

FIELD SAFETY NOTICE

Field Safety Corrective Action required for Imaging Module IM 910 Connector Box

REF. HSC 22-04

Koeniz, August 22, 2022

To whom it may concern

Haag-Streit AG has identified a safety risk present in all Connector Boxes delivered with the Imaging Module IM 910 to date. You have received this notice because our records indicate that you are in possession of at least one affected device.

Please read this information carefully. Your action and formal acknowledgement of the information presented in this document are required.

Identification of affected medical devices

The following devices are affected:

Product	Reference No.	Affected Serial Nos.
Connector Box CB01 for Imaging Module IM 910	1023640	73-79, 100-122, 124, 125, 128-136, 138-164, 172

Description of the problem

The distance between the Connector Box's ethernet-port and internal electronic components is insufficient to provide adequate electrical insulation to the medical device in case of the presence of high voltages on ethernet installations. In its current state, the device does not conform to the relevant requirements set out in EN 60601-1:2006/A1:2013.

Possible safety hazard

In cases where the device is operated while connected to an ethernet network, there is an electrical injury hazard to the user in the unlikely event that an unexpectedly high voltage is simultaneously present on the network. The risk does not exist in single fault condition and is deemed to be remote.

There is no risk to the patient when following the current Instructions for Use.

To date Haag-Streit AG is not aware of any incidents associated with this risk.

Haag-Streit AG

Gartenstadtstrasse 10
3098 Koeniz, Switzerland
Phone: +41 31 978 01 11, Fax: +41 31 978 02 81
vigilance@haag-streit.com, www.haag-streit.com

Remediating action

Please disconnect all connected devices from the ethernet network now. Please do not connect any devices without sufficient voltage protection.

A safety kit, consisting of a network isolator which is tested for compliance with the stipulations set out in EN 60601-1:2006/A1:2013, a supplement to the Instructions for Use, as well as a warning label to be affixed to affected devices, will be provided to all users of affected devices. This safety kit will be dispatched to you by your distributor or by Haag-Streit directly.

Please complete and return the form at the end of this document as soon as the described measures have been taken. We kindly advise you that the return of the completed form is mandatory.

Forwarding of this information

The competent authorities have already been informed about this matter.

Please ensure that all users of the device are made aware of the information supplied in this notice. Should the device have been passed on to third parties since the receipt of your device, please forward this information to the third party and kindly inform the manufacturer.

Please keep a copy of the Instructions for Use supplement with your device documentation.

Contacting the manufacturer

To report any incidents related to this risk, or for inquiries about the information contained in this notice, we ask you to direct them to the Vigilance Manager, as follows:

Name	Mr. J. Kool van Langenberghe
Phone	+41 31 978 02 23
Email	vigilance@haag-streit.com

Should you have any questions regarding the installation instructions or require assistance, we ask you to consult Customer Services, as follows:

Phone	+41 31 978 01 55
Fax	+41 31 978 02 81
Email	service@haag-streit.com

We would like to apologise for any inconvenience caused by this field safety action and thank you in advance for your support in ensuring timely processing.

Yours sincerely

Julian Kool van Langenberghe

Vigilance Manager

Eric Verstegen

Director of Quality Management and Regulatory Affairs

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FIELD SAFETY RESPONSE

Field Safety Corrective Action for Imaging Module IM 910 Connector Box

REF. HSC 22-04

Name of Institution

Address

ZIP/City

Country

Contact details (Name, Number)

Distributor (if applicable)

Hereby confirms that:

- The information was received and understood.
- A copy of the Instructions for Use supplement is kept with device records.
- Warning labels have been applied to affected devices OR were already present.
- All devices have been detached from the ethernet networks OR are being used with a suitable network isolator, such as the one provided by Haag-Streit.

All boxes must be ticked.

Regarding the following devices

Serial numbers of

affected devices on site

Submitted by

Print Name/Stamp,

Date, Signature

Please return the completed form by email or fax as soon as the listed measures have been taken.

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