#NAME_#SITE.txt

e. Setting patient analysis file format
- It sets up patient analysis file format.
- Value : "INI" -> INI file, "TEXT" -> TEXT file
- Default Value : "INI" -> INI file is default value.
- EX) #ID_#NAME.ini

f. Setting patient analysis image file name
- It sets up patient analysis image file name.
- Type : None, ID, Name, BirthDate, Gender
- Default Value : ImageName1 - PatientID, ImageName2 - PatientName
- For the Report, the file name is set to the name of the report type selected.
  EX) Card Reader Report - Renewal Type Detail Report
  File name : #ID_#NAME_#SITE_Renewal_Detail.jpg

g. Setting patient analysis image file format
- It sets up patient analysis image file format.
- Value : "Graph" -> Graph bmp file, "Report" -> Report - jpg file
- Default Value : "Graph" -> Graph bmp file
- EX) #ID_#NAME.bmp

6.3 Doctor registration.

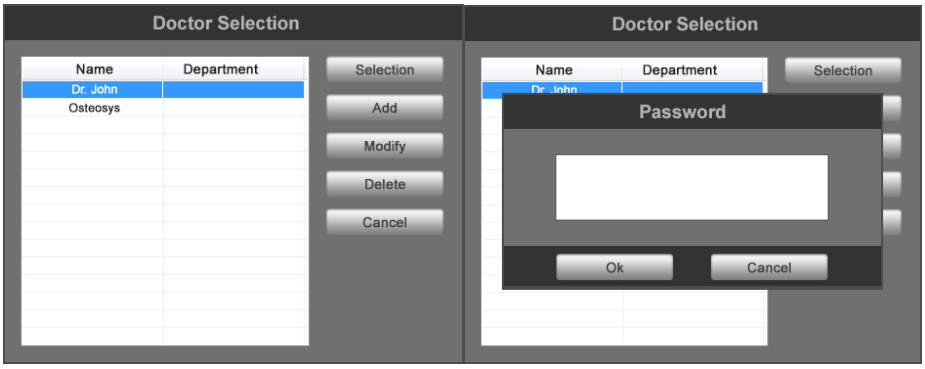
EXCELLUS user program sets PW for each doctor to report on patients if it is used by many doctors.
If it is used by one doctor, refer to 'Doctor' in Configuration. If [Page44 b. doctor] item is checked/set, doctor selection window won't appear.

a. Doctor Selection menu
- Select: When used by many doctors, select a doctor and click 'Select'.
- New : Use it to add a new doctor.

- Modify: Use it to modify doctor information.
- Delete: It deletes all information on the selected doctor:
  patient data will be kept in database.
- Cancel: Use it to exit Doctor Selection menu.

b. Doctor select
- Select a doctor then click 'Select' button or double-click after selecting a doctor.

c. Typing Password
- When Password window pops up, type in password and click OK.

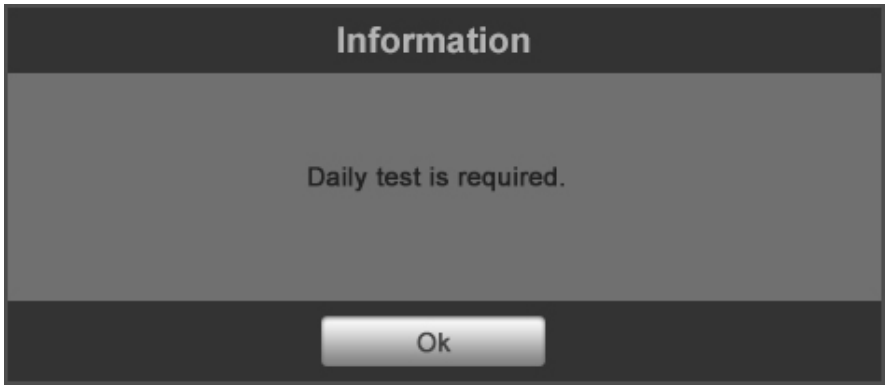


If you forgot your Password, contact our AS center to protect your personal information.

Do not share your password with others.

6.4 Daily inspection.

For accurate measurement, EXCELLUS requires daily inspection in accordance with preset inspection interval.



Daily inspection is required based on the pre-set inspection cycle; when the program requests daily inspection, the inspection should be done, otherwise measuring function will not be available.

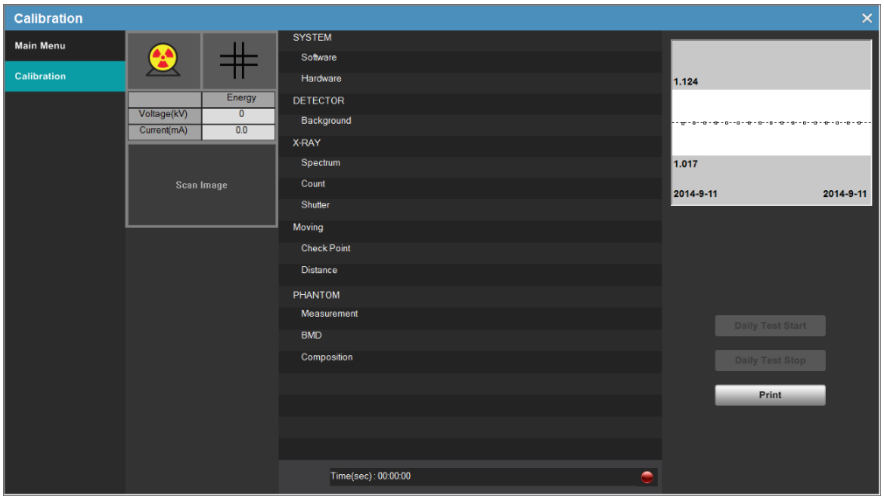
If daily inspection cycle is set to every 3 days, it may affect BMD; it is recommended to set the cycle everyday.

Do not put any object on the bed except the daily inspection phantom during daily inspection.

If the daily inspection fails, contact the manufacturer for re-calibration.

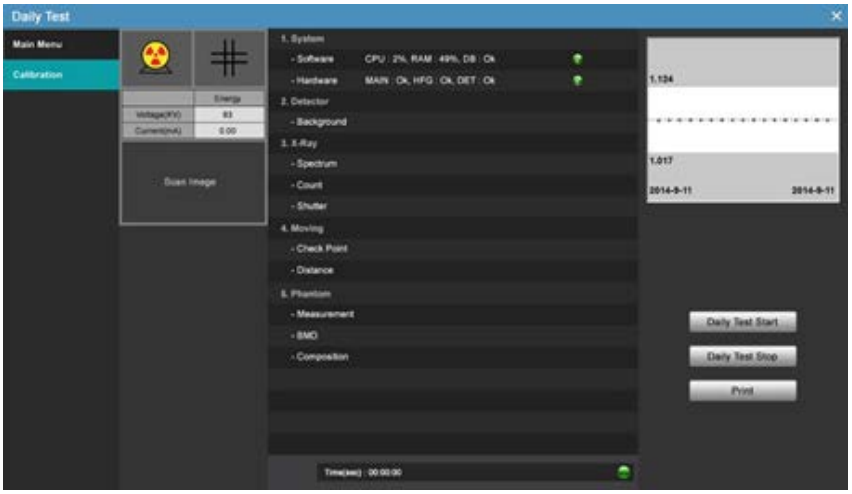
a. Click 'Daily Test', the second icon from the top of the User program main screen.
b. Trend graph will be displayed at the right top, which shows the result of daily inspections (BMD). An indicator lamp will be at the right bottom, which shows the communication connection status.

-  : Communication between the equipment and PC is on standby.
-  : Communication between the equipment and PC is in progress.

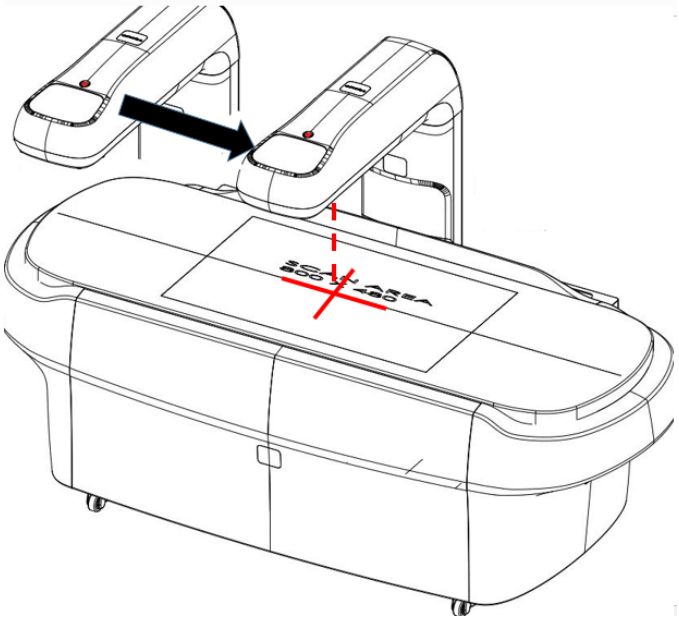


c. When  is ON, click 'Daily Test Start' button.

d. If the system is normal, the equipment carriage will move to where daily phantom will be placed.



e. After the equipment carriage is located where daily phantom is placed, laser pointer will be put on.



Do not stare directly at the laser pointer because it may damage your eyes if staring at it directly.

f. To continue daily inspection, place the phantom in designated place in reference to the following description.

- When a user stands facing the control panel, place the white section of phantom to be seen on front, under the carriage of equipment (Figure A)

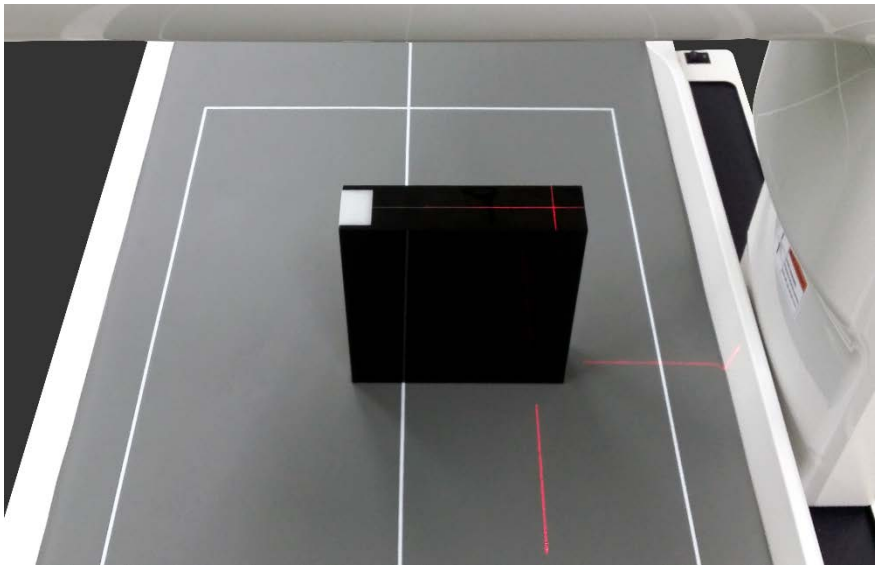
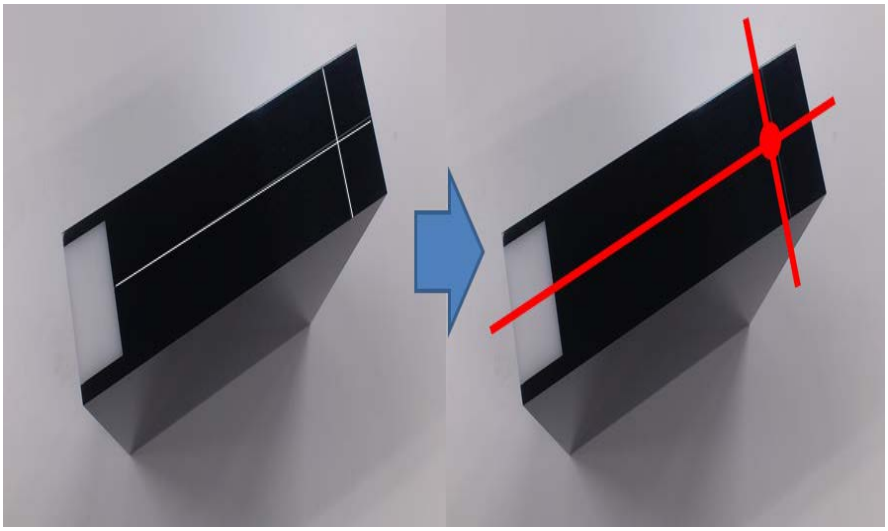


Figure A.

- By changing the location of phantom, align the cross-shaped laser pointer with the cross symbol that is engraved on the top of phantom. (Figure B).



FigureB.

g. Click the confirmation button on the bottom of phantom location guide image (which is displayed on user program), to continue daily inspection. If you would like to cancel daily inspection, click cancel button. After cancelling, the equipment will move back to initial position.
h. After that, all the items will be automatically carried out.
i. After daily inspection is completed, the carriage of equipment will move back to its initial position.

 During daily inspection, it will be automatically carried out until daily inspection on equipment is completed. When approaching near the equipment in operation, pay a close attention to safety because it may cause injury.

6.5 Measuring.

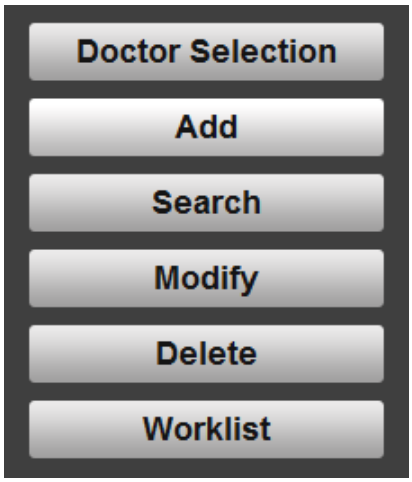
Click 'Measurement' in the main screen for measuring.

Measuring will be done in the following order: 1. Patient information registration -> 2. Patient location setting -> 3. Measuring -> 4. Analysis

NOTE : Proceed with the measurement by referring to the IFU measurement method

6.5.1 Patients' personal information registration.

- Fill in patients' personal information. Measuring mode varies depending on personal data; therefore fill in correct information.
- Doctor Selection: Select a doctor to find applicable patients.
- Add : Register patients.
- Search : Search patients in the list that meet the requirements.
- Modify : Modify the selected patient's personal data.
- Delete : Delete all data of the selected patient.
- Worklist : Export patient information from Worklist server.
- To close the pop-up window, press [X] on the top right.



a. In the user program, Main>click Measurement.
b. Click on the patient list menu and when the submenu window pops up, click 'Add' to register a new patient.
   - ■ Patient New : Fill in the information when the window pops up.
   - ■ Doctor Name : It displays the name of the doctor currently selected.
   - ■ Patient ID : Fill in the chart number of the patient ID.

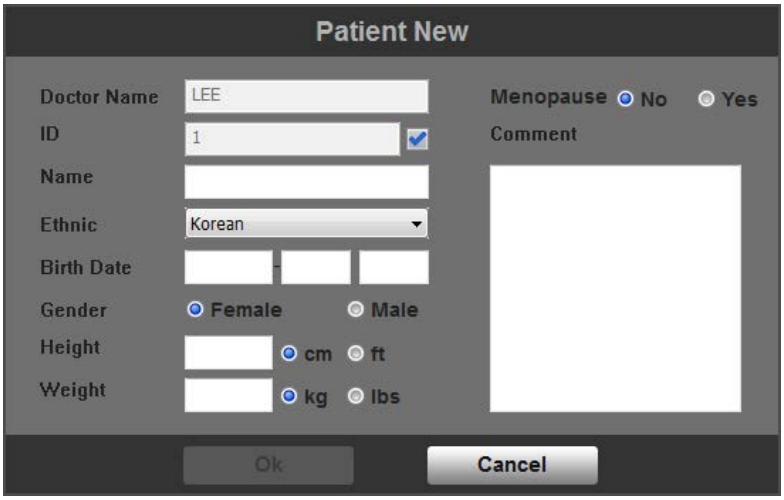
- ID Check : Check if there are same chart numbers or IDs.
- Name : Fill in patient's name.
- Birth data : Fill in patient's DOB.
- Gender : Select patient's gender.
- Ethnicity : Select patient's ethnicity.
- Height : Fill in patient's height. (unit: cm, feet)
- Weight : Fill in patient's weight. (unit: kg, lbs)
- Menopause : Select 'menopause' status for female patients.
- Memo : Fill in comments on patient's status.
- FRAX prediction. : Enter the value of patient's risk factors for fracture risk

Check patient's registration status by pressing 'Double-check ID' button in the patient registration window. However, in Configuration > Settings > Default Setting, if patient's MaskID is in serial number, Double-check ID or Edit ID window won't be available.

NOTE !

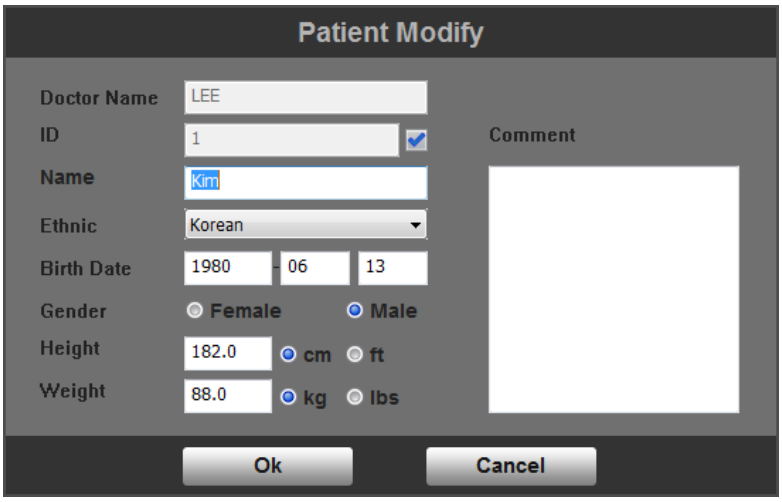
T-scores may vary if patient information is not entered correctly. Please enter correctly.

c. When it is completed, click 'OK'.



6.5.2 Modifying patients' personal information.

To modify patient's personal information, select a patient, click the patient list menu to open the submenu window then click 'Modify'.



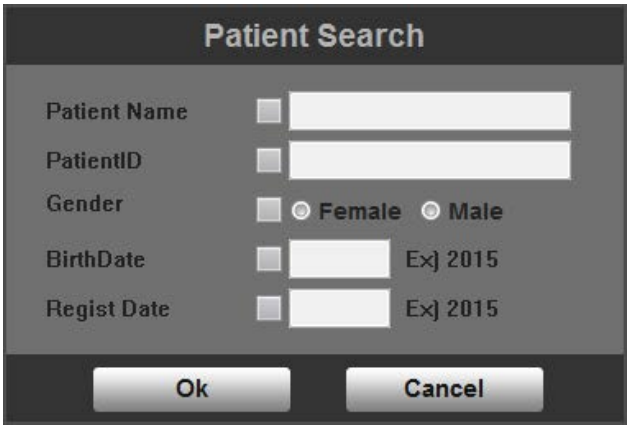
6.5.3 Deleting patient data and personal information

To delete patient data and personal information, select the patient, click the patient list menu; when the menu window pops up, click 'Delete'.

Data deleted by the user cannot be restored and OsteoSys is not responsible for data loss due to user's negligence.

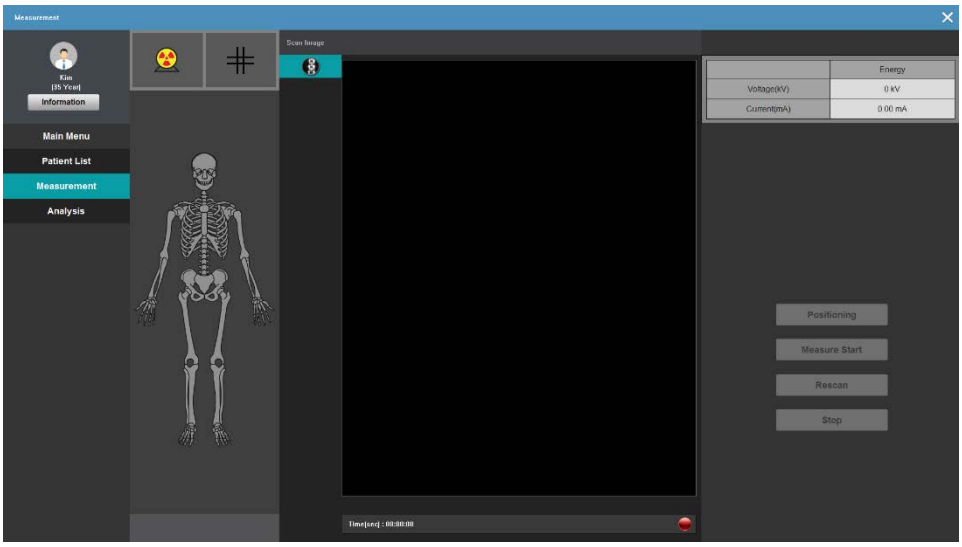
6.5.4 Searching patient data

You can search patients by their DOBs, names or IDs from the patient list when needed and you can create patient lists by your search criteria.



6.5.5 Measuring bone density

a. When patient information is filled for measuring bone density, double-click the patient from the list or click 'Measurement' in the left with the patient selected to show Measurement window.



Measurement screen buttons

- Positioning:
  To keep the measuring equipment stable, warm up the equipment and move to the basic position as the user manual. Turn ON the laser pointer in the equipment operation panel.
- Measure Start:
  In the equipment operation panel, set all scan sites before starting measuring.
- Rescan:
  After starting measuring, if the scan site is not set correctly, press the button to reset the site and measure again.
- Stop:

It stops the equipment.

b. Available Scan type: AP Spine / Left Femur / Right Femur / Left Forearm (GDP and Hand)/ Right Forearm (Hand) / Half Body / LVA / Lateral Spine / Left Orthopedic / Right Orthopedic / One Scan(Multi Scan)

 One Scan feature is not available for Forearm / Half body / LVA / Lateral Spine.

 What is One Scan (Multi Scan)?
Unlike the existing method for measurement of 2 or more sites separately (Equipment setting➔Setting location➔measuring one site ➔Analysis➔ Equipment setting➔Setting location➔measuring other sites➔Analysis➔ Complete)), 'One Scan (Multi Scan)' is done by these steps Equipment setting➔ Setting location➔Setting location for the second site➔Measuring the first site ➔Measuring second site ➔Analysis➔Complete, which reduce patients' waiting time and promote convenient use of the equipment.
To use the one scan (Multi Scan), Please refer to section at next page.
[How to set up One Scan (Multi Scan)].

 In case of Orthopedics,
Select Femur button and select Femur again, then it will change from Femur to Orthopedics.
Ex) Left Femur -> Left Orthopedics ->cancel

 What is GDP?
GDP refers to the prediction of growth that predicts height of the children when he or she gets grow.

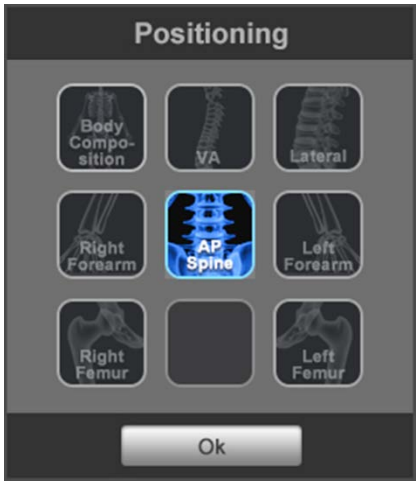
In case of GDP
It can be applied for the patient who is younger than 20 years old.
At the measurement screen after press "Positioning" button, you select Left Forearm on site selection. The scanner move the basic position as the user designated. The manual measurement screen pops up on right top.
Then, click "GDP", set scan area and mode.
When set up is completed, press "Measure start" button.

c. Predict the measuring site by referring to the images.

d. Lay the patient on the equipment and fix the measuring supports according to the site to be scanned.
e. Press 'Positioning' in 'Measurement' window and wait for about 5 seconds at the initial position, then the message about moving to 'Default position' pops up.

What is Fast Mode?
Fast Mode is the function which can complete scanning more quickly than normal scan for the measurement of Spine and Femur (Left, Right). However, resolution of image can be different. Measurement is completed within 15 seconds with Fast Mode.

f. Check for any danger of patient injury by the equipment and click 'OK'. Automatic move to the designated location according to the selected sites to be measured
   i. Click on the site to which you want to move for measuring.



ii. Click the selected site again to cancel the selection.

iii. Select the site for scanning to which you want to move and click OK to move to the designated site according to the selected site for scanning.

⚠ Positioning feature enables the operator to move the equipment as close as possible to the site to be measured. Therefore you should select the site to be measured on the operation panel.

g. Once it is moved to Default position, the laser pointer is ON and the LED of the user operation panel is ON.
h. Press Top/Bottom/Left/Right key in the user operation panel to control and move the arm to a proper location to select patient' AP Spine / Left Femur /

Right Femur / Left Forearm(GDP) / Right Forearm/ Half Body / LVA / Lateral Spine / Left Orthopedic / Right Orthopedic. Press the switch in the user operation panel and press 'Select' for the applicable site.

Once 'Select' key is pressed, the applicable coordinate is saved within the equipment; when you want to use One Scan feature, move and set (again) the equipment to difference sites. Once the coordinate of each site is set, LED(green) is turned ON and the selected sites appear in the user program as shown here.

How to Set Up One Scan (Multi Scan)

1) Press the "Positioning" button in the "Measurement" window.
2) The carriage will move to the selected location.
3) After the carriage moves to the selected location, adjust the laser pointer to the start position of the first measurement area using arrow keys on User Operation Panel. Then select the measurement area on User Operation Panel.
4) Right after the selection, move the laser pointer to the second measurement start position using arrow keys and select the second measurement area.
5) Then return to the computer window screen, click "Scan" button.

For example, [Spine measurement -> Left Femur measurement]
[On 'Measurement' window, select 'Spine'] -> [Using the operation panel, adjust the position for Spine] -> [Select 'Spine' on the operation panel] -> [Using the operation panel, adjust the position for Left Femur] -> [Select 'Left Femur' on the operation panel] -> [Select 'Start Measurement' on 'Measurement' window]

i. If it is out of measurement section, a message of "out of measurement section" will pop up. Then selected measurement section will be unselected with a buzzer signal.

When the swtich for measruing site is pressed, LED(green) is turned ON and the current location is saved. When pressed again, LED(green) is turned OFF and the saved location information is deleted. For the selected site, the color of operation panel changes from green to orange, and if deselected, it changes back to green.
When a site is selected, you can hear a short buzzer sound and when it can't be selected, it means that the site is out of the measurable scanning region.
Reset the measurement site inside the measurement area marked on the bed where the patient lies. At this time, if the patient's position is moved, the previously selected and stored measurement site must be reset due to the change in the patient's position.
Reset should be made within the scanning region; and the status of operation will change the color of the program and the operation panel as described above.

When measuring the forearm, make sure that the head is kept at a sufficient distance from the equipment to prevent injuries from hitting the carriage. In the case of the right forearm, it is measured from the laser pointer position to the inside of the forearm, but in the case of the left forearm, it is measured in the opposite direction by moving the carriage to the inside of the forearm.

j. Positioning of Spine

Lay the patient on the bed with supine position, with the head facing to the top. Adjust the posture to put the spine in parallel with the vertical direction of bed. To secure horizontal placement of lumbar, place an aid tool under knees for adjustment.

After the patient's positioning, select 'Spine' to move the carriage. Using the Move button on the operation panel, move the laser pointer to the patient's navel positions (L3 to L4). When the movement is complete, press the 'Spine' button on the operation panel to determine the measurement site and press the 'Start Measurement' button on the user screen.

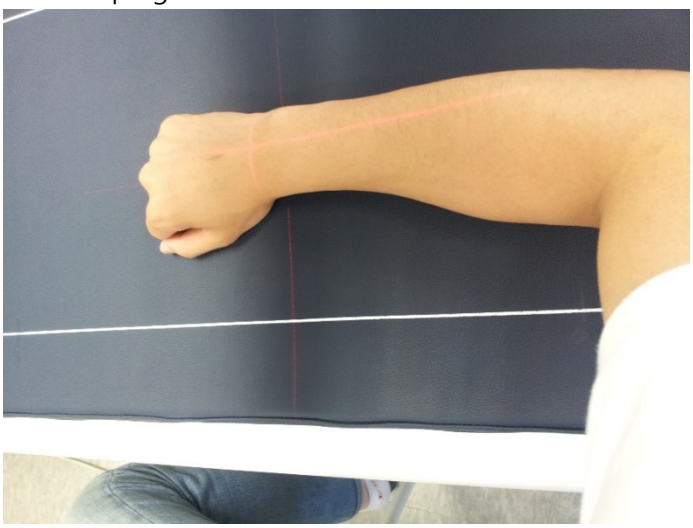
k. Positioning of Femur

Lay the patient on the bed with supine position, with the head facing to the top. Use an aid tool to place the neck of femur to be in parallel with bed surface. As shown in the figure below, fix the foot by adducting it using a Velcro that is attached to aid tool.

After patient's positioning, select either 'Left femur' or 'Right femur' to move the carriage. Using a move button on control panel, move the laser pointer to patient's iliac crest. When the movement is complete, press the 'Spine' button on the peration panel to determine the measurement site and press the 'Start Measurement' button on the user screen.

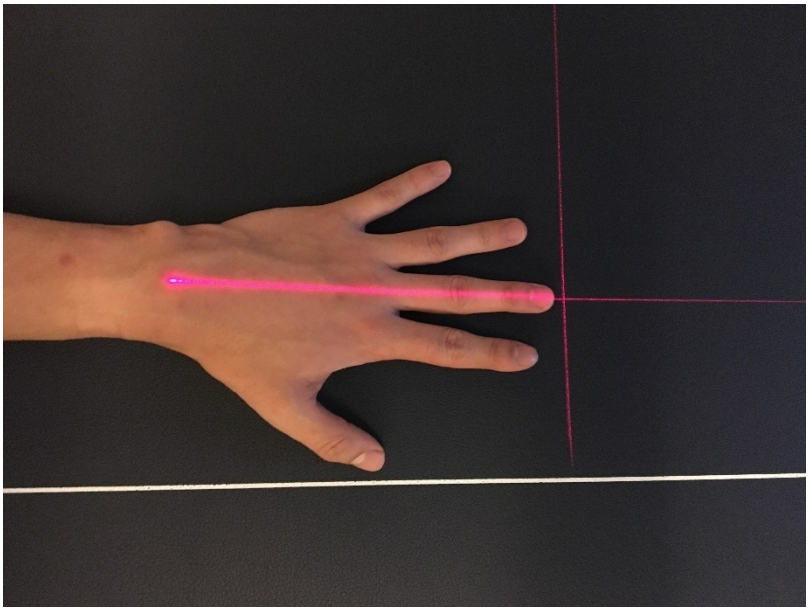
l. Positioning of Forearm

Place the patient in a chair next to the equipment, bend the upper body slightly forward, and place the arms on the bed. Allow the forearm to fit enough into the measurement area and make the patient's elbow bend to 90 degrees. Make sure the fist is in the bottom direction and the direction of the forearm is parallel to the long direction of the bed. Select 'Forearm' button to move the carriage of the equipment. Position the laser pointer about 1 cm from the radio ulna joint as shown in the picture. Select 'Forearm' on the operation panel to determine the measurement site and press the 'Measurement Start' button in the user program to start the measurement.



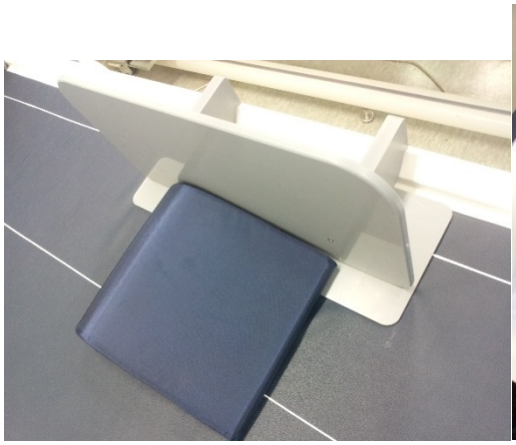
m. Positioning of GDP

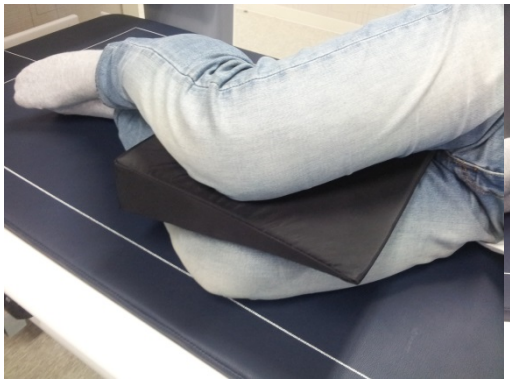
Positioning for Hand is same as with that for Forearm. But make sure that the patient spared his/her hand, not making a closed hand. Then place the laser pointer onto the tip of the middle finger (In case of GDP function, it is applied only for Left Forearm).The direction of Forearm should be parallel to that of long axis of the bed. Select 'Left Forearm' on the operation panel to determine the measurement site and press the 'Measurement Start' button in the user program to start the measurement.



n. Lateral Spine and Positioning of LVA

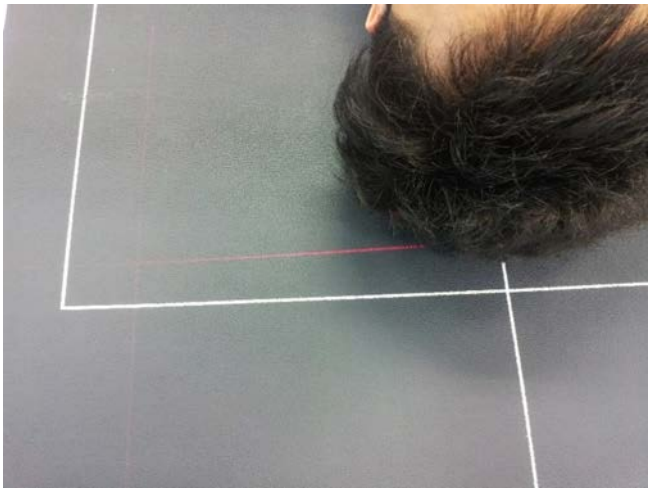
Place the lateral aids on the inner guide of the equipment as shown. Position the patient sideways on the bed and place the head upward. Position the aid cushion against the patient's waist and place the patient's back close to the plate of the aid so that the spine is level with the bed surface. Bend the knees to face forward and put the arms below head to support. Additional aid may be inserted between the knees if necessary. When the patient is finished with positioning, move the carriage by selecting either 'LVA' or 'Lateral Spine'. Use the move button on the operation panel to move the laser point to the top center of the iliac crest. When the movement is complete, press the 'Laterl Spine' or 'LVA' button on the operation panel to determine the measurement site and press the 'Start Measurement' button in the user program to start the measurement.



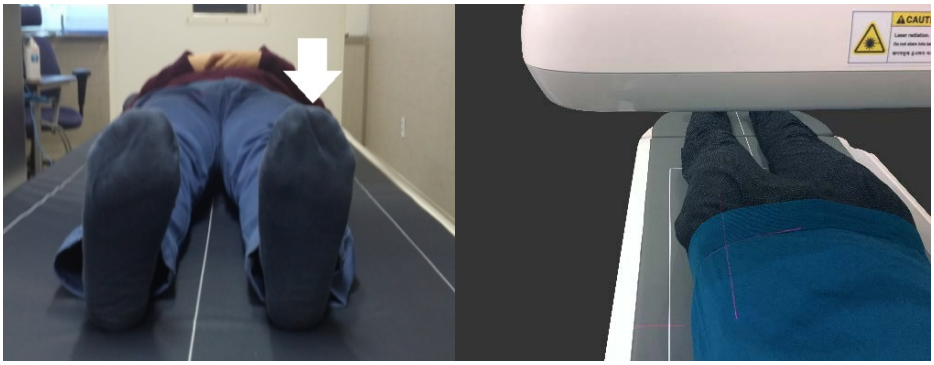

o. Positioning of Half Body

Make sure that the patient lie flat on the bed (supine position). Place the tip of the head 2-3 cm below the measurable area on the top side. Adjust the sagittal line of the body to be parallel with the long direction of the scan area and be careful not to move the arm out of the scan area by keeping the arm close to the body. When the patient is finished with positioning, move the carriage by selecting 'Half Body' to move the carriage. In Half Body function, there is no need to adjust the laser pointer using the operation panel. When the movement is complete, press the 'Half Body' button to determine the measurement area and press the 'Start Measurement' button on the measurement screen.



p. Positioning of Orthopedics

Lay the patient in a supine position on the bed. Make sure patient's toes are facing upward and then straighten the feet in an 11-shape. When the patient is finished with positioning, move the carriage by selecting 'Left Orthopedic' (Select 'Left Femur' and re-select it) or 'Right Orthopedic' (Select 'Right Femur' and re-select it). Use the Move button on the operation panel to move the laser pointer. When the movement is complete, select Mode on the operation panel and press the 'Femur' button (which has been set to Orthopedic) to determine the measurement site and press the 'Start Measurement' button on the measurement screen.



q. Once the setting for the measurement is done, click 'Measure Start' from the user program to start scanning of the set site.

r.

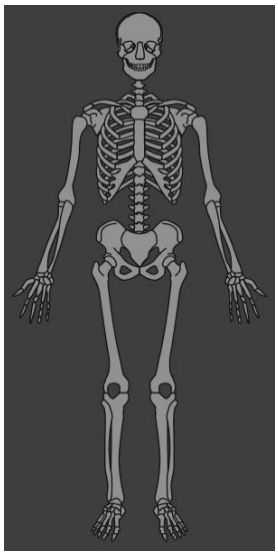


Figure 1 Normal

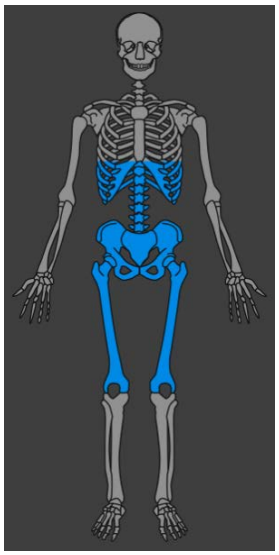


Figure 2 Selected

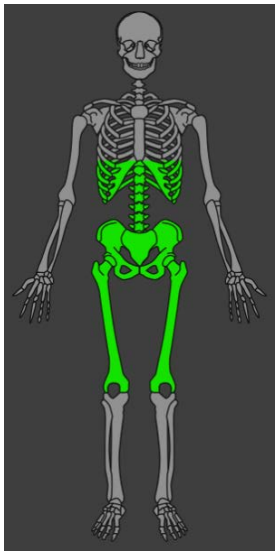


Figure 3 Scanning

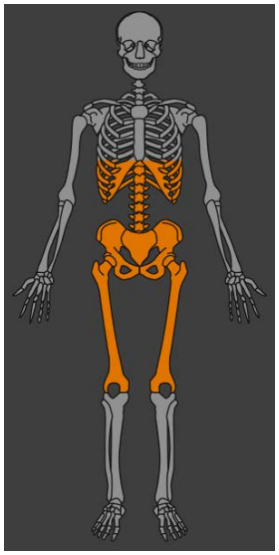


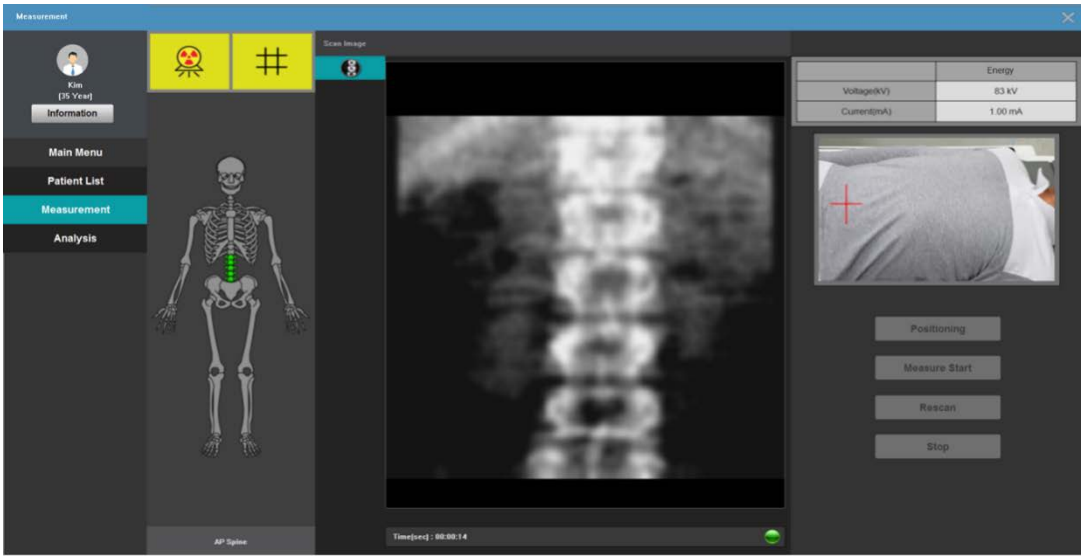
Figure 4 Finished

- Figure1 : Position setting is not done yet.
- Figure 2 : Position is set to the spine.
- Figure 3 : Scanning in progress.
- Figure 4 : Spine Scanning is complete.

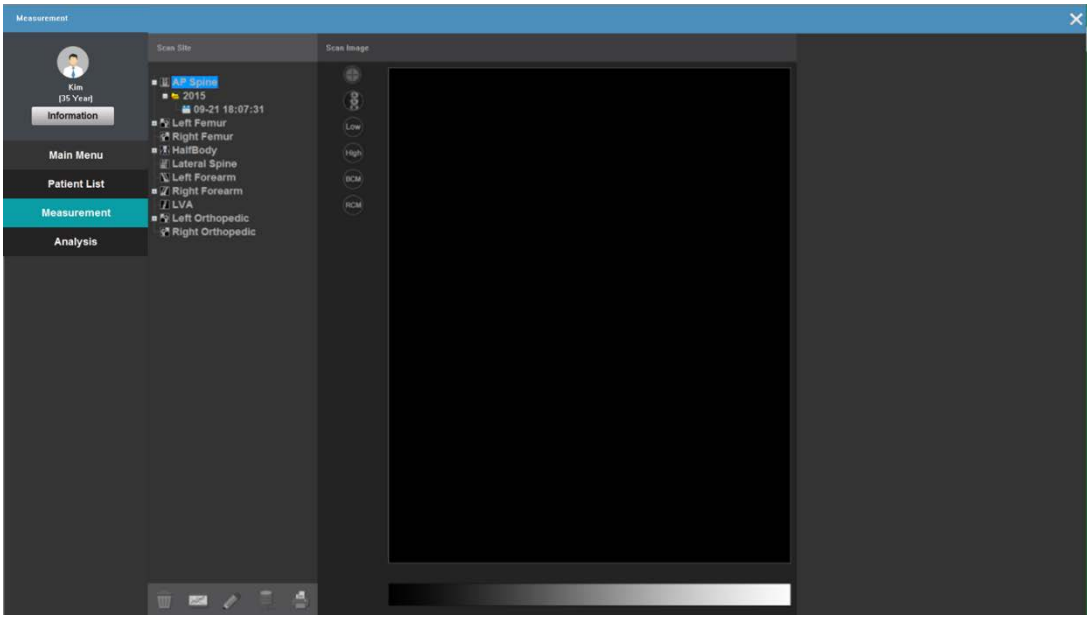
s. Scanning

① Spine: Before scanning, the carriage moves to the left by 5cm to obtain measuring mode data. Once data obtained, it automatically moves by 4cm to the region below the navel and starts scanning.

② Femur: Before scanning, the carriage moves to the bottom by 4cm to obtain measuring mode data. Once data obtained, it automatically moves by 16cm to the region below the pelvis and starts scanning.



t. Once measuring is complete, it automatically moves to the analysis screen and the equipment carriage returns to the initial position.



Make sure that the patient comes down from the table only after the equipment returns to the initial position for safety of the patient.
In One Scan, the carriage moves from the 1st measurement site to the next one without any message. If the patient stands up in the middle of the scanning assuming that the scanning is finished, it can cause injuries due to the moving carriage of the equipment.

6.5.6 Stopping the measurement of bone density

If the measuring should be cancelled during the process or there are any parts where measuring was inaccurate or when the patient experiences inconvenience, stop the measuring process of the bone density.
When emergency, use 'Emergency Switch', and for non-emergency, you can finish the process as follows:

a. Click 'Stop' during measuring.
b. The window as shown below will appear:

c. Click 'OK' to stop the process. A message pops up askomg if you want to save the image.

d. Click 'OK' to save the image. Click 'Cancel 'if you don't want to save the image.

NOTE !
Select whether or not to save the image when the scan is stopped.

6.5.7 Rescan

Rescan function is used to move the measurement area to the ROI without resetting the measurement area if the bone of the patient being measured does not match with the ROI.

a. Click 'Rescan' during the measuring.
b. Using mouse, click and drag the red box to ROI you want to re-scan.
c. Window as shown below appears.
    1. Move and scan: Restart the scanning on the moved region.
    2. Redraw Scan Area : Reset the scan area.
    3. Original Position and Scan : Restart the scanning of the original position.
d. It restarts scanning the new region.

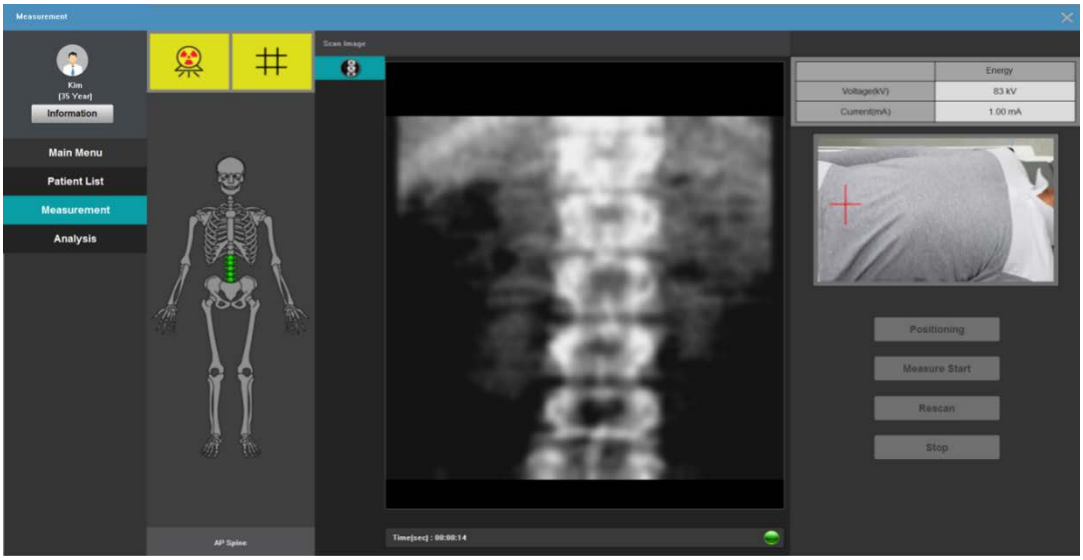


Figure A. Rescan during measuring.

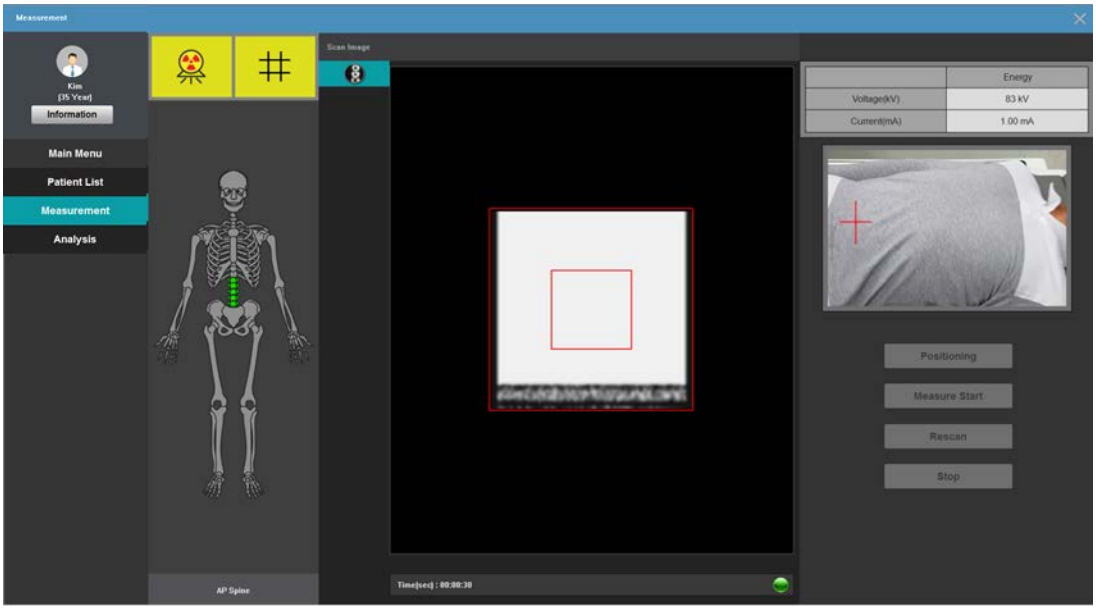


Figure B. Resetting the region

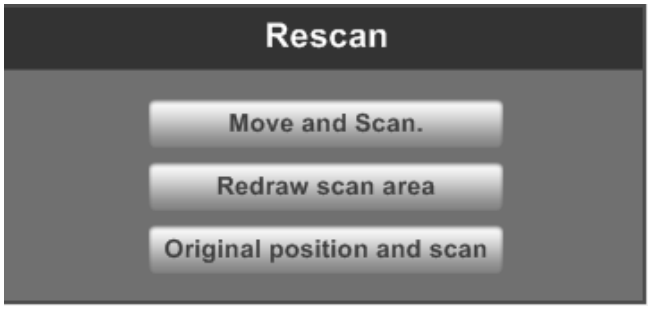


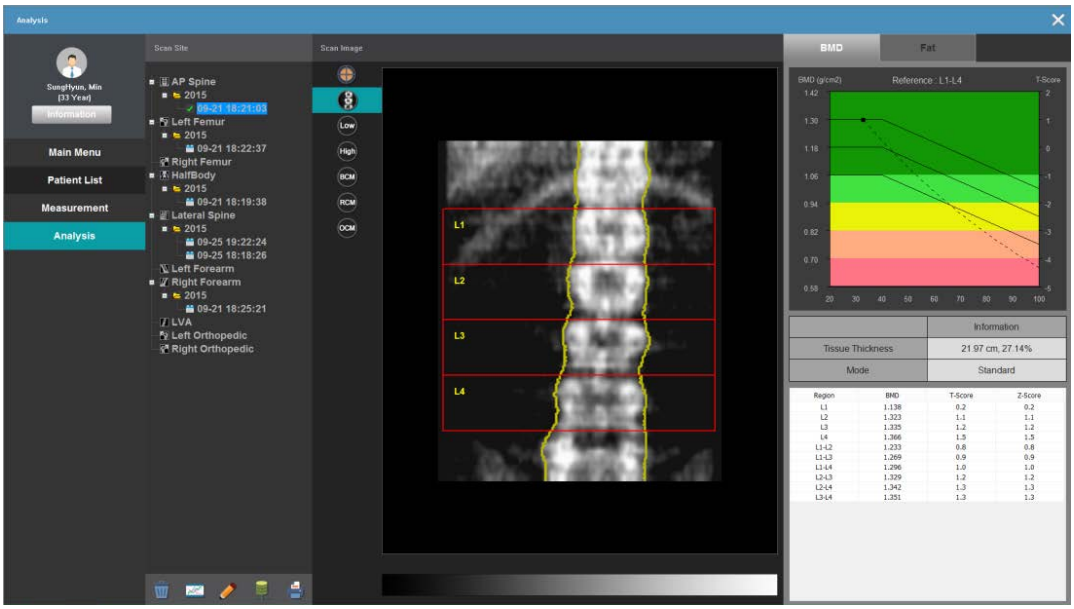
Figure C. Rescanning and Resetting the Region.

If 'One Scan' in Configuration Default Setting on the main screen is checked, it moves automatically to Analysis after a measurement is completed. If unchecked, a message appears every time a measurement is completed and you should manually proceed to 'Analysis'.

The equipment returns to the initial position after all measuring process is completed.

NOTE : When rescanning, adjust the position to fit the correct measurement area.

6.6 Analysis screen.



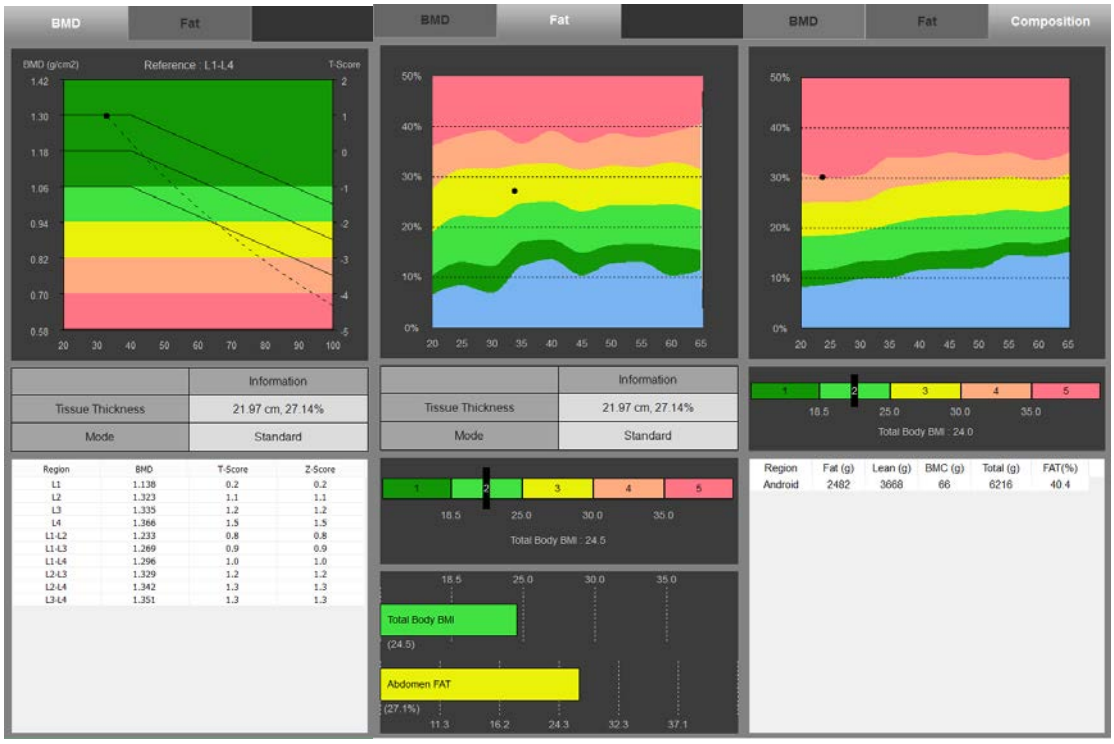
- Measured patient data is analyzed by the doctor.
- Measured data is divided by BMD and T-score values by measuring date and region in the left on the screen. Click data to show the images in the center of the screen.

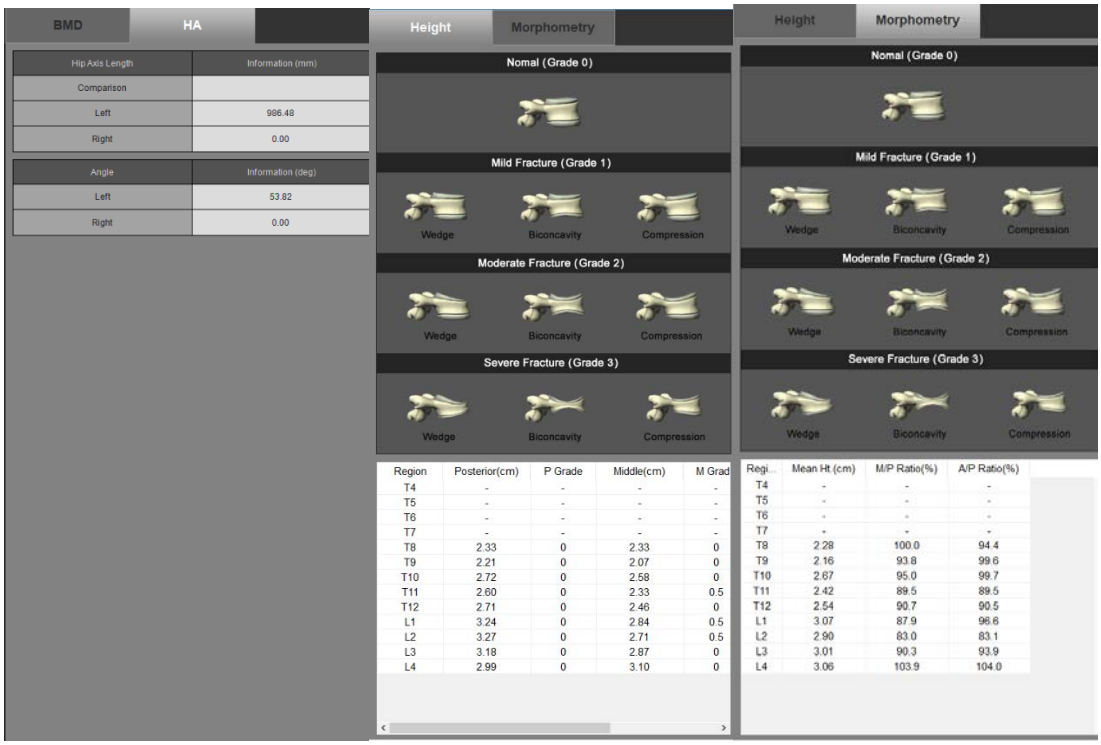
BMD mode

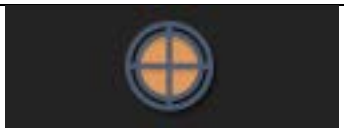
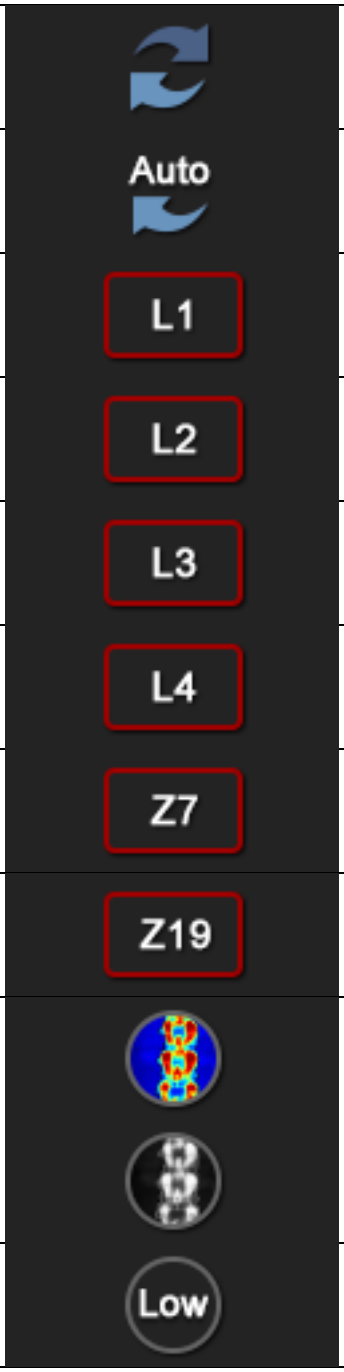
- Click BMD button in the top right to change to BMD mode.
- It indicates normal or osteoporosis by T-score distribution.
- Patient's bone density value, T-score and Z-Score by ROI are shown in the bottom right.

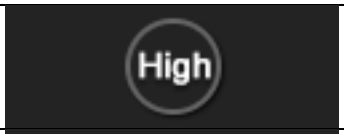
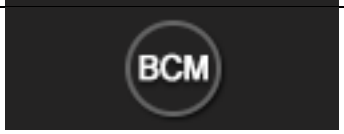
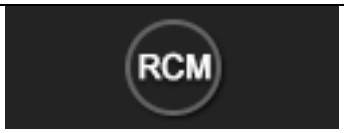
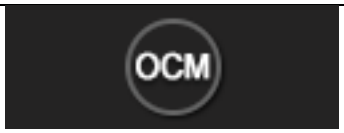
FAT/HA(Hip Analysis)

- Click FAT/HA(Hip Analysis)/Composition button in the top right to change to FAT/HA(Hip Analysis)/Composition mode.
- In case of FAT, it shows Tissue FAT% of Spine.
- In case of HA, it shows Hip Analysis and FRAX information of Femur.
- In case of Composition, it shows Half Body Composition information.
- In case of GDP, it shows the information of growth prediction.


BMD
Fat
Composition
Reference : L1-L4
Information
Tissue Thickness
21.97 cm, 27.14%
Mode
Standard
Total Body BMI : 24.5
Total Body BMI
Abdomen FAT
Region
Fat (g)
Lean (g)
BMC (g)
Total (g)
FAT(%)
Android


BMD
HA
Hip Axis Length
Information (mm)
Comparison
Left
986.48
Right
0.00
Angle
Information (deg)
Left
53.82
Right
0.00
Height
Morphometry
Nomal (Grade 0)
Mild Fracture (Grade 1)
Moderate Fracture (Grade 2)
Severe Fracture (Grade 3)
Wedge
Biconcavity
Compression
Region
Posterior(cm)
P Grade
Middle(cm)
M Grad
Mean Ht (cm)
M/P Ratio(%)
A/P Ratio(%)

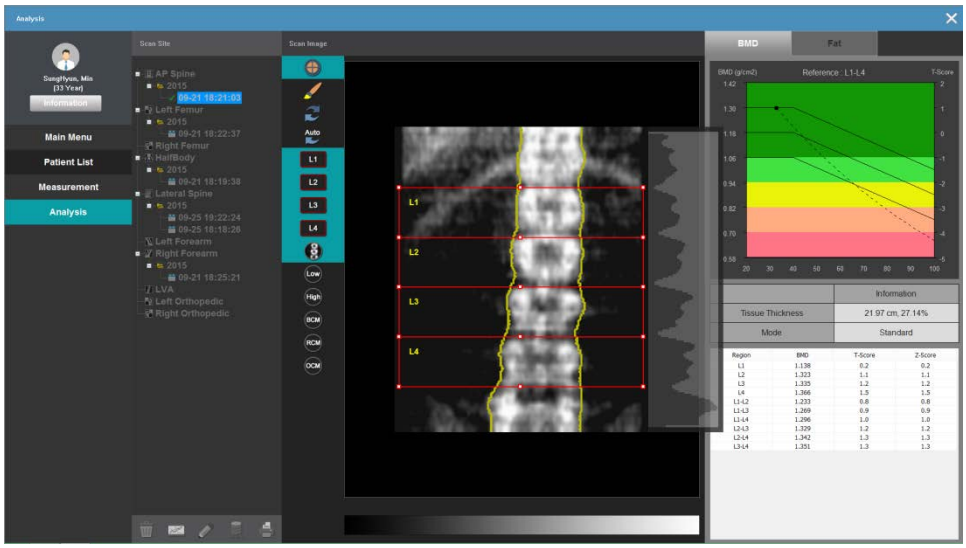
	ROI SET	It fixes or moves ROI(region of interest). If it is fixed, it shows the value of the fixed region; if it is set to moving, doesn't display the value.
	Brush	It removes any problematic elements to the patient's images or includes bone regions that are difficult to detect in ROI.
	ROI aligning	It doesn't automatically detect ROI but forms basic aligning.
	Auto ROI	Algorithm automatically detects ROI.
	L1 on/off	When measuring the spine, it deletes/adds L1 from the overall result.
	L2 on/off	When measuring the spine, it deletes/adds L2 from the overall result.
	L3 on/off	When measuring the spine, it deletes/adds L3 from the overall result.
	L4 on/off	When measuring the spine, it deletes/adds L4 from the overall result.
	Z7 on/off	Use Standard Zone (7 Zone) in ROI for Orthopedic measurements.
	Z19 on/off	Use Extended Zone (19 Zone) in ROI for Orthopedic measurements.
	Image Mode	Display images in color or black and white mode.
	Low Image	Display the image as a Low Image.

	High Image	Display the image as a High Image.
	BCM Mode	Display the image with BCM mode. It shows the bone density with 3 colors based on T-Score.
	RCM Mode	Display the image with RCM mode. It shows the bone density with 7 colors based on the Max/Min value of Patient's T-Score.
	OCM Mode	Display the image with OCM mode. It shows the bone image with colors based on T-Score(Osteoporosis or Normal).
	Result Compare	Compare the data from the same measuring site.
	Global ROI	Enable modification of the Global ROI area. Select the Spine area in the Dual Scan.
	B-Scope	Show FAT, LEAN, FAT% for the small ROI.
	Delete	Delete the selected image.
	Trend	Display the trend data of the selected image.
	Comments	Add comments on patients or on patient's images.
	Send PACS	Send the reports to PACS server.
	Print	Print out the reports.

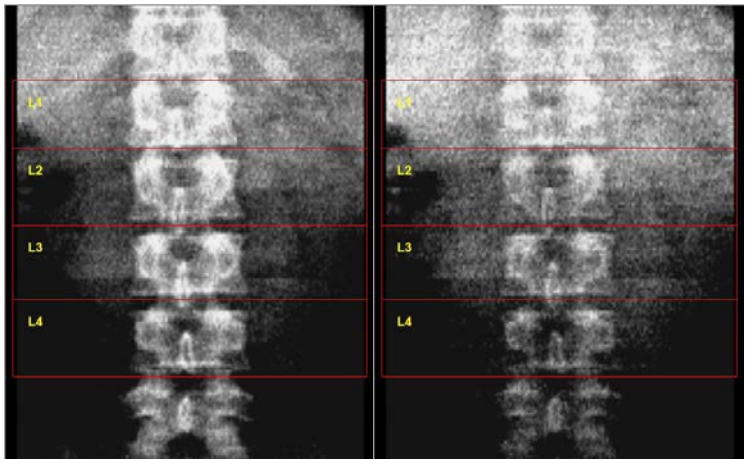
6.6.1 Image analysis (Spine)

Analysis on the measured spine image of a patient.

a. Click the measured image from the list in the left.
b. When the image appears, press 'ROI set'.
c. If ROI is normal by auto ROI, press ROI set button again.
d. If ROI is not properly set, drag the 3 points in the red line on the image to set the correct ROI; ROI should be reset for patients with bent spine or pressed spine.
   Point in the center: Adjusting the line upward/downward
   Points on both sides: Adjusting the line slope
e. If it is difficult to set ROI with eyes, use the histogram on the right.
   Histogram displays the density in the image from top in a graph; if the density is high, the histogram is higher on the right side; if the density is low, the histogram is lower.
   Place the edges between ROIs to the intervertebral discs, which is usually located at the lowest position of local valley indicated on the histogram.
   L1 is below the rib-vertebra junction, L4 is above the iliac creasts.
f. If ROI set is clicked, ROI is fixed and the calculated value is shown as the measured value.



Dual X-ray Energy Image



Low High

It analyzes the VAT of patient after measurement.

a. Click the image of AP Spine of patient at the left side of list after measurement.
b. When image pops up, press ROI set button.
c. When ROI edit mode is activated, check the ROI shape and location, if necessary, do the proper adjustment of ROI.
d. Click BScope button to anaylyze composition.
e. At BScope edit mode, press right side button of mouse on the image, select VAT mode at the pop up screen, activate VAT Mode menu and VAT mode is activated.
f. ROI adjustable point will be created. By moving this point to the left and right, visceral fat area, abdominal area and abdominal wall area will be designated.
g. When ROI adjustment is finished, press ROI set button and finish edit mode.
h. When selecting right top side of Assessment Tab, VAT and its informatiion will be identified.

What is VAT?

It is the abbreviation for “Visceral Adipose Tissue”. It analyzes visceral fat.

6.6.2 Image analysis (Dual Scan Spine)

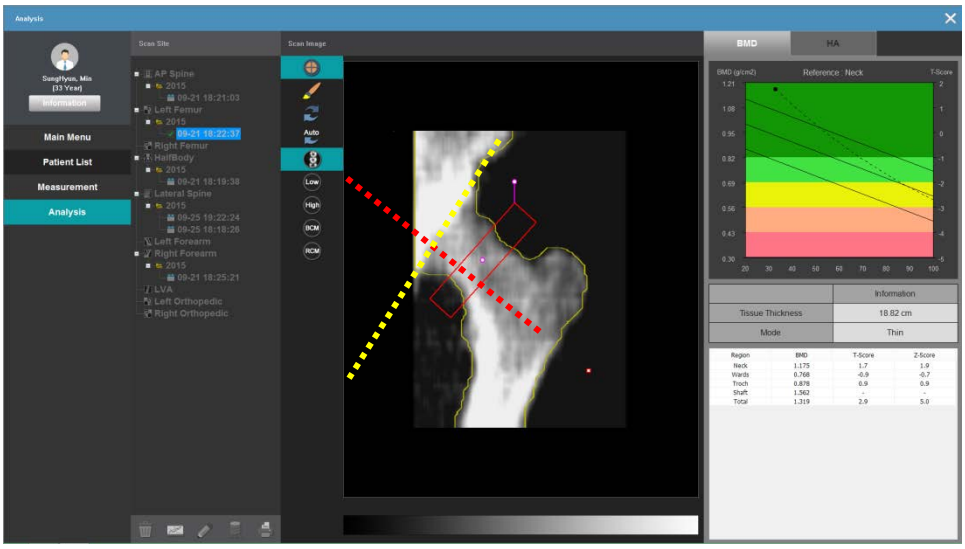
Analysis on the measured dual scan spine image of a patient.

a. When the image appears, press 'ROI set'
b. If Global ROI is not set, Global ROI setting screen will appear immediately.
c. After setting up Global ROI, set Spine ROI and Android ROI.
d. Spine ROI setting is 6-1. See Image Analysis (Spine).
e. After clicking the Dual Scan button, Drag the four points of the yellow line on the image to capture the ROI.
f. When the setting is completed, press the ROI set button once again.
g. When you click the ROI set button, the ROI is fixed so that it can not move, and the calculated value appears as the measured value.

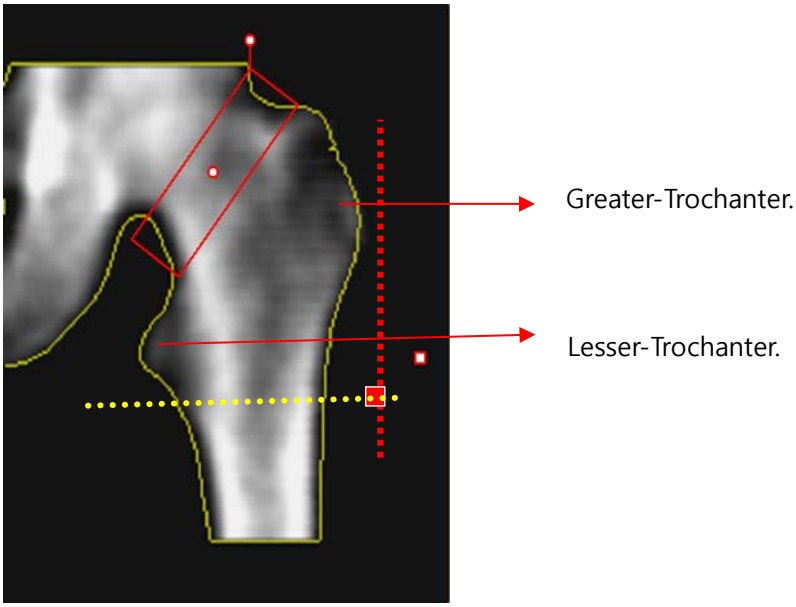
The Android ROI is below the ribs on the image, above the pelvis.

6.6.3 Image analysis (Femur)

- Analysis on the measured femur image of a patient.
  Please refer to 6.6.1.image analysis (spine) since the analysis method is basically the same.

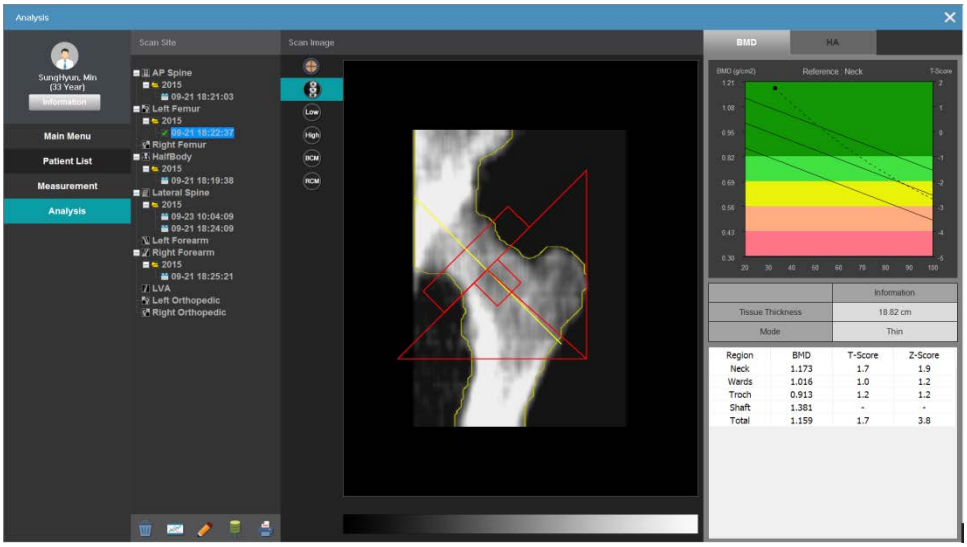


a. If femur ROI is difficult to detect automatically, follow the process below:
   Click 'ROI set' button.
b. Drag the red box that detects femur ROI and position the point in the center of the box in the center of the neck.
c. Control the slope with the pointer outside the box to make the neck and box slope vertical.



d. Align other draggable pointers than the box from underneath the lessor-trochanter to the right and position the convergent point where the line from the outside of the greater-trochanter meets vertically.

e. Click ROI set button to fix ROI and create a triangular area.

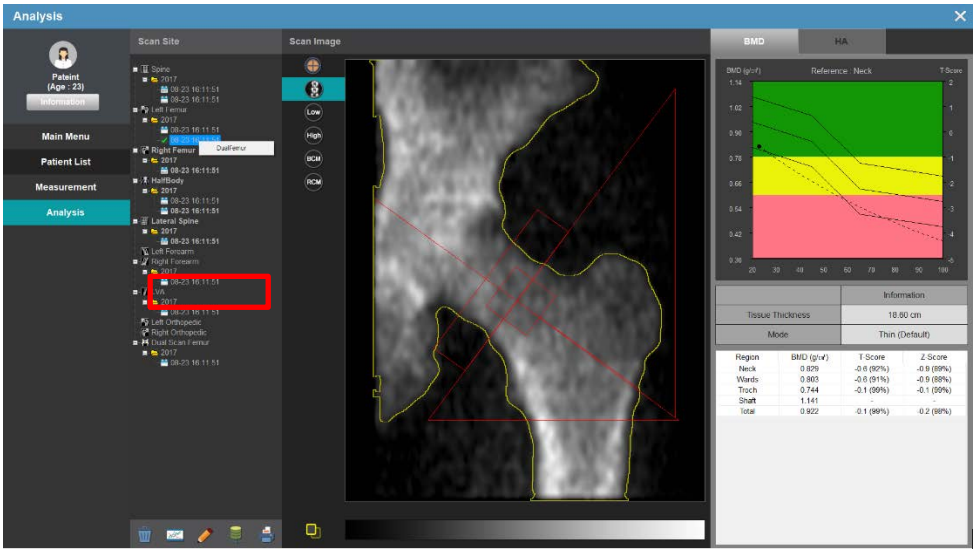


f. The result is displayed.

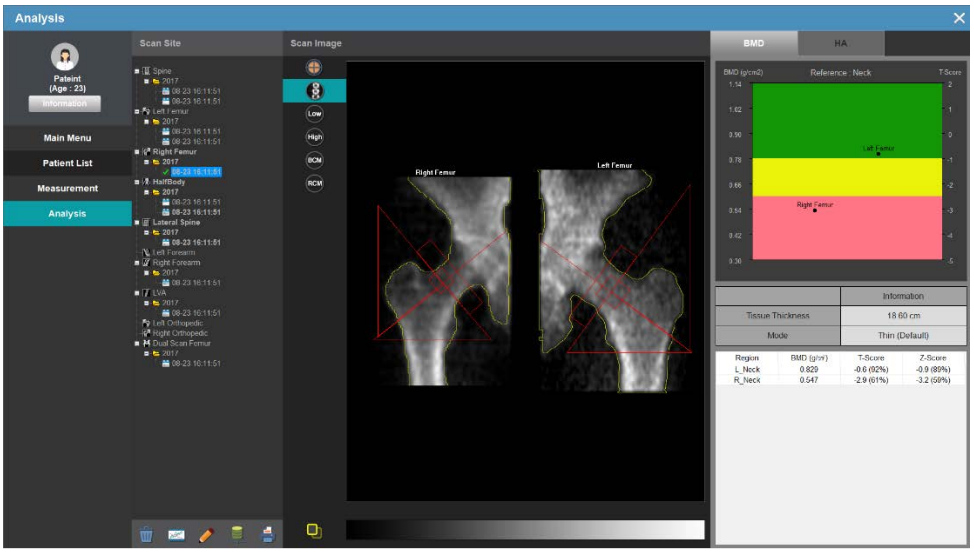
- It also offers Dual Femur image analysis.

a. Please check whether the measured image of Left Femur and Right Femur exists.

b. Please choose Left Femur or Right Femur image on the list. Then click right button of the mouse and check 'Dual Femur' to operate Duar Femur mode.



c. Please select the opposite Femur image on the list.



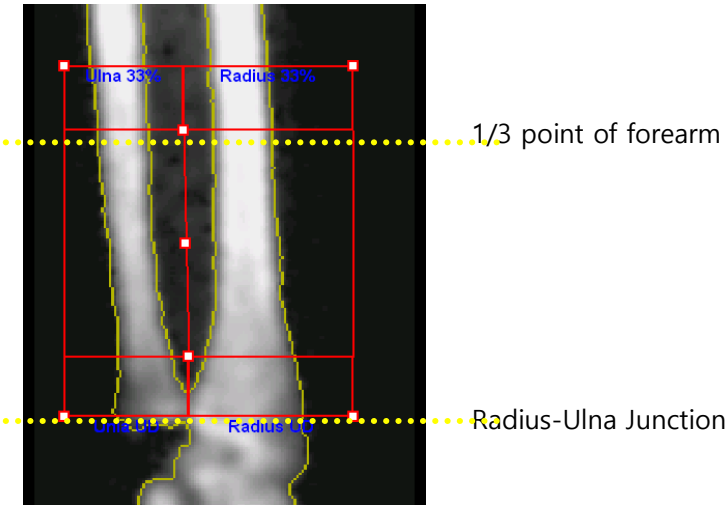
6.6.4 Image analysis (Dual Scan Femur)

a. When the image appears, press 'ROI set'.
b. If Global ROI is not set, Global ROI setting screen will appear immediately.
c. After setting Global ROI, set Femur ROI and Gynoid ROI. (You can set each Global ROI according to Left Femur and Right Femur selection on the right.)
d. For Femur ROI settings, refer to 6-3 Image Analysis (Femur) (You can set the Left and Right Femur ROIs by activating the Left Femur and Right Femur buttons.)
e. After setting the Gynoid ROI, click the Dual Scan button, Drag the four points the yellow line on the image to capture the ROI.
f. When the setting is completed, press the ROI set button once again.
g. When you click the ROI set button, the ROI is fixed so that it can not move, and the calculated value appears as the measured value.

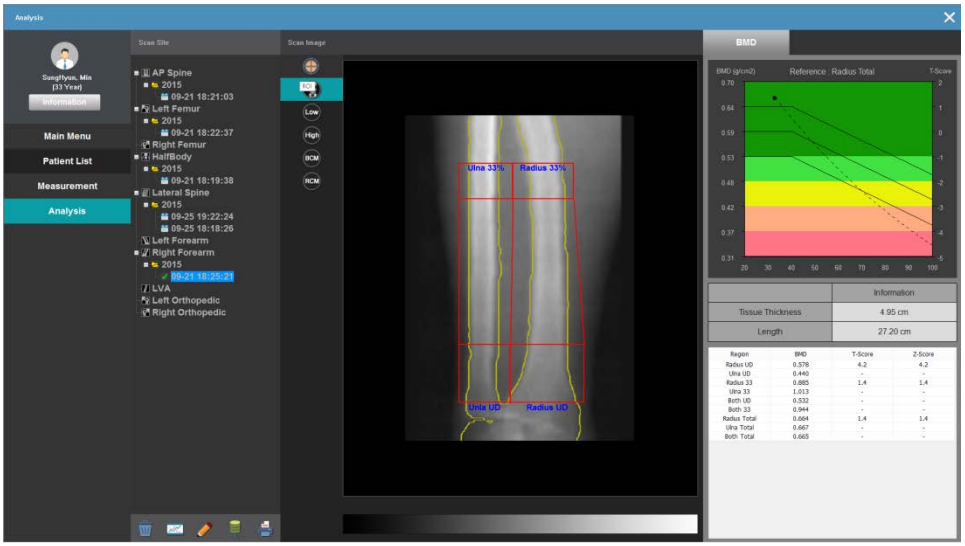
6.6.5 Image analysis (Forearm)

Analysis on the measured forearm image of a patient.

a. If forearm ROI is difficult to detect automatically, follow the process below: Click 'ROI set' button.
b. Drag the point in the center of the forearm ROI box to adjust the overall ROI position.
c. Drag the point in the center of UD ROI box to move the entire UD ROI site. Adjust ROI's bottom edge to match the radius and height of ulna junction point. You can adjust 33% ROI in the same way. 33% ROI site can vary depending on the arm length of the patient; generally ROI's bottom edge is positioned at 1/3 point of the forearm.
d. Drag the point at ROI box edge to adjust the size of each ROI. You can enlarge or reduce the size of each ROI according to the shape of the image. ROI's width is adjustable freely; however it is desirable to keep the thickness given as the initial value.



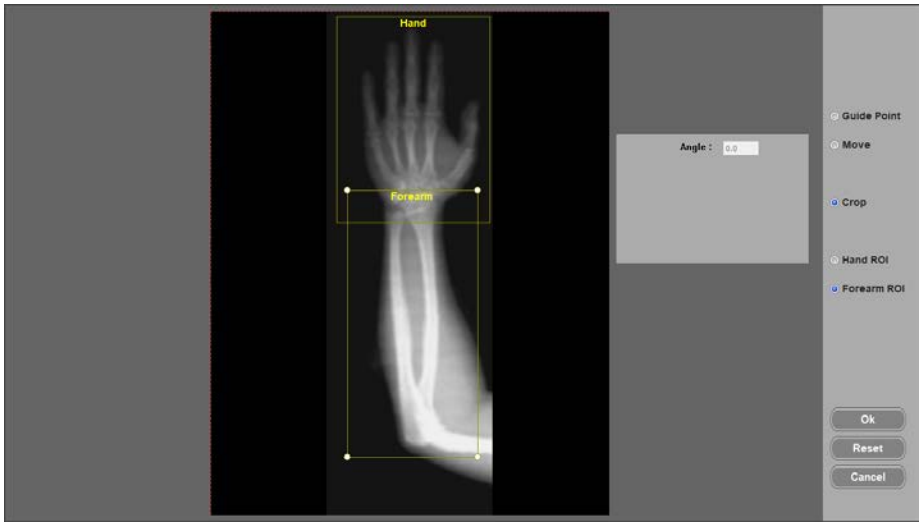
e. Click ROI set button to fix ROI and create the value of each ROI.
f. The result is displayed.


Analysis
Main Menu
Patient List
Measurement
Analysis
Scan Site
Scan Image
BMD
Ulna 33%
Radius 33%
Ulna UD
Radius UD
Information
Tissue Thickness
4.95 cm
Length
27.20 cm

6.6.6 Image analysis (GDP)

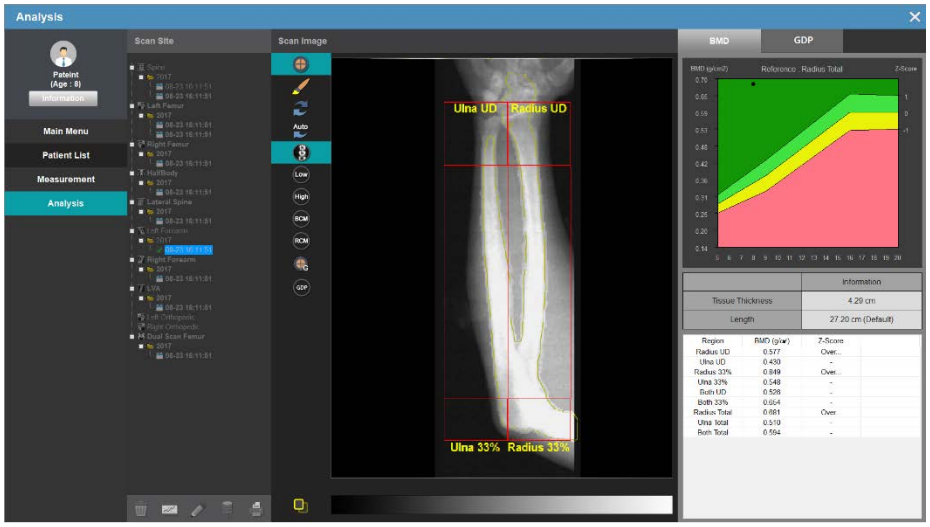
It analyzes GDP image of patient after measurement.

a. After measurement, search GDP image from left forearm list and select it.
b. When you press ROI button, Global ROI edit mode is activated. Select Hand and Forearm and set up Global ROI respectively.



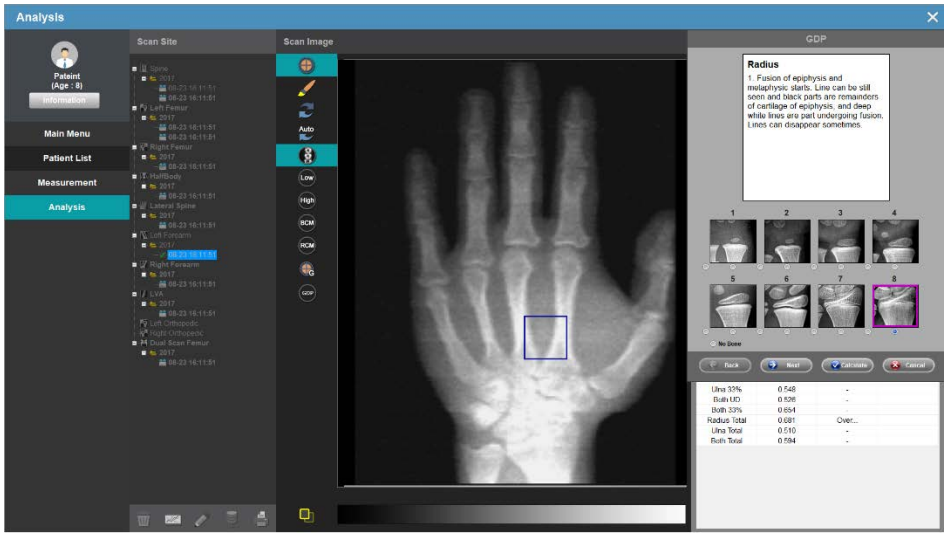
c. You can analyze Hand&Forearm respectively.

d. Basic analysis screen is left forearm. Press ROI button and select ROI and you can analyze left forearm.



e. If you press "GDP" button, you can analyze GDP.

f. With the use of mouse wheel, you can scale up & down the image, and by moving mouse, you can choose picture as similar as possible.

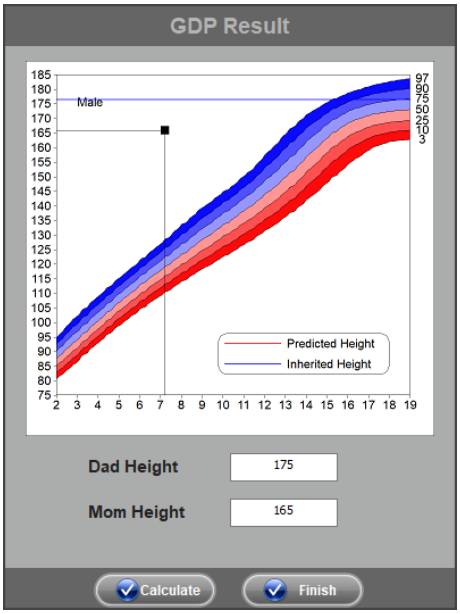


g. After selecting all parameters, there will be pop up screen about height of parent and secondary sex character.

h. If you press, "ok", GDP pop up screen will be disappeared, and you can find the result from GDP tab on the right side

i. If patient is below 20 years old, although patient does not measure GDP function, estimated height of patient can be predicted when he or she grows up based on the height of parents of patient.

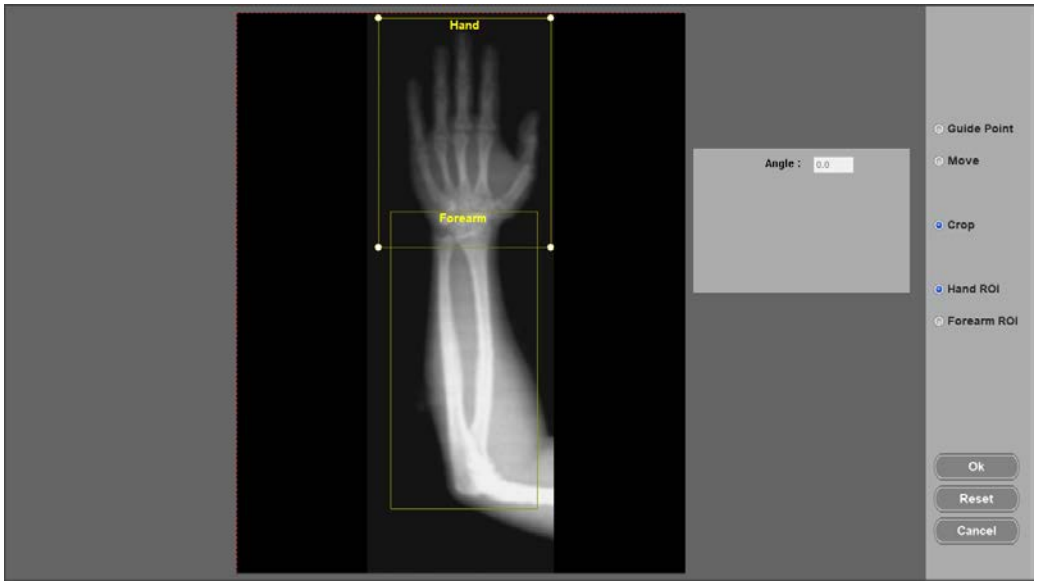
j. When entering height of parent, GDP can be predicted.



6.6.7 Image analysis (Hand)

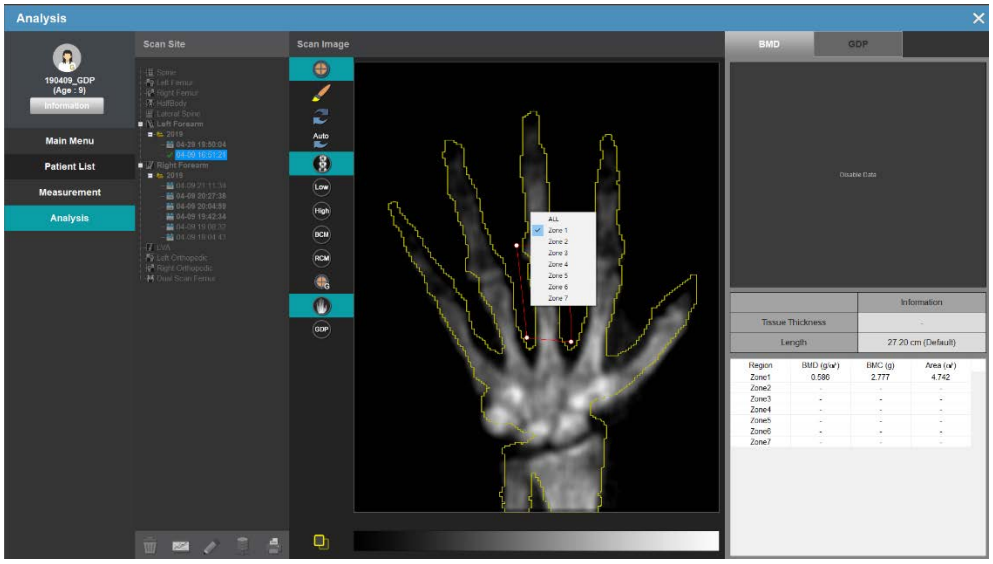
It analyzes hand image of patient after measurement.

a. Please click the hand image on the list.
b. When you press ROI button, Global ROI edit mode is activated.
c. Select Hand and set up Global ROI setting.



I. Guide Point : It's a function to set the Global ROI to the same area.
II. Move : It's a function to move Global ROI.
III. Rotate : It's a function to rotate Global ROI when the image is tilted.
IV. Crop : It's a function to resize the Global ROI.

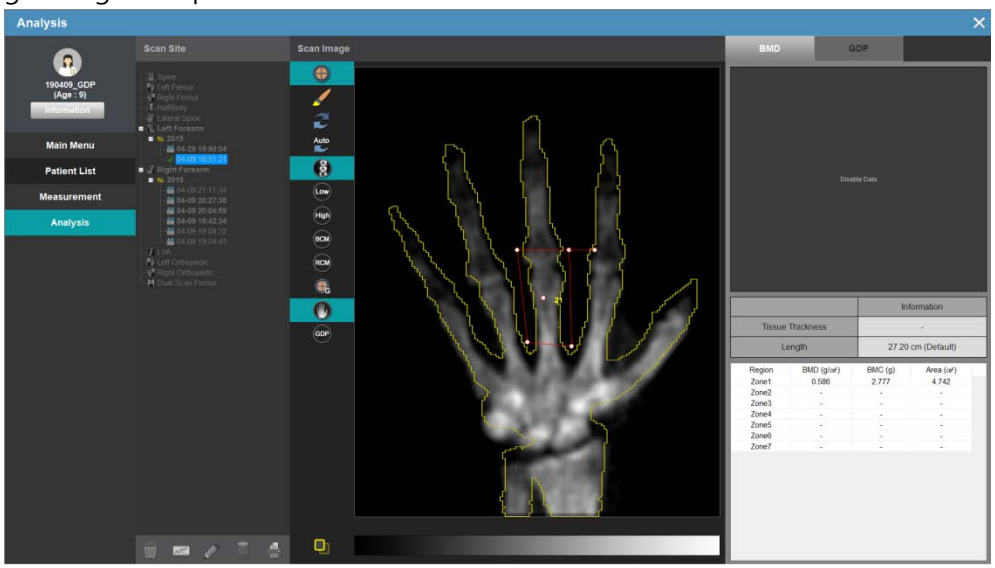
d. Basic analysis screen is Hand. You can select the ROI when you click the right button of the mouse on the image area.



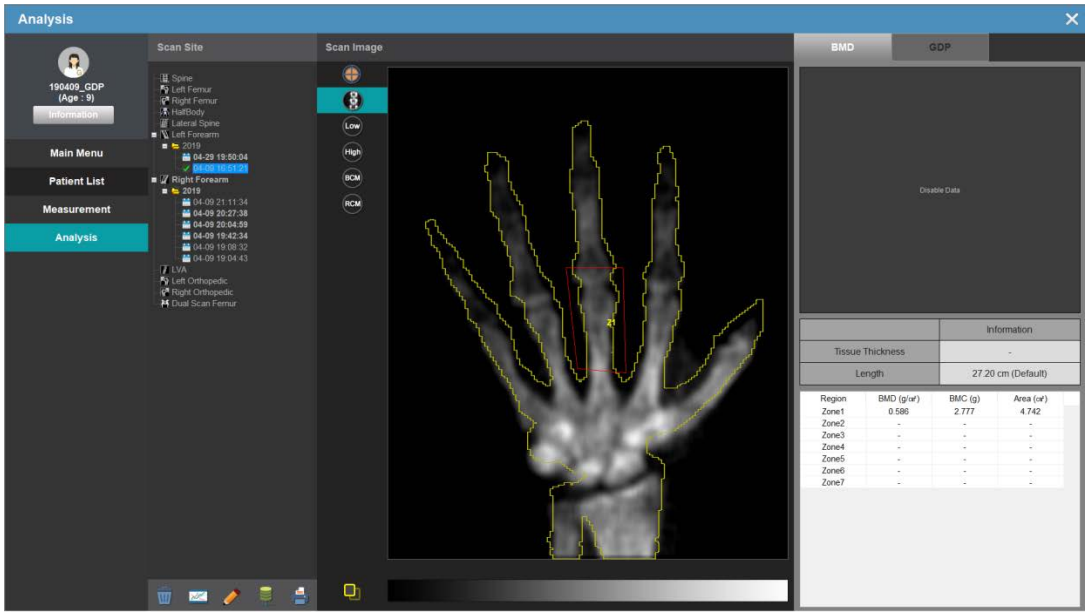
e. Drag the point in the middle to set the ROI that the operator wants to check.

f. Use the pointer outside the box to adjust an inclination

g. Drag the 4 pointers in ROI area to resize the ROI area.



h. When you press ROI button, ROI will be fixed and analysis result of ROI is displayed.

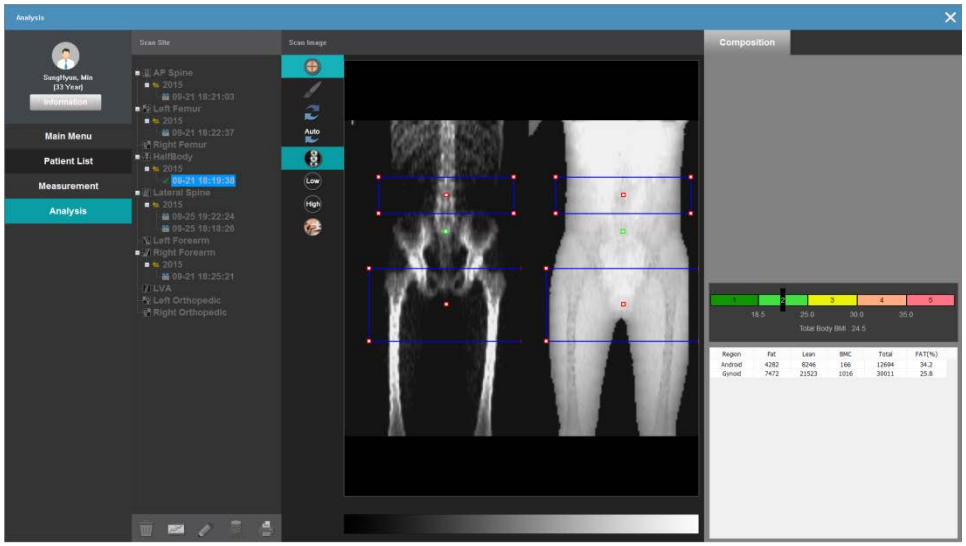


i. If you want to compare with the previous data or copy the ROI, please click 'ROI Compare' button.

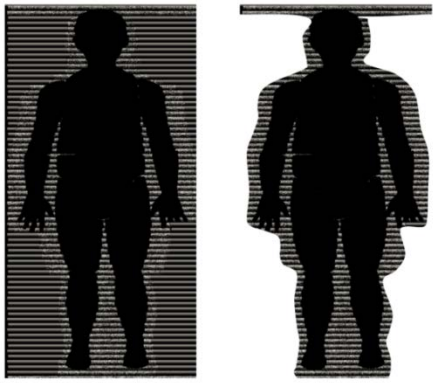
6.6.8 Image analysis (Half body)

Analysis on the measured total body image of a patient.

a. After measuring, ROI is automatically set. When ROI is not set automatically or additional adjustment is needed, follow the process below:
b. Press ROI button to open ROI edit mode. Drag the box-shaped button to adjust the shape and size of each ROI. When changing ROI, ROI is adjusted according to the condition.



Rect Scan



Ergonnomic Scan

c. Pelvis and neck center point can be adjusted only in vertical direction while spine ROI point, head top point and foot point can be adjusted only in horizontal direction. You can adjust so that each body part can be included in

proper ROI.

d. Once ROI adjustment is done, press ROI set button to finish the edit mode. Analysis value is recreated automatically by ROI.

> ⚠ What is Android and Gynoid?
> As a form of central obesity, this is closely related to heart disease, diabetes, illnesses, etc.
> Android (apple-shaped) : Mainly the fat accumulated obesity in the abdominal area is called Android obesity. It appears mainly to men.
> Gynoid (pear-shaped) : The fat accumulated in the form of hip or femoral region is called Gynoid obesity. It appears mainly to women.

It analyzes the VAT of patient after measurement.

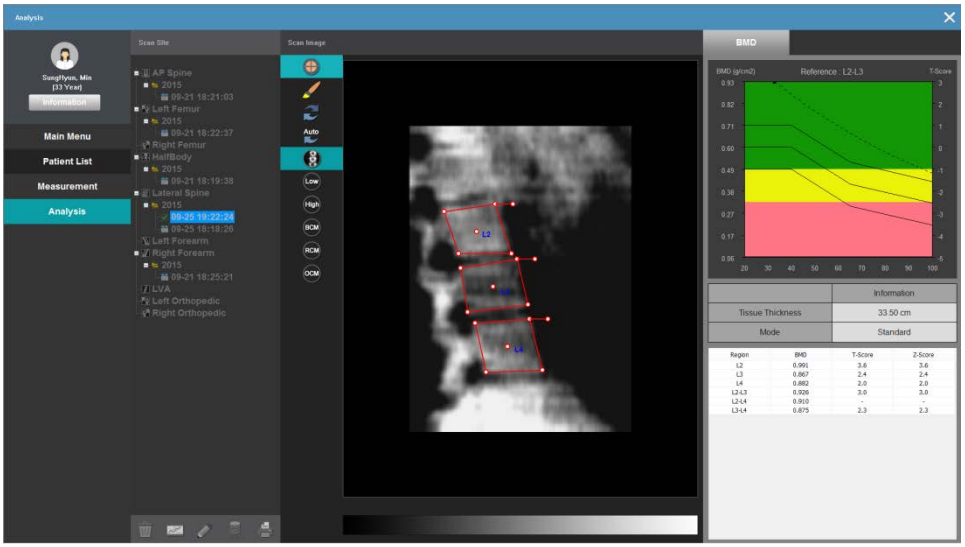
a. Click the image of half body of patient at the left side of list after measurement.
b. When image pops up, press ROI set button.
c. When ROI edit mode is activated, check the ROI shape and location, if necessary, do the proper adjustment of ROI.
d. At ROI edit mode, press right side button of mouse on the image, select VAT mode at the pop up screen, activate VAT Mode menu and VAT mode is activated.
e. When moving square by dragging left screen, expanded image with expanded area will be displayed in the screen.
f. At the expanded image on the right side, ROI adjustable point will be created. By moving this point to the left and right, visceral fat area, abdominal area and abdominal wall area will be designated.
g. When ROI adjustment is finished, press ROI set button and finish edit mode.
h. When selecting right top side of Assessment Tab, VAT and its informatiion will be identified.

> ⚠ What is VAT?
> It is the abbreviation for "Visceral Adipose Tissue". It analyzes visceral fat.

6.6.9 Image analysis (Lateral Spine)

Analysis on the measured lateral spine image of a patient.

a. If the lateral spine ROI is not automatically detected, follow the process below: Press ROI set button.
b. Drag the point in the center of the lateral spine ROI to adjust the entire ROI site.
c. Adjust the slope outside the box with the pointer to adjust the slope of ROI.

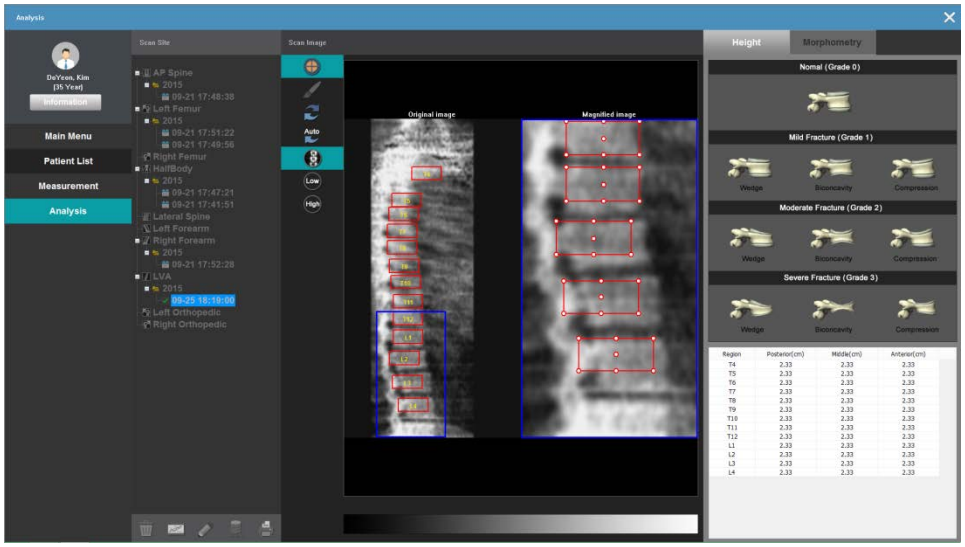


d. Drag 4 points outside ROI to adjust the size of ROI area. For a patient with the lateral spine button pressed, ROI re-adjustment is needed for more accurate test.
e. Click ROI set button to fix ROI and recreate the value of each ROI.

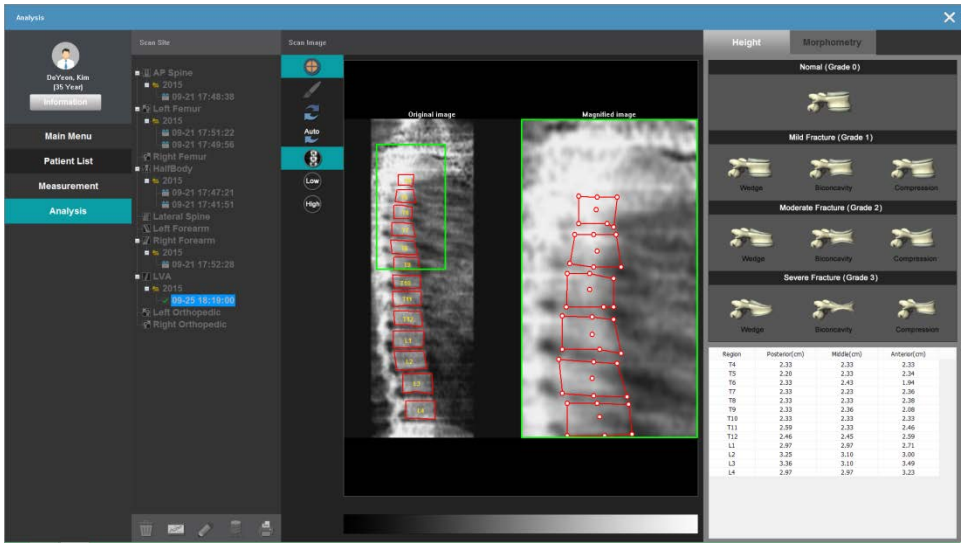
6.6.10 Image analysis (LVA – Lateral Vertevra Assessment)

It measures image of LVA

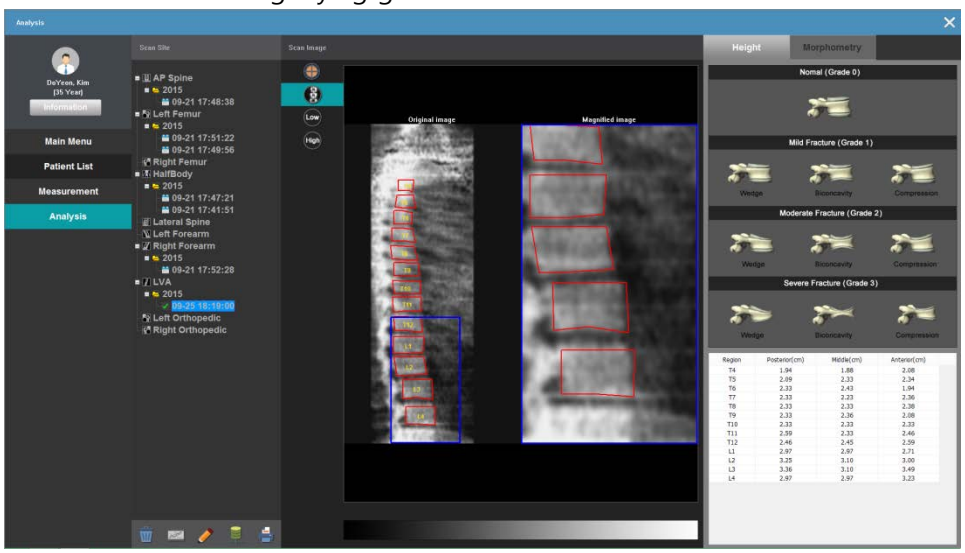
a. From the list in the left, click the patient's image obtained by scanning.
b. If the image appears, click ROI set.
c. If you put the mouse cursor on the original image, the cursor is changed into a magnifying glass and a rectangle is made up surrounding the cursor. The expanded image will appear.



d. If you click on the area, the color of the area will be changed. The area will be fixed, and the points will appear on the magnified image to adjust the ROI. Adjust the location of whole ROI by dragging the middle point.
e. There are 6 points in a ROI area and you can adjust the size of ROI by moving each point.



f. Once the area adjustment is completed, the mouse cursor will change into a magnifying glass again when you click the mouse button on the right. You can move the magnifying glass to other areas.



g. After moving the mouse, repeat the process a forementioned to adjust each area; click ROI set button to analyze each ROI value and show the result.

6.6.11 Image analysis (HA – Hip Anlaysis)

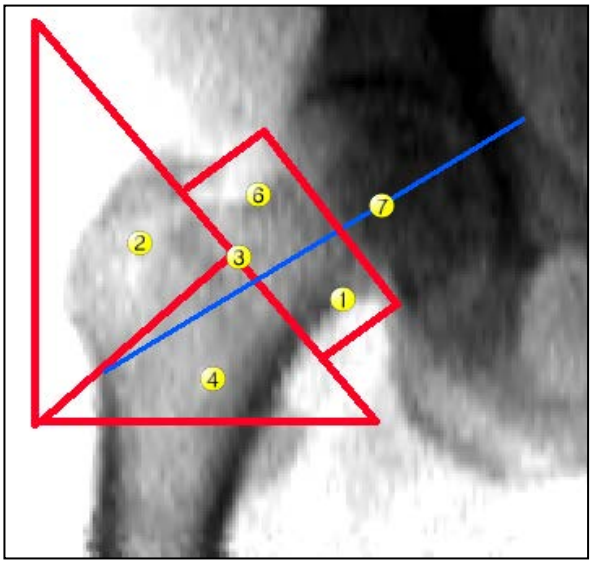
Analysis on the measured femur image of a patient

> We do not recommend to use HA measuring result for clinical diagnosis on femur-related diseases.

a. Definition

It predicts structural characteristics of the measured femur image to help users analyze and predict danger of fracture on patients.

HA displays information on HAL(Hip Axis Length), FNW(Femoral Neck Width), UFN-BMD(Upper Femoral Neck BMD) and FNSA(Femoral Neck Shaft Angle).

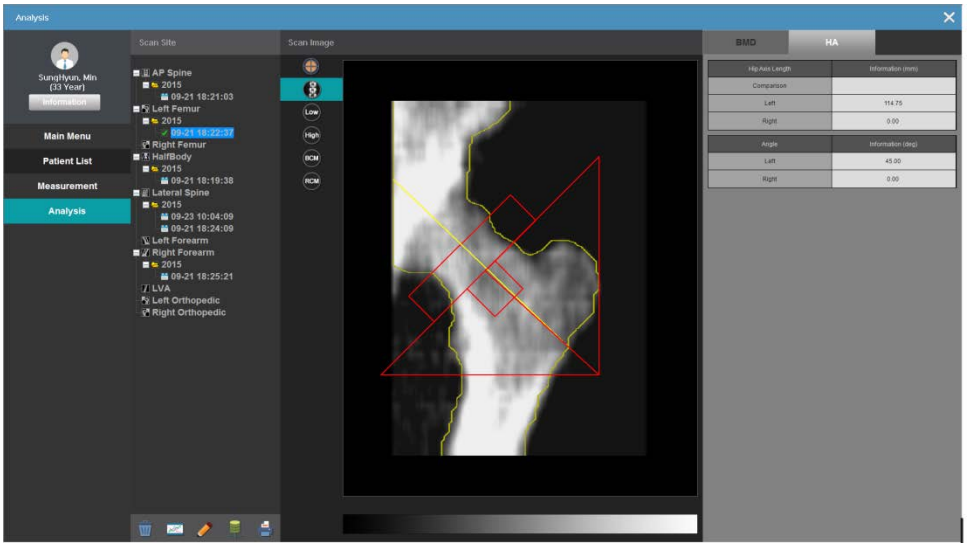


① Lower Femoral Neck
② Femoral Trochanter
③ Ward
④ Shaft
⑤ Upper Femoral Neck
⑥ Hip Axis Length

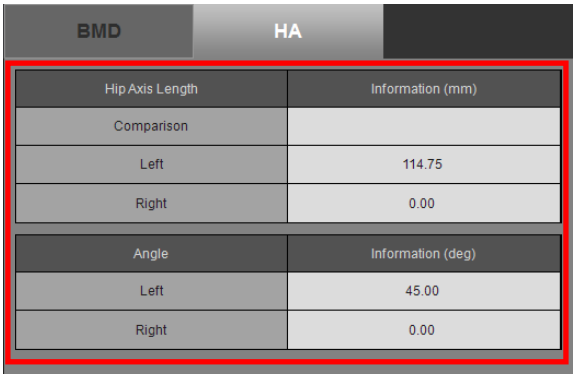
In current software version, only HAL, and FNSA are supported. FNW, UFN-BMD items will be added later.

b. Output information

After measuring the femur, you can check HAL and FNSA values under HA tab. The following figure is analysis screen that displays HA information on both femoral regions.



c. On HA tab, the length of femoral axis of left/right femoral section is displayed in mm, and the femoral axis is displayed in degree. This analytical information is notified to user.



BMD | HA

Hip Axis Length	Information (mm)
Comparison	
Left	114.75
Right	0.00

Angle	Information (deg)
Left	45.00
Right	0.00

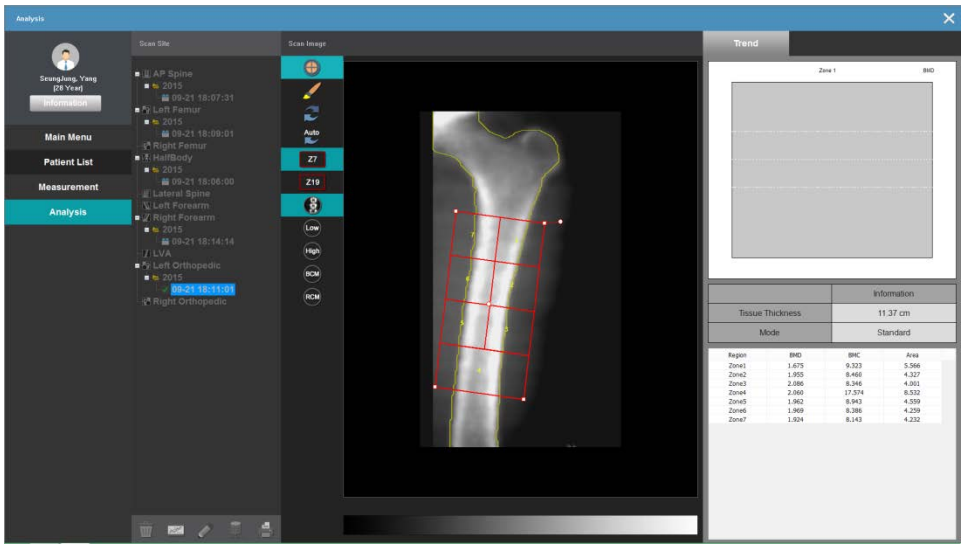
6.6.12 Image analysis (orthopedics)

Orthopedics and Prosthesis Hip function is used for the patient who has surgery of Femur with artificial bone in order to measure BMD and evaluate bone status

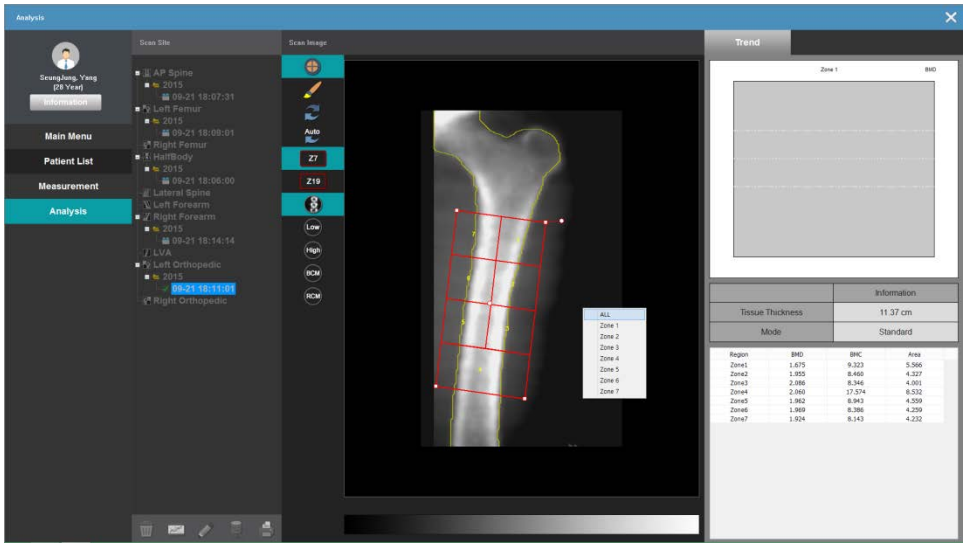
> We supply OrthopedicGroup 7 Zone for BMD analysis as basic standard mode, and by dividing 19 Zone we also supply extended zone

Orthopedic analysis is composed of Standard Mode's 7 zone and Extend Mode with 19 zone. We supply femoral Shaft BMD and its trend

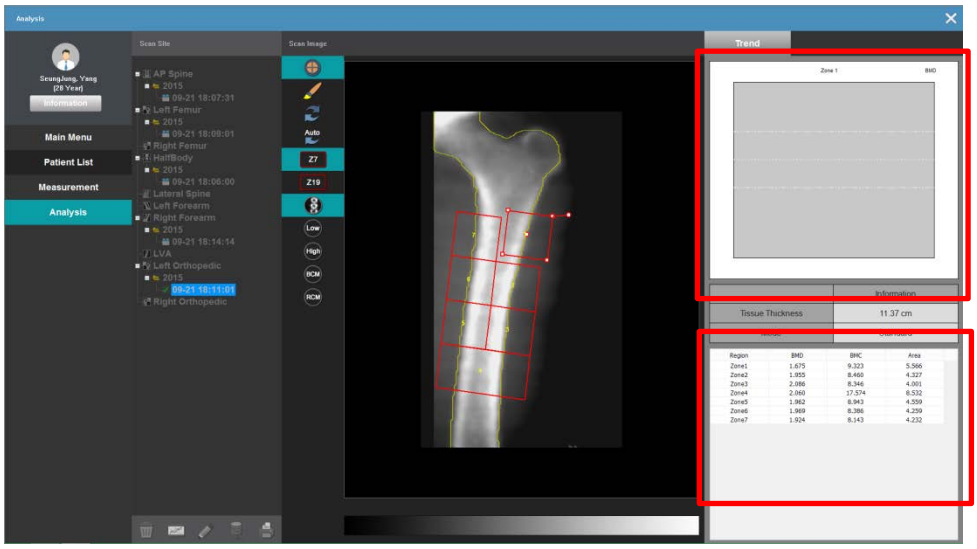
a. Click the image of patient on the left side of list.
b. When image is appeared, press ROI set button.
c. By dragging point in the middle of ROI, adjust overall ROI area.
d. By dragging point out side of square, adjust tile of ROI



e. In the ROI area, there are total 4 points, you can click each of point and can adjust size.(when clicking right side of mouse, pop up screen is appeared and can select each of ROI)



f. When clicking ROI set button, analysis result of ROI is displayed, if there is previous image, ROI trend is also displayed.



It also offers Dual Orthopedics image analysis.

a. Please check whether the measured image of Left Orthopedics and Right Orthopedics exists.

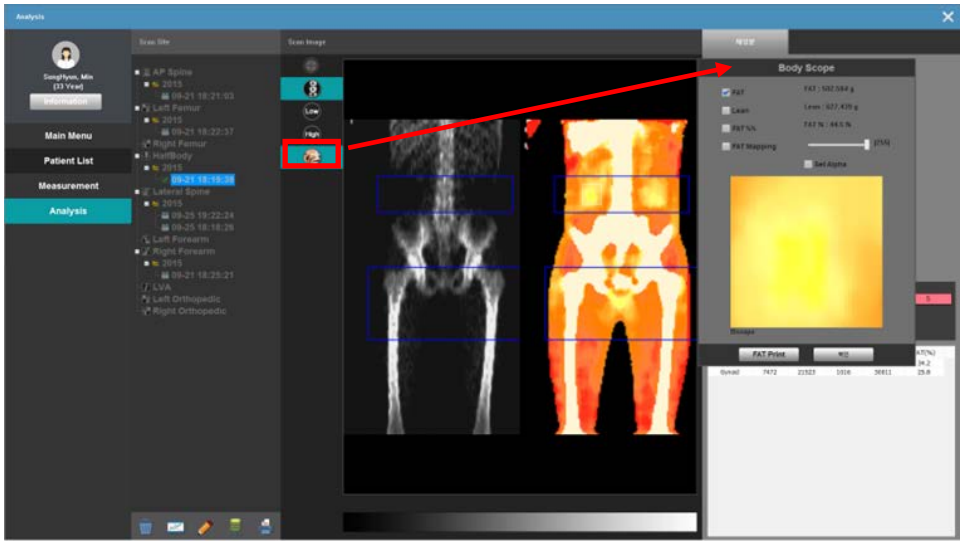
b. Please choose Left Orthopedics or Right Orthopedics image on the list. Then click right button of the mouse and check 'Dual Orthopedics' to operate Dual Orthopedics mode.

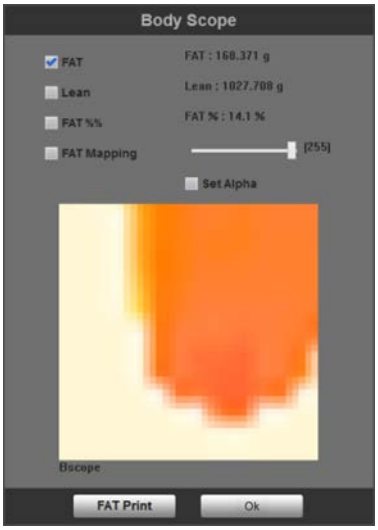
c. Please select the opposite Femur image on the list.

6.6.13 Image analysis (B-scope)

Body Scope Mode shows the FAT, LEAN, FAT% of the patient visually.
In order to manage obesity, it shows FAT (g), LEAN (g), FAT%, etc. in desired area.

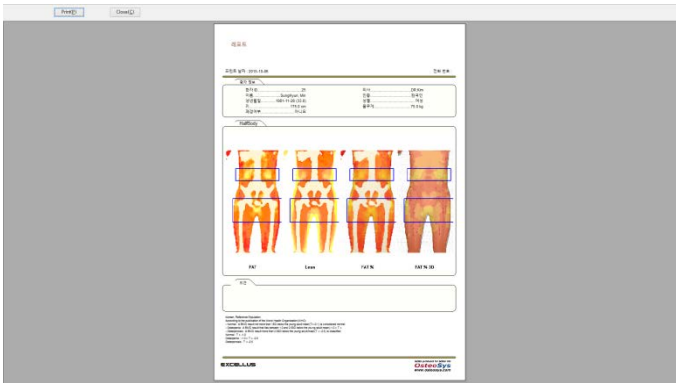
a. When you select the Scope button in the anlaysis screen, Body Scope window appears.





- FAT%: Check the FAT% on the desired area.
- Image box: It shows an image of the corresponding area.
- FAT Print: Print FAT information
- Ok: Exit the window

b. If you choose FAT Print, Print the FAT information of Half Body



6.6.14 Using brush

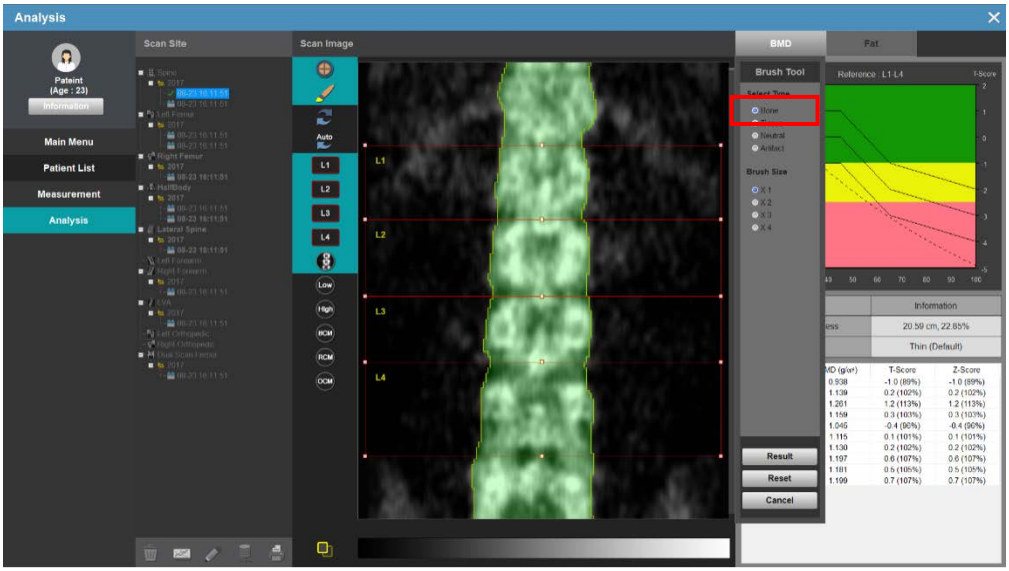
Brush removes any elements that can affect the measured values of the image or is used to include measured values of randomly removed parts.
You can adjust areas for bone, tissue, neutral and artifact images displayed.

a. Click a patient's image from the list.
b. Once the image appears, click ROI set button.
c. Click Brush.
d. Check one of the functions: Bone, Tissue, Neutral and Artifact.
e. Select the brush size.
f. Move the mouse to place it on a specific area and paint the color by rubbing the mouse with it clicked.
g. Once the area setting is done, click Result.
h. Check whether coloring is properly reflected in the result in the image.
i. If it is not done in proper area, click Reset.
It will return to the initial patient image.
j. If you want to cancel the area setting, click Cancel.

 We supply OrthopedicGroup 7 Zone for BMD analysis as basic standard mode, and by dividing 19 Zone we also supply extended zone

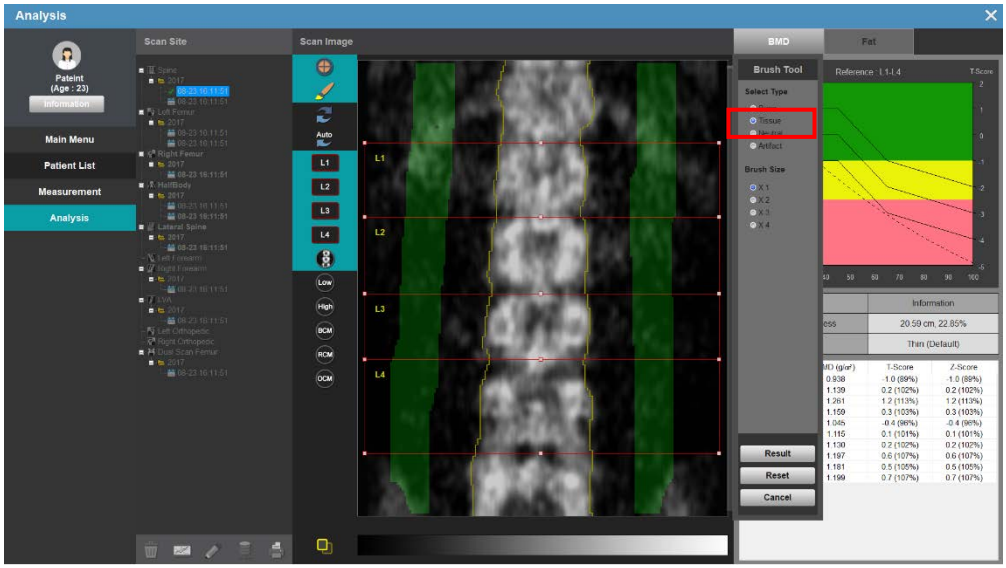
- Marking the bone region

  Use this function when the bone ROI is not detected for calculation.



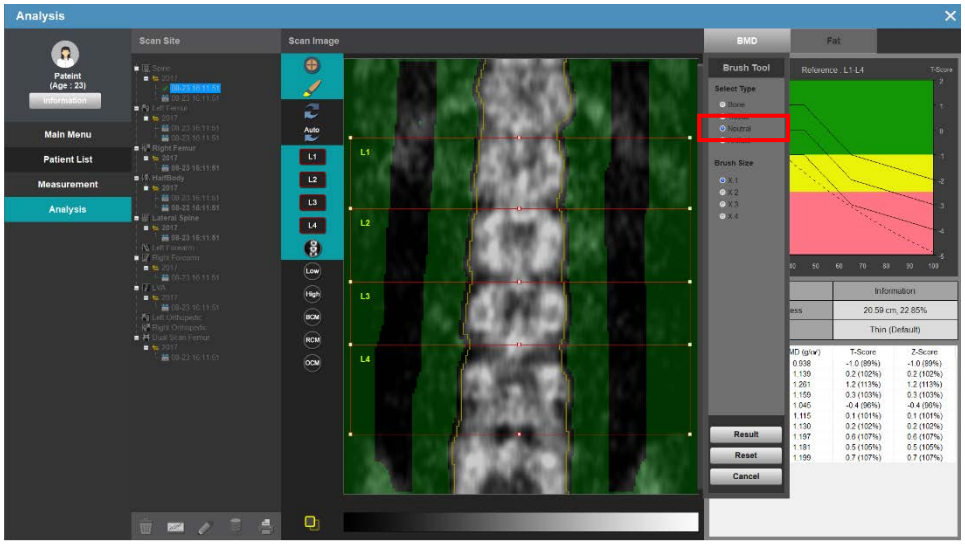
- Marking the Tissue region

  Use it to set both Tissues of the Bone.



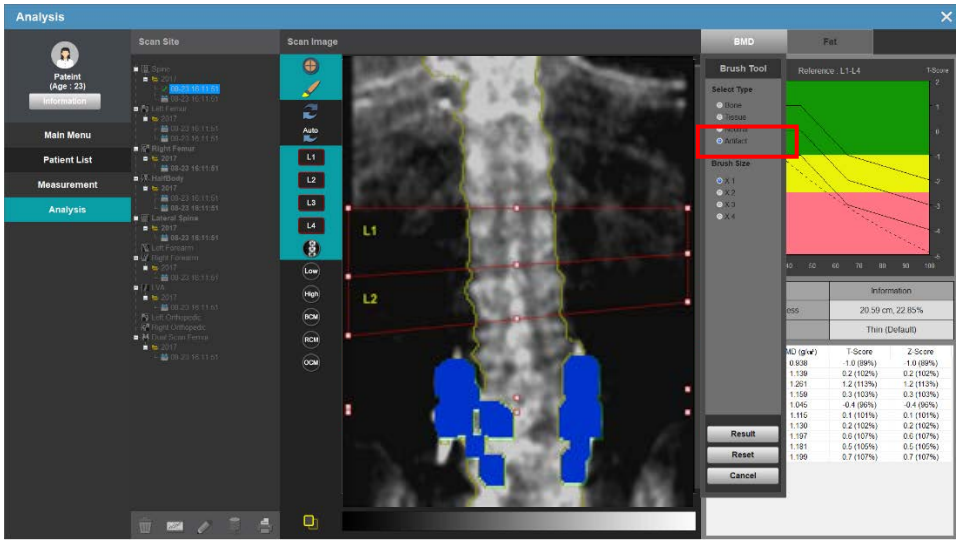
- Marking the neutral region

  Use it to set regions excluded from BMD calculation



- Marking the Artifact region

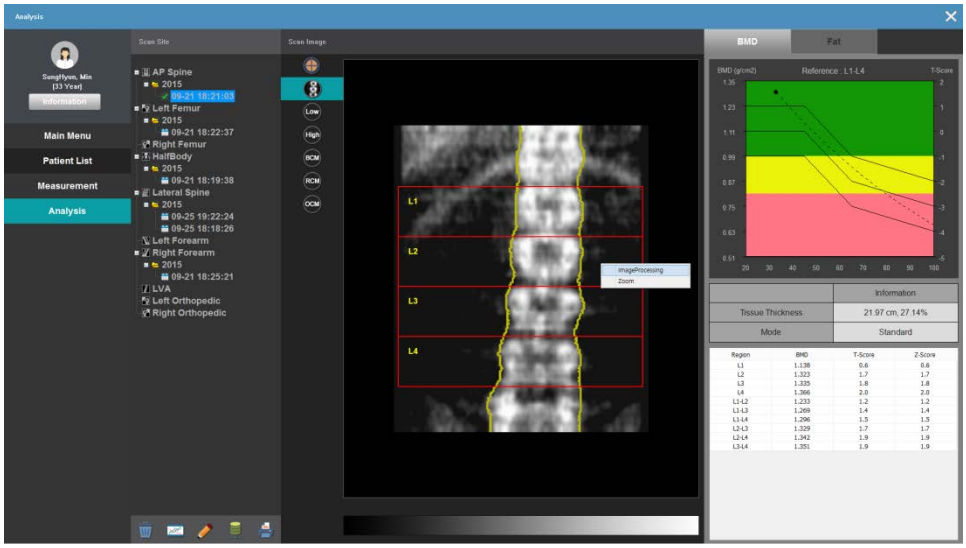
  Use it to remove foreign substances on the image.



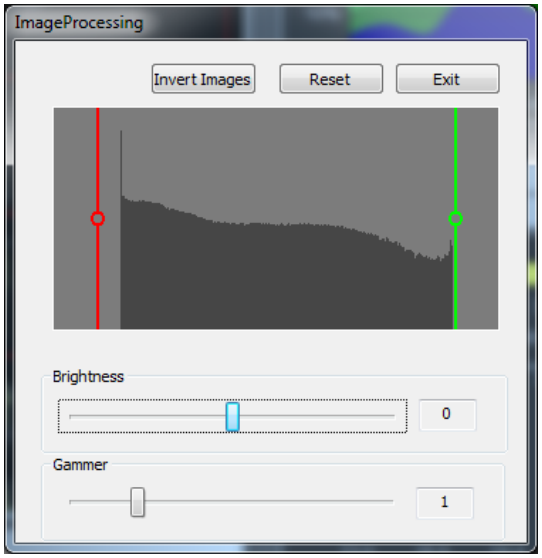
6.6.15 Use of image processing

To preserve image, use image processing function.

a. Place a mouse on printed image, and click right button.



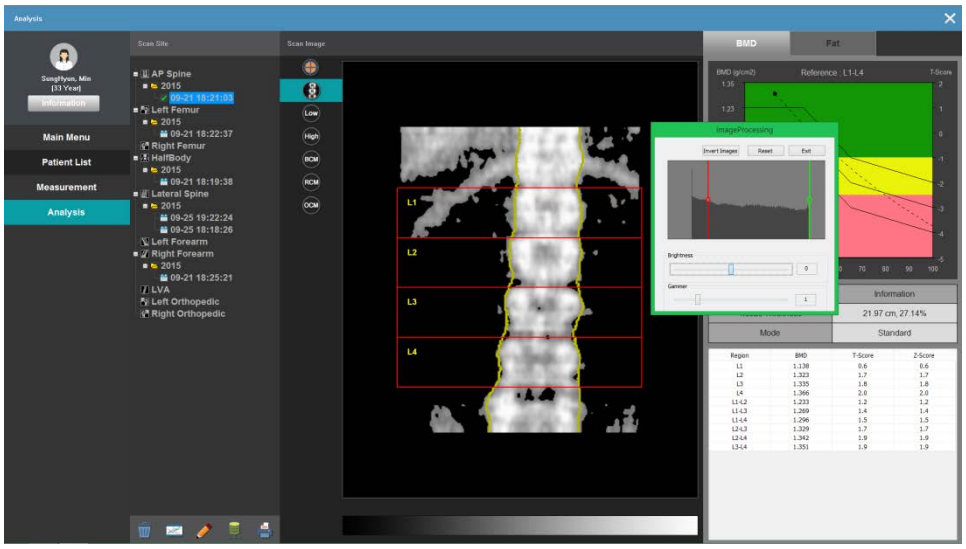
b. Press image Processing button to display image processing screen



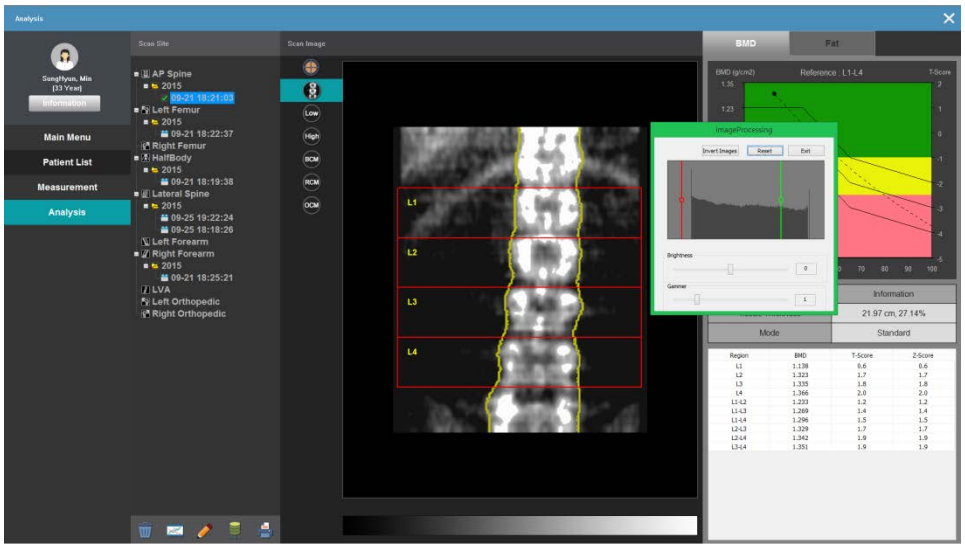
- Image Reversal: It is possible to reverse an image. It can be reversed between black and white.
- Initialization: After an image is changed, it is possible to reverse it back to the original image.
- Closing: Close the image processing window.

c. By moving a stick on screen image, it adjusts the contract of image.

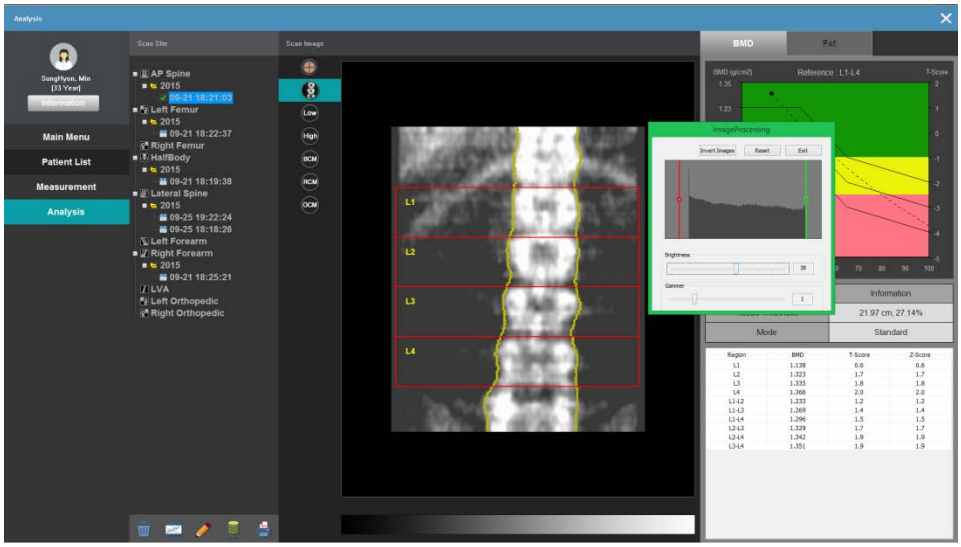
- Moving right or left while clicking the circle in the middle of screen, will change the image. For a red stick, it will darken the dark section of image.



- Moving green stick will lighten the lighter section of image.

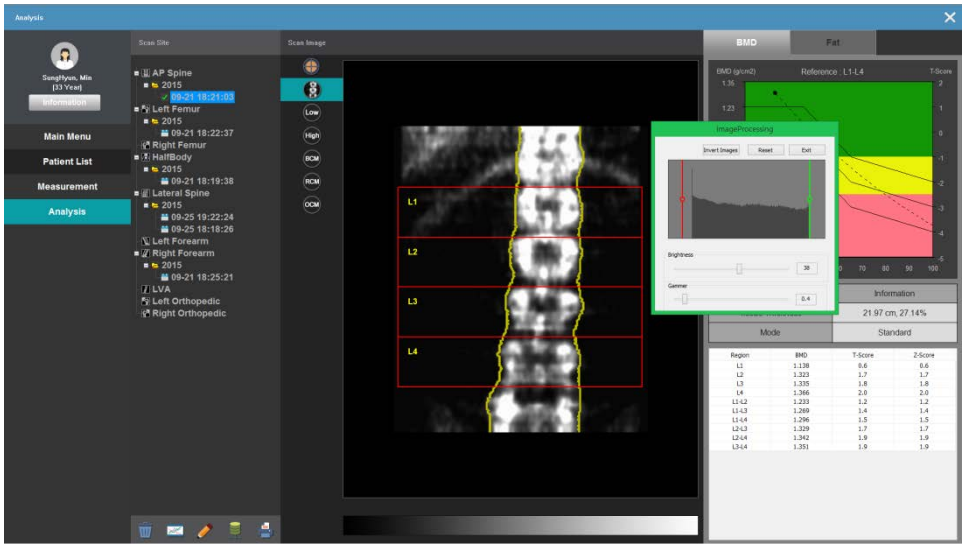


d. For brightness, move a bar at the bottom to change the brightness of Bone section.
As the value on the right side increases, image will be brighter. Otherwise, it will darken. It is possible to easily distinguish Bone section.



e. For Gamma, move a bar at the bottom to change the middle tone of Bone section.

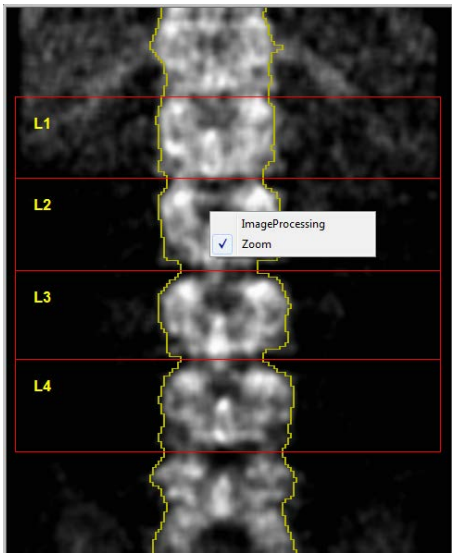
As the value on the right side increases, middle tone of image will be darker. Otherwise, it will brighten. It is possible to easily distinguish Bone section.



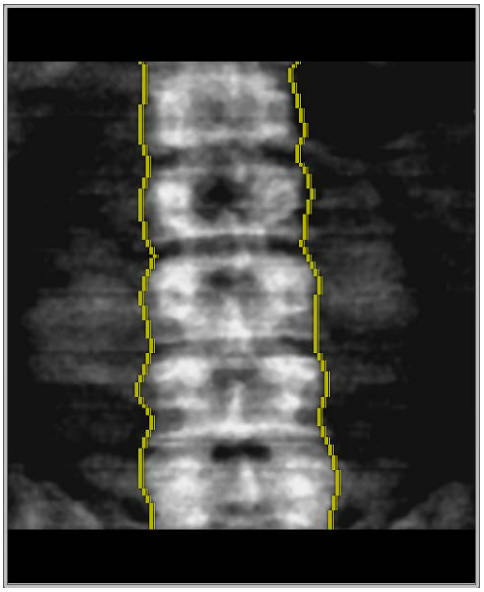
6.6.16 Use of image Magnification

By magnifying a particular section of image, it is possible to see it more clearly.

a. Place a mouse on printed image, and click right button



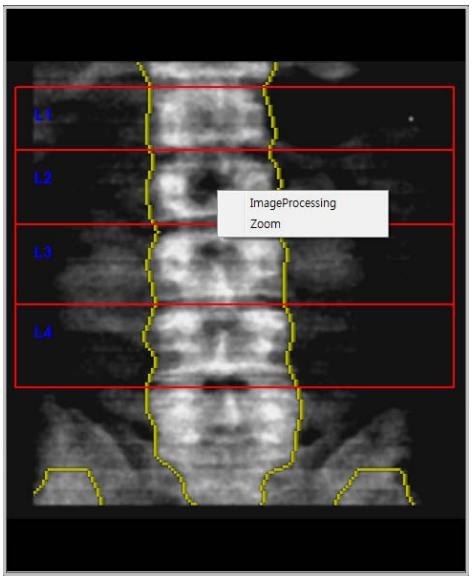
b. Click Zoom button for magnification function by using mouse-wheel



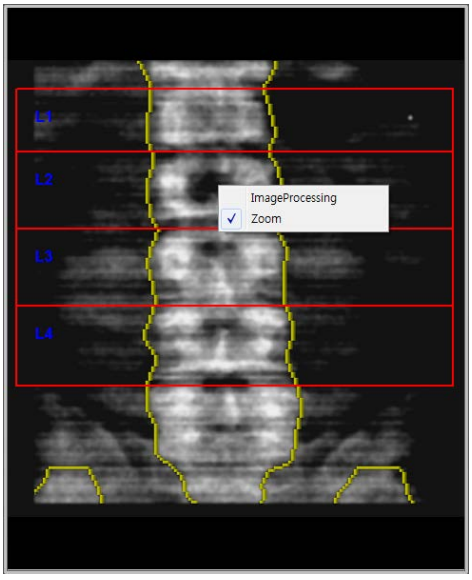
- Place a cursor on the section that you would like to magnify, and drag the mouse-wheel to the direction of your choice to magnify the section.
- To reverse the magnified section to the original, drag mouse-wheel to the opposite direction from user, to reverse it back to the image before magnification.
- If you would not like to use magnification function, click the right button of

mouse, and click zoom button once more.

- When clicking right button of mouse, you may or may not use magnification function depending on whether or not you checked the box of using zoom button.



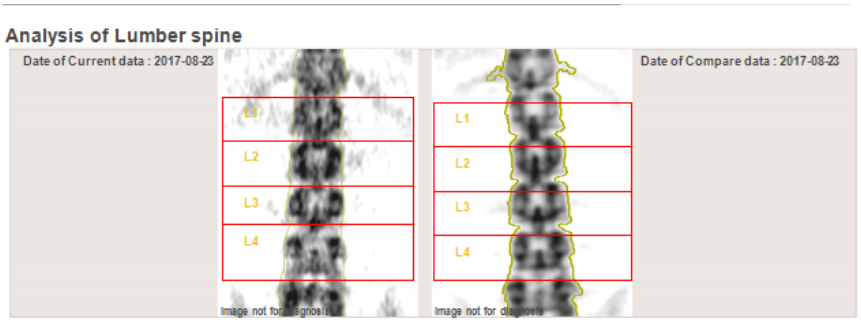
Not using magnification function



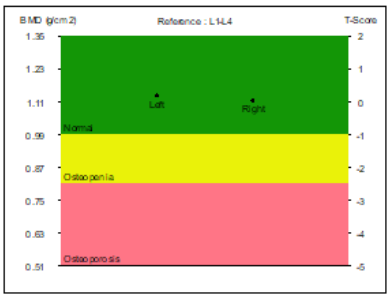
Possible to use magnification function

6.6.17 Use of Compare Function

In order to compare between previous examination and current examination.



1. BMD & T-Score Reference



2. Trend

Date Measured	Age(years)	BMD	T-Score
2017-08-23	23.7	1.130	0.2
2017-08-23	23.7	1.111	0.0

3. Changes(%)

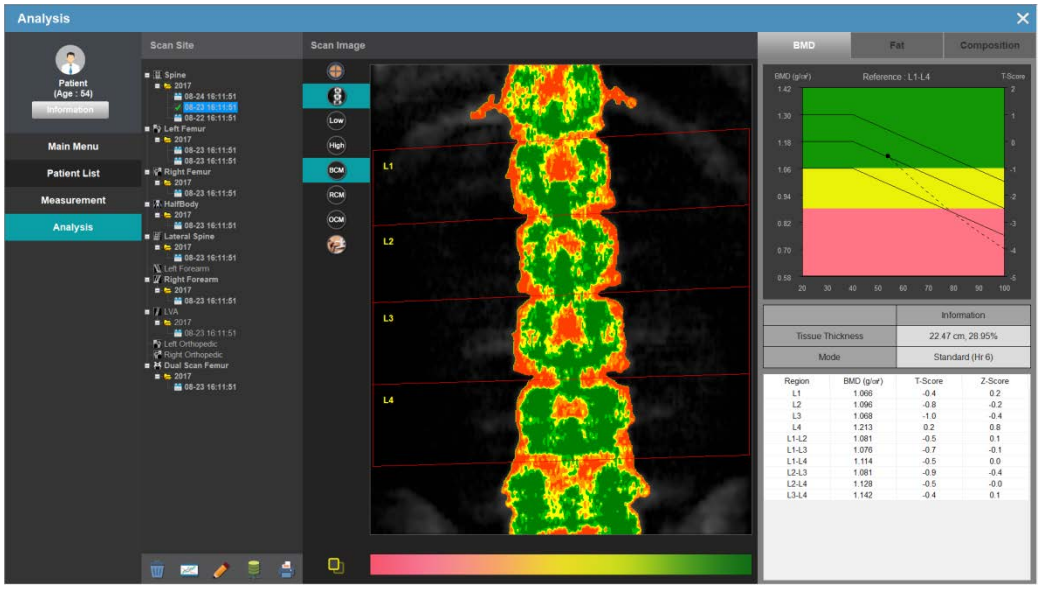
	Left	Right	Changes(%)
BMD	1.130	1.111	-1.7
T-Score	0.2(0.0)	0.0(0.0)	0.0

6.6.18 Image mode (BCM/ RCM/OCM)

- It is a function that can help the analysis by visualizing the intensity of bone.
- BCM / RCM (Except LVA)
- OCM (Spine / Lateral Spine support)

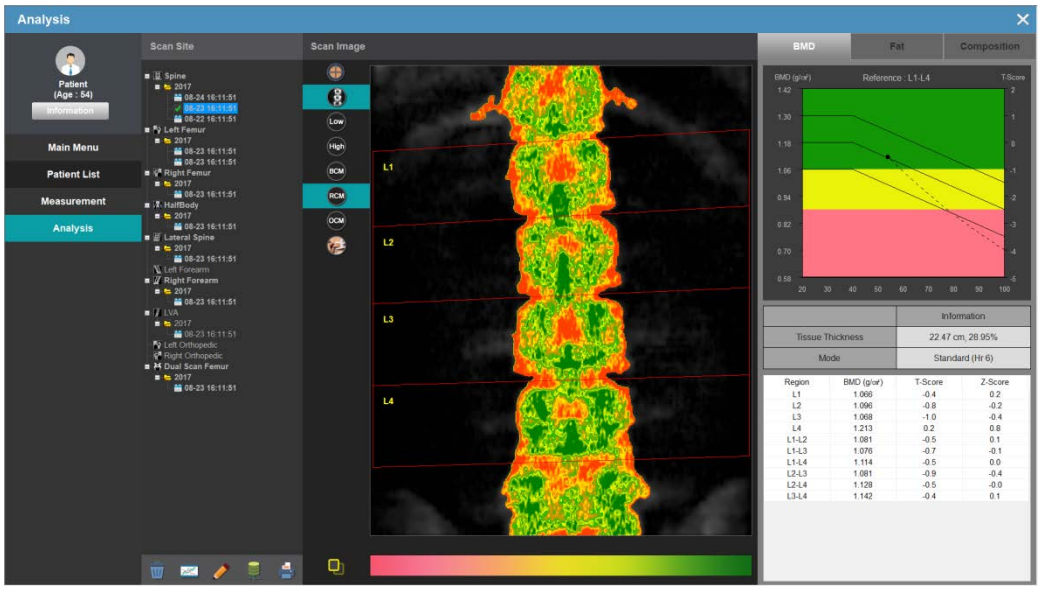
1) BCM

Based on the analyzed T-Score, the color is divided into six equal parts.



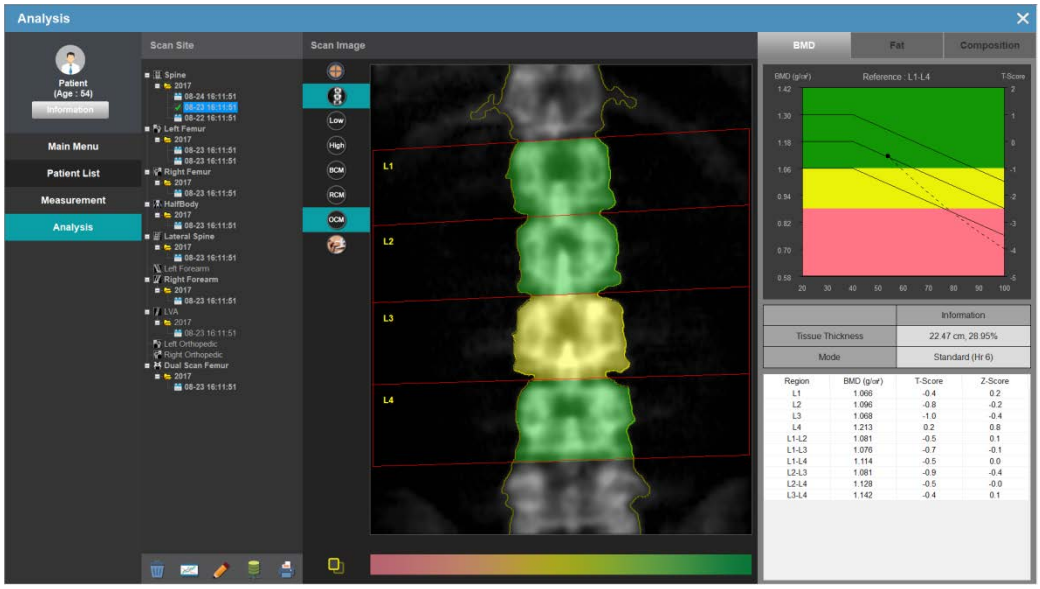
2) RCM

Based on the subject's T-Score, it is divided into 6 parts by MAX / MIN value.



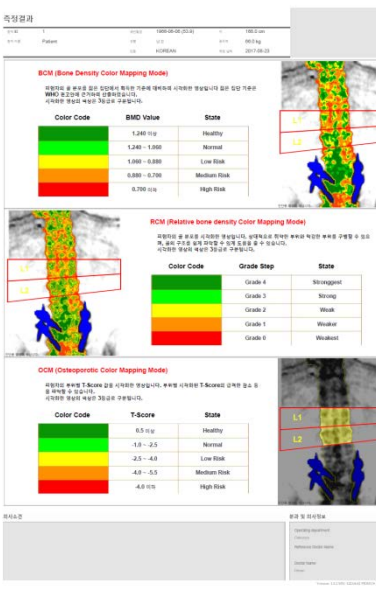
3) OCM

It shows the strength of the bone in the area where the ROI is set.

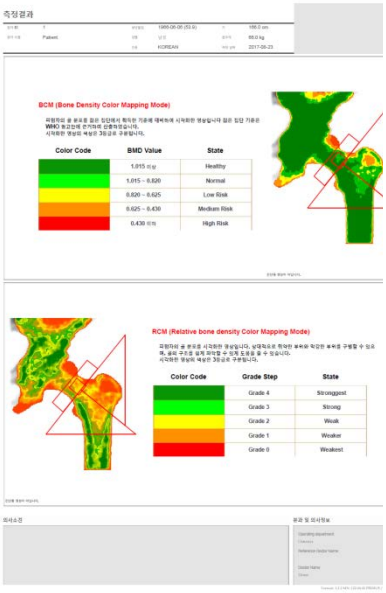


4) Report

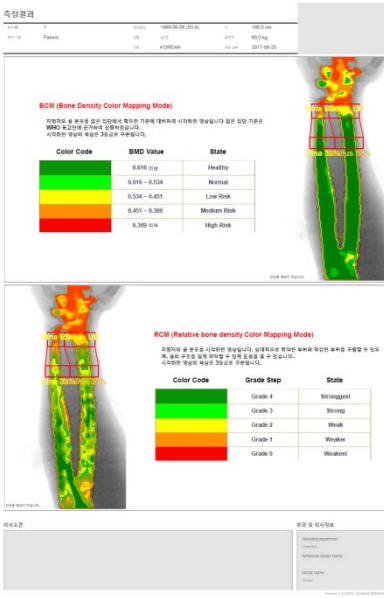
You can print or send PACS Color Mapping Reports



AP Spine

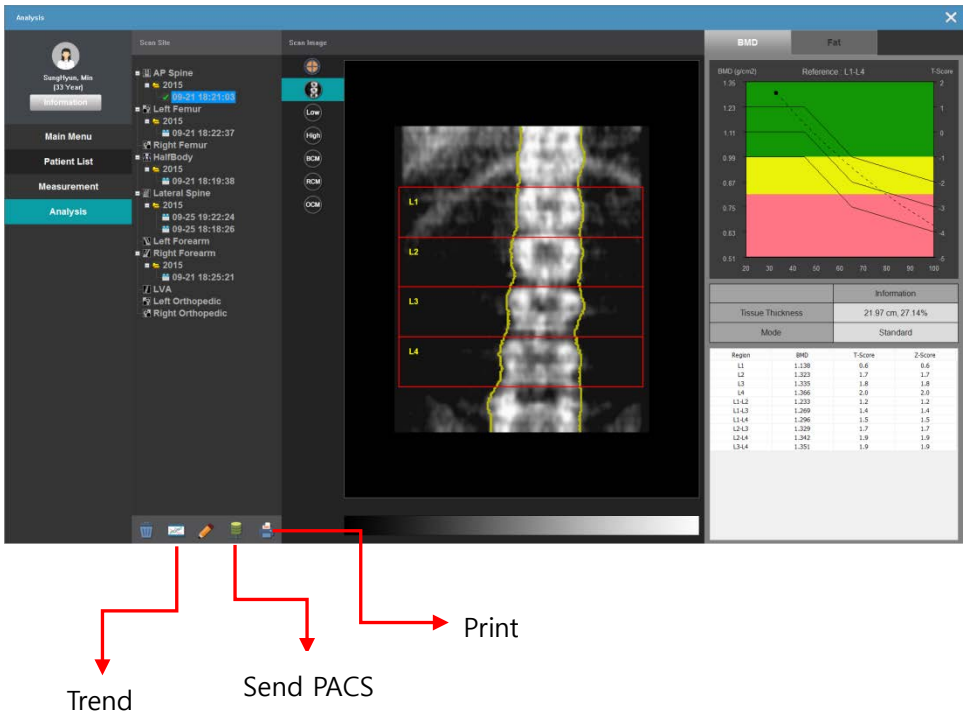


Femur



Forearm

6.7 Output and PACS

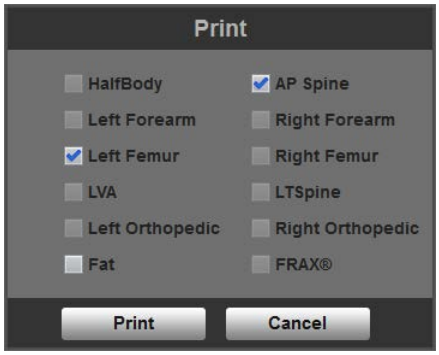


6.7.1 Result output and PACS connection

Print out the obtained result.

a. Once analysis is complete, it is possible to print the result on all possible measurable sections with EXCELLUS such as spine, femur, etc. on analysis window.
b. The given type of results supports 13 types of result format as shown below. Select data in Information. Check and click 'Send PACS'.

The type of result report can be added or deleted depending on software version.



c. After selecting a measurement section to print out on analysis window, press print button to print out the result report.

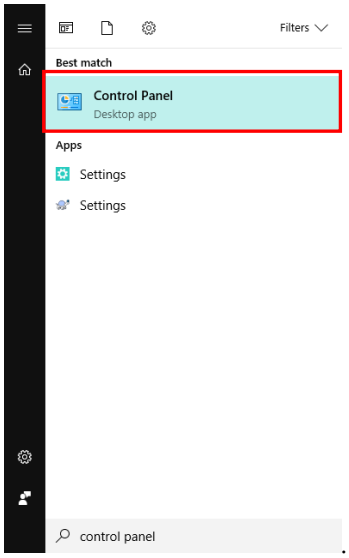
① Hospital logo
② Hospital address, telephone number
③ Patient information
④ Multiple site #1 result
⑤ Multiple site #2 result
⑥ Comment
⑦ Diagnosis Criterion (WHO, Offer)

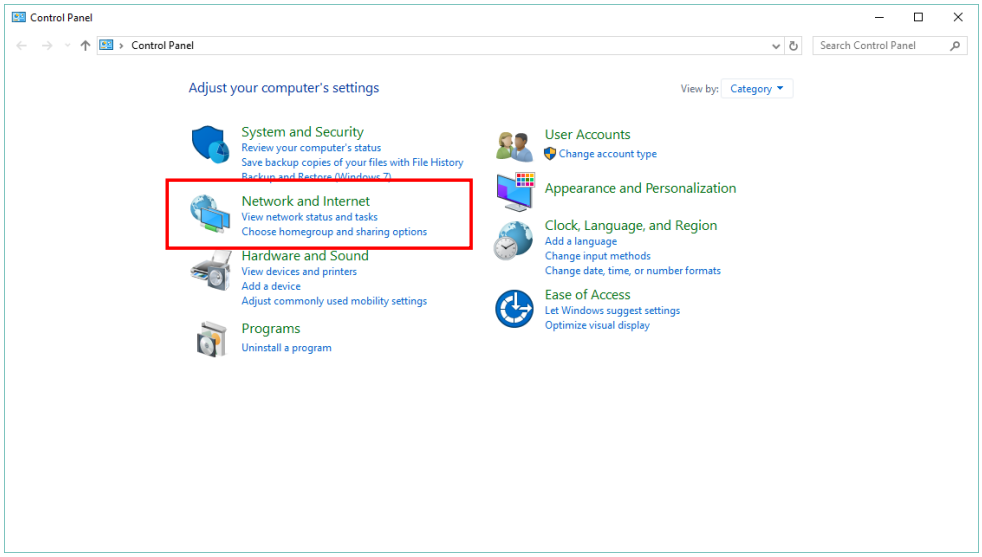
6.7.2 PACS Interlock

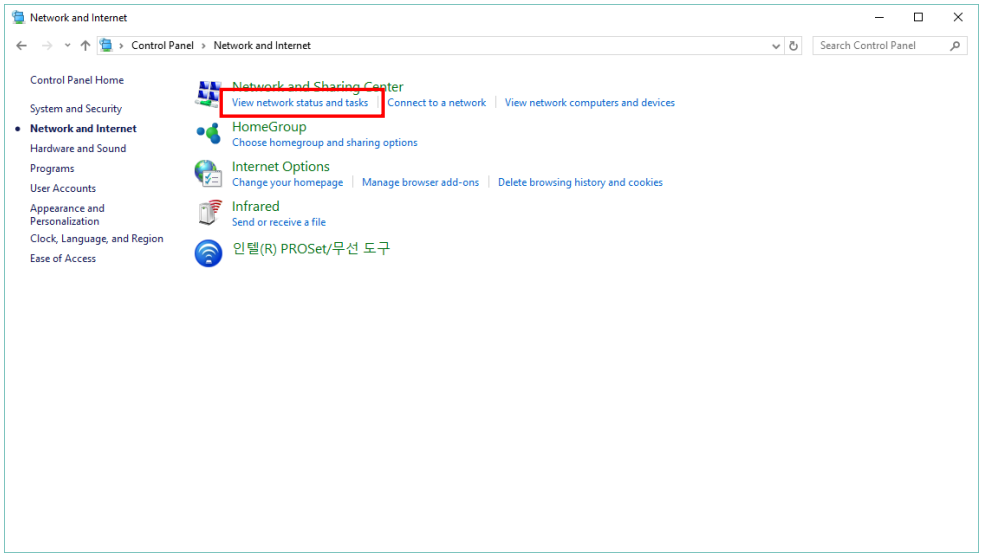
The PACS configuration is explained based on Window 7 environment. If you are using another version of window, consult with A/S center.

- PACS requirements
  - 2 LAN cards (inside EXCELLUS PC)
    It is required to get a given IP, Subnet mask, and basic gateway assigned from hospital network (hospital should provide these)
  - PACS Server IP and Port (hospital has the following information on PACS server)
  - Remote A-title (consult to hospital PACS manager)

- PACS connection method
  a. Network Setting
  Go to "control panel" on the start-up screen, and then go to "network and internet". Among listed items, select the "network selection and work" menu.

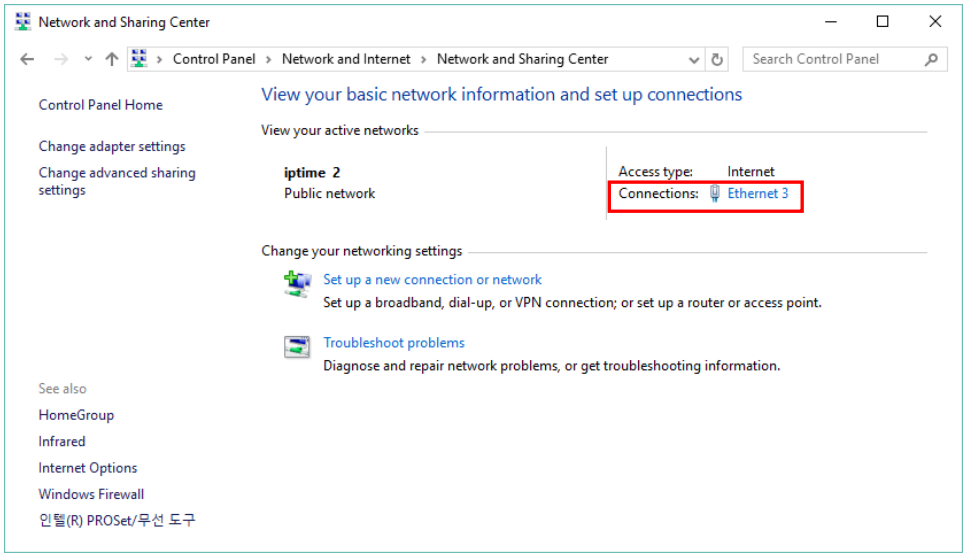




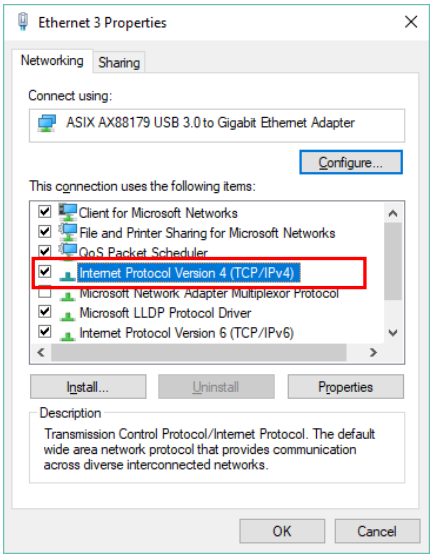


b. Setting LAN Card

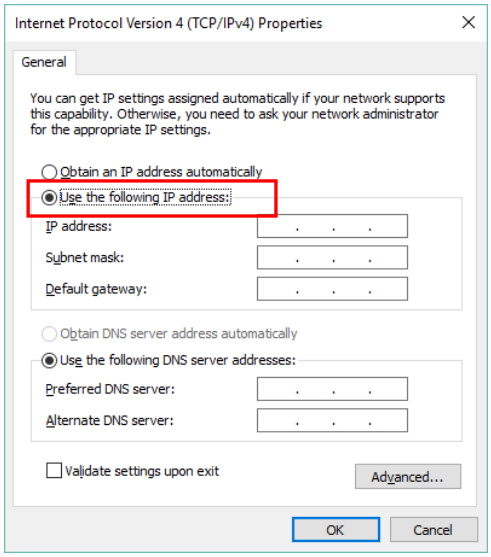
If there are two LAN cards inserted, local domain is divided in half as shown below. One of the two connections is a LAN card that communicates with the equipment, and the other is used in PACS. If it is not clear which LAN is for which, pull out each cable to see local domain that is connected to the equipment. (make sure the equipment is turned on.)



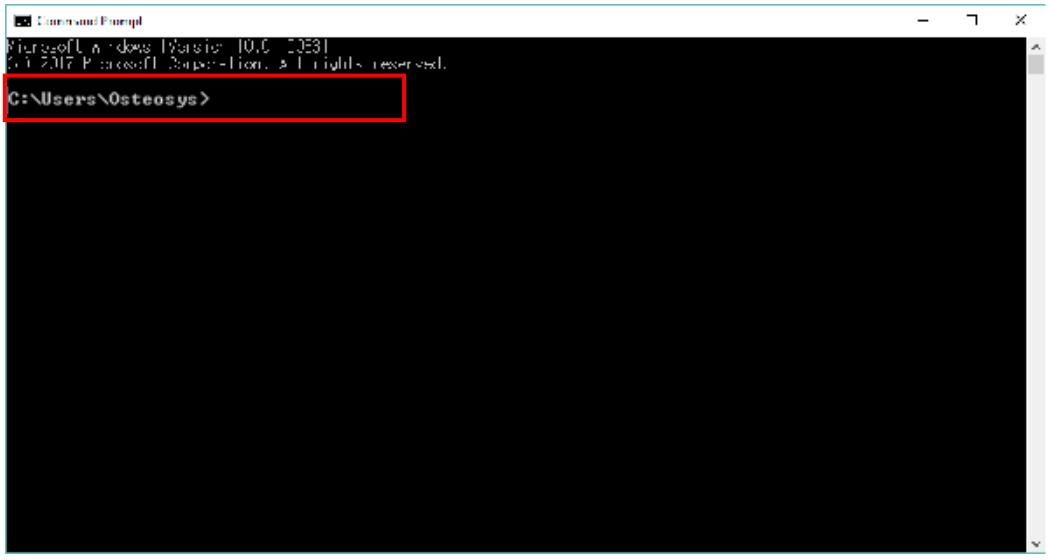
c. To connect with the PACS network of hospital, choose local domain connection2 (a domain that is connected with the equipment). When property window pops up, click Internet Protocol (TCP/IP), and click Properties.



d. Enter the given IP address, Subnet mask and Gateway information to connect with PACS server in hospital, and press enter button. (You should ask the PACS manager of hospital.)



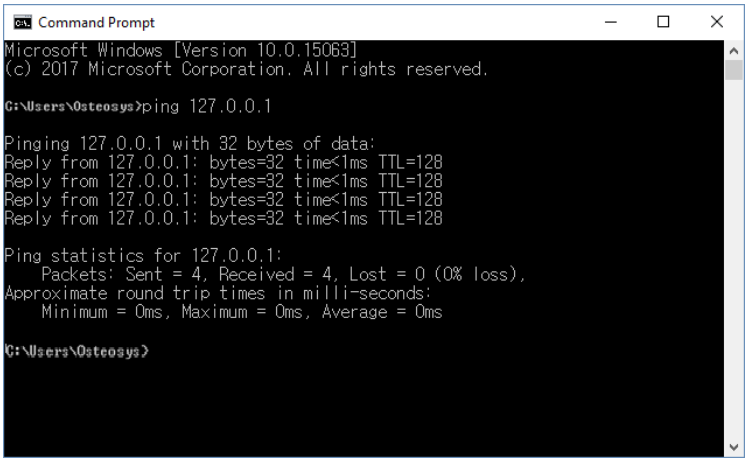
e. To check the connection with PACS server inside hospital, press window start button and click run.When a window pops up, enter CMD, which will show in DOS mode as shown below.



f. Enter the PACS connection IP from hospital as shown below.

ex) C:₩>ping 192.168.20.3

Enter the given IP from hospital at 192.168.20.3 IP.



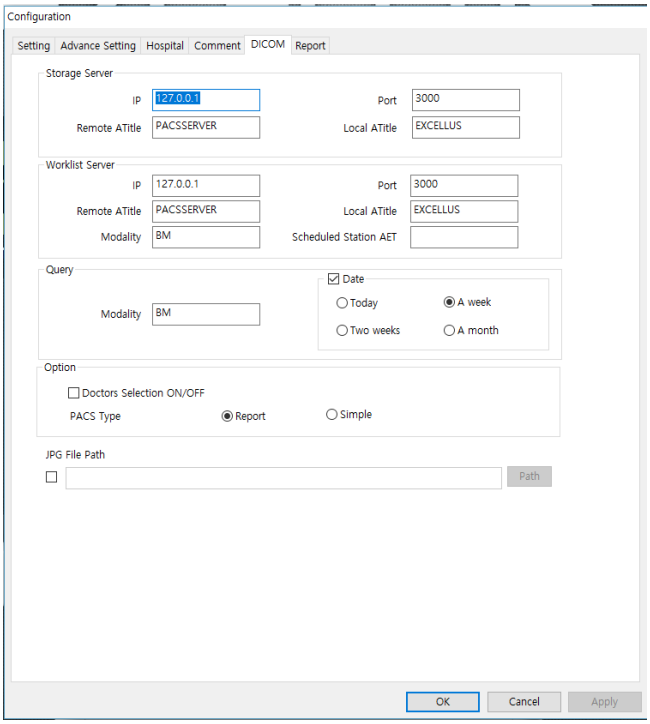
g. Enter the following command, and its relevant contents will pop up in PC. The message of 'Reply from (IP address): byte=32 time=128' popped up in 4 occasions,

If 'Packet: Send = 4, Receive = 4' shows up, it is normal.
If 'Packet: Send = 4, Receive = 4, Lost = 0' shows up, it is also normal.
If Lost is not zero (0), it means that there is an issue. Thus, make sure to check IP, Gateway, Subnet mask, etc.

h. Run the user program (EXCELLUS).

i. Go to configuration screen.

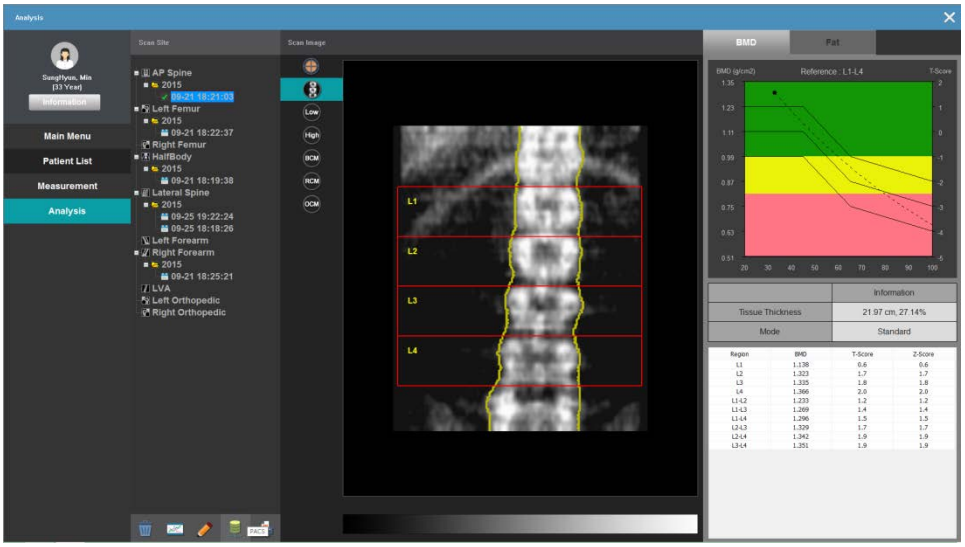
j. Click DICOM tab on configuration screen, to enter PACS server IP, Port number and A-title.

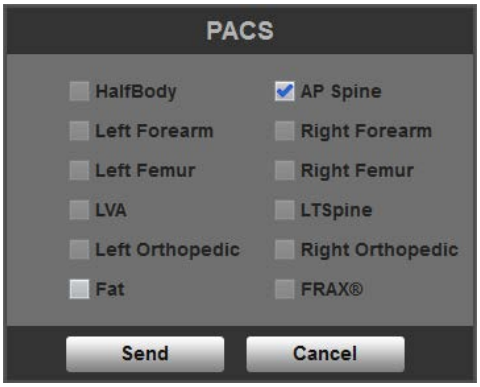


In order to use PACS, make sure to enter correct A-Title, IP and Port in Storage server. (Make sure that it is case-sensitive.)

k. If you would like to change Modality in hospital, you should receive the Modality from PACS manager.

l. After completing the above configuration, run user program. After selecting the examinee who would like to send a result through PACS, go to analysis screen.



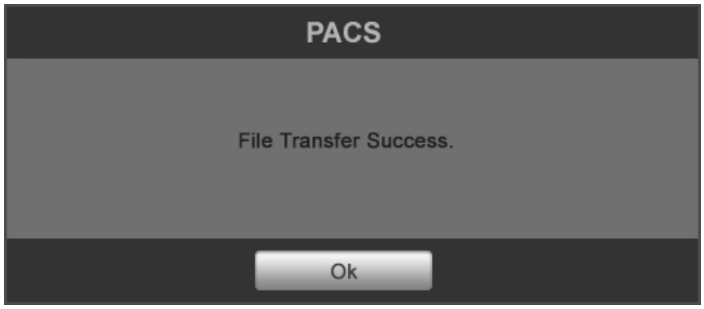


m. Among those chosen examinees, select the measurement section to send, and click PACS button, which will open Report Page window.

n. After selecting measurement section to send, click Send button to send it.

o. If not successful, a message will pop up as shown below. In this case, check if storage server is correctly entered on configuration window. Then try again.

p. If successful, a message will pop up.



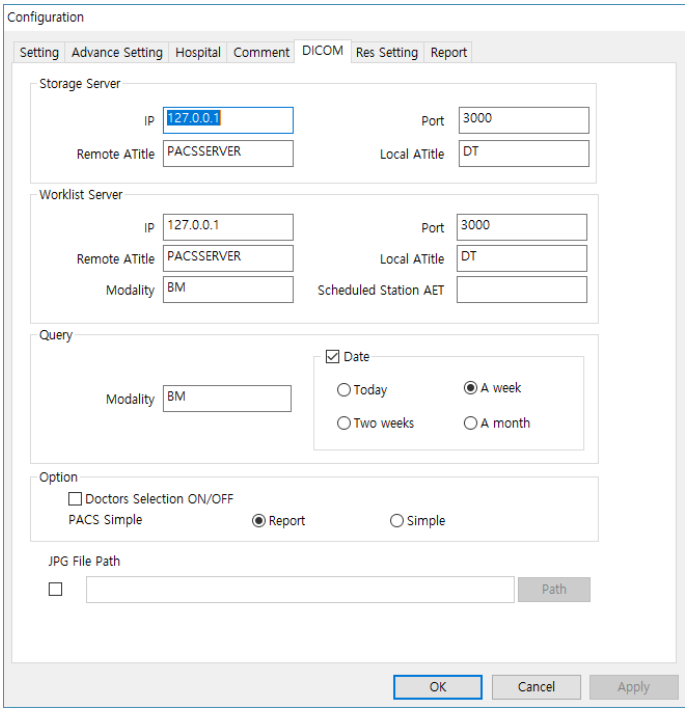
If PACS transmission continues to fail, check the DICOM server of hospital. If there is any abnormality, call our A/S center.

6.7.3 Worklist Interlock

- What is Worklist?

  Worklist is defined as a function that changes examinee's basic data into database (which is to be kept in hospital database), and that provides the examinee's data from all PCs that are connected to server. It is not allowed to change examinee's information from local PCs.

- Program Setting for Worklist Users.
  a. Run EXCELLUS user program.
  b. From the main screen of EXCELLUS, go to configuration.
  c. Select the last DICOM from the configuration window.
  d. Ask hospital personnel or hospital OCS manager to provide the following information, and enter them. (Those that are filled in the figure is an example. Therefore, each hospital has different IP, PORT, etc.)

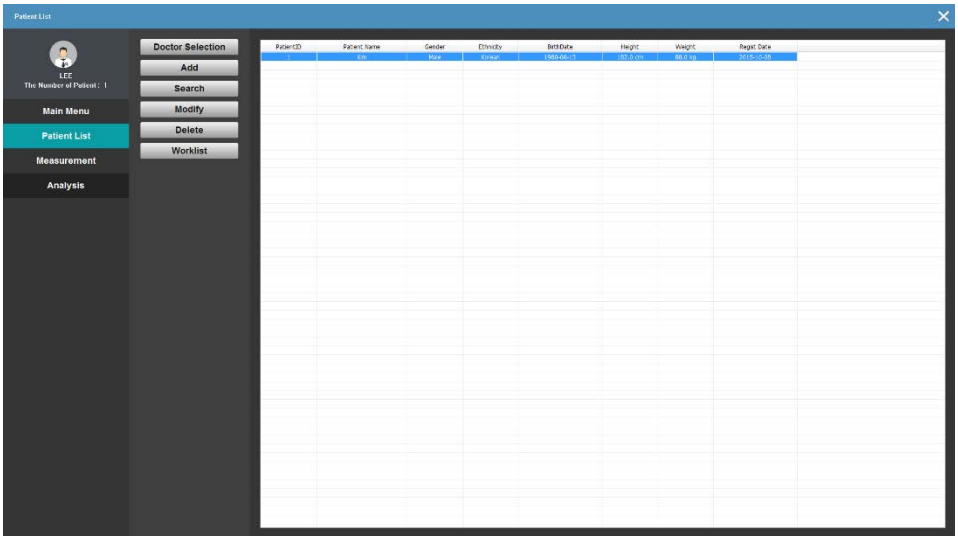


  e. For Local A-title of EXCELLUS, it notifies OCS manager that it is "EXCELLUS". However, it is not allowed to change A-title.
  f. For Modality, "BM" is a default value, which is allowed to change.

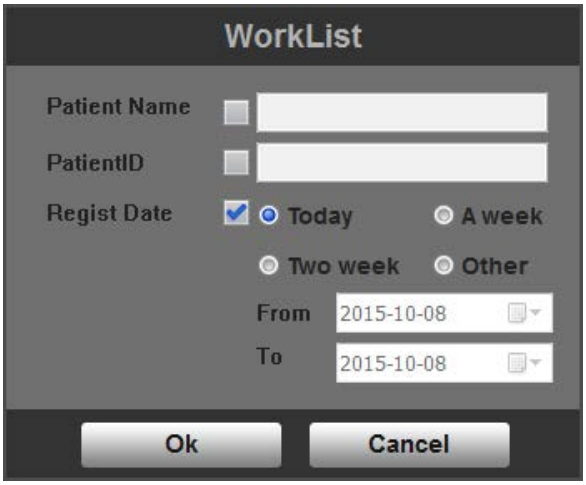
g. Press OK button to store the set value.

> In order to use WORKLIST, make sure to enter correct A-Title, IP and Port in Storage server. (Make sure that it is case-sensitive.)

h. Go to examinee's list and press the button for examinee list. As shown in the figure below, press Worklist button at the bottom of examinee's pop up menu.



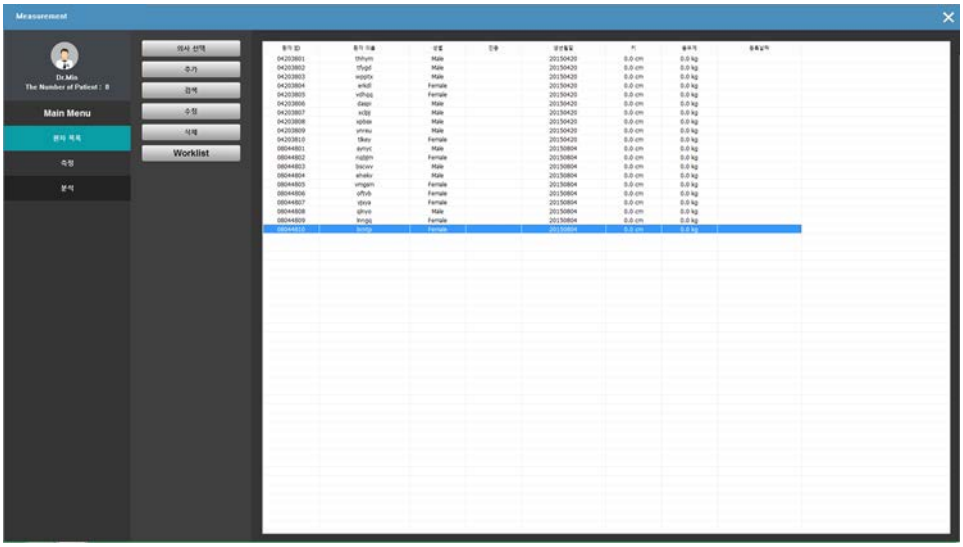
i. Conditional window will pop up to bring up examinee's list as shown in the figure below.
The conditions can be searched with name, ID, and date. The default is to bring up the worklist with date. The date should conform to the setting in query items for No. d.



j. Enter search conditions and press OK button. Then it will bring up the list of examinees who match the conditions registered in server.

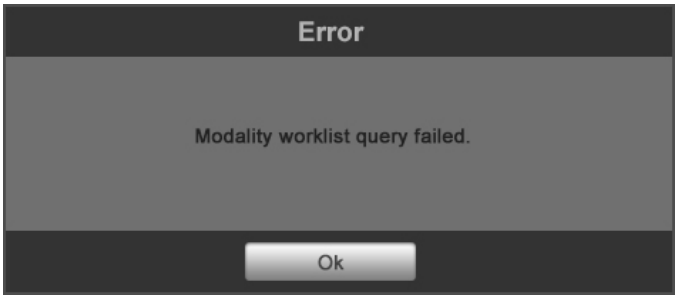
If there is no matching examinee or if the server is not connected, it is not possible to bring up the Worklist. In this case, check if the information from OCS manager is correct. Then change search conditions for another search. If it continues to fail, contact our A/S center.

k. In case of bringing up the Worklist that matches with search conditions, the existing examinee's list will change into the Worklist list.



l. If there is no examinee who matches with a search condition, it will print out nothing.

m. If it is not connected to server, or if search conditions are not correctly entered, the following message will show up. Then check if the server is connected or if DICOM setting is correct. Then try again.



6.8 Database.

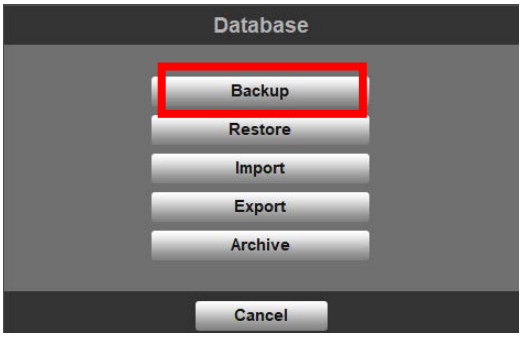
6.8.1 Backup and restoring.

- You can restore data through backup.

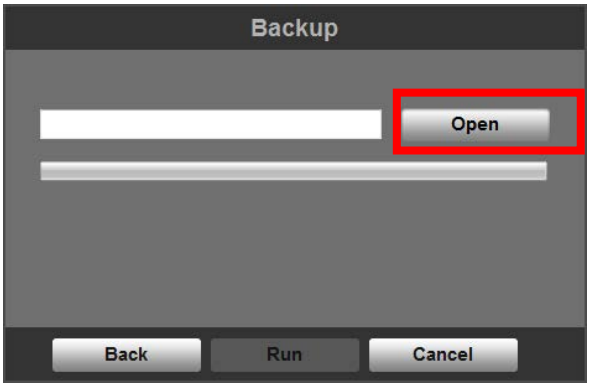
- Backup

a. Select Database menu in the main screen.

b. When the window opens, click Backup button.

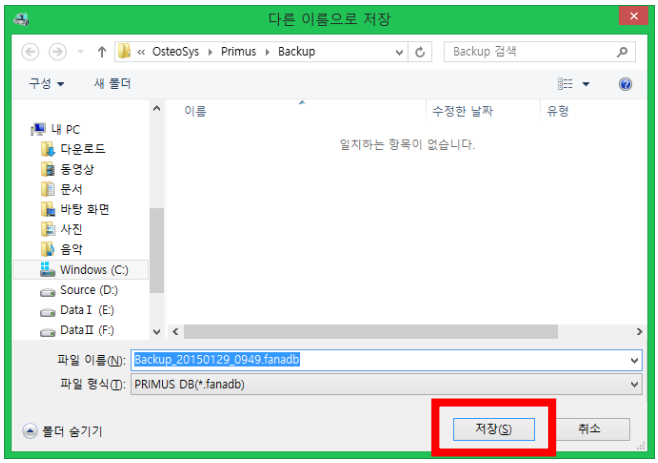


c. When Save dialog box opens, save it in a basic file name or user file name.

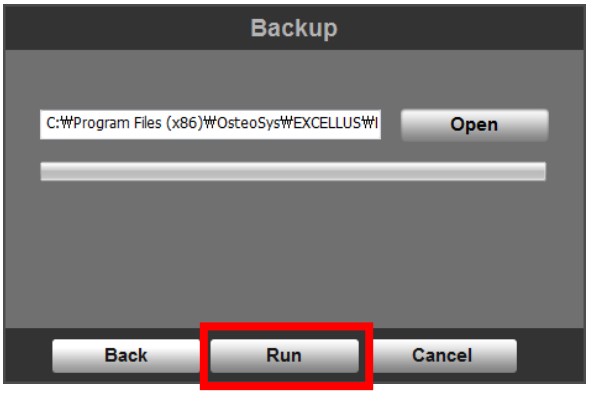


d. Basic file saving path is [./Backup].

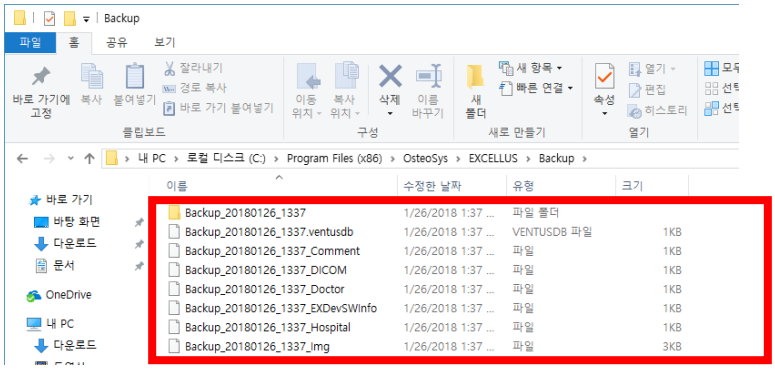
e. Set the file name and click 'Save' to save the file.



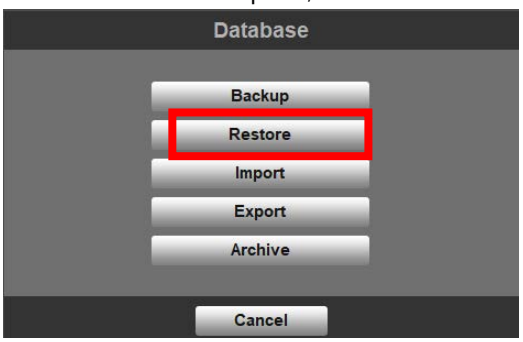
f. Go to back up and click Run.



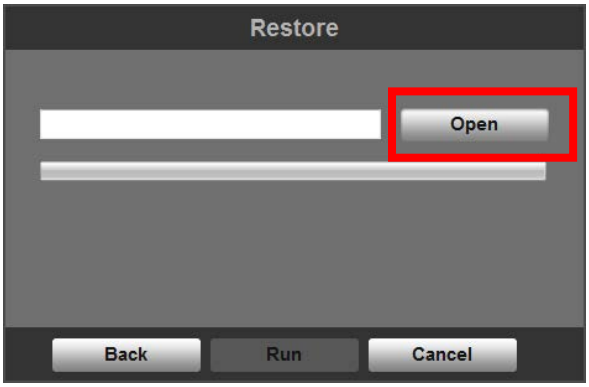
g. 7 files have been created and each file contains information on DB and images. (In the folder created by file name when saving, image files will be stored.)

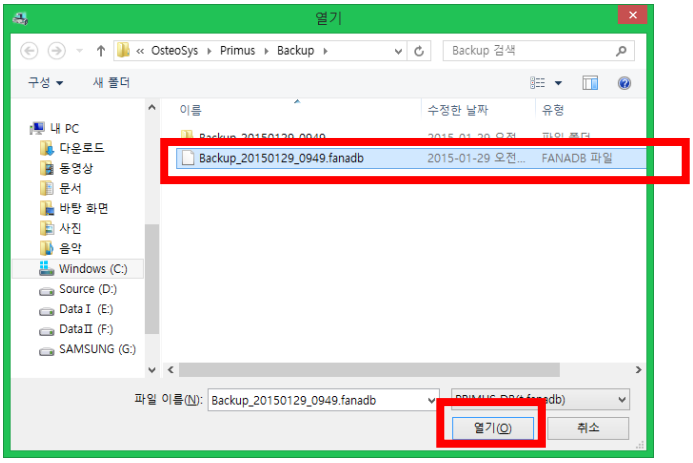


- Restoring
  a. Select Database menu in the main screen.
  b. When the window opens, click Restore button.

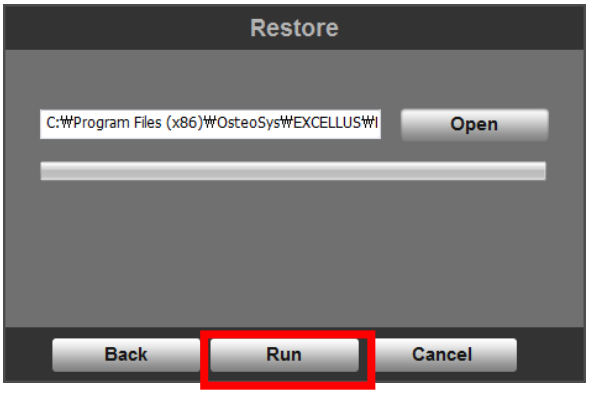


  c. When Open dialog window opens, move to the path where the backup file is saved, select the backup file you want to restore and click Open button.





d. Go back to database window and click run



e. Restoring is complete.

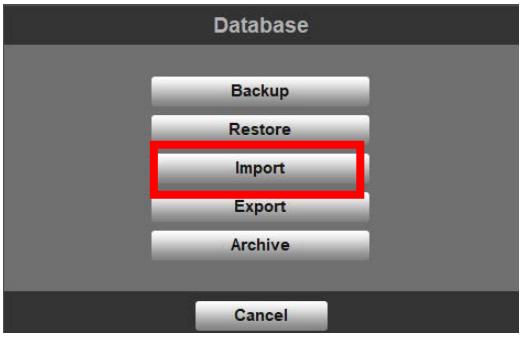
The data will be restored with the backup data, so current data will be deleted completely. During the restore process, the current data will be backed up automatically.
"Backup_current date" folder will be created on [../Backup] directory.

6.8.2 Import and export

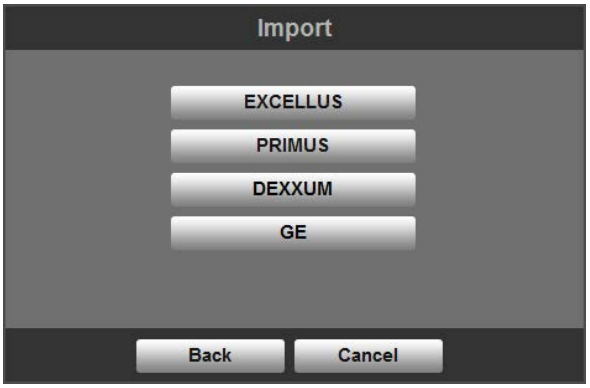
- Use database of compatible equipment by other companies to apply to EXCELLUS. Currently only GE's database is applicable.

- In saving in txt, file to import data of GE equipment, output format should be based on Patient List and select Patient data and full exam history for detail setting. Other settings may not work for import.

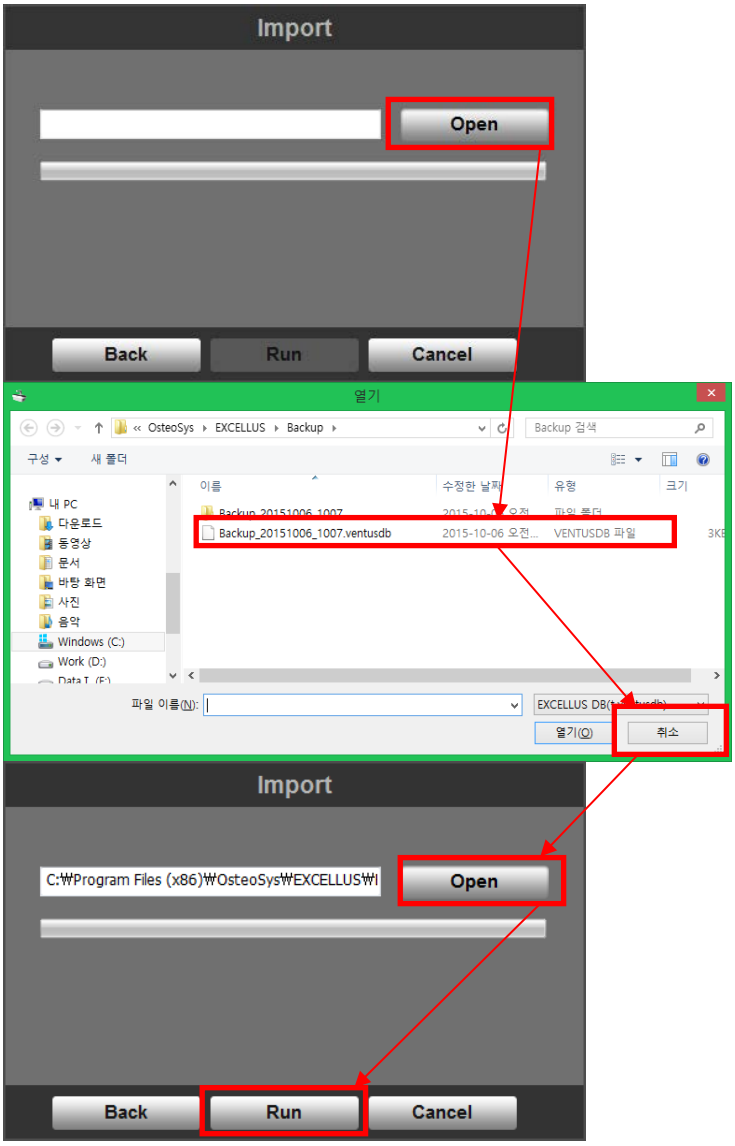
- Import
  a. Click Database in the main screen.



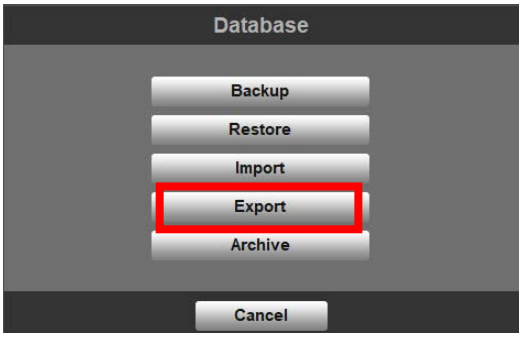
  b. When you click Import you will see our products choice.



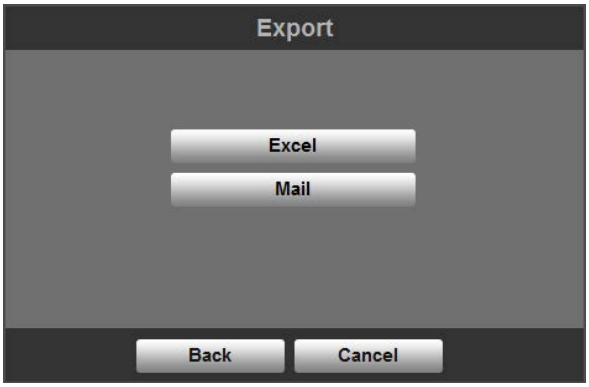
  c. Select the prepared database and click Open.(The same as Restore "c")



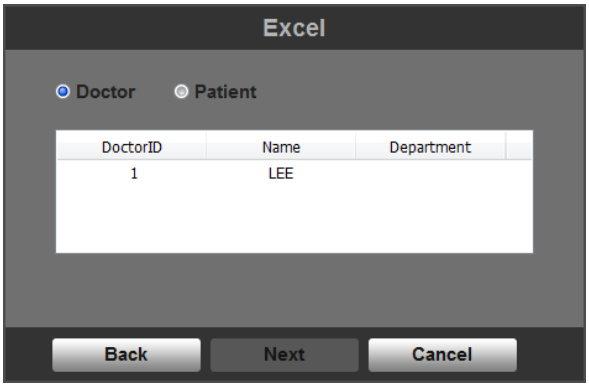
- Export
  a. Like Import, click Database in the main screen.



b. Choose the method you want to send the data.

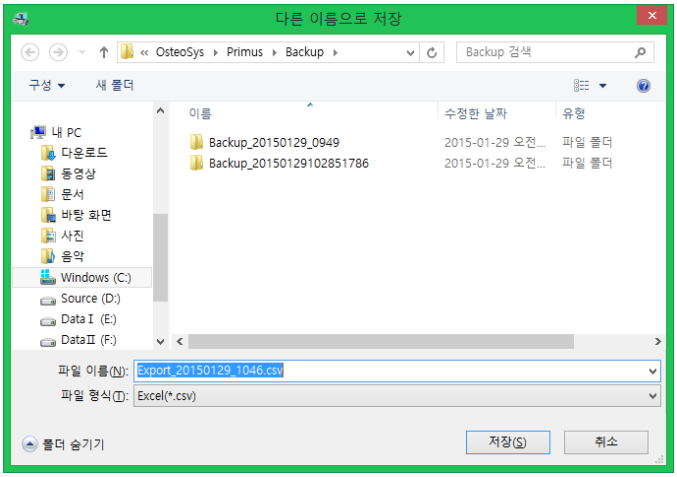


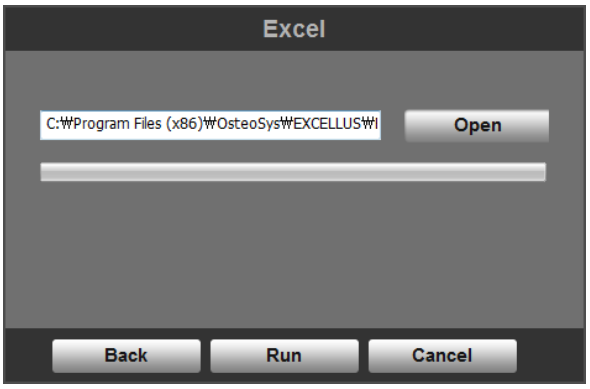
c. Click Excel or E-Mail and choose the data.



d. In case of Excel

Set the folder you want to save and make the file name. (Exactly the same as restore C)





e. In case of E-Mail

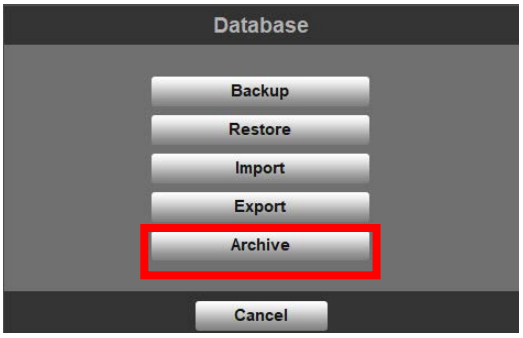
Write the E-Mail address and send the E-mail.

6.8.3 Archive.

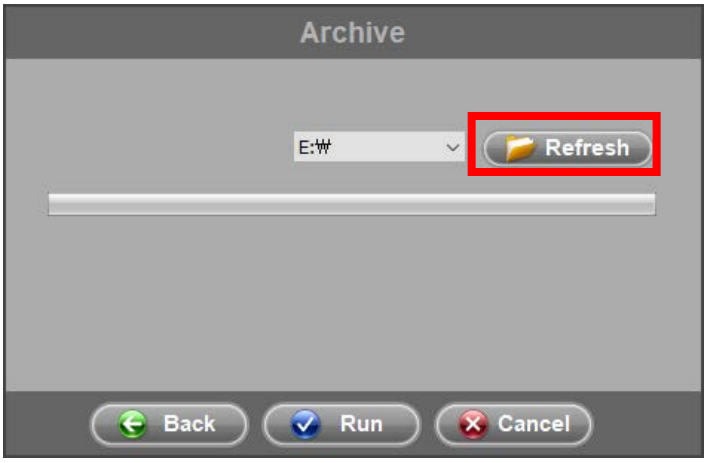
- You can copy or move all the measurement data and patients data in HDD onto Archive direction (CD/DVD).

a. Select Database menu in the main screen.

b. When the window opens, click Archive button.

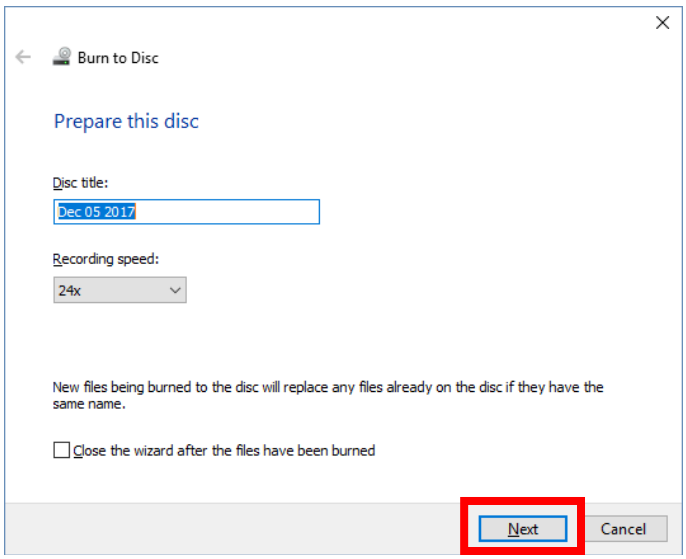


c. When Save dialog box opens, save it in a basic file name or user file name.

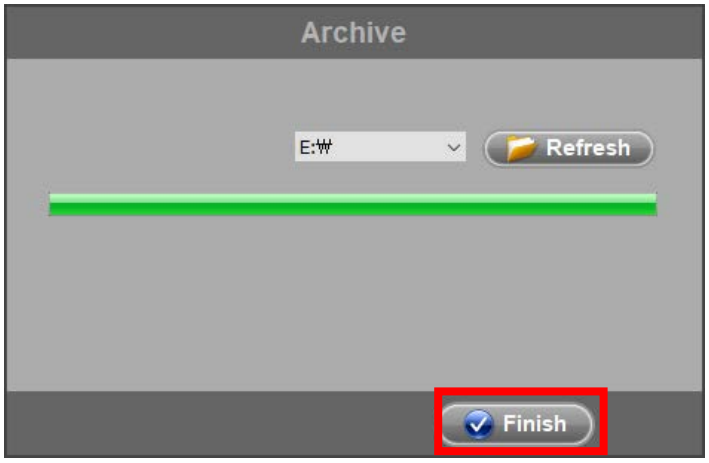


d. Basic file saving path is [DVD RW].

e. Set the file name and click 'Save' to save the file.



f. Go to back up and click Run.



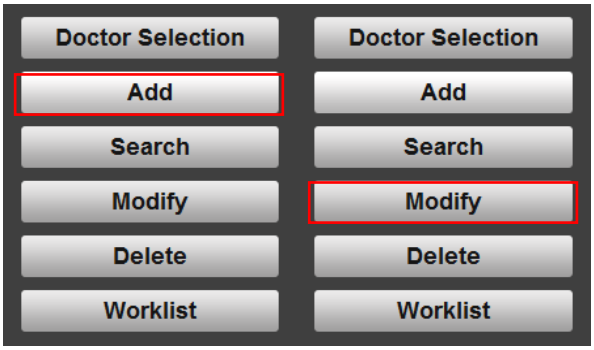
g. 3 files have been created and each file contains information on DB and images.

6.9 FRAX

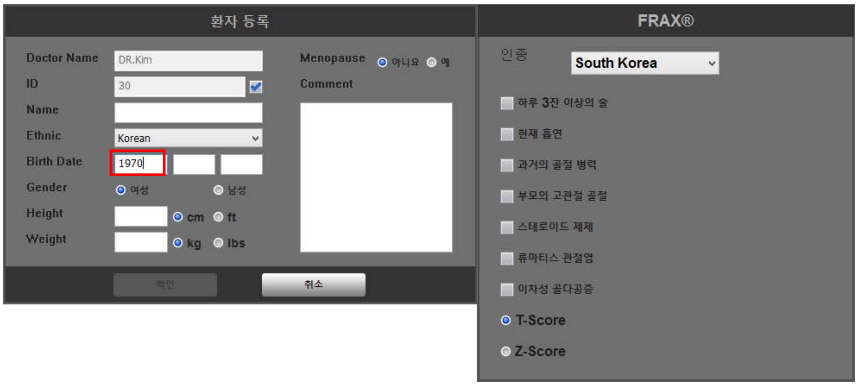
- FRAX is used to predict the patient's future within 10 years in case of fracture risks based on T-score and Z-score, also the patient's lifestyle and medication. The result of FRAX predicts Femur fracture and other major osteoporotic fracture such as spine, forehand, femur, shoulder up to 10 years.
- FRAX is made by WHO (The World Health Organization) to evaluate fracture risk. Osteosys had been offered this so you can get the same information right below the website.
  http://www.shef.ac.uk/FRAX/


In order to use FRAX the patient's age must be between 40 and 90 years old and also need to measure femur before.

a. After Click Add or Modify menu when you use patient list.



FRAX window is activated when the patient is 40 years or more after the data input, you can enter the FRAX information.

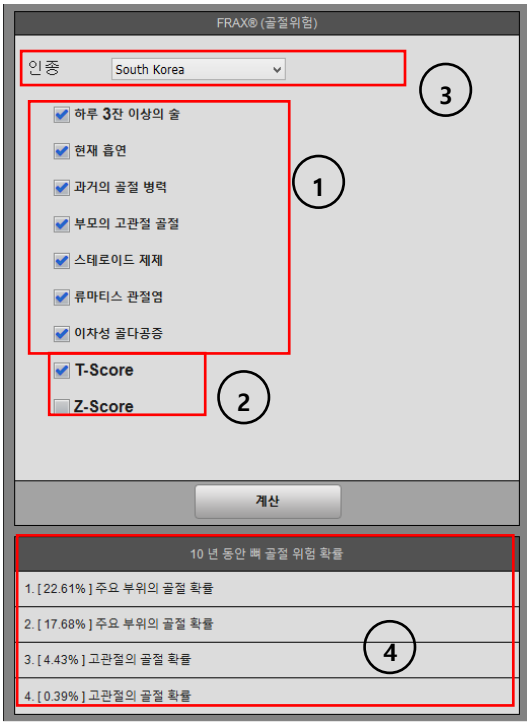


b. In case of using analyze, go to Femur column and click HA tab and write FRAX information.

c. This is the format of FRAX that we provide.

Patient list window.

Analyze window



i. You can choose the patients risk factors to predict fracture risk individually

i. Alcohol 3 or more units/day

If you drink more than three cups of drink per day than check it.
The amount of 1 cup is different from countries to countries but it is about 8~10g of alcohol. For instance, beer (285ml), soju (30ml), wine (120ml), Aperitif (60ml)

ii. Current Smoking
Check if you smoke currently.

iii. Previous fracture
Previous fracture in here means the fracture occurs after being adults or the fracture that usually normal healthy people don't get injured.

iv. Parent fracture hip
Check if either mother or father had or is having the hip fracture.

v. Glucocorticoids
Check if you took more than three months or are taking oral glucocorticoids. Prednisolone more than 5mg per day needs to check it also.

vi. Rheumatoid Arthritis
Check it if you have Rheumatoid arthritis.

vii. Secondary arthritis
If you have strongly related diseases with osteoporosis then check it.
Type 1 diabetes, osteogenesis imperfect adults, not cured hyperthyroidism for a long time, hypogonadism, early menopause, chronic malnutrition or malabsorption, chronic liver disease these diseases can be example for strongly related diseases with osteoporosis.

ii. Measured Femur's T-score and Z-score will be automatically displayed. Choose one from these two choices.

iii. You can choose ethnicity. If there's no exact ethnicity of the patient choose the most similar one.

iv. Show the result of the prediction. Click calculate then the program will show the result according to risk factors that you already wrote above

i. Prediction of major osteoporotic(BMD)
It indicates the calculated probability of major osteoporotic with the value of BMD.

ii. Prediction of hip fracture (BMD)

It indicates the calculated probability of hip fracture with the value of BMD.

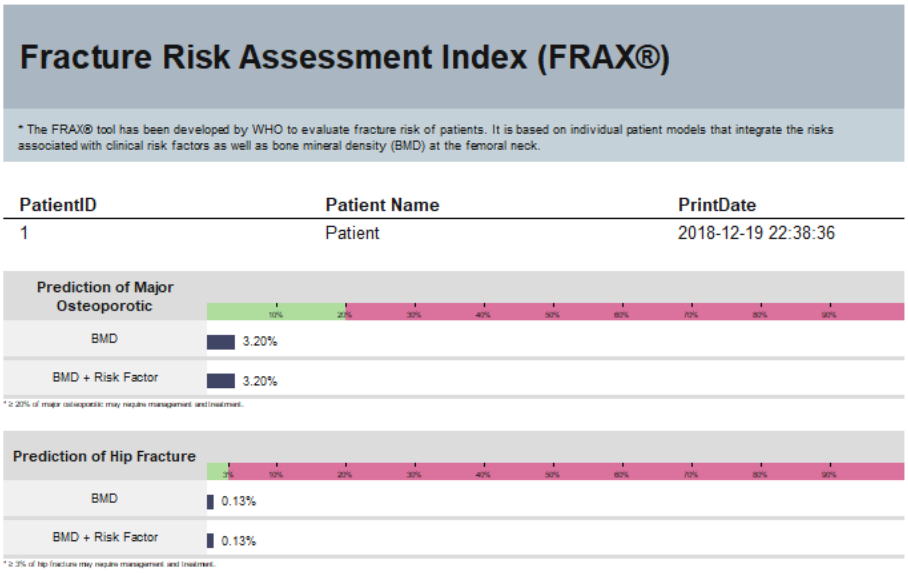
iii. Prediction of major osteoporotic

It indicates the probability of major osteoporotic based on BMD and the risk factors.

iv. Prediction of hip fracture

It indicates the probability of hip fractures based on BMD and the risk factors.

d. FRAX screen (part)



7 EXCELLUS–Related documents

7.1 Detailed Specifications of EXCELLUS

Category	Description	Note
Main body		
Manufacturer	OsteoSys	
Model name	EXCELLUS	
Grade and type	Class 1, B type device	
Product size	1900(L) x 800(W) x 1220(H)mm	
Weight	160 Kg	
Input voltage and frequency	100-120/220-240V~, 50/60Hz	
Power consumption	800VA	
Expiration date	Semi-permanent	
X-ray generator		
Max. tube voltage	90KV	
Max. tube current	3.0mA	
Input voltage and frequency	100/220V, 50/60Hz	
X-ray tube		
Max. tube voltage	110KV	
Max. tube current	15mA	
Focal spot size	0.5mm	
Cathode	Tungsten filament	
Detector		
sensor	Semiconductor detector	
Daily Check Phantom		
Manufacturer	OsteoSys	
Size	195(W) x 200(D) x 50(H)mm	
Performances		
Reproducibility of the Radiation output	≤ 0.05 CV (5 CV%) (Count)	
Reproducibility of tube voltage	±10%	
Reproducibility of tube Current	±20%	
Reproducibility of Radiation time	±10%	

Accuracy of BMD	± 10% (Based on BFP)	
Reproducibility of BMD&FAT	≤ 1.5 CV % (in vitro)	
Precision of BMD&FAT	≤ 1.5 CV % (in vitro)	
Leakage radiation	Below 1 mRem (5m distance)	
OPERATING ENVIRONMENT		
Ambient temperature range	18 to 27 ºC	
Relative humidity range	20 to 80%	
Atmospheric pressure range	800 hPa to 1060 hPa	
TRANSPORT AND STORAGE ENVIRONMENT		
Ambient temperature range	-20 to 50 ºC	
Relative humidity range	0 to 90%	

NOTE : Before using the equipment, fully familiarize yourself with the specifications of the equipment before using it.

7.2 EXCELLUS radiation-related documents

7.2.1 Aluminum equivation

EXCELLUS's aluminum equivation:

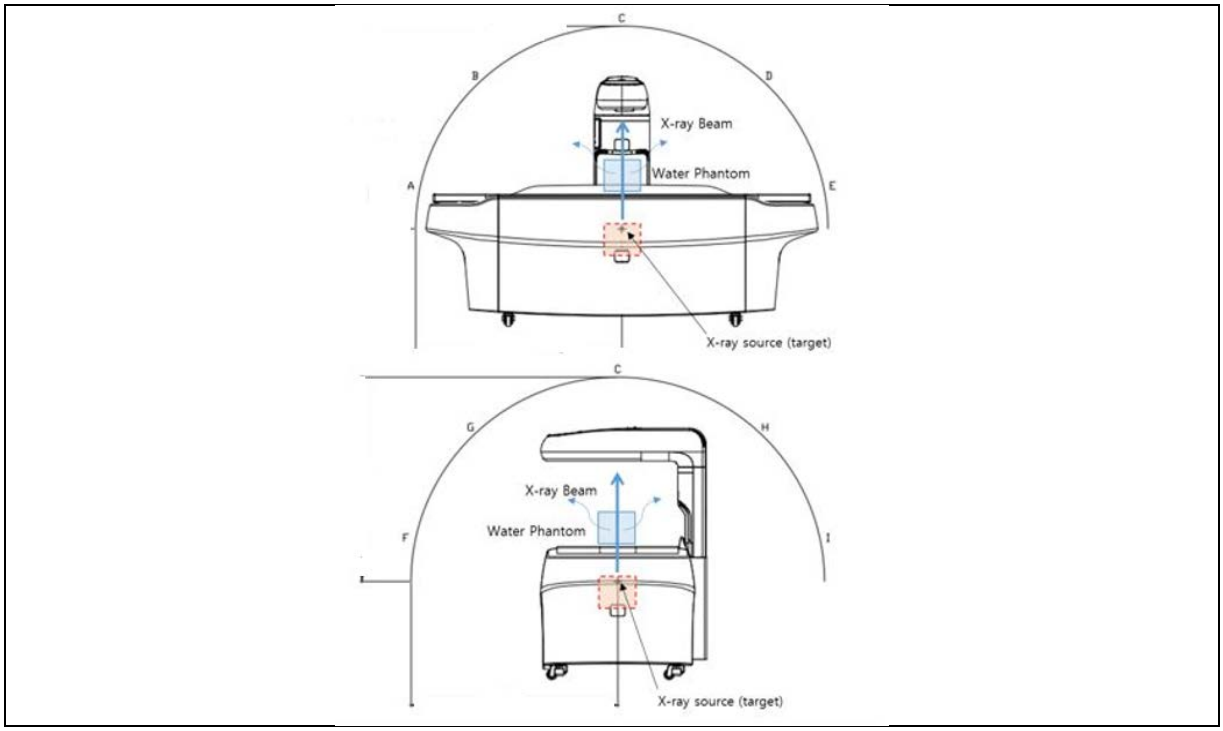
Aluminum filter	2.0mmAL/75kV
X-ray tube inner filtration	0.8mmAL/75kV
Total Filtration Equivalence	**2.8mmAL/75kV**

7.2.2 Radiation amount leaked outside

EXCELLUS scatter dose is as follows:

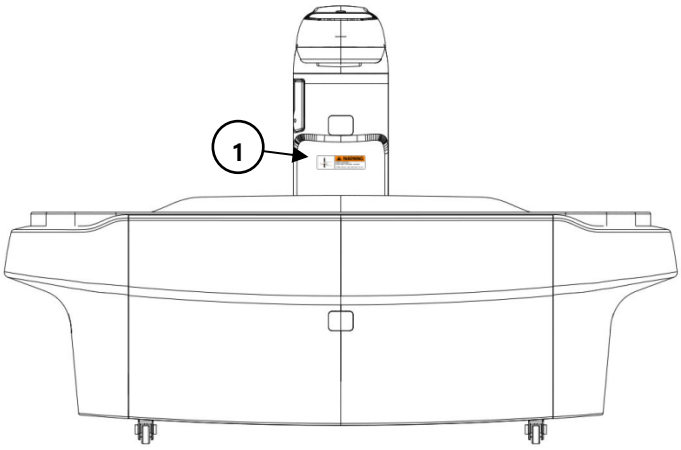
(HFG settings: 83Kv, 3.0mA)

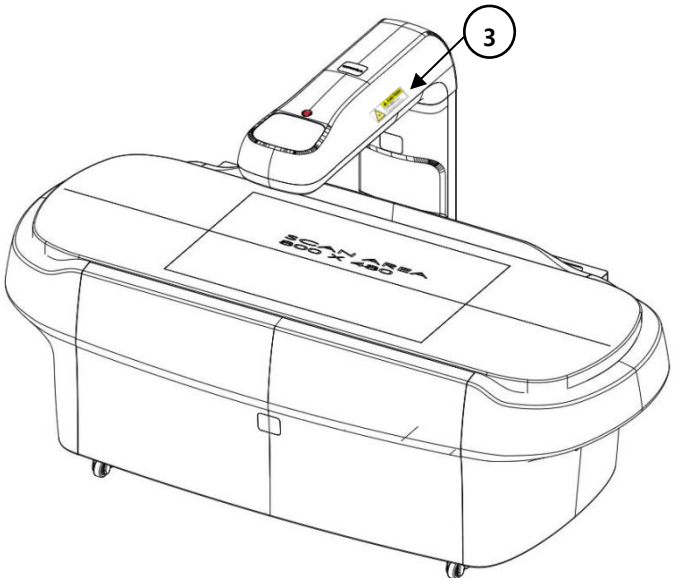
No	Position	Value Of Measured Scatter Radiation (uSv/hr)
1	A	0.24
2	B	0.48
3	C	0.24
4	D	0.35
5	E	0.31
6	F	0.33
7	G	0.53
8	H	0.28
9	I	0.20


C
B
D
A
E
X-ray Beam
Water Phantom
X-ray source (target)
C
G
H
X-ray Beam
Water Phantom
F
I
X-ray source (target)

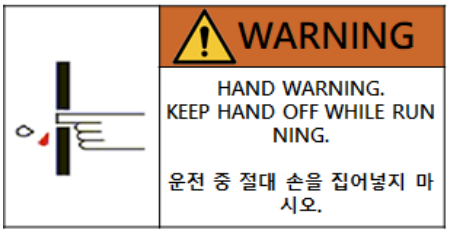
7.3 Labels

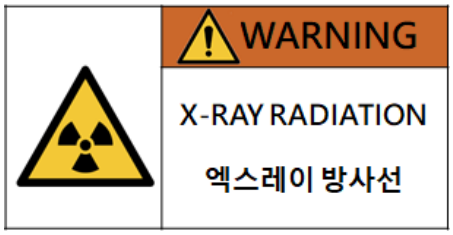
- Locations of the labels are as follows:





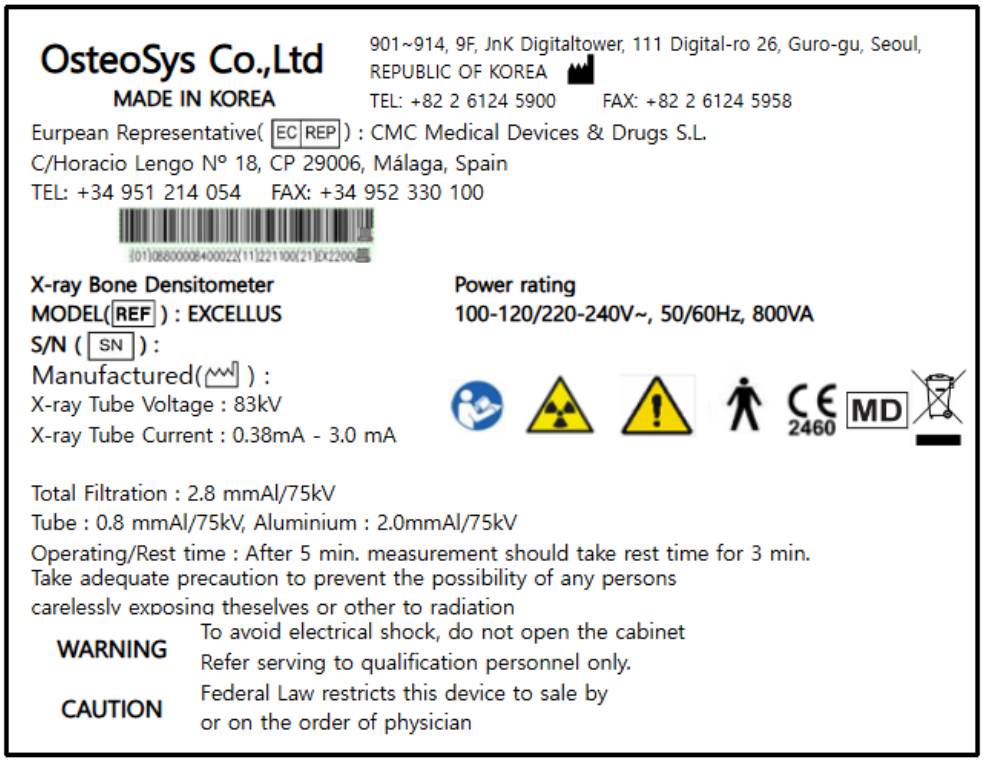
1) Hand warning label and X-RAY warning label





2) Laser pointer caution label

3) Equipment label



NOTE : Be sure to check the label information and location

ATTACHEMENT_Security

Security

SEC.1. Introduction
This section describes the security features, functionality and management requirements of OsteoSys software. The manual is intended to assist medical facilities in using the system in a manner that protects the privacy and security of patients and to perform their work in accordance with national regulatory requirements. This section also covers the expected software usage environment.
Software users should use risk management procedures to assess and prioritize security and privacy risks. Based on your risk assessment, you can make the most of the software's performance. Risk assessments should be closely compared to compliance and patient safety as well as security. If security mitigation is inconsistent with patient safety, patient safety is considered a high priority.

SEC.2. Security features
The software includes security features designed to allow flexible access to safety and security implementations, with a focus on the principles of confidentiality, integrity and availability. Throughout this document, information about the performance and use of these features is described.

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

SEC.3. Access control
Access control is a comprehensive mechanism used to determine and enforce the following:

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

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

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

NOTE !
Without any configuration, every user use this device need to be authorized.

SEC.4. Audit Control

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

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

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

SEC.5. Certification
Authentication is the process of providing an individual's identity and is a key component of an access control system.
A password inspector account is required to restrict access to patient health information to authorized personnel.

SEC.6. Password management
There is a risk of losing or hacking passwords. To create and use secure passwords, you can apply various rules to password generation. The following checklist is determined by the user.

Password	Recommended use pattern	Contents
minimum length	4-16 characters	short passwords are easy to remember, but are easily at risk. Long passwords are secure, but easy to forget or write down. Long passwords increase resistance to brute force attacks.
Expires	30 – 360 days	When the expiration date comes, the user must change their password regularly. A common rule of expiration period is to balance the length of the expiration authority with the password so that it expires before the password is cracked.
Character composition	You must mix uppercase and lowercase letters, 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 computer viruses, worms, Trojan horses, denial of service attacks, and other malware, continue to grow. Various levels of careful defense are necessary to prevent system damage from malicious software. Effective protection requires the cooperation and partnership of OsteoSys and its customers.

SEC.9. Customer's Responsibilities

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

1. OsteoSys software computing system holders must apply a validated Microsoft security software patch for their Windows operating system version.
2. The patch can be downloaded from Microsoft's website (https://support.microsoft.com).
3. Be careful not to forcefully shut down your PC when performing a Windows update.

SEC.10. Product features

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

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

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

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

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

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

Information security requirements should also consider:

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

And OsteoSys provides Cyber security product upgrades.

As soon as possible, third-party security patches need to be installed in medical products in accordance with regulations requiring.
OsteoSys Provides product security patch upgrades in a unified working manner by installation/field service personnel.

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

SEC.12. Software and Application Hardening

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

CAUTION !
The user needs to stop not needed system services to protect the whole system.

CAUTION !
The user needs to close not needed network ports via a firewall to protect the whole system.

SEC.13. Unauthorized network access

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

SEC.14. Virus protection software

You can protect your computer by following the standard computer running procedures. Antivirus programs are an appropriate way to make sure that your electronic media and files are free of viruses before they are introduced to your network. You must also install the latest validated operating system update patch.
You must install and run a virus protection program on the computer that uses the BMD. However, virus protection programs have the following disadvantages:
• Do not start a virus scan while using the device. Certain files are marked read-only.
• Your virus protection program may be false positive. Double check the isolation status before taking permanent action. Virus protection programs may incorrectly recognize medical image files as viruses and can damage them.
• If a virus protection program uses too much memory or system resources, the software may not work properly.

CAUTION !

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

SEC.15. System security
You can set up a screensaver with password protection to block access to the system after a period of inactivity.

CAUTION !

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

NOTE !

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

SEC.16. Data protection
Data protection and privacy are often based on customer management policies and procedures. The software includes features to help implement data protection measures. It supports device-to-device authentication of AE Title and IP addresses for network services such as DICOM.

SEC.17. HEALTH DATA Integrity and Authenticity
HEALTH DATA will be destroyed if it is changed in an unauthorized manner.
To ensure the integrity and authenticity of HEALTH DATA, authorized users must access and modify the health information in an approved manner.

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 could not recover the data not performed latest data backup when the disaster occurred.

SEC.23. Data Backup and Disaster Recovery

The UI Program backs up data and database once a week.
The user can recover after damage or destruction of device data, hardware, software, or site configuration information.

SEC.24. Media access control point

Removable media without security features and ports for media access represent a risk of data loss and theft. Restrict archive media and computer access to stakeholders.
Removable media is used for common backup options. Store media in a safe, locked place.
Secure the same terminal as the USB port and follow the computer security measures.

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

SEC.25. Remote service

Often, the most efficient and effective way to service OsteoSys is to access the system remotely. Every effort is made to ensure the security of these connections.
OsteoSys software requires separate TeamViewer remote access. In no case is the instrument activated remotely.
Unless you use the system or have a site visit, you will not be able to connect to your system.

SEC.26. Network Interface Specification and Risk Management
When properly connected to the network, the product supports the following functionality:
• DICOM connection to other DICOM devices
• Remote service connection via TeamViewer

SEC.27. Network Interface Technical Specification

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

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

SEC.28. Network information flow

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

Warranty

Thank you for using OsteoSys' bone density equipment.
OsteoSys'equipment are developed and manufactured according to the laws related to medical equipment.

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(installation date).

- For the following cases, small amount of service fee will be billed; you will be charged for service after warranty period.

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
5. Failure due to unauthorized disassembly and assembly of the product

- For service, please provide the following information and send the form via FAX +82-2-6124-5958, or contact your local agency or store at +82-2-6124-5900.
  For immediate service, please provide the following information or let us know the problem of your equipment.

  Model name / Serial number: EXCELLUS
  Name of the hospital:
  Contact information of the hospital:
  Date of installation:
  Comments:

OsteoSys (sign/seal)

Note: