CT Simulator for Bone Mineral Analysis

Model 004

SIMPLE • EFFECTIVE • ACCURATE

PRODUCT GUIDE
Background

Since the advent of whole-body Computed Tomography (CT) scanners in the late 1970's, considerable research effort has been expended to develop a method of density measurement. The power of the CT scanner could be applied to studies of bone demineralization, particularly in the lumbar region of the vertebral column where the earliest changes of osteoporosis or diffuse bone loss occur.

It became apparent to early researchers that several problems of scanner variability needed to be overcome before quantitative studies could be generally performed with high reliability.

**Quantitative CT Defined**

Quantitative CT is a description of procedures used to quantify physical characteristics of human tissue deep inside the body through the use of a CT scanner combined with a physical standard of reference.

Over 30 years ago, QCT was developed to evaluate the existence of calcium in lung nodules.\(^1\) The technique has been expanded over the years to evaluate thyroid levels and bone mineral density—specifically the trabecular bone density in the L-Spine.\(^2\)

QCT of the L-Spine is a proven diagnostic technique and is used worldwide. It accurately evaluates trabecular bone in the lumbar vertebra. The quantitative values of trabecular density can be normalized, compared to normative data and tracked serially no matter what scanner is used.

**CT Variability**

Several factors can influence the CT numbers of a given object. It is fallacious to assume that, being scaled to the X-Ray attenuation of water and air, CT numbers are independent of the particular scanner used.

The type of scanner, the reconstruction software, the exposure factors, the slice thickness, the circle of reconstruction, and electronic drifts can all variably influence CT numbers. In addition to shape, position and density of structures surrounding the tissue under study, the position of an object within the field of view can be of importance and play a significant role. The user is referred to the original published research for a more complete description of these factors.\(^{3,4}\)

It can be concluded that CT numbers can not be considered as absolute, but only as relative and dependent upon the performance of each individual scanner.

**Patient Variability**

Compounding the difficulty of scanner variation is the fact that the patient’s anatomy can also variably influence the CT numbers of a particular tissue. Experience has shown differences of 15 to 30 HU between the density of a vertebral reference insert when measured in a phantom with a large fat ring and no fat ring. This is due to the documented “beam hardening effect”. In addition, the amount of fat in vertebral bone marrow normally increases with age and the amount of mineral normally decreases with age introducing additional factors in variability.

**The Concept of an External Reference Standard**

Confronted with the problem of reliably measuring the density of vertebral bone in view of the multiple sources of variance described, the creation of a machine and patient independent, external, and physically constant standard of reference is consistent with time honored methods for comparing biological measurements with normal controls. As with many biological measurements a solution to this variability problem was found in the creation of an external standard control.
The CIRS Approach to Quantitative CT

PRINCIPLES OF DESIGN

The CIRS CT Model 004 Simulator for Bone Mineral Analysis is designed to take into account all the known sources of variance affecting the measurement of density in the vertebral area by simulating the average patient’s anatomy in terms of shape and density by using materials essentially equivalent to human tissues as far as X-ray interactions are concerned, including age-related variations in vertebral composition.

The design of the system permits reduction of all sources of error within acceptable limits. Careful and precise manufacturing and quality controls insure that all phantoms are identical in order to create a general and uniform standard applicable to all scanners. The basic principle of operation is to sufficiently simulate the patient’s anatomy, and then to scan the patient and the phantom in succession with identical technical factors.

The Model 004 works with all CT Scanners and permits serial examinations of the patient irrespective of scanner use. Data interpretation and analysis can be performed “off line” to eliminate unnecessary scanner time.

FEATURES

- Accurately simulates the size, shape and CT density of human tissue
- Includes standard vertebral inserts of varying density to permit accurate correlation of quantitative studies
- Provides the age-related variable corrections for marrow fat and mineral content
- Provides direct measure of calcium hydroxyapatite content avoiding the need for special extrapolations
- Requires no special scanner software
- Ideal for monitoring effects of therapy on trabecula structure
- Includes PC based report software
- Can be used immediately on whole body scanners
The CIRS Model 004 CT Simulator

BASIC SECTION
The phantom represents an average section of the anatomy (2nd to 4th lumbar region) that has been shown to present early demineralization in patients with osteoporosis. The phantom, constructed of specially formulated materials, interacts with X-Radiation in a manner identical to the human body (within the range of diagnostic X-ray energies). The dimensions of the section were derived from a representative series of patients to be examined for possible bone demineralization.

Bone, muscle, and fat are represented.

REFERENCE VERTEBRAL INSERTS
Three vertebral inserts are provided. These inserts have been calibrated to the following densities:

The inserts contain carefully blended amounts of calcium hydroxyapatite – the same mineral composition as found in human vertebral bone, and varying amounts of red and yellow marrow equivalent resin in order to take into account the variation of fat with age. This gives a faithful simulation of the inner bone.

Insert | Age | (Vertebral fat content) | Mineral Content** | Marker
---|---|---|---|---
1 | 45 | (15%) | 50 | “50”
2 | 45 | (15%) | 150 | “150”
3 | 75 | (30%) | 100 | “100-F”

** mg/cc of calcium hydroxyapatite per total volume

ATTENUATOR RINGS
Two fat equivalent rings are provided which can be fitted around the phantom for simulating medium and large patients – to achieve proper beam-hardening corrections.

Our manufacturing methods insure that each part of the phantom is carefully controlled so that each finished phantom is identical to the next. This is why human bone, the quality and consistency of which cannot be controlled, have not been used.

SLICE THICKNESS GAUGE
The CIRS Slice Thickness Gauge is an easy to use evaluation tool for direct reading of CT slice thickness for quantitative applications such as Bone Densitometry and other tissue comparative diagnostic techniques.

CIRSCALC SOFTWARE
The CIRSCALC software program provided allows you to use a personal computer to perform all calculations and produce a printed graphic report.

Our manufacturing methods insure that each part of the phantom is carefully controlled so that each finished phantom is identical to the next. This is why human bone, the quality and consistency of which cannot be controlled, have not been used.
Comparison with Other BMD Measurements

HA vs. K$_2$HPO$_4$

The CIRS simulator provides Bone Mineral Content (BMC) values in mg/cc of calcium hydroxyapatites (HA) that approximate ash weight values. At the range of normal vertebral body ash weight values (100-200 mg/cc), the calcium HA values will be higher than mineral content values calculated on a system employing dipotassium phosphate (K$_2$HPO$_4$) as the correlation medium.

CIRS, in a series of test of correlation systems containing K$_2$HPO$_4$ and the Model 004, found relationships consistent with K$_2$HPO$_4$ to ash weight conversion (JCAT, May 85, Pg. 603) where:

$$\text{K}_2\text{HPO}_4 \text{ in mg/cc} = -8.4 + (0.905 \text{ Ash weight in mg/cc})$$

As ash weight BMC readings become lower in value, the difference between the CIRS system and K$_2$HPO$_4$ systems of reference will diminish. This is due to the variance in the slopes of the correlation curves.

The CIRS system provides sizing rings to compensate for beam hardening effects. This is a new capability and one that “normal value” curves currently represented in published literature do not address. The measure is affected within the simulator thereby truly mimicking the clinical measurement, whereas other systems use reference material either in a table or placed on a patient’s abdomen.

The CIRS system also provides marrow fat correction to compensate for the well documented effect of marrow fat build-up with increasing age (i.e.: If the vertebral calcium content does not change from age 45 to age 75, the observed CT value will decrease significantly due to marrow fat build-up). The CIRS system provides a simple, direct method for the user to calculate the effect of marrow fat build-up in performing CT analysis of vertebral bone mineral content.

Dual energy CT evaluation of vertebral BMC has validated the CIRS simulation system values. For scanner operators having dual energy capability, the CIRS Simulator provides a system calibration capability, but simulation of each patient is not required.

DXA vs. QCT

Dual X-ray Absorptiometry (DXA) may have a precision <1%, but QCT still has the highest level of diagnostic sensitivity ($^6$). While DXA analyzes total bone, CT is the only modality with the 3D capability to isolate and volumetrically measure pure spinal trabecular bone. Trabecular bone has a higher turnover rate of 20% - 25% as opposed to 1% - 3% for cortical bone. Therefore, there is real scientific need to specify what bone the clinician wishes to sample.

DXA is a dual energy method and dampens marrow fat effect on total bone measurements. QCT can be a dual or single energy method but studies have shown that BMC measurement errors due to marrow fat content in postmenopausal women are not significant ($^6$). This aside, CIRS systematically corrects for the normal buildup of marrow fat when using the preferred single energy method.

Dose reported with QCT is at least 200 mrem and has been reported as high as 2000 mrem while DXA patient radiation dose is often reported as <3 mrem. This is an area where terminology plays a big role. A CT-BMC study (1 scout, 3 slices) results in an effective dose roughly equivalent to an AP chest X-ray. This is more than a Posteroanterior DXA exam, but far less than a supine lateral scan of the spine which frequently accompanies these exams ($^7$).

Normal Values

The Model 004 standardizes CT numbers to an unchanging physical standard of reference. This reference mineral is Calcium Hydroxyapatite embedded in a marrow equivalent solid matrix made of epoxy resin.

The Hydroxyapatite equivalence of the patient’s composite vertebral trabecular CT number is compared to a normal curve.

The “Hydroxyapatite Normals” are derived from published normative studies ($^6$) ($^9$)

Since a majority of published trabecular normative data for a North American population was derived using K$_2$HPO$_4$ as a reference mineral, CIRS has mathematically converted the K$_2$HPO$_4$ norms to calcium hydroxyapatite norms. This straight conversion was performed through phantom/phantom scanning protocols. Further, a confirmation study of over 100 patients using 10 different scanners was done by CIRS. This was reported at RSNA in 1986.

The CIRS normative data was further tested for agreement with “Ash weight” mineral values. When “K$_2$HPO$_4$ to Ash weight” conversions are made, the resulting revised expression of normal values is almost identical to the CIRS hydroxyapatite curves ($^1$) ($^3$) ($^1$)

Recently, other vendors of bone density systems for CT have switched from K$_2$HPO$_4$ to calcium as a reference mineral. Close examination will show that these converts to hydroxyapatite as reference mineral express normative values nearly identical to CIRS.

While normative data for the mid-life North American population is considered to be well established and stable, centers which are embarking on studies of special identifiable populations (very old, very young, Asian, black, war victims, etc.) should collect data and revise “norms” as their populations may dictate.
The BMD measured for a patient is compared with age- and sex-matched controls as well as with sex-matched young healthy controls. The values are then expressed as percentiles or standard deviation scores, called Z- or T-scores.

The Z-score is a measure of the difference between the patient’s BMD and the mean BMD of age- and sex-matched peers. The Z-score, in SD values, is calculated as:

$$Z\text{-score}^{(SD)} = \frac{P - M_{AM}}{SD_{AM}}$$

The Z-score, in percent values, is calculated as:

$$Z\text{-score}^{(\%)} = \frac{P}{M_{AM}} \times 100$$

Here P is the measured patient value, M_{AM} is the mean value for age- and sex-matched controls, and SD is the standard deviation of the mean value for age- and sex-matched controls.

The T-score is a measure of the difference between the patient’s BMD and the mean BMD of young normals. The T-score, in SD values, is calculated as:

$$T\text{-score}^{(SD)} = \frac{P - M_y}{SD_y}$$

The T-score, in percent values, is calculated as:

$$T\text{-score}^{(\%)} = \frac{P}{M_y} \times 100$$

Here P is the measured patient value, My is the mean value for young, sex-matched normals, and SDy is the population standard deviation for young normals. The sensitivity of a measurement to prospective bone loss or bone gain depends on the precision and the changes expected. For example, while Single Photon Absorptiometry (SPA) of the forearm and DXA of the spine may both have a nominal precision of 1%, the diagnostic sensitivity of the spine measurement (expected rate of change during menopause 2-4% / year) is approximately twice that of the peripheral SPA measurement (expected rate of change 1-2% / year).
Qualification of Slice Thickness

The optimum technique for CT analysis of vertebral bone density with the CIRS Mode 004 CT Simulator for Bone Mineral Analysis will vary with each type of scanner.

As a rule, 5 mm or 10 mm slice section available on the scanner should be used for vertebral Bone Mineral Content (BMC) analysis. Remember, quantitative CT analysis requires accuracy of slice thickness. (When isolating trabecular bone for analysis by CT, you want to ensure that cortical bone is not included in the slice selected.)

SLICE THICKNESS AND BEAM EVALUATION PROCEDURE

1. Place large attenuator ring on support board. The attenuator ring will simulate a patient in the gantry. Many scanners will not actively scan if an empty gantry is sensed. Using the Velcro side, affix the slice thickness gauge to the support board. Make sure the attenuator and the slice thickness gauge are perpendicular to the foot of the support board.

2. Position the simulator on the table, and verify that setup is perpendicular to the table. Make adjustments as needed. Position the laser light on the alignment line on either edge of the gauge.

3. Set the scanner for 1 mm or 3 mm slice thickness (or whichever thickness you wish to check).

4. Scan the simulator and slice thickness gauge using a normal axial technique.

5. Bring the image to the monitor. Adjust the window level and width to maximize resolution of the steps. The image plane will show a vertical representation of the gauge. It will have a faint vertical line separating the two sets of 1 mm steps on the gauge. Image examples and interpretations are provided in the next section.

6. In review of the image, you will notice a number of rectangles with varying shades of gray. A full black rectangle represents a full mm slice penetration through that portion of the gauge. Lighter rectangles represent partial volumeing. Lighter contrast represents less slice thickness. The examples displayed in this document use 20%, 40%, 60%, 80% and 100% contrast.

IMAGE EVALUATION 1 MM BEAM

1A. Represents a one mm slice through the origin, demonstrating symmetry of the slice and beam alignment along the X / Y axis. The image demonstrates proper alignment. A full black bar is shown on the image in the center origin and two (2) light (20% contrast) bars. This represents a slice thickness slightly greater than 1 mm and proper alignment of the beam.

1B. Represents a one mm slice which is rotated 1 degree clockwise through the origin. A full black bar is shown in the center representing the slice passing through the origin. A light (20% grayscale) half bar on the right and a light half bar on the low left. This represents a slice alignment through the center but offset by approximately 0.5˚ – 1.5˚.

1C. Represents a one mm slice which is rotated 2 degrees clockwise through the origin. A full black bar is shown in the center representing the beam passing through the origin. A slightly darker half bar (40% grayscale) on the right and another darker half bar on the low left. Represents the slice alignment is through the center but indicates an offset approximately 1˚ – 2˚.
Qualification of Slice Thickness

**FIGURE 2A**
Shows a 3 mm slice through origin and demonstrates alignment and symmetry of the image and beam alignment along the X / Y axis. Note the increase in image elements shown on the image plane with the increased beam width. Image demonstrates proper alignment. The 3 full dark bars each represent 1 mm slice. The 2 full length lighter bars (20%) represent partial mm penetration.

**FIGURE 2B**
Shows a 3 mm slice thickness rotated 1 degree clockwise through the origin. Since the beam is through the origin and offset by 1 degree, a reverse mirror image is displayed on the image plane. A full black bar is shown in the center representing the beam passing through the origin. Above the origin are 3 bars of varying contrast. Below the origin a reverse mirror image is present. This represents the 3 mm slice alignment through the center but is offset by approximately 1˚ – 2˚.

**FIGURE 2C**
Shows a 3 mm slice rotated 2 degrees clockwise through the origin. Since the beam is wider and the offset is at a greater angle the number of bars displayed increases on the side of the misalignment. The image shows an increase in bars along the misaligned surface. A full black bar is shown in the center representing the beam passing through the origin. Above the origin are 5 bars of varying contrast. Below the origin is a mirror image. The slice is through the center but is offset by approximately 2˚ - 3˚. As the alignment goes further off center and at an angle, a greater number of image bars will appear on one side of the image. See figure 3C for another example.

**FIGURE 3A**
Shows a 1 mm slice parallel to the Y axis but is missing the origin by approximately 5 mm. The image plane demonstrates this by bars at opposite ends and across from each other. Since the origin is missed entirely, bars in the center of the image plane will not be present.

**FIGURE 3B**
Shows a 1 mm slice parallel to the Y axis on the other side of the gauge but is missing the origin by approximately 4 mm. The image plane shows the bars opposite of image 3A. A few more bars are present on the image plane as the beam passes through partial elements.

**FIGURE 3C**
Shows a 1 mm slice diagonal to the Y axis passing through the origin. The image plane demonstrates the clusters as a mirror image on the same plane. The beam is following the pattern of the Slice Thickness Gauge and passes through the offset pattern.
ALGORITHM OF RECONSTRUCTION

On some scanners there is only one available algorithm of reconstruction for body applications and there is no other option but to use the algorithm provided.

On other scanners there are several types of reconstruction algorithms for body imaging to choose from (the algorithms are sometime called filters of reconstruction or kernels). The CIRS Lumbar Reference Simulator is designed to be essentially independent of any particular reconstruction algorithm. Use the body imaging algorithm recommended by the scanner manufacturer.

Note: Do not use algorithms designed specifically for targeted reconstructions. Use only those algorithms designed for abdominal or soft tissue imaging, not bone imaging.

BEAM PULSE AND SCAN TIME

The kVp should be the one recommended by the manufacturer for body imaging.

In general, a 200-300 mAs exposure for a 10 mm section is adequate and should be verified by making sure the standard deviation of CT numbers of a homogenous part does not exceed 15 HU and should preferably be under 10 HU.

The best way to determine whether or not you have achieved an appropriate technique is to judge images directly on the display screen.

Beware of streak artifacts. These artifacts prevent any sort of reliable quantitative analysis.

CIRCLE OF RECONSTRUCTION

Ideally, the circle into which the patient can exactly and completely fit should be used. Unless you are certain the patient will fit into the selected circle, you should use the circle of reconstruction with the largest diameter available. With some scanners, the most lateral detectors are used as reference detectors during the reconstruction process and, if the patient overlaps one of the reference detectors, incorrect values may be obtained.

Note: Use the largest circle of reconstruction possible. Once the proper technique is defined, do not change parameters.

THE CORRECTION FOR MARROW FAT

Bone marrow fat increases with age, and this increased bone marrow fat affects the CT value reading. Theoretically, a person could maintain the same level of bone mineral content over a period of years and yet have progressively lower CT values due solely to the increase in bone marrow fat and the way in which this increase affects the machine’s reading. This effect has been described by a number of researchers.\(^{(13)}\)

A 45 year old with 15% bone marrow fat and a 75 year old with 30% bone marrow fat may both have bone mineral content of 100mg/cc, but will not record identical CT values. The 75 year old will have a lower CT value because increased bone marrow fat causes the machine to give a lower CT value. The greater the bone marrow fat, the lower the CT value. A correction is needed in order “to give back” in CT units what the machine “has taken away” because of the increased bone marrow fat in a person over 45 years of age. The Model 004 provides a method of correcting the effect of marrow fat build-up on observed CT measurements of vertebral bone mineral content.

DETERMINE BONE MARROW FAT CORRECTION FOR YOUR CT MACHINE

1. Place lumbar section in any size configuration on the support board.
2. Position Simulator on table so that laser light line is centered on top of lumbar section. Be sure that the Simulator’s lumbar section is exactly perpendicular to the table. If necessary, use a sandbag on foot of support board to achieve this perpendicularity.
3. Place 50 mg insert in Simulator and scan.
4. Remove 50 mg insert, place 150 mg insert in Simulator and scan.
5. Remove 150 mg insert, place 100-F mg insert (the high marrow fat insert) in Simulator and scan.
6. Bring each of the three images above to the monitor. Place a region of interest (ROI) indicator in the center of each vertebral insert and record the mean CT value for each ROI.
7. Use the “Fat Correction” utility in the CIRSCALC software program.

NOTE: The software program saves the fat correction factor that is a constant for each individual scanner. If you change scanners, or have a major software update, repeat the Marrow Fat Correction procedure.
Scanning and Data Acquisition Procedure

1. Place patient on table with arms over head.
2. Obtain a lateral scout view (scanography or pilot view) to localize third lumbar vertebral area.
3. After localization, set scanner for quantitative technique. This technique will be used on this patient and simulator in the same fashion. Always use the largest circle of reconstruction possible.
4. Scan the patient’s 2nd, 3rd, 4th, and 5th lumbar area. The CT section should be obtained parallel through the mid-region of each vertebral body. Ensure that the scans are free of motion artifacts. Avoid compression points of fractures. 
   **USE NO CONTRAST.**
5. Get patient up (do not lower table).
6. Looking at the patient’s scan on the monitor, select the sizing of the simulator (small/medium/large). When in doubt, use the larger size.
7. Set up simulator on support board, properly sized and with vertebral insert for 50 mg/cc (age 45) of mineral content in place (be sure to attach velcro backed “marker” to support board so that retained images will reflect which insert was used).
8. Position with laser light in the center of the simulator. (Ensure the simulator is vertical to the table use a sandbag on the foot of the stand if necessary).
9. Scan simulator with same technique as used for patient.
10. Change vertebral insert to 150 mg/cc (age 45) and repeat Step 9.
11. If you have not previously scanned the high-marrow fat insert (100 F - age 75) equivalent for calculation of the marrow fat correction, do so now. If you have established the marrow correction for your scanner, go to the next step.
12. Put the simulator away.
13. Interpret results using the CIRSCALC Software program.
CIRSCALC® Software

CIRSCALC is PC software for use with the CIRS Model 004 Lumbar Reference Simulator. The program performs data analysis calculations and produces printed reports.

The CD contains both “New Installation” and “update” for previous users of Version 6.01. For questions pertaining to this program or the Bone Mineral Measurement System, or to obtain the latest version of CIRSCALC, please contact CIRS.

INSTALLATION PROCEDURE

- Go to “My Computer”
- Select CD
- The program will Self Prompt the installation procedure
- Move CIRSCALC icon to desktop if desired

TO RUN THE PROGRAM

1. Double click on the CIRSCALC Icon or go to “Program” and select “CIRS CT Bone Densitometry”.
2. The first program screen is a logo screen.
3. The second screen is the Main Menu.

OPERATING FUNCTIONS

- To enter New Patient, click “Clean Sheet”
- To back-up within data entry screen, use “Shift- Tab”
- At completion of data entry, click SAVE and BMC calculations are done immediately

1. Select the Patient’s Exam Folder by selecting Patient Exam under File Menu.
2. Click the ADD button (hint: move the mouse pointer slowly over the buttons at the bottom of the screen for a Tool-Tip of their function).
3. After clicking the ADD button the tool bar at the bottom of the screen will change. Most of the buttons will be disabled except for the SAVE button and UNDO button. After entering the Patient’s data, click the SAVE button or click the UNDO button to cancel the addition at any time.

EDITION A PATIENT FOLDER & UPDATING EXAM RESULTS

1. Select the Patient’s Exam Folder by selecting Patient Exams under File Menu.
2. To prevent the accidental changing of data, you must first be in edit mode to change a Patient’s Record. Click the EDIT button at the bottom of the screen to make changes to the Patient’s Record.
3. After clicking the EDIT button, the tool bar at the bottom of the screen will change. Most of the buttons will be disabled except for the SAVE button and UNDO button. After editing the Patient’s data, click the SAVE button or click the UNDO button to cancel the changes made at any time.

UPDATING EXAM DATA AND ADDING PATIENT HISTORY

1. Select the Patient’s Exam Folder by selecting Patient Exams under File Menu.
2. Click the EDIT button at the bottom of the screen to make changes to the Patient’s Record.
3. If an existing Patient is re-examined, update the Simulator Measurements and Exam Date. After pressing the SAVE button, the previous values will automatically be saved in the Patient’s History. Each entry in the History as well as the latest Measurements are reflected by Tick-Marks on the BMC Bone Densitometry Graph. If a new patient is entered you may manually enter any previous Exam results manually if desired.
4. Click the SAVE button or click the UNDO button to cancel changes at any time.
DELETING A PATIENT
1. Select the Patient’s Exam Folder by selection Patient Exams under File Menu.
2. Click the Binocular (look-up), select patient
3. Double click on selected patient
4. Click Red “X” button (i.e. Delete)
5. Verify “Delete Current Record”
6. Click Exit

UPDATE MARROW FAT CORRECTION
1. Select File, System Configuration from top toolbar.
2. Double Click System Configuration.
3. Select Edit Icon from bottom row of icons.
4. Make desired changes
5. Click Save Icon on button row of icons
6. Click Exit Icon

DATA BACK-UP
Use Standard Windows Back-up function
Start/Programs/Accessories/System Tools/Back-up

INTERPRETATION GUIDELINES

The vertebral “ROI” values for the patient and the 50 and 150 mg/cc ROI values for the simulator are entered into the CIRSCALC software program.

Vertebral BMC is calculated by the program and the report is printed.

The bone mineral values calculated with the CIRS system differ from other published systems of reference by 20 mg/cc in the normal range of values measured. This is attributable to the use of calcium hydroxyapatite rather than K$_{2}$HPO$_{4}$. For example, should you be evaluating a patient using K$_{2}$HPO$_{4}$ solutions for a standard of reference and the patient measures 120 mg/cc of K$_{2}$HPO$_{4}$, the same patient will measure in the vicinity of 140 mg/cc calcium hydroxyapatite with additional corrections for beam hardening and marrow fat content.

In a few cases of clearly osteoporotic patients, you may obtain unusually low CT readings and in turn unusually low BMC reading (40 mg/cc or lower). In these cases, the effect of marrow fat is abnormally high and thus numerical BMC readings are beyond the effective limits of the equipment.

It is recommended that users collect observed measurements and determine the norms for their individual patient populations.

REVIEWING THE IMAGES
Once the procedure is complete, the data entered, and the report generated, the reporting radiologist should review the images both for proper adherence to technique and to insure no obvious additional findings exist which should be reported.
Quantitative CT is an assistant to, not a substitute for, a physician’s judgment.
When submitting claims to Medicare, procedural Current Procedural Terminology (CPT) codes are reported with diagnosis codes describing the patient’s documented medical conditions. These diagnoses are reported using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).

It is critical that the proper ICD-9-CM codes be listed with the CPT for Medicare claims to be paid.

Medicare Contractors will pay claims for screening tests only when the claim contains CPT procedure code 77078 and a valid ICD-9-CM diagnosis code.

Most bone densitometry tests are covered when used to screen patients for osteoporosis subject to the frequency standards described in section 80.5.5 of the Medicare Benefit Policy Manual.

Currently, Medicare reimburses diagnostic imaging procedures differently based on the site of care. In a hospital outpatient department, the technical component of a procedure is reimbursed under an Ambulatory Payment Classification (APC) under Medicare's hospital outpatient department prospective payment system (OPPS). For procedures performed in an IDTF or physician office, the technical component is reimbursed under the Medicare physician fee schedule. The professional component is reimbursed under the Medicare physician fee schedule, regardless of the setting.

Third party coverage policies for bone densitometry vary by payer and locality. The local Medicare contractors have discretion to determine the specific circumstances under which a CT bone densitometry scan is covered.

**CPT 77078 – CT BONE DENSITOMETRY**

Computed Tomography, bone mineral density study, 1 or more sites; axial skeleton lumbar spine.

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**ICD-9-CM DIAGNOSIS CODES AND DESCRIPTIONS**

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**PATHOLOGIC FRACTURE**

| 733.10               | Pathologic fracture, unspecified site |
| 733.11               | Pathologic fracture of humerus |
| 733.12               | Pathologic fracture of distal radius and ulna (Wrist NOS) |
| 733.13               | Pathologic fracture of vertebrae (Collapse of vertebrae) |
| 733.14               | Pathologic fracture of neck of femur (Femur/Hip NOS) |
| 733.15               | Pathologic fracture of other specified part of femur |
| 733.16               | Pathologic fracture of tibia and fibula (Ankle NOS) |
| 733.19               | Pathologic fracture of other specified site |
| V54.20-V54.29        | Aftercare for healing pathologic fracture (Site specific) |

**FRACTURE OF NECK AND TRUNK**

| 805.00-829.1        | Fracture of Neck and Trunk (site specific) |

**DISEASES OF ENDOCRINE GLANDS**

| 252.0x               | Hyperparathyroidism ICD-9-CM Diagnosis Codes and Descriptions |
| 255.0                | Cushing’s syndrome |
| 256.2                | Postablative ovarian failure |
| 256.31               | Premature menopause (permanent cessation of ovarian function) |
| 256.39               | Other ovarian failure |
| 259.3                | Ectopic hormone secretion, not elsewhere classified (hyperparathyroidism) |
| 268.2                | Osteomalacia |
| 268.9                | Unspecified vitamin D deficiency |
| 627.*                | Menopausal and postmenopausal disorders |
| V07.4                | Hormone replacement therapy (postmenopausal) |
| V49.81               | Asymptomatic postmenopausal status (age-related) (natural) |
A certification document accompanies all systems that states:

“This is to certify that the CIRS CT Simulator for Bone Mineral Analysis S/N# _____ was tested on ______. Against the certified company Reference Simulator to insure conformity to the original simulator design and construction. The testing procedures utilized for this quality control were developed by independent auditors and were performed by A. Johnson.”

If, at any time, you have reason to believe that the characteristics of the phantom have changed (contact with corrosive substances, high temperatures), CIRS will gladly perform re-certification at nominal charges.

**MODIFICATION AND UNINTENDED USAGE**

The CIRS Model 004 cannot be modified or used for other purposes than those described in this manual without the written permission of CIRS. Unauthorized modifications or usage will void all expressed warranties.

**Warranty**

All standard CIRS products and accessories are warranted by CIRS against defects in material and workmanship for a period as specified below. During the warranty period, the manufacturer will repair or, at its option, replace, at no charge, a product containing such defect provided it is returned, transportation prepaid, to the manufacturer. Products repaired in warranty will be returned transportation prepaid.

There are no warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness, which extend beyond the description on the face hereof. This expressed warranty excludes coverage of, and does not provide relief for, incidental or consequential damages of any kind or nature, including but not limited to loss of use, loss of sales or inconvenience. The exclusive remedy of the purchaser is limited to repair, recalibration, or replacement of the product at manufacturer’s option. This warranty does not apply if the product, as determined by the manufacturer, is defective because of normal wear, accident, misuse, or modification.

**NON-WARRANTY SERVICE**

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with said repair or replacement.

**RETURNS**

If you are not satisfied with your purchase for any reason, please contact Customer Service prior to returning the product. Call 800-617-1177, email rma@cirsinc.com, or fax an RMA request form to 757-857-0523. CIRS staff will attempt to remedy the issue via phone or email as soon as possible. If unable to correct the problem, a return material authorization (RMA) number will be issued. Non-standard or “customized” products may not be returned for refund or exchange unless such product is deemed by CIRS not to comply with documented order specifications. You must return the product to CIRS within 30 calendar days of the issuance of the RMA. All returns should be packed in the original cases and or packaging and must include any accessories, manuals and documentation that shipped with the product. The RMA number must be clearly indicated on the outside of each returned package. CIRS recommends that you use a carrier that offers shipment tracking for all returns and insure the full value of your package so that you are completely protected if the shipment is lost or damaged in transit. If you choose not to use a carrier that offers tracking or insure the product, you will be responsible for any loss or damage to the product during shipping. CIRS will not be responsible for lost or damaged return shipments. Return freight and insurance is to be pre-paid.

**WITH RMA NUMBER, ITEMS MAY BE RETURNED TO:**

CIRS
Receiving
2428 Almeda Avenue Suite 212,
Norfolk, Virginia, 23513 USA

<table>
<thead>
<tr>
<th>Product</th>
<th>Warranty Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODEL 004 - CT Simulator for Bone Mineral Analysis</td>
<td>48 months</td>
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</tbody>
</table>
References

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Dr. Jones
Sincerely,

Office.

To schedule an appointment or for additional information on this service, please call our office.

The study is generally reimbursable with most insurance plans. Our fee is $123.45.

Furthermore, sequential studies can help you in assessing the evolution of the disease and the effectiveness of therapy. The examination is non-invasive and requires only three to four contiguous scans with exposure roughly equivalent to or less than that of a projection x-ray for the area examined.

Osteoporosis is present or whether your patient is at risk for developing Osteoporosis. Hydroxyapatite. This quantitative approach to BMC assessment permits you to determine if

A standard phantom for quantitative analysis of pulmonary nodules by Radiology 149: 767-773, 1983


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