

Sunlight Omnisense® 7000S: Reference Database

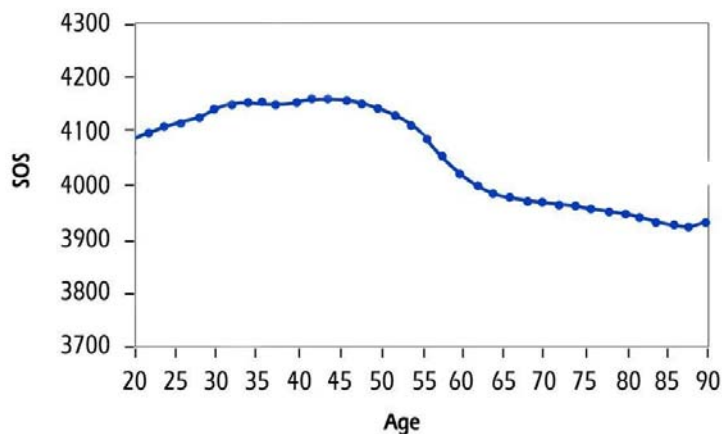


A widely applicable reference database is the foundation of any clinical device. Sunlight Omnisense® 7000S/8000S, the world's only multi-site bone sonometer,¹ boasts a choice of widely applicable reference databases. Its database for Caucasian women has recently been validated by a massive population-based study that included 6000 women in cities around the world.

Initial Establishment of a Reference Data Curve

The initial reference database for Omnisense 7000S was established in 1999, based on data obtained from 1521 healthy Caucasian women (age 20-90).² To further confirm the device's applicability, additional studies established reference databases for female and male Caucasian populations in the United States^{3 4} (n=545 and 588 respectively), the female Caucasian population in the UK⁵ (n=470) and the female Asian population (n=1076). In each study, the subjects were measured for Speed of Sound (SOS) at four skeletal sites, the radius, phalanx, tibia, and metatarsal. All studies were carried out according to established scientific standards.

Caucasian Female Reference Database – SOS at the Radius



All studies produced a clear age-dependent curve for SOS at all skeletal sites.

In all the database studies at all sites, the Omnisense data curve shows an increase in bone measurement values from age 20. Bone measurement values peak between age 35 and 45 at most sites (peaks are somewhat earlier at the tibia). Bone measurement values decrease after reaching this peak, and, among women, decrease sharply after menopause.

When expressed in T-scores (a parameter based on standard deviations), SOS values at the radius and phalanx were consistent with WHO criteria for osteoporosis prevalence.^{6,7} There is significant overlap between the female Caucasian reference values collected in different countries at all skeletal sites.

Confirmation: A 6000-Subject Population-Based Cohort

To test the basic understanding that the female Caucasian reference database is applicable for use in comparison to the general female Caucasian population worldwide, a wider study, using a population-based cohort of some 6000 women, was performed.⁸ The women were measured with 14 Omnisense devices in eight countries in Europe, the USA, and Israel. No exclusion criteria were applied to these subjects, in contrast to the original database study.

The curve produced in this study was compared to the Omnisense reference database curve, according to mean and standard deviation. No statistical differences were observed between the two sets of data. This finding of virtually identical results in the two studies indicates that the original device database can be used for osteoporosis diagnosis and management for Caucasian women worldwide.

In the final analysis, the use of exclusion criteria in the original database was shown to have had little influence on the resultant SOS values, perhaps because different exclusion criteria worked in different directions.

Validation of the Omnisense Database

The population-based recruitment study validates the applicability of the Omnisense Caucasian reference database to Caucasian women worldwide. It provides strong support for the use of the Sunlight Omnisense[®] database for bone assessment and monitoring for people everywhere.

References

¹ Knapp, K.M., G.M. Blake, T.D. Spector, I. Fogelman, "Multisite quantitative ultrasound: precision, age- and menopause-related changes, fracture discrimination, and T-score equivalence with dual-energy X-ray absorptiometry," *Osteoporosis International*, 2001, 12(6):456-64

² Weiss, M., A. Ben Shlomo, P. Hagag, M. Rapoport, "Reference Database for Bone Speed of Sound Measurement By a Novel Quantitative Multi-site Ultrasound Device," *Osteoporosis International* 2000, 11(8):688-96

³ Drake, W.M., M. McClung, C.F. Njeh, H.K. Genant, C. Rosen, N. Watts, D.L. Kendler, "Multisite bone ultrasound measurement on North American female reference population," *Journal of Clinical Denistometry*, 2001, 4(3):239-48

⁴ Kendler, D.L., Genant, H.K., McClung, M., Rosen, C., Watts, N., "Multisite Bone Ultrasound Measurements on a North American Reference Population," Presented at the American College of Rheumatology 63rd Annual Meeting, November 1999, Boston

⁵ Knapp, K.M., G.M. Blake, T.D. Spector, M. Weiss, I. Fogelman, "A Comparison of UK Reference Data and Manufacturers Reference Data for Multi-Site QUS," Presented at the Eighth Bath Conference on Osteoporosis, December 2001, Bath, UK

⁶ WHO Study Group, "Assessment of Fracture Risk and its Application to Screening for Postmenopausal Osteoporosis," Technical Report Series, No. 843, 1994

⁷ Ish-Shalom, S., I. Yaniv, C. Singal, Y. Niv, "Can the WHO Osteoporosis Criteria Be Applied to Ultrasound Measurements?," Presented at the 11th International Workshop in Calcified Tissues, February 1999, Eilat

⁸ Hans, D., D. Geva, G. Conicella, D.O. Slosman, "Can A Large Caucasian Population Based Recruitment without Exclusion Criteria Be Used to Build a Reference Database Compared to Well Defined Normative Population?," Presented at ASBMR 23rd Annual Meeting, October 2001, Phoenix, Arizona