

SCANNING FOREARM

The Forearm Scan procedure estimates bone mineral in the distal and/or proximal regions of either the left or right forearm.

This supplement is to be used in conjunction with the XR Series Operator's Guide or the Excell Operator's Guide.

The Forearm scan process begins with a quick Scout scan over the distal forearm. Host software creates and displays an image of the scanned anatomy. The operator identifies the ulnar end plate and intersection of the ulna and radius on the Scout scan image.

A Measurement scan, consisting of scanning ten lines of the distal forearm, ten lines of the proximal forearm, and one distal soft tissue scan line is taken. The analysis can either be performed with the standard scan-then-analyze sequence of operations, or the scan data may be saved and analyzed later. Results are saved and printed to complete the study. Result Report options include: Detailed (1 or 2 pages) and a Scan History Report.

The patient will be sitting in a chair (without wheels or armrests) in front of the scanner with the forearm resting on the table. Long sleeves should be rolled up above the elbow. Any bracelets, rings, or watches should be removed.

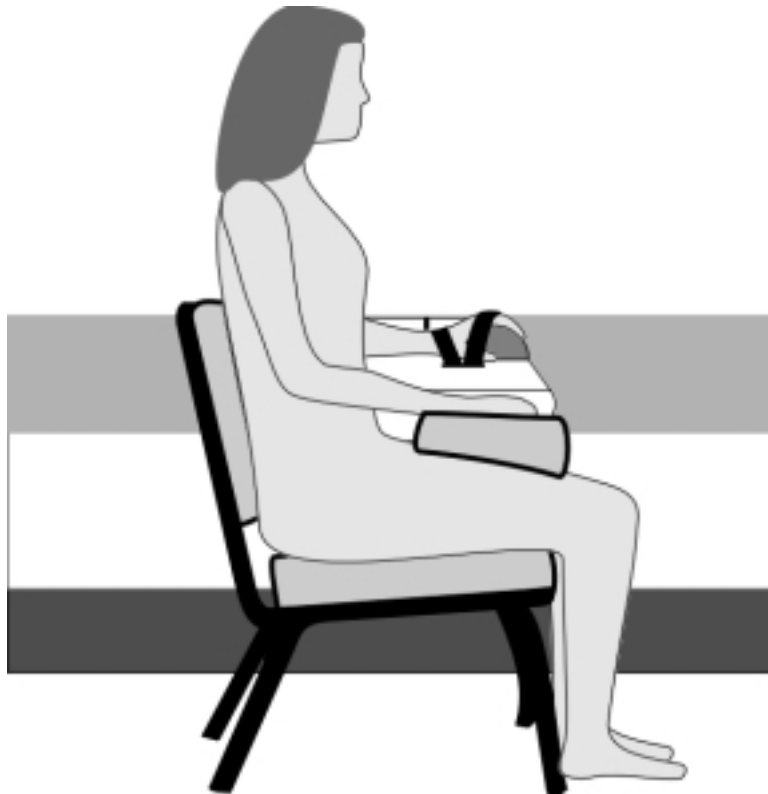


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Detailed Scan Specifications

Detailed specifications for the Forearm Bone Density scan are in the following tables.

Forearm Scan Specifications	
Scan Sites	Distal and/or Proximal radius and ulna and Proximal radius
Accuracy ^a	Typically within 1.0% of industry standard
In vivo Precision ^b	See table below
Scout Scan Resolution	1.0mm x 1.0mm: Point resolution x line spacing (pixel size)
Scout Scan Speed	45 mm/sec
Measurement Scan Resolution	1.0mm x 1.0mm: Point resolution x line spacing (pixel size)
Measurement Scan Speed	High Precision: 2.0 mm/sec Standard: 8.0mm/sec High Speed: 20.0 mm/sec

a. Based on Standard Speed Scans of an anthropomorphic phantom.

b. Based upon 120 scans of 30 subjects and 75 phantom scans using standard procedures.

	Distal Radius & Ulna			Proximal Radius & Ulna			Proximal Radius		
Measurement Scan Mode	BMD	BMC	AREA	BMD	BMC	AREA	BMD	BMC	AREA
High Precision	0.7%	0.9%	0.8%	0.5%	0.6%	0.6%	0.5%	0.7%	0.6%
Standard	0.8%	1.4%	1.0%	0.8%	0.7%	0.6%	0.9%	0.8%	0.7%
High Speed	0.9%	1.3%	1.4%	0.7%	0.7%	0.8%	0.9%	0.9%	0.8%

*** All specifications are subject to change without notice. ***

Patient Dose



The radiation dose to the patient is dependent on the type of scan procedure and the body thickness of the patient. The table below lists typical entrance skin dosages for the Forearm scan based on the listed body thickness.

Scout Scan Skin Entrance Dose

Patient Thickness (cm)	Entrance Dose (mrad)
0-3	0.17
>3-6	0.24
>6-9	0.36
>9-12	0.44

Measurement Scan Skin Entrance Dose (mrems)

Patient Thickness (cm)	High Precision	Standard	High Speed
0-3	3.85	0.96	0.39
>3-6	5.5	1.38	0.55
>6-9	8.05	2.01	0.81
>9-12	10.0	2.50	1.00

Operator Dose



The dose to the operator is negligible. During a scan, the radiation level at a distance of one meter from the scanner table is less than 0.1 millirems per hour.

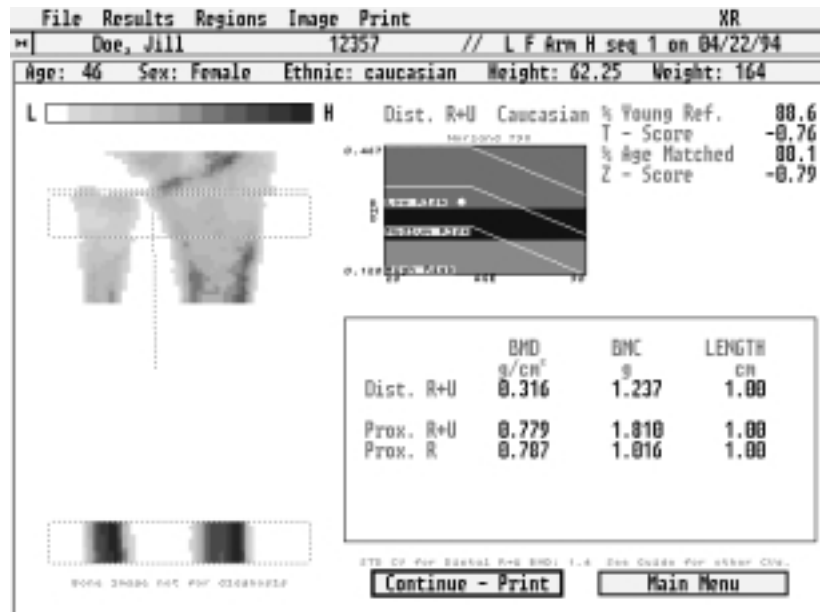
Maintaining High Quality Forearm Scans

Patient positioning, scan and analysis techniques can influence the precision and accuracy of Bone Density estimations. Facilities can reduce the adverse effects of some of these factors by:

- Performing and monitoring the daily QA procedure to verify that other radiation sources (X-ray machines, nuclear imagers) are not affecting the performance of the Norland Bone Densitometer.
- Ensuring that all operators position patients and analyze data in the same manner.
- Screening patients for recent radionuclide uptake procedures. Residual emission may be misinterpreted by Norland Bone Densitometers as x-rays.
- Screening patients for recent ingestion of radiopaque substances. Barium or other dyes used in some x-ray procedures could result in increased soft tissue x-ray absorption.
- Screening patients for prosthetic devices, implants, surgical staples, or other high density sub-dermal materials that may affect density estimates.
- Ensuring that scan and analysis parameters remain constant for all scans of the same patient.
- Repeat any Measurement in which the patient moves.

An example of a good quality Forearm scan is shown in Figure 1.

FIGURE 1



- The arm is centered and straight in the image.
- The ulna endplate is visible, yet few lines of data appear before the endplate.
- The path of the distal Soft Tissue line does not include any bone.
- Both ulna and radius appear in the image and are not cut off.
- There is no visible sign of movement.
- The ROI's seem credible in that the distal is in an area of minimum BMD and proximal at the 1/3 (i.e. cortical) site.

Initial Setup

Scanning Setup

1. Select *Main Menu* item **Setup** and click on **Scanning**.
2. Select "Forearm" at the Scan Type Selection screen. The following screen will display. The defaults shown should be effective for most scanning situations.

FOREARM SCAN SETUP

Resolution:	Scout 1.0 x 1.0	Measure 1.0 x 1.0	mm
Scan Width:	8.00	8.00	cm
Scan Length:	Up to Proximal	10.00	mm
Scan Speed:	45.0	8.0	mm/sec
	<input type="checkbox"/> High Precision	<input checked="" type="checkbox"/> Standard	<input type="checkbox"/> High Speed
Measure Regions:	<input checked="" type="checkbox"/> Both	<input type="checkbox"/> Distal	<input type="checkbox"/> Proximal
<input type="button" value="Accept Changes"/> <input type="button" value="Do Not Accept"/> <input type="button" value="Restore Defaults"/>			

Select desired parameters and click on **[Accept Changes]** to set as default.

- High Speed option sets Measure Scan speed to 20.0 mm/sec (Scout Scan speed is always 45.0 mm/sec).
- High Precision speed sets Measure Scan speed to 2.0 mm/sec (Scout Scan speed is always 45.0 mm/sec).
- User may elect to scan the distal or proximal forearm only, or both the distal and proximal forearm by enabling the appropriate button.

Analysis Setup

1. Select *Main Menu* item **Setup** and click on **Analysis**.
2. Select “Forearm” at the Scan Type Selection screen. The following screen will display. The defaults shown should be effective for most scanning situations.

FOREARM ANALYSIS SETUP

High Density Point Exclusion: ☐ Enabled ☒ Disabled

BMC Calibration: ☒ Comac ☐ Hydroxyapatite

Select desired parameters and click on **[Accept Changes]** to set as default.

- High Density Point Exclusion, when enabled, will automatically exclude data points with a density $>3.75 \text{ g/cm}^2$ for analysis.
- When High Density Point Exclusion is enabled, the abbreviation “MD” (metal detect) will be printed under the image of the Detailed Results Page 1 printout.
- Comac and Hydroxyapatite refer to the types of phantoms used for the forearm calibration. Hydroxyapatite phantoms are preferred in the medical community.



Norland strongly recommends operating the system with High Density Point Exclusion disabled.

Quick Reference Instructions

The Forearm scan takes measurements from the distal and/or proximal radius and ulna or the proximal radius.

- Click on Scan New/Existing Patient and select scan type.
- Enter/Update Patient information.
- Screen patient for contraindications.
- Place the Forearm Fixture on the table, with straps hanging down.
- With the patient seated in a standard chair (without wheels or armrests), position the forearm on the fixture, aligning the head of the ulna with the reference mark on the fixture and secure with straps.
- Position the Forearm Fixture so that the angle formed between the forearm and the upper arm is 90°.



CAUTION the patient not to stare into the beam. Scanner arm will be moved in the next step; take care not to bump the patient.

- Turn laser on and position the laser dot approximately 1 mm off the edge of the patient's wrist immediately adjacent to the ulnar head center and press the MARK button on Scanner Control Panel.
- Position the scanner arm so that laser dot is even with the proximal end of the ulna and press the MARK button.
- At the Scan Review screen, click on **[Start Scan]**.
- Click on the **[Stop Scan]** after the area of minimum BMD is displayed on the image (typically 30 to 45 scan lines) and click on **[Measure Scan]**.
- Position the horizontal cursor at a point distal to the ulnar end plate.
- Position the vertical cursor at the midpoint of the intersection of the ulna and radius and click on **[Continue]**.
- After the Measurement scan has completed, click on **[Analyze]**.

NOTE: The software proceeds automatically from Analysis to the currently selected Results screen.

- Enter comments with "Edit Comments", if desired.
- Click on **[Continue - Print]** to print the Analysis Results Report. The system software automatically saves the scan data file to default storage and returns to the *Main Menu* when report printing has been initiated.



General Cautions

Caution - Properly Mark the Patient. To ensure scanner arm does not contact the patient, always verify patient is positioned properly before scanning or moving the scanner arm.

Caution - Do not move the patient while marking the regions to be scanned. Always remain near the patient, in the event assistance is needed.

Caution - Do not reach around to the back of the unit while the scanner arm is moving. While guards are provided, it is wise to avoid any chance of pinching the arm, hand, or fingers between the scanner arm and the frame, or between the source and the scanner arm.

Caution - Make certain the patient does not dangle their arm or hand over the riser while the scanner arm is moving during a scan. The scan will not be usable, as the patient will not be properly positioned, and the patient may be at risk of pinching their hand or finger between the scanner arm and the riser or between the x-ray source and the scanner arm.

Caution - Make certain the patient does not stick a finger into the slot in the bottom of the upper arm cover during a scan; it could be pinched.

Caution - Do not remove the screws holding the table top during normal use. If the screws are not in place, the table top may tip up if the patient sits on either end. If the screws were not replaced (i.e. after service) and the table top slid forward several inches, it may tip.

Caution - Caution the patient to remain still during the scan to ensure quality results.

Caution - Help the patient up from the chair after scan data collection; some patients may require a few minutes to regain equilibrium after sitting down for a length of time.

Performing Forearm Scan

The patient will be sitting in a chair (without wheels or armrests) in front of the scanner with the forearm resting on the table. Long sleeves should be rolled up above the elbow. Any bracelets, rings, or watches should be removed.

Scanner Preparation (New Patient)

1. Click on the **Scan New Patient** shortcut from the Main Menu. The PATIENT PERSONAL DATA screen will display.

2. Enter personal information and click on **[Continue]**. The “Name” and “ID” entries are mandatory for scanning.
 - Name should be (last name), (first name).
 - ID Number must be unique to be accepted. If the entered number is already in use, a message will display indicating that the number is already in use.
For example: (SSN or Clinic/Hospital ID)
 - Sex, Birthdate and Ethnic fields must be entered in order to automatically display Reference Charts.
 - Ethnic fields are Caucasian, Afro Am, Asian, Hispanic. The Reference Chart will not automatically display on the Results Page(s) if ethnic field entry differs from Reference Set ethnic field entry.
 - If patient’s ethnic background is something other than those listed above (i.e. American Indian), enter the appropriate background.
 - Pressing **[Enter]** or **[Tab]** will move cursor through fields.

3. At the SCAN TYPE screen, click on desired scan type and click on [Continue].

NOTE: Scan the non-dominant forearm unless medical necessity dictates otherwise.

4. Enter the patient's vital statistics and click on [Continue].

Height:

Weight:

Technician:

Physician:

- Use consistent units of measurement for the height and weight fields.
 - This information will be updated for each successive scan of the patient and will not affect scan results.
 - Pressing or will move cursor through fields.
5. Proceed to Patient Positioning to prepare the patient for scanning.

Scanner Preparation (Existing Patient)

1. Click on the **Scan Existing Patient** shortcut from the Main Menu. The patient list will display.

FIGURE 2

NAME	ID
Doe, Jane	12347
Doe, Janet	12346
Doe, Janine	12348
Doe, Janna	12349

- Click on Page Up or Page Down to display the next group or use the arrow buttons to scroll.
- A search may be done by patient ID number or name. Enter appropriate information and click on **[Continue]**; partial information can be used. For example, entering “D” when searching by name will show scan list and highlight first name that starts with “D”, allowing user to fine tune search for patient’s name.

FIGURE 3

2. Click on patient name and click on **[Continue]**. (Or double-click on patient name.)
3. At the SCAN TYPE screen, click on desired scan type and click on **[Continue]**.
4. Update the patient’s vital statistics and click on **[Continue]**.
 - Use consistent units of measurement for the height and weight fields.
 - This information will be updated for each successive scan of the patient and will not affect scan results.
 - Pressing **[Enter]** or **[Tab]** will move cursor through fields.
5. Proceed to Patient Positioning to prepare the patient for scanning.

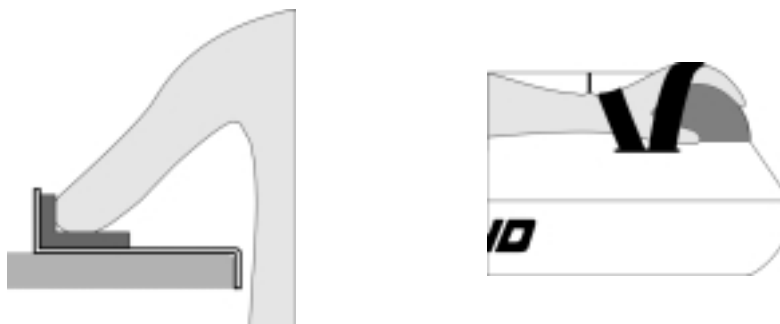
Patient Positioning

The instructions for positioning the forearm are for the left forearm. These instructions can be applied to the right forearm by reversing the physical references.



1. Position a chair (without wheels or armrests) as close as possible to the front of the scanner.
2. Have the patient sit straight in the chair with both feet flat on the floor.
3. Ensure that laser is turned off and move the scanner arm away from the patient.
4. Place the Forearm Positioning Fixture on the scanner table with the front straps hanging over the front edge of the table.
5. Pull the wrist strap (second strap from the right when scanning the left forearm) through the hole in the back of the fixture, forming a large loop.
 - The remaining three straps should hang down over the front of the tray.
6. Place the patient's arm on the fixture rest and slide the hand through the large loop formed by the wrist strap.

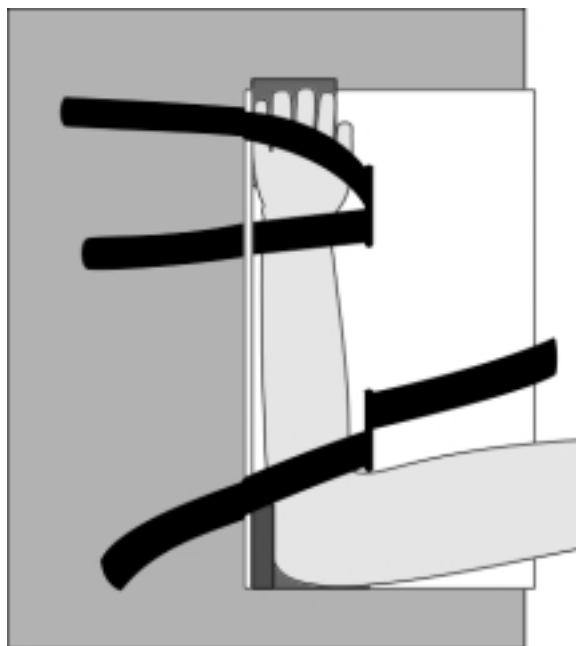
FIGURE 4



- Support the other arm on a pillow in the patient's lap for comfort.
7. Align the head of the ulna with the reference mark on the back of the fixture.
 - The head of the ulna is the lump which protrudes from the top of the wrist. This protusion is typically obvious, however, it may be necessary to palpate some patients to locate the head of the ulna.
 8. Position the Hand Rest under the patient's palm and against the back of the fixture. The patient's fingers should be aligned along the outer front edged of the pad and the thumb must remain flat against the fixture base.
 9. Position the elbow pad under the patient's elbow.

10. Place the proximal (elbow) strap diagonally across the upper forearm and attach to the fixture back rest.
11. Fasten the hands strap diagonally over the thumb and fingers and attach to the back rest, then fasten the wrist strap.

FIGURE 5



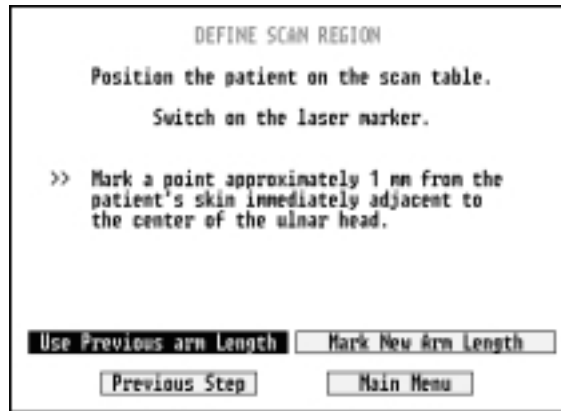
- If the distance between the ulna head and the back of the fixture exceeds 1 cm, reposition the hand rest and re-fasten the wrist strap.
12. The angle formed between the forearm and the upper arm should be 90°. Slide the Forearm Positioning Fixture along the edge of the table to change the angle, if necessary.
- The patient is now ready for scanning. Proceed to Scan Procedure.

Scan Procedure

The DEFINE SCAN REGION screen should be displayed on the computer. (See Figure 6)

- The “Use Previous arm Length” and “Mark New Arm Length” options will be displayed only if the patient has had a previous Forearm scan.

FIGURE 6



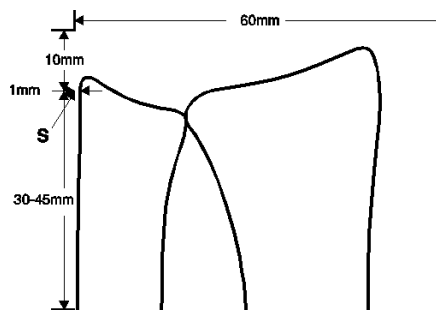
- The [Previous Step] command will return to the previous step.



CAUTION the patient to not stare into the beam.

1. Turn on the laser and move the scanner arm until laser dot is approximately 1 mm off the edge of the patient's wrist immediately adjacent to the ulnar head center.

FIGURE 7

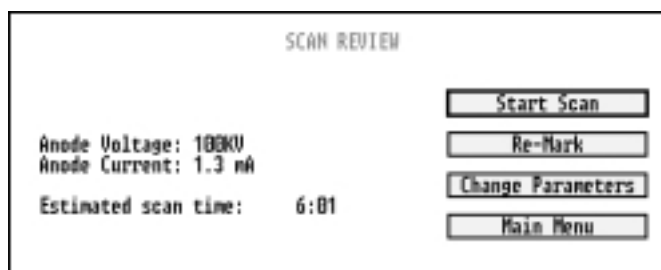


2. Press the MARK button on the Scanner Control Panel. The computer will issue a beep and the laser will flash off briefly, indicating acknowledgement of the scan start point.
3. The DEFINE SCAN REGION screen will request that the end scan point be identified. Position the scanner arm so that laser

dot is even with the end of the elbow and press the MARK button on the Scanner Control Panel.

Once the start and end points have been marked, the **SCAN REVIEW** screen will be displayed on the screen. (See Figure 8)

FIGURE 8

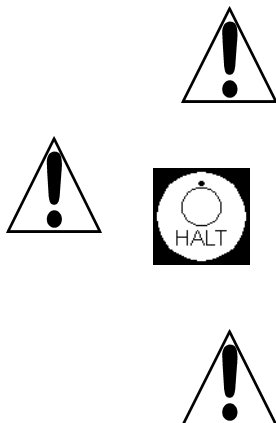


The operator can:

- Click on **[Re-Mark]** to re-mark start and end points.
 - Click on **[Change Parameters]** to edit any of the scan parameters, such as scan speed, scan region, or number of multiple scans of same subject (**multiple scans for scanning phantoms only**).
 - Click on **[Main Menu]** to cancel the scan and return to the Main Menu.
4. Caution the patient to remain still and click on **[Start Scan]** to begin the Scout scan. The system software will:
- Turn off the laser.
 - Select the appropriate filter combinations as determined by the patient thickness.
 - Measure detector counts with no x-rays for background reference.
 - Apply voltage to x-ray source and take baseline measurements for the forearm fixture then start the Scout scan.

X-rays will energize and data collection will start as the scanner arm moves down the patient's arm for the prescribed length of scan. Background detector count will be subtracted from the scan counts to provide a true representation of the amount of x-ray absorption. The Current Scan Progress screen will generate the image based on detector output even as the scan data is being collected. An estimate of the remaining scan time will also be displayed.

5. Observe the image on the Current Scan Progress screen as it updates. The scan should be terminated immediately if patient moves during scan. Patient movement will adversely affect the accuracy of the scan.



- Clicking on **[Stop Scan]** will pause the scan after the current scan line is completed. A warning message indicating that there aren't enough scan lines to analyze may be displayed. The scan can be resumed or terminated at this point.
- In an emergency situation, press the **HALT** button on the Scanner Control Panel to terminate the exposure immediately. The system power will have to be recycled to resume scanning after pressing the HALT button. Leave the computer powered on to retain the current study.

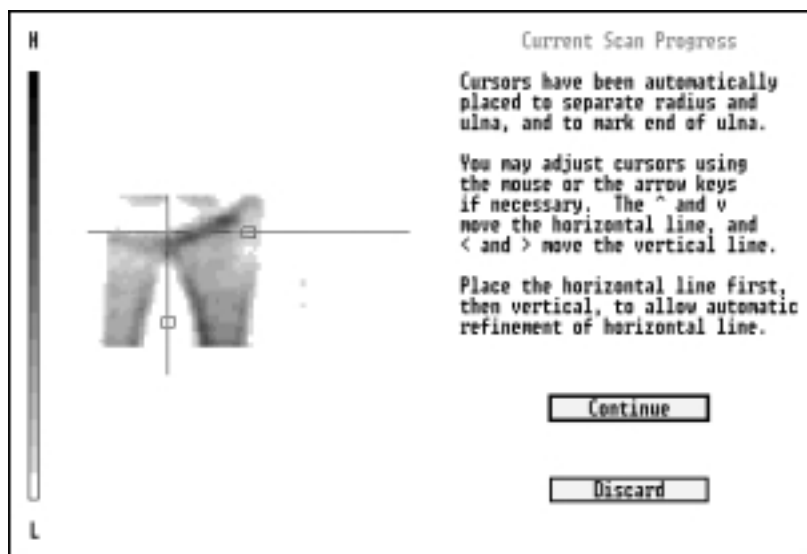
WARNING: If computer power is recycled in this instance, the scanner arm will return to origin position. ENSURE THAT PATIENT IS NOT IN SCANNER ARM PATH!

6. For the initial scan of the patient, click on the **[Stop Scan]** after the area of minimum BMD is displayed on the image (typically 30 to 45 scan lines). Subsequent scans of the same patient require only 5 scan lines past the ulnar end plate be completed before scan termination.

When the Scout scan has completed, the Current Scan Progress screen will be updated to indicate that Scout scan is complete and an audible beep will sound.

7. Verify that the image contains the ulna, the ulna endplate, and radius and click on **[Measure]**. The Current Scan Progress screen will be updated to show cursor placement (as in Figure 9).

FIGURE 9



Norland strongly recommends using the computer-generated cursor placement unless they are blatantly incorrect.

Reposition cursors, if necessary, by:

- Clicking on the control point for the horizontal cursor and dragging to a point distal to the ulnar end plate.
- Clicking on the vertical cursor and dragging to the mid-point of the intersection of the ulna and radius.



NOTE: Positioning the vertical cursor also initiates the automated ulnar end plate location search. If the horizontal cursor is moved after the vertical cursor, the automated search is defeated and the precision may be affected.

8. Caution the patient to remain still and click on **[Continue]** to begin the Measurement scan for both the distal and proximal forearm, which consists of:

- 10 lines (10mm) of the distal ulna and radius.
- 10 lines (10mm) of the proximal ulna and radius.
- 1 axial line between the radius and the ulna (soft tissue).

9. Observe the image on the Current Scan Progress screen as it updates. The scan should be terminated immediately if patient moves during scan. Patient movement will adversely affect the accuracy of the scan.



- Clicking on **[Stop Scan]** will pause the scan after the current scan line is completed. A warning message indicating that there aren't enough scan lines to analyze may be displayed. The scan can be resumed or terminated at this point.
- In an emergency situation, press the **HALT** button on the Scanner Control Panel to terminate the exposure immediately. The system power will have to be recycled to resume scanning after pressing the HALT button. Leave the computer powered on to retain the current study.



WARNING: If computer power is recycled in this instance, the scanner arm will return to origin position. ENSURE THAT PATIENT IS NOT IN SCANNER ARM PATH!

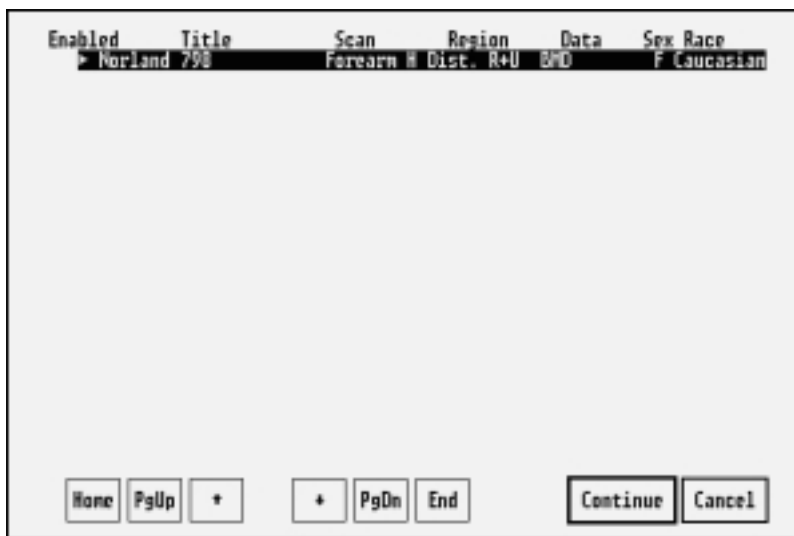
10. When the scan is complete and no evidence of patient movement during the scan is exhibited, click on **[Analyze]**. The currently selected Results Page will be displayed.

- The **Save & Exit** option will save the data to the default storage for analysis at a later time.

11. Release the patient from the forearm fixture if no further scans are to be performed.

- If an exact match of the installed Reference Sets and the ethnic background entered during Scanner Preparation does not exist, a screen similar to the following will display with a list of Reference Sets that match patient's gender.

FIGURE 10



- Select the Reference Set that most closely matches the patient's background and click on **[Continue]** to proceed with the analysis.
- Click on **[Cancel]** if no Reference Set matches the patient's ethnic background; in this case a reference graph will not be displayed on the Result Pages.

Results

- The T-Score will be plotted in the reference chart as a black dot and the value is displayed in the upper right corner of Results Page 1 (Figure 11). (Images in this guide are shown in reversed video mode for illustrative purposes.)
- The BMD, BMC, and LENGTH for the Distal Radius and Ulna, Proximal Radius and Ulna, Proximal Radius, and any other operator-defined regions. Results Page 2 (Figure 12) also shows Width values.
- If the patient has been scanned before, % **Short Term** & % **Long Term** will be displayed below the T-Score and Z-Score information.

T-SCORE	The T-score is the number of standard deviations a patient's BMD value is above or below a young reference value for individuals of same ethnic background and gender.
% YOUNG REFERENCE	The % Young reference value is the ratio of the patient's bone mass to the young reference value for individuals of same ethnic background and gender.
Z-SCORE	The Z-score is the number of standard deviations that the patient's BMD value is above or below the reference value for individuals of same age, ethnic background and gender.
% AGE-MATCHED	The % Age-matched value is the ratio of the patient's bone mass to the reference bone mass value of individuals of the same age, ethnic background and gender.
%SHORT TERM CHANGE	Ratio of change between current scan and most recent previous scan.
%LONG TERM CHANGE	Ratio of change between current scan and patient's initial scan.
%/YR. value	Indicates the percent of change calculated per year

1. View the image (which is not for diagnostic purposes) to ensure that cursors are positioned correctly and analysis results are satisfactory.
 - The **Image** selection on the *Analysis Menu* presents commands for optimizing the displayed image.
 - Click on [**Continue-Print**] to print report as determined by Print Setup. Analysis results will be saved to the default storage location as a scan data file under patient's name and *Main Menu* will be displayed.
 - Click on [**Main Menu**] to save scan data and exit to Main Menu without printing report.
 - Selecting **Print - Print Report** at the *Analysis Menu* will allow customization of Printer Setup for the current scan.

Fracture Risk Assessment

The patient's risk of fracture is plotted in the Reference Charts displayed in the Results Pages. Norland incorporates the WHO (World Health Organization) criteria in plotting a patient's fracture risk assessment. See table below.

Low Risk	Represents the range of values determined by WHO to be 'normal' (having adequate bone mineral). The BMD T-Score values in this region are within 1 SD of the young adult reference mean value. A patient whose value is plotted in this region has no identifiable risk of fracture.
Medium Risk	Represents the range of values determined by WHO to be 'osteopenic' (having low bone mineral). The BMD T-Score values in this region range are more than 1 SD below the young adult mean value but less than 2.5 SD below the mean value. A patient whose value is plotted in this region may be developing a tendency to fracture.
High Risk	Represents the range of values determined by WHO to be 'osteoporotic' (having severely reduced bone mineral). The BMD T-Score values in this region are more than 2.5 SD below the young adult mean. A patient whose value is plotted in this region has a high spontaneous fracture probability.

FIGURE 11

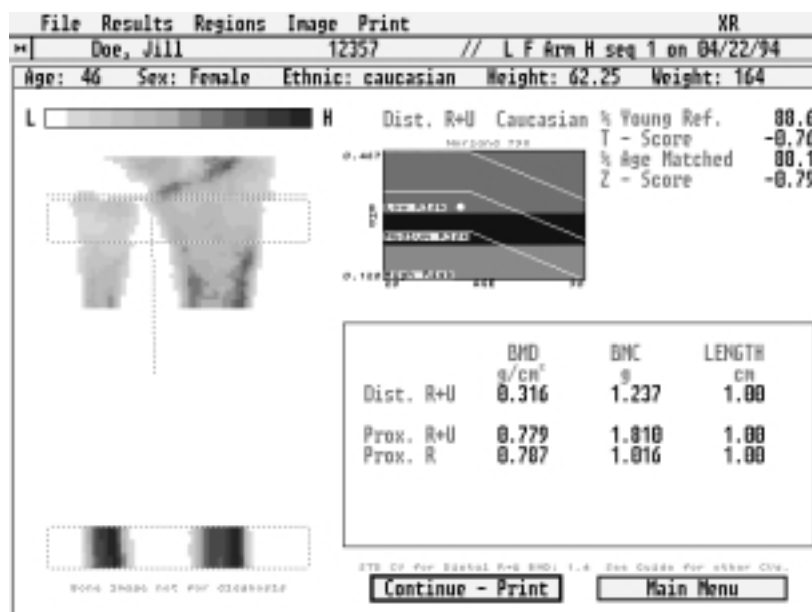
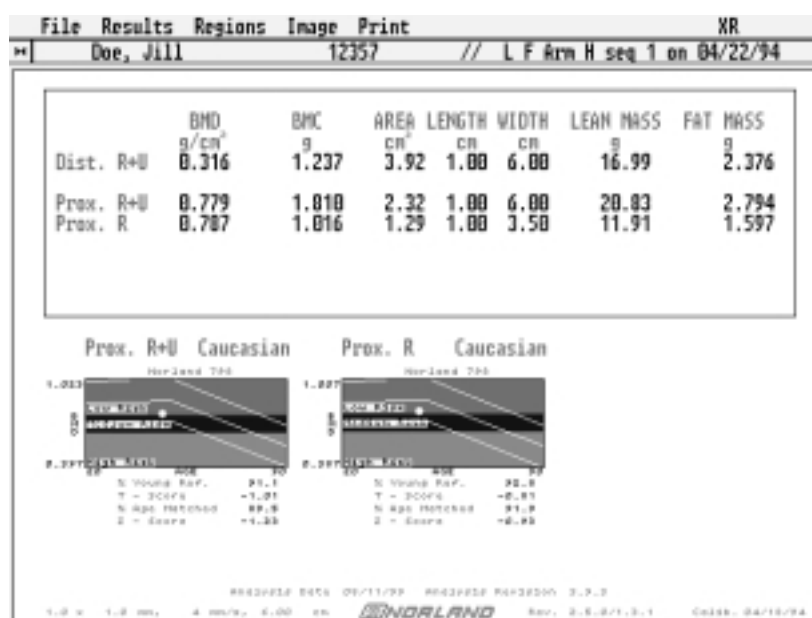


FIGURE 12



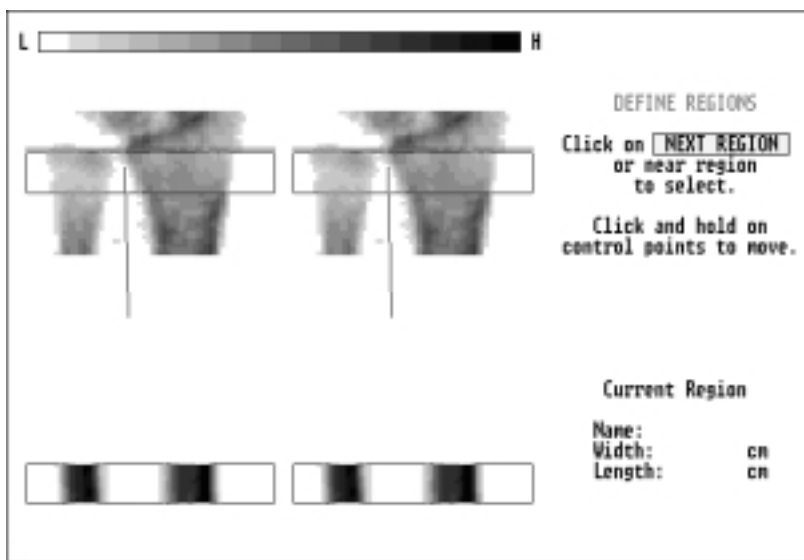
Comparison Image

The Comparison Image is useful for determining that serial scans match the patient's initial scan.

1. At the REVIEW REGIONS screen, select *Analysis Menu* item **Image** and click on **Show Comparison**.

The patient's first scan image is recalled and presented to the right of the current scan using the same linear scale as the existing image.

FIGURE 13

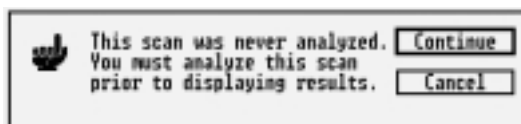


- It will be necessary to rescan if the current scan doesn't match the patient's initial scan.
- It is not necessary to Hide Comparison before displaying the results or saving the data.

Analyzing Saved Scan Data

The Host software allows an operator to perform a scan on a patient, save the data, and then analyze the saved scan data later.

1. Select *Main Menu* item **Select** and click on **Select a Patient**. Double-click on desired patient from list.
A listing of the patient's scans is displayed. A check mark in the right column indicates that the scan has been analyzed.
2. Double click on the scan to be analyzed. The following message will be displayed; click on **[Continue]** to proceed.



3. Select *Analysis Menu* item **Results** and then click on Results Page 1.
 - The operator can add up to two Special Region cursors (see Operator's Guide - Additional Techniques).

