

**STUDY OF OSTEOPOROTIC FRACTURES
DXA Procedures and Quality Assurance Manual
for
Hologic QDR-1000 and QDR-1000/W
Bone Densitometers**

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I. INTRODUCTION

The purpose of this manual is to standardize the scanning and evaluation procedures among the clinical centers participating in the Study of Osteoporotic Fractures. It provides information specific to the Hologic QDR 1000 and 1000W and is intended as a supplement to the Hologic Users' Manual.

Prior to reading this document, it is essential that you have read and understood the entire Hologic manual. The study operators are all experienced Hologic users and are expected to be intimately familiar with all the instrument features and procedures discussed in the Hologic Users' Manual. Some of the information from the Hologic manual is repeated in this document for emphasis; note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic. In these cases, the protocol changes are clearly explained below.

Please be sure that you have upgraded your system software to Version 5.11. You can find your version number at the top of the blue Hologic menu. It will say "Hologic QDR 1000 5.11."

- **Unauthorized software changes must be avoided. If for any reason you think you have to change the software, contact the coordinating center before any changes are made.**

II. DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA)

High quality bone mineral densitometry requires competent and consistent quality assurance. This manual contains information that will help to obtain accurate and reproducible results. Procedures for three major areas are covered:

Scanning the participant
Analysis of participant data
Quality control measures

Each of these procedures is of equal importance. To obtain consistent results, the technologist in charge of the densitometry has to be aware of possible sources of error that may affect data collection and analysis.

Bone density measurements for this particular study will be obtained at four clinical centers. Quality control measures will be carried out to cross-calibrate the individual scanners. Care should be taken to ensure that every participating clinical center obtains results of comparable precision. The SOF study coordinating center will be reviewing and spot checking the data and will notify the clinical centers if we detect any inconsistencies. We will indicate possible error sources, suggest possible solutions, but will not be responsible for the solution of a hardware or software problem; that will rest with the clinical center and the scanner manufacturer.

During the study, any questions regarding procedures that arise should be directed to the coordinating center. Instances in which the operator is unsure of the analysis should be identified by each clinical center on the patient data log sheet (see Appendix A: "When to Flag Scans For Review"). These cases should be compiled and forwarded to the coordinating center for review. Often these problem cases have been analyzed correctly

and will require no further action; however, in some instances the coordinating center may reanalyze a scan by applying an exception to the protocol. Any changes in the analysis will be returned to the clinical centers involved.

All data for the study will be sent at regular intervals to the coordinating center using the mailing labels provided. Any questions or correspondence regarding the manual or the technical aspects of the DXA measurements should be directed to:

Tajalli Spencer
Prevention Sciences Group - UCSF
74 New Montgomery
Suite 600
San Francisco, CA 94105
(415) 597-9287

III. PATIENT BIOGRAPHY

Enter the patient biography following the instructions in the Hologic Users' Manual. Note that no further biography entry action is needed for a follow-up scan or for an additional site for the same individual with the exception of lateral lumbar scans (see below). Avoid creating duplicate biographies by checking that the patient's name is entered identically using the same spelling, initials, spacing, and punctuation.

Enter the following fields:

NAME
PAT ID
SCAN CODE
DOB
SEX
WEIGHT
HEIGHT.

Important: Enter your SOF staff ID number for the SCAN CODE. All other fields may be left blank.

Lateral lumbar scans: These scans require the creation of a new biography. All data must be identical to earlier entries with the exception of the PAT ID. All lateral lumbar scans must have the letters LAT directly following the five digit SOF PAT ID number.

Example: 12345LAT

There are no spaces, hyphens, or other punctuation in this id number. Following this exact format will allow the coordinating center's computer to distinguish between the AP and lateral scans by examining differences in the structure of the patient id. It will also allow operators at the individual clinical centers to easily pick out the lateral scans from the menu without the necessity of calling up the image.

IV. A/P SPINE MEASUREMENTS

A. SCANNING PROCEDURES

1. Baseline

When performing A/P scans, the following guidelines must be adhered to:

1. Change the scan length from 6.0 inches to 8.0 inches for all A/P participant scans. Note that the phantom scans should still be done at the default length of 6.0 inches.
2. The scan width should be 5.2 inches.
3. No metal or plastic object should remain in the scanning area. Check for jewelry, zippers, buttons, rivets, belts or any other clothing fasteners, as well as hip and back braces.
4. Lower any heavy clothing so that nothing obscures the scanning area.
5. Follow the instructions for patient positioning outlined in the Hologic Manual. Make sure that 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.
6. Use a knee elevating pad to reduce lordosis. Always use the same pad for all participants.
7. Keep the participant's hands out of the scanning area by placing them at her sides for A/P scans.
8. The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head, and maintain a comfortable body temperature for the participant throughout the scan.
9. Instruct the participant to remain still until the end of the measurement. Flag any scans in which the participant has moved and has not been rescanned. Movement during a spine scan appears as either a horizontal discontinuity or as a horizontal smear. An isolated discontinuous line is acceptable since it will not significantly alter values in its vicinity. Several discontinuities together will produce inaccurate data, and the participant will need to be rescanned. Try to resolve coughing or other causes you can control.
10. Use the midpoint of the ASIS and the iliac crest to determine the start line of the scan. This should place the lower end of the A/P scan at the midpoint of L5. Perform a preliminary scan to verify patient position, and then restart the scan.
11. Scan from the middle of L5 (include a portion of the iliac crest for reference) up to the middle of T12. Scans for the older women in our SOF study population can be difficult to interpret, so we want to be sure to collect sufficient data for accurate identification of vertebral levels L1-L4.

12. Use the rescan feature (F3 key) freely. It is imperative that the spine be well centered and that part of the pelvis be visible.

2. Follow-Up

Before scanning the participant, load the baseline scan into the hard disk and have a printout of the baseline available. Check the baseline to determine if it was analyzed properly; if the baseline was done improperly, it will be necessary to reanalyze it. Refer to the baseline printout as you go through the positioning of the participant for the follow-up; this is to ensure consistent scanning of the same area. Repeat the follow-up scan if necessary.

B. ANALYSIS PROCEDURES

1. Baseline

Brightness and Contrast The SOF study population exhibits considerable variations in weight, spine condition, and spine anatomy, any of which can result in scans which are difficult to analyze. Adjustments to the brightness and contrast will frequently be necessary to improve the appearance of the image so that regions of interest and intervertebral spaces can most easily be placed.

Global Region of Interest The global region of interest (large, yellow box surrounding all vertebrae to be analyzed) should be created according to the following guidelines:

1. The ROI should be no narrower than 119 pixels.
2. The ROI should be aligned symmetrically around the spine.
3. The ROI must be large enough to include at least 5mm of soft tissue outside the most extreme aspects of both the right and left bone edges of the spine. Special care must be taken with extremely scoliotic individuals to achieve this goal.
4. The above constraints must produce an ROI with all edges at least two steps away from the border of the scan field. This will be important when the baseline scan is used with the COMPARE feature on the follow-up scan analysis (see below).

Scoliotic Spines The special scoliosis feature of the Hologic software is never used on A/P scans for scoliotic participants. According to the experimental protocol, severely scoliotic participants are to be excluded from the study; however, a minor degree of scoliosis may be acceptable. Participants should be analyzed using the standard rectangular ROI. The upper and lower borders of the global ROI are adjusted using the same procedure as is used to adjust scoliotic intervertebral spaces (see below). Since the distinction between 'minor' and 'severe' is somewhat subjective, and since the analysis on these patients may be more difficult to perform, all scoliotic spines should be flagged for later review by the coordinating center.

Intervertebral Spaces The level of the intervertebral space marker is placed at the midpoint of the intervertebral space. In scoliotic participants, this will often result in portions of an adjacent vertebra being above or below the line. This is usually acceptable. The same method is used to place the upper and lower borders of the global ROI for scoliotic individuals.

Labeling of Vertebrae Label the vertebrae using the ribs and the iliac crest as landmarks. Generally speaking, T11 will show a well-developed rib, and T12 will have a "floating" rib or very occasionally no rib. Most individuals have only five lumbar vertebrae; L5 will be at or below the iliac crest, which is why the iliac crest is used as a landmark.

Exclusion of Vertebrae According to the protocol, crush fractures are to be excluded from the analysis. A vertebra is a potential candidate for exclusion if there is a reduction in its height by more than a few scan lines relative to the vertebra above it. Confirm that your intervertebral spaces are properly adjusted. If the vertebra seems to be about 25% or more decreased in height, exclude it from the analysis and flag it for the attention of the coordinating center. If a vertebra's height is less than the one above it but not 25% less, simply flag it for review by the coordinating center.

Filling and Deleting Bone Delete all isolated bone mask structures. Fill in all gaps within the bone edges of the spine; this includes gaps occurring at the L4-L5 and T12-L1 ROI boundaries (Figure 1).

Bone Edges Do not alter the bone edges. Sometimes the transverse spinous processes or closely adjacent ribs can alter the appearance of the bone edge (Figures 2-4). Flag these for review by the coordinating center.

2. Follow-Up

Load the baseline scan into the hard disk. Display this baseline evaluation using the COMPARE feature along with the current scan to be analyzed.

Brightness and Contrast Be sure that the window and level are optimally adjusted.

Global Region of Interest If the global ROI cannot be moved to the appropriate position because it is too large, the baseline scan will have to be reanalyzed with its global ROI sufficiently reduced to accommodate the follow-up scan. After the baseline scan has been reanalyzed, analyze the follow-up scan using the new baseline for the comparison. If the upper and lower edges of the global ROI do not match the corresponding intervertebral spaces on the follow-up scan (i.e., the follow-up spine is shorter), the global ROI of the follow-up may need to be shortened. Be certain that the vertebral levels correspond between baseline and follow-up; mismatched levels can give the appearance of shortening or lengthening of the spine on follow-up. Flag any alterations. **Never change the width of the global ROI on the follow-up scan.**

Intervertebral Spaces It is most important that the intervertebral space markers of the follow-up scan correspond as closely as possible to those of the baseline. The COMPARE feature will generate the baseline vertebral spacing automatically. A slight manual adjustment may be necessary to place the line markers at the same level between the vertebrae. Large discrepancies in spacing may indicate that either the baseline or follow-up scan has had its vertebral levels mislabeled or that a crush fracture has occurred. If the baseline has been misinterpreted, reanalyze it; then repeat the analysis of the follow-up scan using the reanalyzed baseline for the comparison.

Labeling Vertebral Levels Matching corresponding vertebral levels from baseline to follow-up can be difficult (Figure 2). Look carefully at the darker low density features at the intervertebral spaces and count up from the pelvic girdle to determine levels. If levels were mislabeled on the baseline (e.g., T12 was called L1) and the baseline must be

reanalyzed for another reason, correct the level numbers. Otherwise, flag any scans with uncorrected levels for review by the coordinating center.

Crushed Vertebrae If a vertebra appears to have crushed since the baseline scan, both the crushed follow-up vertebra and the normal baseline vertebra must be excluded from these analyses. This will require reanalysis of the baseline scan. Perform the reanalyses and flag these for review by the coordinating center. If the crush is questionable, also flag it for review by the coordinating center.

Filling and Deleting Bone Delete all isolated bone mask structures. Fill in all gaps within the bone edges of the spine; this includes gaps occurring at the L4-L5 and T12-L1 ROI boundaries (Figure 1). If boundary gaps were not filled in on the baseline and the baseline must be reanalyzed for another reason, make sure these are filled in when reanalyzing. Flag any baseline scans which have not had their boundary gaps filled; the coordinating center will review these for possible reanalysis.

Bone Edges Do not alter the bone edges. Unusual bone edges or large differences in the bone edges between baseline and follow-up should be flagged for review by the coordinating center (see Figures 2-4).

V. LATERAL SPINE MEASUREMENTS

A. SCANNING PROCEDURES

1. Baseline

When performing lateral spine scans, the following guidelines must be adhered to:

1. No metal or plastic object should remain in the scanning area. Check for jewelry, zippers, buttons, rivets, belts or any other clothing fasteners, as well as hip and back braces.
2. Lower any thick clothing which might obscure the scanning area.
3. Use the Hologic positioning device to reproducibly position the participant on her side. Use a pillow between the knees and radiographic foam blocks to support the spine. Visually verify that the participant's spine is parallel to the long axis of the table, with the shoulder, back, and legs in complete contact with the lateral positioner. The knees should line up vertically to minimize pelvic tilt.
4. Keep the participant's hands out of the scanning area by placing them in front of the face with the elbows supported while doing a lateral scan.
5. The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head, and maintain a comfortable body temperature for the participant throughout the scan.
6. Instruct the participant to remain still until the end of the measurement. Flag any scans in which the participant has moved and has not been rescanned. Movement during a spine scan appears as either a horizontal discontinuity or as a horizontal smear. An isolated discontinuous line is acceptable since it will not significantly alter values in its vicinity. Several discontinuities together will produce inaccurate data, and the participant will need to be rescanned. Try to resolve coughing or other causes you can control.
7. Use the scan settings recommended by Hologic for scan length and width, line spacing, and point resolution.
8. Use a point a few centimeters below the iliac crest to begin the scan. Perform a low resolution scout scan to verify participant position.
9. The pedicles should be included in the scan FOV, and there should be about 1 vertebral width of soft tissue included on the anterior side at the level of L4 (see Figure 5). Do not widen the FOV, though.
10. After properly positioning the participant, restart the scan just below the iliac crest using high resolution, as detailed in the Hologic Manual.
11. Scan from the iliac crest through L2. On older women the anatomy of the images is sometimes hard to interpret. When in doubt, collect too much rather than too little data.

12. Use the rescan (F3 key) feature freely. It is imperative that the spine be properly positioned and that part of the pelvis be visible.

2. Follow-Up

Before scanning the participant, load the baseline scan into the hard disk and have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential to producing precise measurements. Use the rescan feature as soon as any positioning errors are detected during the current scan.

B. ANALYSIS PROCEDURES

1. Baseline

General Comments The following guidelines are specific for the analysis of lateral scans:

1. Use the scoliosis feature ONLY in evaluation of lateral scans. Hologic uses this tool as part of the lateral analysis to permit angled lines to be drawn to adjust the global ROI, the intervertebral spaces, and painting and deletion subregions S1-S4. All lateral spine analyses make use of this tool.
2. Evaluate L2-L4, if possible. L5 is defined as the vertebra which is wholly or mostly obscured by the iliac crest, so L4 will usually be just above the iliac crest.
3. Exclude L4 if a portion of it is obscured by the iliac crest.
4. Exclude L2 if you can see that it is overlaid by ribs.

Brightness and Contrast The SOF study population exhibits considerable variations in weight, spine condition, and spine anatomy, any of which can result in scans which are difficult to analyze. Adjustments to the brightness and contrast will frequently be necessary to improve the appearance of the image so that regions of interest and intervertebral spaces can most easily be placed.

Global Region of Interest The guidelines below are designed to maximize the precision of the lateral analysis and to produce baseline scan analyses which will make future comparison analyses easier. In regard to the latter purpose, it is particularly important to observe the guidelines for adjusting the upper and lower edges of the global ROI so that future scan fields may be moderately sized. Refer to Figure 6 throughout the following portion of the discussion.

Right Edge

1. The right (anterior) edge should be parallel to the general trend of the spinal axis. This requirement will almost always produce a line which slants upward and to the left.
2. The soft tissue area anterior to the spine should be as wide as L3 is wide, to provide a soft tissue area approximately equal to the area of the vertebral bodies.

3. In cases in which the spine is placed a bit too close to the center of the scan field, the lower portion of the right edge may have to be clipped off with a vertical rather than a slanted line. Adequate positioning of the spine within the scan field is preferred in order to avoid this.

Left Edge

1. The left (posterior) edge is defined as the line stretching between the upper left corner of the uppermost vertebra (L2) to be analyzed and the lower left corner of the lowest vertebra to be analyzed (L4).
2. The left edge of the ROI should be adjusted as closely as possible to the posterior edge of the vertebrae; however, no portion of any of the vertebral bodies should be excluded from the ROI. It is, of course, all right for parts of the pedicles to be outside the global ROI.

Lower Edge

1. The lower edge should run parallel to the base of the lowest vertebra (L4) just as an intervertebral line would. As it extends beyond the anterior edge of the vertebra, it should become horizontal.
2. The exception to making the lower edge horizontal through the soft tissue region occurs when L4 is tilted upwards to the right. The scoliosis program will not let you make a concave (inwards curving) line, so just continue to extend the line along the angle used while paralleling the vertebral base.
3. When L4 tilts downwards to the right, a horizontal line along the soft tissue region will be accepted by the scoliosis program.

Upper Edge

1. The upper edge should run parallel to the top of the vertebra (L2 or L3) just as an intervertebral line would.
2. As the line extends beyond the anterior edge of the vertebra, it should become horizontal. Unlike the inferior edge of the global ROI, the superior edge never continues along the angle established by the tilt of the uppermost vertebra.

Intervertebral Spaces Lateral scans use the scoliosis program for adjusting the intervertebral space lines. These lines should be an equal distance between vertebrae and parallel to the local vertebral tilt rather than parallel to either the upper or lower edges of the global ROI.

Bone Deletion and Filling Subregions S1-S4 Participants frequently have low BMDs and calcified aortas. Proper use of the bone deletion (S1) and bone filling (S2-S4) subregions will allow the analysis program to automatically exclude unwanted bone mask (including ribs) and most accurately define the contours of the vertebral bodies.

First Subregion This subregion is programmed to exclude any bone mask outside of itself; this will free you from manually deleting ribs, etc., from the soft tissue region (Figure 7).

1. Place it a couple clicks outside of the anterior edge of the vertebrae.

2. Be sure to include any spurs within the subregion; they are part of what we want to analyze.
3. Two or three facets may be used on its anterior edge to carefully trace the curve of the vertebrae (Figures 5 and 6).

Second through Fourth Subregions These subregions are programmed to include any area within them as bone mask; these will free you from having to manually paint in holes in the bone mask.

1. When a participant's BMD is low, the edges of the vertebrae are often incompletely drawn in (Figure 8). The only way that the edges may be modified is through placement of subregions (Figure 9). Never draw in either the anterior or posterior edges, even though they are visible.
2. Make sure that your window and level are adjusted so that you can most clearly see the edges of the vertebrae. The subregion lines should never go beyond the visible edge of its vertebra.
3. Be sure the corners of the subregions are within the higher density vertebral endplates (Figure 9). Avoid placing the corners on the extreme ends of the plates. There is a natural lip to the endplates, and occasionally osteophytes will overhang the middle extent of the vertebral body (Figure 7). Placing the corners too far out on the endplates will artificially widen the body of the vertebra by erroneously including soft tissue as part of the vertebral body; the result will be a deceptively low BMD for that vertebra.
4. The Hologic manual suggests that you first only place the large, bone deletion subregion, run the calculation, and then examine the finished product to see if bone needs to be painted in. With our population of older women, it will almost always be necessary to insert the small bone painting subregions, so insert these during the initial calculation to save the reanalysis time (Figure 9).

2. Follow-Up

Load the baseline lateral scan into the hard disk. Display this baseline evaluation using the COMPARE feature along with the current scan to be analyzed. Match the location of the intervertebral space markers as closely as possible to the placement on the baseline analysis. An optimal match would have the markers at an identical distance from each other and at the same anatomical location.

If adjustment cannot be done satisfactorily, it may be necessary to reanalyze the baseline scan and any follow-up scans previously compared to the baseline. Intervertebral space markers should correspond as closely as possible as noted above. Due to the difficulty in positioning the patient identically to the baseline, full use of the COMPARE feature may not always be possible when analyzing follow-up lateral scans. If large differences between vertebral edges of baseline and follow-up remain showing that the area of the vertebrae cannot be determined with certainty, these scans should be flagged for review at the coordinating center. If positioning is greatly different from baseline, the participant should be rescanned.

VI. HIP MEASUREMENTS

A. SCANNING PROCEDURES

1. Baseline

When performing hip scans, the following guidelines must be adhered to:

1. No metal or plastic object should remain in the scanning area. Check for jewelry, coins or other objects in the hip pockets, zippers, buttons, rivets, belts or any other clothing fasteners, as well as hip and back braces.
2. Lower any thick clothing that might obscure the scanning area.
3. Keep the participant's hands out of the scanning area by placing them well away from the hips.
4. Whenever possible, scan the hip which is on the same side as the heel done 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 the least hardware. Scan the other hip if you cannot rotate the foot inward due to pain. In the presence of bilateral hip replacement, do not scan the hip.
5. Ensure rotation of the hip by holding the knee and the ankle when positioning the leg. Optimum positioning of the legs is most important.
6. Attach the measured leg to the angled foot block supplied by the manufacturer.
7. The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head and a small pillow under the knees. Maintain the participant at a comfortable body temperature for the duration of the scan.
8. Instruct the participant to remain still until the end of the measurement. Make sure that the leg is not moved during the scan. Flag any scans in which the participant has moved and has not been rescanned. Movement during a hip scan appears as either a vertical discontinuity or as a vertical smear.
9. Use the default settings for the hip scan.
10. Verify that the proximal femur is projected identically in every follow-up measurement. This requires that the corresponding foot is rotated inward by the same angle.
11. If the scan shows a "short" neck with little space between itself and the ischium, this could be due to poor rotation of the leg (Figure 12). Reposition the participant if possible and rescan.
12. In order to improve the positioning for the measurement, the rescan option (F3 key) should be used freely. Start the hip scan and keep scanning until the lateral contour of the greater trochanter becomes clearly visible. Initiate rescan (F3) and position the blue arrow that appears in a way that it points to the most lateral aspect of the greater trochanter. Allow for approximately 5 scan lines between the arrow and the trochanter. Restart the scan.

13. Interrupt scanning about 1.5cm (15 lines) beyond the medial extent of the acetabulum if scan width limit has not yet been reached.

2. Follow-Up

Before scanning the participant, load the baseline scan into the hard disk and have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential for producing precise measurements. Consistent projection of the femur is more important than the actual angle of the foot rotation. Use the rescan feature as soon as any positioning errors are detected during the current scan.

B. ANALYSIS PROCEDURES

High quality data analysis is strongly dependent on the ability to duplicate the placement of each of the four subregions of the hip. The Hologic analysis software calculates and displays all four regions using default values without any required operator interaction. The default size and location of these regions may be altered by the operator to adapt them more closely to the optimal anatomic location for an individual participant.

1. Baseline

Brightness and Contrast In a given population, large variations in weight, hip condition, and hip anatomy can result in scans which are difficult to analyze. Adjustment of the brightness and contrast may improve the appearance of the image so that regions of interest can most easily be placed.

Global Region of Interest The procedures outlined in the Hologic Manual are followed. Refer to Figure 10 during the following discussion. The points listed below are for emphasis.

1. The left side of the global ROI should be at least 5mm (6 lines) beyond the outer edge of the greater trochanter to provide sufficient soft tissue for analysis, although it should not extend outside the participant's body.
2. The bottom edge of the global ROI should be at least 1cm (10 lines) below the lesser trochanter to provide sufficient soft tissue for analysis.
3. In the event that the global ROI must be expanded to allow complete filling of the bone edges (see below) in low BMD participants, all edges must be at least two steps away from the border of the scan field. This will be important when the baseline scan is used with the COMPARE feature on the follow-up scan analysis.

Bone Edges If the bone edges are not properly determined by the analysis program, increase the size of the global ROI by first moving the top border up 10 lines further from the femoral head, then by moving the medial border 10 lines further out, if possible, to include more soft tissue in the analysis. Repeat as needed. Avoid moving the bottom and especially the lateral border. Do not fill in bone edges manually unless absolutely necessary. Occasionally, the bursa or tendons surrounding the greater trochanter can be calcified. This will produce "knobs" (see page 116 of the Hologic manual) that can merge with the trochanter and throw off the automatic placement of the four regions. Expanding the global ROI will not always separate these from the trochanter, and they will have to be manually excluded. Flag for review by the coordinating center any cases in which you have manually altered the bone edge.

Femoral Midline Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck (Figure 11). This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted on either the baseline or follow-up scan, flag these for review by the coordinating center. Do not attempt to adjust the midline yourself because it throws off the femoral box, Ward's Triangle, and the trochanteric line. Proper analysis would require too much operator interaction.

Femoral Neck Box If the default neck box provided by the Hologic program looks reasonably placed, leave it unchanged.

1. The femoral neck region (the area of the neck covered by the neck box as listed on the scan analysis) should be at least 2.5 cm² (about 8-10 lines wide), and the neck box should be perpendicular to the neck axis. If the maximum area of the neck that can be covered by the femoral neck box is less than 1 cm², the participant should be rescanned with special care taken to improve the rotation and degree of adduction of the leg. Since such a narrow neck box would be only 2-3 lines wide, you will only rarely have a problem with this constraint.
2. If the area of the default neck region is less than 2.5 cm², attempt to increase the width of the neck box to the maximum possible while still avoiding inclusion of the trochanter, ischium, or femoral head and acetabulum.
3. If the default neck box partially extends into the trochanter, ischium, or femoral head and acetabulum, adjust its location or size while maintaining the maximum possible area.
4. The Hologic software is sometimes unable to provide an appropriate placement of the neck box and other regions. This can occur if the projected neck axis is too short or the neck is too close to the ischium (Figure 12). Soft tissue between the neck and ischium will be read as bone, and the automatic placement of the femoral midline will fail. If this happens, flag the scan for review by the coordinating center and also try the following bone deletion method to reanalyze the scan (refer to Figure 13):

Accept the same ROI using <Control-End>. This will put all the region sizes back to default settings.

When the yellow bone mask appears, reduce the green bone fill/delete box to a point; use it on delete mode to carefully trace the true course of the lower neck up to just below the acetabulum. The soft tissue will show through the bone mask as a darker yellow.

Continue erasing with a horizontal line out into the ischium. Erase the island of unwanted bone mask outside the neck.

If you are dissatisfied with your deletion, the original bone mask can be restored by pressing <Control-Home>.

Press <End> when you are satisfied with the deletion and proceed with the analysis.

Ward's Triangle The Hologic software should place the square marking Ward's triangle adjacent to the femoral neck box. In participants with low BMDs or short femoral neck projections, the Ward's Triangle box may be misplaced considerably. If this happens, follow the instructions in the Hologic manual to modify the search region. Flag these scans for review by the coordinating center.

Trochanteric Line The trochanteric line should intercept the bone edge just below the lateral aspect of the greater trochanter. There is no need to correct minor deviations (up to about 3 pixels).

2. Follow-Up

Load the baseline scan into the hard disk. Display this baseline evaluation using the COMPARE feature along with the current scan to be analyzed. It is important to realize that proper comparison of a follow-up hip scan to its baseline depends upon maintaining the identical size and relative position of the region markers. Vertical or horizontal shifts of these regions by one or more pixels can greatly alter the final values of the analysis.

Global Region of Interest

1. The width and height of the global ROI must be the same as that used on the baseline.
2. The dotted lines from the baseline defining the bone region should overlay the follow-up as closely as possible. Occasionally there are small changes in adduction and rotation of the leg which were not eliminated by rescanning. The region surrounding the neck should have the best fit (Figure 10).
3. If the global ROI cannot be moved to the appropriate position because it is too large, the baseline scan will have to be reanalyzed with a properly reduced global ROI. Then the follow-up should be analyzed comparing it to the reanalyzed version of the baseline. Flag cases in which the baseline had to be reanalyzed.

Bone Edges If the bone edges do not fill in properly on the follow-up analysis, first the baseline will have to be reanalyzed with a larger ROI, and then the comparison analysis may proceed. Flag any reanalyzed baseline scans.

Femoral Midline Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist (Figure 11). If the midline looks like it might be off or the box is twisted on either the baseline or follow-up scan, flag these for review by the coordinating center. Do not attempt to adjust the midline yourself because it throws off the femoral box, Ward's Triangle, and the trochanteric line. Proper analysis would require too much operator interaction.

Femoral Neck Box If the current location is optimally matched to the location of the neck box of the baseline analysis, use it unchanged.

1. If the current location is not optimally matched to the location of the neck box on the baseline, adjust the current region to achieve maximum correspondence. The size of the neck box must be the same on both baseline and follow-up.
2. If the current location cannot be satisfactorily adjusted while maintaining the same sized neck box, reanalyze the baseline within the constraints outlined above.
3. The bone deletion method outlined in the baseline analysis section may permit more generously sized and better positioned neck boxes for both the baseline and follow-up scans (Figures 12 and 13). Flag scans which have this method applied to them.
4. It is most important to have the neck box location and size correspond as closely as possible. If you cannot get the neck boxes to match, flag the scan for review by the coordinating center.

Ward's Triangle If the Ward's triangle box appears on the follow-up scan in a significantly different position than on the baseline, or if after reanalysis of the baseline its location is different than that of the original baseline placement, flag these scans for review by the coordinating center.

Trochanteric Lines The trochanteric line should intercept the bone edge at the same point on all scans. Matching is easily done during the compare analysis (Figure 14), especially since you will have the baseline to consult during the compare.

VII. QUALITY CONTROL MEASURES

Quality control measures are the responsibility of the individual clinical centers and must be performed to monitor scanner performance throughout the period of the study.

Phantom Scans

Perform the daily quality control measures outlined by the Hologic manual. The primary outcome parameters of this procedure should be logged in a quality control book. Points of procedure to note:

1. Scan and analyze the Hologic spine phantom daily and the hip phantom once a week.
2. Create only one patient biography per phantom, that is, one for the spine and one for the hip. Avoid duplication of patient biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.
3. Scan the phantoms on top of the pad. Ensure alignment 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.
4. Evaluate the QC scans using the COMPARE feature. There is no need to archive QC scans daily. Keep the original that you use as "baseline" for the compare permanently stored on the hard disk; never keep it stored on floppy.
5. Add the scan to the QC database immediately after scanning, following the procedure outlined in the Hologic manual.
6. Use the plot feature daily to verify that the BMD of your scanner is within normal limits. To do this, select the PLOT option from the QC menu and then press <F10> to generate a graph with the default settings. If the most recent scan falls outside the limits, repeat the scan. If the second scan also falls outside the limits, contact both Hologic and the coordinating center.
7. Be sure to eliminate any unanalyzed scans from the QC database (these will appear as white dots at the bottom of the QC plot). Unanalyzed scans in the QC database will adversely affect the coefficient of variation (CV). The CV should be less than 0.5%; if it is greater than 0.5%, contact both Hologic and the coordinating center.
8. Periodically check the system drift by pressing <R> while viewing the QC plot. The slope of the calculated regression line should be within the range of the standard deviation shown. If this is not the case, check for unanalyzed QC data (white dots at the bottom of the plot). If the drift is greater than the standard deviation, contact both Hologic and the coordinating center.
9. Generate a printout of the QC scan once a week on your designated "QC day." This will facilitate detection of long term drifts as well as short term inconsistencies.
10. The quality control database is archived using the aRchive option from the QC menu. Follow the instructions in the Hologic manual.

11. An update of the QC database is to be sent to the coordinating center for their review on a quarterly basis. Floppies containing the database should be sent at the end of March, June, September, and December.

Cross-Calibration of Scanners among Clinical Centers

In order to accurately assess absolute variations in scanner performance between clinical centers, periodically throughout the study phantoms will be either mailed or brought to each of the clinical centers and scanned. Spine, hip and block phantoms will be used. A detailed protocol will accompany the phantoms.

Other Quality Control Measures

If your machine needs to be repaired or if any adjustment has to be made that possibly might affect your data, perform five scans of the Hologic spine phantom before and after the change. In addition, contact the coordinating center before the repairs or adjustments are made to find out whether additional measures have to be taken.

Unauthorized software changes must be avoided. If for any reason you think you have to change the software, contact the coordinating center before any changes are made.

VIII. DATA MANAGEMENT

Archiving the Databases

Both the patient database and the quality control database need to be archived once a week. The patient database is archived using the dBarchive option from the main Hologic menu. The quality control database is archived through the aRchive option within the QC menu (see above). Follow the instructions provided in the Hologic manual for daily and weekly archiving.

The composite of all submissions from the clinical centers is archived monthly at the coordinating center. The coordinating center also retains a copy of quarterly QC updates from each clinical center.

Data Storage

The principal Hologic operator must review and approve evaluations prior to archiving. Scans should be deleted from the hard disk immediately after archiving and copying. Note that if a scan needs to be restored and reanalyzed for any reason, the latest version will need to be rearchived.

Use only **brand name, double-sided, high density floppies**. Archive daily following the instructions in the Hologic manual. Use the **COPY ONLY** feature at the time you do the archiving to generate floppies for the coordinating center. **Do not use the DISKETTE option to generate the floppies for the coordinating center.** Use of the DISKETTE feature would overwrite the location of your own archivings and make the LOCATE feature useless for your daily needs.

Shipping Procedures

Ship floppies every other week in groups of 20 (approximately one box from each week) to the following address using the coordinating center's address labels:

Tajalli Spencer
Prevention Sciences Group - UCSF
74 New Montgomery Street Suite 600
San Francisco, CA 94105

(415) 597-9287

Include in each shipment the segment of the log listing for these scans along with notes regarding questions, scans flagged for review, a list of reanalyzed baseline scans, and so forth.

Use sturdy boxes with either bubble pack or styrofoam peanuts for shipping. Floppies that are loose or only in their light cardboard boxes within a bubblepack envelope are easily crushed and their data will not restore. If you need to ship a single floppy, as in the case of quarterly QC updates for the coordinating center, use a special floppy disk mailer or two flat pieces of heavy cardboard.

Label all shipments "DO NOT MAGNETIZE" since exposure to magnetic sources will corrupt the data.

Difficulties in Data Retrieval

All data submitted to the coordinating center is stored on optical disk cartridges. If you are unable to restore a scan from an earlier archiving, contact the coordinating center, and they will prepare a replacement copy for your use.

From time to time the coordinating center will have a failure in restoring image data from their optical disks, and individual clinical centers will be requested to provide scan copies. This system will also function as a method for backing up our data that will be secure from natural disasters such as fires and earthquakes.

ACKNOWLEDGEMENT

Several of the procedures that are specific to the Hologic QDR-1000 Series Bone Densitometer have been designed with the technical assistance of Hologic, Inc.

**APPENDIX A - WHEN TO FLAG SCANS FOR REVIEW
BY THE COORDINATING CENTER**

General

Baseline has been reanalyzed at the individual clinical center.

ROI on follow up is different size than that of baseline.

Patient has moved and scan has not been repeated without movement.

Unusual anatomical variations; surgical hardware; superimposed buttons, pins, zippers, vitamin pills; or anything else which might affect scan results.

Hips

Bone edge is altered in any way, including use of bone deletion method.

Midline looks off on either baseline or follow up.

Femoral neck box on follow up cannot be matched to baseline size or placement.

Ward's Triangle box is different on follow up or reanalyzed baseline.

Trochanteric lines cannot be matched between baseline and follow-up.

Positioning changes are so great that compare does not work.

Spines

Intervertebral space changes.

Edge variations between baseline and follow up: excessive, unusual, or incomplete on either.

Scoliosis on baseline and/or follow up.

Crushed vertebrae on baseline and/or follow up.

Gaps in baseline that have not been painted in and have not been reanalyzed.

Vertebral levels mislabelled on baseline (T12 was labelled L1, etc.) and not reanalyzed.

Cannot match vertebral levels on follow up.

Missing vertebrae on baseline and/or follow up.

APPENDIX B - ILLUSTRATIONS AND CAPTIONS

- Figure 1: Illustration of proper placement of global ROI and correct labeling. Gaps in bone mask occurring at the L4-L5 border of the global ROI need to be filled in the subsequent steps of the analysis.
- Figure 2: Edge variations from baseline to follow-up on A/P spine scan. Note that the transverse process is imaged on L3 on the baseline but not on the follow-up, while the transverse process on L2 is not imaged on baseline but is on follow-up. If the vertebral levels had been determined by this feature alone, they could have been easily misassigned. In this case it is quite important to carefully examine the additional features, such as the location of ribs on T12, the paired spurs between L1 and L2, and shape of the darker, less dense regions lower in the spine.
- Figure 3: Edge variations from baseline to follow-up on an A/P spine scan. This is a case of simple accrual over time. Also note the presence of an artifact on the left and over the spine at the level of T12-T11 on the baseline scan. If this had overlaid a portion of the spine slated for analysis, these vertebrae would have had to be excluded.
- Figure 4: Scoliotic spine with edge variations between baseline and follow-up. This scan has been excluded from the study; the extent of the area of the vertebrae cannot be determined with certainty, and the bone mineral content has a significant contribution from osteophytic accrual on the concave side of the spine.
- Figure 5: Correct and incorrect participant positioning on a lateral scan. In the scan on the left, there is insufficient soft tissue imaged anterior to the spine so that the background cannot be properly determined. The example scan to the right has the spine well-positioned within the scan field of view. The pedicles are placed to the left of the field yet still imaged, and there is approximately 1.5 vertebral widths of soft tissue to the right of the vertebral column.
- Figure 6: Proper placement of the global region of interest. All scans in this figure have the global ROI placed properly. The left hand edges are pulled in close to the posterior of the vertebrae and the right hand edges are parallel and approximately the width of L3 away from the the anterior edge of the vertebrae. In all cases, the upper edge of the ROI becomes horizontal as it extends into the soft tissue region. The lower edge of the ROI becomes either horizontal through the soft tissue region or slants upward with the angle established by the base of L4.

The upper right hand scan has the vertebral column placed a bit too closely to the center of the field of view. The lower portion of the right edge was clipped off with a vertical rather than a slanted line. Adequate positioning of the spine within the scan field is preferred in order to avoid this.

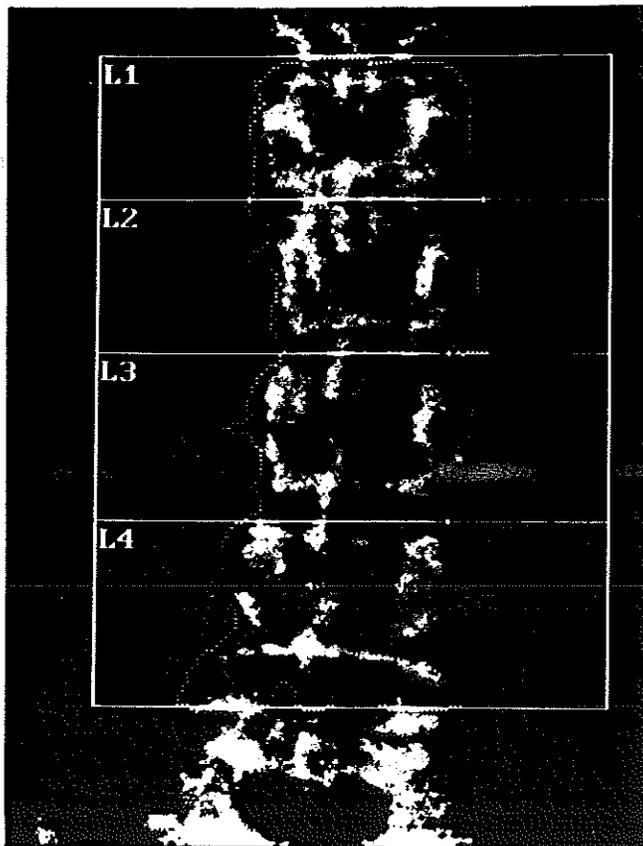
The lower right hand scan is an example of the lower edge of the ROI continuing to extend up and to the right along the line of the intervertebral space. A horizontal line through the soft tissue region, in this case, would

have required a concave (indented) line that the scoliosis program will not allow.

- Figure 7: Placement of bone excluding subregion S1. The image on the left shows exclusion of rib near L3 (upper vertebra imaged). The image on the right shows the inclusion of osteophytic spurs extending from the anterior edge of the vertebrae. Both scans could have benefited from continuation up through L2, although it is likely that L2 in the left hand image would have been excluded from analysis.
- Figure 8: Analysis of vertebrae with low bone mineral density without the use of bone including subregions S2-S4. Although L4 could have been properly analyzed by manually painting in holes in the bone mask, L3 and L2 require the application of a bone including (painting) subregion to define the edges.
- Figure 9: Analysis of vertebrae with low bone mineral density using bone including subregions S2-S4. The scan used in Figure 8 with subregions utilized. It was just as quick to place a subregion on L4 as it would have been to manually paint in holes in the bone mask. The corners of the subregions were placed in the higher density vertebral endplates. The anterior edges of the subregions were arranged so that they did not include soft tissue found beyond the vertebral body.
- Figure 10: Placement of the global ROI on a follow-up hip scan using the compare feature. The dimensions of the ROI must remain the same on the follow-up scan. The dotted lines from the baseline defining the bone region should overlay the follow-up as closely as possible. Occasionally there are small changes in adduction and rotation of the leg which were not eliminated by repositioning and rescanning. The region surrounding the neck should have the best fit
- Figure 11: Notches in the femoral neck region. Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. These notches can be generated when low density areas on the surface of the femoral neck are viewed from the side. Scans containing notches should be flagged for review by the coordinating center.
- Figure 12: Poor adduction and rotation of the femor. The Hologic software is sometimes unable to provide an appropriate placement of the neck box and other regions for this type of positioning. This can occur if the projected neck axis is too short or the neck is too close to the ischium. Sometimes better positioning is not possible with severely arthritic participants.
- Figure 13: Application of the bone deletion method (see under HIP MEASUREMENTS - ANALYSIS PROCEDURES). This method provides more generous space for placement of the femoral neck box and a more realistic determination of the angle of the femoral midline. All instances in which this method has been applied must be flagged for the attention of the coordinating center.

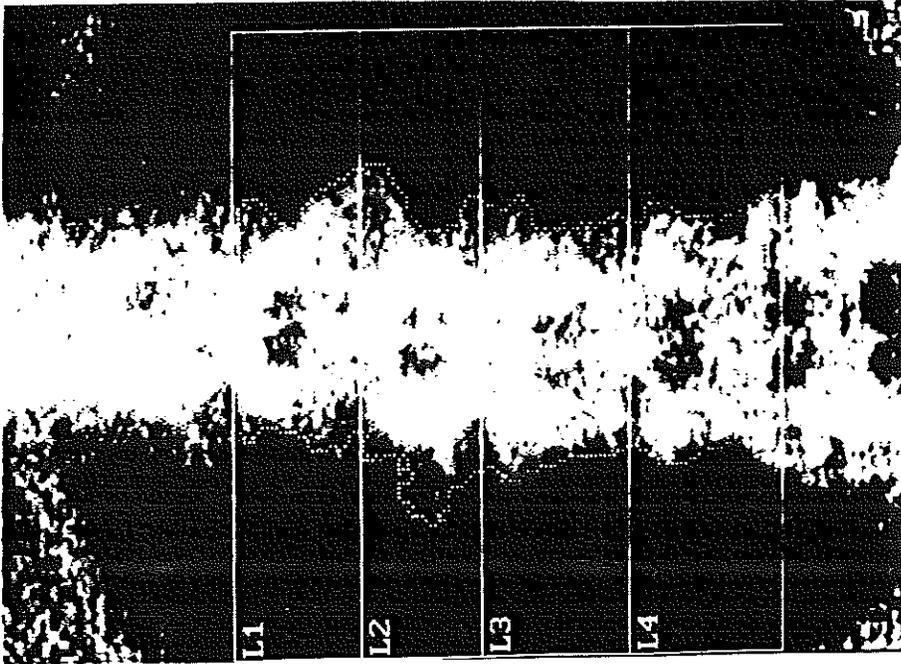
Figure 14: Matching the trochanteric line from baseline to follow-up. In cases in which the curvature between the greater trochanter and the femur is minimal, the trochanteric line will be misaligned. The approximately correct location is accomplished by a visual comparison to the baseline. Because both the areas of the trochanteric and the intertrochanteric regions are relatively large, placement of the line within about 3 pixels will provide an accurate assessment of areas and BMDs.

Fig 1



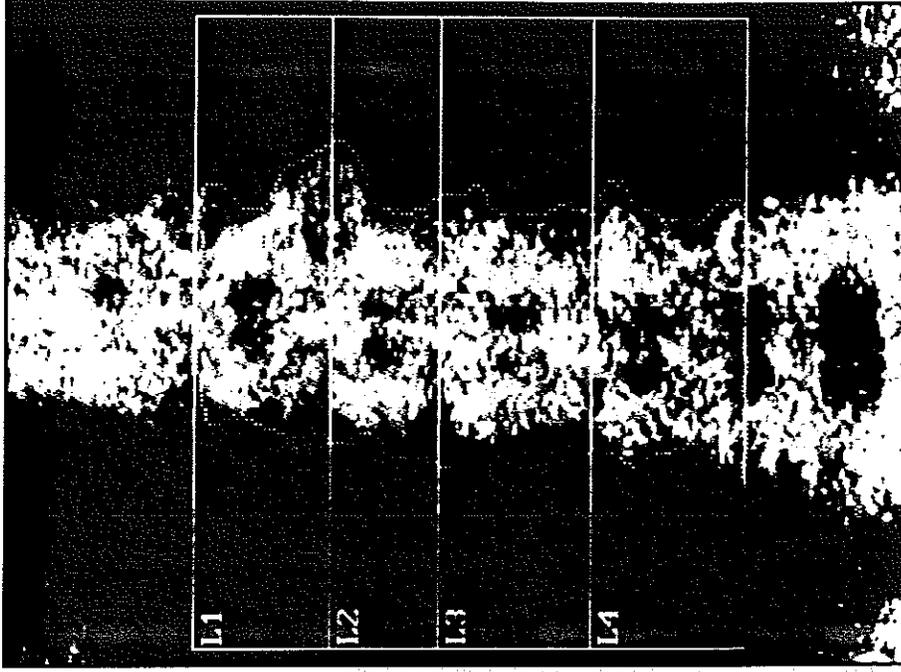
110 x 145

Hologic QDR 1000 (S/N 196)



100 x 128
Hologic QDR 1000 (S/N 191)

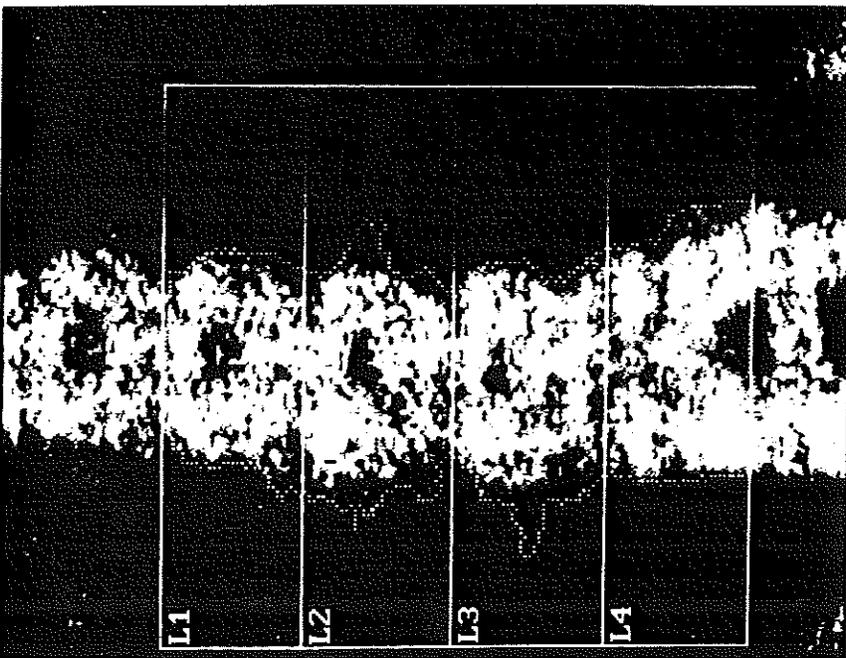
COMPARE



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Hologic QDR 1000 (S/N 191)

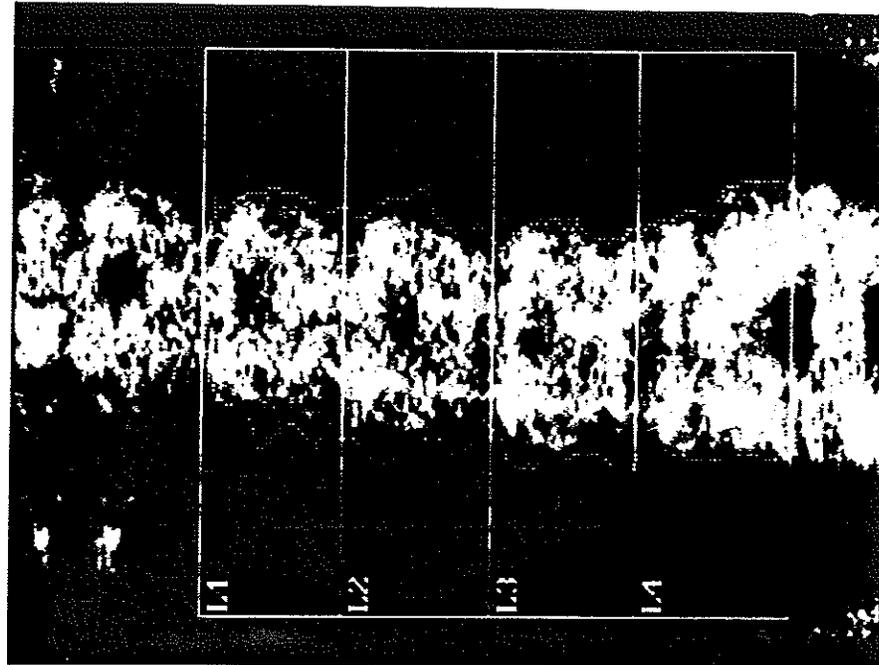
BASELINE

EDGE VARIATIONS



119 x 131
Hologic QDR 1000 (S/N 191)

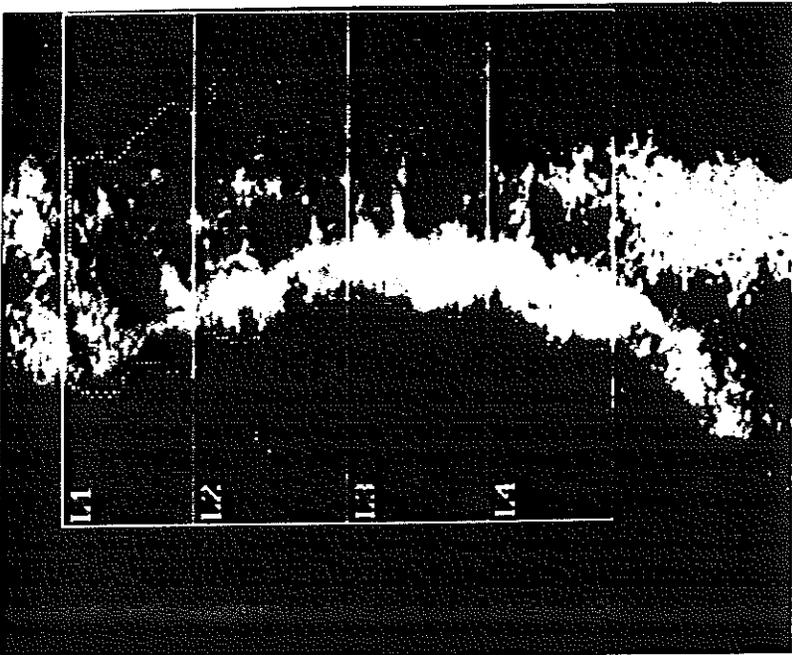
COMPARE



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Hologic QDR 1000 (S/N 191)

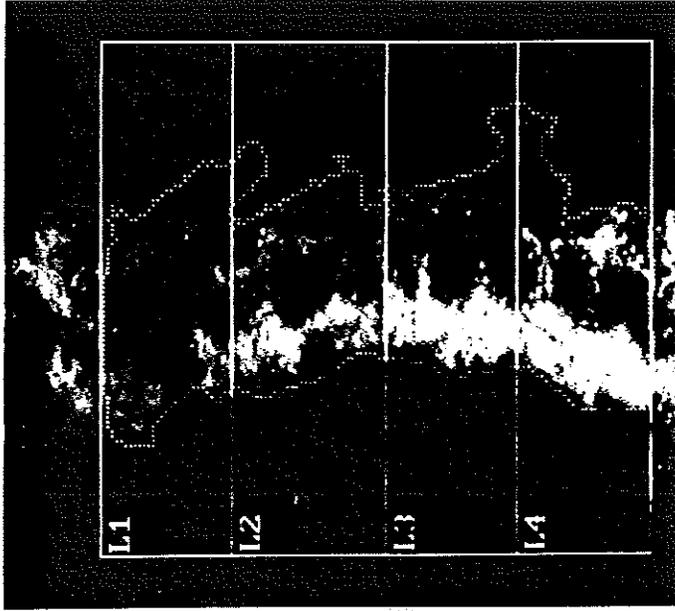
BASELINE

EDGE VARIATIONS



100 x 123
Hologic QDR 1000 (S/N 193)

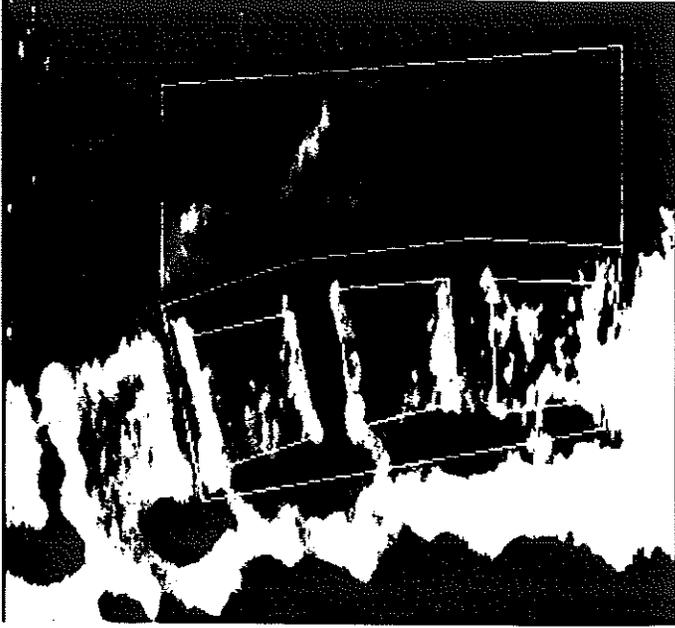
COMPARE



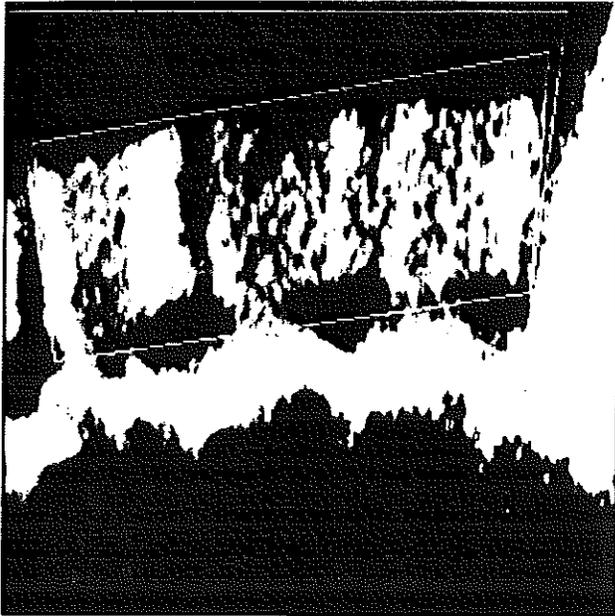
100 x 123
Hologic QDR 1000 (S/N 193)

BASELINE

SCOLIOTIC - EDGE VARIATIONS



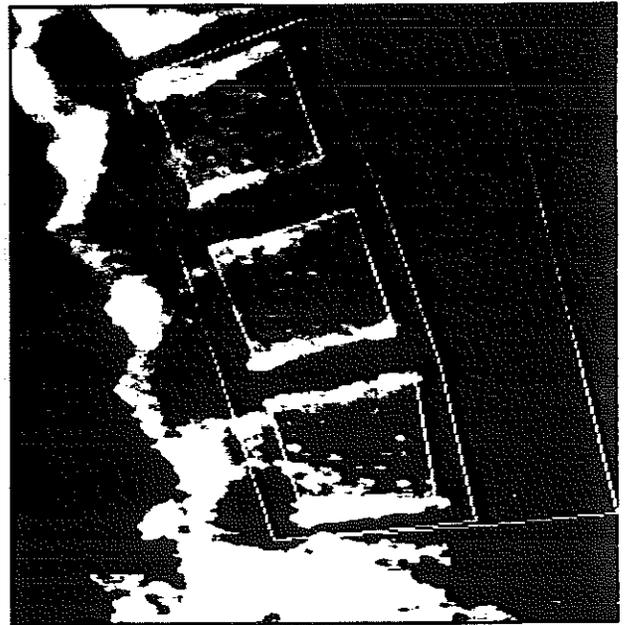
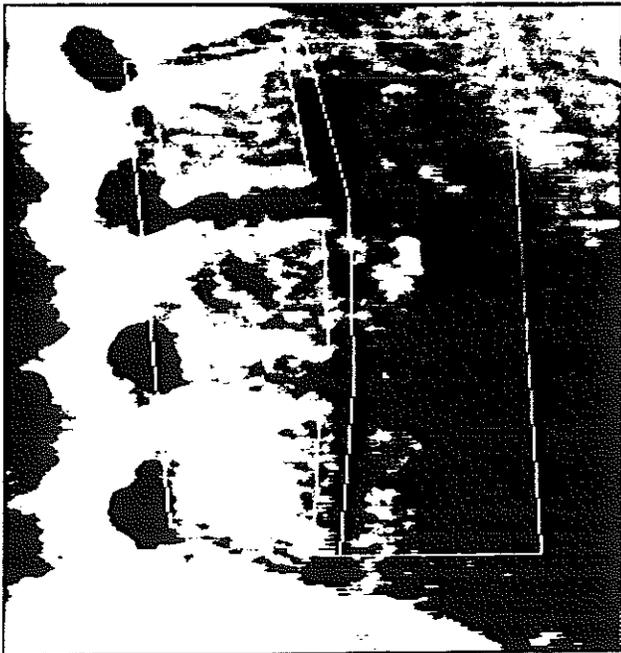
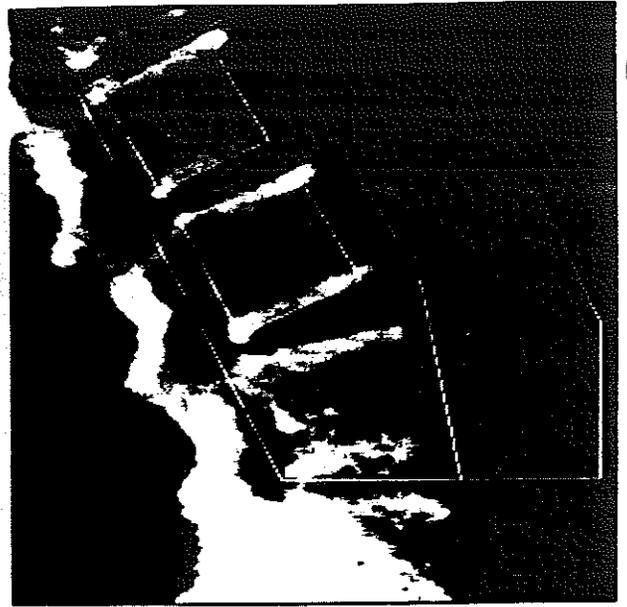
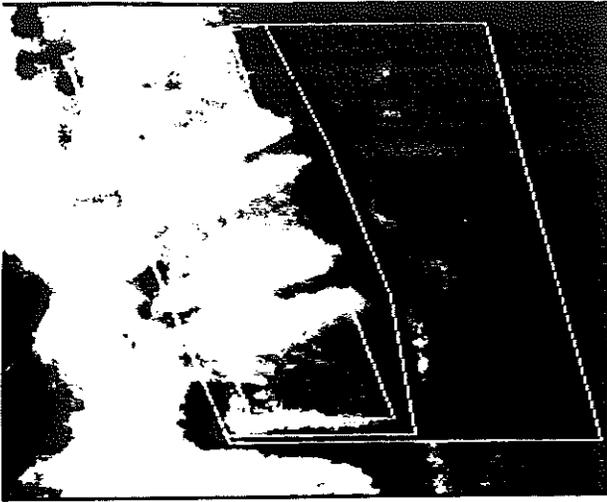
CORRECT



INCORRECT

PATIENT POSITIONING

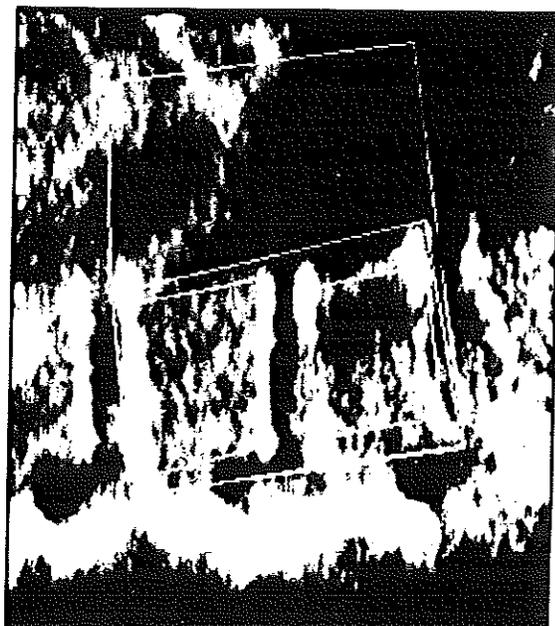
Fig 6



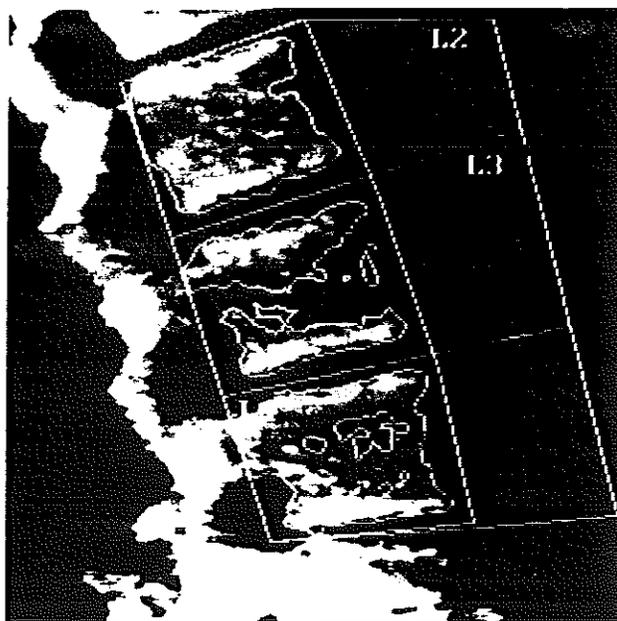
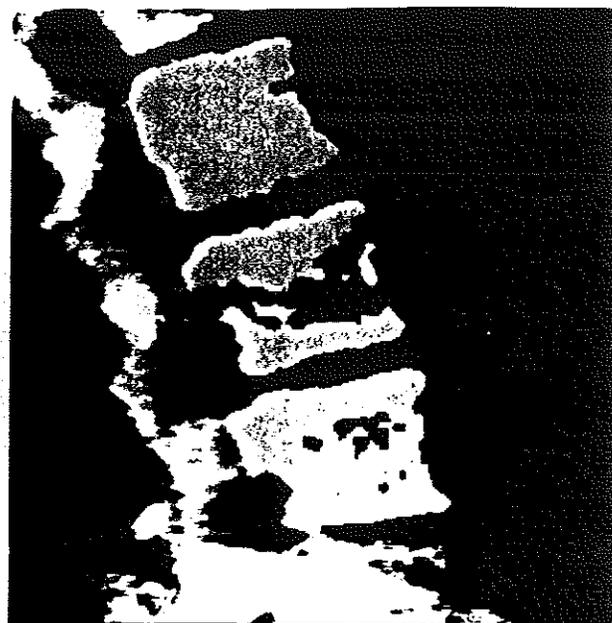
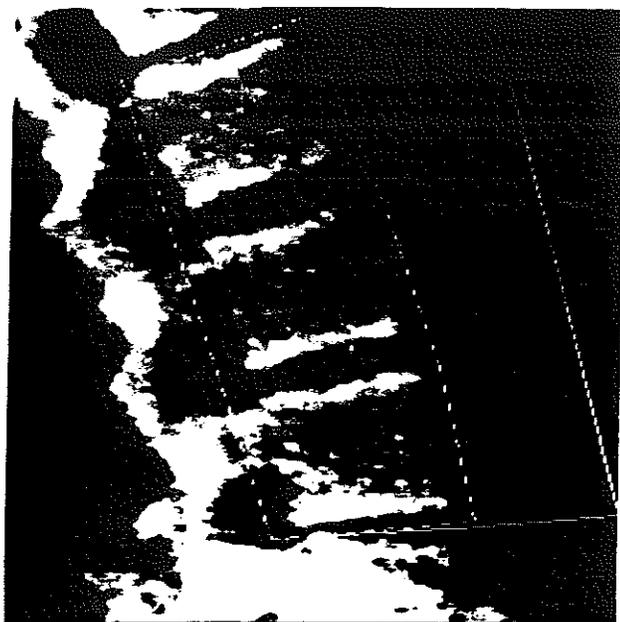
PLACEMENT OF GLOBAL ROI AND FIRST SUBREGION



SPURS INCLUDED

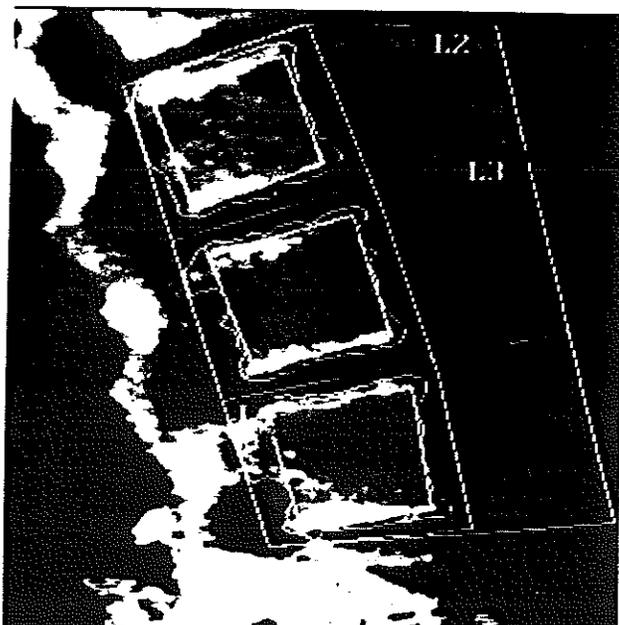
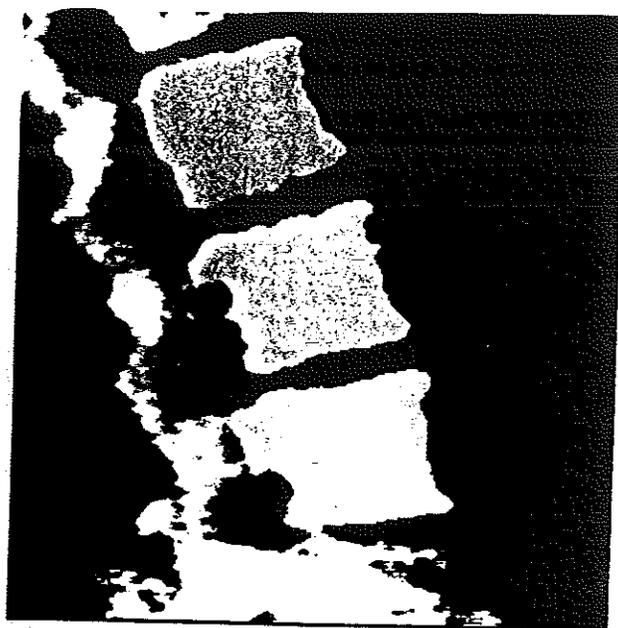
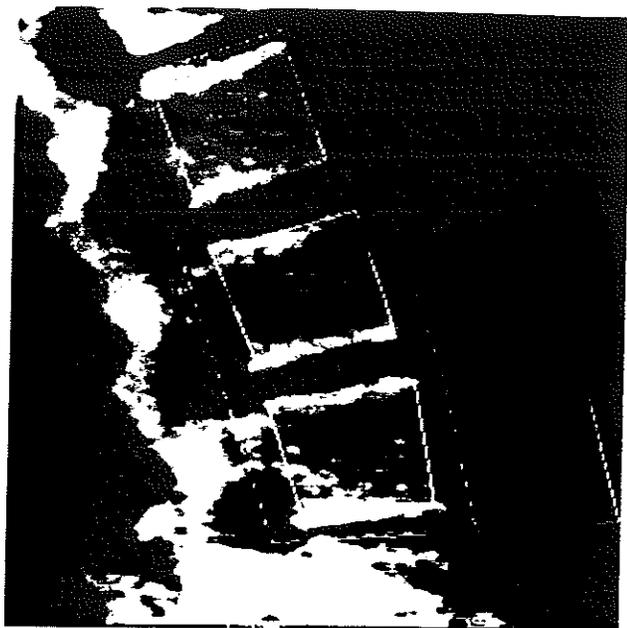


RIB EXCLUDED



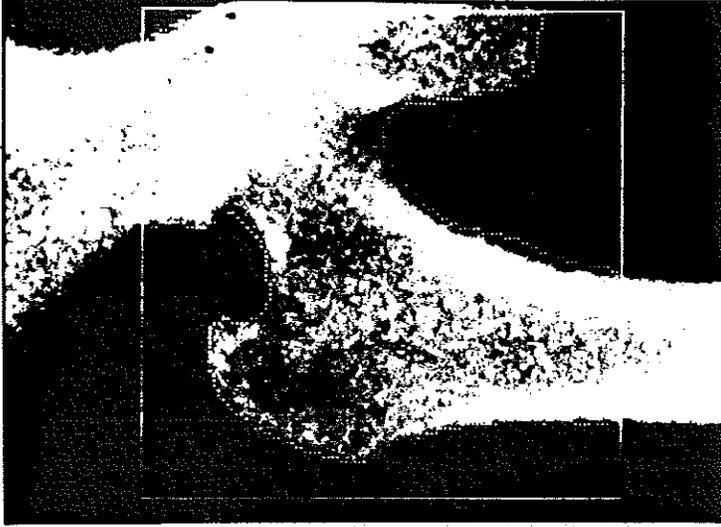
212 x 231 at [47, 51
Hologic QDR 1000 (S/N 196)
Decubitus Spine Version 4.26

ANALYSIS WITHOUT SUBREGIONS S2-S4

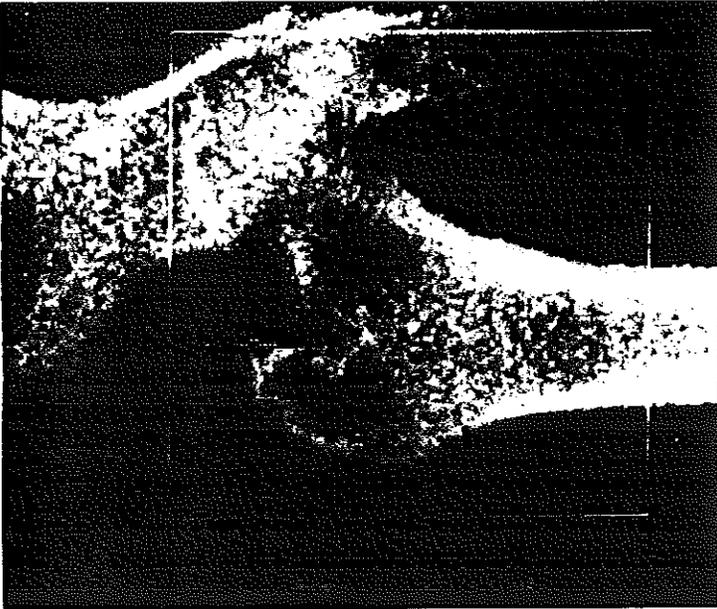


212 x 231 at [47, 51
Hologic QDR 1000 (S/N 196)
Decubitus Spine Version 4.26

ANALYSIS WITH SUBREGIONS S2-S4



BASELINE

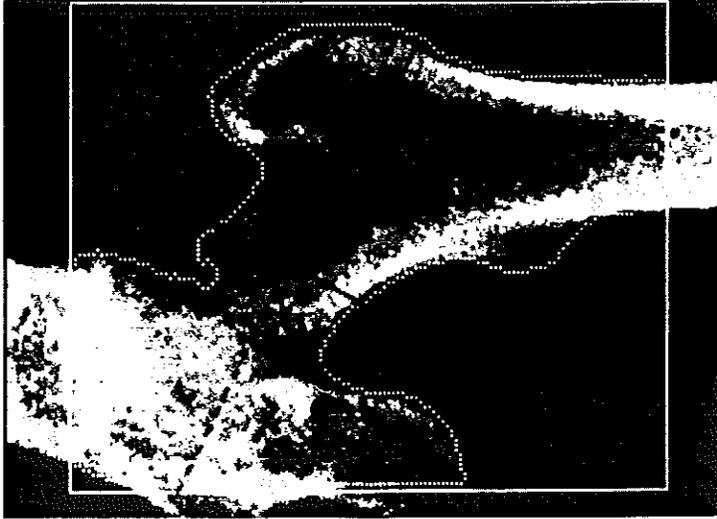


COMPARE

PLACEMENT OF GLOBAL ROI



95 x 126
Hologic QDR 1000 (S/N 193)



103 x 133
Hologic QDR 1000 (S/N 193)

NOTCHES IN FEMORAL NECK REGION



85 x 126

Hologic QDR 1000 (S/N 193)



85 x 126

Hologic QDR 1000 (S/N 193)

Region	Area (cm ²)	BMC (grams)	BMD (gms/cm ²)
Neck	4.29	1.97	0.459
Troch	7.51	3.33	0.444
Inter	20.66	12.79	0.619
TOTAL	32.46	18.10	0.557
Ward's	1.14	0.44	0.383
Midline (68,136)-(16,102)			
Neck	42 x 12 at [-19, 14]		
Troch	-5 x 33 at [0, 0]		
Ward's	11 x 11 at [-6, 10]		

Region	Area (cm ²)	BMC (grams)	BMD (gms/cm ²)
Neck	4.21	2.04	0.484
Troch	8.70	4.10	0.472
Inter	21.22	13.58	0.640
TOTAL	34.13	19.72	0.578
Ward's	1.12	0.41	0.366
Midline (70,140)-(14,104)			
Neck	42 x 12 at [-19, 14]		
Troch	-3 x 33 at [0, 0]		
Ward's	11 x 11 at [-5, 12]		

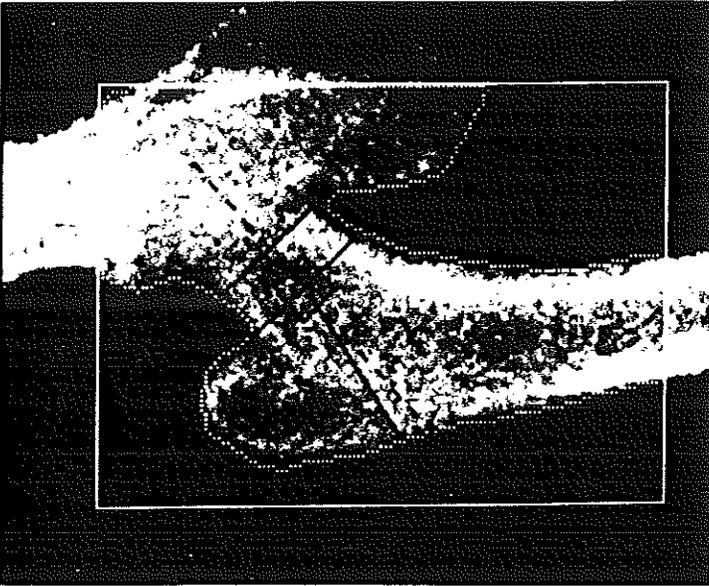
HOLOGIC

HOLOGIC

COMPARE

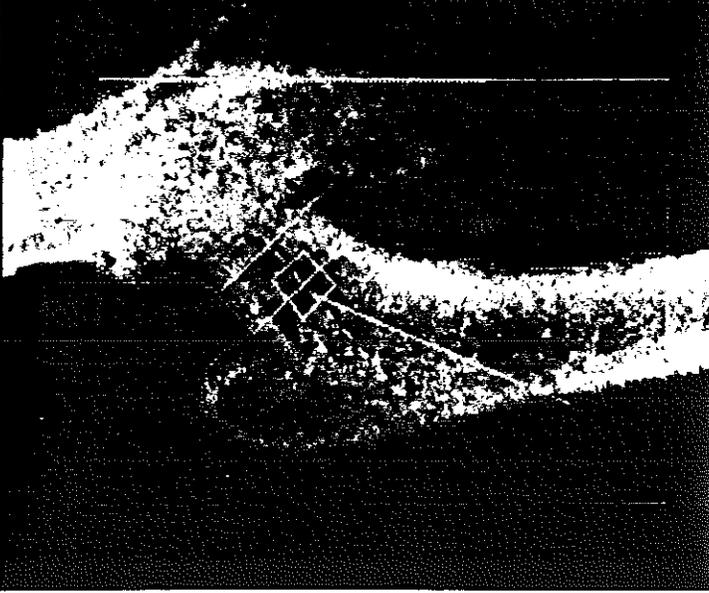
BASELINE

BEFORE REANALYSIS



90 x 120
Hologic QDR 1000 (S/N 193)

COMPARE



MATCH TROCHANTERIC LINE



90 x 120
Hologic QDR 1000 (S/N 193)

BASELINE



85 x 126

Hologic QDR 1000 (S/N 193)



85 x 126

Hologic QDR 1000 (S/N 193)

Region	Area (cm ²)	BMC (grams)	BMD (gms/cm ²)
Neck	3.70	1.82	0.493
Troch	8.78	3.96	0.451
Inter	21.42	13.27	0.619
TOTAL	33.90	19.05	0.562
Ward's	1.08	0.35	0.320
Midline (76,146)-(22, 92)			
Neck	42 x 12 at [-19, 14]		
Troch	-5 x 37 at [0, 0]		
Ward's	11 x 11 at [-6, 10]		

Region	Area (cm ²)	BMC (grams)	BMD (gms/cm ²)
Neck	3.76	1.95	0.520
Troch	9.66	4.56	0.472
Inter	22.19	14.19	0.639
TOTAL	35.61	20.70	0.581
Ward's	1.05	0.36	0.347
Midline (76,150)-(18, 96)			
Neck	42 x 12 at [-19, 14]		
Troch	-3 x 37 at [0, 0]		
Ward's	11 x 11 at [-5, 12]		

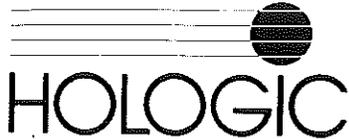
HOLOGIC

HOLOGIC

COMPARE

BASELINE

REANALYZED



Hologic QDR Application Note

This application note contains information to help the user achieve the best results and reproducibility using their Hologic QDR-1000™ X-ray Bone Densitometer. Hologic wishes to thank M.L. Hall, MD and J. Heavens, MD of the University College and Middlesex School of Medicine, London and Peter Steiger, Ph.D. of the University of California, San Francisco for their very helpful analysis input for this application note.

These guidelines have been developed, for successful analysis of femur and spine scans performed with the QDR-1000 and 1000/W X-ray Bone Densitometers. This note is a summary of information contained in the Version 4.10 Operator's Manual dated October 20, 1989.

Femur:

The patient should be placed in the correct position, using the hip fixture supplied with the QDR as described on pages 93 - 95. If at all possible scan the same hip each time the patient is scanned. If the patient has experienced a hip fracture or replacement, scan the opposite hip. If the patient has undergone bilateral replacements, do not scan the hips.

The legs should be abducted by a few degrees to ease the analysis of the neck region (the correct abduction can be obtained by having the point of the foot wedge at the midline of the patient). The hip should be rotated inwards by a fixed amount as indicated by the angle of the foot fixture. Take care when rotating the hips to move the hip joint and not just the ankle. Scan the other hip if rotation of the foot inward is precluded due to discomfort.

The scan length should be at least 6 inches (15 cm) so that any osteoporotic hip can be analyzed. Do not decrease the default scan area. Use the rescan <F3> freely to ensure that the greater trochanter is centered in the scan field top to bottom. Allow the scan to continue until the entire femoral head and the medial acetabulum has been scanned.

At the beginning of the analysis, examine the brightness and contrast of the image. Adjust the brightness and contrast if necessary to clearly visualize anatomical detail. Due to large variations in patient size adjustments will be necessary.

Positioning of the Global ROI

- | | |
|----------------|--|
| Medial edge: | Place near the outer limit of the femoral head but not touching it. (Up to 10 lines outside the femoral head is acceptable) |
| Lateral limit: | Place in a fixed position near the greater trochanter but not touching it. (minimum of 5 pixels). Ensure that the region is entirely within the patient. (Do not include air in the ROI) |

The first part of the document discusses the importance of maintaining accurate records of all transactions. It emphasizes that every entry should be supported by a valid receipt or invoice. This ensures transparency and allows for easy verification of the data.

Furthermore, it is noted that regular audits are essential to identify any discrepancies or errors early on. By conducting these checks frequently, the organization can prevent small mistakes from escalating into larger financial issues.

In addition, the document highlights the need for clear communication between all departments involved in the financial process. Each team should understand their role and how their actions impact the overall financial health of the company.

Finally, it is stressed that staying up-to-date with the latest financial regulations and tax laws is crucial. Failure to do so can result in penalties and legal complications. Therefore, ongoing education and training for the finance team are highly recommended.

Inferior limit: This should be at least 10 pixels below the lesser trochanter. If the lesser trochanter can not be visualized, identify the length of the greater trochanter (L) (from it's superior peak to the point where it "attaches" to the femoral shaft), then double that distance (Lx2) to mark the inferior limit. Please see Figure 1.

The Lx2 distance does not need to be measured, estimating the distance is acceptable. The distance used will always be repeatable with the compare feature on follow-up exams.

Superior limit: Place above the femoral head but not touching it.

In some severely osteoporotic patients, the analysis may not fully outline the bone edge due to the low amount of bone in the presence of a small amount of soft tissue. If the bone edge is not completely outlined, reproducible results can still be achieved. Increase the size of the ROI as shown in Figure 2 and pages 112 - 116 in the operators manual. Expand the superior edge first. If this adjustment still results in incomplete outlining expand the medial edge and lastly the inferior edge. The inferior edge is to be adjusted last, as this will directly affect the definition and measurement of the intertrochanteric region.

Positioning of the smaller regions:

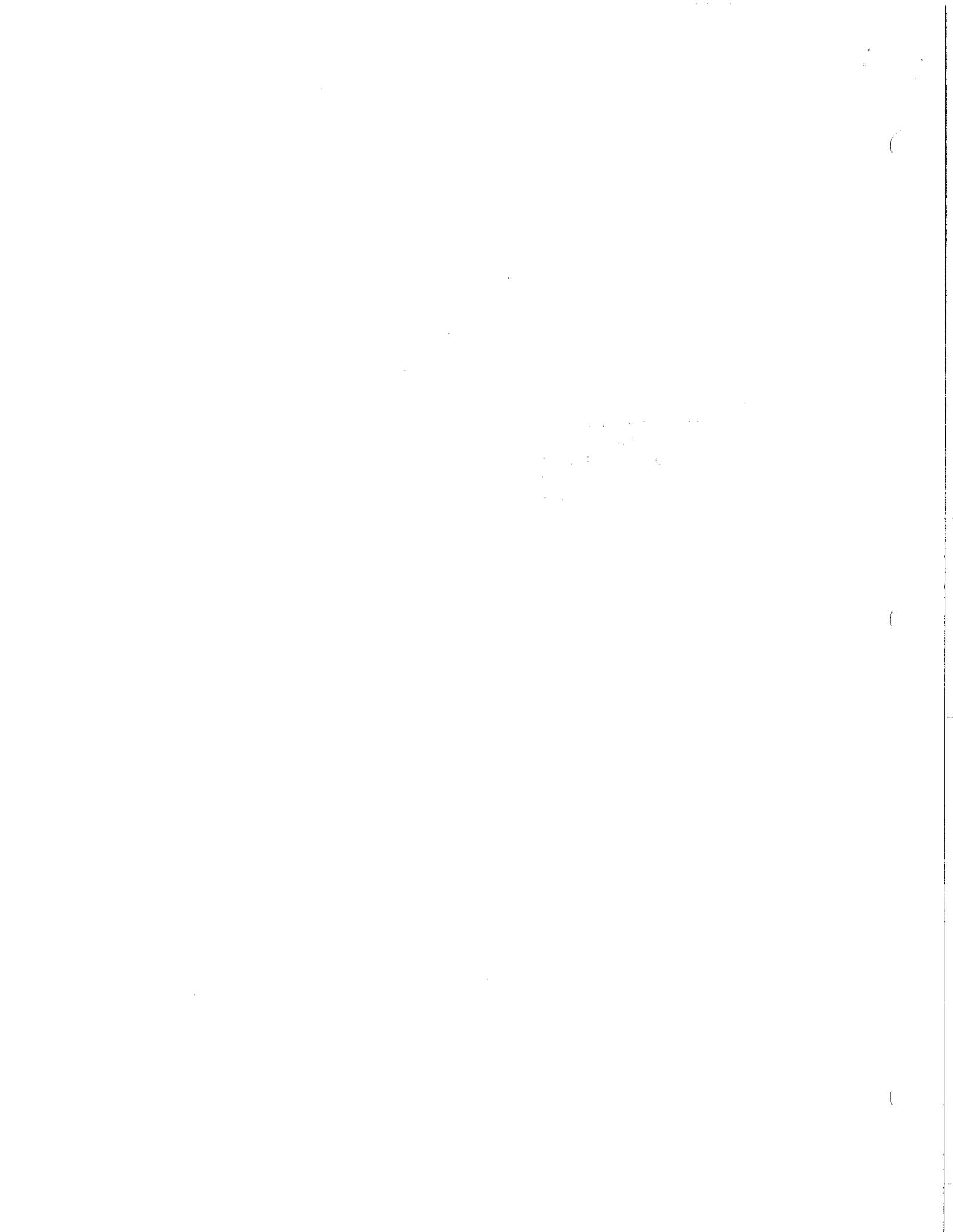
Midline: This should not be adjusted. If it is obviously wrong, the bone edge was incorrect in the previous step.

Femoral neck box: The lower limit should be as near as possible to the greater trochanter without touching it. Ideally the height (distance between the long edges) will be 16 pixels but will have to be reduced if overlying other bone. The neck box should not be higher (distance between the long edges) than 16 pixels. The length of the box does not matter as long as it does not include the ischium or greater trochanter.

It is easiest to move the femoral neck box as a unit (press insert for a whole box) to bring the lower edge as near as possible to the greater trochanter. Then the length can be adjusted to exclude the ischium or greater trochanter.

Wards triangle: Ensure that the search region is within the neck and that the Ward's box remains a fixed size (11 by 11 pixels).

Base of trochanter: Do not adjust unless obviously wrong.



Spine:

Position the patient for a spine scan as described in the operator's manual on pages 20 - 22. Select a scan length 8 inches (20 cm) long for an average height patient. If the patient is over 6 feet (180 cm), select 9 inches (23 cm) for the scan length. If the patient has scoliosis, the scan width can be made wider (it will slightly increase the scan time) Increasing the scan width ensures that the spine will fully fit in the scan area.

When scanning the spine, use the rescan <F3> freely. The spine should be in the center of the scan field.

At the beginning of the analysis, examine the brightness and contrast of the image. Adjust the brightness and contrast if necessary to clearly visualize anatomical detail. Due to large variations in patient size, adjustments may be necessary.

The major guide line for analysis of the spine is to set the initial ROI (yellow box) 10 pixels narrower than the scan area (green box). This ensures that there is enough soft tissue base line for accurate edge detection and that there is enough room for side to side adjustment when using the compare feature for patient follow up.

The ROI (yellow box) should then be centered to the spine as described in the manual.

It is hoped that operators of the Hologic QDR-1000™ X-ray Bone Densitometer will find this application note helpful.

If you have any questions please call:

1-800-343-XRAY or 1-800-343-9729

617-890-9944 in Massachusetts

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The first part of the document discusses the importance of maintaining accurate records of all transactions. It emphasizes that every entry should be supported by a valid receipt or invoice. This ensures transparency and allows for easy verification of the data.

In the second section, the author outlines the various methods used to collect and analyze the data. This includes both primary and secondary data collection techniques. The analysis focuses on identifying trends and patterns over time, which is crucial for making informed decisions.

The third part of the document provides a detailed breakdown of the results. It shows that there has been a significant increase in sales volume, particularly in the online channel. This is attributed to the implementation of the new marketing strategy and the improved user experience on the website.

Finally, the document concludes with a set of recommendations for future actions. It suggests continuing to invest in digital marketing and exploring new product lines to further drive growth. Regular monitoring and reporting will be essential to track the success of these initiatives.

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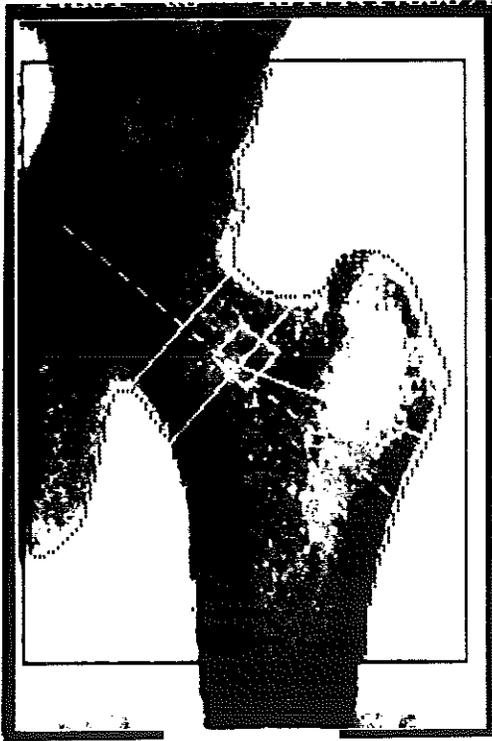


Figure 1

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The hip scan on the right is not outlined correctly. This should prompt the operator to enlarge the ROI. In this case, a larger ROI will enable the system to produce a correct bone map for the hip scan as shown on the left.

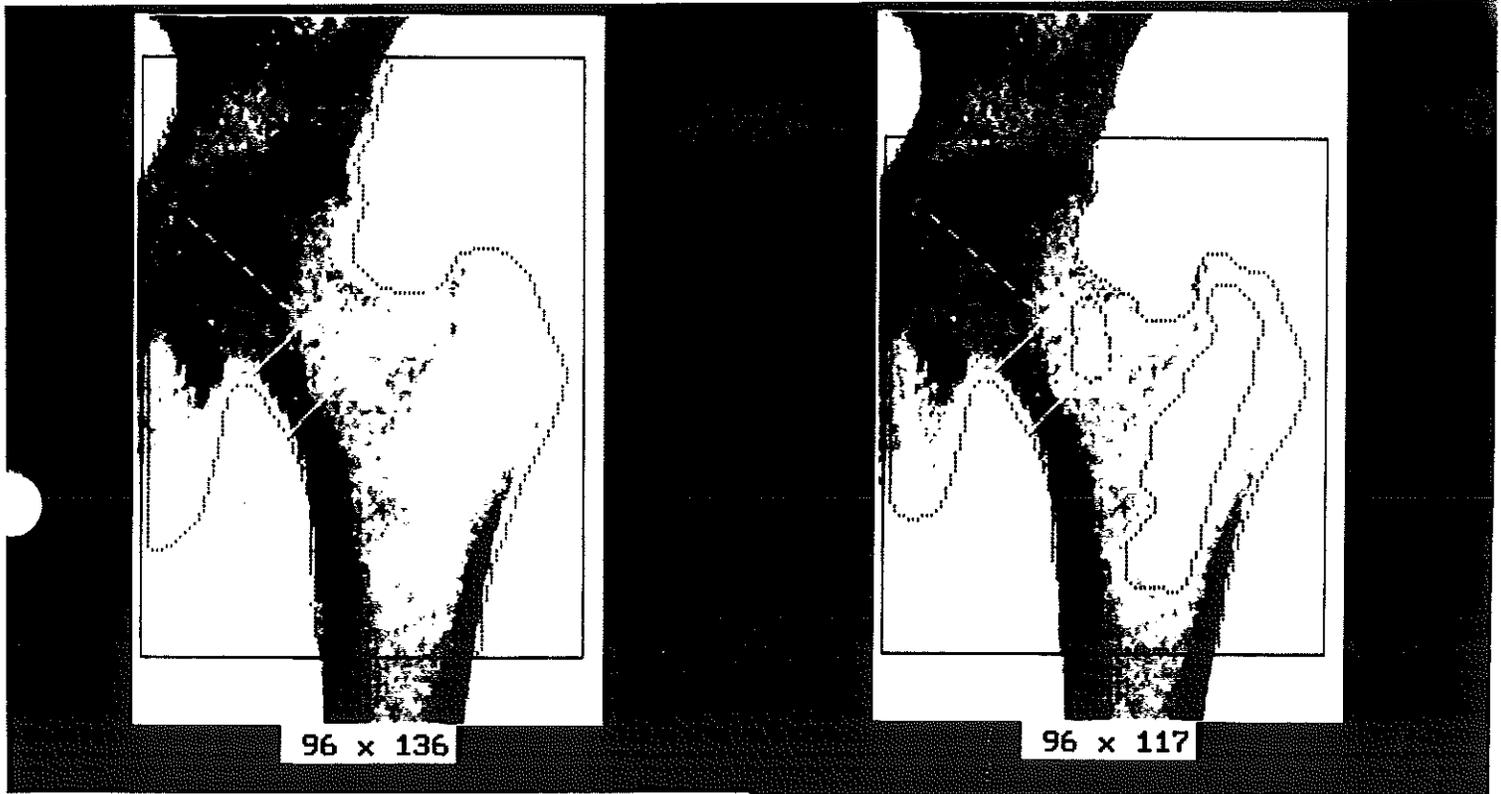
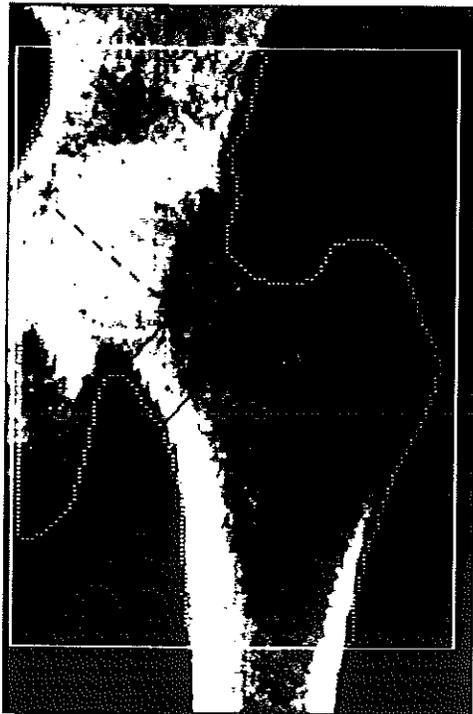


Figure 2

The following information was obtained from the records of the
 Department of the Interior, Bureau of Land Management, regarding
 the land parcels described herein. The information is being
 furnished to you for your information and use only. It is not
 intended to constitute a warranty or representation of any kind.
 The information is based on the best available information at the
 time of the preparation of this report. It is possible that
 the information may be incomplete or incorrect. You should
 consult the appropriate authorities for a complete and accurate
 description of the land parcels described herein.

HOLOGIC, INC.

k = 1.261 d0 = 124.4(1.000)[1]



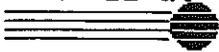
96 x 136

Hologic QDR 1000 (S/N 103)
Left Hip Version 4.13

A04138802 Wed Apr 13 10:47 1988
Name: Honora *
Comment: PG II
I.D.: UCSF Sex: F
S.S.#: - - Ethnic: C
ZIPCode: Height: 167.64 cm
Scan Code: Weight: 64.47 kg
BirthDate: 12/24/28 Age: 59
Physician:

C.F. 1.000 1.040 1.000

Region	Area (cm ²)	BMC (grams)	BMD (gms/cm ²)
Neck	5.62	3.96	0.705
Troch	11.01	5.42	0.493
Inter	23.95	17.92	0.748
TOTAL	40.57	27.31	0.673
Ward's	1.09	0.57	0.525
Midline	(88,134)-(162, 70)		
Neck	-47 x 16 at [24, 12]		
Troch	16 x 44 at [0, 0]		
Ward's	-11 x 11 at [9, 3]		



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