



## **ADVISORY NOTICE**

### **Abbott Medical Optics (AMO) Catalys® Precision Laser System**

**March X, 2015**

Dear CATALYS® System Customer:

Abbott Medical Optics (AMO) is providing this Advisory Notice to all customers who use the CATALYS® System software version 3.00.05 to make you aware of two issues. This Advisory Notice is to reinforce instructions provided in product training and within the existing Operator Manual.

First, a remote, low probability event has been identified where loss of suction during treatment may result in scoring the cornea during lens fragmentation.

The CATALYS® System has mitigations within its design to prevent this event from occurring, including vacuum sensors that continuously monitor the system vacuum level to the patient interface and force sensors that continuously monitor the forces on the patient interface. If the system detects a loss of vacuum or forces outside of the acceptable range, the system will stop the laser from activating during treatment and displays a message.

To prevent this low-likelihood event, follow the instructions for treatment continuation as described in the Operator Manual, specifically:

- Continuously monitor the video image immediately before and throughout each laser treatment, observing for bubbles or other indications of a suction loss. If a bubble or abnormality is observed, remove your foot from the laser foot pedal immediately to stop the laser treatment.
- Verify that the LIQUID OPTICS Interface remains completely filled with sterile balanced saline solution throughout the entire procedure.

In the event that the CATALYS® System detects forces outside of the acceptable range or loses suction during laser treatment, follow the instructions for treatment continuation as described in the Operator Manual or consider reverting to traditional cataract surgery. If the laser treatment has not started, check the fluid catchment and consider reapplying the suction ring to the patient's eye.

Second, another remote, low probability event has been identified for the cataract incision surgeon templates with software version 3.00.05, when selecting and deselecting an eye then selecting the other eye will result in templates for both eyes having the same parameters. This event only affects the cataract incision surgeon templates.

To prevent this low-likelihood event:

- a. Verify the cataract incisions in the cataract incision surgeon templates have the correct parameters, correct architecture and are in the desired location prior to saving.
- b. Within the treatment planning phase and prior to activating the laser, verify all treatment incisions have the correct parameters, correct architecture and are in the desired location which are displayed on the screen.

In AMO's ongoing commitment to safety, AMO will provide an update to the software, to resolve the template issue.

### **REQUIRED SITE ACTION**

For surgeon at your site, complete and return the attached form to AMO via fax at 6297 0684 or return to our Representative within the next 3 business days as an acknowledgement of:

- Receipt of this advisory notice
- Understanding of the information contained within this letter

Please share the information in this Advisory Notice with your staff. AMO appreciates your attention to this issue, and we apologize for any inconvenience this action may cause.

If you have any questions related to the operation of CATALYS® Precision Laser System or the documentation requirements associated with this letter, please call +65 9003 5073 and you will be directed to an AMO representative who will be pleased to assist you.

Very truly yours,

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Christy Ren  
Country Manager  
AMO Singapore Pte. Ltd

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Leonard Chang  
Regional QA Manager  
AMO Singapore Pte. Ltd



## CATALYS® System Notification Acknowledgement

Potential for Corneal Scoring due to Suction Loss: CA12-0115

Potential for Incorrect Cataract Incision Surgeon Template data: ER367199

### Site Information – REQUIRED

Catalys System Serial Number: \_\_\_\_\_

Account Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City, Postal Code: \_\_\_\_\_ Country: \_\_\_\_\_

**Company Stamp:** \_\_\_\_\_

I certify that I have been informed of the Potential for Corneal Scoring due to Suction Loss and Potential for Incorrect Cataract Incision Surgeon Template data related to the Catalys System.

1	Physician Name: <b>PRINT</b>		6	Physician Name: <b>PRINT</b>	
	Physician Signature:			Physician Signature:	
	Date Signed:			Date Signed:	
2	Physician Name: <b>PRINT</b>		7	Physician Name: <b>PRINT</b>	
	Physician Signature:			Physician Signature:	
	Date Signed:			Date Signed:	
3	Physician Name: <b>PRINT</b>		8	Physician Name: <b>PRINT</b>	
	Physician Signature:			Physician Signature:	
	Date Signed:			Date Signed:	
4	Physician Name: <b>PRINT</b>		9	Physician Name: <b>PRINT</b>	
	Physician Signature:			Physician Signature:	
	Date Signed:			Date Signed:	
5	Physician Name: <b>PRINT</b>		10	Physician Name: <b>PRINT</b>	
	Physician Signature:			Physician Signature:	
	Date Signed:			Date Signed:	

Please return this completed fax acknowledgement to AMO within THREE business days.

**Return Fax to: 6297 0684 or to an AMO Representative**