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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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### **About GE Healthcare:**

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality and efficiency around the world. Headquartered in the United Kingdom, GE Healthcare is a \$16 billion unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employs more than 46,000 people committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.





BMD-0146-06.10-EN-US

### **GE** Healthcare

# 

### Innovation and dedication



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.

### 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.

### **Advanced technology**

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.¹ MVIR image reconstruction measures the true size and area of the anatomy without making geometric or dimensional assumptions, providing excellent precision and accuracy.



### Precision you can detect

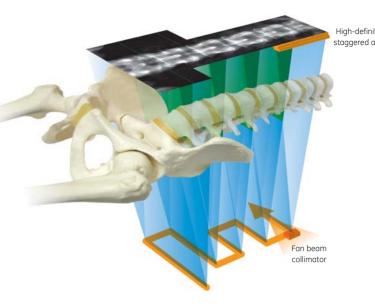
Osteoporosis treatment requires time to monitor. The Lunar iDXA helps to provide quick detection of bone changes with high-definition precision due to it's advanced high-definition, direct-digital detector. Lunar's proprietary calibration technology takes the entire body into account with low, normal and high BMD values, as well as lean, normal and obese %fat values.

Images courtesy of University of Wisconsin Osteoporosis Center.



### **Going digital**

The Lunar iDXA's patented high-definition, direct-digital detector with staggered array provides excellent image quality for clearer and crisper densitometer images.



### Design

iDXA's open architecture and larger table can accommodate patients up to 450 lbs (204kg) and allow for easy positioning of tall and or heavy patients.



### Precision (%CV) for BMD and Body Composition

Region	Mean	CV				
Total Femur BMD (g/cm²)	0.998	0.7%				
Spine L1-L4 BMD g/cm²)	1.184	1.1%				
Total Body BMD (g/cm²)	1.142	0.5%				
Total Body BMC (g)	2586	0.5%				
Total Body Area (cm²)	2248	0.7%				
Total Body %Fat	35.8%	0.8%				
Total Body Fat (g)	25345	0.8%				
Total Body Lean (g)	44283	0.5%				

<sup>\*</sup>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 the hip and spine. 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.



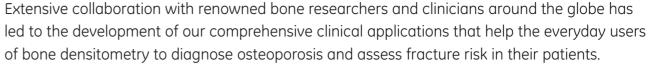




"The biggest advancement with the iDXA is the improved image resolution over previous GE Lunar densitometers. By having clearer pictures of the skeleton, you can be more accurate in placement of regions of interest during scan analysis. This is important in the accuracy of diagnosis and for comparison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



### **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)**

The AHA application provides tools to evaluate the structural properties of the hip:

- Hip Axis Length (HAL) has been demonstrated in prospective studies as an effective adjunct to femur bone density in predicting fracture risk.
- Cross-Sectional Moment of Inertia (CSMI) and Femur Strength Index (FSI) are calculated for the assessment of the load-bearing capacity of the hip.
- Color bone mapping is displayed to differentiate areas of cortical and high/low density trabecular bone

### **DualFemur**

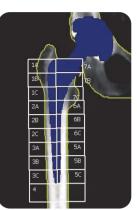
The DualFemur option automatically scans both femurs in one seamless acquisition without repositioning the patient. This critical hip region assessment identifies the weakest side to enhance confidence in your treatment decisions. The trending function enables seamless follow-up of changes over time.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





### Orthopedic

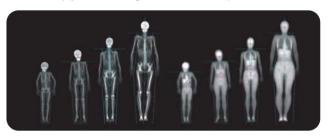
The orthopedic application provides accurate and precise bone mineral density and bone mineral content values. Bone assessment in the vulnerable region surrounding an implant is now possible. This application also enables automated bone assessment of the hip implant using standard Gruen zones (7 zones) 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.



### **FRAX®**

Provides an estimate of 10-year probability of a major fracture (clinical spine, wrist, proximal humerus and hip) or hip alone. This estimate is based on femoral neck BMD and clinical risk factors.

Licensed from the World Health Organization (WHO), FRAX has been seamlessly integrated into the enCORE software (version 13.31) to make it easy to calculate and comply with new osteoporosis guidelines incorporating FRAX.



implemented in the enCORE software.





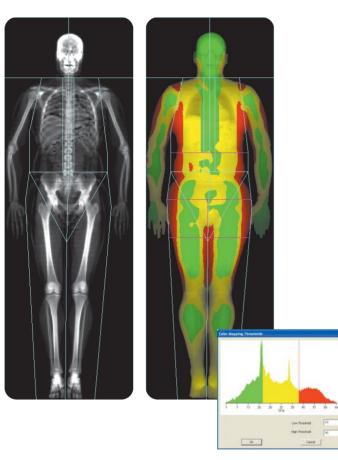
## Body composition

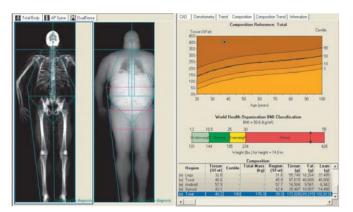
Accurate measurement of body composition can provide valuable information for assessing, monitoring and treating a variety of diseases and disorders.

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





### Mirrorlmage

- 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.



R Huizenga<sup>1</sup>, HS Barden<sup>2</sup>, MK Oates<sup>3</sup>

<sup>1</sup>Cedars Sinai Medical Center, Los Angeles, CA; <sup>2</sup>GE Healthcare, Madison, WI; <sup>3</sup>Santa 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/cm²)	1.08%
BMC (g)	1.00%
Fat Mass (kg)	1.22%
Lean Mass (kg)	0.95%
%Fat (Tissue)*	0.78%
%fat (Region)**	0.78%

"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. Toussirot<sup>1</sup>, C. Semon<sup>2</sup>, F. Penfornis<sup>2</sup>, D. Wendling<sup>1</sup>

<sup>1</sup>Department of Rheumatology, University Hospital Jean Minjoz, Besançon, France, <sup>2</sup>Department of Endocrinology, University Hospital Jean Minjoz, 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 in obese subjects

Measurement	Mean	%CV
BMD (g/cm²)	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 DXA 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, Android %fat, Android %fat, 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 diseases/condition itself, or it's 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. DXA 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, a world-leading provider of densitometry solutions.<sup>4</sup>

### Accurate assessment, reliable trending

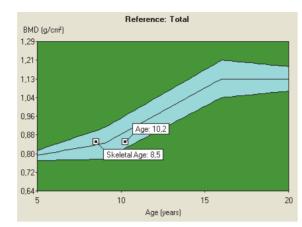
Children grow at unique rates. Our advanced pediatric analysis tools compare skeletal and chronological age analyses and BMD results against gender-specific reference populations.

"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." 5

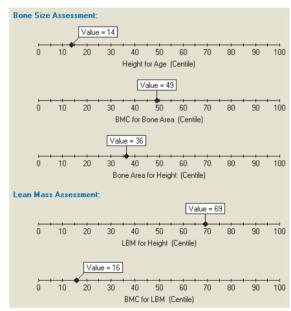
Lunar's DXA pediatric application provides measurements that enable enhanced assessments of growth and development, including:

- Height for age<sup>6</sup>
- BMC for bone area<sup>6</sup>
- Bone area for height<sup>6</sup>
- Lean body mass for height (muscle development)<sup>7,8</sup>
- BMC for lean body mass (muscle-bone balance)<sup>7,8</sup>

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.9,10



Lunar pediatric assessment

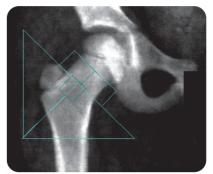
### **Pediatric applications**

### AP spine and femur applications provide:

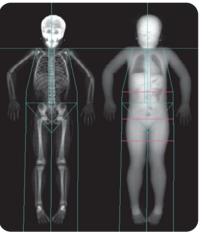
- Rapid scan times at low dose
- Low-density threshold analysis
- User-defined custom analysis tools
- Height-adjusted femoral neck region
- Z-score reference comparison
- Age-dependent standard deviations
- Separate reference populations for boys and girls

### Total body analysis features:

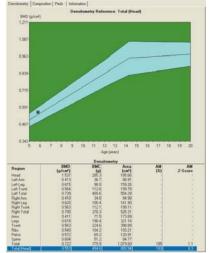
- Automated analysis for bone
- Total and regional fat and lean body composition analysis
- Body size assessments (height for age, bone area for height, BMC for bone area, lean mass for height, and BMC for lean mass)
- Total body and total body without head analysis with reference data



Automatic adjustment of femur, based on child's height



Total body pediatric assessment



Composition									
Region Left Arm	(%Fat) 39.007	Z-Score	Total Mass (kg) 1.17	Region (%Fal) 37.787	1,137	Fat (g) 443	Lean (g) 633	8MC (g) 36.7	Fat Free (g) 730
Left Leg	37,305		3.62	36.373	3,521	1,316	2,205	90.0	2,301
Left Trunk	36,007		5.00	35.274	4.007	1,763	3,123	112.6	3,236
Leh Total	34.649		11.66	33.432	11.253	3.899	7,354	409.E	7.764
Right Arm	38.354		3.17	37.215	1,137	436	701	34.8	736
Flight Ling	37.844		3.63	36.797	3.530	1.336	2.154	100.4	2,295
Right Trunk	25,490		4.04	34.660	4.726	1,677	3,049	112.1	3,161
Flight Total	35.007		11.05	33.834	10.681	3.729	6.942	370.3	7,312
Arms	38,680		2.35	37 501	2.274	990	1.395	71.5	1,466
Legs	37.614		7.25	36.585	7.052	2,652	4,399	198.4	4,538
Trunk	35.793		9.84	34.976	9.612	3,441	8.172	224.6	6.396
Indiod	42.756		1.44	42.391	1.425	629	816	12.3	829
Gynoid	42.454		3.00	41.010	3.030	1,200	1.743	49.0	1.7%
Total	34 823		22.71	33.627	21.934	7,638	14,296	779.9	15,076
Total (Head)	36.818		19.43	35.881	18.938	6.973	11,966	494.6	12,460
Arms Det	-0.654		0.00	-0.572	9	-7	9	-1.9	-
Jegs Diff.	0.453		0.01	0.424	3	-19	-11	25	4
Trunk Dat	0.597		-0.16	-0.607	-161	-00	-75	-0.5	175
Total DW.	0.358		-0.61	0.432	-572	160	412	-39.2	452



"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 spine radiographs

The conventional spine radiograph is today's standard for vertebral fracture assessment. It provides highquality image resolution enabling you to visualize more vertebrae, mild fractures and other features.<sup>11</sup>

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 one acquisition

DVA on the Lunar iDXA has been found to be comparable to X-ray in identifying and classifying vertebral deformities concerning etiology, grade and shape.12



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





77 year old female, 63 in., 117 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.<sup>11</sup> The dual-energy technique utilized by GE Healthcare compensates for these differences to visualize the spine in a single view.

### Two views for enhanced assessment

**AP view –** enhanced visualization of the ribs and pelvis for easier 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 between selected vertebrae is displayed on-screen and in reports that accompany the DVA results.



"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, Richmond, Virginia



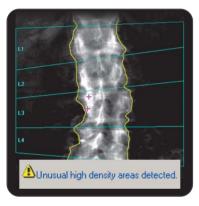


## Automation: So you can focus on the patient



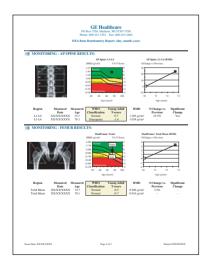
### Automate bone density testing with the enCORE user interface

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 ScanCheck

ScanCheck automatically identifies potential acquisition and analysis errors and provides multimedia help. It alerts the operator 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, 13 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

- DICOM<sup>14</sup> 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 quick problem diagnosis and repair. InSite ExC helps resolve support issues quickly to maximize your equipment investment without compromising data security.<sup>15</sup>





### Lunar iDXA technical specifications: 15,16

### Available applications and options

- AP spine
- Femur
- QuickView (10-second mode for AP Spine & Femur)
- DualFemur
- OneScan
- Advanced Hip Assessment (AHA)
- Total Body/Body Composition (with fat/lean assessment)
- Dual-energy Vertebral Assessment (DVA)
- Spine geometry
- FRAX® fracture risk tool
- ScanCheck
- Estimated Total Body %Fat
- Forearm
- Hand
- Lateral Spine BMD
- Orthopedic
- Pediatric
- Small Animal
- OneVision
- Composer
- TeleDensitometry (e-mail, fax17)
- 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

- 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
- Scan image preview

### Quality assurance

- Automated test program with complete mechanical and electronic tests
- Automated OA 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 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")

### Patient weight limit

204ka (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.

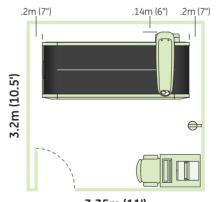
### **Environmental requirements**

- 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

- Windows platform
- · Computer, printer and monitor

### Minimum room dimensions:



3.35m (11')

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.18 The outlet should be placed near the desired location of the operator's console.



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- 13. The World Health Organization (WHO), the International Society of Clinical Densitometry (ISCD) and the National and International Osteoporosis Foundation (NOF and IOF)
- 14. DICOM 3 and IHE Y4, Y5, Y6 and Y7 compliant
- 15. Networking is the user's responsibility.
- Depending on product configuration and availability. Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware. 17. Additional hardware may be required for fax capabilities.
- 18. Consult and Follow local X-ray regulations.