

IGT Systems

FSN 2020-IGTPUN-004 - FCO71800085

May 2020

URGENT – Field Safety Notice

Zenition 50 and Zenition 70

Loss of strain relief in the interconnecting cable between the Mobile Viewing Station and the C-arm Stand
(Stand MVS Trolley Cable)

Dear Customer,

This Medical Device Notice is intended to inform you about a defect that has been detected in the Philips Zenition Systems. This defect could pose a risk for patients or users.

This Medical Device Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients and users
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

The affected systems contain a Stand MVS Trolley Cable (the interconnecting cable between the Mobile Viewing Station and the C-arm Stand) where the strain relief at the stand side may fail. When the strain relief is lost, over time one or more electrical contacts could break due to pulling, twisting or dropping of the connector. If this happens, live parts may be exposed (230 V) and/or the video signal can be lost. No harm to patients or users has been reported to Philips to date.

In the following pages, detailed information and actions required are provided.

If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

R. Kathuria
Head Q&R
Image Guides Therapy Systems

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AFFECTED PRODUCTS	29 systems of the models Zenition 50 (Product Code: 718096) and Zenition 70 (Product Code: 718133).
PROBLEM DESCRIPTION	<p>The affected systems contain a Stand MVS Trolley Cable (the interconnecting cable between the Mobile Viewing Station and the C-arm Stand) where the strain relief at the stand side may fail. When the strain relief is lost, over time one or more electrical contacts could break due to pulling, twisting or dropping of the connector. If this happens, live parts may be exposed (230 V) and/or the video signal can be lost.</p>  <p>Damaged cable due to loss of strain relief</p>
HAZARD INVOLVED	<p>In the event of strain relief loss, the following are potential hazards:</p> <ul style="list-style-type: none">• Electric shock if a live part is touched (230V)• Delay in treatment due to interruption of procedure or system not being available when needed.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Affected systems contain the cable 459800943703 (Stand MVS Trolley Cable).</p> <p>Users can identify if their Zenition 50 (Product Code: 718096) and Zenition 70 (Product Code: 718133) contain this cable by checking the plastic nut of the cable.</p>

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	<div><div>Affected Systems</div></div> <div><div>Non-affected Systems</div></div>									
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Until Philips replaces the Stand MVS Trolley Cable in your system:</p> <ul style="list-style-type: none">○ Please ensure that the following checks indicated in the User Routine Checks Program (section 7.4 of the Instructions for Use provided with the system) are performed: <table border="1"><thead><tr><th>Check</th><th>Description</th><th>Frequency</th></tr></thead><tbody><tr><td>Cabling</td><td>Inspect all cables for kinks and/or cracks</td><td>Daily</td></tr><tr><td>Connectors</td><td>Check correct connection and damage</td><td>Daily</td></tr></tbody></table> <p>In case the strain relief is lost and / or damage to cable/ connector is identified; stop using the system and contact your Philips local representative so that the cable can be replaced.</p>	Check	Description	Frequency	Cabling	Inspect all cables for kinks and/or cracks	Daily	Connectors	Check correct connection and damage	Daily
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	<ul style="list-style-type: none">○ Please ensure that all staff working with the system are informed of the content of this safety notice and place a copy of it with the Instructions for Use.
ACTIONS PLANNED BY PHILIPS	Philips will be replacing the Stand MVS Trolley Cable (459800943703) in all affected systems by a new Stand MVS Trolley Cable that has an improved strain relief design. This action will start in May 2020. You will be contacted by our local Philips representative to schedule an appointment to replace the cable.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: 0800 80 3000



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