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HOLOGIC®

Zaventem, November 2026

URGENT FIELD SAFETY NOTICE
FIELD SAFETY CORRECTIVE ACTION

3Dimensions™ and Selenia® Dimensions® Mammography Systems

FSN Ref.: MISC-12191-EUR-2101 Rev. 002
FSCA Ref.: FA-00314
Manufacturer SRN: US-MF-000003332

Dear Valued Hologic Customer,

The purpose of this letter is to inform you that Hologic is initiating a voluntary Field Safety Corrective Action (FSCA) for all 3Dimensions and Selenia Dimensions Mammography systems. Our records indicate that your facility has one or more of the impacted devices installed at your site. Please review this Field Safety Notice carefully.

Subject to this Field Safety Notice
(All Serial Numbers)

Model Number	Description	UDI-DI
SDA-SYS-3000-2D-HTC	Selenia Dimensions 2D System Avia 3000	15420045510616
SDA-SYS-3000-3D	Selenia Dimensions 3D Performance	15420045517783
SDM-SYS-6000-2D	Selenia Dimensions 2D System 6000	15420045510753
SDM-SYS-6000-3D	Selenia Dimensions 3D System 6000	15420045510760
SDM-00001-2D	Selenia Dimensions Mammography System, Full Field Digital Mammography System, 2D	15420045510623
SDM-00001-3D	Selenia Dimensions Mammography System 3D	15420045510630
SDM-00001-M2D	Selenia Dimensions Mammography System	15420045510647
SDM-00001-M3D	Selenia Dimensions Mammography System	15420045510654
SDM-05000-2A2	Selenia Dimensions FFDM System, 2D Avia, Fixed Height 5000, w/2MP Grayscale	15420045510661
SDM-05000-2A3	Selenia Dimensions FFDM System, 2D Avia, Fixed Height 5000, w/3MP Grayscale	15420045510678
SDM-05000-2AC	Selenia Dimensions FFDM System, 2D Avia, Fixed Height 5000, w/2MP Color	15420045510685
SDM-05000-2D2	Selenia Dimensions Mammography System, Standard, 2D w/2MP Grayscale	15420045510692

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SDM-05000-2DC	Selenia Dimensions Mammography System, Standard, 2D w/2MP Color	15420045510715
SDM-05000-3D2	Selenia Dimensions Mammography System, Standard, 3D w/2MP Grayscale	15420045510722
SDM-05000-3D3	Selenia Dimensions Mammography System, Standard, 3D w/3MP Grayscale	15420045510739
SDM-05000-3DC	Selenia Dimensions Mammography System, Standard, 3D w/2MP Color	15420045510746
SDM-SYS-9000-2D	Selenia Dimensions 9000 System 2D	15420045510777
SDM-SYS-9000-3D	Selenia Dimensions 9000 System 3D	15420045510784
3DM-SYS-INTL2D	3Dimensions System 2D International	15420045510609
3DM-SYS-INTL2D-MOB	3Dimensions System 2D International Mobile	15420045510593
3DM-SYS-INTL3D	3Dimensions System 3D International	15420045510579
3DM-SYS-INTL3D-MOB	3Dimensions System 3D International Mobile	15420045510562
3DM-SYS-STD	3Dimensions System 3D Standard	15420045510524
SDA-SYS-3000-2D	Selenia Dimensions Mammography System, 2D	15420045510616
SDM-SYS-6000-2D-HTC	Selenia Dimensions 2D System 6000	15420045510753
SDM-SYS-9000-3D-HTC	Selenia Dimensions 2D 9000 Package	15420045510777
SDM-SYS-6000-3D-HTC	Selenia Dimensions 3D System 6000	15420045510760
SDM-00001-2D	Selenia Dimensions Mammography System, Full Field Digital Mammography System, 2D	15420045510623
SDM-00001-3D	Selenia Dimensions Mammography System 3D	15420045510630

Note: The impacted products listed in the table above are not being removed from your facility and do not need to be returned.

Reason for the Field Safety Corrective Action

Hologic has identified the potential risk of sudden, unexpected freefall due to significant wear on the vertical lift nut of the C-Arm assembly on 3Dimensions and Selenia Dimensions systems.

Potential Impact to Patient/User

There is minimal impact to device function on systems with typical wear on the lead screw. However, significant wear can cause symptoms such as seizure of vertical travel, loud noises/screeching or abnormal shaking/vibration during vertical positioning, which may result in the following adverse effects to patient and/or user:

- Annoyance/Distraction
- Additional Intervention - Treatment/Scan required
- Minor Delay of Treatment

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In cases where the lead screw has significant wear, freefall of the C-Arm could occur. This may result in the following potential adverse effects to patient and/or user, in addition to those listed above:

- Major Delay of Treatment
- Abrasion
- Perforation
- Pain
- Blunt Trauma
- In extraordinary circumstances, death

As of October 01, 2026, Hologic has received 5 complaints of total system failure since 2019. There have been no reports of serious injury to user or patient.

Actions taken by Hologic through this Field Safety Corrective Action

Hologic provides the following recommendations to prevent any potential harm: If at any time during system operation you observe symptoms such as seizure of vertical travel, unexpected movement/shaking or hear loud screeching during vertical travel, please discontinue use and contact Hologic's Technical Support or distributor representative immediately.

To ensure the continued safe and effective performance of your 3Dimensions™ or Selenia® Dimensions® system, Hologic is implementing a required recurring maintenance inspection to properly identify lift nut wear. This updated inspection procedure will be incorporated into a future release of the service manuals for the Dimensions® product family as a required maintenance task to ensure safe/proper system operation over the life of the system.

For Hologic direct customers that utilize Hologic for preventative maintenance, the inspections will be completed under your standard preventative maintenance appointment biannually.

For customers utilizing alternative service providers for preventative maintenance, a Hologic representative will contact you to schedule an initial system inspection as part of this FSCA. After this initial inspection, bi-annual inspections will be required to ensure the device is maintained properly, and the system continues to operate as intended.

For customers of our distributors, a distributor representative will contact you to schedule an initial system inspection as part of this FSCA. After this initial inspection, bi-annual inspections will be required to ensure the device is maintained properly, and the system continues to operate as intended.

Our goal is to create as little disruption to your practice as possible. This initial inspection and potential remediation will be provided to all impacted systems at no additional cost.

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In response to this notice, please take the following steps.

1. Forward this notice to anyone in your facility who needs to be informed.
2. Post a copy of this notice in a visible area near the affected devices where operators can view for awareness and please keep a copy for your records.
3. Maintain awareness of this communication internally until all actions have been completed at your facility.

Additional information for direct Hologic customers

1. Acknowledge receipt of this communication by completing the online Customer/Distributor Response Form provided by IQVIA (see link below).

Additional information for Hologic distributors or resellers

1. Acknowledge receipt of this communication by completing the online Customer/Distributor Response Form provided by IQVIA (see link below).
2. Please inform your customers of this Field Safety Notice and retain evidence that they have been notified and acknowledged receipt, for regulatory purposes.

IQVIA is Hologic's official partner for this FSCA. Hologic has partnered with IQVIA to conduct follow up communications should no response be received to this letter. Replying promptly will confirm your receipt of the notification and prevent you from receiving repeat notices.

Link to Online Customer/Distributor Response Form:

https://iqvia-response.my.site.com/mt/fca?cid=Hologic-fa00314

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For additional support, please contact Hologic's Technical Support (information below) or your distributor's representative. To report any complaints, or quality issues related to this product, please contact Hologic Technical Support or your distributor representative.

Direct Markets (Contact for Hologic customers)

Country	Phone Number	email
Austria	0800 29 1919 or local +43 720 710 811	TSbsh@hologic.com
Germany	0800 589 1635 or local +49 3222 109 65 91	
Italy	800 786308 or local +390694801337	
Portugal	800841034 or local +351300506262	
Spain (including the Canary Islands and Andorra)	900988004 or local +34932204047	
Switzerland	0800 29 8921 or local +41 215 880 145	
United Kingdom	0800 323 318 or local +441617681658	

Indirect Markets (Contact for distributors)

Country	Phone Number	email
EMEA	+32 2 711 45 45	BE-Techsupport@hologic.com

Regulatory Authorities of your country have been notified of this Field Safety Notice – if applicable.

We apologize for any inconvenience that this may cause and appreciate your patience and your willingness to work with us.

Sincerely,

Marta Szczerczowska-Katillari
Manager Post Market Surveillance

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