APPENDIX A

WHOLE BODY PHANTON PROTOCOL

A.1 Whole Body Phantom Protocol

Before lifting or transporting the phantom, break it down into its individual components. Use care, the impact force of a phantom component dropped from table height can cause severe injury, particularly if the impact is delivered through one of the phantom's beveled edges. Having another person help move the phantom components is strongly recommended.

A thin, gray PVC sheet is attached to the large white plastic piece that contains the two plastic locating pins. This HDPE/PVC combination is the bottom layer (base) of the phantom. Position it on the scanner table such that the PVC is on the bottom (i.e. the gray PVC is in contact with the table pad and the two plastic locating pins project out of the plane of the table towards the ceiling.

Place the second large white plastic piece on top of the phantom base, using the locating pins as a guide. The second piece should be placed such that the beveled edge forms a "V" with the base.

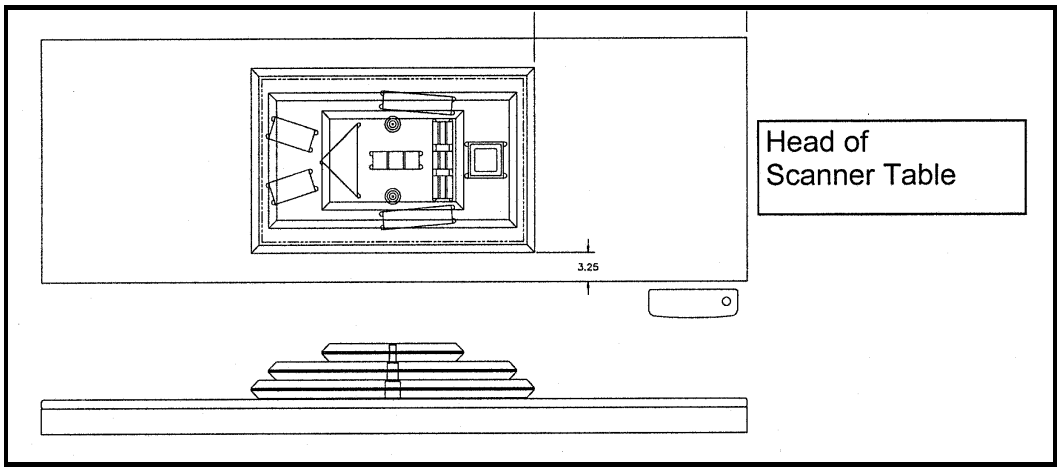
Next, place the medium size white plastic pieces on the phantom, again forming a "V" with the two beveled edges of the middle pieces. Then place the small white plastic pieces on top, forming another "V" with the small pieces. The final assembly will form a pyramid (see Figure A.1, side view). This is the only valid configuration for the phantom measurement. All other configurations including adding materials to the phantom, removing pieces of the phantom, scanning the phantom upside down, etc. violate the intended use of the phantom and may produce invalid results.

A.2

A.3 Phantom Positioning

Carefully position the whole body phantom in the center of the scanner table with the head of the phantom at the head of the table. Allow 24" (61cm) of empty air space at the head of the table. Carefully position the phantom parallel with the long axis of the table, using the table pad markings as a guide. When properly centered, there will be a constant 3.5" (8.9 cm) gap between the side of the phantom and the front and back limits of the QDR 4500 or QDR 2000 scanner table (see Figure A.1). Place the tissue bar vertically, as in a patient scan, being sure that the bar is imaged in the scan. Note that the sample scan has the bar placed horizontally, but the vertical placement is preferred. Use the scan mode that is designated in the study protocol. (For WHI use array mode.)

Figure A.1
Layout of Whole Body Phantom Positioned on the QDR 4500 Scanner Table



Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model).

A.4

A.5 Data Acquisition - Scanning the Whole Body Phantom

1. Make sure that the phantom is centered, is parallel to the long axis of the table and is correctly oriented with respect to the head of the table.

2. Enter "**WB PHANTOM #xxxx** in the Name field of the Patient Biography (where **xxxx** is the phantom serial number, including any letters, found on the phantom label).

3. Remove all artifacts from the table surface. Extraneous objects in the scan field will interfere with the measured results in an unpredictable fashion.

4. Select the standard Adult Whole Body scan mode commonly employed at your facility. Accept the default scan length and scan width. Perform a complete scan of the entire table surface including the phantom. Do not interrupt the scanner during the measurement.

5. Carefully inspect the scan image to ensure that the phantom was

   i. centered,
   ii. parallel to the long axis of the scanner table, and
   iii. the phantom's head appears at the top of the image.

   If the scan image appears satisfactory, proceed to the analysis section. If not, carefully reposition the phantom according to the instructions in Section II and repeat the scan.

6. After receipt of the whole body phantom, scan the phantom four (4) times a day for the first week (20 scans). This will allow the setting of a consistent mean for monitoring performance and comparison purposes. Note that the whole body phantom scans can NOT be added to the QC database. The UCSF will plot and check the data and notify the clinical centers of any problems.

7. After the first 20 scans are performed, scan the phantom three times a week.

6.

A.6 Analysis

A.6.1 General Comments

The goal of the analysis is to carefully delineate the various body regions in a standard and reproducible fashion, so that measured results will reflect instrument performance, not variations in analysis techniques. Of particular importance are the placement of the head ROI cutline and the cutlines that delineate the ribs, since these two regions affect global body composition and BMD. It is essential that the baseline measurement is technically adequate and that the analysis is performed by direct comparison to the sample analysis on the Hologic diskette labeled" SAMPLE ANALYSES: WB PHANTOM "or" Whole Body Phantom Analysis Template". Use the sample scan for your model of scanner (see Table below).

A.6.2 Specific Instructions - Hologic QDR Systems

Follow the instructions in Sections II and III to acquire a technically adequate scan of the Whole Body phantom. Restore the appropriate scan from the Hologic diskette labeled "SAMPLE ANALYSES: WB PHANTOM" or "Whole Body Phantom Analysis Template" to the analysis workstation. (See Table A.1 for the correct scan to restore for your QDR model). Select the newly acquired WB Phantom scan. Then use the Compare feature to register the ROI cutlines of the Sample scan to the newly acquired scan of the WB Phantom. Once the ROIs have been matched as nearly as possible, complete the analysis and print the first and last pages of the report.

Archive the baseline measurement for safekeeping but do not delete it from the analysis workstation. All future whole body phantom measurements will be compared to the initial baseline measurement. After the initial measurement, the sample scan restored from the sample diskette should be deleted. Archive Whole Body Phantom scans to both the clinic and traveling opticals daily.

Table A.1
Scans to Restore for a Given QDR Model #

QDR MODEL #	WB PHANTOM SCAN (RESTORE FROM SAMPLE DISK)
1000W, 1500, 2000 Pencil Beam	1000/1500/2000 Pencil WB Phantom
2000 Fan Beam	2000 Fan WB Phantom
4500W	4500W WB Phantom
4500A	4500A WB Phantom

A.5 Interpretation of Measured Values

The phantom measurements should be printed out and placed in a log book/ file and kept at the Clinic Center. UCSF will plot selected variables periodically from the scans sent on the traveling optical and notify the Clinic Center of any problems.

Please note a correction to the Biography in the following printout. The phantom serial number should be in the ID field: I.D.: #001.

Figure A.2

Phantom Measurement Printout

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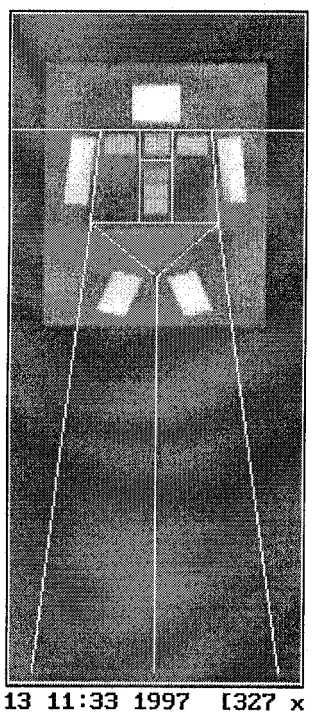

oJun 13 11:33 1997 [327 x 150]
Hologic QDR-4500A (S/N 3006)
Whole Body V8.20a:3

A0530970J Fri May 30 13:51 1997
Name: WHOLE BODY PHANTOM #001
Comment:
I.D.: Sex: F
S.S.#: - - Ethnic:
ZIP Code: Height: ' "
Operator: Weight:
BirthDate: / / Age:
Physician:
Image not for diagnostic use

TOTAL BMC and BMD CV is < 1.0%

C.F.	1.023	1.008	1.000
Region	Area (cm2)	BMC (grams)	BMD (gms/cm2)
L Arm	113.48	132.56	1.168
R Arm	112.29	134.78	1.200
L Ribs	41.01	36.69	0.895
R Ribs	42.21	39.91	0.946
T Spine	31.06	33.46	1.077
L Spine	71.67	77.02	1.075
Pelvis	130.21	105.48	0.810
L Leg	89.19	119.73	1.342
R Leg	93.17	123.91	1.330
SubTot	724.29	803.54	1.109
Head	127.02	311.82	2.455
TOTAL	851.31	1115.36	1.310

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Appendix A
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