



Zaventem, January 2nd, 2023

URGENT FIELD SAFETY NOTICE
Selenia Dimensions Mammography System and 3Dimensions Mammography System

FSN Ref: MISC-08686-EUR-EN Rev. 001

FSCA Ref: FA-00216

For Attention of:

Dear Valued Hologic Customer,

At Hologic, patient and care provider safety are our top priority, and we continually evaluate and improve our product quality and reliability. To that end, we want to advise you of an issue involving:

Selenia[®] Dimensions[®] Mammography System and 3Dimensions Mammography System

Description of the product problem and Hazard giving rise to the FSCA

We have received a single report of a C-arm performing a significant unexpected movement during non-patient related use of the system. The initial investigation determined this event was due to a hardware component single point of failure. The risk assessment has determined that due to the automatic alarms within the system and the very low incidence rate, the potential for this to occur is very unlikely.

Action To Be Taken

Out of an abundance of caution, however, we are initiating a voluntary field safety corrective action. Our goal is to create as little disruption to your practice as possible. As part of the voluntary field safety corrective action:

- We will schedule a service appointment and dispatch a field service engineer to visit your site to inspect your system and, if necessary, make any corrections.
- This will take approximately half an hour, and implementation will need 6-14 hours to be completed if a correction is required.
- Until your service appointment, you will be able to continue to use your Selenia Dimensions or 3Dimensions system.

If at any time during system operation, you observe any unanticipated error messages, or unexpected C-arm movement, please discontinue use and contact your local Hologic Support Representative or our Hologic Technical Support department immediately. Please find contacts in the table below.

MISC-08686-EUR-EN Rev. 001

Hologic BV, the Corporate Village, Building Caprese 8th floor, Da Vincilaan 5, 1930 Zaventem, Belgium

T: +32 711 46 80 | F: +32 2 725 20 87 | Hologic.com

BNP PARIBAS FORTIS, IBAN BE75 2100 8769 7651, BIC BEBABEBB, BTW: BE 0445 434 787, RPR Brussel: 0445 434 787

HOLOGIC®

Acknowledgment Requested

As an annex of this letter, please fill and acknowledge the Reply Form provided wherein we request receipt of this letter.

Please return the Reply Form to the following e-mail address: FSCA@hologic.com

Deadline for returning the Reply Form: January 7th, 2023

The Competent (Regulatory) Authority of your country has been informed about this communication.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Technical & Applications Support - Contacts BSH

Country	e-mail	Phone
Germany	ho.techsupport@hologic.com	+49 2273 989888
Austria	zentrale.at@hologic.com	+49 2273 989888
Switzerland	zentrale.ch@hologic.com	+49 2273 989888

Best Regards,

On behalf of [REDACTED]
Sr. Director of Quality, Breast and Skeletal Health Solutions

[REDACTED]
Senior Manager Post Market Surveillance International

MISC-08686-EUR-EN Rev. 001

Hologic BV, the Corporate Village, Building Caprese 8th floor, Da Vincilaan 5, 1930 Zaventem, Belgium

T: +32 711 46 80 | F: +32 2 725 20 87 | Hologic.com

BNP PARIBAS FORTIS, IBAN BE75 2100 8769 7651, BIC BEBABEBB, BTW: BE 0445 434 787, RPR Brussel: 0445 434 787



Zaventem, January 2nd, 2023

Customer Reply Form

FSN Ref: MISC-08686-EUR-EN Rev. 001

FSCA Ref: FA-00216

Device Names	Selenia [®] Dimensions [®] Mammography System and 3Dimensions Mammography System
---------------------	--

Customer Details	
Healthcare Organization Name	
Organization Address	
Contact Name	
Telephone Number	
Email	

Customer action undertaken on behalf of Healthcare Organization	
I confirm receipt of the Field Safety Notice and that I read and understood its content.	<input type="checkbox"/> Yes
I performed all actions requested by the FSN.	<input type="checkbox"/> Yes

Print Name	
Signature	
Date	

Please return the Reply Form to the following e-mail address: FSCA@hologic.com

Deadline for returning the Customer Reply Form: January 7th, 2023

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.

MISC-08687-EUR-EN Rev. 001

Hologic BV, the Corporate Village, Building Caprese 8th floor, Da Vincilaan 5, 1930 Zaventem, Belgium

T: +32 711 46 80 | F: +32 2 725 20 87 | Hologic.com

BNP PARIBAS FORTIS, IBAN BE75 2100 8769 7651, BIC BEBABEBB, BTW: BE 0445 434 787, RPR Brussel: 0445 434 787