

SmartCurve™ Breast Stabilization System

1.1 Release Notes

The SmartCurve breast stabilization system is designed to provide a more comfortable experience for your patients without compromising accuracy. The contoured compression surfaces better distribute the compression force over the entire breast and reduce pinching at the chest wall.

An image processing algorithm that takes the geometry of the compression surfaces into account is applied to images acquired with the system. This feature ensures that the images are adjusted for optimal reading and can be compared with priors obtained with standard compression.

The system uses the same technologist workflow as a standard exam and there is no impact on image quality or radiologist workflow.



Note

QC testing of the SmartCurve compression devices must be performed prior to first clinical use. The latest revision of the Hologic QC manual (MAN-03706 Revision 007 or later) contains the QC test relevant to the SmartCurve compression devices. Consult the physicist on the performance of these tests.

1.2 Installation

The SmartCurve breast stabilization system includes a system license and two contoured compression devices: small (18 x 24 cm) and large (24 x 29 cm). A Hologic Field Engineer installs the system license on your Selenia® Dimensions® / 3Dimensions™ Mammography system. Each gantry must have a license to enable use of the system.

1.3 Guidelines for Use

The SmartCurve system is installed and used just as you would use standard compression devices for both 2D and 3D Mammography™ exams. It can also be used for patients with implants for standard or implant displaced views. There is no change in workflow, exam duration, patient dose, or compression.

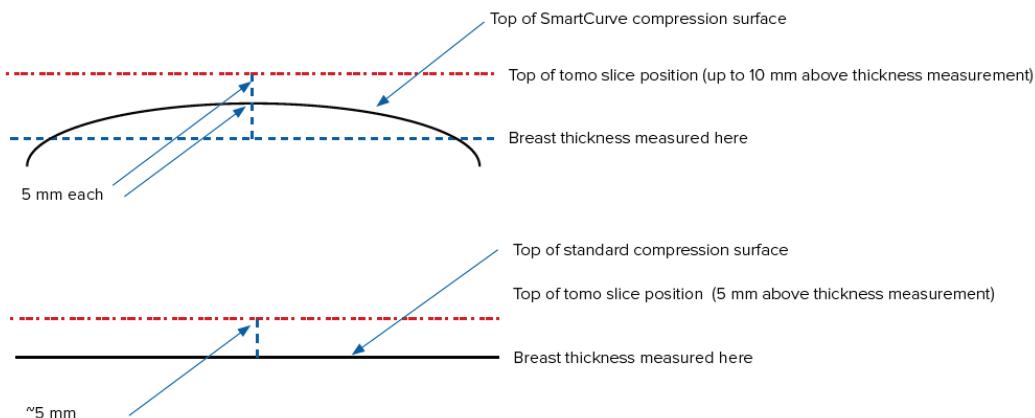
As you explain the exam to patients, mention that you are using a new system with curved surfaces to minimize discomfort during the exam.

For ease of positioning for the technologist, best practices for positioning should be followed. In particular, in the CC view, the hand and arm of the technologist should be positioned parallel to the chest wall of the patient and not angled towards the corner of the detector. It is recommended that you compress only until the breast is stabilized; due to the curvature of the surfaces, more compression than that is not required.

The SmartCurve system accommodates approximately the same breast sizes as a standard system. For optimal positioning with the SmartCurve system, it is important that the proper size is used based on the breast size of the patient. Specifically, the larger compression device should not be used for patients if the smaller size is adequate.

Notes

- The FAST Paddle™ compression mode should be turned off when the SmartCurve system is in use.
- Standard screening paddles are included with the system and should be used if the SmartCurve system is not suitable for a particular patient or view.
 - The SmartCurve system is not recommended for cleavage views, rolled views, or mosaic views of very large breasts.
 - The system should not be used for biopsies or I-View™ procedures.
 - Due to the curvature of the surface, it may not be possible to properly immobilize breasts that are very thin.
- The Dimensions mammography system automatically identifies that the SmartCurve system is in use and applies the licensed algorithm to compensate for the curvature.
- The Dimensions mammography system automatically adjusts the collimator.
- MammoPad® breast cushions may be used with the system for optimal comfort.
- There are up to ten additional slices added to the compression side of the tomosynthesis set due to the curvature and to allow for compression thickness variance (see following illustration).



Refer to your Selenia Dimensions / 3Dimensions system *User Guide* for additional instructions regarding your mammography system.

A video with additional positioning instruction is available on the Hologic® Learning Edge platform.