Lone Oak Medical Technologies' Accudxa2

J.D. Honigberg International Inc.

Overview



- The ACCUDXA2 Bone Mineral Density (BMD) Assessment System provides a quick, convenient, easy and economical solution for determining a patient's fracture risk.
- The test can be performed at the doctor's office by placing the patient's hand in the unit, following a set of commands on the view screen and does not require the removal of garments or the application of gels or creams.
- Results are displaced within 30 seconds.

History

- The Accudexa BMD (Bone Mineral Density System) was first developed by Schick Technologies in 1997.
- The technology was then sold to Lone Oak Medical Technologies in 2008
- Lone Oak Medical Industries introduced the Accudxa2 in 2012.
- The unit is FDA registered and CE certification is pending.



Facts

- The Accudxa2 is a dual-energy X-ray device indicated for use in estimating the bone density (BMD) of the middle finger of the nondominant hand, which is a proven correlator to hip and spine fractures.
- It is a self-contained, portable table-top unit, employing dual energy X-ray absorptiometry (DEXA) technology.
- After the finger is scanned, results are generated in less than one minute.
- The Accudxa2 compares BMD values to a reference (normative) database. This database reflects the mean for a healthy normal (YHN) population having the same gender and ethnicity.

Method

- **Dual-energy X-ray absorptiometry** is a means of measuring bone mineral density (BMD). Two X-Ray beams with different energy levels are aimed at the patient's bones. When soft tissue absorption is subtracted out, the BMD can be determined from the absorption of each beam by bone.
- Dual-energy X-ray absorptiometry is the most widely used and most thoroughly studied bone density measurement technology.

Using the Accudxa2



- Low bone mineral density at the finger has been demonstrated to be as predictive of generalized fracture in the elderly as measurements made at axial sites.
- All bone mineral density measurements should be used in conjunction with other risk factors in determining fracture risk.
- Given published annual changes at finger, BMD can be tracked biannually.
 Physicians should compare results of BMD tests taken on a patient over a period of time.
- Can be hooked up to a printer to generate reports.

Risk Factors for Osteoporosis

- Being female
- A small, thin frame
- Advanced age
- A family history of osteoporosis
- Early menopause
- Abnormal absence of menstrual periods (amenorrhea)
- Anorexia nervosa or bulimia
- A diet low in calcium
- Use of certain medications (steroids, anticonvulsants, excessive thyroid hormones, certain cancer treatments)
- Low testosterone levels in men
- A sedentary lifestyle
- Cigarette smoking
- Excessive alcohol intake
- Malabsorption problems

Indications

- Below normal bone density can be associated with a variety of bone conditions or disorders. Some of the more common conditions associated with below normal bone density include:
 - Premenopausal oophorectomy
 - Spontaneous menopause or estrogen deficiency conditions
 - Treatment-related osteopenia; when the diagnosis of osteopenia is suggested or established by other means (such as X-ray; during long-term immobilization)
 - Endocrinopathies associated with osteopenia; for post-gastrectomy and other malabsorption states leading to osteopenia; during long-term corticosteroid therapy
 - Chronic renal disease, particularly in childhood or adolescence
 - In addition to the above, BMD values can be used to monitor longitudinal changes, as with treatment programs for osteoporosis.

Contraindications

- A deformity that prevents a patient's non-dominant hand from being properly positioned.
- Orthopedic hardware in the middle finger of the non-dominant hand.
- Previous fracture of the middle finger of the non-dominant hand.
- Pregnancy. (Although the radiation exposure from an accuDEXA BMD test is 1/150,000 of a chest X-ray, any radiation exposure during pregnancy must be deemed medically necessary by a physician.)

Accuracy

- Most accurate DXA: 99% correlation with bone ash
- 1.8% accuracy error

Technology	Precision	Accuracy error- BMC	Radiation (uSv)	Estimated Exam Time
hip DXA	1 - 2%*	4 - 8%*	0.6 - 5.9	15 min
spine DXA	1%*	4 - 8%*	2.9	15 min
forearm DXA	<1% - 2%**	4.3% - 5.2%**	0.1	7 min
ultrasound	3%***	n/a	n/a	3 min
AccuDEXA	<1%	1.80%	0.0003	1 min

- Grampp et al. Radiological Diagnosis of Osteoporosis. Eur. Radiology, 7(Suppl 2): 1997.
- ** Hagiwara, S. et al. Dual X-Ray Absorptiometry Forearm Software: Accuracy and Intermachine Relationship. JBMR, 9(9) 1994.
- *** Manufacturer's literature

Correlation to Hip and Spine

 Correlation to peripheral technology: RA, Forearm DXA & SXA, (0.80<r<0.94)

Michaeli DA, Mirshahi A, Singer J, Rapa FG, Plass DB. A new x-ray based osteoporosis screening tool provides accurate and precise assessment of phalanx bone mineral content. Journal of Clinical Densitometry, 1998.

Correlates about as well to hip as spine correlates to hip

Mulder JE, Flaster ER, Michaeli D, Siris E. Comparison of bone mineral density of the phalanges, lumbar spine, hip and forearm for the assessment of osteoporosis in Postmenopausal Women. JCD, Winter 2000.

	accuDEXA	Lumbar Spine	Total Hip	Femoral Neck	Radius
accuDEXA	1	0.546	0.557	0.532	0.73
Lumbar Spine		1	0.672	0.643	0.536
Total Hip			1	0.896	0.583
Femoral Neck				1	0.547
Radius					1

Contacts:

Export Department

J.D. Honigberg International Inc. 155 N. Pfingsten Road, Ste. 150 Deerfield, IL 60015 U.S.A. medical@jdhintl.com www.jdhmedical.com



Manufacturer

Lone Oak Medical Technologies 3805 Old Easton Road Doylestown, PA 18902 USA

info@loneoakmedical.com www.loneoakmedical.com

