

Statement of Equivalency

APEX™ Software Version 5.6.1.4 to APEX Software Version 5.6.1.3

Background

APEX software runs on various hardware platforms of Hologic® Horizon® bone densitometers. The APEX 5.6.1.4 software contains enhancements that are not present in earlier releases and resolves anomalies. Please review the APEX 5.6.1.4 software Release Notes for a description of these changes.

Analysis

The APEX 5.6.1.4 software analysis algorithms were modified to improve the accuracy and concordance of Left and Right Arm %Fat results in whole body exams of small children. The improvement in L/R Arm %Fat Analysis results in small children may cause very small changes in other regions (for example, Left and Right %Fat results may change by 0.1 or 0.2%). For all other exams, APEX 5.6.1.4 software results are identical to results obtained with APEX 5.6.1.3 software.

Reporting

APEX 5.6.1.4 software corrects an issue with DxReports erroneously stating “No significant bone loss was observed” between scans of dissimilar scan modes. The output text has been corrected for this scenario.



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Statement of Equivalency

APEX Software Version 5.6.1.3 to APEX Software Version 5.6.1.2

Background

APEX software runs on various hardware platforms of Hologic Horizon bone densitometers. The APEX 5.6.1.3 software has been updated to support two different types of stepper motors. Also, it contains enhancements that are not present in earlier releases and resolves anomalies. Please review the APEX 5.6.1.3 software Release Notes for a description of these changes.

Analysis

APEX 5.6.1.3 software analysis results are identical to results obtained with APEX 5.6.1.2 software.

Reporting

APEX 5.6.1.3 software reports are identical to reports generated with APEX 5.6.1.2 software.


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Statement of Equivalency

APEX Software Version 5.6.1.2 to APEX Software Version 5.5.3

Background

APEX software runs on various hardware platforms of Hologic Horizon bone densitometers. The APEX 5.6.1.2 software contains enhancements that are not present in earlier releases and resolves anomalies. Please review the APEX 5.6.1.2 software Release Notes for a description of these changes.

Analysis

APEX 5.6.1.2 software analysis results are identical to results obtained with APEX 5.5.3 software.

Reporting

Reference data has changed to incorporate updated data available from the BMDCS study [Journal of Clinical Endocrinology and Metabolism 2011 Oct; 96(10): 3160-9 and 2013 Jan; 98(1): 420]. This will affect Z-scores calculated for children.


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Statement of Equivalency

APEX Software Version 5.5.3 to APEX Software Version 5.5.2

Background

APEX is the software that runs differing hardware platforms for Hologic bone densitometers. APEX Version 5.5.3 software is for use with the Horizon line of densitometers and includes new features not found in earlier versions.

Analysis

APEX 5.5.3 software analysis measurement results are identical to results obtained with APEX 5.5.2 software.

T-score Results

APEX 5.5.3 software T-score results may be different from earlier versions of APEX software. APEX 5.5.2 software can be configured to calculate male T-scores from young normal female reference data, in accordance with some DXA reporting guidelines (for example, International Society of Clinical Bone Densitometry, Japan Society of Bone Mineral Research, etc.). It is the User's responsibility to configure the T-score calculation to achieve the desired output.



Note

T-scores are calculated during report generation using the current software configuration. Previously reported results will change to match the current T-score software configuration if they are re-reported. No reanalysis is necessary. This includes when rate of change reports are generated, the older data will be reported with T-scores calculated from the current software configuration.

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Statement of Equivalency

APEX Software Version 5.5.2.1 to APEX Software Version 5.5

Background

APEX is the software that runs differing hardware platforms for Hologic bone densitometers. APEX Version 5.5.2.1 software runs on Windows 7 and is used by the Horizon densitometer. APEX Version 5.5.2.1 software has been updated to support the Horizon A model.

Quality Control

APEX 5.5.2 software adds an Infant Whole Body Air scan once a month to the Horizon system for additional quality assurance. This occurs ONLY if the Infant Whole Body Option is installed. To avoid this Quality Control step (for example, option bought as part of a package and there is no intention of scanning infants), you can uninstall the Infant Whole Body option from the APEX software main screen by going to **Utilities > Install Options**, select **Infant Whole Body** from the list of options, and select **Uninstall**.

Scan Acquisition

Scan acquisition for all scan modes supported by earlier versions of APEX 5.5 software is identical in APEX 5.5.2.1 software.

Analysis

APEX 5.5.2 software analysis results are identical to results obtained with APEX 5.5 software except as noted below.

APEX 5.5.2.1 software corrects an issue in versions of APEX software 5.5, 4.5, and 3.5 (not present in earlier versions of APEX software 5, 4, or 3) where Whole body BMC/BMD results have a factor of 1.013 applied to the results the first time the analysis of the scan is repeated.



Note

Infant Whole Body: In APEX 5.5.2 software, a new analysis method called “Infant WB” was developed to exclude more bone containing pixels from the body composition analysis. The Infant WB analysis method results in higher %Fat results in most infants and in lean animals (for example, piglets), better agreement with criterion methods in neonates, and only minimal change to the BMD/BMC results. At this time, both the existing “Infant Whole Body” and the new “Infant WB” analysis methods are available. However, Hologic recommends making the transition to the new “Infant WB” analysis as future releases may discontinue support for the older “Infant Whole Body” analysis.

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Statement of Equivalency

APEX Software Version 5.5 to APEX Software Version 4.0 or 3.4

Background

APEX is the software that runs differing hardware platforms for Hologic bone densitometers. APEX software version 5.5 is for use with the Horizon line of densitometers and includes new features not found in earlier versions. However, APEX 5.5 software can analyze scans acquired in previous Hologic software versions and obtain identical results to those obtained in APEX software 4.0 or 3.4.

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