PRIMUS

User Manual

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Doc. version : 4.3 (2024.09.10)

CE 2460

OsteoSys

http://www.osteosys.com

OsteoSys Co., Ltd.

PRIMUS

User Manual

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Contents

1 General Use

1.1 How to write in Manual

1) Marking

User Manual and Installation Manual are 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) Lavel

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 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 equipment's controller and the display monitor when measuring a patient or conducting a daily test.

: X-ray OFF

- It indicates 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

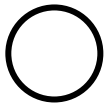
It indicates X-ray is radiated; it could be dangerous for patients and users when exposed to a large amount of radiation.

: Laser Pointer

It displays danger of laser pointer.

: 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 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 toearthing 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 EURIPEAN 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 using 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, the communication can be interrupted depending on the integratedboard 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.
- Operator or user can't adjust measureing parameter. This device is fixxed paramter.

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.
- 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.

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 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 which 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. PATIENT can be exposed to RADIATION dose levels where deterministic effects may occur in NORMAL USE

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 pace maker or implantable defibrillator may cause device malfunction. Avoid direct X-ray irradiation on X-ray implantable cardiac pace maker or implantable defibrillator, and limit X-ray output to a minimum.

1.4 Software

User programs and the application programs for using the equipment 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 official items for the company services.
* When the equipment was used in a location that does not follow the installation/operation standards for the equipment.

Warning: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth

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 our AS team or the local authorized 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 product 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

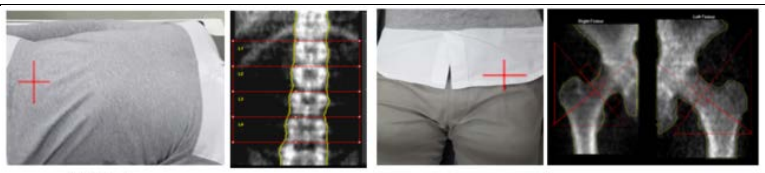
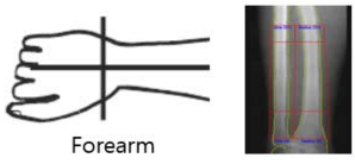
This symbol marked in the product manual or on the packaging indicates the product should not be handled as household waste. To dispose the equipment, send the electric/electronic equipment or electric medical devices to waste collecting locations for recycling. Proper disposal of the product prevents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

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

1.10 Guidance and manufacturer's declaration

Clinical information			
No	**Contents**	**A or N/A**	**Description**
1	Intended Use	A	The PRIMUS 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 PRIMUS system provides an estimate of body composition. The measurement sites in PRIMUS are the spine, femur, forearm and totalbody.
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). Provides an estimate of body composition (PRIMUS only).
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. Any condition that precludes proper positioning of the patient to be able to obtain accurate BMD values
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, Osteoporosis 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) Measure those anatomic sites commonly measured in clinical practice, typically spine and proximal femur(s). and here is more detailed below. Skeletal sites to measure: *Measure BMD at both the pa spine and hop 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 PRIMUS system provides an estimate of body composition. The measurement sites in PRIMUS are the spine, femur, forearm and totalbody.

Guidance and manufacturer's declaration – electromagnetic emissions		
The model PRIMUS is intended for use in the electromagnetic environment specified below. The customer or the user of the model PRIMUS should assure that it is used in such an environment. *Intended user profile		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model PRIMUS uses RF energy only for its internal functions. Therefore, its RF emissions are very low+ and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The model PRIMUS is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
PRIMUS with radiation protection in accordance with IEC 60601-1-3:2008, where PRIMUS represents the object (X-ray equipment) for which complicance is to be stated.		

Guidance and Manufacturer`s Declaration – Electromagnetic Immunity

This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Potrable RF communications equipments shoud be used no closer than 30 cm (12 inches) to any parts of the product. Otherwise, the performance of this equipment could be degraded.

Guidance and manufacturer's declaration – electromagnetic immunity			
The model PRIMUS is intended for use in the electromagnetic environment specified below. The customer or the user of the model PRIMUS 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	Mains 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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model PRIMUS requires continued operation during power mains interruptions, it is recommended that the model PRIMUS 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			
The model PRIMUS is intended for use in the electromagnetic environment specified below. The customer or the user of model PRIMUS should assure that it is used in such an environment.			
Immunityte st	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz Outside ISM	3 Vrms	Portable and mobsile RF communications equipment should be used no closer to any part of the model PRIMUS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the

Radiated RF IEC61000-4-3	Bandsc amateur radio bands Bandsd 6 Vrms 150 kHz – 80 MHz In ISM bandsc amateur radio bands Bandsd 3 V/m 80MHz to 2.7 GHz 10 V/m Home Health	6Vrms, 150 kHz to 80MHz 3 V/m 80MHz to 2.7 GHz	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 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

To 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	IEC60601 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 CDMA 1900 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 LTE Band 7	Pulse modulation 217 Hz	28V/m	28V/m
	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

PRIMUS 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 when 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.

- 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 abnormal movement or noise and contact the applicable agency or our 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.

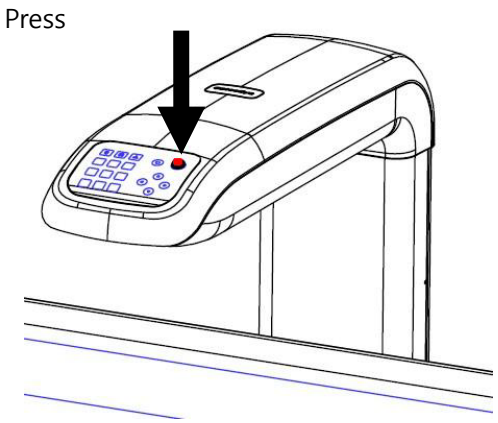
- Check the location of the emergency switch in case of an emergency.

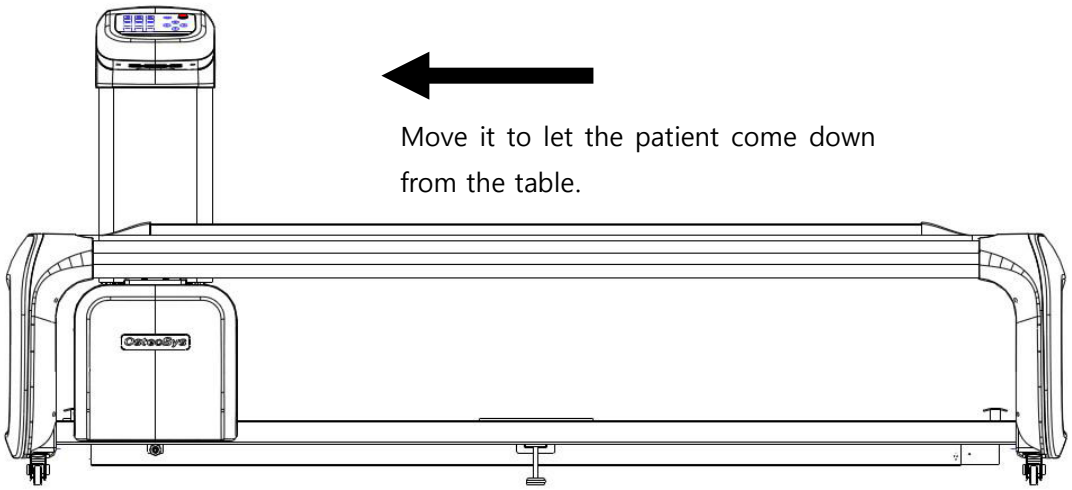
- If the plug is incorrectly connected, check the fuse condition. If the fuse is burnt out, contact the A/S team.

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.
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.





2.3 Stopping the equipment when emergency evacuation

Follow the procedure below for evacuation when 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 fire

a. Turn OFF the main switch, remove the power supply connected to the equipment when 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 PRIMUS product

4.1 About the product

PRIMUS 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. Additionally, it analyzes the whole body and regional body composition including fat mass, lean mass and fat%.

- Type : Whole Body DXA (with total body composition)
- Method : Narrow fast Fan-beam
- Scan method : Rectilinear scan
- Scan site : AP spine (L1-L4)
  Femur
  Forearm
  Totalbody
- Measuring method : One Scan (Simultaneous measuring 3sites among AP Spine and Dual Femur)
  Ergonomic Scan
  Rescan
- Measuring information : BMD(g/cm^2), BMC(g), BMI, T-score, Z-score, Area(cm^2),
  Total body BMD, Total body composition (Fat(g)/Lean(g)/BMC(g)/Fat(%)/BMD%/ Color coding image trend)
  Regional body composition (right/left arm, right/left leg, femur, Fat and Lean analysis, android, gynoid) in the unit of % and gram,
  HA(Hip Analysis), Orthopedics and Prosthesis Hip, Orthopedic Knee, Scoliosis, Kyphosis, AFF, Hand,
  Study mode(Free regional scan and analysis)
- Reference Data : Total 28 types of standard data (Middle East, 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, Hongkong, NHANES(2005-2008)_All, NHANES(2005-2008)_Mexican, NHANES(2005-2008)_White, NHANES(2005-2008)_Black)

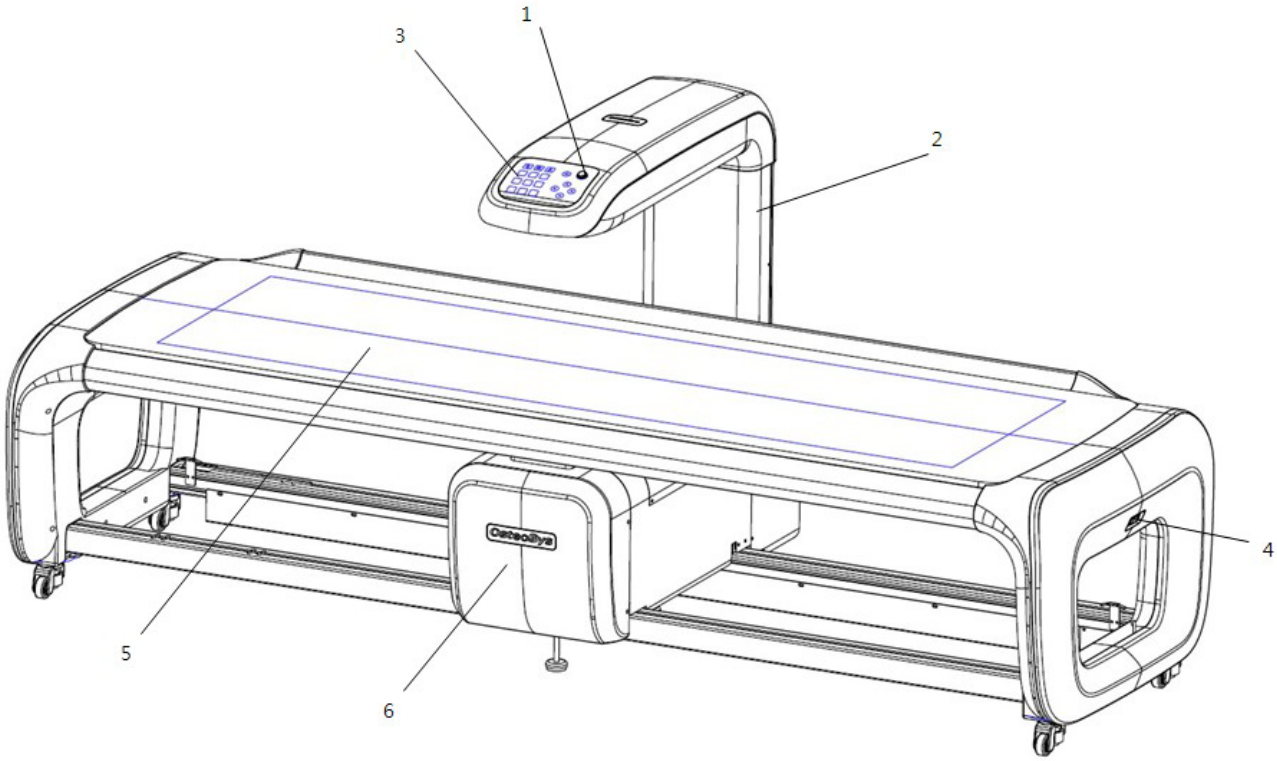
- Target patient group : 20 – 100 years old., Patient weight capacity 230kg Asian, Black, Hispanic and White
- Modifying specific site : A user can add/delete bone and Tissue to reduce errors in calculating BMD for fracture, implant, and surgery area.
- Automatic Calibration : Available with Daily calibration 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 (VAT /Visceral and subcutaneous Adipose Tissue ratio calculation), trend output
- Trend report and Comparison function
- Software : AP spine Measurement and Analysis
  Femur M&A
  Orthopedics(Prosthesis Hip) M&A
  Total Body M&A
  Partial Body M&A (regional)
  Forearm M&A
  Lateral Spine M&A
  VFA(LVA, DVA) M&A
  Whole Body composition
  VAT (Visceral Adipose Tissue/Visceral Fat Ratio)
  SAT (Subcutaneous Adipose Tissue/Subcutaneous Fat Ratio)
  Hand M&A
  Study M&A
  Knee M&A
  FIM Study M&A
  Dual-energy vertebral Assessment (L4-T4, Lateral and

AP)
AFF (Atypical Femural Fracture)
Hip Analysis
Scoliosis Analysis
Kyphosis 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

- X-ray tube information for Standard Mode

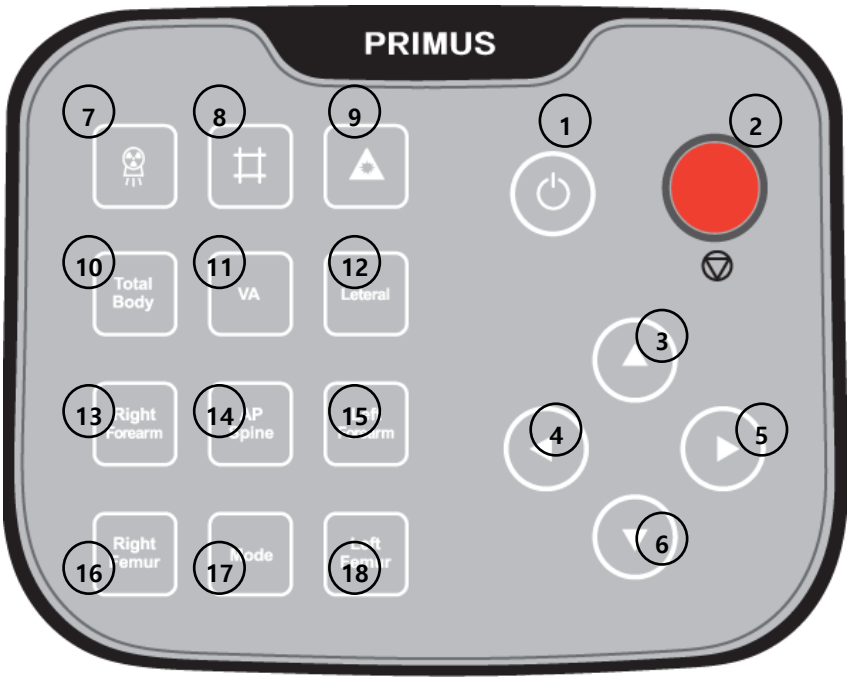
	Mode	X-ray Tube Voltage (kV)	X-ray Tube Current (mA)	Etc.
1	Total body	83	0.38	
2	Forearm	83	0.2	
3	Spine	83	3.0	
4	Femur	83	1.0	

4.2 PRIMUS exterior



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

4.3 User operation pannel exterior



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

4.4 PRIMUS system

Main Body		
No.	product	note
1	Main Body(PRIMUS)	
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 product in the accessory or component list are not included, contact the manufacturer.

5 PRIMUS basic installation

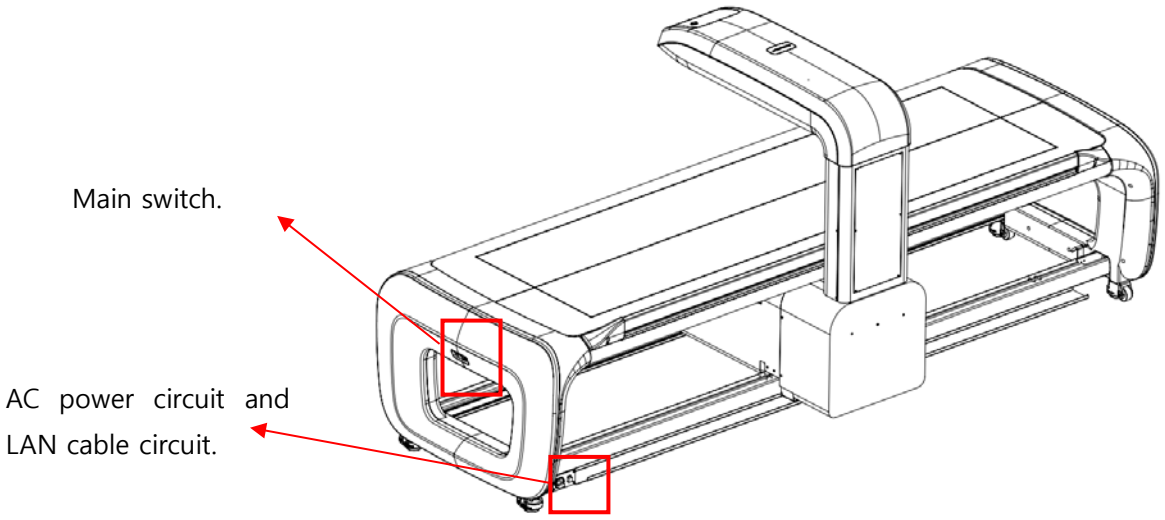
5.1 Moving the equipment

- PRIMUS 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.

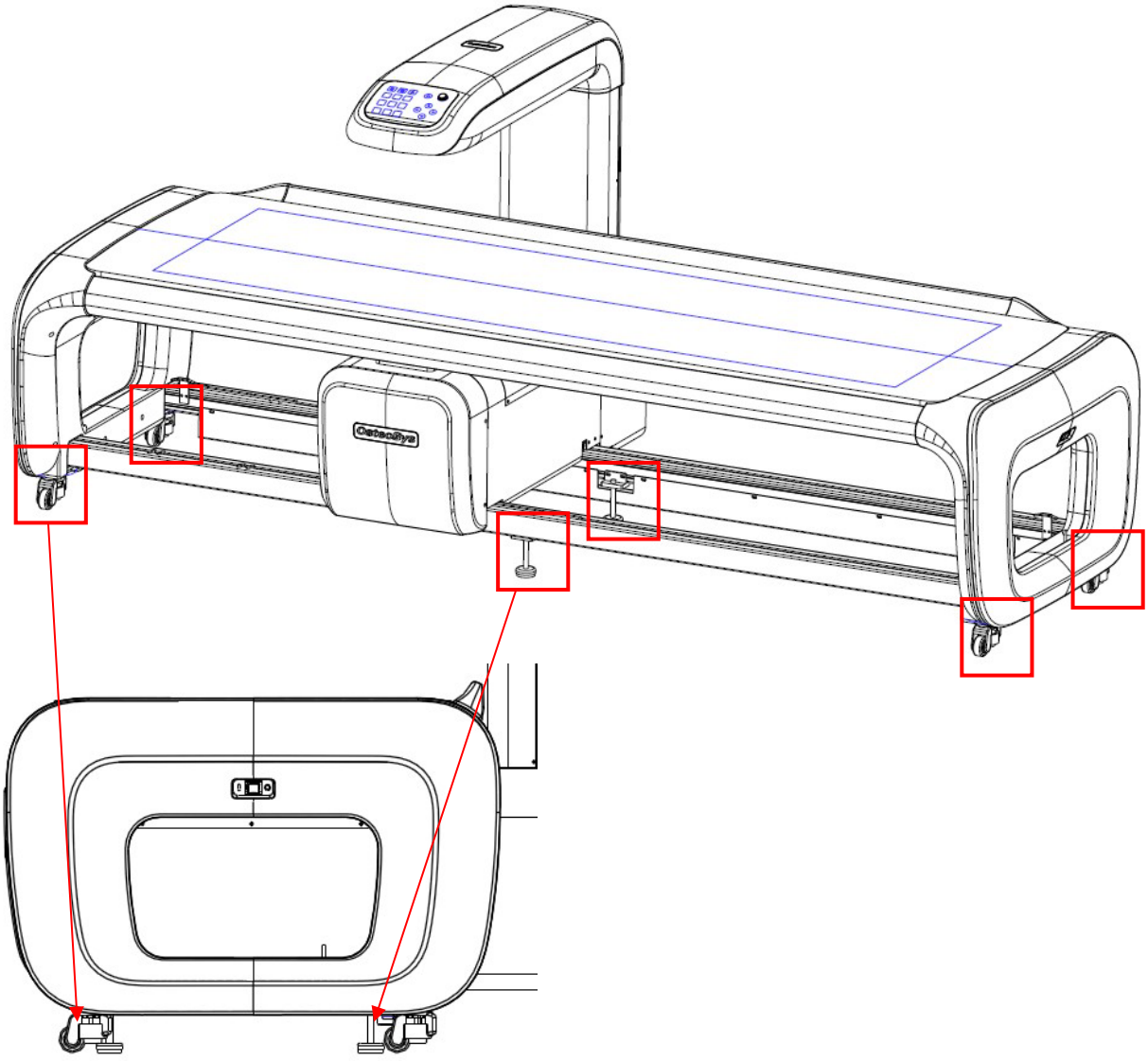

When tilting or moving PRIMUS, the carriage should be protected to protect the equipment; please contact our AS team or an agency.


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

Note : Check the location of the product power switch.



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



Counterclockwise fixing block

Clockwise fixing block

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 PRIMUS 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 abnormal operation.

Examples of improper installation and storing location:

1) Too much humidity.
2) Direct sunlight.
3) Higher temperature than the proper temperature for the product (10℃~40 ℃)
4) Physical impact or vibration that can affect the product.
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.

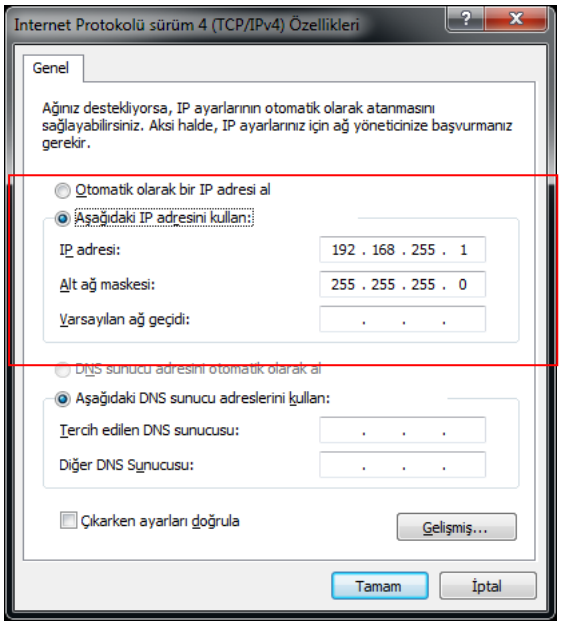
Install the equipment on a flat/horizontal ground. Otherwise the carriage or HFG may move towards the slope when the power is OFF.

5.3 Software installation.

1) PC LANCARD Network IP setting.

- PRIMUS 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.

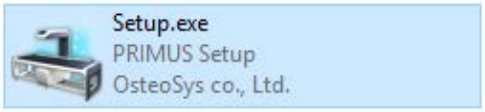


2) Use program installation.

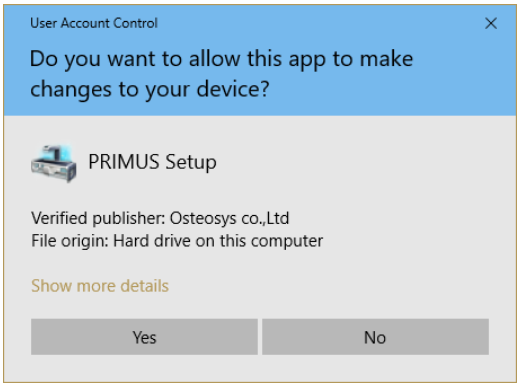
a. Insert the CD into the PC.

b. Click 'My Computer' icon and right-click the drive where the CD is inserted.

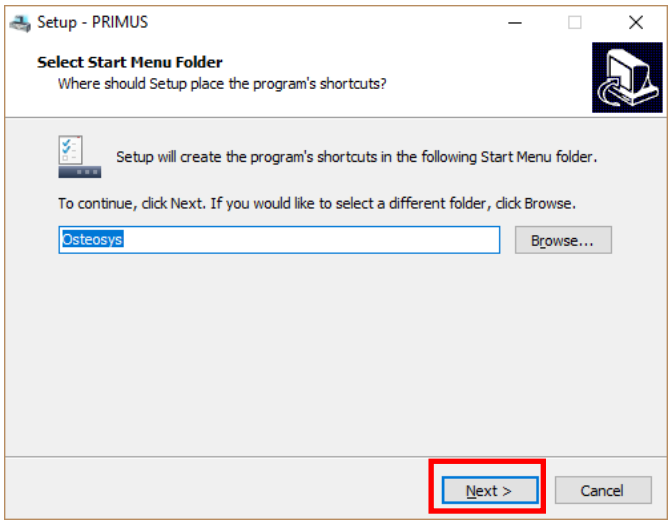
c. Click 'Search'; when the window pops up, find and click 'Setup.exe'.



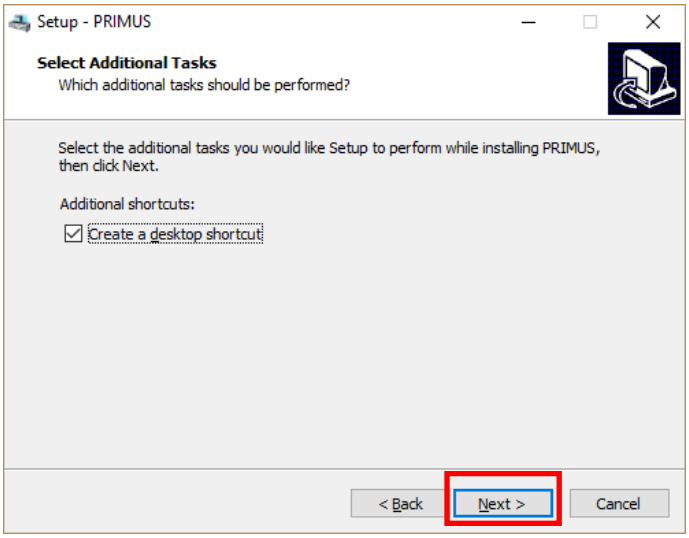
d. Wizard will start for PRIMUS installation.



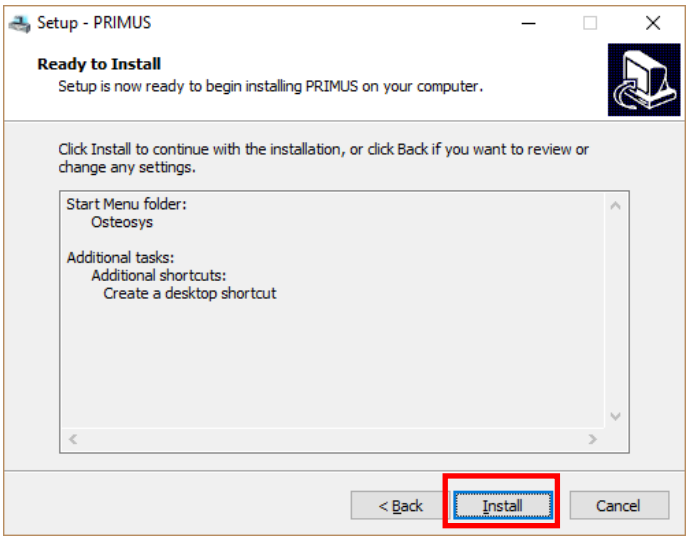
e. Press 'Next' button.



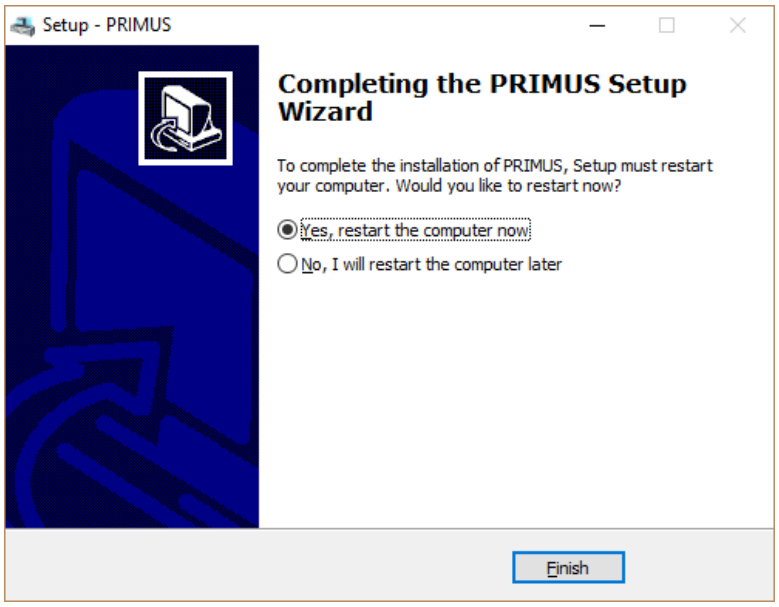
f. If you would like to install an icon on desktop screen, check the box and click "Next' button.



g. Click 'Install' button to start installation.



h. PRIMUS Program installation is completed.



For the normal execution of the program, be 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 PRIMUS folder is created in Application Data folder.

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

6 Using PRIMUS Program

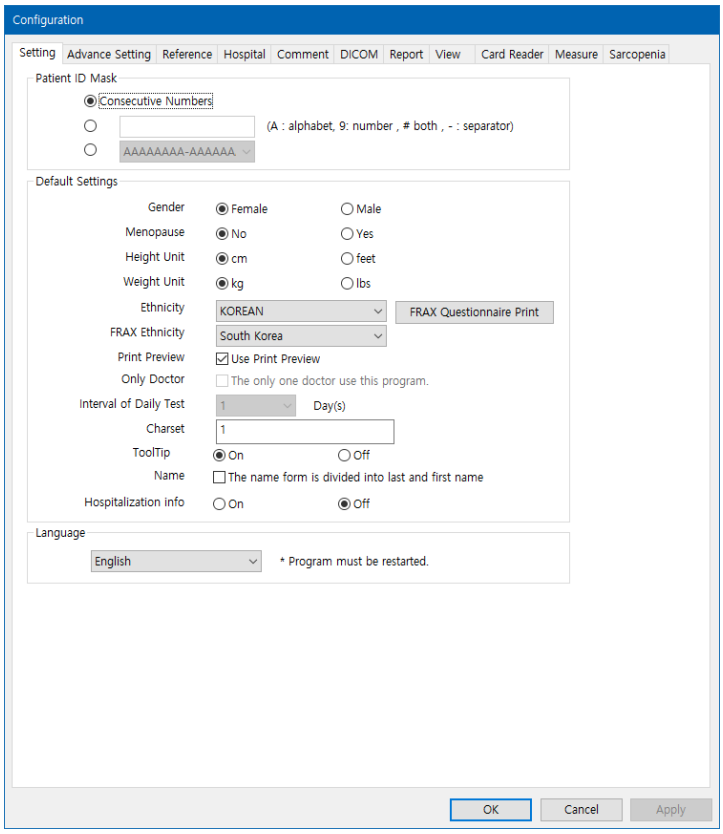
6.1 Starting the program.

- Turn ON the equipment and click PRIMUS 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.
- Hospitalization info : You can enter information about hospitalization.

c. Language

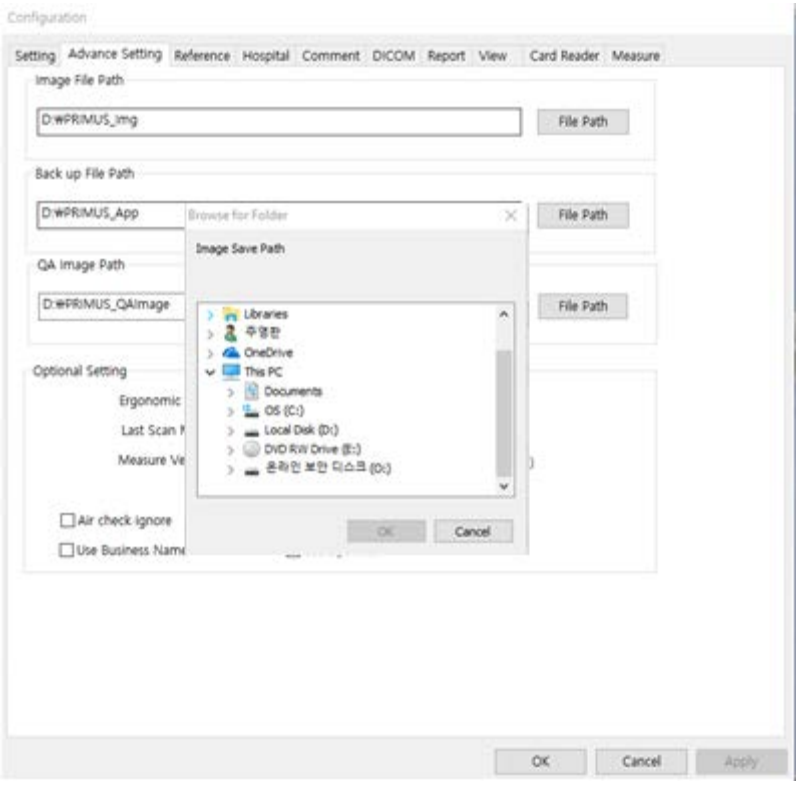
- Various languages are available and the change will apply when restarting the program. Check available languages by selecting the combo boxes.
  (The change will apply only after restarting the program.)

2) Advanced setting

- Set a path to store the result image.
- Set a file path for backup.

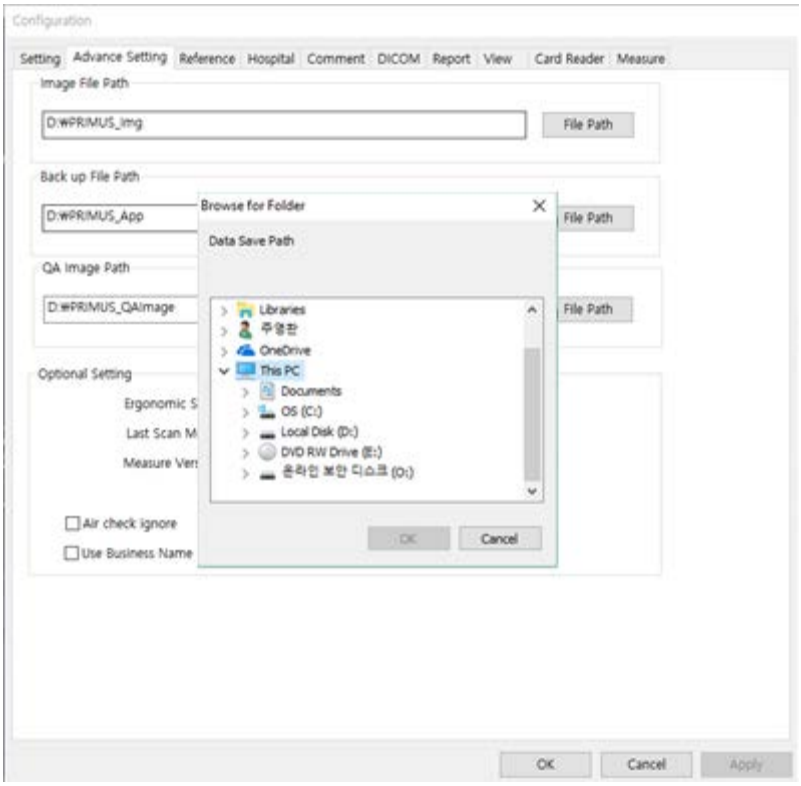
a. Path for Image Files.

- 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.

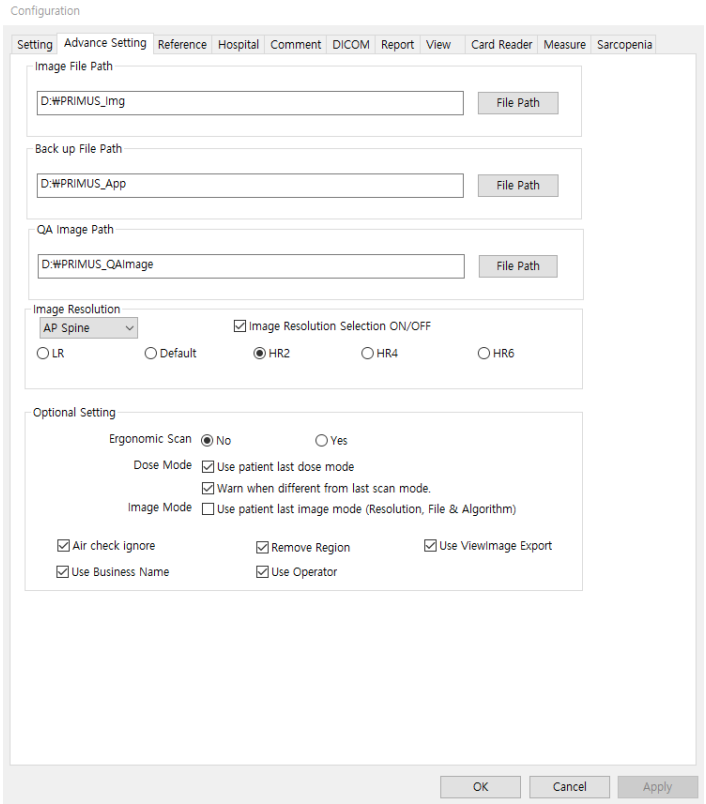


b. Backup File Path.

- 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. Optional Setting



- Ergonomic Scan : It selects whether you would like to use ergonomic scan..

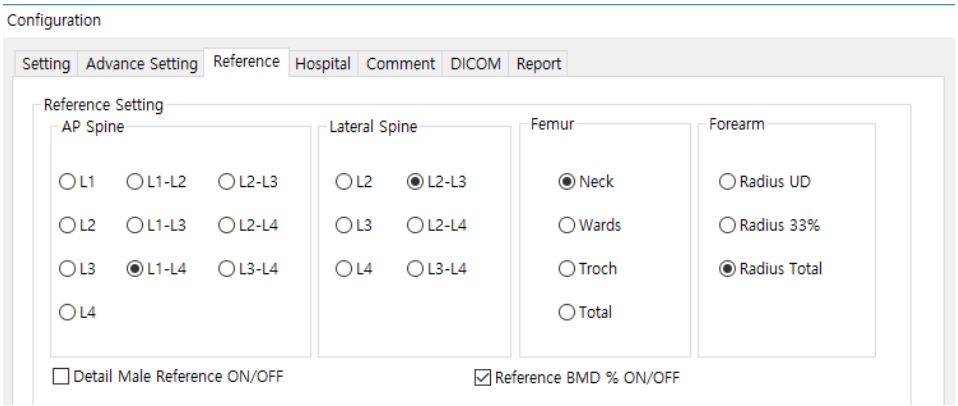
- Last Scan Mode : Use patient last scan mode.
- Measure Version : Use patient last measure version
- Air check ignore : The measurement continues even if there is no object
- Remove Region : Sets the T-Score notation change when removing a region.
- Use Business Name : Use patient's company name. You can check the company name in the Report.
- Use Operator : Use operator. You can check the operator in the PatientList and the Report.
- Use ViewImage Export : You can save the View Image selected in the Analysis tab as an image file.

3) Reference

- Set a value of graph to be drawn on analysis 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.



Detail Male Reference ON/Off

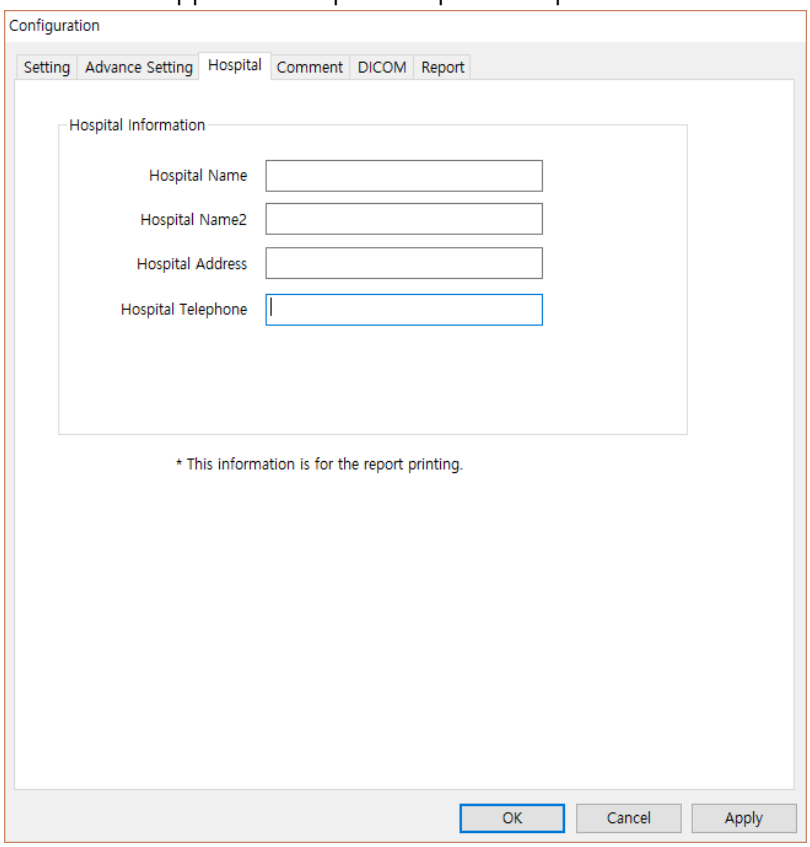
- It shows Male Reference graph into 3 (off) or 5 (on) grades.

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

a. Auto 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

b. Quick Comment

- It is a function to add a preset phase to study comment
- Quick comment appears only when the auto comment setting on the Report tab is turned off.

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, and ATitle)

b. Worklist Server

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

c. Query

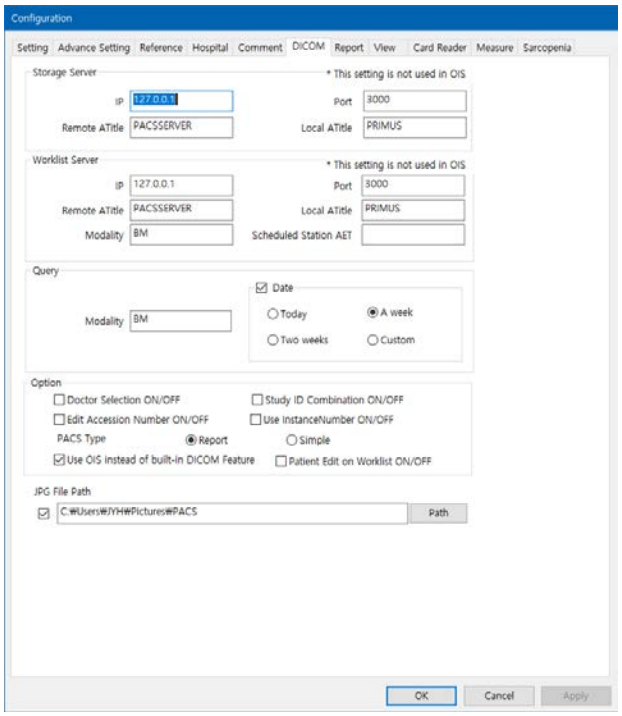
- It sets up a basic modality and period

d. Option

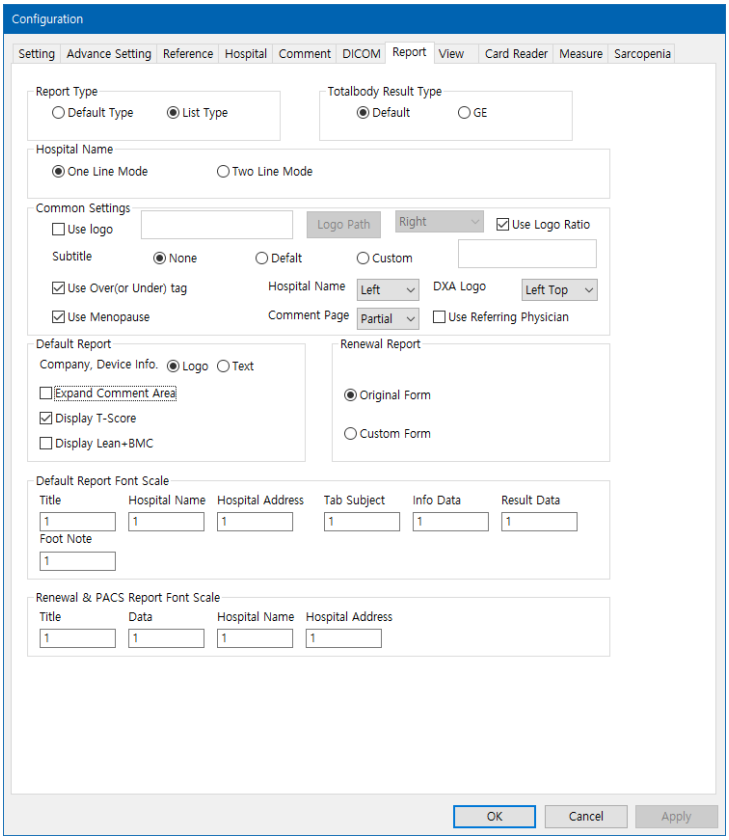
- It sets up the window of selecting Doctor for DICOM
- It selects Report Type and Simple Type for PACS transmission

e. JPG File Path

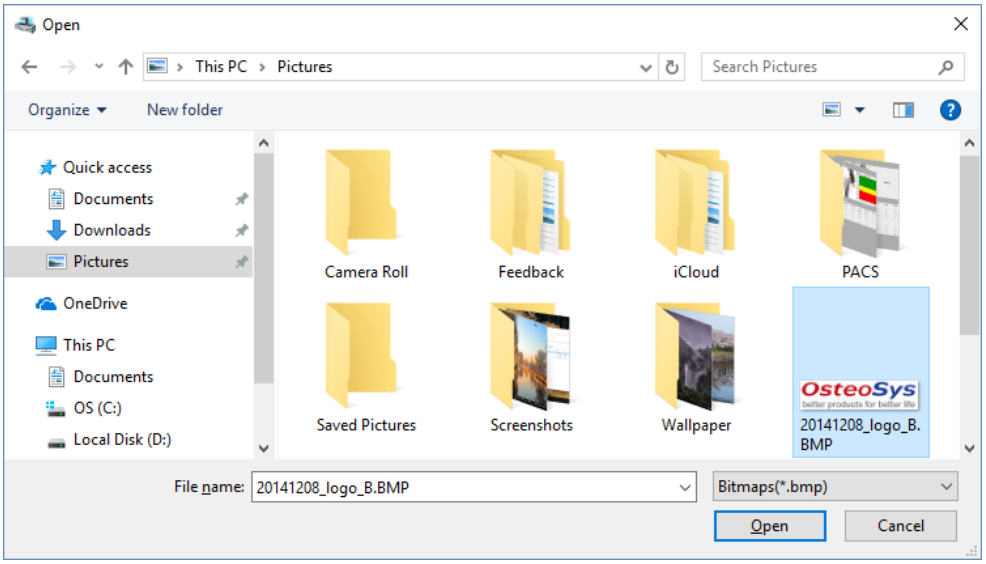
- You can save PCAS image with JPG file into the path that you set for PACS transmission



7) Report



- 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

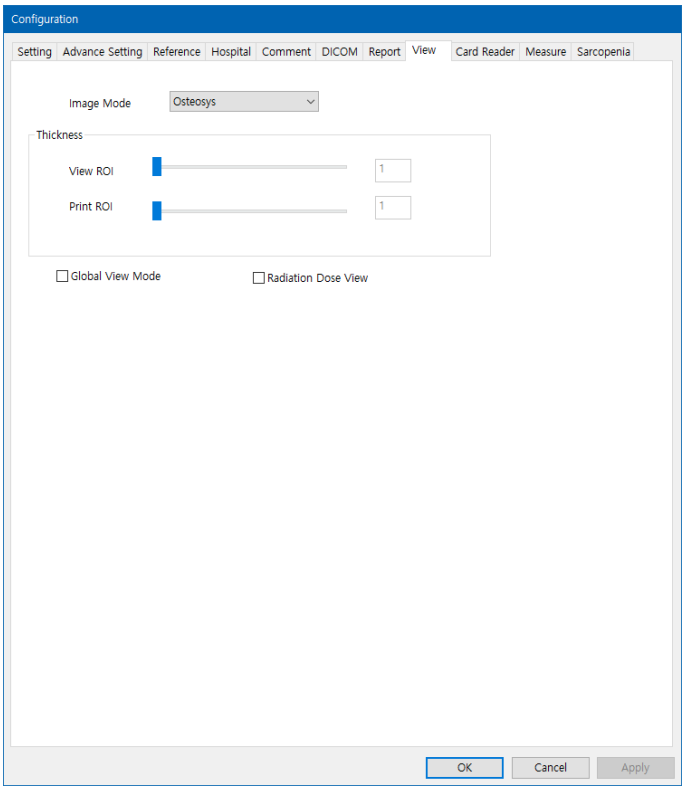
Logo format:

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

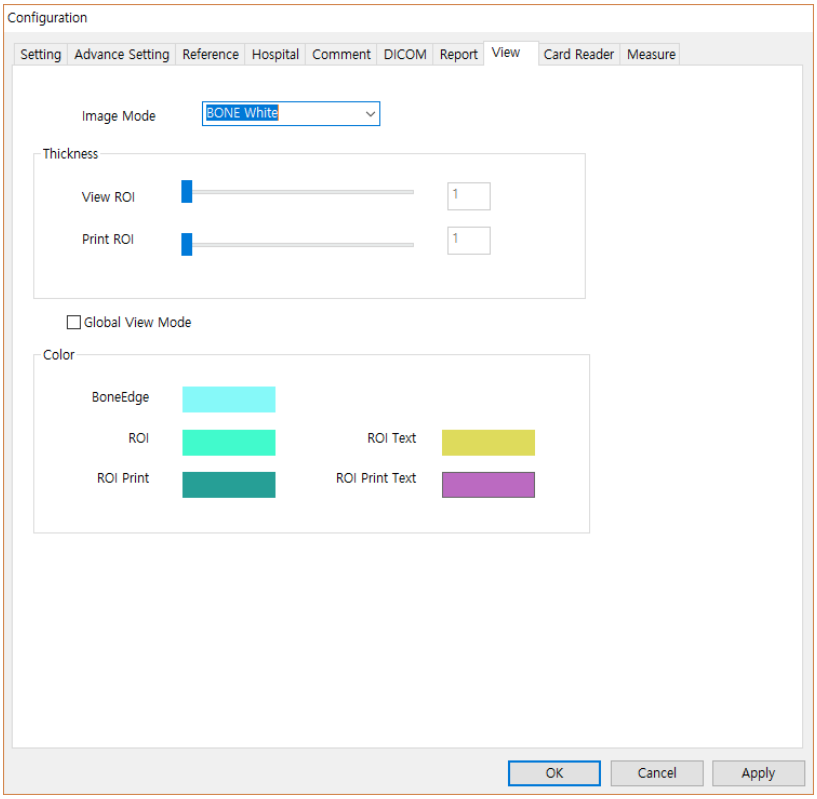
Create a file and save it in [C:₩Program Files₩Osteosys₩PRIMUS₩Resource] folder. You can save it in a folder you want.

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

8) View

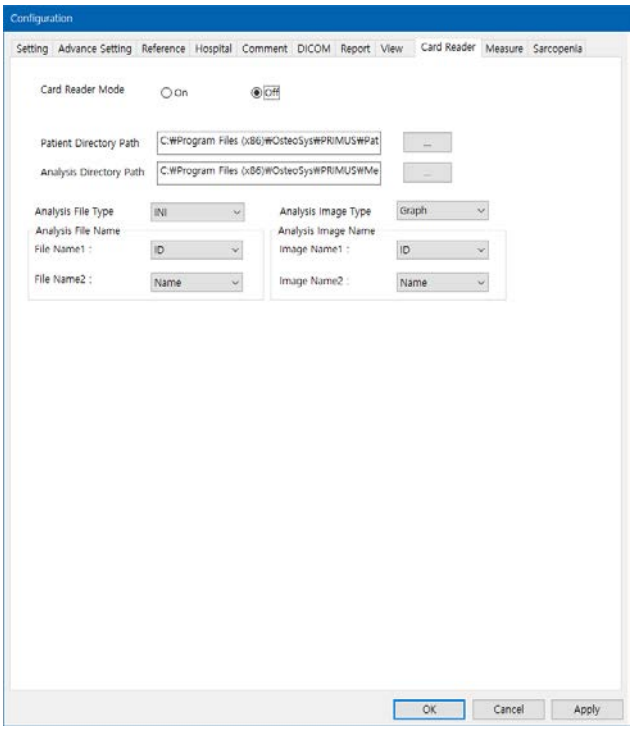


- It sets up image mode, color and ROI thickness.
- Image mode : Osteosys, GE, Hologic, Bone Black, Bone White
- Global View Mode : It shows the area specified as global ROI in the image.



- 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₩PRIMUS₩PatientInputDir"

c. Setting patient analysis file directory

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

d. Setting patient analysis file name

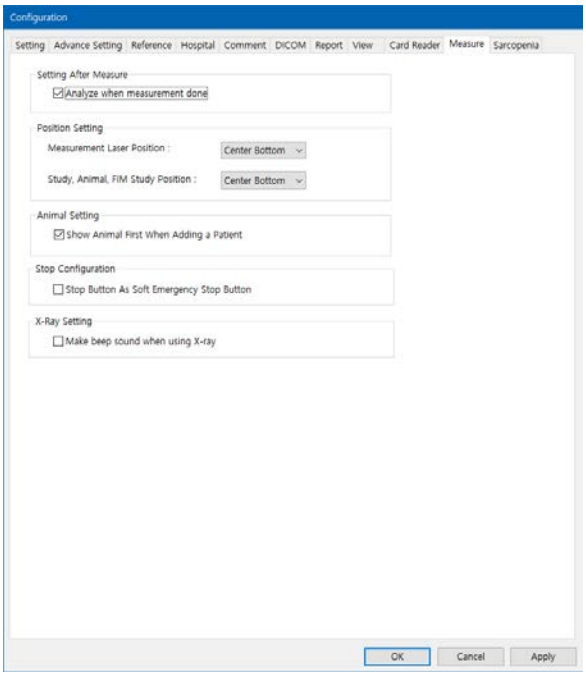
- It sets up patient analysis file name.
- Type : None, ID, Name, BirthDate, Gender
- Default Value : FileName1 - PatientID, FileName2 - PatientName
- EX) FileName1 = ID, FileName2 = Name
  file name : #ID_#NAME_#SITE.ini or #ID_#NAME_#SITE.txt

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

10) Measure



- It sets up measurement.

a. Setting After Measure
   - Analyze when measurement done

b. Position Setting
   - Measurement Laser Position : Except Study, Animal and FIM Study sites, Select Default and Center Bottom mode.
   - Study, Animal, FIM Study Position : Select Right Bottom, Center and Center Bottom mode. Default Position is Right Bottom.

c. Animal Setting
   - Show Animal First When Adding a Patient

d. Stop Configuration
   - Stop Button As Soft Emergency Stop Button

e. X-ray Setting
   - Make beep sound when using X-ray

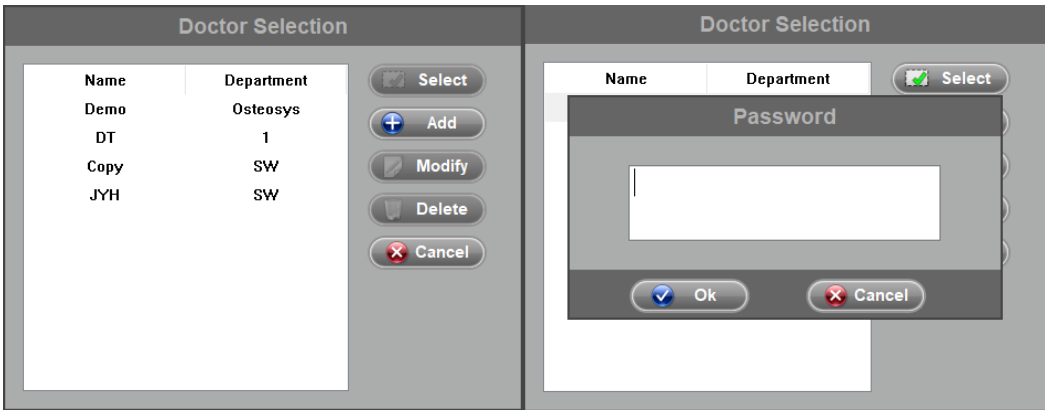
6.3 Doctor registration.

- PRIMUS 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 [Page44b. 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.

- PRIMUS requires daily inspection in accordance with preset inspection interval for accurate measurement.

Daily inspection is required based on the 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, checking daily equipment status is not available which may affect BMD; it is recommended to set the cycle every day.

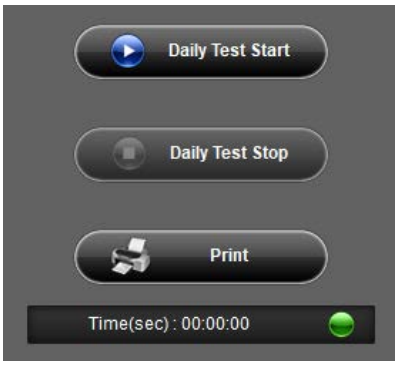
Do not put any object on the bed except the daily inspection phantom when daily inspection.

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

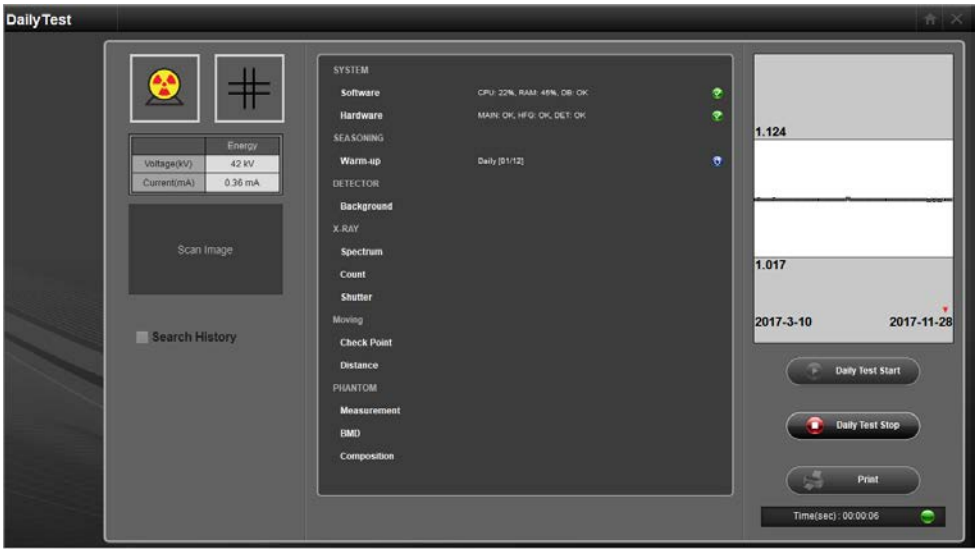
a. Click 'Daily Test', the second icon from the top of the User program main screen.
b. Tendency graph will be displayed at the right top, which shows the result of daily inspections (BMD). An indicator lamp will be at the right bottom, which shows the communication connection status.

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

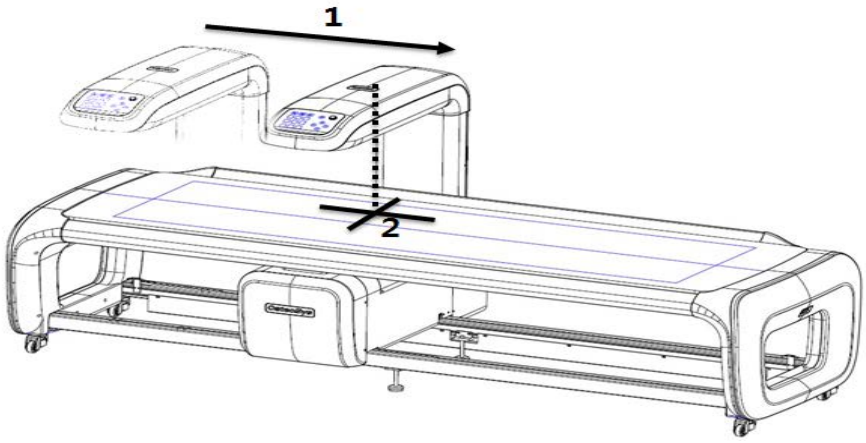
c. When  is ON, click 'Daily Test Start' button.



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

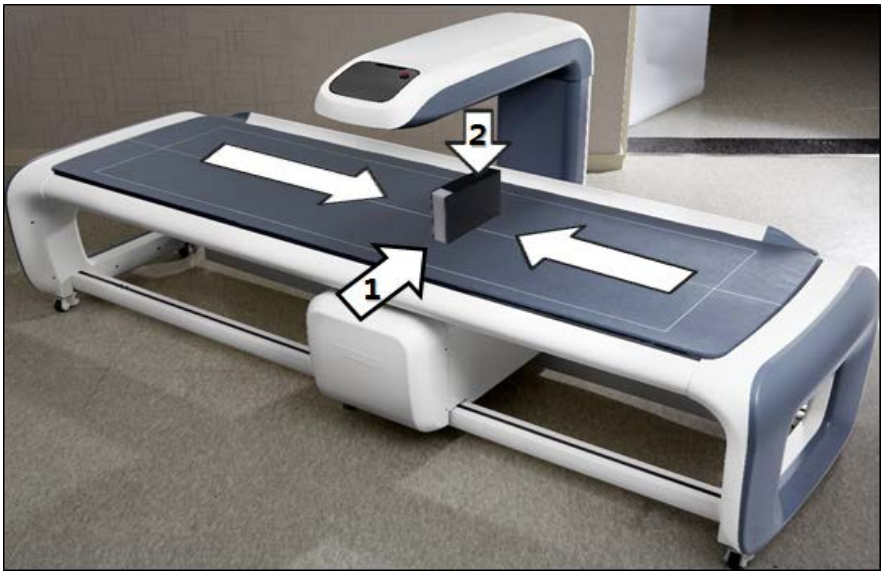


e. After the equipment carriage is located where daily phantom is placed, laser pointer will be put on.



⚠ 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 switch, place the white section of phantom to be seen on front, under the carriage of equipment (Figure A).

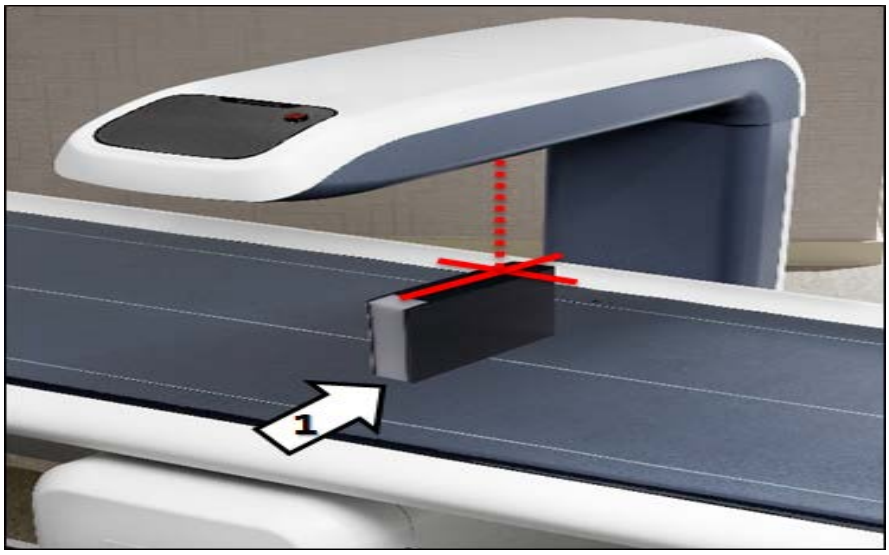


Figure A.

- 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).

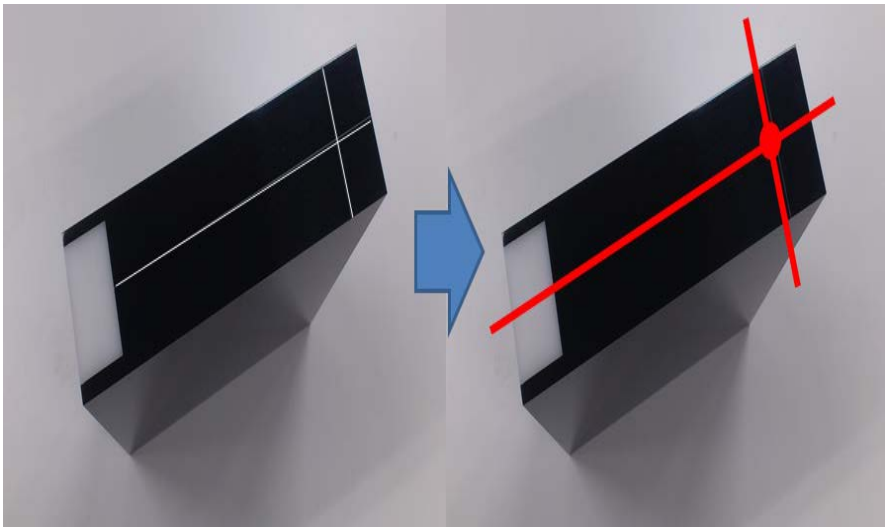


Figure B.

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 complete, 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 complete. When approaching near the equipment in operation, pay a close attention to safety because it may cause injury.

6.5 Measuring.

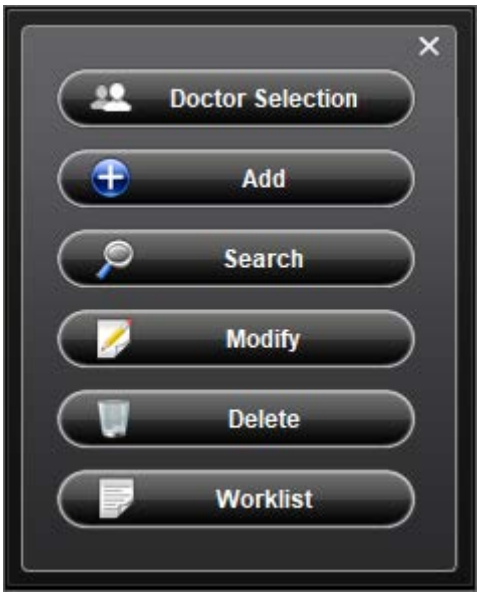
Click 'Measurement' in the main screen for measuring.

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 : Output patient information from Worklist server.
- To close the pop-up window, press [X] in 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.

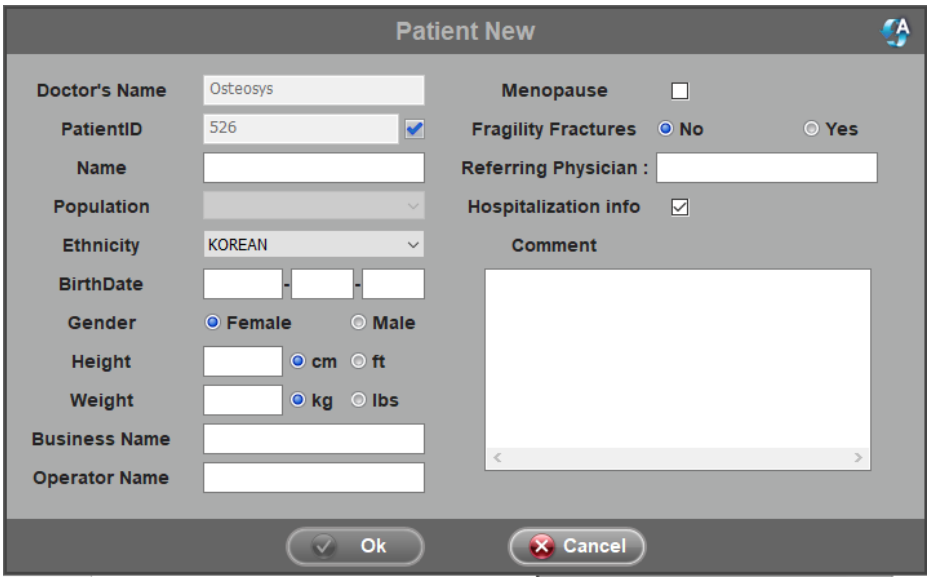
- Doctor Name : It displays the name of the doctor currently selected.
- Patient ID : Fill in the chart number of the patient ID.
- ID Check : Check if there are same chart numbers or IDs.
- Name : Fill in patient's name.
- Birth data : Fill in patient's DOB.
- Gender : Select patient's gender.
- Ethnicity : 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 if 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 complete, click 'OK'.



d. Hospitalization Information registration

A. It can be used by activating "Hospitalization Info" as Yes in the environment setting.

B. It is used when it is necessary to enter hospitalization info.

C. You can enter the following.

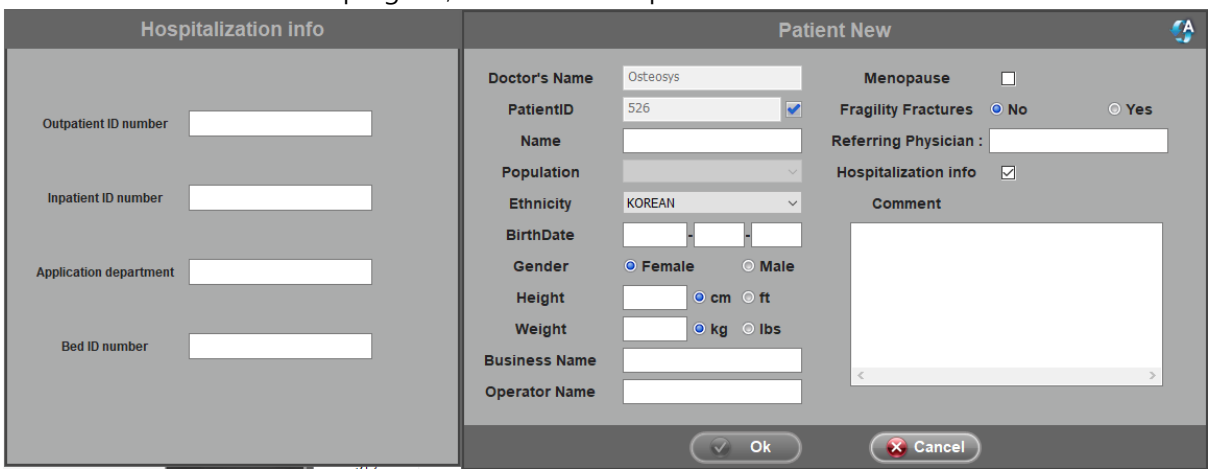
i. Outpatient ID

ii. Inpatient ID

iii. Application Department

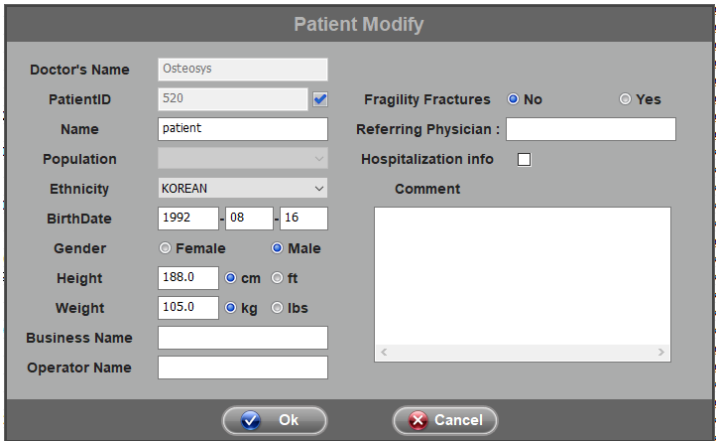
iv. Bed ID

D. In the user program, Main>click Hospitalization info.



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'.



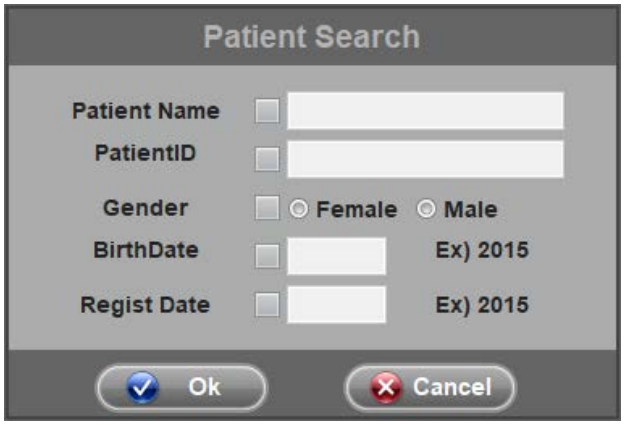
6.5.3 Deleting patient data and personal information

- 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

A. Positioning:
After site selection, to keep the measuring equipment stable, warm up the equipment and move the basic position as the user designated. Turn ON the laser pointer in the equipment operation panel and Show the manual measurement window on right top.

B. Measure Start:
In the equipment operation panel, set all scan sites before starting measuring.

C. Rescan:
After starting measuring, if the scan site is not set correctly, press the button to reset the site and measure again.

D. Stop:
It stops the equipment.

b. Available Scan type: APSpine / Left Femur(AFF) / Right Femur(AFF) / Left Forearm(GDP and Hand) / Right Forearm(Hand) / Total Body / LVA / APVA / Lateral Spine / Left Orthopedic(Prosthesis Hip) / Right Orthopedic(Prosthesis Hip) / Knee / Study(FIM Study) / Animal / One Scan(Multi Scan)

 One Scan feature is not available for Forearm / Total 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)].

 What is AFF?

AFF is the abbreviation for Atypical Femoral Fractures. AFF function predicts and analyzes irregular fracture in the shaft.

 In case of AFF,

Scan area of AFF is same as Left Femur or Right Femur.

At the measurement screen after press "Positioning" button, you select Left Femur or Right Femur on site selection. The scanner move the basic position as the user designated. The manual measurement screen pops up on right top.

Then, click "AFF", set scan area and mode.

When set up is completed, press "Measure start" button.

c. Fast Mode is applicable for Spine / Left Femur / Right Femur, total three area Other than these areas, Fast mode is not applicable.

 What is Fast Mode?

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

 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

 In case of APVA

Select VA button and select VA again, then it will change from VA to APVA

Ex> VA -> APVA ->cancel

 What is GDP?

GDP refers to the prediction of growth that predicts height of the children when he or she grows up by using bone density

 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.

 What is FIM Study?

FIM is the abbreviation for Fat in Muscle Study which measures fat in muscle. FIM Study applies LScope, BScope, VAT function of PRIMUS for analysis. You can quantitatively analyze the area, volume, and mass of fat in muscle.

 In case of FIM Study,

It measure the limb area.

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 "FIM Study", set scan area and mode.

When set up is completed, press "Measure start" button.

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

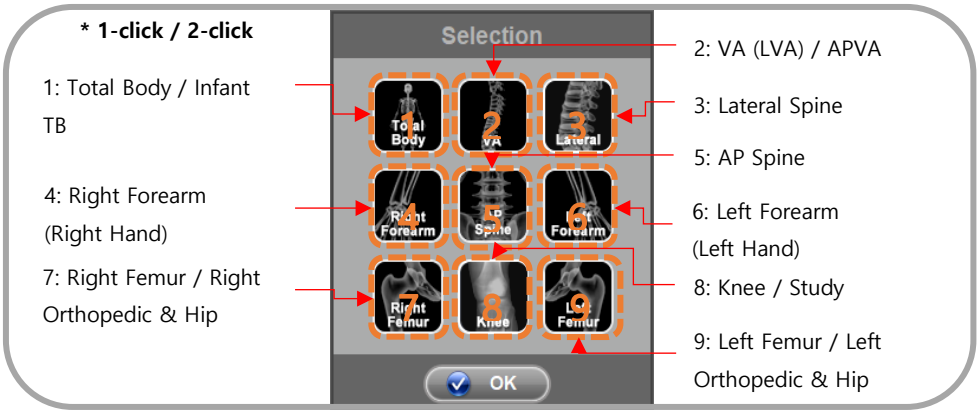
e. Lay the patient on the equipment and fix the measuring supports according to the site to be scanned.
Refer to the figure below and position the subject so that there is no object in the area.

f. Press 'Positioning' in 'Measurement' window.

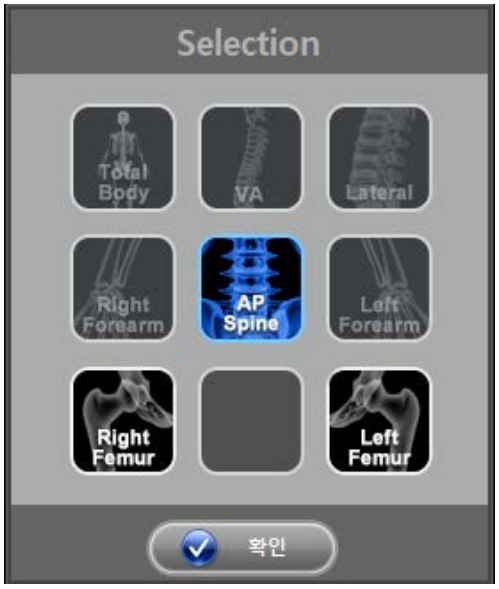
i. The site selection screen appears.

> When positioning, make sure patient's hands or feet not to touch the scanner since the scanner position can move from the bottom to upwards.

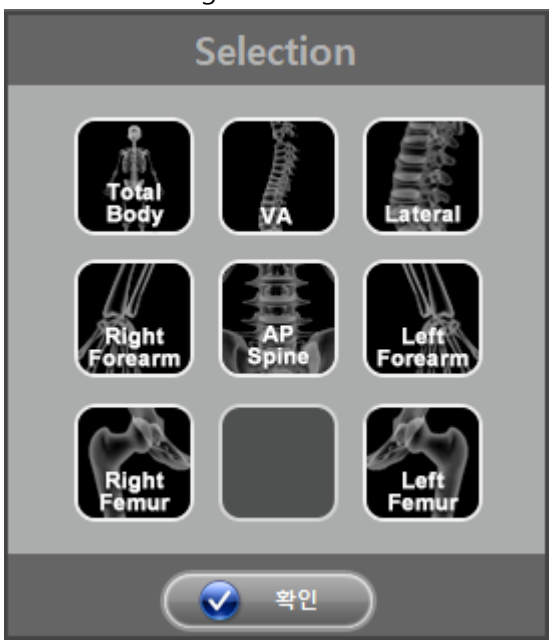
ii. Check for any danger of patient injury by the equipment and click "OK". Automatic move to the designated location according to the selected sites to be measured.



1. Click on the site to which you want to move for measuring. In case of One scan, click all site which you want to move for measuring



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



3. 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.

 When measuring the whole body, make sure to select Total Body to move to its initial position.

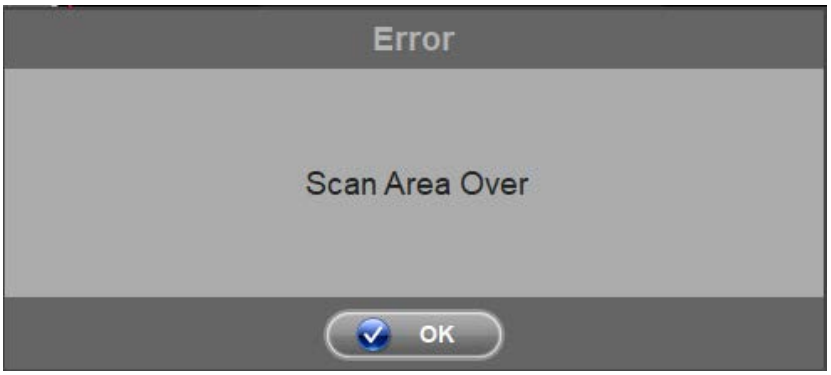
iii. Once it moved to Default position, the laser pointer is ON and the laser pointer LED of the user operation switch is ON. Manual Measurement screen appears on right top in Measurement screen.

iv. Set up measurement info of scan site in Manual Measurement.
(Please refer to p80 for setting the Manual measurement window.)

v. Press Top/Bottom/Left/Right key in the user operation switch to control and move the arm to a proper location to select patient' APSpine / Left Femur(AFF) / Right Femur(AFF) / Left Forearm(GDP and Hand) / Right Forearm(Hand) / Total Body / LVA / APVA / Lateral Spine / Left Orthopedic(Prosthesis Hip) / Right Orthopedic(Prosthesis Hip) / Knee / Study / Animal. Press the switch in the user operation panel and press 'Select' for the applicable site.

vi. Once 'Select' key 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.

vii. 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



How to Set Up Manual measurement

After press "Positioning" button and select scan site, it will show a manual measurement window at right top.

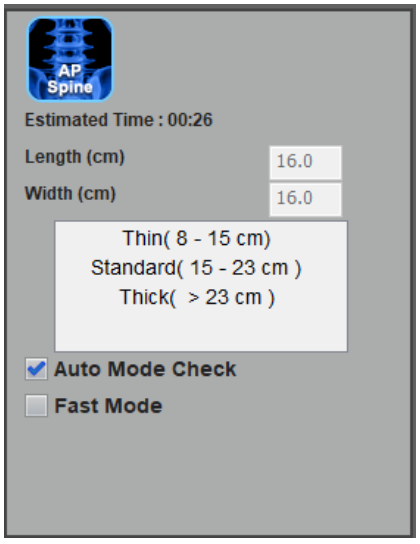
Image Size : Size of scan Area (The size of the Width is adjusted to a multiple of four.)

Mode : Select it based on the thickness of patient body.

- Very Thin : When Thickness is below 8 cm
- Thin : When thickness is between 8 ~ 15 cm
- Standard : When thickness is between 15 ~ 23 cm
- Thick : When thickness is over 23cm

If you use last scan mode in configuration,
mode is selected as to be that of the last scan.
If you check Auto Mode Check, Mode is automatic.

Invert : If it is hard to change the direction or position of object, you can use 'Invert Scan' for measuring.



How to Set Up One Scan (Multi Scan)

i. Press the "Positioning" button in the "Measurement" window.

ii. After click all scan sites and click "OK" button, Scanner move to default position.

iii. Set up measurement info in Manual measurement screen.

iv. 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.

v. Right after the selection, move the laser pointer to the second measurement start position using arrow keys and select the second measurement area.

vi. Then return to the computer window screen, click “Measure Start” button.

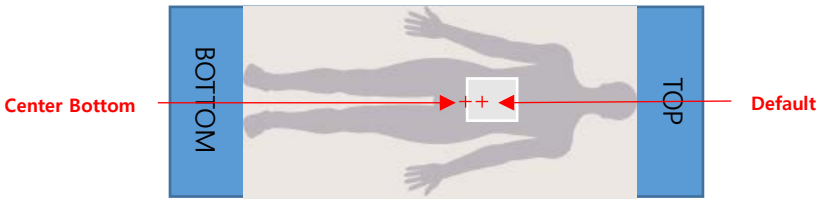
For example, [Spine measurement -> Left Femur measurements]
[Select the measurement window Spine] -> [Spine measurement position adjustment by using the user operation switches] -> [Spine user selection of the operation switch] -> [Left Femur measurement position adjustment by using the user operation switches] -> [User Left Femur selection switch operation] -> [Start measurement select the measurement window]

g. Positioning of Spine

Lay the examinee 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 panel under knees for adjustment.

After examinee's positioning is complete, select the initial position to be Spine to move carriage. By using a move button on control switch, move the laser pointer to examinee's naval area (L3~L4) when Measurement Laser Pointing is Default setting in Measure configuration. In case of Center Bottom, Place the laser pointer at the center of the pelvis. After movement is complete, press the spine button on control switch to determine a section to measure. Then press measurement start button on user screen.

When scanning Spine, set the laser pointer at the initial position of measurement. (Default, Center Bottom)



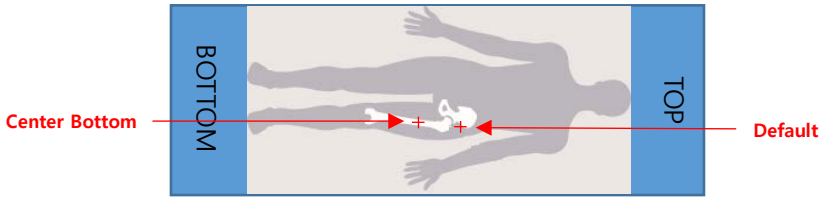
On the Configuration-Measure tab, you can set position setting.

h. Positioning of Femur

Lay the examinee 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 by using a Velcro that is attached to aid tool.

Once the examinee's position adjustment is complete, select the initial position to be either Left femur or Right femur to move the carriage by using a move button on control switch, move the laser pointer to examinee's iliac crest when Measurement Laser Pointing is Default setting in Measure configuration. In case of Center Bottom, place the laser pointer at the thigh. After movement is complete, press the spine button on control switch to determine a section to measure. Then press measurement start button on user screen.

When scanning Femur, set the laser pointer at the initial position of measurement. (Default, Center Bottom)

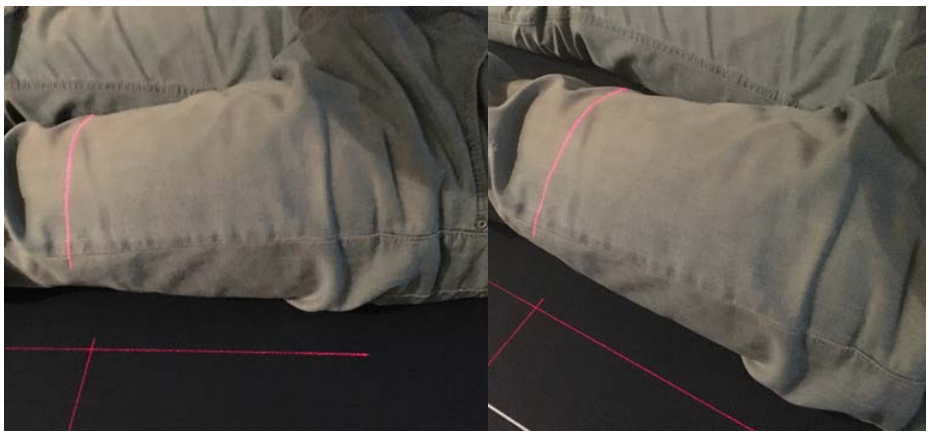


On the Configuration-Measure tab, you can set position setting.

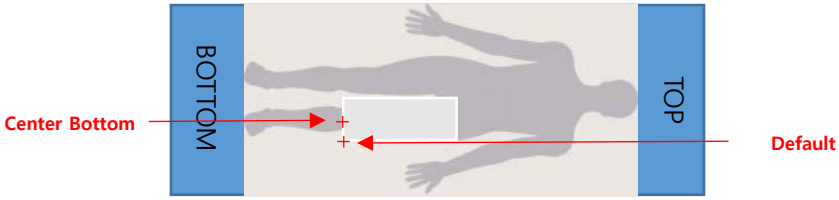
i. Positioning of AFF

Lay the patient on the bed with supine position, with the head facing to the top.

When positioning of patient is completed, by using switch button of operation panel, set the laser pointer at the scan area and move it. After movement is completed, press measurement start button on user screen and start measurement.



When scanning AFF, set the laser pointer at the initial position of measurement. (Default, Center Bottom)

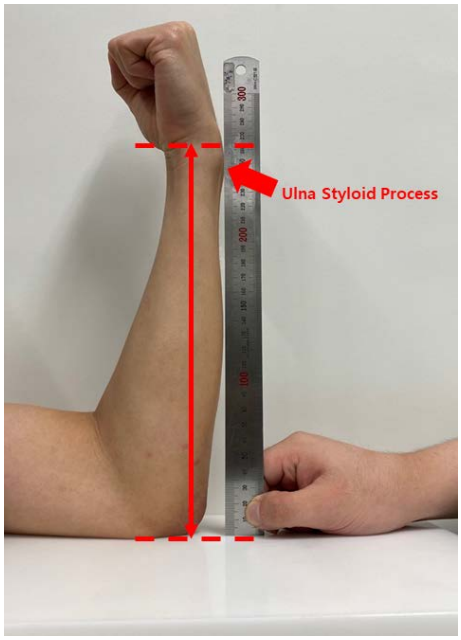


On the Configuration-Measure tab, you can set position setting.

j. Positioning of Forearm

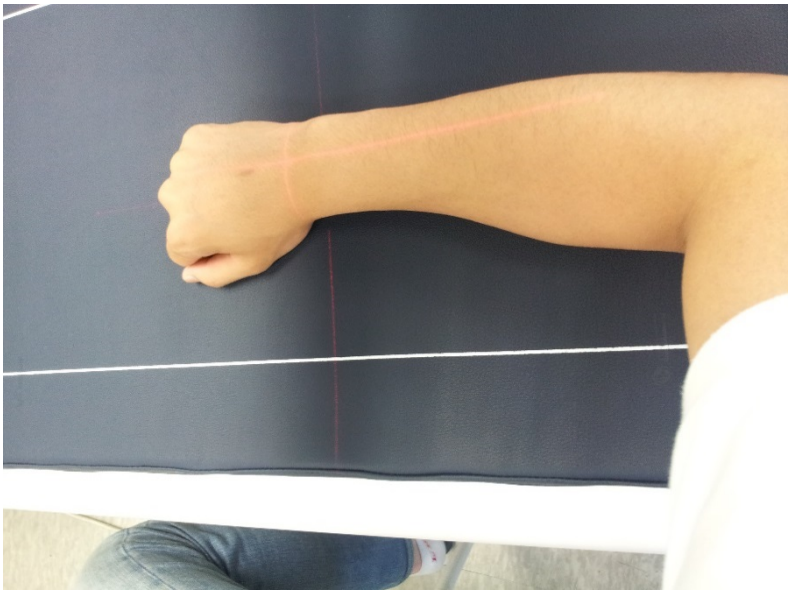
A. Preparation before measurement (Measure Forearm Length)

Measure the forearm length from the ulnar styloid process to the elbow using a ruler. Place your elbows on the floor vertically. Measure the length from the floor to the ulnar styloid process using a ruler. Defines this length as Forearm Length.



B. Positioning

Measure the non-dominant forearm of the arm that you usually use. Position the subject in the chair next to the equipment, bend the upper body slightly forward, and place your arms on the bed. position the forearm sufficiently into the measuring area and bend the elbow to form 90 degrees. Move your fist in the Bottom direction for the right arm and your left arm in the Top direction. Make sure that the forearm direction is parallel to the long direction of the bed. Select Forearm to the initial position to move the carriage of the equipment. Position the laser so that it is centered on the wrist adjacent to the ulna styloid. The entire ulna styloid process must be visible. Select Forearm on the operating switch and press the Start Measurement button in the user program to start the measurement.

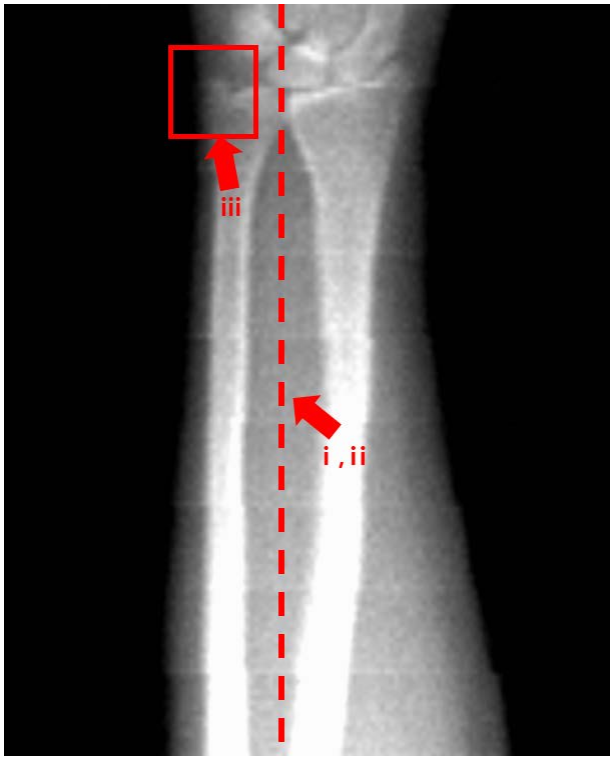


C. Check the correct measured image.

i. The hapac bone is straight in the center.

ii. Completely located in the center of the image.

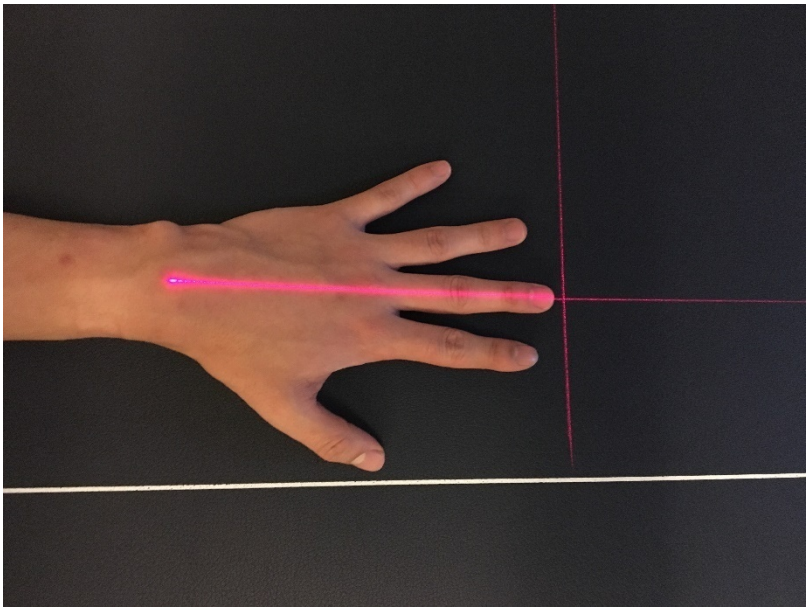
iii. The ulnar styloid process must be located near the top of the image.



k. Positioning for Hand(GDP)

Positioning for Hand is same as measuring Forearm. But do not make a closed hand and spread the patient's hand. Then please 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 major axis of the bed.

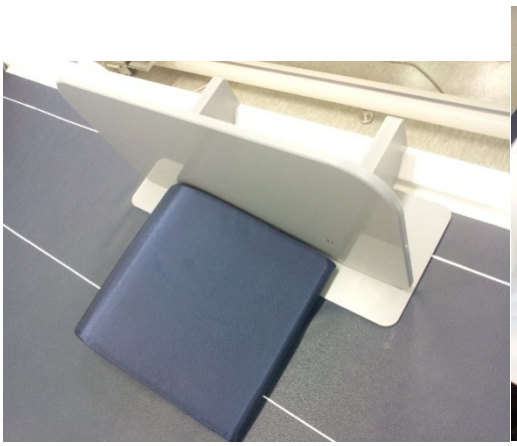
Then select Left Forearm on the OP and click Start button on the software.

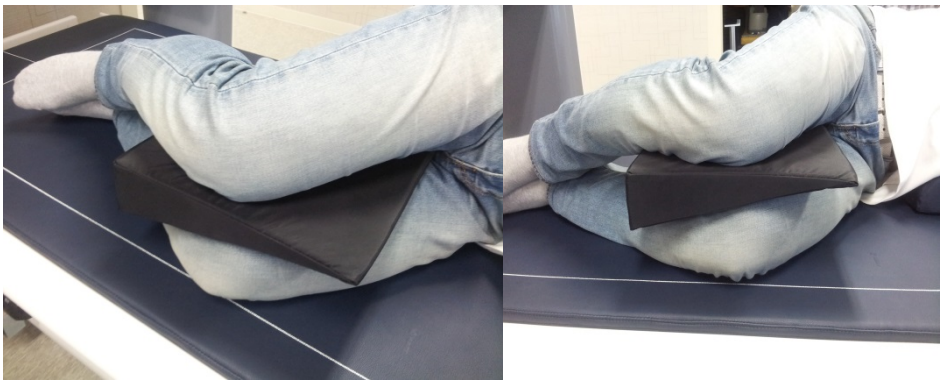


l. Lateral Spine and Positioning of LVA

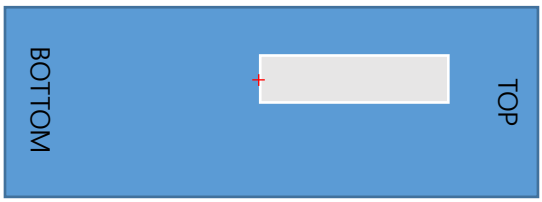
Place aid tools for lateral measurement at the inside guide of equipment as shown in Figure below. Lay the examinee on the bed with lateral position, with the head facing to the top. Place a sponge of aid tool at the waist of examinee. Put the upper section of aid tool tightly close to the back, so that the spine is in parallel with the bed surface. Bend knees to face forward. Fold the arms to place them under head. If necessary, insert an aid tool made of sponge between the knees.

After examinee's positioning is complete, select the initial position as either LVA or Lateral BMD to move the carriage. By using a moving button on control switch, move laser pointer to the top center of iliac crest. Once the movement is complete, press either Lateral spine or LVA button on control switch, to determine a section to measure. Then press a start button for measurement on measurement screen.





When scanning LVA, set the laser pointer at the initial position of measurement.

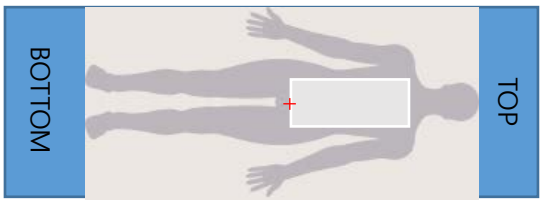


m. Positioning of APVA

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 panel under knees for adjustment.

After positioning of patient is completed, set the initial areas as APVA and move carriage. By using operation panel switch move button, set the laser pointer in the middle of both sides of iliac crest. When moving is completed, select "Mode" in the operation panel switch, press VA button (APVA setting) and decide desired scan area and start measurement on the user screen.

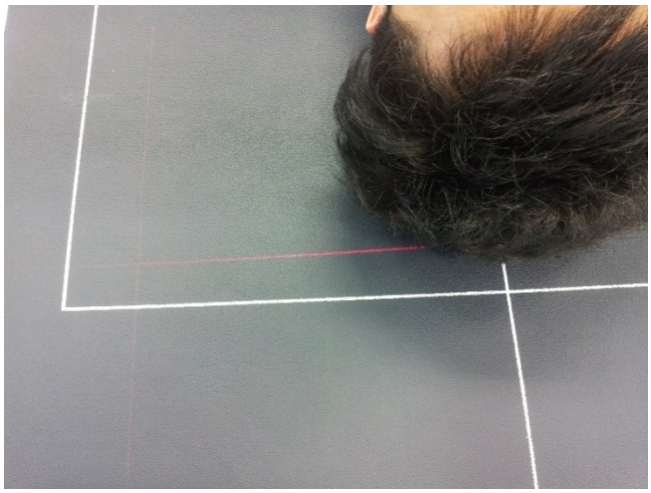
When scanning APVA, set the laser pointer at the initial position of measurement.



n. Positioning of Total Body

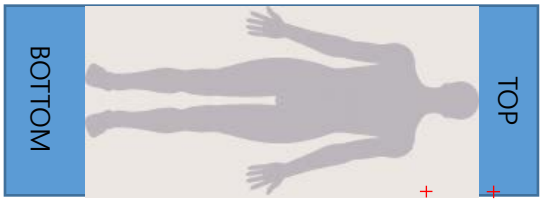
Lay the examinee on the bed with supine position, with the head facing to the top. Place the tip of head 2-3cm away from the top of measurable section. Adjust the sagittal line of body center to be in parallel with the longitudinal direction of scan area. Then put the arms close to body, so that the arms will not move out of scan area.

After positioning is complete, select the initial position to be Total Body, to move the carriage. In Total Body, it is not necessary to adjust laser pointer by using control switch. Once the movement is complete, press Total body button to determine a section to measure. Then press measurement start button on measurement screen



<Adult Position>

When scanning TotalBody, set the laser pointer at the initial position of measurement (Adult)



o. Study/FIM Study Positioning

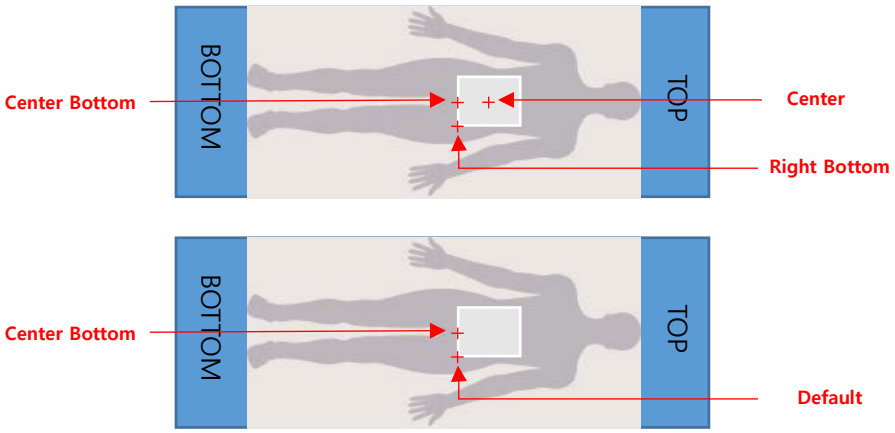
Please carefully lay the patient on the bed and beware that the head has to be put toward to the top.

(If you use 'Invert Scan' mode, please put the head the opposite).

After selecting the measuring site, please move the laser pointer to the exact measuring position. Then please press 'Measure start' on the screen.

Please put the laser pointer as shown below for setting the right position.

(Study: Right Bottom[Default Position], Center, Center Bottom)



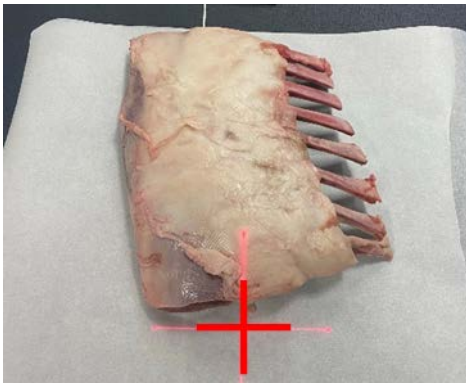
On the Configuration-Measure tab, you can set position setting.

p. Animal Positioning

Please carefully lay the animal on the bed and beware that the head has to be put toward to the top.

(If you use 'Invert Scan' mode, please put the head the opposite).

After selecting the measuring site, please move the laser pointer to the exact measuring position. Then please press 'Measure start' on the screen.

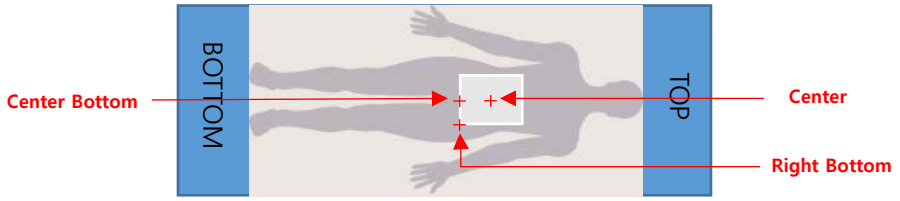



<Animal, Sheep Cut Position>


<Sheep Live(Prone) Position> <Sheep Live(Side) Position>


<Sheep Carcase(Prone) Position> <Sheep Carcase(Side) Position>

Please put the laser pointer as shown below for setting the right position.
(Animal, Sheep Cut : Right Bottom[Default Position], Center, Center Bottom)

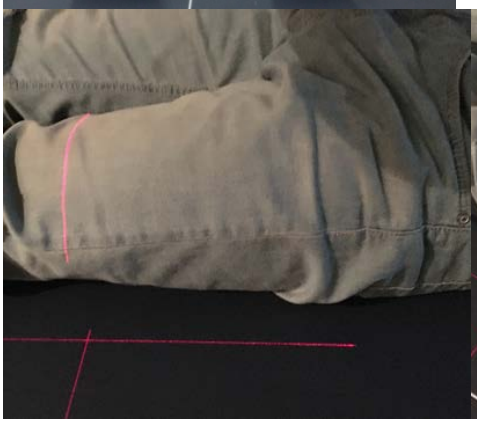


On the Configuration-Measure tab, you can set position setting.

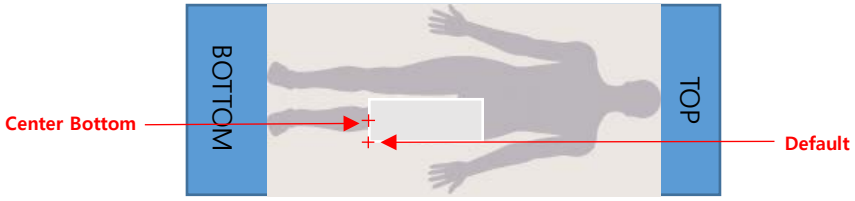
q. Positioning of Orthopedics and Prosthesis Hip

Lay the patient on the bed with supine position, with the head facing to the. Set the toe of patient to the top direction with number 11 stretched shape as you can in the below picture

After finishing adjustment of positioning, set up Left Orthopedics (select Left Femur and select again) or set up Right Orthopedics (select Right Femur and select again) and move carriage. Using switch button on the panel set the laser pointer and move it. After completing movement, select mode in the operation panel and press femur button (set as "Orthopedic) and decide scan area and press measure start button in the user screen.



When scanning Orthopedics and Prosthesis Hip, set the laser pointer at the initial position of measurement (Default, Center Bottom)

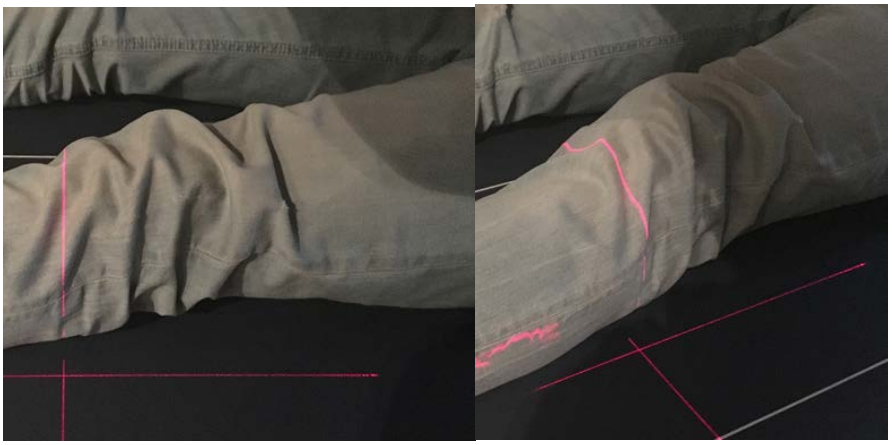


On the Configuration-Measure tab, you can set position setting.

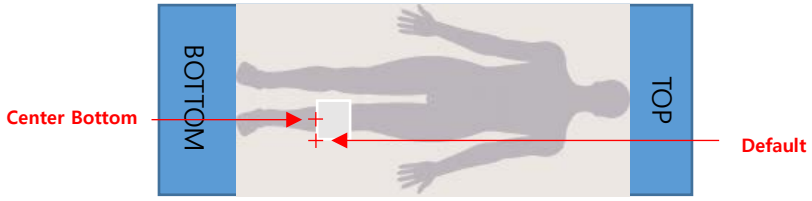
r. Positioning of Knee

Lay the patient on the bed with knee position, with the head facing to the top as you can in the below picture. (When Invert Scanning, head is to be opposite direction of Top.)

After patient's positioning is completed, by using a "move" button on operation panel, move the laser pointer to scan area. After movement is completed, press the knee button on operation panel to determine a section to measure. Then press measurement start button on user screen.



When scanning Knee, set the laser pointer at the initial position of measurement (Default, Center Bottom)



On the Configuration-Measure tab, you can set position setting.

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

Figure 1 Normal

Figure 2 Selected

Figure 3 Scanning

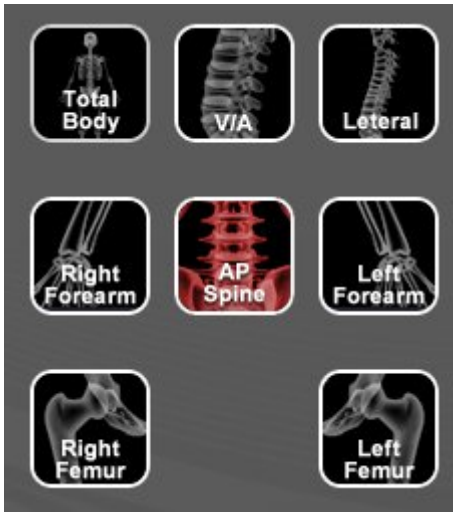


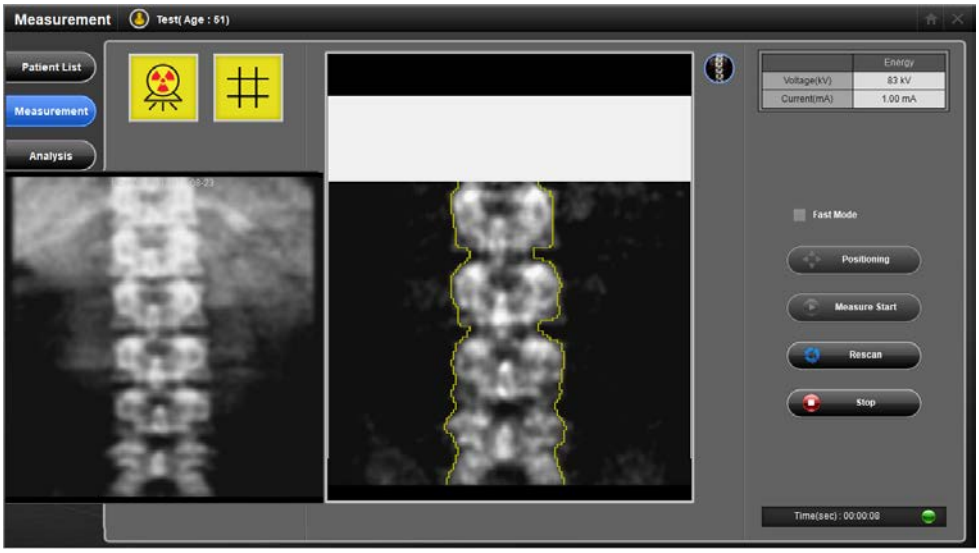
Figure 4 Finished

- 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.

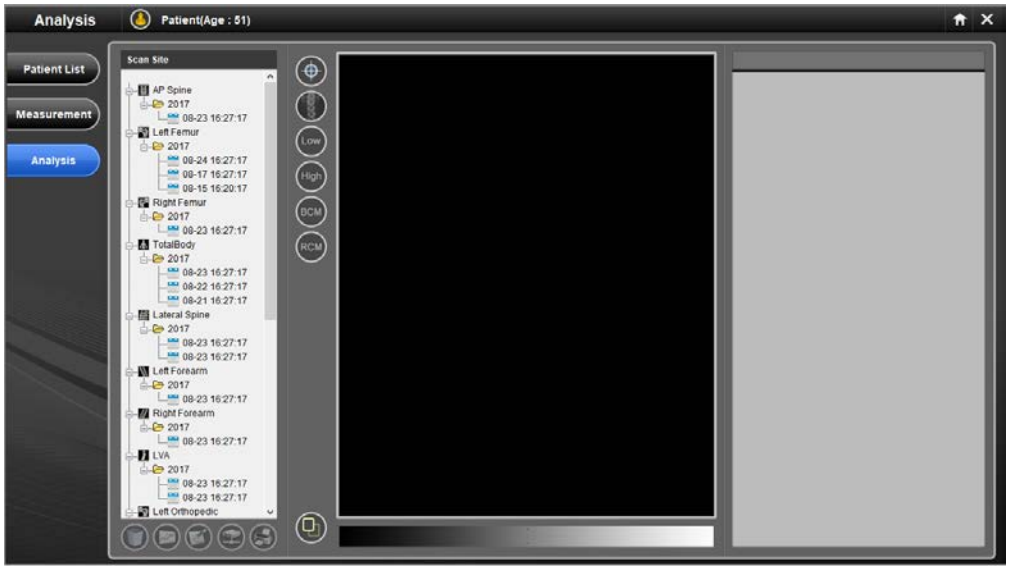
t. Scanning

A. Spine: Before scanning, it moves to the left by 5cm to obtain measuring mode data. Once data obtained, in case of Default Laser Pointing, it automatically moves by 4cm to the region below the navel and starts scanning. In case of Center Bottom, it moves to the left and starts measurement.

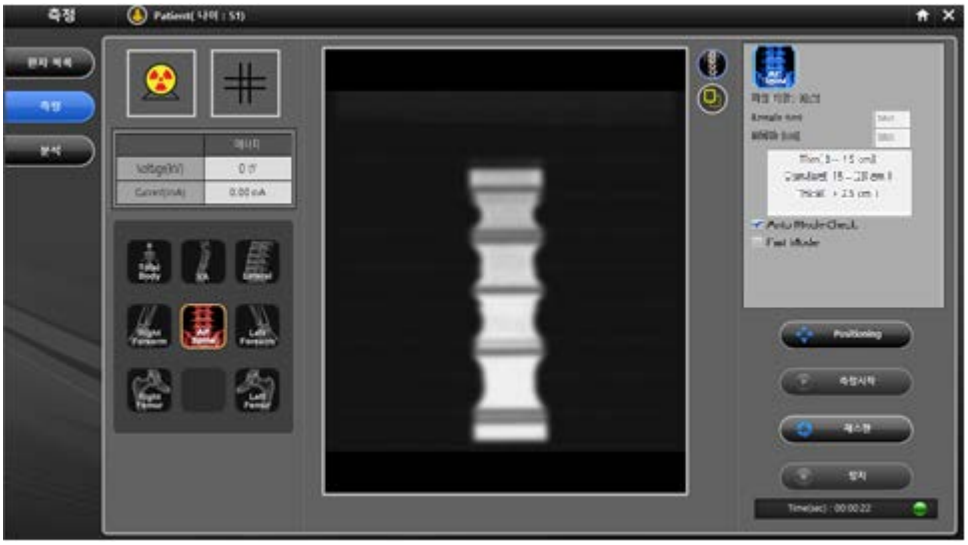
B. Femur: Before scanning, it moves to the bottom by 4cm to obtain measuring mode data. Once data obtained, in case of Default Laser Pointing, it automatically moves by 16cm to the region below the pelvis and starts scanning. In case of Center Bottom, it moves to the left and starts measurement.



u. If it is set to analyze when measurement is done, it automatically moves onto the analysis screen once measuring is complete. And the equipment carriage returns to the initial position. If it is not set to analyze when measurement done, you can check scan image.



<analyze when measurement done>



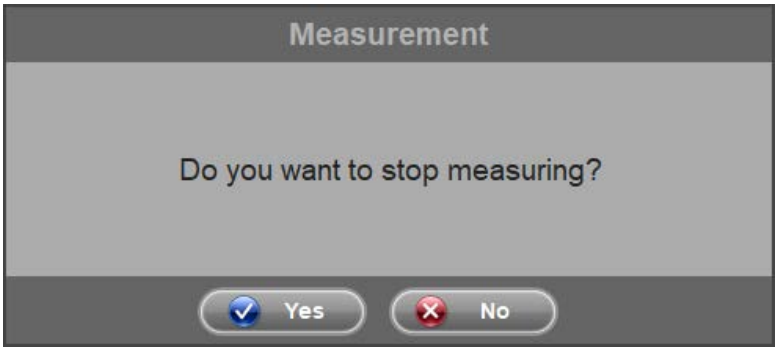
< when measurement done, check scan image>

Even when measuring is finished, let the patient come down from the table only after the equipment returns to the initial position for safety of the patient.
In One Scan, when one site is done, it moves to the next site without any message. If the patient sits up at this point thinking that the scanning is finished, it can cause injuries due to the moving carriage of the equipment.

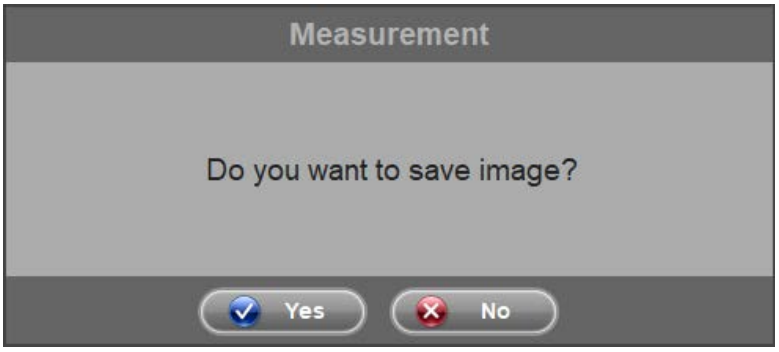
6.5.6 Stopping measuring bone density

- If the measuring should be cancelled during the process or if there are any parts where measuring was inaccurate or when the patient experiences inconvenience, stop the measuring process on the bone density.
  In case of emergency, use 'Emergency Switch'. And in case of 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 then a message pops up asking if you want to save the image.



  d. Click 'OK' to save the image, '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

- If the scanning is being done outside region of interest, or if you want the current scan region to be the region of interest without resetting, use this Rescan feature.

  a. Click 'Rescan' during measuring.
  b. Click and drag the box of red outline with the mouse to show the region you want to measure.
  c. Then the window as shown below appears.
     1. Move and scan: Restart scanning the moved region.
     2. Resume measurement : Resume scan.
     3. Original Position and Scan : Restart scanning the original position.
  d. It restarts scanning the new region.

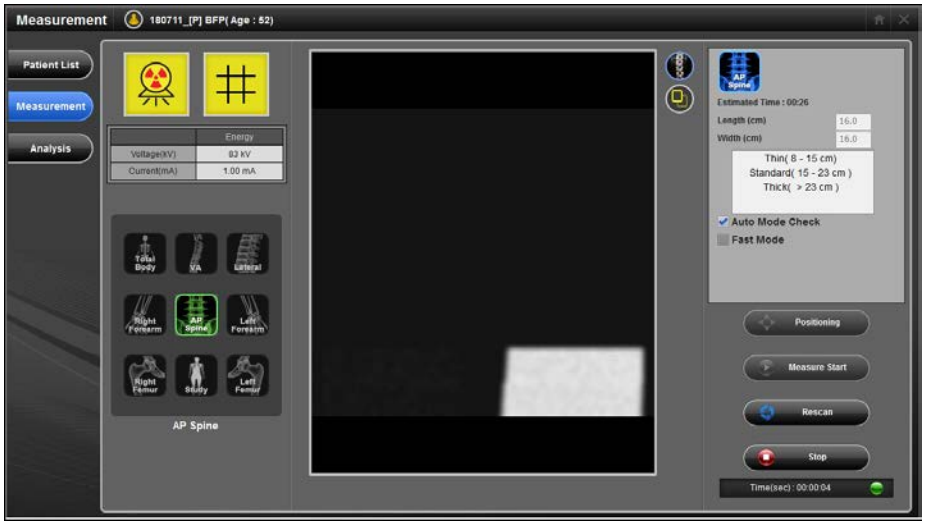


Figure A. Rescan during measuring.

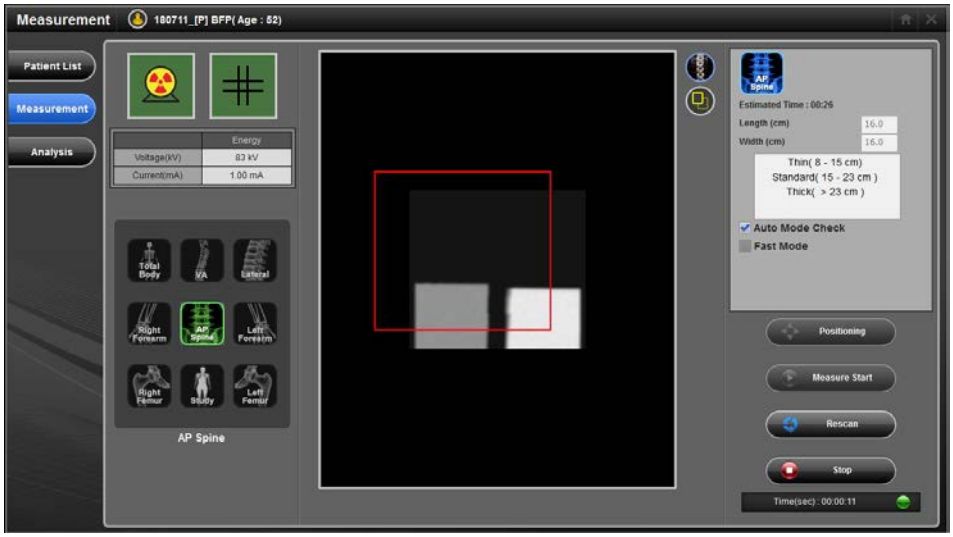


Figure B. Resetting the region

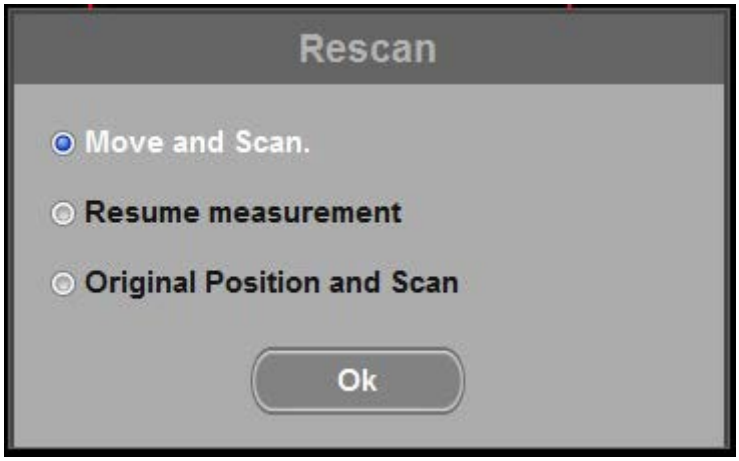
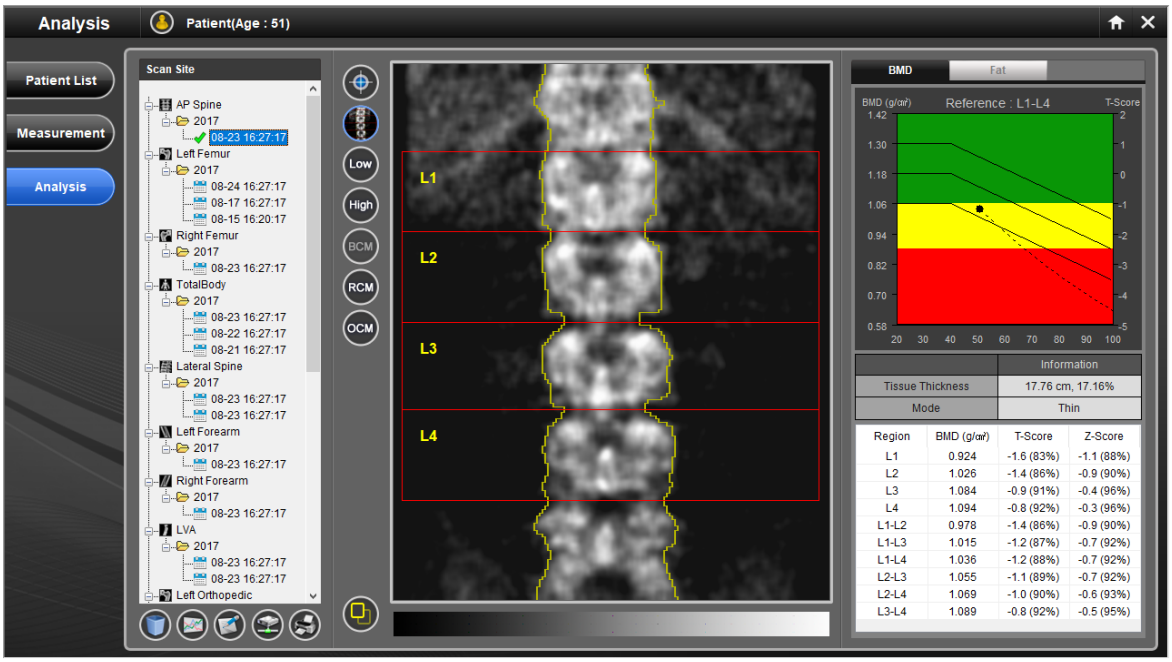


Figure C. Rescanning and Resetting the region.

If [One Scan] of Configuration Default Setting in the main screen is checked, it moves automatically to Analysis after all measuring process is done. If unchecked, a message appears every time one site is measured and you should manually proceed to Analysis. The equipment returns to the initial position after all measuring process is complete.

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 in the screen. Click data to show the images in the center of the screen.

BMD mode

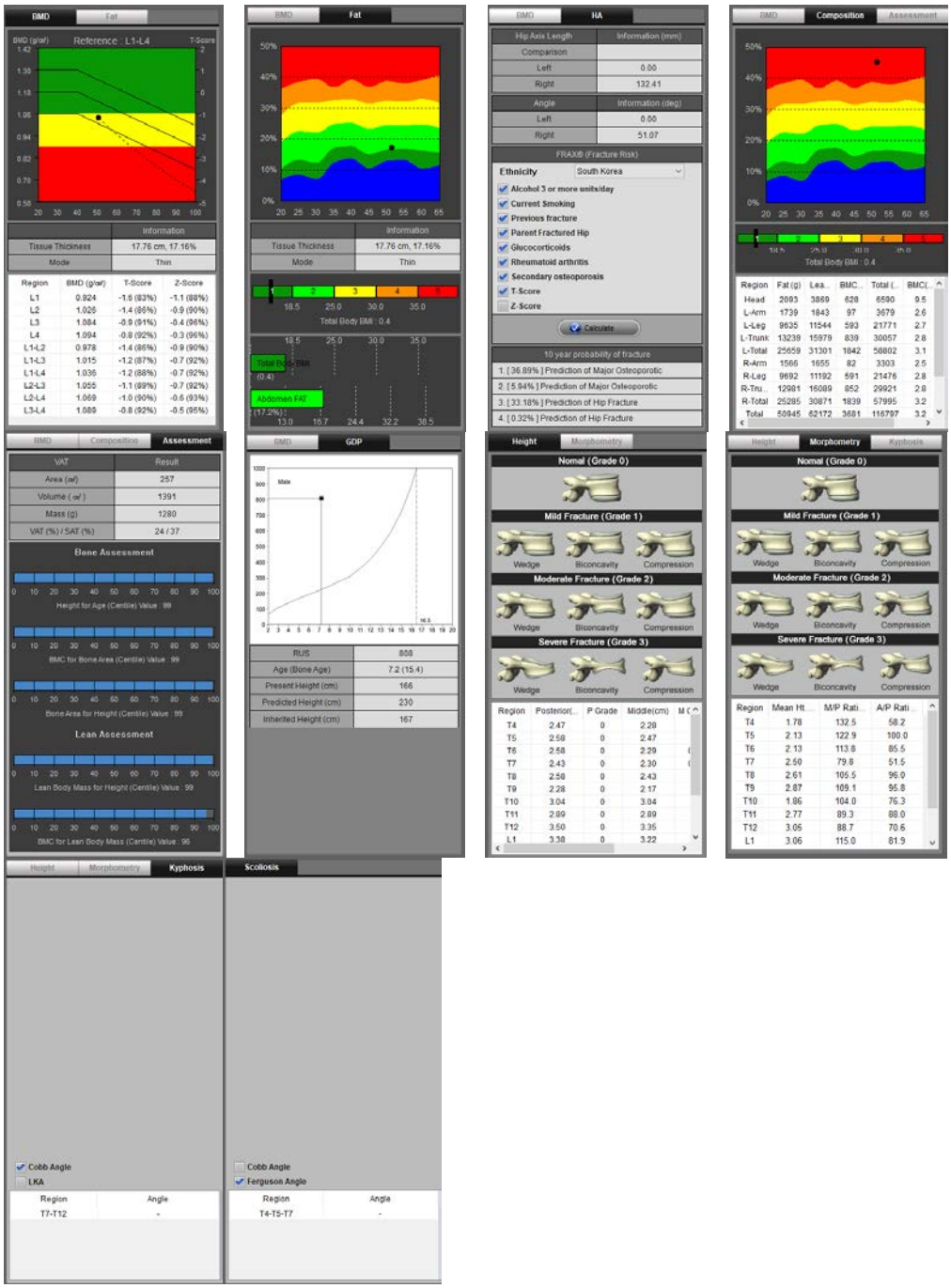
- Click BMD button in the top right to change to BMD mode.
- It shows Normal/Osteoporosis by T-score distribution based on the patient's age analyzed above.
- Patient's bone density value, T-score and Z-Score by ROI are shown in the bottom right.

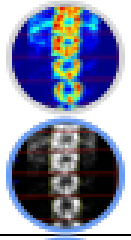
FAT/HA(Hip Analysis)/GDP/Composition mode

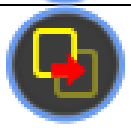
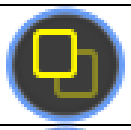
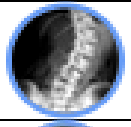
- Click FAT/HA(Hip Analysis)/Composition button in the top right to change to FAT/HA(Hip Analysis)/Composition mode.
- In case of FAT, it shows Tissue FAT% of Spine image
- In case of HA, it shows Hip Analysis and FRAX information of Femur image.
- In case of Composition, it shows Total Body Composition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

Assessment mode

- Click Assessment button in the top right to change to Assessment mode.
- In case of Total Body, it shows the information of VAT and Bone Assessment/Lean Assessment.



	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 ROI in L1.
	L2 on/off	When measuring the spine, it deletes/adds ROI in L2.
	L3 on/off	When measuring the spine, it deletes/adds ROI in L3.
	L4 on/off	When measuring the spine, it deletes/adds ROI in L4.
	Z4 on/off	When measuring Prosthesis Hip, it can be used for Standard Zone(4 Zone) in ROI.
	Z7 on/off	When measuring Orthopedic, it can be used for Standard Zone(7 Zone) in ROI.
	Z19 on/off	When measuring Orthopedic, it can be used for Extend Zone (19 Zone) in ROI.
	Image Mode	You can choose either b/w or color when printing images.
	Low Image	It shows a Low Image

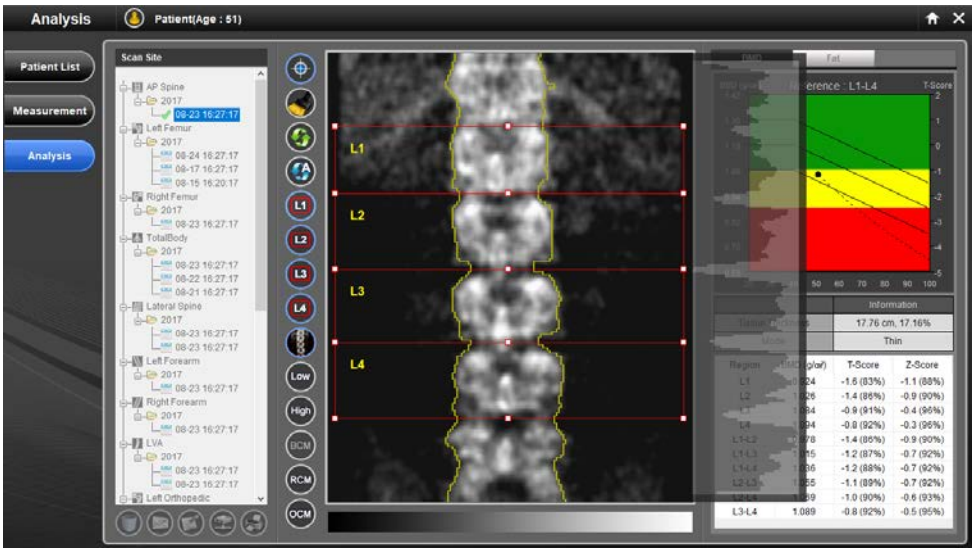
	High Image	It shows a High Image
	BCM Mode (Bone density Color Mapping)	It shows an image with BCM mode. It shows the bone density with 7 colors based on T-Score.
	RCM Mode (Relative bone density Color Mapping)	It shows an image with RCM mode. It shows the bone density with 7 colors based on the Max/Min value of T-Score.
	OCM Mode (Oseoporotic Color Mapping)	It shows an image with OCM mode. It shows the bone image with colors based on T-Score.
	Cancel	It cancels the ROI setting.
	ROI Compare and Copy	It copies or modify the ROI after compares the other data.
	Result Compare	It compares the data of same measuring site.
	Global ROI	It sets the area that the operator want to use.
	B-Scope	It shows the body composition for each body with the image.
	L-Scope	It shows the graph for bone density and body composition.
	AFF	It analyzes AFF.
	Ruler	It shows you the length of the part you want.
	Scoliosis and Kyphosis	It offers a diagnosis tool for Scoliosis and Kyphosis.
	Image Trend	It offers Image and Data Trend information of specific data (3 types).

	Delete	It deletes the selected image.
	Trend	It shows the trend data of the selected image.
	Comments	You can fill in comments on the analysis report on the measured patient's images.
	Send PACS	It sends the reports to PACS server.
	Print	It prints out the reports.

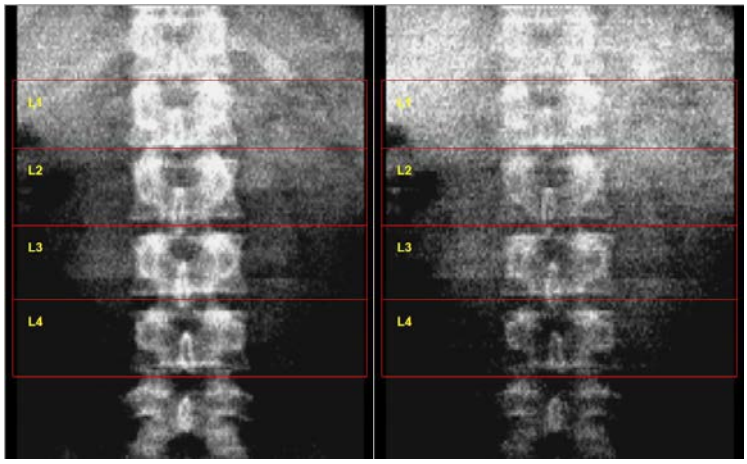
6.6.1 Image analysis (Spine)

- 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 in the right.
   Histogram displays the density in the image from top in a graph; if the density is high, the right side is higher in the histogram; if the density is low, the right side 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 right side 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

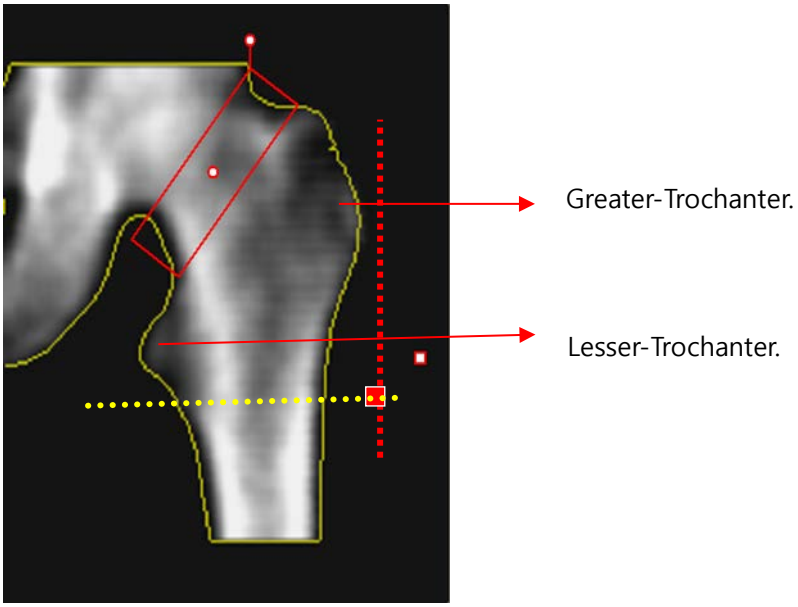


Low High

6.6.2 Image analysis (Femur)

- Analysis on the measured femur image of a patient.
- Please refer to 6-1.image analysis (spine) as 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 pointer 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. Except for the red box, place the draggable point at the intersection of a horizontal straight line below the Lessor-Trochanter and a straight line descending vertically from the Greater-Trochanter.

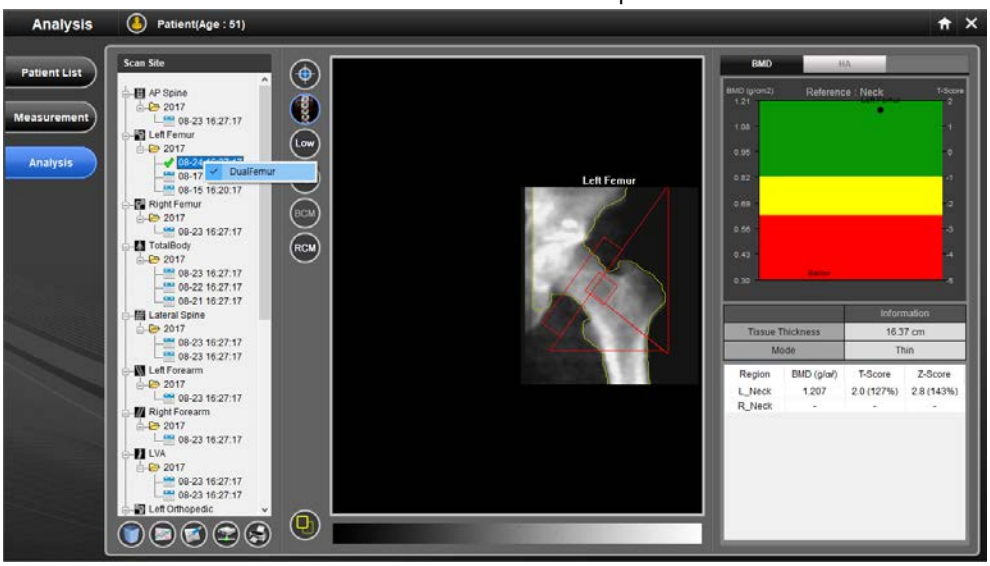
e. Click ROI set button to fix ROI and create a triangular area.

f. The result is displayed.

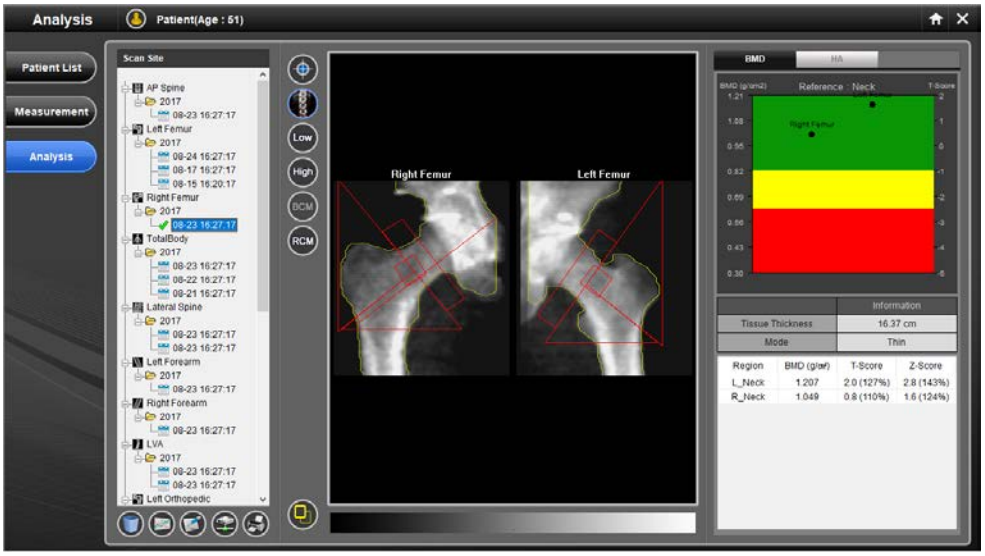
- It also offers Dual Femur image analysis.

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 Dual Femur mode.



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



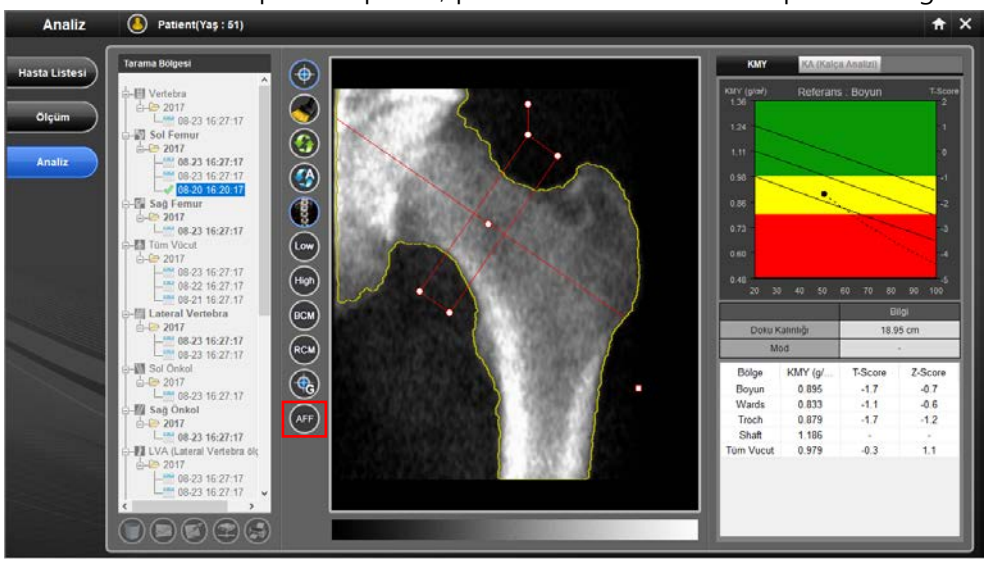
6.6.3 Image analysis (AFF)

- It analyzes image of AFF after measurement is completed.

a. Click measured image of Left Femur or Right Femur.
b. When image is displayed, press ROI set button.
c. In case that Global ROI is not set, it moves to screen of Global ROI set up.

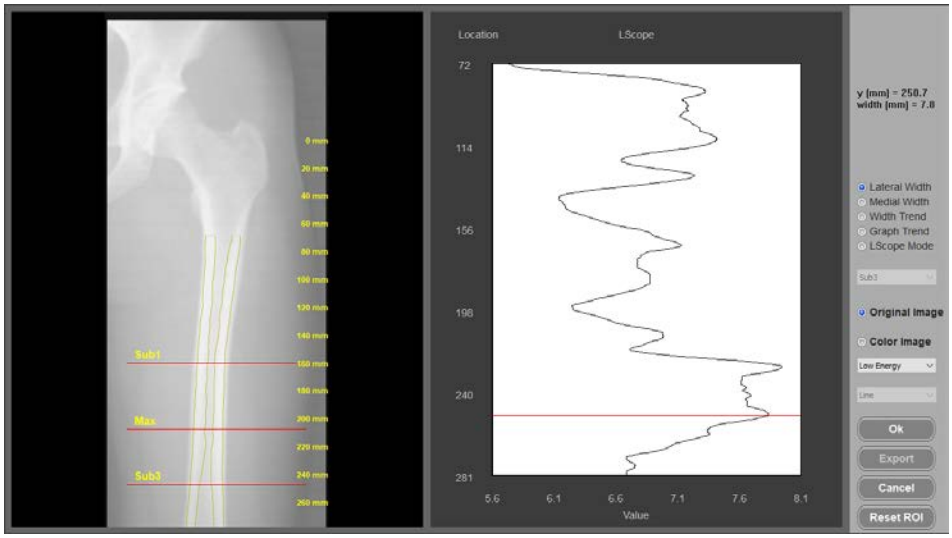
i. Move: It is function that moves Global ROI.

d. Locate Global ROI in order to analyze Femur.
e. When Global ROI set up is completed, press "ok" button and complete setting.



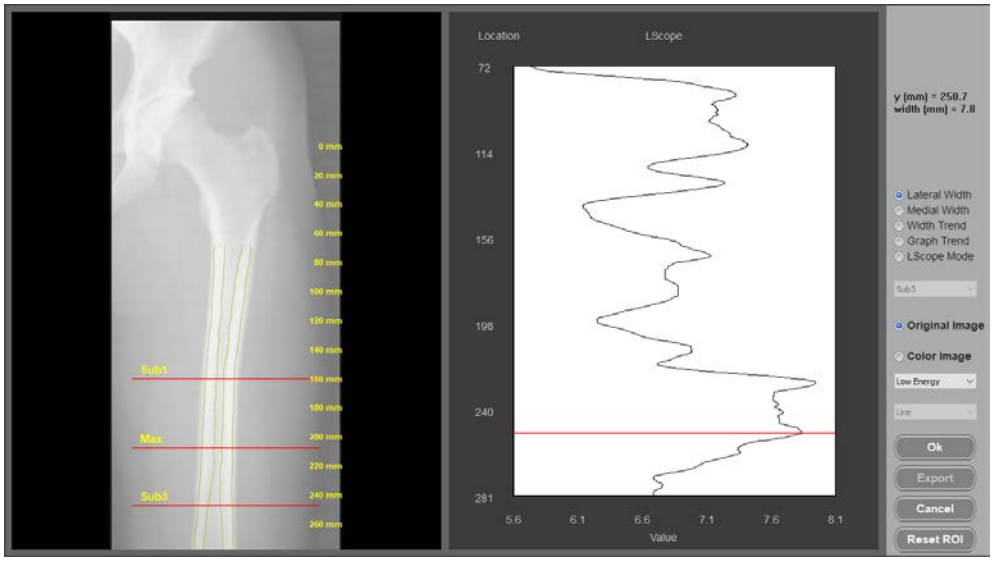
f. For the analysis of Femur Refer to "6-2 image analysis (Femur)", adjust ROI and analyze result.

g. For the AFF analysis, press "AFF" button and move to AFF analysis screen.

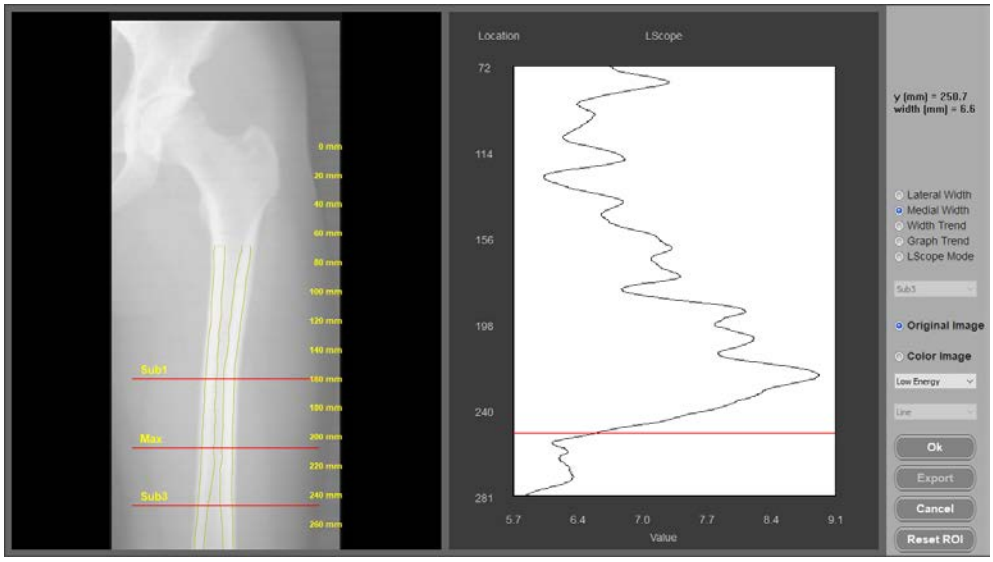


i. Lateral Width : It displays thickness of outside of Y axis.
ii. Medial Width : It displays thickness of inside of Y axis.
iii. Width Trend : It calls up previous information of Lateral Cortical Bone Width and display as graph.
iv. Graph Trend : It compare Width graph trend.
v. L-Scope Mode : Refer to "Image analysis (L-Scope)".

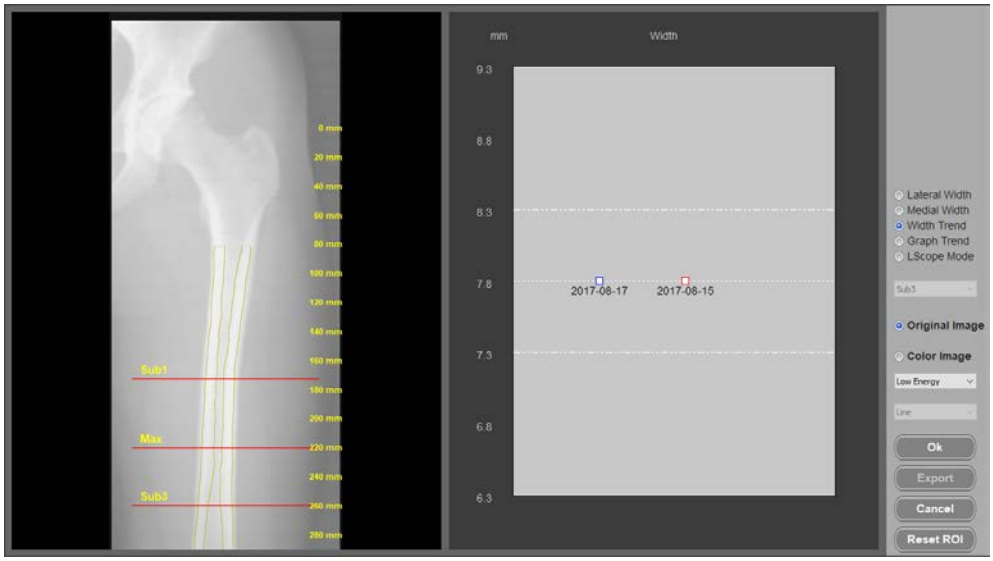
h. Lateral Width analysis is for the outside thickness of Femur.



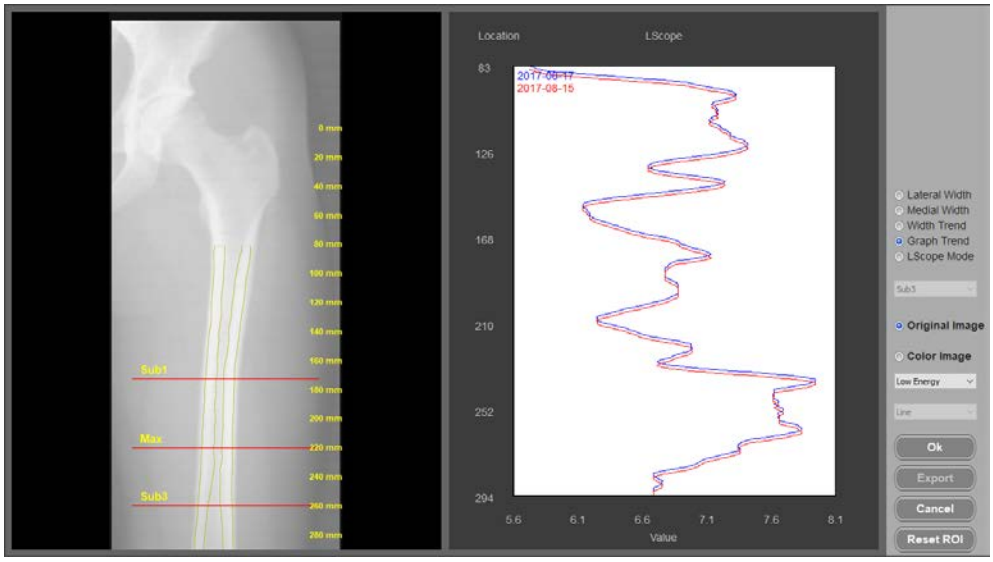
i. Medial Width analysis is for the inside thickness of Femur.



j. Width Trend analysis shows trend of thickness.



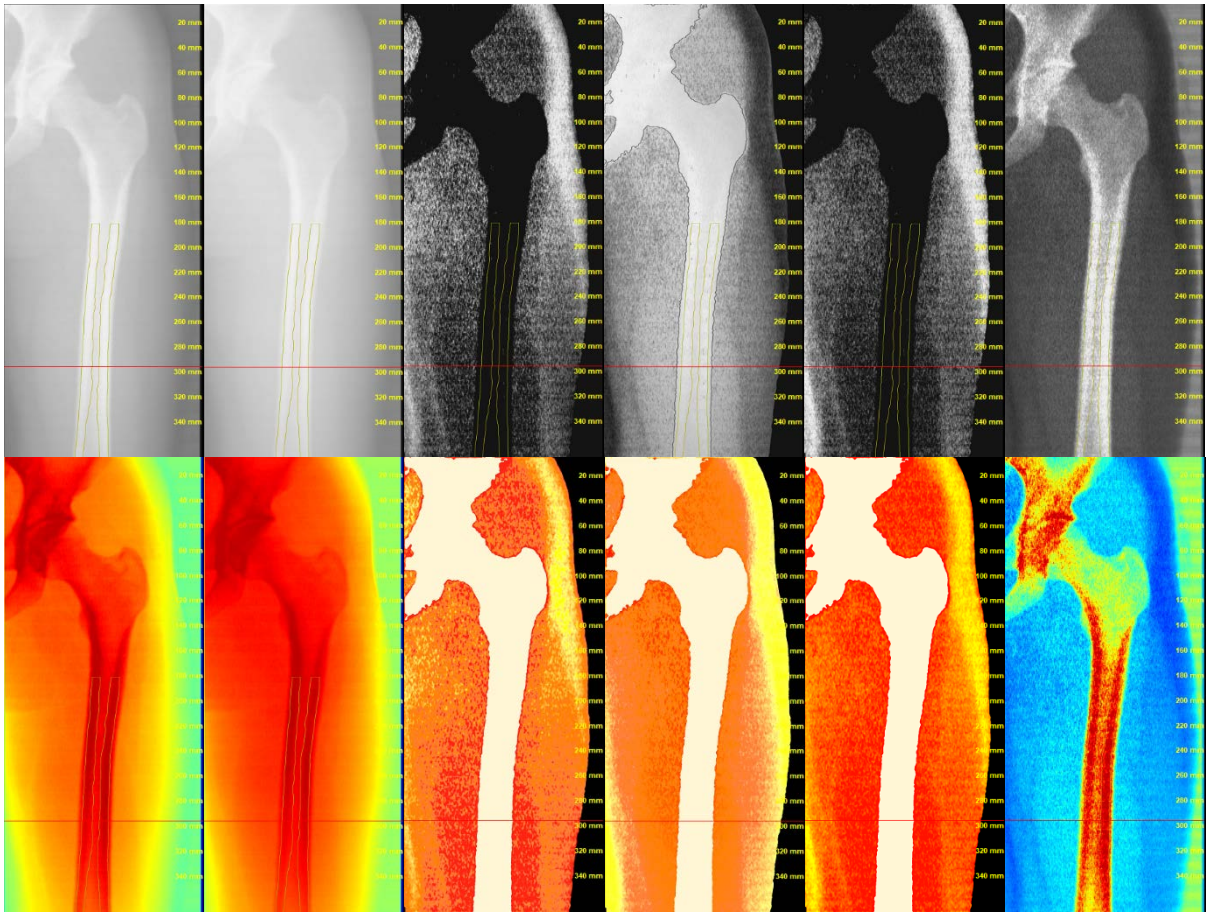
k. Graph Trend displays thickness information of each area with different measurement date.



l. L-Scope Mode analysis refers to "image analysis (L-Scope)".

i. Original Image : Depending on the size of parameter, it shows black and white color image.
ii. Color Image : Depending on the size of parameter, it shows color image.
iii. Low energy : It displays Low energy image.
iv. High energy : It displays High energy image.
v. Fat: It displays image of Fat.
vi. Lean: It displays Lean image.
vii. FAT (%): It displays FAT (%) image.
viii. BMD: It displays BMD image.

m. In order to have accurate analysis we use Original Image/Color Image, Image Mode.

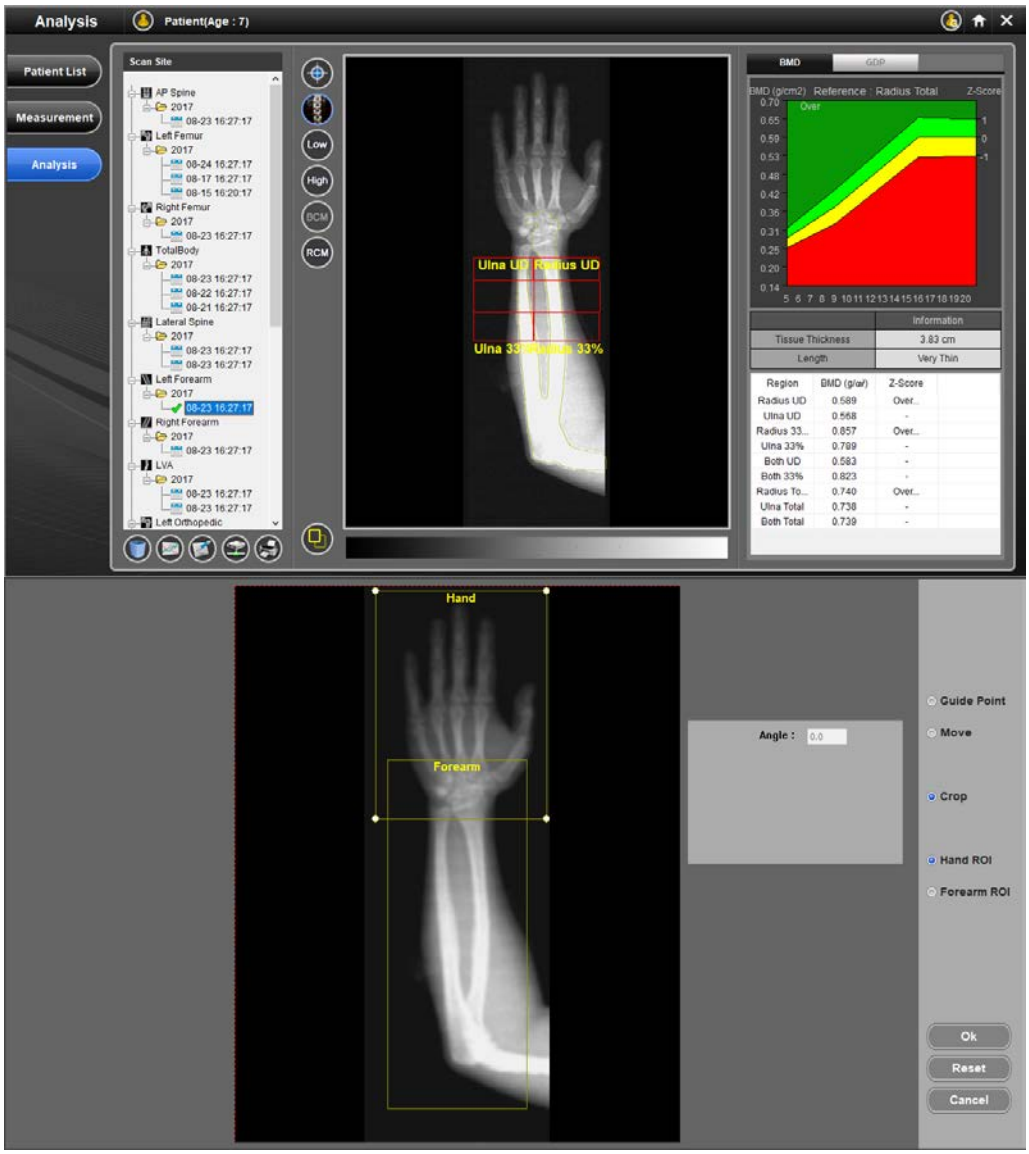


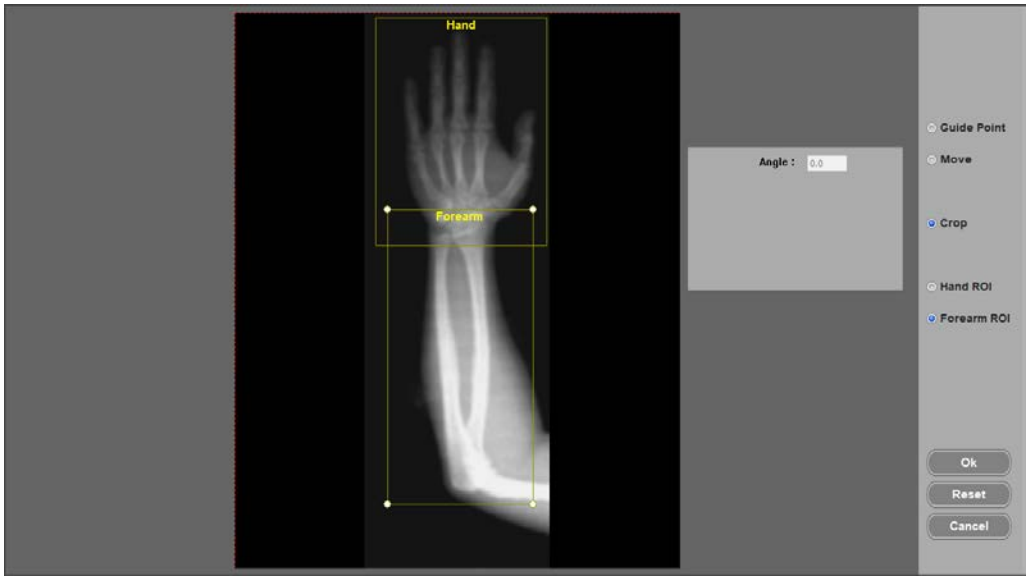
Low energy High energy Fat mass Lean mass FAT (%) BMD

6.6.4 Image analysis (GDP)

- It analyzes GDP image of patient after measurement.

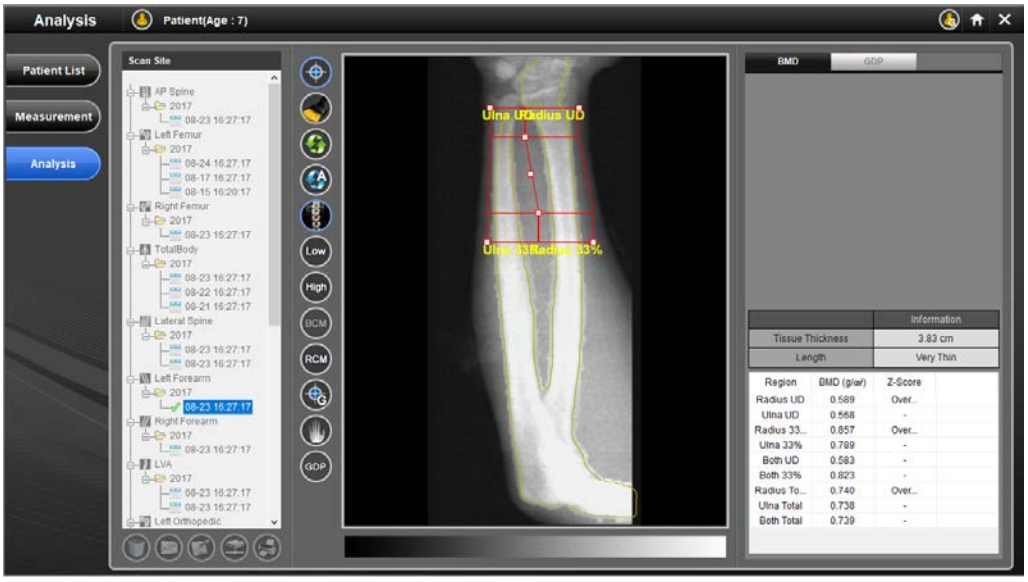
  a. After measurement, search GDP image from left forearm list and select it.
  b. When you press ROI button, Global ROI edit mode is activated. Select Hand and Forearm and set up Global ROI respectively.





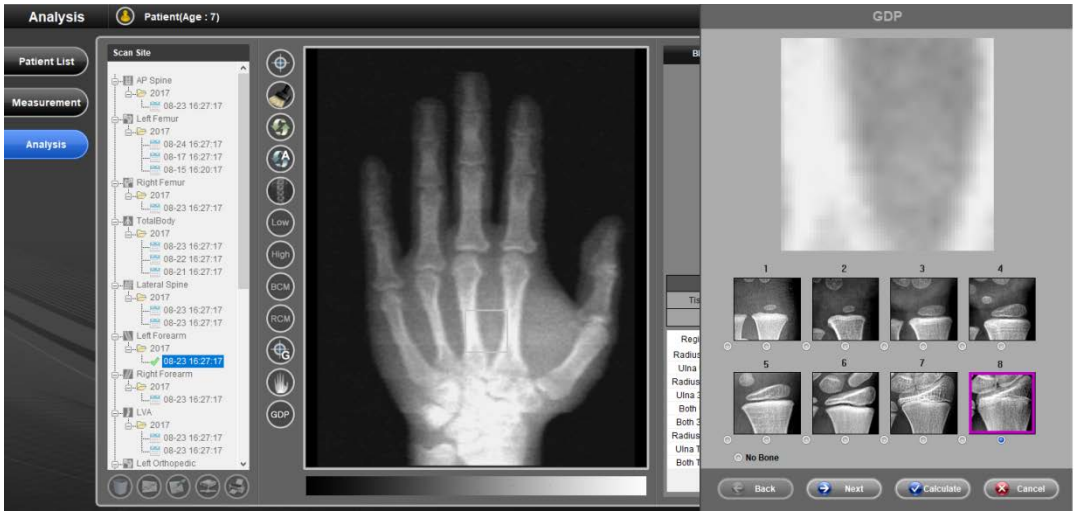
c. You can analyze Hand&Forearm respectively.

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.

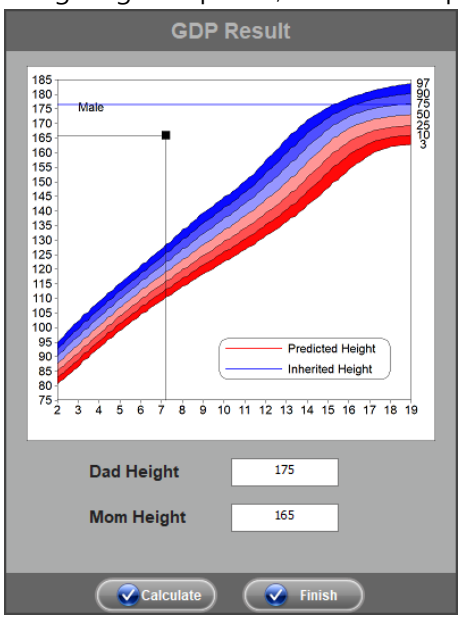
f. With the use of mouse wheel, you can scale up & down the image, and by moving mouse, you can choose picture as similar as possible.



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

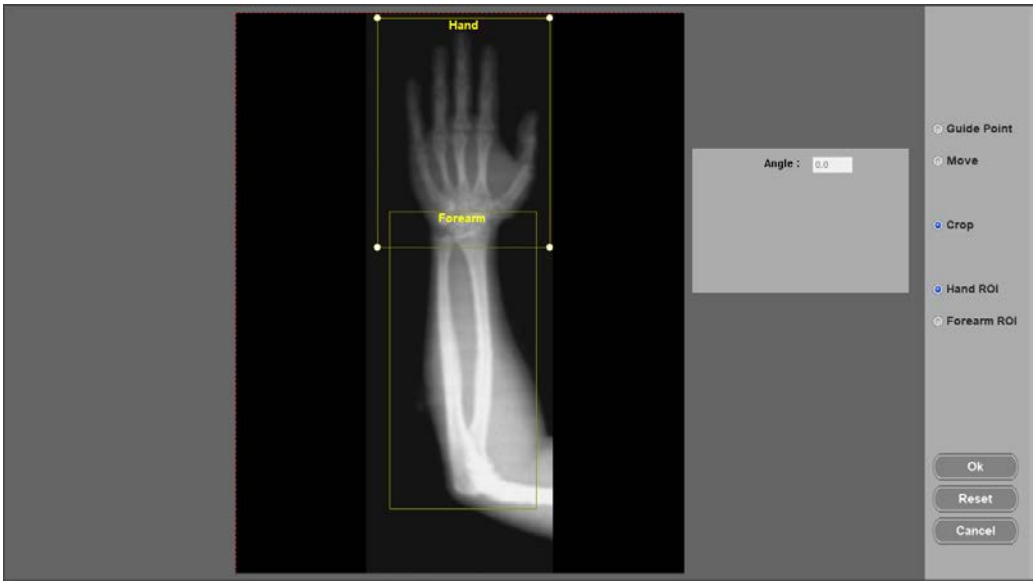
i. When entering height of parent, GDP can be predicted.



6.6.5 Image analysis (Hand)

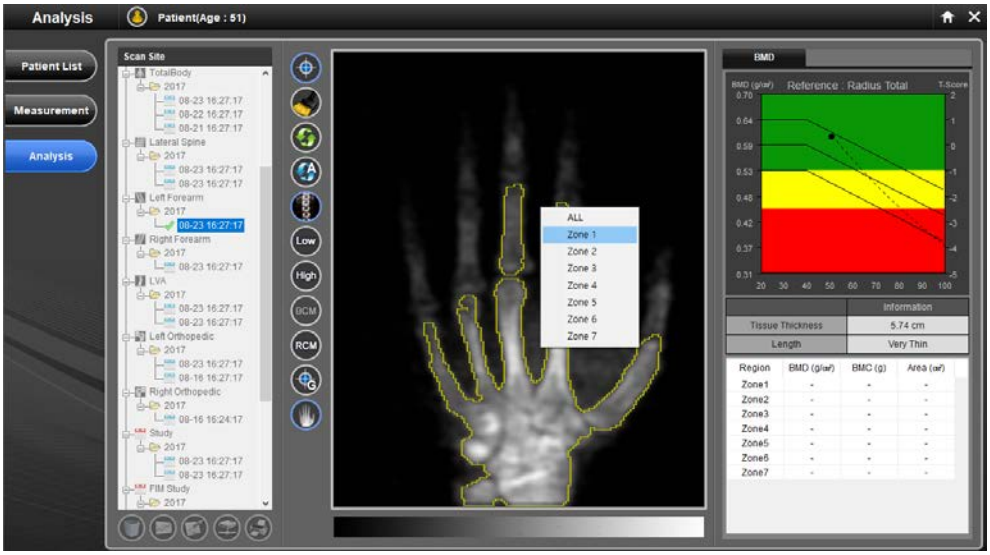
- It analyzes hand image of patient after measurement.

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.

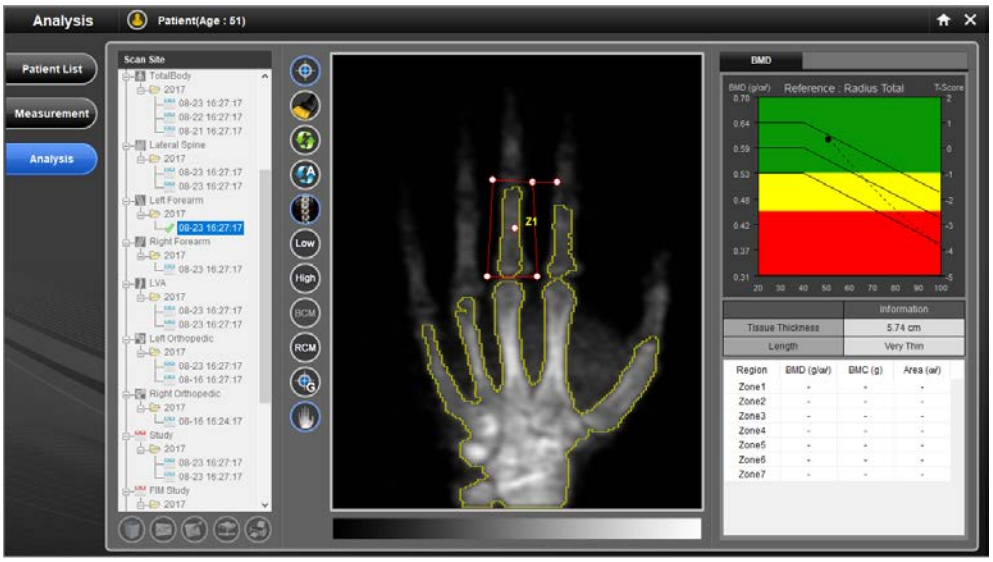
d. Basic analysis screen is Hand. You can select the ROI when you click the right button of the mouse on the image area.



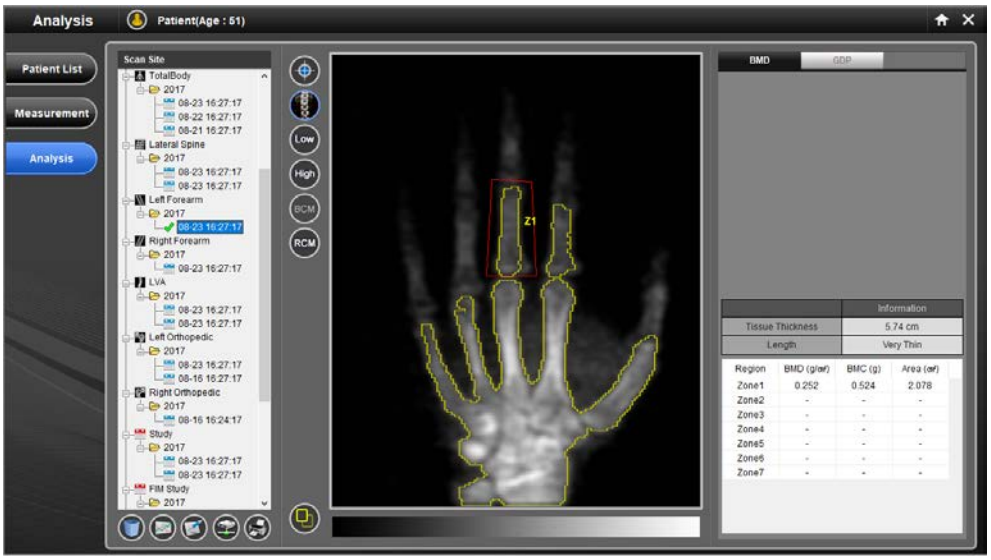
e. Drag the point in the middle to set the ROI that the operator wants to check.

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.

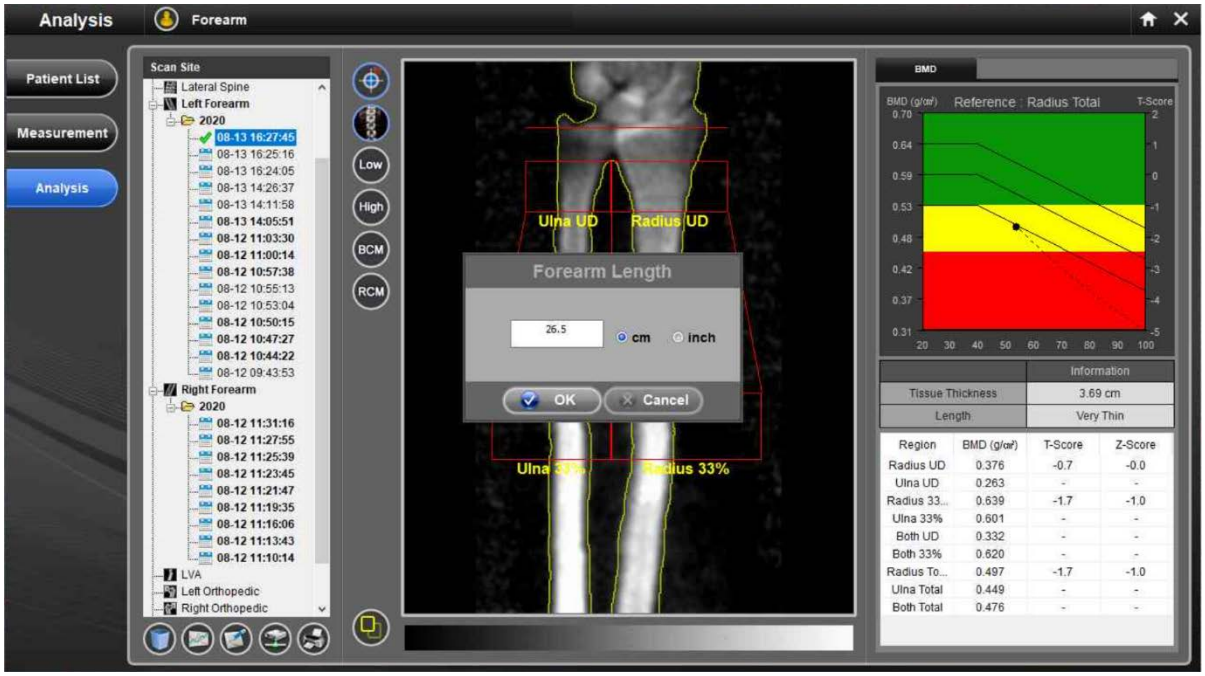


i. If you want to compare with the previous data or copy the ROI, please click 'ROI Compare' button.

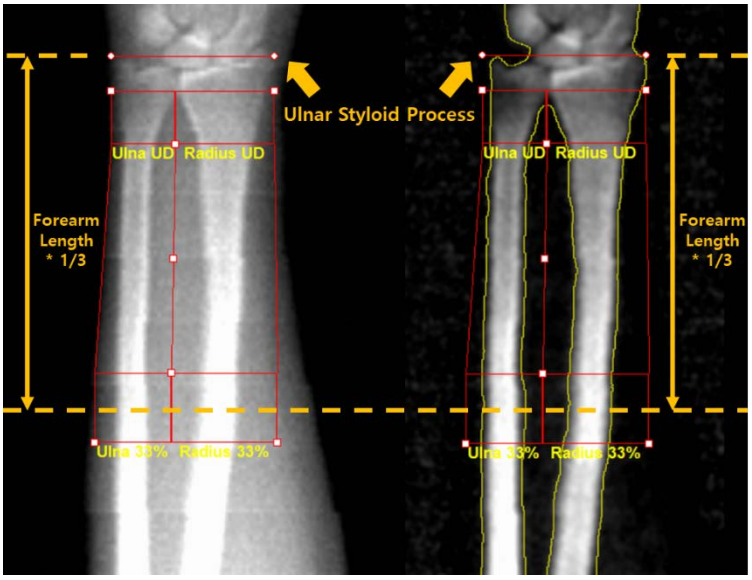
6.6.6 Image analysis (Forearm)

- Analysis on the measured forearm image of a patient.

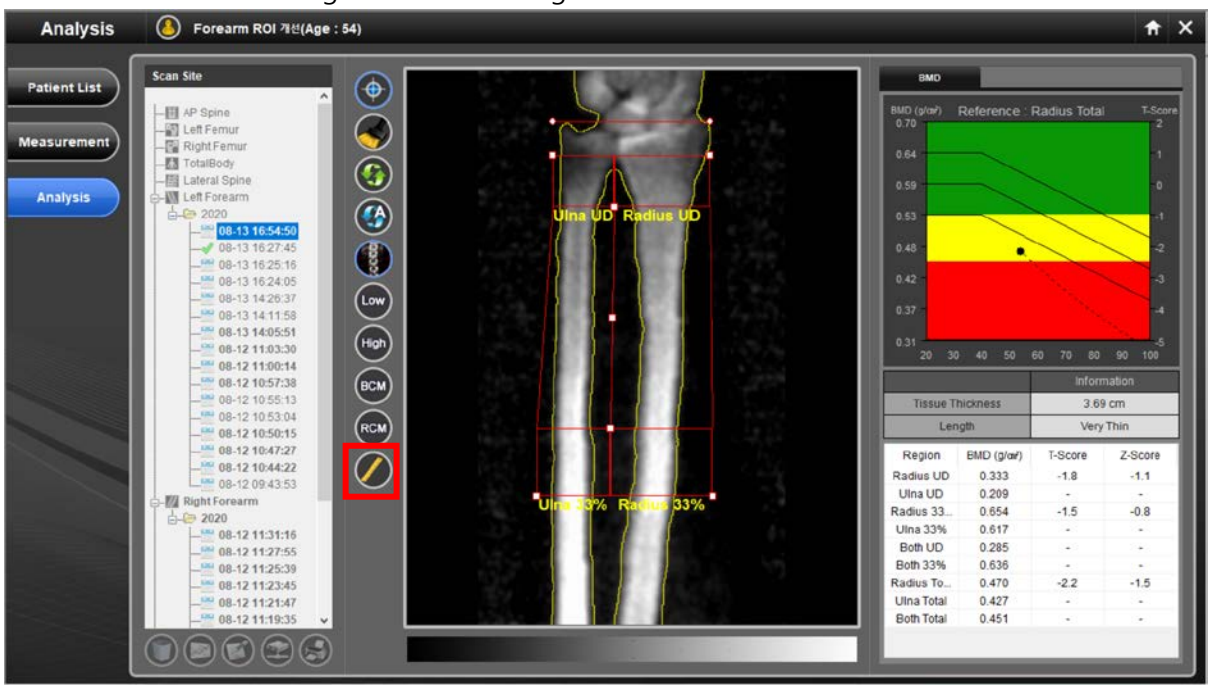
a. When the ROI button is pressed for the first time, a dialog box appears to enter the Forearm Length.
b. Enter the forearm length of the patient measured before bone density measurement.



c. If the ROI of the Forearm is not automatically caught, proceed as follows:
   A. Align the ulnar styloid process reference line to the upper end of the ulnar styloid process.
   B. Drag the point in the center of the ROI box of Forearm to adjust the position of the entire ROI.
   C. Drag the point located in the middle of the UD ROI box to move the position of the UD ROI from side to side. The 33% ROI can be adjusted in the same way. The position of the 33% ROI depends on the arm length of the patient.

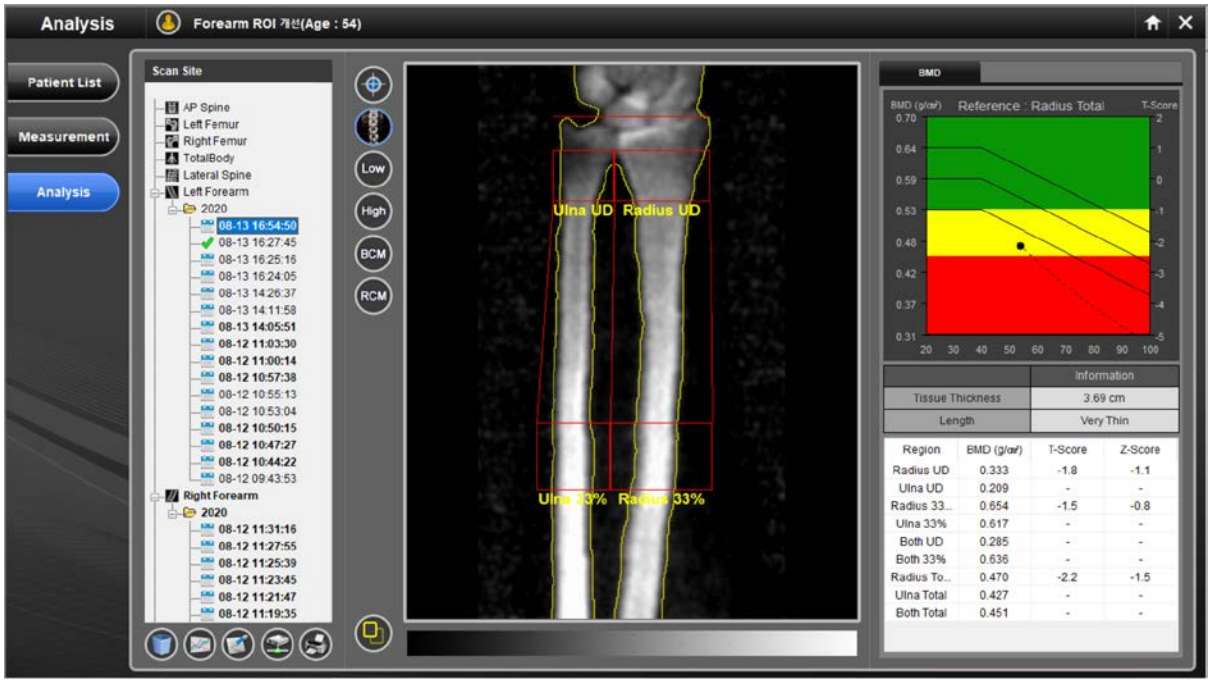


d. To adjust the length of the 33% position, click the Forearm Length button to change the forearm length.



e. Click ROI set button to fix ROI and create the value of each ROI.

f. The result is displayed.

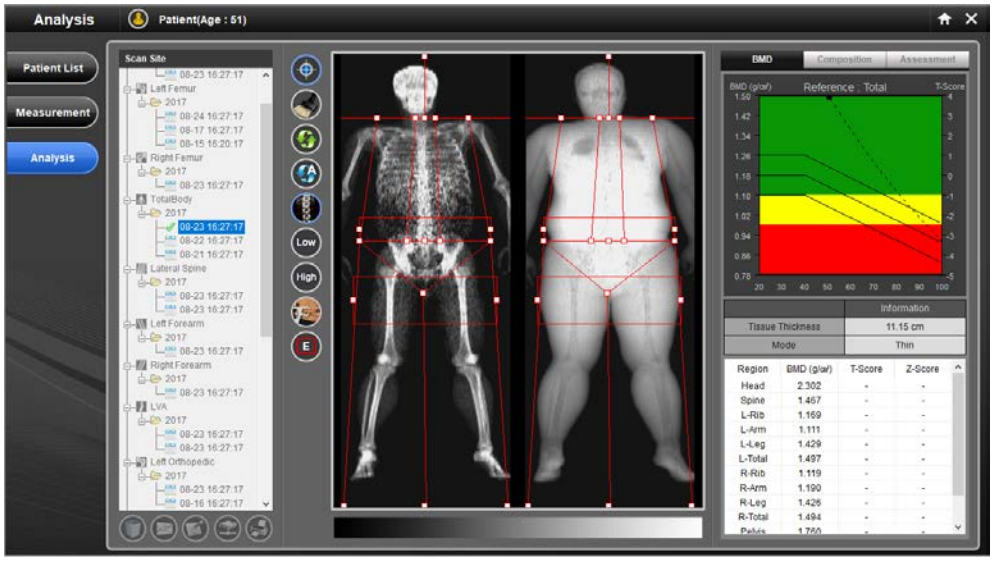

Analysis
Forearm ROI 개선(Age : 54)
Patient List
Measurement
Analysis
Scan Site
AP Spine
Left Femur
Right Femur
TotalBody
Lateral Spine
Left Forearm
2020
08-13 16:54:50
08-13 16:27:45
08-13 16:25:16
08-13 16:24:05
08-13 14:26:37
08-13 14:11:58
08-13 14:05:51
08-12 11:03:30
08-12 11:00:14
08-12 10:57:38
08-12 10:55:13
08-12 10:53:04
08-12 10:50:15
08-12 10:47:27
08-12 10:44:22
08-12 09:43:53
Right Forearm
2020
08-12 11:31:16
08-12 11:27:55
08-12 11:25:39
08-12 11:23:45
08-12 11:21:47
08-12 11:19:35
Low
High
BCM
RCM
Ulna UD
Radius UD
Ulna 33%
Radius 33%
BMD
Reference : Radius Total
Information
Tissue Thickness
3.69 cm
Length
Very Thin
Region
BMD (g/cm²)
T-Score
Z-Score
Radius UD 0.333 -1.8 -1.1
Ulna UD 0.209 - -
Radius 33... 0.654 -1.5 -0.8
Ulna 33% 0.617 - -
Both UD 0.285 - -
Both 33% 0.636 - -
Radius To... 0.470 -2.2 -1.5
Ulna Total 0.427 - -
Both Total 0.451 - -

6.6.7 Image analysis (Total 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.

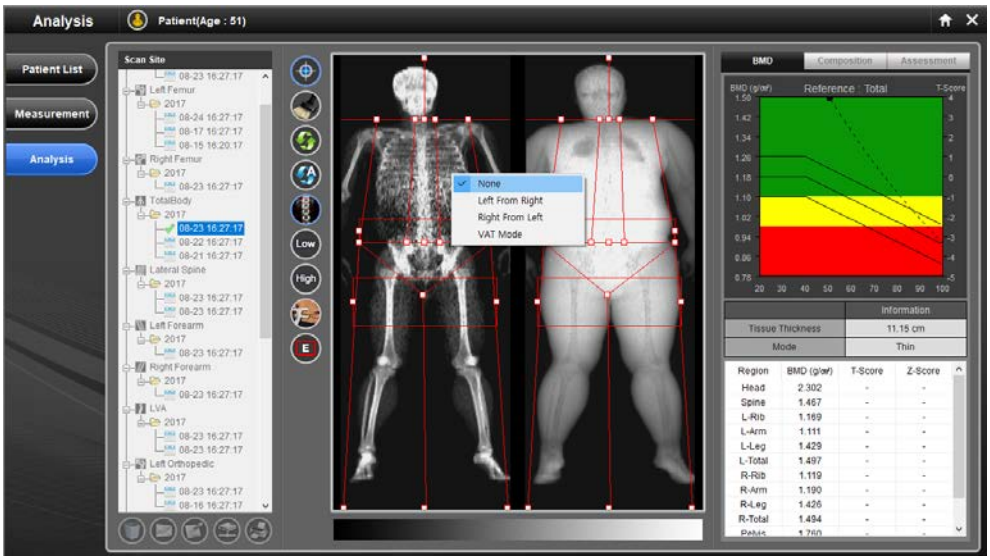


c. Pelvis and neck center point can be adjusted only in vertical direction while spine ROI point, head top point and foot point can be adjusted only in horizontal direction. You can adjust so that each body part can be included in proper ROI.

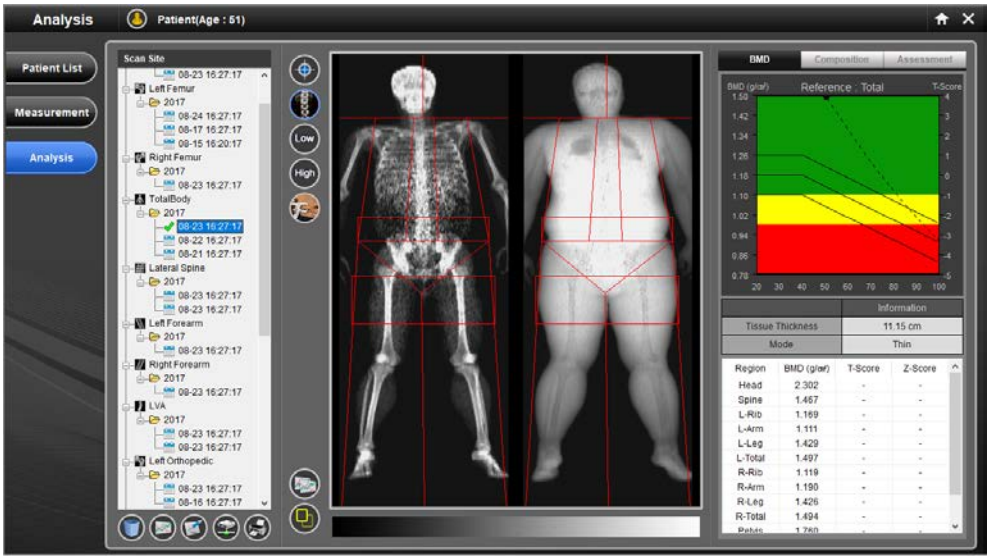
Place Head-Shoulder separator to the neck, which is above shoulder below chin. Rib-Shoulder seprartor separates arm and rib. The arms are only contained in Arm ROIS. Place Vertebra separator to have only vertebra. Side ROIs of vertebra separator has rib cage. Place waist marker to have only the waistm not the arm. Place Pelvis Top marker above the iliac crests. Pelvis Side markers make the pelvis edge crossed femoral necks. Place Leg ROIs to separate one leg. Place Android ROI to contain only belly. Place Gynoid ROI to contain only two-thighs.

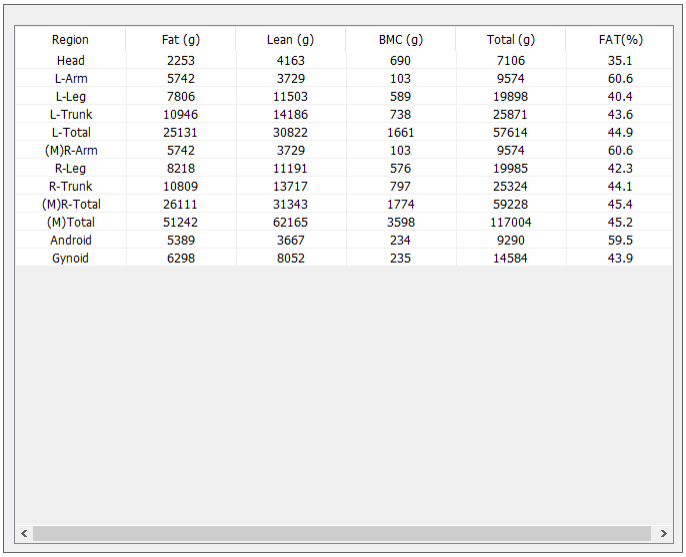
j. Please click the right button of mouse upon the image in the ROI edit mode to activate Mirror Mode if the image of Left Arm or Right Arm is not shown. You can copy the Left Arm value to Right arm or Right Arm value to Left Arm.

You can see (M) mark after activating Mirror Mode for recognition.



k. Please click 'ROI set' button after adjusting ROI to quit edit mode. Then the value will automatically appear.



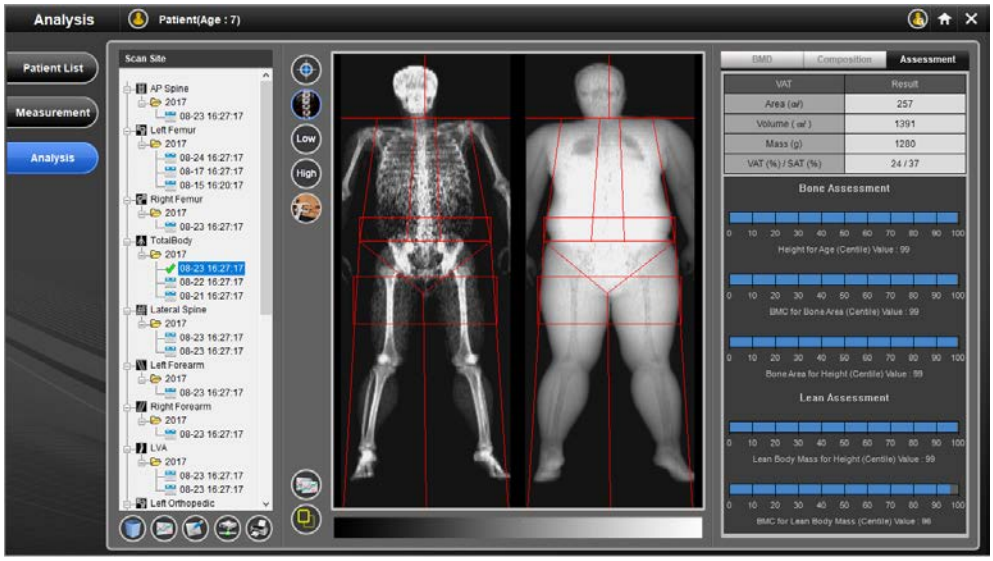


Region	Fat (g)	Lean (g)	BMC (g)	Total (g)	FAT(%)
Head	2253	4163	690	7106	35.1
L-Arm	5742	3729	103	9574	60.6
L-Leg	7806	11503	589	19898	40.4
L-Trunk	10946	14186	738	25871	43.6
L-Total	25131	30822	1661	57614	44.9
(M)R-Arm	5742	3729	103	9574	60.6
R-Leg	8218	11191	576	19985	42.3
R-Trunk	10809	13717	797	25324	44.1
(M)R-Total	26111	31343	1774	59228	45.4
(M)Total	51242	62165	3598	117004	45.2
Android	5389	3667	234	9290	59.5
Gynoid	6298	8052	235	14584	43.9

Table for Body Composition(FAT(g), LEAN(g), FAT(%), BMC(%))

- Body Assessment function will be activated if the patient's age is between 5 ~ 19.

a. Please click 'Assessment' tab after measurement.
b. It shows the result of total body composition and body state information as a percentage.



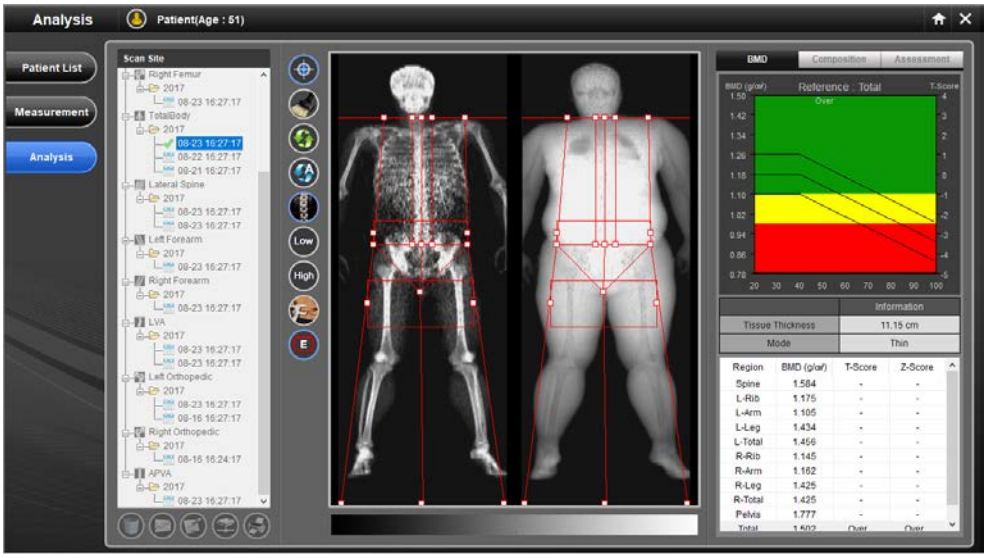
Bone Assessment

- Height for Age : Information of "Bone Length"
- BMC for Bone Area : Information of "Bone Density"
- Bone Area For Height : Information of "Bone Width"

Lean Assessment

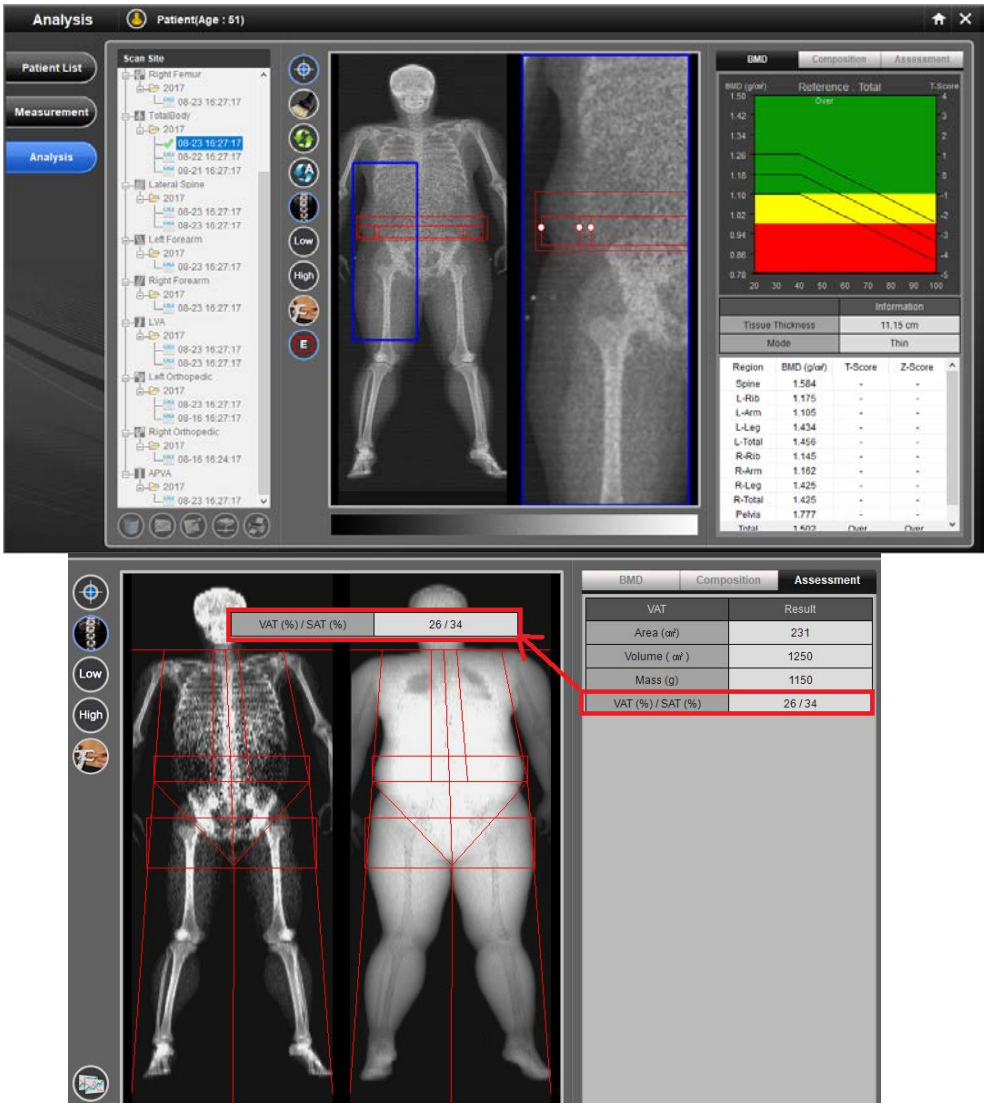
- Lean Body Mass for Height : Information of "Degree of sarcopenia"
- BMC for Lean Body Mass : Information of "Degree of osteopenia"

- For the usage of improved "Mirror Mode", Total Body Extend Mode can be used.
  a. Click "Extend ROI" button at analysis screen.
  b. Select ROI area same as basic ROI setting.



- It analyzes the VAT of patient after measurement.

a. Click the image of total 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.



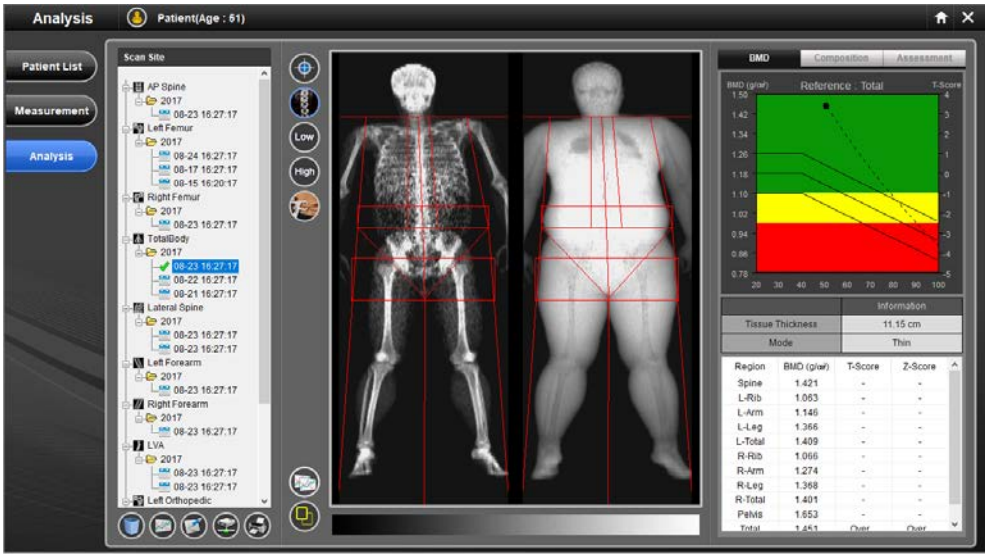
f. At the expanded image on the right side, ROI adjustable point will be created. By moving this point to the left and right, visceral fat area, abdominal area and abdominal wall area will be designated.
g. When ROI adjustment is finished, press ROI set button and finish edit mode.
h. When selecting right top side of Assessment Tab, VAT and its informatiion will be identified.

What is VAT?

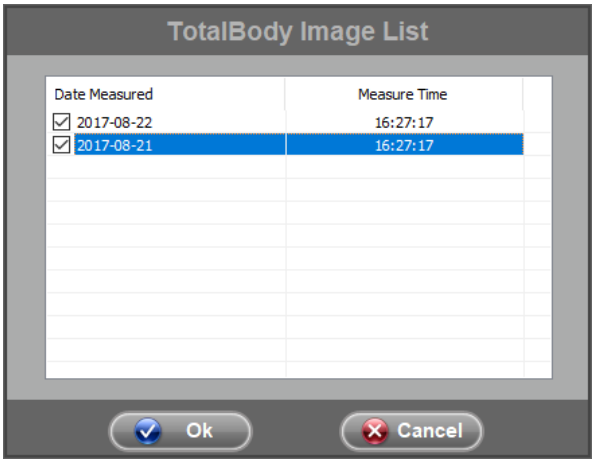
It is the abbreviation for “Visceral Adipose Tissue”. It analyzes visceral fat.

- It offers a trend analysis for body composition (BMC(g) / FAT(g) / LEAN(g) / FAT(%) /BMC(%)).

a. Please click 'Image Trend' button after measurement.

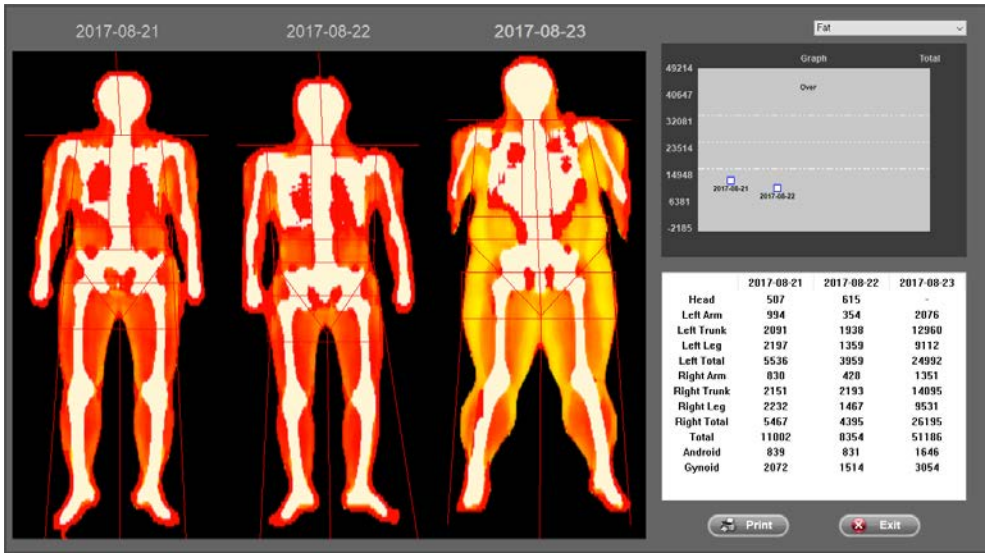


b. Please select the data that you want to compare.



c. It offers image and trend data of selected data.

d. It shows the selected data with BMC(g) / FAT(g) / LEAN(g) / FAT(%) / BMC(%) when you click buttons on the top.

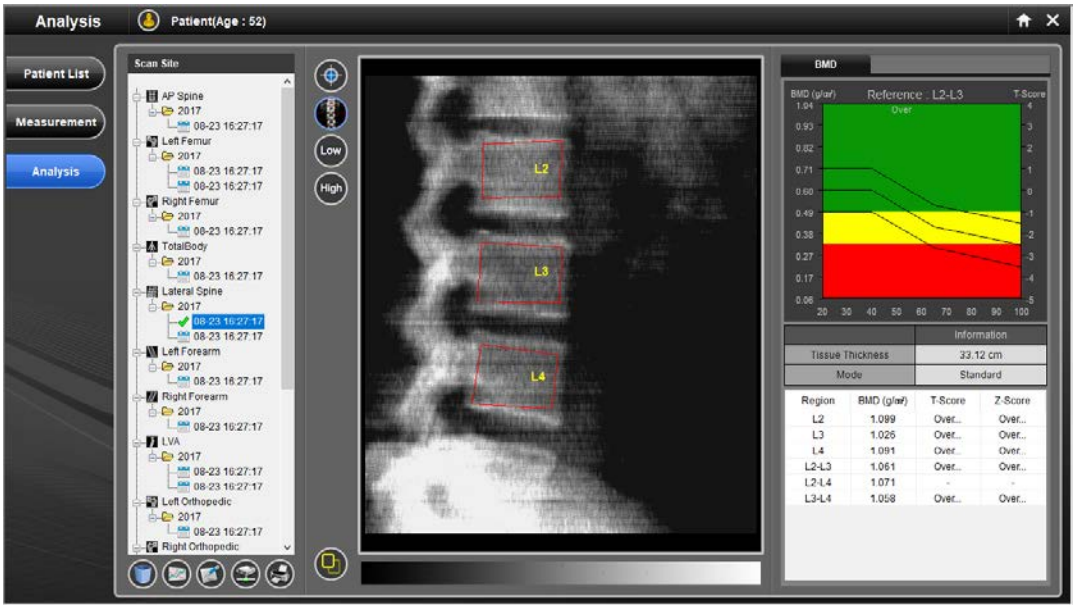


e. You can print all selected data when you click 'Print' button

6.6.8 Image analysis (Lateral Spine)

- Analysis on the measured lateral spine image of a patient.

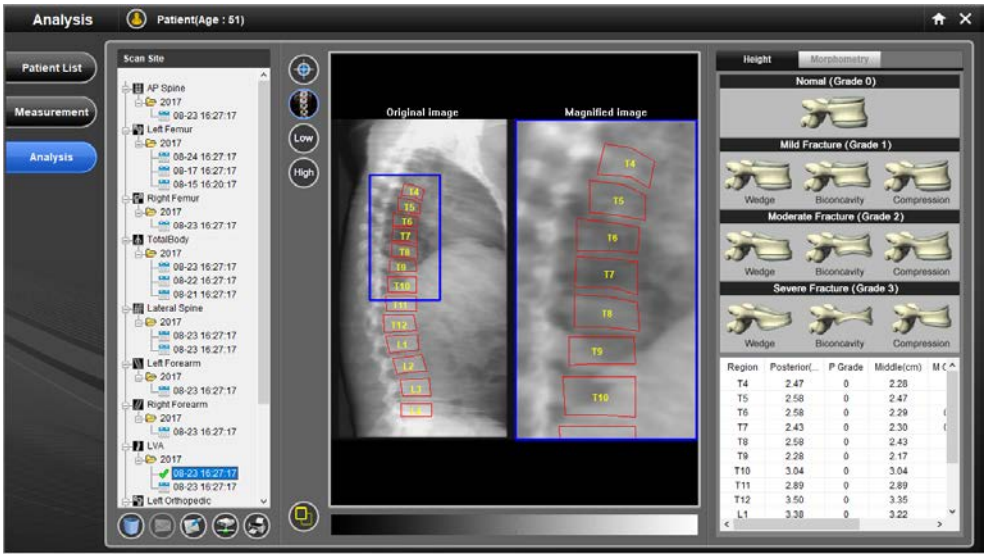
a. If the lateral spine ROI is not automatically detected, follow the process below: Press ROI set button.
b. Drag the point in the center of the lateral spine ROI to adjust the entire ROI site.
c. Adjust the slope outside the box with the pointer to adjust the slope of ROI.
d. Drag 4 points outside 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.



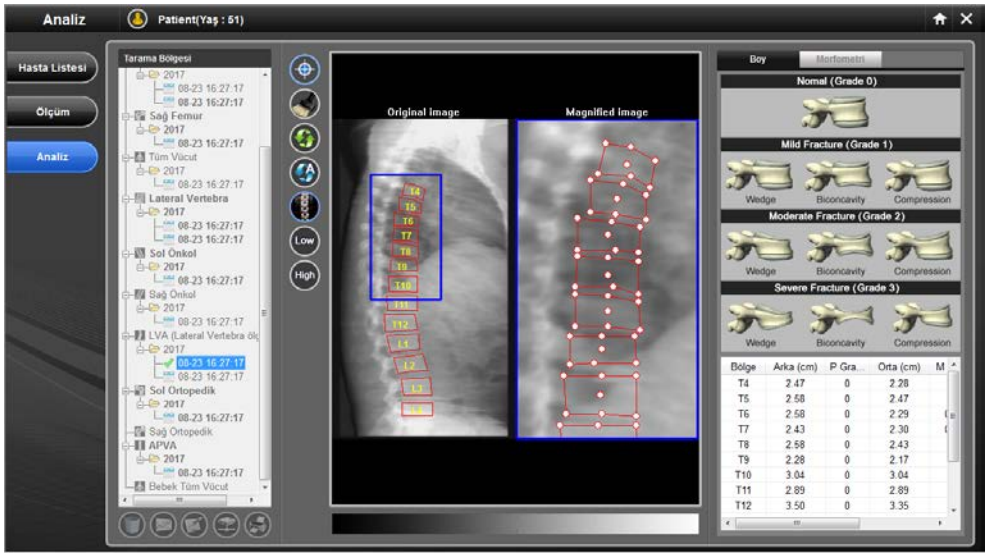
6.6.9 Image analysis (LVA - Lateral Vertebra Assessment)

- It measures image of LVA

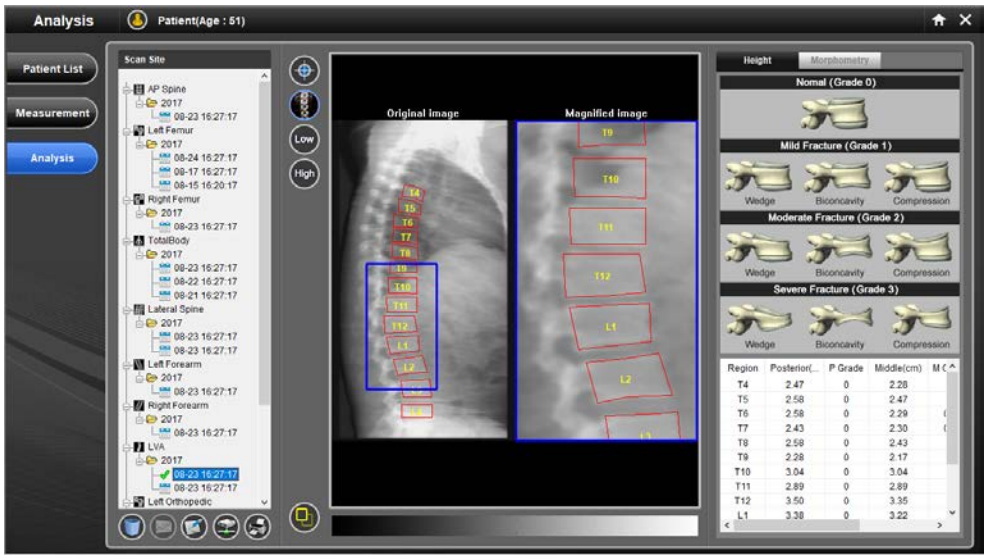
a. From the list in the left, click the patient's image obtained by scanning.
b. If the image appears, click ROI set.
c. If you put the mouse cursor on the original image, the cursor is changed into a magnifying glass and a rectangle is made up surrounding the cursor. The expanded image will appear.



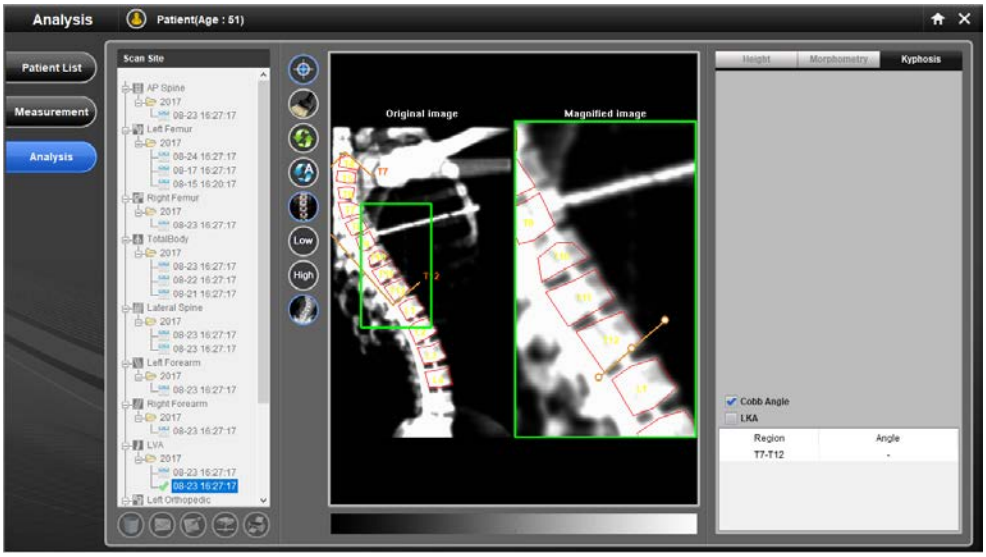
d. If you click on the area, the color of the area will be changed. The area will be fixed, and the points will appear on the magnified image to adjust the ROI. Adjust the location of whole ROI by dragging the middle point.
e. There are 6 points in a ROI area and you can adjust the size of ROI by moving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

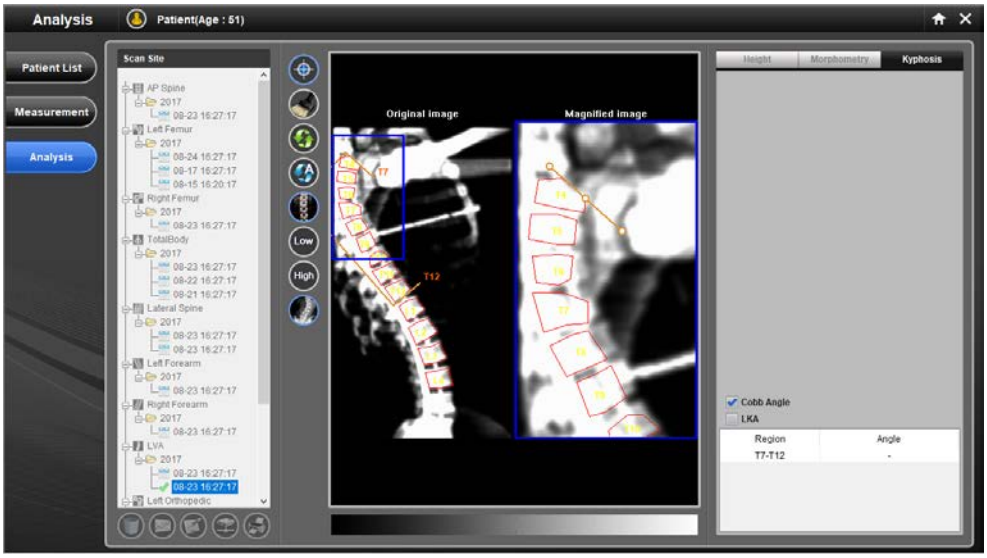


g. You can set ROI for Kyphosis diagnosis and the ROI will be decided according to the Angle Type.



h. There are two options for the Angle Type: Cobb Angle and LKA. Between these two options, the one you select will be activated.

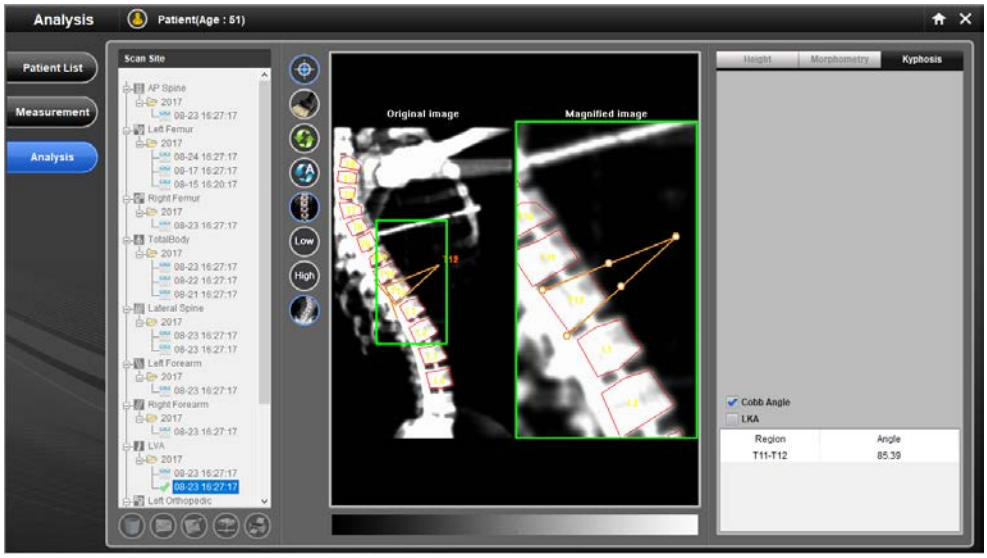
i. In case of Cobb Angle, you can set the ROI by selecting one vertebra located in the most severe curvature point which is the standard for Cobb Angle measurement and other two vertebrae, one from the upper side and the other from the lower side of the standard vertebra. And then, you can adjust the top end line from the higher vertebra and the bottom end line from the lower vertebra.



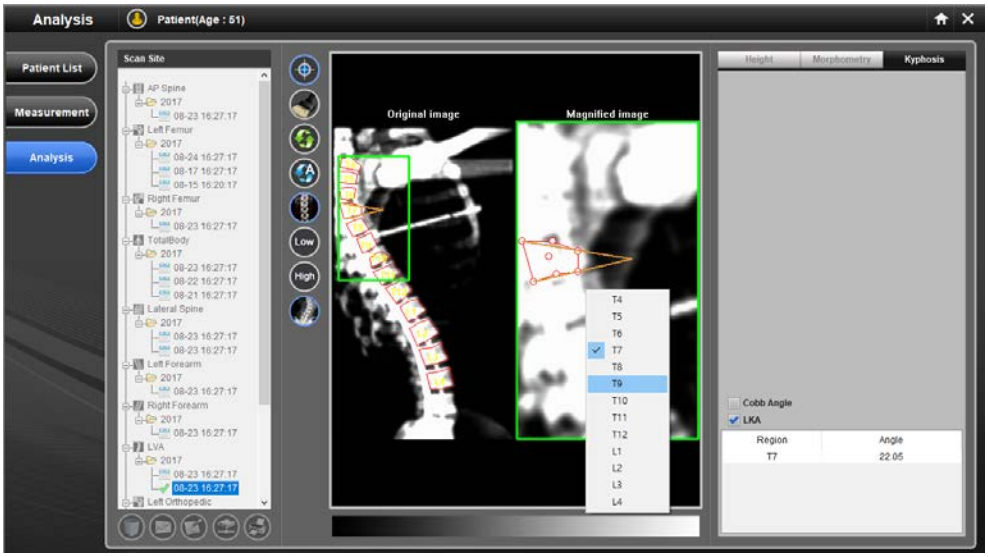
j. You can attach a name tag to each Cobb Ange ROI, and if you click the mouse

on the ROI adjustment window of the right side, you can attach a name tag.

k. In case of LKA Angle, if you select the vertebra as a standard of LKA measurement, the cross point angel between vertebras ROI's top end line and the bottom end line will appear.



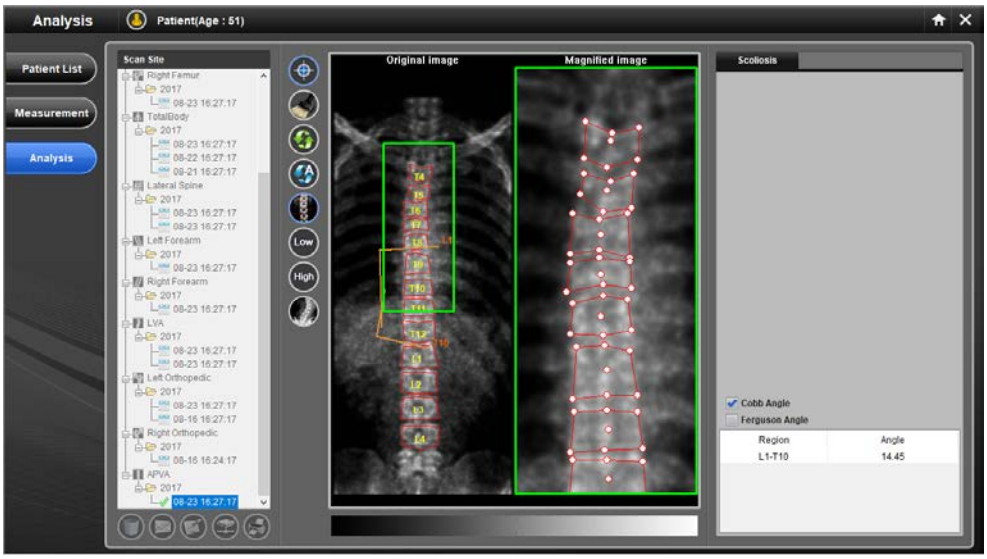
l. If you click the right button of the mouse on the window in the right, you can select LKA standard ROI.



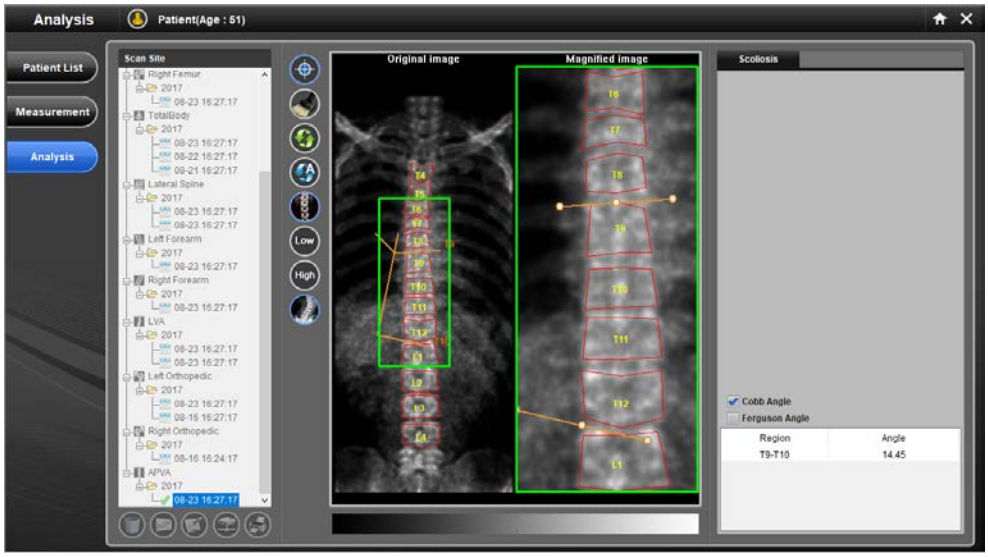
m. If you move your mouse, adjust each area by following above mentioned process, and click the ROI set button, the each ROI's value will be analyzed and appear as a result.

6.6.10 Image analysis (APVA)

a. Select the one of the image file from scan image list which is located on the left side of S/W.
b. Click the ROI set button after image is appeared.
c. When you place the mouse cursor on the original image, the cursor becomes a magnifying glass icon and Green rectangle is created around the cursor on the scan image. The image can be enlarged from the original scan image to make easy ROI setting.



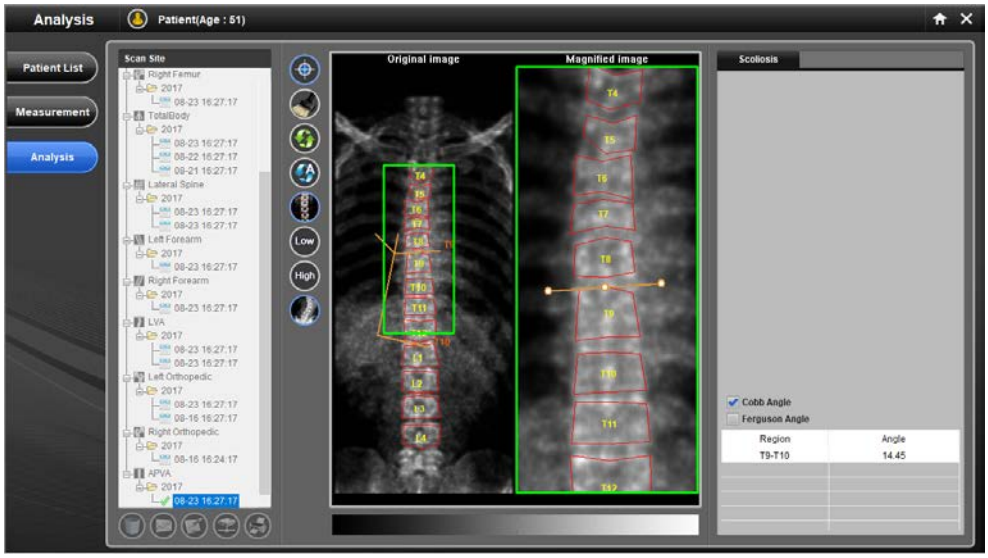
d. Clicking the left mouse button, you can fix the ROI (red rectangle) area and also drag the center point of ROI to fix the location.
e. There are 6 ROI in total, you can adjust to match with enlarged bone image.



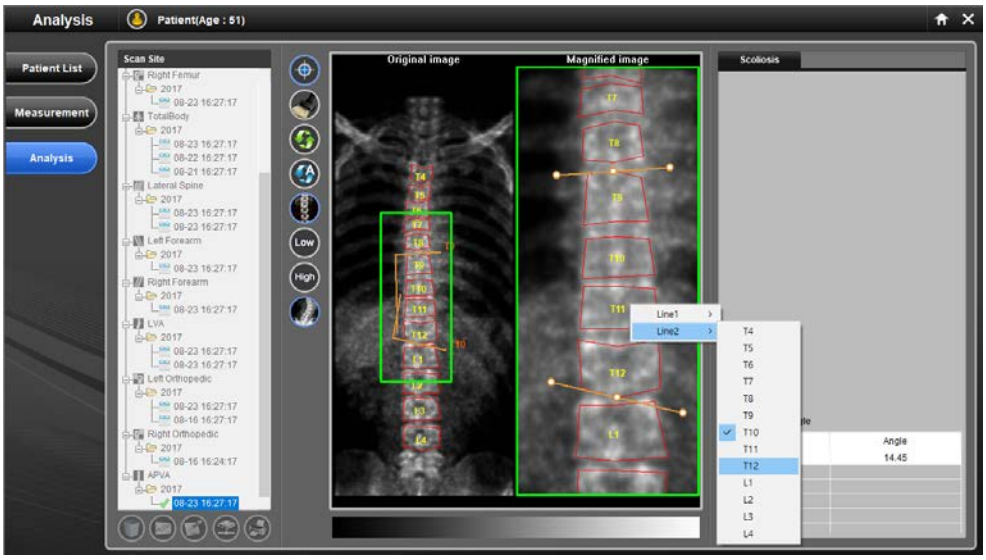
f. When you have finished adjusting the ROI setting, click the right mouse button and the move to another area to set and see the magnifying image again.

g. There are two type of angle adjustment, one is Cobb Angle and Ferguson Angle. Click and activate check box to active these functions.

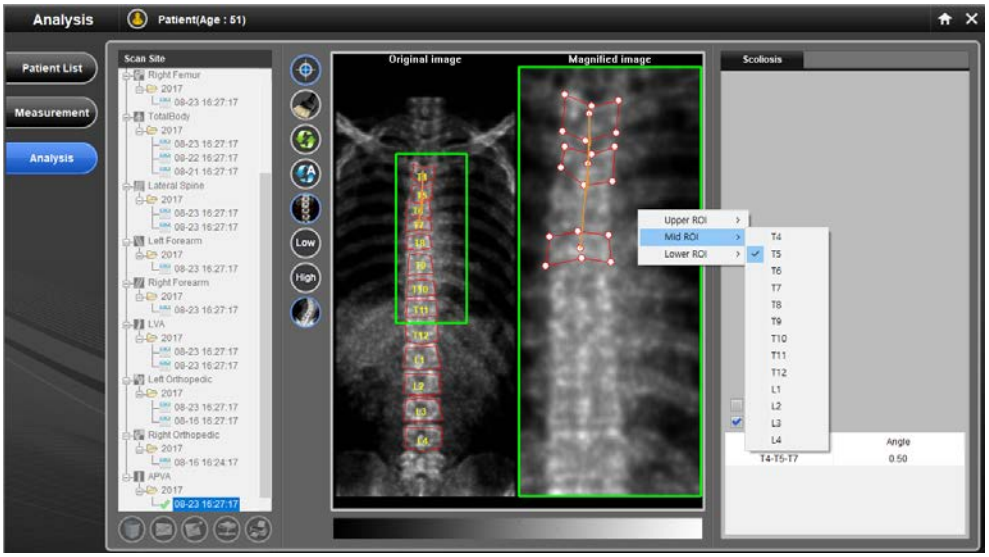
- In order to get Cobb Angle, you need to choose three bones. One is located in peak point of curvature of vertebrae and choose the other two bones which is located upper-end and lower-end bone (refer to the image)



h. Name tags can be attached to each Cobb Angle ROI, and if you click the right mouse button on the magnified image window, you can attached name tag from L4~T4).

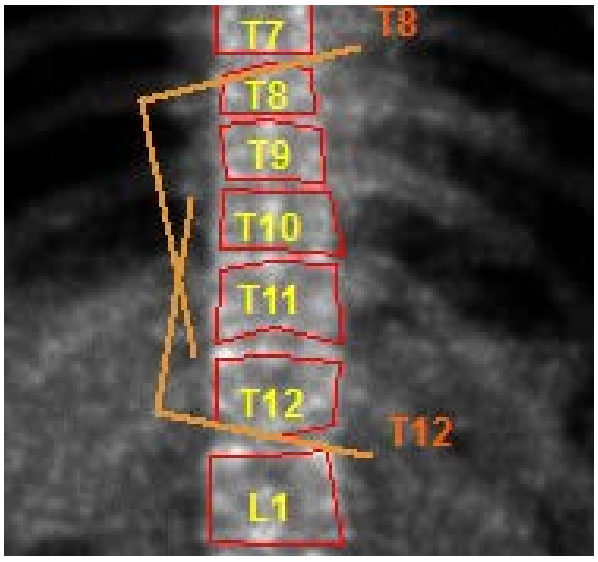


i. If you select Ferguson Angle, you can set up the ROI same ways as Cobb Angle, the angle is created by three vertebrae (Upper, Mid and Low bone).



j. When you finished ROI setting on the magnified image window, then click the ROI set icon to get the result of Ferguson Angle.

6.6.11 Image analysis (Scoliosis-Cobb Angle)



- Scoliosis Cobb Angle can be analyzed with the image which is acquired from APVA scan mode

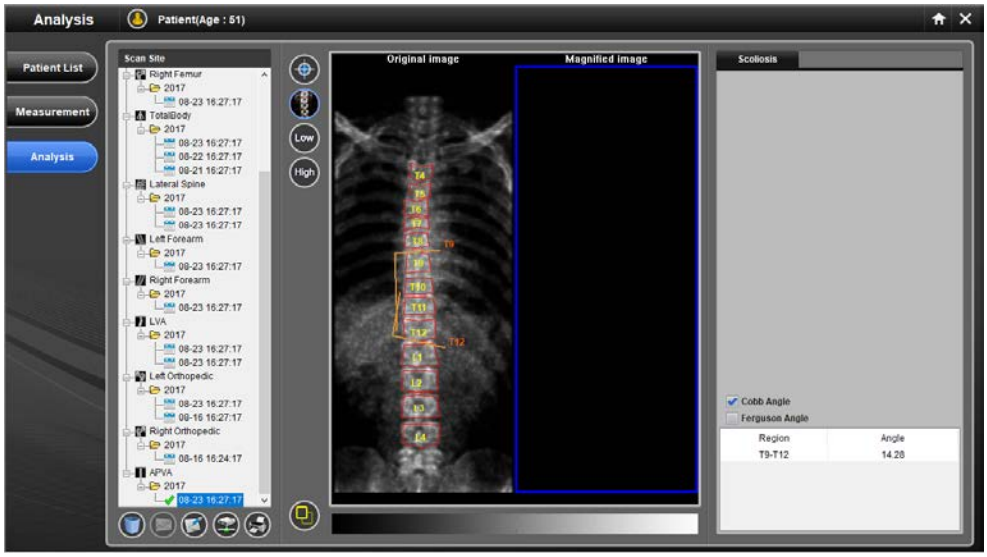
> The results of Scoliosis Cobb Angle are not absolute value to diagnose scoliosis, but that can be help to diagnose scoliosis

a. Definition

Select the upper-end vertebra and lower-end vertebrae from the most bent and severed parts of the vertebrae (from T4 to L4). Read the inner angle of the intersection of the extension lines of these two vertebrae

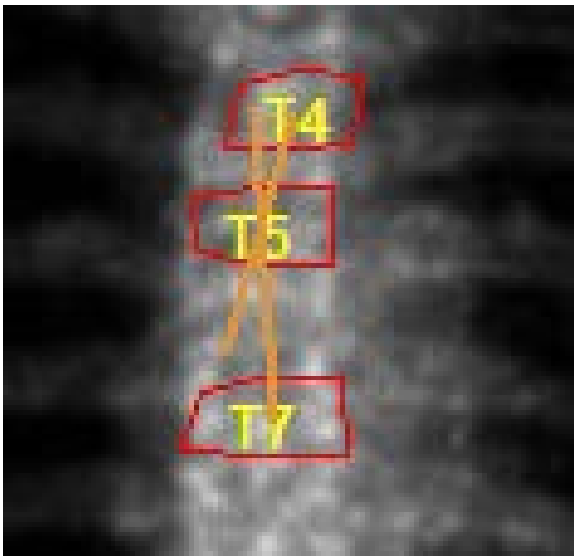
b. Result

After the APVA scanning, you can find out the result of Cobb Angle in the Scoliosis tab. The following image shows the APVA Cobb Angle information and Analysis.



c. Result unit is displayed in degrees at Scoliosis mode.

6.6.12 Image analysis (Scoliosis-Ferguson Angle)



- Scoliosis Ferguson Angle can be analyzed with the image which is acquired from APVA scan mode

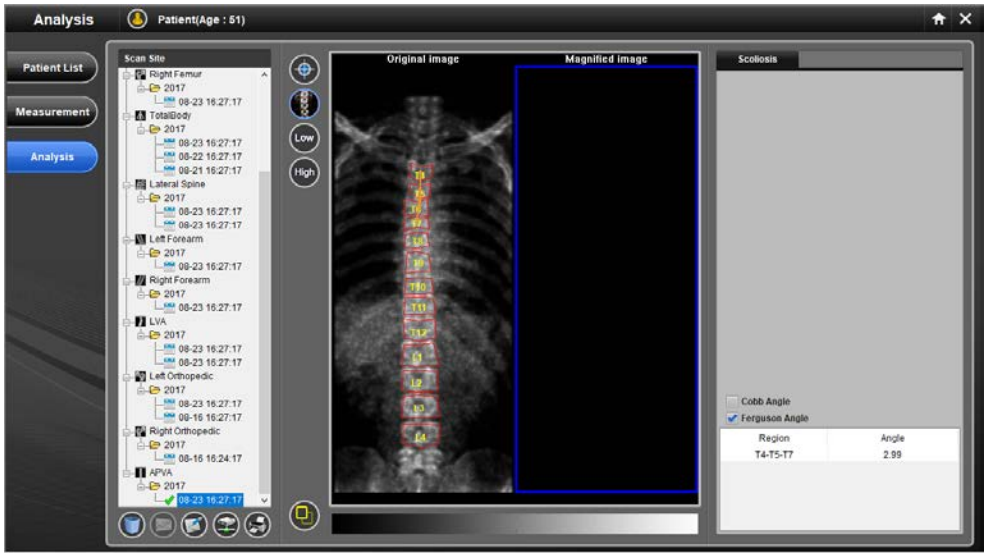
The results of Scoliosis Ferguson Angle are not absolute value to diagnose scoliosis, but that can be help to diagnose scoliosis

a. Definition

Select upper, mid and Lower vertebra those read the inner angle of the intersection of the extension lines of these two vertebrae (Upper and Lower) to the center point of mid vertebra

b. Result

After the APVA scanning, you can find out the result of Ferguson Angle in the Scoliosis tab. The following image shows the APVA Ferguson Angle information and Analysis.



c. Result unit of Scoliosis Ferguson Angle is displayed in degree.

6.6.13 Image analysis (Kyphosis-Cobb Angle)

- Kyphosis Cobb Angle can be analyzed with the image which is acquired from LVA (Lateral Vertebral Assessment) scan mode

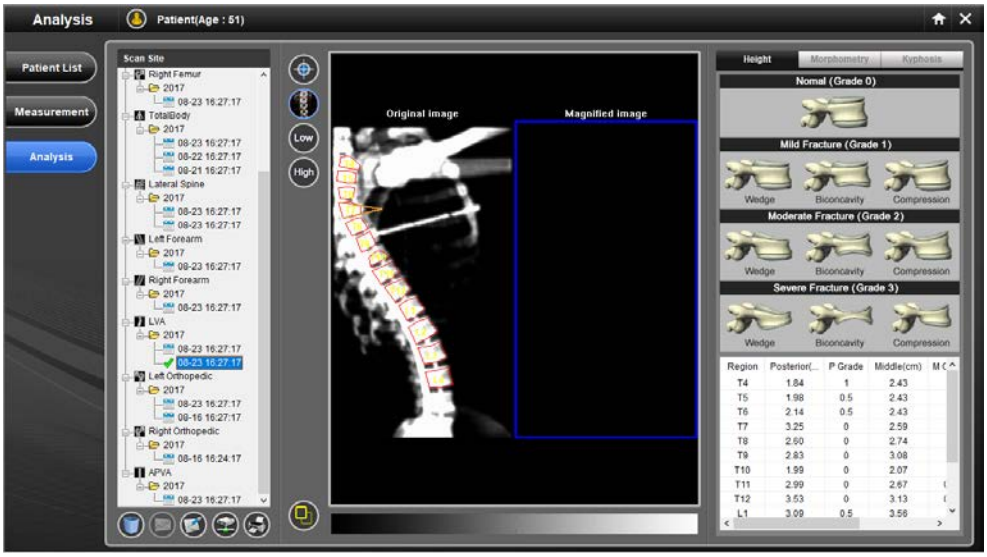
> The results of Kyphosis Cobb Angle are not absolute value to diagnose Kyphosis, but that can be help to diagnose Kyphosis

a. Definition

Select upper-end Lateral vertebra and lower-end Lateral vertebra those are identified the place where the most bent and severed part of Lateral vertebra (From L4~T4), read the inner angle of the intersection of the extension lines of these two Lateral vertebrae.

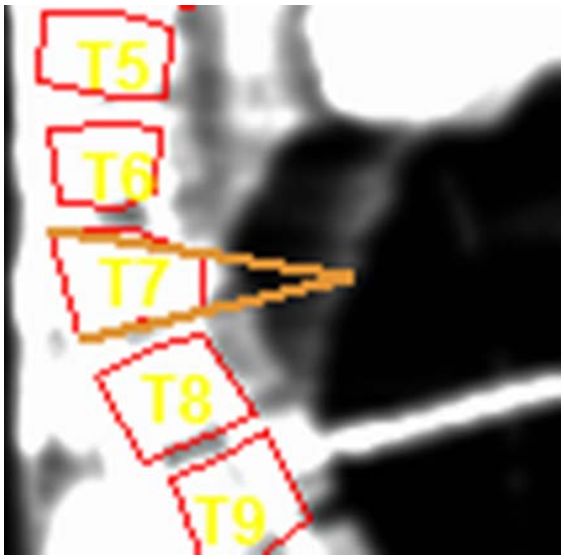
b. Result

After the LVA (Lateral Vertebral Assessment) scanning, you can find out the result of Cobb Angle in the Kyphosis tab. The following image shows the LVA Cobb Angle information and Analysis.



c. The result unit is displayed in degrees.

6.6.14 Image analysis (Kyphosis-LKA<Local Kyphotic angle>)



- Kyphosis-LKA can be analyzed with the image which is acquired from LVA scan mode

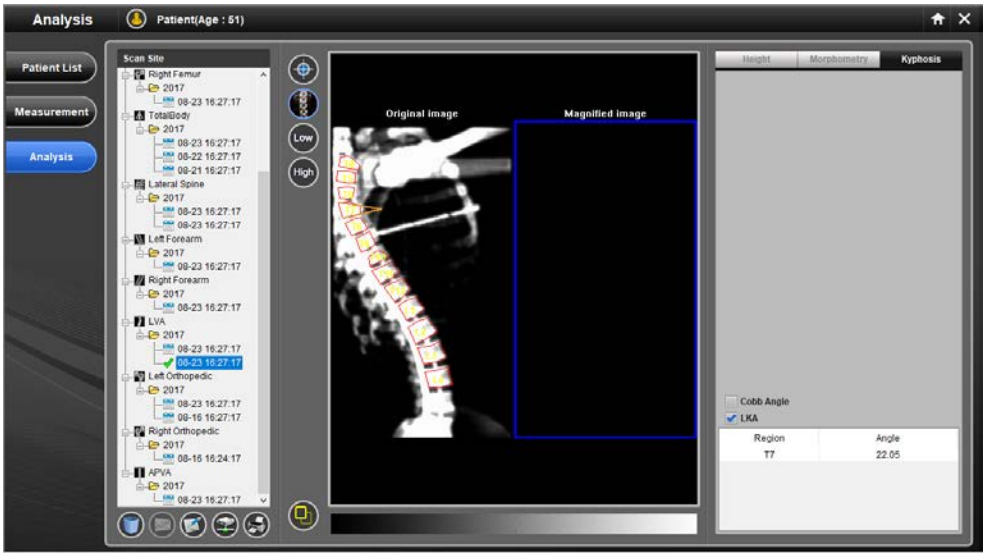
> The results of Kyphosis-LKA are not absolute value to diagnose Kyphosis, but that can be help to diagnose Kyphosis

a. Definition

Select one Lateral vertebra which is most deformed and severe condition(from L4~T4), and read the inner angle of the intersection of the extension lines of upper and lower end side of vertebra

b. Report

After the LVA scanning, you can find out the result of Kyphosis-LKA in the Kyphosis-LKA tab. The following image shows the Kyphosis-LKA Angle information and Analysis.



c. The result unit is displayed in degrees

6.6.15 Image analysis (HA - Hip Analysis)

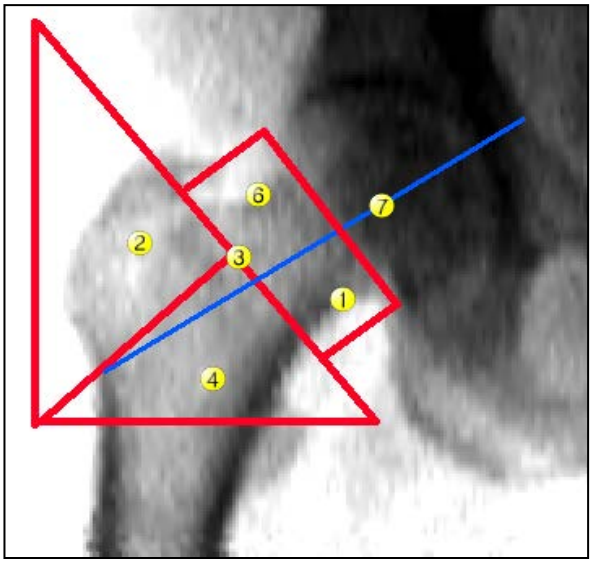
- Analysis on the measured femur image of a patient.

> ⚠ 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).

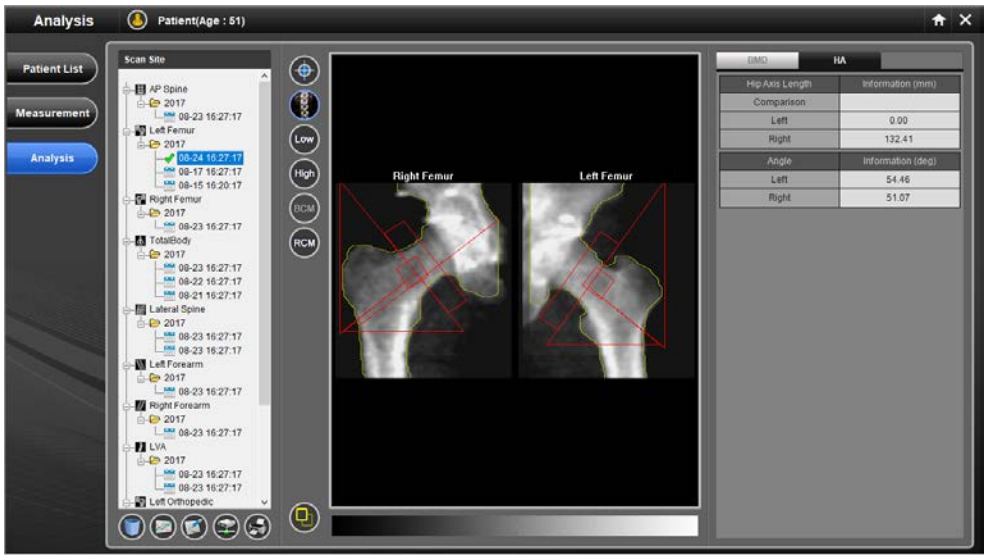


① Lower Femoral Neck
② Femoral Trochanter
③ Ward
④ Shaft
⑥ Upper Femoral Neck
⑦ Hip Axis Length

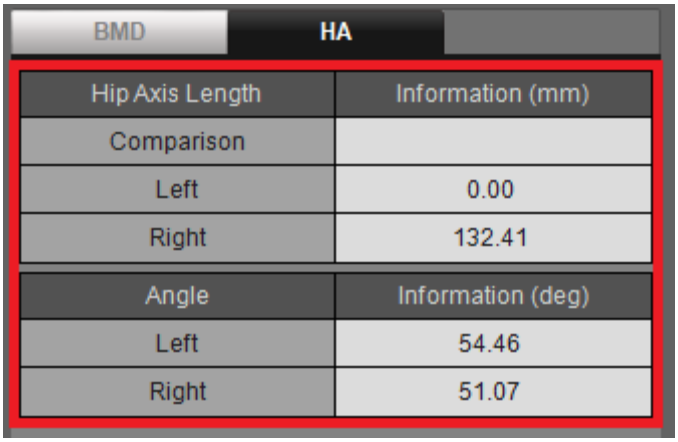
> ⚠ In current software version, only HAL, and FNSA are supported. FNW, UFN-BMD items will be added later.

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.



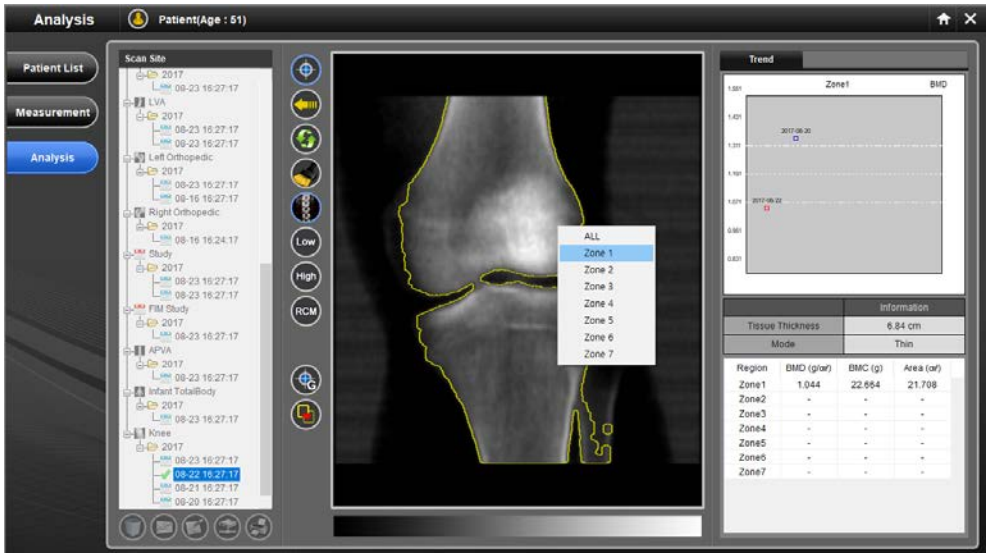
6.6.16 Image analysis (Knee)

- It analyzes Knee image of patient after measurement.

a. Click "Knee" image which was measured.
b. When you find the image, press ROI set button.
c. In case that Global ROI is not set, it moves to screen of Global ROI set up.

i. Guide Point : It is function that can enable Global ROI setting at the same point.
ii. Move : It is function to move Global ROI.
iii. Rotate : When scan area is not properly set with tilted image, it can rotate the image properly.
iv. Crop : It can adjust size of Global ROI

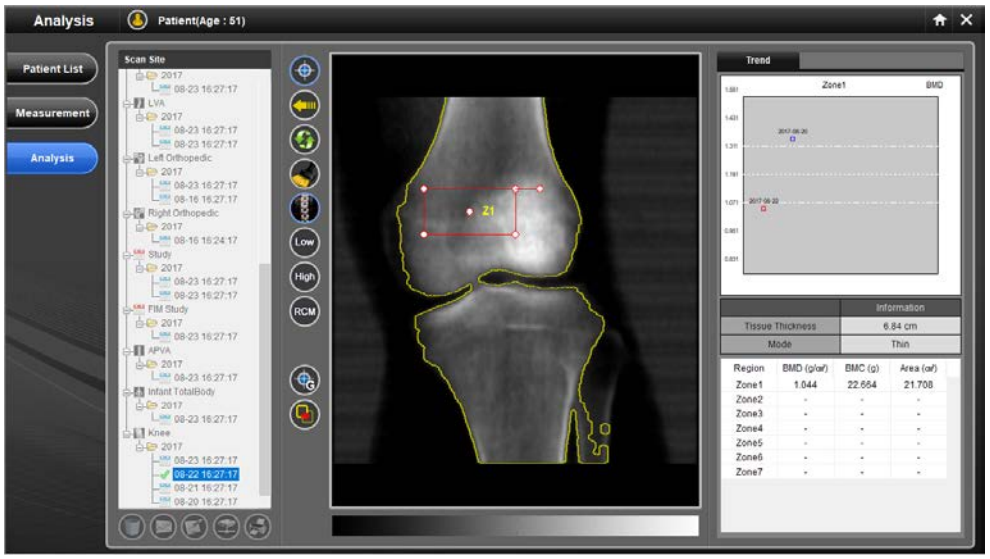
d. When Global ROI set up is completed, press "Ok" button and complete setting.
e. On the image, if you press right side of mouse, you can select ROI that you want to select.



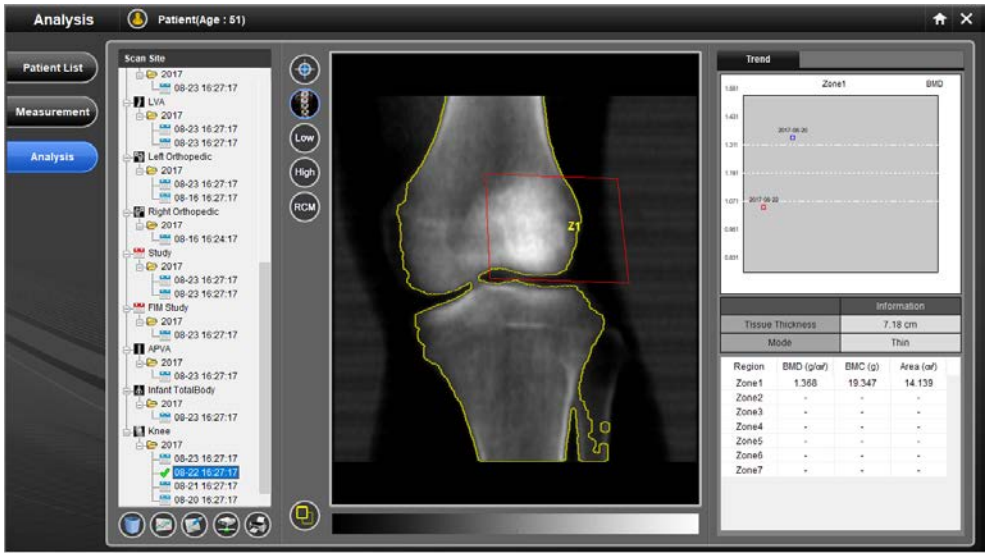
f. By dragging point in the middle of ROI, you can adjust ROI to the point you want to confirm.

g. By adjusting tilt of outside of square, tilt of ROI can be adjusted.

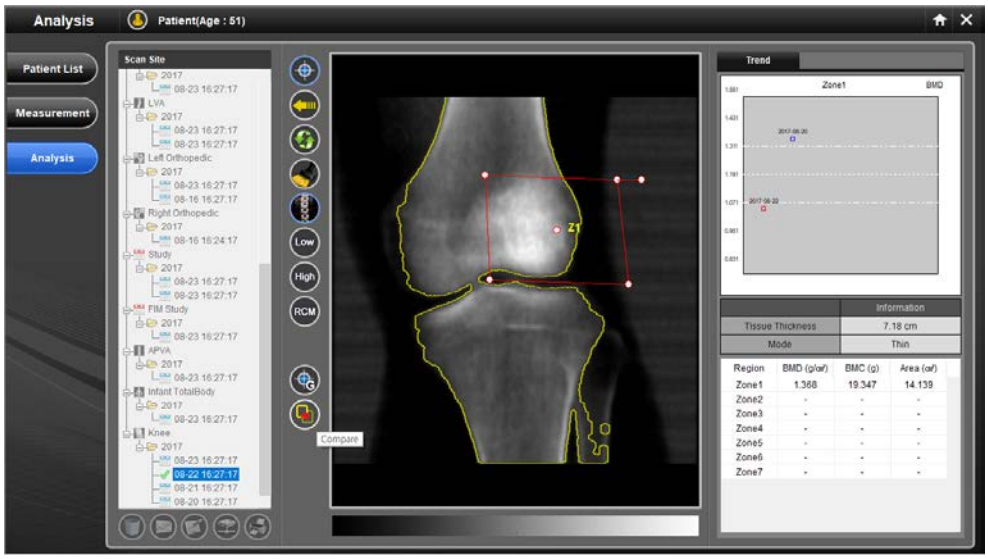
h. By dragging 4 points outside of ROI area, you can adjust size of ROI.



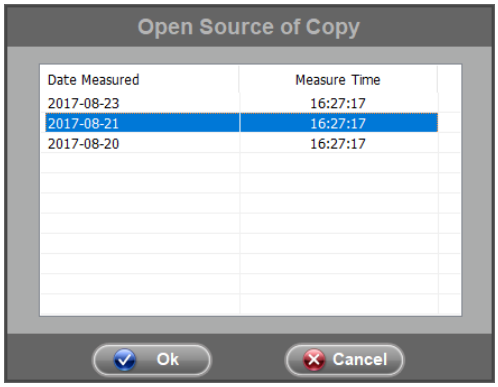
i. If you click "ROI Set" button, ROI is fixed and each of ROI parameter is created.



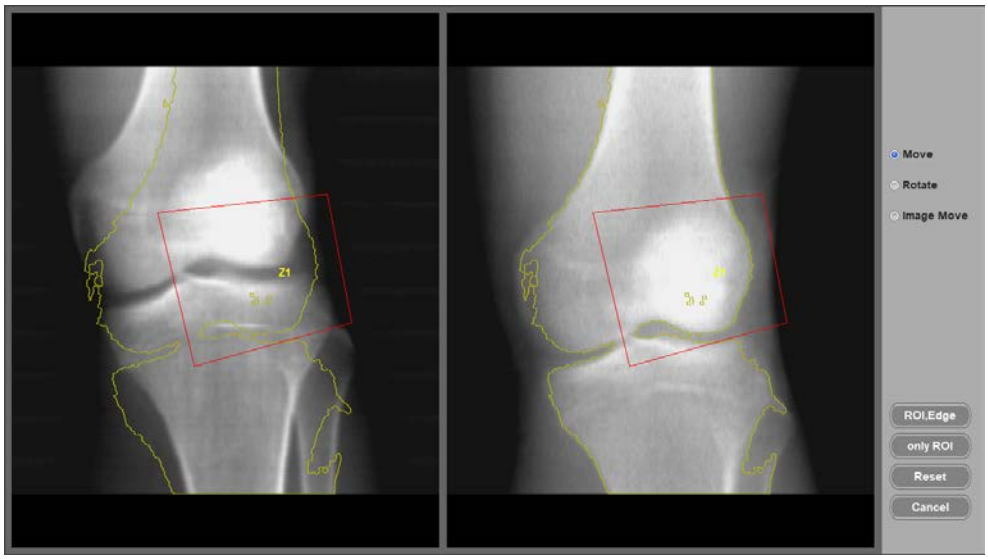
j. When you want to compare image with previous data or want ROI copy, you can select ROI Compare button.



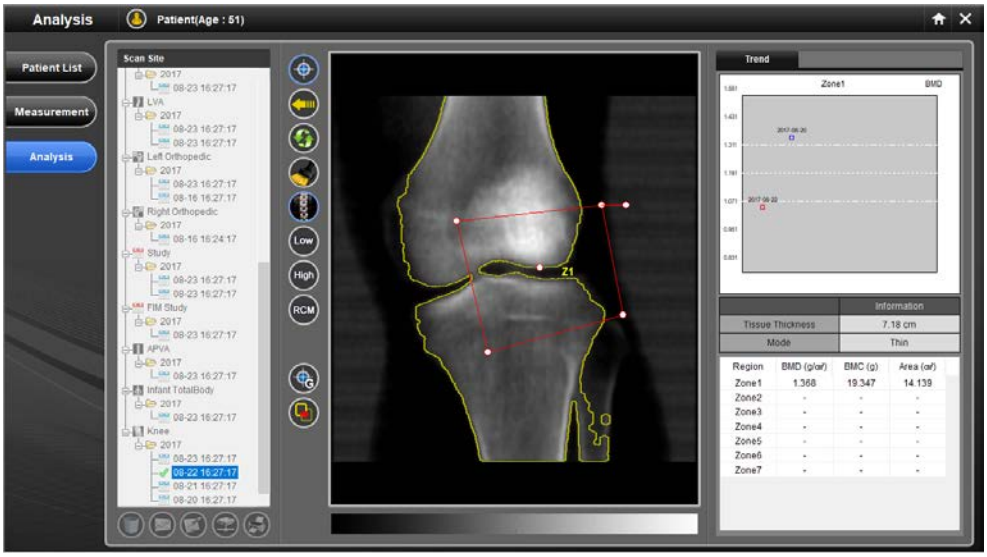
k. Select desired image for the comparision, and press"ok" button.



l. By copying selected image and image to be compared, it compares ROI at the same area.



i. Move : This is function to move ROI.
ii. Rotate : This is function of ROI rotation.
iii. Image Move : This is function of moving of ROI.
iv. ROI, Edge : ROI, Edge copy
v. Only ROI : Only copy of ROI.
vi. Reset : Move to initial ROI location.
vii. Cancel : Comparison, cancellation of copy.



m. Compares previous date by setting same ROI.

6.6.17 Image analysis (Orthopedics, Prosthesis Hip)

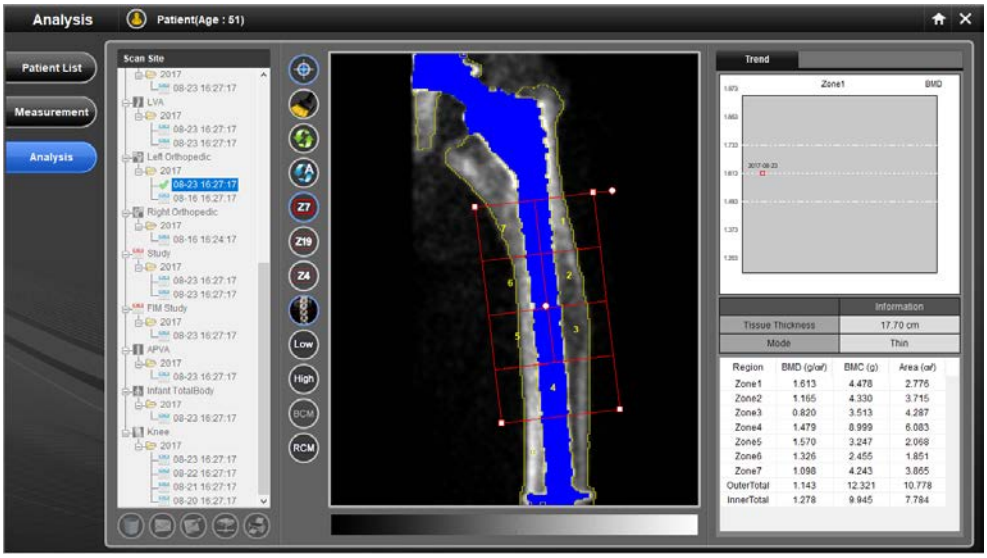
- Orthopedics and Prosthesis Hip function is used for the patient who has surgery of Femur with artificial bone in order to measure BMD and evaluate bone status.

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

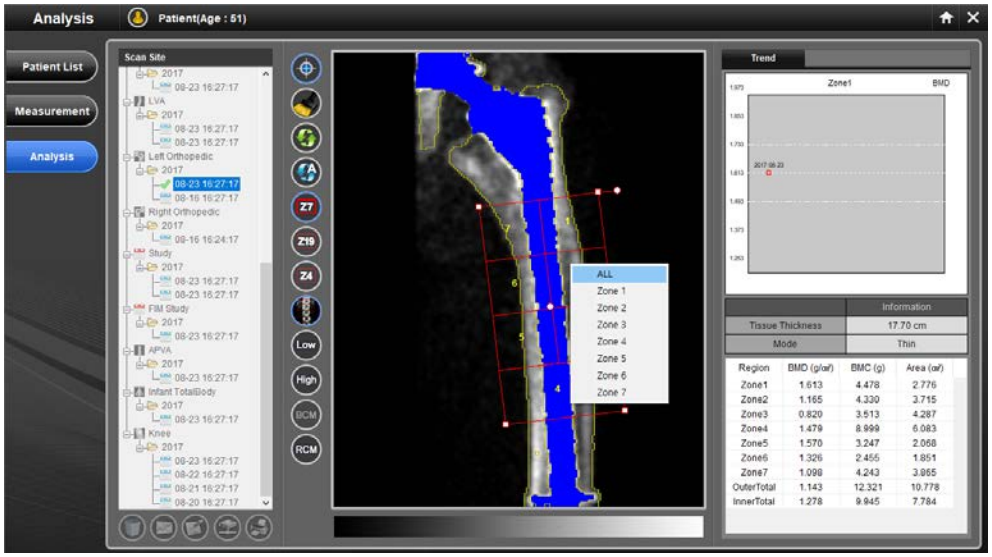
> For Prosthesis Hip analysis, we use 4 Zone ROI.

- Orthopedic analysis is composed of Standard Mode's7 zone and Extend Mode with 19 zone. We supply femoral Shaft BMD and its trend.

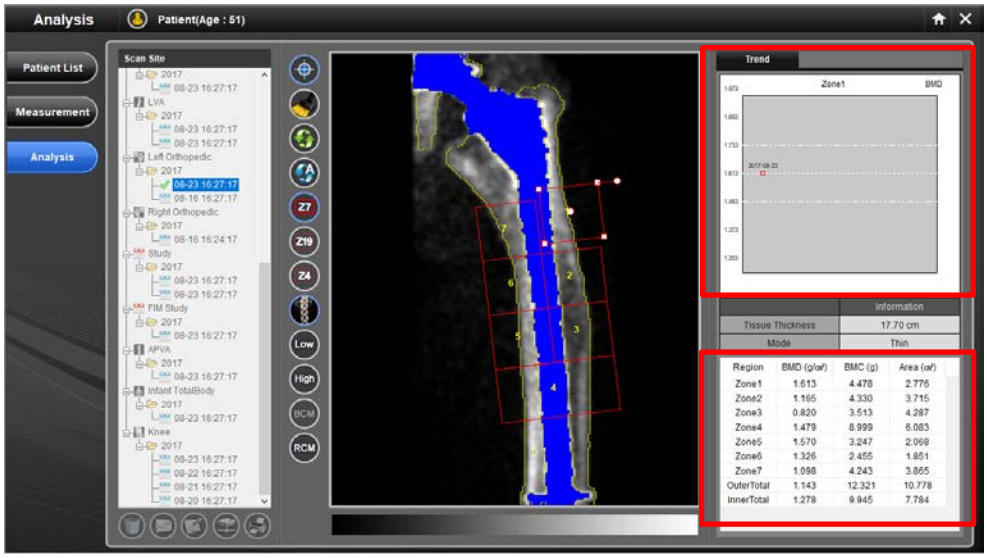
a. Click the image of patient on the left side of list.
b. When image is appeared, press ROI set button.
c. By dragging point in the middle of ROI, adjust overall ROI area.
d. By adjusting point outside the square, adjust tilt of ROI.



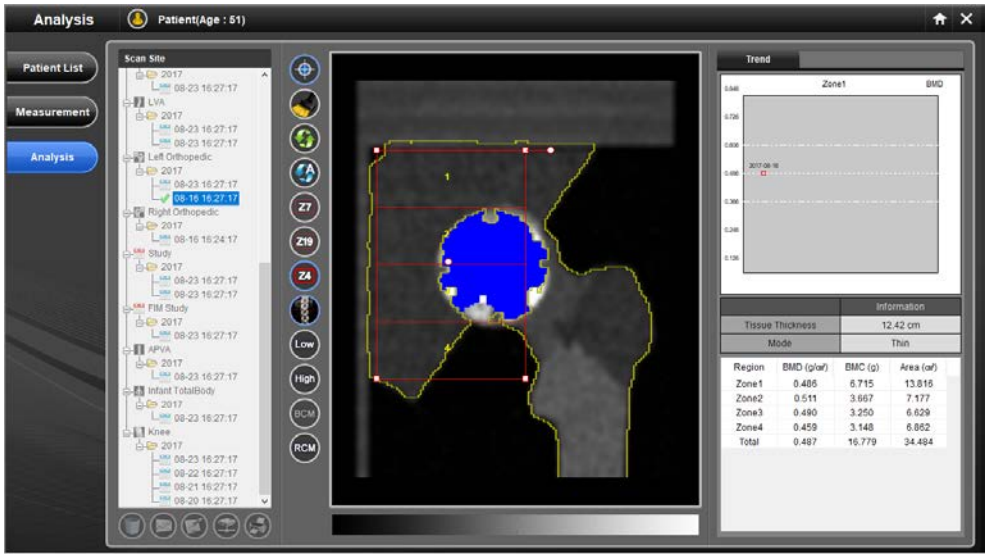
e. In the ROI area, there are total 4 points, you can click each of point and can adjust size.(when clicking right side of mouse, pop up screen appears and can select each of ROI)



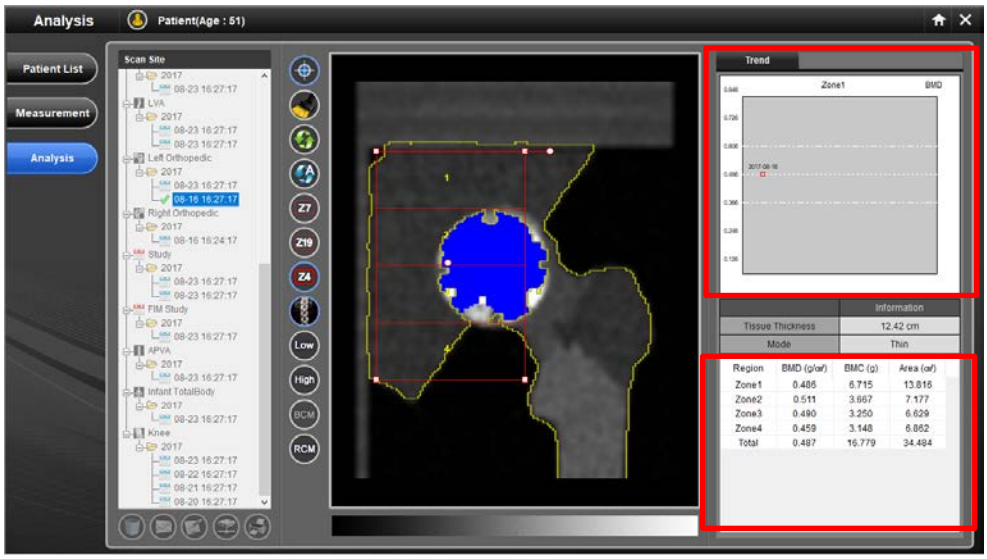
f. When clicking ROI set button, analysis result of ROI is displayed, if there is previous image, ROI trend is also displayed.



- Analysis of Prosthesis Hip is composed of 4 Zone, and it supplies BMD of Femur head and its trend
  a. For the analysis of femur head after the surgery, select Z4 with ROI activated.
  b. Based on Femur head as standard, set ROI and adjust it.
  c. By dragging pointer in the middle of ROI, adjust overall area of ROI.
  d. By adjusting pointer outside the square, adjust ROI tilt.
  e. There are total 4 points in the ROI area. By moving each of point you can adjust size.



  f. If you click ROI set button, result and analysis of ROI is displayed. If there is previous image, trend of each area is also displayed.



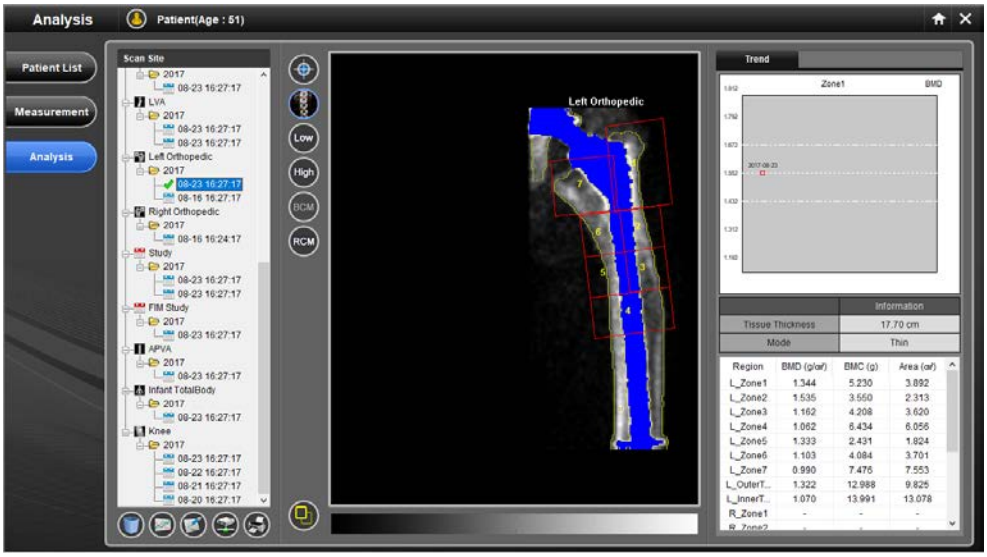
* Orthopedics and Prosthesis Hip is applied and used for tracing function of patient after the Implant surgery for the femur head.

* In case of patient, who did Implant surgery of Femoral head, it is requested to have frequent testing and BMD test in order to verify whether surgery is properly implemented or not.

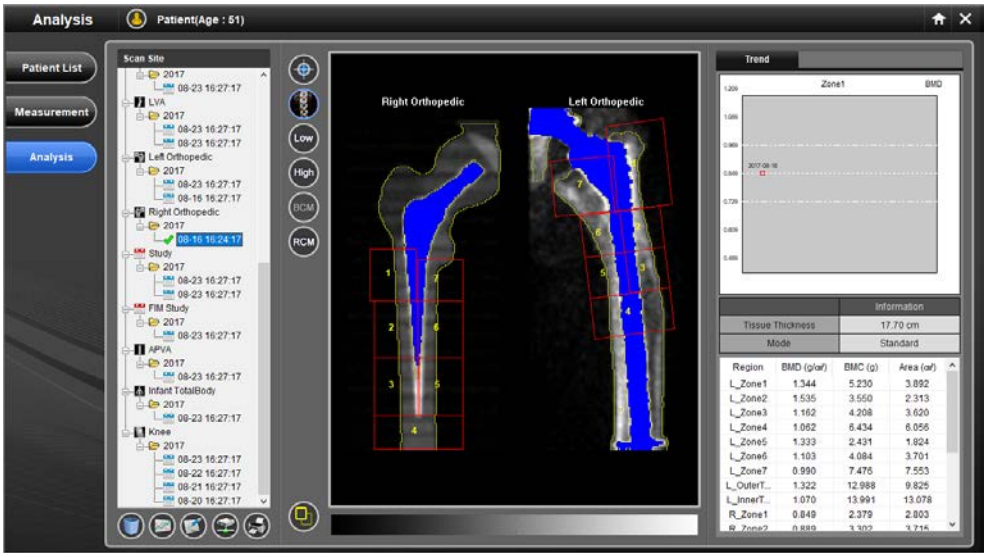
- It also offers Dual Orthopedics image analysis.

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.

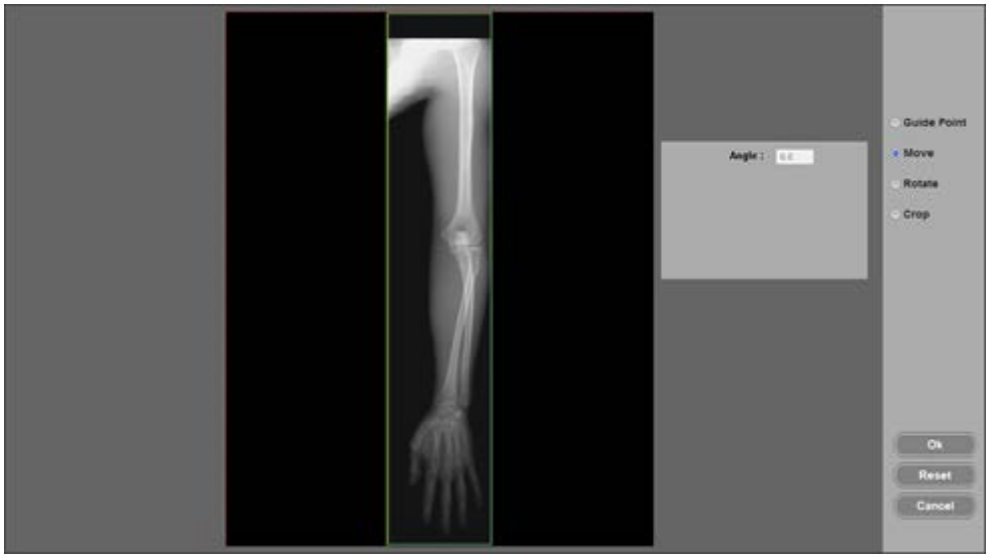


c. Please select the opposite Femur image on the list.



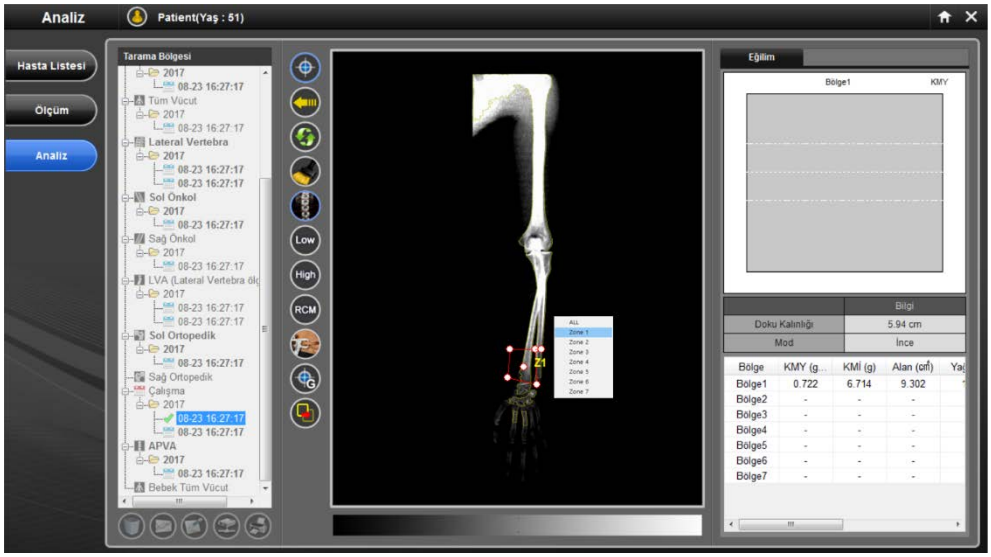
6.6.18 Image analysis (Study)

a. Please click the image on the list.
b. Please press 'ROI set' when the image appears.
c. In case that Global ROI is not set, it moves to screen of Global ROI set up.



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. After finishing the Global ROI setting, please click "Ok" button.
e. You can select the ROI when you click the right button of the mouse on the image area.



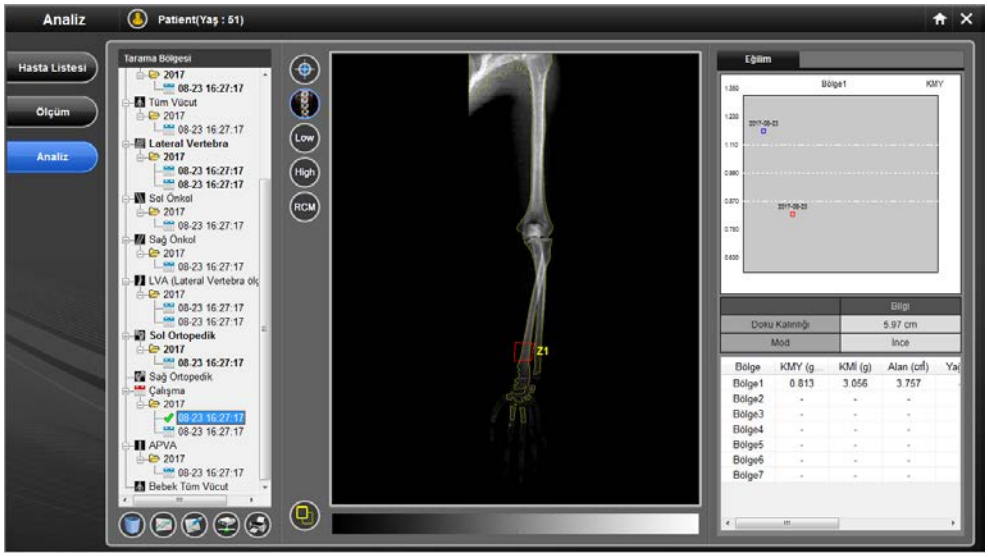
You can set the ROI with clicking left button of mouse in B-Scope mode.

f. Please drag the pointer in the middle to set the ROI that the operator wants to check.

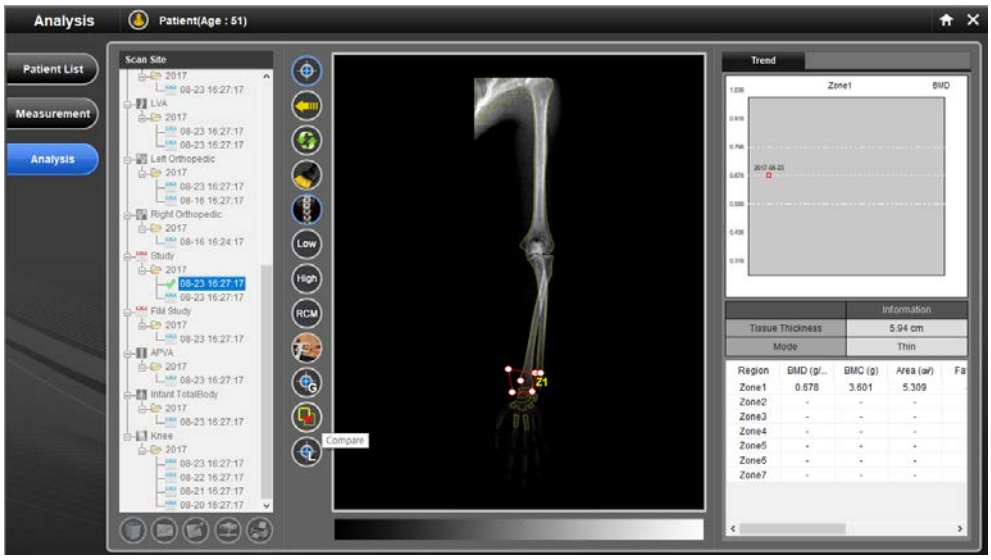
g. Please use the pointer outside the box to adjust an inclination.

h. Please drag the four pointers in ROI area to resize the ROI area.

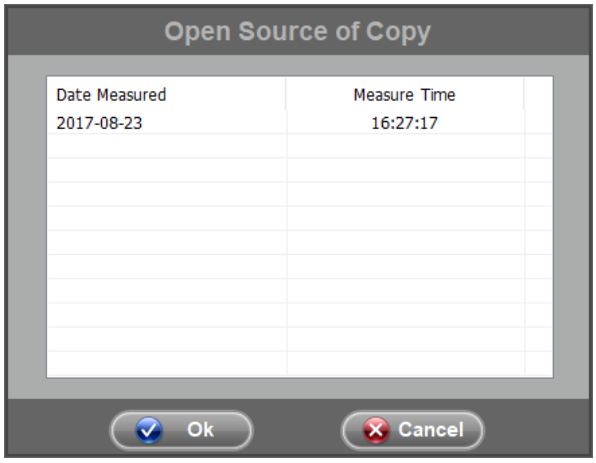
i. ROI will be fixed and shows the value if you click 'ROI Set' button.



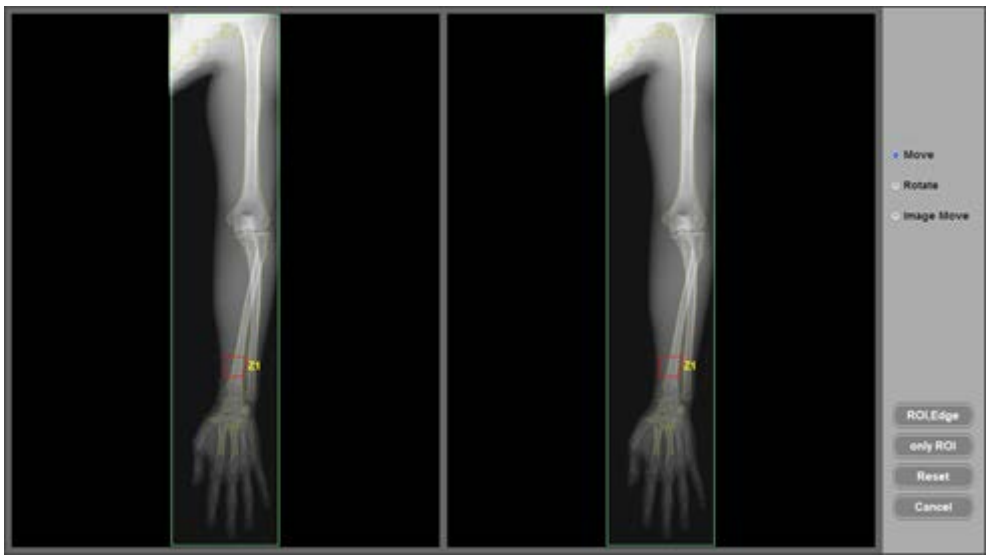
j. If you want to compare with the previous data or copy the ROI, please click 'ROI Compare' button.



k. Please click 'Ok' after selecting the previous data.



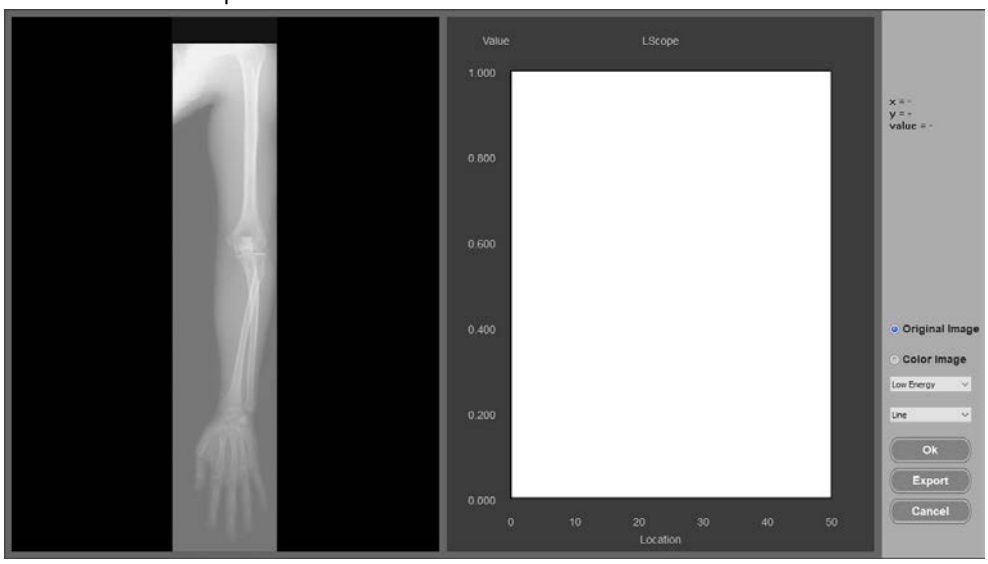
l. Please compare the ROI on the same area.



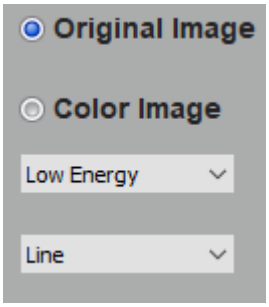
i. Move : It's a function to move ROI.
ii. Rotate : It's a function to rotate ROI.
iii. ROI, Edge : It copies ROI and Edge. (Copy the right image to left image)
iv. Only ROI : It copies only ROI
v. Reset : It resets the ROI to default position.
vi. Cancel : It cancels compare or copy

6.6.19 Image analysis (L-scope)

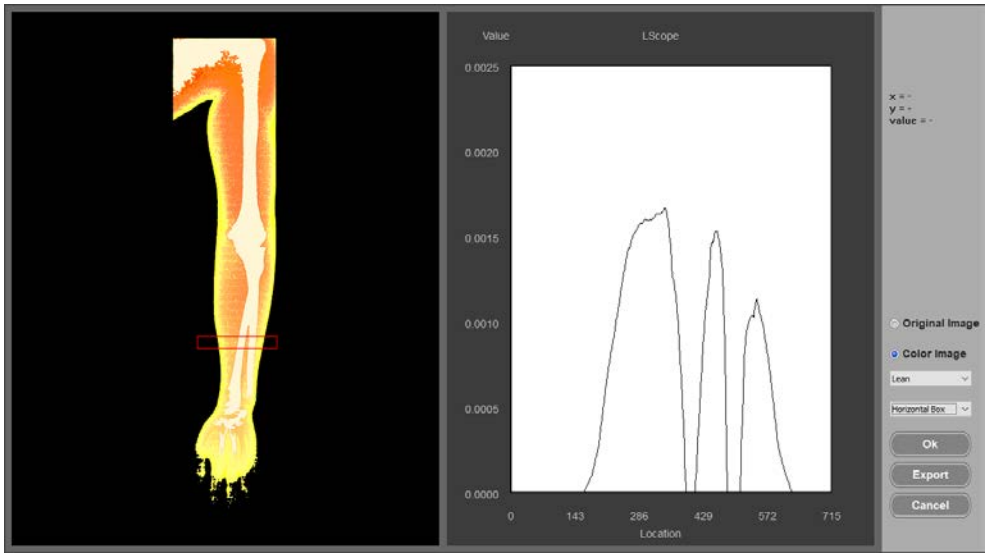
a. Please click the image on the list.
b. Please press 'ROI set' when the image appears.
c. Please click 'L-Scope' button in ROI edit mode.



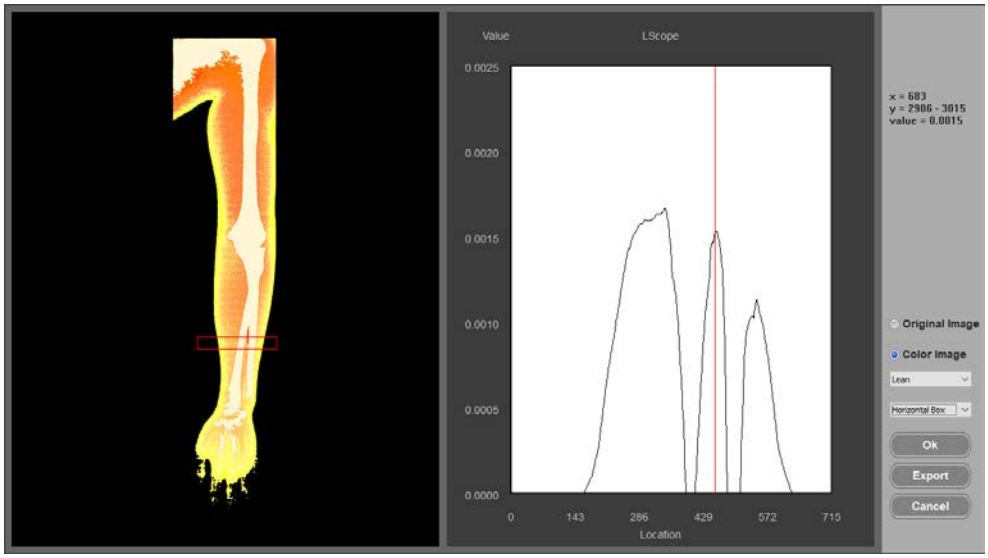
d. Please select the type of area and image that you want to analyze.



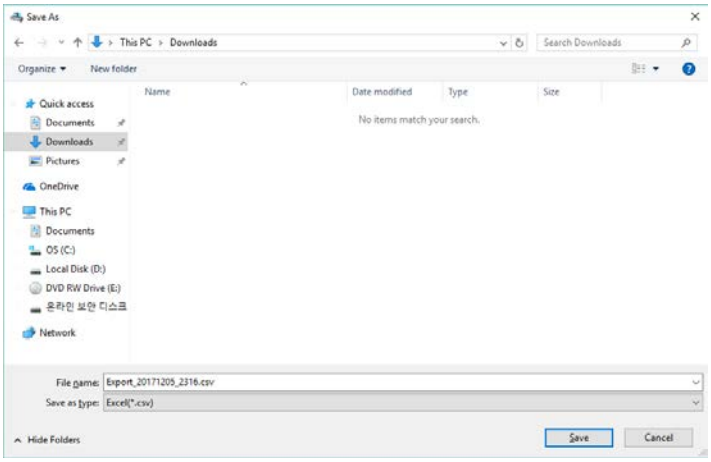
e. Please drag the left button of mouse on the area image to fix the area that you want to analyze.



f. You can check the value and coordinates moving mouse pointer on the right graph.



g. You can save this graph data with CSV file when you press 'Export' button.



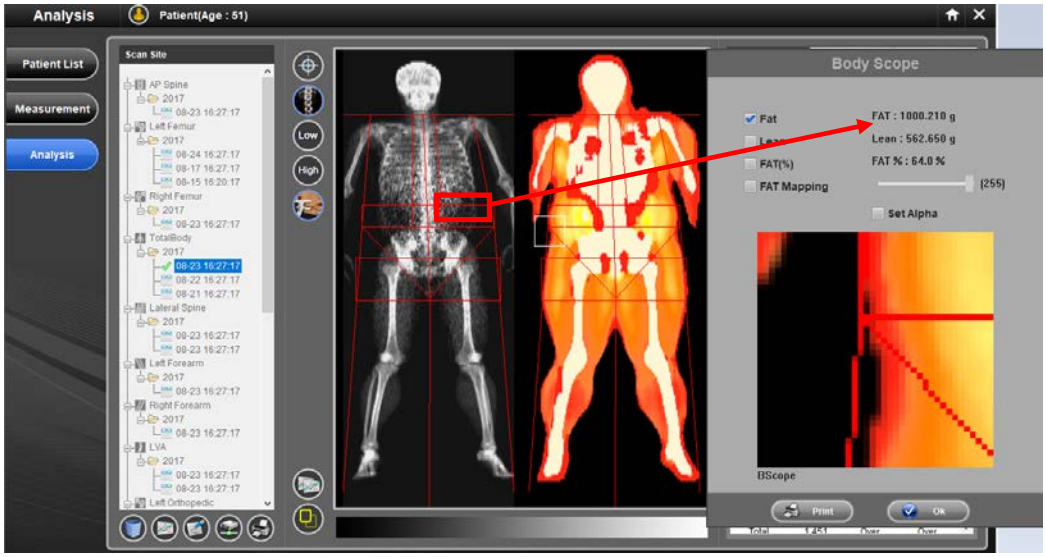
h. If you press 'OK' button, it will go back to the precious screen after saving all the data. And it will save all the analyzed image data when you press 'ROI set' after finishing ROI setting.

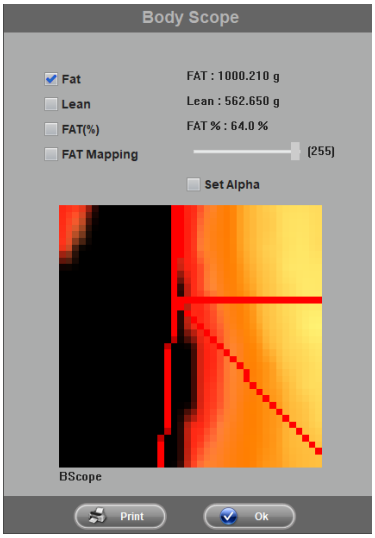
If you press 'Cancel' button, it will go back to the previous screen without saving anything.

6.6.20 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 analysis screen, Body Scope window appears.

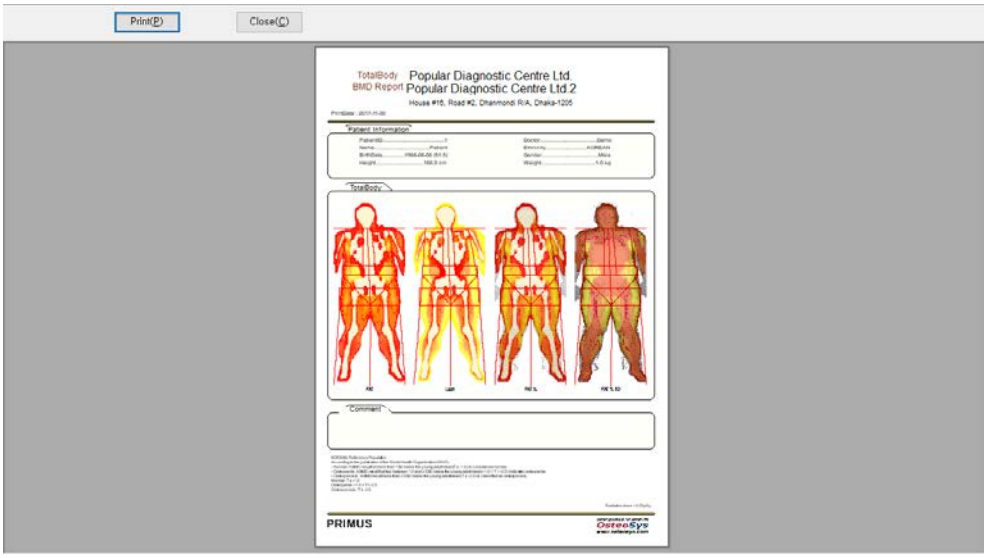




- FAT : Check the FAT(g) on the desired area.
- LEAN : Check the LEAN(g) on the desired area.
- FAT% : Check the FAT% on the desired area.
- Image box : It shows an image of the corresponding area.

- FAT Print : Print FAT information.
- Ok : Exit the window.

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

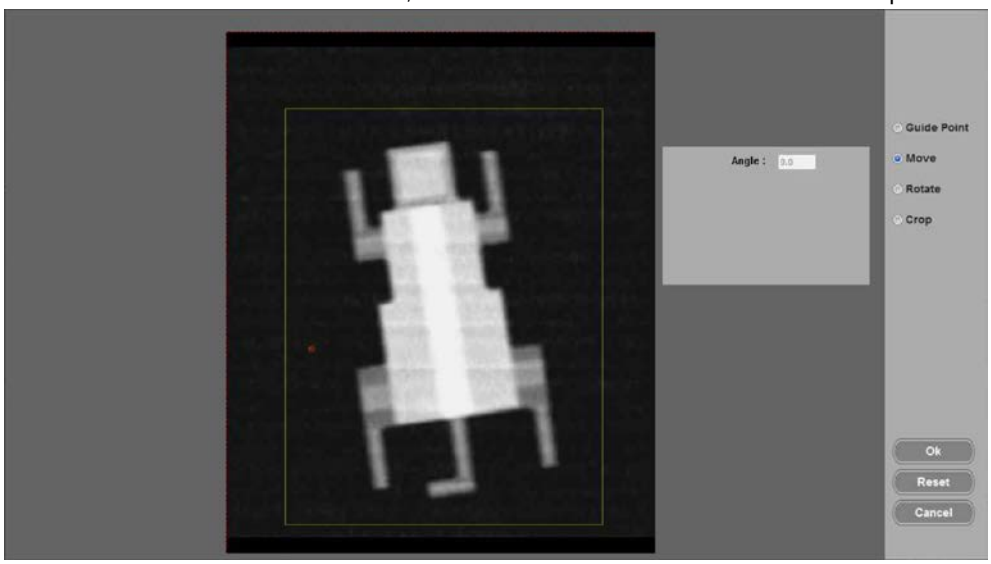


6.6.21 Image analysis (Animal Totalbody)

a. Please click the image on the list.

b. Please press 'ROI set' when the image appears.

c. In case that Global ROI is not set, it moves to screen of Global ROI set up.



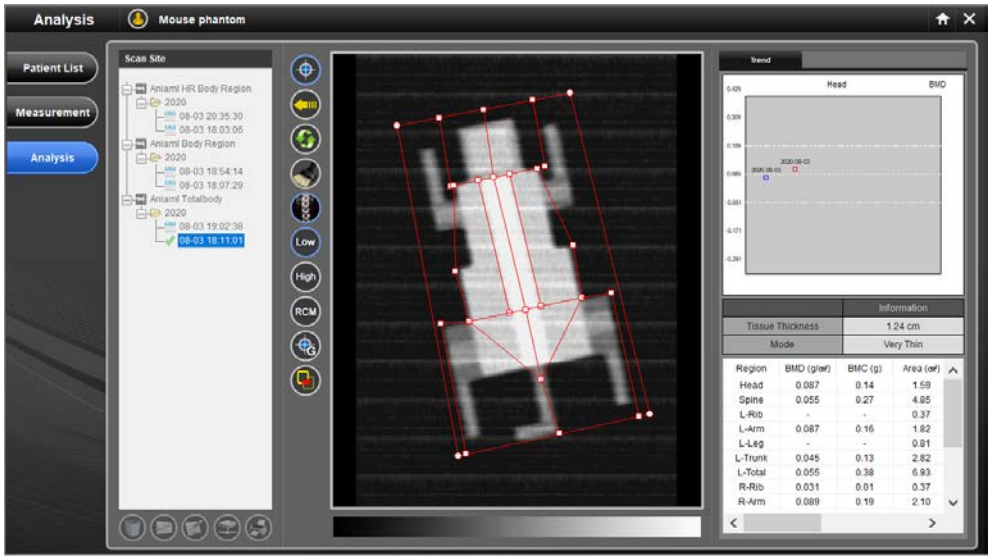
i. Guide Point : It's a function to set the Global ROI to the same area.

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.

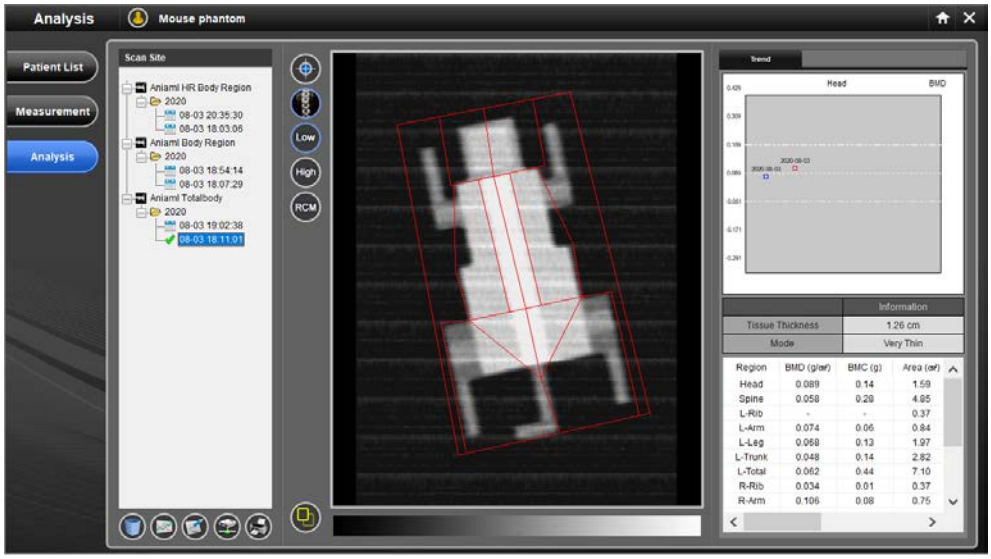
d. After finishing the Global ROI setting, please click "Ok" button.



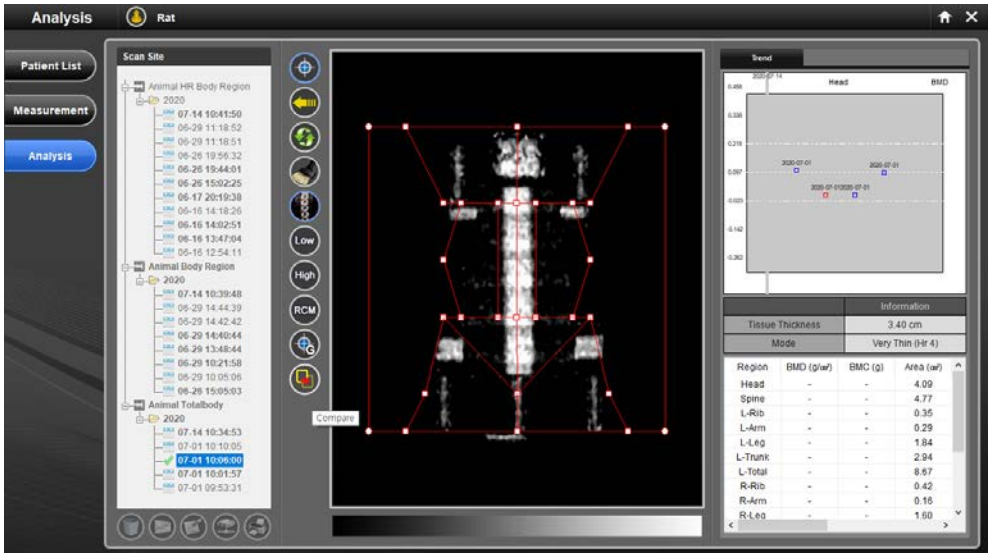
e. Please drag the box-shaped button to adjust the shape and size of each ROI. When changing ROI, ROI is adjusted according to the condition.

f. You can adjust so that each body part can be included in proper ROI. Place Head-Shoulder separator to the neck, which is above shoulder below chin. Rib-Shoulder seprartor separates arm and rib. The arms are only contained in Arm ROIS. Place Vertebra separator to have only vertebra. Side ROIs of vertebra separator has rib cage. Place waist marker to have only the waistm not the arm. Place Pelvis Top marker above the iliac crests. Pelvis Side markers make the pelvis edge crossed femoral necks. Place Leg ROIs to separate one leg.

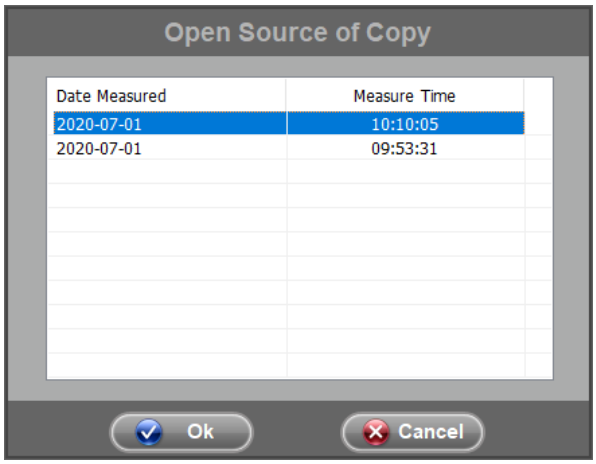
g. ROI will be fixed and shows the value if you click 'ROI Set' button.



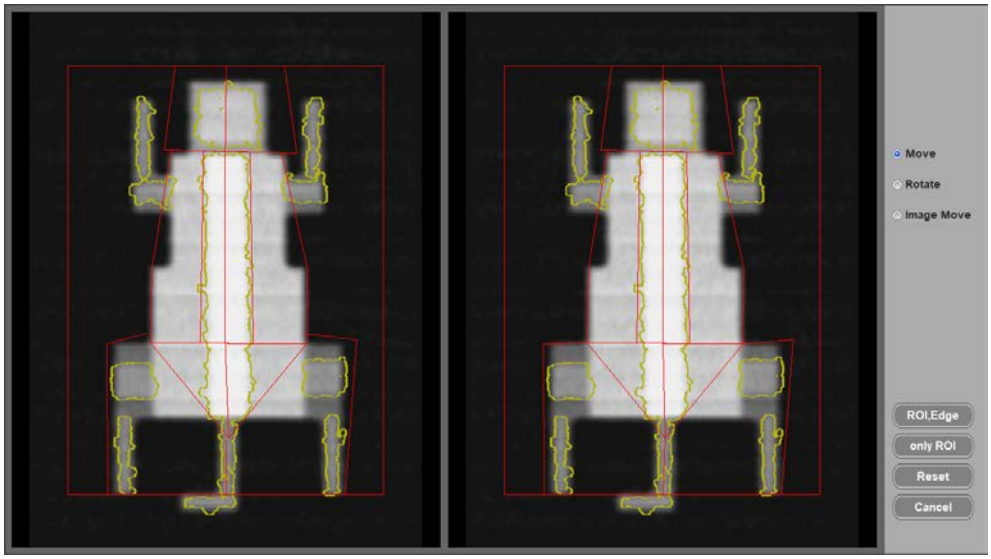
h. If you want to compare with the previous data or copy the ROI, please click 'ROI Compare' button.



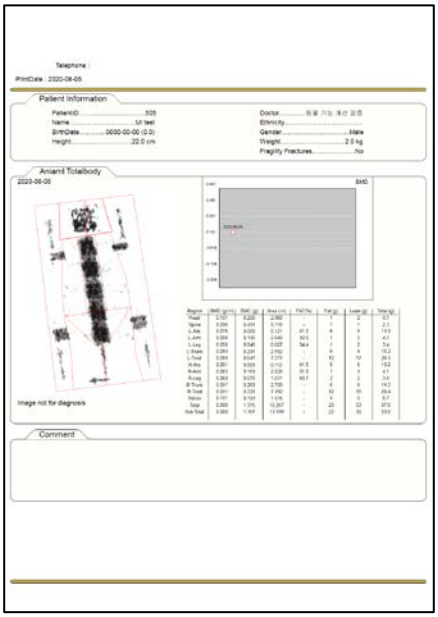
i. Please click 'Ok' after selecting the previous data.



j. Please compare the ROI on the same area.



i. Move : It's a function to move ROI.
ii. Rotate : It's a function to rotate ROI.
iii. ROI, Edge : It copies ROI and Edge. (Copy the right image to left image)
iv. Only ROI : It copies only ROI
v. Reset : It resets the ROI to default position.
vi. Cancel : It cancels compare or copy

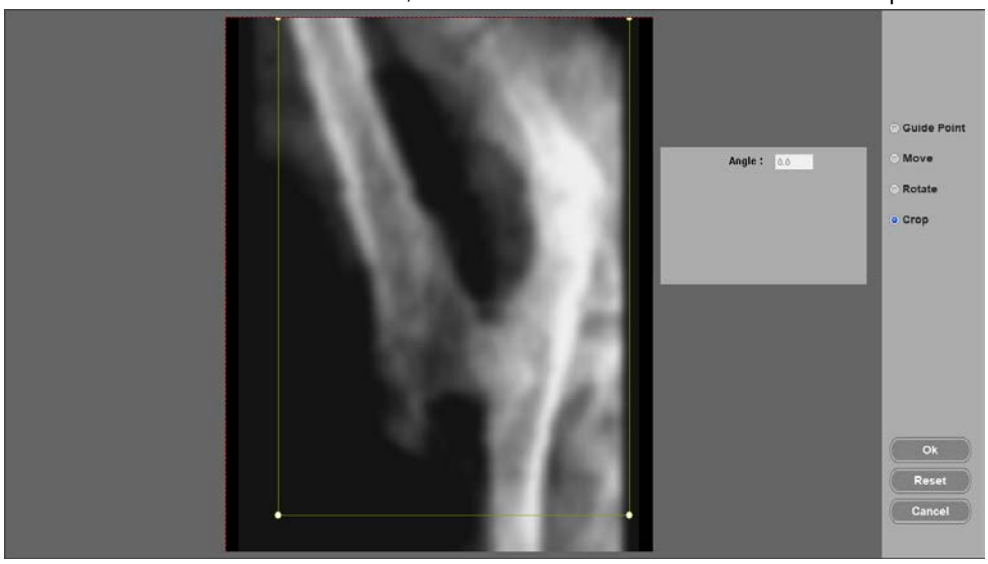


6.6.22 Image analysis (Animal Body Region / Animal HR Body Region)

a. Please click the image on the list.

b. Please press 'ROI set' when the image appears.

c. In case that Global ROI is not set, it moves to screen of Global ROI set up.



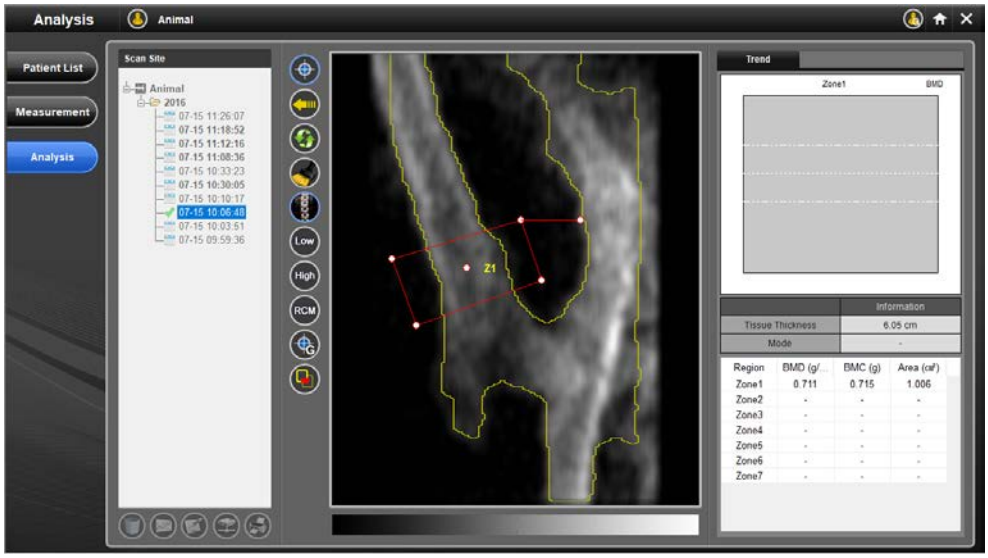
i. Guide Point : It's a function to set the Global ROI to the same area.

ii. Move : It's a function to move Global ROI.

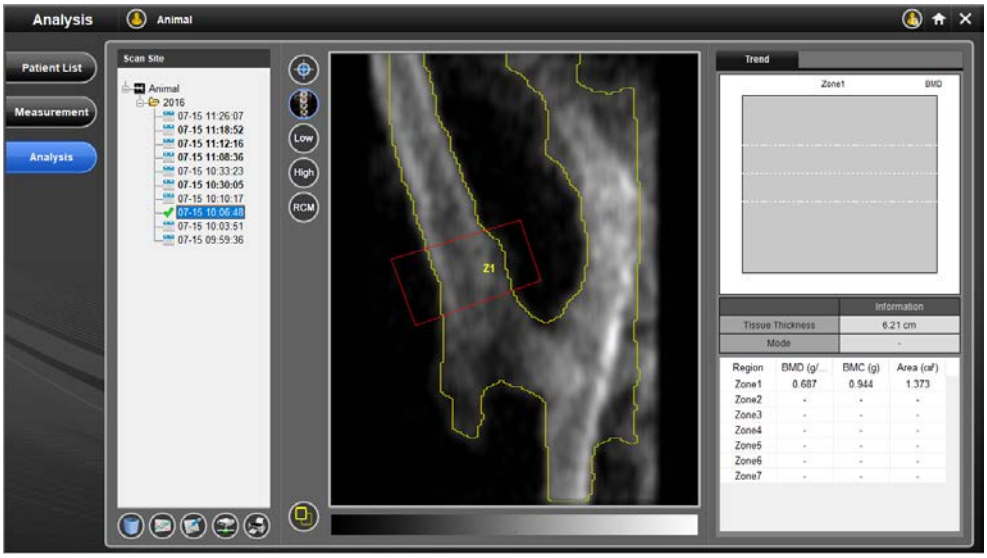
iii. Rotate : It's a function to rotate Global ROI when the image is tilted.

iv. Crop : It's a function to resize the Global ROI.

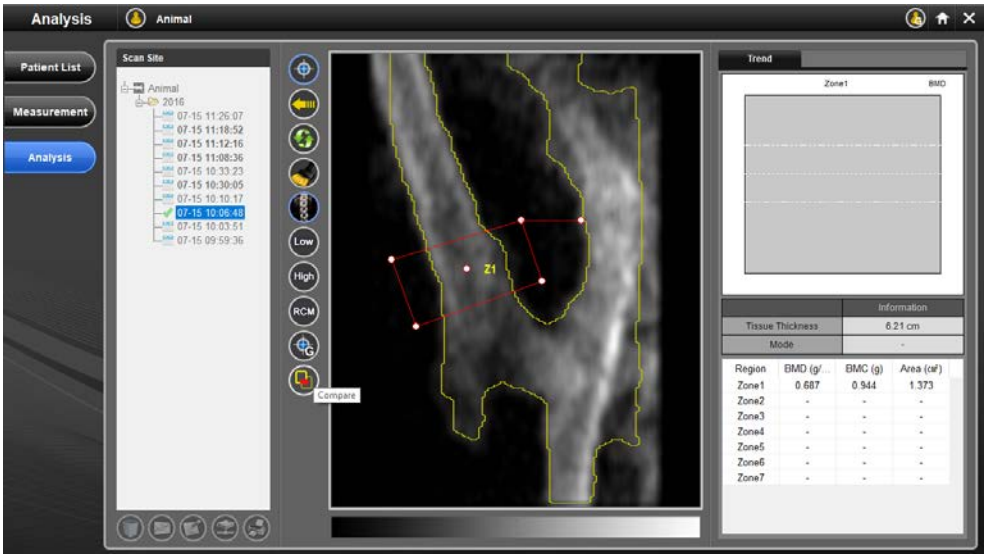
d. After finishing the Global ROI setting, please click "Ok" button.



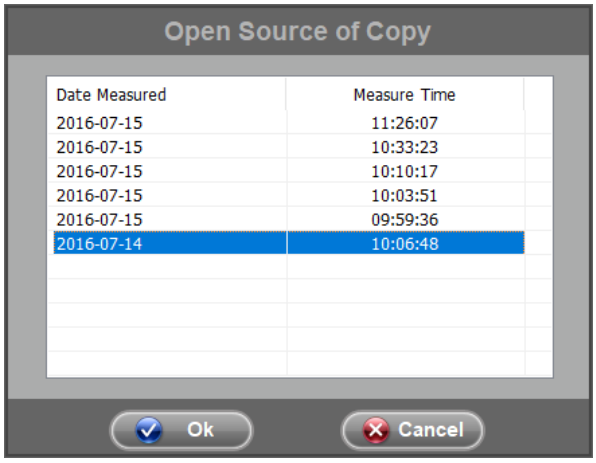
e. Please drag the pointer in the middle to set the ROI that the operator wants to check.
f. Please use the pointer outside the box to adjust an inclination.
g. Please drag the four pointers in ROI area to resize the ROI area.
h. ROI will be fixed and shows the value if you click 'ROI Set' button.



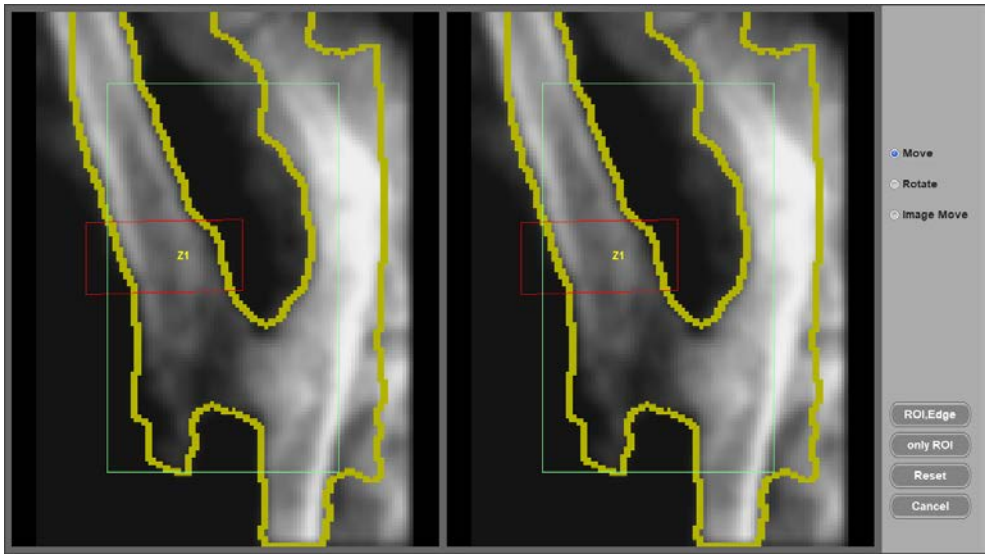
i. If you want to compare with the previous data or copy the ROI, please click 'ROI Compare' button.



j. Please click 'Ok' after selecting the previous data.



k. Please compare the ROI on the same area.



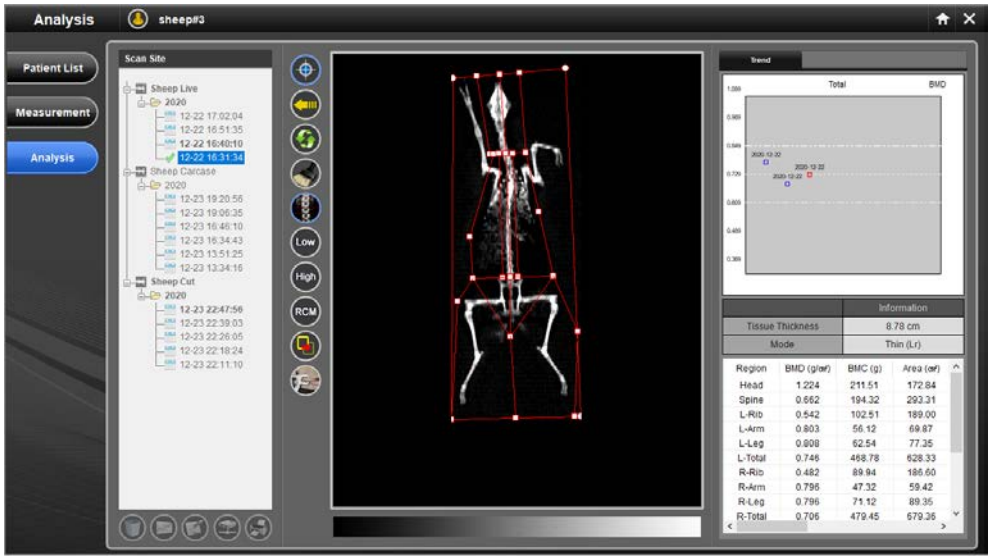
i. Move : It's a function to move ROI.
ii. Rotate : It's a function to rotate ROI.
iii. ROI, Edge : It copies ROI and Edge. (Copy the right image to left image)
iv. Only ROI : It copies only ROI
v. Reset : It resets the ROI to default position.
vi. Cancel : It cancels compare or copy


Print(P)
Close(C)
Report
Patient Information
PRIMUS

6.6.23 Image analysis (Sheep Live / Sheep Carcase)

a. Please click the image on the list.

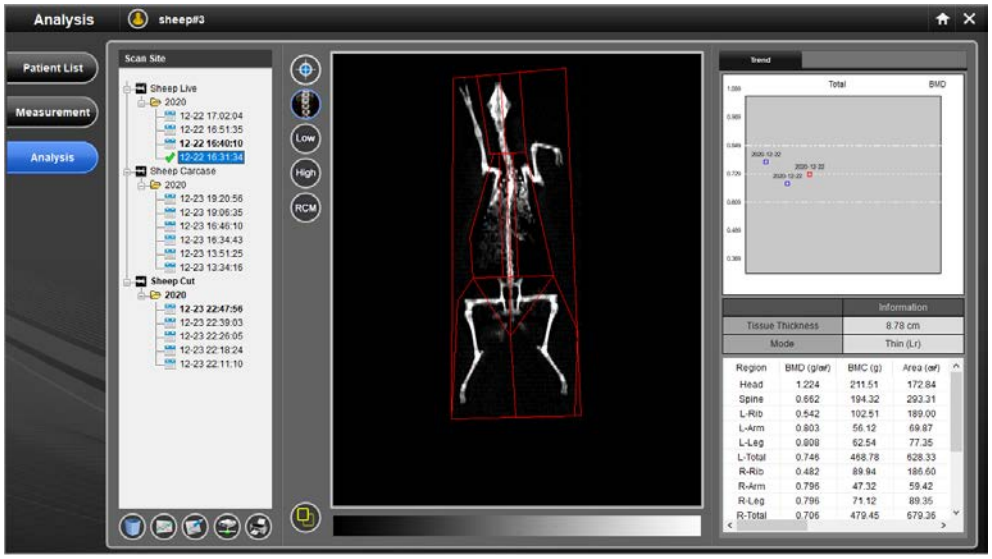
b. Please press 'ROI set' when the image appears.



c. Please drag the box-shaped button to adjust the shape and size of each ROI. When changing ROI, ROI is adjusted according to the condition.

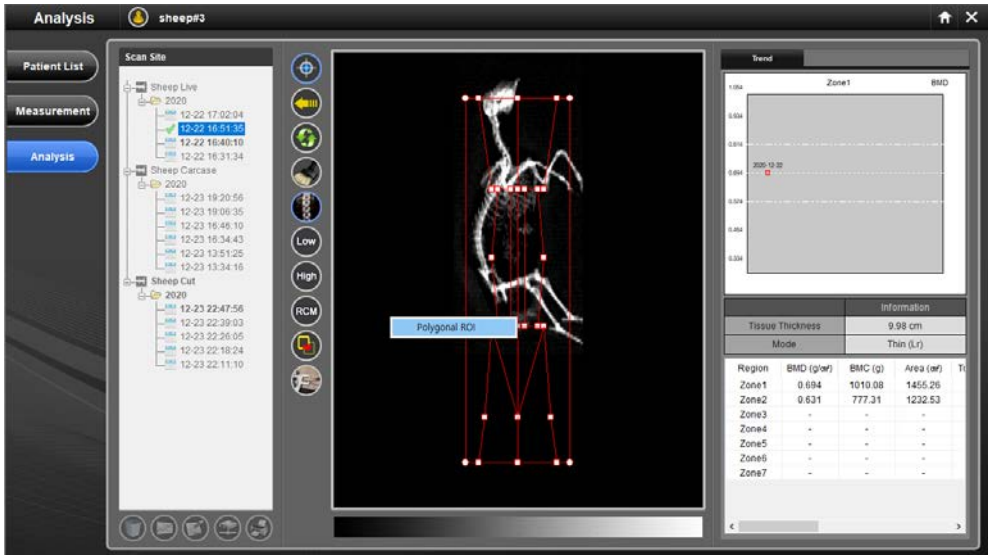
d. You can adjust so that each body part can be included in proper ROI. Place Head-Shoulder separator to the neck, which is above shoulder below chin. Rib-Shoulder seprartor separates arm and rib. The arms are only contained in Arm ROIS. Place Vertebra separator to have only vertebra. Side ROIs of vertebra separator has rib cage. Place waist marker to have only the waistm not the arm. Place Pelvis Top marker above the iliac crests. Pelvis Side markers make the pelvis edge crossed femoral necks. Place Leg ROIs to separate one leg.

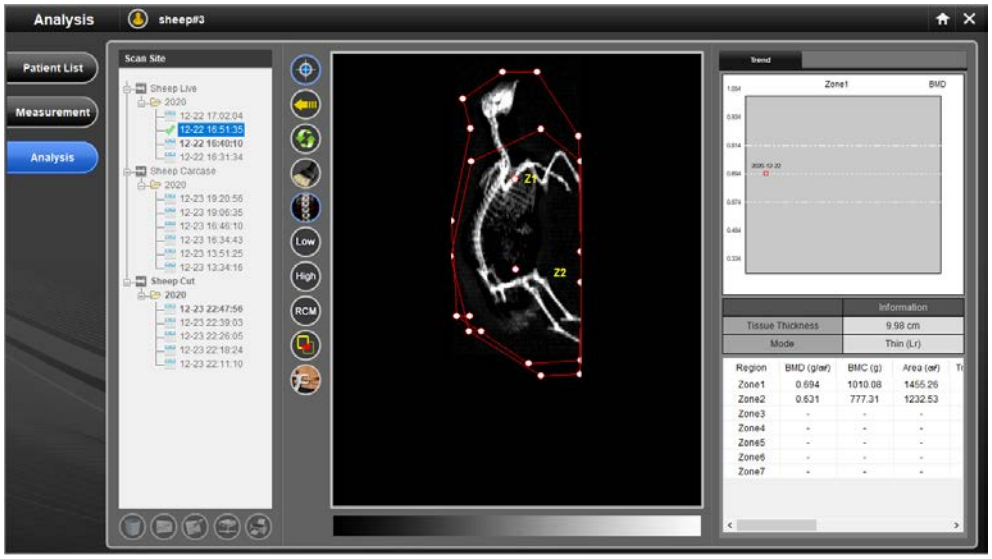
e. ROI will be fixed and shows the value if you click 'ROI Set' button.



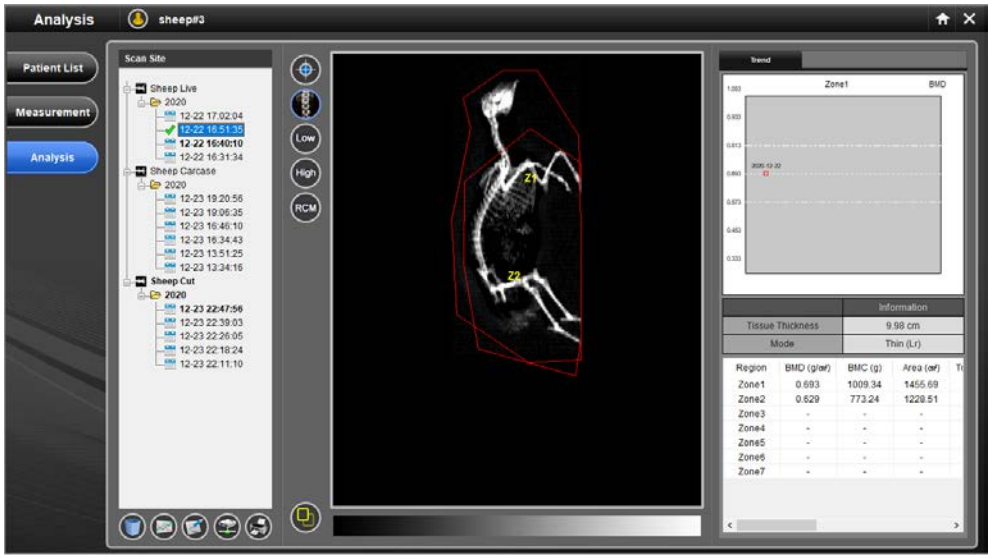
f. In case of the pose of sheep is both prone and side, You can choose polygonal ROI type.

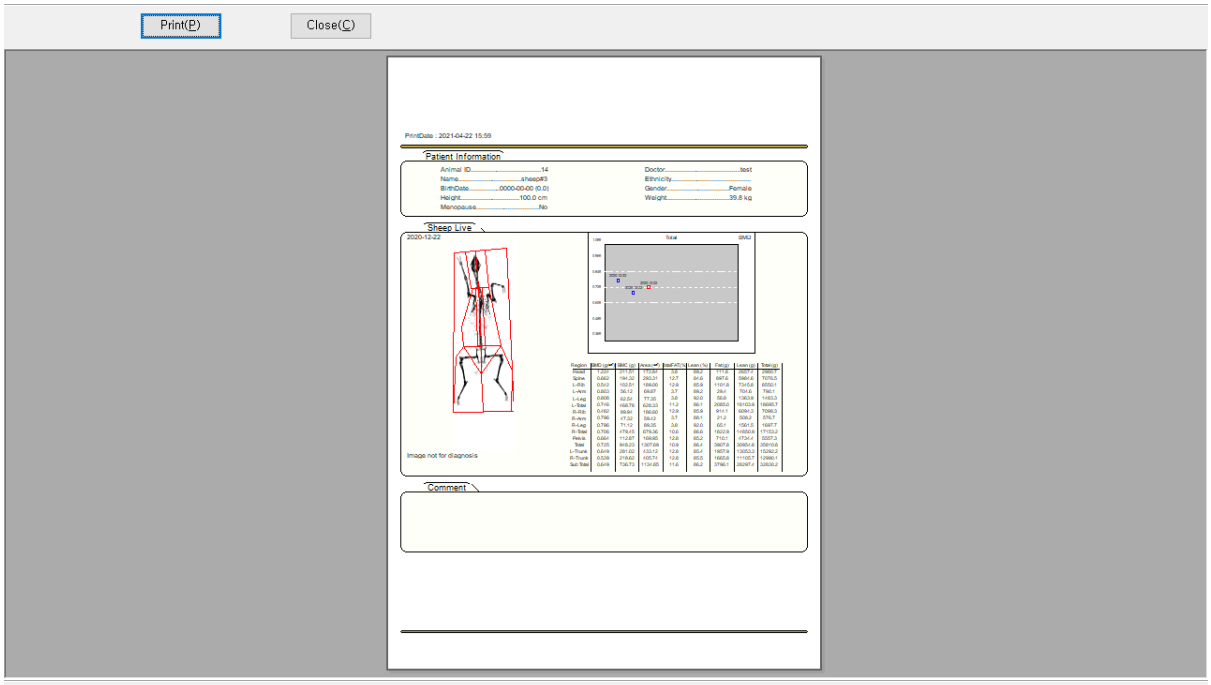
g. If you want to choose Polygonal ROI type, please right click button on the image. Then select "Polygonal ROI".

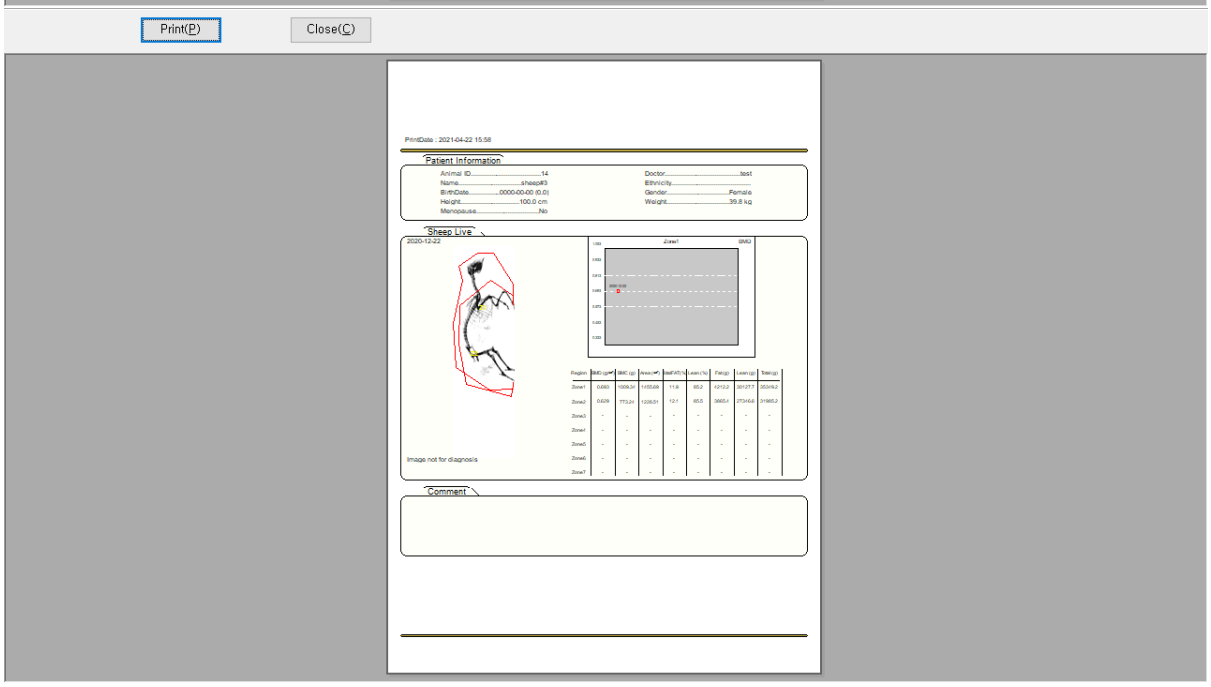




h. Click "Draw Polygonal ROI" button and click consecutively on the image where you want to analyze to create a polygonal ROI. Once you have complated the ROI, click "Draw Polygonal ROI" button again. Finally adjust the ROI with your mouse and click "ROI Button" again to fix the ROI and calculate a value for each ROI.




Print(P)
Close(C)
PrintDate : 2021-04-22 15:59
Patient Information
Sheep Live
Image not for diagnosis
Comment

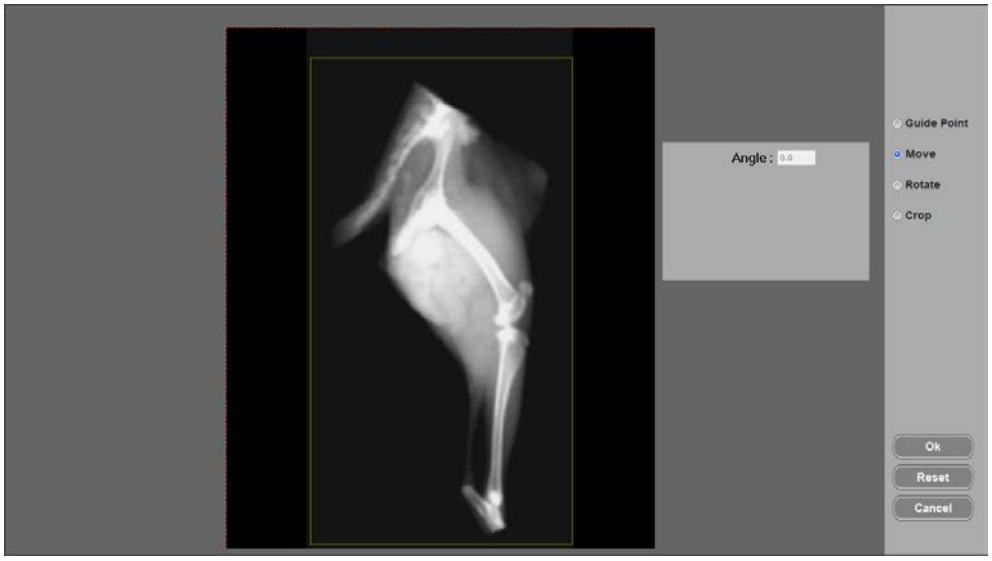

Print(P)
Close(C)
PrintDate : 2021-04-22 15:58
Patient Information
Sheep Live
Image not for diagnosis
Comment

6.6.24 Image analysis (Sheep Cut)

a. Please click the image on the list.

b. Please press 'ROI set' when the image appears.

c. In case that Global ROI is not set, it moves to screen of Global ROI set up.



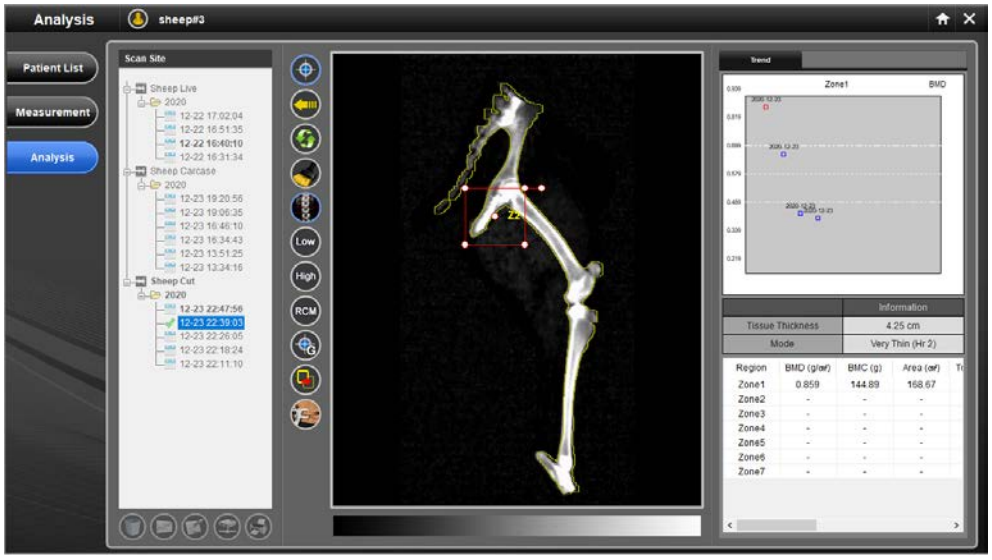
i. Guide Point : It's a function to set the Global ROI to the same area.

ii. Move : It's a function to move Global ROI.

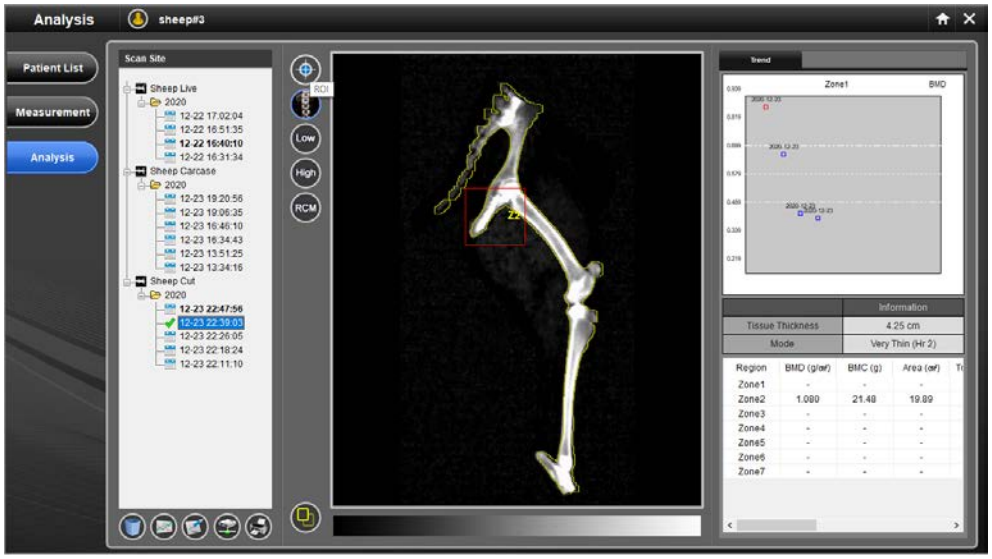
iii. Rotate : It's a function to rotate Global ROI when the image is tilted.

iv. Crop : It's a function to resize the Global ROI.

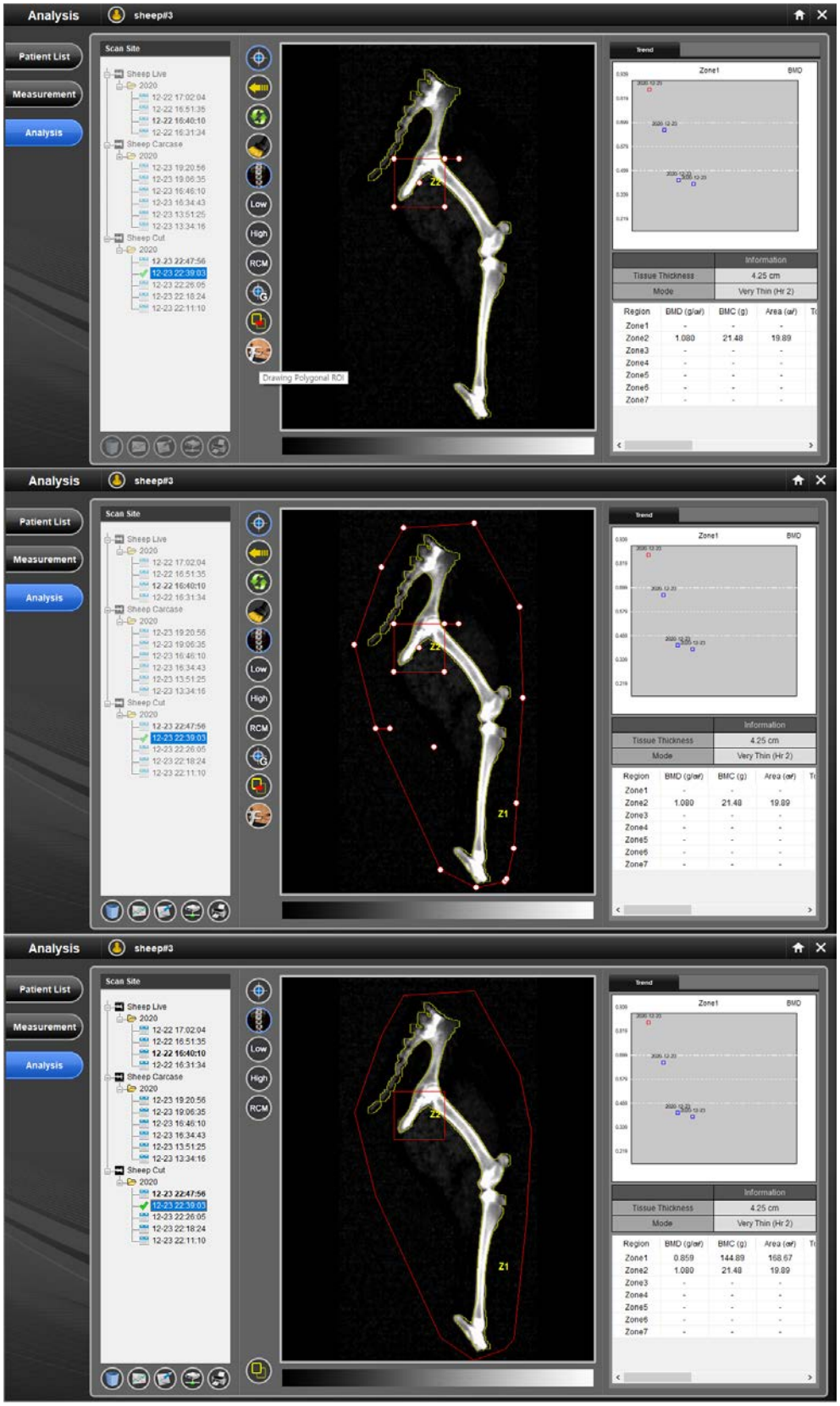
d. After finishing the Global ROI setting, please click "Ok" button.

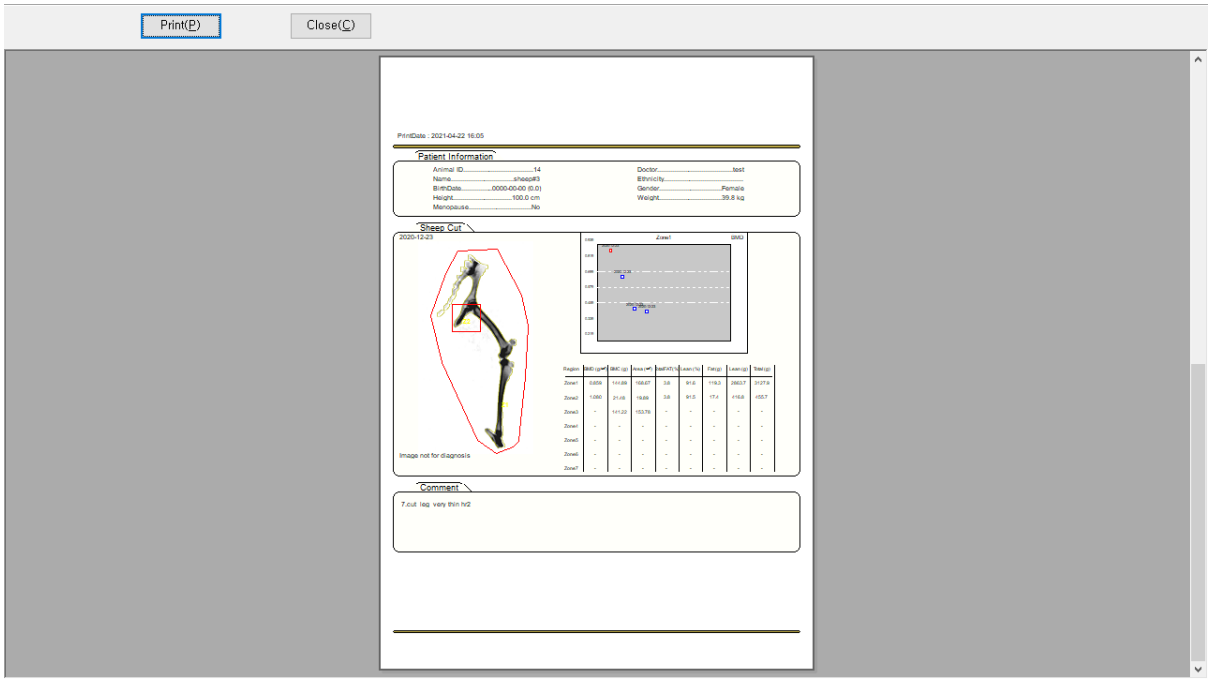


e. Please drag the pointer in the middle to set the ROI that the operator wants to check.
f. Please use the pointer outside the box to adjust an inclination.
g. Please drag the four pointers in ROI area to resize the ROI area.
h. ROI will be fixed and shows the value if you click 'ROI Set' button.



i. You can choose polygonal ROI type.
j. If you want to choose Polygonal ROI type, Click "Draw Polygonal ROI" button and click consecutively on the image where you want to analyze to create a polygonal ROI. Once you have complated the ROI, click "Draw Polygonal ROI" button again. Finally adjust the ROI with your mouse and click "ROI Button" again to fix the ROI and calculate a value for each ROI.

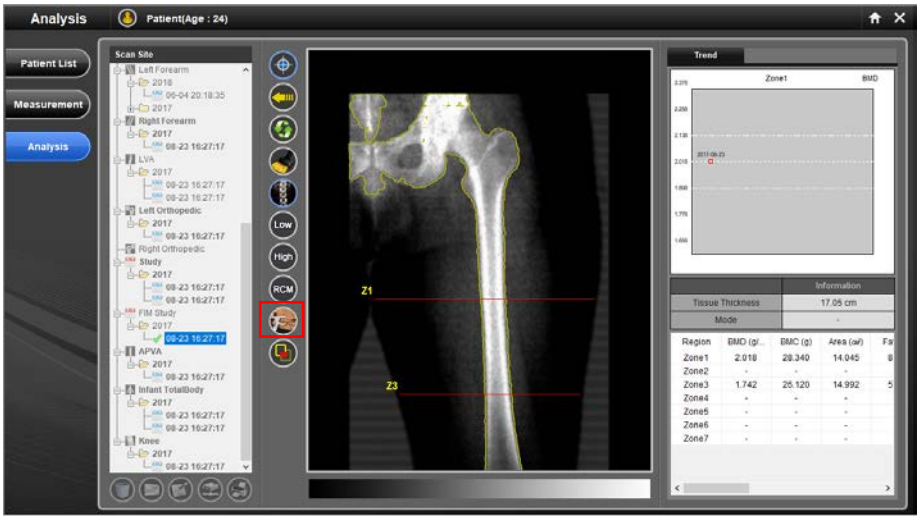

Analysis
sheep#3
Patient List
Measurement
Analysis
Scan Site
Sheep Live
Sheep Carcase
Sheep Cut
Low
High
RCM
Drawing Polygonal ROI
Trend
Zone1
BMD
Information
Tissue Thickness
4.25 cm
Mode
Very Thin (Hr 2)
Region
BMD (g/㎠)
BMC (g)
Area (㎠)
Zone1
Zone2
1.080
21.48
19.89
Zone3
Zone4
Zone5
Zone6
Zone7
Z1
Z2


Print(P)
Close(C)
PrintDate : 2021-04-22 16:05
Patient Information
Sheep Cut
2020-12-23
Image not for diagnosis
Comment

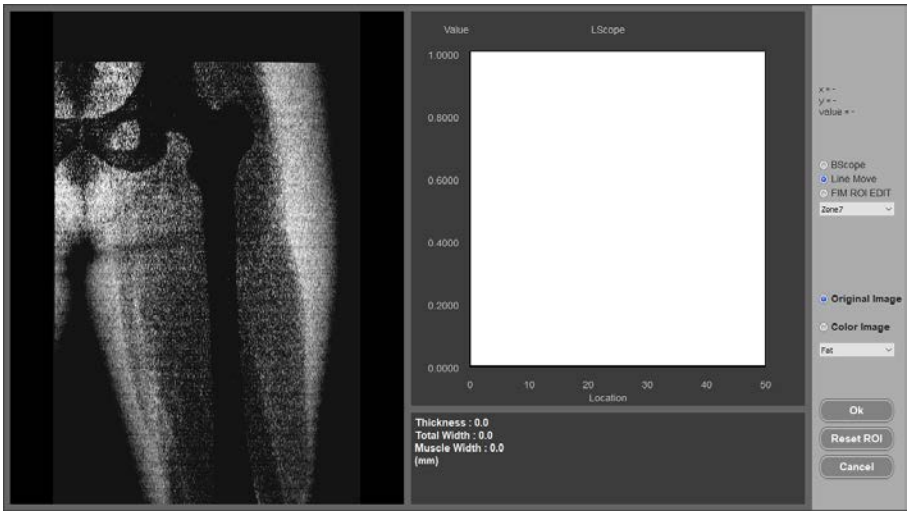
6.6.25 Image analysis (FIM Study)

- It analyzes FIM Study image of patient after measurement.

a. Click "FIM Study" image which was measured.
b. When you find the image, press ROI set button.

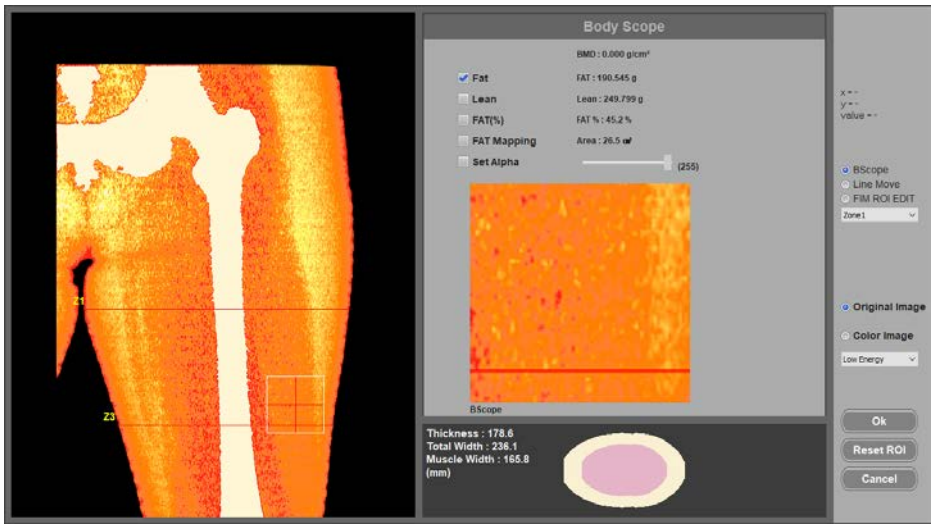


c. Press  button to go to the FIM Study Analysis screen.



i. BScope : This shows the FAT, LEAN, FAT% of the patient visually. Please refer to "Body Scope" for details.
ii. Line Move : Move the line to ROI. You can use Line Scope analysis on the right graph. Please refer to "Line Scope" for details.
iii. FIM ROI EDIT : It is a function to adjust the muscles in subcutaneous fat.
iv. Zone : Select the zone of interest from zone 1 to zone 7.
v. Image Mode : Please select the type of image that you want to analyze.

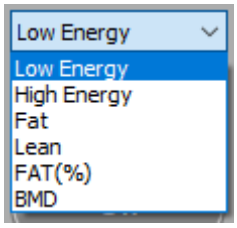
d. BScope Bscope analyzes the FAT, LEAN, FAT% of the patient quantitatively and visually. You select the area of interest.



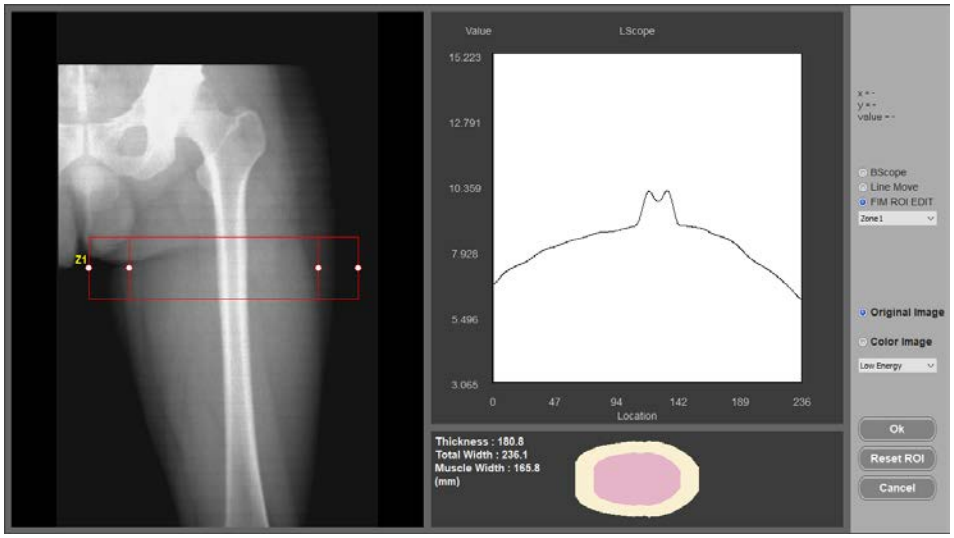
e. The Line Move moves the specified ROI vertically. Move the ROI position while viewing the right LScope.

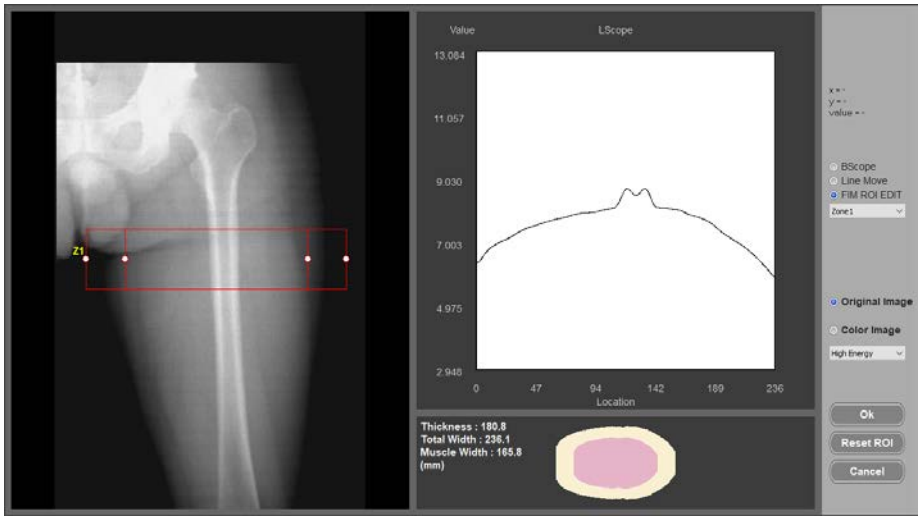
f. FIM ROI EDIT specifies the ROI of the subcutaneous and muscular layers. Look at the bottom image and analyze the thickness, overall width, and width of the muscle layer visually and quantitatively.

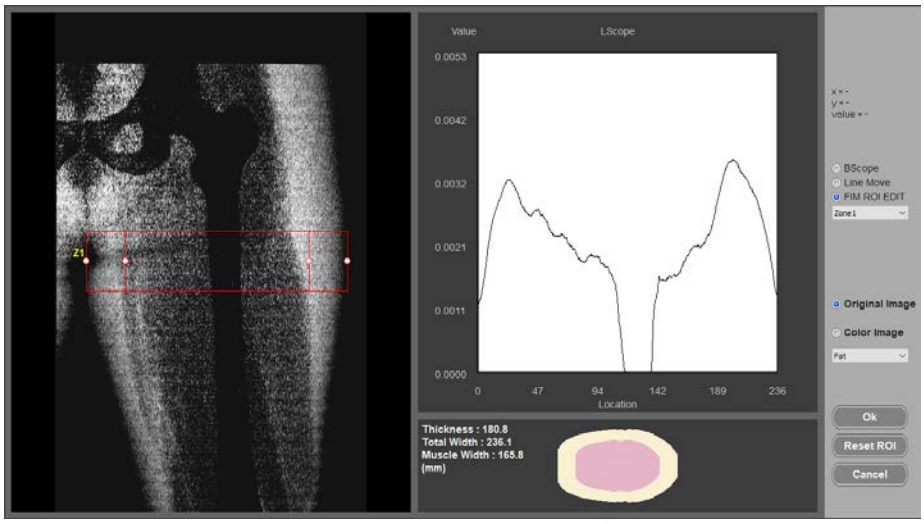
g. Perform analysis while changing image mode and image.

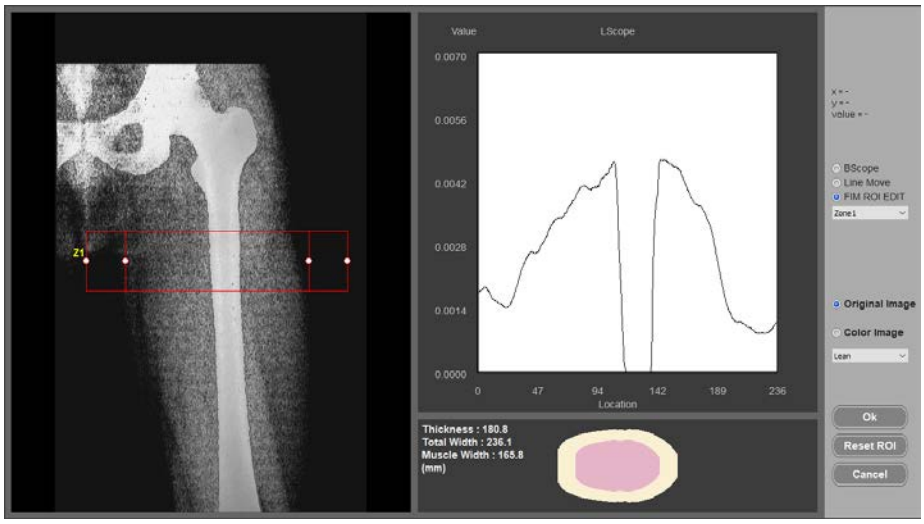


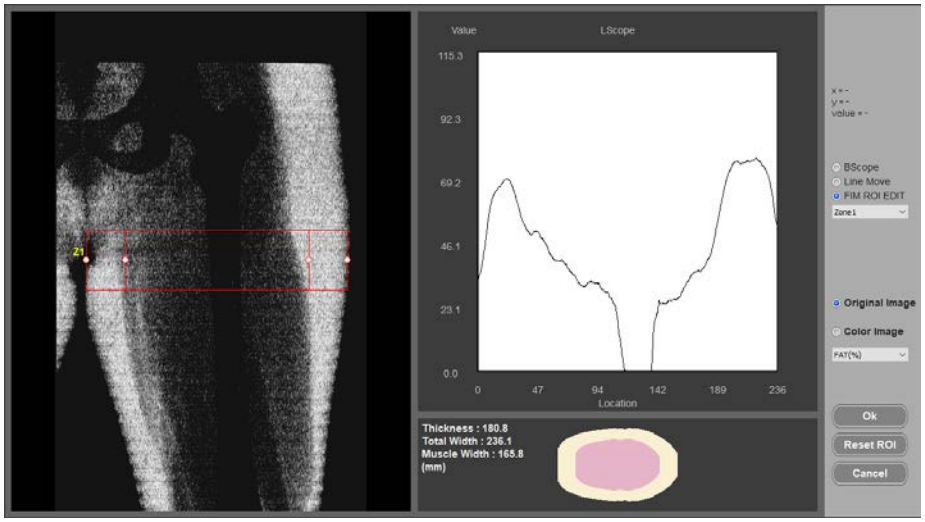
i. Low Energy : This shows the Low Energy Image.
ii. High Energy : This shows the High Energy Image.
iii. Fat : This shows the Fat Image.
iv. Lean : This shows the Lean Image.
v. FAT(%) : This shows the FAT(%) Image.
vi. BMD : This shows the BMD Image.

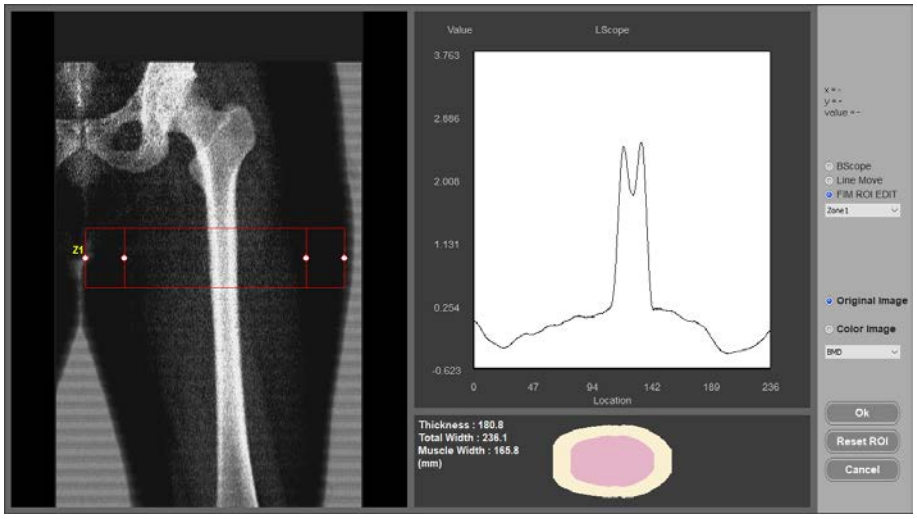


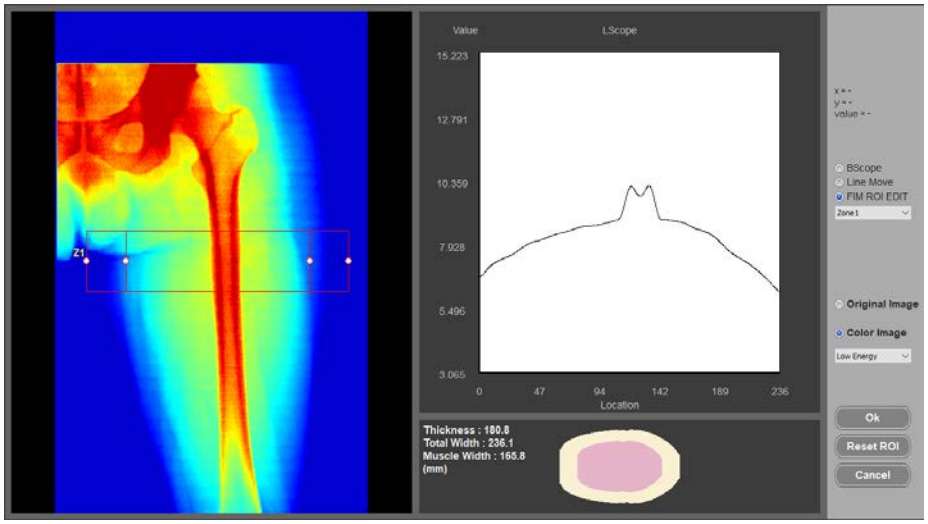

Value
LScope
13.084
11.057
9.030
7.003
4.975
2.948
0
47
94
142
189
236
Location
Z1
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
High Energy
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
Ok
Reset ROI
Cancel

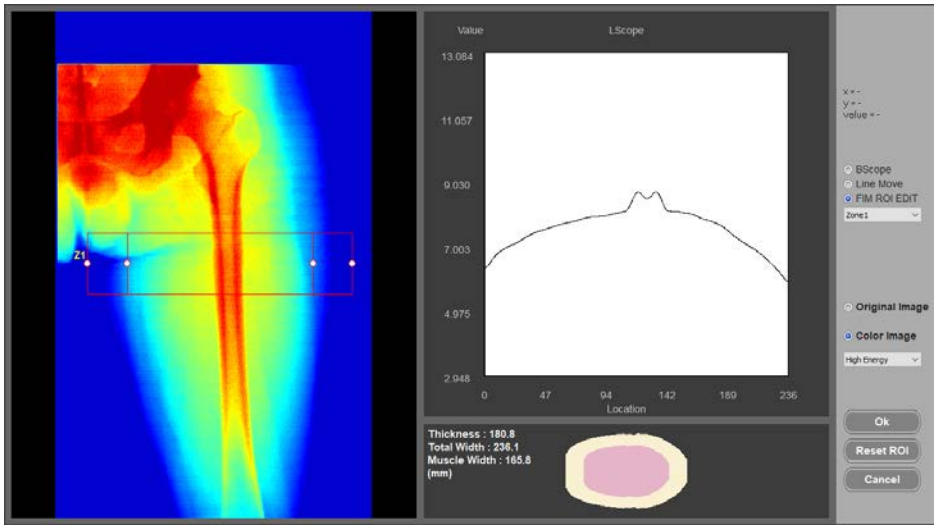

Value
LScope
0.0053
0.0042
0.0032
0.0021
0.0011
0.0000
0
47
94
142
189
236
Location
Z1
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
Fat
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
Ok
Reset ROI
Cancel

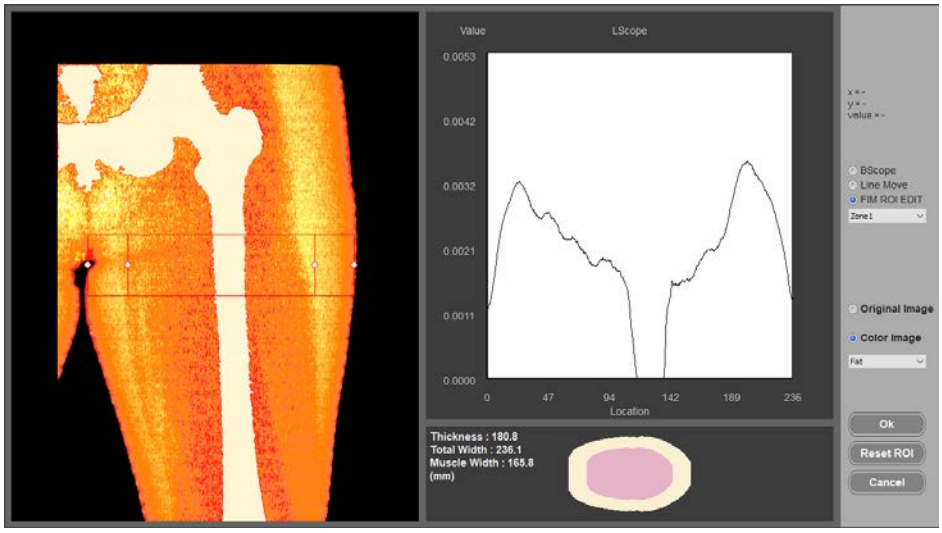

Value
LScope
0.0070
0.0056
0.0042
0.0028
0.0014
0.0000
0
47
94
142
189
236
Location
Z1
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
Lean
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
Ok
Reset ROI
Cancel

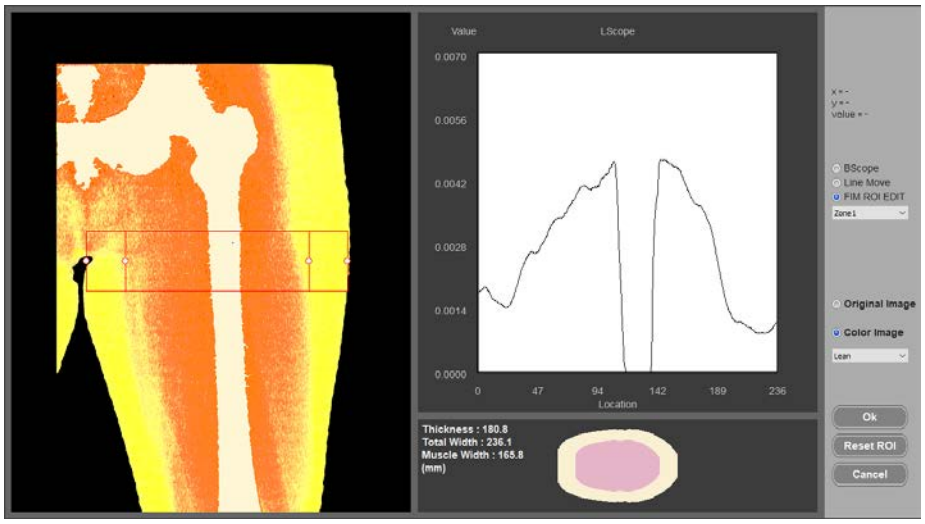

Value
LScope
115.3
92.3
69.2
46.1
23.1
0.0
0
47
94
142
189
236
Location
Z1
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
FAT(%)
Ok
Reset ROI
Cancel

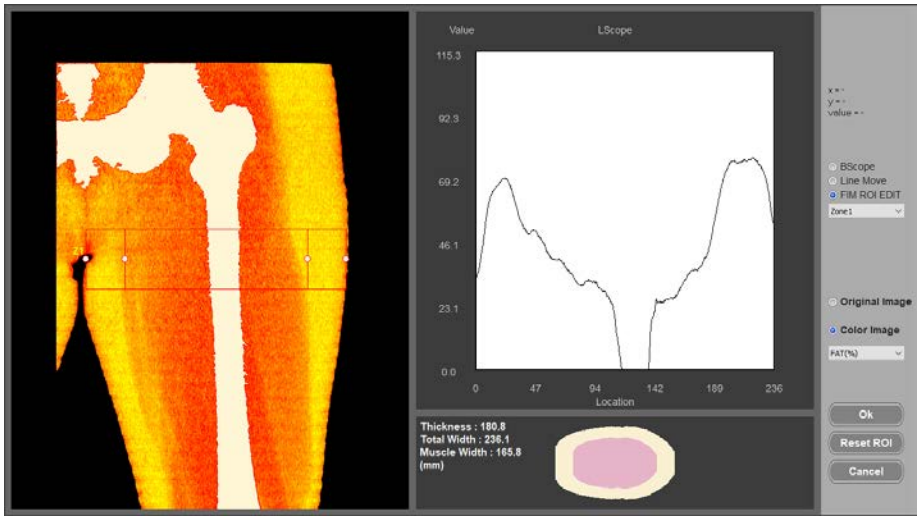

Value
LScope
3.763
2.886
2.008
1.131
0.254
-0.623
0
47
94
142
189
236
Location
Z1
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
BMD
Ok
Reset ROI
Cancel

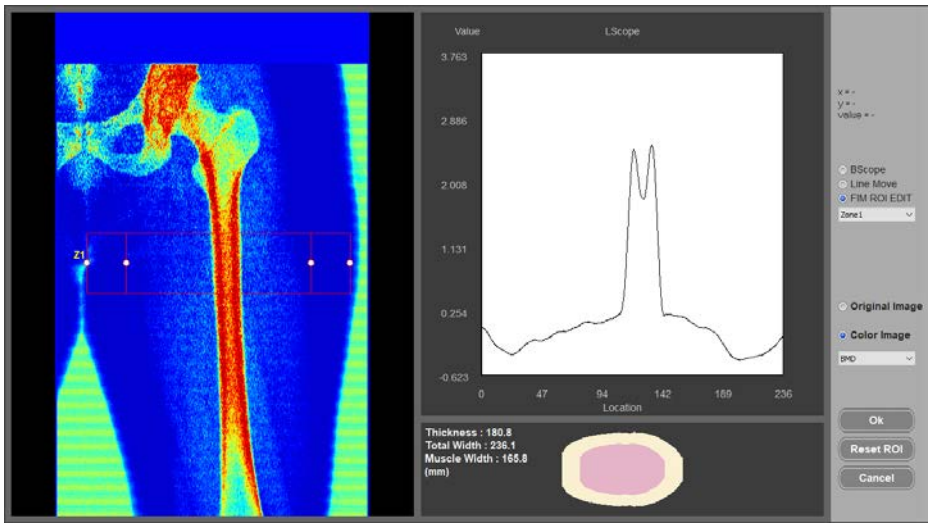

Value
LScope
15.223
12.791
10.359
7.928
5.496
3.065
0
47
94
142
189
236
Location
Z1
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
Low Energy
Ok
Reset ROI
Cancel


Value
LScope
13.084
11.057
9.030
7.003
4.975
2.948
0
47
94
142
189
236
Location
Z1
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
High Energy
Ok
Reset ROI
Cancel

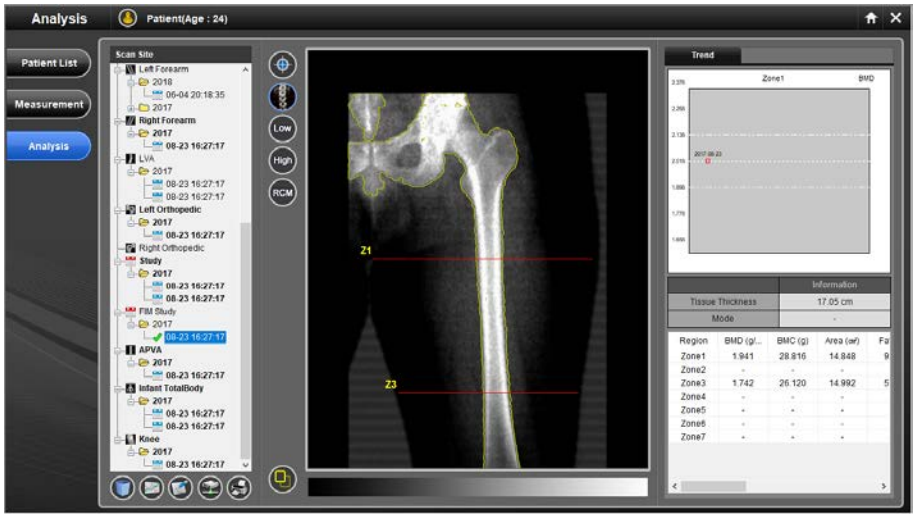

Value
LScope
0.0053
0.0042
0.0032
0.0021
0.0011
0.0000
0
47
94
142
189
236
Location
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
Fat
Ok
Reset ROI
Cancel


Value
LScope
0.0070
0.0056
0.0042
0.0028
0.0014
0.0000
0
47
94
142
189
236
Location
Thickness : 180.8
Total Width : 236.1
Muscle Width : 165.8
(mm)
BScope
Line Move
FIM ROI EDIT
Zone1
Original Image
Color Image
Lean
Ok
Reset ROI
Cancel





h. Check the results.



6.6.26 Using brush.

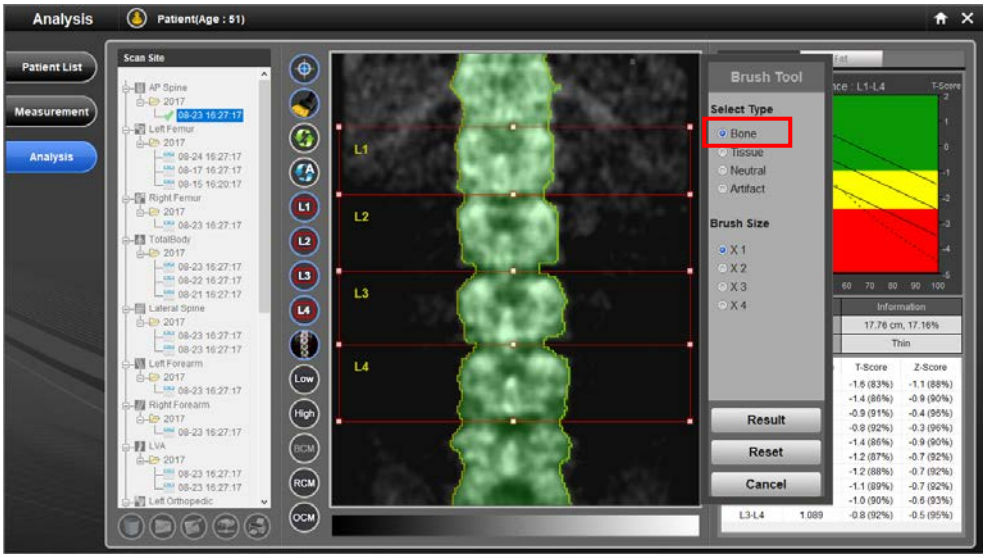
- Brush removes any elements that can affect the measured values of the image or is used to include measured values of randomly removed parts.
  You can adjust areas for bone, tissue, neutral and artifact images displayed.

  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.

 When the brush function is applied to the original image, it directly affects BMD or T-score value.
Therefore be careful when using the brush function.

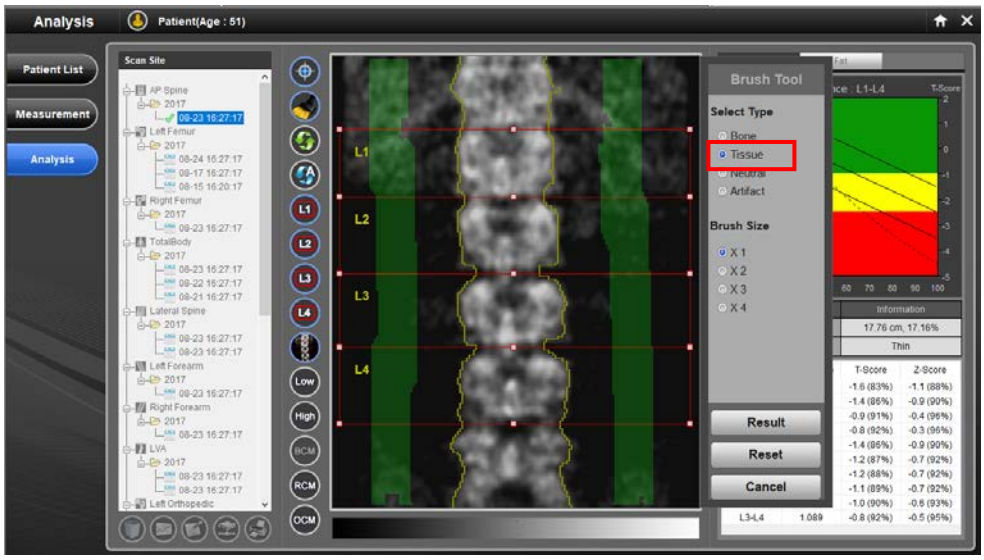
- Marking the bone region

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



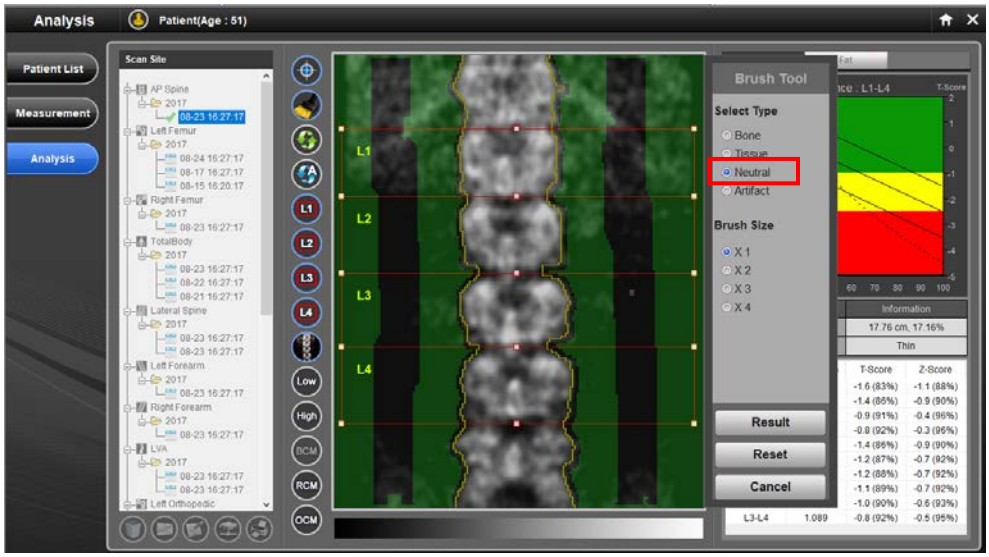
- Marking the Tissue region

  Use it to set both Tissues of the Bone.



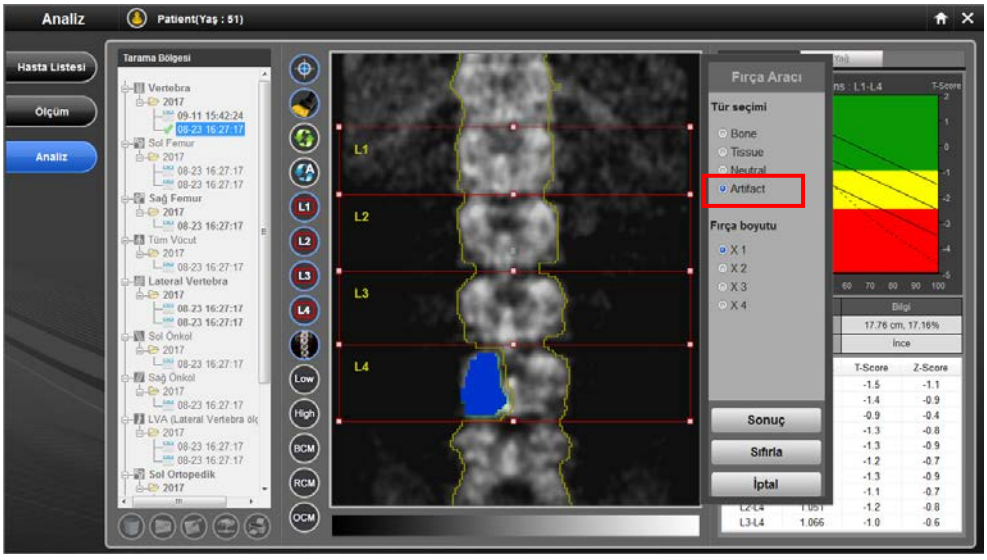
- Marking the neutral region

  Use it to set regions excluded from BMD calculation.



- Marking the Artifact region

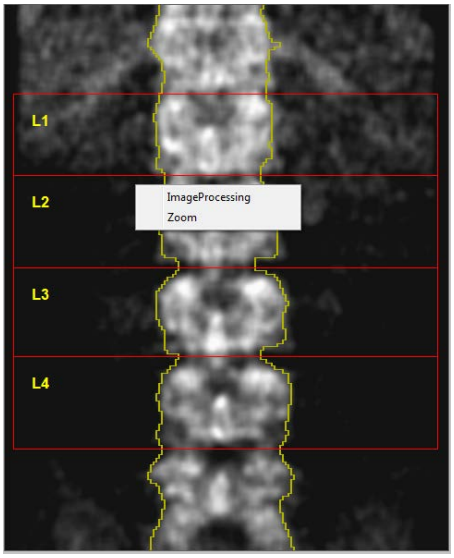
  Use it to remove foreign substances on the image.



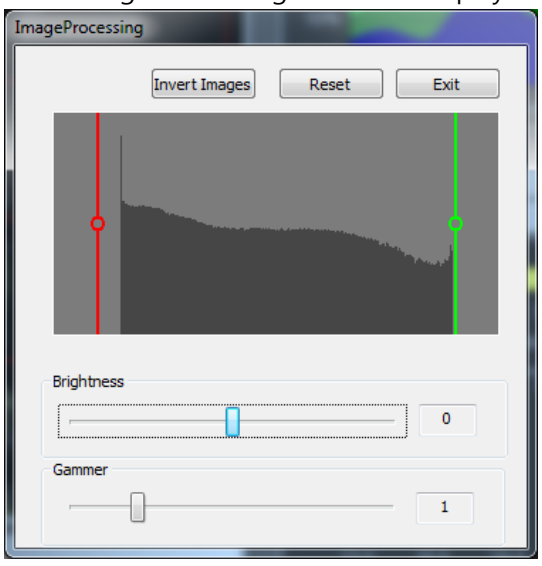
6.6.27 Use of Image Processing

- To preserve image, use image processing function.

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



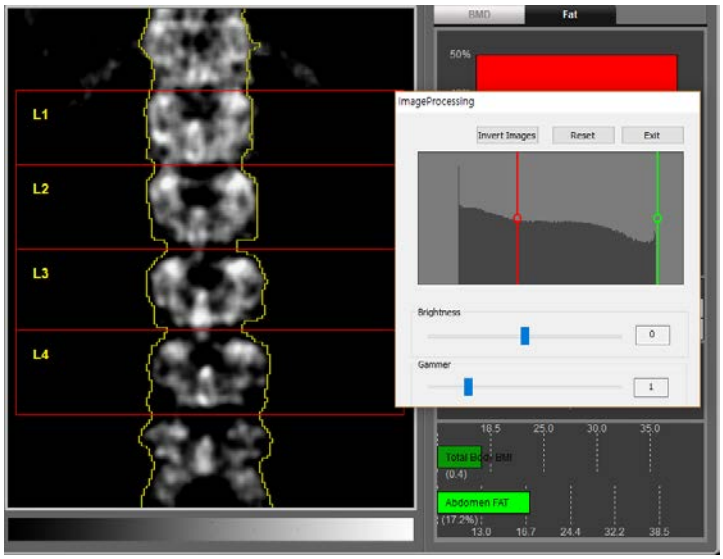
b. Press Image Processing button to display image processing screen.



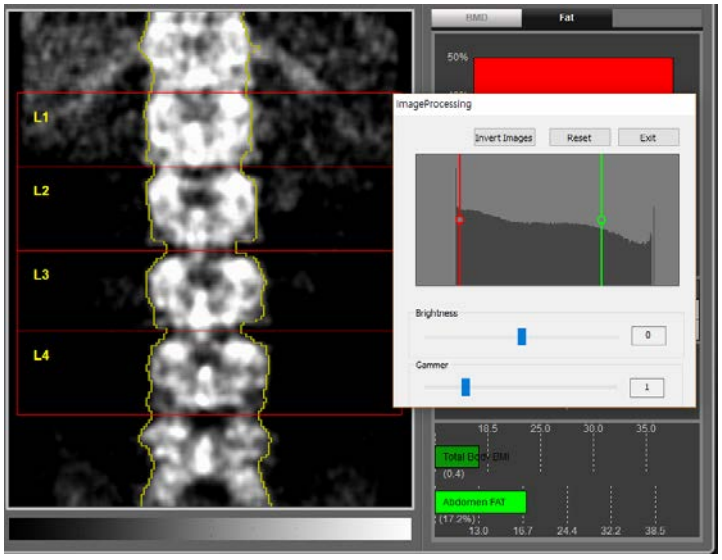
- Image Reversal: It is possible to reverse an image. It can be reversed between black and white.
- Initialization: After an image is changed, it is possible to reverse it back to the original image.
- Closing: Close the image processing window.

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

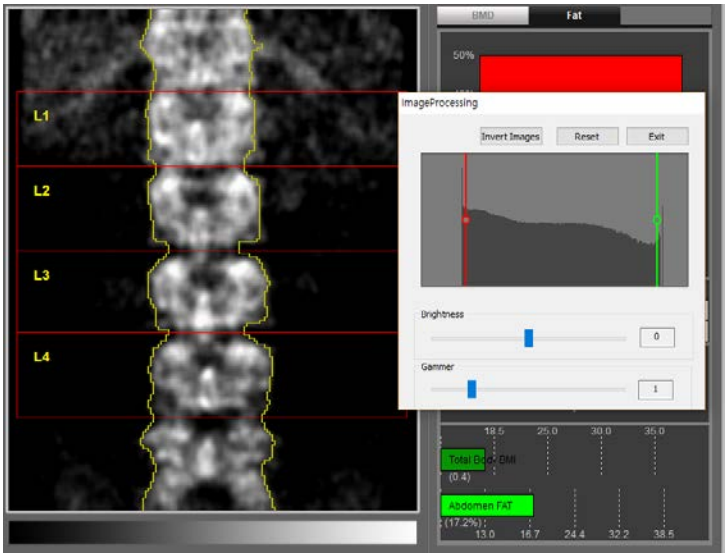
- Moving right or left while clicking the circle in the middle of screen, will change the image. For a red stick, it will darken the dark section of image.



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



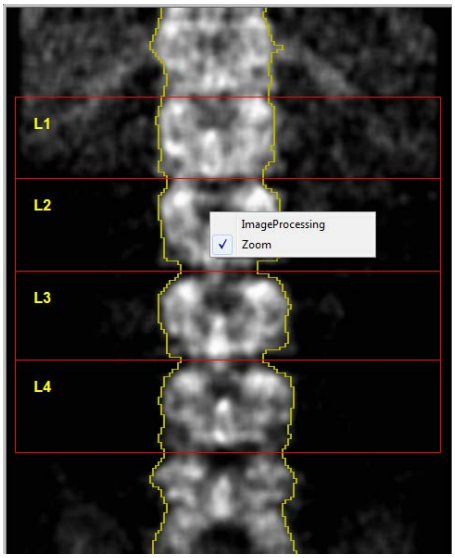
d. For brightness, move a bar at the bottom to change the brightness of Bone section.
As the value on the right side increases, image will be brighter. It is possible to easily distinguish Bone section.


BMD
Fat
50%
L1
L2
L3
L4
ImageProcessing
Invert Images
Reset
Exit
Brightness
0
Gammer
1
18.5
25.0
30.0
35.0
(0.4)
Abdomen FAT
(17.2%)
13.0
16.7
24.4
32.2
38.5

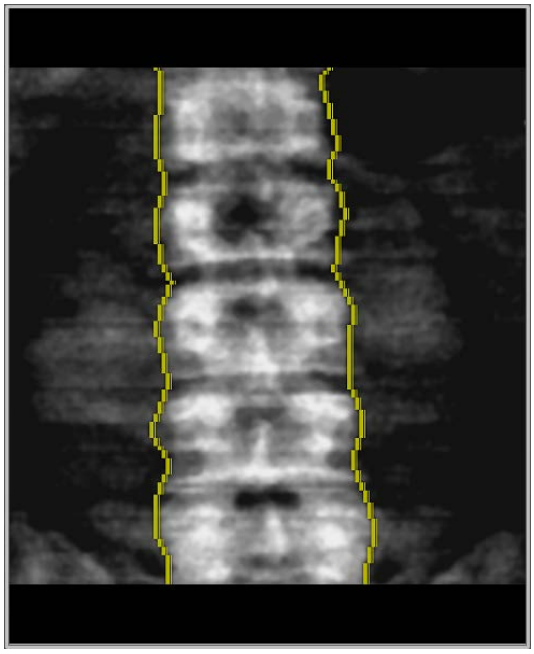
6.6.28 Use of Image Magnification

- 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.

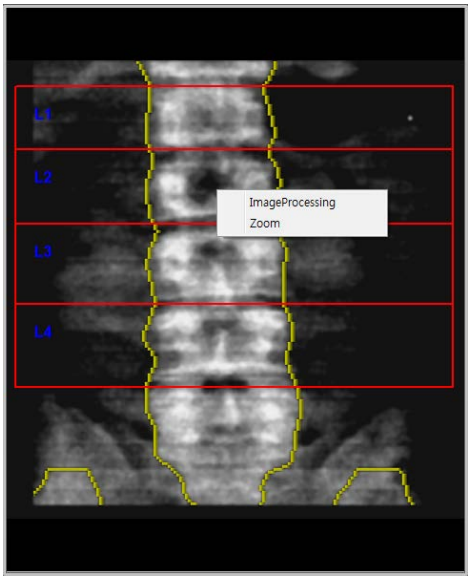


b. Click Zoom button for magnification function by using mouse-wheel.

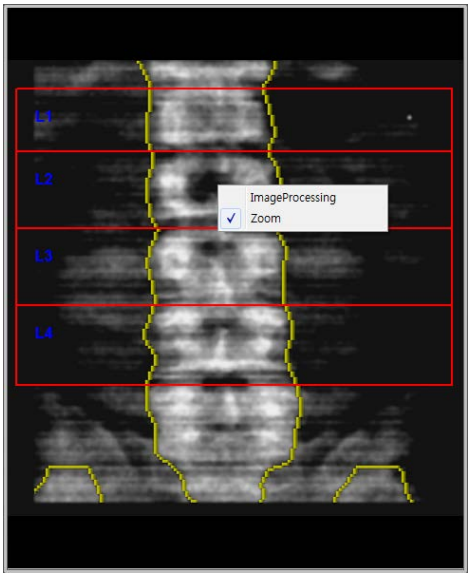


- Place a cursor on the section that you would like to magnify, and drag the mouse-wheel to the direction of your choice to magnify the section.
- To reverse the magnified section to the original, drag mouse-wheel to the opposite direction from user, to reverse it back to the image before magnification.

- 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.



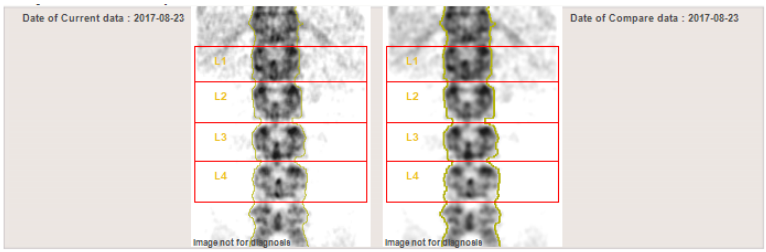
Not using magnification function.



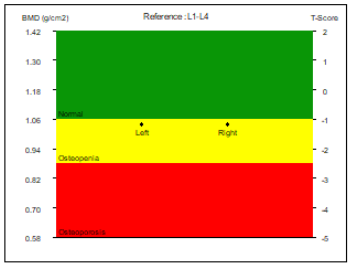
Possible to use magnification function

6.6.29 Use of Compare Function

It is possible 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	27.9	1.036	-1.2
2017-08-23	27.9	1.036	-1.2

3. Changes(%)

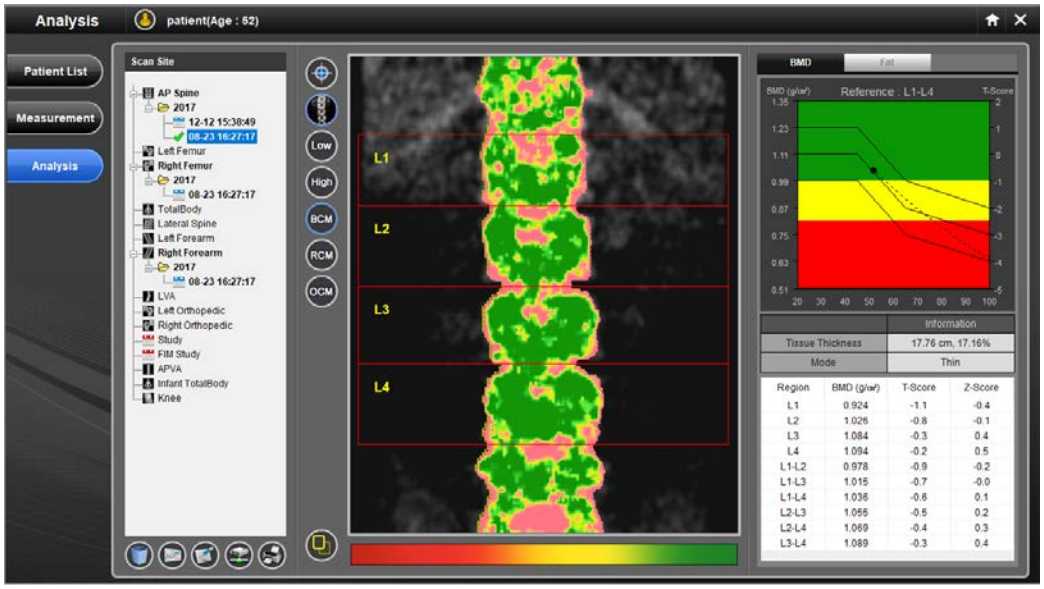
	Left	Right	Changes(%)
BMD	1.036	1.036	0.0
T-Score	-1.2(0.0)	-1.2(0.0)	0.0

6.6.30 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)

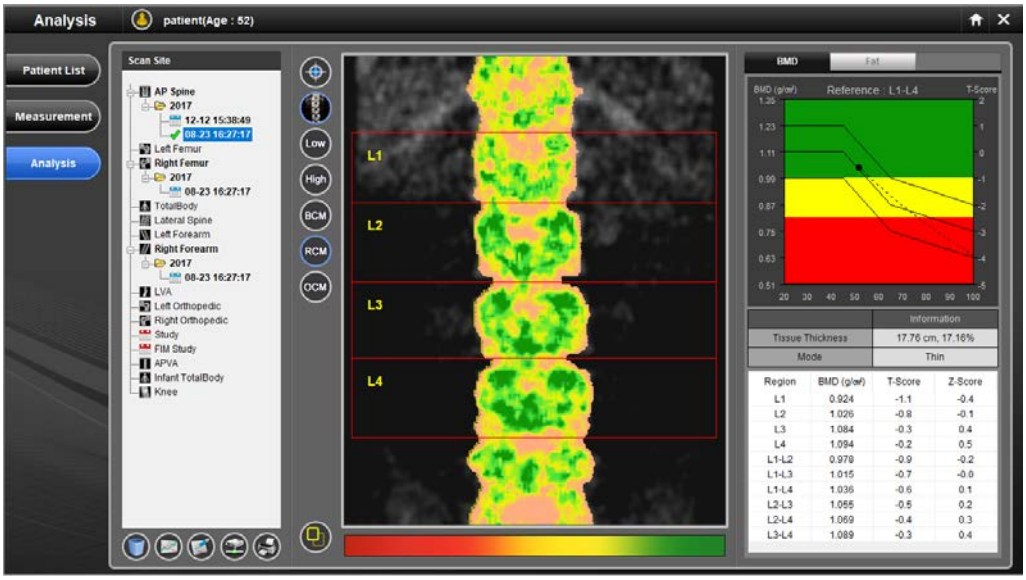
1) BCM

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



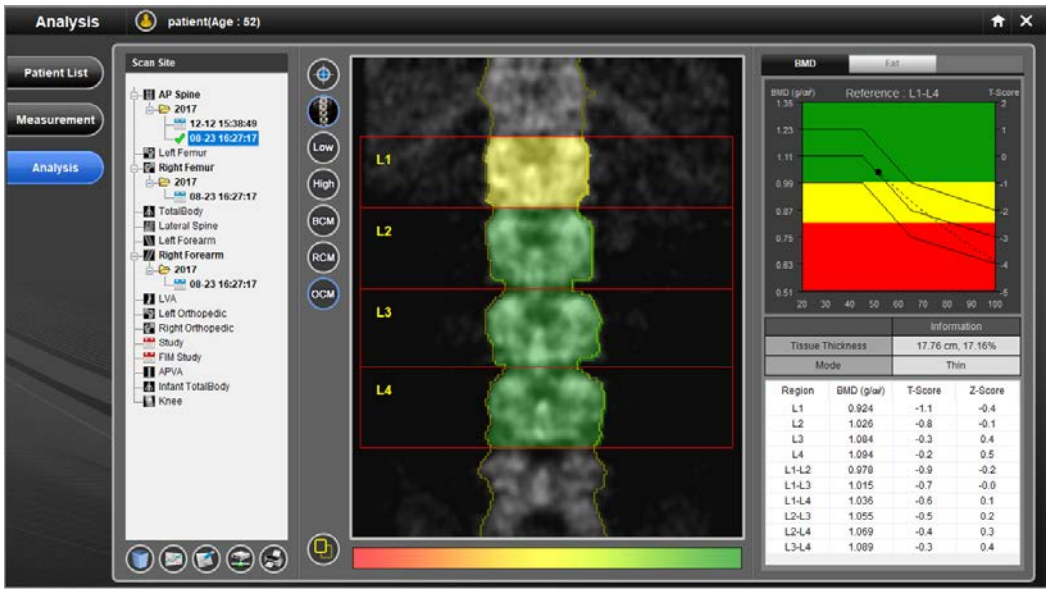
2) RCM

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



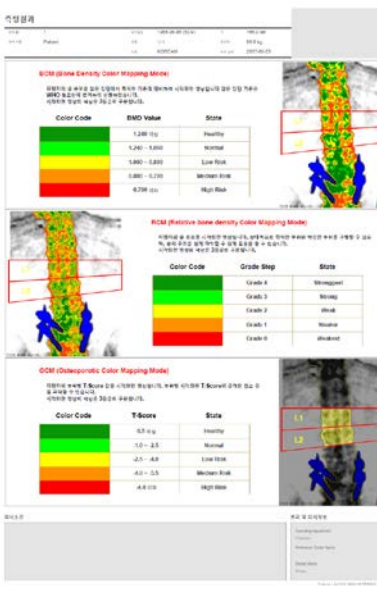
3) OCM

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

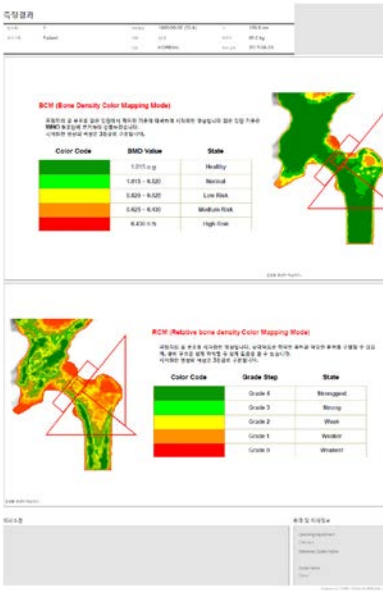


4) Report

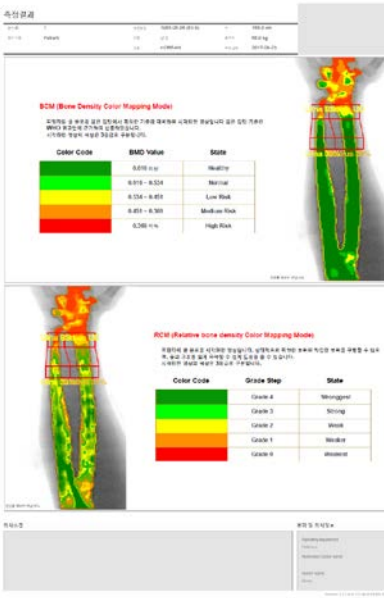
- You can print or send PACS Color Mapping Reports



AP Spine



Femur

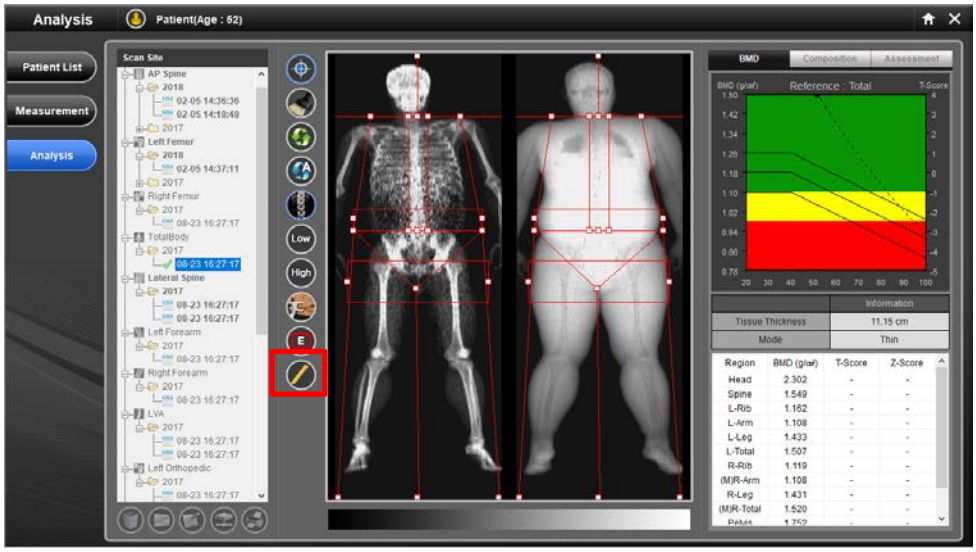


Forearm

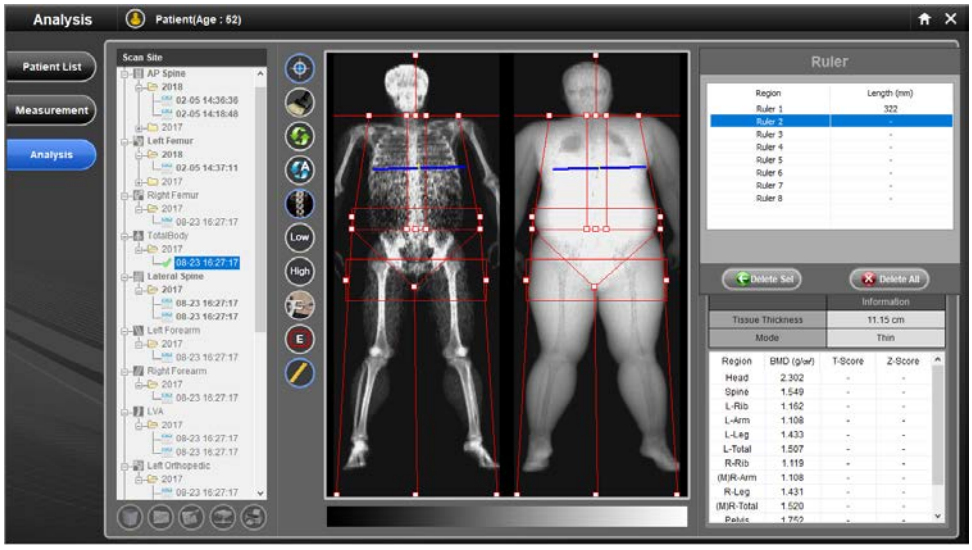
6.6.31 Use of Ruler

- It is a function that provides information about the length in the image.
- Analyzable area : Total Body, Study, FIM Study

a. Please click the image on list.
b. Please press 'ROI set' when the image appears.
c. Please click Ruler Button.



d. Move to the desired location by right clicking the mouse.

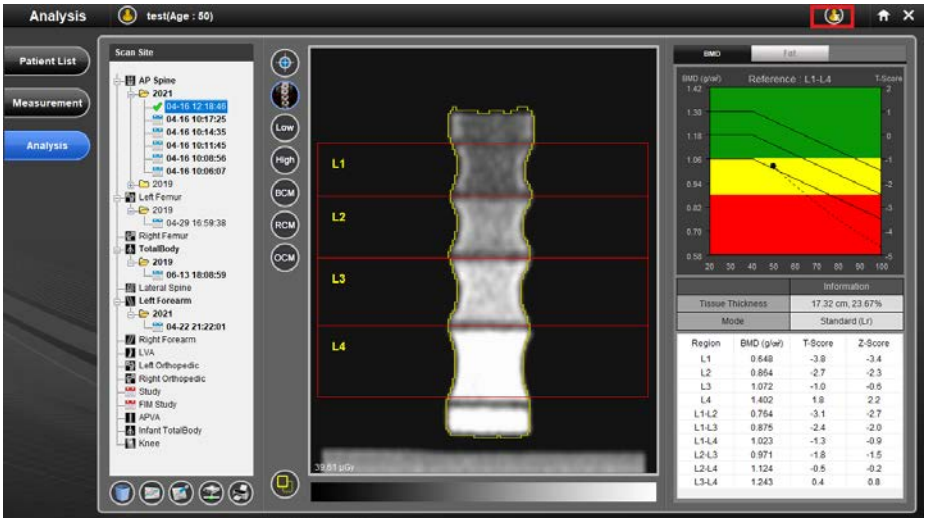


e. The upper right corner shows the length for the area.

6.6.32 View Image Export

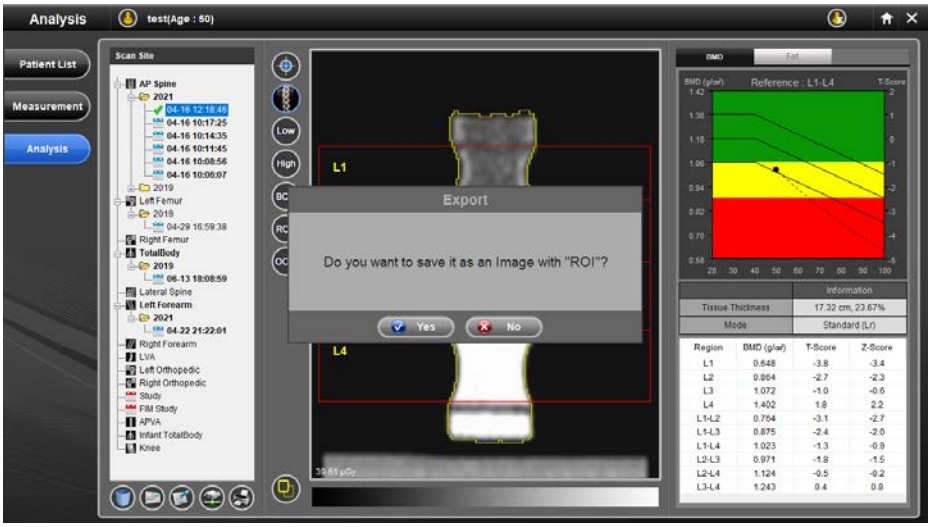
- It can be used by activating "Use ViewImage Export" to Check in the environment setting.
- There are three types of extensions that can be saved: "BMP", "JPG", and "TIF".

a. Please click Image Export Button.

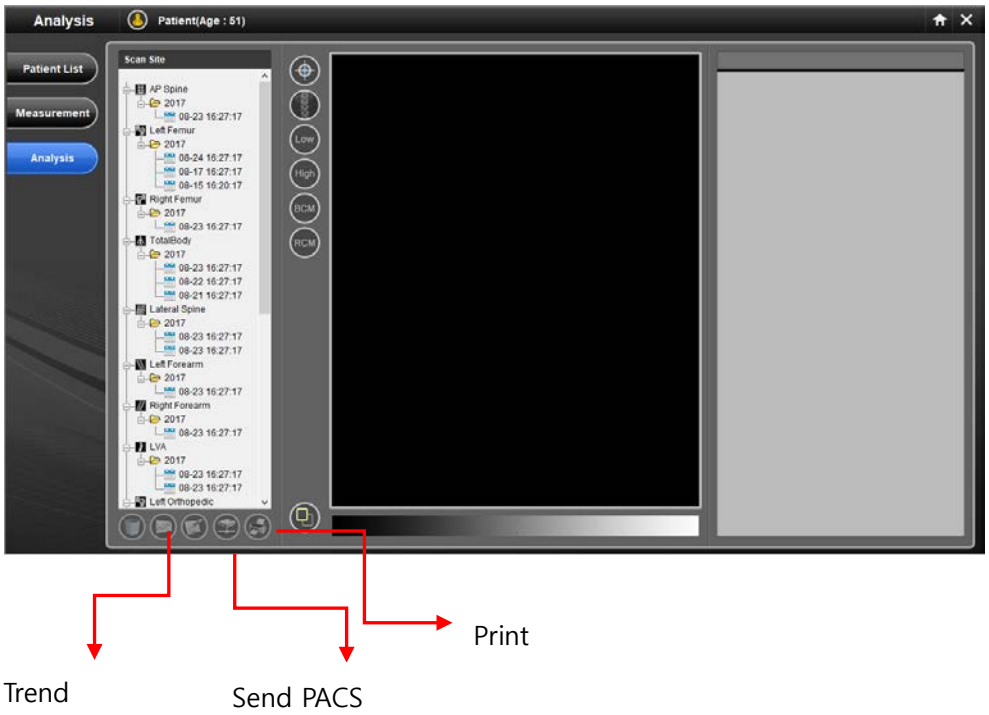


b. Please click Image Export Button.

c. If you click the Yes button, the image containing the ROI is saved, and if you click the No button, the image without the ROI is saved.



6.7 Output and PACS.

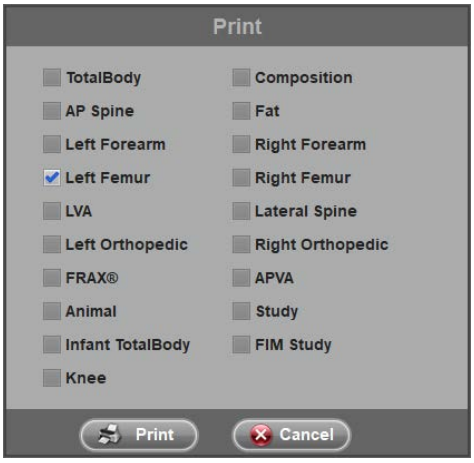


6.7.1 Result output and PACS connection

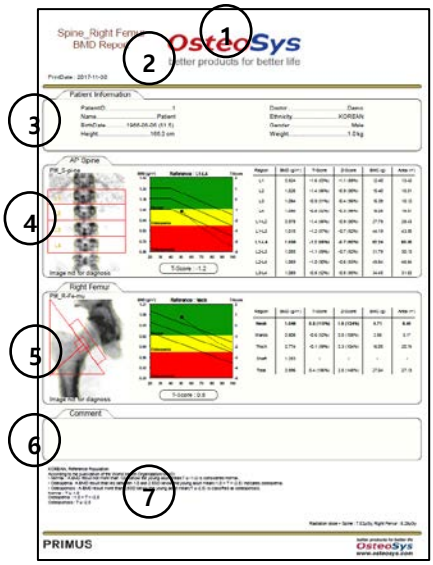
- Print out the obtained result.

a. Once analysis is complete, it is possible to print the result on all possible measurable sections with PRIMUS such as spine, femur, etc. on analysis window.
b. There are 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.



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



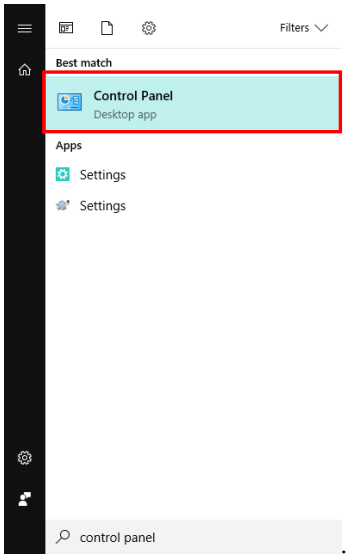
1 : Hospital logo
2 : Hospital address, telephone number
3 : Patient information
4 : Multiple site #1 result
5 : Multiple site #2 result
6 : Comment
7 : Diagnosis Criterion (WHO, Offer)

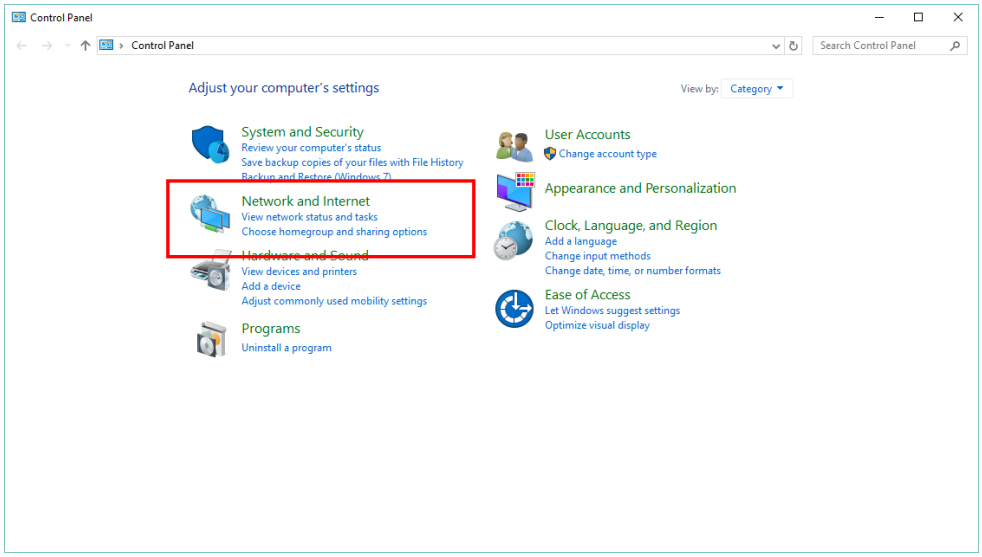
6.7.2 PACS Interlock

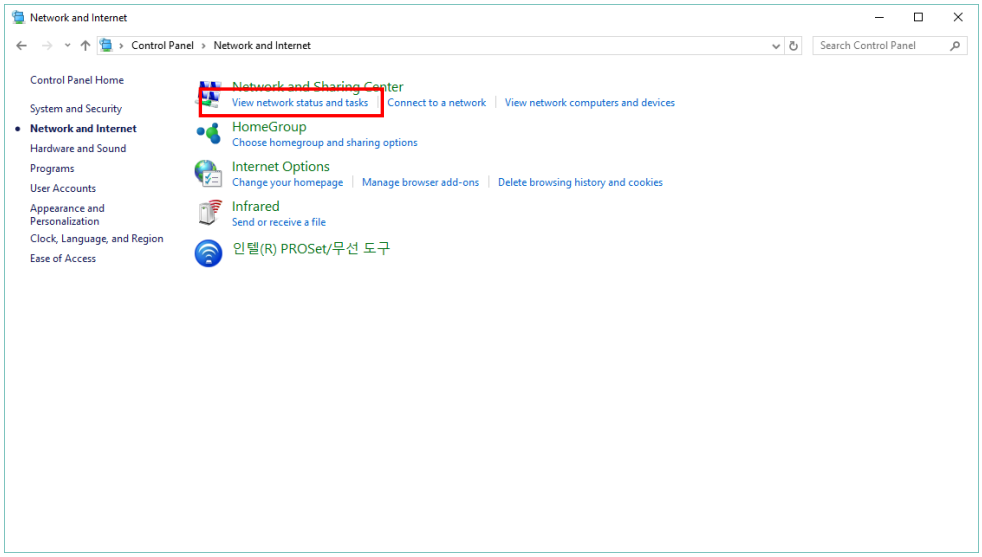
The PACS configuration is explained based on Window 7 environment. If you are using another version of window, consult with A/S center.

- PACS requirements
  - 2 LAN cards (inside PRIMUS 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.

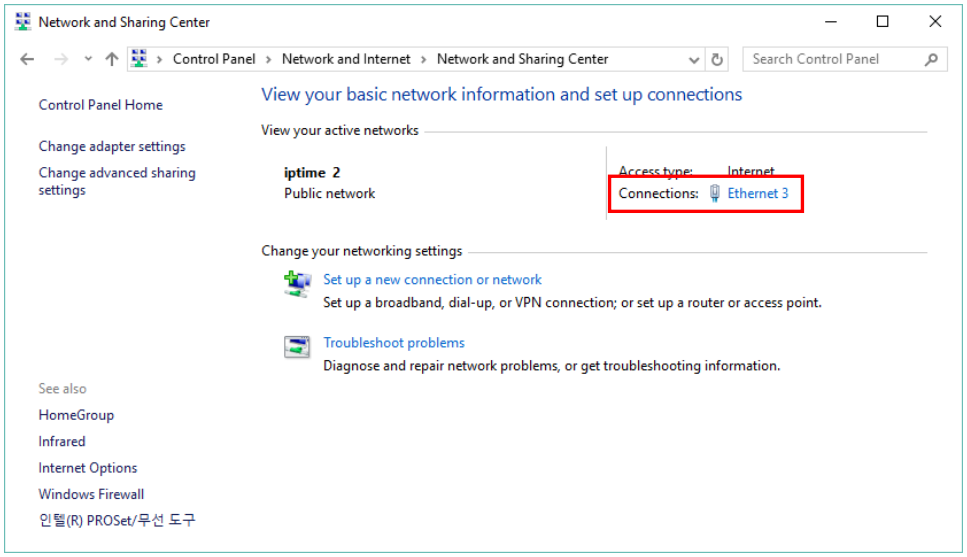




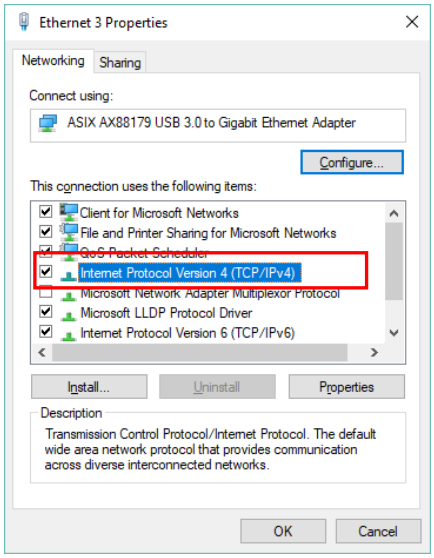


b. Setting LAN Card

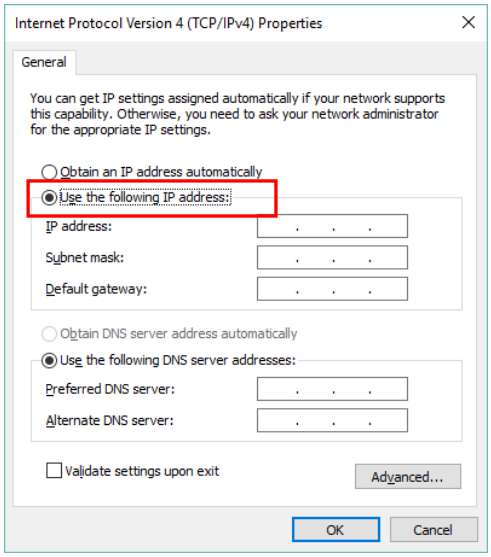
If there are two LAN cards inserted, local domain is divided in half as shown below. One of the two connections is a LAN card that communicates with the equipment, and the other is used in PACS. If it is not clear which LAN is for which, pull out each cable to see local domain that is connected to the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



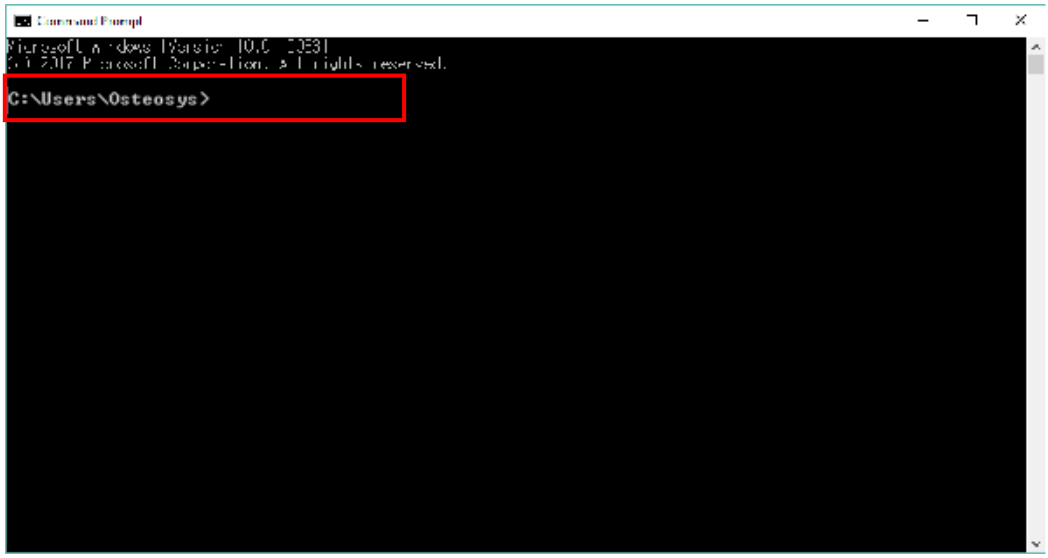
c. To connect with the PACS network of hospital, choose local domain connection2 (a domain that is connected with the equipment). When property window pops up, click Internet Protocol (TCP/IP), and click Properties.



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.)



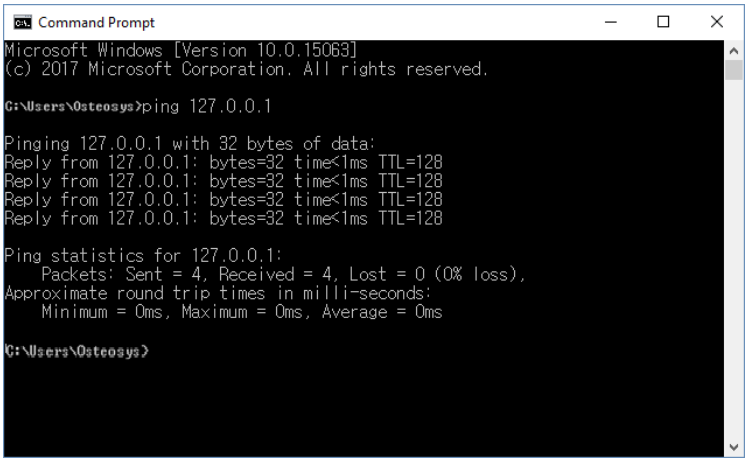
e. To check the connection with PACS server inside hospital, press window start button and click run. When a window pops up, enter CMD, which will show in DOS mode as shown below.



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.

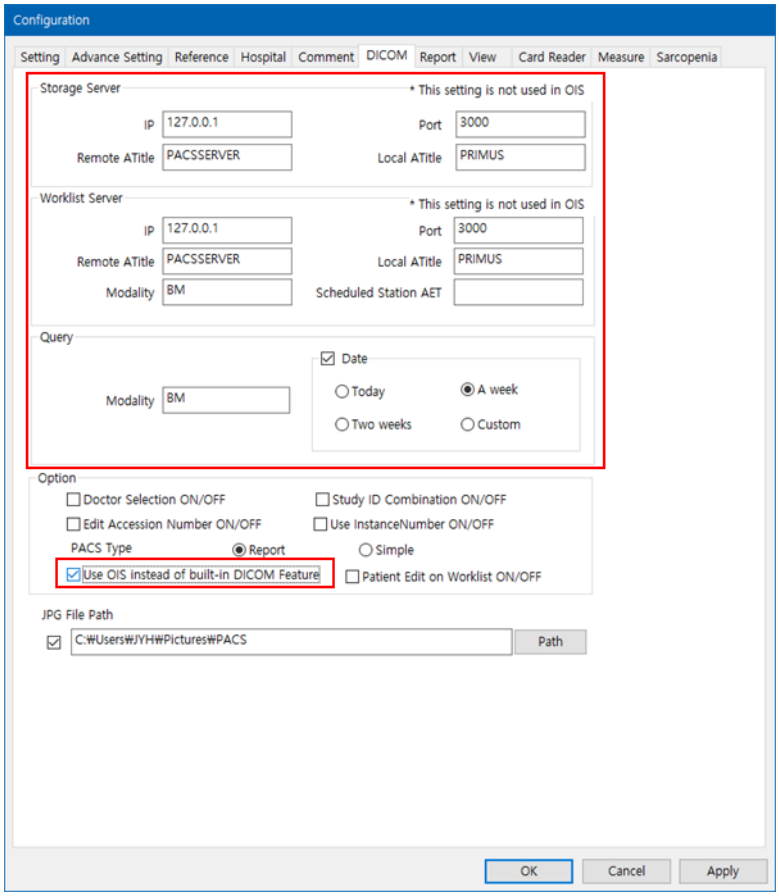
If 'Packet: Send = 4, Receive = 4, Lost = 0' shows up, it is also normal.

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 (PRIMUS).

i. Go to configuration screen.

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



To use OIS, check the "Use OIS instead of built-in DICOM Feature" check box. After that, set it as below.

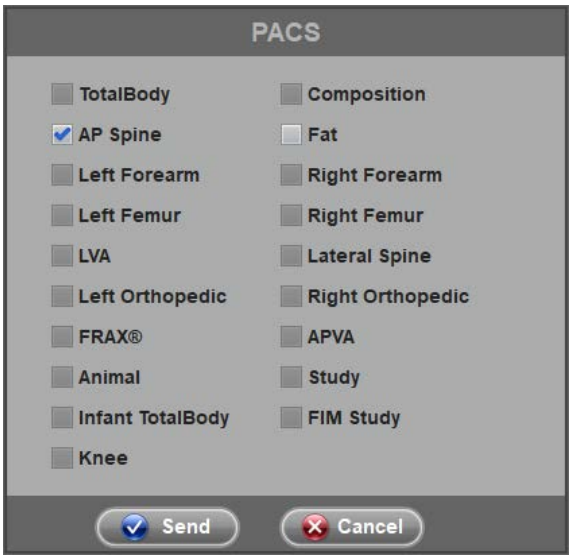
a. Run the OIS Engine program.
b. Open the Settings window with the Options (O) -> Configuration (C) menu.
c. Click the Worklist tab on the setting screen and set the above information.
d. Please refer to OIS Engine manual when setting.

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.

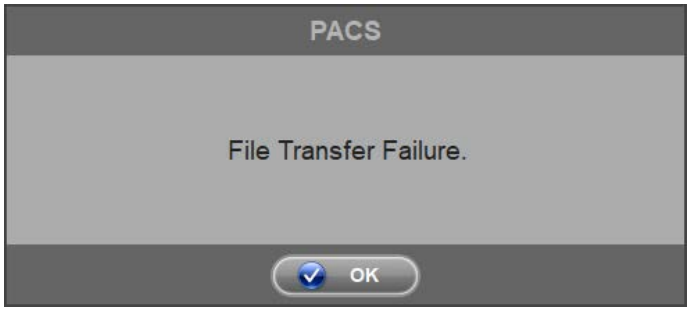
l. After completing the above configuration, run user program. After selecting the examinee who would like to send a result through PACS, go to analysis screen.



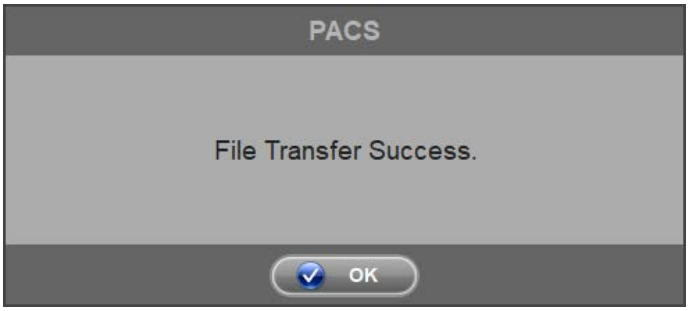
m. Among those chosen examinees, select the measurement section to send, and click PACS button, which will open Report Page window.

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 as shown below.



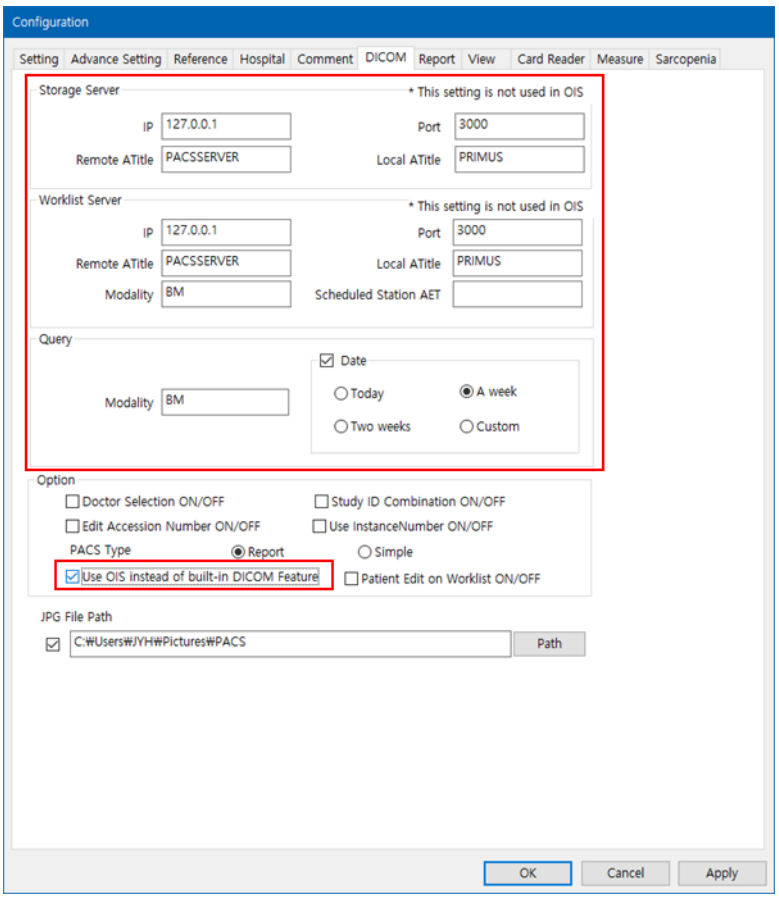
If PACS transmission continues to fail, check the DICOM server of hospital. If there is any abnormality, call our A/S center.

When sending PACS, only Secondary Capture Image data are sent. To send a Structured Report or HL7 message, you must send it manually. Please check the OIS Engine manual for manual conversion and transfer method.

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 PRIMUS user program.
  b. From the main screen of PRIMUS, 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 PRIMUS, it notifies OCS manager that it is "PRIMUS". However, it is not allowed to change A-title.

f. For Modality, "DX" is a default value, which is allowed to change.

g. Press OK button to store the set value.

To use OIS, check the "Use OIS instead of built-in DICOM Feature" check box. After that, set it as below.

a. Run the OIS Engine program.

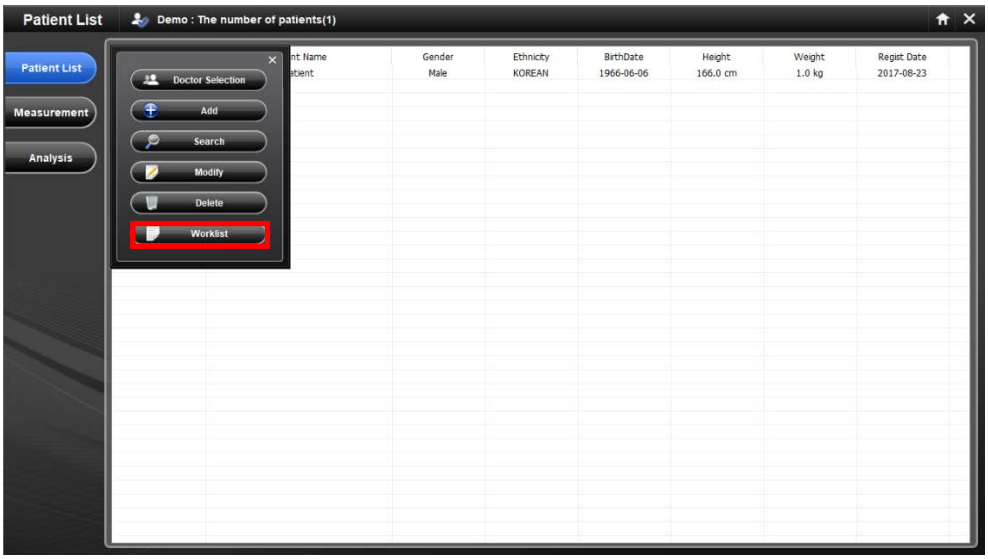
b. Open the Settings window with the Options (O) -> Configuration (C) menu.

c. Click the Worklist tab on the setting screen and set the above information.

d. Please refer to OIS Engine manual when setting.

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

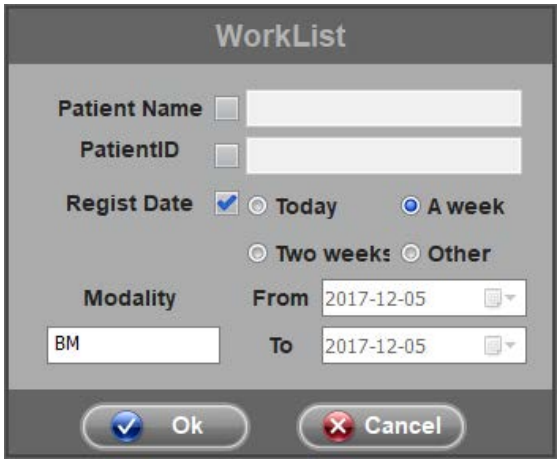
h. Go to examinee's list and press the button for examinee list. As shown in the figure below, press Worklist button at the bottom of examinee's pop up menu.



i. Conditional window will pop up to bring up examinee's list as shown in the figure below. When Use OIS option is set, The window of OIS Engine

Program will pop up.

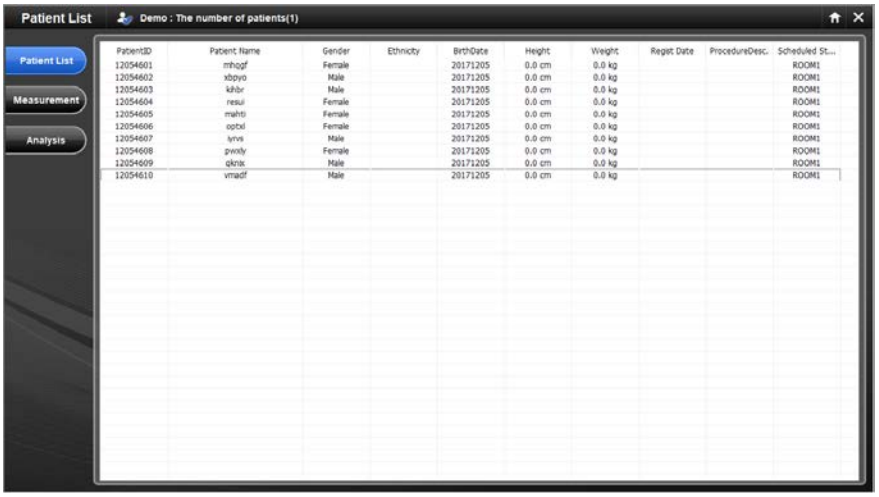
The conditions can be searched with name, ID, and date. The default is to bring up the worklist with date. The date should conform to the setting in query items for No. d.



j. Enter the search conditions and press OK button. Then it will display the list of examinees who match the conditions registered in the server. When Use OIS option is set, list of examinees will be on the OIS Engine program.

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 connection with the list displayed in the PRIMUS user program, the existing subject list is replaced with the Worklist patient data list being searched as shown below.In case of bringing up the Worklist that matches with search conditions, the existing examinee's list will change into the Worklist.



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

m. If the server is not connected, if you enter an incorrect search condition or if you see an error message from the OIS Engine, check that the server is connected or the DICOM settings are correct and try again.

n. When canceling the Worlist list, click the Worklist button again if Use OIS option is set.

o. For more details about OIS Engine, please refer to the manual of OIS Engine.

6.8 Database.

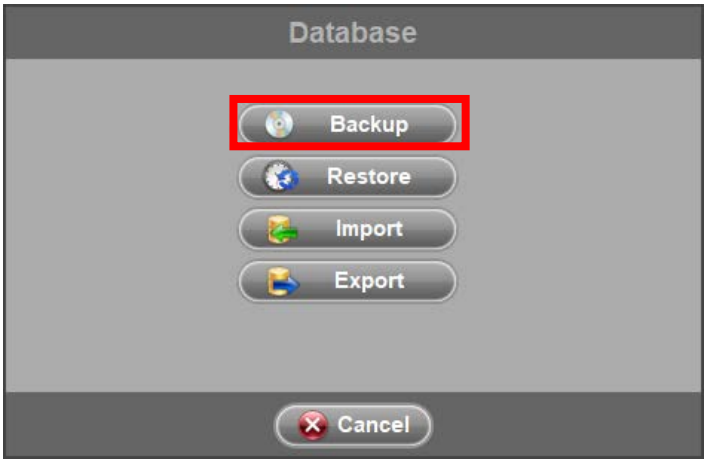
6.8.1 Backup and restoring.

- You can restore data through backup.

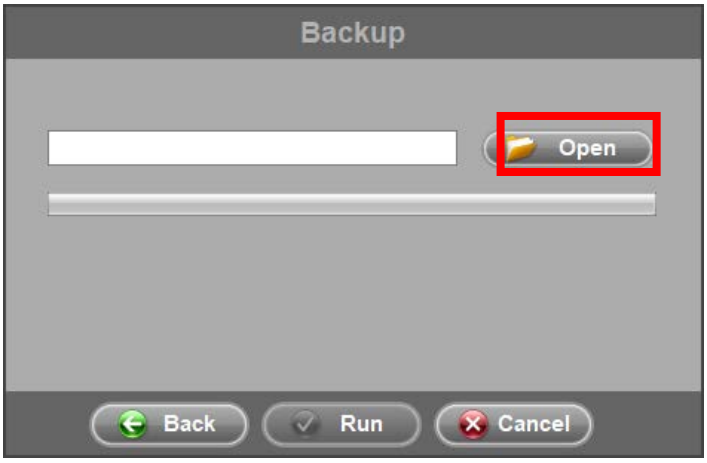
- Backup

a. Select Database menu in the main screen.

b. When the window opens, click Backup button.

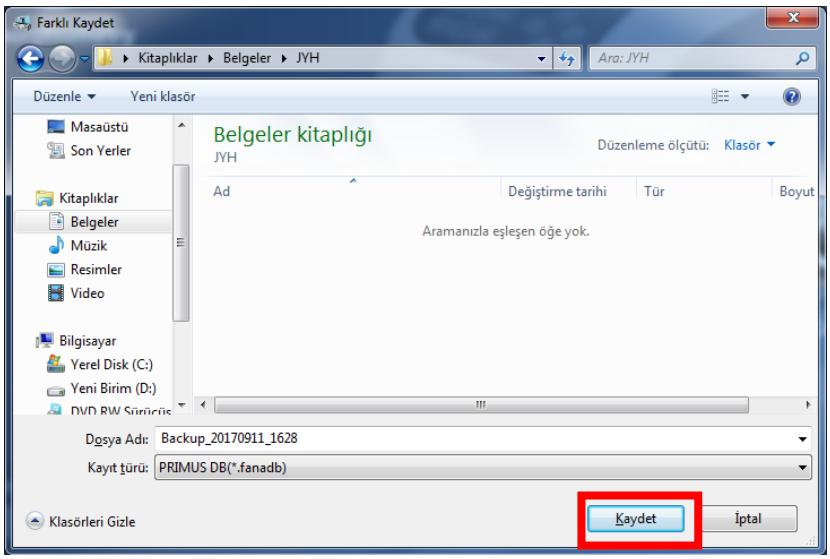


c. When Save dialog box opens, save it in a basic file name or user file name.

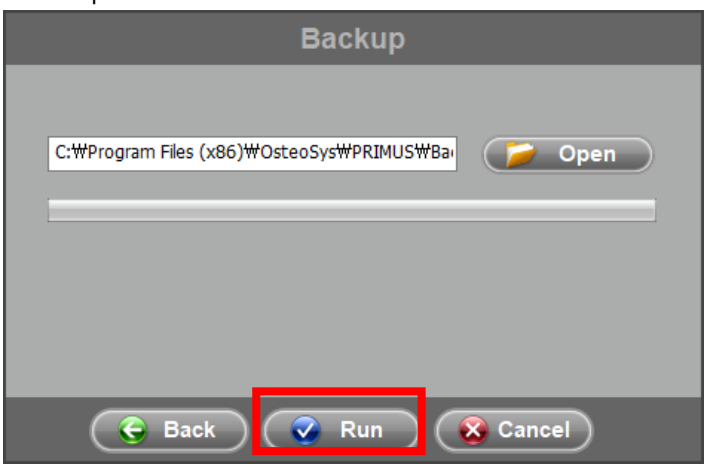


d. Basic file saving path is [./Backup].

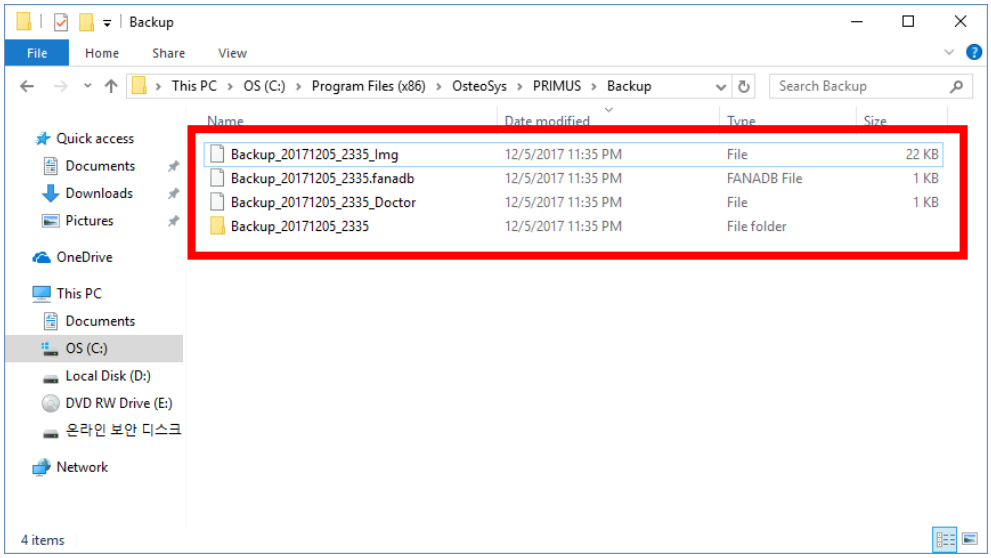
e. Set the file name and click 'Save' to save the file.



f. Go to back up and click Run.



g. 3 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.)

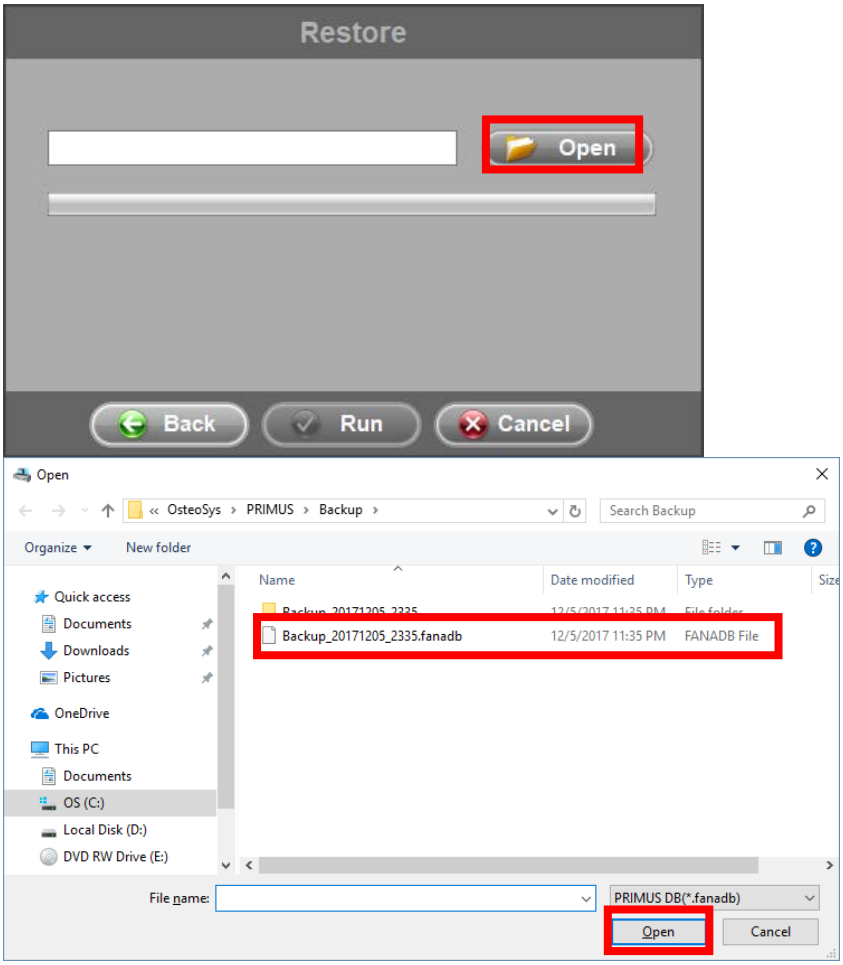


- Restoring

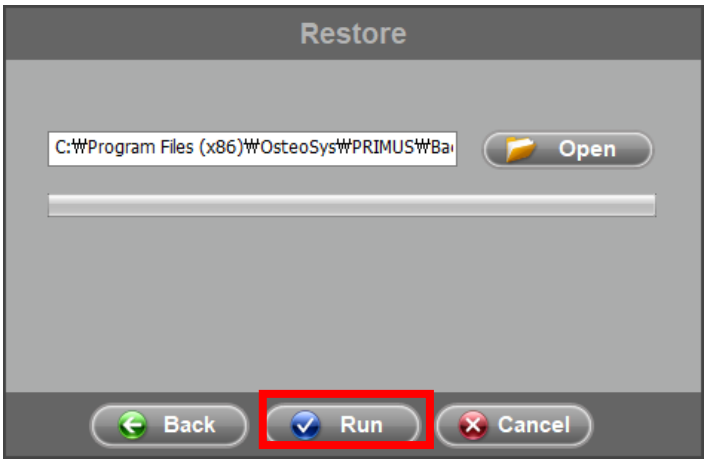
a. Select Database menu in the main screen.

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.

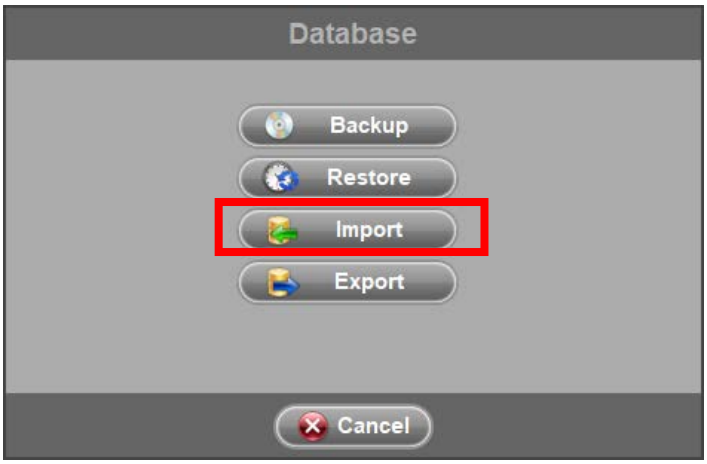
The data will be restored with the backup data, so current data will be deleted completely. During the restore process, the current data will be backed up automatically.
"Backup_current date" folder will be created on [../Backup] directory.

6.8.2 Import and export

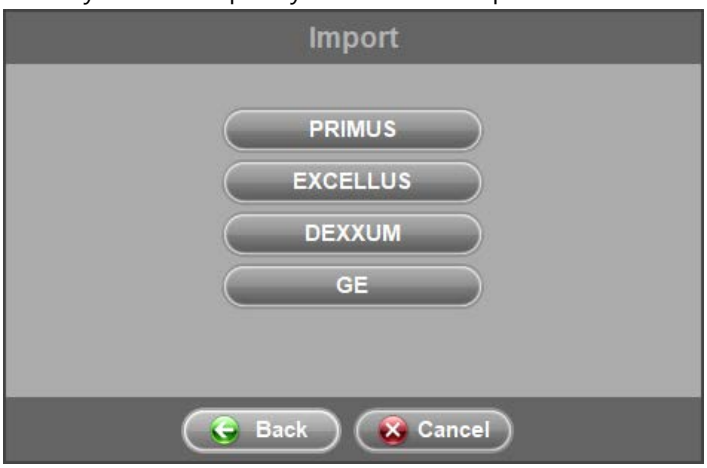
- Use database of compatible equipment by other companies to apply to PRIMUS.

- 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.

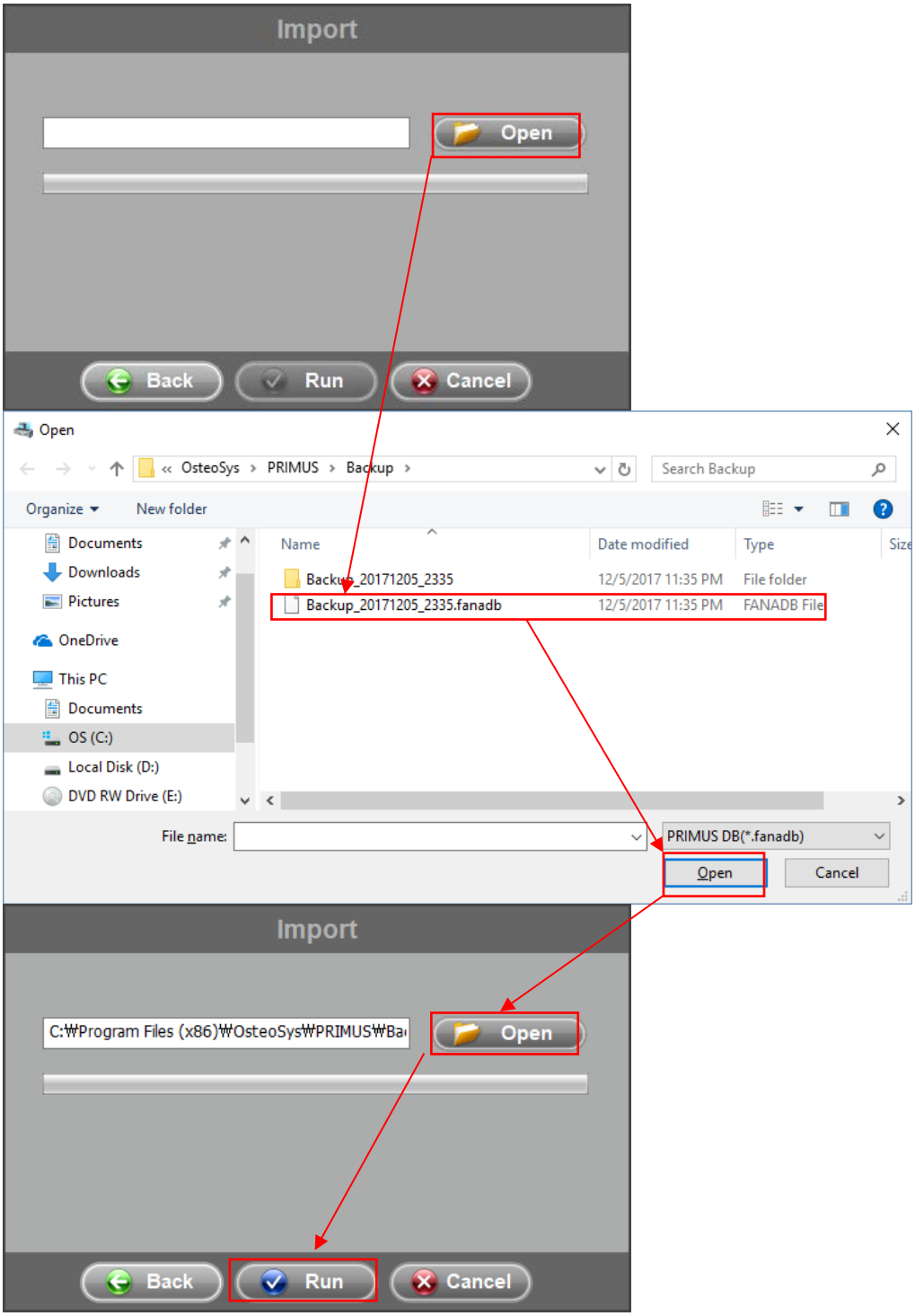
- Import
  a. Click Database in the main screen.



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

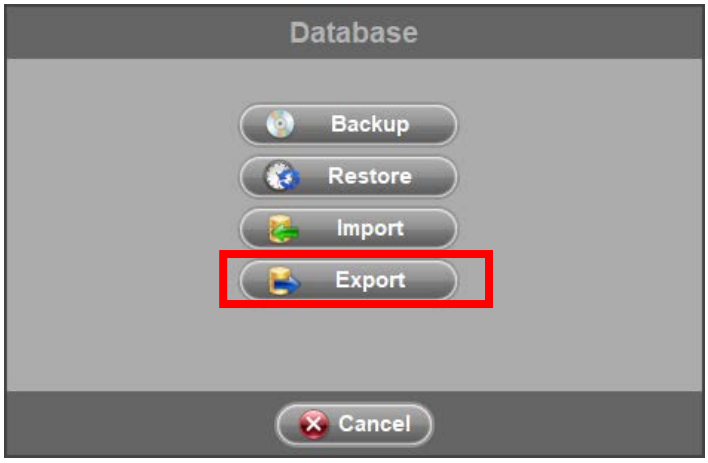


c. Select the prepared database and click Open.(The same as Restore "c")

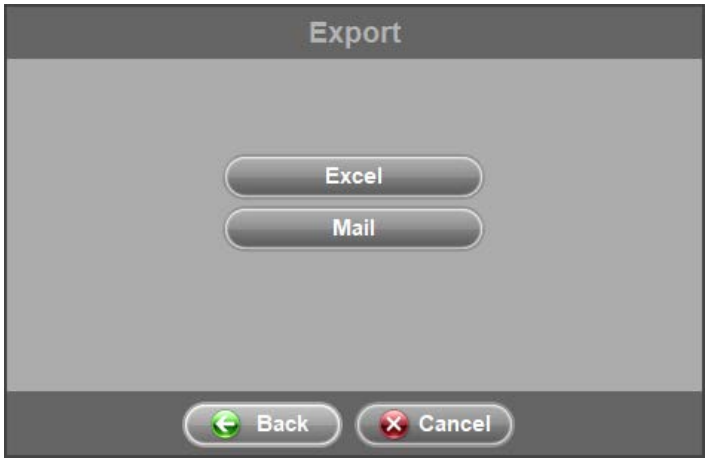


- Export

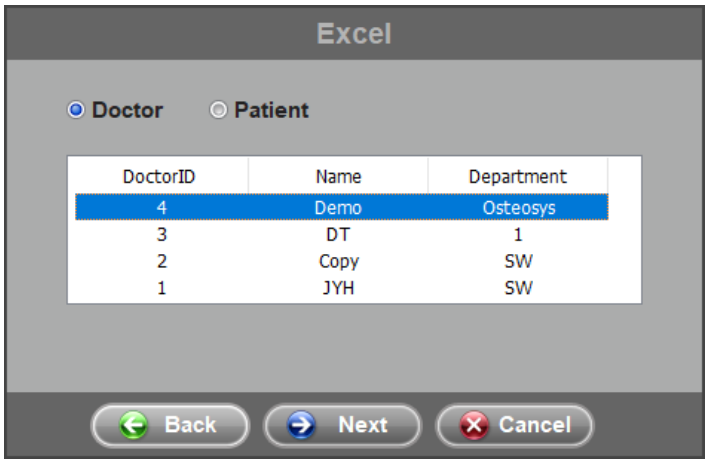
a. Like Import, click Database in the main screen.



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

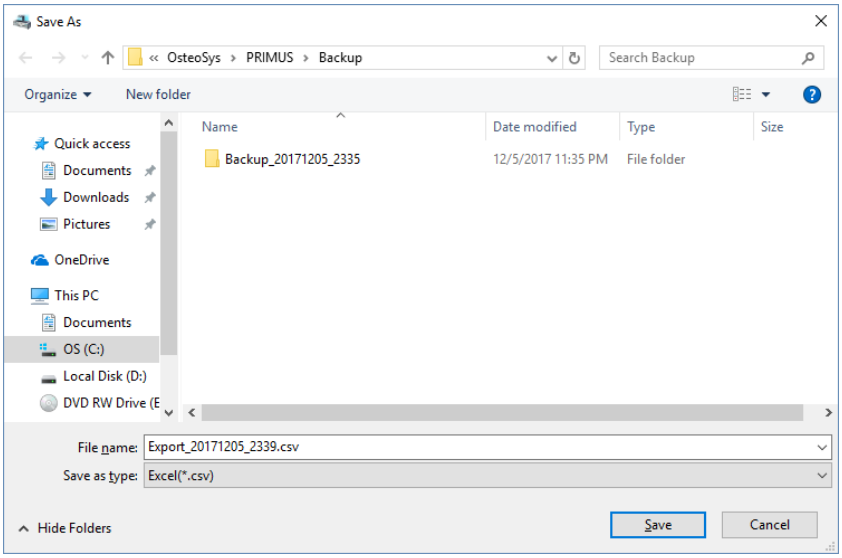


c. Click Excel or E-Mail and choose the data.



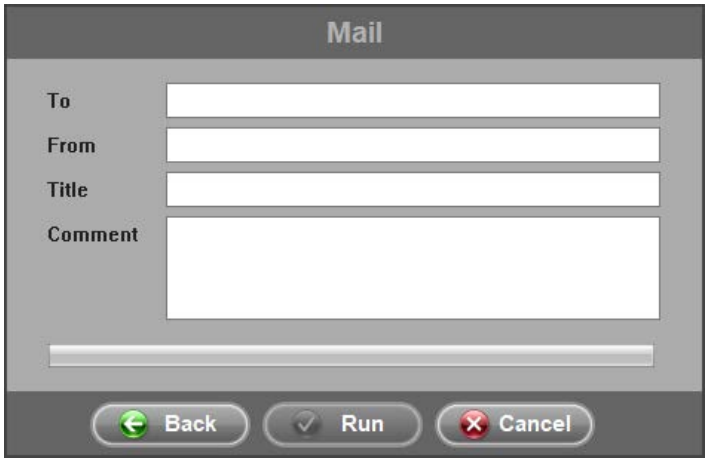
d. In case of Excel

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.



- Import (GE & Hologic data)

i. This section explains how to import into PRIMUS. When importing data, import database and import DICOM file.

ii. Support Site and Data

Database	GE	HOLOGIC
AP Spine	BMD, T-Score, Z-Score	BMD
Femur	BMD, T-Score, Z-Score	BMD
Forearm	BMD, T-Score, Z-Score	BMD
Lateral Spine	BMD, T-Score, Z-Score	BMD
Total Body	BMD, T-Score, Z-Score, Bone Mass, FAT Mass, LEAN Mass	BMD, FAT Mass, LEAN Mass
LVA	Anterior Height, Middle Height, Posterior Height	None
Orthopedic Hip	BMD, T-Score, Z-Score	None

iii. Insufficient data (images, etc.) can be compensated through DICOM data.

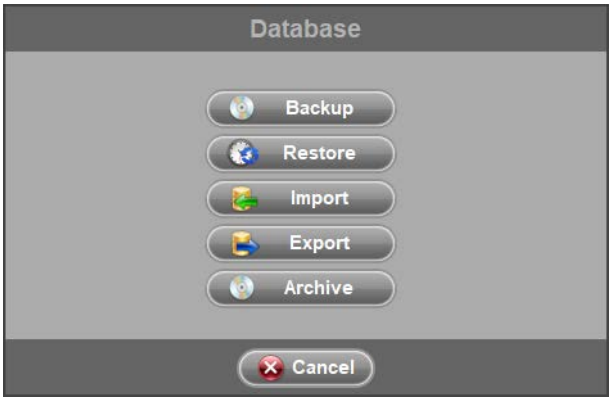
NOTE: The DICOM Import described here uses multiple files to import. To modify DICOM Import by itself, check DICOM Import under View.

iv. **GE Database**

i. Copy the text files saved in the Database Export step to your PC.

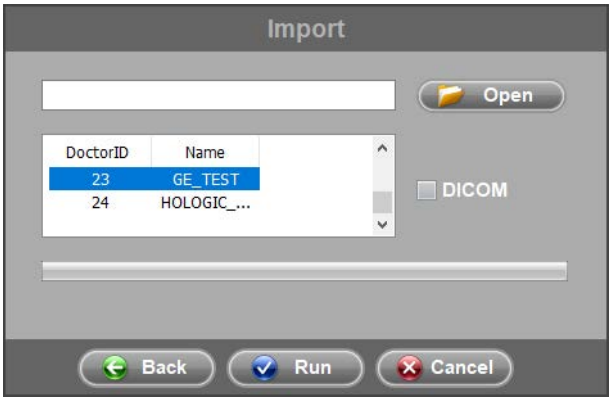
ii. Click Database on the main screen.

iii. In the window that appears, click Import.



iv. Click the GE button.

v. Make sure there is no check mark in the DICOM check box, and select the doctor that will be responsible for the imported data.



vi. Click the Open button.

vii. In the file selection window that appears, specify one copied text file.

viii. Click the Run button to proceed with the import. It may take a long time to proceed.

ix. When the import is complete, click the Finish button.

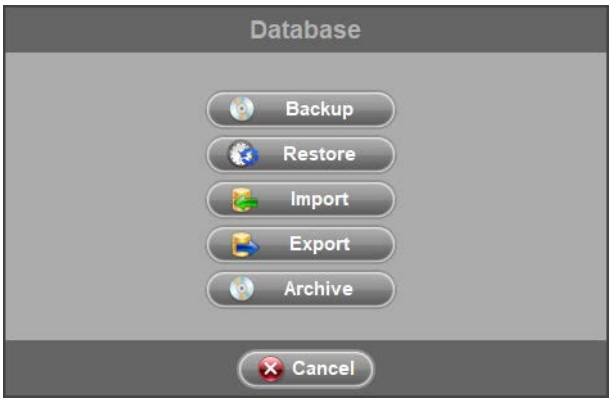
x. Repeat steps 2 through 9 for the remaining text files in the same manner.

v. **GE DICOM Files**

i. Copy the DICOM files saved in the DICOM Files Export step to your PC.

ii. Click Database on the main screen.

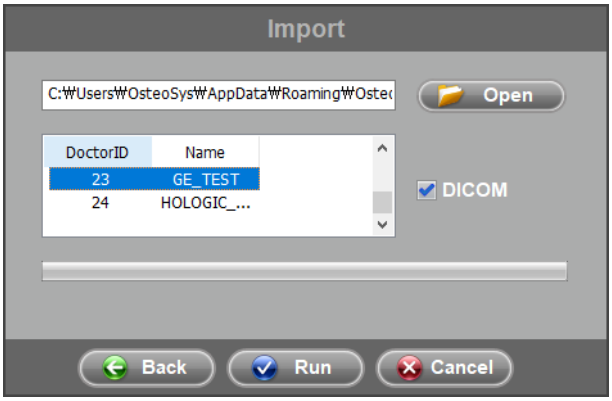
iii. In the window that appears, click Import.



iv. Click the GE button.

v. Modify the DICOM check box so that a check mark appears.

vi. Select the doctor who imported the GE Database.



vii. Click the Open button to select the directory where the GE DICOM file is stored. If you have imported GE DICOM data from the same PC, select the default directory.

viii. Click the Run button to proceed with the import. It may take a long time to proceed.

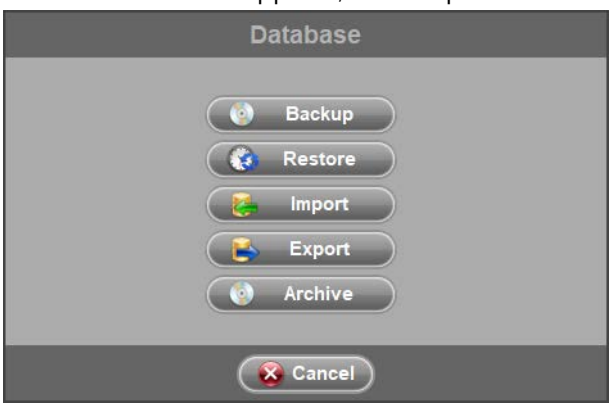
ix. When the import is complete, click the Finish button.

vi. **HOLOGIC Database**

i. Copy the Patient Database saved in the Database Export step to your PC.

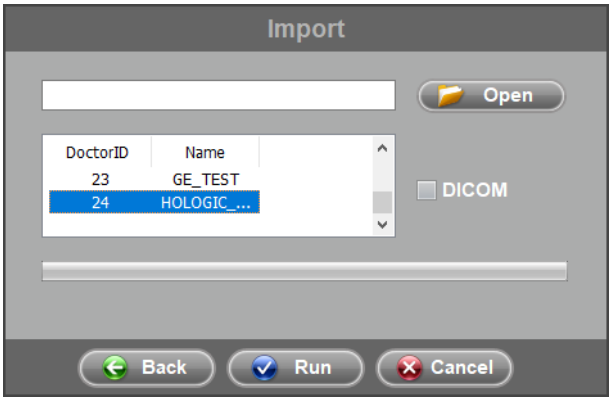
ii. Click Database on the main screen.

iii. In the window that appears, click Import.



iv. Click the HOLOGIC button.

v. Make sure there is no check mark in the DICOM check box, and select the doctor that will be responsible for the imported data.



vi. Click the Open button.

vii. In the file selection window that appears, specify the copied Patient Database.

viii. Click the Run button to proceed with the import. It may take a long time to proceed.

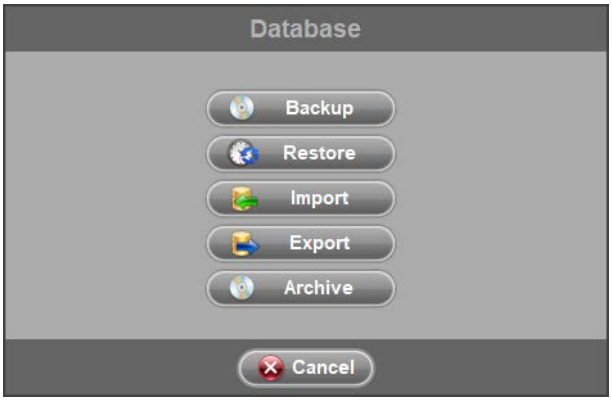
ix. When the import is complete, click the Finish button.

vii. **HOLOGIC DICOM Files**

i. Make a folder on your PC and copy the DICOM files saved in the DICOM Files Export step. If you have imported HOLOGIC data from the same PC, you do not need to process it.

ii. Click Database on the main screen.

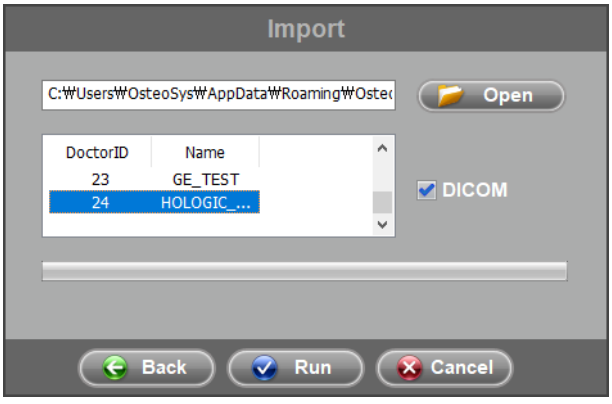
iii. In the window that appears, click Import.



iv. Click the HOLOGIC button.

v. Modify the DICOM check box so that a check mark appears.

vi. Select the physician from which you imported the HOLOGIC Database.



vii. Click the Open button to select the directory where the HOLOGIC DICOM file is stored. If you have imported HOLOGIC DICOM data from the same PC, select the default directory.

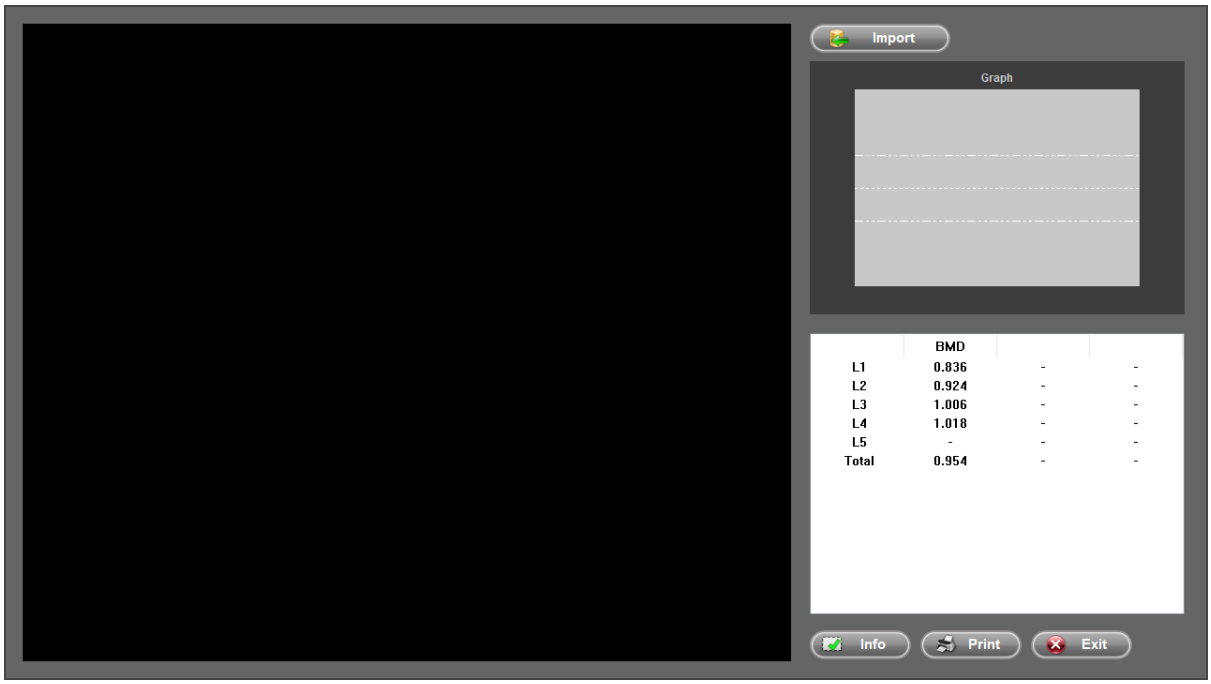
viii. Click the Run button to proceed with the import. It may take a long

time to proceed.

ix. When the import is complete, click the Finish button.

viii. **View**

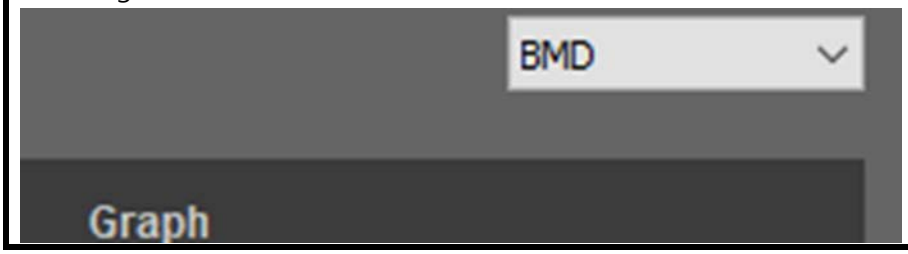
i. After the import, the patient data and the measurement data have been added to the program. Select the imported measurement data and the following window will appear.



ii. The following six operations are available in other company data view windows.

1. Check the data imported from the database
2. Check the trend of data imported from the database
3. Check the image imported from the DICOM file
4. Print the image imported from the DICOM file
5. Check for additional data imported from DICOM files
6. Import a Single DICOM File

NOTE: Total Body can be checked the BMD or Composition data by switching the notation.



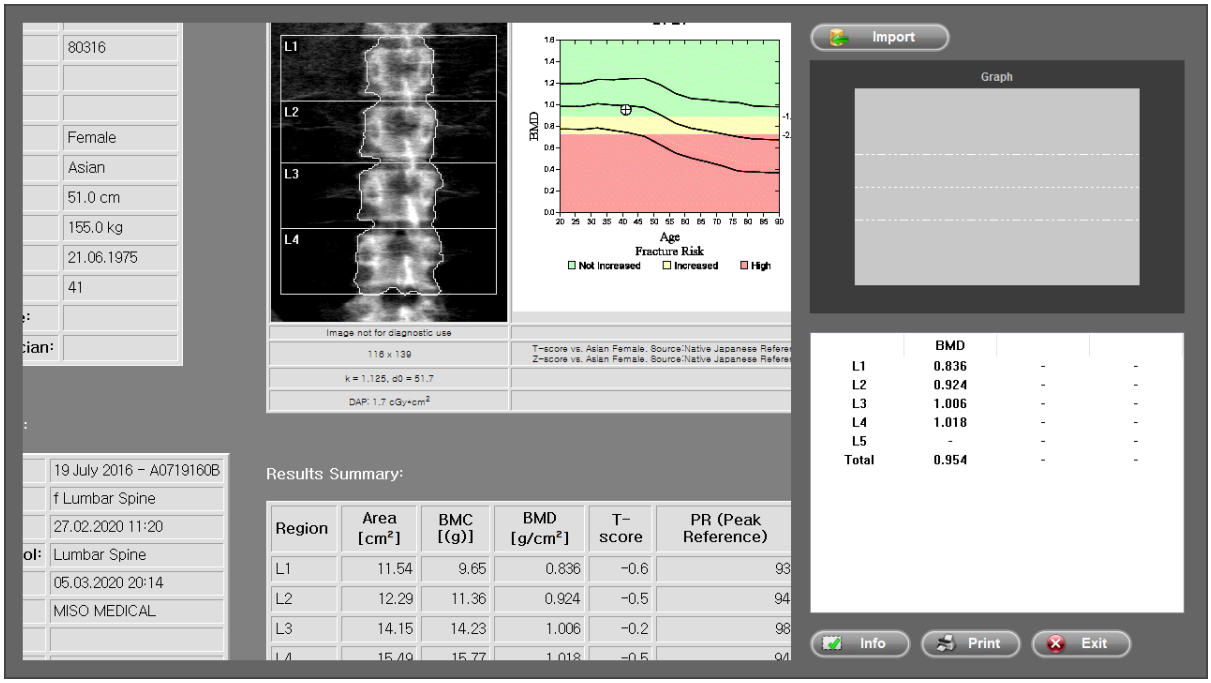
NOTE: Trend currently only supports BMD

i. Check the data imported from the database
ii. You can check the data imported from the database in the table below the trend graph.

iii. Check the trend of data imported from the database
iv. If you select the data in the table, you can check the trend of the region in the graph.

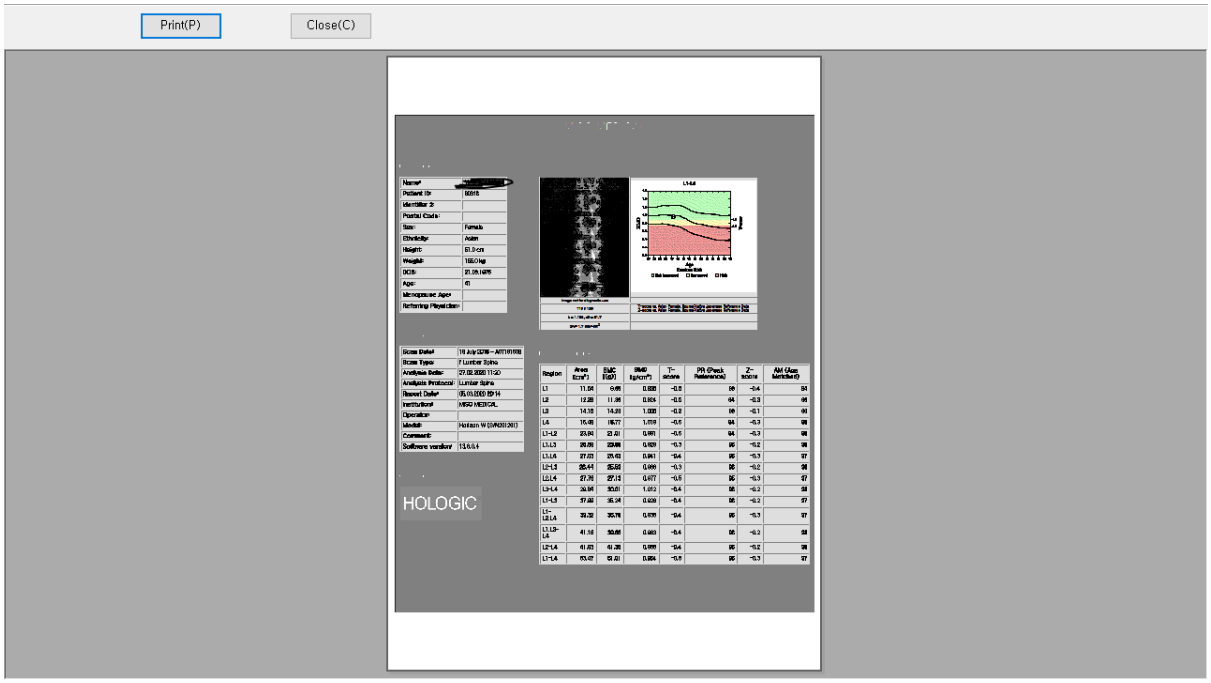
NOTE: Trend currently only supports BMD

i. Check the image imported from the DICOM file
ii. The image is displayed in the area to the left of the trend graph. You can check the image by dragging the image area.



iii. Print the image imported from the DICOM file

iv. Click the Print button when the image is displayed. You can then print the image as shown below.



v. Check for additional data imported from DICOM files

vi. If there was additional information in the DICOM data, the data is displayed when you click the Info button.

vii. Import a Single DICOM File

viii. To represent another DICOM file in the data you are viewing, do the following:

1. Click the Import button.
2. Select the DICOM file to import.

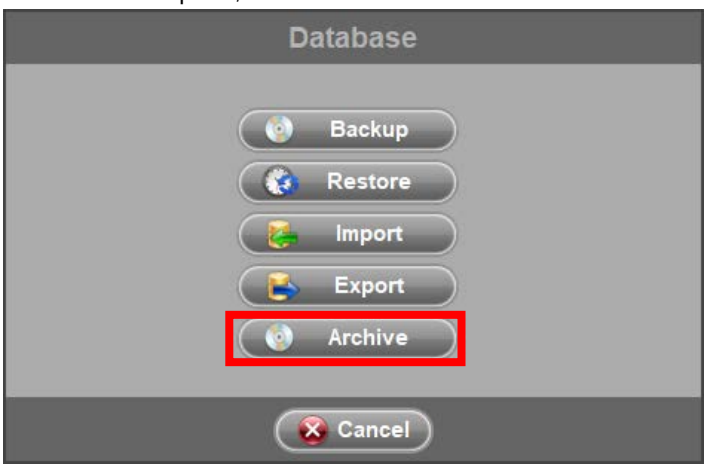
ix. After importing the DICOM file, the image is replaced with the imported image.

6.8.3 Archive.

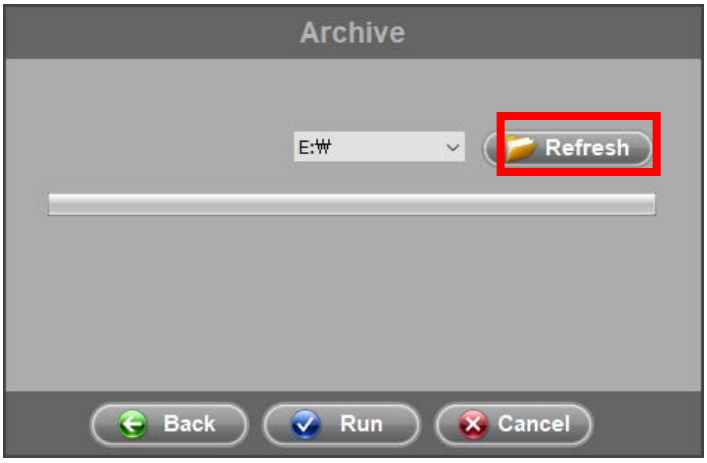
- You can copy or move all the measurement data and patients data in HDD onto Archive direction (CD/DVD).

a. Select Database menu in the main screen.

b. When the window opens, click Archive button.

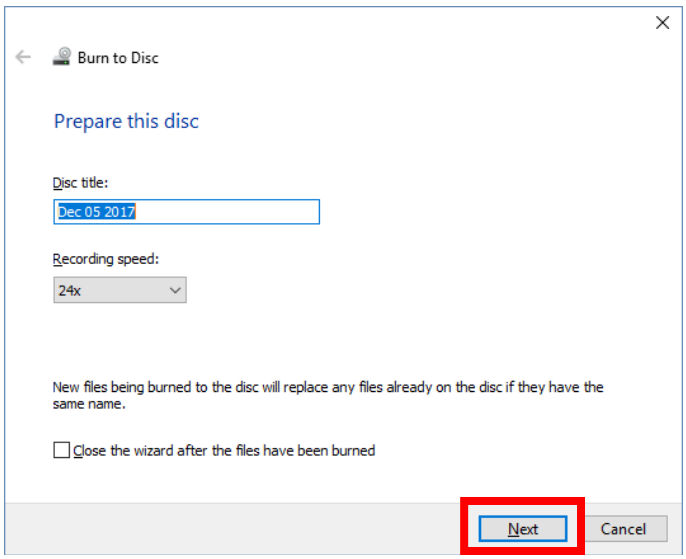


c. When Save dialog box opens, save it in a basic file name or user file name.

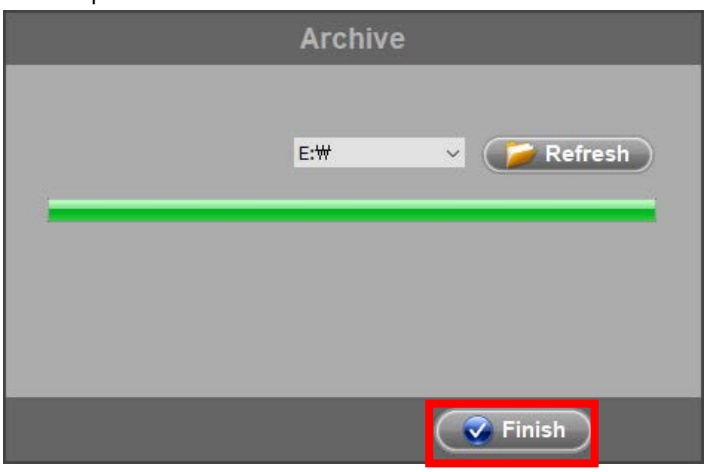


d. Basic file saving path is [DVD RW].

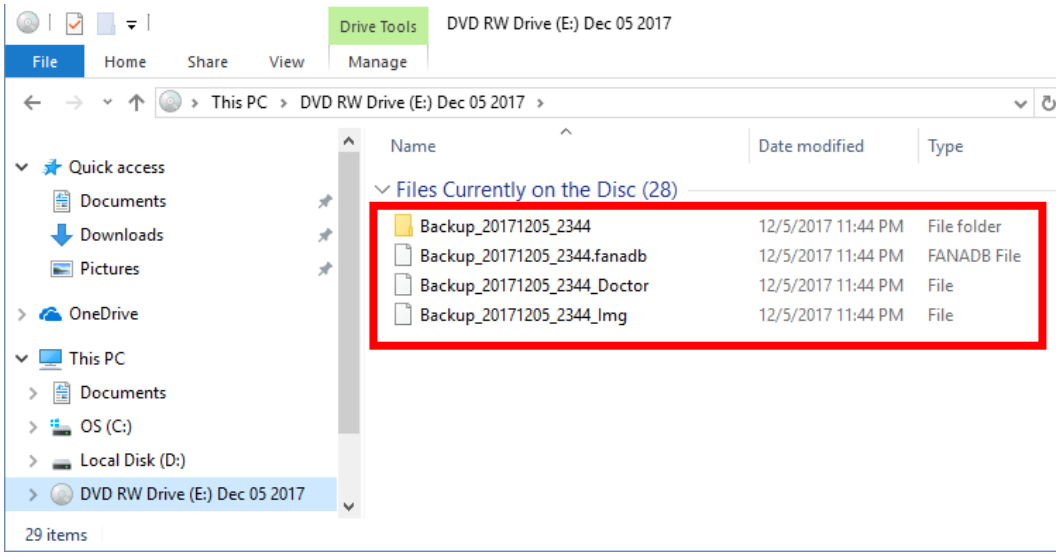
e. Set the file name and click 'Save' to save the file.



f. Go to back up and click Run.



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



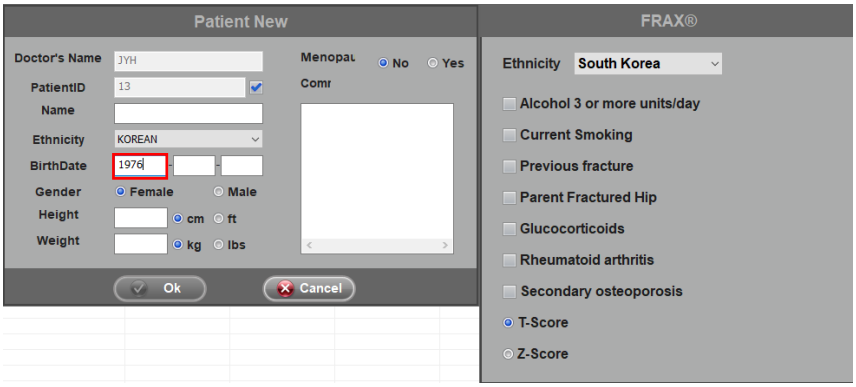
6.9 FRAX

- FRAX is used to predict the patient's fracture risk in 10 years 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, forearm, femur, and shoulder
- FRAX is made by WHO (The World Health Organization) to evaluate fracture risk. Therefore, you can get the same information from the website below. http://www.shef.ac.uk/FRAX/

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

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

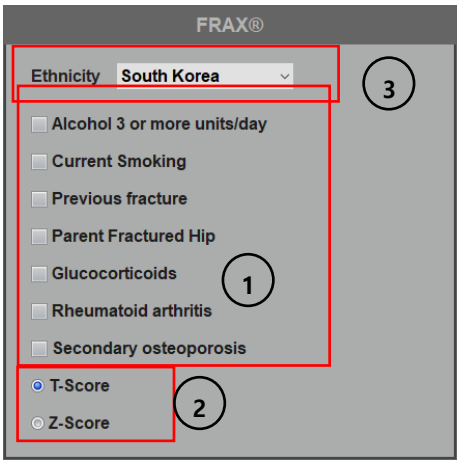
FRAX window is activated when the patient is 40 years or more after the data input, you can enter the FRAX information.



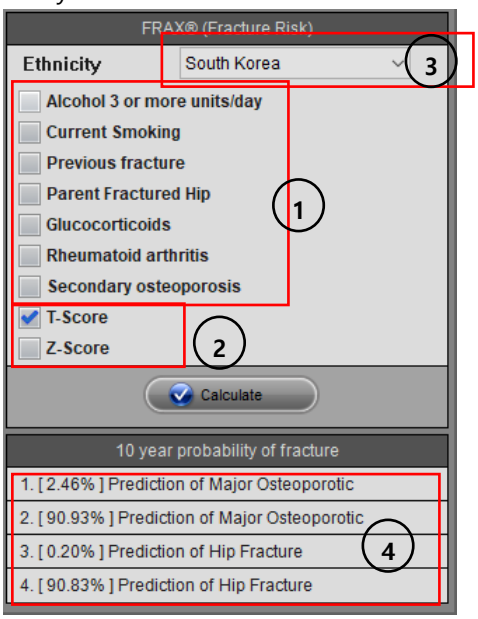
b. In case of analysis, go to Femur column and click HA tab and write FRAX information.

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 as below

i. Alcohol 3 or more units/day

If you drink more than three cups of drink per day, 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 here means the fracture occurs after being adults or the fracture that normal healthy people usually don't get.

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

v. Glucocorticoids
Check if you took Glucocorticoids more than three months or if you are taking oral glucocorticoids now. If you take Prednisolone more than 5mg per day, check it as well.

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 period, hypogonadism, early menopause, chronic malnutrition or malabsorption, chronic liver disease, etc: these diseases can be the example of 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 the risk factors that you checked.

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

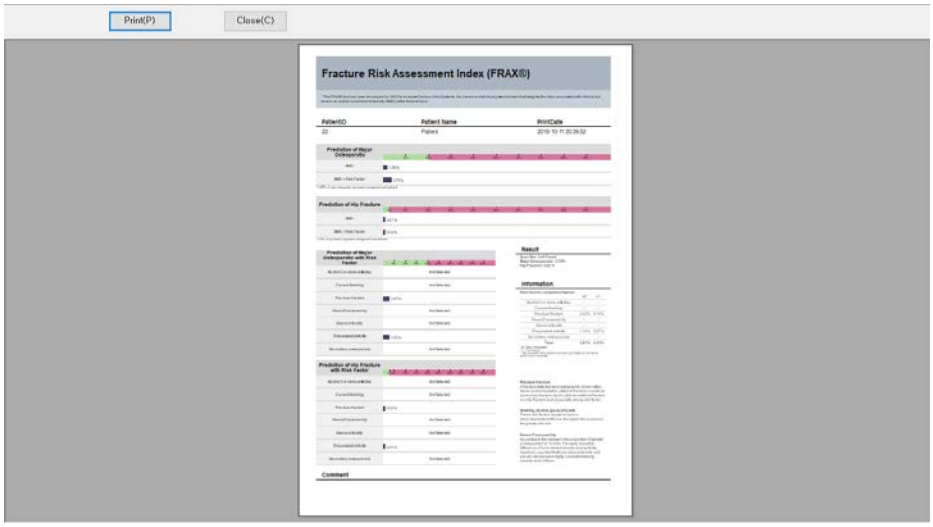
ii. Prediction of hip fracture (BMD)
It indicates the calculated probability of hip fracture with the value of BMD.

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 PRIMUS-related documents

7.1 PRIMUS detail specifications

Category	Description	Note
Main body		
Manufacturer	OsteoSys	
Model name	PRIMUS	
Grade and type	Class 1, B type device	
Product size	2790(W) x 1075(D) x 1255(H)mm or 2100(W) x 1078(D) x 1246(H)mm	
Weight	195kg or 165kg	
Input voltage and frequency	100-120/ 220-240 V~, 50/60Hz	
Power consumption	700VA	
Expiration date	Semi-permanent	
Max. loading weight	230kg	
System Max. Tube voltage	83kV	
Detector cover attaenuation rate	≤ 0.3mmAl	
X-ray generator(HTB-1003)		
Max. tube voltage	90kV	
Max. tube current	3.0mA	
Input voltage and frequency	100-120 / 220-240 V~, 50/60Hz	
X-ray tube(OPX/105)		
Max. tube voltage	120KV	
Max. tube current	15mA	
Lowest Currnet Time product	1mAs (0.2mA, 5seconds)	
Focal spot size (NOMIAL)	0.5mm	
Cathode	Tungsten filament	
Anode angle	5°	
SID Distance	660mm ±5%	
Nominal X-ray output	83kV *3mA = 249W	
X-ray generator(Q1AA-030)		
Max. tube voltage	90kV	
Max. tube current	3.0mA	
Input voltage and frequency	100-120 / 220-240 V~, 50/60Hz	
X-ray tube(DF-151SBR)		
Max. tube voltage	110KV	

Max. tube current	15mA	
Lowest Currnet Time product	1mAs (0.2mA, 5seconds)	
Focal spot size (NOMIAL)	0.5mm	
Cathode	Tungsten filament	
Anode angle	16°	
SID Distance	660mm ±5%	
Nominal X-ray output	83kV *3mA = 249W	
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%	
Reproducibility of BMD&FAT	≤1.5 CV% (in vitro)	
Accuracy of BMD	± 10 % (Based on BFP)	
Precision of BMD&FAT	≤1.5 CV% (in vitro)	
X-ray radiation time	Spine (about 21 sec)	
Leakage radiation	Below 1 mRem (5m distance)	
Use environment		
Operating temperature	18-27℃	
Optimal humidity	20~80%	
Optimal pressure	800 ~ 1060 Hpa	
Impact	Within 2G in 6 X 10-3sec	
Storing temperature	Above -20℃ below 50℃	
Storing humidity	0% ~ 90%	
PC Specification	Use more than Window 7, LAN, USB 2.0	
Max. Operating time / Min. Rest time	Max. operating time: 5 min. Min. rest time: 3 min.	

7.2 PRIMUS radiation-related documents

7.2.1 Aluminum equivation (PRIMUS' aluminum equivation)

X-ray tube(OPX/105)

Aluminum filter r	2.0mmAL/75kV
X-ray tube inner filtration	0.5mmAL/75kV
Total Filtration Equivalence	**2.5mmAL/75kV**

X-ray tube(DF-151SBR)

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

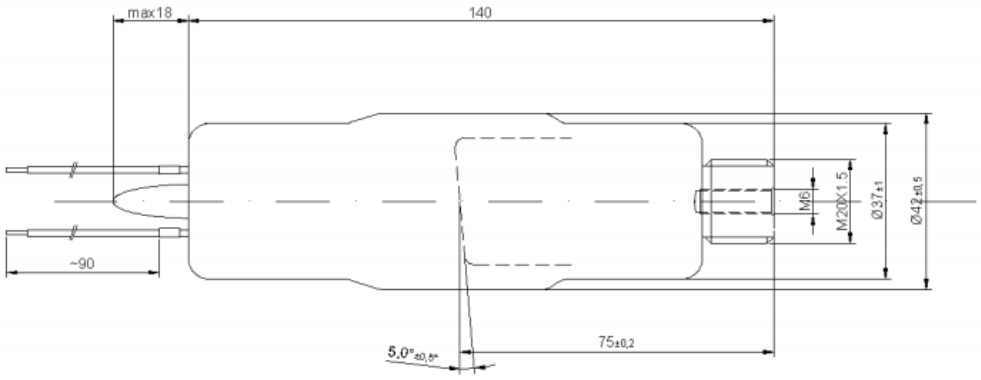
7.2.2 Radiation amount leaked outside

PRIMUS' radiation amount leaked outside is shown below:

Set up HFG : 83Kv , 3.0mA

3) Tube specification

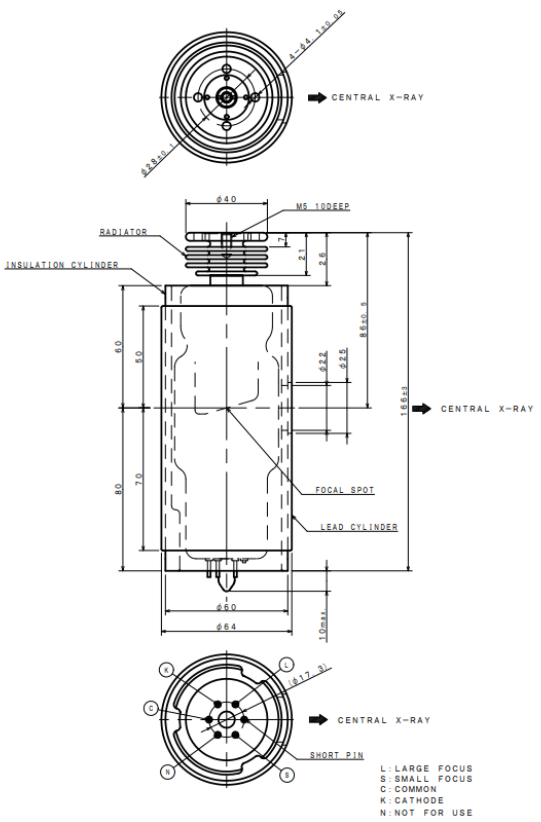
X-ray tube(OPX/105)



Weight: about 1250g

X-ray tube(DF-151SBR)

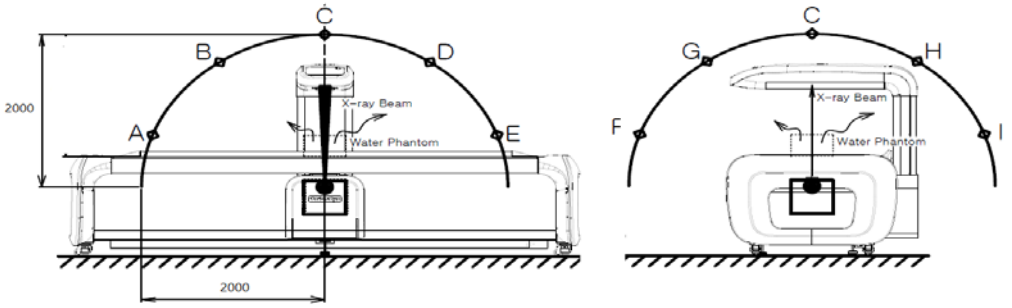
Unit: mm



Weight: 1250g

※ PRIMUS does not require any external shielding

NO	Position	Value of measured scatter radiation(uSv/hr)
1	A	3.18 uSv/hr
2	B	1.56 uSv/hr
3	C	1.35 uSv/hr
4	D	3.15 uSv/hr
5	E	6.16 uSv/hr
6	F	8.34 uSv/hr
7	G	4.22 uSv/hr
8	H	1.38 uSv/hr
9	I	0.71 uSv/hr

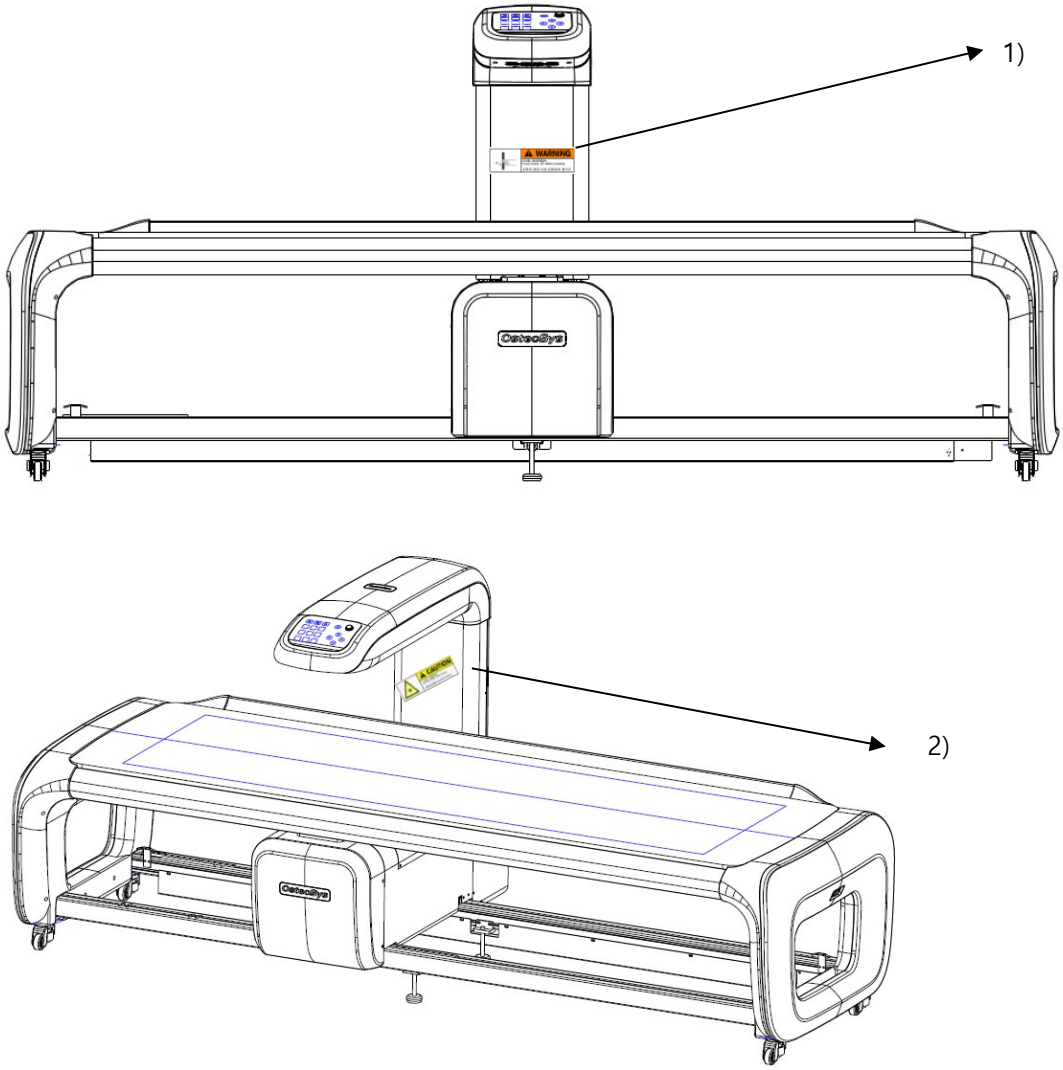


Quantitative information (X-ray)

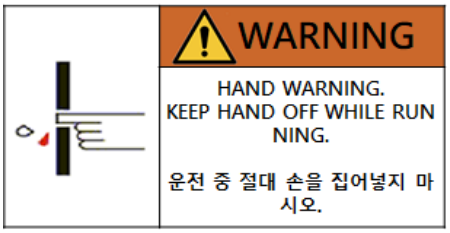
ROI	Scan time (s)	Acrylic thickness (cm)	Tube current (mA)	Dose (uGy)	uGy/s	Absorbed dose	Absorbed dose per unit area
AP spine	20	10	0.2	2.20	0.11	2.09	359.79 uGy/m²
			1.0	11.96	0.60	11.36	1955.93 uGy/m²
			3.0	28.02	1.40	26.62	4582.37 uGy/m²
Femur	13	10	0.2	1.37	0.11	1.26	217.70 uGy/m²
			1.0	8.22	0.63	7.59	1306.20 uGy/m²
			3.0	22.94	1.76	21.18	3645.27 uGy/m²
Dual Femur	26	10	0.2	2.70	0.10	2.60	446.92 uGy/m²
			1.0	15.73	0.61	15.13	2603.72 uGy/m²
			3.0	46.30	1.78	44.52	7663.84 uGy/m²
Forearm	12	5	0.2	1.13	0.09	1.04	178.32 uGy/m²
			1.0	6.68	0.56	6.12	1054.11 uGy/m²
			3.0	19.33	1.61	17.72	3050.30 uGy/m²

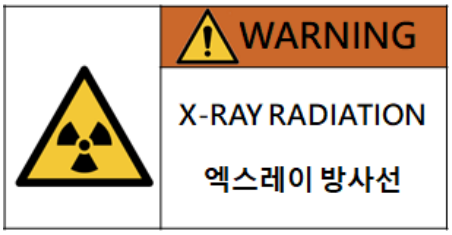
7.3 Labels

- Locations of the labels are as follows:



1) Hand warning label and X-RAY warning label

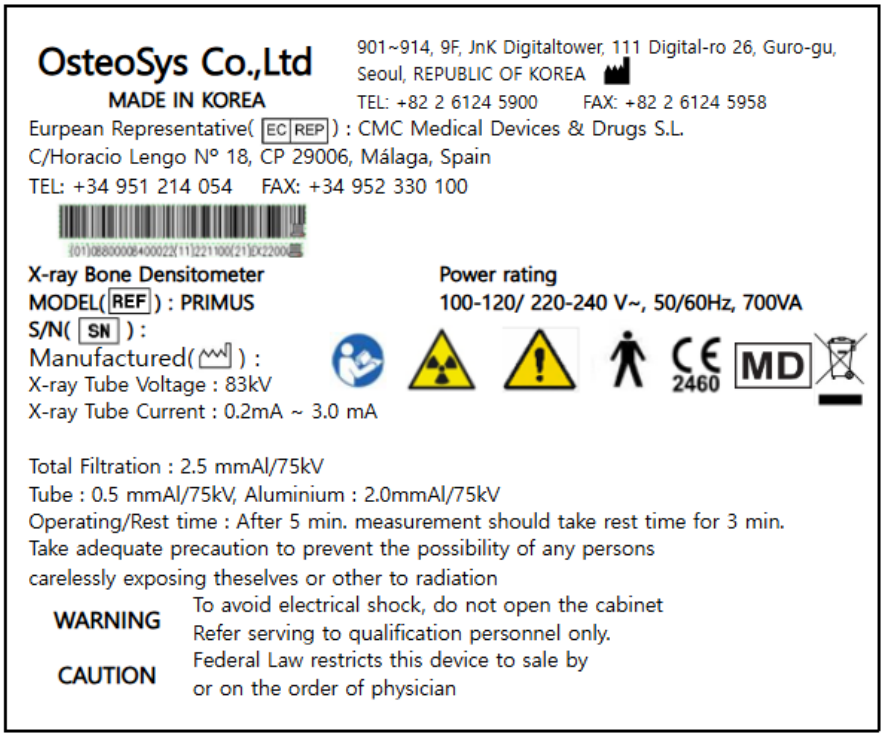




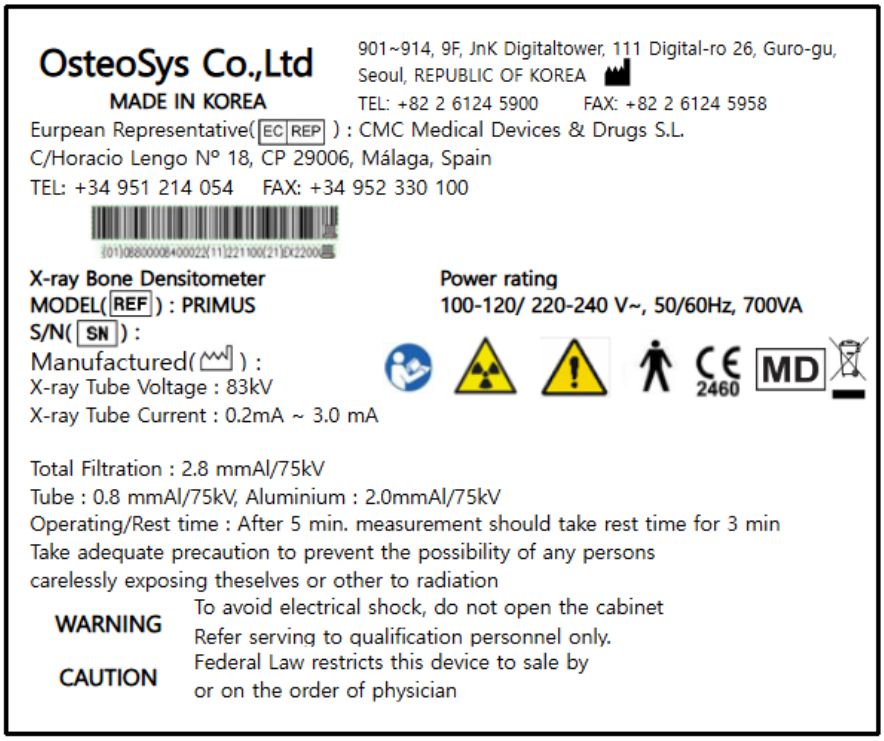
2) Laser pointer caution label

3) Equipment label(English)

X-ray tube(OPX/105)



X-ray tube(DF-151SBR)



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 26124 5958, or contact your local agency or store at +82 26124 5900.
  For immediate service, please provide the following information or let us know the problem of your equipment.

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

OsteoSys (sign/seal)

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.

Note: