



Zaventem, August 26, 2024

**URGENT FIELD SAFETY NOTICE  
VOLUNTARY FIELD CORRECTIVE ACTION  
MEDICAL DEVICE CORRECTION**

**FSN Ref: MISC-10081-EUR-2101 Rev. 001**

**FSCA Ref: FA-00248**

Dear Valued Hologic Customer,

At Hologic, our top priority is patient and health care provider safety. We continually evaluate our products to improve quality and reliability. We are writing to inform you that we have identified an issue with Selenia Dimensions 1.12.0 and 3Dimensions 2.3.0 system software when used in combination with C-View® software in which the quality of the final C-View synthesized 2D image is impacted and may appear blurry. To date, we have received eight complaints related to this issue. This decrease in quality may result in misdiagnosis with the greatest consequence of concern being a false negative diagnosis.

To address this concern, Hologic is initiating a voluntary field corrective action of our Selenia Dimensions 1.12.0 and 3Dimensions 2.3.0 system software as follows:

**Product Name: Dimensions 1.12.0 and 3Dimensions 2.3.0 system software upgrade**

**UDIs Impacted: 15420045505636, 15420045511897**

**Product Codes:**

Part Number	Description
ASY-16824	FMI UPGRADE KIT, DIMENSIONS 1.12.0.3 SYSTEM SOFTWARE UPGRADE FOR 1.11.1 SYSTEMS
ASY-16825	FMI UPGRADE KIT, 3DIMENSIONS 2.3.0.3 SYSTEM SOFTWARE UPGRADE FOR 2.2.1 SYSTEMS
ASY-17219	FMI UPGRADE KIT, DIMENSIONS 1.12.0.3 SYSTEM SOFTWARE UPGRADE FOR 1.10.0 SYSTEMS
ASY-17220	FMI UPGRADE KIT, 3DIMENSIONS 2.3.0.3 SYSTEM SOFTWARE UPGRADE FOR 2.1.0 SYSTEMS
ASY-17221	FMI UPGRADE KIT, DIMENSIONS 1.12.0.3 SYSTEM SOFTWARE UPGRADE FOR 1.11.0 SYSTEMS
ASY-17222	FMI UPGRADE KIT, 3DIMENSIONS 2.3.0.3 SYSTEM SOFTWARE UPGRADE FOR 2.2.0 SYSTEMS
3DM-LIC-SW-UP-V2.3	DIMENSIONS SOFTWARE 2.3 (3DIMENSIONS)
SDM-LIC-SW-UP-V1.12	DIMENSION SOFTWARE 1.12 (SELENIA DIMENSIONS)

MISC-10081-EUR-2101 Rev. 001

Hologic BV.

# HOLOGIC®

This issue does not impact:

- The quality of tomosynthesis or Full Field Digital Mammography (FFDM) images acquired on these systems.
- The performance of Genius® AI Detection, I-View®, Quantra®, 3DQuorum®, or Intelligent 2D® software products.
- The use of C-View software on earlier Selenia Dimensions or 3Dimensions software versions.

Our goal is to create as little disruption to your practice as possible. Below outlines the next steps for any systems with Dimensions 1.12.0 and 3Dimensions 2.3.0 software:

## **For Health Care Providers with systems that do not have C-View software**

Customers may continue to use Dimensions 1.12.0 and 3Dimensions 2.3.0.

## **For Health Care Providers with systems that do have C-View software (regardless of usage)**

Immediate action should be the discontinuation of C-View software usage.

We will contact you to schedule a field visit from your field service engineer. Until your service appointment, you can continue to use your Selenia Dimensions 1.12.0 or 3Dimensions 2.3.0 system in Combo imaging mode to acquire tomosynthesis and FFDM images.

During your appointment, one of the two following options will be completed by your selection:

**Option 1:** C-View software will be disabled, and you can continue to use Selenia Dimensions 1.12.0 and 3Dimensions 2.3.0 system software in Combo imaging mode.

**Option 2:** To resume using C-View software, system software will be downgraded to Selenia Dimensions 1.11.1 or 3Dimensions 2.2.1.

- **PLEASE NOTE: Downgrading to Selenia Dimensions 1.11.1 or 3Dimensions 2.2.1 system software will delete all data saved on the mammography system.** You are responsible for backing up all raw data saved on the mammography system prior to your service appointment.
- The downgrade procedure will take approximately 4-8 hours to complete.
- Once the mammography system is running Selenia Dimensions 1.11.1 or 3Dimensions 2.2.1, you may be able to reprocess certain saved images for reevaluation with C-View software; however, not all prior images may be reprocessed if the raw data associated with the image is no longer available, such as those images saved on a Picture Archiving and Communication System (PACS).

A software upgrade will be available to correct the C-View issue on 1.12.0/2.3.0. A service appointment will be scheduled for an upgrade upon availability.

# HOLOGIC®

We are asking all impacted customers/distributors to acknowledge receipt of this notification. To complete this step, please complete “Annex I: Customer/Distributor Reply Form” within 3 business days of receiving this notice. Replying promptly will confirm your receipt of the notification and prevent you from receiving repeat notices.

If you are a distributor, please inform your customers of this Field Safety Notice.

For additional support, please contact Hologic’s Technical Support (information below),

## Direct Markets (Contact for Customers)

Country	Phone Number	email
United Kingdom	0800 323318 or local +441617681658	tsbsh@hologic.com

## Indirect Markets (Contact for Distributors)

Country	Phone Number	email
EMEA	+32 2 711 45 45	Be-techsupport@hologic.com

Best regards,

On behalf of

# HOLOGIC®

## Annex I: Customer/Distributor Reply Form

**FSN Ref:** MISC-10081-EUR-2101 Rev. 001

**FSCA Ref:** FA-00248

<b>Device Names</b>	Selenia Dimensions 1.12.0 and 3Dimensions 2.3.0 system software
---------------------	---

Customer/Distributor Details	
<b>Organization Name</b>	
<b>Organization Address</b>	
<b>Contact Name</b>	
<b>Telephone Number</b>	
<b>Email</b>	

Action undertaken on behalf of Organization	
I confirm the receipt, the reading and understanding of the Field Safety Notice.	<input type="checkbox"/> Yes
(For distributors), I have informed the identified customers of this FSN.	<input type="checkbox"/> Yes Date of Communication (MM/DD/YYYY):

<b>Print Name</b>	
<b>Signature</b>	
<b>Date</b>	

Please return the Reply Form to the following e-mail address: [FSCA@hologic.com](mailto:FSCA@hologic.com)

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN. Your organization's reply is the evidence we need to monitor the progress of the corrective actions.