PREVENTION SCIENCES CENTER

Mailing Address: 74 New Montgomery, Suite 600 San Francisco, CA 94105

> hone: (415) 597-9100 415) 597-9213

Campus Mail: UCSF Box 0886



SOF MEMO 171

To:

All Hologic Operators

From:

Peter Steiger

Date:

2/24/89

SOF QDR PROCEDURE AND QUALITY CONTROL MANUAL

Enclosed please find the updated SOF QDR quality control and procedure manual. It is a digest of the topics I covered during my visits. I learned a lot on my trip and would like to take this opportunity to thank you once again for your hospitality.

In order to simplify the interaction between all of us, I would like to introduce the notion of Principal Hologic Operator. This person is primarily responsible for the operation of the Hologic at each clinic. That means that she makes sure that all quality control tasks are performed in a timely fashion, that all participants have been scanned and analyzed adequately before they leave the clinic, and that all data is archived, copied and sent to San Francisco as required. The principal Hologic Operator is also responsible for personnel other than those trained in San Francisco operating the equipment. We prefer that only personnel trained in San Francisco operate the scanner. However, if the set-up at your clinic requires other people to perform scans, the principal Hologic operator is responsible for adequate training. Notify the coordinating center of who is operating the equipment. Make sure that you enter your SOF staff number in the Scan Code field of the patient biography. The principal Hologic operators are:

Baltimore:

Bert Hohman Minneapolis: Kristi Jacobson

Pittsburgh:

Mary Nasim

Portland:

Cheryl Ellis

Teaching file: I will be sending out a set of two floppies, one with 6 problem cases as they were analyzed in the clinics, and one with the same 6 cases as I would analyze them. The objective will be for you to try to reanalyze the problem cases on your own, and then compare your efforts with the scans as I would recommend analyzing them.

Scanning the femur phantom is something we did not discuss during my visit. You will need to set up the QC data base for the femur phantom. To do that, follow these steps:

1. Create a Patient Biography for the Femur Phantom

Follow the syntax outlined on page 178 of the Hologic manual.

2. Scan the Phantom 20 Times

This can be accomplished easily over night. Give me a call when you are ready to perform the procedure and I will walk you through it.

Make sure that you use double sided <u>high</u> density floppies. In some instances data has been lost because double density floppies were used. If you have used double density floppies make sure you attempt to retrieve all data for rearchival on high density floppies. Reschedule all patients that you have lost data on.

There had been some questions about the thermal paper used for the printer. According to information I received from Cyndy, Hologic's price for the paper is competitive. There are a number of different qualities and types of thermal paper on the market. Obtaining the paper through Hologic will minimize problems. Please let me know if you do come across another, cheaper source of identical paper.

Some things as described in this version of the manual may have changed a little since my visit. Please read the manual carefully and give me a call with any questions and suggestions you may have. You can reach me at (415) 476-9805 Mo-Th or at (415) 597-9120 on Fridays.

SOF QDR PROCEDURE AND QUALITY CONTROL MANUAL

Peter Steiger, Ph.D University of California Department of Radiology, Box 0628 San Francisco, CA 94143

Version 2/24/89

1. Introduction

This manual is designed as an adjunct to the Hologic QDR-1000 x-ray bone densitometer operator's manual and user's Guide. The SOF Hologic operators are expected to be familiar with all the instrument features and procedures discussed in that document. The purpose of this manual is to standardize scanning, evaluation and quality control procedures and to regulate the interaction of the SOF clinics with the coordinating center.

There have been a number of important changes for version 4 software and it is *imperative* that you have read and understood the *entire* Hologic manual prior to reading this document. Information contained in the Hologic manual will not be repeated. Only points we consider particularly important or procedures that we have chosen to perform slightly different will be mentioned.

Make sure that both hip and spine scans are evaluated before the participant leaves. This will allow you to rescan without the need for rescheduling, should unexpected problems be encountered during analysis.

2. Spine Measurements

2.1. Scanning the patient

Enter the patient biography following the instructions on page 18 of the Hologic manual. Enter your SOF staff id number as scan code. Note that if the spine scan is performed after the femur scan, no biography entry action is needed. Avoid creating duplicate biographies. Enter the following fields: NAME, PAT ID, SCAN CODE, DOB, SEX, WEIGHT, HEIGHT. All other fields may be left blank.

Follow the instructions for patient positioning outlined on page 19 of the Hologic manual. Make sure you can move the scanner arm from approximately 2 inches above the xiphoid process to 2 inches below the ASIS (anterior superior iliac spine). This guarantees that your scan does not abort prematurely. Reposition the participant if necessary.

Select 8 inches as scan length and 5.2 inches as scan width. This increased width is

necessary to accommodate the spinal deformities often found in the SOF population.

Use the rescan feature "F2" freely: it is imperative that the spine is well centered and that part of the pelvis is visible. Allow the scan to continue until half of T12 is visible. On elderly women the anatomy of the images is sometimes hard to interpret. When in doubt, collect too much rather than too little data.

2.2 Data Analysis

Start by judging brightness and contrast of the image. Adjust if necessary. Note that due to the large variation of weight in our study population, and the poor condition and difficult anatomy of some spines, frequent adjustments will be necessary. Changing the appearance of the image will often help make decisions as to the placement of regions of interest and intervertebral markers.

See page 35 of the Hologic manual for instructions on the placement of the region of interest (ROI). The ROI should be symmetrical to the spine and no narrower than 110 pixels.

Marking the intervertebral spaces is often the most difficult task. Sometimes, using the triangular projection of the spinous process can help make the decision (cf. teaching file).

2

2/24/89

Label the vertebrae using the ribs and the iliac crest as landmarks. Make sure to mark any scan for which you feel an exclusion of a vertebra is necessary for review by the coordinating center.

Insert and delete bone as discussed in the manual on pp. 40-43. Note that if an intervertebral space at the top or bottom of the ROI does not show as bone, it should **not** be filled in.

Print the report and file it with the participant's records. Identify the scan for review in San Francisco if you are concerned about possible fractures or other abnormalities. Keep a list (see Data Management) of problematic scans and check the 'review' box on the face exam face page.

3. Femur Measurements

3.1. Scanning the Patient

Enter the patient biography following the instructions on page 18 of the Hologic manual. Enter your SOF staff id number as scan code. Note that if the femur scan is performed after the spine scan, no biography entry action is needed. **Avoid creating duplicate biographies.** See spine scan instructions for fields that need to be filled in for the patient biography.

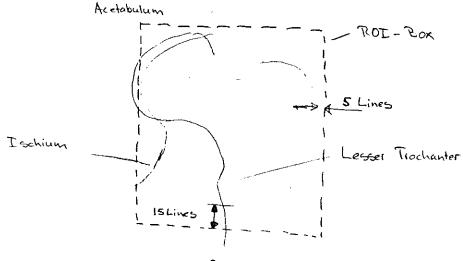
Whenever possible, scan the hip on the same side as the heel earlier. Ask the participant whether she has ever fractured that hip. If she has, scan the other hip. If she fractured both hips, scan the one with less hardware. In the presence of bilateral hip replacement, do not scan the hip. Make sure that the participant has her hands separated from her hips. Scan the other hip if you cannot rotate the foot inward due to pain.

Accept the default scan parameters offered by the system. Use the rescan feature "F3" freely. Make sure that the lower extent of the greater trochanter is approximately centered on the image. Allow at least 5 lines between bone and the "rescan" arrow. Interrupt the scan once the medial extent of the acetabulum is included in the image.

3.2. Analysis

Start by judging brightness and contrast of the image. Adjust if necessary. Note that due to the large variation of weight in our study population, frequent adjustments will be necessary.

Standardization of the choice of the region of interest is most important in order to obtain comparable results across centers. Use the diagram below as a reference:



Read pp 94 and 95 of the Hologic manual carefully, where bone insertion/deletion and incomplete outlining of bone edges is discussed. Make sure you delete and "bone" in the soft tissue area. Use the following priority scheme to increase the ROI when bone outlining fails:

- 1. superior edge
- 2. medial edge
- 3. inferior edge

Do not adjust the lateral edge. Rerun the analysis after each adjustment. The inferior edge should be adjusted last because it directly affects the size and density of the intertrochanteric region.

The only other interaction occasionally needed during the hip analysis is a minor adjustment of the femoral neck box. Use the default height whenever possible. If necessary, reduce the width to avoid inclusion of the ischium. Accept default for the remaining steps of the analysis. If the Ward's triangle search fails, use the automatic positioning technique described on page 107.

Print the report and file it with the participant's records. Mark the scan for review in San Francisco, if you are concerned about abnormalities or any other aspects of the analysis. Keep a list (see Data Management) of problematic scans and check the 'review' box on the face exam face page.

4. Quality Control

The tools built into the Hologic software make quality control easy. This section will discuss a number of tasks, taking approximately 30 minutes, that need to be performed on a weekly basis. We recommend that you identify a "QC-day" such that these tasks are performed at the same time every week.

Follow the instructions of pp 177-181 of the Hologic manual to scan the spine and hip phantoms. Create one and only one patient biography per phantom, i.e. one for the spine and one for the hip. Avoid duplication of phantom patient biographies by using the patient menu to select the biography for the phantom patient name prior to scanning the phantom. Scan the spine phantom daily, the hip phantom once a week, on "QC-Day". Scan the phantoms on top of the pad and make sure that they are aligned with the scanner axis by running the laser light up and down the edge of the phantom or by using the phantom case as a spacer between the ledge on the back of the scanner table and the phantom block. Evaluate QC scans using the *Compare* feature. Add the scan to the QC data base immediately after scanning, following the procedure outlined on pp 182-185 of the Hologic manual.

Use the plot feature daily to verify that your scan is within the limits set up by Peter Steiger during the initial visit. To do that select the Plot option from the QC menu and then F10 to generate a graph with the default settings. If the most recent scan falls outside the limits, repeat the scan. Contact Hologic and Peter Steiger if the scan is out of bounds a second time. There is no need to archive QC scans. Keep the original that you compare to on the disk permanently. Generate a print-out of the QC scan once a week on QC-day.

The data bases need to be archived once a week. The patient data base is archived by using the dBarchive option from the main menu. The quality control data base is archived by the aRchive option from the QC menu. Follow the instructions of pp 151 and 197 of the manual.

5. Data Management

Make sure that you use double sided <u>high</u> density floppies (note that the Hologic manual erroneously states that double density floppies are required). Use brand name diskettes. Archive daily following the instructions on pp 138-143 of the Hologic manual. Use the *Copy only* feature to generate the floppies you will mail to San Francisco at the same time you do the archival. Do not use the *Diskette* Archive Option to generate the floppies for San Francisco. This would cause a mix-up in the Hologic data base system for locating old scans.

Make sure that the principle Hologic operator has reviewed and approved of the evaluations prior to archival. Scans should be deleted from the hard disk immediately after archival and copy. Note that if a scan needs to be restored and reanalyzed for any reason, it will need to be rearchived.

Ship floppies on a biweekly basis in multiples of 20 (i.e. approximately 1 box per week) to the following address:

Peter Steiger, Ph.D.
University of California
Department of Radiology, Box 0628
San Francisco, CA 94143

Include in each shipment a list of scans you want the coordinating center to review. List the patient ID number and acrostic, hip and/or spine to be reviewed, and a brief reason for the review. Also be sure to check the 'review' box for these patients on the face page of the exam forms.