Urgent Field Safety Notice

Commercial name of the affected product,
3D Optical Coherence Tomography DRI OCT Triton / DRI OCT Triton plus
(plus is a catalogue number)

FSCA-identifier:
GVP-2018-Triton-001

Type of action
device modification

Date: 10 January 2018

Attention: Users of these devices

Details on affected devices:

Type of device: 3D Optical Coherence Tomography

Model number: DRI OCT Triton / DRI OCT Triton plus (plus is a catalogue number)

Serial number(s): Please see the Attachment 1

Description of the problem:

We have been aware following defect of "3D Optical Coherence Tomography DRI OCT Triton / DRI OCT Triton plus". As the result of phenomenon confirmation and investigation of the cause, we found that this phenomenon occurs according to the bug of embedded Firmware Ver. 1.13. We will do the correction of this defect by the software upgrade as voluntary field correction.

We apologize for any inconvenience this product update may cause you. Our goal is to ensure that your instrument continues to be as reliable as possible.

Phenomenon:

Under the firmware version 1.13, when the device is in a power save state, the Left & Right eye information based on the Main unit's position is stored in the device data. A software bug can arise when moving the Main unit to the opposite position in the power save state. When a new image is taken after cancelling the power save state, the device

has been observed to display the Left & Right eye information from the previous image instead of the new image, therefore providing inaccurate Left & Right eye information.

Advise on steps to be taken by the user:

1. Check the Triton Serial number with the list in Attachment 1 of this FSN.
2. If there is a Serial number match; check embedded firmware version of this Triton. This firmware version is shown at the start-up screen of the Triton.
3. If this embedded firmware version is version 1.13; Ensure that the power save mode is switched off:
   a. Go into the Triton setting menu.
   b. Go to page 4
   c. Set the value of "power save time" to "0 minutes"
   d. Please keep "power save time" to "0 minutes" to keep the power save mode switched off until following steps will be taken by a certified Service engineer.

Advise on steps to be taken by a certified Service engineer:

1. Check the Triton Serial number with the list in Attachment 1 of this FSN.
2. If there is a Serial number match; be sure to complete the following :
   a. If the embedded firmware version of the Triton is version 1.13; Upgrade the Triton to firmware version 1.14
   b. Check all effected Triton data by using the tool, provided by the manufacturer.
   c. Send Closing Sheet, layout shown in Attachment 2 of this FSN, together with the log file to mentioned contact persons.

Contact reference person:

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Sincerely yours,

Tadahiko Horiuchi

Senior Manager

Quality Assurance Department

Quality Assurance Division

TOPCON CORPORATION

Attachment 1 of FSN GVP-2018-Triton-001

3D Optical Coherence Tomography DRI OCT Triton
101029, 107057, 107091, 107118, 107129, 107137, 107142
307001, 307003, 307004, 307010, 307028, 307046, 307050, 307062, 307065, 307072, 307073
980002, 980011, 980014, 980015, 980016, 980017, 980018, 980021, 980029, 980030, 980039,
980047, 980062, 980076, 980080, 980082, 980091, 980092, 980122, 980135, 980230, 980235,
980293, 980294, 980297, 980330, 980330, 980369, 980375, 980384, 980386, 980401, 980454,
980476, 980477, 980478, 980503, 980514, 980527, 980529, 980576, 980592, 980605, 980611,
980622, 980630, 980634, 980638

3D Optical Coherence Tomography DRI OCT Triton plus
201009, 207062, 207063, 207065, 207066, 207068, 207078, 207093, 207113, 207114
801084, 801257, 807002, 807009, 807011, 807029
990004, 990009, 990010, 990024, 990036, 990046, 990065, 990077, 990080, 990083, 990084,
990102, 990118, 990119, 990122, 990128, 990134, 990136, 990137, 990140, 990141, 990142,
990143, 990177, 990196, 990203, 990210, 990218, 990225, 990250, 990254, 990268, 990273,
990277, 990290, 990293, 990306, 990309, 990329, 990334, 990335, 990338, 990343, 990347,
990356, 990366, 990369, 990372, 990375, 990381, 990396, 990400, 990404, 990419, 990427,
990420, 990440, 990443, 990477, 990480, 990482, 990483, 990488, 990494, 990498, 990499,
990419

TMD-006
Rev.0

Closing Confirmation Sheet

DRI OCT Triton, DRI OCT Triton plus Software, Ver.1.1.4

Customer name		Installation date	/ / /	
		Agency/Supplier	Business office	
Address				
		The body model:	The body S/N:	
TEL ( ) —				

● **Version Up check procedure of a software**

	Procedure item	Check point	PASS	FALL
1	It be Ver1.1.3 in front of Version Up. (Select "information" from the "SETUP" menu.) Basic Serial No Region Code System 1.1.3 OCT Capture Count Fundus Capture Count	It's confirmed that it's a repair target.	☐	☐
2	Version Up, error confirmation	An error message don't be indicated.	☐	☐
3	Version behind Version Up be Ver.1.1.4. (Select "information" from the "SETUP" menu.) Basic Serial No Region Code System 1.1.4 OCT Capture Count Fundus Capture Count	Make sure that the version information is as follows. System 1.1.4	☐	☐
4	Checking existing data	Check existing data by the tool software "PowerSaveLRChecker". If wrong data exist make necessary correction. Nuber of checked images Hours taken for the check	☐	☐

Comment

Name	Signature	Initials	Date
TESTING PERFORMED BY			
CUSTOMER			