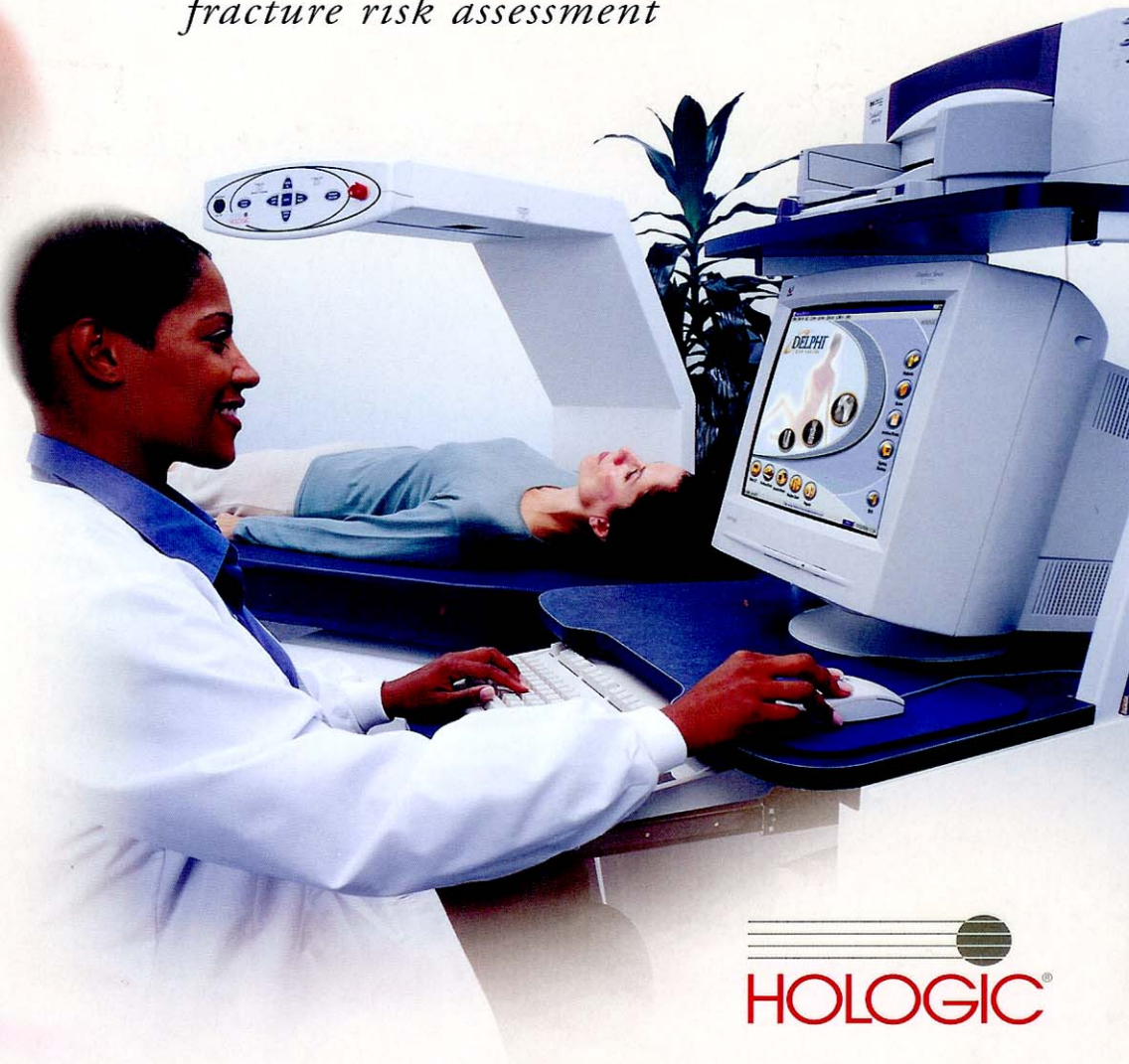




DELPHI™

Q D R® S E R I E S

*The new standard in point-of-care
fracture risk assessment*




HOLOGIC®

True Fracture

DELPHI™

Q D R® S E R I E S

Advancing the Hologic Legacy in Clinical Bone Densitometry

The revolutionary Delphi — a new addition to the Hologic QDR Series — raises the standard in the practice of clinical bone densitometry by integrating bone mineral density (BMD) measurement with Instant Vertebral Assessment™ (IVA). This enables physicians to visually assess vertebral status at the point of care for a more accurate determination of fracture risk than just BMD alone.

Awareness of a vertebral fracture justifies more aggressive treatment — even in patients with normal BMD — and enhances patient awareness about the consequences of osteoporosis. Delphi marks a fundamental change in the evaluation of bone health by providing a practical, reliable approach to comprehensive fracture risk assessment.

In addition to IVA, Delphi features several new capabilities:

- Windows®-based operating system simplifies patient scanning and data reporting, and minimizes operator training requirements.
- OneTime™ Auto Analysis automatically analyzes AP spine and hip scans, reducing examination/analysis time and operator error.
- Dual-Hip™ Analysis compares dominant versus non-dominant femur BMD to identify area with lowest BMD.

Like all Hologic fan-beam systems, Delphi delivers fast, high-resolution images with unsurpassed precision and low patient dose. Plus, a value-added package of clinical and support software, and complete data compatibility with previous generation QDR instruments.



Risk



Instant Vertebral Assessment™ (IVA)

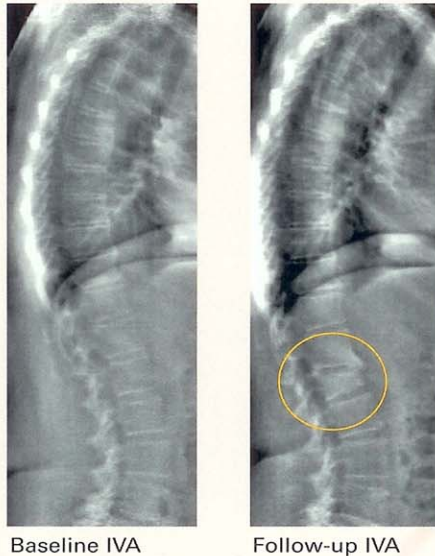


Figure 1
In a 70 year old female patient with AP spine T-score of -1.0 (osteopenia), a wedge deformity subsequent to baseline IVA evaluation indicates increased fracture risk.

With the patient placed in the standard decubitus position used for lateral radiographs, Delphi produces a single, high-resolution image of the entire lateral spine (L4 – T4) in just 10 seconds, and with less than 1% of the dose (<10 μ Sv) of standard lateral spine films. The resulting images can be printed on a high-quality medical imaging printer to transparency or medical paper or viewed, either on the system console, through a DICOM viewing station, or remotely via a stand-alone view/print utility (VPU).

Delphi with IVA is the product of Hologic's continuing mission to improve the assessment of bone health by addressing the two most definitive factors associated with fracture risk: BMD and vertebral fracture.

INSTANT VERTEBRAL ASSESSMENT—available exclusively on the Delphi X-ray Bone Densitometer—advances the state of the art in fracture risk assessment. It enables clinicians to perform a rapid, low-dose evaluation of vertebrae in a single office visit, during a routine bone density exam. The high-resolution, single-energy images obtained with IVA visually reveal existing vertebral deformities, which substantially increase the risk of future fracture and, thereby, affect therapeutic decisions.

Clinical Relevance of IVA in Risk Assessment

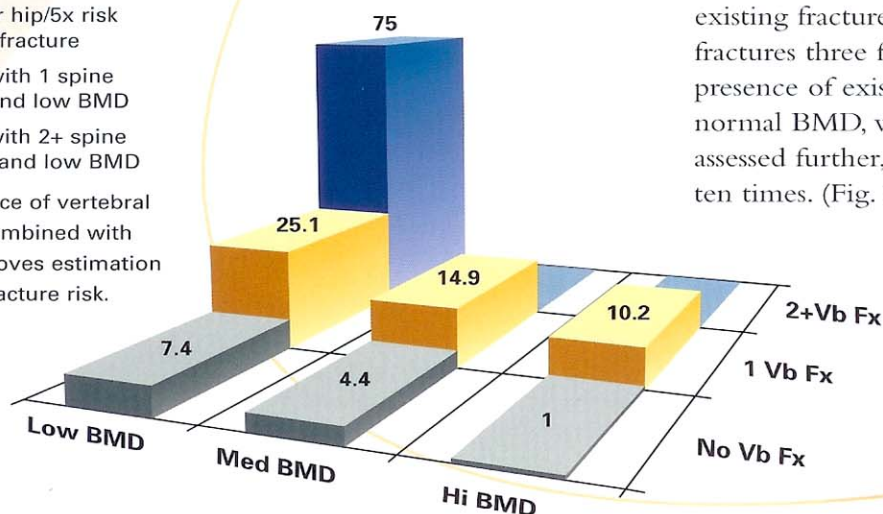
Vertebral fractures, most of which are not clinically apparent, are far more common than one might imagine. Up to one quarter of Caucasian women over age 50 have at least one fracture. The presence of one or more vertebral fractures dramatically increases the risk of future fracture.²⁻⁵

For example, in patients with low BMD, existing fractures increase the risk of subsequent fractures three fold. More importantly, the presence of existing fractures in patients with normal BMD, who usually are not treated or assessed further, increases fracture risk over ten times. (Fig. 2)²

Figure 2
Vertebral Fracture: An Important Risk Factor

- 2x risk for hip/5x risk for spine fracture
- 25x risk with 1 spine fracture and low BMD
- 75x risk with 2+ spine fractures and low BMD

The presence of vertebral fracture, combined with BMD, improves estimation of future fracture risk.



Assessment

Impact on Therapeutic Decisions and Patient Compliance

Relying on BMD alone, physicians are more likely to under-diagnose patients with fractures, since vertebral fractures often elevate BMD values. The clinical importance of having visual confirmation of vertebral deformities cannot be underestimated.

In addition to improved risk stratification, it clearly enhances the clinician's ability to accurately target therapy to those who need it most, and determine the most effective therapy for individual patients. IVA also provides the means for improved patient counseling and compliance by demonstrating the presence or progression of meaningful consequences of osteoporosis.

Summary of IVA Benefits

- Superior prediction of fracture risk
- Very low radiation dose ($<10\mu\text{Sv}$ vs. $800\mu\text{Sv}$ for radiographs)
- Convenient, point-of-care availability eliminates need for additional referrals or subsequent radiographs
- Captures entire spine in one view, eliminating the need for separate lumbar and thoracic views
- Rules out AP spine BMD discordance caused by compression fractures for improved clinical evaluation
- DICOM compatibility offers electronic access to images anywhere in the healthcare system
- Digital image acquisition produces optimal image display, eliminating the need for repeat films
- Electronic archiving provides instant access to patient information

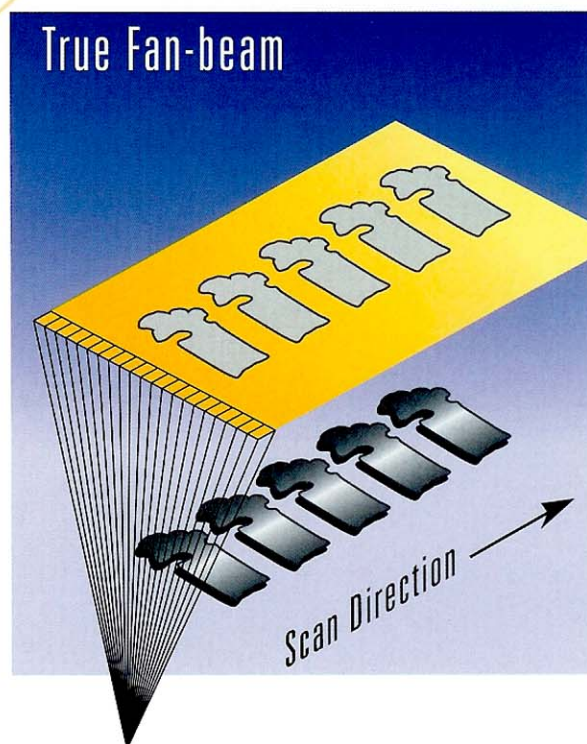
Delphi's high-resolution fan-beam x-ray imaging geometry allows 10-second single energy imaging of entire spine.

True fan-beam technology makes IVA possible

High-resolution fan-beam x-ray imaging, similar to much more expensive computed tomography (CT) systems, provides a technical foundation for high-quality imaging. First introduced by Hologic in 1989, fan-beam DXA systems have since become the method of choice for bone densitometry, due to dramatic improvements in image quality and scanning speed.

Clinical studies prove that fan-beam DXA technology produces high-resolution lateral spine images of sufficient quality for visual evaluation; and that compared to radiographs, the sensitivity and specificity of visual evaluation of these images is excellent.⁹⁻¹¹ For example, the sensitivity vs. radiographs is 92% for moderate to severe deformities, and 77% even including mild deformities. Importantly, overall agreement vs. radiographs was found to be as good as agreement between different radiologists reading the same films.

Compared to the Hologic QDR 4500C—the world's most widely used fan-beam densitometer—Delphi's image resolution has been improved by a factor of two, achieved by doubling the number of detectors and by even finer collimation of the x-ray beam.



QDR for Windows

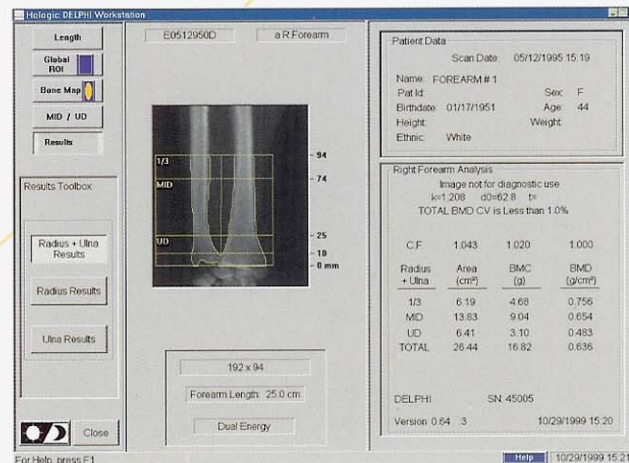
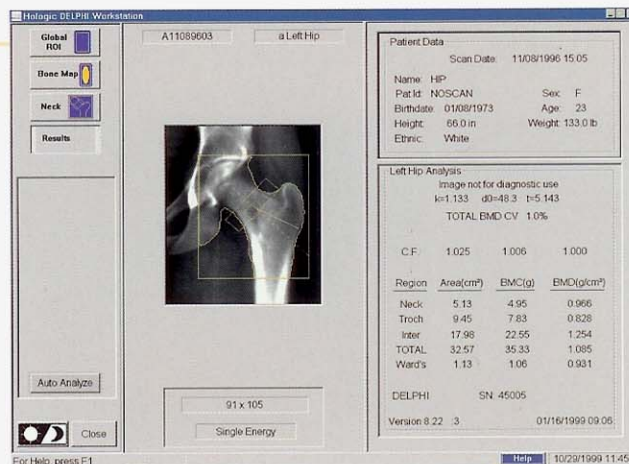
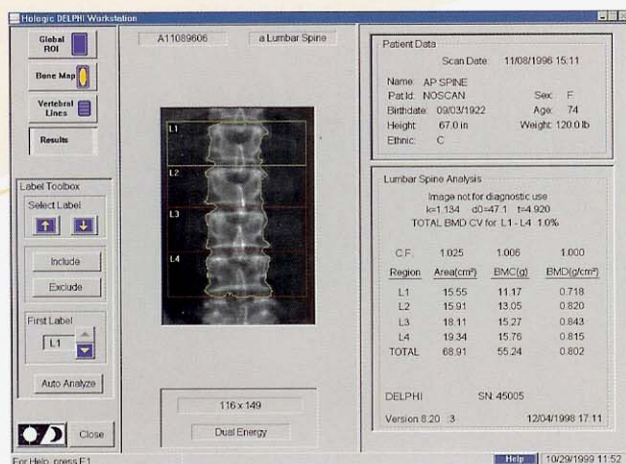
The intuitive, user-friendly QDR for Windows operating system guides operators step-by-step through the patient examination process. With just a single click, operators can access quality control, patient data entry, scan acquisition and analysis, report generation, and archiving functions. Subsequent screens provide an automatic, guided flow through each process, enhancing patient throughput under real clinical conditions.

QDR for Windows offers . . .

- Flexible navigation to accommodate diverse workflow
- Complete data compatibility with DOS-based QDR systems
- Multiple reporting options that can be configured to your specific needs
- Simplified connection to and integration with other systems

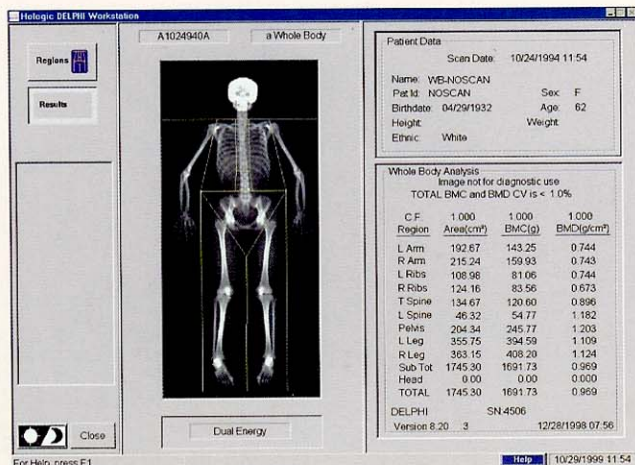


Clinical Applications



BMD plus IVA

Clinical Applications Continued



Whole Body/BMD Analysis*

Delphi can evaluate BMD of the entire skeleton and report on up to 10 continuously adjustable regions of interest. Delphi performs whole body scans in just seven minutes. Typical precision for whole body scans is 0.75% (total region CV at BMD = 1.0 g/cm²).

Optional body composition analysis software enables evaluation of fat mass, lean mass and total mass for the entire skeleton and for individual sub-regions. Both BMD and body composition can be derived from a single whole body scan.

* Requires Delphi with Whole Body model system.

One Time™ Auto Analysis

One Time Auto Analysis delivers expertly analyzed hip and AP spine scans in less than five seconds. Because Delphi automatically and reliably identifies the region of interest, multiple operators of various skill levels do not compromise the accuracy of results. The need for operator intervention is eliminated 85% of the time when analyzing scans of peri- and post-menopausal women.



Scan Comparison

Scan comparison automatically replicates regions of analysis, minimizing operator involvement and performance time. The above example shows a current hip exam displayed simultaneously with a previous baseline study for comparison. This feature can be used in all Delphi scan modes.

Dual Hip™ Analysis

Significant differences in right and left hip BMD can result in a misleading assessment of fracture risk, especially if only one hip is measured. Dual Hip Analysis automatically moves the table and C-arm into position for a "mirror" image and measurement of the opposite hip. Identification of the lowest BMD site improves clinical assessment.

Quality Control

All QDR systems include a program that provides highly automated quality control records. Daily QC scans, which are required prior to patient scanning, are performed on a spine phantom provided with each system and are maintained in a separate quality control database. Statistical analysis includes calculation of mean, standard deviation, coefficient of variation and linear regression (to detect any presence of drift).

Delphi Patient Report

Combine image, scan analysis, and reference curves in a concise, easy-to-read, visually impressive, single-page report. The Delphi patient report also contains pertinent patient information and space for diagnosis and comments. Choose from several preformatted templates and customize your choice with your clinic's name, address, and phone number to save time and materials.

Standard Patient Report

Bedford Osteoporosis Center
35 Crosby Drive
Bedford, MA 01730

Telephone: 781-999-7300 E-Mail: info@hologic.com Fax: 781-280-0614

Name: Gray, Sarah Patient ID: 00367 DOB: July 16, 1957	Sex: Female Ethnicity: White	Height: 68.0 in Weight: 144.0 lb Age: 39
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Referring Physician: BACHMAN




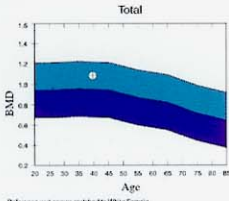
Image not for diagnostic use

Scan Information:
Scan: November 08, 1996 ID: A1108960B
Scan Type: Left Hip
Analysis: October 02, 1999 14:13 Version 8.22
Operator: DP
Model: Delphi (S/N 50005)
Comment: Fast Array

Delphi Results Summary:

Region	Area (cm ²)	BMC (g)	BMD (g/cm ³)	T - Score	Z - Score
Neck	5.28	4.82	0.913	0.3	0.4
Trochanter	12.47	9.52	0.763	0.5	0.6
Inter	28.79	36.40	1.264	0.8	0.8
Total	46.55	50.73	1.090	1.0	1.0
Ward's	1.16	0.93	0.802	0.5	0.8

Total BMD CV 1.0%, ACI=1.025, BCI=1.006, T1=5.021
WHO Classification: Normal
Fracture Risk: Not Increased



Reference curve and scores made for this White Female

Physician's Comment:

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Trend Report

Bedford Osteoporosis Center
35 Crosby Drive
Bedford, MA 01730

Telephone: 781-999-7300 E-Mail: info@hologic.com Fax: 781-280-0614

Name: Smith, Jane Patient ID: 00368 DOB: March 10, 1955	Sex: Female Ethnicity: White	Height: 65.0 in Weight: 125.0 lb Age: 39
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Referring Physician: BACHMAN


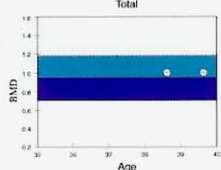


Image not for diagnostic use
97 x 99

Scan Information:
Scan: October 11, 1994 ID: A1011940N
Scan Type: Left Hip
Analysis: October 29, 1999 15:27 Version 0.64
Operator: DP
Model: Delphi (S/N 50005)
Comment:



Reference curve and scores made for this White Female
Source: MAERS

Delphi Results Summary:

Scan Date	Age	BMD (g/cm ³)	T - Score	BMD Change vs Baseline	BMD Change vs Previous
10/11/1994	39	0.991	0.4	-0.0%	-0.0%
10/03/1999	38	0.992	0.4	0.0%	0.0%

Total BMD CV 1.0%
* Denotes significant change at the 95% confidence level

HOLOGIC

Reference Values

The extensive online database of reference values included with QDR for Windows simplifies interpretation of studies. It includes ethnic curves and a utility program that allows customization of user reference values to the local patient population. Several studies can be analyzed to determine annualized or visit-to-visit rate of gain or loss. Hip reference data are based on NHANES in compliance with standardization criteria.

Rate of Change

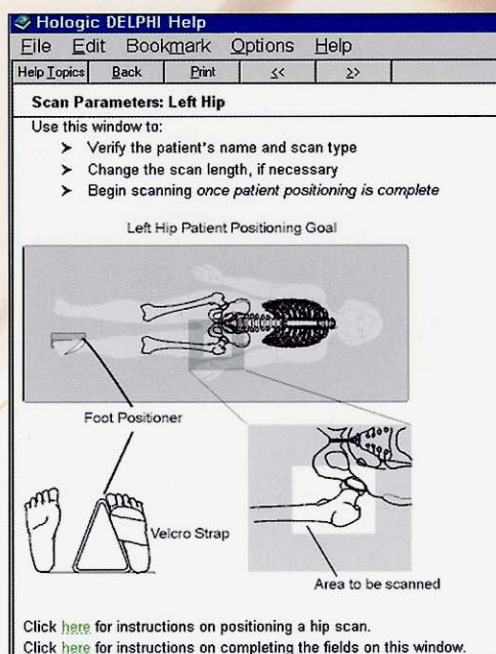
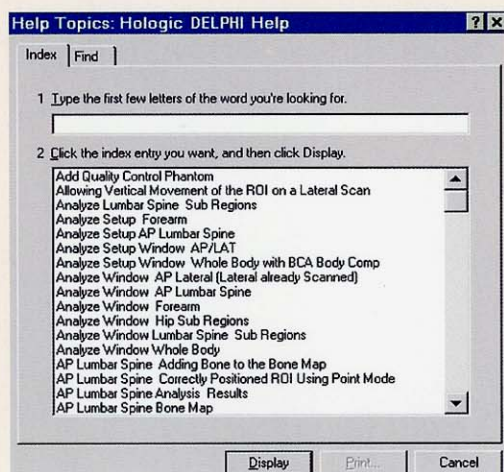
QDR for Windows facilitates serial follow-up of patients. Trend Reports provide an easy method to compare annualized rates of change. Significant changes in bone mineral status are automatically and clearly noted on the report to facilitate clinical management.

Fan-Beam

Delphi Value-Added Package

Context Sensitive Help

The text and graphics in the Help menu provide an overview and virtual "walk through" of Delphi's operation and capabilities. A single click on a topic button produces instructions on scanning, analysis, and data management.



Practice Development Guide

The Practice Development Guide helps you raise public awareness and take full advantage of Delphi's practice-building potential. Two CDs include ready-to-print marketing and patient education materials and tips on how to use the available array of marketing and media options to maximize the return on your investment of time, resources, and capital.

Additional Delphi

FEATURES

- Complete system, including advanced, high-speed CPU, large monitor, and fast, color printer
- 3.5-in. LS 120 Superdisk Drive for scan archiving
- CD ROM for support programs
- **Anthropomorphic Spine Phantom**, used for quality control, assures consistently accurate measurements without the need for waterbaths to perform system calibration.
- QDR's patented **Automatic Internal Reference System** automatically maintains pixel-by-pixel calibration without operator involvement and assures long-term precision.
- **Image Repositioning** makes obtaining the perfect scan easy. With the push of a button, operators can interrupt scanning to adjust the image on screen, without having to reposition the patient on the table.
- **Reanalysis** lets you repeatedly reanalyze scan information—stored as raw data—without rescanning, even a year or more after the initial scan.
- **Scoliotic Spine Analysis** tailors vertebral BMD assessment to the unique curvature of patients with scoliosis.
- **Automatic Bone Mapping** calculates the soft tissue and bone map of any scan without operator involvement.
- **Automatic Locate** feature internally records and monitors the location of patient data saved to a storage media, eliminating the need to log patient data.



Optional 18" flat-panel monitor displays crisp, brilliant images at 1,600 x 1,200 maximum resolution.

References

1. Melton LJ III, Lane AW, Cooper C, Eastell R, O'Fallon WM, Riggs BL. Prevalence and Incidence of Vertebral Deformities. *Osteoporosis Int.* 1993;3:113-119.
2. Ross PD, Davis JW, Epstein RS, Wasnich RD. Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Ann Intern Med.* 1991;114(11):919-23.
3. Kotowicz MA, Melton LJ III, Cooper C, Atkinson EJ, O'Fallon WM, Riggs BL. Risk of hip fracture in women with vertebral fracture. *J Bone Miner Res.* 1994;9(5):599-605.
4. Ross PD, Genant HK, Davis JW, Miller PD, Wasnich RD. Predicting vertebral fracture incidence from prevalent fractures and bone density among non-black, osteoporotic women. *Osteoporosis Int.* 1993;3(3):120-126.
5. Davis JW, Grove JS, Wasnich RD, Ross PD. Spatial relationships between prevalent and incident spine fractures. *Bone.* 1999;24(3):261-4.
6. Pouilles JM, Tremolieres F, Ribot C. Spine and femur densitometry after menopause: are both sides necessary in the assessment of risk of Osteoporosis. *Calcif Tissue Int.* 1993 May; 52 (5): 344-7

Delphi™ QDR® Product Specifications

Scanning method:

X-ray fan-beam, utilizing motorized table and C-arm

X-ray System:

- Switched-pulse dual-energy (140 and 100 kVp)
- Single-energy for IVA (140 kVp)

Detector System:

Multi-element detector array

Scatter Dose:

Less than 1.0 mR/hr (0.01mSv/hr) nominal measured at 2.0m from the examination table for most scan modes

External Shielding:

None required

Note: Installation requirements for X-ray equipment vary. Check with local regulatory authorities.

BMD Precision: <1.0%*

Calibration:

- Self-calibrating using patented Hologic Automatic Internal Reference System
- Automated Quality Control program
- Operator calibration not required

Operating Requirements:

Temperature:

60°-90°F (15°-32°C)

Power:

100VAC (14A)/120VAC (12A)/230VAC (7A)

Humidity:

20%-80% relative humidity, non condensing

Maximum Heat Load:

3,400 BTU/hr

Table Height:

71cm (28in)

Standard Hardware Configuration:

- Computer console
- Pentium III CPU
- 6GB (min) hard disk drive
- 3.5in. LS 120 Superdisk Drive
- 64MB (min) RAM
- 4MB video board
- CD ROM
- High resolution 17 in. monitor
- HP Professional Color DeskJet® Printer
- Medical Imaging Printer (prints on medical paper and transparencies)

Standard Software Configuration:

- Microsoft® Windows '98
- Hologic QDR® for Windows
- Instant Vertebral Assessment™ (IVA)
- OneTime™ Auto Analysis
- Dual Hip™ Analysis
- NHANES Standardized Hip Reference Database
- Context-Sensitive Help
- Fracture Risk Indication
- DICOM

Optional Hardware:

- Magneto Optical Disk Storage
- HP LaserJet® B&W printer
- Flat Panel Monitor
- Workstation

Optional Software:

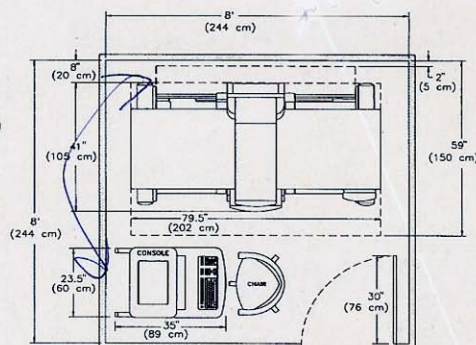
- Whole Body
- Body Composition Analysis
- General Region of Interest
- Prosthetic Hip †
- Stand-Alone View Print Utility (VPU)
- Quantitative Morphometry (QM)

Communication Options:

- Modem Option
- Network Option

*Default Mode

† For investigational use only in the United States



ROOM LAYOUT

DEXAScanners, Inc.
dexascanners.com

Delphi System Performance (60 Hz)†

Exam	ScanTime	Exposure
Lumbar Spine	15s	5mR
Hip	15s	5mR
Forearm	30s	10mR
Whole Body	6.8min	1.5mR
IVA Single Energy	10s*	7mR

†50Hz and other scan modes available.

*15in. scan length

HOLOGIC®

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510, BUS 31
1930 Zaventem, Belgium
Phone: 32.2.711.4680
Fax: 32.2.725.2087
E-mail: info@hologic.be

Specifications

	Delphi	Delphi with Whole Body
Scan Sites	PA lumbar spine Proximal femur (hip) Forearm Lateral spine imaging, L4-T4	PA lumbar spine Proximal femur (hip) Forearm Lateral Spine Imaging, L4-T4 Whole Body
Scan Region	38" x 20" (96cm x 51cm)	77.5" x 26" (197cm x 65cm)
Footprint	76" x 49.5" (1.93m x 1.26m)	79.5" x 48" (2.02m x 1.22m) 119" x 59" (3.02m x 1.50m) (table extended)
System Weight	Table/C-arm: 650 lb (296kg) Computer console: 54 lb (24.3 kg)	Table/C-arm: 680 lb (310kg) Computer console: 54 lb (24.3kg)

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U.S Patent Nos. 4811373, 4947414, 5040199, 5148455, 513853. Canadian Patent No. 1292810. Patents pending.