«Account_Name»
«Salutation» «Degree» «First_Name»
«Last_Name»
«Account_Street_Address»
«Account_Postal_Code» «Account_City»

Name: Dr. Sebastian Broy
Department: Quality Assurance
Phone: +49 (0) 761 1304 331
Fax: [redacted]
E-Mail: [redacted]

Date: July 31st, 2017

Voluntary Medical Device Correction

Alcon ORA Cart with VerifEye

Dear Valued Alcon Customer,

This letter is intended to notify you that Alcon has initiated a Voluntary Medical Device Correction for the ORA System® with VerifEye® and the ORA System® with VerifEye®+ to address a software coding error that may affected an ORA Cart located at your facility.

The ORA System is designed to be used during ophthalmic surgery. It is intended for use in the measurement and analysis of the refractive power of the eye (i.e., sphere, cylinder, and axis measurements).

Alcon has identified the following ORA Cart(s) within your facility:

Product	Catalog Number
Alcon ORA Cart with VerifEye	8065998300

Description of the potential condition:

Through remote monitoring of the intraocular lens (IOL) databases on installed ORA Carts, Alcon has determined that a small number of ORA Carts have the potential to return an incorrect IOL power measurement during cataract surgery. This issue appears to have been caused by a software coding error that results in the lens coefficients for an IOL model being downloaded from Alcon's server in an incorrect order. In the small number of affected ORA Carts identified to date, this issue has affected only a single IOL model. If the surgeon chooses to implant a particular IOL power based on an ORA calculation with an incorrect lens coefficient, the patient may not achieve the intended refractive outcome, and additional refractive correction and/or surgical intervention potentially could be needed.

The software coding error that results in the lens coefficients for an IOL model being downloaded from Alcon's server in an incorrect order occurs only when the IOL database on the ORA Cart is updated as part of the lens optimization process. As such, we will cease further

lens optimization updates for the ORA System until we are able to implement a software update to address the software coding error.

Action to be taken by the user:

You are receiving this letter because Alcon has not been able to assess the IOL database on your ORA Cart remotely. Out of an abundance of caution, we request that you stop using the ORA system for IOL power calculations until Alcon can confirm that this software coding error does not affect your ORA Cart.

Currently we are evaluating which systems are affected. Please excuse any arising inconveniences. We will inform you about further steps as soon as possible.

If your ORA Cart is among those that are affected by the software coding error, Alcon will communicate additional information about which IOL models are affected by the error, and will schedule a service call to replace the database on your ORA Cart at your earliest convenience.

Alcon is requesting that you acknowledge receipt of this letter by completing the attached Acknowledgement form and returning it to Alcon via fax or e-mail.

Transmission of this Voluntary Medical Device Correction:

Please immediately forward this information to all departments within your organization who may be using the ORA Cart identified above. If you have transported this ORA Cart to another location, please provide a copy of this notification to the recipient(s) to make them aware of the Voluntary Medical Device Correction and the requested actions.

Contact reference person:

It is important to Alcon that our patients and customers have a safe, positive experience with our products. We appreciate your cooperation with this voluntary medical device correction and apologize for any inconvenience. If you have any questions or concerns, please contact

Mr. Dr. Sebastian Broy available by phone: +49 (0) 761 1304 – 331
Mrs. Dr. Inga Hoffmann available by phone: +49 (0) 761 1304 – 421.

Sincerely,

Alcon Pharma GmbH

b.o.

Dr. Sebastian Broy
Quality Assurance Specialist

b.o.

Dr. Inga Hoffmann
Quality Assurance Specialist

Attachment: Acknowledgement Form

ACKNOWLEDGEMENT FORM

Corrective Action

Alcon ORA Cart with VerifEye

Stop using your ORA Cart for IOL power calculations until Alcon has confirmed that the software coding error does not affect your ORA Cart. 1) Return this completed Acknowledgement Form via fax or email to Alcon **Fax: +49 (0) 761 1304 200** **E-Mail: fbalde.00063@alcon.com** Your signature below attests that you have read and understood this Alcon Voluntary Medical Device Correction.
Signature of Facility Representative:
Printed Name and Title:
Date:

«Act_Name»
«Address»
«City», «State» «Postal_Code»
«Doctor_or_Contact_Name_First» «Doctor_or_Contact_Name_Last»
Account # «Account_Number»
«Phone_»