

Urgent Field Safety Notice

Commercial name of the affected product

Ophthalmic Data System IMAGEnet 6

FSCA-identifier

GVP-2019-IMAGEnet 6-001

Type of action

Advice given by MANUFACTURER regarding the use of the device

Date: 15 April 2019

Attention: Users of these devices

Details on affected devices:

Type of device : Ophthalmic Data System

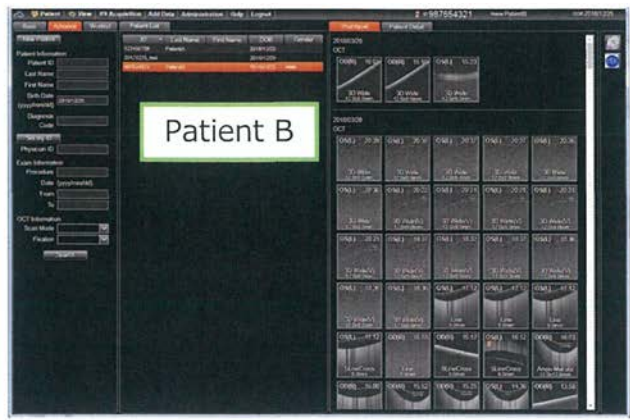
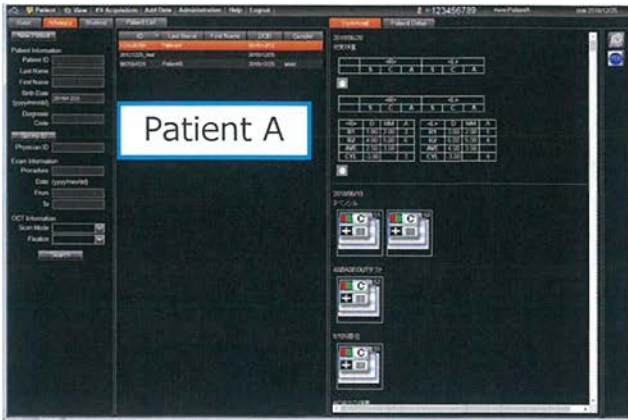
Model number : IMAGEnet 6

Affected Version : Please see the Attachment 1.

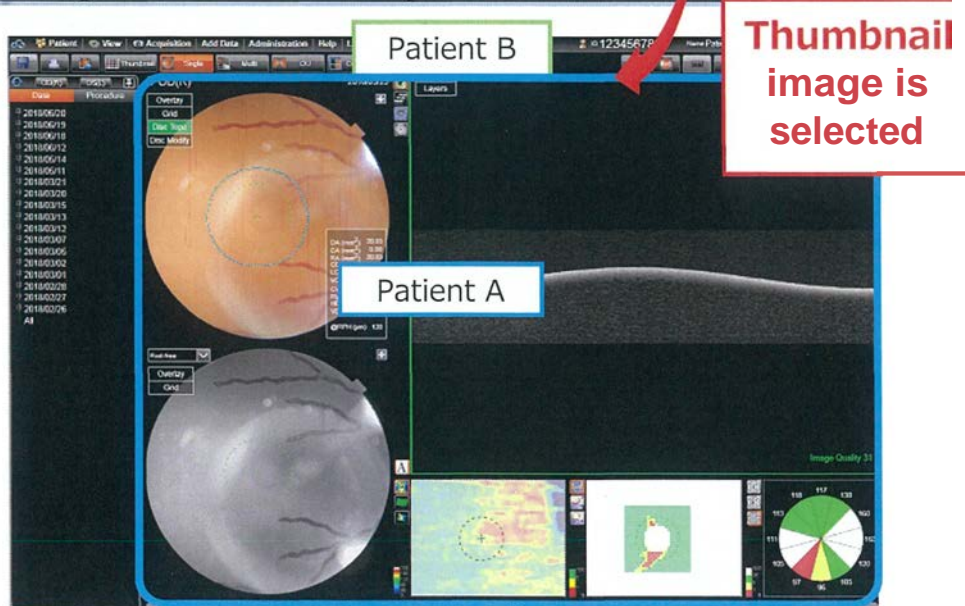
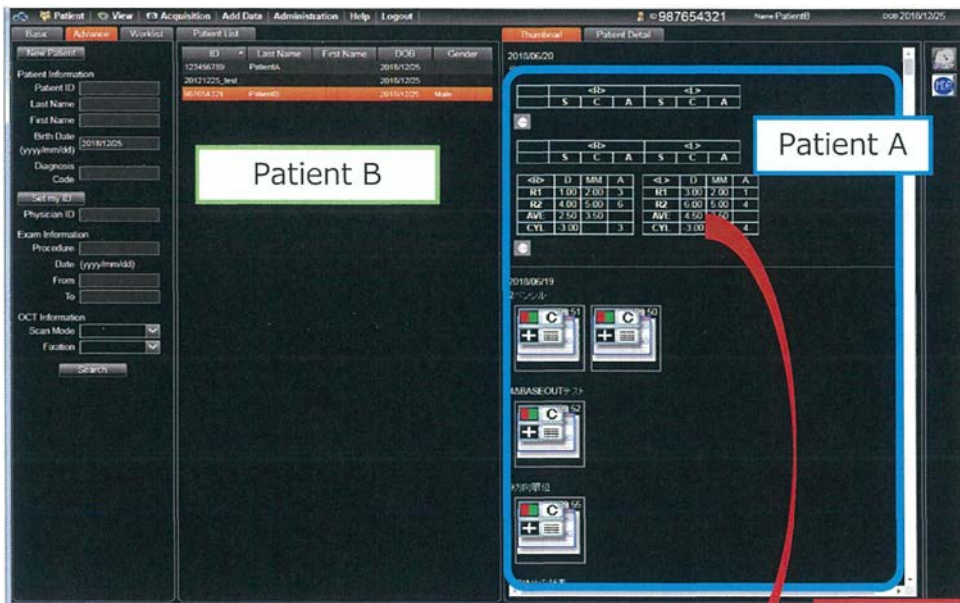
Description of the problem:

The IMAGEnet 6 Ophthalmic Data System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices. It is intended for processing and displaying ophthalmic images and optical coherence tomography data.

TOPCON recognized that during viewing OCT (Optical Coherence Tomography) image with IMAGEnet 6, the scans of a patient under the name of another patient was shown.



After selecting "patient A" in patient selection, if another patient "patient B" is selected before the thumbnail image of "patient A" is displayed, an inconsistency may occur between the patient name "patient B" and the thumbnail image "patient A".



This only occurs when the following conditions are met

1. Number of data registered per patient: generally 600 data or more
2. Time interval of selecting patient B before the thumbnail image of patient A is displayed: within 1 second (depending on the speed of the computer)
3. When thumbnail image is selected without noticing the inconsistency

Advise on action to be taken by the user:

- The corrected IMAGEnet 6 version 1.24.1 has been released. We will arrange the upgrade as the Field Safety Corrective Action. This action being taken by the service engineer of your Topcon representative.
- We will contact you to schedule the upgrade of IMAGEnet 6. Once the upgrade will be finished then your reply will be required for the "Closing Confirmation Sheet". Please follow to the service engineer's guidance.
- Meanwhile, during use of IMAGEnet 6, please do not select the other Patient until the sequence of thumbnail images in the Examination data Panel is finished after selecting a Patient from the Patient List Panel.
- Please double check that the image matches what is expected for the patient being imaged.
- You can recognize the discrepancy between Patient Information and displayed Images. Then no examination date of selected data is highlighted in orange in the Examination list panel. If this discrepancy occurs, then please refresh the page to correct the issue temporarily.
- If you have the disk of IMAGEnet 6 Ver 1.24 or previous, then it no longer can be used. Please do not install once again.

Contact reference person:

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Sincerely yours,

Affected Version number of IMAGEnet 6

| | | | | | | | | | | |
|------|------|------|--------|------|------|------|--------------|--------------|--------------|----------|
| 1.00 | 1.01 | 1.02 | | | | | | | | |
| 1.10 | 1.11 | 1.12 | 1.13 | 1.14 | 1.15 | 1.16 | <u>11.17</u> | <u>11.18</u> | <u>11.19</u> | <u>1</u> |
| 1.20 | 1.21 | 1.22 | 1.22.1 | 1.23 | 1.24 | | | | | |