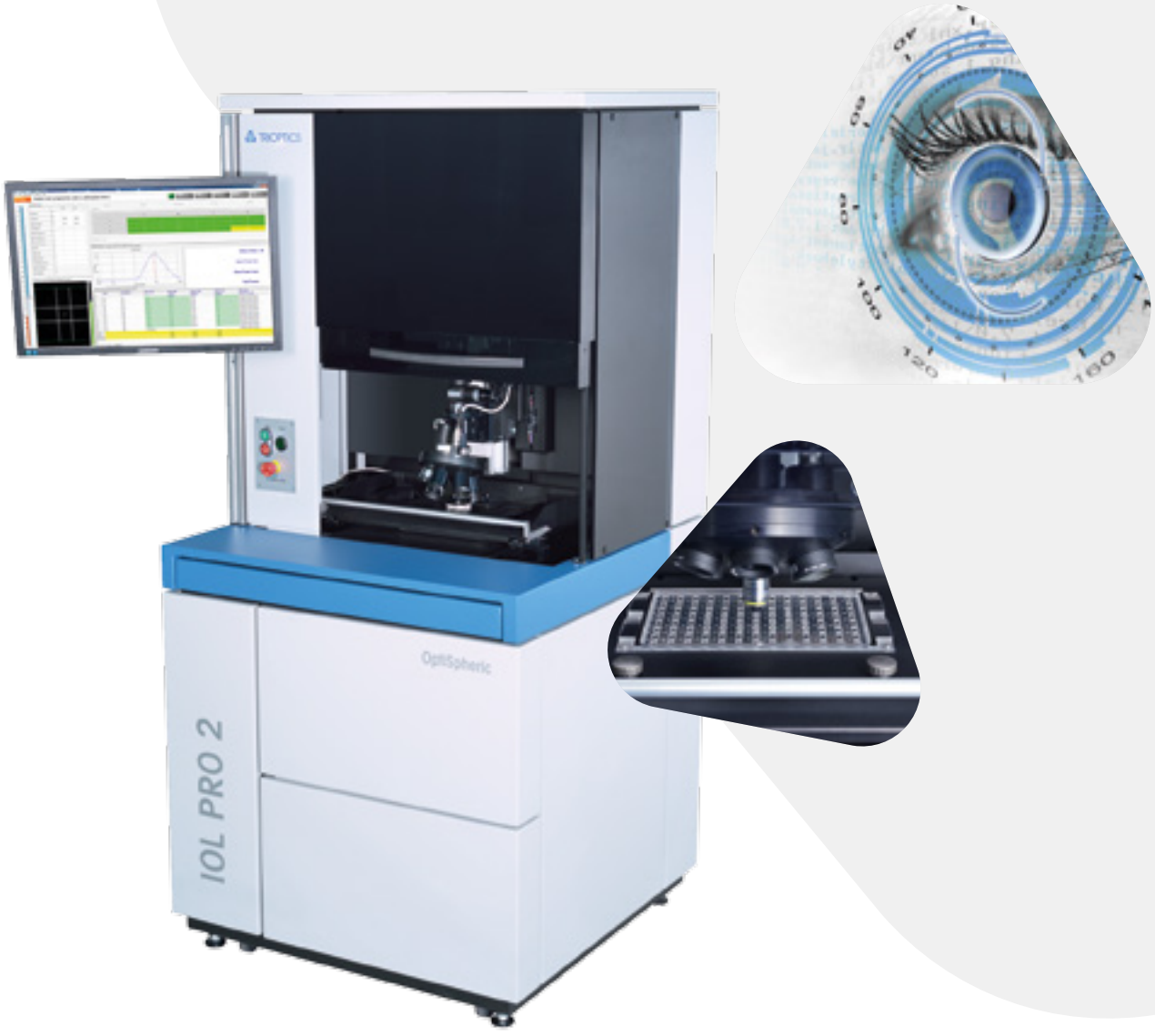
TRIOPTICS

See the Difference.

Quality Testing of Intraocular Lenses

OptiSpheric® IOL Family
and WaveMaster® IOL 2



LEADING TO THE FUTURE OF OPTICS

Optical systems have changed the world. And they will continue to do so. TRIOPTICS is significantly involved in this process.

We are a solution provider for optical measurement and manufacturing systems and offer our customers the right system for their current and future applications.

www.trioptics.com

Supporting Development of High Quality IOLs

Cataract surgery is the most frequently performed operation in the world. Therefore, the demand for intraocular lenses (IOLs) is continuously rising. In addition, patients' expectations of implants are changing and are met by the development of premium lenses. Consequently, all IOL manufacturers are quickly advancing their research and development for new lens models. Additionally, they require efficient and high quality testing of their IOLs.

As for all medical products, IOLs have to be developed, produced and eventually tested in compliance with the applicable ISO standards. ISO 11979 is applied for IOLs. To fulfill these requirements instruments for quality inspection of IOLs need to perform in-situ measurements with a physical model cornea and a model eye simulating natural conditions. Measuring parameters like lens aberrations and toric axis deviation or performing power mapping are also of great interest.

For all those measurement requirements TRIOPTICS offers high-end systems for accurate and reliable IOL evaluation. Two product versions from the OptiSpheric® IOL family as well as the WaveMaster® IOL 2 are available.

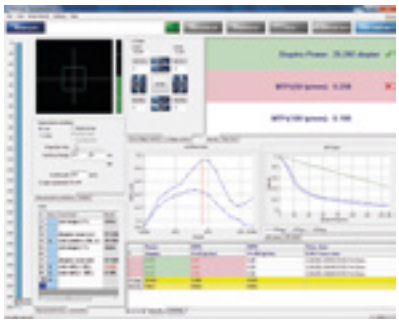
WaveMaster® IOL 2 for power mapping of IOLs

OptiSpheric® IOL Family

The industry's standard for testing intraocular lenses in compliance with ISO 11979 is represented by products from the OptiSpheric® IOL family.

The Gold Standard for ISO-Compliant Testing in Production

Our customers rely on high-precision measurements with an accuracy of 0.3 % for power measurements. Optimized for research and development they use the tabletop instrument OptiSpheric® IOL R&D or alternatively for production purpose the stand alone device OptiSpheric® IOL PRO 2.



Presentation of test result in the OptiSpheric® IOLs software

Both instruments allow a large variety of IOL types to be measured: monofocal, multifocal, trifocal, toric, extended depth of focus (EDOF) as well as aspherical IOLs (diffractive, refractive or sector lens, respectively). For all of them, predefined measurement processes simplify operation and data collection in accordance with international guidelines. Finally, the results are presented in an easy to understand way enabling a comfortable and fast interpretation of the results. With the OptiSpheric® IOL software a pass/fail analysis of specific measurement parameters can be conducted.

Magnification Method: Lens Bench Design in Compliance with ISO 11979

The magnification method is based on the lens bench design as described in ISO 11979 and is implemented in the test devices of the OptiSpheric® IOL family. This method uses the magnification of a test target imaged through the IOL to determine the effective focal length and the refractive power.

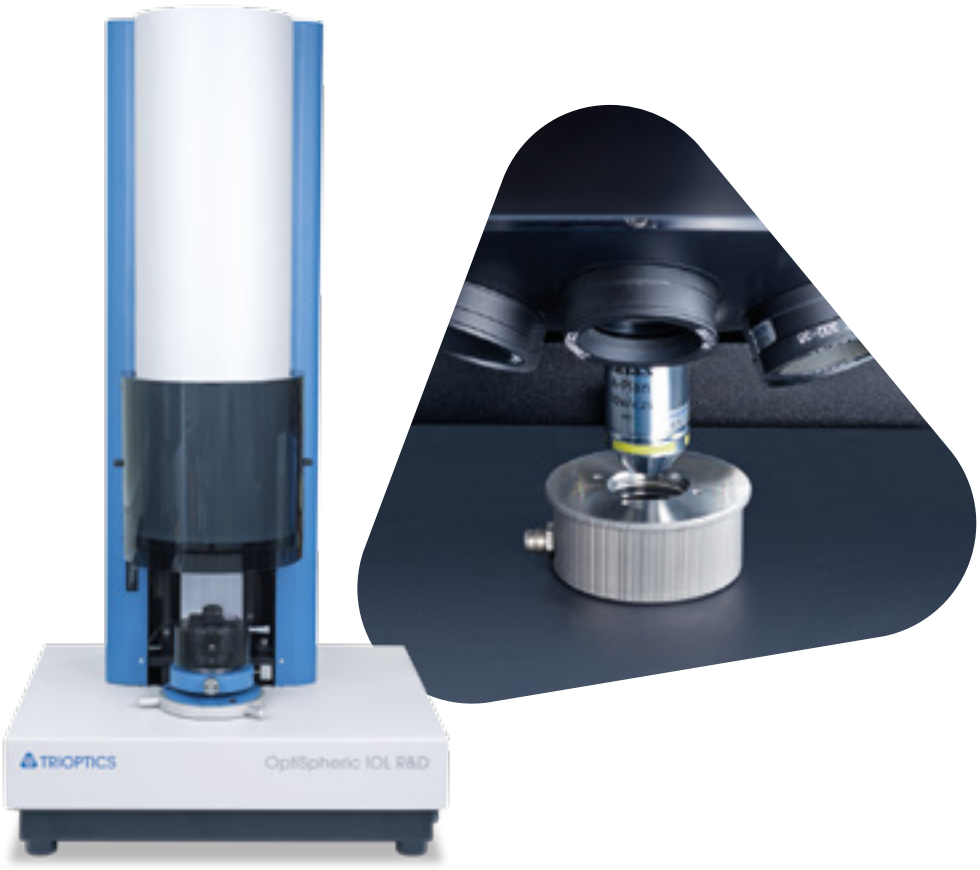
The lens bench design of the OptiSpheric® IOL family permits the on-axis measurement of

- Refractive power (sphere, cylinder and add power)
- Effective focal length (EFL)
- Toric axis, orthogonality and marker deviation
- Modulation transfer function (MTF)
- Through focus scan
- Strehl ratio
- Energy distribution
- Radius of curvature
- Back focal length
- Production accuracy via visual evaluation

Lens bench design in compliance with ISO 11979

Key Features

- High measurement precision with an accuracy of 0.3 % for power measurements and high repeatability
- Measurement of hydrophobic and hydrophilic lenses in-air or in the heatable in-situ eye model with various corneas in accordance with ISO 11979 standard
- Multi-purpose use for all types of intraocular lenses with refractive, diffractive or sector design
  - Monofocal
  - Extended depth of focus (EDOF)
  - Toric
  - Multifocal
  - Aspheric
- Immediate analysis of the measurement result with associated diagram by means of pass/fail analysis
- Flexible, modular software user interface that can be set for different users (R&D, production, administrator)

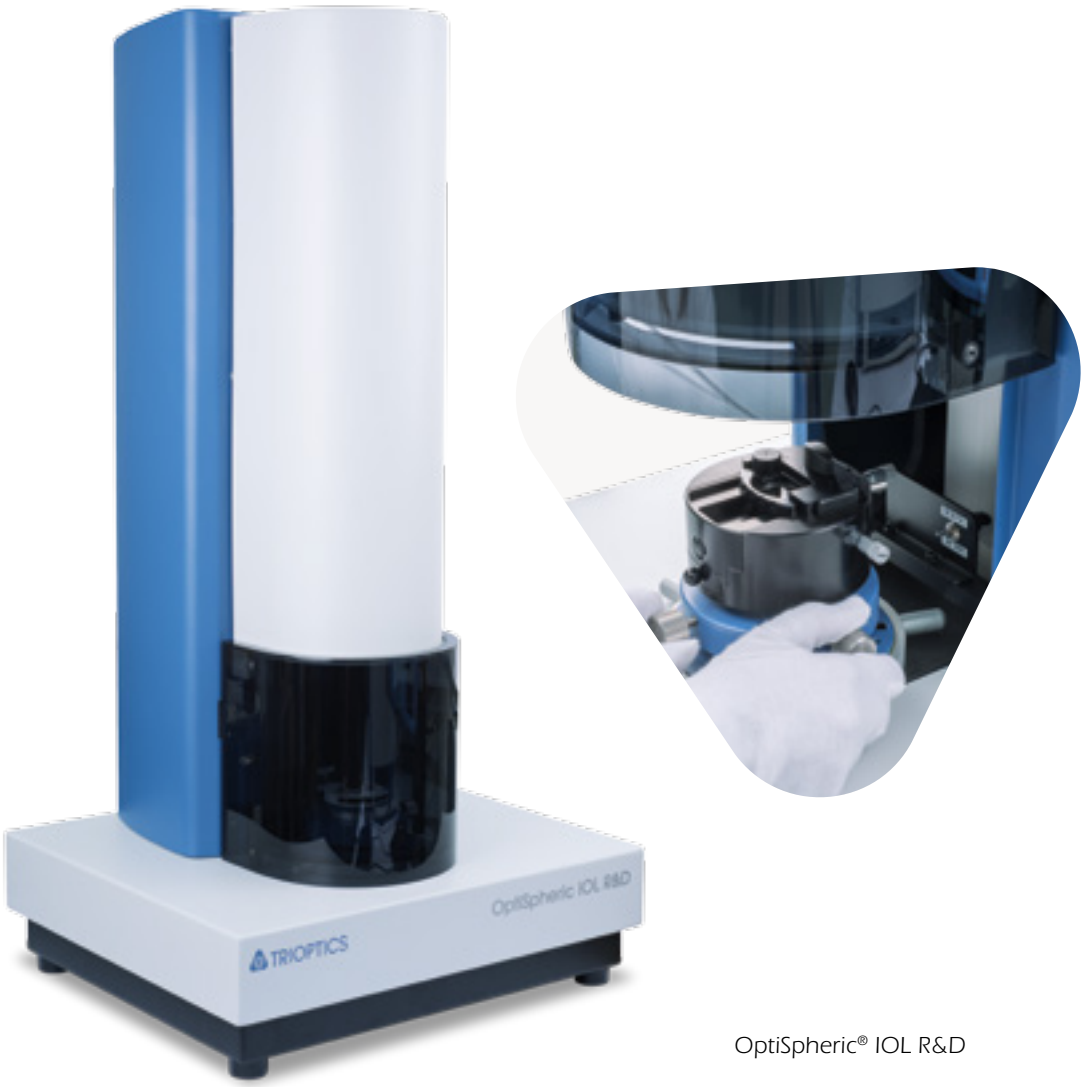


OptiSpheric® IOL: Testing intraocular lenses in compliance with ISO 11979 in R&D and production

OptiSpheric® IOL R&D

Designed for comprehensive usage in research and development, OptiSpheric® IOL R&D provides various adjustment options for hard- and software. Individualized testing procedures are conducted to simulate the performance of the IOL in in-situ conditions. The advanced model eye offers multiple functions that reach as far as tilting the lens. Holders for in-air measurements and the availability of various model corneas and filters emphasize the instrument's high value for R&D. The automated script generator supports easy handling and intuitive operation.

Measurements of IOLs are in compliance with ISO 11979. The test results for all measurement parameters are given in extensive tables and graphical depictions and are automatically saved in .csv format for additional post processing. The individual preparation of test programs in the software's R&D mode enables the user to fully control all test steps and conditions. Furthermore, this test program is used to measure small batches uniformly.



OptiSpheric® IOL R&D

OptiSpheric® IOL PRO 2

OptiSpheric® IOL PRO 2

Efficient production requires the possibility of testing complete batches as perfromed by OptiSpheric® IOL PRO 2. Thus it generates a high throughput of up to 100 lenses in 12 minutes.
For different measurement conditions the multilens tray is available for in-air and in-situ conditions. Additional single lens trays provide possibilities for calibration and validation measurements or tests with a heatable model eye.

The system is easy to set up and with just a few clicks the fully automated and user-independent alignment and measurement process starts. The predefined measurement scripts for different lens types optimize the testing procedures for highest efficiency.

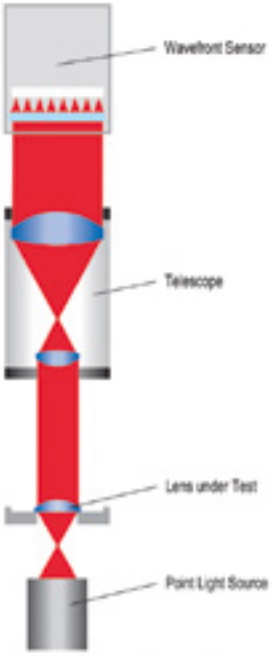
Especially when it comes to toric lenses the user benefits from OptiSpheric® IOL PRO 2 as the measurement is done independently of the lens axis positioning in the sample holder.
The intelligent test algorithm determines the toric axes first, before evaluating the relevant test parameters for each principle section.

Like the OptiSpheric® IOL R&D, the OptiSpheric® IOL PRO 2 can also accommodate various model corneas. The integrated cornea changer provides three seats for this purpose. Various filters and a large range of apertures are also automated and controlled by the predefined test procedure.
The identical measurement principle of the optical setup between OptiSpheric® IOL PRO 2 and OptiSpheric® IOL R&D allows for easy comparison of test results between R&D and production.

WaveMaster® IOL 2

Based on wavefront analysis the WaveMaster® IOL 2 measures key parameters of refractive monofocal and toric, spherical or aspherical intraocular lenses for research and development.

Wavefront Analysis with Shack-Hartmann Sensor



Analyzing the wavefront of an IOL is an alternative to using the magnification method for testing the quality and measuring the key parameters of IOLs. In WaveMaster® IOL 2 the wavefront is measured using WaveSensor®, TRIOPTICS' well established Shack-Hartmann sensor. This permits the complete mapping of intraocular lenses and provides information on

- Refractive power over the entire IOL aperture (power mapping)
- Lens aberrations of lower and higher orders (Zernike analysis)
- Toric axis deviation and marker orientation
- Modulation transfer function (2D MTF)
- Point spread function (PSF)
- Strehl ratio

Measurement principle: A point light source is placed in the focal plane of the lens under test. A telescope images the exit pupil of the sample onto the wavefront sensor.

Key Features

- Quality control of all common refractive intraocular lenses: monofocal, toric, spherical and aspherical
- Fully automated and user-independent determination of refractive power (sphere and cylinder), aberrations, MTF (also for toric samples), PSF and toric axis deviation
- Camera image for visual IOL inspection

WaveMaster® IOL 2

Comprehensive IOL Mapping via Wavefront Analysis

WaveMaster® IOL 2 is capable of measuring lenses in-air or in the optionally heatable in-situ eye model as per ISO 11979. The main measurement parameters are calculated in a quick measurement process. Power measurement with accuracies as low as one third of the allowed tolerances stated in ISO provide confidence in target achievement. Easily exchangeable telescopes allow in-depth quality inspection for an extended range of aperture sizes simulating changing pupil diameters.

The WaveMaster® IOL 2 provides software features for easy to use evaluation of toric lenses. It allows automated MTF measurement in both meridians of the sample as well as fully automated determination of the axis deviation between the optical and the marked toric axis. Apart from automated marker recognition, the integrated live camera permits visual inspection of the lens's manufacturing quality.

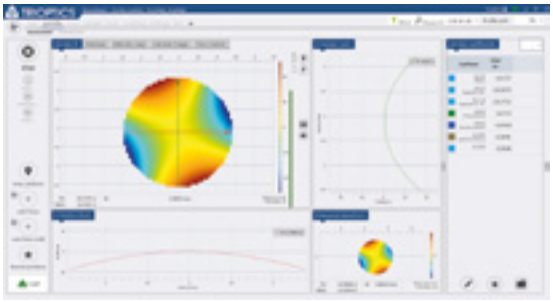
Sophisticated Software Control

It is easy to handle the challenging measurement tasks performed with WaveMaster® IOL 2. All aspects of measurement, from setting up the sample and the measurement process, through data calculation and analysis to data presentation, are arranged in a new intuitively usable interface that guides the user through the process. While the possibility to perform individual measurement procedures optimizes the testing of single IOLs, specific measurement configurations can be stored to reduce work required for future measurements of the same lens type.

Additional software modules are available to extend the possibilities for user-defined analysis to specific demands:

ZERNIKE analysis module

This module allows a Zernike fit with user-specific coefficients and analysis of wavefront files in real time. While design data can be imported from ZEMAX and CODE V the results can be exported to ASCII and, also, ZEMAX format.



Zernike analysis module

MTF/PSF analysis module

The MTF/PSF analysis module provides a real time calculation and display of 1D and 2D MTF and PSF. User-specific analysis angles as well as results based on measured or fitted wavefront and easy analysis for toric samples are supported.

Accessories

For optimal integration of the measurement system into production or R&D departments, TRIOPTICS offers various options that provide further functionality or increase the efficiency.

Model Eyes for In-Situ Measurement

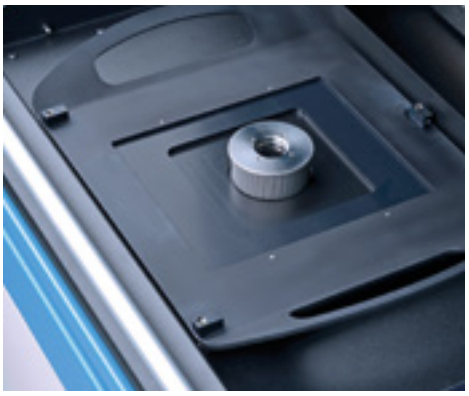
For the in-situ measurement of single lenses TRIOPTICS offers two model eyes. Both are designed in compliance with ISO 11979 and are optionally heatable. To simulate a possible tilting or displacement of the lens after implantation, an advanced model eye is available for the OptiSpheric® IOL R&D. It additionally allows the XY-displacement of the lens compared to the cornea and a tilt of the IOL of up to 5°.

Advanced model eye

Trays for Production

The high throughput of OptiSpheric® IOL PRO 2 is reached through a selected use of one of the four available trays:

- Production tray for the measurement of 100 lenses in-situ
- Production tray for the measurement of 100 lenses in-air
- Single lens tray with self-centering holder for the measurement of single IOLs and glass reference lenses in-air
- Single lens tray with model eye for in-situ testing



Tray with standard model eye

Lens Holders

Lens holders are required for all applications. Our standard holder fits most lenses. However, customized lens holders can be provided for specific measurement conditions or lens positioning if necessary.

Single lens holder

Technical Data

	WaveMaster® IOL	OptiSpheric® IOL R&D	OptiSpheric® IOL PRO 2
Measurement method	Wavefront anaylsis	Magnification method	
Apertures diameter	2.1 mm …5.9 mm [1]	1 mm ... 6 mm with steps of 0.5 mm	
Wavelength	532 nm optional: 546 nm [2]	546 nm optional: 644 nm, 480 nm, photopic eye filter	
Wavefront accuracy	< λ/20 (RMS)	-	
Wavefront repeatability	< λ/200 (RMS)		
Dynamic range	> 1000 λ		
Power range [3]	Spherical Equivalent: +21.3 D … +125.1 D optional: +8.0 D … +125.1 D Cylinder: 0 D … +28.5 D	Without model cornea: -50 D … -2.5 D and +3 D … +125 D With model cornea: -200 D … 0 D and 0 D … +150 D	
Power accuracy [3]	Spherical Equivalent: [4] 21.3 D …+90 D: ±0.3 D … ±0.5 D +90 D … +125.1D: ±2.25 D Cylinder: [4] ±0.3 D … ±0.5 D	0.3 %	
MTF range [3]	+21.3 D … +125.1 D optional: +8.0 D … +125.1 D	Without model cornea: -50 D … -2.5 D and +3 D … +125 D With model cornea: -200 D … 0 D and 0 D … +150 D	
MTF accuracy	±2 %	±2 % (0 … 300 lp/mm)	
Radius and BFL accuracy	-	20 µm	10 µm
Max. batch size	1	1	100
Sample positioning	Manual	Manual	Automatic

[1] Depending on imaging optics
[2] Other wavelengths upon request
[3] Measured and labeled in water
[4] Measured with 3 mm aperture

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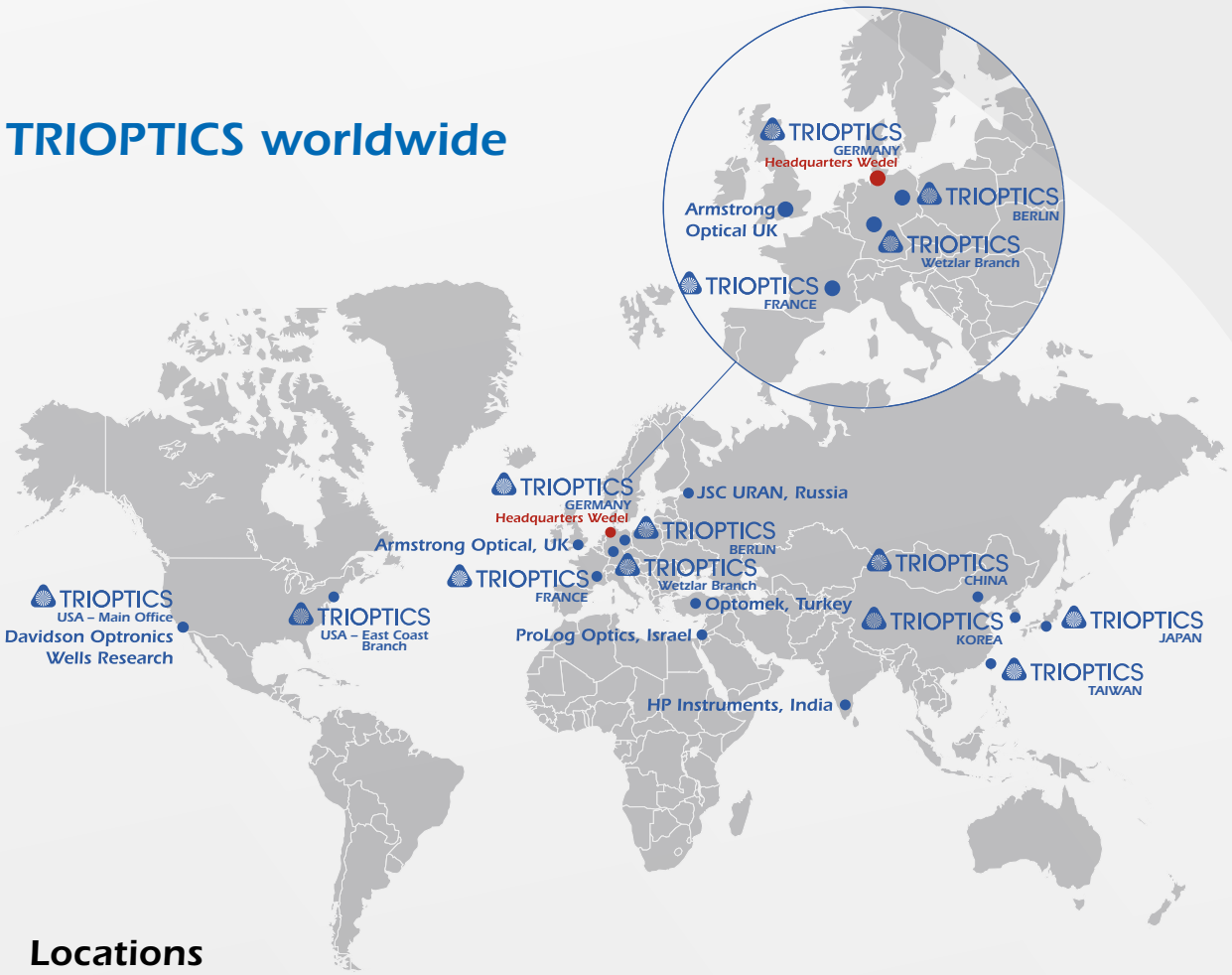
TRIOPTICS worldwide



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