Safety Notes

ZEISS Labscope 4.6 for Windows

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Original Manual

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Contents

1 General Information

1.1 Explanation of Warning Messages and Additional Information

CAUTION, and NOTICE are standard signal words used to determine the levels of hazards and risks of personal injury and property damage. Read all safety messages in the respective chapters carefully. Failure to comply with these instructions and warnings can result in both possible personal injury and property damage and involve the loss of any claims for damages.

The following warning messages indicating dangerous situations and hazards are used in this document.

> **⚠ CAUTION**
>
> **Type and source of danger**
>
> CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

> ***NOTICE***
>
> **Type and source of danger**
>
> NOTICE indicates a potentially harmful situation which, if not avoided, may result in property damage. In addition, NOTICE warns of data loss or corrupt data as well.

> **Info**
>
> Provides additional information or explanations to help the user better understand the contents of this document.

1.2 Further Applicable Documents

Instruction Manuals For detailed information on how to use the hardware (e.g. microscope or microscope system), refer to its Instruction Manual or ask your ZEISS Sales & Service Partner.

Brochures and Certificates For brochures, certificates (e.g. ISO, CSA, SEMI), and declarations of conformity (e.g. EU, UK) ask your ZEISS Sales & Service Partner.

Local and National Health and Safety Regulations Observe local and national health and safety regulations for the location of installation and during the use of the microscope.

Consult with your ZEISS Sales & Service Partner if these regulations are in conflict with the installation requirements of the microscope.

System and Third-Party Components, Accessories Information about the individual components, enhancements, and accessories can be obtained from your ZEISS Sales & Service Partner. Also refer to the documentation of third-party manufacturers.

1.3 Contact and Addresses

ZEISS Contact Find your contact at ZEISS Microscopy at www.zeiss.com/microscopy/contact.

ZEISS Academy For information on microscopy courses, training, and education visit the ZEISS Academy Microscopy at www.zeiss.com/microscopy-training.

Legal Manufacturer

Carl Zeiss Microscopy GmbH
Carl-Zeiss-Promenade 10
07745 Jena
Germany

Authorized Representatives, Importers, etc.

This section informs about responsible entities for certain obligations in the identified country or jurisdiction.

Carl Zeiss Ltd
1030 Cambourne Business Park, Cambourne
CB23 6DW Cambridge
United Kingdom

Carl Zeiss AG
Feldbachstrasse 81
8714 Feldbach
Switzerland

2 Safety

This chapter contains general requirements for safe working practices. Any person using the software or commissioned with installation or maintenance must read and observe these general safety instructions. Knowledge of basic safety instructions and requirements is a precondition for safe and fault-free operation. Operational safety of the supplied software is only ensured if it is operated according to its intended purpose.

If any work is associated with residual risks, this is mentioned in the relevant parts of this document in a specific note. When microscope components must be handled with special caution, they are marked with a warning label. These warnings must always be observed.

Any serious incident that has occurred in relation to the software shall be reported to these institutions:

- the competent authority of the Member State in which the user is established
- ZEISS
  - for users within the EU:
    Carl Zeiss Microscopy GmbH, Jena, Germany
  - for users outside the EU:
    Carl Zeiss Suzhou Co., Ltd., Suzhou, China

2.1 Intended Purpose

Intended purpose of Labscope for Windows

Labscope for Windows is a microscope software used to control and acquire images through connected and compatible microscopes. This combined system is used for in-vitro examination of images to obtain information about physiological or pathological processes or conditions. Labscope for Windows is intended to be used by professional users, among others in the field of life science, cytology, pathology. The connected microscopes are themselves CE-IVD products. For IVD examinations, ensure that the displayed image on the monitor shows the equivalent information as visible through the eyepieces of the microscope. Labscope AI modules are not intended for IVD examinations and may only be used in research.

Note: This Manual is applicable only to the Labscope for Windows. There are separate versions of the product for education, routine and research use only: Labscope for Android and Labscope for iOS. These Labscope for Android and iOS are mobile versions and do neither fulfill the definition of IVD device nor accessory to an IVD device, nor the definition according 2014/35/EU. The intended purpose of mobile versions documented here is just for the sake of clarification.

Intended purpose of Labscope for iOS / Android

Labscope for iOS / Android is a microscope software used to control, image acquisition, image processing and image analysis. Typical application fields of the software are general tasks and applications in microscopy or image acquisition, among others for education, routine and research. The software is not intended to directly or indirectly produce medical diagnostic results.

2.2 Applicable Standards & Regulations

This software product and the corresponding documentation has been designed, created and tested in compliance with the following regulations and directives:

- In Vitro Diagnostic Medical Devices Regulation (EU) 2017/ 746 (IVDR)
- Risk analysis for medical devices according to DIN EN ISO 14971
- Quality management system certified to DIN EN ISO 13485
- Documentation and Safety Notes according to DIN EN 82079-1 (VDE 0039-1)
- If necessary the user has to establish, document, implement and maintain a special process to fulfill all the requirements to be conform with the validate rules of law and standards.

2.3 Before Working with the System

Read the documentation and the safety notes of the corresponding system before you start working with the system.

⚠ CAUTION

Risk of Glare

There is a risk of glare when you switch on the light source, and you have not correctly installed the reflector cubes and/or fluorescence filter cubes in the microscope`s reflector turret.

- Check if all reflector and fluorescence filter cubes are installed correctly before you switch on the light source(s) of the microscope system.

NOTICE

Risk of Damaging Equipment, Corrupt Data or Data Loss

There is a risk of equipment damage, data loss or corrupted data when your system is not properly set up. Therefore, check and observe the following notes, before working with the system:

- Only trained persons are allowed to work with the system, e.g. performing measurements. Each person must have been informed about the possible risks connected with work in the field of microscopy and the relevant area of application.
- Use the system in a clean and dry environment only.
- Do not lay cables near objects that get very hot (e.g. halogen lamps, arc lamps of fluorescence microscopes). There is a risk that the insulation will melt and cause a short circuit.
- Check if all plugs are inserted firmly and securely prior to operation.
- Check cabling and connections of the stage, camera and microscope control units, to avoid incorrect measurements.
- Check if all hardware components are correctly configured in the software.
- Check that you are using the latest software version to avoid possible compatibility issues, which can lead to data loss or corrupt data.

2.4 While Working with the System

⚠ CAUTION

Risk of Glare

There is a risk of glare when you switch on or work with LED illumination.

- Do not look into the ocular when changing settings on the LED illumination.
- Be cautious about the glare from the light source while adjusting the light intensity from software if somebody is looking through the eyepiece. Looking into the eyepiece from a too high light intensity could lead to eye damage from the glare.

NOTICE

Risk of Damaging Equipment, Corrupt Data or Data Loss

There is a risk of equipment damage, data loss or corrupted data (e.g. incorrect measurements) while working with the system. Therefore, read and observe the safety notes below:

- Protect the system from liquids and chemicals anytime.
- Check your computer and, in particular, the hard disk, to avoid data loss.
- Check the accuracy of a generated scaling (pixel sizes) immediately after starting up the system. When using manual microscopes, you must always check that the correct scaling has been selected before the acquisition of each image, in order to avoid incorrect measurements. The accuracy of all scaling generated should be checked at regular intervals.
- Check that the data generated are likely to be correct before processing it. ZEISS does not accept any liability for incorrect conclusions obtained as a result of incorrect raw data.
- Save all your data, such as images, measurement data, archives, reports, forms, and documents at regular intervals on an external storage medium. Otherwise, this data may be lost as a result of operational errors or hardware defects.

NOTICE

Risk of Incorrect Measurements

In the Microscope Configuration, cautiously configure the objective and filler sets according to the actual physical setup on each positions. A wrong configuration in Labscope can lead to wrong scaling info and wrong measurements.

The calibration is correlated to each objective. There is an indicator on a calibrated objective in the Microscope Configuration. A wrong selection or changing the camera adapter selection can lead to wrong scaling info and wrong measurements.

In Live View and Image View, ensure that the current selection of objective magnification is matching with the current physical objective in use, and the camera adapter to be checked from Microscope Configuration or image meta data is matching with the actual one in use. A wrong selection can lead to wrong scaling info and wrong measurements.

NOTICE

Risk of Misuse of AI Modules

Labscope AI Modules are not intended for IVD examinations and may only be used in research. A reminder dialog will pop up for reaffirming this notice when activating AI Modules through Labscope Module manager. Make sure that you do not use Labscope AI Modules for IVD purposes.

Furthermore, check and observe the following:

- Check the function of the light source to ensure there is sufficient brightness. If the light source is too old, it will lose brightness and must be replaced.
- Check the optics, to ensure no dirt is present. If necessary, clean the optics carefully.
- Check the camera's sensor, e.g. when looking at a live image, to ensure it is in perfect condition (no bad pixels). If the sensor is faulty, the camera must be serviced by specialists. In this case, contact ZEISS service.
- For the setting, use and maintenance of the system, the use of settings files and the further use and interpretation of the measured data, we recommend you to develop, maintain and provide proof of a suitable procedure in accordance with current legal and/or normative regulations. This also applies for the selection of images and configuration files in the subsequent (offline) analysis.
- Ensure that the displayed image on the monitor shows the equivalent information visible through the eyepieces of the microscope by adjusting the exposure and white balance settings.

2.5 Explanation of Symbols

CH REP	Swiss authorized representative
	Importer
	Manufacturer
UK CA	UKCA marking (UK conformity assessed)
IVD	In vitro diagnostic medical device
CE	CE marking (Conformité Européene)

3 Application and System Requirements

> **Info**
> Starting with Labscope 4.5 for Windows, it is compatible with ARM64 Snapdragon chip devices, such as the Surface Pro 11, all ZEISS network cameras and Axiovert 5 SCB/digital. Note that standalone ZEISS USB camera connections are not supported on the ARM64 Windows devices.

Application

Category / Field of Application	Education, Documentation, Microphotography, Laboratory, Research, and IVD examinations (Labscope for Windows only)
Compatible ZEISS microscopes	Primostar 3, Primo Star HDcam, Primotech, Primovert, Stemi 305 cam, Axioscope 5/7/Vario, Axiolab 5 and Axiovert 5
Compatible ZEISS cameras	Axiocam ERc 5s, Educam 105, Axiocam 202 mono, Axiocam 203 mono, Axiocam 208 color, Axiocam 212 color, Axiocam 105 color (Windows only) and Axiocam 305 mono/color (Windows only)
Languages	English, Czech, French, German, Italian, Japanese, Korean, Polish, Portuguese, Russian, Simplified Chinese, Spanish

System Requirements

	Labscope for Windows
Operating System	Windows 10 & 11 (64-bit)
Minimum Hardware Requirements	CPU: i3 (8th generation) dual-core @ 2.5GHz RAM: 6GB
Recommended Hardware Requirements	CPU: i5 (9th generation) quad-core @ 3.0GHz or above RAM: 8GB or above

System Requirements ZEISS Labscope Module Fast Panorama

Operating system	Windows 10 & 11 (64-bit)
Minimum hardware	CPU: i5 (8th generation) quad-core @ 3.0 GHz RAM: 8 GB or above
Recommended hardware	CPU: i7 (9th generation) hexa-core @ 4.0 GHz or above RAM: 16 GB or above
Supported camera types	Axiocam 305 mono/color Note that not all performance specifications of the used cameras can be supplied in the Labscope environment due to application specific restrictions.

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