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[gehealthcare.com](http://gehealthcare.com)
1. What information does the body composition application package provide?

The body composition application package for Lunar Bone Densitometers provides total body and regional estimates of fat, lean, and bone mass. In order to aid clinicians in interpreting these values, the application package provides a number of computed values – including percent fat and indices from the National Health and Nutrition Examination Survey (NHANES).¹ The body composition application can also compare the results of any individual scan file to a user-specified reference data set. This allows the physician to compare the subject’s fat or lean mass to a reference population mean.

In order to provide information on heavier subjects who may not fit completely within the scan field, the application has a feature called MirrorImage, which estimates total body and segmental body composition using scan data from body segments that are measured on the opposite side of the body.

One additional feature of the body composition package is the computation of the Resting Metabolic Rate (RMR). The RMR reports the number of calories burned by an individual when he or she is not performing any type of activity.

2. What are the clinical indications in which the body composition application can be used?

The body composition application does not diagnose any diseases or conditions. However, it may be useful in the management of conditions that impact the distribution of lean and fat mass in the body. Some examples of these conditions include chronic renal failure, anorexia nervosa, obesity, HIV/AIDS, and cystic fibrosis.

3. What is the precision for body composition and how do Lunar iDXA and Prodigy compare?

The precision for the body composition feature has been calculated using measurements from standard Lunar inhouse phantoms. The following table shows a comparison of precision for the Lunar iDXA and Prodigy, as well as a comparison between the two systems (correlation coefficient).

Users should expect that small measurement differences will be present when comparing results between Lunar iDXA and Prodigy systems. Every attempt has been made to cross-calibrate the two instruments; however, there are some subgroups of patients where differences can still be expected.

4. What’s the difference between color mapping and color coding?

Tissue threshold mapping (also known as color mapping) is an exclusive Lunar feature that is only available on the Lunar iDXA platform. It allows users to set and/or adjust two %fat thresholds (based on the tissue composition image) that change the way the tissue composition image appears. Interpolation is used to estimate tissue composition over bone. For example, a clinician could decide that all areas of the body where the %fat measurement greater than 60% should appear red, areas measuring less than 25% fat should appear green, and areas between 25% and 60% appear yellow. In effect, a clinician can set the tissue composition image to visually represent areas of high, medium and low fat using different colors to help the clinician facilitate patient understanding of their body composition.

<table>
<thead>
<tr>
<th>Value</th>
<th>Lunar iDXA (SD/%CV)</th>
<th>Prodigy (SD/%CV)</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Mass¹</td>
<td>150 g/1.0%</td>
<td>210 g/1.0%</td>
<td>r&gt;0.9</td>
</tr>
<tr>
<td>Total %Fat</td>
<td>0.4/1.5%</td>
<td>0.8/2.5%</td>
<td>r&gt;0.9</td>
</tr>
<tr>
<td>Total Lean Mass</td>
<td>310 g/1.5%</td>
<td>610 g/2.0%</td>
<td>r&gt;0.9</td>
</tr>
<tr>
<td>Total Fat Mass</td>
<td>280 g/1.5%</td>
<td>520 g/2.5%</td>
<td>r&gt;0.9</td>
</tr>
</tbody>
</table>

¹ Total Mass is BMC + Lean + Fat Mass and %Fat = Fat/(Fat + Lean Mass).
4. **What is the difference between color mapping and color coding?**

Color coding is a new feature that allows users to assign a continuous spectrum of colors based on the tissue type in the composition image. It also allows the user to set and/or adjust two thresholds (based on the composition image), one for displaying bone, and one for displaying tissue composition. The new color coding image displays bone, and presents a spectrum of colors across tissue type.

In effect, a clinician can set the spectrum on the image to visually represent areas of bone, lean mass and fat mass using different colors to help the clinician facilitate patient understanding of their body composition.

5. **What is Resting Metabolic Rate (RMR) used for? What is the difference between the RMR methods?**

Resting Metabolic Rate (RMR) is reported as the number of calories burned in a 24 hour period when no physical activity is being performed. RMR is also referred to as Resting Energy Expenditure (REE), the calculation of total daily energy expenditure, and has been a key component for nutritional assessment and prescription of food intake for various clinical applications. Numerous RMR predictive equations have been published, ranging from whole body parameters (height, weight and age) to molecular level measurements (including body composition). During periods of weight or body composition change, the RMR will increase or decrease to reflect changes in the caloric needs of the body.

As a convenience to users, RMR can be generated using one of the following three methods:

1. **The Harris-Benedict equations**, a widely-used method based on reported age, height (H) and weight (W):
   - **Male**: \[ RMR = 66.473 - 6.775 \times \text{age} + 13.7516 \times \text{W (kg)} + 5.0033 \times \text{H (cm)} \]
   - **Female**: \[ RMR = 655.0955 - 4.6756 \times \text{age} + 9.5634 \times \text{W (kg)} + 1.8496 \times \text{H (cm)} \]

The data for the Harris-Benedict RMR calculation are not derived from a DXA measurement.

2. **The Mifflin-St Jeor equation**, which uses DXA measure of fat free mass (FFM):
   \[ \text{REE (calories/day)} = 413 + 19.7 \times \text{FFM (kg where FFM (kg) = lean mass (kg) + bone mass (kg)}} \]

3. **Manually entered**. The Lunar application provides a place on the biographic information page for the physician to enter a RMR value manually.
6. What are NHANES indices? How are they used?

NHANES reference tables for male and female, and white, black and Mexican-American ethnicities include total body DXA measures of BMD, BMC, %fat, lean mass/height,² fat mass/height,² appendicular (limb) lean mass/height,² trunk %fat/legs %fat ratio, and trunk/appendicular (limb) fat mass ratio for subjects 8 to 85 years old. DXA reference values for adults are normalized to age; reference values for pediatric subjects include total and sub-total total body results and are normalized to age, height, bone area or lean mass. The NHANES indices result from the increasing recognition in the medical community that BMI may not be an optimal indicator of obesity-related disease risk in all subjects. These indices are a proposed method for improving the ability to identify obesity-related risk factors that are associated with disease. Currently, they are research tools and their utility needs to be demonstrated in future studies.

7. If the NHANES data set was collected on a Hologic device, how is it now available on a Lunar device? Is it the same?

The Lunar densitometers have been cross-calibrated with the Hologic devices across pediatric and adult populations for total body BMD and body composition measures. This means, we know the differences in measurements between the two devices and by comparing the results, we are able to provide the NHANES reference data in units useful to users of Lunar DXA systems. Specifically, Lunar and Hologic cross-calibration equations were developed for the following parameters: Total Body BMD, Total Body BMC, Total Body %Fat, Total Body Lean Mass, Total Body Fat Mass, Appendicular (Limb) Lean Mass, Appendicular (Limb) Fat Mass, Trunk Fat Mass, Trunk %Fat, Legs %Fat, Legs Fat Mass, Sub-total Body (Headless) BMD, and Sub-total Body (Headless) BMC.

8. How does Lunar define lean mass for the NHANES indices?

Lunar calculates lean indices for adults and children, including total body (and sub-total body) measures of lean mass/height,² and appendicular (limb) lean mass/height.² It is important to note that lean mass is strictly defined as lean soft tissue mass and does not contain BMC. This will provide a sensitive measure of changes in lean mass.
9. **Does the NHANES 1999-2004 survey include children?**

The current NHANES survey is a program targeted to assess the health and nutritional status of adults and children in the USA. Previous surveys provided DXA results (BMD of the proximal femur) for adults. In 1999, NHANES started collecting data on subjects 8 years old and above, and in 2008, a population-based sample was released on total body DXA results collected from 1999 through 2004. DXA values were analyzed to provide reference population for subjects from 8 to 85 years old. DXA reference values for adult were normalized to age. Reference values for children included total and sub-total (headless) total body results and were normalized to age, height and lean mass.

10. **How does MirrorImage work? What is the minimum scanning area (scan window)? Shouldn’t the left and right sides of the body be different due to organ positioning?**

The MirrorImage feature will estimate anatomy outside the scan window with information from corresponding anatomy on the opposite side of the body that was acquired. In many cases, only a patient’s arm will be estimated while in other cases half of the body will be estimated. Minimally, one complete arm and leg, the head and spine are required to obtain an estimate of the total or regional body composition. It is important to remember that the trunk is not perfectly symmetrical. While there may be some small errors introduced by asymmetry in organ positioning, the amount of organ tissue in the asymmetric organs is generally small relative to the total mass of the region.

11. **How is RSMI (Relative Skeletal Mass Index) used?**

RSMI is an index that compares appendicular (limb) lean mass (lean mass in arms and legs) with height squared. This is an index that characterizes whether the amount of lean tissue in the extremities is appropriate for a given frame size. This may be an important indicator in elderly subjects, or those who suffer from wasting diseases.

## TECHNICAL PERFORMANCE (cont.)

**COMPETITION**

1. **What other methods for body composition exist?**

Other methods for measuring body composition include: CT, MRI, Bio-impedance Analysis, Bio-impedance Spectroscopy, Hydrodensitometry, Near Infrared Interactance, Plethysmography, and Anthropometry.

2. **Why should I invest in a DXA system when I can use bio-impedance at a much lower cost?**

Investing in a DXA system offers tangible advantages over bio-impedance technology. DXA technology offers exacting precision across a wide range of body shapes and sizes. DXA technology also directly measures tissue composition, including bone mineral content (BMC), lean tissue mass, fat tissue mass, %fat, android/gynoid fat ratio and provides both total body and regional (trunk, arms, legs) results. Trending and comprehensive reporting of total and regional body composition is another key differentiator over bio-impedance, which allows for a more customized approach and targeted plan for managing weight loss, disease, and peak performance.
LOGISTICAL POINTS

1. Will the enCORE version 17 application work on existing equipment?

   enCORE v17 application will work on:
   - Prodigy with Advanced, Pro software package
   - Lunar iDXA
   - It is compatible with Microsoft Windows® XP and Windows 7 operating systems. After application purchase, customers that currently have a Prodigy or Lunar iDXA system will receive a CD with a feature code to download the new application to their systems which enables acquisition and automated analysis of DXA scans.

2. Why do you have analysis algorithm options for Prodigy?

   We have two analysis algorithms for Prodigy: Basic and Enhanced. Prodigy Enhanced is a new algorithm with greater sensitivity to bone edges (point typing), especially in younger patients and the soft composition model for better extrapolation of soft tissue over bone as compared to Prodigy Basic. Prodigy Basic is available for existing customers who wish to continue using the current algorithm for maintaining consistency with existing results.

3. How will my results change from my previous Prodigy results with the new Prodigy enhanced algorithm?

   Prodigy Total Body scans using enhanced analysis improves skeletal edge detection and local estimation of tissue composition under the bones. Enhanced analysis uses algorithmic improvements based on the higher resolution Lunar iDXA system to improve detection of low density bone and minimize the impact of soft tissue thickness on BMD.

   For an average adult, differences will be small. However, in special populations, users may notice differences.

   Results on children may change. In children, the Prodigy Enhanced analysis is able to better detect low density bone in the ribs, pelvis, fingers, and toes. The BMD will decrease slightly. However, the change in Z-score is small, with an average increase of about 0.2 for pediatric subjects. Users may also detect differences in composition due to improved local estimation of fat and lean mass under and adjacent to the bones.

   Results on thick subjects may change. In the Prodigy Enhanced application, fewer tissue pixels will be misclassified as bone. The BMD may increase slightly. Users may also detect differences in composition due to improved local estimation of fat and lean mass under and adjacent to the bones.

4. Do you have an option to transfer all of my data from the previous analysis (basic) method on Prodigy to the enhanced algorithm?

   There is an option to transfer data from the older analysis (Basic) to the enhanced algorithm (Enhanced) two ways:

   First, with previous scans on the system, you will be prompted when opening a previous scan whether to upgrade the scan if enhanced analysis is selected (as shown below). Answering "Yes" allows the scan to be reanalyzed in the current mode (Enhanced), and answering "No" leaves the analysis as it is (Basic). Note, the default scan type (Basic or Enhanced) is set in User Options > Analyze > Total Body Analysis Options.

   Secondly, you may transfer your data from the previous basic analysis to the enhanced algorithm within a batch. Go to Analyze Menu > Reanalyze Option. Select the Total Body filter, highlight files contained in the database and “Select All.” Then click “OK” (shown below).
5. **If customers are not able to use human subjects for total body cross-calibration, what do you recommend?**

The use of phantoms is appropriate when conducting total body cross-calibration for quality control analysis to gain clinical confidence with the results from the system.

6. **Are upgrades available post purchase?**

Yes, upgrades are available post purchase.

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**REFERENCES**


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