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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 DPX Series Bravo Bone Densitometer provides an estimate of BMD at the spine, proximal femur and forearm regions. This BMD value 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](http://www.gehealthcare.com).

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GE Healthcare

# Lunar DPX Bravo

Simplicity and dedication

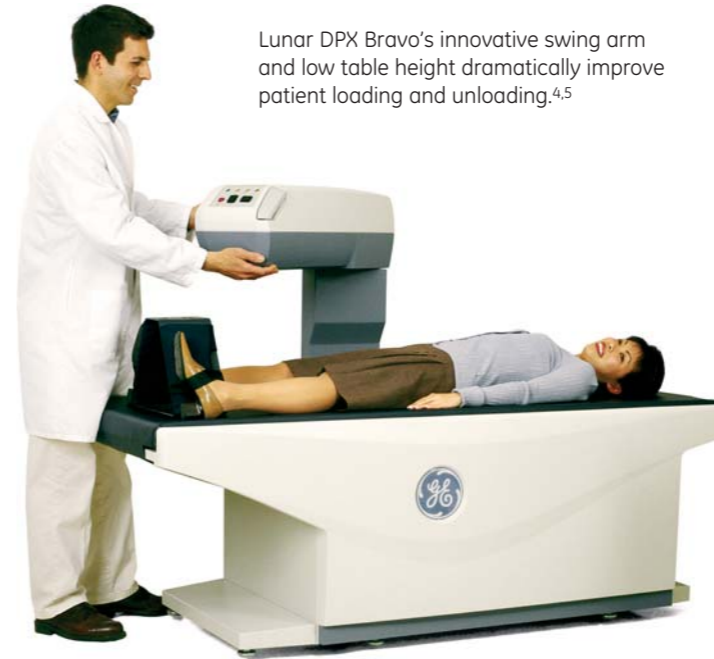


# Bone densitometry that fits your examination room

Due to space restrictions in hospitals or private offices, many physicians are excluded from performing recommended<sup>1</sup> central bone density measurements for accurate osteoporosis and fracture risk assessment. The Lunar DPX<sup>®</sup> Bravo has proven DXA technology combined with a small footprint and low dose<sup>2</sup> to overcome that obstacle.

Independent studies<sup>3,4,5</sup> have demonstrated that the Lunar DPX Bravo densitometer has a very low precision error - key to detecting small bone changes fast - assisting physicians to confidently and efficiently diagnose osteoporosis and assess fracture risk.

Measurement of both hips makes a difference in osteoporosis diagnosis and treatment classification for 1 in 7 postmenopausal women.<sup>6</sup>

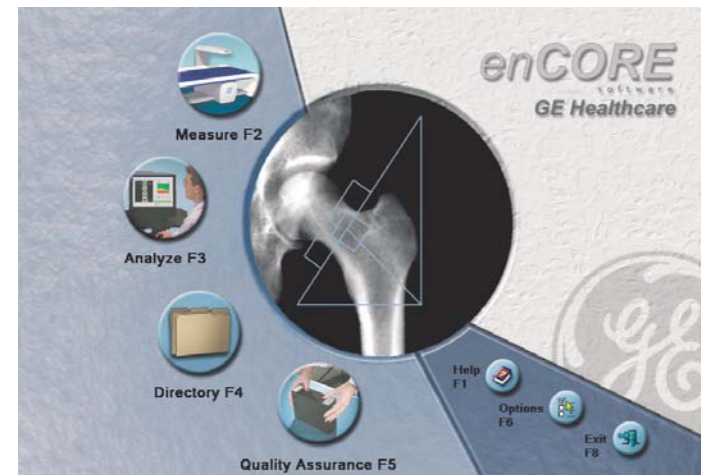


Lunar DPX Bravo's innovative swing arm and low table height dramatically improve patient loading and unloading.<sup>4,5</sup>



# Powerful tools in a small footprint

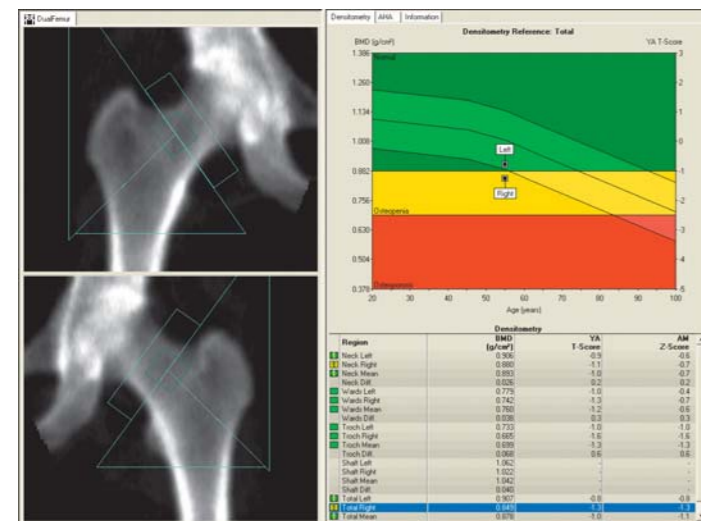
Lunar DPX Bravo offers multiple clinical applications for seamless osteoporosis assessment in a streamlined operator-friendly package, while helping to ensure clinical confidence and fast throughput.<sup>7</sup>



enCORE – brief click path in enCOREExpress mode

## enCORE software platform: easy to use

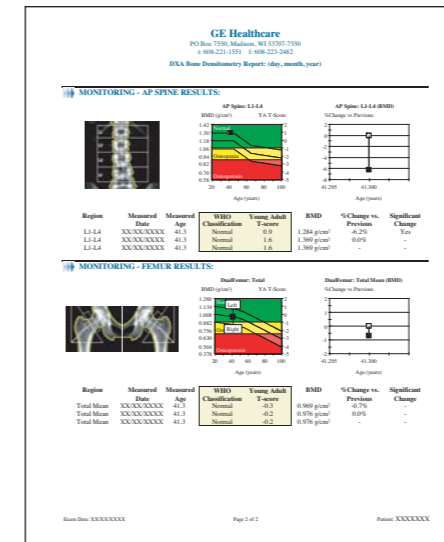
Lunar DPX Bravo is fully automated by the intuitive enCORE Windows\*\*-based software. In addition, the daily testing of the multi-point calibration and the large regional reference population databases offer you quality assurance.



DualFemur with values per region

## DualFemur: identifying the weakest femur

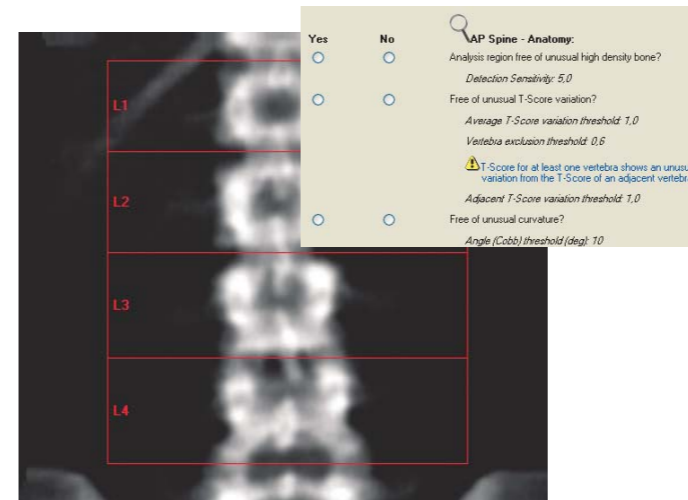
With the DualFemur option, both femurs are automatically scanned in one seamless acquisition without repositioning the patient. As such, DualFemur allows you to assess the density of the critical hip region, including identification of the weakest side, helping to increase confidence in your treatment decisions. In addition, the trending function enables seamless follow-up of change over time.<sup>6,8</sup>



Composer – your single-page report

## Composer: custom reports

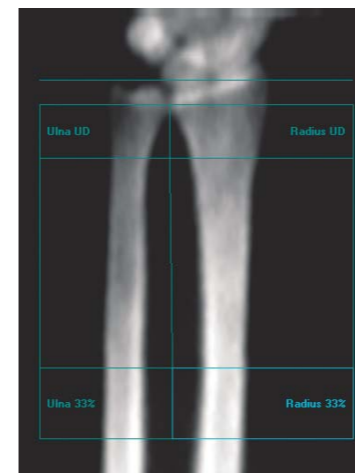
With clinical diagnosis and treatment decisions based on a variety of pre-defined criteria and guidelines established by international and local societies, it might not always be that easy for your referring colleagues to interpret multi-page reports. Composer allows you to automatically generate concise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



ScanCheck - looks for acquisition errors

## ScanCheck: add analysis assistance

ScanCheck automatically studies acquisition inputs and the acquired image, looking for errors and patient irregularities. When it detects anomalies, it displays explanations and instructions which can be reviewed by the interpreting physician.



Forearm application – dedicated to expanded sites

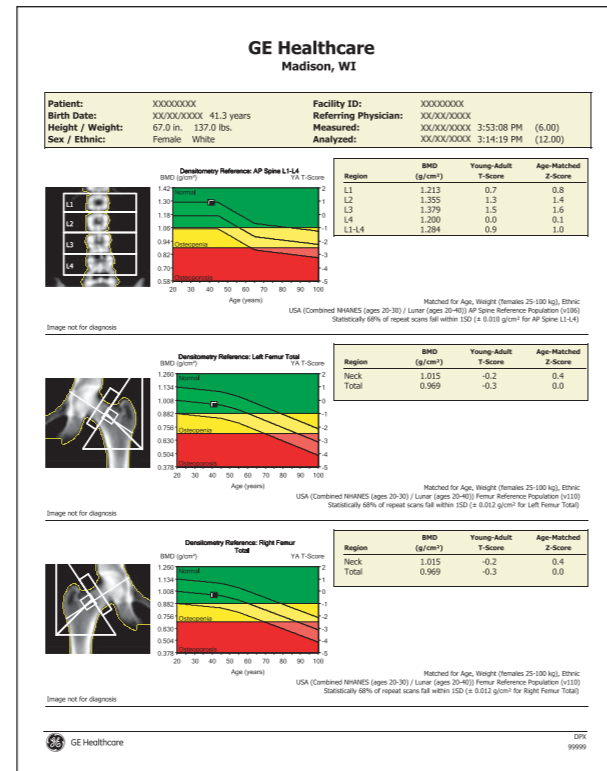
## Bone evaluation at peripheral sites: opening new opportunities

With the forearm application, you can measure the radius and ulna to provide additional clinical information on the skeletal status of your patient.

# Easy to use

## OneScan: three sites in one test

OneScan simplifies BMD testing by acquiring lumbar spine and bilateral femur scans in one automatic process from a single patient position, without compromising diagnostic confidence.<sup>11</sup>



## Complete connectivity: easy communication and workflow in full safety<sup>7,10</sup>

- DICOM 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 faxes or easy e-mail attachments, viewable on any personal computer without special software.

### References:

1. The International Society for Clinical Densitometry (ISCD) recommends to measure BMD at both posterior-anterior (PA) spine and hip in all patients, with forearm BMD as additional situation-specific measurement. EM Lewiecki, NB Watts, MR McClung, SM Petak, LK Bachrach, JA Shepherd, RW Downs. Position statement: Official positions of the International Society for Clinical Densitometry. J Clin Endocrinology & Metabolism. 2004 Vol. 89(8):3652-3655
2. Consult local X-ray regulation for room requirements.
3. L Del Rio, S Di Gregorio, J Rosales (2004). Performance evaluation of a compact DXA system: the Lunar Bravo. Osteoporos Int 15 (Suppl 1): S45. MC Schoeller, C Simonelli (2004). Precision and accuracy of the Bravo, a compact bone densitometer. J Clin Densitom 7:229
4. SB Broy, LG Jankowski (2003). Performance evaluation of a new DXA system: the Lunar Bravo. J Bone Miner Res Vol. 18 (Suppl 2): S316
5. RH Nord, HS Barden, S Krepanith, KG Faulkner. 2003 Precision and accuracy of the GE Lunar DPX Bravo bone densitometer. J Bone Miner Res Vol. 18 (Suppl 2): S204.
6. 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.
7. Depending on product configuration and availability. Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware.
8. M Kamimura, H Hirabayashi, 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.
9. The World Health Organization (WHO), the International Society of Clinical Densitometry (ISCD) and the National and International Osteoporosis Foundation (NOF and IOF)
10. Networking is the user's responsibility.
11. 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.
12. Additional hardware may be required for fax capabilities.
13. Follow local x-ray regulations.
14. Some sites may require power conditioning equipment. Contact GE Healthcare for details and specifications.

## Lunar DPX Bravo technical specifications:

### Available applications and options<sup>7,10</sup>

- AP spine
- Femur
- DualFemur
- OneScan
- Advanced Hip Assessment (AHA)
- ScanCheck
- Estimated Total Body %Fat
- Forearm
- Orthopedic
- OneVision
- Composer
- TeleDensitometry (e-mail, fax<sup>1,2</sup>)
- 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<sup>7,10</sup>

- 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

### Standard features

- Swing arm
- Paper roll dispenser
- Washable table pad

### Quality assurance

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

### Scanning method

- DXA pencil-beam technology with SmartScan technology
- No scout scan required, no moving table

### X-ray characteristics

- Constant potential source at 76kV
- Dose efficient K-edge filter
- Tube current: 0.05 - 3.00mA

### Detector technology

- NaI PM tube detector
- High pulse rate

### Dimensions (L x W x H) and weight

- System: 1.86m x .86m x 1.30m - 202kg (74" x 34" x 51" - 444lbs)
- Operating space: 1.86m x 1.04m x 1.30m (74" x 41" x 51")
- 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: < 0.2 mR/hr (2 µSv/hr) @ 1m (39") from X-ray source
- GE Healthcare recommends consulting your local regulatory agency to comply with local ordinances.

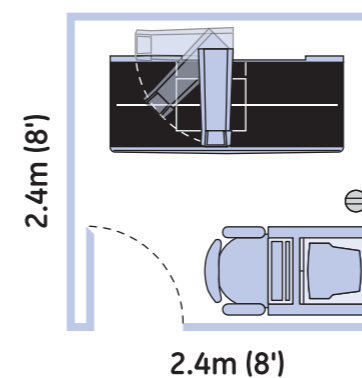
### Environmental requirements

- 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>7,10</sup>

- Windows platform
- Computer, printer and monitor

### Minimum room dimensions:



The Lunar DPX Bravo is designed to have minimal impact on your practice in both installation requirements and required operating space. The system is shown above in a 7.5' x 8' exam room, with a typical workstation. No operator shielding<sup>13</sup> or special site preparation beyond a dedicated 20 Amp 120VAC duplex outlet is required.<sup>14</sup> The outlet should be placed near the desired location of the operators console.