

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 *only* FDA-approved bone sonometer to measure bone mineral density (BMD).

Device Description

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/cm²) 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 in standard deviations (SD) and *z*-score in SD.
- has a precision of 2.1%.



UltraScan 650

- Fifteen (15) second test
- Convenient anatomical location (forearm)
- Portable tabletop device
- No messy gel
- No ionizing radiation
- Provides an estimate of BMD at the 1/3 radius, with a correlation of $r = 0.93$, and an *SEE* of only 0.041 g/cm².

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 grams/cm².
- *BMD_{US}* Index is expressed in grams/cm² 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.