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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 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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### **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.



GF Healthcare

# Lunar Prodigy Primo

Simplicity and dedication



## Seamless osteoporosis management

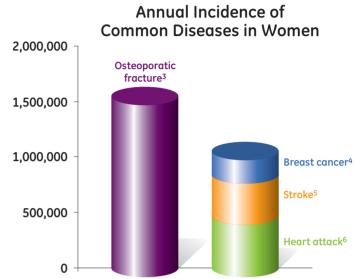
As a bone health specialist, you want to offer your patient the best care possible: exceptional diagnosis and follow-up. GE Healthcare is dedicated to osteoporosis management and, as a leading bone densitometry partner worldwide, we deliver.<sup>1</sup>

The Lunar Prodigy Primo™ is the latest direct-digital narrow-angle fan-beam densitometer in the globally recognized Lunar Prodigy series. From standard AP Spine and DualFemur capabilities to advanced Vertebral Fracture Assessment studies, you can assess your patient's bone health in a fast and seamless computer-driven operation.

The enCORE Windows-driven software platform optimizes automation, saving you time, yet providing consistent results.

Approximately 40% of 50-year-old

A woman's risk of an osteoporotic fracture is much higher than that of breast cancer, stroke and heart attack combined.<sup>3,4,5,6</sup>





### Diagnostic confidence

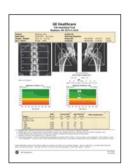
The Lunar Prodigy Primo is a narrow-angle fan-beam platform providing direct-digital scanning and clinical utility. You get measurements of the two most vital clinical sites – spine and femur – at a low radiation dose. The highly-automated Windows-based enCORE software platform optimizes productivity and ensures consistent results. The OneScan feature provides unprecedented ease of use and high precision.<sup>7</sup>



### Confident

The DualFemur feature automatically measures both the left and right femurs in one fast scan. DualFemur improves accuracy by

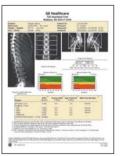
identifying the femur with the lowest density. The 30% improvement in precision<sup>8</sup> seen with the combined left and right BMD enhances the ability to monitor response to therapy at this critical fracture site.



### Efficient

With OneVision you and your referring physicians receive a single, consolidated report that combines the complete risk assessment analysis rather than receiving multiple assessment reports.

The OneScan feature adds further time savings and convenience, by automatically combining AP Spine and DualFemur scans into one acquisition.<sup>7</sup>



### Seamless

The Lunar Prodigy Primo patient report displays T-scores and Z-scores along with the fracture risk assessment graph, based on the World Health Organization (WHO) criteria to define osteoporosis, and key diagnostic information. This makes interpretation of results and fracture risk assessment seamless.



### **Body composition**

Accurate measurement of body composition provides valuable information for assessing, monitoring and treating a variety of diseases and disorders. Most people are used to stepping on a scale before every visit to a doctor's examining room. But monitoring patients' weight – while helpful – is at best a crude and imprecise way to assess their health. Today's body composition measurement tools provide

far more complete and precise information that can help support diagnoses and guide treatment. They can even help athletes make decisions on the training regimens they use to achieve the best performance. 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 – an important risk factor in a variety of serious diseases. More broadly speaking, 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)

### On-demand digital service

It's all about speed. When you contact GE for service, our online engineers can electronically link to your system and work to quickly get you back up and running. If a field engineer needs to be dispatched, he or she will be prepared with a system diagnosis — and if required, have the right parts on hand. In addition, our applications specialists can reach out at your request to support or train. Ask your sales representative how.







DualFemur

AP Spine

DVA: lateral and AP extended view of the spine



### Dual-energy Vertebral Assessment

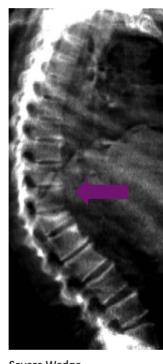
Dual-energy Vertebral Assessment (DVA) expands the clinical applications available for the Lunar Prodigy Primo bone densitometer. DVA provides rapid, dual-energy images of the AP and lateral spine allowing clinicians to visually assess the presence of vertebral deformations. Experts and radiologists agree: dual-energy is the preferred method for imaging the lateral spine.9



Arthritic Calcification



Normal Female, Age 79



Severe Wedge Female, Age 65



**Severe Compression** 

### More than 40% of women with normal or osteopenic BMD had a moderate or severe vertebral deformation seen with DVA<sup>10</sup>

- Based on 2006 global revenue Melton LJ III, Lane AW, Cooper C, Eastell R, O'Fallon WM, Riggs BL, 1993 Prevalence and incidence of vertebral fractures. Osteoporosis Int 3:113-119.
- 3. Annual incidence women all ages. National Osteoporosis Foundation, Physician's Guide to Prevention and Treatment of Osteoporosis, Washington, DC; National Osteoporosis Foundation, 2003.
- 4. Annual estimate women 29+. American Heart Association, Heart & Stroke Facts Dallas, TX; American Heart Association, 2003.
- 5. Annual estimate women 30+. American Heart Association, Heart & Stroke Facts, Dallas, TX: American Heart Association, 2003.
- 6. 2005 new cases women of all ages. American Cancer Society, Cancer Facts & Figures 2005, Atlanta, GA; American Cancer Society, 2005.
- 7. C Simonelli, L Del Rio, N Binkley, Comparison of Spine BMD Measurements from DXA With and Without Leg Elevation. Abstract Published J Bone Miner Res (2004) 19 (Suppl 1):S364. Poster Presented at ASBMR Annual Meeting, October 2004. M Kamimura, H Hirabayashi, M Konishi, O Zhou, HS Barden, H Kato Comparison of lumbar spine BMD and T-scores with conventional and OneScan leg positioning
- in a Japanese population. Presented at the 17th International Bone Densitometry Workshop, Kyoto Japan, November 2006 RH Nord, DL Ergun, KG Faulkner. Effect of patient positioning devices on bone density measuremer Abstract Published J Bone Miner Res (2002) 17 (Suppl 1): S313. Poster Presented at ASBMR Annual Meeting, September 2002.
- Bonnick SL, Nichols DL, Sanborn CF, Payne SG, Moen SM, Heiss CJ (1996) Right and left proximal femur analyses: Is there a need to do both? Calcif Tissue Int
- Rea JA, Li J, Blake GM, Steiger P, Genant HK, Fogelman I, 2000 Visual Assessment of vertebral deformity by X-ray absorptiometry: a highly predictive method to exclude vertebral deformity. Osteoporosis Int 11:660-668.
- 10. Patrick K. Burke, M.D. Osteoporosis Diagnostic and Treatment Center, Retreat Hospital Richmond Virginia
- 11. Depending on product configuration and availability. Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware 12. Networking is under the user's responsibility

### **Lunar Prodigy Primo technical specifications:**

### Available applications and options11,12

- AP spine
- Femur
- · OuickView (10-second mode for AP Spine & Femur)
- DualFemur
- OneScan
- Advanced Hip Assessment (AHA)
- Total Body/Body Composition13 (with fat/lean assessment)
- Dual-energy Vertebral Assessment (DVA)
- Computer-Assisted Densitometry (CAD)
- Estimated Total Body %Fat
- Forearm
- Hand
- Lateral Spine BMD
- Orthopedic
- Pediatric<sup>13</sup>
- 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)
- SOL database
- Applaud™ CD-based training
- Remote connectivity for direct customer support

### enCORE Windows-based user interface11,12

- 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 mechanicals and electronic tests, including calibration and quality control measurement
- Automated QA Trending with complete storage

### Scanning method

• Narrow FanBeam (4.5° angle) with SmartFan, MVIR and TruView

### X-ray characteristics

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

### Detector technology

- Direct-Digital Cadmium Zinc Telluride
- 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" × 43" × 51" - 599lbs)
- Compact: 2.01m x 1.09m x 1.28m 254kg (79" x 43" x 51" - 559lbs)
- Console table:
- .79m x .63m x .48m (31" x 25" x 19")
- 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.

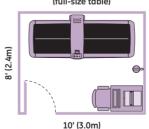
### **Environmental requirements**

- 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<sup>11,12</sup>

- Windows platform
- Computer, printer and monitor

### Minimum room dimensions: (full-size table)



### Minimum room dimensions: (compact table)

