



URGENT FIELD SAFETY NOTICE

August 17, 2010

**Product Name: iVue
Model: iVue100**

[FIRST] [LAST NAME], XX
[ADDRESS 1]
[ADDRESS 2]
[CITY, ST XZIPX]

Dear Dr. _____,

This letter is to inform you of a hardware and software update we are providing for your iVue OCT system. This update is to mitigate the possibility of a positioning anomaly for the iVue scanner head when using the CAM attachment.

We have identified an atypical situation where an aspect of the joystick base assembly might cause a scanned eye identification error. This affects a particular scan requiring the CAM attachment.

If you are using the CAM attachment and attempting to perform a temporal angle scan of the patient's left eye and: 1) the scanner is moved to the extreme right stop position and: 2) within an area between 145mm and 153.8mm from the chinrest support and: 3) not moved more than 9.3mm from the right stop and: 4) the patient is misaligned in the chinrest / forehead rest with their head pulled back away from the headrest and: 5) their head is tilting significantly to the left. If all these conditions are met, the system may register the eye being scanned as OD (right) instead of OS (left). The low probability of such occurrence presents a relatively low risk.

There is a low hazard risk to the general population. Clinical diagnoses are made in the context of all relevant clinical information and slit lamp examinations. Clinical decisions are not made solely on the results of the iVue Scan for diagnostic decision.

In an atypical scenario when this might occur on a retina scan, given the fact that the captured and stored "en face" image - as well as all retina B-scans would show the physiology and layer information of the left eye, you would be able to easily determine which eye is being reviewed.

You may continue to use the iVue until the correction has been made; however, refer to the en face image to verify the eye which was scanned. The Optovue representative who delivered this letter will rework or exchange the joystick base assembly of your iVue OCT system. This will eliminate any possibility of this incorrect identification of eye to occur within this set of circumstances. Our representative will also update the iVue application software which will add an additional protection to prevent any possible incorrect designation from any type of situation.

You must also review any existing iVue patient data to ensure that this situation and an improper designation of eye assignment has not occurred. Upon completion of the updates, you will need to sign the attached form indicating you acknowledge that your iVue has been updated and you understand that you must review existing data. Our representative will return all required paperwork to the company.


All National Competent Authorities have been notified regarding this incident.

If you have any questions regarding these issues, please contact Optovue by phone at 1-866-344-8948, by mail at 45531 Northport Loop W, Fremont, CA 94538.

Outside of US please contact your local distributor for additional information regarding this corrective action.

You may also contact our Authorized Representative MDSS GmbH situated in Germany via email at info@mdss.com or via phone at +49 511 6262 8630.

Sincerely,


Vice President Regulatory & Clinical Affairs
Optovue, Inc.

Attachment Form



Purpose:

Signing this form verifies the OU assembly is operating as intended after software is updated and XYZ Base rework is completed (if required).

Procedure:

Testing of Software Update

1. Start a scan when scanner is to left side of operator, registers Right / OD.
2. Click Joystick button to stop scan and immediately move scanner to right side of operator.
3. After scan saved verify scan remains registered as Right / OD.
4. Start new scan when scanner is to right side of operator, registers Left / OS.
5. Click Joystick button to stop scan and immediately move scanner to left side of operator.
6. After scan saved verify scan remains registered as Left / OS.

Testing of Mechanical Rework (if required)

NOTE: The testing will require the operator to run the joy stick with very slow movements.

1. Start a scan and move the scanner all the way back towards the operator.
2. Move with scanner all the way to operators left and verify the sensor reading indicates Right / OD.
3. Move scanner to the operators right, verify the sensor reading changes to indicate Left / OS.
4. Slowly move the scanner forward toward the chinrest.
5. If scanner can be moved forward all the way to the mechanical stop without this indication changing even briefly to Right / OD this system is operating properly.

Customer Name: _____ Title: _____

Customer Signature: _____

Verified by Name: _____

Verified by Signature: _____

Date: _____