



# User's Guide

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*SAHARA Clinical Bone Sonometer*

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( Sahara )

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# Table of Contents

<b>Introduction and Background .....</b>	<b>1-1</b>
Essential Prescribing Information.....	1-1
Quantitative Ultrasound (QUS) as a Tool for the Assessment of Bone Status .....	1-8
Sahara Clinical System Overview.....	1-9
Ultrasound Measurements Using Sahara .....	1-10
Speed Of Sound (SOS).....	1-11
Broadband Ultrasound Attenuation (BUA) .....	1-12
Estimated Heel BMD and the Quantitative Ultrasound Index (QUI) .....	1-13
Relationship between Sahara Results and Heel BMD Results obtained by X-Ray Densitometry .....	1-14
Relationship between Sahara Results and Risk of Fracture.....	1-15
System Components .....	1-17
Quality Control (QC) Phantom.....	1-18
Ultrasound Coupling gel.....	1-18
Controls and Indicators .....	1-19
Specifications .....	1-21
<b>Initial Set Up.....</b>	<b>2-1</b>
Examination Room Environment.....	2-1
Unpacking the System .....	2-1
Setup and Test .....	2-3
Power On the System .....	2-3
Printer Operation.....	2-6
Set Time .....	2-9
Set Date .....	2-11
Set Language .....	2-13
<b>Quality Control.....</b>	<b>3-1</b>
Quality Control Procedure.....	3-2
Recording/Plotting QC Results.....	3-11
Interpretation of QC Results.....	3-12

<b>Patient Measurement .....</b>	<b>4-1</b>
Note about Ultrasound Coupling Gels .....	4-1
Sahara Patient Measurement Procedure .....	4-3
Prepare Transducer Pads.....	4-3
Position Patient .....	4-7
Measure Patient.....	4-14
Internal (Strip) Printer Report.....	4-17
Patient Report Form.....	4-18
Precision of Sahara Results .....	4-18
Considerations for Patient Monitoring.....	4-19
<b>Comparison of Patient Results to Reference Values.....</b>	<b>5-1</b>
Types of Reference Database Comparisons .....	5-1
Reference Database Comparisons Available with Sahara .....	5-2
Reports .....	5-2
Internal (Strip) Printer Report.....	5-2
Patient Report Form.....	5-4
Estimating the Z-score and Plotting Patient Results vs. Age Dependent Reference Values: .....	5-4
Sahara Caucasian Female Reference Database .....	5-6
Study Overview.....	5-6
Reference Data Ranges for the Sahara Clinical Bone Sonometer.....	5-7
Modify Young Adult Estimated BMD Reference Values (optional) .....	5-9
Development and Use of Reference Data Ranges for Specific Patient Populations .....	5-12
<b>System Care and Maintenance.....</b>	<b>6-1</b>
Ordering Supplies .....	6-1
Cleaning and Re-Use.....	6-1
How Supplied .....	6-1
Infection Control.....	6-2
Cleaning Frequency .....	6-3
How to Clean/Disinfect the Sahara Unit .....	6-3
Cleaning.....	6-3
Disinfecting.....	6-3
Additional Measures .....	6-3
Alternate Practices .....	6-3
Care and Maintenance of Transducer Pads .....	6-4

Care of Transducer Pads.....	6-4
Transducer Pad Discoloration .....	6-4
Removal/Replacement of Transducer Pads .....	6-5
Calibrate System.....	6-9
System Calibration .....	6-9
Calibration Failure.....	6-17
Printer Operation .....	6-18
Display Serial Number .....	6-21
What to do in Case of Trouble .....	6-22
Acquiring Results After a Paper Jam/Clearing a Printer Paper Jam .....	6-22
Printer Operates but Does Not Print.....	6-23
Power Problem .....	6-23
System Malfunction and Error Log .....	6-23
Printing the Exception Report .....	6-24
Quality Control Problem .....	6-25
Patient Measurement Problems .....	6-26
Asterisk after Estimated BMD result (Est. BMD = 0.500* g/cm <sup>2</sup> ).....	6-26
Invalid Measurement, Repeat .....	6-26
Measurement Out-of-Range.....	6-27

## Figures

Figure 1-1 Sahara Clinical System .....	1-10
Figure 1-2 Sahara Measurement Geometry .....	1-11
Figure 1-3 SOS Measurement.....	1-12
Figure 1-4 BUA Measurement .....	1-13
Figure 1-5 System Components.....	1-18
Figure 1-6 Power Status Light.....	1-19
Figure 1-7 Control Panel .....	1-19
Figure 2-1 Unpacking the System.....	2-2
Figure 2-2 Power Supply Connections .....	2-3
Figure 2-3 Power Status Light.....	2-4
Figure 2-4 Removing Printer Cover .....	2-6
Figure 2-5 Threading Printer Paper .....	2-6
Figure 2-6 Feed Printer Paper.....	2-7
Figure 2-7 Insert Paper Roll .....	2-7
Figure 2-8 Printer Cover Replaced.....	2-8
Figure 2-9 Press Program, 9, ENTER .....	2-9
Figure 2-10 Press PROGRAM, 8, ENTER .....	2-11
Figure 3-1 Press ON .....	3-2
Figure 3-2 Transducer Pads Touch.....	3-3

Figure 3-3 Transducer Pads Ready for Gel .....	3-3
Figure 3-4 Press PROGRAM, 1, ENTER .....	3-4
Figure 3-5 Gel Measurement.....	3-5
Figure 3-6 Spread Gel .....	3-5
Figure 3-7 Proper Amount of Gel on Transducer Pad .....	3-6
Figure 3-8 Press OPEN/PREP .....	3-6
Figure 3-9 QC Phantom Position .....	3-7
Figure 3-10 Press MEASURE.....	3-8
Figure 3-11 Press OPEN/PREP .....	3-8
Figure 3-12 Press PRINT .....	3-10
Figure 3-13 QC Log .....	3-11
Figure 4-1 Comparison of Ultrasonic Coupling Gels.....	4-2
Figure 4-2 Press ON.....	4-3
Figure 4-3 Transducer Pads Touch .....	4-3
Figure 4-4 Transducer Pads Ready for Gel .....	4-4
Figure 4-5 Gel Measurement.....	4-5
Figure 4-6 Apply Gel .....	4-5
Figure 4-7 Gel Application .....	4-6
Figure 4-8 Press OPEN/PREP .....	4-7
Figure 4-9 Patient Position.....	4-7
Figure 4-10 Patient Leg Position.....	4-8
Figure 4-11 Patient Foot Position .....	4-9
Figure 4-12 Heel Position .....	4-9
Figure 4-13 Positioning Aid Slightly Loose.....	4-10
Figure 4-14 Correct Leg Angle (front to back) .....	4-10
Figure 4-15 Incorrect Leg Angle (system too close) .....	4-11
Figure 4-16 Incorrect Leg Angle (system too far).....	4-11
Figure 4-17 Correct Leg Position (side to side) .....	4-12
Figure 4-18 Incorrect Leg Position (side to side).....	4-12
Figure 4-19 Incorrect Position of Toes .....	4-13
Figure 4-20 Positioning Aid Strap .....	4-13
Figure 4-21 Press MEASURE.....	4-14
Figure 4-22 Removing Positioning Aid.....	4-15
Figure 4-23 Press OPEN/PREP .....	4-15
Figure 4-24 Cleaning the Pads .....	4-16
Figure 4-25 Press PRINT .....	4-17
Figure 5-1 Press PRINT .....	5-3
Figure 5-2 Patient Report Form .....	5-5
Figure 5-3 Press PROGRAM, 7, ENTER .....	5-10
Figure 6-1 Remove Transducer Pad Housing .....	6-5
Figure 6-2 Cleaning Transducer Face .....	6-6
Figure 6-3 Right Transducer Pad Alignment .....	6-7
Figure 6-4 Left Transducer Pad Alignment.....	6-7
Figure 6-5 Pad Gel Application .....	6-8



Figure 6-6 Pad Guide Marks ..... 6-8  
Figure 6-7 Pads Installed Correctly ..... 6-9  
Figure 6-8 Press ON ..... 6-10  
Figure 6-9 Transducer Pads Touch..... 6-10  
Figure 6-10 Transducer Pads Ready for Gel ..... 6-11  
Figure 6-11 Press PROGRAM, 2, ENTER ..... 6-11  
Figure 6-12 Measure Gel..... 6-13  
Figure 6-13 Apply Gel..... 6-14  
Figure 6-14 Gel Application..... 6-14  
Figure 6-15 Press OPEN/PREP ..... 6-15  
Figure 6-16 QC Phantom in Position..... 6-15  
Figure 6-17 Press MEASURE ..... 6-16  
Figure 6-18 Press OPEN/PREP ..... 6-16  
Figure 6-19 Removing Printer Cover ..... 6-18  
Figure 6-20 Threading Printer Paper ..... 6-18  
Figure 6-21 Feed Printer Paper..... 6-19  
Figure 6-22 Insert Paper Roll ..... 6-19  
Figure 6-23 Printer Cover Replaced..... 6-20  
Figure 6-24 Press PROGRAM, 6, ENTER ..... 6-21

## Tables

Table 1-1 Control Panel ..... 1-20  
Table 1-2 Sahara Specifications ..... 1-21

*Table of Contents*



# 1

## Introduction and Background

This chapter provides overview information about the Sahara Clinical Bone Sonometer with the Advanced Clinical Software Option (the Sahara “Advanced Clinical Bone Sonometer”). It includes a discussion of ultrasound measurement, safety precautions, system components and product specifications.

## Essential Prescribing Information

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

### 1. Device Description:

The Sahara Clinical Bone Sonometer consists of the measurement unit, its power cord/power supply, a foot positioning aide, and accessories. The Advanced Clinical Software Option consists of software for an external personal computer, a communications cable, and an Advanced Clinical User’s Guide. See *How Supplied*, below, for a complete list of accessories.

Ultrasound measurements are performed on the Sahara system with the patient seated and their foot positioned and secured in the Sahara system using a positioning aide. After the patient’s foot is secured, a pair of soft elastomer pads are brought into contact with opposite sides of the patient’s heel by means of a motorized caliper mechanism. Each of the elastomer pads are acoustically coupled to the heel and to a sound transducer using Sahara Ultrasound Coupling Gel. Inaudible high frequency sound waves, produced by one of the sound transducers, are transmitted through the heel and received by the opposite transducer. Quantitative parameters describing the speed and attenuation of the sound waves in the heel are measured.

## 1 Introduction

The Sahara Clinical Bone Sonometer estimates calcaneal (heel) Bone Mineral Density (BMD, in  $\text{g}/\text{cm}^2$ ) from the measured ultrasound parameters. Patient examination time is short, with a measurement time (excluding patient positioning) of less than ten seconds.

### 2. 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 calcaneus, and combines these results linearly 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  $\text{g}/\text{cm}^2$ ) of the calcaneus as measured by Dual Energy X-ray Absorptiometry (DXA).

### 3. Contraindications:

- The 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.

### 4. Warnings:

- Prior to using Sahara, users must read “Individualization of Treatment” and “Relationship between Sahara Results and Heel BMD Results obtained by X-Ray Densitometry,” below, in order to properly interpret patient results.
- Never attempt to operate the Sahara unit with any power module other than the one provided with the system (the Hologic Model Sahara Power Supply). The power supply should only be plugged into a wall outlet that meets all electrical code requirements.
- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

**5. Precautions:**

- Use the Sahara Advanced Clinical Bone Sonometer only indoors, in a clean, dry environment.
- Do not store the Sahara unit near a heat source or air conditioner. Store the phantom near the unit.
- Never store the QC phantom in the footwell with the transducer pads closed on it. This will ruin both the phantom and the transducer pads.
- The Sahara Clinical Bone Sonometer provides no protection against the harmful ingress (entry) of liquids.
- If at any time the patient feels discomfort during use of the Sahara unit, the foot restraint mechanism is designed to allow the foot to be pulled out without having to operate any levers or handles. The foot could also be removed by using the handles that fully release the foot restraint mechanism. In addition, the Open/Prep button may be pushed at any time to open the transducer pads. Note that in an emergency, it is not necessary to open the pads before removing the patient's foot from the instrument.
- Only Hologic approved ultrasound coupling gels should be used with Sahara.
- Sahara Ultrasound Coupling Gel is for external use only.
- For ultrasound coupling gel application, do not use a Q-Tip, examination glove containing talc, or any other applicator that may introduce fibers or other foreign matter.
- When applying gel to the transducer pads, it is important to ensure that the leading edge of the transducer pad is fully covered.
- Interfacing equipment (computer, monitor, printer) used with the Sahara Clinical Bone Sonometer must meet IEC 950, or equivalent safety standards.

**6. Adverse Events:**

There are no known potential adverse effects of the Sahara Clinical Bone Sonometer on health.

- Safety Experience and Sample Size: No adverse events of any kind were reported in the course of the clinical studies performed, in which a total of 2455 subjects underwent Sahara examinations.
- Deaths: There were no patient deaths related to the Sahara Clinical Bone Sonometer either during or after the clinical studies.
- Adverse Events: There were no adverse events related to the Sahara Clinical Bone Sonometer either during or after the clinical studies.
- Adverse Events that may be expected: There are no known potential adverse effects of the Sahara Clinical Bone Sonometer on health. Therefore adverse events are not expected in conjunction with the use of Sahara.

**7. Clinical Studies:**

- Purpose of Studies: The clinical studies were designed to 1) directly compare estimated heel BMD results obtained on Sahara to those obtained on the established Dual Energy X-ray Absorptiometry (DXA) technique, 2) assess the sensitivity of Sahara heel BMD results to skeletal status vs. that of DXA by comparing results obtained for clinically distinct groups of young and elderly subjects, 3) assess the reproducibility of Sahara heel BMD results, 4) document the safety of the Sahara system, 5) obtain age dependent reference ranges for Sahara estimated heel BMD results for a Caucasian female population, and 6) directly compare Sahara results to those obtained by the Walker-Sonix UBA-575+ heel ultrasound system, establishing the relationship between Sahara and fracture risk estimation.
- Patients Studied: Results for 247 Caucasian female subjects were obtained for the direct comparison of Sahara and DXA heel BMD results. Recruitment criteria were set to insure that these subjects spanned the entire clinical range of heel BMD, with an approximately uniform distribution, in order to document the agreement between Sahara and DXA across the entire useful range. Hip BMD results were used to classify elderly subjects using the internationally accepted World Health Organization (WHO) criteria. Results for 2208 subjects (age range 19-97) were obtained for development of reference ranges. Caucasian female subjects were chosen for these studies as they are the group most frequently affected by osteoporosis.
- Methods: Heel BMD was estimated by Sahara for all subjects, including 5 replicate measurements for the 247 subjects in the comparative study. The 247 subjects from the comparative study also underwent BMD assessment by DXA. Walker-Sonix heel ultrasound results were obtained for 212 of the 247 subjects in the comparative study.
- Principal Effectiveness and Safety Results:

Objective	Result
Comparison of BMD Results vs. Heel DXA	Sahara Est. Heel BMD was linearly related to DXA Heel BMD (R=0.85).
Comparison Sensitivity to DXA	Sahara Est. Heel BMD essentially identical to Heel DXA or comparisons of clinically distinct subject groups. Similar in sensitivity to spine DXA.
Reproducibility of Heel BMD	Est. Heel BMD reproducibility was found to be 3.0% in the 247 subjects studied.
Document Safety	No adverse events were observed (2245 subjects evaluated by Sahara).
Reference Data	Reference data ranges were developed based on 2208 Caucasian female subjects, and are included with standard Sahara system.
Comparison of Results to Walker-Sonix UBA-575+	Sahara QUI and Est. Heel BMD results were linearly related to Walker-Sonix results (R=0.93). An relative risk of 1.84 for hip fracture was estimated for Sahara, based on published Walker-Sonix data. <sup>3</sup>

## 8. Individualization of Treatment:

The Sahara Clinical Bone Sonometer estimates the Bone Mineral Density (BMD) of the heel. BMD results are used by the physician to assess skeletal status in the evaluation of patients at risk for osteoporosis and other metabolic bone diseases and/or patients who may have reduced bone density due to medical conditions indirectly affecting bone mineral metabolism, medications prescribed for other conditions, heritable or genetic factors, lifestyle factors, or other reasons. Heel BMD results may be used by the physician, along with other factors such as laboratory test results, radiographs, and family history, in the diagnosis of osteoporosis and other conditions leading to reduced bone density.

When evaluating individual patients, all relevant risk factors (including Sahara results, age, previous fractures, frame size, smoking, etc) should be considered. For additional information, refer to the Physician Learning Series included with the Sahara system

The frequency of use of this device to assess BMD is dependent on a number of factors, including the precision of the device and the expected rate of loss or gain in BMD due to disease progression or therapeutic intervention, and must be determined by the physician who is aware of all of these factors. See Chapter 5, *Patient Measurement* for further information regarding monitoring of bone loss with Sahara.

Other than as indicated in the Contraindications and Warnings sections above, there are no specific populations for which Sahara should not be used. Guidelines for the development and use of reference ranges for populations other than Caucasian females (for which reference ranges are supplied by Hologic) are given in Chapter 6 of the Advanced Clinical User's Guide for the Sahara Clinical Bone Sonometer.

### **Relationship between Sahara Results and Heel BMD Results obtained by X-Ray Densitometry**

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 calcaneus (heel), and combines these results linearly to obtain the Quantitative Ultrasound Index (QUI) and an Estimate of a patient's heel BMD. While ultrasound parameters do not directly measure BMD, BUA and SOS results are correlated ( $R = 0.82 - 0.85$ ) with heel BMD results obtained by the standard Dual Energy X-ray Absorptiometry (DXA) technique, as are results for the combined QUI parameter ( $R=0.85$ ). Thus an estimate of heel BMD results is obtained by a simple linear re-scaling of the QUI parameter into heel BMD units (in  $\text{g}/\text{cm}^2$ ). The level of correlation ( $R=0.85$ ) between Sahara and DXA heel BMD results is similar to that observed between other accepted methods for assessing BMD at the same anatomical site.<sup>1</sup> For individual patients, there may be differences between the Sahara and DXA Heel BMD results. These differences arise due to several factors, including the precision errors inherent in both Sahara and DXA results as well as the subject dependent differences between the ultrasound and DXA measurement methodologies for assessing

bone. For individual patients, differences between Sahara and DXA heel BMD results have a range equal to one standard deviation (SD) of a typical population of subjects of the same age. The 95% confidence interval for differences between Sahara and DXA heel BMD results is therefore  $\pm 2$  population SD's, or  $\pm 2$  T-scores. This means that individual patients may be classified differently by Sahara compared to DXA when using the World Health Organization (WHO) classification criteria.<sup>2</sup> The WHO criteria classify patients with BMD values more than 2.5 SD's below the young adult mean (T-score below -2.5) as osteoporotic, and patients with T scores between -1 and -2.5 as osteopenic. However, the differences in T-score results obtained by Sahara and heel DXA are similar to or smaller than the differences found when patients are assessed by any other two accepted methods for assessing BMD of the same anatomical site.<sup>1</sup> Note that differences for an individual patient when assessed at two different anatomical sites can be even larger due to physiological and anatomical differences between the various sites.<sup>1</sup>

It is widely accepted that while any measure of BMD is a strong indicator of risk for osteoporosis and osteoporotic fractures,<sup>3-5</sup> classification by the WHO criteria is dependent on the measurement technique, and even more so on the measurement site. Thus an understanding of the potential differences in T-score results obtained by different techniques should be considered when applying the WHO classification criteria. When using threshold based criteria to classify patients, the continuous exponential increase in fracture risk with decreasing BMD (see *Relationship Between Sahara Results and Risk of Fracture* below) should be a factor in patient management decisions. Because osteoporosis is a multifactorial disease, consideration of all relevant risk factors is important in the evaluation of a patients. Other risk factors, besides BMD and T-score, include age, previous fractures, frame size, smoking, etc. For example, a 45 year old patient with a T-score of -2.7 and a 75 year old patient with the same T-score of -2.7 have drastically different clinical status, and need to be evaluated appropriately. Similarly, there is no clinical distinction between two patients with T-scores of -2.49 and -2.51 if they have the same age and have no other risk factors. Other risk factors, besides T-score and age, include previous fractures, frame size, smoking, etc. See the Physician Learning Series, included with the Sahara system for additional information.

### **9. Patient Counseling Information:**

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

### **10. Conformance to Standards:**

There are no known potential adverse effects of this device on health. In fact, this device uses ultrasound power levels lower than standard imaging ultrasound devices which are widely used and accepted. No adverse events have been reported for the Sahara Clinical



Bone Sonometer during clinical use, either from the clinical studies or from systems installed internationally.

Non-clinical testing demonstrated conformance to voluntary safety (UL2601-1, EN 60601-1-2 1993, CSA C22.2 No. 601-1-M90), electromagnetic compatibility (EN 55011 Group I Class B, IEC 801-2 1991, IEC 801-3 1984, IEC 801-4 1988) and ISO (ISO 9001) standards.

### **11. How Supplied:**

The Sahara shipping package includes the following:

- One Sahara Ultrasound system
- One Power Supply and One Power cord
- One Positioning aide
- One QC Phantom
- Training Video (The Sahara User Video Guide)
- Starter supplies including:
  - Sahara Ultrasound Coupling Gel (2 tubes)
  - Transducer Towelettes (1 pkg)
  - Dry wipes (1pkg)
  - Pinter paper (2 rolls)
  - Ultrasound exam paper (1pkg)
- Documents package containing:
  - User's Guide
  - Supplies reorder cards
  - Installation, Warranty, and Post Warranty Service Information Sheet
  - QC Log Forms (1 tablet)
  - Patient Report Forms (1 tablet)
  - Patient Information Brochures (1 pkg)
  - Sahara Physician Learning Series
- Sahara Advanced Clinical Software Package including:
  - One User's Guide for the Sahara Advanced Clinical Software
  - One Communications Cable (connects PC to Sahara system)
  - Sahara Advanced Clinical Software (on Floppy Disk)
- One Personal Computer (PC) - if purchased from Hologic

### **12. Operator's Manual:**

Attached

### 13. References:

<sup>1</sup> S. Grampp, H.K. Genant, A Mathur, P. Lang, M. Jergas, M. Takada, C.C. Gluer, Y. Lu, and M. Chavez, "Comparisons of Noninvasive Bone Mineral Measurements in Assessing Age-Related Loss, Fracture Discrimination, and Diagnostic Classification," *J. Bone and Miner. Res.* Vol 12, pg 697-711, (1997).

<sup>2</sup> Kanis J, et al., *Osteoporosis Int.* Vol. 4, pg 368-381 (1994).

<sup>3</sup> Bauer DC, Gluer CC, Cauley JA, Vogt TM, Ensrud KE, Genant HK, Black DM. "Broadband ultrasound attenuation predicts fractures strongly and independently of densitometry in older women." *Archives of Internal Medicine* Vol. 157, pg 629-633, (1997).

<sup>4</sup> Hans D, Dargent-Molina P, Schott AM, et al. "Ultrasonographic heel measurements to predict hip fracture in elderly women: the EPIDOS prospective study." *Lancet* Vol. 348, pg 511-4 (1996).

<sup>5</sup> Gluer CC, Cummings SR, Bauer DC, et al. "Osteoporosis: association of recent fractures with quantitative US findings." *Radiology* Vol. 199, pg 725-32 (1996).

## Quantitative Ultrasound (QUS) as a Tool for the Assessment of Bone Status

Ultrasound is well established in the medical community as a safe and cost effective diagnostic modality. Until recently, medical ultrasound has primarily given clinicians only qualitative images of soft tissue. However, it is also possible to use ultrasound to obtain quantitative information about bone status. In comparison to traditional techniques for assessment of skeletal status (including radiographs, x-ray absorptiometry, and computed tomography) which involve exposure to radiation, QUS is a quick, low cost, and radiation free diagnostic tool. These advantages are especially important in the clinical environment for which Sahara was designed, where unnecessary operator and patient x-ray exposure (for example) are undesirable.

Many bone diseases, including osteoporosis, degrade cancellous (or trabecular) bone much earlier and to a greater extent than cortical bone. Turnover of cancellous bone is about eight-fold higher than of cortical bone, thus age and disease related bone loss are more readily apparent in cancellous bone compartments. Therefore, it is becoming more widely accepted in the medical community that skeletal sites with a high percentage of cancellous bone are important examination sites for patients at risk for osteoporosis and other metabolic bone diseases. The calcaneus (heel), a bone that is 75-90% cancellous bone by volume and is readily accessible because of the small amount of soft tissue surrounding it, is particularly attractive for studies aimed at the identification and/or assessment of patients at risk. QUS is a modality particularly well suited for the examination of cancellous bone of the heel.

QUS results obtained using the Sahara system are correlated to heel Bone Mineral Density (BMD, in  $\text{g}/\text{cm}^2$ ) results obtained by Dual energy X-ray Absorptiometry (DXA), the most widely used technique for assessing BMD. Thus Sahara ultrasound results can be converted into DXA equivalent units ( $\text{g}/\text{cm}^2$ ) in order to be more easily interpreted by physicians. The Sahara system therefore reports the “Estimated BMD” of the heel in  $\text{g}/\text{cm}^2$  as the default output result. Because this Estimated BMD was obtained from ultrasonic measurements, the ultrasound results may also be displayed if desired. Access to the underlying ultrasound measurement results is especially important for Sahara system Quality Control, where monitoring of the ultrasound parameters is critical for tracking of system performance.



## Sahara Advanced Clinical System Overview

The Sahara Advanced Clinical Bone Sonometer consists of a portable medical device (the Sahara “Clinical” Bone Sonometer) that when combined with the optional “Advanced Clinical” Software and an external computer provides a Microsoft Windows®-based workstation and full graphics printer. The Hologic Sahara Advanced Clinical Software Option, installed on the external PC, provides a data base for storage and retrieval of patient records. For operator convenience, the instrument may be controlled using a mouse from the computer, rather than by pressing the keys on the Sahara unit. In addition, full size patient reports including patient history can be obtained. This software option may be installed at any time before or after system installation, as each Sahara system has a standard communication port installed at the factory for communication with the optional Advanced Clinical Software/computer. The system may be used either with or without the external computer at any time, so long as it is understood that the computer must be connected prior to any patient examination for which the operator wishes that the results be stored in the computer database. If the computer is disconnected, the Sahara Clinical System operates exactly the same as the standard system without the Advanced Clinical Software Option.

Sahara measures the ultrasonic Speed Of Sound (SOS) and Broadband Ultrasound Attenuation (BUA) of the calcaneus (heel), and combines these two measured values to obtain a parameter referred to as the Quantitative Ultrasound Index (QUI), sometimes referred to as “stiffness” in the scientific literature. The QUI/Stiffness value obtained for a patient is then converted into Estimated BMD (in units of  $\text{g}/\text{cm}^2$ ) in order to simplify the interpretation of results by the physician. Estimated BMD results may be compared to US Caucasian female reference values, or to user defined reference values (if available) for other populations, in order to assess the bone status of the patient relative to sex and race matched norms.

The measurement is taken with the patient seated and their foot positioned and secured in the Sahara system. Soft rubber pads are brought into contact with either side of the heel, and the measurement is performed by passing sound waves through the heel. An ultrasound coupling gel is used between the pads and the patient’s skin. No water bath is

## 1 Introduction

necessary, and the entire procedure (including patient positioning) takes only a few minutes. Note that the use of coupling gel is critical because it eliminates air at the interface between the pads and the skin, which would otherwise severely inhibit the transmission of sound waves.

To ensure proper operation, use only the couplant gel provided by Hologic (labeled “Sahara Ultrasound Coupling Gel”). Other gels, particularly those that are water based, will adversely affect system performance, giving inaccurate and/or inconsistent results.

The system design provides for a highly repeatable method of positioning the foot with respect to the measurement device. The lower leg is immobilized by a positioning aid fitted with moldable foam, and a padded strap secures the leg into the positioning aid to set the proper leg angle.

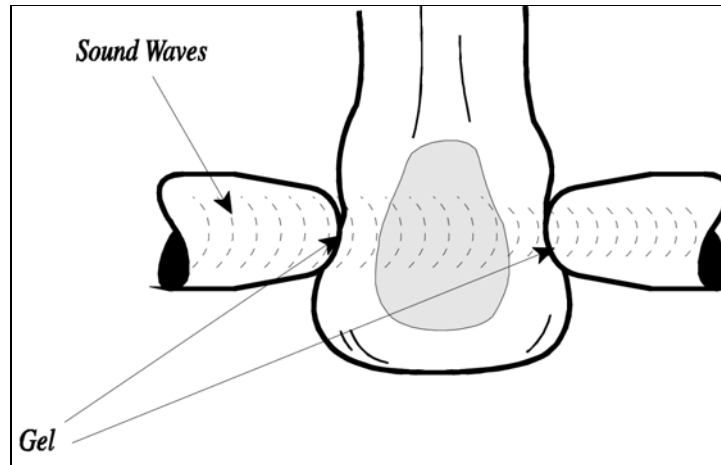
**Figure 1-1**  
*Sahara Advanced  
Clinical System*



## Ultrasound Measurements Using Sahara

The term ultrasound refers to high-frequency (non-audible) sound waves. Ultrasound measurements are made on the Sahara system by measuring the transmission of these sound waves through the heel. The heel is positioned between a pair of sound transducers (Fig 1-2), with one transducer transmitting the ultrasound signal, and the other transducer receiving the signal after passage through the heel. The transducers are acoustically coupled to the heel by elastomer transducer pads using Sahara Ultrasound Coupling gel, which is applied to the transducer pads. From the signal measured by the receiving transducer, two parameters describing the nature of the received sound waves can be simultaneously determined: Speed of Sound (SOS) and Broadband Ultrasonic Attenuation (BUA).

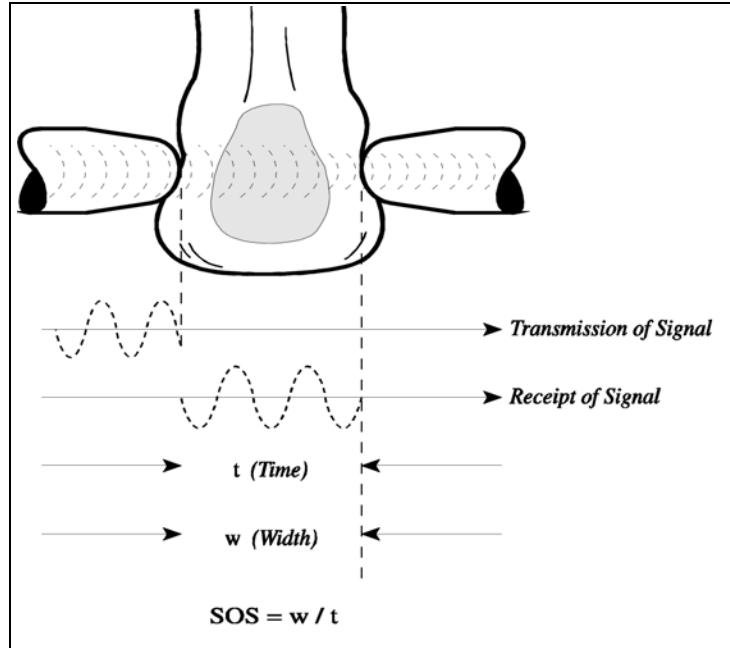
**Figure 1-2**  
Sahara Measurement  
Geometry



## Speed Of Sound (SOS)

SOS is defined as the speed of sound through the heel. SOS is determined (Fig. 1-3) by measuring (1) the width of the heel, and (2) the time delay between the initial transmission of the sound waves (by one transducer) and the receipt of the sound waves (by the second transducer). The Sahara system measures and corrects for the time delay incurred by the sound waves as they travel through the transducer pads by making a similar measurement without the heel (i.e., with the two pads touching one another) in order to determine the time delay due to the heel alone. The time ( $t$ ) the ultrasound signal takes to go through the heel alone is the propagation time of the ultrasound going through the heel and the transducer pads minus the propagation time measured with the pads touching and with no heel interposed. Sahara automatically measures the width of the heel ( $w$ ) using a micrometer attached to the transducers. The SOS value is then equal to  $w/t$  and is measured in meters per second (m/s). The range observed with Sahara in a typical population is approximately 1450-1700 m/s, with young/healthy subjects having higher SOS values than older or osteoporotic subjects.

**Figure 1-3**  
SOS Measurement

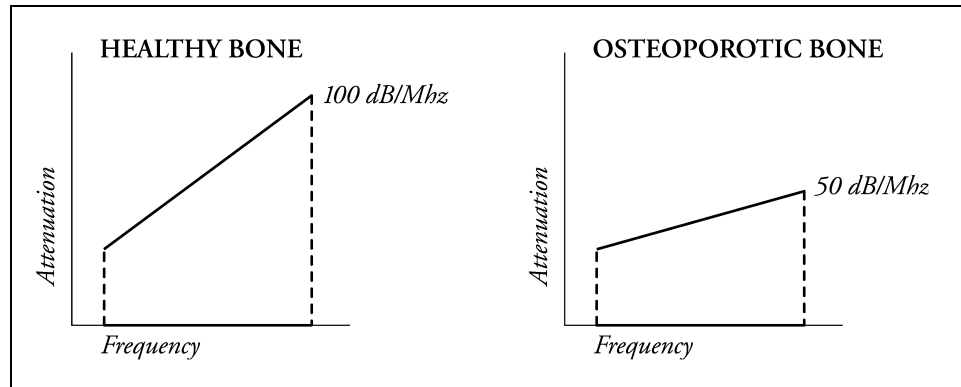


## Broadband Ultrasound Attenuation (BUA)

During early investigations of bone with QUS, it was observed that bone attenuated high frequency sound waves much more than low frequency sound waves. A linear relationship (Fig. 1-4) was observed for the attenuation (in decibels, or dB) of ultrasonic waves in the frequency range of 0.2 to 0.6 MHz. The slope of the linear regression of the ultrasonic attenuation vs. frequency in this range is defined to be the broad-band ultrasound attenuation (BUA) and is measured in dB/MHz. On the Sahara system, the BUA and SOS are measured at the same time. As is the case for the SOS measurement, in order to determine the attenuation of the heel alone, and remove any effects arising from the transducers and/or transducer pads, a comparison measurement must be made through a reference medium. This reference measurement is made using the Sahara QC Phantom (supplied with the Sahara unit) when the unit is calibrated at the factory.\* The range of BUA observed with Sahara in a typical population is approximately 30-130 dB/MHz, with young/healthy subjects having higher BUA results than older or osteoporotic subjects.

*\*Note: In the course of typical usage, it is not necessary to perform a reference measurement/calibration. However, if the transducer pads, transducers, or electronics are removed or disassembled for any reason, the unit must be re-calibrated following the instructions in the Maintenance chapter of this manual.*

**Figure 1-4**  
BUA Measurement



## Estimated Heel BMD and the Quantitative Ultrasound Index (QUI)

In order to optimize the quantitative information obtained by both BUA and SOS measurements, the Sahara system combines (linearly) the two measured values into a single parameter, the Quantitative Ultrasound Index (QUI), sometimes referred to as “Stiffness” in the scientific literature. Compared to the BUA or SOS parameters alone, the combined QUI parameter is both more strongly correlated to the actual heel BMD obtained by the DXA, and also has a reduced precision error. QUI values normally range from 0 to 150, with higher values being obtained for young healthy subjects, and lower values being obtained for older or osteoporotic subjects.

Because the QUI parameter is correlated to heel (DXA) BMD results, a predicted or “Estimated” heel BMD result may be obtained by a simple re-scaling of the QUI value. Thus the re-scaled QUI value (“Estimated Heel BMD, in  $\text{g}/\text{cm}^2$ ) is reported by the Sahara system as the default output parameter. Note that the QUI is a simple linear combination of the BUA and SOS, which is formed merely to improve the estimate of heel BMD, the default output of the Sahara system.

## Relationship of Sahara Results and Heel BMD Results obtained by X-Ray Densitometry

Clinical studies have compared Sahara results to heel BMD assessed using the established Dual Energy X-Ray Absorptiometry (DXA) technique. These studies have shown that BUA and SOS, the parameters directly measured by Sahara, are correlated ( $R = 0.82 - 0.85$ ) with DXA BMD. Sahara QUI and Estimated Heel BMD values are also correlated ( $R=0.85$ ) to DXA BMD results. This level of correlation is similar to that observed between other accepted methods for assessing BMD at the same anatomical site. For

example, published studies have shown that standard posteroanterior (PA) DXA lumbar spine BMD results and spine BMD results obtained by the quantitative computed tomography (QCT) technique have in vivo correlations of 0.83.<sup>1</sup>

The relationship between Sahara and DXA heel BMD results is linear, with the average BMD values (for a group of subjects) obtained by either technique being clinically indistinguishable. For individual patients, however, there may be differences between the Sahara Estimated Heel BMD and the DXA Heel BMD. These differences arise due to several factors, including the precision errors inherent in both Sahara and DXA results as well as the subject dependent differences between the ultrasound and DXA measurement methodologies for assessing bone. Subject dependent differences between Sahara and DXA heel BMD results have a range equal to one standard deviation (SD) of a typical population of subjects of the same age. The 95% confidence interval for differences between Sahara and DXA heel BMD results is therefore  $\pm 2$  population SD's. T-scores, which quantify the difference between a given patient's results and the mean results for a young adult reference group, are reported in population SD units. Thus patients assessed by Sahara and heel DXA will have results that are equal on the average, but that differ by up to  $\pm 2$  T-scores for an individual patient. This means that individual patients may be classified differently by Sahara compared to DXA when using the World Health Organization (WHO) classification criteria.<sup>2</sup> The WHO criteria classify patients with BMD values more than 2.5 SD's below the young adult mean (T-score below -2.5) as osteoporotic, and patients with T scores between -1 and -2.5 as osteopenic. However, the differences in T-score results obtained by Sahara and heel DXA are similar to or smaller than the differences found when patients are assessed by any other two accepted methods for assessing BMD of the same anatomical site.<sup>1</sup> For example, the 95% confidence interval is  $\pm 1.8$  T-scores for DXA vs. QCT of the spine. Furthermore, the differences for an individual patient assessed at two different anatomical sites can be even larger due to physiological and anatomical differences between the various sites.<sup>1</sup>

It is widely accepted that while any measure of BMD is a strong indicator of risk for osteoporosis and osteoporotic fractures, classification by the WHO criteria is dependent on the measurement technique, and even more so on the measurement site. Thus an understanding of the potential differences in T-score results obtained by different techniques should be considered when applying the WHO classification criteria. When using threshold based criteria to classify patients, the continuous exponential increase in fracture risk with decreasing BMD (see *Relationship Between Sahara Results and Risk of Fracture* below) should be a factor in patient management decisions. Because osteoporosis is a multifactorial disease, consideration of all relevant risk factors is important in the evaluation of a patients. Other risk factors, besides BMD and T-score, include age, previous fractures, frame size, smoking, etc. For example, a 45 year old patient with a T-score of -2.7 and a 75 year old patient with the same T-score of -2.7 have drastically different clinical status, and need to be evaluated appropriately. Similarly, there is no clinical distinction between two patients with T-scores of -2.49 and -2.51 if they have the same age and have no other risk factors. Other risk factors, besides T-score



and age, include previous fractures, frame size, smoking, etc. See the Physician Learning Series, included with the Sahara system for additional information.

<sup>1</sup> S. Grampp, H.K. Genant, A Mathur, P. Lang, M. Jergas, M. Takada, C.C. Gluer, Y. Lu, and M. Chavez, "Comparisons of Noninvasive Bone Mineral Measurements in Assessing Age-Related Loss, Fracture Discrimination, and Diagnostic Classification," *J. Bone and Miner. Res.* Vol 12, pg 697-711, (1997).

<sup>2</sup> Kanis J, et al., *Osteoporosis Int.* Vol. 4, pg 368-381 (1994).

## Relationship between Sahara Results and Risk of Fracture

It has been demonstrated in a number of large, multi-center, prospective clinical studies that subjects with low BMD are at higher risk of fracture.<sup>3-5</sup> These studies have found that for elderly Caucasian female subjects (age greater than 70) the risk of future fracture increases exponentially with decreasing BMD. For hip fractures, for example, it was found that for each population standard deviation (SD) decrease in hip BMD, there was a 2 to 3-fold increase in the incidence of fracture. Note that a 2-fold increase in fracture risk per population SD decrease in BMD is referred to as "a relative risk of 2.0." The relative risk result is computed in terms of the difference (in population SD units) between a patient's results and the age matched mean value, which is equivalent to the patient's Z-score. That is, if the relative risk is 2, then a patient with a Z-score of -1 has twice the risk of hip fracture compared to a patient with a Z-score of 0. A patient with a Z-score of -3 has 8 times (2 to the third power) the risk of hip fracture.

The data from the fracture risk studies demonstrates that there is a "gradient of risk," which means that the risk of fracture increases continuously with decreasing BMD. This is in contrast to the "threshold" concept, in which risk suddenly increases below a specific BMD threshold value. Because the results of these and many other studies are consistent with a gradient of risk rather than with a threshold, care must be taken when applying threshold based classification criteria such as those proposed by the WHO. Nonetheless, threshold based guidelines and decision making are in fact commonplace in medical practice even in similar situations (cholesterol testing for example), but should be applied with the understanding that risk is continually increasing above and below the threshold.

The studies found that a similar relationship to hip fracture risk existed for heel ultrasound results, with approximately a 2-fold increase in risk per population SD. In particular, one of the studies included both x-ray based and ultrasound measurements of the heel, and found essentially identical results: the relative risk values for heel ultrasound and heel x-ray BMD were 2.0 and 2.2 respectively.<sup>3</sup> For these studies, heel ultrasound results were obtained using ultrasound systems that use a water bath to couple sound waves to the heel. Sahara is a "dry" heel ultrasound system that uses soft elastomer pads and an ultrasound gel to couple sound to the heel, but is otherwise similar to the "wet" systems used in the fracture risk studies. Data comparing the Sahara and the

Walker-Sonix UBA-575+ (the system used in one of the fracture studies) was obtained in the Sahara clinical study. This comparative data demonstrates the strong linear relationship ( $R=0.93$ ) between Sahara and Walker-Sonix results, which in turn suggests that Sahara results are sensitive to risk of future fracture. In order to estimate quantitatively the sensitivity of Sahara results to risk of fracture, the data from Bauer, et al.<sup>3</sup> were re-analyzed, after using the Walker-Sonix heel ultrasound results to predict Sahara results for all study subjects. In this analysis, Sahara results were estimated using the slope, intercept, and RMSE describing the relationship between Sahara and Walker-Sonix results, as determined in the Sahara clinical study. The estimated Sahara results for all study subjects were then analyzed in exactly the same manner as for the original study data, resulting in a relative risk value of 1.84. Receiver-operator-characteristic (ROC) curves were constructed, indicating that there were no clinically significant differences between the discriminatory abilities of Sahara and Walker-Sonix results.

In summary, large prospective studies have thus demonstrated the strong exponential relationship between heel ultrasound and x-ray results and the risk of fracture. The strong relationship between Sahara and Walker-Sonix results suggests that Sahara results will be equally predictive of fracture risk. For additional information, see the Physician Learning Series included with the Sahara system.

<sup>3</sup> Bauer DC, Gluer CC, Cauley JA, Vogt TM, Ensrud KE, Genant HK, Black DM. "Broadband ultrasound attenuation predicts fractures strongly and independently of densitometry in older women." *Archives of Internal Medicine* Vol. 157, pg 629-633, (1997).

<sup>4</sup> Hans D, Dargent-Molina P, Schott AM, et al. "Ultrasonographic heel measurements to predict hip fracture in elderly women: the EPIDOS prospective study." *Lancet* Vol. 348, pg 511-4 (1996).

<sup>5</sup> Gluer CC, Cummings SR, Bauer DC, et al. "Osteoporosis: association of recent fractures with quantitative US findings." *Radiology* Vol. 199, pg 725-32 (1996).

## System Components

The key components of the Sahara Advanced Clinical Bone Sonometer system, shown in Figure 1-5, include the ultrasound unit (including positioning aid), power supply, power cord, QC phantom, Sahara Ultrasound Coupling Gel, and an external desktop or laptop Windows-based PC (not shown). The PC functions as a remote controller, data base manager and data storage device for the ultrasound system.

A complete list of accessories and supplies for the Sahara system with the Advanced Clinical Software option is given in the Essential Prescribing Information above, and also in Chapter 2 of this User's Guide.

**Figure 1-5**  
System  
Components



## Sahara External Computer Specifications

The computer (PC) used with the Sahara Research System must meet the following minimum specifications. The PC may be a desktop or a laptop (with either a color or monochrome display). Computers with more memory, larger disks, and faster processors are allowed, and are likely to improve performance of the system.

Processor:	80486
Co-Processor:	recommended, but not required
CPU Speed:	33 Mhz
RAM:	8 MB
Display:	640 by 480 by 16 greyscale
Hard Disk:	100 MB
Floppy:	3.5", 1.44 MB
Serial port:	COM STD, 16550 UART or equivalent high speed
Parallel port:	Printer (Centronics) standard
Windows Version:	3.1 or Win95
Safety Rating:	IEC 950 or equivalent

There are no controller boards to add to the computer. All communication between the Sahara and the computer takes place over a standard serial port and cable. (RS232 connection). One end of the cable plugs into the Sahara serial port connector and the other end plugs into the computer's COM1 or COM2 serial port connector.

The serial cable is provided with the Advanced Clinical Software. This communication cable (Hologic PN 180-0318) is an industry standard PC to PC null modem cable with 9 pin D female connectors on each end. For older computers with only a 25-pin D connector, adapters are readily available wherever computers are sold.

The Advanced Clinical Software is supplied on 3.5 inch disks, along with an automatic installation program.

## Quality Control (QC) Phantom

The QC phantom supplied with the Sahara system serves two distinct purposes:

1. Daily measurements of SOS and BUA using this phantom allows monitoring of system performance over time. See the Quality Control chapter, in this manual, for more information.
2. The QC phantom is used to calibrate the Sahara system for BUA and SOS measurement in the event of malfunction, or if the transducers, transducer pads, or electronics are removed or replaced for any reason.

*Note:* The QC phantom should be stored with the unit but not in the heel well. The phantom and pads can both be ruined by long term contact with each other.

## Ultrasound Coupling gel

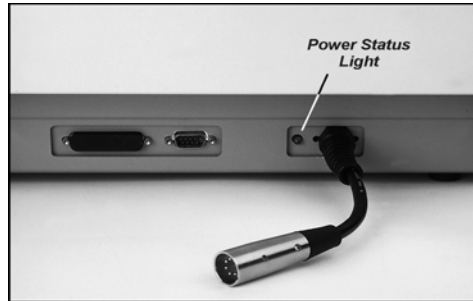
The Sahara Clinical Bone Sonometer requires the use of a special couplant gel that is supplied with the unit. Standard ultrasound coupling gel will not provide the specified performance level. To ensure proper operation, use only the couplant gel provided by Hologic (labeled "Sahara Ultrasound Coupling Gel"). Other gels, particularly those that are water based, will adversely affect the measurement results. Information on ordering Sahara Ultrasound Coupling Gel can be found in the *System Care and Maintenance* chapter of this manual.

## Controls and Indicators

This section describes the controls and indicators on the Sahara Control Panel.

The power status light is located at the rear of the instrument near the power connection. This light will illuminate when power is applied to the unit. Note that the Sahara instrument does not have an on/off switch. Power is applied by plugging in the power module.

**Figure 1-6**  
Power Status Light



The Control Panel, shown in Figure 1-7, contains a display screen, numeric keypad and five functional switches.

**Figure 1-7**  
Control Panel

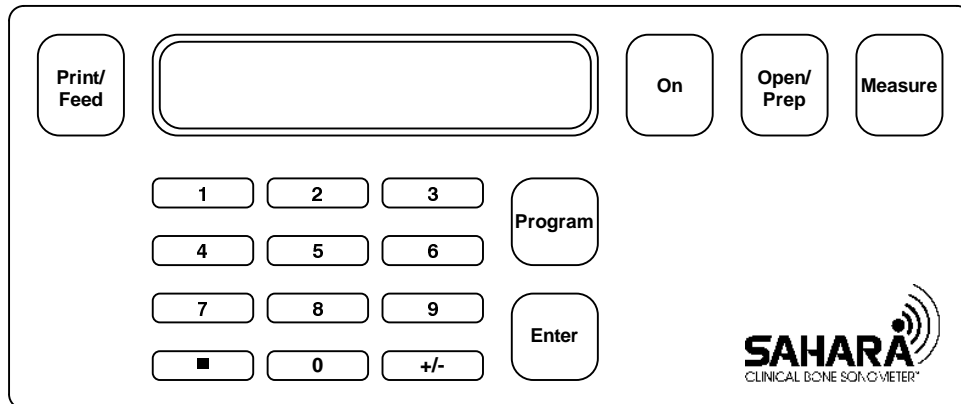


Table 1-1 describes the functions on the Sahara Control Panel.

<i>Table 1-1</i> <i>Control Panel</i>	<b>Control</b>	<b>Description</b>
	<b>Numeric Keypad</b>	The Numeric Keypad consists of the numbers 0 through 9, the Program and Enter buttons. These are used to enter phantom information and other numeric data. The Numeric Keypad is not normally used during patient measurements.
	<b>LCD Screen</b>	The LCD display screen displays messages to prompt the user through a measurement, and displays the result of a measurement.
	<b>ON Button</b>	This button takes the system out of standby mode, or initializes the system to prepare for a new measurement.
	<b>OPEN/PREP Button</b>	This button places the transducer pads in the Open (fully open), or Prepare (half open), positions, and may be used to open the pads anytime they are closed, or are closing.
	<b>MEASURE Button</b>	This button commands the system to close the transducer pads and perform an ultrasound measurement.
	<b>PRINT/FEED Button</b>	This button commands the system to print the current results or advance printer paper if the optional line printer is supplied.
	<b>Program Button</b>	This button is used to inform the Sahara that program information (such as setting time and date) will follow.
	<b>ENTER Button</b>	This button is used to initiate functions entered with the PROGRAM and Numeric Keypad.
	<b>+/- Button</b>	This button allows the user to toggle between Estimated BMD results and QUI/BUA/SOS results after a measurement. It is also used in the PROGRAM mode to alter numeric sign and select choices.

## Specifications

IEC 601-1 Class 1 Type BF, IPX0. The UL classification for the Sahara Clinical Bone Sonometer is Class 1 Equipment. Table 1-2 lists the specifications for the Sahara clinical system.

**Table 1-2**  
Sahara Specifications

<b>Measurement Site:</b>	Calcaneus (heel)
<b>Coupling Method:</b>	Sahara Coupling Gel only
<b>Measurement Time:</b>	less than 10 seconds
<b>Patient Reports:</b>	Built-in Strip Printer
<b>Measurement Results:</b>	Estimated Heel BMD and Quantitative Ultrasound Index (QUI), obtained from measured BUA and SOS
<b>Estimated Heel BMD</b>	
C.V.:	3%
Absolute Precision:	0.014 g/cm <sup>2</sup>
<b>QUI</b>	
C.V.:	2.6%
Absolute Precision:	2.2
<b>SOS</b>	
C.V.:	0.22%
Absolute Precision:	3.4 m/s
<b>BUA</b>	
C.V.:	3.7%
Absolute Precision:	2.6 dB/MHz
<b>QC Check:</b>	Daily, utilizing supplied QC phantom
<b>Operating temperature range:</b>	60° - 100° F (15° - 37.7° C)
<b>Operating humidity range:</b>	20-80% R.H. non condensing
<b>Shipping and Storage:</b>	
Ambient Temperature	0° to 120° F (-17.8° C to 49° C)
Relative Humidity	20% to 95%
Atmospheric Pressure	500 hPa to 1060 hPa
<b>Power Requirements:</b>	100-240 VAC, 50-60 Hz, <60 watts (automatically adjusts from 100 VAC to 240 VAC, and 50 Hz to 60Hz)
<b>CPU</b>	Embedded microprocessor
<b>Ultrasonic Energy:</b>	I <sub>sppa</sub> < 0.001 W/ cm <sup>2</sup> typical I <sub>spta</sub> < 0.001 mW/ cm <sup>2</sup> typical Mechanical Index (MI) < 0.01 typical Pulse Repetition Rate (PRR) < 200 Hz
<b>Safety Standards:</b>	IEC601-1, UL2601-1, CSA C22.2
<b>Size:</b>	17"D x 14"W x 12"H (43cm x 36cm x 30cm)
<b>Weight:</b>	22 lb. (10 kg)

**1** *Introduction*



# 2

## Initial Set Up

This chapter describes how to set up the Sahara Clinical Bone Sonometer. It covers examination room requirements, unpacking, system set up, and printer operation.

### Examination Room Environment

Hologic recommends a clean, dry examination room, with the temperature of the room maintained between 65° and 75° F (20° and 27° C). If possible, store the Sahara in the same room used for patient measurement (to minimize temperature changes to the instrument). Do not store the unit near a heat source or air conditioner. Store the phantom near the unit.

*Note: Never store the QC phantom in the footwell with the transducer pads closed on it. This will ruin both the phantom and the transducer pads.*

The exam room should have a standard electrical outlet, and a stationary (not rocking or gliding) straight back chair for the patient. The patient chair should have arms for patient comfort and a seat height of approximately 16 to 18 inches (41 to 46 cm) from the floor. The Sahara operator should be seated on a low height stool such as an exam stool.

### Unpacking the System

Figure 2-1 shows the key components of the Sahara Clinical Bone Sonometer. Refer to the figure, and the list below it, to insure that all items were received.

## 2 Initial Set Up

**Figure 2-1**  
Unpacking the System



The Sahara shipping package includes the following:

- Sahara system
- Power Supply and Power Cord
- Positioning Aid
- QC Phantom
- Training Video (Sahara User Video Guide)
- Starter supplies including:
  - Sahara Ultrasound Coupling Gel (2 tubes)
  - Transducer Towelettes (1 pkg)
  - Dry wipes (1pkg)
  - Pinter paper (2 rolls)
  - Ultrasound exam paper (1pkg)
- Documents package containing:
  - User's Guide
  - Supplies reorder cards
  - Installation, Warranty, and Post Warranty Service Information Sheet
  - QC Log Forms (1 tablet)
  - Patient Report Forms (1 tablet)
  - Patient Information Brochures (1 pkg)
  - Sahara Physician Learning Series

To unpack the system, follow the procedure below.

### 2-2 SAHARA Clinical Bone Sonometer

1. Remove the top tray containing the Power Supply, QC Phantom, Training Video, starter supplies, and documents package.
2. Remove the foam packaging material that covers the top of the system.
3. Remove the positioning aid (wrapped in packaging material and located on the system).
4. Carefully remove the system from the box by its handle, and take the system out of the plastic bag.
5. Locate the power supply and power cord and unwrap.

**Note:** *The box and packing materials should be saved in case the system has to be transported elsewhere, or returned for service, at some future date.*

## Setup and Test

This section describes how to set up and test the Sahara Clinical Bone Sonometer.

### Power On the System

Follow the procedure below to complete the initial set up and test of the system.

1. Place the system on the floor where it will be used.
2. Plug the power supply into the system (the figure below shows the power supply connections).

**Figure 2-2**  
*Power Supply  
Connections*

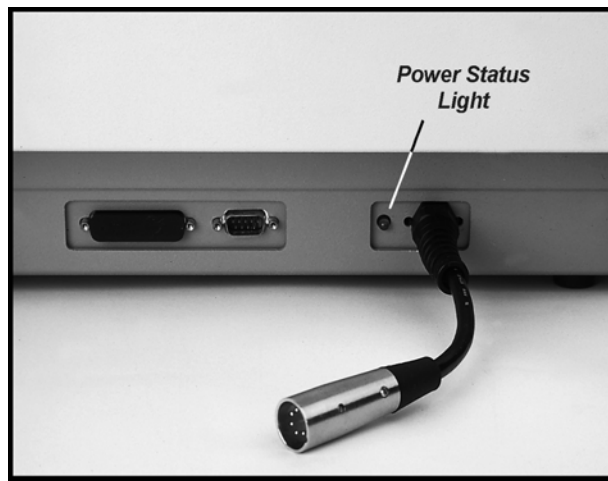


## 2 Initial Set Up

3. Plug the power supply into the wall outlet. The green power status light, located near the power connection, will illuminate.

**Note:** Always perform Steps 2 and 3 in this order to avoid damaging the unit.

**Figure 2-3**  
Power Status Light



4. The Control Panel Screen initially displays:

HOLOGIC \*\*Sahara\*\*  
Version x.y

Followed by:

Power On Self Test:  
In Progress...

5. Upon completion of the self test, the Control Panel Screen displays:

Power On Self Test:  
Passed

OR

Power On Self Test:  
Failed

The above messages will be displayed anytime the system is plugged in after being unplugged.

If the Power On Self Test fails, see the System Malfunction section in Chapter 6 of this manual.

6. When the Self Test passes, the Control Panel Screen displays:

Press ON

7. Press ON to initialize Sahara. The Control Panel Screen displays:

Initializing...

Then:

Gel Pads  
Press OPEN



## Printer Operation

Follow the procedure below to load printer paper:

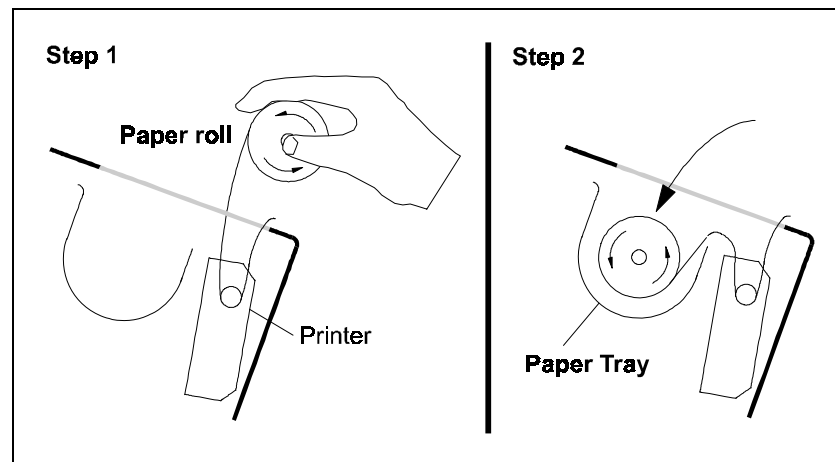
1. Remove the printer cover by sliding the cover towards the rear.

**Figure 2-4**  
Removing Printer Cover



2. Grasp the paper roll in your hand and feed the paper through the printer as shown in Step 1 of Figure 2-5 and Figure 2-6. Insert the paper into the paper slot where arrows indicate. The paper should feed from the underside of the roll.

**Figure 2-5**  
Threading Printer  
Paper



3. To feed the paper press the **PRINT/FEED** button while the display screen is displaying “Gel Pads press OPEN”.

**Figure 2-6**  
Feed Printer Paper



4. Place the paper roll into the printer tray. Insert the paper roll in the tray as shown in Figure 2-7 and Step 2 of Figure 2-5.

**Figure 2-7**  
Insert Paper Roll



## 2 Initial Set Up

5. Insert the paper through the slot in the printer cover and reinstall the cover.

**Note:** *Never pull the paper (either forwards or backwards) through the printer. Always advance the paper using the Print/Feed button, and tear off using the cover slit.*

**Figure 2-8**  
*Printer Cover Replaced*





## Set Time

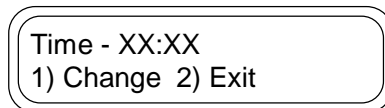
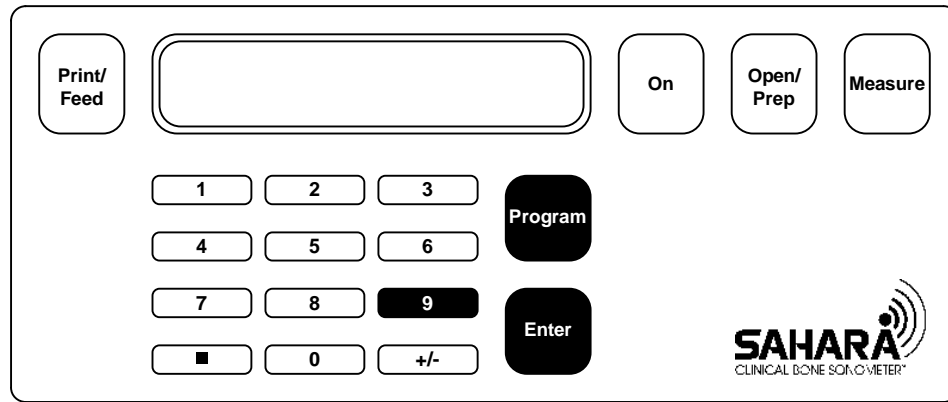
To set the time in your Sahara system, follow the procedure below:

1. Press **ON**. The Control Panel Screen displays the following.



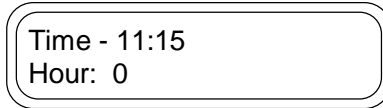
2. To set the time, press **PROGRAM, 9, ENTER**. The Control Panel Screen displays the time (in 24 hour format).

**Figure 2-9**  
Press **Program, 9,**  
**ENTER**



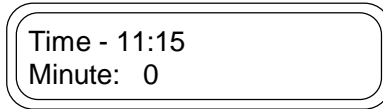
3. If the time displayed is correct, press **2**.
4. If the time displayed is incorrect, set the correct time as follows:
5. Press **1**. The Control Panel Screen displays the following:

## 2 Initial Set Up



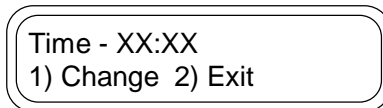
Time - 11:15  
Hour: 0

6. Insert the hour in 24 hour format, then press **ENTER**. The Control Panel Screen displays the following:



Time - 11:15  
Minute: 0

7. Insert the minute, then press **ENTER**. The Control Panel Screen displays the following (XX:XX represents the time you set):



Time - XX:XX  
1) Change 2) Exit

8. Press **2** to set the time as shown, or press **1** to start over.
9. After the time has been set, the Control Panel Screen displays:



Gel Pads  
Press OPEN

## Set Date

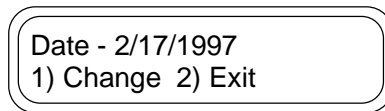
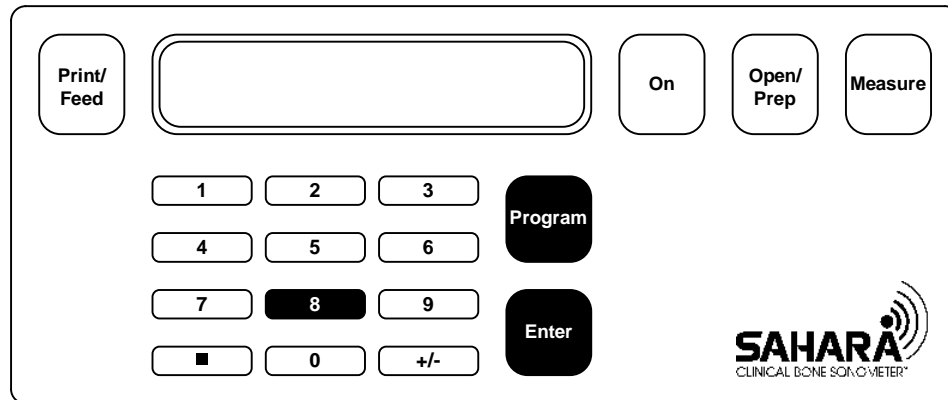
To set the date, in your Sahara system, follow the procedure below:

1. Press **ON**. The Control Panel Screen displays the following:

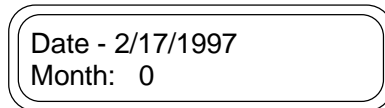


2. To set the date, press **PROGRAM, 8, ENTER**. The Control Panel Screen displays the date.

*Figure 2-10*  
Press **PROGRAM, 8,**  
**ENTER**



3. If the date displayed is correct, press **2**.
4. If the date displayed is incorrect, set the correct date as follows:
5. Press **1**. The Control Panel Screen displays the following:



## 2 Initial Set Up

6. Insert the month, then press **ENTER**. The Control Panel Screen displays the following:

Date - 2/17/1997  
Day: 0

7. Insert the day, then press **ENTER**. The Control Panel Screen displays the following:

Date - 2/17/1997  
Year: 0

8. Insert the year, for example "1997", then press **ENTER**. The Control Panel Screen displays the following (XX/XX/XXXX represents the date you set):

Date - 2/17/1997  
1) Change 2) Exit

9. Press **2** to set the date as shown, or press **1** to start over.
10. After the date has been set, the Control Panel Screen displays:

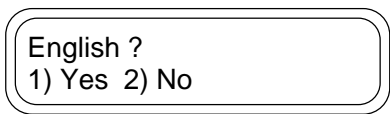
Gel Pads  
Press OPEN

**Note:** Time and date may be set whenever the "Gel Pads Press OPEN" or "Gel Pads for QC Press OPEN" screens are displayed.

## Set Language

You may now can choose between different languages to be used on the SAHARA display. Use the following procedure:

1. Press **Program** on the SAHARA keypad.
2. Press **4** on the SAHARA keypad.
3. Press **2** on the SAHARA keypad.
4. Press **Enter** on the SAHARA keypad.
5. Press 9 on the SAHARA keypad
6. Press 8 on the SAHARA keypad
7. Press **Enter** on the SAHARA keypad. The language menu will appear on the display



By continually pressing 2 (No) you can cycle through the following languages:

ENGLISH PORTUGUESE  
 ITALIANO DEUTSCH  
 FRANCAIS SLOVIK  
 ESPANOL CROATIAN

8. At any time you press 1 (Yes), the SAHARA will use that language on its display and in its printouts. The program returns you to the **Gel Pad** menu displayed in the selected language:



- Notes:**
1. If you cycle through all the languages by press 2 (No), after the CROATIAN language selection you will be returned to the **Gel Pad** menu.
  2. The major display modes (as well as the SAHARA report printouts) will be translated into the selected language. Error messages appear in the English language at this time.

## **2** *Initial Set Up*

## 3

## Quality Control

This chapter describes how to perform the Quality Control (QC) procedure on the Sahara Clinical Bone Sonometer.

Each Sahara is supplied with a Quality Control phantom to monitor system performance over time. It is recommended that a QC phantom measurement be performed each day, prior to using the system to measure patients. However, it is acceptable for the QC measurement to be performed after patients are measured if the system and phantom are not at the same temperature as described in the note below.

**Note:** *Always store the QC phantom near the Sahara system. BUA and SOS readings for the phantom are temperature dependent, and may vary if the phantom and system are not maintained at the same (room) temperature. Thus it is important that the phantom be kept near the system so that they are at the same temperature. If the phantom has not been kept in the same location, allow one hour for the temperature of the phantom to stabilize before using the phantom for calibration or QC. Never store the phantom in the unit footwell with the pads closed on it, as this will destroy both the pads and the phantom.*

Because the variation of the ultrasonic properties of the phantom due to temperature are larger than the Sahara unit's short and long term precision, QC results provide a conservative estimate of the performance of the Sahara system. It is common to observe fluctuations in QC results within the normal acceptable range defined by the dashed lines on the Quality Control Log forms (see below). Occasionally, QC results will be outside of these ranges, and repeating the QC procedure after 1 hour will give acceptable results due to the stabilization of the phantom temperature. In addition, Sahara also automatically identifies QC results that are far enough outside of the acceptable range as to indicate either a procedural error (no gel used, for example) or a system malfunction. In such a case, the system displays a "QC Failed" message, and the system should not be used to evaluate patients until an acceptable result is obtained or the unit is serviced.

The remainder of this chapter describes the procedure for performing QC measurements and guidelines for interpreting results. QC measurement consists of initializing the system, applying gel to the pads, opening the pads, positioning and securing the QC

phantom in the system, performing the measurement, printing the measurement results, removing the phantom from the system, and cleaning the phantom and the pads.

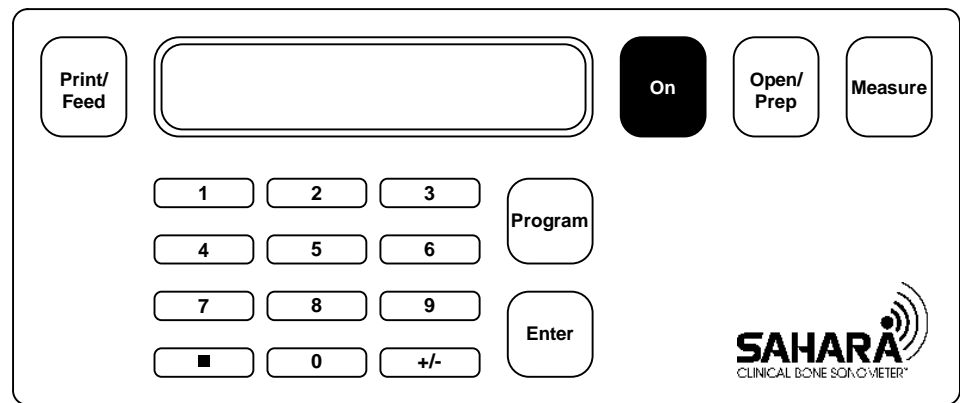
QC results may be plotted as a function of time using the Quality Control Log sheets described in the section titled Recording/Plotting QC Results, in this chapter. The QC Log sheets will allow recording and plotting of QC results, with one month of QC data recorded on each sheet.

## Quality Control Procedure

To perform QC, follow the procedure below.

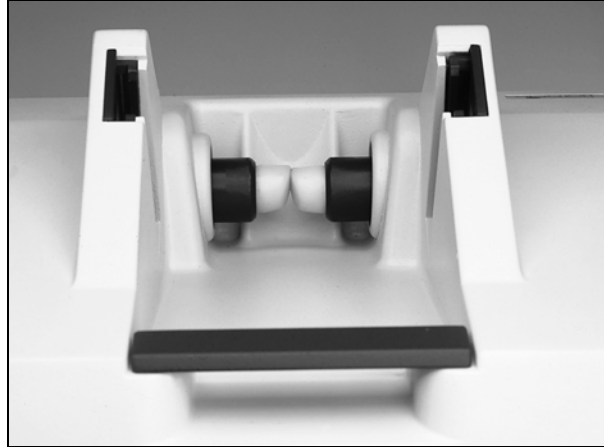
1. Press the **ON** button. The system initializes itself and closes the transducer pads until they touch, and then opens them for gel application.

*Figure 3-1*  
Press ON

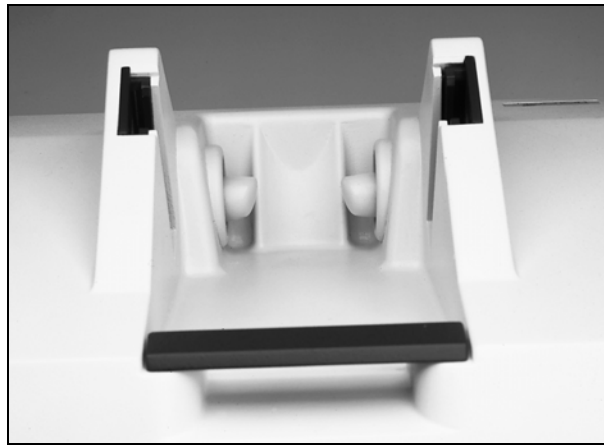




**Figure 3-2**  
Transducer Pads Touch



**Figure 3-3**  
Transducer Pads Ready  
for Gel

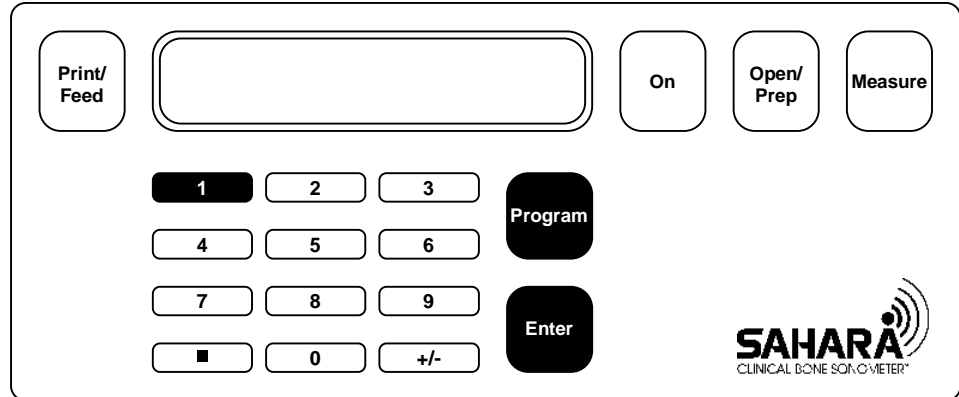


**Note:** *If there is no operator action within ten minutes after ON is pressed, the unit goes to Power Saver Mode (the screen goes blank). Press the ON key to return to the last screen.*

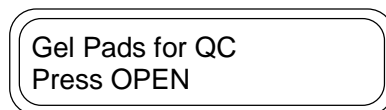
2. Press the **PROGRAM** button on the keypad, then press the **1** button, and then press **ENTER**. This tells the system that a QC measurement is about to be made.

### 3 Quality Control

**Figure 3-4**  
Press **PROGRAM**, **1**,  
**ENTER**



The Control Panel Screen displays:



3. For each transducer pad, squeeze out about a one inch (2.5 cm) bead of gel onto your finger (see the figure below).

*Note: Do not use a Q-Tip, examination glove containing talc, or any other applicator that may introduce fibers or other foreign matter.*

**Figure 3-5**  
Gel Measurement



**Figure 3-6**  
Spread Gel

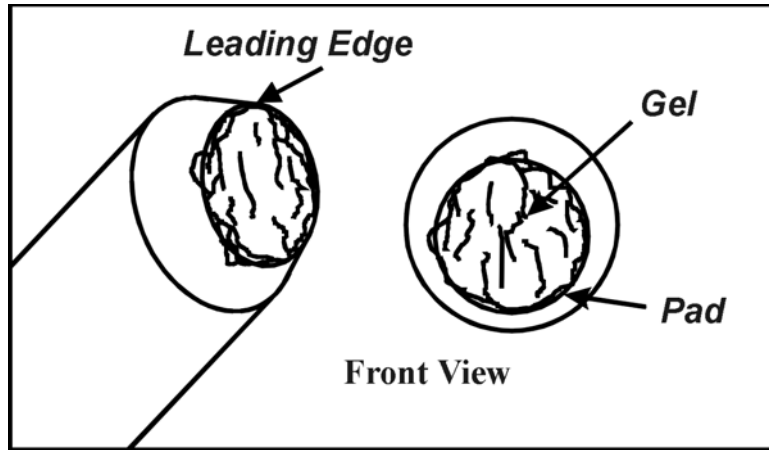


3 Quality Control

4. Apply gel evenly on the face of the pad.

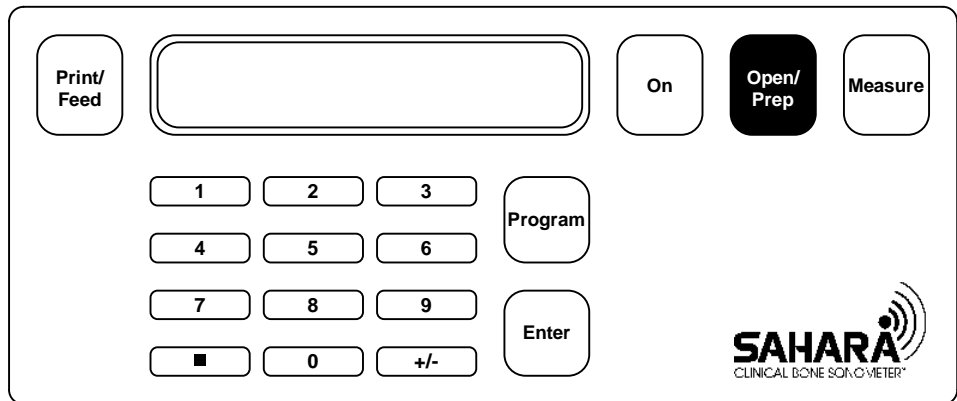
*Note: It is important that the leading edge of the transducer pad is fully covered.*

**Figure 3-7**  
Proper Amount of Gel  
on Transducer Pad



5. When gel has been applied to both transducer pads press the **OPEN/PREP** button. The scanner opens the transducer pads to the fully open position.

**Figure 3-8**  
Press **OPEN/PREP**

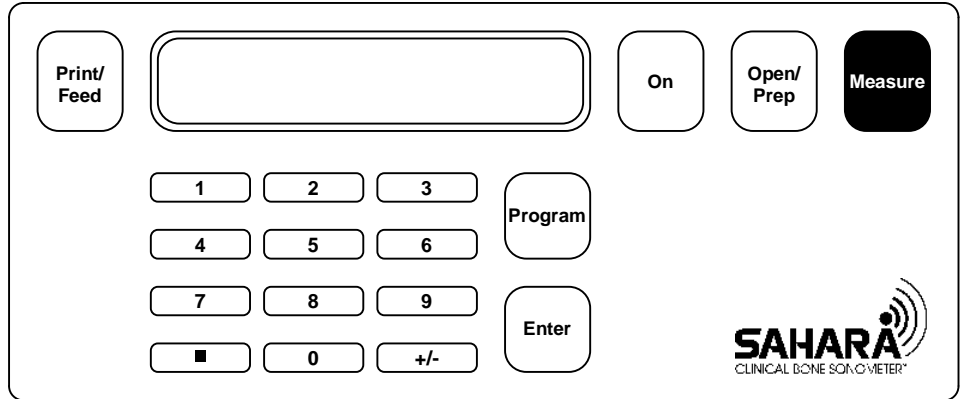


The Control Panel Screen displays:

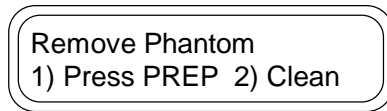


3 Quality Control

**Figure 3-10**  
Press **MEASURE**

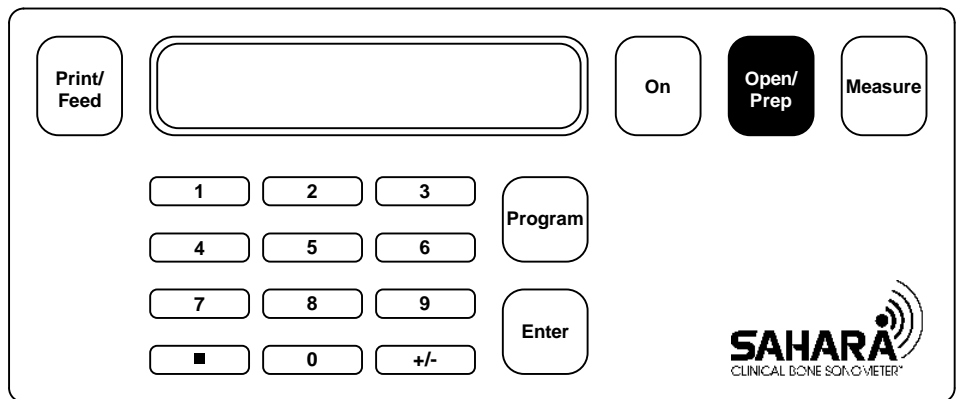


8. The Control Panel Screen displays the following. Remove the QC phantom.



9. Press **OPEN/PREP**. The transducer pads return to the ready position.

**Figure 3-11**  
Press **OPEN/PREP**



10. Carefully clean and dry the phantom and the transducer pads. Use towelettes supplied in the Accessories Kit to clean the phantom and transducer pads, and dry wipes to dry them.

11. If the QC test is within limits the display screen will display:

QC Passed  
Press On

12. To obtain the results, press the +/- button. The Control Panel Screen displays:

QAB=x  
QAS=y

The QC results are reported in terms of QAB and QAS, which are unitless parameters defined as follows:

QAB is calculated by dividing the measured BUA by the actual phantom BUA value that was entered at the factory and also appears on the phantom.

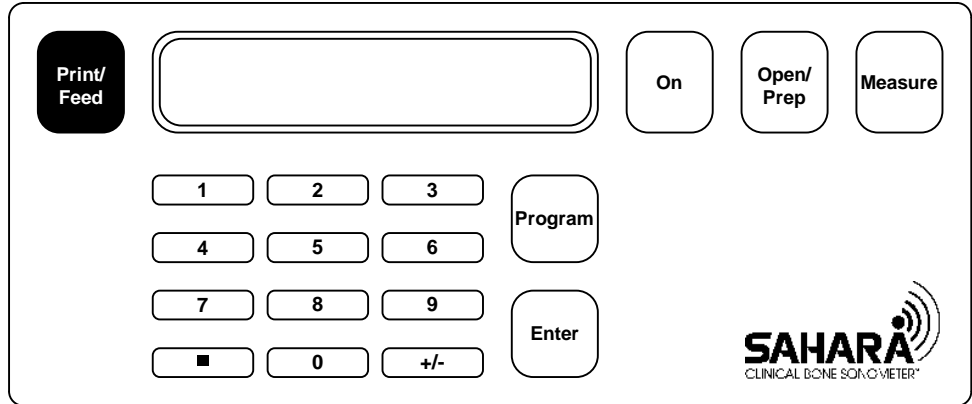
QAS is calculated by dividing the measured SOS by the actual phantom SOS value that was entered at the factory and also appears on the phantom.

12. If desired, pressing the +/- button again will display the absolute BUA and SOS values. The Control Panel Screen displays:

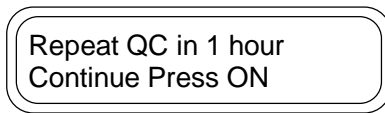
BUA=x  
SOS=y

13. A printout of the QC results may be obtained by pressing the **PRINT/FEED** button on the control panel.

Figure 3-12  
Press PRINT

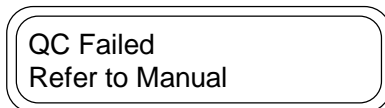


14. If the QC is outside of normal limits, then the screen will display:



In most cases, the cause of the REPEAT message is not a system malfunction but is due to the phantom not being stabilized at room temperature. Repeat the test in one hour. If you suspect this is the problem, it is acceptable to perform patient measurements before completing the QC procedures, as patient results are not affected by incorrect phantom temperature. However, if this is not believed to be the problem, or if the repeat message appears after waiting one hour, refer to the *Quality Control Problem* section of the Chapter 6 - *System Care and Maintenance*, before performing patient measurements.

15. If the QC results are well outside normal operating limits, and outside of the range encountered when the temperature of the phantom is not stabilized, the screen will display:



Repeat the QC procedure starting at Step 1. If the QC fails again, refer to the *Quality Control Problem* section of the *System Care and Maintenance* chapter of this manual. If the QC Failed message is displayed, do not perform patient examinations

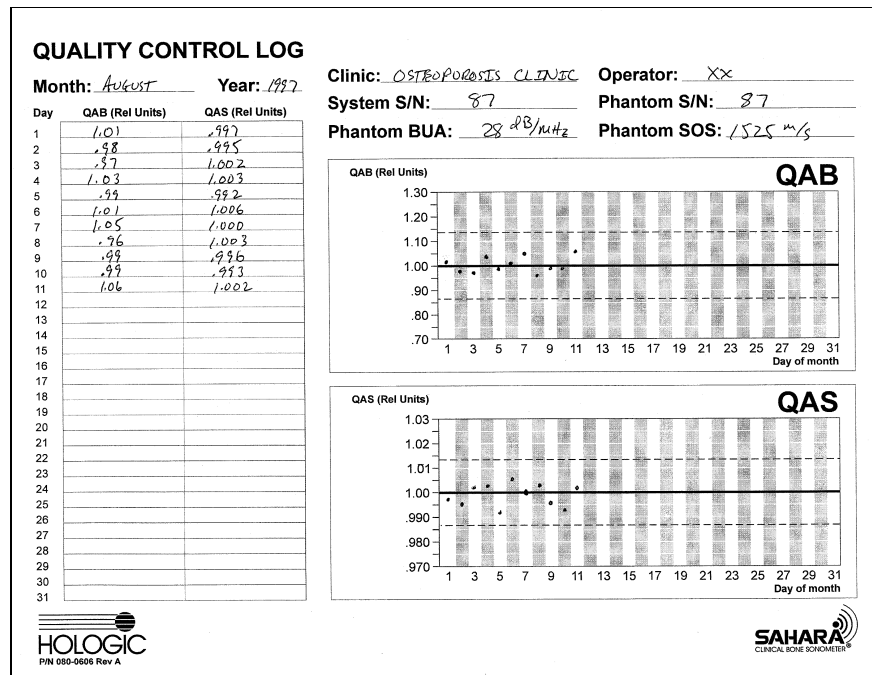


until the QC procedure has been successfully completed or the system has been serviced.

## Recording/Plotting QC Results

A "PASSED" QC result indicates that the Sahara system is functioning properly. If desired, QAB and QAS results may be recorded and plotted on the Sahara QC worksheets supplied with the unit. These worksheets allow the daily QC results to be documented and the long-term stability of BUA and SOS QC results to be visually monitored. Log the displayed results on the Quality Control Log sheets provided. Each log sheet can accommodate one month of QC results, and in order to simplify the graphical plots, only the QAB and QAS values are recorded. Note that it is simple to convert the QAB and QAS values to BUA and SOS values by multiplying the QAB value by the phantom BUA value (on the phantom label) and by multiplying the QAS value by the phantom SOS value (on the phantom label).

Figure 3-13  
QC Log



At the beginning of each month, a new QC Log sheet should be started by filling in the Month, Year, Institution Name, System Serial Number, Phantom Serial Number, Phantom

BUA, Phantom SOS, and operator name. Note that Phantom Serial Number, BUA and SOS values are given on the label attached to the phantom.

Each day, after the QC measurement is performed, enter the QAB and QAS values on the log sheet in the "QAB (Rel Units)" and "QAS (Rel Units)" columns, respectively. Make sure that the results are entered into the row labeled with the corresponding day of the month (i.e. the results obtained on the seventh day of the month are entered in the row with a 7 at the left side).

The results can then be plotted on the graph, on the right side of the log sheet. The day of the month is indicated along the horizontal axis on each graph, with shading of alternate days to assist in plotting. The measurement value is indicated on the vertical axis of each graph, with breaks in the shaded areas to assist in plotting. Finally, the area between the two horizontal dashed lines indicates the normal acceptable range for measurement results. Note that the PASSED indication on the Sahara control panel screen indicates that the results will be in the acceptable range on the plot. QC results may occasionally fall outside of the normal range. In most cases, QC measurements that fall outside of the acceptable range are caused by a phantom that is not stabilized at room temperature, leading to a REPEAT message rather than a PASSED message. If the phantom has definitely stabilized at room temperature for more than one hour, and the system returns a REPEAT message, then it is recommended that the results be recorded in the log and plotted to document the QC failure. See the *System Care and Maintenance* chapter in this manual for further information if a PASSED QC result is not obtained.

## Interpretation of QC Results

A "QC PASSED" result indicates that the Sahara system is functioning properly. Thus the system may be used for patient examinations, regardless of the QAB and QAS values, as long as the "QC PASSED" message is displayed at the conclusion of the QC procedure. It is common to observe fluctuations in QC results within the normal acceptable range defined by the dashed lines on the Quality Control Log forms. Occasionally, QC results will be outside of these ranges, and repeating the QC procedure after 1 hour will give acceptable results due to the stabilization of the phantom temperature. In addition, Sahara also automatically identifies QC results that are far enough outside of the acceptable range as to indicate either a procedural error (no gel used, for example) or a system malfunction. In such a case, the system displays a "QC Failed" message (refer to procedure above for details) and the system should not be used to evaluate patients until an acceptable result is obtained or the unit is serviced.

Because the variation of the ultrasonic properties of the phantom due to temperature are larger than the Sahara unit's short and long term precision, QC results provide a conservative estimate of the performance of the Sahara system. This means that some fluctuation in phantom results would be expected even if the Sahara system had no variation. For this reason, QC phantom results should not be confused with expected results in vivo. However, it is important to perform QC in order to verify that the system is performing properly and that the results are in the acceptable range.

Over long periods of time (several months or more), it is typical for the results of the two QC parameters to have mean (or average) values ranging between 0.93 and 1.07 for QAB and between 0.993 and 1.007 for QAS. That is, the mean values for QAB and QAS fall approximately within the middle portion of the acceptable range for each parameter. Note that QC results for a given day, or for a few days, can fall outside of the middle of the acceptable range. However, if the QC results are consistently (for more than two weeks) falling near to the edge of the acceptable limits, the System should be re-calibrated, as described in the System Care and Maintenance Chapter of the User's Guide. It is important to understand that as long as the QC results fall within the acceptable range (as indicated by the "QC Passed" message) it is acceptable to perform patient examinations as the system is performing within specifications.

The typical daily fluctuations observed over long periods of time (several months or more) can be described in terms of the standard deviation (SD) of the QAB or QAS results. Note that in order to obtain a reliable estimate of the SD, at least 2 weeks (10 or more QC measurements) must be obtained. Typical SD values obtained with Sahara are 0.05 for QAB and 0.005 for QAS. If results on your system are poorer than these values, review the QC procedure (above) to insure that the measurements are being performed properly before contacting your service representative.



### **3** *Quality Control*

#### **3-14** *SAHARA Clinical Bone Sonometer*

## 4

## Patient Measurement

This chapter describes how to perform a patient measurement on the Sahara Clinical Bone Sonometer.

**Warning:** If the patient's skin, in the area to be tested and/or the area that comes into contact with the Sahara system, transducer pads, or foot positioning aid (i.e. heel, foot, ankle, shin, or calf), is abraded and/or has an open sore, do not measure that heel. If skin is abraded and/or has an open sore on both heels/legs, the patient should not be assessed with the Sahara system.

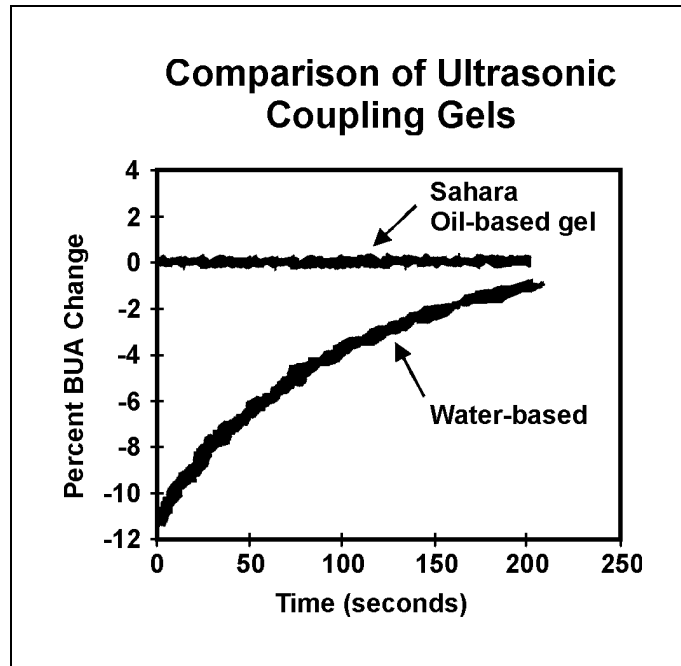
### Note about Ultrasound Coupling Gels

The selection and proper application of coupling gel are critical in obtaining correct ultrasound test results.

Water based gels - used so effectively for *qualitative* imaging ultrasound modalities - cause a significant delay in pad-to-skin coupling, which can have a significant effect on *quantitative* ultrasound results. Because Sahara ultrasound measurements are obtained so quickly, the time dependence of quantitative ultrasound results (Figure 4-1) obtained using water-based coupling gels will result in unacceptably variable results. Of course the variability shown in Figure 4-1, while typical of the general population, may vary on an individual basis. Certain oil based gels also exhibit this time dependence, and it is therefore critical that **ONLY** Hologic approved ultrasound coupling gels be used with Sahara.

Two tubes of Sahara Ultrasound Coupling Gel are supplied with each Sahara unit. Additional tubes can be reordered from Hologic. Use the reorder form included in the Sahara starter kit or contact your Hologic representative.

**Figure 4-1**  
Comparison of  
Ultrasonic Coupling  
Gels



**In order to obtain highly reproducible results, avoid these common causes of measurement imprecision:**

Poor Patient Seating - The patient should be seated in a straight chair without rollers.

Poor Foot Preparation - The foot should be dry and clean when making a measurement.

Improper Foot Placement - Use the exam paper for each measurement as it allows the foot to slide easily against the rear of the footwell. Make sure the positioning line is between the second and third toe.

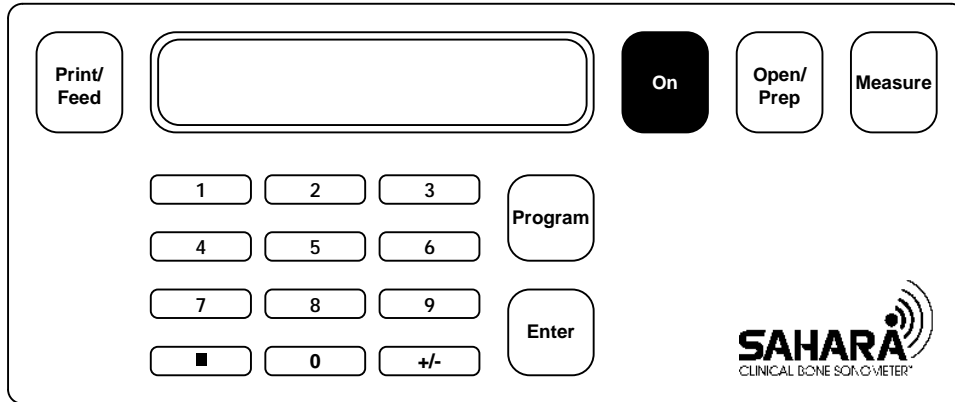
Misuse or Lack of Use of Foot Positioner - Always use the foot positioner. Make sure that when it is applied, the patient is comfortable.

# Sahara Patient Measurement Procedure

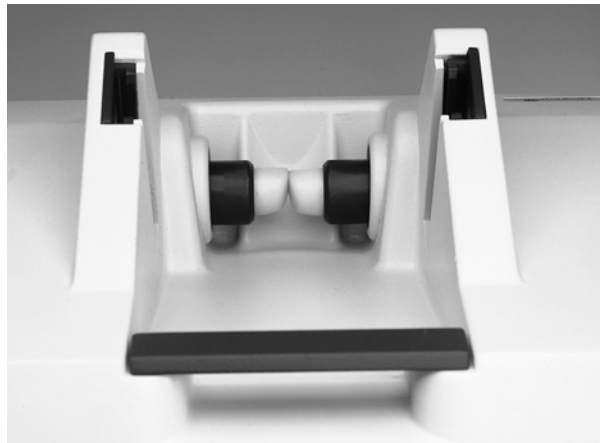
## Prepare Transducer Pads

1. Press the **ON** button. The system initializes itself, closes the transducer pads until they touch, pauses momentarily, and then opens them for gel application.

**Figure 4-2**  
Press ON

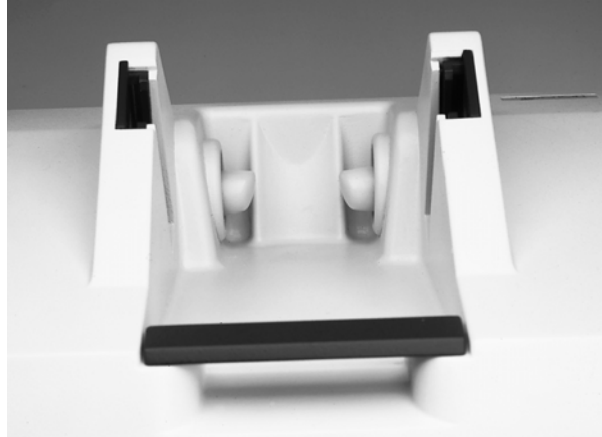


**Figure 4-3**  
Transducer Pads Touch



#### 4 Patient Measurement

**Figure 4-4**  
Transducer Pads Ready  
for Gel



**Note:** If there is no operator action within ten minutes after **ON** is pressed, the unit goes to *Power Saver Mode* (the screen goes blank). Press the **ON** key to return to the last screen.

The Control Panel Screen displays:

Gel Pads  
Press OPEN

2. For each transducer pad, squeeze out about a one inch (2.5 cm) bead of gel onto your finger.

**Note:** Do not use a *Q-Tip*, examination glove containing talc, or any other applicator that may introduce fibers or other foreign matter.



**Figure 4-5**  
Gel Measurement



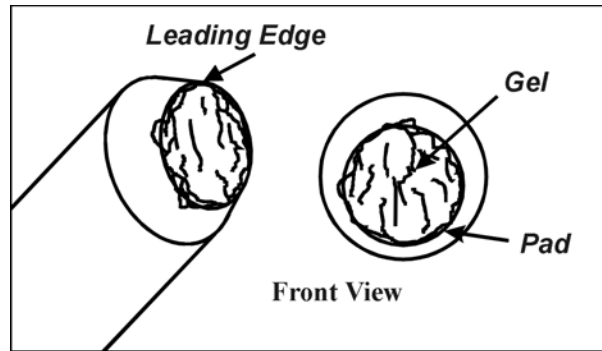
**Figure 4-6**  
Apply Gel



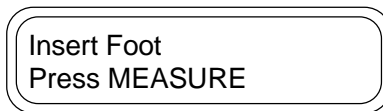
3. Apply gel evenly on the face of the pad.

**Note:** It is important that the leading edge of the transducer pad is fully covered.

**Figure 4-7**  
Gel Application

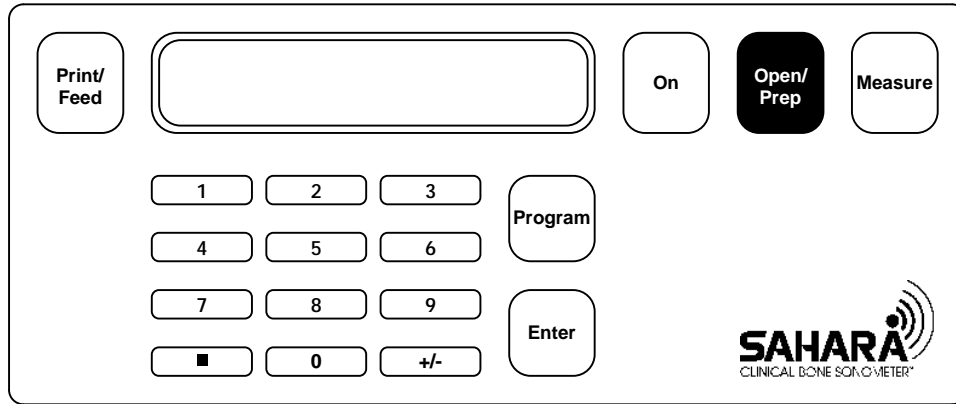


The Control Panel Screen displays:



4. When gel has been applied to both transducer pads press the **OPEN/PREP** button. The scanner opens the transducer pads to the fully open position.

**Figure 4-8**  
Press OPEN/PREP



## Position Patient

1. The patient should be seated in a stationary, straight-back chair approximately 12 to 18 inches (30 to 46 cm) from the scanner.

**Figure 4-9**  
Patient Position



#### 4 Patient Measurement

2. Ask the patient to remove their shoes, socks, nylons, etc. so that the foot is bare. If the patient's skin, in the area to be tested, is abraded and/or has an open sore, do not measure that heel.
3. Clean the sides of the heel to be measured using towelettes supplied in the Accessories Kit, then dry thoroughly with dry wipes.
4. Place exam paper on the bottom of the scanner foot well.
5. Place the patient's foot into the foot well. Ensure that the middle of the heel is snug against the center of the positioning contour (heel cup) and that the foot is positioned in the well (see the figures below) with the positioning line aligned with the gap between the patient's second and third toe.

**Figure 4-10**  
*Patient Leg Position*



**Figure 4-11**  
Patient Foot Position



**Figure 4-12**  
Heel Position



6. Position the patient's leg at about the same angle as the positioning aid.

#### 4 Patient Measurement

7. Place the positioning aid down on the leg leaving it slightly loose (about enough room to place two fingers between the leg and the positioning aid).

**Figure 4-13**  
*Positioning Aid Slightly  
Loose*



8. Adjust the leg to the angle of the positioning aid by moving the Sahara (the scanner and calf should line up). The figures below show correct, and incorrect, leg angle.

**Figure 4-14**  
*Correct Leg Angle  
(front to back)*



**Figure 4-15**  
*Incorrect Leg Angle*  
*(system too close)*



**Figure 4-16**  
*Incorrect Leg Angle*  
*(system too far)*

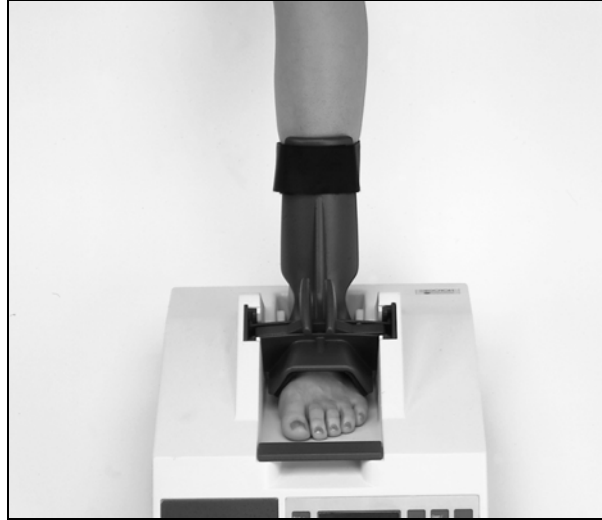


9. Ensure that the patient's leg is straight (see the figures below), and push the positioning aid down firmly to insure it is snug.



#### 4 Patient Measurement

**Figure 4-17**  
*Correct Leg Position*  
*(side to side)*



**Figure 4-18**  
*Incorrect Leg Position*  
*(side to side)*



#### 4-12 SAHARA Clinical Bone Sonometer



**Figure 4-19**  
*Incorrect Position of  
Toes*



10. With the positioning aid down tight, attach the positioning aid strap firmly around the leg.

**Figure 4-20**  
*Positioning Aid Strap*



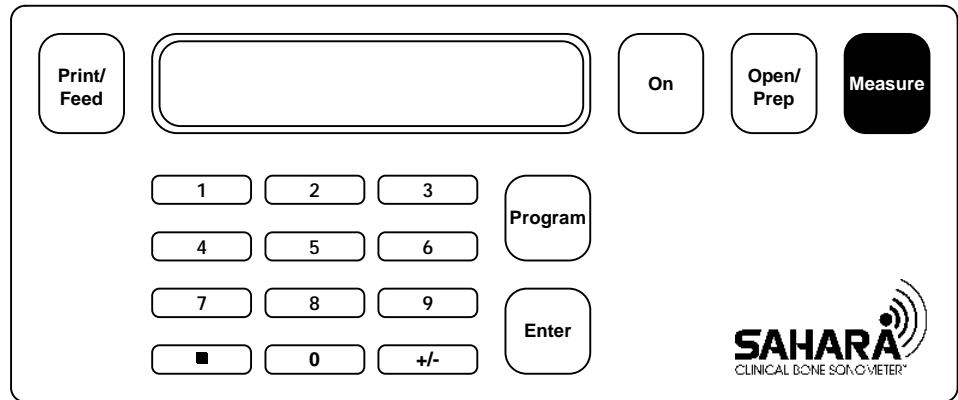
11. Ensure that the patient is sitting straight up, with their back against the back of the chair and hands folded in their lap. The patient should be comfortable and must remain still during the measurement.

**Safety Note:** The positioning aid incorporates a safety release mechanism. In the event that it is necessary for the patient to remove their foot from the scanner unit at any time during the scan, arching the foot (by pressing the toes down and lifting the heel up) will release the positioning aid. Detach the positioning aid strap to remove positioning aid from the leg.

## Measure Patient

1. Before taking the measurement, double check the patient's heel to ensure that it is in the center of the heel cup. If the patient's heel is not centered, remove the positioning aid and start over at Step 9.
2. Press the MEASURE button on the Control Panel. The system closes the transducer pads to the measurement position and performs the SOS and BUA measurements. The measurement takes less than ten seconds.

**Figure 4-21**  
Press MEASURE



3. Upon completion of the measurement the system sounds an audio tone (beep) and opens the transducer pads to the fully open position. The Control Panel Screen displays:

1) Remove Foot  
2) Press PREP 3) Clean

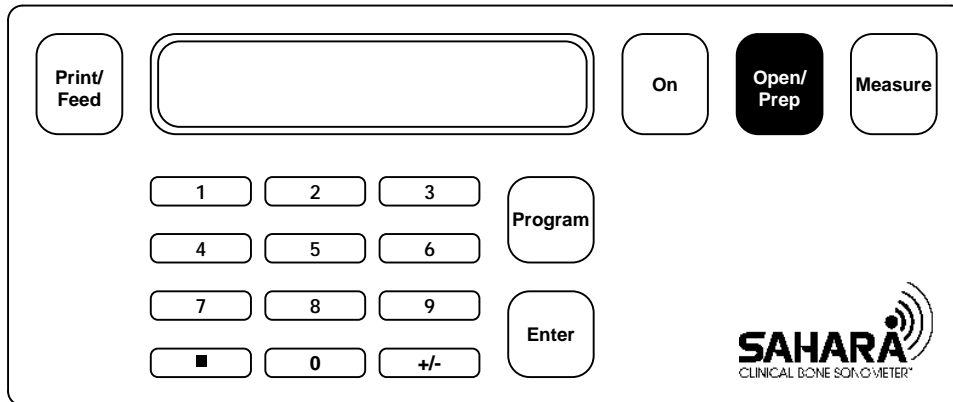
4. Remove the positioning aid strap and positioning aid. The positioning aid is released by pressing the release latches and lifting the guide (see the figure below).

**Figure 4-22**  
Removing  
Positioning Aid



5. Remove the patient's foot from the scanner unit. Provide the patient with tissues or towelettes to remove gel from their foot, assist if necessary.
6. Press **OPEN/PREP**. The scanner moves the transducer pads to the cleaning position.

**Figure 4-23**  
Press **OPEN/PREP**



7. Carefully clean and dry the transducer pads. Use the towelettes supplied in the Accessories Kit to clean the transducer pads, and dry wipes to dry them.

**Figure 4-24**  
Cleaning the Pads



8. The Control Panel Screen displays the Estimated BMD result and corresponding T-score:

Est.Heel BMD=0.340  
T-Score=-2.2

If the Control Panel Screen displays “Invalid Measurement, Repeat” or “Out-of-Range, Repeat” message, refer to the System Care and Maintenance chapter in this manual.

**Note:** An asterisk appearing after the Estimated BMD value, indicates that the Estimated BMD was calculated using the SOS data alone. The Estimated BMD is calculated from the SOS alone in those rare cases where the BUA data is considered unreliable due to the fact that the assumption of a linear attenuation vs. frequency relationship was not fulfilled. This condition is rare, occurring almost entirely in a small percentage of younger males and females with high bone density. On occasion, this condition may also be caused by improper foot positioning or not enough coupling gel. Therefore, if the measurement has an asterisk, it is recommended that the operator repeat the measurement. If the second measurement does not have an asterisk, it should be used and the first measurement ignored. If the second measurement also has an asterisk, these results should be interpreted with caution, especially if used for patient monitoring.

9. Press the **Print/Feed** button on the Control Panel to obtain a hard copy record if desired. Fill in the patient information immediately, before the patient leaves, in order to avoid confusion later. A sample printout is shown (see “Internal (Strip) Printer Report” and Fig. 4-25 below).

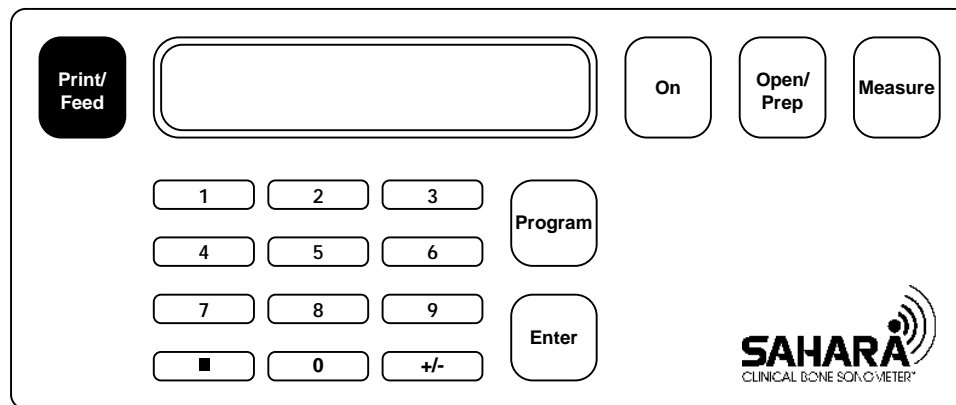
If desired, press the +/- button to display the results for the ultrasound parameters (QUI, BUA, and SOS) before conversion to Estimated Heel BMD units (pressing the +/- button again toggles back to the Estimated BMD result). Note that the printed report will include the QUI, BUA, and SOS results as well as the Est. BMD results if the **Print/Feed** button is pressed when the ultrasound parameters are displayed on the LCD screen.

10. To see the most recent measurement results after the LCD screen has gone blank, press ON to initialize the system, and then press the +/- button to display the results of the last examination.

## Internal (Strip) Printer Report

Sahara Clinical systems may obtain a printed report that includes the measurement results by pressing the **PRINT/FEED** button on the Sahara control panel. Note that the printed report will include the QUI, BUA, and SOS results as well as the Est. BMD results if the **PRINT/FEED** button is pressed when the ultrasound parameters are displayed on the LCD screen.

**Figure 4-25**  
Press **PRINT**



Patient biography data (name, sex, age, etc.) should be noted on the printed report immediately after the exam. Remember to indicate the foot measured (Left or Right). The printed report will have date and time of the exam.

**HOLOGIC**

Date: 8/04/1997      Time: 11:22  
 Serial No: 87

Name: \_\_\_\_\_  
 Sex: M   F  
 ID#: \_\_\_\_\_  
 Ethnicity: \_\_\_\_\_  
 DOB: \_\_\_\_\_      Age: \_\_\_\_\_  
 Foot: L   R

Est. Heel BMD: 0.340 g/cm<sup>2</sup>  
 T-Score: -2.2

Estimated Heel BMD T-Score

-4   -3   -2   -1   0   1  
 Young Adult

## Patient Report Form

Refer to Chapter 5 *Comparison of Patient Results to Reference Values* for information on use of the Patient Report Form.

## Precision of Sahara Results

The precision, or reproducibility, of Sahara results was determined by repeated patient measurements, with complete re-positioning between measurements. Precision results are given in the table below, in absolute units (SD) and in terms of the coefficient of variation (C.V.), which is expressed in percent of the mean value for the population studied.

Parameter	SD	C.V.
Est. Heel BMD	0.014 g/cm <sup>2</sup>	3.0%
QUI/Stiffness	2.22	2.6%
BUA	2.64 dB/MHz	3.7%
SOS	3.38 m/sec	0.22%

## Considerations for Patient Monitoring

### General Considerations:

For any type of bone densitometry equipment, the frequency of use for monitoring of individual patients is dependent on a number of factors. These factors include the precision of the device and the expected rate of BMD loss or gain, which is in turn dependent on the status of the individual patient. For example, the changes expected due to aging or disease progression are quite different than those that could be expected for patients undergoing therapeutic intervention. Furthermore, the expected changes in BMD for subjects on therapeutic regimens is highly dependent on the type of treatment used (e.g., hormonal replacement therapy, calcitonin, bisphosphonates, etc.). Subjects on certain treatments for other conditions (e.g. corticosteroids, which are known to rapidly degrade BMD) are also subject to special consideration. Results of an initial baseline evaluation of BMD are also important, as a patient with high BMD may not need to be evaluated as frequently as a patient with low BMD. Therefore, decisions regarding follow-up time using Sahara must be individualized, taking into account the patient's age, disease status, treatment status, baseline BMD results, and other risk factors. The physician, who is aware of all of these factors, is thus the most appropriate judge of how frequently a patient should be evaluated with bone densitometry equipment.

### Considerations for Monitoring with Sahara:

For Sahara, the absolute precision error for Est. BMD results is  $0.014 \text{ g/cm}^2$  which corresponds to about 2.4 times the annual rate of loss in the U.S. Caucasian female reference population ( $0.0057 \text{ g/cm}^2/\text{yr}$ ). For comparison, standard Dual Energy X-ray Absorptiometry (DXA) measurements of the spine or hip have a precision error equal to about 1 to 2 times the annual rate of loss in a reference population. Bone loss rates may be higher for individual patients immediately after menopause.

From the absolute precision error, the magnitude of the minimum change which can be determined with 95% confidence can be calculated:

$$\text{min. significant change (95\% conf.)} = 1.96 \times 1.414 \times 0.014 \text{ g/cm}^2 = 0.0388 \text{ g/cm}^2$$

This minimum significant change corresponds to about 7% of the mean BMD value for a 55 year old caucasian female. This amount of change is approximately what might be expected after 2 to 3 years of therapy with commonly available treatments. Some patients will have larger BMD increases, and some will have smaller increases, and therefore follow-up time will depend on the patient's individual clinical situation. Changes of this order of magnitude may also be expected in as little as 6 months to a year for patients treated for a variety of conditions such as hyper-parathyroidism and hyper-thyroidism, and may also be observed for patients treated with corticosteroids.

#### **4** *Patient Measurement*



## 5

## Comparison of Patient Results to Reference Values

This chapter describes standard terminology used for comparison of patient results to reference ranges and the reference ranges supplied with the Sahara Clinical Bone Sonometer. The Sahara system provides age dependent reference values for Caucasian U.S. females. These reference values were obtained in a large multi-center study, in which Sahara results were obtained for 2208 Caucasian females at 9 clinical centers located across the U.S. For situations in which the Caucasian female reference values are not appropriate, Sahara also provides the capability of entering user defined young adult reference values, enabling automatic comparisons of patient results to these values if available. Guidelines for development, entry, and use of reference values for specific populations are described. It is also possible to disable the reporting of reference comparisons with the Sahara software, for those cases in which no appropriate reference data exists.

### Types of Reference Database Comparisons

In general, two kinds of comparisons to a reference database can be performed:

1. T-score comparison: T-score is defined as the difference in patient results from the mean results obtained in a young adult population, expressed in units of the young adult population standard deviation. Mathematically, the T-score is defined as:

$$T = (P-YA)/SD_{YA}$$

where P = patient results

YA = young adult average value

SD<sub>YA</sub> = standard deviation of the young adult population

2. Z-score comparison: Z-score is defined as the difference in patient results from the mean results obtained in an age-matched population, expressed in units of the age matched population standard deviation. Mathematically, the Z-score is defined as:

$$Z = (P-AM)/SD_{AM}$$

where P = patient results

AM = age-matched average value

SD<sub>AM</sub> = standard deviation of the age matched population

## Reference Database Comparisons Available with Sahara

T-score results are automatically calculated (unless disabled by the user) and reported with patient Estimated BMD on the LCD display. T-score results similarly included on the printout obtained by pressing the **Print/Feed** button.

Z-score results may estimated using the Patient Report Forms, as described below, or may be calculated manually by the operator using the equation above and the age dependent reference data. When using the Patient Report Forms, estimated Z-scores are based on a Caucasian female population.

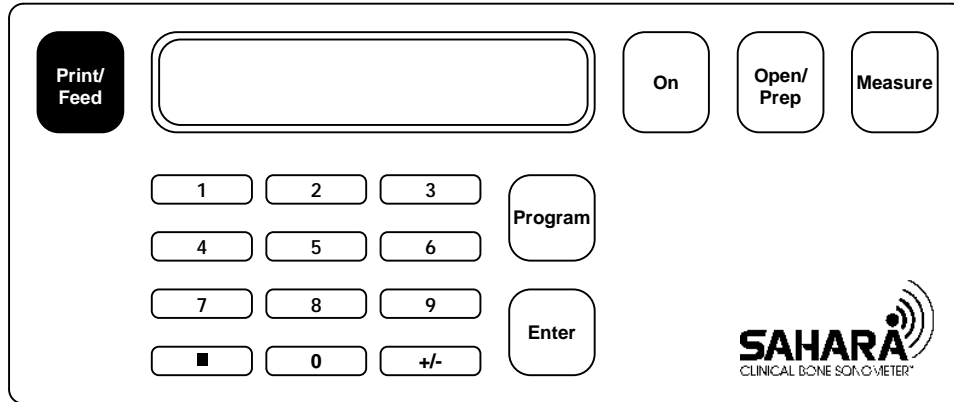
## Reports

### Internal (Strip) Printer Report


Print each patient measurement immediately after it is taken (see the Patient Measurement chapter of this manual). The printed report shows the Estimated BMD and the T-score corresponding to the young adult mean and population standard deviation values. The operator adds the patient biography, referring physician, operator name, and foot measured (left or right) information to the printed report.

The printed report is obtained by pressing the **PRINT/FEED** button on the Sahara control panel. Note that the printed report will include the QUI, BUA, and SOS results as well as the Est. BMD results if the **PRINT/FEED** button is pressed when the ultrasound parameters are displayed on the LCD screen.

Figure 5-1  
Press PRINT



Patient biography data (name, sex, age, etc.) should be noted on the printed report immediately after the exam. Remember to indicate the foot measured (Left or Right). The printed report will have date and time of the exam.

  
**HOLOGIC**

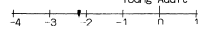
Date 8/04/1997 Time 11:22  
 Serial No: 87

Name \_\_\_\_\_  
 Sex: M F  
 ID# \_\_\_\_\_  
 Ethnicity \_\_\_\_\_  
 DOB \_\_\_\_\_ Age \_\_\_\_\_  
 Foot: L R

Est Heel BMD: 0.340 g/cm<sup>2</sup>  
 T-Score: -2.2

Estimated Heel BMD T-Score

Young Adult




## Patient Report Form

A tablet of Patient Report Forms is included with each Sahara system. This form is provided to record patient information and measurement results, and to allow patient results to be graphically plotted against age dependent US Caucasian female reference values.

1. Fill in the biographical information for the patient in the spaces provided.
2. Enter the results of the measurement (Est. BMD and T-score) as reported on the LCD screen.
3. Staple the printout from the internal strip printer to the Report Form where indicated to provide a permanent record of results and to insure that no transcription errors were made.
4. Plot the patient result on the graph of the age dependent reference values and estimate the corresponding Z-score for the patient as described below.
5. Record the estimated Z-score on the form.

## Estimating the Z-score and Plotting Patient Results vs. Age Dependent Reference Values:


Z-scores can be manually computed, using the age-dependent reference ranges given in this section of the User's Guide, and can be estimated from the Patient Report Form as follows:

- Mark the plot at the point corresponding to the age and Est. BMD value for the patient
- The curves shown on the plot correspond to the mean BMD vs. age (middle curve), and 1 and 2 population standard deviations above the mean and below the mean (curves above and below the middle curve).
- If a patient's result falls exactly on the middle curve, the Z-score is 0.0, and the patient's Est. BMD is equal to the mean value for Caucasian female subjects of the same age.
- If the patient's result falls exactly on the upper-most curve, the Z-score is +2.0, because it is 2 standard deviations above the age matched mean (middle curve).
- Similarly, if the patient's result falls midway between the lower-most and next to lower-most curve, the Z-score is -1.5, because it is 1.5 standard deviations below the age matched mean (middle curve).

By this method, the patient's Z-score can be estimated graphically, allowing their results to be interpreted both in comparison to age-matched peers (Z-score) as well as to Young Adult subjects (T-score).

Figure 5-2  
Patient Report Form

### PATIENT REPORT FORM



Patient Name: JANE DOE Exam Date: AUG 4, 1997

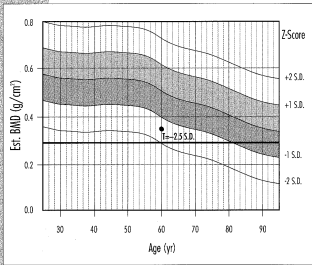
ID#: 999-99-9999 Study: BASELINE EXAM Sex: M

DOB: DEC. 14, 1936 Age at Menopause: 55 Age: 60


Height: 5' 3" Weight: 129 Operator: XX

Ethnic: CAUCASIAN Foot Measur: R Physician: JONES

**RESULTS**



Remarks: BMD = 0.340 g/cm<sup>2</sup>  
T<sub>a</sub> = -2.2



Date: 8/04/1997 Time: 11:28  
Serial No: 87

Name: JANE DOE  
Sex: M   
ID#: 999-99-9999  
Ethnicity: CAUCASIAN  
DOB: 12/14/36 Age: 60  
Foot: L


Est. Heel BMD: 0.340 g/cm<sup>2</sup>  
T-Score: -2.2 ^

Est. (netted) Heel BMD T-Score ^  
Young Adult

-4 -3 -2 -1 0 1

^ T-Score based on US Caucasian female reference data

Reference data based on USA Caucasian Women



## Sahara Caucasian Female Reference Database

### Study Overview

The Sahara Reference Data and Normative Ranges Study was designed to acquire data from which age dependent reference values for Caucasian American females could be derived. These reference ranges are based on Sahara results for 2208 Caucasian female subjects from ages 19 to 97, who were recruited at 9 clinical sites, located across the United States. The large number of clinical sites and subjects enrolled allows for maximum confidence in the reference ranges obtained and also reduces the possibility of regional bias. This reference data study is unique in that the number of subjects and clinical sites are significantly larger than that of typical manufacturer sponsored reference data studies for bone densitometry equipment.

Sahara results were obtained for each subject enrolled in the study, as was information regarding medical conditions and therapeutic regimens that may have an effect on bone mineral metabolism. This information allowed the effects of including or excluding these subjects to be evaluated statistically. The study was unique in that even after excluding all subjects with these conditions or treatments, the number of subjects is still larger than that of most typical bone densitometry reference data sets.

#### Clinical Sites for the Sahara Reference Data Study

	State	City	Site Name	# Subjects
1	DE	Wilmington	Alfred duPont Institute	291
2	MA	Worcester	U. Mass. Medical Ctr.	473
3	MO	St. Louis	Washington Univ.	26
4	NY	Manhasset	North Shore Univ. Hosp.	254
5	PA	Philadelphia	Presbyterian Medical Ctr.	78
6	TN	Memphis	Univ. of Tennessee	211
7	UT	Salt Lake City	Univ. of Utah	98
8	VT	Burlington	Univ. of Vermont	383
9	WA	Seattle	Pacific Medical Ctr.	394

## Reference Data Ranges for the Sahara Clinical Bone Sonometer

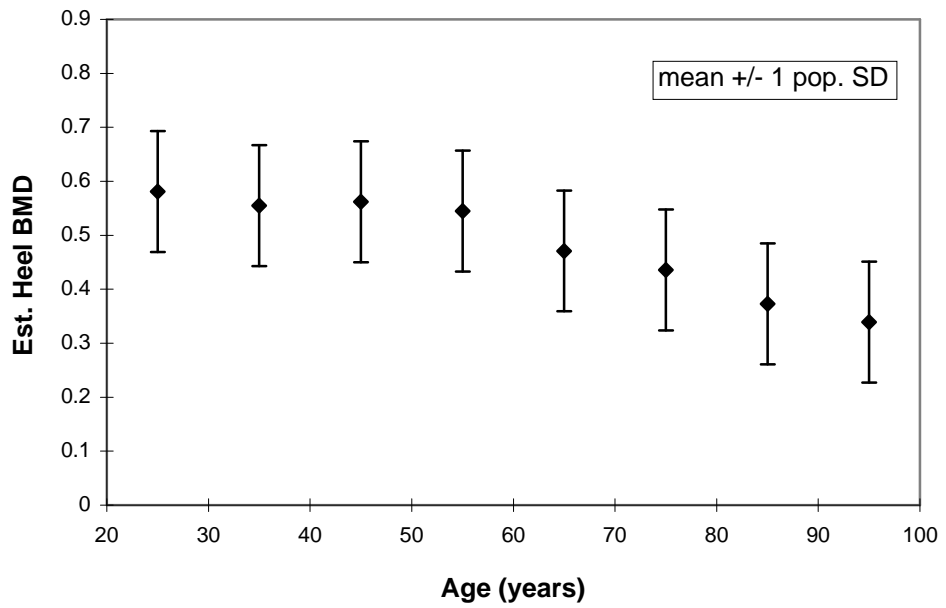
The Sahara study data was analyzed by computing the mean values, standard deviations, and percentiles on a decade by decade basis. Statistical testing demonstrated that the population standard deviation was age independent, and that the percentiles described a normal distribution within statistical limits. Statistical testing indicated that the effect of excluding subjects with conditions/medications which may effect bone metabolism was negligibly small. Thus the final reference ranges were based on all 2208 enrolled subjects, and consist of the decade specific mean values and the mean (from all the subjects pooled) population Standard Deviation.

The resultant reference ranges implemented into the Sahara system are tabulated, where the mean and population standard deviation are given for each decade. Note that for ages between those in the table, reference mean values are obtained by linearly interpolating between the values in the table. The population standard deviation is constant and is not interpolated. Age dependent reference ranges were similarly analyzed and developed for the raw ultrasound parameters reported by the Sahara system, including Broadband Ultrasonic Attenuation (BUA), Speed of Sound (SOS), and Quantitative Ultrasound Index (QUI/Stiffness). These reference values are also tabulated below.

Sahara Estimated Heel BMD Reference Data vs. Age

Age (yrs)	Est. Heel BMD (g/cm <sup>2</sup> )	Standard Deviation (g/cm <sup>2</sup> )
25	0.581	0.112
35	0.555	0.112
45	0.562	0.112
55	0.545	0.112
65	0.471	0.112
75	0.436	0.112
85	0.373	0.112
95	0.339	0.112

### Sahara Reference Data vs. Age



Reference Data vs. Age for Sahara Ultrasound Parameters

Age (yrs)	Mean Value (population SD)		
	QUI/Stiffness	BUA (dB/MHz)	SOS (m/sec)
25	103.92 (17.65)	76.71 (14.80)	1569.4 (30.43)
35	99.88 (17.65)	74.82 (14.80)	1561.4 (30.43)
45	100.88 (17.65)	75.89 (14.80)	1562.7 (30.43)
55	98.19 (17.65)	74.13 (14.80)	1558.1 (30.43)
65	86.53 (17.65)	65.02 (14.80)	1538.7 (30.43)
75	80.98 (17.65)	59.81 (14.80)	1530.4 (30.43)
85	71.06 (17.65)	51.53 (14.80)	1514.5 (30.43)
95	65.65 (17.65)	49.82 (14.80)	1503.0 (30.43)



## Modify Young Adult Estimated BMD Reference Values (optional)

Young adult reference values for Estimated Heel BMD are supplied automatically with each Sahara system. These young adult reference values are specific to United States Caucasian female subjects, and are used by the Sahara system to compute T-score results for each patient measurement. T-score results are reported on the LCD screen and on the paper strip report along with the Estimated Heel BMD.

If a Caucasian female population is not appropriate for the subjects to be assessed, it is possible to enter locally derived young adult reference values into the Sahara system. Once entered into the system, these local, user defined reference values will then automatically be used to compute T-score results for subsequent patient measurements. It is also possible to disable the T-score calculation, if the US Caucasian female population is not appropriate and local reference values are not available. To disable the T-score calculation, enter 0.0 for both the Young Adult Mean Value and the Young Adult Population SD in the procedure described below. Once disabled, the T-score will not appear on the LCD screen or on the paper strip printout.

**NOTE:** If the young adult reference values have been modified from the original (factory set) Caucasian female values, the “T-score based on US Caucasian female reference data” annotation at the bottom of the paper strip printout will no longer appear. This annotation will re-appear if the reference values are re-set to the US Caucasian reference values as given in the procedure below and in Section 5 of this User’s Guide.

If local young adult reference values are available, and comparison of patient results to these values is desired, manually enter the young adult reference values into the Sahara system following the procedure below. (Guidelines for development of reference values are described in the next section.)

To set the young adult reference values in your Sahara system, follow the procedure below:

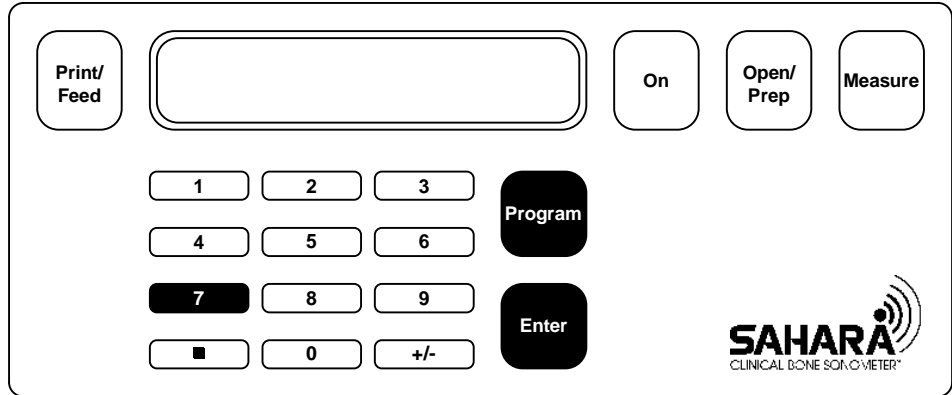
1. Press **ON**. The Control Panel Screen displays the following:



2. Press **PROGRAM, 7, ENTER**.

5 Comparison of Patient Results to a Reference Database

Figure 5-3  
Press PROGRAM, 7,  
ENTER



- The Control Panel Screen displays the previously set young adult BMD reference mean. (Note that 0.581 is the US Caucasian female reference value, and 0.112 is the US Caucasian female population standard deviation.)

YAdlt BMD Mean=0.581  
1) Change 2) Exit

- If you do not wish to change the young adult reference mean, press **2**.
- If you want to set a new young adult reference mean, set the correct mean as follows:
- Press **1**. The Control Panel Screen displays the following:

YAdlt BMD Mean=0.581  
New Value= 0

- Insert the young adult BMD reference mean, then press ENTER. (0.581 is the US Caucasian female reference value, and entering 0.0 disables the T-score calculation.) The Control Panel Screen then displays the previously set young adult population standard deviation:

YAdlt BMD SD=0.112  
1) Change 2) Exit

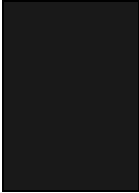
- If you do not wish to change the young adult BMD reference standard deviation, press **2**.

9. If you want to set a new young adult BMD reference standard deviation, proceed as follows:
10. Press **1**. The Control Panel Screen displays the following:

YAdlt BMD SD=0.112  
New Value= 0

11. Insert the young adult BMD reference standard deviation, then press ENTER. (0.112 is the US Caucasian female population standard deviation, and entering 0.0 disables the T-score calculation).
12. Repeat steps 3-10 to modify the young adult reference values for the QUI parameter, if desired. The US Caucasian female reference values for QUI are: mean = 103.9, SD = 17.6. The Control Panel Screen displays the following:

Gel Pads  
Press OPEN



## Development and Use of Reference Data Ranges for Specific Patient Populations

The instructions given in the previous section describe how to enter user defined young adult reference ranges for populations other than US Caucasian females. These young adult reference values are used to calculate T-scores, which are reported on the LCD display and on the strip paper printout obtained by pressing the PRINT/FEED button on the keypad. Age dependent reference ranges for Caucasian females are also supplied with Sahara, as shown on the Patient Report Form, from which Z-scores are estimated. In this section, guidelines for development of young adult and age dependent reference values for other populations (such as males, or non-Caucasian females) are described.

Reference values for specific populations can either be obtained from published scientific literature, or alternatively, may be developed by the physician. When using reference values obtained from published scientific literature, it is important to verify that the population studied is applicable to the patients that you will be evaluating, and that the guidelines described below have been followed in the published study.

### Guidelines for Development and Use of Young Adult Reference Values:

A minimum of 50 subjects between the ages of 20 and 30 years should be recruited randomly from the target population. A single Sahara measurement should be performed on each subject. If the Sahara result is marked by an asterisk (indicating unreliable ultrasound results as described in Chapter 4, Patient Measurement), the patient should be repositioned and the measurement should be repeated. If the second measurement also is marked by an asterisk, the patient's results should not be used for the development of the reference values, and an additional subject should be recruited. If the second measurement is not marked by an asterisk, then it is acceptable to include the second result in the calculation of young adult reference values. For each subject, press the +/- key on the keypad prior to pressing the PRINT/FEED key, in order to get a hardcopy printout that includes all of the ultrasound parameters.

Results for the 50 subjects should be analyzed to determine the mean (or average) value and the population standard deviation (SD) value for each Sahara output parameter (Est. BMD, QUI, BUA, and SOS). The mean value and standard deviation can be computed using most hand-held scientific calculators, and does not require sophisticated computer software.

Check that the SD value for the Est. BMD is in the range of 0.070 to 0.150 g/cm.<sup>2</sup> If the SD is not in this range, it is possible that an error was made in the calculation of the SD. Check that the mean value for the Est. BMD is in the range of 0.400 to 0.700 g/cm.<sup>2</sup> If the mean value is not in this range, it is possible that an error was made in the calculation

of the mean. Note that any values may be entered into the Sahara system for the mean and SD, and there may be populations for which values outside of these ranges are valid, but most populations should have values that fall in these ranges.

Enter the mean and population SD values into the Sahara system using the procedure described in the preceding section. For the first patient evaluated, perform the T-score calculation manually using the equation given earlier in this chapter (see *Types of Reference Data Comparisons*), in order to check that the mean and population SD were entered properly.

### **Guidelines for Development and Use of Age Dependent Reference Values:**

A minimum of 50 subjects for each decade of age should be recruited randomly from the target population. A single Sahara measurement should be performed on each subject. If the Sahara result is marked by an asterisk (indicating unreliable ultrasound results as described in Chapter 4, Patient Measurement), the patient should be repositioned and the measurement should be repeated. If the second measurement also is marked by an asterisk, the patient's results should not be used for the development of the reference values, and an additional subject should be recruited. If the second measurement is not marked by an asterisk, then it is acceptable to include the second result in the calculation of young adult reference values. For each subject, press the +/- key on the keypad prior to pressing the PRINT/FEED key, in order to get a hardcopy printout that includes all of the ultrasound parameters.

Results for the subjects in each decade of age should be analyzed independently to determine the mean (or average) value and the population standard deviation (SD) value for each Sahara output parameter (Est. BMD, QUI, BUA, and SOS). The mean value and standard deviation can be computed using most hand-held scientific calculators, and does not require sophisticated computer software.

Check that for the 20 - 30 year age group the SD value for the Est. BMD is in the range of 0.070 to 0.150 g/cm.<sup>2</sup> If the SD is not in this range, it is possible that an error was made in the calculation of the SD. Check that for the 20 - 30 year group the mean value for the Est. BMD is in the range of 0.400 to 0.700 g/cm.<sup>2</sup> If the mean value is not in this range, it is possible that an error was made in the calculation of the mean. Note that any values may be entered into the Sahara system for the mean and SD, and there may be populations for which values outside of these ranges are valid, but most populations should have values that fall in these ranges.

Z-scores may be obtained either graphically, by generating a reference data plot similar to the one on the Sahara Patient Report Form, or using the equation for Z-score given earlier in this chapter (see *Types of Reference Data Comparisons*). The results for each of the decade averages correspond to the results at the middle of the decade, i.e., the results for the 20 - 30 year decade correspond to the results for age = 25. The decade by decade

## **5** *Comparison of Patient Results to a Reference Database*

results therefore correspond to values for ages 25, 35, 45, etc. For ages in between these, the reference values are obtained by linear interpolation. Thus the reference value for age = 50 is the average of the age 45 and 55 values.

6

## System Care and Maintenance

This chapter describes care and maintenance procedures on the Sahara Clinical Bone Sonometer. It covers ordering supplies, cleaning the unit, printer maintenance, transducer pad care and maintenance, and what to do if a problem occurs.

### Ordering Supplies

To order Sahara Ultrasound Coupling Gel, towelettes, dry wipes, Examination paper, printer paper, or other supplies for the Sahara system:

International customers should contact their authorized Hologic distributor.

USA customers may complete a reorder card or call Hologic at (800) 321-4659.

### Cleaning and Re-Use

The Sahara Clinical Bone Sonometer is a reusable device and is considered a noncritical device for infection control practices. The transducer pads, foot well, control panel, positioning aide and rest of the scanner are the surfaces of the Sahara unit that may be cleaned between use.

### How Supplied

Towelettes and dry wipes are supplied with the Sahara system for cleaning of gel from the transducer pads, phantom, and patient. The towelettes supplied are standard baby-wipes, which are a commonly available over the counter product. Additional towelettes may be purchased either from Hologic, or at any local pharmacy or supermarket. The dry wipes supplied (Kim-wipes®, manufactured by Kimberly-Clark) are a standard product, commonly available from medical supplies dealers and medical supplies catalogs. Additional dry wipes may be ordered from Hologic, or purchased through your medical supplies dealer or catalog. It is acceptable to substitute other equivalent brands of dry wipes,

if Kim-wipes® are not available, but it is NOT acceptable to use facial tissues, which can leave residues and particles on the transducer pads.

## Infection Control

Hologic recommends the use of Cavicide® disinfecting cleaner to clean the Sahara unit's surfaces between use. Cavicide<sup>1</sup> is a disinfecting cleaner that destroys pathogens and other microorganisms. Cavicide is available by contacting the Metrex Research Corporation, IL {phone# (800) 841-1428}.

The chemical composition of Cavicide is:

Active Ingredients:	
<i>Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride</i>	0.25%
<i>Isopropanol</i>	15.30%
Inert Ingredients	84.45%
	-----
Total	100%

Cavicide has been tested on inanimate surfaces against:

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Mycobacterium tuberculosis var: bovis (BCG)
- Methicillin Resistant Staphylococcus aureus (MRSA)
- Vancomycin Resistant Enterococcus faecalis (VRE)
- Trichophyton mentagrophytes
- Herpes simplex virus types 1 and 2
- Human Immunodeficiency Virus (HIV-1)
- Poliovirus types 1 and 2
- Coxsackievirus

<sup>1</sup> EPA Reg No.: 38526-1. EPA Est. No.: 39234-WV-1



## Cleaning Frequency

The transducer pads and foot well should be cleaned *after each patient or phantom measurement*. The rest of the scanner and positioning aide may be cleaned *as necessary*.

## How to Clean/Disinfect the Sahara Unit

### Cleaning

Remove all coupling gel first from transducer pads, after each patient or phantom measurement by wiping the surface with the towelettes or dry wipes supplied with the Sahara unit. Spray Cavicide disinfectant cleaner on transducer pads, foot well, positioning aide, and other scanner surfaces as necessary. Wipe clean using the towelette or dry wipes. Discard the used towelette or dry wipe.

### Disinfecting

Remove all coupling gel first from transducer pads, after each patient or phantom measurement by wiping the surface with the towelettes or dry wipes supplied with the Sahara unit. Spray Cavicide disinfectant cleaner on transducer pads, foot well, positioning aide, and other scanner surfaces as necessary. Allow to remain wet for 3 minutes at room temperature. Follow by wiping clean with the towelette or dry wipe. Discard the used towelette or dry wipe.

### Additional Measures

As an additional precautionary measure, exam paper should be placed under the patient's foot on the Sahara unit, during use, to provide a physical barrier against possible soiling or contamination. Exam paper should be discarded after every single patient measurement.

### Alternate Practices

If another disinfectant cleaner provides the same level of protection as Cavicide, the customer, at their own discretion, may clean the Sahara unit's surfaces with an alternate product.

Always clean any gel thoroughly off the exterior of the scanner with a towelette. Pay careful attention to ensure that the foot well and control panel are clean. Also, clean the rest of the scanner and positioning aid as necessary.



## Care and Maintenance of Transducer Pads

**Warning:** *The Sahara system must be calibrated after removing or replacing transducer pads. Therefore it is important not to remove the transducer pads unless necessary. If the transducer pads become damaged and do need to be removed or replaced, it is imperative that the instructions below be carefully followed to ensure proper system performance. Never store the phantom in the unit footwell with the pads closed on it, as this will destroy both the pads and the phantom.*

### Care of Transducer Pads

Transducer pads should be cleaned, removing all coupling gel, after each patient or phantom measurement as specified in the measurement procedures in this manual. Use the towelettes supplied with the Sahara system to remove gel from the pads, and then the dry wipes (supplied) to dry the pads.

*Note: When cleaning the transducer pads, it is acceptable to substitute other equivalent brands of dry wipes if Kim-wipes® are not available, but it is NOT acceptable to use facial tissues, which can leave residues and particles on the transducer pads that could degrade system performance.*

Rubbing alcohol may also be used to remove built-up dirt or stains on the pads, followed by wiping with towelettes and dry wipes. Do not remove the pads from the unit to clean dirt or stains.

Do not touch the transducer pads with any sharp objects, as cuts or tears in the pads will effect system performance. Replace torn, cut, or damaged pads immediately following the procedures described below.

Inspect the pads occasionally, looking especially at the surfaces that contact the heel. Replace pads if there is damage (pitting, tears, cuts) to these surfaces.

### Transducer Pad Discoloration

The transducer pads will discolor to a dark red, purple, or black if left in contact with the phantom supplied with the instrument. Customers are alerted to this fact in the Clinical User's Guide in several places. If the phantom and transducer pads are left in contact with one another for an extended period, discoloration of the pads may occur. Minor discoloration, particularly on the edges of the pads, has no impact on the performance of the machine. In the event of major discoloration of the pad faces, it may be necessary to replace both the pads and phantom. If QC continues to pass after discoloration occurs, the discoloration is merely cosmetic. If, however, QC failures occur at the same time

major discoloration is noticed, the pads require replacement and the instrument must be recalibrated. Additionally, check the phantom for deformity in the area of pad/phantom interface. If the phantom is noticeably deformed, a new phantom is necessary.

Transducer pads will slowly and evenly turn yellow over the course of several months. This is due to UV (ultraviolet) degradation of the surface of the pads and does not affect the instrument's performance.

## Removal/Replacement of Transducer Pads

**Note:** *Transducer pads must always be replaced in pairs. Do not replace one pad without replacing the other.*

Transducer pads may be removed, cleaned, and re-installed if they are excessively dirty. Follow the procedure for replacing the pads below, re-installing the same pads (after cleaning with towelettes and dry wipes) rather than installing new pads.

If one or both transducer pads has become damaged (cut, torn, or has become pitted) replace both transducer pads following carefully the procedure below. This procedure includes system re-calibration, which must be performed any time the pads have been removed or replaced.

1. Unscrew the transducer pad housing (see the figure below).

**Figure 6-1**  
Remove Transducer Pad  
Housing



2. Clean the transducer face (see figure below) with towelettes and dry wipes, making sure not to leave any residual coupling gel on the transducer face.

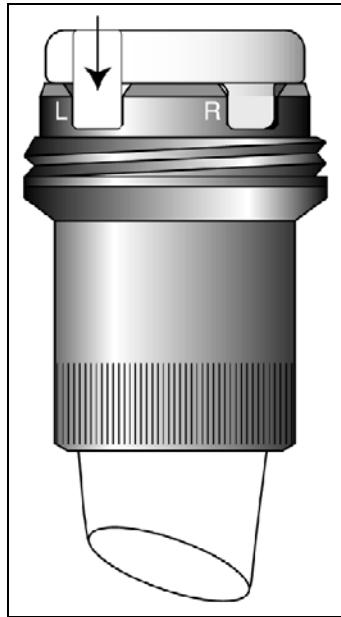
**Figure 6-2**  
*Cleaning Transducer  
Face*



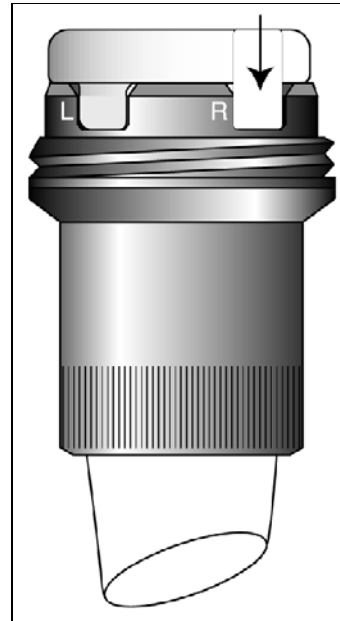
3. Locate the bag containing the replacement transducer pads and remove one pad. Clean the new pad with towelettes, and dry with dry wipes to remove any dirt, lint, etc. Visually inspect the pad, looking for tears or cuts in the surface, especially the ends of the pad.
4. Place the pad in the housing making sure the key, on the pad, is aligned to the correct slot (see the figures below). Pull on the end contacting the heel to finish seating and aligning the pad.

The figures below shows how to align the left and right transducer pads:

**Figure 6-4**  
Left Transducer Pad  
Alignment



**Figure 6-3**  
Right Transducer Pad  
Alignment



5. Apply Hologic Sahara Pad Installation Gel, which is included in the pad replacement kit, to the flat end of the pad before positioning it in place in the system. Spread the gel evenly with your finger so that there is about a 1/16 inch (1.6 mm) coating on the pad. Be careful not to introduce air bubbles, dirt or other contaminants (see the figure below).

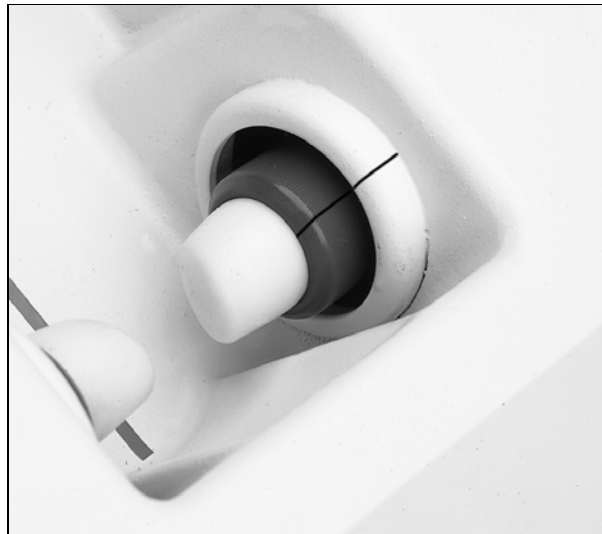


**Figure 6-5**  
*Pad Gel Application*



6. With gel applied, screw the housing/pad onto the transducer as far as it will go. The guide mark on the Sahara enclosure should line up with the mark on the transducer housing (see the figure below). Repeat steps 1-6 for the other transducer pad.

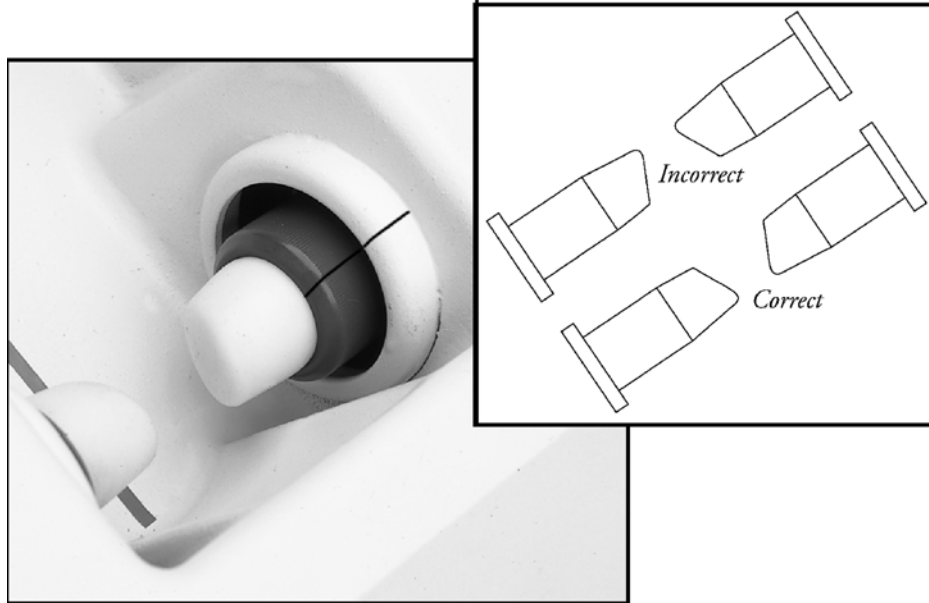
**Figure 6-6**  
*Pad Guide Marks*



7. With both pads installed, the system should look like the figure below (note the position of the leading edge of the transducer pads). If the pads are not correctly

installed, remove them, clean all surfaces including transducer face with a no-lint tissue, and repeat the procedure from the beginning.

**Figure 6-7**  
Pads Installed Correctly



## Calibrate System

The Sahara system must be calibrated after removing/replacing transducer pads. Follow the procedure below.

## System Calibration

Each Sahara is supplied with a QC phantom which can also be used to calibrate the system.

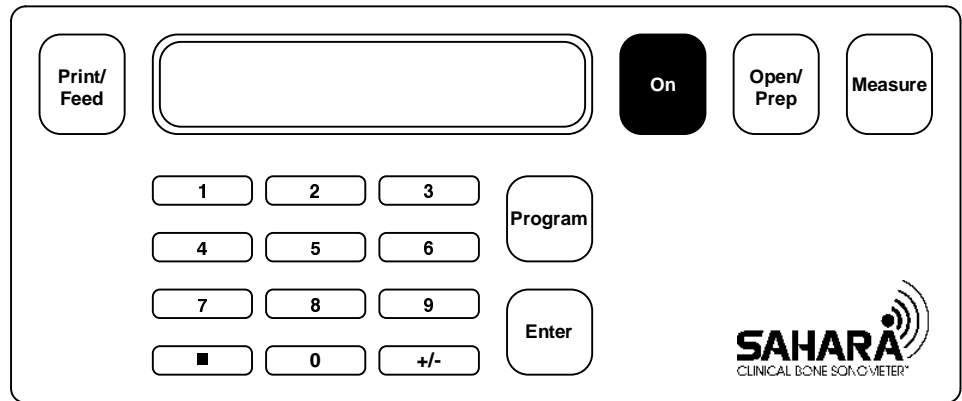
System calibration is not usually necessary unless the transducer pads are removed, or a malfunction has occurred requiring service. To perform system calibration, follow the procedure below.

**Note:** *It is important that the system and phantom have equilibrated to room temperature for at least one hour before performing this procedure.*

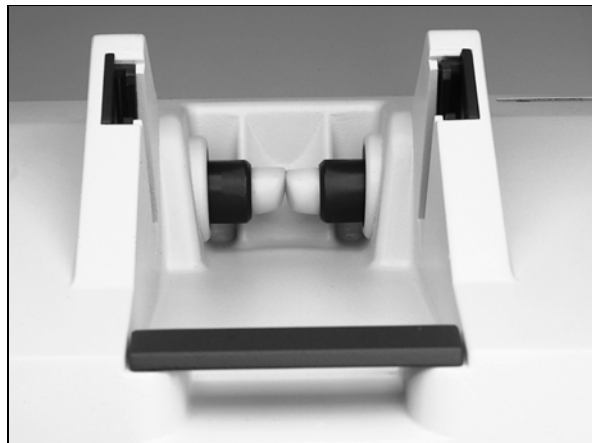
6 System Care and Maintenance

1. Press the **ON** button. The system initializes itself and closes the transducer pads until they touch, and then opens them for gel application.

**Figure 6-8**  
Press ON



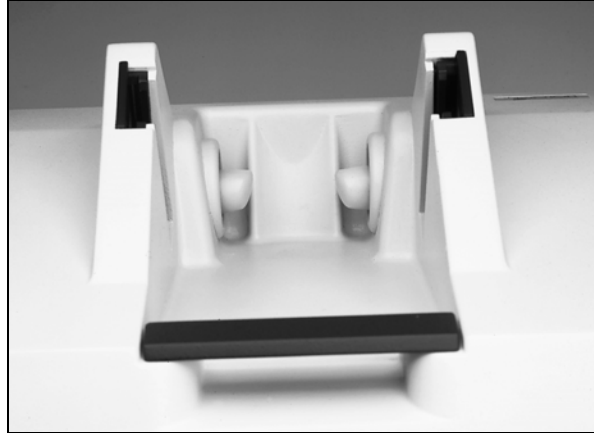
**Figure 6-9**  
Transducer Pads Touch



**6-10** SAHARA Clinical Bone Sonometer



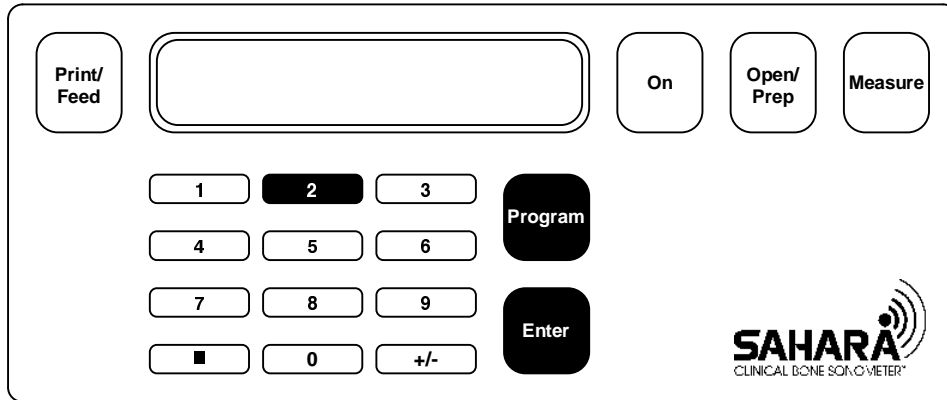
**Figure 6-10**  
Transducer Pads Ready  
for Gel



**Note:** If there is no operator action within ten minutes after ON is pressed, the unit goes to Power Saver Mode (the screen goes blank). Press the ON key to return to the last screen.

2. Press the **PROGRAM** button, then the **2** button and then **ENTER** on the control panel. This initiates calibration of the system.

**Figure 6-11**  
Press **PROGRAM**, **2**,  
**ENTER**



The Control Panel Screen displays the following message:



CAUTION - Enter calib procedure? 1) Yes 2) No

3. Press **1** to start calibration (if 2 is pressed the system will return to the “Gel Pads - Press OPEN” screen).

*Note: The phantom should not be in place at this point.*

The Control Panel Screen displays the following message:

Calib takes 15 min  
Continue? 1) Yes 2) No

4. Press **1** to continue calibration (if 2 is pressed the system will return to the “Gel Pads - Press OPEN” screen). The Control Panel Screen displays the following message:

Phantom Label  
BUA= 0\_\_\_\_\_

5. Enter the BUA number from the phantom label, and press **ENTER**. The Control Panel Screen displays the following message:

Phantom Label  
SOS= 0\_\_\_\_\_

6. Enter the SOS number from the phantom label, and press **ENTER**. The Control Panel Screen displays the following message:

Phantom Label  
Width= 0\_\_\_\_\_

7. Enter the width number from the phantom label, and press **ENTER**. The Control Panel Screen displays the following message:

Phantom Label  
S/N= 0\_\_\_\_\_

8. Enter the serial number from the phantom label, and press **ENTER**. The Control Panel Screen displays the following message:

[1 of 5] Gel pads  
2) Press OPEN

9. For each transducer pad, squeeze out about a one inch (2.5 cm) bead of gel onto finger (see the figure below).

**Note:** Do not use a Q-Tip, examination glove containing talc, or any other applicator that may introduce fibers or other foreign matter.

**Figure 6-12**  
Measure Gel



10. Apply gel to the transducer pad. Cover the entire surface area of the pad making sure that the leading edge of the pad is covered (see the figure below).

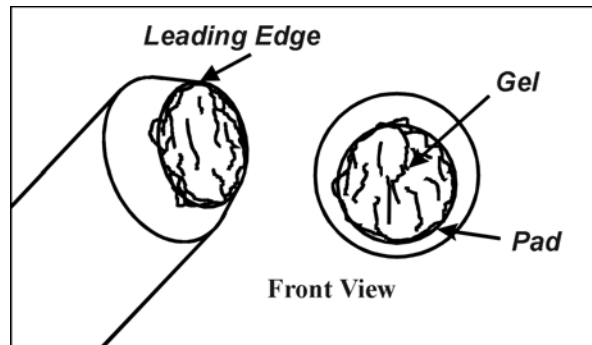
**Note:** It is important that the leading edge of the transducer pad is fully covered.



**Figure 6-13**  
*Apply Gel*

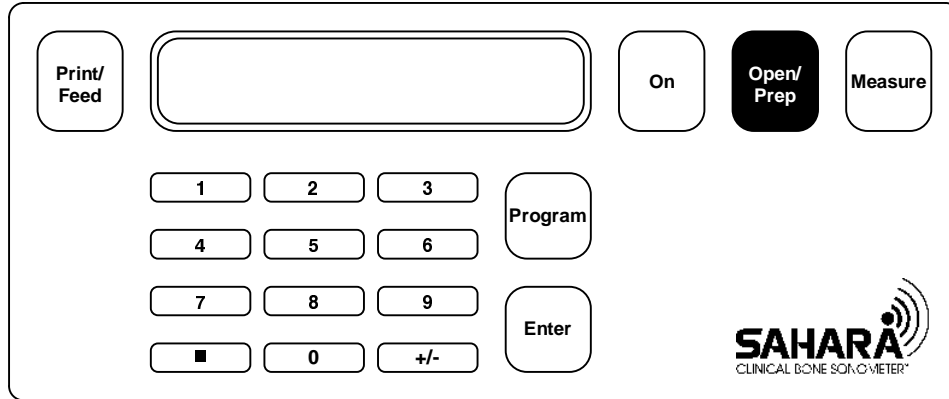


**Figure 6-14**  
*Gel Application*



11. When gel has been applied to both transducer pads press the **OPEN/PREP** button. The system opens the transducer pads to the fully open position.

**Figure 6-15**  
Press **OPEN/PREP**



- Place the QC phantom in the Sahara. Position the phantom so that its rounded end is snugly in the positioning contour (heel cup), and the flat side of the phantom is lying flat against the bottom of the system (see the figure below).

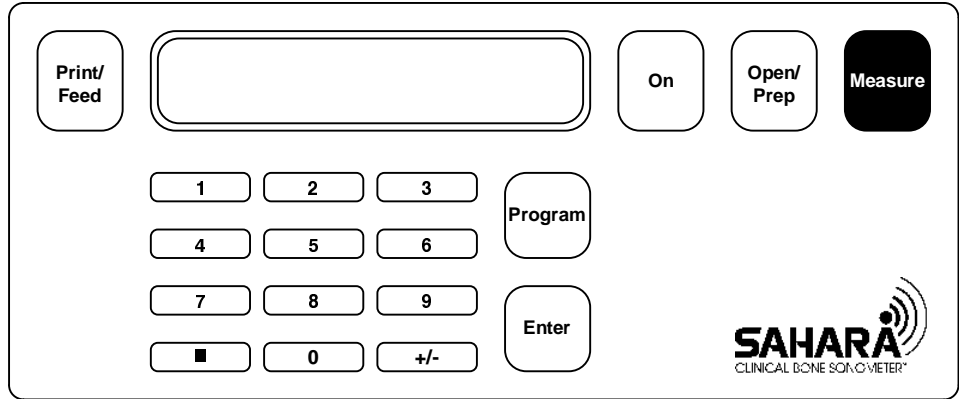
**Figure 6-16**  
QC Phantom in Position



- Press the **MEASURE** button. The system performs a measurement, then automatically opens the transducer pads.

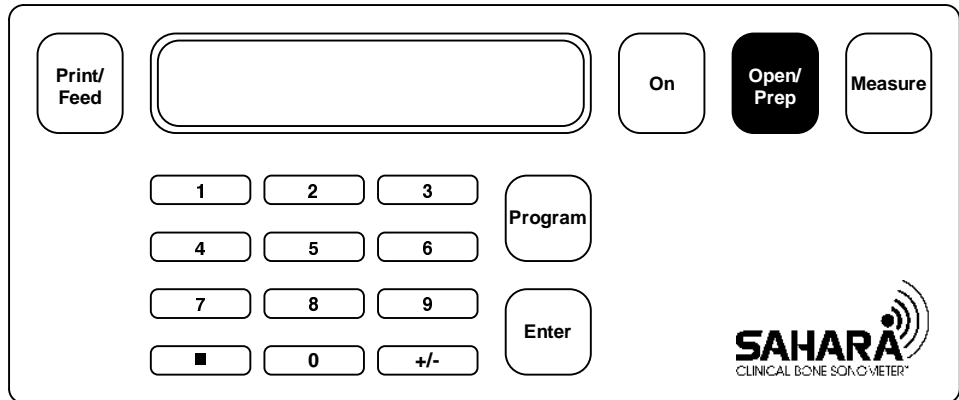


**Figure 6-17**  
Press **MEASURE**



14. Remove the phantom.
15. Press **OPEN/PREP**. The transducer pads return to the ready position.

**Figure 6-18**  
Press **OPEN/PREP**



16. Carefully clean and dry the phantom and the transducer pads. Use the towelettes supplied in the Accessories Kit to clean the phantom and transducer pads, and dry wipes to dry them.

**Note:** *It is important that the phantom and the transducer pads are thoroughly cleaned and dried after every pass of the calibration procedure.*

17. Press **ON**. The Control Panel Screen displays the following message:

[2 of 5] Gel pads  
2) Press OPEN

18. Repeat Steps 9 through 16 until all 5 passes of the calibration procedure are complete. The Control Panel Screen displays the following message at the completion of the procedure:

Calibration  
Successful

19. Press **ON**. This completes the calibration procedure. The device will print out the complete calibration records. Please save them for future reference.
20. Perform a QC measurement following the procedure in the chapter titled Quality Control in this manual.

## Calibration Failure

If the calibration procedure fails, the Control Panel Screen displays the following message:

Calibration Failed  
Please Repeat

If this occurs, the calibration has not been changed. Start the procedure over from the beginning. Repeat all steps carefully.

If the calibration procedure fails again, wait at least one hour for the phantom to stabilize at room temperature and repeat the procedure from the beginning. Repeat all steps carefully.

If the calibration procedure fails a third time, call your authorized Hologic service representative.



## Printer Operation

Follow the procedure below to load printer paper:

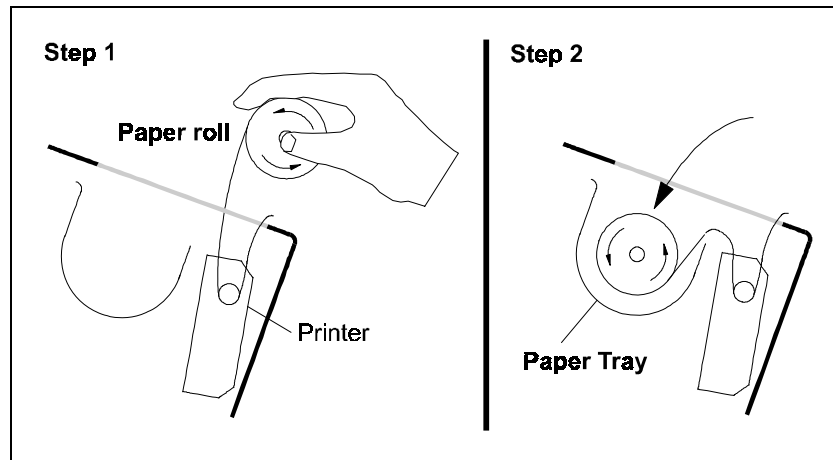
1. Remove the printer cover by sliding the cover towards the rear.

**Figure 6-19**  
Removing Printer Cover



2. Grasp the paper roll in your hand and feed the paper through the printer as shown in Step 1 of Figure 6-20 and Figure 6-21. Insert the paper into the paper slot where arrows indicate. The paper should feed from the underside of the roll.

**Figure 6-20**  
Threading Printer  
Paper





3. To feed the paper press the **PRINT/FEED** button while the display screen is displaying “Gel Pads press OPEN”.

**Figure 6-21**  
Feed Printer Paper



4. Place the paper roll into the printer tray. Insert the paper roll in the tray as shown in Figure 6-22 and Step 2 of Figure 6-20.

**Figure 6-22**  
Insert Paper Roll



5. Insert the paper through the slot in the printer cover and reinstall the cover.

**Note:** Never pull the paper (either forwards or backwards) through the printer. Always advance the paper using the Print/Feed button, and tear off using the cover slit.

**Figure 6-23**  
Printer Cover Replaced



## Display Serial Number

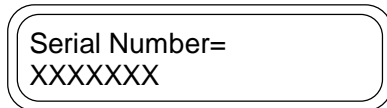
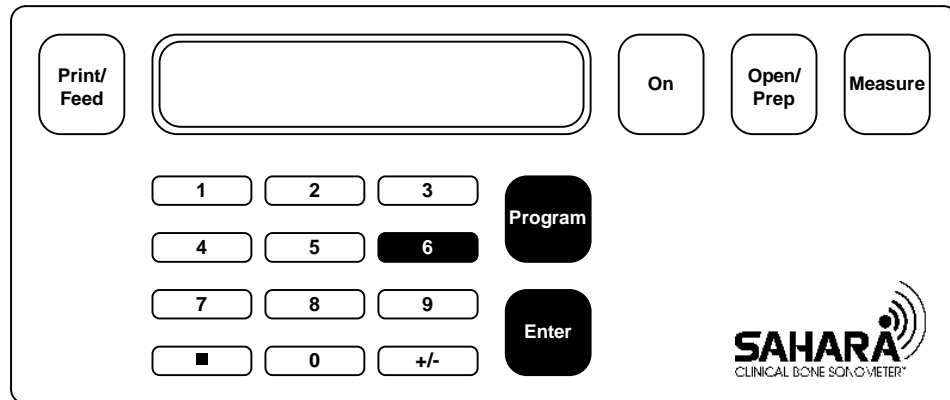
To display the unit's serial number from your Sahara system, follow the procedure below:

1. Press **ON**. The Control Panel Screen displays the following:



2. Press **PROGRAM, 6, ENTER**. The Control Panel Screen displays the serial number.

*Figure 6-24*  
Press **PROGRAM, 6,**  
**ENTER**



3. After the serial number displays briefly, the Control Panel Screen displays:



## What to do in Case of Trouble

This section provides information to assist the user in case something goes wrong with the system.

### Acquiring Results After a Paper Jam/Clearing a Printer Paper Jam

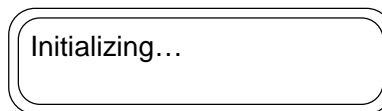
If any of the following printer problems occur:

- the printer paper jams, or
- the edge of the paper frays or tears, or
- the printer does not feed paper continuously,

stop further printing and perform the procedure below to obtain measurement results and clear the printer.

In the event of a printer jam, *before* unplugging the machine, follow the procedure described below in order to obtain the results.

1. Press ON, to clear the error message from the screen. The screen will display



2. Press the +/- key once. This will display the QUI and T-Score results from the measurement calculated before the printer jam. *Write these results down. Once the instrument is unplugged these results will be lost.*
3. Press the +/- key again. The BUA and SOS results will be displayed. Write these results down.
4. Unplug the unit.
5. Remove the printer cover from the machine (refer to *Printer Operation* in this chapter).
6. Remove as much paper as possible. Tweezers or long nose pliers may be necessary for this step. A straightened paper clip may be used if those tools are not available.
7. Clip off the end of the paper roll with scissors to obtain a straight edge.
8. Plug the unit back in. Refer to the section **Initial Set Up** to reload the paper.

## Printer Operates but Does Not Print

If this occurs, the printer paper may be installed backwards. The printer uses thermal paper that is coated on one side only. To correct this problem, carefully remove the roll of paper and reinstall correctly.

## Power Problem

If the screen does not display Version Number when power is applied, check the following:

- Is the power supply plugged into the system?
- Is the power cord plugged into the power supply?
- Is the power cord plugged into the wall outlet?
- Are you certain there is power at the wall outlet? If not, try another outlet.
- Is the power status light (small green light near the system power connector) on? If all of the above conditions are OK, and the power status light is off, there may be a problem with the power supply.
- Try unplugging the system from the wall outlet, waiting a few seconds, and plugging it in again. This causes the system to automatically run an internal diagnostic test which may clear the problem. If this does not clear the problem, contact your authorized Hologic service representative.

## System Malfunction and Error Log

There are extensive diagnostics embedded in the Sahara system to monitor the operating performance of the software, electronics and mechanical aspects of the product. When a malfunction occurs, the type of malfunction is automatically stored in an internal log and one of the following messages is displayed:

Power On Self Test:  
Failed

followed by:

Error Code=a  
Cat=b HiCat=c

Or:



Fault: Mid=a Pid=b  
Vid=c FC=d e

followed by:

XXXXXXXXXXXXXXXX  
YYYYYYYYYYYYYY

If this message is seen:

International customers should contact their authorized Hologic service representative.

US customers should contact Hologic Customer Service at (800) 321-4659.

The service department will ask you to print out an exception report. Make sure the unit is powered on and follow the procedure below to print an exception report.

## Printing the Exception Report

1. Press **ON** and wait for the pads to move apart.
2. Press **PROGRAM**.
3. Press **4**.
4. Press **2**.
5. Press **ENTER**.
6. Press **9**.
7. Press **3**.
8. Press **ENTER**.

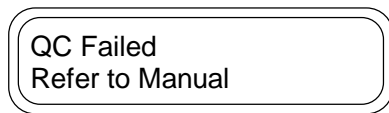
The printer will print an exception report (see example below):

<u>Exception Report</u>
Date: 8/22/96
Serial Number: 123456
FAULT: Mid=40 Pid=4 Vid=1 FC=7 FV=42 Invalid Msg - DataTask
ERROR: Code=0 Cat=24 HiCat=24
End of Exception Report

FAX this to your authorized Hologic service representative.

## Quality Control Problem

At the completion of the Quality Control procedure (using the QC phantom) the Control Panel Screen should display the word Passed. If the system fails this procedure the Control Panel Screen will display:



If, after trying the procedure twice, the system does not pass, check the following:

1. Is the small green light (near the scanner power connector) on? If all of the above conditions are OK, and the green power indicator light is off, there may be a problem with the power supply.
2. Try unplugging the system from the wall outlet and plugging it in again. This causes the system to automatically run an internal diagnostic test which may indicate or clear the problem.
3. Is the system (including the phantom) acclimated to room temperature? Temperature is the most likely cause of this problem. If you are not sure if the system (including the phantom) is acclimated to room temperature, wait at least one hour with the system on, then try again.
4. If the transducer pads have been removed or replaced, has the procedure been followed carefully (including calibration)? Check the procedure titled Removal/Replacement of Transducer Pads in this manual, and repeat it if necessary. Ensure that the pad couplant is spread evenly (about a 1/16 inch coating) on the flat

side of the pad. Ensure that the transducer housings are screwed in securely (so that the guide marks line up).

5. If the above does not fix the problem:

International customers should contact their authorized Hologic service representative.

US customers should contact Hologic Customer Service at (800) 321-4659.

## Patient Measurement Problems

### Asterisk after Estimated BMD result (Est. BMD = 0.500\* g/cm<sup>2</sup>)

An asterisk appearing after the Estimated BMD value, indicates that the Estimated BMD was calculated using the SOS data alone. The Estimated BMD is calculated from the SOS alone in those rare cases where the BUA data is considered unreliable due to the fact that the assumption of a linear attenuation vs. frequency relationship was not fulfilled. This condition is rare, occurring almost entirely in a small percentage of younger males and females with high bone density. On occasion, this condition may also be caused by improper foot positioning or not enough coupling gel. Therefore, if the measurement has an asterisk, it is recommended that the operator repeat the measurement. If the second measurement does not have an asterisk, it should be used and the first measurement deleted from the database. If the second measurement also has an asterisk, these results should be interpreted with caution, especially when used for patient monitoring.

### Invalid Measurement, Repeat

This error indicates that the unit could not make a proper measurement. Some possible causes of this error are:

- foot moved during measurement
- inadequate gel on pad tips
- no foot between the pads
- measured heel width outside of specified foot size range

If the patient's foot size is outside of the specified foot range (see Specifications in Chapter 1 of this User's Guide), the patient cannot be assessed with Sahara. Otherwise,



repeat the measurement. If, after three attempts to measure a patient the display still indicates REPEAT, contact your authorized Hologic service representative.

## Measurement Out-of-Range

This error indicates that the calculated SOS and/or BUA is outside the unit's measurement range. Some possible causes of this error are:

- inadequate gel on pad tips
- something between pads and foot (stockings on?)

Repeat the measurement. If, after three attempts to measure a patient the display still indicates REPEAT, contact your authorized Hologic service representative.



