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Denzlingen, 25-Jan-2017

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Urgent Safety Information

Corrective action: Replacement of the monitor cable EV2-000086

concerning

EinsteinVision® 3D-Endoscopy Systems

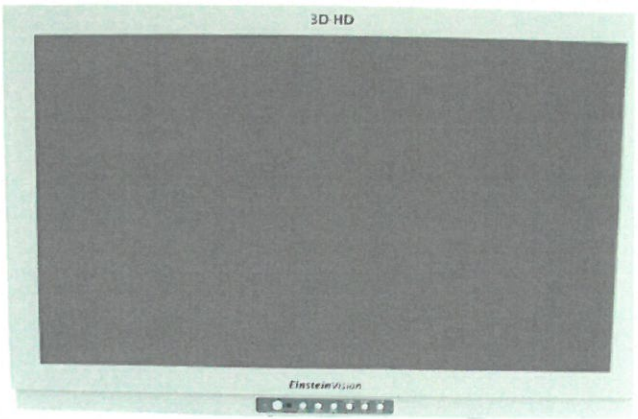
Recipient:

Users and operators of EinsteinVision® 3D endoscopy systems, exclusively distributed by Aesculap AG.

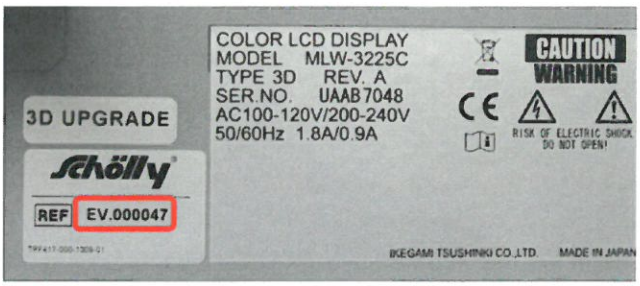
Identification of affected medical devices:

The 3D monitors with item number EV.000047 of the EinsteinVision® 3D endoscopy system from Aesculap AG are affected.

The identification of the monitor can be carried out using the item number on the back of the monitor.



Picture: Front of the monitor.



Picture: Type plate on the back of the monitor.

Description of the problem including the determined cause:

In individual cases image distortions and image failure can occur with the 32" 3D monitor EV.000047. The operator loses sight of the endoscopically observed surgical field if an image failure occurs intraoperatively.

The problem originates due to electromagnetic extraneous radiation, particularly in connection with the use of HF surgical devices. The problem can be avoided by replacing the monitor cable with item number EV2-000086.

In the event of an image failure, the problem can usually be solved by switching the monitor off and on again. The system is not affected by the problem and ensures the view of the operating area if it is operated with an additional 2D monitor.

To this day there has not yet been a patient at risk in connection with the problem.

Aesculap AG will arrange an exchange of all monitor cables with item number EV2-000086.

Aesculap AG recommends to not use the EinsteinVision® 3D endoscopy systems until the corrective action has been completed.

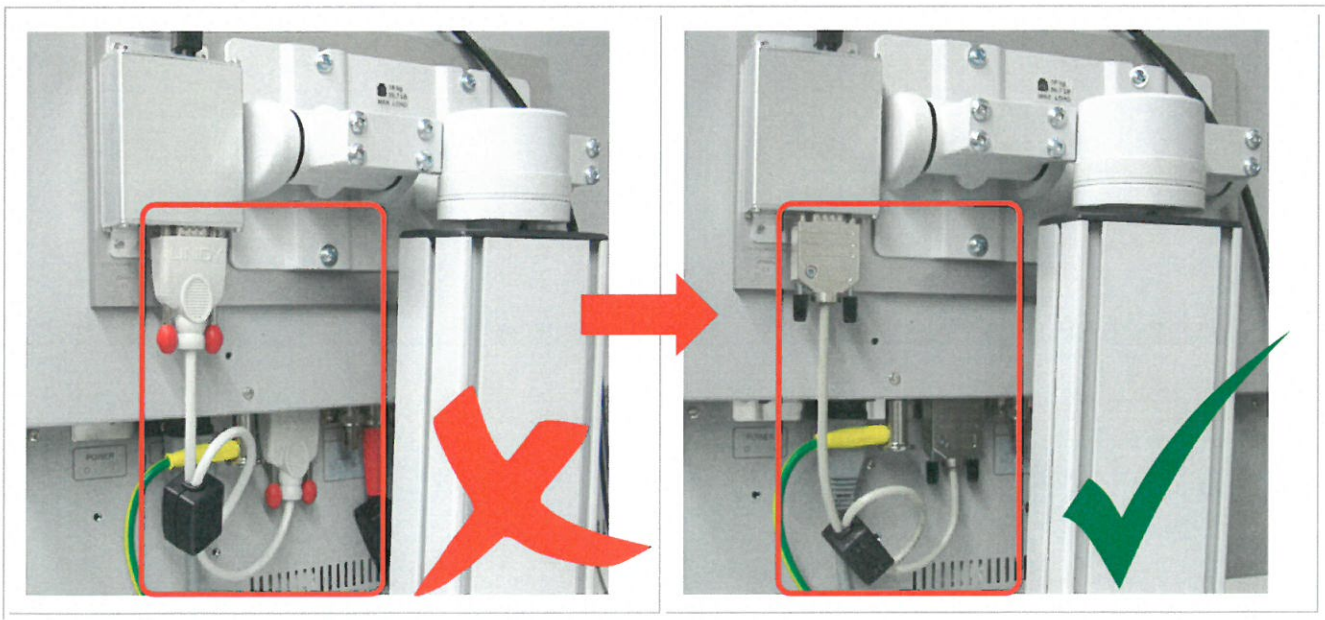
Which measures are to be taken by the recipient?

Operators should ensure that affected endoscopy systems are not used until replacement cables have been delivered and causative cables have been replaced. Furthermore, the operator also has to ensure that cables which were replaced or affected are no longer used in conjunction with a EinsteinVision® 3D endoscopy system.

The replacement cable is expected to be available starting early in February 2017.

Operators are asked to replace the affected cable with the new cable. Procedure: 1. Remove and dispose the affected cable. 2. Install the new cable and secure it with the screws.

The cable to be replaced is discernible by red components (illustration to the left). The right illustration shows the new cable after the conversion:



Picture: Cable before and after the replacement

Disclosure of the information described above:

Please ensure that all users of the above mentioned products and other individuals to be informed in your organization are aware of this "Urgent Safety Information". Please forward a copy of this information or inform the contact person listed below if you have distributed the products to a third party.

Please keep this information on file at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Please fill in the enclosed feedback form and send it to the contact person stated therein.

Contact persons:

Contact person for this safety information

Aesculap AG

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Contact person for technical questions

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We regret the inconveniences caused by the implementation of these measures and thank you for your comprehension and cooperation.

Best regards

SCHÖLLY FIBEROPTIC GMBH

ppa.

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i.V.

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