


Artwork consists of two (2) 8½ x 11 inch pages.

REV AUTHORED BY P LEWIS	DATE 5/5/10	HOLOGIC ® Osteoporosis Assessment LORAD® Breast Cancer Detection DirectRay® Digital Imaging FLUOROSCAN® C-arm Imaging A FAMILY OF COMPANIES	 SIGNATURES ON FILE	
REV DRAFTED BY G CORRIDORI	DATE 5/6/10			
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REV. RELEASE DATE: 05/10/10	ARTWORK		SIZE A	SHEET 1 OF 1

Statement of Equivalency Of APEX Version 3.1 to APEX Version 3.0.1

Background

APEX 3.1 represents the latest bone density application software, replacing previous versions of APEX.

Scan Acquisition

Scan acquisition for all scan modes supported by earlier versions of APEX is identical in APEX 3.0.1.

Analysis and BMD Values

Identical results are obtained with all supported APEX 3.1 analysis as compared to APEX 3.0.1.

APEX 3.1 supports a new AP Spine analysis method for subjects age zero to three years old. The analysis of subjects age 3 and under depends on the accurate scan date and date of birth. Thus, it is important that the operator enter the correct date of birth and that the date of the computer be accurate. Additionally, it is important that scans for subjects less than four years old not have their scan date and date of birth deidentified for scan transfer, as this will change analysis results if the scan is reanalyzed.

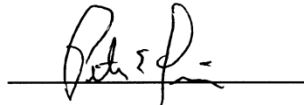
Results

APEX 3.1 gives identical T- and Z-scores compared to APEX 3.0.1 for all supported analysis types scan types and regions. If new reference data becomes available and is loaded into APEX 3.1 (e.g. with the release of a new option) T- and Z-scores may change and the release notes and statement of equivalency for the reference database option should be consulted.

Fracture Risk is calculated automatically using FRAX® version 3.0. For non-USA countries that were available in APEX 3.0.1, minor differences (last significant digit) may be observed. This is due to differences between FRAX V 1.1 (as used in APEX 3.0.1) and FRAX 3.0. The minor differences in how inputs into FRAX are rounded account for the difference between FRAX 1.1 and FRAX 3.0. USA regions were not available in APEX version 3.0.1. Using the FRAX program embedded into APEX 3.1, there is no need for an adjustment of T-scores or Z-scores as is necessary for the Web-based version of FRAX for some combination of genders and ethnicities.



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Statement of Equivalency Of APEX Version 3.0.1 to APEX Version 2.3 or 2.4

Background

APEX 3.0.1 represents the latest bone density application software, replacing previous versions of APEX.

Scan Acquisition

Scan acquisition for all scan modes supported by earlier versions of APEX is identical in APEX 3.0.1.

Analysis and BMD Values

Identical results are obtained with all supported APEX 3.0.1 analysis as compared to APEX 2.3 or APEX 2.4. See the APEX 2.3 or 2.4 Statement of Equivalency for differences with APEX 2.0, 2.1 and 2.2.

APEX 3.0.1 no longer supports analysis of whole body scans from scanners that did not have body composition installed and enabled at scan time. Whole Body in APEX 3.0.1 comes standard with body composition. Whether an older whole body scanner without body composition can be upgraded to APEX 3.0.1 depends on the scanner's date of manufacture. Please contact customer service or your dealer with the serial number of the scanner in question before attempting to upgrade a whole body scanner without body composition to APEX 3.0.1.

APEX 3.0.1 no longer supports "pediatric whole body" analysis. The "pediatric whole body" analysis was improved and incorporated into the standard "Auto WB" analysis which provides superior results in children compared with "pediatric whole body", but requires body composition being part of the scan. Auto WB analysis first became the standard whole body analysis in QDR for Windows XP V12.1. The "Auto WB" analysis is not changed in APEX 3.0.1.

APEX 3.0.1 will no longer provide legacy "Low Density Spine" as an analysis type available for new patients. Hologic strongly discourages the use of the Low Density Spine analysis, as it was made obsolete by improvements in the standard AP Spine analysis (with Auto Low Density). However, for returning patients, if you use Compare and the baseline scan was analyzed with Low Density Spine, the software will use the Low Density Spine analysis on the follow-up scan so that rates of change can be measured using the same analysis method. If the Low Density Spine analysis method is used or reported on, it is important to consult the "QDR Reference Manual" on the CD that is labeled "QDR Reference Documents" for further information and special considerations regarding the use of this analysis method.

Results

APEX 3.0.1 gives identical T- and Z-scores compared to APEX 2.3 or 2.4 for all supported analysis types scan types and regions. If new reference data becomes available and is loaded into APEX 3.0.1 (e.g. with the release of a new option) T- and Z-scores may change and the release notes and statement of equivalency for the reference database option should be consulted.

Fracture Risk is calculated automatically using FRAX® version 1.1. Using the FRAX program embedded into APEX 3.0.1, there is no need for an adjustment of T-scores or Z-scores as is necessary for the Web-based version of FRAX for some combination of genders and ethnicities.



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