510 (k): K122481

510(k) SUMMARY

DEC 3 1 2012

PREPARATION DATE:	December 12, 2012
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 459-4815 Fax: (877) 468-5335
CONTACT PERSON:	Christy Stevens, OD, MPH Vice President, Clinical & Regulatory
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAME:	Ophthalmic Camera
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.1120 and 886.1850
PRODUCT CODE:	HKI, HJO
PREDICATE DEVICE:	LipiView® Ocular Surface Interferometer Class II under 21 CFR 886.1120 and 21 CFR 886.1850; Product Code HKI, HJO; Applicant: TearScience, Inc.; Cleared under K091935 on October 23, 2009

DEVICE DESCRIPTION:

The LipiView® Ocular Surface Interferometer is a bench-top imaging device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touch screen display. The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display, in a printed report, or captured on video and exported to USB-attached storage or a mapped network drive.

The LipiView® Interferometer has been modified to software version 2.0, which includes changes to refine the interferometric color matching and blink detection methods used on interferometric images and to provide minor usability enhancements.

INTENDED USE:

The LipiView® Interferometer is intended to image the tear film. The LipiView® Interferometer is a prescription device for use by a physician during an in-office exam.

Indications for Use: The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

The LipiView® Interferometer with software version 2.0 has the same intended use as the predicate LipiView® Interferometer (K091935). In addition, the Indications for Use are similar to the predicate device, except that the Indications for Use have been expanded for the LipiView® Interferometer with software version 2.0 to include measurement of the tear film lipid layer thickness, as supported by performance testing. The expanded Indications for Use do not alter the intended use of the LipiView® Interferometer.

TECHNOLOGICAL CHARACTERISTICS:

The LipiView® Interferometer with software version 2.0 has the same fundamental scientific technology as the predicate device. As summarized below, most of the technological characteristics of the LipiView® Interferometer with the modification to software version 2.0 remain unchanged from the predicate device cleared under K091935. Minor differences in technology between the predicate device and the LipiView® Interferometer with software version 2.0 are described below.

Similarities: The LipiView® Interferometer with software version 2.0 and the predicate device share many of the same design features. Both devices have the same operating principle of real-time imaging of tear film dynamics based on the interference pattern from specular reflections. Both devices have an AC power source in compliance with IEC 60601 standards for electrical safety and electromagnetic compatibility. Both devices use the same Class I white light LED illuminator with exposure and level of illumination in compliance with ISO 15004-2 (Group 1 instrument) for safety. The patient contact materials for the chin and forehead rest and the method of disinfection are the same for both devices. Also, both devices have a digital video camera, personal computer with Microsoft Windows-based operating system, touchscreen display graphical user interface and computer accessory support for printing and data storage.

Furthermore, analogous software features on both devices include: password-protected user login; patient database; real-time video display to acquire tear film images; touchscreen user controls for camera and video playback; image acquisition process with storage of lossless AVI format video images; and tear film video playback and analysis.

Differences: Compared to the predicate device, the LipiView® Interferometer with software version 2.0 has refined interferometric color matching and blink detection methods used on interferometric images. In the predicate device, the interferometric color palette was theoretically derived; whereas in software version 2.0, the palette was developed and validated to a known standard for measurement of the tear film lipid layer thickness. Software version 2.0 also has enhancements for user convenience including: playback blink visualization; automated documentation of blinks; example tear film videos; adjustable video capture length; and ability to export video to an external USB storage device or mapped network drive.

PERFORMANCE TESTING:

The LipiView® Interferometer with software version 2.0 was developed and tested in compliance with design controls and the FDA Guidance documents for software validation in medical devices. To support the expanded Indications for Use, the LipiView® Interferometer was validated to physical phantoms representative of the pre-corneal tear film of a known thickness, as measured independently by ellipsometry. This testing demonstrated the

LipiView® Interferometer can make absolute measurements of the tear film lipid layer thickness by imaging interferometric colors. Test results showed the *in vivo* device measurement variability is 0.31 interferometric color unit (ICU) on average, or slightly less than one-third of the reporting precision of the device (1 ICU). Verification and validation test results demonstrated that the interferometric color matching performance of the LipiView® Interferometer with software version 2.0 is equal to or better than the predicate device. Tests also showed that version 2.0 had a higher overall percentage of correctly identified valid blink frames as compared to the predicate device. Enhancements for user convenience in software version 2.0 performed as intended and did not introduce any new risks to the device.

CONCLUSIONS:

The LipiView® Ocular Surface Interferometer with software version 2.0 has the same intended use and the same fundamental scientific technology as the predicate device. Performance testing demonstrates the LipiView® Interferometer with software version 2.0 is substantially equivalent in technological characteristics to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 3 1 2012

Tearscience, Inc.
c/o Christy Stevens, OD
VP, Clinical & Regulatory Affairs
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560

Re: K122481
Trade/Device Name: LipiView Ocular Surface Interferometer
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, HJO
Dated: December 18, 2012
Received: December 19, 2012

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K122481 (To Be Assigned By FDA)

Device Name: LipiView® Ocular Surface Interferometer with Software Version 2.0

Indications for Use:

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K122481

Page __ of ___

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 02, 2012

TEARSCIENCE, INC.
5151 McCrimmon Parkway
Suite 250
Morrisville, NORTH CAROLINA 27560
ATTN: CHRISTY STEVENS

510k Number: K122481
Product: LIPIVIEW OCULAR SURFACE INTERF
On Hold As of 10/31/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 15, 2012

TEARSCIENCE, INC.
5151 McCrimmon Parkway
Suite 250
Morrisville, NORTH CAROLINA 27560
ATTN: CHRISTY STEVENS

510k Number: K122481

Received: 8/14/2012

Product: LIPIVIEW OCULAR SURFACE INTERF

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not ontain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Microsoft Outlook
To: cstevens@tearscience.com
Sent: Wednesday, August 15, 2012 9:24 AM
Subject: Relayed: K122481 ACK Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

cstevens@tearscience.com (cstevens@tearscience.com)

Subject: K122481 ACK Letter

K122481
OP|DONED

TearScience®

August 13, 2012

FDA/CDRH/DCC
AUG 14 2012
RECEIVED K38

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: SPECIAL 510(K): DEVICE MODIFICATION

APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560
ESTABLISHMENT REGISTRATION NO.:	3008169506
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.1120 and 886.1850
PRODUCT CODE:	HKI, HJO
CLASSIFICATION PANEL:	Ophthalmic
ORIGINAL 510(K) NUMBER:	K091935
ORIGINAL 510(K) CLEARANCE DATE:	October 23, 2009
USER FEE PAYMENT ID:	MD 6063078-956733

Dear Sir or Madam:

Pursuant to the provision of Section 510(k) of the Federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990, notification is made of the intention of TearScience to market and distribute a modified ophthalmic imaging device, the LipiView® Ocular Surface Interferometer with Software Revision 2.0. TearScience hereby submits this Special 510(k): Device Modification to request a modification to the LipiView® Interferometer. The modification is a software change to refine the interferometric color matching and blink detection methods used on interferometric images and to provide minor usability enhancements. TearScience believes this device modification is eligible for the Special 510 (k) process since the modified device has the same intended use and fundamental scientific technology as the cleared predicate device.

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. The indications for use and intended use have not changed from the cleared predicate device.

The LipiView® Ocular Surface Interferometer is a Class II prescription device classified under 21 CFR 886.1120 and 886.1850 with a common name of ophthalmic imaging device. The LipiView® Interferometer was previously cleared under K091935 on October 23, 2009. The K091935 filing included a Traditional Premarket Notification dated June 24, 2009 and a Response to FDA Memorandum dated October 5, 2009.

Based on the FDA Guidance Document, *Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1);* issued January 10, 1997, there were two software changes in LipiView® software version 2.0 that were assessed to require submission of a 510(k):

1. Interferometric color matching has been improved by using certified thin film optical phantoms to establish the interferometric color reference palette and by refining the method for identifying and localizing the interferometric colors on the tear film.
2. The blink detection method has been refined to allow the device to better differentiate valid tear film frames from blink frames as compared to the cleared device.

In addition, we have made other minor usability enhancements for user convenience including: playback blink visualization; automated documentation of blinks; example tear film videos; adjustable video capture length; and ability to export video to an external USB storage device or mapped network drive.

As explained in this submission, none of these changes affect the intended use, principles of operation, control mechanism, energy source or device hardware. The device operation and graphical user interface are fundamentally unchanged in software version 2.0 from the predicate device. Risk analysis showed that none of the changes in software version 2.0 pose any additional risk to the patient and/or user as compared to the cleared device. Performance testing demonstrated the LipiView® Interferometer with software version 2.0 is substantially equivalent in technological characteristics to the predicate device.

This submission has been formatted per the guidelines in *How To Prepare A Special 510(k).*[1] Two copies of this submission (one paper and one electronic) are enclosed for review. The electronic copy is provided per FDA's web instructions 'Electronic Copies for Pre-Market Submissions', and is an exact duplicate of the original paper submission.

TearScience regards information provided in this submission to be confidential and proprietary and afforded such protection under 21 CFR 807.95 and other applicable regulations and statutes. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. If there are any questions, or if additional information is required, please contact me at (919) 459-4815, via fax at (877) 468-5335, or by email at CStevens@TearScience.com.

Sincerely,

Christy Stevens

Christy Stevens, OD, MPH
Vice President, Clinical & Regulatory Affairs

[1] FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm, updated 12/7/2009

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Attachment 13-A: 510(k) Summary for the LipiView® Ocular Surface Interferometer K091935 (October 23, 2009)

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K091935

510(k) SUMMARY

PREPARATION DATE:	September 30, 2009
APPLICANT:	TearScience, Inc. 1101G Aviation Parkway Morrisville, NC 27560 Tel: (919) 467-4007 Fax: (919) 467-3300
CONTACT PERSON:	Christy Stevens, OD Vice President, Clinical and Regulatory Affairs
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAMES:	Ophthalmic Camera (21 CFR 886.1120) and AC-powered Slit Lamp Biomicroscope (21 CFR 886.1850)
DEVICE CLASSIFICATION:	Class II
PRODUCT CODES:	HKI and HJO
PREDICATE DEVICES:	1. OphthaVision Imaging System, MRP Group, Inc. (K980295; cleared May 19, 1998; Product Code HKI; 21 CFR 886.1120; Class II) 2. Tearscope-Plus, Keeler Instruments, Inc. (K973064; cleared April 7, 1998; Product Code HJO; 21 CFR 886.1850; Class II)

OCT 23 2009

DEVICE DESCRIPTION:

The LipiView® Ocular Surface Interferometer is a bench-top imaging device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touch screen display. The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display and in a printed report.

INTENDED USE

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

SUBSTANTIAL EQUIVALENCE TO THE PREDICATE DEVICES

The intended use and technologic characteristics of the LipiView® Interferometer are substantially equivalent to the OphthaVision Imaging System (K980295) and Tearscope-Plus (K973064). All three devices are prescription devices for imaging use by a physician during an in-office exam.

The LipiView® Interferometer and the OphthaVision Imaging System are intended to capture, archive, and manipulate digital images of the eye. The imaging focal plane with the LipiView® Interferometer is at the ocular surface and tear film, whereas the OphthaVision Imaging System can be used for intraocular imaging. Both devices provide a means to store digital images to allow a physician to monitor and photographically document conditions.

The LipiView® Ocular Surface Interferometer has similar technological characteristics to the OphthaVision Imaging System. Both devices use a digital camera, Microsoft Windows-based software, computer, monitor, graphical user interface, user controls, printer support, image storage drives, and AC power source. Both devices allow the user to select functions to process, analyze, archive and retrieve images. Analogous software features include image enhancement, alignment, comparison, animation, capture/save and print. The two devices store data in a similar Lossless file format.

Furthermore, the LipiView® Interferometer and the Tearscope-Plus have the same intended use to observe the tear film by specular reflection. Both devices allow the physician to observe tear film. The LipiView® Interferometer has similar technological characteristics to the Tearscope-Plus. Both devices use a diffuser and low-level white light to illuminate the eye on an angle and view real-time tear film dynamics. Both devices show the interference patterns for evaluation of the colors observed in the tear film. The LipiView® Interferometer and Tearscope-Plus are required to meet optical radiation safety standards.

The LipiView® Interferometer, OphthaVision Imaging System and Tearscope-Plus are all AC-powered devices that are required to meet electrical safety and electromagnetic compatibility standards. All three devices do not contact the patient's eye.

The LipiView® Interferometer includes a chin rest support system to position the patient's head during imaging, whereas the OphthaVision Imaging System and the Tearscope-Plus are used with a slit lamp biomicroscope that provides a chin rest support to position the patient's head. The chin rest support materials for the LipiView® Interferometer are widely used in ophthalmic slit lamp biomicroscopy products and are known for biocompatibility. Therefore, this difference does not raise new questions of safety and effectiveness. In addition, the LipiView® Ocular Surface Interferometer conforms to disinfection of patient contact surfaces for slit lamp biomicroscopes.

Minor differences in technology between the predicate devices and the LipiView® Interferometer do not raise new questions of safety and effectiveness and are supported by performance testing to applicable standards and software verification and validation. Table 5-1 compares the LipiView® Interferometer to the predicate devices.

PERFORMANCE TESTING:

The LipiView® Ocular Surface Interferometer conforms to the requirements under the applicable standards for slit lamp biomicroscopes; optical radiation safety; electrical safety; and material flammability. In addition, the LipiView® Interferometer is designed and will be manufactured in compliance with voluntary consensus standards for risk management and quality management systems. The LipiView® Interferometer software was developed and tested in compliance with FDA Guidance documents for software validation in medical devices.

CONCLUSIONS:

The LipiView® Ocular Surface Interferometer has comparable intended use and technologic characteristics to the predicate devices. Minor technological differences between the LipiView® Interferometer and the predicate devices do not raise new questions of safety and effectiveness and are supported by performance testing. TearScience has demonstrated through its evaluation of the LipiView® Ocular Surface Interferometer that the device is substantially equivalent to the predicate devices.

Table 5-1: Predicate Device Comparison Table

Comparison Feature	LipiView® Ocular Surface Interferometer	OphthaVision Imaging System (K980295)	Tearscope-Plus (K973064)
Indications For Use	The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.	The OphthaVision Imaging System is intended for use to capture, archive, and manipulate digital images of the eye obtained through use of an ophthalmic camera.	Specular observation of the tear film
Prescription/OTC Device	Prescription diagnostic	Prescription diagnostic	Prescription diagnostic
Method of Operation Ophthalmic Imaging	Ophthalmic camera with digital imaging system Graphical User Interface Touchscreen user control Microsoft Windows-based software	Ophthalmic camera with digital imaging system Graphical User Interface Mouse, keyboard and joystick user controls Microsoft Windows-based software	No software imaging capability
Method of Operation Tear Film Observation	Real-time tear film dynamics based on interference pattern from specular reflection Provides isolated tear film view and interferometric color analysis	None	Real-time tear film dynamics based on interference pattern from specular reflection
Illumination Source	Angled Class I white LEDs with diffuser	No direct illumination source Used with a slit lamp for illumination	Angled cold cathode light with diffuser May be used with a slit lamp, which provides additional illumination
Exposure Parameters	Illuminates lower half of eye Exposure and level of illumination complies with ISO 15004-2 Group 1 instrument for safety	Not applicable	Illuminates full eye including pupil Exposure level not specified Required to comply with safety standard
Brightness Control	No brightness control adjustment by user	Not applicable	High and low level brightness control
Material Flammability	Materials near light source comply with UL 94V-1	Not applicable	Not specified
Maximum Temperature of Held or Accessible Parts	Ambient temperature of parts of device held by operator or accessible to patient	Not applicable	Ambient temperature of parts of device held by operator or accessible to patient

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Christy Stevens, OD
VP, Clinical & Regulatory Affairs
Tearscience, Inc.
1101 G Aviation Parkway
Morrisville, NC 27560

OCT 23 2009

Re: K091935
Trade/Device Name: LipiView Ocular Surface Interferometer
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, HJO
Dated: October 5, 2009
Received: October 6, 2009

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

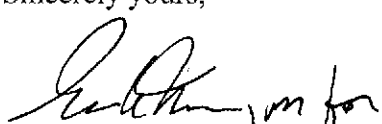
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091935

INDICATIONS FOR USE

510(k) Number: K091935

Device Name: LipiView® Ocular Surface Interferometer

Indications for Use:

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091935

Page __ of __

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TearScience®

LIPIVIEW®

Ocular Surface Interferometer

Operation Manual

Model # LVI-1001
For System Version 2.x

Manufactured by:

TearScience, Inc.
5151 McCrimmon Parkway Suite 250
Morrisville, NC 27560
Phone: (919) 467-4007
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EC REP
Donawa Lifescience Consulting
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00153 Rome, Italy

Rx only

CE

011119-ENG Rev A

Revision History

Revision	Date	Description of Changes	ECR # or PCR #
A	6/29/12	Initial release for 2.0 software in English. This manual was created from Part Number 010792 Rev M (mat spec). Updates from 1.1D software include: updated screenshots with system and version numbers, new screenshots and explanation for partial blink detection mode; new screenshots and explanations for display and camera settings in the Admin interface; new screenshots and explanations for example videos; new screenshots and explanations for revisions to reporting and for "save video" functionality.	P1206251

Table of Contents

Table of Figures

List of Tables

1 Introduction

This manual provides the indications, contraindications, warnings, precautions, potential adverse effects and instructions for use for the *TearScience*® LipiView® Ocular Surface Interferometer (LipiView® Interferometer). **Carefully read this manual in its entirety before using the LipiView® Interferometer. Failure to follow these instructions may result in improper use of the device.**

Use of the LipiView® Interferometer includes User and Administrator functionality, both of which are described in this manual. Section 10, *Instructions for Use,* contains the information about the proper procedures for operating the LipiView® Interferometer. Section 16, *Administrator Instructions for Use,* contains information about the initial setup and maintenance of the LipiView® Interferometer by an Administrator. **Prior to initial use of the LipiView® Interferometer, the Administrator must follow the administrative setup instructions in this manual for proper device use.** Table 1-1 identifies the tasks an Administrator may be required to perform and the prerequisite knowledge.

Table 1-1: Administrator Prerequisite Knowledge

Task	Prerequisite Knowledge
User Administration	Create usernames and passwords.
Printer Setup (required before printing)	Install a Network or USB printer. Installation of a network printer requires knowledge of networking. For installation of a USB printer, follow the manufacturer's instructions.
Network Setup (optional)	Configure the system to gain access to the wireless networking environment (selection of server, setting of security keys, etc).
Electronic Medical Records (EMR) Export (optional)	Configuration for export of records to other office system(s) using the HL7 data transfer protocol.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

Contact TearScience with any questions about the information contained in this manual or for additional information on the operation and safety of the LipiView® Interferometer.

2 Device Description

The LipiView® Interferometer is a bench-top device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touchscreen display. Figure 2-1 shows the base LipiView® Interferometer. Additional views and a description of the components are provided in Section 9, *LipiView® Interferometer Operation*.

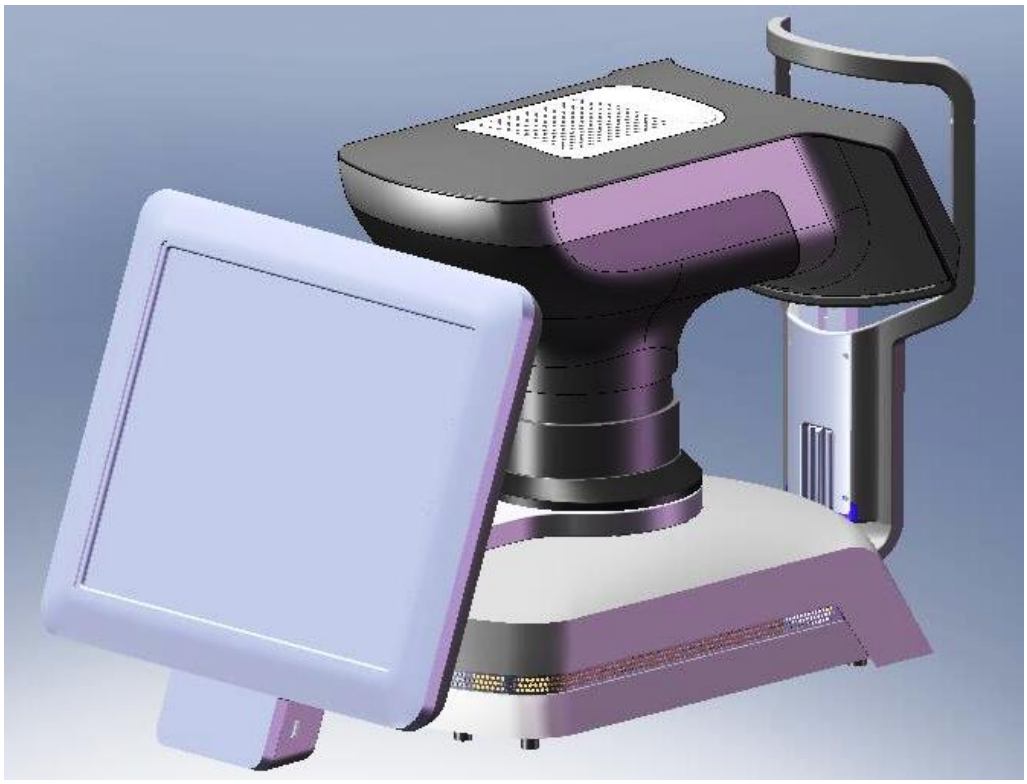


Figure 2-1: LipiView® Interferometer

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The patient's eye is positioned in front of an illumination source directed toward the tear film on the corneal surface. Light from the illumination source passes through the tear film and is specularly reflected into a camera. The light reflecting back through the lens in the camera forms an interference pattern, called an "interferogram". The computer system

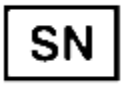
captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking.

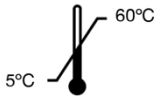
The computer system captures and enhances the interference pattern and displays a profile corresponding to an interferometry color scale. The interferometry color assessment is measured in Interferometric Color Units (ICU). An ICU for the LipiView® Interferometer is defined as the color scale resulting from the interference pattern which occurs at the boundary of the tear film. The measured ICU may range from 0 to 240, with a precision of 1 ICU. The accuracy of the measured interference pattern is displayed as a "C-factor," which is equal to the proportion of measured colors that match the predicted interferometric color scale. The video image of the ocular surface may be viewed on the computer screen display and in a printed report.

3 Labeling

Table 3-1 provides a description of the symbols used on the LipiView® Interferometer labeling.

Table 3-1: Description of Labeling Symbols

Label Symbol	Symbol Description
	Type B applied part.
	Consult operating instructions
	Device transmits radiofrequency (RF) energy
	Text consists of a warning or precaution relating to safety. Read the text carefully and use the equipment as instructed to ensure safety.
	Reference Number
	Serial Number.
	**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.
	Mandatory conformity mark for medical device products in the European Economic Area (EEA). The **CE marking** certifies that a product has met consumer safety, health or environmental requirements.
	This model/product is Listed in Intertek's Directory of Listed Products.

Label Symbol	Symbol Description
	Date of Manufacture
	Manufacturer
	Store between 5 and 60 degrees Celsius
	Authorized Representative in the European Community
P/N	Part Number
Rev	Revision Level

4 Indications for Use

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

5 Contraindications

Contraindications are conditions in which the device should not be used because the risk of use clearly outweighs any benefit. No contraindications have been identified for the LipiView® Interferometer.

6 Precautions

The following patient conditions may affect the interferometry assessment of a patient's tear film using the LipiView® Interferometer:

- **Use of ophthalmic drops such as artificial tear lubricants, ointments, and medications.** Advise patients not to instill oil-based ophthalmic drops (e.g., Soothe®, Restasis®) for at least 12 hours prior to device use and not to instill ointments for at least 24 hours prior to device use. Wait at least 4 hours after the instillation of all other ophthalmic drops prior to device use.
- **Soft or rigid contact lens wear**. Advise patients to remove contact lenses at least 4 hours prior to device use.
- **Use of oil-based facial cosmetics around the eye.**
- **Eye rubbing.**

- **Recent swimming in a chlorinated pool.** Advise patients not to swim for at least 12 hours prior to device use.
- **Any ocular surface condition** that affects the stability of the tear film. These conditions include disease, dystrophy, trauma, scarring, surgery, or abnormality.

7 Warnings

Review the following warnings prior to using the LipiView® Interferometer.

Table 7-1: General and Operation Warnings

GENERAL WARNINGS
WARNING: No modification of this equipment is allowed.
Caution: **Power Requirements.** The LipiView® Interferometer is a continuous operation device which requires a power source of 100-240 Volts AC ± 10%, 50/60 Hz single phase, 4 Amps. Connection to a power supply other than a supply mains with protective earth may result in electric shock.
Caution: The LipiView® Interferometer has protection against electric shock of applied part classified as Type B. This device is classified as an IEC Class 1 product.
Caution: **Voltage Protection and Fuse Selection.** Contact TearScience to replace a blown fuse. TearScience personnel must replace only with a 5 x 20 mm, 4 A, 300 ms, 40 A breaking capacity fuse to avoid risk of fire. TearScience personnel must disconnect from power before servicing to avoid risk of electrical shock.
Caution: Backup Battery Replacement**.** Backup battery cannot be replaced.
Caution: Keep the LipiView® Interferometer away from strong magnetic fields as it could damage the device's hard drive, but is not a safety hazard to the user or patient.
Caution: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the LipiView® Interferometer or shielding the location.
Caution: Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
Caution: The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or Device.
Caution: The EQUIPMENT or DEVICE should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EQUIPMENT or DEVICE should be observed to verify normal operation in the configuration in which it will be used.
Caution: Degree of protection against harmful ingress of liquid: IPXO. This equipment has no protection against ingress of liquids.

OPERATION WARNINGS
Caution: Federal law restricts this device to sale by or on the order of a physician.
Caution: The chin and forehead rest surface must be disinfected with alcohol immediately prior to use and prior to storage.
Caution: **Photo-toxicity hazard.** No acute optical radiation hazards have been identified for the LipiView® Interferometer under intended use conditions. Since prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. Aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours.
Caution: Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.
Caution: If a problem occurs with the LipiView® Interferometer, identify the symptom then attempt to resolve the problem as indicated in Section 15, *Troubleshooting*. If the problem cannot be resolved, stop using the device and contact TearScience.
Caution: To prevent electric shock or performance alteration, do not attempt to service the device or remove the cover. No maintenance is required for the LipiView® Interferometer, and the device and all of its associated parts are not serviceable by the user.
Caution: This device is not suitable for use in the presence of flammable mixtures.
Caution: This device is not suitable for use in oxygen rich environments.
Caution: In order to isolate this equipment from supply mains the equipment must be unplugged from the wall. Do not position the equipment in a location which would prevent the unit from being unplugged in an emergency.
Caution: Do not store this instrument in conditions where the temperature may rise above 60°C or fall below 5°C.
Caution: When lifting or handling the LipiView® Interferometer, caution should be taken to prevent injury or damage to the device. Prior to moving the device, put the monitor arm into a locked position and unplug the power cord from the wall. If an external monitor is attached, disconnect the external monitor prior to moving the device.
Caution: The device monitor and base unit may exceed 41°C. Device will remain within safe momentary contact temperature, below 51°C.
Caution: Shock hazard. Do not touch patient and device under top cover simultaneously.

8 Potential Adverse Effects

There are no known or anticipated adverse effects associated with use of this device.

9 LipiView® Interferometer Operation

9.1 Device Overview

The LipiView® Interferometer is a bench-top device containing the following components, which are identified on Figures 9-1 (Front/Patient View) and 9-2 (Rear/User View):

- Base and Computer System
  - Computer system
  - Electronics
- Ophthalmic Chin Rest Support
  - Chin Rest
  - Forehead Rest
- Motion Stage
  - Camera and zoom lens
  - Illuminator
- Touchscreen Display
  - USB Ports

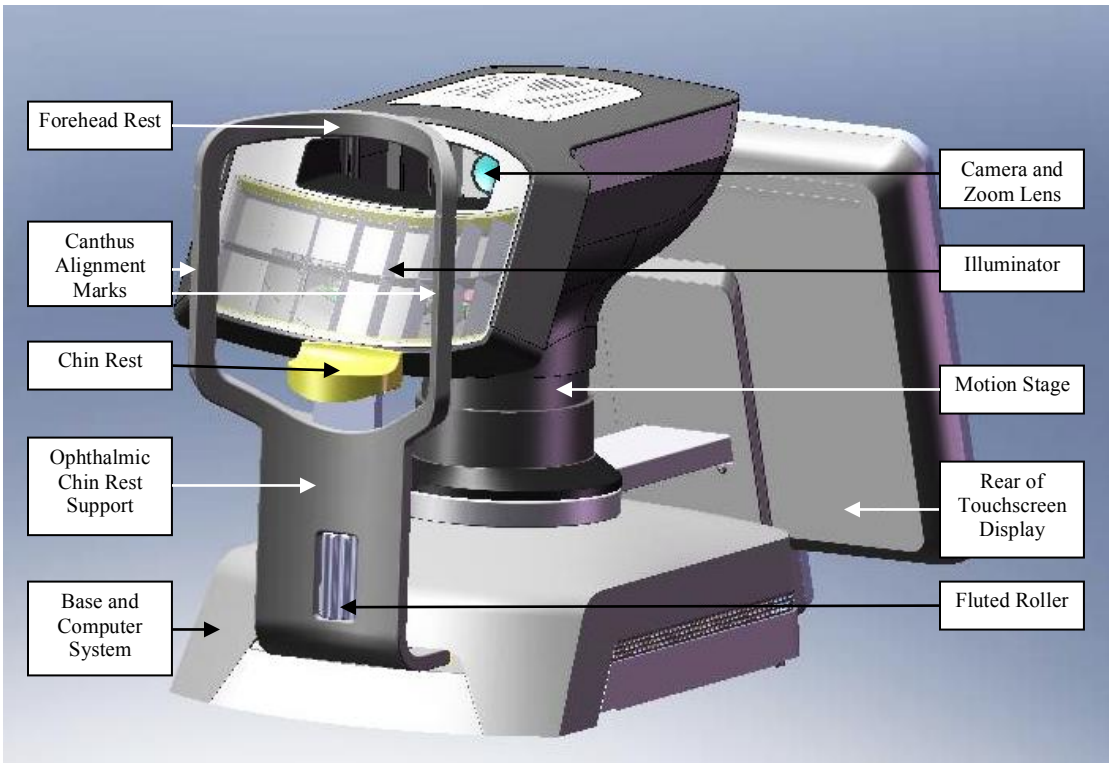


Figure 9-1: Front (Patient) View of LipiView® Interferometer

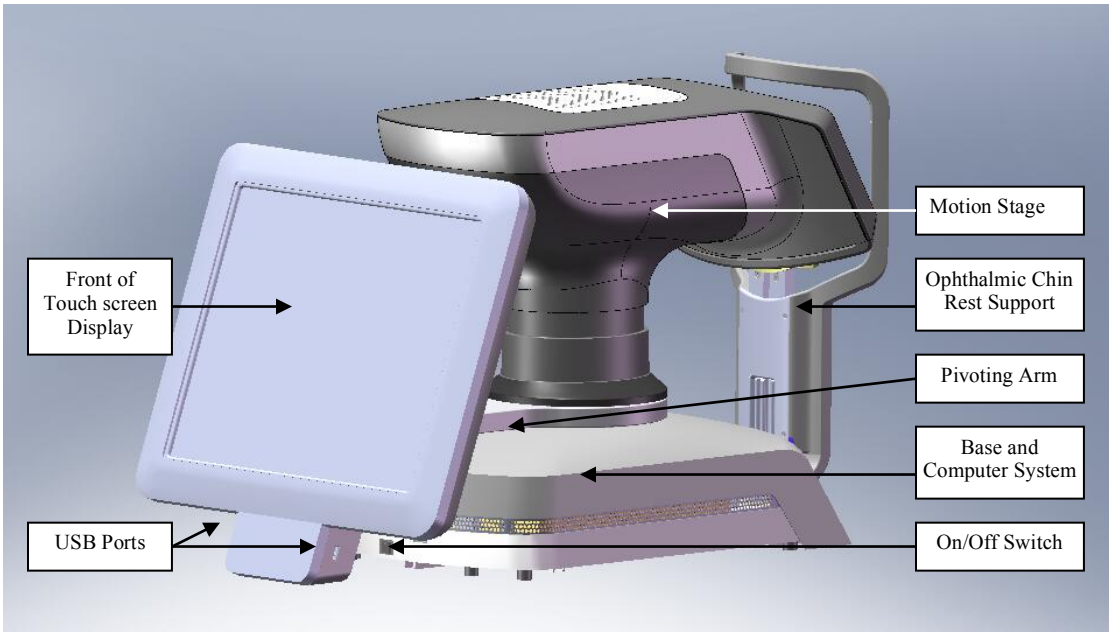


Figure 9-2: Rear (User) View of LipiView® Interferometer

9.1.1 Base and Computer System

The base of the device sits on a flat surface. It houses the power connection, and computer hardware, and connects with the ophthalmic chin rest support, motion stage and touchscreen display. The on/off switch is located on the rear of the base opposite the back surface of the display screen. Refer to Figure 9-2 for the switch location. A connection for an external monitor is hardwired into the base.

9.1.2 Ophthalmic Chin Rest Support

The ophthalmic chin rest support shown in Figure 9-1 consists of an adjustable height chin rest and fixed forehead rest. The chin rest support is attached to the front base of the device, and is designed to allow proper positioning of the patient's head to evaluate the ocular surface tear film. To ensure a properly focused image, the patient must place his/her chin and forehead firmly against the chin and forehead rests. The chin rest may be raised or lowered to accommodate different facial dimensions by spinning the fluted roller. Two canthus alignment marks about half way down the left and right sides of the forehead rest indicate the center of the camera range in the up/down direction. Adjusting the chin rest to position the lateral canthus of the patient's eye at these marks will optimize the range of camera motion.

The chin rest support is the only component of the LipiView® Interferometer that comes in contact with the patient. Disinfect the chin and forehead rest surfaces with alcohol immediately prior to use and prior to storage.

9.1.3 Motion Stage

The motion stage is mounted on the top center of the base. It contains the camera, zoom lens, illuminator and motor controls used to adjust the camera and illuminator. The height of the motion stage (which includes the camera and illuminator) is adjusted as part of the Capture Images process discussed in Section 10.3.2, *Capture the Video*.

9.1.4 Camera and Zoom Lens

The camera is located behind the zoom lens inside the motion stage and is not visible externally. The height of the camera can be adjusted as part of the motion stage. The camera can also be adjusted to the left and right as well as backwards and forwards with separate controls. Refer to Section 10.3, *Video Image Capture and Recording* for additional information.

9.1.5 Illuminator

The grid-like fixture attached to the top front of the motion stage is the illuminator. The illuminator faces the patient and reflects light off the tear film. The height of the illuminator is adjusted automatically with camera alignment as part of the motion stage. There are no separate controls for the illuminator.

9.1.6 Touchscreen Display

Attached to the rear of the base is the Touchscreen Display. Figure 9-1 provides a rear view of the screen and Figure 9-2 shows the front view of the screen. The screen is on a pivoting arm, which allows it to be positioned ± 45 degrees or ± 90 degrees from its location shown in Figure 9-2. To reposition the screen, press the button under the pivoting arm while moving the arm left or right to the approximate 45 or 90 degree location. Release the button and continue moving the arm until it locks into place.

In addition to displaying information to the user, the screen also functions as a touchscreen user interface to the interferometer. The user touches the screen to operate the motion stage and camera controls and to progress through the imaging process. Section 9.2, *User Interface* provides additional details.

9.1.7 USB Ports

The lower base of the Touchscreen Display contains two USB ports as shown in Figure 9-2. These ports may be used to connect a printer or storage device if the LipiView® Interferometer is not on a wireless network. Refer to Section 9.1.9.4, *Accessory Support* for information on compatible accessories.

9.1.8 External Monitor Connection

The LipiView® Interferometer supports the use of an external monitor. A connection for an external monitor is hardwired into the base. The connection will support HDMI or DVI inputs on an off the shelf external monitor which has at least 1280 x 1024 resolution and supports 60Hz frame rates. Instructions for attaching the external monitor are provided in Section 18, *Appendix B: External Monitor Hookup*.

9.1.9 Operating Environment

9.1.9.1 Electrical Specifications

Table 9-1: Electrical Specifications

Input Voltage	120 – 240 VAC, 50 – 60 Hz

9.1.9.2 Medical Electrical Classifications

Table 9-2: Medical Electrical Classifications

Product Safety Classification	Type B Applied Part
IEC 60601-1— Medical electrical equipment—Part 1: General requirements for safety	
IEC 60601-1-2 — Medical electrical equipment—Part 1: General requirements for safety—Section 2: Collateral standard—Electromagnetic compatibility—Requirements and tests;	CISPR 11 (Class A, Group 1)

9.1.9.3 Environmental Specifications

Table 9-3: Environmental Specifications

Operating Temperature	10°C to 35°C
Operating Relative Humidity	Up to 90% non-condensing
Storage Temperature	5°C to 60°C
Transport Temperature	5°C to 60°C

9.1.9.4 Accessory Support

The LipiView® Interferometer may be used with the following USB accessories that are compatible with Windows XP and USB1.0:

- USB printer (Printer Support)
- USB external hard drive (External Backup Support)
- USB flash drive (USB / Thumb Drive Support)

The LipiView® Interferometer is designed to operate wirelessly with other network devices, such as a printer. Placement of the LipiView® Interferometer should be within range of the network, if a network system is used.

The LipiView® Interferometer supports connection to an external monitor; refer to Section 19, *Appendix B: External Monitor Hookup*, for more information.

9.2 User Interface

9.2.1 Touchscreen Display Layout

After user login, all touchscreen displays are formatted with a menu bar across the top containing a disk space indicator and up to seven tabs, one for each key function of the system. A light gray colored tab indicates the active function. Any other tabs shown on the menu bar may be selected. On screens involving a patient record, patient identifier information is displayed on the right end of the menu bar.

Figure 9-3 shows a sample menu bar. The light gray color on the View Images tab indicates it is the active function. Functions have one or more associated screens. From left to right, the menu bar contains: Help tab, Log Out tab, Disk Space Indicator, Admin tab, Patient Records tab, Capture Images tab, View Images tab, Print/Save tab, and patient identifier information.

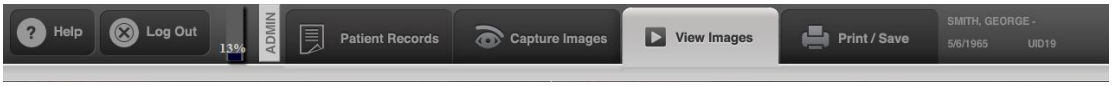


Figure 9-3: Menu Bar from View Images Tab

The Login screen contains the *Help* tab and the disk space indicator:

- **Help** – Pressing *Help* displays information related to the active screen. Pressing *Help* again closes the screen. Refer to section 10.6, *Online Help*.
- **Disk Space Indicator** – The bar to the right of the *Help* tab indicates the percentage of the available disk space that has been used for video storage. The Administrator can configure at what hard drive fullness level (e.g., 75%) the LipiView® Interferometer will no longer capture new images due to a full disk. Refer to Section 16.7, *Admin Networking* for information on setting the fullness level, cloning and archiving content to free up disk space.

Once the user logs in, up to six additional tabs are visible, depending on the current screen:

- **Log Out** – Pressing *Log Out* exits the user from the device and the Login screen described in Section 10.1.3, *User Login* is displayed.
- **Admin** - If the Username that is logged into the system has been set up as an Administrator, an *Admin* tab will be visible to the right of the disk space indicator

on all screens. Refer to Section 15, *Administrator Instructions for Use* for a description of Administrator functionality.

- **Patient Records** – Pressing *Patient Records* displays patient information, and allows the user to search for, add or edit patient information. Refer to Section 10.2, *Patient Data Entry*.
- **Capture Images** – Pressing *Capture Images* allows the user to record video for each eye, preview video, rerecord video (if needed), and save video. Refer to Section 10.3, *Video Image Capture and Recording*. If the power on self-test described in Section 10.1.1 detects a problem that would potentially affect this modality, this tab will not be functional and will be grayed out (refer to Section 9.2.4). The LipiView® Interferometer will not be able to capture images but prior data can still be reviewed.
- **View Images** – Pressing *View Images* allows the user to review saved videos and request a computer analysis. Refer to Section 10.4, *Video Review and Analysis*.
- **Print / Save** – Pressing *Print / Save* allows the image with the video analysis to be printed and/or saved to an HL7 compatible database. Refer to Section 10.5, *Video Print and Save*.

Patient identifier information is shown on the right end of the menu bar when a patient record has been selected. This includes the Captures Images, View Images and Print / Save tabs. The information is extracted from the Patient Record, so the contents may vary. At a minimum, it includes the Patient ID or the Last Name, First Name and Date of Birth.

The screen below the menu bar contains information relevant to the active function tab. When entering information is allowed, an onscreen keyboard is displayed at the bottom of the screen, as discussed in the next section.

9.2.2 Onscreen Keyboard

When the cursor is positioned in a location that requires user input, the onscreen keyboard in Figure 9-4 is displayed. This keyboard contains an alphabet keypad (uppercase only), a numeric keypad, and five special keys that perform as specified below. The onscreen keyboard does not contain or support the use of special characters other than the backslash (\) and colon (:) between the two keypads.

- **Left arrow above the "Q"** – Scrolls backwards through entered text to facilitate the insertion or deletion of characters.
- **Right arrow above the "W"** – Scrolls forwards through entered text to facilitate the insertion or deletion of characters.
- **Delete key above the "O" and "P"** – Deletes the character to the left of the cursor.
- **Left tab above the "8"** – Moves the cursor to the prior field allowing user input. Repeated presses on the left tab key will continue looping the cursor backwards through fields on the current screen, but it does not return to the previous screen.

- **Right tab above the "9"** – Moves the cursor to the next field on the screen allowing user input. Repeated presses on the right tab key will continue looping the cursor forwards through fields on the current screen, but it does not advance to the next screen.

Each key press yields one character or cursor movement of one position. Keys do not repeat if they are held down.

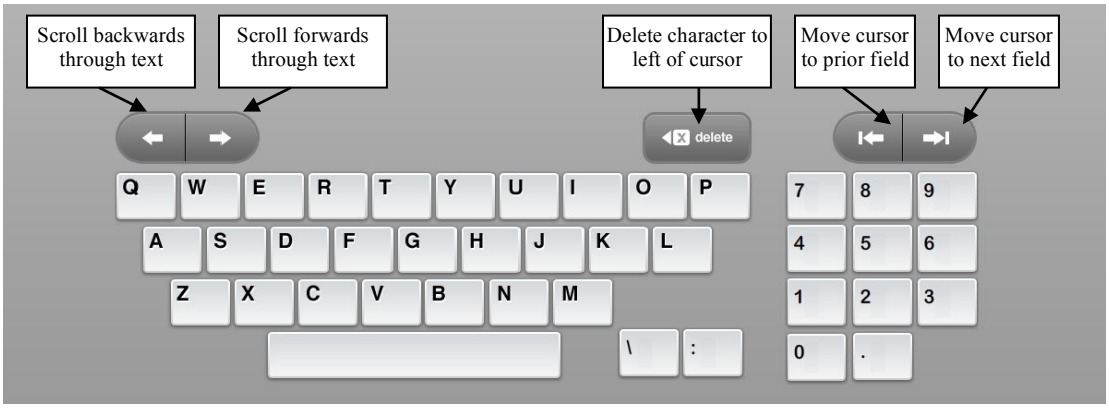


Figure 9-4: Keyboard

9.2.3 Positioning the Cursor

The LipiView® Interferometer touchscreen display allows the user to position the cursor by touching the desired area of the screen, or by pressing the arrow, delete or tab keys described in the previous section.

When making an edit to an existing field without positioning the cursor, any new characters entered are appended to the existing text, rather than replacing it. Use the Delete key to clear a field first, and then re-enter the information, or use the arrow keys to position the cursor in the correct location.

To facilitate editing, multiple characters on the screen can be highlighted by touching and then dragging a finger to the left or right. The series of highlighted characters is treated as one character when the arrow, delete and tab keys are used. The left or right direction of the finger movement determines where the cursor is placed when the special key is used.

9.2.4 Screen Interaction and System Messages

At times a portion of the active screen may be grayed out indicating it is temporarily inaccessible to the user. For example, if the onscreen keyboard is present, user input would be restricted to the keyboard. Selecting other tabs or pressing other areas of the screen will result in no action.

System messages are generated by the software running on the device when the user attempts to perform an invalid operation, or when something unexpected occurs or to confirm completion of an event. These messages may instruct the user on a particular

action to take (e.g., enter a missing field, or correct the format of a date field). When a system message is visible it requires a response from the user before any other input from the screen is accepted. The user must respond by pressing a button on the system message. Typically this is the *Close* button, but it may also be a confirmation or other dialog.

System messages related to Windows error codes will also be listed in the System Log described in Section 16.9, *Admin System Log*.

9.3 Patient Interface

The only part of the LipiView® Interferometer that directly interfaces with the patient is the ophthalmic chin rest support. **Ensure that all parts of this support are cleaned with an alcohol wipe prior to each patient use and prior to storage.**

9.4 Device Setup

Prior to initial use, ensure that the instructions in Section 16.1, *First Time Setup* have been completed by an Administrator. Other administrative functions should be completed at the discretion of the Administrator.

Ensure that the power cord is plugged into an electrical outlet. The power cord connection is located underneath the base of the device.

10 Instructions for Use

This section provides instructions for use of the LipiView® Interferometer to image the ocular surface and to observe the tear film of the eye through specular reflection of light. The instructions include:

- Device Startup (Section 10.1);
- Patient Data Entry (Section 10.2);
- Video Image Capture and Recording (Section 10.3);
- Video Review and Analysis (Section 10.4);
- Video Print and Save (Section 10.5);
- Online Help (Section 10.6); and
- Log Out (Section 10.7).

Additional administrative functionality is described in Section 16, *Administrator Instructions for Use*.

10.1 Device Startup

10.1.1 Power On and Self-Test

Upon powering on the device, the LipiView® Interferometer performs a self-test, confirms that the camera is connected, verifies system voltages, checks remaining hard drive space, and calibrates the camera motors. Version information at the bottom of the screen indicates the software running on the interferometer.

1. ***Power On*** - Power on the LipiView® Interferometer by pressing the rocker switch on the base of the device behind the touchscreen. Refer to Figure 9-2 for the location of the power switch. An indicator light on the power switch illuminates when the device is powered on.

   NOTE: The LipiView® Interferometer should be powered off overnight to allow the device to cool down. However, the device does not need to be powered off between patient examinations.
2. ***Software Boot Up*** - The touchscreen display remains blank while the software boots up. After a short time a "Welcome" message is briefly displayed. Shortly thereafter the screen in Figure 10-2 is displayed as the initialization process begins. The system version number displayed represents the software release which is currently installed. This manual is designed for all software releases that are labeled as 2.x. The exact letter of your system version may not match Figure 10-2.

   The system will display a warning (shown in Figure 10-1 below) that must be acknowledged before the initialization process continues: "Ensure patient and operator are clear of the chinrest area. The unit will now automatically home the motor system. Press the Continue button to begin."

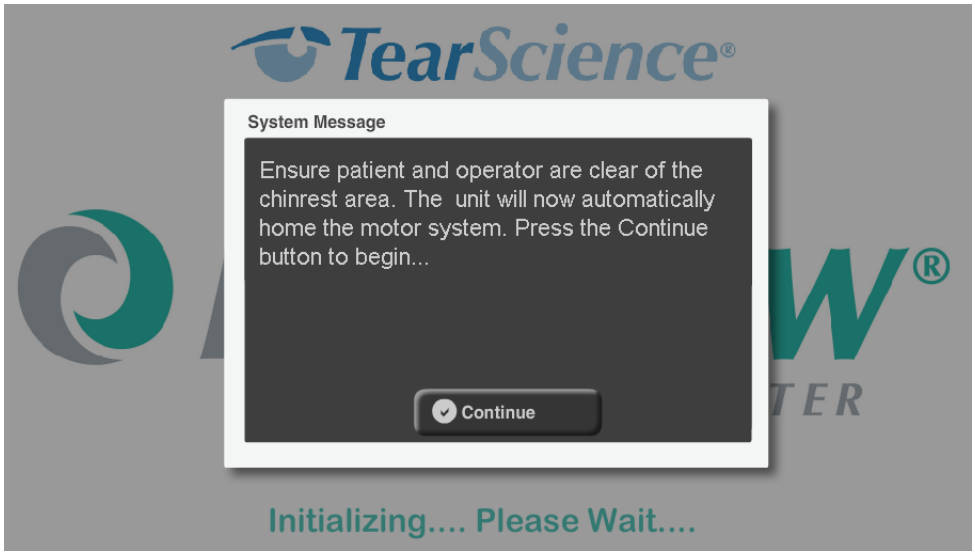


Figure 10-1: Warning screen

Figure 10-2: Initialization Screen

3. ***Equipment Location and Calibration*** - Figure 10-2 is displayed as equipment is located and calibrated. The motion stage moves up and down during the motor calibration process. When the initialization process completes after about 20 seconds, the screen in Figure 10-3 is displayed indicating that the device is ready for use. Continue with Section 10.1.2, *Device Ready*.

10.1.2 Device Ready

At the completion of the self-test, the words *Initializing*.... *Please wait*.... on the screen are replaced with the words *Touch Screen To Continue* as shown in Figure 10-3.

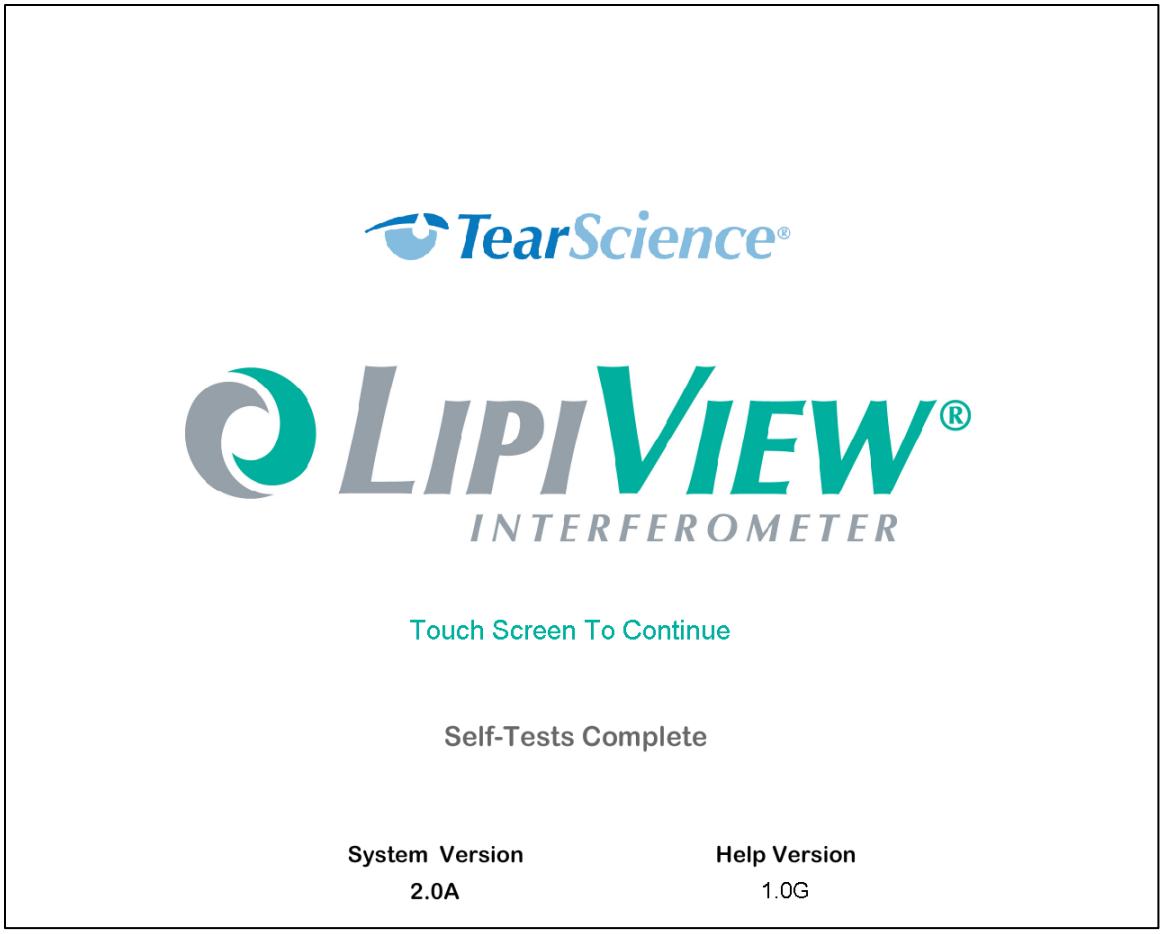


Figure 10-3: Device Ready Screen

When ready to continue, press anywhere on the screen. The login screen in Figure 10-4 will be displayed. Continue with Section 10.1.3, *User Login*.

10.1.3 User Login

The User Login screen in Figure 10-4 is displayed until *Submit* is pressed after a valid username and password have been entered. Refer to Section 16, *Administrator Instructions for Use* for setting up usernames and passwords prior to use of the device.

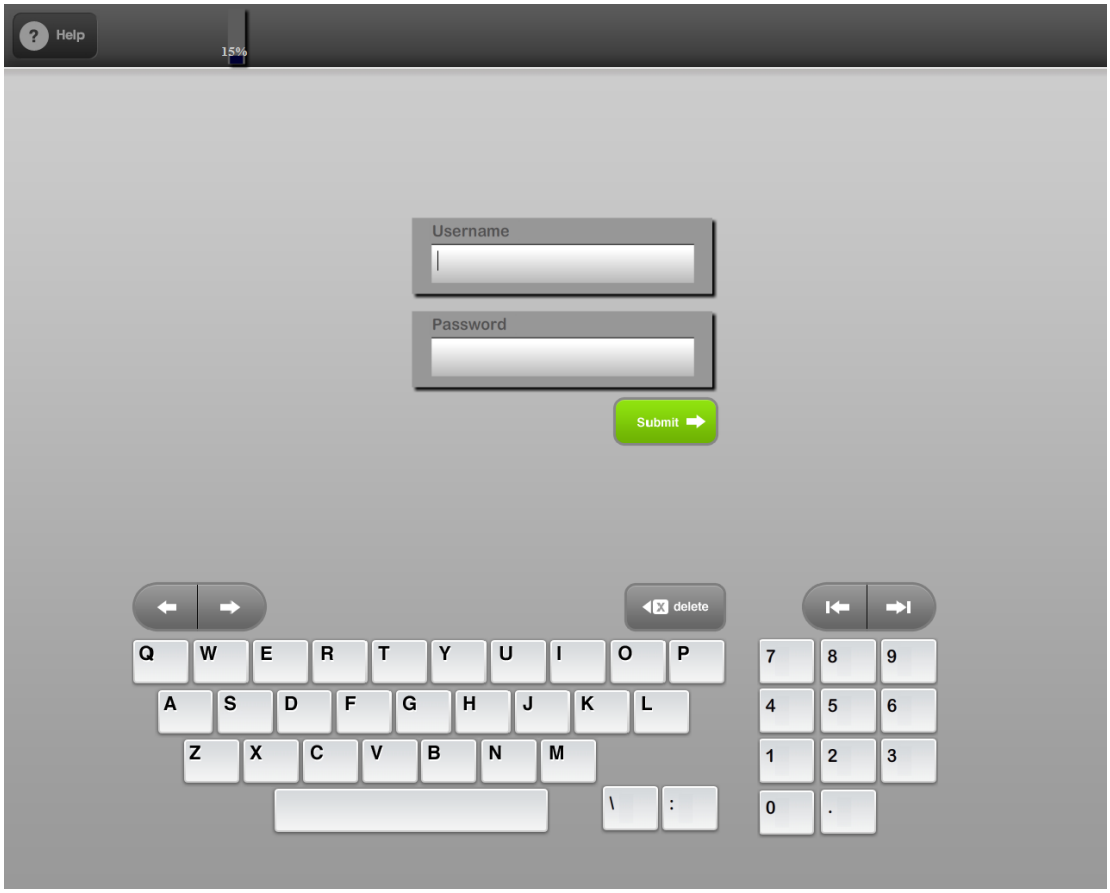


Figure 10-4: Login Screen

1. ***Username and Password*** - Using the onscreen keyboard, enter the Username and Password as follows:
   A. Type the name of the user.

      NOTE: Prior to device use, the Administrator must enter the Username and Password in the system.

   B. Position the cursor in the text box for the Password by touching the tab key or the password field.

   C. Type the password.

      NOTE: In the event of a forgotten password, or to change a password, contact the Administrator. Only the Administrator can set or change a password.
2. ***Submit*** - Press *Submit* and continue with Section 10.2, *Patient Data Entry*.

10.2 Patient Data Entry

After successfully logging in, the Patient Records screen shown in Figure 10-5 is displayed. The Patient Records screen is used to find an existing patient record or to add a new patient record if it is not found in the database.

Prior to beginning an examination, a patient's record must be selected. A patient's record must also be selected to view any previous videos. Until a patient record is selected, the Capture Images and View Images tabs on the menu bar are not active.

Figure 10-5: Patient Records Screen

10.2.1 Patient Records Screen

All patient records contain up to five pieces of information: Patient ID, Last Name, First Name, Middle Initial and Date of Birth. At a minimum, each patient record must include 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. The Patient Records screen contains these five blank fields, which are used to locate, create or update a patient record, followed by a tabular list of existing patient records.

The Patient ID field can contain up to 16 characters. Fields for the Last Name and First Name can contain up to 25 characters each. The middle initial contains up to one

character. The Date of Birth includes a one or two-digit month, followed by a one or two-digit day, followed by four-digit year.

The patient records table in the center of the screen lists the first eight patients in the database in alphabetical order. Once more than eight names have been saved, the step keys to the right of the table can be used to move backwards or forwards through the table. Each time the backwards (upper) key is pressed the previous eight names are displayed. Pressing the backwards key when the beginning of the list is displayed does not elicit a response. When the forward (lower) key is pressed, the next eight names are displayed in the table. Pressing the forward key when the last eight names are displayed also results in no change to the tabular display.

When the list of patient records spans multiple pages, sorting the table may facilitate searching for a record. Pressing the Patient ID, Last Name, First Name or Date of Birth header will sort the table by that column. Pressing the same header a second time will sort the table in the reverse order. A small triangle in the column header indicates that the table is being displayed according to the data sorted by this column. The triangle points down or up to specify the direction.

10.2.2 Locate a Patient Record

A patient record must be in the database before images can be captured or viewed. To attempt to locate a patient record in the database, search for the record using one of the following two methods. For existing patients, using the step keys in method 1 may be preferred. For new patients, use method 2. If uncertain as to whether a patient record is in the database, use either or both of these methods to determine whether the patient record exists.

1. ***Locate Patient Record with Step Keys -*** Use the step keys to move backwards (upper key) or forwards (lower key) through the database, while examining the records displayed in the table for a match. If desired, press the table header for Patient ID, Last Name, First Name or Date of Birth to sort the table by that field.
   A. If the record cannot be found in the table, then continue with method 2 to confirm the patient record does not exist.
   B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action*.
2. ***Locate Patient Record by Typing*** - Begin typing the patient's Last Name, First Name and/or Date of Birth in the fields above the table, or position the cursor in the Patient ID field and begin entering the ID. As each character is entered, the patient records table is filtered displaying only the possible matches that exist in the database.
   A. If no records are displayed in the table then the patient record does not exist. Either correct the entered information, or continue with Section 10.2.3, *Add a New Patient Record*.
   B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action*.

10.2.3 Add a New Patient Record

When a patient record could not be located in the database, the screen shown in Figure 10-6 is displayed, allowing the user to enter new patient information and save it.

NOTE: Depending on the information entered when trying to locate a patient, one or more of the five fields in the patient record may be empty or partially filled in. As soon as the system determined there was no patient record match in the database it transitioned to Figure 10-6.

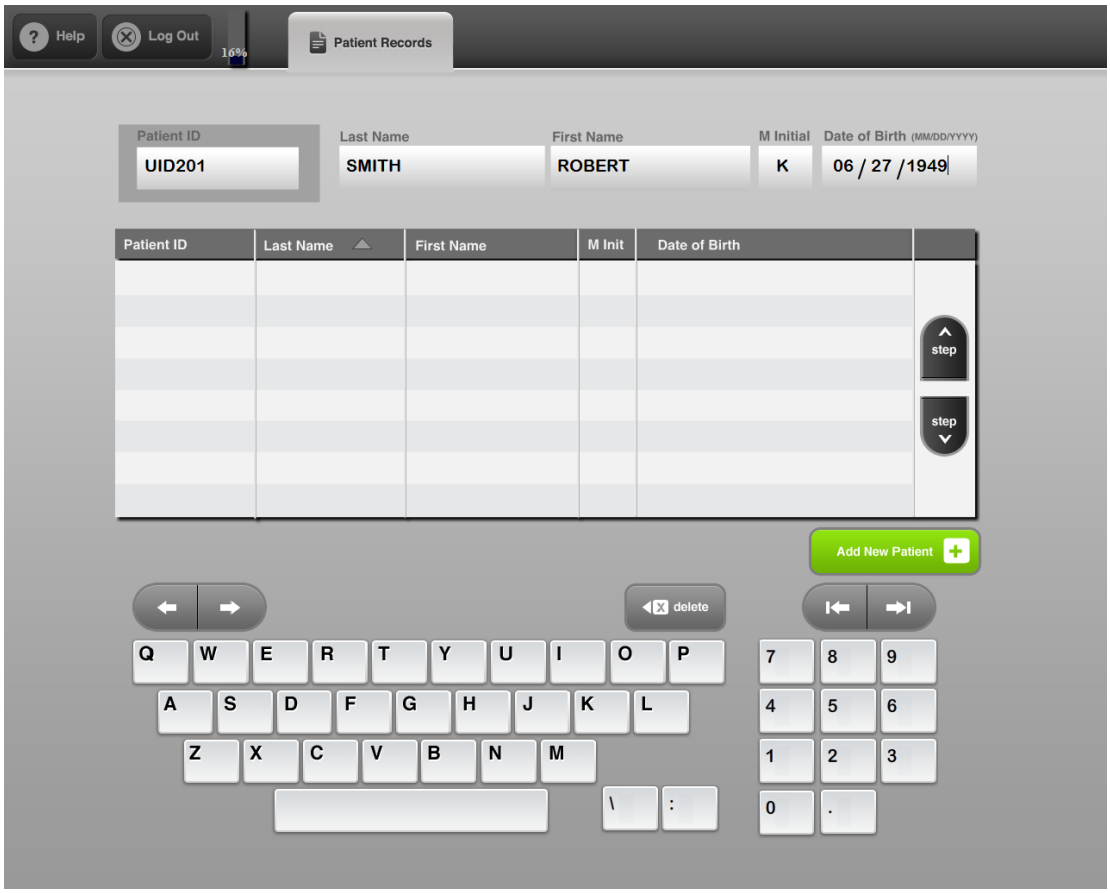


Figure 10-6: Patient Records Screen - Add a New Patient

At a minimum each patient record must contain 1) a Patient ID or 2) the Last Name, First Name and Date of Birth fields to proceed. The instructions below specify entering new patient information beginning with the Last Name; however, information may be entered into the fields in any order, and only the minimum information is required. Touch the appropriate fields or use the tab keys to move from field to field.

1. ***Patient Name*** – Enter the patient's Last Name and First Name and optional middle initial:
   A. Enter the Last Name, up to a maximum of 25 characters.
   B. Enter the First Name, up to a maximum of 25 characters.

C. Enter the middle initial if desired. Entry may be helpful with common last names.

2. ***Date of Birth*** - Enter the patient's Date of Birth, using a one or two-digit month, followed by a one or two-digit day, followed a four-digit year. If an invalid date is specified, a system message is displayed indicating required information. Press *Close* and try again.

   NOTE: If a one-digit month or day is entered, position the cursor in the next field by touching the field or the tab key. If a two-digit month or day is entered, the cursor will automatically move to the next field.

3. ***Patient ID*** - Enter the Patient ID, up to a maximum of 16 characters. If a patient ID is entered, no other information is required to complete the patient record.

4. ***Review Record before Adding*** - Confirm that the information for the new patient is correct, and that the minimum fields have been filled in. Once a patient record has been entered into the database it cannot be deleted.

5. ***Add Patient Record to Database*** - Press *Add New Patient*.

   A. If a required field is empty or the new record is a duplicate of one that already exists in the database, a system message indicating the error is displayed. Touch *Close* to shut the system message. Make the appropriate corrections and press *Add New Patient* again.

   B. If the minimum required fields have information, there is a valid Date of Birth, and the patient record is not a duplicate of an existing record, it is saved in the database. The Patient Records screen in Figure 10-5 is redisplayed with the new patient record highlighted, and showing at the top of the table.

      NOTE: If the record added is the last record in the table, it appears to be the only record until the backwards (upper) step key is pressed showing other records.

   C. Return to Section 10.2.2, *Locate a Patient Record* to add another patient or find an existing patient, or touch any field on any record in the table and continue with Section 10.2.4, *Select a Patient Action*.

10.2.4 Select a Patient Action

Once a patient's record is visible in the patient records table, press on any field in the patient record. The row will become highlighted, the *Select a Patient Action* system message will appear, and the remainder of the screen will be grayed as shown in Figure 10-7, indicating that it is temporarily inaccessible for user input. Choose one of the four options in the system message:

- **Edit Patient** – Select this option to proceed to the Edit Patient Information screen, and continue with Section 10.2.5, *Edit Patient Information*.

  NOTE: A patient record may only be edited if video images have not previously been saved.

- **Capture New Images** – Select this option to proceed to the Capture Images screen, and continue with Section 10.3, *Video Image Capture and Recording*.

- **View Past Images** – Select this option to proceed to the Patient History screen, and continue with Section 10.4, *Video Review and Analysis*.
- **Close** – Select this option if the incorrect record was chosen, and return to Section 10.2.2, *Locate a Patient Record* to try again. The system will close the system message, but the row will remain highlighted until another row is selected.

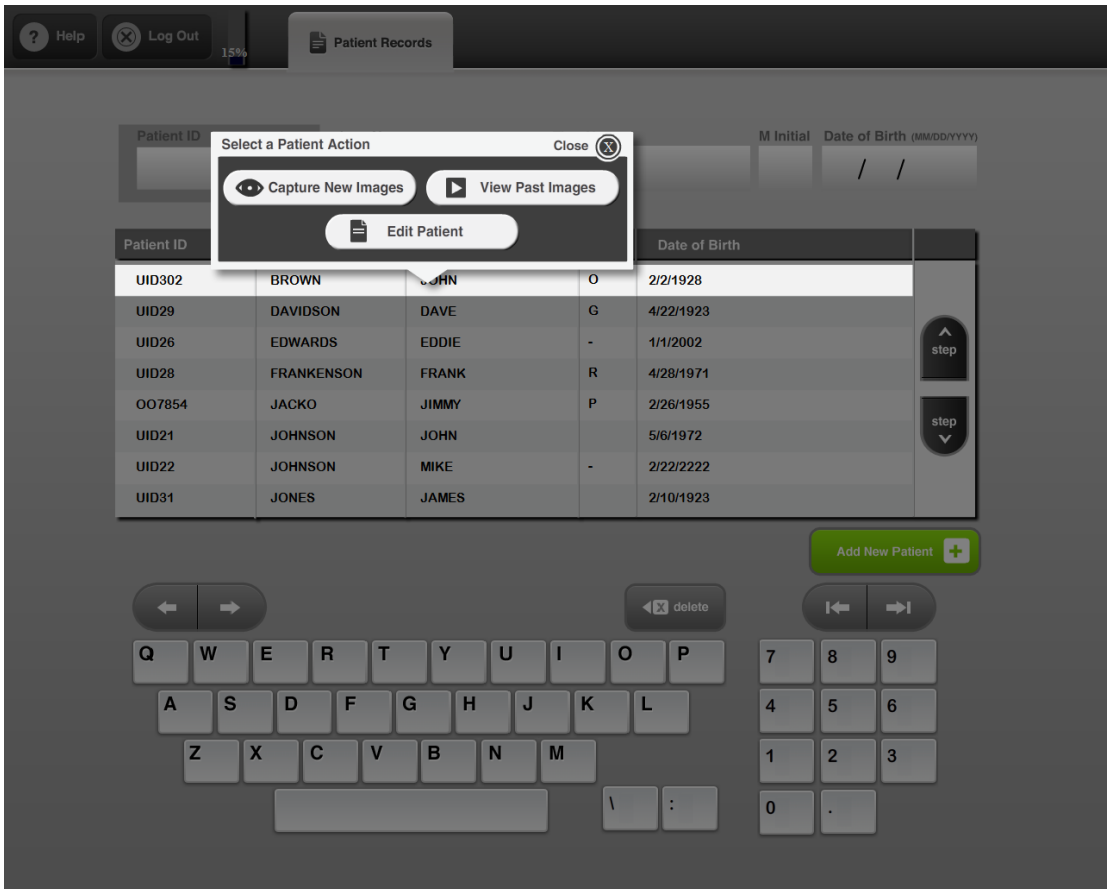


Figure 10-7: Patient Records Screen - Select a Patient Action

10.2.5 Edit Patient Information

When *Edit Patient* is pressed in the *Select a Patient Action* system message, either the screen in Figure 10-8 will be displayed showing the current information for the chosen patient, or a system message will be displayed indicating that video data has been captured for this patient and the record cannot be modified.

Figure 10-8: Patient Records Screen - Edit Patient Information

1. ***Edit Patient Record*** - Position the cursor in the field(s) to be edited and make the changes. At a minimum, the patient record must contain 1) a Patient ID, or 2) the Last Name, First Name and Date of Birth. Continue with step 2 to save the edited data or step 3 to cancel the edit.
2. ***Save Patient Record Edits*** - Press *Continue* to update the patient's information in the database.
   A. A system message will result if a mandatory field is empty or the modified record is a duplicate of one that already exists in the database. Touch *Close* to shut the system message. Return to step 1 to correct the entered fields, or go to step 3 to cancel.

      NOTE: It is not possible to remove a patient record from the database by clearing out all fields. Once a patient record has been added it cannot be deleted.

   B. If the required fields exist and the record is unique, the system returns to the Patient Records screen in Figure 10-5 with the updated record highlighted and showing at the top of the table. Continue with Section 10.2.2, *Locate a Patient Record*.
3. ***Exit without Saving Patient Record Edits*** - Press *Cancel* to return to the Patient Records screen in Figure 10-5 without saving any edits. The highlighted row will be displayed in the same location. Continue with Section 10.2.2, *Locate a Patient Record*.

10.3 Video Image Capture and Recording

When *Capture New Images* was chosen from the *Select a Patient Option* system message shown in Figure 10-7, the Capture Images screen in Figure 10-9 is displayed. As the screen displays, the illuminator is turned on and the system initializes the camera for approximately 1-2 seconds. The right end of the menu bar contains the patient information as entered in the selected patient record.

NOTE: If the Capture Images screen was reached by mistake, or to exit without capturing a video, press the *Log Out* tab, or press *Save All/Continue*, which will transition to the View Images function. From the menu bar on the View Images screens, all tabs are available for selection.

Figure 10-9: Capture Images Screen

10.3.1 Capture Images Screen

The Capture Images screen is split into left and right sections.

From the left side below the *Selected Frames* header, the user chooses which eye will have video captured. Information about the video image may be selected or entered from the tags below.

- **View OD** (Right Eye) – Select this to move the camera into position to view the right eye. This selection automatically illuminates the appropriate fixation bank for the patient's left eye. The patient fixates on a light with the left eye while the right eye image is being captured.
- **View OS** (Left Eye) – Select this to move camera into position to view the left eye. This selection automatically illuminates the appropriate fixation bank for the patient's right eye. The patient fixates on a light with the right eye while the left eye image is being captured.

  NOTE: The frame that is white indicates the selected eye. The frame that is grayed out was not selected.
- **Pre-set Tags** (rounded, gray color) – If applicable, the user may select one or both of these configurable, descriptive tag names before or after the video is captured. Once the video is saved, information selected here is permanently retained with the video data. These tags are pre-set by the Administrator as described in Section 16.3, *Admin System Setup*.
- **Key-in Tags** (rectangular, white color) – If desired, the user can enter up to 15 characters of information into each of these two fields before or after the image is captured. Information is typically specific to the patient or image. Once the video is saved, information entered here is permanently retained with the video data.

The right side of the screen is initially blank, but will display images of the selected eye as the video is recorded. Prior to recording the video image, the following controls are used to obtain the best possible image:

- **Left slider** – Touch the step keys to move the entire motion stage (including camera and illuminator) up and down for proper positioning. The button on the slider indicates the current motor position.
- **Horizontal slider** – This slider moves the camera inside the motion stage to the left or right. When *View OD* or *View OS* is pressed, the camera is moved to a default location for the selected eye near the OD or OS button on the slider. The camera position is fine-tuned by touching a location on the slider or by pressing the left or right step keys. While on the Capture Images screen the software will remember the last position of the camera for both *View OD* and *View OS* until *Save All/Continue* has been pressed. This enables the operator to easily move between the right and left eyes by touching *OD* and *OS* on the slider bar.

- **Automatic Image Centering-** An alternative method of centering the eye on the screen is to touch the location on the live video that should be in the center (typically the pupil). The camera will automatically be moved to the location that was touched on the screen, and that location becomes the center of the video image.
- **Fixation Light** – The three-way button on the top right of the Capture Images screen operates a fixation light, which consists of a vertical set of three light emitting diodes (LEDs) behind the camera for the patient to look up, look straight ahead or look down. The default position is straight ahead.
- **Focus slider** – This slider moves the camera inside the motion stage forwards and backwards to bring the image in (-) or out (+).

NOTE: To change the position of the item controlled by a slider, press the desired location on the slider. The item and the button will move accordingly. Touching the button and dragging it has no effect.

10.3.2 Capture the Video

The following steps instruct the user on how to set up the device, position the patient and capture the video:

1. ***Eye Selection*** - On the left side of the screen touch *View OD* or *View OS* for the eye to be captured. *View OD* is the initial default if no selection is made. Once a video has been recorded, the default selection is the last eye captured. The selected view will be white and the other will be a gray color.
2. ***Pre-set Tags*** - Select one or both of the pre-set tags, if desired. The system will note a selection with a checkmark. The selection may be made here or while previewing the captured image in Section 10.3.3. If selected here, it may be updated anytime until the video is saved.

   NOTE: Press the checked tag again to deselect it.
3. ***User Defined Key-In Tags*** - If desired, use the key-in tags to record additional information in each tag. Information may be entered here or as part of previewing the captured image in Section 10.3.3. If entered here, it may be updated anytime until the video is saved.
   C. Touch a key-in field to display the onscreen keyboard.
   D. Enter information in one or both of the key-in tags.
   E. Touch *Submit* on the left of the onscreen keyboard. The screen in Figure 10-9 will be displayed with the updated tag names.
4. ***Disinfect*** – Disinfect the chin and forehead rest surfaces with alcohol prior to patient use.
5. ***Patient Positioning*** - Have the patient sit facing the LipiView® Interferometer. Ensure the patient's chin is placed fully forward into the chin rest and the patient's forehead is placed firmly against the forehead rest to ensure proper attitude of the patient's head. If the patient's head is not in the proper position, valid video data may not be collected. Instruct the patient to look at the orange fixation light.

Caution: **Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct the patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.**

6. ***Chin Rest Height Adjustment*** - Adjust the height of the chin rest by spinning the fluted roller near the base of the chin rest so that the lateral (temporal) canthus is aligned with the horizontal canthus alignment marks on the left and right sides of the forehead rest. Spin the roller to the right to lower the chin rest and spin the roller to the left to raise it.
7. ***Camera Adjustment*** – By default the camera should be in the general location of OD or OS (depending on the view selected in step 1, as shown in Figure 10-10. Position the height of the camera by stepping the motors up and down using the left slider. Use the horizontal slider to adjust the camera sideways. Alternatively, touch the desired location the screen which will automatically move the motion stage and the camera to that position and then center on it. Adjust the image until the pupil appears in the center of the live video screen and the reflected tear film image is within the green targeting rectangle.

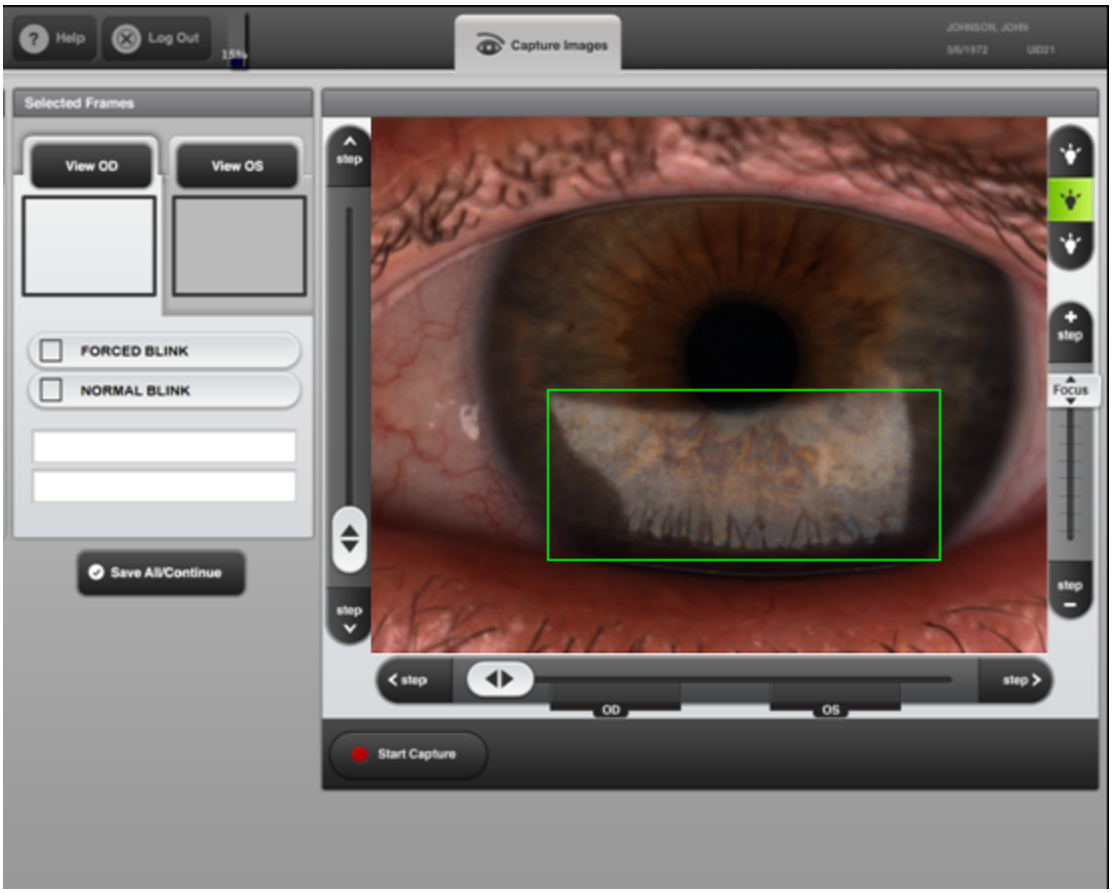


Figure 10-10: Capture Images Screen - Centering Eye Before Recording

8. ***Camera Focus*** - Adjust the closeness of the image with the Focus slider on the right. The focus should be adjusted so that the tear film image is clear and not blurred.

   NOTE: If the tear film image is not in focus, invalid video data may be saved. As shown in Figure 10-16, analysis of invalid video data is unable to produce a graph and numerical results.
9. ***Fixation Light / Patient Gaze*** - Ensure the patient is looking in the proper direction to facilitate obtaining a well-centered and focused picture for the patient's eye. If necessary, press the upper or lower sections of the Fixation light, guiding the patient to look up or down.
10. ***Capture Image Start*** - Press *Start Capture* to begin recording approximately 20 seconds of video. Typically 10-15 seconds of video is enough to capture the tear film image as the patient blinks. Instruct the patient to blink naturally (e.g., NORMAL BLINK) or to perform a squeezed blink (e.g., FORCED BLINK) as desired, to evaluate the distribution of the tear film.

    NOTE: The blinking red light indicates the LipiView® Interferometer is recording, and the *Start Capture* button is renamed to *End Capture*. Other than pressing *End Capture,* the grayed out screen does not allow user interaction.
11. ***Capture Image End*** - Press *End Capture* to stop recording before 20 seconds has elapsed, or the system will automatically end the video after 20 seconds.
12. The illuminator is turned off when recording stops, and the screen in Figure 10-11 is displayed allowing the user to choose from several options. Continue with Section 10.3.3, *Preview Captured Image*.

10.3.3 Preview Captured Image

The right side of the Preview Captured Images screen in Figure 10-11 contains the video image just recorded. The left side of the screen contains the same functionality as the Capture Images screen (Figure 10-9), indicating information about the image. *View OD* or *View OS* indicate the eye being shown. When video for both eyes has been captured, the most recently captured video is the one displayed by default.

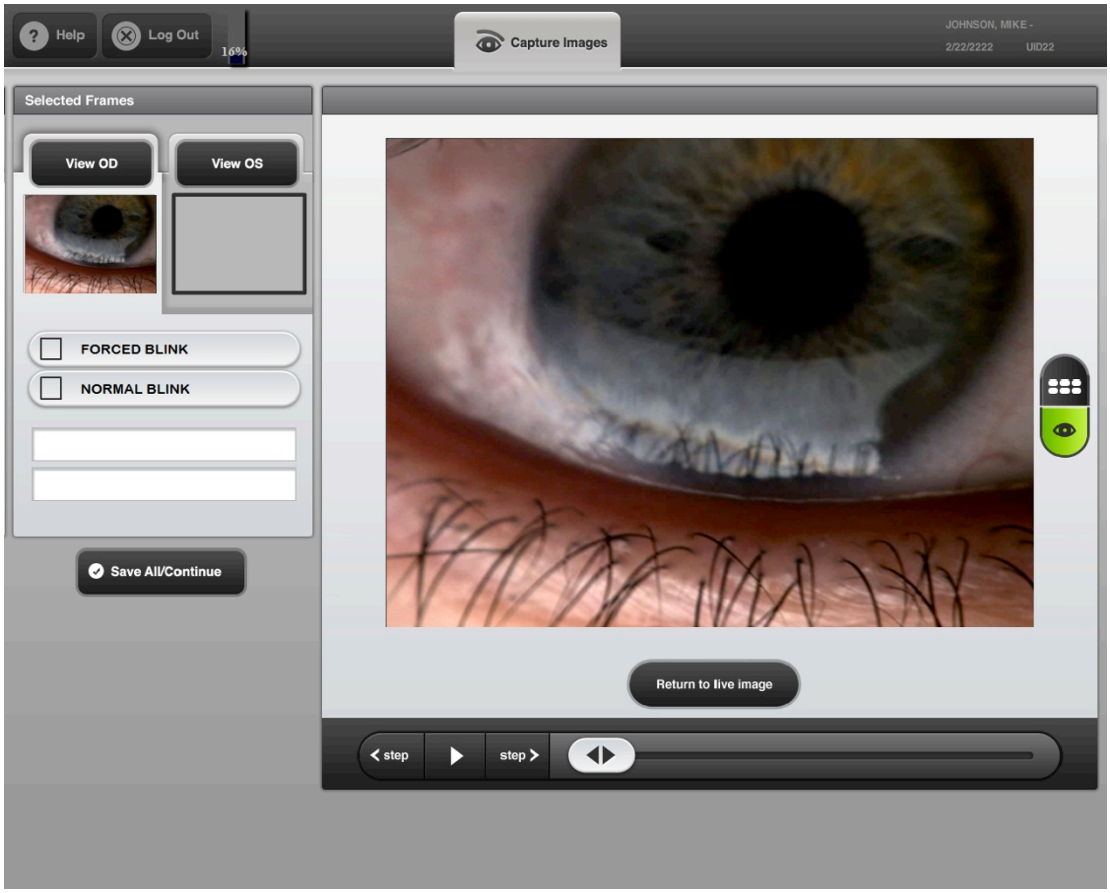


Figure 10-11: Capture Images Screen - Preview Captured Images

The Preview Captured Images screen enables the user to perform one or more of the following steps. Steps 1 – 4 are optional and they may be combined with other steps. Unless the user logs out of the system, the captured video must be saved (step 5) before other tabs become visible.

1. ***Preview Image*** - Preview the image using the following control keys:
   - **< step** – Press to step backwards through the video one frame at a time.
   - **Triangle/Vertical lines** – Press to play (triangle) or pause (two vertical lines) the video.
   - **step >** – Press to step forwards through the video one frame at a time.
   - **Video slider** – When in play mode, the button moves along the slider indicating the current position within the video. When in pause mode, press any location on the slider to move the video to the position indicated by the touch. The button will move to the new location.
   - **Toggle key** - The toggle key positioned to the right of the screen switches between a tear-film view and a full-eye view. Press the tiles to select the tear-film view. Press the eyeball to select the full-eye view. The green portion of the key indicates the active view.

2. ***Rerecord Video*** - Rerecord the video by pressing *Return to live image* above the video controls. The Rerecord Video screen in Figure 10-12 will be displayed. Continue with Section 10.3.4, *Rerecord Video*.
3. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the preview screen.
4. ***Eye Selection*** - Press the tab for the other eye (*View OD* or *View OS*). Figure 10-9 will be displayed for the selected eye. Return to Section 10.3.2, *Capture the Video* and follow the instructions. When the second video capture ends, Figure 10-11 is displayed with the most recently captured video showing. Return to step 1 and follow these steps for the second eye.
5. ***Save Video*** - Save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Rerecord Video screen in the next section.
   B. After the image is saved, the illuminator is turned off and the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

10.3.4 Rerecord Video

The Rerecord Video screen in Figure 10-12 is used when the captured image for one or both eyes is not acceptable to the user and it is necessary to rerecord the live image before it is saved. When this screen is displayed, the illuminator light is turned on.

This screen operates like Capture Images screen in Figure 10-10 except that when *Start Capture* is pressed, a system message asks the user to confirm that the user is intentionally overwriting the previous image. The image may be rerecorded any number of times. There is also an additional button on the bottom center of the screen allowing the user to return to the previously recorded image.

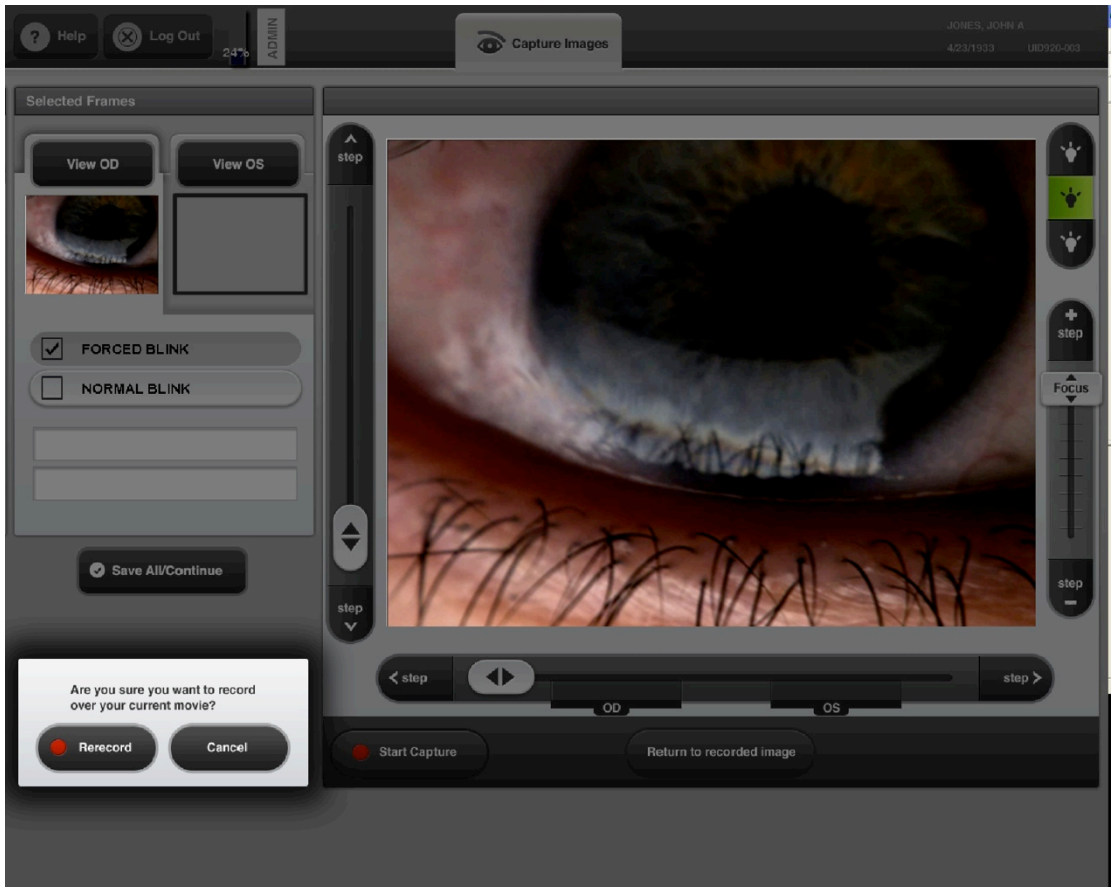


Figure 10-12: Capture Images Screen - Rerecord Video

1. ***Confirm Whether to Rerecord*** - If unsure whether to rerecord the image or if this screen was reached in error, press *Return to recorded image* to return to the Preview Captured Image screen in Figure 10-11. Follow the steps in Section 10.3.3, *Preview Captured Image*.

   NOTE: Toggle between these two screens by pressing *Return to recorded image* and *Return to live image*.
2. ***Eye Selection*** - If video for both eyes has been captured, ensure that the correct eye has been selected.
3. ***Camera Focus and Settings*** - Prior to rerecording, touch the screen or use the slider bars to reposition the camera, and modify the Fixation Light and Focus settings if needed.
4. ***Rerecord Image or Cancel*** - Press *Start Capture*. A system message will appear on the bottom left of the screen to rerecord or cancel the request.

   A. Press *Rerecord* on the system message to begin capturing another image. When *End Capture* is pressed, the illuminator is turned off and the system returns to the screen in Figure 10-11. Return to Section 10.3.3, *Preview Captured Image*.

NOTE: When *Rerecord* is pressed, the original captured image will be overwritten with the new one. Recording of the image can be repeated as many times as needed until the image is acceptable.

B. Press *Cancel* on the system message when unsure whether to rerecord. The system message will be removed. Return to the recorded image (step 1), rerecord the image (step 4A) or continue with step 5.

5. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the previous screen.
6. ***Save Video*** - When the captured image is satisfactory, save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Preview Captured Images screen in the previous section.

   B. After the image is saved the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

10.4 Video Review and Analysis

The Video Review and Analysis function is used to review information about a captured video for one or both of a patient's eyes. The View Images screen used to perform this function may be accessed after capturing a new video (continue with Section 10.4.1) or after selecting an image(s) from the patient's history (continue with Section 10.4.2). Patient information as entered in the selected patient record is listed on the right side of the menu bar. Other information on the screen will vary depending whether video was captured for both eyes, and whether the video has been analyzed.

10.4.1 View Images Screen after Capturing New Video

When *Save All/Continue* is pressed from any of the Capture Images screens in Section 10.3, *Video Image Capture and Recording*, the View Images screen in Figure 10-13 is displayed. From this entry point, the image on the screen is that of the eye(s) just saved. The OD eye is displayed on the left side of the screen and the OS eye is displayed on the right side of the screen. If only one eye was captured, the other half of the screen is blank. Since the images have not yet been analyzed, the numerical calculations below the images will be zero, and a message on the graph indicates that the user needs to press *ANALYZE IMAGES* to view the data.

Continue with Section 10.4.3, *View Images and Analyze Data.*

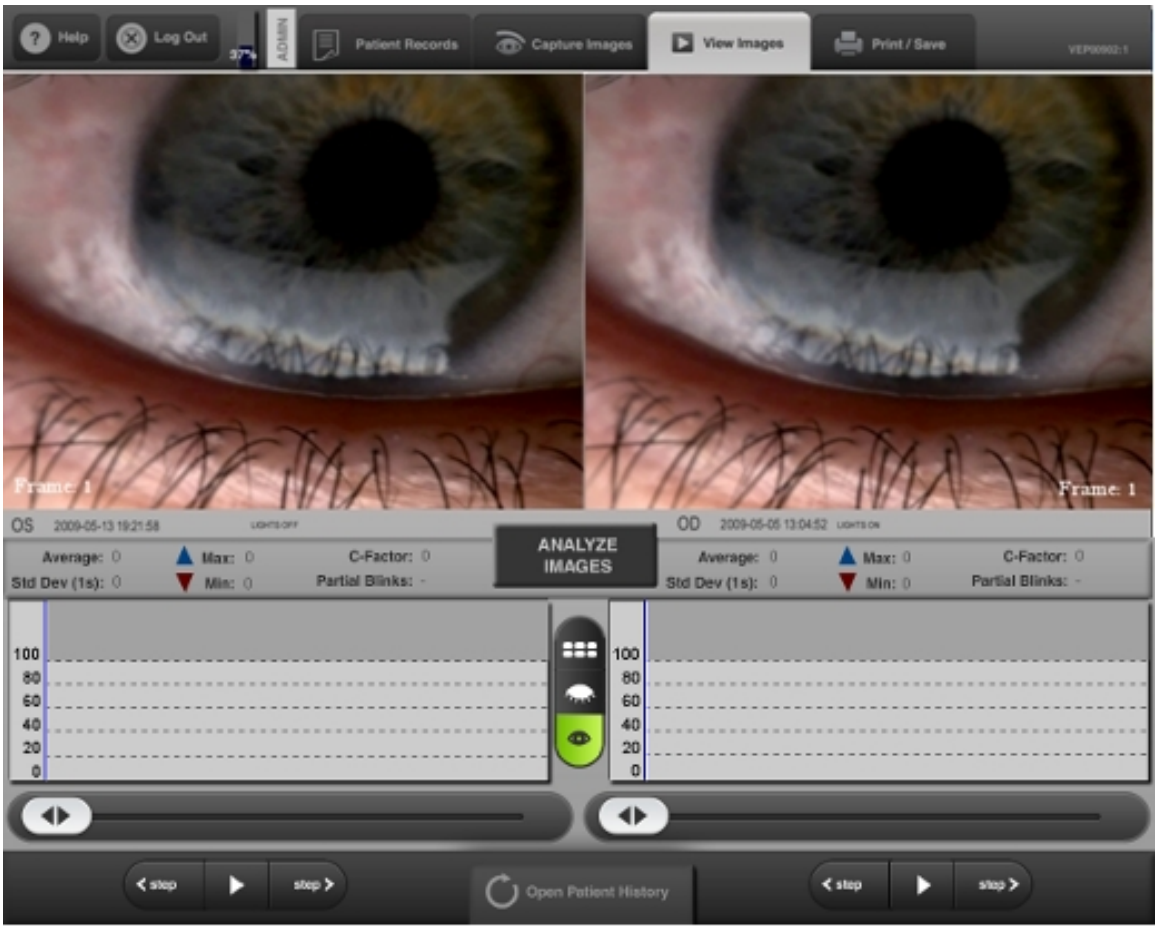


Figure 10-13: View Images Screen – Images not Analyzed

10.4.2 View Images Screen after Selecting from Patient History

When *View Past Images* is chosen from the *Select a Patient Action* system message, the user is directed to the screen in Figure 10-14 or to the screen in Figure 10-16, depending on the previous video that was reviewed. Note that, in either case, the first set of OD/OS images presented are standard reference video images of eyes with different ICU levels, provided for purposes of comparison.

If the previous video reviewed was from the same patient record that is currently selected, Figure 10-16 is displayed with the previously reviewed video showing and the Patient History list closed. Continue with Section 10.4.3, *View Images and Analyze Data*.

If the previous video reviewed was from a different patient record, the View Images screen is displayed with the tabular Patient History list open, as shown in Figure 10-14, so that the user can select which video(s) to display. The Patient History contains an inventory of all videos saved for the selected patient with the date and time as well as any information in the pre-set or key-in tags. If a video has been cloned, the patient history file will display “CLONED” to the right of the time. If the video has been archived and is

no longer online, “ARCHIVED” will be displayed to the right of the time. The process of cloning and archiving videos is an Administrator function, discussed in Section 16.7.1, *Disk Cloning*. An empty Patient History table (no video images) indicates that video data has not been saved for this patient.

The top left and right frames of the View Images screen are blank until videos have been selected. From the Patient History, the user will either select one or two videos, or press the *Close Patient History* so that other tabs become visible for selection.

Figure 10-14: View Images Screen - Select Past Images from Patient History

If a video will not be selected from Patient History, skip to step 6; otherwise, follow the steps below to select the video(s):

1. ***Locate First Video*** - Locate a video that will be loaded. Touch the step keys on the right to move backwards and forwards through the list if the Patient History table contains more than eight videos.
2. ***Load First Video*** - To load the video:
   A. Touch the thumbnail image located next to the date/time stamp of the video. If the video was archived, a system message appears asking for confirmation to restore the video. Choose from one of the following:

- Press *Close* to return to the open Patient History list, and repeat step 1 to locate a different video, or continue with step 6 to close the Patient History list.
- Press *Restore Video* on the system message to start copying the archived video. A progress dialog will appear showing the status of the restore. Once the file has been restored, the word ARCHIVED will be removed from the Patient History list. Touch the video again and continue with step B.

  NOTE: If a progress dialog does not appear indicating the start of the restore process, contact the Administrator to check the validity of the of the clone path on the Networking screen.

B. Drag the thumbnail image into the rectangular frame in the upper corner on either the OD or the OS side.

   NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

C. Drop the image by releasing your finger.

3. ***Video Loaded*** - The eye selection, date of captured video, pre-set and key-in descriptions, Username that captured the video and an image of the selected video will be copied into the blank tag cells as shown in Figure 10-15.
4. ***Locate / Load Second Video*** - Repeat steps 1 and 2 to select the second thumbnail image if desired, dropping in into the frame in the other corner.

   NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

Figure 10-15: View Images Screen - Videos Loaded from Patient History

5. ***Confirm Images Loaded*** - Confirm that the images loaded are the ones to be displayed. Update the left and right frames if desired, by dragging and dropping alternate thumbnail images.

   NOTE: Once an image has been dragged to either corner it cannot be removed; however, each additional image that is dragged and dropped will replace the previous one.

6. ***Close Patient History*** - Press *Close Patient History* at the top of the tabular list. The list will shut and the button will move the bottom of the screen. A message to wait will be displayed while the selected video(s) are loaded. Upon completion, continue with Section 10.4.3, *View Images and Analyze Data*.

   NOTE: If the Patient History table is closed without selecting a video, the screen in Figure 10-16 is displayed; however, there are no images shown on the top half of the screen. This sequence typically happens when the user has pressed the *Capture Images* tab in error, and wants to make the other tabs available. Since there are no images to view, the user should select from one of the tabs in the menu bar at the top of the screen.

10.4.3 View Images and Analyze Data

The View Images screen contains seven key sections, which are described below. Figure 10-16 shows the View Images after the images have been analyzed. One video shows valid image data; the other does not.

- **Video Images** – The top half of the screen contains frames for the OD and OS videos, when they are captured/selected for viewing. Each "Frame" is set to "1" initially, and the frame number is incremented as the video plays.
- **Video Descriptor** – Identifying information just beneath each video image includes OD or OS, the date and time of capture, and any pre-set or keyed in descriptive tag names.
- **Analyze Images button** – Pressing *Analyze Images* results in a numerical analysis of the interferometric colors and a graph for each of the videos. If for some reason the analysis cannot be performed, a message *NO VALID ANALYSIS DATA FOR VIDEO* replaces the graph, and the numerical information remains zero. After the analysis has been completed, the records are saved to the database. (Note: recorded images may only be analyzed once; attempting to "re-analyze" a set of images will result in an error.)
- **Numerical Analysis** – After the video has been analyzed, the following statistics above each graph are updated:
  - **Average** - The average ICU of all the frame averages (denoted by the black line in the graph).
  - **Std Dev** - The standard deviation of the frame averages.
  - **Maximum** - The maximum ICU recorded for a given frame.
  - **Minimum** - The minimum ICU recorded for a given frame.
  - **C-Factor** - The tear film Conformance factor for the entire video. The C-factor is defined as the percentage of pixels in the tear film that fall on the interferometric color spectrum. A C-factor of 1.0 indicates that every tear film pixel throughout the entire video loop has found a close match to an Interferometric color.
  - **Partial Blinks** – The number of partial blinks out of the number of total blinks counted, expressed as a fraction. The numerator (top number) is the number of partial blinks; the denominator (bottom number) is the total number of blinks counted. A partial blink value of 3/9 means that out of nine total blinks detected, three were evaluated as "partial blinks."
- **Graph** – After the videos have been analyzed, each graph shows the average Interferometry Color Unit (ICU) and standard deviation for each frame corresponding to the location in the video. Each point on the graph is the ICU value for that frame. The blue line and region is the upper standard deviation of the ICU score data. The red line and region is the lower standard deviation of the ICU score data. The blue triangle marker denotes the point on the graph that contains the maximum ICU score. The red marker triangle marker denotes the point on the graph that contains the minimum ICU score.

- **Video Controls** – The controls under each graph include a slider bar, backwards (< step) and forwards (step>) buttons and a play/pause button and function as described in Section 10.3.3, *Preview Captured Image*. Videos may be played before or after they have been analyzed.
- **Open Patient History button** – Pressing this button opens the Patient History list on top of the View Images screen and allows different videos to be selected for this patient. When the list is closed it returns to this button.

When the View Images screen is displayed after capturing new video, an analysis of the image data has not occurred yet, as seen in Figure 10-13. When the View Images screen is displayed with video from the Patient History, an analysis of the image data may or may not have occurred. If the data has been analyzed, the numerical information will be filled in and a graph will show under the video as shown in Figure 10-16.

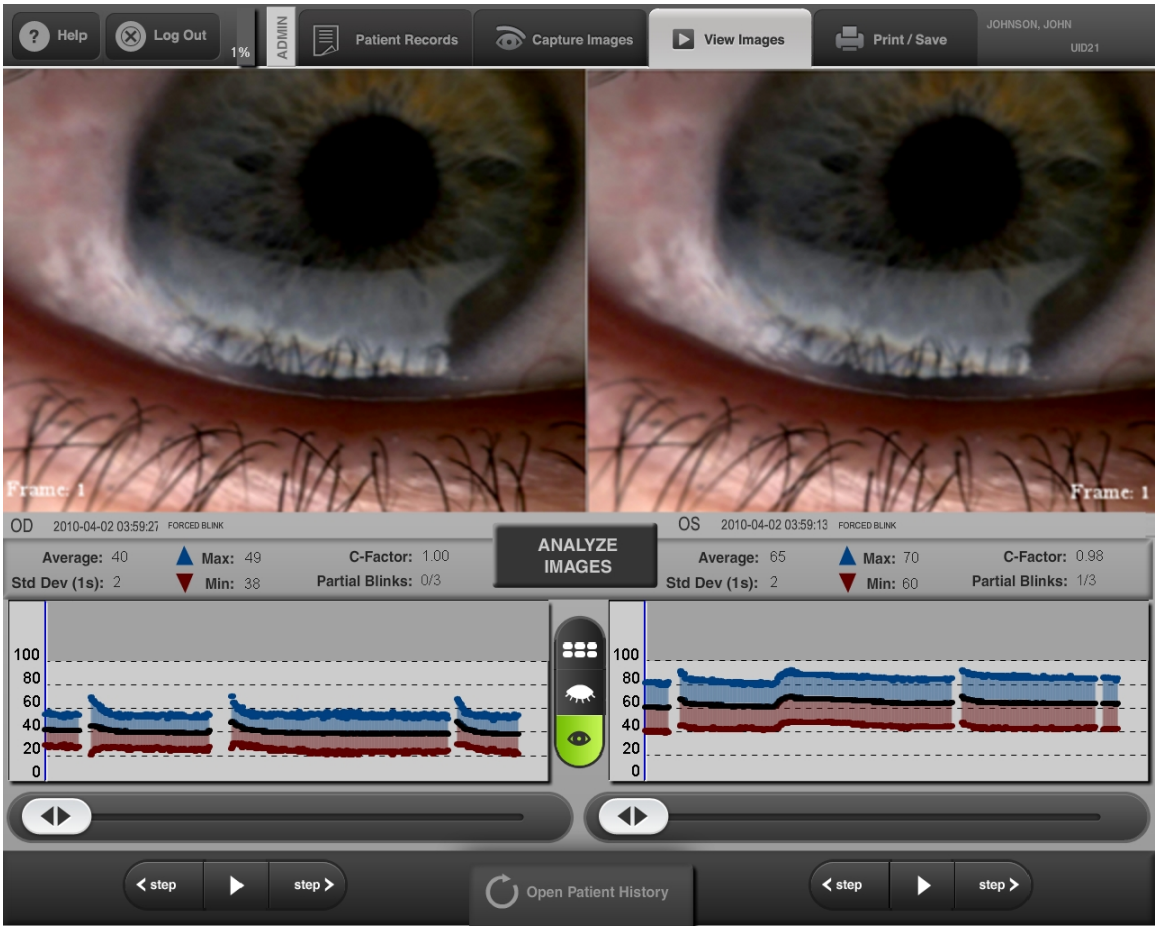


Figure 10-16: View Images Screen – Analyze Images

The following steps provide guidance on options for viewing and analyzing the video image data.

1. ***Select View of Eye*** - Press the toggle key between the graphs to select a full-eye view (eyeball), blink-only view (closed eye) or the isolated tear film view (tiles).

Blink-only view displays only the segments of the video in which the subject is blinking. The isolated tear film view separates the tear film area and indicates the area being analyzed. The green portion of the key indicates the active view.

2. ***Analyze Images*** - If the video image data has not been analyzed, press *Analyze Images* in the center of the screen to generate a graph (see Figure 10-16) of the ICU values for each frame. This may take several seconds. The graph shows the average ICU for each frame along with ranges for the standard deviation. Blank spots on the graph occur when the patient is blinking or the patient's eye is not stationary. Data resulting from the analysis is automatically saved in the database.
3. ***View Left Video*** - To view video of the eye on the left side of the screen (typically the OD):
   A. Press the triangular "play" button centered between the two "step" buttons on the lower left of the screen to loop through the video. As the video plays, the button on the slider indicates position and a vertical line moves across the graph.

      NOTE: When pressed, the "play" button changes to a "pause" button indicated by two vertical lines.

   B. When the video is paused, use the backwards (< step) and forwards (step >) buttons to move through the video frame-by-frame, or touch a spot on the slider bar to move the video to that location.
4. ***View Right Video*** - To play the video of the OS eye on the right of the screen (typically the OS), follow the instructions in step 3, using the controls on the lower right of the screen.
5. ***Select New Video*** - To view a different video for the selected patient record, press *Open Patient History* at the bottom of the screen, and follow the instructions in Section 10.4.2, *View Images Screen after Selecting from Patient History*.
6. ***Print and Save Video*** - To print the image and graphical analysis or to save it to an HL7 compatible system, press the *Print / Save* in the menu bar at the top of the screen and continue with Section 10.5, *Video Print and Save*.

10.5 Video Print and Save

From the View Images screen, the Print /Save tab is visible, allowing the report of the analyzed images to be printed, saved to an external drive as an Adobe PDF (Portable Document Format) file, or saved to an HL7 compatible system. Refer to Section 16, *Administrator Instructions for Use* for more information on HL7 and instructions on how to set up the HL7 parameters. The HL7 database must be configured by the Administrator prior to use.

The report header contains patient and practice information. Patient information is taken from the patient record, and consists of the Patient ID and the name if entered. The date of report and the Username of the operator who captured the video follow. Practice information consists of the name, address and phone number of the practice, and the serial number of the LipiView® Interferometer used. Practice information is set up by the Administrator per the instructions in Section 16.3, *Admin System Setup*.

Below the patient and practice information, the report contains information about the eye displayed (OD/OS), the date and time of video capture, and information contained in the pre-set and key-in tags. An image of the frames containing the maximum average ICU displayed both in full-eye and tear-film views. Beneath the images are the graphs and various metrics about the frames captured, and the ICU values.

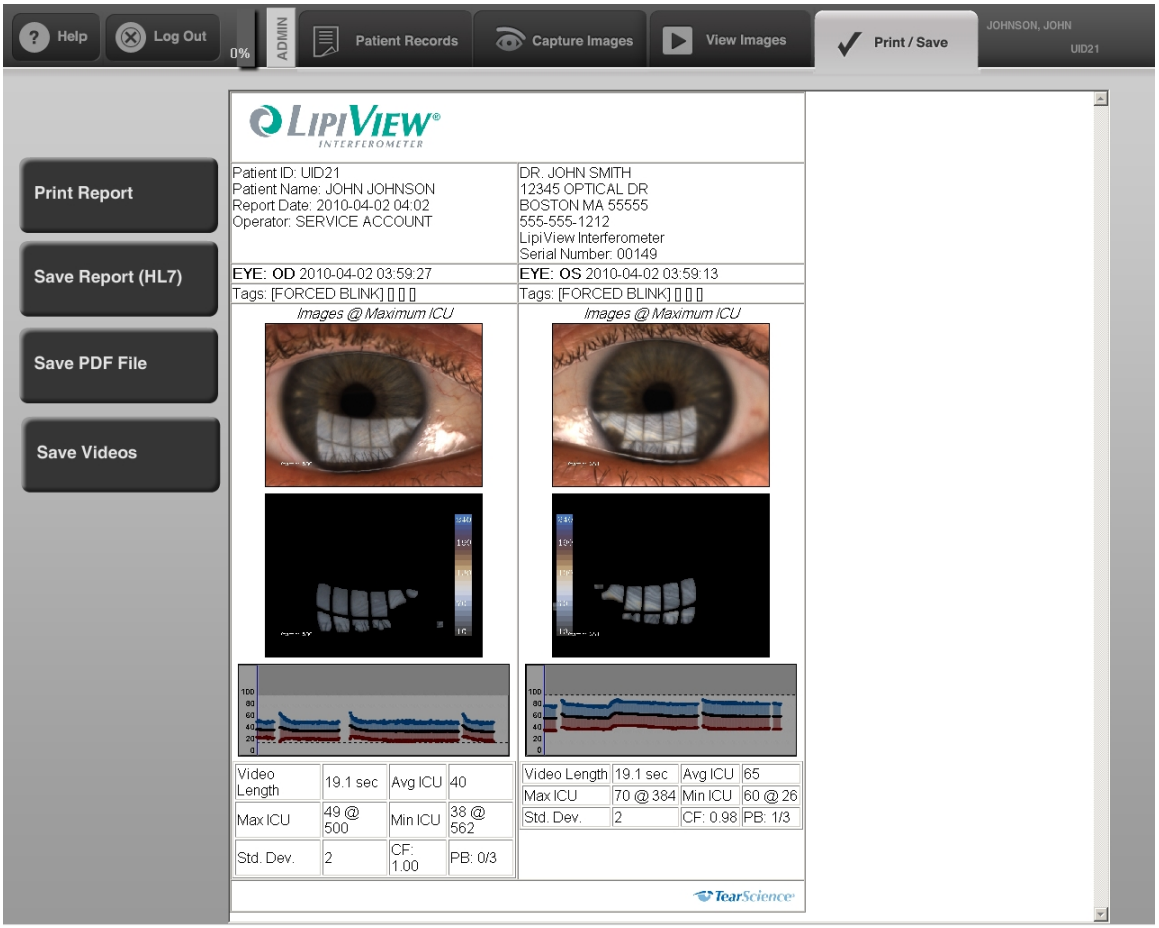


Figure 10-17: Print/Save Screen - Sample Report

Print Report - To print the report:

1. Press *Print Report* on the left menu.
2. Follow the standard windows printing prompts for sending the report to the printer attached to the LipiView® Interferometer.

   NOTE: The printer must be attached by the Administrator prior to use. Refer to Section 16.8, *Admin System Options* for a description on printer setup.

Save Report to HL7 - To save the printed report to an HL7 compatible system:

1. Press *Save Report (HL7)* on the left menu.
2. A system message called HL7 Basic Socket Transfer is displayed.

A. Press *Send HL7* to store the data in the HL7 database.

B. Press *EXIT* to return to Figure 10-17 without saving.

NOTE: The HL7 database must be configured by the Administrator prior to use. If the system message does not appear, contact the Administrator. Refer to Section 16.7.2, *HL7* for instructions on how to set up the HL7 parameters.

Save Report to External USB Drive as a PDF - To save the printed report as a PDF file:

1. Connect an external USB drive or USB key to the LipiView.
2. Press *Save PDF* on the left menu.
3. When the system reports that the PDF has been saved successfully, press *Close*.

Save Video to External USB Drive - To save the video to an external drive:

1. Connect an external USB drive or USB key to the LipiView.
2. Press *Save Videos* on the left menu.
3. Choose the videos you want to save for each side. You may choose one or more of the following for each side: full eye, isolated, or blink, as shown in Figure 10-18 below.
4. You will see a progress window, as shown in Figure 10-19. When the system reports that the video has been saved successfully, press *Close*.

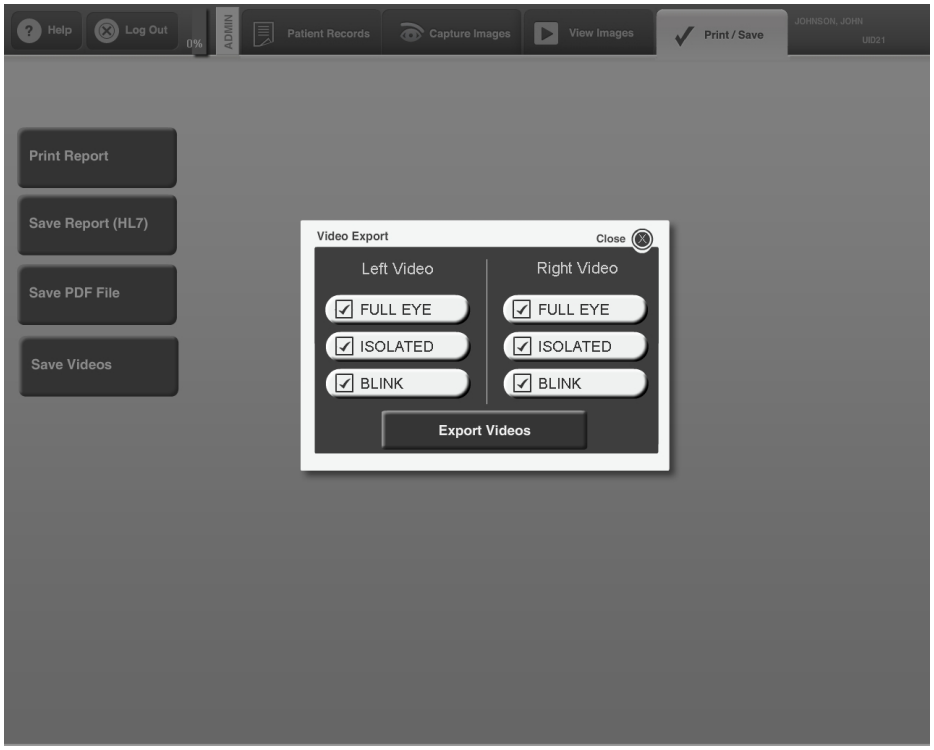


Figure 10-18: Make Selections for Video Export

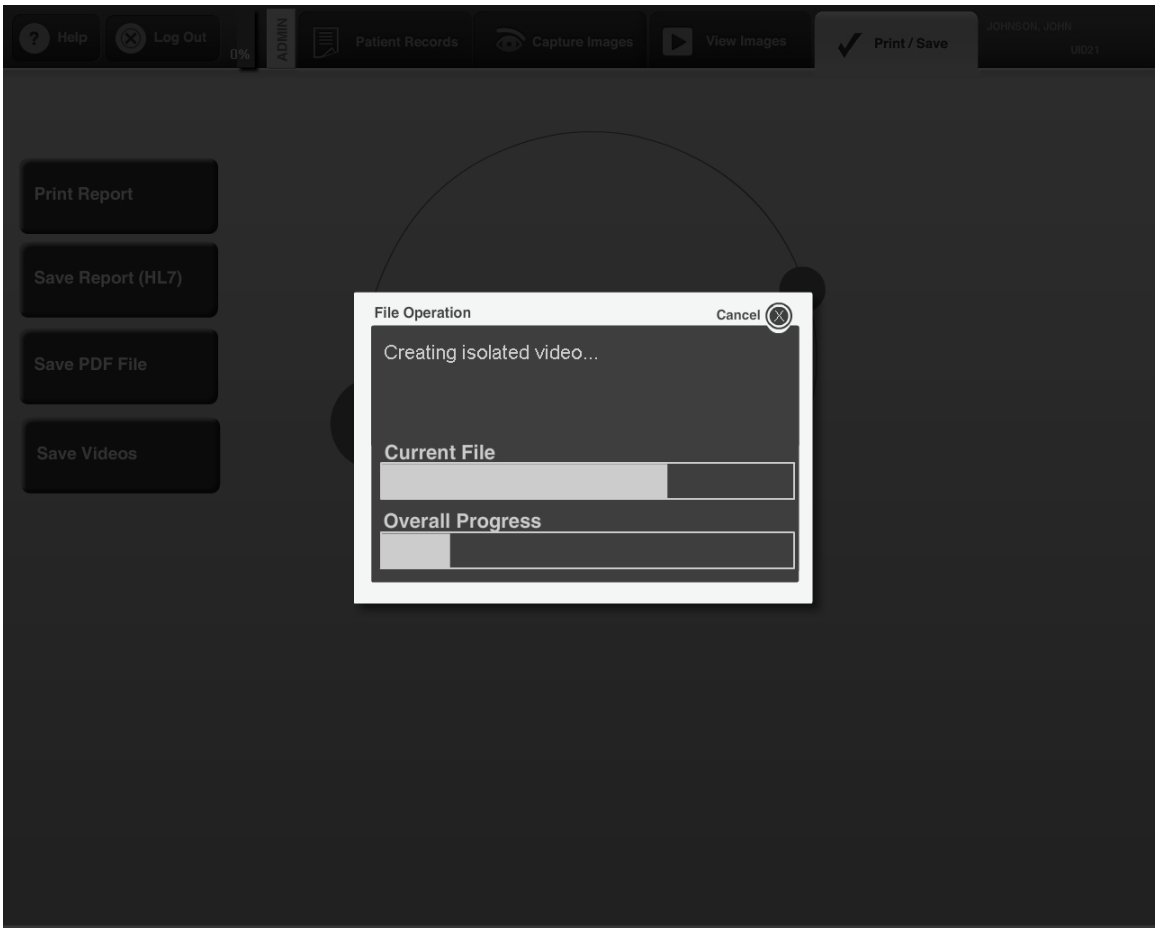


Figure 10-19: Progress Window for Video Export

10.6 Online Help

Online help is available for each of the screens in the system. Press the *Help* on the left side of the menu bar at the top of the screen to display information pertinent to that screen. Press *Help* again to close the file.

10.7 Log Out

After the user has logged into the system the Log Out tab is visible on the menu bar of each screen. Pressing *Log Out* returns the user to the Login screen described in Section 10.1.3, *User Login*.

11 Cleaning

Table 11-1 identifies the components of the LipiView® Interferometer that requirement cleaning. For each component, the frequency and method of cleaning is provided.

Table 11-1: LipiView® Interferometer Cleaning Information

Component	Frequency	Method
Chin rest and forehead rest surfaces	Immediately prior to use and prior to storage.	Alcohol.
Camera lens	Monthly.	Wipe with a lint-free photographic quality lens cloth.
Touchscreen Display Monitor	When soiled or as needed.	• Power off the device. • Apply window or glass cleaner to a cloth rag and wipe the screen. • Do not apply cleaner directly to the screen. • Do not clean the monitor with alcohol, paint thinner, benzene or compressed air.
LipiView® Interferometer exterior	When soiled or as needed.	• Wipe down the exterior of the LipiView® Interferometer with a mild soapy cloth. • Do not use bleach, chlorine or acetone-based solutions to clean any part of the chin rest support or the system enclosure.
Optional external monitor	Follow manufacturer's cleaning instructions.	Follow manufacturer's cleaning instructions.

12 Storage and Transport of the LipiView® Interferometer

Before storing the LipiView® Interferometer, ensure that the power switch is off, and that the chin and forehead rest surfaces have been cleaned according to the instructions in Section 11, *Cleaning*. The LipiView® Interferometer should be stored in a way that prevents contamination and damage between uses.

To transport the LipiView® Interferometer, ensure power cord is unplugged and secured off the ground. Grip on metal portion of the device, in two locations: 1) base of the chin rest, 2) monitor arm behind the screen. Carefully lift and transport in an upright position.

13 Maintenance and Servicing

Expected life of the LipiView® Ocular Surface Interferometer is 5 years.

> **Note**: No user serviceable components are inside the unit.
> Maintenance is not required. The LipiView® Ocular Surface Interferometer performs a calibration process upon powering on. See Section 10.1.1

For Field Service contact TearScience in North America at +1 919 459 4891 or by email at customerservice@tearscience.com.

14 Disposal

The LipiView® Interferometer consists of an ABS plastic enclosure, aluminum chassis, circuit boards, and electrical components. In the unlikely event that the controller is damaged and cannot be repaired, never dispose of the device. The LipiView® Interferometer should be returned to TearScience. Refer to the contact information on the first page of this manual for the appropriate return address.

15 Troubleshooting

15.1 Unexpected Events

Table 15-1 lists actions to take if an unexpected event occurs.

Table 15-1: Troubleshooting Unexpected Events

Event	Action to Take
Device will not power up (after pressing the power switch, the screen remains dark.)	(1) Ensure the system is connected to a power outlet and connection into the device is secure, then press the power switch again. (2) If Step 1 is not successful, carefully lift the system to expose the underside of the base and determine if a red Reset button is located at the back of the unit, near the power switch. If so, press the Reset button. If no Reset button is found, contact Customer Service for assistance. If the problem persists contact TearScience.
Problem reported during Power On Self Test (POST).	Power cycle the device. If the problem persists contact TearScience.
Touch Screen does not respond.	Power cycle the device. If the problem persists contact TearScience.
Illuminator does not light during image capture.	Power cycle the device. If the problem persists contact TearScience.
Camera stops working.	Power cycle the device. If the problem persists contact TearScience
Disk Space Indicator shows internal disk drive is full.	Contact the Administrator to archive data (refer to Section 15, *Administrator Instructions for Use*). If the problem persists contact TearScience.
The system works except the Capture Image tab will not respond.	An error was detected during power on self-test, which affects image acquisition. Power cycle the device. If the error persists contact TearScience.
Device will not process images after acquisition.	The internal hard drive is full. Contact the Administrator to archive data (refer to Section 16, *Administrator Instructions for Use*). If the problem persists contact TearScience.
Device no longer allows image acquisition.	A power on self-test problem has been found. Contact TearScience if problem persists.

Event	Action to Take
The message *NO VALID ANALYSIS DATA FOR VIDEO* is displayed instead of the numerical and graphical analysis when the *Analyze Images* button is pressed on the View Images screen.	The patient's head may not have been pushed forward, the patient's forehead may not have been firmly pressed against the forehead rest, or the tear film image may have been out of focus. Collect another video of the patient after ensuring that the patient's head is positioned properly and that the eye is clearly focused.
Network is not connected.	Contact your Administrator (refer to Section 16, *Administrator Instructions for Use*). If the problem persists call TearScience.
External monitor does not work.	Ensure the monitor is powered on. Ensure connections to the DVI or HDMI are made, and proper input is selected. Ensure the isolation receiver cable has power applied. Refer to Section 19, *Appendix B: External Monitor Hookup* for information on proper monitor connection.
Administrator forgets password after resetting it	Contact TearScience.
When accessing options on the System Options Administration screen, a message is displayed stating 'Too much time has elapsed since system startup to access this function'.	Selected options on the System Options Administration screen cannot be accessed after more than 10 minutes has elapsed since the system was started. Power cycle the machine and attempt to access the option again.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the warning level.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the critical level.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

15.2 System Messages

Table 15-2 lists system messages and provides a description with actions to consider.
NOTE: The four messages: Practice information saved, Display information saved, Saved map network drive parameters and mapping drive, and Network information saved are informative only and do not indicate a problem.

Table 15-2: System Messages

System Messages	Description / Action to Take

System Messages	Description / Action to Take
Invalid operator name and/or password.	The login failed because the username and/or password being used to log into the device are not recognized. Correct and reenter, or confirm with the Administrator that this username and password have been set up and that the username is enabled.
Capture disabled. Contact Tear Science for support.	Videos cannot be captured because the power on self-test detected errors with the motors or camera during startup, or the Disk Space Indicator has reached the limit set by the Administrator. Existing videos can be viewed. If the disk is full, contact the Administrator to archive data. For motor or camera errors, contact TearScience.
Patient ID already exists.	The patient record cannot be added because it contains a Patient ID that already exists in the database. If a Patient ID is being included on a new patient record, it must be unique. Correct and reenter.
Patient with same first name, last name, middle initial and birth date already exists. Select the existing user or enter a unique patient ID.	The patient record cannot be added because a patient record with the same Last Name, First Name, Middle Initial and Date of Birth already exists in the database. Either select the existing patient, or to add a new patient with the same name, enter a unique Patient ID.
Either patient ID or last name, first name and birth date are required.	The patient record cannot be added or updated because required information is missing. At a minimum, a patient record must contain a Patient ID or it must contain a Last Name, First name and Date of Birth.
Videos captured for patient. Cannot edit patient information.	The patient record cannot be edited because a video(s) exist for this patient. Once a video has been captured and saved for a patient, that patient record can no longer be updated.
Enter date in MM/DD/YYYY format. Invalid date:	The patient record cannot be added because the format of the date is incorrect. One or more of the date fields is missing or does not contain a number. Confirm that the month field is a number between 0-12, the day field is a number between 0-31 and the year is a 4-digit number.
Video capture setup failed.	The video cannot be captured due to a device failure. If this occurs, exit from the Captures Images screen by logging out or pressing *Save All/Continue*. Try again, and if the error is not corrected, contact TearScience.

System Messages	Description / Action to Take
Unable to load video file X.	The video file named X could not be found on the disk when attempting to show it on the View Images screen. Try again, and if the error is not corrected, contact TearScience.
The following errors occurred: Missing username; Missing password; Missing full name;	The Operator cannot be added because one or more of the required fields (as noted) are empty. The Username, Password and Full Name are required to add an Operator.
Username already exists	The Operator cannot be added because the Username entered already exists in the database. Correct the Username and try again, or select the Username and edit the Password and Full Name fields.
Practice information saved.	This message is displayed to the Administrator to confirm that information on the System Setup screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Display information saved.	This message is displayed to the Administrator to confirm that information on the Display Options screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Disconnect failure: X	The Map Drive process cannot be completed because the Drive Letter named "X" cannot be disconnected. Try again, and if the error is not corrected consult with the Network Administrator.
Saved map network drive parameters and mapping drive.	This message is displayed to the Administrator to confirm that information on the Map Drive screen or has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Network information saved.	This message is displayed to the Administrator to confirm that the cloning and HL7 server information on the Networking screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.

System Messages	Description / Action to Take
Cannot write to clone folder: X:\OSICLONE	The Network folder named OSICLONE on the Drive Letter named X is not accessible for writing. Confirm that the Drive Letter is listed as a mapped drive on the Networking Screen. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning operation failed to start.	There was a failure with the cloning process most likely caused by an internal Windows error, and no videos were copied. Confirm that the Drive Letter entered for Disk Cloning on the Networking Screen is valid. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning canceled by user.	This message is displayed to the Administrator to confirm that the *CANCEL* button has been pressed and that the Cloning process has been stopped.
Cloning failed. Restart or contact Tear Science for assistance.	There was a failure with the Cloning process. Press *CLONE SYSTEM* again, to continue the Cloning process where it left off. If the problem continues, contact TearScience.
The used space of the system disk has surpassed the warning level. Please go to the Networking/Backup Administrator page.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
The used space of the system disk has surpassed the critical level. Please go the Networking/Backup Administrator page.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

16 Administrator Instructions for Use

16.1 First Time Setup

The LipiView® Interferometer has been set up with a default Operator Username and Password that has administrator privileges. When the system is first powered on, the Administrator should log in using LIPIVIEW for the Username and LIPIVIEW for the Password (the onscreen keyboard only supports upper case characters).

After successful log in, it is recommended but not required that the Administrator reset the password as follows:

1. Power on the system.
2. When the Login screen in Figure 10-4 is displayed:
   A. Enter LIPIVIEW for the Username.
      NOTE: The onscreen keyboard only supports upper case characters.
   B. Enter LIPIVIEW for the Password.
   C. Touch *Submit*. The Patient Records screen in Figure 10-5 should be displayed.
3. Touch the *Admin* tab at the top of the screen. The Admin Main Menu in Figure 15-1 should be displayed.
4. Press *Operator Setup* on the left menu. The Admin Operator Setup Screen in Figure 16-3 should be displayed.
5. Follow instructions in Section 16.4, *Admin Operator Setup* to modify the password and/or add additional operator usernames.

The Administrator should review Section 16 of this manual to determine any other functionality that requires set up before the LipiView® Interferometer is used for observation of tear film. At a minimum:

- Set the system date and time (refer to Section 16.8, *Admin System Options*)
- Determine at what point videos will be archived (refer to Section 16.7.1, *Disk Cloning*)

Prior to printing, a printer must either be connected through one of the USB ports on the bottom of the Touchscreen Display, or through a wireless network. Printer setup is discussed in Section 16.8, *Admin System Options*.

Prior to cloning or archiving, an external storage location must be connected. An external hard drive can be connected through one of the USB ports on the bottom of the Touchscreen Display, or a network drive can be mapped on the wireless network. Refer to Section 16.6, *Admin Map Drive*.

16.2 Admin Main Menu

When an operator's Username is set up with *Administrator Access* (refer to Section 16.3, Admin System Setup), the *Admin* tab is visible between the Disk Space Indicator and the Patient Records tab on the menu bar of each screen.

When the *Admin* tab is pressed, the Administrator Main Menu screen in Figure 16-1 is displayed. This screen prompts the Administrator to select from one of the menu options on the left side or the top. Each Administrator screen contains the same menu. Once a button is pressed, it turns white indicating the active menu, and buttons for inactive functions are grayed out. Buttons may be selected from the Main Menu in any order, but once a menu option is active, the user must exit from that screen and return to the Main Menu before choosing another option.

The *Help* tab may be selected anytime it is not grayed out. To return to normal usage, press *Patient Records* at the top of the screen.

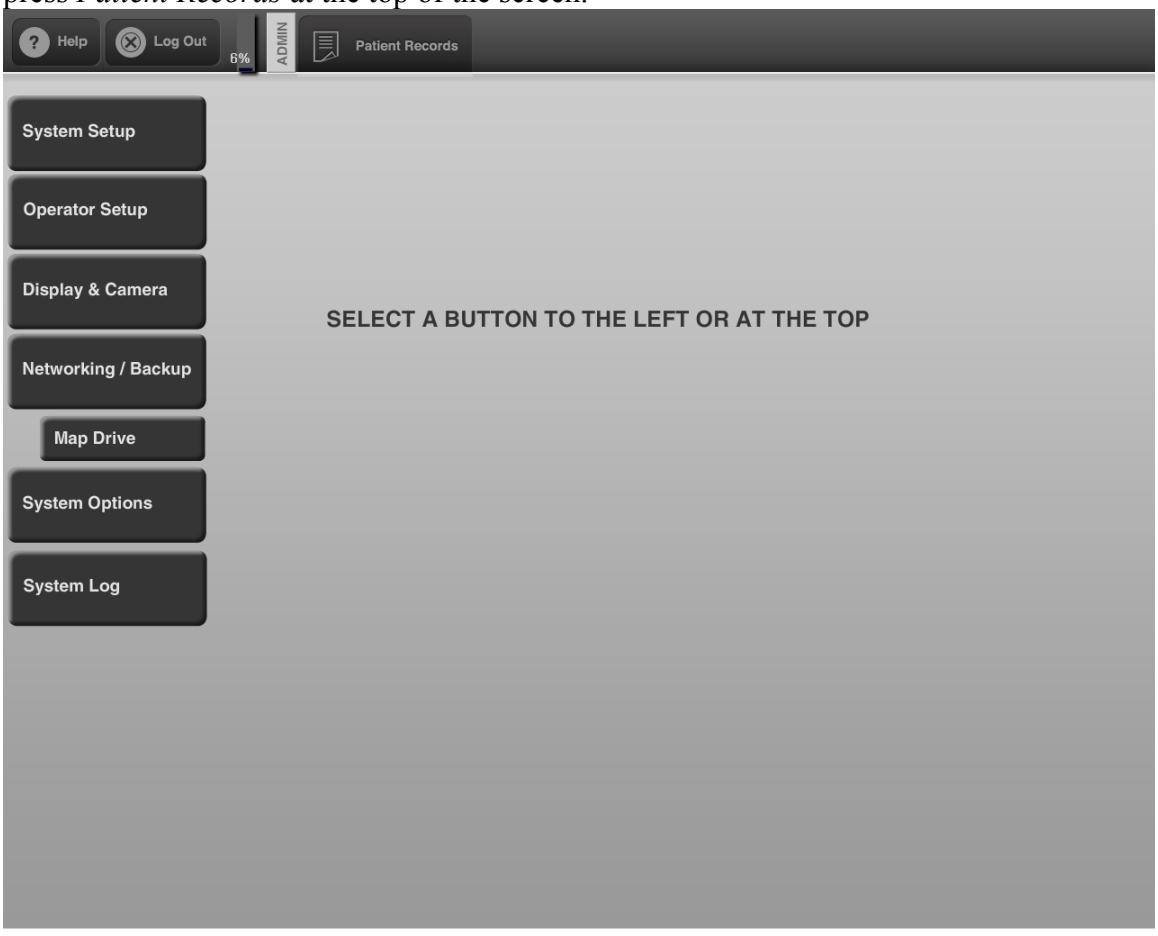


Figure 16-1: Admin – Main Menu Screen

16.3 Admin System Setup

The System Setup screen in Figure 16-2 is displayed when the *System Setup* button is selected from the Admin menu.

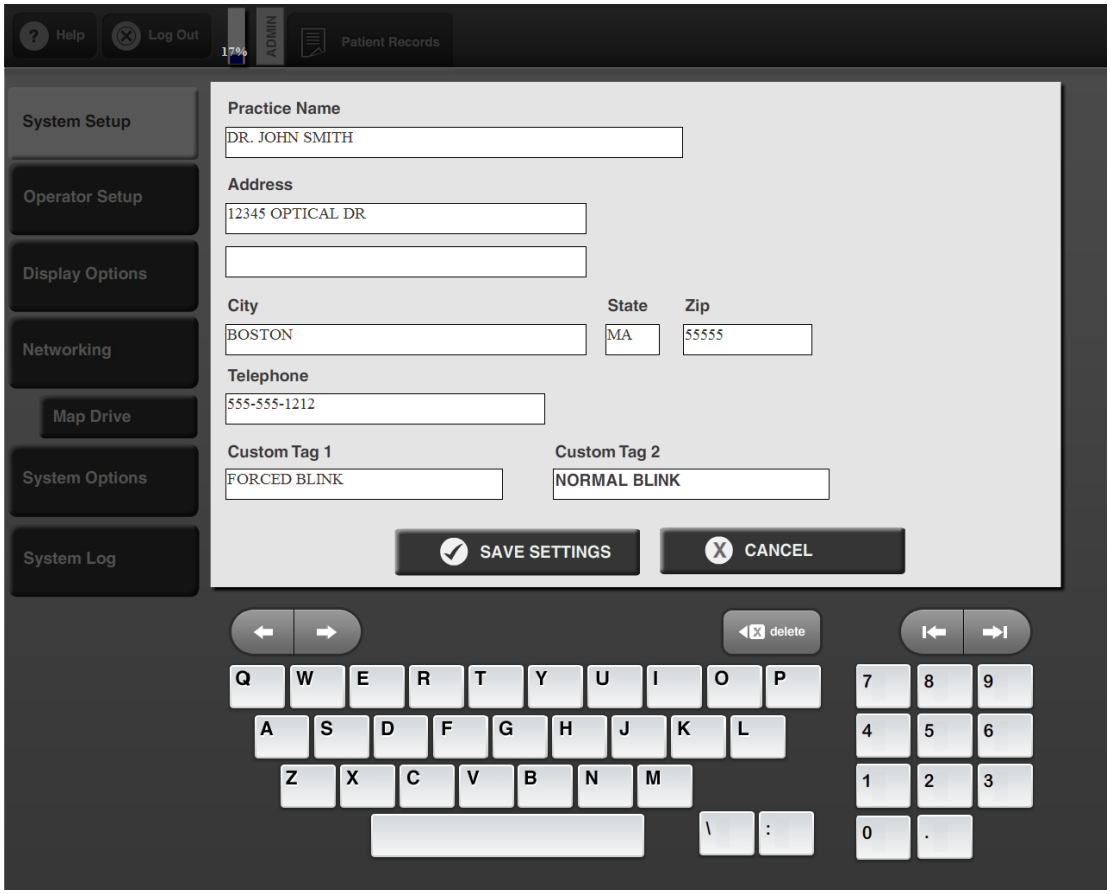


Figure 16-2: Admin - System Setup Screen

The System Setup screen contains the fields listed in step 1 for the Administrator to complete. All fields are optional. The Practice information is used for the reports as discussed in Section 10.5, *Video Print and Save*. Custom Tags 1 and 2 allow up to two tags to be pre-set with commonly used information that may be applicable to multiple videos (e.g., normal blink, forced blink). These custom, pre-set tags are displayed on the Capture Images Screens (Figure 10-9, 10-10, 10-11 and 10-12) and discussed in Section 10.3, *Video Image Capture and Recording*. If selected, information from these tags is saved with the video data, displayed on all Video Review and Analysis screens (Section 10.4), and included on the report.

1. Use the keyboard to update one or more of the fields below.
   - Practice Name
   - Address line 1
   - Address line 2

- City
- State
- Zip
- Telephone
- Custom Tag 1
- Custom Tag 2

2. To exit this screen and return to the Main Menu in Figure 16-1, choose from one of the following and then continue with Section 16.2, *Admin Main Menu*:
   A. To immediately update the information before returning to the Admin Main Menu, press *SAVE SETTINGS*.
   B. To return to the Main Menu without saving the edits, press *CANCEL*.

16.4 Admin Operator Setup

For first time use, make sure to review Section 16.1, *First Time Setup* before making any changes to usernames and passwords.

Do not modify the ADMIN Username. This is for TearScience personnel, in the event service is required.

The Operator Setup screen in Figure 16-3 is the main screen displayed when the *Operator Setup* button is selected from the Admin menu. This screen is used to display the list of operators who have been entered into the database. The list of operators is displayed in the order of entry. Once the table contains more than six names, the step keys on the right are used to scroll backwards (upper key) or forwards (lower key) through the list.

The Operator Setup screen is also used to add new operators. To perform this task, continue with Section 16.4.1, *Add an Operator*.

Operator information, which includes granting or preventing access to the device, can be modified using a secondary operator setup screen in Figure 16-4. To make any changes to an operator's record, follow the instructions in Section 16.4.2, *Edit Operator Information*. Information about an operator may be updated but an operator's record can never be removed.

Figure 16-3: Admin - Operator Setup Screen

16.4.1 Add an Operator

Add an operator to the system as follows:

1. Enter a Username.
2. Enter a Password. There are no requirements other than the limitation of the onscreen keyboard characters.
3. Enter the full name.
4. If the user will be allowed to access the Admin tab and the administrator screens, touch the box for *Administrator Access*. A checkmark indicates selection. If this box is not selected, the *Admin* tab will not be visible when this Username is logged in.
5. Press *Add Operator* to enter the new information into the database. When a new operator is added, the status for this operator's Username defaults to "User Enabled". An enabled Username means that this Username has permission to access the device through the Login screen in Figure 10-4. A new Username may log in as soon as the current Username logs out.

NOTE: All fields are required. If *Add Operator* is pressed when any field is empty or incorrect, or if the record is a duplicate of an existing operator, a system message will be returned.

6. Press *CLOSE* when finished and the Admin Main Menu in Figure 16-1 will be displayed.

16.4.2 Edit Operator Information

1. To edit information associated with an Operator's Username, select the record by pressing anywhere on the row in the table. Use the step keys on the right of the table to scroll backwards or forwards through the list if more than six names have been entered.
2. The selected name will be highlighted and then overlaid onto the top of the screen, as shown in Figure 16-4. If the Username is currently allowed access to the device, the *User Enabled* box is checked. If the Username was added as an Administrator, the *Administrator Access* box is checked.

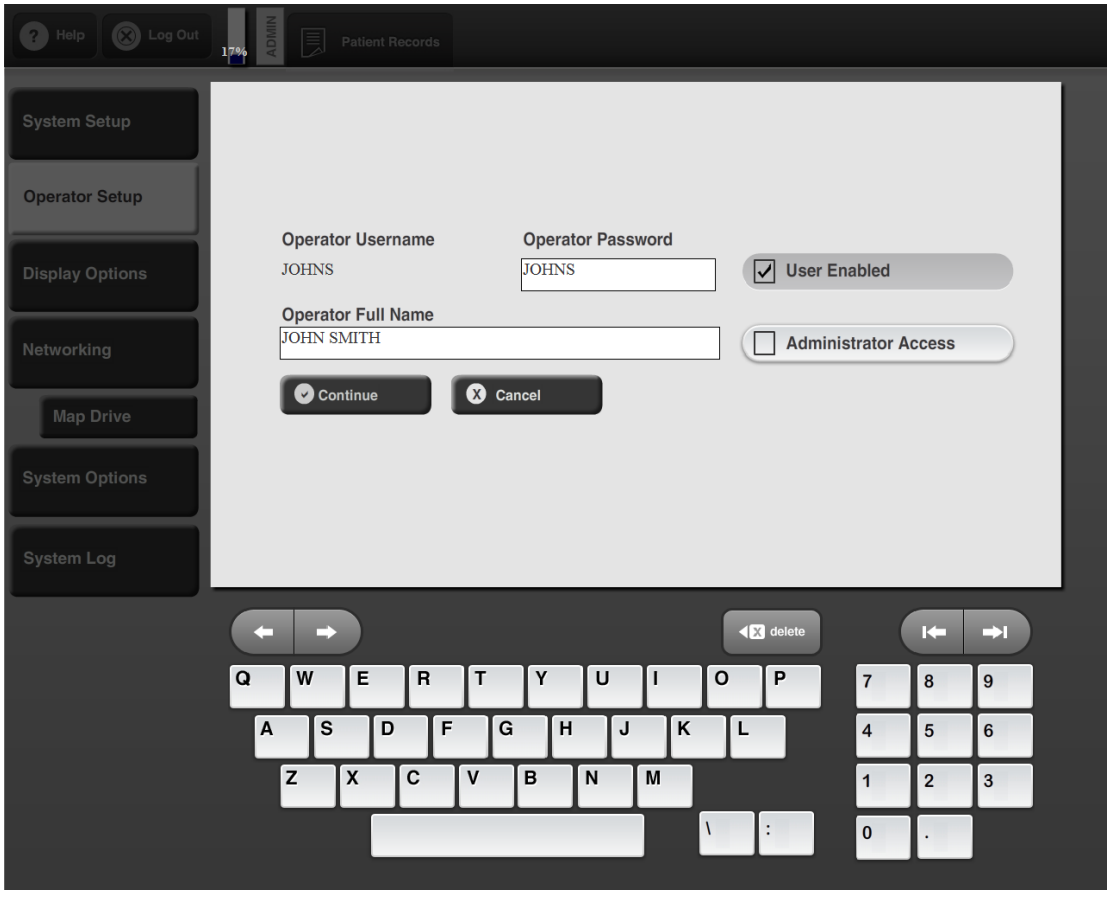


Figure 16-4: Admin - Modify Operator Information

3. Update the operator's password or full name if needed. Select or deselect the boxes for *User Enabled* and *Administrator Access*.

   NOTE: Once an operator has been added, the Username cannot be deleted.

4. To exit this screen and return to the Operator Setup screen in Figure 16-3, choose one of the following:
   A. Press *Continue* to return with the record updated.
   B. Press *Cancel* to return without saving edits.
5. From the Operator Setup screen, press *CLOSE* to return to the Admin Main Menu, continue with Section 16.4.1, *Add an Operator*, or repeat Section 16.4.2 to edit an operator.

16.5 Admin Display Options

When *Display &Camera* is selected from the Admin Main Menu, the screen in Figure 16-5 is used to set the saturation, contrast and brightness levels for the video display, and the capture time for the video camera.

Each display level has a range of 0 – 100. The camera capture time setting has a minimum of 5 seconds and a maximum of 19 seconds. Settings here do not affect the GUI.

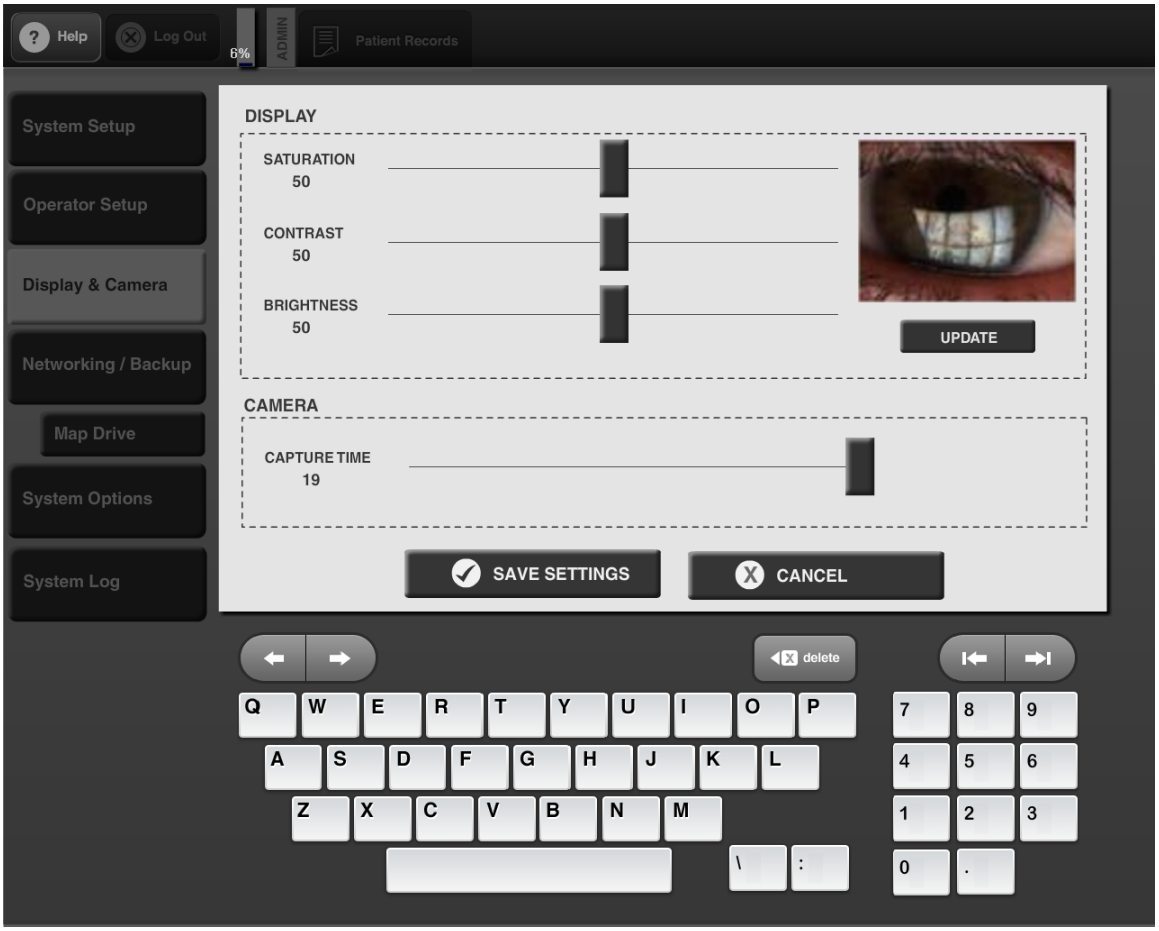


Figure 16-5: Admin - Display Options Screen

1. To modify the setting for Saturation level follow steps A-C, or skip to step 2:
   A. Move the locator bar to the left to lower the value or to the right to increase it. The new setting number will be displayed under the name on the left.

      NOTE: Touching a location on the slider bar will not change the setting; the locator bar must be moved.

   B. Preview the display with the new value by pressing *Update*. This allows the user to visualize the effect on a representative tear film image.

      NOTE: The Contrast and Brightness levels may also be adjusted before pressing *Update.*

   C. Repeat steps A and B as needed.
2. To modify the setting for Contrast level, repeat step 1 using the Contrast slider; otherwise, skip to step 3
3. To modify the setting for Brightness level, repeat step 1 using the Brightness slider; otherwise, continue with step 4.
4. To modify the video camera capture time, move the locator bar to the left to lower the value or to the right to increase it.
5. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:
   A. To permanently retain the saturation, contrast and brightness values on the screen, press *SAVE SETTINGS*. All future video images will use these values when displaying. A system message will indicate the display information has been saved. Press *Close.*
   B. To exit without saving any changes, press *CANCEL*.

16.6 Admin Map Drive

When *Map Drive* is selected from the Admin Main Menu, the screen in Figure 16-6 is used to setup one or more network drives on the LipiView® Interferometer. A mapped drive is a location on the network, and the location is designated by the Drive Letter. Mapped drives are typically used for cloning and archiving, which is discussed in Section 16.7, *Admin Networking*.

Depending on how the network is set up, the mapped drive on the network may require that a valid username and password be entered in order to gain access. If this is the case, the username and password associated with the drive being mapped should be entered on this screen.

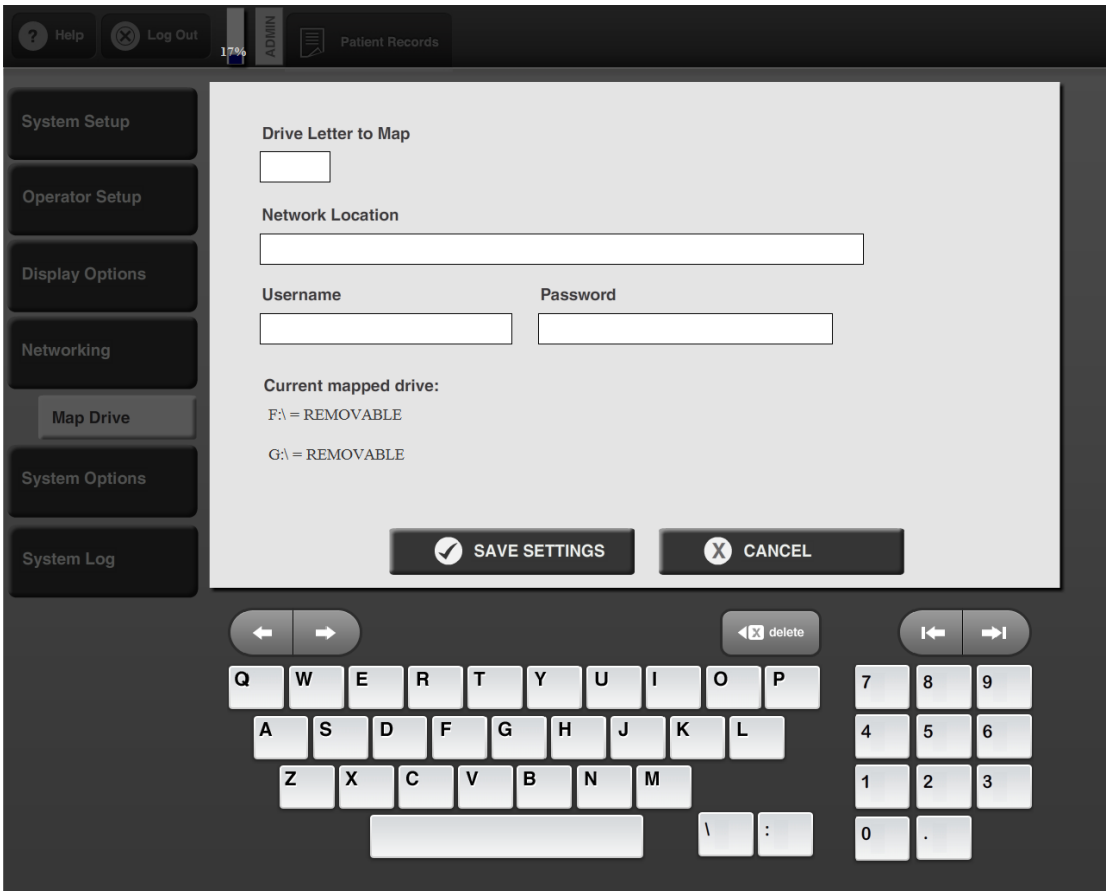


Figure 16-6: Admin - Map Drive Screen

Enter the information on this screen as follows, consulting with the Network Administrator to obtain this information if necessary:

1. In the *Drive Letter to Map* field, enter the drive letter of the network drive to which the LipiView® Interferometer will be mapped.
2. For *Network Location* – enter the server location (e.g., \\SERVER\\Location) that will be mapped to the drive letter.
3. If required to access the network location entered in step 2, enter the *Username* and *Password* interacting with your network.
4. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*.
   A. To permanently retain the drive mapping information shown on the screen, press *SAVE SETTINGS.* A system message will indicate the mapping information has been saved. Press *Close*.
   B. To exit without saving any changes, press *CANCEL*.
5. To determine whether the connection was successful, press *Map Drive* to return to this screen.
   A. If the connection was successful, the heading *Current mapped drive:* will be followed by the name and location of the mapped drive in the format

"*:\\network_location", where '*' is the drive letter and 'network_location' is the network path.

NOTE: When storage devices such as an external hard drive or a USB flash drive are connected to the USB ports, these drives are also listed under *Current mapped drive*. In Figure 16-6, "F" and "G" are the drive letters, and "REMOVABLE" indicates the location is the USB port (rather than a network drive). When the USB port is the location only one backslash (\) is used.

B. If no network drives have been mapped, the words "No available drives found" will follow the heading.

6. If more than one drive will be mapped, repeat these instructions as many times as needed, or press *CANCEL* to return to the Admin Main Menu.

   NOTE: Once a network drive has been mapped it cannot be unmapped; however, the drive letter can be mapped to a new path.

16.7 Admin Networking/Backup

When *Networking/Backup* is selected from the Admin Main Menu, the screen in Figure 16-7 is displayed, allowing the Administrator to perform two functions: Disk Cloning, and setting up access to an HL7 server.

Figure 16-7: Admin – Networking/Backup Screen

16.7.1 Disk Cloning

As video information is stored on the LipiView® Interferometer, the disk drive becomes full. When the disk usage level reaches the level specified by the *Backup Notification at Percent Drive Full* slider bar, the LipiView® Interferometer issues a system message to notify the user to perform a backup. However, the device will continue to allow the user to capture additional videos. The user may either backup the database or backup the database and the videos to an external drive or network. **The backup process will permanently delete the videos from the LipiView® Interferometer.** When the disk usage level reaches 95%, the device notifies the user that a backup is required and will not allow the user to capture additional videos until the backup process is performed.

To free used disk space, one of the two following operations must be performed:

1) **Backup Database Only** – This option will copy the system database to the location specified in the Target Drive field, and then permanently delete all videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

2) **Backup Database and Videos** – This option will copy the system database and all video files to the location specified in the Target Drive field, and then permanently delete all the videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

NOTE: The Backup Database and Video process can take up to several hours to copy the videos to the external drive. Before beginning the copy process, please ensure you have adequate time to complete the process.

16.7.2 HL7

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

HL7 is a communications standard used so that a piece of medical equipment (such as the LipiView® Interferometer) can talk with an Electronic Medical Records (EMR) server. HL7 is the common language used so that information can be exchanged between EMR systems and medical devices.

After review of a video, an HL7 message with the patient information can be sent from the LipiView® Interferometer to the specified EMR server (identified by an IP address and port). The conversation is one-way from the interferometer to the EMR server. The message is sent out but the interferometer does not know if the message was received by the EMR server. Refer to Section 10.5, *Video Print and Save* for instructions on how to send the report.

The LipiView® Interferometer can communicate with any EMR system that understands HL7 V2.5 messages. The HL7 group of controls allows the Administrator to configure the HL7 export destination. To set up an HL7 export connection:

1. Once the LipiView® Interferometer is mapped as a network drive on the network, enter its drive letter in the *Network Drive Letter of OSI* field. The network drive letter is sent as part of the HL7 message and allows the server to access report files that reside on the LipiView® Interferometer.
2. Enter the IP address of the HL7 server. If more than one HL7 server is available, select the desired server.
3. Enter the port address on which the HL7 server is listening for HL7 messages.
4. The connection to the HL7 server can be tested by pressing *Test HL7 Server*. When pressed, a standard IP ping will be performed on the HL7 server and the results will be reported. This feature should only be used by TearScience service personnel and is beyond the scope of this manual.
5. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:
   A. To save all data entered on this screen (for both Disk Cloning and HL7), press *SAVE SETTINGS*. A system message will indicate the mapping information has been saved. Press *Close*.
   B. To exit without saving any changes to the screen, press *CANCEL*.

16.8 Admin System Options

When *System Options* is selected from the Admin Main Menu, the screen shown in Figure 16-8 provides the Administrator with information about the system, including software versions of the shell, application and GUI, and the serial number of the system.

Figure 16-8: Admin - System Options Screen

There are also five functions available on this screen:

- **Join Wireless Network** – Pressing this button displays a standard Windows *Wireless Network Connection* dialog. Use the browse dialog to connect the LipiView® Interferometer to a wireless network. Contact the Network Administrator for assistance in joining a wireless network if needed.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

- **Calibrate Touchscreen** – Pressing this button launches a calibration program for the touchscreen. This calibration can be performed when it is observed that the onscreen cursor is not matching correctly to the finger-touch locations. The program instructs the user to touch various targets on the screen, and then to press *OK* to accept the calibration. The user must press *Save Changes* to cause the calibration to be written to the disk. The calibration wizard will ask the user if the cursor is following his finger but the curser will not be visible. This is normal and should be ignored. **This option should not be used unless instructed to do so by a TearScience representative. If the touchscreen is not calibrated correctly, the touchscreen operation may be affected.**
- **Recreate Thumbnails** – Pressing this button restores the system in the event of a hard drive failure. The restore process reads all the video files present in the database, and extracts the thumbnail image that appears in the Patient History list for that video. **This option should not be used unless instructed to do so by a TearScience representative.**
- **Setup Printer** – Pressing this button will display the standard Windows *Setup Printer and Faxes* dialog. Use this dialog to set up a printer on the LipiView® Interferometer. The printer can be attached to the LipiView® Interferometer via a USB port, or it may be a network printer accessed via a wireless network. Contact the network Administrator for assistance in setting up a printer if needed.

  NOTE: If installing a USB printer, follow the manufacturer's instructions and to press *SAVE SETTINGS & REBOOT* when finished.
- **Set System Time** – Pressing this button brings up the standards Windows *Setup Date and Time Properties* dialog, and allows the Administrator to input the current date, time, and time zone into the LipiView® Interferometer. The date and time should be set during system first time setup discussed in Section 16.1.

  NOTE: It is not necessary to use the *Save Settings and Reboot* function after setting the system time.

Access to the System Option screen functions is disabled if more than 10 minutes has elapsed since the system was started.

For any of the setting changes to become active, the system must be rebooted. Press *Save Settings and Reboot*. A system message confirming the reboot is displayed. Press *Continue* to begin the reboot, or press *Cancel* to return to the System Options screen.

Press any tab on the left menu or press *Patient Records* to exit this screen without changes becoming activated.

16.9 Admin System Log

When *System Log* is selected from the Admin Main Menu, the screen shown in Figure 16-9 allows the Administrator to review system codes that have occurred and the results of Power On Self Tests. Items are listed in this table for the current day only; however,

all system codes in this list are stored in a database and the errors are never cleared. Use the step keys to the right of the table to scroll forwards and backwards through the table.

This page is intended to be accessed by TearScience representatives, or as directed by a TearScience technician.

After reviewing the log, press *CLOSE* to return to the Admin Main Menu.

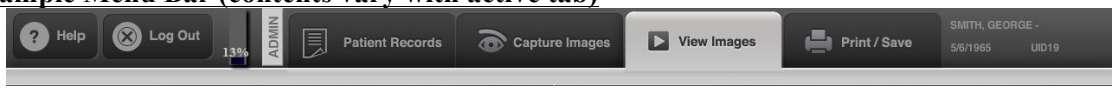
Figure 16-9: Admin - System Log Screen

17 Warranty

TearScience, Inc. warrants that each LipiView® Interferometer 1) is free from defects in materials and workmanship and 2) conforms to TearScience Inc.'s official specifications. The warranty period for each LipiView® Interferometer is one year commencing on the date of purchase. *Any tampering or modifications to the device by the user will void the warranty.*

18 Appendix A: Quick Start Reference Guide

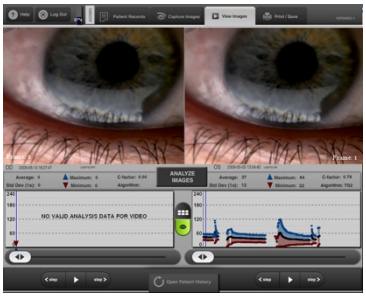
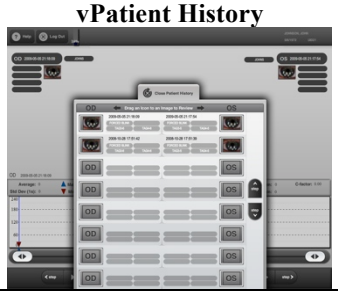
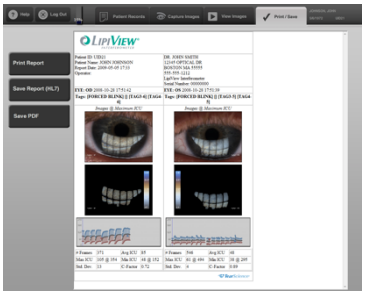
Sample Menu Bar (contents vary with active tab)



The light gray color shows View Images is active. Tabs may have multiple screens.
Help – Press to display information for the active screen. Press again to close.
Log Out – Press to exit the user from the device. The Login screen is displayed.
Disk Space Indicator – Shows the disk space that has been used for video storage.
Admin – Visible if Username has Administrator privileges. Press for Admin Main Menu.
Patient Records – Press to display patient table. Search for, add or edit a patient. Select a patient record and the next action to take.
Capture Images – Press to record video, preview video, rerecord video, and save video.
View Images – Press to review previous videos. Enter after capturing new images to view new video and request a computer analysis.
Print / Save – Press to print the video analysis, save it as a PDF file, or save it to an HL7 database.
Patient information – Shows information from a patient record after it is selected.

Startup
Power on the LipiView® Interferometer by pressing the rocker switch. System may take several minutes to boot up.
At Login Screen, enter a Username and Password. Press *Submit*. Refer to **Patient Records**.

Patient Records 	All records must have at minimum 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. Locate record by typing name or using step keys. Must select a record to Capture Images or View Images. If not found, enter data; press *Add New Patient*. If found, choose record; Select a Patient Action. • Edit Patient – Update record if no saved video images. • Capture Images - Refer to **Capture Images**. • View Past Images - Select video from **Patient History** and then Refer to **Patient History.** • Close – Return to Patient Records. Get another record.
Capture Images 	Press *View OD* (right) or *View OS* (left) for eye to capture. Select pre-set tags; enter key-in tags. Clean chinrest support. Caution on hand/finger placement. Question patient on listed precautions; note conditions. Position patient: chin fully forward, forehead firmly against forehead rest. Look at orange fixation light. Adjust so lateral canthus aligns with marks on forehead rest using manual adjustment (fluted roller) located on chinrest support column. Use controls or touchscreen to adjust camera height and focus. Eye should be in center and clear. Press *Start Capture.* Approximately 20 seconds of video can be recorded. Have patient blink as needed. Press *End Capture to stop recording*. Refer to **Preview Video**.
Preview Video (just captured) Before saving, decide whether to rerecord. Capture images for second eye.	Preview image using controls and tear-film/full-eye toggle key. If desired, refer to **Rerecord Video**. Update pre-set or key-in tag information. Press *View OS* / *View OD* for 2nd eye. Refer to **Capture Images**. Press *Save All/Continue* to save video, tags. Refer to **View Images**.

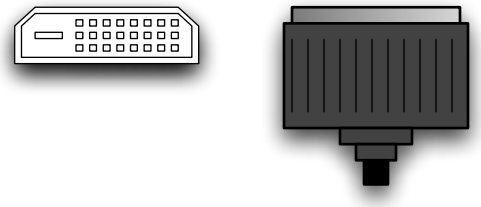
Rerecord Video Screen has same functionality as Capture Images except for system message confirming Rerecord.	Toggle between Preview and Rerecord screens by pressing *Return to recorded image* and *Return to live image*. To rerecord: Press View OS or View OD. Adjust patient and camera height, and focus. Press *Start Capture*. Confirm rerecord. Press *End Capture*. Update pre-set or key-in tag information. Press *Save All/Continue* to save video, tags. Refer to **View Images**.
View Images  	Entered after saving captured images. View and analyze. Or Entered from **Patient History** after choosing *View Past Images* from *Select a Patient Action* (Patient Records). View videos using play and step controls. Press *Analyze Images* if needed to view numerical data. • Average - Average ICU of all frame averages • Std Dev - Standard deviation of frame averages • Maximum – Max. recorded ICU for a given frame • Minimum – Min. recorded ICU for a given frame • C-Factor - Tear film Conformance factor for entire video After images are analyzed, review graph: • Toggle  – Switch between full-eye and isolated tear-film. • Each point on graph is ICU value for frame. • Blue line and region is the upper standard deviation of the ICU score data. • Red line and region is the lower standard deviation of the ICU score data. • Blue triangle marker denotes the point on the graph that contains the maximum ICU score. • Red marker triangle marker denotes the point on the graph that contains the minimum ICU score Refer to **Print/Save**. Press ***Open Patient History*** to view other files.
vPatient History 	Select videos from the list in Patient History to view. If table is empty, no video data saved for patient. Drag and drop videos into two frames at top. • If a video was archived, follow messages to restore. • When videos are selected, press Close Patient History. • Refer to **View Images**. Data may or may not need analysis.
Print/Save 	To print report (USB/Network printer must be set up): • Press *Print Report* on the left menu. • Follow standard windows printing prompts for sending the report to the attached printer. To export report to an HL7 compatible system (must be connected): • Press *Save Report (HL7)* on the left menu. • An HL7 Basic Socket Transfer message is displayed. • Press *Send HL7* to store the data in the HL7 database. To save the printed report as a PDF file: • Connect an external USB drive or USB key to the LipiView. • Press Save PDF on the left menu. • When the system reports that the PDF has been saved successfully, press Close.

19 Appendix B: External Monitor Hookup

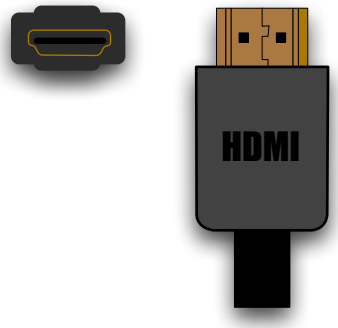
The LipiView® Interferometer is equipped with an optional external monitor connection. The following instructions provide the user with the steps needed to connect the external monitor to the interferometer.

The external monitor connection may be DVI output or HDMI output. TearScience does not supply cables for connecting external monitors. Users wishing to connect an external monitor should inspect the connectors on the monitor they wish to use, and the connector on the underside of the LipiView® Interferometer, and then purchase a cable that has the appropriate connectors on each end and is long enough to reach from the underside of the LipiView® Interferometer to the external monitor input.

The DVI connector and cable look like this:



The HDMI connector and cable look like this:



1. Ensure the LipiView® Interferometer is powered off.
2. Ensure that the separately purchased external monitor has either a DVI or HDMI port and is capable of displaying a 1280 x 1024 image.
3. Locate the digital video cable cover on the underside of the LipiView® Interferometer. The cover has four screws attaching it to the LipiView® Interferometer. Use an M2.5 hex driver and remove the four screws. The LipiView® Interferometer's digital video output cable should now be exposed.
4. Connect the separately purchased digital video cable to the LipiView® Interferometer's video output.
5. Connect the other end of the digital video cable to the external monitor.

6. Apply power to the LipiView® Interferometer and external monitor.

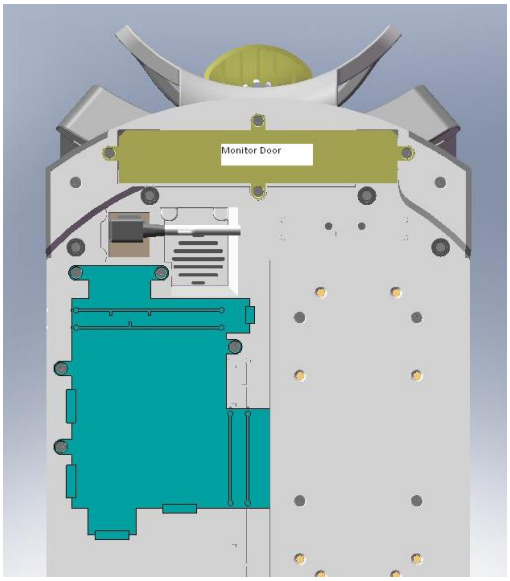


Figure B1. Location of External Monitor Interface Door

20 Appendix C: Electromagnetic Compatibility Requirements

20.1 Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Table 20-1: Guidance and Manufacturers Declaration-Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The LipiView® Interferometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	NA
Harmonic emissions IEC 61000-3-2	Class A	NA
Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	The LipiView® Interferometer is suitable for use in all establishments **other than** domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.

20.2 Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Table 20-2: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 1)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
*NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 20-3: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 2)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the HCS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = [3.5/V1]\sqrt{P}$ $d = [3.5/E1]\sqrt{P}$ 80MHz to 800MHz $d = [7.0/E1]\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, are determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-3	3 Vrms 80 MHz to 2,5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LipiView® Interferometer is used exceeds the applicable RF compliance level above, the LipiView® Interferometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LipiView® Interferometer. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

20.3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Table 20-4: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer			
The LipiView® Interferometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LipiView® Interferometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LipiView® Interferometer as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d=[3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz** $d=[3.5/E_1]\sqrt{P}$	**800 MHz to 2,5 GHz** $d=[7/E_1]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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TearScience®

LIPIVIEW®

Ocular Surface Interferometer

Operation Manual

Model # LVI-1001
For System Version 2.x

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Manufactured by:

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Rx only

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011119-ENG Rev A

Revision History

Revision	Date	Description of Changes	ECR # or PCR #
A	6/29/12	Initial release for 2.0 software in English. This manual was created from Part Number 010792 Rev M (mat spec). Updates from 1.1D software include: updated screenshots with system and version numbers, new screenshots and explanation for partial blink detection mode; new screenshots and explanations for display and camera settings in the Admin interface; new screenshots and explanations for example videos; new screenshots and explanations for revisions to reporting and for "save video" functionality.	P1206251

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1 Introduction

This manual provides the indications, contraindications, warnings, precautions, potential adverse effects and instructions for use for the *TearScience*® LipiView® Ocular Surface Interferometer (LipiView® Interferometer). **Carefully read this manual in its entirety before using the LipiView® Interferometer. Failure to follow these instructions may result in improper use of the device.**

Use of the LipiView® Interferometer includes User and Administrator functionality, both of which are described in this manual. Section 10, *Instructions for Use,* contains the information about the proper procedures for operating the LipiView® Interferometer. Section 16, *Administrator Instructions for Use,* contains information about the initial setup and maintenance of the LipiView® Interferometer by an Administrator. **Prior to initial use of the LipiView® Interferometer, the Administrator must follow the administrative setup instructions in this manual for proper device use.** Table 1-1 identifies the tasks an Administrator may be required to perform and the prerequisite knowledge.

Table 1-1: Administrator Prerequisite Knowledge

Task	Prerequisite Knowledge
User Administration	Create usernames and passwords.
Printer Setup (required before printing)	Install a Network or USB printer. Installation of a network printer requires knowledge of networking. For installation of a USB printer, follow the manufacturer's instructions.
Network Setup (optional)	Configure the system to gain access to the wireless networking environment (selection of server, setting of security keys, etc).
Electronic Medical Records (EMR) Export (optional)	Configuration for export of records to other office system(s) using the HL7 data transfer protocol.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

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Contact TearScience with any questions about the information contained in this manual or for additional information on the operation and safety of the LipiView® Interferometer.

2 Device Description

The LipiView® Interferometer is a bench-top device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touchscreen display. Figure 2-1 shows the base LipiView® Interferometer. Additional views and a description of the components are provided in Section 9, *LipiView® Interferometer Operation*.

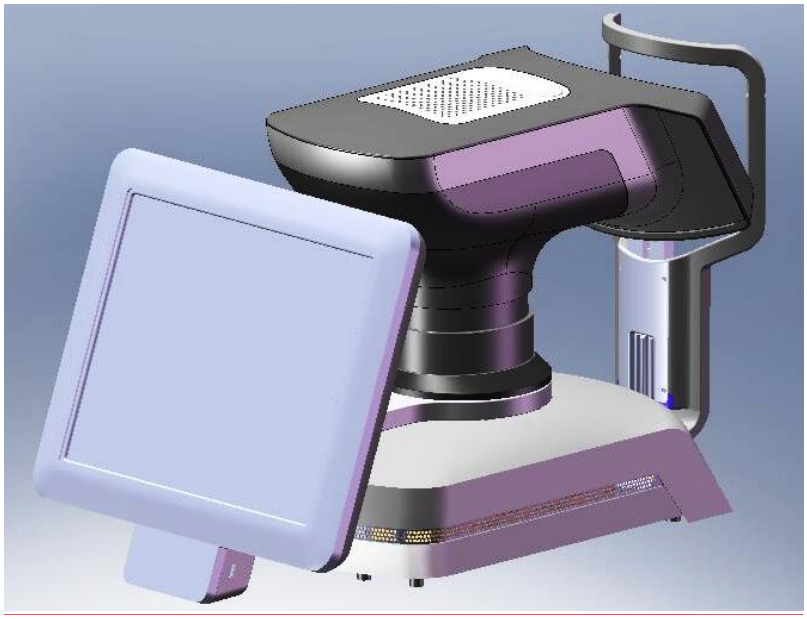

Figure 2-1: LipiView® Interferometer

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The patient's eye is positioned in front of an illumination source directed toward the tear film on the corneal surface. Light from the illumination source passes through the tear film and is specularly reflected into a camera. The light reflecting back through the lens in the camera forms an interference pattern, called an "interferogram". The computer system

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captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking.

The computer system captures and enhances the interference pattern and displays a profile corresponding to an interferometry color scale. The interferometry color assessment is measured in Interferometric Color Units (ICU). An ICU for the LipiView® Interferometer is defined as the color scale resulting from the interference pattern which occurs at the boundary of the tear film. The measured ICU may range from 0 to 240, with a precision of 1 ICU. The accuracy of the measured interference pattern is displayed as a "C-factor," which is equal to the proportion of measured colors that match the predicted interferometric color scale. The video image of the ocular surface may be viewed on the computer screen display and in a printed report.

3 Labeling

Table 3-1 provides a description of the symbols used on the LipiView® Interferometer labeling.

Table 3-1: Description of Labeling Symbols

Label Symbol	Symbol Description
	Type B applied part.
	Consult operating instructions
	Device transmits radiofrequency (RF) energy
	Text consists of a warning or precaution relating to safety. Read the text carefully and use the equipment as instructed to ensure safety.
	Reference Number
	Serial Number.
	**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.
	Mandatory conformity mark for medical device products in the European Economic Area (EEA). The **CE marking** certifies that a product has met consumer safety, health or environmental requirements.
	This model/product is Listed in Intertek's Directory of Listed Products.

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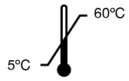
Label Symbol	Symbol Description
	Date of Manufacture
	Manufacturer
	Store between 5 and 60 degrees Celsius
	Authorized Representative in the European Community
P/N	Part Number
Rev	Revision Level

4 Indications for Use

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

5 Contraindications

Contraindications are conditions in which the device should not be used because the risk of use clearly outweighs any benefit. No contraindications have been identified for the LipiView® Interferometer.

6 Precautions

The following patient conditions may affect the interferometry assessment of a patient's tear film using the LipiView® Interferometer:

- **Use of ophthalmic drops such as artificial tear lubricants, ointments, and medications.** Advise patients not to instill oil-based ophthalmic drops (e.g., Soothe®, Restasis®) for at least 12 hours prior to device use and not to instill ointments for at least 24 hours prior to device use. Wait at least 4 hours after the instillation of all other ophthalmic drops prior to device use.
- **Soft or rigid contact lens wear**. Advise patients to remove contact lenses at least 4 hours prior to device use.
- **Use of oil-based facial cosmetics around the eye.**
- **Eye rubbing.**

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- **Recent swimming in a chlorinated pool.** Advise patients not to swim for at least 12 hours prior to device use.
- **Any ocular surface condition** that affects the stability of the tear film. These conditions include disease, dystrophy, trauma, scarring, surgery, or abnormality.

7 Warnings

Review the following warnings prior to using the LipiView® Interferometer.

Table 7-1: General and Operation Warnings

GENERAL WARNINGS
WARNING: No modification of this equipment is allowed.
Caution: **Power Requirements.** The LipiView® Interferometer is a continuous operation device which requires a power source of 100-240 Volts AC ± 10%, 50/60 Hz single phase, 4 Amps. Connection to a power supply other than a supply mains with protective earth may result in electric shock.
Caution: The LipiView® Interferometer has protection against electric shock of applied part classified as Type B. This device is classified as an IEC Class 1 product.
Caution: **Voltage Protection and Fuse Selection.** Contact TearScience to replace a blown fuse. TearScience personnel must replace only with a 5 x 20 mm, 4 A, 300 ms, 40 A breaking capacity fuse to avoid risk of fire. TearScience personnel must disconnect from power before servicing to avoid risk of electrical shock.
Caution: Backup Battery Replacement**.** Backup battery cannot be replaced.
Caution: Keep the LipiView® Interferometer away from strong magnetic fields as it could damage the device's hard drive, but is not a safety hazard to the user or patient.
Caution: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the LipiView® Interferometer or shielding the location.
Caution: Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
Caution: The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or Device.
Caution: The EQUIPMENT or DEVICE should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EQUIPMENT or DEVICE should be observed to verify normal operation in the configuration in which it will be used.
Caution: Degree of protection against harmful ingress of liquid: IPXO. This equipment has no protection against ingress of liquids.

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OPERATION WARNINGS
Caution: Federal law restricts this device to sale by or on the order of a physician.
Caution: The chin and forehead rest surface must be disinfected with alcohol immediately prior to use and prior to storage.
Caution: **Photo-toxicity hazard.** No acute optical radiation hazards have been identified for the LipiView® Interferometer under intended use conditions. Since prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. Aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours.
Caution: Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.
Caution: If a problem occurs with the LipiView® Interferometer, identify the symptom then attempt to resolve the problem as indicated in Section 15, *Troubleshooting*. If the problem cannot be resolved, stop using the device and contact TearScience.
Caution: To prevent electric shock or performance alteration, do not attempt to service the device or remove the cover. No maintenance is required for the LipiView® Interferometer, and the device and all of its associated parts are not serviceable by the user.
Caution: This device is not suitable for use in the presence of flammable mixtures.
Caution: This device is not suitable for use in oxygen rich environments.
Caution: In order to isolate this equipment from supply mains the equipment must be unplugged from the wall. Do not position the equipment in a location which would prevent the unit from being unplugged in an emergency.
Caution: Do not store this instrument in conditions where the temperature may rise above 60°C or fall below 5°C.
Caution: When lifting or handling the LipiView® Interferometer, caution should be taken to prevent injury or damage to the device. Prior to moving the device, put the monitor arm into a locked position and unplug the power cord from the wall. If an external monitor is attached, disconnect the external monitor prior to moving the device.
Caution: The device monitor and base unit may exceed 41°C. Device will remain within safe momentary contact temperature, below 51°C.
Caution: Shock hazard. Do not touch patient and device under top cover simultaneously.

8 Potential Adverse Effects

There are no known or anticipated adverse effects associated with use of this device.

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9 LipiView® Interferometer Operation

9.1 Device Overview

The LipiView® Interferometer is a bench-top device containing the following components, which are identified on Figures 9-1 (Front/Patient View) and 9-2 (Rear/User View):

- Base and Computer System
  - Computer system
  - Electronics
- Ophthalmic Chin Rest Support
  - Chin Rest
  - Forehead Rest
- Motion Stage
  - Camera and zoom lens
  - Illuminator
- Touchscreen Display
  - USB Ports

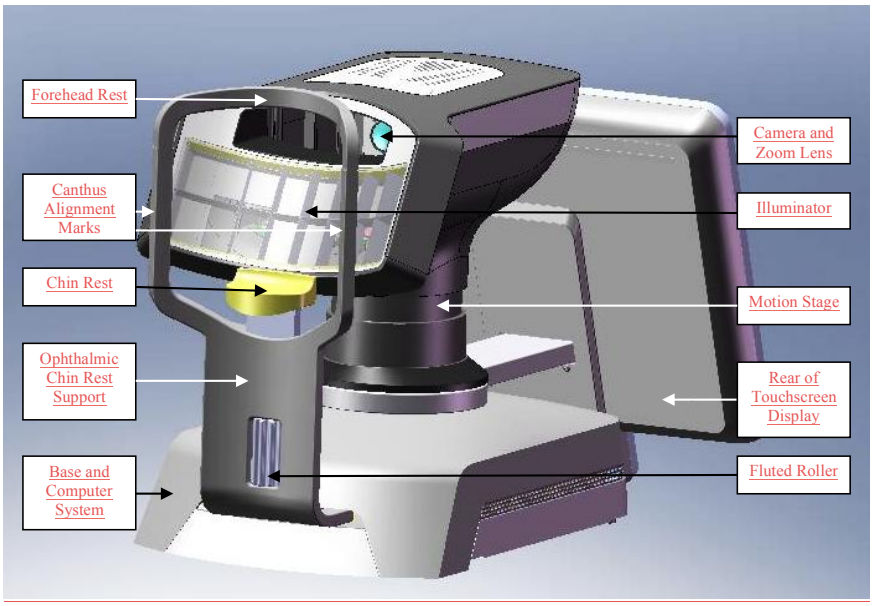

Figure 9-1: Front (Patient) View of LipiView® Interferometer

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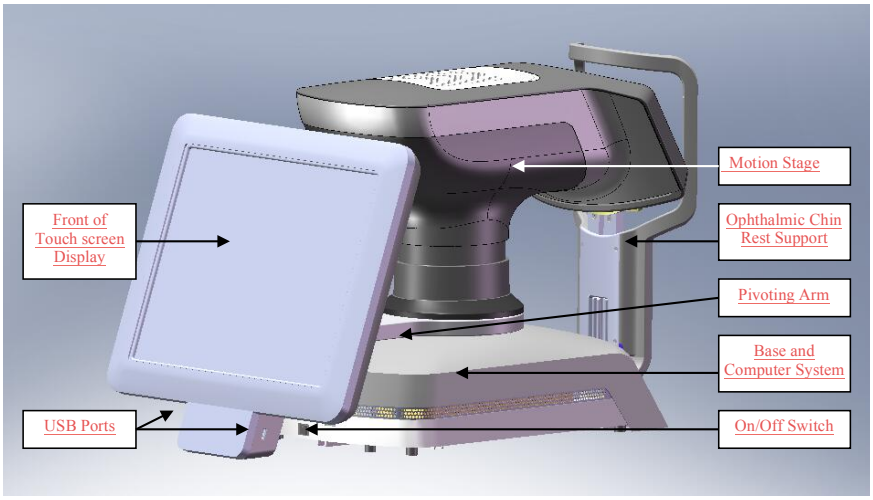

Figure 9-2: Rear (User) View of LipiView® Interferometer

9.1.1 Base and Computer System

The base of the device sits on a flat surface. It houses the power connection, and computer hardware, and connects with the ophthalmic chin rest support, motion stage and touchscreen display. The on/off switch is located on the rear of the base opposite the back surface of the display screen. Refer to Figure 9-2 for the switch location. A connection for an external monitor is hardwired into the base.

9.1.2 Ophthalmic Chin Rest Support

The ophthalmic chin rest support shown in Figure 9-1 consists of an adjustable height chin rest and fixed forehead rest. The chin rest support is attached to the front base of the device, and is designed to allow proper positioning of the patient's head to evaluate the ocular surface tear film. To ensure a properly focused image, the patient must place his/her chin and forehead firmly against the chin and forehead rests. The chin rest may be raised or lowered to accommodate different facial dimensions by spinning the fluted roller. Two canthus alignment marks about half way down the left and right sides of the forehead rest indicate the center of the camera range in the up/down direction. Adjusting the chin rest to position the lateral canthus of the patient's eye at these marks will optimize the range of camera motion.

The chin rest support is the only component of the LipiView® Interferometer that comes in contact with the patient. Disinfect the chin and forehead rest surfaces with alcohol immediately prior to use and prior to storage.

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9.1.3 Motion Stage

The motion stage is mounted on the top center of the base. It contains the camera, zoom lens, illuminator and motor controls used to adjust the camera and illuminator. The height of the motion stage (which includes the camera and illuminator) is adjusted as part of the Capture Images process discussed in Section 10.3.2, *Capture the Video*.

9.1.4 Camera and Zoom Lens

The camera is located behind the zoom lens inside the motion stage and is not visible externally. The height of the camera can be adjusted as part of the motion stage. The camera can also be adjusted to the left and right as well as backwards and forwards with separate controls. Refer to Section 10.3, *Video Image Capture and Recording* for additional information.

9.1.5 Illuminator

The grid-like fixture attached to the top front of the motion stage is the illuminator. The illuminator faces the patient and reflects light off the tear film. The height of the illuminator is adjusted automatically with camera alignment as part of the motion stage. There are no separate controls for the illuminator.

9.1.6 Touchscreen Display

Attached to the rear of the base is the Touchscreen Display. Figure 9-1 provides a rear view of the screen and Figure 9-2 shows the front view of the screen. The screen is on a pivoting arm, which allows it to be positioned ± 45 degrees or ± 90 degrees from its location shown in Figure 9-2. To reposition the screen, press the button under the pivoting arm while moving the arm left or right to the approximate 45 or 90 degree location. Release the button and continue moving the arm until it locks into place.

In addition to displaying information to the user, the screen also functions as a touchscreen user interface to the interferometer. The user touches the screen to operate the motion stage and camera controls and to progress through the imaging process. Section 9.2, *User Interface* provides additional details.

9.1.7 USB Ports

The lower base of the Touchscreen Display contains two USB ports as shown in Figure 9-2. These ports may be used to connect a printer or storage device if the LipiView® Interferometer is not on a wireless network. Refer to Section 9.1.9.4, *Accessory Support* for information on compatible accessories.

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9.1.8 External Monitor Connection

The LipiView® Interferometer supports the use of an external monitor. A connection for an external monitor is hardwired into the base. The connection will support HDMI or DVI inputs on an off the shelf external monitor which has at least 1280 x 1024 resolution and supports 60Hz frame rates. Instructions for attaching the external monitor are provided in Section 18, *Appendix B: External Monitor Hookup*.

9.1.9 Operating Environment

9.1.9.1 Electrical Specifications

Table 9-1: Electrical Specifications

Input Voltage	120 – 240 VAC, 50 – 60 Hz

9.1.9.2 Medical Electrical Classifications

Table 9-2: Medical Electrical Classifications

Product Safety Classification	Type B Applied Part
IEC 60601-1— Medical electrical equipment—Part 1: General requirements for safety	
IEC 60601-1-2 — Medical electrical equipment—Part 1: General requirements for safety—Section 2: Collateral standard—Electromagnetic compatibility—Requirements and tests;	CISPR 11 (Class A, Group 1)

9.1.9.3 Environmental Specifications

Table 9-3: Environmental Specifications

Operating Temperature	10°C to 35°C
Operating Relative Humidity	Up to 90% non-condensing
Storage Temperature	5°C to 60°C
Transport Temperature	5°C to 60°C

9.1.9.4 Accessory Support

The LipiView® Interferometer may be used with the following USB accessories that are compatible with Windows XP and USB1.0:

- USB printer (Printer Support)
- USB external hard drive (External Backup Support)
- USB flash drive (USB / Thumb Drive Support)

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The LipiView® Interferometer is designed to operate wirelessly with other network devices, such as a printer. Placement of the LipiView® Interferometer should be within range of the network, if a network system is used.

The LipiView® Interferometer supports connection to an external monitor; refer to Section 19, *Appendix B: External Monitor Hookup*, for more information.

9.2 User Interface

9.2.1 Touchscreen Display Layout

After user login, all touchscreen displays are formatted with a menu bar across the top containing a disk space indicator and up to seven tabs, one for each key function of the system. A light gray colored tab indicates the active function. Any other tabs shown on the menu bar may be selected. On screens involving a patient record, patient identifier information is displayed on the right end of the menu bar.

Figure 9-3 shows a sample menu bar. The light gray color on the View Images tab indicates it is the active function. Functions have one or more associated screens. From left to right, the menu bar contains: Help tab, Log Out tab, Disk Space Indicator, Admin tab, Patient Records tab, Capture Images tab, View Images tab, Print/Save tab, and patient identifier information.

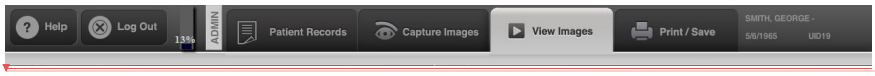

Figure 9-3: Menu Bar from View Images Tab

The Login screen contains the *Help* tab and the disk space indicator:

- **Help** – Pressing *Help* displays information related to the active screen. Pressing *Help* again closes the screen. Refer to section 10.6, *Online Help*.
- **Disk Space Indicator** – The bar to the right of the *Help* tab indicates the percentage of the available disk space that has been used for video storage. The Administrator can configure at what hard drive fullness level (e.g., 75%) the LipiView® Interferometer will no longer capture new images due to a full disk. Refer to Section 16.7, *Admin Networking* for information on setting the fullness level, cloning and archiving content to free up disk space.

Once the user logs in, up to six additional tabs are visible, depending on the current screen:

- **Log Out** – Pressing *Log Out* exits the user from the device and the Login screen described in Section 10.1.3, *User Login* is displayed.
- **Admin** - If the Username that is logged into the system has been set up as an Administrator, an *Admin* tab will be visible to the right of the disk space indicator

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on all screens. Refer to Section 15, *Administrator Instructions for Use* for a description of Administrator functionality.

- **Patient Records** – Pressing *Patient Records* displays patient information, and allows the user to search for, add or edit patient information. Refer to Section 10.2, *Patient Data Entry*.
- **Capture Images** – Pressing *Capture Images* allows the user to record video for each eye, preview video, rerecord video (if needed), and save video. Refer to Section 10.3, *Video Image Capture and Recording*. If the power on self-test described in Section 10.1.1 detects a problem that would potentially affect this modality, this tab will not be functional and will be grayed out (refer to Section 9.2.4). The LipiView® Interferometer will not be able to capture images but prior data can still be reviewed.
- **View Images** – Pressing *View Images* allows the user to review saved videos and request a computer analysis. Refer to Section 10.4, *Video Review and Analysis*.
- **Print / Save** – Pressing *Print / Save* allows the image with the video analysis to be printed and/or saved to an HL7 compatible database. Refer to Section 10.5, *Video Print and Save*.

Patient identifier information is shown on the right end of the menu bar when a patient record has been selected. This includes the Captures Images, View Images and Print / Save tabs. The information is extracted from the Patient Record, so the contents may vary. At a minimum, it includes the Patient ID or the Last Name, First Name and Date of Birth.

The screen below the menu bar contains information relevant to the active function tab. When entering information is allowed, an onscreen keyboard is displayed at the bottom of the screen, as discussed in the next section.

9.2.2 Onscreen Keyboard

When the cursor is positioned in a location that requires user input, the onscreen keyboard in Figure 9-4 is displayed. This keyboard contains an alphabet keypad (uppercase only), a numeric keypad, and five special keys that perform as specified below. The onscreen keyboard does not contain or support the use of special characters other than the backslash (\) and colon (:) between the two keypads.

- **Left arrow above the "Q"** – Scrolls backwards through entered text to facilitate the insertion or deletion of characters.
- **Right arrow above the "W"** – Scrolls forwards through entered text to facilitate the insertion or deletion of characters.
- **Delete key above the "O" and "P"** – Deletes the character to the left of the cursor.
- **Left tab above the "8"** – Moves the cursor to the prior field allowing user input. Repeated presses on the left tab key will continue looping the cursor backwards through fields on the current screen, but it does not return to the previous screen.

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- **Right tab above the "9"** – Moves the cursor to the next field on the screen allowing user input. Repeated presses on the right tab key will continue looping the cursor forwards through fields on the current screen, but it does not advance to the next screen.

Each key press yields one character or cursor movement of one position. Keys do not repeat if they are held down.

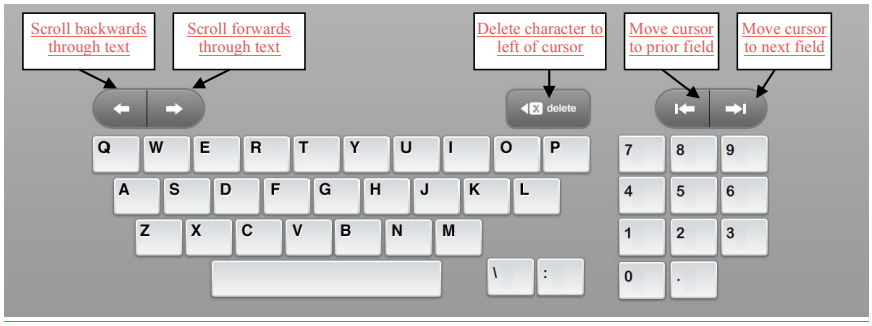

Figure 9-4: Keyboard

9.2.3 Positioning the Cursor

The LipiView® Interferometer touchscreen display allows the user to position the cursor by touching the desired area of the screen, or by pressing the arrow, delete or tab keys described in the previous section.

When making an edit to an existing field without positioning the cursor, any new characters entered are appended to the existing text, rather than replacing it. Use the Delete key to clear a field first, and then re-enter the information, or use the arrow keys to position the cursor in the correct location.

To facilitate editing, multiple characters on the screen can be highlighted by touching and then dragging a finger to the left or right. The series of highlighted characters is treated as one character when the arrow, delete and tab keys are used. The left or right direction of the finger movement determines where the cursor is placed when the special key is used.

9.2.4 Screen Interaction and System Messages

At times a portion of the active screen may be grayed out indicating it is temporarily inaccessible to the user. For example, if the onscreen keyboard is present, user input would be restricted to the keyboard. Selecting other tabs or pressing other areas of the screen will result in no action.

System messages are generated by the software running on the device when the user attempts to perform an invalid operation, or when something unexpected occurs or to confirm completion of an event. These messages may instruct the user on a particular

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action to take (e.g., enter a missing field, or correct the format of a date field). When a system message is visible it requires a response from the user before any other input from the screen is accepted. The user must respond by pressing a button on the system message. Typically this is the *Close* button, but it may also be a confirmation or other dialog.

System messages related to Windows error codes will also be listed in the System Log described in Section 16.9, *Admin System Log*.

9.3 Patient Interface

The only part of the LipiView® Interferometer that directly interfaces with the patient is the ophthalmic chin rest support. **Ensure that all parts of this support are cleaned with an alcohol wipe prior to each patient use and prior to storage.**

9.4 Device Setup

Prior to initial use, ensure that the instructions in Section 16.1, *First Time Setup* have been completed by an Administrator. Other administrative functions should be completed at the discretion of the Administrator.

Ensure that the power cord is plugged into an electrical outlet. The power cord connection is located underneath the base of the device.

10 Instructions for Use

This section provides instructions for use of the LipiView® Interferometer to image the ocular surface and to observe the tear film of the eye through specular reflection of light. The instructions include:

- Device Startup (Section 10.1);
- Patient Data Entry (Section 10.2);
- Video Image Capture and Recording (Section 10.3);
- Video Review and Analysis (Section 10.4);
- Video Print and Save (Section 10.5);
- Online Help (Section 10.6); and
- Log Out (Section 10.7).

Additional administrative functionality is described in Section 16, *Administrator Instructions for Use*.

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10.1 Device Startup

10.1.1 Power On and Self-Test

Upon powering on the device, the LipiView® Interferometer performs a self-test, confirms that the camera is connected, verifies system voltages, checks remaining hard drive space, and calibrates the camera motors. Version information at the bottom of the screen indicates the software running on the interferometer.

1. ***Power On*** - Power on the LipiView® Interferometer by pressing the rocker switch on the base of the device behind the touchscreen. Refer to Figure 9-2 for the location of the power switch. An indicator light on the power switch illuminates when the device is powered on.

   NOTE: The LipiView® Interferometer should be powered off overnight to allow the device to cool down. However, the device does not need to be powered off between patient examinations.

2. ***Software Boot Up*** - The touchscreen display remains blank while the software boots up. After a short time a "Welcome" message is briefly displayed. Shortly thereafter the screen in Figure 10-2 is displayed as the initialization process begins. The system version number displayed represents the software release which is currently installed. This manual is designed for all software releases that are labeled as 2.x. The exact letter of your system version may not match Figure 10-2.

   The system will display a warning (shown in Figure 10-1 below) that must be acknowledged before the initialization process continues: "Ensure patient and operator are clear of the chinrest area. The unit will now automatically home the motor system. Press the Continue button to begin."

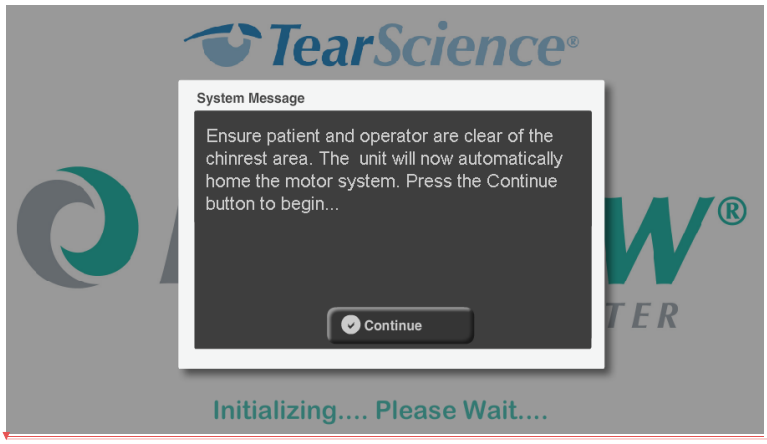

Figure 10-1: Warning screen

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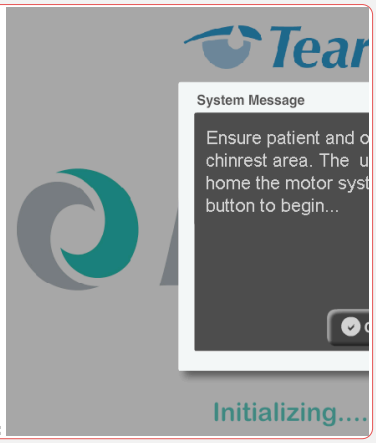

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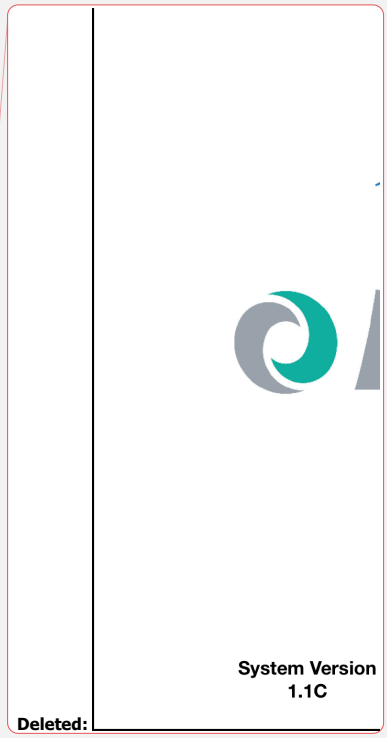

Figure 10-2: Initialization Screen

3. ***Equipment Location and Calibration*** - Figure 10-2 is displayed as equipment is located and calibrated. The motion stage moves up and down during the motor calibration process. When the initialization process completes after about 20 seconds, the screen in Figure 10-3 is displayed indicating that the device is ready for use. Continue with Section 10.1.2, *Device Ready*.

10.1.2 Device Ready

At the completion of the self-test, the words *Initializing…. Please wait….* on the screen are replaced with the words *Touch Screen To Continue* as shown in Figure 10-3.

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Figure 10-3: Device Ready Screen

When ready to continue, press anywhere on the screen. The login screen in Figure 10-4 will be displayed. Continue with Section 10.1.3, *User Login*.

10.1.3 User Login

The User Login screen in Figure 10-4 is displayed until *Submit* is pressed after a valid username and password have been entered. Refer to Section 16, *Administrator Instructions for Use* for setting up usernames and passwords prior to use of the device.

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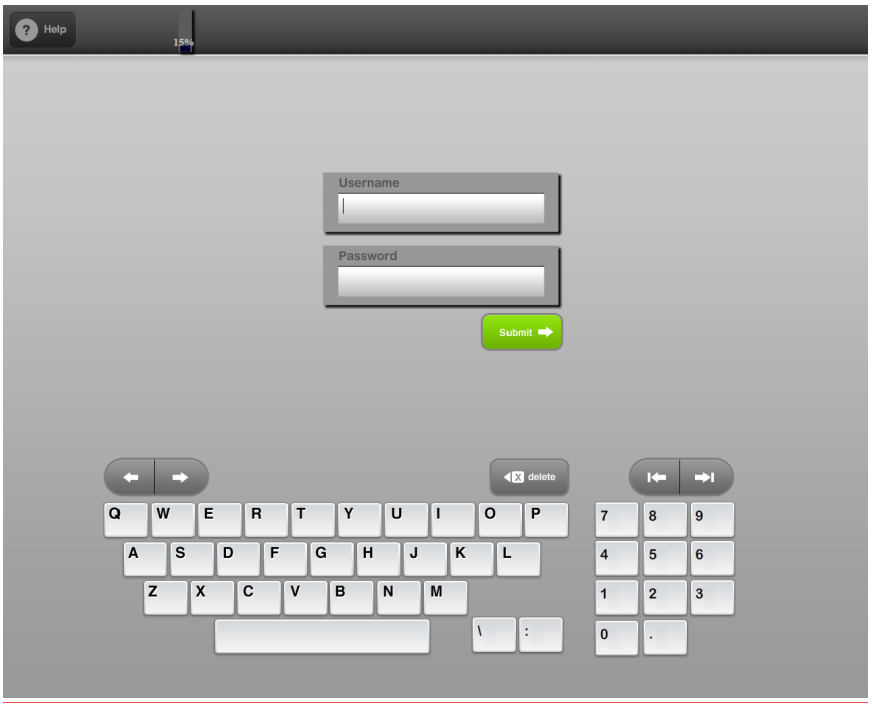

Figure 10-4: Login Screen

1. ***Username and Password*** - Using the onscreen keyboard, enter the Username and Password as follows:
   A. Type the name of the user.

      NOTE: Prior to device use, the Administrator must enter the Username and Password in the system.

   B. Position the cursor in the text box for the Password by touching the tab key or the password field.

   C. Type the password.

      NOTE: In the event of a forgotten password, or to change a password, contact the Administrator. Only the Administrator can set or change a password.
2. ***Submit*** - Press *Submit* and continue with Section 10.2, *Patient Data Entry*.

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10.2 Patient Data Entry

After successfully logging in, the Patient Records screen shown in Figure 10-5 is displayed. The Patient Records screen is used to find an existing patient record or to add a new patient record if it is not found in the database.

Prior to beginning an examination, a patient's record must be selected. A patient's record must also be selected to view any previous videos. Until a patient record is selected, the Capture Images and View Images tabs on the menu bar are not active.

Figure 10-5: Patient Records Screen

10.2.1 Patient Records Screen

All patient records contain up to five pieces of information: Patient ID, Last Name, First Name, Middle Initial and Date of Birth. At a minimum, each patient record must include 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. The Patient Records screen contains these five blank fields, which are used to locate, create or update a patient record, followed by a tabular list of existing patient records.

The Patient ID field can contain up to 16 characters. Fields for the Last Name and First Name can contain up to 25 characters each. The middle initial contains up to one

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character. The Date of Birth includes a one or two-digit month, followed by a one or two-digit day, followed by four-digit year.

The patient records table in the center of the screen lists the first eight patients in the database in alphabetical order. Once more than eight names have been saved, the step keys to the right of the table can be used to move backwards or forwards through the table. Each time the backwards (upper) key is pressed the previous eight names are displayed. Pressing the backwards key when the beginning of the list is displayed does not elicit a response. When the forward (lower) key is pressed, the next eight names are displayed in the table. Pressing the forward key when the last eight names are displayed also results in no change to the tabular display.

When the list of patient records spans multiple pages, sorting the table may facilitate searching for a record. Pressing the Patient ID, Last Name, First Name or Date of Birth header will sort the table by that column. Pressing the same header a second time will sort the table in the reverse order. A small triangle in the column header indicates that the table is being displayed according to the data sorted by this column. The triangle points down or up to specify the direction.

10.2.2 Locate a Patient Record

A patient record must be in the database before images can be captured or viewed. To attempt to locate a patient record in the database, search for the record using one of the following two methods. For existing patients, using the step keys in method 1 may be preferred. For new patients, use method 2. If uncertain as to whether a patient record is in the database, use either or both of these methods to determine whether the patient record exists.

1. ***Locate Patient Record with Step Keys -*** Use the step keys to move backwards (upper key) or forwards (lower key) through the database, while examining the records displayed in the table for a match. If desired, press the table header for Patient ID, Last Name, First Name or Date of Birth to sort the table by that field.
   A. If the record cannot be found in the table, then continue with method 2 to confirm the patient record does not exist.
   B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action*.
2. ***Locate Patient Record by Typing*** - Begin typing the patient's Last Name, First Name and/or Date of Birth in the fields above the table, or position the cursor in the Patient ID field and begin entering the ID. As each character is entered, the patient records table is filtered displaying only the possible matches that exist in the database.
   A. If no records are displayed in the table then the patient record does not exist. Either correct the entered information, or continue with Section 10.2.3, *Add a New Patient Record*.
   B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action*.

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10.2.3 Add a New Patient Record

When a patient record could not be located in the database, the screen shown in Figure 10-6 is displayed, allowing the user to enter new patient information and save it.

NOTE: Depending on the information entered when trying to locate a patient, one or more of the five fields in the patient record may be empty or partially filled in. As soon as the system determined there was no patient record match in the database it transitioned to Figure 10-6.

Figure 10-6: Patient Records Screen - Add a New Patient

At a minimum each patient record must contain 1) a Patient ID or 2) the Last Name, First Name and Date of Birth fields to proceed. The instructions below specify entering new patient information beginning with the Last Name; however, information may be entered into the fields in any order, and only the minimum information is required. Touch the appropriate fields or use the tab keys to move from field to field.

1. ***Patient Name*** – Enter the patient's Last Name and First Name and optional middle initial:
   A. Enter the Last Name, up to a maximum of 25 characters.
   B. Enter the First Name, up to a maximum of 25 characters.

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C. Enter the middle initial if desired. Entry may be helpful with common last names.

2. ***Date of Birth*** - Enter the patient's Date of Birth, using a one or two-digit month, followed by a one or two-digit day, followed a four-digit year. If an invalid date is specified, a system message is displayed indicating required information. Press *Close* and try again.

   NOTE: If a one-digit month or day is entered, position the cursor in the next field by touching the field or the tab key. If a two-digit month or day is entered, the cursor will automatically move to the next field.

3. ***Patient ID*** - Enter the Patient ID, up to a maximum of 16 characters. If a patient ID is entered, no other information is required to complete the patient record.
4. ***Review Record before Adding*** - Confirm that the information for the new patient is correct, and that the minimum fields have been filled in. Once a patient record has been entered into the database it cannot be deleted.
5. ***Add Patient Record to Database*** - Press *Add New Patient*.

   A. If a required field is empty or the new record is a duplicate of one that already exists in the database, a system message indicating the error is displayed. Touch *Close* to shut the system message. Make the appropriate corrections and press *Add New Patient* again.

   B. If the minimum required fields have information, there is a valid Date of Birth, and the patient record is not a duplicate of an existing record, it is saved in the database. The Patient Records screen in Figure 10-5 is redisplayed with the new patient record highlighted, and showing at the top of the table.

      NOTE: If the record added is the last record in the table, it appears to be the only record until the backwards (upper) step key is pressed showing other records.

   C. Return to Section 10.2.2, *Locate a Patient Record* to add another patient or find an existing patient, or touch any field on any record in the table and continue with Section 10.2.4, *Select a Patient Action*.

10.2.4 Select a Patient Action

Once a patient's record is visible in the patient records table, press on any field in the patient record. The row will become highlighted, the *Select a Patient Action* system message will appear, and the remainder of the screen will be grayed as shown in Figure 10-7, indicating that it is temporarily inaccessible for user input. Choose one of the four options in the system message:

- **Edit Patient** – Select this option to proceed to the Edit Patient Information screen, and continue with Section 10.2.5, *Edit Patient Information*.

  NOTE: A patient record may only be edited if video images have not previously been saved.

- **Capture New Images** – Select this option to proceed to the Capture Images screen, and continue with Section 10.3, *Video Image Capture and Recording*.

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- **View Past Images** – Select this option to proceed to the Patient History screen, and continue with Section 10.4, *Video Review and Analysis*.
- **Close** – Select this option if the incorrect record was chosen, and return to Section 10.2.2, *Locate a Patient Record* to try again. The system will close the system message, but the row will remain highlighted until another row is selected.

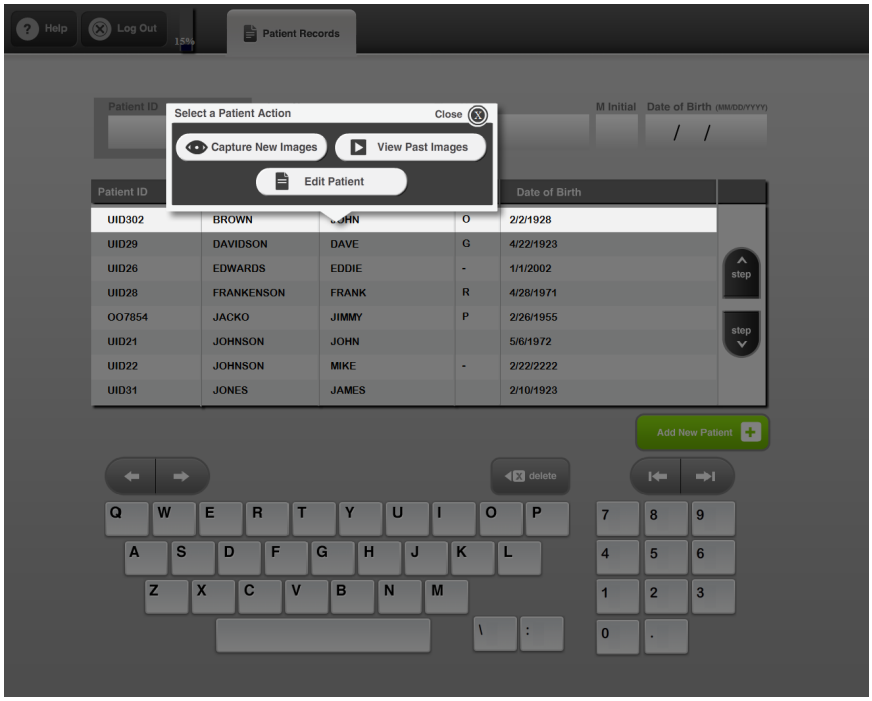

Figure 10-7: Patient Records Screen - Select a Patient Action

10.2.5 Edit Patient Information

When *Edit Patient* is pressed in the *Select a Patient Action* system message, either the screen in Figure 10-8 will be displayed showing the current information for the chosen patient, or a system message will be displayed indicating that video data has been captured for this patient and the record cannot be modified.

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Figure 10-8: Patient Records Screen - Edit Patient Information

1. ***Edit Patient Record*** - Position the cursor in the field(s) to be edited and make the changes. At a minimum, the patient record must contain 1) a Patient ID, or 2) the Last Name, First Name and Date of Birth. Continue with step 2 to save the edited data or step 3 to cancel the edit.
2. ***Save Patient Record Edits*** - Press *Continue* to update the patient's information in the database.
   A. A system message will result if a mandatory field is empty or the modified record is a duplicate of one that already exists in the database. Touch *Close* to shut the system message. Return to step 1 to correct the entered fields, or go to step 3 to cancel.

      NOTE: It is not possible to remove a patient record from the database by clearing out all fields. Once a patient record has been added it cannot be deleted.

   B. If the required fields exist and the record is unique, the system returns to the Patient Records screen in Figure 10-5 with the updated record highlighted and showing at the top of the table. Continue with Section 10.2.2, *Locate a Patient Record*.
3. ***Exit without Saving Patient Record Edits*** - Press *Cancel* to return to the Patient Records screen in Figure 10-5 without saving any edits. The highlighted row will be displayed in the same location. Continue with Section 10.2.2, *Locate a Patient Record*.

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10.3 Video Image Capture and Recording

When *Capture New Images* was chosen from the *Select a Patient Option* system message shown in Figure 10-7, the Capture Images screen in Figure 10-9 is displayed. As the screen displays, the illuminator is turned on and the system initializes the camera for approximately 1-2 seconds. The right end of the menu bar contains the patient information as entered in the selected patient record.

NOTE: If the Capture Images screen was reached by mistake, or to exit without capturing a video, press the *Log Out* tab, or press *Save All/Continue*, which will transition to the View Images function. From the menu bar on the View Images screens, all tabs are available for selection.

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Figure 10-9: Capture Images Screen

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10.3.1 Capture Images Screen

The Capture Images screen is split into left and right sections.

From the left side below the *Selected Frames* header, the user chooses which eye will have video captured. Information about the video image may be selected or entered from the tags below.

- **View OD** (Right Eye) – Select this to move the camera into position to view the right eye. This selection automatically illuminates the appropriate fixation bank for the patient's left eye. The patient fixates on a light with the left eye while the right eye image is being captured.
- **View OS** (Left Eye) – Select this to move camera into position to view the left eye. This selection automatically illuminates the appropriate fixation bank for the patient's right eye. The patient fixates on a light with the right eye while the left eye image is being captured.

  NOTE: The frame that is white indicates the selected eye. The frame that is grayed out was not selected.
- **Pre-set Tags** (rounded, gray color) – If applicable, the user may select one or both of these configurable, descriptive tag names before or after the video is captured. Once the video is saved, information selected here is permanently retained with the video data. These tags are pre-set by the Administrator as described in Section 16.3, *Admin System Setup*.
- **Key-in Tags** (rectangular, white color) – If desired, the user can enter up to 15 characters of information into each of these two fields before or after the image is captured. Information is typically specific to the patient or image. Once the video is saved, information entered here is permanently retained with the video data.

The right side of the screen is initially blank, but will display images of the selected eye as the video is recorded. Prior to recording the video image, the following controls are used to obtain the best possible image:

- **Left slider** – Touch the step keys to move the entire motion stage (including camera and illuminator) up and down for proper positioning. The button on the slider indicates the current motor position.
- **Horizontal slider** – This slider moves the camera inside the motion stage to the left or right. When *View OD* or *View OS* is pressed, the camera is moved to a default location for the selected eye near the OD or OS button on the slider. The camera position is fine-tuned by touching a location on the slider or by pressing the left or right step keys. While on the Capture Images screen the software will remember the last position of the camera for both *View OD* and *View OS* until *Save All/Continue* has been pressed. This enables the operator to easily move between the right and left eyes by touching *OD* and *OS* on the slider bar.

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- **Automatic Image Centering-** An alternative method of centering the eye on the screen is to touch the location on the live video that should be in the center (typically the pupil). The camera will automatically be moved to the location that was touched on the screen, and that location becomes the center of the video image.
- **Fixation Light** – The three-way button on the top right of the Capture Images screen operates a fixation light, which consists of a vertical set of three light emitting diodes (LEDs) behind the camera for the patient to look up, look straight ahead or look down. The default position is straight ahead.
- **Focus slider** – This slider moves the camera inside the motion stage forwards and backwards to bring the image in (-) or out (+).

NOTE: To change the position of the item controlled by a slider, press the desired location on the slider. The item and the button will move accordingly. Touching the button and dragging it has no effect.

10.3.2 Capture the Video

The following steps instruct the user on how to set up the device, position the patient and capture the video:

1. ***Eye Selection*** - On the left side of the screen touch *View OD* or *View OS* for the eye to be captured. *View OD* is the initial default if no selection is made. Once a video has been recorded, the default selection is the last eye captured. The selected view will be white and the other will be a gray color.
2. ***Pre-set Tags*** - Select one or both of the pre-set tags, if desired. The system will note a selection with a checkmark. The selection may be made here or while previewing the captured image in Section 10.3.3. If selected here, it may be updated anytime until the video is saved.

   NOTE: Press the checked tag again to deselect it.
3. ***User Defined Key-In Tags*** - If desired, use the key-in tags to record additional information in each tag. Information may be entered here or as part of previewing the captured image in Section 10.3.3. If entered here, it may be updated anytime until the video is saved.
   C. Touch a key-in field to display the onscreen keyboard.
   D. Enter information in one or both of the key-in tags.
   E. Touch *Submit* on the left of the onscreen keyboard. The screen in Figure 10-9 will be displayed with the updated tag names.
4. ***Disinfect*** – Disinfect the chin and forehead rest surfaces with alcohol prior to patient use.
5. ***Patient Positioning*** - Have the patient sit facing the LipiView® Interferometer. Ensure the patient's chin is placed fully forward into the chin rest and the patient's forehead is placed firmly against the forehead rest to ensure proper attitude of the patient's head. If the patient's head is not in the proper position, valid video data may not be collected. Instruct the patient to look at the orange fixation light.

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Caution: **Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct the patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.**

6. ***Chin Rest Height Adjustment*** - Adjust the height of the chin rest by spinning the fluted roller near the base of the chin rest so that the lateral (temporal) canthus is aligned with the horizontal canthus alignment marks on the left and right sides of the forehead rest. Spin the roller to the right to lower the chin rest and spin the roller to the left to raise it.
7. ***Camera Adjustment*** – By default the camera should be in the general location of OD or OS (depending on the view selected in step 1, as shown in Figure 10-10. Position the height of the camera by stepping the motors up and down using the left slider. Use the horizontal slider to adjust the camera sideways. Alternatively, touch the desired location the screen which will automatically move the motion stage and the camera to that position and then center on it. Adjust the image until the pupil appears in the center of the live video screen and the reflected tear film image is within the green targeting rectangle.

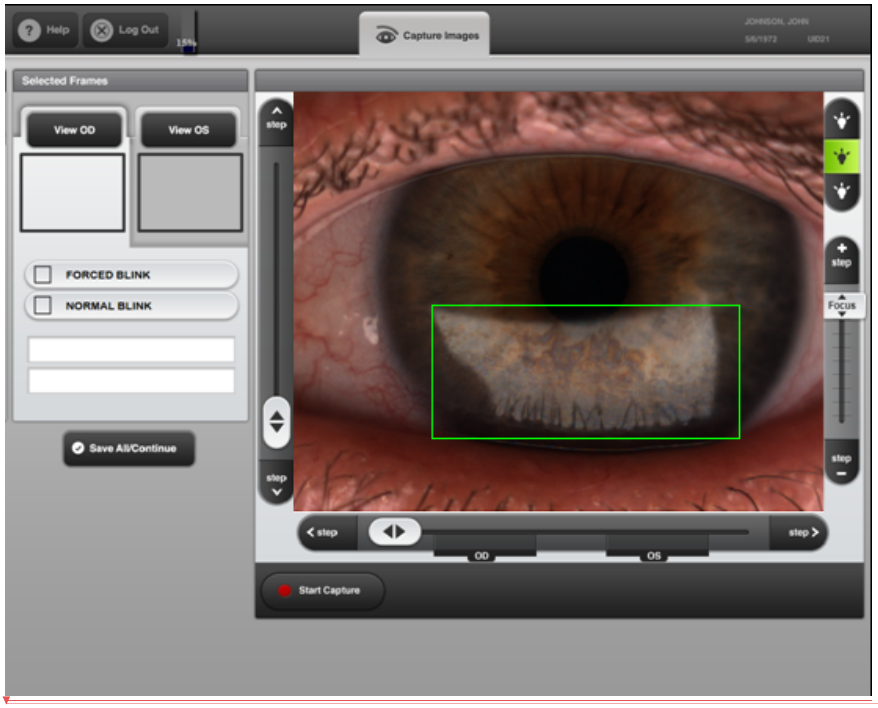

Figure 10-10: Capture Images Screen - Centering Eye Before Recording

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8. ***Camera Focus*** - Adjust the closeness of the image with the Focus slider on the right. The focus should be adjusted so that the tear film image is clear and not blurred.

   NOTE: If the tear film image is not in focus, invalid video data may be saved. As shown in Figure 10-16, analysis of invalid video data is unable to produce a graph and numerical results.

9. ***Fixation Light / Patient Gaze*** - Ensure the patient is looking in the proper direction to facilitate obtaining a well-centered and focused picture for the patient's eye. If necessary, press the upper or lower sections of the Fixation light, guiding the patient to look up or down.

10. ***Capture Image Start*** - Press *Start Capture* to begin recording approximately 20 seconds of video. Typically 10-15 seconds of video is enough to capture the tear film image as the patient blinks. Instruct the patient to blink naturally (e.g., NORMAL BLINK) or to perform a squeezed blink (e.g., FORCED BLINK) as desired, to evaluate the distribution of the tear film.

    NOTE: The blinking red light indicates the LipiView® Interferometer is recording, and the *Start Capture* button is renamed to *End Capture*. Other than pressing *End Capture,* the grayed out screen does not allow user interaction.

11. ***Capture Image End*** - Press *End Capture* to stop recording before 20 seconds has elapsed, or the system will automatically end the video after 20 seconds.

12. The illuminator is turned off when recording stops, and the screen in Figure 10-11 is displayed allowing the user to choose from several options. Continue with Section 10.3.3, *Preview Captured Image*.

10.3.3 Preview Captured Image

The right side of the Preview Captured Images screen in Figure 10-11 contains the video image just recorded. The left side of the screen contains the same functionality as the Capture Images screen (Figure 10-9), indicating information about the image. *View OD* or *View OS* indicate the eye being shown. When video for both eyes has been captured, the most recently captured video is the one displayed by default.

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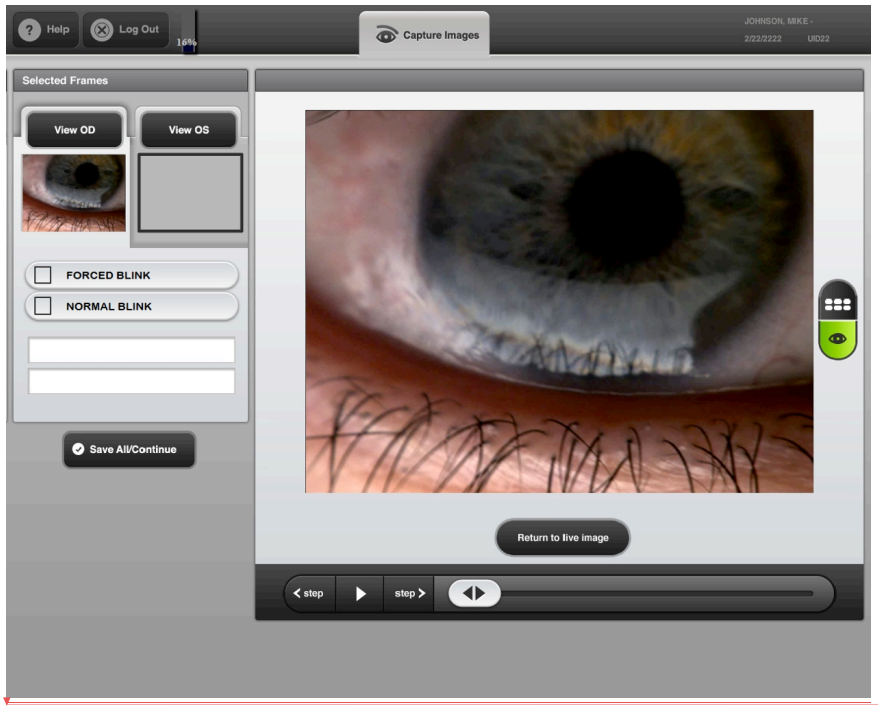

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Figure 10-11: Capture Images Screen - Preview Captured Images

The Preview Captured Images screen enables the user to perform one or more of the following steps. Steps 1 – 4 are optional and they may be combined with other steps. Unless the user logs out of the system, the captured video must be saved (step 5) before other tabs become visible.

1. ***Preview Image*** - Preview the image using the following control keys:
   - **< step** – Press to step backwards through the video one frame at a time.
   - **Triangle/Vertical lines** – Press to play (triangle) or pause (two vertical lines) the video.
   - **step >** – Press to step forwards through the video one frame at a time.
   - **Video slider** – When in play mode, the button moves along the slider indicating the current position within the video. When in pause mode, press any location on the slider to move the video to the position indicated by the touch. The button will move to the new location.
   - **Toggle key** - The toggle key positioned to the right of the screen switches between a tear-film view and a full-eye view. Press the tiles to select the tear-film view. Press the eyeball to select the full-eye view. The green portion of the key indicates the active view.

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2. ***Rerecord Video*** - Rerecord the video by pressing *Return to live image* above the video controls. The Rerecord Video screen in Figure 10-12 will be displayed. Continue with Section 10.3.4, *Rerecord Video*.
3. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the preview screen.
4. ***Eye Selection*** - Press the tab for the other eye (*View OD* or *View OS*). Figure 10-9 will be displayed for the selected eye. Return to Section 10.3.2, *Capture the Video* and follow the instructions. When the second video capture ends, Figure 10-11 is displayed with the most recently captured video showing. Return to step 1 and follow these steps for the second eye.
5. ***Save Video*** - Save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Rerecord Video screen in the next section.
   B. After the image is saved, the illuminator is turned off and the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

10.3.4 Rerecord Video

The Rerecord Video screen in Figure 10-12 is used when the captured image for one or both eyes is not acceptable to the user and it is necessary to rerecord the live image before it is saved. When this screen is displayed, the illuminator light is turned on.

This screen operates like Capture Images screen in Figure 10-10 except that when *Start Capture* is pressed, a system message asks the user to confirm that the user is intentionally overwriting the previous image. The image may be rerecorded any number of times. There is also an additional button on the bottom center of the screen allowing the user to return to the previously recorded image.

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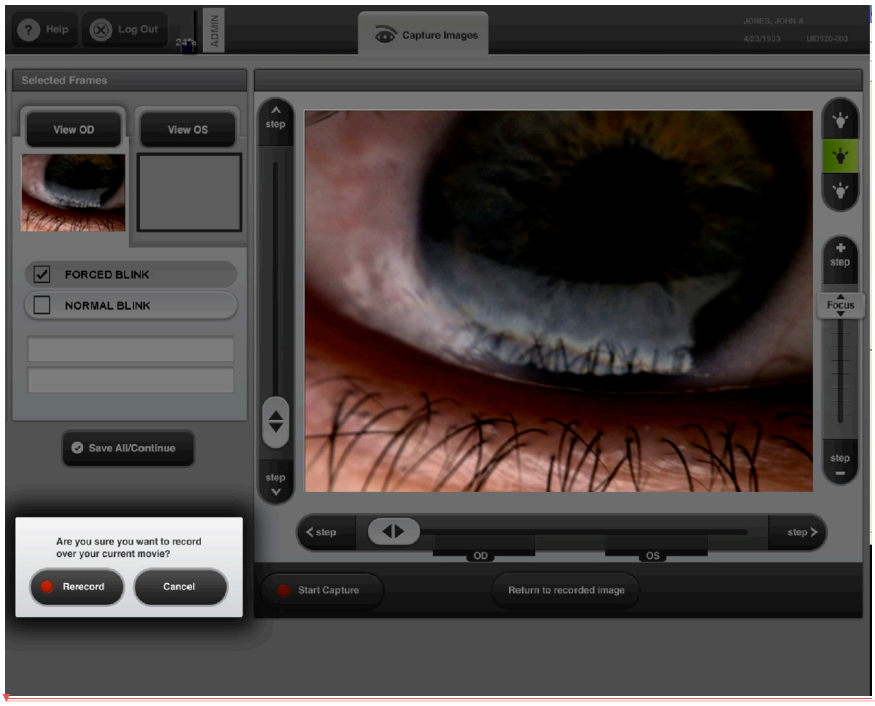

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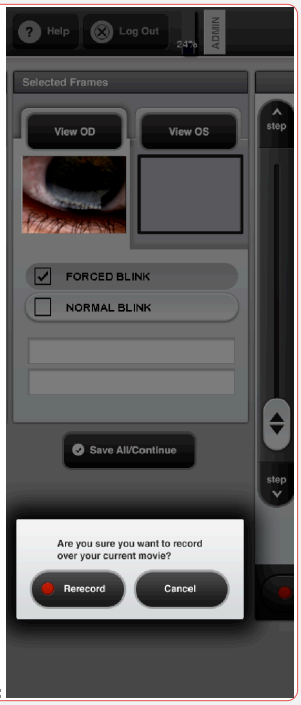

Figure 10-12: Capture Images Screen - Rerecord Video

1. ***Confirm Whether to Rerecord*** - If unsure whether to rerecord the image or if this screen was reached in error, press *Return to recorded image* to return to the Preview Captured Image screen in Figure 10-11. Follow the steps in Section 10.3.3, *Preview Captured Image*.

   NOTE: Toggle between these two screens by pressing *Return to recorded image* and *Return to live image*.
2. ***Eye Selection*** - If video for both eyes has been captured, ensure that the correct eye has been selected.
3. ***Camera Focus and Settings*** - Prior to rerecording, touch the screen or use the slider bars to reposition the camera, and modify the Fixation Light and Focus settings if needed.
4. ***Rerecord Image or Cancel*** - Press *Start Capture*. A system message will appear on the bottom left of the screen to rerecord or cancel the request.

   A. Press *Rerecord* on the system message to begin capturing another image. When *End Capture* is pressed, the illuminator is turned off and the system returns to the screen in Figure 10-11. Return to Section 10.3.3, *Preview Captured Image*.

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NOTE: When *Rerecord* is pressed, the original captured image will be overwritten with the new one. Recording of the image can be repeated as many times as needed until the image is acceptable.

B. Press *Cancel* on the system message when unsure whether to rerecord. The system message will be removed. Return to the recorded image (step 1), rerecord the image (step 4A) or continue with step 5.

5. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the previous screen.
6. ***Save Video*** - When the captured image is satisfactory, save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Preview Captured Images screen in the previous section.
   B. After the image is saved the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

10.4 Video Review and Analysis

The Video Review and Analysis function is used to review information about a captured video for one or both of a patient's eyes. The View Images screen used to perform this function may be accessed after capturing a new video (continue with Section 10.4.1) or after selecting an image(s) from the patient's history (continue with Section 10.4.2). Patient information as entered in the selected patient record is listed on the right side of the menu bar. Other information on the screen will vary depending whether video was captured for both eyes, and whether the video has been analyzed.

10.4.1 View Images Screen after Capturing New Video

When *Save All/Continue* is pressed from any of the Capture Images screens in Section 10.3, *Video Image Capture and Recording*, the View Images screen in Figure 10-13 is displayed. From this entry point, the image on the screen is that of the eye(s) just saved. The OD eye is displayed on the left side of the screen and the OS eye is displayed on the right side of the screen. If only one eye was captured, the other half of the screen is blank. Since the images have not yet been analyzed, the numerical calculations below the images will be zero, and a message on the graph indicates that the user needs to press *ANALYZE IMAGES* to view the data.

Continue with Section 10.4.3, *View Images and Analyze Data.*

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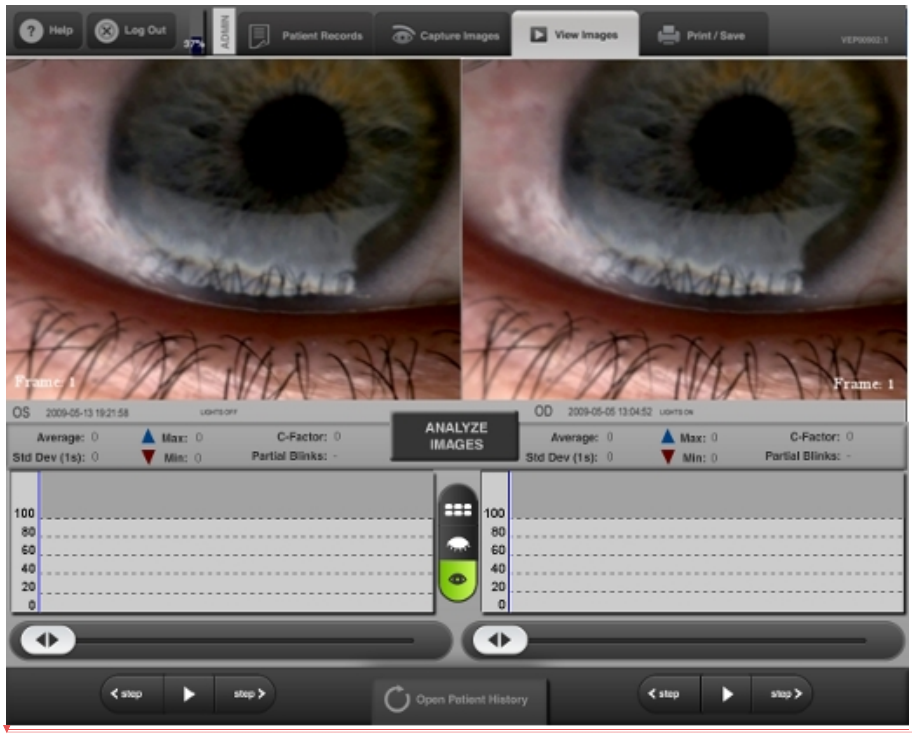

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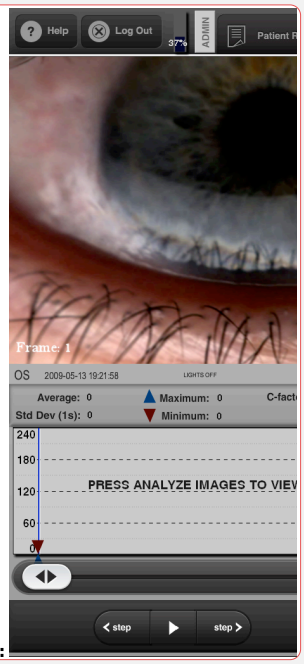

Figure 10-13: View Images Screen – Images not Analyzed

10.4.2 View Images Screen after Selecting from Patient History

When *View Past Images* is chosen from the *Select a Patient Action* system message, the user is directed to the screen in Figure 10-14 or to the screen in Figure 10-16, depending on the previous video that was reviewed. Note that, in either case, the first set of OD/OS images presented are standard reference video images of eyes with different ICU levels, provided for purposes of comparison.

If the previous video reviewed was from the same patient record that is currently selected, Figure 10-16 is displayed with the previously reviewed video showing and the Patient History list closed. Continue with Section 10.4.3, *View Images and Analyze Data*.

If the previous video reviewed was from a different patient record, the View Images screen is displayed with the tabular Patient History list open, as shown in Figure 10-14, so that the user can select which video(s) to display. The Patient History contains an inventory of all videos saved for the selected patient with the date and time as well as any information in the pre-set or key-in tags. If a video has been cloned, the patient history file will display "CLONED" to the right of the time. If the video has been archived and is

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no longer online, “ARCHIVED” will be displayed to the right of the time. The process of cloning and archiving videos is an Administrator function, discussed in Section 16.7.1, *Disk Cloning*. An empty Patient History table (no video images) indicates that video data has not been saved for this patient.

The top left and right frames of the View Images screen are blank until videos have been selected. From the Patient History, the user will either select one or two videos, or press the *Close Patient History* so that other tabs become visible for selection.

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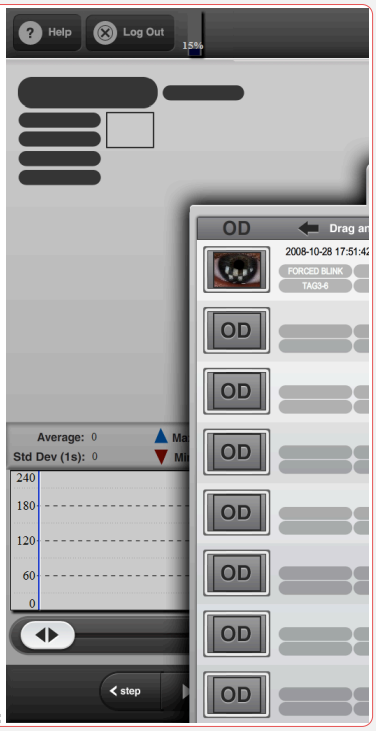

Figure 10-14: View Images Screen - Select Past Images from Patient History

If a video will not be selected from Patient History, skip to step 6; otherwise, follow the steps below to select the video(s):

1. ***Locate First Video*** - Locate a video that will be loaded. Touch the step keys on the right to move backwards and forwards through the list if the Patient History table contains more than eight videos.
2. ***Load First Video*** - To load the video:
   A. Touch the thumbnail image located next to the date/time stamp of the video. If the video was archived, a system message appears asking for confirmation to restore the video. Choose from one of the following:

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- Press *Close* to return to the open Patient History list, and repeat step 1 to locate a different video, or continue with step 6 to close the Patient History list.
- Press *Restore Video* on the system message to start copying the archived video. A progress dialog will appear showing the status of the restore. Once the file has been restored, the word ARCHIVED will be removed from the Patient History list. Touch the video again and continue with step B.

  NOTE: If a progress dialog does not appear indicating the start of the restore process, contact the Administrator to check the validity of the of the clone path on the Networking screen.

B. Drag the thumbnail image into the rectangular frame in the upper corner on either the OD or the OS side.

   NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

C. Drop the image by releasing your finger.

3. ***Video Loaded*** - The eye selection, date of captured video, pre-set and key-in descriptions, Username that captured the video and an image of the selected video will be copied into the blank tag cells as shown in Figure 10-15.
4. ***Locate / Load Second Video*** - Repeat steps 1 and 2 to select the second thumbnail image if desired, dropping in into the frame in the other corner.

   NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

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Figure 10-15: View Images Screen - Videos Loaded from Patient History

5. ***Confirm Images Loaded*** - Confirm that the images loaded are the ones to be displayed. Update the left and right frames if desired, by dragging and dropping alternate thumbnail images.

   NOTE: Once an image has been dragged to either corner it cannot be removed; however, each additional image that is dragged and dropped will replace the previous one.

6. ***Close Patient History*** - Press *Close Patient History* at the top of the tabular list. The list will shut and the button will move the bottom of the screen. A message to wait will be displayed while the selected video(s) are loaded. Upon completion, continue with Section 10.4.3, *View Images and Analyze Data*.

   NOTE: If the Patient History table is closed without selecting a video, the screen in Figure 10-16 is displayed; however, there are no images shown on the top half of the screen. This sequence typically happens when the user has pressed the *Capture Images* tab in error, and wants to make the other tabs available. Since there are no images to view, the user should select from one of the tabs in the menu bar at the top of the screen.

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10.4.3 View Images and Analyze Data

The View Images screen contains seven key sections, which are described below. Figure 10-16 shows the View Images after the images have been analyzed. One video shows valid image data; the other does not.

- **Video Images** – The top half of the screen contains frames for the OD and OS videos, when they are captured/selected for viewing. Each "Frame" is set to "1" initially, and the frame number is incremented as the video plays.
- **Video Descriptor** – Identifying information just beneath each video image includes OD or OS, the date and time of capture, and any pre-set or keyed in descriptive tag names.
- **Analyze Images button** – Pressing *Analyze Images* results in a numerical analysis of the interferometric colors and a graph for each of the videos. If for some reason the analysis cannot be performed, a message *NO VALID ANALYSIS DATA FOR VIDEO* replaces the graph, and the numerical information remains zero. After the analysis has been completed, the records are saved to the database. (Note: recorded images may only be analyzed once; attempting to "re-analyze" a set of images will result in an error.)
- **Numerical Analysis** – After the video has been analyzed, the following statistics above each graph are updated:
  - **Average** - The average ICU of all the frame averages (denoted by the black line in the graph).
  - **Std Dev** - The standard deviation of the frame averages.
  - **Maximum** - The maximum ICU recorded for a given frame.
  - **Minimum** - The minimum ICU recorded for a given frame.
  - **C-Factor** - The tear film Conformance factor for the entire video. The C-factor is defined as the percentage of pixels in the tear film that fall on the interferometric color spectrum. A C-factor of 1.0 indicates that every tear film pixel throughout the entire video loop has found a close match to an Interferometric color.
  - **Partial Blinks** – The number of partial blinks out of the number of total blinks counted, expressed as a fraction. The numerator (top number) is the number of partial blinks; the denominator (bottom number) is the total number of blinks counted. A partial blink value of 3/9 means that out of nine total blinks detected, three were evaluated as "partial blinks."
- **Graph** – After the videos have been analyzed, each graph shows the average Interferometry Color Unit (ICU) and standard deviation for each frame corresponding to the location in the video. Each point on the graph is the ICU value for that frame. The blue line and region is the upper standard deviation of the ICU score data. The red line and region is the lower standard deviation of the ICU score data. The blue triangle marker denotes the point on the graph that contains the maximum ICU score. The red marker triangle marker denotes the point on the graph that contains the minimum ICU score.

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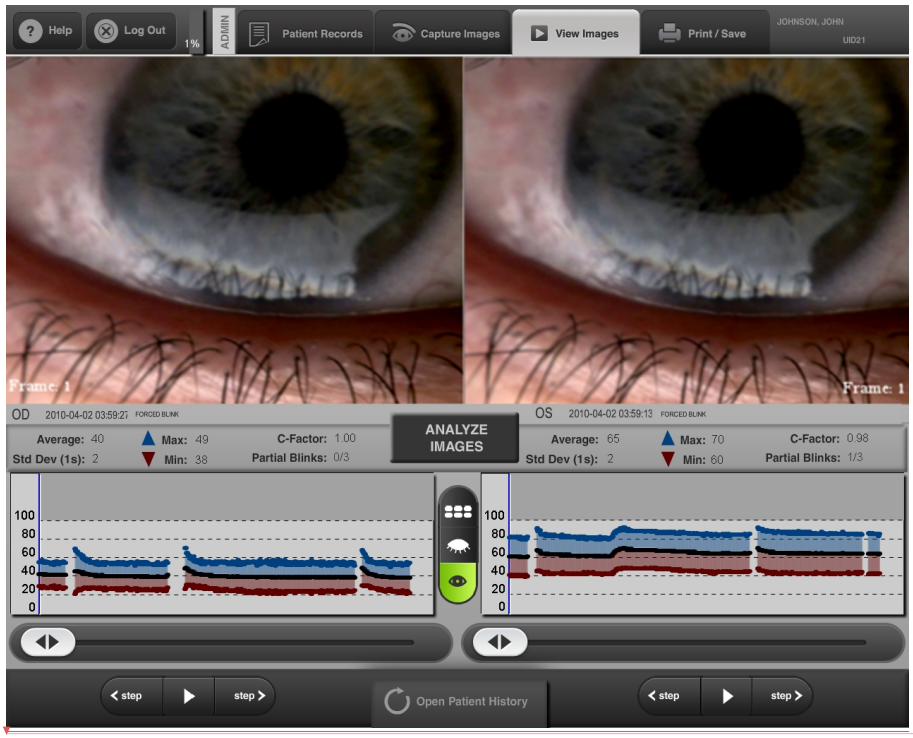
- **Video Controls** – The controls under each graph include a slider bar, backwards (< step) and forwards (step>) buttons and a play/pause button and function as described in Section 10.3.3, *Preview Captured Image*. Videos may be played before or after they have been analyzed.
- **Open Patient History button** – Pressing this button opens the Patient History list on top of the View Images screen and allows different videos to be selected for this patient. When the list is closed it returns to this button.

When the View Images screen is displayed after capturing new video, an analysis of the image data has not occurred yet, as seen in Figure 10-13. When the View Images screen is displayed with video from the Patient History, an analysis of the image data may or may not have occurred. If the data has been analyzed, the numerical information will be filled in and a graph will show under the video as shown in Figure 10-16.



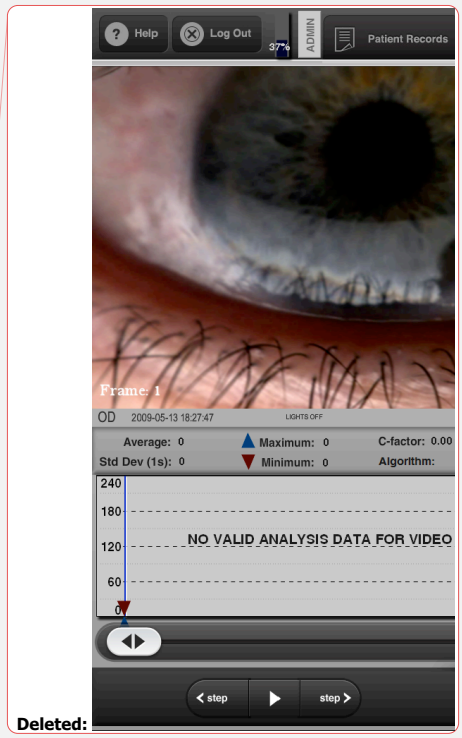


Figure 10-16: View Images Screen – Analyze Images

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The following steps provide guidance on options for viewing and analyzing the video image data.

1. ***Select View of Eye*** - Press the toggle key between the graphs to select a full-eye view (eyeball), blink-only view (closed eye) or the isolated tear film view (tiles). Blink-only view displays only the segments of the video in which the subject is blinking. The isolated tear film view separates the tear film area and indicates the area being analyzed. The green portion of the key indicates the active view.
2. ***Analyze Images*** - If the video image data has not been analyzed, press *Analyze Images* in the center of the screen to generate a graph (see Figure 10-16) of the ICU values for each frame. This may take several seconds. The graph shows the average ICU for each frame along with ranges for the standard deviation. Blank spots on the graph occur when the patient is blinking or the patient's eye is not stationary. Data resulting from the analysis is automatically saved in the database.
3. ***View Left Video*** - To view video of the eye on the left side of the screen (typically the OD):
   A. Press the triangular "play" button centered between the two "step" buttons on the lower left of the screen to loop through the video. As the video plays, the button on the slider indicates position and a vertical line moves across the graph.

      NOTE: When pressed, the "play" button changes to a "pause" button indicated by two vertical lines.

   B. When the video is paused, use the backwards (< step) and forwards (step >) buttons to move through the video frame-by-frame, or touch a spot on the slider bar to move the video to that location.
4. ***View Right Video*** - To play the video of the OS eye on the right of the screen (typically the OS), follow the instructions in step 3, using the controls on the lower right of the screen.
5. ***Select New Video*** - To view a different video for the selected patient record, press *Open Patient History* at the bottom of the screen, and follow the instructions in Section 10.4.2, *View Images Screen after Selecting from Patient History*.
6. ***Print and Save Video*** - To print the image and graphical analysis or to save it to an HL7 compatible system, press the *Print / Save* in the menu bar at the top of the screen and continue with Section 10.5, *Video Print and Save*.

10.5 Video Print and Save

From the View Images screen, the Print /Save tab is visible, allowing the report of the analyzed images to be printed, saved to an external drive as an Adobe PDF (Portable Document Format) file, or saved to an HL7 compatible system. Refer to Section 16, *Administrator Instructions for Use* for more information on HL7 and instructions on how to set up the HL7 parameters. The HL7 database must be configured by the Administrator prior to use.

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The report header contains patient and practice information. Patient information is taken from the patient record, and consists of the Patient ID and the name if entered. The date of report and the Username of the operator who captured the video follow. Practice information consists of the name, address and phone number of the practice, and the serial number of the LipiView® Interferometer used. Practice information is set up by the Administrator per the instructions in Section 16.3, *Admin System Setup*.

Below the patient and practice information, the report contains information about the eye displayed (OD/OS), the date and time of video capture, and information contained in the pre-set and key-in tags. An image of the frames containing the maximum average ICU displayed both in full-eye and tear-film views. Beneath the images are the graphs and various metrics about the frames captured, and the ICU values.

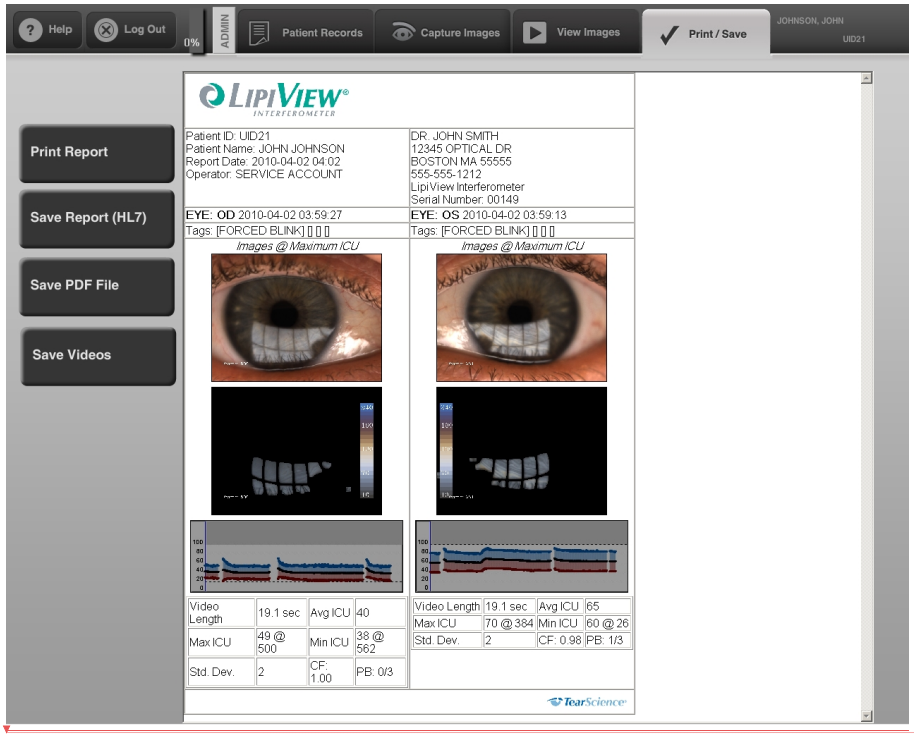

Figure 10-17: Print/Save Screen - Sample Report

Print Report - To print the report:

1. Press *Print Report* on the left menu.
2. Follow the standard windows printing prompts for sending the report to the printer attached to the LipiView® Interferometer.

NOTE: The printer must be attached by the Administrator prior to use. Refer to Section 16.8, *Admin System Options* for a description on printer setup.

Save Report to HL7 - To save the printed report to an HL7 compatible system:

1. Press *Save Report (HL7)* on the left menu.
2. A system message called HL7 Basic Socket Transfer is displayed.
   A. Press *Send HL7* to store the data in the HL7 database.
   B. Press *EXIT* to return to Figure 10-17 without saving.

   NOTE: The HL7 database must be configured by the Administrator prior to use. If the system message does not appear, contact the Administrator. Refer to Section 16.7.2, *HL7* for instructions on how to set up the HL7 parameters.

Save Report to External USB Drive as a PDF - To save the printed report as a PDF file:

1. Connect an external USB drive or USB key to the LipiView.
2. Press *Save PDF* on the left menu.
3. When the system reports that the PDF has been saved successfully, press *Close*.

Save Video to External USB Drive - To save the video to an external drive:

1. Connect an external USB drive or USB key to the LipiView.
2. Press *Save Videos* on the left menu.
3. Choose the videos you want to save for each side. You may choose one or more of the following for each side: full eye, isolated, or blink, as shown in Figure 10-18 below.
4. You will see a progress window, as shown in Figure 10-19. When the system reports that the video has been saved successfully, press *Close*.

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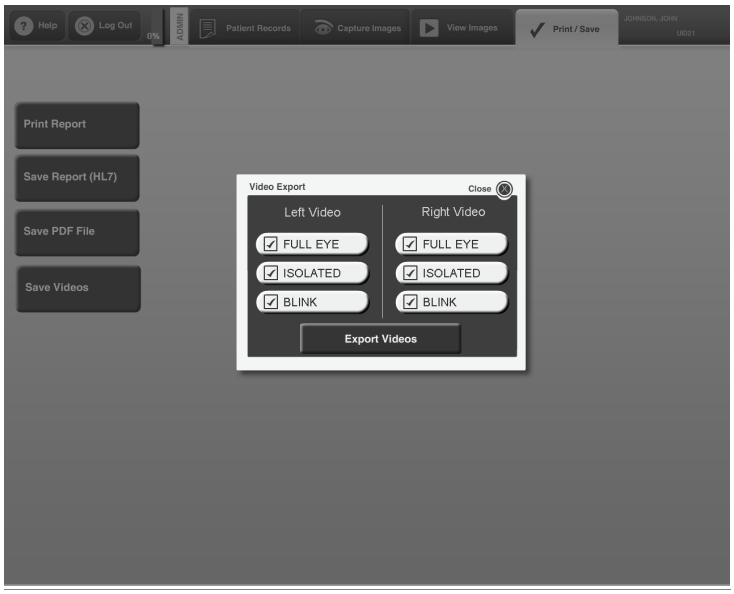

Figure 10-18: Make Selections for Video Export

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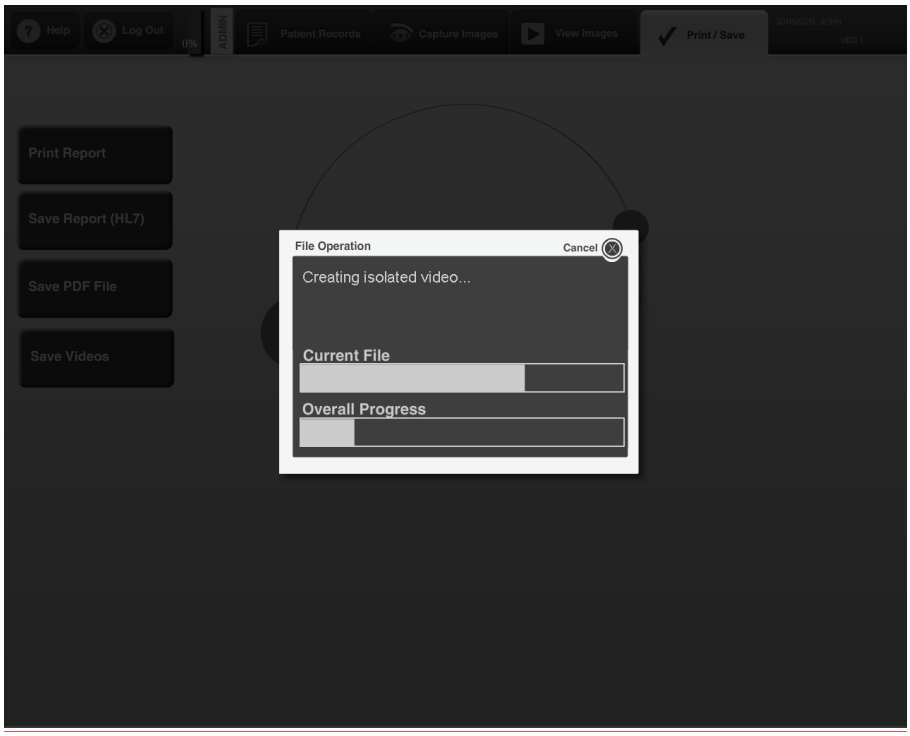

Figure 10-19: Progress Window for Video Export

10.6 Online Help

Online help is available for each of the screens in the system. Press the *Help* on the left side of the menu bar at the top of the screen to display information pertinent to that screen. Press *Help* again to close the file.

10.7 Log Out

After the user has logged into the system the Log Out tab is visible on the menu bar of each screen. Pressing *Log Out* returns the user to the Login screen described in Section 10.1.3, *User Login*.

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11 Cleaning

Table 11-1 identifies the components of the LipiView® Interferometer that requirement cleaning. For each component, the frequency and method of cleaning is provided.

Table 11-1: LipiView® Interferometer Cleaning Information

Component	Frequency	Method
Chin rest and forehead rest surfaces	Immediately prior to use and prior to storage.	Alcohol.
Camera lens	Monthly.	Wipe with a lint-free photographic quality lens cloth.
Touchscreen Display Monitor	When soiled or as needed.	• Power off the device. • Apply window or glass cleaner to a cloth rag and wipe the screen. • Do not apply cleaner directly to the screen. • Do not clean the monitor with alcohol, paint thinner, benzene or compressed air.
LipiView® Interferometer exterior	When soiled or as needed.	• Wipe down the exterior of the LipiView® Interferometer with a mild soapy cloth. • Do not use bleach, chlorine or acetone-based solutions to clean any part of the chin rest support or the system enclosure.
Optional external monitor	Follow manufacturer's cleaning instructions.	Follow manufacturer's cleaning instructions.

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12 Storage and Transport of the LipiView® Interferometer

Before storing the LipiView® Interferometer, ensure that the power switch is off, and that the chin and forehead rest surfaces have been cleaned according to the instructions in Section 11, *Cleaning*. The LipiView® Interferometer should be stored in a way that prevents contamination and damage between uses.

To transport the LipiView® Interferometer, ensure power cord is unplugged and secured off the ground. Grip on metal portion of the device, in two locations: 1) base of the chin rest, 2) monitor arm behind the screen. Carefully lift and transport in an upright position.

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13 Maintenance and Servicing

Expected life of the LipiView® Ocular Surface Interferometer is 5 years.

> **Note**: No user serviceable components are inside the unit.
> Maintenance is not required. The LipiView® Ocular Surface Interferometer performs a calibration process upon powering on. See Section 10.1.1

For Field Service contact TearScience in North America at +1 919 459 4891 or by email at customerservice@tearscience.com.

14 Disposal

The LipiView® Interferometer consists of an ABS plastic enclosure, aluminum chassis, circuit boards, and electrical components. In the unlikely event that the controller is damaged and cannot be repaired, never dispose of the device. The LipiView® Interferometer should be returned to TearScience. Refer to the contact information on the first page of this manual for the appropriate return address.

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15 Troubleshooting

15.1 Unexpected Events

Table 15-1 lists actions to take if an unexpected event occurs.

Table 15-1: Troubleshooting Unexpected Events

Event	Action to Take
Device will not power up (after pressing the power switch, the screen remains dark.)	(1) Ensure the system is connected to a power outlet and connection into the device is secure, then press the power switch again. (2) If Step 1 is not successful, carefully lift the system to expose the underside of the base and determine if a red Reset button is located at the back of the unit, near the power switch. If so, press the Reset button. If no Reset button is found, contact Customer Service for assistance. If the problem persists contact TearScience.
Problem reported during Power On Self Test (POST).	Power cycle the device. If the problem persists contact TearScience.
Touch Screen does not respond.	Power cycle the device. If the problem persists contact TearScience.
Illuminator does not light during image capture.	Power cycle the device. If the problem persists contact TearScience.
Camera stops working.	Power cycle the device. If the problem persists contact TearScience
Disk Space Indicator shows internal disk drive is full.	Contact the Administrator to archive data (refer to Section 15, *Administrator Instructions for Use*). If the problem persists contact TearScience.
The system works except the Capture Image tab will not respond.	An error was detected during power on self-test, which affects image acquisition. Power cycle the device. If the error persists contact TearScience.
Device will not process images after acquisition.	The internal hard drive is full. Contact the Administrator to archive data (refer to Section 16, *Administrator Instructions for Use*). If the problem persists contact TearScience.
Device no longer allows image acquisition.	A power on self-test problem has been found. Contact TearScience if problem persists.

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Event	Action to Take
The message *NO VALID ANALYSIS DATA FOR VIDEO* is displayed instead of the numerical and graphical analysis when the *Analyze Images* button is pressed on the View Images screen.	The patient's head may not have been pushed forward, the patient's forehead may not have been firmly pressed against the forehead rest, or the tear film image may have been out of focus. Collect another video of the patient after ensuring that the patient's head is positioned properly and that the eye is clearly focused.
Network is not connected.	Contact your Administrator (refer to Section 16, *Administrator Instructions for Use*). If the problem persists call TearScience.
External monitor does not work.	Ensure the monitor is powered on. Ensure connections to the DVI or HDMI are made, and proper input is selected. Ensure the isolation receiver cable has power applied. Refer to Section 19, *Appendix B: External Monitor Hookup* for information on proper monitor connection.
Administrator forgets password after resetting it	Contact TearScience.
When accessing options on the System Options Administration screen, a message is displayed stating 'Too much time has elapsed since system startup to access this function'.	Selected options on the System Options Administration screen cannot be accessed after more than 10 minutes has elapsed since the system was started. Power cycle the machine and attempt to access the option again.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the warning level.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the critical level.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

15.2 System Messages

Table 15-2 lists system messages and provides a description with actions to consider. **NOTE:** The four messages: Practice information saved, Display information saved, Saved map network drive parameters and mapping drive, and Network information saved are informative only and do not indicate a problem.

Table 15-2: System Messages

System Messages	Description / Action to Take

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System Messages	Description / Action to Take
Invalid operator name and/or password.	The login failed because the username and/or password being used to log into the device are not recognized. Correct and reenter, or confirm with the Administrator that this username and password have been set up and that the username is enabled.
Capture disabled. Contact Tear Science for support.	Videos cannot be captured because the power on self-test detected errors with the motors or camera during startup, or the Disk Space Indicator has reached the limit set by the Administrator. Existing videos can be viewed. If the disk is full, contact the Administrator to archive data. For motor or camera errors, contact TearScience.
Patient ID already exists.	The patient record cannot be added because it contains a Patient ID that already exists in the database. If a Patient ID is being included on a new patient record, it must be unique. Correct and reenter.
Patient with same first name, last name, middle initial and birth date already exists. Select the existing user or enter a unique patient ID.	The patient record cannot be added because a patient record with the same Last Name, First Name, Middle Initial and Date of Birth already exists in the database. Either select the existing patient, or to add a new patient with the same name, enter a unique Patient ID.
Either patient ID or last name, first name and birth date are required.	The patient record cannot be added or updated because required information is missing. At a minimum, a patient record must contain a Patient ID or it must contain a Last Name, First name and Date of Birth.
Videos captured for patient. Cannot edit patient information.	The patient record cannot be edited because a video(s) exist for this patient. Once a video has been captured and saved for a patient, that patient record can no longer be updated.
Enter date in MM/DD/YYYY format. Invalid date:	The patient record cannot be added because the format of the date is incorrect. One or more of the date fields is missing or does not contain a number. Confirm that the month field is a number between 0-12, the day field is a number between 0-31 and the year is a 4-digit number.
Video capture setup failed.	The video cannot be captured due to a device failure. If this occurs, exit from the Captures Images screen by logging out or pressing *Save All/Continue*. Try again, and if the error is not corrected, contact TearScience.

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System Messages	Description / Action to Take
Unable to load video file X.	The video file named X could not be found on the disk when attempting to show it on the View Images screen. Try again, and if the error is not corrected, contact TearScience.
The following errors occurred: Missing username; Missing password; Missing full name;	The Operator cannot be added because one or more of the required fields (as noted) are empty. The Username, Password and Full Name are required to add an Operator.
Username already exists	The Operator cannot be added because the Username entered already exists in the database. Correct the Username and try again, or select the Username and edit the Password and Full Name fields.
Practice information saved.	This message is displayed to the Administrator to confirm that information on the System Setup screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Display information saved.	This message is displayed to the Administrator to confirm that information on the Display Options screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Disconnect failure: X	The Map Drive process cannot be completed because the Drive Letter named "X" cannot be disconnected. Try again, and if the error is not corrected consult with the Network Administrator.
Saved map network drive parameters and mapping drive.	This message is displayed to the Administrator to confirm that information on the Map Drive screen or has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Network information saved.	This message is displayed to the Administrator to confirm that the cloning and HL7 server information on the Networking screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.

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System Messages	Description / Action to Take
Cannot write to clone folder: X:\OSICLONE	The Network folder named OSICLONE on the Drive Letter named X is not accessible for writing. Confirm that the Drive Letter is listed as a mapped drive on the Networking Screen. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning operation failed to start.	There was a failure with the cloning process most likely caused by an internal Windows error, and no videos were copied. Confirm that the Drive Letter entered for Disk Cloning on the Networking Screen is valid. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning canceled by user.	This message is displayed to the Administrator to confirm that the *CANCEL* button has been pressed and that the Cloning process has been stopped.
Cloning failed. Restart or contact Tear Science for assistance.	There was a failure with the Cloning process. Press *CLONE SYSTEM* again, to continue the Cloning process where it left off. If the problem continues, contact TearScience.
The used space of the system disk has surpassed the warning level. Please go to the Networking/Backup Administrator page.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
The used space of the system disk has surpassed the critical level. Please go the Networking/Backup Administrator page.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

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16 Administrator Instructions for Use

16.1 First Time Setup

The LipiView® Interferometer has been set up with a default Operator Username and Password that has administrator privileges. When the system is first powered on, the Administrator should log in using LIPIVIEW for the Username and LIPIVIEW for the Password (the onscreen keyboard only supports upper case characters).

After successful log in, it is recommended but not required that the Administrator reset the password as follows:

1. Power on the system.
2. When the Login screen in Figure 10-4 is displayed:
   A. Enter LIPIVIEW for the Username.
      NOTE: The onscreen keyboard only supports upper case characters.
   B. Enter LIPIVIEW for the Password.
   C. Touch *Submit*. The Patient Records screen in Figure 10-5 should be displayed.
3. Touch the *Admin* tab at the top of the screen. The Admin Main Menu in Figure 15-1 should be displayed.
4. Press *Operator Setup* on the left menu. The Admin Operator Setup Screen in Figure 16-3 should be displayed.
5. Follow instructions in Section 16.4, *Admin Operator Setup* to modify the password and/or add additional operator usernames.

The Administrator should review Section 16 of this manual to determine any other functionality that requires set up before the LipiView® Interferometer is used for observation of tear film. At a minimum:

- Set the system date and time (refer to Section 16.8, *Admin System Options*)
- Determine at what point videos will be archived (refer to Section 16.7.1, *Disk Cloning*)

Prior to printing, a printer must either be connected through one of the USB ports on the bottom of the Touchscreen Display, or through a wireless network. Printer setup is discussed in Section 16.8, *Admin System Options*.

Prior to cloning or archiving, an external storage location must be connected. An external hard drive can be connected through one of the USB ports on the bottom of the Touchscreen Display, or a network drive can be mapped on the wireless network. Refer to Section 16.6, *Admin Map Drive*.

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16.2 Admin Main Menu

When an operator's Username is set up with *Administrator Access* (refer to Section 16.3, Admin System Setup), the *Admin* tab is visible between the Disk Space Indicator and the Patient Records tab on the menu bar of each screen.

When the *Admin* tab is pressed, the Administrator Main Menu screen in Figure 16-1 is displayed. This screen prompts the Administrator to select from one of the menu options on the left side or the top. Each Administrator screen contains the same menu. Once a button is pressed, it turns white indicating the active menu, and buttons for inactive functions are grayed out. Buttons may be selected from the Main Menu in any order, but once a menu option is active, the user must exit from that screen and return to the Main Menu before choosing another option.

The *Help* tab may be selected anytime it is not grayed out. To return to normal usage, press *Patient Records* at the top of the screen.

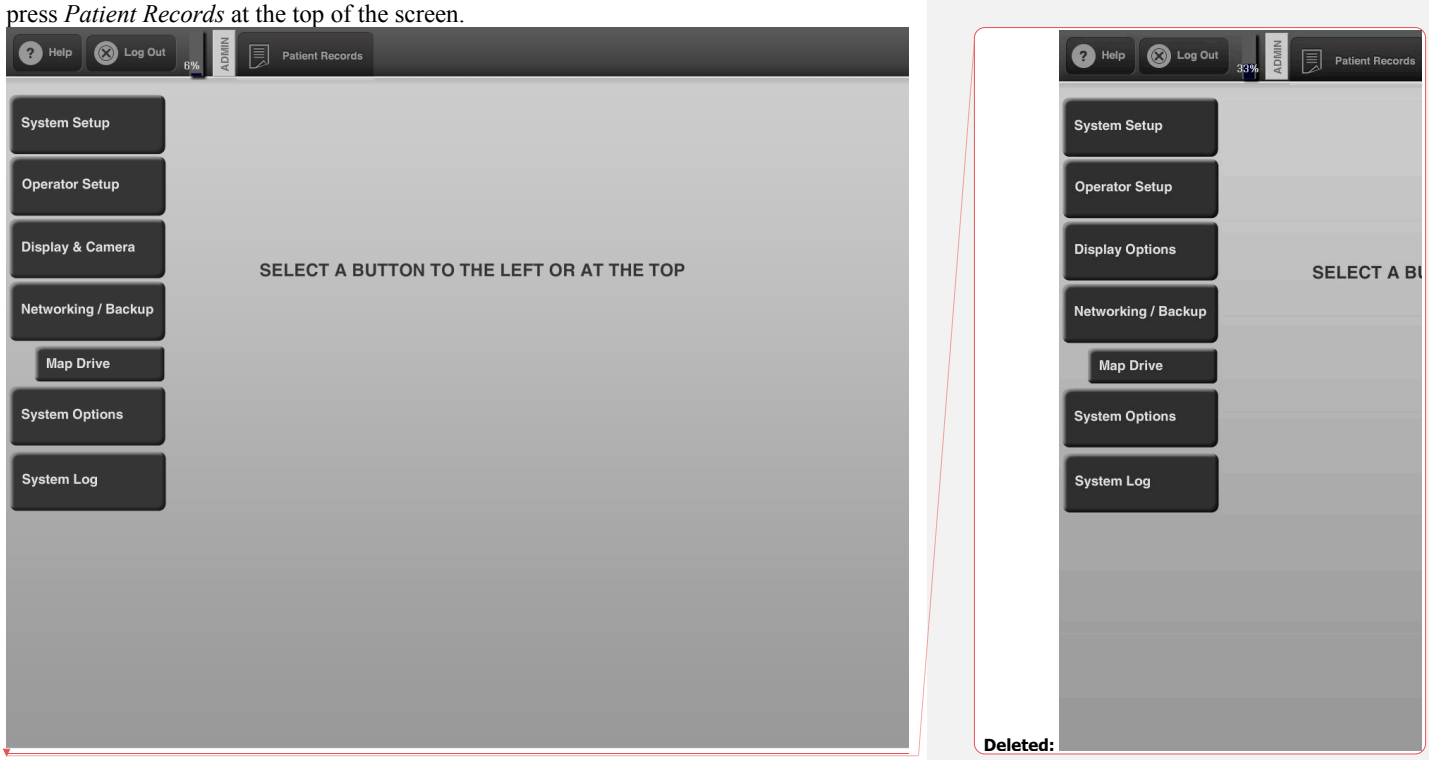

Figure 16-1: Admin – Main Menu Screen

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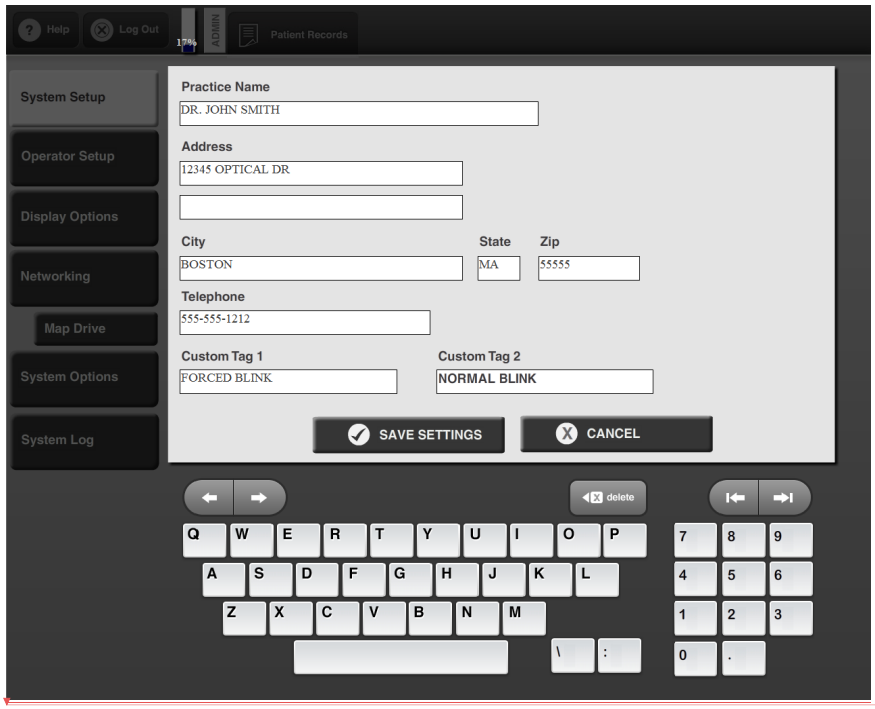
16.3 Admin System Setup

The System Setup screen in Figure 16-2 is displayed when the *System Setup* button is selected from the Admin menu.



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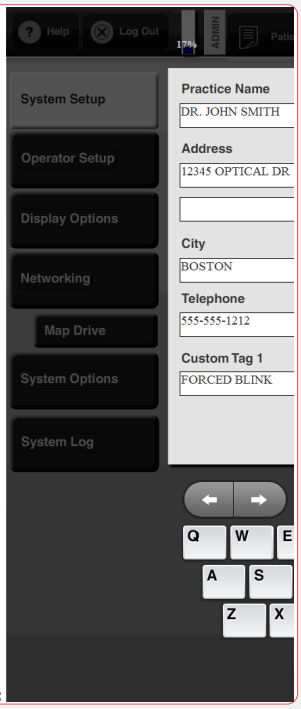

Figure 16-2: Admin - System Setup Screen

The System Setup screen contains the fields listed in step 1 for the Administrator to complete. All fields are optional. The Practice information is used for the reports as discussed in Section 10.5, *Video Print and Save*. Custom Tags 1 and 2 allow up to two tags to be pre-set with commonly used information that may be applicable to multiple videos (e.g., normal blink, forced blink). These custom, pre-set tags are displayed on the Capture Images Screens (Figure 10-9, 10-10, 10-11 and 10-12) and discussed in Section 10.3, *Video Image Capture and Recording*. If selected, information from these tags is saved with the video data, displayed on all Video Review and Analysis screens (Section 10.4), and included on the report.

1. Use the keyboard to update one or more of the fields below.
   - Practice Name
   - Address line 1
   - Address line 2

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- City
- State
- Zip
- Telephone
- Custom Tag 1
- Custom Tag 2

2. To exit this screen and return to the Main Menu in Figure 16-1, choose from one of the following and then continue with Section 16.2, *Admin Main Menu*:
   A. To immediately update the information before returning to the Admin Main Menu, press *SAVE SETTINGS*.
   B. To return to the Main Menu without saving the edits, press *CANCEL*.

16.4 Admin Operator Setup

For first time use, make sure to review Section 16.1, *First Time Setup* before making any changes to usernames and passwords.

Do not modify the ADMIN Username. This is for TearScience personnel, in the event service is required.

The Operator Setup screen in Figure 16-3 is the main screen displayed when the *Operator Setup* button is selected from the Admin menu. This screen is used to display the list of operators who have been entered into the database. The list of operators is displayed in the order of entry. Once the table contains more than six names, the step keys on the right are used to scroll backwards (upper key) or forwards (lower key) through the list.

The Operator Setup screen is also used to add new operators. To perform this task, continue with Section 16.4.1, *Add an Operator*.

Operator information, which includes granting or preventing access to the device, can be modified using a secondary operator setup screen in Figure 16-4. To make any changes to an operator's record, follow the instructions in Section 16.4.2, *Edit Operator Information*. Information about an operator may be updated but an operator's record can never be removed.

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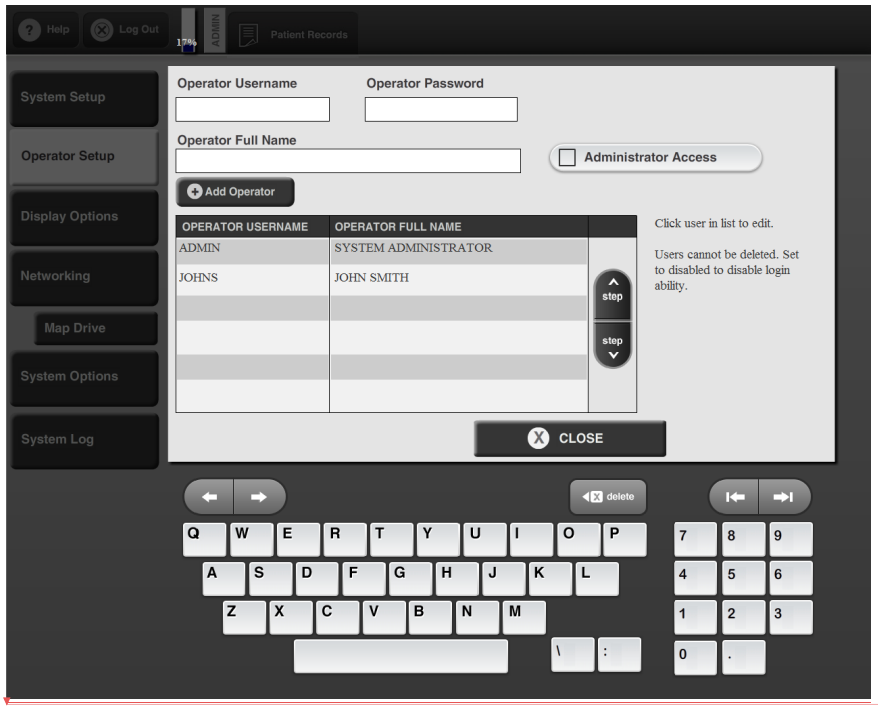

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Figure 16-3: Admin - Operator Setup Screen

16.4.1 Add an Operator

Add an operator to the system as follows:

1. Enter a Username.
2. Enter a Password. There are no requirements other than the limitation of the onscreen keyboard characters.
3. Enter the full name.
4. If the user will be allowed to access the Admin tab and the administrator screens, touch the box for *Administrator Access*. A checkmark indicates selection. If this box is not selected, the *Admin* tab will not be visible when this Username is logged in.
5. Press *Add Operator* to enter the new information into the database. When a new operator is added, the status for this operator's Username defaults to "User Enabled". An enabled Username means that this Username has permission to access the device through the Login screen in Figure 10-4. A new Username may log in as soon as the current Username logs out.

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NOTE: All fields are required. If *Add Operator* is pressed when any field is empty or incorrect, or if the record is a duplicate of an existing operator, a system message will be returned.

6. Press *CLOSE* when finished and the Admin Main Menu in Figure 16-1 will be displayed.

16.4.2 Edit Operator Information

1. To edit information associated with an Operator's Username, select the record by pressing anywhere on the row in the table. Use the step keys on the right of the table to scroll backwards or forwards through the list if more than six names have been entered.
2. The selected name will be highlighted and then overlaid onto the top of the screen, as shown in Figure 16-4. If the Username is currently allowed access to the device, the *User Enabled* box is checked. If the Username was added as an Administrator, the *Administrator Access* box is checked.

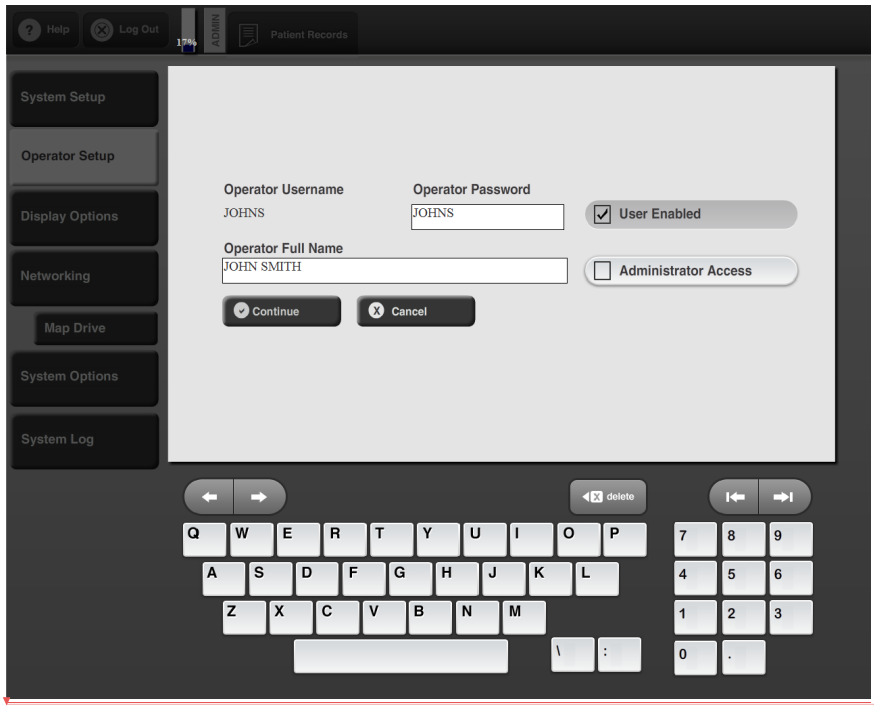

Figure 16-4: Admin - Modify Operator Information

3. Update the operator's password or full name if needed. Select or deselect the boxes for *User Enabled* and *Administrator Access*.

NOTE: Once an operator has been added, the Username cannot be deleted.

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4. To exit this screen and return to the Operator Setup screen in Figure 16-3, choose one of the following:
   A. Press *Continue* to return with the record updated.
   B. Press *Cancel* to return without saving edits.
5. From the Operator Setup screen, press *CLOSE* to return to the Admin Main Menu, continue with Section 16.4.1, *Add an Operator*, or repeat Section 16.4.2 to edit an operator.

16.5 Admin Display Options

When *Display & Camera* is selected from the Admin Main Menu, the screen in Figure 16-5 is used to set the saturation, contrast and brightness levels for the video display, and the capture time for the video camera.

Each display level has a range of 0 – 100. The camera capture time setting has a minimum of 5 seconds and a maximum of 19 seconds. Settings here do not affect the GUI.

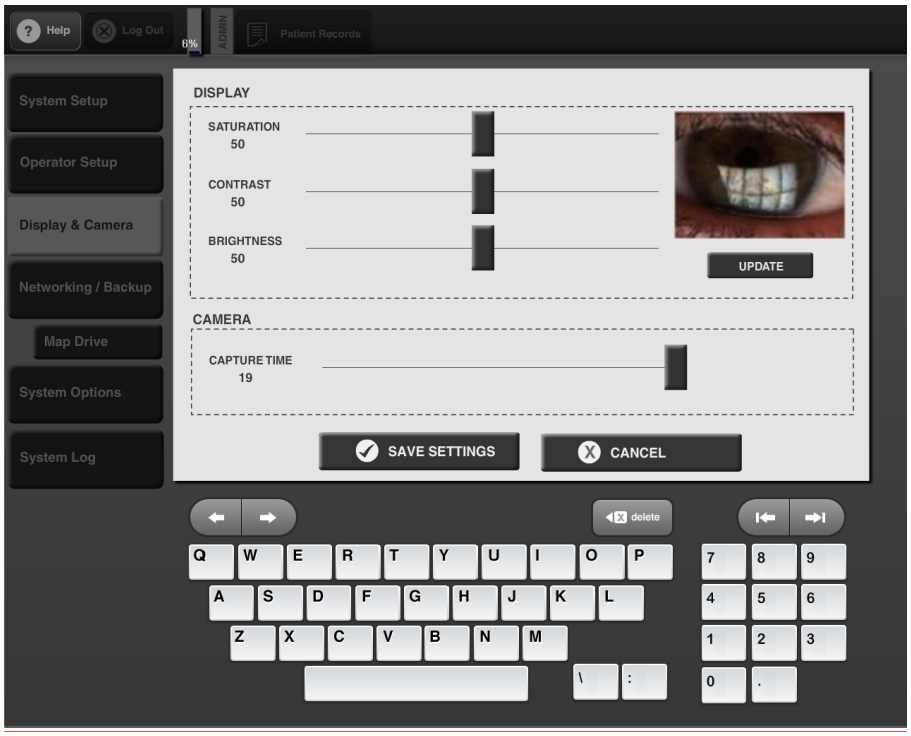

Figure 16-5: Admin - Display Options Screen

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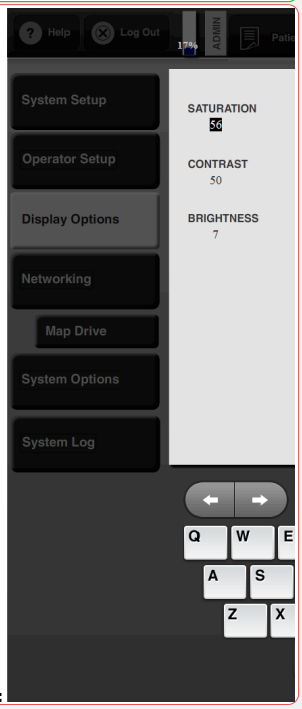

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1. To modify the setting for Saturation level follow steps A-C, or skip to step 2:
   A. Move the locator bar to the left to lower the value or to the right to increase it. The new setting number will be displayed under the name on the left.

      NOTE: Touching a location on the slider bar will not change the setting; the locator bar must be moved.

   B. Preview the display with the new value by pressing *Update*. This allows the user to visualize the effect on a representative tear film image.

      NOTE: The Contrast and Brightness levels may also be adjusted before pressing *Update.*

   C. Repeat steps A and B as needed.
2. To modify the setting for Contrast level, repeat step 1 using the Contrast slider; otherwise, skip to step 3
3. To modify the setting for Brightness level, repeat step 1 using the Brightness slider; otherwise, continue with step 4.
4. To modify the video camera capture time, move the locator bar to the left to lower the value or to the right to increase it.
5. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:
   A. To permanently retain the saturation, contrast and brightness values on the screen, press *SAVE SETTINGS*. All future video images will use these values when displaying. A system message will indicate the display information has been saved. Press *Close.*
   B. To exit without saving any changes, press *CANCEL*.

16.6 Admin Map Drive

When *Map Drive* is selected from the Admin Main Menu, the screen in Figure 16-6 is used to setup one or more network drives on the LipiView® Interferometer. A mapped drive is a location on the network, and the location is designated by the Drive Letter. Mapped drives are typically used for cloning and archiving, which is discussed in Section 16.7, *Admin Networking*.

Depending on how the network is set up, the mapped drive on the network may require that a valid username and password be entered in order to gain access. If this is the case, the username and password associated with the drive being mapped should be entered on this screen.

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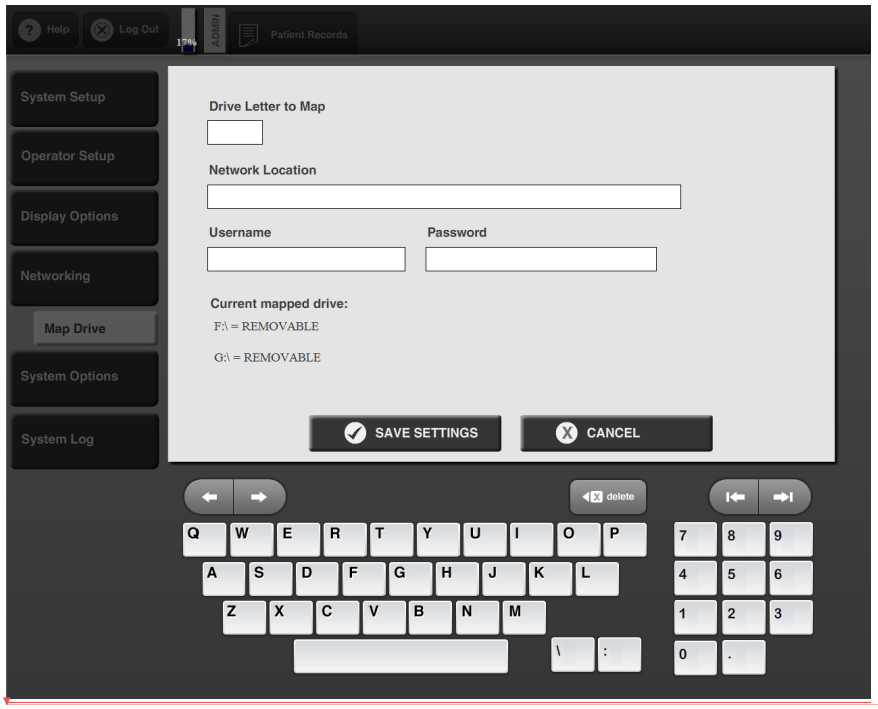

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Figure 16-6: Admin - Map Drive Screen

Enter the information on this screen as follows, consulting with the Network Administrator to obtain this information if necessary:

1. In the *Drive Letter to Map* field, enter the drive letter of the network drive to which the LipiView® Interferometer will be mapped.
2. For *Network Location* – enter the server location (e.g., \\SERVER\\Location) that will be mapped to the drive letter.
3. If required to access the network location entered in step 2, enter the *Username* and *Password* interacting with your network.
4. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*.
   A. To permanently retain the drive mapping information shown on the screen, press *SAVE SETTINGS.* A system message will indicate the mapping information has been saved. Press *Close*.
   B. To exit without saving any changes, press *CANCEL*.
5. To determine whether the connection was successful, press *Map Drive* to return to this screen.
   A. If the connection was successful, the heading *Current mapped drive:* will be followed by the name and location of the mapped drive in the format

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"*:\\network_location", where '*' is the drive letter and 'network_location' is the network path.

NOTE: When storage devices such as an external hard drive or a USB flash drive are connected to the USB ports, these drives are also listed under *Current mapped drive*. In Figure 16-6, "F" and "G" are the drive letters, and "REMOVABLE" indicates the location is the USB port (rather than a network drive). When the USB port is the location only one backslash (\) is used.

B. If no network drives have been mapped, the words "No available drives found" will follow the heading.

6. If more than one drive will be mapped, repeat these instructions as many times as needed, or press *CANCEL* to return to the Admin Main Menu.

   NOTE: Once a network drive has been mapped it cannot be unmapped; however, the drive letter can be mapped to a new path.

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16.7 Admin Networking/Backup

When *Networking/Backup* is selected from the Admin Main Menu, the screen in Figure 16-7 is displayed, allowing the Administrator to perform two functions: Disk Cloning, and setting up access to an HL7 server.

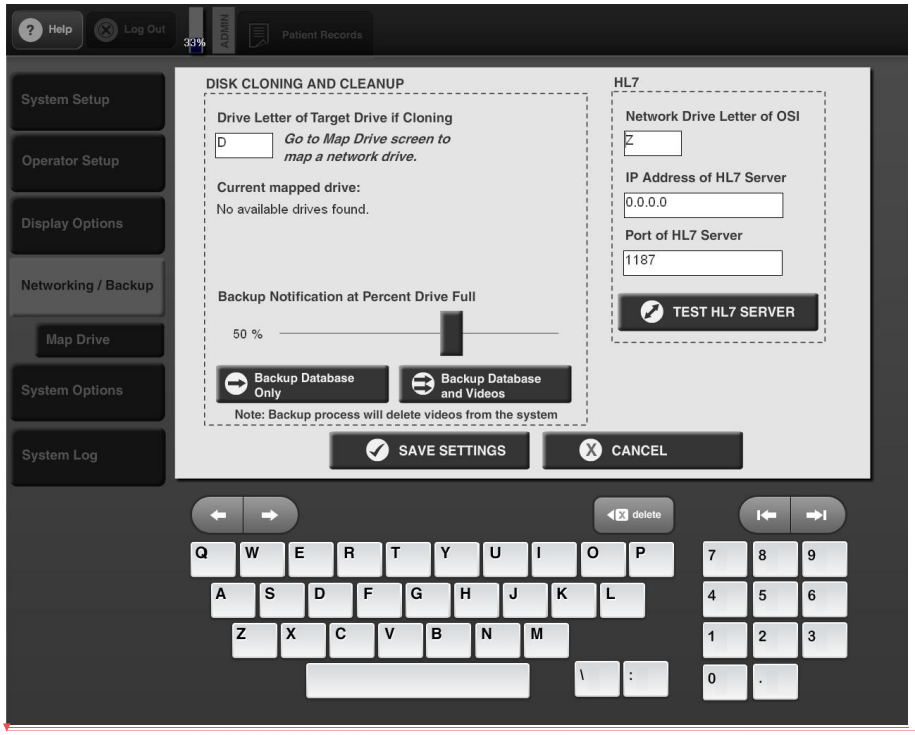

Figure 16-7: Admin – Networking/Backup Screen

16.7.1 Disk Cloning

As video information is stored on the LipiView® Interferometer, the disk drive becomes full. When the disk usage level reaches the level specified by the *Backup Notification at Percent Drive Full* slider bar, the LipiView® Interferometer issues a system message to notify the user to perform a backup. However, the device will continue to allow the user to capture additional videos. The user may either backup the database or backup the database and the videos to an external drive or network. **The backup process will permanently delete the videos from the LipiView® Interferometer.** When the disk usage level reaches 95%, the device notifies the user that a backup is required and will not allow the user to capture additional videos until the backup process is performed.

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To free used disk space, one of the two following operations must be performed:

1) **Backup Database Only** – This option will copy the system database to the location specified in the Target Drive field, and then permanently delete all videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

2) **Backup Database and Videos** – This option will copy the system database and all video files to the location specified in the Target Drive field, and then permanently delete all the videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

NOTE: The Backup Database and Video process can take up to several hours to copy the videos to the external drive. Before beginning the copy process, please ensure you have adequate time to complete the process.

16.7.2 HL7

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

HL7 is a communications standard used so that a piece of medical equipment (such as the LipiView® Interferometer) can talk with an Electronic Medical Records (EMR) server. HL7 is the common language used so that information can be exchanged between EMR systems and medical devices.

After review of a video, an HL7 message with the patient information can be sent from the LipiView® Interferometer to the specified EMR server (identified by an IP address and port). The conversation is one-way from the interferometer to the EMR server. The message is sent out but the interferometer does not know if the message was received by the EMR server. Refer to Section 10.5, *Video Print and Save* for instructions on how to send the report.

The LipiView® Interferometer can communicate with any EMR system that understands HL7 V2.5 messages. The HL7 group of controls allows the Administrator to configure the HL7 export destination. To set up an HL7 export connection:

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1. Once the LipiView® Interferometer is mapped as a network drive on the network, enter its drive letter in the *Network Drive Letter of OSI* field. The network drive letter is sent as part of the HL7 message and allows the server to access report files that reside on the LipiView® Interferometer.
2. Enter the IP address of the HL7 server. If more than one HL7 server is available, select the desired server.
3. Enter the port address on which the HL7 server is listening for HL7 messages.
4. The connection to the HL7 server can be tested by pressing *Test HL7 Server*. When pressed, a standard IP ping will be performed on the HL7 server and the results will be reported. This feature should only be used by TearScience service personnel and is beyond the scope of this manual.
5. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:
   A. To save all data entered on this screen (for both Disk Cloning and HL7), press *SAVE SETTINGS*. A system message will indicate the mapping information has been saved. Press *Close*.
   B. To exit without saving any changes to the screen, press *CANCEL*.

16.8 Admin System Options

When *System Options* is selected from the Admin Main Menu, the screen shown in Figure 16-8 provides the Administrator with information about the system, including software versions of the shell, application and GUI, and the serial number of the system.

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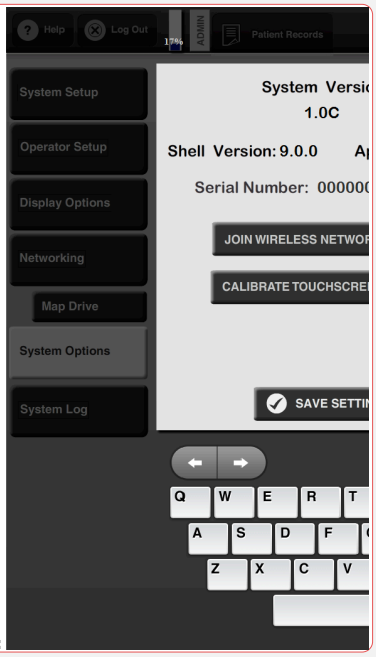

Figure 16-8: Admin - System Options Screen

There are also five functions available on this screen:

- **Join Wireless Network** – Pressing this button displays a standard Windows *Wireless Network Connection* dialog. Use the browse dialog to connect the LipiView® Interferometer to a wireless network. Contact the Network Administrator for assistance in joining a wireless network if needed.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

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- **Calibrate Touchscreen** – Pressing this button launches a calibration program for the touchscreen. This calibration can be performed when it is observed that the onscreen cursor is not matching correctly to the finger-touch locations. The program instructs the user to touch various targets on the screen, and then to press *OK* to accept the calibration. The user must press *Save Changes* to cause the calibration to be written to the disk. The calibration wizard will ask the user if the cursor is following his finger but the curser will not be visible. This is normal and should be ignored. **This option should not be used unless instructed to do so by a TearScience representative. If the touchscreen is not calibrated correctly, the touchscreen operation may be affected.**
- **Recreate Thumbnails** – Pressing this button restores the system in the event of a hard drive failure. The restore process reads all the video files present in the database, and extracts the thumbnail image that appears in the Patient History list for that video. **This option should not be used unless instructed to do so by a TearScience representative.**
- **Setup Printer** – Pressing this button will display the standard Windows *Setup Printer and Faxes* dialog. Use this dialog to set up a printer on the LipiView® Interferometer. The printer can be attached to the LipiView® Interferometer via a USB port, or it may be a network printer accessed via a wireless network. Contact the network Administrator for assistance in setting up a printer if needed.

  NOTE: If installing a USB printer, follow the manufacturer's instructions and to press *SAVE SETTINGS & REBOOT* when finished.
- **Set System Time** – Pressing this button brings up the standards Windows *Setup Date and Time Properties* dialog, and allows the Administrator to input the current date, time, and time zone into the LipiView® Interferometer. The date and time should be set during system first time setup discussed in Section 16.1.

  NOTE: It is not necessary to use the *Save Settings and Reboot* function after setting the system time.

Access to the System Option screen functions is disabled if more than 10 minutes has elapsed since the system was started.

For any of the setting changes to become active, the system must be rebooted. Press *Save Settings and Reboot*. A system message confirming the reboot is displayed. Press *Continue* to begin the reboot, or press *Cancel* to return to the System Options screen.

Press any tab on the left menu or press *Patient Records* to exit this screen without changes becoming activated.

16.9 Admin System Log

When *System Log* is selected from the Admin Main Menu, the screen shown in Figure 16-9 allows the Administrator to review system codes that have occurred and the results of Power On Self Tests. Items are listed in this table for the current day only; however,

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all system codes in this list are stored in a database and the errors are never cleared. Use the step keys to the right of the table to scroll forwards and backwards through the table.

This page is intended to be accessed by TearScience representatives, or as directed by a TearScience technician.

After reviewing the log, press *CLOSE* to return to the Admin Main Menu.

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Figure 16-9: Admin - System Log Screen

17 Warranty

TearScience, Inc. warrants that each LipiView® Interferometer 1) is free from defects in materials and workmanship and 2) conforms to TearScience Inc.'s official specifications. The warranty period for each LipiView® Interferometer is one year commencing on the date of purchase. *Any tampering or modifications to the device by the user will void the warranty.*

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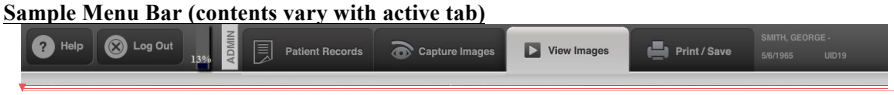
18 Appendix A: Quick Start Reference Guide

Sample Menu Bar (contents vary with active tab)



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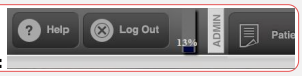
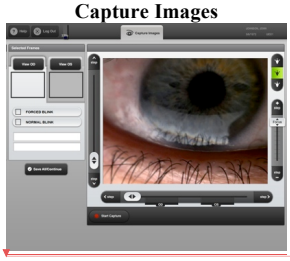


The light gray color shows View Images is active. Tabs may have multiple screens.
Help – Press to display information for the active screen. Press again to close.
Log Out – Press to exit the user from the device. The Login screen is displayed.
Disk Space Indicator – Shows the disk space that has been used for video storage.
Admin – Visible if Username has Administrator privileges. Press for Admin Main Menu.
Patient Records – Press to display patient table. Search for, add or edit a patient. Select a patient record and the next action to take.
Capture Images – Press to record video, preview video, rerecord video, and save video.
View Images – Press to review previous videos. Enter after capturing new images to view new video and request a computer analysis.
Print / Save – Press to print the video analysis, save it as a PDF file, or save it to an HL7 database.
Patient information – Shows information from a patient record after it is selected.

Startup

Power on the LipiView® Interferometer by pressing the rocker switch. System may take several minutes to boot up.
At Login Screen, enter a Username and Password. Press *Submit*. Refer to **Patient Records**.

Patient Records 	All records must have at minimum 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. Locate record by typing name or using step keys. Must select a record to Capture Images or View Images. If not found, enter data; press *Add New Patient*. If found, choose record; Select a Patient Action. • Edit Patient – Update record if no saved video images. • Capture Images - Refer to **Capture Images**. • View Past Images - Select video from **Patient History** and then Refer to **Patient History.** • Close – Return to Patient Records. Get another record.
Capture Images 	Press *View OD* (right) or *View OS* (left) for eye to capture. Select pre-set tags; enter key-in tags. Clean chinrest support. Caution on hand/finger placement. Question patient on listed precautions; note conditions. Position patient: chin fully forward, forehead firmly against forehead rest. Look at orange fixation light. Adjust so lateral canthus aligns with marks on forehead rest using manual adjustment (fluted roller) located on chinrest support column. Use controls or touchscreen to adjust camera height and focus. Eye should be in center and clear. Press *Start Capture*. Approximately 20 seconds of video can be recorded. Have patient blink as needed. Press *End Capture to stop recording*. Refer to **Preview Video**.
Preview Video (just captured) Before saving, decide whether to rerecord. Capture images for second eye.	Preview image using controls and tear-film/full-eye toggle key. If desired, refer to **Rerecord Video**. Update pre-set or key-in tag information. Press *View OS* / *View OD* for 2nd eye. Refer to **Capture Images**. Press *Save All/Continue* to save video, tags. Refer to **View Images**.

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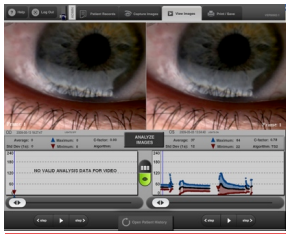
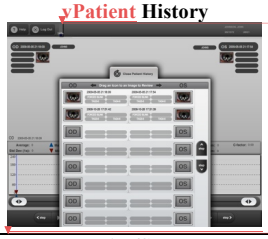
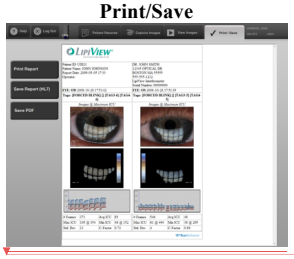
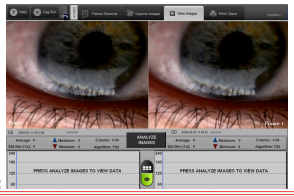
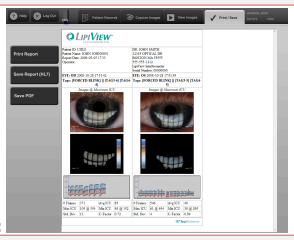
Rerecord Video Screen has same functionality as Capture Images except for system message confirming Rerecord.	Toggle between Preview and Rerecord screens by pressing *Return to recorded image* and *Return to live image*. To rerecord: Press View OS or View OD. Adjust patient and camera height, and focus. Press *Start Capture*. Confirm rerecord. Press *End Capture*. Update pre-set or key-in tag information. Press *Save All/Continue* to save video, tags. Refer to **View Images**.
View Images  	Entered after saving captured images. View and analyze. Or Entered from **Patient History** after choosing *View Past Images* from *Select a Patient Action* (Patient Records). View videos using play and step controls. Press *Analyze Images* if needed to view numerical data. • Average - Average ICU of all frame averages • Std Dev - Standard deviation of frame averages • Maximum – Max. recorded ICU for a given frame • Minimum – Min. recorded ICU for a given frame • C-Factor - Tear film Conformance factor for entire video After images are analyzed, review graph: • Toggle – Switch between full-eye and isolated tear-film. • Each point on graph is ICU value for frame. • Blue line and region is the upper standard deviation of the ICU score data. • Red line and region is the lower standard deviation of the ICU score data. • Blue triangle marker denotes the point on the graph that contains the maximum ICU score. • Red marker triangle marker denotes the point on the graph that contains the minimum ICU score Refer to **Print/Save**. Press ***Open Patient History*** to view other files.
Patient History 	Select videos from the list in Patient History to view. If table is empty, no video data saved for patient. Drag and drop videos into two frames at top. • If a video was archived, follow messages to restore. • When videos are selected, press Close Patient History. • Refer to **View Images**. Data may or may not need analysis.
Print/Save 	To print report (USB/Network printer must be set up): • Press *Print Report* on the left menu. • Follow standard windows printing prompts for sending the report to the attached printer. To export report to an HL7 compatible system (must be connected): • Press *Save Report (HL7)* on the left menu. • An HL7 Basic Socket Transfer message is displayed. • Press *Send HL7* to store the data in the HL7 database. To save the printed report as a PDF file: • Connect an external USB drive or USB key to the LipiView. • Press Save PDF on the left menu. • When the system reports that the PDF has been saved





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	successfully, press Close.

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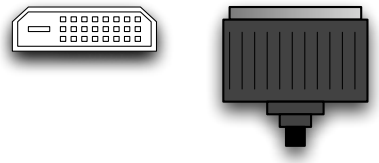
19 Appendix B: External Monitor Hookup

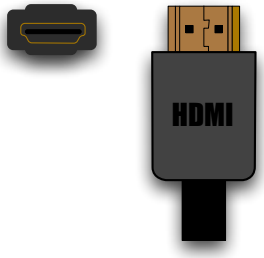
The LipiView® Interferometer is equipped with an optional external monitor connection. The following instructions provide the user with the steps needed to connect the external monitor to the interferometer.

The external monitor connection may be DVI output or HDMI output. TearScience does not supply cables for connecting external monitors. Users wishing to connect an external monitor should inspect the connectors on the monitor they wish to use, and the connector on the underside of the LipiView® Interferometer, and then purchase a cable that has the appropriate connectors on each end and is long enough to reach from the underside of the LipiView® Interferometer to the external monitor input.

The DVI connector and cable look like this:



The HDMI connector and cable look like this:



1. Ensure the LipiView® Interferometer is powered off.
2. Ensure that the separately purchased external monitor has either a DVI or HDMI port and is capable of displaying a 1280 x 1024 image.
3. Locate the digital video cable cover on the underside of the LipiView® Interferometer. The cover has four screws attaching it to the LipiView® Interferometer. Use an M2.5 hex driver and remove the four screws. The LipiView® Interferometer's digital video output cable should now be exposed.
4. Connect the separately purchased digital video cable to the LipiView® Interferometer's video output.
5. Connect the other end of the digital video cable to the external monitor.

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6. Apply power to the LipiView® Interferometer and external monitor.

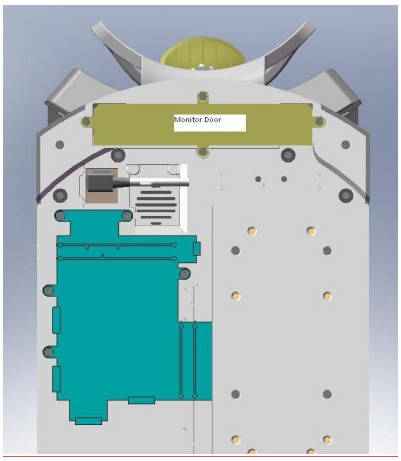

Figure B1. Location of External Monitor Interface Door

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20 Appendix C: Electromagnetic Compatibility Requirements

20.1 Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Table 20-1: Guidance and Manufacturers Declaration-Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The LipiView® Interferometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	NA
Harmonic emissions IEC 61000-3-2	Class A	NA
Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	The LipiView® Interferometer is suitable for use in all establishments **other than** domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.

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20.2 Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Table 20-2: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 1)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
*NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

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Table 20-3: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 2)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the HCS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	$d = [3.5/V1]\sqrt{P}$ $d = [3.5/E1]\sqrt{P}$ 80MHz to 800MHz $d = [7.0/E1]\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Conducted RF IEC 61000-4-3	3 Vrms 80 MHz to 2,5 GHz	3 V/m	Field strengths from fixed RF transmitters, are determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LipiView® Interferometer is used exceeds the applicable RF compliance level above, the LipiView® Interferometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LipiView® Interferometer. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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20.3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Table 20-4: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer			
The LipiView® Interferometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LipiView® Interferometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LipiView® Interferometer as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d=[3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz** $d=[3.5/E_1]\sqrt{P}$	**800 MHz to 2,5 GHz** $d=[7/E_1]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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TearScience®

LIPIVIEW®

Ocular Surface Interferometer

Operation Manual

Model # LVI-1001
For System Version 1.1x

Manufactured by:

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Rx only

CE

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Revision History

Revision	Date	Description of Changes	ECR # or PCR #
A	05/20/09	Initial Release	ECR# 0905201
B	6/10/09	Grammatical fixes; spelling fixes; Clarification to instructions and changes required by IEC60601; Changed all references of type BF applied part to type B; Reduced maximum operating temperature to 35° C from 40° C.	ECR# 0906101
C	6/18/09	Added a caution and instructions on lifting and handling the device in the Warnings section	ECR# 0906181
D	10/01/09	Made changes for EMC requirements by adding "continuous operation" to Warnings section and updating Appendix C based on Intertek testing; Updated REF numbers. Updated device labels to meet EN980 and CE requirements; Revised Indications for Use and removed language related to diagnosis and lipid layer thickness	ECR# 0909091
E	9/20/2010	Added information on software enhancements included in release 1.1A. Updated appendix B for new cabling requirements. Added United States part number.	PCR# 1009201
F	11/18/2011	Included updated screen shots reflecting minor user interface and workflow changes. Updated Appendix B to account for new connectors for external monitors. Added instructions for new functionality (save reports as PDF). Updated system version on cover page. Added instructions for wireless network security. Added RF energy emitter symbol to Table 3-2.	PCR # 1111111
G	4/5/12	Changed company address on cover page. Removed text caution indicating that device is restricted for sale by or on the order of a physician and replaced it with the Rx Only symbol. Added EC Rep information and CE mark to cover. Removed all labels from text. Corrected symbol table. Updated references to ISO standards. Replaced screenshots to reflect minor software updates – correct system and help file versions, and the presence of an "algorithm" tag on analysis displays. Added guidance on good passwords to the security section, and added Save as PDF information to the Quick Start Guide.	PCR # 1203202
H	6/26/12	Added: warning regarding ingress of liquids, warning regarding oxygen rich environment use, warning that the monitor may be hot, and a section on maintenance & servicing. Added a section on transporting device to storage. Changed backup battery caution to indicate no replacement can be made. Removed reference to ISO 15004-1 in warnings section. Added screenshot of power-up warning regarding homing sequence.	PCR# 1205291
J	8/2/12	Added Warning to general warning section, updated Table 14-1 first action to indicate some computers have a red reset button and some do not.	PCR # 1206251

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Table of Contents

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1 Introduction

This manual provides the indications, contraindications, warnings, precautions, potential adverse effects and instructions for use for the *TearScience*® LipiView® Ocular Surface Interferometer (LipiView® Interferometer). **Carefully read this manual in its entirety before using the LipiView® Interferometer. Failure to follow these instructions may result in improper use of the device.**

Use of the LipiView® Interferometer includes User and Administrator functionality, both of which are described in this manual. Section 10, *Instructions for Use,* contains the information about the proper procedures for operating the LipiView® Interferometer. Section 16, *Administrator Instructions for Use,* contains information about the initial setup and maintenance of the LipiView® Interferometer by an Administrator. **Prior to initial use of the LipiView® Interferometer, the Administrator must follow the administrative setup instructions in this manual for proper device use.** Table 1-1 identifies the tasks an Administrator may be required to perform and the prerequisite knowledge.

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Table 1-1: Administrator Prerequisite Knowledge

Task	Prerequisite Knowledge
User Administration	Create usernames and passwords.
Printer Setup (required before printing)	Install a Network or USB printer. Installation of a network printer requires knowledge of networking. For installation of a USB printer, follow the manufacturer's instructions.
Network Setup (optional)	Configure the system to gain access to the wireless networking environment (selection of server, setting of security keys, etc).
Electronic Medical Records (EMR) Export (optional)	Configuration for export of records to other office system(s) using the HL7 data transfer protocol.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

Contact TearScience with any questions about the information contained in this manual or for additional information on the operation and safety of the LipiView® Interferometer.

2 Device Description

The LipiView® Interferometer is a bench-top device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touchscreen display. Figure 2-1 shows the base LipiView® Interferometer. Additional views and a description of the components are provided in Section 9, *LipiView® Interferometer Operation*.

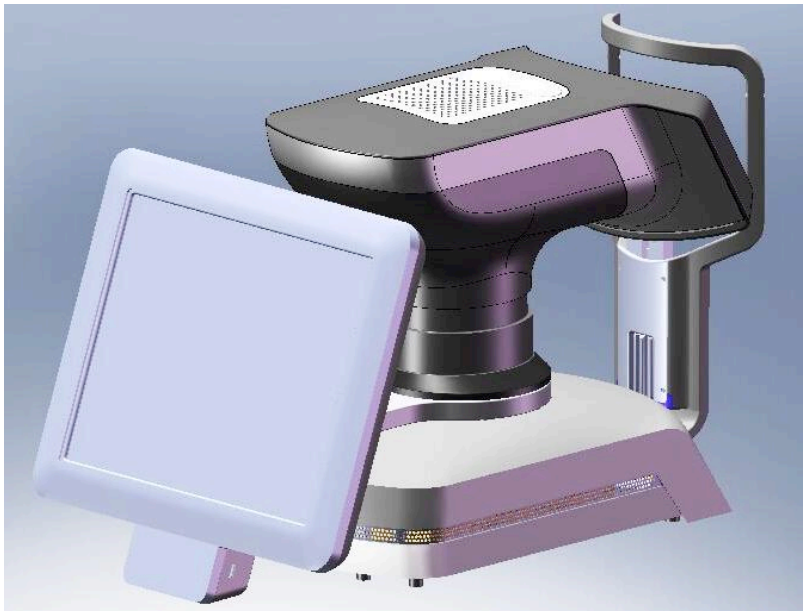

Figure 2-1: LipiView® Interferometer

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The patient's eye is positioned in front of an illumination source directed toward the tear film on the corneal surface. Light from the illumination source passes through the tear film and is specularly reflected into a camera. The light reflecting back through the lens in the camera forms an interference pattern, called an "interferogram". The computer system

captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking.

The computer system captures and enhances the interference pattern and displays a profile corresponding to an interferometry color scale. The interferometry color assessment is measured in Interferometric Color Units (ICU). An ICU for the LipiView® Interferometer is defined as the color scale resulting from the interference pattern which occurs at the boundary of the tear film. The measured ICU may range from 0 to 240, with a precision of 1 ICU. The accuracy of the measured interference pattern is displayed as a "C-factor," which is equal to the proportion of measured colors that match the predicted interferometric color scale. The video image of the ocular surface may be viewed on the computer screen display and in a printed report.

3 Labeling

Table 3-1 provides a description of the symbols used on the LipiView® Interferometer labeling.

Table 3-1: Description of Labeling Symbols

Label Symbol	Symbol Description
	Type B applied part.
	Consult operating instructions
	Device transmits radiofrequency (RF) energy
	Text consists of a warning or precaution relating to safety. Read the text carefully and use the equipment as instructed to ensure safety.
	Reference Number
	Serial Number.
	**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.
	Mandatory conformity mark for medical device products in the European Economic Area (EEA). The **CE marking** certifies that a product has met consumer safety, health or environmental requirements.
	This model/product is Listed in Intertek's Directory of Listed Products.

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Deleted: The labels in Table 3-1 are affixed to the LipiView® Interferometer device or packaging. Table 3-2

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Deleted: Electromagnetic interference may occur in the vicinity of the equipment.

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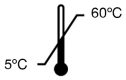
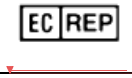
Label Symbol	Symbol Description
	Date of Manufacture
	Manufacturer
	Store between 5 and 60 degrees Celsius
	Authorized Representative in the European Community
P/N	Part Number
Rev	Revision Level

4 Indications for Use

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

5 Contraindications

Contraindications are conditions in which the device should not be used because the risk of use clearly outweighs any benefit. No contraindications have been identified for the LipiView® Interferometer.

6 Precautions

The following patient conditions may affect the interferometry assessment of a patient's tear film using the LipiView® Interferometer:

- **Use of ophthalmic drops such as artificial tear lubricants, ointments, and medications.** Advise patients not to instill oil-based ophthalmic drops (e.g., Soothe®, Restasis®) for at least 12 hours prior to device use and not to instill ointments for at least 24 hours prior to device use. Wait at least 4 hours after the instillation of all other ophthalmic drops prior to device use.
- **Soft or rigid contact lens wear**. Advise patients to remove contact lenses at least 4 hours prior to device use.
- **Use of oil-based facial cosmetics around the eye.**
- **Eye rubbing.**

- **Recent swimming in a chlorinated pool.** Advise patients not to swim for at least 12 hours prior to device use.
- **Any ocular surface condition** that affects the stability of the tear film. These conditions include disease, dystrophy, trauma, scarring, surgery, or abnormality.

7 Warnings

Review the following warnings prior to using the LipiView® Interferometer.

Table 7-1: General and Operation Warnings

GENERAL WARNINGS
WARNING: No modification of this equipment is allowed.
Caution: **Power Requirements.** The LipiView® Interferometer is a continuous operation device which requires a power source of 100-240 Volts AC ± 10%, 50/60 Hz single phase, 4 Amps. Connection to a power supply other than a supply mains with protective earth may result in electric shock.
Caution: The LipiView® Interferometer has protection against electric shock of applied part classified as Type B. This device is classified as an IEC Class 1 product.
Caution: **Voltage Protection and Fuse Selection.** Contact TearScience to replace a blown fuse. TearScience personnel must replace only with a 5 x 20 mm, 4 A, 300 ms, 40 A breaking capacity fuse to avoid risk of fire. TearScience personnel must disconnect from power before servicing to avoid risk of electrical shock.
Caution: Backup Battery Replacement. Backup battery cannot be replaced.
Caution: Keep the LipiView® Interferometer away from strong magnetic fields as it could damage the device's hard drive, but is not a safety hazard to the user or patient.
Caution: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the LipiView® Interferometer or shielding the location.
Caution: Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
Caution: The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or Device.
Caution: The EQUIPMENT or DEVICE should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EQUIPMENT or DEVICE should be observed to verify normal operation in the configuration in which it will be used.

Caution: Degree of protection against harmful ingress of liquid: IPXO. This equipment has no protection against ingress of liquids.

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 *OPERATION WARNINGS*
Caution: Federal law restricts this device to sale by or on the order of a physician.
Caution: The chin and forehead rest surface must be disinfected with alcohol immediately prior to use and prior to storage.
Caution: **Photo-toxicity hazard.** No acute optical radiation hazards have been identified for the LipiView® Interferometer under intended use conditions. Since prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. Aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours.
Caution: Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.
Caution: If a problem occurs with the LipiView® Interferometer, identify the symptom then attempt to resolve the problem as indicated in Section 15, *Troubleshooting*. If the problem cannot be resolved, stop using the device and contact TearScience.
Caution: To prevent electric shock or performance alteration, do not attempt to service the device or remove the cover. No maintenance is required for the LipiView® Interferometer, and the device and all of its associated parts are not serviceable by the user.
Caution: This device is not suitable for use in the presence of flammable mixtures.
Caution: This device is not suitable for use in oxygen rich environments.
Caution: In order to isolate this equipment from supply mains the equipment must be unplugged from the wall. Do not position the equipment in a location which would prevent the unit from being unplugged in an emergency.
Caution: Do not store this instrument in conditions where the temperature may rise above 60°C or fall below 5°C.
Caution: When lifting or handling the LipiView® Interferometer, caution should be taken to prevent injury or damage to the device. Prior to moving the device, put the monitor arm into a locked position and unplug the power cord from the wall. If an external monitor is attached, disconnect the external monitor prior to moving the device.
Caution: The device monitor and base unit may exceed 41°C. Device will remain within safe momentary contact temperature, below 51°C.
Caution: Shock hazard. Do not touch patient and device under top cover simultaneously.

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Deleted: ***Caution:*** This instrument does not meet the temperature requirements of ISO15004-1 for storage.

8 Potential Adverse Effects

There are no known or anticipated adverse effects associated with use of this device.

9 LipiView® Interferometer Operation

9.1 Device Overview

The LipiView® Interferometer is a bench-top device containing the following components, which are identified on Figures 9-1 (Front/Patient View) and 9-2 (Rear/User View):

- Base and Computer System
  - Computer system
  - Electronics
- Ophthalmic Chin Rest Support
  - Chin Rest
  - Forehead Rest
- Motion Stage
  - Camera and zoom lens
  - Illuminator
- Touchscreen Display
  - USB Ports

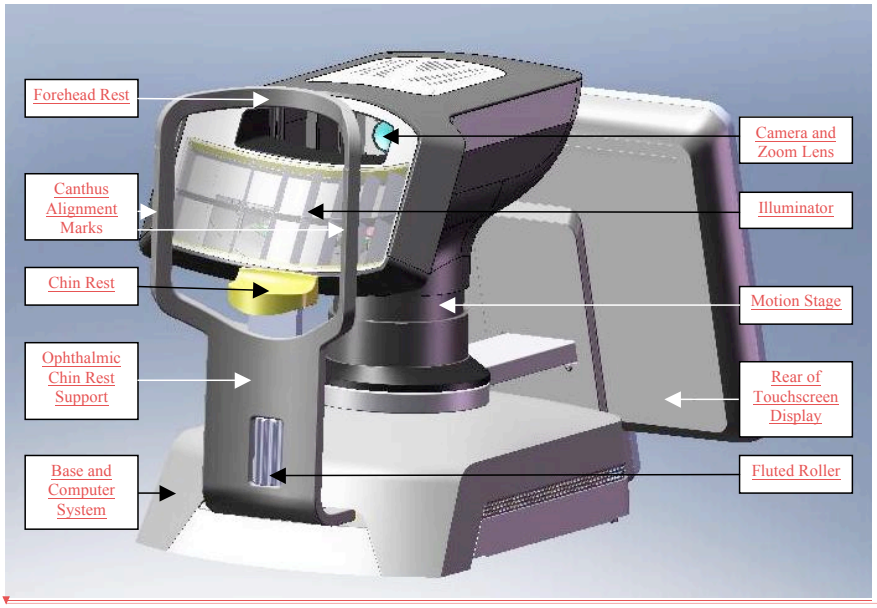

Figure 9-1: Front (Patient) View of LipiView® Interferometer

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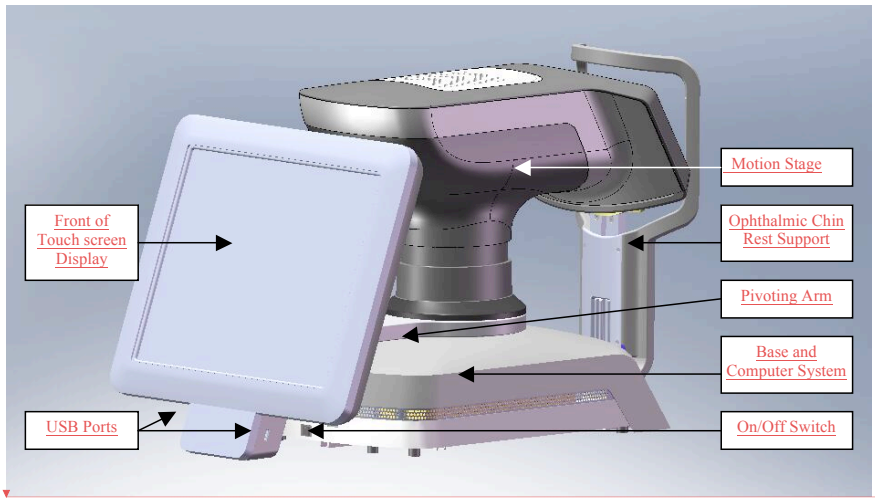

Figure 9-2: Rear (User) View of LipiView® Interferometer

9.1.1 Base and Computer System

The base of the device sits on a flat surface. It houses the power connection, and computer hardware, and connects with the ophthalmic chin rest support, motion stage and touchscreen display. The on/off switch is located on the rear of the base opposite the back surface of the display screen. Refer to Figure 9-2 for the switch location. A connection for an external monitor is hardwired into the base.

9.1.2 Ophthalmic Chin Rest Support

The ophthalmic chin rest support shown in Figure 9-1 consists of an adjustable height chin rest and fixed forehead rest. The chin rest support is attached to the front base of the device, and is designed to allow proper positioning of the patient's head to evaluate the ocular surface tear film. To ensure a properly focused image, the patient must place his/her chin and forehead firmly against the chin and forehead rests. The chin rest may be raised or lowered to accommodate different facial dimensions by spinning the fluted roller. Two canthus alignment marks about half way down the left and right sides of the forehead rest indicate the center of the camera range in the up/down direction. Adjusting the chin rest to position the lateral canthus of the patient's eye at these marks will optimize the range of camera motion.

The chin rest support is the only component of the LipiView® Interferometer that comes in contact with the patient. Disinfect the chin and forehead rest surfaces with alcohol immediately prior to use and prior to storage.

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Deleted: The external monitor connection option is discussed in Section 9.1.8, *Optional External Monitor Connection*.

9.1.3 Motion Stage

The motion stage is mounted on the top center of the base. It contains the camera, zoom lens, illuminator and motor controls used to adjust the camera and illuminator. The height of the motion stage (which includes the camera and illuminator) is adjusted as part of the Capture Images process discussed in Section 10.3.2, *Capture the Video*.

9.1.4 Camera and Zoom Lens

The camera is located behind the zoom lens inside the motion stage and is not visible externally. The height of the camera can be adjusted as part of the motion stage. The camera can also be adjusted to the left and right as well as backwards and forwards with separate controls. Refer to Section 10.3, *Video Image Capture and Recording* for additional information.

9.1.5 Illuminator

The grid-like fixture attached to the top front of the motion stage is the illuminator. The illuminator faces the patient and reflects light off the tear film. The height of the illuminator is adjusted automatically with camera alignment as part of the motion stage. There are no separate controls for the illuminator.

9.1.6 Touchscreen Display

Attached to the rear of the base is the Touchscreen Display. Figure 9-1 provides a rear view of the screen and Figure 9-2 shows the front view of the screen. The screen is on a pivoting arm, which allows it to be positioned ± 45 degrees or ± 90 degrees from its location shown in Figure 9-2. To reposition the screen, press the button under the pivoting arm while moving the arm left or right to the approximate 45 or 90 degree location. Release the button and continue moving the arm until it locks into place.

In addition to displaying information to the user, the screen also functions as a touchscreen user interface to the interferometer. The user touches the screen to operate the motion stage and camera controls and to progress through the imaging process. Section 9.2, *User Interface* provides additional details.

9.1.7 USB Ports

The lower base of the Touchscreen Display contains two USB ports as shown in Figure 9-2. These ports may be used to connect a printer or storage device if the LipiView® Interferometer is not on a wireless network. Refer to Section 9.1.9.4, *Accessory Support* for information on compatible accessories.

9.1.8 External Monitor Connection

The LipiView® Interferometer supports the use of an external monitor. A connection for an external monitor is hardwired into the base. The connection will support HDMI or DVI inputs on an off the shelf external monitor which has at least 1280 x 1024 resolution and supports 60Hz frame rates. Instructions for attaching the external monitor are provided in Section 19, *Appendix B: External Monitor Hookup*.

9.1.9 Operating Environment

9.1.9.1 Electrical Specifications

Table 9-1: Electrical Specifications

Input Voltage	120 – 240 VAC, 50 – 60 Hz

9.1.9.2 Medical Electrical Classifications

Table 9-2: Medical Electrical Classifications

Product Safety Classification	Type B Applied Part
IEC 60601-1— Medical electrical equipment—Part 1: General requirements for safety	
IEC 60601-1-2— Medical electrical equipment—Part 1: General requirements for safety—Section 2: Collateral standard—Electromagnetic compatibility—Requirements and tests;	CISPR 11 (Class A, Group 1)

9.1.9.3 Environmental Specifications

Table 9-3: Environmental Specifications

Operating Temperature	10°C to 35°C
Operating Relative Humidity	Up to 90% non-condensing
Storage Temperature	5°C to 60°C
Transport Temperature	5°C to 60°C

9.1.9.4 Accessory Support

The LipiView® Interferometer may be used with the following USB accessories that are compatible with Windows XP and USB1.0:

- USB printer (Printer Support)
- USB external hard drive (External Backup Support)
- USB flash drive (USB / Thumb Drive Support)

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Deleted: with associated cable. The base LipiView® Interferometer is NOT field upgradeable if it was originally ordered without the

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Deleted: of the device. The device will come with an external optical to electrical converter that will convert the optical signal from the LipiView® Interferometer to the electrical signal needed for an HDMI or DVI input

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The LipiView® Interferometer is designed to operate wirelessly with other network devices, such as a printer. Placement of the LipiView® Interferometer should be within range of the network, if a network system is used.

The LipiView® Interferometer supports connection to an external monitor; refer to Section 19, *Appendix B: External Monitor Hookup*, for more information.

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Deleted: connection option, then the monitor must have a DVI port and be capable of displaying a 1280 x 1024 resolution image.

9.2 User Interface

9.2.1 Touchscreen Display Layout

After user login, all touchscreen displays are formatted with a menu bar across the top containing a disk space indicator and up to seven tabs, one for each key function of the system. A light gray colored tab indicates the active function. Any other tabs shown on the menu bar may be selected. On screens involving a patient record, patient identifier information is displayed on the right end of the menu bar.

Figure 9-3 shows a sample menu bar. The light gray color on the View Images tab indicates it is the active function. Functions have one or more associated screens. From left to right, the menu bar contains: Help tab, Log Out tab, Disk Space Indicator, Admin tab, Patient Records tab, Capture Images tab, View Images tab, Print/Save tab, and patient identifier information.

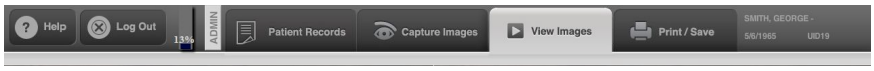

Figure 9-3: Menu Bar from View Images Tab

The Login screen contains the *Help* tab and the disk space indicator:

- **Help** – Pressing *Help* displays information related to the active screen. Pressing *Help* again closes the screen. Refer to section 10.6, *Online Help*.
- **Disk Space Indicator** – The bar to the right of the *Help* tab indicates the percentage of the available disk space that has been used for video storage. The Administrator can configure at what hard drive fullness level (e.g., 75%) the LipiView® Interferometer will no longer capture new images due to a full disk. Refer to Section 16.7, *Admin Networking* for information on setting the fullness level, cloning and archiving content to free up disk space.

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Once the user logs in, up to six additional tabs are visible, depending on the current screen:

- **Log Out** – Pressing *Log Out* exits the user from the device and the Login screen described in Section 10.1.3, *User Login* is displayed.
- **Admin** - If the Username that is logged into the system has been set up as an Administrator, an *Admin* tab will be visible to the right of the disk space indicator

on all screens. Refer to Section 16, *Administrator Instructions for Use* for a description of Administrator functionality.

- **Patient Records** – Pressing *Patient Records* displays patient information, and allows the user to search for, add or edit patient information. Refer to Section 10.2, *Patient Data Entry*.
- **Capture Images** – Pressing *Capture Images* allows the user to record video for each eye, preview video, rerecord video (if needed), and save video. Refer to Section 10.3, *Video Image Capture and Recording*. If the power on self-test described in Section 10.1.1 detects a problem that would potentially affect this modality, this tab will not be functional and will be grayed out (refer to Section 9.2.4). The LipiView® Interferometer will not be able to capture images but prior data can still be reviewed.
- **View Images** – Pressing *View Images* allows the user to review saved videos and request a computer analysis. Refer to Section 10.4, *Video Review and Analysis*.
- **Print / Save** – Pressing *Print / Save* allows the image with the video analysis to be printed and/or saved to an HL7 compatible database. Refer to Section 10.5, *Video Print and Save*.

Patient identifier information is shown on the right end of the menu bar when a patient record has been selected. This includes the Captures Images, View Images and Print / Save tabs. The information is extracted from the Patient Record, so the contents may vary. At a minimum, it includes the Patient ID or the Last Name, First Name and Date of Birth.

The screen below the menu bar contains information relevant to the active function tab. When entering information is allowed, an onscreen keyboard is displayed at the bottom of the screen, as discussed in the next section.

9.2.2 Onscreen Keyboard

When the cursor is positioned in a location that requires user input, the onscreen keyboard in Figure 9-4 is displayed. This keyboard contains an alphabet keypad (uppercase only), a numeric keypad, and five special keys that perform as specified below. The onscreen keyboard does not contain or support the use of special characters other than the backslash (\) and colon (:) between the two keypads.

- **Left arrow above the "Q"** – Scrolls backwards through entered text to facilitate the insertion or deletion of characters.
- **Right arrow above the "W"** – Scrolls forwards through entered text to facilitate the insertion or deletion of characters.
- **Delete key above the "O" and "P"** – Deletes the character to the left of the cursor.
- **Left tab above the "8"** – Moves the cursor to the prior field allowing user input. Repeated presses on the left tab key will continue looping the cursor backwards through fields on the current screen, but it does not return to the previous screen.

- **Right tab above the "9"** – Moves the cursor to the next field on the screen allowing user input. Repeated presses on the right tab key will continue looping the cursor forwards through fields on the current screen, but it does not advance to the next screen.

Each key press yields one character or cursor movement of one position. Keys do not repeat if they are held down.

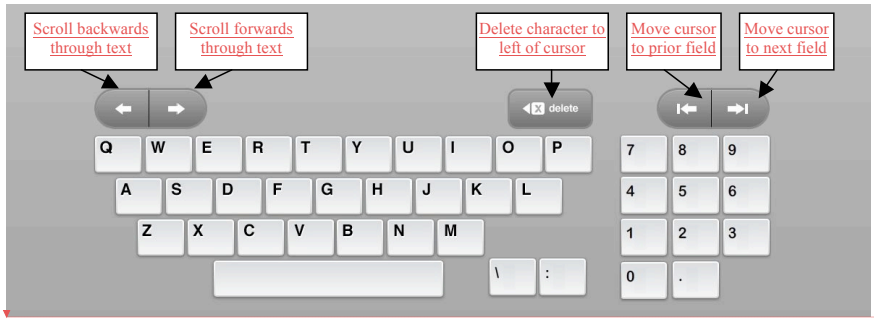

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Figure 9-4: Keyboard

9.2.3 Positioning the Cursor

The LipiView® Interferometer touchscreen display allows the user to position the cursor by touching the desired area of the screen, or by pressing the arrow, delete or tab keys described in the previous section.

When making an edit to an existing field without positioning the cursor, any new characters entered are appended to the existing text, rather than replacing it. Use the Delete key to clear a field first, and then re-enter the information, or use the arrow keys to position the cursor in the correct location.

To facilitate editing, multiple characters on the screen can be highlighted by touching and then dragging a finger to the left or right. The series of highlighted characters is treated as one character when the arrow, delete and tab keys are used. The left or right direction of the finger movement determines where the cursor is placed when the special key is used.

9.2.4 Screen Interaction and System Messages

At times a portion of the active screen may be grayed out indicating it is temporarily inaccessible to the user. For example, if the onscreen keyboard is present, user input would be restricted to the keyboard. Selecting other tabs or pressing other areas of the screen will result in no action.

System messages are generated by the software running on the device when the user attempts to perform an invalid operation, or when something unexpected occurs or to

confirm completion of an event. These messages may instruct the user on a particular action to take (e.g., enter a missing field, or correct the format of a date field). When a system message is visible it requires a response from the user before any other input from the screen is accepted. The user must respond by pressing a button on the system message. Typically this is the *Close* button, but it may also be a confirmation or other dialog.

System messages related to Windows error codes will also be listed in the System Log described in Section 16.9, *Admin System Log*.

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9.3 Patient Interface

The only part of the LipiView® Interferometer that directly interfaces with the patient is the ophthalmic chin rest support. **Ensure that all parts of this support are cleaned with an alcohol wipe prior to each patient use and prior to storage.**

9.4 Device Setup

Prior to initial use, ensure that the instructions in Section 16.1, *First Time Setup* have been completed by an Administrator. Other administrative functions should be completed at the discretion of the Administrator.

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Ensure that the power cord is plugged into an electrical outlet. The power cord connection is located underneath the base of the device.

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10 Instructions for Use

This section provides instructions for use of the LipiView® Interferometer to image the ocular surface and to observe the tear film of the eye through specular reflection of light. The instructions include:

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- Device Startup (Section 10.1);
- Patient Data Entry (Section 10.2);
- Video Image Capture and Recording (Section 10.3);
- Video Review and Analysis (Section 10.4);
- Video Print and Save (Section 10.5);
- Online Help (Section 10.6); and
- Log Out (Section 10.7).

Additional administrative functionality is described in Section 16, *Administrator Instructions for Use*.

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10.1 Device Startup

10.1.1 Power On and Self-Test

Upon powering on the device, the LipiView® Interferometer performs a self-test, confirms that the camera is connected, verifies system voltages, checks remaining hard drive space, and calibrates the camera motors. Version information at the bottom of the screen indicates the software running on the interferometer.

1. ***Power On*** - Power on the LipiView® Interferometer by pressing the rocker switch on the base of the device behind the touchscreen. Refer to Figure 9-2 for the location of the power switch. An indicator light on the power switch illuminates when the device is powered on.

   NOTE: The LipiView® Interferometer should be powered off overnight to allow the device to cool down. However, the device does not need to be powered off between patient examinations.

2. ***Software Boot Up*** - The touchscreen display remains blank while the software boots up. After a short time a "Welcome" message is briefly displayed. Shortly thereafter the screen in Figure 10-2 is displayed as the initialization process begins. The system version number displayed represents the software release which is currently installed. This manual is designed for all software releases that are labeled as 1.1x where x is any letter combination. The exact letter of your system version may not match Figure 10-2.

   For software releases 1.1D and later, the system will display a warning (shown in Figure 10-1 below) that must be acknowledged before the initialization process continues: "Ensure patient and operator are clear of the chinrest area. The unit will now automatically home the motor system. Press the Continue button to begin."

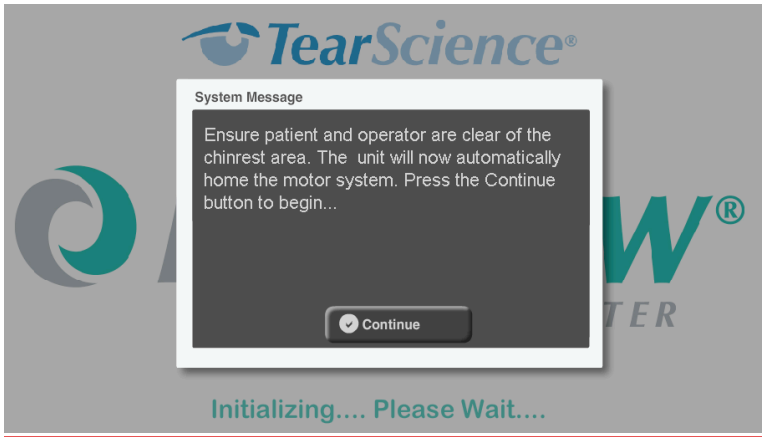

Figure 10-1: Warning screen (in software release 1.1D or later)

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Figure 10-2: Initialization Screen

3. ***Equipment Location and Calibration*** - Figure 10-2 is displayed as equipment is located and calibrated. The motion stage moves up and down during the motor calibration process. When the initialization process completes after about 20 seconds, the screen in Figure 10-3 is displayed indicating that the device is ready for use. Continue with Section 10.1.2, *Device Ready*.

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10.1.2 Device Ready

At the completion of the self-test, the words *Initializing…. Please wait….* on the screen are replaced with the words *Touch Screen To Continue* as shown in Figure 10-3.

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Figure 10-3: Device Ready Screen

When ready to continue, press anywhere on the screen. The login screen in Figure 10-4 will be displayed. Continue with Section 10.1.3, *User Login*.

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10.1.3 User Login

The User Login screen in Figure 10-4 is displayed until *Submit* is pressed after a valid username and password have been entered. Refer to Section 16, *Administrator Instructions for Use* for setting up usernames and passwords prior to use of the device.

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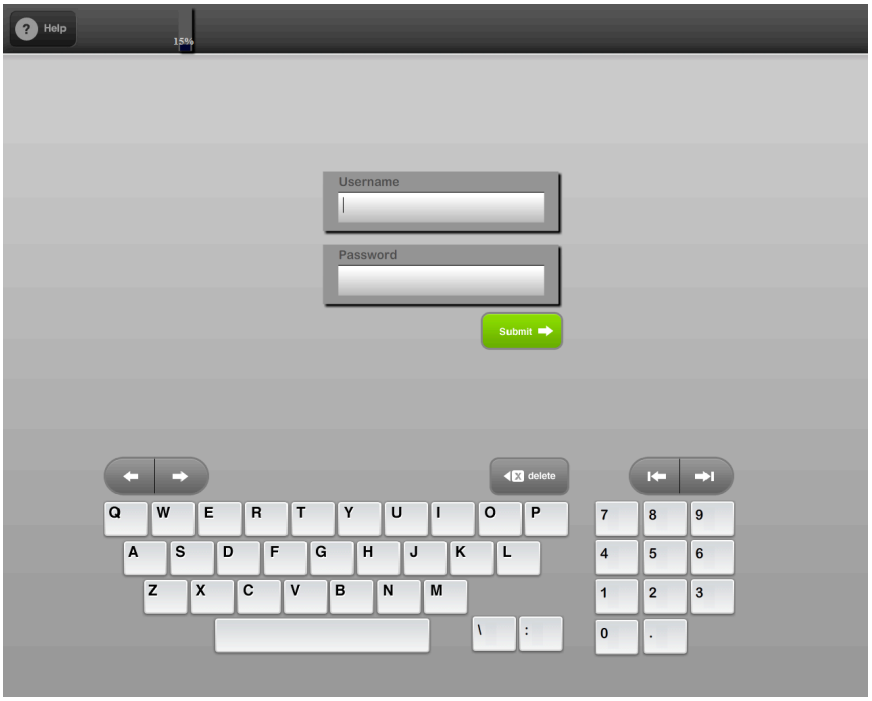

Figure 10-4: Login Screen

1. ***Username and Password*** - Using the onscreen keyboard, enter the Username and Password as follows:
   A. Type the name of the user.

      NOTE: Prior to device use, the Administrator must enter the Username and Password in the system.

   B. Position the cursor in the text box for the Password by touching the tab key or the password field.
   C. Type the password.

      NOTE: In the event of a forgotten password, or to change a password, contact the Administrator. Only the Administrator can set or change a password.
2. ***Submit*** - Press *Submit* and continue with Section 10.2, *Patient Data Entry*.

10.2 Patient Data Entry

After successfully logging in, the Patient Records screen shown in Figure 10-5 is displayed. The Patient Records screen is used to find an existing patient record or to add a new patient record if it is not found in the database.

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Prior to beginning an examination, a patient's record must be selected. A patient's record must also be selected to view any previous videos. Until a patient record is selected, the Capture Images and View Images tabs on the menu bar are not active.

Figure 10-5: Patient Records Screen

10.2.1 Patient Records Screen

All patient records contain up to five pieces of information: Patient ID, Last Name, First Name, Middle Initial and Date of Birth. At a minimum, each patient record must include 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. The Patient Records screen contains these five blank fields, which are used to locate, create or update a patient record, followed by a tabular list of existing patient records.

The Patient ID field can contain up to 16 characters. Fields for the Last Name and First Name can contain up to 25 characters each. The middle initial contains up to one character. The Date of Birth includes a one or two-digit month, followed by a one or two-digit day, followed by four-digit year.

The patient records table in the center of the screen lists the first eight patients in the database in alphabetical order. Once more than eight names have been saved, the step keys to the right of the table can be used to move backwards or forwards through the table. Each time the backwards (upper) key is pressed the previous eight names are displayed. Pressing the backwards key when the beginning of the list is displayed does not elicit a response. When the forward (lower) key is pressed, the next eight names are displayed in the table. Pressing the forward key when the last eight names are displayed also results in no change to the tabular display.

When the list of patient records spans multiple pages, sorting the table may facilitate searching for a record. Pressing the Patient ID, Last Name, First Name or Date of Birth header will sort the table by that column. Pressing the same header a second time will sort the table in the reverse order. A small triangle in the column header indicates that the table is being displayed according to the data sorted by this column. The triangle points down or up to specify the direction.

10.2.2 Locate a Patient Record

A patient record must be in the database before images can be captured or viewed. To attempt to locate a patient record in the database, search for the record using one of the following two methods. For existing patients, using the step keys in method 1 may be preferred. For new patients, use method 2. If uncertain as to whether a patient record is in the database, use either or both of these methods to determine whether the patient record exists.

1. ***Locate Patient Record with Step Keys -*** Use the step keys to move backwards (upper key) or forwards (lower key) through the database, while examining the records displayed in the table for a match. If desired, press the table header for Patient ID, Last Name, First Name or Date of Birth to sort the table by that field.
   A. If the record cannot be found in the table, then continue with method 2 to confirm the patient record does not exist.
   B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action*.
2. ***Locate Patient Record by Typing*** - Begin typing the patient's Last Name, First Name and/or Date of Birth in the fields above the table, or position the cursor in the Patient ID field and begin entering the ID. As each character is entered, the patient records table is filtered displaying only the possible matches that exist in the database.
   A. If no records are displayed in the table then the patient record does not exist. Either correct the entered information, or continue with Section 10.2.3, *Add a New Patient Record*.

B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action*.

10.2.3 Add a New Patient Record

When a patient record could not be located in the database, the screen shown in Figure 10-6 is displayed, allowing the user to enter new patient information and save it.

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NOTE: Depending on the information entered when trying to locate a patient, one or more of the five fields in the patient record may be empty or partially filled in. As soon as the system determined there was no patient record match in the database it transitioned to Figure 10-6.

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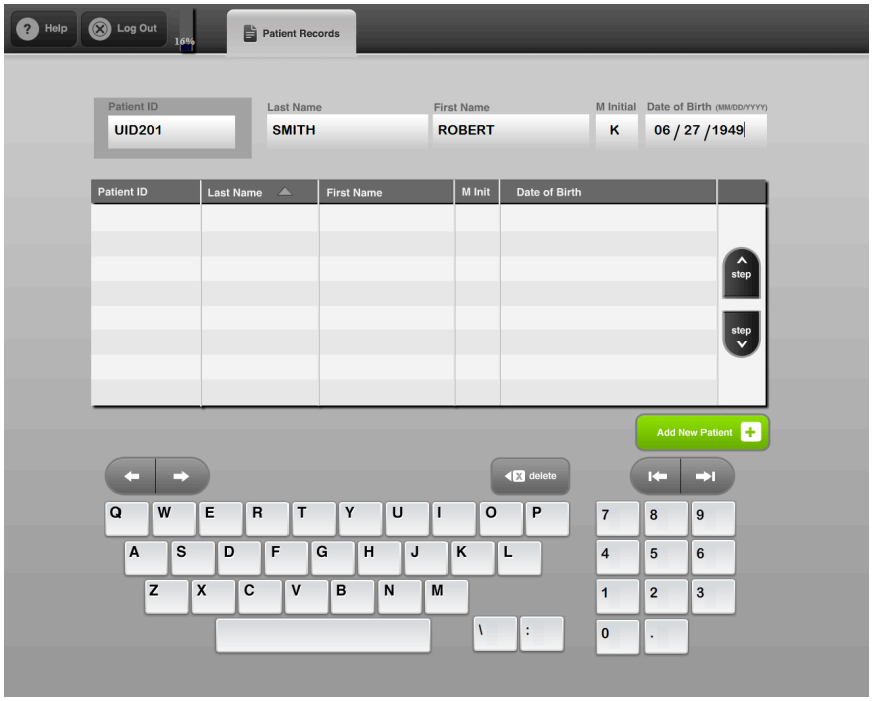

Figure 10-6: Patient Records Screen - Add a New Patient

At a minimum each patient record must contain 1) a Patient ID or 2) the Last Name, First Name and Date of Birth fields to proceed. The instructions below specify entering new patient information beginning with the Last Name; however, information may be entered into the fields in any order, and only the minimum information is required. Touch the appropriate fields or use the tab keys to move from field to field.

1. ***Patient Name*** – Enter the patient's Last Name and First Name and optional middle initial:
   A. Enter the Last Name, up to a maximum of 25 characters.
   B. Enter the First Name, up to a maximum of 25 characters.
   C. Enter the middle initial if desired. Entry may be helpful with common last names.
2. ***Date of Birth*** - Enter the patient's Date of Birth, using a one or two-digit month, followed by a one or two-digit day, followed a four-digit year. If an invalid date is specified, a system message is displayed indicating required information. Press *Close* and try again.

   NOTE: If a one-digit month or day is entered, position the cursor in the next field by touching the field or the tab key. If a two-digit month or day is entered, the cursor will automatically move to the next field.
3. ***Patient ID*** - Enter the Patient ID, up to a maximum of 16 characters. If a patient ID is entered, no other information is required to complete the patient record.
4. ***Review Record before Adding*** - Confirm that the information for the new patient is correct, and that the minimum fields have been filled in. Once a patient record has been entered into the database it cannot be deleted.
5. ***Add Patient Record to Database*** - Press *Add New Patient*.
   A. If a required field is empty or the new record is a duplicate of one that already exists in the database, a system message indicating the error is displayed. Touch *Close* to shut the system message. Make the appropriate corrections and press *Add New Patient* again.
   B. If the minimum required fields have information, there is a valid Date of Birth, and the patient record is not a duplicate of an existing record, it is saved in the database. The Patient Records screen in Figure 10-5 is redisplayed with the new patient record highlighted, and showing at the top of the table.

      NOTE: If the record added is the last record in the table, it appears to be the only record until the backwards (upper) step key is pressed showing other records.
   C. Return to Section 10.2.2, *Locate a Patient Record* to add another patient or find an existing patient, or touch any field on any record in the table and continue with Section 10.2.4, *Select a Patient Action*.

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10.2.4 Select a Patient Action

Once a patient's record is visible in the patient records table, press on any field in the patient record. The row will become highlighted, the *Select a Patient Action* system message will appear, and the remainder of the screen will be grayed as shown in Figure 10-7, indicating that it is temporarily inaccessible for user input. Choose one of the four options in the system message:

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- **Edit Patient** – Select this option to proceed to the Edit Patient Information screen, and continue with Section 10.2.5, *Edit Patient Information*.

NOTE: A patient record may only be edited if video images have not previously been saved.

- **Capture New Images** – Select this option to proceed to the Capture Images screen, and continue with Section 10.3, *Video Image Capture and Recording*.
- **View Past Images** – Select this option to proceed to the Patient History screen, and continue with Section 10.4, *Video Review and Analysis*.
- **Close** – Select this option if the incorrect record was chosen, and return to Section 10.2.2, *Locate a Patient Record* to try again. The system will close the system message, but the row will remain highlighted until another row is selected.

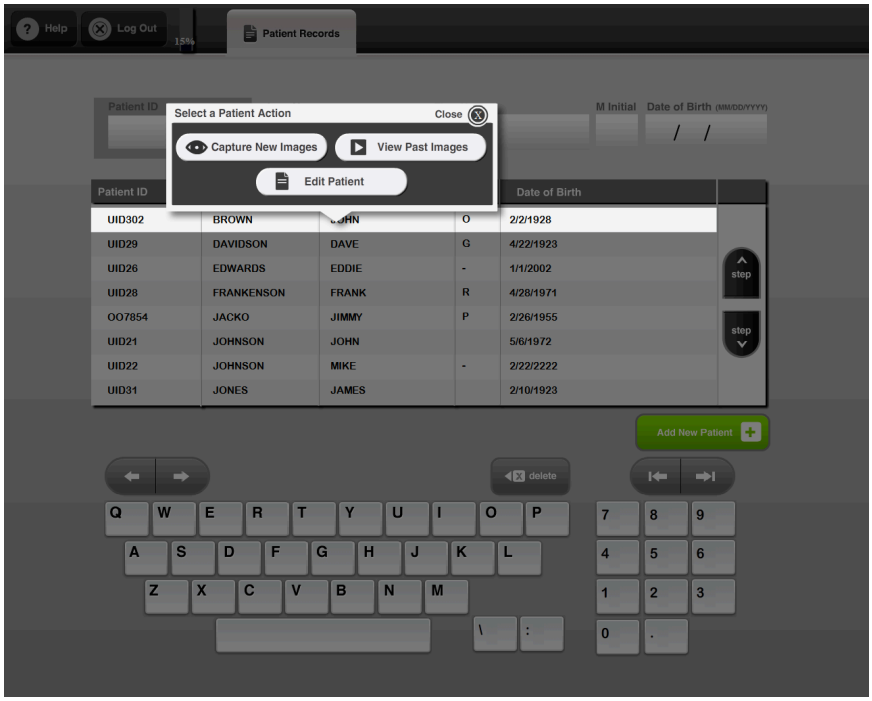

Figure 10-7: Patient Records Screen - Select a Patient Action

10.2.5 Edit Patient Information

When *Edit Patient* is pressed in the *Select a Patient Action* system message, either the screen in Figure 10-8 will be displayed showing the current information for the chosen patient, or a system message will be displayed indicating that video data has been captured for this patient and the record cannot be modified.

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Figure 10-8: Patient Records Screen - Edit Patient Information

1. ***Edit Patient Record*** - Position the cursor in the field(s) to be edited and make the changes. At a minimum, the patient record must contain 1) a Patient ID, or 2) the Last Name, First Name and Date of Birth. Continue with step 2 to save the edited data or step 3 to cancel the edit.
2. ***Save Patient Record Edits*** - Press *Continue* to update the patient's information in the database.
   A. A system message will result if a mandatory field is empty or the modified record is a duplicate of one that already exists in the database. Touch *Close* to shut the system message. Return to step 1 to correct the entered fields, or go to step 3 to cancel.

      NOTE: It is not possible to remove a patient record from the database by clearing out all fields. Once a patient record has been added it cannot be deleted.

   B. If the required fields exist and the record is unique, the system returns to the Patient Records screen in Figure 10-5 with the updated record highlighted and showing at the top of the table. Continue with Section 10.2.2, *Locate a Patient Record*.
3. ***Exit without Saving Patient Record Edits*** - Press *Cancel* to return to the Patient Records screen in Figure 10-5 without saving any edits. The highlighted row will be displayed in the same location. Continue with Section 10.2.2, *Locate a Patient Record*.

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10.3 Video Image Capture and Recording

When *Capture New Images* was chosen from the *Select a Patient Option* system message shown in Figure 10-7, the Capture Images screen in Figure 10-9 is displayed. As the screen displays, the illuminator is turned on and the system initializes the camera for approximately 1-2 seconds. The right end of the menu bar contains the patient information as entered in the selected patient record.

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NOTE: If the Capture Images screen was reached by mistake, or to exit without capturing a video, press the *Log Out* tab, or press *Save All/Continue*, which will transition to the View Images function. From the menu bar on the View Images screens, all tabs are available for selection.

Figure 10-9: Capture Images Screen

10.3.1 Capture Images Screen

The Capture Images screen is split into left and right sections.

From the left side below the *Selected Frames* header, the user chooses which eye will have video captured. Information about the video image may be selected or entered from the tags below.

- **View OD** (Right Eye) – Select this to move the camera into position to view the right eye. This selection automatically illuminates the appropriate fixation bank for the patient's left eye. The patient fixates on a light with the left eye while the right eye image is being captured.
- **View OS** (Left Eye) – Select this to move camera into position to view the left eye. This selection automatically illuminates the appropriate fixation bank for the patient's right eye. The patient fixates on a light with the right eye while the left eye image is being captured.

  NOTE: The frame that is white indicates the selected eye. The frame that is grayed out was not selected.
- **Pre-set Tags** (rounded, gray color) – If applicable, the user may select one or both of these configurable, descriptive tag names before or after the video is captured. Once the video is saved, information selected here is permanently retained with the video data. These tags are pre-set by the Administrator as described in Section 16.3, *Admin System Setup*.
- **Key-in Tags** (rectangular, white color) – If desired, the user can enter up to 15 characters of information into each of these two fields before or after the image is captured. Information is typically specific to the patient or image. Once the video is saved, information entered here is permanently retained with the video data.

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The right side of the screen is initially blank, but will display images of the selected eye as the video is recorded. Prior to recording the video image, the following controls are used to obtain the best possible image:

- **Left slider** – Touch the step keys to move the entire motion stage (including camera and illuminator) up and down for proper positioning. The button on the slider indicates the current motor position.
- **Horizontal slider** – This slider moves the camera inside the motion stage to the left or right. When *View OD* or *View OS* is pressed, the camera is moved to a default location for the selected eye near the OD or OS button on the slider. The camera position is fine-tuned by touching a location on the slider or by pressing the left or right step keys. While on the Capture Images screen the software will remember the last position of the camera for both *View OD* and *View OS* until *Save All/Continue* has been pressed. This enables the operator to easily move between the right and left eyes by touching *OD* and *OS* on the slider bar.

- **Automatic Image Centering-** An alternative method of centering the eye on the screen is to touch the location on the live video that should be in the center (typically the pupil). The camera will automatically be moved to the location that was touched on the screen, and that location becomes the center of the video image.
- **Fixation Light** – The three-way button on the top right of the Capture Images screen operates a fixation light, which consists of a vertical set of three light emitting diodes (LEDs) behind the camera for the patient to look up, look straight ahead or look down. The default position is straight ahead.
- **Focus slider** – This slider moves the camera inside the motion stage forwards and backwards to bring the image in (-) or out (+).

NOTE: To change the position of the item controlled by a slider, press the desired location on the slider. The item and the button will move accordingly. Touching the button and dragging it has no effect.

10.3.2 Capture the Video

The following steps instruct the user on how to set up the device, position the patient and capture the video:

1. ***Eye Selection*** - On the left side of the screen touch *View OD* or *View OS* for the eye to be captured. *View OD* is the initial default if no selection is made. Once a video has been recorded, the default selection is the last eye captured. The selected view will be white and the other will be a gray color.
2. ***Pre-set Tags*** - Select one or both of the pre-set tags, if desired. The system will note a selection with a checkmark. The selection may be made here or while previewing the captured image in Section 10.3.3. If selected here, it may be updated anytime until the video is saved.

   NOTE: Press the checked tag again to deselect it.
3. ***User Defined Key-In Tags*** - If desired, use the key-in tags to record additional information in each tag. Information may be entered here or as part of previewing the captured image in Section 10.3.3. If entered here, it may be updated anytime until the video is saved.
   C. Touch a key-in field to display the onscreen keyboard.
   D. Enter information in one or both of the key-in tags.
   E. Touch *Submit* on the left of the onscreen keyboard. The screen in Figure 10-9 will be displayed with the updated tag names.
4. ***Disinfect*** – Disinfect the chin and forehead rest surfaces with alcohol prior to patient use.
5. ***Patient Positioning*** - Have the patient sit facing the LipiView® Interferometer. Ensure the patient's chin is placed fully forward into the chin rest and the patient's forehead is placed firmly against the forehead rest to ensure proper attitude of the patient's head. If the patient's head is not in the proper position, valid video data may not be collected. Instruct the patient to look at the orange fixation light.

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Caution: **Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct the patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.**

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6. ***Chin Rest Height Adjustment*** - Adjust the height of the chin rest by spinning the fluted roller near the base of the chin rest so that the lateral (temporal) canthus is aligned with the horizontal canthus alignment marks on the left and right sides of the forehead rest. Spin the roller to the right to lower the chin rest and spin the roller to the left to raise it.
7. ***Camera Adjustment*** – By default the camera should be in the general location of OD or OS (depending on the view selected in step 1, as shown in Figure 10-10. Position the height of the camera by stepping the motors up and down using the left slider. Use the horizontal slider to adjust the camera sideways. Alternatively, touch the desired location the screen which will automatically move the motion stage and the camera to that position and then center on it. Adjust the image until the pupil appears in the center of the live video screen and the reflected tear film image is within the green targeting rectangle.

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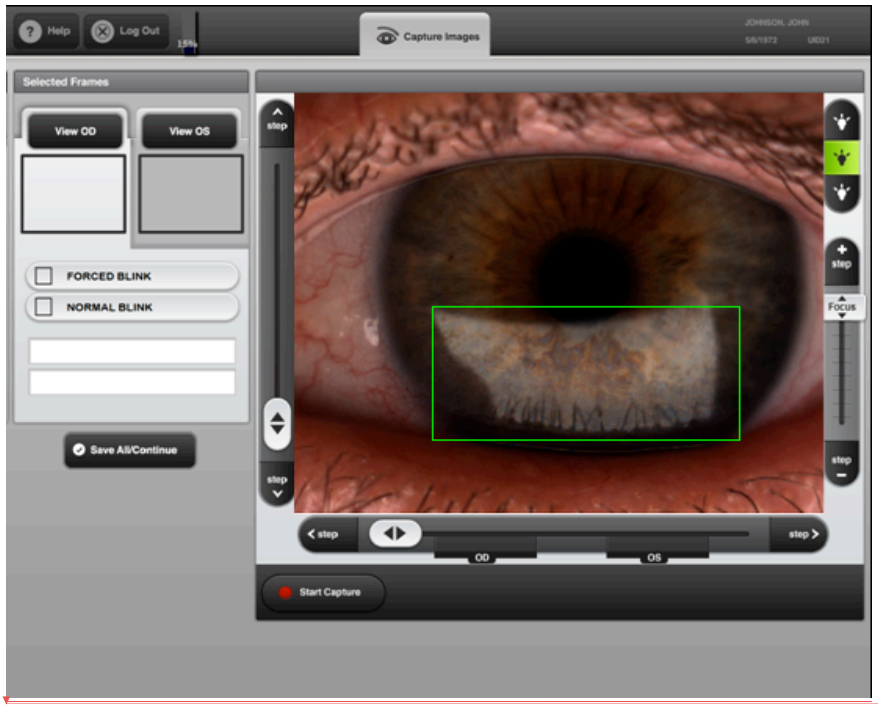

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Figure 10-10: Capture Images Screen - Centering Eye Before Recording

8. ***Camera Focus*** - Adjust the closeness of the image with the Focus slider on the right. The focus should be adjusted so that the tear film image is clear and not blurred.

   NOTE: If the tear film image is not in focus, invalid video data may be saved. As shown in Figure 10-16, analysis of invalid video data is unable to produce a graph and numerical results.

9. ***Fixation Light / Patient Gaze*** - Ensure the patient is looking in the proper direction to facilitate obtaining a well-centered and focused picture for the patient's eye. If necessary, press the upper or lower sections of the Fixation light, guiding the patient to look up or down.
10. ***Capture Image Start*** - Press *Start Capture* to begin recording approximately 20 seconds of video. Typically 10-15 seconds of video is enough to capture the tear film image as the patient blinks. Instruct the patient to blink naturally (e.g., NORMAL BLINK) or to perform a squeezed blink (e.g., FORCED BLINK) as desired, to evaluate the distribution of the tear film.

    NOTE: The blinking red light indicates the LipiView® Interferometer is recording, and the *Start Capture* button is renamed to *End Capture*. Other than pressing *End Capture,* the grayed out screen does not allow user interaction.
11. ***Capture Image End*** - Press *End Capture* to stop recording before 20 seconds has elapsed, or the system will automatically end the video after 20 seconds.
12. The illuminator is turned off when recording stops, and the screen in Figure 10-11 is displayed allowing the user to choose from several options. Continue with Section 10.3.3, *Preview Captured Image*.

10.3.3 Preview Captured Image

The right side of the Preview Captured Images screen in Figure 10-11 contains the video image just recorded. The left side of the screen contains the same functionality as the Capture Images screen (Figure 10-9), indicating information about the image. *View OD* or *View OS* indicate the eye being shown. When video for both eyes has been captured, the most recently captured video is the one displayed by default.

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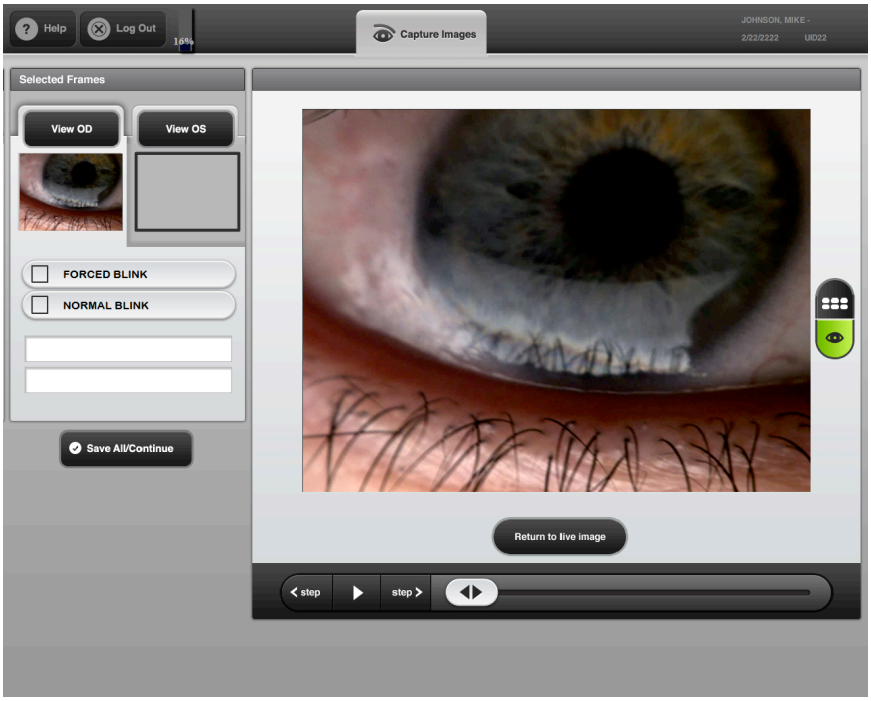

Figure 10-11: Capture Images Screen - Preview Captured Images

The Preview Captured Images screen enables the user to perform one or more of the following steps. Steps 1 – 4 are optional and they may be combined with other steps. Unless the user logs out of the system, the captured video must be saved (step 5) before other tabs become visible.

1. ***Preview Image*** - Preview the image using the following control keys:
   - **< step** – Press to step backwards through the video one frame at a time.
   - **Triangle/Vertical lines** – Press to play (triangle) or pause (two vertical lines) the video.
   - **step >** – Press to step forwards through the video one frame at a time.
   - **Video slider** – When in play mode, the button moves along the slider indicating the current position within the video. When in pause mode, press any location on the slider to move the video to the position indicated by the touch. The button will move to the new location.
   - **Toggle key** - The toggle key positioned to the right of the screen switches between a tear-film view and a full-eye view. Press the tiles to select the tear-film view. Press the eyeball to select the full-eye view. The green portion of the key indicates the active view.

2. ***Rerecord Video*** - Rerecord the video by pressing *Return to live image* above the video controls. The Rerecord Video screen in Figure 10-12 will be displayed. Continue with Section 10.3.4, *Rerecord Video*.
3. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the preview screen.
4. ***Eye Selection*** - Press the tab for the other eye (*View OD* or *View OS*). Figure 10-9 will be displayed for the selected eye. Return to Section 10.3.2, *Capture the Video* and follow the instructions. When the second video capture ends, Figure 10-11 is displayed with the most recently captured video showing. Return to step 1 and follow these steps for the second eye.
5. ***Save Video*** - Save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Rerecord Video screen in the next section.
   B. After the image is saved, the illuminator is turned off and the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

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10.3.4 Rerecord Video

The Rerecord Video screen in Figure 10-12 is used when the captured image for one or both eyes is not acceptable to the user and it is necessary to rerecord the live image before it is saved. When this screen is displayed, the illuminator light is turned on.

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This screen operates like Capture Images screen in Figure 10-10 except that when *Start Capture* is pressed, a system message asks the user to confirm that the user is intentionally overwriting the previous image. The image may be rerecorded any number of times. There is also an additional button on the bottom center of the screen allowing the user to return to the previously recorded image.

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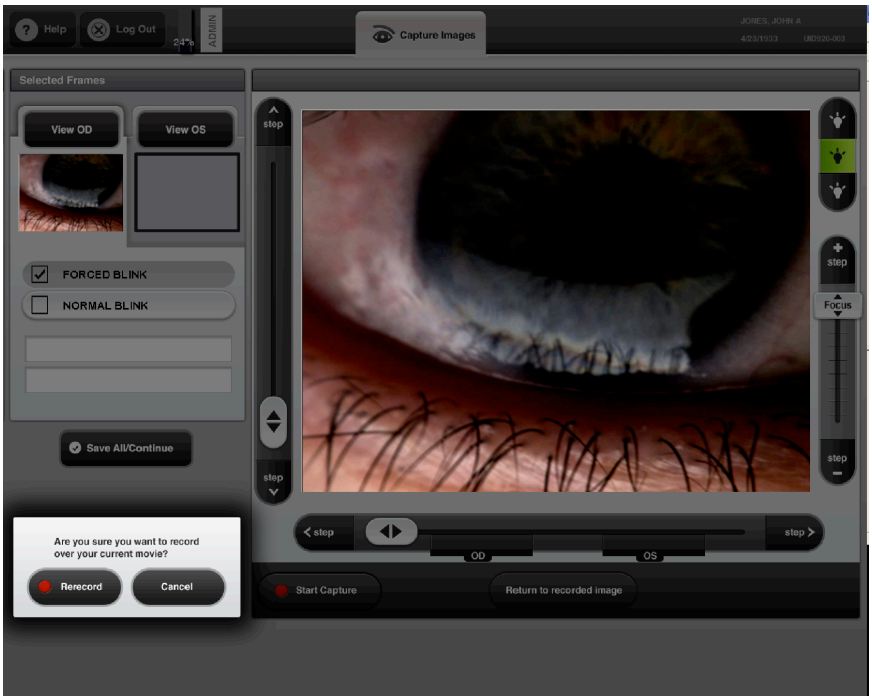

Figure 10-12: Capture Images Screen - Rerecord Video

1. ***Confirm Whether to Rerecord*** - If unsure whether to rerecord the image or if this screen was reached in error, press *Return to recorded image* to return to the Preview Captured Image screen in Figure 10-11. Follow the steps in Section 10.3.3, *Preview Captured Image*.

   NOTE: Toggle between these two screens by pressing *Return to recorded image* and *Return to live image*.
2. ***Eye Selection*** - If video for both eyes has been captured, ensure that the correct eye has been selected.
3. ***Camera Focus and Settings*** - Prior to rerecording, touch the screen or use the slider bars to reposition the camera, and modify the Fixation Light and Focus settings if needed.
4. ***Rerecord Image or Cancel*** - Press *Start Capture*. A system message will appear on the bottom left of the screen to rerecord or cancel the request.

   A. Press *Rerecord* on the system message to begin capturing another image. When *End Capture* is pressed, the illuminator is turned off and the system returns to the screen in Figure 10-11. Return to Section 10.3.3, *Preview Captured Image*.

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NOTE: When *Rerecord* is pressed, the original captured image will be overwritten with the new one. Recording of the image can be repeated as many times as needed until the image is acceptable.

B. Press *Cancel* on the system message when unsure whether to rerecord. The system message will be removed. Return to the recorded image (step 1), rerecord the image (step 4A) or continue with step 5.

5. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the previous screen.
6. ***Save Video*** - When the captured image is satisfactory, save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Preview Captured Images screen in the previous section.
   B. After the image is saved the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

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10.4 Video Review and Analysis

The Video Review and Analysis function is used to review information about a captured video for one or both of a patient's eyes. The View Images screen used to perform this function may be accessed after capturing a new video (continue with Section 10.4.1) or after selecting an image(s) from the patient's history (continue with Section 10.4.2). Patient information as entered in the selected patient record is listed on the right side of the menu bar. Other information on the screen will vary depending whether video was captured for both eyes, and whether the video has been analyzed.

10.4.1 View Images Screen after Capturing New Video

When *Save All/Continue* is pressed from any of the Capture Images screens in Section 10.3, *Video Image Capture and Recording*, the View Images screen in Figure 10-13 is displayed. From this entry point, the image on the screen is that of the eye(s) just saved. The OD eye is displayed on the left side of the screen and the OS eye is displayed on the right side of the screen. If only one eye was captured, the other half of the screen is blank. Since the images have not yet been analyzed, the numerical calculations below the images will be zero, and a message on the graph indicates that the user needs to press *ANALYZE IMAGES* to view the data.

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Continue with Section 10.4.3, *View Images and Analyze Data.*

Figure 10-13: View Images Screen – Images not Analyzed

10.4.2 View Images Screen after Selecting from Patient History

When *View Past Images* is chosen from the *Select a Patient Action* system message, the user is directed to the screen in Figure 10-14 or to the screen in Figure 10-16, depending on the previous video that was reviewed.

If the previous video reviewed was from the same patient record that is currently selected, Figure 10-16 is displayed with the previously reviewed video showing and the Patient History list closed. Continue with Section 10.4.3, *View Images and Analyze Data*.

If the previous video reviewed was from a different patient record, the View Images screen is displayed with the tabular Patient History list open, as shown in Figure 10-14, so that the user can select which video(s) to display. The Patient History contains an inventory of all videos saved for the selected patient with the date and time as well as any information in the pre-set or key-in tags. If a video has been cloned, the patient history file will display "CLONED" to the right of the time. If the video has been archived and is no longer online, "ARCHIVED" will be displayed to the right of the time. The process of cloning and archiving videos is an Administrator function, discussed in Section 16.7.1, *Disk Cloning*. An empty Patient History table (no video images) indicates that video data has not been saved for this patient.

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The top left and right frames of the View Images screen are blank until videos have been selected. From the Patient History, the user will either select one or two videos, or press the *Close Patient History* so that other tabs become visible for selection.

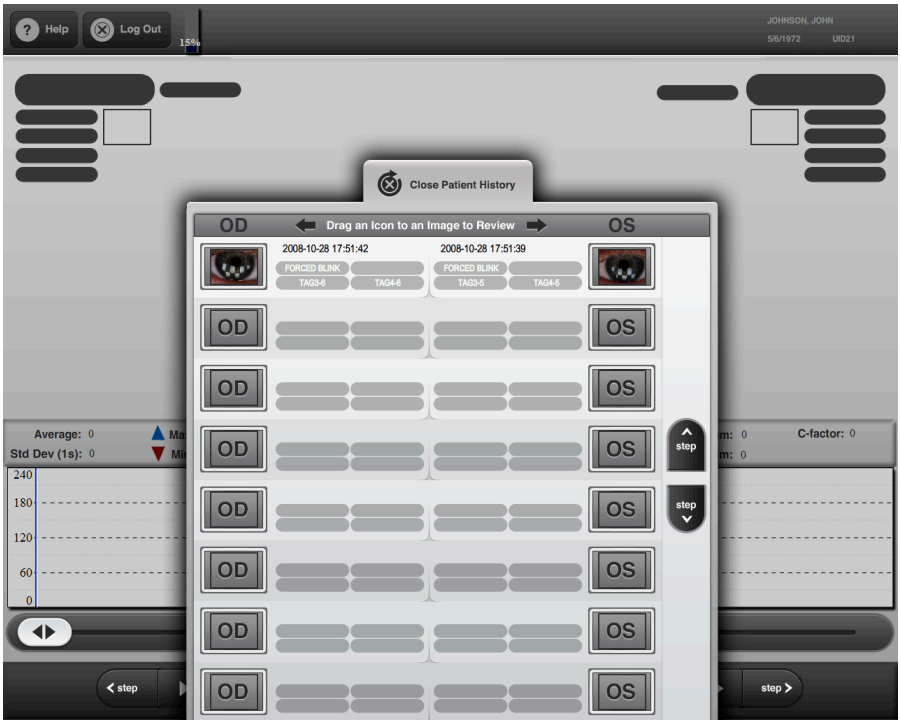

Figure 10-14: View Images Screen - Select Past Images from Patient History

If a video will not be selected from Patient History, skip to step 6; otherwise, follow the steps below to select the video(s):

1. ***Locate First Video*** - Locate a video that will be loaded. Touch the step keys on the right to move backwards and forwards through the list if the Patient History table contains more than eight videos.
2. ***Load First Video*** - To load the video:
   A. Touch the thumbnail image located next to the date/time stamp of the video. If the video was archived, a system message appears asking for confirmation to restore the video. Choose from one of the following:
      - Press *Close* to return to the open Patient History list, and repeat step 1 to locate a different video, or continue with step 6 to close the Patient History list.

- Press *Restore Video* on the system message to start copying the archived video. A progress dialog will appear showing the status of the restore. Once the file has been restored, the word ARCHIVED will be removed from the Patient History list. Touch the video again and continue with step B.

  NOTE: If a progress dialog does not appear indicating the start of the restore process, contact the Administrator to check the validity of the of the clone path on the Networking screen.

B. Drag the thumbnail image into the rectangular frame in the upper corner on either the OD or the OS side.

   NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

C. Drop the image by releasing your finger.

3. ***Video Loaded*** - The eye selection, date of captured video, pre-set and key-in descriptions, Username that captured the video and an image of the selected video will be copied into the blank tag cells as shown in Figure 10-15.

4. ***Locate / Load Second Video*** - Repeat steps 1 and 2 to select the second thumbnail image if desired, dropping in into the frame in the other corner.

   NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

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Figure 10-15: View Images Screen - Videos Loaded from Patient History

5. ***Confirm Images Loaded*** - Confirm that the images loaded are the ones to be displayed. Update the left and right frames if desired, by dragging and dropping alternate thumbnail images.

   NOTE: Once an image has been dragged to either corner it cannot be removed; however, each additional image that is dragged and dropped will replace the previous one.

6. ***Close Patient History*** - Press *Close Patient History* at the top of the tabular list. The list will shut and the button will move the bottom of the screen. A message to wait will be displayed while the selected video(s) are loaded. Upon completion, continue with Section 10.4.3, *View Images and Analyze Data*.

   NOTE: If the Patient History table is closed without selecting a video, the screen in Figure 10-16 is displayed; however, there are no images shown on the top half of the screen. This sequence typically happens when the user has pressed the *Capture Images* tab in error, and wants to make the other tabs available. Since there are no images to view, the user should select from one of the tabs in the menu bar at the top of the screen.

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10.4.3 View Images and Analyze Data

The View Images screen contains seven key sections, which are described below. Figure 10-16 shows the View Images after the images have been analyzed. One video shows valid image data; the other does not.

- **Video Images** – The top half of the screen contains frames for the OD and OS videos, when they are captured/selected for viewing. Each "Frame" is set to "1" initially, and the frame number is incremented as the video plays.
- **Video Descriptor** – Identifying information just beneath each video image includes OD or OS, the date and time of capture, and any pre-set or keyed in descriptive tag names.
- **Analyze Images button** – Pressing *Analyze Images* results in a numerical analysis of the interferometric colors and a graph for each of the videos. If for some reason the analysis cannot be performed, a message *NO VALID ANALYSIS DATA FOR VIDEO* replaces the graph, and the numerical information remains zero. After the analysis has been completed, the records are saved to the database. (Note: recorded images may only be analyzed once; attempting to "re-analyze" a set of images will result in an error.)
- **Numerical Analysis** – After the video has been analyzed, the following statistics above each graph are updated:
  - **Average** - The average ICU of all the frame averages (denoted by the black line in the graph).
  - **Std Dev** - The standard deviation of the frame averages.
  - **Maximum** - The maximum ICU recorded for a given frame.
  - **Minimum** - The minimum ICU recorded for a given frame.
  - **C-Factor** - The tear film Conformance factor for the entire video. The C-factor is defined as the percentage of pixels in the tear film that fall on the interferometric color spectrum. A C-factor of 1.0 indicates that every tear film pixel throughout the entire video loop has found a close match to an Interferometric color.
- **Graph** – After the videos have been analyzed, each graph shows the average Interferometry Color Unit (ICU) and standard deviation for each frame corresponding to the location in the video. Each point on the graph is the ICU value for that frame. The blue line and region is the upper standard deviation of the ICU score data. The red line and region is the lower standard deviation of the ICU score data. The blue triangle marker denotes the point on the graph that contains the maximum ICU score. The red marker triangle marker denotes the point on the graph that contains the minimum ICU score.
- **Video Controls** – The controls under each graph include a slider bar, backwards (< step) and forwards (step>) buttons and a play/pause button and function as described in Section 10.3.3, *Preview Captured Image*. Videos may be played before or after they have been analyzed.

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- **Open Patient History button** – Pressing this button opens the Patient History list on top of the View Images screen and allows different videos to be selected for this patient. When the list is closed it returns to this button.

When the View Images screen is displayed after capturing new video, an analysis of the image data has not occurred yet, as seen in Figure 10-13. When the View Images screen is displayed with video from the Patient History, an analysis of the image data may or may not have occurred. If the data has been analyzed, the numerical information will be filled in and a graph will show under the video as shown in Figure 10-16.

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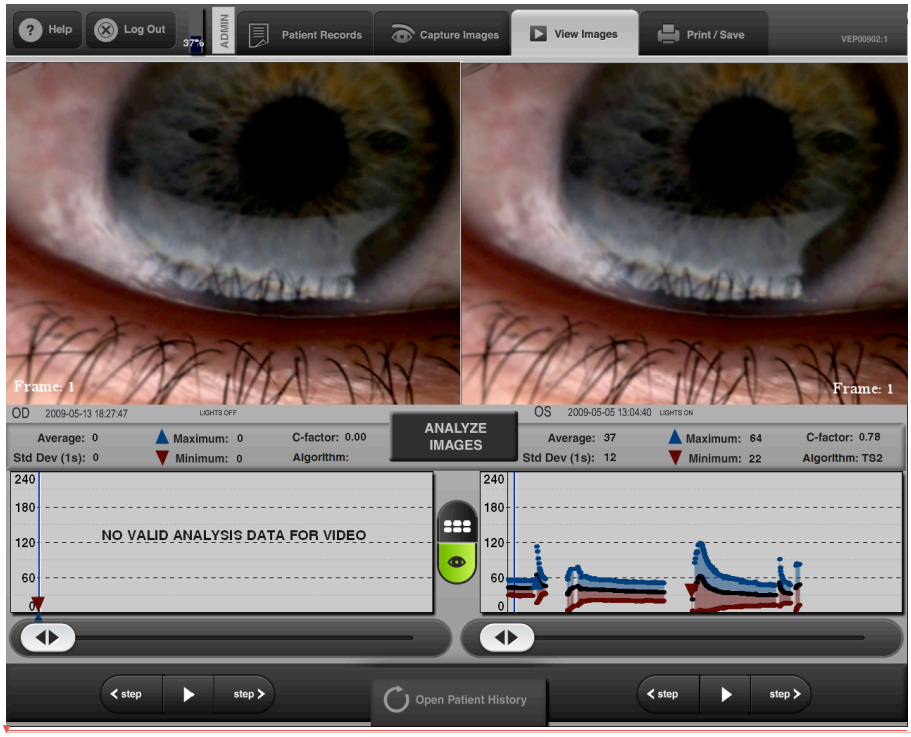

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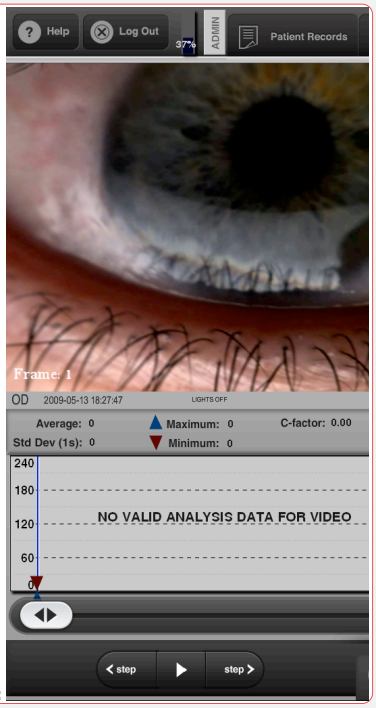

Figure 10-16: View Images Screen – Analyze Images

The following steps provide guidance on options for viewing and analyzing the video image data.

1. ***Select View of Eye*** - Press the toggle key between the graphs to select a full-eye view (eyeball) or the isolated tear-film view (tiles). The isolated tear film view separates the tear film area and indicates the area being analyzed. The green portion of the key indicates the active view.
2. ***Analyze Images*** - If the video image data has not been analyzed, press *Analyze Images* in the center of the screen to generate a graph (see Figure 10-16) of the

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ICU values for each frame. This may take several seconds. The graph shows the average ICU for each frame along with ranges for the standard deviation. Blank spots on the graph occur when the patient is blinking or the patient's eye is not stationary. Data resulting from the analysis is automatically saved in the database.

3. ***View Left Video*** - To view video of the eye on the left side of the screen (typically the OD):
   A. Press the triangular "play" button centered between the two "step" buttons on the lower left of the screen to loop through the video. As the video plays, the button on the slider indicates position and a vertical line moves across the graph.

      NOTE: When pressed, the "play" button changes to a "pause" button indicated by two vertical lines.

   B. When the video is paused, use the backwards (< step) and forwards (step >) buttons to move through the video frame-by-frame, or touch a spot on the slider bar to move the video to that location.
4. ***View Right Video*** - To play the video of the OS eye on the right of the screen (typically the OS), follow the instructions in step 3, using the controls on the lower right of the screen.
5. ***Select New Video*** - To view a different video for the selected patient record, press *Open Patient History* at the bottom of the screen, and follow the instructions in Section 10.4.2, *View Images Screen after Selecting from Patient History*.
6. ***Print and Save Video*** - To print the image and graphical analysis or to save it to an HL7 compatible system, press the *Print / Save* in the menu bar at the top of the screen and continue with Section 10.5, *Video Print and Save*.

10.5 Video Print and Save

From the View Images screen, the Print /Save tab is visible, allowing the report of the analyzed images to be printed, saved to an external drive as an Adobe PDF (Portable Document Format) file, or saved to an HL7 compatible system. Refer to Section 16, *Administrator Instructions for Use* for more information on HL7 and instructions on how to set up the HL7 parameters. The HL7 database must be configured by the Administrator prior to use.

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The report header contains patient and practice information. Patient information is taken from the patient record, and consists of the Patient ID and the name if entered. The date of report and the Username of the operator who captured the video follow. Practice information consists of the name, address and phone number of the practice, and the serial number of the LipiView® Interferometer used. Practice information is set up by the Administrator per the instructions in Section 16.3, *Admin System Setup*.

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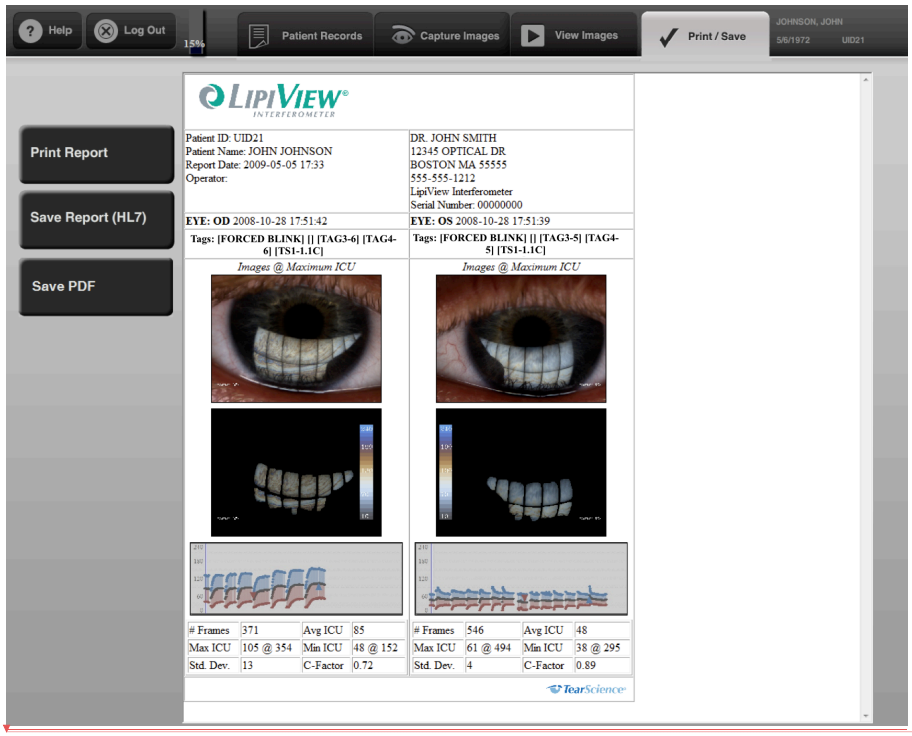
Below the patient and practice information, the report contains information about the eye displayed (OD/OS), the date and time of video capture, and information contained in the pre-set and key-in tags. An image of the frames containing the maximum average ICU

displayed both in full-eye and tear-film views. Beneath the images are the graphs and various metrics about the frames captured, and the ICU values.



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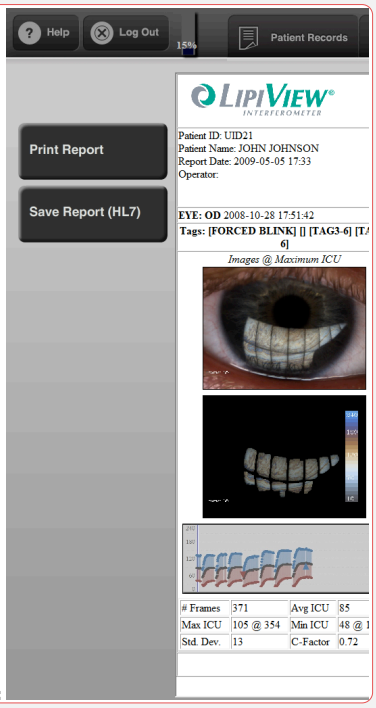

Figure 10-17: Print/Save Screen - Sample Report

Print Report - To print the report:

1. Press *Print Report* on the left menu.
2. Follow the standard windows printing prompts for sending the report to the printer attached to the LipiView® Interferometer.

   NOTE: The printer must be attached by the Administrator prior to use. Refer to Section 16.8, *Admin System Options* for a description on printer setup.

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Save Report to HL7 - To save the printed report to an HL7 compatible system:

1. Press *Save Report (HL7)* on the left menu.
2. A system message called HL7 Basic Socket Transfer is displayed.
   A. Press *Send HL7* to store the data in the HL7 database.
   B. Press *EXIT* to return to Figure 10-17 without saving.

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NOTE: The HL7 database must be configured by the Administrator prior to use. If the system message does not appear, contact the Administrator. Refer to Section 16.7.2, *HL7* for instructions on how to set up the HL7 parameters.

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Save Report to External USB Drive as a PDF - To save the printed report as a PDF file:

1. Connect an external USB drive or USB key to the LipiView.
2. Press *Save PDF* on the left menu.
3. When the system reports that the PDF has been saved successfully, press *Close*.

10.6 Online Help

Online help is available for each of the screens in the system. Press the *Help* on the left side of the menu bar at the top of the screen to display information pertinent to that screen. Press *Help* again to close the file.

10.7 Log Out

After the user has logged into the system the Log Out tab is visible on the menu bar of each screen. Pressing *Log Out* returns the user to the Login screen described in Section 10.1.3, *User Login*.

11 Cleaning

Table 11-1 identifies the components of the LipiView® Interferometer that requirement cleaning. For each component, the frequency and method of cleaning is provided.

Table 11-1: LipiView® Interferometer Cleaning Information

Component	Frequency	Method
Chin rest and forehead rest surfaces	Immediately prior to use and prior to storage.	Alcohol.
Camera lens	Monthly.	Wipe with a lint-free photographic quality lens cloth.
Touchscreen Display Monitor	When soiled or as needed.	• Power off the device. • Apply window or glass cleaner to a cloth rag and wipe the screen. • Do not apply cleaner directly to the screen. • Do not clean the monitor with alcohol, paint thinner, benzene or compressed air.
LipiView® Interferometer exterior	When soiled or as needed.	• Wipe down the exterior of the LipiView® Interferometer with a mild soapy cloth.

Component	Frequency	Method
		• Do not use bleach, chlorine or acetone-based solutions to clean any part of the chin rest support or the system enclosure.
Optional external monitor	Follow manufacturer's cleaning instructions.	Follow manufacturer's cleaning instructions.

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12 Storage and Transport of the LipiView® Interferometer

Before storing the LipiView® Interferometer, ensure that the power switch is off, and that the chin and forehead rest surfaces have been cleaned according to the instructions in Section 11, *Cleaning*. The LipiView® Interferometer should be stored in a way that prevents contamination and damage between uses.

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To transport the LipiView® Interferometer, ensure power cord is unplugged and secured off the ground. Grip on metal portion of the device, in two locations: 1) base of the chin rest, 2) monitor arm behind the screen. Carefully lift and transport in an upright position.

13 Maintenance and Servicing

Expected life of the LipiView® Ocular Surface Interferometer is 5 years.

> **Note**: No user serviceable components are inside the unit.
> Maintenance is not required. The LipiView® Ocular Surface Interferometer performs a calibration process upon powering on. See Section 10.1.1

For Field Service contact TearScience in North America at +1 919 459 4891 or by email at customerservice@tearscience.com.

14 Disposal

The LipiView® Interferometer consists of an ABS plastic enclosure, aluminum chassis, circuit boards, and electrical components. In the unlikely event that the controller is damaged and cannot be repaired, never dispose of the device. The LipiView® Interferometer should be returned to TearScience. Refer to the contact information on the first page of this manual for the appropriate return address.

15 Troubleshooting

15.1 Unexpected Events

Table 15-1 lists actions to take if an unexpected event occurs.

Table 15-1: Troubleshooting Unexpected Events

Event	Action to Take
Device will not power up (after pressing the power switch, the screen remains dark.)	(1) Ensure the system is securely connected to a power outlet and connection into device is secure, then press the power switch again. (2) If Step 1 is not successful, carefully lift the system to expose the underside of the base and determine if a red Reset button is located at the back of the unit, near the power switch. If so, press Reset button. If no Reset button is found, contact Customer service for assistance. If the problem persists contact TearScience.
Problem reported during Power On Self Test (POST).	Power cycle the device. If the problem persists contact TearScience.
Touch Screen does not respond.	Power cycle the device. If the problem persists contact TearScience.
Illuminator does not light during image capture.	Power cycle the device. If the problem persists contact TearScience.
Camera stops working.	Power cycle the device. If the problem persists contact TearScience
Disk Space Indicator shows internal disk drive is full.	Contact the Administrator to archive data (refer to Section 16, *Administrator Instructions for Use*). If the problem persists contact TearScience.
The system works except the Capture Image tab will not respond.	An error was detected during power on self-test, which affects image acquisition. Power cycle the device. If the error persists contact TearScience.
Device will not process images after acquisition.	The internal hard drive is full. Contact the Administrator to archive data (refer to Section 16, *Administrator Instructions for Use*). If the problem persists contact TearScience.
Device no longer allows image acquisition.	A power on self-test problem has been found. Contact TearScience if problem persists.

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Event	Action to Take
The message *NO VALID ANALYSIS DATA FOR VIDEO* is displayed instead of the numerical and graphical analysis when the *Analyze Images* button is pressed on the View Images screen.	The patient's head may not have been pushed forward, the patient's forehead may not have been firmly pressed against the forehead rest, or the tear film image may have been out of focus. Collect another video of the patient after ensuring that the patient's head is positioned properly and that the eye is clearly focused.
Network is not connected.	Contact your Administrator (refer to Section 16, *Administrator Instructions for Use*). If the problem persists call TearScience.
External monitor does not work.	Ensure the monitor is powered on. Ensure connections to the DVI or HDMI are made, and proper input is selected. Ensure the isolation receiver cable has power applied. Refer to Section 19, *Appendix B: External Monitor Hookup* for information on proper monitor connection.
Administrator forgets password after resetting it	Contact TearScience.
When accessing options on the System Options Administration screen, a message is displayed stating 'Too much time has elapsed since system startup to access this function'.	Selected options on the System Options Administration screen cannot be accessed after more than 10 minutes has elapsed since the system was started. Power cycle the machine and attempt to access the option again.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the warning level.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the critical level.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

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15.2 System Messages

Table 15-2 lists system messages and provides a description with actions to consider.
NOTE: The four messages: Practice information saved, Display information saved, Saved map network drive parameters and mapping drive, and Network information saved are informative only and do not indicate a problem.

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Table 15-2: System Messages

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System Messages	Description / Action to Take

System Messages	Description / Action to Take
Invalid operator name and/or password.	The login failed because the username and/or password being used to log into the device are not recognized. Correct and reenter, or confirm with the Administrator that this username and password have been set up and that the username is enabled.
Capture disabled. Contact Tear Science for support.	Videos cannot be captured because the power on self-test detected errors with the motors or camera during startup, or the Disk Space Indicator has reached the limit set by the Administrator. Existing videos can be viewed. If the disk is full, contact the Administrator to archive data. For motor or camera errors, contact TearScience.
Patient ID already exists.	The patient record cannot be added because it contains a Patient ID that already exists in the database. If a Patient ID is being included on a new patient record, it must be unique. Correct and reenter.
Patient with same first name, last name, middle initial and birth date already exists. Select the existing user or enter a unique patient ID.	The patient record cannot be added because a patient record with the same Last Name, First Name, Middle Initial and Date of Birth already exists in the database. Either select the existing patient, or to add a new patient with the same name, enter a unique Patient ID.
Either patient ID or last name, first name and birth date are required.	The patient record cannot be added or updated because required information is missing. At a minimum, a patient record must contain a Patient ID or it must contain a Last Name, First name and Date of Birth.
Videos captured for patient. Cannot edit patient information.	The patient record cannot be edited because a video(s) exist for this patient. Once a video has been captured and saved for a patient, that patient record can no longer be updated.
Enter date in MM/DD/YYYY format. Invalid date:	The patient record cannot be added because the format of the date is incorrect. One or more of the date fields is missing or does not contain a number. Confirm that the month field is a number between 0-12, the day field is a number between 0-31 and the year is a 4-digit number.
Video capture setup failed.	The video cannot be captured due to a device failure. If this occurs, exit from the Captures Images screen by logging out or pressing *Save All/Continue*. Try again, and if the error is not corrected, contact TearScience.

System Messages	Description / Action to Take
Unable to load video file X.	The video file named X could not be found on the disk when attempting to show it on the View Images screen. Try again, and if the error is not corrected, contact TearScience.
The following errors occurred: Missing username; Missing password; Missing full name;	The Operator cannot be added because one or more of the required fields (as noted) are empty. The Username, Password and Full Name are required to add an Operator.
Username already exists	The Operator cannot be added because the Username entered already exists in the database. Correct the Username and try again, or select the Username and edit the Password and Full Name fields.
Practice information saved.	This message is displayed to the Administrator to confirm that information on the System Setup screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Display information saved.	This message is displayed to the Administrator to confirm that information on the Display Options screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Disconnect failure: X	The Map Drive process cannot be completed because the Drive Letter named "X" cannot be disconnected. Try again, and if the error is not corrected consult with the Network Administrator.
Saved map network drive parameters and mapping drive.	This message is displayed to the Administrator to confirm that information on the Map Drive screen or has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Network information saved.	This message is displayed to the Administrator to confirm that the cloning and HL7 server information on the Networking screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.

System Messages	Description / Action to Take
Cannot write to clone folder: X:\OSICLONE	The Network folder named OSICLONE on the Drive Letter named X is not accessible for writing. Confirm that the Drive Letter is listed as a mapped drive on the Networking Screen. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning operation failed to start.	There was a failure with the cloning process most likely caused by an internal Windows error, and no videos were copied. Confirm that the Drive Letter entered for Disk Cloning on the Networking Screen is valid. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning canceled by user.	This message is displayed to the Administrator to confirm that the *CANCEL* button has been pressed and that the Cloning process has been stopped.
Cloning failed. Restart or contact Tear Science for assistance.	There was a failure with the Cloning process. Press *CLONE SYSTEM* again, to continue the Cloning process where it left off. If the problem continues, contact TearScience.
The used space of the system disk has surpassed the warning level. Please go to the Networking/Backup Administrator page.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
The used space of the system disk has surpassed the critical level. Please go the Networking/Backup Administrator page.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

16 Administrator Instructions for Use

16.1 First Time Setup

The LipiView® Interferometer has been set up with a default Operator Username and Password that has administrator privileges. When the system is first powered on, the Administrator should log in using LIPIVIEW for the Username and LIPIVIEW for the Password (the onscreen keyboard only supports upper case characters).

After successful log in, it is recommended but not required that the Administrator reset the password as follows:

1. Power on the system.
2. When the Login screen in Figure 10-4 is displayed:
   A. Enter LIPIVIEW for the Username.
      NOTE: The onscreen keyboard only supports upper case characters.
   B. Enter LIPIVIEW for the Password.
   C. Touch *Submit*. The Patient Records screen in Figure 10-5 should be displayed.
3. Touch the *Admin* tab at the top of the screen. The Admin Main Menu in Figure 16-1 should be displayed.
4. Press *Operator Setup* on the left menu. The Admin Operator Setup Screen in Figure 16-3 should be displayed.
5. Follow instructions in Section 16.4, *Admin Operator Setup* to modify the password and/or add additional operator usernames.

The Administrator should review Section 16 of this manual to determine any other functionality that requires set up before the LipiView® Interferometer is used for observation of tear film. At a minimum:

- Set the system date and time (refer to Section 16.8, *Admin System Options*)
- Determine at what point videos will be archived (refer to Section 16.7.1, *Disk Cloning*)

Prior to printing, a printer must either be connected through one of the USB ports on the bottom of the Touchscreen Display, or through a wireless network. Printer setup is discussed in Section 16.8, *Admin System Options*.

Prior to cloning or archiving, an external storage location must be connected. An external hard drive can be connected through one of the USB ports on the bottom of the Touchscreen Display, or a network drive can be mapped on the wireless network. Refer to Section 16.6, *Admin Map Drive*.

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16.2 Admin Main Menu

When an operator's Username is set up with *Administrator Access* (refer to Section 16.3, Admin System Setup), the *Admin* tab is visible between the Disk Space Indicator and the Patient Records tab on the menu bar of each screen.

When the *Admin* tab is pressed, the Administrator Main Menu screen in Figure 16-1 is displayed. This screen prompts the Administrator to select from one of the menu options on the left side or the top. Each Administrator screen contains the same menu. Once a button is pressed, it turns white indicating the active menu, and buttons for inactive functions are grayed out. Buttons may be selected from the Main Menu in any order, but once a menu option is active, the user must exit from that screen and return to the Main Menu before choosing another option.

The *Help* tab may be selected anytime it is not grayed out. To return to normal usage, press *Patient Records* at the top of the screen.

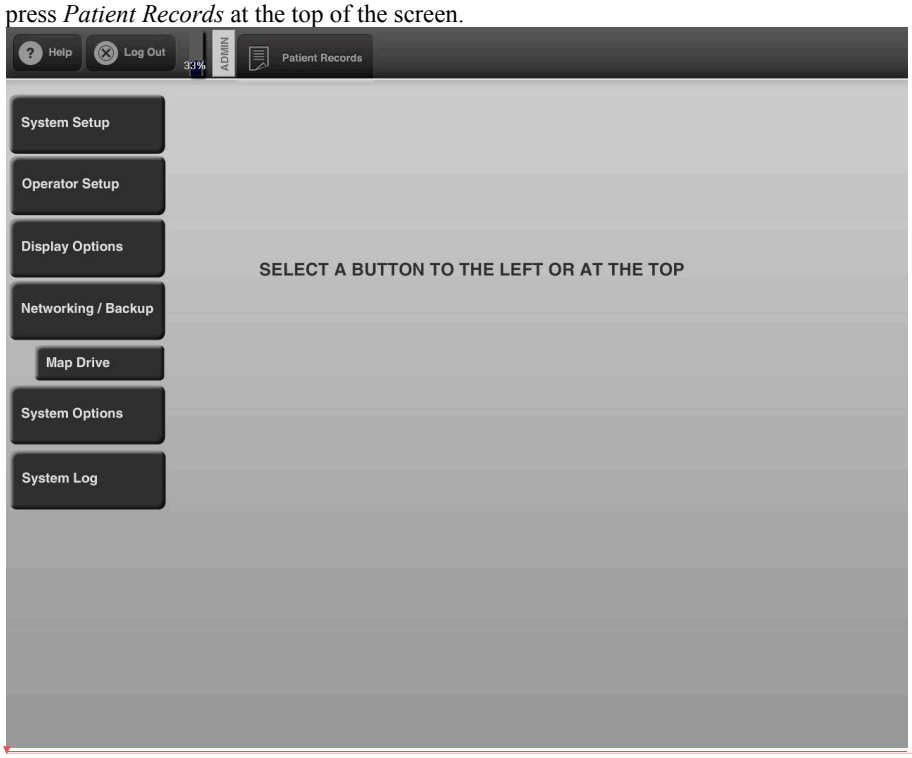

Figure 16-1: Admin – Main Menu Screen

16.3 Admin System Setup

The System Setup screen in Figure 16-2 is displayed when the *System Setup* button is selected from the Admin menu.

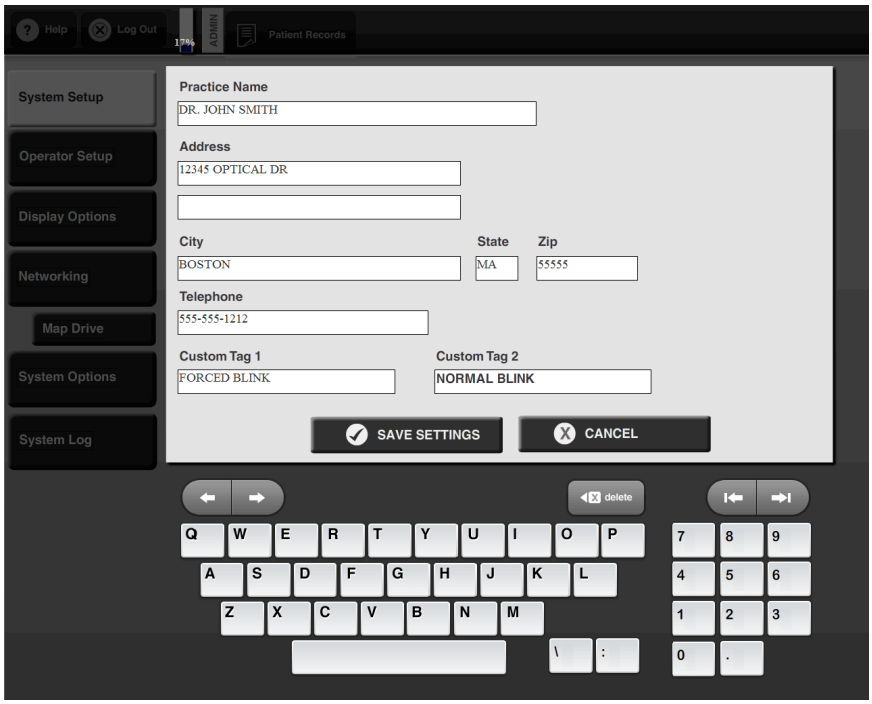

Figure 16-2: Admin - System Setup Screen

The System Setup screen contains the fields listed in step 1 for the Administrator to complete. All fields are optional. The Practice information is used for the reports as discussed in Section 10.5, *Video Print and Save*. Custom Tags 1 and 2 allow up to two tags to be pre-set with commonly used information that may be applicable to multiple videos (e.g., normal blink, forced blink). These custom, pre-set tags are displayed on the Capture Images Screens (Figure 10-9, 10-10, 10-11 and 10-12) and discussed in Section 10.3, *Video Image Capture and Recording*. If selected, information from these tags is saved with the video data, displayed on all Video Review and Analysis screens (Section 10.4), and included on the report.

1. Use the keyboard to update one or more of the fields below.
   - Practice Name
   - Address line 1
   - Address line 2

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- City
- State
- Zip
- Telephone
- Custom Tag 1
- Custom Tag 2

2. To exit this screen and return to the Main Menu in Figure 16-1, choose from one of the following and then continue with Section 16.2, *Admin Main Menu*:
   A. To immediately update the information before returning to the Admin Main Menu, press *SAVE SETTINGS*.
   B. To return to the Main Menu without saving the edits, press *CANCEL*.

16.4 Admin Operator Setup

For first time use, make sure to review Section 16.1, *First Time Setup* before making any changes to usernames and passwords.

Do not modify the ADMIN Username. This is for TearScience personnel, in the event service is required.

The Operator Setup screen in Figure 16-3 is the main screen displayed when the *Operator Setup* button is selected from the Admin menu. This screen is used to display the list of operators who have been entered into the database. The list of operators is displayed in the order of entry. Once the table contains more than six names, the step keys on the right are used to scroll backwards (upper key) or forwards (lower key) through the list.

The Operator Setup screen is also used to add new operators. To perform this task, continue with Section 16.4.1, *Add an Operator*.

Operator information, which includes granting or preventing access to the device, can be modified using a secondary operator setup screen in Figure 16-4. To make any changes to an operator's record, follow the instructions in Section 16.4.2, *Edit Operator Information*. Information about an operator may be updated but an operator's record can never be removed.

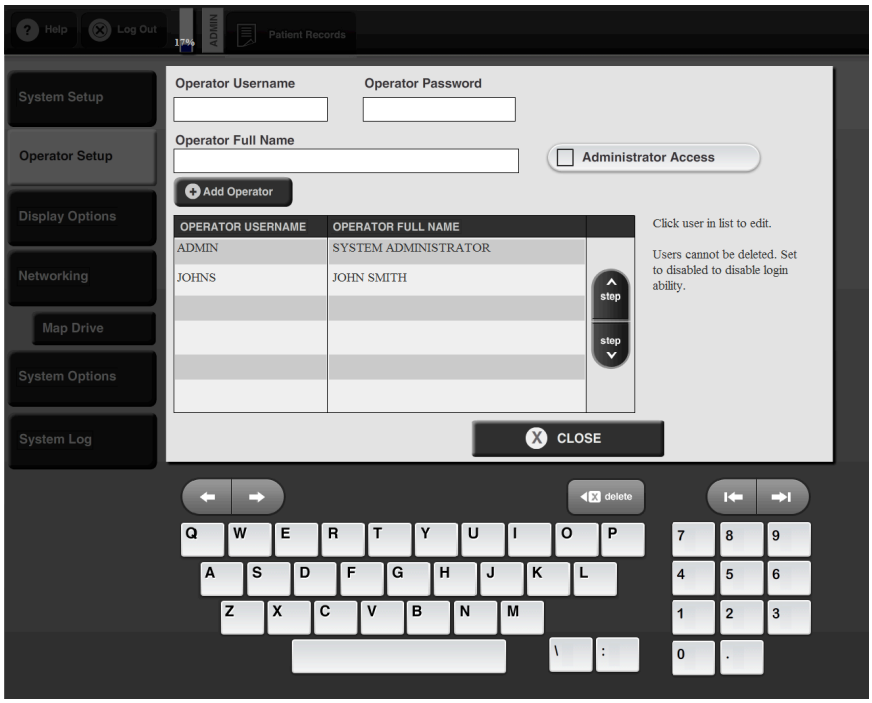

Figure 16-3: Admin - Operator Setup Screen

16.4.1 Add an Operator

Add an operator to the system as follows:

1. Enter a Username.
2. Enter a Password. There are no requirements other than the limitation of the onscreen keyboard characters.
3. Enter the full name.
4. If the user will be allowed to access the Admin tab and the administrator screens, touch the box for *Administrator Access*. A checkmark indicates selection. If this box is not selected, the *Admin* tab will not be visible when this Username is logged in.
5. Press *Add Operator* to enter the new information into the database. When a new operator is added, the status for this operator's Username defaults to "User Enabled". An enabled Username means that this Username has permission to access the device through the Login screen in Figure 10-4. A new Username may log in as soon as the current Username logs out.

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NOTE: All fields are required. If *Add Operator* is pressed when any field is empty or incorrect, or if the record is a duplicate of an existing operator, a system message will be returned.

6. Press *CLOSE* when finished and the Admin Main Menu in Figure 16-1 will be displayed.

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16.4.2 Edit Operator Information

1. To edit information associated with an Operator's Username, select the record by pressing anywhere on the row in the table. Use the step keys on the right of the table to scroll backwards or forwards through the list if more than six names have been entered.
2. The selected name will be highlighted and then overlaid onto the top of the screen, as shown in Figure 16-4. If the Username is currently allowed access to the device, the *User Enabled* box is checked. If the Username was added as an Administrator, the *Administrator Access* box is checked.

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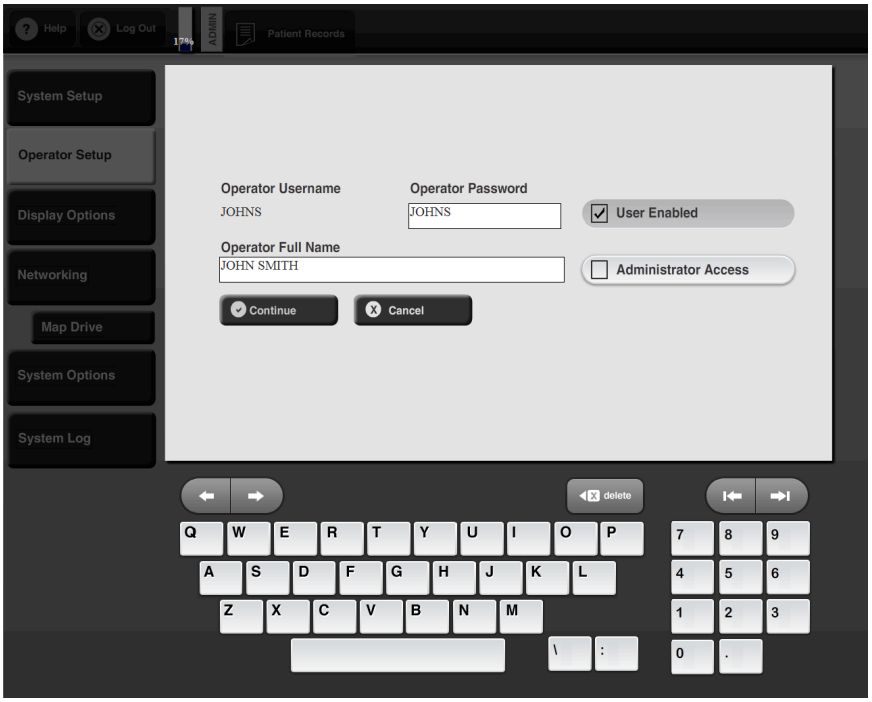

Figure 16-4: Admin - Modify Operator Information

3. Update the operator's password or full name if needed. Select or deselect the boxes for *User Enabled* and *Administrator Access*.

NOTE: Once an operator has been added, the Username cannot be deleted.

4. To exit this screen and return to the Operator Setup screen in Figure 16-3, choose one of the following:
   A. Press *Continue* to return with the record updated.
   B. Press *Cancel* to return without saving edits.
5. From the Operator Setup screen, press *CLOSE* to return to the Admin Main Menu, continue with Section 16.4.1, *Add an Operator*, or repeat Section 16.4.2 to edit an operator.

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16.5 Admin Display Options

When *Display Options* is selected from the Admin Main Menu, the screen in Figure 16-5 is used to set the saturation, contrast and brightness levels for the video display. Each level has a range of 0 – 100. Settings here do not affect the GUI.

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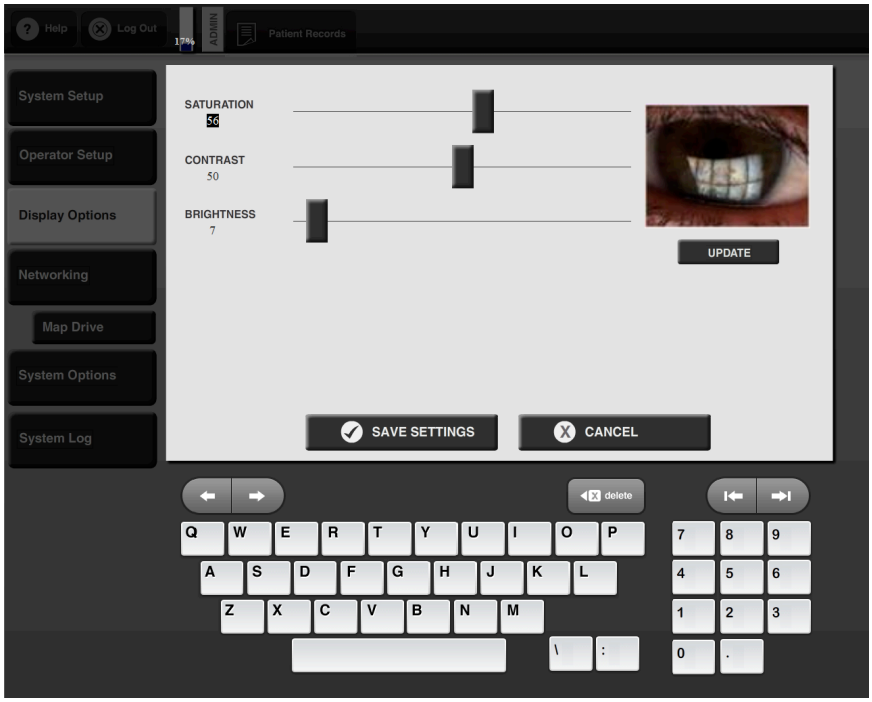

Figure 16-5: Admin - Display Options Screen

1. To modify the setting for Saturation level follow steps A-C, or skip to step 2:
   A. Move the locator bar to the left to lower the value or to the right to increase it. The new setting number will be displayed under the name on the left.

NOTE: Touching a location on the slider bar will not change the setting; the locator bar must be moved.

B. Preview the display with the new value by pressing *Update*. This allows the user to visualize the effect on a representative tear film image.

NOTE: The Contrast and Brightness levels may also be adjusted before pressing *Update.*

C. Repeat steps A and B as needed.

2. To modify the setting for Contrast level, repeat step 1 using the Contrast slider; otherwise, skip to step 3
3. To modify the setting for Brightness level, repeat step 1 using the Brightness slider; otherwise, continue with step 4.
4. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:

A. To permanently retain the saturation, contrast and brightness values on the screen, press *SAVE SETTINGS*. All future video images will use these values when displaying. A system message will indicate the display information has been saved. Press *Close.*

B. To exit without saving any changes, press *CANCEL*.

16.6 Admin Map Drive

When *Map Drive* is selected from the Admin Main Menu, the screen in Figure 16-6 is used to setup one or more network drives on the LipiView® Interferometer. A mapped drive is a location on the network, and the location is designated by the Drive Letter. Mapped drives are typically used for cloning and archiving, which is discussed in Section 16.7, *Admin Networking*.

Depending on how the network is set up, the mapped drive on the network may require that a valid username and password be entered in order to gain access. If this is the case, the username and password associated with the drive being mapped should be entered on this screen.

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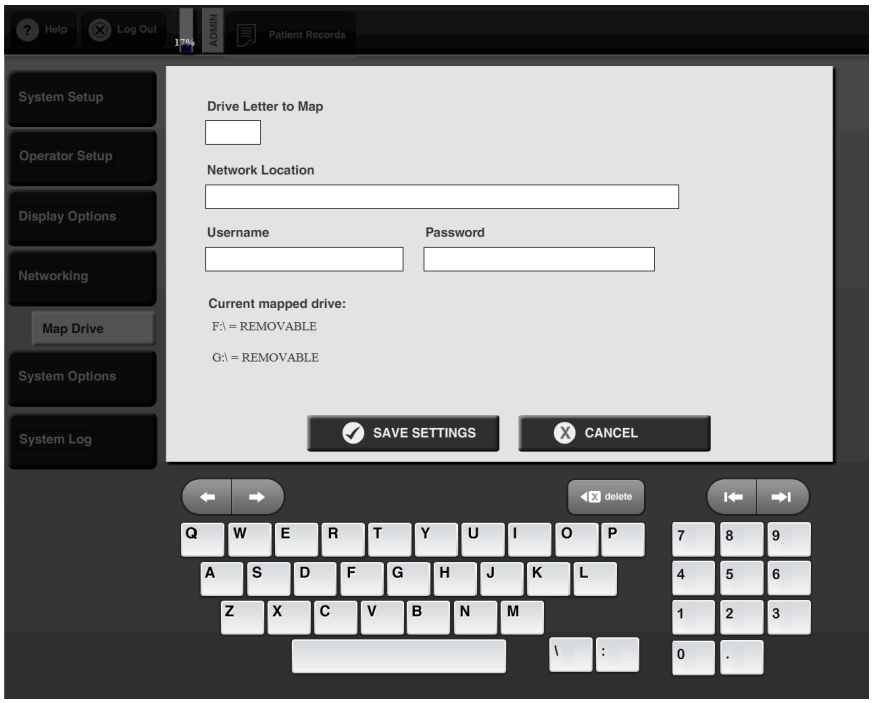

Figure 16-6: Admin - Map Drive Screen

Enter the information on this screen as follows, consulting with the Network Administrator to obtain this information if necessary:

1. In the *Drive Letter to Map* field, enter the drive letter of the network drive to which the LipiView® Interferometer will be mapped.
2. For *Network Location* – enter the server location (e.g., \\SERVER\\Location) that will be mapped to the drive letter.
3. If required to access the network location entered in step 2, enter the *Username* and *Password* interacting with your network.
4. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*.
   A. To permanently retain the drive mapping information shown on the screen, press *SAVE SETTINGS*. A system message will indicate the mapping information has been saved. Press *Close*.
   B. To exit without saving any changes, press *CANCEL*.
5. To determine whether the connection was successful, press *Map Drive* to return to this screen.
   A. If the connection was successful, the heading *Current mapped drive:* will be followed by the name and location of the mapped drive in the format

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"*:\\network_location", where '*' is the drive letter and 'network_location' is the network path.

NOTE: When storage devices such as an external hard drive or a USB flash drive are connected to the USB ports, these drives are also listed under *Current mapped drive*. In Figure 16-6, "F" and "G" are the drive letters, and "REMOVABLE" indicates the location is the USB port (rather than a network drive). When the USB port is the location only one backslash (\) is used.

B. If no network drives have been mapped, the words "No available drives found" will follow the heading.

6. If more than one drive will be mapped, repeat these instructions as many times as needed, or press *CANCEL* to return to the Admin Main Menu.

   NOTE: Once a network drive has been mapped it cannot be unmapped; however, the drive letter can be mapped to a new path.

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16.7 Admin Networking/Backup

When *Networking/Backup* is selected from the Admin Main Menu, the screen in Figure 16-7 is displayed, allowing the Administrator to perform two functions: Disk Cloning, and setting up access to an HL7 server.

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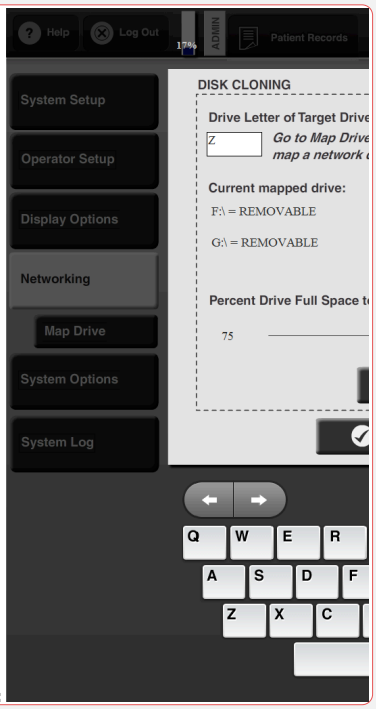

Figure 16-7: Admin – Networking/Backup Screen

16.7.1 Disk Cloning

As video information is stored on the LipiView® Interferometer, the disk drive becomes full. When the disk usage level reaches the level specified by the *Backup Notification at Percent Drive Full* slider bar, the LipiView® Interferometer issues a system message to notify the user to perform a backup. However, the device will continue to allow the user to capture additional videos. The user may either backup the database or backup the database and the videos to an external drive or network. **The backup process will permanently delete the videos from the LipiView® Interferometer.** When the disk usage level reaches 95%, the device notifies the user that a backup is required and will not allow the user to capture additional videos until the backup process is performed.

To free used disk space, one of the two following operations must be performed:

1) **Backup Database Only** – This option will copy the system database to the location specified in the Target Drive field, and then permanently delete all videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

2) **Backup Database and Videos** – This option will copy the system database and all video files to the location specified in the Target Drive field, and then permanently delete all the videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

NOTE: The Backup Database and Video process can take up to several hours to copy the videos to the external drive. Before beginning the copy process, please ensure you have adequate time to complete the process.

16.7.2 HL7

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

HL7 is a communications standard used so that a piece of medical equipment (such as the LipiView® Interferometer) can talk with an Electronic Medical Records (EMR) server. HL7 is the common language used so that information can be exchanged between EMR systems and medical devices.

After review of a video, an HL7 message with the patient information can be sent from the LipiView® Interferometer to the specified EMR server (identified by an IP address and port). The conversation is one-way from the interferometer to the EMR server. The message is sent out but the interferometer does not know if the message was received by the EMR server. Refer to Section 10.5, *Video Print and Save* for instructions on how to send the report.

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Deleted: Disk cloning means videos are copied from the LipiView® Interferometer's hard drive to an external location, which is one of the drives mapped in Section 15.6, *Admin Map Drive*. Disk cloning is like performing a backup in that the files are copied but not deleted. ... [9]

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Deleted: the predetermined fullness level is 75% for example, and the Disk Space Indicator is less (e.g., 25%), pressing *CLONE SYSTEM* will clone (copy) the files to a specific location. If the disk space level is 75% or more when *CLONE SYSTEM* is pressed, enough files will be archived to bring the hard drive level down to 10% below the predetermined percentage (in this case 65%). Archiving files begins with the oldest accessed timestamp. After a file is cloned or archived, the Patient History List is updated noting the action taken. ... [11]

Deleted: <#>save all data entered on this screen (for both Disk Cloning and HL7) without starting to clone at this time, press *SAVE SETTINGS*. A system message will indicate the mapping information has been saved. Press *Close*.
To exit without saving any changes to the screen, press *CANCEL*. ... [12]

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To exit without saving any changes to the screen, press *CANCEL*.

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Deleted: <#>all information entered on the screen, and to execute a disk clone process, press *CLONE SYSTEM*. The video files are very large (approximately 900MB), and the cloning process may take several hours to complete (or approximately 20 minutes per file). No other screens are available while the cloning process is running. Therefore, run the cloning process overnight or during some other period where the LipiView® Interferometer will not need to be used for 6 to 7 hours. ... [14]

The LipiView® Interferometer can communicate with any EMR system that understands HL7 V2.5 messages. The HL7 group of controls allows the Administrator to configure the HL7 export destination. To set up an HL7 export connection:

1. Once the LipiView® Interferometer is mapped as a network drive on the network, enter its drive letter in the *Network Drive Letter of OSI* field. The network drive letter is sent as part of the HL7 message and allows the server to access report files that reside on the LipiView® Interferometer.
2. Enter the IP address of the HL7 server. If more than one HL7 server is available, select the desired server.
3. Enter the port address on which the HL7 server is listening for HL7 messages.
4. The connection to the HL7 server can be tested by pressing *Test HL7 Server*. When pressed, a standard IP ping will be performed on the HL7 server and the results will be reported. This feature should only be used by TearScience service personnel and is beyond the scope of this manual.
5. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:
   A. To save all data entered on this screen (for both Disk Cloning and HL7), press *SAVE SETTINGS*. A system message will indicate the mapping information has been saved. Press *Close*.
   B. To exit without saving any changes to the screen, press *CANCEL*.

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16.8 Admin System Options

When *System Options* is selected from the Admin Main Menu, the screen shown in Figure 16-8 provides the Administrator with information about the system, including software versions of the shell, application and GUI, and the serial number of the system.

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Figure 16-8: Admin - System Options Screen

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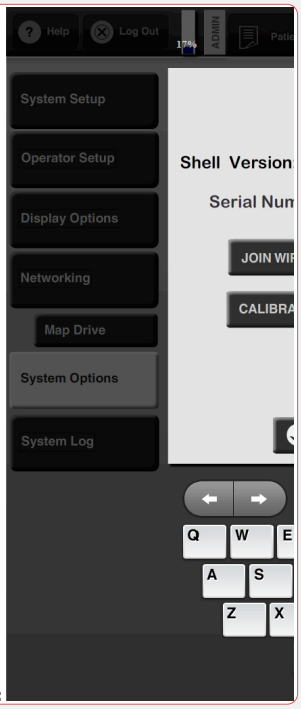

There are also five functions available on this screen:

- **Join Wireless Network** – Pressing this button displays a standard Windows *Wireless Network Connection* dialog. Use the browse dialog to connect the LipiView® Interferometer to a wireless network. Contact the Network Administrator for assistance in joining a wireless network if needed.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

- **Calibrate Touchscreen** – Pressing this button launches a calibration program for the touchscreen. This calibration can be performed when it is observed that the onscreen cursor is not matching correctly to the finger-touch locations. The program instructs the user to touch various targets on the screen, and then to press *OK* to accept the calibration. The user must press *Save Changes* to cause the calibration to be written to the disk. The calibration wizard will ask the user if the cursor is following his finger but the curser will not be visible. This is normal and should be ignored. **This option should not be used unless instructed to do so by a TearScience representative. If the touchscreen is not calibrated correctly, the touchscreen operation may be affected.**
- **Recreate Thumbnails** – Pressing this button restores the system in the event of a hard drive failure. The restore process reads all the video files present in the database, and extracts the thumbnail image that appears in the Patient History list for that video. **This option should not be used unless instructed to do so by a TearScience representative.**
- **Setup Printer** – Pressing this button will display the standard Windows *Setup Printer and Faxes* dialog. Use this dialog to set up a printer on the LipiView® Interferometer. The printer can be attached to the LipiView® Interferometer via a USB port, or it may be a network printer accessed via a wireless network. Contact the network Administrator for assistance in setting up a printer if needed.

  NOTE: If installing a USB printer, follow the manufacturer's instructions and to press *SAVE SETTINGS & REBOOT* when finished.
- **Set System Time** – Pressing this button brings up the standards Windows *Setup Date and Time Properties* dialog, and allows the Administrator to input the current date, time, and time zone into the LipiView® Interferometer. The date and time should be set during system first time setup discussed in Section 16.1.

  NOTE: It is not necessary to use the *Save Settings and Reboot* function after setting the system time.

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Access to the System Option screen functions is disabled if more than 10 minutes has elapsed since the system was started.

For any of the setting changes to become active, the system must be rebooted. Press *Save Settings and Reboot*. A system message confirming the reboot is displayed. Press *Continue* to begin the reboot, or press *Cancel* to return to the System Options screen.

Press any tab on the left menu or press *Patient Records* to exit this screen without changes becoming activated.

16.9 Admin System Log

When *System Log* is selected from the Admin Main Menu, the screen shown in Figure 16-9 allows the Administrator to review system codes that have occurred and the results of Power On Self Tests. Items are listed in this table for the current day only; however,

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all system codes in this list are stored in a database and the errors are never cleared. Use the step keys to the right of the table to scroll forwards and backwards through the table.

This page is intended to be accessed by TearScience representatives, or as directed by a TearScience technician.

After reviewing the log, press *CLOSE* to return to the Admin Main Menu.

Figure 16-9: Admin - System Log Screen

17 Warranty

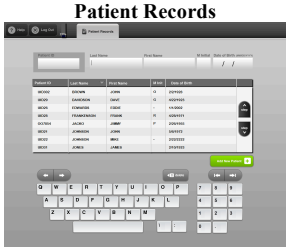
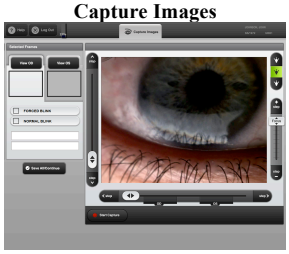
TearScience, Inc. warrants that each LipiView® Interferometer 1) is free from defects in materials and workmanship and 2) conforms to TearScience Inc.'s official specifications. The warranty period for each LipiView® Interferometer is one year commencing on the date of purchase. *Any tampering or modifications to the device by the user will void the warranty.*

18 Appendix A: Quick Start Reference Guide

Sample Menu Bar (contents vary with active tab)

The light gray color shows View Images is active. Tabs may have multiple screens.
Help – Press to display information for the active screen. Press again to close.
Log Out – Press to exit the user from the device. The Login screen is displayed.
Disk Space Indicator – Shows the disk space that has been used for video storage.
Admin – Visible if Username has Administrator privileges. Press for Admin Main Menu.
Patient Records – Press to display patient table. Search for, add or edit a patient. Select a patient record and the next action to take.
Capture Images – Press to record video, preview video, rerecord video, and save video.
View Images – Press to review previous videos. Enter after capturing new images to view new video and request a computer analysis.
Print / Save – Press to print the video analysis, save it as a PDF file, or save it to an HL7 database.
Patient information – Shows information from a patient record after it is selected.

Startup
Power on the LipiView® Interferometer by pressing the rocker switch. System may take several minutes to boot up.
At Login Screen, enter a Username and Password. Press *Submit*. Refer to **Patient Records**.

Patient Records 	All records must have at minimum 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. Locate record by typing name or using step keys. Must select a record to Capture Images or View Images. If not found, enter data; press *Add New Patient*. If found, choose record; Select a Patient Action. • Edit Patient – Update record if no saved video images. • Capture Images - Refer to **Capture Images**. • View Past Images - Select video from **Patient History** and then Refer to **Patient History.** • Close – Return to Patient Records. Get another record.
Capture Images 	Press *View OD* (right) or *View OS* (left) for eye to capture. Select pre-set tags; enter key-in tags. Clean chinrest support. Caution on hand/finger placement. Question patient on listed precautions; note conditions. Position patient: chin fully forward, forehead firmly against forehead rest. Look at orange fixation light. Adjust so lateral canthus aligns with marks on forehead rest using manual adjustment (fluted roller) located on chinrest support column. Use controls or touchscreen to adjust camera height and focus. Eye should be in center and clear. Press *Start Capture*. Approximately 20 seconds of video can be recorded. Have patient blink as needed. Press *End Capture to stop recording*. Refer to **Preview Video**.
Preview Video (just captured) Before saving, decide whether to rerecord. Capture images for second eye.	Preview image using controls and tear-film/full-eye toggle key. If desired, refer to **Rerecord Video**. Update pre-set or key-in tag information. Press *View OS* / *View OD* for 2nd eye. Refer to **Capture Images**. Press *Save All/Continue* to save video, tags. Refer to **View Images**.

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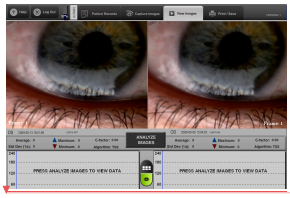
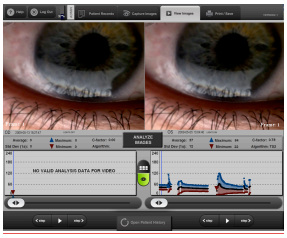
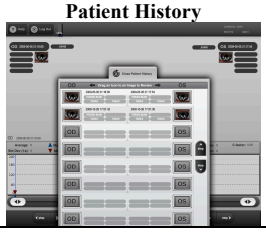
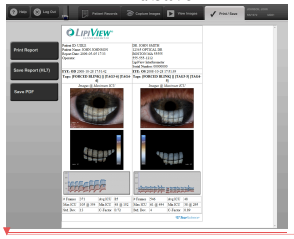
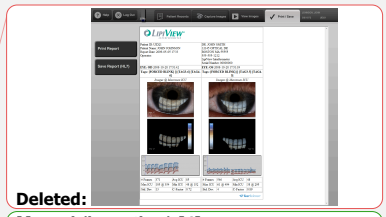
Rerecord Video Screen has same functionality as Capture Images except for system message confirming Rerecord.	Toggle between Preview and Rerecord screens by pressing *Return to recorded image* and *Return to live image*. To rerecord: Press View OS or View OD. Adjust patient and camera height, and focus. Press *Start Capture*. Confirm rerecord. Press *End Capture*. Update pre-set or key-in tag information. Press *Save All/Continue* to save video, tags. Refer to **View Images**.
View Images  	Entered after saving captured images. View and analyze. Or Entered from **Patient History** after choosing *View Past Images* from *Select a Patient Action* (Patient Records). View videos using play and step controls. Press *Analyze Images* if needed to view numerical data. • Average - Average ICU of all frame averages • Std Dev - Standard deviation of frame averages • Maximum – Max. recorded ICU for a given frame • Minimum – Min. recorded ICU for a given frame • C-Factor - Tear film Conformance factor for entire video After images are analyzed, review graph: • Toggle – Switch between full-eye and isolated tear-film. • Each point on graph is ICU value for frame. • Blue line and region is the upper standard deviation of the ICU score data. • Red line and region is the lower standard deviation of the ICU score data. • Blue triangle marker denotes the point on the graph that contains the maximum ICU score. • Red marker triangle marker denotes the point on the graph that contains the minimum ICU score Refer to **Print/Save**. Press ***Open Patient History*** to view other files.
Patient History 	Select videos from the list in Patient History to view. If table is empty, no video data saved for patient. Drag and drop videos into two frames at top. • If a video was archived, follow messages to restore. • When videos are selected, press Close Patient History. • Refer to **View Images**. Data may or may not need analysis.
Print/Save 	To print report (USB/Network printer must be set up): • Press *Print Report* on the left menu. • Follow standard windows printing prompts for sending the report to the attached printer. To export report to an HL7 compatible system (must be connected): • Press *Save Report (HL7)* on the left menu. • An HL7 Basic Socket Transfer message is displayed. • Press *Send HL7* to store the data in the HL7 database. To save the printed report as a PDF file: • Connect an external USB drive or USB key to the LipiView. • Press Save PDF on the left menu. • When the system reports that the PDF has been saved successfully, press Close.

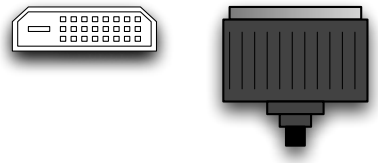


19 Appendix B: External Monitor Hookup

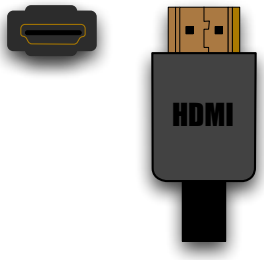
The LipiView® Interferometer is equipped with an optional external monitor connection. The following instructions provide the user with the steps needed to connect the external monitor to the interferometer.

The external monitor connection may be DVI output or HDMI output. TearScience does not supply cables for connecting external monitors. Users wishing to connect an external monitor should inspect the connectors on the monitor they wish to use, and the connector on the underside of the LipiView® Interferometer, and then purchase a cable that has the appropriate connectors on each end and is long enough to reach from the underside of the LipiView® Interferometer to the external monitor input.

The DVI connector and cable look like this:



The HDMI connector and cable look like this:



1. Ensure the LipiView® Interferometer is powered off.
2. Ensure that the separately purchased external monitor has either a DVI or HDMI port and is capable of displaying a 1280 x 1024 image.
3. Locate the digital video cable cover on the underside of the LipiView® Interferometer. The cover has four screws attaching it to the LipiView® Interferometer. Use an M2.5 hex driver and remove the four screws. The LipiView® Interferometer's digital video output cable should now be exposed.
4. Connect the separately purchased digital video cable to the LipiView® Interferometer's video output.
5. Connect the other end of the digital video cable to the external monitor.

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Deleted: 1020
Deleted: fiber-optic receiver
Deleted: external monitor that has four color-coded receptacles. ... [16]
Deleted: cable has four color-coded fiber-optic connectors that mate with the same color-coded receptacles. ... [17]
Deleted: DVI port on the

6. Apply power to the LipiView® Interferometer and external monitor.

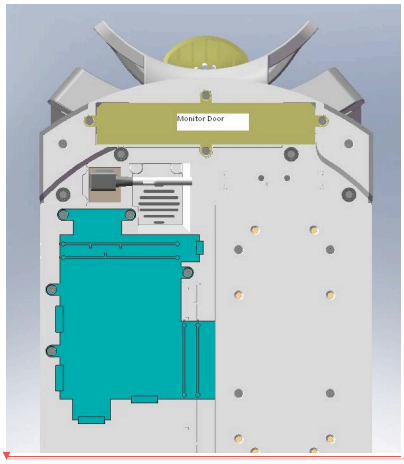

Figure B1. Location of External Monitor Interface Door

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20 Appendix C: Electromagnetic Compatibility Requirements

20.1 Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Table 20-1: Guidance and Manufacturers Declaration-Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The LipiView® Interferometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	NA
Harmonic emissions IEC 61000-3-2	Class A	NA
Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	The LipiView® Interferometer is suitable for use in all establishments **other than** domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.

20.2 Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Table 20-2: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 1)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
*NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 20-3: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 2)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the HCS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = [3.5/V1]\sqrt{P}$ $d = [3.5/E1]\sqrt{P}$ 80MHz to 800MHz $d = [7.0/E1]\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, are determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-3	3 Vrms 80 MHz to 2,5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LipiView® Interferometer is used exceeds the applicable RF compliance level above, the LipiView® Interferometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LipiView® Interferometer. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

20.3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Table 20-4: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer			
The LipiView® Interferometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LipiView® Interferometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LipiView® Interferometer as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d=[3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz** $d=[3.5/E_1]\sqrt{P}$	**800 MHz to 2,5 GHz** $d=[7/E_1]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Revision History

Donawa Lifescience Consulting
Piazza Albania, 10
00153 Rome, Italy

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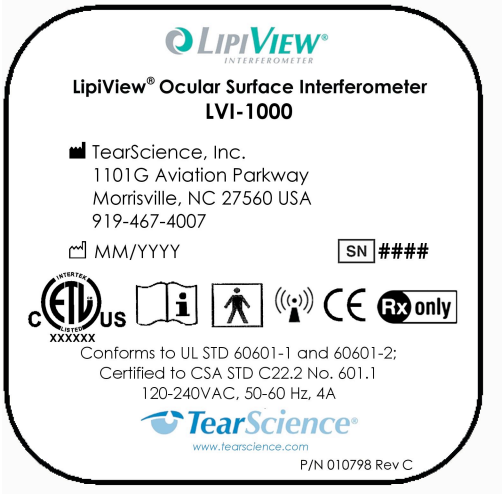
Label	Label Type
	Main Device Label
	External Monitor Cable Label

Label	Label Type
Fuse Type: 5x20 mm 4A, 250V, 300ms, 40A breaking capacity **Warning:** Risk of fire, replace only with the same type and rating fuse **Caution:** Risk of electrical shock. Disconnect from power before servicing. P/N 010796 Rev A	Fuse Label
U.S. AND FOREIGN PATENTS APPLIED FOR AND PENDING P/N 010120 Rev A	Patent Pending Label
LIPIVIEW® INTERFEROMETER **Contents:** (1) **LipiView® Ocular Surface Interferometer** **LVI-1000** MM/YYYY TearScience, Inc. 1101G Aviation Parkway Morrisville, NC 27560 USA 919-467-4007 EC REP Contract Medical Int'l, GmbH Zur Wetterwarte 50, House 302 01109 Dresden, Germany +49 (351) 213-8889 REF **100000** SN #### c ETL us LISTED XXXXXX Rx only Conforms to UL60601-1 and UL60601-2 Certified to CSA C22.2#601.1 120-240VAC, 50-60 Hz, 4A TearScience® www.tearscience.com P/N 010797 Rev B	Package Label

Table 3-2: Description of Labeling Symbols

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OPERATION WARNINGSCaution: Degree of protection against harmful ingress of liquid: IPXO. This equipment has no protection against ingress of liquids.

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connection option.

When the external monitor connection option is ordered, cables supporting the external monitor are

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NOTE: The external monitor connection can be used outside the United States if the customer has an electrical adapter that can adapt the standard US plug to the plug their country uses. The adapter is NOT included as part of the external monitor connection option.

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If the external monitor connection option was included, the device may run without attaching the monitor.

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Disk cloning means videos are copied from the LipiView® Interferometer's hard drive to an external location, which is one of the drives mapped in Section 15.6, *Admin Map Drive*. Disk cloning is like performing a backup in that the files are copied but not deleted.

Eventually the hard drive will fill up and files will be moved to make space for new files. This process is called Archiving. Archiving is like disk cloning, except that after the video is copied it is deleted from the device's hard drive. Whereas cloning is like copying, archiving is like moving.

Pressing *CLONE SYSTEM* on the Networking screen performs both the disk cloning and archiving functions. Whether a file is cloned or archived depends on how full the disk is compared to a predetermined number. The Disk Space Indicator on the menu bar indicates how full the disk drive is, and this number increases as captured videos are saved. During initial setup, the Administrator should determine at what point the ability to capture videos will be disabled as a result of a full disk. The predetermined number is set by moving the slider titled *Percent Drive Full Space to Start Archiving Videos* to the desired level.

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the predetermined fullness level is 75% for example, and the Disk Space Indicator is less (e.g., 25%), pressing *CLONE SYSTEM* will clone (copy) the files to a specific location. If the disk space level is 75% or more when *CLONE SYSTEM* is pressed, enough files will be archived to bring the hard drive level down to 10% below the predetermined percentage (in this case 65%). Archiving files begins with the oldest accessed timestamp. After a file is cloned or archived, the Patient History List is updated noting the action taken.

The *Drive Letter of Target Drive* specifies the network drive that the video files will be cloned (copied) or archived (moved) to. Enter the appropriate Drive Letter, which must be one of the currently mapped drives listed. Refer to Section 15.6, *Admin Map Drive* for instructions on how to set up a network drive and for a description of the *Current Mapped Drive* heading. Note that cloning and archiving may be done on the same network drive, or they may be done on different drives.

To exit this screen and return to the Admin Main Menu in Figure 15-1, choose one of the following and continue with Section 15.2, *Admin Main Menu*:

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save all data entered on this screen (for both Disk Cloning and HL7) without starting to clone at this time, press *SAVE SETTINGS*. A system message will indicate the mapping information has been saved. Press *Close*.

NOTE: If cloning / archiving will be performed after entering the Drive Letter, this step is not needed. The data is automatically saved as part of the cloning process in step 3.

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To exit without saving any changes to the screen, press *CANCEL*.

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all information entered on the screen, and to execute a disk clone process, press *CLONE SYSTEM*. The video files are very large (approximately 900MB), and the cloning process may take several hours to complete (or approximately 20 minutes per file). No other screens are available while the cloning process is running. Therefore, run the cloning process overnight or during some other period where the LipiView® Interferometer will not need to be used for 6 to 7 hours.

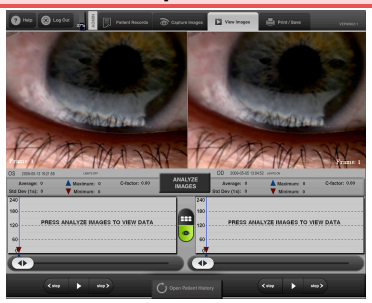
After *CLONE SYSTEM* has been pressed, the cloning process should start. If progress dialog is not displayed, then check the validity of the clone path on the Networking page.

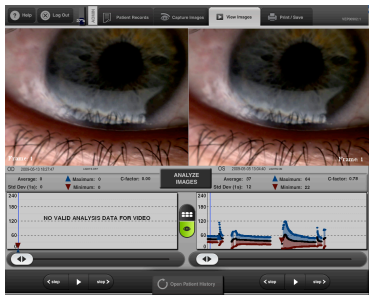
The cloning process can be stopped at any time by pressing *CANCEL* on the progress dialog. After a few seconds a system message will indicate that cloning has been stopped by the user. Press *Close* to acknowledge and return to the Networking screen. If cloning is aborted for any reason, it will be resumed from where it left off the next time *CLONE SYSTEM* is pressed.

When the cloning has ended and the progress dialog is closed, the Networking screen in Figure 15-7 is redisplayed. Return to the Admin Main Menu in Figure 15-1, by pressing *SAVE SETTINGS* or *EXIT*.

HL7

Page 73: [15] Deleted **Update** **8/8/12 1:09 PM**





Page 74: [16] Deleted **Update** **8/8/12 1:09 PM**

external monitor that has four color-coded receptacles.

1. Locate the fiber-optic cable emerging from the base

Page 74: [17] Deleted **Update** **8/8/12 1:09 PM**

cable has four color-coded fiber-optic connectors that mate with the same color-coded receptacles.

Each receptacle is marked with a color that should be mated with the connector marked with the same color.

Push each fiber-optic connector into the matching fiber-optic receiver and snap into place.

2. Attach the fiber-optic receiver

Page 75: [18] Deleted **Update** **8/8/12 1:09 PM**

Attach the fiber-optic receiver's power supply (comes with the receiver from the manufacturer) to the receiver.

Plug the power supply plugged into a 110VAC outlet.

NOTE: The external monitor connection can be used outside the United States if the customer has an electrical adapter that can adapt the standard US plug to the plug their country uses. The adapter IS NOT included as part of the external monitor connection option.

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SPECIAL 510(k): DEVICE MODIFICATION

TEARSCIENCE, INC.

LIPIVIEW® OCULAR SURFACE INTERFEROMETER

WITH SOFTWARE VERSION 2.0

APPLICANT

TearScience, Inc.
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560

OFFICIAL CORRESPONDENT

Christy Stevens, OD, MPH
Vice President, Clinical & Regulatory Affairs
Tel: (919) 459-4815
Fax: (877) 468-5335

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1. Medical Device User Fee Cover Sheet (Form FDA 3601)

Payment Identification Number: MD6063078-956733
Small Business Decision Number: SBD128176
TearScience, Inc.

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Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
TEARSCIENCE INC 5151 MCCRIMMON PARKWAY MORRISVILLE NC 27560 US	Barry Campbell
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3933	2.1 E-MAIL ADDRESS bcampbell@tearscience.com
	2.2 TELEPHONE NUMBER (include Area code) 919-4594828
	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD128176

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of

this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted]

27-Jul-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
31 July 2012	(b) (4) [redacted]	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
TearScience, Inc	3008169506		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
N/A	(919) 459-4815		
Street Address	**FAX Number *(including area code)***		
5151 McCrimmon Parkway, Ste 250	(877) 468-5335		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Morriville	NC	27560	USA
Contact Name			
Christy Stevens			
Contact Title	**Contact E-mail Address**		
Vice President, Clinical and Regulatory Affairs	cstevens@tearscience.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☒ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HKI	2	HJO	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☒ 510 (k) summary attached
- ☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K091935	LipiView® Ocular Surface Interferometer	TearScience, Inc
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Common Name: Ophthalmic Imaging Device
Classification Name: Ophthalmic Camera and AC-powered Slit Lamp Biomicroscope

	Trade or Proprietary or Model Name for This Device		Model Number
1	LipiView® Ocular Surface Interferometer	1	LVI-1000
2		2	LVI-1001
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K091935	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HKI, HJO	21 CFR 886.1120 and 886.1850	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Ophthalmic

Indications *(from labeling)*

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: TearScience		Establishment Registration Number: 3008169506	
Division Name *(if applicable)*: N/A		Phone Number *(including area code)*: (919) 467-4007	
Street Address: 5151 McCrimmon Parkway Ste 250		FAX Number *(including area code)*: (919) 467-3300	
City: Morrisville		State / Province: NC	ZIP Code: 27519 / Country: USA
Contact Name: Christy Mocny	Contact Title: Directory, Quality and Regulatory Compliance	Contact E-mail Address: cmocny@tearscience.com	

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: Sparton Medical Systems		Establishment Registration Number: 3003144120	
Division Name *(if applicable)*: N/A		Phone Number *(including area code)*: (440) 878-4630	
Street Address: 22740 Lunn Rd		FAX Number *(including area code)*: (440) 878-4636	
City: Strongsville		State / Province: OH	ZIP Code: 44149 / Country: USA
Contact Name: Margaret Heuser	Contact Title: Quality Manager	Contact E-mail Address: mheuser@sparton.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	15004-2	ISO	Ophthalmic Instruments - Fundamental requirements and test methods: Part 2: Light hazard protection	First edition	2/15/2007
2	60601-1	IEC	Medical Electrical Equipment - Part 1 General Requirements for basic safety and essential performance	Second edition	01/01/1995
3	60601-1-2	IEC	Medical Electrical Equipment - Part 1-2 General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility- Requirements and tests	Second edition	01/01/2001
4	14971	ISO	Medical Devices - Application of Risk Management to Medical Devices	Second edition	3/1/2007
5	13485	ISO	Medical devices - Quality management systems - Requirements for regulatory purposes		6/6/2003
6	UL 94V-1	UL	Flammability requirements	Edition 5	01/01/2006
7	N/A	FDA	General Principles of Software Validation; Final Guidance for Industry and FDA Staff		1/11/2002

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET (continued) SECTION I: UTILIZATION OF STANDARDS (continued from Page 5 of Form 3514)

	Standard No.	Standards Organization	Standards Title	Version	Date
8	N/A	FDA	Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices		9/9/1999
9	N/A	FDA	Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices		5/11/2005
10	N/A	FDA	How To Prepare A Special 510(k)		12/7/2009

3. Certification of Compliance with Requirements for Clinical Trials.gov Data Bank (Form FDA 3674)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   TearScience, Inc

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   9 August 2012

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   5151 McCrimmon Parkway Ste 250
   Morrisville, NC 27560 USA

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) (919) 467-4007
   (Fax) (919) 467-3300

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

   Common name: Ophthalmic Imaging Device — Classification II; 21 CFR 886.112, 21 CFR 886.1850

   Trade or propreitary name: LipiView® Ocular Surface Interferometer

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

   ☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

   ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

   ☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

    NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
    Christy Stevens

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) Christy Stevens
    (Title) Vice President, Clinical and Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    5151 McCrimmon Parkway Suite 250
    Morrisville, NC 27560 USA

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 919-459-4815
    (Fax) 877-468-5335

15. DATE OF CERTIFICATION
    9 August 2012

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

4. Cover Letter

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TearScience®

August 13, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: SPECIAL 510(K): DEVICE MODIFICATION

APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560
ESTABLISHMENT REGISTRATION NO.:	3008169506
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.1120 and 886.1850
PRODUCT CODE:	HKI, HJO
CLASSIFICATION PANEL:	Ophthalmic
ORIGINAL 510(K) NUMBER:	K091935
ORIGINAL 510(K) CLEARANCE DATE:	October 23, 2009
USER FEE PAYMENT ID:	MD 6063078-956733

Dear Sir or Madam:

Pursuant to the provision of Section 510(k) of the Federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990, notification is made of the intention of TearScience to market and distribute a modified ophthalmic imaging device, the LipiView® Ocular Surface Interferometer with Software Revision 2.0. TearScience hereby submits this Special 510(k): Device Modification to request a modification to the LipiView® Interferometer. The modification is a software change to refine the interferometric color matching and blink detection methods used on interferometric images and to provide minor usability enhancements. TearScience believes this device modification is eligible for the Special 510 (k) process since the modified device has the same intended use and fundamental scientific technology as the cleared predicate device.

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. The indications for use and intended use have not changed from the cleared predicate device.

The LipiView® Ocular Surface Interferometer is a Class II prescription device classified under 21 CFR 886.1120 and 886.1850 with a common name of ophthalmic imaging device. The LipiView® Interferometer was previously cleared under K091935 on October 23, 2009. The K091935 filing included a Traditional Premarket Notification dated June 24, 2009 and a Response to FDA Memorandum dated October 5, 2009.

Based on the FDA Guidance Document, *Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1);* issued January 10, 1997, there were two software changes in LipiView® software version 2.0 that were assessed to require submission of a 510(k):

1. Interferometric color matching has been improved by using certified thin film optical phantoms to establish the interferometric color reference palette and by refining the method for identifying and localizing the interferometric colors on the tear film.
2. The blink detection method has been refined to allow the device to better differentiate valid tear film frames from blink frames as compared to the cleared device.

In addition, we have made other minor usability enhancements for user convenience including: playback blink visualization; automated documentation of blinks; example tear film videos; adjustable video capture length; and ability to export video to an external USB storage device or mapped network drive.

As explained in this submission, none of these changes affect the intended use, principles of operation, control mechanism, energy source or device hardware. The device operation and graphical user interface are fundamentally unchanged in software version 2.0 from the predicate device. Risk analysis showed that none of the changes in software version 2.0 pose any additional risk to the patient and/or user as compared to the cleared device. Performance testing demonstrated the LipiView® Interferometer with software version 2.0 is substantially equivalent in technological characteristics to the predicate device.

This submission has been formatted per the guidelines in *How To Prepare A Special 510(k).*[1] Two copies of this submission (one paper and one electronic) are enclosed for review. The electronic copy is provided per FDA's web instructions 'Electronic Copies for Pre-Market Submissions', and is an exact duplicate of the original paper submission.

TearScience regards information provided in this submission to be confidential and proprietary and afforded such protection under 21 CFR 807.95 and other applicable regulations and statutes. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification. If there are any questions, or if additional information is required, please contact me at (919) 459-4815, via fax at (877) 468-5335, or by email at CStevens@TearScience.com.

Sincerely,

Christy Stevens, OD, MPH
Vice President, Clinical & Regulatory Affairs

[1] FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm, updated 12/7/2009

5. *Table of Contents*

TEARSCIENCE, INC.
LIPIVIEW® OCULAR SURFACE INTERFEROMETER
SPECIAL 510(k): DEVICE MODIFICATION

6. 510(K) Screening Checklist

This screening checklist is based on FDA's instructions in in *How To Prepare A Special 510(k)* (FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm, updated 12/7/2009.)

Title	Location	Present	Inadequate	N/A
MDUFMA Cover Sheet –Form FDA 3601	Section 1			
CDRH Premarket Review Submission Cover Sheet – Form FDA 3514	Section 2			
Certification of Compliance with ClinicalTrials.gov Data Bank	Section 3			
510(k) Cover Letter	Section 4			
Table of Contents	Section 5			
510(k) Screening Checklist	Section 6			
Indications for Use Statement	Section 7			
510(k) Summary	Section 8			
Standards Data Report for 510(k)s – Form FDA 3654	Section 9			
Truthful and Accurate Statement	Section 10			
Class III Summary and Certification	Section 11			
Device Description	Section 12			
Comparison to Cleared Device/ Substantial Equivalence	Section 13			
Proposed Labeling	Section 14			
Concise Summary of Design Control Activities	Section 15			

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7. Indications For Use Statement

The Indications for Use statement for the LipiView® Ocular Surface Interferometer with the device modification for software version 2.0 is provided in the recommended format on the following page.

Note: *The Indications for Use statement remains unchanged from the legally marketed predicate device, TearScience LipiView® Ocular Surface Interferometer (K091935).*

INDICATIONS FOR USE

510(k) Number: _____ (To Be Assigned By FDA)

Device Name: LipiView® Ocular Surface Interferometer

Indications for Use:

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

8. 510(K) Summary

The following 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) SUMMARY

PREPARATION DATE:	August 13, 2012
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 459-4815 Fax: (877) 468-5335
CONTACT PERSON:	Christy Stevens, OD, MPH Vice President, Clinical & Regulatory
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAME:	Ophthalmic Camera
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.1120 and 886.1850
PRODUCT CODE:	HKI, HJO
PREDICATE DEVICE:	LipiView® Ocular Surface Interferometer Class II under 21 CFR 886.1120 and 21 CFR 886.1850; Product Code HKI, HJO; Applicant: TearScience, Inc.; Cleared under K091935 on October 23, 2009

DEVICE DESCRIPTION:

The LipiView® Ocular Surface Interferometer is a bench-top imaging device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touch screen display. The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display, in a printed report, or captured on video and exported to USB-attached storage or a mapped network drive.

The LipiView® Interferometer has been modified to software version 2.0, which includes changes to refine the interferometric color matching and blink detection methods used on interferometric images and to provide minor usability enhancements.

INTENDED USE:

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

The LipiView® Interferometer with software version 2.0 has the same intended use and same indications for use as the predicate LipiView® Interferometer (K091935).

TECHNOLOGICAL CHARACTERISTICS:

The LipiView® Interferometer with software version 2.0 has the same fundamental scientific technology as the predicate device. As summarized below, most of the technological characteristics of the LipiView® Interferometer with the modification to software version 2.0 remain unchanged from the predicate device cleared under K091935. Minor differences in technology between the predicate device and the LipiView® Interferometer with software version 2.0 are described below.

***Similarities**:* The LipiView® Interferometer with software version 2.0 and the predicate device share many of the same design features. Both devices have the same operating principle of real-time imaging of tear film dynamics based on the interference pattern from specular reflections. Both devices have an AC power source in compliance with IEC 60601 standards for electrical safety and electromagnetic compatibility. Both devices use the same Class I white light LED illuminator with exposure and level of illumination in compliance with ISO 15004-2 (Group 1 instrument) for safety. The patient contact materials for the chin and forehead rest and the method of disinfection are the same for both devices. Also, both devices have a digital video camera, personal computer with Microsoft Windows-based operating system, touchscreen display graphical user interface and computer accessory support for printing and data storage.

Furthermore, analogous software features on both devices include: password-protected user login; patient database; real-time video display to acquire tear film images; touchscreen user controls for camera and video playback; image acquisition process with storage of lossless AVI format video images; and tear film video playback and analysis.

***Differences**:* Compared to the predicate device, the LipiView® Interferometer with software version 2.0 has refined interferometric color matching and blink detection methods used on interferometric images. Software version 2.0 also has enhancements for user convenience including: playback blink visualization; automated documentation of blinks; example tear film videos; adjustable video capture length; and ability to export video to an external USB storage device or mapped network drive.

PERFORMANCE TESTING:

The LipiView® Interferometer with software version 2.0 was developed and tested in compliance with design controls and the FDA Guidance documents for software validation in medical devices. Verification and validation test results demonstrated that the interferometric color matching performance of the LipiView® Interferometer with software version 2.0 is equal to or better than the predicate device. Tests also showed that version 2.0 had a higher overall percentage of correctly identified valid blink frames as compared to the predicate device. Enhancements for user convenience in software version 2.0 performed as intended and did not introduce any new risks to the device.

CONCLUSIONS:

The LipiView® Ocular Surface Interferometer with software version 2.0 has the same intended use and the same fundamental scientific technology as the predicate device. Performance testing demonstrates the LipiView® Interferometer with software version 2.0 is substantially equivalent in technological characteristics to the predicate device.

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9. Standards Data Report for 510(k)s – FDA Form 3654

A Standards Data Report for 510k(s) (Form FDA 3654) is enclosed for each of the following standards referenced in this Special 510(k).

- ISO 15004-2 Ophthalmic Instruments - Fundamental requirements and test methods: Part 2: Light hazard protection.
- IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – requirements and tests.
- UL94V-1 - The materials used in the LipiView® Interferometer comply with UL 94V-1 or better flammability requirements.
- ISO 13485 Medical Devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical Devices – Application of risk management to medical devices.

International Organization for Standardization (ISO)
International Electrotechnical Commission (IEC)
Underwriters Laboratories (UL)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15004-2: Ophthalmic Instruments - Fundamental requirements and test methods Part 2: Light hazard protection

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#10-51	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Ophthalmic Instruments - Fundamental requirements and test methods Part 2: Light hazard protection

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1 to 7 and annexes	Entire document	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Section 5.2 - Device is a Group 1 instrument

DESCRIPTION
Classification of device determines test and requirements

JUSTIFICATION
Device is classified based on the definitions in this standard

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1: Medical Electrical Equipment - Part I: General Requirements for Basic Safety and Essential Performance, 2005

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-52	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1: Medical Electrical Equipment - Part I: General Requirements for Basic Safety and Essential Performance, 2005

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1 to 17 and Annexes	Entire document	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Section 5: Classification Selected Options: Class 1-ME, Type B Applied Part, Continuous Operation

DESCRIPTION
Classification of device determines test and requirements

JUSTIFICATION
Device is classified based on the definitions in this standard

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: Electromagnetic Compatibility - Requirements and Tests, 2001

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-53	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: Electromagnetic Compatibility - Requirements and Tests, 2001

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1 to 6 and annexes	Entire document	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Options selected: radiated and conducted emissions - Class B; Harmonic emissions - Class A

DESCRIPTION
Classification of device determines tests and requirements

JUSTIFICATION
Device is classified based on the definitions in this standard

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

UL 94 Standard for Tests for Flammability of Plastic Materials for Parts in Devices and Appliances

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	N/A	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes, 2003

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes, 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.5.3.2.2	Particular requirements for active implantable medical devices...	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Exclusion

DESCRIPTION
Traceability records required for active implantable medical devices and implantable medical devices

JUSTIFICATION
TearScience Inc does not produce an active implantable medical device or an implantable medical device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.2.4.2	Particular requirements for active implantable medical devices....	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Exclusion

DESCRIPTION
Inspection and testing records required for active implantable medical devices and implantable medical devices

JUSTIFICATION
TearScience Inc does not produce an active implantable medical device or an implantable medical device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Remaining sections	Remainder of document	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971: Medical devices - Application of risk management to medical devices, 2007

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971: Medical devices - Application of risk management to medical devices, 2007

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1 to 9 and annexes	Entire document	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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10. Truthful and Accurate Statement

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as President and Chief Executive Officer (CEO) of TearScience, I believe to the best of my knowledge that all data and information submitted in the premarket notification for the LipiView® Ocular Surface Interferometer are truthful and accurate and that no material fact has been omitted.

Tim Willis
President and CEO
TearScience, Inc.

8/10/12
Date

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11. Class III Summary and Certification

The LipiView® Ocular Surface Interferometer is a Class II medical device regulated under 21 CFR 886.1120 and 886.1850. Therefore, the Class III Summary and Certification requirement as described in 21 CFR 807.87(j) and 21 CFR 807.94 do not apply to this device and submission.

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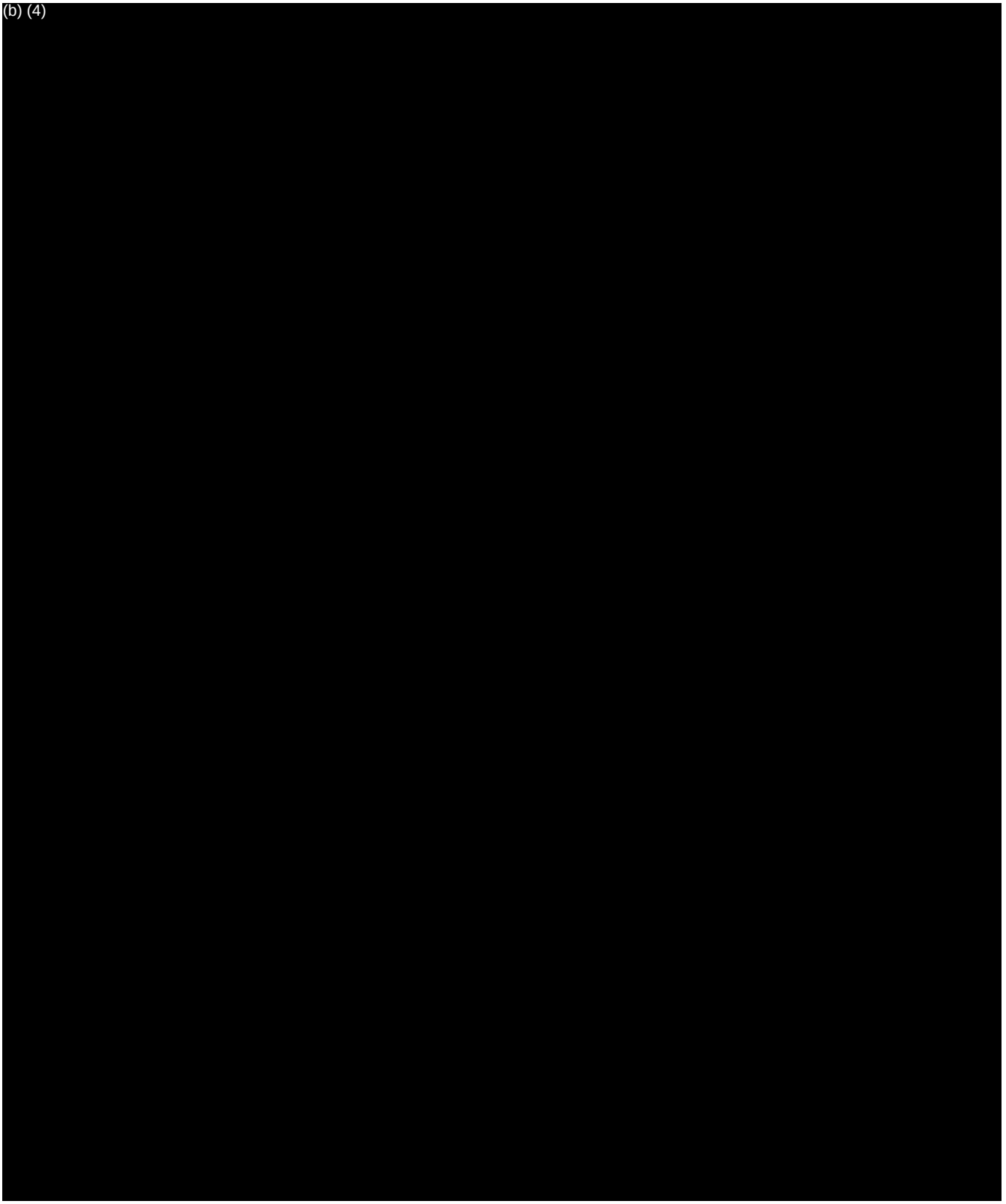
12. Device Description

(b) (4)



(b) (4) Device Description

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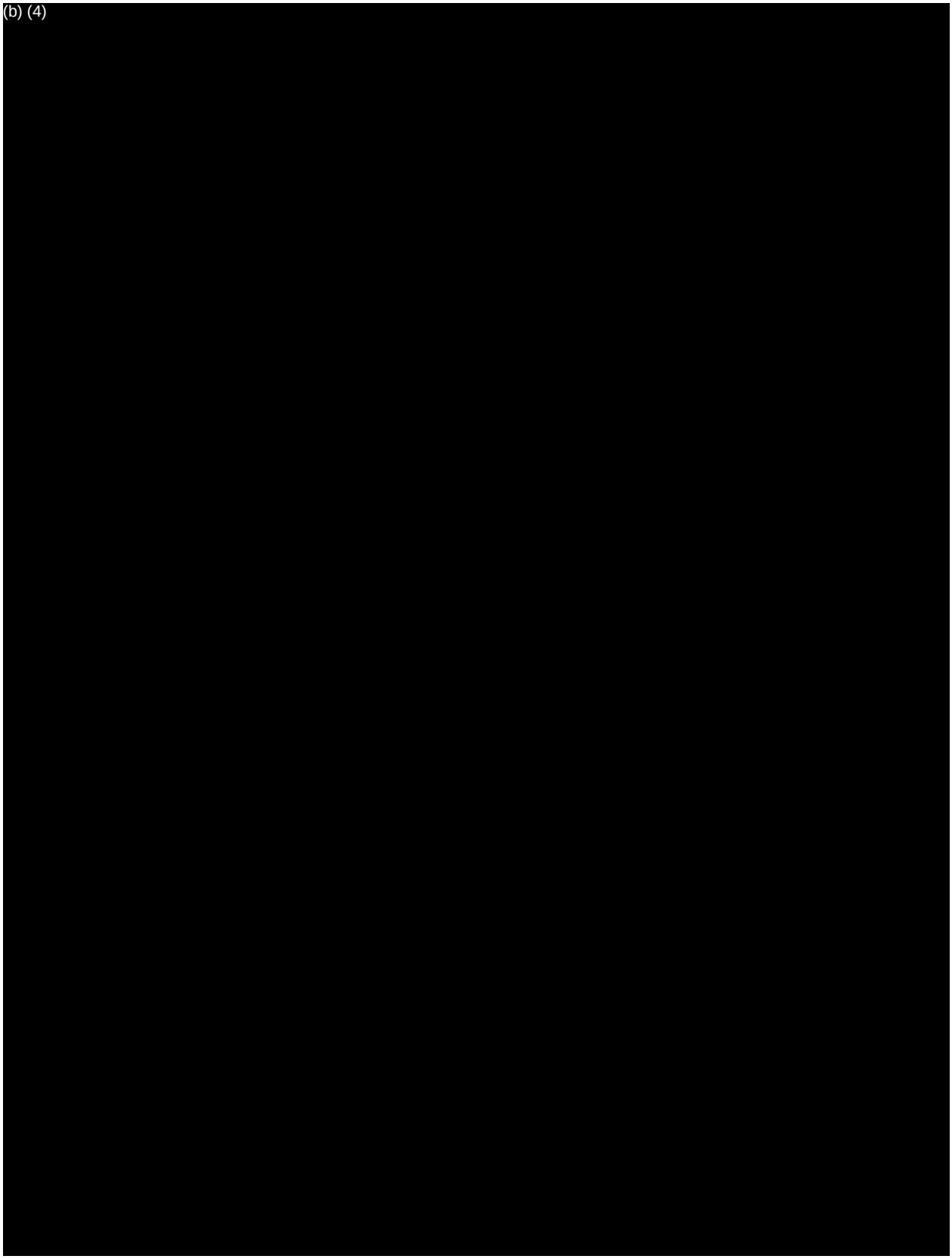
13. Comparison to Cleared Device / Substantial Equivalence

(b) (4)



(b) (4) Comparison to Cleared Device/Substantial Equivalence

(b) (4) Comparison to Cleared Device/Substantial Equivalence

(b) (4) Comparison to Cleared Device/Substantial Equivalence

(b) (4) Comparison to Cleared Device/Substantial Equivalence

(b) (4) Comparison to Cleared Device/Substantial Equivalence

(b) (4) Comparison to Cleared Device/Substantial Equivalence

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14. Proposed Labeling

TearScience has proposed changes to LipiView® Ocular Surface Interferometer Operation Manual for the minor user interface changes in software version 2.0. The proposed LipiView® Operation Manual for software version 2.0 is provided in Attachment 14-A. In addition, a redlined version of the LipiView® Operation Manual, which shows the changes to the user interface screens in version 2.0 as compared to the prior software version on the cleared predicate device, is provided in Attachment 14-B.

The proposed changes to the LipiView® Operation Manual for software version 2.0 are summarized as follows:

- Updated screenshots with new system and software version numbers.
- Added new screenshots and explanations for example tear film videos, which are displayed when the user enters the *View Past Images* screen. The first set of OD/OS images presented to the user are standard reference example video images of eyes with different ICU levels for purposes of comparison.
- Added new screenshots and explanation for partial blink detection mode. The number of partial blinks out of the number of total blinks counted, expressed as a fraction is displayed on the *View Images* and *Print/Save Report* screens. The numerator (top number) is the number of partial blinks; the denominator (bottom number) is the total number of blinks counted. A partial blink value of 3/9 means that out of nine total blinks detected, three were evaluated as "partial blinks". In addition, a blink-only view, which displays only the segments of the video in which the patient is blinking, has been added to the user interface.
- Added new screenshots and explanations for revisions to reporting and for "save video" functionality. The user can save video images by exporting to a USB drive.
- Added new screenshots and explanations for display and camera settings in the Admin interface. Under the Admin Display Options, the user can set the default capture video recording time to between 5 and 19 seconds.

Prior to software version 2.0, labeling changes have been made to the cleared LipiView® Interferometer since the last 510(k) (K091935). These changes were determined not to require a 510(k) based on the FDA Guidance Document, *Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1);* issued January 10, 1997. Changes to the Operation Manual that have been implemented since the last filing (K091935) to the currently released Operation Manual are summarized in Section 12.8, *Device Changes Since Last Filing* (K091935). A redlined version of the LipiView® Operation Manual, which shows the changes from the Operation Manual filed in K091935 (Response to an FDA Memorandum dated October 5, 2009, Appendix 4) to the currently released Operation Manual, is provided in Attachment 14-C.

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Attachment 14-A: Proposed LipiView® Ocular Surface Interferometer Operation Manual for System Version 2.x

Attachment 14-B: Redline of Proposed Labeling Changes to LipiView® Operation Manual for System Version 2.x

- Includes proposed labeling changes from currently released Operation Manual for software version 1.1D to proposed Operation Manual for Software Version 2.0

Attachment 14-C: Redline of Labeling Changes Implemented to LipiView® Operation Manual Since Last Filing (K093937)

- Includes labeling changes implemented from Operation Manual filed in K091935 (Response to an FDA Memorandum dated October 5, 2009, Appendix 4) for software version 1.0 to currently released Operation Manual for software version 1.1D

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15. Concise Summary of Design Control Activities

(b) (4)

(b) (4) Concise Summary of Design Control Activities

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(b) (4) Concise Summary of Design Control Activities

15.3.2. Signed Statement: Manufacturing facility is in conformance with design control procedure requirements and records are available for review

August 9, 2012

I certify, in my capacity as Director of Quality and Regulatory Compliance of TearScience, that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30, and that all records pertaining to Design Controls for the LipiView® Ocular Surface Interferometer with Software Release 2.0 are available for review.

Christy Mocny

Director, Quality and Regulatory Compliance

TearScience, Inc.

8/9/12

Date

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name KA NAM TO for Rahul Rana

Subject: 510(k) Number K120461

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐ NO	NSE for lack of predicate
☐ NI	NSE for new intended use
☐ NQ	NSE for new technology that raises new questions of safety and effectiveness
☐ NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐ NP	NSE for lack of performance data
☐ NS	NSE no response
☐ NL	NSE for lack of performance data AND no response
☐ NM	NSE pre-amendment device call for PMAs (515i)
☐ NC	NSE post-amendment device requires PMAs
☐ NH	NSE for new molecular entity requires PMA
☐ TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):	YES	NO
Indications for Use Page *Attach IFU*		
510(k) Summary /510(k) Statement *Attach Summary*		
Truthful and Accurate Statement. *Must be present for a Final Decision*		
Is the device Class III?		
If yes, does firm include Class III Summary? *Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC		
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		
Is this device intended for pediatric use only?		
Is this a prescription device? (If both prescription & OTC, check both boxes.)		
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		
Is clinical data necessary to support the review of this 510(k)?		
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was		

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

_____

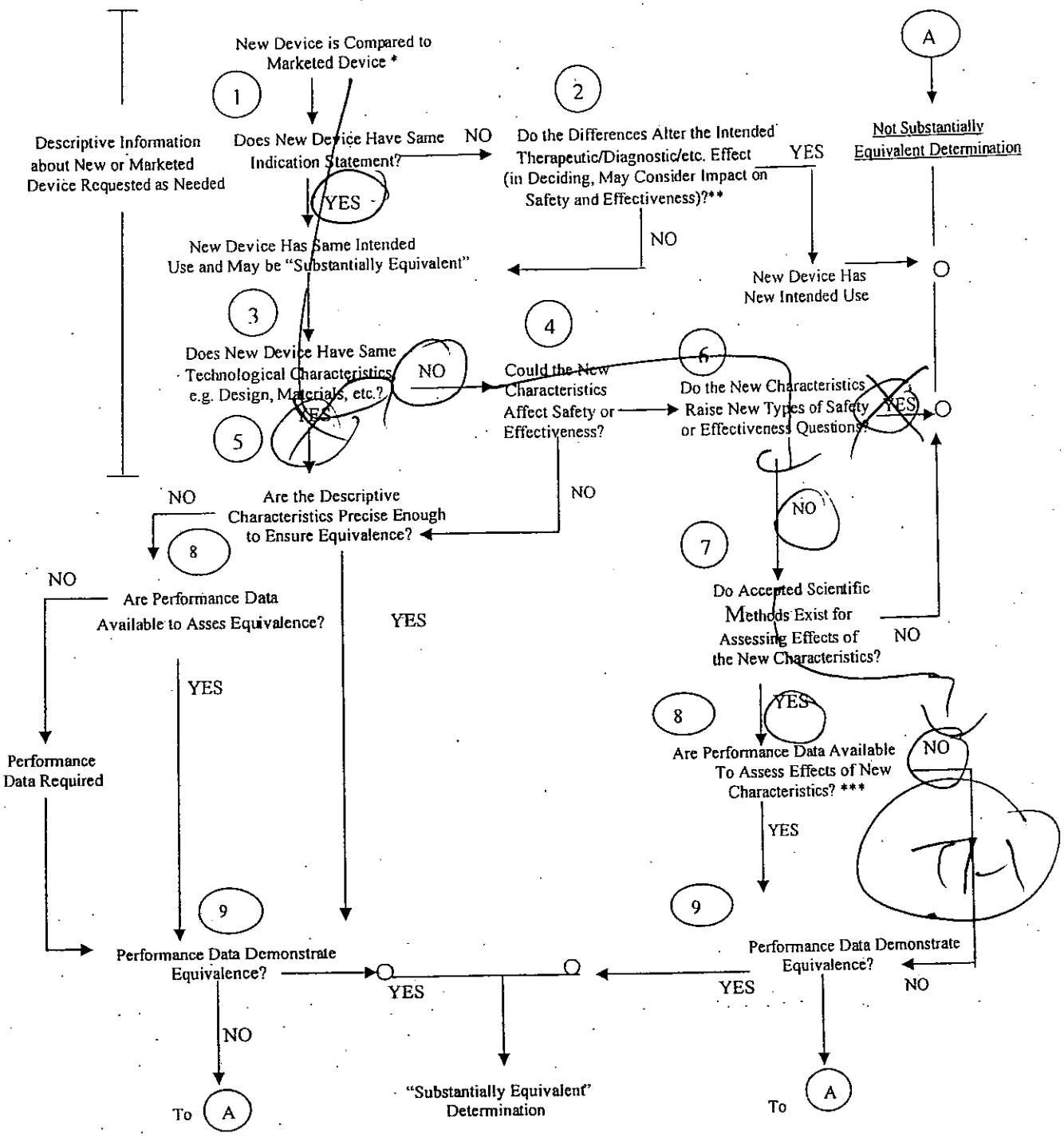
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Devices & Radiological Health

Division of Ophthalmic, Neurologic, Ear, Nose, and Throat Devices
Ophthalmic Lasers, Neurostimulators, and Diagnostic Devices Branch
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
(301) 796-6620

ORIGINAL (S0) PREMARKET NOTIFICATION [510(K)] REVIEW

DATE: October 31st, 2012
TO: RECORD
FROM: Rahul Ram
SUBJECT: Special-to-Traditional, K122481 / S0

510(K) HOLDER: TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560	**OFFICIAL CORRESPONDENT:** Christy Stevens VP, Clinical & Regulatory Affairs **Email:** cstevens@tearscience.com **Phone:** (919) 459-4815 **Fax:** (877) 468-5335
DEVICE TRADE NAME: LipiView Ocular Surface Interferometer	
DESCRIPTION: Interferometer to Observe Ocular Tear Film	
510(K) DATED DATE: August 13th, 2012	
510(K) RECEIVED DATE: August 14th, 2012	

APPLICANT-IDENTIFIED PREDICATE DEVICE:

510(K) NUMBER	PRODUCT CODE	DEVICE NAME	510(K) HOLDER
K091935	HKI, HJO	LipiView Ocular Surface Interferometer	TearScience, Inc.

RECOMMENDATION:

The submission concerning the **LipiView Ocular Surface Interferometer** requires additional information in order to proceed with the review. Therefore, I recommend that the submission be placed on **telephone hold (TH).**

Regulation Number: **21 CFR 886.1120**
Regulation Name: **Ophthalmic Camera**
Regulatory Class: **Class II**
Product Code: **HKI**
Produce Code Description: **Camera, Ophthalmic, AC-Powered**
Additional Product Codes: **HJO**

INDICATIONS FOR USE (IFU) STATEMENT:	☒ Prescription ☐ Over-the-Counter
"The LipiView Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented."	

I SUBMISSION REVIEWERS

- Rahul Ram (ODE/DONED/ONDB) – Lead Reviewer, S0
- Bradley Cunningham (ODE/DONED/ONDB) – Branch-Level Concurrence

II PURPOSE OF SUBMISSION

As per the submission cover letter, the applicant has submitted this 510(k) premarket notification, in the "Special" type, in order to solicit marketing clearance for a modified version of the **LipiView Ocular Surface Interferometer**. The unmodified version of the device was cleared under K091935.

III SUBMISSION HISTORY

A PREDICATE SUBMISSION HISTORY

- (b) (4) [redacted]

- The supplement (S1) to K091935 was received in FDA on June 24th, 2009. This supplement included revised claims, which no longer included anything regarding aiding in diagnosis. Additionally, the applicant removed all references from the device and labeling regarding measurement of absolute tear film lipid layer thicknesses. The device retained the ability to visualize relative lipid layer thicknesses via color mapping.

- Due to the resolution of all outstanding deficiencies, K091935 was found Substantially Equivalent (SE) to its predicate devices on October 23rd, 2009.

B CURRENT SUBMISSION HISTORY

- (August 14th, 2012) K122481 / S0, Received in FDA

IV BACKGROUND

A ANATOMY

Tears are liquid droplets secreted ("lacrimation") onto the anterior surface of the cornea to keep it moist, provide essential nutrients, and wash away dust and other particles; tears are composed of lipids (secreted by the meibomian glands), aqueous (secreted by lacrimal glands), and a mucin component (secreted by goblet cells in the conjunctiva). The tear film is a composition of these layers and exists on the anterior surface of the cornea, where lipids compose the most anterior layer.

B DIAGNOSTIC IMPLICATIONS FOR CLINICAL PRACTICE

As is stated in *Eye* (2003) **17,** 79–83, the thickness of the lipid layer of the tear film has been suggested to correlate with meibomian gland function, composition of meibomian gland secretions, effectiveness of blinking, width of the interpalpebral fissure (the separation between the upper and lower eyelids), tear film evaporation characteristics, tear film disassociation characteristics, and dry eye (keratitis sicca).

C CURRENT DEVICE

The previous iteration of this device (cleared under K091935) employed white light interferometry to produce a specular color map of the tear film (a topographic representation of the tear film in relative units), similar to the features offered by the Keeler Tearscope (cleared under K97064).

The current version of the LipiView Ocular Surface Interferometer modifies the previous iteration by including claims that each color on this color map is correlated to an absolute thickness, thus asserting the claim that the device can measure absolute thicknesses of the lipid layer of the tear film.

V OVERALL ADMINISTRATIVE REQUIREMENTS

REQUIREMENT	CURRENT SUBMISSION (S0) LOCATION
MDUFMA Cover Sheet (FDA Form 3601)	SECTION 1
CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)	SECTION 2
Cover Letter	SECTION 4
Indications for Use Statement	SECTION 7
510(k) **SUMMARY**	SECTION 8
Truthful and Accuracy Statement	SECTION 10
Class III Summary or Certification	SECTION 11 (N/A)
Financial Certification or Disclosure Statement	N/A
Clinical Certification Statement (FDA Form 3674)	N/A
Standards Data Report(s) (FDA Form 3654)	SECTION 9
Executive Summary	NO

S0 REVIEW COMMENT: **Administrative requirements appear to have been met.**

SECTION RECOMMENDATION: ADEQUATE

VI INDICATIONS FOR USE

The Indications for Use (IFU) statement, as reported in Section 7 of the current submission (S0), is the following:

> *"The LipiView Ocular Surface Interferometer in an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented."* (Prescription (Rx) Use)

A CONSISTENCY THROUGHOUT SUBMISSION

Aside from Section 7, the applicant provides the IFU statement in the following locations in the current submission (S0):

- Page 11/405 (FDA Form 3514, Page 3/5) → ***Identical***
- Page 28/405 (510(k) Summary, albeit under heading "Intended Use") → ***Identical***
- Page 124/405 (Substantial Equivalence Discussion, Table 13-1) → ***Identical***
- Page 153/405 (Page 11/81 of the Operation Manual) → ***Identical***

S0 REVIEW COMMENT: **The four instances of the IFU throughout the submission are identical to that which is provided in the IFU statement (Section 7) this is ADEQUATE.**

B COMPARISON TO PREDICATE DEVICES

The following is the IFU statement of the predicate device (the applicant's own, the previous iteration), the previous iteration of the LipiView Ocular Surface Interferometer (cleared under K091935, obtained from IMAGE):

> *"The LipiView Ocular Surface Interferometer in an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented."* (Prescription (Rx) Use)

C DECISION-MAKING

- **SAME INDICATIONS FOR USE?**

  YES. The Indications for Use of the current submission are identical to those of K091935.

- **DO THE DIFFERENCES ALTER THE EFFECT OR RAISE NEW QUESTIONS OF SAFETY AND/OR EFFECTIVENESS?**

  NOT APPLICABLE. The IFU are identical between those of the current submission and of the predicate device.

S0 REVIEW COMMENT: **There are no concerns regarding the IFU in comparison to predicate devices.**
SECTION RECOMMENDATION: ADEQUATE

VII TECHNOLOGICAL CHARACTERISTICS

The applicant provides a description of the technological characteristics of the LipiView device in the following places in the current submission (S0):

- Section 8 (510(k) Summary)
- Section 12 (Device Description)
- Section 13 (Substantial Equivalence Discussion)
- Section 15 (Summart of Design Control Activities)
- Section 14 (Proposed Labeling)

In Section 12.1 ("Introduction") of the current (S0) submission, the applicant states that they seek clearance of a "software upgrade to version 2.0." The applicant describes this software upgrade in Section 12.7 ("Description of Software Changes in Version 2.0"). Furthermore, the applicant lists manufacturing, hardware, software, and labeling changes made to the device since K091935 but unrelated to the software upgrade to Version 2.0.

A SOFTWARE CHANGES RELATED TO VERSION 2.0 UPGRADE

The applicant states that the following changes have been as part of the software upgrade to Version 2.0:

- (Primary Device Change) The color lookup table now includes absolute thicknesses; therefore, the color map provided
- Modification of criteria used by the software to determine if a particular image frame occurred during a patient blink
- Inclusion of a new feature to allow users to selectively view frames during which blinks occurred
- Inclusion of a new feature to automatically document the number of complete and partial blinks
- A reduction in the maximum amount of video allowed to be captured
- New ability to export videos
- Inclusion of "example Tear Film videos"

S0 REVIEW COMMENT: **The applicant should provide a narrative**

description, software requirements, software design specifications, and a hazard analysis specific to these software changes. This is important to ensure that each of these changes is well described. DEFICIENCY 1 SHOULD BE CONVEYED TO THE APPLICANT.

Furthermore, please refer to the "Performance Testing" section of this review (*below*) for validation of these changes.

B OTHER HARDWARE / SOFTWARE CHANGES SINCE K091935

In Section 12.8 ("Device Changes Since Last Filing") of the current submission, the applicant lists hardware and software changes, other than those related to the Version 2.0 software upgrade, since clearance under K091935. These are listed below:

- Lens aperture changed from F2 to F2.8
- Modification of structural components (stated to be for ease of assembly)
- Hardware fit and finish changes
- Manufacturability-related changes
- Software anomaly fixes
- "Replaced color checker calibration with lens black in calibration procedure" (12.8.10)
- New computer general hardware upgrades

S0 REVIEW COMMENT: **While most of the above changes are minor enough that no further information is required, a few items are of concern:**

- **Regarding the lens aperture change, the applicant should provide a rationale for this change and discuss how image quality is affected; DEFICIENCY 2 SHOULD BE CONVEYED TO THE APPLICANT**
- **Please refer to the "Performance Testing" section of this review for a validation of the software anomaly fixes**
- **The change in calibration procedures is not clear; the applicant should provide a description of the new procedure; if software changes were made, the applicant should provide a narrative description, software requirements, software design specifications, and a hazard analysis specific to these software changes; DEFICIENCY 2 SHOULD BE CONVEYED TO THE APPLICANT**

C DECISION-MAKING

- **SAME TECHNOLOGICAL CHARACTERISTICS?**

  NO. The applicant has made hardware and software modifications since clearance under K091935; please refer to the previous sub-sections for more information regarding these changes.

- **COULD THE NEW CHARACTERISTICS AFFECT SAFETY AND/OR EFFECTIVENESS?**

  YES / NOT CLEAR. Based on the brief descriptions of each change provided, overall software functionality, image quality, and the diagnostic utility of the device may be affected. However, details regarding these changes have not been provided *(please see Deficiencies 1 & 2)*

- **ARE THERE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?**

  NO. These questions are identical to those of the device cleared under K091935.

- **DO ACCEPTED SCIENTIFIC METHODS EXIST FOR ASSESSING THE EFFECTS OF THE NEW CHARACTERISTICS? YES** *(See Below)*

VIII PERFORMANCE TESTING

- **ARE PERFORMANCE DATA AVAILABLE TO ALLOW FOR ASSESSMENT OF EQUIVALENCE? NO.**

A TESTING TO VERIFY FUNCTIONALITY OF VERSION 2.0 SOFTWARE CHANGES

> ***S0 REVIEW COMMENT:*** **To verify functionality of each of the changes due to the Version 2.0 software upgrade, the applicant should provide testing which tests against design specifications for each change. DEFICIENCY 3 SHOULD BE CONVEYED TO THE APPLICANT.**

B TESTING TO VERIFY FUNCTIONALITY OF SOFTWARE ANOMALY FIXES

> ***S0 REVIEW COMMENT:*** **To verify functionality of each of the software anomaly fixes (identified in 12.8.5, 12.8.10, and 12.8.13), the applicant should provide testing which tests against design specifications for each change. DEFICIENCY 3 SHOULD BE CONVEYED TO THE APPLICANT.**

C TESTING TO VERIFY FUNCTIONALITY OF SOFTWARE CHANGES ASSOCIATED WITH CALIBRATION PROCEDURE CHANGES

> ***S0 REVIEW COMMENT:*** **If changes to the calibration procedure involve software changes, to verify functionality of these changes, the applicant should provide testing which tests against design specifications for each change. DEFICIENCY 3 SHOULD BE CONVEYED TO THE APPLICANT.**

D VALIDATION OF ABSOLUTE THICKNESS MEASUREMENTS, CALIBRATION

S0 REVIEW COMMENT: **To validate the ability of the device to make absolute tear film lipid layer thickness measurements, the applicant should provide the following information (to the extent that calibration is involved in measurement-making, this should be considered in the response):**

- **A complete description of the tear film phantoms used, including materials, dimensions (with manufacturing tolerances), refractive indices, and evidence that these phantoms are an accurate representation of the pre-corneal tear film**
- **Clarification as to whether these phantoms were used to develop device measurements or validate device measurements (or both), and a description of how**
- **In-vivo testing that quantifies device measurement variability (precision)**

DEFICIENCY 4 SHALL BE CONVEYED TO THE APPLICANT.

IX LABELING

The applicant provides the following labeling in Section 14 of the current submission:

- Red-lined Operation Manual related to software upgrade to Version 2.0
- Red-lined Operation Manual related to other device modifications

S0 REVIEW COMMENT: **Although the labeling will be re-reviewed based on the response to Deficiency 4, it is of concern that neither of the above provided documents include information regarding example videos or absolute thickness measurements. The applicant should provide a revised Operation Manual that includes this information.**

DEFICIENCY 5 SHALL BE CONVEYED TO THE APPLICANT.

X RECOMMENDATION

I RECOMMEND THAT K122481 / S0 BE PLACED ON HOLD, AND THAT THE FOLLOWING DEFICIENCIES BE CONVEYED TO THE APPLICANT.

XI DEFICIENCIES

1) (b) (4) [redacted]

(b) (4)

(b) (4)

2) (b) (4)

3) (b) (4)

4) (b) (4)

(b) (4)

[redacted]

5) You provide the following labeling in Section 14 of the submission:

(b) (4)

[redacted]

S0 REVIEW COMMENT: **Please note that these deficiencies may be slightly modified in the telephone hold memorandum. Please refer to the actual telephone hold memorandum for the actual deficiency language.**

Lead Reviewer Signoff:

Ka N. To 2012.10.31 17:03:15 -04'00'

Rahul Ram (ODE/DONED/ONDB)

Management Signoff:

Bradley S. Cunningham 2012.10.31 17:18:44 -04'00'

Brad Cunningham (ODE/DONED/ONDB)

Date_____. Concur: Yes ☐ No ☐

Division Level_____

Date_____. Concur: Yes ☐ No ☐

To, Ka

ɔm:	Cunningham, Bradley
Sent:	Wednesday, October 31, 2012 5:19 PM
To:	To, Ka
Cc:	Washington, Evella
Attachments:	K122481S0 TL (bsc signed).pdf

please print out and put into the submision and hand to Evella

16

To, Ka

m: To, Ka
Sent: Wednesday, October 31, 2012 5:11 PM
To: 'cstevens@tearscience.com'
Cc: Cunningham, Bradley; Ram, Rahul
Subject: K122481/S0
Attachments: K122481S0 TH Letter.pdf

Dear Ms. Stevens,

Enclosed is our review of your submission, K122481/S0. Your submission has been placed on hold.

I am sending this on behalf of Rahul Ram, the lead reviewer for this submission. Please contact Rahul Ram for any questions or concerns.

Best Regards,
Ka Nam To

Ka Nam To
ODE Reviewer, Biomedical Engineer
FDA/OMPT/CDRH/ODE/DONED/ONDB
Email: Ka.To@fda.hhs.gov
Phone: (301)-796-4634
‹: (301)-796-8126

Public Health Service
DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration

Memorandum

Date: October 31, 2012

From: Rahul Ram
Lead Reviewer, K122481
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch
Division of Ophthalmic, Neurologic and ENT Devices
Center for Devices and Radiological Health

To: Ms. Christy Stevens
Tear Science, Inc.
5151 McCrimmon Parkway, Suite 250
Morriville, NC 27560
cstevens@tearscience.com

Subject: Traditional 510(k): K122481
Trade Name: LipiView Ocular Surface Interferometer
Dated: August 13, 2012
Received: August 14, 2012

Dear Ms. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require:

1. (b) (4)

2. (b) (4) [redacted]

3. (b) (4) [redacted]

4. (b) (4) [redacted]

5. (b) (4) [redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter and would like to set up a teleconference, please contact Mr. Rahul Ram at (301) 796-6620. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

To, Ka

m: Cunningham, Bradley
Sent: Wednesday, October 31, 2012 4:33 PM
To: To, Ka
Cc: Ram, Rahul
Subject: K122481S0 TH Letter (bsc).doc
Attachments: K122481S0 TH Letter (bsc).doc

attached are my edits. I have some comments; but they are really for future consideration. Meaning, Nam, if you would, please clean up the letter and digitally sign Rahul's review for him. Please also include this email in the file as a record of me asking you to sign for Rahul while he's out of the office.

After signing the review, please send it to me so I may sign it as well. Please also make sure it's logged out in CTS.

Thanks!
Brad

K122481/S1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

V.1

DEC 31 2012

Tearscience, Inc.
c/o Christy Stevens, OD
VP, Clinical & Regulatory Affairs
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560

Re: K122481
Trade/Device Name: LipiView Ocular Surface Interferometer
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, HJO
Dated: December 18, 2012
Received: December 19, 2012

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K122481 (To Be Assigned By FDA)

Device Name: LipiView® Ocular Surface Interferometer with Software Version 2.0

Indications for Use:

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K122481

Page __ of ___

* * * COMMUNICATION RESULT REPORT (JAN. 3. 2013 3:12PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : JAN. 3. 2013 3:10PM

E MODE	OPTION	ADDRESS	RESULT	PAGE
2278 MEMORY TX		18774685335	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 3 1 2012

Tearscience, Inc.
c/o Christy Stevens, OD
VP, Clinical & Regulatory Affairs
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560

Re: K122481
Trade/Device Name: LipiView Ocular Surface Interferometer
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, HJO
Dated: December 18, 2012
Received: December 19, 2012

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Rahul Ram

Subject: 510(k) Number K122481/S1

To: The Record

Please list CTS decision code: **SE**

o Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

o Hold (Additional Information or Telephone Hold).

X **Final Decision (SE**, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

o	NO	NSE for lack of predicate
o	NI	NSE for new intended use
o	NQ	NSE for new technology that raises new questions of safety and effectiveness
o	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
o	NP	NSE for lack of performance data
o	NS	NSE no response
o	NL	NSE for lack of performance data AND no response
o	NM	NSE pre-amendment device call for PMAs (515i)
o	NC	NSE post-amendment device requires PMAs
o	NH	NSE for new molecular entity requires PMA
o	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			☒
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			☒

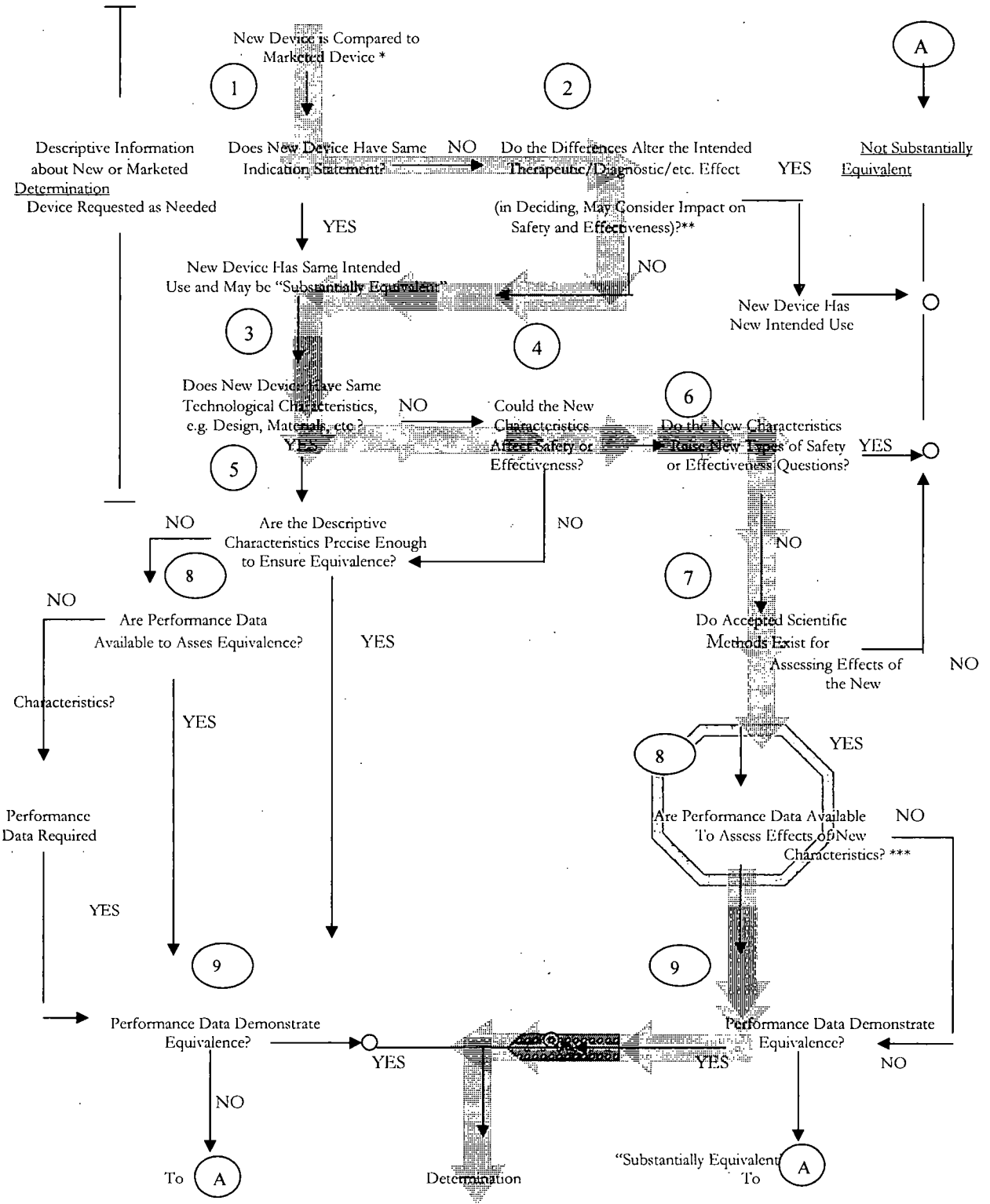
conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	**Class***	**Product Code**
21 CFR 886.1120	II	HKI
	(*If unclassified, see 510(k) Staff)	

Additional Product Codes: HJO

Digital Signature Concurrence Table	
Reviewer Sign-Off	Digitally signed by Rahul K. Ram -S (Affiliate) DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000627332, cn=Rahul K. Ram -S (Affiliate) Date: 2012.12.31 14:16:25 -05'00'
Branch Chief Sign-Off	Bradley S. Cunningham 2012.12.31 14:21:06 -05'00'
Division Sign-Off	Deborah L. Falls 2012.12.31 14:34:20 -05'00'

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Center for Devices & Radiological Health

Division of Ophthalmic, Ear, Nose, and Throat Devices
Diagnostic & Surgical Devices Branch
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
(301) 796-6620

SUPPLEMENTAL (S1) PREMARKET NOTIFICATION [510(K)] REVIEW

DATE: December 31st, 2012
TO: RECORD
FROM: Rahul Ram
SUBJECT: Traditional Supplement, K122481 / S1

510(K) HOLDER: TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560	**OFFICIAL CORRESPONDENT:** Christy Stevens VP, Clinical & Regulatory Affairs **Email:** cstevens@tearscience.com **Phone:** (919) 459-4815 **Fax:** (877) 468-5335
DEVICE TRADE NAME: LipiView Ocular Surface Interferometer	
DESCRIPTION: Interferometer to Observe Ocular Tear Film	
510(K) DATED DATE: December 18th, 2012	
510(K) RECEIVED DATE: December 19th, 2012	

APPLICANT-IDENTIFIED PREDICATE DEVICE:

510(K) NUMBER	PRODUCT CODE	DEVICE NAME	510(K) HOLDER
K091935	HKI, HJO	LipiView Ocular Surface Interferometer	TearScience, Inc.

RECOMMENDATION:

The submission concerning the **LipiView Ocular Surface Interferometer** requires no additional information in order to proceed with the review, and all safety / effectiveness concerns have been addressed. Therefore, I recommend that the submission be found **SUBSTANTIALLY EQUIVALENT (SE).**

Regulation Number: **21 CFR 886.1120**
Regulation Name: **Ophthalmic Camera**
Regulatory Class: **Class II**
Product Code: **HKI**
Produce Code Description: **Camera, Ophthalmic, AC-Powered**

Additional Product Codes: **HJO**

INDICATIONS FOR USE (IFU) STATEMENT: ☒ **Prescription** ☐ **Over-the-Counter**

"The LipiView Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView Interferometer measures the absolute thickness of the tear film lipid layer."

I SUBMISSION REVIEWERS

- Rahul Ram (ODE/DONED/ONDB) – Lead Reviewer, S0
- Bradley Cunningham (ODE/DONED/ONDB) – Branch-Level Concurrence

II PURPOSE OF SUBMISSION

As per the submission cover letter, the applicant has submitted this 510(k) premarket notification, in the "Special" type, in order to solicit marketing clearance for a modified version of the **LipiView Ocular Surface Interferometer**. The unmodified version of the device was cleared under K091935.

III FORMAT OF REVIEW

To ensure that this review is wholly inclusive of all pertinent information, it contains almost all the information from the review of the original submission (S0). Please note the following conventions in this review:

1. Updated information as per the current submission (S1) is included as **bold** text, and indicated by the following symbol: "**/**".
2. New, S1 Review Comments are bolded.
3. Review Comments from S0 are un-bolded.

IV SUBMISSION HISTORY

A PREDICATE SUBMISSION HISTORY

- The submission for the predicate device (K091935 / S0) was received in FDA on June 24th, 2009. In review of that submission, it was noted that the applicant had not

validated claims of providing an aid to the diagnosis of tear film conditions, nor had the applicant validated the ability of the device to correlate measured reflections to absolute tear film lipid layer thicknesses.

- The supplement (S1) to K091935 was received in FDA on June 24th, 2009. This supplement included revised claims, which no longer included anything regarding aiding in diagnosis. Additionally, the applicant removed all references from the device and labeling regarding measurement of absolute tear film lipid layer thicknesses. The device retained the ability to visualize relative lipid layer thicknesses via color mapping.

- Due to the resolution of all outstanding deficiencies, K091935 was found Substantially Equivalent (SE) to its predicate devices on October 23rd, 2009.

B CURRENT SUBMISSION HISTORY

- (August 14th, 2012) K122481 / S0, Received in FDA
- **(October 31st, 2012) K122481 / S0, Placed on Telephone Hold**
- **(December 19th, 2012) K122481 / S1, Received in FDA**

V BACKGROUND

A ANATOMY

Tears are liquid droplets secreted ("lacrimation") onto the anterior surface of the cornea to keep it moist, provide essential nutrients, and wash away dust and other particles; tears are composed of lipids (secreted by the meibomian glands), aqueous (secreted by lacrimal glands), and a mucin component (secreted by goblet cells in the conjunctiva). The tear film is a composition of these layers and exists on the anterior surface of the cornea, where lipids compose the most anterior layer.

B DIAGNOSTIC IMPLICATIONS FOR CLINICAL PRACTICE

As is stated in *Eye* (2003) **17,** 79–83, the thickness of the lipid layer of the tear film has been suggested to correlate with meibomian gland function, composition of meibomian gland secretions, effectiveness of blinking, width of the interpalpebral fissure (the separation between the upper and lower eyelids), tear film evaporation characteristics, tear film disassociation characteristics, and dry eye (keratitis sicca).

C CURRENT DEVICE

The previous iteration of this device (cleared under K091935) employed white light interferometry to produce a specular color map of the tear film (a topographic representation of the tear film in relative units), similar to the features offered by the Keeler Tearscope (cleared under K97064).

The current version of the LipiView Ocular Surface Interferometer modifies the previous iteration by including claims that each color on this color map is correlated to an absolute thickness, thus asserting the claim that the device can measure absolute thicknesses of the lipid layer of the tear film.

VI OVERALL ADMINISTRATIVE REQUIREMENTS

REQUIREMENT	CURRENT SUBMISSION (S0) LOCATION
MDUFMA Cover Sheet (FDA Form 3601)	SECTION 1
CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)	SECTION 2
Cover Letter	SECTION 4
Indications for Use Statement	SECTION 7
510(k) SUMMARY	SECTION 8
Truthful and Accuracy Statement	SECTION 10
Class III Summary or Certification	SECTION 11 (N/A)
Financial Certification or Disclosure Statement	N/A
Clinical Certification Statement (FDA Form 3674)	N/A
Standards Data Report(s) (FDA Form 3654)	SECTION 9
Executive Summary	NO

S0 REVIEW COMMENT: Administrative requirements appear to have been met.
SECTION RECOMMENDATION: ADEQUATE

VII INDICATIONS FOR USE

The Indications for Use (IFU) statement, as reported in Section 7 of the original submission (S0), was the following:

> *"The LipiView Ocular Surface Interferometer in an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented."* (Prescription (Rx) Use)

A CONSISTENCY THROUGHOUT SUBMISSION

Aside from Section 7, the applicant provided the IFU statement in the following locations in the original submission (S0):

- Page 11/405 (FDA Form 3514, Page 3/5) → ***Identical***
- Page 28/405 (510(k) Summary, albeit under heading "Intended Use") → ***Identical***
- Page 124/405 (Substantial Equivalence Discussion, Table 13-1) → ***Identical***
- Page 153/405 (Page 11/81 of the Operation Manual) → ***Identical***

S0 REVIEW COMMENT: The four instances of the IFU throughout the

submission are identical to that which is provided in the IFU statement (Section 7) this is ADEQUATE.

B COMPARISON TO PREDICATE DEVICES

The following is the IFU statement of the predicate device (the applicant's own, the previous iteration), the previous iteration of the LipiView Ocular Surface Interferometer (cleared under K091935, obtained from IMAGE):

"The LipiView Ocular Surface Interferometer in an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented." (Prescription (Rx) Use)

The applicant was asked, via interactive review (please see Pages 37 and 38 of the current (S1) submission), to revise their IFU statement to make explicit the claim of making absolute thickness measurements in their IFU. Accordingly the applicant provides a revised IFU statement, 510(k) Summary, and Substantial Equivalence Discussion section in Sections 4, 5, and 6, respectively, in the current (S1) submission. The new IFU statement is as follows:

"The LipiView Ocular Surface Interferometer in an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView Interferometer measures the absolute thickness of the tear film lipid layer." (Prescription (Rx) Use)

C DECISION-MAKING

- **SAME INDICATIONS FOR USE?**

No. The Indications for Use of the current submission includes the claim of making absolute thickness measurements, whereas the predicate IFU did not include this claim.

- **DO THE DIFFERENCES ALTER THE EFFECT OR RAISE NEW QUESTIONS OF SAFETY AND/OR EFFECTIVENESS?**

YES, HOWEVER... This new claim has been validated (see sections of this review below).

S1 REVIEW COMMENT: **There are no concerns regarding the IFU in comparison to predicate devices.**

SECTION RECOMMENDATION: ADEQUATE

VIII TECHNOLOGICAL CHARACTERISTICS

The applicant provided a description of the technological characteristics of the LipiView device in the following places in the original submission (S0):

- Section 8 (510(k) Summary)
- Section 12 (Device Description)
- Section 13 (Substantial Equivalence Discussion)
- Section 15 (Summart of Design Control Activities)
- Section 14 (Proposed Labeling)

In Section 12.1 ("Introduction") of the original (S0) submission, the applicant stated that they seek clearance of a "software upgrade to version 2.0." The applicant described this software upgrade in Section 12.7 ("Description of Software Changes in Version 2.0"). Furthermore, the applicant listed manufacturing, hardware, software, and labeling changes made to the device since K091935 but unrelated to the software upgrade to Version 2.0.

A SOFTWARE CHANGES RELATED TO VERSION 2.0 UPGRADE

The applicant stated that the following changes have been as part of the software upgrade to Version 2.0:

- (Primary Device Change) The color lookup table now includes absolute thicknesses; therefore, the color map provided
- Modification of criteria used by the software to determine if a particular image frame occurred during a patient blink
- Inclusion of a new feature to allow users to selectively view frames during which blinks occurred
- Inclusion of a new feature to automatically document the number of complete and partial blinks
- A reduction in the maximum amount of video allowed to be captured
- New ability to export videos
- Inclusion of "example Tear Film videos"

In review of this information in the original (S0) submission, the following comment was noted:

S0 REVIEW COMMENT: The applicant should provide a narrative description, software requirements, software design specifications, and a hazard analysis specific to these software changes. This is important to ensure that each of these changes is well described. DEFICIENCY 1 SHOULD BE CONVEYED TO THE APPLICANT. Furthermore, please refer to the "Performance Testing" section of this review (*below*) for validation of these changes.

Accordingly, Deficiency 3 was conveyed to the applicant in the October 31st hold memorandum (reproduced below):

You state that the following changes have been as part of the software upgrade to Version 2.0:

- *The color lookup table now includes absolute thicknesses; therefore, the color map provided*
- *Modification of criteria used by the software to determine if a particular image frame occurred during a patient blink*
- *Inclusion of a new feature to allow users to selectively view frames during which blinks occurred*
- *Inclusion of a new feature to automatically document the number of complete and partial blinks*
- *A reduction in the maximum amount of video allowed to be captured*
- *New ability to export videos*
- *Inclusion of "example Tear Film videos"*

(b) (4)

[redacted]

In the current submission (S1), the applicant responds to Deficiency 3 by providing a full description of each change (Section 16), hazard analysis documentation (Sections 17-22) and software requirement and design specifications (Sections 23-25).

S1 REVIEW COMMENT: **The information provided fully characterizes each change and describes the hazards associated with each change. The applicant's response to Deficiency 3 is ADEQUATE.**

B OTHER HARDWARE / SOFTWARE CHANGES SINCE K091935

In Section 12.8 ("Device Changes Since Last Filing") of the original submission, the applicant listed hardware and software changes, other than those related to the Version 2.0 software upgrade, since clearance under K091935. These are listed below:

- Lens aperture changed from F2 to F2.8
- Modification of structural components (stated to be for ease of assembly)
- Hardware fit and finish changes
- Manufacturability-related changes
- Software anomaly fixes
- "Replaced color checker calibration with lens black in calibration procedure" (12.8.10)
- New computer general hardware upgrades

In review of this information in the original (S0) submission, the following comments were noted:

S0 REVIEW COMMENT: While most of the above changes are minor enough that no further information is required, a few items are of concern:

- Regarding the lens aperture change, the applicant should provide a rationale for this change and discuss how image quality is affected; DEFICIENCY 2 SHOULD BE CONVEYED TO THE APPLICANT
- Please refer to the "Performance Testing" section of this review for a validation of the software anomaly fixes
- The change in calibration procedures is not clear; the applicant should provide a description of the new procedure; if software changes were made, the applicant should provide a narrative description, software requirements, software design specifications, and a hazard analysis specific to these software changes; DEFICIENCY 2 SHOULD BE CONVEYED TO THE APPLICANT

Accordingly, Deficiency 4 was conveyed to the applicant in the October 31st hold memorandum (reproduced below):

In Section 12.8 ("Device Changes Since Last Filing"), you list hardware and software changes (other than those related to the Version 2.0 software upgrade) since clearance under K091935. To ensure that these changes pose no unmitigated concerns of safety and/ or effectiveness, please address the following concerns regarding these changes:

a. *You state that the lens aperture has changed from F2 to F2.8. Please provide the rationale for this change and justification for why image quality is not compromised.*

b. *You state that you have "replaced color checker calibration with lens black in calibration procedure." This change is not clear. Please provide a complete description of this change. If this change involved software modifications, please provide a narrative description, software requirements, software design specifications, and a hazard analysis specific to these software modifications.*

In the current submission (S1), the applicant responds to Deficiency 4 by clarifying that the change was actually the reverse; the aperture was changed from F2.8 to F2. The applicant states that this change was performed to provide a "longer illumination life," and to reduce reflex tearing in photo-sensitive patients. The applicant states that image quality is not compromised because light intensity has been reduced by a commensurate amount to compensate for the larger aperture. Furthermore, the applicant acknowledges that depth of field is reduced with a larger aperture; however a deep field of view is not necessary for measurements of the device. Finally, the applicant describes changes to the calibration procedure and states that no software changes were required for these changes.

S1 REVIEW COMMENT: **The applicant's response to Deficiency 4 is**

ADEQUATE.

C DECISION-MAKING

- **SAME TECHNOLOGICAL CHARACTERISTICS?**

  NO. The applicant has made hardware and software modifications since clearance under K091935; please refer to the previous sub-sections for more information regarding these changes.

- **COULD THE NEW CHARACTERISTICS AFFECT SAFETY AND/OR EFFECTIVENESS?**

  YES. Based on the brief descriptions of each change provided, overall software functionality, image quality, and the diagnostic utility of the device may be affected.

- **ARE THERE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?**

  NO. These questions are identical to those of the device cleared under K091935.

- **DO ACCEPTED SCIENTIFIC METHODS EXIST FOR ASSESSING THE EFFECTS OF THE NEW CHARACTERISTICS? YES** *(See Below)*

IX PERFORMANCE TESTING

- **ARE PERFORMANCE DATA AVAILABLE TO ALLOW FOR ASSESSMENT OF EQUIVALENCE? YES.**

A TESTING TO VERIFY FUNCTIONALITY OF VERSION 2.0 SOFTWARE CHANGES, TESTING TO VERIFY FUNCTIONALITY OF SOFTWARE ANOMALY FIXES

In the original (S0) submission, it was noted that the applicant had provided no testing to verify functionality of software changes. Accordingly, Deficiency 2 was conveyed to the applicant in the October 31st memorandum (reproduced below):

You provide no testing to verify functionality of the software changes you have made to your device. This is important to ensure that device functionality is not affected adversely by your software changes. Therefore, please provide the following information:

a. *Testing, as per design specifications, to ensure that the functionalities of Version 2.0 software changes are verified*
b. *Testing, as per design specifications, to ensure that the functionalities of other software changes (identified in Sections 12.8.5, 12.8.10, and 12.8.13) are verified*
c. *Testing, as per design specifications, to ensure that functionalities of software changes (if any) related to calibration procedure changes are verified*

d. *System-level regression testing to ensure that software changes have not adversely affected other parts of the software*

In the current submission (S0), the applicant responds by clarifying that the software version is now 2.0b, and provides testing to verify functionality of the new changes and regression testing to ensure the rest of the software still functions properly (Sections 16, 26-30).

S1 REVIEW COMMENT: **The applicant's response to Deficiency 2 is ADEQUATE.**

B VALIDATION OF ABSOLUTE THICKNESS MEASUREMENTS, CALIBRATION

In the original (S0) review, the following comment was noted regarding the lack of validation of the ability of the device to make absolute thickness measurements:

S0 REVIEW COMMENT: To validate the ability of the device to make absolute tear film lipid layer thickness measurements, the applicant should provide the following information (to the extent that calibration is involved in measurement-making, this should be considered in the response):

- A complete description of the tear film phantoms used, including materials, dimensions (with manufacturing tolerances), refractive indices, and evidence that these phantoms are an accurate representation of the pre-corneal tear film
- Clarification as to whether these phantoms were used to develop device measurements or validate device measurements (or both), and a description of how
- In-vivo testing that quantifies device measurement variability (precision)

DEFICIENCY 4 SHALL BE CONVEYED TO THE APPLICANT.

To that end, Deficiency 1 was conveyed to the applicant in the October 31st hold memorandum (reproduced below):

You did not provide evidence to validate the ability of the device to make absolute thickness measurements of the tear film lipid layer (and calibration, to the extent that calibration affects the measurement). This is important to ensure that the functions of all features of your device have been validated. Therefore, please provide the following:

a. *A complete description of the tear film phantoms used, including materials, dimensions (with manufacturing tolerances), refractive indices, and evidence that these phantoms are an accurate representation of the pre-corneal tear film*
b. *Clarification as to whether these phantoms were used to develop device measurements or validate device measurements (or both), and a description of how*
c. *In-vivo testing that quantifies device measurement variability (precision)*

In the current (S1) submission, the applicant provides a description of the phantoms in Section 8, and precision testing in Section 15. Furthermore, the applicant provides additional pre-clinical validation testing in Sections 9 – 15.

S1 REVIEW COMMENT: **Based upon the applicant's description o the phantoms and corresponding testing, it appears that they sufficiently represent the optical properties of the human tear film, and that the device will measure lipid layer thicknesses reasonably accurately and precisely. The applicant's response to Deficiency 1 is ADEQUATE.**

X LABELING

The applicant provides the following labeling in Section 14 of the current submission:

- Red-lined Operation Manual related to software upgrade to Version 2.0
- Red-lined Operation Manual related to other device modifications

In the original (S0) review, it was noted that the applicant had not included mentions of example videos or absolute thickness measurements in the labeling. Accordingly, Deficiency 5 was conveyed to the applicant in the October 31st hold memorandum (reproduced below):

You provide the following labeling in Section 14 of the submission:

- *Red-lined Operation Manual related to software upgrade to Version 2.0*
- *Red-lined Operation Manual related to other device modifications*

However, neither of these documents includes descriptions of absolute thickness measurements or example videos. These are significant features of your device that should be described in the labeling. Therefore, please provide a revised, red-lined copy of the Operation Manual that includes descriptions of these features.

In the current (S1) submission, the applicant provides a revised Operation Manual with the requested information included (Section 7).

S1 REVIEW COMMENT: **The applicant's response to Deficiency 5 is ADEQUATE.**

XI RECOMMENDATION

The submission concerning the LipiView Ocular Surface Interferometer requires no additional information in order to proceed with the review, and all safety / effectiveness concerns have been addressed. Therefore, I recommend that the submission be found SUBSTANTIALLY EQUIVALENT (SE).

Lead Reviewer Signoff: Digitally signed by Rahul K. Ram -S (Affiliate)
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000627332, cn=Rahul K. Ram -S (Affiliate)
Date: 2012.12.31 13:17:33 -05'00'

Rahul Ram (ODE/DONED/ONDB)

Management Signoff:

Bradley S. Cunningham
2012.12.31 14:06:42 -05'00'

Brad Cunningham (ODE/DONED/ONDB)

Date_____. Concur: Yes ☒ No ☐

Division Level Deborah L. Falls 2012.12.31 14:31:57 -05'00'

Date_____. Concur: Yes ☒ No ☐

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 19, 2012

TEARSCIENCE, INC.
5151 McCrimmon Parkway
Suite 250
Morrisville, NORTH CAROLINA 27560
ATTN: CHRISTY STEVENS

510k Number: K122481

Product: LIPIVIEW OCULAR SURFACE INTERF

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

EXPLANATION FOR ECOPY ATTACHMENT

You provided an eCopy along with the required number of paper copies. Your eCopy did not pass our validation software. The specific reasons for this failure are identified in the attachment.

Because eCopies are currently voluntary and because you already provided the necessary number of paper copies, you do NOT need to provide a replacement eCopy to FDA.

Instead, FDA is providing you with this information so that you can understand the reasons why your eCopy failed in order to better assure that an eCopy that you submit for another submission will not have similar issues.

As additional resources:

- Refer to our eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. The eCopy program is not implemented (i.e., eCopy remain voluntary) at this time; however, the technical specifications/standards in Attachment 1 of the guidance are already in place.

- We strongly encourage you to take advantage of our free new eSubmitter-eCopies tool at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm317334.htm, which will help create an eCopy that passes the new technical specifications/standards.

Please keep in mind that once we implement the new eCopy program, most submissions types will go on eCopy hold until a valid eCopy is received.

If you have any questions about the eCopy program or the technical specifications/standards, please contact Ms. Samie Allen at samie.allen@fda.hhs.gov or at 301-796-6055.

Attachment

Attachment for Submission Number(s):

K122481/S001

(b) (4)

[redacted]

Pugh, Dominique *

From: Microsoft Outlook
To: CStevens@TearScience.com
Sent: Wednesday, December 19, 2012 1:10 PM
Subject: Relayed: K122481 AI LETTER & ECOPY ATTACHMENT

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

CStevens@TearScience.com (CStevens@TearScience.com)

Subject: K122481 AI LETTER & ECOPY ATTACHMENT

K122481/S001

TearScience®

K4

December 18, 2012

Rahul Ram
Lead Reviewer, K122481
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch
Division of Ophthalmic, Neurologic and ENT Devices
Center for Devices and Radiological Health

Re: Traditional 510(k): K122481
Response to Telephone Hold Memorandum dated October 31, 2012
Trade Name: LipiView® Ocular Surface Interferometer with Software Version 2.0

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[redacted]

(b) (4)

[redacted]

K122481/S001

TearScience®

December 18, 2012

Rahul Ram
Lead Reviewer, K122481
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch
Division of Ophthalmic, Neurologic and ENT Devices
Center for Devices and Radiological Health

Re: Traditional 510(k): K122481
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Trade Name: LipiView® Ocular Surface Interferometer with Software Version 2.0

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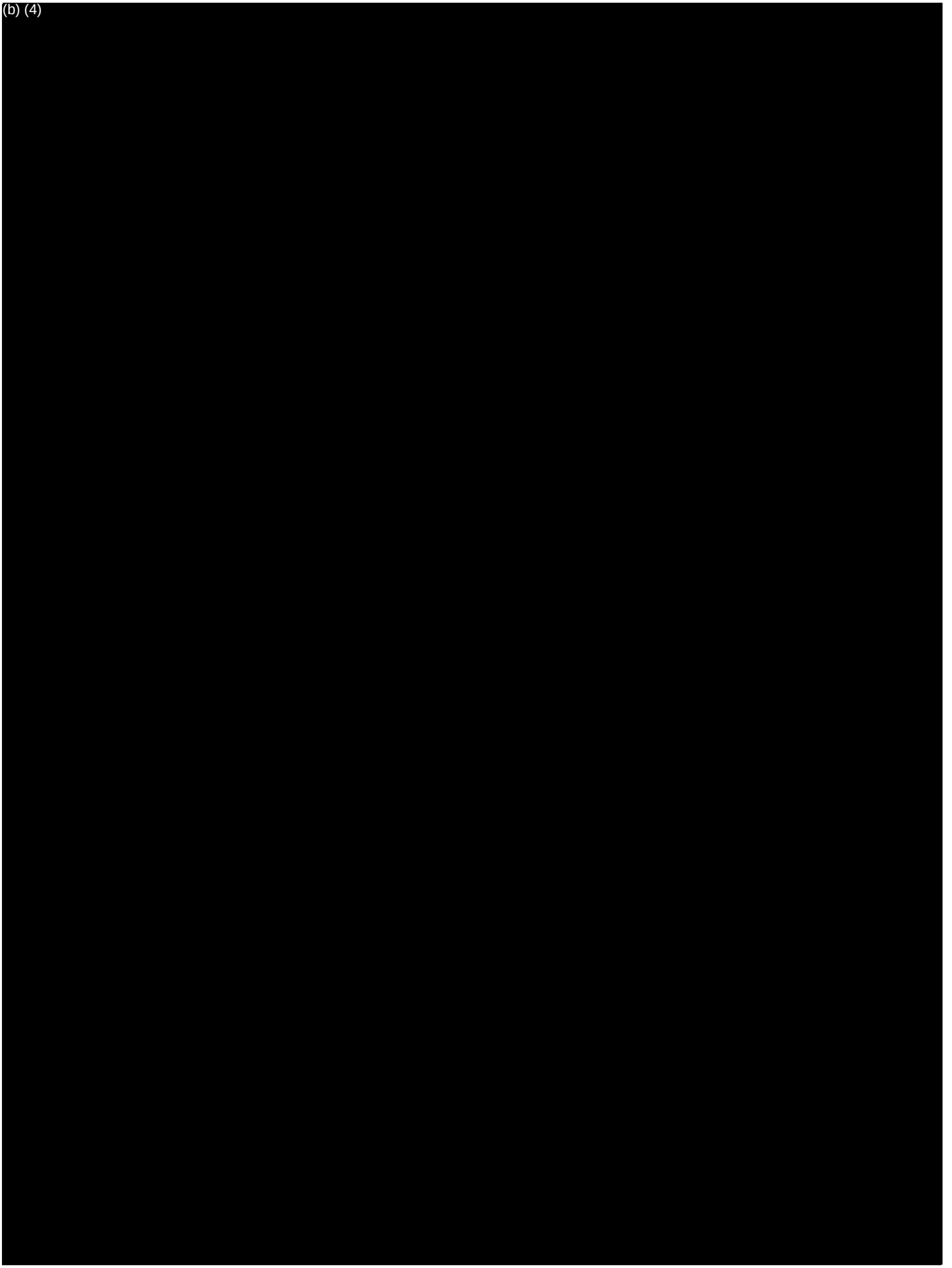

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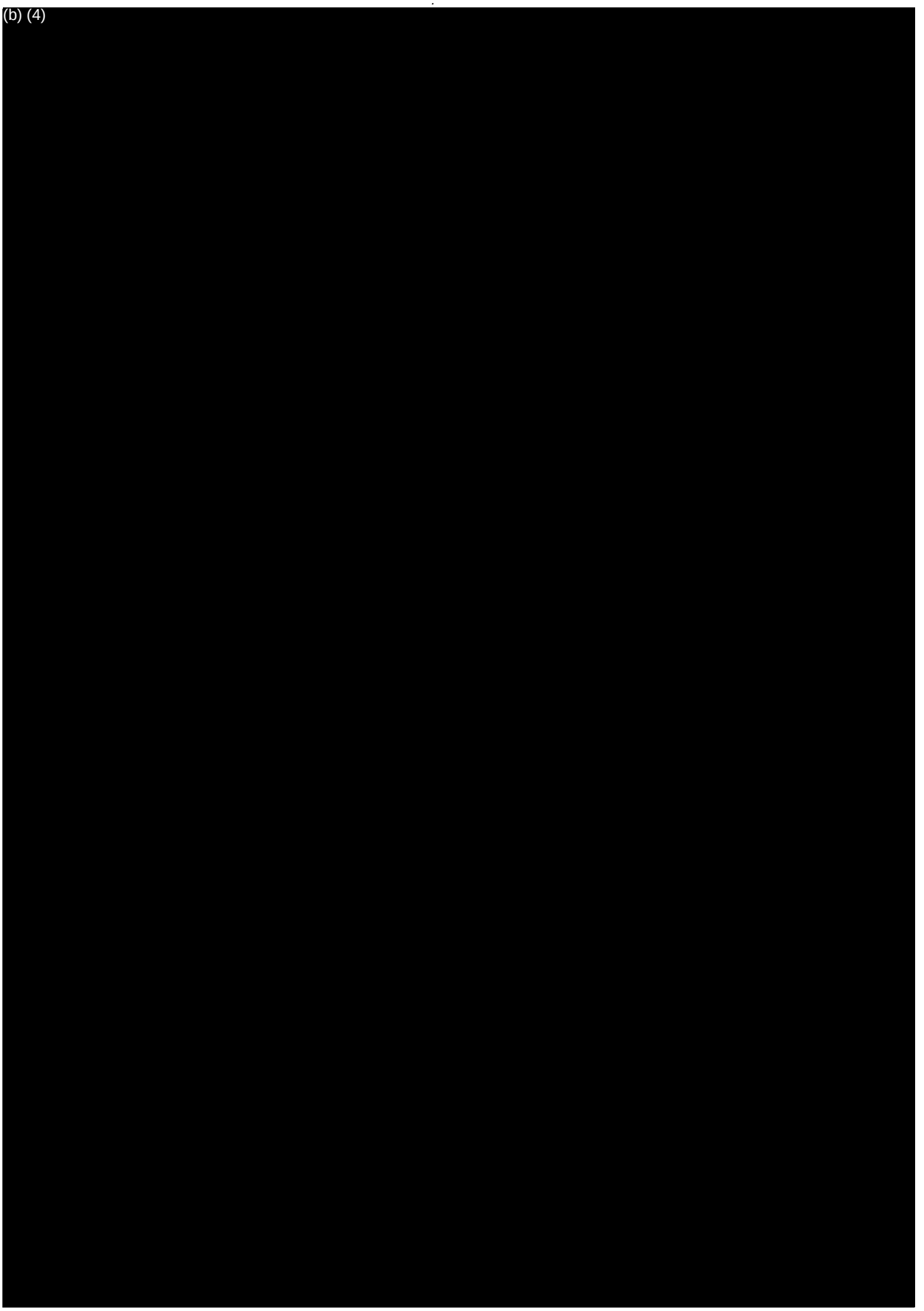

3. RESPONSE TO MEMORANDUM DATED OCTOBER 31, 2012

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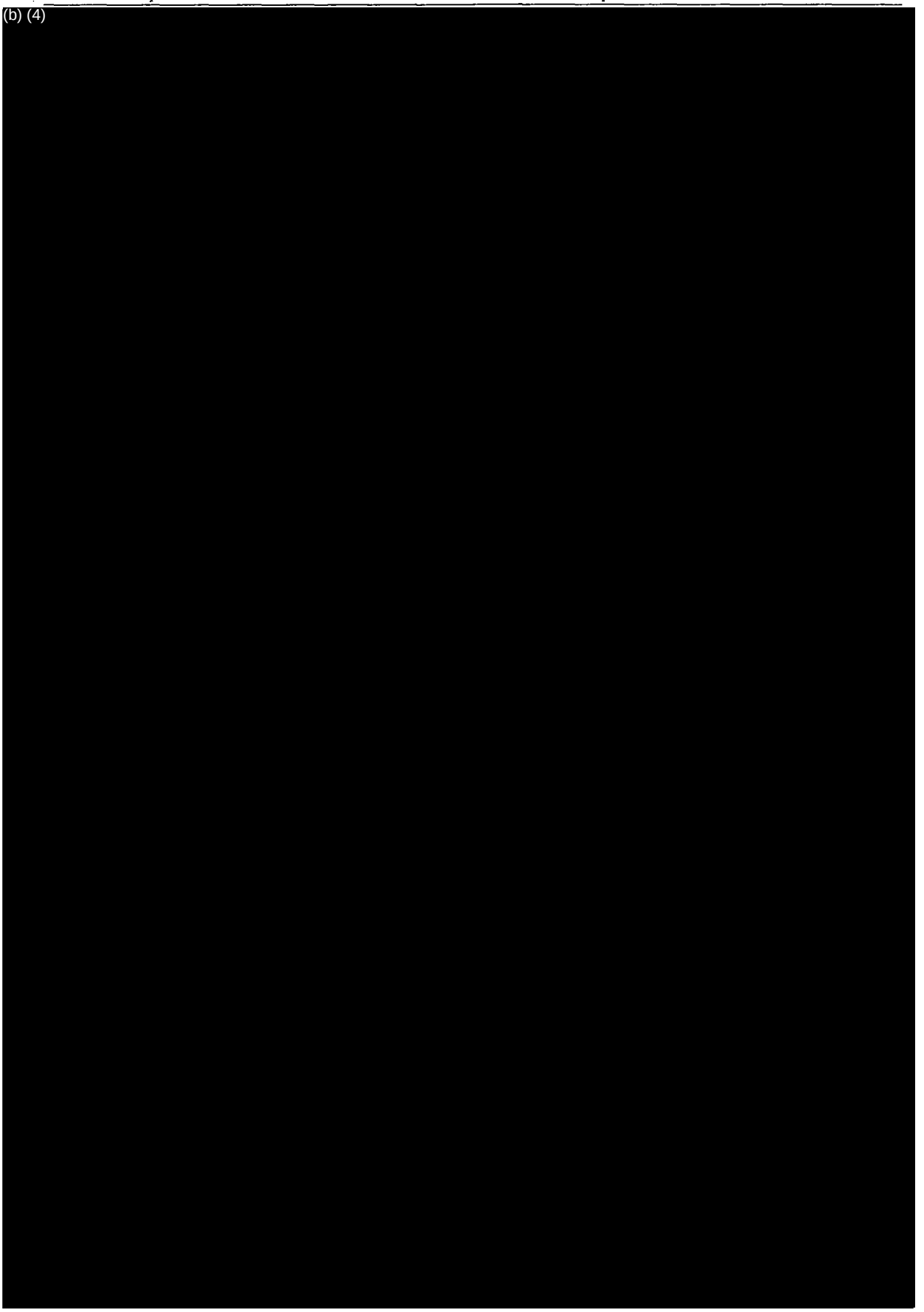

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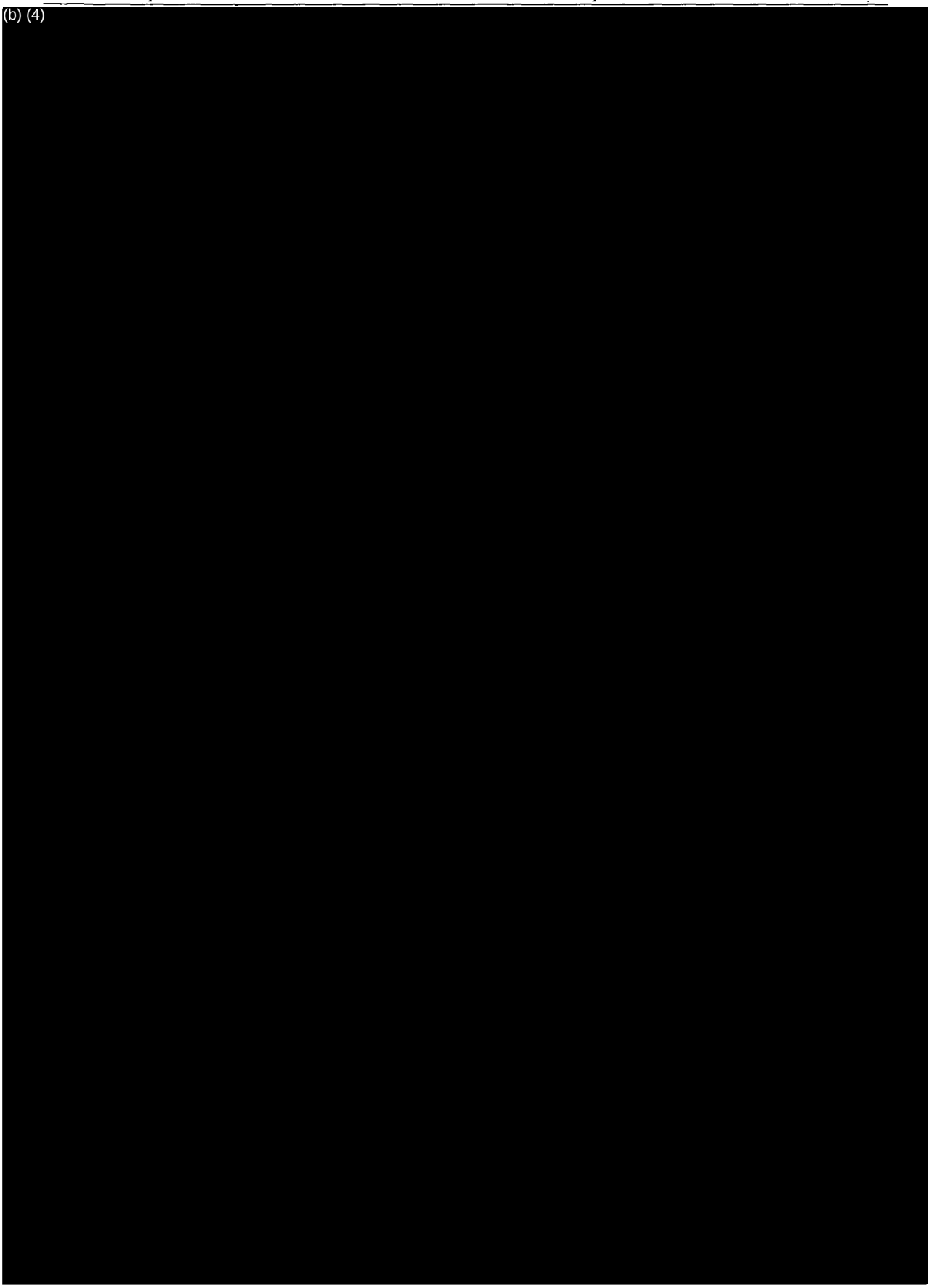

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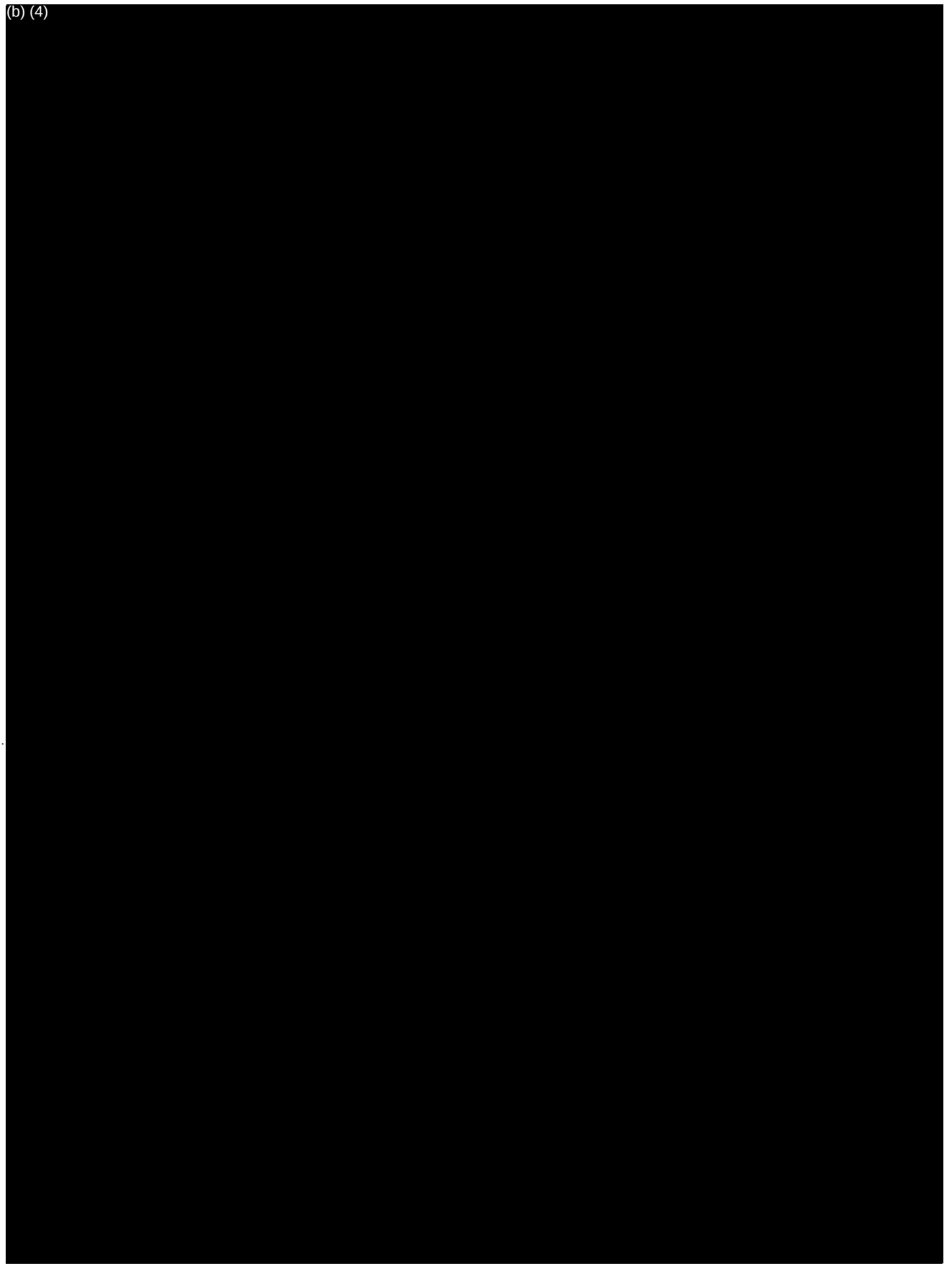

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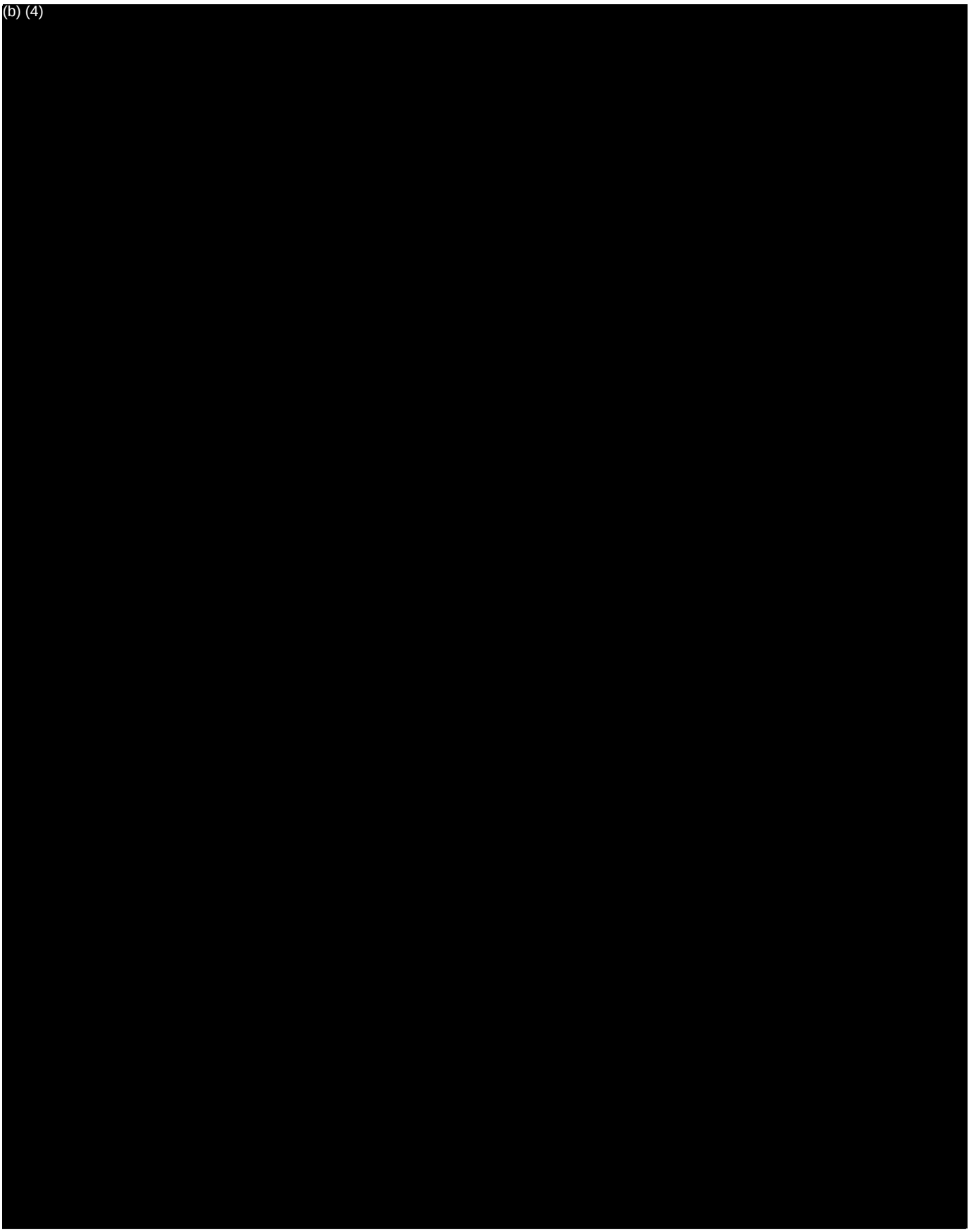

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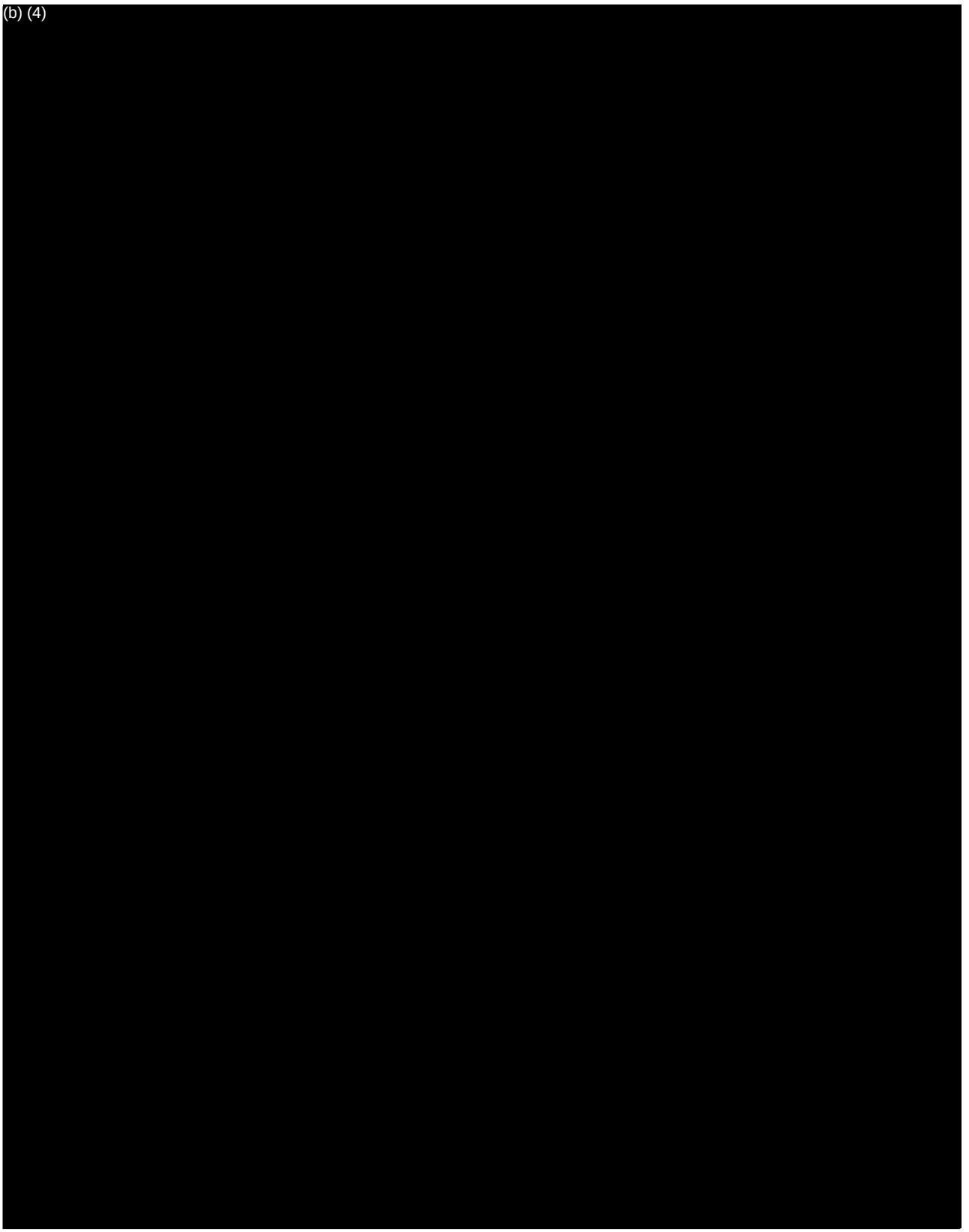

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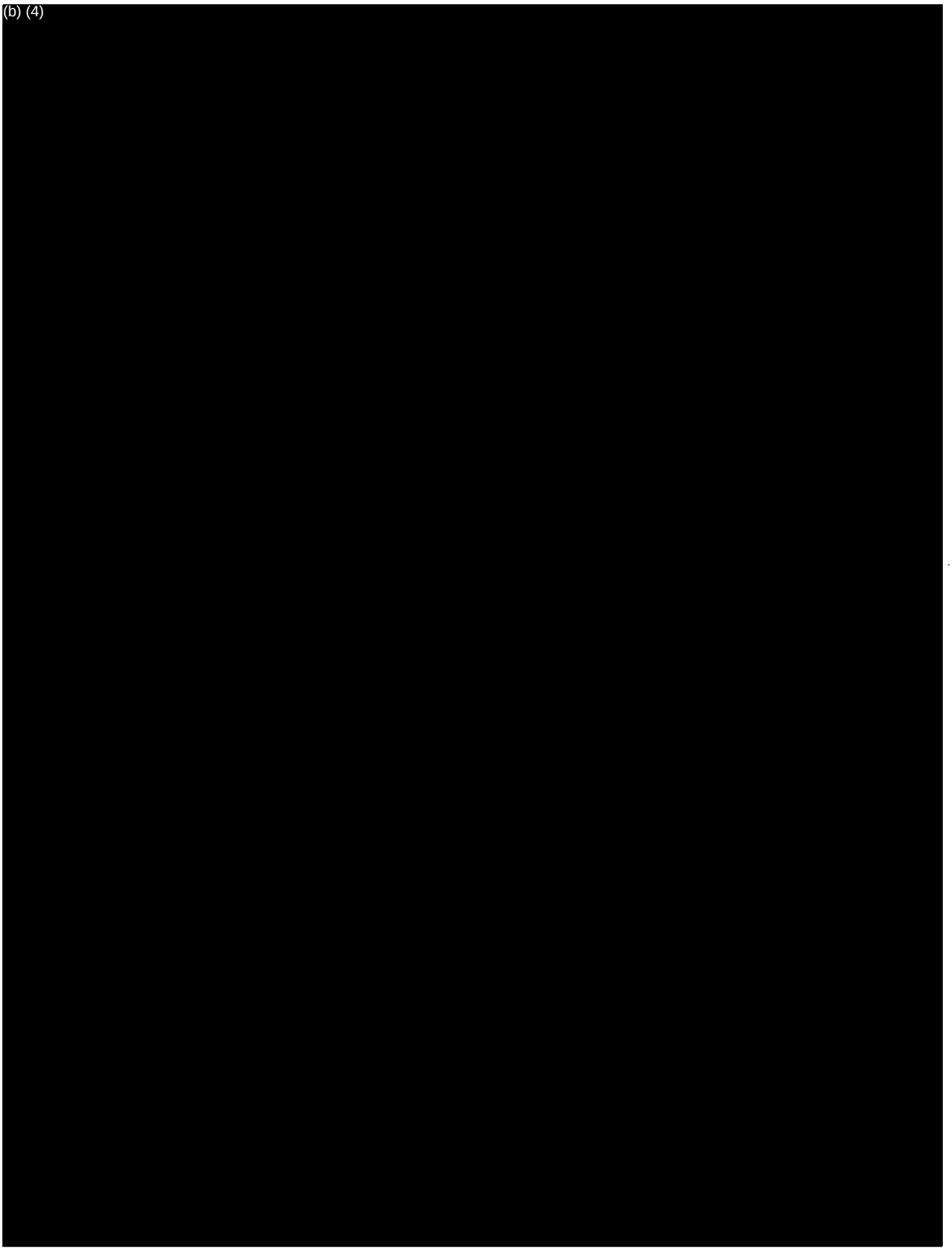

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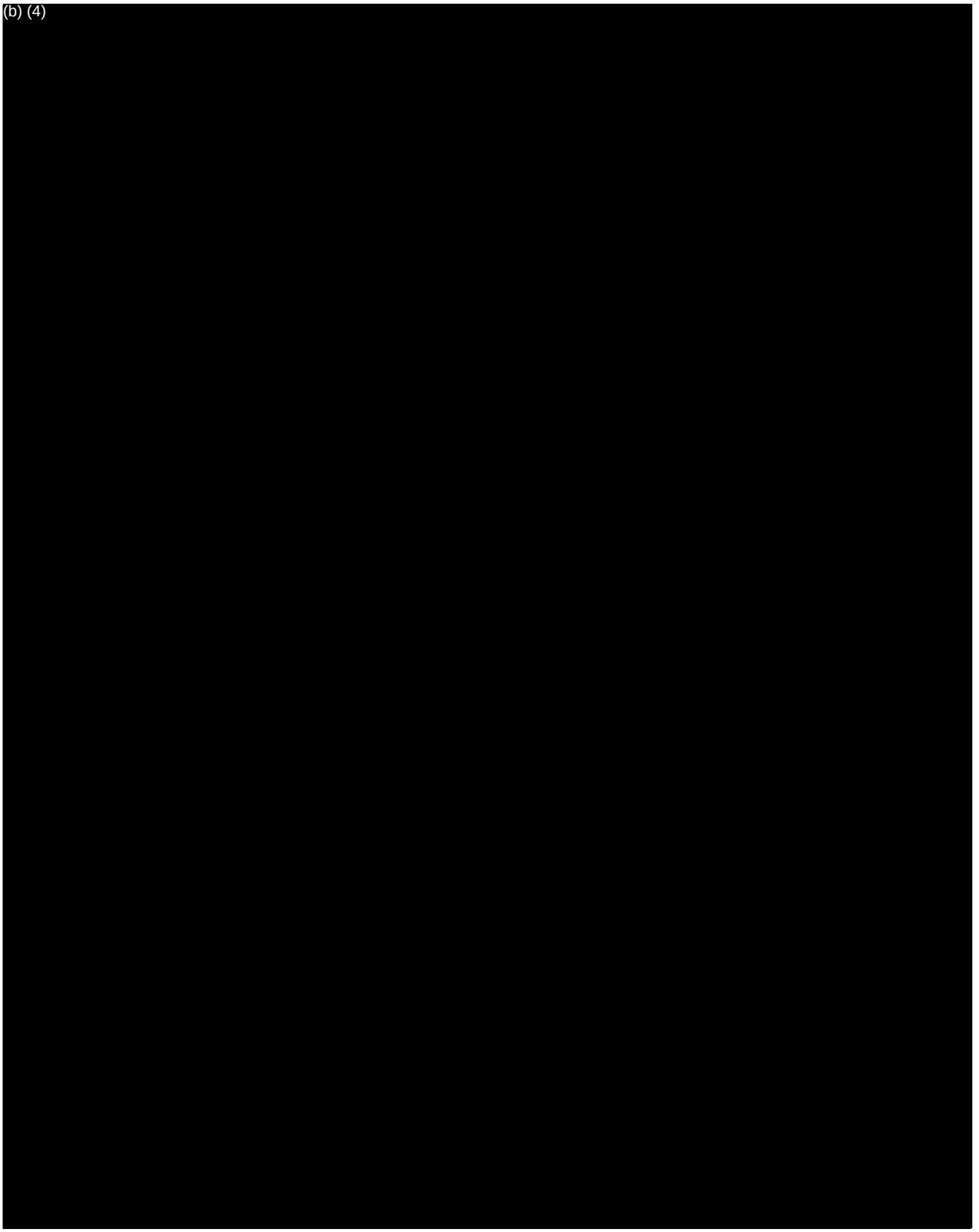

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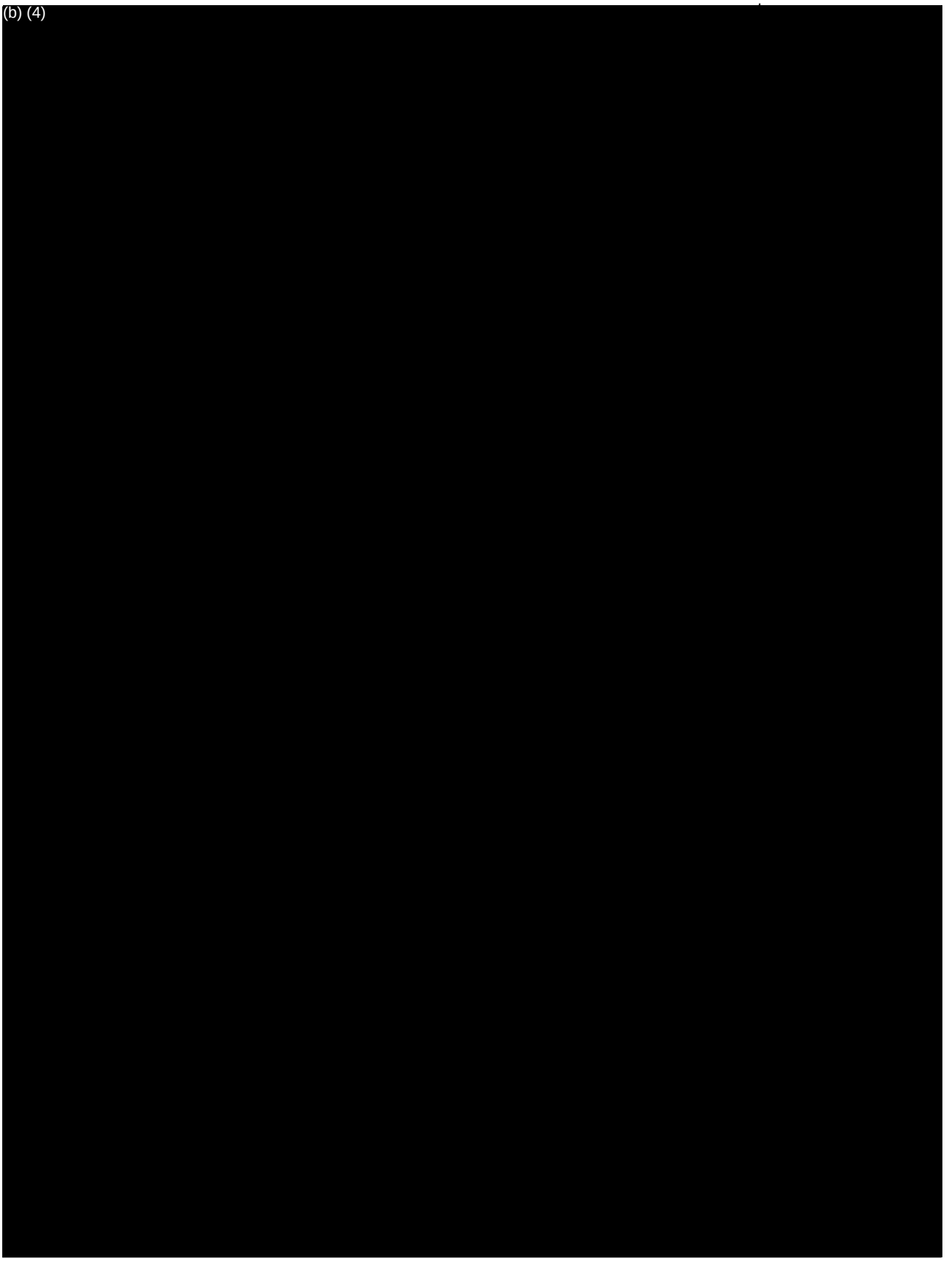

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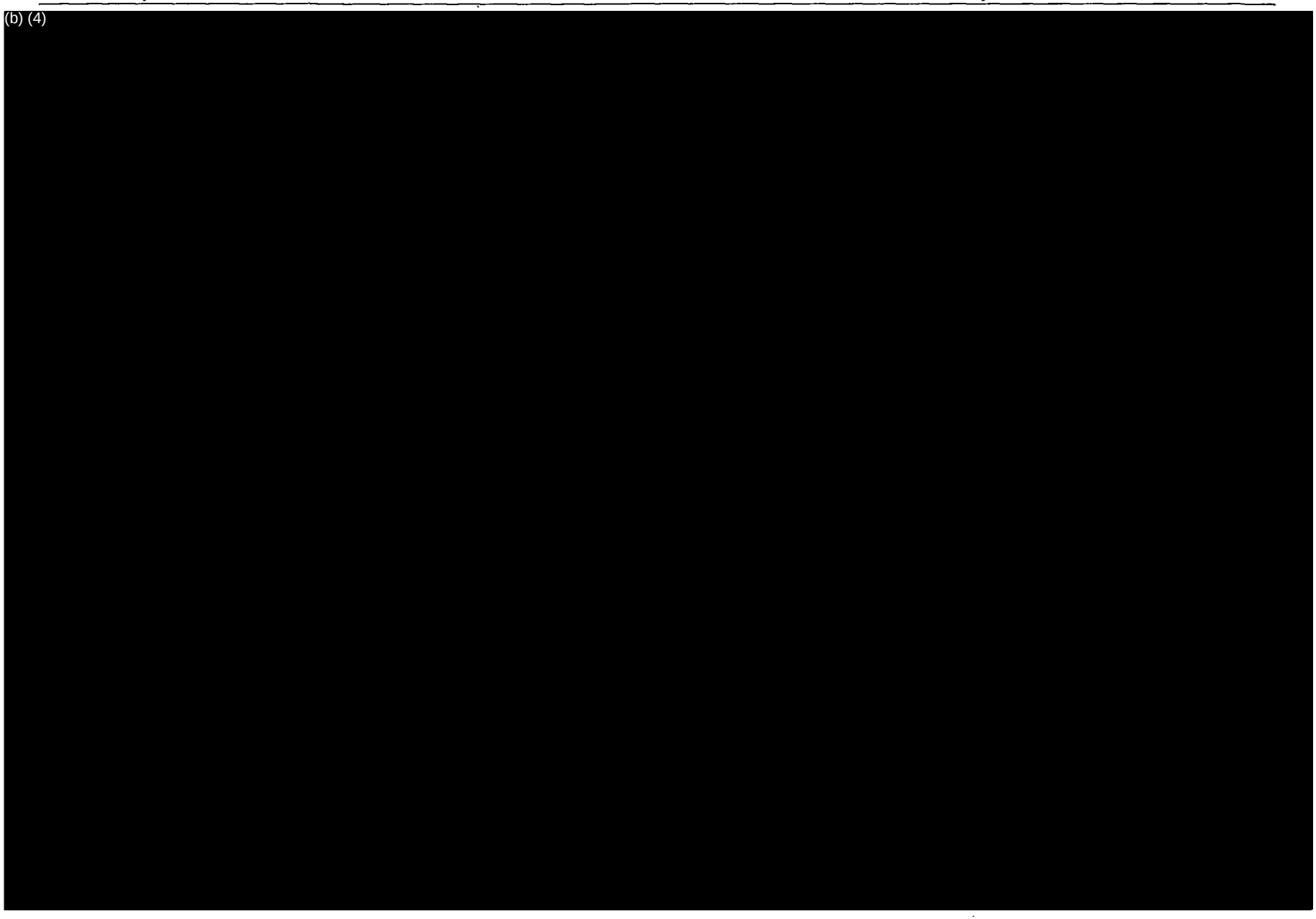

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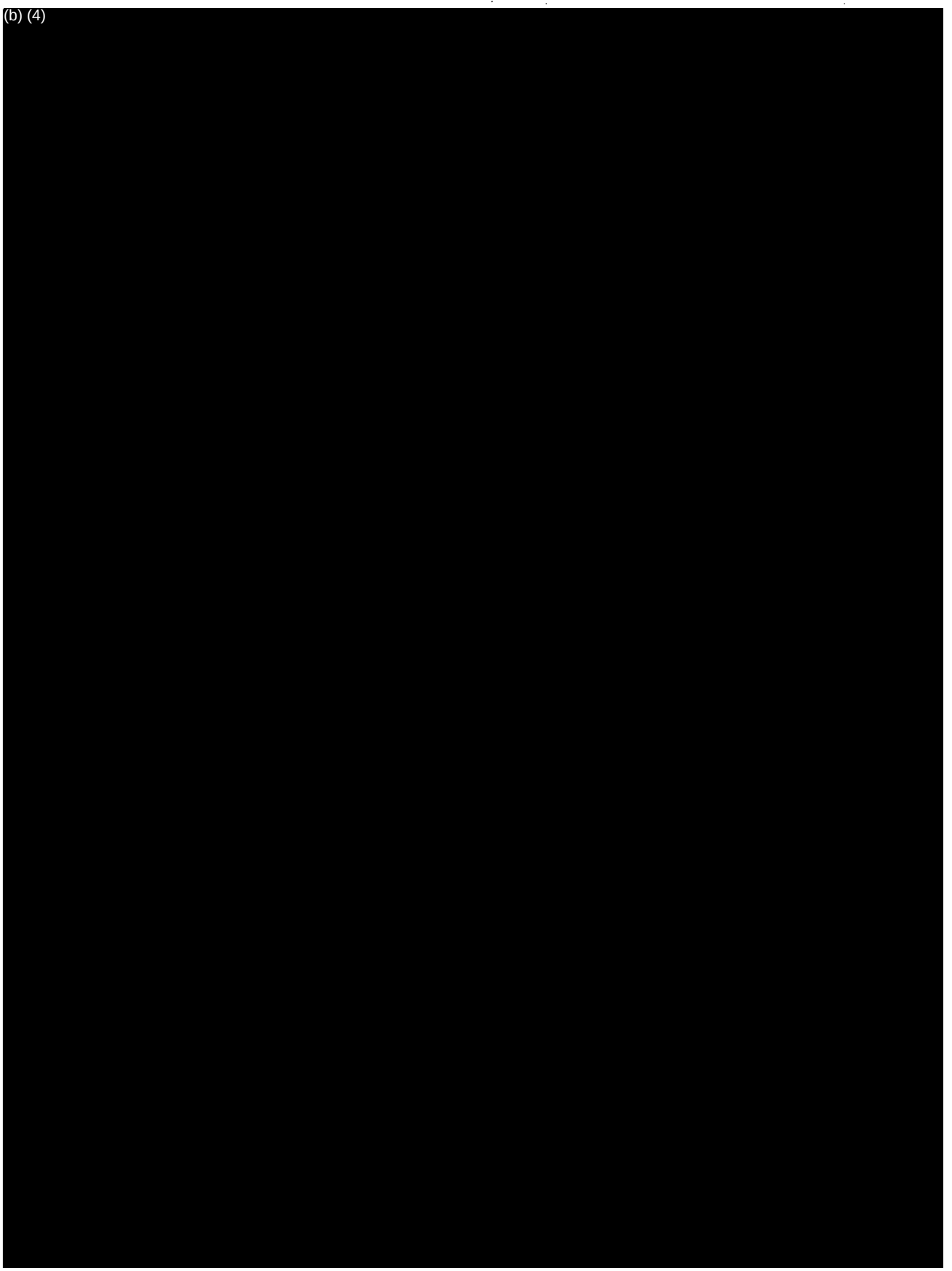

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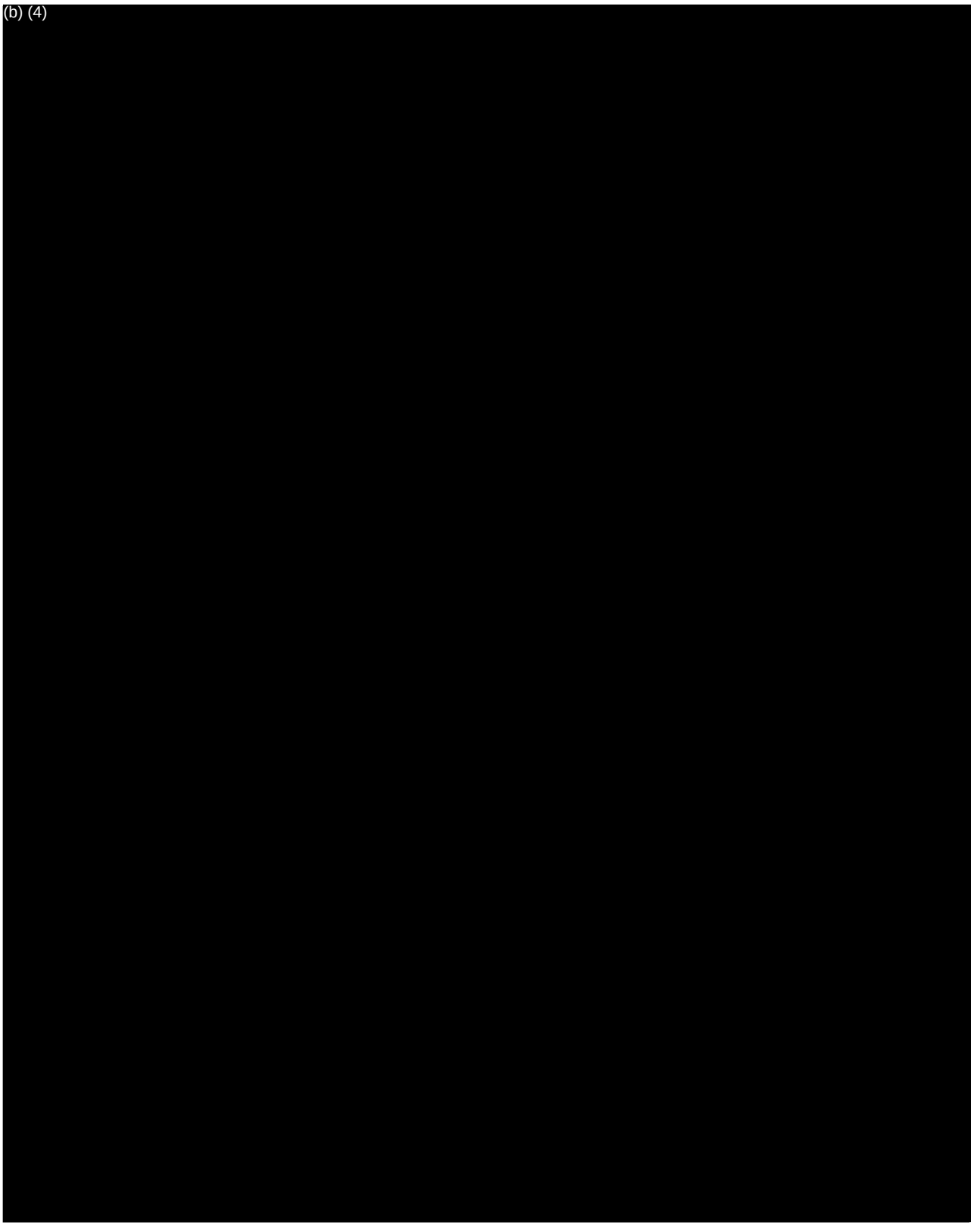

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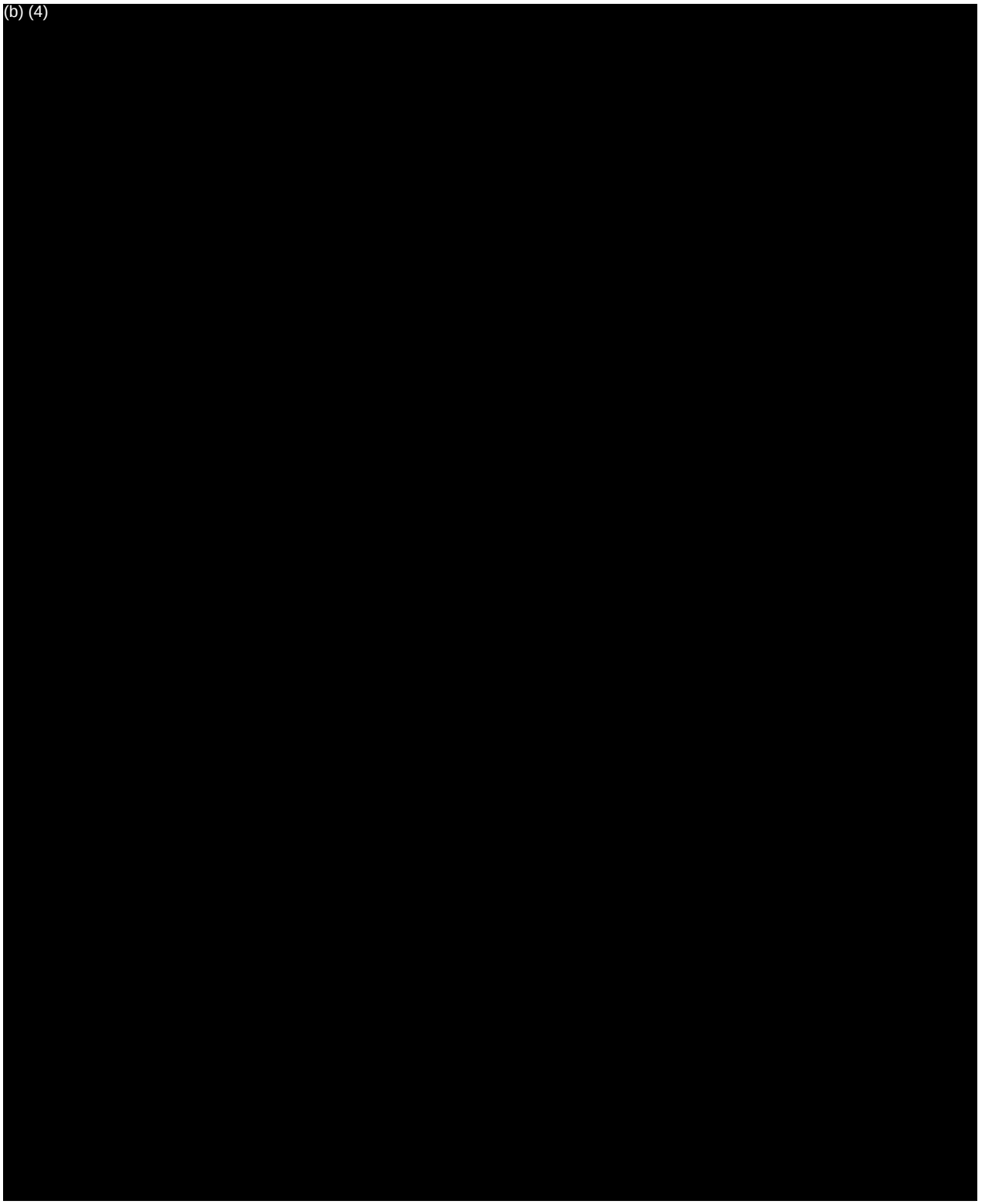

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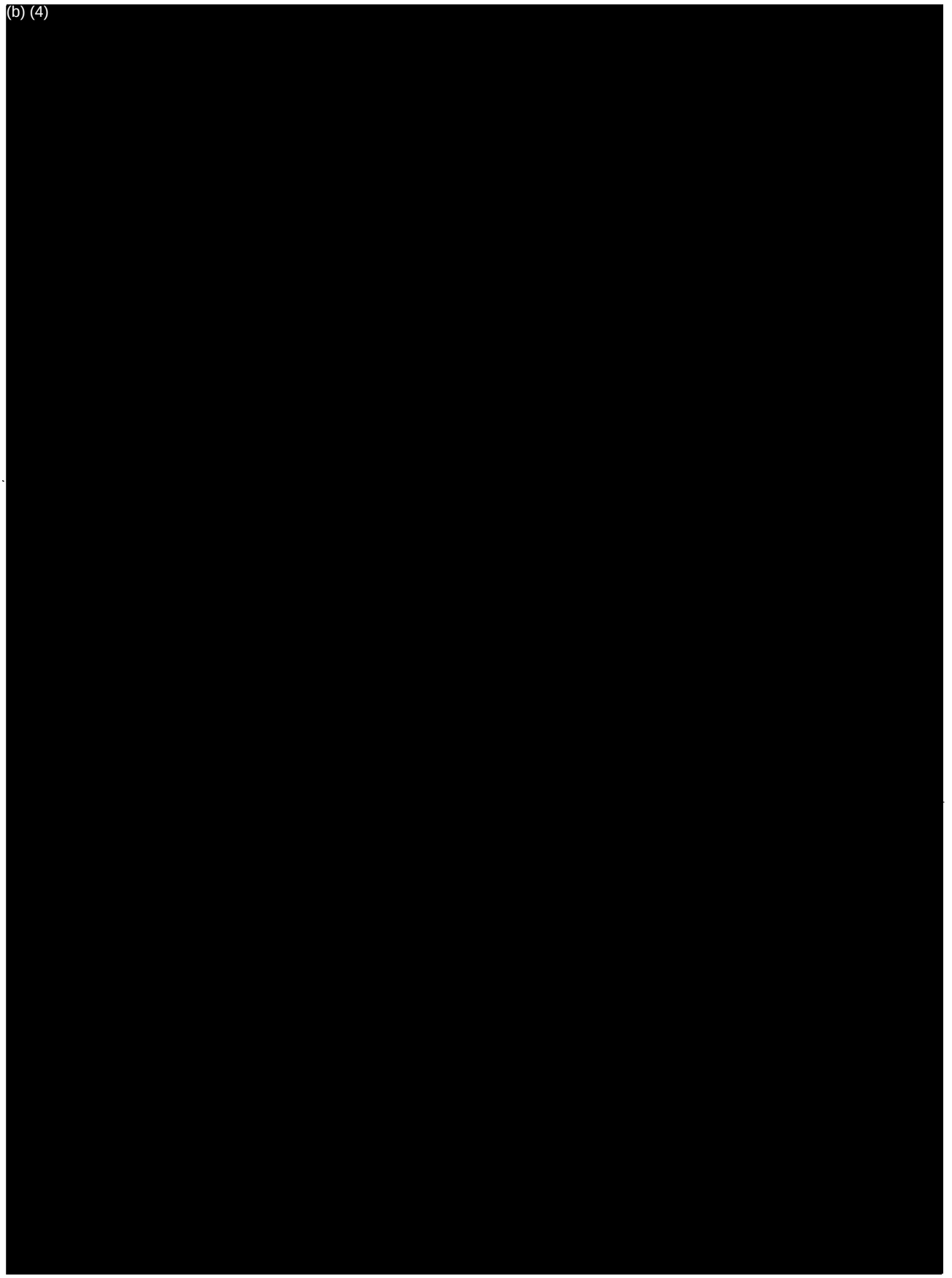

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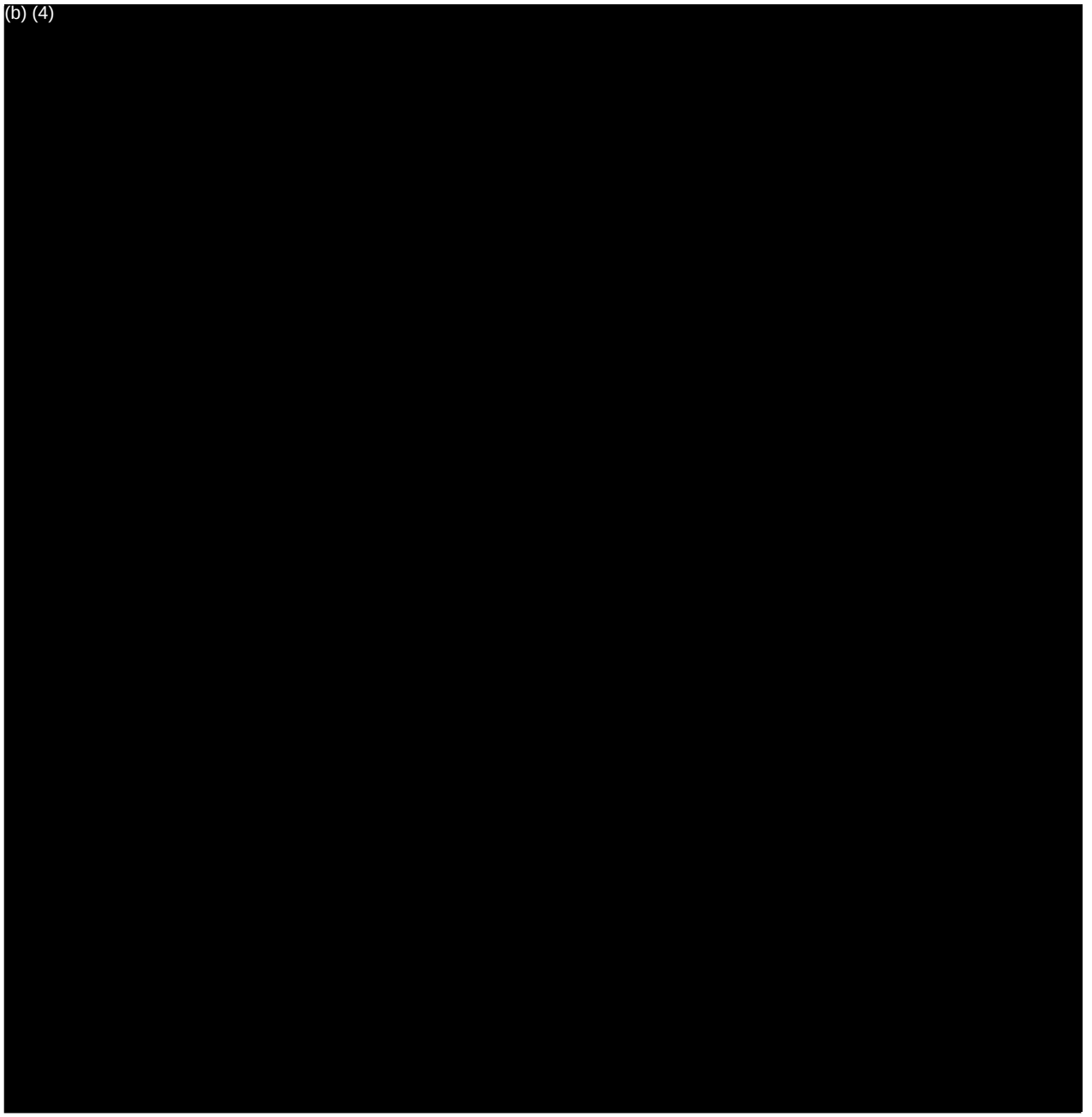

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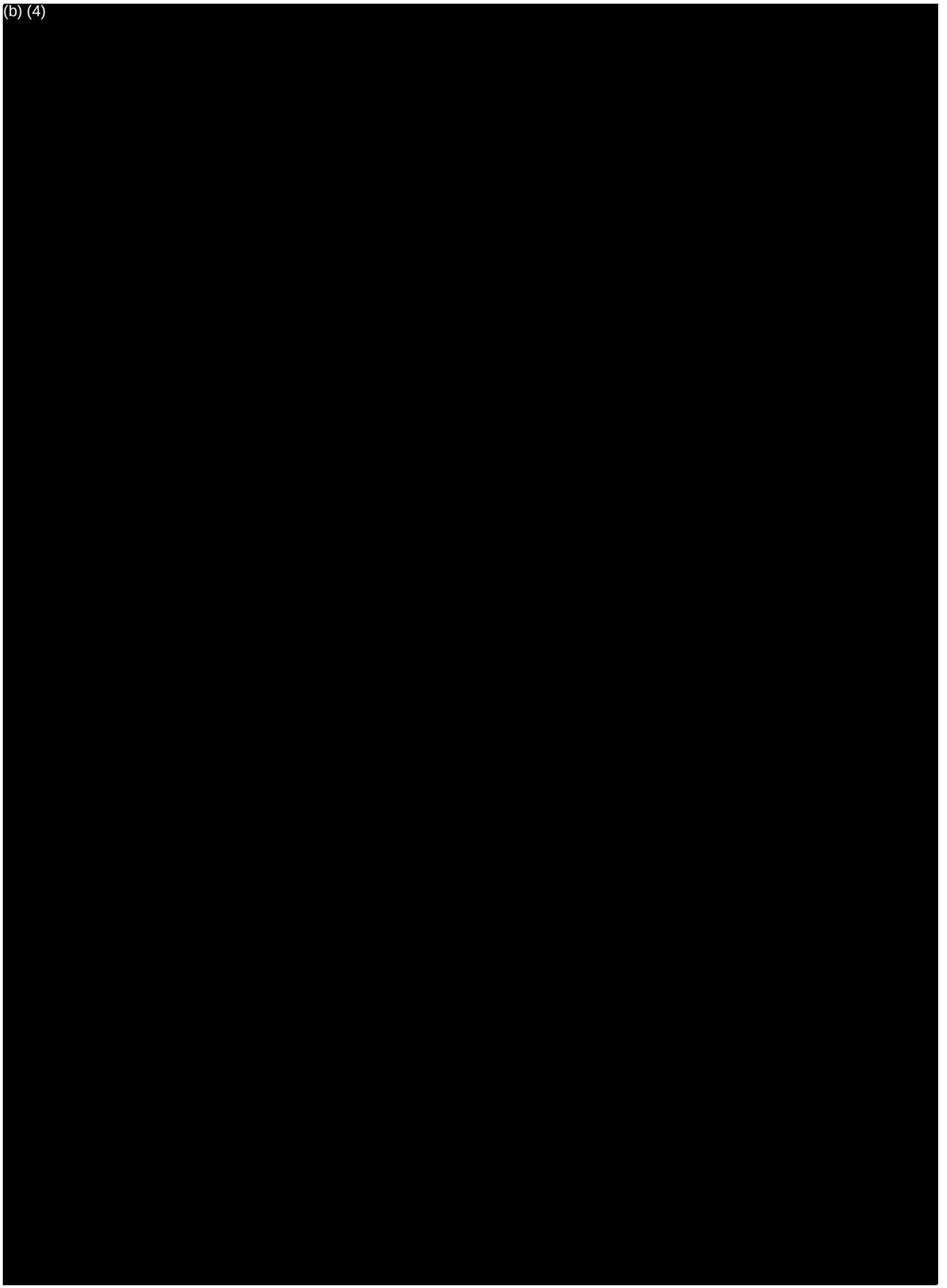

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4. REVISED INDICATIONS FOR USE STATEMENT

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INDICATIONS FOR USE

510(k) Number: _____ (To Be Assigned By FDA)

Device Name: LipiView® Ocular Surface Interferometer with Software Version 2.0

Indications for Use:

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

5. REVISED 510(K) SUMMARY

The 510(k) Summary has been updated from the original K122481 submission, dated August 13, 2012, to include the revised Indications for Use statement. Both red-lined and clean copies of the revised 510(k) summary are enclosed in this section.

As explained in **Section 3, Response to Question 5**, the Indications for Use for the LipiView® Interferometer with software version 2.0 was expanded to include the device feature of making absolute thickness measurements, as discussed in prior telephone and email correspondence with FDA on K122481. The expanded Indications for Use are supported by performance testing provided in **Sections 9 to 15**.

While the Indications for Use of the LipiView® Interferometer with software version 2.0 have been expanded from the predicate device (LipiView® Interferometer, K091935), the intended use and technological characteristics are the same as the predicate device. Therefore, the LipiView® Interferometer with software version 2.0 is substantially equivalent to the predicate device. The basis for substantial equivalence is discussed further in the revised Substantial Equivalence Discussion in **Section 6**.

510(k) SUMMARY

PREPARATION DATE:	~~August 13~~December 12, 2012
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 459-4815 Fax: (877) 468-5335
CONTACT PERSON:	Christy Stevens, OD, MPH Vice President, Clinical & Regulatory
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAME:	Ophthalmic Camera
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.1120 and 886.1850
PRODUCT CODE:	HKI, HJO
PREDICATE DEVICE:	LipiView® Ocular Surface Interferometer Class II under 21 CFR 886.1120 and 21 CFR 886.1850; Product Code HKI, HJO; Applicant: TearScience, Inc.; Cleared under K091935 on October 23, 2009

DEVICE DESCRIPTION:

The LipiView® Ocular Surface Interferometer is a bench-top imaging device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touch screen display. The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display, in a printed report, or captured on video and exported to USB-attached storage or a mapped network drive.

The LipiView® Interferometer has been modified to software version 2.0, which includes changes to refine the interferometric color matching and blink detection methods used on interferometric images and to provide minor usability enhancements.

INTENDED USE:

The LipiView® Interferometer is intended to image the tear film. The LipiView® Interferometer is a prescription device for use by a physician during an in-office exam.

Indications for Use: The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

The LipiView® Interferometer with software version 2.0 has the same intended use ~~and same indications for use~~ as the predicate LipiView® Interferometer (K091935). In addition, the Indications for Use are similar to the predicate device, except that the Indications for Use have been expanded for the LipiView® Interferometer with software version 2.0 to include measurement of the tear film lipid layer thickness, as supported by performance testing. The expanded Indications for Use do not alter the intended use of the LipiView® Interferometer.

TECHNOLOGICAL CHARACTERISTICS:

The LipiView® Interferometer with software version 2.0 has the same fundamental scientific technology as the predicate device. As summarized below, most of the technological characteristics of the LipiView® Interferometer with the modification to software version 2.0 remain unchanged from the predicate device cleared under K091935. Minor differences in technology between the predicate device and the LipiView® Interferometer with software version 2.0 are described below.

Similarities: The LipiView® Interferometer with software version 2.0 and the predicate device share many of the same design features. Both devices have the same operating principle of real-time imaging of tear film dynamics based on the interference pattern from specular reflections. Both devices have an AC power source in compliance with IEC 60601 standards for electrical safety and electromagnetic compatibility. Both devices use the same Class I white light LED illuminator with exposure and level of illumination in compliance with ISO 15004-2 (Group 1 instrument) for safety. The patient contact materials for the chin and forehead rest and the method of disinfection are the same for both devices. Also, both devices have a digital video camera, personal computer with Microsoft Windows-based operating system, touchscreen display graphical user interface and computer accessory support for printing and data storage.

Furthermore, analogous software features on both devices include: password-protected user login; patient database; real-time video display to acquire tear film images; touchscreen user controls for camera and video playback; image acquisition process with storage of lossless AVI format video images; and tear film video playback and analysis.

Differences: Compared to the predicate device, the LipiView® Interferometer with software version 2.0 has refined interferometric color matching and blink detection methods used on interferometric images. In the predicate device, the interferometric color palette was theoretically derived; whereas in software version 2.0, the palette was developed and validated to a known standard for measurement of the tear film lipid layer thickness. Software version 2.0 also has enhancements for user convenience including: playback blink visualization; automated documentation of blinks; example tear film videos; adjustable video capture length; and ability to export video to an external USB storage device or mapped network drive.

PERFORMANCE TESTING:

The LipiView® Interferometer with software version 2.0 was developed and tested in compliance with design controls and the FDA Guidance documents for software validation in medical devices. To support the expanded Indications for Use, the LipiView® Interferometer was validated to physical phantoms representative of the pre-corneal tear film of a known thickness, as measured independently by ellipsometry. This testing demonstrated the

LipiView® Interferometer can make absolute measurements of the tear film lipid layer thickness by imaging interferometric colors. Test results showed the *in vivo* device measurement variability is 0.31 interferometric color unit (ICU) on average, or slightly less than one-third of the reporting precision of the device (1 ICU). Verification and validation test results demonstrated that the interferometric color matching performance of the LipiView® Interferometer with software version 2.0 is equal to or better than the predicate device. Tests also showed that version 2.0 had a higher overall percentage of correctly identified valid blink frames as compared to the predicate device. Enhancements for user convenience in software version 2.0 performed as intended and did not introduce any new risks to the device.

CONCLUSIONS:

The LipiView® Ocular Surface Interferometer with software version 2.0 has the same intended use and the same fundamental scientific technology as the predicate device. Performance testing demonstrates the LipiView® Interferometer with software version 2.0 is substantially equivalent in technological characteristics to the predicate device.

510(k) SUMMARY

PREPARATION DATE:	December 12, 2012
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 459-4815 Fax: (877) 468-5335
CONTACT PERSON:	Christy Stevens, OD, MPH Vice President, Clinical & Regulatory
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAME:	Ophthalmic Camera
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.1120 and 886.1850
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PREDICATE DEVICE:	LipiView® Ocular Surface Interferometer Class II under 21 CFR 886.1120 and 21 CFR 886.1850; Product Code HKI, HJO; Applicant: TearScience, Inc.; Cleared under K091935 on October 23, 2009

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CONCLUSIONS:

The LipiView® Ocular Surface Interferometer with software version 2.0 has the same intended use and the same fundamental scientific technology as the predicate device. Performance testing demonstrates the LipiView® Interferometer with software version 2.0 is substantially equivalent in technological characteristics to the predicate device.

6. REVISED SUBSTANTIAL EQUIVALENCE DISCUSSION

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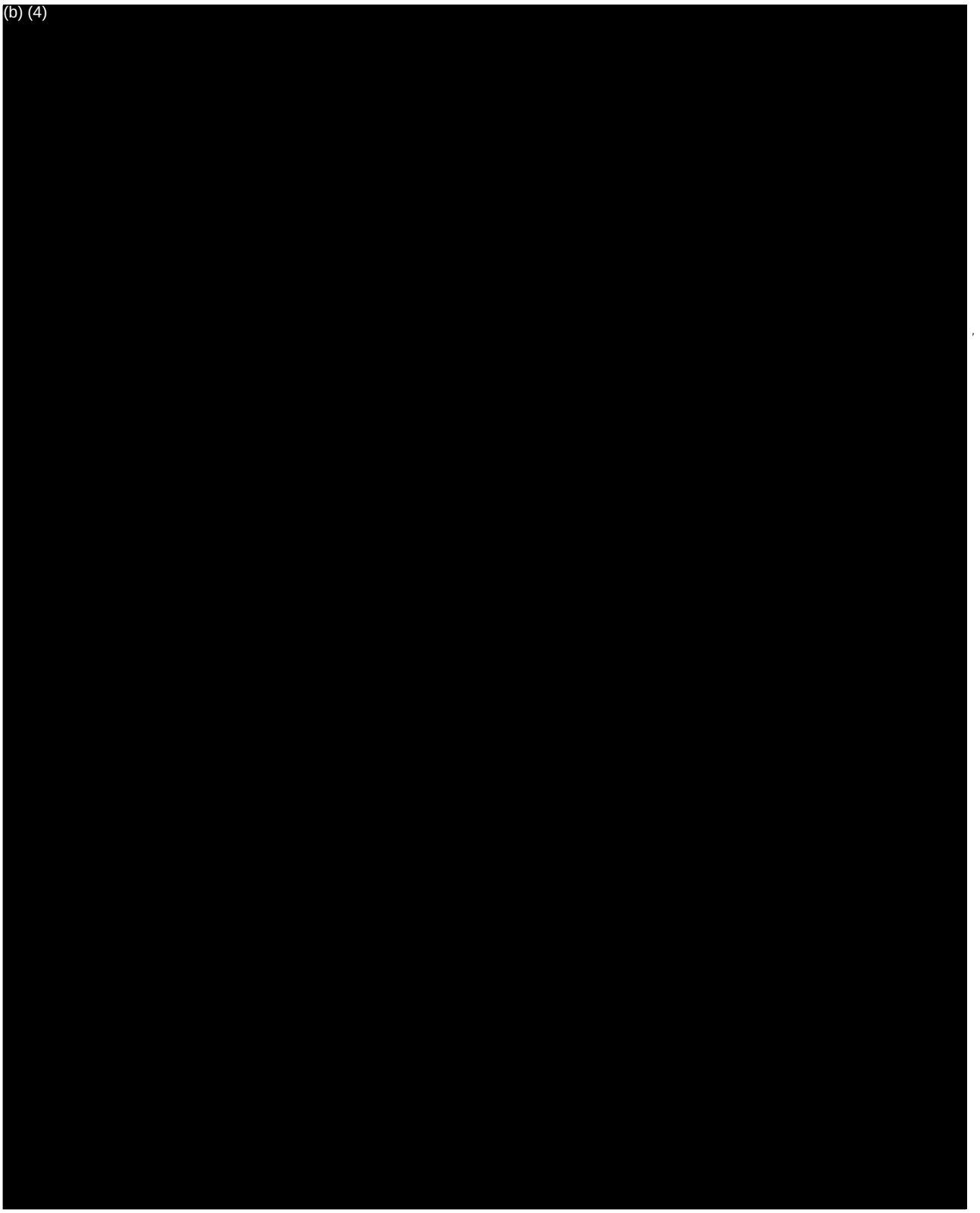

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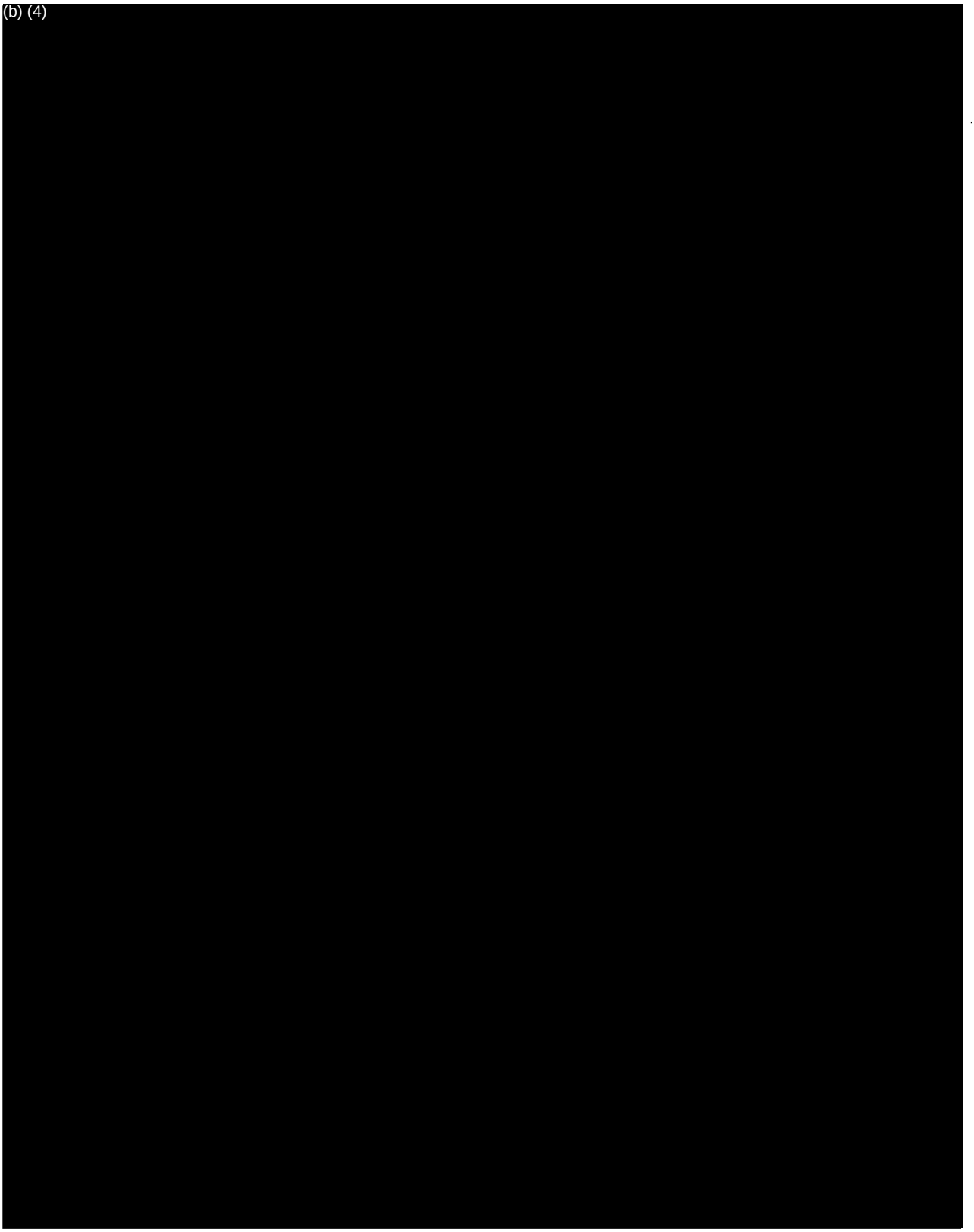

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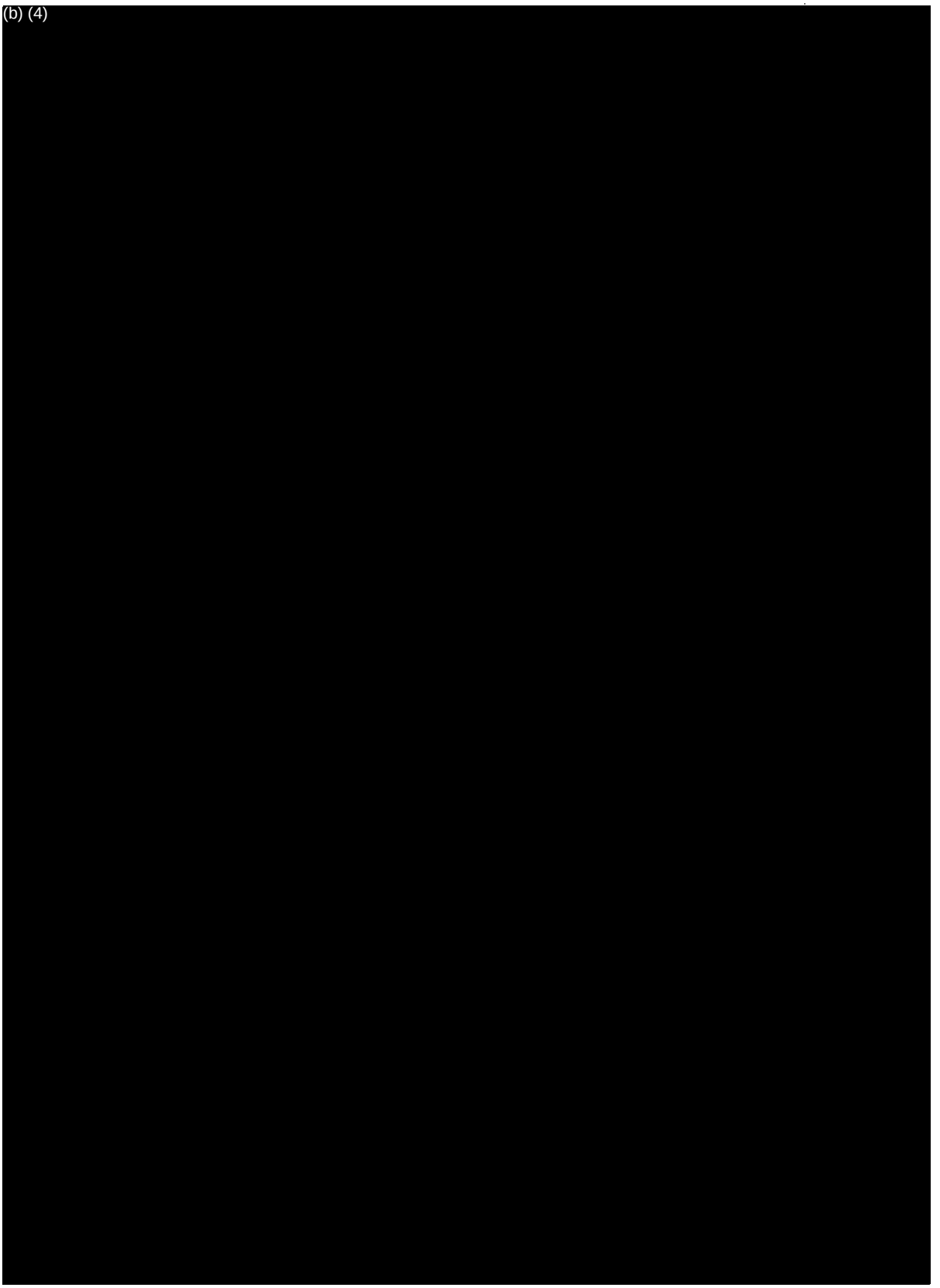

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TearScience®

LipiView®

Ocular Surface Interferometer

Operation Manual

Model # LVI-1001
For System Version 2.x

Manufactured by:

TearScience, Inc.
5151 McCrimmon Parkway Suite 250
Morrisville, NC 27560
Phone: (919) 467-4007
Fax: (919) 467-3300

EC REP
Donawa Lifescience Consulting
Piazza Albania, 10
00153 Rome, Italy

Rx only

CE

011119-ENG Rev ~~A~~B

Revision History

Revision	Date	Description of Changes	ECR # or PCR #
A	6/29/12	Initial release for 2.0 software in English. This manual was created from Part Number 010792 Rev M (mat spec). Updates from 1.1D software include: updated screenshots with system and version numbers, new screenshots and explanation for partial blink detection mode; new screenshots and explanations for display and camera settings in the Admin interface; new screenshots and explanations for example videos; new screenshots and explanations for revisions to reporting and for "save video" functionality.	P1206251
B	12/10/2012	Added to Section 2 the expanded indications for use to measure the absolute thickness of the tear film lipid layer and a description of absolute thickness measurement. Added to Section 4 the expanded indications for use. Added to Section 10.4.2 a description of example videos and example images. Added to Section 10.4.3 a description of absolute thickness measurement and reference ICU color scale. Updated Section 10.4.3 for the maximum numerical and graphical display. Added to Section 10.5 a reference to absolute thickness measurement. Updated Quick Start Guide to reflect minor interface change in 2.0.	

Table of Contents

Table of Figures

List of Tables

1 Introduction

This manual provides the indications, contraindications, warnings, precautions, potential adverse effects and instructions for use for the *TearScience*® LipiView® Ocular Surface Interferometer (LipiView® Interferometer). **Carefully read this manual in its entirety before using the LipiView® Interferometer. Failure to follow these instructions may result in improper use of the device.**

Use of the LipiView® Interferometer includes User and Administrator functionality, both of which are described in this manual. Section 10, *Instructions for Use,* contains the information about the proper procedures for operating the LipiView® Interferometer. Section 16, *Administrator Instructions for Use,* contains information about the initial setup and maintenance of the LipiView® Interferometer by an Administrator. **Prior to initial use of the LipiView® Interferometer, the Administrator must follow the administrative setup instructions in this manual for proper device use.** Table 1-1 identifies the tasks an Administrator may be required to perform and the prerequisite knowledge.

Table 1-1: Administrator Prerequisite Knowledge

Task	Prerequisite Knowledge
User Administration	Create usernames and passwords.
Printer Setup (required before printing)	Install a Network or USB printer. Installation of a network printer requires knowledge of networking. For installation of a USB printer, follow the manufacturer's instructions.
Network Setup (optional)	Configure the system to gain access to the wireless networking environment (selection of server, setting of security keys, etc.).
Electronic Medical Records (EMR) Export (optional)	Configuration for export of records to other office system(s) using the HL7 data transfer protocol.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

Contact TearScience with any questions about the information contained in this manual or for additional information on the operation and safety of the LipiView® Interferometer.

2 Device Description

The LipiView® Interferometer is a bench-top device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touchscreen display. Figure 2-1 shows the base LipiView® Interferometer. Additional views and a description of the components are provided in Section 9, *LipiView® Interferometer Operation*.

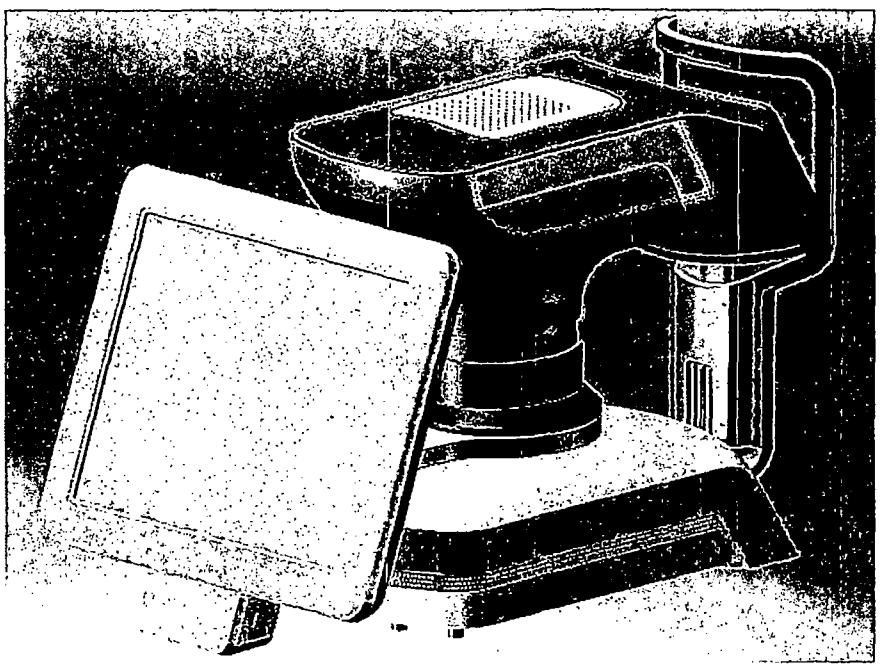


Figure 2-1: LipiView® Interferometer

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

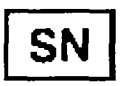
The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The patient's eye is positioned in front of an illumination source directed toward the tear film on the corneal surface. Light from the illumination source passes through the tear film and is specularly reflected into a camera. The light reflecting back through the lens in the camera forms an interference pattern, called an "interferogram". The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking.

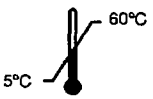
The computer system captures and enhances the interference pattern and displays a profile corresponding to an interferometry color scale. This color scale has been validated to a known standard for measurement of thin film thickness, demonstrating that the LipiView® Interferometer has the ability to make absolute thickness measurements of the tear film lipid layer by the imaging interferometric colors. The interferometry color assessment is measured in Interferometric Color Units (ICU), where 1 ICU is equivalent to 1 nanometer (nm). An ICU for the LipiView® Interferometer is defined as the color scale resulting from the interference pattern which occurs at the boundary of the tear film. The measured ICU may range from 0 to 240, with a precision of 1 ICU. The accuracy of the measured interference pattern is displayed as a "C-factor," which is equal to the proportion of measured colors that match the predicted interferometric color scale. The video image of the ocular surface may be viewed on the computer screen display and in a printed report.

3 Labeling

Table 3-1 provides a description of the symbols used on the LipiView® Interferometer labeling.

Table 3-1: Description of Labeling Symbols

Label Symbol	Symbol Description
	Type B applied part.
	Consult operating instructions
	Device transmits radiofrequency (RF) energy
	Text consists of a warning or precaution relating to safety. Read the text carefully and use the equipment as instructed to ensure safety.
	Reference Number
	Serial Number.
	**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.
	Mandatory conformity mark for medical device products in the European Economic Area (EEA). The **CE marking** certifies that a product has met consumer safety, health or environmental requirements.

Label Symbol	Symbol Description
	This model/product is Listed in Intertek's Directory of Listed Products.
	Date of Manufacture
	Manufacturer
	Store between 5 and 60 degrees Celsius
	Authorized Representative in the European Community
P/N	Part Number
Rev	Revision Level

4 Indications for Use

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

5 Contraindications

Contraindications are conditions in which the device should not be used because the risk of use clearly outweighs any benefit. No contraindications have been identified for the LipiView® Interferometer.

6 Precautions

The following patient conditions may affect the interferometry assessment of a patient's tear film using the LipiView® Interferometer:

- **Use of ophthalmic drops such as artificial tear lubricants, ointments, and medications.** Advise patients not to instill oil-based ophthalmic drops (e.g., Soothe®, Restasis®) for at least 12 hours prior to device use and not to instill ointments for at least 24 hours prior to device use. Wait at least 4 hours after the instillation of all other ophthalmic drops prior to device use.

- **Soft or rigid contact lens wear**. Advise patients to remove contact lenses at least 4 hours prior to device use.
- **Use of oil-based facial cosmetics around the eye.**
- **Eye rubbing.**
- **Recent swimming in a chlorinated pool.** Advise patients not to swim for at least 12 hours prior to device use.
- **Any ocular surface condition** that affects the stability of the tear film. These conditions include disease, dystrophy, trauma, scarring, surgery, or abnormality.

7 Warnings

Review the following warnings prior to using the LipiView® Interferometer.

Table 7-1: General and Operation Warnings

⚠ ***GENERAL WARNINGS***
WARNING: No modification of this equipment is allowed.
Caution: **Power Requirements.** The LipiView® Interferometer is a continuous operation device which requires a power source of 100-240 Volts AC ± 10%, 50/60 Hz single phase, 4 Amps. Connection to a power supply other than a supply mains with protective earth may result in electric shock.
 ***Caution:*** The LipiView® Interferometer has protection against electric shock of applied part classified as Type B. This device is classified as an IEC Class 1 product.
Caution: **Voltage Protection and Fuse Selection.** Contact TearScience to replace a blown fuse. TearScience personnel must replace only with a 5 x 20 mm, 4 A, 300 ms, 40 A breaking capacity fuse to avoid risk of fire. TearScience personnel must disconnect from power before servicing to avoid risk of electrical shock.
Caution: Backup Battery Replacement. Backup battery cannot be replaced.
Caution: Keep the LipiView® Interferometer away from strong magnetic fields as it could damage the device's hard drive, but is not a safety hazard to the user or patient.
Caution: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the LipiView® Interferometer or shielding the location.
Caution: Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
Caution: The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or Device.
Caution: The EQUIPMENT or DEVICE should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EQUIPMENT or DEVICE should be observed to verify normal operation in the configuration in which it will be used.

Caution: Degree of protection against harmful ingress of liquid: IPXO. This equipment has no protection against ingress of liquids.

⚠ *OPERATION WARNINGS*
Caution: Federal law restricts this device to sale by or on the order of a physician.
Caution: The chin and forehead rest surface must be disinfected with alcohol immediately prior to use and prior to storage.
Caution: **Photo-toxicity hazard.** No acute optical radiation hazards have been identified for the LipiView® Interferometer under intended use conditions. Since prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. Aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours.
Caution: Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.
Caution: If a problem occurs with the LipiView® Interferometer, identify the symptom then attempt to resolve the problem as indicated in Section 15, *Troubleshooting*. If the problem cannot be resolved, stop using the device and contact TearScience.
Caution: To prevent electric shock or performance alteration, do not attempt to service the device or remove the cover. No maintenance is required for the LipiView® Interferometer, and the device and all of its associated parts are not serviceable by the user.
Caution: This device is not suitable for use in the presence of flammable mixtures.
Caution: This device is not suitable for use in oxygen rich environments.
Caution: In order to isolate this equipment from supply mains the equipment must be unplugged from the wall. Do not position the equipment in a location which would prevent the unit from being unplugged in an emergency.
Caution: Do not store this instrument in conditions where the temperature may rise above 60°C or fall below 5°C.
Caution: When lifting or handling the LipiView® Interferometer, caution should be taken to prevent injury or damage to the device. Prior to moving the device, put the monitor arm into a locked position and unplug the power cord from the wall. If an external monitor is attached, disconnect the external monitor prior to moving the device.
Caution: The device monitor and base unit may exceed 41°C. Device will remain within safe momentary contact temperature, below 51°C.
Caution: Shock hazard. Do not touch patient and device under top cover simultaneously.

8 Potential Adverse Effects

There are no known or anticipated adverse effects associated with use of this device.

9 LipiView® Interferometer Operation

9.1 Device Overview

The LipiView® Interferometer is a bench-top device containing the following components, which are identified on Figures 9-1 (Front/Patient View) and 9-2 (Rear/User View):

- Base and Computer System
  - Computer system
  - Electronics
- Ophthalmic Chin Rest Support
  - Chin Rest
  - Forehead Rest
- Motion Stage
  - Camera and zoom lens
  - Illuminator
- Touchscreen Display
  - USB Ports

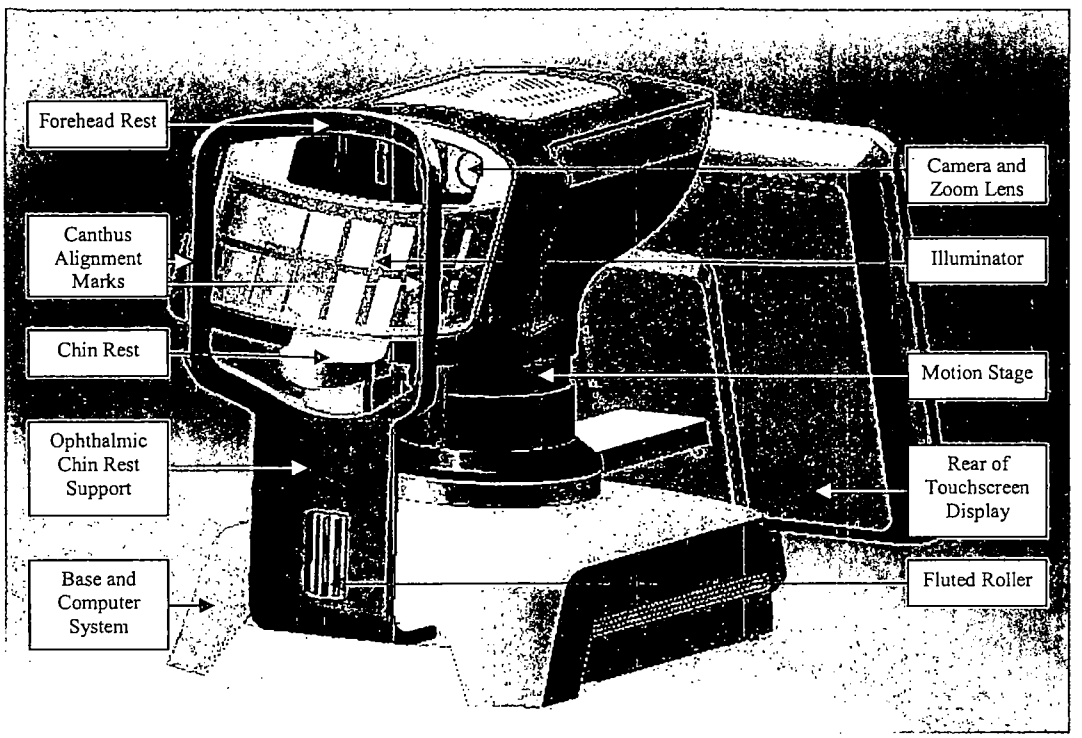


Figure 9-1: Front (Patient) View of LipiView® Interferometer

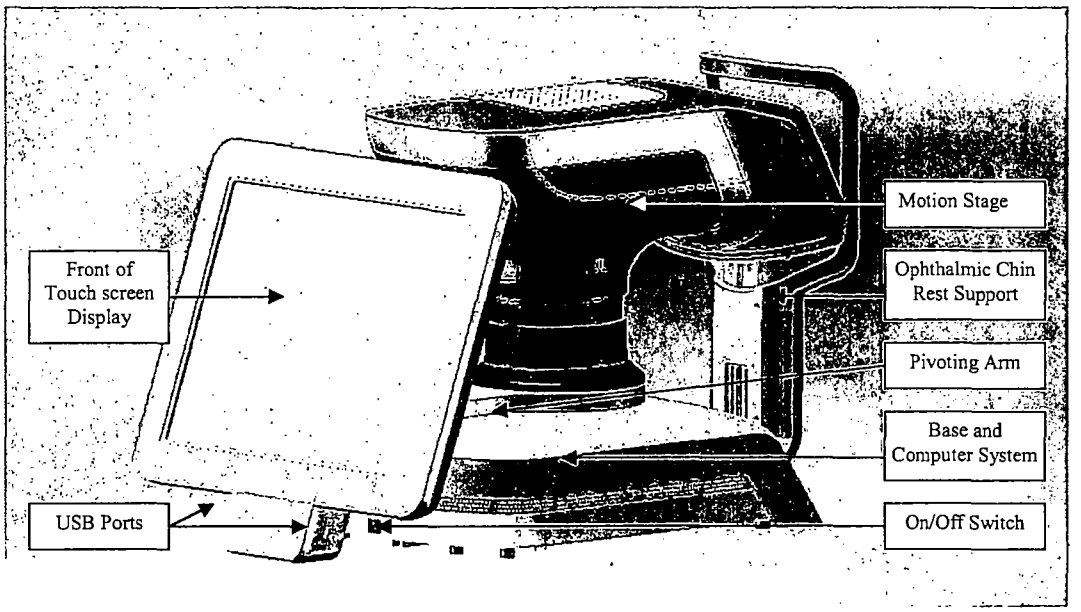


Figure 9-2: Rear (User) View of LipiView® Interferometer

9.1.1 Base and Computer System

The base of the device sits on a flat surface. It houses the power connection, and computer hardware, and connects with the ophthalmic chin rest support, motion stage and touchscreen display. The on/off switch is located on the rear of the base opposite the back surface of the display screen. Refer to Figure 9-2 for the switch location. A connection for an external monitor is hardwired into the base.

9.1.2 Ophthalmic Chin Rest Support

The ophthalmic chin rest support shown in Figure 9-1 consists of an adjustable height chin rest and fixed forehead rest. The chin rest support is attached to the front base of the device, and is designed to allow proper positioning of the patient's head to evaluate the ocular surface tear film. To ensure a properly focused image, the patient must place his/her chin and forehead firmly against the chin and forehead rests. The chin rest may be raised or lowered to accommodate different facial dimensions by spinning the fluted roller. Two canthus alignment marks about half way down the left and right sides of the forehead rest indicate the center of the camera range in the up/down direction. Adjusting the chin rest to position the lateral canthus of the patient's eye at these marks will optimize the range of camera motion.

The chin rest support is the only component of the LipiView® Interferometer that comes in contact with the patient. Disinfect the chin and forehead rest surfaces with alcohol immediately prior to use and prior to storage.

9.1.3 Motion Stage

The motion stage is mounted on the top center of the base. It contains the camera, zoom lens, illuminator and motor controls used to adjust the camera and illuminator. The height of the motion stage (which includes the camera and illuminator) is adjusted as part of the Capture Images process discussed in Section 10.3.2, *Capture the Video*.

9.1.4 Camera and Zoom Lens

The camera is located behind the zoom lens inside the motion stage and is not visible externally. The height of the camera can be adjusted as part of the motion stage. The camera can also be adjusted to the left and right as well as backwards and forwards with separate controls. Refer to Section 10.3, *Video Image Capture and Recording* for additional information.

9.1.5 Illuminator

The grid-like fixture attached to the top front of the motion stage is the illuminator. The illuminator faces the patient and reflects light off the tear film. The height of the illuminator is adjusted automatically with camera alignment as part of the motion stage. There are no separate controls for the illuminator.

9.1.6 Touchscreen Display

Attached to the rear of the base is the Touchscreen Display. Figure 9-1 provides a rear view of the screen and Figure 9-2 shows the front view of the screen. The screen is on a pivoting arm, which allows it to be positioned ± 45 degrees or ± 90 degrees from its location shown in Figure 9-2. To reposition the screen, press the button under the pivoting arm while moving the arm left or right to the approximate 45 or 90 degree location. Release the button and continue moving the arm until it locks into place.

In addition to displaying information to the user, the screen also functions as a touchscreen user interface to the interferometer. The user touches the screen to operate the motion stage and camera controls and to progress through the imaging process. Section 9.2, *User Interface* provides additional details.

9.1.7 USB Ports

The lower base of the Touchscreen Display contains two USB ports as shown in Figure 9-2. These ports may be used to connect a printer or storage device if the LipiView® Interferometer is not on a wireless network. Refer to Section 9.1.9.4, *Accessory Support* for information on compatible accessories.

9.1.8 External Monitor Connection

The LipiView® Interferometer supports the use of an external monitor. A connection for an external monitor is hardwired into the base. The connection will support HDMI or DVI inputs on an off the shelf external monitor which has at least 1280 x 1024 resolution and supports 60Hz frame rates. Instructions for attaching the external monitor are provided in Section 18, *Appendix B: External Monitor Hookup.*

9.1.9 Operating Environment

9.1.9.1 Electrical Specifications

Table 9-1: Electrical Specifications

Input Voltage	120 – 240 VAC, 50 – 60 Hz

9.1.9.2 Medical Electrical Classifications

Table 9-2: Medical Electrical Classifications

Product Safety Classification	Type B Applied Part
IEC 60601-1— Medical electrical equipment—Part 1: General requirements for safety	
IEC 60601-1-2 — Medical electrical equipment—Part 1: General requirements for safety—Section 2: Collateral standard—Electromagnetic compatibility—Requirements and tests;	CISPR 11 (Class A, Group 1)

9.1.9.3 Environmental Specifications

Table 9-3: Environmental Specifications

Operating Temperature	10°C to 35°C
Operating Relative Humidity	Up to 90% non-condensing
Storage Temperature	5°C to 60°C
Transport Temperature	5°C to 60°C

9.1.9.4 Accessory Support

The LipiView® Interferometer may be used with the following USB accessories that are compatible with Windows XP and USB1.0:

- USB printer (Printer Support)
- USB external hard drive (External Backup Support)
- USB flash drive (USB / Thumb Drive Support)

The LipiView® Interferometer is designed to operate wirelessly with other network devices, such as a printer. Placement of the LipiView® Interferometer should be within range of the network, if a network system is used.

The LipiView® Interferometer supports connection to an external monitor; refer to Section 19, *Appendix B: External Monitor Hookup*, for more information.

9.2 User Interface

9.2.1 Touchscreen Display Layout

After user login, all touchscreen displays are formatted with a menu bar across the top containing a disk space indicator and up to seven tabs, one for each key function of the system. A light gray colored tab indicates the active function. Any other tabs shown on the menu bar may be selected. On screens involving a patient record, patient identifier information is displayed on the right end of the menu bar.

Figure 9-3 shows a sample menu bar. The light gray color on the View Images tab indicates it is the active function. Functions have one or more associated screens. From left to right, the menu bar contains: Help tab, Log Out tab, Disk Space Indicator, Admin tab, Patient Records tab, Capture Images tab, View Images tab, Print/Save tab, and patient identifier information.

Figure 9-3: Menu Bar from View Images Tab

The Login screen contains the *Help* tab and the disk space indicator:

- **Help** – Pressing *Help* displays information related to the active screen. Pressing *Help* again closes the screen. Refer to section 10.6, *Online Help*.
- **Disk Space Indicator** – The bar to the right of the *Help* tab indicates the percentage of the available disk space that has been used for video storage. The Administrator can configure at what hard drive fullness level (e.g., 75%) the LipiView® Interferometer will no longer capture new images due to a full disk. Refer to Section 16.7, *Admin Networking* for information on setting the fullness level, cloning and archiving content to free up disk space.

Once the user logs in, up to six additional tabs are visible, depending on the current screen:

- **Log Out** – Pressing *Log Out* exits the user from the device and the Login screen described in Section 10.1.3, *User Login* is displayed.
- **Admin** - If the Username that is logged into the system has been set up as an Administrator, an *Admin* tab will be visible to the right of the disk space indicator

on all screens. Refer to Section 15, *Administrator Instructions for Use* for a description of Administrator functionality.

- **Patient Records** – Pressing *Patient Records* displays patient information, and allows the user to search for, add or edit patient information. Refer to Section 10.2, *Patient Data Entry*.
- **Capture Images** – Pressing *Capture Images* allows the user to record video for each eye, preview video, rerecord video (if needed), and save video. Refer to Section 10.3, *Video Image Capture and Recording*. If the power on self-test described in Section 10.1.1 detects a problem that would potentially affect this modality, this tab will not be functional and will be grayed out (refer to Section 9.2.4). The LipiView® Interferometer will not be able to capture images but prior data can still be reviewed.
- **View Images** – Pressing *View Images* allows the user to review saved videos and request a computer analysis. Refer to Section 10.4, *Video Review and Analysis*.
- **Print / Save** – Pressing *Print / Save* allows the image with the video analysis to be printed and/or saved to an HL7 compatible database. Refer to Section 10.5, *Video Print and Save.*

Patient identifier information is shown on the right end of the menu bar when a patient record has been selected. This includes the Captures Images, View Images and Print / Save tabs. The information is extracted from the Patient Record, so the contents may vary. At a minimum, it includes the Patient ID or the Last Name, First Name and Date of Birth.

The screen below the menu bar contains information relevant to the active function tab. When entering information is allowed, an onscreen keyboard is displayed at the bottom of the screen, as discussed in the next section.

9.2.2 Onscreen Keyboard

When the cursor is positioned in a location that requires user input, the onscreen keyboard in Figure 9-4 is displayed. This keyboard contains an alphabet keypad (uppercase only), a numeric keypad, and five special keys that perform as specified below. The onscreen keyboard does not contain or support the use of special characters other than the backslash (\) and colon (:) between the two keypads.

- **Left arrow above the "Q"** – Scrolls backwards through entered text to facilitate the insertion or deletion of characters.
- **Right arrow above the "W"** – Scrolls forwards through entered text to facilitate the insertion or deletion of characters.
- **Delete key above the "O" and "P"** – Deletes the character to the left of the cursor.
- **Left tab above the "8"** – Moves the cursor to the prior field allowing user input. Repeated presses on the left tab key will continue looping the cursor backwards through fields on the current screen, but it does not return to the previous screen.

- **Right tab above the "9"** – Moves the cursor to the next field on the screen allowing user input. Repeated presses on the right tab key will continue looping the cursor forwards through fields on the current screen, but it does not advance to the next screen.

Each key press yields one character or cursor movement of one position. Keys do not repeat if they are held down.

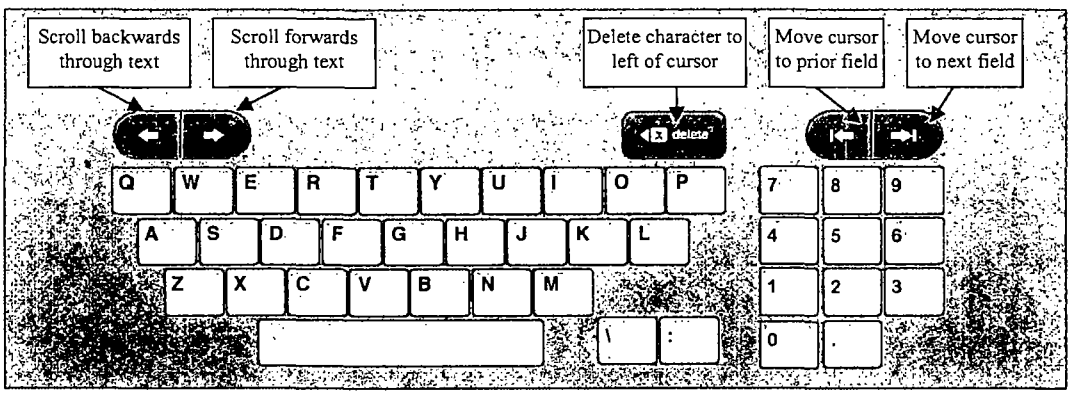


Figure 9-4: Keyboard

9.2.3 Positioning the Cursor

The LipiView® Interferometer touchscreen display allows the user to position the cursor by touching the desired area of the screen, or by pressing the arrow, delete or tab keys described in the previous section.

When making an edit to an existing field without positioning the cursor, any new characters entered are appended to the existing text, rather than replacing it. Use the Delete key to clear a field first, and then re-enter the information, or use the arrow keys to position the cursor in the correct location.

To facilitate editing, multiple characters on the screen can be highlighted by touching and then dragging a finger to the left or right. The series of highlighted characters is treated as one character when the arrow, delete and tab keys are used. The left or right direction of the finger movement determines where the cursor is placed when the special key is used.

9.2.4 Screen Interaction and System Messages

At times a portion of the active screen may be grayed out indicating it is temporarily inaccessible to the user. For example, if the onscreen keyboard is present, user input would be restricted to the keyboard. Selecting other tabs or pressing other areas of the screen will result in no action.

System messages are generated by the software running on the device when the user attempts to perform an invalid operation, or when something unexpected occurs or to confirm completion of an event. These messages may instruct the user on a particular

action to take (e.g., enter a missing field, or correct the format of a date field). When a system message is visible it requires a response from the user before any other input from the screen is accepted. The user must respond by pressing a button on the system message. Typically this is the *Close* button, but it may also be a confirmation or other dialog.

System messages related to Windows error codes will also be listed in the System Log described in Section 16.9, *Admin System Log*.

9.3 Patient Interface

The only part of the LipiView® Interferometer that directly interfaces with the patient is the ophthalmic chin rest support. **Ensure that all parts of this support are cleaned with an alcohol wipe prior to each patient use and prior to storage.**

9.4 Device Setup

Prior to initial use, ensure that the instructions in Section 16.1, *First Time Setup* have been completed by an Administrator. Other administrative functions should be completed at the discretion of the Administrator.

Ensure that the power cord is plugged into an electrical outlet. The power cord connection is located underneath the base of the device.

10 Instructions for Use

This section provides instructions for use of the LipiView® Interferometer to image the ocular surface and to observe the tear film of the eye through specular reflection of light. The instructions include:

- Device Startup (Section 10.1);
- Patient Data Entry (Section 10.2);
- Video Image Capture and Recording (Section 10.3);
- Video Review and Analysis (Section 10.4);
- Video Print and Save (Section 10.5);
- Online Help (Section 10.6); and
- Log Out (Section 10.7).

Additional administrative functionality is described in Section 16, *Administrator Instructions for Use*.

10.1 Device Startup

10.1.1 Power On and Self-Test

Upon powering on the device, the LipiView® Interferometer performs a self-test, confirms that the camera is connected, verifies system voltages, checks remaining hard drive space, and calibrates the camera motors. Version information at the bottom of the screen indicates the software running on the interferometer.

1. ***Power On*** - Power on the LipiView® Interferometer by pressing the rocker switch on the base of the device behind the touchscreen. Refer to Figure 9-2 for the location of the power switch. An indicator light on the power switch illuminates when the device is powered on.

   NOTE: The LipiView® Interferometer should be powered off overnight to allow the device to cool down. However, the device does not need to be powered off between patient examinations.

2. ***Software Boot Up*** - The touchscreen display remains blank while the software boots up. After a short time a "Welcome" message is briefly displayed. Shortly thereafter the screen in Figure 10-2 is displayed as the initialization process begins. The system version number displayed represents the software release which is currently installed. This manual is designed for all software releases that are labeled as 2.x. The exact letter of your system version may not match Figure 10-2.

   The system will display a warning (shown in Figure 10-1 below) that must be acknowledged before the initialization process continues: "Ensure patient and operator are clear of the chinrest area. The unit will now automatically home the motor system. Press the Continue button to begin."

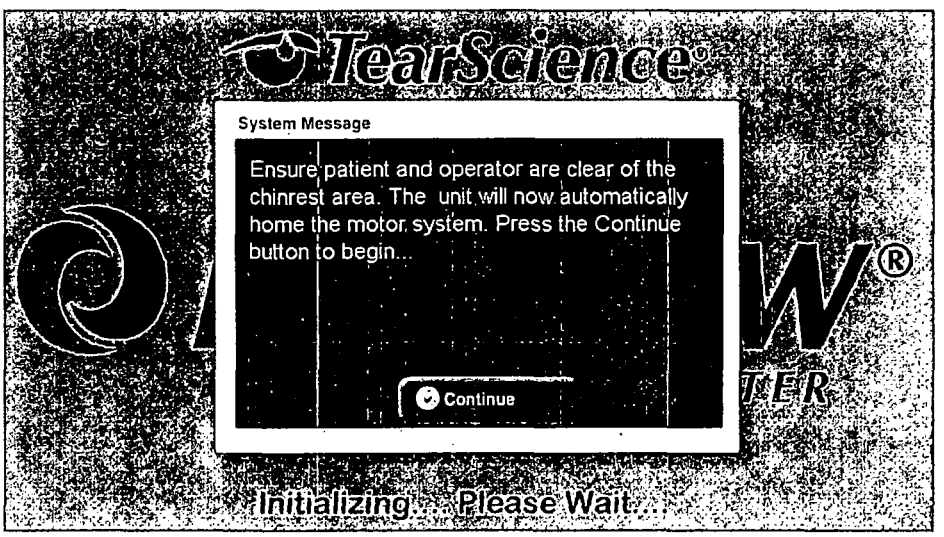


Figure 10-1: Warning screen

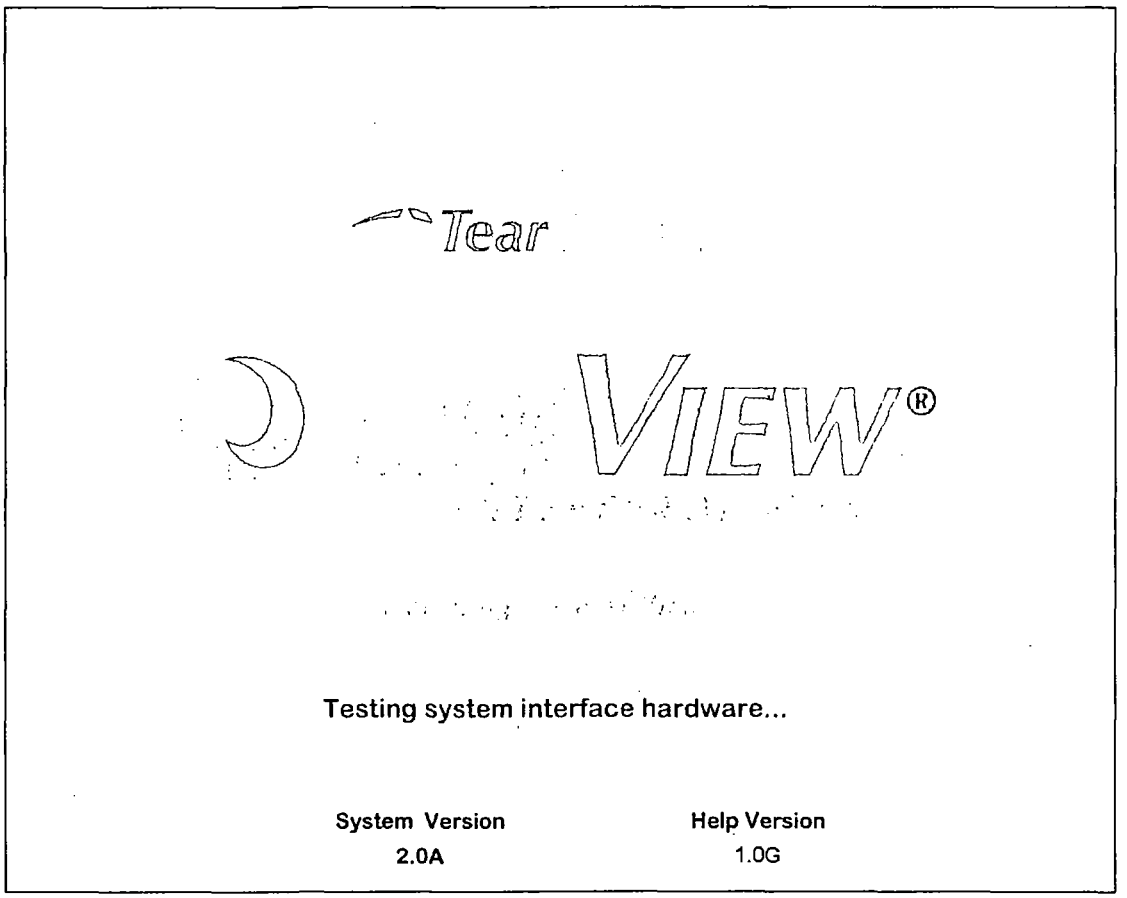


Figure 10-2: Initialization Screen

3. ***Equipment Location and Calibration*** - Figure 10-2 is displayed as equipment is located and calibrated. The motion stage moves up and down during the motor calibration process. When the initialization process completes after about 20 seconds, the screen in Figure 10-3 is displayed indicating that the device is ready for use. Continue with Section 10.1.2, *Device Ready*.

10.1.2 Device Ready

At the completion of the self-test, the words *Initializing.... Please wait....* on the screen are replaced with the words *Touch Screen To Continue* as shown in Figure 10-3.

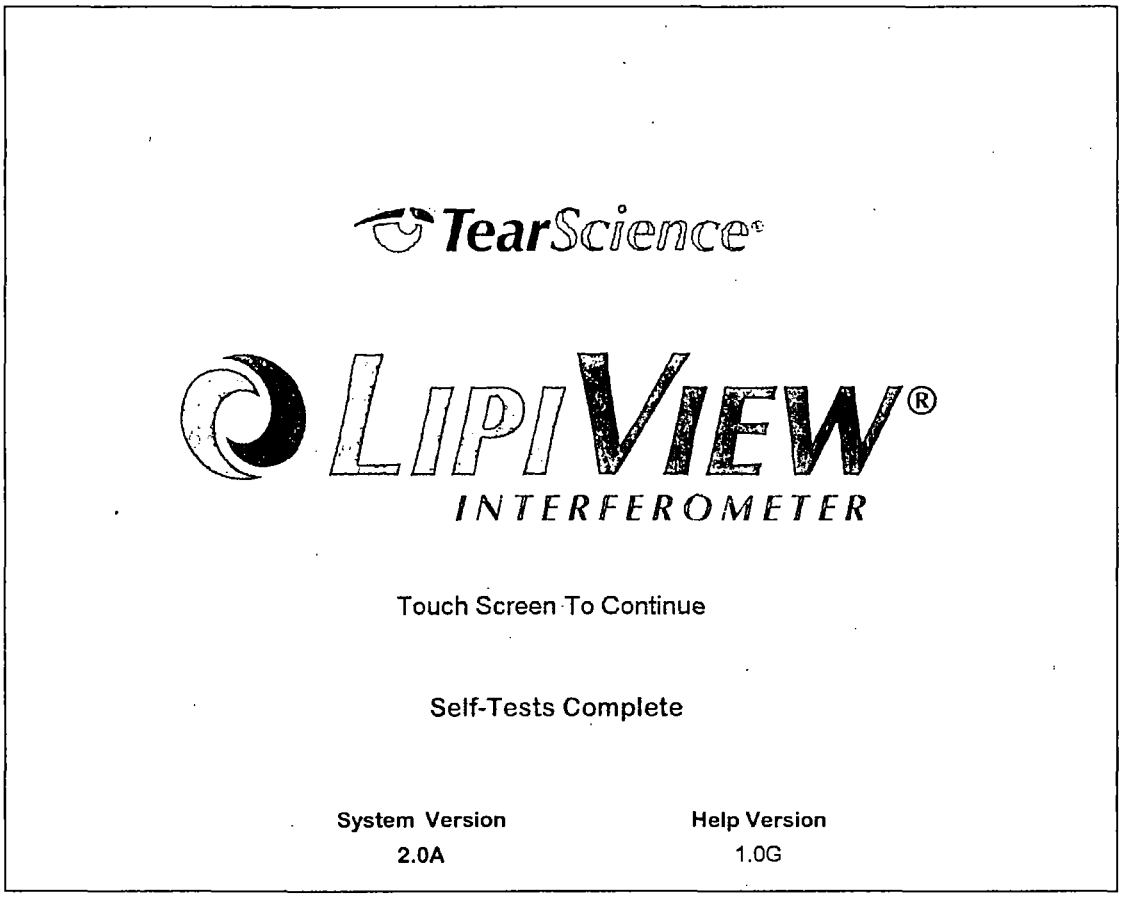


Figure 10-3: Device Ready Screen

When ready to continue, press anywhere on the screen. The login screen in Figure 10-4 will be displayed. Continue with Section 10.1.3, *User Login*.

10.1.3 User Login

The User Login screen in Figure 10-4 is displayed until *Submit* is pressed after a valid username and password have been entered. Refer to Section 16, *Administrator Instructions for Use* for setting up usernames and passwords prior to use of the device.

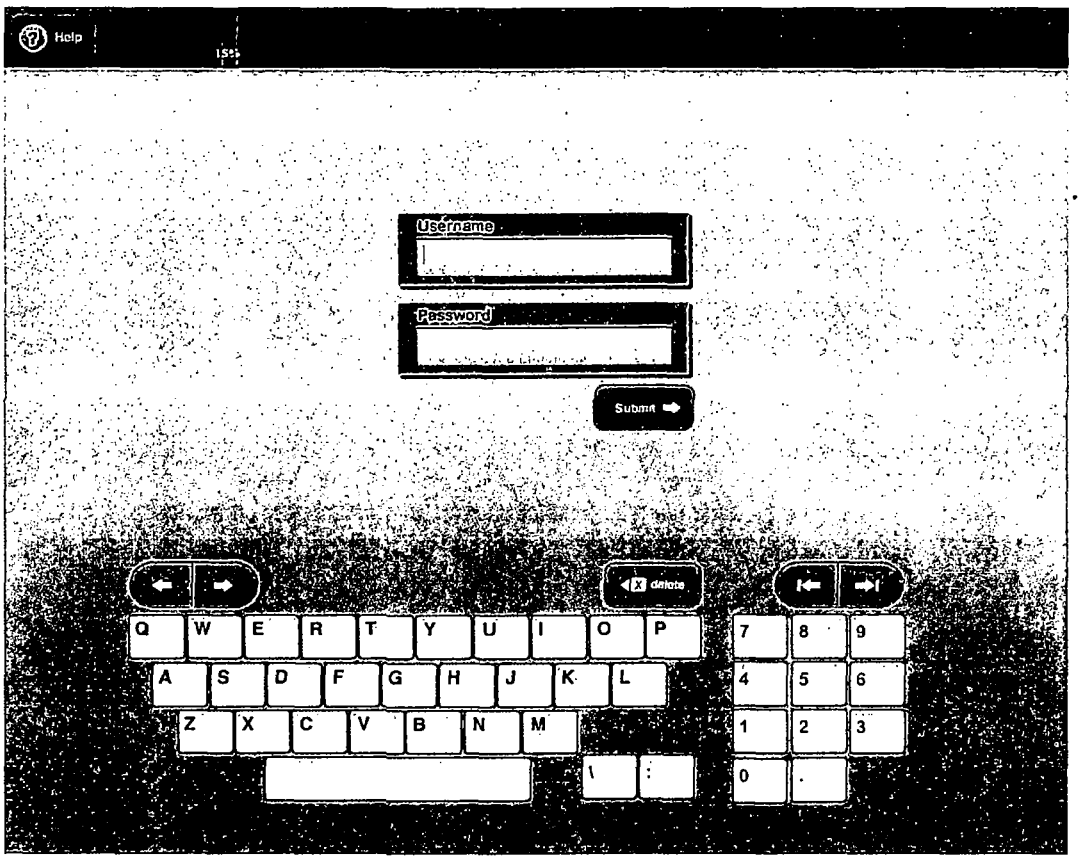


Figure 10-4: Login Screen

1. ***Username and Password*** - Using the onscreen keyboard, enter the Username and Password as follows:
   A. Type the name of the user.

      NOTE: Prior to device use, the Administrator must enter the Username and Password in the system.

   B. Position the cursor in the text box for the Password by touching the tab key or the password field.
   C. Type the password.

      NOTE: In the event of a forgotten password, or to change a password, contact the Administrator. Only the Administrator can set or change a password.
2. ***Submit*** - Press *Submit* and continue with Section 10.2, *Patient Data Entry.*

10.2 Patient Data Entry

After successfully logging in, the Patient Records screen shown in Figure 10-5 is displayed. The Patient Records screen is used to find an existing patient record or to add a new patient record if it is not found in the database.

Prior to beginning an examination, a patient's record must be selected. A patient's record must also be selected to view any previous videos. Until a patient record is selected, the Capture Images and View Images tabs on the menu bar are not active.

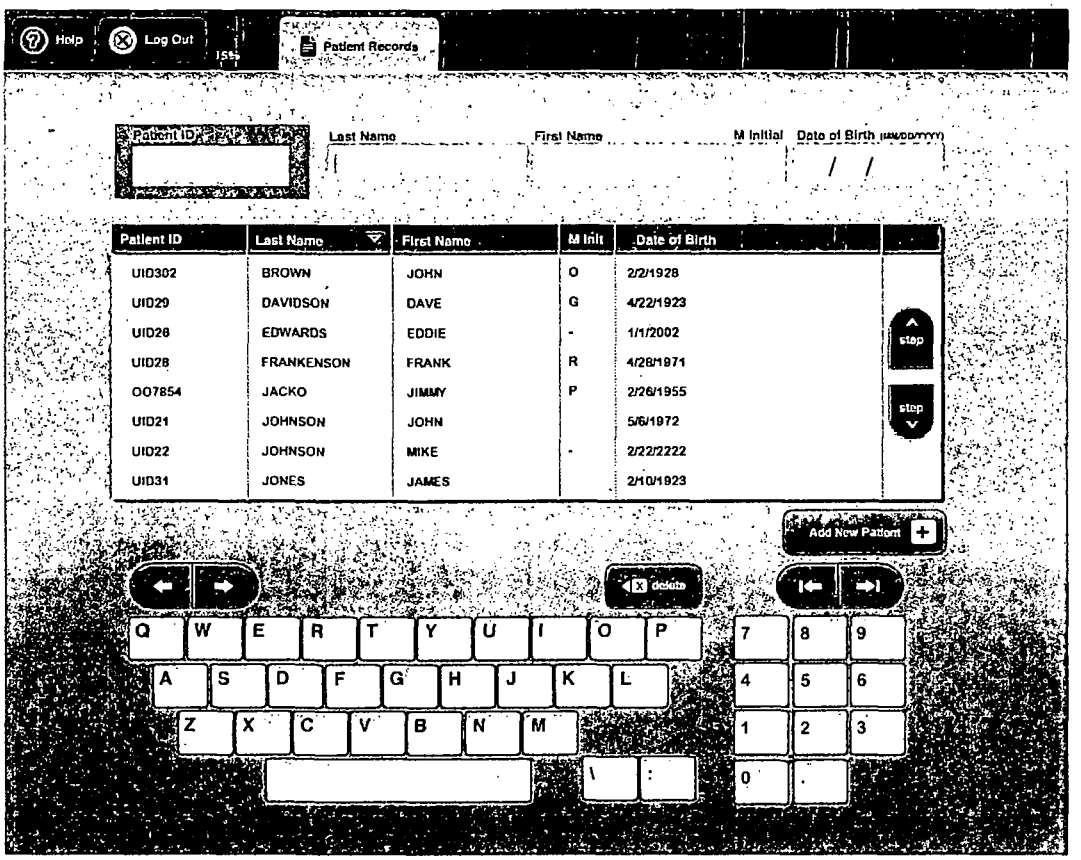


Figure 10-5: Patient Records Screen

10.2.1 Patient Records Screen

All patient records contain up to five pieces of information: Patient ID, Last Name, First Name, Middle Initial and Date of Birth. At a minimum, each patient record must include 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. The Patient Records screen contains these five blank fields, which are used to locate, create or update a patient record, followed by a tabular list of existing patient records.

The Patient ID field can contain up to 16 characters. Fields for the Last Name and First Name can contain up to 25 characters each. The middle initial contains up to one

character. The Date of Birth includes a one or two-digit month, followed by a one or two-digit day, followed by four-digit year.

The patient records table in the center of the screen lists the first eight patients in the database in alphabetical order. Once more than eight names have been saved, the step keys to the right of the table can be used to move backwards or forwards through the table. Each time the backwards (upper) key is pressed the previous eight names are displayed. Pressing the backwards key when the beginning of the list is displayed does not elicit a response. When the forward (lower) key is pressed, the next eight names are displayed in the table. Pressing the forward key when the last eight names are displayed also results in no change to the tabular display.

When the list of patient records spans multiple pages, sorting the table may facilitate searching for a record. Pressing the Patient ID, Last Name, First Name or Date of Birth header will sort the table by that column. Pressing the same header a second time will sort the table in the reverse order. A small triangle in the column header indicates that the table is being displayed according to the data sorted by this column. The triangle points down or up to specify the direction.

10.2.2 Locate a Patient Record

A patient record must be in the database before images can be captured or viewed. To attempt to locate a patient record in the database, search for the record using one of the following two methods. For existing patients, using the step keys in method 1 may be preferred. For new patients, use method 2. If uncertain as to whether a patient record is in the database, use either or both of these methods to determine whether the patient record exists.

1. ***Locate Patient Record with Step Keys*** - Use the step keys to move backwards (upper key) or forwards (lower key) through the database, while examining the records displayed in the table for a match. If desired, press the table header for Patient ID, Last Name, First Name or Date of Birth to sort the table by that field.
   A. If the record cannot be found in the table, then continue with method 2 to confirm the patient record does not exist.
   B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action.*
2. ***Locate Patient Record by Typing*** - Begin typing the patient's Last Name, First Name and/or Date of Birth in the fields above the table, or position the cursor in the Patient ID field and begin entering the ID. As each character is entered, the patient records table is filtered displaying only the possible matches that exist in the database.
   A. If no records are displayed in the table then the patient record does not exist. Either correct the entered information, or continue with Section 10.2.3, *Add a New Patient Record.*
   B. If the record is visible in the table, then a match has been found. Continue with Section 10.2.4, *Select a Patient Action.*

10.2.3 Add a New Patient Record

When a patient record could not be located in the database, the screen shown in Figure 10-6 is displayed, allowing the user to enter new patient information and save it.

NOTE: Depending on the information entered when trying to locate a patient, one or more of the five fields in the patient record may be empty or partially filled in. As soon as the system determined there was no patient record match in the database it transitioned to Figure 10-6.

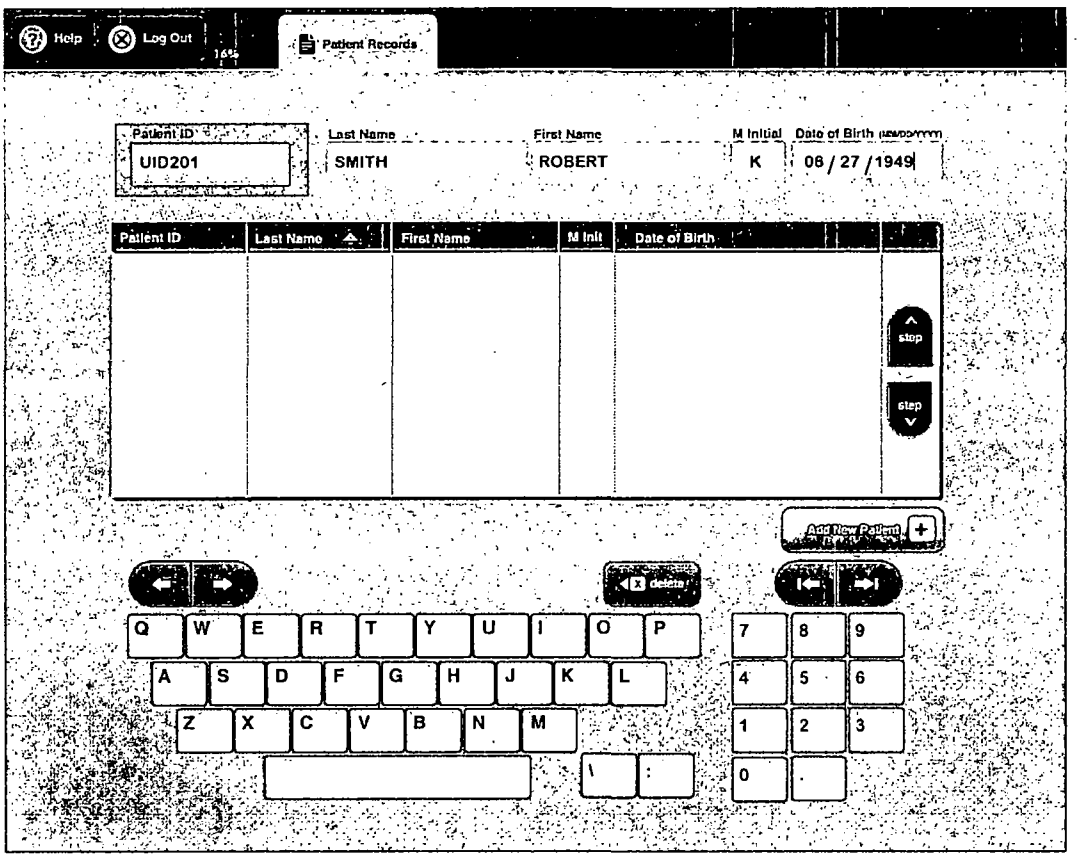


Figure 10-6: Patient Records Screen - Add a New Patient

At a minimum each patient record must contain 1) a Patient ID or 2) the Last Name, First Name and Date of Birth fields to proceed. The instructions below specify entering new patient information beginning with the Last Name; however, information may be entered into the fields in any order, and only the minimum information is required. Touch the appropriate fields or use the tab keys to move from field to field.

1. ***Patient Name*** – Enter the patient's Last Name and First Name and optional middle initial:
   A. Enter the Last Name, up to a maximum of 25 characters.
   B. Enter the First Name, up to a maximum of 25 characters.

C. Enter the middle initial if desired. Entry may be helpful with common last names.

2. ***Date of Birth*** - Enter the patient's Date of Birth, using a one or two-digit month, followed by a one or two-digit day, followed a four-digit year. If an invalid date is specified, a system message is displayed indicating required information. Press *Close* and try again.

   NOTE: If a one-digit month or day is entered, position the cursor in the next field by touching the field or the tab key. If a two-digit month or day is entered, the cursor will automatically move to the next field.

3. ***Patient ID*** - Enter the Patient ID, up to a maximum of 16 characters. If a patient ID is entered, no other information is required to complete the patient record.
4. ***Review Record before Adding*** - Confirm that the information for the new patient is correct, and that the minimum fields have been filled in. Once a patient record has been entered into the database it cannot be deleted.
5. ***Add Patient Record to Database*** - Press *Add New Patient.*
   A. If a required field is empty or the new record is a duplicate of one that already exists in the database, a system message indicating the error is displayed. Touch *Close* to shut the system message. Make the appropriate corrections and press *Add New Patient* again.
   B. If the minimum required fields have information, there is a valid Date of Birth, and the patient record is not a duplicate of an existing record, it is saved in the database. The Patient Records screen in Figure 10-5 is redisplayed with the new patient record highlighted, and showing at the top of the table.

      NOTE: If the record added is the last record in the table, it appears to be the only record until the backwards (upper) step key is pressed showing other records.

   C. Return to Section 10.2.2, *Locate a Patient Record* to add another patient or find an existing patient, or touch any field on any record in the table and continue with Section 10.2.4, *Select a Patient Action.*

10.2.4 Select a Patient Action

Once a patient's record is visible in the patient records table, press on any field in the patient record. The row will become highlighted, the *Select a Patient Action* system message will appear, and the remainder of the screen will be grayed as shown in Figure 10-7, indicating that it is temporarily inaccessible for user input. Choose one of the four options in the system message:

- **Edit Patient** – Select this option to proceed to the Edit Patient Information screen, and continue with Section 10.2.5, *Edit Patient Information.*

  NOTE: A patient record may only be edited if video images have not previously been saved.

- **Capture New Images** – Select this option to proceed to the Capture Images screen, and continue with Section 10.3, *Video Image Capture and Recording.*

- **View Past Images** – Select this option to proceed to the Patient History screen, and continue with Section 10.4, *Video Review and Analysis*.
- **Close** – Select this option if the incorrect record was chosen, and return to Section 10.2.2, *Locate a Patient Record* to try again. The system will close the system message, but the row will remain highlighted until another row is selected.

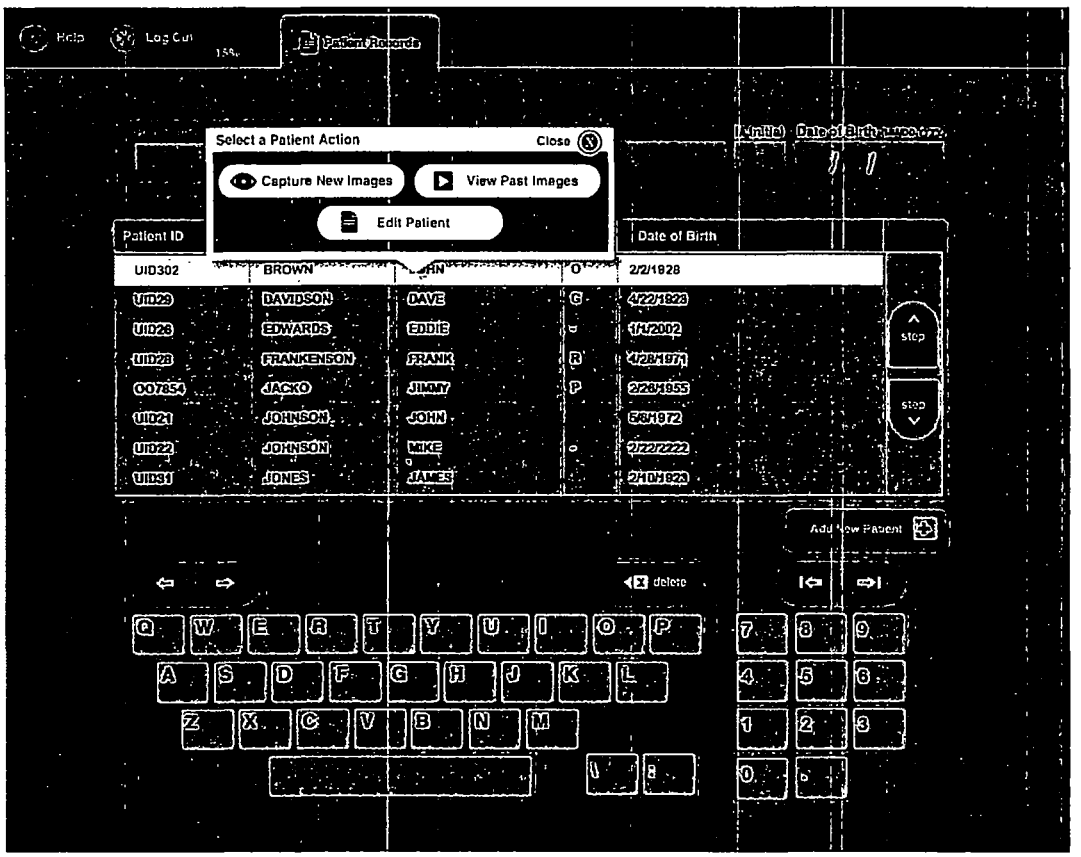


Figure 10-7: Patient Records Screen - Select a Patient Action

10.2.5 Edit Patient Information

When *Edit Patient* is pressed in the *Select a Patient Action* system message, either the screen in Figure 10-8 will be displayed showing the current information for the chosen patient, or a system message will be displayed indicating that video data has been captured for this patient and the record cannot be modified.

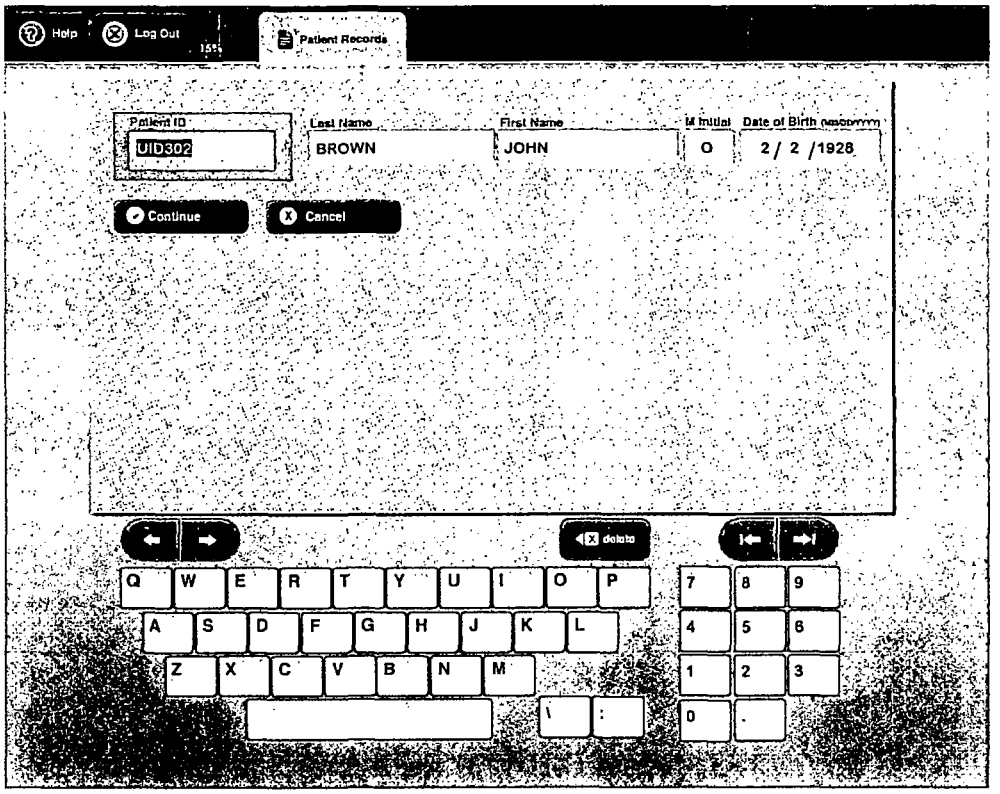


Figure 10-8: Patient Records Screen - Edit Patient Information

1. ***Edit Patient Record*** - Position the cursor in the field(s) to be edited and make the changes. At a minimum, the patient record must contain 1) a Patient ID, or 2) the Last Name, First Name and Date of Birth. Continue with step 2 to save the edited data or step 3 to cancel the edit.
2. ***Save Patient Record Edits*** - Press *Continue* to update the patient's information in the database.
   A. A system message will result if a mandatory field is empty or the modified record is a duplicate of one that already exists in the database. Touch *Close* to shut the system message. Return to step 1 to correct the entered fields, or go to step 3 to cancel.

      NOTE: It is not possible to remove a patient record from the database by clearing out all fields. Once a patient record has been added it cannot be deleted.

   B. If the required fields exist and the record is unique, the system returns to the Patient Records screen in Figure 10-5 with the updated record highlighted and showing at the top of the table. Continue with Section 10.2.2, *Locate a Patient Record.*
3. ***Exit without Saving Patient Record Edits*** - Press *Cancel* to return to the Patient Records screen in Figure 10-5 without saving any edits. The highlighted row will be displayed in the same location. Continue with Section 10.2.2, *Locate a Patient Record.*

10.3 Video Image Capture and Recording

When *Capture New Images* was chosen from the *Select a Patient Option* system message shown in Figure 10-7, the Capture Images screen in Figure 10-9 is displayed. As the screen displays, the illuminator is turned on and the system initializes the camera for approximately 1-2 seconds. The right end of the menu bar contains the patient information as entered in the selected patient record.

NOTE: If the Capture Images screen was reached by mistake, or to exit without capturing a video, press the *Log Out* tab, or press *Save All/Continue*, which will transition to the View Images function. From the menu bar on the View Images screens, all tabs are available for selection.

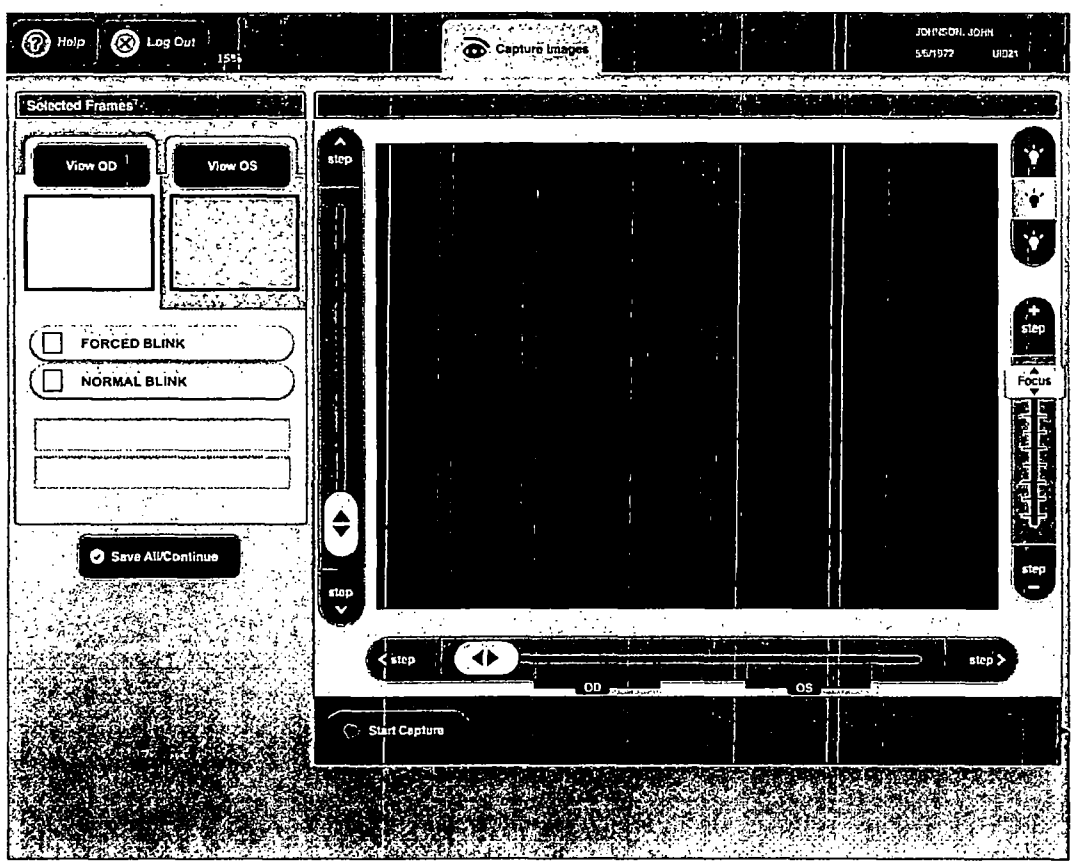


Figure 10-9: Capture Images Screen

10.3.1 Capture Images Screen

The Capture Images screen is split into left and right sections.

From the left side below the *Selected Frames* header, the user chooses which eye will have video captured. Information about the video image may be selected or entered from the tags below.

- **View OD** (Right Eye) – Select this to move the camera into position to view the right eye. This selection automatically illuminates the appropriate fixation bank for the patient's left eye. The patient fixates on a light with the left eye while the right eye image is being captured.
- **View OS** (Left Eye) – Select this to move camera into position to view the left eye. This selection automatically illuminates the appropriate fixation bank for the patient's right eye. The patient fixates on a light with the right eye while the left eye image is being captured.

  NOTE: The frame that is white indicates the selected eye. The frame that is grayed out was not selected.
- **Pre-set Tags** (rounded, gray color) – If applicable, the user may select one or both of these configurable, descriptive tag names before or after the video is captured. Once the video is saved, information selected here is permanently retained with the video data. These tags are pre-set by the Administrator as described in Section 16.3, *Admin System Setup*.
- **Key-in Tags** (rectangular, white color) – If desired, the user can enter up to 15 characters of information into each of these two fields before or after the image is captured. Information is typically specific to the patient or image. Once the video is saved, information entered here is permanently retained with the video data.

The right side of the screen is initially blank, but will display images of the selected eye as the video is recorded. Prior to recording the video image, the following controls are used to obtain the best possible image:

- **Left slider** – Touch the step keys to move the entire motion stage (including camera and illuminator) up and down for proper positioning. The button on the slider indicates the current motor position.
- **Horizontal slider** – This slider moves the camera inside the motion stage to the left or right. When *View OD* or *View OS* is pressed, the camera is moved to a default location for the selected eye near the OD or OS button on the slider. The camera position is fine-tuned by touching a location on the slider or by pressing the left or right step keys. While on the Capture Images screen the software will remember the last position of the camera for both *View OD* and *View OS* until *Save All/Continue* has been pressed. This enables the operator to easily move between the right and left eyes by touching *OD* and *OS* on the slider bar.

- **Automatic Image Centering-** An alternative method of centering the eye on the screen is to touch the location on the live video that should be in the center (typically the pupil). The camera will automatically be moved to the location that was touched on the screen, and that location becomes the center of the video image.
- **Fixation Light** – The three-way button on the top right of the Capture Images screen operates a fixation light, which consists of a vertical set of three light emitting diodes (LEDs) behind the camera for the patient to look up, look straight ahead or look down. The default position is straight ahead.
- **Focus slider** – This slider moves the camera inside the motion stage forwards and backwards to bring the image in (-) or out (+).

NOTE: To change the position of the item controlled by a slider, press the desired location on the slider. The item and the button will move accordingly. Touching the button and dragging it has no effect.

10.3.2 Capture the Video

The following steps instruct the user on how to set up the device, position the patient and capture the video:

1. ***Eye Selection*** - On the left side of the screen touch *View OD* or *View OS* for the eye to be captured. *View OD* is the initial default if no selection is made. Once a video has been recorded, the default selection is the last eye captured. The selected view will be white and the other will be a gray color.
2. ***Pre-set Tags*** - Select one or both of the pre-set tags, if desired. The system will note a selection with a checkmark. The selection may be made here or while previewing the captured image in Section 10.3.3. If selected here, it may be updated anytime until the video is saved.

   NOTE: Press the checked tag again to deselect it.
3. ***User Defined Key-In Tags*** - If desired, use the key-in tags to record additional information in each tag. Information may be entered here or as part of previewing the captured image in Section 10.3.3. If entered here, it may be updated anytime until the video is saved.

   C. Touch a key-in field to display the onscreen keyboard.

   D. Enter information in one or both of the key-in tags.

   E. Touch *Submit* on the left of the onscreen keyboard. The screen in Figure 10-9 will be displayed with the updated tag names.
4. ***Disinfect*** – Disinfect the chin and forehead rest surfaces with alcohol prior to patient use.
5. ***Patient Positioning*** - Have the patient sit facing the LipiView® Interferometer. Ensure the patient's chin is placed fully forward into the chin rest and the patient's forehead is placed firmly against the forehead rest to ensure proper attitude of the patient's head. If the patient's head is not in the proper position, valid video data may not be collected. Instruct the patient to look at the orange fixation light.

Caution: **Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct the patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest.**

6. ***Chin Rest Height Adjustment*** - Adjust the height of the chin rest by spinning the fluted roller near the base of the chin rest so that the lateral (temporal) canthus is aligned with the horizontal canthus alignment marks on the left and right sides of the forehead rest. Spin the roller to the right to lower the chin rest and spin the roller to the left to raise it.
7. ***Camera Adjustment*** – By default the camera should be in the general location of OD or OS (depending on the view selected in step 1, as shown in Figure 10-10. Position the height of the camera by stepping the motors up and down using the left slider. Use the horizontal slider to adjust the camera sideways. Alternatively, touch the desired location the screen which will automatically move the motion stage and the camera to that position and then center on it. Adjust the image until the pupil appears in the center of the live video screen and the reflected tear film image is within the green targeting rectangle.

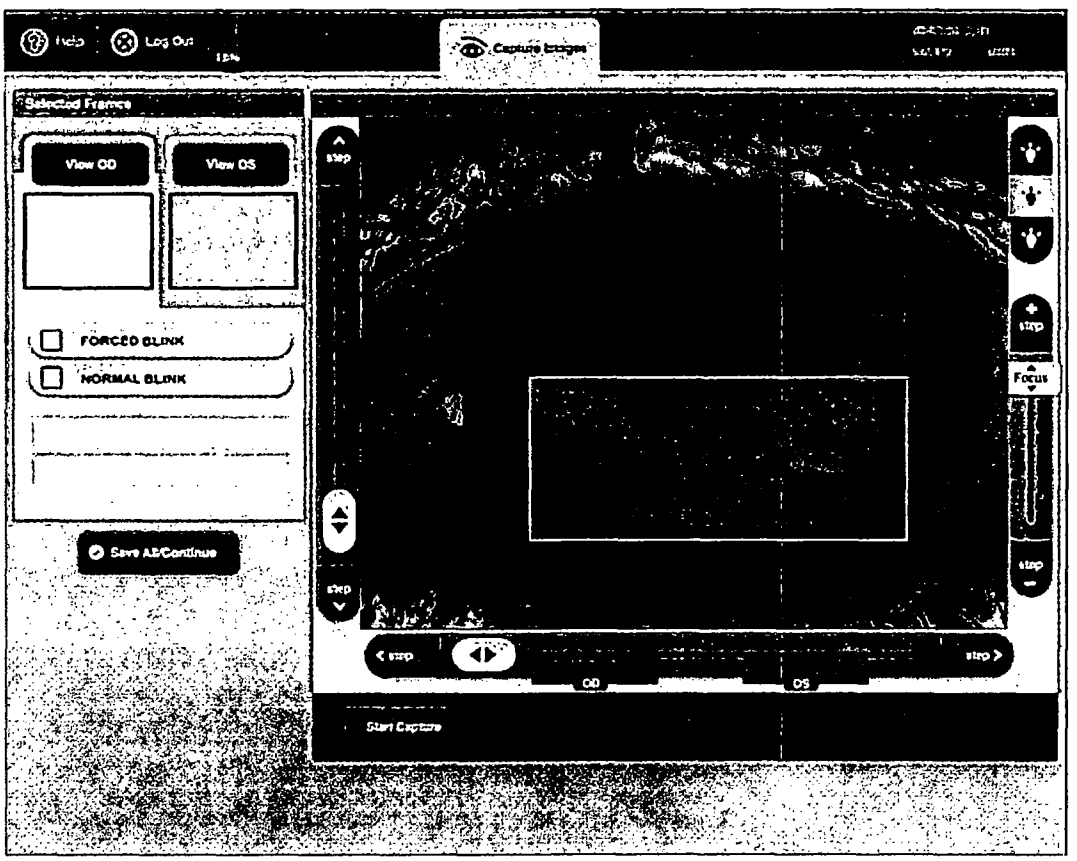


Figure 10-10: Capture Images Screen - Centering Eye Before Recording

8. ***Camera Focus*** - Adjust the closeness of the image with the Focus slider on the right. The focus should be adjusted so that the tear film image is clear and not blurred.

   NOTE: If the tear film image is not in focus, invalid video data may be saved. As shown in Figure 10-16, analysis of invalid video data is unable to produce a graph and numerical results.

9. ***Fixation Light / Patient Gaze*** - Ensure the patient is looking in the proper direction to facilitate obtaining a well-centered and focused picture for the patient's eye. If necessary, press the upper or lower sections of the Fixation light, guiding the patient to look up or down.

10. ***Capture Image Start*** - Press *Start Capture* to begin recording approximately 20 seconds of video. Typically 10-15 seconds of video is enough to capture the tear film image as the patient blinks. Instruct the patient to blink naturally (e.g., NORMAL BLINK) or to perform a squeezed blink (e.g., FORCED BLINK) as desired, to evaluate the distribution of the tear film.

    NOTE: The blinking red light indicates the LipiView® Interferometer is recording, and the *Start Capture* button is renamed to *End Capture*. Other than pressing *End Capture,* the grayed out screen does not allow user interaction.

11. ***Capture Image End*** - Press *End Capture* to stop recording before 20 seconds has elapsed, or the system will automatically end the video after 20 seconds.

12. The illuminator is turned off when recording stops, and the screen in Figure 10-11 is displayed allowing the user to choose from several options. Continue with Section 10.3.3, *Preview Captured Image*.

10.3.3 Preview Captured Image

The right side of the Preview Captured Images screen in Figure 10-11 contains the video image just recorded. The left side of the screen contains the same functionality as the Capture Images screen (Figure 10-9), indicating information about the image. *View OD* or *View OS* indicate the eye being shown. When video for both eyes has been captured, the most recently captured video is the one displayed by default.

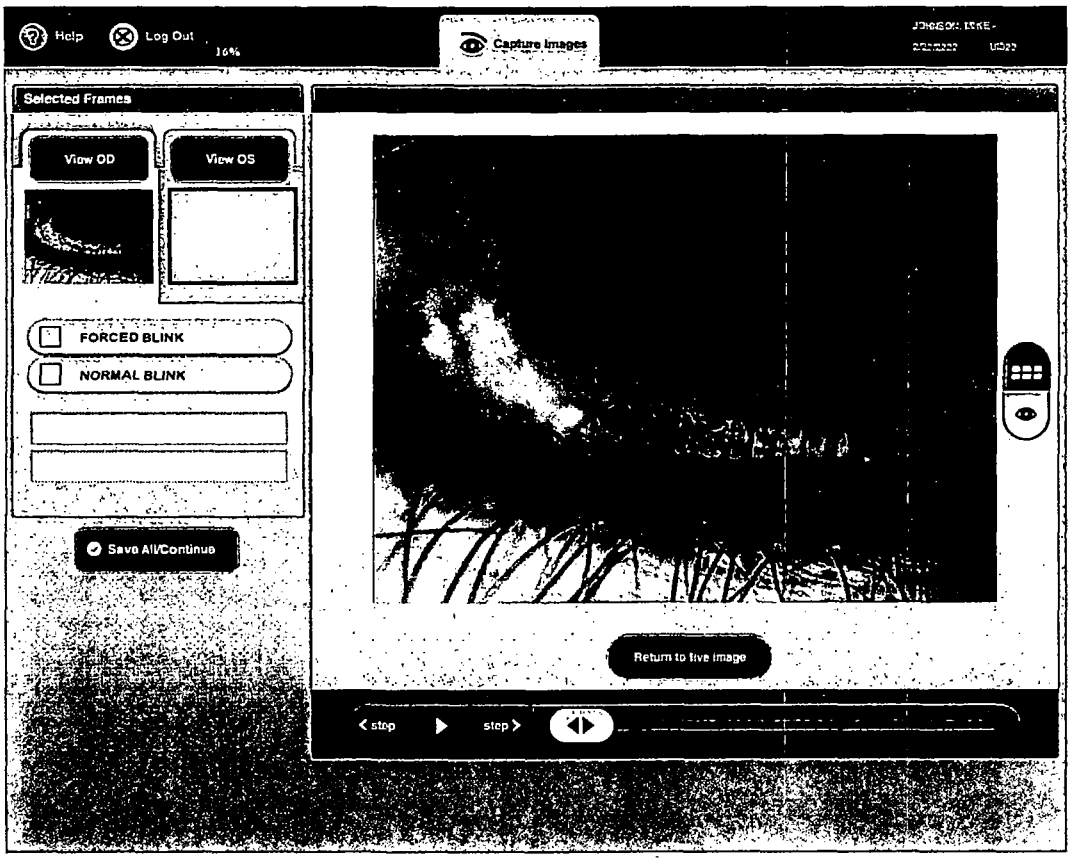


Figure 10-11: Capture Images Screen - Preview Captured Images

The Preview Captured Images screen enables the user to perform one or more of the following steps. Steps 1 – 4 are optional and they may be combined with other steps. Unless the user logs out of the system, the captured video must be saved (step 5) before other tabs become visible.

1. ***Preview Image*** - Preview the image using the following control keys:
   - **< step** – Press to step backwards through the video one frame at a time.
   - **Triangle/Vertical lines** – Press to play (triangle) or pause (two vertical lines) the video.
   - **step >** – Press to step forwards through the video one frame at a time.
   - **Video slider** – When in play mode, the button moves along the slider indicating the current position within the video. When in pause mode, press any location on the slider to move the video to the position indicated by the touch. The button will move to the new location.
   - **Toggle key** - The toggle key positioned to the right of the screen switches between a tear-film view and a full-eye view. Press the tiles to select the tear-film view. Press the eyeball to select the full-eye view. The green portion of the key indicates the active view.

2. ***Rerecord Video*** - Rerecord the video by pressing *Return to live image* above the video controls. The Rerecord Video screen in Figure 10-12 will be displayed. Continue with Section 10.3.4, *Rerecord Video*.
3. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the preview screen.
4. ***Eye Selection*** - Press the tab for the other eye (*View OD* or *View OS*). Figure 10-9 will be displayed for the selected eye. Return to Section 10.3.2, *Capture the Video* and follow the instructions. When the second video capture ends, Figure 10-11 is displayed with the most recently captured video showing. Return to step 1 and follow these steps for the second eye.
5. ***Save Video*** - Save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Rerecord Video screen in the next section.
   B. After the image is saved, the illuminator is turned off and the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

10.3.4 Rerecord Video

The Rerecord Video screen in Figure 10-12 is used when the captured image for one or both eyes is not acceptable to the user and it is necessary to rerecord the live image before it is saved. When this screen is displayed, the illuminator light is turned on.

This screen operates like Capture Images screen in Figure 10-10 except that when *Start Capture* is pressed, a system message asks the user to confirm that the user is intentionally overwriting the previous image. The image may be rerecorded any number of times. There is also an additional button on the bottom center of the screen allowing the user to return to the previously recorded image.

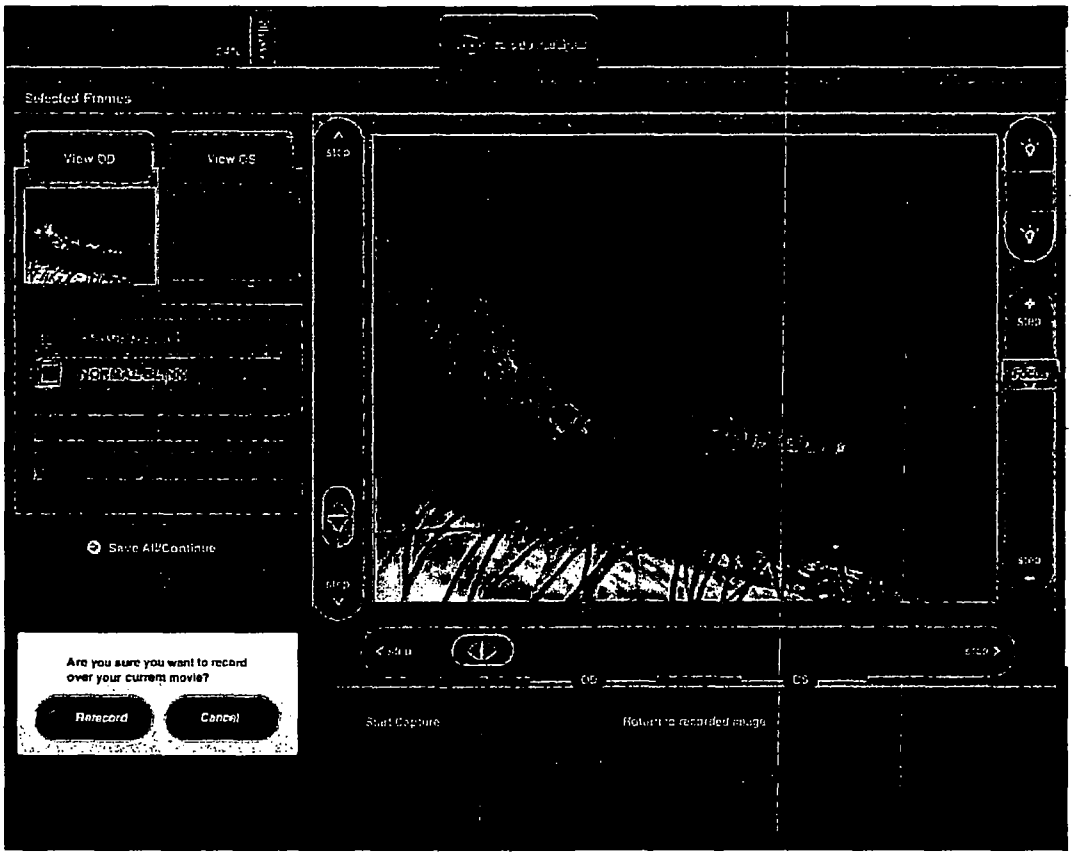


Figure 10-12: Capture Images Screen - Rerecord Video

1. ***Confirm Whether to Rerecord*** - If unsure whether to rerecord the image or if this screen was reached in error, press *Return to recorded image* to return to the Preview Captured Image screen in Figure 10-11. Follow the steps in Section 10.3.3, *Preview Captured Image.*

   NOTE: Toggle between these two screens by pressing *Return to recorded image* and *Return to live image.*
2. ***Eye Selection*** - If video for both eyes has been captured, ensure that the correct eye has been selected.
3. ***Camera Focus and Settings*** - Prior to rerecording, touch the screen or use the slider bars to reposition the camera, and modify the Fixation Light and Focus settings if needed.
4. ***Rerecord Image or Cancel*** - Press *Start Capture.* A system message will appear on the bottom left of the screen to rerecord or cancel the request.
   A. Press *Rerecord* on the system message to begin capturing another image. When *End Capture* is pressed, the illuminator is turned off and the system returns to the screen in Figure 10-11. Return to Section 10.3.3, *Preview Captured Image.*

NOTE: When *Rerecord* is pressed, the original captured image will be overwritten with the new one. Recording of the image can be repeated as many times as needed until the image is acceptable.

B. Press *Cancel* on the system message when unsure whether to rerecord. The system message will be removed. Return to the recorded image (step 1), rerecord the image (step 4A) or continue with step 5.

5. ***Update Tags*** - Update or enter tag information as follows:
   A. Select or deselect a pre-set tag.
   B. Add or modify any descriptive information about the image in the key-in tags.

      NOTE: Pressing on one of the key-in tags will bring up the onscreen keyboard. After entering the information press *Submit* to return to the previous screen.
6. ***Save Video*** - When the captured image is satisfactory, save the recorded video(s) as follows:
   A. Press *Save All/Continue* to save the current video(s) to the database. A message will flash indicating that the user should wait. Saving the image may take several seconds, depending on the length of the video.

      NOTE: Images can be saved from this screen, or from the Preview Captured Images screen in the previous section.
   B. After the image is saved the system displays the View Images screen in Figure 10-13 with the captured image(s) loaded. Continue with Section 10.4, *Video Review and Analysis*.

10.4 Video Review and Analysis

The Video Review and Analysis function is used to review information about a captured video for one or both of a patient's eyes. The View Images screen used to perform this function may be accessed after capturing a new video (continue with Section 10.4.1) or after selecting an image(s) from the patient's history (continue with Section 10.4.2). Patient information as entered in the selected patient record is listed on the right side of the menu bar. Other information on the screen will vary depending whether video was captured for both eyes, and whether the video has been analyzed.

10.4.1 View Images Screen after Capturing New Video

When *Save All/Continue* is pressed from any of the Capture Images screens in Section 10.3, *Video Image Capture and Recording*, the View Images screen in Figure 10-13 is displayed. From this entry point, the image on the screen is that of the eye(s) just saved. The OD eye is displayed on the left side of the screen and the OS eye is displayed on the right side of the screen. If only one eye was captured, the other half of the screen is blank. Since the images have not yet been analyzed, the numerical calculations below the images will be zero, and a message on the graph indicates that the user needs to press *ANALYZE IMAGES* to view the data.

Continue with Section 10.4.3, *View Images and Analyze Data.*

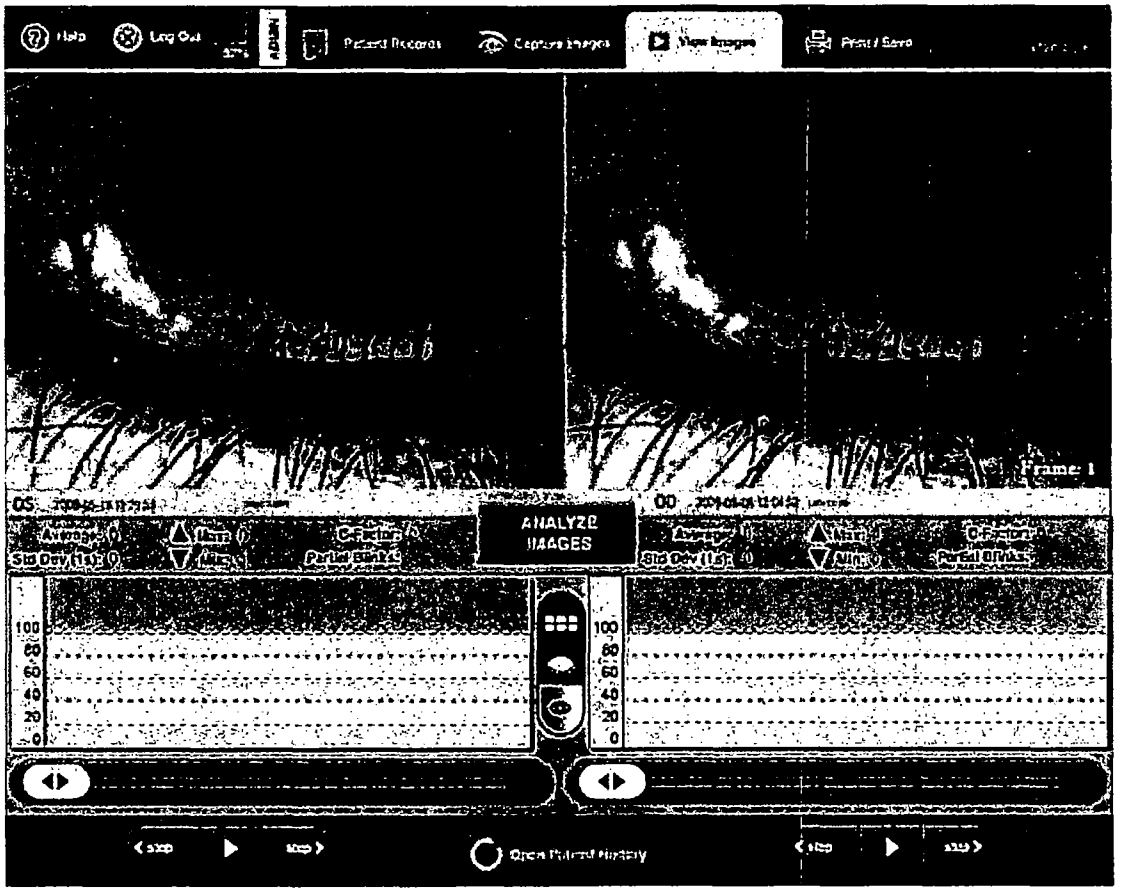


Figure 10-13: View Images Screen – Images not Analyzed

10.4.2 View Images Screen after Selecting from Patient History

When *View Past Images* is chosen from the *Select a Patient Action* system message, the user is directed to the screen in Figure 10-~~14~~16 or to the screen in Figure 10-~~16~~19, depending on the previous video that was reviewed.

Note that, in either case, the first set of OD/OS images presented are standard reference video images of eyes with different ICU levels, provided for purposes of comparison. Each video is clearly labeled as "EXAMPLE VIDEO." These videos allow the physician to observe differences in interference colors for a variety of tear films. As shown in Figure 10-14, the OD image is an example of an average ICU of approximately 40 ICU, which shows a relatively thinner tear film lipid layer with very little color appearing mostly gray. Conversely, Figure 10-15 displays the OS image as an example of an average ICU above 100, where brown and blue colors are visible indicating a relatively thicker tear film lipid layer. Refer to Section 10.4.3, *View Images and Analyze Data* for more information on the interferometric color analysis.

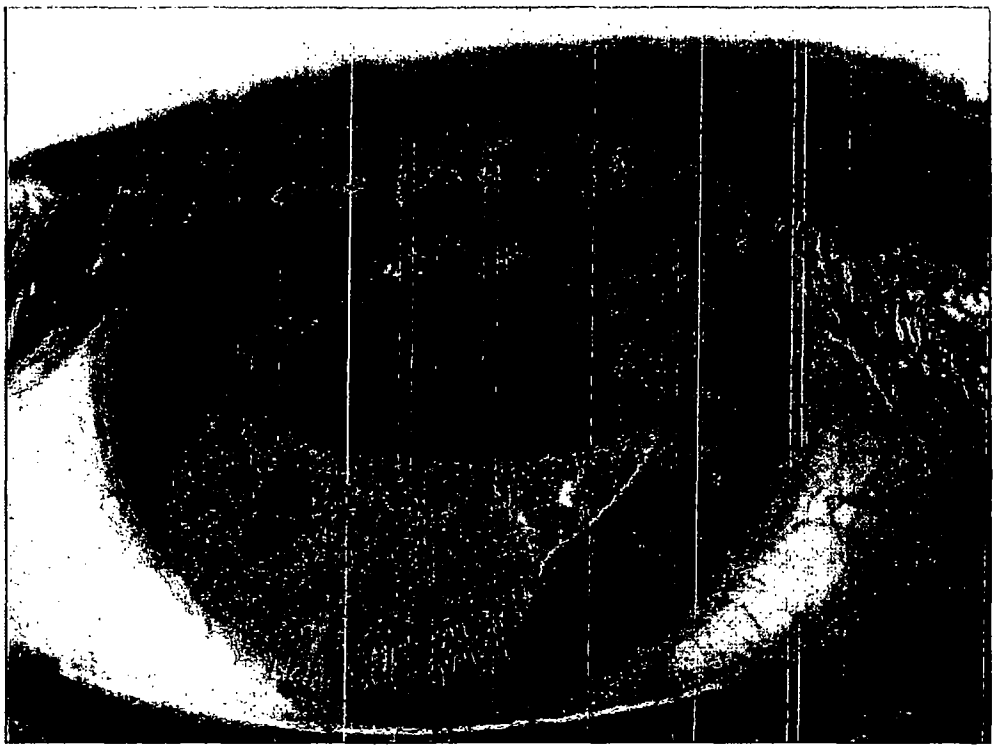


Figure 10-14: Example OD Image – Average ICU Approximately 40 ICU

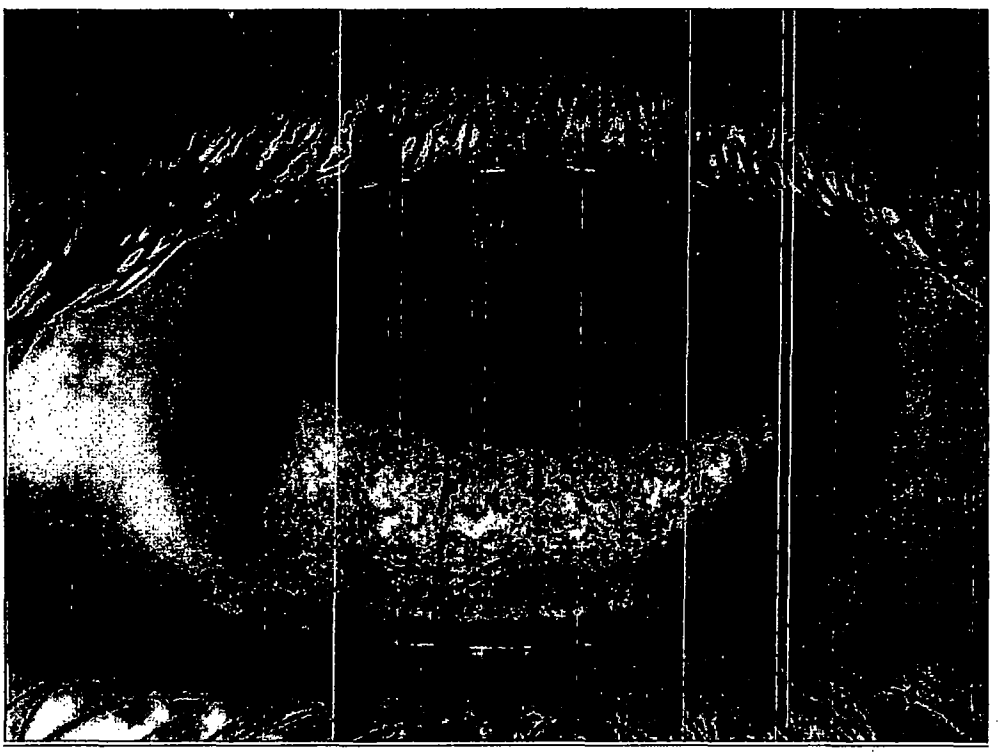


Figure 10-15: Example OS Image – Average ICU 100+ ICU

If the previous video reviewed was from the same patient record that is currently selected, Figure 10-~~16~~19 is displayed with the previously reviewed video showing and the Patient History list closed. Continue with Section 10.4.3, *View Images and Analyze Data*.

If the previous video reviewed was from a different patient record, the View Images screen is displayed with the tabular Patient History list open, as shown in Figure 10-~~14~~16, so that the user can select which video(s) to display. The Patient History contains an inventory of all videos saved for the selected patient with the date and time as well as any information in the pre-set or key-in tags. If a video has been cloned, the patient history file will display "CLONED" to the right of the time. If the video has been archived and is no longer online, "ARCHIVED" will be displayed to the right of the time. The process of cloning and archiving videos is an Administrator function, discussed in Section 16.7.1, *Disk Cloning*. An empty Patient History table (no video images) indicates that video data has not been saved for this patient.

The top left and right frames of the View Images screen are blank until videos have been selected. From the Patient History, the user will either select one or two videos, or press the *Close Patient History* so that other tabs become visible for selection.

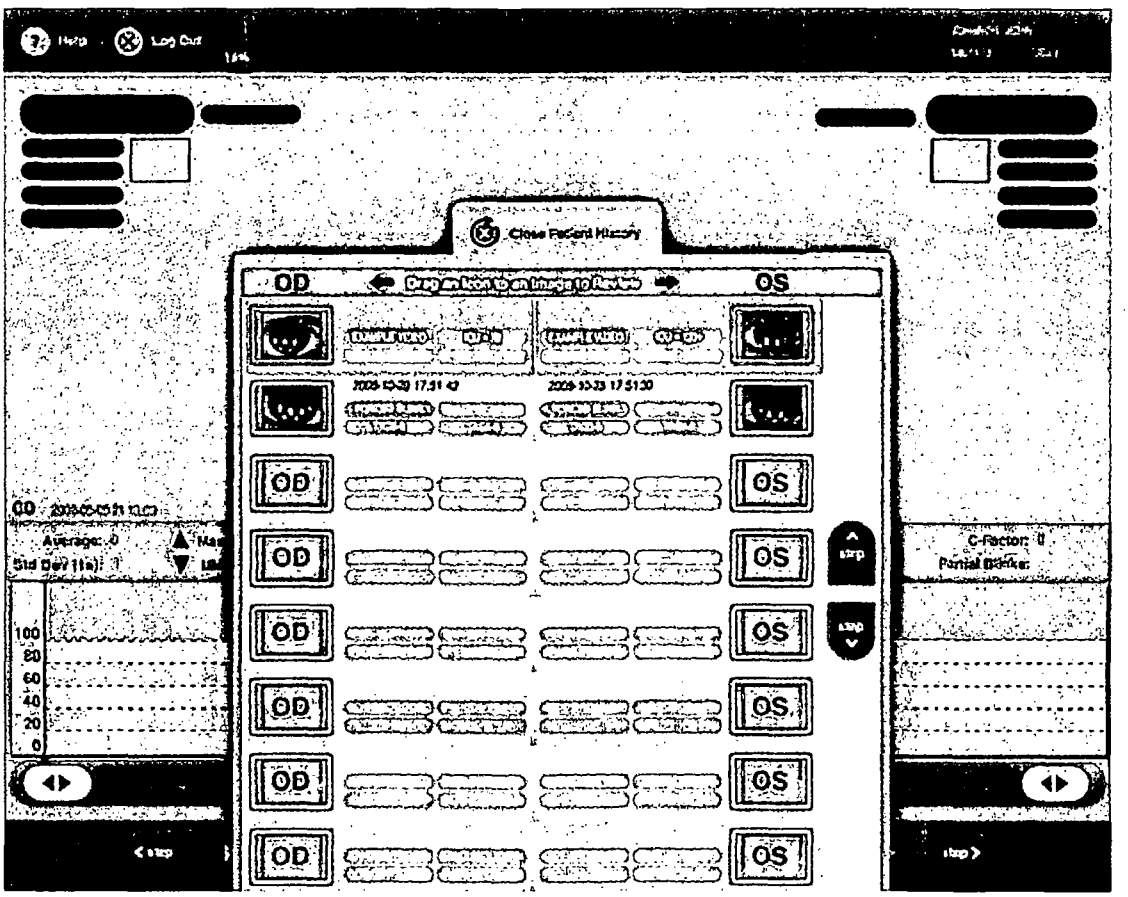


Figure 10-~~16~~14: View Images Screen - Select Past Images from Patient History

If a video will not be selected from Patient History, skip to step 6; otherwise, follow the steps below to select the video(s):

1. ***Locate First Video*** - Locate a video that will be loaded. Touch the step keys on the right to move backwards and forwards through the list if the Patient History table contains more than eight videos.
2. ***Load First Video*** - To load the video:
   A. Touch the thumbnail image located next to the date/time stamp of the video. If the video was archived, a system message appears asking for confirmation to restore the video. Choose from one of the following:
      - Press *Close* to return to the open Patient History list, and repeat step 1 to locate a different video, or continue with step 6 to close the Patient History list.
      - Press *Restore Video* on the system message to start copying the archived video. A progress dialog will appear showing the status of the restore. Once the file has been restored, the word ARCHIVED will be removed from the Patient History list. Touch the video again and continue with step B.

        NOTE: If a progress dialog does not appear indicating the start of the restore process, contact the Administrator to check the validity of the of the clone path on the Networking screen.

   B. Drag the thumbnail image into the rectangular frame in the upper corner on either the OD or the OS side.

      NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

   C. Drop the image by releasing your finger.
3. ***Video Loaded*** - The eye selection, date of captured video, pre-set and key-in descriptions, Username that captured the video and an image of the selected video will be copied into the blank tag cells as shown in Figure 10-~~15~~17.
4. ***Locate / Load Second Video*** - Repeat steps 1 and 2 to select the second thumbnail image if desired, dropping in into the frame in the other corner.

   NOTE: Typically a thumbnail image from the OD list is dropped on the left side and a thumbnail image from the OS list is dropped on the right side, but videos from the same eye may be dropped into both frames.

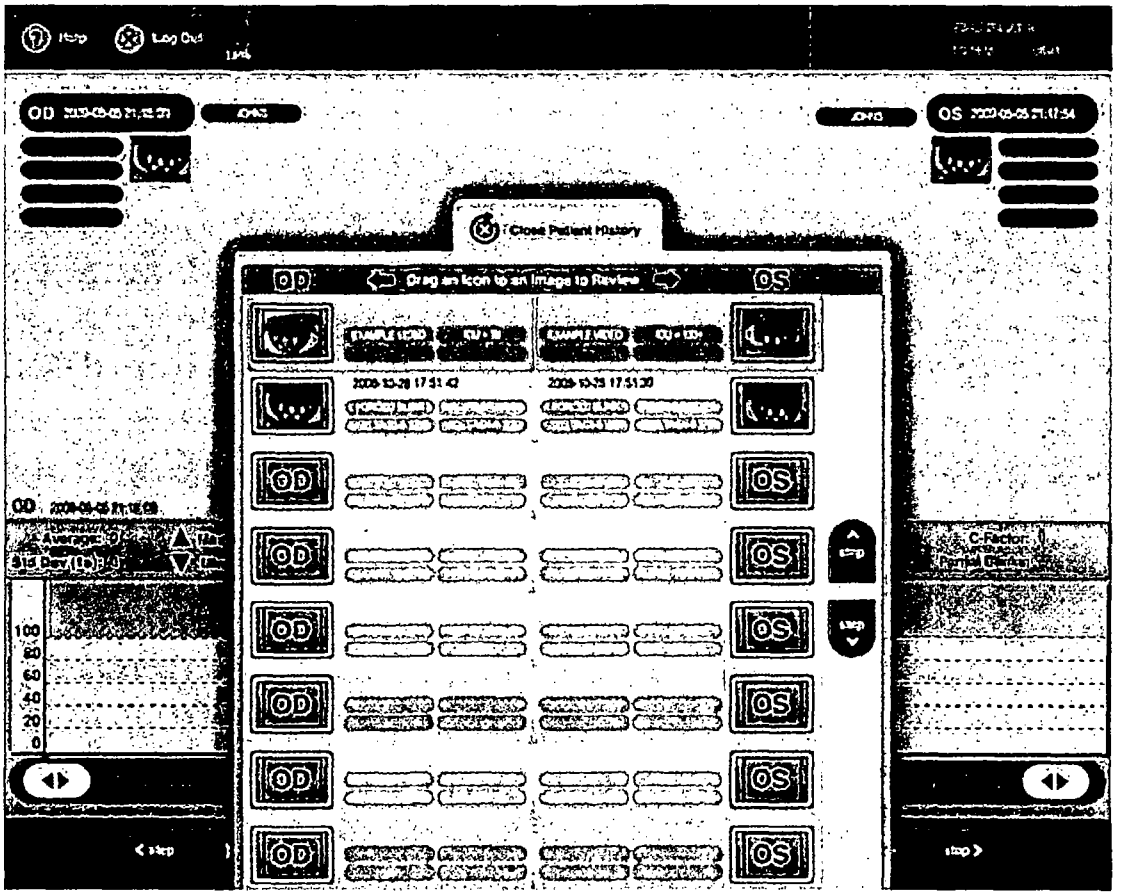


Figure 10-1715: View Images Screen - Videos Loaded from Patient History

5. ***Confirm Images Loaded*** - Confirm that the images loaded are the ones to be displayed. Update the left and right frames if desired, by dragging and dropping alternate thumbnail images.

   NOTE: Once an image has been dragged to either corner it cannot be removed; however, each additional image that is dragged and dropped will replace the previous one.

6. ***Close Patient History*** - Press *Close Patient History* at the top of the tabular list. The list will shut and the button will move the bottom of the screen. A message to wait will be displayed while the selected video(s) are loaded. Upon completion, continue with Section 10.4.3, *View Images and Analyze Data.*

   NOTE: If the Patient History table is closed without selecting a video, the screen in Figure 10-16 is displayed; however, there are no images shown on the top half of the screen. This sequence typically happens when the user has pressed the *Capture Images* tab in error, and wants to make the other tabs available. Since there are no images to view, the user should select from one of the tabs in the menu bar at the top of the screen.

10.4.3 View Images and Analyze Data

The View Images screen contains seven key sections, which are described below. Figure 10-~~16~~-19 shows the View Images after the images have been analyzed. ~~One video shows valid image data; the other does not.~~ The analyzed data includes numerical and graphical analysis of the Interferometry Color Units (ICU), where 1 ICU is equivalent to 1 nanometer (nm). An ICU for the LipiView® Interferometer is defined as the color scale resulting from the interference pattern which occurs at the boundary of the tear film. The measured ICU may range from 0 to 240, with a precision of 1 ICU. For reference, the interferometric colors across the range of 10 ICU (thinnest) to 240 ICU (thickest) are displayed in Figure 10-18. This color scale has been validated to a known standard for measurement of thin film thickness. By comparison to this known standard, the ICU values are absolute thickness measurements of the tear film lipid layer.

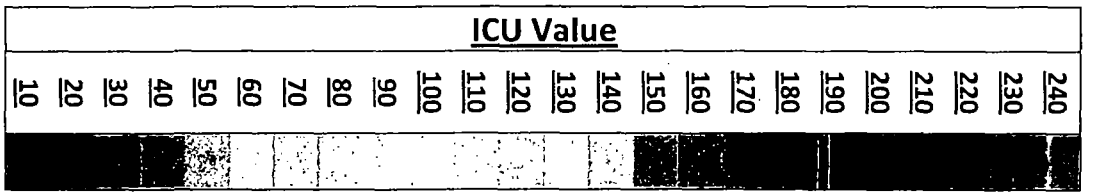


Figure 10-18: Interferometric Colors by ICU Value

- **Video Images** – The top half of the screen contains frames for the OD and OS videos, when they are captured/selected for viewing. Each "Frame" is set to "1" initially, and the frame number is incremented as the video plays.
- **Video Descriptor** – Identifying information just beneath each video image includes OD or OS, the date and time of capture, and any pre-set or keyed in descriptive tag names.
- **Analyze Images button** – Pressing *Analyze Images* results in a numerical analysis of the interferometric colors and a graph for each of the videos. If for some reason the analysis cannot be performed, a message *NO VALID ANALYSIS DATA FOR VIDEO* replaces the graph, and the numerical information remains zero. After the analysis has been completed, the records are saved to the database. (Note: recorded images may only be analyzed once; attempting to "re-analyze" a set of images will result in an error.)
- **Numerical Analysis** – After the video has been analyzed, the following statistics above each graph are updated. Since most tear film images have an average ICU value well below 100, the maximum numerical ICU values displayed are 100 with values above 100 represented as "100+". ÷
  - **Average** - The average ICU of all the frame averages (denoted by the black line in the graph).
  - **Std Dev** - The standard deviation of the frame averages.
  - **Maximum** - The maximum ICU recorded for a given frame.
  - **Minimum** - The minimum ICU recorded for a given frame.

- **C-Factor** - The tear film Conformance factor for the entire video. The C-factor is defined as the percentage of pixels in the tear film that fall on the interferometric color spectrum. A C-factor of 1.0 indicates that every tear film pixel throughout the entire video loop has found a close match to an Interferometric color.
- **Partial Blinks** – The number of partial blinks out of the number of total blinks counted, expressed as a fraction. The numerator (top number) is the number of partial blinks; the denominator (bottom number) is the total number of blinks counted. A partial blink value of 3/9 means that out of nine total blinks detected, three were evaluated as "partial blinks."

- **Graph** – After the videos have been analyzed, each graph shows the average ~~Interferometry Color Unit (~~ICU~~)~~ and standard deviation for each frame corresponding to the location in the video. Each point on the graph is the ICU value for that frame. The blue line and region is the upper standard deviation of the ICU score data. The red line and region is the lower standard deviation of the ICU score data. The blue triangle marker denotes the point on the graph that contains the maximum ICU score. The red marker triangle marker denotes the point on the graph that contains the minimum ICU score. To maximize visualization of the graphical results, the y-axis scale runs from 0 to 100 with values above 100 shown above the 100 line.
- **Video Controls** – The controls under each graph include a slider bar, backwards (< step) and forwards (step>) buttons and a play/pause button and function as described in Section 10.3.3, *Preview Captured Image*. Videos may be played before or after they have been analyzed.
- **Open Patient History button** – Pressing this button opens the Patient History list on top of the View Images screen and allows different videos to be selected for this patient. When the list is closed it returns to this button.

When the View Images screen is displayed after capturing new video, an analysis of the image data has not occurred yet, as seen in Figure 10-13. When the View Images screen is displayed with video from the Patient History, an analysis of the image data may or may not have occurred. If the data has been analyzed, the numerical information will be filled in and a graph will show under the video as shown in Figure 10-~~16~~19.

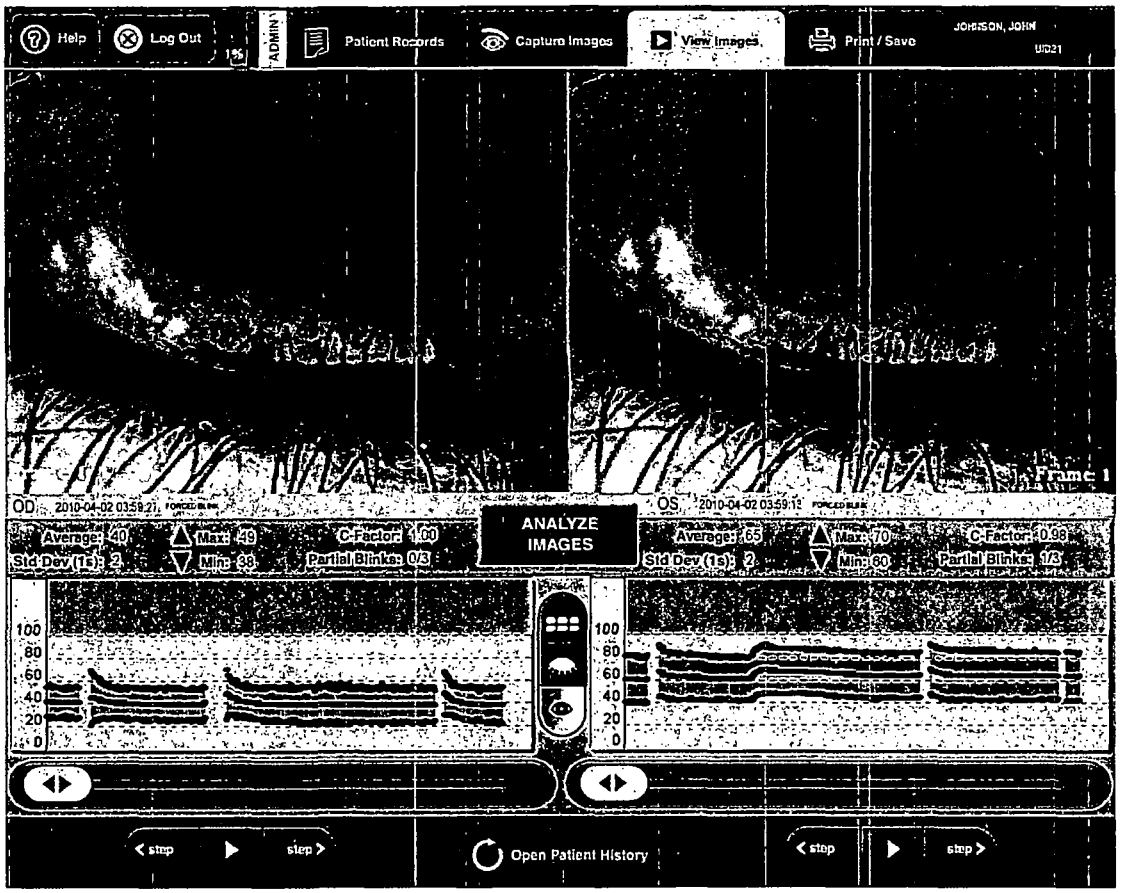


Figure 10-~~1916~~: View Images Screen – Analyze Images

The following steps provide guidance on options for viewing and analyzing the video image data.

1. ***Select View of Eye*** - Press the toggle key between the graphs to select a full-eye view (eyeball), blink-only view (closed eye) or the isolated tear film view (tiles). Blink-only view displays only the segments of the video in which the subject is blinking. The isolated tear film view separates the tear film area and indicates the area being analyzed. The green portion of the key indicates the active view.
2. ***Analyze Images*** - If the video image data has not been analyzed, press *Analyze Images* in the center of the screen to generate a graph (see Figure 10-16) of the ICU values for each frame. This may take several seconds. The graph shows the average ICU for each frame along with ranges for the standard deviation. Blank spots on the graph occur when the patient is blinking or the patient's eye is not stationary. Data resulting from the analysis is automatically saved in the database.
3. ***View Left Video*** - To view video of the eye on the left side of the screen (typically the OD):
   A. Press the triangular "play" button centered between the two "step" buttons on the lower left of the screen to loop through the video. As the video plays, the

button on the slider indicates position and a vertical line moves across the graph.

NOTE: When pressed, the "play" button changes to a "pause" button indicated by two vertical lines.

B. When the video is paused, use the backwards (< step) and forwards (step >) buttons to move through the video frame-by-frame, or touch a spot on the slider bar to move the video to that location.

4. ***View Right Video*** - To play the video of the OS eye on the right of the screen (typically the OS), follow the instructions in step 3, using the controls on the lower right of the screen.
5. ***Select New Video*** - To view a different video for the selected patient record, press *Open Patient History* at the bottom of the screen, and follow the instructions in Section 10.4.2, *View Images Screen after Selecting from Patient History*.
6. ***Print and Save Video*** - To print the image and graphical analysis or to save it to an HL7 compatible system, press the *Print / Save* in the menu bar at the top of the screen and continue with Section 10.5, *Video Print and Save*.

10.5 Video Print and Save

From the View Images screen, the Print /Save tab is visible, allowing the report of the analyzed images to be printed, saved to an external drive as an Adobe PDF (Portable Document Format) file, or saved to an HL7 compatible system. Refer to Section 16, *Administrator Instructions for Use* for more information on HL7 and instructions on how to set up the HL7 parameters. The HL7 database must be configured by the Administrator prior to use.

The report header contains patient and practice information. Patient information is taken from the patient record, and consists of the Patient ID and the name if entered. The date of report and the Username of the operator who captured the video follow. Practice information consists of the name, address and phone number of the practice, and the serial number of the LipiView® Interferometer used. Practice information is set up by the Administrator per the instructions in Section 16.3, *Admin System Setup*.

Below the patient and practice information, the report contains information about the eye displayed (OD/OS), the date and time of video capture, and information contained in the pre-set and key-in tags. An image of the frames containing the maximum average ICU displayed both in full-eye and tear-film views. Beneath the images are the graphs and various metrics about the frames captured, and the ICU values. By comparison to a known standard for measurement of thin film thickness, the ICU values are absolute thickness measurements of the tear film lipid layer.

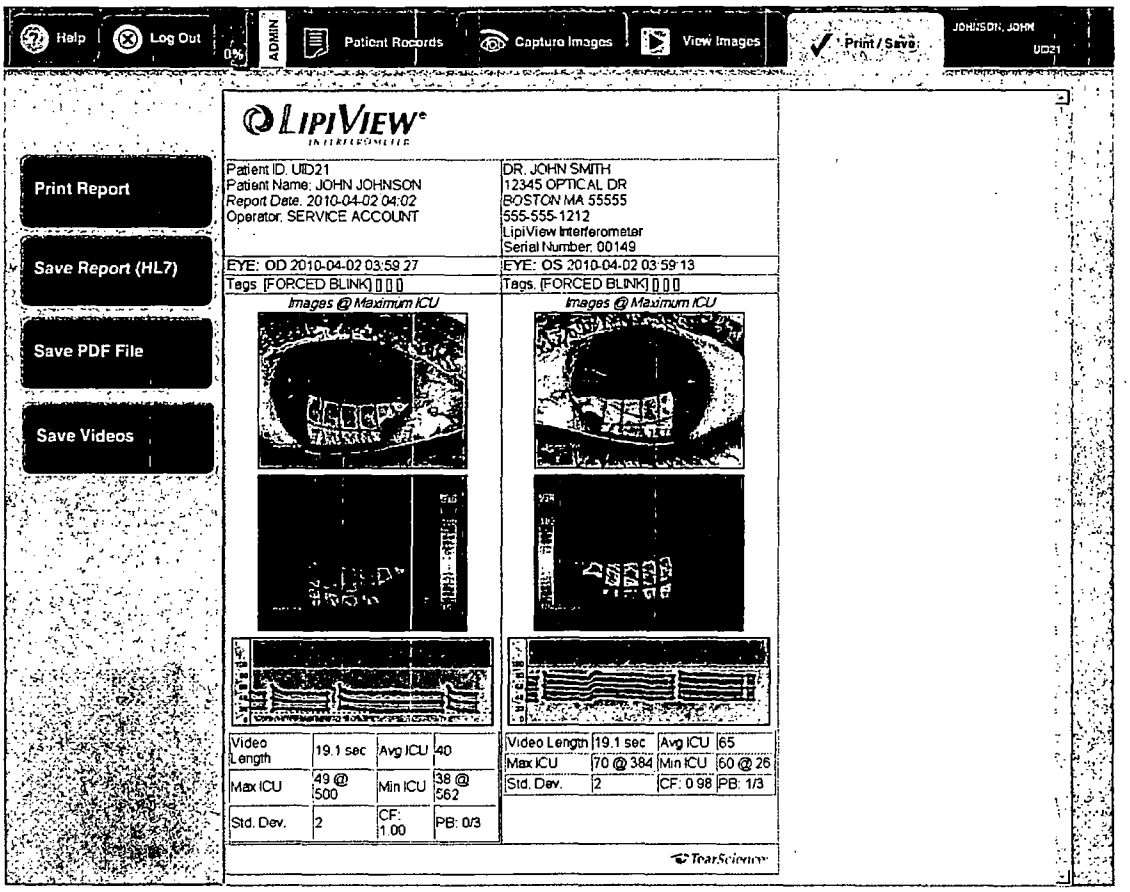


Figure 10-2017: Print/Save Screen - Sample Report

Print Report - To print the report:

1. Press *Print Report* on the left menu.
2. Follow the standard windows printing prompts for sending the report to the printer attached to the LipiView® Interferometer.

   NOTE: The printer must be attached by the Administrator prior to use. Refer to Section 16.8, *Admin System Options* for a description on printer setup.

Save Report to HL7 - To save the printed report to an HL7 compatible system:

1. Press *Save Report (HL7)* on the left menu.
2. A system message called HL7 Basic Socket Transfer is displayed.
   A. Press *Send HL7* to store the data in the HL7 database.
   B. Press *EXIT* to return to Figure 10-~~17~~20 without saving.

   NOTE: The HL7 database must be configured by the Administrator prior to use. If the system message does not appear, contact the Administrator. Refer to Section 16.7.2, *HL7* for instructions on how to set up the HL7 parameters.

Save Report to External USB Drive as a PDF - To save the printed report as a PDF file:

1. Connect an external USB drive or USB key to the LipiView.
2. Press *Save PDF* on the left menu.
3. When the system reports that the PDF has been saved successfully, press *Close*.

Save Video to External USB Drive - To save the video to an external drive:

1. Connect an external USB drive or USB key to the LipiView.
2. Press *Save Videos* on the left menu.
3. Choose the videos you want to save for each side. You may choose one or more of the following for each side: full eye, isolated, or blink, as shown in Figure 10-~~18~~ 21~~below~~.
4. You will see a progress window, as shown in Figure 10-~~19~~22. When the system reports that the video has been saved successfully, press *Close*.

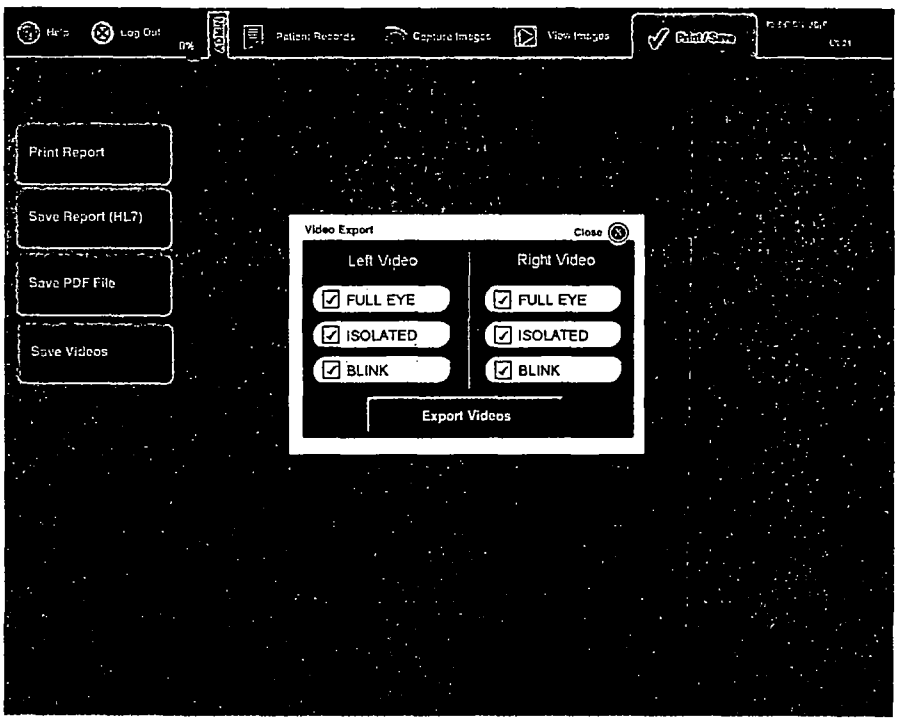


Figure 10-2~~1~~18: Make Selections for Video Export

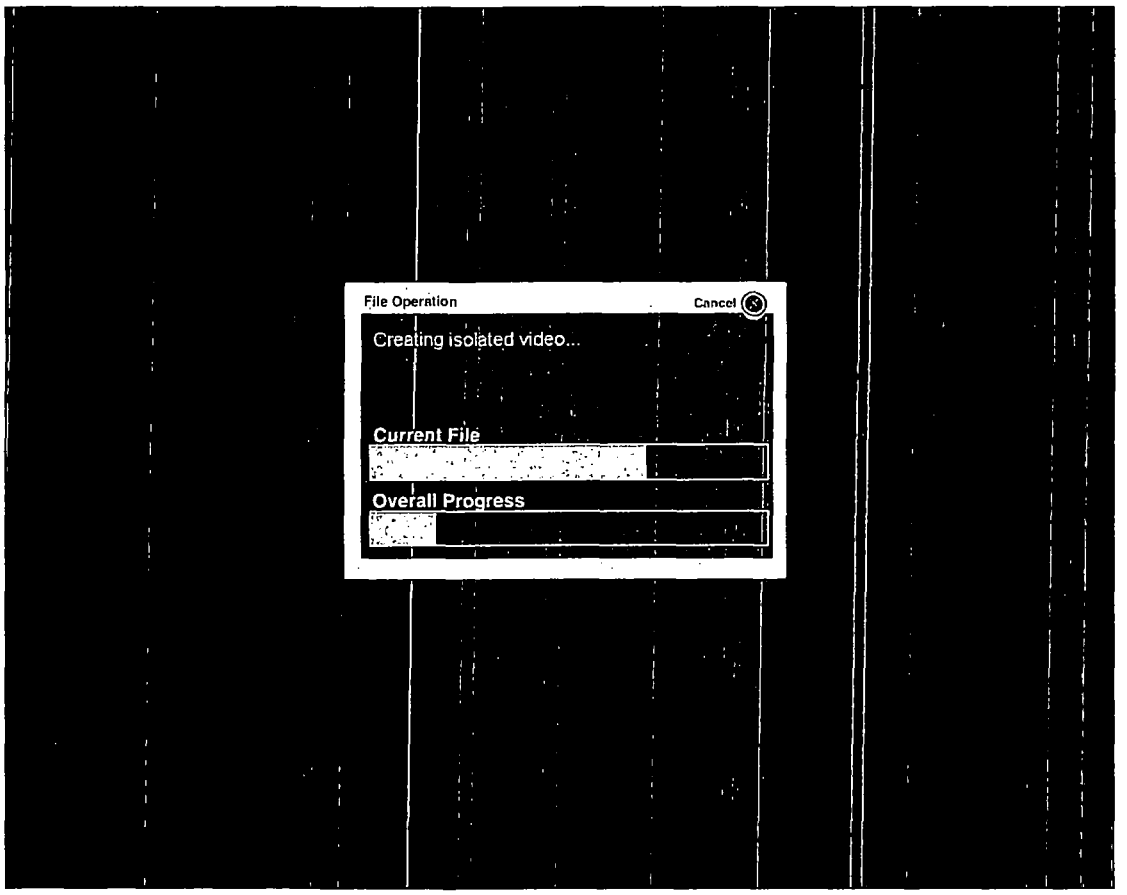


Figure 10-~~22~~19: Progress Window for Video Export

10.6 Online Help

Online help is available for each of the screens in the system. Press the *Help* on the left side of the menu bar at the top of the screen to display information pertinent to that screen. Press *Help* again to close the file.

10.7 Log Out

After the user has logged into the system the Log Out tab is visible on the menu bar of each screen. Pressing *Log Out* returns the user to the Login screen described in Section 10.1.3, *User Login*.

11 Cleaning

Table 11-1 identifies the components of the LipiView® Interferometer that requirement cleaning. For each component, the frequency and method of cleaning is provided.

Table 11-1: LipiView® Interferometer Cleaning Information

Component	Frequency	Method
Chin rest and forehead rest surfaces	Immediately prior to use and prior to storage.	Alcohol.
Camera lens	Monthly.	Wipe with a lint-free photographic quality lens cloth.
Touchscreen Display Monitor	When soiled or as needed.	• Power off the device. • Apply window or glass cleaner to a cloth rag and wipe the screen. • Do not apply cleaner directly to the screen. • Do not clean the monitor with alcohol, paint thinner, benzene or compressed air.
LipiView® Interferometer exterior	When soiled or as needed.	• Wipe down the exterior of the LipiView® Interferometer with a mild soapy cloth. • Do not use bleach, chlorine or acetone-based solutions to clean any part of the chin rest support or the system enclosure.
Optional external monitor	Follow manufacturer's cleaning instructions.	Follow manufacturer's cleaning instructions.

12 Storage and Transport of the LipiView® Interferometer

Before storing the LipiView® Interferometer, ensure that the power switch is off, and that the chin and forehead rest surfaces have been cleaned according to the instructions in Section 11, *Cleaning*. The LipiView® Interferometer should be stored in a way that prevents contamination and damage between uses.

To transport the LipiView® Interferometer, ensure power cord is unplugged and secured off the ground. Grip on metal portion of the device, in two locations: 1) base of the chin rest, 2) monitor arm behind the screen. Carefully lift and transport in an upright position.

13 Maintenance and Servicing

Expected life of the LipiView® Ocular Surface Interferometer is 5 years.

> **Note**: No user serviceable components are inside the unit.
> Maintenance is not required. The LipiView® Ocular Surface Interferometer performs a calibration process upon powering on. See Section 10.1.1

For Field Service contact TearScience in North America at +1 919 459 4891 or by email at customerservice@tearscience.com.

14 Disposal

The LipiView® Interferometer consists of an ABS plastic enclosure, aluminum chassis, circuit boards, and electrical components. In the unlikely event that the controller is damaged and cannot be repaired, never dispose of the device. The LipiView® Interferometer should be returned to TearScience. Refer to the contact information on the first page of this manual for the appropriate return address.

15 Troubleshooting

15.1 Unexpected Events

Table 15-1 lists actions to take if an unexpected event occurs.

Table 15-1: Troubleshooting Unexpected Events

Event	Action to Take
Device will not power up (after pressing the power switch, the screen remains dark.)	(1) Ensure the system is connected to a power outlet and connection into the device is secure, then press the power switch again. (2) If Step 1 is not successful, carefully lift the system to expose the underside of the base and determine if a red Reset button is located at the back of the unit, near the power switch. If so, press the Reset button. If no Reset button is found, contact Customer Service for assistance. If the problem persists contact TearScience.
Problem reported during Power On Self Test (POST).	Power cycle the device. If the problem persists contact TearScience.
Touch Screen does not respond.	Power cycle the device. If the problem persists contact TearScience.
Illuminator does not light during image capture.	Power cycle the device. If the problem persists contact TearScience.
Camera stops working.	Power cycle the device. If the problem persists contact TearScience
Disk Space Indicator shows internal disk drive is full.	Contact the Administrator to archive data (refer to Section 15, *Administrator Instructions for Use*). If the problem persists contact TearScience.
The system works except the Capture Image tab will not respond.	An error was detected during power on self-test, which affects image acquisition. Power cycle the device. If the error persists contact TearScience.
Device will not process images after acquisition.	The internal hard drive is full. Contact the Administrator to archive data (refer to Section 16, *Administrator Instructions for Use*). If the problem persists contact TearScience.
Device no longer allows image acquisition.	A power on self-test problem has been found. Contact TearScience if problem persists.

Event	Action to Take
The message *NO VALID ANALYSIS DATA FOR VIDEO* is displayed instead of the numerical and graphical analysis when the *Analyze Images* button is pressed on the View Images screen.	The patient's head may not have been pushed forward, the patient's forehead may not have been firmly pressed against the forehead rest, or the tear film image may have been out of focus. Collect another video of the patient after ensuring that the patient's head is positioned properly and that the eye is clearly focused.
Network is not connected.	Contact your Administrator (refer to Section 16, *Administrator Instructions for Use*). If the problem persists call TearScience.
External monitor does not work.	Ensure the monitor is powered on. Ensure connections to the DVI or HDMI are made, and proper input is selected. Ensure the isolation receiver cable has power applied. Refer to Section 19, *Appendix B: External Monitor Hookup* for information on proper monitor connection.
Administrator forgets password after resetting it	Contact TearScience.
When accessing options on the System Options Administration screen, a message is displayed stating 'Too much time has elapsed since system startup to access this function'.	Selected options on the System Options Administration screen cannot be accessed after more than 10 minutes has elapsed since the system was started. Power cycle the machine and attempt to access the option again.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the warning level.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
When accessing the Capture screen, a message is displayed stating the disk space usage has surpassed the critical level.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

15.2 System Messages

Table 15-2 lists system messages and provides a description with actions to consider.
NOTE: The four messages: Practice information saved, Display information saved, Saved map network drive parameters and mapping drive, and Network information saved are informative only and do not indicate a problem.

Table 15-2: System Messages

System Messages	Description / Action to Take
Invalid operator name and/or password.	The login failed because the username and/or password being used to log into the device are not recognized. Correct and reenter, or confirm with the Administrator that this username and password have been set up and that the username is enabled.
Capture disabled. Contact Tear Science for support.	Videos cannot be captured because the power on self-test detected errors with the motors or camera during startup, or the Disk Space Indicator has reached the limit set by the Administrator. Existing videos can be viewed. If the disk is full, contact the Administrator to archive data. For motor or camera errors, contact TearScience.
Patient ID already exists.	The patient record cannot be added because it contains a Patient ID that already exists in the database. If a Patient ID is being included on a new patient record, it must be unique. Correct and reenter.
Patient with same first name, last name, middle initial and birth date already exists. Select the existing user or enter a unique patient ID.	The patient record cannot be added because a patient record with the same Last Name, First Name, Middle Initial and Date of Birth already exists in the database. Either select the existing patient, or to add a new patient with the same name, enter a unique Patient ID.
Either patient ID or last name, first name and birth date are required.	The patient record cannot be added or updated because required information is missing. At a minimum, a patient record must contain a Patient ID or it must contain a Last Name, First name and Date of Birth.
Videos captured for patient. Cannot edit patient information.	The patient record cannot be edited because a video(s) exist for this patient. Once a video has been captured and saved for a patient, that patient record can no longer be updated.
Enter date in MM/DD/YYYY format. Invalid date:	The patient record cannot be added because the format of the date is incorrect. One or more of the date fields is missing or does not contain a number. Confirm that the month field is a number between 0-12, the day field is a number between 0-31 and the year is a 4-digit number.
Video capture setup failed.	The video cannot be captured due to a device failure. If this occurs, exit from the Captures Images screen by logging out or pressing *Save All/Continue*. Try again, and if the error is not corrected, contact TearScience.

System Messages	Description / Action to Take
Unable to load video file X.	The video file named X could not be found on the disk when attempting to show it on the View Images screen. Try again, and if the error is not corrected, contact TearScience.
The following errors occurred: Missing username; Missing password; Missing full name;	The Operator cannot be added because one or more of the required fields (as noted) are empty. The Username, Password and Full Name are required to add an Operator.
Username already exists	The Operator cannot be added because the Username entered already exists in the database. Correct the Username and try again, or select the Username and edit the Password and Full Name fields.
Practice information saved.	This message is displayed to the Administrator to confirm that information on the System Setup screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Display information saved.	This message is displayed to the Administrator to confirm that information on the Display Options screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Disconnect failure: X	The Map Drive process cannot be completed because the Drive Letter named "X" cannot be disconnected. Try again, and if the error is not corrected consult with the Network Administrator.
Saved map network drive parameters and mapping drive.	This message is displayed to the Administrator to confirm that information on the Map Drive screen or has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.
Network information saved.	This message is displayed to the Administrator to confirm that the cloning and HL7 server information on the Networking screen has been successfully updated. Press *Close* to acknowledge the message, and select another option from the Admin Main Menu screen.

System Messages	Description / Action to Take
Cannot write to clone folder: X:\OSICLONE	The Network folder named OSICLONE on the Drive Letter named X is not accessible for writing. Confirm that the Drive Letter is listed as a mapped drive on the Networking Screen. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning operation failed to start.	There was a failure with the cloning process most likely caused by an internal Windows error, and no videos were copied. Confirm that the Drive Letter entered for Disk Cloning on the Networking Screen is valid. Confirm that the wireless network connection to the LipiView® Interferometer is operating properly. Consult with the Network Administrator.
Cloning canceled by user.	This message is displayed to the Administrator to confirm that the *CANCEL* button has been pressed and that the Cloning process has been stopped.
Cloning failed. Restart or contact Tear Science for assistance.	There was a failure with the Cloning process. Press *CLONE SYSTEM* again, to continue the Cloning process where it left off. If the problem continues, contact TearScience.
The used space of the system disk has surpassed the warning level. Please go to the Networking/Backup Administrator page.	The system's disk drive usage is beyond the level specified in the Networking/Backup Administration screen. Contact the System Administrator to perform a system backup.
The used space of the system disk has surpassed the critical level. Please go the Networking/Backup Administrator page.	The system's disk drive usage is beyond the maximum level specified by TearScience. Contact the System Administrator to perform a system backup. Video capture is disabled until the system backup is performed.

16 Administrator Instructions for Use

16.1 First Time Setup

The LipiView® Interferometer has been set up with a default Operator Username and Password that has administrator privileges. When the system is first powered on, the Administrator should log in using LIPIVIEW for the Username and LIPIVIEW for the Password (the onscreen keyboard only supports upper case characters).

After successful log in, it is recommended but not required that the Administrator reset the password as follows:

1. Power on the system.
2. When the Login screen in Figure 10-4 is displayed:
   A. Enter LIPIVIEW for the Username.
      NOTE: The onscreen keyboard only supports upper case characters.
   B. Enter LIPIVIEW for the Password.
   C. Touch *Submit*. The Patient Records screen in Figure 10-5 should be displayed.
3. Touch the *Admin* tab at the top of the screen. The Admin Main Menu in Figure 15-1 should be displayed.
4. Press *Operator Setup* on the left menu. The Admin Operator Setup Screen in Figure 16-3 should be displayed.
5. Follow instructions in Section 16.4, *Admin Operator Setup* to modify the password and/or add additional operator usernames.

The Administrator should review Section 16 of this manual to determine any other functionality that requires set up before the LipiView® Interferometer is used for observation of tear film. At a minimum:

- Set the system date and time (refer to Section 16.8, *Admin System Options*)
- Determine at what point videos will be archived (refer to Section 16.7.1, *Disk Cloning*)

Prior to printing, a printer must either be connected through one of the USB ports on the bottom of the Touchscreen Display, or through a wireless network. Printer setup is discussed in Section 16.8, *Admin System Options*.

Prior to cloning or archiving, an external storage location must be connected. An external hard drive can be connected through one of the USB ports on the bottom of the Touchscreen Display, or a network drive can be mapped on the wireless network. Refer to Section 16.6, *Admin Map Drive*.

16.2 Admin Main Menu

When an operator's Username is set up with *Administrator Access* (refer to Section 16.3, Admin System Setup), the *Admin* tab is visible between the Disk Space Indicator and the Patient Records tab on the menu bar of each screen.

When the *Admin* tab is pressed, the Administrator Main Menu screen in Figure 16-1 is displayed. This screen prompts the Administrator to select from one of the menu options on the left side or the top. Each Administrator screen contains the same menu. Once a button is pressed, it turns white indicating the active menu, and buttons for inactive functions are grayed out. Buttons may be selected from the Main Menu in any order, but once a menu option is active, the user must exit from that screen and return to the Main Menu before choosing another option.

The *Help* tab may be selected anytime it is not grayed out. To return to normal usage, press *Patient Records* at the top of the screen.

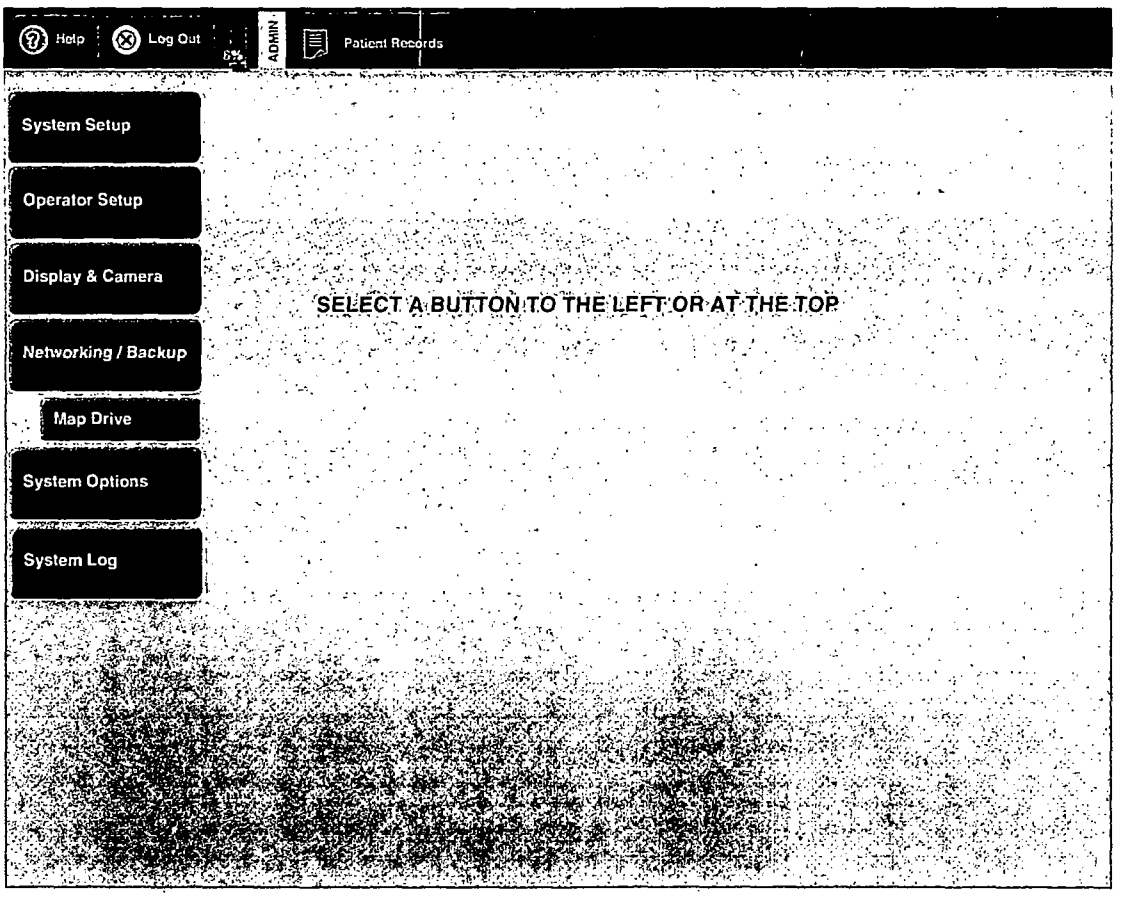


Figure 16-1: Admin – Main Menu Screen

16.3 Admin System Setup

The System Setup screen in Figure 16-2 is displayed when the *System Setup* button is selected from the Admin menu.

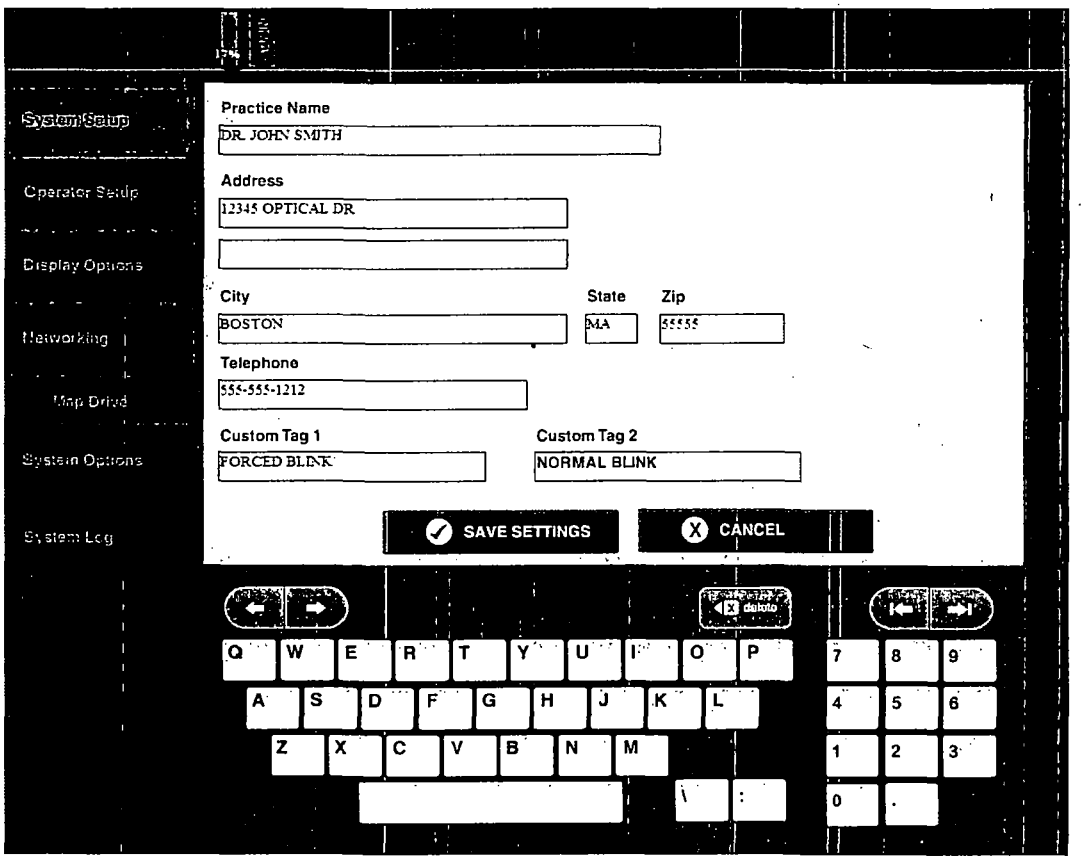


Figure 16-2: Admin - System Setup Screen

The System Setup screen contains the fields listed in step 1 for the Administrator to complete. All fields are optional. The Practice information is used for the reports as discussed in Section 10.5, *Video Print and Save*. Custom Tags 1 and 2 allow up to two tags to be pre-set with commonly used information that may be applicable to multiple videos (e.g., normal blink, forced blink). These custom, pre-set tags are displayed on the Capture Images Screens (Figure 10-9, 10-10, 10-11 and 10-12) and discussed in Section 10.3, *Video Image Capture and Recording*. If selected, information from these tags is saved with the video data, displayed on all Video Review and Analysis screens (Section 10.4), and included on the report.

1. Use the keyboard to update one or more of the fields below.
   - Practice Name
   - Address line 1
   - Address line 2

- City
- State
- Zip
- Telephone
- Custom Tag 1
- Custom Tag 2

2. To exit this screen and return to the Main Menu in Figure 16-1, choose from one of the following and then continue with Section 16.2, *Admin Main Menu*:
   A. To immediately update the information before returning to the Admin Main Menu, press *SAVE SETTINGS*.
   B. To return to the Main Menu without saving the edits, press *CANCEL*.

16.4 Admin Operator Setup

For first time use, make sure to review Section 16.1, *First Time Setup* before making any changes to usernames and passwords.

Do not modify the ADMIN Username. This is for TearScience personnel, in the event service is required.

The Operator Setup screen in Figure 16-3 is the main screen displayed when the *Operator Setup* button is selected from the Admin menu. This screen is used to display the list of operators who have been entered into the database. The list of operators is displayed in the order of entry. Once the table contains more than six names, the step keys on the right are used to scroll backwards (upper key) or forwards (lower key) through the list.

The Operator Setup screen is also used to add new operators. To perform this task, continue with Section 16.4.1, *Add an Operator*.

Operator information, which includes granting or preventing access to the device, can be modified using a secondary operator setup screen in Figure 16-4. To make any changes to an operator's record, follow the instructions in Section 16.4.2, *Edit Operator Information*. Information about an operator may be updated but an operator's record can never be removed.

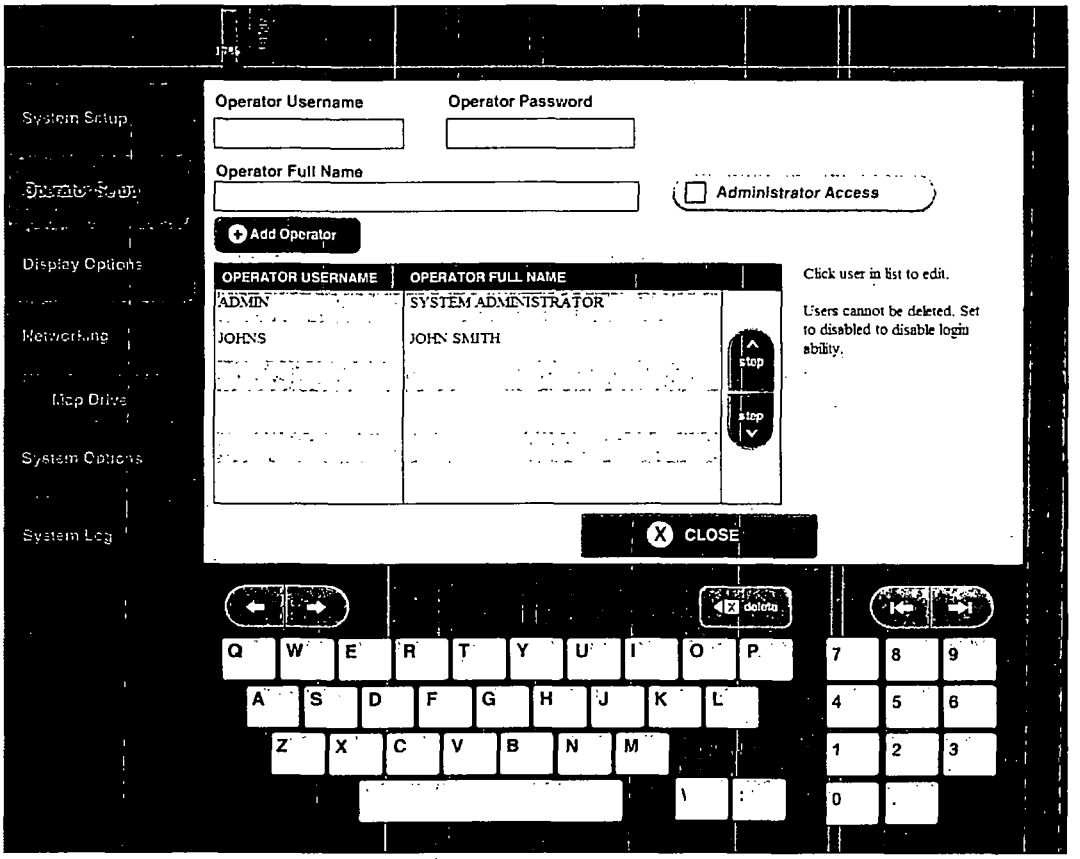


Figure 16-3: Admin - Operator Setup Screen

16.4.1 Add an Operator

Add an operator to the system as follows:

1. Enter a Username.
2. Enter a Password. There are no requirements other than the limitation of the onscreen keyboard characters.
3. Enter the full name.
4. If the user will be allowed to access the Admin tab and the administrator screens, touch the box for *Administrator Access*. A checkmark indicates selection. If this box is not selected, the *Admin* tab will not be visible when this Username is logged in.
5. Press *Add Operator* to enter the new information into the database. When a new operator is added, the status for this operator's Username defaults to "User Enabled". An enabled Username means that this Username has permission to access the device through the Login screen in Figure 10-4. A new Username may log in as soon as the current Username logs out.

NOTE: All fields are required. If *Add Operator* is pressed when any field is empty or incorrect, or if the record is a duplicate of an existing operator, a system message will be returned.

6. Press *CLOSE* when finished and the Admin Main Menu in Figure 16-1 will be displayed.

16.4.2 Edit Operator Information

1. To edit information associated with an Operator's Username, select the record by pressing anywhere on the row in the table. Use the step keys on the right of the table to scroll backwards or forwards through the list if more than six names have been entered.
2. The selected name will be highlighted and then overlaid onto the top of the screen, as shown in Figure 16-4. If the Username is currently allowed access to the device, the *User Enabled* box is checked. If the Username was added as an Administrator, the *Administrator Access* box is checked.

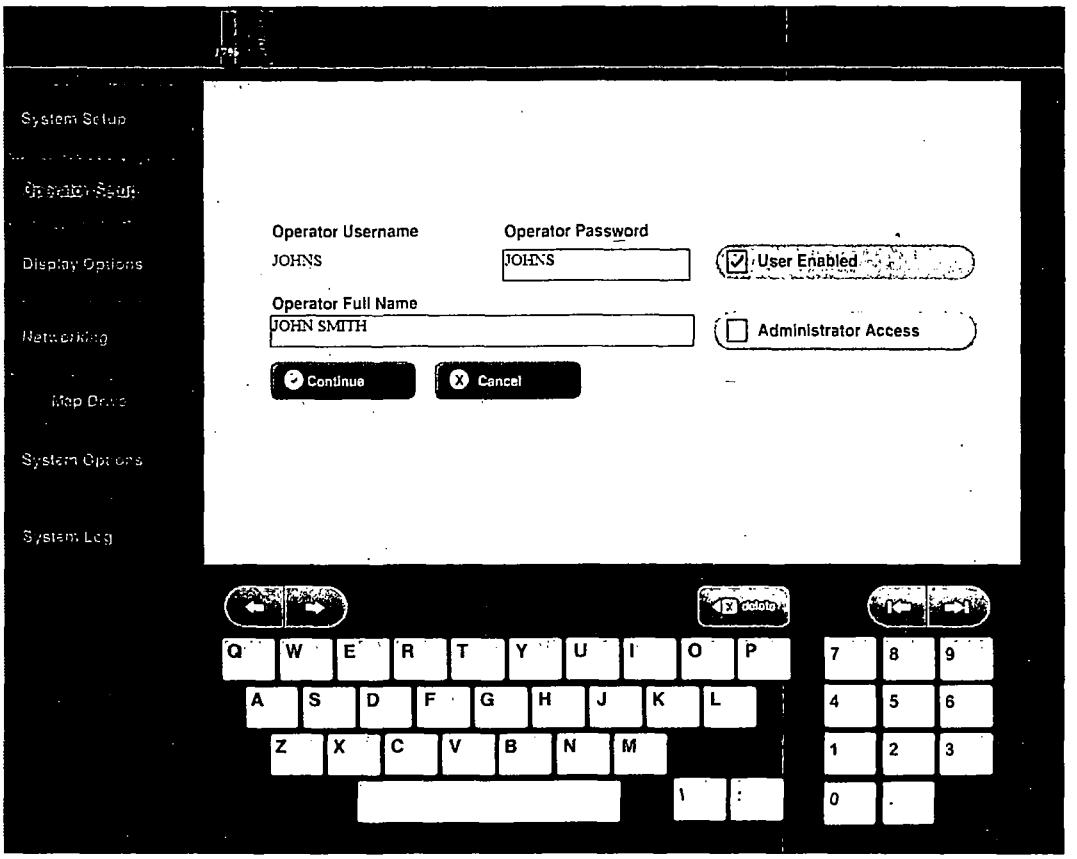


Figure 16-4: Admin - Modify Operator Information

3. Update the operator's password or full name if needed. Select or deselect the boxes for *User Enabled* and *Administrator Access*.

   NOTE: Once an operator has been added, the Username cannot be deleted.

4. To exit this screen and return to the Operator Setup screen in Figure 16-3, choose one of the following:
   A. Press *Continue* to return with the record updated.
   B. Press *Cancel* to return without saving edits.
5. From the Operator Setup screen, press *CLOSE* to return to the Admin Main Menu, continue with Section 16.4.1, *Add an Operator*, or repeat Section 16.4.2 to edit an operator.

16.5 Admin Display Options

When *Display &Camera* is selected from the Admin Main Menu, the screen in Figure 16-5 is used to set the saturation, contrast and brightness levels for the video display, and the capture time for the video camera.

Each display level has a range of 0 – 100. The camera capture time setting has a minimum of 5 seconds and a maximum of 19 seconds. Settings here do not affect the GUI.

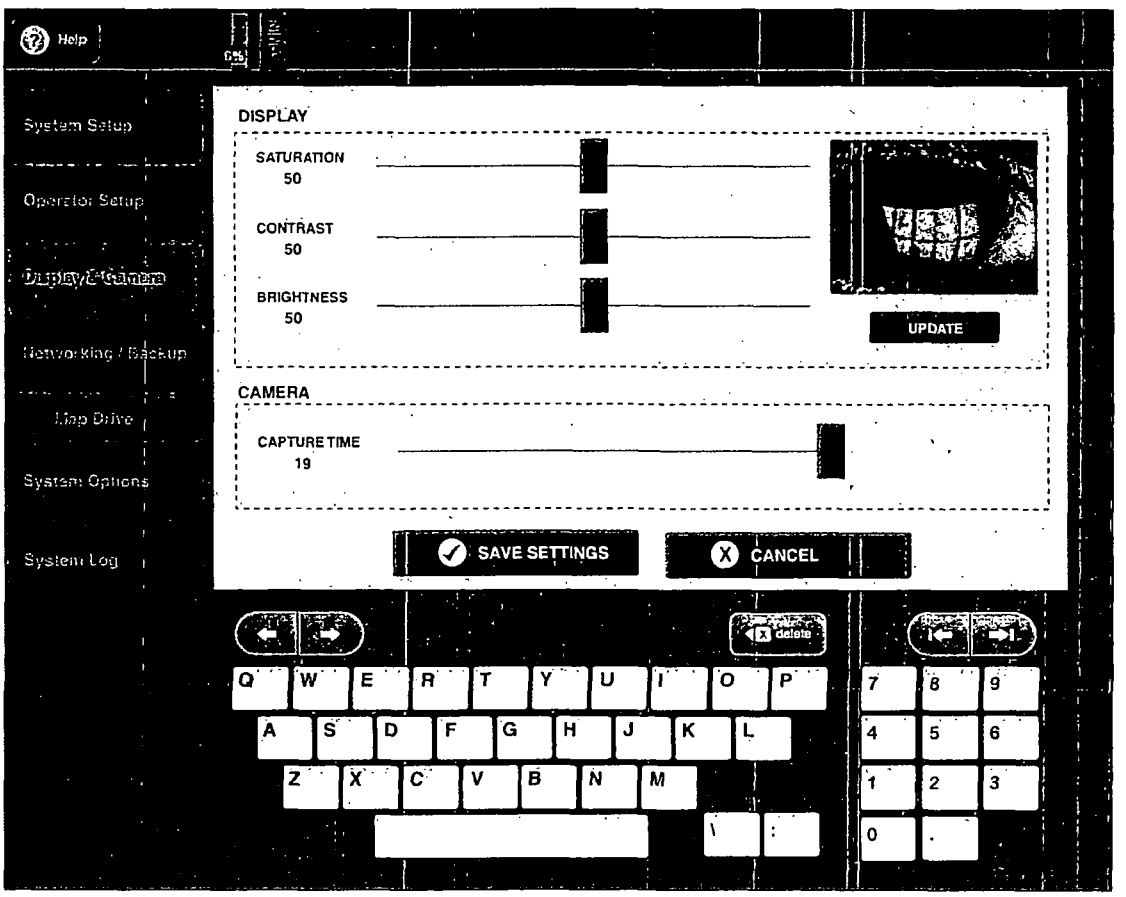


Figure 16-5: Admin - Display Options Screen

1. To modify the setting for Saturation level follow steps A-C, or skip to step 2:
   A. Move the locator bar to the left to lower the value or to the right to increase it. The new setting number will be displayed under the name on the left.

      NOTE: Touching a location on the slider bar will not change the setting; the locator bar must be moved.

   B. Preview the display with the new value by pressing *Update*. This allows the user to visualize the effect on a representative tear film image.

      NOTE: The Contrast and Brightness levels may also be adjusted before pressing *Update*.

   C. Repeat steps A and B as needed.
2. To modify the setting for Contrast level, repeat step 1 using the Contrast slider; otherwise, skip to step 3
3. To modify the setting for Brightness level, repeat step 1 using the Brightness slider; otherwise, continue with step 4.
4. To modify the video camera capture time, move the locator bar to the left to lower the value or to the right to increase it.
5. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:
   A. To permanently retain the saturation, contrast and brightness values on the screen, press *SAVE SETTINGS*. All future video images will use these values when displaying. A system message will indicate the display information has been saved. Press *Close*.
   B. To exit without saving any changes, press *CANCEL*.

16.6 Admin Map Drive

When *Map Drive* is selected from the Admin Main Menu, the screen in Figure 16-6 is used to setup one or more network drives on the LipiView® Interferometer. A mapped drive is a location on the network, and the location is designated by the Drive Letter. Mapped drives are typically used for cloning and archiving, which is discussed in Section 16.7, *Admin Networking*.

Depending on how the network is set up, the mapped drive on the network may require that a valid username and password be entered in order to gain access. If this is the case, the username and password associated with the drive being mapped should be entered on this screen.

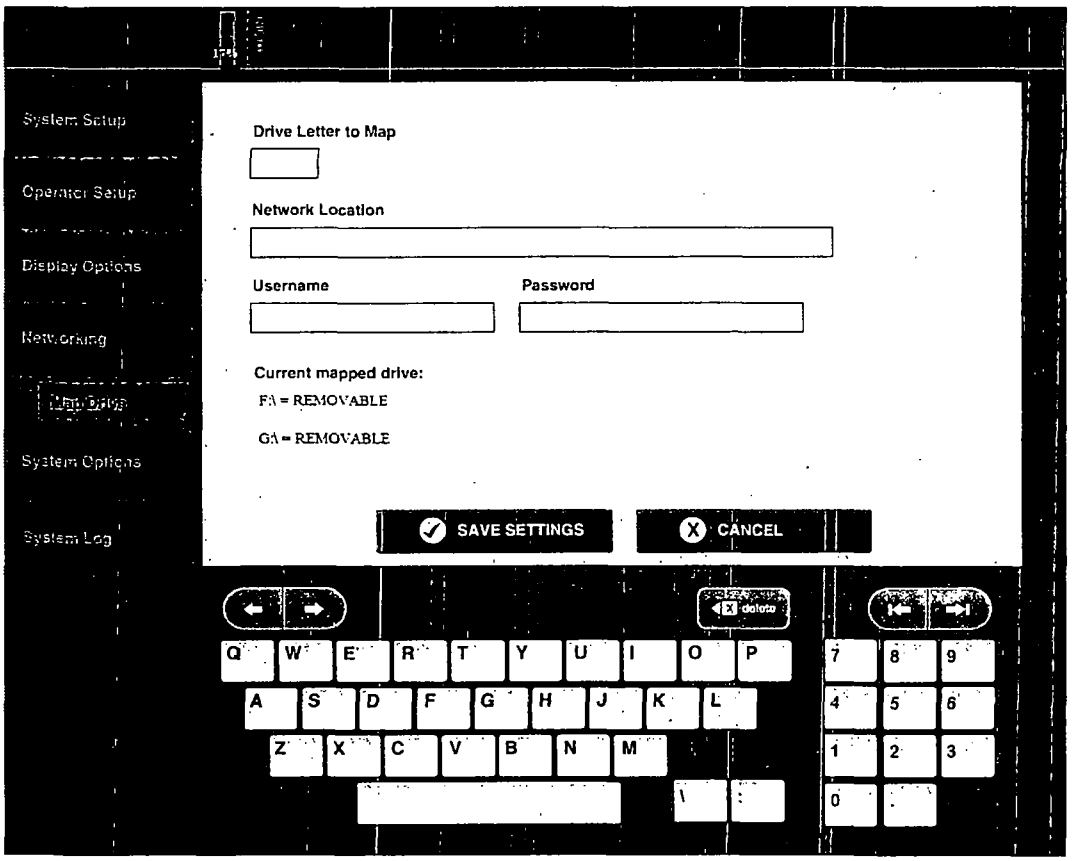


Figure 16-6: Admin - Map Drive Screen

Enter the information on this screen as follows, consulting with the Network Administrator to obtain this information if necessary:

1. In the *Drive Letter to Map* field, enter the drive letter of the network drive to which the LipiView® Interferometer will be mapped.
2. For *Network Location* – enter the server location (e.g., \\SERVER\\Location) that will be mapped to the drive letter.
3. If required to access the network location entered in step 2, enter the *Username* and *Password* interacting with your network.
4. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu.*
   A. To permanently retain the drive mapping information shown on the screen, press *SAVE SETTINGS.* A system message will indicate the mapping information has been saved. Press *Close.*
   B. To exit without saving any changes, press *CANCEL.*
5. To determine whether the connection was successful, press *Map Drive* to return to this screen.
   A. If the connection was successful, the heading *Current mapped drive:* will be followed by the name and location of the mapped drive in the format

"*:\\network_location", where '*' is the drive letter and 'network_location' is the network path.

NOTE: When storage devices such as an external hard drive or a USB flash drive are connected to the USB ports, these drives are also listed under *Current mapped drive*. In Figure 16-6, "F" and "G" are the drive letters, and "REMOVABLE" indicates the location is the USB port (rather than a network drive). When the USB port is the location only one backslash (\) is used.

B. If no network drives have been mapped, the words "No available drives found" will follow the heading.

6. If more than one drive will be mapped, repeat these instructions as many times as needed, or press *CANCEL* to return to the Admin Main Menu.

   NOTE: Once a network drive has been mapped it cannot be unmapped; however, the drive letter can be mapped to a new path.

16.7 Admin Networking/Backup

When *Networking/Backup* is selected from the Admin Main Menu, the screen in Figure 16-7 is displayed, allowing the Administrator to perform two functions: Disk Cloning, and setting up access to an HL7 server.

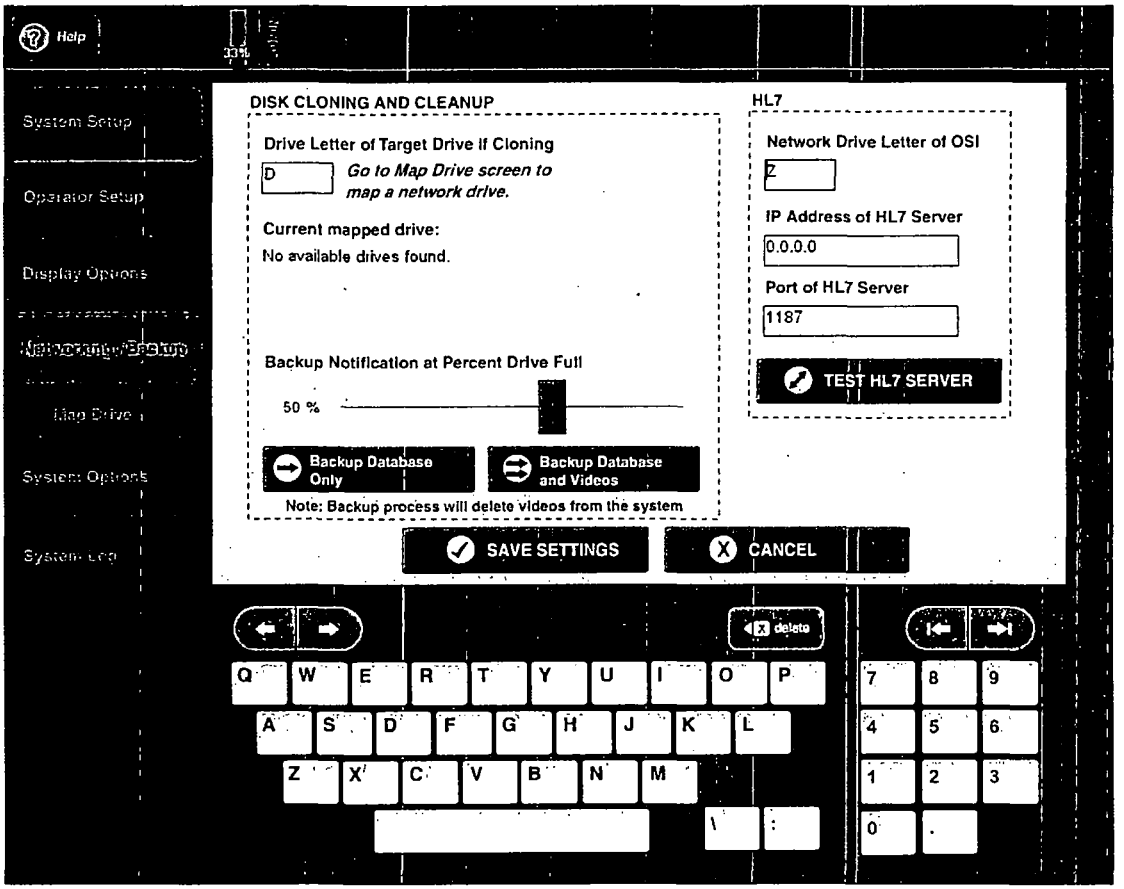


Figure 16-7: Admin – Networking/Backup Screen

16.7.1 Disk Cloning

As video information is stored on the LipiView® Interferometer, the disk drive becomes full. When the disk usage level reaches the level specified by the *Backup Notification at Percent Drive Full* slider bar, the LipiView® Interferometer issues a system message to notify the user to perform a backup. However, the device will continue to allow the user to capture additional videos. The user may either backup the database or backup the database and the videos to an external drive or network. **The backup process will permanently delete the videos from the LipiView® Interferometer.** When the disk usage level reaches 95%, the device notifies the user that a backup is required and will not allow the user to capture additional videos until the backup process is performed.

To free used disk space, one of the two following operations must be performed:

1) **Backup Database Only** – This option will copy the system database to the location specified in the Target Drive field, and then permanently delete all videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

2) **Backup Database and Videos** – This option will copy the system database and all video files to the location specified in the Target Drive field, and then permanently delete all the videos from the LipiView® Interferometer. The report data for the deleted videos will be retained on the system after backup.

NOTE: The Backup Database and Video process can take up to several hours to copy the videos to the external drive. Before beginning the copy process, please ensure you have adequate time to complete the process.

16.7.2 HL7

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records.

Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

HL7 is a communications standard used so that a piece of medical equipment (such as the LipiView® Interferometer) can talk with an Electronic Medical Records (EMR) server. HL7 is the common language used so that information can be exchanged between EMR systems and medical devices.

After review of a video, an HL7 message with the patient information can be sent from the LipiView® Interferometer to the specified EMR server (identified by an IP address and port). The conversation is one-way from the interferometer to the EMR server. The message is sent out but the interferometer does not know if the message was received by the EMR server. Refer to Section 10.5, *Video Print and Save* for instructions on how to send the report.

The LipiView® Interferometer can communicate with any EMR system that understands HL7 V2.5 messages. The HL7 group of controls allows the Administrator to configure the HL7 export destination. To set up an HL7 export connection:

1. Once the LipiView® Interferometer is mapped as a network drive on the network, enter its drive letter in the *Network Drive Letter of OSI* field. The network drive letter is sent as part of the HL7 message and allows the server to access report files that reside on the LipiView® Interferometer.
2. Enter the IP address of the HL7 server. If more than one HL7 server is available, select the desired server.
3. Enter the port address on which the HL7 server is listening for HL7 messages.
4. The connection to the HL7 server can be tested by pressing *Test HL7 Server*. When pressed, a standard IP ping will be performed on the HL7 server and the results will be reported. This feature should only be used by TearScience service personnel and is beyond the scope of this manual.
5. To exit this screen and return to the Admin Main Menu in Figure 16-1, choose one of the following and continue with Section 16.2, *Admin Main Menu*:
   A. To save all data entered on this screen (for both Disk Cloning and HL7), press *SAVE SETTINGS*. A system message will indicate the mapping information has been saved. Press *Close*.
   B. To exit without saving any changes to the screen, press *CANCEL*.

16.8 Admin System Options

When *System Options* is selected from the Admin Main Menu, the screen shown in Figure 16-8 provides the Administrator with information about the system, including software versions of the shell, application and GUI, and the serial number of the system.

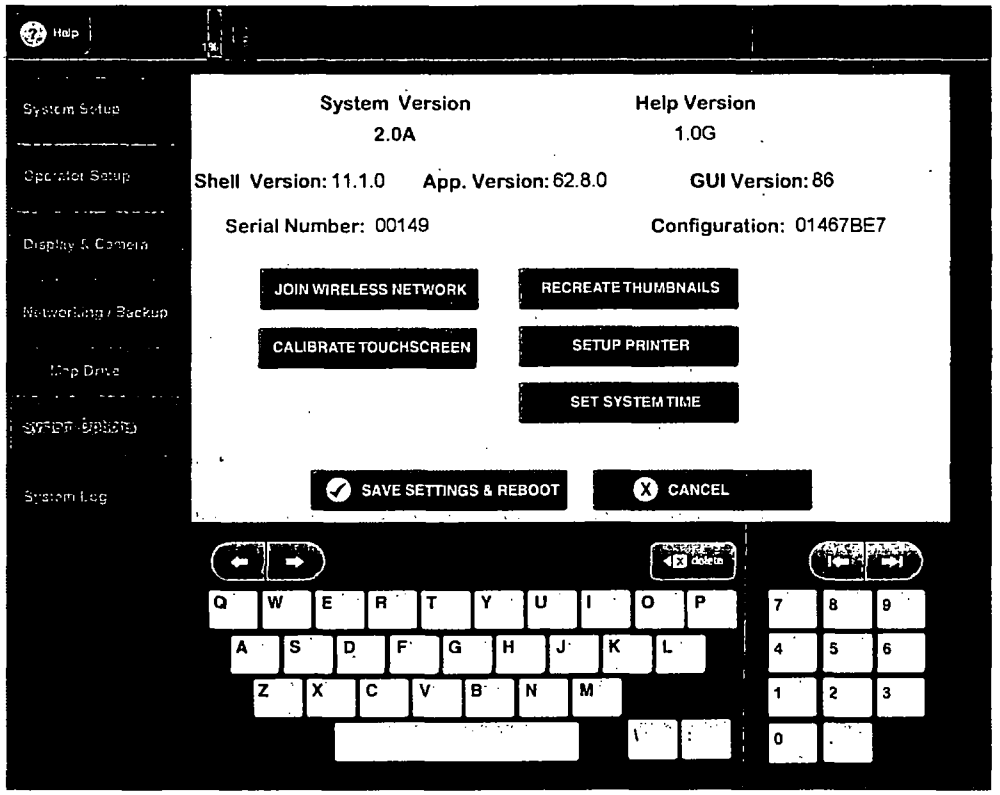


Figure 16-8: Admin - System Options Screen

There are also five functions available on this screen:

- **Join Wireless Network** – Pressing this button displays a standard Windows *Wireless Network Connection* dialog. Use the browse dialog to connect the LipiView® Interferometer to a wireless network. Contact the Network Administrator for assistance in joining a wireless network if needed.

NOTE: LipiView® has a firewall and disabled remote access to protect the device and ensure privacy of patient records over a network. However, if LipiView® is connected to a non-secure wireless network, exported patient data will not be protected from unauthorized access. TearScience recommends the LipiView® be connected to a password-protected wireless router utilizing the WPA or WPA2 security protocols to ensure protection of the device and patient records. Strong passwords do not contain words that appear in a dictionary, are at least six characters long, and consist of a mixture of letters and numbers. TearScience recommends that you choose a strong password and change it regularly (for example, every 90 days.)

- **Calibrate Touchscreen** – Pressing this button launches a calibration program for the touchscreen. This calibration can be performed when it is observed that the onscreen cursor is not matching correctly to the finger-touch locations. The program instructs the user to touch various targets on the screen, and then to press *OK* to accept the calibration. The user must press *Save Changes* to cause the calibration to be written to the disk. The calibration wizard will ask the user if the cursor is following his finger but the curser will not be visible. This is normal and should be ignored. **This option should not be used unless instructed to do so by a TearScience representative. If the touchscreen is not calibrated correctly, the touchscreen operation may be affected.**
- **Recreate Thumbnails** – Pressing this button restores the system in the event of a hard drive failure. The restore process reads all the video files present in the database, and extracts the thumbnail image that appears in the Patient History list for that video. **This option should not be used unless instructed to do so by a TearScience representative.**
- **Setup Printer** – Pressing this button will display the standard Windows *Setup Printer and Faxes* dialog. Use this dialog to set up a printer on the LipiView® Interferometer. The printer can be attached to the LipiView® Interferometer via a USB port, or it may be a network printer accessed via a wireless network. Contact the network Administrator for assistance in setting up a printer if needed.

  NOTE: If installing a USB printer, follow the manufacturer's instructions and to press *SAVE SETTINGS & REBOOT* when finished.
- **Set System Time** – Pressing this button brings up the standards Windows *Setup Date and Time Properties* dialog, and allows the Administrator to input the current date, time, and time zone into the LipiView® Interferometer. The date and time should be set during system first time setup discussed in Section 16.1.

  NOTE: It is not necessary to use the *Save Settings and Reboot* function after setting the system time.

Access to the System Option screen functions is disabled if more than 10 minutes has elapsed since the system was started.

For any of the setting changes to become active, the system must be rebooted. Press *Save Settings and Reboot*. A system message confirming the reboot is displayed. Press *Continue* to begin the reboot, or press *Cancel* to return to the System Options screen.

Press any tab on the left menu or press *Patient Records* to exit this screen without changes becoming activated.

16.9 Admin System Log

When *System Log* is selected from the Admin Main Menu, the screen shown in Figure 16-9 allows the Administrator to review system codes that have occurred and the results of Power On Self Tests. Items are listed in this table for the current day only; however,

all system codes in this list are stored in a database and the errors are never cleared. Use the step keys to the right of the table to scroll forwards and backwards through the table.

This page is intended to be accessed by TearScience representatives, or as directed by a TearScience technician.

After reviewing the log, press *CLOSE* to return to the Admin Main Menu.

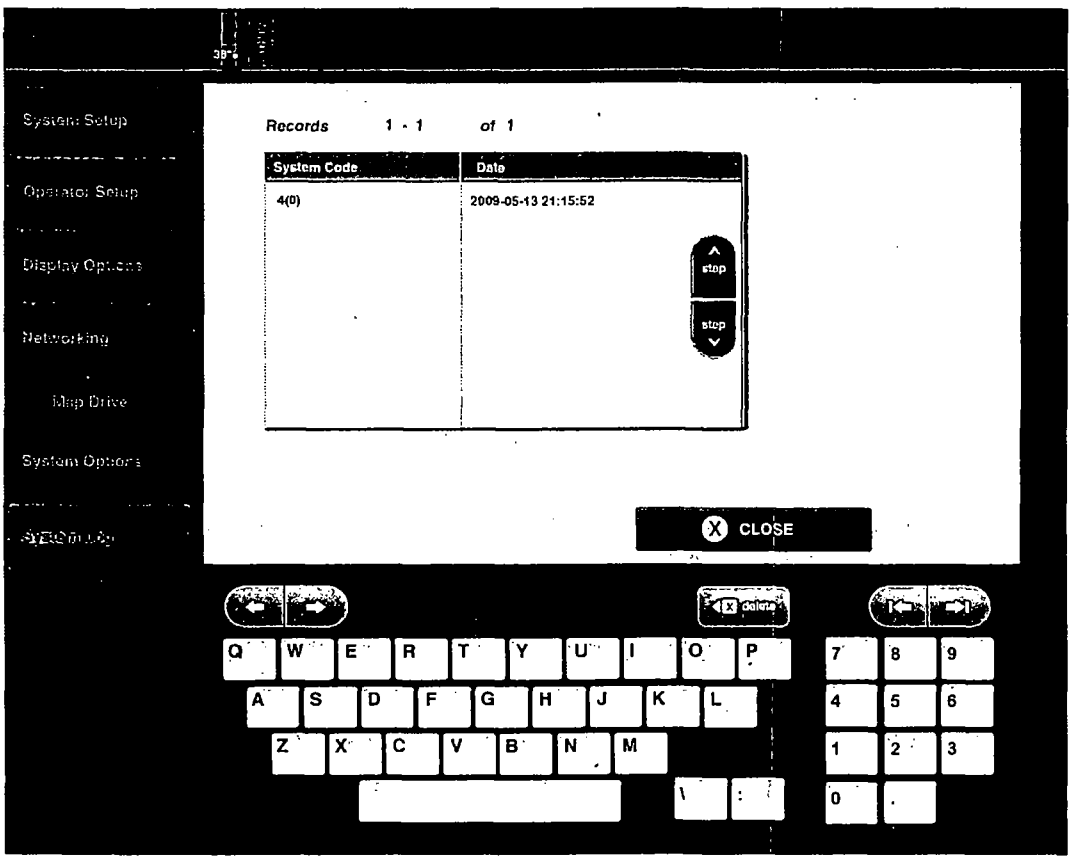


Figure 16-9: Admin - System Log Screen

17 Warranty

TearScience, Inc. warrants that each LipiView® Interferometer 1) is free from defects in materials and workmanship and 2) conforms to TearScience Inc.'s official specifications. The warranty period for each LipiView® Interferometer is one year commencing on the date of purchase. *Any tampering or modifications to the device by the user will void the warranty.*

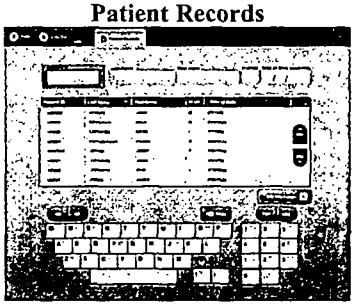
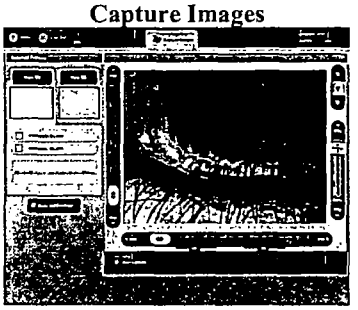
18 Appendix A: Quick Start Reference Guide

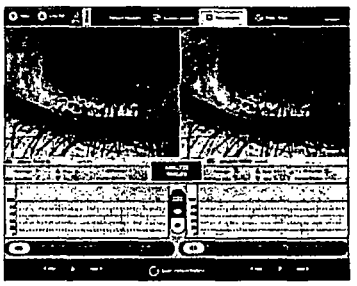
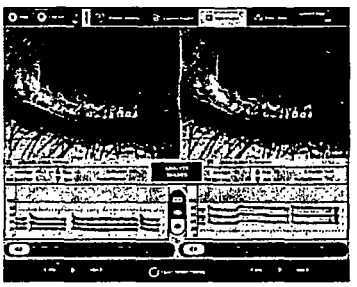
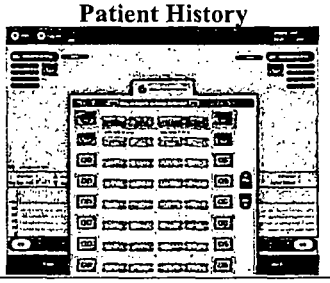
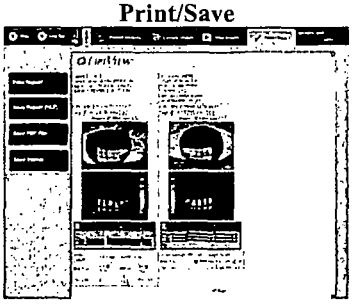
Sample Menu Bar (contents vary with active tab)

The light gray color shows View Images is active. Tabs may have multiple screens.
Help – Press to display information for the active screen. Press again to close.
Log Out – Press to exit the user from the device. The Login screen is displayed.
Disk Space Indicator – Shows the disk space that has been used for video storage.
Admin – Visible if Username has Administrator privileges. Press for Admin Main Menu.
Patient Records – Press to display patient table. Search for, add or edit a patient. Select a patient record and the next action to take.
Capture Images – Press to record video, preview video, rerecord video, and save video.
View Images – Press to review previous videos. Enter after capturing new images to view new video and request a computer analysis.
Print / Save – Press to print the video analysis, save it as a PDF file, or save it to an HL7 database.
Patient information – Shows information from a patient record after it is selected.

Startup

Power on the LipiView® Interferometer by pressing the rocker switch. System may take several minutes to boot up.
At Login Screen, enter a Username and Password. Press *Submit*. Refer to **Patient Records**.

Patient Records 	All records must have at minimum 1) a Patient ID, or 2) the Last Name, First Name and Date of birth. Locate record by typing name or using step keys. Must select a record to Capture Images or View Images. If not found, enter data; press *Add New Patient*. If found, choose record; Select a Patient Action. • Edit Patient – Update record if no saved video images. • Capture Images - Refer to **Capture Images**. • View Past Images - Select video from **Patient History** and then Refer to **Patient History.** • Close – Return to Patient Records. Get another record.
Capture Images 	Press *View OD* (right) or *View OS* (left) for eye to capture. Select pre-set tags; enter key-in tags. Clean chinrest support. Caution on hand/finger placement. Question patient on listed precautions; note conditions. Position patient: chin fully forward, forehead firmly against forehead rest. Look at orange fixation light. Adjust so lateral canthus aligns with marks on forehead rest using manual adjustment (fluted roller) located on chinrest support column. Use controls or touchscreen to adjust camera height and focus. Eye should be in center and clear. Press *Start Capture.* Approximately 20 seconds of video can be recorded. Have patient blink as needed. Press *End Capture to stop recording*. Refer to **Preview Video**.
Preview Video (just captured) Before saving, decide whether to rerecord. Capture images for second eye.	Preview image using controls and tear-film/full-eye toggle key. If desired, refer to **Rerecord Video**. Update pre-set or key-in tag information. Press *View OS / View OD* for 2nd eye. Refer to **Capture Images**. Press *Save All/Continue* to save video, tags. Refer to **View Images**.

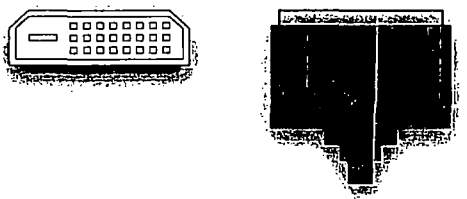
Rerecord Video Screen has same functionality as Capture Images except for system message confirming Rerecord.	Toggle between Preview and Rerecord screens by pressing *Return to recorded image* and *Return to live image*. To rerecord: Press View OS or View OD. Adjust patient and camera height, and focus. Press *Start Capture*. Confirm rerecord. Press *End Capture*. Update pre-set or key-in tag information. Press *Save All/Continue* to save video, tags. Refer to **View Images**.
View Images  	Entered after saving captured images. View and analyze. Or Entered from **Patient History** after choosing *View Past Images* from *Select a Patient Action* (Patient Records). View videos using play and step controls. Press *Analyze Images* if needed to view numerical data. • Average - Average ICU of all frame averages • Std Dev - Standard deviation of frame averages • Maximum – Max. recorded ICU for a given frame • Minimum – Min. recorded ICU for a given frame • C-Factor - Tear film Conformance factor for entire video After images are analyzed, review graph: • Toggle – Switch between full-eye, blink, and isolated tear-film view. • Each point on graph is ICU value for frame. • Blue line and region is the upper standard deviation of the ICU score data. • Red line and region is the lower standard deviation of the ICU score data. • Blue triangle marker denotes the point on the graph that contains the maximum ICU score. • Red marker triangle marker denotes the point on the graph that contains the minimum ICU score Refer to **Print/Save**. Press ***Open Patient History*** to view other files.
Patient History 	Select videos from the list in Patient History to view. If table is empty, no video data saved for patient. Drag and drop videos into two frames at top. • If a video was archived, follow messages to restore. • When videos are selected, press Close Patient History. • Refer to **View Images**. Data may or may not need analysis.
Print/Save 	To print report (USB/Network printer must be set up): • Press *Print Report* on the left menu. • Follow standard windows printing prompts for sending the report to the attached printer. To export report to an HL7 compatible system (must be connected): • Press *Save Report (HL7)* on the left menu. • An HL7 Basic Socket Transfer message is displayed. • Press *Send HL7* to store the data in the HL7 database. To save the printed report as a PDF file: • Connect an external USB drive or USB key to the LipiView. • Press Save PDF on the left menu. • When the system reports that the PDF has been saved successfully, press Close.

19 Appendix B: External Monitor Hookup

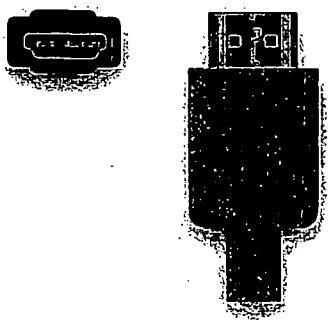
The LipiView® Interferometer is equipped with an optional external monitor connection. The following instructions provide the user with the steps needed to connect the external monitor to the interferometer.

The external monitor connection may be DVI output or HDMI output. TearScience does not supply cables for connecting external monitors. Users wishing to connect an external monitor should inspect the connectors on the monitor they wish to use, and the connector on the underside of the LipiView® Interferometer, and then purchase a cable that has the appropriate connectors on each end and is long enough to reach from the underside of the LipiView® Interferometer to the external monitor input.

The DVI connector and cable look like this:



The HDMI connector and cable look like this:



1. Ensure the LipiView® Interferometer is powered off.
2. Ensure that the separately purchased external monitor has either a DVI or HDMI port and is capable of displaying a 1280 x 1024 image.
3. Locate the digital video cable cover on the underside of the LipiView® Interferometer. The cover has four screws attaching it to the LipiView® Interferometer. Use an M2.5 hex driver and remove the four screws. The LipiView® Interferometer's digital video output cable should now be exposed.
4. Connect the separately purchased digital video cable to the LipiView® Interferometer's video output.
5. Connect the other end of the digital video cable to the external monitor.

6. Apply power to the LipiView® Interferometer and external monitor.

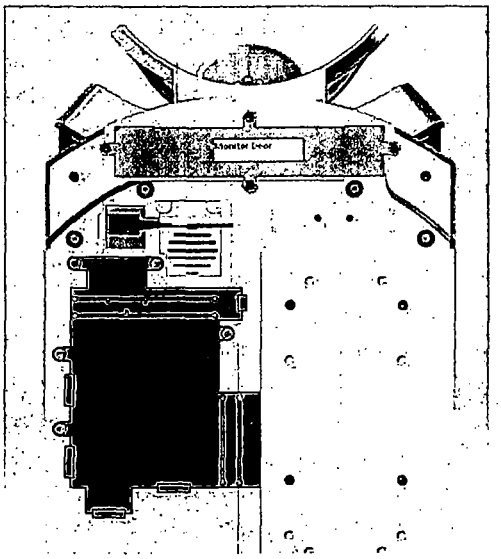


Figure B1. Location of External Monitor Interface Door

20 Appendix C: Electromagnetic Compatibility Requirements

20.1 Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Table 20-1: Guidance and Manufacturers Declaration-Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The LipiView® Interferometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	NA
Harmonic emissions IEC 61000-3-2	Class A	NA
Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	The LipiView® Interferometer is suitable for use in all establishments **other than** domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.

20.2 Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Table 20-2: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 1)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
*NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 20-3: Guidance and Manufacturers Declaration-Electromagnetic Immunity (part 2)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LipiView® Interferometer is intended for use in the electromagnetic environment specified below. The customer or the user of the LipiView® Interferometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the HCS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	$d = [3.5/V1]\sqrt{P}$ $d = [3.5/E1]\sqrt{P}$ 80MHz to 800MHz $d = [7.0/E1]\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Conducted RF IEC 61000-4-3	3 Vrms 80 MHz to 2,5 GHz	3 V/m	Field strengths from fixed RF transmitters, are determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LipiView® Interferometer is used exceeds the applicable RF compliance level above, the LipiView® Interferometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LipiView® Interferometer. . [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

20.3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Table 20-4: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and LipiView® Interferometer			
The LipiView® Interferometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LipiView® Interferometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LipiView® Interferometer as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d=[3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz** $d=[3.5/E_1]\sqrt{P}$	**800 MHz to 2,5 GHz** $d=[7/E_1]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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LIPIVIEW®

INTERFEROMETER

LipiView® Phantom Measurement and Color Palette Modification Report

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LIPIVIEW®

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LipiView® INTERFEROMETER

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LIPIVIEW®

INTERFEROMETER

LipiView *In Vivo* Precision Quantification

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LIPIVIEW®
INTERFEROMETER

LipiView *In Vivo* Precision Quantification Results

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Scott Liddle	R&D Engineer, Author	12/12/12 Date
Steve Grenon	VP of Research and Development	12/12/12 Date
Christy Stevens	VP of Regulatory and Clinical	12/12/12 Date

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DESIGN CONTROL FORM

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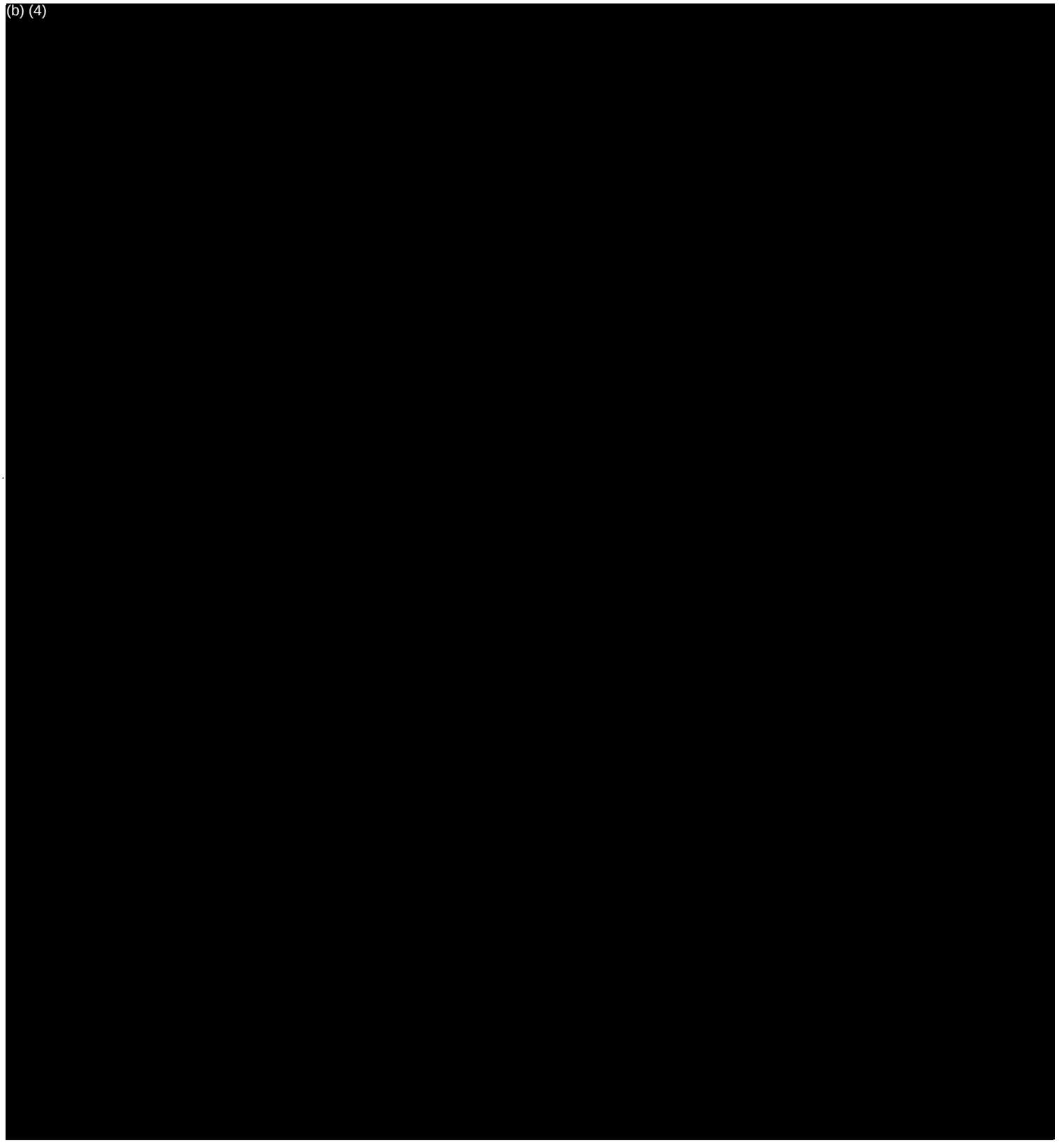

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GUI Design Document

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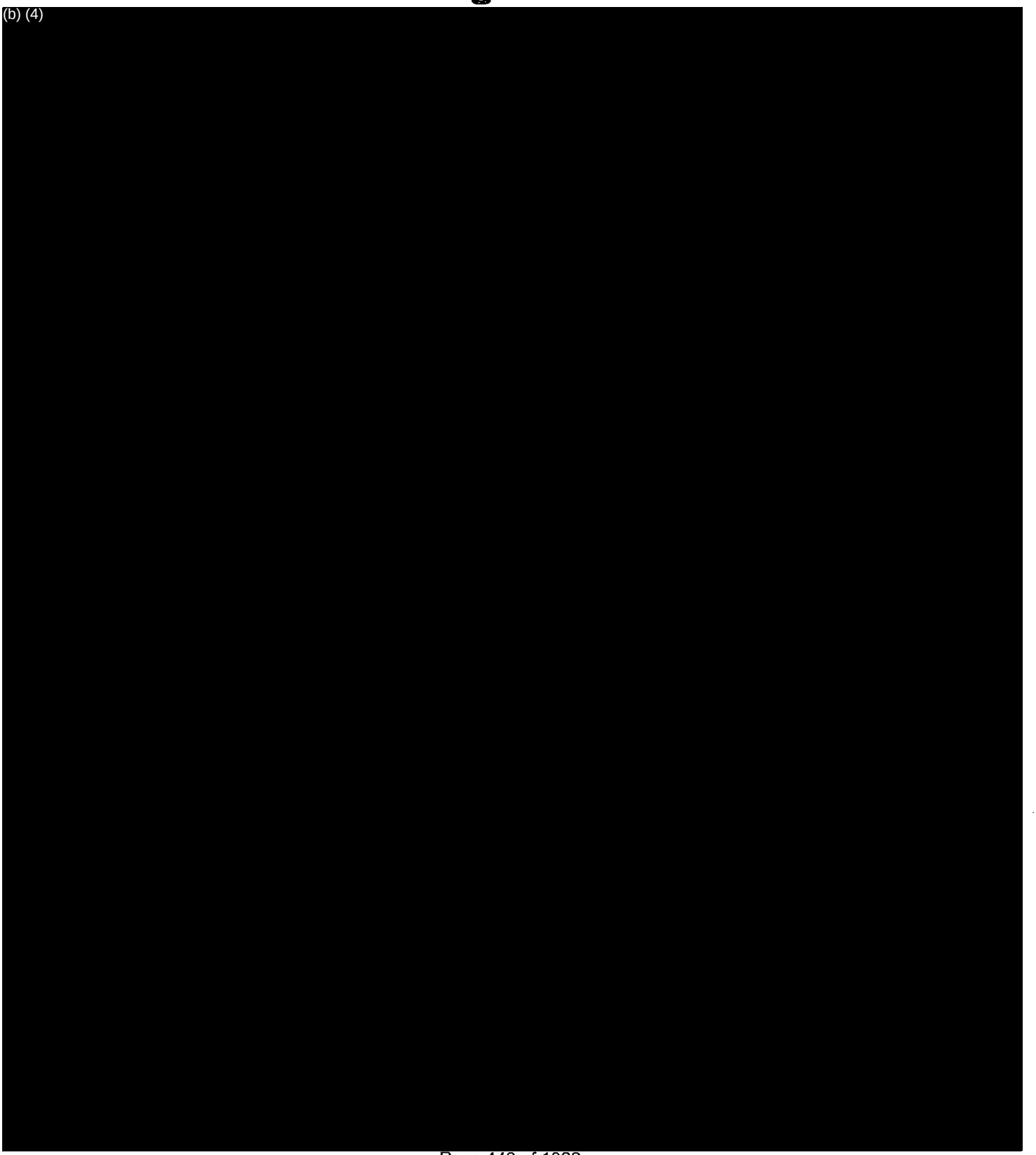

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200.4.1.5.1. Eye Selection – A selection control will permit the user to choose the eye for which data capture is selected.

200.4.1.5.2. A Default axis-position shall be defined for each eye.

200.4.1.5.3. Position Memory – When changing the capture screen from one eye to the other, the last position shall be stored before the transition and restored upon return.

200.4.1.5.4. Screen Memory – The state of all screen features (tags, images, etc.) shall be maintained when switching from one eye to the next, then back.

200.5. Fixation LED

200.5.1. Control – The user shall be able to set the state of the Fixation LEDs using a GUI control.

200.5.2. State – The GUI control shall indicate the state of the Fixation LEDs

200.5.3. OD/OS Control – The System shall activate the Fixation LEDs visible to the Patients' Right eye when in OD mode and shall activate those visible to the Patients' Left eye when in OS mode.

200.6. Capture Image OD/OS

200.6.1. Capture Control – A start/stop button having a recording indicator shall be provided to control the capture sequence. The illuminator shall be illuminated in tiled mode only during a capture sequence.

200.6.2. Live Video Display – During a recording sequence, the illuminator shall be active in tiled-mode and the live video shall be displayed to the user. Live video with the illuminator enabled shall also be enabled during camera alignment. The illuminator shall be disabled when alignment and capture are not active.

200.6.3. Capture Timeout – All capture sequences shall have a preset max-duration timeout ~~defined in an .ini or other configuration file~~which defaults to 19 seconds and can be altered by the system administrator.

200.7. Preview Image OD/OS

200.7.1. Playback Control – Controls shall be provided to Play, Step Fwd, Step Back, and to select a desired position using the Playback Slider Track.

200.7.2. Live Mode Control – User may return to live (camera active) mode by pressing this button.

200.8. Re-Capture Image OD/OS

200.8.1. Overwrite Confirmation – When capturing a second sequence without having saved the first one, a confirmation dialog shall be displayed before overwriting the first sequence.

200.9. Save –

200.9.1. Data Storage - A save button will save both OS and OD capture-sequences along with tag information.

200.9.2. AutoAdvance - The system will advance to the View Images screen after save.

300. Help Screen - The help button shall open a help file and shall index into the section relevant to the current user screen.

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LipiView (OSI) Software Architecture

And

LipiView (OSI) Software Design Specification

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LIPIVIEW®

INTERFEROMETER

LipiView Digital Phantom Verification

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LIPIVIEW®

INTERFEROMETER

LipiView Blink Detection Verification

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LipiView Software Sequence Protocol Results

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Attachment 1

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LIPIVIEW® INTERFEROMETER

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INTERFEROMETER

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LIPIVIEW®
INTERFEROMETER

LipiView Labeling requirements

Report Number: REP12-028

PCR1206251

Jordan Hutchinson	R&D		8/9/12
Author			Date
Gail Sauers	Reg Compliance		8/9/12
Author			Date
Christy Mocny	Quality & Regulatory Compliance Director		8/9/12
			Date

TearScience

LIPIVIEW®
INTERFEROMETER

LipiView Labeling requirements

Report Number: REP12-028

PCR1206251

Author	R&D	Date
Author	Reg. Compliance	Date
Christy Mocny	Quality & Regulatory Compliance Director	Date

1.0 SCOPE

1.1. Verification of changes to the LipiView Ocular Surface Interferometer product manual to conform to IEC 60601-1 3rd ed standard updates.

2.0 RESPONSIBILITIES

2.1. Author - Report manages labeling needs by documenting wording agreed to by TearScience and Intertek for compliance to IEC 60601-1 3rd ed. standard.

2.2. R&D - IEC 60601-1 3rd ed. requirements are met.

2.3. Quality/Regulatory - Quality and regulatory needs are met in conformance to the IEC 60601-1 3rd ed. standard.

3.0 SUMMARY

3.1. This report provides a summary of key points in the LipiView Operation Manual P/N 010792-ENG Rev H to document pass/fail criteria for labeling changes to meet IEC 60601-1 3rd ed requirements.

3.2. Chart captures requirements by referencing specific sections of IEC 60601-1 3rd ed. standard. Additionally, some important labeling requirements are included with their regulatory references.

4.0 REFERENCES

4.1. LipiView Operations Manual P/N 010792-ENG Rev H

4.2. IEC 60601-1 3rd ed standard

4.3. Attachment A, Outline of IEC 60601-1 3rd ed standard requirements

5.0 TEST RESULTS

5.1. Output includes this report.

6.0 CONCLUSION

6.1. Label changes for IEC 60601-1 3rd. ed. conformance.

6.2. This document provides verification of the LipiView Surface Interferometer operation manual PN 010792-ZZ Revision H for compliance with IEC 60601-1 3rd ed.

6.3. Requirements for IEC 60601-1 3rd ed. were met.

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Labeling requirement	Comments	Requirement Source	pass	fail
Cover Page Manufacturer Name, Address and Phone Number	Ensured new address was provided (pg 1)	• 21 CFR 801.1 • EU 93/42/EEC– Annex I, Section 13.3(a) • BS EN 1041:2008 • Canadian MDR SOR/98-282	X	
Cover Page EC Representative	Ensured new authorized rep information was provided: (pg 1)	• EU 93/42/EEC– Annex I, Section 13.3(a) • EN 980:2008	X	
Cover Page Rx Only	Replaced CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician with symbol (pg 1)	• 21 CFR 801.109 • FDA Guidance on Alternative to Certain Prescription Device Labeling Requirements	X	
Cover Page CE Mark	Ensured correct CE mark was applied (pg 1)	• EU 93/42/EEC– Article 17	X	
Product Name Model #	(pg 1)	• 93/42/EEC–Annex I, Section 13.3(b) • BS EN 1041:2008 • Canadian MDR SOR/98-282	X	
Description of label symbols	Pg 10	• US description of symbols is not specifically called out in FDA device regulations this infers that symbols are not accepted in the US and meanings must be provided. TearScience has found this to be true in talks with FDA during submissions. • AU – Therapeutic goods regulations 2002 13.1 – meaning of symbols must be explained in the information provided • NZ- GHTF	X	

TearScience

Labeling requirement	Comments	Requirement Source	pass	fail
language Format	*English* *French* *Other foreign languages*	◦ *21 CFR 801.15(c) (1)* ◦ *EU 93/42/EEC– Article 4 (4)* ◦ *BS EN 1041:2008* • *Canadian MDR SOR/98-282 section 23*	X	
Overview of Principles of Device Operation *(Route and method of administration)*	*US:* ◦ Indications for use (pg 11) ◦ Effects , Routes, Methods, Frequency, Duration (pg 32-36) ◦ Hazards(pg 13) ◦ Contraindications (pg 11) ◦ Side effects (pg 13) ◦ Precautions (pg 11) ◦ "caution: Federal law restricts this device to sale by or on the order of a licensed physician" (pg 1) *EU:* • *Installed or connected to other devices (connection pg 15)* ◦ *Information to verify devices are properly installed* ◦ *Information to avoid risks (pg 11-12)* ◦ *Reusable – appropriate reuse including cleaning, disinfection, resterilization, etc. (pg 15 & 34)* ◦ *Emitting radiation: nature, type, intensity, distribution (pg 76-79)* • *Contraindications & precautions including change in performance, exposure to magnetic fields electrostatic discharge pressure variations etc (pg 11-13)* • *Degree of accuracy for measuring functions (pg 45)* • *Revision level and date (pg 2)* *Canada:* • *Directions (pg 24)* • *Adverse effects (pg 13)* ◦ *Contraindications (pg 11)* ◦ *Warnings and precautions (pg 11-12)*	◦ *21 CFR 801.109 (b) and 801.109 (c)* ◦ *21 CFR 801.5* ◦ *EU 93/42/EEC– Annex I, Section 13.6* ◦ *BS EN 1041:2008* • *Canadian MDR SOR/98-282*	X	

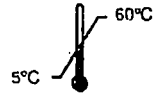
TearScience

Labeling requirement	Comments	Requirement Source	pass	fail
Warnings	Review the following warnings prior to using the LipiView®.  GENERAL WARNINGS (pg 12)	• 21 CFR 801.109 (c) • EU 93/42/EEC– Annex I, Section 13.3(k) & 13.6 • BS EN 1041:2008 • Canadian MDR SOR/98-282 • EN 980:2008 • ISO 15223-1: 2007	X	
	Caution: Power Requirements. The LipiView® Interferometer is a continuous operation device which requires a power source of 100-240 Volts AC ±10%, 50/60 Hz single phase, 4 Amps. Connection to a power supply other than a supply mains with protective earth may result in electric shock. (pg 12)	**IEC 60601** **7.9.2.1** **7.9.2.2**	X	
	 Caution: The LipiView® Interferometer has protection against electric shock of applied part classified as Type B. This device is classified as an IEC Class 1 product. (pg 12)	**IEC 60601** **7.9.2.1**	X	
	Caution: Voltage Protection and Fuse Selection. Contact TearScience to replace a blown fuse. TearScience personnel must replace only with a 5 x 20 mm, 4 A, 300 ms, 40 A breaking capacity fuse to avoid risk of fire. TearScience personnel must disconnect from power before servicing to avoid risk of electrical shock. (pg 12)	**IEC 60601** **7.2.12** **7.9.3.2**	X	
	Caution: Backup Battery Replacement. Backup battery cannot be replaced. (pg 12)	**IEC 60601** **7.3.3**	X	
	Caution: Keep the LipiView® Interferometer away from strong magnetic fields as it could damage the device's hard drive, but is not a safety hazard to the user or patient. (pg 12)	**IEC 60601** **7.9.2.2**	X	
	Caution: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating	**IEC 60601-1-2** **5.1.3**	X	

Labeling requirement	Comments	Requirement Source	pass	fail
	the LipiView® Interferometer or shielding the location. (pg 12)			
	All characteristics of the ME equipment including range(s), accuracy & precision of displayed values or indication where it can be found (pg 12) **Ranges, accuracy and precision are not required. ME was not designed as a measuring device.**	***IEC 60601 7.9.3.1***	*N/A*	*N/A*
	Caution: Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT. (pg 12)	***IEC 60601-1-2 5.2.1.1***	X	
	Caution: The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or Device. (pg 12)	***IEC 60601-1-2 5.2.2.1***	X	
	Caution: The EQUIPMENT or DEVICE should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EQUIPMENT or DEVICE should be observed to verify normal operation in the configuration in which it will be used. (pg 12)	***IEC 60601-1-2 5.2.2.1***	X	
	Caution: Degree of protection against harmful ingress of liquid: IPXO. This equipment has no protection against ingress of liquids. (pg 12)	***IEC 60601 7.9.2.1***	X	
	 *OPERATION WARNINGS* (pg 13)	• *21 CFR 801.109 (c)* • *EU 93/42/EEC– Annex I, Section 13.3(k)* • *BS EN 1041:2008* • *Canadian MDR SOR/98-282*	X	
	Caution: Federal law restricts this device to sale by or on the order of a licensed physician. (pg 13)	• *21 CFR 801.109(b)*	X	
	Caution: The chin and forehead rest surface must be	***IEC 60601***	X	

Labeling requirement	Comments	Requirement Source	pass	fail
	disinfected with alcohol immediately prior to use and prior to storage. (pg 13)	***7.9.2.12***		
	Caution: Photo-toxicity hazard. No acute optical radiation hazards have been identified for the LipiView® Interferometer under intended use conditions. Since prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. Aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. (pg 13)	***IEC 60601 7.9.2.5***	X	
	WARNING: No Modification of this equipment is allowed	***IEC 60601 7.9.3.1***		
	Caution: Do not place hands on the LipiView® Interferometer during operation, and do not put fingers near the illuminator, lens or chin rest during focusing. Instruct patient to not place hands on the LipiView® Interferometer during operation, and to not put fingers near the illuminator, lens or chin rest during focusing. (pg 13)	***IEC 60601 7.9.2.5 9.2.1***	X	
	Caution: If a problem occurs with the LipiView® Interferometer, identify the symptom then attempt to resolve the problem as indicated in Section 15, Troubleshooting. If the problem cannot be resolved, stop using the device and contact TearScience. (pg 13)	***TearScience***	X	
	Caution: To prevent electric shock or performance alteration, do not attempt to service the device or remove the cover. No maintenance is required for the LipiView® Interferometer, and the device and all of its	***IEC 60601 7.9.3.1***	X	

Labeling requirement	Comments	Requirement Source	pass	fail
	associated parts are not serviceable by the user. (pg 13)			
	Caution: This device is not suitable for use in the presence of flammable mixtures. (pg 13)	**IEC 60601 7.9.3, 7.9.2.1**	X	
	Caution: This device is not suitable for use in oxygen rich environments. (pg 13)	**IEC 60601 7.9.3, 7.9.2.1**	X	
	Caution: In order to isolate this equipment from supply mains the equipment must be unplugged from the wall. Do not position the equipment in a location which would prevent the unit from being unplugged in an emergency. (pg 13)	**IEC 60601 7.9.2.2**	X	
	Caution: Do not store this instrument in conditions where the temperature may rise above 60°C or fall below 5°C. (pg 13)	**IEC 60601 7.9.3.1**	X	
	Caution: When lifting or handling the LipiView® Interferometer, caution should be taken to prevent injury or damage to the device. Prior to moving the device, put the monitor arm into a locked position and unplug the power cord from the wall. If an external monitor is attached, disconnect the external monitor prior to moving the device. (pg 13)	**IEC 60601 7.9.2.2**	X	
	Caution: The device monitor and base unit may exceed 41°C. Device will remain within safe monetary contact temperature, below 51°C. (pg 13)	**IEC 60601 11.1**	X	
	Caution: Shock hazard. Do not touch patient and device under top cover simultaneously. (pg 13)	**IEC 60601 8.4.2c 16.2c**	X	
Potential Adverse Effects	There are no known or anticipated adverse effects associated with use of this device. (pg 13)	• 21 CFR 801.109 (c) • EU 93/42/EEC– Annex I, Section 13.6(b) • Canadian MDR SOR/98-282	X	

Labeling requirement	*Comments*	*Requirement Source*	*pass*	*fail*
 WiFi	Device transmits radiofrequency (RF) energy (pg 78-80))	**IEC 60601-1-2 5.1.1**	**X**	
Storage and Handling Instructions 	Store between 5 and 60 degrees Celsius (pg 17*)* To transport the LipiView Interferometer ensure power cord is unplugged and secured off the ground. Grip on metal portion or the device, in two locations. 1) base of the chinrest, 2) monitor arm behind the screen. Carefully lift and transport in an upright position.	***IEC 60601 7.9.3.1 7.9.2.2 11.6.6 9.4.4 9.4.2.2***	**X**	
Maintenance and servicing	*Expected life of the LipiView is 5 years* *Note: no user servable components are inside the unit. Maintenance is not required. The LipiView performs a calibration process upon powering on, see section 10.1.1. (pg 51)* *For field service contact TearScience*	***IEC 60601 4.4 7.9.2.13***	**X**	
Manufacturer's Declarations for Electromagnetic Emissions	*Manufacturer's declarations for electromagnetic emissions must be included as directed under the IEC Standard, including:* • *Guidance and Manufacturer's Declaration-Electromagnetic Emissions* • *Guidance and Manufacturer's Declaration-Electromagnetic Immunity for all Equipment and Systems* • *Guidance and Manufacturer's Declaration-Electromagnetic Immunity-for Equipment and Systems that are not Life-Supporting* • *Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Device (pg 78)*	***IEC 60601 17 IEC 60601-1-2 5.2.2***	**X**	

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Attachment A
REP 12-028

Outline of IEC 60601-1 3rd ed standard requirements

Attachment A
Outline of IEC 60601-1 3rd ed standard requirements

Clause	Requirement +Test	Result — Remark	Verdict
6	**IDENTIFICATION, MARKING AND DOCUMENTS**		—
6.1	Marking on the outside of equipment or equipment parts		—
	c) Markings of the specific power supply affixed	Equipment does not have a specific power supply	N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Equipment of sufficient size	N/A
	e) Name and/or trademark of the manufacturer or supplier .....:	TearScience	P
	f) Model or type reference..... .....:	LipiView	P
	g) Rated supply voltages or voltage range(s)	120—240VAC	P
	Number of phases.....:	Equipment is Single Phase	N/A
	Type of current .....:	AC	P
	h) Rated frequency or rated frequency range(s) (Hz) .....:	50—60Hz	P
	j) Rated power input (VA, W or A) .....:	4A	P
	k) Power output of auxiliary mains socket—outlets		N/A
	l) Class II symbol	Equipment is Class I	N/A
	Symbol for degree of protection against ingress of water provided.....:	Equipment is IPX0	N/A
	Symbol for protection against electric shock.....:	Type B applied part	P
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation—proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation—proof with protection partly in patient cable		N/A
	m) Mode of operation (if no marking, suitable for continuous operation)		P
	n) Types and rating of external accessible fuses....:	5x20mm, 4A, 250V, 300ms	P
	p) Ratings of external output.....:		N/A
	q) Symbol for physiological effect(s):		—
	— attention, consult accompanying documents	Found on Mains Label	P

Attachment A
Outline of IEC 60601-1 3rd ed standard requirements

Clause	Requirement +Test	Result — Remark	Verdict
	— non—ionizing radiation, or symbols as adopted by ISO or IEC 417	Found on Mains Label	P
	r) Anesthetic—proof symbol: AP or APG.....:	Equipment is not AP or APG	N/A
	s) Dangerous voltage symbol		N/A
	t) Special cooling requirements	None	N/A
	u) Limited mechanical stability	Pass the tests of clause 24	N/A
	v) Protective packing requirement(s)	No special requirements	N/A
	— Marking(s) for unpacking safety hazard(s)		N/A
	— Equipment or accessories supplied sterile, marked as sterile		N/A
	y) Potential equalization terminal	No potential equalization terminals provided	N/A
	— Functional earth terminal	No functional earth terminals provided	N/A
	z) Removable protective means	No removable protective means	N/A
	Durability of marking test	(see appended table 6.1)...	P
6.2	Marking on the inside of equipment or equipment parts		—
	a) Nominal voltage of permanently installed equipment	Equipment is not permanently installed	N/A
	b) Maximum power loading for heating elements or holders for heating lamps	b) Maximum power loading for heating elements or holders for heating lamps	N/A
	c) Dangerous voltage symbol	None produced	N/A
	d) Type of battery and mode of insertion	No removable batteries provided	N/A
	— Marking referring to accompanying documents used for battery not intended to be changed by the operator	Part of motherboard	P
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram		P
	f) Protective earth terminal	Marked adjacent to the protective earth terminal	P
	g) Functional earth terminal	No functional earth terminal provided	N/A
	h) Supply neutral conductor in permanently installed equipment (N)	Equipment is not permanently installed	N/A
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed		P
	— Markings comply with IEC 445		P
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	Equipment is not permanently installed	N/A
	l) Statement for suitable wiring materials at temperatures over 75 °C		N/A
	n) Capacitors and/or circuit parts marked as required in Sub—clause 15c	No markings required	N/A

Attachment A
Outline of IEC 60601-1 3rd ed standard requirements

Clause	Requirement +Test	Result — Remark	Verdict
6.3	Marking of controls and instruments		—
	a) Mains switch clearly identified		P
	— ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	One off switch marked with symbols 15 & 16 as well as a Indicator light	P
	b) Indication of different positions of control devices and switches		P
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device	Via touch screen monitor	P
	f) The functions of operator controls and indicators are identified		P
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2		P
6.4	Symbols		—
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		P
6.5	Colors of the insulation of conductors		—
	a) Protective earth conductor has green/yellow insulation		P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		P
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	Only protective earth is green/yellow	P
	d) Color of neutral conductor .....:		N/A
	e) Colors of phase conductor(s) .....:		N/A
	— Compliance with IEC 227 and IEC 245		N/A
	f) Additional protective earthing in multi—conductor, cords are marked green/yellow at the ends of the additional conductors		P
6.6	Medical gas cylinders and connections		—
	a) In accordance with ISO ISO/R 32		N/A
	b) Identification of connection point		N/A
6.7	Indicator lights and push—buttons		
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	Equipment has no red indicator lights	N/A
	— Yellow used to indicate caution or attention required	Equipment has no yellow indicator lights	N/A
	— Green used to indicate ready for action		P
	b) Color red used only for push—buttons by which a function is interrupted in case of emergency	None provided or required	N/A

Attachment A
Outline of IEC 60601-1 3rd ed standard requirements

Clause	Requirement +Test	Result — Remark	Verdict
6.8	ACCOMPANYING DOCUMENTS		—
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided on the cover page of the Operation Manual	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Provided in section 7 Warnings of the Operation Manual	P
	Markings specified in Sub—clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Provided in section 3, Labelling of the Operation Manual	P
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Provided in section7, Warnings of the Operation Manual	P
6.8.2	Instructions for use		—
	a) General information provided in instructions for use	TearScience® LipiView® Ocular Surface Interferometer Operation Manual, 010792 Rev D	P
	— state the function and intended application of the equipment	Included in section 2, Device Description of Operation Manual I	P
	— include an explanation of: the function of controls, displays and signals	Included in section 9, LipiView Interferometer Operation of Operation Manual	P
	— the sequence of operation	Included in section 10, Instructions for Use of Operation Manual	P
	— the connection and disconnection of detachable parts and accessories	Included in section 9, LipiView Interferometer Operation of Operation Manual	P
	— the replacement of material which is consumed during operation	Information regarding fuse replacement included in Operation Manual. No other materials consumed during operation	P
	— information regarding potential electromagnetic or other interference and advice regarding avoidance	EMC information included in Table 0—1: Medical Electrical Classifications of Operation Manual Applicable warnings emissions and immunity warning included Warnings section of Operation Manual	P
	— include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	No Accessories of detachable parts	N/A
	— instructions concerning cleaning,	Table 0—2: LipiView®	P

Attachment A
Outline of IEC 60601-1 3rd ed standard requirements

Clause	Requirement +Test	Result — Remark	Verdict
	preventive inspection and maintenance to be performed including the frequency of such maintenance	Interferometer Cleaning Information of Operation Manual calls out components, frequency, and method	
	General information provided in instructions:		—
	— information for the safe performance or routine maintenance	Provided in Sections 1 and 7 or Operation Manual	P
	— parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Provided in Sections 1 and 7 or Operation Manual	P
	— explanation of figures, symbols, warning statements and abbreviations on the equipment		P
	c) Signal output or signal input parts intended only for connection to specified equipment described	Provided in Section 9 of Operation Manual	P
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Provided in Section 11 of the Operation Manual	P
	e) Warning statement for mains operated equipment with additional power source	Provided Section 7 of the Operation Manual	P
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	Equipment does not have a primary battery	N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	Provided Section 7 of the Operation Manual	P
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601—1		N/A
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	Provided in Section 13 of the Operation Manual	P
	— Advice in minimizing these risks.		P
6.8.3	Technical description		—
	a) All characteristics essential for safe operation provided	Provided Section 2 of the Operation Manual	P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	Provided Section 7 of the Operation Manual	P
	— Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	Provided Section 7 of the Operation Manual	P
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Provided Section 13 of the Operation Manual	P

Attachment A
Outline of IEC 60601-1 3rd ed standard requirements

Clause	Requirement +Test	Result — Remark	Verdict
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Provided in Section 7 of the Operation Manual	P

6.1	TABLE: marking durability	P
Marking tested	Remarks	
Mains Label		
Fuse Label		
Supplementary information:		

Clause	Requirement + Test	Result — Remark	Verdict
ADDENDUM #1: The following clauses were not included in the general standard, and were added to make the Test Report complete			
6	**IDENTIFICATION. MARKING AND DOCUMENTS**		—
6.1	Marking on the outside		—
q)	Physiological effect(s):		—
	Symbol provided for hazard associated with equipment		P
	Durability of markings test		P
6.8.1	Equipment is accompanied at least by		—
	Language of accompanying documents	English	P
6.8.2	Instructions for use		—
	contain all information necessary to operate the equipment in accordance to its specification		P
e)	For Class I equipment using an alternate internal source, a warning to use the alternate source if the integrity of the protective earth conductor is in doubt	Equipment does not use an alternate internal source	N/A
6.8.3	Technical description		—
a)	General — The technical description shall provide		—
	— all data required by sub clause 6.1		P
	— information if particular measures or conditions need to be observed during installation and start up.		P

Canadian Deviations from CB Bulletin			
Clause	Requirement + Test	Result — Remark	Verdict
6.1	Marking on the outside		—
	Written Equipment warnings should appear in French and English	Translation appropriate when shipping units into Canada	P

European Deviations from EN 60601—1: 1990 + A1 + A2			
Clause	Requirement + Test	Result — Remark	Verdict
6.8.1	Finland (Resolution of the Ministry of Trade and Industry on Electrical Safety Regulations,		—

	205/74)		
	Warnings and instructions for use, required to be on the outside of the equipment, shall be in Finnish and Swedish.	Translation appropriate when shipping units into Finland and Sweden	P

Korean Deviations from CB Bulletin			
Clause	Requirement + Test	Result — Remark	Verdict
	LIMITATIONS		—
	Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417.	Translation appropriate when shipping *units into Korea*	P
6.8.1	Insert the following sub—clause after the last paragraph		—
	Language of accompanying documents shall be included Korean	Translation appropriate when shipping units into Korea	P

Singaporean Deviations from CB Bulletin			
Clause	Requirement + Test	Result — Remark	Verdict
6.1 g	Connection to Supply		—
	Add between the first and second items		
	The following voltage requirements shall be used: Single—phase: 230 V ± 6 %, 50 Hz ± 1 Hz; Threephase: 400 V ± 6 %, 50 Hz ± 1 Hz (phase to phase)	100—240VAC	P

UL Deviations from UL 60601—1, First Edition, 2003 * Represents US Deviations from CB Bulletin			
Clause	Requirement + Test	Result — Remark	Verdict
6DV.1	Markings on the outside		
* 6	The text of the marking prefaced with an upper case signal word "CAUTION", "WARNING", or "DANGER, shall consist of upper and lower case letters, in English, that comply with the following:		P
a)	All words comprising the text of the marking, excluding the signal word, shall be in letters not less than 1,6 mm (1/16 inch) high, based upon upper case,		P
b)	The signal word shall be in letters at least 2,8 mm (7/64 inch),		P
c)	The letters shall be in contrast color to the background. Letters that are raised or indented and do not have a contrasting color to the background are not acceptable.		P
* 6	A "WARNING" Statement is required for ionizing radiation producing equipment		N/A
6DV.2	EQUIPMENT capable of emitting ionizing radiation shall bear a warning statement		N/A

Attachment A
Outline of IEC 60601-1 3rd ed standard requirements

	concerning the risk of injury to persons from Xradiation. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X—ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."		
6DV.3	When a manufacturer produces or assembles equipment at more than one factory, the equipment shall have a distinctive marking – which may be in code – by means of which it may be identified as the product of a particular factory		N/A
6DV.4	Multiple voltage equipment for permanent connection to the branch circuit shall be marked to indicate the particular voltage for which it is connected when shipped from factory. The marking may be in the form of a paper tag or any other nonpermanent material.		N/A
6*.6.2l)	Replace 75°C with 60°C		P
6.8DV	Cord—connected equipment shall be provided with instructions to indicate the type of attachment plug used for alternate voltages		N/A

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LipiView® INTERFEROMETER

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System Cleanup and System Backup Functionality Verification

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LIPIVIEW®
INTERFEROMETER

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System Cleanup and System Backup Functionality Verification

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LIPIVIEW® INTERFEROMETER

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Verification of Issue Resolution for Release 1.1A

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INTERFEROMETER

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LipiView® INTERFEROMETER

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LipiView Remote Support Functionality Verification

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INTERFEROMETER

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LipiView Remote Support Functionality Verification

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INTERFEROMETER

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Software Sequence Report

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Software Sequence Protocol

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Software Sequence Protocol

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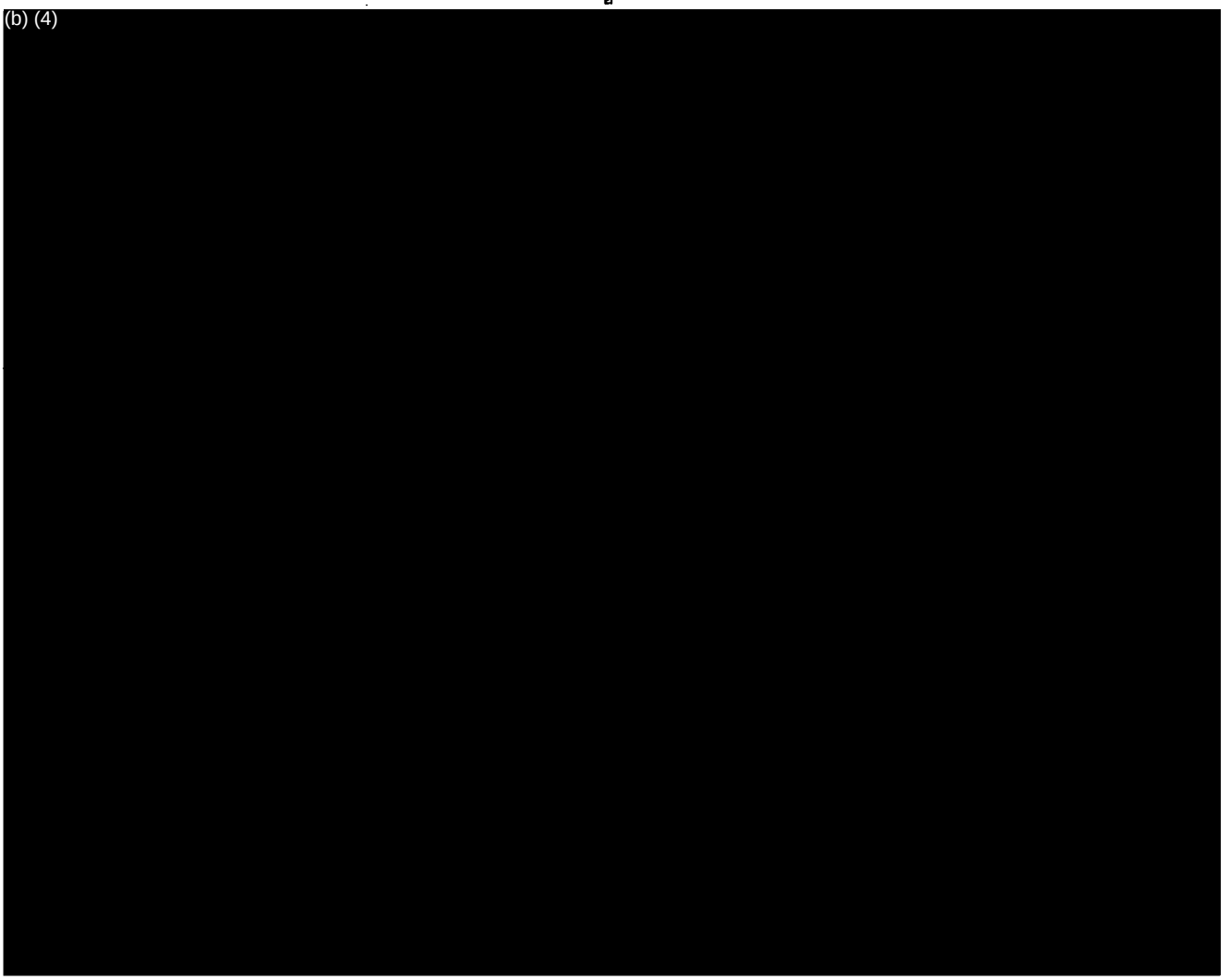

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LipiView Issue 456 Resolution and Test Discussion

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LipiView Software Sequence Protocol Results

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User Interaction	Expected Result	Confirm Result (Pass/Fail)	Issue No./Comments
	operator name and/or password."	Pass	
43 Press CLOSE and clear fields	Dialog closes and fields clear	Pass	

12 Display Options

User Interaction	Expected Result	Confirm Result (Pass/Fail)	Issue No./Comments
Refer to PSP00900 Rule 600.4; DCF00900 section 9.10b			
1 In user name field, press keys ADMIN	ADMIN shown in user name field	Pass	
2 Press forward tab	Focus set to password field	Pass	
3 Press keys KOLIS	***** shown in password field	Pass	
4 Press Submit	Patient list shown	Pass	
5 Press ADMIN	System setup screen shown	Pass	
6 Press Display Options	Display Options screen shown	Pass	
7 Set brightness to 50		Pass	50 ok
8 Set contrast to 50		Pass	50 ok
9 Set saturation to 0		Pass	0 ok
10 Press UPDATE button	Image shows muted colors	Pass	
11 Set saturation to 100		Pass	100 ok

(b) (4) LipiView Software Sequence Protocol Results

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TearScience

Ocular Surface Interferometer

Software Sequence

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LipiView Issue 544 Resolution Testing Results

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LipiView Software Sequence Protocol Results

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