Zaventem, March 25, 2026

FIELD SAFETY NOTICE
VOLUNTARY FIELD SAFETY CORRECTIVE ACTION

3Dimensions™ Mammography System and Selenia® Dimensions® Mammography System

FSN Ref.: MISC-11479-EUR-2101 Rev. 001
FSCA Ref.: FA-00295
Manufacturer SRN: US-MF-000003332

Subject to this Field Safety Notice
(All Serial Numbers)

Model Number	Model Description	UDI
SDA-SYS-3000-2D-HTC	Selenia Dimensions 2D System Avia 3000	15420045510616
SDM-SYS-3000-2D	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-M2	Selenia Dimensions Mammography System	15420045510647
SDM-00001-M3D	Selenia Dimensions Mammography System	15420045510654
SDA-SYS-3000-2D-CN	Selenia Dimensions 2D System Avia 3000-China	15420045517745
SDM-SYS-6000-3D-CN	Selenia Dimensions 3D System 6000-China	15420045517776
SDA-SYS-3000-3D-CN	Selenia Dimensions 3D Performance-China	15420045517677
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
SDM-05000-2D3	Selenia Dimensions Mammography System, Standard, 2D w/3MP Grayscale	15420045510708
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

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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-INTL2D-NS	3Dimensions System 2D International No Shield	15420045510586
3DM-SYS-INTL3D	3Dimensions System 3D International	15420045510579
3DM-SYS-INTL3D-MOB	3Dimensions System 3D International Mobile	15420045510562
3DM-SYS-INTL3D-NS	3Dimensions System 3D International No Shield	15420045510555
3DM-SYS-STD	3Dimensions System 3D Standard	15420045510524
3DM-SYS-STD-CN	3Dimensions System 3D Standard-China	15420045517622
3DM-SYS-STD-MOB	3Dimensions System 3D Standard Mobile	15420045510531
3DM-SYS-STD-NS	3Dimensions System 3D Standard No Shield	15420045510548

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Dear Valued Hologic Customer,

Hologic is initiating a voluntary Field Safety Corrective Action (FSCA) for all serial numbers related to the models of 3Dimensions™ and Selenia® Dimensions® systems listed above to implement an updated maintenance inspection for the Vertical Travel Assembly (VTA). Our records show that your facility has an active system within the scope of this FSCA.

Reason for the Field Safety Corrective Action

Hologic is initiating this voluntary FSCA because the VTA on 3Dimensions™ and Selenia® Dimensions® systems may experience internal bolt failure over time. The VTA contains eight internal bolts that secure the C-Arm to the assembly. In 2022, Hologic received a single report of unexpected C-Arm movement during nonpatient use. Investigation of this event determined that no serious injury had occurred, and the device malfunctioned as all eight bolts had sheared, allowing the C-Arm to rotate freely. Loose VTA bolts can experience increased mechanical stress, which may lead to bolt failure over time. Devices with loose, missing, or broken bolts may exhibit shaking, vibration, or uncommanded C-Arm motion. A corrective action was previously implemented and affected systems were remediated at that time.

Since 2022, Hologic has received a total of one hundred fourteen (114) Medical Device Report (MDR) malfunction reports affecting 99 systems out of a global installed base of over 16,000 systems. Hologic has determined that the earlier corrective actions required further improvement to ensure adequate risk mitigation, and the scope of impacted systems covered by those actions should be expanded. Although no additional cases of systems with shearing on all eight bolts have been reported since the initial event in 2022, to ensure continued safe use, Hologic is taking further steps to enhance detection and prevention of VTA bolt related- issues.

Our objective is to minimize any disruption to your practice while reducing possible patient and user risk. Hologic is implementing an updated maintenance inspection for the VTA to identify loose, missing, or broken VTA bolts on all affected systems to prevent potential full failure of the bolts on VTAs in use.

Potential Impact to Patient/User

In cases where a system has only loose bolts, or fewer than eight sheared bolts, there is minimal impact on device function. However, the system may show signs such as abnormal shaking, vibration, or uncommanded C-Arm movement, resulting in the following potential adverse effects to patient and/or user:

- Annoyance/Distractions
- Additional Intervention/Treatment/Scan required
- Delay of Treatment

This state of operation places additional stress on the remaining bolts, which may lead to further bolt shearing.

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In cases where all eight VTA bolts have sheared, free, unexpected rotation of the C-Arm could occur, which presents risk to patients or users if in close proximity to the device at time of failure. Contact may result in the following potential adverse effects:

- Annoyance/Distractions
- Additional Intervention/Treatment/Scan required
- Delay of Treatment
- Abrasion
- Perforation
- Pain
- Blunt Trauma
- In extraordinary circumstances, death

To date, only one system globally had all eight bolts shear, resulting in free C-Arm motion. Due to systems often exhibiting early-stage symptoms such as noticeable shaking and vibration, and our recommendation to discontinue use when such shaking and vibration occurs, the potential for total failure to occur remains minimal.

Actions taken through this Field Safety Corrective Action

To ensure the continued safe and effective performance of your 3Dimensions™ or Selenia® Dimensions® system, Hologic is implementing an updated recurring maintenance inspection for detecting loosened, missing, or broken bolts within the VTA. This updated inspection procedure will also 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. The updated inspection procedure will also be added to existing manual resources and also issued through a customer technical bulletin.

We are urgently aligning our supply chain and field resources to support this action and will contact you promptly once this alignment is complete. Hologic or distributor representative will then reach out to schedule your service appointment and perform the required inspection.

This initial inspection by Hologic or distributor representative includes the application of alignment marks to the system hardware, followed by a torque inspection based on the system configuration to identify any loose, missing, or broken VTA bolts. If any of these conditions are identified, the system will be evaluated for VTA bolt replacement or VTA assembly replacement, as appropriate.

Following the initial inspection, recurring inspections are required to be conducted at least every 6 months to ensure continued safe/proper operation of the system. Future inspections will consist of torque and visual confirmation that all bolts are present and that there is no indication of loosening.

For Hologic direct customers with Hologic service plans, ongoing inspections using the updated inspection method will be scheduled by Hologic as service appointments. During these visits, we will inspect your system and, if needed, make corrections to the VTA.

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For Hologic direct customers who are using alternate service providers, Hologic representatives will coordinate the initial system inspection activity as part of the field action activities. After this initial inspection is completed, the system must be inspected at least every 6 months using the instructions to be provided in a forthcoming customer technical bulletin until the service manual is formally updated to include these requirements.

Next steps for Users

- You may continue to use your 3Dimensions™ or Selenia® Dimensions® for its intended use.
- If at any time during system operation, you observe unexpected C-Arm movement, please discontinue use and contact immediately Hologic's Technical Support or distributor representative.
- Report suspected device complaints and/or adverse events to Hologic or distributor representative.
- After initial inspection by Hologic or distributor representative, it is required to have the inspection performed at least every 6 months as well as the other defined maintenance and service activities which are critical for continued safe and effective operation of the Selenia Dimensions or 3Dimensions system.

In response to this notice, please take the following steps

1. Forward this notice to anyone in your facility that 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.

Additional information for Direct Hologic customers

1. Acknowledge receipt of this communication by completing the online Customer Response Form provided by IQVIA.

Additional information for Hologic distributors or resellers

1. Acknowledge receipt of this communication by completing the online Customer Response Form provided by IQVIA.
2. If you are a distributor or reseller, please inform your customers of this Field Safety Notice and request acknowledgment from your impacted customers.
3. If you are a distributor or a reseller, coordinate scheduling service appointment for the VTA inspection with your impacted customers.
4. Following the initial inspection, recurring inspections are required to be conducted by at least every 6 months to ensure continued safe/proper operation of the system.

IQVIA is Hologic 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.

In some countries, Hologic may partner with service provider to coordinate the field correction process including scheduling of onsite visits.

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

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	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.

Marta Szczerczowska-Katillari
Manager Post Market Surveillance

On behalf of Tim Crowley
Director, Post Market Quality Engineering

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