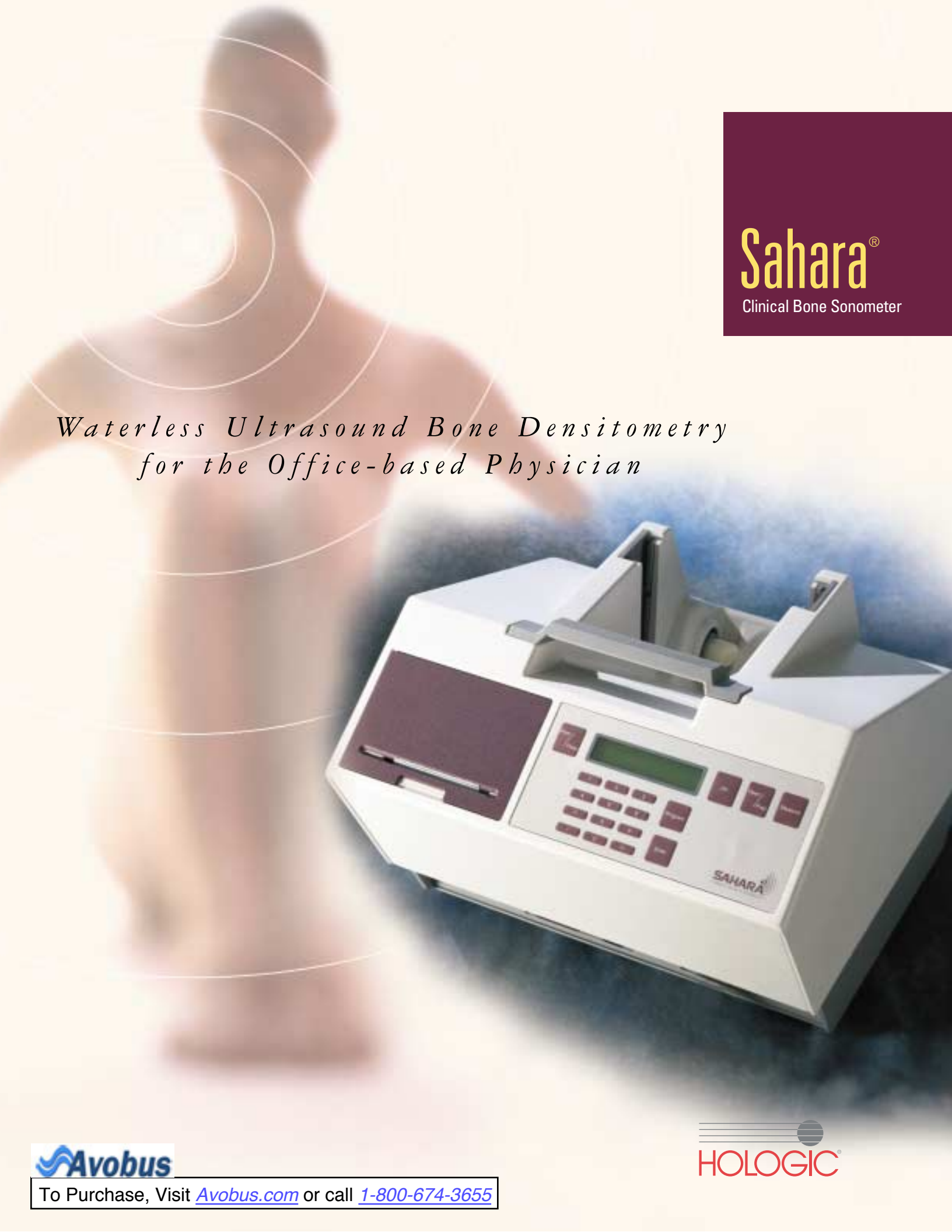
Sahara®

Clinical Bone Sonometer

Waterless Ultrasound Bone Densitometry for the Office-based Physician



HOLOGIC®

Build Your Practice Serving a Critical Medical Need

Osteoporosis:

Affects Millions, Costs Billions.

"The direct and indirect costs of [osteoporotic] fractures are so great, in terms of morbidity and mortality, that this disease must be confronted early, especially because new therapy is so effective."[1]

Osteoporosis and related bone disorders affect 28 million Americans—80% of whom are women. Each year, this debilitating disease contributes to more than 1.5 million new fractures of the hip, spine and forearm. In the U.S. alone, the costs of long-term care and rehabilitation related to the incidence of fracture exceeds $14 billion![2]

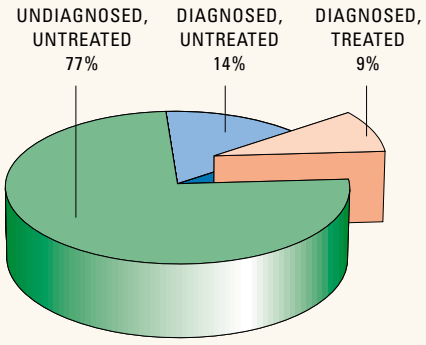
Osteoporosis is four times greater in post-menopausal women than in men, yet three out of four women ages 45-75 have never even talked to a doctor about this potentially crippling disease.

With the availability of effective drug therapies, there's now new hope for millions of women with osteoporosis. However to assure that patients at risk for fracture receive proper treatment, they must first be identified.

Just as no physician would prescribe a medication for hypertension without first taking the patient's blood pressure, the treatment of osteoporosis should begin with an objective, quantifiable measurement of the patient's bone density.

In the United States...

- *30 million Americans are affected by diseases treated with corticosteroids, a class of drugs known to cause rapid and severe bone loss.*[3]
- *A woman's risk of hip fracture alone is equal to her combined risk of developing breast, uterine or ovarian cancer.*[2]
- *Osteoporosis-related hip fractures are the leading cause of hospital bed utilization.*[1]
- *20% of all hip fracture patients die within one year after fracture.*[1]
- *50% of hip fracture survivors require some form of assisted living.*[1]
- *The "aging of America" could increase the incidence of hip fracture by as much as 280% by the year 2040.*[4]



Less than 10% of women who are at risk of osteoporosis are currently diagnosed and treated.

Fast, Convenient and Simple to Use . . .

Advanced Bone Measurement Technology for the Office-based Physician

In response to a growing array of effective drug therapies now available for the treatment of osteoporosis, the evaluation of bone status has become an essential component of women's health. Ultrasound bone sonometry—a safe, non-ionizing modality—provides precise quantitative assessment of skeletal status, information that is particularly useful for identifying patients at risk of developing osteoporosis and for assessing their risk of future fracture.

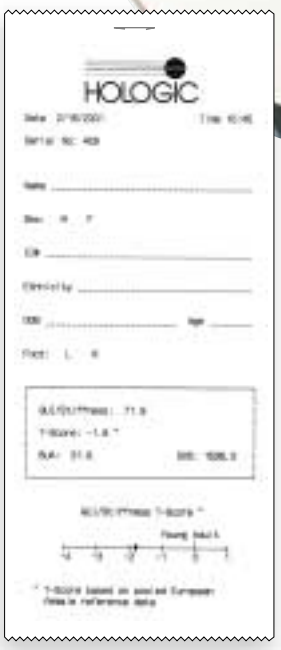
Now you can add bone-testing capabilities to your private practice or clinic with the portable, easy-to-use Sahara Clinical Bone Sonometer. In less than one minute and with the push of a button, you can determine a patient's bone mineral density (BMD), based on an ultrasound measurement of the calcaneus (heel bone)—the preferred peripheral site proven in numerous prospective studies to predict fracture risk. With Sahara, there's finally an ultrasound modality for bone assessment that is simple, convenient and practical enough for the office-based physician.

- *Sahara's dry technology eliminates the problems inherent in water-based systems that affect precision*
- *Sahara is FDA approved with **no age limit** on fracture risk prediction. Caucasian reference data are based on subjects 19 to 97.*

Compact, lightweight unit requires a minimum ... skeletal assessment in

The patient sits comfortably with a foot secured in the Sahara unit for the seconds it takes to perform the test.

Within seconds after completing the test, Sahara's LCD panel displays QUI/stiffness, estimated BMD, and T-score results. BMD is the accepted international standard for measuring bone density. T-scores help physicians identify patients at risk of developing osteoporosis.



Sahara's internal printer provides hardcopy documentation of test results in seconds.

SAHARA
CLINICAL BONE SONOMETER®

PATIENT REPORT FORM

SAHARA
CLINICAL BONE SONOMETER

RESULTS

HOLOGIC

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Transfer patient information and test results to the provided Patient Report Form for a permanent record. Plotting the Z-score provides an easy-to-read, quantitative assessment of fracture risk.

Immediate Results and Documentation

1. Radiation-free

Improves patient acceptance. Does not require a registered x-ray technologist to operate the system.

2. Fully Dry Operation

No water required! No water bladders that can puncture and leak. No mixing of water and surfactant. No variability in test results due to air bubbles or fluctuations in water temperature. Easier, portable, more convenient for patients and operator.

3. Minimal Gel

Gel is applied only to the transducer pads, not to the patient's heel. Easy to clean for faster throughput.

4. Simple to Operate

Pressing one button starts and completes the test.

5. Compact and lightweight

Just 10 kg (22 lbs.), Sahara comes equipped with a built-in handle for portability and requires less than 1,550 square centimeters of floor space.

6. Minimal Operator Training

Supplied 20-minute training video covers all the instruction needed for basic operation.

7. Rapid Measurement Time

A Sahara measurement takes only 10 seconds! Sahara oil-based gel produces faster measurement than systems that use water or water-based gels.

8. Estimates BMD, provides T-Score and Z-Score

Sahara is the only ultrasound bone sonometer that estimates BMD and determines BMD T-scores. Risk of fracture is determined by the Z-score plotted on the Patient Report Form.

9. Built-in Microprocessor and Printer

External computer and printer not required. Saves space and contributes to ease of operation.

10. Reimbursed by Medicare

Medicare reimburses Sahara bone density studies under CPT Code 76977 (ultrasound bone density measurement and interpretation, peripheral site(s), any mehtod).

The Calcaneus: An Effective Site for Bone Densitometry

The calcaneus is composed primarily of high-turnover trabecular bone.

Heel: The Preferred Peripheral Site for Predicting Fracture Risk

- Almost entirely trabecular bone
- Easily accessible
- Little soft tissue
- Fracture risk prediction second only to central DXA

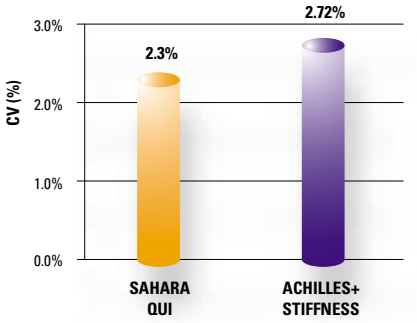
The calcaneus (heel) consists of 75%-90% trabecular bone, a "spongy" bone tissue that is more responsive to age, disease, and therapy-induced bone changes. It has long been a favorite site among researchers investigating osteoporosis and bone loss. More than 200 papers, published since 1969, reference calcaneal bone density. The potential for evaluating bone with quantitative ultrasound (QUS) was reported as early as 1984.[4]

In 1990, the Study of Osteoporotic Fractures (SOF) documented a relationship between bone density of the calcaneus and future fracture risk.[2] Subsequent publications and additional studies confirm the initial findings, and also show that heel ultrasound results are equally predictive of future fracture risk.[3-8]

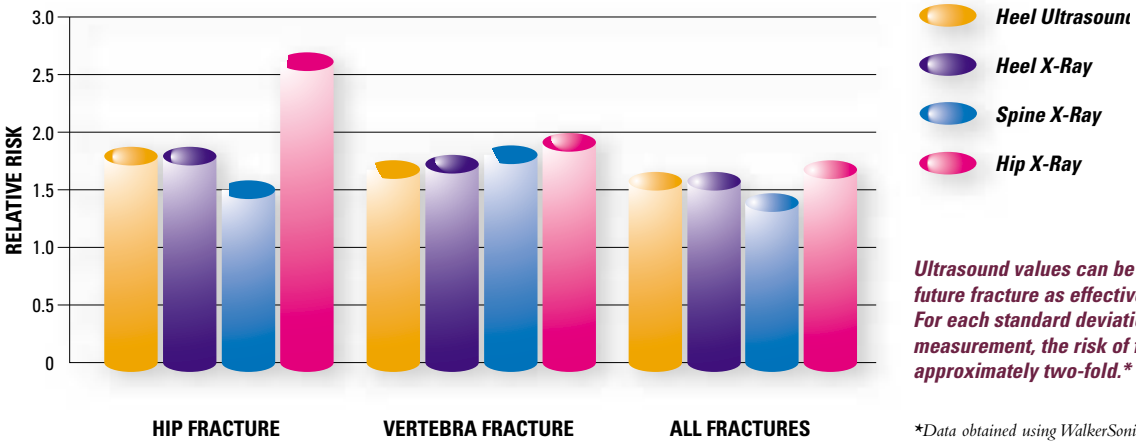
Unsurpassed Performance

- Superior Precision—no air bubbles to interrupt sound transmission
- No variability in results due to fluctuations in water temperature
- Superior accuracy—direct measurement of heel width, not an estimate

Head-to-Head Precision Comparison



Prediction of Fracture Risk



Ultrasound values can be used to estimate the risk of future fracture as effectively as DXA bone densitometry. For each standard deviation decrease in the measurement, the risk of fracture increases approximately two-fold.*

**Data obtained using WalkerSonix UBA-575 Ultrasonic Bone Analyzer. Sahara results are highly correlated to WalkerSonix. (r=0.91).*

Dry Ultrasound Technology: More Convenient and Accurate than Water-based Systems

View of patient's heel positioned properly between transducers. Direct contact with heel produces an accurate measurement of heel width, not an estimation like water-based systems.

The Limitations of Water-Based Systems

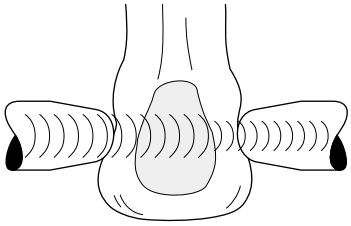
Water-based systems generally fall into two categories: systems that contain water with balloon-like membranes and systems that require patients to submerge their foot in a water bath. Besides the obvious inconvenience of the operator having to drain and refill the system with water and the high likelihood of leaks, the differences between water-based systems and Sahara not only impact convenience and practicality, but can also have serious ramifications regarding clinical results.

The Advantages of Dry Technology

Sahara's waterless design is easier to use and more convenient for both operator and patients. There's no messy clean up, leaks, or signal interference caused by air bubbles. Direct contact with the patient's heel also assures a more accurate measurement for better precision and results you can trust.

Compare Operation and Performance	Water-Based Systems	Sahara
Ease of Use	• Water must be temperature-stabilized • Water must be mixed with a soapy surfactant to improve skin wetting • Coat membranes with 1mm of gel • Membranes can leak and must be replaced • Extensive clean-up after use.	• Apply small strip of gel to transducer pads • Press a single button to initiate test • Easy clean-up after use
Patient Comfort	• Patient's foot must be either submerged in water 3 to 5 minutes; or • Entire bottom and sides of heel must be covered with 1mm layer of gel	• Foot positioning aide holds patient foot comfortably in place • No gel applied to patient's foot
Time	• Requires 5 to 10 minutes settling time to reach a stable value	• Sahara yields accurate measurements in under 10 seconds
Mobility	• Portable and lightweight *when empty* (10 Kg)	• Portable and lightweight (10 Kg)
Quality Control	• Recommended every seven (7) days • Utilizes plastic cylinder with no ultrasonic properties • Measures transmission of sound through water only • Takes 5 minutes	• Daily QC takes 10 seconds • Utilizes phantom with known ultrasonic properties
Performance	• Assumes all patients have the same heel width, resulting in varying SOS results • Air bubbles in water can significantly impair transmission of sound waves	• Makes direct, mechanical measurement of heel width, providing consistent, accurate SOS results independent of heel width

Sahara Helps Calculate the Most Meaningful Metric—Fracture Risk



Sahara transducers send and receive the ultrasound signal through the calcaneus.

Bone mineral density or BMD, expressed in g/cm², has long been accepted as the international standard for reporting bone mass. The Sahara Clinical Bone Sonometer is the first and only bone sonometer that estimates BMD using non-ionizing ultrasound.

Sahara measures the transmission of high-frequency sound waves (ultrasound) through the heel. Within 10 seconds, Sahara determines three ultrasound parameters from the measured signal: Speed of Sound (SOS), Broadband Ultrasonic Attenuation (BUA), and the Quantitative Ultrasound Index (QUI)—sometimes called "stiffness"—which is a combination of SOS and BUA. The Sahara system software automatically estimates BMD from the QUI/stiffness value.

Sahara Calculates Estimated BMD T-Scores and Enables Determination of Fracture Risk

Sahara's built-in microprocessor compares patient estimated BMD results to a reference database of young normal Caucasian females to produce a T-score. According to World Health Organization (WHO) guidelines, a patient with a T-score below –1.0 has low bone mass and is at increased risk for fracture. Hip fracture risk doubles with each population standard deviation decrease in Sahara results compared to the age matched mean, or Z-score.

T-Score Interpretation

T-Score	Interpretation
T < –1.0 SD	Low bone mass; at increased risk for fracture

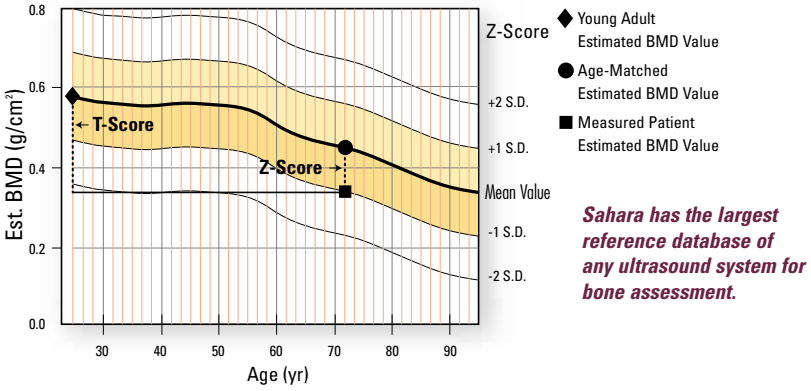
Kanis, et al. JBMR, Vol. 9, p 1137-=1140 (1994)

Z-scores—the comparison of patient results with sex-, age-, and ethnicity-matched—are used to predict risk of future fracture quantitatively.

Risk of hip fracture doubles for each Z-score decrease. For example, a patient with a Z-score of –1 has twice the risk of hip fracture compared to age-matched peers.

Clinical Use of Sahara Results

The two sites most sensitive to fracture risk are the hip and the heel. Although the "average" bone loss with age is highly dependent on the measurement site, age does not affect the site's sensitivity to fracture risk. Instead, sensitivity to fracture risk is reflected in the different results between subjects of a given age. However, many patients may be classified as "osteoporotic" at one site and "Normal" at another. Therefore, WHO guidelines and Sahara test results are intended to be used in conjunction with a complete patient assessment, including evaluation of other risk factors that may affect fracture risk, such as the presence of other conditions that could affect bone mineral metabolism (i.e., hyperthyroidism) and the evidence provided by other testing procedures.



Sahara has the largest reference database of any ultrasound system for bone assessment.

Advanced Clinical Software

The Sahara Advanced Clinical software is an easy-to-use Windows-based program that combines patients' real-time test results with biographical information and population reference data. Simply install the program on any standard PC or laptop to perform on-line bone density testing with a comprehensive database for research and clinical applications. Connect to a standard color printer to produce full color Patient Test Reports to enhance your presentation of test results to patients and referring physicians.

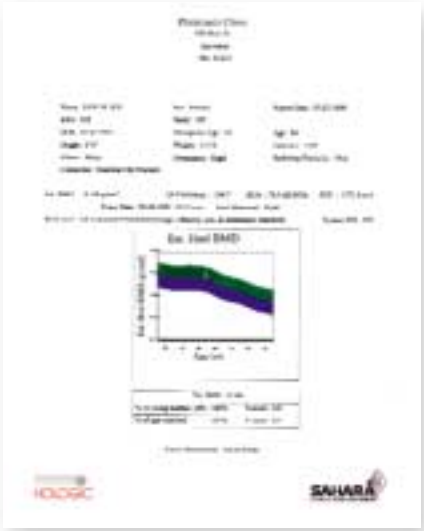
- Menu driven
- User friendly menus prompt you through all operations
- Automatically operates the Sahara Bone Sonometer
- Captures Sahara test results on-line

Automated Quality Control Monitoring

- QC results conveniently captured on-line
- Automatically plots day-to-day QC data
- Saves valuable time by eliminating the need for manual logs and charts
- Automatically calculates QC plot statistics
- Provides a permanent QC record

Automated Database Management

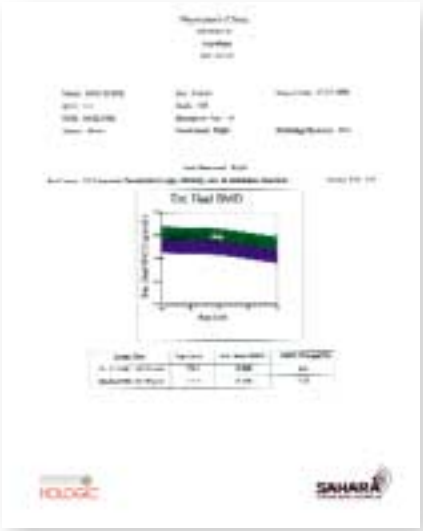
- Provides a reliable back-up of patient and QC data
- Easy and convenient data storage and retrieval
- Microsoft Access compatible for data analysis and sorting



Customized Patient Report

Enhances presentation to patients and referring physicians

- Customize with your practice name and address
- Colorful, graphic display of test results
- Comprehensive report includes Z-score for fracture risk assessment



Rate of Change Report

Conveniently tracks test result changes over time

- Graphically depicts changes in patient test results over a user-defined length of time
- Results are conveniently listed in chronological order
- Automatically calculates the changes in percentage from the first or baseline examination
- Highlights statistically significant changes to attract attention

Sahara Accessories

Sahara Soft Pack

A Mobile Storage System

The Sahara soft pack mobile storage system makes the Sahara Clinical Bone Sonometer easy to use, move, and store. With structure and dimensions designed to provide maximum convenience, mobility, and protection, the rolling Soft Pack assures that all your Sahara components, supplies, accessories, patient information, and documentation travel together easily and securely.

- Durable nylon Cordura® fabric exterior provides good looks and durability
- Push handle with a lock/release button that secures the handle in an upright position for effortless wheeling and retracts the handle for easy storage
- ABS plastic rigid liner protects the Sahara unit and accessories from impact
- Separate interior zippered compartments provide additional document storage
- Rubber friction-bearing wheels simplify moving the unit from one location to another
- Heavy duty zippers allow quick and easy access to interior
- Luggage-quality handles fit hands comfortably

Specifications:

Size:	29"(H) x 16"(W) x 14"(D) 74cm x 41cm x 36cm
Weight:	16lbs. (7.3kg) empty 38lbs. (17.3kg) w/unit & supplies
Exterior fabric:	Dupont Cordura® nylon
Color:	Burgundy red
Rigid liner:	3/32" (.24cm) ABS plastic
Inner liner:	5/8" (1.6cm) padding w/nylon shell

Specifications subject to change

Sahara Soft Pack

Sahara Air Transport Case

Extra Protection for Air Transport

The Sahara Air Transport Case is designed specifically to withstand the rigors of modern airport luggage handling and storage. Use with the Sahara Accessory Bag for comfortable travel with the complete Sahara system.

- Hard-shell exterior provides the extra protection recommended during air transport
- Telescoping handle for easy storage in the office, the airport, or in the trunk of a mid-size car
- Wheels make one-handed navigation and transportation easy

Specifications:

Size:	51cm(H) x 43cm(W) x 42cm(D) 20" x 17" x 16.5"
Weight:	12.7kg (28lbs) empty 22.7kg (50lbs) w/unit & supplies
Exterior fabric:	Dupont Cordura® nylon
Color:	Grey with zinc plated and aluminum fixtures
Rigid liner:	2.5cm (1") polyether foam
Inner liner:	2.5cm (1") polyether foam

Specifications subject to change

Sahara Accessory Bag

Sahara Accessory Bag

Carry Everything You Need in One Convenient Bag

The soft-sided Sahara Accessory Bag is comfortable to carry and fits into the overhead compartment of an airplane. Keep everything you need—Patient Record Forms, power supply, gel, foot positioner, and wipes—all in one place.

Specifications:

Size:	25cm(H) x 41cm(W) x 25cm(D) 10" x 16" x 10"
Weight:	1.4kg (3lbs)
Exterior fabric:	Dupont Cordura® nylon
Color:	Burgundy red
Liner:	1.3cm (0.5") foam panels

Specifications subject to change

Sahara Air Transport Case

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Specifications

IEC 601-1 Class II Type BF.IPXO. The UL classification for the Sahara Clinical Bone Sonometer is Class II Equipment.

Measurement Site	Calcaneus (heel)
Coupling Method	Sahara Coupling Gel only
Measurement Time	Less than 10 seconds
Patient Reports	Built-in Strip Printer
Measurements	Estimated heel BMD and Quantitative Ultrasound Index (QUI/Stiffness), obtained from measured BUA and SOS

	C.V.:	**Absolute Precision:**
Estimated Heel BMD	3%	0.014g/cm
SOS	0.22%	3.4 m/s
QUI/Stiffness	2.6%	2.2
BUA	3.7%	26 dB/Mhz

QC Check	Daily, using supplied QC phantom
Operating Temperature Range	60°-100° F (15°-37.8° C)
Operating Humidity Range	20-80% R.H. non condensing
Shipping and Storage	Ambient Temperature: 0° to 120° F (-17.8° - 49° C) Relative Humidity: 20% -95% Atmospheric Pressure: 500hPa –1060 hPap
Power Requirements	100-240 VAC, 50-60 Hz, <60 watts (automatically adjusts from 100 VAC to 240 VAC, and 50 Hz to 60 Hz)
CPU	Embedded microprocessor
Ultrasonic Energy	Isppa < 0.001 W/cm typical Isppa < 0.001 mW/cm typical Mechanical Index (MI) < 0.01 typical Pulse Reception Rate (PRR) <200 Hz
Safety Standards	IEC601-1, UL2601-1, CSA C22.2 No 601-1-M90I
Size	43 cm x 36 cm x 30 cm (17"D x 14"W x 12"H)
Weight	10 kg (22 lb.)

Declaration of Acoustic Output in Accordance with IEC61157	
Nominal Frequency:	0.6MHz
Peak-negative acoustic pressure (p-)	<1 MPa
Output beam intensity: (I_{ob}) :	<20mW/cm
Spatial-peak temporal-average intensity (I_{spta}):	<100mW/cm

The Sahara Clinical Bone Sonometer

Intended Use/Indications: The intended use of the Sahara Clinical Bone Sonometer is to perform a quantitative ultrasound measurement of the calcaneus (heel bone), the results of which can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the determination of fracture risk. Sahara measures the speed of sound (SOS, in m/s) and broadband ultrasonic attenuation (BUA, in dB/MHz) of an ultrasound beam passed through the heel, and combines these results to obtain the Quantitative Ultrasound Index (QUI). The output is also expressed as a T-score and as an estimate of the Bone Mineral Density (BMD, in g/cm^2) of the heel.

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

Sahara should not be used to assess patients whose skin is abraded and/or have an open sore in the area that comes into contact with the system.Sahara ultrasound coupling gel should be used in accordance with the directions for use specified in the User's Guide. Other coupling gels should not be substituted. The Sahara User's Guide provides detailed information regarding the relationship between heel BMD estimates obtained by Sahara and by the Dual Energy X-Ray Absorptiometry (DXA) technique.

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