

CONTACT

For sales and marketing info, to place an order for an *UltraScan 650*, or to discuss potential investment and licensing, please contact:

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U.S. FDA approval (510(k) summary¹) can be found at:

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161919.pdf

CYBERLOGIC[®], INC.

CyberLogic is a research and development firm in New York City (corner of Broadway and Houston Street, see image), founded in 1992. CyberLogic has been working in the field of biomedical ultrasound for over 20 years.



The *UltraScan 650* is protected by several U.S. and international patents, including U.S. Patent Nos. 7,862,510, 8,202,219, and 9,039,616, and China Patent No. ZL2008 1 0004839.7, among others.

The *UltraScan 650* has been developed with peer-reviewed funding from the Small Business Innovative Research (SBIR) program of the National Institutes of Health.

UltraScan[™] 650



The radiation-free alternative to DXA, with the only ultrasound device cleared by U.S. FDA to measure bone mineral density (BMD).

Device Description¹

The *UltraScan 650*

- is an ultrasound device designed to non-invasively and quantitatively assess the amount of bone at the 1/3 location of the radius in the forearm of an individual.
- is designed for the estimation of bone mineral density (BMD in g/cm^2) of the radius at the 1/3 radius.
- outputs a BMD_{us} Index, an estimate of BMD that would be measured by DXA at the same anatomical location, that is, an estimate of BMD_{DXA} , at the 1/3 radius.
- outputs the T -score and z -score in standard deviations (SD).
- has a precision of 2.1%.

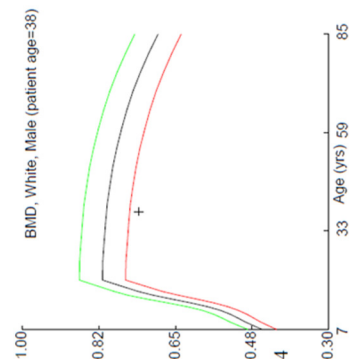
CyberLogic UltraScan Bone Data Report

CyberLogic, Inc.
Room 707, 611 Broadway
New York, NY 10012 (美国)
Tel. 212-260-1353

Doctor: Dr. Smith, Technician: Mr. Smith

Patient : Smith, John
Patient ID : C001
Birth Date : 1980-06-01
Gender : Male
Ethnic : White
Height (cm) : 168.0
Weight (kg) : 56.0
Ultra Len. (cm) : 27.0
Test Site : Left Forearm
Test Date : 2018-06-21

Test Result
BMD : 0.734 (g/cm^2), $T = -1.6$, $Z = -1.4$
NTD : 1.76 (ts)
NTDI : 3.38 (ts)
Note : Wrist Fx - 3-15-2017
Product : US650-A



UltraScan 650

- Ten (10) second test
- Convenient anatomical location (forearm)
- Portable (8 lb, 10x15 inches)
- USB-powered
- No ionizing radiation
- No messy gel
- Estimates DXA BMD at the 1/3 radius, with a correlation of $r = 0.93$, and an SEE of only $0.041 \text{ g}/\text{cm}^2$
- Osteoporosis screening
- BMD Test Report (see above)

Indications for Use¹

- *UltraScan 650* can be used to determine BMD_{us} Index in adult men and women and to assess appendicular fracture risk in postmenopausal women.
- The BMD_{us} Index is a clinical measure based on ultrasound variables of the forearm which is highly correlated with the value of BMD of the 1/3 radius as provided by DXA, with a standard error of the estimate of $0.041 \text{ grams}/\text{cm}^2$.
- BMD_{us} Index is expressed in grams/cm^2 and as a T - and z -score, derived from comparison to a normative DXA reference database.
- BMD_{us} Index has a precision comparable to that of DXA, which makes it suitable for monitoring bone changes in postmenopausal women.