Tuesday, 06 December 2022

Field Safety Notice

RayOne EMV RAO200E A-Constant Incorrect on some Biometers – Update to Biometers Required

Dear Customer,

Healthcare professionals are advised that Rayner has identified that the Barrett Universal II Lens Factor (LF) and Design Factor (DF) values for RayOne EMV from the website IOL con (https://iolcon.org) had been inverted (i.e., LF = 0 and DF = 1.67 as opposed to correct value LF = 1.67 and DF = 0) and appeared incorrectly (i.e., 1.7 instead of 1.67). Various biometry devices use the data provided by IOLcon. It has come to our attention in certain markets that some biometers are using download data from the site prior to February 2022 which potentially may generate incorrect patient outcomes for RayOne EMV RAO200E.

The correct Barrett Universal II values for RayOne EMV are: LF = 1.67 and DF = 0; they can also be found on www.rayner.com and/or https://IOLcon.org.

The impact for patients of the flipped constants could be a post-operative refractive error of up to ±3.0 D across the power range.

We advise you to verify the entered LF and DF constants on your biometer are as above in the IOL Management settings menu. The correct Barrett Universal II LF and DF constants for RayOne EMV RAO200E need to be entered in the biometry device (please check your instructions for use of the biometer or call your local representative for support).

The risk to patient visual acuity does not apply if A-Constant values for RayOne EMV RAO200E have been sourced from www.rayner.com or downloaded from https://IOLcon.org after February 2022 or have been manually input into a biometer.

Information for optometrists and surgeons:

Please be aware of the potential for an unexpected refractive outcome being reported by your patient. Please notify Rayner of any such reports via e-mail to feedback@rayner.com.

Please note that the constants indicated for all Rayner lenses are estimates and are for guidance purposes only. Surgeons must always expect to personalise their own constants based on initial patient outcomes, with further personalisation as the number of eyes increases.

Healthcare professionals and surgeons are advised to treat any patient reporting a refractive outcome as per standard procedures, exercising clinical judgement.

Should you have any questions or concerns regarding this notice, please do not hesitate to contact Rayner's Vigilance Team on feedback@rayner.com.

Best Regards,

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Vigilance Manager

Rayner Intraocular Lenses Limited
10 Dominion Way, Worthing, West Sussex,
BN14 8AQ, United Kingdom.
Registered in England: 615539.

Main office enquiries: +44 (0) 1903 258 900
Email: iol_enquiries@rayner.com
rayner.com

EC Representative
Rayner Surgical GmbH, Rudower Chaussee 9,
D-12489 Berlin, Deutschland.

Recall Response Form

☐ I have read and understood the contents of this Field Safety Notice	
☐ I have notified all affected persons of this Field Safety Notice	
☐ I have checked the RayOne EMV RAO200E LF and DF constants on the biometer and updated if required	
Facility name:	
Name and title of person completing form:	
Signature:	
Date	
Please return the completed form by e-mail to feedback@rayner.com or by fax to +44 (0) 1903 751470.	