



ADVISORY NOTICE
Abbott Medical Optics (AMO) STAR Excimer Laser System
Models S2, S3, S4 and S4 IR

September XX, 2013

Dear STAR Excimer Laser Customer:

Abbott Medical Optics (AMO) is providing this Advisory Notice to all customers who use the AMO STAR S2, S3, S4 and S4 IR Excimer Laser Systems to make you aware of an issue that has the potential to result in loss of illumination due to an unexpected failure of a component under high use conditions of the oblique and ring illumination lamps. This issue can be traced to a specific component found in a limited amount of STAR systems.

In AMO's ongoing commitment to safety, if your system is found to have the component we will be replacing a printed circuit board in the laser at the next service visit at no additional cost to you. In the unlikely event that the STAR system loses both oblique and ring illumination, contact an AMO service representative for assistance. AMO recommends using the lowest level of illumination required during the patient treatment in order to reduce high use conditions caused by the oblique and ring illumination lamps being on simultaneously. It is recommended that only two oblique lamps be used (not activating the optional third oblique lamp) in order to further reduce the remote possibility of complete illumination loss.

For each surgeon at your site, complete and return the attached form to AMO via fax at [Insert regional fax number] 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. AMO is committed to providing you with state-of-the-art technology that allows you to perform the safest and most effective laser vision correction treatments possible and as such, we are constantly improving our technology and ensuring it always meets our mutual high quality standards. We appreciate your cooperation in these efforts.

If you have any questions related to the operation of STAR Excimer Laser System or the documentation requirements associated with this letter, please call [Insert regional contact information] and you will be directed to a representative who will be pleased to assist you.

Thank you,

[Insert regional QA contact name]
Abbott Medical Optics Inc.



Star Notification Acknowledgement
Potential Loss of Illumination: 347118

Site Information – REQUIRED

Star System Serial Number: _____

Account Name: _____

Street Address: _____

City, Postal Code: _____

Country : _____

I certify that I have been informed of the Potential Loss of Illumination Advisory Notice related to the STAR S2, S3, S4, and SR IR Systems.

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

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

[Insert regional fax number]