



## Urgent safety information regarding possible unintentional radiation release due to defective hand switches on mobile X-ray devices

May 27<sup>th</sup>, 2024

Dear customers,

Ziehm Imaging GmbH specializes in the development, production and worldwide marketing of mobile X-ray devices. The safety of patients and users during everyday use of our products is our top priority.

With this safety information, we would like to inform you about a measure that we are introducing for our products.

---

<b>Addressees:</b>	<p>This document is intended for physicians, medical professionals, sales partners and users of the above-mentioned mobile X-ray systems.</p> <p>It contains important information that will enable you to continue to use your mobile X-ray unit safely and correctly.</p>
<b>Scope:</b>	<p>Ziehm hand switch #88036 Version 1.02 for the device type:</p> <p>Ziehm 8000 Ziehm Solo, Ziehm Solo FD Ziehm Vision, Ziehm Vision FD Ziehm Vision R, Ziehm Vision RFD, Ziehm Vision RFD 3D</p>
<b>Problem description:</b>	<p>Mechanical stress such as shocks (e.g. dropping) or impacts can irreversibly damage the switching element in the hand switch. A defective switching element may then potentially initiate unintended radiation of the connected mobile X-ray unit.</p>
<b>Preventive measures:</b>	<p>Do not use the affected hand switches.</p> <p>Do not connect the affected hand switches to a device.</p> <p>Instead, use alternative operating options for initiating radiation, such as foot switches or radiation buttons on the control panel (optional).</p>

---

---

In case you are using a device with an analog image intensifier for radiography, this function is not available since it depends on the hand switch until the hand switch is replaced by a compliant component.

---

**Corrective actions on the device:**

Our service or service representative will contact you as soon as possible and arrange for the hand switch to be replaced.

---

**Forwarding of information**

Please ensure in your organization that all users of the above-mentioned products and other persons who need to be informed are made aware of this urgent safety information.

If you have given affected products to third parties, please forward a copy of this information or inform the named contact person at Ziehm Imaging

---

**Contact person:**

Simon Schildbach

Person Responsible for Regulatory Compliance (PMS-Delegate)

Mail: [FSCA@ziehm.com](mailto:FSCA@ziehm.com)

Tel: +49 (0) 911.660 67-0

---

The described procedure was coordinated with the Competent Authorities.

Compliance with the highest safety and quality standards is a top priority for Ziehm Imaging. If you have any questions about this product information or require further assistance, please contact -preferably in writing- our Person Responsible for Regulatory Compliance (FSCA@ziehm.com).

Yours sincerely

