

DELPHI™

Q D R® S E R I E S

The standard in point-of-care fracture risk assessment. Now with Image Pro.



True Fracture Risk

DELPHI™

Q D R® S E R I E S

Advancing the Hologic Legacy in Clinical Bone Densitometry

The revolutionary Delphi—the latest 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). IVA 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.

Utilizing true, fan-beam x-ray imaging geometry as its technological foundation, Delphi features:

- **Superior BMD measurement**—fast, high resolution, linear scanning provides accurate BMD results with superior precision
- **Instant Vertebral Assessment**—rapid, 10-second, single-energy imaging of the entire spine (L4–T4)
- **Image Pro™***—advanced digital imaging processing sharpens your view of vertebral fractures
- **e-Reporting**—the most advanced remote interpretation and reporting software available, including speech recognition compatibility

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.

* Optional

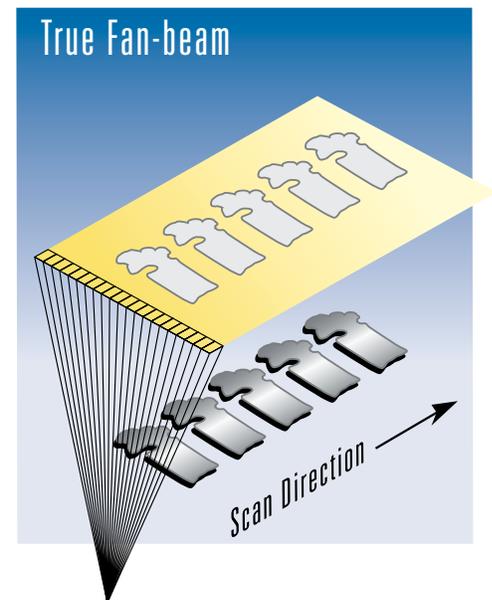


Figure 1

Utilizing true fan-beam x-ray imaging geometry, similar to that found on high-end CT systems, Delphi produces high-resolution images of the entire spine in just 10 seconds.

Instant Vertebral Assessment™ (IVA)

Clinical Relevance of IVA in Risk Assessment

Vertebral fractures, 75% 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

Published studies using IVA demonstrate that up to 30% of patients needing treatment are missed using BMD results alone.⁶ These patients, many of whom have moderately decreased BMD but have already suffered a fracture, are at particularly high risk.

Image Pro* Produces High-quality Images

The optional Image Pro image-processing software—now available for all new Delphi systems and as an upgrade for existing systems—improves visualization of vertebral fractures without increased dose, allowing clinicians to more accurately assess fracture risk.

All digital imaging technologies (CT, MR, CR and DR) utilize imaging processing techniques to enhance visualization of anatomy. Image Pro applies advanced, frequency dependent filtration to IVA images, enhancing visualization of vertebral end-plates.

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.

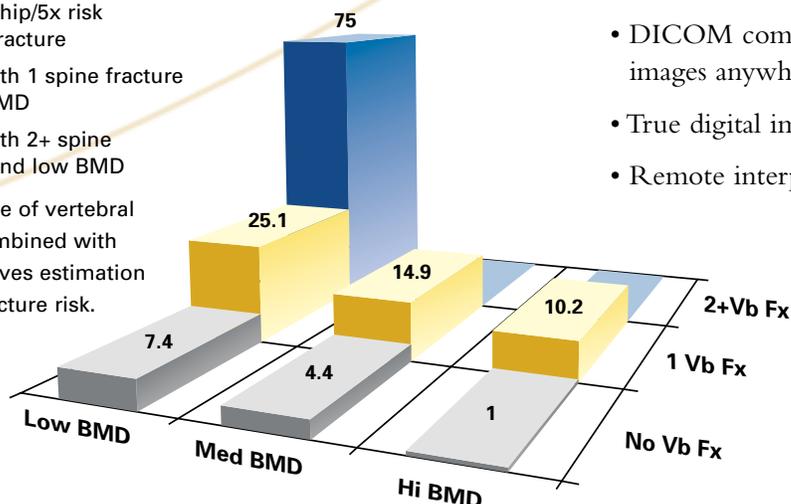
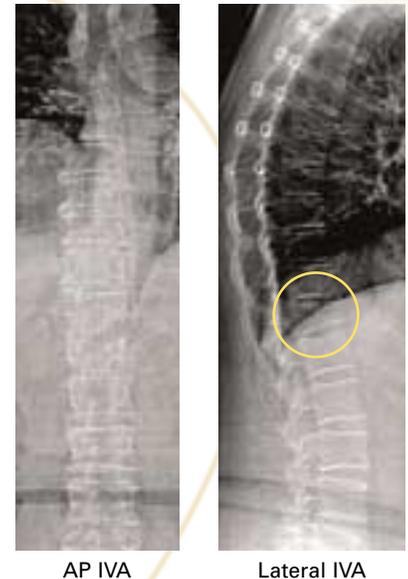


Figure 3

IVA images of a woman, 72, with BMD T-scores of -0.9, -0.4 and -1.0 at the femoral neck, total hip and lumbar spine, respectively. While her BMD results classify her as normal, a vertebral fracture puts her at increased risk for subsequent fractures and, therefore, in need of treatment for osteoporosis.



Summary of IVA Benefits

- Clear, crisp images in just 10 seconds
- Superior prediction of fracture risk
- Very low radiation dose (<10 μ Sv vs. 800 μ Sv for radiographs)
- Convenient, point-of-care availability eliminates need for additional referrals or subsequent radiographs
- AP view reveals vertebral deformities missed with lateral imaging alone
- DICOM compatibility offers electronic access to images anywhere in the healthcare system
- True digital images with full image fidelity
- Remote interpretation and electronic reporting
- Electronic archiving provides instant access to patient information
- Additional reimbursable examination**

* Optional

** Insurers vary widely in the services they cover and reimburse.

The Experts

What the Experts Say About IVA

“IVA would benefit the subset of women who have osteopenia, but whose fracture history is unknown. If you knew they had fractures, you would certainly be more aggressive in your treatment.”

Susan L. Greenspan, M.D.

*Director, Osteoporosis Prevention and Treatment
Division of Endocrinology, Metabolism and Geriatrics
Associate Director, General Clinic Research Center,
University of Pittsburgh Medical Center
Professor of Medicine, University of Pittsburgh School of Medicine*

“Because the presence of a vertebral fracture doubles the risk of future hip fractures and increases the risk of vertebral fractures five times, it is important to identify these high-risk patients and provide them with proper therapy... We have seen the value of using IVA in clinical practice. Even for those [patients] with normal BMD, the presence of a low-trauma fracture indicates the need for treatment.”

Walter Briney, M.D.

*Clinical Professor of Medicine, University of Colorado Health Science Center
Director of Medical Specialty Clinic, Denver Health Medical Center
Director of Metabolic Bone Clinic, Denver Health Medical Center*

“Traditionally, BMD was used as the sole indicator of a patient’s bone health and fracture risk, but now technology has advanced to incorporate vertebral fracture evaluation and BMD assessment on the same instrument. Using Instant Vertebral Assessment™ (IVA), a feature on the Hologic Delphi™, we are able to obtain a low-dose (just 1/100 of a conventional spine radiograph), 10-second scan of the spine during a routine bone density exam ... Overall, incorporating IVA into our osteoporosis evaluation has given us an additional, important tool to identify those at risk of future fracture. We also are able to recommend intervention for those who will benefit the most from therapy—a step that’s likely to reduce fracture rate, and consequently, help patients maintain independence and quality of life.”

John Schousboe, M.D.

*Director, Osteoporosis Center, Park Nicollet Clinic,
St. Louis Park, Minn.*



In a 66 year old female patient with AP spine T-score of -1.0 (normal), a L2 wedge deformity indicates increased fracture risk and the need for aggressive treatment.



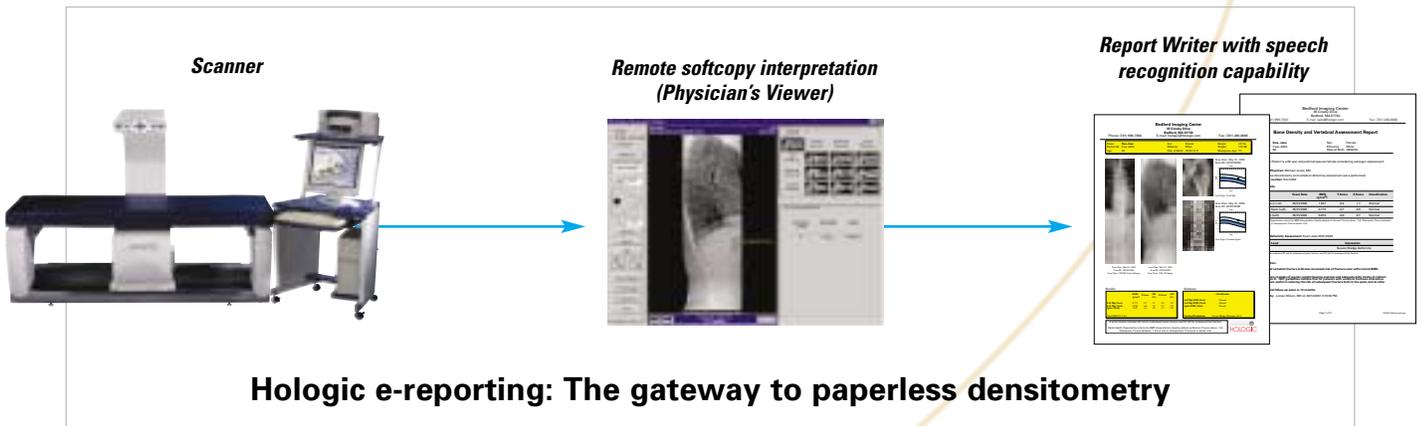
IVA Toolbox Remote Interpretation and e-Reporting

Physician's Viewer with IVA Toolbox

Physician's Viewer is a stand-alone software package for remote softcopy review of BMD and IVA scans. The IVA Toolbox simplifies interpretation by providing graphical and quantitative fracture-grading tools. Optional Physician's Report Writer generates electronic reports for paperless distribution.

Benefits:

- Remote soft-copy interpretation
- Maintains full image fidelity
- Optimize image with interactive zoom, brightness and contrast control
- Intuitive graphical interpretation aids
- On-screen labeling of vertebral levels and fracture status
- Quantitative confirmation of vertebral deformation
- Platform for e-reporting



Optional

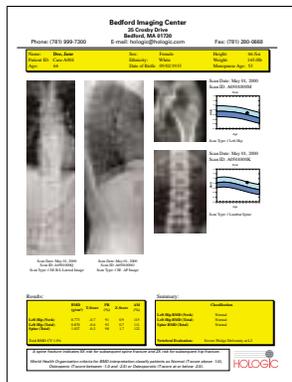
Physician's Report Writer (Optional)

Produces a comprehensive electronic report in Microsoft® Word format for electronic distribution and printing.

OnePage Dx™ Report

Combine multiple risk factors into a comprehensive, one-page report

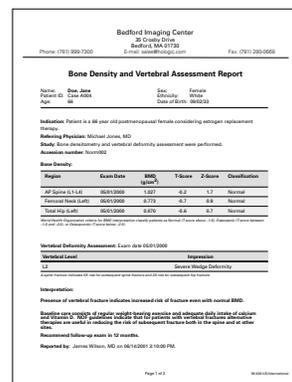
The OnePage Dx Report combines BMD and IVA results in a concise, single-page format for better assessment of fracture risk. This comprehensive summary of results displays both AP and lateral IVA images along with BMD results in our easy-to-read and interpret format.



Physician's Interpreting Report

Streamline report writing and workflow

The Physician's Interpreting Report automatically downloads and formats key information into a customizable electronic report that includes patient biographical information, BMD, T-/Z-scores, and IVA results. The physician can enter final comments via keyboard or speech recognition dictation.



Clinical Applications

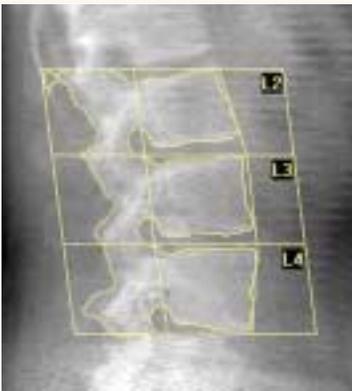


AP Spine and Proximal Femur

Delphi provides unmatched precision for lumbar spine and proximal femur studies with scanning times as rapid as 10 seconds. In default mode, spine and proximal femur precision is better than 1.0% (CV at BMD=1.0g/cm²).

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.



Supine Lateral BMD*

Supine lateral spine BMD enables clinicians to obtain reliable, quantitative measurements of trabecular-rich vertebral bodies in the supine position. Supine lateral measurements have demonstrated superior precision (1%) over quantitative measurements in the decubitus position.

*Requires Delphi SL or A models

Forearm

A 30-second forearm scan performed on Delphi produces simultaneous assessments of 1/3, mid-, and ultra-distal regions. Delphi can scan and analyze the radius and ulna either separately or combined.

Whole Body/BMD Analysis*

Delphi can evaluate BMD of the entire skeleton and report on up to 10 continuously adjustable regions of interest. Delphi can perform whole body scans in as little as 3.5 minutes. Typical precision for whole body scans is 0.75% (total region CV at BMD = 1.0 g/cm²).

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 W or A models

**Optional

Research Applications



Pediatric Spine and Femur

Rapid, 30-second scanning and enhancements to data analysis protocols make Delphi particularly well suited for pediatric studies. The analysis algorithms automatically detect and measure very low-density bone, making Delphi the instrument of choice for pediatric densitometry.



Small Animal*

Perform In Vivo scans of rat whole body with BMD and body composition measurements, including lean and fat tissue mass, total mass and % fat determinations. Unique, small step phantom assures accuracy and repeatability of results.

*Requires Delphi A model. Optional software.



Prosthetic Hip*

Bone resorption around a hip prosthesis can eventually contribute to loosening of the implant device. Monitoring changes in the bone surrounding the prosthesis provides clinicians with pertinent information regarding bone status and the viability of the implant.

The QDR Prosthetic Hip software option automatically identifies and removes the influence of a metal prosthesis to produce precise BMD measurements.

*Optional



Infant Whole Body*

Provides bone mineral and body composition measurements for human infants ranging from 26 weeks gestational age to one year birth age, or approximately 1kg to 10 kg in weight. The measurement system uses the lowest x-ray tube current available and exposes the patient to a very low dose (less than 2mrem).

*Requires Delphi A model. Optional software. For investigational use in the USA.

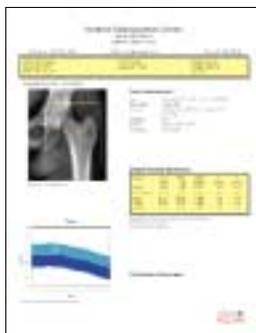
Advanced Reporting

QDR One-Page 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.

Standard Patient Report

The extensive online database of reference values included with Delphi simplifies interpretation of studies. It includes ethnic-matched reference data and utilities that allow customization of user reference values to the local patient population. Hip reference data are based on NHANES in compliance with standardization criteria.



Trend Report

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



Additional Delphi

FEATURES

- Complete system, including advanced, high-speed CPU, large monitor, and fast, color printer
- **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. Operators can adjust the image on screen without having to reposition the patient on the table.
- **Scoliotic Spine Analysis** tailors vertebral BMD assessment to the unique curvature of patients with scoliosis.
- **Automatic Low-density Spine and Hip** Improves bone detection in low-density AP spine and proximal femur images by decreasing operator manipulation of the bone map.
- **Automatic Locate** feature internally records and monitors the location of patient data saved to a storage media, eliminating the need to log patient data.
- **Context Sensitive Help Menu** provides an overview and virtual "walk through" of Delphi's operation and capabilities.
- **Practice Development Guide** contains two CDs with ready-to-print marketing and patient education materials to build public awareness and help you take full advantage of Delphi's practice-building potential.
- **One Time™ Auto Analysis** One Time Auto Analysis delivers expertly analyzed hip and AP spine scans in seconds. Because Delphi automatically and reliably identifies the region of interest, the need for operator intervention is virtually eliminated.
- **Dual Hip™** 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 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 an anthropomorphic spine phantom provided with each system and are maintained in a separate quality control database.
- **Pediatric Reference Data** QDR software now incorporates reference data for children aged 4-20. The database provides whole body, hip* and AP spine reference data for North American, Caucasian boys and girls.
* *Optional software. For investigational use in the U.S.*

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