

CTB-00488

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Product: Dimensions/3Dimensions **Subsystem:** Clarity HD, Intelligent 2D, and Smartcurve

Subject: FDA Quality Control Requirements for Clarity HD-Intelligent 2D and SmartCurve Features for Selenia Dimensions-3Dimensions Systems

Purpose:

To provide information about the Quality Control (QC) requirements when installing the Clarity HD/Intelligent 2D and/or SmartCurve features to Selenia Dimensions and 3Dimensions systems.

Listed below are the QC requirements for Selenia Dimensions and 3Dimensions. (Reference: Selenia Dimensions/3Dimensions Quality Control Manual for Software Version 1.8, 1.9 or 2.0, MAN-03706, Rev 007 and higher)

Existing 3Dimensions in the field

- ClarityHD/Intelligent 2D Calibration
 - Requires American College of Radiology (ACR) Phantom Image Quality Evaluation per the Selenia Dimensions/3Dimensions QC Manual: Can be performed by the technologist.
 - Average Glandular Dose (AGD) of the ACR Phantom: Medical Physicist (MP) oversight – ACR Phantom dose to be reported to the MP by the customer.
 - Full Physicist Medical Equipment Evaluation (MEE) NOT required.

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- SmartCurve Calibration
 - Requires a Medical Physicist to perform the Collimation Assessment (Compression Paddle to Image Receptor Alignment) per the Selenia Dimensions/3Dimensions QC Manual prior to use of the SmartCurve System. The customer should contact the MP on how to proceed with the performance of this test.
 - Full Physicist Medical Equipment Evaluation (MEE) NOT required

Existing Selenia Dimensions in the field: (Requires Detector, Grid and AWS replacement)

- Clarity HD Calibration: Requires Detector, Grid and Acquisition Workstation (AWS) replacement: **Full Medical Equipment Evaluation (MEE) is required**
- SmartCurve Calibration
 - Requires a Medical Physicist to perform the Collimation Assessment (Compression Paddle to Image Receptor Alignment) per the Selenia Dimensions/3Dimensions QC Manual prior to use of the SmartCurve System. The customer should contact the MP on how to proceed with the performance of this test.
 - Full Physicist Medical Equipment Evaluation (MEE) NOT required