
Urgent Field Safety Notice
Recall of TIVITA Cameras
Reference number: 190705

Diaspective Vision GmbH

Am Salzhaff, 26/07/2019

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Strandstraße 15
18233 Am Salzhaff

To distribution partners, customers und operators

Dear Ladies and Gentlemen,

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

Identification of the affected medical devices:

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

T-1608-109	0102-00011	0102-00026	0102-00053	0102-00083	0202-00107
T-1701-115	0102-00012	0102-00029	0102-00054	0102-00084	0202-00108
0101-00117	0102-00013	0102-00031	0102-00055	0102-00085	0202-00109
0101-00120	0102-00014	0102-00035	0102-00056	0102-00087	0202-00110
0101-00121	0102-00015	0102-00037	0102-00057	0103-00025	0202-00111
0101-00125	0102-00016	0102-00040	0102-00059	0103-00027	0202-00112
0101-00126	0102-00017	0102-00041	0102-00060	0103-00030	0202-00113
0102-00001	0102-00019	0102-00043	0102-00076	0103-00034	0202-00114
0102-00006	0102-00020	0102-00044	0102-00077	0103-00036	0502-00082
0102-00007	0102-00021	0102-00046	0102-00078	0202-00102	1302-00001
0102-00008	0102-00022	0102-00047	0102-00079	0202-00103	1302-00002
0102-00009	0102-00023	0102-00048	0102-00080	0202-00104	
0102-00010	0102-00024	0102-00051	0102-00081	0202-00105	

Defect description und cause:

While operating the TIVITA Camera the connecting element between retention arm and the TIVITA Camera broke. When the ball head is not properly loosened before adjusting the position of the camera there will be a strong leverage effect that can lead to the defect.

In the worst-case scenario, the recurrence of the defect could compromise the safety of the operator or the patient.



Recommended actions:

- Please send your TIVITA Camera back to us. We will exchange the concerning component. Turn off the TIVITA Camera, pull out all three cables located at the back and disconnect the TIVITA Camera from the ball head including the connecting component using a hex wrench size 4 (*Figure 1*).
- Until you send your TIVITA Camera to us, you should always loosen the screw on the ball head before adjusting the position (*Figure 2*).
- Check the concerning component for possible external damages (*yellow arrow in Figure 1*). In case of damages, stop operating the TIVITA Camera immediately.
- As soon as we receive your TIVITA Camera, we will exchange the concerning component and immediately send it back to you.

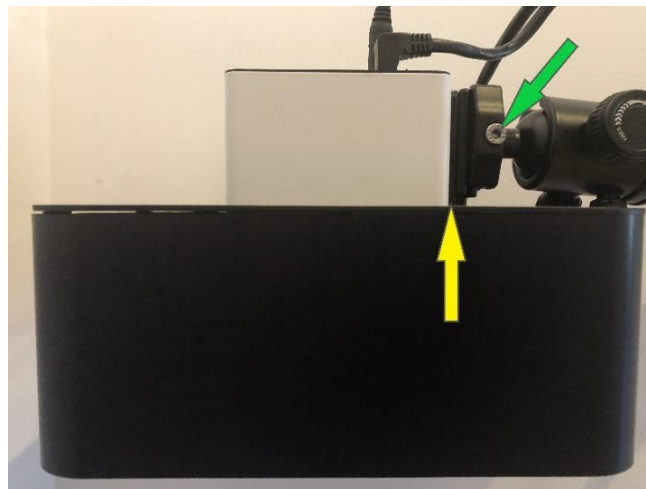


Figure 1: the green arrow marks the hex wrench for disconnecting the camera from the ball head; the yellow arrow marks the concerning component



Figure 2: the green arrow marks the screw that loosens the ball head for adjusting the position of the TIVITA Camera; the green circle marks the label where you can find the serial number

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:

Monday – Friday 7:30 am – 4:30 pm

+49 38294 153730

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Thank you for your cooperation.

With best regards

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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 recall of the TIVITA Cameras 190705. 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)

Institution:

Department:

Address:

Phone:

E-Mail:

Date and signature:

To be filled out by Diaspective Vision GmbH:

Date of receipt:

Name and signature

