

Contact Person: Dominik Neumeister

Phone: 07461 95-31139

Fax: 07461 95-1555

Mail: vigilance_aag.de@aesculap.de

Internet: <http://www.aesculap.de>

Date: 14th June 2021

Update from 14. June 2021 to
Urgent Safety Information from 04. June 2021

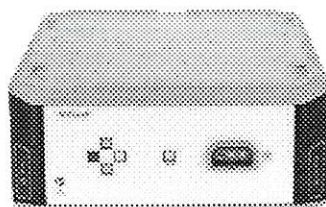
Product Group :

- EV3.0 CAMERA CONTROL UNIT

Product Name :

- PV630

Internal Reference-Number : FSCA 257



For the attention of users, importers and distributors of the affected products.

1. Information on affected products

1.1 Product		
Catalogue number / product model	Product Name	Product Group
PV630	EV3.0 CAMERA CONTROL UNIT	2D & 3D Camera Platform EinsteinVision®
1.2 Primary Intended Use		
A Full HD spatial, three-dimensional vision combined with a proven sterile delivery concept for all laparoscopic surgeries in surgery, gynecology, urology and cardiac surgery.		
1.3 Catalogue number / product model		
See 1.1		
1.4 Associated product(s)		
See Appendix 1		

2. Reason for this Field Safety Corrective Action (FSCA)

2.1 Description of the possible malfunction

During the manufacture of the product EV3.0 CAMERA CONTROL UNIT PV630, an incorrect circuit board was installed, which can lead to so-called ESD damage (electrostatic discharge).

In the event of such ESD damage, the operability of the camera system may be restricted during use and the electronic control of the image brightness may fail.

2.2 Reason for initialization of this FSCA

During the manufacture of the product EV3.0 CAMERA CONTROL UNIT PV630, an incorrect circuit board was installed, which can lead to so-called ESD damage (electrostatic discharge).

The potential damage for patients, users and third person through getting a possible electric shot is ranked as a high-risk health danger with eventual result in death. We expect a usual occurrence (0.57% affected products). Until today no incidents related to this error pattern have been reported to us.

2.3 Root cause analysis

A digital isolator, which has a lower than required resistance to the effects of electrostatic discharges, was installed on a circuit board used with PV630.

3. Type of action to mitigate the risk

3.1 Actions to be taken by users, importers and distributors

- ☒ Identify Product ☐ Quarantine Product ☒ Return Product ☐ Destroy Product
- ☐ On-site product modification/inspection
- ☐ Follow patient management recommendations
- ☐ Take note of amendment/reinforcement of Instructions For Use (IFU)
- ☐ Other ☐ None

Based on the above risk scenario Aesculap AG **decided to recall the affected products** (Appendix 1). Please identify the affected products at your side and return them to Aesculap AG by using the return form (Appendix 3) attached. Please take care that the return form (Appendix 3) is always returned together with the returned products. After replacement of the circuit board, you will receive your reworked product back.

If you need a replacement device for the bridgeover, please let us know as soon as possible.

Please identify the affected products at your side and return them to Aesculap AG by using the return form (Appendix 3) attached. Please take care that the return form (Appendix 3) is always returned together with the returned products

Please confirm the understanding of this urgent field safety notice by returning the feedback form (Appendix 2) until 13th July 2021.

This safety information replaces the previous safety information dated 04.06.2021.

3.2 Special considerations for already treated patients

There are no additional follow-up measures for already treated patients required.

If you have any further questions, please contact the following contact persons:

For product related questions:

Jürgen Lippert

Senior Product Manager

Laparoscopic Surgery

☎ + 49 7461 95 - 31873

juergen.lippert@aesculap.de

For related questions to this security information:

Dominik Neumeister

Vigilance Coordinator

Quality Management

☎ + 49 7461 95 - 31139

vigilance_aag.de@aesculap.de

Please ensure in your organization that all users of the affected product and other persons to be informed are aware of this urgent field safety notice.

The Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) has received a copy of this urgent field safety notice.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all product related incidents to Aesculap AG or to your local distributor and the national Competent Authority if appropriate.

We would like to point out that all users who have received the affected products from us in the past will be informed of this urgent field safety notice.

We apologize for any inconveniences caused.

Yours sincerely,

Aesculap AG



Appendix 1 – Affected Products

Appendix 2 – Feedback Form

Appendix 3 – Return Form

Appendix 1 – Affected Products

Serial-Nr.	Serial-Nr.
845943	956999
875275	957000
894175	957517
900167	957518
956257	957519
956258	957897
956259	957898
956260	957899
956261	957922
956403	957923
956404	957924
956405	958342
956630	958343
956631	958344
956632	958658
956807	958659
956808	958660
956809	958700
956934	958701
956935	958702
956936	959057
956937	959058
956938	959143
956939	959144
956998	959145

FEEDBACK FORM

FSCA No. 257

Product description: EV3.0 CAMERA CONTROL UNIT (PV630)

Please return this form by fax or e-mail to:

Department QMV / Recall Coordinator: Dominik Neumeister

Fax: +49 7461-95 1555

E-Mail: vigilance_aag.de@aesculap.de**We have an affected product available and return it for board replacement:**☐ YES ☐ NO

Number of products: _____

Serial Number(s): _____

We require a replacement device for the period until recommissioning the affected product:☐ YES ☐ NO**We have no affected product available:**☐ YES ☐ NO

Comment:

FACILITY _____

LOCATION _____

NAME _____

DEPARTMENT _____

PHONE _____

SIGNATURE _____

DATE _____

**PRODUCT RECALL FSCA 257 (PV630)**Hygienic condition:☐ New good☐ used – decontaminated*☐ used - not decontaminated

Pos. No.	Article No.	Serial No.	Quantity	Remark

RETURN ADDRESS:

Aesculap AG
Department ATS
Am Aesculap-Platz
D-78532 Tuttlingen – Germany

ADDRESS / SENDER:DATE / SIGNATURE:

* Decontamination record has to be inserted into return shipment.