LONE OAK
MEDICAL TECHNOLOGIES

accuDEXA®
User Guide

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Preface

The accuDEXA device

The accuDEXA device from Lone Oak Medical Technologies. is a bone densitometer that estimates bone mineral density (BMD) of the middle finger of the non-dominant hand. It is a self-contained, table-top unit, employing dual energy X-ray absorptiometry (DEXA) technology. After the finger is scanned, results are generated in less than one minute.

This accuDEXA User Guide contains operation and maintenance information, procedures and guidelines for testing, interpretation of test results, and technical specifications on the accuDEXA device.

Indications for use

The accuDEXA is a dual-energy X-ray device indicated for use in estimating the bone density (BMD) of the middle finger of the non-dominant hand. This BMD value is a relative indicator of bone density elsewhere in the body. The accuDEXA's BMD estimates can be used as an aid to the physician in determining fracture risk.

Warnings

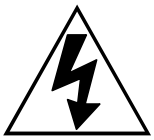
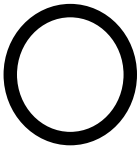
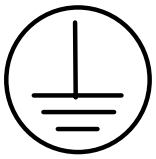
- This X-ray unit may be dangerous to the patient and operator unless safe operating instructions are observed.
- The need or appropriateness for BMD measurements of phalanges in the management of renal osteodystrophy has not yet been established.

Precautions

- Federal law restricts this device to sale by or on the order of a physician.
- The BMD values obtained with this device should be only one factor in a medical judgment that treatment is warranted for a disease or disorder.
- The accuDEXA compares BMD values to a reference (normative) database. This database reflects the mean for a healthy normal (YHN) population having the same gender and ethnicity. Users are reminded of risks in misinterpretation when comparing a patient's BMD results with a database population of different gender or ethnicity.
- In accordance with international standard IEC-601-3: General Requirements for Radiation Protection in Diagnostic X-ray Equipment, use of the accuDEXA shall be limited to no more than 20 patient scans per hour.

Symbols and markings

Listed below are the descriptions of the various safety and operational symbols that appear either inside or outside the accuDEXA device.

SYMBOL	DESCRIPTION
	Indicates the presence of **dangerous voltage** within the enclosure of the device. This voltage may constitute a risk of electric shock voltage when the device is connected to a service outlet. This safety issue warning symbol is located on the back panel. For additional electrical details, see page 46.
	Indicates an attention to users to consult accompanying documents (this User Guide) for more information on the device. This symbol is located on the accuDEXA back panel and on the finger phantom.
	Indicates the ON position of AC power (located on the front panel).
	Indicates the OFF position of AC power (located on the front panel).
	Indicates the point where the safety ground wire or protective earth connector connects inside the accuDEXA.
	Indicates that the accuDEXA is a Class B diagnostic device. This label is placed on the back panel.

- To protect against electrical shock, the accuDEXA device is grounded with a three-prong cable and plug. Insert this power cable only into a properly grounded three-contact outlet.
- Please do not remove the protective cover of the accuDEXA device. Since there are no serviceable parts, all internal adjustments and replacements must be made by the manufacturer.
- Always disconnect the system from the power source before moving or cleaning.
- The accuDEXA device uses low X-ray dosage. Please refer to your state or national regulator regarding radiological safety procedures and precautions.

Registering your accuDEXA

In most areas of the United States, users will be required to register the product with their states' radiation board. To facilitate registration, we have provided a list of contacts that you may find helpful. This list can be found in the documentation kit supplied with your unit.

In order to register your accuDEXA, you will need to supply some basic technical information to the state radiation board. In the following table we have included information to help you respond to those questions correctly. More detailed specifications may be found in the Specifications and Electrical Summary tables on pages 45 and 46, respectively, of this manual.

Maximum kVp	70 kVp
Maximum X-ray current	10 ma
Part number	B7100
Serial number	Check the product label near the fan on the back of your unit
Scatter radiation	6.1 mR/h at 1 meter distance Time of two DEXA pulses is 60 and 90 milliseconds
Absorbed dose (Effective radiation)	3E-4 uSv per scan
Number of tubes	1
X-ray head number	Check the regulatory label near the electrical inlet on the back of your unit

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accuDEXA overview and setup

Overview

The accuDEXA is a dual-energy X-ray device that estimates the bone mineral density (BMD) of the region of the third finger of the non-dominant hand. Finger BMD is a relative indicator of bone density in other parts of the body.

The t-score and z-score

The accuDEXA reports an individual's relative BMD status by calculating a t-score and z-score. This calculation is performed automatically by the accuDEXA and can be viewed on-screen and/or printed out at the conclusion of an exam. For a concise definition of t- and z-scores, please refer to the glossary on page 68. The t-score or z-score is often used by a physician as one factor, in conjunction with other clinical indicators, to diagnose osteoporosis and other bone disorders.

T-scores and z-scores can only be computed if a normative database of other individuals with the same age, gender, and ethnicity of the patient is available. When the matching reference database is unavailable, the patient's BMD can still be used to compare with an initial baseline value.

Using accuDEXA t-scores in your practice

Low bone mineral density at the finger has been demonstrated to be as predictive of generalized fracture in the elderly as measurements made at axial sites.[1] All bone mineral density measurements should be used in conjunction with other risk factors in determining fracture risk. Other clinical measurements such as blood pressure and cholesterol indicate risk of stroke and myocardial infarction. Similarly, evidence of osteoporosis, according to the World Health Organization (WHO), indicates risk of fracture not certainty. Evidence of normal bone mass according to WHO criteria provides no assurance that a patient will not fracture. Nevertheless, bone mineral density is just as predictive of future fracture as blood pressure measurements are of future risk of stroke.

A recent consensus article published by the scientific advisory board of the Bone Measurement Institute suggests using an intervention threshold on peripheral instruments of t<–1.0.[1] According to independent data collected on the accuDEXA, using hip DXA as the *gold standard*, the Bone Measurement Institute's suggested threshold of t<–1.0 results in good test sensitivity and moderate test specificity.[2] Nevertheless, those who chose to use the accuDEXA to make treatment decisions may choose a somewhat lower T-score threshold of –2.0.

The National Osteoporosis Foundation suggests initiating drug therapy in women with t-scores below –2 (in the absence of risk factors) and in women with t-scores below –1.5 (if other risk factors are present).[3] Whatever intervention level you choose be aware that no single site BMD measurement will agree diagnostically with other measurements 100% of the time.

For more information about osteoporosis and using t-scores in your practice, please fax your request for the "Physician's Guide to Prevention and Treatment of Osteoporosis" to the

[1] Miller PD, Bonnick, SL, Johnston CC, Kleerekoper M, Lindsay R, Sherwood LM, Siris E. The Challenges of Peripheral Bone Density Testing: Which Patients Need Additional Central Density Skeletal Measurements: *Journal of Clinical Densitometry*, 1(3):211-217.

[2] Mulder JE, Michaeli D, Flaster ER, Siris E. A Comparison of Bone Mineral Density of the Phalanges with Bone Mineral Density of the Lumbar Spine, Hip, and Forearm for the Assessment of Osteoporosis in Postmenopausal Women: *Journal of Clinical Densitometry*, December 2000 (in press).

[3] Physicians Guide to Prevention and Treatment of Osteoporosis. National Osteoporosis Foundation, *Exerpta Medica*, 1998.

National Osteoporosis Foundation (fax number (202) 223-2237).

Monitoring Changes in Bone Mineral Density

BMD is an appropriate parameter by which to monitor changes in bone mineral density effected by drug therapy or aging. Physicians should compare results of BMD tests taken on a patient over a period of time with the reported accuDEXA precision (repeatability). To determine whether a significant change in BMD has occurred, physicians must calculate the percentage change in results over time according to the following formula:

$$\% \text{ change} = (BMD_{\text{previous exam}} - BMD_{\text{current exam}}) / BMD_{\text{previous exam}} * 100\%$$

The information below will help the physician determine the statistical significance of the BMD test result changes. (As a general rule, a greater-than-1.8% difference in BMD results would indicate consequential change.)

Percentage Change in BMD	Level of Statistical Significance
2.77%	95%
2.33%	90%
1.84%	85%

(These values are based on accuDEXA's published precision of 1%.)

Indications

The Society of Nuclear Medicine and American College of Nuclear Physicians has identified specific medical indications that warrant the evaluation of a patient's bone density. Below normal bone density can be associated with a variety of bone conditions or disorders. Some of the more common conditions associated with below normal bone density include:

- Premenopausal oophorectomy
- Spontaneous menopause or estrogen deficiency conditions
- Treatment-related osteopenia; when the diagnosis of osteopenia is suggested or established by other means (such as X-ray; during long-term immobilization)
- Endocrinopathies associated with osteopenia; for post-gastrectomy and other malabsorption states leading to osteopenia; during long-term corticosteroid therapy
- Chronic renal disease, particularly in childhood or adolescence

In addition to the above, BMD values can be used to monitor longitudinal changes, as with treatment programs for osteoporosis.

Contraindications

- A deformity that prevents a patient's non-dominant hand from being properly positioned.
- Orthopedic hardware in the middle finger of the non-dominant hand.
- Previous fracture of the middle finger of the non-dominant hand.
- Pregnancy. (Although the radiation exposure from an accuDEXA BMD test is 1/150,000 of a chest X-ray, any radiation exposure during pregnancy must be deemed medically necessary by a physician.)

Known adverse reactions

None

Controls and indicators

Identified on the following figures are the external features of the accuDEXA device.

Figure 1. The accuDEXA Device, front view

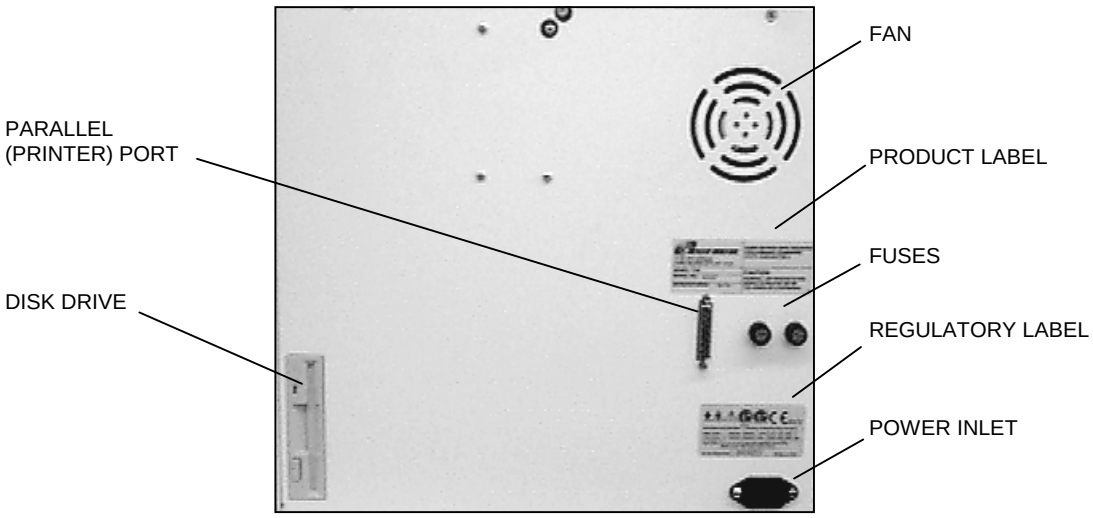


Figure 2. The accuDEXA Device, back view

Printer installation

1. Verify that the printer is compatible with accuDEXA. Refer to Appendix E on page 64.
2. To install a compatible printer, perform steps 3 through 6, then perform “Changing the printer” procedure on page 27.
3. Make sure the accuDEXA is off (the On/Off key switch is in the Off position).
4. Attach the printer cable to the accuDEXA parallel port (Figure 2). If a power supply was supplied with the printer, make that connection also.
5. If not already connected, plug one end of the power cable to the power inlet and plug the other end into an appropriately grounded outlet.
6. Insert the key in the On/Off key switch (Figure 1) and turn it counter clock-wise to the On position. The On/Off indicator light will illuminate and the Welcome Screen appears.

Printer connections

The block diagram below details the external connections of the accuDEXA, the printer, and the printer power supply (optional, depending on the printer).

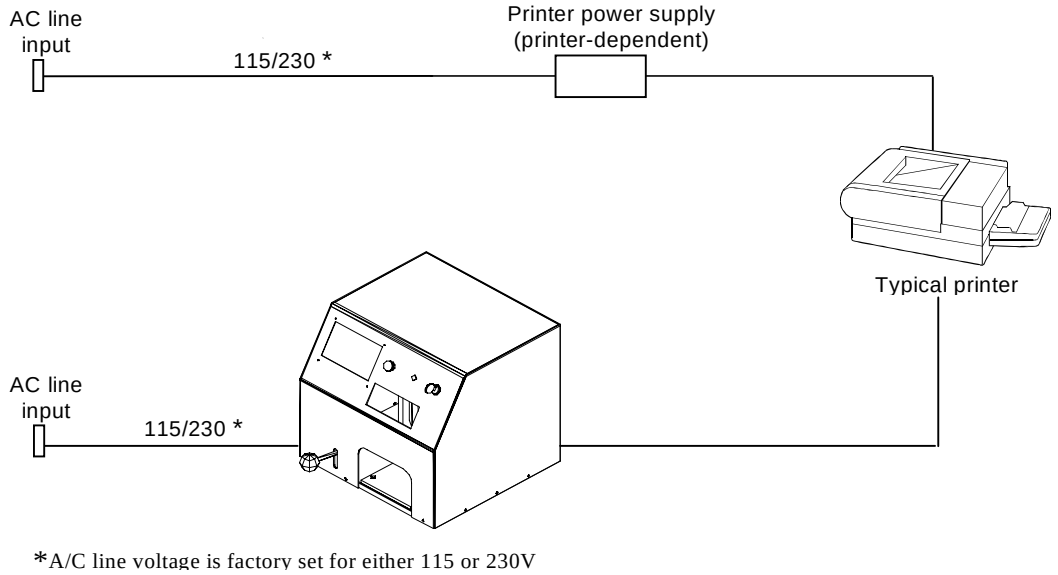


Figure 3. Typical Printer Connections

Turning on the accuDEXA

> **PLEASE NOTE:** The accuDEXA must be kept in the prescribed temperature range. If this is the first time you are turning on the accuDEXA, let the unit acclimate to the indoor temperature for at least 30 minutes before turning it on. If a temperature error occurs, adjust room temperature, let the unit re-acclimate, and try again. If the error occurs again, contact Schick Technologies for assistance.

1. Ensure that the accuDEXA, the printer, and the printer power supply (depending on the printer used with the system) are connected to each other and the A/C service outlet.
2. Insert the key into the On/Off key switch and turn it counter-clockwise to On.
3. The On/Off indicator illuminates and after approximately 60 seconds, the **Welcome Screen** appears on the display.

Turning off the accuDEXA

1. Insert the key into the On/Off key switch (if it is not inserted already) and turn it clockwise to Off.
2. The On/Off indicator will turn off and the display screen will clear.

> **PLEASE NOTE:** Turn off the accuDEXA at the end of every day and whenever it is not in use.

New features in software version 1.50

The new software release for accuDEXA includes the following features.

- New data (ages 80 to 89) for FEMALE ASIAN database
- New Latin American data (ages 80 to 89) for FEMALE HISPANIC database
- New sensor verification test for determining system effectiveness on start-up
- New quality control test for current and ongoing review of system performance
- New Patient Log Report
- Support for additional printers

Software upgrade procedure

To upgrade the accuDEXA with the latest software release, perform the following procedure.

> **PLEASE NOTE:** To maintain reliable system performance, do not install older versions of accuDEXA software after upgrading your unit.

1. If necessary, power down the accuDEXA by turning the On/Off key clockwise to Off.
2. Insert the upgrade diskette into the disk drive located in the back panel.
3. Power up the accuDEXA by turning the On/Off key counter-clockwise to On (indicator illuminates). The new software will be installed automatically.
4. Wait for the message, **Upgrade is complete**.
5. Remove the upgrade disk.
6. Power down the accuDEXA by turning the On/Off key switch clockwise to Off.
7. Pause for ten seconds.
8. Power up the accuDEXA by turning the On/Off key counter-clockwise to On.

Conventions used in text

Several text conventions are used in this manual to emphasize the text displayed on the touch screen and to provide additional help and information in the procedural areas.

The names of menu screens and the wording on the LCD screen display are shown in bold when they appear in text.	**Main Menu Screen, Ethnicity Screen, BMD Test**, **Change Printer**, **OK**, **Cancel**, etc.
Suggestions provide usage hints or reminders.	**TIP:** If you enter the wrong ID, press **CLEAR** and re-enter the number.
Items of special note provide additional user information or instruction.	**PLEASE NOTE:** If a particular ethnicity is not listed, it is not installed in the accuDEXA.

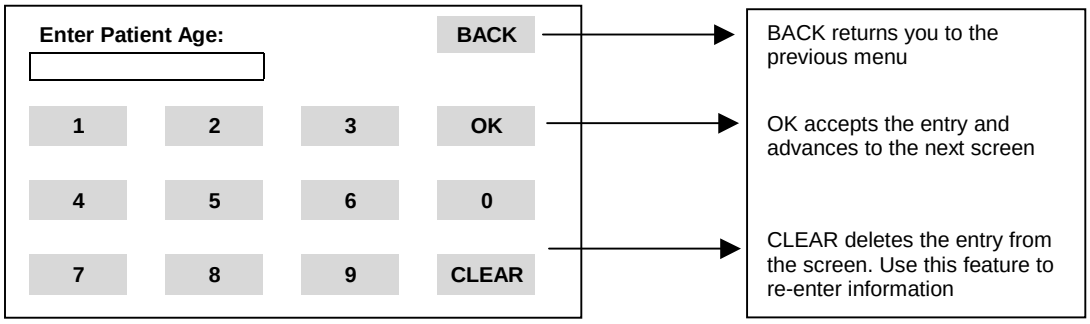
Using accuDEXA

The touch screen

The operator enters information and initiates a BMD test by using the touch-sensitive LCD screen. The touch screen reacts to the contact of the operator's finger, and only minimal pressure, a simple light touch or a tap, is necessary. The touch screen will not respond if the operator is wearing a glove.

Screen navigation

A description of some of the on-screen features of the accuDEXA appear below using the **Age Screen** as an example.



Finger placement

1. Push down the handle knob. This will raise two levers located in the hand slot.
2. Instruct the patient to place their non-dominant hand inside the hand slot. If the patient is right handed, they should place their *left hand* into the hand slot. If the patient is left handed, they should place their *right hand* into the hand slot. The patient's hand must be placed *palm down* and rest as far forward as possible. Refer to the following figure.

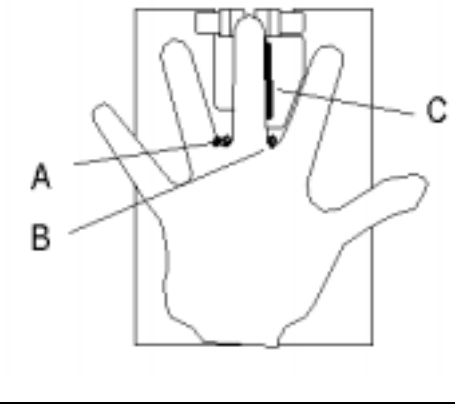
The hand must contact the pegs at both sides of the middle finger at points **A** and **B**. The middle finger must rest firmly against the guard at **C.**	

Figure 4. Finger Placement

3. Slowly release the handle knob. This will lower two levers onto the patient's middle finger (one lever will rest near the tip of the finger and the other will rest near the base). These levers will gently secure the finger in place during the BMD test.

Finger placement and jewelry

Since proper finger placement is essential for an accurate and precise BMD test, all hand and wrist jewelry should be removed. Removing jewelry may improve finger positioning, increase patient comfort, and help the patient to remain still during the procedure. Incorrect positioning or finger movement during testing may lead to inaccurate test results.

What if hand jewelry cannot be removed?

If jewelry cannot be removed, extra care must be taken to ensure correct positioning. For example, a ring could prevent a patient from resting their finger against the finger guide. As long as the finger placement approximates the description on page 6, and the X-ray image contains no part of a ring or jewelry, the exam is valid.

Obtaining successful BMD test results

For best results, the operator must follow several simple guidelines.

- The patient's hand must be positioned *palm down* and held completely motionless throughout the exam.
- During an exam, the accuDEXA should rest on a table roughly 30 inches from the floor. Patients should be in a comfortable position during the BMD Test. The patient's seat should be stationary and approximately 18 inches from the floor.
- The accuDEXA is only accurate and precise within the prescribed temperature and humidity range listed on page 44.

Operator checklist

The operator is responsible for ensuring the following:

- An audible signal should be heard for each of the two X-ray exposures that occur during the BMD test.
- The radiation label should be affixed and visible on the front panel and a small indicator (X-ray Exposure Light) should illuminate during each exposure.
- The accuDEXA performs a system check each time the device is powered on. The software also performs an internal calibration before the X-ray exposures are taken and before the BMD values are calculated. If the system check or the internal calibration is unsuccessful, an error message will be displayed on the LCD screen. If the problem cannot be corrected, write down the error message number (if one appears at the upper right portion of the screen) and contact Schick Technologies, Inc. at 888-818-4BMD for assistance.

Getting started

1.

A. On the accuDEXA front panel, turn the On/Off key switch to On. The **Welcome Screen** appears

Figure 5. Welcome Screen

2.

The **System Check Screen** appears.

A. Please wait as the accuDEXA performs its internal checks.

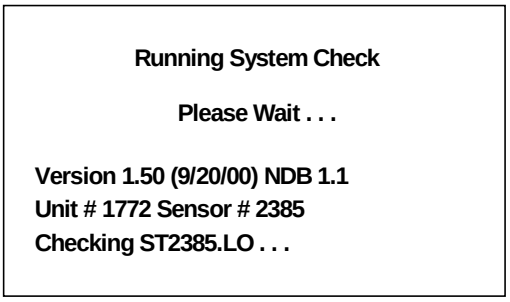


Figure 6. System Check Screen

3.

The **Sensor Verification Screen** appears.

A. Press **OK**.

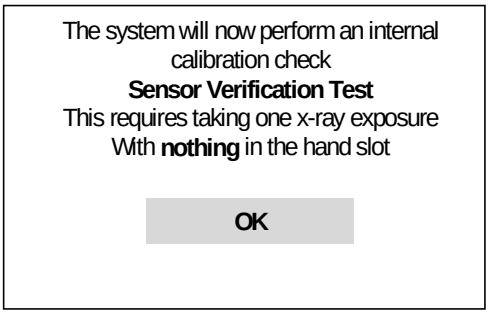


Figure 7. Sensor Verification Initial Screen

4.

The **Sensor Verification Screen** appears.

A. Press **OK**.

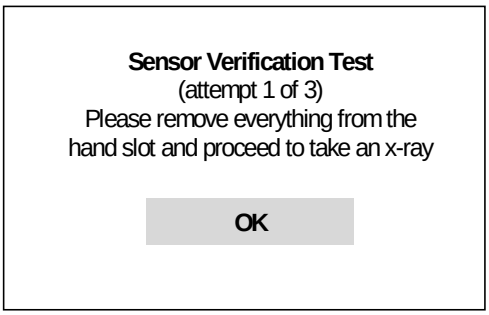


Figure 8. Sensor Verification Follow-up Screen

5.

The **Exposure Screen** appears.

A. Press and hold down the X-ray Enable button to take one test exposure.

OR

B. Press **CANCEL**. If **CANCEL** is pressed, the system will revert to the system check screen in Figure 6.

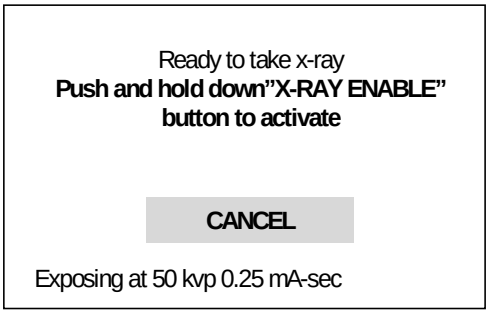


Figure 9. Exposure Screen

6.

The **Release Button Screen** appears.

A. Release the X-ray enable button.

B. Please wait for a moment while the system continues the test.

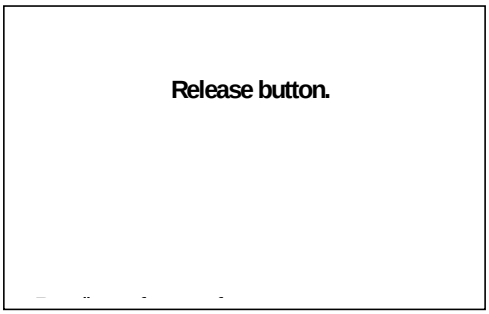


Figure 10. Release Button Screen

7.

When the test is complete, the system will pass or fail. A brief message reporting the test results is displayed on the touch screen.

A. The system passes and no other actions are needed. Click **OK**.

OR

B. The system passes, but we recommend that users verify system performance by running the phantom test. A successful phantom test provides the best guarantee of system accuracy. Click **OK**.

OR

C. The system fails. An error message will appear on the screen. Make sure everything is removed from the hand slot. You will not be able to perform BMD tests. Contact us at 888-818-4BMD for further assistance. Click **OK**.

Figure 11. Test Results Screen

8.

The **Welcome Screen** re-appears.

A. Touch any part of the **Welcome Screen** to start using the system.

Performing a BMD test

Follow this procedure to generate a Bone Densitometry Report. Users are encouraged to print BMD reports when prompted by the program, particularly to retain the X-ray image and graph portion of the report.

1.

If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

2.

The **Main Menu Screen** appears.

A. Press **BMD Test**.

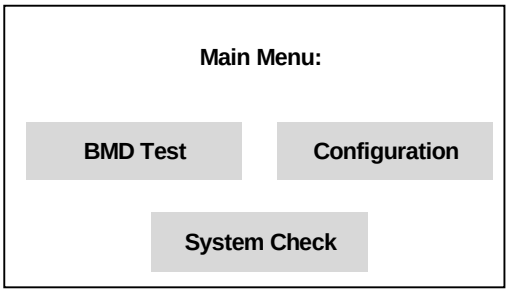


Figure 12. Main Menu Screen

3.

The **Patient ID Screen** appears.

A. Enter the patient's identification number. The patient's ID number can have a maximum of ten digits.

The ID can be a social security number, hospital chart number, or an ID number defined by the operator.

B. Press **OK**.

TIP: If you enter the wrong ID, press **CLEAR** and re-enter the number.

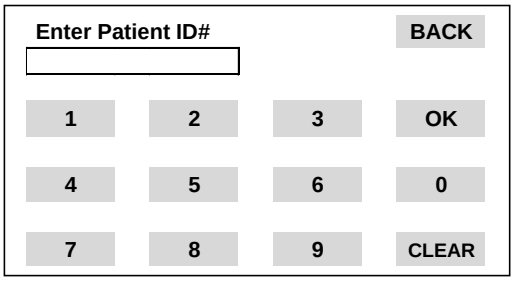


Figure 13. Patient ID Screen

4. The **Age Screen** appears.

A. Enter the patient's age. The age can be a maximum of 3 digits and can range from 1 to 120 years.

B. Press **OK**.

TIP: If you enter the wrong age, or an age outside the range of 1 to 120, press **CLEAR** and re-enter the number.

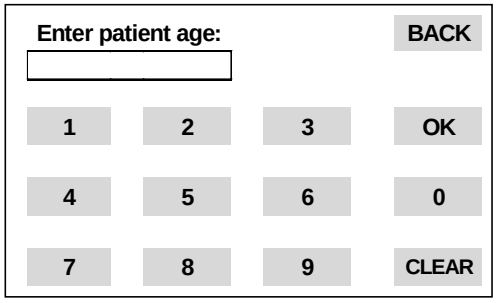


Figure 14. Age Screen

5. The **Gender Screen** appears.

A. Select the patient's gender.

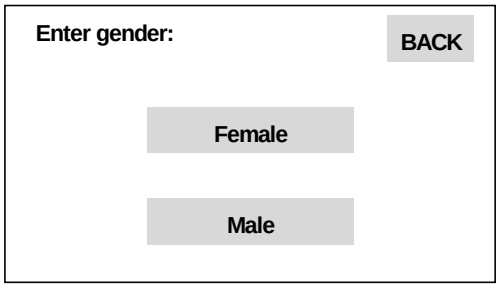


Figure 15. Gender Screen

6. The **Ethnicity Screen** appears.

A. Select the patient's ethnicity.

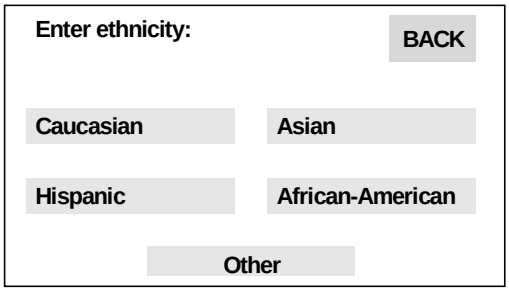


Figure 16. Ethnicity Screen

7.

The **Database Information Screen** shown at right appears only if a normative database is not available for the patient's gender and/or ethnicity. Refer to Appendix A for a list of available normative databases.

Another screen, typical to the one shown at the right, will appear if the patient's age is outside the range in the normative database. In this case, no z-score is possible.

A. Press **OK**.

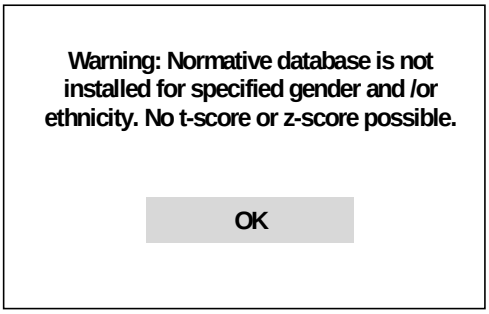


Figure 17. Database Information Screen

8.

The **Summary Screen** appears. This screen contains the information entered in the previous screens.

The user has three options:

A. Press **OK** to accept the summary screen entries.

OR

B. Press **REDO** to re-enter patient information. The **Ethnicity Screen** will re-appear. Press **BACK** and **OK** to navigate among the previous information screens and re-enter patient information as needed. Return to the **Summary Screen** and press **OK** to accept new entries.

OR

C. Press **CANCEL** to terminate the BMD test. Previous entries are deleted and the **Welcome Screen** re-appears.

(Information shown in Figure 18, **Summary Screen**, is provided only as an example.)

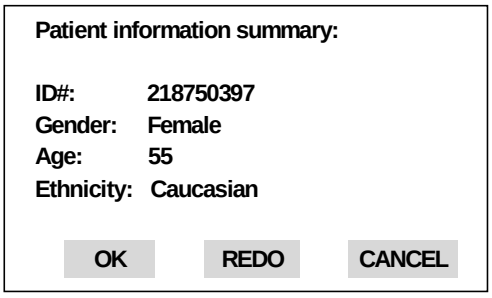


Figure 18. Summary Screen

9.

The **Positioning Screen** appears.

Place the patient's hand into the hand slot. If needed, refer to the Finger Placement picture on page 6.

A. Press **OK** and proceed to next step.

OR

B. Press **CANCEL** to terminate the BMD test**.** All entries will be deleted and the **Welcome Screen** will appear.

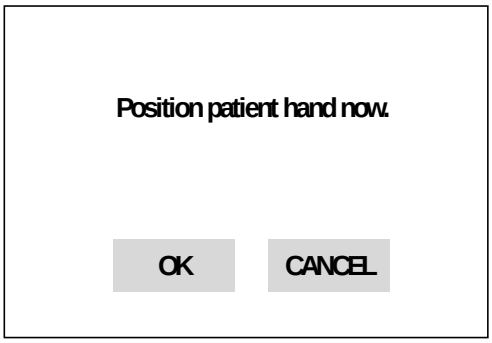


Figure 19. Positioning Screen

10.

The first X-ray screen appears. Wait for the X-ray Enable light to turn on.

Perform steps A through E to take the X-ray or perform step F to reposition the patient's hand or to terminate the BMD test.

A. Press and *hold down* the X-ray Enable button.

B. Listen for two beeps. Each beep represents an X-ray exposure and there is approximately a 5-second pause between each beep. During the beep, the X-ray Exposure light turns on momentarily.

C. Release the button when the **Release button** message appears.

D. Lower the lever knob and instruct the patient to remove his/her hand.

E. Wait for an X-ray image to appear on the display, as shown in step 11.

OR

F. Press **CANCEL**. You can either resume testing by repositioning the patient's hand or terminate the BMD test entirely. If you choose to terminate the test, the **Welcome Screen** will re-appear.

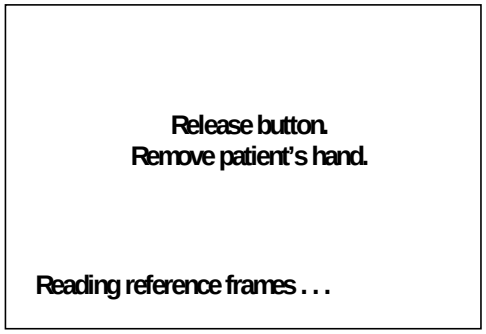


Figure 20. X-ray Screens

PLEASE NOTE: If the patient's hand is removed during the X-ray process, or was not positioned properly, the message **No finger detected** is displayed and the **Positioning Screen** will re-appear.

11.

The accuDEXA produces an X-ray image.

A. Press **ACCEPT** if the X-ray image is acceptable (refer to examples of acceptable images below) and proceed to the next step.

OR

B. Press **REJECT** if the X-ray image is unacceptable (refer to examples of unacceptable images below).

When **REJECT** is pressed, the **Positioning Screen** re-appears. Re-position the patient's hand and repeat the X-ray exposure by completing steps 9-10.

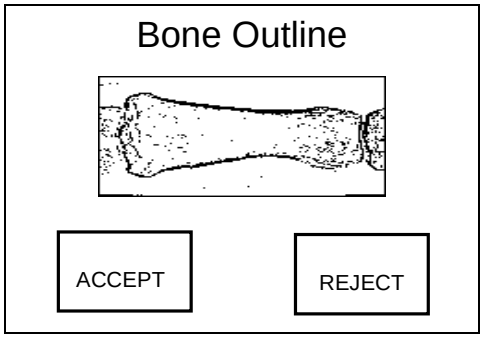
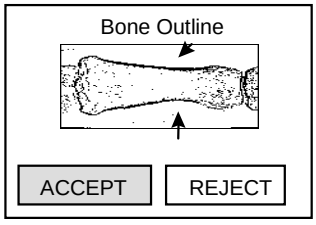
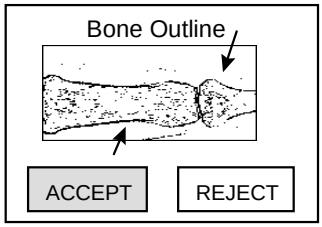


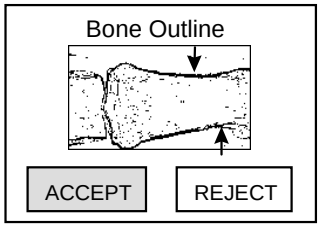
Figure 21. Bone Outline Screen

Finger positioning guidelines

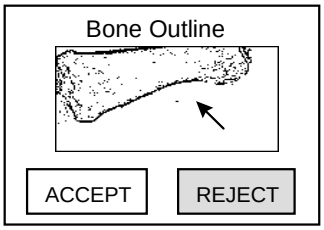
The following images are acceptable because the sensor captured both sides of the middle finger (as shown by the arrows).

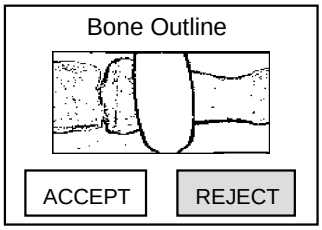






The following images are unacceptable. The image on the left is unacceptable because the sensor did not completely capture both sides of the middle finger (as shown by the arrow). The image on the right is unacceptable because a ring is within the field of view. These images will yield inaccurate results and should be rejected.





12.

The **Computing BMD Screen** appears.

This screen appears while the accuDEXA is computing the results for the BMD Test. The process takes less than a minute.

When completed, the accuDEXA will automatically advance to the BMD test results screen.

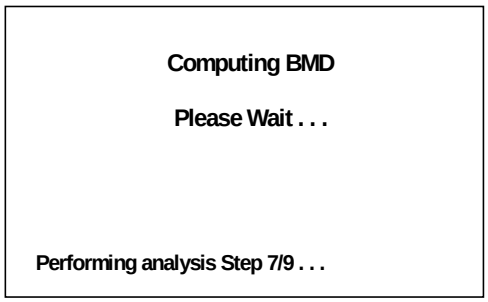


Figure 22. Computing BMD Results Screen

13.

The **BMD Test Results Screen** (normative database is available) appears.

The screen shows that a normative database exists for the patient's ethnicity, gender, and age. The results include the BMD, BMC, t-score, and z-score.

A. Press **YES** to print the test results and proceed to the next numbered step.

OR

B. Press **NO** to exit the **BMD Test Results Screen**. The **Welcome Screen** re-appears.

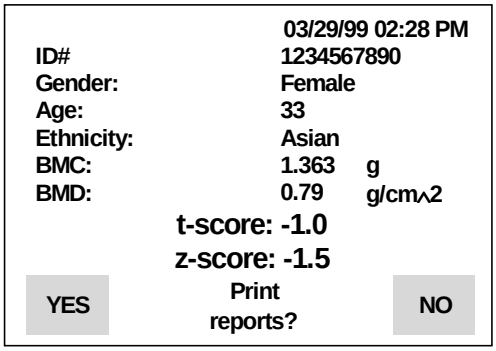


Figure 23. BMD Test Results Screen (with t- and z-scores)

The **BMD Test Results Screen** (normative database is not available) appears.

The screen shows that a normative database does not exist for the patient's ethnicity, gender, and age. The t-score and z-score have not been calculated.

A. Press **YES** to print the results and proceed to the next numbered step.

OR

B. Press **NO** to exit the **BMD Test Results Screen**. The **Welcome Screen** re-appears.

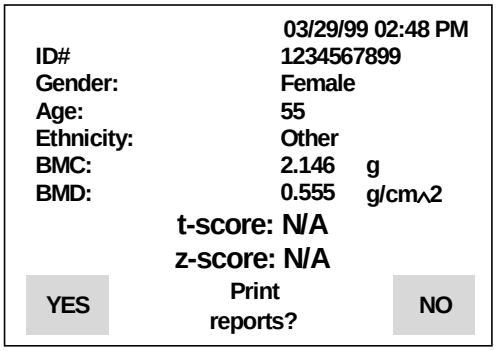


Figure 24. BMD Test Results Screen (without t- and z-scores)

14.

The **Confirm Multiple Copies Screen** appears.

A. Press **YES** and proceed to the next step.

OR

B. Press **NO** to print only one copy of the report. After the copy is printed, the **Welcome Screen** re-appears.

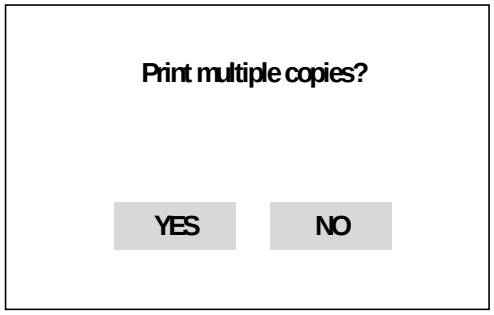


Figure 25. Multiple Copies Confirmation Screen

15.

The **Enter Multiple Copies Screen** appears.

A. Enter the number of copies to be printed (from 1 to 9).

B. Press **OK**.

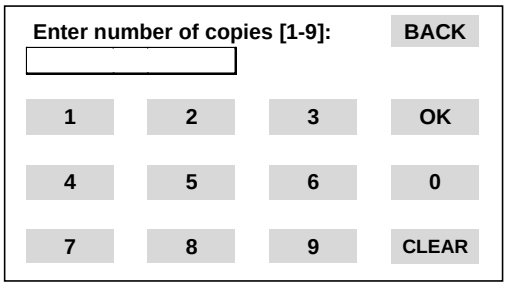


Figure 26. Multiple Copies Screen

16.

The **Printing Copies Screen** appears.

After the last copy is printed, the **Welcome Screen** re-appears.

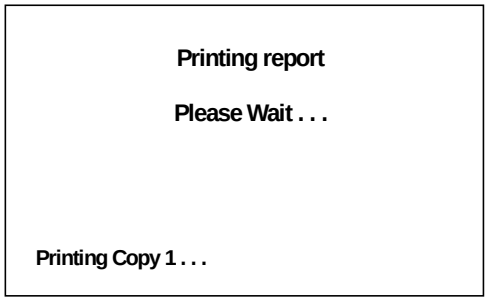


Figure 27. Printing Copies Screen

Bone densitometry report

Several examples of bone densitometry reports appear on the following pages. All of the reports share some common features, including general report information (report date and time, software version, and device serial number), patient information (Patient ID, Gender, Age, and Ethnicity), and BMD test information (X-ray image area and BMC and BMD results). There are also some report differences as described below.

In Figure 28 a patient's BMD results were compared with an available normative database. The t-score was calculated from the BMD results of the patient and a database population matching the patient's gender and ethnicity. The z-score was generated using those same parameters (gender and ethnicity) and the patient's age.

In Figure 29 a patient's BMD results were also compared with an available normative database. In this report, however, the z-score could not be calculated because the patient's age (95) was "out of range" and could not be matched with an equivalent age in the database.

In Figure 30 a patient's BMD results were generated but could not be compared to a database that matched the patient's ethnicity and gender. Instead, the accuDEXA report will graph the results using reference curves based on the Caucasian database for the same gender. These results cannot be used for diagnosis. The t-score and z-score are omitted from the report also. Refer to Appendix A for a list of available databases.

Calculating t-scores, z-scores, and fracture risk

The following formulas are used in the accuDEXA software to calculate the t-score, z-score, and to provide, as a percentage, where those scores lie in relation to the mean BMD. The analysis is calculated automatically, based on t-score, and reported as Normal, Osteopenia, or Osteoporosis.

SAMPLE RESULTS

t-score	**-1** ①	**85%** ③	Relative to YHN
z-score	**-0.5** ②	**92%** ④	Age-matched BMD
Analysis	**Normal**		Based on WHO guidelines

ITEM		FORMULA
t-score =	①	$\frac{BMD_{patient} - BMD_{YHN}}{\text{Standard Deviation}}$
z-score =	②	$\frac{BMD_{patient} - BMD_{AGE}}{\text{Standard Deviation}}$
Percentage of YHN BMD =	③	$\frac{BMD_{patient} \text{ x } 100\ \%}{BMD_{YHN}}$
Percentage of Age-matched BMD =	④	$\frac{BMD_{patient} \text{ x } 100\ \%}{BMD_{AGE}}$

On the sample reference curve shown below, the scale of t-scores is shown at the left and the scale for age is at the bottom.

The three curved lines are isometric z-scores.

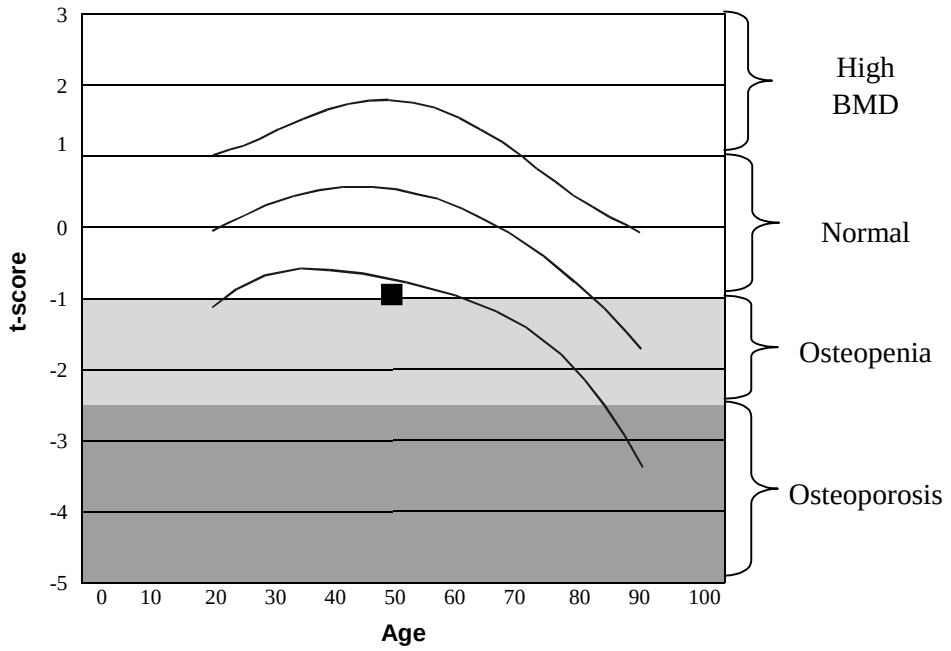
- The top curve represents one standard deviation **above** the age-matched mean BMD.
- The middle curve represents the age-matched mean BMD.
- The bottom curve represents one standard deviation **below** the age-matched mean BMD.

Isometric t-scores are displayed on the y-axis.

- The t-scores can be positive or negative and correspond to standard deviation increases or decreases in BMD as compared to a young, healthy normal (YHN) individual.

The range of ages for z-scores is displayed on the x-axis.

- The t-score and z-score for the scanned patient can be seen graphically on the curve, and is represented by a small square box ■. In this example the patient has a lower than mean BMD compared to a young healthy normal (t-score) and age-matched (z-score) database.



Categories of risk for fracture

Bone mineral estimates can be used to provide an index of fracture risk. Individuals who fall below the range of young healthy normal individuals are at a greater risk for fracture. The World Health Organization (WHO) has established four general diagnostic categories that define categories for low bone density.

Normal	A value for bone mineral density (BMD) or bone mineral content (BMC) within 1 standard deviation (SD) of the young adult reference mean.
Low Bone Mass (osteopenia)	A value for BMD or BMC more than 1 SD below the young adult mean but less than 2.5 SD.
Osteoporosis	A value for BMD or BMC of 2.5 SD or more below the young adult mean.
Severe Osteoporosis	A value for BMD or BMC more than 2.5 SD below the young adult mean in the presence of one or more fragility fractures.

The accuDEXA automatically calculates a patient's risk based on the t-score and reports the results as Normal, Osteopenia, or Osteoporosis. The accuDEXA cannot make an analysis of Severe Osteoporosis, since this analysis is dependent upon the presence of one or more fragility fractures.

Other risk factors

While low BMD is an important factor in determining a patient's risk for fracture, there are several other factors that also contribute to risk. Patients with a combination of several risk factors are at an increased risk of fracture. The following is a summary of risk factors, compiled by the National Osteoporosis Foundation.

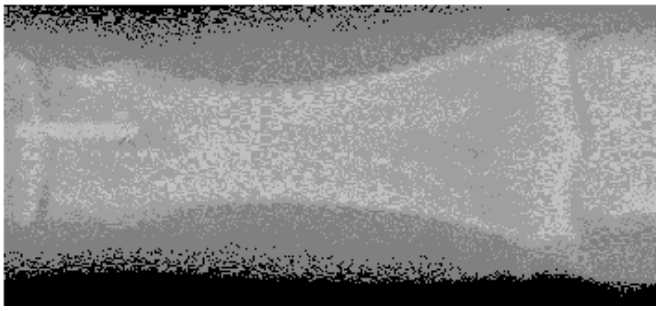
- Being female
- A small, thin frame
- Advanced age
- A family history of osteoporosis
- Early menopause
- Abnormal absence of menstrual periods (amenorrhea)
- Anorexia nervosa or bulimia
- A diet low in calcium
- Use of certain medications (steroids, anticonvulsants, excessive thyroid hormones, certain cancer treatments)
- Low testosterone levels in men
- A sedentary lifestyle
- Cigarette smoking
- Excessive alcohol intake
- Malabsorption problems

accuDEXA BONE DENSITOMETRY REPORT

Date: 04/20/00 11:11 AM Version 1.50 (04/20/00) NDB 1.1 Unit # 1772 Serial # 2395

Patient ID	**123**
Gender	**Female**
Age	**50 years**
Ethnicity	**Caucasian**

Image not for diagnosis



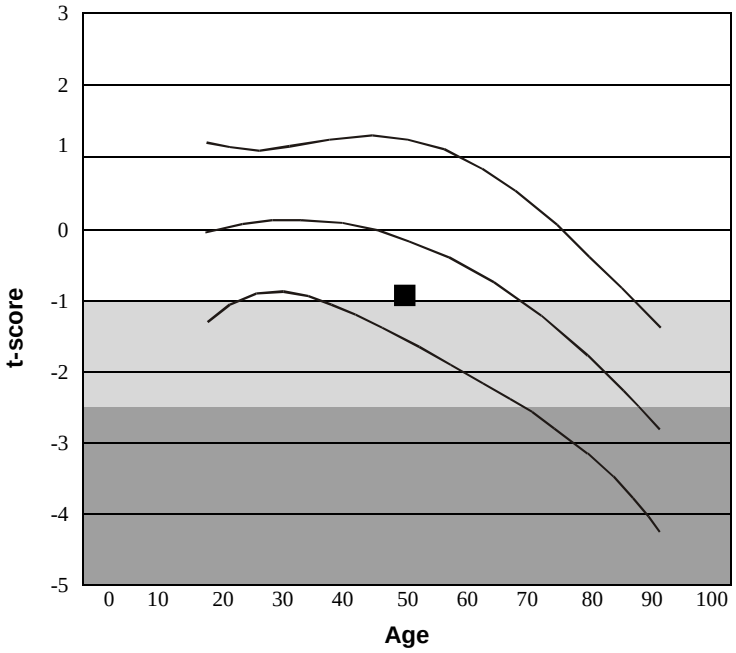
Calibration status: Passed

BMD Test Results

BMC	**2.146 g**
Area:	**3.865 cm^2**
BMD:	**0.555 g/cm^2**

z-score	**-0.5**	**92%**	Age-matched BMD
t-score	**-1**	**85%**	Relative to YHN
Analysis	**Normal**		Based on WHO guidelines

Female Caucasian reference curve



Legend

t-score	Analysis
t > 1	High BMD
1 ≥ t ≥ -1	Normal
-1 > t > -2.5	Osteopenia
t ≤ -2.5	Osteoporosis

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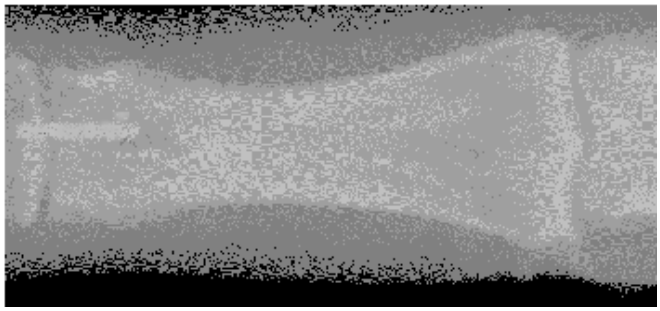
Figure 28. Example of Densitometry Report (with t- and z-scores)

accuDEXA BONE DENSITOMETRY REPORT

Date: 09/25/00 11:11 AM Version 1.50 (09/20/00) NDB 1.1 Unit # 1772 Serial # 2395

Patient ID	**124**
Gender	**Female**
Age	**95 years**
Ethnicity	**Caucasian**

Image not for diagnosis



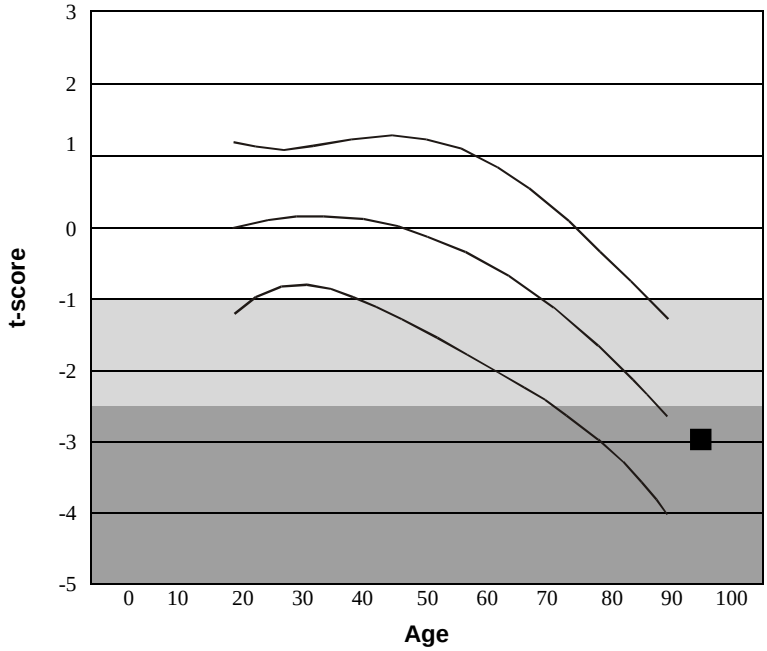
Calibration status: Passed

BMD Test Results

BMC	**0.595 g**
Area:	**1.674 cm^2**
BMD:	**0.356 g/cm^2**

z-score	**-**	**-**	**Age out of range**
t-score	**-3**	**69%**	Relative to YHN
Analysis	**Osteoporosis**		Based on WHO guidelines

Female Caucasian reference curve



Legend

t-score	Analysis
t > 1	High BMD
1 ≥ t ≥ -1	Normal
-1 > t > -2.5	Osteopenia
t ≤ -2.5	Osteoporosis

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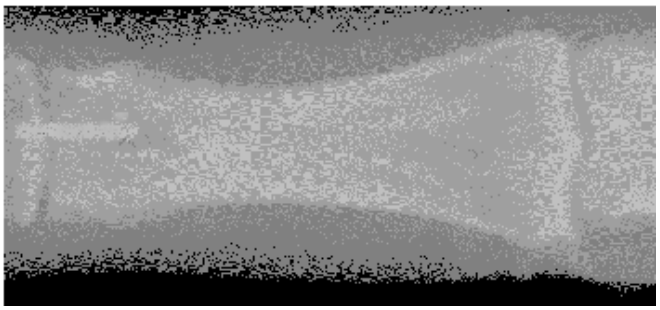
Figure 29. Example of Densitometry Report (without z-score)

accuDEXA BONE DENSITOMETRY REPORT

Date: 09/25/00 11:11 AM Version 1.50 (09/20/00) NDB 1.1 Unit # 1772 Serial # 2395

Patient ID	124
Gender	**Male**
Age	**25 years**
Ethnicity	**Hispanic**

Image not for diagnosis



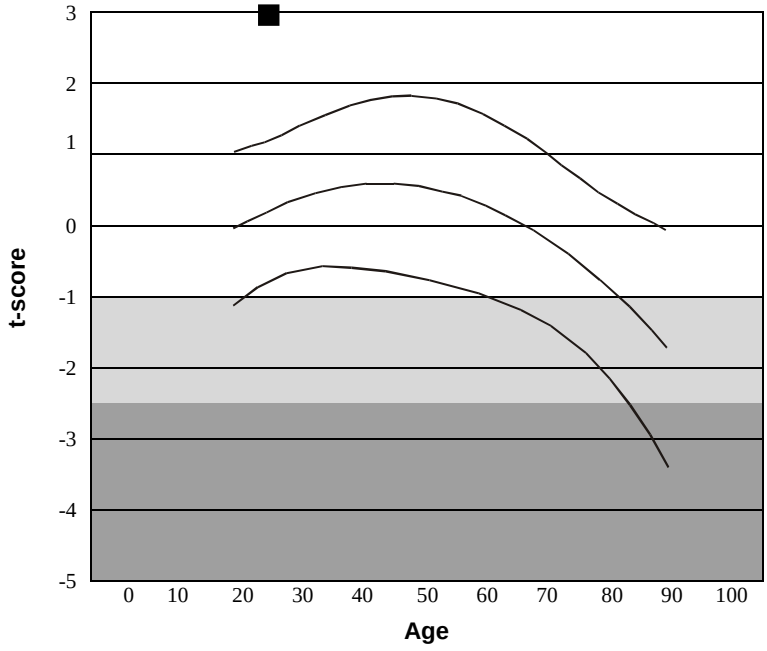
Calibration status: Passed

BMD Test Results

BMC	**1.348 g**
Area:	**1.709 cm^2**
BMD:	**0.789 g/cm^2**

z-score	-	-	Age-matched BMD (See Note)
t-score	-	-	Relative to YHN (See Note)

Male Caucasian reference curve



Note:

A normative database is not currently installed for this patient's ethnicity or gender. The reference curves are based on the Caucasian database for the same gender. These results cannot be used for diagnosis.

Age-matched BMD	3.3 SD	131%
Relative to YHN	3.5 SD	132%

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Figure 30. Example of Densitometry Report (no database available)

Changing the time

1.

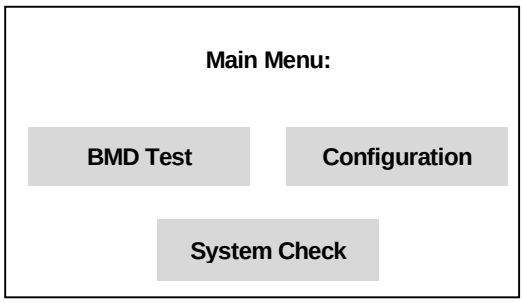
If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

2.

The **Main Menu Screen** appears.

A. Press **Configuration.**



3.

The **Configuration Menu Screen** appears.

A. Note where the date and time appear on the screen.

B. Press **Change Time**.

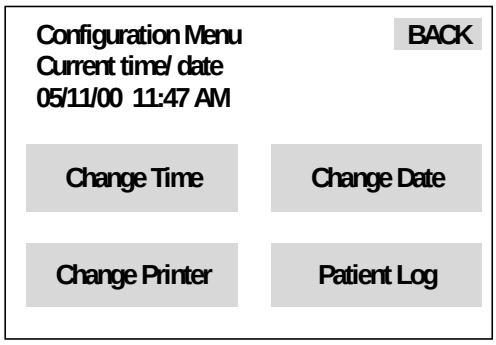


Figure 31. Configuration Menu Screen

4.

The **Time Screen** appears.

A. Enter a four-digit time value.

PLEASE NOTE:

The accuDEXA uses a twenty-four hour clock (HHMM). The user must enter two digits for the hour and two digits for the minute. If an entry has only one digit (0-9), a zero must be added in front of it (00-09).

Below are some examples.

If the time is . . .	Enter . . .	To Display
9:30 PM	2130	9:30 PM
Noon	1200	12:00 PM
Midnight	0000	12:00 AM

B. Press **OK**. The **Configuration Menu Screen** will re-appear with the revised time.

TIP: If you entered the wrong time, press **CLEAR** and re-enter.

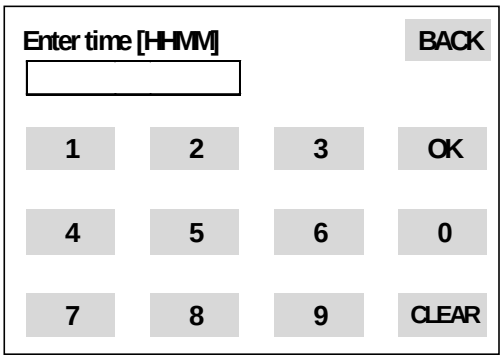


Figure 32. Time Screen

Changing the date

1.

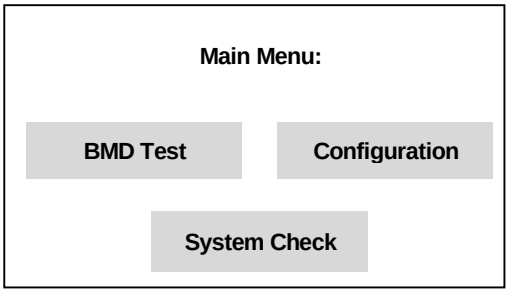
If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

2.

The **Main Menu Screen** appears.

A. Press **Configuration**.

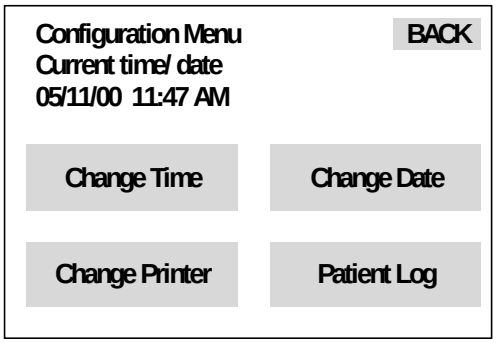


3.

The **Configuration Menu Screen** appears.

A. Note where the date and time appear on the screen.

B. Press **Change Date**.



4.

The **Date Screen** appears.

A. Enter the six digit date, 2 digits each for the month, day, and year.

PLEASE NOTE: The user must enter two digits each for the month, day, and year. If an entry has only one digit (0-9), a zero must be added in front of it (00-09).

Below are some examples.

If the date is . . .	Enter . . .	To Display
May 3, 1998	050398	05/03/98
October 10, 1998	101098	10/10/98

B. Press **OK**. The **Configuration Menu Screen** will re-appear with the revised date.

TIP: If you entered the wrong date, press **CLEAR** and re-enter.

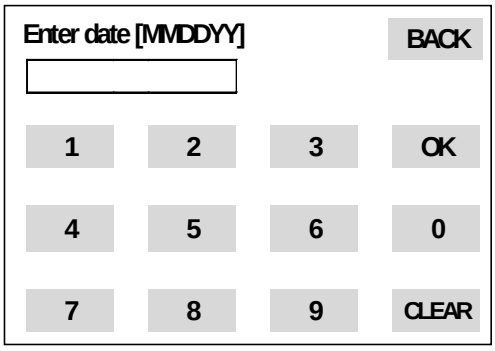


Figure 33. Date Screen

Changing the printer

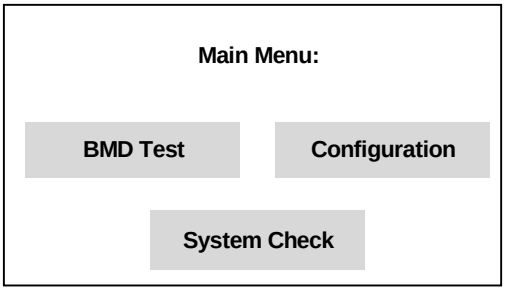
PLEASE NOTE: Users performing this procedure should first refer to the printer code that applies to their printer. This code number can be found in Appendix E.

1. If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

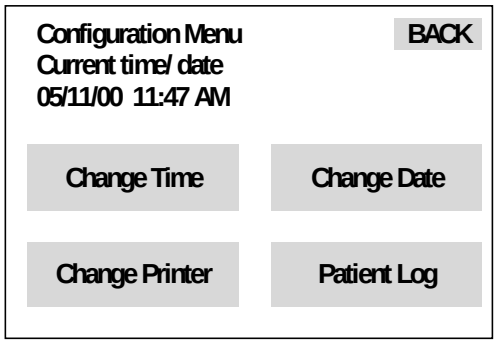
2. The **Main Menu Screen** appears.

A. Press **Configuration**.



3. The **Configuration Menu Screen** appears.

A. Press **Change Printer**.



4.

The **Printer Screen** appears with the default printer code displayed.

A. Press **CLEAR** to delete the default printer code from the display. Enter the appropriate printer code provided in Appendix E of this User Guide.

TIP: If your particular printer model is not listed, try a printer code from the same manufacturer. If you receive an error message, call Schick Technologies for assistance.

B. Press OK to accept the printer. This number is now stored by the system and will be used to configure the printer.

TIP: If you entered the wrong printer number, press **CLEAR** and re-enter.

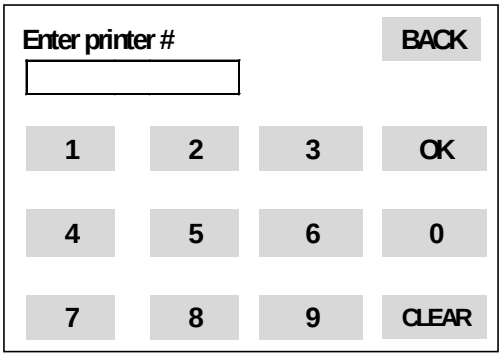


Figure 34. Printer Screen

5.

A. If the **Insert Printer Driver Screen** appears, insert Printer Driver Disk #1 into the floppy drive and press **OK**.

B. The **Upgrading Printer Screen** appears.

C. Upgrade is complete when the **Printer Driver Changed Successfully Screen** (Figure 36) appears (in about one minute). Remove the printer driver disk and press **OK**.

D. When the **Configuration Menu Screen** appears, press **BACK**.

E. The **Main Menu Screen** appears. Now you can perform BMD tests using the new printer.

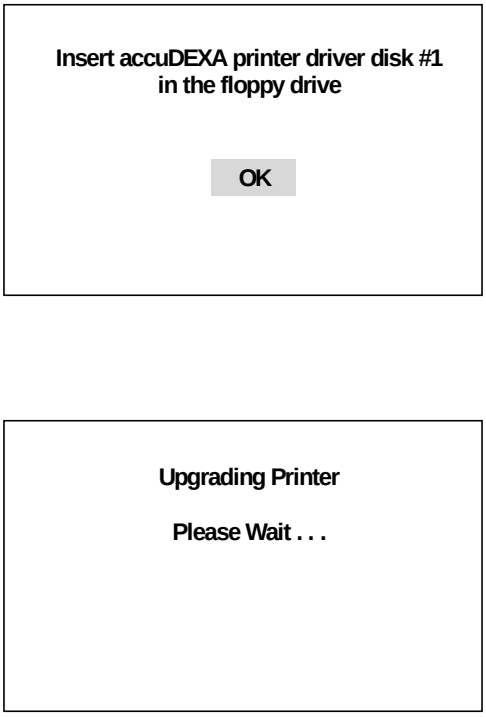


Figure 35. Printer Driver Screens

6.

A. If the **Insert Printer Driver Screen** did not appear, you will see the **Printer Driver Changed Screen** almost instantly. When this screen appears, the upgrade is complete.

B. Press **OK**

C. When the **Configuration Menu Screen** appears, press **BACK**.

D. **The Main Menu Screen** appears. Now you can perform BMD tests using the new printer.

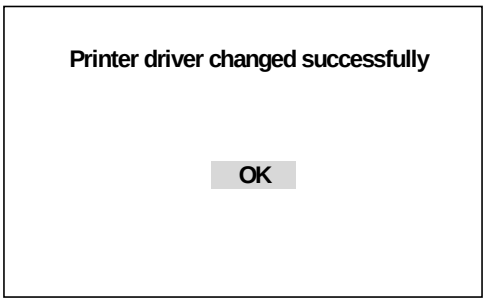


Figure 36. Printer Driver Changed Screen

Printing a test page

PLEASE NOTE: If the print quality of your test page is poor, you may have the wrong printer driver selected for your printer. Refer to the section on "Changing the printer" to verify your printer is using the correct driver.

1.

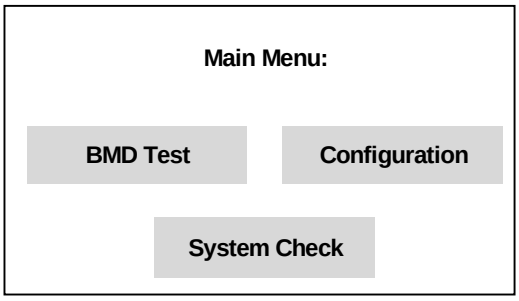
If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

2.

The **Main Menu Screen** appears.

A. Press **System Check**.



3.

The **System Check Menu** appears.

A. Press **Printer Test**.

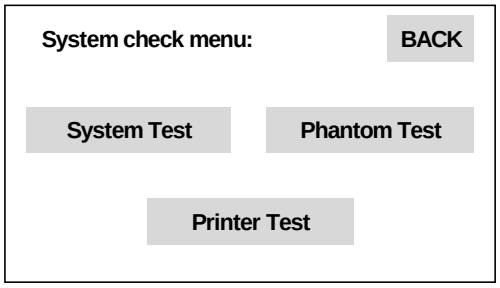


Figure 37. System Check Screen

4.

The **Print Test Page Screen** appears.

A. Press **YES** to print a test page. The test page will print only the following items:

- Print date and accuDEXA equipment information at the top of the page (to evaluate the readability of text)
- Schick Technologies logo at the bottom of the page (to evaluate the print quality of graphics).

OR

B. Press **NO**. The Main Menu Screen will appear.

TIP: If test page printing fails the first time, check the printer cable connections and the paper tray. The system will try to print the test page a second time. If the task fails again, the Main Menu screen will appear.

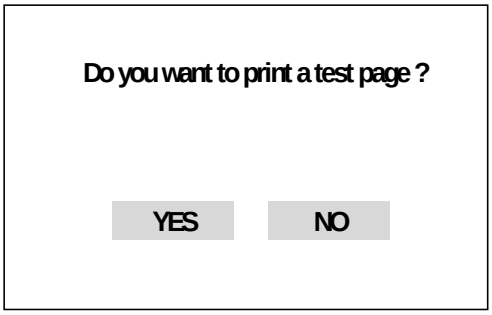


Figure 38. Print Test Page Screen

accuDEXA PRINTER TEST PAGE

Date: 09/25/00 11:11 AM Version 1.50 (09/20/00) NDB 1.1 Unit # 1772 Serial # 2395

Figure 39. Example of Test Page

Performing a phantom test

The phantom test is an additional quality-control check of the accuDEXA system. It requires a finger phantom (Schick Part Number B7123100) and takes about 2 minutes to complete.

Like any diagnostic tool, the accuDEXA may, over time, require servicing to assure the accuracy of the unit. The phantom test is a quick way for users to verify that the accuDEXA is maintaining its highest level of performance. Please keep in mind that the phantom test does not affect or replace the other system checks conducted by the accuDEXA. Internally, both calibration and quality control are performed each time the unit is turned on.

There are other good reasons for performing the phantom test. More frequently, medical practitioners are being asked by insurance companies to provide quality control printouts for all their diagnostic devices. By performing the phantom test, users are automatically prompted to print a QC test report, which can be used to satisfy a request from the insurer or for personal record keeping. Even if an insurance carrier does not request this report, we recommend performing the test at least weekly.

Understanding phantom test results

With the release of software version 1.50, the phantom test report has been expanded to provide additional information about system performance. This information is grouped in two areas: QC Phantom Test Results and QC Phantom Test Graph. (Samples of the phantom test report can be found on Figure 40 and Figure 45.)

The QC Phantom Test Results table summarizes the results from the current phantom test and reports other information on the status of BMD testing. The result of the current phantom test is called Phantom BMD and is an indicator of how well the system compares to pre-defined limits in accuDEXA's configuration file. This is one measure of system performance. A second measure, QC Average BMD, considers both the current and previous Phantom Test results. QC Average BMD is a "moving average" — the result of averaging the last 10 Phantom BMD values. For this reason QC Average BMD is a good indicator of how closely the system is performing to its baseline value (Reference BMD). *(If QC Average BMD is listed as Not Available (n/a) on your printed report, refer to Appendix F, Calculating Reference BMD, on page 65.)*

The QC Phantom Test Graph is plotted below the test results table. To review the graph it is necessary to print the phantom report, as the amount of detail cannot be displayed effectively in the small viewable area of the touch screen.

Looking at the QC Phantom Test Graph, it is easy to follow certain trends in Phantom BMD and QC Average BMD results. The x-axis in the middle of the table (Reference BMD) provides the guideline for interpreting these results. When the system is performing optimally, Phantom BMD values (shown as *'s on the graph) will fall within Phantom limits and QC Average BMD values (shown as +'s) will fall within QC Limits. (Limits are specified in the configuration file.) It is important to remember that whether users choose to print the report or not, the system displays the results of the current phantom test and will provide, if necessary, any additional direction.

When both Phantom BMD and QC Average BMD are within the limits for the system, the precision for the unit is considered satisfactory and is reported as OK. If precision is listed as "Out of Range", it means that the BMD result is outside the 0.52 and 0.58 range for acceptable results. In this event, users will be prompted for additional action.

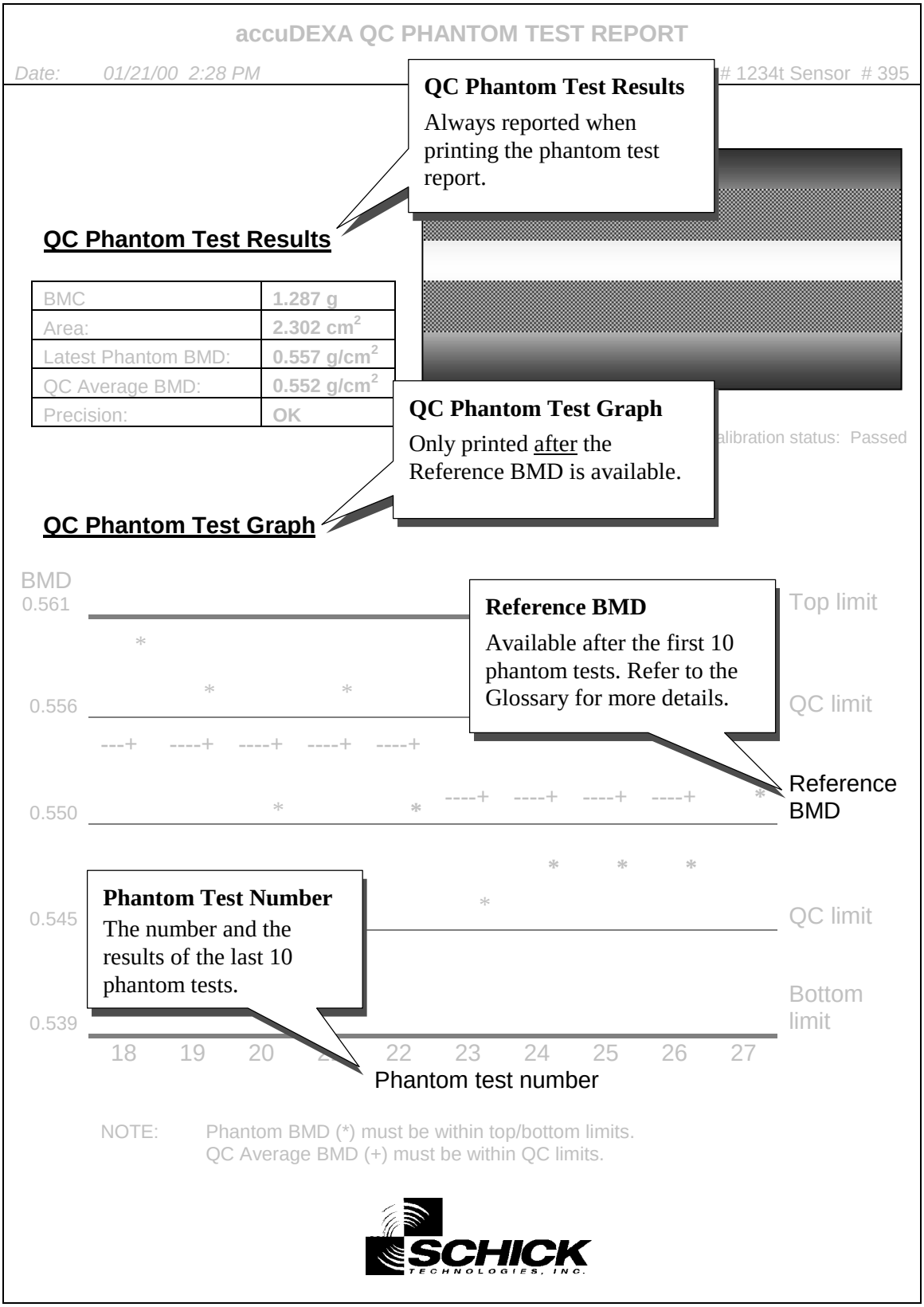


Figure 40. Details of Phantom Test Report

1.

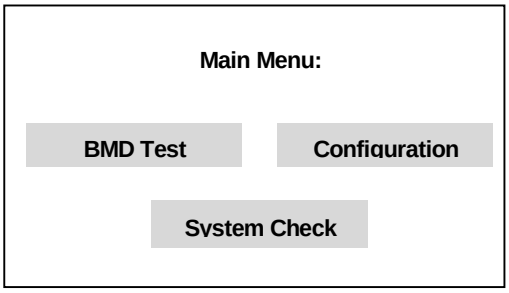
If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

2.

The **Main Menu Screen** appears.

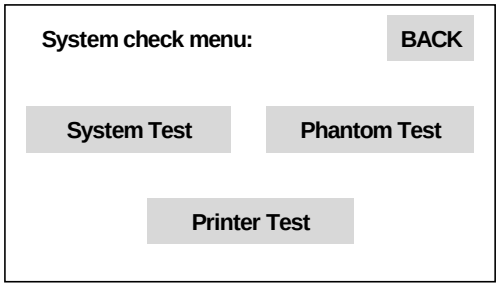
A. Press **System Check**.



3.

The **System Check Menu** appears.

A. Press **Phantom Test**.



4.

The **Phantom Positioning Screen** appears.

Place the finger phantom (Schick Part Number B7123100) into the hand slot. Refer to the figure shown.

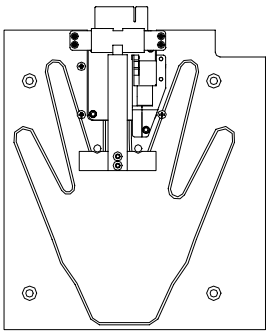
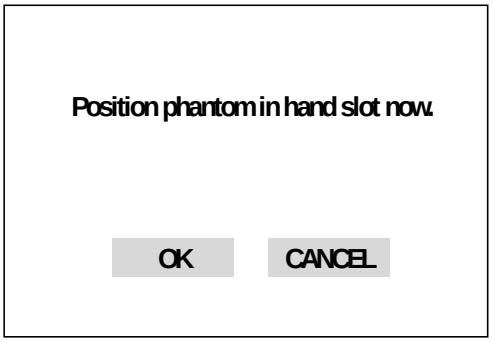


Figure 41. Phantom Placement

A. Press **OK** and proceed to next step.

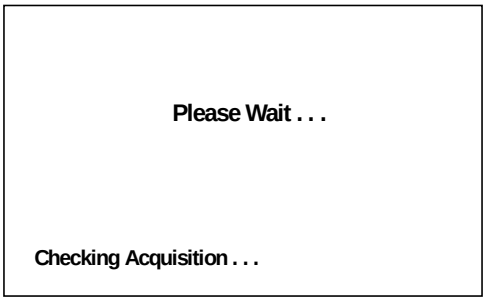
OR

B. Press **CANCEL** to terminate the phantom test. The **Welcome Screen** will appear.



5.

Please wait for a moment while the accuDEXA prepares to take an X-ray.



6.

The **Ready to take X-ray** message appears. Wait for the X-ray Enable light to turn on. Perform steps A through E to take the X-ray or perform step F to reposition the phantom or to terminate the phantom test.

A. Press and *hold down* the X-ray Enable button.

B. Listen for two beeps. Each beep represents an X-ray exposure and there is approximately a 5-second pause between each beep. During the beep, the X-ray Exposure light turns on momentarily.

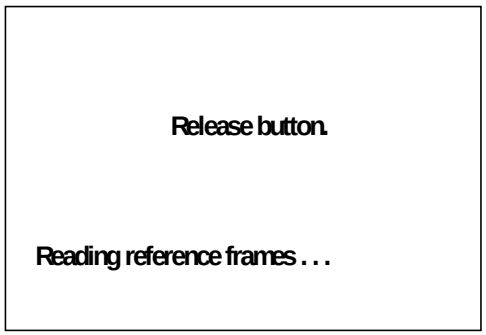
C. Release the button when the second X-ray screen displays the **Release button** message.

D. Lower the lever knob and remove the phantom.

E. Wait for an X-ray image to appear on the display, as shown in step 7.

OR

F. Press **CANCEL**. You can either resume testing by repositioning the phantom or terminate the phantom test entirely. If you wish to terminate the phantom test, the **Welcome Screen** re-appears.



PLEASE NOTE: If the phantom is removed during the X-ray process, or was not positioned properly, the message **No finger detected** is displayed. The test will be terminated and the **Phantom Positioning Screen** will re-appear.

7. The **Bone Outline Screen** appears.

A. Press **ACCEPT** and proceed to the next step.

OR

B. Press **REJECT** to repeat the phantom test. The **Phantom Positioning Screen** will appear again.

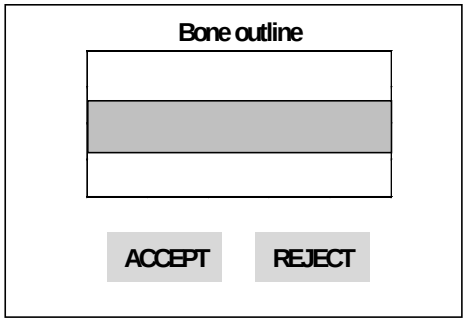


Figure 42. Bone Outline Screen

8.

The **Computing BMD Screen** appears.

This screen appears while the accuDEXA is computing the results for the BMD Test. The process takes less than a minute.

When completed, the accuDEXA will automatically advance to the phantom test results screen.

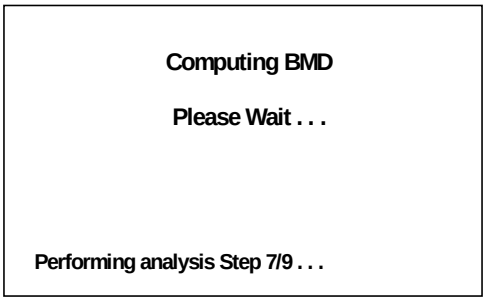


Figure 43. Computing BMD Results Screen

9.

The **Phantom Test Results Screen** shown at right appears.

A. Press **OK**.

PLEASE NOTE:. If Average BMD value and range are listed as Not Available (n/a), refer to Appendix F, Calculating Reference BMD, on page 65.

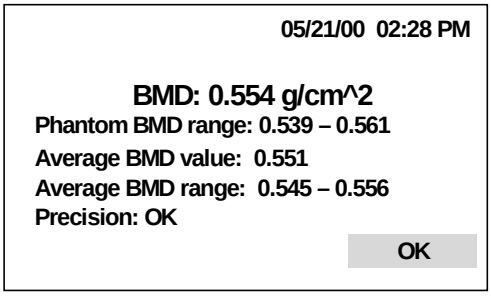


Figure 44. Phantom Test Results Screen

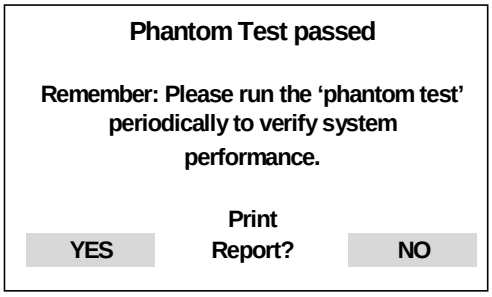
10.

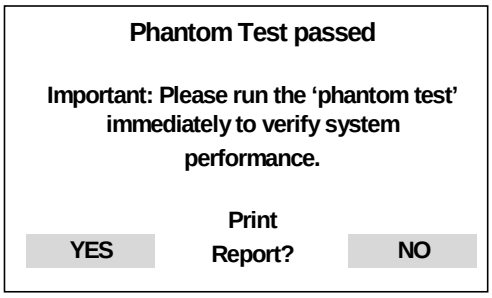
Based on phantom test results, one of the several screens will be displayed.

At the end of a successful phantom test, users have the option of printing the results in report format.

A. Press **YES** to print the report. Pressing Yes displays the Confirm Multiple Copies Screen (shown in Figure 25). Up to 9 copies of the report can be printed.

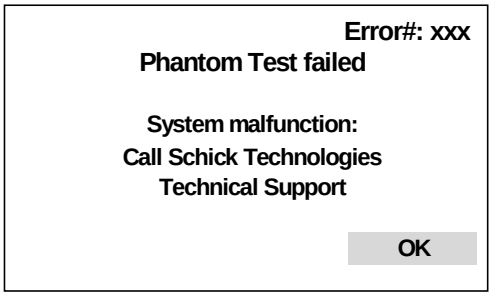
B. Press **NO** to return to the **Welcome Screen**





If the system fails the phantom test, an out-of-range message is displayed and the phantom test is repeated. If the system fails this second test as well, you will not be able to perform BMD tests. Some features, however, like retrieving and printing patient data, will be available

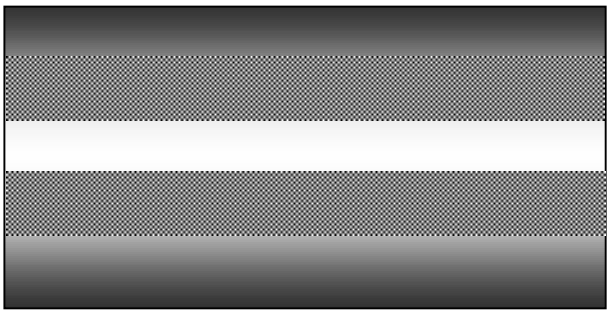
Contact us at 888-818-4BMD for further assistance. Click **OK**.



accuDEXA QC PHANTOM TEST REPORT

Date: 09/25/00 11:11 AM Version 1.50 (09/20/00) NDB 1.1 Unit # 1772 Serial # 2395

Image not for diagnosis

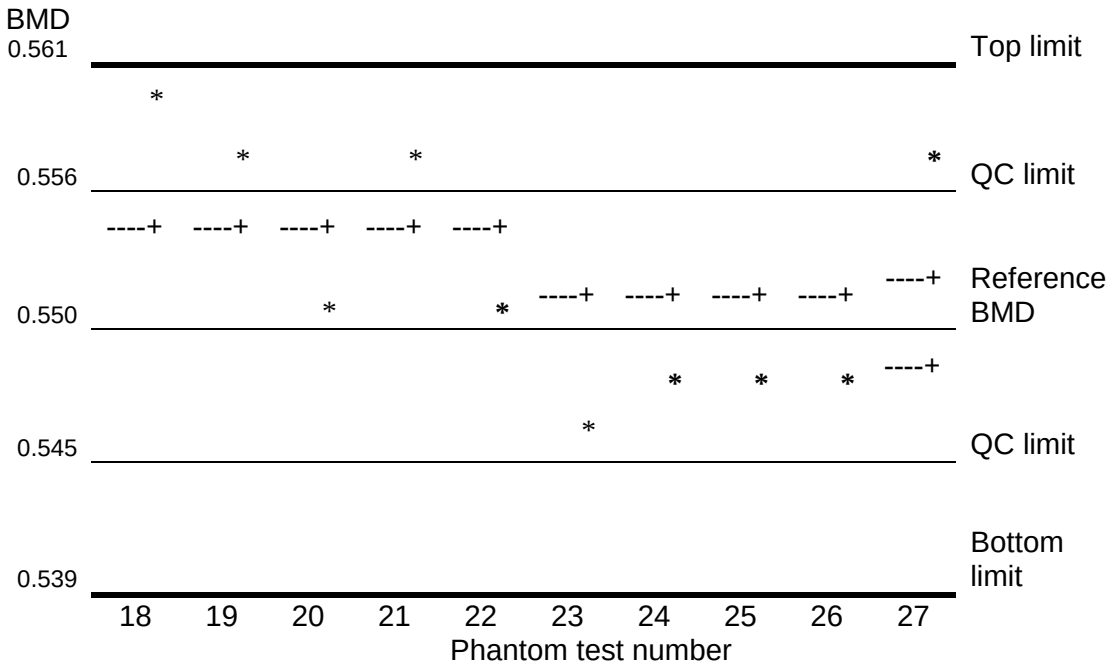


QC Phantom Test Results

BMC	**1.287 g**
Area:	**2.302 cm^2**
Latest Phantom BMD:	**0.557 g/cm^2**
QC Average BMD:	**0.552 g/cm^2**
Precision:	**OK**

Calibration status: Passed

QC Phantom Test Graph



NOTE: Phantom BMD (*) must be within top/bottom limits.
QC Average BMD (+) must be within QC limits.

Figure 45. Example of Phantom Test Report

Performing a system test

Follow this procedure to run a system check of your accuDEXA unit. This test initiates several internal checks that are similar to those performed automatically on start-up. Some checks performed only when the accuDEXA is turned on are not repeated by the system test.

1.

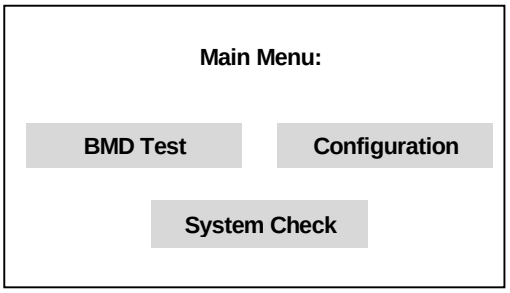
If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

2.

The **Main Menu Screen** appears.

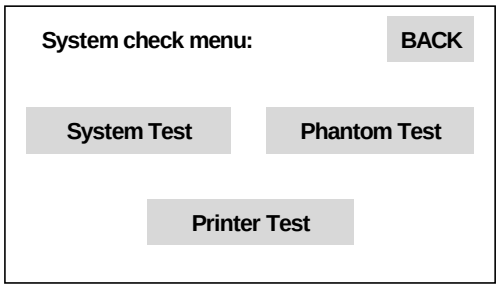
A. Press **System Check**.



3.

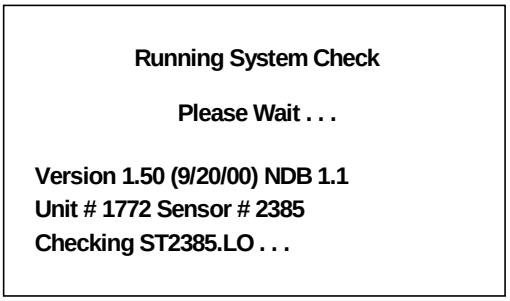
The **System Check Menu** appears.

A. Press **System Test**.

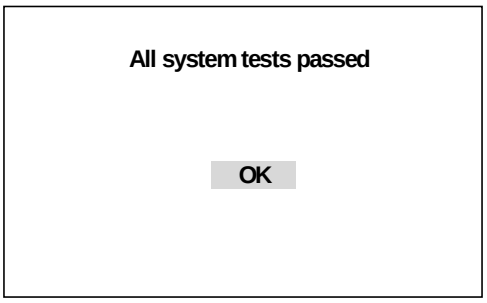


4.

Please wait as the accuDEXA performs its internal checks.



5.

Press **OK** to return to the **Main Menu Screen**.	

Service

Maintenance

There are no serviceable parts inside the accuDEXA and no scheduled maintenance is required. If there are any problems with the accuDEXA, please contact Schick Technologies at (888) 818-4BMD or 718-937-5765.

Fuse replacement instructions

Replacement fuses are provided with every accuDEXA device. If the accuDEXA does not respond when power is applied (On/Off indicator does not light and LCD display stays blank), one of the fuses may have blown.

> **CAUTION**: Ensure the accuDEXA is turned off and disconnected from its power source before inspecting and replacing fuses.

Fuses are located on the back of the accuDEXA and can be removed by inserting a flat-blade screwdriver into the fuseholder slot, pushing forward slightly, and turning it counterclockwise. Remove the fuse and examine it. If the fuse has blown, replace it, and reinsert the fuseholder by pushing it forward slightly with the screwdriver, then turning it clockwise to secure it.

Cleaning instructions

Before cleaning any part of the accuDEXA, turn off power and disconnect the power cord. Keep the fan area clean and unobstructed and vacuum it from the outside as needed.

To clean the exterior and hand plate of the accuDEXA, moisten a damp lint-free cloth with a minimal amount of rubbing alcohol. Wipe the external surfaces but avoid allowing any fluid to seep into the accuDEXA.

> **CAUTION**: Never pour or spray any liquid cleansers into the accuDEXA.

System checks

The accuDEXA performs an automatic check of its ability to operate whenever it is turned on. Components verified by this check include:

AUTOMATIC CHECKS:

- Software executable and system files
- Sensor and interface
- Mechanical fixture

If the device fails the system check, an error message will appear on the screen display, listing the cause of the problem. For example, if normal operating temperature limits are exceeded, the system will report, **Error: System temperature too hot (70-85 F/21-29 C only)** or **Error: System temperature too cold (70-85 F/21-29 C only)** as appropriate.

Users can choose to run a test of the accuDEXA system at any time. Pressing **System Test** at the **System Check Menu** initiates several internal checks that are similar to those performed automatically on startup. Some checks performed only during equipment turn-on are not repeated by the **System Test**.

Also available from the **System Check Menu** are the printer and phantom tests.

USER-INITIATED CHECKS:

- System Test
- Printer Test
- Phantom Test

During BMD tests, the accuDEXA verifies X-ray exposures as they are taken. This verification calculates the difference between high and low energy exposure to ensure that only X-rays taken at the correct energy and exposure times are accepted.

Static electricity

Static electricity may cause the accuDEXA touch screen to go blank. If this occurs, the accuDEXA must be reset to resume normal operation. To do so, turn the accuDEXA off by turning the key in a clockwise direction, wait ten (10) seconds and turn the accuDEXA back on.

Reference Information

Technical description

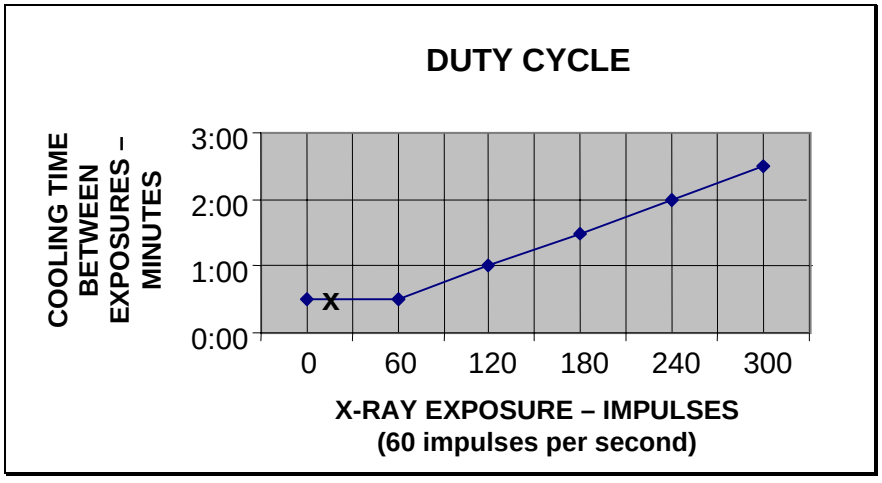
The accuDEXA estimates bone mineral content (BMC, g) and bone mineral density (BMD, g/cm^2) in a region of the middle phalanx of the third finger of the non-dominant hand using dual-energy X-ray absorptiometry (DEXA).

The technology used in the accuDEXA compensates for the density of soft tissue by acquiring information at two distinct energy levels. The accuDEXA emits a low-energy X-ray pulse at 50 kVp and a high-energy X-ray pulse at 70 kVp. At 70 kVp, a zinc plate is used to filter out the low energy X-rays.

An epoxy and an aluminum finger wedge of known density are aligned in the field of view (FOV) of the sensor. The known density of the wedge is used in bone density estimation, allowing for a relationship to be established between X-ray attenuation and density, which is applied to every pixel of the X-ray sensor in the FOV. Furthermore, the inclusion of the wedge within the FOV allows a calibration test to be performed during each exam.

Duty cycle (cooling)

The X-ray tube used in the accuDEXA has the following duty cycle:



The accuDEXA pulses last approximately 0.14 seconds, which is equivalent to 8.4 pulses (indicated by the x in the above graph).

The accuDEXA has two X-ray exposures:

Impulse	Duration
High Energy	.09 seconds (maximum)
Low Energy	.06 seconds (maximum)

Specifications

Mechanical	
Weight	66 lbs (29.7 kg)
Size	14 x 15 x 14 in (35.56 x 38.1 x 35.56 cm)
Window Clearance	6 x 4.5 in (15.24 x 11.43 cm)
Electrical	
Safety and EMC Standards Compliance	IEC 601-1, IEC 601-1-2, IEC 601-1-3, IEC 601-2-7, IEC 601-2-28, IEC 601-2-32, UL2601-1, CAN/CSA-C22.2 No. 601.1-M90
Maximum Line Current And Voltage	127 VAC, at 2.5 Amps (115 VAC units) 253 VAC, at 1.25 Amps (230 VAC units)
Environmental	
Operating Temperature	40° to 110° F (4° to 43° C)
Storage Temperature	-30° to +150° F (-34° to +66° C)
Humidity	20% to 80%
Highest Permissible Temperature Limit	150° F (66° C)
X-ray Head/General	
Maximum Heat Dissipation into Oil	110 Watts Continuous
Nominal Anode Input Power	700W
Maximum Anode Input Power	700W
X-ray Source	Schick Technologies P/N B7119000 Low Energy: 50 kVp, 0.5 mAs High Energy: 70 kVp, 0.9 mAs, zinc filtered
Collimator	Schick Technologies P/N B7119200 1.165 x 0.915 in (2.9591 x 2.3241 cm) lead window, non-detachable, identified by X-ray Source Assembly Serial Number marked on X-Ray Source Assembly
Image Receptor Accessories Attenuation	Negligible
X-ray Source Assembly Compliance	See Safety and EMC Standards, above
X-ray Tube Voltage Measured By	Victoreen Neromax 8000
Serial Number of X-ray Tube	Make and Serial Number on X-ray Source Assembly
Single Load Rating	63 Joules
Serial Load Rating	88 Joules
Maximum X-ray Tube Assembly Heat Content	7000 Joules
Target Material	Titanium
Target Angle	19°
Nominal Focal Spot Value	0.8 mm (I.E.C.)
Filtration (High Energy Only)	0.5 mm Zn (equivalent to 4 mm Al approximately)
Total Filtration	Equivalent to 4.5 mm Al approximately
High Voltage Generator Model	Schick X-ray Corp. P/N 2426-2050X
High Voltage Generator Input Power	197V, 22KHz, 3.75A at 70KVp

General	
Receptor Size	2 x 1.75 in (5.08 x 4.445 cm)
Reference Axis to Receptor Angle	90°
Source To Finger Distance	10 in (25.4 cm)
Focal Spot to Target Distance	10.4 in (26.42 cm)
Focal Spot to Skin Distance	9.75 ± 0.2 in (24.77 ± 0.5 cm)
BMD Precision	within 1%
X-ray Leakage	0.8 mR per hour at 1 meter distance
Effective X-ray Dose	3E-04 uSv per scan
Scatter Radiation	6.1 mR per hour at 1 meter distance
Calibration	Automatic, no user intervention required
Scan Time	Less than 1 minute
Printer	See Appendix E for a list of compatible printers.

The X-ray Source Assembly can handle 70KVp at 2mA (continuous).

Electrical summary

Input electrical ratings	115 VAC systems: 115 VAC, 2.5 A, 50/60 Hz 230 VAC systems: 230 VAC, 1.25 A, 50/60 Hz
Equipment type	Type B equipment  (on back panel).
Protective earth	Protective Earth  (adjacent to the protective earth conductor inside the system).
Fuses	115 VAC Systems: 2.5 Amps, 3AG, SLO BLO 230 VAC Systems: 1.6 Amps, 5 x 20 mm, T
Restricted service statement	Unless otherwise specified, this unit should be serviced only by the manufacturer. It contains no user-serviceable parts.

Appendix A

Normative databases

Listed below are the current normative databases used by the accuDEXA. As databases for other ethnicities and genders become available, these databases will be incorporated into the accuDEXA by software upgrades.

Ethnicity	Age	Gender
Caucasian	20-89	Female
Caucasian	20-89	Male
Asian	20-89	Female
Hispanic *	20-89	Female
African-American	20-79	Female

* The Hispanic database is representative of individuals living in Latin America and the United States.

Appendix B

Printing and copying the Patient Log Report

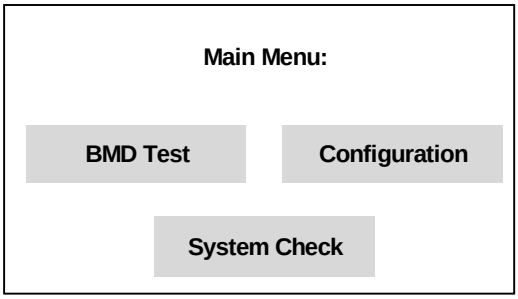
Follow this procedure to print the Patient Log Report or to copy it to floppy disk. The Patient Log Report consists of patient information, BMD and BMC scores, and t- and z-scores. (X-ray images and BMD report graphs are not included.) After performing the procedure, a single log file is generated including test results from the range of dates (one day or many) specified by the user. An example of the Patient Log Report is provided in Figure 53.

1. If the accuDEXA is not on already, turn the On/Off key switch to On. The **Welcome Screen** appears.

A. Touch any part of the **Welcome Screen**.

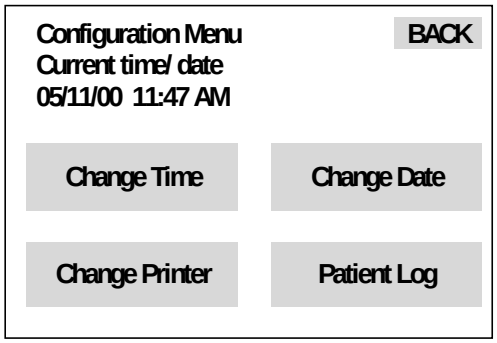
2. The **Main Menu Screen** appears.

A. Press **Configuration**.



3. The **Configuration Menu Screen** appears.

A. Press Patient Log.



4.

The **Patient Log Selection Screen** appears.

A. Press **Print** to proceed to the next screen.

OR

B. Press **File** to proceed to the next screen.

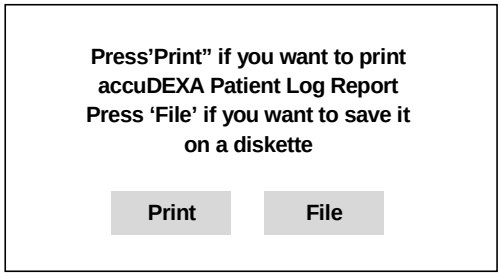


Figure 46. Patient Log Screen

5.

If you are printing the Patient Log report, the **Print Data Screen** appears. You will see a brief message reminding you to turn on your printer.

If you are copying the Patient Log Report to file, the **File Data Screen** appears. You will see a brief message prompting you to insert a formatted (PC) diskette into the accuDEXA floppy drive.

A. Press **OK** to proceed to the next screen and to enter the start and end date information.

OR

B. Press **Cancel** to return to the **Configuration Menu Screen**.

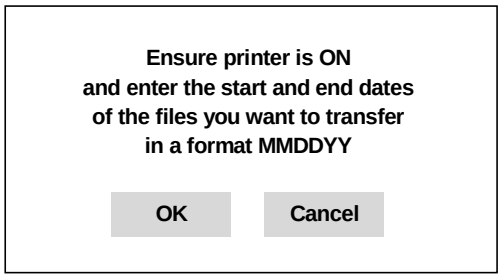


Figure 47. Print Data Screen

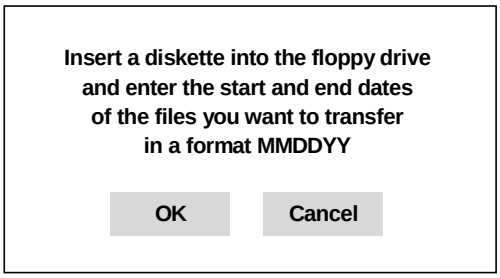


Figure 48. File Data Screen

6.

The **Transfer Date Screens** appear.

A. Enter the six-digit date, two digits each for the month, day, and year for the start and end dates.

TIP: If you need the results for one day only (for example, August 15, 1998), the start date (08/15/98) and end date (08/15/98) would be the same.

B. Press **OK** to accept the start and end dates.

TIP: If you entered the wrong date, press **CLEAR** and re-enter.

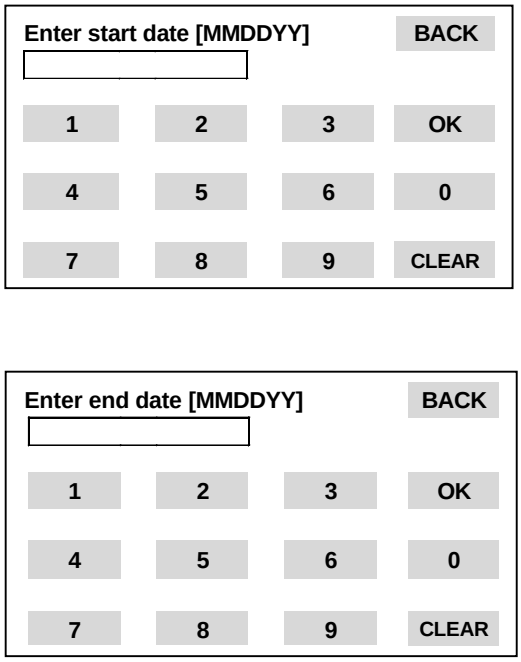


Figure 49. Transfer Date Screens

7.

The **Transfer Confirmation Screen** appears.

A. Press **OK** to accept the entered dates and to initiate the transfer process.

OR

B. Press **Retry** to re-enter the dates. The **Transfer Date Screens** will re-appear.

OR

C. Press **Cancel** to return to the **Configuration Menu Screen**

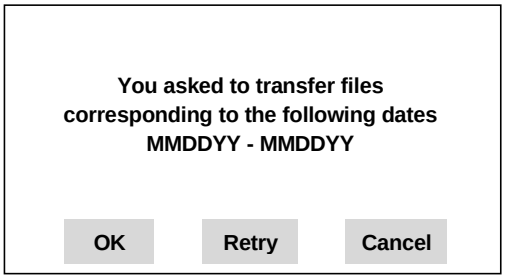


Figure 50. Transfer Confirmation Screen

8.

The **Transfer in Process Screen** appears.

A. Wait for the transfer process to finish. When the transfer has been completed successfully, the following message is generated: **Data transfer successfully completed**.

OR

B. Press **CANCEL** to halt the transfer process. The **Configuration Menu Screen** will re-appear

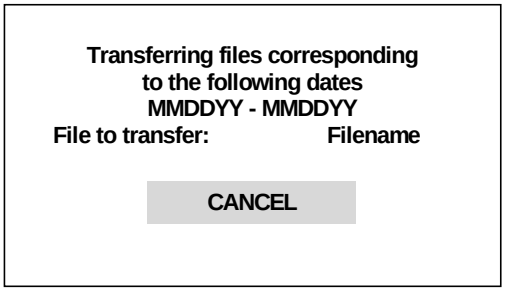


Figure 51. Transfer in Process Screen

9.

A. When the transfer has been completed successfully, press **OK** to return the **Configuration Menu Screen**.

B. If you chose to print the report, the Patient Report will begin printing when data transfer is complete.

C. If you chose to copy the Patient Report to floppy disk, remove the disk when data transfer is complete.

D. If you wish to use the Patient Report in another application, continue with the section, “Copying the Patient Log Report into Excel” on page 53 or “Copying the Patient Log Report into Notepad or WordPad” on page 56.

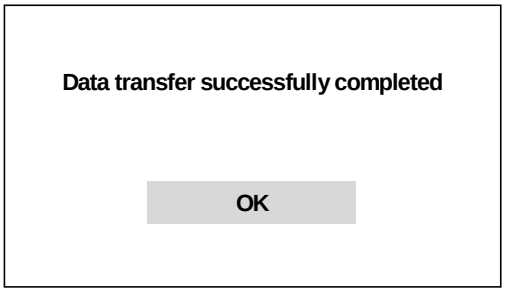


Figure 52. Transfer Complete Screen

accuDEXA PATIENT LOG REPORT

Date: 01/21/00 2:28 PM

Unit #701T

Date	Time	ID #	Age	Ethnicity	Gender	BMC	BMD	T-score	Z-score
2/25/00	10:59 AM	1	85	Asian	Female	1.28	0.56	0.894	3.57
2/25/00	11:01 AM	2	85	Hispanic	Female	1.26	0.551	1.022	3.96
2/25/00	11:03 AM	1	85	Asian	Female	1.258	0.551	0.72	3.446
2/25/00	11:13 AM	1	85	Asian	Female	1.259	0.55	0.718	2.854
2/25/00	1:25 PM	1	25	Asian	Female	1.262	0.552	0.757	0.385
2/25/00	1:27 PM	2	35	Asian	Female	1.261	0.552	0.745	0.323
2/25/00	1:30 PM	3	35	Asian	Female	1.251	0.548	0.664	0.254
2/25/00	1:31 PM	4	45	Asian	Female	1.245	0.545	0.618	0.355
2/25/00	1:33 PM	5	55	Asian	Female	1.262	0.553	0.76	0.767
2/25/00	1:35 PM	6	65	Asian	Female	1.247	0.546	0.634	1.214
2/25/00	1:38 PM	6	65	Asian	Female	1.255	0.549	0.69	1.254
2/25/00	1:40 PM	7	75	Asian	Female	1.256	0.549	0.701	2.068
2/25/00	1:42 PM	8	85	Asian	Female	1.254	0.549	0.686	2.831
2/25/00	1:44 PM	2	25	Hispanic	Female	1.25	0.547	0.953	0.81
2/25/00	1:45 PM	3	35	Hispanic	Female	1.268	0.554	1.078	0.784
2/25/00	1:47 PM	4	45	Hispanic	Female	1.231	0.539	0.803	0.64
2/25/00	1:48 PM	5	55	Hispanic	Female	1.252	0.548	0.963	1.085
2/25/00	1:50 PM	6	65	Hispanic	Female	1.246	0.546	0.922	1.597
2/25/00	1:51 PM	7	75	Hispanic	Female	1.261	0.552	1.034	2.549
2/25/00	1:53 PM	88	85	Hispanic	Female	1.253	0.548	0.971	3.914
2/25/00	3:34 PM	6	65	Asian	Female	1.268	0.555	0.804	1.335
2/25/00	3:36 PM	7	75	Asian	Female	1.27	0.556	0.819	2.157
2/25/00	3:38 PM	2	25	Asian	Female	0.771	0.354	-3.08	-3.115
2/25/00	3:41 PM	35	35	Asian	Female	0.793	0.363	-2.899	-2.741
2/25/00	3:47 PM	2	25	Asian	Female	0.774	0.339	-3.358	-3.368
2/25/00	3:51 PM	3	35	Asian	Female	0.764	0.336	-3.425	-3.182
2/25/00	3:53 PM	4	45	Asian	Female	0.774	0.34	-3.353	-2.573
2/25/00	3:56 PM	5	55	Asian	Female	0.789	0.346	-3.23	-2.014
2/25/00	3:58 PM	0	65	Asian	Female	0.772	0.339	-3.36	-1.633
2/25/00	4:00 PM	7	75	Asian	Female	0.775	0.34	-3.345	-0.975
2/25/00	4:02 PM	8	88	Asian	Female	0.777	0.341	-3.329	0.249
2/25/00	4:03 PM	8	85	Asian	Female	0.782	0.343	-3.289	-0.006
2/25/00	4:04 PM	8	85	Asian	Female	0.778	0.342	-3.313	-0.023
2/25/00	4:06 PM	20	25	Hispanic	Female	0.778	0.341	-2.773	-2.974
2/25/00	4:08 PM	3	35	Hispanic	Female	0.771	0.339	-2.815	-2.821
2/25/00	4:09 PM	3	35	Hispanic	Female	0.774	0.34	-2.797	-2.804
2/25/00	4:11 PM	4	45	Hispanic	Female	0.767	0.337	-2.847	-2.403
2/25/00	4:12 PM	5	54	Hispanic	Female	0.779	0.342	-2.758	-1.866
2/25/00	4:14 PM	63	65	Hispanic	Female	0.778	0.342	-2.763	-1.218
2/25/00	4:15 PM	7	75	Hispanic	Female	0.772	0.339	-2.816	-0.507
2/25/00	4:17 PM	8	85	Hispanic	Female	0.773	0.339	-2.805	0.576

Figure 53. Patient Log Report

Copying the Patient Log Report into Excel

Follow this procedure to copy the Patient Log Report into a spreadsheet program (like Microsoft Excel). To perform this procedure you will need a floppy disk with a Patient Log Report file on it and a recent version of Microsoft's Excel program on your computer. Your version of Windows should also be Windows 95B or higher. If you need information on copying log files to floppy disk, refer to the previous section.

1.

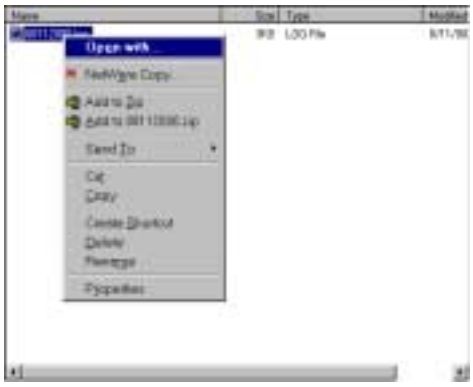
A. Insert the floppy disk containing the Patient Log Report into your computer.

B. Start Windows Explorer and browse to the drive letter on your system corresponding to the floppy drive.

C. Do the following:

- Click once on the *.log file (the Patient Log Report) to select it.
- Press and hold down the Shift key.
- Click the right mouse button (right-click).

D. A short menu, similar to the one shown, appears. Select the "Open with" option.



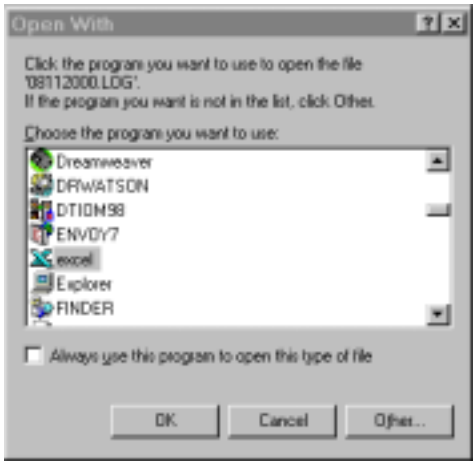
2.

The Open With dialog box appears.

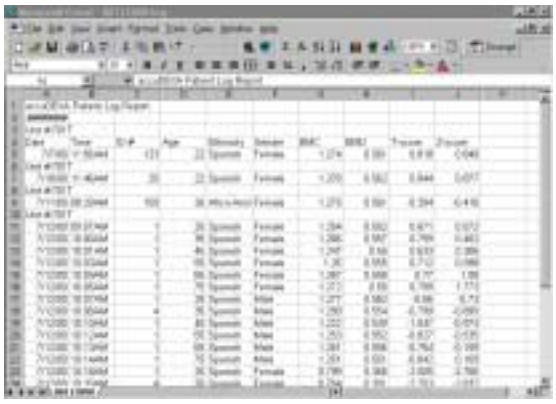
A. Scroll down the list of programs and click once on "excel"to select it.

B. For now, make sure the checkbox for "Always use this program to open this type of file" is clear. (You can check this box at a later time, if you want to always start Excel when opening a *.log file.)

C. Click **OK**.



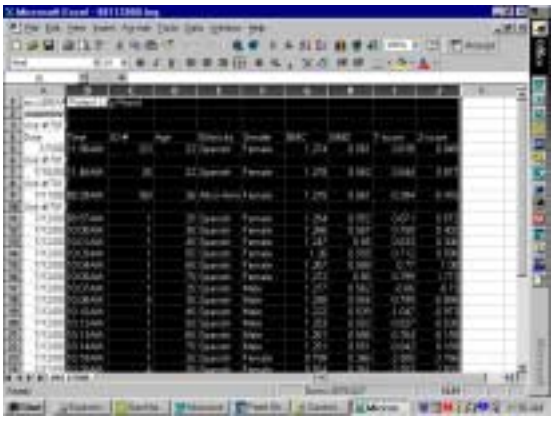
3. The Patient Log Report appears in Excel's workbook window.



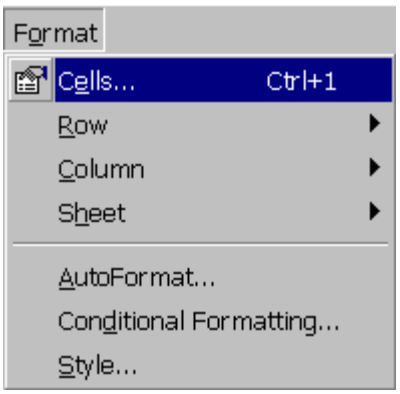
4. At this point, a few formatting steps are needed to improve the look and readability of the table.

A. Starting with Column B, click and hold down the remaining columns in the table.

B. When the last column in the table is selected, release the mouse button. The selected columns should remain highlighted.



5. Click on the **Format** menu to open the list of options. Click on **Cells**.

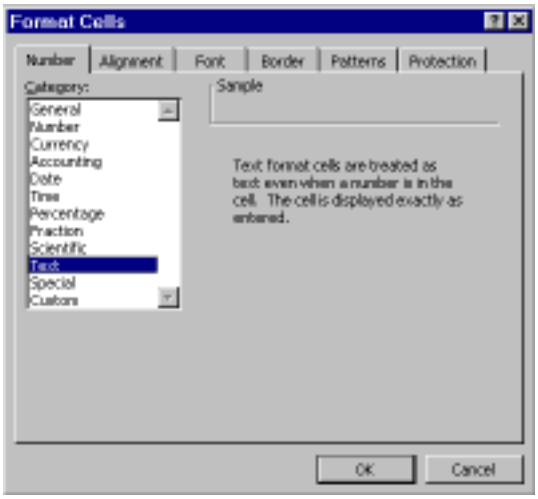


6.

The Format Cells dialog box appears.

A. Scroll down the list of categories and click once on "Text" to select it.

B. Click **OK**.

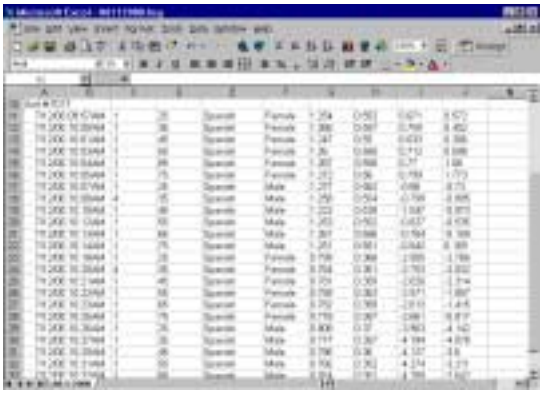


7.

A. The Excel workbook window is displayed again.

B. Take a moment to look over the data. If some of the data had a very long string of numbers or letters, you may want to adjust the width of that column, as follows.

- Click in the column heading (the shaded area)
- Drag the boundary on the right side of the column heading to a larger width.

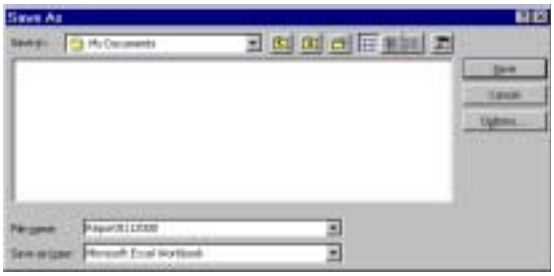


8.

A. Click on the **File** menu, and then on **Save As**.

B. When the dialog box opens, name the file and select Microsoft Excel Workbook from the **Save as type** drop-down box. When saving the file, make sure you save it to your hard drive.

C. Click **Save**. Your data has now been saved as an Excel spreadsheet.



Copying the Patient Log Report into Notepad or WordPad

Follow this procedure to copy the Patient Log Report into a text editor program (like Notepad or WordPad). To perform this procedure you will need a floppy disk with a Patient Log Report file on it and a recent version of the Notepad or WordPad program on your computer. If you need information on copying log files to floppy disk, refer to the section, "Printing and copying the Patient Log Report" on page 48.

1.

A. Insert the floppy disk containing the Patient Log Report into your computer.

B. Start Windows Explorer and browse to the drive letter on your system corresponding to the floppy drive.

C. Do the following:

- Click once on the *.log file (the Patient Log Report) to select it.
- Press and hold down the Shift key.
- Click the right mouse button (right-click).

D. A short menu, similar to the one shown, appears. Select the "Open with" option.

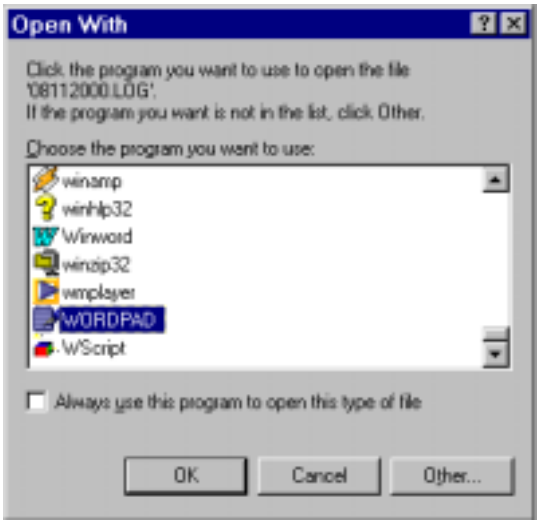
2.

The Open With dialog box appears.

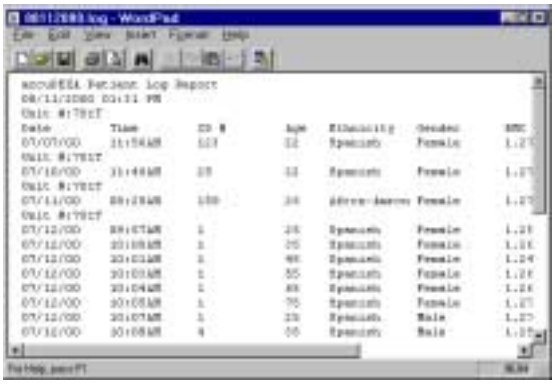
A. Scroll down the list of programs and click once on "WORDPAD" to select it.

B. For now, make sure the checkbox for "Always use this program to open this type of file" is clear. (You can check this box at a later time, if you want to always start Excel when opening a *.log file.)

C. Click **OK**.



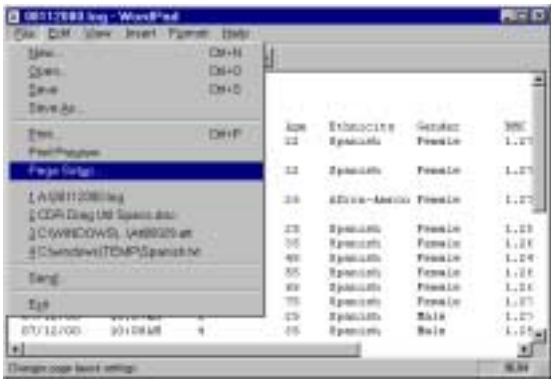
3. The Patient Log Report appears in the WordPad window.



4.

A. At this point, a few formatting steps are needed to improve the appearance of the table when printed.

B. Click on the **File** menu to open the list of options. Click on **Page Setup**.



5. The Page Setup dialog box appears.

A. Under “Orientation”, click on Landscape.

B. Under “Margins”, delete the measurement in each text box. As the measurements are deleted, new minimum margin values will appear in the text boxes.

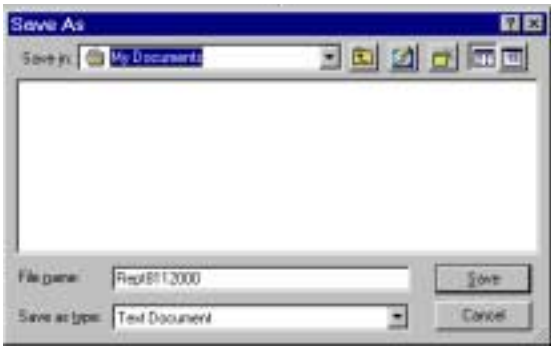
C. Click **OK**.

6.

A. Click on the **File** menu, and then on **Save As**.

B. When the dialog box opens, name the file and select Text Document from the **Save as type** drop-down box. When saving the file, make sure you save it to your hard drive.

C. Click **Save**. Your data has now been saved as a text document in WordPad.



Appendix C

Error messages

If a problem occurs during any procedure, the accuDEXA immediately displays an error message. The messages are brief and describe the cause of the problem. Some error messages may also include an error message number, located above the message and on the right. Refer to the sample below.

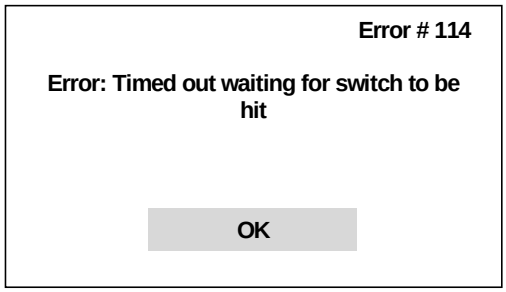


Figure 54. Error Message Screen

Users may be able to correct errors reported by accuDEXA. Errors that occur during patient data entry, data transfer, or printing can often be fixed easily. If the problem persists, however, please write down the error message number (if applicable) and call us at 888-818-4BMD for assistance.

Error Message	Error Message Number	Can be corrected by user	May be corrected by user	Cannot be corrected by user
Data Entry Errors				
Patient ID # cannot be greater than 10 digits. Please re-enter.	None	☒	☐	☐
No patient ID # entered	None	☒	☐	☐
Age is out of range. Please enter a number between 1 and 120	None	☒	☐	☐
Patient information is incomplete	None	☒	☐	☐
Invalid time format; must be HHMM (24-hour clock)	None	☒	☐	☐
Too many digits in time (maximum 4)	None	☒	☐	☐
Invalid date format; must be MMDD or MMDDYY	None	☒	☐	☐
Too many digits in date (must be 4 or 6)	None	☒	☐	☐
Too many digits or invalid digits in <filename>	None	☒	☐	☐
Too many digits in printer number	None	☒	☐	☐
Printer Errors				
Printer out of paper	121	☒	☐	☐
No printer attached or could not print	120	☐	☒	☐
Invalid printer # <printer number>	None	☒	☐	☐
Printer not ready. Please push on-line button. Try again?	122	☐	☒	☐

Error Message	Error Message Number	Can be corrected by user	May be corrected by user	Cannot be corrected by user
Could not print	146	☐	☒	☐
Cannot change printer driver. Floppy disk is wrong or not ready	163	☐	☒	☐
Could not change printer driver	162	☐	☐	☒
Printing job cancelled due to repeated printer errors	167	☐	☐	☒
Data Transfer Errors				
Floppy drive error: Disk is not ready	154	☒	☐	☐
Floppy drive error: Disk is full or damaged	155	☒	☐	☐
Floppy drive error: Printer driver's disk # <disk number> is not ready	None	☒	☐	☐
Disk space is available for storing only <number of> more patients	159	☒	☐	☐
End date cannot precede the start date	None	☒	☐	☐
Error: Cannot find file specified	None	☒	☐	☐
Data Retrieval Errors				
Could not acquire image from sensor	129	☐	☐	☒
Cannot read data in sensor calibration file	134	☐	☐	☒
Initialization file <filename> cannot be read	150	☐	☐	☒
System file <filename> failed system check	142	☐	☐	☒
Could not read <filename> to perform system check	145	☐	☐	☒
Cannot read wedge data in setup file	133	☐	☐	☒
Cannot read data in normative database	135	☐	☐	☒
Hardware Errors				
Switch closed prematurely. Possible hardware problem	103	☐	☒	☐
Incorrect X-ray exposure. Please reposition hand.	168	☐	☒	☐
Timed out waiting for switch to be hit	114	☐	☒	☐
No finger detected or x-ray source error	152	☐	☒	☐
Timed out waiting for limit switch and/or filter motion	112	☐	☐	☒
X-ray energy or filter failure	128	☐	☐	☒
Sensor or high energy X-ray emission failure	131	☐	☐	☒
Sensor or low energy X-ray emission failure	132	☐	☐	☒
Filter, solenoid and/or limit switch failed system check	101	☐	☐	☒
Filter/solenoid status unknown	101	☐	☐	☒
Filter, solenoid and/or limit switch failed system check	103	☐	☐	☒
Hard tissue equivalent linear wedge calibration failure	116	☐	☐	☒
Soft tissue equivalent linear wedge calibration failure	117	☐	☐	☒

Error Message	Error Message Number	Can be corrected by user	May be corrected by user	Cannot be corrected by user
Aluminum step wedge calibration failure	118	☐	☐	☒
Cannot store images	160	☐	☐	☒
System Check Errors				
System temperature too cold (70-85 F/21-29 C only)	149	☐	☒	☐
System temperature too hot (70-85 F/21-29 C only)	148	☐	☒	☐
Wedge verification error: Please make sure the hand slot is empty	169	☐	☒	☐
Sensor verification error: Please make sure the hand slot is empty	170	☐	☒	☐
Sensor verification error: X-ray source failure or switch was not pressed	172	☐	☒	☐
System file <filename> failed system check	142	☐	☐	☒
Could not run system check on system file <filename>	151	☐	☐	☒
Filter, solenoid and/or limit switch failed system check	108	☐	☐	☒
Could not read <filename> to perform system check	145	☐	☐	☒
Sensor verification error: Sensor connection failure	171	☐	☐	☒
Sensor malfunction	173	☐	☐	☒
Sensor failed system check	141	☐	☐	☒
General Errors				
Internal error	113	☐	☐	☒
Memory failure	130	☐	☐	☒

Notice messages

Notice messages perform two functions: to confirm the user's action to cancel, interrupt, or continue with a procedure and to indicate, prior to X-ray scans, when t- or z-scores cannot be provided in the BMD Test Report.

Acquisition canceled upon request from user
Data transfer interrupted by the user
Timed out waiting for switch to be hit
No finger detected
Age is outside range of normative database for specified gender and ethnicity. No z-score possible.
Normative database not installed for specified gender and ethnicity. No t-score or z-score possible.

Appendix D

Troubleshooting the Canon printer

The following list summarizes typical solutions in the event you experience printing problems with the Canon BJC-250. For additional troubleshooting information, refer to the Canon printer manual. Users with printers other than the Canon BJC-250, should refer to their product manuals for assistance.

Problem	Solution
If printing speed is too slow	The printer comes supplied with a Color BJ Cartridge BC-05. Replacing this cartridge with a less expensive Black BJ Cartridge BC-02 will cut printing time in half.
If the print head moves but nothing prints	Try printing a test page from the printer. See Canon's User Manual for instructions on printing a test page using the operator panel. If you are still unable to print, perform at least two thorough cleanings of the print head as described in the Printer Manual. If the printing problem persists, replace the printer cartridge.
If the paper will not feed or if the printout is stuck in the printer	If the paper will not feed into the printer, please ensure the paper was placed properly in the paper tray. Remove the paper from the tray and make sure the edges of the paper rest against the back and right sides of the sheet feeder.
If the power light does not stop blinking	Remove and then reinsert the printer ink cartridge.
If a printed report is scrambled and cannot be read clearly or at all	Make sure you are using the correct code number for your printer. Follow the steps in "Changing the printer" to verify that your printer is using the correct code. If this does not correct the problem, check and/or replace the printer cable.
If the accuDEXA touch panel displays the error, **Note: Could Not Print**	Check that the printer cable is properly connected between the accuDEXA unit and the printer. You may need to replace the printer cable. Check the printer cartridge. It may need to be replaced. Try printing a test page from the printer. If the printer is able to print a test page but not an accuDEXA printout, you may need to service the accuDEXA unit.

Appendix E

List of printers

The following table lists the printers compatible with the accuDEXA device and the codes required when changing printers. Non-compatible printers are also noted in the following table.

Manufacturer and Model		Compatible with accuDEXA?	Printer Code	Time to Print BMD Report
Brother	Laser Printer HL-1240†	Yes	13	30 seconds
Canon	BJC-250	Yes	1	2 minutes*
	BJC-4000 LQ	Yes	7	**
	BJC-300	Yes	8	**
	LBP-465	Yes	9	30 seconds
	BJC-1000, 2000, 2100, 3000, 5100, 6000, 8200, S400, S450	Not Compatible		
Compaq	InkJet IJ-300, IJ-600, IJ-3750, IJ-1200	Not Compatible		
Epson	Stylus Color 440	Yes	4	2 minutes
	Stylus Color 740, 800, 850, 900 ‡	Yes	4	1 minute
	Action Laser II	Yes	5	**
	Action Laser 1600	Yes	6	**
	EPL-N2000	Yes	14	**
	Stylus Color 640, 860	Not Compatible		
Hewlett Packard	LaserJet Series II, III, IV	Yes	2	30 seconds
	DeskJet 610CL/612C, 648C, 695C/697C, 812C, 840C/842C, 880C/882C, 895Cse, 930C/932C, 935C, 950C/952C, 970Cse/970Cxi, 990Cxi/990Cse, 1220C/1220Cse/1220Cxi/1220C/PS, 1125C (only available in Europe & Japan)	Yes	3	1 minute
	LaserJet Series 5, 6, 1100, 4000	Yes	13	30 seconds
	DeskJet 340, 420C, 710C/712C, 720C/722C	Not Compatible		
Lexmark	Optra Laser Printers E312/E312L Series	Yes	10	30 seconds
	ExecJet IIc	Yes	11	1 minute
	JetPrinter 1100, 3200, Z11, Z22, Z32, Z42, Z52	Not Compatible		

* With black ink cartridge (BC-02) installed. When color ink cartridge (BC-05) is used, print time is 4 minutes.
** Exact time to print BMD reports is not available for these printers.
† Compatible with accuDEXA software version 1.50 or higher only.
‡ After printing BMD report, printer may execute an extra page feed.

Appendix F

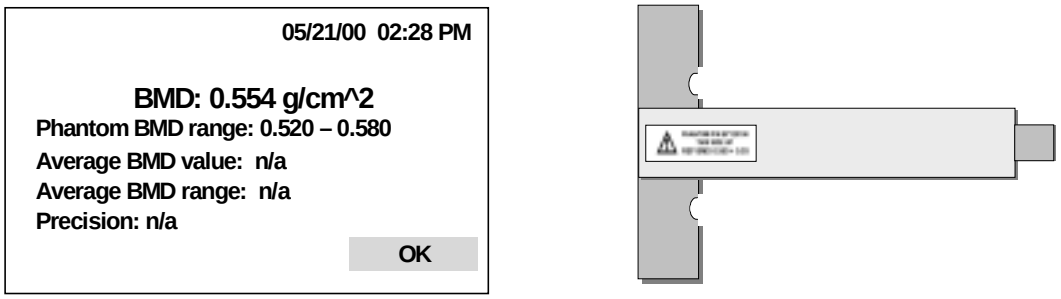
Calculating Reference BMD

The information in this appendix is intended for:

- Users upgrading their accuDEXA units to software version 1.50.

Version 1.50 software provides additional reporting about the accuDEXA system. This reporting uses phantom tests to evaluate the system's range of performance — how well the system is performing within predefined thresholds. To help describe this range, a baseline measurement (Reference BMD) is needed.

Reference BMD is the result of averaging the first 10 Phantom BMD values that fall within the range of the phantom standard. To verify whether the result is within range, users can refer either to the Phantom Test Results screen (A) or the label on the phantom standard (B).



(A) Phantom Results Screen (B) Phantom Standard

Figure 55. Reading the Results of the First 10 Phantom Tests

Until there are 10 in-range results, Average BMD value and range are listed as not available ("n/a") on the Phantom Results Screen. Similarly, the graph on the Phantom Test Report cannot be plotted until a Reference BMD is calculated. (Refer to Figure 56 for an example.)

Reference BMD is calculated when 10, in-range Phantom BMD values are available. From that point, users should refer to the Phantom Test Results screen, instead of the label on the phantom standard, for test results. The Reference BMD is specific to the particular accuDEXA unit and does not change once it is calculated.

Once the Reference BMD is determined, it becomes possible to track the performance of the system. By performing a phantom test and printing the Phantom Test Report, users have the opportunity to review the historical system performance based on the last 10 phantom tests.

accuDEXA QC PHANTOM TEST REPORT

Date: 08/12/00 10:15 AM Version 1.50 (09/20/00) NDB 1.1 Unit # 701T Serial # 5100

QC Phantom Test Results

BMC	**1.285 g**
Area:	**2.273 cm^2**
Latest Phantom BMD:	**0.565 g/cm^2**
QC Average BMD:	**n/a**
Precision:	**OK**

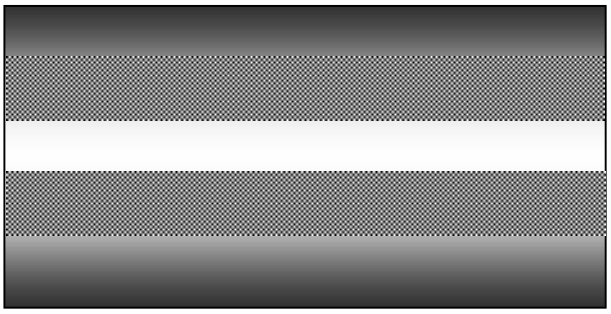


Image not for diagnosis Calibration status: Passed

NOTE:
QC graph cannot be printed until a reference BMD is available.
The reference BMD is the result of running the QC phantom test 10 times. You do not need to run all 10 tests at one time, but you should perform them at your convenience.
To date you have run the QC phantom test 2 times.

SCHICK TECHNOLOGIES, INC.

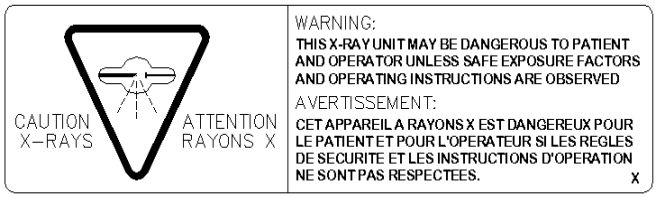
Figure 56. Example of Phantom Test Report Before Reference BMD is Available

Appendix G

Equipment Labels

The following labels are located on the front and back panels of the accuDEXA.

Front Panel Warning Label:



Back Panel Product Label:

SCHICK TECHNOLOGIES, INC.	**COMPLIES WITH DHHS RADIATION PERFORMANCE STANDARDS, 21CFR, SUBCHAPTER J**
31-00 47th AVENUE LONG ISLAND CITY, NY 11101	**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN**
MODEL 7100	
SERIAL NO:	
MANUFACTURED:	

Back Panel Regulatory Label:

Conforms to UL Std 2601-1. Certified to CAN/CSA C22.2 No. 601.1.

230V Units:____ 230VAC, 50/60 Hz, 1.25A, Fuse: 1.6 A, 250V, T
115V Units ____ 115VAC, 50/60 Hz, 2.5A, Fuse: 2.5 A, 250V, SB

CAUTION: For continued protection against risk of fire replace only with same type of fuse

X-ray Head S/N: **Made in USA**

Glossary of Terms

Area
Estimated projected image area (measured in cm^2).

BMC
Estimated bone mineral content of the imaged portion of the finger (measured in grams).

BMD
Estimated bone mineral density of the imaged portion of the finger (measured in mass per projected area).

Non-dominant Hand
All accuDEXA exams are performed on the non-dominant hand. If a patient is right handed, they should place their left hand into the hand slot. If the patient is left handed, they should place their right hand into the hand slot.

Phantom BMD
The BMD of the accuDEXA phantom (P/N B7123100). When phantom BMD is reported out-of-range, there may be a problem with system performance. Users are prompted to repeat the phantom test to verify results and, if necessary, take additional actions.

QC (Quality Control) Average BMD
A measure used in accuDEXA software to help verify system performance. QC Average BMD (also called Average BMD) is calculated from *results of the last 10* phantom tests.

Reference BMD
A measure used in accuDEXA software to help verify system performance. Reference BMD is calculated from *results of the first 10* phantom tests. (To be included as one of the first 10 tests, the phantom BMD must fall within the 0.52 and 0.58 range.)

Standard Deviation (SD)
A measure of the spread of a distribution. In a normal (or bell curve) distribution, 68% of all estimations lie within one standard deviation of the mean and 95% of all measurements lie within two standard deviations of the mean.

t-score
A measure of a patient's BMD compared with a young healthy normal population (ages 20-29) of the same gender and ethnicity. The t-score is reported in terms of the number of standard deviations above (positive t-score) or below (negative t-score) the mean reference BMD.

World Health Organization (WHO)
A specialized agency of the United Nations promoting technical cooperation for health among nations and the improvement in the quality of human life.

Young Healthy Normal (YHN)
A population sample defined as young healthy normal adults (ages 20-29) of the same gender and ethnicity.

z-score
A measure of how the BMD of an individual patient compares with the BMD of a reference population of the same age group, gender, and ethnicity. The z-score is the number of standard deviations above (positive z-score) or below (negative z-score) the mean BMD of an age-matched control.

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