



medical systems, inc.

Bringing Insight Into Vision

5775 West Las Positas Blvd. • Suite 200 • Pleasanton, CA 94588-4084 • (800) 215-6005 ph(925) 463-7984 fx(925) 251-0078 • www.claritymsi.com

English

URGENT SAFETY ALERT

SOFTWARE ANOMALY: Patient Age Calculation

RetCam3, RetCam Shuttle, RetCam Portable

With Software Versions 6.0.x, 6.1.x, and 6.2.x

Our records indicate that you have a RetCam Ophthalmic Imaging System inclusive of software version 6.0, 6.1, or 6.2 installed.

Clarity has recently identified a software anomaly that impacts these three software versions. Under certain conditions, the display may show the calculated age of the patient to be 2 weeks less than the actual age. This miscalculation occurs at certain time intervals. This anomaly does not affect the entered date of birth. It has no impact on any other functions of the RetCam system. There have been no reported injuries.

What should you do:

1. Do not rely on the RetCam Ophthalmic Imaging System for calculating the patient's age.
2. Use the entered birth date to calculate the patient's age.
3. Any medical decisions (e.g. timing of a screening) that were based on the age as calculated by RetCam should be reviewed.

Clarity is developing a software solution to remedy this anomaly. We will contact you again within a few weeks with additional information. There will be no charge to you for this correction.

We apologize for any inconvenience. If you have any questions or concerns, please contact



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FIELD SAFETY NOTICE CUSTOMER RESPONSE FORM

I have received, read and understand the content within the Field Safety Notice (FSN) ref Clarity P/N 30-000154

I acknowledge Clarity's instructions to stop using the patient age dating application.

HealthCare Facility Name:	
Address:	
NAME: (PRINT)	
TITLE: (PRINT)	
SIGNATURE:	
DATE:	

**** IMPORTANT: Please complete this "FIELD SAFETY NOTICE CUSTOMER RESPONSE FORM" and return the signed and dated response form WITHIN 10 DAYS OF RECEIPT:**

FAX _____

Email _____

Complete this form regardless of whether your system is still in use at your facility.

English