Indications for use: Lunar Densitometry software is used on Lunar Densitometry systems. The software provides measurements of bone mineral mass, and estimates of fat and lean tissue mass. The values can then be compared to a reference population at the sole discretion of the physicians. United States Federal Law restricts this device to the sale, distribution, and or use by or on the order of a physician.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE representative for the most current information.

GE Lunar, a General Electric company,
doing business as GE Healthcare.

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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** 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

BMD-0179-02.07-EN-GL

GE Healthcare

Lunar DPX Pro™

Simplicity and dedication

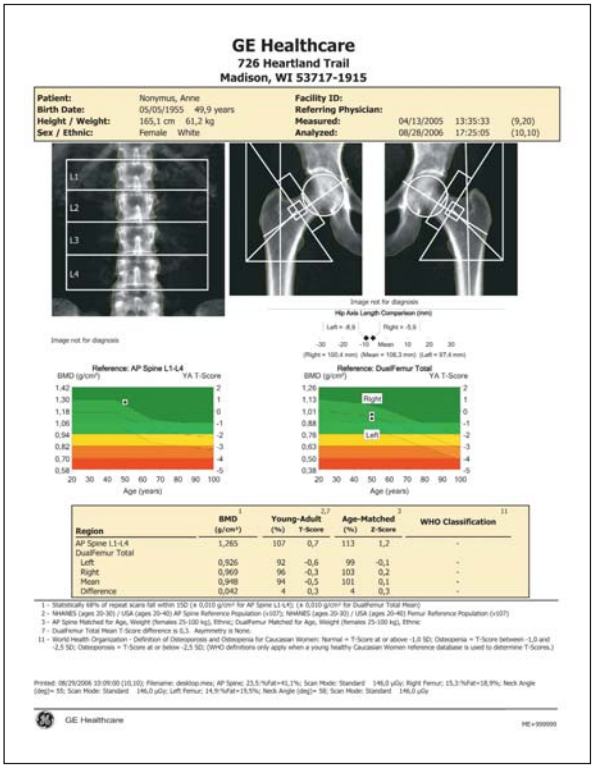
High performance bone dens

itometer

Bone densitometry has reached a new landmark in clinical performance with the Lunar DPX Pro™ densitometer.

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

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



GE Healthcare
726 Heartland Trail
Madison, WI 53717-1915

Patient:	Nonymus, Anne	Facility ID:	
Birth Date:	05/05/1955 49,9 years	Referring Physician:	
Height / Weight:	165,1 cm 61,2 kg	Measured:	04/13/2005 13:35:33 (9,20)
Sex / Ethnic:	Female White	Analyzed:	08/28/2006 17:25:05 (10,10)

Image not for diagnosis

Hip Axis Length Comparison (mm)

Left = -8,9 | Right = -5,9

-30 -20 -10 Mean 10 20 30

(Right = 100,4 mm) (Mean = 108,3 mm) (Left = 97,4 mm)

Image not for diagnosis

Reference: AP Spine L1-L4

BMD (g/cm²) | YA T-Score

Age (years)

Reference: DualFemur Total

BMD (g/cm²) | YA T-Score

Right

Left

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	1,265	107	0,7	113	1,2	-
DualFemur Total						
Left	0,926	92	-0,6	99	-0,1	-
Right	0,969	96	-0,3	103	0,2	-
Mean	0,948	94	-0,5	101	0,1	-
Difference	0,042	4	0,3	4	0,3	-

1 - Statistically 68% of repeat scans fall within 1SD (± 0,010 g/cm² for AP Spine L1-L4) (± 0,010 g/cm² for DualFemur Total Mean)

2 - NHANES (ages 20-30) / USA (ages 20-40) AP Spine Reference Population (v107); NHANES (ages 20-30) / USA (ages 20-40) Femur Reference Population (v107)

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 Mean T-Score difference is 0,3. 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: 08/29/2006 13:09:00 (10,10); Filename: desktop.mes; AP Spine; 23,5 %Fat=41,1%; Scan Mode: Standard 146,0 µGy; Right Femur; 15,3 %Fat=18,9%; Neck Angle (deg)= 55; Scan Mode: Standard 146,0 µGy; Left Femur; 14,9 %Fat=15,5%; Neck Angle (deg)= 58; Scan Mode: Standard 146,0 µGy

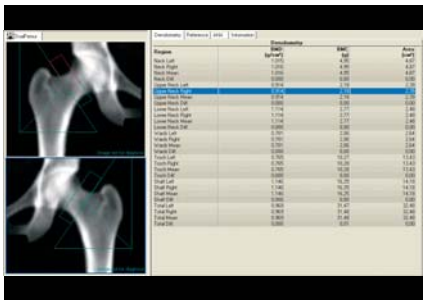
GE Healthcare

Connectivity and productivity

enCORE software

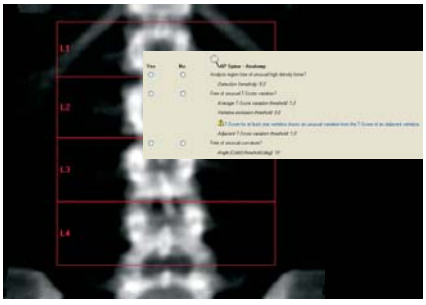
Revolutionary enCORE software – for seamless osteoporosis management

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

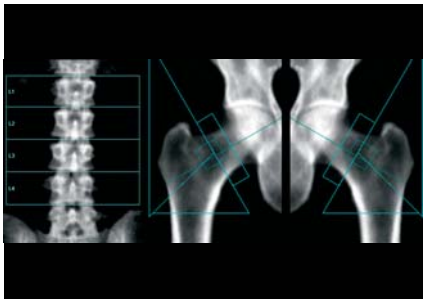
DualFemur – identifying the weakest femur

With the DualFemur option, both femora 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]


CAD - Computer Assisted Densitometry

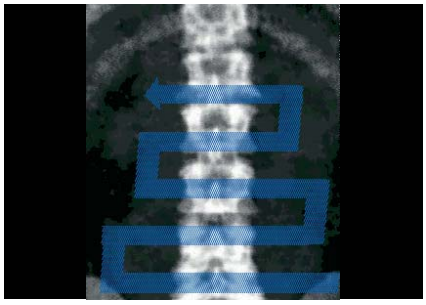
CAD - add quality and diagnostic power

Computer Assisted Densitometry (CAD) 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. CAD 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

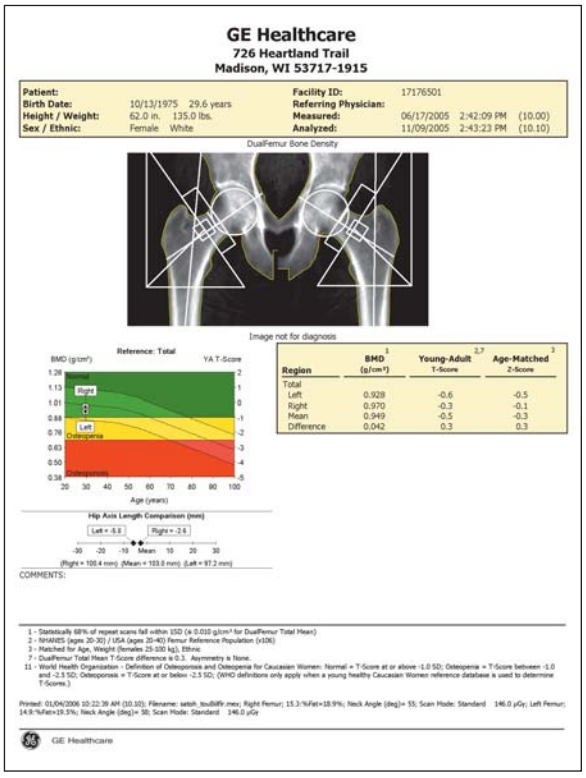
OneScan simplifies BMD testing by acquiring lumbar spine and bilateral femur scans in one, automatic process from a single patient position, without compromising diagnostic confidence.[6,7,8]


SmartScan

SmartScan – increase throughput

Patient scanning is quick and safe with the SmartScan feature: this unique scanning technique automatically adapts the scan path to the skeletal structure, imaging the necessary anatomy only, resulting in further speed gains and dose reduction.

solutions


GE Healthcare
726 Heartland Trail
Madison, WI 53717-1915

Patient:
Birth Date: 10/13/1975 29.6 years
Height / Weight: 62.0 in. 135.0 lbs.
Sex / Ethnic: Female White

Facility ID: 17176501
Referring Physician:
Measured: 06/17/2005 2:42:09 PM (10.00)
Analyzed: 11/09/2005 2:43:23 PM (10.10)

DualFemur Bone Density

Image not for diagnosis

Region	BMD (g/cm²)	Young-Adult T-Score	Age-Matched Z-Score
Total			
Left	0.928	-0.6	-0.5
Right	0.970	-0.3	-0.1
Mean	0.949	-0.5	-0.3
Difference	0.042	0.3	0.3

COMMENTS:

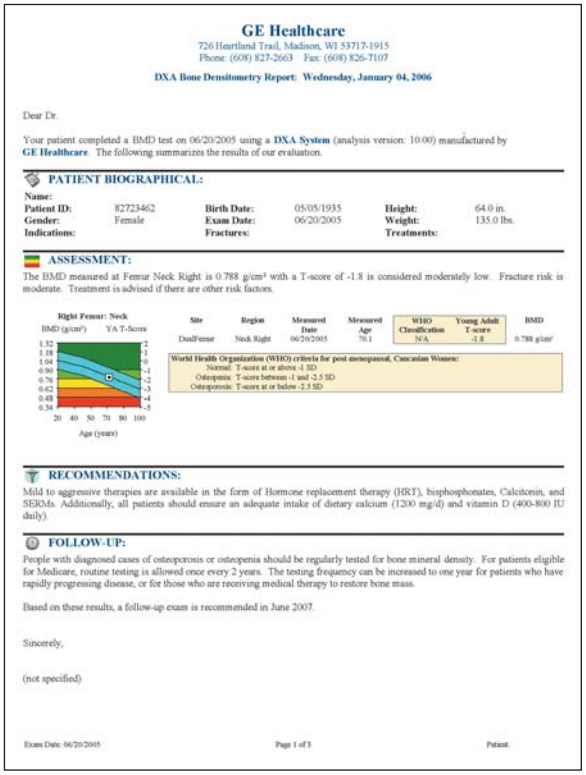
Complete connectivity[9] with DICOM, HL7, MUdbA and TeleDensitometry

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


GE Healthcare
726 Heartland Trail, Madison, WI 53717-1915
Phone: (608) 827-2663 Fax: (608) 826-7107

DXA Bone Densitometry Report: Wednesday, January 04, 2006

Dear Dr.

Your patient completed a BMD test on 06/20/2005 using a DXA System (analysis version: 10.00) manufactured by GE Healthcare. The following summarizes the results of our evaluation.

PATIENT BIOGRAPHICAL:

Name:
Patient ID: 82723462
Gender: Female
Indications:
Birth Date: 05/05/1935
Exam Date: 06/20/2005
Fractures:
Height: 64.0 in.
Weight: 135.0 lbs.
Treatments:

ASSESSMENT:

The BMD measured at Femur Neck Right is 0.788 g/cm² with a T-score of -1.8 is considered moderately low. Fracture risk is moderate. Treatment is advised if there are other risk factors.

Right Femur: Neck

Site	Region	Measured Date	Measured Age	WHO Classification	Young Adult T-score	BMD
DualFemur	Neck Right	06/20/2005	70.1	N/A	-1.8	0.788 g/cm²

World Health Organization (WHO) criteria for post-menopausal, Caucasian Women:
Normal: T-score at or above -1 SD
Osteopenia: T-score between -1 and -2.5 SD
Osteoporosis: T-score at or below -2.5 SD

RECOMMENDATIONS:

Mild to aggressive therapies are available in the form of Hormone replacement therapy (HRT), bisphosphonates, Calcitonin, and SERMs. Additionally, all patients should ensure an adequate intake of dietary calcium (1200 mg/d) and vitamin D (400-800 IU daily).

FOLLOW-UP:

People with diagnosed cases of osteoporosis or osteopenia should be regularly tested for bone mineral density. For patients eligible for Medicare, routine testing is allowed once every 2 years. The testing frequency can be increased to one year for patients who have rapidly progressing disease, or for those who are receiving medical therapy to restore bone mass.

Based on these results, a follow-up exam is recommended in June 2007.

Sincerely,

(not specified)

Exam Date: 06/20/2005 Page 1 of 3 Patient:

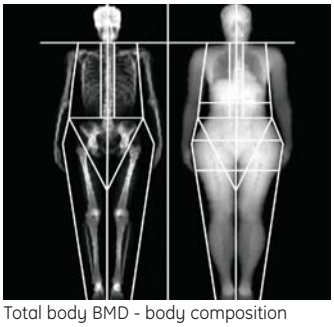
Composer: custom reports

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 femora in one comprehensive report

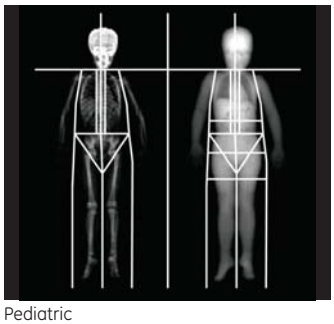
OneVision automatically combines scans of the spine and both hips into one comprehensive report, acquired in one process and evaluated in one analysis. Rather than receiving multiple assessment reports, the referring physician receives a single, consolidated report that combines all risk assessment analyses.

Dedicated to BMD and beyond


Total body BMD - body composition

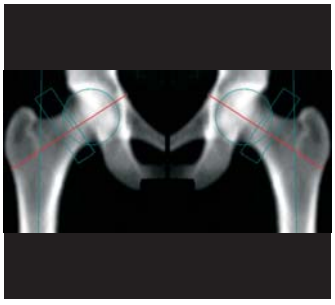
Total body, body composition

The total body exam, the ultimate in skeletal assessment, provides precise bone density and body composition (total fat, lean tissue and bone mineral content) results in one scan.


Pediatric

Lunar DXA pediatric application

BMD and soft tissue assessment may provide valuable clinical information in children with growth disorders and metabolic diseases among other conditions.[11] With the Lunar DXA pediatric application you can compare BMD results against gender-specific reference populations (including skeletal and chronological age), while the soft tissue and bone parameters enable an enhanced assessment of the growth and development of children.[12,13]

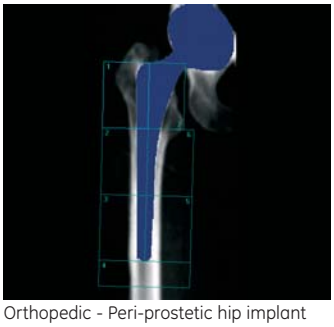

Hip Axis Length & Femur Strength Index

Advanced Hip Assessment (AHA)

The Lunar DPX Pro™ provides the first major breakthroughs in femoral densitometry assessment since the introduction of DXA in 1987.

AHA includes all the standard femoral regions of interest that were previously available, plus additional key measurements and assessments:

- **Hip Axis Length (HAL)** - demonstrated in prospective studies to be an effective adjunct to femur bone densitometry in predicting fracture risk.[14,15]
- **Femur Strength Index (FSI)** - automatically combines BMD and geometric measurements to provide an additional, clinically validated indication of the hip strength.


Orthopedic - Peri-prostetic hip implant

Orthopedic - Peri-prostetic hip implant

The orthopedic software measures BMD around the peri-prostetic hip implant with utmost precision and accuracy, providing orthopedists with a valuable tool for both clinical practice and research studies. Included in this package is the automated classification and analysis of the BMD assessment into the standard (7) or extended Gruen zones (19).


Forearm

Bone evaluation of peripheral sites

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

Technical specifications

Available applications and options[16]

- AP spine
- Femur
- DualFemur
- Advanced Hip Assessment including Hip Axis Length, Femur Strength Index and Cortical Thickness Measurement
- Total Body
- Body Composition
- Forearm
- Lateral Spine BMD
- Orthopedic Hip analysis
- Pediatric
- OneVision
- OneScan
- Composer
- 10-year Fracture Risk Calculator
- Practice Management Tools
- TeleDensitometry[9]
- DICOM (worklist, color print, and store)[9]
- Multi-user database access (MUdbA) (3/10)[9]
- HL7 bidirectional interface[9]
- SQL database[9]
- Remote connectivity for direct customer support[9,16]
- **enCORE software platform**
- Advanced intuitive graphical interface
- Multiple patient directories with Microsoft Access® database
- SmartScan for scan window optimization and dose reduction
- Automated scan mode selection
- AutoAnalysis for better precision
- Customized analysis for clinical flexibility
- Exam comparison process
- 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 Adults and % Age Matched
- WHO guidelines for diagnosis of osteoporosis
- Patient trending with previous exam importation
- Multiple languages available
- Multimedia online help

Typical scan time and radiation dose at the best precision

- AP Spine : 90 sec ; 20 µGy (1%CV)
- Femur : 90 sec ; 20 µGy (1%CV)
- Total Body/Body Composition: 8 min; 0.2 µGy (< 1%CV)

Calibration and quality assurance

- Automated test program with complete mechanicals, electronics tests and global measurement calibration
- Automated QA trending with complete storage

Scanning method

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

X-ray characteristics

- Constant potential source at 76kV
- Dose efficient K-edge filter

Detector technology

- NaI PM tube detector
- High pulse rate

Magnification

- None

Dimensions (L x H x W) and weight

- 242 x 103 x 128 cm - 272 kg (Full)

External shielding

- Not required : x-ray safety requirements may vary upon destination. Please inquire with local regulatory authorities.
- Operating scatter: < 0.2 mR/hr (2 µSv/hr) @ 1m distance from X-ray source
- GE Healthcare recommends consulting your local regulatory agency to comply with local ordinances.

Environmental requirements

- Ambient temperature: 18-27°C
- Power: 20A dedicated circuit 100-120 VAC 60 Hz or 10A dedicated circuit 200-240 VAC 50Hz 600 VA rating
- Humidity: 20% - 80%, non-condensing

Computer workstation

- Windows® platform
- Intel processor computer, printer and monitor
- Contact GE Healthcare or our local distributor for the detailed current configuration and optional hardware.

References:

1. M Kamimura, H Hirabayashi, M Konishi, Q Zhou, H Kato. Osteoporosis diagnosis and treatment decisions with Dual Femur in Japanese women. Presented at the 17th International Bone Densitometry Workshop, Kyoto Japan, November 2006
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, 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.
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. JD Landoll, HS Barden, WK Wacker, W King, JT Kissel, KG Faulkner, V Matkovic (2004) Skeletal assessment in Duchenne muscular dystrophy using new DXA pediatric tools. J Bone Miner Res 19 (Suppl 1):S470. 1095-1101.
12. NJ Crabtree, MS Kibirge, JN Fordham, LM Banks, F Muntoni, D Chinn, CM Boivin, NJ Shaw (2004) The relationship between lean body mass and bone mineral content in paediatric health and disease. Bone 35:965-972.
13. E Schoenau, CM Neu, B Beck, F Manz, F Rauch (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. KG Faulkner, WK Wacker, HS Barden, C Simonelli, PK Burke, S Ragi, L Del Rio. 2006 Femur strength index predicts hip fracture independent of bone density and hip axis length. Osteoporos Int 17: 593–599
15. G Maalouf, J Wehbe, A Nehme, R Moucharafieh, M Gannage, R Chidiac, Y Yaghi Characteristics of the proximal femur in fractured Lebanese subjects: Hip Axis Length predicts hip fracture risk. Abstract Published Bone (2005) 36 (Suppl 2):S353. Poster Presented Joint Meeting of ECTS and IBMS, June 2005.
16. Depending on product configuration and availability