STUDY OF OSTEOPOROTIC FRACTURES (V6)
Quantitative Ultrasound of Bone

Introduction/overview of ultrasound measurements in SOF

Bone mass explains 30-90% of the variance in bone strength determined in vitro. However, bone mass is not the only determinant of bone strength: the geometry and quality of bone play vital roles Current methods of assessing bone health are inadequate. Parfitt postulated that bones are weakened by accumulation of fatigue damage, including microscopic fractures, as bone ages. In support of this hypothesis, Parfitt observed that women with vertebral fractures had greater bone age than women without fractures who had similar degrees of osteopenia.

The strength of trabecular bone also depends on the number and integrity of connections between trabecular rods and plates. Loss of these connections (decreased "connectivity") accounts for about 40% of the decrease in trabecular bone mass with aging in women. For the same bone mass, the strength of trabecular bone will vary inversely with its connectivity.

Ultrasound may be a useful measure of both the quality and quantity of bone. Two quantitative ultrasonic measurements in particular, sound velocity and broadband ultrasonic attenuation (BUA), may correlate with bone fragility. Ultrasonic transmission velocity, or speed of sound (SOS), is related to both the mass density and modulus of elasticity of a substance. The elastic modulus of a material depends upon a number of physical properties, and is believed to reflect fatigue damage and the size and spatial orientation of bone microstructure. BUA is thought to measure the attenuation of sound energy from scattering and absorption for a spectrum of frequencies (typically 0.2-0.6 MHz), but the exact correlates of BUA in bone remain unclear. Both SOS and BUA measurements correlate with bone strength in vitro, but in vivo the two measurements are not highly correlated with BMD at other sites, nor are they highly correlated to each other.

SOF is the largest prospective study of QUS to date. Thus far we have demonstrated that low calcaneal QUS is associated with a variety of fractures in our cohort, and more importantly, QUS is strongly associated with the risk of future hip fractures. The relationship between QUS and hip fractures is similar to that observed with hip BMD.

Besides its potential for assessing bone quality, quantitative ultrasound has several practical advantages over densitometry: it is quicker, less expensive, entails no radiation exposure, and portable devices may soon be available. Both ultrasonic velocity and BUA measurement are sufficiently reproducible, generally 0.5-1.0% and 2-4%, respectively, for clinical applications. If ultrasound predicts hip and other types of fractures as well as measurements of bone mass, it would be the best approach to screening women to assess their risks of fracture.

We collected ultrasound data in SOF at V4 (calcaneal ultrasound using the Walker Sonix device) and V5 (calcaneal with the Walker Sonix and tibial with the Myriad device). At V6 we will only be measuring calcaneal ultrasound with a new dry (no water bath!) device, the Hologic Sarah. The advantages of this device include reduced scan time, improved precision, and best of all, no cold water!

Calcaneal Ultrasound

1. Equipment:

Quantitative ultrasound (QUS) measurements are carried out using Hologic Sahara. A matrix of 3x3 locations is measured and the final results are obtained by averaging of these 9 measurements which in turn are averages of signals obtained in the left-right and right-left ultrasound propagation directions.

The scanner allows for assessment of BUA as well as velocity parameters. BUA reflects the frequency dependence of ultrasound attenuation. Speed of Sound (SOS) measurements are also obtained with the Sahara, but Ultrasound Velocity through Bone (UVB), which was measured with the Walker Sonix devices is not. Lastly, the Sahara combines both BUA and SOS measurements into a single parameter called the Quantitative Ultrasound Index (QUI).

Details regarding the initial set up, including room requirements, unpacking, set up, printer operations and system calibration are in Chapter 2 of the Sahara User's Guide.

For equipment or repair problems related to the Sahara system, please contact Hologic directly. They may be reached at (800) 321-4659.

2. Subject preparation

SOF participants should be informed that a painless, radiation-free measure of heel bone integrity will be done during Visit 6, the same measure that they had at visit 4 and 5. The test will require removing the shoe and sock or stocking, placing the heel into the ultrasound device (no water) and then sitting quietly for approximately 5-10 minutes.

Each participant should be told not to use lotions, creams, powders or ointments on the lower extremities the day of her visit. The foot must be completely dry before the measurement made!

3. Measurement Procedure:

The protocol for obtaining Sahara measurements is detailed in Chapter 3 of the Sahara User's Guide . Be sure that the device is kept at room temperature for at least 1-2 hours prior to use.

Deciding which side to scan

We will obtain ultrasound measurements at V6 on the same side as the ultrasound measurement performed at V5. In general, this was the right heel unless the participant had recently injured that extremity.

If ultrasound measurements were not done at V5, follow these guidelines: ask each participant the following:

1) "Have you ever broken your right heel bone?"

2) "Do you have any permanent weakness in your right leg, ankle, or foot from an old injury or stroke? (do not include isolated toe weakness)."

3) "Have you broken any bones in your right leg, ankle, or foot in the last year? (do not include isolated toe fractures)"

If the answer to any of these questions is "Yes," scan the left foot. If the participant admits to weakness from a stroke or injury on both sides, scan the least afflicted side. If a participant has had fractures of both legs, ankles, feet or in the last year, or has broken both heels at some point, scan the side with most remote fracture(s).

Number of scans to obtain

Each participant will have at least two measurements of the same heel. The foot should be removed from the water bath and repositioned between measurements. If the second BUA measurement differs by more than ten units, obtain a third measurement. It is not necessary to obtain more than three measurements on a participant

Interpretation of results

Some participants will want to know the results of their test and its interpretation. Indicate that low ultrasound measurements may be an indication of poor bone quality, but the exact meaning is unclear. It is important to emphasize that ultrasound measures of bone are still experimental and that we hope to determine the relationship between ultrasound measures and subsequent fractures in this study. Refrain from discussing the exact meaning of a specific ultrasound values. The vast majority of physicians, even those who are knowledgeable about osteoporosis, will not be able to interpret the meaning of a specific BUA, SOS or QUI levels.

4. Data Collection

All data collection and storage for the Sahara measurements will be made on paper: first the results will be printed out by the machine, and then the results will be transcribed onto the SOF V6 Ultrasound Data Collection Form. There will be no electronic database or backup of the paper documents, therefore it is extremely important that measurements be recorded accurately.

a. Participant Identification.

Each SOF participant will be identified by her name (last name, first name, middle initial) and SOF ID number. Participant date of birth, sex, height, weight, etc., do not need to be recorded on the ultrasound forms.

b. Sahara Printed Results

After each measurement, remove the printed results from the machine and label it with the name, SOF ID, date, and measurement number (1-3).

Save the hard copy generated at the time the examination is done and, after transcribing the information onto the SOF Ultrasound data collection form, attach it securely to the bottom of the data form

c. SOF Ultrasound Data Collection Form

Record the Examiner ID and participant's SOF ID on the form. For each Sahara measurement, record on the Ultrasound Data Collection Form the BUA, SOS, and QUI values as they appear on the Sahara print out.

If Sahara measurements are not obtained for any reason, write an explanation in the space provided on the Ultrasound Data Collection Form. a

c. Data Backup and Transfer

Currently there are no plans for unique systems of data backup and transfer for the Sahara data. Be sure the Ultrasound Data Collection Forms are entered in a timely fashion.

5. Quality Control

a. Training and Certification of Operators

Although BUA measurements are relatively simple compared to SPA, to obtain reproducible results considerable attention must be paid to preparing the participant and

positioning the foot. All trained staff who wish to be certified to perform BUA measurements on SOF participants must complete the following:

- Carefully read this section and the Sahara User's Guide
- Receive training from the SOF QC Officer or the designated staff who attended the central training session at the coordinating center
- Practice scanning with the acoustic phantoms, then on other staff or volunteers
- Perform at least one scan on a participant while being observed by the SOF QC Officer or designate

b. Phantom Scans

Each site will receive an acoustic phantoms from Hologic. Phantom scans must be done in duplicate. Turn on the Sahara at least 15 minutes before performing the QC scans. As phantom results are temperature dependent, keep the phantom at room temperature to the extent possible.

Duplicate phantoms scans should be performed on a daily basis, preferably before any participants are scanned, and the results recorded in the QC log maintained at the site. Follow the instructions detailed in the User's Manual, Chapter 3, "Quality Control"

c. Cross Calibration

A study wide ("gold standard") phantom will be circulated to each site with instructions on its use. The phantoms will be circulated periodically during the course of the study as well.

d. Reproducibility

We plan to assess the reproducibility of the Sahara units in the near future. Detailed description of these in vitro (phantom) and in vivo (staff or participants) studies will be distributed.

6. Equipment maintenance

Routine maintenance of the Sahara is discussed in detail in the User's Guide, Chapter 6. Do not use other brands of coupling gel. Be sure to record (with dates) all scheduled and unscheduled maintenence performed on your device, as well as any change in hardware or software. Report any significant device malfunction to the UCSF Coordinating Center by FAX as soon as possible. Should you need to replac

7. General remarks

Unlike bone densitometry, ultrasound scanners are fairly new devices and there is not much knowledge about what kind of problems will be encountered. Therefore, we encourage you to call not only Hologic, but also the coordinating center when problems arise. Doug Bauer (415) 597-9289 will be available to help you.

8. Quality control checklist

☐ QC scans

- ☐ • Phantom maintained at room temperature
- ☐ • Proper placement of phantom
- ☐ • Duplicate measurements

☐ Participant preparation

- ☐ • Shoe, stockings removed
- ☐ • Chair, leg positioned properly

☐ Foot positioning

- ☐ • Uses same side as Visit 5 measurement
- ☐ • Gel applied correctly
- ☐ • Positioning/restraint applied correctly

☐ Scanning of participant

- ☐ • Duplicate scans performed
- ☐ • Third scan performed if indicated

☐ Print results transcribed and attached to Ultrasound Data Collection Form

☐ Results given to participant, placed in chart

SAHARA
CLINICAL BONE SONOMETER™

User's Guide

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1

Introduction

This chapter provides overview information about the Sahara Clinical Bone Sonometer. It includes a discussion of ultrasound measurement, safety precautions, system components and product specifications.

Safety Summary

Use the Sahara Clinical Bone Sonometer only indoors, in a clean, dry environment.

IPX0 - This equipment provides no protection against the harmful ingress of liquids.

Never attempt to operate the Sahara 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.

Interfacing equipment (computer, monitor, printer) used with the Sahara Clinical Bone Sonometer must meet IEC 950, or equivalent safety standards.

This unit is designed for continuous operation.

This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The Sahara Ultrasound Coupling Gel is for external use only.

If the patient's skin, in the area to be tested, is abraded and/or has an open sore, do not measure that heel.

The ultrasonic energy produced by the Sahara system is well below standard limits for diagnostic ultrasound systems as indicated in the *Specifications* section. Because the frequency of the sound waves produced by the Sahara system is outside the sensation range of human tissue, patients will not even notice the short pulse of sound waves that are transmitted through the heel for a Sahara measurement.

In the event of an emergency, the patient's foot may be removed at any time

from the Sahara unit by squeezing the release handles on the shin guide. 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.

Quantitative Ultrasound (QUS) as a Tool for 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. Ultrasound is unique in that the transmission of sound through a porous structure such as bone depends not only on the properties of the bone material itself, but also on the sponge-like structure, or architecture, of the bone. The sensitivity of ultrasound to architecture and material properties can be exploited to obtain information about the skeletal health of an individual, which can be useful in the identification of patients at risk for osteoporosis and osteoporosis related fractures. In comparison to traditional techniques for assessment of skeletal status (including radiographs, x-ray absorptiometry, and computed tomography) which involve exposure to radiation and have limited or no sensitivity to bone architecture, QUS is a quick, low cost, and radiation free diagnostic tool.

Many bone diseases, including osteoporosis, degrade cancellous (or trabecular) bone much earlier and to a greater extent than cortical bone. Degradation of cancellous bone is marked not only by a reduction in bone density, but also by diminished integrity of the sponge-like structure of the bone, which ultimately may lead to increased fragility and risk of fracture. 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 the preferred 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 identification and/or assessment of patients at risk. QUS is a modality particularly well suited both to the examination of cancellous bone (due to its sensitivity to both material properties and bone architecture) and also to the examination of the heel (due to its accessibility).

Sahara Clinical System Overview

Sahara is a portable medical instrument that 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". The QUI/Stiffness value obtained for a patient may then be compared to a reference database 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 comfortably secured in the Sahara scanner. 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 contact gel is used between the pads and the patient's skin. No water bath is necessary, and the procedure takes less than two minutes. The gel is important because it eliminates air which inhibits the transmission of sound waves

The scanner 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.

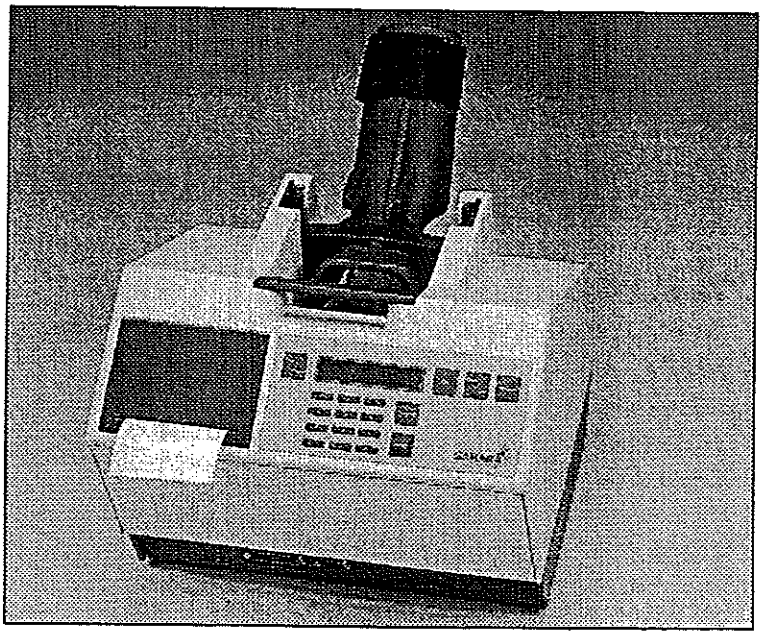

Figure 1.1
Sahara Clinical System

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).

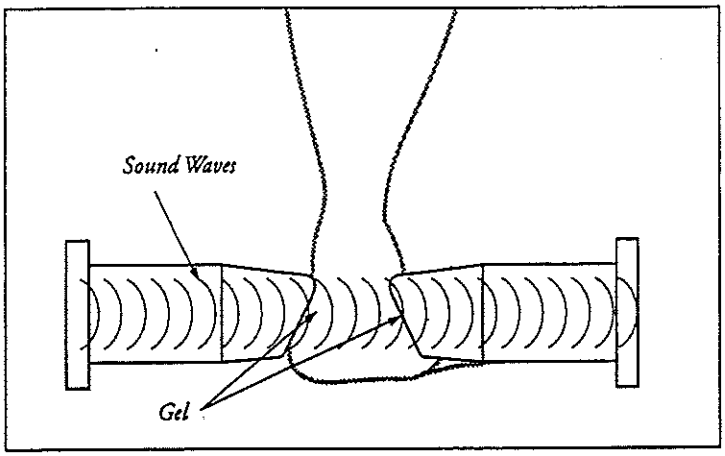

Figure 1-2
Sahara Measurement Geometry

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 propa-

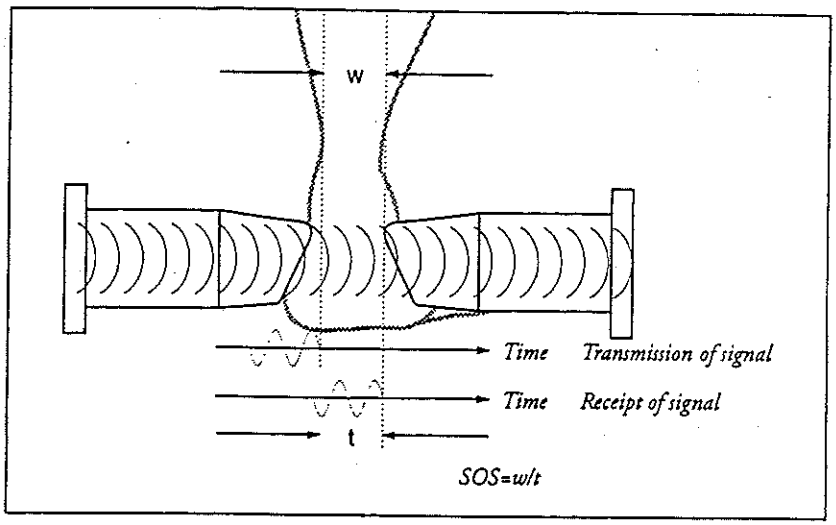

Figure 1-3
SOS Measurement

gation 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 healthy subjects having a higher SOS than osteoporotic subjects.

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 healthy subjects

having higher BUA results than osteoporotic subjects. This is because osteoporotic bone is characterized by a coarser and less dense trabecular network which is more transparent to high frequencies than the fine, dense trabecular network of healthy bone.

**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.*

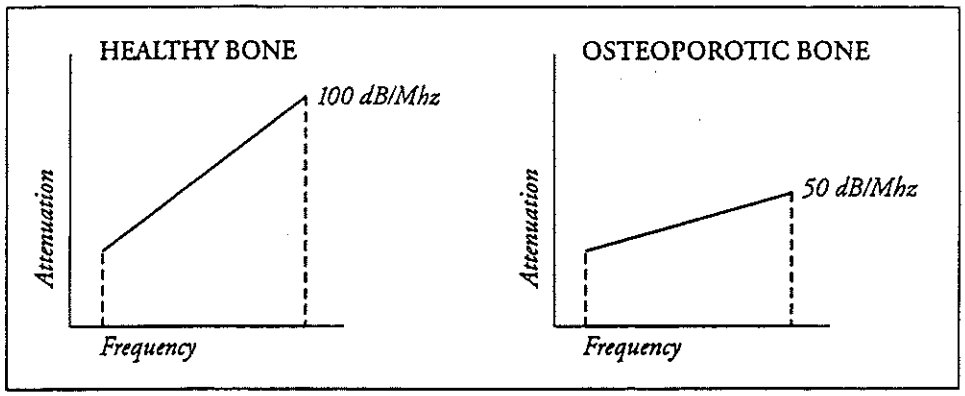

Figure 1-4
BUA Measurement

Quantitative Ultrasound Index (QUI)

In order to optimize the diagnostic information obtained by both BUA and SOS measurements, the Sahara system combines the two measured values into a single parameter, the Quantitative Ultrasound Index (QUI), sometimes referred to as "Stiffness." The QUI value is a more diagnostically sensitive measure of the bone status because it combines the sensitivity of both BUA and SOS while simultaneously reducing the 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 osteoporotic subjects. Note that while QUI is the default value reported, it is also possible to obtain the measured BUA and SOS values, and to compare these values to reference data.

Relationship of QUS Results to Measurements of Densitometric Parameters and Fracture Risk

Over the last several years, quantitative ultrasound has been applied by a growing number of researchers to the assessment of bone status and risk for fracture.[1,2] *In vitro* studies have shown that QUS parameters are related to both architectural and material properties of bone, with SOS related to density and elastic modulus ("strength"), and BUA related to density as well as bone micro-architecture, orientation, and strength.[3-6] Thus it is expected that QUS may also be sensitive *in vivo* to properties of bone (in addition to density) that are predictive of bone strength and future fracture risk.

Initial *in vivo* studies compared QUS results to bone density measurements, in most cases assessed using the Dual Energy X-Ray Absorptiometry, or DXA technique. These studies have shown that BUA and SOS are only moderately correlated with bone density measurements (correlation coefficients generally falling between 0.5 and 0.8), even when compared to BMD at the same site (heel).[7-9] These relatively weak correlation coefficients seem to indicate that properties other than density are also being assessed by QUS, consistent with *in vitro* results indicating that other parameters influence QUS results. Recently, longitudinal (*in vivo*) studies involving mostly women over the age of 65 have shown that QUS results are nearly as predictive of future fracture risk as is densitometry.[10-13] These studies show that patients with lower QUS values are at increased risk for future fractures. For example, when comparing the BUA for a single patient to the average BUA value for a representative age-matched population, there is roughly a doubling of the risk for future fractures for each standard deviation decrease in BUA.[10-12] This gradient of risk is approximately the same as that observed for DXA bone density measurements in the same populations,[10-12] indicating that QUS may be as sensitive a predictor of fracture risk as DXA. In addition, SOS values have been shown to be correlated to BUA values[9] and approximately as predictive of fracture risk,[11,13] leading to efforts to combine BUA and SOS results into a single predictive parameter. Thus Sahara reports a combined parameter (QUI/Stiffness) as well as the measured BUA and SOS results.

Reproducibility of Sahara Results: Standardized Precision

Traditional Methods for Quantifying Precision Error: Coefficient of Variation (C.V.)

Knowledge of the magnitude of the precision error of any quantitative technique is critical to understanding the ability of that technique to (1) stratify patients relative to normal values, and (2) monitor changes in measured parameters as a consequence of age, disease, and/or treatment. In the field of Dual Energy X-Ray Absorptiometry (DXA), for example, it is commonplace to express the precision error of a Bone Mineral Density (BMD) result in terms of the Coefficient of Variation (C.V.), defined by reporting the precision error in percent of the mean measured value. Thus for PA spine BMD measurements by the DXA technique, the precision error (typically about 0.01 g/cm²) is usually quoted as "1%," meaning 1% the normal value of about 1.0 g/cm². This method of quoting the C.V. is useful for DXA in that it allows a clinician to compare the precision error to typical age related changes (also about 1% per year), or to the population range (standard deviation of about 10%). The C.V. of a DXA measurement is also useful because it provides a means for comparing the performance of devices from different manufacturers.

For quantitative ultrasound, however, the shortcomings of using C.V. to define precision have been widely recognized. Unlike the case of DXA systems, all of which yield essentially equivalent results with similar mean values and similar ranges between old and young, C.V. values can be misleading when used in conjunction with measurement parameters that have very large mean values compared to the changes associated with age and/or disease. The SOS measurement is a good illustration of this point as the mean value is about 1600 m/sec and the precision error is about 3 m/sec, yielding a C.V. value of about 0.2%. This C.V. value would seem far superior to that of DXA until it is realized that the difference between old and young normal values for SOS is only about 80 m/sec (or 5% of young normal value) compared to about a 30 - 40% difference for DXA. In addition, it is also recognized that due to differences in measurement site or technologies used, different ultrasound devices have in general rather different mean values as well as different responses to age and/or disease related changes.

Standardized Precision for Quantitative Ultrasound:

In response to the problems associated with using C.V. to describe the precision error for quantitative ultrasound techniques, researchers and manufacturers of QUS

equipment have proposed several different methods of calculating a "Standardized Precision" value. The goal of these various methods for calculating Standardized Precision is to provide a means of comparing the performance of different ultrasound devices to each other and also to other techniques such as DXA. In order to select a useful definition for Standardized Precision, it is important to note that (1) precision error for ultrasound is small enough to be considered irrelevant for stratifying patients by comparison to reference populations, and (2) precision error is therefore meaningful ONLY as a means of assessing the ability of a system or technique to monitor serial change. As is generally accepted for DXA, the critical factor for patient monitoring is how long (in months or years) will it take until a real change in patient bone status can be detected with statistical confidence. This question can only be answered by comparing the precision error of the technique to the expected change in patient results over time. Thus Standardized Precision for Sahara has been defined (see below) as the ratio of the precision error to the average annual rate of change in a reference population. Using this definition, meaningful comparisons of monitoring capability can be made not only between different ultrasound instruments, but also between different techniques (e.g., ultrasound, DXA, etc.). This definition has the additional benefit of being simple to calculate and use, as the Standardized Precision for PA DXA measurements is 1, making comparisons to the monitoring capability of DXA intuitively clear.

Definition of Standardized Precision:

Standardized Precision for any measured parameter (by ANY technique) is defined as the ratio of the precision error to the average annual rate of change for that parameter in a reference population:

$$\text{Standardized Precision} = \frac{\text{(Precision error)}}{\text{(Annual rate of change in a reference population)}}$$

Note: By this definition, Standardized Precision is a unitless number, and is not given in percent. A smaller standardized precision number indicates higher sensitivity to changes in patient results.

Example: For DXA of the PA Spine, the precision error is 0.01 g/cm² and the annual rate of change is 0.01 g/cm², leading to a Standardized Precision value of:

Standardized Precision (AP DXA) = (0.01 g/cm²) / (0.01 g/cm²) = 1.0

System Components

The Hologic Sahara Clinical Bone Sonometer system shown in Figure 1-5 consists of the ultrasound scanning unit (including positioning aid), power module, QC phantom, Sahara Ultrasound Coupling Gel, Patient Report Forms and Quality Control Log forms. An optional thermal dot matrix printer contained within the scanner module is used to provide an alphanumeric printout of measurement results. The Patient Report Form included with the Sahara Clinical system provides a means for recording patient information and measurement results, including graphical comparison, to a reference database. Similarly, the Quality Control Log sheets provide a means for recording and tracking QC results over time.

Information on ordering Hologic Report Form and/or QC Pads can be found in the *System Care and Maintenance* chapter of this manual.

An optional external PC, either desktop or laptop, can be used and will function as a remote controller, data base manager and mass data storage device. When configured with an optional PC, the Sahara provides enhanced graphical displays and printouts including reference curves and trend reports.

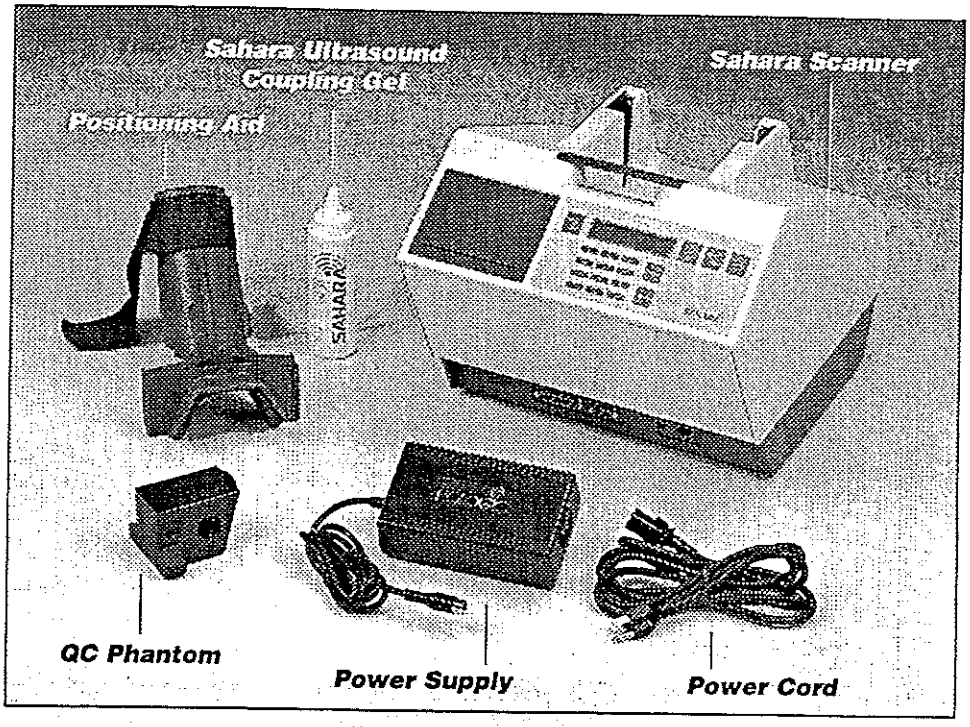

Figure 1-5
System Components

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 ultrasonic based couplant 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 scan results and will give false (too high or too low), or inconsistent, readings. Information on ordering Sahara Ultrasound Coupling Gel can be found in the *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 scanner near the power connection. This light will illuminate when power is applied to the unit. Note that the Sahara scanner does not have an on/off switch. Power is applied by plugging in the power module.

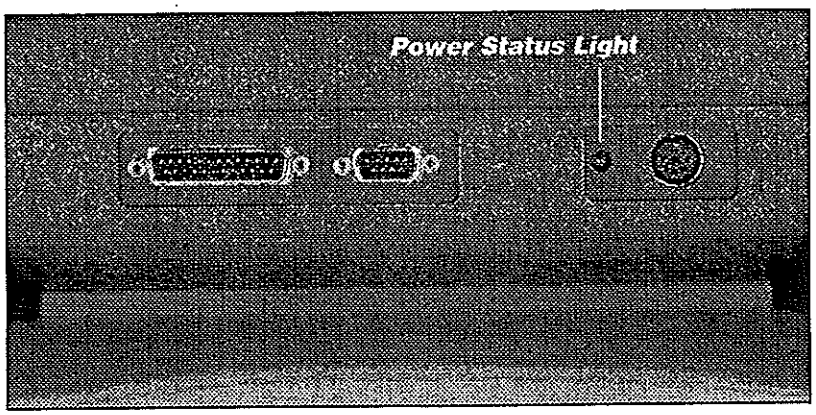

Figure 1-6
Power Status Light

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

Figure 1-7
Control Panel

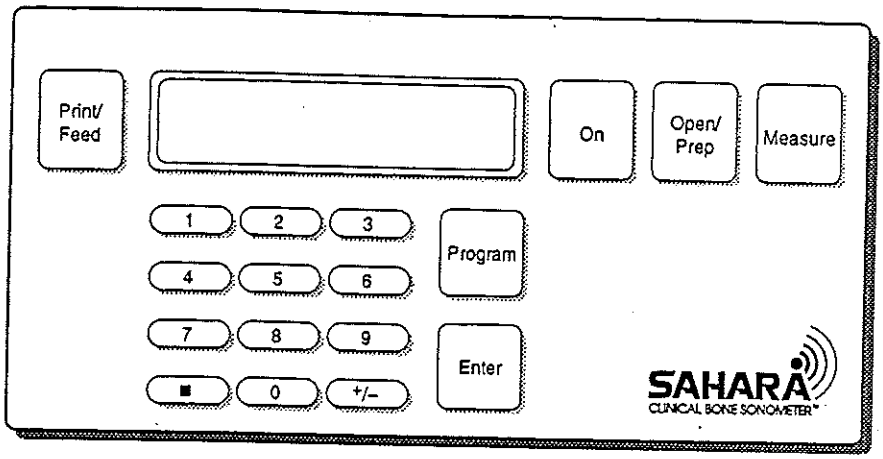

Table 1-1 describes the functions on the Sahara Control Panel.

Table 1-1
Control Panel

Control	Description
Numeric Keypad	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.
LCD Screen	The LCD display screen displays messages to prompt the user through a measurement, and displays the result of a measurement.
ON Button	This button switches the system on (i.e. takes it out of standby mode), or initializes the system to prepare for a new measurement.
OPEN/PREP Button	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.
MEASURE Button	This button commands the system to close the transducer pads and perform an ultrasound measurement.

PRINT/FEED Button	This button commands the system to print the current results or advance printer paper if the optional line printer is supplied.
PROGRAM Button	This button is used to inform the Sahara that program information (such as initiating a QC measurement or setting time and date) will follow.
ENTER Button	This button is used to initiate functions entered with the PROGRAM and Numeric Keypad.
+/– Button	This button allows the user to toggle between QUI results and 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.

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

Measurement Site:	Calcaneus
Coupling Method:	Sahara Coupling Gel only
Measurement Time:	less than 10 seconds
Patient Reports:	Built-in Strip Printer
Measurements:	BUA, SOS, Quantitative Ultrasound Index (QUI)
QUI	
Range:	
In Vivo:	30 - 140
In Vitro:	0 - 150
Standardized Precision*†	<2
Absolute Precision†:	1.2

SOS	
Range:	
In Vivo:	1440 - 1630 m/s
In Vitro:	1400 - 1800 m/s
Standardized *In Vivo* Precision*	<2
Absolute *In Vivo* Precision:	2 m/s
BUA	
Range:	
In Vivo:	20 - 130 dB/MHz
In Vitro:	0 - 130 dB/MHz
Standardized *In Vivo* Precision*	<4
Absolute *In Vivo* Precision:	2 dB/MHz
QC Check:	Daily, utilizing supplied QC phantom
Operating temperature range:	60° - 100° F (15° - 37.7° C)
Operating humidity range:	20-80% R.H. non condensing
Shipping and Storage:	
Ambient Temperature	0° to 120° F (-18° C to 50° C)
Relative Humidity	20% to 95%
Atmospheric Pressure	500 hPa to 1060 hPa
Power Requirements:	100-240 VAC, 50-60 Hz, <60 watts (automatically adjusts from 100 VAC to 240 VAC, and 50 Hz to 60Hz)
CPU	Embedded microprocessor
Ultrasonic Energy:	I_{sppa} < 0.0013 W/cm² typical (see Note 1) Mechanical Index (MI) < 0.01 typical (see Note 2) Pulse Repetition Rate (PRR) < 200 Hz
Safety Standards:	IEC601-1, UL2601-1, CSA C22.2
Size:	17"D x 14"W x 12"H (43cm x 36cm x 30cm)
Weight:	18 lb. (8.2kg)

*Standardized Precision = (Precision error)/(annual rate of loss in a reference population)
† in osteoporotic subjects
Note 1: FDA limit: I_{sppa} < 190W/cm². Reference 4/14/94 FDA Guidance Document #634.
Note 2: FDA limit: MI < 0.3. Reference 4/14/94 FDA Guidance Document #634.

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2

Initial Set Up

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

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 items contained in the Sahara Clinical Bone Sonometer shipping package. Refer to the figure, and the list below it, to insure that all items were received.

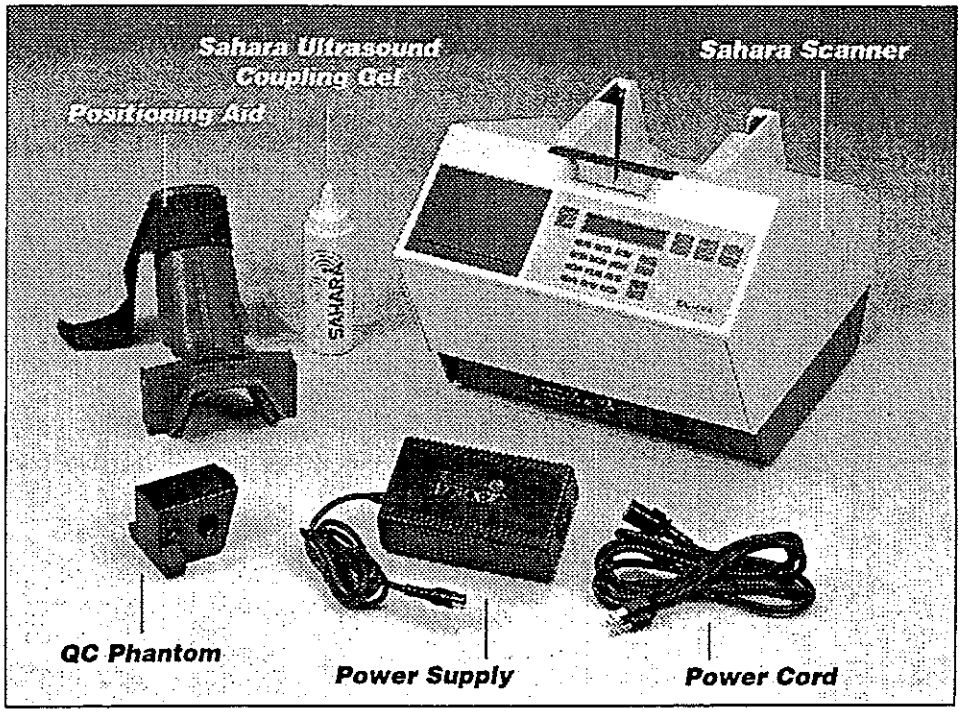


Figure 2-1
Unpacking the System

The Sahara shipping package includes the following:

- Sahara scanner
- Power Supply and Power Cord
- Positioning Aid
- QC Phantom
- Starter supplies with Sahara Ultrasound Coupling Gel, Transducer Towelettes, printer paper and exam paper (Figure 2-1 shows Sahara Ultrasound Coupling Gel)
- Documents package containing User's Guide, Software (if applicable), Warranty Statement, supplies reorder cards and pre-printed tablet-style forms for recording patient and QC results (not shown on Figure 2-1)

To unpack the system, follow the procedure below.

1. Remove the top tray containing the Power Supply, QC Phantom, patient pack, and documents package.
2. Remove the foam packaging material that covers the top of the scanner.
3. Remove the positioning aid (wrapped in packaging material and located on the scanner).
4. Carefully remove the scanner from the box by its handle, and take the scanner 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 scanner on the floor where it will be used.
2. Plug the power supply into the scanner (the figure below shows the power supply connections).
3. Plug the power cord into the power supply.

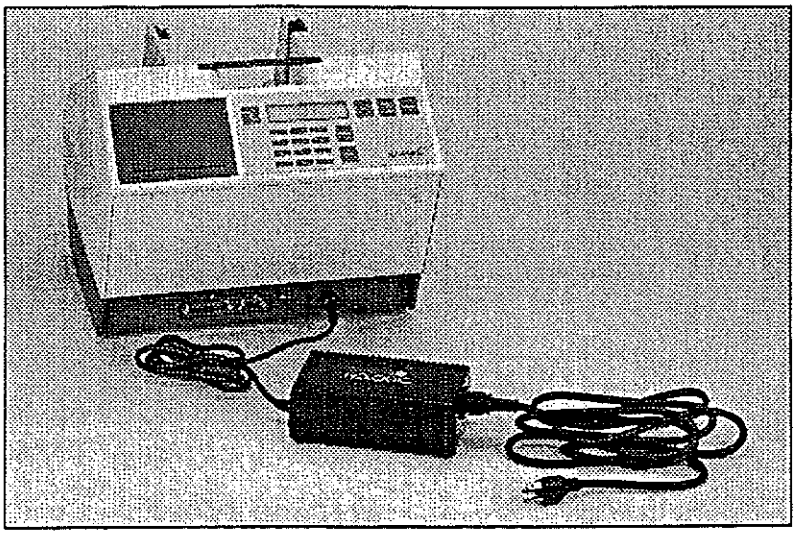


Figure 2-2
Power Supply Connections

4. 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, 3 and 4 in this order to avoid damaging the unit.

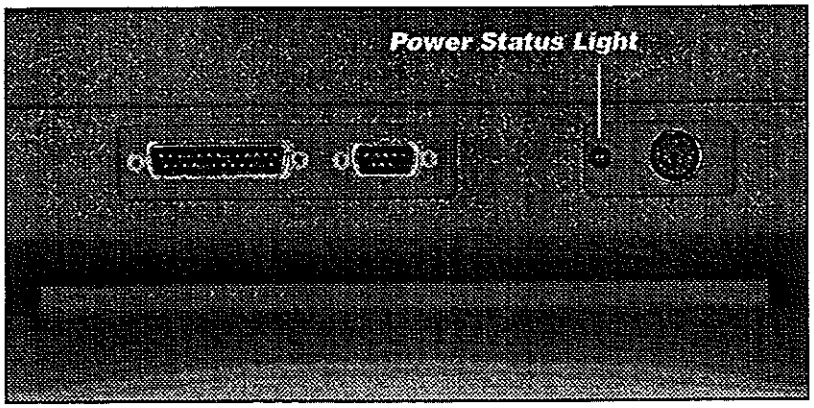
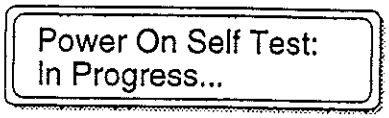


Figure 2-3
Power Status Light

5. The Control Panel Screen initially displays:

```
HOLOGIC **Sahara**
Version 1.0
```

Followed by:



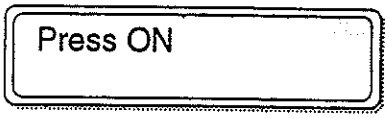
6. Upon completion of the self test, the Control Panel Screen displays:

OR

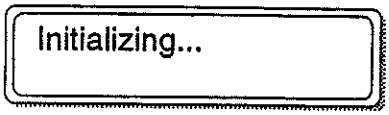
The above messages will be displayed anytime the system is plugged in after being unplugged.

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

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



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



Then:

Printer Operation

Follow the procedure below to load printer paper:

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

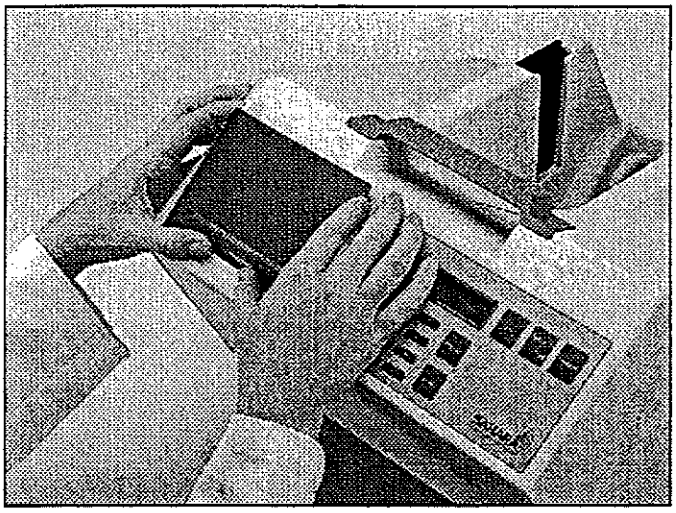


Figure 2-4
Removing Printer Cover

2. Place the paper roll into the printer tray.

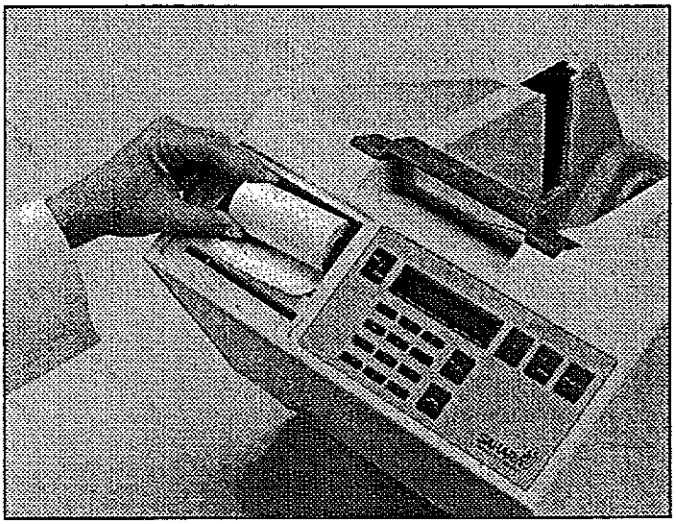


Figure 2-5
Installing Printer Paper

3. Remove any tape on the paper roll and insert the paper into the paper feed slot.

Figure 2-6
Paper Feed

4. Press the **PRINT/FEED** button while the screen is displaying "Gel Pads Press OPEN". Wait until 2 to 3 inches (5 to 8 cm) of paper appears with the Hologic logo.

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.

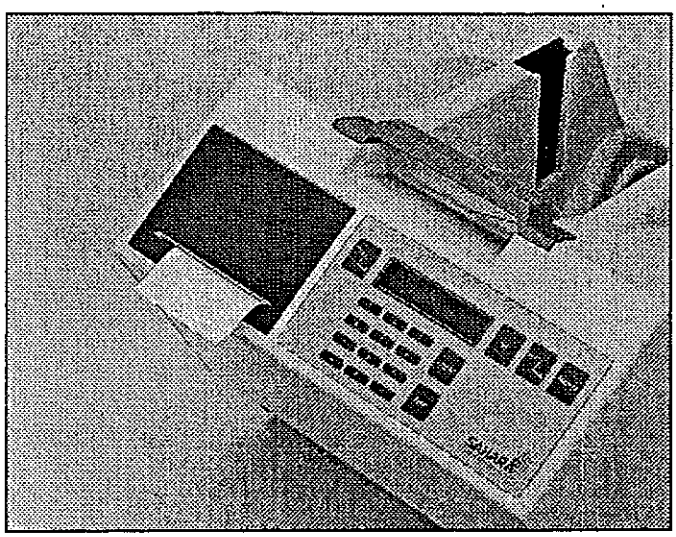


Figure 2-7
Printer Cover Replaced

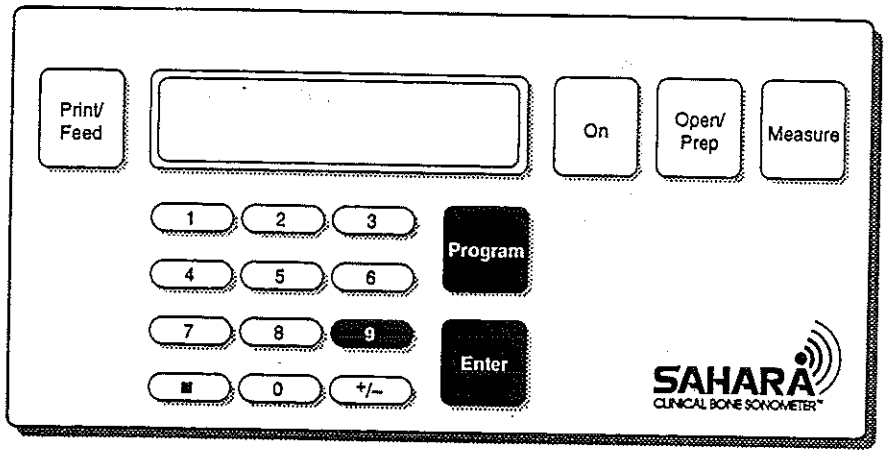
Set Time

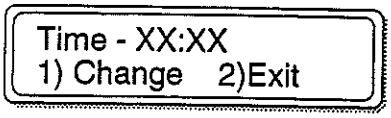
To set the time, in your Sahara system, follow the procedure below:

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 2-8
Press ***PROGRAM, 9, ENTER***

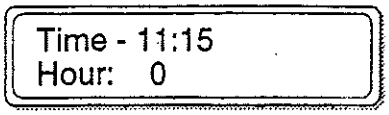




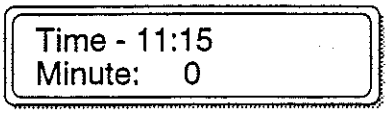
3. If the time displayed is correct, press **2.**

4. If the time displayed is incorrect, set the correct time as follows:

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



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



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

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:

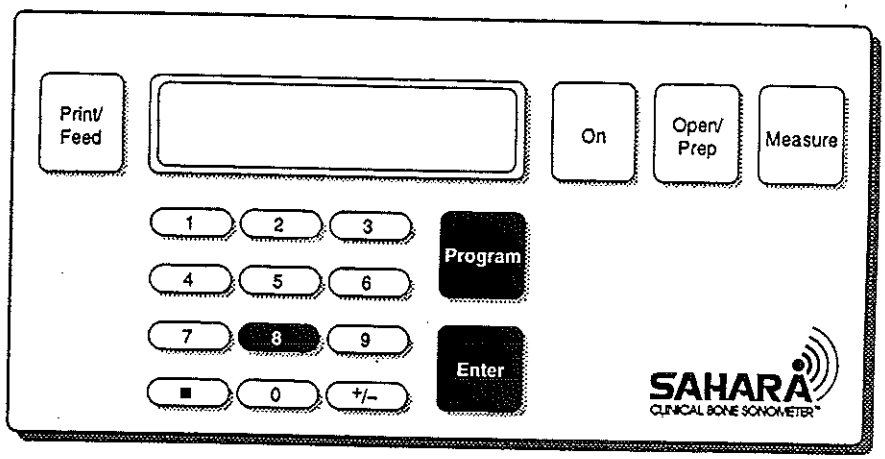
Set Date

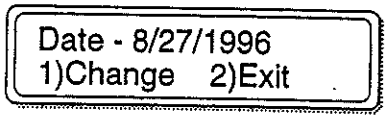
To set the date, in your Sahara system, follow the procedure below:

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 2-9
Press ***PROGRAM, 8, ENTER***

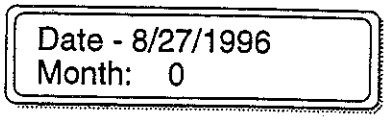




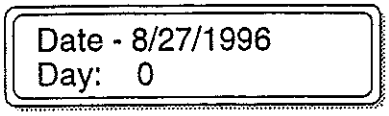
3. If the date displayed is correct, press **2**.

4. If the date displayed is incorrect, set the correct date as follows:

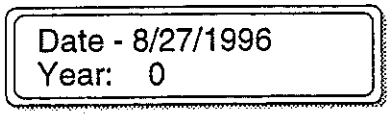
5. Press **1**. The Control Panel Screen displays the following:



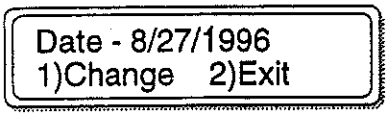
6. Insert the month, then press **ENTER**. The Control Panel Screen displays the following:



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



8. Insert the year, for example "1996", then press **ENTER**. The Control Panel Screen displays the following (XX/XX/XXXX represents the date you set):



9. Press **2** to set the date as shown, or press **1** to start over.

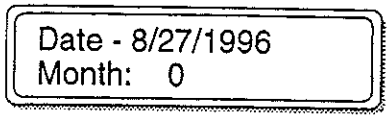
10. After the date has been set, the Control Panel Screen displays:

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

Set Young Normals

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

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



2. Press **PROGRAM, 7, ENTER.** The Control Panel Screen displays the young normal mean.

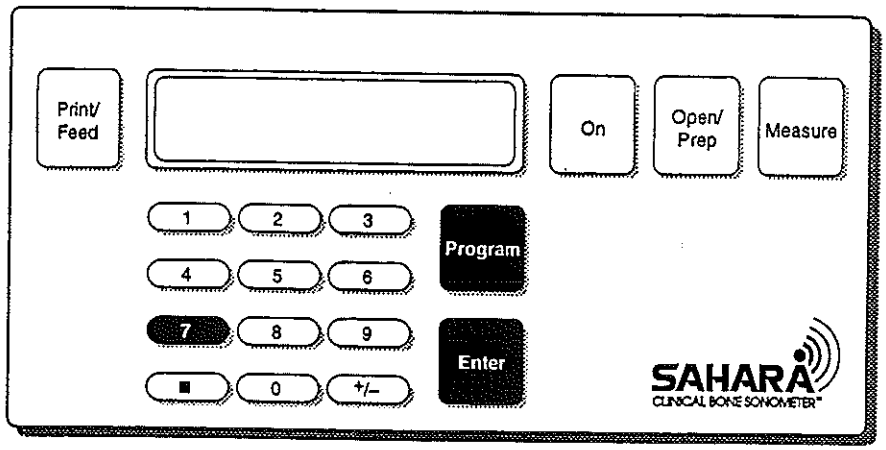
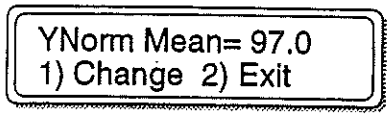
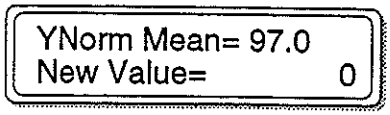


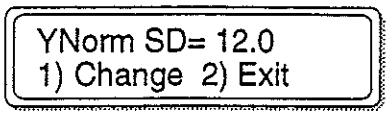
Figure 2-10
Press ***PROGRAM, 7, ENTER***



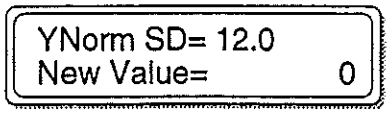
3. If the young normal mean is correct, press **2.**
4. If the young normal mean is incorrect, set the correct mean as follows:
5. Press **1.** The Control Panel Screen displays the following:



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



7. If the young normal standard deviation is correct, press **2**.
8. If the young normal standard deviation is incorrect, set the correct standard deviation as follows
9. Press **1**. The Control Panel Screen displays the following:



10. Insert the young normal standard deviation, then press **ENTER**. The Control Panel Screen displays the following:

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.

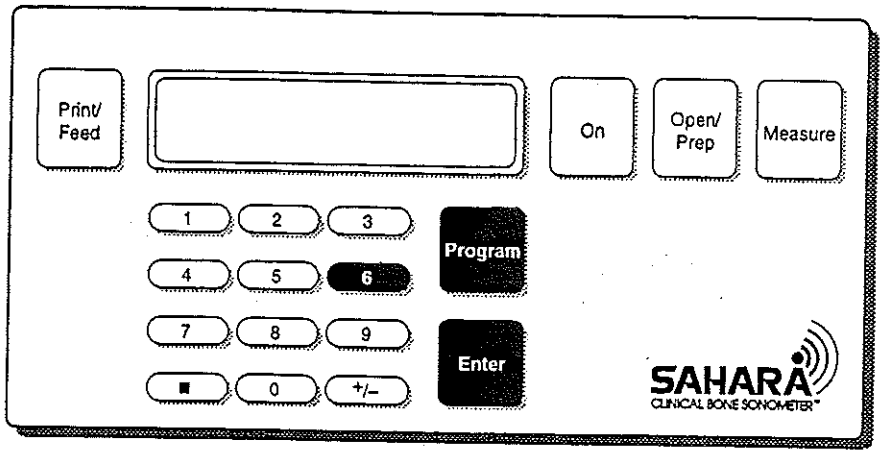
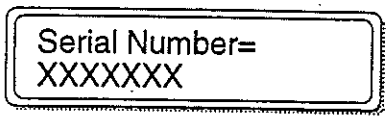


Figure 2-11
Press ***PROGRAM, 6, ENTER***



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

Quality Control

Each Sahara is supplied with a Quality Control phantom to check the measurements of SOS and BUA. It is recommended that a QC phantom measurement be done 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 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.

The QC measurement is the final step of the Initial Set Up procedure. After allowing one hour for the temperature of the phantom to stabilize to room temperature, perform a QC measurement following the procedure in the chapter titled *Quality Control* in this manual.

3

Quality Control

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

Quality Control Procedure

Each Sahara is supplied with a Quality Control phantom to monitor system performance over time. It is recommended that a QC phantom measurement be done 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 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.

QC measurement consists of initializing the system, applying gel to the both pads of the scanner, opening the scanner pads, positioning and securing the QC phantom in the scanner, performing the measurement, printing the measurement results, removing the phantom from the scanner, and cleaning the phantom and the scanner's 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.

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.

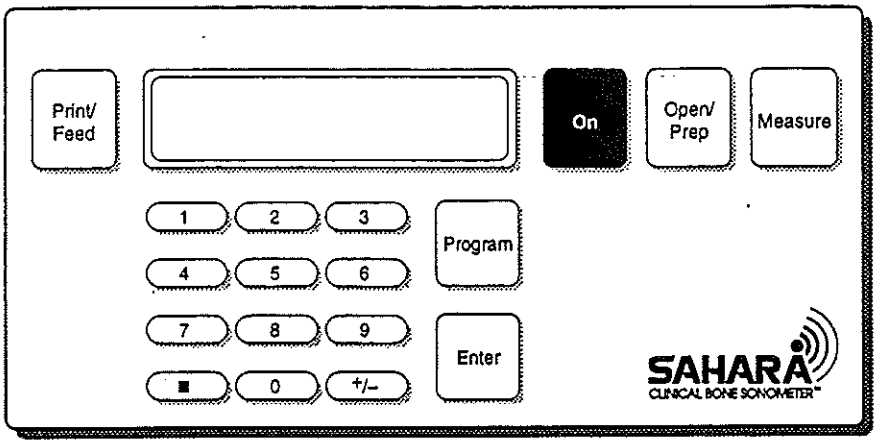


Figure 3-1
Press ON

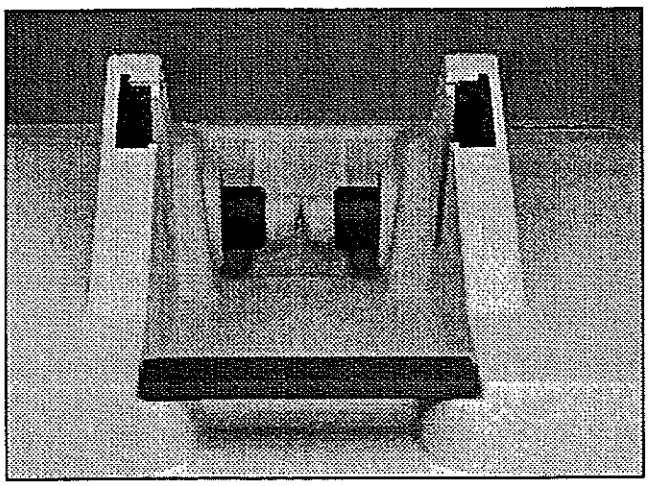


Figure 3-2
Transducer Pads Touch

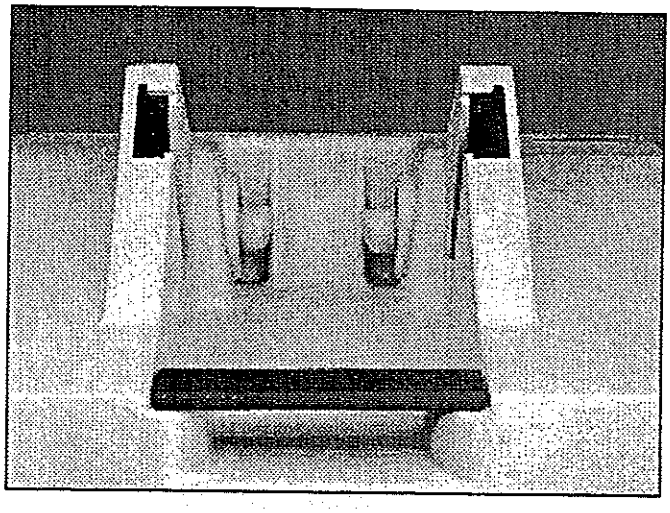


Figure 3-3
Transducer Pads Ready for Gel

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 any 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.

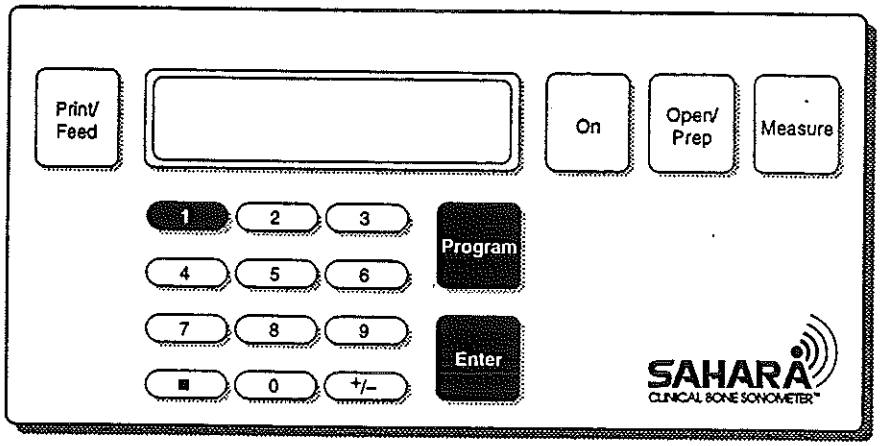


Figure 3-4
Press ***PROGRAM, 1, ENTER***

The Control Panel Screen displays:

Gel Pads for QC Press OPEN

3. For each transducer pad, squeeze out about a one inch (2.5 cm) bead of gel (or about 1/4 teaspoon) onto pads, finger, or tongue depressor (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.

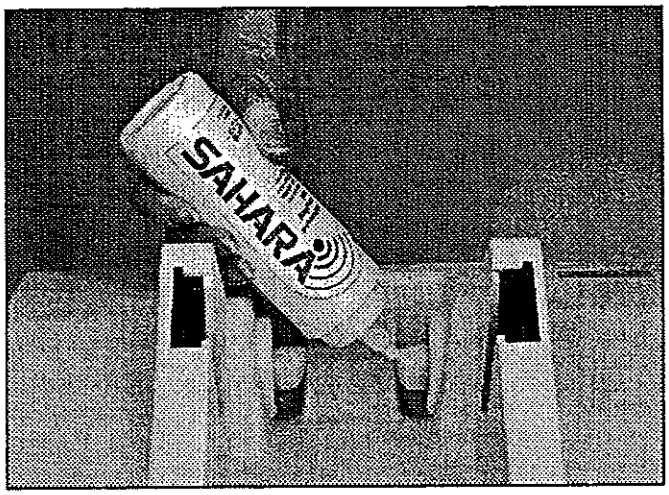


Figure 3-5
Gel Application

4. 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.

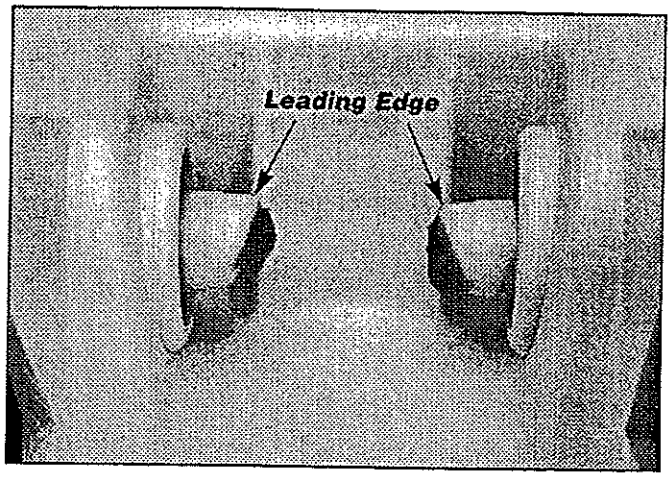


Figure 3-6
Proper Amount of Gel on Transducer Pad

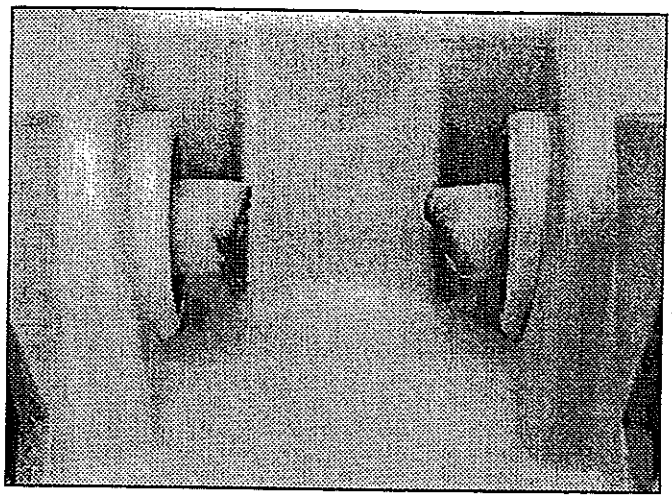


Figure 3-7
Insufficient Amount of Gel on Transducer Pad

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.

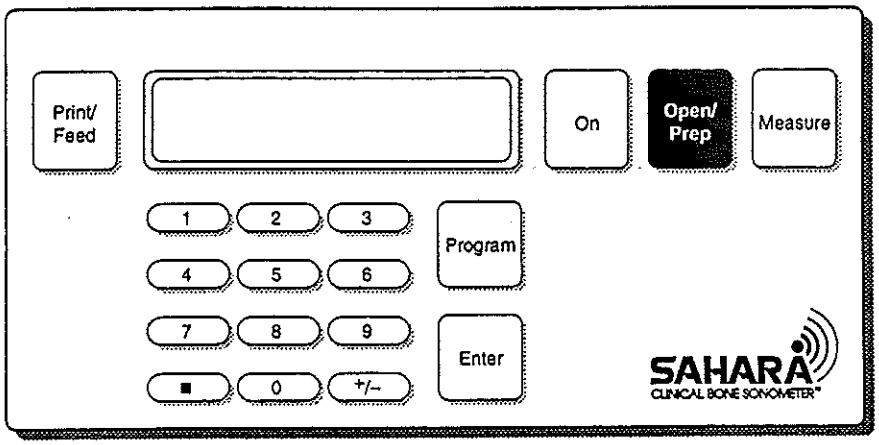
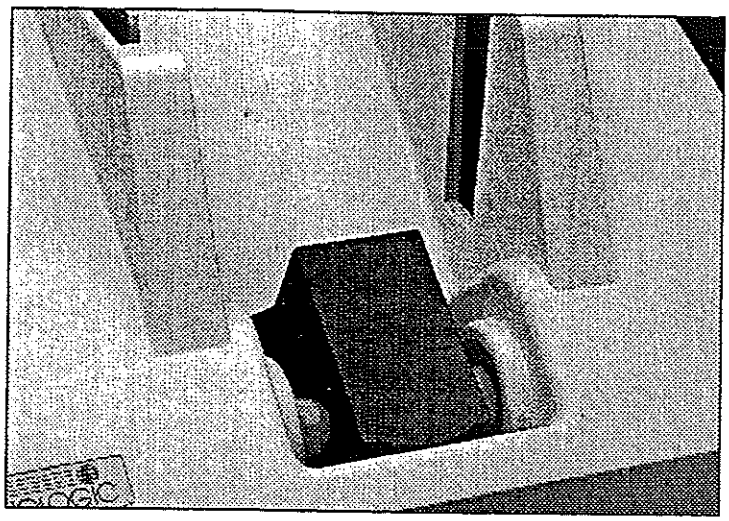


Figure 3-8
Press ***OPEN/PREP***

The Control Panel Screen displays:

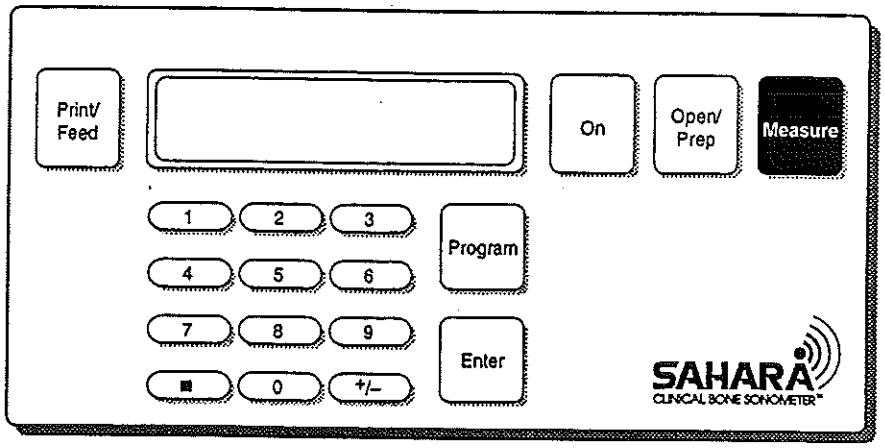
6. Place the QC phantom in the Sahara. Position the phantom so that its rounded end is snugly in the positioning contour (heel cup), and the label is on top.

Figure 3-9
QC Phantom Position

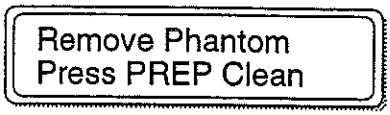


7. Press the **MEASURE** button. The scanner performs the measurement, then automatically opens the transducer pads.

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.

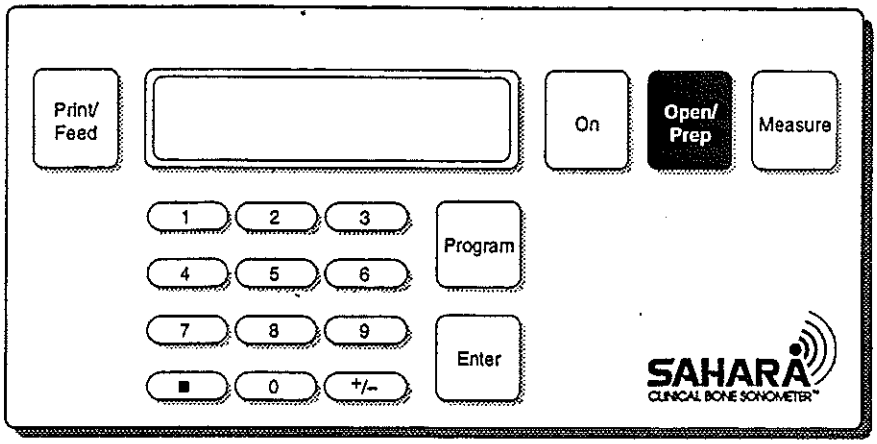


Figure 3-11
Press ***OPEN/PREP***

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

11. The display screen will display two values (QAB and QAS) calculated from the BUA and SOS measurement results, QAB = BUA/(actual BUA) and QAS = SOS/(actual SOS).* The values should be entered on the QC worksheet as described below. The screen will also indicate PASSED if the QC measurement is within the acceptable range, or REPEAT if it is not. In most cases, the cause of a REPEAT message is *not* a system malfunction, but is due to the phantom not being stabilized at room temperature. If the phantom has not been kept with the Sahara system, or may for any other reason not be stabilized at room temperature, wait a minimum of one hour before repeating the QC scan. If you suspect that this is the problem, it is acceptable to perform patient measurements before completing the QC procedure.

**Note: The "actual" BUA and SOS values (as noted on the phantom) are entered at the factory.*

12. The Control Panel Screen displays the QAB and QAS values.

```
QC Passed
QAB= x   QAS= y
```

13. To display the BUA and SOS values press the **+/-** button. The Control Panel Screen displays:

```
BUA= x
SOS= y
```

14. If the phantom temperature has been stabilized for at least one hour, and the display screen indicates REPEAT, repeat Steps 1 through 10. If, after three attempts, the unit does not pass, refer to the *System Care and Maintenance* chapter of this manual.

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

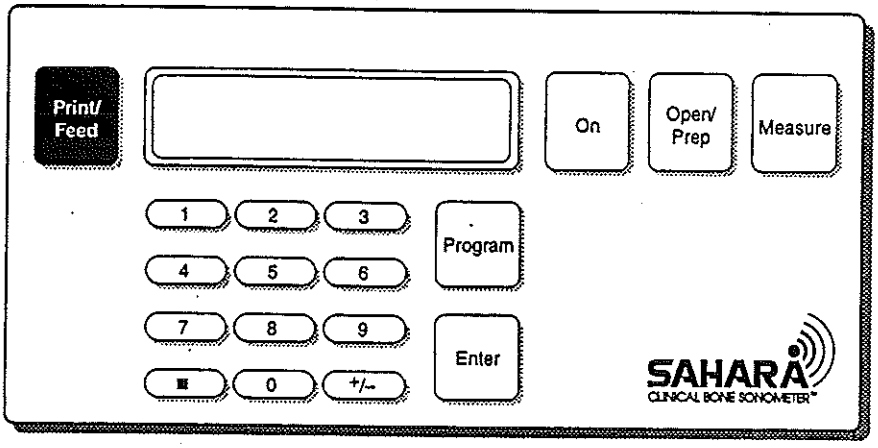


Figure 3-12
Press ***PRINT***

Recording/Plotting QC Results

QC 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 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).

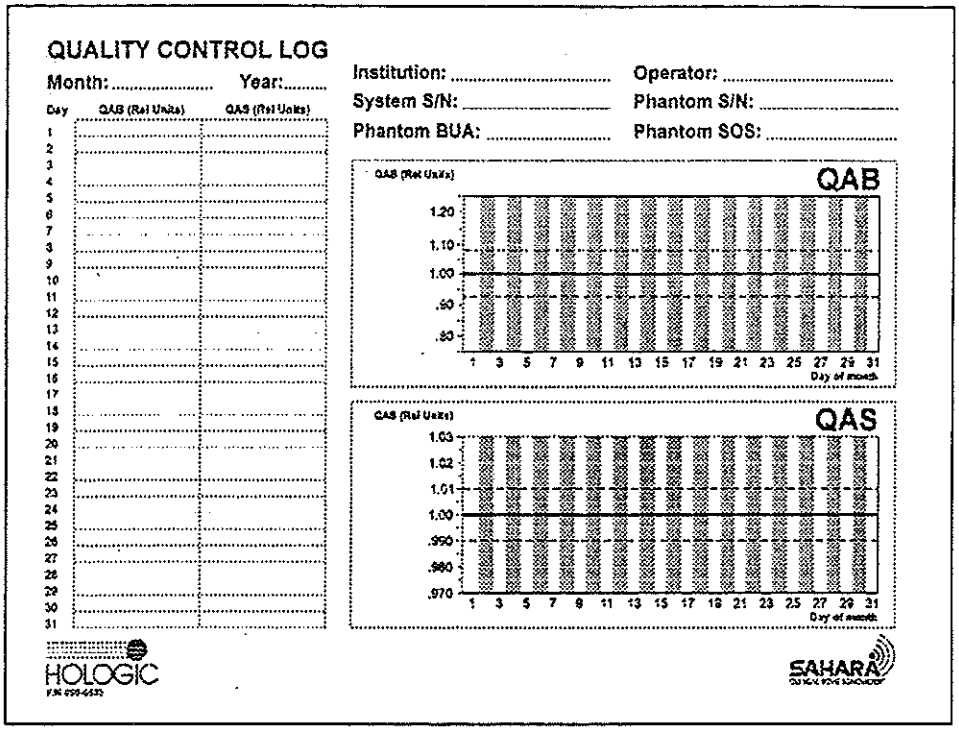


Figure 3-13
QC Log

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 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. 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 all results be recorded in the log and plotted.

4

Patient Measurement

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

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.

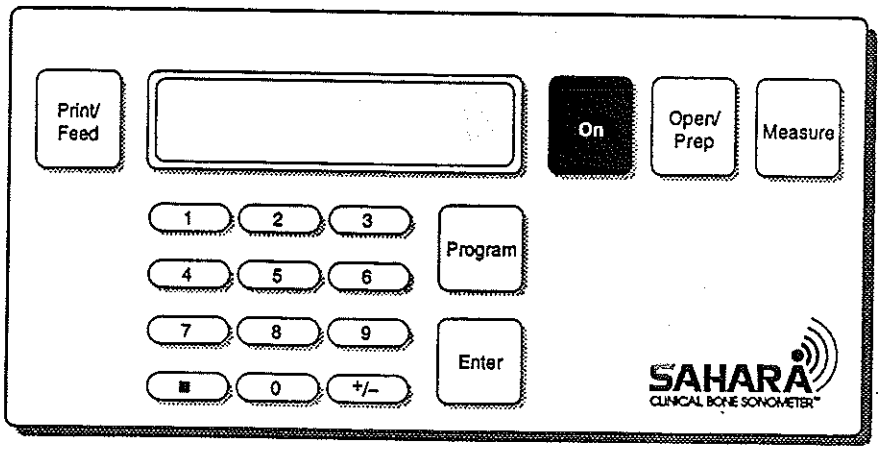


Figure 4-1
Press ON

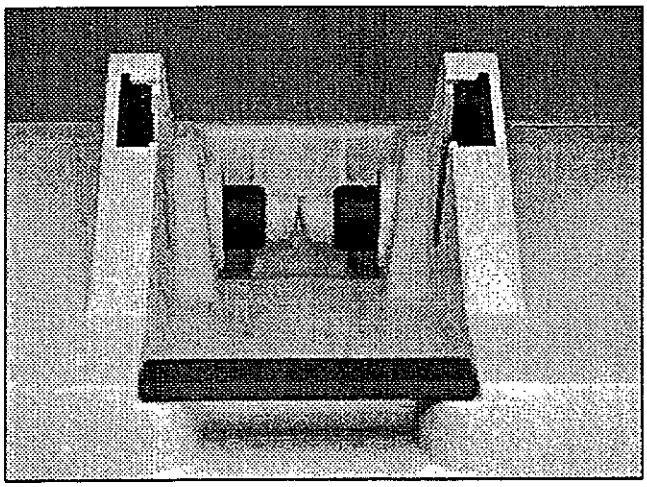


Figure 4-2
Transducer Pads Touch

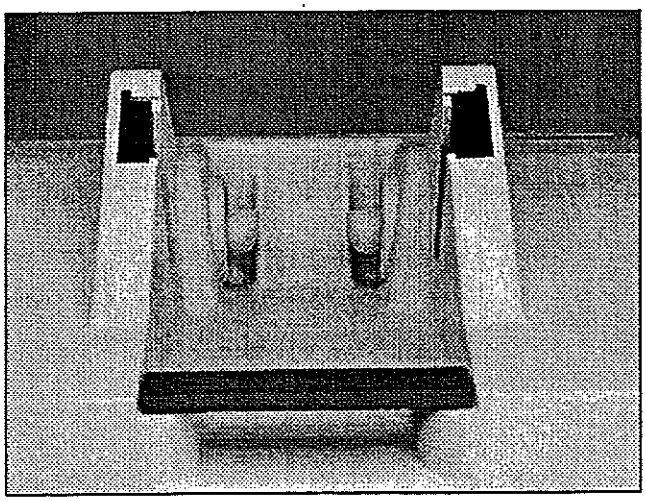


Figure 4-3
Transducer Pads Ready for Gel

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 any 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 (or about 1/4 teaspoon) onto transducer pad, finger, or tongue depressor.

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

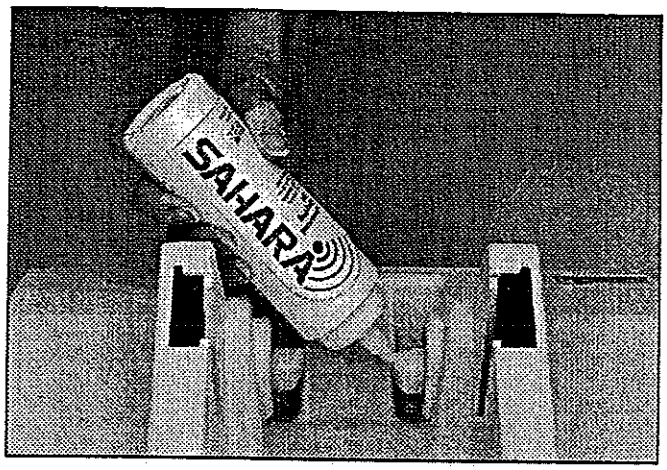


Figure 4-4
Apply Gel

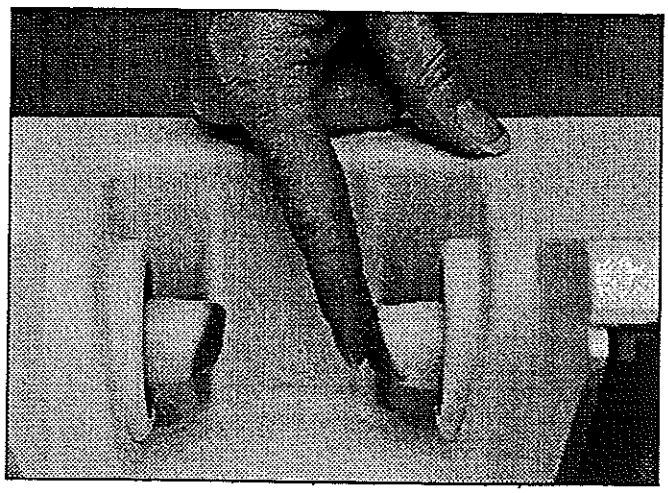


Figure 4-5
Spread Gel

3. 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.

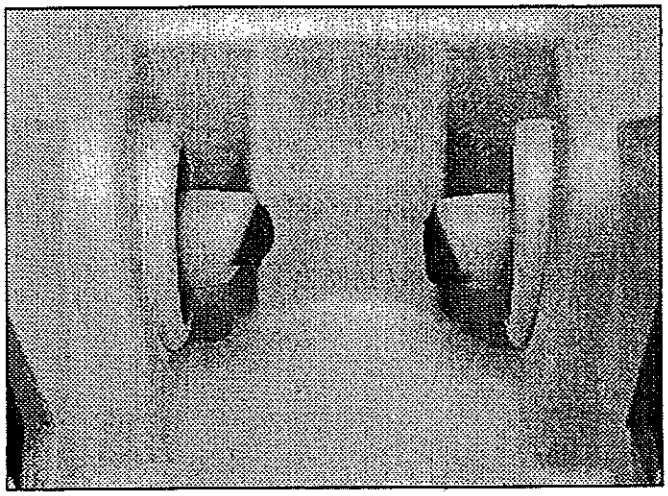


Figure 4-6
Proper Amount of Gel on Transducer Pad

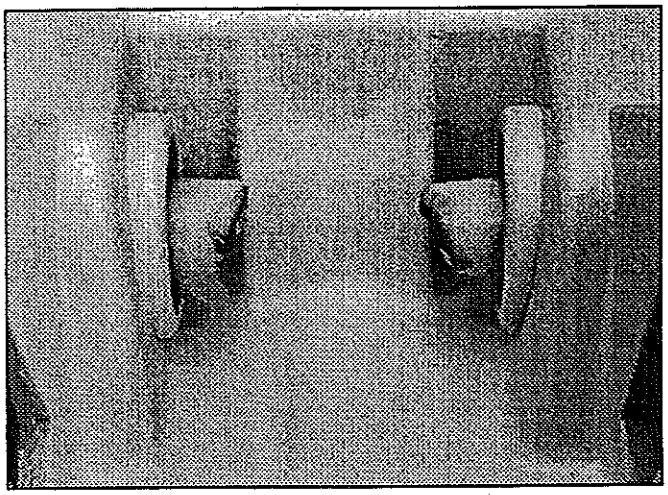


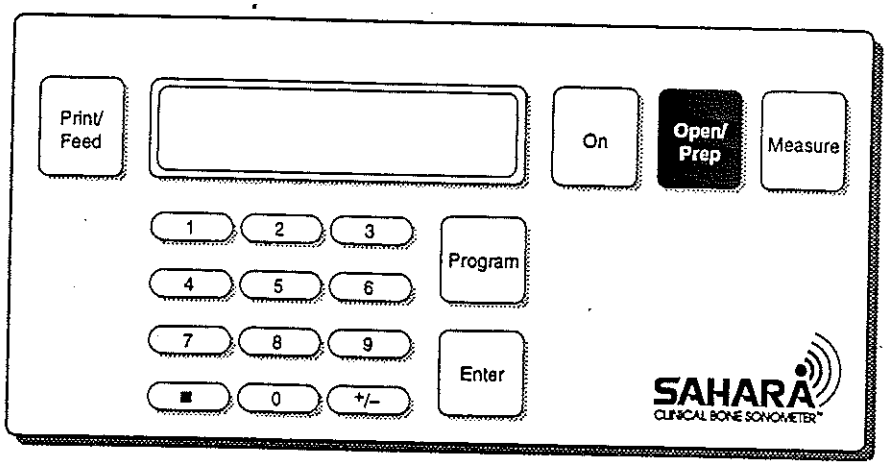
Figure 4-7
Insufficient Amount of Gel on Transducer Pad

The Control Panel Screen displays:

Insert Foot
Press MEASURE

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.

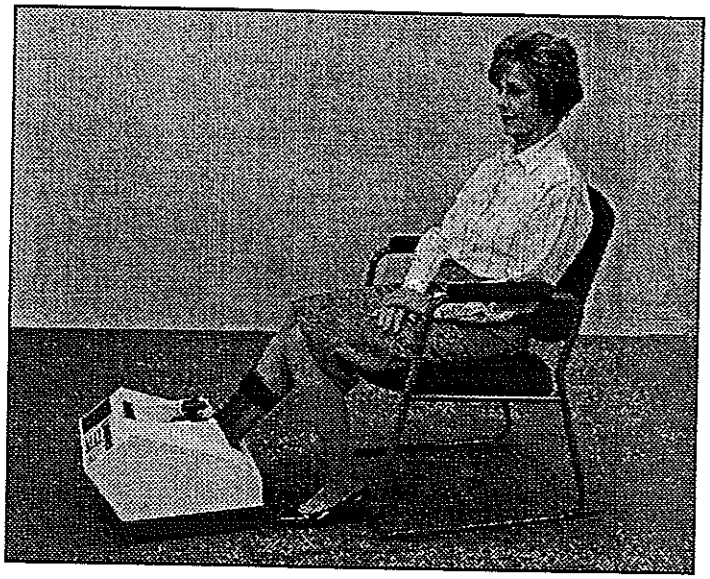
Figure 4-8
Press ***OPEN/PREP***



Position Patient

5. 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



6. 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.

7. Clean the sides of the heel to be measured using towelettes supplied in the Accessories Kit, then dry thoroughly with dry wipes.

8. Place exam paper on the bottom of the scanner foot well.

9. 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.

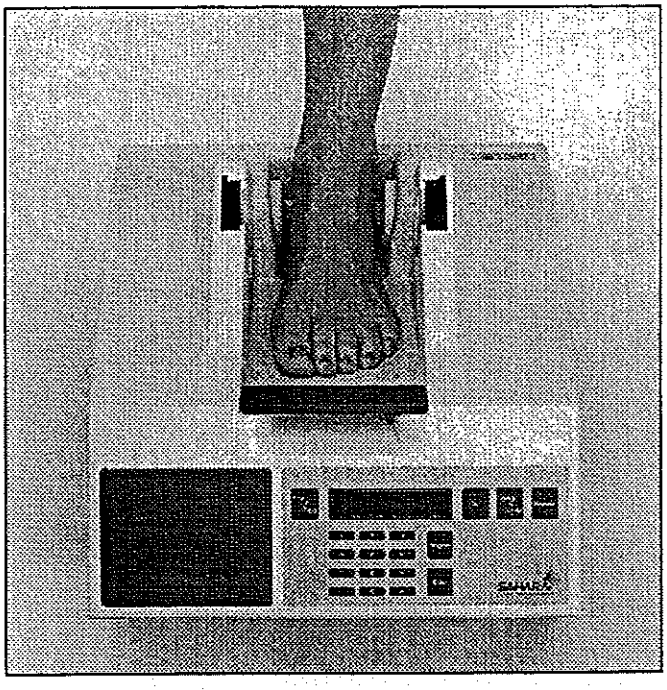


Figure 4-10
Patient Leg Position

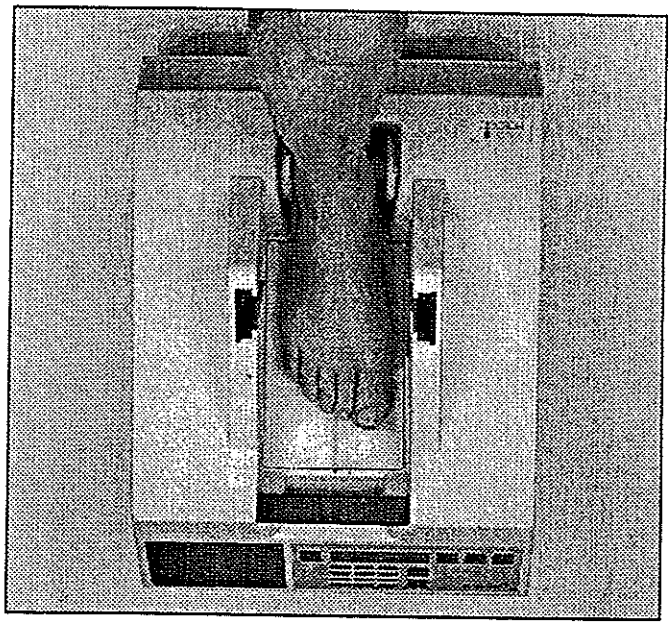


Figure 4-11
Patient Foot Position

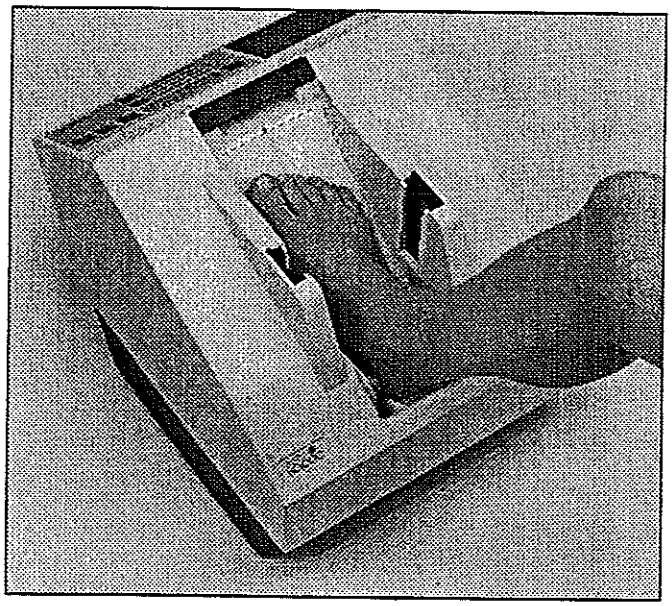


Figure 4-12
Heel Position

10. Position the patient's shin at about the same angle as the positioning aid.

11. 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).

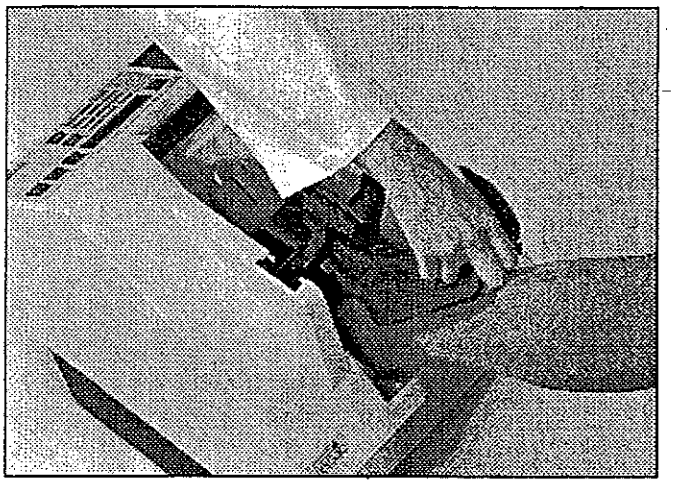


Figure 4-13
Positioning Aid Slightly Loose

12. Adjust the shin 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.

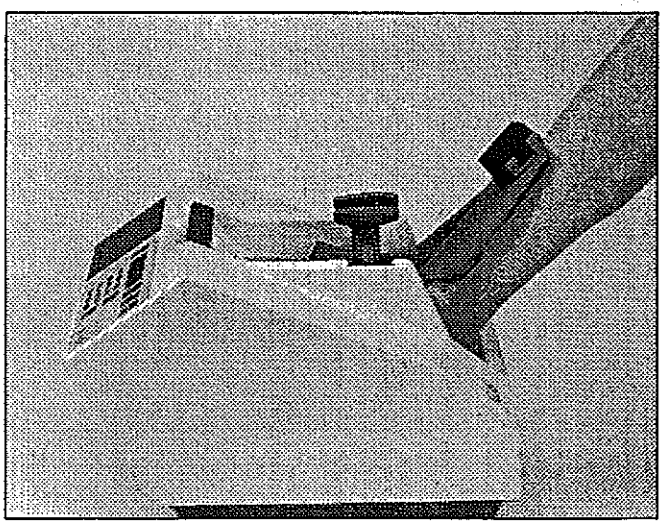


Figure 4-14
Correct Leg Angle (front to back)

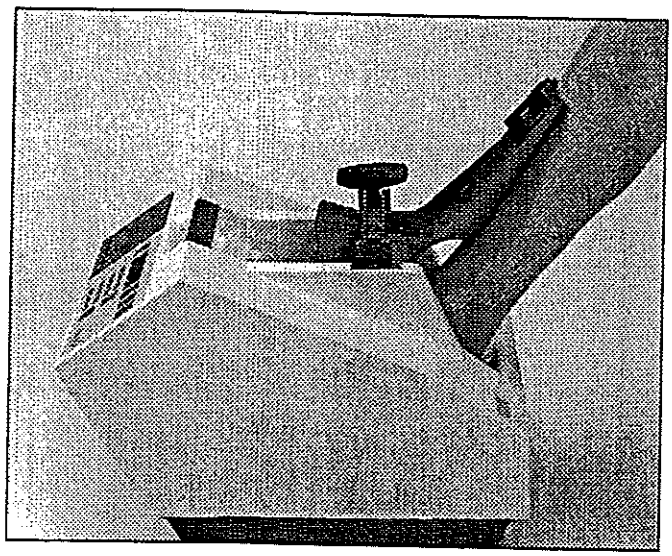


Figure 4-15
Incorrect Leg Angle (system too close)

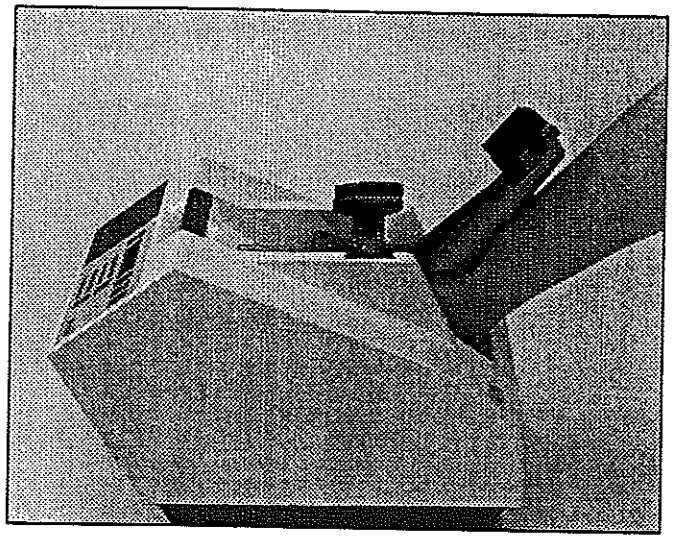


Figure 4-16
Incorrect Leg Angle (system too far)

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

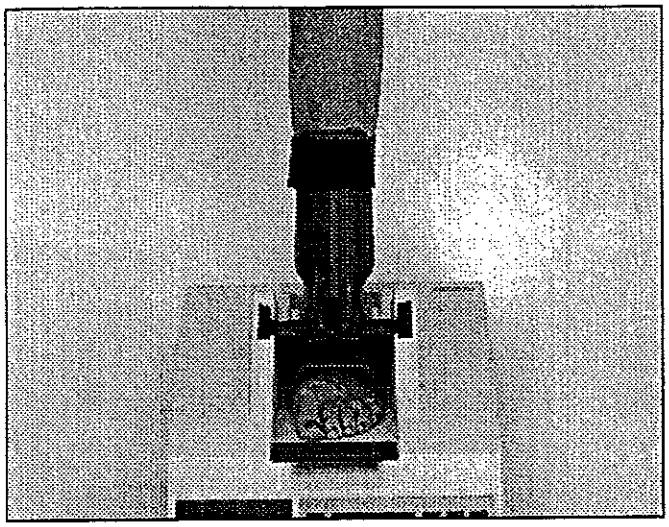


Figure 4-17
Correct Leg Position (side to side)

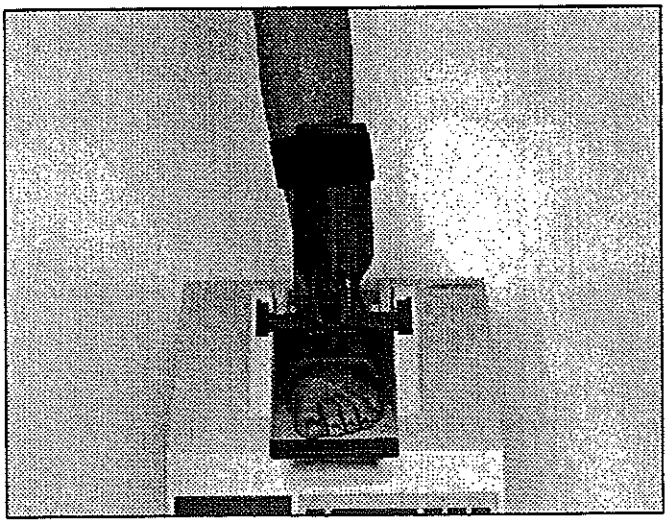
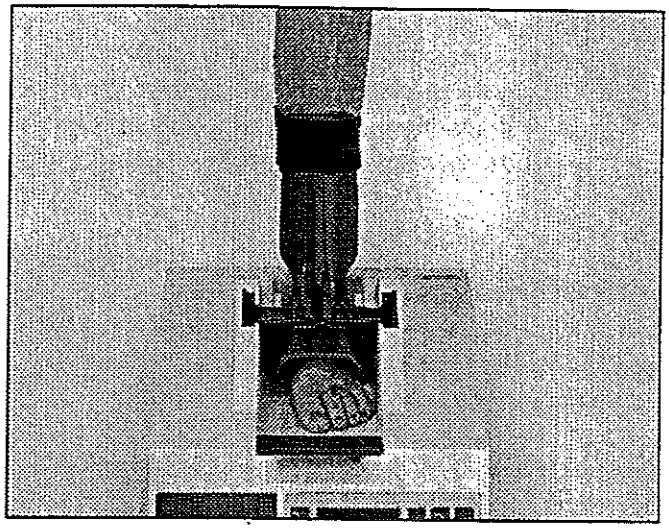


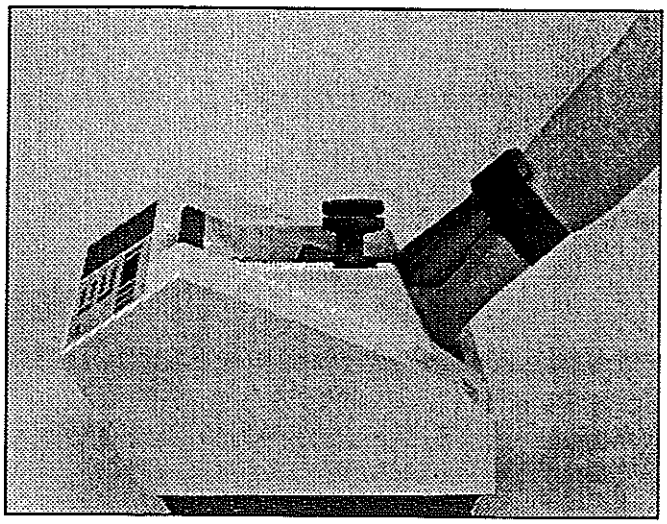
Figure 4-18
Incorrect Leg Position (side to side)

Figure 4-19
Incorrect Position of Toes



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

Figure 4-20
Positioning Aid Strap



15. 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 the 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. Remove the positioning aid strap to remove positioning aid from the leg.

Measure Patient

16. 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.

17. 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.

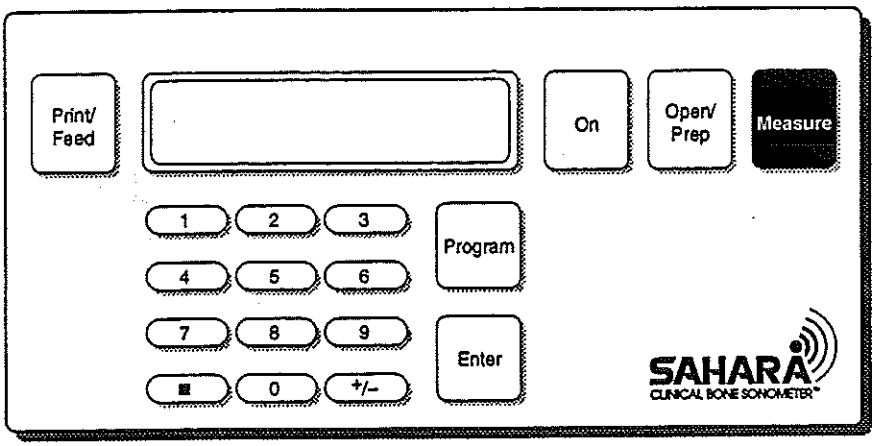
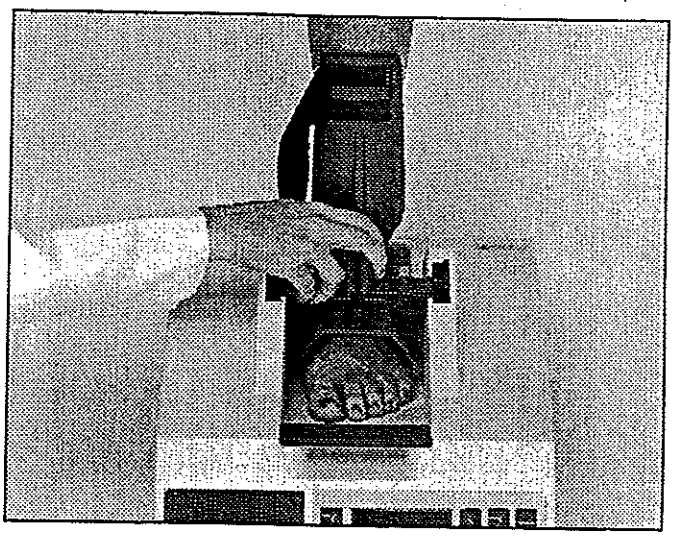


Figure 4-21
Press ***MEASURE***

18. 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:

19. 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).

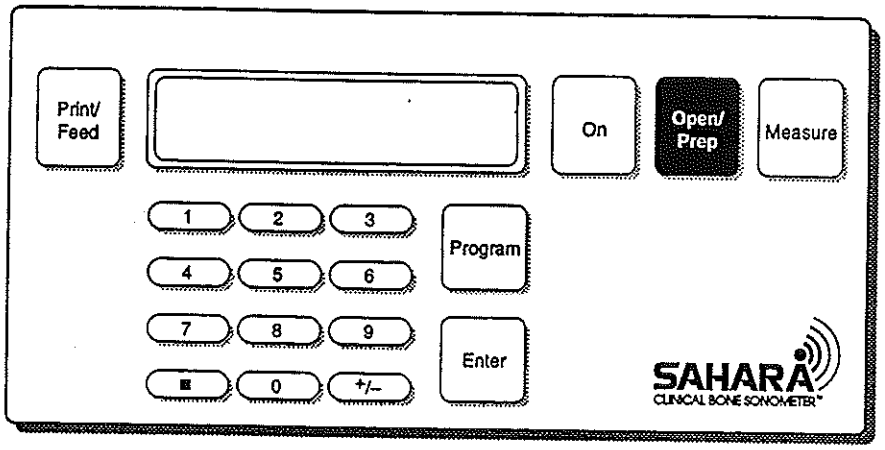
Figure 4-22
Removing Positioning Aid



20. 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.

21. Press **OPEN/PREP.** The scanner moves the transducer pads to the cleaning position.

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



22. Carefully clean and dry the transducer pads. Use Transducer Towelettes supplied in the Accessories Kit to clean the transducer pads, and dry wipes to dry them.

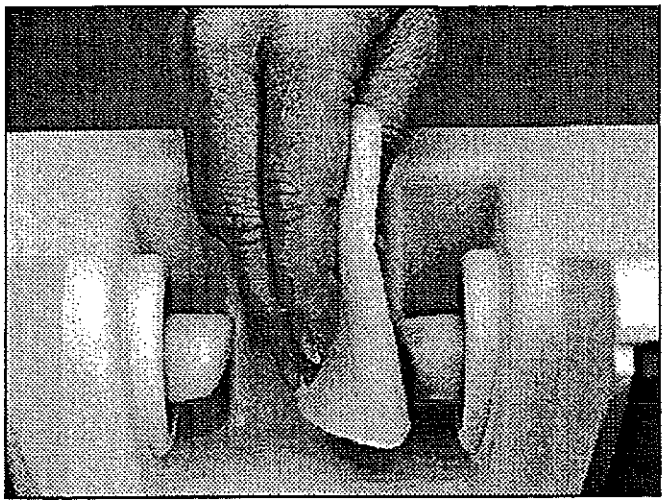


Figure 4-24
Cleaning the Pads

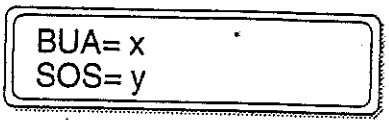
23. The Control Panel Screen displays:

```
QUI/Stiffness= x
T-Score= y
```

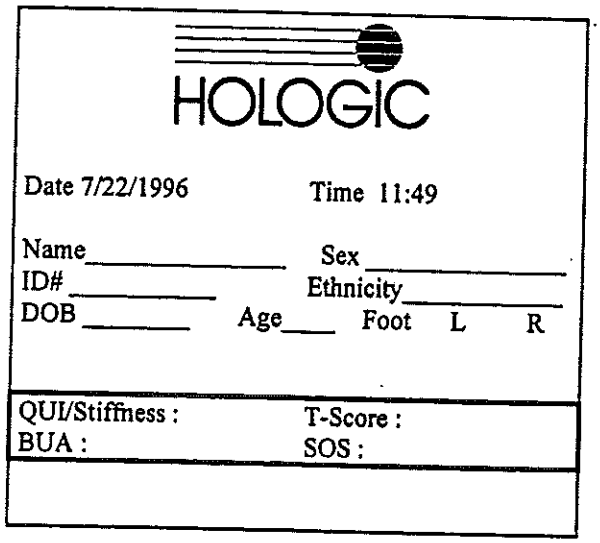
If the Control Panel Screen displays "**Invalid Measurement, Repeat**" or "**Out-of-Range, Repeat**" message, refer to the *System Care and Maintenance* chapter in this manual.

Note: If there is an asterisk after QUI/Stiffness, then the BUA result was imprecise and QUI/Stiffness was calculated using only the SOS data. An imprecise result may be caused by improper foot positioning or not enough coupling gel. 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. If the second measurement also has an asterisk, these results are imprecise and should not be used for follow-up.

24. Press the **+/-** button to display the BUA and SOS values:



25. Record the QUI result displayed using the Patient Report forms provided. Press the **PRINT/FEED** button on the Control Panel to obtain a hard copy record if desired (printer is optional). A sample printout is shown below.



Pressing the **+/-** button will toggle the display to show the BUA and SOS results (together), and pressing **+/-** again toggles back to QUI/Stiffness and T-Score.

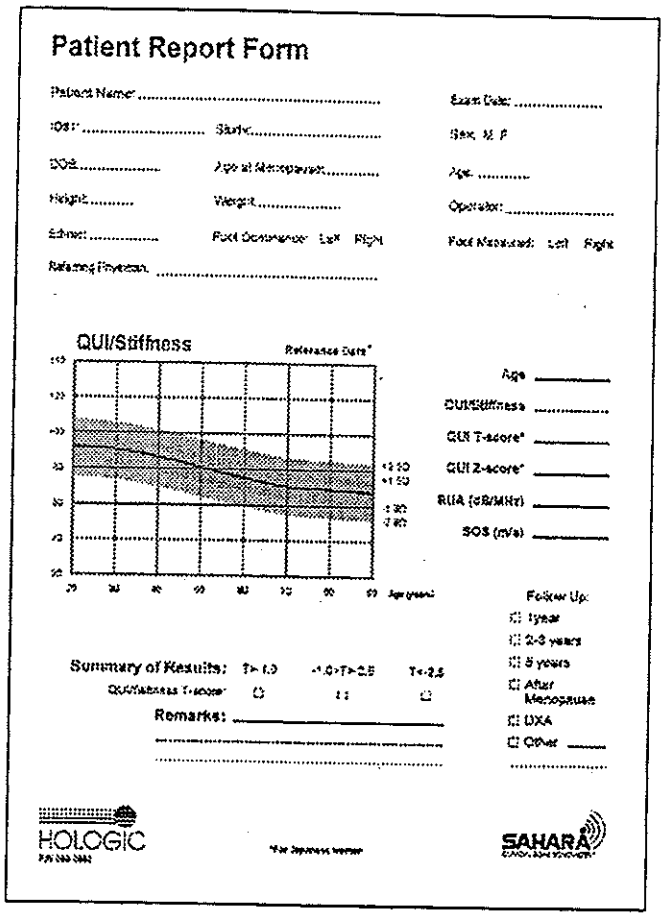
26. To see the most recent measurement results after the LCD screen has gone blank, press **ON** to initialize the system, and then press the **+/-** button to display the last QUI/Stiffness and T-Score results. Press the **+/-** button again and the last BUA and SOS results are displayed.

Patient Report Tablet

The Patient Report tablets are provided to record and save patient measurement results, and to provide a means to graphically and numerically compare results to reference data. Refer to the *Comparison of Patient Results to a Reference Database* chapter for instructions for making reference database comparisons using the Patient Report tablet.

Enter the following information, on the front of the Report Form, prior to the exam.

- Enter patient name and date of the report
- Enter ID# (the patient identification number may be any unique number your facility assigns to patients)
- Enter sex of the patient
- Enter Study (Study can be any sequence of numbers or letters that identify this patient as a participant in a particular research project or clinical trial)
- Enter patient's date of birth (DOB)
- Enter Menopausal Age (Menopausal Age refers to the age of the patient at the time of her last menstrual period)
- Enter patient's age, height and weight
- Enter Operator (your name)
- Enter patient's ethnic background
- Enter Foot Dominance (Foot Dominance refers to the foot favored by the patient, for example: the foot they would kick a ball with, or the lead foot used when climbing a flight of stairs)
- Enter Referring physician and foot measured (left or right)


Patient Report Form

Patient Name: ..... Exam Date: .....

ID#: ..... Birth: ..... Sex: M F

DOB: ..... Age at Menopause: ..... Age: .....

Height: ..... Weight: ..... Operator: .....

Ethnic: ..... Foot Dominance: Left Right Foot Measured: Left Right

Referring Physician: .....

QUI/Stiffness

Reference Data*

Age _____

QUI/Stiffness .....

QUI T-score* _____

QUI Z-score* _____

BUA (dB/MHz) _____

SOS (m/s) _____

Summary of Results: T> -1.0 -1.0>T>-2.5 T<-2.5

QUI/Stiffness T-score ☐ ☐ ☐

Remarks: _____

Follow Up:

☐ 1 year

☐ 2-3 years

☐ 5 years

☐ After Menopause

☐ DXA

☐ Other _____

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Immediately after the exam, the QUI results, displayed on the Control Panel Screen, should be entered on the form in the space provided. Remember to indicate the foot measured (Left or Right), and the date of the exam. If BUA and SOS results are desired, display them on the screen by pressing the **+/-** button and record them on the reverse side of the tablet. BUA and SOS reference data may not be available for all ethnicities.

Note that it is recommended that the measurement results be printed by pressing the **PRINT** button on the Sahara control panel. The results printout from the unit can be stapled to the Patient report as a hard copy record of results, minimizing the possibility of transcription errors.

If the unit's screen is blank, the latest measurement results can be displayed by pressing **ON**, waiting for the system to intialize, and then pressing the **+/-** button.

Figure 4-25
Report Form

Printed 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.

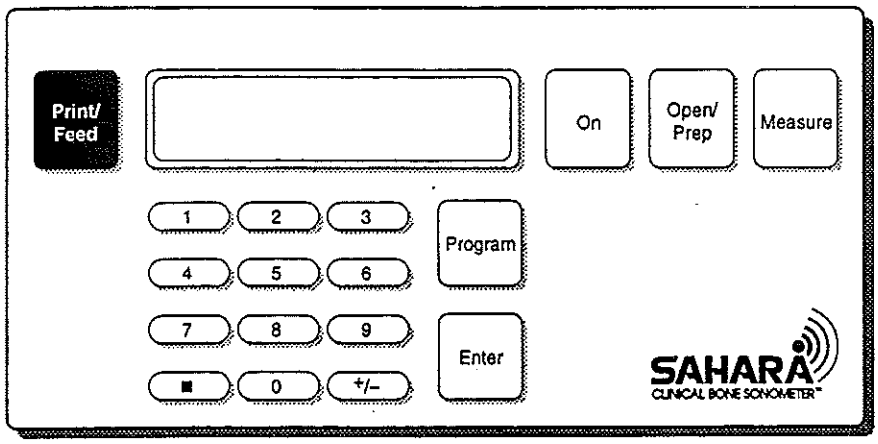


Figure 4-26
Press ***PRINT***

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.

For interpretation of results, refer to the chapter titled *Comparison of Patient Results to a Reference Database* in this manual.

5

Comparison of Patient Results to a Reference Database

This chapter describes the Sahara Patient Report Form, and how it is used to obtain numerical comparisons of individual patient results with a reference database.

Two kinds of comparison 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 normal population, expressed in units of the young normal population standard deviation. Mathematically, the T-score is defined as:

$$(P\text{-}YN)/SD_{YN}$$

where P = patient results
YN = young normal average value
SD = standard deviation of the young normal 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:

$$(P\text{-}AM)/SD_{AM}$$

where P = patient results
AM = age-matched average value
SD = standard deviation of the age matched population

See the *Reference Database Information* section in this chapter for specific information on the Sahara Reference Database.

Patient measurement results may be recorded (by the operator) on the Patient Report Form supplied by Hologic, or printed. Refer to the appropriate section heading below that applies to the configuration of your Sahara system.

Operator Recorded Measurement

On Sahara systems that do not include a printer, it is recommended that the operator record each patient measurement on the Hologic supplied Patient Report Form. The completed report includes fields or spaces for patient biography, referring physician, operator name, foot measured (left or right), and measurement results. Patient and measurement results should be recorded immediately after the measurement to insure that results are not lost.

Obtaining Z-Score Results from Operator Recorded Measurement

The Z-score is obtained by plotting the patient measurement result vs. the patient's age on the Reference Data plot. Follow the procedure below to obtain Z-score for the desired measurement parameter.

1. Look up the patient's age on the x-axis. Using QUI Value and Age, place a mark, on the graph labeled QUI Reference Data where Value and Age intersect.

2. The mark entered in Step 1 can now be used to obtain the corresponding Z-score by comparing the position of the mark to the reference database lines drawn on the graph. The center (darker) reference database line corresponds to the mean QUI value as a function of age. The lines above labeled +1 SD and +2 SD) correspond to a change of one population standard deviation (i.e. one "Z-score") from the mean or "normal" SOS value at any age. Similarly, the lines below the center reference (labeled -1 SD) indicate the number of population standard deviations *below* the "normal" value. By estimating the position of the mark corresponding to the patient result relative to the positions of the Z-score lines, the Z-score can be estimated.

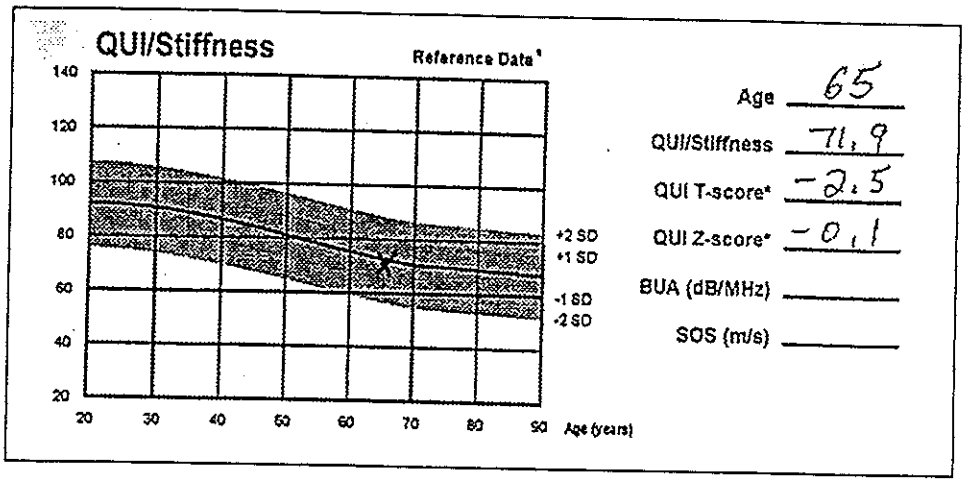


Figure 5-1
Z-Score Example

Printed Report

Print each patient measurement immediately after it is taken (see the *Patient Measurement* chapter of this manual). The printed report shows the QUI measurement results (or BUA, SOS if desired). The operator adds the patient biography, referring physician, operator name, and foot measured (left or right) information to the printed report.

T-Score from Printed Report

T-score is shown on the printed report. This value depends on the user entered Young Normal Mean and Young Normal Standard Deviation. See *Set Young Normals* section in Chapter 2 of this manual.

Reference Database Information

Hologic has created the standard curves used for plotting. These curves are for the convenience of the physician and are based upon the best available data at the time of publishing. These databases may be revised or updated as new data become available.

Hologic provides information about each reference curve it supplies. This information, available from Hologic, may be helpful for deciding whether a particular database is appropriate for a specific patient population.

5 *Comparison of Patient Results to a Reference Database*

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, Transducer Towelettes, dry wipes, report form tablets, printer paper, or other supplies for the Sahara system:

International customers should contact their authorized Hologic distributor.

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

Cleaning

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: It is important to use only *the towelettes and dry wipes supplied with the Sahara system for cleaning the transducer pads, as other types of wipes/towelettes may leave fibers or residues on the 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.

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).

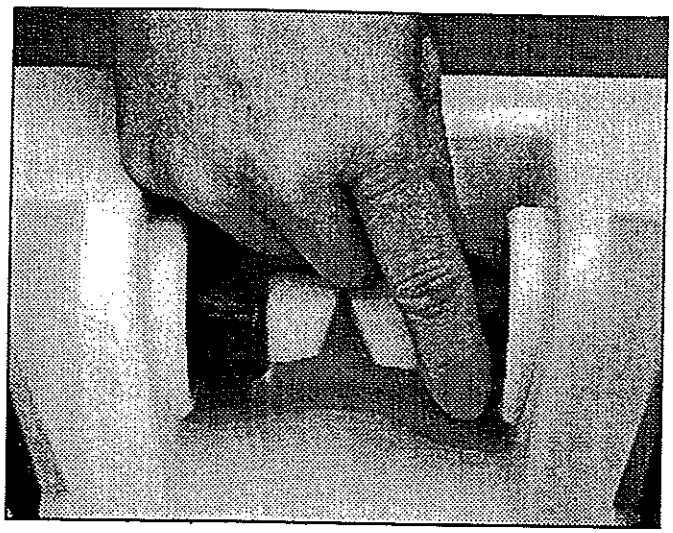


Figure 6-1
Remove Transducer Pad Housing

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.

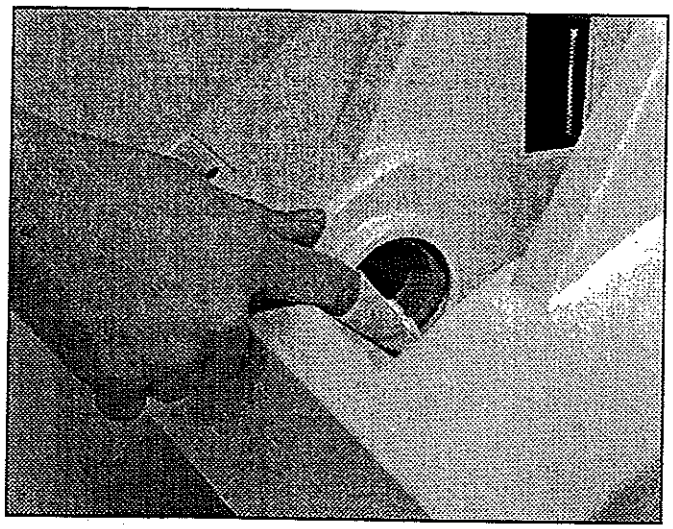


Figure 6-2
Cleaning Transducer Face

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:

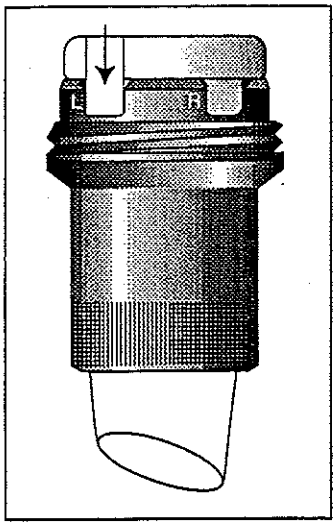


Figure 6-3
Left Transducer Pad Alignment

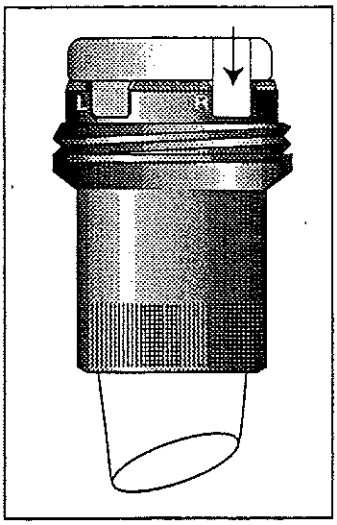


Figure 6-4
Right Transducer Pad Alignment

5. Apply Hologic Sahara Pad Installation Gel to the flat end of the pad before positioning it in place in the scanner. Spread the gel evenly with your finger so that there is about a 1/8 inch (3 mm) coating on the pad. Be careful not to introduce air bubbles, dirt or other contaminants (see the figure below).

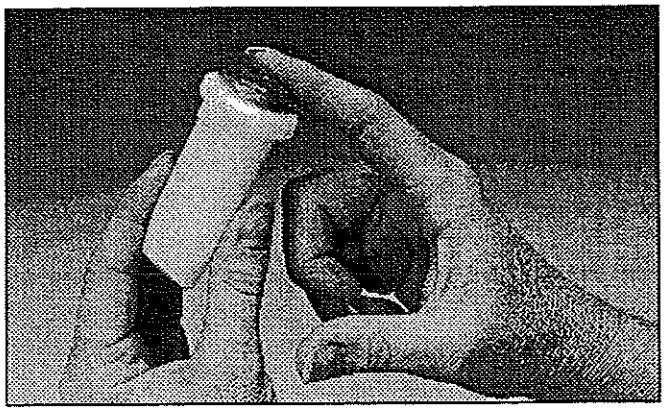
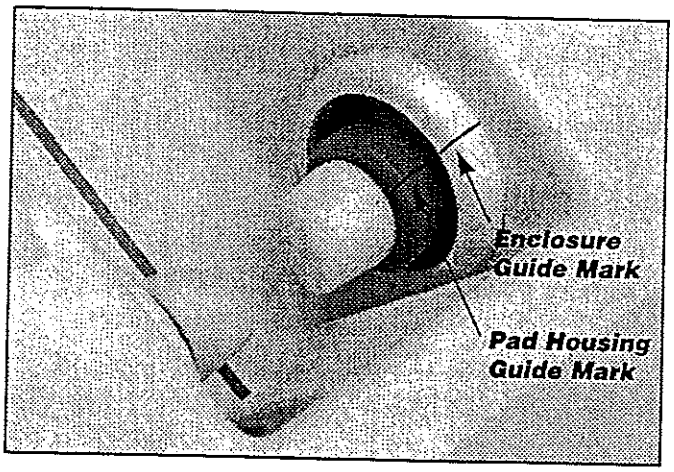


Figure 6-5
Pad gel Application

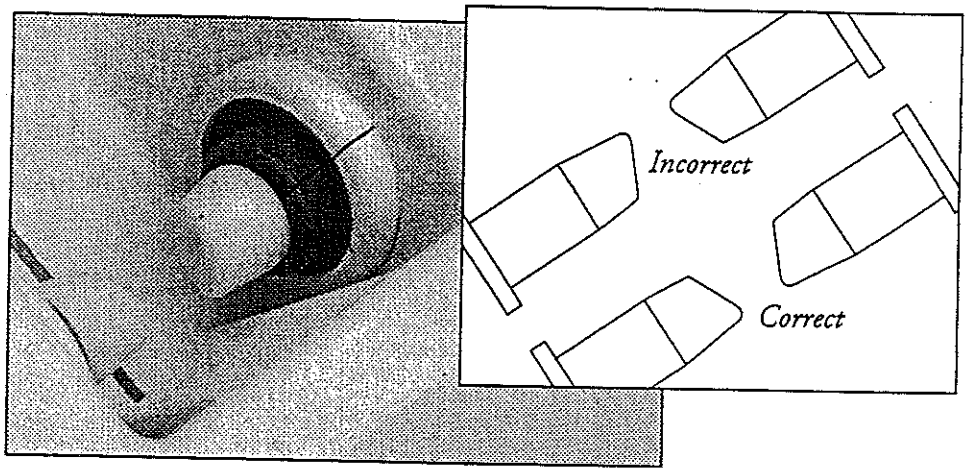
6. With gel applied, screw the housing/pad onto the transducer as far as it will go. The guide mark on the Sahara enclosure should line up with the mark on the transducer housing (see the figure below). Repeat steps 1-6 for the other transducer pad.

Figure 6-6
Pad Guide Marks



7. With both pads installed, the scanner 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 equilibriated to room temperature for at least one hour before performing this procedure.

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

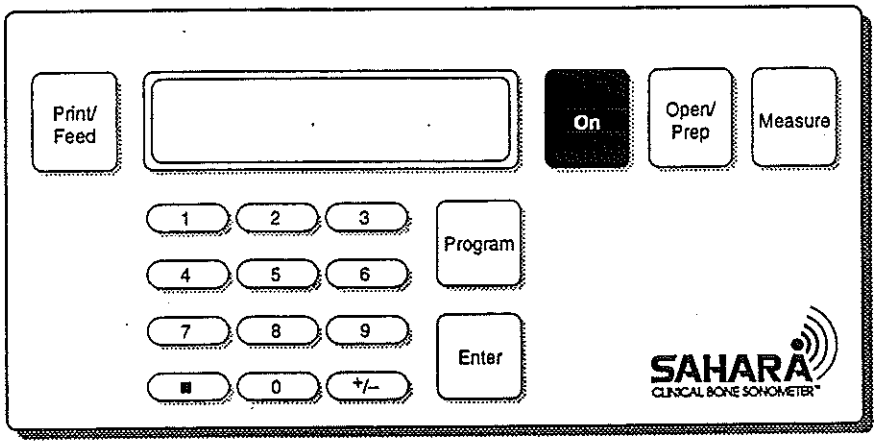


Figure 6-8
Press ON

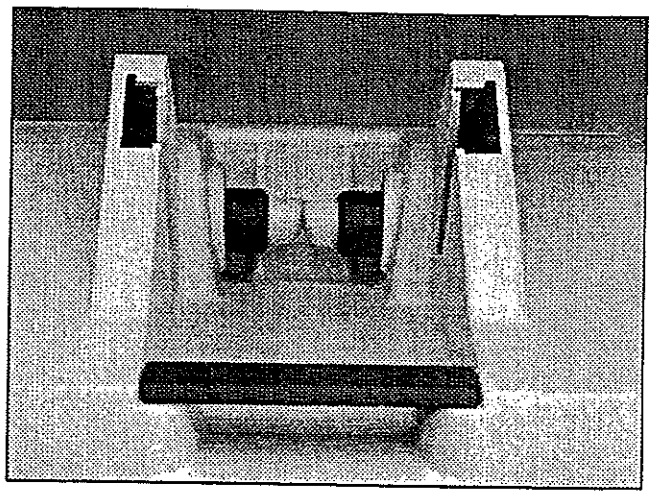


Figure 6-9
Transducer Pads Touch

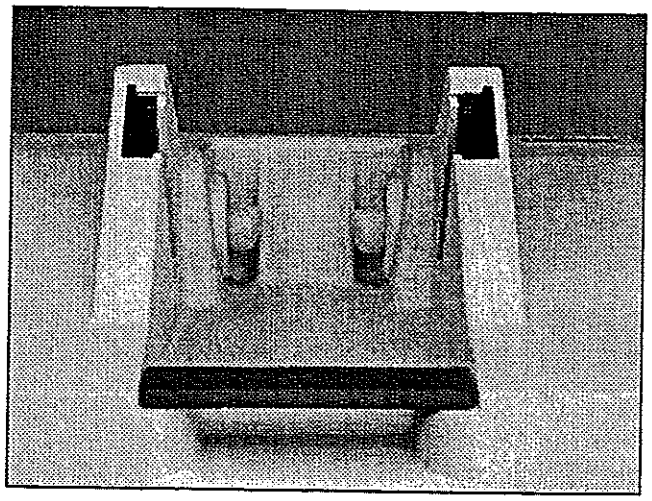


Figure 6-10
Transducer Pads Ready for Gel

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 any key to return to the last screen.

2. When the phantom is properly positioned, press the **PROGRAM** button, then the **2** button and then **ENTER** on the control panel. This initiates calibration of the system.

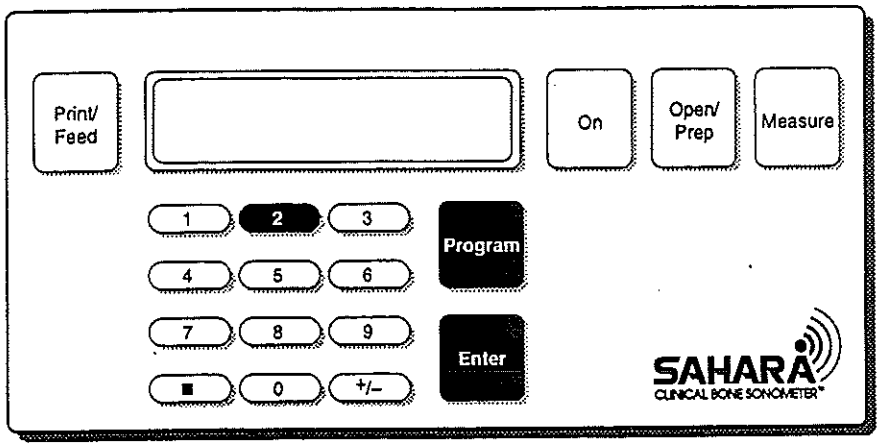


Figure 6-11
Press ***PROGRAM, 2, ENTER***

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). 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]  1) Gel pads
2) Press Open
```

9. For each transducer pad, squeeze out about a one inch (2.5 cm) bead of gel (or about 1/4 teaspoon) onto transducer pads, finger, or tongue depressor (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.

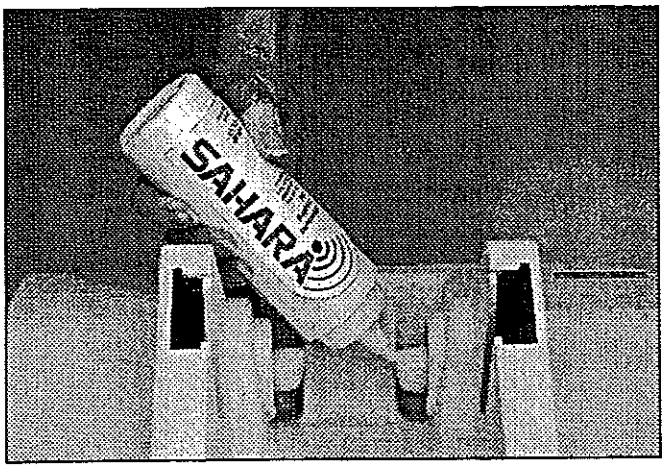


Figure 6-12
Gel Measurement

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.

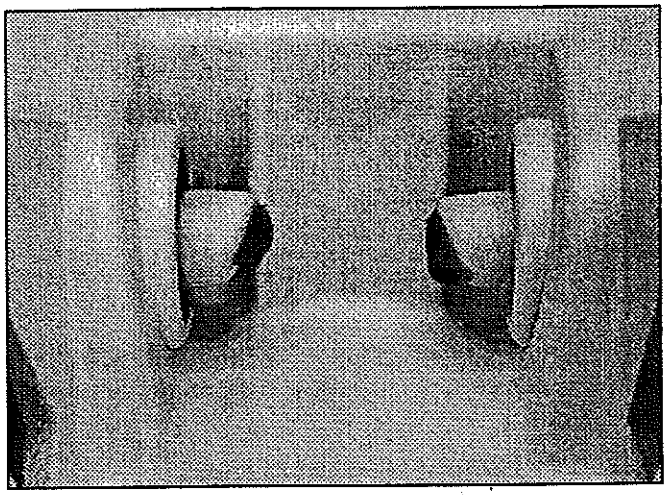


Figure 6-13
Proper Amount of Gel on Transducer Pad

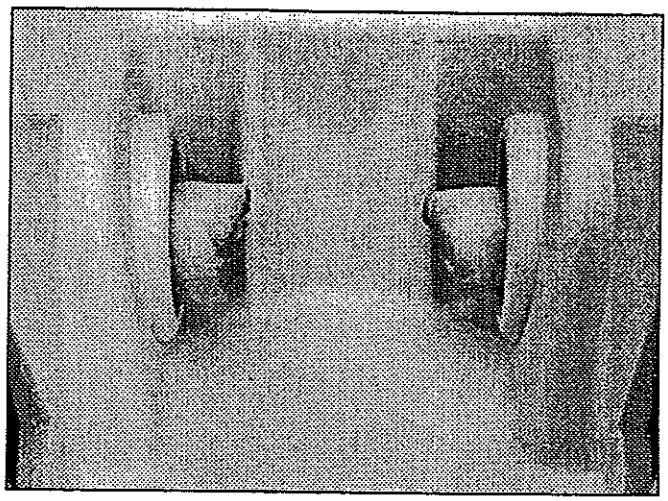


Figure 6-14
Insufficient Amount of Gel on Transducer Pad

11. 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.

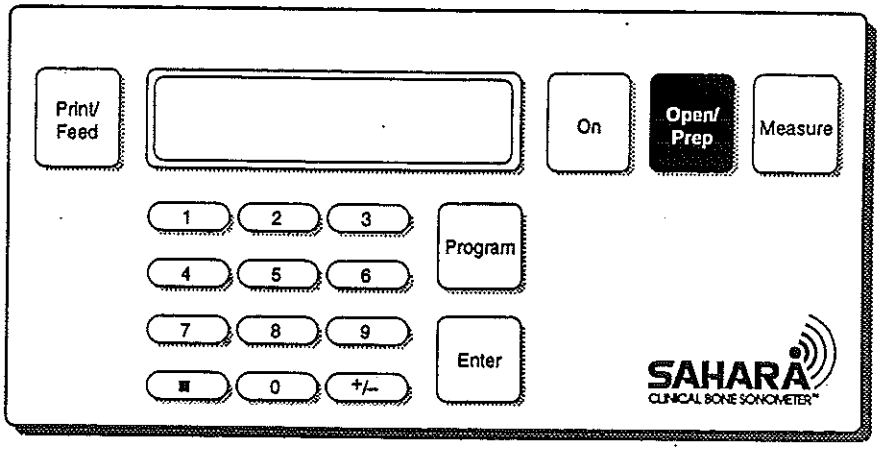


Figure 6-15
Press ***OPEN/PREP***

12. Locate the QC phantom and place it 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 scanner (see the figure below).

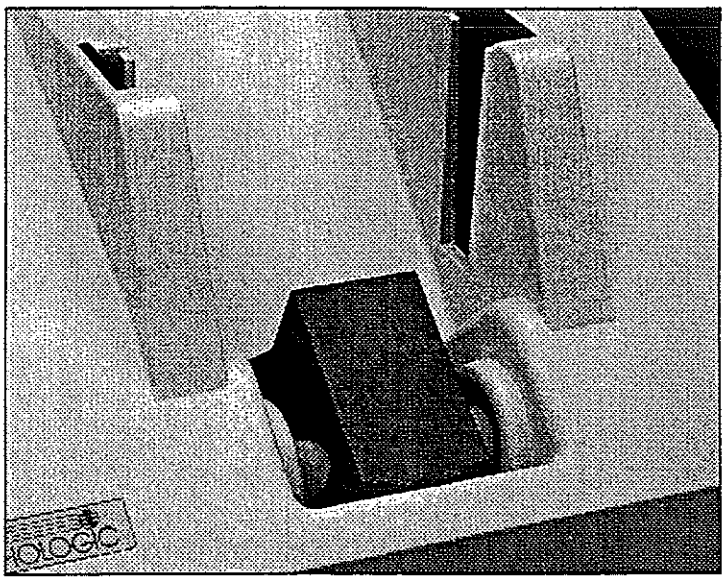


Figure 6-16
QC Phantom in Position

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

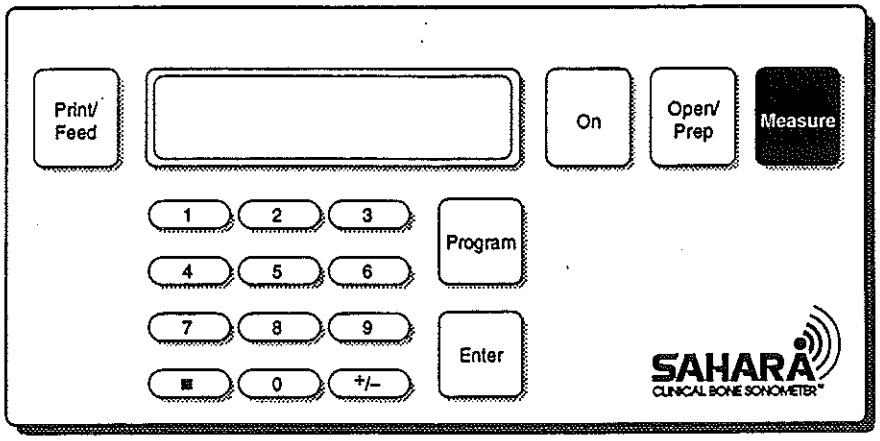


Figure 6-17
Press ***MEASURE***

14. Remove the phantom.

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

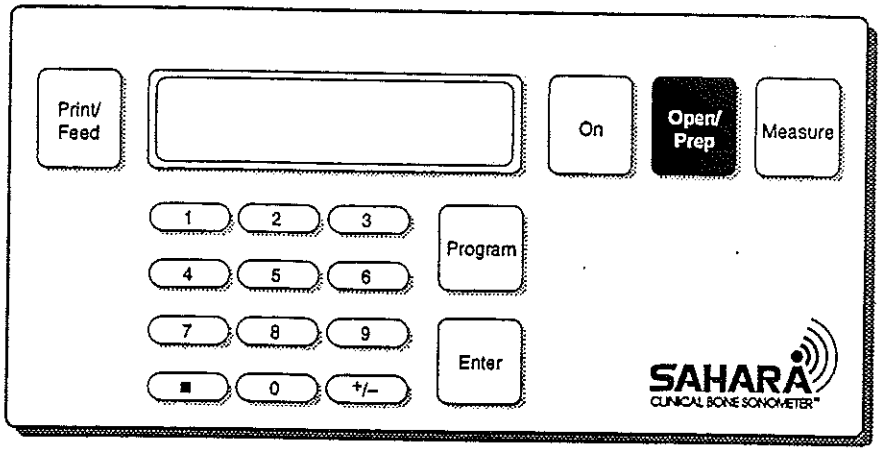


Figure 6-18
Press ***OPEN/PREP***

16. Carefully clean and dry the phantom and the transducer pads. Use Transducer 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.

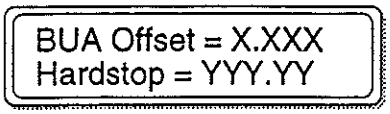
17. Press **ON**. The Control Panel Screen displays the following message:

```
[2 of 5]  1) 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:

```
BUA Offset = X.XXX
Hardstop = YYY.YY
```

19. Press **ON**. This completes the calibration procedure. The system will now allow a QC measurement to be performed.



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:

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.

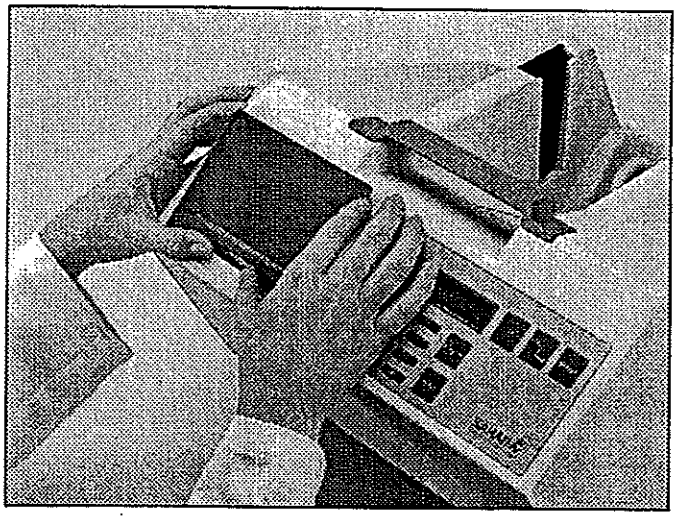


Figure 6-19
Removing Printer Cover

2. Place the paper roll into the printer tray.

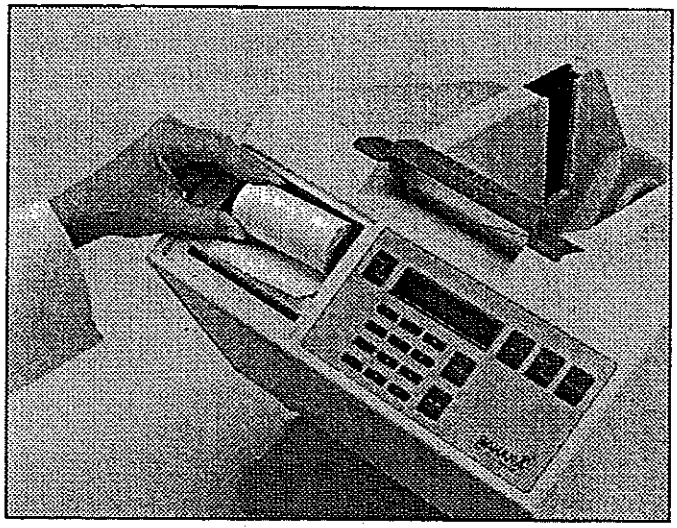


Figure 6-20
Installing Printer Paper

3. Remove any tape on the paper roll and insert the paper into the paper feed slot.

Figure 6-21
Paper Feed

4. Press the **ON** button while the screen is displaying "Gel Pads Press OPEN", then press the **Print/Feed** button. Wait until 2 to 3 inches (5 to 8 cm) of paper appears with the Hologic logo.

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 6-22
Printer Cover Replaced

What to do in Case of Trouble

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

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 clear the printer.

Remove the printer cover. Make sure that there is at least 1 inch (2.5 cm) of paper accessible above the enclosure's printer outlet slot. Pull up a 2 inch (5 cm) loop of paper between the paper supply roll and the printer feed-in slot. With scissors make a clean perpendicular cut across this loop. Gently pull out the section of paper from the printer outlet by pulling straight up so that no pieces of the paper's edge tear off and remain in the mechanism. Finish by performing a normal new paper feed as described in the *Printer Operation* section of this chapter.

Power Problem

If the system will not power up, check the following:

- Is the power supply plugged into the scanner?
- 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 scanner 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.

System Malfunction

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:

```
xxxxxxxxxxxxxx
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.

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 **4.**
8. Press **ENTER.**

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

Exception Report

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:

QC Failed
Repeat

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

- 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.
- 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 1/8 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).
- 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.
- 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 clear the problem.

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
- foot is too narrow or too wide

Repeat the measurement. If, after five 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

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