

NORLAND

XR - 46TM

X-Ray Bone Densitometer



Operator's Guide

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NORLAND

EXCELLTM Whole Body

X-Ray Bone Densitometer



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X-Ray Bone Densitometer



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EXCELLTM plus

X-Ray Bone Densitometer



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X-ray Device Registration

The Norland Bone Densitometer is an x-ray device that emits small amounts of radiation to acquire bone density information. Although the dose is very small, some countries and all states in the United States require registration of such devices, regardless of dose. It is the purchaser's responsibility to contact the government agency responsible for x-ray devices and to comply with any specific information concerning device registration and operation for the area in which the system is to be operated.

Table of Contents

Indications for Use	- - - - -	1-1
Contraindications	- - - - -	1-1
X-Ray Device Registration	- - - - -	1-1
About This Manual	- - - - -	1-3

1 GENERAL INFORMATION

Radiation Safety Precautions	- - - - -	1-2
Scanner Features	- - - - -	1-3
Dual Energy X-Ray Absorptiometry	- - - - -	1-3
Dynamic Filtering	- - - - -	1-3
QuikScan™ Technology	- - - - -	1-3
Radiation Safety Features	- - - - -	1-4
Exposure Control	- - - - -	1-4
Technique Factors	- - - - -	1-4
Communication Watchdog	- - - - -	1-4
Exposure Indications	- - - - -	1-4
Radiation Shielding	- - - - -	1-4
Audible Indication	- - - - -	1-4
Norland Components	- - - - -	1-5
Scanner Unit	- - - - -	1-5
<i>Scanner Control Panel</i>	1-6
Laser Positioning Aid	- - - - -	1-6
Control/Analysis Computer	- - - - -	1-7
Accessories	- - - - -	1-8
Quality Assurance	- - - - -	1-9
Patient Comparison	- - - - -	1-10
Trend Comparison	- - - - -	1-10

Precision, Accuracy, S.D. and C.V. - - - - -	1-11
Reference Set Comparison - - - - -	1-12
Norland Report Options - - - - -	1-14
Patient Analysis Results - - - - -	1-14
Other Reports - - - - -	1-15
Software Operation - - - - -	1-16
Mouse Control - - - - -	1-16
Keyboard Equivalents to Mouse Techniques - - - - -	1-17
Entering Data - - - - -	1-17
Main Menu - - - - -	1-19
Drop-down Menus - - - - -	1-20
<i>Main Menu Bar</i>	1-21
<i>Analysis Menu Bar</i>	1-26
Software Conventions - - - - -	1-29

2 BASIC OPERATION

Patient Scanning Basics - - - - -	2-2
Attaining Precision and Accuracy in Scans - - - - -	2-2
Daily Startup/Shutdown - - - - -	2-3
System Startup - - - - -	2-3
Daily Calibrations - - - - -	2-6
<i>QA Results Interpretation</i>	2-12
System Shutdown - - - - -	2-15
System Backup - - - - -	2-16
System Backup (Volume Diskettes) - - - - -	2-17

3 INITIAL SETUP

Setting the Date & Time - - - - -	3-2
Set System Parameters - - - - -	3-2
Preferences - - - - -	3-3
Scanning - - - - -	3-5
Analysis - - - - -	3-7
Default Storage - - - - -	3-9

Reference Data	- - - - -	3-10
Service Setup	- - - - -	3-10
Printer	- - - - -	3-11
Printout Headers	- - - - -	3-12

4 SCANNING AP SPINE

AP Spine Scan Specification	- - - - -	4-2
Patient Dose	- - - - -	4-3
Operator Dose	- - - - -	4-3
Maintaining High Quality AP Spine Scans	- - - - -	4-3
Quick Reference Instructions	- - - - -	4-5
General Cautions	- - - - -	4-6
Performing AP Spine Scan	- - - - -	4-7
Scanner Preparation (New Patient)	- - - - -	4-7
Scanner Preparation (Existing Patient)	- - - - -	4-8
Patient Positioning	- - - - -	4-10
Scan Procedure	- - - - -	4-11
Analysis	- - - - -	4-15
Results	- - - - -	4-18
<i>Fracture Risk Assessment</i>	4-20

5 SCANNING HIP

Hip Scan Specification	- - - - -	5-2
Patient Dose	- - - - -	5-3
Operator Dose	- - - - -	5-3
Maintaining High Quality Hip Scans	- - - - -	5-4
Quick Reference Instructions	- - - - -	5-6
General Cautions	- - - - -	5-7
Performing Hip Scan	- - - - -	5-8
Scanner Preparation (New Patient)	- - - - -	5-8
Scanner Preparation (Existing Patient)	- - - - -	5-9
Patient Positioning	- - - - -	5-11

Scan Procedure	5-14
<i>Modify Regions</i>	5-23
Results	5-25
<i>Fracture Risk Assessment</i>	5-27

6 ADDITIONAL TECHNIQUES

Printing Options	6-2
Printing from the Analysis Menu	6-2
Printing from the Main Menu	6-2
Start / Stop Printing Queue	6-3
<i>Start Print Queue</i>	6-3
<i>Stop Print Queue</i>	6-3
<i>Cancel Remaining Copies</i>	6-3
Patient Personal Data	6-4
Contrast Scaling	6-6
Composition Mode	6-7
Scaling Mode	6-8
Special Region Cursors	6-9
Number of Special Regions Permitted	6-9
Add a Special Region	6-9
Modify Existing Special Region	6-10
Delete A Special Region	6-11
Rename A Special Region	6-11
Include/Exclude	6-12
Exclude	6-12
Include	6-13
Ruler Tool	6-15
Reanalyzing Scan Data	6-16
Comparison Image	6-18
Analyzing Saved Scan Data	6-19
Special Techniques	6-19
AP Spine Analysis Options	6-19
<i>Angulated Cursors</i>	6-20
AP Spine Scanning Options	6-21

<i>Change Parameters</i>	6-21
<i>Auto Centering Mode</i>	6-21
<i>Force Mark Points On-Axis</i>	6-23
<i>AP Spine Scan Progress Screen Options</i>	6-24
Hip Analysis Options - - - - -	6-26
Hip Scanning Options - - - - -	6-27
<i>Change Parameters</i>	6-27
<i>Scout Scan Progress Screen Options</i>	6-28

7 GENERAL MAINTENANCE

Routine Maintenance - - - - -	7-2
Cleaning Scanner Exterior - - - - -	7-2
Cleaning QC Phantom - - - - -	7-2
Cleaning Patient Pad Cover - - - - -	7-2
Cleaning Positioning Aids - - - - -	7-2
Replacing Exam Paper - - - - -	7-2
Computer - - - - -	7-3
Printer - - - - -	7-3
Optimizing Patient Database File - - - - -	7-3
Checking the Norland File Structure - - - - -	7-3
<i>Check Hard Drive</i>	7-3
<i>Check Diskettes</i>	7-3
Corrective Procedures - - - - -	7-4
Performing Multiple QC Scans - - - - -	7-4
Emptying Print Queue - - - - -	7-5
File Management - - - - -	7-6
Disk Status Check - - - - -	7-6
Moving Scan Data Files - - - - -	7-6
<i>Move a Scan</i>	7-7
<i>Move All Scans</i>	7-7
Copying Scan Data Files - - - - -	7-8
<i>Copy Specific Scan Data File</i>	7-8
<i>Copy All Scan Files from Selected Patient</i>	7-9
Retrieving Copied Scan Data Files - - - - -	7-9
<i>Retrieving a Single Copied Scan</i>	7-9
<i>Retrieving All Copied Scans for Selected Patient</i>	7-10
<i>Retrieving All Copied Scans from Diskette</i>	7-10
Deleting Files - - - - -	7-11

Deleting Patient File	7-11
Delete Scan Data File	7-11
Formatting Diskettes - - - - -	7-12
Duplicating Copy or Volume Diskettes - - - - -	7-12
Reference Set Maintenance - - - - -	7-13
Create Reference Set - - - - -	7-13

8 TROUBLESHOOTING

Startup - - - - -	8-2
Scanner Operation - - - - -	8-3
Software Operation - - - - -	8-3
Calibration - - - - -	8-5
Printer - - - - -	8-6
Reference/Trend Chart Display - - - - -	8-7
Items Which Could Fail Within the Warranty Period - - - - -	8-9

9 TECHNICAL REFERENCE

Norland Bone Densitometer Specifications - - - - -	9-2
Technical Description - - - - -	9-4
Scanner Labels - - - - -	9-11

INDEX

Caution:
Federal law restricts this device to sale by
or on the order of a physician

INTRODUCTION

Congratulations on purchasing the Norland DXA Bone Densitometer. Expect the Norland DXA Bone Densitometer to be a valuable aid to the physician in the estimation of bone density, the assessment of fracture risk and trend analysis of patient bone density.

Indications for Use

The Norland DXA Bone Densitometer is a prescription device used to perform non-invasive estimates of bone mineral density (BMD).

Contraindications



Do not perform a x-ray bone density scan on a pregnant subject. X-rays may be harmful to developing fetuses.

An Norland system bone density study should not be performed within 10 half-lives of a radionuclide uptake procedure. The system detectors may misinterpret residual emissions from recent radionuclide uptake procedures as energy generated by the Norland x-ray source.

Scanning patients with prosthetic devices, implants, or other sub-dermal metallic objects could result in extreme density measurements from such items. Some examples are hip prosthetics, pins, or staples.

Scanning patients with external opaque (metal and plastic) objects. Jewelry, buttons, zippers, rivets, buckles, pens, keys etc. can affect the results if they are in the scanning region.

X-Ray Device Registration



The Norland Bone Densitometer is an x-ray device that emits small amounts of radiation to acquire bone density information. Although the dose is very small, some countries and all states in the United States require registration of such devices, regardless of dose. It is the purchaser's responsibility to contact the government agency responsible to comply with any specific information concerning device registration and operation for the area in which the system is to be operated.

ISO 13485 Certified

Norland is proud to be ISO-13485 Certified and dedicated to providing a quality product, on time delivery, and exceptional customer service.

Customer Service

All requests for replacement parts, service or product related information should be directed to one of the following worldwide locations. To help the Norland representatives provide prompt and efficient service, please have the serial number of the instrument available. The Technical Reference contains information for the location of the serial number.

Norland, A CooperSurgical Co.

95 Corporate Drive

Trumbull, CT 06611 USA

Phone 800-645-3760

Europe/Middle East/India/Africa

7 Kingsmill Road

Basingstoke, Hampshire RG21 3JJ, UK

Phone 44 1 256 324433

Fax 44 1 256 359217

North America / Latin America

W6340 Hackbarth Rd.

Fort Atkinson, WI 53538 USA

Toll Free 800-444-8456

Phone 920-563-9504

Fax 920-568-4216

Asia / Pacific Rim

#82 Jalan Lokam

Singapore 537 907

Phone 65 738 9942

Fax 65 738 9945

About This Manual

This manual was originally drafted, approved, and supplied in the English language. A copy of this document can be obtained by contacting Norland, A CooperSurgical Company.

This manual contains information and operating procedures for bone densitometry acquisition and analysis using the Norland DXA Bone Densitometer. The operator should become familiar with the Operator's Guide prior to patient scanning.

The original software diskettes are located in the back of this manual. Store software diskettes in a safe place. Software updates are provided free of charge under initial warranty (12 month period after date of installation) and in conjunction with extended warranty contracts. Installation instructions will accompany any software upgrade.

Chapter 1 discusses some of the features of the Norland DXA Bone Densitometer. Information on radiation safety and some of the software conventions will also be found in Chapter 1. Additional information on radiation safety is found in the Technical Reference.

Chapter 2 discusses the basic operation of the system as well as detailed information on daily startup/shutdown. The QA procedure is detailed as well.

Chapter 3 contains the information for initial setup. There are several options available, but the most commonly used features are set as defaults.

Chapters 4 & 5 discuss scanning the AP Spine and Hip. Patient positioning, operational considerations and some hints for maintaining precision and accuracy are discussed. All other scan procedures are located in the back of this manual.

Some additional techniques for imaging, reanalyzing and other options can be found in Chapter 6.

Chapter 7 contains maintenance information. This typically involves basic cleaning and operational checks. Patient file management (part of Disk Utilities) is also detailed in this chapter.

Chapter 8 contains basic troubleshooting procedures to assist the operator.

Chapter 9 contains a Technical Reference guide. Equipment specifications and other regulatory information will be found in this chapter.

The Index is included at the end of the Operator's Guide.



Indicates information, general caution or possible safety hazard.



Indicates radiation from laser apparatus.

GENERAL INFORMATION 1

The Norland DXA Bone Densitometer uses a technique known as Dual Energy X-Ray Absorptiometry (DXA) to perform non-invasive estimates of bone mineral density (BMD) in specific regions of the body. The bone density estimates from the Norland DXA system can be used to aid the physician in diagnosing and managing osteoporosis, as well as an aid in assessing risk of fracture.

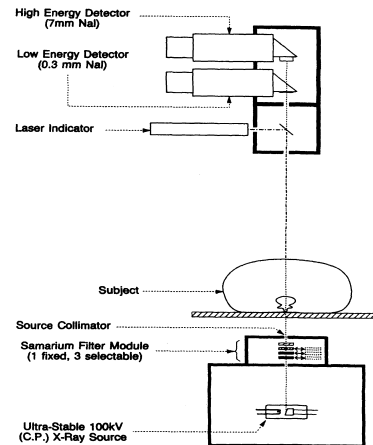
Information on radiation safety and some of the operational characteristics of the Norland system are on the following pages.

Radiation Safety Precautions

Radiation safety is an important consideration whenever working with x-ray devices. The Norland system emits very little radiation to the patient or scatter radiation to the operator, however certain precautions should be followed to ensure a safe environment for operators and patients.

Stay Out of the Beam

The Norland unit produces a narrow x-ray beam, which cannot be seen or felt, that passes from the x-ray source in the table through the scan subject to the detectors in the scanner arm. Although the Norland x-ray system produces a much lower powered beam in comparison to more traditional x-ray devices, do not expose any part of your body to it unnecessarily. Refer to Figure 9-1 of the Technical Reference Chapter for possible x-ray beam locations.



Avoid Scatter Radiation

As the beam passes through the patient, some of it is scattered in all directions. This scatter radiation is specified to be less than 0.1 mRem per hour three feet from the beam, and is only present when x-rays are being emitted, such as during the scan. Although this amount of scatter radiation is relatively low, minimize exposure wherever possible. Operators should position themselves three (or more) feet from the scanner whenever the x-ray beam is present.

State Requirements

All states (of the US) have regulations for x-ray devices that apply to the owners of bone densitometers. You are strongly encouraged to contact your state's department of Radiation Control for details.

Control General Access

Whenever possible, the scanner should be placed in a controlled environment that is not accessible by the public. In general, if this is not possible, keep the public at least six feet from the beam during the scan process. State regulations may vary therefore it is important to comply with the specific regulation in your state.



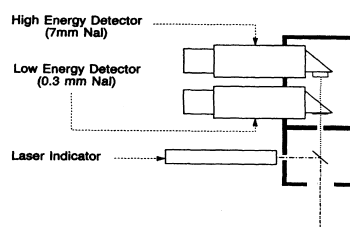
CAUTION: For patient and user safety, position the back of the scanner (open area under the tabletop) within a few inches of the wall to prevent unauthorized access to the interior of the device.

Scanner Features

Some of the innovative features used in the Norland system are described in the following sections.

Dual Energy X-Ray Absorptiometry

Dual Energy X-Ray Absorptiometry (DXA) is a method of estimating bone mineral utilizing a pencil beam x-ray beam filtered to provide the two distinct energy peaks necessary to distinguish bone from soft tissue. Dual NaI scintillation crystals are used to separately detect the two x-ray energies.



The technique for separating x-ray output into two distinct energy levels is known as K-edge filtration. In K-edge filtering, a rare earth element is placed in the beam path and x-rays are sharply attenuated at energy levels particular to that element. Norland uses samarium as the filter material because it produces energy peaks at 46.8keV and 80keV, which have proven to be most effective at differentiating between soft tissue and bone tissue.

Dynamic Filtering

Norland has developed a method of optimizing the photon count rate for varying patient thickness by automatically selecting the proper samarium filter combination. This filter selection feature prevents starvation or saturation of the detector assembly.

QuikScan™ Technology

All Norland central DXA bone densitometers incorporate our exclusive QuikScan™ technology. QuikScan™ technology incorporates a combination of mechanical, hardware, and software improvements that have resulted in a reduced patient dose and scan time, while maintaining optimum precision and accuracy.

Radiation Safety Features

Exposure Control

The exposure is controlled solely by the operator. The operator must activate the Start Scan command when technique factors are displayed to initiate the exposure.

The exposure can be terminated by the operator at any time by clicking the Stop Scan box on the computer screen, or by pressing the HALT button on the Scanner Control Panel.(See Figure 1-2)

Technique Factors

The Technique Factors (Loading Factors) are the operating parameters that determine the radiation exposure to the patient. The parameters (tube voltage, tube current, and exposure time), are fixed, highly regulated, and not subject to line conditions. The operator does not adjust or control the technique factors.

Communication Watchdog

The Norland scanner includes a 'watchdog' circuit which monitors data collection communication during the scan. If communication fails, the exposure is terminated.

Exposure Indications

The green READY indicator on the Scanner Control Panel (See Figure 1-2) illuminates to indicate that the x-ray source is energized.

The yellow X-RAY indicator, located on the Scanner Control Panel, is illuminated only when the beam shutter is open and the x-ray source is energized. The X-RAY indicator extinguishes after the end of a scan when the beam shutter has closed and the beam is not present. To prevent inadvertent x-ray exposure, the x-ray source will be disabled if the indicator malfunctions.

Radiation Shielding

System leakage and scatter radiation levels are very low and special shielding is not required. Room shielding is not necessary and the operator does not have to be behind a barrier during the scan. At the typical distance of 3 feet from the beam, the radiation level is <0.1 mRem/hour. Norland recommends that operators position themselves at least three feet from the beam during the scan or as indicated by local state x-ray regulations.

Audible Indication

An audible "beep" indicates the end of each scan.

Norland Components

The Norland Bone Densitometer consists of a Scanner Unit and a Control/Analysis Computer with a color printer.

Scanner Unit

The Scanner Unit is a specially constructed table that accommodates the patient in a supine position. The easily removable patient pad is cushioned and upholstered with a highly durable wool fabric. A fixture for a roll of standard exam paper is located at the head end (right side when facing front of scanner unit) of the patient table. Fixtures are provided for special positioning of the patient during spine, hip, lateral, and forearm procedures.

The radiation source is an x-ray tube with heavy K-edge filtering. The x-ray tube is mounted within a lead-shielded chamber, which has an electrically operated shutter across the beam exit path. The beam is aligned with the detector assembly in the scanner arm. The x-ray source is specially designed for densitometry and has a low operating temperature and long life.

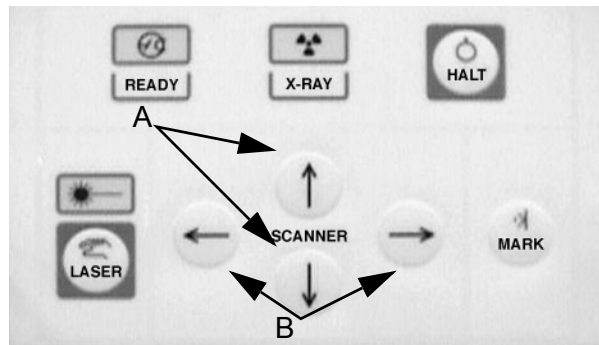
FIGURE 1-1



Scanner Control Panel

The Scanner Arm contains the Scanner Control Panel (Figure 1-2). The operator uses the buttons on this panel to position the scanner arm directly over anatomical landmarks to define the desired scan area. The up and down buttons (A) move the x-ray source/detector assembly in the X-axis (or across the patient table, front to back). The left and right (B) arrows move the scanner arm along the plane of the patient table (Y-axis). The MARK button is used to identify scan coordinates for scanning patients and phantoms. The READY and X-RAY indicators and the HALT button are discussed on page 1-4.

FIGURE 1-2



Laser Positioning Aid

A low-power laser located in the scanner arm indicates the exact position of the x-ray beam. The laser beam is aligned with the narrow x-ray beam in the table and serves as an aid in marking or defining anatomical landmarks. The laser is controlled by the button on the Scanner Control Panel. When the laser is on, the indicator above the button is illuminated.



Although it is a low-power laser, the following precautions should be noted:

- **Do not stare into the beam.**
- **Do not allow the laser to shine into your eyes. If the laser light does briefly shine into your eyes, it may startle you, but will not cause immediate damage.**
- **Do not allow shiny objects to reflect laser light into your eyes.**

Control/Analysis Computer

The Norland Bone Densitometer is controlled by a desktop PC (or optional laptop). Either computer is designed and configured for operation of the Norland system and should not be used for any other purpose. The computer is certified as an X-Ray Controller at Norland's manufacturing facility. Menu driven operation for system calibrations, scan data collection, scan analysis and patient file management are features of the Norland software. A 'mouse' pointing device provides easy program operation. Other features are:

- High volume internal tape backup system (desktop PC only)
- Color display monitor with full graphics capability
- Color printer for hard copy reports

Accessories

The Norland system comes complete with a 77-step Calibration Standard and a QC Phantom for establishing a Quality Assurance Program.

Calibration Standard

The 77-step Calibration Standard is an exclusive combination of layered plastic and metal material used for system calibration. It is equipped with handles and labeled with characterization values established at the factory.

QC Phantom

The anatomically correct QC Phantom provides an accurate representation of the human spine bone density and soft tissue distribution. Each phantom (unique for each system) has a serial number and includes a label listing the assigned Bone Mineral Density (BMD), Bone Mineral Content (BMC), and BMD Standard Deviation (BMD SD) values as determined by factory characterization. Depending on your options, the phantom may also include Fat, Fat SD, Lean, and Lean SD values. Refer to Cleaning QC Phantom on page 7-2 for special instructions.

Patient Positioning Aids

Hip Sling (433A134)	Used to orient the patient's legs in a position best suited for accurate and precise hip scans.
Leg Separator Block (388D550)	Used with hip sling to achieve proper abduction.
Leg Rest Block (433D132)	Used to raise the legs to straighten the spine.
Forearm Positioning Fixture (433A211) *	Used to position patient's forearm. Includes the elbow and hand pads.
Lateral Positioning Blocks (388A568) *	Used to properly position the patient's body for a lateral scan. Includes the rib cage support, back rest block, limb blocks, and head support pillow.

* These aids may or may not be included depending on your options.

Exam Paper

A 21" W x 125' L x 1 5/8" (ID) roll of examination paper (4799301) is supplied for maintaining proper hygiene of the patient scan surface.

Quality Assurance



Norland equipment is configured to assist facilities in establishing an effective Quality Assurance Program.

Precision and accuracy of bone mineral density assessments are dependent on an effective Quality Assurance Program.

Norland strongly recommends performing patient scans on the Norland system only after successful completion of the daily Quality Assurance calibration. The calibration compensates for spectral shifts in the x-ray source, slight differences in the interface circuitry and other factors.

The daily calibration procedure consists of:

- scanner stabilization
- diagnostic tests
- a scan of the Calibration Standard
- and a scan of the QC Phantom

Once the calibration routine is initiated, it proceeds automatically until all data is collected and the results of scans of the Calibration Standard and the QC Phantom are displayed.

- QA results should be printed and kept in a log for quick reference.
- Norland software will automatically display a "QA PROCEDURE OVERDUE" message when more than 24 hours has elapsed since the last calibration.
- After seven days the following message will be displayed if **[Cancel]** is selected on the "QA Procedure Overdue" screen: "It has been XX days since your last calibration. Norland strongly recommends performing a daily calibration before scanning patients."
- It is not necessary to calibrate the system on a day that the Norland Bone Densitometer will not be used to scan patients.

Patient Comparison

Patient results are compared to reference populations or to previous scans for comparisons for diagnosis. Much has been written on the use of bone mineral analysis techniques.^{1 2 3}

Trend Comparison

Assessment of the rate of change in bone mineral density provides the clinician with the best information regarding whether the patient is losing or gaining bone mineral. If previous assessments have been made of the patient, the current assessment may be compared with past scans to determine the rate of change.

Statistical reasoning is required to interpret scan results. Differences in two serial assessments of a patient that are close in value could simply be due to random variation. In order to have 95% confidence ($p < 0.05$) that a change in value represents a change in actual BMD, the change must be at least:

$$2\sqrt{2} \times \frac{C.V.}{100} \times BMD \text{ value}$$

The above equation would be valid for two scans of the same anatomical site on one patient from the same Norland unit. The Coefficients of Variation (C.V.) furnished for each measurement type are valid for subjects having well defined bones and non-calcified soft tissue. The following table shows an example of the above equation using manufacturer C.V. values.

AP Spine Change	Femoral Neck Change
C.V. of 0.9% ^a	C.V. of 1.4% ^b
If the first value is 1.0 g/cm ² then change must be 0.025g/cm ² .	If the first value is 1.0 g/cm ² then change must be 0.039 g/cm ² .

a. As specified on page 4-2.

b. As specified on page 5-2.

NOTE: C.V.'s for individual facilities may be different from manufacturer specified C.V.'s, depending on operator technique and experience.

1. Ross, P. D., Davis, J. W. Vogel, J. M., and Wasnich, R. D.: "A Critical Review of Bone Mass and the Risk of Fractures in Osteoporosis". Calcified Tissue International 46:149-161, 1990.
2. Melton III, J. L., Eddy, D. M., Johnson Jr., C. C.: "Screening for Osteoporosis". Annals of Internal Medicine. 112:516-528, 1990.
3. "Assessment of Fracture Risk and its Application for Postmenopausal Osteoporosis", WHO Technical Reports Series, No. 843.

Precision, Accuracy, S.D. and C.V.

Precision - is the degree to which the same value is obtained when a measurement is repeated. *In vivo* precision in the Norland Bone Densitometer is the degree to which the device presents the same bone mineral value when a measurement is repeated at the same anatomical site on the same subject.

Factors affecting precision are:

- **inherent instrumentation errors**
- **operator technique**
- **the *in vivo* nature of the measurement**

All precision specifications given in this guide and on the Norland outputs assume:

- **a properly operating instrument**
- **a stationary scan subject**
- **an experienced operator**
- **proper and consistent positioning and analysis techniques**

Precision can be improved by averaging a number of repeated measurements. Then the precision of the mean value is improved by a factor of the square root of the number of measurements. This technique is used with phantoms for evaluating instrument accuracy.

Accuracy - is the degree to which a measurement value reproduces the actual value of the quantity being measured.

Although the accuracy of a single measurement includes the imprecision of that measurement, it is customary to specify instrumental accuracy with the imprecision effect removed. This is called "accuracy of the mean" because taking the mean or average of many measurements minimizes the imprecision. The accuracy specifications for the Norland Bone Densitometer are stated in terms of accuracy of the mean.

Several manufacturers have adopted phantoms fabricated of calcium hydroxyapatite and epoxy. The calibration of each Norland instrument is based on hydroxyapatite phantoms constructed to specifications described by White (White, D. R., Martin, R.J., and Darlinson, R.: "Epoxy resin based tissue substitutes." Brit. J. Radiol. 50, 814-821, 1977).

Standard deviation (S.D.) - is used to specify precision. In a normal (or bell-curve) distribution, 68% of all the estimations lie within one standard deviation of the mean, and 95% of all measurements lie within two standard deviations of the mean.

Coefficient of variation (C.V.) - is used to specify precision, it is the standard deviation expressed as a percent of the measured quantity. The coefficient of variation is the standard deviation divided by the mean.

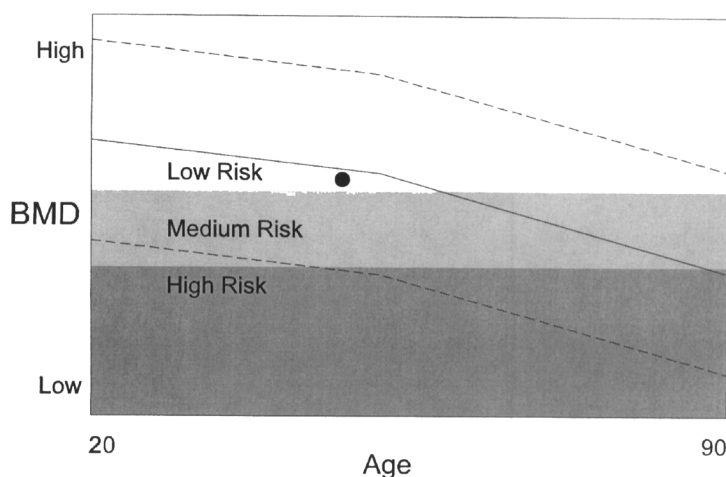
Reference Set Comparison

The patient's Bone Mineral Density (BMD) estimate can be compared to a reference population that is clinically free of bone disease and matches the patient's gender, ethnic background, and age. This variance of the patient's BMD value relative to the mean of the reference population is graphed and expressed as a standard deviation. Norland software contains many reference sets for comparisons and facilities can create reference sets based on local populations.

Reference Set upgrades are provided free of charge and are usually distributed as they become available.

Reference sets are displayed as a chart containing the average BMD value of the reference population for the prescribed anatomy. Many reference charts are color coded to assist with Fracture Risk Assessment. A sample chart is displayed below.

The middle line represents the average value for BMD for the ages included in the chart. The dashed lines above and below the middle line are (+2) and (-2) standard deviations from the mean value.



Norland incorporates the WHO (World Health Organization) criteria (see table below) in plotting a patient's fracture risk assessment.

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.

Norland Report Options

Patient Analysis Results

Quantities of bone mass are reported as Bone Mineral Density (BMD), Bone Mineral Content (BMC), and Area. The BMD is the bone mineral content value divided by the bone area value, in grams per square centimeter, which is defined as the total amount of bone determined by absorptiometry, and Area.

Optional Whole Body scans display the lean and fat composition of the soft tissue, which is presented in grams. Total body fat percent and underwater weighing equivalents are also displayed.

These quantities are displayed in numeric terms with the BMD also plotted on reference and trend charts. Analysis results include image displays, graphical displays and numeric information and are typically printed as a two page report. The report can be customized to print only the first page.

- Sample reports can be found at the end of this chapter.

Results Page 1 - Results Page 1 report contains basic patient and scan data. It includes an image of the scanned region, reference and/or trend information for the measured region(s), and basic scan conditions. The printed Results Page 1 report includes a customized header and reflects specific operator-entered comments.

Results Page 2 - Results Page 2 report contains all the patient personal data and detailed scan information, such as scan speed and resolution, detailed numeric results for the region(s) scanned, reference and trending charts and information, and more. The printed Results Page 2 report also includes a customized header.

Other Reports

Other report formats include:

QA Report - Daily QA Calibration results are printed and should be filed in a calibration log. (See Daily Calibrations on page 2-6)

sBMD Report - The Committee for Standards in DXA instituted correlation equations for AP Spine (1995) and Hip (1997). sBMD (standard Bone Mineral Density) values provide the physician with T- and Z-score results of hip and spine scans that are derived from accepted reference data sets, including NHANES III. The sBMD values are reported in mg/cm² for the region of interest. The sBMD report can be printed with the Patient Detailed Results reports. More detail about this topic may be found in the data sheets that accompany the Norland Reference Sets.

Scan History Report - The Norland Scan History report may be generated for those patients who have more than one scan of the same type. The Scan History report is a summary of measurement changes that occurred between scans of the same type and anatomical region performed on the same subject. It can be printed in addition to the 1 or 2 Page Detailed Results printout and consists of the currently-selected printout header, the patient's name, ID, gender, age, ethnic background, and one tabulated chart for each region of interest.

Software Operation

Norland Bone Densitometry devices are controlled by menu driven software. All Norland program actions are initiated by moving an arrow-shaped pointer to executable commands, usually with a mouse (keyboard pointer control is also available).

Mouse Control

The mouse does not need a special pad or grid, just a few inches of clear desk space. If you run out of space to move the mouse, simply pick it up and set it down in the center of a cleared area. The pointer can only move when the mouse is in contact with the desk surface.

It is best to hold the mouse in a relaxed manner, with your thumb and little finger at either side of the mouse. Use a light touch. Rest your wrist naturally on the desk surface and let your hand pivot from the wrist to move the mouse. The faster you move the mouse, the faster the pointer moves.

The buttons on the mouse device are used to tell the program when an operation or procedure is desired. Most mouse devices have at least two control buttons, but only the left button is active in Norland software.









Mouse Techniques

Technique	Action	Function in Norland
Click	Press & release left button once.	left mouse click selects and/or initiates a menu function
Double-Click	Press & release left button twice quickly.	double-click will step to the next logical place in the program without having to select and click on Menu functions
Click & Drag	Press and hold left button. Move mouse. Release left button.	used to size regions of interest and position cursors

Keyboard Equivalents to Mouse Techniques



If the mouse is connected to the computer, it will become the principal device for executing commands. If a mouse is temporarily unavailable, it is a simple matter to use the computer keyboard to simulate the mouse commands. Once system software is started, Norland software provides keyboard equivalents to mouse techniques.

Keyboard Equivalents for Mouse





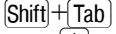






Technique	Keyboard Key	
Click		Press the HOME key once.
Double-Click	 	Press and release the HOME key twice, quickly.
Click & Drag	    	Press and release the END key. Use the cursor arrow keys to move pointer where desired. When finished dragging, press and release HOME key.

Entering Data

The menu driven nature of the software requires little keyboard use, however, the keyboard remains the principal method of entering patient personal data, scan comments, and similar information. As data is entered into fields, it is checked by Norland software for appropriate data type. If an inappropriate entry is attempted, such as a letter within a date field, the operator must correct the error before other fields can be edited.

To enter information in any field displayed on an Norland screen, position the pointer in the desired field and click. A narrow vertical line appears just to the left of any information present in that field. Use any character or symbol found on the keyboard to enter data into the Norland program. Click on a new field for data entry or press the keyboard's  or  key to move to the next field.

Data Screen Navigation

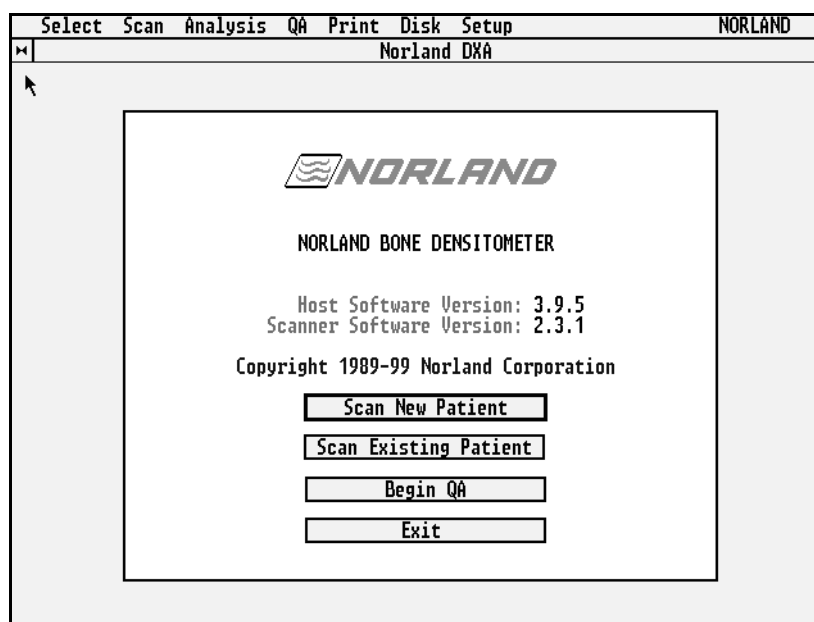
Keyboard	Numeric Keypad	Action
	4	Moves the text cursor one character left without deleting
	6	Moves the text cursor one character right without deleting
 or 	2	Moves the text cursor to the next field
 or 	8	Moves the text cursor to the previous field
	N/A	Deletes the character to the right of the text cursor
	N/A	Deletes the character to the left of the text cursor
	N/A	Erases all characters in field where the text cursor is located
	N/A	Moves text entry cursor to next line in a field or to next field or selects the default button in 'non-editable' screens
	N/A	Saves all data entry and advances the Norland program to the next operation

Main Menu

When the software is initiated (double-clicking the **NORLAND** icon on the desktop), the Main Menu is displayed. Shortcuts for the most common functions, like scanning patients and QA Calibrations, are listed in the center of the screen (see Figure 1-3). Along the top of the Main Menu is the *Main Menu Bar*. These items are titles of drop-down menus that contain commands to perform functions in the system software. An additional menu bar is displayed when one of the Analysis options is selected. That menu bar will be referred to as the *Analysis Menu Bar*. Throughout this manual, menu bar titles are typically referred to as **items**.

In the upper left corner of the screen (below and left of **Select**), the "bowtie" icon will page back to the previous screen until, at the Main Menu, it exits system software and restarts Windows. The "NORLAND" in the Menu Bar, when selected by the cursor, will show a drop-down menu that includes "About NORLAND". This command will display information on the system and any enabled options.

FIGURE 1-3 Main Menu



Scan New Patient	initiates addition of new patient and starts scan sequence
Scan Existing Patient	initiates patient selection and starts scan sequence
Begin QA	initiates QA procedure
Exit	exits the host software

Drop-down Menus

When you select one of the *Main Menu* or *Analysis Menu* items, a sub-menu 'drops' down.

Menu commands that are grayed out are due to one of the following:

- The option is not valid for the current operation.
- The option is already in effect.

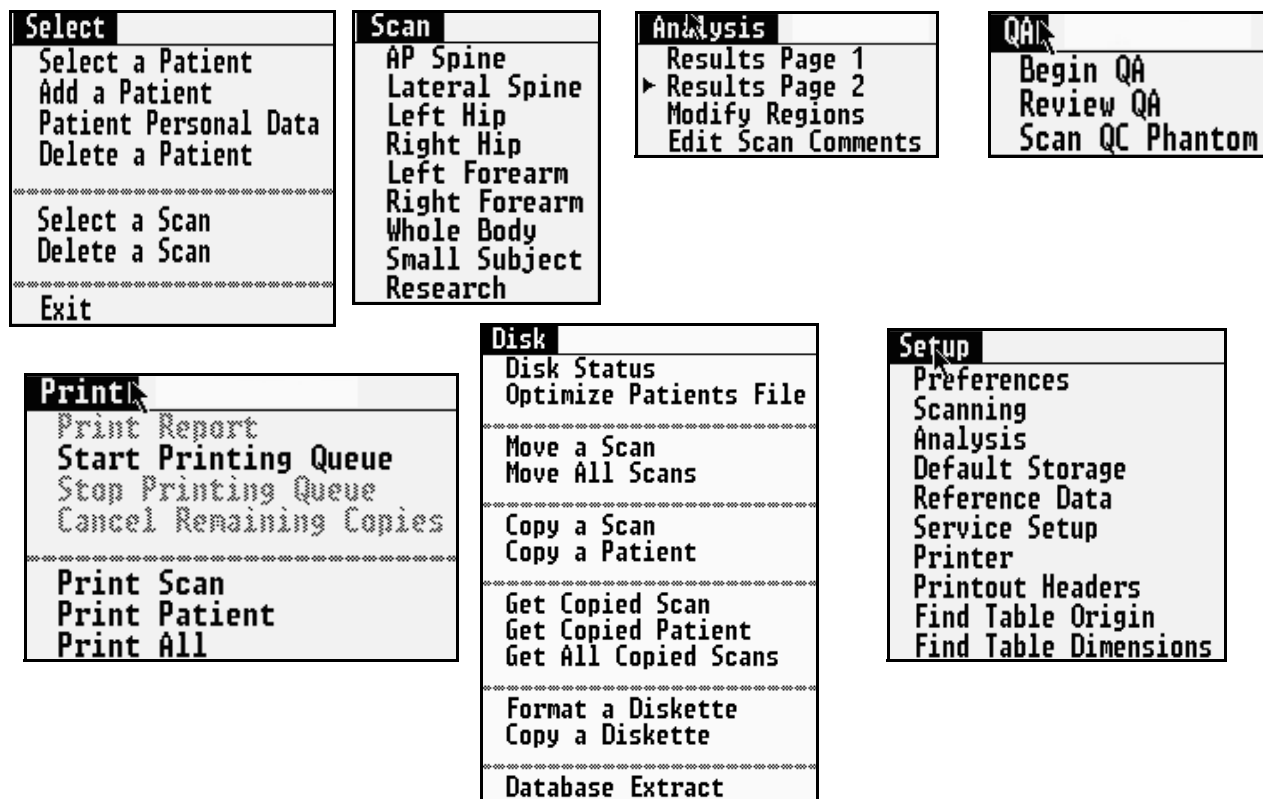
In addition to appearing in a diffused print, a pointer will be displayed to the left of the command in effect.

To choose a command, move the pointer on top of one of the menu bar titles. While the sub-menu is visible, move the pointer to the desired command. The commands will change to reverse print (black letters against a white background) as the pointer moves over them. Click when the desired command is reversed to activate.

To clear a drop-down menu from the screen, move the pointer out of the drop-down menu area and press the left mouse button. The drop down menu will close. Brief descriptions of the *Main Menu* and *Analysis Menu* drop-down menus are on the following pages.

Main Menu Bar

FIGURE 1-4 Main Menu Items

*Select*

Sub-menu item	action
Select a Patient	displays list of patients in database to allow selection of one
Add a Patient	displays extensive input screen for new patient information
Patient Personal Data	displays personal data for currently selected patient
Delete a Patient	deletes currently selected patient & all patient's scans from database
Select a Scan	selects a scan data file from the currently selected patient file
Delete a Scan	deletes selected scan data file from the currently selected patient file
Exit	exits host software and restarts Windows

Scan

Sub-menu item	Action
AP Spine	prepares system for AP Spine scan data collection of currently selected patient
Lateral Spine	prepares system for Lateral Spine data collection of currently selected patient
Left/Right Hip	prepares system for Hip scan data collection of currently selected patient
Left/Right Forearm	prepares system for Forearm scan data collection of currently selected patient
Whole Body	prepares system for Whole Body scan data collection of currently selected patient

Research and Small Subject scans are available as options.

Analysis

Sub-menu item	Action
Results Page 1	displays Results Page 1 of currently selected scan
Results Page 2	displays Results Page 2 of currently selected scan
Modify Regions	displays screen for modifying the regions of interest for analysis of currently selected scan
Edit Scan Comments	allows edit of Scan Comments field for currently selected scan

QA

Sub-menu item	Action
Begin QA	initiates the QA procedure; performed daily
Review QA	displays most recent QA results
Scan QC Phantom	prepares system for scan of QC Phantom independent of QA procedure

Print

Sub-menu item	Action
Print Report	opens Print Setup for immediate print of QA results
Start Printing Queue	prints contents of print queue
Stop Printing Queue	cancel queue print job
Cancel Remaining Copies	cancels print of remaining copies of currently printing report
Print Scan	prints currently selected scan
Print Patient	prints all scans for current patient
Print All	prints all scans on files specified by operator

Disk

Sub-menu item	Action
Disk Status	displays disk status (disk type, storage space available, etc.)
Optimize Patients File	reorders Patient Database to improve system efficiency
Move a Scan	displays menus to move a scan data file from one disk location to another (i.e. system hard drive to diskette or vice versa)
Move All Scans	displays menus to move all scan data files from one disk location to another (i.e. system hard drive to diskette or vice versa)
Copy a Scan	displays menus to copy a scan data file from one disk location to another (i.e. system hard drive to diskette)
Copy a Patient	displays menus to copy all scan data files for a patient from one disk location to another (i.e. system hard drive to diskette)
Get Copied Scan	displays menus to retrieve previously copied scan data file from one disk location to another (i.e. diskette to system hard drive)
Get Copied Patient	displays menus to retrieve previously copied scan data files for a patient from one disk location to another (i.e. diskette to system hard drive)
Get All Copied Scans	displays menu to retrieve all previously copied scan data files from one disk location to another (i.e. diskette to system hard drive)
Format a Diskette	displays menu to format floppy diskettes
Copy a Diskette	displays menu to perform diskette to diskette copies
Database Extract	displays the user interface screen for the Xtract program

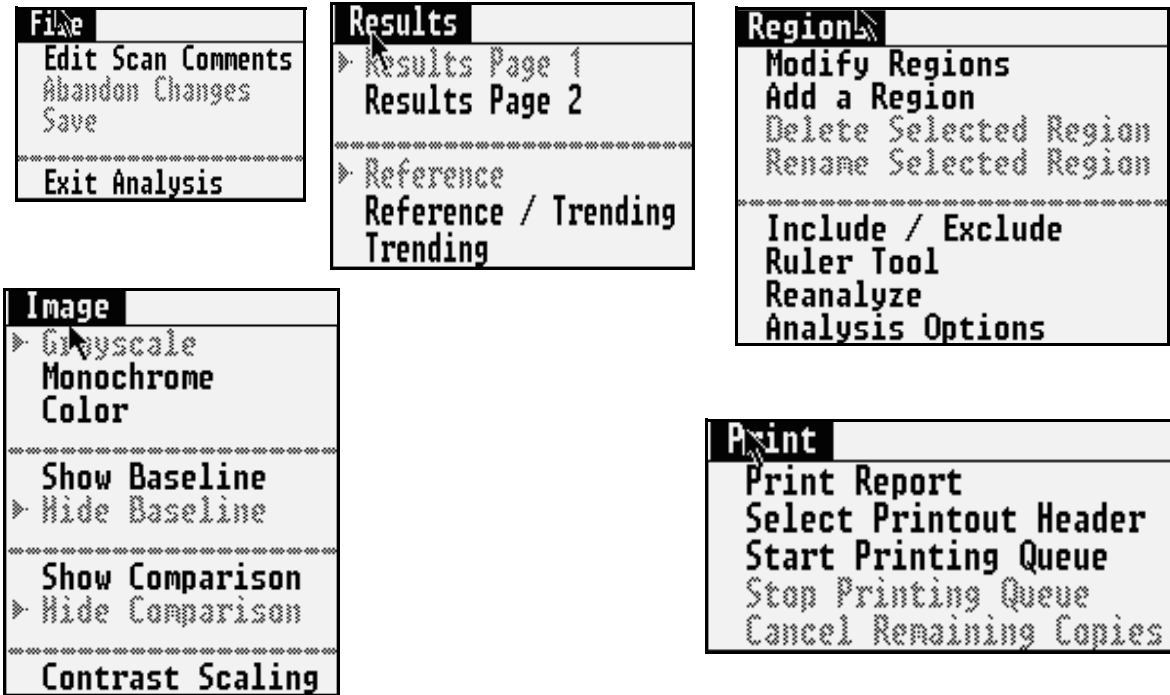
Setup

Sub-menu item	Action
Preferences	displays menu for setup of default system preferences
Scanning	displays menu for setting default scanning parameters
Analysis	displays menu for setting default analysis parameters
Default Storage	displays menu to set up default scan data storage location
Reference Data	displays a menu to create, delete, edit, add and copy reference sets
Service Setup	displays menu for input of Calibration Standard and QC Phantom characterization values (performed by Norland Customer Service Rep)
Printer	displays menu for setting default printer parameters (paper size, number of copies, etc.)
Printout Headers	displays editable list of headers for analysis report printouts
Find Table Origin	moves scanner arm to origin
Find Table Dimensions	moves scanner arm to origin position and to opposite corner to define scan area

Analysis Menu Bar

When modifying cursors or displaying a Results Page, the *Analysis Menu* bar replaces the *Main Menu* bar. Brief descriptions of the *Analysis Menu* drop-down menus are on the following pages.

FIGURE 1-5 Analysis Menu Items



File

Sub-menu item	Action
Edit Scan Comments	displays screen to add comments to Results Page 1 report
Abandon Changes	abandons any changes made to analysis
Save	saves scan data file to default storage
Exit Analysis	returns to Main Menu

Results

Sub-menu item	Action
Results Page 1	displays Results Page 1 for currently selected scan
Results Page 2	displays Results Page 2 for currently selected scan
Reference	displays matching reference chart for current scan
Reference / Trending	displays reference chart for currently selected scan if first scan; displays trend charts if not
Trending	displays trend charts for current patient if not first scan

Regions

Sub-menu item	Action
Modify Regions	switches display to REVIEW REGIONS screen to modify cursor placement
Add a Region	adds new region of interest
Delete Selected Region	deletes selected region of interest from scan
Rename Selected Region	renames selected region of interest
Include / Exclude	allows inclusion or exclusion of selected regions for analysis
Ruler Tool	enables a ruler for physical measurements
Reanalyze	reanalyzes current scan data file
Analysis Options	displays Analysis Setup screen for current scan

Image

Sub-menu item	Action
Grayscale	converts image to 33-level gray scale image; and charts in color
Monochrome	converts all displays to black & white
Color	converts image to 27 spectrum color; text and charts in color as well
Show Baseline	displays non bone data points in image in baseline color or shade (not in density spectrum)
Hide Baseline	displays all data points in image display according to density spectrum
Show Comparison	displays image from baseline patient scan to right of current image
Hide Comparison	removes comparison image from current display
Contrast Scaling	displays screen to enhance image and select alternate methods of viewing image

Print

Sub-menu item	Action
Print Report	displays Report Setup screen to print current report
Select Printout Header	displays list to select Printout Header for current scan
Start Printing Queue	starts print of files in Print Queue
Stop Printing Queue	stops current printing of Printing Queue
Cancel Remaining Copies	cancels print of remaining copies of current scan report

Software Conventions

Throughout the system software, command buttons will be used to navigate the screens. Some of the more common command buttons are detailed below.

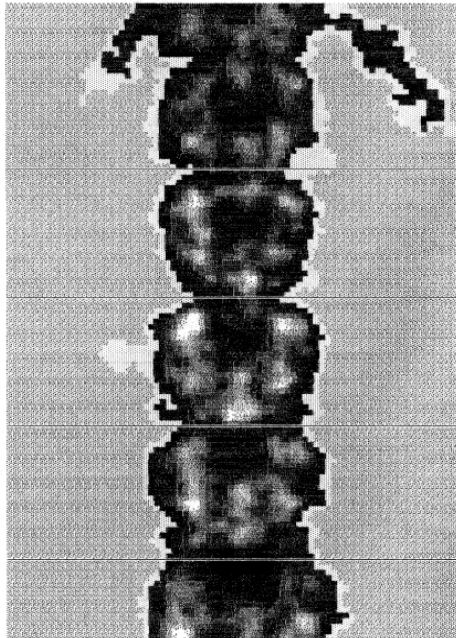
[Main Menu]	exits current screen, saves any data or changes and returns to the Main Menu
[Continue]	continues to the next screen in the program or step
[Cancel]	cancels action
[Accept Changes]	saves selected changes in an entry screen and continues to next step in program
[Restore Defaults]	abandons any user changes and returns system to default parameters
[Do Not Accept]	abandons any user changes and returns system to previously entered parameters
[Continue-Print]	saves scan data to default location, prints report as determined by print setup, and returns to the main menu
[Previous Step]	returns to the previous step

FIGURE 1-6 RESULTS PAGE 1 (AP SPINE)

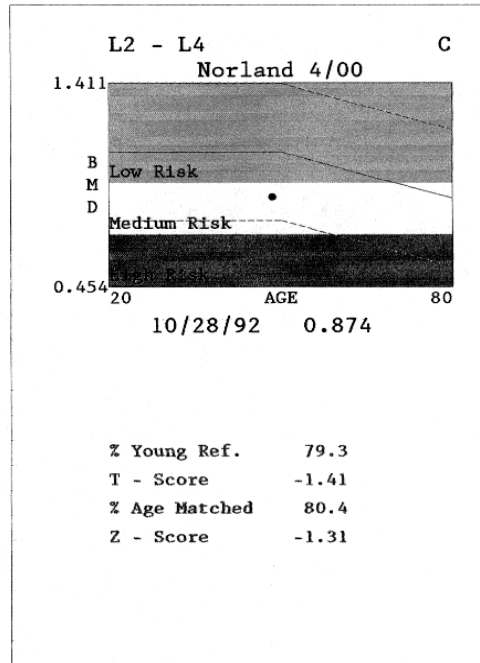
Norland Medical Systems, Inc.
 W6340 Hackbarth Road Fort Atkinson, WI 53538 920-563-8456

<i>Name</i> Doe, Janet	<i>Ethnic</i> C
<i>ID</i> 12346	<i>Height</i> 5'4"
<i>Age</i> 48	<i>Weight</i> 142
<i>Sex</i> Female	

L  H AP Spine on 10/28/92 # 1



Bone image not for diagnosis



	BMD g/cm ²	BMC g	LENGTH cm	AREA cm
L2	0.8528	11.60	3.60	13.61
L3	0.9169	13.89	3.60	15.14
L4	0.8521	13.63	3.75	16.00
L2 - L4	0.8742	39.12	10.95	44.75

STD CVs for L2-L4 BMD: 1.0 BMC: 1.5 See Guide for other CVs.
 1.5 x 1.5 mm, 60 mm/s, 12.00 cm Rev. 2.3.0/1.3.0 Calib. 10/28/92

COMMENTS

 NORLAND

FIGURE 1-7 RESULTS PAGE 2 (AP SPINE)

Norland Medical Systems, Inc.
W6340 Hackbarth Road Fort Atkinson, WI 53538 920-563-8456

<p><i>Name</i> Doe, Janet</p> <p><i>Address</i> 123 N. State New York City, NY</p> <p><i>Telephone</i> 555-3456 <i>days</i> 555-1234 <i>eves</i></p> <p><i>History</i> Fractured Radius Right Arm</p> <p><i>Treatment</i> ERT</p> <p><i>Medications</i> Vitamins, Calcium</p> <p><i>Comments</i> Family History of Osteoporosis (Mother)</p>	<p><i>ID</i> 12346</p> <p><i>Ethnic</i> C</p> <p><i>Age</i> 48</p> <p><i>Menoage</i> 3</p> <p><i>Sex</i> Female</p> <p><i>Height</i> 5'4"</p> <p><i>Weight</i> 142</p> <p><i>Armspan</i> 5'4"</p>
--	---

SCAN INFORMATION

<p><i>Type</i> AP Spine</p> <p><i>Scan Date</i> 10/28/92 1</p> <p><i>Analysis Date</i> 09/05/00</p> <p><i>Calibration Date</i> 10/28/92</p> <p><i>Technician</i> DRD</p> <p><i>Physician</i> ESC</p>	<p><i>Resolution</i> 1.5 x 1.5 mm</p> <p><i>Speed</i> 60 mm/s</p> <p><i>Width</i> 12.00 cm</p> <p><i>Host/Scanner</i> 2.3.0/1.3.0</p> <p><i>Analysis Revision</i> 3.9.5</p>
---	---

DETAILED RESULTS

	BMD g/cm ²	BMC g	AREA cm ²	LENGTH cm	WIDTH cm	LEAN MASS g	FAT MASS g
L2	0.8528	11.60	13.61	3.60	12.00		
L3	0.9169	13.89	15.14	3.60	12.00		
L4	0.8521	13.63	16.00	3.75	12.00		
L2 - L4	0.8742	39.12	44.75	10.95	12.00		

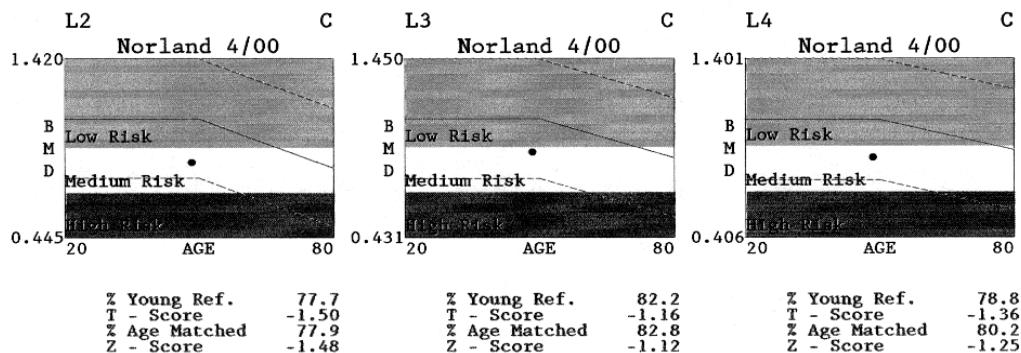
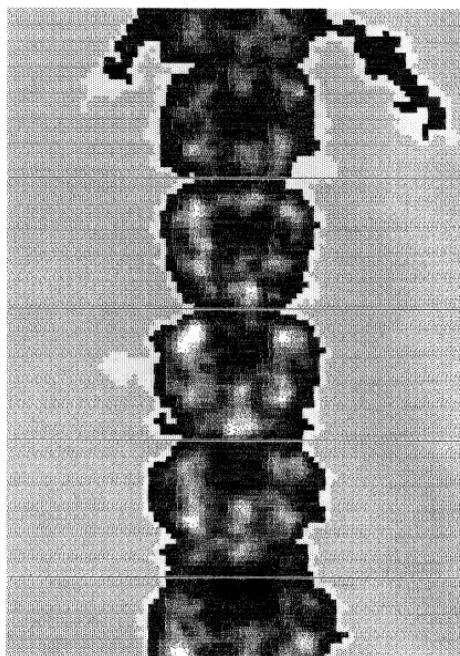


FIGURE 1-8 sBMD REPORT (AP SPINE)

Norland Medical Systems, Inc.
W6340 Hackbarth Road Fort Atkinson, WI 53538 920-563-8456

L  H



Bone image not for diagnosis

AP Spine on 10/28/92 # 1

Name: Doe, Janet

123 N. State
New York City, NY

ID: 12346

Ethnic: C Sex: Female
Birth Date: 05/10/44 Height: 5'4"
Menoage: 3 Weight: 142
Age: 48

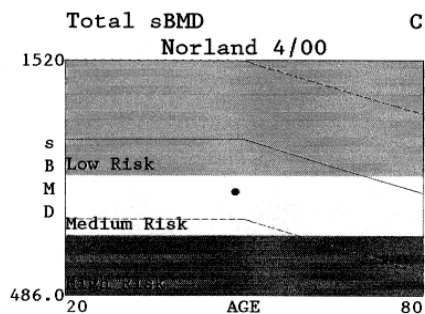
Physician: ESC
Technologist: DRD

Comments

AP Spine L2 - L4 Results

sBMD (mg/cm²) (1) = 941
Z-Score (age matched sBMD) (2) = -1.31

T-Score (relative to peak sBMD) (3) = -1.40



- (1) sBMD = Standardized Bone Mineral Density
(2) Z-Score = Standard deviations above or below age matched mean sBMD
(3) T-Score = Standard deviations above or below peak sBMD for young reference

STD CV for L2-L4 sBMD: 1.0 See Guide for other CVs.

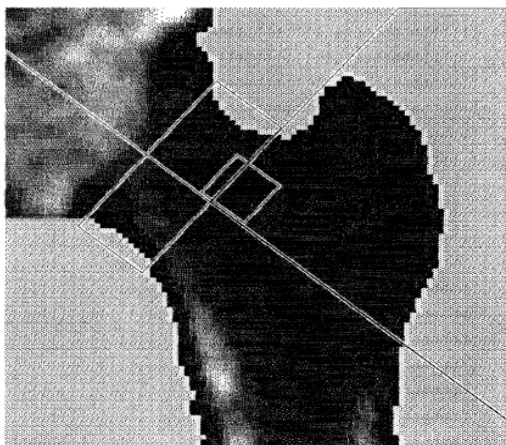
 **NORLAND**

FIGURE 1-9 RESULTS PAGE 1 (HIP)

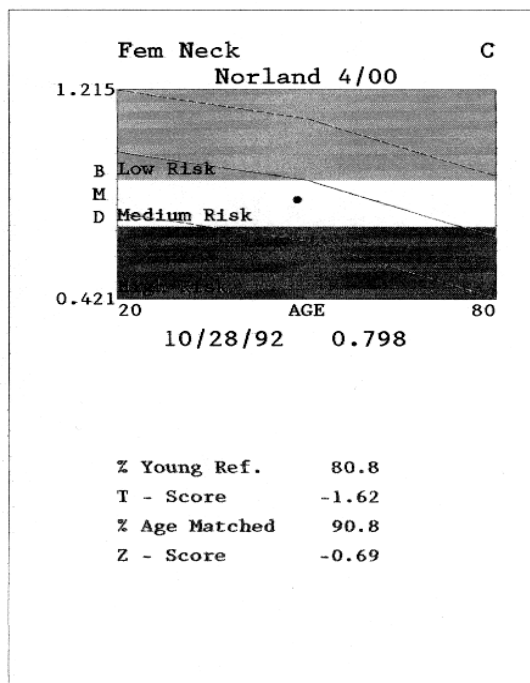
Norland Medical Systems, Inc.
 W6340 Hackbarth Road Fort Atkinson, WI 53538 920-563-8456

<i>Name</i> Doe, Jane	<i>Ethnic</i> C
<i>ID</i> 12347	<i>Height</i> 5'6"
<i>Age</i> 48	<i>Weight</i> 145
<i>Sex</i> Female	

L  H Left Hip on 10/28/92 # 1



Bone image not for diagnosis



	BMD g/cm ²	BMC g	LENGTH cm	AREA cm
Fem Neck	0.7979	3.813	1.50	4.778
Troch	0.5667	6.892		12.16
Wards Tri	0.5824	0.5824	1.00	1.000

STD CVs for Neck BMD: 1.2 BMC: 1.7 See Guide for other CVs.
 1.0 x 1.0 mm, 45 mm/s, 9.00 cm Rev. 2.3.0/1.3.0 Calib. 10/27/92

COMMENTS

 NORLAND

FIGURE 1-10 RESULTS PAGE 2 (HIP)

Norland Medical Systems, Inc.
W6340 Hackbarth Road Fort Atkinson, WI 53538 920-563-8456

<i>Name</i> Doe, Jane	<i>ID</i> 12347
<i>Address</i> 3890 Washington Street Chicago, IL 60639	<i>Ethnic</i> C
	<i>Age</i> 48
	<i>Menoage</i> 4
<i>Telephone</i> 223-555-4567 <i>days</i> 223-555-2345 <i>eves</i>	<i>Sex</i> Female
<i>History</i> No Previous Fractures	<i>Height</i> 5'6"
	<i>Weight</i> 145
<i>Treatment</i> Excercise	<i>Armspan</i>

Medications

Comments Early Hysterectomy

SCAN INFORMATION

<i>Type</i> Left Hip	<i>Resolution</i> 1.0 x 1.0 mm
<i>Scan Date</i> 10/28/92 1	<i>Speed</i> 45 mm/s
<i>Analysis Date</i> 02/25/99	<i>Width</i> 9.00 cm
<i>Calibration Date</i> 10/27/92	<i>Host/Scanner</i> 2.3.0/1.3.0
<i>Technician</i> CC	<i>Analysis Revision</i> 3.9.0
<i>Physician</i> ESC	

DETAILED RESULTS

	BMD g/cm ²	BMC g	AREA cm ²	LENGTH cm	WIDTH cm	LEAN MASS g	FAT MASS g
Fem Neck	0.7979	3.813	4.778	1.50			
Troch	0.5667	6.892	12.16				
Wards Tri	0.5824	0.5824	1.000	1.00	1.00		

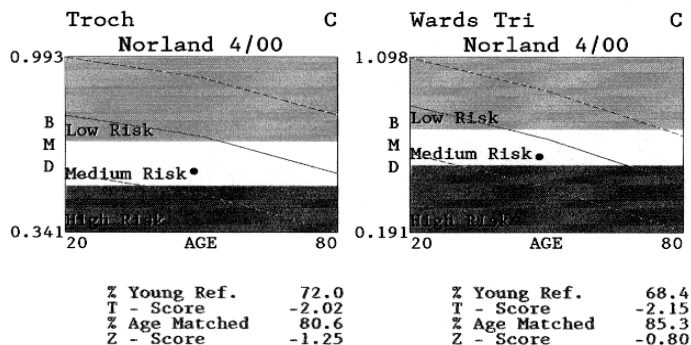


FIGURE 1-11 sBMD REPORT (HIP)

Norland Medical Systems, Inc.
W6340 Hackbarth Road Fort Atkinson, WI 53538 920-563-8456

L  H

Left Hip on 10/28/92 # 1

Name: Doe, Jane

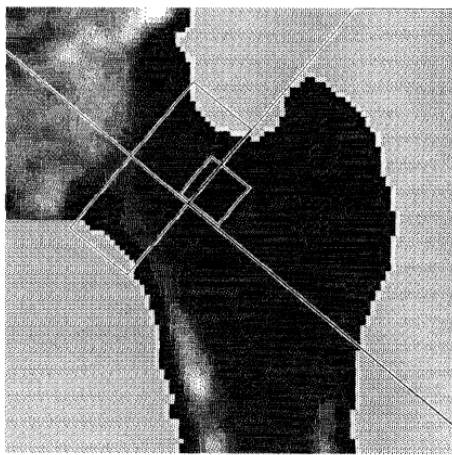
3890 Washington Street
Chicago, IL 60639

ID: 12347

Ethnic: C Sex: Female
Birth Date: 05/10/44 Height: 5'6"
Menoage: 4 Weight: 145
Age: 48

Physician: ESC
Technologist: CC

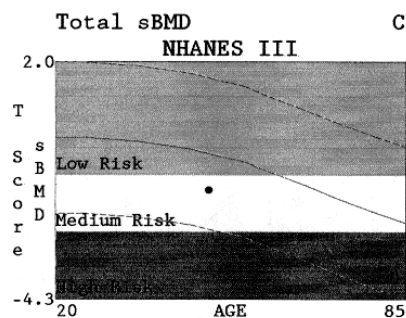
Comments



Bone image not for diagnosis

Left Hip Total sBMD Results

sBMD (mg/cm²) (1) = 785
Z-Score (age matched sBMD) (2) = -0.97



C

T-Score (relative to peak sBMD) (3) = -1.39

- (1) sBMD = Standardized Bone Mineral Density
- (2) Z-Score = Standard deviations above or below age matched mean sBMD
- (3) T-Score = Standard deviations above or below peak sBMD for young reference

STD CV for Total sBMD: 1.1 See Guide for other CVs.

 NORLAND

FIGURE 1-12 QA BMD RESULTS

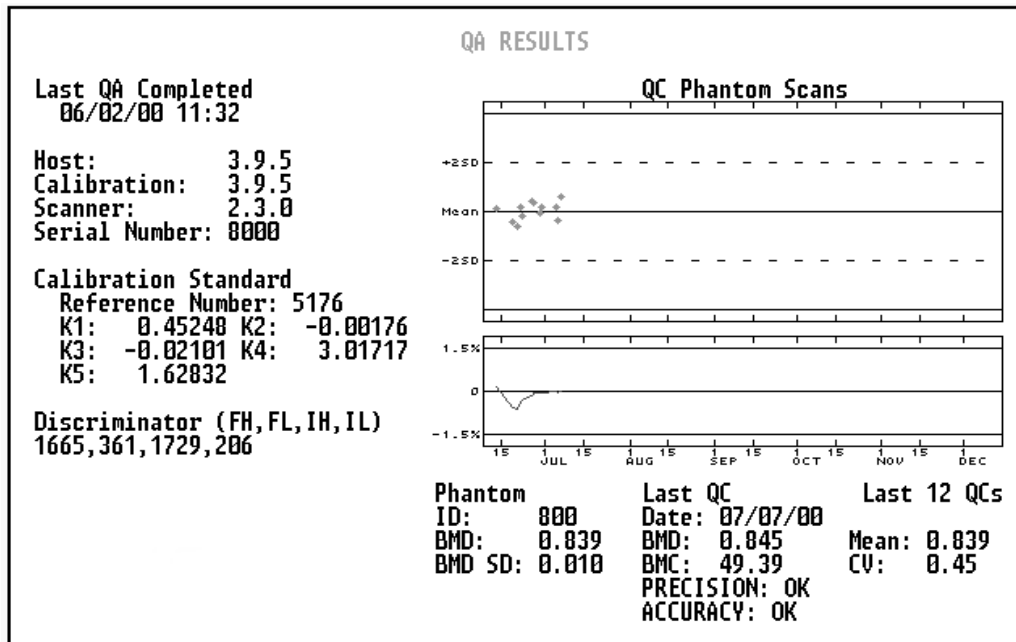


FIGURE 1-13 (Optional) QA FAT RESULTS

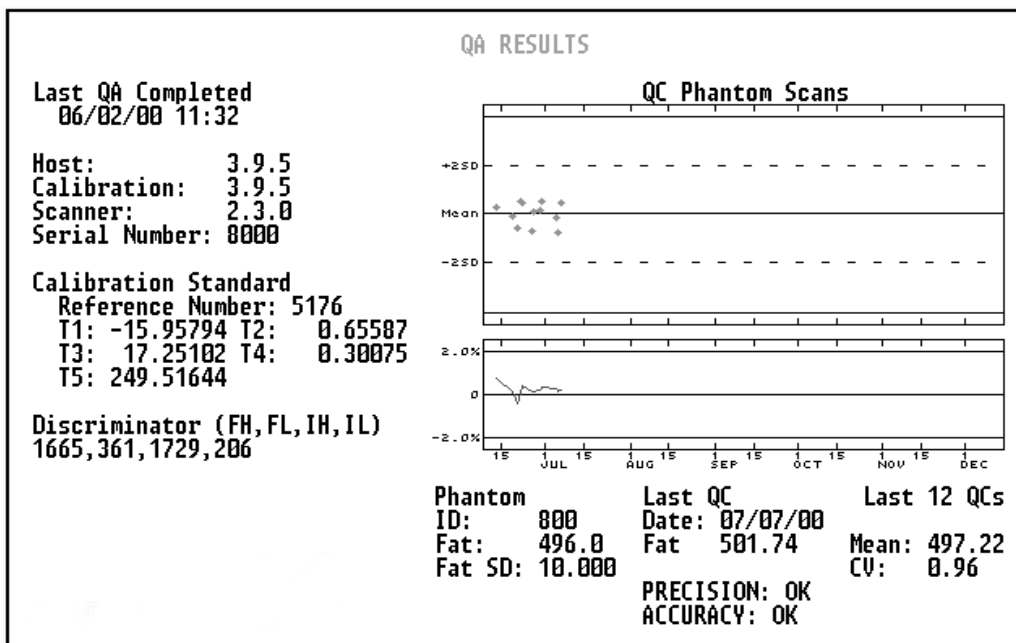


FIGURE 1-14 (Optional) QA LEAN RESULTS

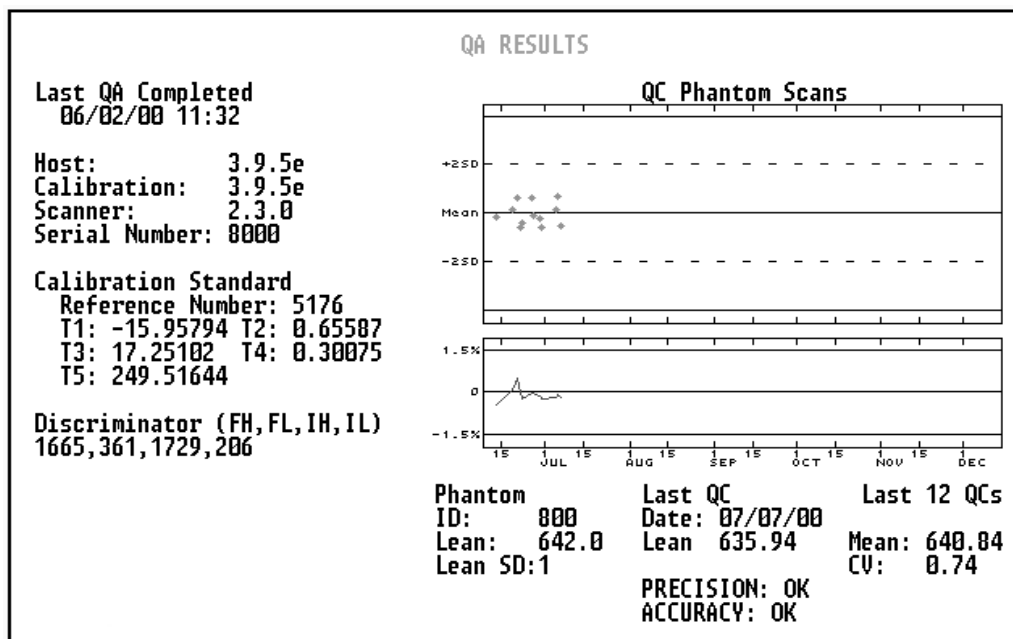


FIGURE 1-15 SCAN HISTORY REPORT

Name: Doe, Jayne	Sex: Female	Ethnic: CAUCASIAN
ID: Scan History	Age: 69	

BMD Percentage Changes (Relative to Older Scan)		
L2 - L4		07/30/96
04/15/97		+7.5%
L2		07/30/96
04/15/97		+7.9%
L3		07/30/96
04/15/97		+6.4%
L4		07/30/96
04/15/97		+8.3%

BASIC OPERATION 2

This chapter discusses the basic scanning procedure as well as more detailed instruction on daily system startup and shutdown procedures. The QA procedure is detailed.

Patient Scanning Basics

The Norland software automatically programs the system for the correct techniques and parameters based on the selected scan type. The Norland DXA system quantifies bone mineral in the lumbar spine, hip, lateral spine, forearm, and whole body for computer and user-defined regions of interest.

- The operator selects the patient's name from the system directory or enters new patient demographics.
- The patient is positioned on the scan table, and a scan type selected from the software.
- Operator positions the scanner arm to anatomy and defines the scan region. (A scout scan is used on some studies to assist in defining scan region.)
- The defined scan completes without interruption or operator intervention, the end of which is signaled with an audible beep.
- After the scan has completed, the operator can analyze the scan immediately or save the scan data and analyze it later.
- After scan analysis is completed, the results are printed on paper and saved to default storage location.

Attaining Precision and Accuracy in Scans

Patient variability, operator techniques and external radiation may adversely affect the precision and accuracy of DXA estimations. It is not possible to eliminate all of these factors. However, the operator can reduce their effects on scans by following these guidelines:

- Perform the Daily Quality Assurance Calibration.
- Screen patients for recent radionuclide uptake procedures. (Within ten half-lives)
- Make sure that each operator follows the same procedure for patient positioning and analysis. If the patient has been scanned before, use the same scan parameters as those used for the patient's initial scan. Use the same scan area size for all scans of the same patient.
- Be aware that operating an Norland system near external radiation sources, such as other x-ray generating devices or devices that involve radionuclides, may affect results.



Daily Startup/ Shutdown



Norland Bone Densitometers do not require any warm-up period before calibration or patient scanning. Norland Customer Service recommends that the scanner system be left on overnight and weekends. The scanner system should be turned off if system is to be inactive for an extended time (1 week or longer).

Norland STRONGLY recommends that the QA Calibration be performed prior to patient scanning as part of a regular Quality Assurance Program.

Norland STRONGLY recommends that system backup be a routine procedure during shutdown of the equipment to protect valuable patient data.

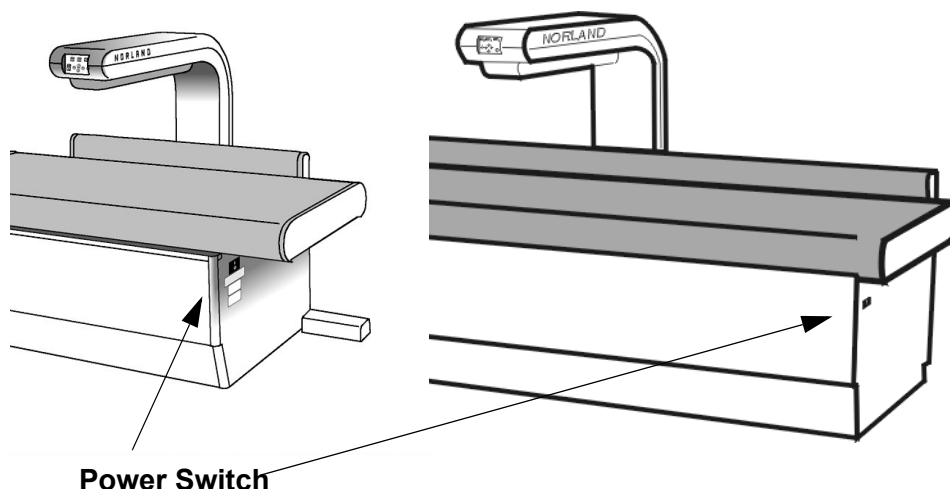
Detailed information for powering up the Norland system and shutting the system down (including data backup) is detailed in the following pages.

System Startup

The operator should follow these instructions to power up the Norland system after it has been shut down.

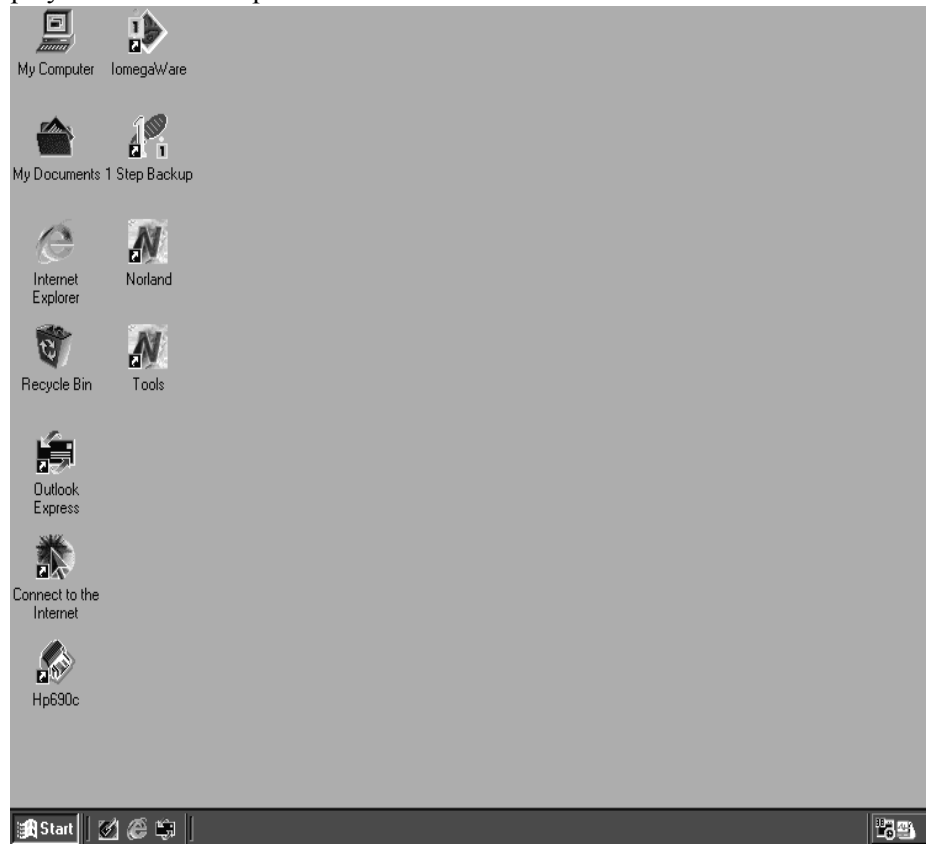
1. Turn on the power to the scanner table by depressing the rocker switch located on the end of the scanner table.

FIGURE 2-1



2. Turn on the computer and monitor.
3. Turn on the printer.

The computer will boot into Windows 98 with an icon for Norland Host Software displayed on the desktop.



Double-clicking on the "NORLAND" icon will start the Norland software program and initialize the scanner. The system will close Windows and any applications that are open and exit to DOS.

- The operator will be asked to check the hard drive (using SCANDISK). Enter 'y' to check the hard drive. The program will check the media descriptor, file allocation tables, directory structure, file system, and free space.
- Upon completion, click on "no" for the surface scan. At the "SCAN-DISK" summary page, confirm that no problems were found and click on "Exit" and the Host software will initialize.

NOTE: If SCANDISK is unable to correct errors, contact Customer Service IMMEDIATELY.

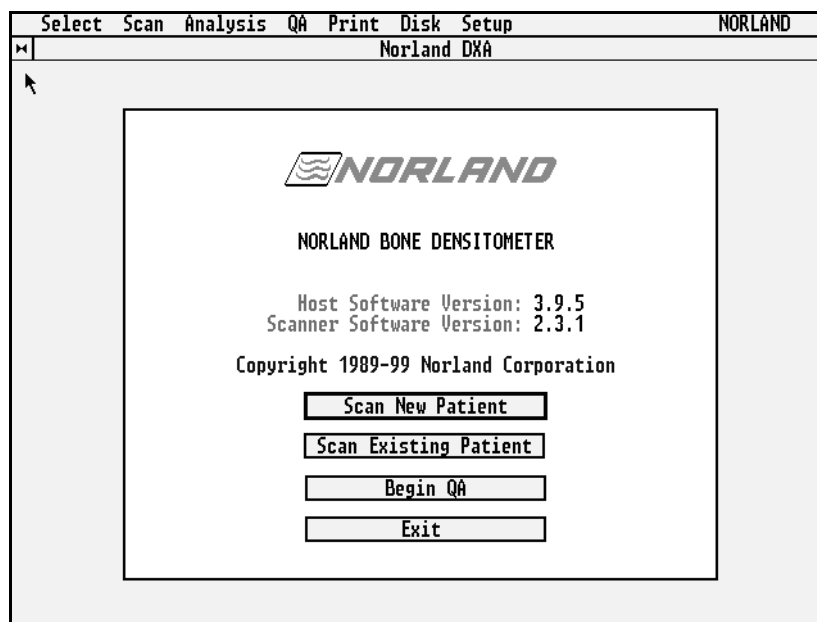
- If it is necessary to start the Norland software program from the DOS C:\> prompt, simply type in 'norland' and press .

CAUTION: The Scanner Arm will move to origin position during initialization. STAY CLEAR OF SCANNER ARM.



After initialization, the Scanner Software Version will be displayed.

FIGURE 2-2



Norland software is now ready to perform system calibration, patient scanning, or patient scan data analysis. To ensure a high level of precision and accuracy, a system calibration should be performed at the beginning of the day when scanning patients.



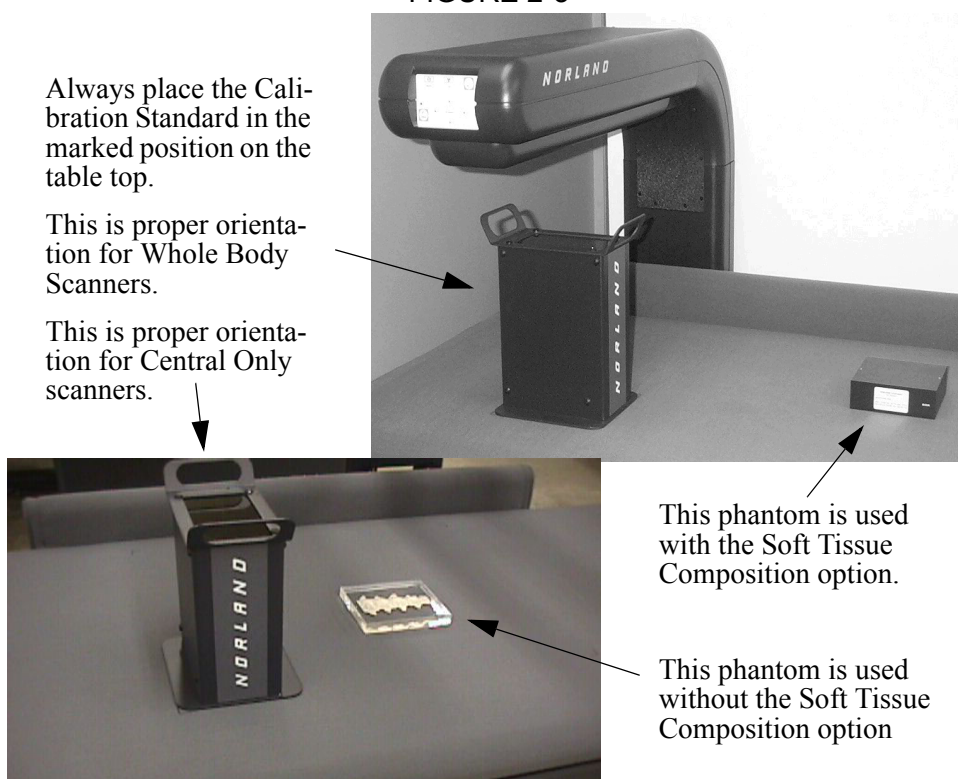
- In the event of a start-up problem or other difficulty, please contact your Norland Customer Service Representative.

Daily Calibrations

Daily Calibrations should be performed prior to patient scanning to ensure quality bone density estimates. Before each calibration, check the Calibration Standard and the QC Phantom for damage. Calibration failure may occur if internal elements in the standard become misaligned, bent, or cracked. This kind of damage can occur if the standard is dropped.

- Check the Calibration Standard for bent corners or damaged plastic.
 - No loose parts should be heard if it is shaken.
 - If the standard is damaged, contact your Norland Customer Service representative.
1. Click on **Begin QA** at the Main Menu. The system will prompt the operator to place the calibration standard on the scanner and MARK point A. (The calibration can be terminated at any time by clicking on **[Cancel]** or press **[Esc]**).
 2. Place the standard on the patient surface and align the standard with the corresponding marks on the table surface.

FIGURE 2-3



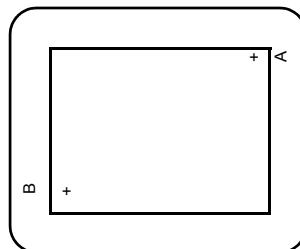


3. Switch ON the positioning laser.

CAUTION: Do not stare into the beam.

4. Use the scanner control buttons to move the scanner arm so that the laser beam spot is on the '+' point on Plexiglas identified by the inscribed letter 'A'.

FIGURE 2-4 Top of Calibration Standard

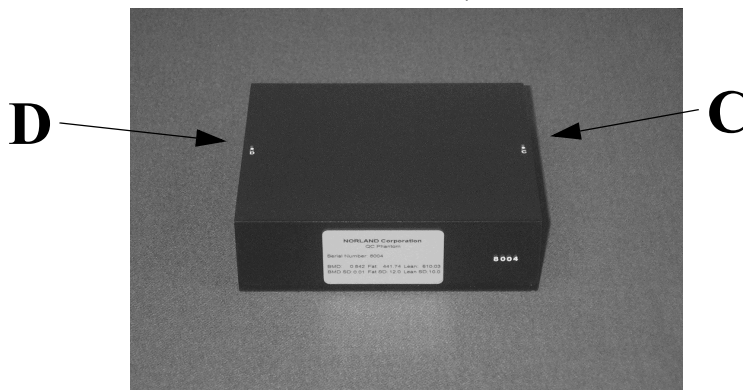


5. Press the MARK button. The laser light will briefly blink off, then back on while the computer emits a beep, signifying that the MARK position is acknowledged.
 - To re-mark point 'A', click on **[Remark]** or press the keyboard's **[Esc]** key.
6. The computer display will prompt the operator to MARK point B. Use the scanner control buttons to position the scanner arm so that the laser beam spot is on the '+' point on Plexiglas identified by the inscribed letter 'B' and press the MARK button.

FOR SCANNERS WITH BLACK PHANTOM

7. Place the QC Phantom at the center of the scanning surface. The 'C' should be to the head of the table (or to the right if facing the table) and the phantom parallel with the back rest (see Figure 2-5).

FIGURE 2-5 QC Phantom



8. Move the scanner arm so that the laser positioning dot shines directly on the dot by point 'C'; move the arm down to the dot by point 'D' to verify the phantom is straight. Move the laser back to the dot by point 'C'.
9. Press the MARK button to mark point 'C'.

FOR SCANNERS WITH CLEAR PHANTOM

7. Place the QC Phantom at the center of the scanning surface. The top of the spine should be to the head of the table (or to the right if facing the table) and the phantom parallel with the back rest (see Figure 2-6).

FIGURE 2-6 QC Phantom



8. Move the scanner arm so that the laser positioning dot shines directly on point 'C'.
 - Point 'C' is not labeled but it is the 'X' embedded above the top of the spine (which should be to the right if facing the table).
 - Verify the QC phantom is straight by moving the laser to the 'X' at the opposite end of the phantom. Re-position the phantom if it is not straight. Move the laser back to point 'C'.
9. Press the **MARK** button to mark point 'C'.
10. Move the scanner arm so that the laser dot is positioned over point 'D' (the 'X' on the left end of the QC phantom).
11. Press the **MARK** button to mark point 'D'.

FOR ALL SCANNERS

Norland software turns the laser off and positions the scanner arm over the Calibration Standard. A sequence of instrument diagnostic tests will be performed automatically and the results of each test will be displayed as they occur. The scan of the Calibration Standard proceeds automatically to completion without operator intervention and the estimated remaining time is updated periodically.

After the Calibration Standard data is collected, the software begins the QC Phantom scan and the screen indicates the estimated time and scan lines remaining. The QA Results screen will be displayed at the completion of the QC Scan. The entire process takes approximately 30 minutes to complete.

FIGURE 2-7 In Progress QA Screen

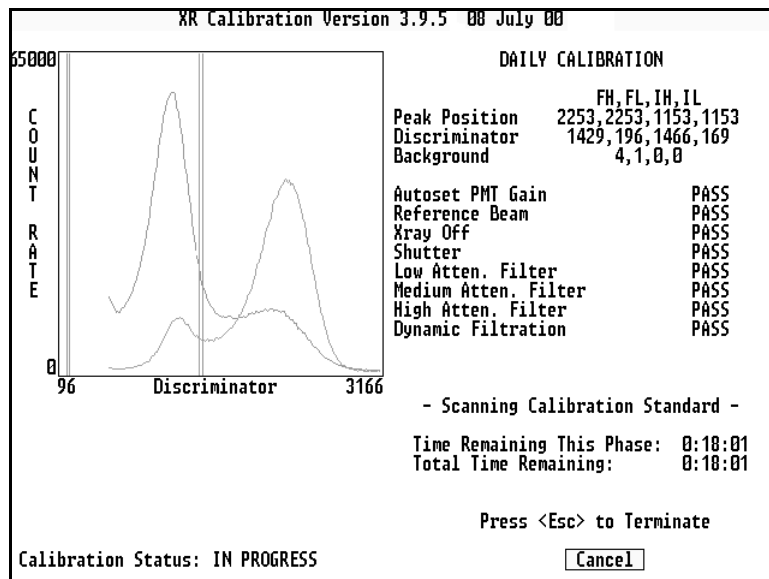
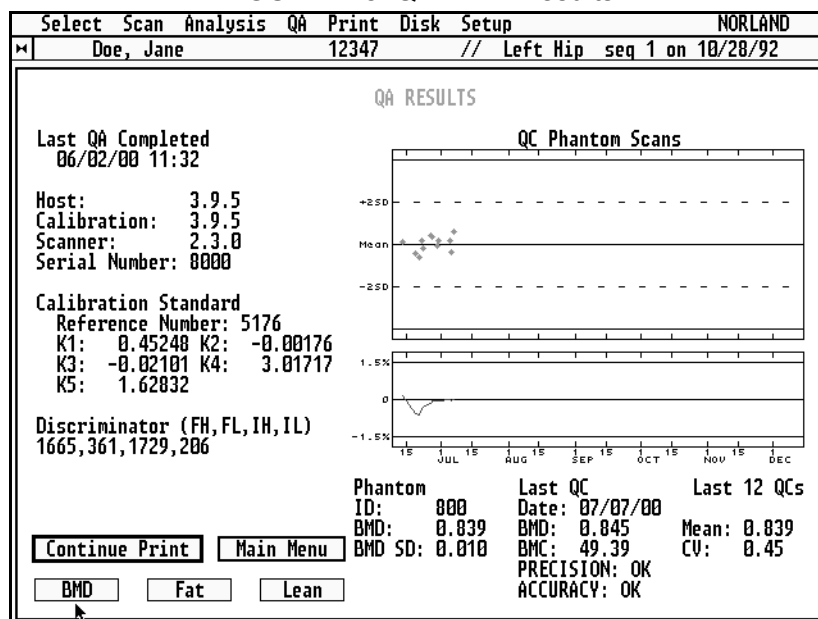
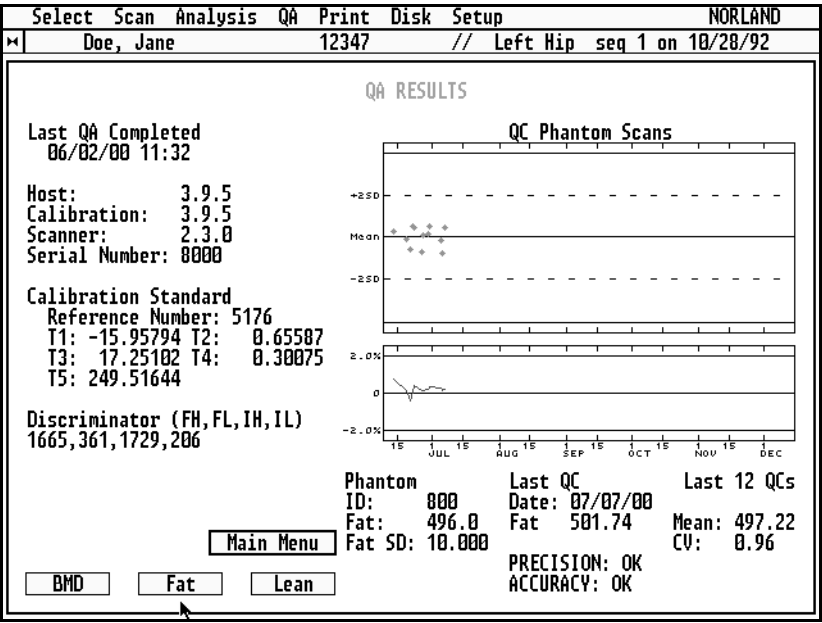


FIGURE 2-8 QA BMD Results



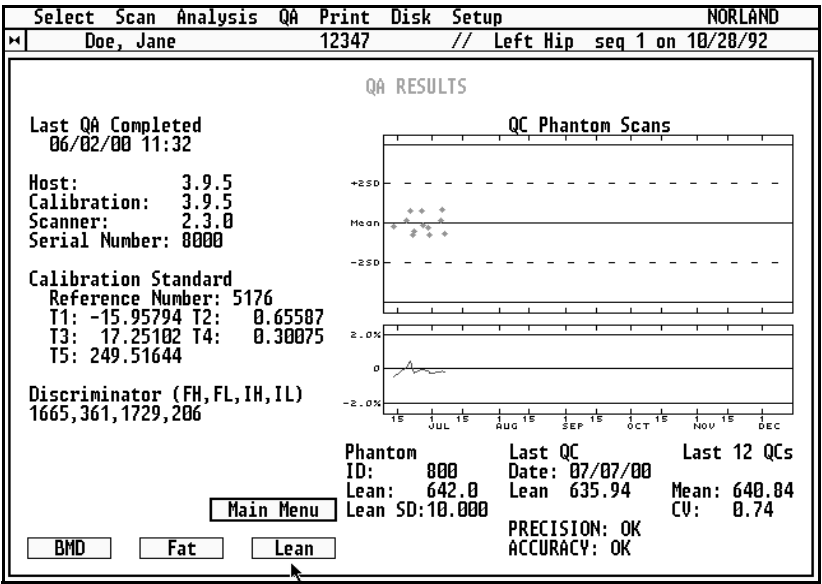
12. Verify that the **PRECISION** and **ACCURACY** fields display the **OK** status for BMD.
13. Click on **[Fat]** and verify that the **PRECISION** and **ACCURACY** fields display the **OK** status (only with Soft Tissue Composition option).

FIGURE 2-9 QA Fat Results (optional).



14. Click on **[Lean]** and verify that the **PRECISION** and **ACCURACY** fields display the **OK** status (only with Soft Tissue Composition option).

FIGURE 2-10 QA Lean Results (optional)



15. Repeat the calibration if the precision and accuracy are not "OK". If results are not OK on the repeat calibration, contact the Norland Customer Service representative.
16. Click on [**Continue - Print**] on the BMD screen to print the results for storing in the calibration log.
 - Clicking on [**Cancel**] or pressing the keyboard's **[Esc]** key any time before the QA Results screen appears terminates the calibration procedure and the calibration files will revert to the previously recorded values.



Should any part of the calibration process fail, repeat the calibration once. If the diagnostic tests fail the second time, shut the system down, re-start and perform calibration. If further difficulty is encountered, contact your Norland Customer Service representative. See also "Calibration" on page 8-5 for other troubleshooting options.

QA Results Interpretation

The most important parts of the QA Results display are the two text lines at the bottom, which indicate the precision and accuracy status of the system. As seen in Figure 2-8, Figure 2-9, and Figure 2-10 both of the messages read "OK". In the event that the QC scan statistics are not OK, other messages will be displayed.

The QA Results screen also displays two graphs based on QC Phantom scans. If no QC Phantom scans exist for the scanner, this screen area will be blank and the parameters below the graphs will show '???' as values.

The upper graph displays the precision of the Norland system. The values from the last 180 QC Phantom scans are displayed, showing their scatter about the mean. The dashed lines indicate (± 2) S.D. about the mean. Points shown in green are within (± 2) standard deviations. Statistically, 95% of the values obtained will fall in this range. Note that 5% of the points, or 1 out of 20, are statistically expected to lie outside the dashed lines.

- Points shown in yellow are those scans that exceed the (± 2) S.D.; points shown in red may indicate severe mechanical failure which will result in FAIL messages.

The lower graph displays the accuracy of the system, based on QC Phantom scans. The mean values of the last 180 calculations are plotted against the assigned BMD, Fat, and Lean value of the QC Phantom. The two horizontal lines indicate deviations of $\pm 1.5\%$ from the BMD assigned value, and $\pm 2\%$ from the Fat and Lean values. Values within these specifications are shown in blue.

Below the graphs are the numeric results of the QC scans. The "Phantom" column is the assigned value of BMD, Fat, or Lean used in the lower graph, the standard deviation of each BMD, Fat, or Lean used in the upper graph, and the serial number of the QC Phantom. The assigned values were entered into the system at installation, based on factory characterization of the system's QC Phantom.

The "Last QC" column is the value for the most recent scan, and the Precision and Accuracy status.

The "Last 16 QC's" column lists the mean value and C.V. for the 16 most recent scans. If fewer than 16 scans have been performed, all calculated values are used in the computation.

The information to the left of the graphs contain the serial numbers of Calibration Standard and the Scanner. Host software and scanner firmware version numbers are listed as well as discriminator values for current valid calibration.

The criteria for generating the precision and accuracy warning messages are modeled after those of Shewart (see Table 2 in Orwoll, et. al., J. Bone and Mineral Res. 6:1991, p.196.)

QC Phantom Statistics Messages

The tables below describe possible messages for Precision and Accuracy.

Precision

PRECISION MESSAGE	MESSAGE INDICATION	OPERATOR ACTION
OK	Precision of the system is within specification.	Backup files
OUT OF RANGE	Standard deviation estimated from 16 scans is greater than the expected value.	Repeat QA
WARNING 1	A single value for is outside ± 3 standard deviations from the mean.	Repeat QA
WARNING 2	Two consecutive values exceed ± 2 standard deviations from the mean.	Repeat QA
WARNING 3	Four consecutive values of the same sign (either plus or minus), exceed one standard deviation from the mean.	Repeat QA

Accuracy

ACCURACY MESSAGE	MESSAGE INDICATION	OPERATOR ACTION
OK	Accuracy of the system is within specification.	Backup files
OUT OF RANGE	The Mean BMD, Fat, or Lean computed for the last 16 phantom scans exceeds $\pm 1.5\%$ of the expected value for BMD, or $\pm 2\%$ for Fat or Lean.	Repeat QA
TREND WARNING	Eight consecutive values fall on the same side of the mean outside $\pm 1SD$.	Repeat QA

NOTE: The Quality Assurance Calibration should be repeated if:

- An Accuracy or Precision OUT OF RANGE message is received.
- Precision: WARNING 1, 2, 3, are received.
- Accuracy: TREND WARNING is received.

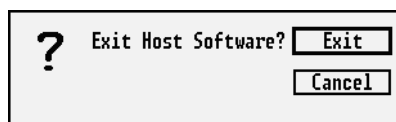
NOTE: Please contact your local Norland Customer Service representative if any of the following occurs:

- OUT OF RANGE messages are generated on repeated Quality Assurance Calibrations.
- WARNING messages are generated on repeated Quality Assurance Calibrations.
- An Accuracy TREND WARNING message is displayed.
- The "QC.FIL DATES ARE OUT OF SEQUENCE" message is displayed.

System Shutdown

The following shut down routine will help ensure consistent backups and system operation.

1. Click on **Exit** at the *Main Menu*.
2. Click on **[Exit]** at the following screen to exit the Host software and restart windows.



- Host software can also be closed by clicking on the "bowtie" symbol at the upper left of the *Main Menu*, then clicking on **Exit**.
3. If reports are printing at time of exit, following message should display.

"A report is printing. If you exit now you will need to reset your printer before restarting the host software."

The operator is provided with three options:

WAIT	Will continue exit after the current copy of report is printed.
EXIT to DOS	Continues the exit to DOS. The current report copy will not complete printing. When the host software is re-initialized the complete report of the current scan and all other scans in the print queue will begin printing.
CANCEL	Returns to the host software program.

4. Pressing **[Enter]** will select the default "WAIT" option and the DOS prompt will be displayed after current copy of report is printed.
5. The system should be backed up daily. See the appropriate backup procedure on the next two pages for the computer installed.

Norland strongly recommends that system is backed up daily.

6. Ensure that the host software has been closed before turning the scanner off.
 - Norland recommends that the scanner be left on overnight or over the weekend. If the scanner is to remain idle for a week or more, then the system should be shut off by the rocker switch located on the bottom right front of the scanner table. (See Figure 2-1)
7. Click on "Start" and perform Windows Shutdown before turning off the computer.

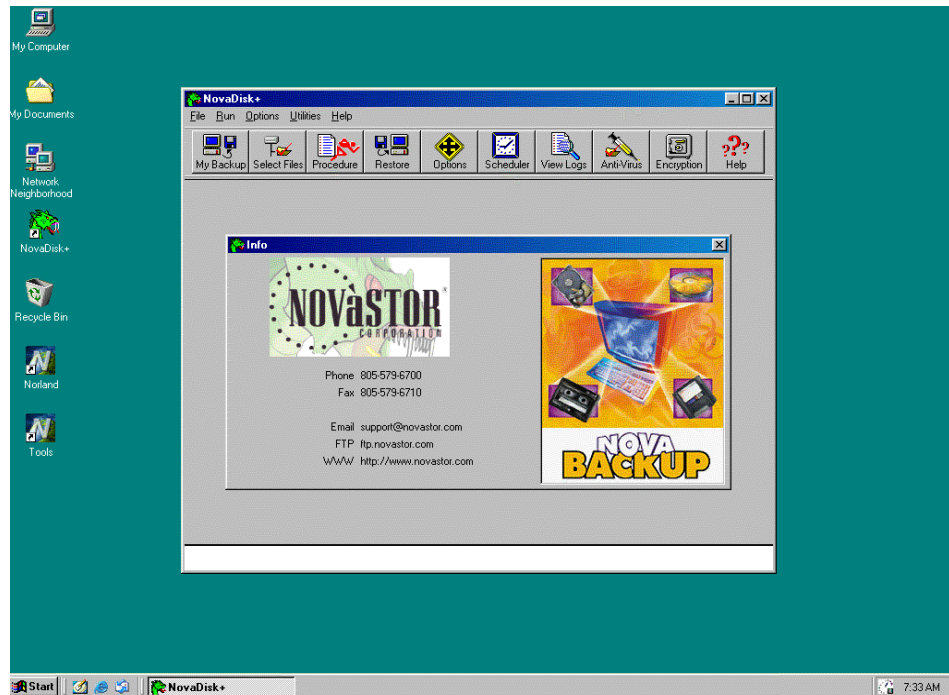
The computer must be left on while performing a backup.



System Backup

Desktop PC's are equipped with a high capacity storage device for system backup. Norland recommends that daily system backups be performed as part of the routine shut down procedure.

1. Exit the host software to the Windows desktop.
2. Insert the media into the drive, and click on the "NovaDisk+" icon.
3. When the main screen appears, click on the "Procedure" button.



4. Click on "Norland_Default.bup", on the "Select Backup Procedure Screen", then click on the "Run" button. If the drive is not ready click on "Retry".
5. The "Backup to..." dialog will appear, (verify the "Save In" pull down menu points to Removable Disk D:), and click on the "Save" button to save the procedure.
6. Select "Erase Disk Unconditionally" from the "Options are" pull down menu.
7. Click on "OK" to begin the backup operation, on "Backup Confirmation" screen.
8. If your system files are too large to fit on one media you will be prompted to insert media 2. During the compare function it is necessary to re-insert media 1 and then media 2 again when prompted by the software.
9. Click on the "OK" button when the Backup and Verification completion message is displayed.
10. Select "Exit" from the "File" pull down menu.
11. Remove the media from the drive and store in a safe place.

System Backup (Volume Diskettes)

1. If the default storage location is volume diskettes (recommended for laptop users), the following message will be displayed after exiting to DOS.

"Do you want to back up any volume diskettes?"
2. Enter 'Y' for yes and the screen will instruct the operator to insert the desired volume diskette to be backed up. After inserting the volume diskette and pressing , the system will run CHKDSK and XFCHECK on the volume diskette.
3. If no errors are found, the operator will be instructed to press to continue the backup procedure. The contents of the volume diskette will be read into a temporary file on the computer's hard drive.
4. The operator will then be instructed to insert a blank formatted diskette into the floppy drive and press .
 - A previous backup diskette could also be used. If a previous backup diskette is used, the system will request confirmation for overwriting a volume diskette.
 - The contents of the temporary file on the system hard drive will be copied onto the backup diskette.
5. When the copy is complete, the CHKDSK program will check the backup diskette and the following message will display.

"Do you want to backup another disk (y/n)"
6. Repeat the process with any remaining diskettes to be backed up. Be sure to properly label backup diskettes.

INITIAL SETUP 3

The general operating parameters of the Norland DXA system can be customized to suit each facility's needs. They should be set during installation and changed on an "as needed" basis to fit a facility's scanning requirements. When set from the main menu, the parameters become the default condition for subsequent procedures and remain so until changed by the operator. Most parameters will be established by the installer prior to applications training; selections will be discussed with operator during the training to ensure complete understanding. However, when the needs of the facility changes, the system can easily be reconfigured.

Setting the Date & Time

The Host software uses the computer's internal clock to include date and time stamps on all scan data files. The internal clock runs continuously, even when the computer is turned off.

To change or verify the computer's date or time setting, **right** click on the time displayed in the lower right corner of the Windows desktop.

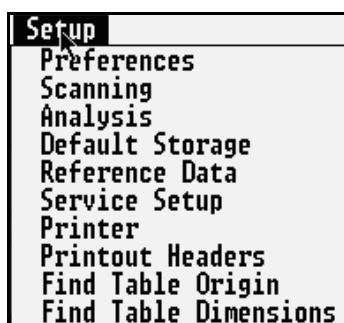
Left click on "Adjust Date/Time".

Change the Date, Time, or Time Zone as needed and click on OK to save the changes.

Set System Parameters

The Setup menu, accessed from the *Main Menu*, is used to set default parameters for scanning, analysis, printing, and general operation. All setup options are typically reviewed and modified during system installation or training.

Select *Main Menu* item **Setup** and click on the desired setup option to display parameter options.



The last two **Setup** options, **Find Table Origin** and **Find Table Dimensions** are diagnostic functions that allow operators to redefine system origin location and table limits if arm was bumped during operation (thus losing a step) or if Customer Service requests operation during troubleshooting efforts.



Ensure that Scanner Arm path is clear of obstructions when using these features.

Preferences

The Preferences Setup screen is used to select general operating parameters, such as drop-down menu mode, mouse double-click sensitivity, image mode, date format, and age format.

1. Select *Main Menu* item **Setup**, then click on **Preferences**. The Preferences Setup screen will be displayed with the current default settings. (See Figure 3-1)
 - Changes are effected by clicking on selection with mouse. Click on **[Accept Changes]** to save any changes. Preferences highlighted will remain in effect until changed.

FIGURE 3-1

PREFERENCES SETUP	
Drop Down Menus The drop down menus may be set drop down when the pointer touches a menu title, or when a menu title is clicked on. <div> <input checked="" type="button" value="Touch"/> <input type="button" value="Click"/> </div>	Image The image may be enhanced by interpolation. <div> <input type="button" value="Interpolate"/> <input checked="" type="button" value="Normal"/> </div>
Mouse The mouse button's double-click response time may be set to one of five speeds. <div> <input type="button" value="Slow"/> <input type="button" value="2"/> <input checked="" type="button" value="3"/> <input type="button" value="4"/> <input type="button" value="Fast"/> </div>	Date Format MM - Month <input checked="" type="button" value="MM/DD/YY"/> DD - Day <input type="button" value="DD/MM/YY"/> YY - Year
	Age Format Format for age on screens and reports. <div> <input checked="" type="button" value="Years"/> <input type="button" value="Years Plus Tenths"/> </div>
<div> <input checked="" type="button" value="Accept Changes"/> <input type="button" value="Do Not Accept"/> </div>	

Drop Down Menus

- If **[Touch]** is selected, moving the pointer on top of the titles in the *Main Menu* or *Analysis Menu* causes sub-menus to 'drop down' under the menu bar title.
- If **[Click]** is selected, the operator must click on the menu bar title before the sub-menu will appear. This choice is referred to as the 'pull-down' menu mode.

Mouse

- The default selection, [3], for double-click speed is recommended. [3] is an average level of sensitivity for double-click operation.

Image

- NORMAL image display presents each scan data point as a rectangular region in a density shade within the display spectrum value. NORMAL mode scan data can appear rather coarse, depending on scan resolution.
- INTERPOLATED mode utilizes averaging algorithms to produce a smoother image that more closely resembles the underlying bone structure. The actual data is not affected. The interpolated mode affects screen images only; hardcopy images are always printed in NORMAL mode.

Date Format

The date on reports is displayed in numerical format.

- MM/DD/YY (typical for USA)
- DD/MM/YY (most other countries)



NOTE: Do not switch between the two date formats. Do not change after making the initial setup selection.

Age Format

- The patient's age may be printed as integer years (adults) or as years plus tenths of years (for pediatric patients).

Scanning

1. Select *Main Menu* item **Setup** and click on **Scanning**.
2. Select AP Spine, Hip, Forearm, Lateral Spine, or Whole Body.¹

AP Spine Scan

The following screen shows the default AP Spine Scan parameters.

AP SPINE SCAN SETUP

Resolution: 1.5 x 1.5 mm

Scan Width: 12.00 cm

Scan Length: As Marked cm

Scan Speed: 130.0 mm/sec

High Precision Standard High Speed

Auto Centering: ON OFF

Force mark points on-axis: Enabled Disabled

Scan Resolution: 1.0 x 1.0 1.5 x 1.5 mm

Accept Changes Do Not Accept Restore Defaults

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

- The scan speed for a High Precision scan is 65 mm/sec, for Standard is 130 mm/sec, and for High Speed is 260 mm/sec.
- *Auto Centering*, when enabled, centers the image in region of interest despite small variances in actual patient orientation. For more information see Change Parameters on page 6-21.
- *Force mark points on-axis*, when disabled, straightens the image in region of interest despite small variances in actual patient orientation. When enabled, forces the densitometer to transverse the scan region in X & Y axis only (will not allow scanning on a diagonal). **To achieve the highest quality AP Spine scans, this feature should be DISABLED.** For more information see Force Mark Points On-Axis on page 6-23.
- Scan Resolution is the (data point size) x (scan line size) in millimeters.
- Scan Width is 12cm, unless Auto Centering fails, in which case the Scan Width is automatically set to 14cm.
- Scan Resolution of 1.0 x 1.0 with High Speed will generate a message indicating Scan Speed too fast for selected resolution. In this event, either select alternate Scan Speed or Scan Resolution.

1. For scan modalities other than AP Spine and Hip refer to the appropriate supplement. Forearm, Lateral Spine, and Whole Body are not available on some models.

Hip Scan

The following screen shows the default Hip Scan parameters. The defaults shown should be effective for most scanning situations.

HIP SCAN SETUP			
Resolution:	Scout 1.0 x 4.0	Measure 1.0 x 1.0	mm
Scan Width:	12.00	9.00	cm
Scan Length:	12.00	9.00	cm
Scan Speed:	180.0	90.0	mm/sec
	<input type="button" value="High Precision"/>	<input checked="" type="button" value="Standard"/>	<input type="button" value="High Speed"/>
Scan Type:	<input checked="" type="button" value="Standard"/> <input type="button" value="Extended Width"/>		
	<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.

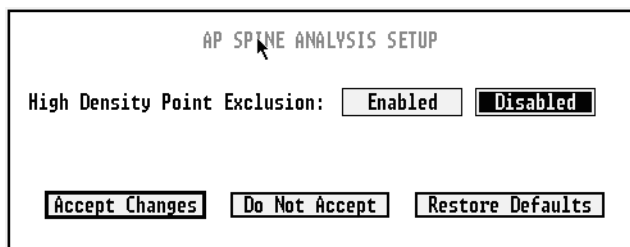
- High Precision speed sets Measure Scan speed to 45 mm/sec (Scout Scan speed is always 180 mm/sec).
- Standard speed option sets Measure Scan speed to 90 mm/sec (Scout Scan speed is always 180 mm/sec).
- High speed option sets Measure Scan speed to 180 mm/sec (Scout Scan speed is always 180 mm/sec).
- The Extended Width option (used for larger patients) sets the Measure Scan dimensions to 12 cm x 12 cm.
- Scan Resolution is fixed for the Hip Scan.

Analysis

1. Select *Main Menu* item **Setup** and click on **Analysis**.
2. Select AP Spine, Hip, Forearm, Lateral Spine, or Whole Body ¹.

AP Spine

The following screen shows the default AP Spine parameters. The default shown should be effective for most scanning situations.



AP SPINE ANALYSIS SETUP

High Density Point Exclusion:

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.



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

1. For scan modalities other than AP Spine and Hip refer to the appropriate supplement. Forearm, Lateral Spine, and Whole Body are not available on some models.

Hip Analysis

The following screen shows the default Hip parameters. The defaults shown should be effective for most scanning situations.

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.



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

- Femoral Neck Length determines the length of the region of interest along the femoral neck axis. 1.5 cm is recommended because the larger area is more precise. The software will automatically default to 1 cm if unable to attain a 1.5 cm region.
- If the "Alternate R Value Analysis" function is enabled, the software algorithms will first use standard methods to analyze hip data. If the computed R value is determined to be outside of an acceptable range, a second analysis method will automatically be invoked to analyze the hip scan data.

An R value is a computed value used during the analysis process to allow the software to estimate the amount of soft tissue above and below bone. In some individuals with very low density, the routine algorithms for calculating the "R" value do not allow for the proper processing of hip data.

Default Storage

Scan Data must be stored after collection. Norland recommends that the default storage should be set to fixed (system hard drive) for those systems using the desktop computer. The Norland desktop computer uses a tape backup to regularly backup the scan data stored on the system hard drive.

1. Select *Main Menu* item **Setup** and click on **Default Storage Location**. The default storage selection will be displayed. All available storage choices recognized by the computer are shown.

DEFAULT STORAGE LOCATION

Select the default storage media for scan data files
(where files are normally accessed).

Removable Media: ☒ A:

Fixed Media: ☐ C: ☒ D: ☐ E: ☐ F:
☐ G: ☐ H: ☐ I: ☐ J:

Scan Storage: ☐ Removable ☒ Fixed

Removable

Stores scan data on diskettes. This will make efficient patient database management difficult and is not recommended for the desktop PC. This method is recommended for those systems using the laptop computer to ensure that a full backup of system data is always available.

Fixed

Maintains patient database on system hard drive. Recommended for efficient patient database management. Default selection should initially be set to the last drive available.

- Systems configured to run with Windows 98 will have only one partition configured for the system hard drive.
2. Click on desired default storage location and on **[Accept Changes]** to save settings.

Reference Data

Reference Sets are installed on the system before leaving the factory. The Reference Data option allows for creation of new reference sets, installing and deleting reference sets, and copying or editing of existing reference sets.

Select *Main Menu* item **Setup** and click on **Reference Data**.

The Reference Data Setup screen will be displayed.

Create	Displays a screen for inputting reference data from a hard copy or from a statistical analysis of a local population. Created reference sets will not display color bands on the charts.
Edit	Allows selection of installed Reference Set for editing. Reference Sets are enabled and disabled here.
Delete	Allows selection of installed Reference Set for deletion from system. Copy to diskette first.
Get	Installs Reference Set to system hard drive from diskette. (Reference Sets are installed one at a time.)
Copy	Copies Reference Set to diskette.

- Data sheets that accompany the Reference Sets should be inserted in this Operator's Guide for future use. These data sheets describe the source of the data and explain the information gathering criteria.

Service Setup



The Service Setup should not be modified by operators without direct communication from an authorized Norland Customer Service Representative.

Printer

Select *Main Menu* item **Setup** and click on **Printer**. Click on options and enter choices to establish default settings for printing functions and routines. This allows printing to be customized to the specific requirements of this facility.

FIGURE 3-2

Report Setup (AP Spine / Hip)
(Default Settings)

Paper Length (inches):

Print Mode:

Results Copies:

Calibration Copies:

Detailed Results:

Print Scan History:

sBMD Report:

Print Report Setup

Paper Length	11" - 8.5 x 11 paper 12" - A4 (210 mm x 294 mm)
Print Mode	IMMEDIATE - prints the report immediately after a print request is made. QUEUE - places the report in a temporary file for printing later. ((See Start / Stop Printing Queue on page 6-3))
Results Copies	Number of copies of analysis reports per print request. Click on the [??] button to select more than two copies (up to 99) and enter desired number of copies.
Calibration Copies	Number of copies of calibration reports per print cycle. Click on the [??] button to select more than two copies (up to 99) and enter desired number of copies.
Detailed Results	[1 Page] - prints only Results Page 1 [2 Page] - prints both Results Pages [Disable] - disables Detailed Report.
Print Scan History	When enabled, a Scan History report is printed.
sBMD Report	When enabled, an sBMD report is printed.

- Click on **[Accept Changes]** to save settings.

Printout Headers

Printout Headers consist of two lines of text (maximum of 72 characters per line) centered at the top of the printed report. Up to twenty-two unique headers may be created. (Selection of Printout Header is accomplished with *Analysis Menu - Print* command. Once selected, a Printout Header remains in effect until a new one is selected.)

1. Select *Main Menu* item **Setup** and click on **Printout Headers**. The Edit Printout Headers screen is displayed.

EDIT PRINTOUT HEADERS

1.	Norland Medical Systems, Inc.
	W6340 Hackbarth Road Fort Atkinson, WI 53538 800 563-9504
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	

Previous Page Next Page Accept Changes Do Not Accept

2. Position cursor in any header selection to edit or enter a header.
3. Click on [**Accept Changes**] to save the new or edited header information.

SCANNING AP SPINE 4

The AP Spine Scan procedure estimates bone mineral in the lumbar spine using a posterior-anterior projection. The region of interest is the L2-L3-L4 segment, which is analyzed for individual and total vertebrae. The analysis will exclude transverse vertebral process areas from the bone mineral estimations.

The scan is typically started at the xiphoid process and ends just below the iliac crests. The scan procedure includes an autocentering routine to ensure the spine is centered and straight in the scan area. The analysis begins with the operator placing initial cursors to begin the computer automated analysis. Results are automatically displayed. The region of interest can be modified, but it is usually not necessary. 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), Standard BMD (sBMD) and a Scan History Report.

AP Spine Scan Specification

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

AP Spine Scan Specifications	
Scan Sites	Lumbar Spine (L2-L4)
Accuracy ^a	Typically within 1.0% of industry standard
In vivo Precision ^b	See table below
Scan Times	Refer to Technical Reference Section
Scan Resolution	Selectable: 1.0mm x 1.0mm 1.5mm x 1.5mm [Point resolution x line spacing (pixel size)]
Scan Speed	Selectable: High Precision - 65mm/sec Standard - 130mm/sec High Speed - 260mm/sec

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

b. Based upon scans of 14 subjects, 3 scans each using standard procedures, 1.5 X 1.5 mm resolution, and 260 mm/sec scan speed.

		Total L2-L4 C.V.			Average Single Vertebra C.V.		
Measurement Scan Mode	Measurement Scan Speed	BMD	BMC	AREA	BMD	BMC	AREA
High Speed	260mm/sec	0.9%	1.2%	0.7%	1.6%	2.1%	1.3%

*** 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 AP Spine Measurement scan based on the listed body thickness.

AP Spine Skin Dose

Patient Thickness (cm)	Entrance Skin Dose (millirems)		
	High Precision	Standard	High Speed
0-3	0.08	0.04	0.02
>3-6	0.11	0.06	0.03
>6-9	0.16	0.08	0.04
>9-12	0.20	0.10	0.05
>12-15	0.38	0.19	0.10
>15-18	0.65	0.32	0.16
>18-21	1.20	0.60	0.30
>21	1.87	0.94	0.47

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 AP Spine Scans

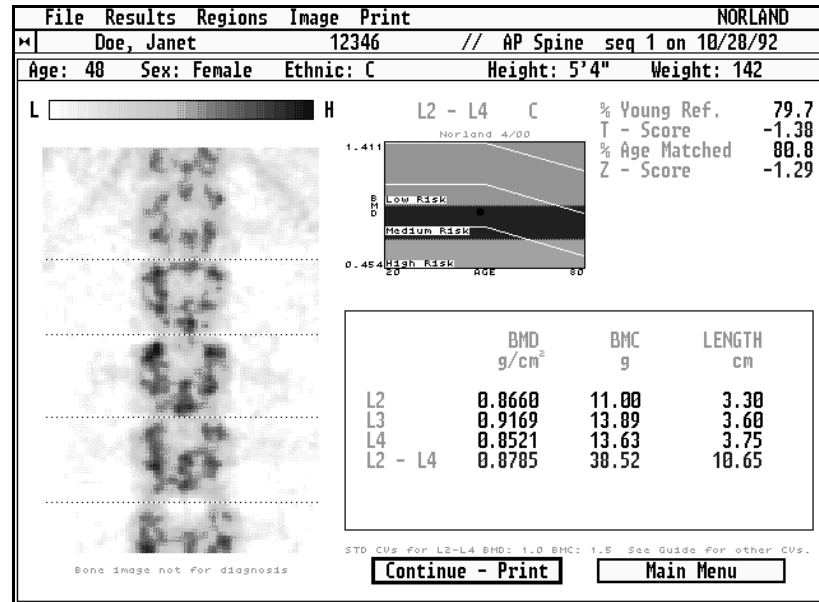
Patient positioning, scan and analysis techniques can influence the precision and accuracy of Norland Bone Density estimations. Facilities can reduce the adverse effects of some of these factors by:

- 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 system. The daily QA procedure verifies proper operation as well.
- 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 the Norland system 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 external opaque (metal and plastic) objects. Jewelry, buttons, zippers, rivets, buckles, pens, keys etc. can affect the results if they are in the scanning region.

- 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.
- Ensuring the patient does not move during the scan.

An example of a good quality AP Spine scan is shown in Figure 4-1.

FIGURE 4-1



- The vertebral column is centered and straight. Autocentering helps to ensure that the vertebral column is centered and straight in the scan region.
- Anatomical landmarks such as the ribs off T12 and the top of the iliac crests are visible in the scan image.

Quick Reference Instructions

The AP Spine scan takes measurements from L2 through L4.

- Click on Scan New/Existing Patient and select scan type.
- Enter/Update Patient information.
- Screen patient for contraindications.
- Position the patient face up in center of the scanner table. Position the scanner arm over the patient's midsection. Use the leg rest block to stretch the spine and relax the curvature.



CAUTION the patient not to stare into the beam.

- Turn laser on and position the laser dot 2cm below the xiphoid process and press the MARK button on Scanner Control Panel to set scan start point. *If it is desired to include L1 in the scan, position the laser dot at the xiphoid process.*
- Position the laser dot 2cm below the iliac crests and press the MARK button on Control Panel to set scan end point.
- At the Scan Review screen, click on **[Start Scan]**.
- When the scan is finished, click on **[Analyze]**.
- While system performs analysis, remove positioning aid to make patient comfortable.
- When the initial analysis is complete, place the top cursor at the space between L1/L2 on displayed image.
- Place the bottom cursor at the space between L4/L5 and click on **[Continue]**.
- Confirm that cursors are set between L1/L2, L2/L3, L3/L4, and L4/L5.
- Click on Results Page 1 under the Results menu.
- Enter comments with "Edit Comments", if desired.
- Click on **[Continue - Print]** to print the report as determined by Print Setup. The Norland 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 touch the patient and the computer system at the same time as this could increase leakage currents.

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 - Do not allow the patient to bump, push, or lean on the scanner arm. Manually moving the arm could result in an error message which will require removing the patient from the table and doing the Find Table Dimensions routine.

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 - When positioning the patient, ensure they start by sitting near the center of the table and then swing their legs up. Sitting at either end makes positioning awkward.

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

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

Performing AP Spine Scan

The patient will be lying in supine position with legs raised and supported. Light-weight or cotton clothing is acceptable but jewelry, zippers, buttons, back braces, or any metal or high density plastic will affect bone mineral estimations. An examination gown or robe may be more suitable.

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.
 - To automatically display the Reference Chart on the Result Page(s) enter the appropriate letter from the table below in the Ethnic field.

A	Asian
B	Black
C	Caucasian
CH	Caucasian/Hispanic
H	Hispanic

- If patient's ethnic background is something other than those listed above (i.e. American Indian), enter the appropriate background. A list of available reference sets will be displayed when the patient's results are displayed or printed. See Figure 4-11.
- Pressing **[Enter]** or **[Tab]** will move cursor through fields.

3. At the SCAN TYPE screen, click on **[AP Spine]** and click on **[Continue]**.
4. Enter the patient's vital statistics and click on **[Continue]**.

Height:

Weight:

Technician:

Physician:

Continue **Main Menu**

- 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 (i.e. values are not adjusted for height and weight).
 - Pressing **[Enter]** or **[Tab]** 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 4-2

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

Home **PgUp** **↑**

End **PgDn** **↓**

Search by Name

Search by ID

Continue **Cancel**

- 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 4-3

Figure 4-3 displays two search screens. The left screen, titled "SEARCH BY NAME", features a text input field labeled "Name:" and two buttons, "Continue" and "Cancel". The right screen, titled "SEARCH BY ID", features a text input field labeled "ID:" and two buttons, "Continue" and "Cancel".

2. Click on patient name and click on **[Continue]**. (Or double-click on patient name.)
3. At the SCAN TYPE screen, click on **[AP Spine]** 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 (i.e. values are not adjusted for height and weight).
 - Pressing **[Enter]** or **[Tab]** will move cursor through fields.
5. Proceed to Patient Positioning to prepare the patient for scanning.

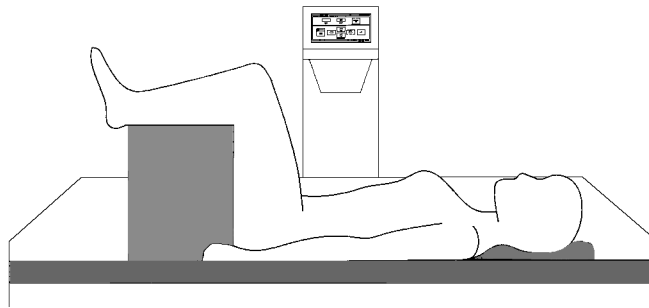
Patient Positioning

Ensure that the patient removes all items from pockets and that clothing is free of metal (i.e. rivets, buttons, zippers) or anything else that might be of a high density. It might be necessary to have the patient change to an examination gown or robe. Shoes should also be removed.



1. Discard any used exam paper and cover the patient table with clean paper from roll. (Special disposal of exam paper is not necessary.)
2. Have the patient lie face up on the scanner table (right side to the table back rest).
3. Position patient to be ***straight and centered*** on the scanner table.
4. Ensure that laser is turned off and move the scanner arm to a position above the patient's midsection.
5. Position the AP Leg Rest under the patient's legs in its most upright position so that thighs rest at a 90° angle (see Figure 4-4). The leg rest block helps to straighten the natural curvature in the spine and aids in separating the vertebrae.

FIGURE 4-4



- Ensure that the patients hands are not in the scan area. Having them placed at the patient's sides on the table is effective.
- Make the patient as comfortable as possible since movement during the scan will affect the results. The use of a sheet or light blanket will not interfere with scan results. Use of a pillow under the head is recommended.

The patient is now ready for scanning.

Scan Procedure

1. The DEFINE SCAN REGION screen should be displayed on the computer.
(See Figure 4-5)

FIGURE 4-5

DEFINE SCAN REGION

Position the patient on the scan table.

Switch on the laser marker.

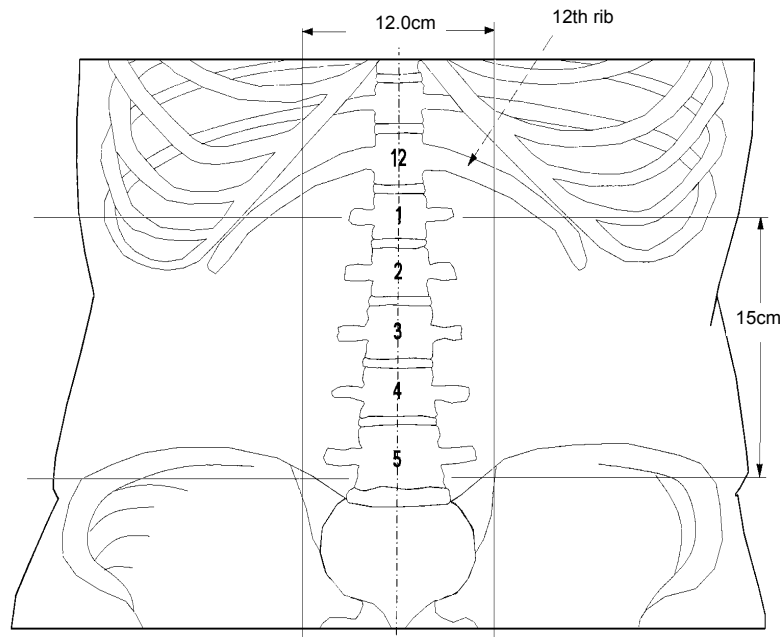
>> Mark a point 2 cm below the xiphoid.

Mark a point 2 cm below the iliac crests.

Force on Axis:

- If "Force on Axis" is enabled, disable at this point to allow Auto Centering to function at its full capabilities.
- The [**Previous Step**] command will return to the previous step.
- The [**Main Menu**] command will cancel the scan and return to the main menu.

FIGURE 4-6



2. Ensure that the laser is off and position the scanner arm over the patient's midsection.



CAUTION the patient to not stare into the beam.

3. Turn on the laser and move the scanner arm until laser is positioned 2 cm below the xiphoid process. (See Figure 4-6). *If you want to include L1 in the scan, position the laser dot at the xiphoid process.*

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.

- To include L1 in the scan, use the xiphoid process as the start point.

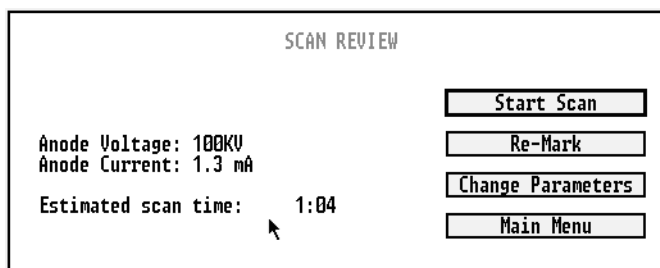
4. The DEFINE SCAN REGION screen will request that the end scan point be identified. Position the scanner arm so that laser is positioned 2 cm below the iliac crests and press the MARK button on the Scanner Control Panel.

- Take care not to bump the patient's legs with the scanner arm. Positioning marks may have to be re-identified if scanner arm movement is interrupted or patient moves.



Once the start and end points have been marked, the **SCAN REVIEW** screen will be displayed on the screen. (See Figure 4-7)

FIGURE 4-7

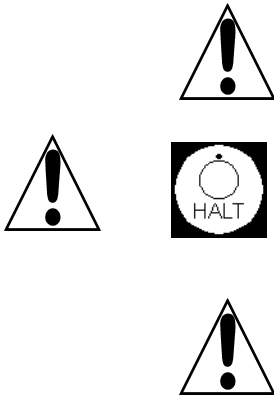


The operator can:

- 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, auto centering, or number of multiple scans of same subject (**multiple scans for scanning phantoms only**). (See Change Parameters on page 6-21)
 - Click on **[Main Menu]** to cancel the scan and return to the Main Menu.
5. Caution the patient to remain still and click on **[Start Scan]** to begin the scan. The Norland 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 start the scan.
 - If Auto Centering mode is enabled, a 'U' shaped scan will precede the Measurement scan.

X-rays will energize and data collection will start as the scanner arm moves down the patient 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.

6. 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.

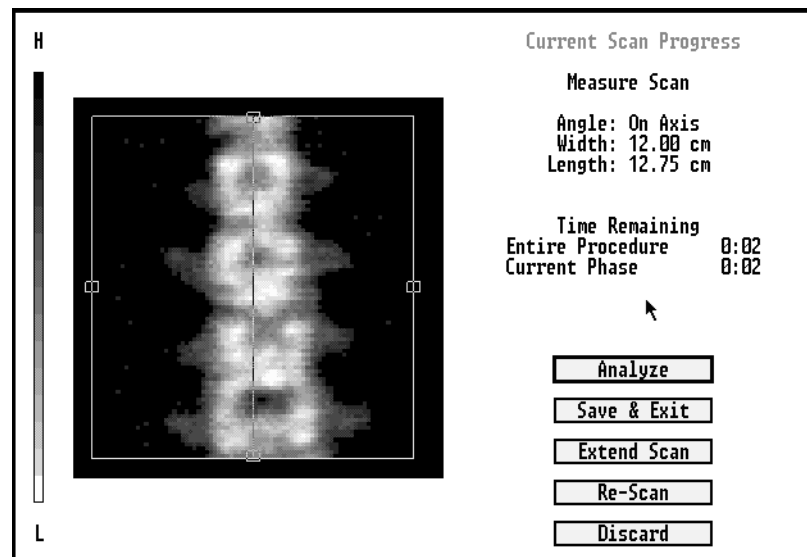


- Clicking on **[Stop Scan]** will pause the scan after the current scan line is completed. A warning message indicating that there aren't enough scan lines to analyze may be displayed. The scan can be resumed or terminated at this point.
- If it is necessary to immediately terminate the x-ray exposure or stop the scanner arm movement, press the **HALT** button on the Scanner Control Panel. 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.

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!

- An audible beep will sound to indicate that the scan is complete. Norland software will also update the Current Scan Progress screen with the "Scan Complete" message. (See Figure 4-8)

FIGURE 4-8



7. Verify that image shows L2-L4 and image is centered, straight, and landmarks such as iliac crest appear in the region of interest.
 - If not, see AP Spine Scan Progress Screen Options on page 6-24 for **[Extend Scan]**, **[Re-Scan]**, and **[Discard]**.
8. If image is satisfactory and no evidence of patient movement during the scan is exhibited, click on **[Analyze]**.
 - The **[Save & Exit]** option will save the data to the default storage for analysis at a later time.

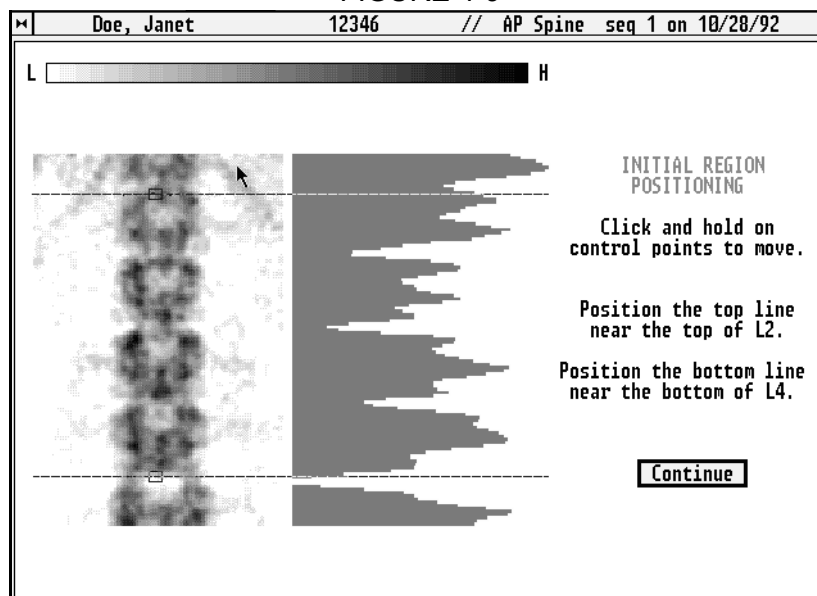


9. Help the patient up from the scanner table if no further scans are to be performed. Make sure scanner arm will not impede patient's ability to sit up. Remember that some patients may require a few minutes to regain equilibrium after lying down for a length of time.

Analysis

1. The image of the scanned spine is displayed on the INITIAL REGION POSITIONING screen (Figure 4-9) with a histogram to the right. The histogram is a line-by-line graphic presentation of the bone mineral content. The "valleys" of the histogram represent areas of low bone mineral content (BMC); longer lines denote higher BMC. In a normal spine, the BMC value will be the lowest at the intervertebral gaps, so the cursors should be positioned on the shortest histogram lines.

FIGURE 4-9



2. Using the click and drag technique, position the top cursor at the top of L2.
3. Position the bottom cursor at the bottom of L4 and click on **[Continue]**.

4. The REVIEW REGIONS screen (Figure 4-10) will display cursors for the vertebral gaps between L2/L3 & L3/L4. If the patient was previously scanned, the original inter-vertebral spacing is used for current scan.
 - The following message may be displayed. If so, click on **[Continue]** to proceed to the REVIEW REGIONS screen.

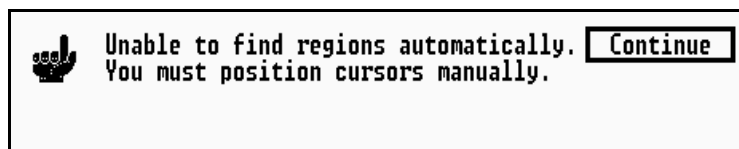
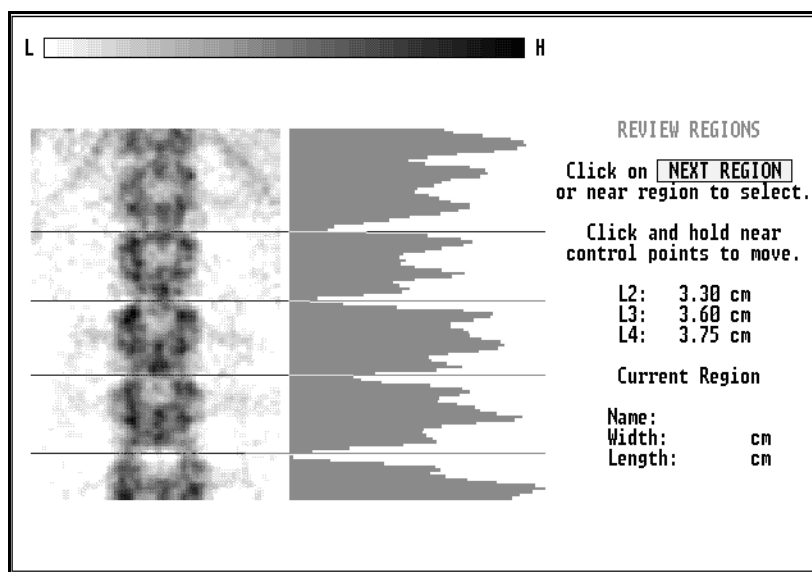


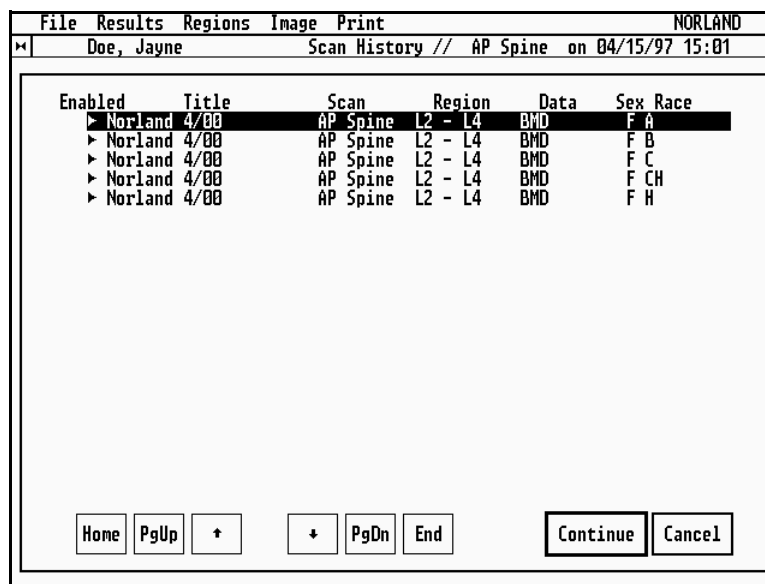
FIGURE 4-10



5. If regions of interest aren't positioned properly, click on **[NEXT REGION]** to activate the cursors.
 - If this is the patient's first AP Spine scan, click on individual control points and drag to move horizontal lines independently of each other.
 - If this is a subsequent AP Spine scan, click anywhere within a vertebral body and drag to move cursors as a group.
 - Position cursors at the valleys of the histogram. The image may be enhanced using the **Contrast Scaling** option under the **Image** menu. (See Contrast Scaling on page 6-6)
 - If patient has been scanned previously, modify cursors to match Comparison Image. (See Comparison Image on page 6-18)
 - If patient has scoliosis, it may be necessary to adjust the angles of the cursors to align with vertebral gaps. (See Angulated Cursors on page 6-20)

6. Once cursors are in position, select *Analysis Menu* item **Results** and then click on Results Page 1.
 - If an exact match of the installed Reference Sets and the ethnic background entered during Scanner Preparation does not exist, the following screen will display with a list of Reference Sets that match patient's gender.

FIGURE 4-11



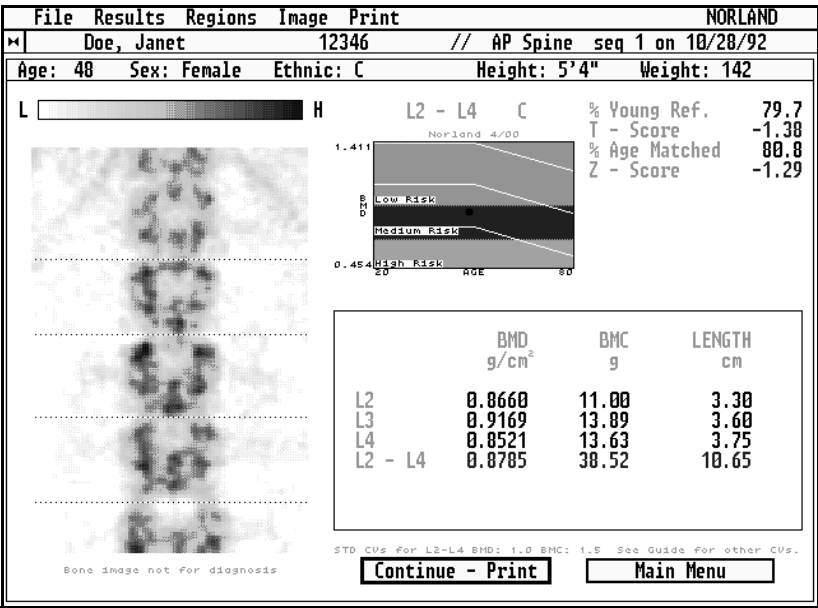
- Select the Reference Set that most closely matches the patient's background and click on **[Continue]** to proceed with the analysis.
- Clicking on **[Cancel]** will cancel the reference set selection, and the Results Page(s) will be display without a reference graph.

Results

The image (which is not for diagnostic purposes), trending or reference population graphs, and results are displayed on Results Page 1. (Figure 4-12)

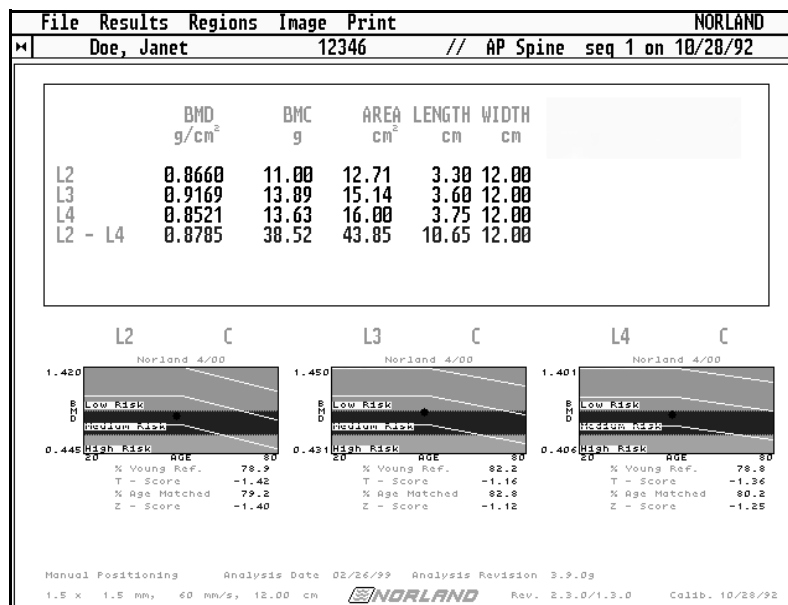
- The T-Score and Z-Score for L2-L4 will be plotted in the reference chart as a black dot and the value is displayed in the upper right corner.

FIGURE 4-12



- If the patient has been scanned before, % Short Term and % Long Term will be displayed below the T-Score and Z-Score information.
- The BMD, BMC, and LENGTH for each vertebral body are displayed as well as for the L2-L4 segment on both pages. Results Page 2 (Figure 4-13) also shows the Total Area and Scan Width.
- Select *Analysis Menu* item **Results** and click on **Results Page 2** or press the [PgDn] key to view Results Page 2.
- Reference graphs for individual vertebral bodies, and detailed scan information are displayed on Results Page 2.

FIGURE 4-13



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 REFER- ENCE	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.

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.

1. View the image on Results Page 1 (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.
2. Click on **[Continue-Print]** on Results Page 1 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. Selecting **Print - Select Printout Header** at the *Analysis Menu* will allow selection of a different printout header.
 - See Figure 1-6, "RESULTS PAGE 1 (AP SPINE)," on page 30 for an example of a printed report.

SCANNING HIP 5

The Hip Scan procedure estimates bone mineral in the Femoral Neck, Greater Trochanter, and Ward's Triangle regions of the left or right hip. Estimates for Total Hip and sBMD Hip are also available.

The process begins with a Scout scan of the hip area. The scan should start above the neck of the femur and extend far enough down the femur so that the femoral neck is in the analysis area. The operator identifies the center of the Femoral Neck on the scout scan image. The operator visually confirms the computer defined measurement regions of interest are correct, then the Measurement scan is taken. Computer-generated regions of interest are analyzed and results are displayed. The region of interest can be modified, but is usually not recommended. The results are saved and printed to complete the study.

Hip Scan Specification

Detailed Hip Scan Specifications	
Scan Sites	Femoral neck, Greater Trochanter, Ward's Triangle, Total Hip
Accuracy ^a	Typically within 1.0% of industry standard
In vivo Precision ^b	See table below
Scan Time	Refer to Technical Reference Section.
Scout Scan Resolution	1.0mm x 4.0mm: Point resolution x line spacing (pixel size)
Measurement Scan Resolution	1.0mm x 1.0mm: Point resolution x line spacing (pixel size)
Scan Speed	Selectable: High Precision - 45mm/sec Standard - 90mm/sec High Speed - 180mm/sec

- a. Based on Standard Speed scans of an anthropomorphic phantom.
- b. Based on scans of 14 subjects, 3 scans each, using standard procedure, scout and measurement scan speed of 180 mm/sec, scout scan resolution of 1mm x 4mm, and measurement resolution of 1mm x 1mm.

		Femoral Neck C.V.			Greater Trochanter C.V.			Ward's Triangle C.V.
Measurement Scan Mode	Measurement Scan Speed	BMD	BMC	AREA	BMD	BMC	AREA	BMD
High Speed	180mm/sec	1.4%	1.8%	0.7%	1.4%	1.8%	1.3%	3.9%

*** 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.

Scout Scan Skin Entrance Dose

Patient Thickness (cm)	Entrance Dose (mrems)
0-7	0.01
>7-10	0.02
>10-13	0.02
>13-16	0.03
>16-19	0.05
>19-22	0.09
>22-25	0.17
>25	0.26

Measurement Scan Skin Entrance Dose

Patient Thickness (cm)	High Precision	Standard	High Speed
0-7	0.17	0.09	0.04
>7-10	0.24	0.12	0.06
>10-13	0.36	0.18	0.09
>13-16	0.44	0.22	0.11
>16-19	0.84	0.42	0.21
>19-22	1.42	0.71	0.36
>22-25	2.64	1.32	0.66
>25	4.11	2.06	1.03

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.

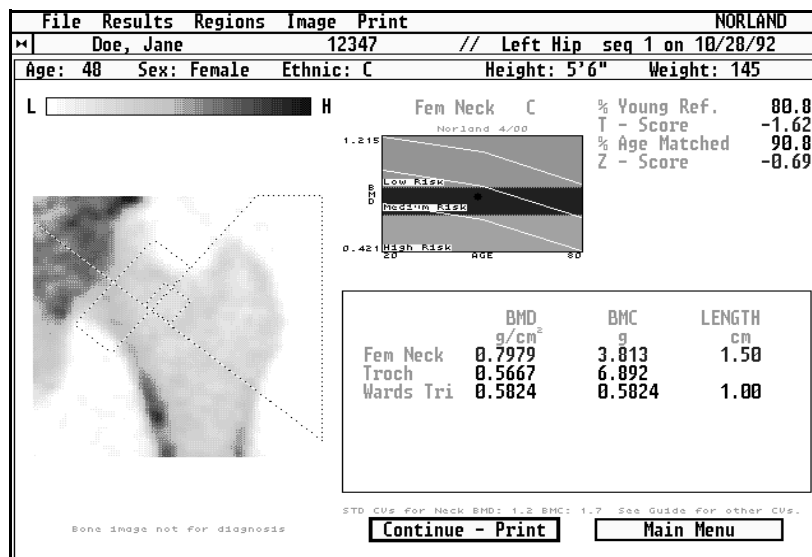
Maintaining High Quality Hip Scans

Patient positioning, scan and analysis techniques can influence the precision and accuracy of Norland 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 system.
- 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 the Norland system 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 external opaque (metal and plastic) objects. Jewelry, buttons, zippers, rivets, buckles, pens, keys etc. can affect the results if they are in the scanning region.
- 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.
- Always allow the Hip Measurement Scan to complete without interaction.
- Ensuring the patient does not move during the scan.

An example of a good quality hip scan is displayed in Figure 5-1.

FIGURE 5-1



- The Femoral Neck cursor should be a 1.5 cm horizontal slice of Femoral Neck, centered on axis, and should not include any other anatomy.
- The scan includes the entire Greater Trochanter, shows the Lesser Trochanter and some of the femoral shaft.
- The Lesser Trochanter is minimized in the region of interest, indicating proper rotation.
- The Femoral shaft is straight, indicating proper abduction.

Quick Reference Instructions

The Hip scan process consists of a brief Scout scan over the Femoral Neck area, a Measurement scan, calculation of numeric results, and saving of data.

- Click on Scan New/Existing Patient.
- Select scan type. (Scan non-dominant hip)
- Enter/Update Patient information.
- Screen patient for contraindications.
- Position the patient face up in center of the scanner table. Place the Leg Separator Block between the patient's heels. Place the Hip Sling with straps under the patient's legs as close to the pelvic area as possible.
- Pull up on the Velcro strap to remove any slack from the leg that will not be scanned. Repeat the process on the leg that will be scanned.
- On the leg that will not be scanned, gently pull the Velcro strap to the next reference number to rotate the hip. Repeat the process on the leg that will be scanned.
- Position the scanner arm over the patient's midsection.



CAUTION the patient not to stare into the beam.

- Turn the laser on and position the laser dot at the approximate center of the Femoral Neck and press the MARK button on Scanner Control Panel to identify the approximate location of the center of the Femoral Neck.
- At the Scan Review screen, click on **[Start Scan]**.
- When the Scout scan is finished, place the cursor at the center of the Femoral Neck on displayed image.

NOTE: The Scout scan may be terminated when the entire femoral neck is visible.

- Click on **[Measure Scan]** and allow the Measurement scan to complete without intervention.
- While system performs analysis, remove positioning aid to make patient comfortable.
- Results Page with analysis will be displayed.

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 report as determined by Print Setup. The Norland software automatically saves the scan data file and returns to the Main Menu when the 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 touch the patient and the computer system at the same time as this could increase leakage currents.

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 - Do not allow the patient to bump, push, or lean on the scanner arm. Manually moving the arm could result in an error message which will require removing the patient from the table and doing the Find Table Dimensions routine.

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 - When positioning the patient, ensure they start by sitting near the center of the table and then swing their legs up. Sitting at either end makes positioning awkward.

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

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

Performing Hip Scan

The patient will be lying in supine position with femurs rotated using the Norland Hip Sling. Light-weight or cotton clothing is acceptable but jewelry, zippers, buttons, back braces, or any metal or high density plastic will affect bone mineral estimations. An examination gown or robe may be more suitable.



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 number is already in use.
For example: (SSN or Clinic/Hospital ID)
 - Sex, Birthdate and Ethnic fields must be entered in order to display Reference Charts.
 - To automatically display the Reference Chart on the Result Page(s) enter the appropriate letter from the table below in the Ethnic field.

A	Asian
B	Black
C	Caucasian
CH	Caucasian/Hispanic
H	Hispanic

- If patient's ethnic background is something other than those listed above (i.e.: American Indian), enter the appropriate background. A list of available reference sets will be displayed when the patient's results are displayed or printed. See Figure 5-17.
 - Pressing **[Enter]** or **[Tab]** will move cursor through fields.
3. At the SCAN TYPE screen, click on appropriate scan type and click on **[Continue]**.

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

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

Height:

Weight:

Technician:

Physician:

[Continue] **[Main Menu]**

- 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 (i.e. values are not adjusted for height and weight).
 - Pressing **[Enter]** or **[Tab]** 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 5-2

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

Home PgUp ↑

End PgDn ↓

Search by Name

Search by ID

Continue Cancel

- 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 5-3

Figure 5-3 displays two search screens. The left screen, titled "SEARCH BY NAME", features a text input field labeled "Name:" and two buttons, "Continue" and "Cancel", at the bottom. The right screen, titled "SEARCH BY ID", features a text input field labeled "ID:" and two buttons, "Continue" and "Cancel", at the bottom.

2. Click on patient name and click on **[Continue]**. (Or double-click on patient name.)
3. At the SCAN TYPE screen, click on appropriate scan type and click on **[Continue]**.
 - Scan the non-dominant hip for best results.
 - Avoid scanning areas of previous surgical procedure or implants for routine Bone Density studies.
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 (i.e. values are not adjusted for height and weight).
 - Pressing **[Enter]** or **[Tab]** will move cursor through fields.
5. Proceed to Patient Positioning to prepare the patient for scanning.

Patient Positioning

Ensure that the patient removes all items from pockets and that clothing is free of metal (i.e. rivets, buttons, zippers) or anything else that might be of a high density. It might be necessary to have the patient change to an examination gown or robe. Shoes should also be removed.

- The illustrations used in these instructions are for a left hip procedure, however these instructions are easily applied to right hip scans by adopting a mirror image of the anatomy presented.
1. Discard any used exam paper and cover the patient table with clean paper from roll. (Special disposal of exam paper is not necessary.)
 2. With the patient lying face up on the scanner table (right side to the table back rest), place the Leg Separator Block between the patient's heels. (See Figure 5-4)
 - Make sure that patient is centered and straight on the table.

FIGURE 5-4



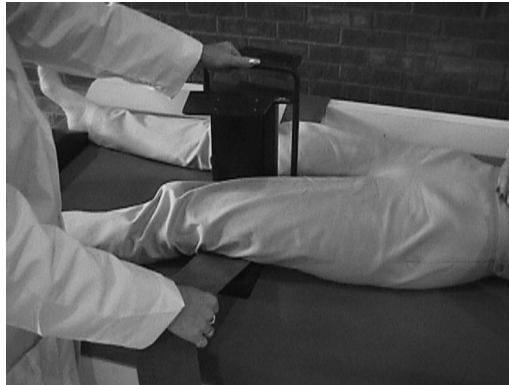
3. Ensure that laser is turned off and move the scanner arm above the patient's chest.



DO NOT position the scanner arm directly over the patient's face.

4. Position the Hip Sling with straps under patient's legs. (See Figure 5-5)

FIGURE 5-5



5. Gently slide the Hip Sling toward the pelvic area.
 - The patient may aid the operator by pulling the Hip Sling as close as possible to the pelvic area without causing undue discomfort. (See Figure 5-6)

FIGURE 5-6



NOTE: Instruct the patient to relax. It is important that the rotation of the leg is a direct result of using the hip sling and not due to the patient rotating the leg in an effort to help the operator.

- Scan the non-dominant side except in case of a previous fracture or prosthetic device.
6. Position the leg that will not be scanned in the fixture and pull up on the Velcro strap to remove any slack. Hold the strap taut but do not rotate the leg. Then secure the strap to the top of the fixture. Repeat for the other leg.

FIGURE 5-7



- Each strap is marked with a scale consisting of letters and numbers. (A-1 through A-7, B1-B7, etc.)
7. On the leg that will not be scanned, note the letter-number combination on the edge of the strap that is closest to the reference line on the top of the fixture.

FIGURE 5-8



8. Pull gently on the strap. The patient's leg should begin to rotate almost immediately.
 - If it does not, start over. Make sure that the strap is free of slack.
 - The operator may find it helpful to grasp the top of the positioning aid with one hand and pull on the strap with the other hand.
 - Patient must not "help" rotate the femur. Improper and inconsistent positioning may result.
9. As the strap is pulled, the numbers on the strap will increment. When the original number returns to the reference mark, the rotation is complete. Secure the strap to the Velcro area on the top of the fixture.
 - For example: if initially at B-4, pull to C-4.



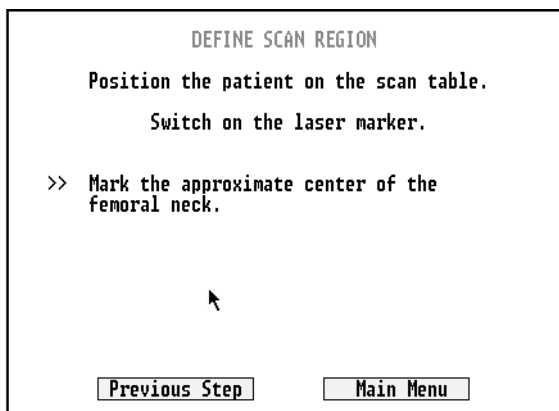
10. Repeat the process on the leg that will be scanned.
 - If the patient's leg does not begin to rotate almost immediately, start over.
11. Position the patient's hands over the chest or at the sides to ensure that they will not be in the scan field.
 - Make the patient as comfortable as possible since movement during the scan will affect the results. The use of a sheet or light blanket will not interfere with scan results. Use of a pillow under the head is recommended.

The patient is now ready for scanning.

Scan Procedure

The DEFINE SCAN REGION should be displayed on the screen. (See Figure 5-9)

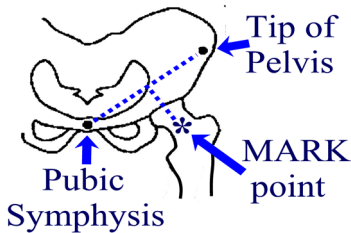
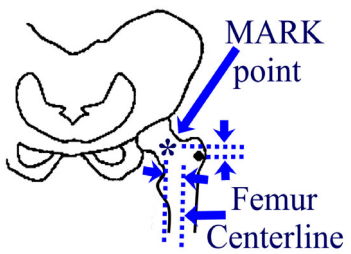
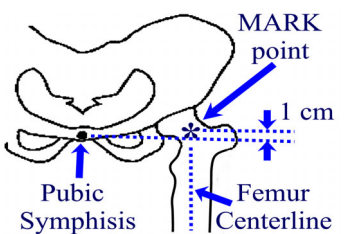
FIGURE 5-9



- The [**Previous Step**] command will return to the previous step.
- The [**Main Menu**] command will cancel the scan and return to the main menu.

1. Ensure that the laser is off and position the scanner arm over the patient's midsection.
2. Locate the approximate center of the Femoral Neck. Three methods are described below.

Locating Femoral Neck Center

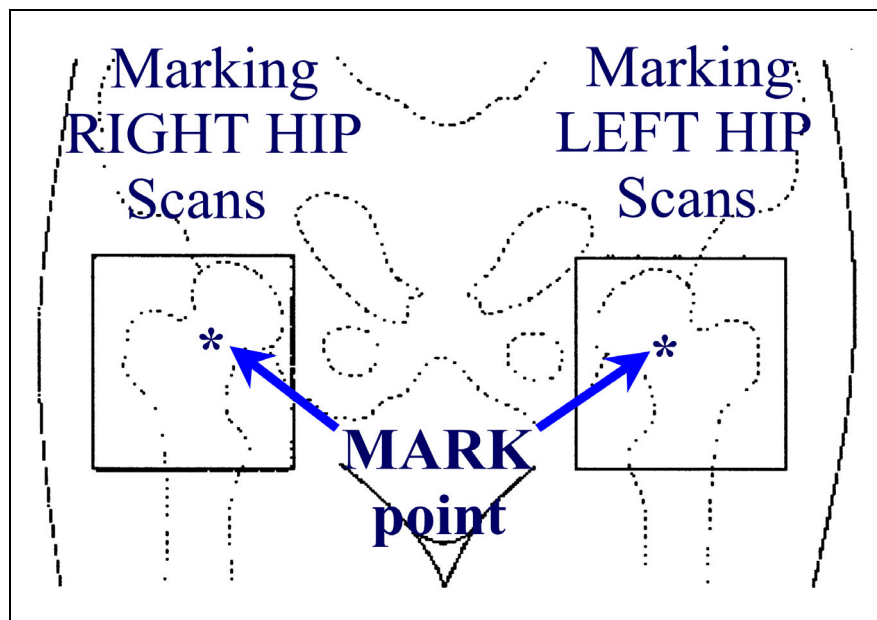
Pelvis tip and pubic symphysis	locate the tip of the pelvis (anterior superior) and the pubic symphysis. Place the laser positioning dot perpendicular to the midpoint of this line and about 4" (10cm) out from the line	
Greater Trochanter	locate the Greater Trochanter and position the laser positioning dot on a point several centimeters above the trochanter, and several centimeters from the centerline of the femur (anterior superior)	
Pubic symphysis	imagine a transverse line across the pubic symphysis. Imagine another line down the center of the femur. Place the laser positioning dot 1cm above the intersection of these two lines	



CAUTION: Do not stare into the beam.

3. Turn on the laser and position the scanner arm to the center of the femoral neck.
 - The typical left and right hip Scout scan regions (default settings) are shown in Figure 5-10. Each region is centered about the recommended MARK point. * corresponds to the recommended MARK point (the center of the femoral neck).

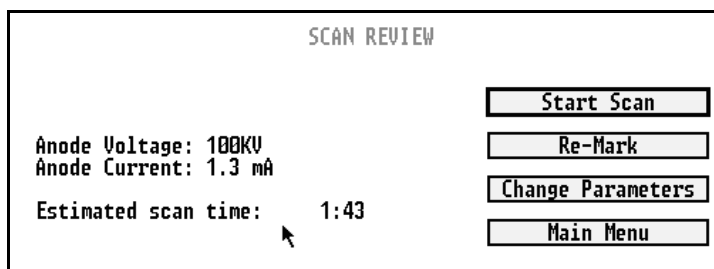
FIGURE 5-10 Recommended Scan Area



4. Press the MARK button on the Scanner Control Panel when the laser is positioned properly. This action tells the computer the approximate center of the femoral neck. The laser will turn off briefly as the computer emits a beep, indicating that the MARK point was acknowledged by the software.

Once the center of the femoral neck has been marked, the SCAN REVIEW screen (Figure 5-11) will be displayed on the screen.

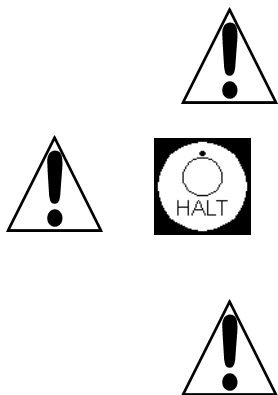
FIGURE 5-11



The estimated scan time is the combined time for the Scout and Measurement scans. The operator can:

- Click on **[Re-Mark]** to re-mark the femoral neck.
 - Click on **[Change Parameters]** to edit any of the scan parameters, such as scan speed, extended width, or number of multiple scans of same subject (**multiple scans for scanning phantoms only**). The Scan Width defines the size of the Region of Interest. (See Change Parameters on page 6-27)
 - Click on **[Main Menu]** to cancel the scan and return to the Main Menu.
5. Click on **[Start Scan]** to begin the scan. The Norland 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 start the Scout scan.

X-rays will energize and data collection will start as the scanner arm moves down the patient for the prescribed length of scout 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.



6. Close observation of the screen image will allow detection of patient movement. 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.
- If it is necessary to terminate the x-ray exposure or stop the scanner arm movement, press the **HALT** button on the Scanner Control Panel. 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.

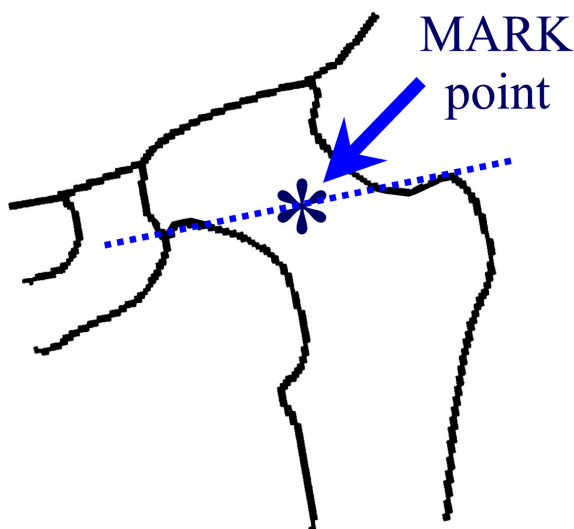
If computer power is recycled in this instance, the scanner arm will return to origin position. ENSURE THAT PATIENT IS NOT IN SCANNER ARM PATH!

7. The Scout scan may be terminated when the entire femoral neck is visible.

When the Scout scan has completed or terminated, the Current Scan Progress screen (Figure 5-13) will be updated to indicate that Scout scan is complete and an audible beep will sound. If Scout is satisfactory, proceed to Step 8 to prescribe the Measurement scan. If not, go to Scout Scan Progress Screen Options on page 6-28 for options.

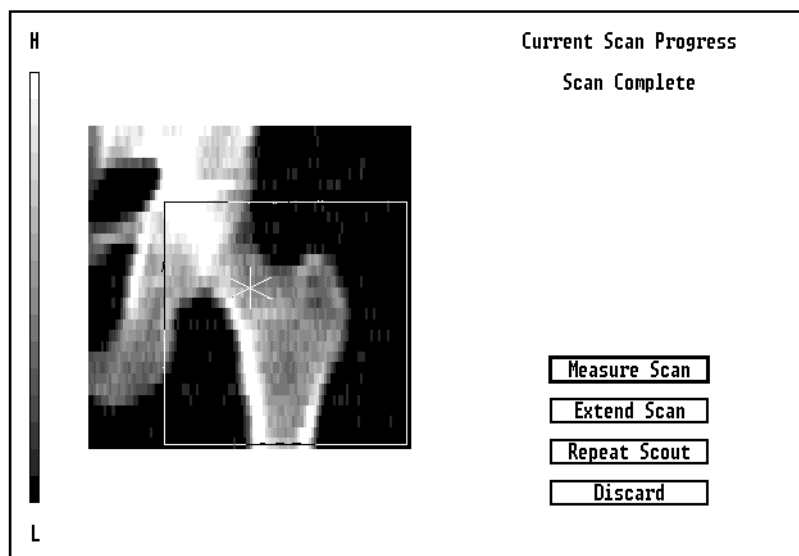
8. Imagine a line across the femoral neck, as shown in Figure 5-12.

FIGURE 5-12



9. Click on the cursor, drag it to the midpoint of the imaginary line, and release the mouse button to deposit the cursor. (See Figure 5-13)

FIGURE 5-13



- A routine Hip Measurement scan should include the entire Femoral Neck, the entire Greater Trochanter, part of the femoral shaft and the ilium in the scanned area.



NOTE: If the size of the ROI is insufficient, terminate the scan and restart. When the **SCAN REVIEW** screen is reached (See Figure 5-11) click on **[Change Parameters]** to select **Extended Width** to resize ROI to 12 cm x 12 cm.

10. Click on **[Measure Scan]** to start the Measurement scan after cursor is placed correctly. The software will:
 - Select the appropriate filter combinations as determined by the patient thickness.
 - Measure detector counts with no x-rays for background reference.
 - Open the beam shutter and start the Measurement scan.

X-rays will energize and data collection will start as the scanner arm moves down the patient for the prescribed measurement 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 display the image as it develops, show how many lines will be scanned and give an estimate of the remaining Measurement scan time.



NOTE: Always allow the Measurement scan to complete without interruption. This will ensure that the region of interest is the same from scan to scan and will ensure the best precision.

11. Monitor the image closely for any indication of patient movement. The scan should be terminated immediately if patient moves during scan. Patient movement will adversely affect the quality of the scan.

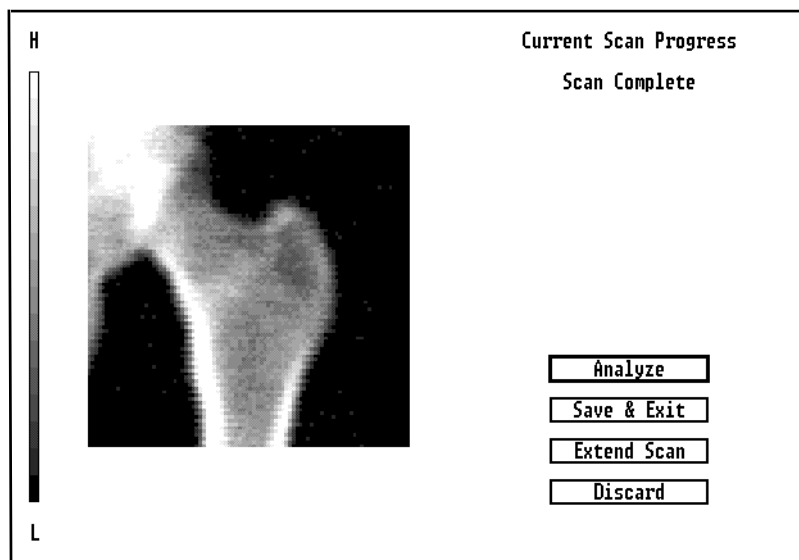
- Clicking on **[Stop Scan]** will pause the scan after the current scan line is completed. A warning message indicating that there aren't enough scan lines to analyze may be displayed. The scan can be resumed or terminated at this point.
- If it is necessary to terminate the x-ray exposure or stop scanner arm movement, press the **HALT** button on the Scanner Control Panel. 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.



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!

An audible beep will sound to indicate that the scan is complete. Norland software will also update the Current Scan Progress screen with the "Scan Complete" message. (See Figure 5-14)

FIGURE 5-14



12. Review the image. If image quality is satisfactory and no evidence of patient movement during the scan is exhibited, click on **Analyze**.

- The **Save & Exit** option will save the data to the default storage for analysis at a later time.
 - The **Extend Scan** option allows extension of the measurement scan by adding a user-defined number of scan lines to the current scan.
 - The **Discard** option will, after confirmation by the operator, discard collected data and return to the Main Menu.
13. Help the patient up from the scanner table if no further scans are to be performed. Make sure scanner arm will not impede patient's ability to sit up. Remember that patient may require a few minutes to regain equilibrium after lying down for a length of time.
14. If automatic computer analysis is successful, the currently selected Results Page will be displayed. (See Figure 5-15)
- If either of the following messages is displayed, the regions of interest must be re-defined. See Modify Regions on page 5-23 to reposition cursors and redefine the regions of interest.

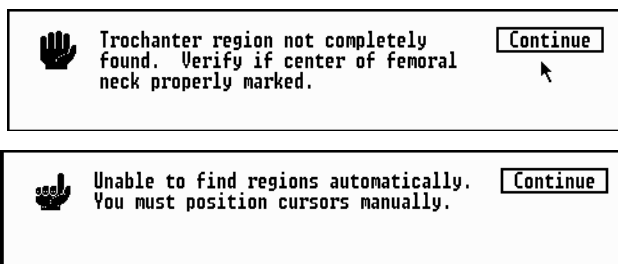
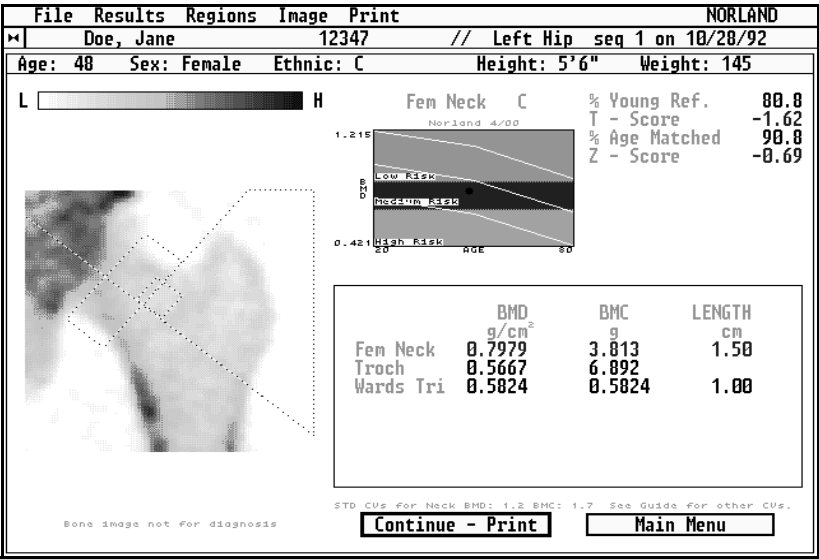


FIGURE 5-15



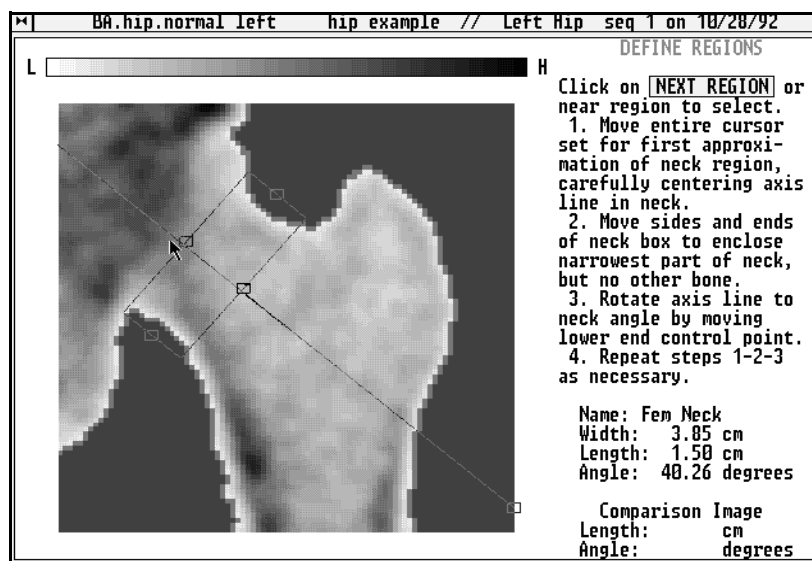
The cursor box should define an area in the Femoral Neck that doesn't include trochanter or pelvis and the centerline cursor should pass through the center of the Femoral Neck.

Norland strongly recommends using the computer-generated analysis unless the regions of interest are blatantly incorrect.

Modify Regions

1. Select *Analysis Menu* item **Regions** and click on **Modify Regions**. The DEFINE REGIONS screen will display.

FIGURE 5-16



2. Click on **[Next Region]** at the DEFINE REGIONS screen to select the cursor box.
 - Click and drag from anywhere within the cursor box to drag the cursor group to the new position. Center the axis line in the Femoral Neck.
 - The side cursors should be adjusted to include all of the neck. The neck cursor box should include only the neck. It should not include any other bone. Reposition the side cursors by using the pointer to click on a control point. Drag the cursor to its new location.
 - The neck cursor box should enclose the narrowest part of the neck. To adjust the length of the Femoral Neck cursor box, use the pointer to click on one of the control points of the box that are on the centerline axis. Drag it along the centerline to adjust the length. Ideal length is 1.5 cm (or longest length possible).
 - Align the centerline by clicking on the centerline control point (the box located in the lower right corner of the image; opposite corner on right hip scan) and angulate to attain a horizontal slice of Femoral Neck.



NOTE: If it is not possible to attain either a 1.5cm or 1.0cm femoral neck length without including pelvis, adjust the cursors to a maximum femoral neck length and note this dimension on the Edit Scan Comments screen. Use the same Femoral Neck length on subsequent scans of the same patient.

3. Once all regions are properly positioned, select Analysis Menu item **Results** to view result values.
 - If an exact match of the installed Reference Sets and the ethnic background entered during Scanner Preparation does not exist, the following screen will display with a list of Reference Sets that match patient's gender.

FIGURE 5-17

File Results Regions Image Print						NORLAND	
Doe, Jayne						Scan History // Left Hip on 04/15/97 15:11	
Enabled	Title	Scan	Region	Data	Sex	Race	
▶ Norland	4/00	Hip	Fem Neck	BMD	F	A	
▶ Norland	4/00	Hip	Fem Neck	BMD	F	B	
▶ Norland	4/00	Hip	Fem Neck	BMD	F	C	
▶ Norland	4/00	Hip	Fem Neck	BMD	F	CH	
▶ Norland	4/00	Hip	Fem Neck	BMD	F	H	

Home
PgUp
↑
↓
PgDn
End

Continue
Cancel

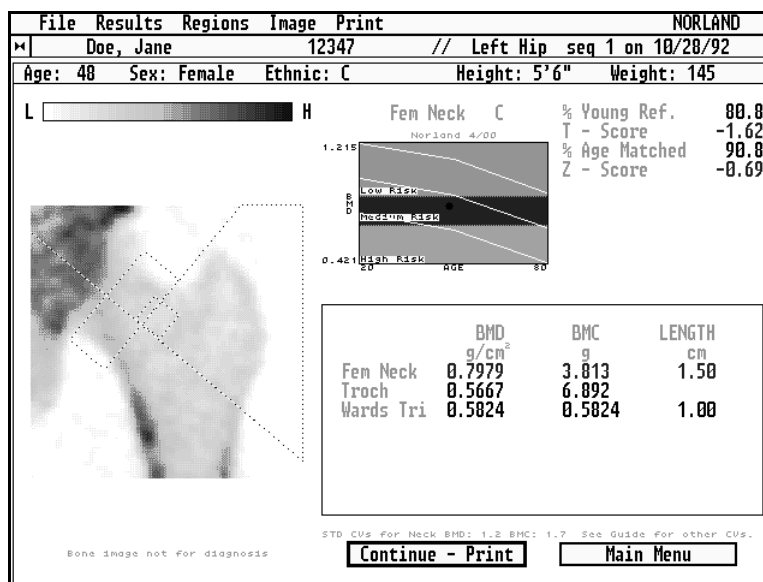
- Select the Reference Set that most closely matches the patient's background and click on **[Continue]** to proceed with the analysis.
- Clicking on **[Cancel]** will cancel the reference set selection, and the Results Page will be display without a reference graph.

Results

The image (which is not for diagnostic purposes), trending or reference population graphs, and results are displayed on Results Page 1.

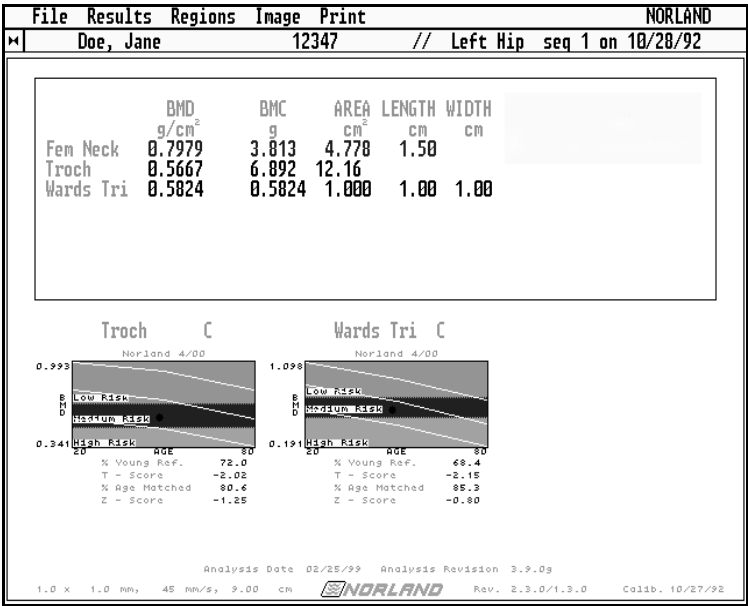
- The T-Score and Z-Score for the Femoral Neck will be plotted in the reference chart as a black dot and the results will be displayed in the upper right of the Results Page 1 (Figure 5-18).

FIGURE 5-18



- If the patient has been scanned before, % Short Term & % Long Term will be displayed below the T-Score and Z-Score information.
- The BMD, BMC, and Length for each region of interest are displayed on both pages. Results Page 2 also shows the Area and Width (Figure 5-19).
- Select *Analysis Menu* item **Results** and click on **Results Page 2** or press the [PgDn] key to view Results Page 2.
- Reference graphs for other regions of interests, and detailed scan information are displayed on Results Page 2.

FIGURE 5-19 .



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 individual 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

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.

- Once cursors are positioned correctly and analysis results are satisfactory, click on **[Continue-Print]** on Results Page 1 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. Selecting **Print - Select Printout Header** at the *Analysis Menu* will allow selection of a different printout header.
 - See Figure 1-9, "RESULTS PAGE 1 (HIP)," on page 33 for an example of a printed report

ADDITIONAL TECHNIQUES 6

Norland software has been designed to offer the operator automatic analysis routines. Chapter 6 provides information on creating user-defined regions of interest, tools for enhancing image display, and other utilities for performing non-routine operations. Alternate methods of performing printing operations are also presented.

Printing Options

The typical method of printing reports is by clicking the **[Continue-Print]** command from Results Page 1 after the cursor placement has been verified.

- The report is printed according to the parameters set in the Print Setup.
- Scan data is saved to the default storage location.
- The Main Menu is re-displayed.

Printing from the Analysis Menu

The *Analysis Menu* is displayed whenever a Results Page is displayed. The **Print** option on the *Analysis Menu* allows control of the Print Queue. The current report can be printed and the Printout Header is selected here.

Printing from the Main Menu

The **Print** option on the Main Menu allows control of the Print Queue and the following print options.

Print Report	Opens Print Setup for printing immediate QA report.
Start Printing Queue	Starts printing files in queue. See next page.
Stop Printing Queue	Stops printing files in queue. See next page.
Cancel Remaining Copies	Cancels printing of remaining copies. See next page.
Print Scan	Prints the currently selected scan. Current print setup dictates the print parameters.
Print Patient	Prints all scan files for the currently selected patient. Current print setup dictates the print parameters.
Print All	Prints reports for all scan files in system (filtered by a date range; screen shown below). Current print setup dictates the print parameters.

PRINTING DATE RANGE

Starting Date:

Ending Date: 03/23/99

Starting Time:

Ending Time: 10:00

Note: Pressing <Esc> will cancel this operation once in process.

Start / Stop Printing Queue

When Print Setup is configured for Queue printing, reports are sent to the Print Queue when the **[Continue-Print]** command is clicked.

Start Print Queue

Select **Print** from the *Main* or *Analysis Menu* and click on **Start Printing Queue**.

All reports in the Print Queue will begin printing with the oldest file printing first. The reports will continue printing until one of the following conditions exist.

- All reports are printed.
- The Stop Print Queue command is executed.
- The printer runs out of paper.
- Drop-down menu is visible on screen.

The ink cartridge(s) could be depleted during the queued print job. Remaining reports will exhibit poor print quality.

NOTE: If the **Start Printing Queue** command is shown in grayed-out typeface, the printing queue is empty.

Stop Print Queue

Select **Print** from the *Main* or *Analysis Menu* and click on **Stop Printing Queue**.

- The current report copy finishes printing. Any reports that remain in the print queue may be printed later.

Cancel Remaining Copies

Select **Print** from the *Main* or *Analysis Menu* and click on **Cancel Remaining Copies**.

- The printout in progress will finish printing. The remaining additional copies of the queued report will not be printed. The next report in the queue will begin printing after clicking on **[Continue]**.

Patient Personal Data

Although the patient's name, ID number, and information necessary for effective analysis are entered when scanning a new patient, there is more information that can be kept in the patient's file. Billing information and more detailed personal background can be entered using the Patient Personal Data screen.

1. Select *Main Menu* item **Select** and click on **Select a Patient**. The patient list will display.

FIGURE 6-1

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

None PgUp ↑

End PgDn ↓

Search by Name

Search by ID

Continue Cancel

- 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 6-2

SEARCH BY NAME

Name:

Continue Cancel

SEARCH BY ID

ID:

Continue Cancel

2. Click on patient name so that it is highlighted.

3. Select *Main Menu* item **Select** and click on **Patient Personal Data**. The PATIENT PERSONAL DATA screen will display.
 - Use this screen to correct gender, birthdate and ethnic information if initially entered incorrectly, resulting in incorrect or no reference chart on Results pages.
 - This screen is also displayed when adding a patient from the *Main Menu (Select)*.

FIGURE 6-3

PATIENT PERSONAL DATA	
<div>Mandatory Information</div> <div>Name: Doe, Jane</div> <div>ID: 12347</div>	<div>Phone Numbers Evening: <input type="text"/></div> <div>Daytime: <input type="text"/></div> <div>Address: <input type="text"/></div> <div>Address: <input type="text"/></div> <div>Address: <input type="text"/></div> <div>Arm Span: <input type="text"/> Menopause Year: 00</div> <div>Bone History: <input type="text"/></div> <div>Treatment: <input type="text"/></div> <div>Billing Information: <input type="text"/></div> <div>Other Medications: <input type="text"/></div> <div>Comments: <input type="text"/></div> <div>Comments: <input type="text"/></div> <div>Comments: <input type="text"/></div>
<div>Important Information</div> <div> <input checked="" type="radio"/> Female <input type="radio"/> Male <input type="radio"/> N/A </div> <div>Birth Date: 05/10/44</div> <div>Ethnic: CAUCASIAN</div> <div>Height: 5'6"</div> <div>Weight: 145</div> <div>Physician: <input type="text"/></div> <div>Technician: <input type="text"/></div>	
<div>Accept Changes</div> <div>Do Not Accept</div>	

The Mandatory Information and Important Information sections should already be complete. The information on the right can be entered or updated at any time and will be in effect for future studies.

Billing information will not be displayed on a Results Page or on a printed report.

The "Menopause Year" field requires an entry indicating the year that the patient started menopause.

The "Arm Span" field is the measurement from finger tip to finger tip with arms extended. Use consistent units of measurements.

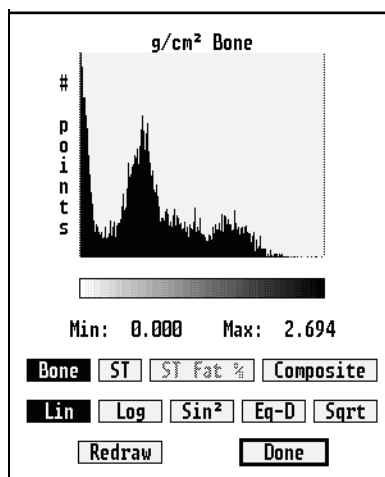
4. Click on **Accept Changes** to save any changes; clicking on **Do Not Accept** will exit without saving changes.

Contrast Scaling

The Image option on the *Analysis Menu* has a command for Contrast Scaling. Contrast Scaling allows customization of the scan image on the screen by moderating the image brightness or selecting an alternate density spectrum distribution algorithm. **Quantitative results and scan data remain unchanged**, but the image on the display and the printed report can be enhanced in several ways.

1. Selecting *Analysis Menu* item **Image** and clicking on **Contrast Scaling** will display the Contrast Scaling window (Figure 6-4).

FIGURE 6-4



This window consists of a title, a graph of the number of data points plotted against BMD (in g/cm^2), a density spectrum, the minimum and maximum BMD values for the selected image, and control buttons for selecting the composition and scaling options.

Composition Mode

The first row of options control the Composition Mode. Each mode has a unique title and cursors. Selections will impact the scan image when the Redraw button is clicked.

[Bone]	Default setting for all scan types that permits viewing the image in terms of bone value of each point.
[ST]	Provides an image scaled in terms of the non-bone tissue value of each point.
[ST Fat %]	Provides an image of the scan region showing regional fat distribution, such as pockets of fatty tissue.
[Composite]	Provides a low energy attenuation image, similar in appearance to an X-ray film image.

- All modes have adjustable cursors for filtering noise.
1. Adjust cursors by:
 - Click on one of the vertical composition cursors (a dotted line found at each end of the graph). Drag the cursor to a new location, thus narrowing the range of density values on the graph.
 - As the vertical composition cursors change position, the MIN and MAX density values are updated to indicate the graph's change in density scaling.
 2. To view the effects of composition cursor position or composition mode selection on the image, click on **[Redraw]**.

Scaling Mode

The second row of controls contain 5 Scaling Modes.

[Lin]	Denotes a linear distribution of data points, from minimum to maximum, when presenting a scan image. Lin is the default scaling mode when entering analysis and is the most commonly used mode.
[Log]	Denotes a logarithmic scaling of data points. Log accommodates a wide distribution of dynamic ranges of values.
[Sin2]	Denotes a Sin^2 density scaling. This mode permits the viewer to focus-in on specific regions of change, such as bone edges, by moving the MIN and MAX composition cursors.
[Eq-D]	Denotes 'equalized distribution' of data values with an equal number of data points assigned to each of the 27 (Color) or 33 (Grayscale) density spectrum levels.
[Sqrt]	Is a plot of the square root of the data points and is similar to Log.

- To view the effects of scaling cursor position or scaling mode selection on the image, click on **[Redraw]**.
- Click on **[Done]** to close the Contrast Scaling window.

System software does not retain the Contrast Scaling settings for subsequent scans of the same patient. Upon return to the Main Menu, Contrast Scaling parameters are reset to the default settings. Therefore, print the report for the contrast-scaled image before returning to the Main Menu.

- Click on **[Continue - Print]** at Results Page.

Special Region Cursors

Special Region Analysis software estimates bone mineral in operator-defined regions of the DXA scan.

Norland software automatically includes defined special regions when it calculates and presents numeric results, and it saves the cursor placement and size information with the analysis.

Subsequent scans should incorporate the Show Comparison feature to aid in replication of any special region cursors.

Number of Special Regions Permitted

The maximum number of special regions permitted depends on the scan type. The table below lists the maximum number of Special Regions permitted for each Norland scan option.

Scan Modality	Maximum # of Special Regions
AP Spine	2
Left/Right Hip	2
Whole Body ^a	2
Left/Right Forearm ^a	2
Lateral Spine ^a	2
Research ^b	5
Small Subject ^b	5

a. This modality is not available on all models.

b. This modality is optional.

Add a Special Region

The special region analysis process begins with placement of the first cursor box to circumscribe the area of interest.

1. Select **Regions** from the *Analysis Menu* and click on **Add a Region**.
2. Type in a name to identify the special region (up to 10 characters).

3. Select a cursor type from the list. See table below for more information.

Special Region Cursors

4 Sides / Side Control	Cursor is the original on-axis rectangular area defined with side placement. It is commonly used for regular on-axis areas or areas that need dimensions to be displayed or printed.
4 Sides / Corner Control	Cursor is a quadrilateral area defined with corner placement, resulting in angular special region cursors.
8 Sides / Corner Control	Cursor is an eight-sided area also defined with corner placement. It can be used to circumscribe more complex regions.

4. Click on **[Continue]**.

On the REVIEW REGIONS display, the name of the special region appears under the heading of Current Region, seen in the lower right corner of the screen. The dimensions of the On-Axis cursor box are listed under Width and Length.

- The REVIEW REGIONS screen is displayed for AP Spine; the DEFINE REGIONS screen is displayed for Hip scans. Cursors work the same in either screen.

The cursor can be modified as any other cursor.

1. Click on any point inside the cursor and drag to new location.
2. Click on any control point to reshape cursor.
3. When cursor is in place, select Results Page from *Analysis Menu* to initiate calculations.

NOTE: The 4 Sides / Side Control cursor will update width and length as control points are adjusted.

The special region will be saved with the scan data file. Future scans should use the same dimensions for effective trending comparisons.

Modify Existing Special Region

1. Select **Regions** from the *Analysis Menu* and click on **Modify Regions**. The REVIEW REGIONS screen will display.
 - The REVIEW REGIONS screen is displayed for AP Spine; the DEFINE REGIONS screen is displayed for Hip scans. Cursors work the same in either screen.
2. Click near the center of the desired region. The Current Region name appears at the screen's lower right corner.
 - Or click on **[Next Region]** to display the name(s) of the defined region(s) under Current Region. The cursor box control points appear when a named region is selected.
3. Position the pointer anywhere inside the box and drag the box to the new region. Then, click on one of the box control points and drag it to the desired location.

4. Continue positioning the remaining sides or corners of the cursor box until you are satisfied with the cursor box size and placement for the modified region.

Delete A Special Region

1. Select **Regions** from the *Analysis Menu* and click on **Modify Regions**. The REVIEW REGIONS screen will display.
 - The REVIEW REGIONS screen is displayed for AP Spine; the DEFINE REGIONS screen is displayed for Hip scans. Cursors work the same in either screen.
2. Click near the center of the desired region. The Current Region name appears at the screen's lower right corner.
 - Or click on **[Next Region]** to display the name(s) of the defined region(s) under Current Region. The cursor box control points appear when a named region is selected.
3. Select **Regions** from the *Analysis Menu* and click on **Delete Selected Region**.
4. Click on **[Delete]** to confirm the deletion.

Rename A Special Region

1. Select **Regions** from the *Analysis Menu* and click on **Modify Regions**. The REVIEW REGIONS screen will display.
 - The REVIEW REGIONS screen is displayed for AP Spine; the DEFINE REGIONS screen is displayed for Hip scans. Cursors work the same in either screen.
2. Click near the center of the desired region. The Current Region name appears at the screen's lower right corner.
 - Or click on **[Next Region]** to display the name(s) of the defined region(s) under Current Region. The cursor box control points appear when a named region is selected.
3. Select **Regions** from the *Analysis Menu* and click on **Rename Selected Region**.
4. Type in the new name in place of the existing Current Region name in the screen.
5. Click on **[Continue]** to confirm the new name.

Include/ Exclude



Although not recommended, it may be necessary to remove artifacts from a scan region. Doing so will negate the automatic analysis provided by Norland software.

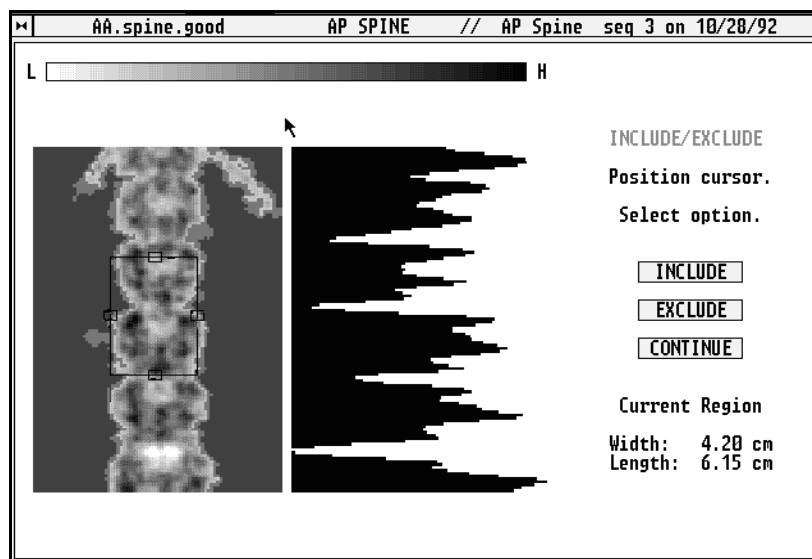
Norland software provides both an EXCLUDE and an INCLUDE function to be used for editing scan results. If it is necessary to use the function to remove artifacts or islands of tissue from a scan region, subsequent scans of the same patient must have the identical INCLUDE or EXCLUDE operation performed in order to obtain meaningful serial analyses.

Exclude

The EXCLUDE function allows an operator to delete tissue from a scan region. The excluded area is subtracted from the resulting calculations. Scan data is not changed, but tabulated result values are affected by this operation.

1. Select **Image** from the *Analysis Menu* and click on **Show Baseline**.
 - All non-bone tissue in scan image will be displayed in the baseline color or shade. (Not related to density spectrum)
2. Select **Regions** from the *Analysis Menu* and click on **Include/Exclude**. The INCLUDE/EXCLUDE screen will display.

FIGURE 6-5



3. Position the pointer anywhere inside the box and drag the box to the general area to be excluded.
4. Use click and drag technique to position the cursor around the artifact to be excluded.



NOTE: If an external object such as buttons or zippers are included in the scan region, it is better to re-scan the patient after removing the object. Using the **EXCLUDE** function deletes underlying or superior tissue values in the excluded region from the calculations.

5. Click on **[Exclude]**.
 - The excluded area is removed from the image and the cursor box remains positioned over the excluded area.
6. Click on **[Continue]** to define another region to be excluded.
 - To exclude an irregularly-shaped artifact, make the size of the box small. Drag it so it covers a part of the artifact, then click on **[Exclude]**. Drag it to cover another part of the artifact and click on **[Exclude]**. Continue this incremental excluding process until the entire artifact is eliminated.
7. Select **Results** from the *Analysis Menu*.
 - Click on **Results Page 1** to view the scan image along with the numeric results.
 - Click on **Results Page 2** to view only the numeric results.

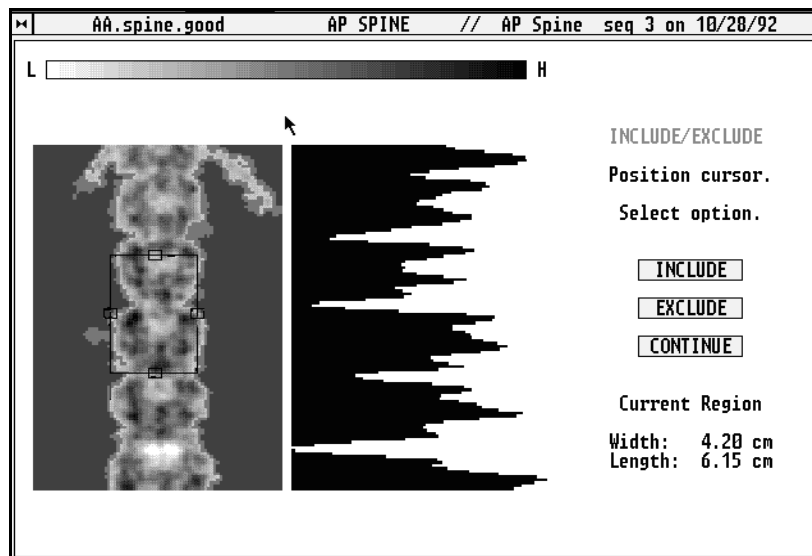
Data within any excluded region is removed from the results calculations. Norland software stores the EXCLUDE region information with the scan analysis.

Include

The INCLUDE process is used in a similar fashion to the EXCLUDE process. It may be used to include odd-shaped islands of the scan, which did not contribute to BMD results as bone information or were separated from the primary investigation site. It may also be used to recover data points previously excluded (see previous section). Scan data is not changed, but tabulated result values may be affected by this operation.

1. Select **Image** from the *Analysis Menu* and click on **Show Baseline**.
 - All non-bone tissue in scan image will be displayed in the baseline color or shade.
2. Select **Regions** from the *Analysis Menu* and click on **Include/Exclude**. The INCLUDE/EXCLUDE screen will display.

FIGURE 6-6



3. Position the pointer anywhere inside the box and drag the box to the general area to be included.
4. Use click and drag technique to position the cursor around the artifact to be included.
5. Click on [**I**nclude].
 - The included area is included in the region of analysis.
6. Click on [**C**ontinue].
 - To include an irregularly-shaped artifact, make the size of the box small. Drag it so it covers a part of the artifact, then click on [**I**nclude]. Drag it to cover another part of the artifact and click on [**I**nclude]. Continue this incremental including process until the entire artifact is enclosed.
7. Select **Results** from the *Analysis Menu*.
 - Click on **Results Page 1** to view the scan image along with the numeric results.
 - Click on **Results Page 2** to view only the numeric results.

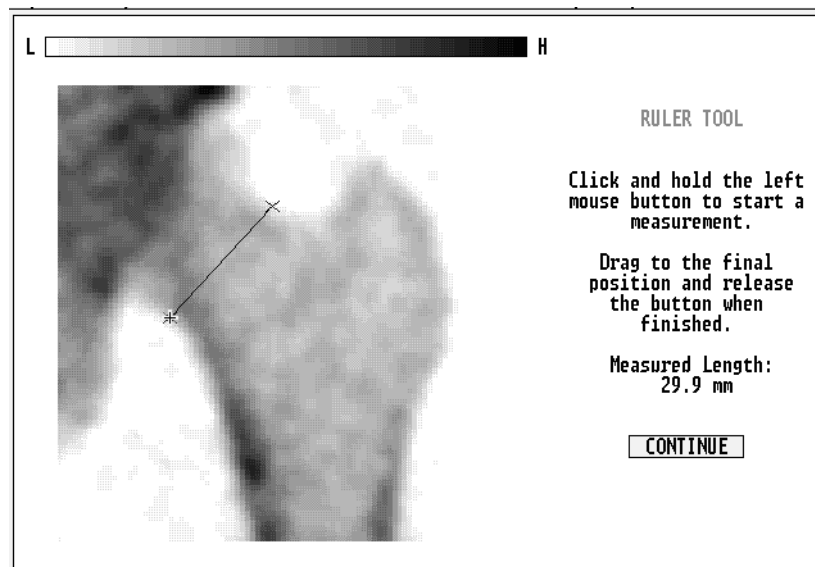
Data within any included region is added to the results calculations. Norland software stores the INCLUDE region information with the scan analysis.

Ruler Tool

A ruler tool is included in the software for displaying linear measurements of anatomical features.

1. Select **Regions** from the *Analysis Menu* and click on **Ruler Tool**. The RULER TOOL screen will display.

FIGURE 6-7



2. Position the cursor at start point of measurement and click & hold left mouse button to begin measurement.
3. Drag to the final position and release the button when finished. The measured length will be displayed in millimeters on the screen.
4. Click on **[Continue]** to display the DEFINE REGIONS screen.
 - The measurement will not be a permanent part of the image.

Reanalyzing Scan Data

Norland software allows an operator to reanalyze a scan using the Reanalyze command. This command starts the analysis process over from the beginning, retaining any operator-defined special regions.

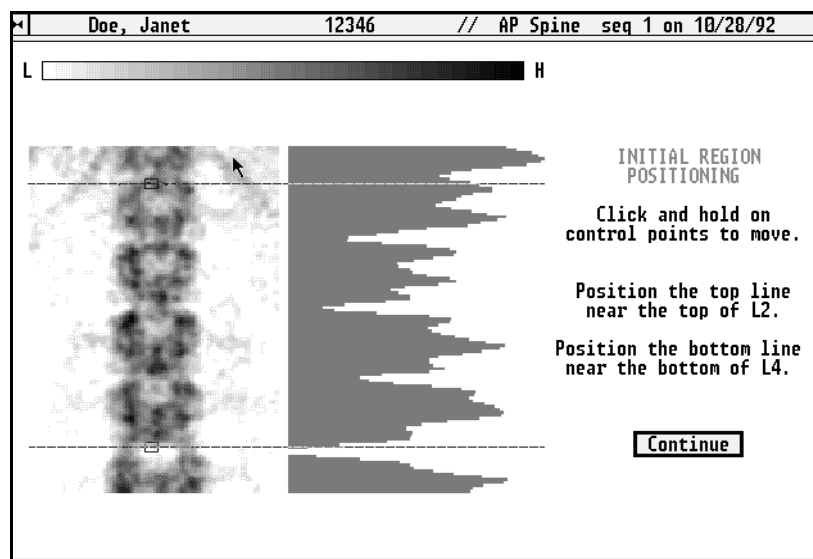
- After the scan data is collected, the measurement region of interest cannot be changed using **Reanalyze**.
- The Reanalyze command may also be used to reanalyze old scans with a new version of Norland software, or to recover all regions, in one operation, which may have been excluded with the Include/Exclude function.



If a series of scans are to be reanalyzed, it is important to reanalyze the patient's initial scan first. This will establish new baseline areas and values to which subsequent scans may be compared.

1. Select **Modify Regions** from the *Main Menu (Analysis)* or *Analysis Menu (Regions)*.
2. Click on **Reanalyze**. The INITIAL CURSOR POSITIONING screen will display (a spine scan is shown in Figure 6-8 and a hip scan is shown in Figure 6-9 on the next page).

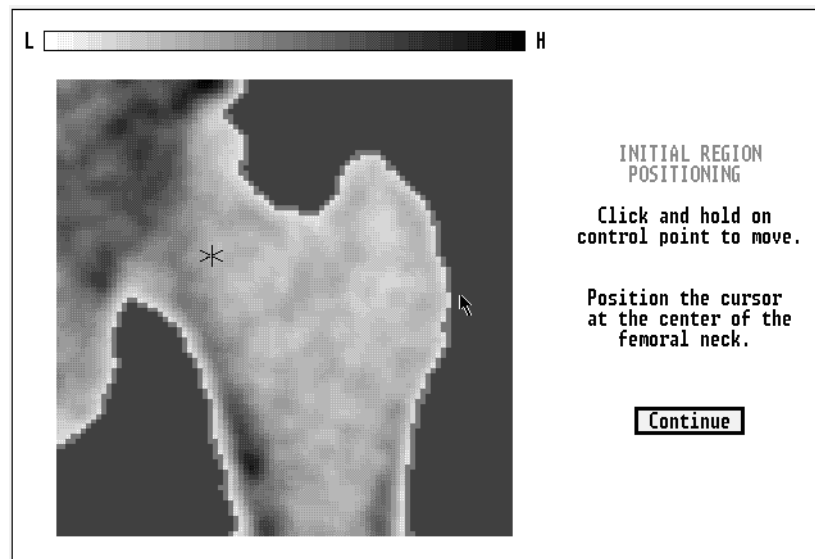
FIGURE 6-8



3. Position cursors as in normal analysis.
 - Analysis Options can be changed prior to Reanalyze.

Norland software reprocesses the data to complete the reanalysis, retaining operator-defined special regions.

FIGURE 6-9



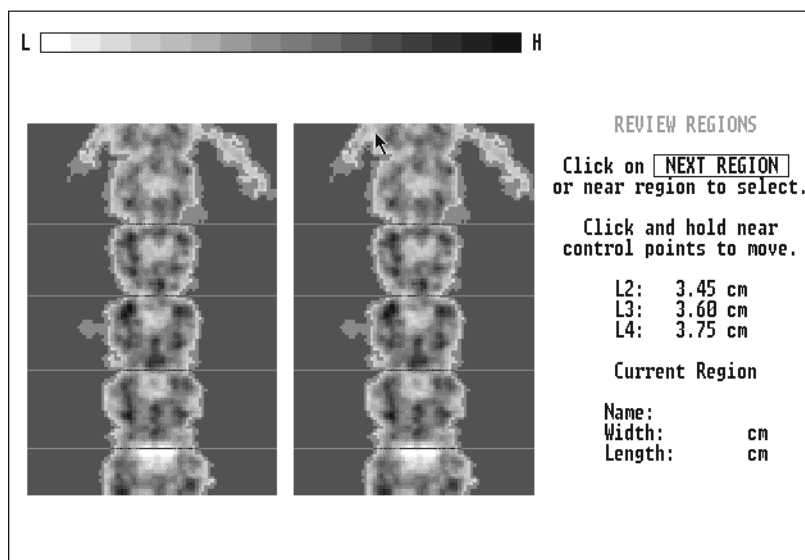
Comparison Image

Modifying regions of interest to match previous scans of the patient can be performed using a comparison image of 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 6-10 shows an AP Spine Comparison.

FIGURE 6-10

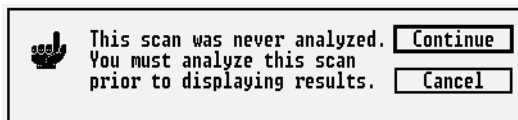


- Cursors can be positioned to match the comparison image.
2. Once positioned, selecting **Results** from the *Analysis Menu* will recalculate the data with the new cursor positions. It is not necessary to Hide Comparison before displaying the results or saving the data.

Analyzing Saved Scan Data

The Norland 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.



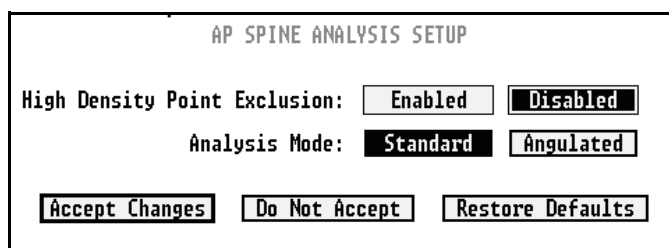
3. Position regions of interest as described in the normal scan procedure.
4. Once cursors are in position, select *Analysis Menu* item **Results** and then click on Results Page 1.
 - If patient has been scanned previously, modify cursors to match Comparison Image.

Special Techniques

The techniques described in this section are specific to the AP Spine Bone Density Scan.

AP Spine Analysis Options

Selecting **Regions** from the *Analysis Menu* and clicking on **Analysis Options** displays the AP SPINE ANALYSIS SETUP screen.



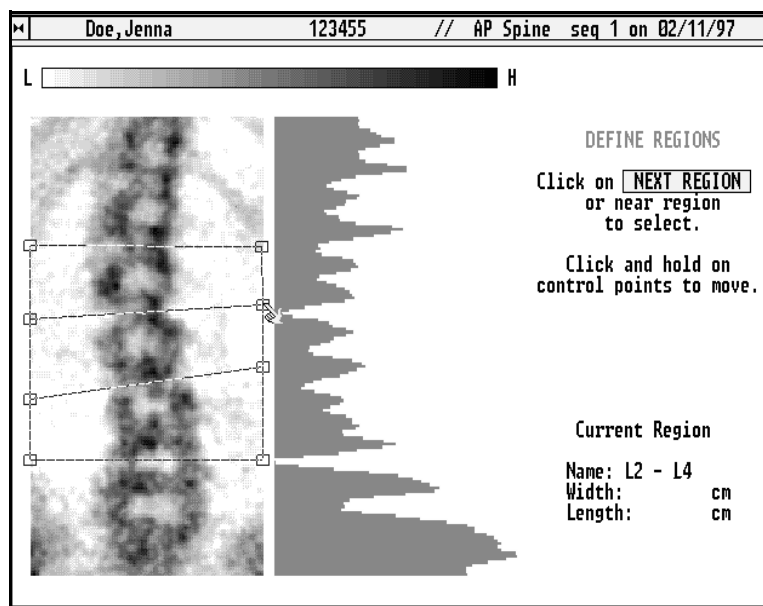
- High Density Point Exclusion will exclude data points with a density $>3.75 \text{ g/cm}^2$ from the analysis.
- Analysis Mode refers to the cursors. The Standard option displays the cursors in the horizontal plane. Angulated allows the cursors to be positioned at whatever angle is necessary to line up on the vertebral gaps, such as would be needed for patients with angled spines.

Angulated Cursors

To angulate the cursors, select **Angulated** and click on **[Accept Changes]** at the AP SPINE ANALYSIS SETUP screen.

The DEFINE REGIONS screen will display. Click on **[NEXT REGION]** to activate cursors.

FIGURE 6-11



- The control points on the cursors will be at the ends instead of the centers. Click and drag the endpoints to align with vertebral gaps of angulated spines.
- The histogram will not be of much help in this case.
- Regions of interest (L2, L3, L4, L2-L4) will be compared to reference populations which did not include studies with scoliotic spines.

AP Spine Scanning Options

Change Parameters

To edit scan parameters for an individual scan click on **[Change Parameters]** on the SCAN REVIEW screen. Edit any of the scan parameters, such as scan speed, extended width, or number of multiple scans of same subject (**multiple scans for scanning phantoms only**). The Scan Width defines the size of the Region of Interest.

Figure 6-12 shows the scan parameters. The defaults shown should be effective for most scanning situations

FIGURE 6-12

AP SPINE SCAN SETUP

Resolution:	1.5 x 1.5	mm
Scan Width:	12.00	cm
Scan Length:	As Marked	cm
Scan Speed:	130.0	mm/sec
	<input type="button" value="High Precision"/> <input checked="" type="button" value="Standard"/> <input type="button" value="High Speed"/>	
Auto Centering:	<input checked="" type="button" value="ON"/> <input type="button" value="OFF"/>	
Force mark points on-axis:	<input checked="" type="button" value="Enabled"/> <input type="button" value="Disabled"/>	
Scan Resolution:	<input type="button" value="1.0 x 1.0"/> <input checked="" type="button" value="1.5 x 1.5"/>	mm
<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.

- The scan speed for a High Precision scan is 65 mm/sec.
- The scan speed for Standard scan is 130 mm/sec.
- The scan speed for High Speed scan is 260 mm/sec.
- *Auto Centering*, when enabled, centers the image in region of interest despite small variances in actual patient orientation.
- Scan Resolution is the (data point size) x (scan line size) in millimeters.
- Scan Width is 12cm, unless Auto Centering fails, in which case the Scan Width is automatically set to 14cm.

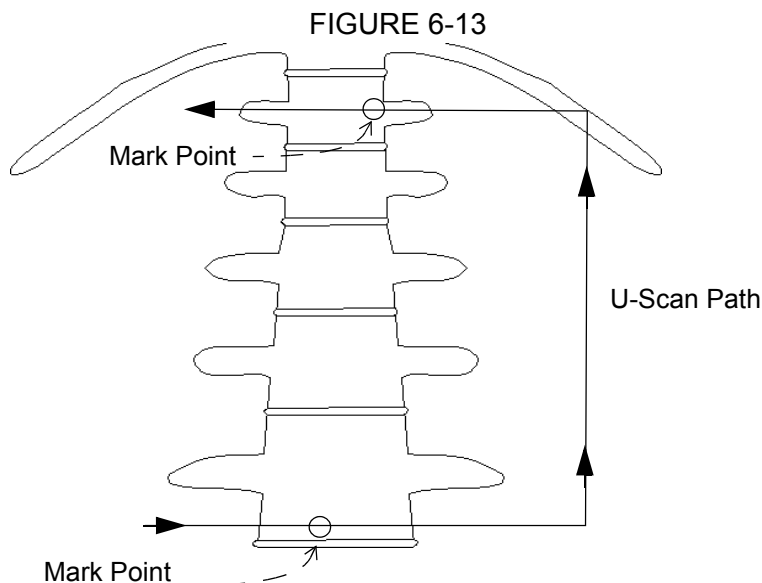
Scan Resolution of 1.0 x 1.0 with High Speed will generate a message indicating Scan Speed too fast for selected resolution. In this event, either select alternate Scan Speed or Scan Resolution.

Auto Centering Mode

The auto centering option automatically centers the spine in the image. When auto centering is enabled, a 'U' shaped scan is performed prior to the measurement scan. The start and end points marked by the operator will be on the path of the U. See Figure 6-13 on the next page.

- The "Force Mark on Axis" option should be disabled to fully take advantage of the Auto Centering mode.

If the start and end points are found to be off center, they are recalculated and implemented for the Measurement scan. No operator intervention is required and there is no need to physically reposition the patient.



- If automatic centering was not successful, the original start and end points would be used for the measurement scan and the following warning message will display.

The original mark points are being used because the automatic centering of the spine was not successful.



- If metal was detected on the U shaped scan, the following warning message will display.

The original mark points are being used because metal was detected.



- If auto centering determined that the start and end points would require shifting by 5 cm or more, the following warning will display.

The original mark points are being used because the scan was moved 5 cm or more.



- If auto centering determined that the scan would exceed the scanner arm travel limits, the following warning will display.

The scan extends off of the table. Either remark the scan location or adjust the scan parameters.

1. Click on **[Continue]** to acknowledge any of the warnings.
2. Click on **[Stop Scan]** to reposition or remark the patient.

Force Mark Points On-Axis



When this option is enabled it forces the densitometer to transverse the scan region in X & Y axis only. When disabled it will allow scanning on a diagonal which will automatically straighten the spine in the scan image, despite patient orientation. (Will not straighten scoliotic spines.) **To achieve the highest quality spine scans, this feature should be DISABLED.** See Figure 6-14 for an example of a scan with the Force Mark Points On-Axis Enabled. Figure 6-15 is the same patient without repositioning and Force Mark Points On-Axis Disabled.

FIGURE 6-14 Force On-Axis Enabled

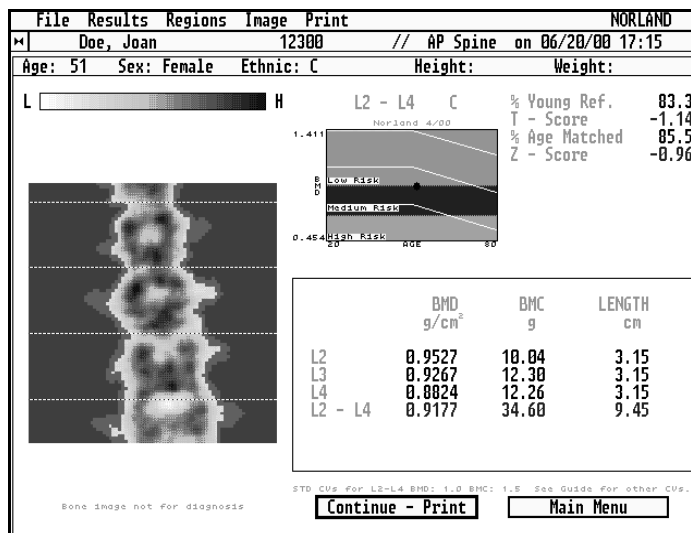
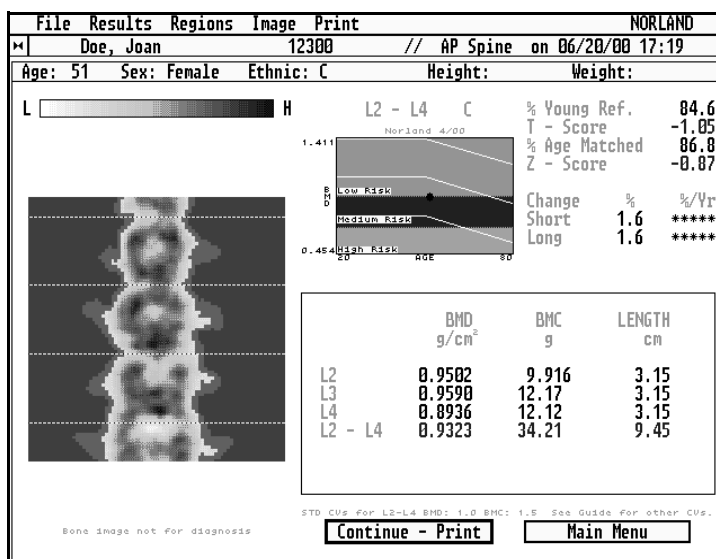


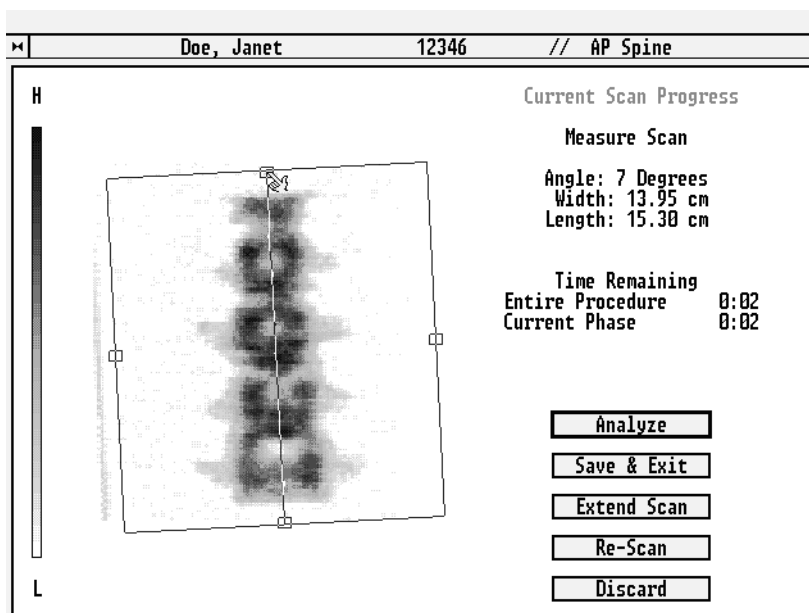
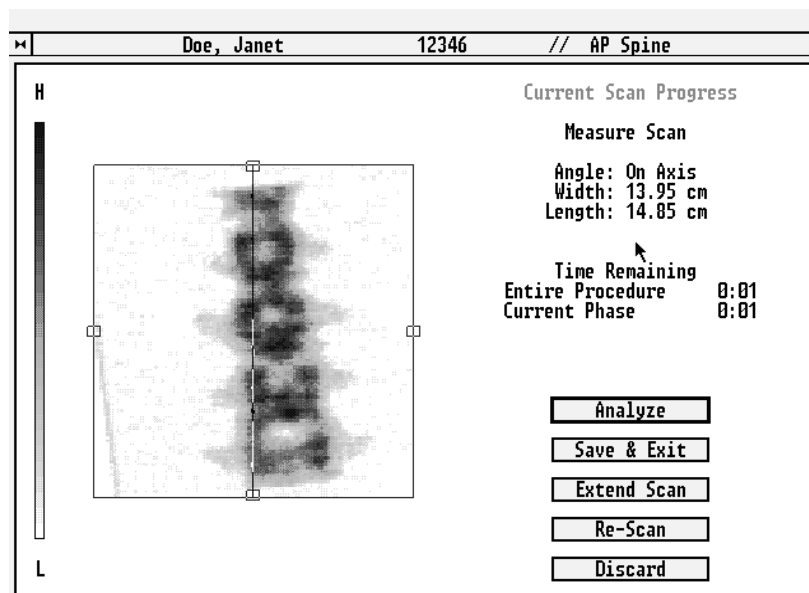
FIGURE 6-15 Force On-Axis Disable



AP Spine Scan Progress Screen Options

Scan Progress Screen Options	
Extend Scan	<p>Enter number of scan lines to extend.</p> <p>Caution the patient to lie still.</p> <p>The extend scan option may be repeated until the scan length has reached 255 lines.</p>
Re-Scan	<p>If the operator is not satisfied with the scanned area, a new Measurement scan can be defined without repositioning the patient. (See Figure 6-16 on the next page for example of uncentered spine scan.)</p> <p>Use click and drag technique to position the start and end points and re-center the bisecting line. Do not move patient.</p> <p>Caution the patient to lie still.</p> <p>Click on [Re-Scan].</p> <p>Scanner arm will re-position and re-scan the defined area.</p>
Discard	<p>System software cautions the operator with the message:</p> <p style="padding-left: 40px;">Are you sure you want to discard your data?</p> <p>Click on [Discard] to abandon the scan data and return to the Main Menu.</p> <p>Click on [Cancel] to return to the Current Scan Progress screen.</p>

FIGURE 6-16 Rescan Option



Angling the scan region as above picture is possible only if the "Force Mark Points on Axis" option is disabled.

Hip Analysis Options

The techniques described in this section are specific to the Hip Bone Density Scan.

Selecting **Regions** from the *Analysis Menu* and clicking on **Analysis Options** displays the HIP ANALYSIS SETUP screen.

HIP ANALYSIS SETUP

High Density Point Exclusion:

Femoral Neck Length: cm

Alternate R Value Analysis:

- High Density Point Exclusion will exclude data points with a density >3.75 g/cm² from the analysis.
- Femoral Neck Length determines the length of the region of interest along the femoral neck axis. 1.5 cm is recommended because the longer length ensures better precision.
- If the "Alternate R Value Analysis" function is enabled, the software algorithms will first use standard methods to analyze hip data. If the computed R value is determined to be outside of an acceptable range, a second analysis method will automatically be invoked to analyze the hip scan data.

An R value is a computed value used during the analysis process to allow the software to estimate the amount of soft tissue above and below bone. In some individuals with very low density, the routine algorithms for calculating the "R" value do not allow for the proper processing of hip data.

Hip Scanning Options

Change Parameters

To edit scan parameters for an individual scan click on **[Change Parameters]** on the SCAN REVIEW screen. Edit any of the scan parameters, such as scan speed, extended width, or number of multiple scans of same subject (**multiple scans for scanning phantoms only**). The Scan Width defines the size of the Region of Interest.

Figure 6-17 shows the scan parameters. The defaults shown should be effective for most scanning situations

FIGURE 6-17 Change Parameters Screen

HIP SCAN SETUP			
Resolution:	Scout 1.0 x 4.0	Measure 1.0 x 1.0	mm
Scan Width:	12.00	9.00	cm
Scan Length:	12.00	9.00	cm
Scan Speed:	180.0	90.0	mm/sec
	<input type="button" value="High Precision"/>	<input checked="" type="button" value="Standard"/>	<input type="button" value="High Speed"/>
Scan Type:	<input checked="" type="button" value="Standard"/> <input type="button" value="Extended Width"/>		
Number of Scans:	1		
	<input type="button" value="Accept Changes"/>	<input type="button" value="Do Not Accept"/>	<input type="button" value="Restore Defaults"/>

- High Precision speed sets Measure Scan speed to 45 mm/sec (Scout Scan speed is always 180 mm/sec).
- Standard speed option sets Measure Scan speed to 90 mm/sec (Scout Scan speed is always 180 mm/sec).
- High speed option sets Measure Scan speed to 180 mm/sec (Scout Scan speed is always 180 mm/sec).
- The Extended Width option (used for larger patients) sets the Measure Scan dimensions to 12 cm x 12 cm.
- Scan Resolution is fixed for the Hip Scan.

Select desired parameters and click on **[Accept Changes]** to set for an individual scan.

Scout Scan Progress Screen Options

Hip Scan Progress Screen Options	
Extend Scan	<p>A new scan length screen is displayed when the extend scan option is selected.</p> <p>Enter the desired extended length (the default extend length is 10.0mm).</p> <p>Caution the patient to lie still and click on [Extend Scan] to resume scanning. The Extend Scan command may be repeated until the scan length has reached its limit of 255 lines.^{a b}</p>
Repeat Scout	<p>If scanned area is unsatisfactory, a new Scout and Measurement scan can be defined.</p> <p>Use the pointer to click onto the cursor and drag it to the correct start point.</p> <p>Caution the patient to lie still.</p> <p>Click on [Repeat Scout].</p> <p>The scanner will perform a new Scout scan.</p>
Discard	<p>System software cautions the operator with the message:</p> <p>Are you sure you want to discard your data?</p> <p>Click on [Discard] to abandon the scan data and return to the Main Menu.</p> <p>Click on [Cancel] to return to the Current Scan Progress screen.</p>

- a. It is important that subsequent scans of patient use the same region of interest (ROI).
- b. If additional lines are added, make the appropriate entry in Scan Comments to ensure that the same number of lines are collected on subsequent scans.

GENERAL MAINTENANCE 7

The only maintenance performed by the operator on the Norland system is routine cleaning and Patient file management. Daily calibrations will verify proper operation of the x-ray source and detector assembly, as well as any moving parts. If system fails to operate properly for any reason, contact the local Norland Customer Service representative. No part of the Norland system is suitable for repair by the user. Only Norland trained personnel have access to Norland certified components. Other manufacturer's components are not compatible with Norland systems. Norland will make available service documentation upon request to those qualified technicians who have received Norland service training.

Neither the x-ray source nor the laser positioning aid requires any maintenance or adjustment by the user. Some guidelines for Patient and Scan file management are included. Faithfully performing the procedures in this section will minimize the risk of losing patient data, and help insure trouble free operation.

Routine Maintenance

Detailed routine maintenance procedures are documented on the following pages.

Cleaning Scanner Exterior

The scanner exterior should be cleaned with a soft towel moistened (but not soaked) with standard antiseptic cleaning solution. The scanner should be cleaned as part of the daily cleanup associated with most facilities.



NOTE: Cleaning solutions must not be sprayed directly onto scanner to avoid possible damage to interior electronic components.

Cleaning QC Phantom

Clean the QC Phantom with water and a soft cloth.



IMPORTANT: DO NOT USE ALCOHOL TO CLEAN QC PHANTOM.

Cleaning Patient Pad Cover

The cover is secured to the Patient Pad by Velcro strips at each end. The cover can be cleaned with a damp cloth or may be removed and dry cleaned.



NOTE: MAKE SURE THE TABLE TOP IS REPLACED WITH THE MARKINGS IN THE PROPER PLACE.

Cleaning Positioning Aids

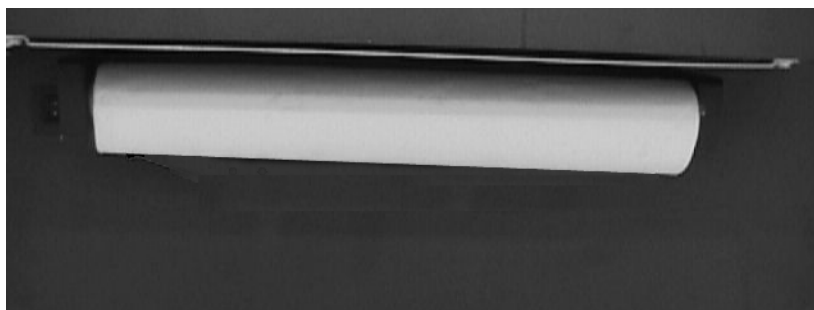
Clean the vinyl coated positioning aids by wiping them with a standard antiseptic cleaning solution.

Clean the fabric covered leg block with a damp cloth or by removing the cover and dry cleaning.

Replacing Exam Paper

To remove the roll of exam paper, simply lift up and slide out. With new roll in place, feed paper through guides at the bottom of the table on each end.

FIGURE 7-1



Computer

The accompanying OEM documentation will provide maintenance information for the computer. Use only 1.44 MB High Density, Double Sided diskettes.

Printer

The accompanying OEM documentation will provide maintenance information for the printer.

Optimizing Patient Database File

As the patient database grows, selecting patients and scan files from the database may take longer than usual. The Optimize Patients File command will restructure the database for quicker operation. The optimize patients file function can be applied to any drive but it is really designed to improve the performance of the system hard drive.

1. Select *Main Menu* item **Disk** and click on **Optimize Patients File**. The Optimize Patients File screen will display.
2. Click on the drive containing the Patient Database, then click on **[Continue]**.
3. Repeat for all drives and/or diskettes containing patient data.
 - Clicking on **[Cancel]** will terminate the optimizing process and return to the Main Menu.

Checking the Norland File Structure

The DOS command, XFCHECK [Drive:], checks the file system for inconsistencies in the patient, scans and regions files. The default drive is 'C:'. XFCHECK can be performed on any drive where scan data files are stored.

Check Hard Drive

To use the command XFCHECK to check the hard drive,


- Type **XFCHECK** followed by the drive letter to be checked at the 'C:\>' prompt, then press **[Enter]**. The drive letter must have a colon after it. (For example, **XFCHECK D:**)
- After checking the drive, XFCHECK displays a list of any problems it encountered.

NOTE: Notify your Norland Customer Service Representative if any errors are reported.

Check Diskettes

To use the command XFCHECK to check any diskette,

- Insert the diskette in the floppy drive.
- Type **XFCHECK A:** at the 'C:\>' prompt.
- After checking the diskette, XFCHECK displays a list of any problems it encountered.

- To print XFCHECK results, type **XFCHECK [Drive:] >prn** and press .
(For example, **XFCHECK D: >PRN**)

NOTE: Notify your Norland Customer Service Representative if any errors are reported.

Corrective Procedures

Operational problems are usually identified by warning messages as the situation occurs. Most of the messages prescribe the necessary action. Other problems can usually be resolved by shutting down and restarting. Whenever further repairs are needed, contact the local Norland Customer Service Number.

Performing Multiple QC Scans

Scans of the QC Phantom can be performed independently of the QA Procedure outlined in Chapter 2, or the Quick Reference. This procedure will typically be under the direction of a Norland Customer Service Representative.

- Place the QC Phantom on the scanner table, parallel to the backrest, and the end marked 'C' toward the right as you face the scanner.
- Select *Main Menu* item **QA** and click on **Scan QC Phantom**.
- Enter the desired number of scans to be performed and click on **[Continue]**.
- Turn on the laser.

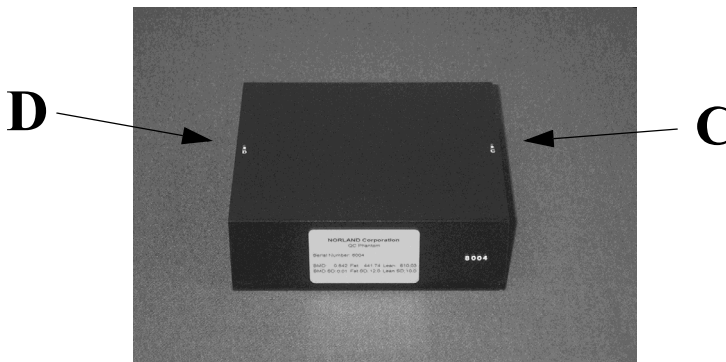


CAUTION: Do not stare into the beam.

For Whole Body Scanners

- Move the scanner arm so that the laser shines directly on the dot by 'C', move the arm down to the dot by 'D' to verify the phantom is straight. Move the laser back to the dot by 'C'.
- Press the MARK button to mark point 'C'.

FIGURE 7-2 QC Phantom



For Central Only Scanners

5. Using the scanner control panel, position the laser on the 'X' at the right of the phantom (point C), move the arm down to the 'X' at the left of the phantom (point D) to verify the phantom is straight. Re-position the phantom if necessary. Move the laser back to point 'C'.
6. Press the **MARK** button to mark point 'C'.
7. The scanner arm will automatically move to the dot by 'D'.
8. Press the **MARK** button to mark point 'D'.

FIGURE 7-3 QC Phantom

***For both Whole Body and Central Only Scanners***

The scans will begin automatically. The screen will display the scan image as it develops and display updating status of the current scan.

At completion, an audible beep will sound, indicating that the shutter has closed and x-ray beam is no longer present. The results will be displayed on the QA Result Screen.

Emptying Print Queue

Norland software includes a DOS batch file that permits the operator to remove all spooled but unwanted print files from the print queue. This situation occurs if system software is exited before print jobs are completed and the printer power is not recycled (turned off for a moment, then turned back on). This may result in garbled report printouts, poor print quality, or an accumulation of unneeded printout files, which take up hard disk space.

1. Exit to the DOS prompt. (Desktop users double-click on Tools icon at the Windows desktop.)
2. At the "C:\\" prompt, type 'XEMPTYQ' and press **Enter**.
3. Press **Enter** to remove all files from the print queue. Or press **Esc** to cancel.
4. Type 'exit' and press **Enter** to return to the Windows desktop.

All existing printout files residing on the hard drive will be erased and the print queue is re-initialized.

File Management

Main Menu item **Disk** contains many utilities for managing patient scan data files. An understanding of the system's file structure is necessary for these commands to be used correctly.

The system hard drive is "partitioned" into a number of sections. Each section is given its own drive designation. The C: drive is where all system software is residing as well as the system's index files (listed below).

- PATIENTS.FIL
- SCANS.FIL
- REGIONS.FIL

Scan data files are stored on the remaining drive partitions. Each drive that contains scan data files will be automatically initialized to a volume number by the system software.

- Those systems using laptop computers will typically store scan data files on diskettes.

Disk Status Check

If diskettes are being used as the default storage location, it isn't difficult to get disks confused or mislabeled. The Disk Status check feature will check the volume label and display how much available space is remaining on the volume disk. Disk Status can also be used to check the space available on the system hard drive.

NOTE: Norland recommends that system hard drive is used for default storage location.

1. Select *Main Menu* item **Disk** and click on **Disk Status**.
2. Click on drive designator to be checked. Insert the proper volume diskette first if performing a check on removable media.
3. Click on **[Continue]** to get status or **[Cancel]** to return to the Main Menu.

Moving Scan Data Files

Scan data files can be moved from the default storage location (system hard drive) to a volume diskette (and vice versa) with the Move function under Main Menu item Disk. The "Move" function relocates individual scan data files for the currently selected patient file or all scan data files from one storage location to another.

The patients' personal data remains on the system hard drive (C:), but the scan data files are stored on diskettes or disk partitions that are labeled as sequential volumes.

Whenever a scan data file is moved to a volume diskette or partition, the assigned volume number is stored in the patient file. When scan data files for a patient are listed, the VOL number for the file indicates where the file is located. (VOL 0 is always the system hard drive.)

Volume diskettes or partitions are assigned a volume number by the system software. Since these volume numbers are used to track scan data files for patients

listed on the system hard drive, a volume diskette can only be used on the system that created it.

The term 'machine specific' is used to describe volume diskettes.



Never use Windows Explorer to move, copy, or delete Scan Data files!!!

Move a Scan

The "Move a Scan" option will move a selected scan data file from its current location to specified new location.

1. Select a patient (**Main Menu Select - Select a Patient**).
2. Select *Main Menu* item **Select** and click on **Select a Scan**. A list of scan data files for the currently selected patient will be displayed.
3. Click on the patient scan data file to be moved.
 - If selected scan data file is on a volume diskette, operator will be directed to insert volume diskette.
4. Select *Main Menu* **Disk** and click on **Move a Scan**. The "Move a Scan" screen will be displayed.
5. Click on the target (destination) drive. If drive A is selected, insert a volume or a blank formatted diskette in the drive.
6. Click on **[Continue]** to start the transfer process. When the transfer is complete, the Main Menu will be displayed.
 - Click on **[Cancel]** to terminate and return to the Main Menu.

If a blank formatted diskette is inserted (or if uninitialized fixed drive partition is selected), software will prompt operator to create a new volume.

- Click on **[Continue]** to proceed. The Norland software will assign a new volume number to the diskette, direct the operator to remove the diskette, label it, and re-insert it in the drive.
- Clicking on **[Continue]** will return to the "Move a Scan" screen to resume the transfer process.

Move All Scans

Some facilities may choose to store all patient scan data on the system hard drive during the day's operations. Then, at the end of the day, transfer all the scans to diskette or different fixed drive partition.

1. Select Main Menu item **Disk** and click on **Move All Scans** from the sub-menu. The Move All Scans screen will be displayed.
2. Click on the source drive.
 - Drive partition where scans are to be moved from if moving from system hard drive to volume diskette.
 - Drive A, if moving from volume diskette to system hard drive.
3. Click on **[Continue]**. The Move All Scans screen will be updated and the original media choice is no longer highlighted.

4. Select the target drive and click on **[Continue]**.
 - Insert diskette if Drive A is the target drive.

If a blank formatted diskette is used or if uninitialized fixed drive partition is selected), software will prompt operator to create a new volume.

- Click on **[Continue]** to proceed. The Norland software will assign a new volume number to the diskette, direct the operator to remove the diskette, label it, and re-insert it in the drive.
- Clicking on **[Continue]** after diskette is inserted will return to the Move a Scan to resume the transfer process.

Should there be more scans to move than can fit onto the diskette, the operation will pause and prompt the operator to request that another diskette be inserted. Each diskette typically will hold approximately 30-35 scan data files.

Copying Scan Data Files

Scan data files can be copied to diskette without affecting the original file. Selected scan data files can be copied or all scan data files for the selected patient can be copied. Copy diskettes are not assigned volume numbers, but they are initialized as "copy media" during the copy process. "Copy media" are not 'machine specific'.

Copy Specific Scan Data File

The "Copy a Scan" option will copy the selected scan data file to another disk (typically a floppy diskette).

1. Select a patient (**Main Menu Select - Select a Patient**).
2. Select *Main Menu* item **Select** and click on **Select a Scan**. A list of scan data files for the currently selected patient will be displayed.
3. Click on the patient scan data file to be copied.
 - If selected scan is on a volume diskette, operator will be directed to insert volume diskette.
4. Select *Main Menu* item **Disk** and click on **Copy a Scan**.
 - The display will prompt the operator to select the target drive when the selected scan data is available for access.
5. Remove the volume diskette (if necessary) and insert a previously initialized copy diskette or a blank formatted diskette.
6. Click on the target drive (usually drive A) to select it and click on **[Continue]**.
 - If a blank formatted diskette (or previously uninitialized partition) is used, the system will indicate that the media is not initialized as copy media. Click on **[Continue]** to initialize and resume copy process.
7. Repeat the above procedure to copy additional scan records for the same patient, or for other patients.

Copy All Scan Files from Selected Patient

All scan data files for a patient can be copied to a copy diskette.

1. Select a patient (**Main Menu Select - Select a Patient**).
2. Select *Main Menu* item **Disk** and click on **Copy a Patient**.
 - If the selected scan data file is on a volume diskette that is not in the floppy drive, the operator will be directed to insert the volume diskette. Click on **[Continue]** after inserting the correct volume diskette.
3. The display will prompt the operator to select the target drive when the selected scan data is available for access.
4. Remove the volume diskette (if used) and insert a previously initialized copy diskette or a blank formatted diskette.
5. Click on the target drive (usually drive A) to select it and click on **[Continue]**.
 - If a blank formatted diskette is used, the system will indicate that the media is not initialized as copy media. Click on **[Continue]** to initialize and resume copy process.
6. When transfer is complete, the Patient List will be displayed.

Retrieving Copied Scan Data Files

The "Get" commands restore scan data files that have been previously copied to a diskette. The copy diskette remains intact.

Retrieving a Single Copied Scan

Use the Get Copied Scan command to retrieve a single patient scan data file from copy diskette to system hard drive.

NOTE: It is possible that duplicate scan data files may exist after using the copy process.

1. Select Main Menu item **Disk** and click on **Get Copied Scan**. The following screen will display with drive A already selected as the source drive.
2. Insert copy diskette into drive and click on **[Continue]**.
 - The screen will update to target drive selection with current default storage location already selected.
3. Click on **[Continue]**. The patient list on the source drive will display.
4. Double click on desired patient name. A list of scans for the selected patient will display.
5. Double-click on desired scan data file to start transfer.
 - If the patient ID does not exist on the system hard drive (target drive), all patient information will be copied to the system hard drive as well as the selected scan data file.
 - If the patient ID for a scan file exists on the system hard drive, the scan data file will be added to the files under that patient.
 - Be aware duplicate scan data files can happen. Duplicate scan data files should be removed.

- A warning message will display if a patient ID number has two different names associated with it.

Retrieving All Copied Scans for Selected Patient

Use the "Get Copied Patient" command to retrieve all scan data files from a selected patient from copy diskette to system hard drive.

NOTE: It is possible that duplicate scan data files may exist after using the copy process.

1. Select *Main Menu* item **Disk** and click on **Get Copied Patient**.
2. Insert copy diskette in drive and click on **[Continue]**.
 - The screen will update to target drive selection with current default storage location already selected.
3. Click on **[Continue]**. The patient list on the source drive will display.
4. Double click on desired patient name to start transfer.
 - If the patient ID does not exist on the system hard drive (target drive), all patient information will be copied to the system hard drive as well as the selected scan data file.
 - If the patient ID for a scan file exists on the system hard drive, the scan data file will be added to the files under that patient
 - Be aware duplicate scan data files can happen. Duplicate scan data files should be removed.
 - A warning message will display if a patient ID number has two different names associated with it.

Retrieving All Copied Scans from Diskette

Use the "Get All Copied Scans" command to retrieve all scan data files from a copy diskette to system hard drive.

NOTE: It is possible that duplicate scan data files may exist after using the copy process.

1. Select *Main Menu* item **Disk** and click on **Get All Copied Scans**.
2. Insert copy diskette in drive and click on **[Continue]**.
3. The screen will update to target drive selection with current default storage location already selected.
4. Click on **[Continue]** to start transfer.
 - If the patient ID does not exist on the system hard drive (target drive), all patient information will be copied to the system hard drive as well as the selected scan data file.
 - If the patient ID for a scan file exists on the system hard drive, the scan data file will be added to the files under that patient
 - Be aware duplicate scan data files can happen. Duplicate scan data files should be removed.
 - A warning message will display if a patient ID number has two different names associated with it.

Deleting Files

When duplicate files exist, trending analysis is hampered. Patient files can be deleted as well as individual scan data files.

- Remember: Deleting a patient file will also delete all associated scan data files.

Deleting Patient File

1. Select a patient (**Main Menu Select - Select a Patient**).
2. Select *Main Menu* item **Select** and click on **Delete a Patient**.
 - If any of the selected patient's scan data files are on a volume diskette that is not in the floppy drive, the operator will be directed to insert the volume diskette. Click on **[Continue]** after inserting the correct volume diskette.
3. A confirmation message will be displayed (click on **[Delete]** to continue).
 - The selected patient file will be deleted from the patient list.

Delete Scan Data File

1. Select a patient (**Main Menu Select - Select a Patient**).
2. Double-click on patient's name to display list of scan data files for that patient.
3. Click on scan data file to be deleted.
 - If the selected scan data file is on a volume diskette that is not in the floppy drive, the operator will be directed to insert the volume diskette. Click on **[Continue]** after inserting the correct volume diskette.
4. Select *Main Menu* item **Select** and click on **Delete a Scan**. A confirmation message will be displayed (click on **[Delete]** to continue).
 - The selected scan data file will be deleted and the Patient's file will be updated.

Formatting Diskettes

Diskettes must be formatted in order to be used as copy or volume media. Formatted disks can be purchased; however, diskettes can be formatted on any computer. Formatting is also effective for erasing data from a diskette. System software provides a shortcut that temporarily exits system software and initiates the DOS format utility. Only 1.44 MB HD diskettes may be used on Norland equipment.

1. Select *Main Menu* item **Disk** and click on **Format a Diskette**.
2. Click on [**Continue**] to temporarily exit system software and start the format utility.

Simply follow the instructions on the screen to format diskettes.

- When prompted for volume label, press **[Enter]** for none.
- When format is complete, format another disk or press 'n' to return to the Main Menu.
- Follow the instructions on the resulting display.
- Pressing the **[Ctrl]** and C key at any time will cancel the format and return to the Main Menu.

Duplicating Copy or Volume Diskettes

Sometimes making copies of diskettes (such as Reference Diskettes) can be useful. System software provides a shortcut that temporarily exits system software and initiates the DOS disk to disk copy utility.

1. After all reports have printed, select *Main Menu* item **Disk** and click on **Copy a Diskette**.
2. Click on [**Continue**] and the screen will update to show drive A as the target diskette.
3. Click on [**Continue**] to temporarily exit system software and initiate the DOS disk to disk copy utility.
4. Insert the source diskette in the floppy drive and press **[Enter]**. The contents of the diskette will be copied into a temporary file on the system hard drive.
5. When prompted, replace the source diskette with the target diskette and press enter. The contents of the temporary file will be copied onto the diskette.
6. Additional copies can be made or press 'n' to return to the Main Menu.
 - Pressing the **[Ctrl]** and C key simultaneously at any time will cancel the copy process and return to the Main Menu.

Reference Set Maintenance

Reference sets are copied into the system at installation and stored on the system hard drive. The Setup option on the Main Menu provides some tools for maintaining and creating Reference Sets on the system.

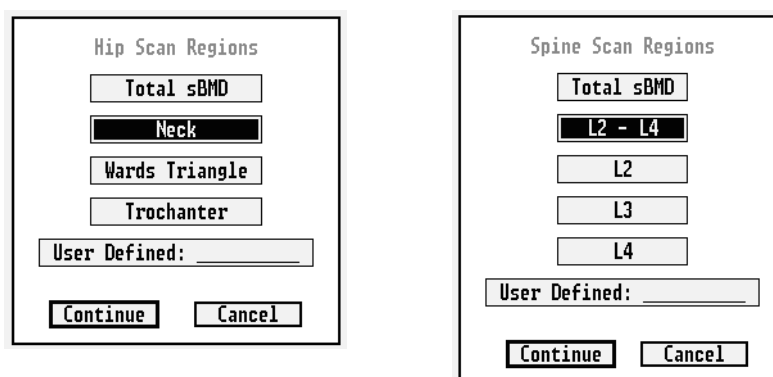
Create	Displays a screen for inputting reference data from a hard copy or from local population. Created reference sets will not display color bands on the charts.
Edit	Allows selection of installed Reference Set for editing. Reference Sets are enable and disabled here.
Delete	Allows selection of installed Reference Set for deletion from system. Copy to diskette first.
Get	Installs Reference Set to system hard drive from diskette.
Copy	Copies Reference Set to diskette.

Data sheets that accompany the Reference Sets should be inserted in this Operator's Guide for future use. These data sheets describe the source of the data and explain the information gathering criteria.

Create Reference Set

1. Reference sets can be created for local populations. However, reference charts displayed will not have color bands.
2. Select Main Menu item **Setup** and click on **Reference Data**.
3. Click on **Create** at the REFERENCE DATA SETUP screen.
4. Select scan type and click on **[Continue]**. A screen for defining scan regions will be displayed.
 - The **User Defined** region would be a special region designed by the operator.

FIGURE 7-4



5. Select region and click on **[Continue]**. The EDIT REFERENCE DATA screen will display.

FIGURE 7-5

REFERENCE DATA SET	Age	Value	2 S.D.
Scan Type: AP Spine			
Region Type: L2 - L4			
Title: <input type="text"/>			
Ethnic: <input type="text"/>			
Young Ref.: <input type="text"/>			
<input checked="" type="checkbox"/> Enabled <input type="checkbox"/> Disabled			
<input type="checkbox"/> Female <input type="checkbox"/> Male <input checked="" type="checkbox"/> N/A			
Display By:			
<input checked="" type="checkbox"/> Value <input type="checkbox"/> T-Score			
<input checked="" type="checkbox"/> Accept Changes <input type="checkbox"/> Do Not Accept			

6. Enter data and make desired selections. Click on **[Accept Changes]** to save.

TROUBLESHOOTING 8

Most operational difficulties can be easily rectified through the use of installed software utilities or through established troubleshooting procedures. During operation, occasionally minor warning messages will display to notify operator of current condition or status. Sometimes these messages will be accompanied by a suggested action. This section will assist in overcoming those not so obvious situations.

Startup

Startup Faults

Condition	Action
No Communication (Main Menu displays Scanner Software Version as "None")	Turn off power and ensure that the cable from the computer to the scanner is secure. Retry. Verify there is power to the scanner. <ul style="list-style-type: none">• Scanner arm should not move freely when pushed, and the source fan should be audible. Turn off the scanner and computer, wait 10 seconds, turn them back on.
No power to the scanner	If the scanner is plugged into the power strip, verify the power strip is turned on and the green light is on. Verify there is power to the outlet into which the scanner is plugged.
"non-system disk" or "disk error" displayed on computer	Non-bootable floppy in drive. Remove floppy and press any key. Hard drive failure. Contact Customer Service Rep.

Scanner Operation

Scanner Faults

Condition	Action
Scanner arm motion erratic	<p>Verify nothing is blocking the arm movement. It may be necessary to remove the table top and check for obstructions.</p> <p>Clean the dust off the back rail using a clean cloth. Oil the rail with a light lubricant. Do not use lubricants with a degreaser (i.e. WD40) or it may ruin the bearings.</p>
Scanner arm is not moving	<p>Manually push the scanner arm. If it moves freely there is no power to the scanner motors. Verify the scanner and power strip is turned on.</p> <p>Turn the scanner and computer off, wait 10 seconds, turn them back on, and retry.</p> <p>At <i>Main Menu</i> item Setup, click on Find Table Origin to see if the arm will move to home position.</p> <p>Turn the scanner off. While holding down the left and right arrow keys on the front panel, turn the scanner back on, hold the arrow keys for approximately 1 second then release. Verify that the scanner arm will now move manually.</p> <p>Contact Customer Service Rep.</p>

Software Operation

Software Faults

Condition	Action
Drive 'A' invalid	<p>Verify the floppy diskette is 1.44 IBM Formatted Double Sided High Density.</p> <p>Ensure the floppy diskette is firmly in place in the drive. (Try again)</p> <p>Remove the disk and slide the spring-loaded metal strip (located at the top of the diskette) to ensure it is retracting properly.</p>
Continuous Error messages displayed during normal operation	<p>Press the "Print Screen" key on the computer keyboard to print the errors, or write them down, and contact Customer Service Rep.</p>

Software Faults

Condition	Action
Time/date display incorrect	Exit to DOS (double-click on Tools from Windows desktop) to verify the time and data on the computer are set correctly. At the C:\> prompt type ' time ' and press Enter to verify it is correct. Type ' date ' and press Enter to verify the date is correct. If either is incorrect, enter in the new time or date in the same format that is displayed.
Patient scanned under wrong name	Contact Customer Service Rep. (Have formatted diskette ready)
Errors when processing or storing scan data file, or entering patient's name	Record the error. Exit to DOS (double-click on Tools from Windows desktop) and enter ' xfcheck >prn ' to check the integrity of the index files and print the results. Also perform xfcheck on the drive where the scan is stored, by typing the drive letter after Xfcheck(i.e. ' xfcheck d:\>prn ' & Enter). If any errors are listed contact Customer Service Rep.

Calibration

Calibration Faults

Condition	Action
Calibration Diagnostics: Fail Reference Beam X-ray Off Shutter Low Atten. Filter Med. Atten. Filter High Atten. Filter Dynamic Filtration	<p>Verify the calibration standard is placed in the correct calibration area.</p> <p>Verify points 'A' and 'B' were marked in the correct order and on the 'X' in the Plexiglas of the calibration standard.</p> <p>Turn off the scanner and computer and repeat the calibration.</p> <p>If the calibration fails a second time follow the instructions below to print the errors and contact Customer Service Rep.</p> <ol style="list-style-type: none"> 1. Exit to DOS. (Double-click on Tools from Windows desktop.) 2. Type 'CD XR26\CALTRACE' and press Enter. 3. Verify the printer is turned on and ready, type 'type diagnost.trc >prn' and press Enter.
Calibration Status: Failed	<p>Verify the calibration standard (QA Phantom) is placed in the correct calibration area.</p> <p>Verify points 'A' and 'B' were marked in the correct order and on the 'X' in the Plexiglas of the calibration standard.</p> <p>Turn off the scanner and computer and repeat the calibration.</p> <p>If the calibration fails a second time follow the instructions below to print the errors and contact Customer Service Rep.</p> <ol style="list-style-type: none"> 1. Exit to DOS. (Double-click on Tools from Windows desktop.) 2. Type 'CD XR26\CALTRACE' and press Enter. 3. Verify the printer is turned on and ready, type 'type errors.trc >prn' and press Enter.
Precision or Accuracy - Out of Range	<p>Verify the QC (spine) phantom was placed on the table in the scan area, and the phantom was marked on the X's.</p> <p>Verify the phantom was not moved after it was marked.</p> <p>If the last QC Scan taken during calibration is an invalid measurement due to operator error, contact Customer Service Rep. for assistance in deleting the invalid scan. Customer Service will advise:</p> <ol style="list-style-type: none"> 1. Exit to DOS. (Double-click on Tools from Windows desktop.) 2. For BMD errors type 'xd_qc', and press Enter. For Fat or Lean errors type 'xd_qc -t', and press Enter. 3. Note the record number (left hand column) of the invalid scan. 4. Type 'xd_qc -dXX', where XX is the record number. This will delete the invalid scan.

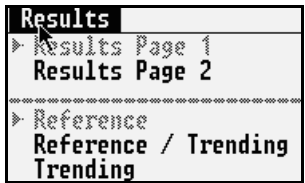
Printer

Printer Faults

Condition	Action
Printer excessively loud	Check to ensure the printer cartridges are latched in place by lifting the printer cover and verifying both cartridges are secure in their respective holders. If necessary apply silicone lubricant on the printer drive rod to reduce noise and friction.
Text missing from the printed report	Replace the printer cartridges. Replace them with the same model number as on the print cartridge. Install them in the correct holder.
Lines through the text or image	Use a Qtip to clean both sides of metal bar under cartridges. Replace printer cartridge (refer to printer manual for details).
Will not print, large print type, or random letters	Reset printer. If problem persists, empty print queue. (see Emptying Print Queue on page 7-5)
Only printing one page or report appears different	Verify the print setup is correct. Under the Setup menu click on Printer. Verify "2 Page" is selected for Detailed Results, and sBMD Report is "Disabled". If Printed report is different than last years and has different information. Verify the same report was printed, Detailed Results Vs sBMD Report.

Reference/ Trend Chart Display

Reference/Trend Charts

Condition	Action
No trend chart appears	Only one scan exists for the patient or trend option not selected.
No color bars appear on the graph	The selected Reference Set does not contain factory-defined color bars.
Reference Sets are installed but are not plotted	<ul style="list-style-type: none"> • Patient does not have a birthdate entered in the Patient Personal History. • Patient gender does not match that of the installed data sets or it has not been selected for the patient in the Patient Personal History. • There is no Reference Set available for the specific regions being graphed. • There is no matching Ethnic group for the specific regions being graphed or it has not been entered in the Patient Personal History. • The Reference Set is disabled. Enable the Reference Set using the Edit Reference Data Setup command. • "Reference" under <i>Analysis Menu</i> item Results is not selected. Select the Reference mode. 
Reference Sets are incorrect	<ul style="list-style-type: none"> • The wrong Reference Set was selected. • Ensure that the correct ethnic information is entered in the patient's Patient Personal Data screen.
The percent change or % change/year values do not appear or appears as '*****'	<ul style="list-style-type: none"> • The current scan has the same date as the scan it is being compared to. Inadvertent copying of two or more identical patient scans may cause this. Compare the identical scans and delete all but one of them. • The current scan is the first scan being graphed. A later scan in the series must be selected to obtain % change values. • The calculated value requires more than five digits.

Reference/Trend Charts

Condition	Action
Percent Young value does not appear or appears as '*****'	<ul style="list-style-type: none"> • A Young Ref(ERENCE) value has not been included in the reference set. Enter the Young Ref(ERENCE) value. • The current Results mode is not Reference. Select the Reference mode. • The calculated value requires more than five digits.
Percent Age-Matched value does not appear or appears as '*****'	<ul style="list-style-type: none"> • The patient value is younger or older than the age range included in the selected Reference Set. • The current Results mode is not Reference. Select the Reference mode. • The calculated value requires more than five digits.
The Z-Score value does not appear or appears as '*****'	<ul style="list-style-type: none"> • The patient age is younger or older than the age range included in the selected Reference Set. • The current Results mode is not Reference. Select the Reference mode. • The calculated value requires more than five digits. • The Reference Set does not contain information for a full age range.

Items Which Could Fail Within the Warranty Period

Items Which Could Fail Within the Warranty Period

Item	How	Recovery
Calibration Standard (77 step)	If it is dropped, it will have internal damage.	Once broken it cannot be used. It must be replaced.
Limit Switches	They have an actuator arm that can get caught on clothes, wires, etc., especially during installation. Once the unit is assembled, they are protected.	Most of the time the only damage is the actuator arm getting bent, which can be repaired by bending it back. If it is broken off, then the switch must be replaced.
Fuses	If the power entry module is not set for the proper mains voltage during installation, the fuses will blow.	The fuses must be replaced. The unit comes with an extra set of fuses. Otherwise, they can be purchased locally. The type and values are on a label near where the fuse is used.
Software problem – won't boot to windows.	Depending on the computer used with the unit, it is possible to get this error.	The problem is solved by the installer (or operator) changing a file in the computer via the keyboard.
Fiber optic interconnect between the computer and the scanner	Can be caused by not properly inserting the optical fiber into the transmitter or receiver modules. Also, by damaging the optical fiber by rolling a chair over it, kinking it, etc.	Reassembling the optical fiber and modules. Or in the event of damage, replacing it.
Rail alignment	During unpacking, handling, or installation, the rails can be misaligned if they receive an impact; or if they are used as handles for lifting, etc. This is unlikely because they are quite robust.	Difficult to recover from because factory tooling is not available. However, there are special techniques that the serviceman can use to solve the problem on site.
X-ray Source	It can be damaged by dropping it during installation (it is heavy and awkward). Also, it could start arcing or have a component failure. Sources typically last for many years.	Sometimes it can be fixed by replacing the Control Board at the customer's site. But usually the entire Source must be replaced.
Filter Changer	Can cause the daily calibration to fail the Dynamic Filtration test. The filter changer typically lasts for many years.	Sometimes the problem is corrected by reinstalling the filter changer assembly and board. Most of the time it has to be replaced.
Computer	Can experience failures of the Hard Drive or the Mother Board. Does not happen often.	The Serviceman can get it fixed locally.

TECHNICAL REFERENCE 9

System specifications and required regulatory information can be found in this chapter.

Norland Bone Densitometer Specifications¹

System Description

Dual Energy X-ray Absorptiometer

Laser

Type: Laser diode
 Class: Class 1 (CE); Class II (FDA)
 Color: Red (670 nm)
 Power: Less than 0.2 mW

Scanner Arm Drive

Stepper motors
 Kevlar re-reinforced drive belts
 x-y axis positioning

X-Ray Detector Assembly

2 NaI Scintillation Crystals
 Pulse Counting

Electrical Requirements

Voltage Source 100-120V~; 220/230/240V~; ($\pm 10\%$)
 50/60 Hz, 700 VA maximum

Mains Impedance < 0.18 ohms

Environmental

Operating:

Temperature 60° - 90° F (15° - 32° C)
 Relative Humidity Up to 80% non-condensing

Transportation and Storage:

Temperature -40° to 150° F (-40° to 65° C)
 Relative Humidity Up to 80% non-condensing
 Altitude Unlimited
 DO NOT DROP, TUMBLE OR TIP

Computer² Description

Industry standard desktop (PC)
 Choice of Monitors
 High capacity Backup device
 56K Fax/Modem
 Windows
 Norton Antivirus
 Color Inkjet printer

Computer for CE Marked Scanners

Computers used with CE Marked scanners must be marked for compliance with EMC standards, such as 60601-1-2 latest edition (Electromagnetic Compatibility Requirements for Medical Equipment) or CISPR-22 (EMC Requirements for Information Technology Equipment (ITE), as appropriate to the facility.

The computer and its associated components must be powered from the Isolated Multiple Portable Socket Outlet (IMPSO) device supplied with the scanner. This includes the processor, monitor, printer, and any external backup devices. The IMPSO must be plugged directly into the Mains supply (wall outlet). No other devices can be plugged into the IMPSO. Do not plug the scanner into the IMPSO. See the specific cautions for the IMPSO elsewhere in this Technical Reference Section of the Operator's Guide.

1. The AP Spine and Hip scans are available on all models. The other scan modalities are not available on all models.

2. Computers used in the U.S. must be tested by Norland and certified to meet FDA performance standards as required by 21CFR1010.2.

Performance

Scan Times

- <1.5 minutes AP Spine, high speed
- 1.5 minutes Hip, high speed
- <4.0 minutes Lateral Spine, high speed
- 3.0 minutes Forearm, distal only, high speed
- 5.0 minutes Whole Body

Dose Values

- <1.0 mRem (High Speed mode)
Forearm, AP Spine, and Hip
- < 0.1 mRem Whole Body
- <2.0 mRem (High Speed mode)
Lateral Spine

Operational Features

Calibrations	Automatic with supplied 77-step Calibration Standard QC Phantom
Scan sites	AP Spine Left or Right Hip Lateral Spine (optional) Right or Left Forearm (optional) Whole Body (optional) Research (optional) Small Subject (optional)
Others	Soft Tissue Composition ^a Reference Data Sets ^b

a. Not available on all models.

b. Not available for all scan sites.

Spatial Resolution

AP Spine	Line Spacing - 1.5 mm (1.0 mm selectable) Point Resolution - 1.5 mm (1.0 mm selectable)
Hip	Line Spacing - 1.0 mm Point Resolution - 1.0 mm
Forearm	Line Spacing - 1.0 mm Point Resolution - 1.0 mm
Whole Body	Line Spacing - 13.0 mm (9.0 mm and 7.8 mm selectable) Point Resolution - 6.5 mm (4.5 mm and 2.8 mm selectable)
Lateral Spine	Line Spacing - 1.0 mm Point Resolution - 1.0 mm

Dimensions

FOR WHOLE BODY SCANNERS

Tabletop

Length	Width	Height
102"	36"	29"
2591 mm	914 mm	737 mm

Overall

Length	Width	Height
102"	48"	52"
2591 mm	1220 mm	1321 mm

Weight

560 lbs (254 kg)

Table Weight Limit

450 lbs (205 kg)

Scanning Area

25.5" x 76" (648 mm x 1930 mm)

Table to Scanner Arm Distance

16" (406 mm)

FOR CENTRAL ONLY SCANNERS

Tabletop

Length	Width	Height
72"	36"	29"
1828 mm	914 mm	737 mm

Overall

Length	Width	Height
72"	48"	52"
1828 mm	1220 mm	1321 mm

Weight

400 lbs (181 kg)

Table Weight Limit

450 lbs (205 kg)

Scanning Area

25.5" x 29.5" (648 mm x 748 mm)

Table to Scanner Arm Distance

16" (406 mm)

Miscellaneous

Laser Marking

Positioning Aids

Hip Sling	Forearm Fixture (optional)
Foot Separator Block	Lateral Spine System (optional)
Leg Rest Block	

Technical Description

Significant Zone of Occupancy/Patient Environment

The operator should be at least three feet from the beam when the system is emitting x-rays. See Figure 9-1 for Position of X-ray Beam on page 9-7. If the operator stays at least one meter from the beam during the scan, the dose rate will be < 0.1 mRem/hr. For a one minute scan this is a 0.0017 mRem dose. For comparison, background radiation received per year is 150 mRems, and a cross-country round trip airline flight results in 5 mRems of additional exposure to the passengers and crew.

The computer should be located outside the perimeter of three feet from the beam and positioned such that the operator cannot touch the computer and the patient simultaneously. However, the computer can be closer if necessary as long as it is powered from the isolated multiple portable socket-outlet (IMPSO) device provided with the system.

Focal Spot to Image Receptor Distance (SID)

The SID is equal to 765 mm. It is fixed and the operator does not adjust it.

X-ray Generator

- Combination Tube Housing and High Voltage Generator
- 100 kV (± 150 V) constant potential
- 1.3 mA (± 0.02 mA) constant current
- Maximum heat dissipation = 300 W
- Minimum filtration is 2.7 mm Al.; Samarium k-edge @ 46.8 KeV
- Focal Spot - 0.5 mm
- Stationary anode and air cooled
- Power output of high voltage generator = 130 W
- Suitable for continuous operation
- Target is tungsten

Classification

Class I - Type of protection against electrical shock.



Type B - Degree of protection against electrical shock.



Continuous - Mode of operation.



Laser product (used for patient marking).

Class II (FDA) per 21CFR1040.

Class 1 (CE) per IEC60825-1:1993+A1/EN60825-1:1994+A11

Cooling Curves & Tube Rating Charts

The operator is not required to make any decisions regarding patient scanning based on cooling curves & tube ratings. However, this information is available from your Norland Customer Service representative, if required.

Duty Cycle

No duty cycle limits apply. The system can be operated continuously without any degradation in performance as long as the ambient temperature and humidity specifications are not exceeded.

Technique (or Loading) Factors

X-ray tube voltage & current and scan time are the technique factors.

- Tube voltage = 100 kV (± 150 V) constant potential. This is fixed and the operator does not adjust it.
- Tube current = 1.3 mA (± 0.02 mA) constant current. This is fixed and the operator does not adjust it.
- Scan time depends on the scan type selected. Refer to specifications.

Electrical Requirements

A hospital grade receptacle should be used to ensure safety ground continuity. No special voltage or current regulation or conditioning is required.

Installations

- Unit should be installed in such a way that the user can achieve optimum use of it.
- Minimum room size is 7 feet (213 cm) X 9 feet (274 cm) for Whole Body scanners, and 7 feet (213 cm) X 7 feet (213 cm) for Central Only scanners.
- No user installation. Authorized Norland service agent installs the device and trains the operator on proper use.
- CAUTION: For patient and user safety position the back of the scanner (open area under the table-top) as close to the wall as possible to inhibit unauthorized access to the interior of the device.
- Do not install near devices that produce large EMI fields (i.e. electro-cautery, elevator motors, etc.)
- Do not install near other x-ray emitting or radioisotope devices

Service

- No user serviceable parts inside unit.
- Norland will make technical servicing information available upon request to qualified technicians who receive Norland service training.
- Only Norland trained personnel have access to Norland certified components.
- Other manufacturer's components are not compatible with Norland systems.

FCC and EN60601-1-2 EMC Statement

Note: This equipment has been tested and found to comply with the limits for a Class B digital device pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communication. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet that is on a circuit different from the receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Fuse Ratings

Location	Fuse Rating
Power Tray F4 & F5 Filter Motor Driver Board F2, F3, F4	2A, 250V, 0.25" X 1.25" Slow Blow
Power Supply Board F1 & F2	2.5A, 250V, 0.25" X 1.25" Slow Blow
Filter Motor Driver Board F1	8A, 250V, 0.25" X 1.25" Fast Blow
Source Control Board F1	10A, 250V, 0.25" X 1.25" Slow Blow
Power Tray F6 & F7 Power Supply Board F3	15A, 250V, 0.25" X 1.25" Slow Blow

Beam Quality Information^a

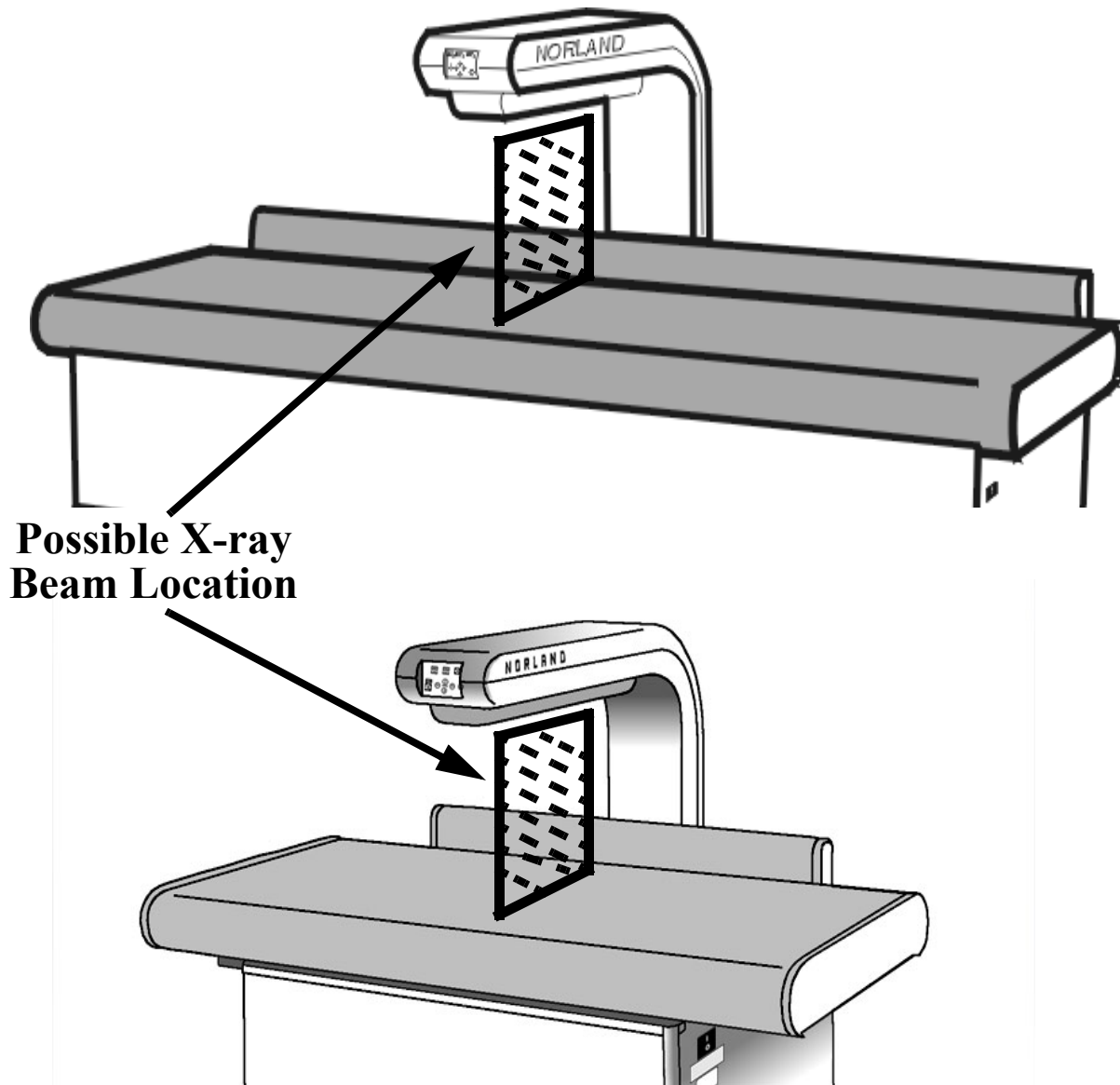
Item	Equivalent Filtration	Notes
Half Value Layer (HVL)	6.6 mmAl	Tested at 100 kV & 1.3 mA.
Irremovable Materials	1.9 mmAl	Tested with 70 kV, 2.5 mmAL Source.
Added Filters	13.2 mmAl	Tested with 70 kV, 2.5 mmAl source. Minimum fixed filters is 0.003 mm Sm.
Total Filtration	15.1 mmAl	Sum of irremovable and added filters.
Table Top	0.8 mmAl	Tested with 70 kV, 2.5 mmAl source.
Materials between patient & detector	0.1 mmAl	Tested with 100 kV, 5.5 mmAl source.

a. These values are fixed. The operator does not select filtration.

Position of X-ray Beam

The x-ray beam is located under the scanner arm. It may be located in any position under the arm. The exact location can be identified by activating the laser.

FIGURE 9-1



General Cautions

Caution - Do not touch the patient and the computer system at the same time as this could increase leakage currents.

Caution - Device is not designed to be defibrillator proof.

Caution - Device is not anesthesia proof.

Caution - Not a patient connected device; patient equalization terminal not provided.

Caution - The laser within this product is not user serviceable. In the event it fails to operate, contact Norland Customer Service.

Caution - Use of controls or adjustments or performance of procedures other than those specified may result in hazardous radiation exposure.

Caution - Follow the procedures in the General Maintenance section of this manual to insure patient data is not lost.

Note - The device of which this x-ray source is a part is a Class I device, (per clause 5 of EN60601-1). However, this x-ray source is not designed, intended, or capable of operating as a stand-alone x-ray source.

Note - There are no user serviceable parts or user accessible fuses inside the unit.

Cautions for the Isolated Multiple Portable Socket-Outlet (IMPSO)

Caution - The IMPSO provided with this system is for use with the computer (computer, monitor, and printer). Used this way it will reduce the risk of leakage currents for the patient and operator.

Caution - Do not connect the computer directly to a wall outlet instead of to the IMPSO because this would increase leakage currents.

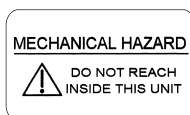
Caution - The maximum load for the IMPSO is 300 VA for 115/230 Vac at 50/60 Hz.???

Caution - Do not connect any other equipment to the IMPSO as this could increase leakage currents.

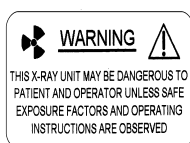
Caution - Do not use additional IPMSOs, or extension cords, because they could increase leakage currents.

Caution - Do not place the IPMSO on the floor. Place it on a table or shelf to protect it from damage and spilled liquids, which could result in increased leakage currents.

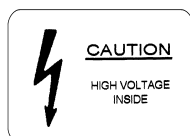
Specific Cautions



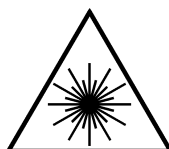
Warning - If you reach into the back of the unit, you could get your finger, hand or arm pinched between the scanner arm and scanner housing.



Warning - This device produces x-ray to achieve its intended purpose. It should only be used by qualified persons according to the instructions in this manual. Even though dose levels are very low, State and Federal regulations require scans of human subjects to be ordered by a physician.

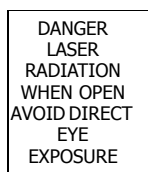


100KV is generated inside the source. It is not accessible on the outside of the source or on the printed circuit board attached to the source.



A laser is used for marking the area of the patient to be scanned. Do not allow the beam to hit the patient's eyes and be careful that it does not reflect off shiny surfaces. The only operator control is on and off.

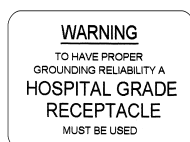
Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser light exposure.



Disassembling this part could result in exposure to laser radiation, Class II (FDA), Class 2 (CE). In particular the laser module will continue to operate even if it is removed from its housing.



The laser beam will come through the long slot next to this label.

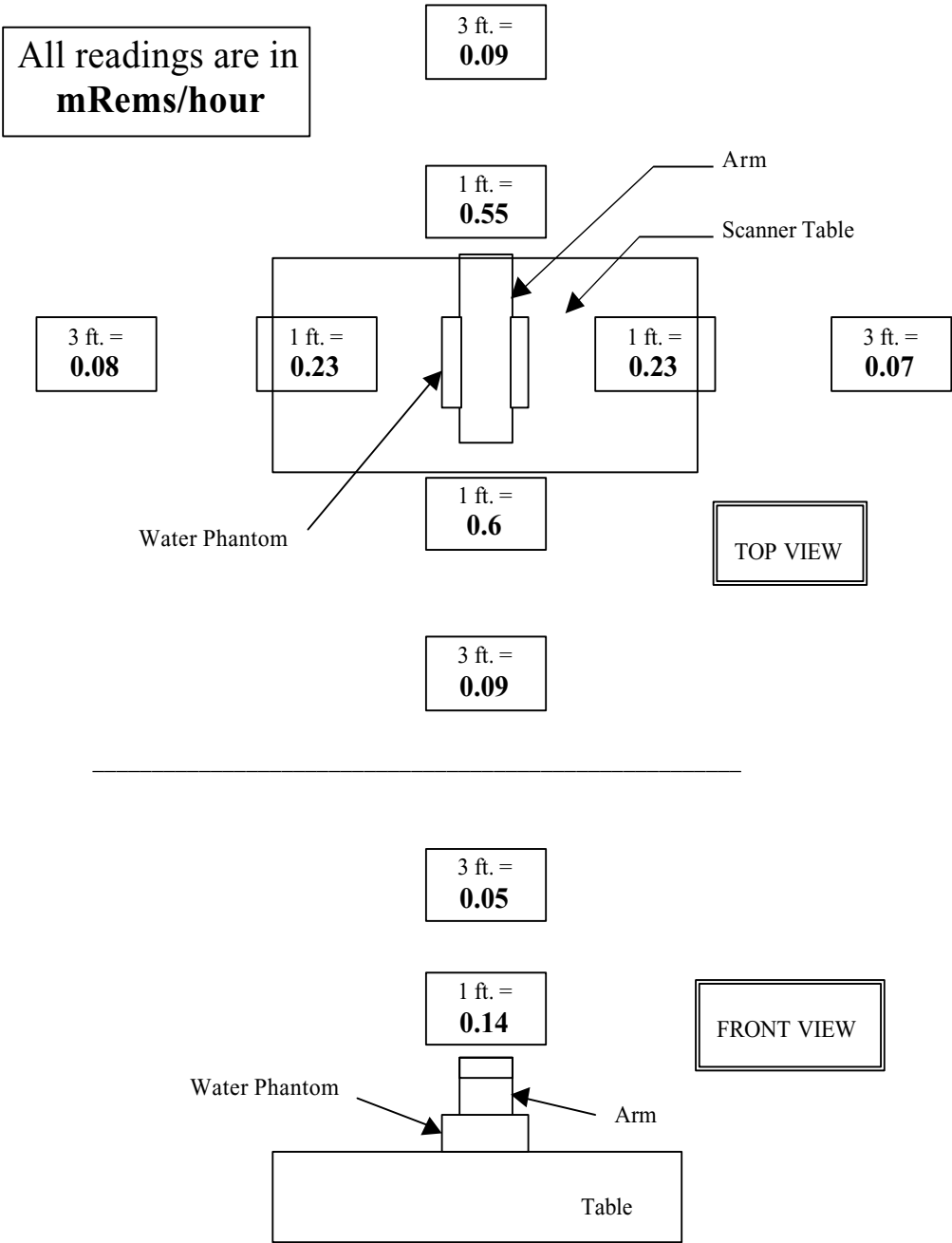


This unit is to be powered from a hospital grade receptacle to insure proper safety grounding.

Stray Radiation

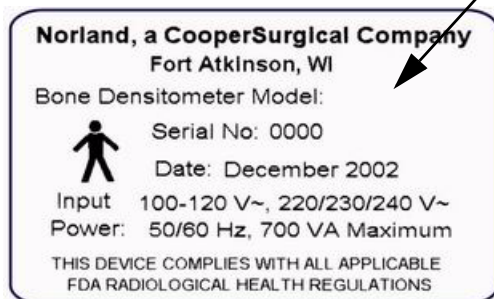
Specified to be less than 0.1 mRem/hr at a distance of three feet from the beam.

This test was done while scanning a 20 x 30 x 15 cm water phantom. A Victoreen Model 450P Ion Chamber (300 cc) was used to measure the radiation levels at approximately one foot and three feet from the beam. The 450P had a current calibration from its manufacturer.



Scanner Labels

The scanner Model is designated by a part number (433A025, 434A063, or 434A064).



OR

The scanner Model for China is designated by a part name (EXCELL, EXCELLplus, or XR-46).



Identification Label

(Only one of these labels will be on the unit, because they are model or country specific.)

Norland, a CooperSurgical Company Fort Atkinson, WI

Beam Limiter

Model No: 387A030
Serial No: 0000
Date: December 2002
Filtration: See Manual

THIS DEVICE COMPLIES WITH ALL APPLICABLE
FDA RADIOLOGICAL HEALTH REGULATIONS

Norland, a CooperSurgical Company Fort Atkinson, WI

Tube Housing & High Voltage Generator

Model No: 391A168
Serial No: 0000
Filtration: 1.9 mmAl
Date: December 2002

Tube: Toshiba, D-051, S/N: 0000

THIS DEVICE COMPLIES WITH ALL APPLICABLE
FDA RADIOLOGICAL HEALTH REGULATIONS

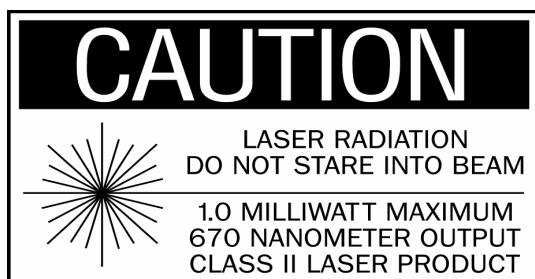
Norland, a CooperSurgical Company Fort Atkinson, WI

Table Top

Filtration: See Manual

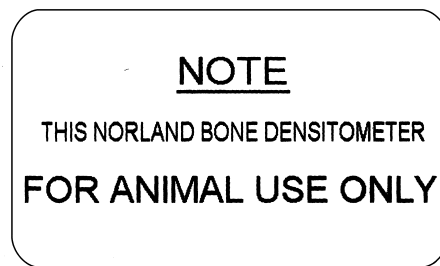
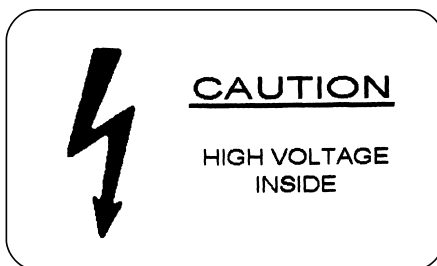
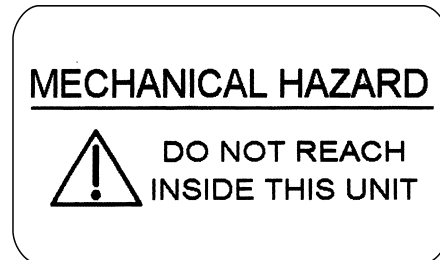
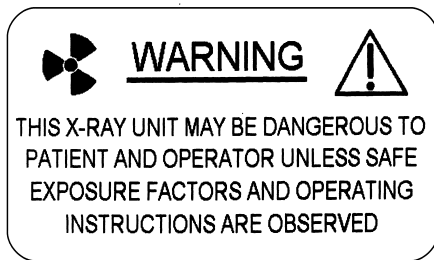
CAUTION

FEDERAL LAW RESTRICTS
THIS DEVICE TO SALE
BY OR ON THE ORDER
OF A PHYSICIAN

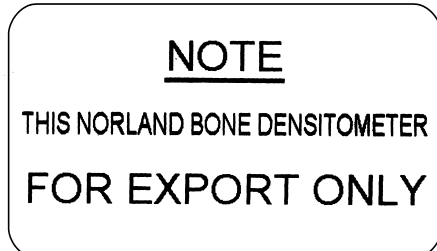


LASER
APERTURE

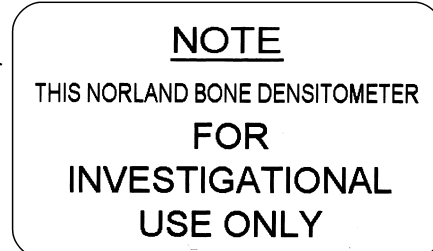
DANGER
LASER
RADIATION
WHEN OPEN
AVOID DIRECT
EYE
EXPOSURE



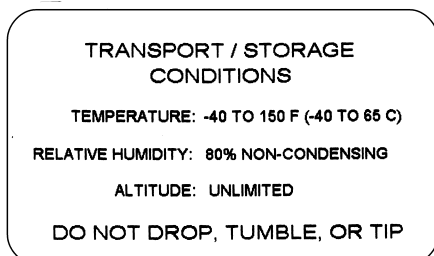
*If applicable



*If applicable



*If applicable

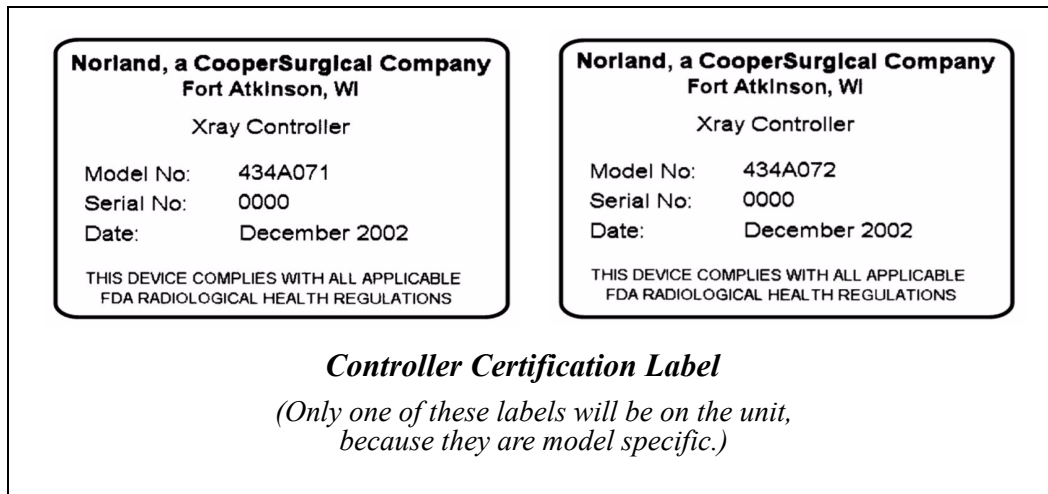


*Located on the outside of
the shipping container.



*EU Configuration Only

Controller Labels



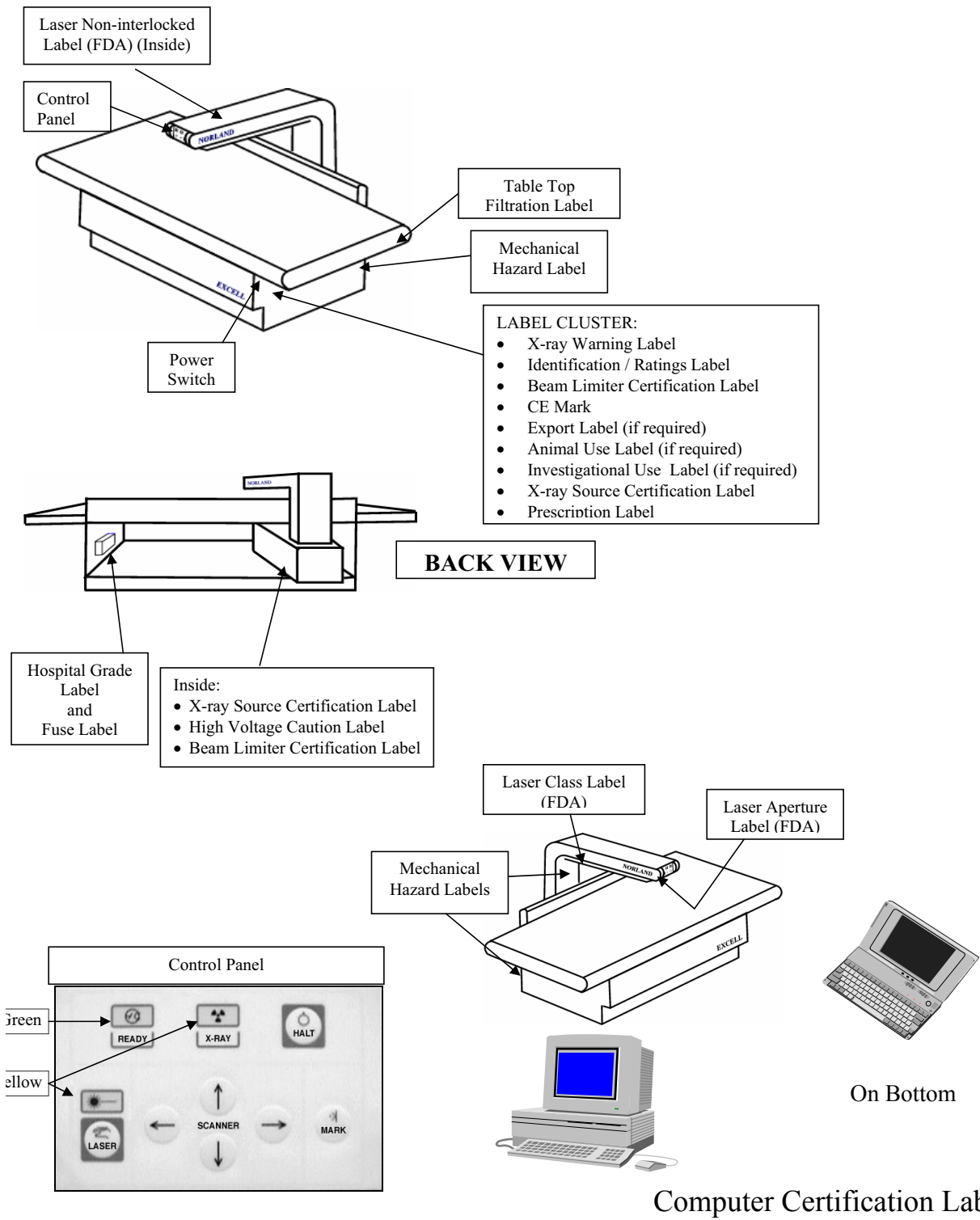
Power Entry Module Labels

The labels below are affixed to the Power Entry Module, located inside the table.

LINE VOLTAGE	FUSE 1/4 x11/4 250 V	FUSE 5 x20 mm 250 V
100 -120 V~	10 A slow	6.3 A (T)
220/230/240 V~	5 A slow	3.15 A (T)
INPUT POWER: 700 VA MAX. 50/60 Hz		

WARNING
TO HAVE PROPER
GROUNDING RELIABILITY A
**HOSPITAL GRADE
RECEPTACLE**
MUST BE USED

Label Locations



INDEX

A

- Accessories
 - calibration standard 1-8
 - patient positioning 1-8
 - phantom 1-8
- Accuracy 1-11
- Add
 - new patient 1-21
- Alternate R Value Analysis 3-8, 6-26
- Analysis
 - AP Spine options 3-7
 - Hip options 3-8
 - Hip scan 5-21 *through* 5-24
 - Lateral Spine options 3-7
 - sub-menu 1-21
- Analyzing Saved Scan Data 6-19
- Angulated cursors
 - modifying 6-20
 - selection 6-19
- AP Leg Rest
 - reason for 4-10
 - use of 4-10
- AP Spine
 - analysis options 6-19
 - Quick Reference 4-5
 - scan overview 4-1
 - setting analysis defaults 3-7
 - setting scan defaults 3-5
- Auto Centering 6-21

B

- Backup
 - diskettes 2-17

C

- Calibration
 - procedure 2-6 *through* 2-11
 - results display 2-9, 2-10
 - results interpretation 2-12 *through* 2-14
- Calibration Standard description 1-8
- Cautions
 - general 4-6, 5-7
- Change Parameters
 - AP Spine 6-21
 - Hip 6-27
- Cleaning
 - patient pad cover 7-2
 - Positioning Aids 7-2
 - QC phantom 7-2
 - scanner exterior 7-2
- Coefficient of Variation 1-11
- Comparison
 - reference set 1-11
 - trend overview 1-10
- Comparison Image 6-18
- Composition Mode 6-7

- Copyright 1-9
- Create Reference Set 7-13
- Customer Service
 - locations 1-2

D

- Data
 - backup procedure 2-16 *through* 2-17
 - entering 1-17
 - field navigation 1-18
 - File Management 7-6
- Default storage
 - setting location 3-9
- Delete
 - patient 1-21, 7-11
 - scan 1-21, 7-11
- Disk
 - functions 1-24
 - sub-menu 1-21
- Disk Status 7-6
- Dose
 - AP Spine skin 4-3
 - Hip Scan 5-3
 - Operator 4-3
- Dropdown menus
 - operation 3-3
- Duplicating Diskettes 7-12

E

- Empty Print Queue 7-5
- Exam paper
 - dimensions 1-8
 - disposal 4-10, 5-11
 - part number 1-8
 - replacing 7-2

F

- Fault diagnosis
 - calibration 8-5
 - printer operation 8-6
 - Reference/Trend chart display 8-7
 - Scanner unit 8-3
 - software operation 8-3
 - system startup 8-2
- File
 - sub-menu 1-26
- Force Mark Points On-Axis 6-23
- Formatting Diskette 7-12
- Fracture Risk
 - sample chart 1-12
 - WHO criteria 1-13, 4-20, 5-27

H

- HALT button 1-4, 4-14, 5-18, 5-20
- High Density Point Exclusion 3-7, 3-8, 6-19, 6-26
- Hip
 - analysis options 6-26
 - locating femoral neck 5-15
 - Quick Reference 5-6
 - scan overview 5-1

- setting analysis defaults 3-8
- setting scan defaults 3-6
- Hip Sling
 - use 5-11 *through* 5-14

I

- Image
 - composition mode 6-7
 - contrast scaling 6-6
 - display 1-26, 1-28, 3-4
 - Include/Exclude 6-12
 - scaling mode 6-8
 - sub-menu 1-26
- Indications for Use 1-1
 - Contraindications 1-1
- Indicators
 - audible 1-4
 - exposure 1-4
 - laser 1-6
- ISO 9001 Certification 1-2

L

- Label Locations 9-14
- Laser
 - control 1-6
 - precautions 1-6
 - use of 1-6
- Lateral
 - setting analysis defaults 3-7

M

- Maintenance 7-2
- Menus
 - Analysis Menu details 1-26 *through* 1-28
 - Analysis Menu items 1-26
 - dropdown 1-20
 - Main Menu description 1-19
 - Main Menu details 1-21 *through* 1-25
 - Main Menu display 1-19, 2-5
 - Main Menu items 1-21
- Mouse
 - double-click speed 3-4
 - keyboard equivalents 1-17
 - techniques 1-16
- Multiple QC Scans 7-4

O

- Optimize Patient Files 7-3

P

- Patents 1-9
- Patient Personal Data 6-4
- Patient positioning
 - AP Spine 4-10
 - Hip 5-11 *through* 5-14
- Positioning Aids
 - cleaning 7-2
- Precision 1-11
- Precision & Accuracy

- attaining 2-2

Print

- from main menu 6-2
- sub-menu 1-21, 1-26

Print Queue

- emptying 7-5
- start 6-3
- stop 6-3

Printer

- setting options 3-11

Printout Headers

- defining 3-12
- selecting 3-12, 4-20, 5-27

Q

QA

- sub-menu 1-21

QC Phantom

- cleaning 7-2
- description 1-8
- scanning 7-4

Quality Assurance

- overview 1-9

QuikScan 1-3

R

- Reanalyze scan data 6-16

Reference Chart

- display 1-12, 1-27, 8-7

Reference Data

- commands 3-10
- sub-menu 3-10

Reference Data Set

- maintenance 7-13
- selection 4-17, 5-24

Region of interest

- AP Spine 4-1
- defining 4-16
- excluding 6-12
- Hip 5-1
- including 6-13
- initial positioning 4-15, 5-19
- modifying 4-16, 6-10, 6-12, 6-14

Regions

- sub-menu 1-26

Reports

- available reports 1-14 *through* 1-15
- printer setup 3-11
- printing from Analysis Menu 6-2
- printing from Main Menu 6-2
- printing from Results Page 1 4-20, 5-27, 6-2

Results

- AP Spine 4-18
- Hip 5-25
- sub-menu 1-26

Ruler tool 6-15

S

- sBMD Report 1-15

- AP Spine 1-32

- Hip 1-35
- Scaling Mode 6-8
- Scan
 - sub-menu 1-21
 - type 1-22
- Scan data
 - default storage 3-9
- Scan Data File
 - maintenance 7-3
- Scan Data Files
 - Copy All Scan Files from Selected Patient 1-24, 7-9
 - Copy Specific Scan Data File 1-24, 7-8
 - management 7-6
 - Move a Scan 1-24, 7-7
 - Move All Scans 1-24, 7-7
 - Moving 7-6
 - Retrieving a Single Copied Scan 1-24, 7-9
- Scan History Report 1-15, 1-37
- Scan Region
 - defining AP spine 4-11
 - defining Hip 5-15 *through* 5-19
 - image characteristics 4-4, 5-5
- Scanner
 - control panel 1-6
 - exposure control 1-4
 - features 1-3
 - filtering 1-3
 - laser 1-6
 - table 1-5
- Scanning
 - AP Spine options 3-5
 - AP Spine procedure 4-7 *through* 4-15
 - AP Spine techniques 4-13
 - basics 2-2
 - existing patient 4-8, 5-9
 - Hip options 3-6
 - Hip procedure 5-8 *through* 5-21
 - Hip techniques 5-17
 - implants 1-1
 - new patient 4-7, 5-8
 - prosthetic devices 1-1
 - sub-dermal objects 1-1
- Select
 - existing patient 1-21
 - scan 1-21
 - sub-menu 1-21
- Setup
 - sub-menu 1-21, 3-2
- Shutdown procedures 2-15
- Software
 - operation 1-16 *through* 1-20
- Special regions
 - adding 6-9
 - deleting 6-11
 - modifying 6-10
 - renaming 6-11
- Specifications
 - AP Spine scan 4-2
 - Hip Scan 5-2
- Standard Deviation 1-11

- Startup procedures 2-3
- Stop Scan 4-14, 5-18
- System
 - setup 1-25, 3-2 *through* 3-12
- System Specifications 9-2

T

- Trademark 1-9
- Trend comparison 1-10
- T-Score 4-18, 4-19, 5-25, 5-26

W

- WHO Criteria 1-13, 4-20, 5-27

X

- Xfcheck 7-3
- X-ray
 - beam 1-2
 - device registration 1-1
 - exposure control 1-4
 - filtering 1-3
 - raditation safety 1-2
 - scatter radiation 1-2

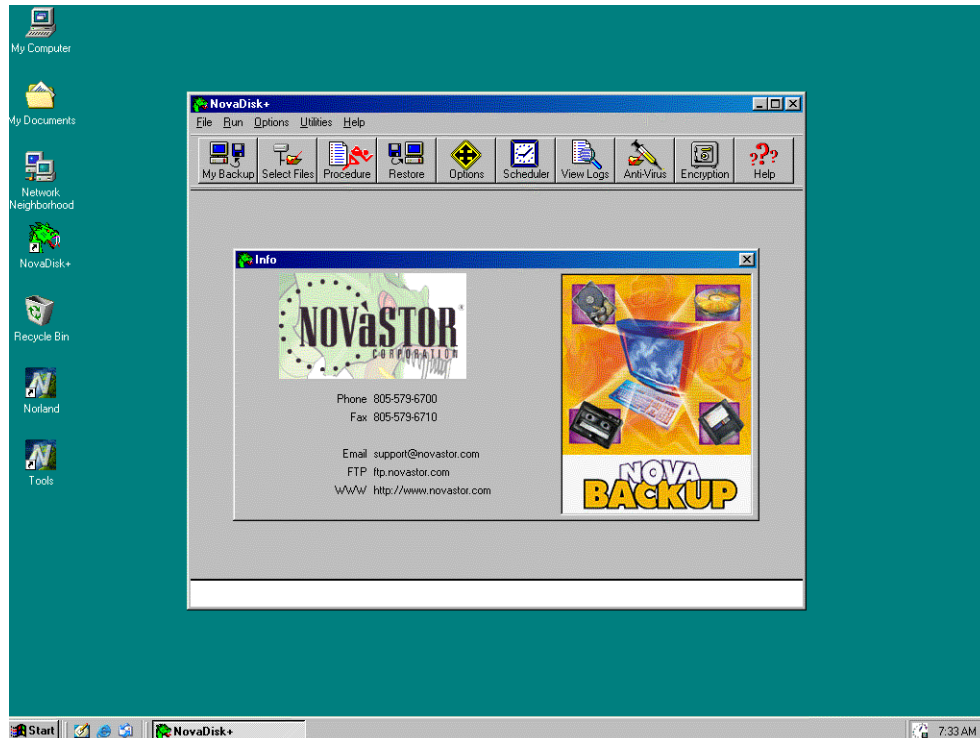
Z

- Z-Score 4-18, 4-19, 5-25, 5-26

System Backup

Desktop PC's are equipped with a high capacity storage device for system backup. Norland recommends that daily system backups be performed as part of the routine shut down procedure.

1. Exit the host software to the Windows desktop.
2. Insert the media into the drive, and click on the "NovaDisk+" icon.
3. When the main screen appears, click on the "Procedure" button.



4. Click on "Norland_Default.bup", on the "Select Backup Procedure Screen", then click on the "Run" button. If the drive is not ready click on "Retry".
5. The "Backup to..." dialog will appear, (verify the "Save In" pull down menu points to Removable Disk D:), and click on the "Save" button to save the procedure.
6. Select "Erase Disk Unconditionally" from the "Options are" pull down menu.
7. Click on "OK" to begin the backup operation, on "Backup Confirmation" screen.
8. If your system files are too large to fit on one media you will be prompted to insert media 2. During the compare function it is necessary to re-insert media 1 and then media 2 again when prompted by the software.
9. Click on the "OK" button when the Backup and Verification completion message is displayed.
10. Select "Exit" from the "File" pull down menu.
11. Remove the media from the drive and store in a safe place.

QA Calibration

Daily Calibrations should be performed prior to patient scanning to ensure quality bone density estimates.

- Check the Calibration Standard for bent corners, damaged plastic, or loose parts (when shaken). If damaged, contact Norland Customer Service.
- Click on **Begin QA** at the Main Menu. The system will prompt the operator to place the calibration standard on the scanner and MARK point A.
- Place the standard on the patient surface in the proper orientation as shown. Align it with the corresponding marks on the table surface.
- Switch ON the positioning laser.



Whole Body
Scanners



Central Only
Scanners



CAUTION: Do not stare into the beam.

- Position the scanner arm so that the laser beam spot is on the '+' point on Plexiglas identified by the inscribed letter 'A' and press the MARK button.
- Position the scanner arm so that the laser beam spot is on the '+' point on Plexiglas identified by the inscribed letter 'B' and press the MARK button.
- Place the QC Phantom at the center of the scanning surface, parallel with the backrest. The 'C' should be to the head of the table (to the right if facing the scanner).
- Move the scanner arm so that the laser positioning spot is on the dot/x by point 'C'.
- Verify the phantom is straight by moving the laser to the dot/x by point 'D'.
- If you have the BLACK phantom, only Mark the dot at point 'C'.
- If you have the CLEAR phantom, first Mark the x at point 'C', then the x at point 'D'.

The QA Results screen will be displayed at the completion of the QC Scan.

- Verify that the **PRECISION** and **ACCURACY** fields display the **OK** status on the BMD, Fat and Lean screens.
- Click on [**Continue - Print**] on the BMD screen to print the results for storing in the calibration log.

*Clicking on [**Cancel**] or pressing the keyboard's **[Esc]** key any time before the QA Results screen appears terminates the calibration procedure and the calibration files will revert to the previously recorded values.*

WARNING Should any part of the calibration process fail, repeat the calibration once. If the diagnostic tests fail the second time, shut the system down, re-start and perform calibration. If further difficulty is encountered, contact your Norland Customer Service representative. Refer to the Operator's Guide for other troubleshooting options.



Scanning AP Spine

The AP Spine scan takes measurements from L2 through L4.

- Click on Scan New/Existing Patient.
- Select scan type.
- Enter/Update Patient information.
- Screen patient for contraindications.
- Position the patient face up in center of the scanner table. Position the scanner arm over the patient's midsection.
- Use the leg rest block to stretch the spine and relax the curvature.



CAUTION the patient not to stare into the beam.

- Turn laser on and position the laser dot 2cm below the xiphoid process and press the MARK button on Scanner Control Panel to set scan start point. If you want to include L1 in the scan, position the laser dot at the xiphoid process.
- Position the laser dot 2cm below the iliac crests and press the MARK button on Control Panel to set scan end point.
- At the Scan Review screen, click on **[Start Scan]**.
- When the scan is finished, click on **[Analyze]**.
- While system performs analysis, remove positioning aid to make patient comfortable.
- When the initial analysis is complete, place the top cursor at the space between L1/L2 on displayed image.
- Place the bottom cursor at the space between L4/L5 and click on **[Continue]**.
- Confirm that cursors are set between L1/L2, L2/L3, L3/L4, and L4/L5.
- Click on Results Page 1, under the Results menu.
- Enter comments with Edit Comments, if desired.
- Click on **[Continue - Print]** to print the report as determined by Print Setup. The Norland software automatically saves the scan file to default storage and returns to the Main Menu when the report printing has been initiated.

Scanning Hip

The Hip scan process consists of a brief Scout scan over the femoral neck area, a Measurement scan, calculation of numeric results, and saving of data.

- Click on Scan New/Existing Patient.
- Select scan type. (Scan non-dominant hip)
- Enter/Update Patient information.
- Screen patient for contraindications.
- Position the patient face up in center of the scanner table. Place the Leg Separator Block between the patient's heels. Place the Hip Sling with straps under the patient's legs as close to the pelvic area as possible.
- Pull up on the Velcro strap to remove any slack from the leg that will not be scanned. Repeat the process on the leg that will be scanned.
- On the leg that will not be scanned, gently pull the Velcro strap to the next reference number to rotate the hip. Repeat the process on the leg that will be scanned.
- Position the scanner arm over the patient's midsection.



CAUTION the patient not to stare into the beam.

- Turn the laser on and position the laser dot at the approximate center of the Femoral Neck and press the MARK button on Scanner Control Panel to set Scout scan start point.
- At the Scan Review screen, click on **[Start Scan]**.
- When the Scout scan is finished, place the cursor at the center of the Femoral Neck on displayed image.

NOTE: The Scout scan may be terminated when the entire femoral neck is visible.

- Click on **[Measure Scan]** and allow the Measurement scan to complete without intervention.
- While system performs analysis, remove positioning aids to make patient comfortable.
- Results Page with analysis will be displayed.

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 report as determined by Print Setup. The software automatically saves the scan file to default storage and returns to the Main Menu when the report printing has been initiated.