DXA Patient Acquisition Manual
for GE/HOLOGIC – MRA1166

Table of Contents

Requirements

DEXA scanner: GE or HOLOGIC

Model: N/A - if able to perform Hip, Lumbar Spine; whole body acquisitions are optional.

Software version: N/A

Phantom Quality Control (QC): In order to ensure that the DXA results are reliable and precise at all time points, QC using a dedicated DXA Phantom, or Quality Assurance (QA), using a QA block, must be performed at least every 7 days and on the day of the DXA scan, before the research subject is scanned.

⚠️ *Please, do refer to your specific manufacturer guidelines for DXA Quality Controls and assessment.* ⚠️

General contraindications

- Pregnancy (28 days rule). Follow departmental procedure in the event of research subject being pregnant;

- Any investigation carried out in the last 15 days using a radioisotope, as these will affect DXA measurements and results;

- Any imaging investigation (MRI, CT, Fluoroscopy, etc.), carried out in the last 7 days using a radiographic contrast medium/agent (Gadolinium, Manganese, Iodine or Barium), as these will increase local tissue density and make the DXA results unreliable;

- Presence of removable metallic implants, thick, reflective and/or antibacterial clothing, as these will affect DXA measurements and results. If object(s) is/are removable then it/they should be removed, otherwise see more details below in the Patient/Subject Pre-Scan Preparation Section;

- Presence of non-removable metallic implants. See more details within the sections for each exam type;

- Subject exceeding scanner weight limit (quite variable in between manufacturers and scanner versions, but generally up to a maximum of 450lb/204kg);

- Subjects that are unable to lie flat/semi-flat on the DXA table for less than 15 minutes.

⚠️ *Please, do refer to your specific manufacturer guidelines and specific manuals to determine weight limits.*

Please, do also refer to your own SOPs (Standard Operating Procedures) for contraindications and safety checks. ⚠️

Patient/Subject Registration

- Register Subject with agreed ID, correct weight, height (to be measured on the day), biological sex, ethnicity and year of birth (use Jan 1st for day and month);
- Enter your initials in the Study Comments field (Operator Initials or similar);
- Data with PII (Personal Identifiable Information) must <u>NOT</u> be sent to Perspectum Diagnostics.
  - If departmental guidelines require that subjects must be register using their PII, then the exam must be re-labelled (PII removed) prior to exporting the data/results outside of the scanner and printing the results to a PDF file.

Patient/Subject Pre-Scan Preparation

- **Check Subjects' personal details, Subject's Study ID (SSID) and scan time point** to ensure that it's the correct subject being scanned at the correct time point;
- Confirm that the subject understands what examination will be performed and that it will be conducted for research purposes;
- The menopausal status should be re-checked whether a pregnancy test or question relating to possible pregnancy has been administered and possible pregnancy has been reliably ruled-out;
  - Follow departmental practice relating to pregnancy assessment prior to examination.
- **All radio-opaque** (e.g. metallic, reflective or thick plastic) **objects should be removed** (e.g. underwired bras, jewellery, belts, removable braces/dentures, etc.), **prior to scan**;
  - If the object cannot be removed but can be displaced for the area(s) to be scanned (e.g. colostomy bag), then carefully displace the object to a region outside of the scanning area.
- **All thick reflective and/or antibacterial clothing must also be removed** (if present). Ideally the research subject should change clothes to either a thin linen hospital or thin linen scrubs;
  - Remember to remove footwear.
- Measure subject's weight and height after subjects has changed into gown/scrubs and prior to starting the scan;
- **Prior to performing follow-up scans, make sure to check the previous exam/images** (baseline and/or last time point) available in order to <u>replicate the positioning and scan acquisition modes used previously;</u>

Whole body scan

The DXA whole body scan performs an acquisition of the entire body (from tip of head to bottom of the feet) in a single acquisition. It's designed to acquire precise and reliable information regarding the Body Mass Density and Body Mass Composition of the scanned subject. In addition to this, other important information (e.g. Fat percentage, Fat-Muscle Ratios, BMI, quantity of Fat-free tissue, estimated Resting Metabolic Rate and Relative Skeletal Muscle Index) can also be automatically calculated post-acquisition.
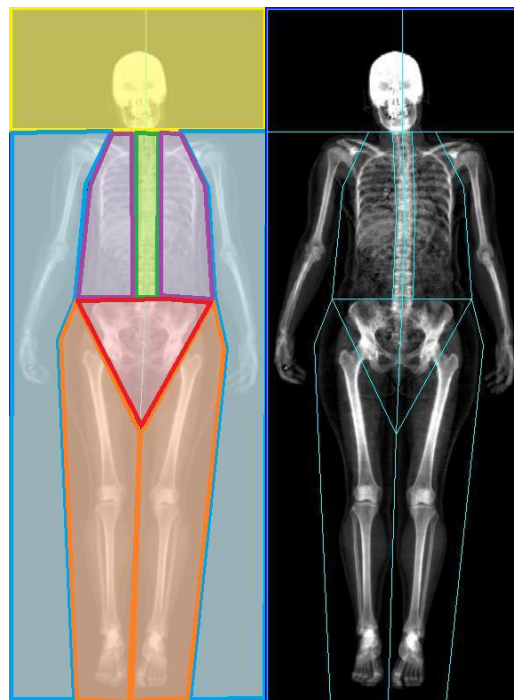

Figure 1: Example of whole-body scan. Coloured regions: yellow=Head; blue= Upper limbs (arms); orange= Lower limbs (legs); red=Pelvis; purple= Ribs; green=Spine. More regions can be calculated by dividing there regions by side or by combining them into other larger regions (e.g. Trunk or Total body).

Figure 2: Patient positioning for Whole body scan, including hand positioning. Also of note the use of linen scrubs and lack of metal jewellery.

Figure 3: Alternative position for hands during whole body scan, if standard positioning cannot be used.

Scan Positioning

- The subject must lie on their back straight, with the lower limbs fully straight and upper limbs alongside the thorax and abdomen;
- The mid-sagittal plane of the subject's body must be aligned parallel to and on top of the mid-line of the scanner's Field of Acquisition (e.g. Rectangle delineated in the scanner's table)
- Gently, yet firmly, pull the subject, by their ankles, slightly downwards to ensure that the whole spine is straightened.
- The subject's entire body must be contained within the Field of Acquisition (FoA);
  - If the subject is too large/wide to fit within the FoA then perform a hemi whole-body scan (see more information below)

- If the subject is too tall to fit within the FoA, then the head of the subject can be placed outside of the FoA and acquisition of the Subject's head can be forgone.
  - Record this position variation during the upload of the scans results in the comments section on Edison.
- Both hands should lie prone flat on the table close to the body but never under or touching the body;
  - If when the hands lay prone, part of either hand remains outside of the FoA, reposition both hands from a prone position to a lateral position.
- **Internally rotate both lower limbs**, approximately 20 to 30 degrees, using a fabric strap or another appropriate positioning aid;
  - If, for any reason, the subject cannot internally rotate the one or both lower limbs forgo the internal rotation and do not force the patient into a painful limb position.
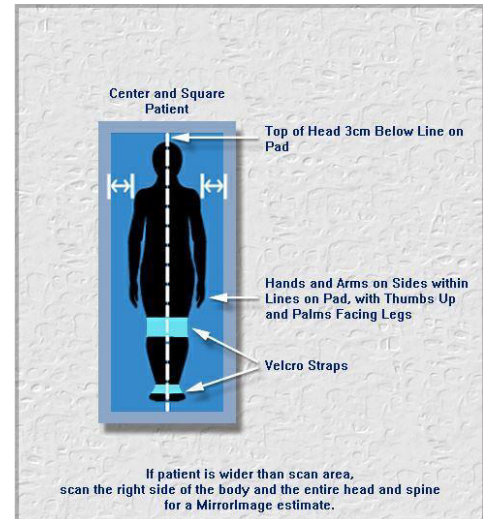

Figure 4: GE's enCORE Whole body instructions. Screenshot from enCORE v14.10

Hemi Whole-body Scan

The Hemi whole-body scan follows the same preparation, technique and purpose of the Whole body scan, with the caveat that instead of providing real values for all body regions, the scanner estimates the values for the unscanned side of the body based on the measured values of the scanned side (assumes that both sides' values are identical).

- It's only meant to be used in subject's that are too width to fit within the FoA;
- In this scenario, the only subject positioning variant required is that the subject's body should be shuffled to a side in order to have one of the upper and/or lower limb(s) placed deliberately outside of the FoA;
- **Please, make sure that at least the head, spine and one entire side of the subject is placed within the FoA before starting the scan acquisition.**
  - Record this position variation during the upload of the scans results in the comments section on Edison.

Scan Acquisition

- Instruct the subject to remain still while the machine is operative (moving);
- Select the scan acquisition mode that it's most suitable for the subject's body type/size;
- Start acquisition/radiation exposure;

Figure 5: Patient positioning for hemi whole-body DXA scan.

- Pay attention to the console monitor and check that the entire body is scanned (top of the head until the tip of the toes) and that no motion or other artefacts are seen/present on the image;

- Repeat acquisition if necessary. However, review and re-adjust all preparation, positioning and acquisition details before repeating the acquisition.

⚠️ *Please, do refer to your specific manufacturer guidelines and specific manuals to determine whether or not your particular scanner has the requirements for the hemi whole-body scan.* ⚠️

Data Post-Processing

When post-processing the Whole-body scan/image data attention must be given to the presence of metal artefacts and the adequate delineation of the different regions of interest (ROIs).

- Make sure that the ROIs are defined carefully and in close resemblance to the picture below (considering the different anatomy/body type/size of the scanned subject):

- Ensure that all ROIs are correctly labelled;

- Ensure that the correct Reference Population Database is being employed (see more details below);

- Areas (pixels) that contain metal (e.g. hip replacements, knee replacements, dentures, etc.) must be excluded from the scanner's calculations by re-categorizing (if your scanners allow this) the related pixels with "artefact" or "neutral" instead of "bone" or "soft tissue".
  - Record this position variation during the upload of the scans results in Edison.
  - Include trending graphs in the follow-up results.

Shoulder included within the Upper limb (Arm) ROI

border between head ROI and Arms ROI place at the level of the chin

Spine ROI thighly defined around borders of the spine

Hands not touching the rest of the body

Boundary between Abdomen and Pelvis placed at the level of iliac crests

Soft tissue of the tight within the Lower limb (Leg) ROI

Head of femurs placed within Pelvis ROI
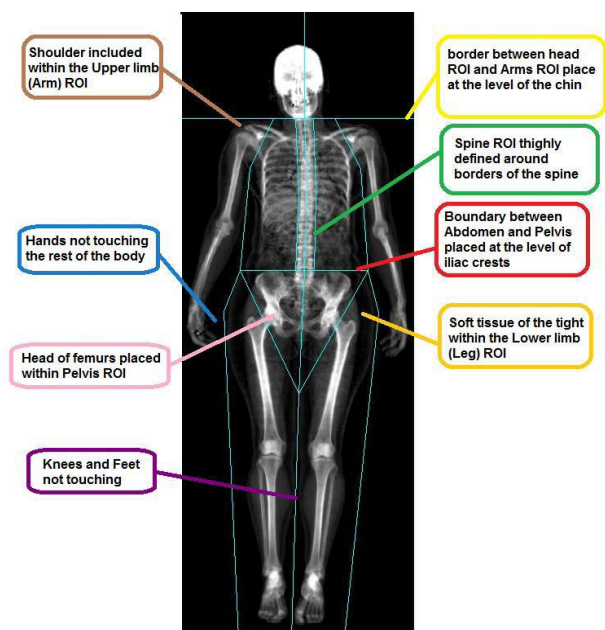
Knees and Feet not touching

Figure 6: Criteria to adequately separate the ROIs of a whole-body scan during post-processing.
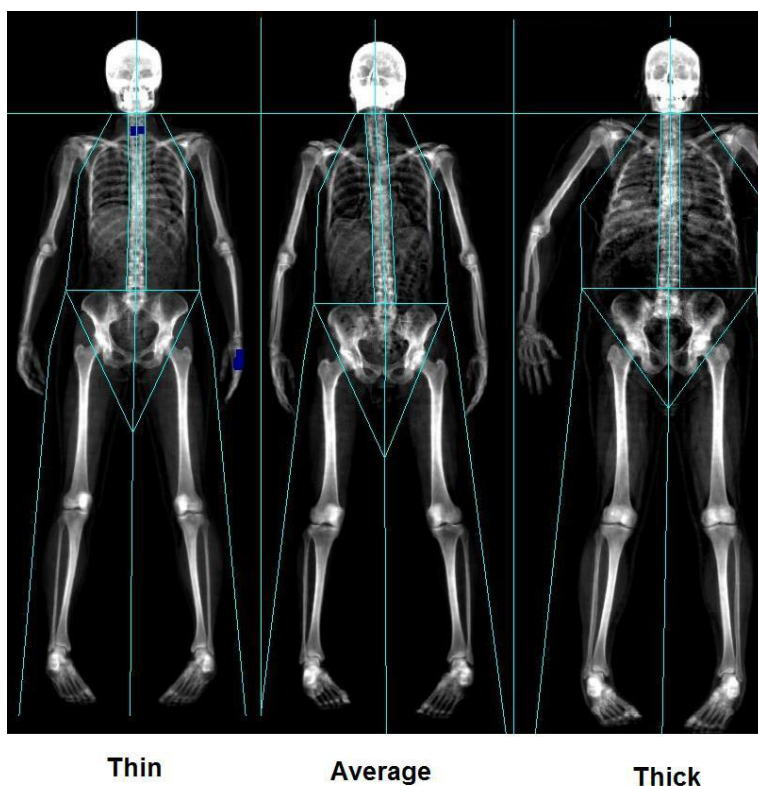
Figure 7: Different body types that require different scan modes. Blue pixels indicate areas that contain metallic implants and were excluded from calculation. Right arm on the thick scan example depicts minor motion artefacts of the forearm.

Thin   **Average**   **Thick**

Hip scan

A DXA hip scan is part of what is known as a routine DXA scan. Its aim it to provide precise and reliable information regarding the subject's bone mineral density, bone mineral composition, T & Z-scores for several regions of the hip (e.g. neck of femur, ward, greater trochanter, femoral shaft and total hip). In conjunction with the Lumbar Spine scan, it is possible to extrapolate reliable and precise information regarding the average bone mineral density, T & Z-scores of the subject's entire skeleton. International guidelines recommend always scanning the non-dominant hip.

Scan Positioning

- Confirm with research subject what is the dominant foot (warning: may not be the same as dominant hand)

Figure 8: Example of hip DXA scan. Note the lack of minor trochanter and lack of superimposition between the neck of femur and greater trochanter, all indicating adequate hip rotation.

- e.g. ask subject:
  - Which foot does the subject use to kick a ball?
  - Which foot moves first when moving forward or climbing stairs?
- Ensure that the subject's thighs are aligned with the long plane of the FoA;
- Rotate internally the entire lower limb (not just the foot) about 10 to 30 degrees;
  - Use the positioning aid for the hip scan for unsure standardized rotation;
    - If this doesn't provide adequate rotation of the hip, increase degree of rotation;
    - If the subject cannot rotate the hip, do not force the rotation.
      - Record this position variation during the upload of the scans results in Edison.
- Place subject's both hands on top of the subject's chest.
- **If metal implant is located on the non-dominant hip, scan the contralateral hip;**
- **If both hips have metal implants, do not scan the hips, only the Lumbar spine**

Figure 9: GE's enCORE Hip instructions. Screenshot from enCORE v14.10

Figure 10: Incorrect hip rotation. Note the superimposition between the neck of femur and greater trochanter (green arrow).

Scan Acquisition

- Position the machine's laser at mid-thigh (on the side to be scanned), just below the level of the pubic symphysis;
- Instruct the subject to remain still while the machine is operative (moving);
- Select the Field of view (FoV) (height and width) that is more adequate for the subject's being scanned (e.g. 18cm x 15cm);
- Select the scan acquisition mode that it's most suitable for the subject's body type/size;
- Start acquisition/radiation exposure;
- Pay attention to the console monitor and check:
  - The entire ROIs are scanned (from femoral shaft to above the acetabulum);
  - The hip position is adequate:
    - The greater trochanter is not superimposed on top of the neck of the femur;
    - The femoral shaft is aligned parallel the acquisition axis (feet to head), instead of oblique/diagonal.
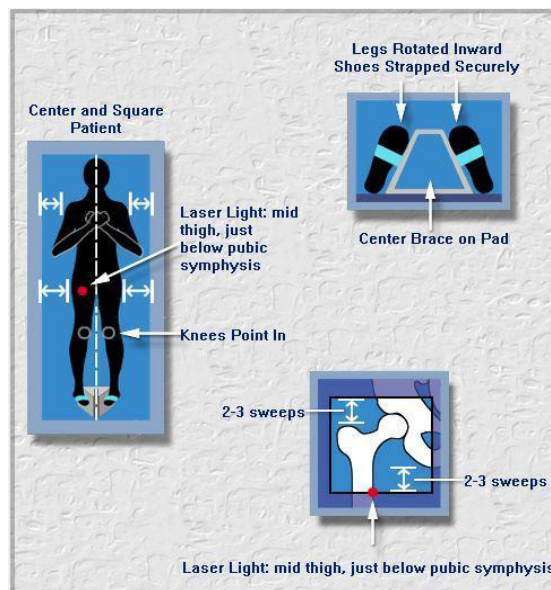 - There is no motion or other artefacts seen/present on the image;

- Repeat acquisition if necessary. However, review and re-adjust all preparation, positioning and acquisition details before repeating the acquisition.

Data Post-Processing

When post-processing the hip scan data/image attention must be given to the presence of metal artefacts and the adequate delineation of the different regions of interest (ROI).

- Make sure that the ROIs are defined carefully and in close resemblance to the picture below (taking into account the different shape/size of relevant anatomy of the scanned subject);

- Ensure that all ROIs are correctly labelled;

- Ensure that the correct Reference Population Database is being employed (see more details below);

- Areas (pixels) that contain metal (e.g. hip replacements, knee replacements, dentures, etc.) must be excluded from the scanner's calculations by re-categorizing (if your scanners allow this) the related pixels with "artefact" or "neutral" instead of "bone" or "soft tissue"

- Include trending graphs in the follow-up results.
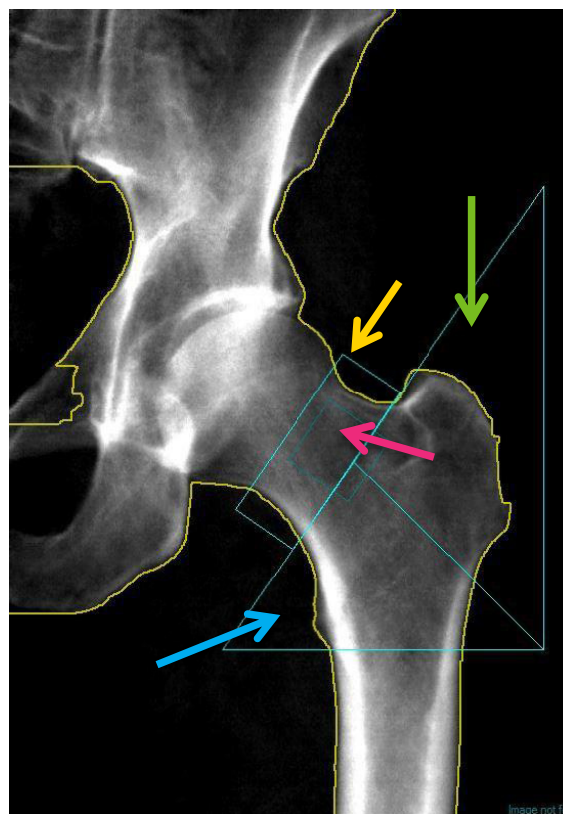
Figure 11: Regions of interest for the Hip. Yellow arrow= Neck of Femur; Green arrow= Greater Trochanter; Blue Arrow=Shaft of Femur; Purple arrow= Ward region. The combination of all regions generates the Total Hip ROI. Only the Neck of Femur and Total Hip values have good clinical significance. The Ward Region has no clinical significance whatsoever.

Lumbar Spine scan

A DXA Lumbar Spine scan is part of what is known as a routine DXA scan. Its aim is to provide precise and reliable information regarding the subject's bone mineral density, bone mineral composition, T & Z-scores for several regions of the Lumbar spine (e.g. L1, L2, L3, L4 and any combinations of these structures). In conjunction with the hip scan, it is possible to extrapolate reliable and precise information regarding the average bone mineral density, T & Z-scores of the subject's entire skeleton.

Figure 12: Patient positioning for DXA Lumbar spine.

Scan Positioning

- Ensure that the patient's spine is aligned with the long plane of the FoA and no positional scoliosis is present;

- Raise the subject's legs and place a large foam block under the subject's legs, so as to make both knees flexed at an angle equal or close to 90 degrees, therefore reducing the subject's lumbar lordosis;

- Place Subject's hands alongside the body.

Scan Acquisition

- Position the machine's laser approximately 2 inches (5 centimetres) below the level of the navel within the mid-line of the body (e.g. position of the navel);

- Instruct the subject to remain still while the machine is operative (moving);

- Select the FoV (height and width) that is more adequate for the subject's being scanned (e.g. 20cmx18cm);

- Select the scan acquisition mode that it's most suitable for the subject's body type/size;

- Start acquisition/radiation exposure;

- Pay attention to the console monitor and check:
  - The entire ROIs are scanned (from below S1-L5 (including the top of the sacroiliac joints) to above T12-L1);
  - The Lumbar spine positioned as straight as possible (no positional scoliosis) and along (parallel to) the acquisition axis (feet to head), instead of oblique/diagonal.
    - If non-positional scoliosis is present not do repeat exam because of bad spine positioning, but instead record this variation during the upload of the scans results in the comments section on Edison.
  - There is no motion or other artefacts seen/present on the image.

- Repeat acquisition if necessary. However, review and re-adjust all preparation, positioning and acquisition details before repeating the acquisition.

Figure 13: Centring of laser for Lumbar spine DXA.
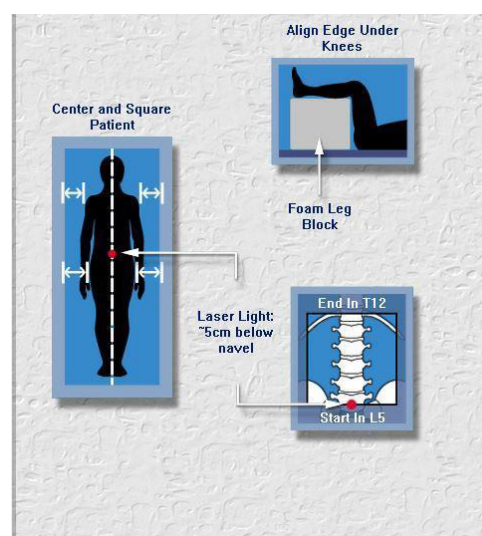
Figure 14: GE's enCORE Lumbar spine instructions. Screenshot from enCORE v14.10

Data Post-Processing

When post-processing the Lumbar Spine scan data/image, attention must be given to the presence of metal artefacts and the adequate delineation of the different regions of interest (ROIs).

- Make sure that the ROIs are defined carefully and in close resemblance to the picture below (taking into account the different shape/size of relevant anatomy of the scanned subject);

- Include trending graphs in the follow-up results.

Figure 15: ROIs for Lumbar spine DEXA. Of note the straight position of the spine. The ROI borders (blue lines) must be placed between the vertebral bodies. Either the top of sacroiliac joints (purple arrows) or the T12 pair of ribs (green arrows) can be used to correctly label the vertebral bodies and respective ROIs.

- Ensure that all ROIs are correctly labelled;
- Ensure that the correct Reference Population Database is being employed (see more details below);
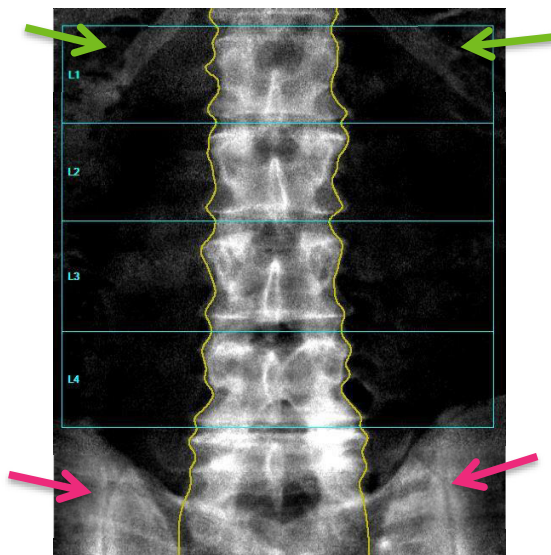- Areas (pixels) that contain metal (e.g. spinal fixation, Harrington rods, etc.) must be excluded from the scanner's calculations by re-categorizing (if your scanners allow this) the related pixels with "artefact" or "neutral" instead of "bone" or "soft tissue".
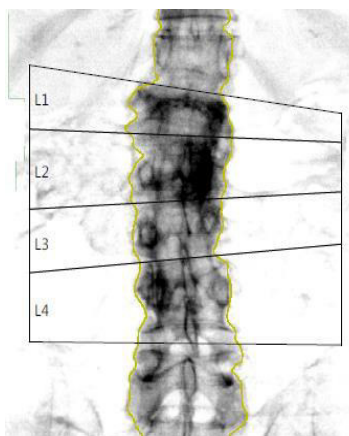

Figure 17: Example of slightly scoliotic lumbar spine with partially collapsed L1 and L2 vertebral bodies

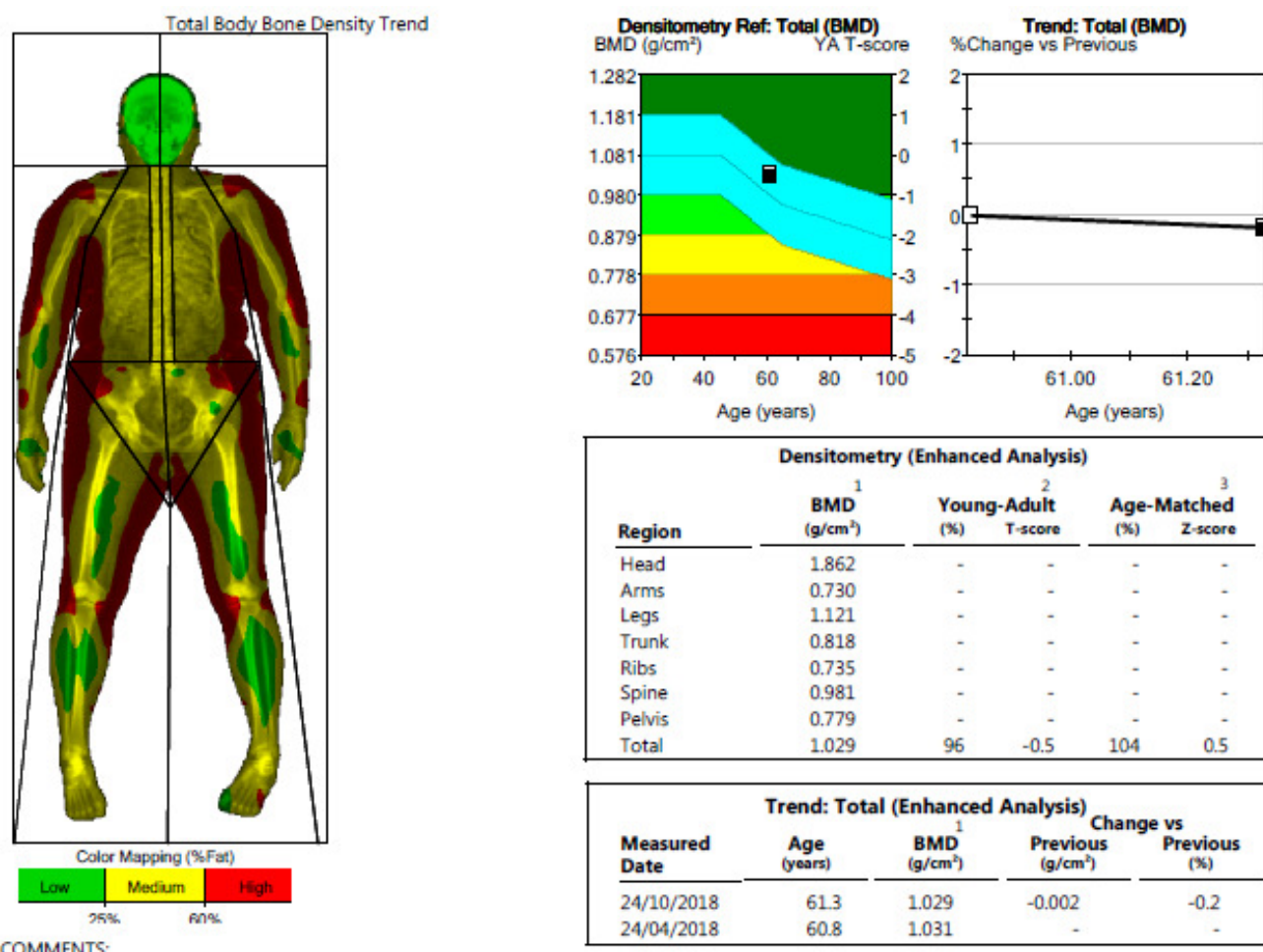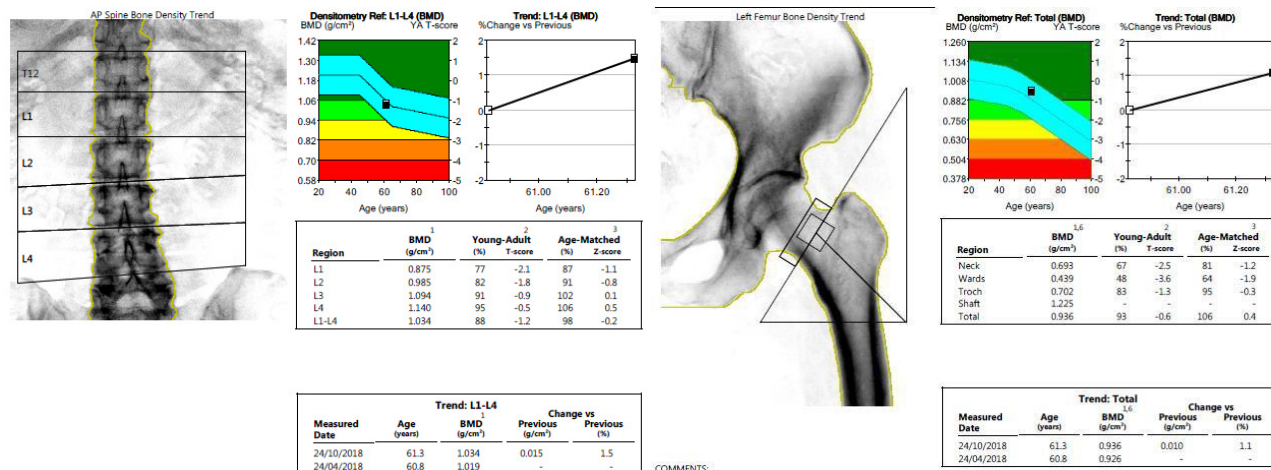*Figure 16: Example of cervico-thoracic scoliosis seen on whole body DXA scan.*

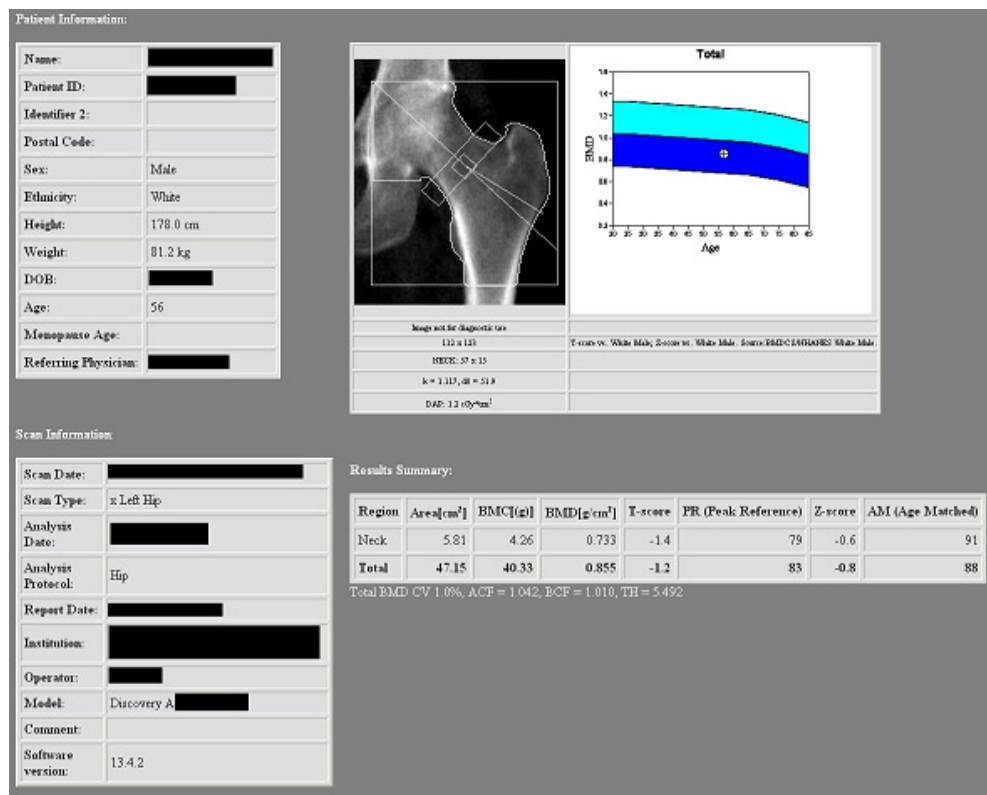⚠️ **Please, do refer to your specific manufacturer guidelines and specific manuals for post-processing and ROIs positioning.** ⚠️

Perspectum Diagnostics™
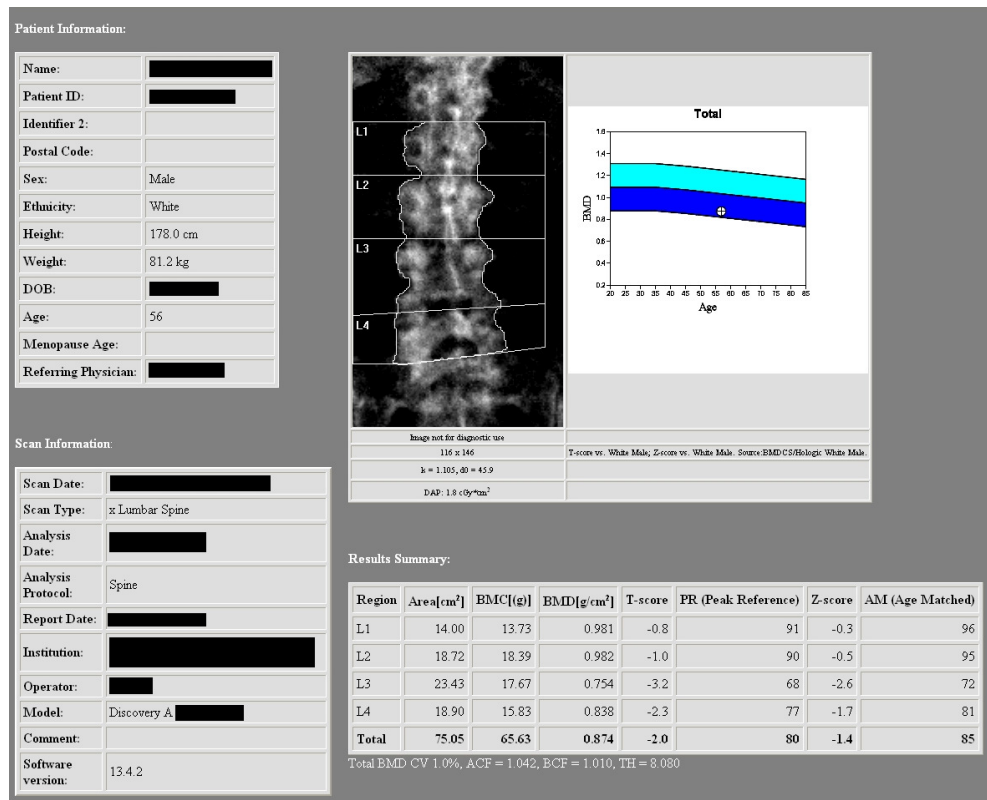
Example of GE Lunar DXA results:

Example of Hologic DXA results:

Patient Information:

Name:	
Patient ID:	
Identifier 2:	
Postal Code:	
Sex:	Male
Ethnicity:	White
Height:	178.0 cm
Weight:	81.2 kg
DOB:	
Age:	56
Menopause Age:	
Referring Physician:	

Scan Information:

Scan Date:	
Scan Type:	x Lumbar Spine
Analysis Date:	
Analysis Protocol:	Spine
Report Date:	
Institution:	
Operator:	
Model:	Discovery A
Comment:	
Software version:	13.4.2

Image not for diagnostic use
116 x 146
k = 1.105, d0 = 45.9
DAP: 1.8 cGy*cm²

T-score vs. White Male; Z-score vs. White Male. Source:BMDCS/Hologic White Male.

Results Summary:

Region	Area[cm²]	BMC[(g)]	BMD[g/cm²]	T-score	PR (Peak Reference)	Z-score	AM (Age Matched)
L1	14.00	13.73	0.981	-0.8	91	-0.3	96
L2	18.72	18.39	0.982	-1.0	90	-0.5	95
L3	23.43	17.67	0.754	-3.2	68	-2.6	72
L4	18.90	15.83	0.838	-2.3	77	-1.7	81
Total	75.05	65.63	0.874	-2.0	80	-1.4	85

Total BMD CV 1.0%, ACF = 1.042, BCF = 1.010, TH = 8.080

Patient Information:

Name:	
Patient ID:	
Identifier 2:	
Postal Code:	
Sex:	Male
Ethnicity:	White
Height:	178.0 cm
Weight:	81.2 kg
DOB:	
Age:	56
Menopause Age:	
Referring Physician:	

Scan Information:

Scan Date:	
Scan Type:	x Left Hip
Analysis Date:	
Analysis Protocol:	Hip
Report Date:	
Institution:	
Operator:	
Model:	Discovery A
Comment:	
Software version:	13.4.2

Image not for diagnostic use
112 x 123
NECK: 57 x 15
k = 1.115, d0 = 51.9
DAP: 3.2 cGy*cm²

T-score vs. White Male; Z-score vs. White Male. Source:BMDCS/NHANES White Male.

Results Summary:

Region	Area[cm²]	BMC[(g)]	BMD[g/cm²]	T-score	PR (Peak Reference)	Z-score	AM (Age Matched)
Neck	5.81	4.26	0.733	-1.4	79	-0.6	91
Total	47.15	40.33	0.855	-1.2	83	-0.8	88

Total BMD CV 1.0%, ACF = 1.042, BCF = 1.010, TH = 5.492

Reference Population Database

DXA T & Z-Scores are ratios between the measured bone mineral density of the scanned subject and the average bone mineral density of a given normalized healthy population, that possess the same biological sex and ethnicity as the scanned subject. The difference in T-scores and Z-scores relates to bone mineral density variation with age. In the case of T-score the reference value for bone mineral density relates to a healthy young adult (approximately 20 years old), while in Z-score the reference bone mineral density value used is age matched with the scanned subject.

Reference values for bone mineral density are provided by Reference Population Databases (RPD). If the wrong RDP is used, then the T & Z-scores calculated are unreliable. In addition to this, there is also the issue, in multi-site clinical research trial, of comparing results from multiple imaging centres and the need to avoid RPD variation.

It's therefore crucial to make sure that all imaging centres use the same RPD and that said RPD is highly reliable, largely adjusted to the population being scanned and standardized across multiple DXA vendors/manufacturers.

- **All Imaging Centers must use the Reference Population Database:**
  - **USA Combined: NHANES/BMDCS/LUNAR**
  - If your DXA scanner doesn't possess this RPD, please use the closest available RPD for USA (e.g. USA Combined: NHANES/LUNAR, USA Combined: BMDCS/LUNAR or USA NHANES (1994-2004)

Saving and transferring results to Perspectum Diagnostics

- Please make sure that no PII is present within the DXA results/raw data before exporting it out of the scanner and printing the results into a PDF file;
- Compress all data into a single ZIP folder in order to be able to upload it into Edison;
- Ensure that both the Raw data (e.g. scan.mex or patient.dbf files, depending on the manufacturer) and PDF file are uploaded to Edison;
- Prior being able to upload data into Edison, Perspectum must beforehand create and account for you;
  - please contact support@perspectum-diagnostics.com in other to request the creation of an account for you
- Uploading data into Edison is fast, easy and requires little training;
- Simply complete the scan details requested and then drag and drop the compressed Zip folder in the upload area of the screen.
  - Nonetheless, please contact support@perspectum-diagnostics.com or check Edison's help section if you require assistance.

Issue Control

Issue	Paragraph	Details	Reason	Date/Initial
0.1	All	New document	First draft for review	28Feb2019 AB
0.2	All	Edits	Edits	17Mar2019 CP
0.3	All	Edits	Reviewed by AB	19 Mar2019 AB
1.0	All	Final version	For sign-off	20 Mar2019 ZDC

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Approvals

Job Title	Name	Signature
MR Application Specialist	Andrea Borghetto	*Andrea Borghetto* A Borghetto (Mar 20, 2019)
Head of MR Applications	Dr Peggy Xu	*Piaojun Pu* P Xu (Mar 20, 2019)

Validity: Please ensure that the required digital signatures are valid prior to publication of a new issue.

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1. Signed by: Andrea Borghetto <andrea.borghetto@perspectum-diagnostics.com>
Signed at: March 20, 2019, 10:50 a.m. GMT

Andrea Borghetto

2. Signed by: Peggy Xu <peggy.xu@perspectum-diagnostics.com>
Signed at: March 20, 2019, 1:12 p.m. GMT

Piaojun Pu

Validation

Upload the document to the URL encoded in this QR code to verify its authenticity.

Document Information

Document

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Dept/business ID	perspectum-diagnostics
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History

Event	User	IP address	Date/Time
DXA Patient Acquisition Manual for GE,HOLOGIC – MRA1166 v1.0 created by Zenobia D'Costa	Zenobia D'Costa (zenobia.dcosta@perspectum-diagnostics.com)	82.6.1.118	Wed, 20 Mar 2019 10:31:03 +0000
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Ticked checkbox for statement: I confirm that I am authorised to accept the terms of this document, and that I am the intended recipient.	Andrea Borghetto (andrea.borghetto@perspectum-diagnostics.com)	211.25.30.80	Wed, 20 Mar 2019 10:50:17 +0000
Ticked checkbox for statement: I confirm that I have reviewed the document, and approve of its content, and that it is the legally binding equivalent of a handwritten signature.	Andrea Borghetto (andrea.borghetto@perspectum-diagnostics.com)	211.25.30.80	Wed, 20 Mar 2019 10:50:17 +0000
Signer offered option to accept or reject document	Andrea Borghetto (andrea.borghetto@perspectum-diagnostics.com)	211.25.30.80	Wed, 20 Mar 2019 10:50:17 +0000
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