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 around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are 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-0169-06.10-EN-US

GE Healthcare

Prodigy Primo

Simplicity and dedication

Seamless osteoporosis management

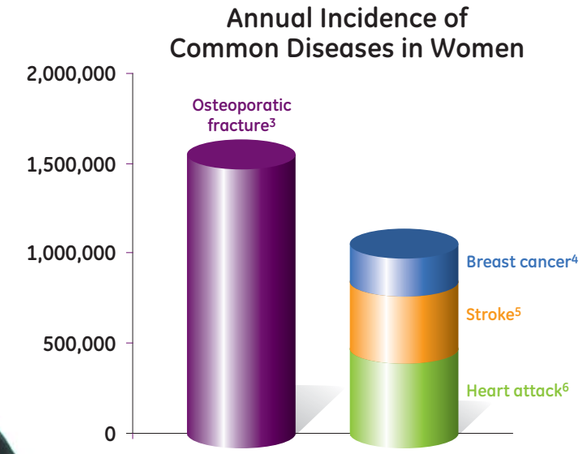
As a bone health specialist, you want to offer your patient the best care possible: exceptional diagnosis and follow-up. GE Healthcare is dedicated to osteoporosis management and, as a leading bone densitometry partner worldwide, we deliver.[1]

The Prodigy® Primo is the latest direct-digital narrow-angle fan-beam densitometer in the globally recognized 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.

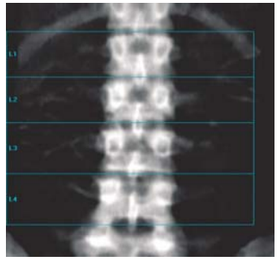
Approximately 40% of 50-year-old women will experience at least one osteoporotic fracture during their remaining lifetime.[2]

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

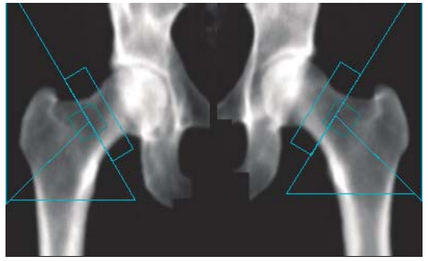


Diagnostic confidence

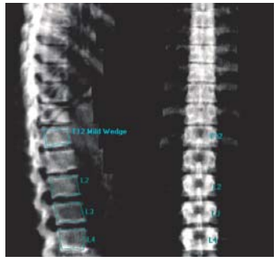
The Prodigy Primo is a narrow-angle fan-beam platform providing direct-digital scanning and clinical utility. You get measurements of the two most vital clinical sites – spine and femur – at a low radiation dose. The highly-automated Windows-based enCORE software platform optimizes productivity and ensures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



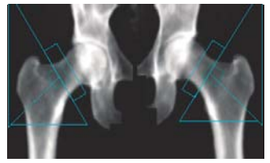
AP Spine



DualFemur

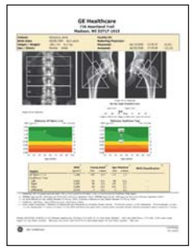


DVA: lateral and AP extended views of the spine



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[8] seen with the combined left and right BMD enhances the ability to monitor response to therapy at this critical fracture site.



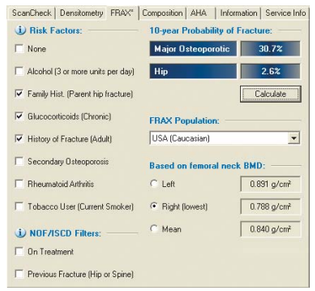
Efficient

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.[7]

FRAX®

The Prodigy Primo 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.



FRAX tool as implemented in the enCORE software.

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.

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:

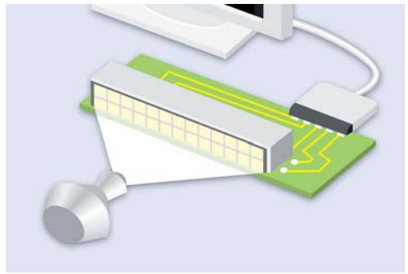
- Obesity
- Anorexia nervosa
- Wasting syndrome (caused by HIV/Aids)
- Cystic fibrosis
- Chronic renal failure

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.**

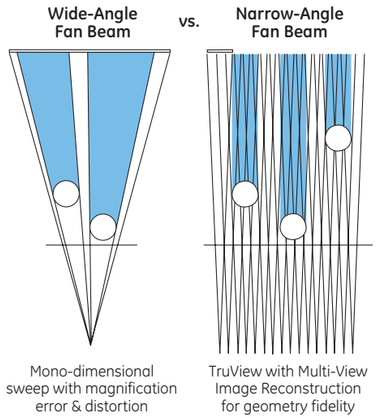
Innovative technology

The Prodigy Primo 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.



True “no magnification” measurement

To achieve optimal precision and accuracy, TrueView with the MultiView Image Reconstruction (MVIR) algorithm processes multiple narrow-angle fan beam sweeps. This process reduces the magnification inherent to wide-angle fan beams to an absolute minimum for accurate results.[9]



Mono-dimensional sweep with magnification error & distortion

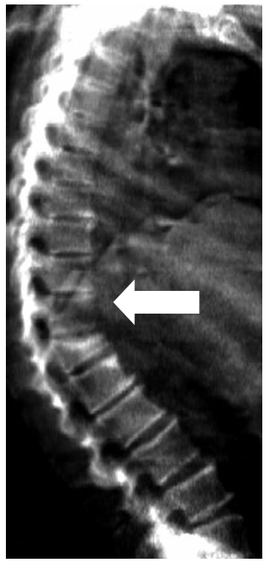
TruView with Multi-View Image Reconstruction for geometry fidelity

Dual-energy Vertebral Assessment

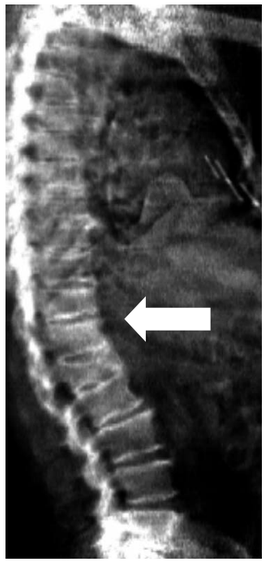
Dual-energy Vertebral Assessment (DVA) expands the clinical applications available for the Prodigy Primo bone densitometer. DVA provides rapid, dual-energy images of AP and lateral views of the spine, allowing clinicians to visually assess the presence of vertebral deformations. Experts and radiologists agree: dual-energy is the preferred method for detecting deformations in lateral views of the spine.[10]

Arthritic Calcification
Female, Age 80

Normal
Female, Age 79



Severe Wedge
Female, Age 65



Severe Compression
Female, Age 75

More than 40% of women with normal or osteopenic BMD had a moderate or severe vertebral deformation seen with DVA.[11]

References:
1. Based on 2006 global revenue
2. 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, Q 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 measurements. Abstract Published J Bone Miner Res (2002) 17 (Suppl 1): S313. Poster Presented at ASBMR Annual Meeting, September 2002.
8. 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 58:307-310.
9. Boudousq V, Goulart DM, Dinten JM, Caderas de Kerleau C, Thomas E, Mares O, Kotzki PO (2005) Image resolution and magnification using a cone beam densitometer: optimizing data acquisition for hip morphometric analysis. *Osteoporos Int* 16 (7):813–822
10. 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.
11. Patrick K. Burke, M.D. – Osteoporosis Diagnostic and Treatment Center, Retreat Hospital, Richmond, Virginia
12. Depending on product configuration and availability. Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware.
13. Networking is the user's responsibility
14. On full size table only
15. Additional hardware may be required for fax capabilities.

Prodigy Primo technical specifications:[12,13]

Available applications and options
- AP spine
- Femur
- DualFemur
- OneScan
- Advanced Hip Assessment (AHA)
- Total Body/Body Composition[14] (with fat/lean assessment)
- Dual-energy Vertebral Assessment (DVA)
- FRAX® fracture risk tool
- ScanCheck
- Estimated Total Body %Fat
- Forearm (seated or supine)
- Lateral-view spine BMD
- Orthopedic
- Pediatric[14]
- OneVision
- Composer
- TeleDensitometry (e-mail, fax[15])
- 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
- Previous scan image
- 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 SmartScan, 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 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")

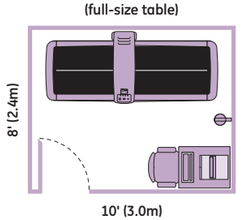
Patient weight limit
- 159kg (350lbs)

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
- Windows platform
- Computer, printer and monitor

Minimum room dimensions:
(full-size table)



Minimum room dimensions:
(compact table)