CLARUS Ultra-Widefield Fundus Imaging
A comparative overview with Optos

Global marketing and Product Management
Department

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ZEISS CLARUS Fundus Imaging

Clinical and Workflow Advantages

Purpose and Intended Use

Both CLARUS and Optos are **advanced ultra wide-field fundus imaging systems** and provide utility equivalent in many clinical situations but there are situations where one is more aptly suited due to technological, feature, and design differences. This slide deck aims to provide a guide to help practices choose the best system in accordance to their clinical and patient priorities.

The following provides an objective summary of clinical situations comparing efficiency and efficacy of both systems based on published results. This was collaborated by ZEISS cross functional teams from Product Management, Clinical and Medical affairs.

Supporting published examples and excerpts are included in supplementary slides referenced in the summary tables.

ZEISS CLARUS Fundus Imaging
Clinical Advantages

Clinical Advantages	CLARUS	OPTOS	Comments	Reference Slide / Study
Early Detection of AMD	✓	X	CLARUS was considered superior for diagnosing neovascular AMD with high sensitivity and specificity	Slide 18
AMD Progression	✓	✓	Shows Equivalence	Slide 18
ETDRS with one shot capture (Early DR)	✓	✓	Shows Equivalence	Slides 9,10,11
Higher levels of DR Severity	✓	X	CLARUS DR Severity level higher than Optos	Slides 9,10,11
Glaucoma (Disc color & resolution)	✓	X	CLARUS due to true color and better resolution of ONH	Slide 21
Retinal Tear / Retinal Detachment	✓	✓	Shows Equivalence – depends on location within 4 quadrants	Slides 12, 16
Ocular Cancer	✓	X	CLARUS due to true color and better resolution of tumors, Optos losing inferior/superior FOV	Slide 18
Uveitis	✓	✓	Shows Equivalence	Slide 16
Lesions / Microaneurysms in superior	✓	X	Optos lid and lash prevents from viewing – limited capability	Slide 11
Lesions / Microaneurysms in inferior	✓	X	Optos lid and lash prevents from viewing – limited capability	Slide 11
Lesions / Microaneurysms in nasal	✓	✓	CLARUS is able to detect due to BLFI (Broadline Fundus Imaging)	Slide 11
Lesions / Microaneurysms in temporal	X	✓	CLARUS is able to identify more branches due to BLFI , Optos can see more temporal	Slide 11
Anterior Segment infections	✓	X	CLARUS has external eye modality to capture anterior seg	Article
Retinopathy of Prematurity (ROP)	✓	X	Study shows the pseudo color image acquisition by Optos could be a disadvantage	Slide 20
Pathologies in the Ora Serrata	X	X	Limited capabilities for both.	Article

ZEISS CLARUS Fundus Imaging
Technical and Workflow Advantages

Technology / Workflow Efficiencies	CLARUS	OPTOS	Comments	Reference Slide / Study
Imaging Modality: Color	✓	✓	CLARUS has True Color / Optos has Pseudo Color	Slide 18
Imaging Modality: FAF-B	✓	X	FAF-B is gold standard and Optos does not have it	Slide 23 (Tech Specs)
Imaging Modality: FAF-G	✓	✓	Equivalent	Slide 23 (Tech Specs)
Imaging Modality: IR	✓	✓	Equivalent (CLARUS- IR not available in US)	Slide 23 (Tech Specs)
Imaging Modality: RGB separation	✓	✓	CLARUS has RGB separation and export. Optos Daytona/California RG do not have Blue channel.	Slide 23 (Tech Specs)
Imaging Modality: FA	✓	✓	Equivalent –CLARUS can capture early phase FA	Slide 23 (Tech Specs)
Imaging Modality: ICG	X	✓	**ICG is coming for CLARUS (FY 24)**	Slide 23 (Tech Specs)
Imaging Modality: External Eye	✓	X	Optos cannot capture external eye, need add'l device	Slide 23 (Tech Specs)
Contact-less Imaging	✓	X	Optos still requires operator to manipulate patient's head for alignment	Slide 14, 20
IR-preview for patient alignment	✓	X	CLARUS has Live IR Preview to align and review prior to capture.	Slide 14
Re-position patient for other eye	✓	X	CLARUS does not require this. For Optos, this increases time in workflow.	Slide 14
High resolution images	✓	X	7 µm in CLARUS vs 14 µm in Optos	Slide 23 (Tech Specs)
Browser–based Review	X	✓	CLARUS uses FORUM/ workplaces and Review s/w	Slide 23 (Tech Specs)
Ultra-widefield imaging	✓	✓	CLARUS has capability to do both 133 □ and 200 □ FOV	Slide 23 (Tech Specs)
Mydriatic / Non-mydriatic	✓	✓	Equivalent	Slide 23 (Tech Specs)

ZEISS CLARUS Fundus Imaging
Clinical and Workflow Advantages

To summarize: CLARUS has several Clinical and Workflow/Technology advantages over Optos

- **Clinical Advantages**
  - For early detection of AMD
  - For assessment of severity of diabetes
  - For Glaucoma
  - For Ocular tumors
  - For ROP and neonatal exams
  - For documentation of ocular adnexa

Reference Studies

Assessment of diabetic retinopathy using two ultra-wide-field fundus imaging systems, the Clarus® and Optos™ systems (Slide 19)

Sensitivity and specificity of high-resolution wide field fundus imaging for detecting neovascular age-related macular degeneration (Slide 17)

Applications of Widefield Imaging in Ocular Oncology (Slide 18)

Optic Disc Segmentation Based on Active Contour Model for Detection and Evaluation of Glaucoma on a Real-Time Challenging Dataset (Slide 21)

Non-contact widefield neonatal retinal imaging (NC-WFI) for retinopathy of prematurity using the Clarus 700 high resolution true color reflectance imaging (slide 20)

clarus-500-from-zeiss-analysis-and-interpretation-guide.pdf

- **Workflow Efficiencies**
  - Additional imaging modalities vs Optos (all in one system w/ FAF B and Ant Seg)
  - No-Contact imaging (Slides 16, 20)
  - Patient alignment without repositioning (Slide 16)
  - Eyelash image occlusion removal with partial confocal optics and broadline fundus imaging
  - Integral to the ZEISS Retina and Glaucoma Workflows (FORUM, Workplaces) for more diagnostic data (registration with OCT/OCTA)
  - SMART Services 2.0
  - Cybersecurity features included to comply with latest standards (Slide 22)

Studies and Reference Slides

It’s proven 1 CLARUS image with 133 ? FOV covers 7-field ETDRS

Reference Studies

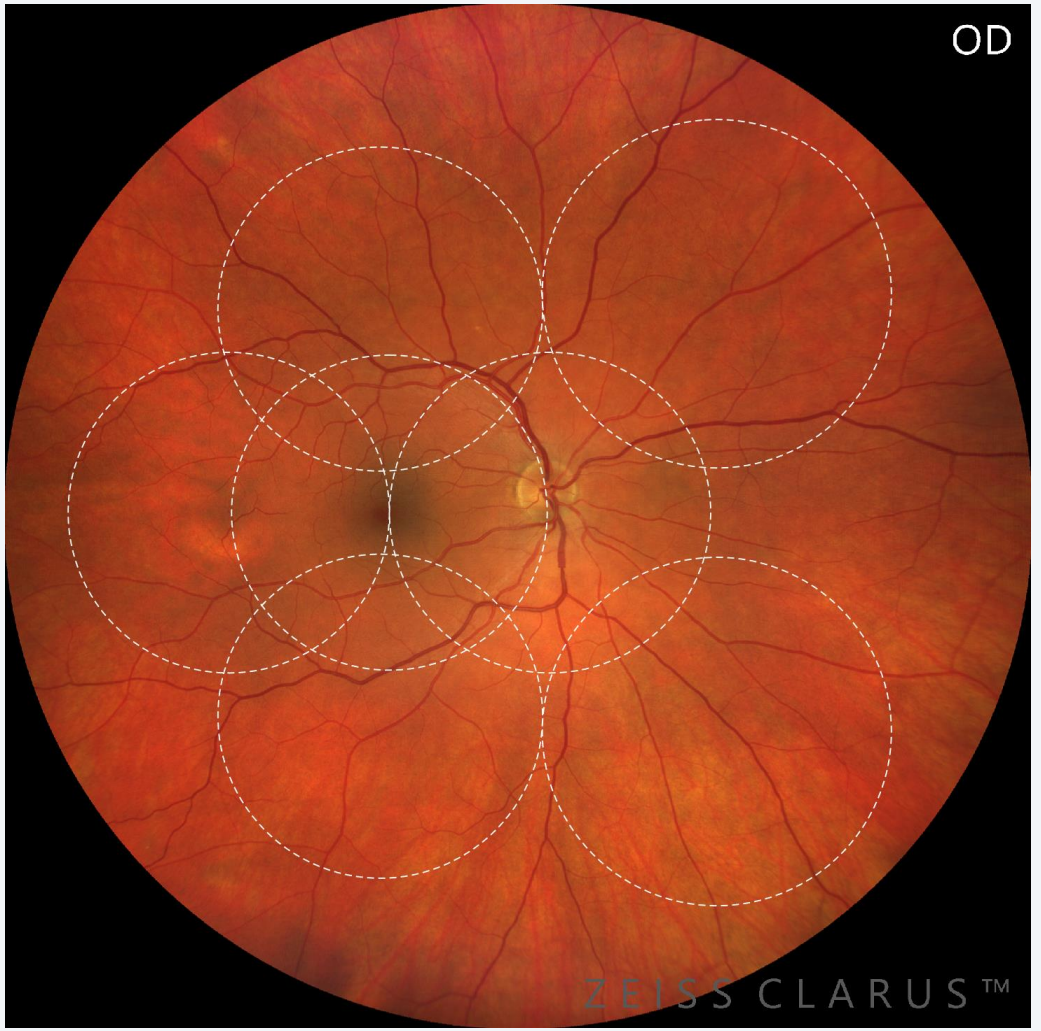
Comparison of quantitative assessment and efficiency of diabetic retinopathy diagnosis using ETDRS seven-field imaging and two ultra-widefield imaging

Link: https://doi.org/10.1038/s41433-023-02549-1

Ultra-widefield fundus imaging using CLARUS improves ETDRS grading with classic 7-field fundus photographs

https://iovs.arvojournals.org/article.aspx?articleid=2787616

- UWF-Clarus fundus imaging offers a suitable assessment approach for DR severity; it could improve DR diagnosis and has the potential to replace ETDRS seven-field imaging after additional clinical trials.
- …it is quite challenging to capture small retinal DR lesions using UWF-Optos fundus imaging.
- …eyelashes and eyelids can prevent clear imaging of peripheral fundus areas.
- These issues might affect the assessment of DR severity level. The UWF-Clarus fundus imaging can avoid these issues when assessing DR severity level.
- Notably, its [CLARUS] partially confocal optics can reduce artifacts in retinal images caused by eyelashes and eyelids, and it features true color imaging combining red, green, and blue scanning laser ophthalmoscopy scans with a high-resolution of 7.3 microns [16].



Quantitative assessment and efficiency of DR

The ROYAL COLLEGE of OPHTHALMOLOGISTS

www.nature.com/eye

ARTICLE

Check for updates

Comparison of quantitative assessment and efficiency of diabetic retinopathy diagnosis using ETDRS seven-field imaging and two ultra-widefield imaging

Yuanyuan Xiao[1], Zixu Huang[1], Qiongqiong Yuan[1], Xiaofeng Du[1], Zeyu Li[1], Xiaodong Nie[1], Qianqian Shi[1], Handong Dan[1]✉ and Zongming Song[1]✉

PURPOSE: This study compared the efficiency of diabetic retinopathy (DR) diagnosis and differences in the relative visible retinal area among the Early Treatment Diabetic Retinopathy Study (ETDRS) seven-field, ultra-widefield (UWF)-Optos, and UWF-Clarus fundus imaging methods.
METHODS: This was a prospective and clinic-based comparative study. All patients underwent three fundus examinations, and all images were graded using the ETDRS severity scale. We compared and analysed the agreement of DR severity and the relative visible retinal area among the three fundus examination methods, and the number and type of lesions outside the ETDRS seven-field (peripheral lesions) between the two UWF imaging methods.
RESULTS: A total of 202 patients (386 eyes) were included. Weighted kappa for the agreement between ETDRS seven-field and blinded Optos images was 0.485; between ETDRS seven-field and blinded Clarus images, 0.924; and between blinded Optos and Clarus images, 0.461. Blinded Clarus showed excellent performance when a ETDRS scale was used for grading the images. The relative visible retinal area for ETDRS seven-field images was 195 ± 28 disc area (DA); single Optos images, 371 ± 69 DA; single Clarus images, 261 ± 65 DA; two-montage Clarus images, 462 ± 112 DA; and four-montage Clarus images, 598 ± 139 DA. The relative visible retinal area was statistically significant between any two of the imaging systems used. In total, 2015 and 4200 peripheral lesions were detected in single Optos and Clarus images, respectively ($P < 0.001$). These peripheral lesions on two UWF images suggested a more severe DR level in approximately 10% and 12% of eyes, respectively.
CONCLUSION: UWF-Clarus fundus imaging offers a suitable assessment approach for DR severity; it could improve DR diagnosis and has the potential to replace ETDRS seven-field imaging after additional clinical trials.

Eye; https://doi.org/10.1038/s41433-023-02549-1

Link: https://doi.org/10.1038/s41433-023-02549-1

- …eyelashes and eyelids can prevent clear imaging of peripheral fundus areas.
- Notably, its [CLARUS] partially confocal optics can reduce artifacts in retinal images caused by eyelashes and eyelids, and it features true colour imaging combining red, green, and blue scanning laser ophthalmoscopy scans with a high-resolution of 7.3 microns [16].

Inconsistencies in DR severity after side-by-side analyses were caused primarily by the following factors:

- first, fundus pigmented nevus and/or vitreous cavity turbidity in 8 (2.1%) eyes were misclassified as haemorrhages and/or microaneurysms in blinded Optos images;
- second, haemorrhages and/or microaneurysms in 87 (22.5%) eyes, intraretinal microvascular abnormalities in 33 (8.5%) eyes, and new vessels on the disc or/and new vessels elsewhere in 29 (7.5%) eyes were not detected in blinded Optos images.
- Comparisons of DR severity between ETDRS seven-field and blinded Clarus images yielded exact matches for 362 (93.8%) eyes, with an almost perfect agreement (weighted Kappa 0.924 [95% CI 0.893–0.952]).
- The blinded Clarus images captured more lesions, therefore, establishing amplified DR severity in the grading.

Ultra-widefield fundus imaging using CLARUS improves ETDRS grading with classic 7-field fundus photographs

PURPOSE

- To analyze and compare grading of diabetic retinopathy (DR) severity level using standard 30° Early Treatment Diabetic Retinopathy Study (ETDRS) 7-field photography and CLARUS 500 ultra-widefield (UWF) imaging system.

METHODS

- A cross-sectional analysis of retinal images from 63 patients having type 2 diabetes with varying degrees of DR was performed. A total of 123 eyes from these 63 patients were considered for analysis.
- Inclusion criteria involved eyes from patients between ages 18 to 90, across a range of ETDRS levels of 10-65, and with visual acuity of at least 20/40 or 20/200 for diabetic macular edema (DME) cases.
- Eyes with significant media opacity and previous photocoagulation treatment were excluded from the final dataset.
- All patients underwent 7-field color fundus photography (CFP) at 30° on a standard Topcon TRC-50DX® camera and UWF imaging at 135° on a CLARUS™ 500 (ZEISS, Dublin, CA) by an automatic montage of two 90° images (nasal and temporal).
- 7-field photographs were graded by two graders, according to the ETDRS criteria.
- For CLARUS UWF images, a 7-field grid was applied using prototype CLARUS software, and the same ETDRS grading procedures were performed inside the grid area only.
- Grading of DR severity level was compared between these two methods to evaluate the agreement between both imaging techniques.

ETDRS severity grading from CLARUS showed agreement with 7-field photography and improved ability to detect IRMA

7-Field CFP \ CLARUS CFP	10-15	20	35	43	47	53	61	n
10-15	0	4	3	0	0	0	0	7
20	0	2	5	0	0	0	0	7
35	0	1	38	14	5	0	0	58
43	0	0	6	16	8	1	0	31
47	0	0	1	2	7	4	0	14
53	0	0	0	0	0	5	0	5
61	0	0	0	0	0	0	1	1
n	0	7	53	32	20	10	1	123

Eyes with lower severity level in CLARUS 500: 10 (8%)
Eyes with higher severity level in CLARUS 500: 44 (36%)
Eyes with same severity in CLARUS 500 as in 7-field CFP: 69 (56%)

ETDRS severity level: 7-Field CFP		Clarus CFP	N	% of higher/lower severity with CLARUS
10-15	→	20	4	57%
10-15	→	35	3	43%
20	→	35	5	71%
35	→	43	14	24%
35	→	47	5	9%
43	→	47	8	26%
43	→	53	1	3%
47	→	53	4	29%
35	→	20	1	2%
43	→	35	6	19%
47	→	35	1	7%
47	→	43	2	14%

Table 1: (Left) Displays the distribution of subjects showing lower, higher or same ETDRS grading in CLARUS 500 compared to 7-Field CFP, (Right) displays the percentages associated with disagreement of ETDRS grading

Figure 1: (a) Displays a CLARUS 500 UWF image which shows higher severity grading, (b) with a lower severity grading than 7-Field CFP due to possible artifacts caused by blurred zones, opacities, or poor dilation.

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Disclosures: SG (E), JGCV (C) – Carl Zeiss Meditec, Inc.; ML, ARS, SR, TS, DRF - None

RESULTS

- According to the CFP 30° images, 14 eyes were considered DR severity level 10-20, 58 eyes were considered level 35, 31 eyes level 43, 14 eyes level 47, 5 eyes level 53 and 1 eye level 61.
- The same DR severity level was achieved with CLARUS 500 UWF images in 56% of the cases.
- However, 44 eyes (36%) showed a worse DR level with UWF images, mostly due to a better visualization of hemorrhages and a higher detection of intraretinal microvascular abnormalities (IRMA).
- Only 8% (n=10) of the cases showed a decrease in severity level with CLARUS 500 system, mainly due to the presence of artifacts in the montage junctions of the 2 images (blurred zones) and presence of cortical cataracts.

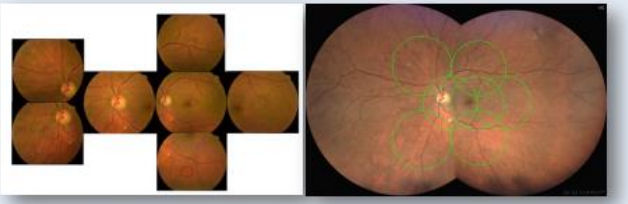


Figure 2: Comparison of 7-field CFP vs. CLARUS UWF CFP

CONCLUSIONS

- The UWF CLARUS 500 system showed a considerable agreement with standard 30° 7-field CFP in all ETDRS levels in images with unambiguous structures.
- CLARUS images showed an improved ability to detect IRMA and to evaluate hemorrhage severity demonstrating that one UWF montage image comprising of 2 widefield CLARUS images can be used to grade DR severity more accurately owing to efficient workflow with overall superior image quality and visualization.

Clinical situations sacrificed due to eyelash artifacts with OPTOS

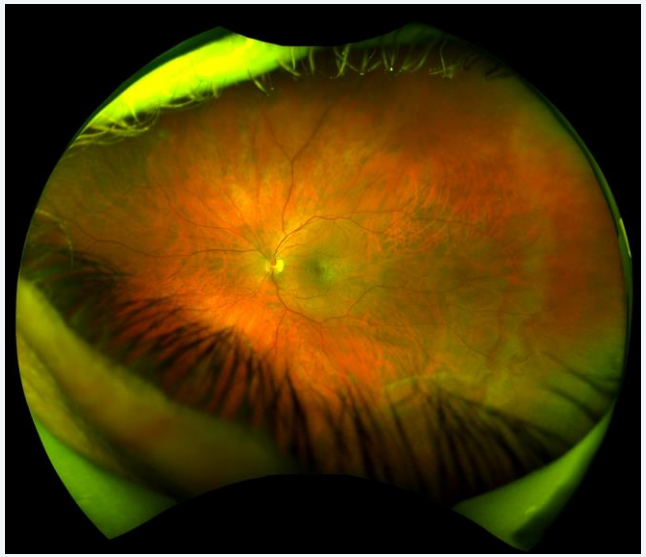
Although both Clarus and Optos cover 200 degrees**, Clarus allows for better visualization of the inferior-nasal field** while Optos allows for better visualization of the temporal field. Retinal detachment, tears and DR can be missed. Early diabetics with small/dot blot or micro aneurysms can be mask by lid and lashes.

Comparison of Two Ultra-Widefield Cameras With High Image Resolution and Wider View for Identifying Diabetic Retinopathy Lesions
https://tvst.arvojournals.org/article.aspx?arti

The Sensitivity of Ultra-Widefield Fundus Photography versus Scleral Depressed Examination for Detection of Retinal Horseshoe Tears
https://pubmed.ncbi.nlm.nih.gov/37468086/

Comparisons of Effective Fields of Two Ultra-Widefield Ophthalmoscopes, Optos 200Tx and Clarus 500 (2019)
https://doi.org/10.1155/2019/7436293

Quantitative Comparison of Fundus Images by Two Ultra-Wide Field Fundus Cameras
https://pubmed.ncbi.nlm.nih.gov/32866664/



- Eyelash artifacts may confound the diagnosis, obscure the retina and require reimaging to generate a usable image. This would especially cause an issue with high volume practices that do not have time to reimage.
- Optos imaging - there was 74% and 45% sensitivity for detection of lesions posterior and anterior to the equator, respectively, but **noted challenges to the inferior periphery due to eyelash obstructions.**
- Another study of 34 patients with RRDs evaluated by Optos imaging also noted that the **detection of retinal holes, tears and post-operative scarring was particularly poor in the superior and inferior poles**

Missed HST using UWF (Optos) due to lashes

The Sensitivity of Ultra-Widefield Fundus Photography versus Scleral Depressed Examination for Detection of Retinal Horseshoe Tears

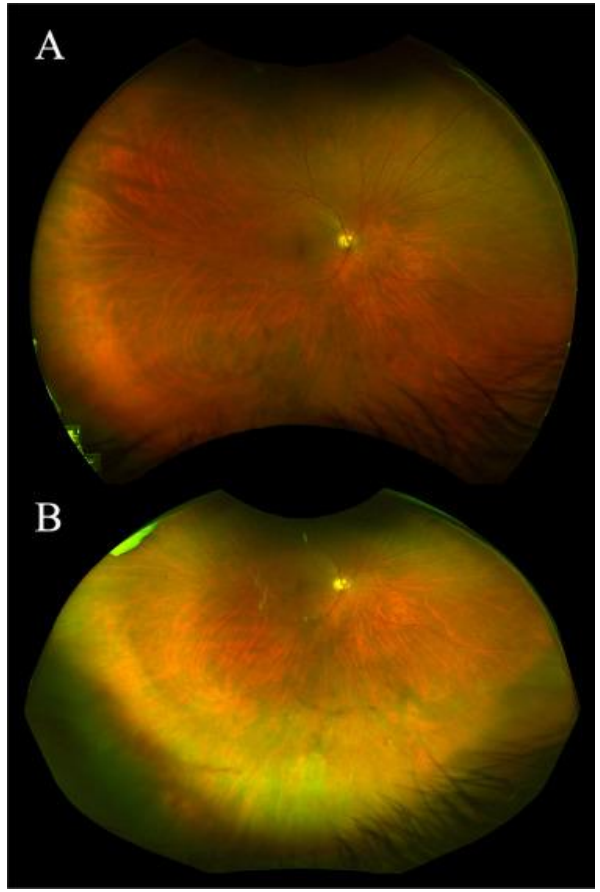
Andrew C. Lin [1], Fritz Gerald P. Kalaw [1 2], Etienne M. Schönbach [1], Delu Song [1], Zachary Koretz [1], Evan Walker [1], Mark P. Breazzano [3 4], Nathan L. Scott [1], Shyamanga Borooah [1], Henry Ferreyra [1], Doran B. Spencer [1], Michael H. Goldbaum [1], Eric D. Nudleman [1], William R. Freeman [1], Christopher B. Toomey [1 5]

https://doi.org/10.1016/j.ajo.2023.07.010

ABSTRACT

Purpose

Ultra-widefield (UWF) imaging is commonly used in ophthalmology in tandem with



"We found that nearly half of HSTs diagnosed on SDE were not visible on screening UWF imaging (Optos), with the majority of missed HSTs located in the superior quadrant."

Comparing field of view in ultra-widefield fundus imaging

Charles M Wu, BS; Keith Brock, BS; Michael Chen, OD
Carl Zeiss Meditec, Inc., Dublin, CA

Poster# 1565 - A0325

PURPOSE

The ISO standard for ophthalmic fundus imaging 10940-2009 defines angular field of view (FoV) as the largest angle subtended at the exit pupil for the eye. According to this standard, CLARUS and OPTOS have comparable FoV for ultra-widefield (UWF) images. For a clinician, however, it may be more important to understand the usable FoV in terms of clinically relevant features that are not obscured. The purpose of this study was to characterize the usable FoV for two UWF retinal imaging systems.

METHODS

- UWF images were acquired using both the CLARUS™ 500 (ZEISS, Dublin, CA) and Optos® UWF system (Optos, Marlborough, MA)
- The red-reflectance images were analyzed to determine how many of four vortex vein ampullae (VVA) (1 per peripheral quadrant) were seen by a clinician according to the criteria used in a clinic for whether or not additional peripheral shots are needed (Figure 1 left shows 4 ampullae visible, Figure 1 right shows only 3 ampullae which may require a rescan)
- Early treatment diabetic retinopathy (ETDRS) seven standard 30° fields were overlaid on the images without accounting for distortion due to optics
- The overlaid images were evaluated to determine how many of the seven fields were impacted by artifact.

CONCLUSION

Using the two separate analyses we found that less of the retina was obscured by artifacts in the CLARUS images than in the Optos UWF images. It is likely that the partially confocal broad-line fundus imaging used in Clarus™ system helps in reducing lid and lash artifacts.

Reference:
Hirano, Takao, et al. "Assessment of diabetic retinopathy using two ultra-wide-field fundus imaging systems, the Clarus® and Optos™ systems." *BMC ophthalmology* 18.1 (2018): 332.

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Disclosures: CW(C), KB(E), MC(E): Carl Zeiss Meditec, Inc.

RESULTS

- 44 images were acquired from 22 subjects
- 17 images, including both eyes from 6 subjects, and one eye each from 5 subjects, were excluded for having insufficient quality images for clinical grading, leaving a total of 27 images from 16 subjects to be evaluated.
- CLARUS was able to image an average of 3.1 out of 4 VVA searched for, while the Optos ® had 1.5 out of 4 searched for (Figure 1).
- Out of 7 ETDRS 30° fields, an average of 1.1 fields per image were obscured in CLARUS. (Figure 2 left).
- Out of 7 ETDRS 30° fields, an average of 1.8 fields per image were obscured in Optos. (Figure 2 right).

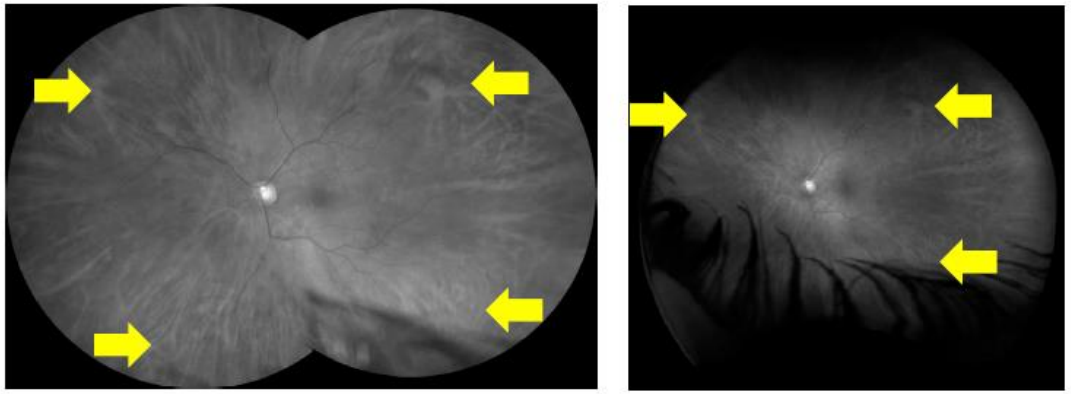


Figure 1. Determining visibility of VVA in red-reflectance UWFI using Clarus (left) Optos (right).

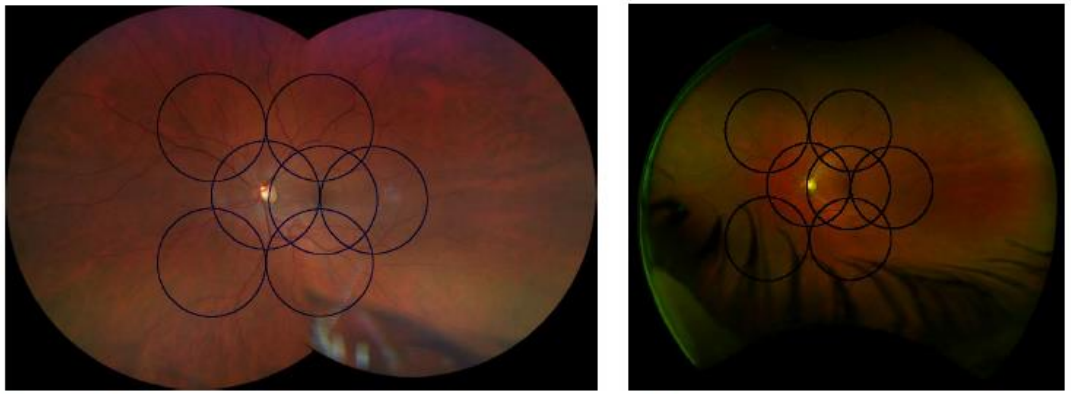


Figure 2. ETDRs fields used to examine obscuration Clarus (left) Optos (right).

Acknowledgement: Susan Su, O.D, Carl Zeiss Meditec, Inc., for grading the ETDRS images

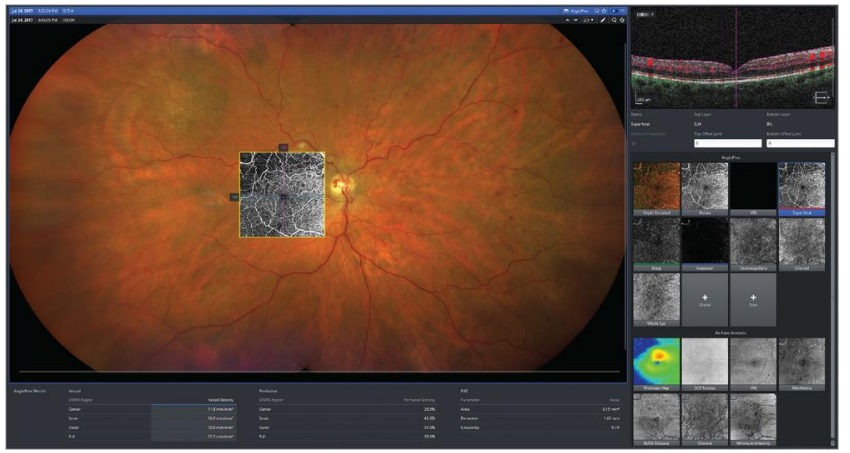
Workflow Efficiencies with CLARUS

- **Imaging modalities all-in 1 system to decrease patient chair time**

- **Patient Comfort – contactless and easier alignment**
  - CLARUS truly non-contact (patient vs device, patient vs user)
  - Fewer recaptures with CLARUS Live IR preview vs manual patient alignment with OPTOS.
  - Supports neonatal and pediatric patients (CLARUS better for ROP)
  - Gazepoint feature – Find the ONH quickly and accurately
  - No need to reposition patient for fellow eye

- **ZEISS SMART SERVICES** for higher uptime of connected devices and high-performance

- **Connectivity with ZEISS FORUM and auto-registration to OCTA for <u>overlay</u>** <u>allows</u> you to quickly see both FI and OCT on one screen.



A deep learning approach to patient alignment and retina tracking

Muzammil A Arain, PhD; Niranchana Manivannan, PhD; Homayoun Bagherinia, PhD; and David Nolan, MS
Carl Zeiss Meditec, Inc., Dublin, CA.

Poster # 6120 - A0617

PURPOSE

Optical nerve head (ONH) can be used as a key point to track the eye motion. ONH tracking can be used for:

- Initial patient alignment
- Registration of montage images for widefield fundus images
- Registration of images among different visits

We demonstrate a deep learning based approach for fast, accurate, and robust ONH tracking using the **widefield infrared (IR) fundus imaging mode** in CLARUS™ 500 instrument (ZEISS, Dublin, CA)

Robust patient alignment and retina tracking using deep learning

METHODS

Data Collection:

- Widefield IR preview images were collected on a CLARUS 500 instrument as part of an IRB approved study
- Images were collected @ **10 frames per second**
- Some subjects were asked to intentionally look around to simulate poor fixation
- A total of six eyes were imaged

Deep learning algorithm:

- Input images were preprocessed by down sampling the images by a factor of 24
- An optimized U-Net* architecture was used with three contraction/expansion layers
- Ground truth was created by manual annotation of ONH in the input images
- Dice coefficient was used as loss function and sigmoid activation was used in the final layer

(*O. Ronneberger, P. Fischer, T. Brox, "U-net: Convolutional networks for biomedical image segmentation", *Proc. Med. Image Comput. Comput.-Assisted Intervention*, pp. 234-241, 2015.)

CONCLUSION

We demonstrated a **deep learning** based algorithm that detects **ONH location** in the widefield IR images in CLARUS 500 instrument robustly with an **accuracy of > 85% in detecting the ONH** in an image. This algorithm can enable fast and reliable automated patient alignment and can be used to register repeated acquisitions and subsequent patient visits.

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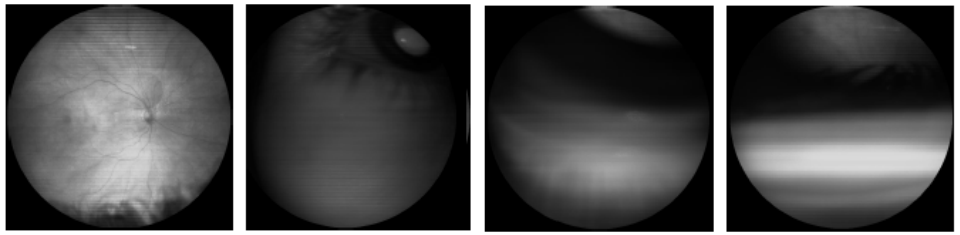
Disclosures: MA(E), NM(E), HB(E), DN(E): Carl Zeiss Meditec, Inc.

RESULTS

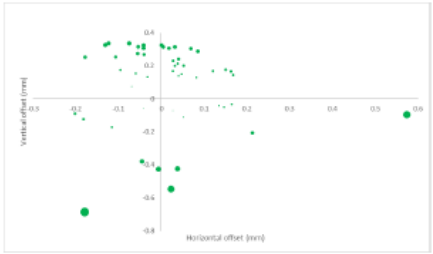


Typical true positive images; perfectly focused and without shadows

Typical false positive images where algorithm erroneously detects iris

Typical false negative images where ONH is obscured by shadows

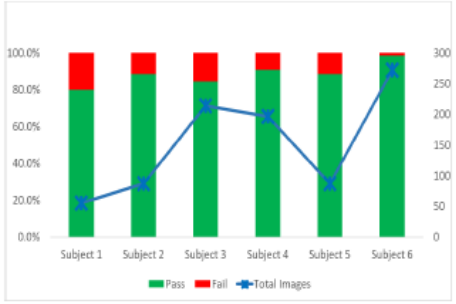
Typical true negative images when ONH is completely obscured



Tracking results with the center of circles showing motion of detected ONH during alignment and the size representing the error in detection of the ONH compared to ground truth

Average statistics for six human subjects with a total of 912 test images

Average Algorithm Performance	
Correct detection rate (%)	88.5%
False negative rate (%)	6.2
ONH detection accuracy (pixel)	1.25
ONH detection accuracy (µm)	267
Running time (ms)	< 100



Deep learning algorithm performance for six human subjects

A larger field of view is more beneficial when using fundus imaging as a screener and for capturing more peripheral lesions.

- Retinal detachment / tears
- Diabetic Retinopathy
- Pediatric diseases (Coat's disease, familial exudative vitreoretinopathy, and ROP
- Uveitis
- Retinal and Choroidal dystorphies
- Tumors

CRVO with partial PRP, Images courtesy of Jean François Korobelnik, MD

Ultra-wide field retinal imaging: A wider clinical perspective

doi: 10.4103/ijo.IJO_1403_20

Non-contact widefield neonatal retinal imaging (NC-WFI) for retinopathy of prematurity using the Clarus 700 high resolution true colour reflectance imaging

https://pubmed.ncbi.nlm.nih.gov/36195674/

Comparison of two ultra-widefield Imaging for detecting peripheral retinal breaks requiring treatment

https://doi.org/10.1007/s00417-020-04938-8

Both Optomap and Clarus were equally effective in detecting peripheral treatment-requiring retinal breaks.

Detecting neovascular age-related macular degeneration

Sensitivity and specificity of high-resolution wide field fundus imaging for detecting neovascular age-related macular degeneration

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Article | Authors | Metrics | Comments | Media Coverage | Peer Review

Abstract

Purpose

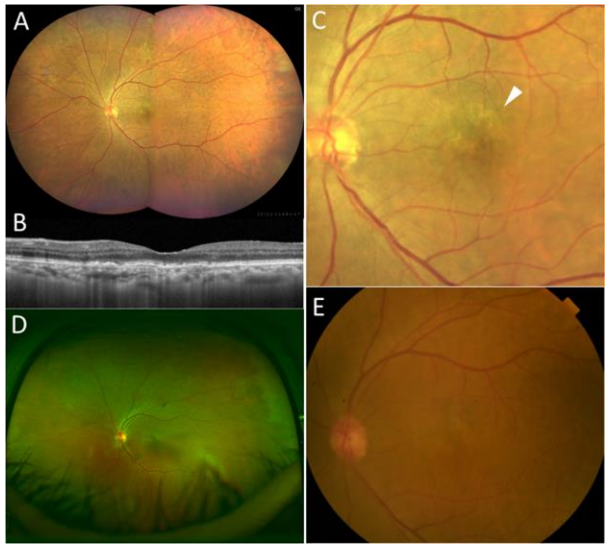
Early detection and treatment are important management strategies for neovascular age-related macular degeneration (AMD). The purpose of this study was to determine the sensitivity and specificity in detecting neovascular AMD using two wide-field imaging systems: Clarus™ (CLARUS 500™, Carl Zeiss Meditec AG, Jena, Germany) and Optos®(Optos California®, Optos PLC, Dunfermline, United Kingdom), compared to conventional digital fundus photographs.

Methods

We retrospectively analyzed 109 eyes of 73 consecutive patients with neovascular AMD, who underwent standard examination and multimodal imaging, including fundus photography, and optical coherence tomography (OCT). Unmasked graders utilized slit-lamp biomicroscopy and

Statements from Study:

Clarus™, with its ability to image high-resolution wide field fundus, was considered superior for diagnosing neovascular AMD with high sensitivity and specificity. **It may be a useful screening tool for early detection of neovascular AMD, facilitating prompt referral and treatment.**



Fundus photographs of an eye with neovascular AMD which was diagnosed by 3 graders as **AMD** using CLARUS (A & C), but as **normal** by 2/3 graders using Optos (D) and 3/3 graders digital fundus photograph (E)

Applications of Widefield Imaging in Ocular Oncology

Applications of Widefield Imaging in Ocular Oncology

Uses include screening, diagnosis, treatment planning, and tumor monitoring.

By Janani Singaravelu, MD; Alexander Melendez, MD; Jacquelyn Wrenn, MSN, APRN-CNP; Arun D. Singh, MD January 1, 2022

Widefield imaging has enabled retina specialists to document and assess the retinal periphery, thereby revolutionizing the understanding of retinal disorders. Specifically, this imaging technique has facilitated the ability to diagnose and manage intraocular tumors. This article will highlight the role of widefield fundus photography and imaging modalities including fluorescein angiography, indocyanine green angiography, and fundus autofluorescence as it applies to ocular oncology.

Related

Current Imaging Techniques for Intraocular Tumors

Enhancing Clinical Flow in the Retina Practice

Ocular Tumor Masquerade Syndromes

DEFINITION

Traditional fundus cameras are limited to capturing only 30° to 50° of the retina. Montage images have been used to overcome the limitations of standard fundus photos. The Early Treatment Diabetic Retinopathy Study developed a protocol that captured up to 75° by creating a montage of 7 standard 30° fields.[1]

With the advent of widefield imaging systems, the need for standardized terminology was initially addressed by the Diabetic Retinopathy Clinical Research Network (DRCR Retina Network). They adopted the "field of view" approach as a framework and defined ultrawidefield (UWF) fundus images as those that have at least a 100° view of the fundus.[2] More recently, the International Widefield Imaging Study Group developed a definition that used a different approach, utilizing anatomical landmarks. This is reflective of the process of performing clinical fundus exams, with widefield images defined as single capture images that extend up to and include vortex vein ampullae in all 4 quadrants. Within this paradigm, UWF images are those that include the retina anterior to the vortex vein ampullae in all 4 quadrants in a single capture. Finally, panretinal images span ora to ora in 360° and currently rely on montage techniques.[3]

Statements from Study:

- Limitations – no single-capture ora to ora imaging system
- The use of Optos, a cSLO system, create "pseudocolor" which alters the appearance of lesions and may introduce artifacts. Although current systems provide good visualization of nasal temporal periphery, superior and inferior views are limited.

Retinal Physician - Applications of Widefield Imaging in Ocular Oncology

Assessment of diabetic retinopathy

Assessment of diabetic retinopathy using two ultra-wide-field fundus imaging systems, the Clarus® and Optos™ systems

Takao Hirano, Akira Imai, Hirotsugu Kasamatsu, Shinji Kakihara, Yuichi Toriyama & Toshinori Murata

BMC Ophthalmology **18**, Article number: 332 (2018) | Cite this article

7021 Accesses | **40** Citations | **1** Altmetric | Metrics

Abstract

Background

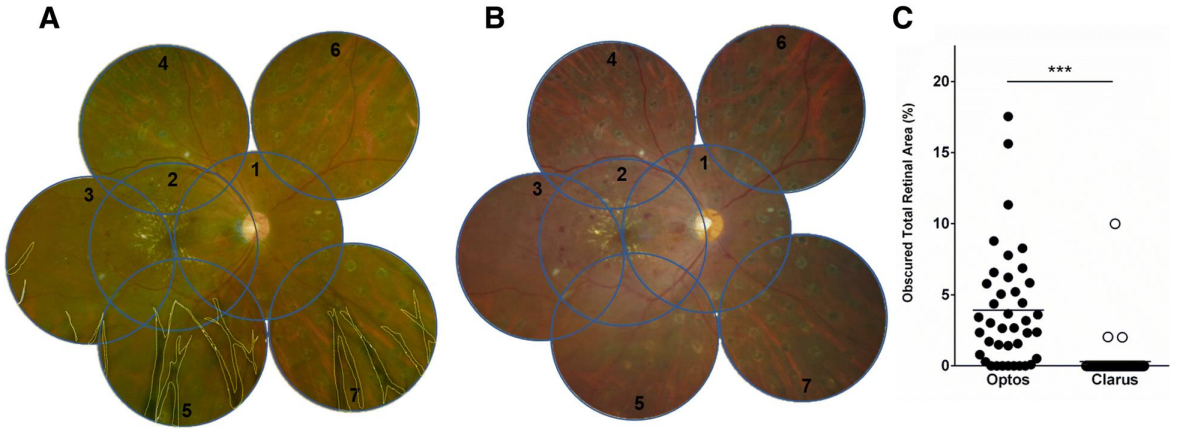
The ability to image wide fundus fields and to conduct swift, non-invasive examinations is increasingly important with the escalation in patients with diabetic retinopathy (DR).

Methods

Fifty eyes of 28 consecutive patients with DR were examined in this prospective observational study. A total of 46 eyes, 25 right and 21 left eyes, of 27 patients (male, 19; female, 8) were ultimately included in the analysis. All patients underwent comprehensive ophthalmological examination. A single image each was obtained using two ultra-wide-field (UWF) imaging systems: Optos® (Optos Carfornia®, Optos PLC, Dunfermline, United Kingdom) and Clarus™ (CLARUS 500™, Carl Zeiss Meditec Inc., Californea, USA), without mydriasis. The total retinal area captured and the obscured retinal area were compared between the two systems using nonparametric Wilcoxon matched-pairs signed-rank analysis. Early Treatment of Diabetic Retinopathy Study (ETDRS) and International Clinical DR severity were analyzed by κ statistics.

Evaluation of obscured retinal area

- In 85% of Optos® images and 7% of Clarus™ images, a slightly obscured area was observed within the ETDRS-7 field area.
- The obscured total retinal area in the ETDRS-7 field had significantly higher values in Optos® images than in Clarus™ images
- A region comprising of the area in the inferior fundus were obscured in the Optos® images.



ROP and Neonatal Exams

Article | Published: 04 October 2022

Non-contact widefield neonatal retinal imaging for retinopathy of prematurity using the Clarus 700 high resolution true colour reflectance imaging

Akash Belenje, Rakasi Ugandhar Reddy, B. Optom, Komal Agarwal, Deepika C. Parmeswarappa & Subhadra Jalali

Eye **37**, 1904–1909 (2023) | Cite this article

98 Accesses | **3** Altmetric | Metrics

Abstract

Objective

To illustrate the role of non-contact widefield retinal imaging (NC-WFI) of retinopathy of prematurity (ROP) using the Clarus 700 high resolution true colour reflectance imaging.

Methods

All babies were examined by the vitreoretinal faculty in a tertiary eye care centre from a period of March 2021 to November 2021 using the indirect ophthalmoscope after pupillary dilatation. ROP grading was done according to the revised ICROP (2005) classification. NC-WFI was then performed using the Clarus 700 high resolution true colour reflectance imaging (Carl Zeiss Meditec, Dublin, CA) in the retina diagnostic set up of a tertiary eye care centre.

Statements from Study:

- The pseudo color image acquisition by Optos could be a disadvantage as previous reports have shown that staging the ROP at the periphery at times becomes difficult.

- The contact imaging system can pose a risk of eye infection and can lead to lot of stress on the new-born due to indentation on the cornea.

CLARUS in Glaucoma

Structure and function comparison of cup/disc ratio and perimetric mean deviations

Katharina G. Foote; Patricia Sha; Tara Pahlevan-Chaleshtari; Iryna A. Falkenstein; Todd Severin; Gary C Lee; Thomas Callan

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science June 2022, Vol.63, 628 – A0368. doi:

SHARE TOOLS

Abstract

Purpose : Structural loss often precedes functional loss in cases of primary open-angle glaucoma, thus driving the importance of early detection and monitoring. While established correlations between structure and function in glaucomatous eyes have been studied in various modalities (particularly in traditional narrow field of view (FOV) cameras which assume a constant pixel to distance mapping), it is vital to establish these correlations in widefield (WF) cameras which are widely available, and have not yet been assessed.

Methods : A WF slit-scanning ophthalmoscope (CLARUS™ 500, ZEISS, Dublin, CA) and automated perimeter (HFA3 Model 860 perimeter, ZEISS, Dublin, CA) were used to acquire color fundus photography images and perimetric data respectively. Both

Statements from Study:

This study demonstrated a capability of providing structure/function comparisons using a WF fundus imager and perimeter. This measurement technique could be useful for enhancing research in the field of glaucoma. The study also **confirms the trend that in the early to medium/advanced stages of glaucoma, the vCDR has a stronger correlation than hCDR and that vCDR is traditionally more useful in determining glaucoma severity**.

Cybersecurity features (1.1.4)

CLARUS (and ZEISS) has been recognized to fulfill cybersecurity requirements by the USA Department of Defense.

(SW update 1.1.4)

• Increased cybersecurity and password complexity control

Windows User types:

• Active Directory (AD) : Active Directory is proprietary directory service developed by Microsoft for Windows domain networks. It provides benefits such as centralized resources and security administration, a single logon for access to global resources, and simplified resource location.

• Standard User: A standard user is a user or operator with limited system access. Standard users can perform everyday tasks like running software, changing settings, and personalizing their desktop. They can't do complicated system tweaks, install apps, or run elevated commands. Standard users must also have administrator approval before installing any program. CLARUS application does not require Administrator privileges anymore to run. This protects the OS from malicious users.

• User Access Control (UAC): User Access Control is a security feature in Windows that ensures important system changes are only made with approval from an administrator. UAC reduces the risk of malware by limiting the ability of malicious code to execute with administrator privileges. It requires every admin functionality to request for user permission.

• DICOM TLS: DICOM specifies the use of Transport Layer Security (TLS) for encrypting traffic. TLS is the protocol standard for secure DICOM communication. DICOM over TLS has equally strong protection against unauthorized listeners as HTTP over TLS, which is known as HTTPS and is the most common method of protecting web browser traffic. CLARUS has now an option in Settings to use TLS encryption for DICOM data. Note: FORUM supports DICOM TLS starting from version 4.4.

• Federal Information Processing Standard (FIPS): FIPS are a set of standards and guidelines for federal computer systems that are developed by the USA National Institute of Standards and Technology (NIST). FIPS standards describe document processing, encryption algorithms and other information technology standards for use within non-military government agencies and by government contractors and vendors who work with the agencies. CLARUS now complies with FIPS standards.

• MySQL 8.0: previous language used for Database management MySQL 5.7 going in End Of Support.

Technical Specifications

Reference Information from IFU

CLARUS 700

Parameters			
Imaging Modes:			
■ True Color (with Red, Green and Blue channel split)		■ Infrared reflectance	
■ Fluorescein Angiography		■ External eye image (ocular surface)	
■ Autofluorescence-Green		■ Stereo	
■ Autofluorescence-Blue			
Field of View (measured from the center of the eye):			
■ Widefield (one image)	133°		
■ Ultra-widefield (two images)	200°		
■ Montage (up to six images)	up to 267°		
Resolution:			
■ Optical	7.3 µm		
Minimum Pupil Diameter:	2.5 mm		
Working Distance:	25 mm (patient's eye to front lens)		
Compensation for ametropia:	- 24 D to + 20 D continuous		
Light Sources:			
■ Red LED	585 - 640 nm		
■ Green LED	500 - 585 nm		
■ Blue LED	435 - 500 nm		
■ Infrared laser diode	785 nm		
Automatic Operations:		**Aquisition Speed:**	
■ Auto-focus	Auto Montage	■ Live IR Preview	10 frames/second
■ Auto-gain	Auto-laterality	■ Image Capture	≤ 0.2 seconds

Instrument Specifications			
Instrument Weight:	50 lbs (22.7 kg)		
Instrument Dimensions (W x D x H):	15" (38.1 cm) x 18" (45.7 cm) x 27" (68.6 cm)		
Instrument Table:			
■ Description	Wheelchair accessible, electronic lift		
■ Table Dimensions	37" (94 cm) x 27.5" (70 cm)		
■ Weight	81 lbs (37 kg)		
Instrument Input Power:			
■ Voltage and Mains Frequency	100-240VAC, 50/60 Hz		
■ Electrical Class	IEC 60601-1 Class I		

At-Instrument Computer			
Monitor:	22" Full HD MVA LCD with LED Backlight	**Touch Screen:**	Capacitive, Multi-Touch
Resolution:	1920 x 1080	**RAM:**	32GB
Processor:	Intel® 6th Generation Core i5-6500TE	**Input/Output:**	USB 3.0 x 3; RS-232 x 2; 1.5 kV Isolated Gigabit Ethernet Port x 2; HDMI; and DisplayPort
Hard Drive:	2 TB (minimum 200,000 images)	**Operating System:**	Windows 10
Dimensions (W x D x H):	21.5" (54.6 cm) x 2.5" (6.4 cm) x 13.75" (34.9 cm)		
Weight:	17.2 lbs (7.8 kg)	**Mounting:**	VESA 75/100 mm

Optos California

Technical Specifications

MODEL NAME/ NUMBER	P200DTx / A10650			
TRADE NAME	California			
CONFIGURATION NAME	*rg*	*fa*	*fa-rgb*	*icg*
optomap UWF Imaging				
IMAGING MODALITIES*				
color rg	X	X	X	X
Sensory (red-free)	X	X	X	X
choroidal	X	X	X	X
color rgb			X	
Autofluorescence	X	X	X	X
Fluorescein Angiography		X	X	X
icg Angiography				X
RESOLUTION	optomap: 20 µm, optomap *plus*: 14 µm			
LASER WAVELENGTHS	Red laser: 635 nm Green laser: 532 nm (for AF) Blue laser: 488 nm (for FA & RGB color) Infrared laser: 802 nm (for ICG)			
EXPOSURE TIME	Less than 0.4 seconds			
System				
TRIM COLOR	Blue	Gray	Gray	Aqua
DEVICE DIMENSIONS	Width: 550 mm / 22 in Depth: 550 mm / 22 in including chinrest Height: 608-632 mm / 24-25 in			
WEIGHT	34 kg/ 75 lbs			
TABLE SPACE REQUIREMENTS (excluding wheel position)	Width: 887 mm / 35 in Depth: 600 mm / 24 in Height: 725 to 1205 mm / 29 - 48 in			
LASER CLASS	Laser safety class-1 following EN60825-1: 2014 and 21 CFR1040.10 and 1040.11			
SYSTEM VOLTAGE	100-240Vac, 50/60Hz			
POWER CONSUMPTION	300VA			
COMMUNICATION PROTOCOL	DICOM Compatible			

* The imaging modalities boxed together are produced in a single image capture.
Specifications subject to change without notice.

Seeing beyond