1. Essential Prescribing Information

The Sunlight Omnisense™ Ultrasound Bone Sonometer (Omnisense) is an accurate and easy to use tool for assessing the condition of bone. This chapter provides an introductory overview of the Omnisense System and the Information for Prescribers.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

1.1 Device Description

The Sunlight Omnisense™ (Omnisense) Ultrasound Bone Sonometer is a non-invasive ultrasound device capable of measuring bone speed of sound (SOS) at one or more skeletal sites. It is comprised of a Main Unit and small hand held probes, each designed to measure SOS at one or more specific skeletal sites. The basic system is offered with one probe and the reference database for measurement of the distal one-third radius. See "How Supplied" section for a complete list of accessories.

A brief description of SOS measurement at the distal one-third radius follows. First, the patient personal information is entered, using Windows 95® graphic user interface. The CM probe is used to measure SOS along the distal one-third of the radius. In particular, the arm is marked at the midpoint between the elbow and the tip of the third finger, and the probe is positioned adjacent to the mark on the proximal side. After marking the precise measurement site the operator enters measurement mode. A uniform layer of Sunlight Ultrasound Gel is then applied to the hand-held probe and the measurement area. The probe is positioned parallel to the bone axis and is held at the base. The probe is moved around the circumference of the radius, with its longest dimension approximately in parallel to the axis of the bone. The measurement consists of three consistent measurement cycles, each of which is comprised of several bone scans.

Results are expressed in meters per second (m/sec), reflecting the upper 95th percentile of the SOS values. Sunlight Omnisense™ reports the bone SOS, together with the T-score (units of standard deviations relative to population reference values of healthy young caucasian female adults) and Z-score values (units of standard deviations relative to age matched

population reference values), computed using the patient's SOS value and a reference database.

No calibration is required. Daily system verification is accomplished using the System Quality Verification (SQV) phantom supplied with the device.

1.2 Intended Use/Indications

The Sunlight Omnisense™ (Omnisense) Ultrasound Bone Sonometer is a non-invasive device that is designed for the quantitative measurement of the velocity of ultrasound waves ("Speed of Sound" or "SOS in m/sec") propagating along the distal one-third of the radius bone. SOS provides a measure of skeletal fragility. The output is also expressed as a T-score and Z-score and can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and, ultimately, in the determination of fracture risk.

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).

1.3 Contraindications

None known.

1.4 Warnings

- Never attempt to operate the Sunlight Omnisense™ unit if it is plugged into an outlet that does not meet all electrical code requirements.
- Make sure that there is proper grounding in the wall outlet.
- The Sunlight Omnisense™ is not suitable for use in the presence of a flammable anesthetic mixture containing air, oxygen or nitrous oxide.
- Always shut down the system using the switch at the rear panel before plugging or unplugging the Main unit.

The United States (U.S.) version of the Omnisense is approved for SOS measurements at the distal 1/3 radius and as such is provided with measurement and database capabilities for this skeletal site. The use of the device to perform SOS measurements at other skeletal sites has not yet been approved by the FDA.

1.5 Precautions

- The Omnisense probe should not be used on subjects with breached skin or open sores on the skin area that comes with contact with the probe.
- Use the Sunlight Omnisense™ only indoors, in a clean, dry environment.
- To prevent fire or electric shock, do not open or expose the Sunlight Omnisense™ Desktop Unit to rain or moisture.
- Do not operate or store the Sunlight Omnisense™ near a heat source or air conditioner and always store the System Quality Verification (SQV) phantom near the Sunlight Omnisense™ Desktop Unit.
- The system is not sterile. Thus, the probe must be cleaned and disinfected before each patient session. The proper cleaning and disinfection procedure is described in this User Guide, "Cleaning and Disinfecting the Omnisense", in Chapter 11.
- The Sunlight Omnisense™ provides no protection against the harmful ingress (entry) of liquids. Hence, when cleaning the unit, avoid applying liquid near probe connections and the sockets.
- SQV phantom and probes should not be immersed in liquid of any kind. Alcohol-free, dry or pre-moistened wipes may be used to clean them.
- Use Sunlight recommended and approved ultrasound coupling gels with the Omnisense sonometer to generate and maintain acoustical contact of the probe with the skin.
- Sunlight ultrasound gel is for external use only.
- When applying ultrasound coupling gel, do not use a Q-tip, an examination glove treated with talc, or any other applicator that may introduce fibers or other foreign matter into the probe.
- Do not expose the SQV phantom and the monitor screen to direct sunlight.
- When conducting the System Quality Verification procedure, avoid touching the temperature indication strip on the phantom with the fingers, as this affects the phantom temperature reading required for correct interpretation of the procedure results.

The United States (U.S.) version of the Omnisense is approved for SOS measurements at the distal 1/3 radius and as such is provided with measurement and database capabilities for this skeletal site. The use of the device to perform SOS measurements at other skeletal sites has not yet been approved by the FDA.

- When conducting System Quality Verification, be sure that no air bubbles are trapped in the gel between the phantom and probe, as this affects the acoustic contact of the probe with the phantom.
- Refer all service problems to qualified Sunlight representative only.
- Monitors, printers and other interfacing accessories used with the Sunlight Omnisense™ bone sonometer must meet IEC 601-1, IEC 950, UL 2601 or equivalent safety standards.

1.6 Adverse Events

No adverse events were reported in the course of the clinical studies performed, in which a total of approximately 4000 subjects underwent Omnisense measurement.

There are no known potential adverse effects of the Omnisense on health.

1.7 Clinical Studies

Five clinical studies were performed involving a total of 2,059 women. These studies are briefly summarized below.

1.7.1 North America Normative Database

Objective: To construct a geographically representative database of mean distal one-third radius SOS values by age for Caucasian women in North America.

Methods: Caucasian females between the ages of 20 and 90 years old were recruited from the general population. Data were collected from five sites at different geographic locations in North America (4 in the US and 1 in Canada). Participating subjects had a negative history of osteoporotic fracture or chronic conditions affecting bone metabolism, were not taking medications known to alter bone metabolism, and none had experienced premature menopause.

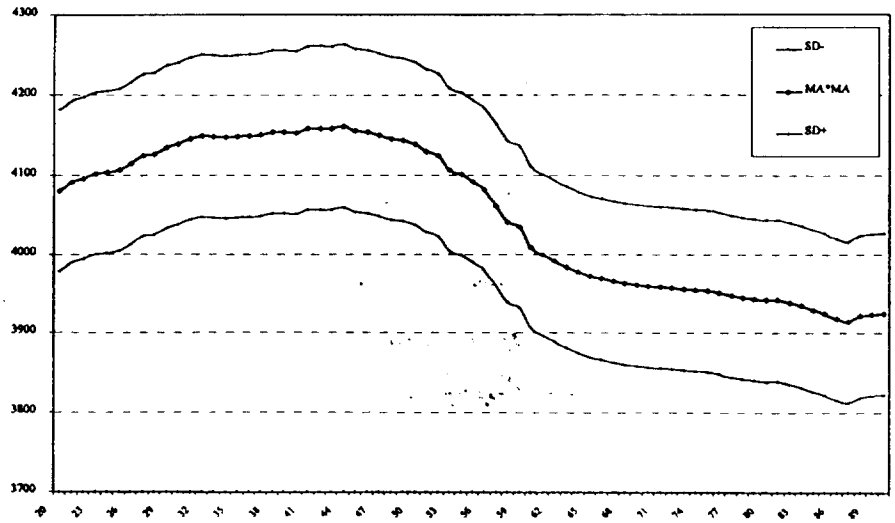
Results: SOS measurements of the distal one-third radius were obtained from 521 subjects. The mean SOS was 4083±146 m/sec with a range of 3532 to 4490. **Table 1** presents mean SOS results by age decade. **Figure 1** depicts the moving average of the SOS results as a function of age. The moving average SOS increases to a peak of 4158 m/sec at the

age of 41, with population standard deviation of 102 m/sec, and declines thereafter. The peak mean and standard deviation results are used for generating T-scores. The largest decline, about 15 m/sec/year, is observed around age 58, eight years past the mean age of menopause. At older ages, 65 to 90, the decline slows to about 2-5 m/sec/year. The mean T-score of the population was -0.75±1.43 with a range of -6.16 to 3.24. Among women aged 60-90, 35% had T-scores less than -2.5 and 42% had T-scores between -2.5 and -1.0.

Table 1: SOS Measurements by Age
North America Normative Database

Age (years)	N	Mean±SD
20-29	92	4103±107
30-39	100	4150±93
40-49	102	4161±130
50-59	90	4095±131
60-69	64	3971±141
70-79	48	3949±125
80-90	25	3921±149
All	**521**	**4083±146**

Figure 1: Moving Average SOS by Age
North America Normative Database



Conclusion: The study provides a representative sample of Caucasian women in North America for use as a reference population and for computing T-scores and Z-scores.

1.7.2. Israel Normative Database

Objective: To construct a database of mean distal one-third radius SOS values by age for Caucasian women in Israel.

Methods: Caucasian females between the ages of 20 and 90 years old were recruited from the general population of a large metropolitan area in Israel. Participating subjects had a negative history of osteoporotic fracture or chronic conditions affecting bone metabolism, were not taking medications known to alter bone metabolism, and none had experienced premature menopause.

Results: SOS measurements of the distal one-third radius were obtained from 1,132 subjects. The mean SOS was 4082±151 m/sec with a range of 3510 to 4602. The moving average SOS increases to a peak of 4173 m/sec at the age of 39, with population standard deviation of 99 m/sec, and declines thereafter. The largest decline, about 15 m/sec/year, is observed around age 55, four years past the mean age of menopause. At older ages, 65 to 90, the decline slows to about 5 m/sec/year. The mean T-score of the population was -0.92±1.53 with a range of -6.70 to 4.33. Among women aged 60-90, 45% had T-scores less than -2.5 and 34% had T-scores between -2.5 and -1.0.

Conclusion: The study provides a representative sample of Caucasian women in Israel for use a reference population and for computing T-scores and Z-scores.

1.7.3. Cross-Sectional Study of Hip Fracture Risk

Objective: To determine the ability of the Omnisense to discriminate osteoporotic hip fracture subjects from age matched non-fracture subjects and young healthy subjects, and to determine the fracture risk estimate.

Methods: The study was carried out by one investigator at two investigational sites in Israel. A total of 365 Caucasian women were recruited into three groups. Hip fracture subjects were 65 to 85 years of age and were not taking medications having a positive effect on bone metabolism. Elderly non-fracture subjects were age matched to hip fracture subjects. Young healthy subjects were 35 to 45 years of age.

Results: **Table 2** contains a summary of SOS results for each study group. All pairwise differences between the three groups were statistically significant ($p<0.0001$).

Table 2: SOS Results by Study Group

	Hip Fracture N=50	Non-Fracture N=135	Young Healthy N=180
SOS Mean±SD	3861±149	3966±145	4165±96
T-Score <-2.5 (%)	70%	39%	1%
T-Score >-1.0 (%)	10%	24%	85%

Logistic regression for hip fracture discrimination indicates that the area under the ROC curve, unadjusted for age, is 0.63 (95% CI: 0.61-0.79). The fracture odds ratio, unadjusted for age, is 2.16 (95% CI: 1.46-3.19) and the age-adjusted odds ratio is 1.75 (95% CI: 1.15-2.65). For every 100 m/sec decrease in SOS the odds of fracture increase by about 50% and for every decrease of 162 m/sec in SOS the odds of fracture doubles.

Conclusions: This case-control based study has shown that the Omnisense can significantly discriminate between osteoporotic hip fracture subjects, age-matched elderly non-fracture subjects, and young healthy subjects. This finding is noted despite a high likelihood that there are a significant number of osteoporotic subjects in the non-fracture group.

The odds ratios found in this study can be considered fracture risk estimates, and are comparable to those of other bone assessment devices.

1.7.4. Cross-Sectional Study of Hip, Vertebral and Wrist Fracture Risk

Objective: To determine the ability of Omnisense Speed of Sound measurements to discriminate subjects with major osteoporotic fractures from non-fracture subjects, and to determine the fracture risk estimate.

Methods: The study was carried out by one investigator in Israel. A total of 274 Caucasian women were recruited into three fracture groups (hip, vertebral and wrist) and an elderly non-fracture group. All subjects were 55 to 85 years of age and fracture subjects were not taking medications having a positive effect on bone metabolism.

Results: **Table 3** contains a summary of SOS results for each study group. All differences between the three fractures groups and the non-fracture group were statistically significant ($p<0.01$).

Table 3: SOS Results by Study Group

	Hip Fracture N=94	**Vertebral Fracture N=50**	**Wrist Fracture N=41**	**Non-Fracture N=89**
SOS Mean±SD	3873±154	3877±144	3880±154	3878±154
T-Score <-2.5 (%)	60%	52%	54%	46%
T-Score >-1.0 (%)	7%	8%	7%	24%

Logistic regression for fracture discrimination indicates that the area under the ROC curve, unadjusted for age, is 0.63 (95% CI: 0.56-0.70). The fracture odds ratio, unadjusted for age, is 1.72 (95% CI: 1.29-2.30) and the age-adjusted odds ratio is 1.41 (95% CI: 1.04-1.93). For every 174 m/sec decrease in SOS the odds of fracture increase by about 50% and for every decrease of 297 m/sec in SOS the odds of fracture double.

Conclusions: This case-control based study has shown that the Omnisense can significantly discriminate between subjects having any of the most common osteoporotic fractures and age matched non-fracture controls This finding is noted despite a high likelihood that there are a significant number of osteoporotic subjects in the non-fracture group.

The odds ratios found in this study can be considered fracture risk estimates, and are comparable to those of other bone assessment devices.

1.7.5. Pooled Cross-Sectional Studies

Background: The two cross-sectional studies were very similar in many respects. Both studies recruited hip fracture subjects and both studies recruited healthy non-fracture subjects in the same age groups. Both studies had similar eligibility criteria, the population characteristics of these groups in the two studies were similar, and the Omnisense measurements were performed using identical procedures. Since hip fracture may be the most important osteoporotic fracture, it is important to obtain estimates of Omnisense hip fracture discrimination ability that are as accurate as possible. Thus, the hip fracture and healthy non-fracture groups in the two cross-sectional studies have been pooled in order to arrive at a more precise estimate.

Results: Hip fracture subjects had a mean SOS of 3869±152 m/sec, while non-fracture subjects had a mean SOS of 3960±142 m/sec; this differences was statistically significant ($p<0.0001$).

Among hip fracture subjects, 63% had T-scores less than -2.5, while 42% of non-fracture subjects had T-scores less than -2.5. Conversely, 8% of hip fracture subjects had T-scores greater than –1.0, while 24% of non-fracture subjects had T-scores greater than –1.0.

Logistic regression for hip fracture discrimination indicates that the area under the ROC curve, unadjusted for age, is 0.67 (95% CI: 0.61-0.73). The fracture odds ratio, unadjusted for age, is 1.95 (95% CI: 1.53-2.49) and the age-adjusted odds ratio is 1.54 (95% CI: 1.18-2.00). For every 150 m/sec decrease in SOS the odds of fracture increase by about 50% and for every decrease of 257 m/sec in SOS the odds of fracture doubles.

Conclusions: Pooling of data from the two cross-sectional studies is justified on the basis of the similarities between the two studies. The results from combining the two studies show that the Omnisense can significantly discriminate between osteoporotic hip fracture subjects and age-matched non-fracture subjects even after controlling for age and BMI.

1.7.6. Precision Studies

Three *in vivo* precision studies were performed to evaluate various aspects of reproducibility of SOS measurements. The objective of all

three studies was to estimate the variability of SOS measurements of the Distal 1/3 Radius of a human subject between device components, different operators and with repeated measurements. In each study reproducibility is measured by the coefficient of variation (CV), which is the standard deviation divided by the mean.

Reproducibility of Instruments and Probes

In this study three PC-based main units, four CMX probes, and three operators were evaluated to determine the reproducibility of each. All possible combinations of each element (system unit, slot number, and probe) were tested, for a total of 36 SOS measurements (3 system units x 3 slots x 4 probes). The reproducibility (CV) of the probes, for a given combination of system and slot ranged from 0.36% to 0.90% (0.29% overall). The reproducibility of the system units, for a given combination of slot and probe, ranged from 0.21% to 1.01% (0.13% overall). The reproducibility of the slots, for a given combination of system and probe, ranged from 0.18% to 1.01% (0.25% overall).

Reproducibility of Operators and Probes

In this study three operators and four CMX probes were evaluated. Each operator measured the subject three times with each probe. As before, all possible combinations (probe and operator) were tested, for a total of 36 measurements (3 operators x 4 probes x 3 repeats). The reproducibility of the probes, for a given combination of operator and repetition number, ranged from 0.13% to 1.04% (overall 0.52%). Combining all repetitions for a single operator into one group, the probe CV for different operators ranged from 0.60% to 0.83%. The reproducibility for the operators, for a given combination of probe and repetition number, ranged from 0.19% to 0.80% (overall 0.35%). Combining all repetitions for a single operator into one group, the probe CV for different operators ranged from 0.54% to 0.64%.

Reproducibility of Repeated Measurements

In this study the distal one-third radius SOS of each subject was measured twice by three different operators. Probes were repositioned between each measurement. The CV was reported for all measurements, as well as stratified by operator and by menopausal status. The variance

of each CV was also calculated so that 95% confidence intervals could be reported. Fifteen subjects were measured, 10 premenopausal women and 5 postmenopausal women.

Since there were 15 subjects measured by three different operators, a total of 45 pairs of repeated SOS measurements are available to assess the reproducibility of repeated measurements. The overall CV was 0.40% (95% CI: 0.39% to 0.41%). For pre-menopausal women the CV was 0.29% and for postmenopausal women the CV was 0.57%. A total of six different operators performed SOS measurements in this study. Their CVs ranged from 0.27% to 0.66%.

The coefficient of variation can also be calculated in two different "standardized CV" forms, SCV_1 and SCV_2. SCV_1 is computed by dividing the measured mean square error by 95% of the individual range, which is taken from the North America Normative Database (Section X.A.1 above). SCV_1 was found to be 1.8%. SCV_2 is computed by dividing the mean square error by the difference of the young healthy mean SOS (taken from the North America Normative Database) and that of the osteoporotic fracture mean SOS (the mean of the "All Fracture" group in the 202 Study). SCV_2 is higher than SCV_1, and equals 5.9%.

Another measurement of precision is the standard deviation of the T-score (TSD), defined as the mean square error divided by the young health SOS standard error (taken from the North America Normative Database). In this study the TSD is 0.16 (16%).

CONCLUSIONS

The *in vivo* precision (reproducibility), expressed by CV, for the Omnisense system when performing repeated SOS measurements of the Distal 1/3 Radius of the forearm was very good regardless of the ultrasound probe, the system, the probe connecting slots within each main unit, or the operator used to perform the measurement. Results indicated a high level of reproducibility regardless of the hardware used or the operator performing the measurements, and demonstrated a very narrow dispersion of the SOS measurement results.

The *in vivo* precision of repeated Omnisense measurements in the same subject is also extremely high, with a CV of 0.40%. There were some relative differences in CV between premenopausal and postmenopausal

subjects. Differences in precision between premenopausal subjects and postmenopausal subjects have been found in DXA measurements (postmenopausal CV higher than premenopausal CV) as well as in QUS measurements of the calcaneus (postmenopausal CV lower than premenopausal CV). There were also differences between CVs measured by different operators. Nevertheless, all CVs were well below 1%, indicating good precision for all subgroups, and thus allowing for a meaningful assessment of patient status relative to the reference range.

The mean square error, about 17m/sec, is similar in magnitude to the average change per year which is observed during the first years of sharp decline in SOS post menopause. Thus, the Omnisense can provide precise estimates of bone status during this important time when bone changes are most pronounced.

1.8 Individualization of Treatment

The Omnisense measures the Speed of Sound (SOS) in m/sec of an ultrasound wave that propagates along the bone. These results may be used by the physician, along with other factors such as laboratory test results, radiographs, life style, and family history in the diagnosis of osteoporosis and other conditions leading to reduced bone strength and bone fragility.

The following detailed information is intended to guide the physician on how to interpret the Omnisense results and its relationship to the currently accepted densitometry methods.

SOS Result, T-Score and Z-Score - Definitions

Any patient measurement result consists of three different parameters:

The absolute result of the measured Speed of Sound (SOS) expressed in units of meters per second (m/sec). For the purposes of the following definitions, the term young healthy population is defined as that age group in which bone mineral density (BMD) is at its peak (Kanis *et al.* 1997). For devices that show BMD to be constant between ages 20 to 40 it is typical to use the average value for ages 20 to 40 as the young healthy population reference value. However, Sunlight found that SOS was not constant between ages 20 and 40, but instead gradually increases starting at age 20 and reaches a peak at around age 40. Thus, the "young healthy population" mean is taken as the "peak bone SOS",

which occurs at age 41 in the company's US Normative Database Study, based on averaging the population SOS values within a window 5 years above and below each age point. T and Z-scores are defined as follows:

- T-score - The difference between the patient's SOS result and the peak average SOS of young healthy population, in units of population standard deviation. Positive value means that the measured result is above the peak average SOS, while negative value represents a value which is lower than the peak average SOS. A value of T = -2 means that the SOS of the patient is two population standard deviations below the peak average SOS.
- Z-score - The difference between the patient's SOS result and the average SOS of a population of the same age and gender in units of population standard deviation. A value of Z=+0.5 means that the SOS of the patient is half a population standard deviation above the mean of her age-matched peers.

T and Z-scores provide additional information for bone assessment because they take into account both the mean and statistical distribution of population reference values. Those results, together with the patient's clinical profile, provide the physician with useful data on which therapeutic decisions can be based.

On the next page is an example of a patient report, showing the above results as measured by the Omnisense.

[NOTE: The Sunlight Omnisense Measurement Report is not included in this file due to the diskette space required for the graphics. If required, this graphic will be supplied separately.]

Bone Ultrasonometry and Fracture Risk

The Omnisense-reported T-scores can be used to assess a patient's risk of osteoporotic fracture in a manner similar to that used in X-ray absorptiometry.

In 1994, a Study Group commissioned by the World Health Organization (WHO) has proposed clear guidelines for physicians diagnosing osteoporosis, based on T-scores:

a. Normal. T-score above -1.0.

b. Osteopenia. T-score between -1.0 and -2.5.

c. Osteoporosis. T-score below -2.5.

These cut-off values related initially to Bone Mineral Density (BMD) measured at the forearm. Nevertheless, they were shortly adopted for axial BMD measurements, including BMD of the spine and the hip, whereby the lowest value reported is usually considered for diagnostic purposes (Kanis *et al.* 1994).

The Omnisense sensitivity and categorization capability was found in various studies to be similar to those of hip and spine BMD, and it is therefore suggested that the WHO criteria be adopted and applied to the Omnisense-measured T-scores. The physician should, of course, consider other risk factors, such as low body weight, fracture history, family history, corticosteroids use, etc. in patient evaluation.

Concerning risk of fracture, research shows that the odds ratio of osteoporotic hip fractured to non-fractured subjects measured by the Omnisense is about 1.5. That means that a decrease of 1.5 T-score units corresponds to a 50% increase in the odds of hip fracture while a decrease of about 2.5 T-score units doubles the odds of hip fracture.

1.9 Patient Counseling Information

Information for Patient Brochures are supplied with the Omnisense Bone Sonometer. These brochures give a brief summary of the importance of bone density testing and information about the Omnisense Bone Sonometer.

1.10Conformance to Standards

The Sunlight Omnisense™ Bone Sonometer conforms to U.S. and international standards, as described below, for safety, electromagnetic compatibility and acoustic output relative to ultrasound devices. The Sunlight Omnisense™ Bone Sonometer generates and emits ultrasonic energy. Emissions have been tested and found to be in conformance with the accepted standard limits for medical diagnostic devices of this type.

The United States (U.S.) version of the Omnisense is approved for SOS measurements at the distal 1/3 radius and as such is provided with measurement and database capabilities for this skeletal site. The use of the device to perform SOS measurements at other skeletal sites has not yet been approved by the FDA.

Non-clinical testing demonstrated conformance to the following international standards:

IEC 60601-1 (EN 60601-1) Medical electrical equipment, Part 1: General requirements for safety.

IEC 60601-1-2 (EN 60601-1-2) Medical electrical equipment electromagnetic compatibility - Requirements and tests.

IEC 61157: 1993 Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment

NEMA, ID-2, revision 2: 1997 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

FDA Guide 510(k) Track 1 Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices (1985); and FDA 510(k) Guidance: "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" (September 30, 1997)

ISO 10993: 1992 "Biological evaluation of medical devices"
ISO 10993-1:1992 "Guidance on selection of tests"
ISO 10993-5:1993 "Test for cytotoxicity: in vitro methods"
ISO 10993-10:1994 "Test for irritation and sensitization"

The Sunlight Omnisense™ Bone Sonometer meets the provisions of the Medical Device Directive 93/42/EEC and has been certified by KEMA EC Notified Body (Identification number 0344) for CE Marking of Conformity of Medical Devices. Certificate number 87757CE01 issued by KEMA July 10, 1998.

Monitors, printers and other interfacing accessories used with the Sunlight Omnisense™ bone sonometer must meet IEC 601-1, IEC 950, UL 2601 or equivalent safety standards.

1.11How Supplied

The basic Omnisense packaging includes the following:

- Main Unit (230VAC or 115VAC),

The United States (U.S.) version of the Omnisense is approved for SOS measurements at the distal 1/3 radius and as such is provided with measurement and database capabilities for this skeletal site. The use of the device to perform SOS measurements at other skeletal sites has not yet been approved by the FDA.

- Keyboard with integrated trackball,
- 14" color display monitor,
- Ultrasound probes according to order specification (each probe contains a set of transducers, some acting as transmitters and the others acting as receivers, housed tightly together in a compact holder),
- Foot Pedal,
- System Quality Verification Phantom,
- User's Guide,
- Power supply cable,
- Gauges for marking the region of measurement (according to the skeletal site order specification),
- Measurement accessories (according to the skeletal site order specification),
- Earphones,
- Starter Kit (see below).

Also, included as a Starter Kit:

- Multimedia Presentation including training,
- Acoustic contact gel bottles (250 cc each),
- Zip and 1.44MB Diskettes,
- Skin Marker,
- Screw Driver.

1.12Operators Manual

Refer to Chapters 2 through 14 for the complete directions for use and maintenance of the Omnisense Bone Sonometer.

1.13References

Kanis JA, Melton LJ 3rd, Christiansen C, Johnston CC, and Khaltaev N. "The Diagnosis of Osteoporosis." J Bone Miner Res 1994 Aug; 9(8): 1137-1141.

Kanis JA, Delmas P, Burckhardt C, Cooper C, and Torgerson D. "Guidelines for Diagnosis and Management of Osteoporosis." Osteoporos Int 1997; 7:390-406.