



Eye & Health Care

**NIDEK CO., LTD.**

January 29, 2019

## Notification for Nidek SPECULAR MICROSCOPE

Dear QA representative

Cc to Chairman Medical Board and Head of Department

NIDEK inform you that we found Specular Microscope CEM-530 does not meet the EMC standards. Therefore it requires taking field corrective action to the devices you distributed in your country or area.

Please find below further details:

We found that electromagnetic noise (EMI: Electromagnetic Interference) for Model: CEM-530 (applicable products serial numbers are described below) has exceeded the upper limit of the Electromagnetic Compatibility Standard (EMC: IEC 60601-1-2) while at the same time, medical electrical device is required not to erroneously operate from external electromagnetic noise under EMC standard.

< Electromagnetic noise strength for CEM-530 against EMS standard of each product >

- Medical Electrical Device (Medical Equipment) :1 / 230
- Implant Device (Pacemaker etc.) :1 / 1230

Therefore, it is unlikely that other medical electrical devices (Medical Equipment) will be affected even if they are placed close to CEM-530 and it is unlikely that CEM-530 is hazardous to health.

We are preparing the countermeasure on this problem.

Nidek will be reaching out to you within next month to provide instruction for this correction.

< Applicable Products Serial Number >

Model: CEM-530 [REDACTED]

<Contact information> Nidek Singapore Pte Ltd

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We sincerely apologize for your inconvenience. Your kind understanding and cooperation will be most appreciated.

Acknowledged by

[REDACTED]

Hiroshi Shimazaki  
Corporate Officer and General Manager  
Quality Assurance Division

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Name:  
Designation:  
Date: