

Revised Intended Use

This addendum modifies your Selenia® Dimensions® and 3Dimensions™ Systems *User Guides* for 3DQuorum™ imaging software. The following text replaces the Intended Use statement for the respective system. Place this addendum with your User Guide for future reference.

Intended Use for Selenia Dimensions System

RxOnly Caution: United States federal law restricts this device to sale by or on the order of a physician.

The Hologic® Selenia® Dimensions® system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the Selenia Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set; or
- a 2D and 3D image set, where the 2D image can be either an FFDM or a 2D image generated from the 3D image set and the 3D image set can be viewed as either 1-mm 3D slices or 6-mm 3D SmartSlices.

The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.



Note

In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either an FFDM image or 2D image generated from the 3D image set).

Contrast Enhanced Digital Mammography

Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion.

Intended Use for 3Dimensions System

R_xOnly

Caution: United States federal law restricts this device to sale by or on the order of a physician.

The Hologic® 3Dimensions™ system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The 3Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the 3Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set; or
- a 2D and 3D image set, where the 2D image can be either an FFDM or a 2D image generated from the 3D image set and the 3D image set can be viewed as either 1-mm 3D slices or 6-mm 3D SmartSlices.

The 3Dimensions system may also be used for additional diagnostic workup of the breast.



Note

In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either an FFDM image or 2D image generated from the 3D image set).

Contrast Enhanced Digital Mammography

Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the 3Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion.