

***Please note: A copy of Innovative Imaging Inc.'s response follows the full report.***

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## **ECRI Hazard Report 2005-A-37**

### **Mismeasurement Using an Ophthalmic Ultrasound Scanner Results in Repeat Surgical Procedure**

#### **PROBLEM:**

A member hospital reports that an error in measuring the axial length of a patient's eye led to the implantation of an inappropriate intraocular lens (IOL) following cataract removal. The problem was discovered when the patient, a 35-year-old female, exhibited poor visual acuity during a follow-up examination. The scanner that was used in the reported incident can take an axial-length measurement in either of two ways. In this case, the scanner was set for one measurement method, but the other method was actually used. The resulting mismeasurement caused an inappropriate IOL to be chosen; consequently, the patient's postoperative vision was 20/300. The patient consented to a second surgery, which successfully corrected the error, resulting in 20/30 vision. The ultrasound measurements were performed with a model I<sup>3</sup>System-ABD scanner manufactured by Innovative Imaging. However, other similar devices from the same or different manufacturers may also be subject to this problem.

#### **DISCUSSION:**

During routine cataract surgery, the natural lens of the eye is replaced with an artificial lens. The focal-length parameters of the replacement lens are determined preoperatively using ultrasound A-scan (amplitude-scan) biometry, which measures the eye's axial length. In this technique, amplitude waves representing the echoes of each acoustic interface are displayed on the scanner. Electronic cursors are automatically positioned on the echoes from the cornea and retina, providing an axial-length measurement. The accuracy of A-scan measurements and IOL calculations is determined mainly by the use of proper measurement techniques and interpretation by a trained biometrist. Two different measurement techniques are currently in use: contact and immersion. In the contact method, an ultrasound probe is placed directly on the cornea. However, with this method, it is possible to inadvertently exert slight pressure on the cornea's surface, distorting the axial measurement. Consequently, the immersion method is more commonly used; it is accomplished by placing a scleral shell between the eyelids, filling it with saline, and immersing the ultrasound probe in the fluid. This still provides effective acoustic coupling but eliminates corneal compression because the probe does not touch the cornea. A switch on the scanner is used to select the contact or immersion operating mode, configuring the scanner's measurement and lens-calculation parameters. However, if the selected operating mode does not match the actual technique used, as happened in the reported incident, the measurements of the eye's axial length will be wrong, as will the resulting IOL calculations. On some scanners, the printout of the scan will include text indicating the type of scan that was performed. Checking the printout will allow users to verify the switch position that was used, and thus the accuracy of the measurements, before surgery begins.

**RECOMMENDATIONS:**

1. Determine whether your ultrasound scanners perform automatic measuring and thus might be susceptible to the mismatching described in this article.
2. Before performing A-scan biometry, be sure to verify the position of the contact / immersion switch.
3. When performing measurements, ensure that the anterior electronic cursor is positioned on the corneal echo and the posterior cursor on the retinal echo on the display.
4. After performing the procedure and before cataract surgery, verify the switch position used by observing the appropriate text on the printout of the A-scan (if provided).
5. Owners of an I<sup>3</sup>System-ABD scanner earlier than version 5.02 should purchase and install a \$500 software upgrade from Innovative Imaging. The upgrade is primarily intended to provide updated IOL calculation tables, but it also includes a modification to the data displayed on the A-scan monitor. With the modification, the monitor will display either "IMMERSION A-SCAN" or "CONTACT A-SCAN," depending on the position of the mode switch. Having this onscreen text available should help reduce erroneous measurements.

**UMDNS term.** Scanning Systems, Ultrasonic, Ophthalmic  
[11-389]

**Supplier.** Innovative Imaging Inc. [174830], Sacramento, California (USA); +1 (800) 765-7226, +1 (916) 363-0774;  
[www.innovative-imaging.com](http://www.innovative-imaging.com).

Note, however, that ophthalmic ultrasound scanners from other suppliers may also be subject to the problem described in this article.

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# RESPONSE by Innovative Imaging Inc. To ECRI Hazard Report 2005 A-37

## HISTORY OF INCIDENT

A technician, who had successfully used our I<sup>3</sup>SYSTEM-ABD™ for A-scan biometry for nearly 2 years, had an incident that resulted in a report by the ECRI. Apparently, someone used the instrument in the contact mode and did not reset the caliper positions for the immersion mode which was normally used. During axial length measurements in the immersion technique, the technician did not detect the improper caliper placement or the notation of "Contact" technique on the display screen. Consequently, the incorrect IOL was implanted resulting in a second surgery to exchange the IOL.

The technician should be commended for his diligence in reporting the incident as well as his commitment to further education to prevent misinterpretation in the future.

As a result of a longstanding tradition of clinical education as well as providing the highest quality ophthalmic ultrasound imaging systems, Innovative Imaging Inc. has taken a proactive measure to add a label for the printout denoting the technique the instrument uses to evaluate scans. See section below "Software Upgrades"

## POSITION STATEMENT

Innovative Imaging Inc. has a longstanding commitment to clinical education and we ensure that our US customers are provided an opportunity to be trained by credentialed sonographers.

Please refer to some of the many customer comments we have received throughout our 15 year history at <http://eye-imaging.com/aboutus/testimonials/>.

## RESPONSE TO QUOTATIONS TAKEN FROM THE ECRI REPORT

*(Note: quotations taken from the ECRI Report are bolded, indented, and italicized for easy identification)*

***"The ultrasound measurements were performed with a model I<sup>3</sup>System-ABD scanner manufactured by Innovative Imaging. However, other similar devices from the same or different manufacturers may also be subject to this problem."***

There are no completely automated instruments. All instruments require an operator to confirm the use of appropriate system settings. In the case of axial length A-scan measurements, this includes, but is not limited to:

- Correct recording of patient name or medical record number
- Correct indication of right (OD) or left (OS) eye being measured
- Correct selection of type of eye being measured
- Correct initial gain (dB) level
- Correct entry of patient keratometry values
- Correct selection of surgeon IOL preferences
- Correct selection of operator performing measurements
- Correct selection of examination technique for initial caliper positions (contact or immersion)
- Evaluation of each echo for qualities of sharply rising edges
- And equally important, is the verification of caliper placement on individual echoes with the resultant measurements

The measurements are then correlated with the visual history of the patient to confirm that the calculated IOL power will provide optimal visual rehabilitation for the patient.

**“The accuracy of A-scan measurements and IOL calculations is determined mainly by the use of proper measurement techniques and interpretation by a trained biometrist.”**

It is the responsibility of each physician to assess the skill level of the biometrist performing axial eye length measurements with IOL calculations. In A-scan echo pattern interpretation, the skilled biometrist is required to obtain valid echo patterns with properly placed measurement calipers. Final responsibility lies with the surgeon to confirm the validity of the A-scan pattern, caliper placement and the correlation of the measurement with the patient’s visual history. Any unusual result should be investigated prior to performing surgery.

**“However, if the selected operating mode does not match the actual technique used, as happened in the reported incident, the measurements of the eye’s axial length will be wrong, as will the resulting IOL calculations.”**

This clearly indicates operator error.

**“On some scanners, the printout of the scan will include text indicating the type of scan that was performed.”**

A notation on the printout does not indicate the type of scan performed; rather it indicates the type of scan technique for which the instrument is set. It continues to be the responsibility of the examiner to confirm that the type of scan performed matches the instrument setting.

**“Checking the printout will allow users to verify the switch position that was used, and thus the accuracy of the measurements, before surgery begins.”**

Checking the printout will, in fact, verify the contact/immersion switch position, however, it does not verify the accuracy of the measurement. Correct evaluation of the A-scan echo pattern, caliper placement and correlation of the patient history is essential to assure accuracy of measurements.

**ECRI RECOMMENDATIONS:** (Inovative Imaging response follows each item listed)

1. ***“Determine whether your ultrasound scanners perform automatic measuring and thus might be susceptible to the mismatching described in this article.”***

It is not automatic measuring that is the issue in this case; it is the improper placement of calipers

2. ***Before performing A-scan biometry, be sure to verify the position of the contact / immersion switch.***

We agree.

3. ***When performing measurements, ensure that the anterior electronic cursor is positioned on the corneal echo and the posterior cursor on the retinal echo on the display.***

We agree.

4. ***After performing the procedure and before cataract surgery, verify the switch position used by observing the appropriate text on the printout of the A-scan (if provided).***

That is not sufficient to ensure measurement accuracy. Each A-scan echo pattern must be evaluated individually.

5. ***Owners of an I<sup>3</sup>System-ABD scanner earlier than version 5.02 should purchase and install a \$500 software upgrade from Innovative Imaging. The upgrade is primarily intended to provide updated IOL calculation tables, but it also includes a modification to the data displayed on the A-scan monitor. With the modification, the monitor will display either "IMMERSION A-SCAN" or "CONTACT A-SCAN," depending on the position of the mode switch. Having this onscreen text available should help reduce erroneous measurements."***

An upgrade is not required for a trained biometrist to properly operate any of our systems in either contact or immersion mode. The upgrade enables less accomplished examiners to have an additional visual cue to remind them of which examination technique is selected. A notation of "contact" or "immersion" on the display or printout will not prevent an error from being made. It is our assumption that a skilled biometrist recognizes correct echo patterns and caliper placement without relying on reading a text field that states the technique. Errors are prevented by the proficient evaluation of echo patterns, caliper placement, and patient history. It is not automatic measuring

## **IMPRESSION**

The previous ECRI Hazard Report is a perfect illustration of the ongoing need to have a qualified biometrist perform and evaluate A-scans that have such a vital impact on the quality of patient care.

## **RECOMMENDATION FROM INNOVATIVE IMAGING INC.**

Innovative Imaging Inc. recommends that clinics not permit the use of any instrument by an untrained examiner. It is important to understand that even the best trained technicians and physicians make errors. The key to resolution of errors is to (1) recognize the error and (2) take corrective and preventive action.

For the last 15 years we have been available to assist our customers with questions about exam techniques and caliper placement. We welcome any questions you may have. Please call (800) 765-7226 or send an email via the "Contact" page of our website [www.eye-imaging.com](http://www.eye-imaging.com).

As this report makes clear, there exists a serious responsibility, usually delegated to technicians, of performing axial eye length biometry with IOL calculations. We believe that technicians should meet a minimum skill standard. The Registered Ophthalmic Ultrasound Biometrist credential is the current standard of proficiency with a continuing education requirement designed to maintain expertise. See section below "Additional Training."

## **SOFTWARE UPGRADE**

The \$500 upgrade stated in the ECRI report is available to many I<sup>3</sup>SYSTEM-ABD™ owners. It will provide a notation on the IOL printout denoting with which technique the instrument evaluates the scan. On most of our instruments, it is already displayed on the monitor and video prints.

For information regarding additional training or the additional features included in software upgrades, and to determine the age and upgradeability of your instrument, please contact our office from our website: [www.eye-imaging.com](http://www.eye-imaging.com) or by phone in the USA at 800-765-7226.

## **ADDITIONAL TRAINING**

### **JCAHPO**

**[www.jcahpo.org](http://www.jcahpo.org)**

- Joint Commission on Allied Health Personnel in Ophthalmology
- Credential ROUB = Registered Ophthalmic Ultrasound Biometry (A-scan)

### **ARDMS (RDMS)**

**[www.ardms.org](http://www.ardms.org)**

- American Registry of Diagnostic Medical Sonographers
- Credential RDMS = Registered Diagnostic Medical Sonographer (B-scan)

### **Eye Scan consulting**

**[eyescan@comcast.net](mailto:eyescan@comcast.net)**

### **Innovative Imaging Inc.**

**[www.eye-imaging.com](http://www.eye-imaging.com)**