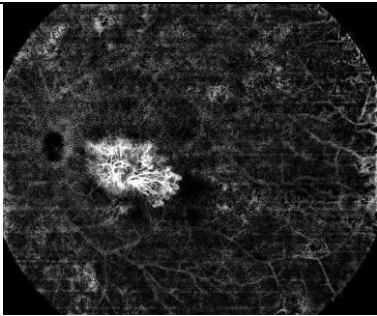
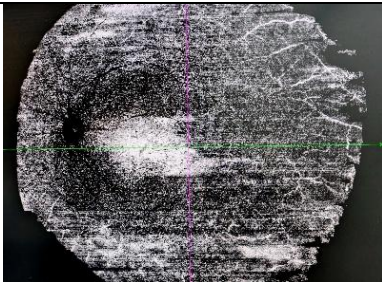
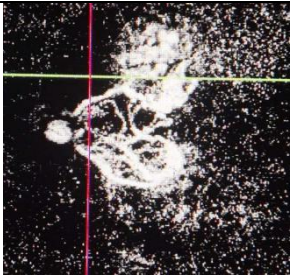
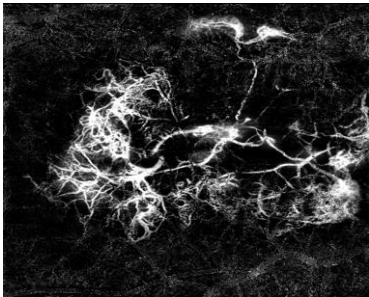
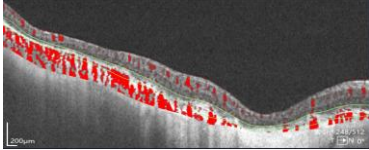
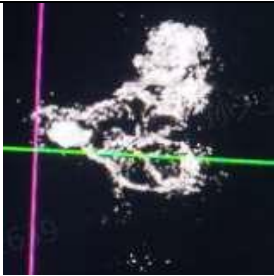
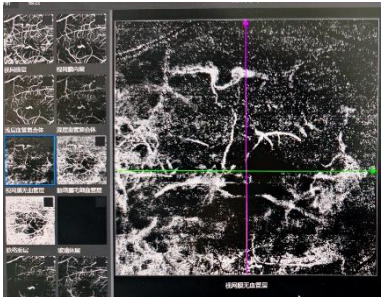
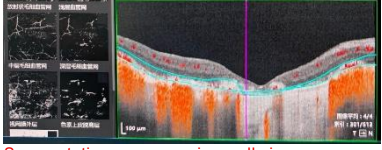
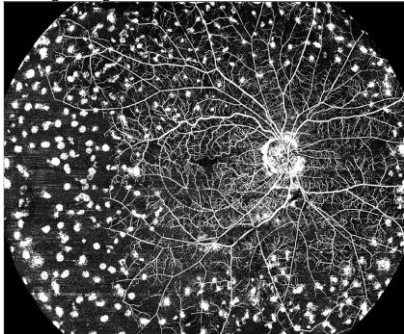
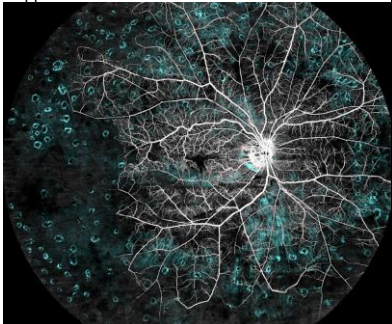
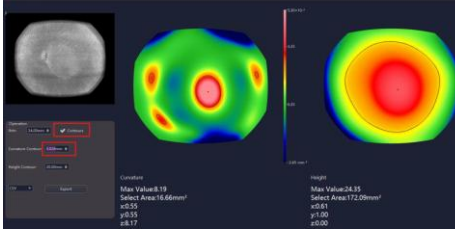
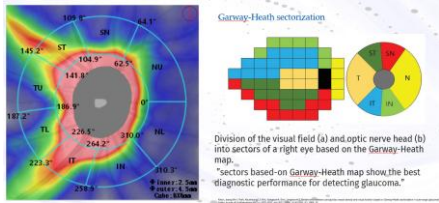
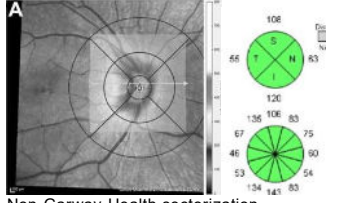
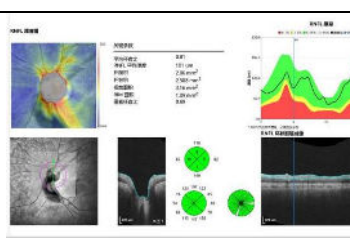
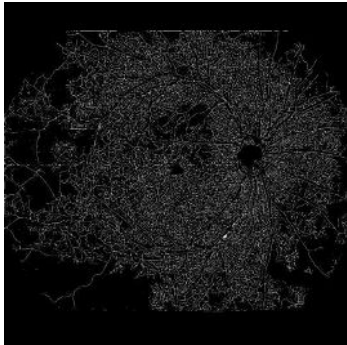
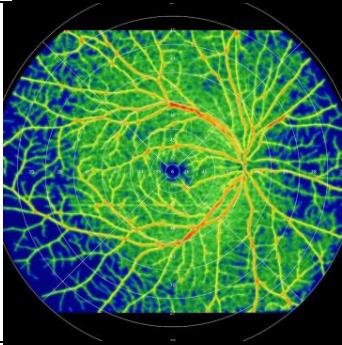
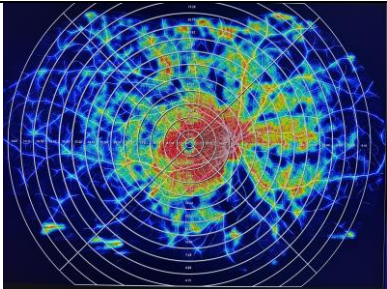
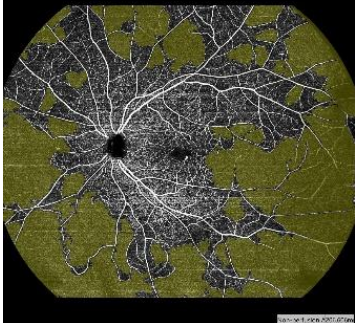
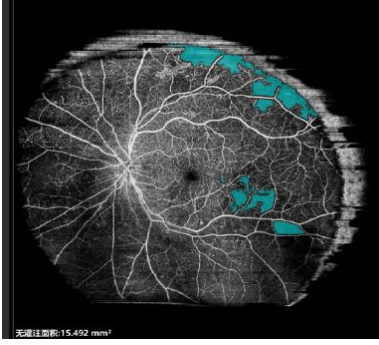
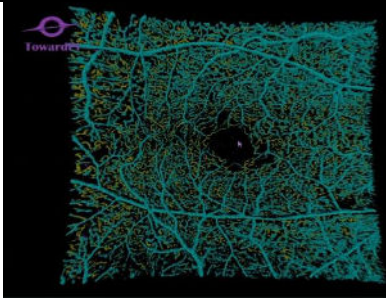
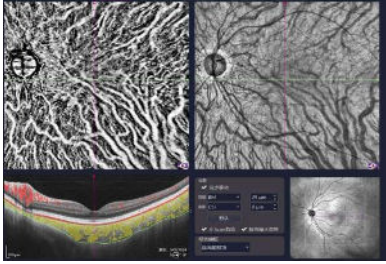
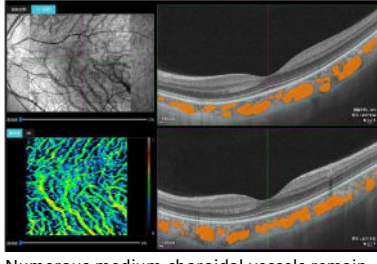
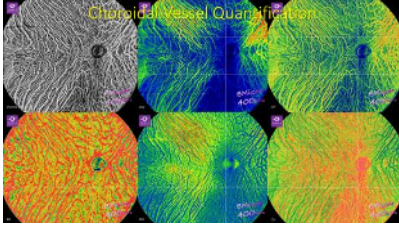
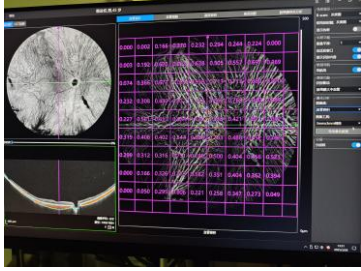
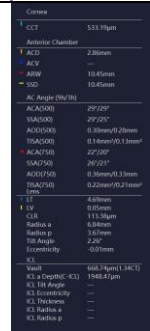
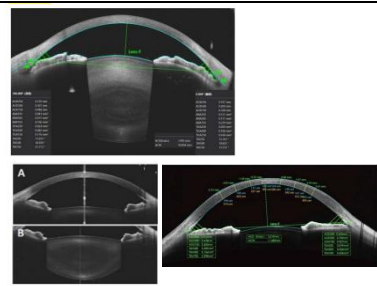
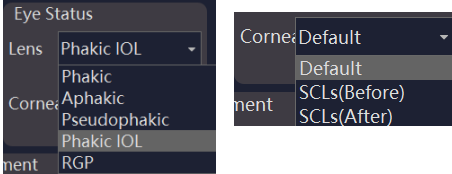


		TowardPi BM-400K	Intalight VG-200
OCT	Light Source	Swept Source	Swept Source
	Center Wavelength	1060nm	1050nm
	A-Scan Speed	★400,000 A-scans/s	100,000/200,000/400,000 A-scan/s
	Axial Optical Resolution	≤6μm	≤5.5μm (without additional lens) (External lens degrades resolution)
	Transverse Optical Resolution	≤10μm	≤15μm (External lens degrades resolution)
	Posterior Scan Length	3~24mm	3~16mm; 26mm (with additional lens)
	Posterior Scan Depth	★12mm in tissue	100kHz: Max 12mm in tissue 200kHz: Max 10mm in tissue 400kHz: Max 5mm in tissue No independent 400kHz system!
	Anterior Scan Length	24mm	20mm
	Anterior Scan Depth	★12mm in tissue	16.2mm (Air)=12mm (Tissue) (Scan speed drops to 100,000 A-scan/s)
	Refractive Adjustment Range	-35D~+45D	-20D ~+20D (without add-on lens) -33D ~ +48D (with add-on lens)
	Scan Modes	Line, Cross, Radial, Grid, Raster, 3D Macula, 3D 15°9, ONH, 3D Disc, GMA, OCTA Disc, Retina OCTA, AS-Line/AS-Radial/AS-3D/AS-OCTA (Iris/Cornea/Limbus), Custom Scans	Line, Cross, Radial, 3D Macula, 3D Disc, Macular OCTA, OCTA Disc, Custom Scans
	Max 3D Scan Range	30mm×25mm	15mm×12mm
	Max 3D Scan Lines	★1536 x 1280	1536*1240 (usually use 1240×768 for saving time)
	3D Min Scan Interval	6μm	6μm
	Eye Tracking	★128Hz Real-time Tracking	Real-time Tracking (60 Hz)
Fundus Imaging	Denoise	AI-based Denoise Algorithm!	Supports
	OCT-Fundus Alignment	OCT & Fundus Point to Point	OCT & Fundus Point to Point
	Vitreous Mode	Independent Vitreous Enhancement Mode	None
	Follow-up	Comprehensive follow-up analysis for all parameters, progression analysis and point-to-point comparison. Follow-up scan: reload same scan mode to same location with last visit. Support pipeline follow-up scans.	Supports
	Methodology	Scanning Laser Ophthalmoscopy (SLO)	cSLO, High-Brightness LED
OCTA Retina	Wavelength	850nm	830nm
	SLO FoV	★107.25°	40°×40° (without add-on lens) 60°×60° (with add-on lens)
	Auto-Focus	Fully Automatic, < 1s	Fully Automatic
	Minimum pupil diameter	≥2mm	≥2mm
	Max. OCTA Scan Size	★ 30mm*25mm (Size from 3x3mm to 24x20mm) 250+ publications!	Without Lens: 3°3, 6°6, 9°9, 12°12, 15°12 With Lens: 29°24, 26°21, 22°18, 18°18 (Resolution compromised) Limited publications (non-UWF)
	UWF Design	 Built-in UWF Imaging System	 Standard Lens + External Add-on UWF Lens All external Ultra-Widefield lenses degrade image resolution! Waste too much time on adding on lens for wide field (including wider single line scan) and taking off lens for small scans.
	UWF OCTA data info	★10 billion voxels! in 7-15 seconds! 1536x1280, Max 9mm scan depth	At least 25% less! 1536x1280, 6.3mm scan depth (Barely use!) 1024x1024, 5.3mm scan depth (less than 50% of TowardPi data) 1024x1024, ≥6mm scan depth (drop to 200kHz!) 1024x828, 4.5mm scan depth (Most frequently use)
	OCTA Montage Range	Flexible montage 220° (44mm*42mm)	With lens: 200° Without lens: 23.5mm*17.5mm
	UWF Image Quality	 Superficial vascular complex Perfect details on periphery.	 Superficial vascular complex Overexposed posterior pole and terrible signal loss on periphery.

			
		Avascular slab	Avascular slab (same patient)
	Small Size OCTA (same patient from clinic)	  	  
	OCTA Segmentation	AI-based segmentation algorithm! Including Bruch's membrane and choroid sclera interface. 7 slabs by default. Manual adjustment to any layer.	Segmentation error even in small size... support
	OCTA Denoise	AI-based denoise algorithm!	support
	UWF OCTA Clinical Utility	Comprehensive measurements and flow quantifications for all sizes and all slabs! 250+ SCI on UWF study, UWF choroid quantifications, AS-OCTA, animal research!	Mode 1: Default standard lens does not show peripheral lesions. Mode 2: Default added-on UWF lens, loss details; requires manual lens removal to scan small sizes. No publication on UWF or flow quantification! They claim 200 publications (including Chinese journals)
	iSpot	AI-based iSpot function. Available with UWF and Montage image. 	Support  (same patient from clinic)
	Comparison Conclusion	TowardPi provides high-resolution UWF-OCTA with comprehensive measurements and flow quantifications for all sizes and all slabs with AI-based segmentation algorithm, denoise algorithm and choroid OCTA! Integrated UWF lens meets real clinical needs with seamless workflow, reducing the misdiagnosis rate and increasing the lesion detection rate without switching lenses.	
Anterior segment	Lens Switching Method	Quick professional lens switching ensures optimal image quality.	Built-in anterior lens with poor image quality and high noise signals
	Refractive Correction	supports	Supports

	Imaging	One scan includes cornea, anterior chamber, anterior chamber angles, partial sclera, lens, and anterior vitreous; AS-OCTA	includes the cornea, anterior chamber, anterior chamber angles, partial sclera, lens, and anterior vitreous
	AS-3D Scan Size	★Max 24mm*24mm	16mm*16mm
	AS-OCTA Scan Size	★Max 24mm*24mm	15mm*12mm No certification for AS-OCTA.
Retinal Analysis	Retinal Thickness	Supports for all sizes and for all layers with detailed data in ETDRS rings and grids.	Support
	Accuracy & Repeatability	Verified by test reports	No test reports
	Segmentation & Quantification	Automated B-scan segmentation with quantitative thickness analysis for each layer	Supports retinal thickness analysis
	Macular Volume Measurement	Thickness & Volume measurement for all sizes and all layers.	Supports macular volume analysis
	En-face Imaging	Independent sagittal imaging for all retinal and choroidal layers with 3D reconstruction technology.	Supports En-face and automated segmentation
	Choroidal Thickness	Automated or manual measurement of choroidal thickness and volume in all sizes based on AI segmentation.	Supports choroidal thickness analysis
	★Retinal Curvature	 More than 10 publications!	They claim support. No publication. Not validated. Lacking clinical evidence.
Glaucoma	★Morphology Analysis	Supports UWF Retinal Curvature, Height Map	None
	RNFL Thickness Map	6 mm RNFL thickness map (512 x512); 2.5–4.5 mm diameter annular 8-sector analysis; 3.45 mm circle thickness profile with normative database comparison and probability deviation calculation	Supports quantitative RNFL thickness analysis (includes a Chinese normative database)
	GCC Thickness Map	6 mm GCC thickness map; point-to-point normative database comparison and probability deviation calculation	Supports GCC
	★ 3D 15°9 ★ iHealth	Support. Effective disease screen with comprehensive retinal thickness, GMA, ONH, and RNFL analysis in a single scan!	None
	3D Disc	including peripapillary RNFL thickness and morphological analysis; Automatically detects optic cup/disc position and disc margins; measures vertical and horizontal area C/D ratio, rim area, and cup volume	Supports 3D optic disc analysis and peripapillary RNFL thickness analysis
	OCTA Disc	Support RNFL flow quantification together with RNFL thickness analysis and optic disc analysis	Supports OCTA disc quantification
	ONH & RNFL Analysis	 Garway-Heath sectorization for ONH & RNFL thickness analysis. Sensitive to RNFL loss. Compared with normative database.	 Non-Garway-Heath sectorization
	Glaucoma Report		
	★ GO Combo	Smart one-page report generated from GMA & Disc analysis.	None
	OCTA Disc Quantification	Full vascular density analysis from retina to choroid RNFL vascular density analysis via Garway-Heath sectorization. Software support delay-large-vessel function	support
Angio Analysis	Artifact Removal	Default 3D full-layer artifact removal	Full-retinal 3D Projection Artifact Removal
	Vascular Density	Supports vascular density measurement for all scan sizes and all slabs with detailed data in multiple partitioning patterns (Grid & ETDRS)	No certification for flow quantifications Vascular density in limited scan size.
	★ Vessel Length Density	Supports Length Vessel Density quantification for ETDRS and grid patterns across all scan sizes	None

				
	UWF Vessel density			 Ridiculous data!
	Non-perfusion identification			 无灌注面积: 15.492 mm²
	★ FAZ index	Supports FAZ Auto-Identification in any scan size 		Only supports 3*3 , 6*6 mm OCTA
	★ 3D OCTA	 3D vessels for all slabs and all sizes.		None

	★AI-based Choroid OCTA Algorithm	 Proprietary choroid OCTA algorithm!	 Numerous medium choroidal vessels remain unidentified
	★Choroidal Vessel Quantification	 2D vessel density; 3D-CVV/a, CVI/a, CSV/a, and CSI/a for all sizes. 100+ publications using UWF choroid quantifications!	 No publication.
AS analysis	AS parameters	 One scan for all parameters!	 Separate scan for different parameters.
	★ Precise Quantification for Various Eye States	Lens status: Phakic, Aphakic, Pseudophakic, Phakic IOL, RGP Cornea status: Scleral Lens (before & after) 	Not supports
	Anterior Chamber Measurement	CCT ACD ACV ARW SSD ACA 500/750 SSA 500/750 AOD 500/750	CCT (Requires entering a specific analysis module) ACD ACW AOD 250/500/750 ARA 250/500/750 TISA 250/500/750 TIA 250/500/750
	ICL Measurement	Automated or manual measurement ICL vault	Supports
	★AS-OCTA quantification	Support AS vessel density (data in grids) Support flow area quantification with circle and contour tool.	None.
	AS 3D reconstruction	Support	Support
Animal study	★No additional lens	No additional lens. Support all kinds of animals. (Beastie mode available for tiny animals)	Not support. Multiple lens needed for different animals. 
CE Mark	Diagnostic Scope	★Imaging and Quantification	Imaging only
	OCT/ Angio Imaging	★Includes OCT Angiography	Structural imaging only

< Declaration of Conformity.pdf ...

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Man

EU Declaration of Conformity

Legal Manufacturer Name: TowardPI (Shanghai) Medical Technology Ltd.
Address: Room 2B1, Building 147, No. 505, Zhennan Road, Putuo District, Shanghai,
200331 China
SRN: CM-MP-000033952

EU Authorized Representative
Authorized Representative Name: MedNet EC-REP GmbH
Address: Bohlstrasse 10, 48153, Münster, Germany
SPIN: DE-AR-00000002

Product Name	Trade Name	Model #	Class	Basic UCL ID
Optimalim optical coherence tomography systems	BMORE	BM-400K MAX, BM 400K, BM Lite, BM 400K NF	Ia	0975564928IM000002
Optimalim optical coherence tomography systems	VAlkatz	YG-100K MAX, YG 100K PRO, YG Lite, YG 100K NF	Ib	0975594455YG100000

Intended purpose
The system

Intended purpose
The system is an ophthalmic optical coherence tomography system, which is intended for the in vivo cross sectional and three-d dimensional imaging and measurement of ocular tissue, and non-invasive visualization of ocular vasculature based on OCT angiography (OCTA).

Applicable Directive
Regulation (EU) 2017/745

Applicable Directive
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Device Classification
Class IIIa (cont'd)

Device Classification
Class I/II according to in rule 10, annex VIII, MDR
P/View Image System Classification
Class I/II according to in rule 11, annex VIII, MDR

Route to Conformity

Route to Conformity
Regulation (EU) 2017/745 Annex IX

HARMONIZED STANDARDS
Attached Harmonized Standards List

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Annex to EU Quality Management Certificate
SRN of Manufacturer: CN-MF-00025982
Certificate ID: 100186550

Authorised Representative of the company:

Eurotor GmbH
Kunze dyckstr. 5
40474 Düsseldorf
Germany

599-DE-48-00005381

Device categories and variants covered by this certificate:

Device category:	MSG 0002 - Accessory for implantable imaging devices emitting nonionizing radiation
Product name:	DR54M OCT
Code of classification:	21.01
Device UDI-DE:	69754002MSG2

Intended purpose: D-scanOCT, a swept source optical coherence tomography instrument, is a non-contact, high-resolution tomographic and tomographic imaging device intended for the detection, monitoring, and cross-sectional, and three-dimensional imaging of anterior and posterior ocular structures.

Examinations and tests performed:
5/20/06, 4/25/2006, 4/25/06, 4/25/06

552776, A2141062MED, Dream OCT, dated 2015-04-28

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate ID	Description of change
01	n/a	n/a	n/a

This notice is only valid in connection with the above mentioned certificate.