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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 NT 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 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**

To receive **Lunar News** and be informed about the latest developments in Densitometry, **please register for SmartMail.** You will find the SmartMail registration link on the left side of all pages of **www.gehealthcare.com**

GE imagination at work

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BMD-0179-01.10-EN-GL

GE Healthcare

Lunar DPX NT

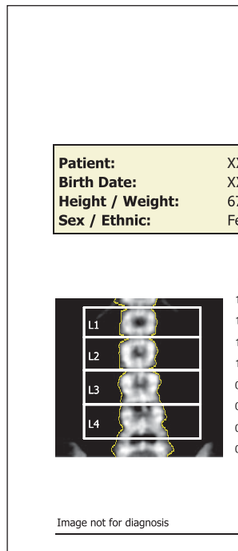
Office-based bone densitometry

High performance bone densitometer

Bone densitometry has reached a landmark in clinical performance with the Lunar DPX NT® densitometer.

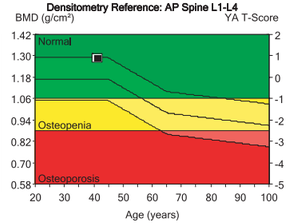
With the combination of clinical confidence and dedicated utility, easy-to-use enCORE software and high performance low dose scanning, Lunar DPX NT assists physicians to confidently and efficiently diagnose osteoporosis and assess fracture risk.

Also available for the Lunar DPX NT are innovative tools to increase productivity, such as the DualFemur feature for seamlessly scanning both femorae in one automatic process, and Composer for automated generation of custom reports.



GE Healthcare
Madison, WI

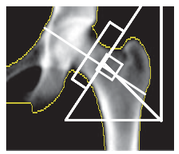
Patient:	XXXXXXXX	**Facility ID:**	XXXXXXXX
Birth Date:	XX/XX/XXXX 41.3 years	**Referring Physician:**	XX/XX/XXXX
Height / Weight:	67.0 in. 137.0 lbs.	**Measured:**	XX/XX/XXXX 3:53:08 PM (6.00)
Sex / Ethnic:	Female White	**Analyzed:**	XX/XX/XXXX 3:14:19 PM (12.00)

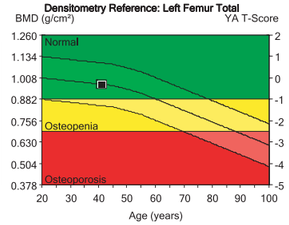


Region	BMD (g/cm²)	Young-Adult T-Score	Age-Matched Z-Score
L1	1.213	0.7	0.8
L2	1.355	1.3	1.4
L3	1.379	1.5	1.6
L4	1.200	0.0	0.1
L1-L4	1.284	0.9	1.0

Matched for Age, Weight (females 25-100 kg), Ethnic
USA (Combined NHANES (ages 20-30) / Lunar (ages 20-40)) AP Spine Reference Population (v106)
Statistically 68% of repeat scans fall within 1SD (± 0.010 g/cm² for AP Spine L1-L4)

Image not for diagnosis

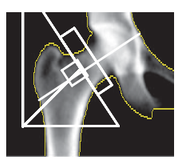


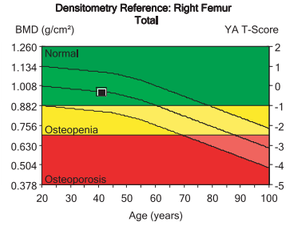


Region	BMD (g/cm²)	Young-Adult T-Score	Age-Matched Z-Score
Neck	1.015	-0.2	0.4
Total	0.969	-0.3	0.0

Matched for Age, Weight (females 25-100 kg), Ethnic
USA (Combined NHANES (ages 20-30) / Lunar (ages 20-40)) Femur Reference Population (v110)
Statistically 68% of repeat scans fall within 1SD (± 0.012 g/cm² for Left Femur Total)

Image not for diagnosis





Region	BMD (g/cm²)	Young-Adult T-Score	Age-Matched Z-Score
Neck	1.015	-0.2	0.4
Total	0.969	-0.3	0.0

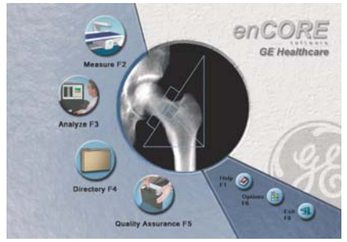
Matched for Age, Weight (females 25-100 kg), Ethnic
USA (Combined NHANES (ages 20-30) / Lunar (ages 20-40)) Femur Reference Population (v110)
Statistically 68% of repeat scans fall within 1SD (± 0.012 g/cm² for Right Femur Total)

Image not for diagnosis

GE Healthcare

DPX
99999

Connectivity and productivity solutions



enCORE software

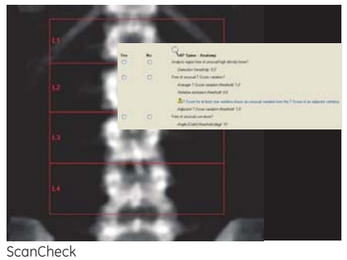
enCORE software – seamless osteoporosis management

The intuitive graphical enCORE software provides a dedicated palette of clinical applications for seamless osteoporosis assessment in a streamlined operator-friendly package, while ensuring clinical confidence and fast throughput. The embedded AutoAnalysis feature facilitates the assessments even more, by automatically placing the (adjustable) standard regions of interest (ROI).

DualFemur with values per ROI

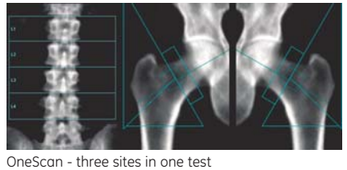
DualFemur – identifying the weakest femur

With the DualFemur option, both femorae 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 increasing confidence in your treatment decisions. In addition, the trending function enables seamless follow-up of change over time.[1,2,3]


ScanCheck

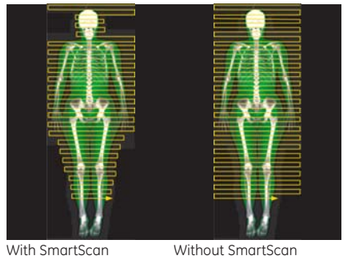
ScanCheck – add quality and diagnostic power

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. ScanCheck helps speed throughput and reduces errors. It also helps technologists provide information to the interpreting physician.[4,5]


OneScan - three sites in one test

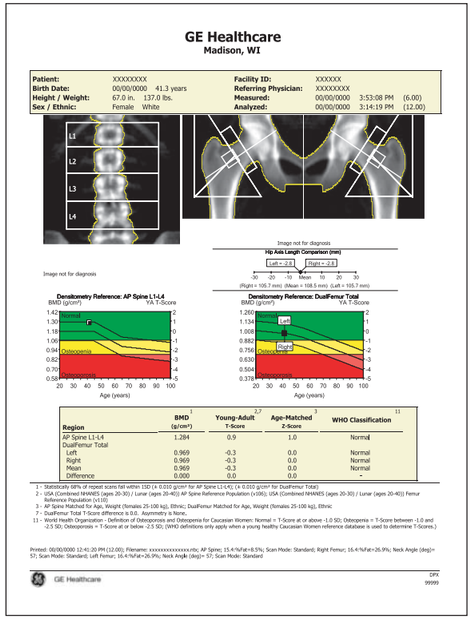
OneScan – three sites in one test

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.[6,7,8]


With SmartScan Without SmartScan

SmartScan – increase throughput

Patient scanning speed is improved with the SmartScan feature: this time-saving scanning technique automatically adapts the scan path to the skeletal structure, imaging the necessary anatomy only, resulting in further speed gains and dose reduction. Utilizing this feature, AP spine and femur scan times are typically less than two minutes in standard mode.


GE Healthcare
Madison, WI

Patient: XXXXXXX
Birth Date: 00/00/0000 41.3 years
Height / Weight: 67.0 in. 137.0 lbs.
Sex / Ethnic: Female White

Facility ID: XXXXXX
Referring Physician: XXXXXXX
Measured: 00/00/0000 3:53:08 PM (6.00)
Analyzed: 00/00/0000 3:14:19 PM (12.00)

Image not for diagnosis

Hip Axis Length Comparison (mm)
Left = 21 Right = 21
-50 -25 -10 Mean 10 20 30
(Right = 105.7 mm) (Mean = 108.5 mm) (Left = 105.7 mm)

Densitometry Reference: AP Spine L1-L4
BMD (g/cm²) YA T-Score
Normal
Osteopenia
Osteoporosis
Age (years)

Densitometry Reference: DualFemur Total
BMD (g/cm²) YA T-Score
Normal
Left
Right
Osteopenia
Osteoporosis
Age (years)

Region	BMD [1] (g/cm²)	Young-Adult [2,7] T-Score	Age-Matched [3] Z-Score	WHO Classification [11]
AP Spine L1-L4	1.284	0.9	1.0	Normal
DualFemur Total				
Left	0.969	-0.3	0.0	Normal
Right	0.969	-0.3	0.0	Normal
Mean	0.969	-0.3	0.0	Normal
Difference	0.000	0.0	0.0	-

1 - Statistically 68% of repeat scans fall within 1SD (± 0.022 g/cm² for AP Spine L1-L4); (± 0.010 g/cm² for DualFemur Total)
2 - USA (Combined NHANES (ages 20-30) / Lunar (ages 20-40)) AP Spine Reference Population (v106); USA (Combined NHANES (ages 20-30) / Lunar (ages 20-40)) Femur Reference Population (v110)
3 - AP Spine Matched for Age, Weight (females 25-100 kg), Ethnic; DualFemur Matched for Age, Weight (females 25-100 kg), Ethnic
7 - DualFemur Total T-Score difference is 0.0. Asymmetry is None.
11 - World Health Organization - Definition of Osteoporosis and Osteopenia for Caucasian Women: Normal = T-Score at or above -1.0 SD; Osteopenia = T-Score between -1.0 and -2.5 SD; Osteoporosis = T-Score at or below -2.5 SD. (WHO definitions only apply when a young healthy Caucasian Women reference database is used to determine T-Scores.)

Printed: 00/00/0000 12:41:20 PM (12.00); Filename: xxxxxxxxxxxxxxx.xtc; AP Spine; 15.4 %Fat=8.5%; Scan Mode: Standard; Right Femur; 16.4 %Fat=26.9%; Neck Angle (deg)= 57; Scan Mode: Standard; Left Femur; 16.4 %Fat=26.9%; Neck Angle (deg)= 57; Scan Mode: Standard

GE Healthcare DPX 99999

Complete connectivity[9] with DICOM, HL7, MUDB and TeleDensitometry

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, present in both DICOM and HL7, enables you to automatically use patient information from scheduling applications, increasing throughput while also 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.

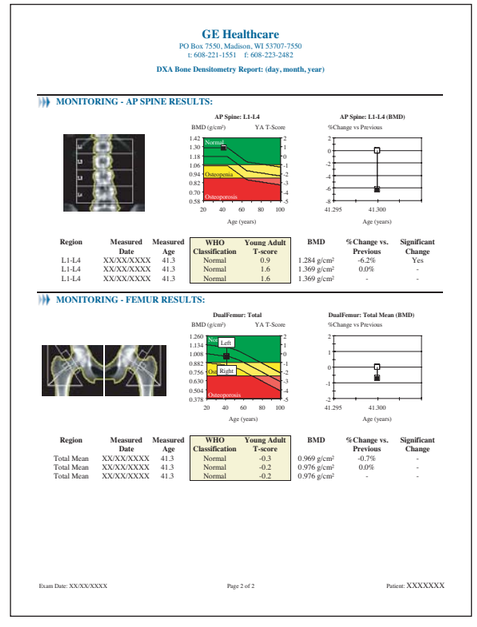
TeleDensitometry enables you to send paperless reports as easy e-mail attachments, viewable on any personal computer without special software.

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,[10] it might not always be that easy for your referring colleagues and administrations 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.

OneVision: the spine and both femurs in one comprehensive report

OneVision automatically combines scans of the spine and both hips into one comprehensive report, acquired in one process and evaluated in one analysis. Rather than receiving multiple assessment reports, the referring physician receives a single, consolidated report that combines all risk assessment analyses.


GE Healthcare
PO Box 7550, Madison, WI 53707-7550
t: 608-221-1551 f: 608-223-2482

DXA Bone Densitometry Report: (day, month, year)

MONITORING - AP SPINE RESULTS:

AP Spine: L1-L4
BMD (g/cm²) YA T-Score
Normal
Osteopenia
Osteoporosis
Age (years)

AP Spine: L1-L4 (BMD)
%Change vs Previous
Age (years)

Region	Measured Date	Measured Age	WHO Classification	Young Adult T-score	BMD	% Change vs. Previous	Significant Change
L1-L4	XX/XX/XXXX	41.3	Normal	0.9	1.284 g/cm²	-6.2%	Yes
L1-L4	XX/XX/XXXX	41.3	Normal	1.6	1.369 g/cm²	0.0%	-
L1-L4	XX/XX/XXXX	41.3	Normal	1.6	1.369 g/cm²	-	-

MONITORING - FEMUR RESULTS:

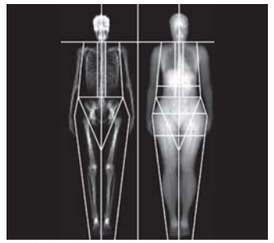
DualFemur: Total
BMD (g/cm²) YA T-Score
Left
Right
Osteopenia
Age (years)

DualFemur: Total Mean (BMD)
%Change vs Previous
Age (years)

Region	Measured Date	Measured Age	WHO Classification	Young Adult T-score	BMD	% Change vs. Previous	Significant Change
Total Mean	XX/XX/XXXX	41.3	Normal	-0.3	0.969 g/cm²	-0.7%	-
Total Mean	XX/XX/XXXX	41.3	Normal	-0.2	0.976 g/cm²	0.0%	-
Total Mean	XX/XX/XXXX	41.3	Normal	-0.2	0.976 g/cm²	-	-

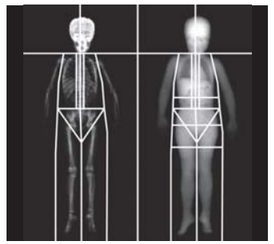
Exam Date: XX/XX/XXXX Page 2 of 2 Patient: XXXXXXX

Dedicated to BMD and beyond


Total body BMD - body composition

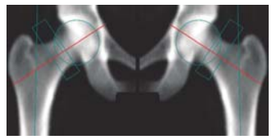
Total body, body composition

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


Pediatric

Lunar DXA pediatric application

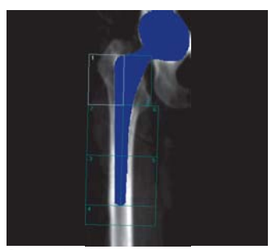
Now you can use one powerful set of tools to get valuable clinical information about growth and development in children. The Lunar DXA pediatric application measures more than BMD - it provides assessment of bone, fat and lean tissue composition. These measurements enable enhanced evaluation of growth and development that include height for age (bone length)[11], BMC for bone area (bone mineralization)[11], bone area for height (bone width)[11], lean body mass for height (muscle development)[12,13], and BMC for lean body mass (muscle-bone balance)[12,13]


Hip Axis Length & Femur Strength Index

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


Orthopedic - hip implant

Orthopedic - Peri-prostetic hip implant

The orthopedic application provides highly 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.

Forearm

Bone evaluation of peripheral sites

The optional peripheral applications, such as the radius and ulna can be evaluated to provide additional clinical information on the skeletal status of your patient, or patient population.

Lunar DPX NT technical specifications:[9,14]

Available applications and options

- AP spine
- Femur
- DualFemur
- OneScan
- Advanced Hip Assessment (AHA)
- ScanCheck
- Total body/body composition
- Estimated Total Body %Fat
- Forearm
- Orthopedic
- Pediatric
- OneVision
- Composer
- Lateral spine BMD
- TeleDensitometry (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

- 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

- 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 - 1.50 mA

Detector technology

- NaI PM tube detector
- High pulse rate

Dimensions (L x W x H) and weight

- System: 2.42m x 1.03m x 1.28m - 272kg (95" x 41" x 50" - 599lbs)
- Table height: .63m (25")

Patient weight limit

- 136kg (300lbs)

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.

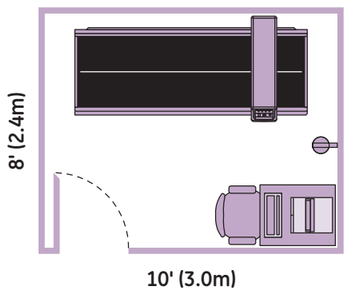
Environmental requirements

- 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

- Windows platform
- Computer, printer and monitor

Minimum room dimensions:



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2. RE Cole. Dual Femur densitometry – Effect on diagnosis and treatment decisions. Presented at the American Society for Bone and Mineral Research Annual meeting. October 2004.
3. RE Cole. The effect of DualFemur scanning on Osteoporosis diagnosis and treatment decision making.
4. EN Schwartz, DM Steinberg. Performance of Computer Assisted Densitometry (CAD) in Spine and Femur Analysis: Comparison with Visual Assessment by Experienced Densitometrists. Abstract Published Osteoporos Int 15 (Suppl 1):S39. Poster Presented at the IOF World Congress on Osteoporosis, May 2004.
5. HS Barden, P Markwardt, R Payne, B Hawkins, M Frank, KG Faulkner (2003) Automated assessment of exclusion criteria for DXA lumbar spine scans. J Clin Densitom 6:401–409.
6. 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.
7. 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
8. 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.
9. Networking is under the user's responsibility
10. The World Health Organization (WHO), the International Society of Clinical Densitometry (ISCD) and the National and International Osteoporosis Foundation (NOF and IOF)
11. Molgaard C, Thomsen BL, Prentice A, Cole TJ, Michaelsen KF (1997) *Arch Dis Child* 76:9-15.
12. 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.
13. 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.
14. Depending on product configuration and availability. Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware.