

**Aesculap AG
Quality Management**

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Date: 04th June 2021

Urgent Field Safety Notice from 02. June 2021

**Product Name: EV3.0 CAMERA CONTROL UNIT (PV630)
Internal Reference Number : FSCA 257**



Dear Madam or Sir,

Aesculap AG, being the legal manufacturer of the product EV3.0 CAMERA CONTROL UNIT PV630, imposes an immediate application stop of this product. The serial numbers of the affected products are listed in **Appendix 1**.

We very much regret the inconveniences resulting from this and will inform you about the further course of action in the next few days.

Reason for the application stop

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.

Furthermore, it cannot be ruled out that under certain circumstances high voltage may be discharged via this ESD-damaged component during use, thus endangering patients, users or third parties due to inadmissibly increased leakage currents.

Vorsitzender des Aufsichtsrates:
Prof. Dr. Heinz-Walter Große

Vorstand:
Dr. Joachim Schulz
(Vorsitzender)
Dr. Jens von Lackum
(Stellv. Vorsitzender)
Dr. Katrin Sternberg

Sitz der Gesellschaft: Tuttlingen
Reg. Gericht: Stuttgart HRB 726261
USt. Id.-Nr. DE812160059
WEEE-Reg.-Nr. DE 65109852

Bankverbindungen:
Deutsche Bank AG Tuttlingen
BLZ 653 700 75 Konto 21 22 000 00
IBAN DE 44 6537 0075 0212 2000 00
SWIFT / BIC DEUTDE33
Baden-Württembergische Bank
BLZ 600 501 01 Konto 487 1905
IBAN DE31 6005 0101 0004 8719 05
SWIFT / BIC SOLADEST

Hausanschrift:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Deutschland

Please confirm immediately that you have taken note of this urgent safety information (application stop) by using the enclosed feedback form.

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

For product related questions:

Jürgen Lippert

Senior Product Manager
Laparoscopic Surgery

juergen.lippert@aesculap.de

For related questions to this security information:

Dominik Neumeister

Vigilance Coordinator
Quality Management

vigilance_aag.de@aesculap.de

Yours sincerely,

Aesculap AG

i.V.



Georg Erhard
Safety Officer
Quality Management

i.A.



Christian Strobel
Vigilance Manager
Quality Management

Appendix 1– affected Serial Numbers

Serial-Nr.
845943
875275
894175
900167
956257
956258
956259
956260
956261
956403
956404
956405
956630
956631
956632
956807
956808
956809
956934
956935
956936
956937
956938
956939
956998

Serial-Nr.
956999
957000
957517
957518
957519
957897
957898
957899
957922
957923
957924
958342
958343
958344
958658
958659
958660
958700
958701
958702
959057
959058
959143
959144
959145