

QUANTITATIVE ULTRASOUND OF BONE**TABLE OF CONTENTS**

1.	Introduction/overview of ultrasound measurements in Health ABC.....	2
2.	Equipment.....	3
2.1	Equipment maintenance and repair	3
3.	Safety Issues and Exclusions.....	4
4.	Participant and Exam Room Preparation.....	4
5.	Measurement Procedures.....	5
6.	Data Collection	6
7.	Data Backup and Transfer	7
7.1	Archiving the Sahara Database	7
7.2	Monthly data transfer.....	7
8.	Procedures for Performing the Measurement at Home	8
9.	Alert Values/Follow-up/Reporting to Participants.....	8
10.	Quality Assurance	8
10.1	Phantom Scans	8
10.2	Training and Certification of Operators	9
10.3	Quality Control Checklist.....	10
	HABC SAHARA REPAIR / SERVICE LOG SHEET.....	11
	Sahara Quality Control Log.....	12
	Health ABC Sahara Data Transfer Log.....	13

QUANTITATIVE ULTRASOUND OF BONE

1. Introduction/overview of ultrasound measurements in Health ABC

Bone mass explains 30 to 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 directly with its connectivity.

Quantitative ultrasound (QUS) may be a useful measure of both the quality and quantity of bone. Two 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 to 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 ($r=0.4$ to 0.6), nor are they highly correlated to each other.

Although QUS is not a good surrogate measurement for bone density, it does have clinical utility because it appears to assess bone strength. In the Study of Osteoporotic Fractures we have demonstrated that low calcaneal QUS is associated with a variety of fractures, 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. Other large prospective studies have found similar relationships. There is little data on the relationship between QUS and weight loss, inactivity or major medical illness.

Besides its potential for assessing bone strength, quantitative ultrasound has several practical advantages over densitometry: it is quicker, less expensive, entails no radiation exposure, and is portable. Both ultrasonic velocity and BUA measurements are sufficiently reproducible, generally 0.5 to 1.0% and 2 to 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.

In Health ABC we will be measuring QUS with the Hologic Sahara. This device has recently been approved by the FDA and will be widely available soon. Compared to other available devices, the advantages of the Sahara include reduced scan time, improved precision, dry coupling to the heel (no water bath), and importantly, an established and reliable service network.

2. Equipment

Quantitative ultrasound (QUS) measurements will be carried out using a Hologic Sahara. A matrix of 3x3 locations is measured and the final results are obtained by averaging 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. 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.

Equipment list

- Sahara Clinical Bone Sonometer
- Laptop PC with Research Software Version 1.2
- Sahara ultrasound coupling gel
- Baby wipes
- QC phantom
- Positioning aid
- Power module

2.1 Equipment maintenance and repair

Routine maintenance of the Sahara is discussed in detail in the User's Guide, Chapter 6. Do not use other brands of coupling gel.

Sahara Maintenance Logs

The UCSF Coordinating Center would like to keep track of repairs, upgrades and equipment replacement. Please use the attached Sahara Repair/Service Log Sheet to document any equipment, hardware (including the computer), or software problems and their resolution. These should be sent to Elizabeth Edwards at the UCSF Coordinating Center (fax 415-597-9213). Be sure to record (with dates) all scheduled and unscheduled maintenance performed on your device, as well as any change in hardware or software. Please make copies of the Sahara Repair/Service Log as needed.

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. Elizabeth Edwards (415) 597-9318 will be available to help you.

3. Safety Issues and Exclusions

A small proportion of participants will have very large heels because of foot edema or other problems. If the heel does not fit easily into the Sahara, do not attempt to scan the participant.

4. Participant and Exam Room Preparation

Health ABC participants should be informed that a painless, radiation-free measure of heel bone integrity will be done during their Year 2 Health ABC clinic visit. 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 to 10 minutes.

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

5. Measurement Procedures

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 to 2 hours prior to use. Follow this procedure:

For each transducer pad, squeeze out about an inch bead of gel onto your finger.

Apply a bead of gel along the face of each pad, from the tip to the bottom. The tip of the pad should be covered with gel.

Select the OPEN button on the <Measure the Patient's Heel> window. This will open the transducer pads to the fully open position.

Please refer to pages 5-7 to 5-9 of the Sahara Clinical Bone Sonometer Advanced Clinical User's Guide by Hologic) for additional details.

Deciding which side to scan

In general, scan the right heel unless the participant had recently injured that extremity, has a deformity on that side, has permanent right-sided weakness (usually from a stroke), or has an open wound in the heel/ankle area.

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 device and repositioned between measurements. If the second BUA measurement differs by more than ten units obtain a third measurement. Do not obtain a third measurement if the first two BUA measurements do not differ by 10 or more units. It is not necessary to obtain more than three measurements on a participant, even if they all differ by more than 10 BUA measurements.

Asterisk results.

Asterisk results indicate a non-linear BUA result which may be inaccurate. They may occur with unusual-sized or shaped heels.

If asterisks are obtained on the first scan, pay special attention to positioning of the heel when repeating the measurement. If an asterisk is obtained on a scan, obtain a third measurement.

Special problems

- a. Bunions. The centering device for the Sahara assumes normal foot anatomy. Some participants will have significant bunions (outward deviation of the toes) which complicates positioning of the foot. If a bunion is present, do not use the centering line (normally placed between the participants second and third toes), simply position the foot as best as possible so that the long axis of the proximal foot is perpendicular to an imaginary line drawn between the two heel transducers.
- b. Swollen/big feet. A small proportion of participants will have very large heels because of foot edema or other problems. If the heel does not fit easily into the Sahara, do not attempt to scan the participant.
- c. Sores on shin. A small number of participants may have sores on their shins. If this is the case, place a paper sheet between the participant's shin and the positioning device.

6. Data Collection

All data collected for the Sahara measurements will be stored and transmitted to the Coordinating Center electronically. Results will also be recorded on the Health ABC Clinic Visit Workbooklet.

a. Participant Identification.

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

b. Health ABC Ultrasound Data Collection Form

Record the Staff ID # and participant's Health ABC 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.

c. Sahara Printed Results

Although the Sahara is capable of printing results, this will not be done in Health ABC as the data will be captured electronically and on the Health ABC workbooklet.

7. Data Backup and Transfer

During the Health ABC study it is expected that the database on the Sahara will become very large. This situation would require many floppy disks in order to archive completely. In order to save clinic time during the archiving process and facilitate the transfer of data to the coordinating center, each clinic has been asked to purchase and install an external 'zip' drive onto the Lap Top computer that is used for the Sahara. The data back-up and transfer procedures will require several zip cartridges: we recommend that each site purchase at least four cartridges. Each cartridge should be clearly labeled with the clinic name. The zip drive will probably occupy either the 'e' or 'f' drive on the Lap Top. Whoever does the installation of the zip can tell you which drive has been assigned to the zip function. In order to set the archive path to the zip drive (the default is the 'a' drive) the following directions should be followed:

At the Sahara main menu, click on the <Utilities> pull down menu on the menu bar at the top of the screen. Select <Set Program Defaults> on the pull down menu. See the box labeled 'Directories' and select <Change Directory>. See <Choose Archive Path>. The current archive path probably reads **a:\arch_dat**. Highlight the current drive letter (the 'a') and change the current drive letter to the zip drive letter. The zip will probably be 'e' or 'f'. Then close the window.

This is a one-time set-up and need only be re-set when it is necessary to change the archiving media.

7.1 Archiving the Sahara Database

To prevent data loss from computer or other system failures, we are requesting that each Health ABC clinic archive the entire Sahara database at the end of each week. We recommend that each field center devote two zip cartridges to the weekly archiving of data (although both zip cartridges do not have to be used every week). The zip cartridges that are used for the weekly back-ups should be rotated every other week.

To archive the database, open the Sahara main menu. Put a zip cartridge into the zip drive. Click on the <Database> pull down menu on the menu bar at the top of the screen. Select <Archive Database>.

Keep the archived database in a safe location in the clinic.

7.2 Monthly Transfer of Sahara Data to the Coordinating Center

Starting immediately and then on or about the first of every month, please make an additional zip cartridge using the instructions for archiving described above and send it by Federal Express (2-day delivery is sufficient) to the Coordinating Center. Complete a Health ABC Sahara Data Transfer Log and enclose it with the zip cartridge. Please make copies of the Health ABC Sahara Data Transfer Log as needed. Also send a copy of the Quality Control Log (Hologic form P/N 080-0606 Rev A)

Send the zip disk to: Elizabeth Edwards

UCSF Prevention Sciences Group
74 New Montgomery Street, Suite 600
San Francisco, CA 94105
(415) 597-9318

The disks will be downloaded onto computers at the Coordinating Center and then the zip cartridges will be returned to each clinic for re-use.

Please designate one examiner and a back-up examiner, to serve as the local Sahara data contact. This person should be familiar with the weekly back-up and monthly data transfer procedures, and will be contacted by the Coordinating Center or Hologic for Sahara-related data issues.

8. Procedures for Performing the Measurement at Home

Not applicable.

9. Alert Values/Follow-up/Reporting to Participants

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 less well established than bone densitometry, particularly for African-American men and women, and that we hope to further study the relationship between ultrasound measures and skeletal health in this study. Refrain from discussing the exact meaning of specific ultrasound values. Keep in mind that the vast majority of physicians, even those who are knowledgeable about osteoporosis, will not be able to interpret the meaning of specific BUA, SOS or QUI levels.

10. Quality Assurance

10.1 Phantom Scans

1) Each site will receive acoustic phantoms from Hologic. Phantom scans must be performed daily. As phantom results are very temperature dependent, we recommend that the phantoms be kept at room temperature (to the extent possible), and that daily phantom scans be performed after the ambient temperature of the room and machine have been stable for several hours (for example, during the noon hour or early afternoon).

A single phantom scan should be performed each day the machine is used, and the results recorded in the Hologic QC Log (see attached) maintained at the site. Follow the instructions detailed in the User's Manual, Chapter 3, "Quality Control."

2) 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.

3) Reproducibility

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

10.2 Training and Certification of Operators

Although BUA measurements are relatively simple compared to BMD measurements, 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 Health ABC participants must complete the following:

- Carefully read this section and the Sahara User's Guide
- Receive training from the Health ABC QC Officer or the designated staff who attended the central training session
- 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 Health ABC QC Officer or designate

10.3 Quality Control Checklist

- QC scans
 - Phantom maintained at room temperature
 - Proper placement of phantom
 - Results recorded on QC log

- Participant preparation
 - Shoe, stockings removed
 - Foot is completely dry
 - Chair, leg positioned properly

- Foot positioning
 - Correctly assesses side to scan
 - Gel applied correctly
 - Positioning/restraint applied correctly

- Scanning of participant
 - Two measurements of the same heel performed
 - Third measurement performed if second BUA measurement differs by more than ten units.
 - Third measurement performed if either the first or second BUA measurement is asterisked.

- Results properly transcribed and attached to Ultrasound Data Collection Form
 - Participant's Health ABC Enrollment ID # properly recorded
 - BUA, SOS, and QUI values are recorded as they appear on the Sahara printout or computer screen



Field Center		Date log completed		
<input type="checkbox"/> Memphis	<input type="checkbox"/> Pittsburgh	<input type="text"/>	<input type="text"/>	<input type="text"/>
		Month	Day	Year

SAHARA REPAIR/SERVICE LOG

Instructions: Please complete this log thoroughly and attach a copy of the Hologic service report. Fax one copy to Elizabeth Edwards (fax: 415-597-9213) at the Health ABC Coordinating Center. Keep one copy with your scanner in your own repair log.

1 Date problem(s) encountered: / /
 Month Day Year

2 Describe problem: _____

3 Was the Sahara operational during the problem period?

Yes

No

a. Did problem affect scans? Yes No
 b. Please describe: _____

How long was the Sahara out of service?
 days

4 Describe the action taken: _____

5 Was the problem resolved? Yes No

a. Date problem was resolved: / /
 Month Day Year
 b. Please describe how the problem was resolved: _____

6 Was a recalibration of the Sahara necessary? Yes No

7 Were phantom scans performed after the repair or the recalibration?

Yes No

Did you notice a change in the phantom values?
 Yes No

Version 1.1, 8/12/98

QUALITY CONTROL LOG

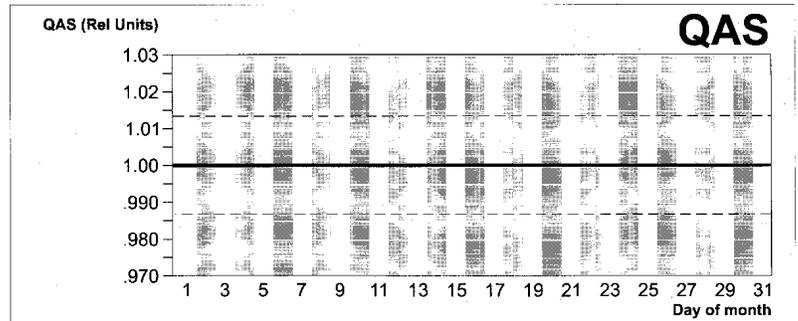
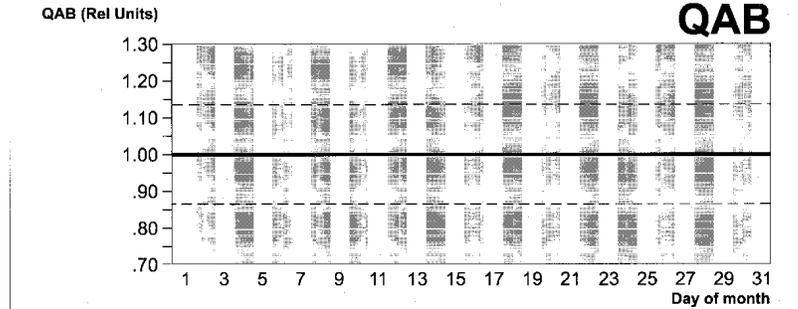
Month: _____ Year: _____

Clinic: _____ Operator: _____

System S/N: _____ Phantom S/N: _____

Phantom BUA: _____ Phantom SOS: _____

Day	QAB (Rel Units)	QAS (Rel Units)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31		





**MONTHLY
ULTRASOUND (SAHARA) DATA TRANSFER**

To: Elizabeth Edwards
UCSF Preventions Sciences Group
74 New Montgomery, Suite 600
San Francisco, CA 94105
(415) 597-9318

From: _____

Staff ID #:

Field Center: Memphis Pittsburgh

Telephone #: () -
Area Code Number

Date data backed-up on Zip cartridge: / /
Month Day Year

Comments: _____

UCSF Coordinating Center Use Only:

Date Zip cartridge received: / /
Month Day Year

Date Zip cartridge mailed back to field center: / /
Month Day Year

Zip cartridge mailed back to: _____
(Name of Field Center Staff)

Comments: _____

Version 1.1, 8/12/98