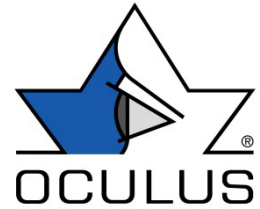


# Urgent safety information Corrective Action

Urgent – Immediate notice required

Specular Microscope CEM 530 von NIDEK Co., Ltd. Japan



OCULUS Optikgeräte GmbH, Münchholzhäuser Straße 29, 35582 Wetzlar

<Name>

<Address>

<zip code / City>

Wetzlar, 08.02.2019

**Applies to Specular Microscope CEM 530 from NIDEK Co., Ltd. Japan**

**Serial number: xxxxxx**

Dear Sirs and Madams,

we, OCULUS Optikgeräte GmbH, as importer and distributor of NIDEK Co., Ltd. Japan, sending this letter due to a Field Safety Corrective Action involving some NIDEK Specular Microscope CEM 530 devices.

You receive this Field Safety Notice because, according to our records, you are the owner of a product affected by this action.

## **Problem Description:**

It has been discovered that the NIDEK Specular Microscope CEM 530 transmits electromagnetic waves that may exceed the limits required by IEC 60601-1-2 (Electromagnetic Compatibility for electronic medical devices).

## **Risk assessment:**

Electromagnetic compatibility (EMC) refers to the ability of a technical device not to disturb other devices by unwanted electrical or electromagnetic effects (interference emission) or to be disturbed by other devices (immunity to interference).

Since the interference emitted by the NIDEK Specular Microscope CEM 530 is lower than the level of protection required for other medical devices (immunity to interference), there is currently no risk to patients, users or third parties.

There have been no reported injuries related to this issue.

## **Measures by the user:**

No special actions required

## **Measures by the manufacturer:**

The manufacturer NIDEK prepares corrective measures (replacement of the causative electronics) so that the NIDEK Specular Microscope CEM 530 can provide the electromagnetic compatibility required by the current standard.

OCULUS Optikgeräte GmbH will organize the implementation of the corrective measures planned by the manufacturer for all users affected by the problem in Germany until 30.04.2019.

An OCULUS service technician will contact you to arrange an appointment to complete the corrective action.

**Passing on the information described here:**

Please make sure in your organization that all users of the above stated products and other persons which have to be informed (such as the representative for medical product safety according to §6 MPBetreibV) receive this urgent safety notice.

If you have given the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please retain this information 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".

**Further information and support:**

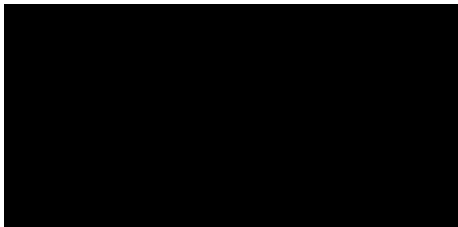
We would like to point out that OCULUS is performing these corrective actions on behalf of NIDEK Co., Ltd. Japan. Responsible for the corrective action and for the safety of the product is the manufacturer NIDEK Co., Ltd. Japan respectively the authorized representative in the European Economic Area (acc. to § 5 MPG) NIDEK SA, 13 rue Auguste Perret, 94 042 Creteil, France.

If you require any further information or assistance in connection with this issue, please contact your local OCULUS representative or the OCULUS Service at 0641-2005 800 or [service@oculus.de](mailto:service@oculus.de)

In urgent cases you can contact our safety officer for medical devices (see below).

We apologize on behalf of NIDEK Co., Ltd. Japan for any inconvenience caused by this action.

Yours sincerely



OCULUS Optikgeräte GmbH  
Münchholzhäuser Straße 29  
35582 Wetzlar  
GERMANY

Tel. +49 641 2005-470  
Fax +49 641 2005-455  
Mobile +49 151 2816 0580