
Urgent Field Safety Notice
Repair of TIVITA Camera systems
Reference number: 191007-01

Diaspective Vision GmbH
 Strandstraße 15
 18233 Am Salzhaff

Am Salzhaff, 05/11/2019

To distribution partners, customers und operators

Dear Ladies and Gentlemen,

We hereby inform you about a product recall of our hyperspectral TIVITA camera systems. This letter contains all relevant information.

Identification of the affected medical devices:

The following serial numbers of the hyperspectral camera systems with the trading name TIVITA are affected:

Camera: 0102-00050 Cart: 0912-00025	Camera: 0102-00083 Cart: 0909-00022	Camera: 0102-00036 Cart: 1109-00079
Camera: 0102-00095 Cart: 0909-00046	Camera: 0102-00079 Cart: 0909-00037	Camera: 0102-00029 Cart: 0909-00063
Camera: 0102-00094 Cart: 0909-00045	Camera: 0102-00078 Cart: 0909-00036	Camera: 0102-00024 Cart: 0909-00005
Camera: 0102-00093 Cart: 0909-00039	Camera: 0102-00076 Cart: 0909-00012	Camera: 0102-00020 Cart: 0909-00009
Camera: 0102-00092 Cart: 0909-00043	Camera: 0102-00060 Cart: 0909-00013	Camera: 0102-00014 Cart: 0909-00029
Camera: 0102-00092 Cart: 0909-00043	Camera: 0102-00059 Cart: 0909-00016	Camera: 0202-00115 Cart: 0912-00002
Camera: 0102-00090 Cart: 0909-00044	Camera: 0102-00056 Cart: 0909-00034	Camera: 0202-00114 Cart: 1112-00001
Camera: 0102-00089 Cart: 0909-00042	Camera: 0102-00055 Cart: 0909-00035	Camera: 0202-00054 Cart: 0909-00032
Camera: 0102-00088 Cart: 0909-00041	Camera: 0102-00054 Cart: 0909-00030	
Camera: 0102-00087 Cart: 0909-00004	Camera: 0102-00047 Cart: 0909-00024	

The serial numbers (SN) can be found on the back of the camera or on the back of the cart.





Defect description und cause:

While using the TIVITA camera system, the upper end of the arm element broke, which is directly attached to the cart, causing the other two arm elements, including the camera, to fall down. If the arms are aligned in an unfavorable position, a lever is created which can lead to this defect.

In the worst case, a recurrence of such a defect may endanger the operator or the patient.

Recommended actions:

- Please check the affected arm segment (Figure 1) for possible damage before each use of the camera.
- If obvious damage (missing screw, broken arm, etc.) can be detected, please refrain from using the system and contact us.
- **If there are no recognizable defects, you can use the system as usual!**
- Please avoid the arm position shown in Figure 2.
- If possible, try to replace arm elements 1 and 2 (Figure 3).
- We are working on a new solution for this element. As soon as a working solution is available, we will inform you about the next steps.

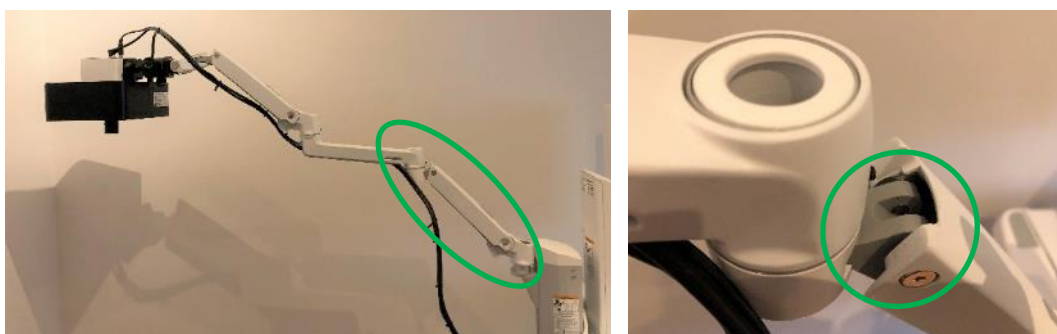


Figure 1: affected arm segment to be visually inspected

Diaspective Vision GmbH

Strandstraße 15
D-18233 Am Salzhaff
Phone: +49 38294 1667 60
E-Mail: office@diaspective-vision.com
Internet: www.diaspective-vision.com

Geschäftsführer: Dr. Axel Kulcke

Registriergericht Rostock: HRB 13203
St.Nr.: 079/107/07609
USt.Nr.: DE300302038

Bankverbindung

Postbank Leipzig
IBAN: DE78 8601 0090 0983 7909 00
BIC: PBNKDEFF





Figure 2: Please avoid this unfavorable positioning of the arms, as when adjusting the height of the camera in this position, high leverage forces act on the first arm element.

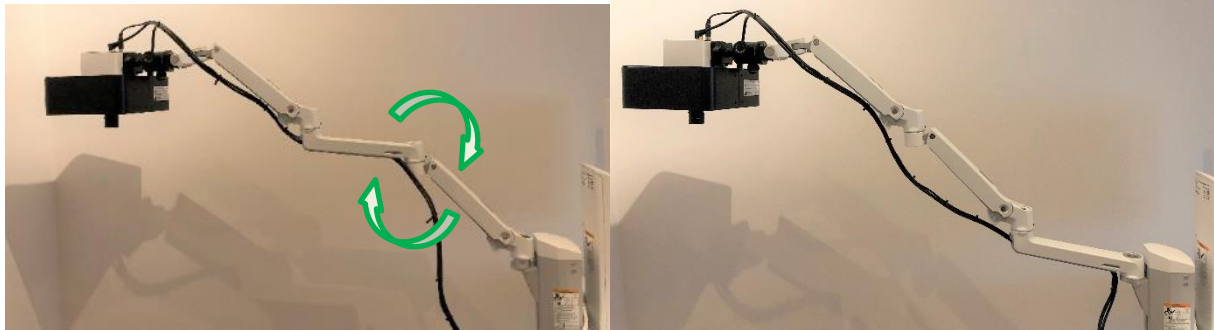


Figure 3: Exchange of the arm elements 1 and 2

Please fill out the form of confirmation for the receipt and the execution of actions and send it to one of the reference persons.

Transfer of the described information:

Please ensure that all operators and other persons in contact with the above-named products get access to the urgent field safety notice immediately. In case you gave our products to a third party, please redirect a copy of the information to them or contact our reference persons.

Please keep this information until our corrective actions are completed.

The *Federal Institute for Drugs and Medical Devices* has already received a copy of this urgent field safety notice.

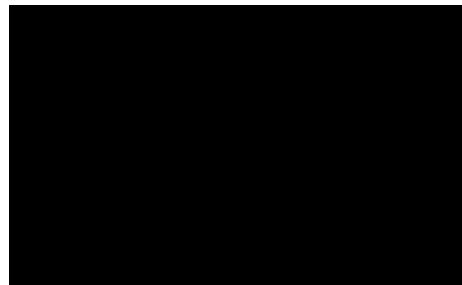
Reference Persons: Philip Wahl, Eric Beck
Monday – Friday 7:30 am – 4:30 pm
+49 38294 153730
philip.wahl@diaspective-vision.com
eric.beck@diaspective-vision.com

Thank you for your cooperation.

With best regards



Philip Wahl
-Safety officer for medical devices-



Form of confirmation

Please fill out this form and send it to the following address or send it by e-mail:

Diaspective Vision GmbH
z.H. Herrn Philip Wahl
Strandstraße 15
18233 Am Salzhaff OT Pepelow
Germany
philip.wahl@diaspective-vision.com

I hereby declare the receipt of the urgent field safety notice regarding the repair of the TIVITA Camera systems 191007-01. I will initiate the recommended actions. Furthermore, I will inform all operators and other relevant persons about the urgent field safety notice.

At our establishment, TIVITA Camera/s with the following serial number/s is/are affected:

(Format: XXYY-ZZZZZ or T-XXXX-YYY, the serial number is on the back of the TIVITA Camera or the cart)

Institution:

Department:

Address:

Phone:

E-Mail:

Date and signature:

To be filled out by Diaspective Vision GmbH:

Date of receipt:

Name and signature

