NORLAND®

at Swissray

Norland Densitometry

A Tradition of Excellence

Norland DXA

Bone Density Measurement

Osteoporosis is a disease marked by reduced bone strength leading to an increased risk of fractures. About 54 million Americans have osteoporosis and low bone mass. Osteoporosis is the major underlying cause of fractures in postmenopausal women and the elderly. These fractures can occur in the bones of the hip, spine, and wrist, but any bone can be affected. Sometimes these fractures can be disabling, especially when they occur in the hip.

Patients with osteoporosis usually have no symptoms before fracture, as such early diagnosis and treatment of the disease are of great importance to the quality of life in these patients. Early diagnosis can prevent acute or chronic pain, limitation in the ability to do daily activities, depression and loss of independence. Norland's dual energy x-ray absorptiometry (DXA) XR600/XR800 can measure central sites, such as lumbar spine and hip, as well as distal forearm. Norland DXA is noninvasive, rapid, accurate, and safe. The high precision and accuracy of Norland DXA allows testing of central sites to be used for monitoring as well as diagnosis of osteoporosis.

Body Composition Measurement

Obesity has reached epidemic proportions globally, with at least 2.8 million people dying each year as a result of being overweight or obese. Obesity can and usually does lower overall quality of life. Obese individuals may not participate in the level of physical activity that other people enjoy. Other weight-related issues that may affect quality of life include type 2 diabetes, high blood pressure, heart disease and stroke.

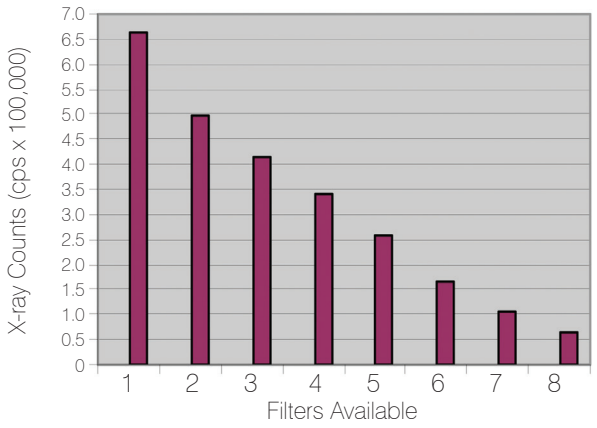
Norland DXA assessment directly measures Fat Mass, Lean Mass, Bone Mineral Content and the % Total Body BMC/Fat Free Mass for the Whole Body or isolated regions of the body in a swift, painless, noninvasive measurement. Norland DXA provides results for bone, lean and fat content in 8 default regions of the body or in operator defined regions of interest. DXA measurements allow total body or regional fat, lean or bone mass to be followed over time so that the effect of disease or treatment can be monitored. Also the Norland DXA provides the Total Percent Fat as well as the Siri and Brozek Underwater Weight Equivalent Fat Percentages.

Norland Technology

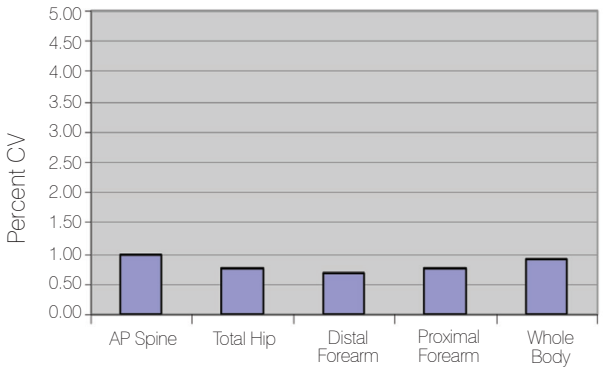
Norland Flux Adjustment

Norland employs automatic point-by-point adjusted x-ray flux so that every study, regardless of subject size, is optimized to be free of detector saturation or starvation to achieve the best precision and accuracy while exposing the patients to lowest radiation dose.

Flux Range Available in Norland Scanners



In vivo Precision on Norland Scanners



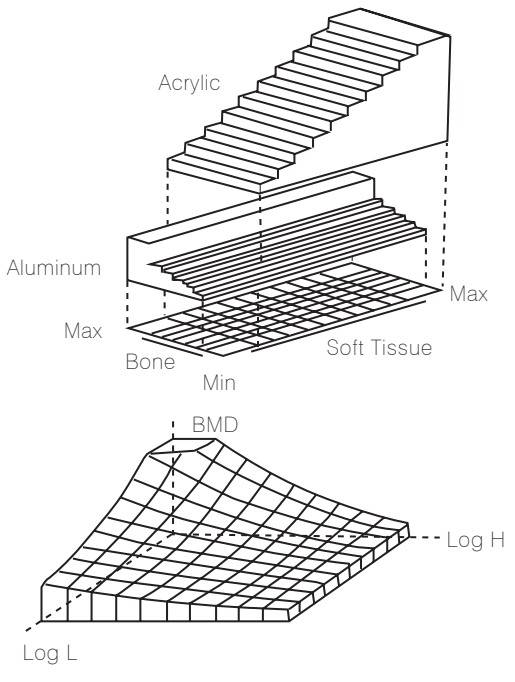
Norland Automatic Analysis

As validated in clinical studies (Journal of Clinical Densitometry. 11:455, 2008) advanced Norland technology, unlike competitive equipment, provides analysis routines that automatically place all bone edges and regions of interest insuring that over time and between operators the studies will be comparable and consistent.

Advanced Calibration

Unlike other equipment that calibrates their technology to unspecified standard materials of the moment, Norland calibration supports absolute accuracy of hard and soft tissue measurements tied to pure chemical standards for bone, lean and fat content that can be reexamined when required as technology or software changes over time.

Furthermore, while others calibrate their technology to a simplified linear regression, the Norland system calibrates results to a mixed combination of minimal to maximal hard and soft tissue contents that empirically corrects for ever changing x-ray beam hardening.



Norland–Technology with Lowest Dose

Radiation Dose

Norland technology employs a pencil-beam design minimizing radiation scatter for the benefit of operators. Norland technology also applies its exclusive dynamic filter system so that only the x-ray needed to obtain good study statistics is used. As a result Norland generates the lowest patient radiation doses in the market.

Operator Radiation Dose

Investigators (Radiation Protection Dosimetry. 117:288, 2005) confirm the lowest operator doses are obtained on Norland equipment. Indeed, unlike what is seen with other systems, Norland equipment rates well below the Controlled Area Limit set by the International Commission on Radiological Protection (Annals of the ICRP. 21:No 1-3, 1991).

Patient Radiation Dose

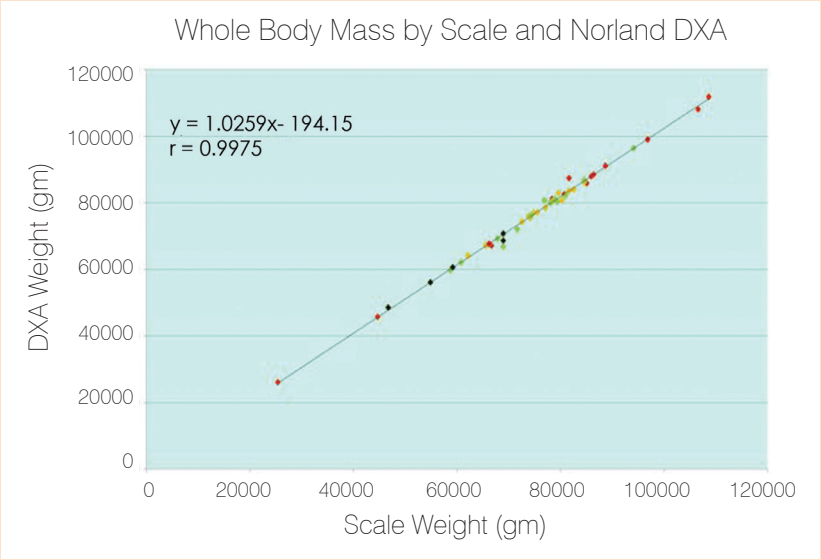
System Beam Geometry	AP Spine Scan Patient Dose
Cone Beam	30 mSv
Wide-Angle Fan Beam	36 mSv
Narrow-Angle Fan Beam	10 mSv
Fixed Filter Pencil-beam	5 mSv
Dynamic Filter Pencil-beam	2 mSv

Sheahan and associates (Radiation Protection Dosimetry. 117:288, 2005) examined patient radiation dose in systems applying different beam geometries and found that Norland equipment consistently showed studies with the substantially lowest patient dose.

True Body Composition

Body Composition Validation of Norland

Being a direct three compartment assessment of body composition, DXA has the unique potential to provide advanced "gold standard" accuracy in bone, lean and fat content measurements. Norland DXA is especially well suited to accurately provide these measurements because it operates with the advantages of pencil beam geometry, dynamic filtration control of flux, a sophisticated regional analysis routine and chemically indexed calibration. This superior accuracy is demonstrated by the consistency with which the results match total body weight.



Wang and associates (Journal of Clinical Densitometry. 16:264, 2013) using a Norland scanner have demonstrated a very strong relationship between weight by scale and DXA.

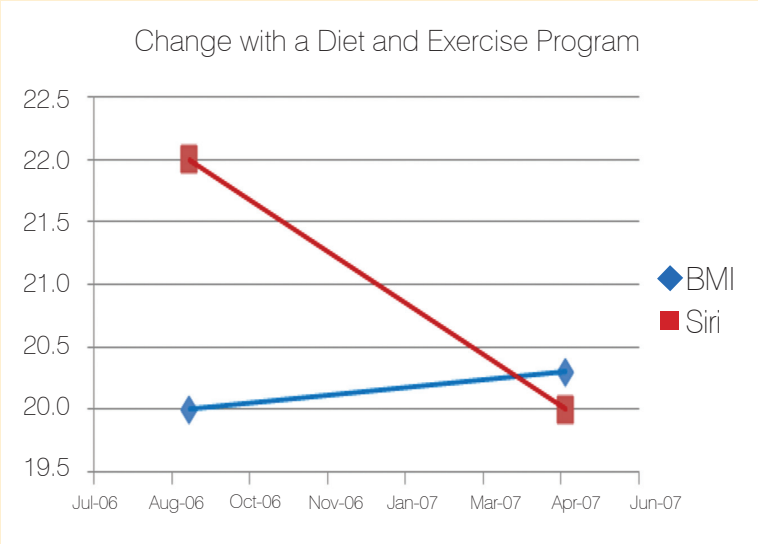
The subjects were assessed by Siri Underwater Equivalent Fat Classification as

- Underfat,
- Healthy,
- Overfat or
- Obese.

Norland Composition Detects True Change in Fat Over Time

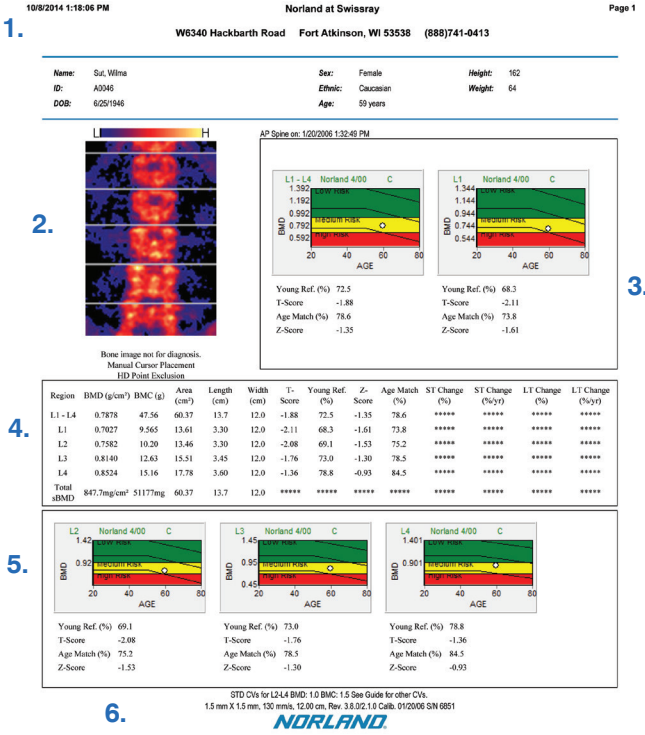
Norland DXA is a true direct assessment of body composition and, unlike BMI, has been shown to be a valuable assessment of changes in fat and lean content in exercise programs (Revista Espanola de Medicina Nuclear e Imagen Molecular. 32:281, 2013).

This can be especially critical when clinical programs are trying to treat obesity with a clinically directed diet and exercise program and individuals respond with some loss in fat but some gain in lean mass as seen in the following example.



- As seen in the graph, before beginning a treatment program in Autumn, 2006, a girl had a BMI of 20.0 and a Norland DXA Siri % Fat of 22.0%.
- As seen in the graph, following seven months of clinically directed exercise and diet shows BMI has increased slightly to 20.3 while the Norland DXA Siri% Fat has decreased substantially to 20.0%.
- The Norland DXA studies demonstrate a positive clinical response exists with soft tissue change being the result of increased lean mass and decreased fat mass.

Bone Reports

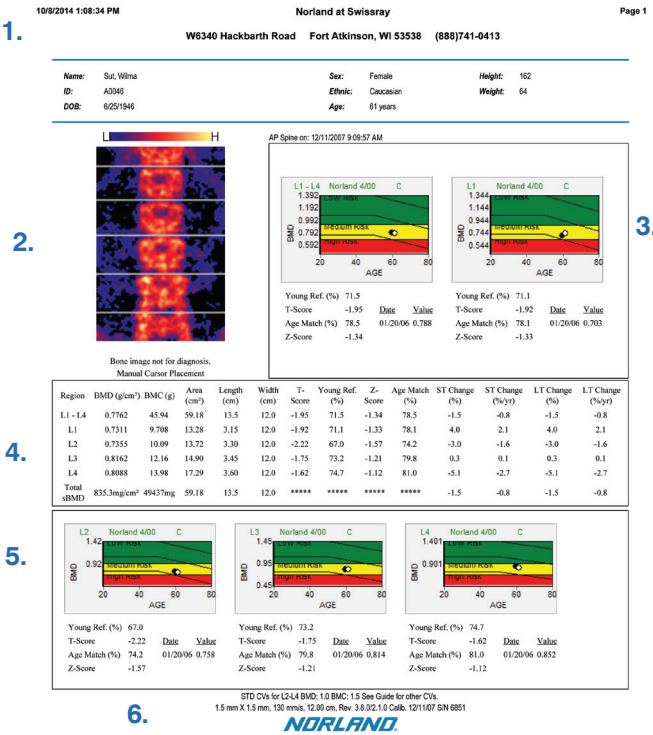


Bone Density Study

The initial assessment of bone density is carried out to directly quantify bone in the regions of interest. Understanding the regional bone density allows subjects and the physician to know where they currently are so that an appropriate clinical program can be undertaken.

The bone density report for an initial study provides:

1. facility and patient background information,
2. images of the current study on a minimum to maximum scale,
3. reference graphs, absolute and scored values for selected regions of interest of the current study,
4. absolute bone density, bone mineral content and bone area for each region of interest with T- and Z-scores for each region,
5. reference graphs, absolute and scored values for selected regions of interest of the current study,
6. specified study precision, study settings and scanner details.



Bone Density Trending Study

The follow-up assessment of a bone density study is carried out to directly quantify change in bone regions of interest. This report allows the clinician to evaluate treatment and the patient to understand their current progress.

The bone density report for an initial study provides:

1. facility and patient background information,
2. images of the current study on a minimum to maximum scale,
3. reference graphs, absolute and scored values for selected regions of interest of the current study,
4. absolute bone density, bone mineral content and bone area for each region of interest with T- and Z-scores for each region and short and long term change,
5. reference graphs, absolute and scored values for selected regions of interest of the current study,
6. specified study precision, study settings and scanner details.

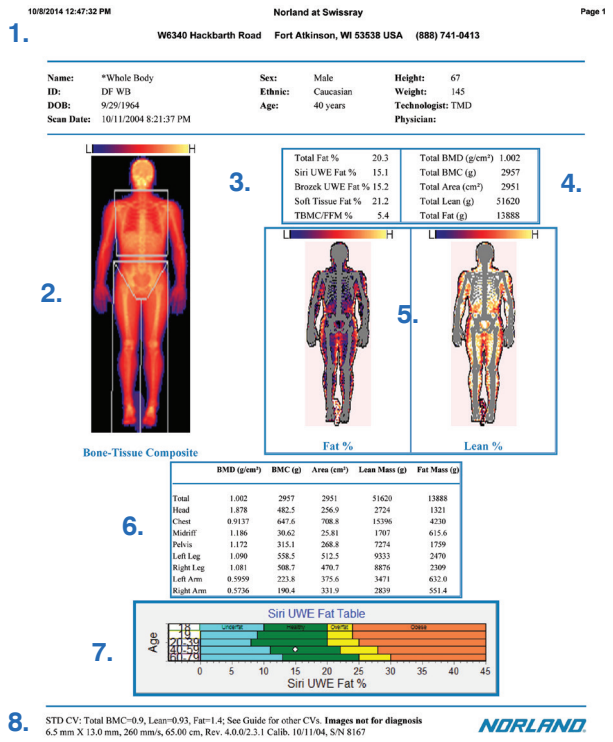
Composition Reports

Body Composition Study

The initial assessment of body composition is carried out to directly quantify bone, lean and fat mass. Understanding their body composition allows subjects to know where they currently are so that future comparison will produce effective evaluations of a program.

The composition report for an initial study provides:

1. patient background information,
2. an image made up of bone, lean and fat scaled on a minimum to maximum range,
3. fat assessments as a percentage value,
4. total absolute bone, lean and fat results,
5. images of %Fat and %Lean on a minimum to maximum scale,
6. absolute regional bone, lean and fat results,
7. Siri % Fat Mass grading of Underfat, Healthy, Overfat or Obese for age and sex,
8. specified study precision, study settings and scanner details.

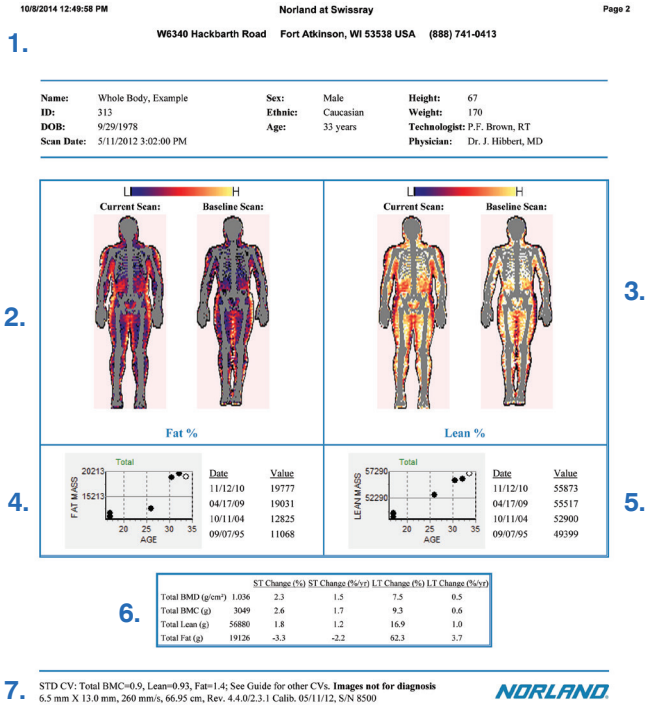


Body Composition Trending Study

The follow-up assessment of body composition is carried out to directly quantify change in bone, lean and fat mass. This report allows the clinician to evaluate treatment and the patient to understand their current progress.

The composition report for a follow-up study provides:

1. facility and patient background information,
2. images of the first and current %Fat study on a minimum to maximum scale,
3. images of the first and current %Lean study on a minimum to maximum scale,
4. trending graphs and absolute values of fat mass for all studies done on the subject,
5. trending graphs and absolute values of lean mass for all studies done on the subject,
6. total absolute bone, lean and fat results with calculated short term (current study to prior study) and long term (current study to first study) change,
7. specified study precision, study settings and scanner details.



First in the World

1968 Norland produces the first commercial densitometer in the world.

1978 Norland applies microprocessor controlled technology in the densitometer.

1983 With Gd-153 commercially available Norland releases one of first dual energy systems—the Norland 2600—a spine and hip scanner.

1988 Norland produces the XR-26, the only x-ray based densitometer in the world that is fitted with step-wedge calibration and tied to chemical standards for bone, lean and fat assessment.

1993 Norland produces the dynamic filtration systems allowing the scanner to produce swift studies to regulate x-ray flux for every point in the study—this allows swift scanning in every type of scan and avoids the need to use fan-beam geometry.

1998 Norland gets FDA market clearance to use Fracture Risk Assessment to classify a patient as Osteoporotic or Osteopenic.

2007 Norland produces the XR-600 and XR-800 with auto-gain detector technology that optimizes scanner performance allowing faster studies without loss of long-term precision.

2009 Norland gets FDA market clearance to use a Siri % Fat Assessment to directly classify fat content as Underfat, Healthy, Overfat or Obese.

NORLAND AT SWISSRAY **PIONEER OF DENSITOMETRY** **LEADER IN TECHNOLOGY**

Norland at Swissray, W6340 Hackbarth Road, Fort Atkinson, WI 53538 USA,
920-563-8456
www.swissray.com

Form No. 600P170 Rev A 3/15
Printed in USA
Certified ISO 13485