Indications for use: The Prodigy series 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 $17 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**

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imagination at work

BMD-0195-12.09-EN-US

GE Healthcare

Lunar Prodigy Pro

Innovation, throughput and dedication

It’s all about dedication to the fight against osteoporosis.

For over 30 years, the sole focus of Lunar bone densitometry has been the advancement of skeletal health assessments to help physicians improve patient outcomes.

GE’s vision of early health and the expansion of preventative osteoporosis assessments with Lunar DXA provide opportunities to expand and diversify your practice. In addition to osteoporosis management, performing accurate body composition analysis may aid you in assessing your patients’ overall total body health.

Precision – key to effective results

Effective use of serial DXA measurements for monitoring changes in BMD requires the minimization of precision error. Precision can vary widely depending on operator experience, the type of DXA used, and the skeletal site measured.[1]

The International Society for Clinical Densitometry (ISCD) has established standards for precision error at the spine, total femur and femoral neck. The Lunar Prodigy Pro™ has been demonstrated to have a precision error that easily meets the ISCD standards for all regions.[2]

Innovative technology

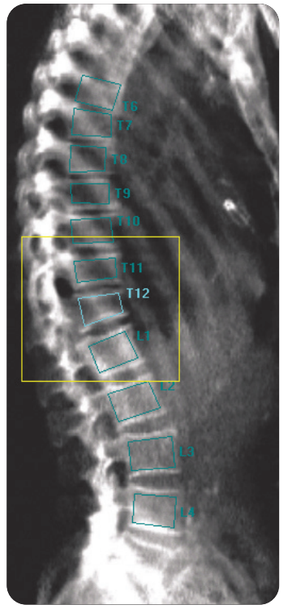
The Lunar Prodigy Pro utilizes a direct-digital array detector and narrow-angle fan-beam technology to enhance dose efficiency and achieve excellent precision and patient throughput in spine, femur and total body measurements.

enCORE

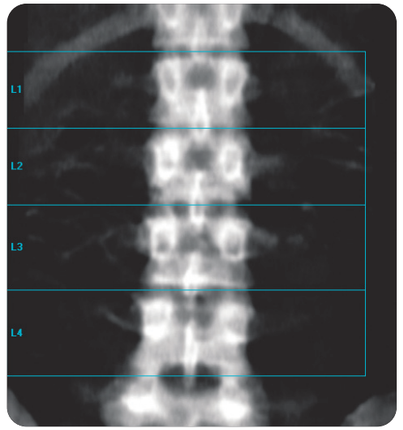
The enCORE Windows®-based operator platform makes bone density testing seamless and automated. The user interface enables clinical features to be added through software only – with no downtime to your facility. Highly trained and certified staff will install the Lunar Prodigy Pro and offer on-site applications training.

The World Health Organization (WHO) recommends that women aged 65 and older be routinely measured for osteoporosis to reduce the risk of fracture and spinal abnormalities often associated with the disease.[3]

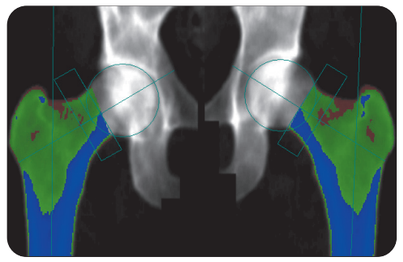
Beyond T-score

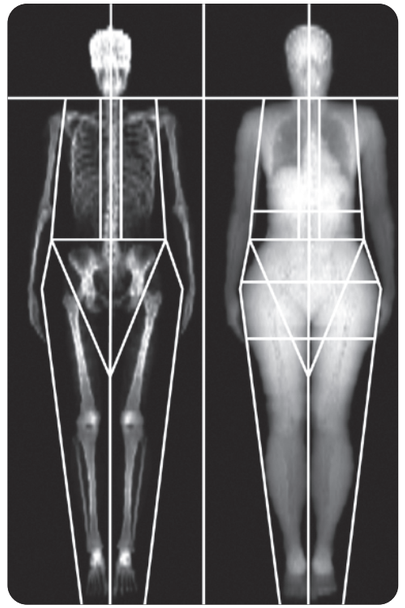


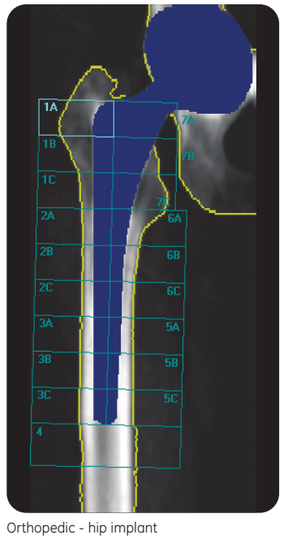
Lateral DVA



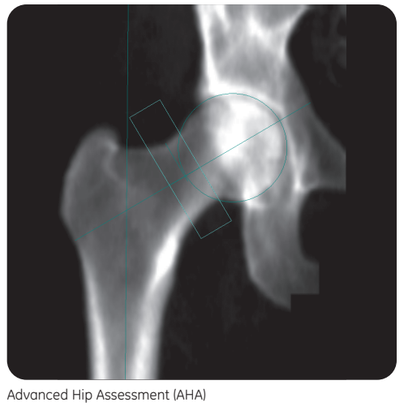
AP spine


Hip Axis Length (HAL) - color bone mapping


Total body



Orthopedic - hip implant


Advanced Hip Assessment (AHA)


Pediatric

Extensive collaboration with renowned bone mineral researchers and clinicians around the globe has led to the development of our clinical applications:

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

Total body/body composition[1]

Body composition measurement with dual-energy X-ray absorptiometry (DXA) can look beyond weight and the traditional body mass index (BMI) to determine body fat distribution.

Body composition measurement contributes to a thorough patient evaluation and helps physicians monitor the effects of therapy, diet or exercise.

Body composition scans with DXA provide precise and accurate data on bone and tissue composition, including bone mineral density (BMD), lean and fat tissue mass, and %fat. They provide both total body data and regional results (trunk, arms, legs, pelvis and android/gynoid regions). The measurements are fast and non invasive.

Dual-energy Vertebral Assessment (DVA)

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

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 treatment decisions. The trending function enables seamless follow-up of changes over time.[4,5]

Pediatric

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 provides a complete assessment of bone, fat and lean tissue composition. These measurements enable enhanced evaluation of growth and development that include:

- Height for age (bone length)[6]
- BMC for bone area (bone mineralization)[6]
- Bone area for height (bone width)[6]
- Lean body mass for height (muscle development)[7,8]
- BMC for lean body mass (muscle-bone balance)[7,8]

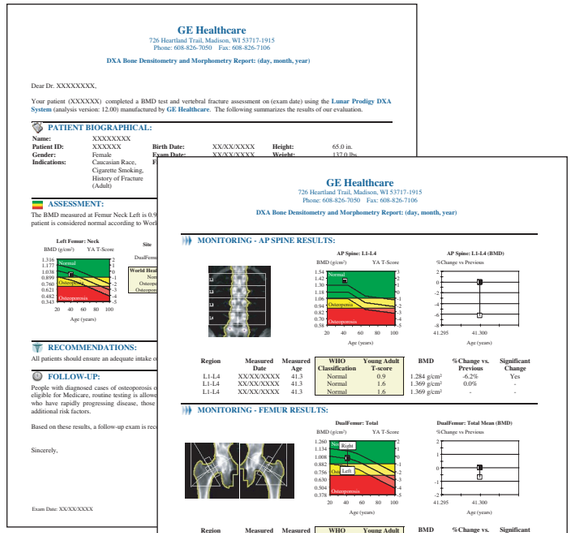
Orthopedic

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 exceptional evaluation for practitioners and clinical researchers specialized in the fields of orthopedics and surgery.

Connectivity and productivity

Composer

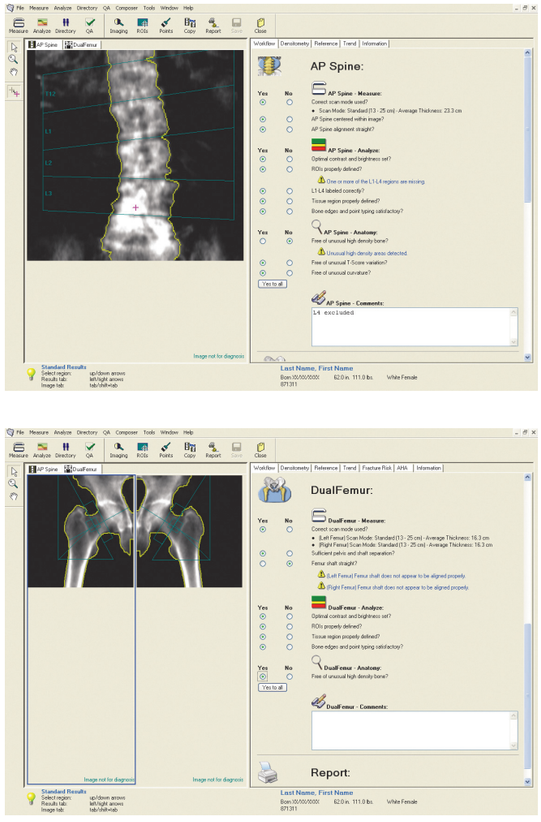
Automated physician reporting comes complete with the National Osteoporosis Foundation (NOF) treatment guidelines and World Health Organization (WHO) diagnostic criteria for a complete osteoporosis assessment. Composer™ is designed to follow diagnostic guidelines proposed by the International Society of Clinical Densitometry (ISCD), determining the lowest T-score based on defined regions. Recommendation text is inserted to aid productivity.



Composer is a flexible tool for customized physician reports

ScanCheck

ScanCheck automatically studies acquisition inputs and the acquired image, looking for errors and patient irregularities.



ScanCheck detects and flags characteristics that require closer review.

DICOM

Lunar Prodigy Pro DICOM is flexible to meet your needs and is IHE compliant. Features include DICOM structured reports, image storage and commitment, and DICOM worklist. Reports and images can be sent to your PACS server in color or black and white.

HL7

The Lunar Prodigy Pro receives and transmits HL7 information, including importing patient demographics and exporting patient exam results. This solution for electronic medical records closes the loop, completing the integration of the densitometer with existing electronic medical records.

TeleDensitometry

TeleDensitometry provides the ability to send paperless reports as e-mail attachments or faxes that can be viewed on any personal computer.

Worklist feature

In both DICOM and HL7, the Worklist enables automatic use of patient information from scheduling applications, helping to reduce data entry errors.

Lunar Prodigy Pro technical specifications:

Available applications and options[9,10]
- AP spine
- Femur
- DualFemur
- OneScan
- Advanced Hip Assessment (AHA)
- Total body/body composition[11] (with fat/lean assessment)
- Dual-energy Vertebral Assessment (DVA)
- ScanCheck
- Estimated total body %Fat
- Forearm
- Hand
- Lateral spine BMD
- Orthopedic
- Pediatric[11]
- Small animal[12]
- 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[9,10]
- 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

Complete quality assurance
- Automated test program with complete mechanical and electronic tests, including multi-point calibration and quality control measurement
- Automated QA trending with complete storage

Scanning method
- Narrow fan beam (4.5° angle) with SmartFan and MVIR

X-ray characteristics
- Constant potential source at 76kV
- Dose efficient K-edge filter
- Tube current: 0.15-3.00mA

Detector technology
- Direct-digital detector
- Energy-sensitive, solid state array

Magnification
- None - object-plane measured

Dimensions (L x W x H) and weight
- Full-size: 2.62m x 1.09m x 1.28m - 272kg (103" x 43" x 51" - 599lbs)
- Compact: 2.01m x 1.09m x 1.28m - 254kg (79" x 43" x 51" - 559lbs)
- Table height: .63m (25")

Patient weight limit
- 159kg (350lbs)

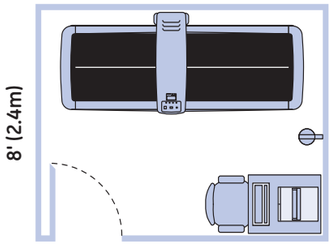
External shielding
- Not required: X-ray safety requirements may vary by location. Please inquire with local regulatory authorities.
- Operating scatter: <0.6 mR/hr (6 µSv/hr) @ 1m (39") from X-ray source
- GE Healthcare recommends consulting your local regulatory agency to comply with local ordinances.

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[9,10]
- Windows platform
- Computer, printer and monitor

Small room configuration:
Room dimensions must be at least 3.0m x 2.4m if the computer and peripherals are powered by an isolation transformer. Equipment powered by an isolation transformer can be located anywhere in the room with the scanner. The isolation transformer and scanner must be plugged into the same dedicated line outlet.

Minimum room dimensions:
(full-size table)



References:
1. ISCD 2005 positioning statement
2. Shepard et at, 2004, presented at ISCD annual meeting
3. WHO technical report series, Prevention and management of osteoporosis, 2003
4. RE Cole, J Larson (2006). The Effect of Measurement of the Contralateral Hip if the Spine Is Not Included in the Bone Mineral Density Analysis. J Clin Densitom 9:210-216.
5. M Kamimura, H Hirabyashi, M Konishi, Q Zhou, H Kato (2006). Osteoporosis diagnosis and treatment decisions with Dual Femur in Japanese women. Presented at the 17th International Bone Densitometry Workshop, Kyoto Japan, November 2006.
6. Molgaard C, Thomsen BL, Prentice A, Cole TJ, Michaelsen KF (1997) *Arch Dis Child* 76:9-15.
7. Crabtree NJ, Kibirge MS, Fordham JN, Banks LM, Muntoni F, Chinn D, Boivin CM, Shaw NJ (2004) The relationship between lean body mass and bone mineral content in paediatric health and disease. *Bone* 35:965-972.
8. Schoenau E, Neu CM, Beck B, Manz F, Rauch F (2002) Bone mineral content per muscle cross-sectional area as an index of the functional muscle-bone unit. *J Bone Miner Res* 17:1095-1101.
9. Depending on product configuration and country availability. Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware.
10. Networking is the user's responsibility
11. On full size table only
12. Laboratory animals only

† **Indications for use:**The GE Lunar Body Composition Software option (body composition) used on GE Lunar DEXA bone densitometer 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 iseases/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 judgments. 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.