

SOFT TISSUE COMPOSITION

The Norland Soft Tissue Composition option estimates the lean and fat composition of the soft tissue in the Whole Body, and special regions of Research and Small Subject scans. It works in conjunction with the Whole Body, Research, and Small Subject scans to provide lean and fat soft tissue mass values in addition to the bone density values.

No additional dose is required to obtain these soft tissue composition values.

When Soft Tissue Composition is resident on the system, soft tissue values are automatically presented for the computer-generated and operator-defined regions of interest on Whole Body scans and for operator-defined regions of interest on Research and Small Subject scans. Refer to the appropriate scan supplements for more details on Whole Body, Research and Small Subject scans.

This supplement is to be used in conjunction with the Operator's Guide.

Using DXA technology to determine fat content is a much quicker and simpler process than underwater weighing (UWW), which is often said to be the "gold standard". Underwater weighing requires that subjects be able and willing to be completely submerged in water while exhaling rather forcibly. This method is ill suited for subjects who are sick, infirm, unconscious, or afraid of water.

Another advantage of DXA over UWW is its insensitivity to body gas. The effect of gases contained in the body must be compensated for when using underwater weighing, while the x-ray beam used in DXA is unaffected by such gases.

DXA provides independent values of bone mineral content (BMC) and bone mineral density (BMD) and non-bone lean mass (LEAN), as well as fat mass (FAT) from which the true bone mass fraction for a subject can be calculated for Research and Small Subject scans. Siri and Brozek equations for underwater weighing equivalent values are reported in addition to the BMD, BMC, LEAN MASS and FAT MASS values for Whole Body scans.

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Detailed Specifications

Detailed specifications for Soft Tissue Composition are in the following tables.

| Soft Tissue Composition Specifications | |
|--|---|
| Scan Site | Whole Body: System-defined and operator-defined regions of interest Research and Small Subject: Operator-defined regions of interest |
| Accuracy ^a | Typically within 2.0% |
| In vivo Precision ^b | See table below |

a. Standard for calibration: BONE - hydroxyapatite; FAT - stearic acid; LEAN- 0.6% NaCl in H₂O.

b. Based upon 3 scans each of 14 subjects Whole Body procedures outlined in the Whole Body Supplement, using 6.5 X 13 mm resolution and 260 mm/sec scan speed.

In vivo Precision

| | Total Body C.V. | Head C.V. | Trunk C.V. | Abdomen C.V. | Arms C.V. | Legs C.V. |
|------------------|--------------------|--------------|---------------|-----------------|--------------|--------------|
| Soft Tissue Mass | 0.1% | 1.4% | 0.81% | 2.3% | 1.8% | 0.57% |
| Lean Body Mass | 0.93% | 1.4% | 1.6% | 2.6% | 2.3% | 1.5% |
| Fat Mass | 1.4% | 1.9% | 1.9% | 3.7% | 4.8% | 2.1% |
| Percent Fat | 1.4% | 0.91% | 1.7% | 2.2% | 3.5% | 2% |

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

Tissue Composition Standards

Bone mineral assessment instruments have traditionally been calibrated with reference to an “ash study”, a means of determining the amount of bone mineral in an excised bone which has been scanned. Sources of error in ash studies result in wide differences in calibration in instruments from different manufacturers.

In order to minimize or eliminate this inter-manufacturer variation in x-ray based instruments, several device manufacturers have agreed to develop industry standards for tissue estimations.

- The standard for bone is hydroxyapatite, a substance equal to the mineral component in bone. It is available in purified form as calcium phosphate tribasic, type IV, from the Sigma Chemical Company of St. Louis, Missouri, USA. Two of the United States DXA equipment manufacturers have chosen to use this material as the standard for bone mineral characterization and phantom construction.
- The standard for fat is stearic acid, a fatty acid which closely approximates the triglyceride esters which make up mammalian fat in molecular composition and in photon attenuation properties.
- The standard for lean soft tissue is 0.6% sodium chloride in water. This saline solution closely approximates the photon attenuation properties of the various lean soft tissues, such as muscle, blood and skin.

Soft Tissue Composition

Whole Body

All Soft Tissue values are derived from data acquired during a Whole Body scan. Soft Tissue values will be calculated for the computer-generated regions of interest.

1. After completing the Whole Body scan, perform the routine analysis. (See Whole Body Supplement.)
 - When performing serial soft tissue characterizations of the same patient, it is important to position all cursors the same as in the initial (baseline) scan. Use *Comparison Image* (see Whole Body Supplement) to aid in positioning cursors for serial patients.

Research & Small Subject

All Soft Tissue values are derived from data acquired during the scan. Soft Tissue values will be calculated for operator-defined regions of interest (see Special Regions in the Operator's Guide).

1. After completing the scan, perform the routine analysis. (See the appropriate scan supplement.)
2. Add and position Special Regions for desired soft tissue calculations. The operator can place up to five (5) Special Regions on Research or Small Subject scans.
 - When performing serial soft tissue characterizations of the same subject, it is important to position all cursors the same as in the initial (baseline) scan. Use *Comparison Image* to aid in positioning cursors for serial subjects.

Results

Whole Body

Measured Values

| | |
|-------------------------|-------------------------------|
| BMC (g) | Bone Mineral Content in grams |
| Lean Mass (g) | Lean Tissue in grams |
| Fat Mass (g) | Fat Tissue in grams |
| Area (cm ²) | Area in squared centimeters |

Calculated Values

| | |
|---|--|
| Total Fat % | Total Fat Mass/(BMC + LEAN + FAT) |
| SIRI UWE Fat % | $[(4.95/Dt) - 4.142] * 100$ (Dt = Total Density) |
| BROZEK UWE Fat % | $[(4.57/Dt) - 4.142] * 100$ (Dt = Total Density) |
| Soft Tissue Fat % | Fat Mass/(Lean + Fat) |
| %TBMC/FFM (Total Bone Mineral Content/Fat Free Mass) | Total BMC/(Total BMC + Total Lean Mass) |

- Total Lean Mass (g), Total Fat Mass (g), Total Fat %, Siri and Brozek Underwater Weighing Equivalents (UWE) Fat %, Soft Tissue Fat % and the %TBMC/FFM values are displayed below the image on Results Page 1 (Figure 1).
- Lean and Fat Mass values for head, trunk, abdomen, arms, legs, and total body will be displayed on Results Page 2 (Figure 2).
- SIRI AND BROZEK underwater weighing equivalents are presented for comparisons to DXA % Fat as underwater weighing may be considered the gold standard in fat content determinations.
- TBMC/FFM is the ratio of Total Bone Mineral Content (bone) and Fat Free Mass (lean tissue).

Research & Small Subject

- Lean Mass (g) and Fat Mass (g) values for any operator-defined regions will be displayed on Results Page 2. Soft Tissue values for a scan of a rat is shown in Figure 4.

FIGURE 3

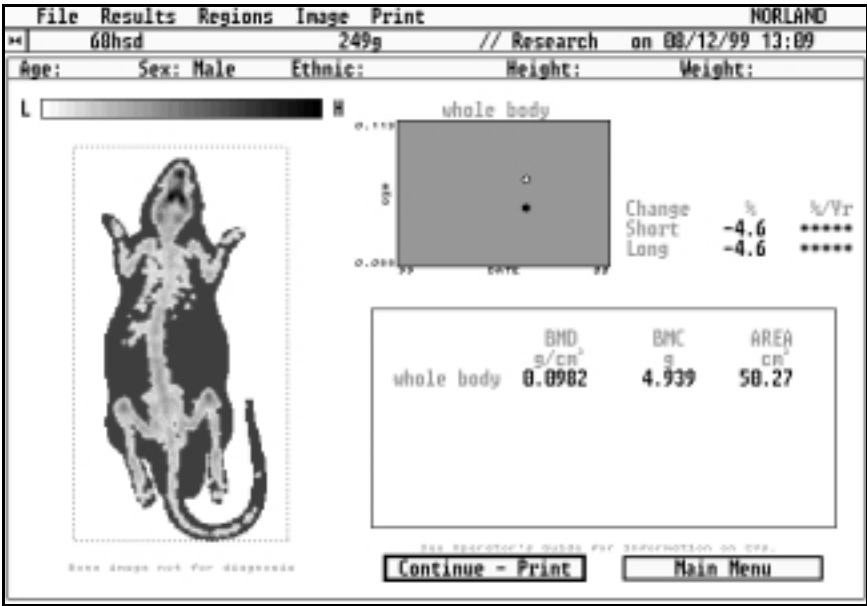
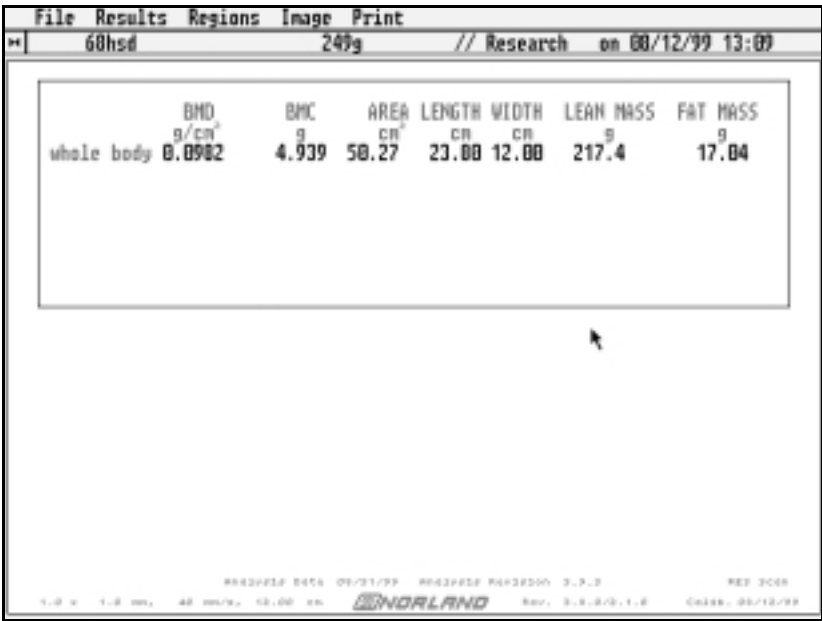


FIGURE 4



Print Report

1. View the image to ensure that cursors are positioned correctly and analysis results are satisfactory.
 - The **Image** selection on the *Analysis Menu* presents commands for optimizing the displayed image. (See “Additional Techniques” of the Operator’s Guide.)
2. Click on **[Continue-Print]** to print report as determined by Printer Setup. Analysis results will be saved to the default storage location as a scan data file under patient's name and *Main Menu* will be displayed.
 - Click on **[Main Menu]** to save scan data and exit to Main Menu without printing report.
 - Selecting **Print - Print Report** at the *Analysis Menu* will allow customization of Printer Setup for the current scan.

