optovue ifusion80

User Manual

P/N 580-48483-004 Rev B

VISIONIX

INNOVATION TO UNLOCK YOUR POTENTIAL

Publishing Details

iFusion
Please refer to the iVue 100 User's Manual and the iCam 100 User's Manual for full details before attempting to image patients with this device.

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Item	Part Number	
iFusion manual	580-48483-004	ECR#02979

iVue 100

iCam 100

Cautions

Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician. Proper procedures and techniques are the responsibility of the medical professional. It is the operator's responsibility to use, check, and maintains this device according to the labels of the product, accompanying instruction manuals, and any revisions of the labeling or instructions that may be subsequently issued.

No User serviceable parts, please contact your Optovue, Inc. service representative. Aucune pièce réparable par l'utilisateur, retourner l'instrument au fabricant pour réparation.Installation of this equipment is intended to be performed by Optovue trained service personnel only.

License and use of the iFusion system is intended only for trained medical personnel in accordance with the license agreement – all other usage is prohibited – warranty restrictions and possible claim limitations apply. All warnings and restrictions that apply to iVue 100 and iCam 100 apply to iFusion combination. Please read both iCam 100 and iVue 100 manuals prior to using this configuration.

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1. Introduction

iFusion from Optovue is the combination of the non-mydriatic fundus camera, iCam 100, and the Spectral Domain Optical Coherence Tomography (SD-OCT) iVue 100 on a shuttle platform. The combination is a single retinal imaging system.

iFusion is designed to provide fundus images as well as SD-OCT images of the patients. The utilization of the iShuttle combines the heads of both systems on one joystick to conserve space and improve efficiency.

Please read both the iCam 100 and iVue 100 manual for safety, warnings and instructions for use before attempting to use this equipment.

☞ **Note:** The iFusion Manual is not a modification of the iCam 100 or iVue 100 manuals. It is a separate manual which includes additions for iFusion. For specific details related to iCam 100 or iVue 100 refer to the User or install manuals.

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2. Safety Notes

This instrument has been developed and tested in accordance with Optovue safety standards as well as national and international regulatory guidelines to ensure a high degree of instrument safety. Please observe all safety notes and information in this manual and on the device labels. This product contains no material which has a chemical hazard concern.

Conditions for Proper Instrument Use

1. Always enter patient information first.
2. Prepare patient contact surfaces (forehead and chin rest according to the requirements of Section 8.0, Maintenance).
3. Instantly turn off the power switch of the instrument and disconnect the power cable if uncertain problems arise.
4. Clean ocular lens frequently to ensure good image quality (refer to Section 8.0, Maintenance).
5. Adjust power table height properly to ensure patient comfort during the examination.
6. Align the patient's head and eye position to the canthus indicator mark on the chin and forehead rest assembly.
7. Dim the room lights to allow natural dilation of the patient's pupil and to provide a comfortable visualization of the fixation target without glare.

   Note: Chemically induced pupil dilation is not normally needed.

8. Lock all wheels when not moving table

Unlocked
Locked. Verrouillé

Déverrouillé

9. Ensure that when lowering the table the areas indicated by pinch points are clear. Ensure people and articles are clear, do not store articles in these areas.

10. To avoid pinching when raising the chin rest, check patient head position before turning knob to raise it.
11. The operator should warn people not to sit or stand on any part of the table, including the base and the top of the table.

Indications for Use

The iFusion connects the iCam (K122572) and iVue (K121739) devices via a sliding bracket mechanism (iShuttle), to facilitate switching between the two devices. The iShuttle provides position adjustment ability of the iCam or iVue device during use. The iFusion interfaces with the iCam and iVue devices to enable the operation of the iCam and iVue devices from one computer unit.

Intended Use

iCam Fundus Camera (K122572) – The iCam is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions. The iCam takes digital images of the posterior and external structures of the eye without the use of a mydriatic agent and is intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health. iCam provides images only and does not provide any diagnostic, pathological analysis or classification of ocular health or disease.

AND

iVue 100 with Normative Database (K121739) – The iVue is a non-contact, high resolution optical coherence tomography system intended for in vivo imaging, axial cross-sectional, three dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, and anterior chamber of the eye. The iVue with Normative Database is a quantitative tool for comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects.

Equipment Classification

- Type of protection against electric shock: Class 1
- Degree of protection against harmful ingress of water: IPX0
- Class of operation: Continuous
- Degree of protection against electric shock of applied part (chin and forehead rests). Type B

Note: The iFusion is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The iFusion provides data to be used in conjunction with other information, intended to assist an eye care clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.

Remarque : L'instrument iFusion n'est pas destiné à être utilisé comme seul outil de diagnostic pour l'identification, le classement ou le traitement des maladies. Les données produites par le iFusion peuvent être utilisées de pair avec d'autres données destinées à aider le clinicien des soins oculaires à établir un diagnostic. Le diagnostic du patient est le domaine exclusif du clinicien de soins oculaires qualifié.

2.2 Alerts for Danger, Warning, Caution, Important, and Note

Refer to User's Manual.

Reportez-vous au livret du mode d'emploi

Presence of electrical shock hazard.

Voltage inside the instrument. Do not remove the instrument cover or parts.

General Warning Sign

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis (does not apply to all products).

CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis (does not apply to all products).

NOTE is used to call attention to notable information that should be followed during installation, use, or servicing of this equipment.

European Conformity Mark for TUV Rheinland
European Notified Body:
TÜV Rheinland LGA Products GmbH
Tillystrasse 290431 Nuremburg Germany

Type B Applied parts.

This instrument complies with the specified requirements to provide protection against electrical shock, particularly regarding allowable patient leakage current.

Manufacturer
Optovue, Inc.
2800 Bayview Drive,
Fremont, CA., USA, 94538

General mandatory action sign

Authorized European Community Representative
Medical Device Safety Services (MDSS) GMbH
Schiffgraben 41
30175 Hannover, Germany

Serial number

Catalog number / part number

No Sitting. Ne pas s'asseoir.

No Pushing. Ne pas appuyer.

Warning: Crushing of Hands.

Avertissement: Risque d'écrasement des mains.

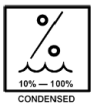
2.3. Protective Packing Symbols

The protective packing symbols specify the handling requirements and the transport and storage conditions.

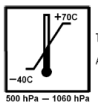
Fragile, Handle with care

Keep Dry

This end up



Relative Humidity (10% to 100%, including condensation)



Temperature (-40 to 70 deg. C)

Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

When determined that the device is ready for disposal, it is to be recycled following the policies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.

Recycling Label

This symbol is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:

1. The device was put on the European market after August 13, 2005
2. The device is not to be disposed of via the municipal waste collection system of any member state of the

European Union. It is very important that customers understand and follow all laws regarding the proper decontamination and safe disposal of electrical equipment.

2.4. System Warnings Avertissements du système

WARNING: THE iFusion CANNOT REPLACE CLINICAL JUDGEMENT AND IS INTENDED TO BE USED ONLY IN CONJUCTION OTHER CLINICAL TOOLS CONSIDERED TO BE THE STANDARD OF CARE FOR DIAGNOSIS OF EYE DISEASE.
AVERTISSEMENT: LE iFusion NE PEUT PAS REMPLACER LE JUGEMENT CLINIQUE. IL EST DESTINÉ A ÊTRE UTILISÉ UNIQUEMENT DE PAIR AVEC LES AUTRES INSTRUMENTS CLINIQUES CONSIDÉRÉS COMME RESPECTANT LES NORMES EN MATIÈRE DE POSE DE DIAGNOSTIC POUR LES MALADIES OCULAIRES.

WARNING: During normal usage of iFusion, software periodically polls the system status through the USB. Whenever software detects abnormality in status, it halts operation and flags error messages to warn users. Upon seeing the error messages, please exit the application program, check USB cable connection, and reboot the system.

The iFusion is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The iCam 100 and iVue 100 provide data to be used in conjunction with other information, intended to assist an eye care clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.

WARNING: No Modification of this equipment is allowed.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

WARNING: It is recommended that no accessories other than those specifically called out in this User manual may be connected to the system. Any customer accessory equipment connected to the interface ports must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1:2005. Any person who connects or installs accessories to the system has the responsibility to verify the compliance. If in doubt, consult an Optovue representative.

Avertissement: Il est recommandé de ne pas brancher sur l'instrument d'autres accessoires que ceux expressément mentionnés dans ce mode d'emploi. Tout équipement accessoire client branché aux ports d'interface doit être certifié selon les normes CEI respectives (p. ex. la norme CEI 60950 pour le matériel informatique et la norme CEI 60601-1 pour l'équipement médical). En outre, toutes les configurations doivent être conformes à la norme système IEC 60601-1: 2005. Il incombe à toute personne qui branche ou qui installe des accessoires à l'appareil de vérifier la conformité de ces accessoires. En cas de doute, parlez à un représentant d'Optovue.

WARNING: User Changes to Software or Hardware
The iFusion is a medical device. The software and hardware has been designed in accordance with U.S., European and other international medical device design and manufacturing standards. Unauthorized modification of the iFusion software or hardware, or any addition or deletion of any application in any way can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data.

WARNING: <u>Any changes, additions or deletions to factory installed applications, operating system or modifications to hardware in any manner VOIDS the Warranty completely and can cause safety HAZARDS.</u>
Avertissement: Modifications apportées par l'utilisateur au logiciel ou au matériel informatique.

Le iFusion est un instrument médical. Le logiciel et le matériel informatique ont été conçus conformément aux normes de conception et de fabrication des appareils médicaux en vigueur aux É.-U., en Europe et ailleurs. Toute modification non autorisée du logiciel ou du matériel informatique du iFusion, ou tout ajout ou suppression d'une application de quelque manière que ce soit peut présenter un risque pour la sécurité des opérateurs et des patients, le fonctionnement de l'instrument et l'intégrité des données des patients.

Tout changement, ajout ou suppression aux applications installées en usine et au système d'exploitation et toute modification au matériel informatique, de quelque manière que ce soit, ANNULERONT complètement la garantie et pourraient présenter un DANGER.

WARNING: Phototoxicity
Avertissement: Phototoxicité

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.
The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

Du fait que l'exposition prolongée à une lumière intense peut endommager la rétine, l'utilisation du dispositif pour l'examen oculaire ne doit pas être inutilement prolongée, et le réglage de la luminosité ne doit pas dépasser l'intensité nécessaire pour obtenir une visualisation claire des structures cibles.

La dose d'exposition rétinienne susceptible de présenter un danger photochimique est le résultat de l'intensité de radiation et de la durée d'exposition. Lorsque la valeur de rayonnement est réduite de moitié, le délai nécessaire pour atteindre la limite d'exposition maximale double.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, 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 to the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

Caution: Federal law restricts this device to the sale by or on the order of a physician or practitioner (CFR 801.109(b) (1).

« Même si aucune étude ne montre que les rayonnements optiques des ophtalmoscopes directs ou indirects ont un effet de toxicité aiguë, il est recommandé de réduire l'intensité de la lumière dirigée dans l'œil du patient au niveau strictement nécessaire pour établir le diagnostic. Les nourrissons, les personnes souffrant d'aphakie (absence de cornée) et les personnes souffrant d'une maladie oculaire sont les plus à risque. Le risque peut également augmenter lorsque la personne examinée a été exposée au même instrument ou à tout autre instrument ophtalmique utilisant une source de lumière visible au cours des 24 dernières heures. Cela est particulièrement vrai lorsque les yeux ont été exposés à une photographie rétinienne. »

Mise en garde: La loi Fédérale Américaine limite la vente de cet appareil directement aux médecins ou praticiens ou sur ordonnance (CFR 801.109 (b) (1)).

No stepping on surface.
Ne pas marcher sur la surface.

Warning: Electrical
Avertissement: Électricité.

ON for part of the Equipment.
Une partie de l'équipement est en marche (« ON »).

Alternating Current Courant alternatif.

Contraindications
Contre-indications
This device is not designed, sold or intended for use except as indicated.
Cet appareil n'est pas conçu ni vendu pour être utilisé de toute autre manière que celle spécifiée.

ESD Warning:

Prior to assembly, install or interconnection of the iFusion, it is recommended that any staff (i.e., biomedical engineers and health care staff) that could touch connectors identified with the ESD warning symbol undergo ESD training. At minimum, ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an operator who is electro statically charged. Further, an explanation should be given of methods to prevent build-up of electrostatic charge, and the how and why to discharge one's body to earth or to the frame of the equipment or system, or bond oneself by means of a wrist strap to the equipment or system or to earth prior to making a connection. Finally, staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a handheld tool unless proper precautionary procedures have been followed.
WARNING: During normal usage of the iCam 100, AC power fluctuations may cause an error message "unable to snap a frame." Upon seeing this error message, please exit the application program and reboot the system.

Warning Light Sources
IR source: The iCam 100 has continuous IR imaging for the observation of the patient.
External Fixation light: A continuous light for external fixation.
External LED: external LED light source for external imaging.
Internal LED flash; intermittent LED light source for the capture of images.

CE 0197

93/42/EEC Medical Device Directive CE Mark.

Indicates this equipment contains Type B applied parts

The iFusion is classified as follows:

- Class I Equipment – Protection against electrical shock.
- Type B – Degree of protection against electric shock of applied part (chin and forehead rests).
- IPXO - Degree of protection against ingress of liquids
- Continuous - Mode of operation

2.5. Table Handling Instructions
Directives de manipulation de la table

Moving Parts

Wheel Lock Label.
Étiquette de blocage de roue :

LOCK VERROUILLÉ

UNLOCK DÉVERROUILLÉ

Table Up/Down Label: DO NOT PUT FOOT UNDER COMPUTER **Étiquette d'abaissement/relèvement de la table : NE PAS METTRE LE PIED SOUS L'ORDINATEUR**

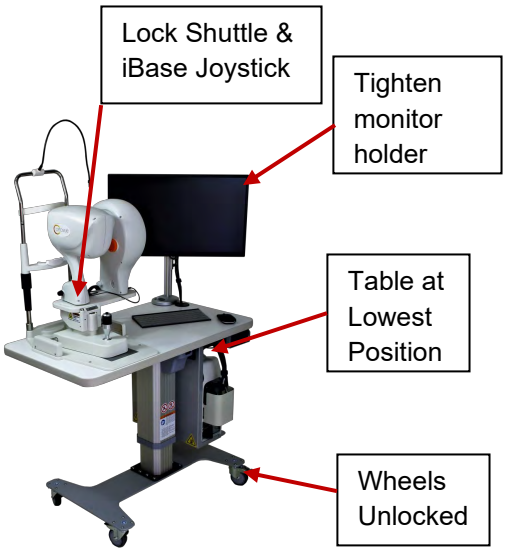
Foot Rest Trapping Warning:
Avertissement de risque de coincement dans le repose-pied:

Étiquette d'abaissement/relèvement de la table

Table Up/Down Label

Pinch Warning LocationsEmplacements pour les avertissements de risque de pincement

<u>Prior to moving the iFusion system, lock iFusion base, ensure the monitor is folded down and the table is lowered to the bottom position. Unlock the wheels and follow the table handling instructions. Movement of the iFusion system is accomplished more easily</u> with two people, one at each end of the table



iFusion System Locked Moving Parts

Lock all wheels when not moving table.
Locked

Disposal:
Dispose of the equipment per local regulations.

Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions
Déchets d'équipements électriques et électroniques (DEEE) Instructions de recyclage

When determined that the device is ready for disposal, it is to

be recycled following the policies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.

Lorsque l'instrument est considéré prêt à l'envoi au rebut, il doit être recyclé conformément aux politiques et procédures en vigueur dans le pays. L'instrument à éliminer ne doit pas être traité comme un déchet ordinaire.

Standard Accessories

Description	Part No.	Quantity
iShuttle with 2-pin connector	500-47989-003	1 pc.
User's Manual	580-48483-004	1 pc.
Installation Manual	810-48474-002	1 pc.

WARNING: Do not connect the instrument with anything other than those connections specified. Otherwise, it may result in fire or electric shock. For details of purchasing accessories, please contact an Optovue representative or distributor. To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Note: Avoid the use of extension cords or a power strip.

WARNING:
The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the iFusion system

WARNING:
Components of the iFusion system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the iFusion System should be observed to verify normal operation in the configuration in which it will be used.

Warning:
Equipment is not suitable for use in the presence of a Flammable Anesthetic Mixture with Air, Oxygen, or Nitrous Oxide.

Warning:
The iFusion has no special protection against harmful ingress of water or other liquids (classified IPX0). To avoid damage to the instrument and cause a safety hazard, the cleaning solutions, including water, should not be directly applied to the device. Using a dampened cloth (without dripping), is a good method to clean the exterior surface of the enclosure. . The table can be cleaned in the same manner as the iFusion instrument. Care should be taken to avoid excessive fluid near any of the system components.

Warning:
The patient cannot touch any electrical device that is not powered by iFusion with any part of his or her body while being examined. In addition, the iFusion operator must not attempt to touch the patient and any electrical device that is not powered by iFusion at the same time while examining the patient. Failure to do so could result in electrical shock to the patient and/or operator.

Use power cords only provided by Optovue. Do not block the access to unplug the power cord. Unplug the power cord to the table in the event of an emergency, since there is no switch to disconnect the power to the table.

In order to remove main power from the system, mains plug to wall outlet must be disconnected.

In order to remove power from Computer the mains plug to the wall outlet must be disconnected.

In order to remove power from iFusion the mains plug to the wall outlet must be disconnected.

Do not position system where plugs are inaccessible during operation.

Caution:

The iVue 100 Normative database and the results displayed are based on estimated percentiles and should be used only as an aid for making clinical decisions. The results from the normative database comparison should never be used in isolation, only as one part of the entire clinical armamentarium. Patients who are not represented by the patients in the normative database may not be suitable for comparison to the normative database. In these patients, the normative database results should be used with caution, if at all. This includes patients outside the age range of the normative database (outside 18 – 82 years of age), or outside the range of refractive error (worse than eight diopters spherical error or two diopters cylindrical error). Results in patients 30 years of age or younger and 80 years of age or older should be interpreted with caution since only four subjects below the age of 30 and three subjects above the age of 80 were included in the normative database. It should be noted that this normative database does not have any subject younger than 18 years of age. The color categorization of a pixel presents the percentile with regard to the distribution of thickness at the specific location of a given pixel.

Caution:

The iVue 100 color normative maps provide a way to represent whether a given patient is similar or dissimilar to a “Normal” patient. This information does not provide further diagnostic information beyond representing whether a given patient is similar or dissimilar to a “Normal” patient.

Caution:

The iVue 100 Normative database comparisons are based on statistical comparisons only, and there are possible normal outliers. You should reduce the risk of misclassification by using multiple clinical tools for diagnosis.

Caution:

OCT image is a plot of optical path length. Depending on the optical design and scanning location, the image can be distorted from its actually physical shape. For example, a

relatively flat retinal OCT image might not reflect the true curvature of the retina.

Certification

To ensure full system quality, iVue 100, iCam 100 and iFusion have been manufactured in a registered ISO 9001 or 13485 facility. It has been designed and tested to be compliant (when used with the laboratory equipment requirements of applicable regulatory agencies. Declarations of conformity and certificates of compliance are available at www.optovue.com.

Product Compliance
Electromagnetic Compatibility (EMC): EN 60601-1-2:2007

The iFusion device has been tested to comply with the emission and Immunity requirements of EN60601-1-2:2007. The iFusion is intended for use in an electromagnetic environment where radiated RF disturbances are not beyond the standard defined in EN60601-1-2:2007.

CB Certification: under IEC 60601-1

This device is classified according to UL/IEC/EN 60601-1 (2005) as follows: Continuous Operation, Class 1, Type B. With respect to electrical shock, fire and mechanical hazards only in
accordance with UL/IEC/EN 60601-1 Third edition (2005) and CAN/CSA C22.2
No. 601.1

Radio Interference

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with this instruction manual, may cause interference to radio communications. Operation of this equipment in a residential area is likely to cause interference, in which case the user

will be required to correct the interference at their own expense.

Canadian Regulations

This equipment does not exceed the Class A limits for radio noise emissions from digital apparatus as set out in the radio interference regulations of the Canadian Department of Communications.

Le présent appareil numérique n'émet pas de bruits radioélectriques dépassant les limites applicables aux appareils numériques de Classe A prescrites dans le reglement sur le brouillage radioelectrique édicté par le Ministère des Communications du Canada.

Note: Intended Use for iCam 100 and iVue 100 has not been changed as a result of the formation of iFusion.

WARNING: Do not connect the instrument with anything other than those specified. Otherwise, it may result in fire or electric shock. For details of purchasing accessories, please contact an Optovue representative or distributor. To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The iFusion System is intended for use in the electromagnetic environment specified below. The customer or the user of the iFusion System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11 EN 55011	Group 1	The 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 EN 55011	Class A	The iFusion System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system 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 iFusion System or shielding the location.
Harmonics IEC/EN 61000-3-2	Class A	
Flicker IEC/EN 61000-3-3	Complies	

Software Adaptation for iFusion

iFusion is a display format that allows running two separate programs easily. The addition of a tab to each program allows the user to switch from iVue 100 to iCam 100 and vice versa. The two programs use the same data accumulation and storage programming. iFusion allows both programs to share a single database. This saves possible transcription errors that could occur when entering patient information twice. The iFusion software allows the visualization of the iCam 100 image while in iVue 100 mode.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

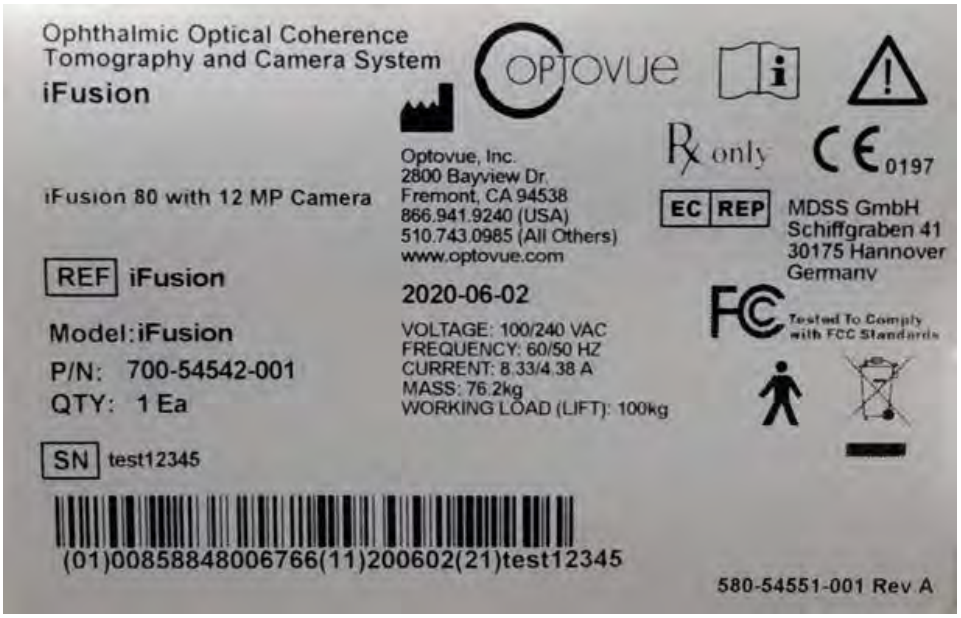
The iFusion System is intended for use in the electromagnetic environment specified below. The customer or the user of the iFusion System should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 2, 4, 6 kV contact ± 2, 4, 8 kV air	± 2, 4, 6 kV contact ± 2, 4, 8 kV air	An ESD warning label adjacent to the rear USB connector and precautionary user manual documentation are required. 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/EN 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	Main power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC/EN 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main 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/EN 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 s	<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 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the iFusion System requires continued operation during power main interruptions, it is recommended that the iFusion System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC/EN 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 AC main voltage prior to application of the test level.

Service Life
The service life of iVue 100 and iCam 100 is five years if specified inspections and maintenance are done.

2.6. iFusion System Label sample



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3 Instrument Description

3.1 iFusion System Configuration

3.1.1 iCam 100 Camera Head

This is the main component of the iCam 100 system. It is used to provide non-mydriatic color posterior and external images of the eye. The scanner and computer communicate via two USB connections. The iCam 100 comes with a medical-grade power supply, released software and manuals.

3.1.2 iVue 100 Scanner Head

This is the main component of the iVue 100 system. It is used to capture SD-OCT images of the posterior and anterior structures of the eye. The system communicates externally with USB connections. The power supply for iVue 100 head is in the control box and includes released software and manuals.

3.1.3 Computer

The computer will be provided with the system. The computer meets the minimum requirements established in Section 7.

3.1.3.1 Data Backup

iFusion system is supplied with a computer system that contains one hard drive for storing the captured images. The iVue 100 control box contains a backup drive. **Using one of the following additional back up scenarios IS STRONGLY RECOMMENDED**:

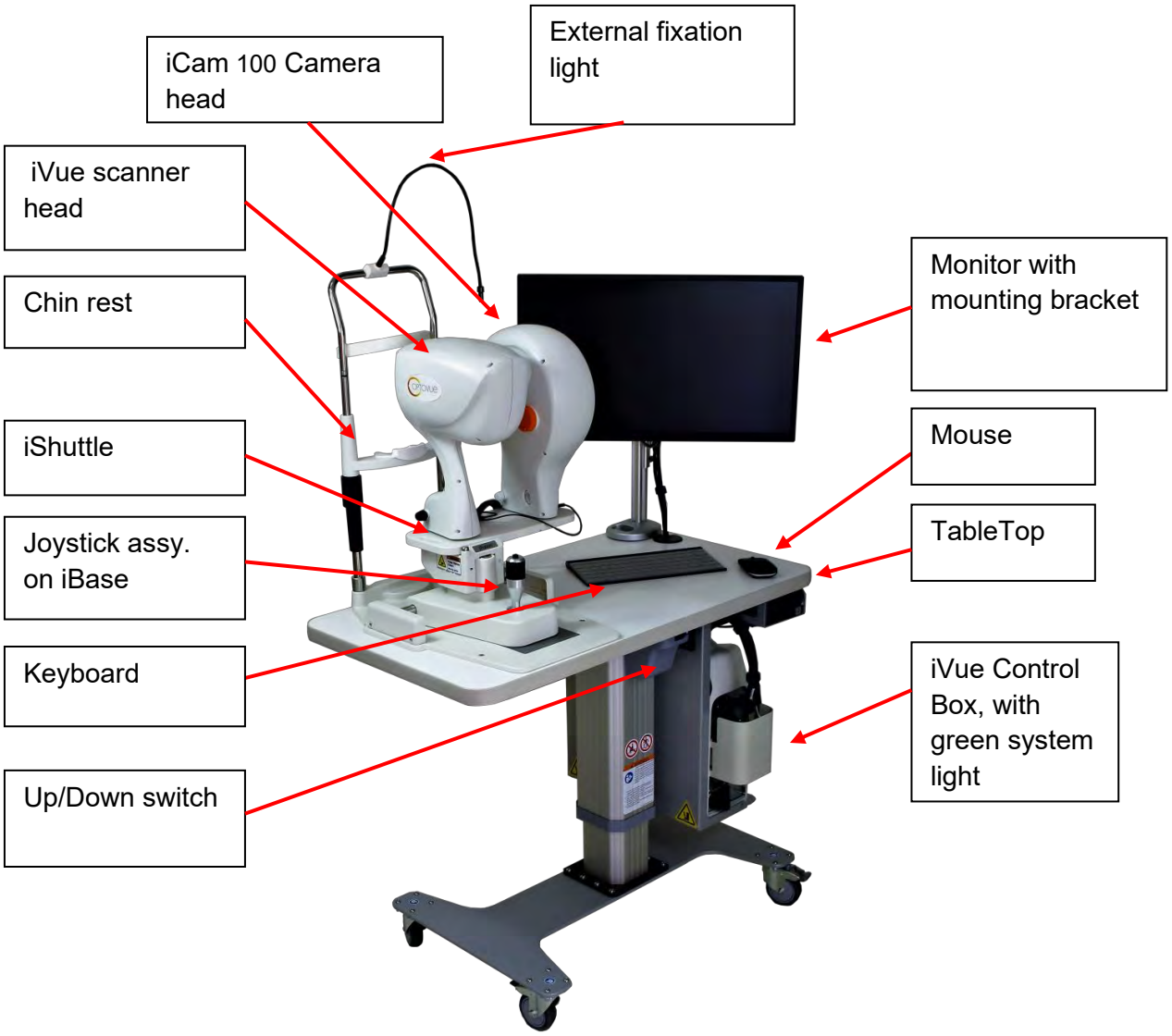
- A network connection to the system computer, to allow the data to be backed up to the network server (or designated folder in your network).
- A USB external hard drive connected to the system computer USB port. (This should be connected at all times in which iFusion is turned ON).

3.1.4 Joystick/Chin Rest Assembly

The joystick assembly moves the iFusion system in the X, Y, and Z directions. The joystick has a button that captures a scan when pressed. The chinrest supports the patients chin and forehead, with the eye aligned with the canthus marker.

3.1.5 iShuttle

The iShuttle mounts to the joystick assembly using a central nut and bolt and four adjustable set screws. Only Optovue personnel should assemble the iFusion system. The iShuttle consists of a sliding metal plate with mounting devices for the iVue 100 and iCam 100 and it moves on tracks fitted with ball bearing rollers allowing it to shift left and right. The base of the shuttle attaches to the X-Y-Z joystick. This movement allows independent the iCam 100 or iVue 100 positioning. The iShuttle front release button is pressed to unlock the metal slide plate. This metal slide should then be pushed until it locks at the opposite end. Before sliding the iShuttle, ensure that the joystick assembly with iShuttle is pulled all the way back toward the operator to avoid contacting the patient.



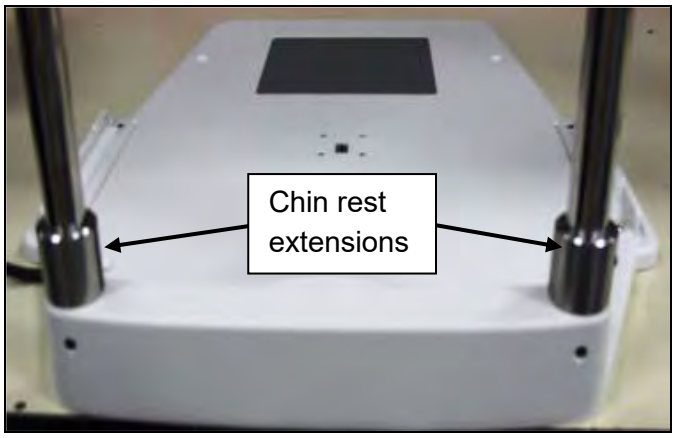
iFusion System Components

4 Getting Started

☞ **NOTE**: See the iFusion installation manual, P/N 810-48474-002 Rev.B, for complete instructions.

4.1 Chin Rest

Chin rest extensions are required for iFusion installation. The chin rest extensions should be added to the chin rest assembly prior to use.

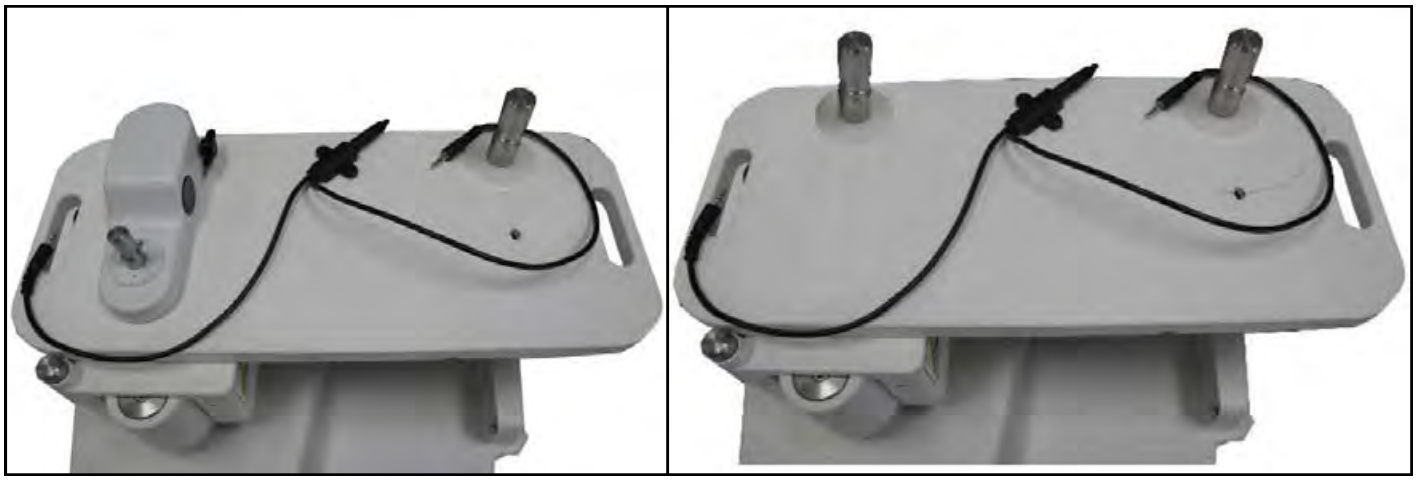


Chin Rest Extensions Mounted

4.2 Connecting iCam 100 And iVue 100 To Computer

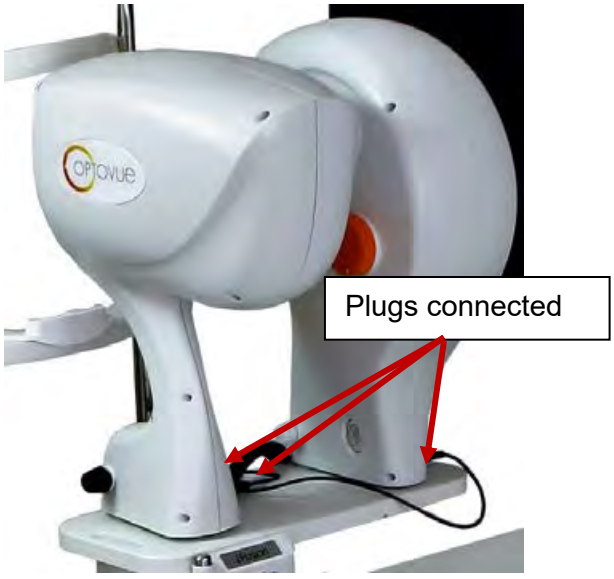
Follow the procedure below to connect the iCam and iVue cabling to the iFusion system computer.

1. Connect the USB wire from the camera head to the computer.
2. Connect the USB from the iVue 100 control box.
3. Plug in the mouse and keyboard antenna.
4. Plug in the power cable.



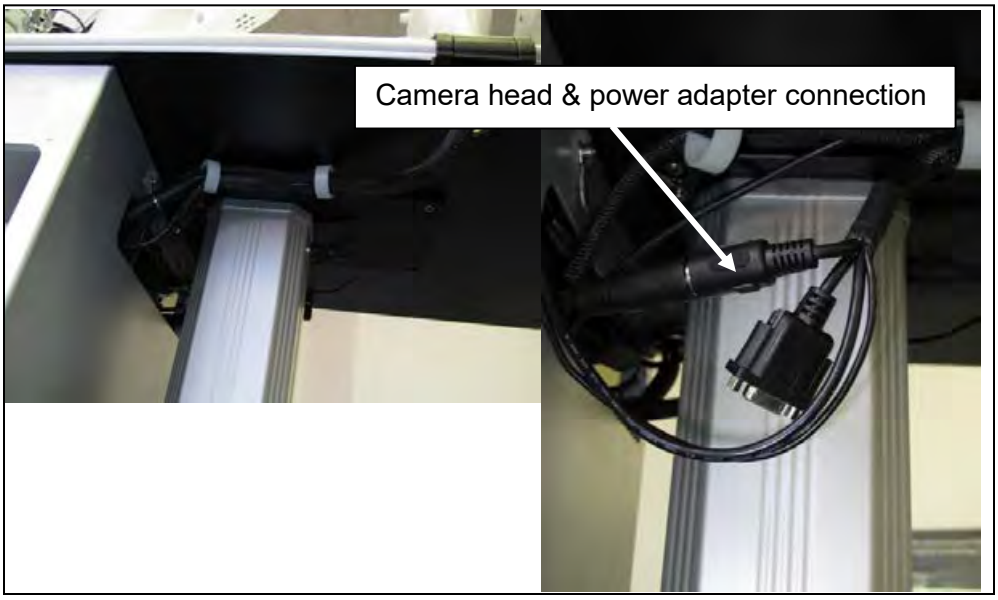
iShuttles with Unattached Cables for Original iVue (Left) And Current iVue (Right)

5. Connect the 3-way plug in, one to each head and the base as shown in the figure below.



iVue-100 And iCam 100 3-Way Joystick Plug Connections

6. Position the arrow marks on the power cord of the camera head against the arrow marks on the power adapter connector and make the connections, secure with cable hooks.

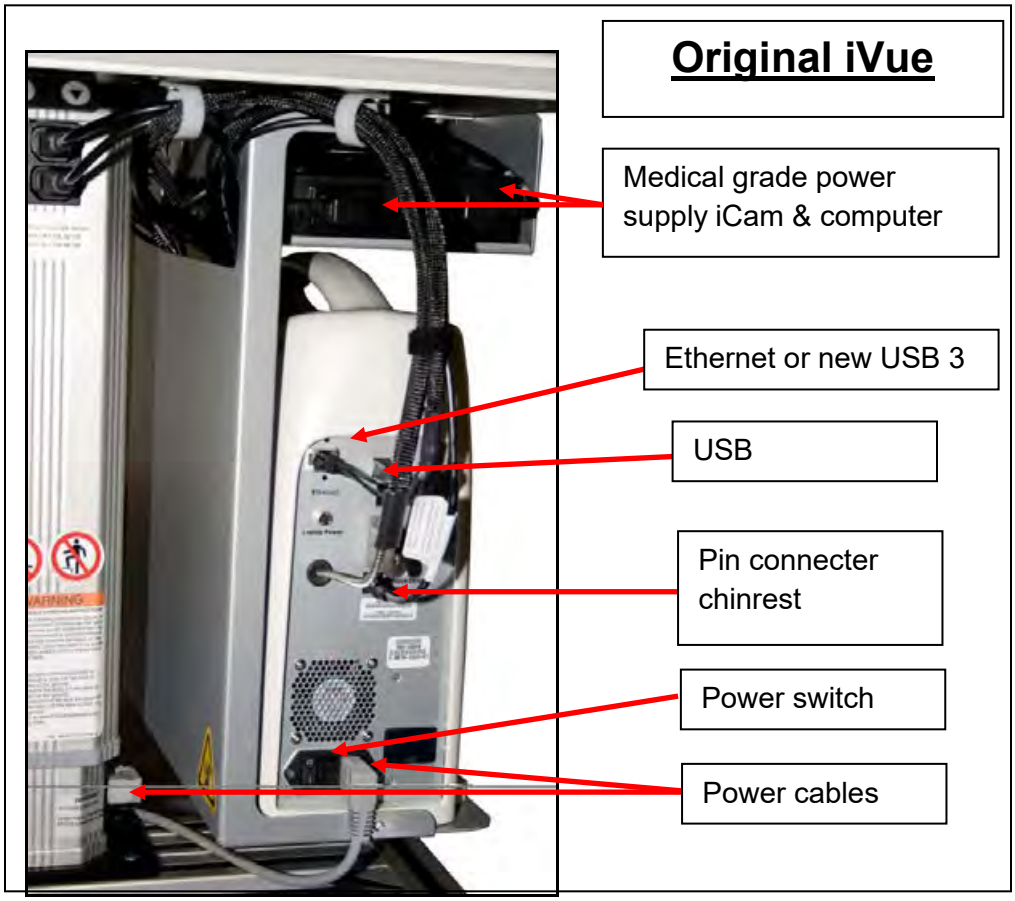


Camera Head Power Cord And Power Adapter Connected

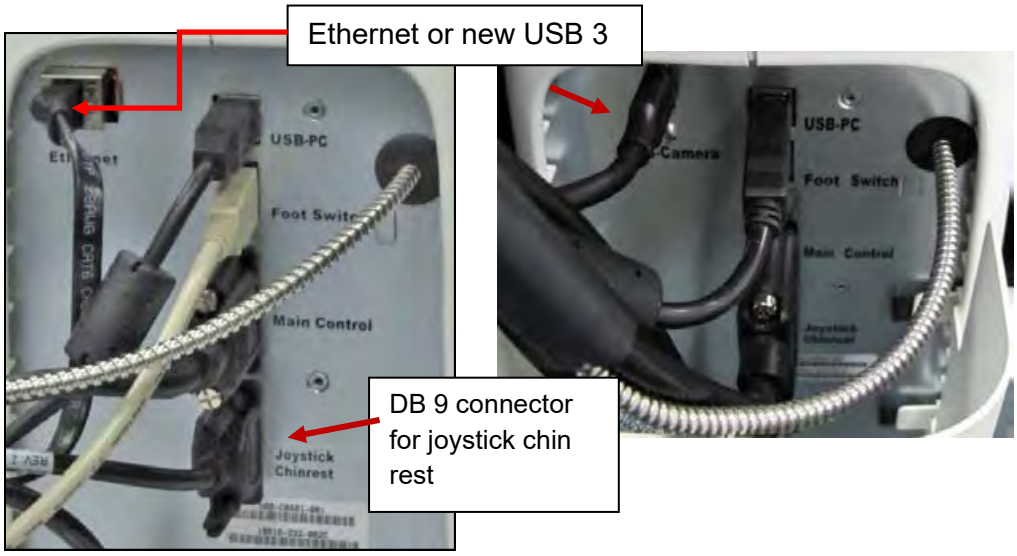
7. Insert the iVue power cord and computer power adaptor cord into the plug receptacles.

8. Attach the cables to the iVue 100 controller box. Connect the round pin cable from the chin rest, and the USB as shown in the figure below.

9. Plug in the iCam 100



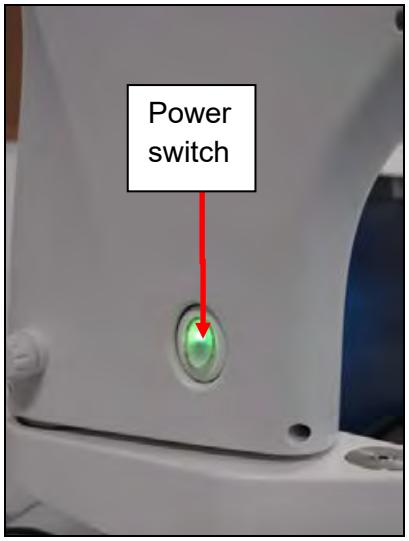
Original iVue 100 Control Box Cabling Connections



Current iVue Cabling With DB 9 Joystick Chin Rest Connector

4.3 Starting the System

This section describes the iFusion system startup.



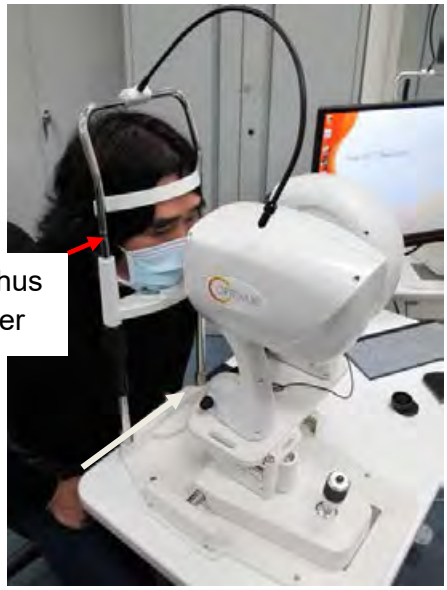
Power Switch on Camera Head

1. Click the power switch on the camera head to turn it on.
2. Turn on the iVue 100 controller power switch.
3. Start the computer by clicking the power button. After Windows™ has fully initialized, double click the iCam 100 icon on the desktop to launch the application. It may require approximately a minute or two for Windows™ to fully initialize.
4. Double click on the iVue 100 icon and wait for the iVue application to fully load.

5. Patient Imaging

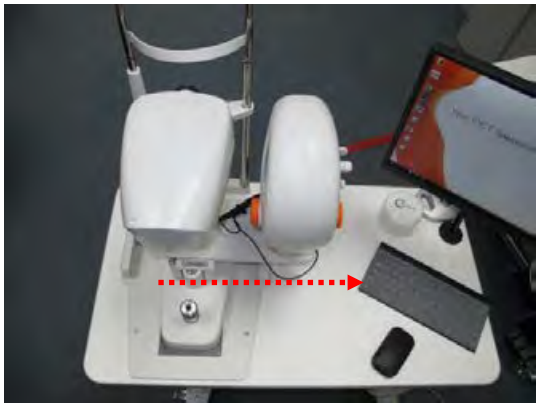
5.1 Patient And System Position

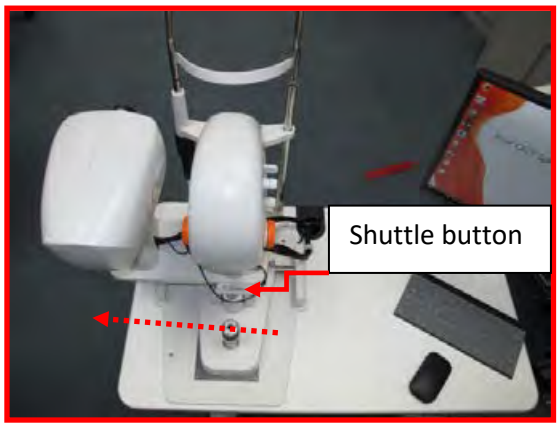
1. Ensure that either the iCam 100 or iVue 100 head is locked into the appropriate position on the iShuttle.
2. Pull the joystick into a position all the way back toward the operator and opposite the eye to be imaged.
3. Have patient sit in front and position the patient's head on the chin rest. The patient should be leaning slightly forward to help maintain good positioning. The patient's lateral canthus of the eye should be in parallel position with the indicator.
4. Scan or image as described per the appropriate iCam or iVue manual.



Patient Positioned In Forehead And Chin Rests With Canthus Marker

The iFusion shuttle, AKA the iShuttle, can be moved left or right to position either the iCam 100 or iVue 100 in front of the patient as shown in the figure below. Pull the joystick all the way toward the operator to position the iShuttle so that it does not contact the patient during the sliding process. Press the button and slide the platform. Ensure the iShuttle locks into place in either the iVue operative position (A) or the iCam operative position (B).





Position A

Position B

iCAM 100 And iVue 100 Positions With iShuttle Y-Axis Movement

5.2 Suggested Capture Sequence

1. With the joystick pulled back, position the iVue 100 head as the instrument to be used (with the iShuttle positioned so the iVue 100 head is over the joystick as shown in **position A).** Ensure the iShuttle locks in place.
2. Position the patient to the canthus marker using the chinrest adjustment.
3. Scan the right eye. Pull the iShuttle all the way back, move to the left eye and scan.
4. Pull the joystick all the way back. Push the iShuttle button and position the iCam 100 (iShuttle positioned with iCam 100 over joystick **position B**). Ensure iShuttle locks.

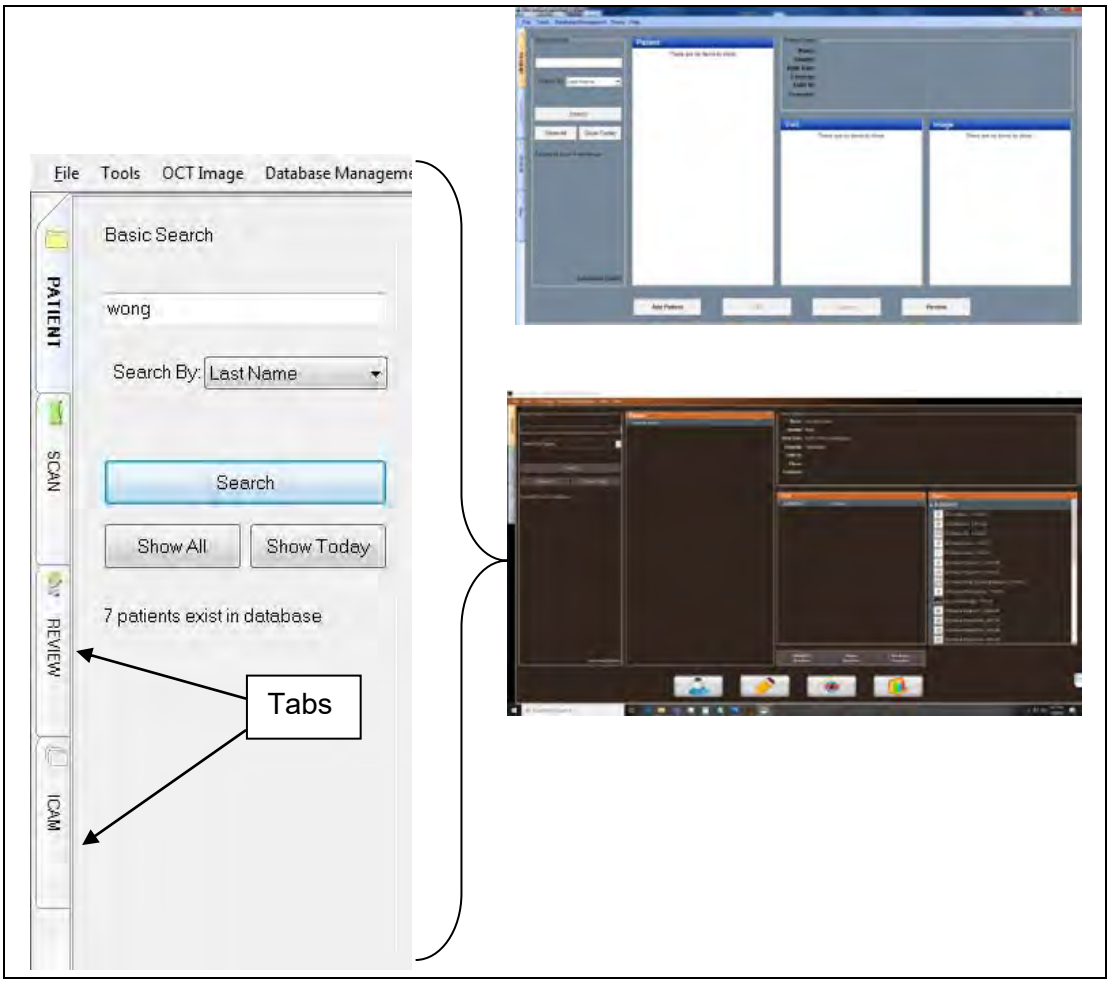
☞ **Note**: if one eye is of more interest, photograph that eye first as the flash may cause pupil constriction which could reduce visibility.

5. With the joystick all the way back, select the eye to be photographed.

6. Pull the joystick all the way back, position iCam in front of other eye and follow the steps to capture.

5.3 Beginning Image Capture

Please refer to both the iCam 100 and iVue 100 User's Guides for information on image capture. Switch between the vertical tabs shown here to display the associated software.



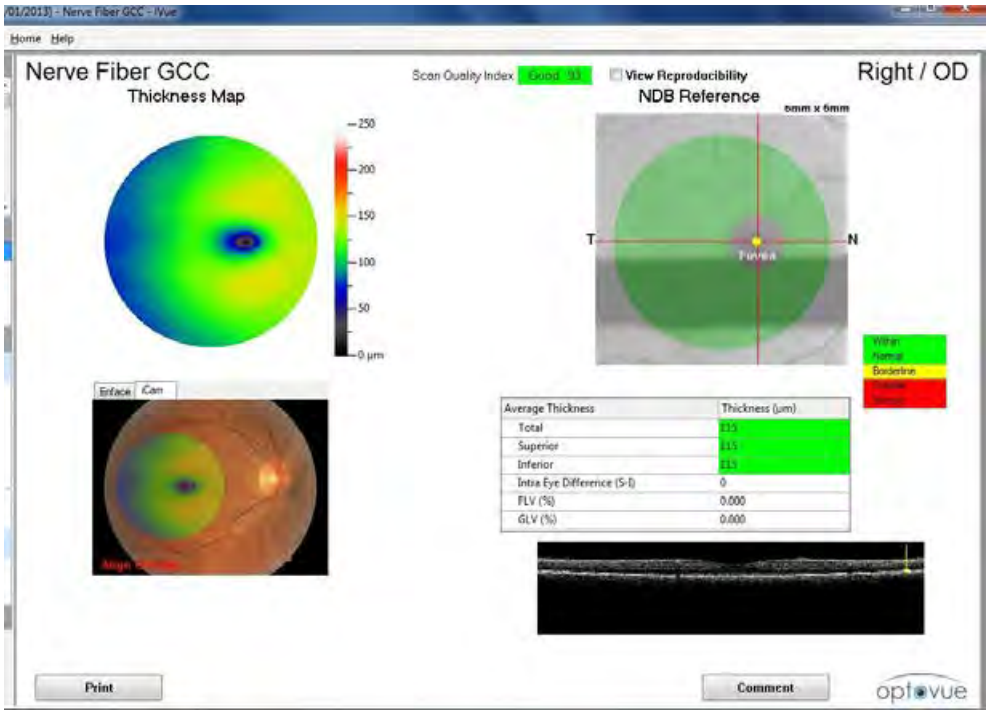
Software Selection Tabs to Switch Between Displays

5.4 Image Transfer From iCam

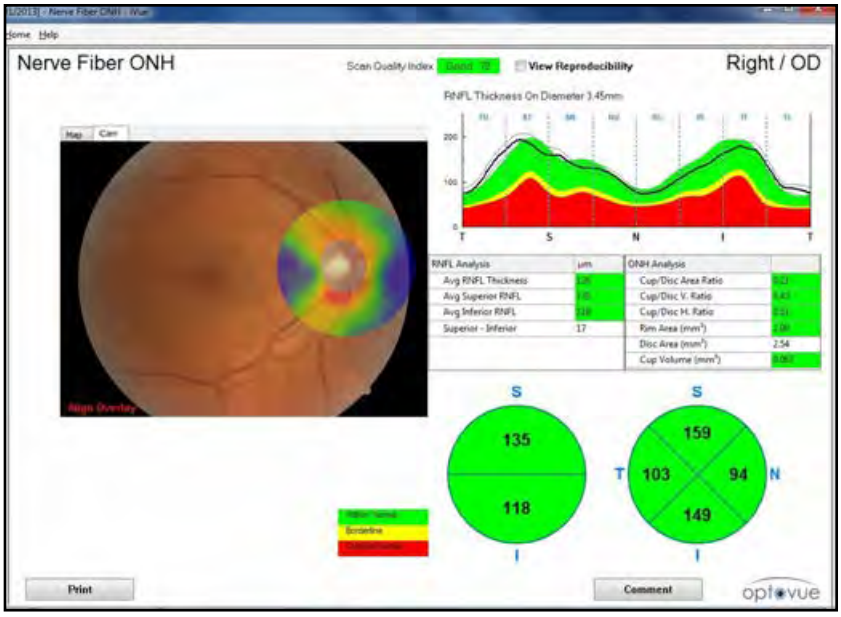
Fundus Image to Be Exported to iVue In REVIEW Mode

To export a fundus photo:

1. Right click on the iCam 100 image.
2. Select **Export to iVue**. The image will be transferred to the iVue 100 scans of that patient taken on the same day. This allows for easy visualization of the fundus photo and OCT image in the iVue 100 **REVIEW** mode.
3. Tabs will be displayed on the en face image of the 3-D retina, retina scan, 3-D Optic Nerve, ONH scan, GCC scan and iWellness.
4. The iCam image will be the default image if an image is transferred.
5. Open the iVue 100 scan. A tab will be displayed above the en face as shown in the figure on the next page.

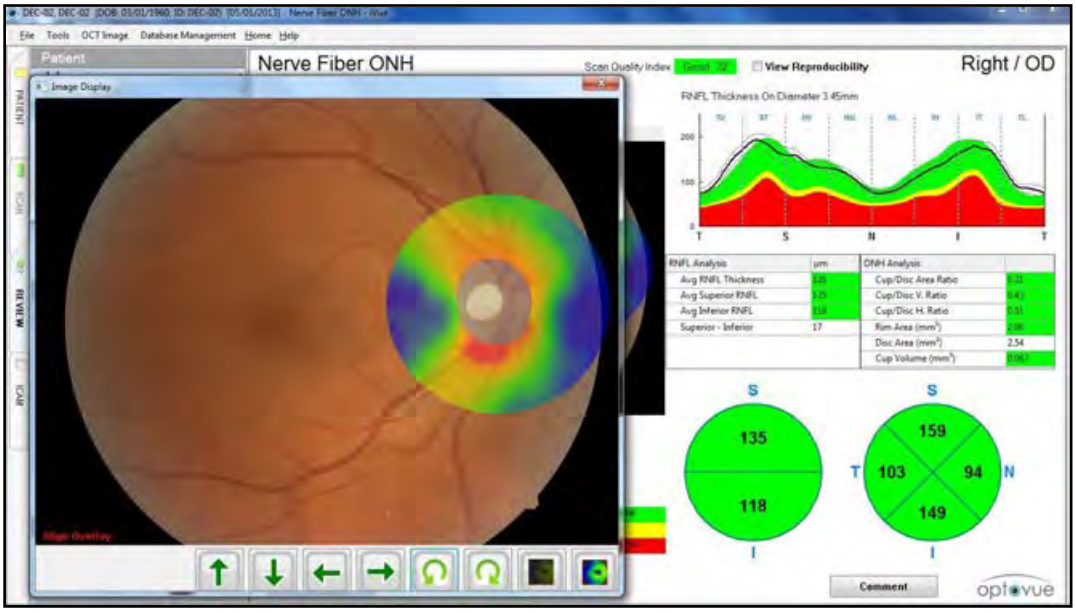


GCC Report With iCam 100 Image And iVue Thickness Map Overlay, Or En Face Image

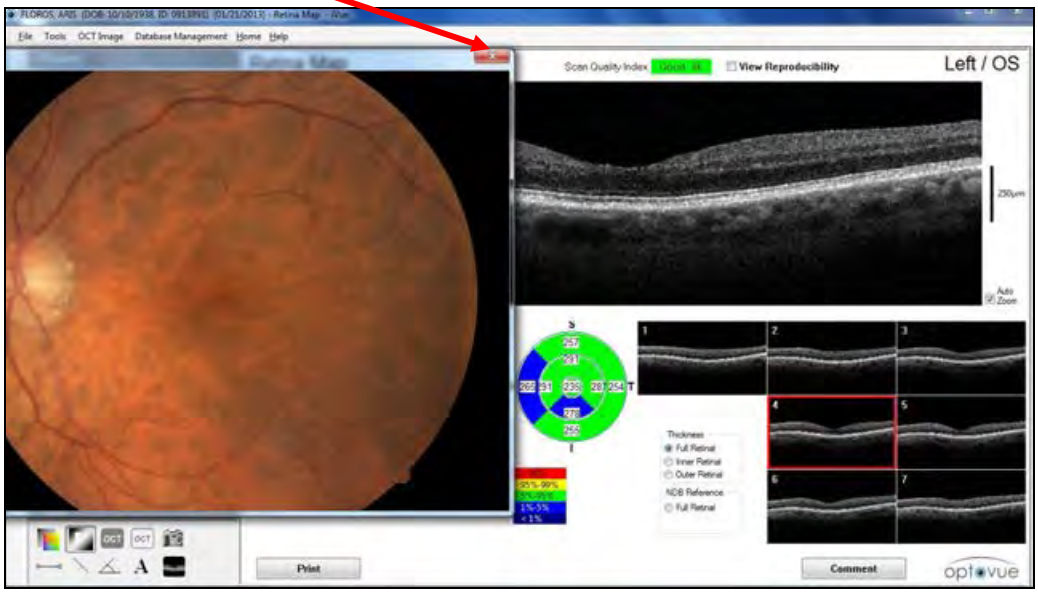


ONH Report With iCam Image And Thickness Map Overlay

ONH Report With Enlarged iCam 100 Image And Thickness Map



Double clicking on the iCam 100 image will open the fundus photo in a separate page. Overlays can be aligned at this time. (Section 6.1) Click the red box with **X** in the right corner to save and close the image.



Retina Map With Large iCam 100 Image

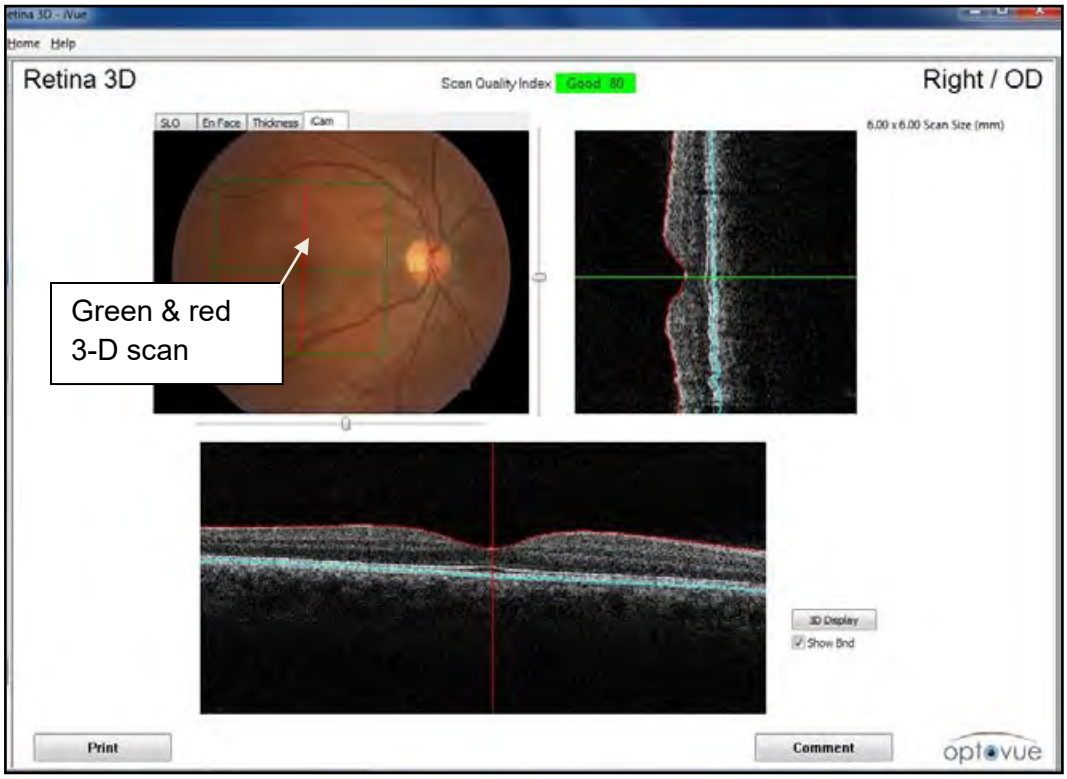
6. iFusion Overlay

Note: Please review and align all images.

All scans use the same process for overlay alignment.

6.1. Overlay Alignment Process

For 3-D scans the green box outlines the perimeter of the scan and the red and green cross lines can be used to view the B-scans on 3-D type exams as shown in the figure. Mapping scans have thickness maps instead of cross lines.



Scan Perimeter Green Box Overlaid on Retina 3-D Report

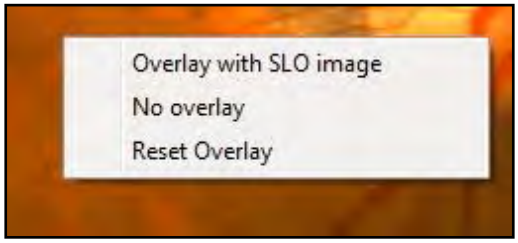
1. Check the **Scan Quality Index** rating, shown "**Good 80"** in green in the figure, and compare it to the table for the scan type.

Image Quality Classification Based On SQI Cutoffs

SQI	"Poor"
Retina	SQI < 40
Glaucoma	SQI < 27
Cornea	SQI < 27
GCC	SQI < 32
iWellness	SQI < 40

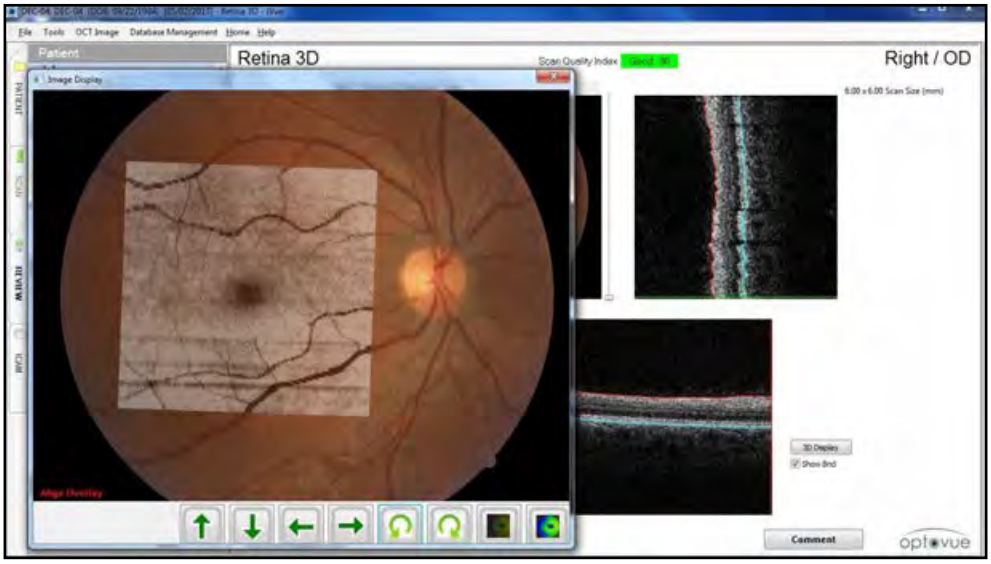
Ensure the quality is sufficient, i.e., **Greater than "Poor"** as shown in the table above, to continue the overlay alignment process.

2. Right click on the iCam image and the popup menu shown below is displayed.



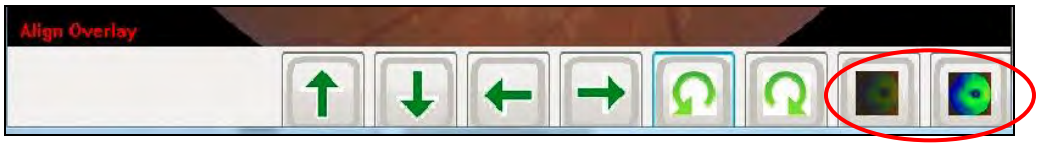
Overlay Menu

3. Select **Overlay with SLO image**. The overlay used to align the images is displayed over the fundus image as shown below with the **Align Overlay** toolbar.



Overlay With SLO Image With Align Overlay Message

4. The SLO image opacity can be adjusted using the two buttons located in the lower right of the popup window as shown in the figure, or by scrolling the mouse wheel.



Align Overlay Toolbar

5. Compare the vessel structure of the OCT SLO image with the Fundus photo vessels by adjusting the opacity of the SLO.

6. Examine the vessel pattern on the SLO and match it to the fundus image vessel pattern. Find a recognizable feature on the SLO (i.e. vessel bifurcation), click on that location and drag it to the corresponding location on the fundus image.

   ☞ **Note**: For smaller movements use the toolbar four directional arrows and two rotational arrows. Holding down the control key while clicking on the arrow button increases the size of each movement.

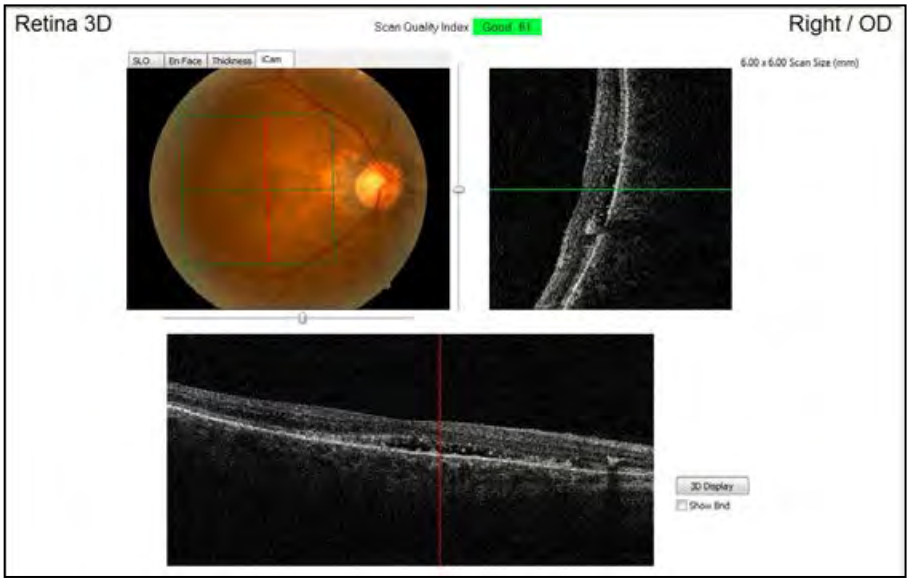
7. Select **No overlay** from the overlay menu and the overlay image is no longer displayed.

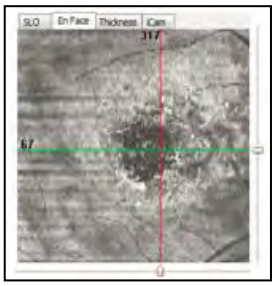
8. To reset an overlay and return it to the original position, select **Reset overlay** from the menu.

6.2 Retina 3-D Scan with Overlay

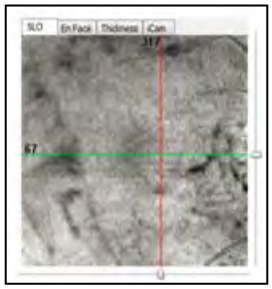
Click on the appropriate tab for the image type to be displayed, **SLO, En Face, Thickness,** or **iCam** as shown in the upper left corner of the fundus image below.

Note: Images corresponding to the other tabs are displayed below. The iCam image will have the OCT X and Y indicator lines superimposed.

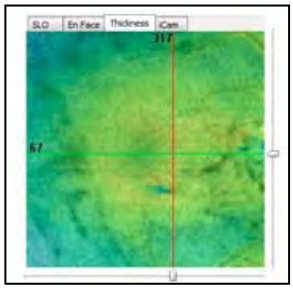




SLO



En Face



Thickness

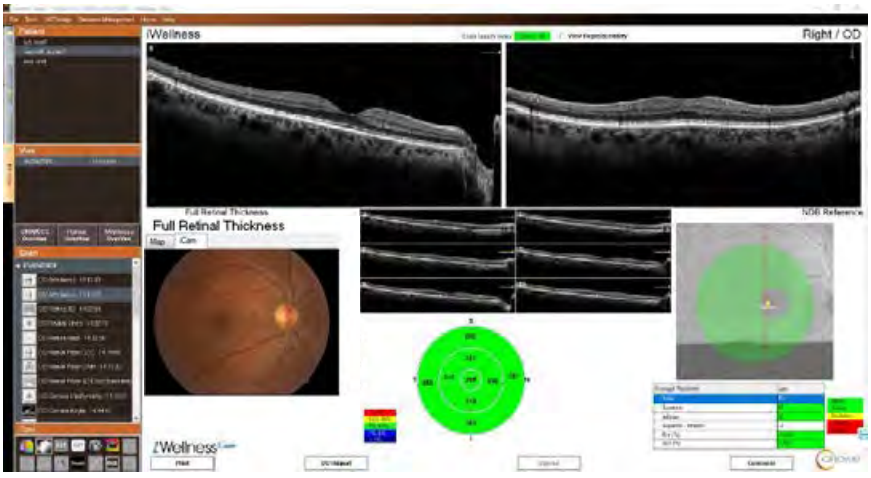
3-D Retina Example Showing iCam Image and Overlay: Also SLO, En Face, Thickness Images With Tabs Enabled

6.3 iWellness With iCam Image

☞ **Note**: iWellness is a separately purchased feature.

The figure below shows the iWellness report screen with the iCam image (overlay is not available).

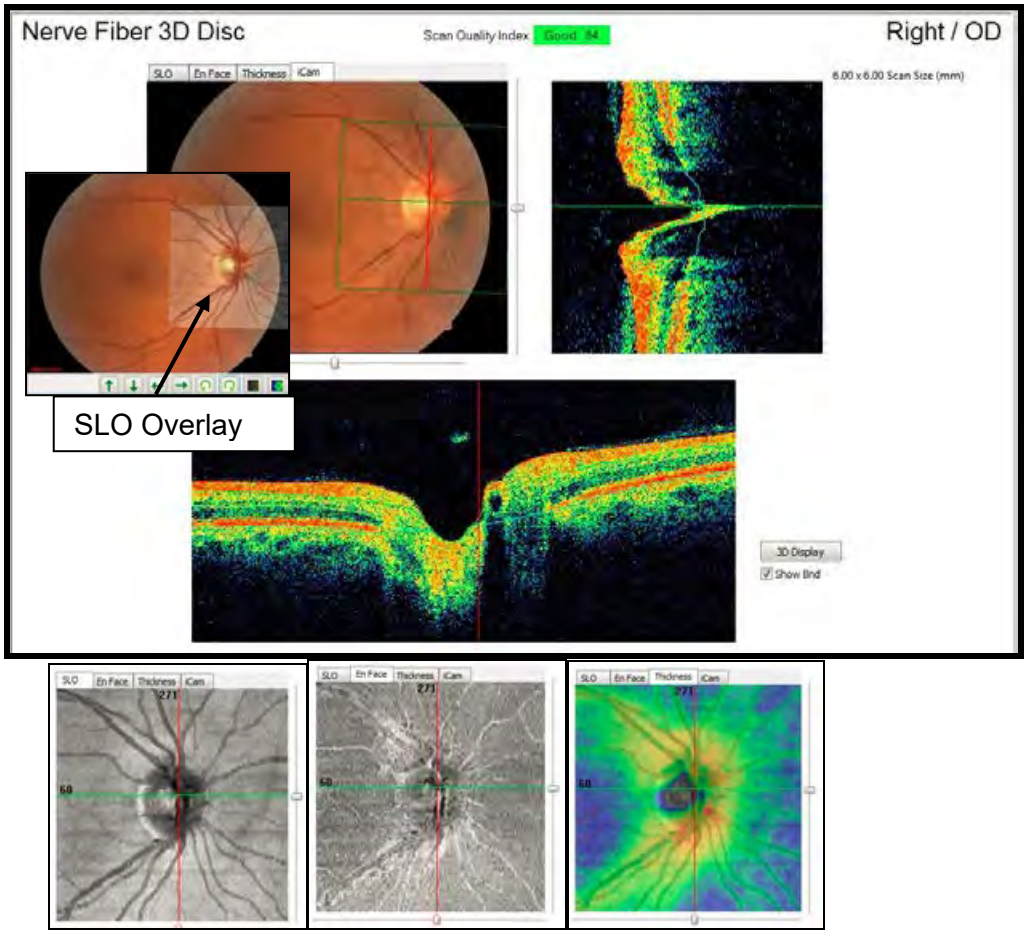
1. Click the **Map** tab to view the **Full Retinal Thickness** image. The GCC NDB reference image is superimposed on the retinal en face image.
2. Click the iCam tab above the image to display the original iCam image only.



iWellness Report Screen With iCam Image And Thickness Map

6.4 3-D Optic Nerve Scan with Overlay

A 3-D optic nerve scan is shown in the figure with an SLO overlay and three additional tab views: **SLO**, **EnFace**, and RNFL **Thickness**.

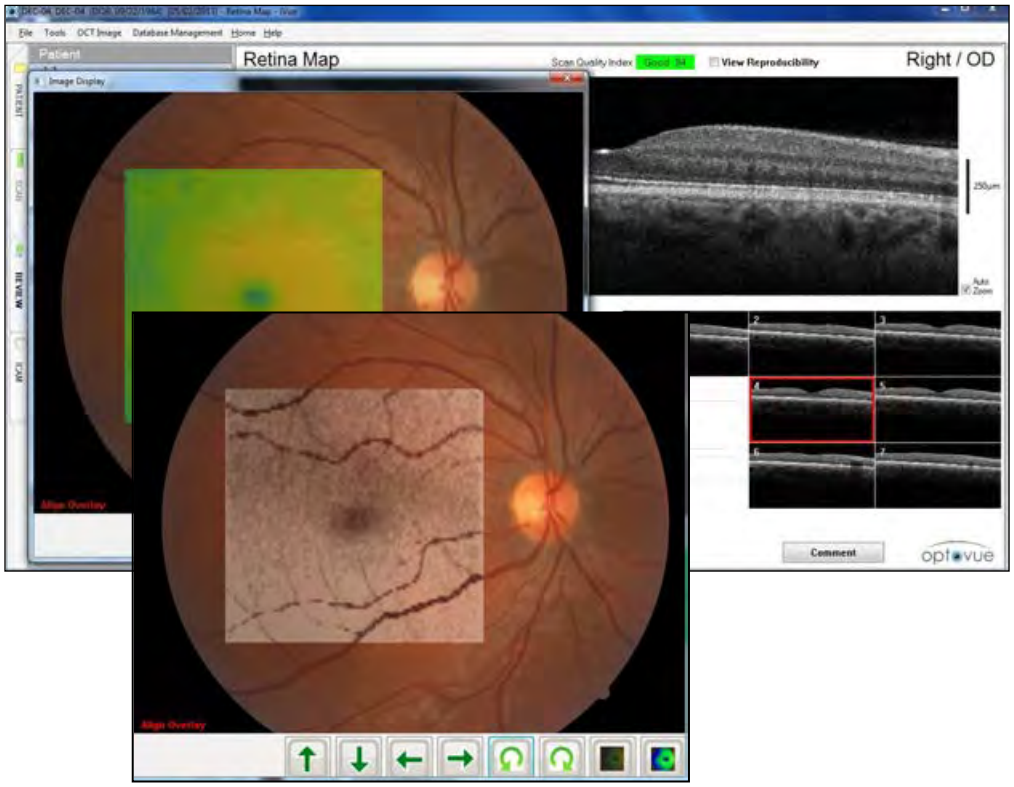


SLO **En Face** **Thickness**

3-D Optic Nerve Scan With OCT SLO Overlay And Three Tab-Generated Views

6.5 Retina Map with Overlay

A sample Retina Map report with iCam image showing a thickness map overlay and an SLO overlay is displayed below.



Retina Map Showing Thickness And SLO Overlays

6.6 Troubleshooting

The image overlay troubleshooting table below deals with fundus photo and OCT issues concerning alignment problems and the associated solutions.

Image Overlay Troubleshooting Table

Image Problem	Resulting Alignment Problem	Solution
Fundus Photo		
Central Macula Too Dark/Light	Difficult to find macular vessels to align retina map, 3-D retina, GCC	Increase/decrease brightness using iCam software, adjust contrast, or retake image
Poor Fundus Photo Contrast & Brightness	Difficult for all scans to align	Adjust brightness using iCam software, adjust contrast or retake image
Optic Nerve Area Too Dark/Light	Difficult for OMH scan & nerve fiber 3-D	Increase/decrease brightness using iCam software, adjust contrast, or retake image
Optic Nerve Not Centered In Image	Difficult for OMH scan & nerve fiber 3-D	Retake image
OCT Issues		
Poor Signal Strength Causes Poor En Face	Poor vessel outline difficult to align	Attempt manual alignment or retake OCT scan
En Face Image Blanks Caused By Blinks During Scanning	Misalignment along black line	Manual alignment & visible vessels
En Face Eye Movement Recorded As Horizontal Or Vertical Lines	Misalignment along horizontal & vertical lines	Manual alignment & visible vessels
Poor Fixation (Incorrect Area Scanned)	Fundus image & OCT differently located	Retake incorrect image

7. Product Specifications

7.1 iVue 100 Scanner & iCam 100

Please see individual manuals for details.

☞ **Note**: The environmental conditions that were specified for each product apply to the system as whole to ensure safety for all components and are the same as those for iVue 100 and iCam 100.

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8. Maintenance

Please refer to the iCam 100 and iVue 100 manuals for information on individual system maintenance.

8.1 Routine Care

8.1.1 Ocular (Front Objective) Lens and Cornea Lens Cleaning

It is recommended that the ocular (front objective) lens of the iVue 100 be cleaned weekly or as needed. A weak OCT image or blurry video fundus image may be caused by an unclean front lens (eyelash, finger or nose prints, or excessive environmental dust or dirt).

Material Required:

- Diluted acetone or lens cleaning solution
- Lens cleaning paper

Method:

Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until the lens is clean.

8.2 Forehead and Chin Rest

A biological barrier should be used for the chin rest and forehead rest on the iVue. Use the same disposable biological barrier tissues that you use on your other examination devices where the patient chin and forehead contact a surface. The tissues must be replaced before scanning each patient.

For forehead and chin rest maintenance, it is recommended to clean the surfaces periodically.

Material Required:

Disinfecting agent such as an anti-germicide or isopropyl alcohol; Cloth or cleaning towels

or wet isopropyl alcohol cleaning paper pad.

Method: Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the forehead and chin rest pads.

8.3 Instrument Body Cleaning

The iVue 100 and iCam 100 have no special protection against harmful ingress of water or other liquids (classified IPX0). To avoid damage to the instrument and cause a safety hazard, the cleaning solutions, including water, should not be directly applied to the device. Using a dampened cloth (without dripping), is a good method to clean the exterior surface of the enclosure.

Calibration and Maintenance

This equipment does not require routine calibration. Refer all other technical service maintenance to Optovue service personnel.

Detachable Parts: There are no detachable parts on the system.

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