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GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC, a General Electric company, doing business as GE Healthcare.

Indications for use: The Lunar iDXA Bone Densitometer provides an estimate of bone mineral density and fat and lean tissue mass. The values can then be compared to a reference population at the sole discretion of the physician.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

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GE Healthcare

iDXA

Innovation and dedication

Healthcare Re-imagined

GE is dedicated to helping you transform healthcare delivery by driving critical breakthroughs in biology and technology. Our expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, and biopharmaceutical manufacturing technologies is enabling healthcare professionals around the world to discover new ways to predict, diagnose and treat disease earlier. We call this model of care "Early Health." The goal: to help clinicians detect disease earlier, access more information and intervene earlier with more targeted treatments, so they can help their patients live their lives to the fullest. Re-think, Re-discover, Re-invent, Re-imagine.

To receive Lunar News online, please register for SmartMail. Go to www.gehealthcare.com and click on the SmartMail icon and complete the registration form. Select online newsletter, select BMD, click submit and you will automatically receive the newsletter.



We uphold a clear vision of innovation.

GE Healthcare, Lunar is dedicated to the fight against osteoporosis – and has been for the past 30 years.

Our high level of customer satisfaction is achieved through delivering clinically relevant features and productivity enhancements to bone densitometry. In fact, 6 out of 10 customers choose Lunar bone densitometry over other vendors.¹

Bone densitometry re-imagined

A focused team coupled with the passion for innovation. Stunning image clarity, advanced diagnostic capabilities and workflow efficiencies make the Lunar iDXA™ a prime example of GE Healthcare's breakthrough strategy with an emphasis on image quality, ease of use, precision and productivity.

Technology at its best

The distance of a patient's spine or femur from the tabletop may vary considerably due to the wide range of body sizes. This can cause inaccurate bone measurements. The Lunar iDXA's narrow-angle fan-beam technology with Multi-View Image Reconstruction (MVIR) eliminates the distortion effects seen in non-Lunar fan-beam densitometers. This CT-like image reconstruction measures the true size and area of the anatomy without making geometric or dimensional assumptions – your guarantee for excellent precision and accuracy.

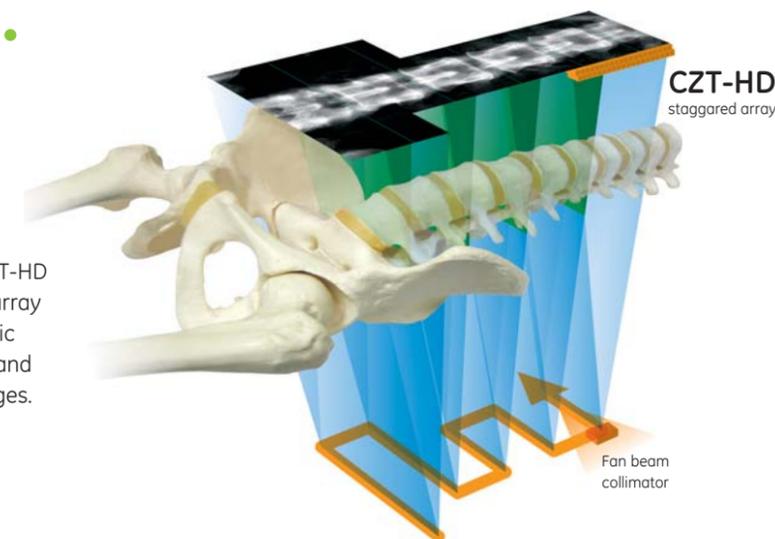


Precision you can detect

Osteoporosis treatment requires time to monitor. The Lunar iDXA provides quick detection of bone changes with high-definition precision due to the Cadmium Zinc Telluride (CZT-HD) detector. Lunar's proprietary calibration technology takes the entire body into account with low, normal and high BMD values, as well as lean, normal and obese %fat values.

Going digital

The Lunar iDXA's newly-patented direct-digital CZT-HD detector with staggered array provides near-radiographic image quality for clearer and crisper densitometer images.



Design

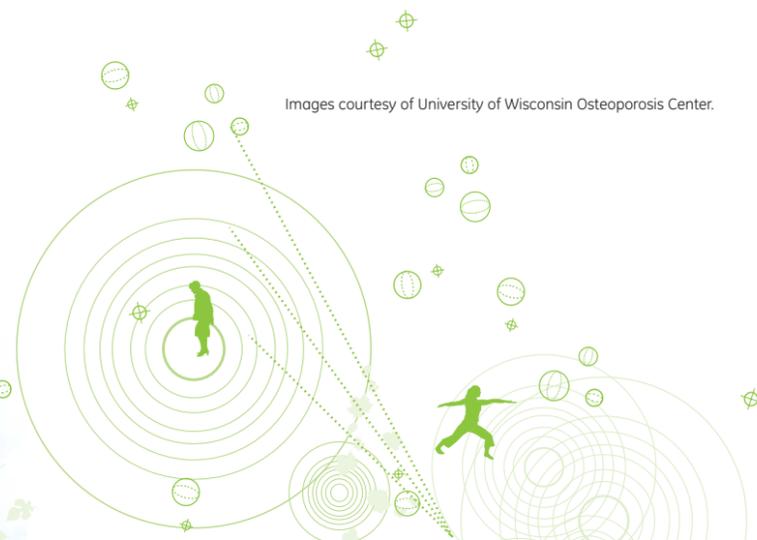
iDXA's open architecture and larger table accommodate patients up to 450 lbs (205kg) and allow for easy positioning of tall and or heavy patients.



Precision (%CV) for BMD and Body Composition

Region	Mean	CV
Femur Neck BMD (g/cm ²)	0.936	1.4%
Total Femur BMD (g/cm ²)	0.998	0.7%
Spine L1-L4 BMD g/cm ²	1.184	1.1%
Total Body BMD (g/cm ²)	1.142	0.5%
Total Body BMC (g)	2586	0.5%
Total Body Area (cm ²)	2248	0.7%
Total Body %Fat	35.8%	0.8%
Total Body Fat (g)	25345	0.8%
Total Body Lean (g)	44283	0.5%

* Abstract from Evaluation of Precision and Accuracy of the Lunar iDXA Fan-Beam Densitometer. KG Faulkner, WK Wacker, JR Franz, KP Riewe, HS Barden, GE Healthcare, Madison, WI, USA. Presented at the International Osteoporosis Foundation World Congress on Osteoporosis, Toronto, Canada, June 2006.



The more you see, the more you know.

The Lunar iDXA delivers crisp, high-resolution images of all skeletal sites, including total body images. End plates on spine images are clearly rendered to easily identify intervertebral spaces. The higher resolution enhances proximal femur details, and aids in visualization of cortical thickness.



"The biggest advancement with the iDXA is the improved image resolution over previous GE Lunar densitometers. By having clearer pictures of the skeleton, you can be more accurate in placement of regions of interest during scan analysis. This is important in the accuracy of diagnosis and for comparison with previous tests.

Secondly, with the remarkable image resolution it provides, the iDXA will be very helpful in using vertebral fracture assessment to diagnose spine fractures. Our experience has also demonstrated that the BMD results obtained with iDXA are similar to those measured with GE's current DXA technology. This allows you to upgrade from other densitometers to take advantage of the improved image resolution without having to re-calibrate or re-calculate the bone density results."

– Michael R. McClung, MD, bone clinician and researcher and founding director of the Oregon Osteoporosis Center in Portland, OR.

Extensive collaboration with renowned bone researchers and clinicians around the globe has led to the development of our comprehensive clinical applications that help the everyday users of bone densitometry to better diagnose osteoporosis and assess fracture risk in their patients.

Dual-energy Vertebral Assessment (DVA)

DVA aids in the diagnosis and assessment of vertebral deformations. DVA provides a rapid, dual-energy image of the AP and lateral spine, allowing clinicians to visually assess the presence of vertebral deformations.

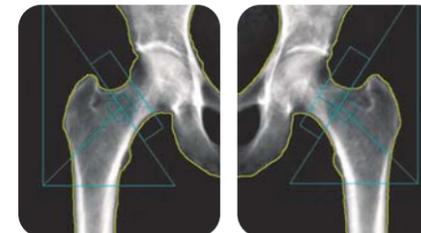
Advanced Hip Assessment (AHA)

AHA includes all of the standard femoral regions of interest previously available, plus additional key measurements including Hip Axis Length (HAL).



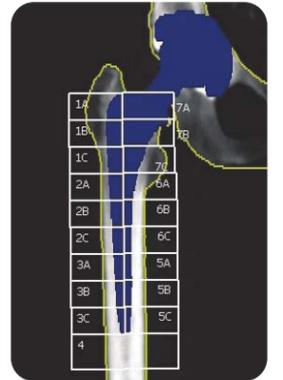
DualFemur

The DualFemur option automatically scans both femurs in one seamless acquisition without repositioning the patient. This critical hip region assessment identifies the weakest side to enhance confidence in your treatment decisions. The trending function enables seamless follow-up of changes over time.^{2,3,4}



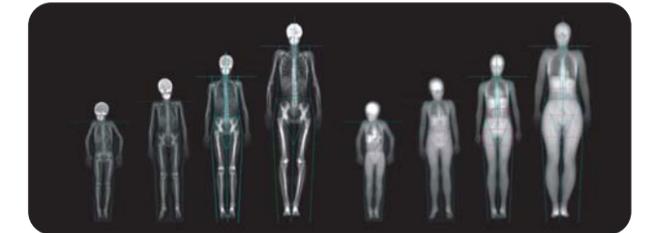
Orthopedic

The orthopedic application provides accurate and precise bone mineral density and bone mineral content values. Bone assessment in the vulnerable region surrounding an implant is now possible. This application also enables automated bone assessment of the hip implant using standard Gruen zones (7 zones) and extended Gruen zones (19 zones) to provide better evaluation for practitioners and clinical researchers specialized in the fields of orthopedics and surgery.



Pediatric

The pediatric application measures lean mass, fat mass, and bone to help you monitor growth and development in children.



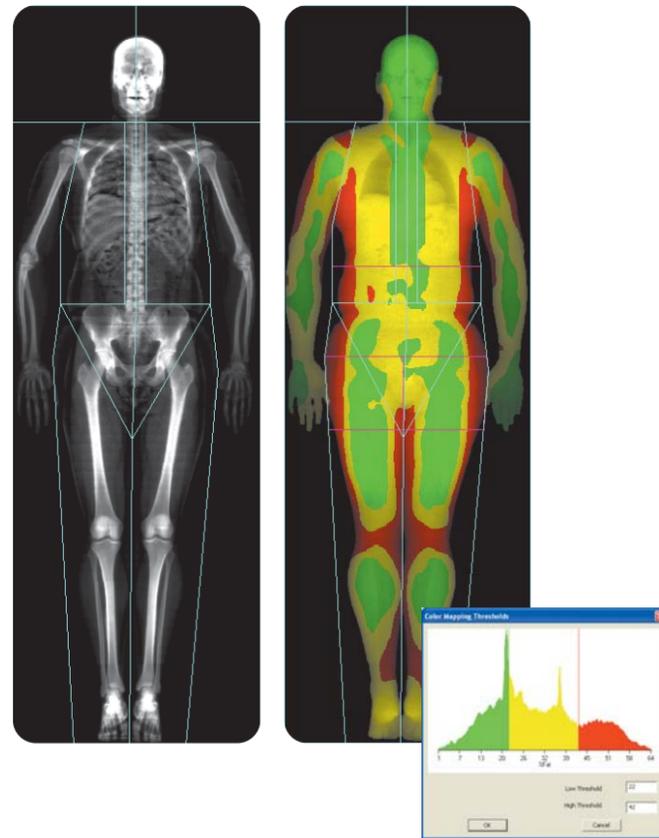
Body composition

Accurate measurement of body composition can provide valuable information for assessing, monitoring and treating a variety of diseases and disorders.

Clinicians today consider dual-energy X-ray absorptiometry (DXA) to be exceptional for measuring body composition because it accurately shows exactly where fat is distributed throughout the body. Lunar DXA systems directly measure and calculate total fat, lean and bone tissue instead of only estimating body composition.

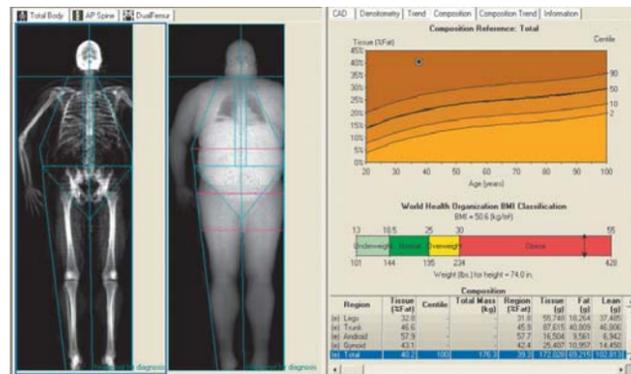
Most people are used to stepping on a scale at every visit to a doctor's examining room. But monitoring weight – while helpful – is at best a crude and imprecise way to assess a patient's health. Today's body composition measurement tools provide far more complete and precise information that can help support diagnoses and guide treatment, and can even help athletes make decisions on the training regimens they use to achieve the best performance. Body composition measurement with DXA can look beyond weight and traditional body mass index (BMI) to determine body fat distribution – an important risk factor in a variety of serious diseases. Information from DXA exams can prove valuable in conditions such as:

- Obesity
- Anorexia nervosa
- Wasting syndrome (caused by HIV/Aids)
- Cystic fibrosis
- Chronic renal failure



MirrorImage™

- MirrorImage increases the iDXA scan window virtually by 50%
- The patient is positioned with one half of the body fully in the scan window
- MirrorImage automatically estimates the body composition of the portion of the patient outside the scan window by doubling the imaged side.



Precision of Lunar iDXA Total Body BMD and Composition Measurements on Obese Subjects

R Huizenga¹, HS Barden², MK Oates³
¹Cedars Sinai Medical Center, Los Angeles, CA; ²GE Healthcare, Madison, WI; ³Santa Maria, CA
 Excerpt from poster presented at ISCD Annual Meeting; March 2007, Tampa, FL, USA.

Subject characteristics: mean values

n	Age (yr) [range]	Height (cm) [range]	Weight (kg) [range]	BMI [range]	Total %Fat [range]
29	33.4 [22.1 – 53.9]	173.5 [157.5 – 193.8]	132.8 [95.7 – 184.7]	43.6 [36.2 – 54.4]	46.7% [37.7 – 53.6]

Precision error (%CV) for BMD and body composition

Measurement	%CV
BMD (g/cm ²)	1.08%
BMC (g)	1.00%
Fat Mass (kg)	1.22%
Lean Mass (kg)	0.95%
%Fat (Tissue)*	0.78%
%fat (Region)**	0.78%

* %Fat (Tissue) = fat/(fat + lean) ** %Fat (Region) = fat/(fat + lean + BMC)

“Lower precision error improves confidence in clinical decision-making and minimizes the time necessary to detect a significant change in an individual. We conclude that iDXA precision was excellent, despite the known challenges of scanning very obese subjects. With the increasing incidence of obesity in society, the higher table weight limit and wider patient portal on the iDXA system combined with excellent precision make this system a valuable tool in the measurement of body composition in larger individuals.”

Precision Evaluation of Lunar iDXA Body Composition Measurements

E. Toussiro¹, C. Semon², F. Penforis², D. Wendling¹
¹Department of Rheumatology, University Hospital Jean Minjot, Besançon, France, ²Department of Endocrinology, University Hospital Jean Minjot, Besançon, France
 Excerpt from poster presented at ASBMR Annual Meeting; September 2007, Honolulu, HI, USA.

Mean values and precision error (%CV) for BMD and body composition

Measurement	Mean	%CV
BMD (g/cm ²)	1.065	0.56%
BMC (g)	2318	0.57%
%Fat (Tissue)	38%	0.63%
Fat Mass (kg)	28.78	0.59%
Lean Mass (kg)	42.78	0.45%

“Clinical decision making is considerably improved by lower precision error, because the time necessary to detect a significant change in an individual is minimized. Despite scanning obese subjects, we conclude that the Lunar iDXA provided excellent precision for total body measurements, including BMD, BMC and body composition. This system proved to be a valuable tool in the measurement of body composition in individuals in the normal and higher weight range.”

Indications for use: The GE Lunar Body Composition Software option (body composition) used on GE Lunar DEXA bone densitometers measures the regional and whole body bone mineral density (BMD), lean and fat tissue mass and calculates derivative values of bone mineral content (BMC), area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional/total soft tissue mass ratio, %fat, region %fat, total body %fat, Android %fat, Gynoid %fat, Android/Gynoid ratio (A/G ratio) and Body Mass Index (BMI). The values can be displayed in user-defined statistical formats and trends with color image mapping, and compared to reference populations at the sole discretion of the health care professional.

These body composition values are useful to health care professionals in their management of diseases/conditions where the disease/condition itself, or its treatment, can affect the relative amounts of patient fat and lean tissue. The GE Lunar Body Composition Software option does not diagnose disease, or recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make these judgements. Some of the diseases/conditions for which body composition values are useful include chronic renal failure, anorexia nervosa, obesity, AIDS/HIV and cystic fibrosis. DEXA body composition is a useful alternative to hydrostatic weighing and skin fold measurements.



Watching children grow: Pediatric analysis tools

Innovation and dedication

Now you can use one powerful set of tools to get valuable clinical information about growth and development in children. The Lunar DXA pediatric application measures more than BMD. It analyzes all three tissue types – lean mass, fat mass, and bone – to help monitor growth and development in children. The Lunar DXA pediatric application comes to you from GE Healthcare, the world's leading provider of densitometry solutions.⁵

Accurate assessment, reliable trending

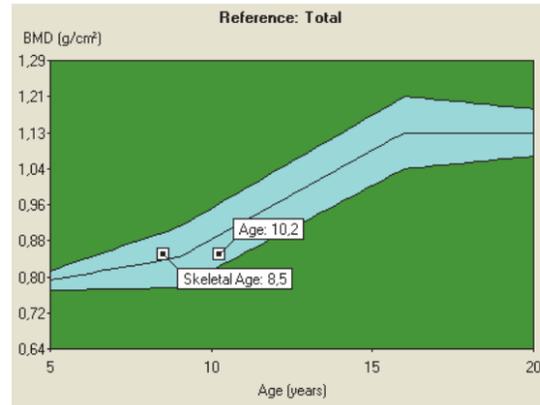
Children grow at unique rates. Our advanced pediatric analysis tools compare skeletal and chronological age analyses and BMD results against gender-specific reference populations.

"Children with growth abnormalities often show deficient BMD for chronological age, but this deficit might be a reflection of growth irregularities rather than poor bone mineralization."⁶

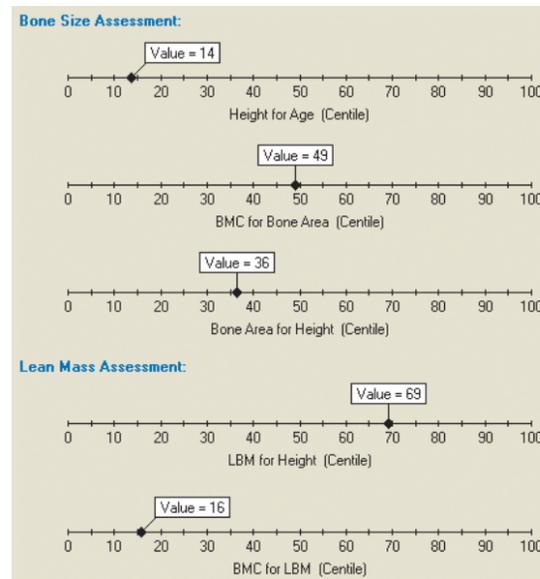
Lunar's DXA pediatric application provides measurements that enable enhanced assessments of growth and development, including:

- Height for age⁷
- BMC for bone area⁷
- Bone area for height⁷
- Lean body mass for height (muscle development)^{8,9}
- BMC for lean body mass (muscle-bone balance)^{8,9}

Exam results provide excellent diagnostic quality information and a comprehensive trending tool, coupled with full reporting and connectivity options.



Age-specific standard deviations provide enhanced diagnostic confidence.^{10,11}

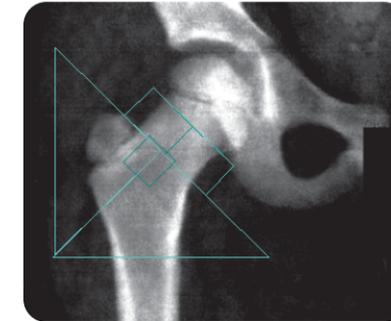


Lunar pediatric assessment

Pediatric applications

AP spine and femur applications provide:

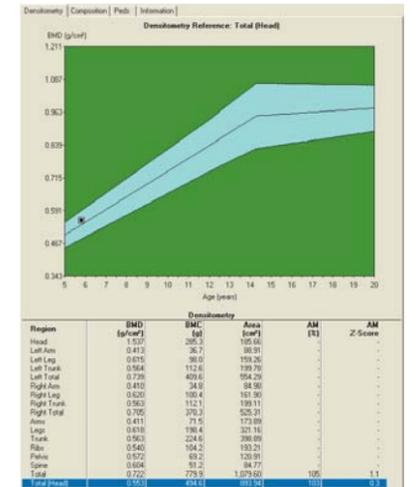
- Rapid scan times at low dose
- Low-density threshold analysis
- User-defined custom analysis tools
- Height-adjusted femoral neck region
- Z-score reference comparison
- Age-dependent standard deviations
- Separate reference populations for boys and girls



Automatic adjustment of femur, based on child's height



Total body pediatric assessment



Densitometry		Composition	
Region	BMD (g/cm²)	Tissue (g/cm²)	Z-Score
Head	1.037	205.3	105.66
Left Arm	0.413	36.7	1.137
Left Leg	0.615	96.0	1.916
Left Trunk	0.864	112.6	1.763
Left Total	0.726	403.6	1.954
Right Arm	0.410	34.6	1.090
Right Leg	0.620	105.4	1.921
Right Trunk	0.963	112.1	1.911
Right Total	0.705	376.3	1.923
Arm	0.411	71.5	1.739
Leg	0.616	198.4	1.921
Trunk	0.963	224.6	1.919
Head	0.940	104.2	1.925
Pat	0.572	63.2	1.911
Spine	0.604	81.2	1.877
Total	0.722	775.9	1.979
Total (Head)	0.755	644.1	1.974

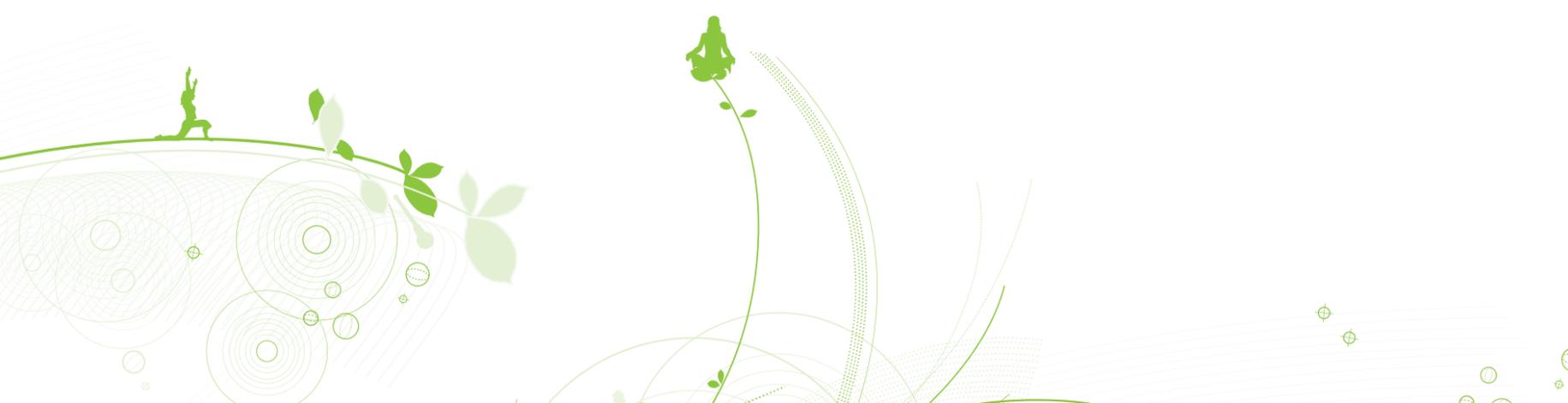


Total body analysis features:

- Automated analysis for bone
- Total and regional fat and lean body composition analysis
- Body size assessments (height for age, bone area for height, BMC for bone area, lean mass for height, and BMC for lean mass)
- Total body and total body without head analysis with reference data

"Growth and illnesses in children do not always follow a standard path. Analyzing a child's body status with skeletal and lean mass parameters enhances our ability to confidently assess bone and lean tissue."

Hans Fors (MD), GP-GRC, Sahlgrenska Academy of Göteborg University, Göteborg (SE)



Vertebral assessment

DVA vs. conventional radiographs

The conventional spine radiograph is today's standard for vertebral assessment. It provides high-quality image resolution enabling you to visualize more vertebrae, mild fractures and other features.¹⁰

However, a DVA performed on the iDXA densitometer offers several key advantages in assessing vertebral fractures:

- Low-dose point of care
- Subtraction of soft-tissue artifacts
- Single- and dual-energy images from a single acquisition



80 year old female, 61 in., 127 lbs.



48 year old male, 67 in., 148 lbs.



77 year old female, 63 in., 117 lbs.
(reverse lateral view)



65 year old female, 66 in., 138 lbs.

A single view of the spine

Conventional radiographs require separate thoracic and lumbar films to adjust for the considerable differences in soft-tissue density between the chest and abdomen.¹⁰ The dual-energy technique utilized by GE Healthcare compensates for these differences to visualize the entire spine (T7-L4) in a single view.

Two views for enhanced assessment

AP view – enhanced visualization of the ribs and pelvis and labeling of vertebral bodies

Lateral view – visual and quantitative assessment using the morphometry wizard

- View single- and dual-energy images in one exam
- Visualize vertebral fractures using single- and dual-energy views
- Reverse VFA for improved visualization

Morphometry

The morphometry wizard automatically labels vertebral deformations by using a six-point measurement of the anterior, posterior and mid-heights of vertebrae.

ClearView filter

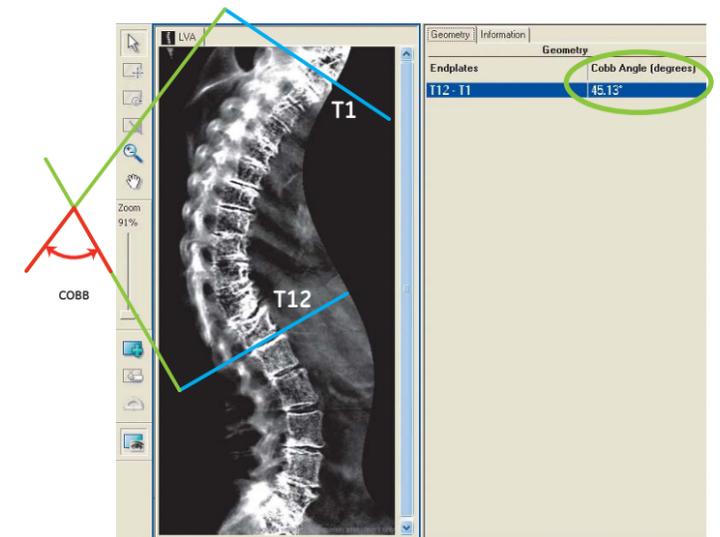
The ClearView filter enhances images by reducing soft tissue noise and improving bone edge detail. The filter is dynamically adjustable as the operator controls the enhancement, with a slide bar for viewing real-time image changes.

Digital acquisition and storage

The fully digital DVA image allows enhanced control for viewing and analysis, and is DICOM compatible for easy electronic storage and access.

iDXA Spine Geometry

The DVA application on iDXA has been enhanced with Cobb angle calculations for spine geometry analysis. The Cobb angle, in degrees, between selected vertebrae is displayed in separate reports that accompany the on-screen and DVA results.

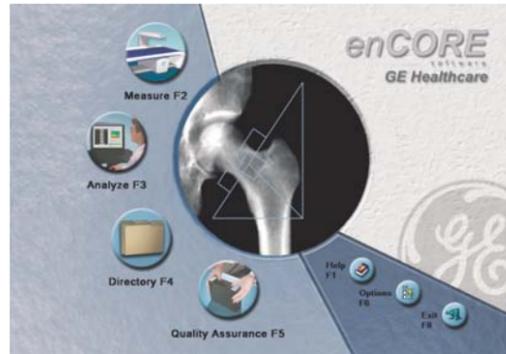


Cobb angle

“High-resolution radiographs are the optimal choice for fracture determination, but are not always easily available. We’ve found dual-energy DVA to be a convenient and rapid alternative to spine X-ray. The dual-energy image is easier to read than single-energy scans, and it can be combined with a bone density exam.”

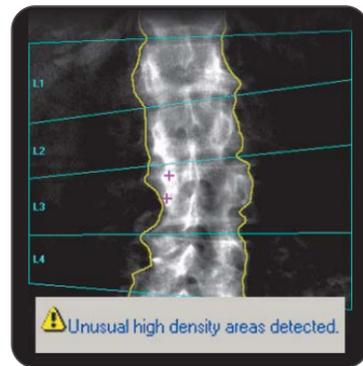
Patrick K. Burke, M.D. - Osteoporosis Diagnostic and Treatment Center, Retreat Hospital, Richmond, Virginia

Automation: So you can focus on the patient



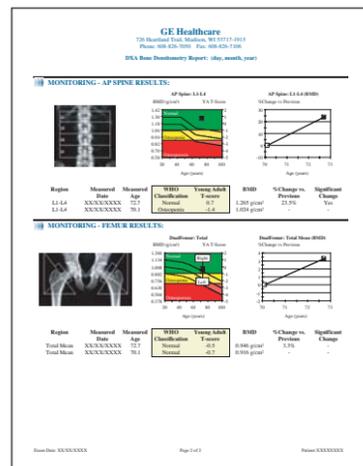
Automate bone density testing with the enCORE user interface

GE Healthcare's Windows®-based enCORE software platform brings speed and automation to today's bone densitometry. In addition, the daily testing of the multi-point calibration coupled with the large reference population database ensures accurate and precise bone assessments.



Save time with Computer-Assisted Densitometry (CAD)

CAD automatically identifies potential acquisition and analysis errors and provides multimedia help. It alerts of incorrect positioning, unusual anatomy, high-density areas and artifacts, and makes recommendations for correction.



Create customized physician reports with Composer™

With clinical diagnosis and treatment decisions based on a variety of criteria and guidelines established by international and local societies,¹¹ it might not always be easy for referring colleagues to interpret multi-page reports. Composer generates concise patient reports including imagery, clinician diagnosis and monitoring assessments, in full accordance with the pre-defined criteria and guidelines in your locality.

Connectivity

- **DICOM¹² and HL7 connectivity** seamlessly integrate densitometry results with Picture Archival and Communication Systems (PACS) and Radiology/Hospital Information Systems (RIS/HIS), respectively.
- The **Worklist feature** in both DICOM and HL7 enables automatic use of patient information from scheduling applications, helping to reduce data entry errors.
- **Multi-User Database access (MUDB)** improves flexibility and productivity by offering the possibility to access and/or reanalyze scans remotely, and to share with clinical partners.
- **TeleDensitometry** provides the ability to send paperless reports as e-mail attachments or faxes that can be viewed on any personal computer.
- **Insite with ExC** is a real-time service that allows remote monitoring "on screen", application support and immediate problem diagnosis and repair. Insite ExC helps resolve support issues quickly to maximize your equipment investment without compromising data security.
- The **SQL database format** is offered in addition to the MDB database format to increase the flexibility in statistical data management.



We've got your back.

Backed by a dedicated team of bone densitometry specialists

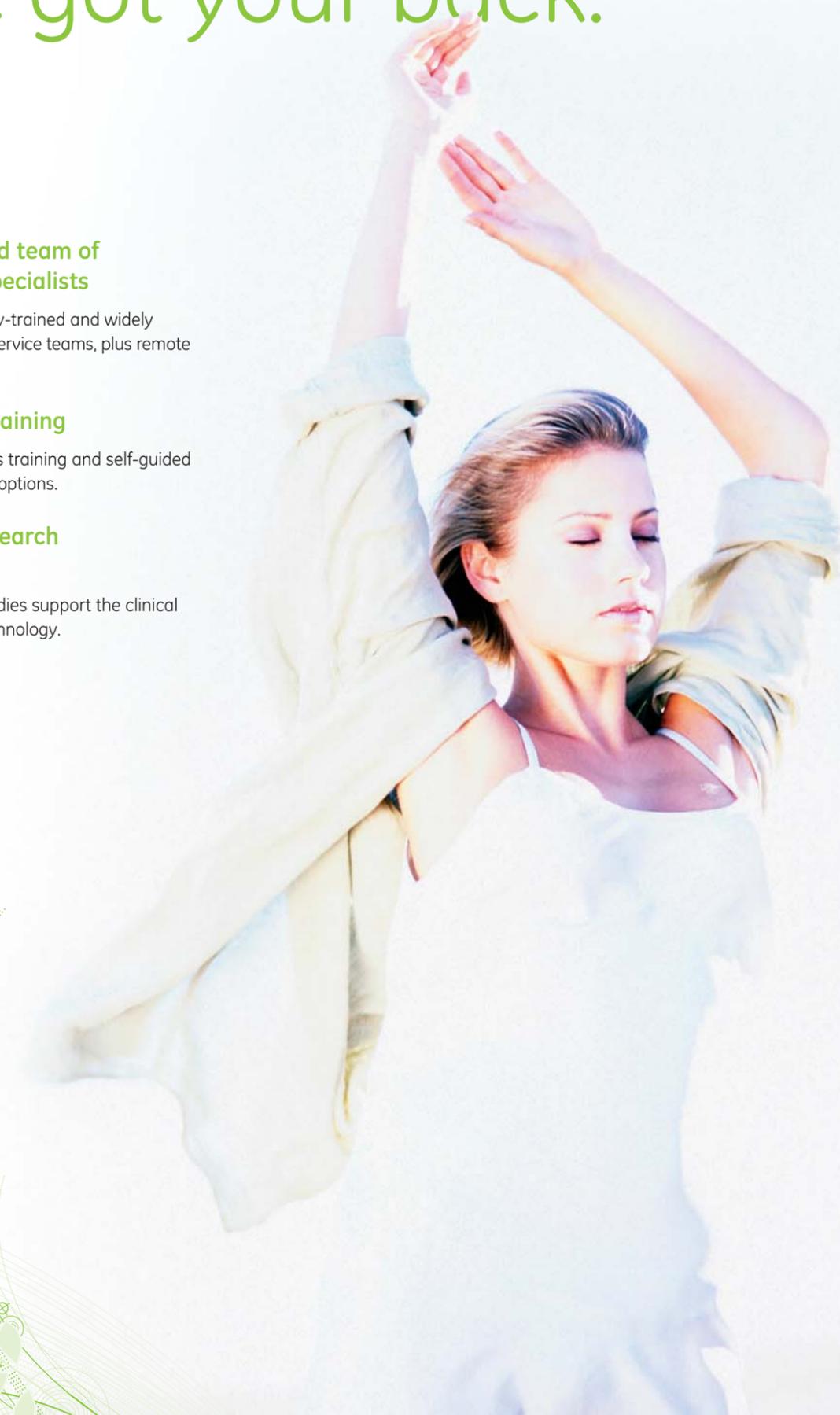
Get assistance from our highly-trained and widely deployed bone densitometry service teams, plus remote applications support.

Backed by in-depth training

Dedicated on-site applications training and self-guided tutorials extend your training options.

Backed by clinical research and development.

Thousands of articles and studies support the clinical use of our innovative DXA technology.



Lunar iDXA technical specifications:

Available applications and options^{13,14}

- AP spine
- Femur
- QuickView (10-second mode for AP Spine & Femur)
- DualFemur
- OneScan
- Advanced Hip Assessment (AHA)
- Total Body/Body Composition¹¹ (with fat/lean assessment)
- Dual-energy Vertebral Assessment (DVA)
- Spine geometry
- Computer-Assisted Densitometry (CAD)
- Estimated Total Body %Fat
- Forearm
- Hand
- Lateral Spine BMD
- Orthopedic
- Pediatric¹¹
- Small Animal
- OneVision
- Composer
- TeleDensitometry (fax, e-mail)
- HIPAA SecureView
- Practice Management tools
- DICOM (worklist, color print and store)
- HL7 bidirectional interface
- Multi-User Database access (MUDB) (1-3 or 1-10 users)
- SQL database
- Applaud™ CD-based training
- Remote connectivity for direct customer support

enCORE Windows-based user interface^{13,14}

- Advanced intuitive graphical interface with multimedia on-line help
- Multiple languages available
- SmartScan for scan window optimization and dose reduction
- Automated scan mode selection
- AutoAnalysis for better precision
- Customized analysis for clinical flexibility
- Exam comparison process
- Multiple patient directories with database
- BMD or sBMD results, BMC and area
- Extensive reference data: >12,000 USA/Northern European subjects, as well as NHANES, and numerous regional databases
- T-score, Z-score, % young adult and % age matched
- WHO guidelines for diagnosis of osteoporosis
- Patient trending with previous exam importation
- enCORExpress mode for brief click path

Quality assurance

- Automated test program with complete mechanical and electronic tests
- Automated QA trending with complete storage

Scanning method

- Narrow-angle fan-beam technology with Smartscan and MVIR
- No scout scan required, no moving table

X-ray characteristics

- Constant potential source at 100kV
- Dose efficient K-edge filter
- Tube current: 0.188-2.500mA

Detector technology

- High-definition Cadmium Zinc Telluride (CZT-HD) detector
- Direct-digital
- Energy-sensitive, solid state array

Magnification

- None - Object-plane measured

Dimensions (L x W x H) and weight

- 2.87m x 1.31m x 1.25m - 360kg (113" x 52" x 49" - 792lbs)
- Table height: .63m (25")
- Console table: .79m x .63m x .48m (31" x 25" x 19")

Patient weight limit

- 205kg (450lbs)

External shielding

- Not required: X-ray safety requirements may vary by location. Please inquire with local regulatory authorities.
- Operating scatter: < 0.8 mR/hr (8 µSv/hr) @ 1m (39") from X-ray source
- GE Healthcare recommends consulting your local regulatory agency to comply with local ordinances.

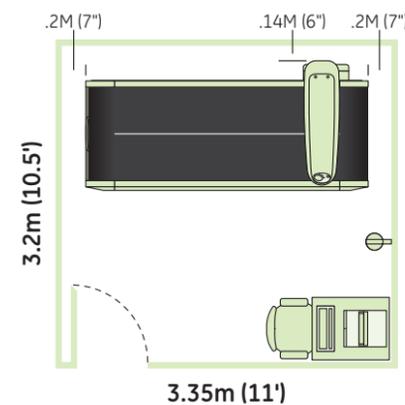
Environmental requirements

- Ambient temperature: 18-27°C (65-81°F)
- 120 VAC 50-60 Hz 20A dedicated circuit or 230-240 VAC 50-60Hz 10A dedicated circuit ±10%
- Humidity: 20%-80%, non-condensing

Computer workstation^{13,14}

- Windows platform
- Computer, printer and monitor

Minimum room dimensions:



The Lunar iDXA is designed to have minimal impact on your practice in both the installation requirements and required operating space. The Lunar iDXA is shown in a 3.5 m x 3.2 m exam room with the included workstation. No operator shielding or special site preparation beyond a dedicated 100-127/200-240 VAC duplex outlet is usually required.¹⁵ The outlet should be placed near the desired location of the operator's console.



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13. Depending on product configuration and availability. Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware.
14. Networking is the user's responsibility.
15. Consult and Follow local x-ray regulations.