



Omnisense 7000S/8000S

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OMNISENSE 7000S

Ultrasound Bone Sonometer Technical Specifications	
Parameter	Specification
Manufacturer	Sunlight Medical, Ltd.
U.S. Distribution and Support	Sunlight Medical, Inc.
Model	Sunlight Omnisense™ 7000S
Precision	RMS CV = 0.4% - 0.81% in-vivo precision, depending on site
Measurement Sites	<ul style="list-style-type: none"> • Distal 1/3 radius (forearm) • Proximal phalanx III (finger) • Metatarsus V (foot)
Technology	Quantitative ultrasound, using Omnipath™ axial transmission technology
Measured parameter	Axially transmitted speed of sound (SOS), expressed in m/sec
Scan time	Less than one minute per skeletal site
Data Analysis	Compares SOS results with reference database and reports T-scores and Z-scores
Display	Flat color display monitor (LCD)
Printers	Standard PC printers; Recommended list of printers appears in User Guide
Power	<ul style="list-style-type: none"> • 115-230V (autoswitchable) • ~50-60 Hz
Power consumption	<ul style="list-style-type: none"> • Approximately 85 VA (including LCD display) • 80 VA (system alone)
Main unit dimensions	15.1" x 5.05" x 12.08"
Weight	Approximately 13 lbs.
Warranty	12-month warranty for parts and labor
Special Features	<ul style="list-style-type: none"> • Windows operating system • Proprietary analysis software for Omnipath™ • Calibration-free system - no drift • Radiation-free • Precise and accurate, enabling effective monitoring • Multi-site measurement • On-screen comparison and trending of prior results and reports • Patient scheduling and database management • Multi-media training tutorial

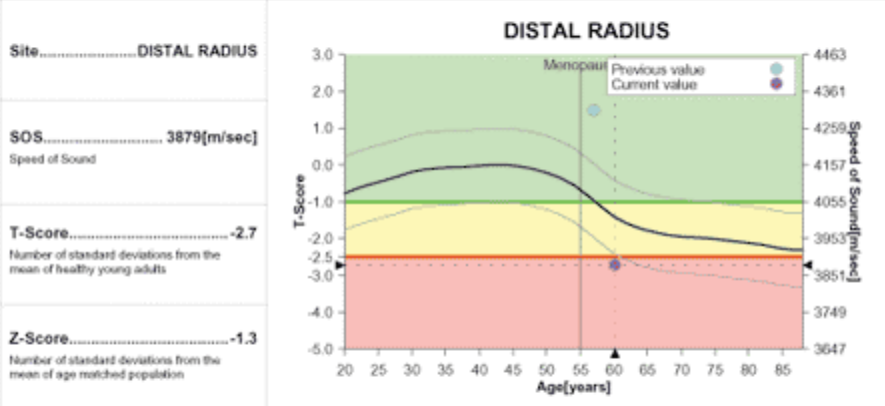
Measurement Report

04-03-01

Patient Information

First Name.....	Ann	ID.....	556130505
Family Name.....	Walsh	Gender.....	Female
Age.....	60y2m	Menopausal age.....	55
Height.....	5'5"	Referring Physician.....	Smith
Weight.....	135.0 Lb	Reporting Physician.....	Fisher
BMI.....	22	Operator.....	Fisher

Measurement Results



Findings and Comments

- Bone strength is within the normal range.
- Bone strength is low; Medical attention is recommended.
- Bone strength shows deterioration; Medical attention is recommended.

Signature _____

Device Details

System S/N.....00097000 Probe S/N.....CMB126
S/W.....2.2.2428
RDB.....NorthAm, Female

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OMNISENSE 7000/8000S

Sunlight Omnisense™ 7000S--Wrist Watch

Consider this: 28 million Americans face the threat of osteoporosis and its 1.5 million related bone fractures--about half your female patients. You know one key to beating it lies in spotting trends through early detection and frequent follow-up. Cost prohibitive for patient and physician alike--until now.



Enter the Sunlight Omnisense™ 7000S bone sonometer--so accurate and economical, it's poised to become the new standard in bone strength assessment. Sunlight's patented Omnipath™ technology takes the Omnisense 7000S beyond the one-time snapshot. Its low cost allows you to offer and perform in-office measurements more frequently with just a one-minute pass over the wrist--developing a profile that flags osteoporotic development early on.

Finally, a way to meet the burgeoning demand for a complete bone assessment solution cost-effectively, with no compromise in accuracy or precision. *It's about time.*

Diagnose and monitor osteoporosis

- Test bone mineral density (BMD) plus elasticity, cortical thickness, micro-architecture
- Patented Omnipath™ axial transmission technology--eliminates soft tissue effects
- High accuracy and precision
- Uses WHO criteria and standard T- and Z-scores
- Easy, point-of-care testing
- Built-in data management
- Radiation free

At Last: Diagnose and Monitor Osteoporosis at the Point of Care

Sunlight's Omnisense™7000S bone sonometer is an office-based solution so accurate, it has an FDA approved claim for monitoring bone changes over time. The technician simply scans the patient's wrist and, in minutes, generates a comprehensive picture of fracture risk.

The Omnisense 7000S uses a patented axial transmission form of quantitative ultrasound we call Omnipath™. Instead of relying on x-rays, Omnipath measures the velocity of ultrasonic waves (speed of sound) that propagate axially along the distal 1/3 radius. The resulting output considers multiple bone strength properties such as bone mineral density (BMD), elasticity, cortical thickness, and micro-architecture--without soft-tissue-related inaccuracies so typical with other testing devices.

The system uses World Health Organization (WHO) criteria in assessing fracture risk and user-friendly software allows you to store comprehensive patient information. This scalable platform includes a record management database and patient scheduling system.

Sample of Common ICD-9 Codes for Bone Densitometry*

626.0	Absence of menstruation	307.1	Anorexia nervosa	550.0-579.0	Colitis
252.0	Hyperparathyroidism	6270.0	Premenopausal menorrhagia	550.0-555.9	Crohn's disease
253.0	Acromegaly	714.0	Rheumatoid arthritis	585.0	Chronic renal failure
253.1	Hyperprolactinemia	731.0	Osteitis deformans	V82.81	Special screening code for osteoporosis — added October, 2000
253.3	Growth hormone deficiency	733.0	Osteoporosis, unspecified	V49.81	Status code for post menopausal woman — added October, 2000
255.0	Cushings syndrome	733.01	Senile osteoporosis		
256.2	Postablative ovarian failure	733.02	Idiopathic osteoporosis		
256.3	Primary ovarian failure	733.03	Disuse osteoporosis		
588.0	Renal osteodystrophy	733-09	Drug-induced osteoporosis		
259.3	Ectopic hormone secretion	V17.8	Family history of musculoskeletal osteomalacia		

* Suggested list of ICD-9 codes used in conjunction with bone density studies. Some carriers may have a specific list of ICD-9 codes. We advise that you verify with your local carrier policy.

Reimbursement Information

Bone Mass Measurement Rule: rule for coverage and payment of bone mass measurements as published in *The Federal Register* Volume 63 November 121/Wednesday, June 24, 1998, states that bone strength assessment with an FDA-approved bone sonometer is reimbursable.

Reimbursement: Medicare reimbursement ultrasound testing is covered under **CPT code 76977**. HCFA/Medicare 2001 national average is approximately \$58 per study. Most insurance companies reimburse for Ultrasonometry studies.

Conditions for Coverage: A woman determined by the physician to be estrogen deficient and at clinical risk for osteoporosis, based on medical history and other findings.

An individual with vertebral abnormalities as demonstrated by an x-ray indicating osteoporosis, osteopenia, or vertebral fracture.

An individual receiving or expecting to receive glucocorticoid steroid therapy.

An individual with primary hyperparathyroidism.

An individual being monitored to assess response to or efficacy of an FDA-approved osteoporosis drug therapy.

Repetitive Testing: Medicare may cover repetitive testing after 23 months of last test, more frequently if medically necessary.

**Medicare reimbursement rates vary by region. Please check your local carrier for exact amount and guidelines for filing of claims.*

OMNISENSE 7000S/8000S

Clinical Summary #1

A New Method for Quantitative Ultrasound Measurements at Multiple Skeletal Sites

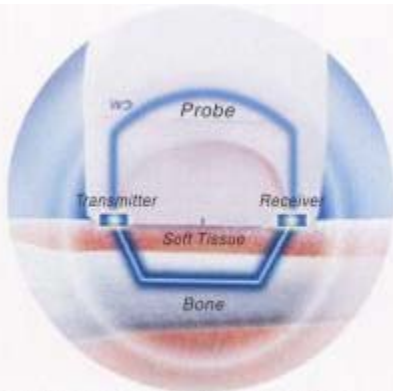
A study of Omnisense by pioneers and leaders in the fields of Osteoporosis and Ultrasound Technology

Reinhard Barkmann, Edvard Kantorovich, Chaim Singal, Didier Hans, Harry K. Genant, Martin Heller, and Claus-Christian Gluer
Journal of Clinical Densitometry, Vol. 3, No. 1, 1-7, Spring 2000

Omnisense's unique technology (Omnipath™) and methodology yield reproducible results that effectively discriminate between fractured and non-fractured populations.

Technology

Omnisense is designed to measure the speed of sound (SOS) of ultrasonic waves axially transmitted along the bone. Axial transmission technology (Omnipath™) improves accuracy and precision by eliminating the effects of soft tissue and temperature. It also enables measurements on bones that were previously inaccessible. The article describes the innovative technology and methods used by Omnisense in clinical procedures.



Schematic Diagram of the Ultrasonic Wave Propagation

Precision Testing

One aspect of this study was to determine Omnisense's precision, that is, its ability to yield reproducible results. Repetitive measurements were taken from healthy subjects to establish Omnisense's precision rating. Precision is given in terms of coefficient of variance or CV with a lower number indicating a better rating. Intra-observer precision errors ranged from 0.2% to 0.3% for triplicate measurements with repositioning at the measured sites. Inter-observer errors ranged from 0.3% to 0.7%.

Fracture Discrimination

Discrimination is a device's ability to differentiate between fractured and non-fractured populations. To determine Omnisense's discrimination ability, subjects with osteoporotic fractures were measured against a control group of healthy subjects. The results showed that Omnisense's SOS of the distal 1/3 radius were significantly lower in the fractured group. As a low SOS is the indicator for unhealthy bone, Omnisense's discriminating ability makes it suitable for fracture risk assessment.

Conclusion

Omnisense's patented technology and unique methodology give Omnisense superior precision and an enhanced ability to identify patients at risk for fracture. It is a useful device in the assessment of bone status by offering the possibility of measuring at a large variety of bone sites.

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Clinical Summary #2

Multisite Bone Ultrasound Measurement on a North American Female Reference Population

W. M. Drake, C. F Njeh, M. McClung, H. K. Genant, C. Rosen, N. Watts, D. L. Kendler

This study describes the method of data collection for the North American Female Reference Database of the Omnisense device.

Study Design

This study measured the speed of sound (SOS) at four skeletal sites with the **Sunlight Omnisense™7000S**. For the study, 545 healthy Caucasian women aged 20-90 were recruited from five centers across North America. Data was collected and analyzed to establish the Omnisense reference curve and peak speed of sound (SOS) for each site.

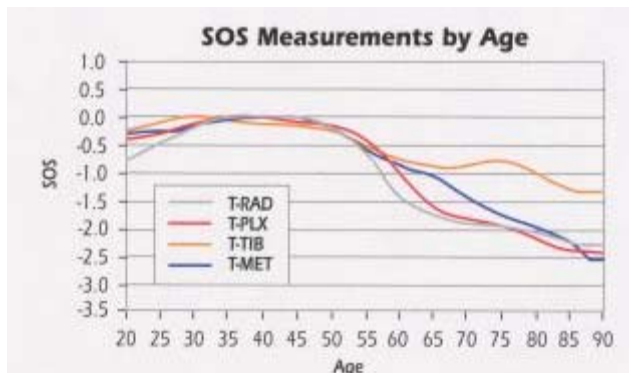
Subjects

Subjects for the study were required to meet the following criteria:

- No history of osteoporotic fracture or any condition affecting bone metabolism.
- No exposure for more than a year within the preceding three years to a medication affecting bone.

Results

Results demonstrated that peak SOS occurs around the age of 40. The maximal rate of decline of SOS was seen in the decade following menopause at the radius, tibia, metatarsal, and phalanx respectively. Reproducibility between successive measurements indicates high precision.



The graph depicts SOS results as a function of age for the Caucasian female distal 1/3 radius. Note that the SOS increases to a peak of 4158 m/sec at the age of 41 and declines thereafter. The overall change, from the maximal SOS value at the age of 45 to the minimal SOS at the age of 85, is -3.0 in T-score units. This is among the greatest changes observed by systems designed for bone assessment.

When comparing Omnisense SOS to bone density assessment devices such as DXA, it is noted that SOS measurements peak at a later age. This demonstrates that Omnisense SOS

measurements reflect additional bone properties, including elasticity, cortical thickness, and micro-architecture.

Conclusion

Sunlight Omnisense™ bone measurements clearly established the age-dependent pattern of bone loss for adult North American Caucasian females. Omnisense-measured prevalence of osteoporosis in the female population between the ages of 60-90 is about 35%--the same as vertebral DXA. Based on this prevalence, Omnisense measurements meet WHO criteria for osteoporosis.

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Clinical Summary #3

An In-Vitro Investigation of the Dependence on Sample Thickness of the Speed of Sound Along the Specimen

C.F. Njeh, D. Hans, C. Wu, E. Kanorovich, M. Sister, T. Fuerst, H.K. Genant
Medical Engineering & Physics 21 (1999) 651-659

The article describes the effect of cortical thickness effect on Speed Of Sound measurement using Omnisense.

Introduction

Quantitative ultrasound (QUS) has been shown to be a valid technique in the non-destructive evaluation of the elastic properties of bone tissue in vitro. Since the work of Langton et al. in 1984, there has been increasing interest in the assessment of bone status in vivo. QUS is particularly attractive because it is simple, relatively inexpensive, portable, non-invasive and free of ionizing radiation. As such, QUS has much greater potential for widespread application than standard bone densitometry approaches.

The Technology

Omnisense generates pulsed acoustic waves at a center frequency of 1.25 MHz (bandwidth 0.7-1.8 MHz). Four sets of transducers are embodied within the probe. A pair of transducers acts as transmitters, while the other pair acts as receivers. When ultrasound waves are incident on a specimen (bone), depending on the angle of incidence, the waves are reflected, refracted and transmitted. The refracted wave which propagates along the sample can be measured. The transit time is defined as the time it takes for the first detectable signal above noise to arrive at the receiving transducer. According to Snell's Law and the Principle of Minimal Action, the first signal to arrive always follows a path which is characterised by the shortest propagation time.

Study Design

The study examined the dependence of SOS measured along the sample by Sunlight Omnisense™ on the thickness and composition of the bone sample. The measurements were carried out using Perspex* phantoms and bovine mid and trochanteric femurs.

Results

SOS was found to depend on the sample thickness (when the thickness is smaller than the wavelength, approx. 2 mm), shape, and global composition, all of which define a sample's overall strength. These results concur with the theoretical predictions.

Conclusion

This study measured the sensitivity of the Omnisense™ device to sample thickness. Omnisense's proven sensitivity means that it will also be sensitive to the changes in thickness of cortical bone that accompany aging and lead to osteoporosis.

*Perspex was used for its well-known and documented ultrasound properties.

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Clinical Summary #4

North American Male Reference Population for Speed of Sound (SOS) in Bone at Multiple Skeletal Sites

S. R. Hayman, W. M. Drake, D. L. Kendler, W. P. Olszynski, J. D. Adachi,
C. E. Webber, C. J. Rosen, H. K. Genant, E. S. Orwoll, L. E. Pickard

This study describes the establishment of the North American Male Reference Database for the Omnisense device.

Study Design

In this study the speed of sound (SOS) was measured at four skeletal sites in healthy North American Caucasian men, aged 20-90, with the Sunlight Omnisense™ 7000S. To establish the Omnisense reference database curve, 588 healthy Caucasian males (age range 20-90) were recruited.

Subjects

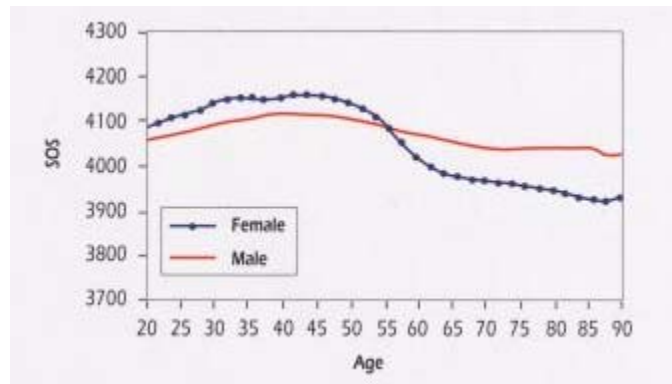
To be eligible for the study the subjects had to meet the following criteria:

- No history of osteoporotic fracture or chronic condition affecting bone metabolism.
- No exposure for more than a year within the preceding three years to medication affecting bone.

Results

SOS of all sites, except the tibia, increased to a peak between the ages of 42 and 46. Comparison to the female SOS demonstrates that the female SOS is higher from age 20 to 39, with a significant difference between male and female at the radius and phalanx. Between the ages of 45 and 59, the radius, phalanx, and metatarsal SOS declines in females at a greater rate than in males. The reference curves cross at around 60 years of age. Female SOS remains lower than male SOS for the remainder of life at the radius, phalanx, and metatarsal.

Male and Female Reference Database SOS as Measured at the Radius



Conclusion

This study established the reference curves for male SOS in North America, to be used for the calculation of Z-scores with the Sunlight Omnisense 7000S bone sonometer. Omnisense™ is the only QUS device today that provides a male reference data base.

OMNISENSE 7000S/8000S

Clinical Summary #5

Discrimination of Proximal Hip Fracture by Quantitative Ultrasound Measurement at the Radius

M. Weiss, A. Ben-Shlomo, P. Hagag, and S. Ish-Shalom
Osteoporosis Int. (2000) 11:411-416

Omnisense demonstrates its ability to assess hip fracture risk of subjects by speed of sound measurements at the radius.

Introduction

Osteoporosis is a disease that culminates with fragility fractures and imposes a major burden on health care costs. In dealing with this worldwide condition, it is prudent to use a reliable, non-expensive, portable diagnostic device that does not use ionizing radiation and is capable of measuring bone properties at several sites. Sunlight Omnisense 7000S, a quantitative ultrasound device which measures the speed of sound (SOS) along the bone at multiple skeletal sites, provides such a solution.

Study Design

The study was designed to evaluate the ability of the Omnisense to assess fracture risk. Three groups of women were recruited for this cross-sectional study:

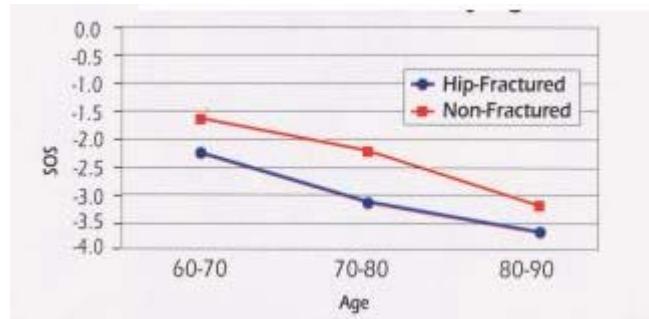
- Elderly women with osteoporotic proximal hip fractures
- Elderly women without any evidence of osteoporotic fractures
- Young, healthy women

Speed of Sound measurements were performed at the distal 1/3 of the radius.

Results

SOS was found to be significantly lower in the fractured group than in the non-fractured group. Hip fracture subjects had a mean speed of sound (SOS) of 3861 ± 149 m/s, while non-fracture subjects had a mean SOS of 3966 ± 145 m/s. Thus, there was a difference of 105 m/s between the two groups (t-test $p < 0.0001$). A low SOS is an indication of unhealthy bone and increased fracture risk (ROC curves indicate an AUC of 0.79 (95% CI, 0.73 - 0.86)). Assessment of fracture risk can be presented by odds ratio (OR). In this study, OR was 2.16 (95% CI, 1.46 - 3.19). This analysis shows that for every 100 m/s decrease in SOS the odds of fracture increase by about 50% and that for every decrease of 162 m/s in SOS the odds of fracture double.

T-Score Discrimination by Age



Conclusion

SOS, as measured by the Omnisense, can be considered an important factor in aiding the physician when diagnosing a patient for osteoporosis and determining the patient's risk of fracture.

OMNISENSE 7000S/8000S

Frequently Asked Questions



Following is a compiled list of questions frequently received from customers. You may find valuable information in our responses.

Who is eligible to have a bone density test under Medicare and what is the average reimbursement amount?

As covered under the Bone Mass Measurement Act (1998), there are five groups of qualified individuals that are covered by Medicare for bone strength testing if ordered by a treating physician or qualified non-physician practitioner:

- An estrogen deficient woman at clinical risk for osteoporosis
- An individual with vertebral abnormalities
- An individual receiving long-term glucocorticoid therapy
- An individual with primary hyperparathyroidism
- An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

The average reimbursement for testing with Omnisense 7000S (Ultrasound, code 76977) was \$33.00

How often can the test be repeated?

In general, bone strength assessment tests can be repeated and will be paid for every two years, as long as the person falls into one of the above five groups and the test is ordered by the beneficiary's treating physician or other treating practitioner.

Do private insurance carriers cover bone strength tests?

Reimbursement amounts and coverage criteria for bone strength assessment tests offered through private employer-sponsored health plans are variable. There is currently no federal law, as there is for Medicare, that standardizes coverage criteria and reimbursement rates for bone density tests on the private side. Often though, private health plans follow the Medicare rules.

How well can a measurement at the wrist predict the risk of fracture of hip or spine?

A wealth of data and clinical studies support Omnisense' fracture prediction abilities by measuring at the radius. Hip and spine are the traditional sites measured by DXA. Omnisense' clinical studies demonstrate that by measuring the Radius, Omnisense' fracture prediction ability is equal to that of DXA obtained at the hip and spine.

Further, it is important to know that Omnisense measures a major fracture site--the wrist. This peripheral site is the earliest to fracture, often preceding hip and spine fractures by as much as 10 to 28 years.

What is being measured with Omnisense?

Omnisense measures Speed of Sound (SOS) expressed as meters per second. SOS is the most appropriate technology to measure bone strength since multiple bone properties--microstructure, elasticity, cortical thickness, bone density--are accounted for in the result.

DXA measurements are based on bone mineral density only, a limited predictor of bone strength and changes, over time.

What is Omnipath™ axial transmission technology?

Sunlight's patented axial transmission technology, Omnipath™--is based on the measurement of the speed of ultrasonic waves (SOS) propagating *along the bone*. Omnipath™ enables measurement along the bone's maximal strength axis, eliminating soft tissue effects and providing a more accurate measurement.

What advantage does a radius measurement offer over a heel measurement?

The radius site, when measured by the Omnisense, enables a more accurate measurement by allowing for a measurement *along-the-bone*, eliminating soft tissue discrepancies. Heel ultrasound technologies, on the other hand, transmit signals through the bone. When measuring

through or 'across' the bone, soft tissue discrepancies affecting measurement accuracy, are often a problem.

Is there a difference between weight bearing and non-weight bearing bone in predicting the risk of fracture?

In predicting the risk of fracture it is important to keep in mind that osteoporosis is a systemic disease that affects the entire skeleton. Ergo one bone can potentially predict fracture risk as well as another. The key lies in the device's sensitivity to bone change. In test after test, Omnisense has proven itself sensitive to bone changes due to aging and in response to treatment.

How precise is Omnisense?

Omnisense precision is 0.4% at the radius, one of the highest precision ratings in the industry. Precision is important because it gives the system the ability to monitor bone changes due to aging, treatment and other disorders.

Based on Omnisense's high precision levels, the FDA approved the Omnisense indication for use in monitoring bone changes in the relevant age groups (50-65, peri & post-menopause).

Does Omnisense comply with WHO diagnosis criteria?

Yes, Omnisense is WHO compliant. The Omnisense reference database has the same osteoporosis prevalence as Spine and Forearm DXA crossing the -2.5 diagnosis line at approximately 75 years of age.

What should a physician do when there are different results between Omnisense and DXA measurement results?

Each measurement is case dependent and the physician would need to take into consideration all the clinical factors such as age, family history, ongoing treatment, etc. to arrive at a diagnosis. It is very common to receive different results when measuring both, at different sites as in the case of DXA or between two different technologies like Omnisense and DXA.

OMNISENSE 7000S/8000S

Omnisense or DXA An In-Depth Comparison

Introduction

The following document summarizes a series of clinical studies conducted to compare Sunlight Omnisense™ technology and Dual X-ray Absorptiometry (DXA) technology. These studies consistently show that Omnisense provides an accurate aid to physicians in the diagnosis of osteoporosis and can serve as a viable alternative to radiation-based technologies.

It is important to note that a comparison between a *Quantitative Ultrasound* (QUS) device - Omnisense - and a *Dual X-ray Absorptiometry* (DXA) device is complex. The Omnisense and DXA devices are based on two distinctly different technologies and measure two different parameters; *Speed of Sound (SOS)* and *Bone Mineral Density (BMD)*.

However, since the diagnosis of Osteoporosis concerns ***assessment of fracture risk*** - and not assessment of bone mass - there is, indeed, a basis for comparison. In order to compare the two technologies, one must evaluate each device's ability to assess fracture risk, along with their relative advantages and disadvantages.

This document presents data that show Omnisense measurements to be a valid estimate of osteoporotic fracture risk. Hence, Omnisense SOS measurements have profound clinical value that, in many cases, may even be considered superior to that of DXA.

During the last two decades, DXA has been used extensively, and has been accepted as a standard for assessment of fracture risk. However, it is neither a perfect technology nor is it without controversy. The following are a few of the many limitations of the technology and the problems associated with its diagnostic capabilities:

- ***BMD discriminatory ability for fractures is not very high:***

Research has shown that there is a large overlap between Bone Mineral Density (BMD) measurements of non-fractured subjects and measurements of fractured subjects. This implies that low-trauma fractures can occur at *low, normal* or even *high* BMD. This research further suggests that factors other than BMD may be significant in the occurrence of fracture.¹

- ***Accuracy errors, especially in the case of Lumbar Spine BMD:***

After the age of 60, false high values of spine BMD are encountered. This may occur due to various other diseases, such as vascular calcification, osteomalacia and osteoarthritis. These false high measurements may lead to a misdiagnosis (false negative), and consequently to an incorrect decision regarding treatment.

- ***BMD is not a valid measure of bone strength:***

BMD is a crude expression of bone mineral concentration for a given area. It does not take into account such properties as bone size or architecture. BMD is also influenced by body mass and growth, while the measurement of true density should not be influenced by these factors.^{2,3}

- ***Problems of reproducibility (precision):***

In order to monitor bone changes following treatment, as well as over time, it is essential that a diagnostic tool have the lowest precision error possible. Unfortunately, DXA technology is unable to insure an adequate degree of precision. For example, a patient's position during a DXA hip measurement, may be at a slightly different angle --thus causing the marking of a different *Region of Interest (ROI)* between one exam and the next.

- ***Discrepancies between different devices of the same brand:***

There is a significant degree of variability between one DXA device and another. This is so even when the devices are of the same type and by the same manufacturer⁴. Thus implying that when a patient undergoes follow up testing for monitoring purposes, the results, if not taken on the exact same device, must be referred to with caution. It has also been found that accuracy errors sometimes occur following a repair. These errors can be difficult to detect even when using the routine recommended operating procedures⁵. Moreover, in the case of a new model even of the same brand, there is normally no backward compatibility.

The Omnisense Solution

1. Omnisense SOS is more informative than DXA BMD

"Osteoporosis is a systemic skeletal disease, characterized by reduced bone mass and micro architectural deterioration of bone tissue. Consequently, the disease increases bone fragility and susceptibility to fracture, typically at the Hip, Spine, and Wrist⁶".

Traditional Dual X-ray Absorptiometry is limited to measuring one property only, *Bone Mineral Density* (BMD) also known as Bone Mass. Conversely, *Speed of Sound* (SOS) measurements give a much broader perspective. SOS measurements reflect several varied bone properties such as; density, elasticity, cortical thickness and micro-architecture, thus providing a more complete picture of the bone's fragility^{7,20}.

2. Diagnostic ability

The Omnisense's ability for diagnosis and fracture prediction was tested and evaluated in *in-vivo* and *in vitro* studies.^{8,10,11,14,15,21} All studies concluded that Omnisense's measurements of the distal 1/3 radius are a reliable predictor of fractures. In addition, measurements at the radius by Omnisense could predict any type of osteoporotic fracture equal to or better than Dual X-ray Absorptiometry. A summary of these studies is presented below.

- ***Omnisense can predict hip fractures***

An *in vitro* study of the ability of ultrasound velocity measurements at the radius, phalanx and femur to predict the failure load of elderly cadaveric femura was performed in the Orthopedic Biometrics Laboratory, Beth Israel Deaconess Medical Center, Boston MA.⁸ A high correlation was observed between femoral failure load and femur BMD measurements ($r=0.83$, $p<0.001$) as well as with SOS measured at the distal 1/3 radius using the Omnisense ($r=0.73$, $p=0.008$). Velocity at the radius, correlated significantly with trochanteric BMD ($r=0.59$, $p=0.03$). It was concluded that velocity measurements at the radius are potentially useful predictors of femoral failure loads.

- **Fracture discrimination by Omnisense**

Knapp, *et al.*, at the Osteoporosis Unit of the Guy's Hospital and the Twin and Genetic Epidemiology Unit of the St. Thomas Hospital in London, UK, report the results of vertebral and wrist fracture discrimination in two different studies.^{10,11} The Omnisense's ability to discriminate vertebral fractures was compared to that of conventional DXA of the hip and spine. The measurements at the radius were found to have similar differentiation power to those of DXA of the spine. Results from the second study suggest that the Omnisense SOS measurements of the radius are equal to or superior than DXA in predicting wrist fracture patients from controls (odds ratio of 2.4; 95% C.I. 1.2-5.0, compared to odds ratio <2.0 of DXA of L 1-4, neck of femur and total hip).

3. Omnisense displays better sensitivity than DXA

Due to the nature of the disease, no absolute test has been developed to determine the presence of osteoporosis in the case of a specific patient. The only indisputable clinical evidence for diagnosing osteoporosis is the presence of a low traumatic or a traumatic fracture.

The following classification study was based on the above concept: A group of individuals, diagnosed with osteoporosis as determined by the presence of an atraumatic fracture, was measured by both DXA and Omnisense. This approach was used as a definitive method to evaluate the sensitivity of each device. To make this determination, the researchers looked at the percentage of subjects who were **actually classified** as Osteoporotic, according to the WHO criteria (T-score < -2.5). A "normal" result (T-score > -1) would of course mean a misdiagnosis (false negative). (see 'red bars' Figure 1)

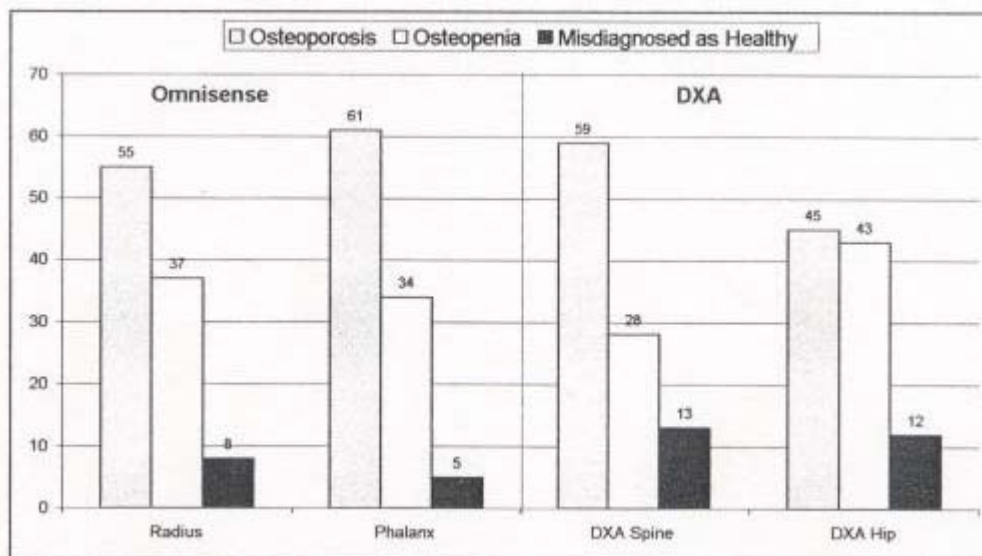


Figure 1: Study results for 150 fractured individuals, classified according to the WHO criteria

Omnisense classified a higher percentage of osteoporotic individuals as osteoporotic or osteopenic than DXA. Conversely, DXA had a higher rate of misdiagnosis.

- **Omnisense's Reference Database demonstrates WHO criteria applicability**

The following chart presents a comparison of Omnisense and other diagnostic devices' Reference Data curves, in terms of T-scores. Omnisense's Reference database demonstrates that "SOS curves of the RAD and PLX expressed as T-scores cross the T=-2.5 level close to age of 75. This T-score value is the WHO threshold for osteoporosis diagnosed by BMD measured at any site."⁹

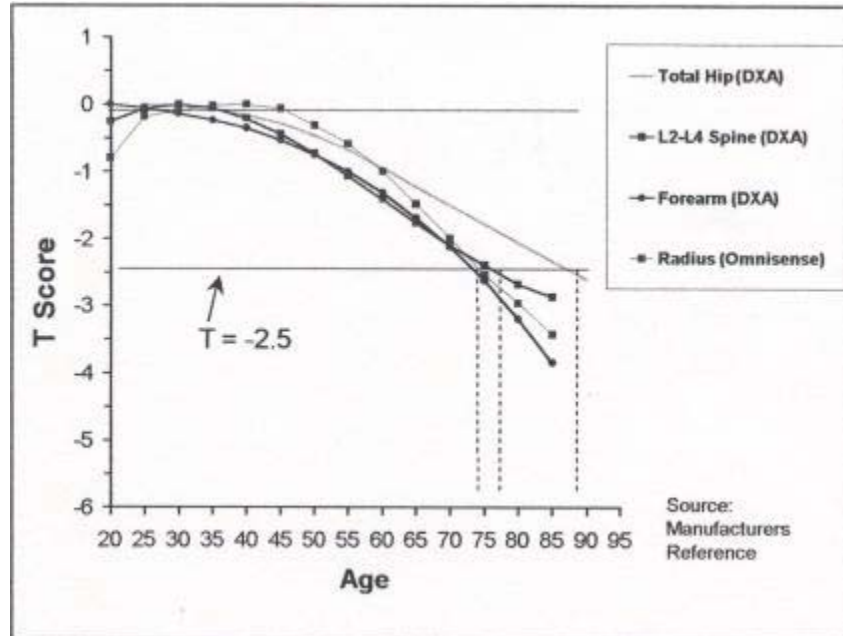


Figure 2 - Comparison between reference database of different devices (applicability of WHO criteria)

It should also be noted that, the DXA hip database indicates a consistently higher T-score signifying a lower suggested prevalence of osteoporosis in each age group.

4. Omnisense detects and monitors bone changes

"The SOS measured by Omnisense has a precision error low enough in comparison with the expected annual change in a patients' measurement to make it suitable for monitoring bone changes which occur in the early years following menopause (i.e., age range approximately 50-65 years)"¹²

Several studies were undertaken to evaluate the Omnisense's ability to detect bone changes, both due to aging and as response to treatment.^{13,15,16,17,19,22}

- **Precision**

The precision of Omnisense measurements was studied by Barkmann, et al. and reported in a paper published in the Journal of Clinical Densitometry.¹⁵ Inter-observer and intra-observer *in-vivo* precision errors, Coefficient of Variation (CV), were found to range from 0.2-0.3% and 0.3-0.7%, respectively, while measuring at different skeletal sites. Another study by Knapp, *et al.*, presented at

the ASBMR 20th Annual Meeting in 1998, reports *in vitro* CV of 0.03% and *in-vivo* root mean square of CV (RMSCV) of 0.54% for the radius.²²

- **HRT Studies**

The discriminatory ability, at the radius, by Omnisense, is also demonstrated while comparing a treated to an untreated population. Hormone Replacement Therapy (HRT) is a well-recognized treatment for the prevention of osteoporosis. Knapp, *et al.* performed a study aimed at investigating the ability of Omnisense QUS measurements at the radius and the tibia to differentiate between subjects receiving HRT and age matched controls.¹⁶ The study findings confirmed that, even with small study groups, the "QUS measurements demonstrate significant and relatively large differences (in units of T-scores between the two subject groups. DXA measurements, of Total Hip, Neck of Femur and L1-L4 (spine) on the other hand, show less than half the difference between the groups, none of which achieve statistical significance". In other words DXA did not find any appreciable difference between the HRT treated group and the untreated group.

In a similar study⁷, Omnisense demonstrated significant discriminatory ability and determined that more women in the non-treated group were osteoporotic than in the treated group. This further demonstrates the Omnisense's high sensitivity to bone change following treatment.

- **Follow up studies**

A longitudinal study¹⁹ designed to measure bone response to treatment, was presented at the ASBMR 2000, Toronto. The interim results demonstrated a significant increase in SOS values at the radius and tibia as a result of Alendronate (Fosamax) treatment. They further determined that bone changes induced by treatment are detectable as early as 6 months after initiation of treatment at the radius and 9 months after initiation of treatment at the tibia.

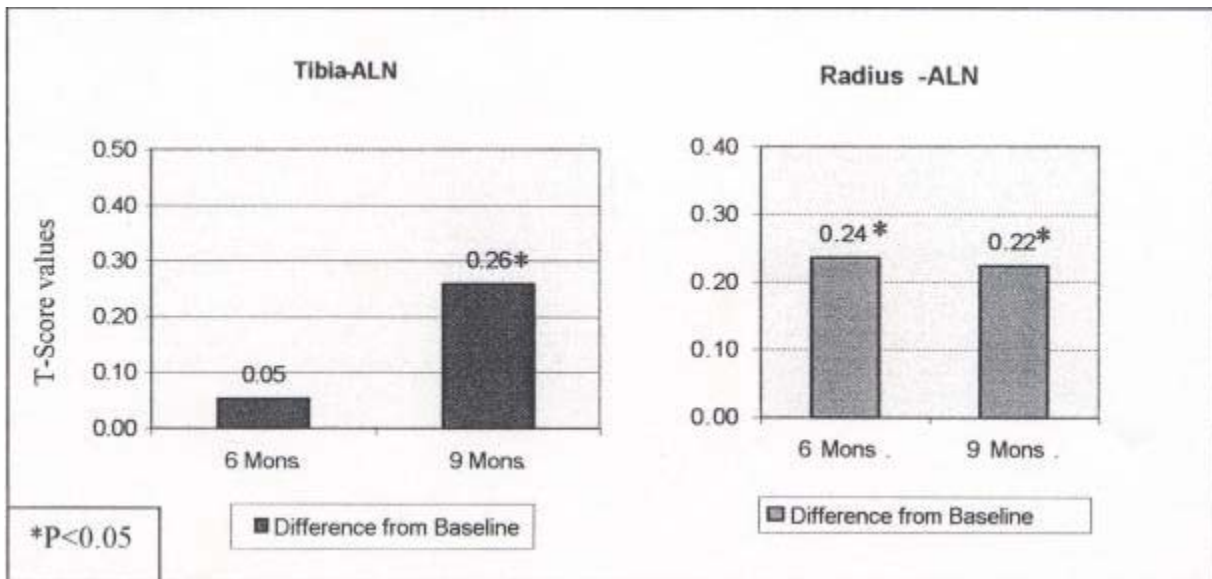


Figure 3 - Increase in SOS values at the Tibia and Radius

5. Secondary Osteoporosis

A study¹⁸ was performed to evaluate the discrimination ability of Omnisense in patients with metabolic diseases. The study provides *in-vivo* evidence that hyperthyroidism affects cortical more than trabecular bone. DXA measurements detect lower BMD at the femoral neck but not at the lumbar spine. In contrast to DXA, SOS, measured by Omnisense, was sensitive to hyperthyroidism to the same degree at all measurement sites.

Conclusions

The above data from recent scientific publications and meetings substantiate Omnisense's diagnostic abilities and the clinical value of its quantitative ultrasound measurements. These studies confirm that Omnisense has proven itself to be an accurate aid to physicians in the diagnosis of osteoporosis and is a viable office-based alternative to radiation based DXA technologies.

Due to its:

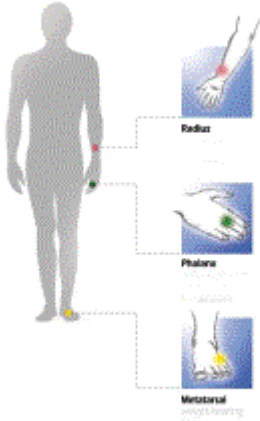
- Accuracy in predicting osteoporotic fractures
- Capacity to monitor and detect bone changes
- Increased sensitivity over DXA
- Ability in fracture discrimination
- Applicability of WHO criteria
- Sensitivity to secondary osteoporosis

Sunlight Omnisense™'s QUS technology is fast becoming the accepted method of choice for the assessment and monitoring of bone changes due to aging and in response to treatment.

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OMNISENSE 7000S/8000S

Bone Assessment at Multiple Skeletal Sites

The Multi-Site Advantage

Sunlight Omnisense™ 7000S is the only multi-site bone sonometer available worldwide. This unique advantage is crucial in the diagnosis of osteoporosis, a systemic disease that involves the deterioration of bone in the entire skeleton. Osteoporosis strikes different bones at different rates. It is therefore important for the physician to test bone strength at various skeletal sites in order to increase confidence in the prediction of fracture risk for osteoporotic patients.

Combining Measurement Sites – A Proven Benefit

Diagnosis of osteoporosis at multiple sites is a well-established procedure in X-ray-based technologies.^{i[i]ii[iii]iv[iv]} Omnisense is the only bone sonometer that is capable of assessing bone strength at a number of proven skeletal sites, an innovation that brings multi-site measurement to primary care facilities with safe, user-friendly equipment.^{v[v]}

Testing at multiple sites reveals additional important skeletal information to the physician. It enables the testing of bones with different combinations of cortical and cancellous bone and weight-bearing and non-weight-bearing bone, and thus provides a more comprehensive analysis of the skeleton. Information from several sites is also useful in the monitoring of treatment for osteoporosis^{vi[vi]}, because different bones reflect changes after treatment at different rates.^{2,4^{vii[vii]}}

The use of multi-site measurement also provides better measurement sensitivity than single site, increasing the likelihood of osteoporosis detection in the individual patient.^{5,7^{viii[viii]},ix[ix]} As in X-ray-based assessment, the accepted clinical measurement method uses the lower T-score between the results at the two sites as the diagnostic score. In the study recording the collection of the Omnisense reference database^{x[x]}^{xi[xi]}, multi-site measurement found a significantly higher prevalence of women with an osteoporotic T-score (T-score <-2.5) than measurement at any single site.

Improved Measurement Flexibility

Multi-site measurement is essential for patients who cannot be measured at a particular measurement site. Obesity, edema at a particular site, a previous fracture, or an IV line can all cause difficulties in measuring a patient's SOS at a specific site. While measurement problems at one measurement site are revealed in five percent of patients, 99 percent of patients can be measured in at least one of the Sunlight Omnisense™ measurement sites.⁴

Three Informative Skeletal Sites

Radius

The third distal radius (wrist) is a measurement site that boasts a wealth of clinical data showing its efficacy in predicting fracture risk. In addition, a number of cross-sectional studies^{5,xii[xii]} found that measurements at this site significantly discriminate between fractured and non-fractured subjects. These findings clearly demonstrate Omnisense's capability to detect osteoporosis.

Phalanx

The 3rd proximal phalanx (finger) is a site clinically proven to predict fracture risk.^{10,11,xiii[xiii]} Measurement at the phalanx is particularly useful when combined with measurement from the radius, since differences in cortical thickness at the two sites provide more information, creating a more comprehensive picture of bone health.

Metatarsus

Measurements at the 5th metatarsus (foot), a weight-bearing bone, have been shown to be useful in the assessment of fracture risk.¹¹ Measurement at this site is particularly important because weight-bearing bone may lose strength at a different rate than non-weight-bearing bone.

OMNISENSE 7000S/8000S

Reasons why Omnisense is superior to calcaneal ultrasound

The Sunlight Omnisense™ 7000S is the first and only non-radiation based device approved by the Food and Drug Administration (FDA) for monitoring both female and male bone strength changes at multiple sites. Two points are critical here. First, the "monitoring" indication by the FDA is huge; monitoring gives you the capability to track over time the efficacy of a specific bone strengthening prescription on one comprehensive report. This designation was given to the Omnisense in great part due to our ability to reproduce (i.e., precision) a valid result. Clinical studies confirm the Omnisense's high precision level of 0.6%. Calcaneal ultrasound units have precision levels of 2.5-3.0%. This translates to approximately four to five times the opportunity for an erroneous measurement.

Additionally, heel units typically are characterized as "screening" devices, a distinction well below that of "monitoring." Screening units provide you with some sense of what may or may not be happening within the bone and are most definitely not indicated for monitoring changes in bone strength. Simply put, you can screen with a monitoring approved device, but you cannot monitor with a screening device.

And second, multi-site capability (i.e., radius and phalanx (the fifth metatarsal was also part of the FDA approval in June of 2001)) gives the physician improved diagnostic accuracy when an assessment is based on a speed of sound (SOS) measurement. This convention is well supported by two independently published articles in peer review medical journals. Furthermore, the ability to look at multiple sites is very much in line with the central DXA philosophy of measuring both hip and spine. Osteoporosis is a systemic disease and thus travels through different bones at different rates. Again, the physician has the opportunity to make a decision based upon multiple site, and not single site, information.

From a competitive selling standpoint, heel units have offered far more sizzle than steak. Their approach has followed this line of thought: they tout the merits of measuring weight bearing bone in an attempt to mimic the central DXA convention of measuring hip and spine bone. Yet they overlook two key components.

First, they control rather poorly for the effect and impact of soft tissue (i.e., edema at the ankle) since they measure through the bone versus the patented Omnisense convention of measuring along the bone. Thus, a heel unit may yield two very different results depending upon the time of day the measurement is done. And second, since the heel is composed primarily of trabecular bone, its rate of re-generation is especially high given the impact nature of walking. This may be the last skeletal site we would want to measure as an indication of bone loss and fracture risk in other bony structures.

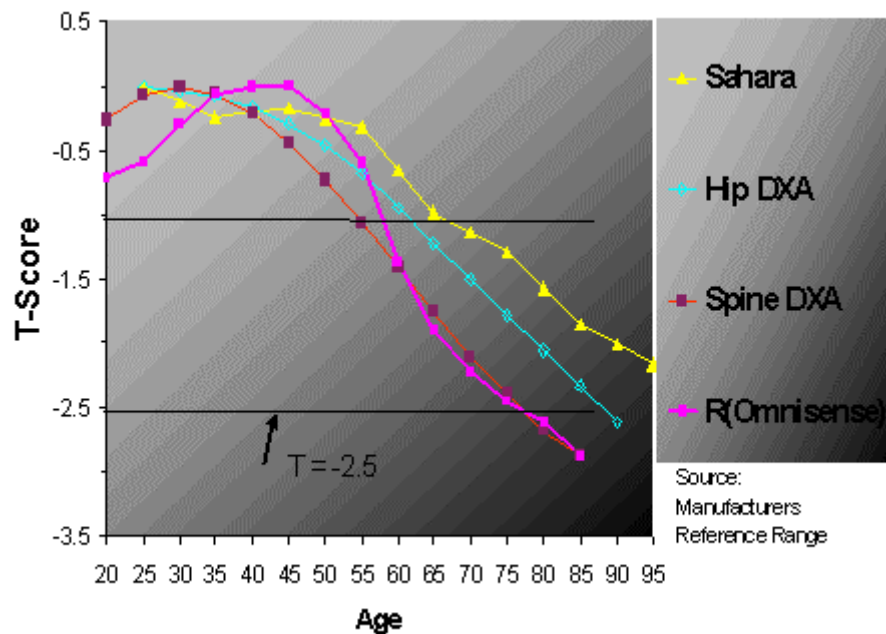
All in all, your decision to incorporate the Omnisense 7000S within your product line is sound for a multitude of reasons. I hope you find this helpful; please feel free to call or reply with any further thoughts or questions you or your associates may have.

OMNISENSE 7000S/8000S

Compliance with the WHO Criteria

Similar Reference Database Curves

Age Dependence of T-scores



OMNISENSE 7000/8000S

Sunlight Omnisense™ 7000S-- NORA Summary

Statement of Sandra C. Raymond, Executive Director and CEO, National Osteoporosis Foundation on the National Osteoporosis Risk Assessment (NORA)

The findings of the National Osteoporosis Risk Assessment (NORA), published in the Dec. 12, 2001, Journal of the American Medical Association, confirm the National Osteoporosis Foundation's (NOF) concern that a large number of postmenopausal women are at high risk for osteoporosis and its associated fractures.

Setting and Participants: A total of 200,160 ambulatory postmenopausal women aged 50 years or older with no previous osteoporosis diagnosis, derived from 4236 primary care practices in 34 states.

The study found that nearly 40 percent of postmenopausal women in the United States have undetected low bone mass and 7.2 percent have previously undiagnosed osteoporosis, placing them at serious risk for osteoporotic fracture as they age.

The large survey size of more than 200,000 women, including 18,000 minority women, makes the NORA findings a critical wake-up call to the nearly 40 million American women in this country over age 50 to make healthy bone behaviors a part of their daily routine. NOF has consistently advised women to consume enough calcium and vitamin D in their daily diets, engage in weight-bearing exercise, avoid smoking and, when appropriate, take daily or weekly medications and get regular bone density tests.

Conclusions: Almost half of this population had previously undetected low BMD, including 7% with osteoporosis. Peripheral BMD results were highly predictive of fracture risk. Given the economic and social costs of osteoporotic fractures, strategies to identify and manage osteoporosis in the primary care setting need to be established and implemented.

NORA was funded by Merck & Co., Inc.

OMNISENSE 7000S

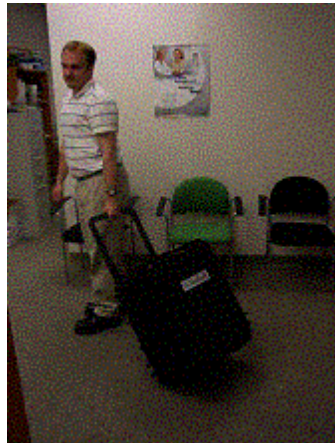
Travel Case

How to use Omnisense with the Field Transport Case

(Temporary Solution for InterFit)

1. Testing site preparation

- a. Make sure there is a table large and stable enough to support the Omnisense 7000S in the Field-use case.
- b. Set the case close to its final position (use two people to lift it onto the table by using the dedicated latches)
- c. Set up two chairs:



- i. Operator chair facing the unit
- ii. Patient chair at the front end of the table, facing the operator

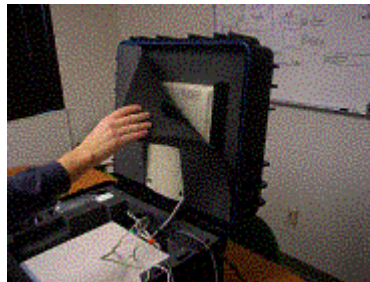
2. Open the case

- a. Make sure the unit is in its final, safe position prior to opening it
- b. Open the top by undoing the 6 latches (two on each side)
- c. If the unit does not open, release the air by opening the pressure release valve on the front (this case is air and water tight!)



3. Start setting up Omnisen for testing

- a. Follow these steps for a smooth set-up
- b. Remove the keyboard and set it up in front of the case
- c. Remove the mouse and set on the mouse pad next to the keyboard
- d. Remove the foam over the monitor (held by velcro)



4. Set-up of monitor

- a. Carefully remove the monitor from its position in the case top
- b. Turn it towards you and tilt the stand up (NOTE: Do not touch or squeeze the blank screen, avoid pulling on the cables).
- c. Place the foam back in the original position for later use



5. Final check

- a. Check all connections in the back of the computer for a secure, tight fit

-
- b. If you use an external printer: connect the printer cable to the parallel printer port.
 - c. Locate the power cable and plug it in to main power (110V).
 - d. Power up the unit by pushing the on-button in the front of the unit.
 - e. Start testing



6. Packing up Omnisense

- a. Clean probes with alcohol tissues and put in dedicated place holders
- b. Follow the set up steps in reverse order – starting with the monitor
- c. Prior to closing the case, make sure that all cables are inside of the case and do not overlap the case top **CABLES WILL BE PERMANENTLY DAMAGED IF SQUEEZED BETWEEN CASE TOP AND BOTTOM!**
- d. Make sure all accessories are packed in the appropriate location. **DO NOT PACK ANY ADDITIONAL PARTS OR ACCESSORIES**
- e. Carefully and gently close the case top, check one more time that nothing is being squeezed
- f. Secure all 6 latches



OMNISENSE 7000S/8000S

Screening for Osteoporosis in Postmenopausal Women: Recommendations and Rationale

U.S. Preventive Services Task Force*

This statement summarizes the current U.S. Preventive Services Task Force (USPSTF) recommendations on screening for osteoporosis and the supporting scientific evidence and updates the 1996 USPSTF recommendations on this topic. The complete USPSTF recommendation and rationale statement on this topic, which includes a brief review of the supporting evidence, is available through the USPSTF Web site (www.preventiveservices.ahrq.gov), the National Guideline Clearinghouse (www.guideline.gov), and in print through the Agency for Healthcare Research and Quality Publications Clearinghouse (telephone, 800-358-9295; e-mail, ahrqpubs@ahrq.gov). The complete information on which this statement is based, including evidence tables and references, is available in the accompanying article in this issue and in the summary of the evidence and the systematic evidence review on the Web sites already mentioned.

Ann Intern Med. 2002;137:526-528. www.annals.org See related article on pp 529-541. *For a list of the members of the U.S. Preventive Services Task Force, see the Appendix.

SUMMARY OF RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) recommends that women 65 years of age and older be screened routinely for osteoporosis. The USPSTF recommends that routine screening begin at 60 years of age for women at increased risk for osteoporotic fractures (see Clinical Considerations for a discussion of women at increased risk). This is a **grade B recommendation**. (See **Appendix Table 1** for a description of the USPSTF classification of recommendations.)

*The USPSTF found good evidence that the risk for osteoporosis and fracture increases with age and other factors, that bone density measurements accurately predict the risk for fractures in the short term, and that treating asymptomatic women with osteoporosis reduces their risk for fracture. (See **Appendix Table 2** for a description of the USPSTF classification of levels of evidence.) The USPSTF concludes that the benefits of screening and treatment are of at least moderate magnitude for women at increased risk by virtue of age or presence of other risk factors.*

The USPSTF makes no recommendation for or against routine osteoporosis screening in postmenopausal women who are younger than 60 years of age or in women 60 to 64 years of age who are not at increased risk for osteoporotic fractures. This is a **grade C recommendation**.

The USPSTF found fair evidence that screening women at lower risk for osteoporosis or fracture can identify additional women who may be eligible for treatment for osteoporosis, but it would prevent a small number of fractures. The USPSTF concludes that the balance of benefits and harms of screening and treatment is too close to make a general recommendation for this age group.

CLINICAL CONSIDERATIONS

Modeling analysis suggests that the absolute benefits of screening for osteoporosis among women 60 to 64 years of age who are at increased risk for osteoporosis and fracture are comparable to those of routine screening in older women. The exact risk factors that should trigger screening in this age group are difficult to specify based on evidence. Lower body weight (weight < 70 kg) is the single best predictor of low bone mineral density (1, 2). Low weight and no current use of estrogen therapy are incorporated with age into the three-item Osteoporosis Risk Assessment Instrument (1). There is less evidence to support the use of other individual risk factors (for example, smoking, weight loss, family history, decreased physical activity, alcohol or caffeine use, or low calcium and vitamin D intake) as a basis for identifying high-risk women younger than 65 years of age. At any given age, African-American women on average have higher bone mineral density than white women and are thus less likely to benefit from screening.

Among different bone measurement tests performed at various anatomic sites, bone density measured at the femoral neck by dual-energy x-ray absorptiometry is the best predictor of hip fracture and is comparable to forearm measurements for predicting fractures at other sites. Other technologies for measuring peripheral sites include quantitative ultrasonography, radiographic absorptiometry, single-energy x-ray absorptiometry, peripheral dual-energy x-ray absorptiometry, and peripheral quantitative computed tomography. Recent data suggest that peripheral bone density testing in the primary care setting can also identify postmenopausal women who have a higher risk for fracture over the short term (1 year). Further research is needed to determine the accuracy of peripheral bone density testing in comparison with dual-energy x-ray absorptiometry. The likelihood of being diagnosed with osteoporosis varies greatly depending on the site and type of bone measurement test, the number of sites tested, the brand of densitometer used, and the relevance of the reference range.

Estimates of the benefits of detecting and treating osteoporosis are based largely on studies of bisphosphonates. Some women, however, may prefer other treatment options (for example, hormone replacement therapy, selective estrogen receptor modulators, or calcitonin) based on personal preferences or risk factors. Clinicians should review with patients the relative benefits and harms of available treatment options, and uncertainties about their efficacy and safety, to facilitate an informed choice. No studies have evaluated the optimal intervals for repeated screening. Because of limitations in the precision of testing, a minimum of 2 years may be needed to reliably measure a change in bone mineral density; however, longer intervals may be adequate for repeated screening to identify new cases of osteoporosis. Yield of repeated screening will be higher in older women, those with lower bone mineral density at baseline, and those with other risk factors for fracture.

There are no data to determine the appropriate age to stop screening and few data on osteoporosis treatment in women older than 85 years of age. Patients who receive a diagnosis of osteoporosis fall outside the context of screening but may require additional testing for diagnostic purposes or to monitor response to treatment.

The brief review of the evidence and other sections that are normally included in USPSTF recommendations are available in the complete recommendation and rationale statement on the USPSTF Web site (www.preventiveservices.ahrq.gov).

RECOMMENDATIONS OF OTHERS

In 1998, the National Osteoporosis Foundation, in collaboration with other professional organizations, issued screening guidelines recommending bone density testing for all women 65 years of age or older, as well as younger postmenopausal women who have had a fracture or who have one or more risk factors for osteoporosis (3). Collaborating groups included the American Academy of Orthopaedic Surgeons, the American College of Obstetricians and Gynecologists, the American Geriatrics Society, the American College of Radiology, the American College of Rheumatology, the American Academy of Physical Medicine and Rehabilitation, the American Association of Clinical Endocrinologists, the Endocrine Society, and the American Society for Bone and Mineral Research. The American Association of Clinical Endocrinologists released revised guidelines in 2001 (4). A 2000 Consensus Development Conference sponsored by the U.S. National Institutes of Health concluded that the value of universal osteoporosis screening was not yet established (5). The conference panel recommended an individualized approach to screening, noting that bone density measurement is appropriate when it will aid the patient's decision to institute treatment. The Canadian Task Force on Preventive Health Care is currently revising its recommendations on screening for osteoporosis.

APPENDIX

Members of the U.S. Preventive Services Task Force are Alfred O. Berg, MD, MPH, *Chair* (University of Washington, Seattle, Washington); Janet D. Allan, PhD, RN, CS, *Vice-Chair* (School of Nursing, University of Maryland, Baltimore, Baltimore, Maryland); Paul S. Frame, MD (Tri-County Family Medicine, Cohocton, and University of Rochester, Rochester, New York); Charles J. Homer, MD, MPH (National Initiative for Children's Healthcare Quality, Boston, Massachusetts); Mark S. Johnson, MD, MPH (University of Medicine and Dentistry of New Jersey–New Jersey Medical School, Newark, New Jersey); Jonathan D. Klein, MD, MPH (University of Rochester School of Medicine, Rochester, New York); Tracy A. Lieu, MD, MPH (Harvard Pilgrim Health Care and Harvard Medical School, Boston, Massachusetts); Cynthia D. Mulrow, MD, MSc (University of Texas Health Science Center, Audie L. Murphy Memorial Veterans Hospital, San Antonio, Texas); C. Tracy Orleans, PhD (The Robert Wood Johnson Foundation, Princeton, New Jersey); Jeffrey F. Peipert, MD, MPH (Women and Infants' Hospital, Providence, Rhode Island); Nola J. Pender, PhD, RN (University of Michigan, Ann Arbor, Michigan); Albert L. Siu, MD, MSPH (Mount Sinai School of Medicine, New York, New York); Steven M. Teutsch, MD, MPH (Merck & Co., Inc., West Point, Pennsylvania); Carolyn Westhoff, MD, MSc (Columbia University College of Physicians and Surgeons, New York, New York); and Steven H. Woolf, MD, MPH (Virginia Commonwealth University, Fairfax, Virginia).

*Appendix Table 1. U.S. Preventive Services Task Force Grades and Recommendations**

Grade	Recommendation
A	The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. <i>The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.</i>
B	The USPSTF recommends that clinicians routinely provide [the service] to eligible patients. <i>The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.</i>

C	The USPSTF makes no recommendation for or against routine provision of [the service]. <i>The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.</i>
D	The USPSTF recommends against routinely providing [the service] to asymptomatic patients. <i>The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.</i>
I	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. <i>Evidence that the [service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.</i>

* The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

Appendix Table 2. U.S. Preventive Services Task Force Grades for Strength of Overall Evidence*

Grade	Definition
Good	Evidence includes consistent results from well-designed, wellconducted studies in representative populations that directly assess effects on health outcomes
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes
Poor	Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes

* The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a three-point scale (good, fair, poor).

From the U.S. Preventive Services Task Force, Agency for Healthcare Research and Quality, Rockville, Maryland.

Requests for Single Reprints: Reprints are available from the USPSTF Web site (www.preventiveservices.ahrq.gov) and in print through the Agency for Healthcare Research and Quality Publications Clearinghouse (800-358-9295).

Experts recommend routine osteoporosis screening

September 17, 2002 Posted: 8:17 AM EDT (1217 GMT)

PHILADELPHIA (AP) -- Women 65 and older should be regularly screened for osteoporosis by getting bone density tests, a government panel recommended.

The recommendation, published in the *Annals of Internal Medicine*, was issued by the U.S. Preventive Services Task Force, a panel of health experts.

The task force's last report on bone-weakening osteoporosis, in 1996, said there was not enough evidence to say whether routine screening is an effective prevention tool. Since then, additional research has shown there is a benefit, said Janet Allen, vice chair of the task force.

Low-dose X-rays of the hip to measure bone density generally cost between \$125 and \$200 dollars, according to the task force.

Women at higher risk for osteoporosis-related fractures should start getting tested earlier, at age 60, the task force said.

The disease is more common among women who are older, have a sedentary lifestyle and a family history of osteoporosis, and are taking estrogen. But many women do not even realize they have the condition until they break a bone.

Osteoporosis affects 10 million Americans -- 80 percent of them women -- and leads to more than 1.5 million fractures per year, according to the National Institutes of Health.

OMNISENSE 7000S/8000S

Multi-Site

The Right Way to Measure Bone

Omnisense's unique probe technology is the only one of its kind. By enabling measurement at multiple skeletal sites, the Omnisense probe system provides you with greater diagnostic ability and enhanced measurement flexibility.

Getting The Whole Picture

Due to the systemic nature of osteoporosis, having a multiple site option provides an overall picture of the skeleton and offers many advantages to the physician:

- ❖ Combining measurement results of different skeletal sites can optimize fracture risk assessment.
- ❖ Using multiple measurement sites enables the physician to overcome the dilemma of how to diagnose patients who:
 - have a clinical indication of osteoporosis but whose measurement results do not support this.
 - are not clearly defined and require a more conclusive diagnosis.

Monitoring Response To Treatment

Different bones respond to treatment at varying rates and degrees. Using multi-site measurements, the physician can identify and monitor small bone changes in a relatively short period of time, allowing more effective monitoring and treatment decisions.

For further reading on the advantages of multi-site measurements, please refer to the following abstracts at: www.sunlightmedical.com

[Does Combining the Results from Multiple Bone Sites measured by a New Quantitative Ultrasound Device Improve Discrimination of Hip Fracture?](#)

D. Hans et. al.

[Multiple Site Ultrasound Measurements Predict Vertebral Fractures in Postmenopausal Women](#)

K.M. Knapp, et. al.

[Discrimination Between Hip Fracture and Age-Matched Controls Using a Commercialized Multi-Site Quantitative Ultrasound Device](#)

D. Hans, et. al.

[Thyroid Dysfunctional State Detected by QUS Measurement at Multiple Skeletal Sites](#)

A. Ben-Shlomo, et. al.



OMNISENSE 7000S/8000S RDB

Exclusive Reference Database

Omnisense 7000S includes male and female reference databases, making it the only bone sonometer in the United States to offer an approved male reference database collected in North America. Each database includes reference curves for each of the recommended skeletal sites; the distal 1/3 radius, the proximal third phalanx, and the fifth metatarsal.

The Omnisense North American male and female reference databases were collected in various geographic regions in the United States and Canada. All subjects were between the ages of 20 - 90 and met strict eligibility criteria. Each skeletal site was measured in accordance with Omnisense's strict measurement methodology.

WHO Compliant

The Omnisense reference curve meets the WHO definition for osteoporosis, crossing the -2.5 T-score threshold at an age range similar to that of vertebral DXA.

Proven

Much discussion has been devoted to the appropriate sample size needed to establish a statistically significant reference database. Sunlight researchers have taken the initiative to gather measurement data from over 6000 subjects measured at 14 different centers from around the world. These subjects were not pre-selected nor were there any special qualification criteria applied to them. Both the system curve and the new curve were then compared by their mean and standard deviation, and no statistical differences were found to exist, reinforcing the validity of the Omnisense reference curve.

OMNISENSE 7000S/8000S

Omnipath™

The Omnipath™ Advantage

Sunlight Omnisense's unique, patented axial transmission technology, Omnipath™, provides comprehensive and accurate bone strength assessment.

A Breakthrough Technology

Omnisense's innovative technology is based on the measurement of the speed of ultrasonic waves propagating along the bone. Omnipath technology enables measurement along the bone's maximal strength axis, eliminating soft tissue effects and providing an accurate diagnosis. Axially transmitted speed of sound (SOS) is independent of bone size and body size (that is, the height and weight of the patient).



Speed of Sound

Omnisense generates inaudible high-frequency pulsed acoustic waves.

Ultrasonic

waves are successively transmitted and received by transducers embedded in the hand-held ultrasound probe. By measuring the propagation time along the different trajectories

(Time of Flight), the SOS of the bone is determined.

Bone Strength Assessment You Can Rely On

As ultrasound waves pass through bone, the speed, dispersion, and attenuation of the signals are strongly influenced by density, elasticity and cohesiveness. The higher the density of the bone, the greater its modulus of elasticity, and the more cohesive its microstructure, the faster the speed of propagation. Therefore, the faster the speed of propagation, the stronger the bone.

Omnisense is designed to perform measurements along bones such as the distal 1/3 radius, the phalanx, and the metatarsal. Results, when used in conjunction with clinical risk factors, aid the physician in the management of osteoporosis and the assessment of fracture risk.

US PATENT # 6221019 (International patents pending)

OMNISENSE 7000S/8000S

Reimbursement

Reimbursement

Bone strength assessment with Omnisense 7000S/8000S may be a covered service, if it meets the requirements established by Medicare and private payers. It is always recommended that you check with your local Medicare contractors and private health plans regarding their local coverage policies.

Coding Requirements

Codes are necessary for physicians and freestanding clinics to report their services and procedures. Accurate coding may lead to faster processing of submitted claims. In the absence of a national coding policy it is advisable to check with your local Medicare contractors or private insurance plans regarding their accepted coding policy. A submission for payment requires two codes for each procedure, a diagnosis code (ICD-9-CM) and a procedure code (CPT).

ICD-9-CM

To comply with Medicare and third-party payer requirements, claim forms must indicate the ICD-9-CM code or codes that describe the principal diagnosis responsible for the patient's condition. Sunlight has compiled a suggested list of ICD-9-CM codes that may relate to the Omnisense 8000S bone strength assessment test. Some carriers may have a specific list of ICD-9-CM codes. It is advised that you contact your local carrier to obtain its current policy.

CPT Coding

Physicians' Current Procedural Terminology (CPT), Fourth Edition, is a listing of descriptive terms and identifying codes for reporting medical services and procedures that physicians and other medical professionals perform. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, thereby serving as a means for nationwide communication among physicians, patients, and third parties. The CPT code used for bone assessment with Omnisense is CPT Code 76977 (Ultrasound bone density measurement and interpretation, peripheral site(s), any method).

CPT is a trademark of the American Medical Association (AMA). The AMA assumes no liability for the information contained herein.

Billing Requirements: Documentation

Documentation is the key to providing a carrier with the information necessary for making a decision whether to approve or deny a claim. Essential medical information should include documentation that Sunlight Omnisense™ 7000S/8000S was used to assess the patient's bone strength in accordance with approved indications.

Insurance Procedures

Sunlight has prepared a list of procedures for insurance coverage for patients covered by Medicare and patients covered by private insurers.

The coding, coverage, and payment information contained herein is gathered from third party sources and is subject to change. The codes listed are possible coding options. It is always the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for the services that are furnished. Providers should contact their local payers for specific information on pertinent coding, coverage and payment policies before a claim is submitted. Sunlight Medical Inc. cannot guarantee success in obtaining payments for medical services.