ziemer
OPHTHALMOLOGY

GALILEI

Operator manual

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

1 GENERAL INFORMATION

We would like to thank you for your decision to purchase this ZIEMER product. Please read this manual carefully and follow the instructions precisely.

1.1 About this Manual

The Operator Manual describes the functions and the operation of the GALILEI™ G4 Dual Scheimpflug Analyzer and GALILEI G6 Lens Professional™.

Table 1: General information about the Product and Company

Title	**GALILEI™ Models – Operator Manual**
Sales item	REF 410.951.011
Document number	CM3940-0304
Revision	Version 06
Release date	August 2019
Products	**GALILEI™ G4 Dual Scheimpflug Analyzer** **GALILEI G6 Lens Professional™** Throughout this manual, the device will be referred to as "GALILEI", whenever the description is model independent.
Disclaimer	Please note that while every effort has been made to ensure that the data provided in this document is accurate, it is the policy of **SIS AG, Surgical Instrument Systems*** to continuously improve the operating performance and overall quality of its medical devices. Accordingly, the information, figures, illustrations, tables, specifications, and schematics herein are subject to change without notice.
Copyright Notice	
Trademarks	**GALILEI™** is a trademark of **Ziemer Group*** Other trademark names are used in an editorial fashion only with no intention of infringement of the trademark of the respective owner.
Manufacturer	**SIS AG, Surgical Instrument Systems***, a **Ziemer Group Company** Allmendstrasse 11, CH-2562 Port, Switzerland.
Licensee and distributor	**Ziemer Ophthalmic Systems AG***, a **Ziemer Group Company** Allmendstrasse 11, CH-2562 Port, Switzerland. www.ziemergroup.com

* Note: Throughout this manual, Ziemer Group and its subsidiaries, namely SIS AG, Surgical Instrument Systems and Ziemer Ophthalmic Systems AG, will be collectively referred to as "ZIEMER".

CAUTION: Federal U.S. law restricts this device to sale by, or on the order of, a physician or practitioner.

1.2 How to Use this Manual

This Manual should be carefully read before device operation. In particular, close attention should be given to section 2 Safety Instructions.

The Manual provides descriptions of the operation and settings of the GALILEI. It does not provide information about clinical decisions which may be derived from GALILEI data output. ZIEMER is not responsible, nor liable for any advice, course of treatment, diagnosis or any other information, pertaining to patient outcomes based on the decision of a trained eye care professional. Data derived from the GALILEI is intended as supplementary information and should not replace clinical observation from a trained professional or data obtained from other devices or methods.

This Manual has been updated to correspond to software versions CMS V6.4.1 and EBR V2.3.1 or higher.

1.3 Supporting Documentation

The documents listed in Table 2 are to be used in conjunction with this Manual depending on the GALILEI model purchased:

Table 2: Accompanying documentation

Title	Document Number
GALILEI Topography / Tomography Application Manual	CM3941-0232
GALILEI Biometry Application Manual	CM3912-200-0008
GALILEI G4 Quick Guide to taking successful measurements	CM3941-0126
GALILEI G6 Quick Guide to taking successful measurements	CM3912-200-0004

1.4 Symbols and Abbreviations

1.4.1 Symbols on safety

Throughout this manual, symbols are used to alert the reader of special situations. Their meaning is described in Table 3.

Table 3: Symbols used for safety

Symbol	Description
	**WARNING** A warning indicates an action or procedure that, if not performed correctly, could result in serious injury or a safety hazard. Strict compliance with these instructions is required.
	**CAUTION** A caution indicates an action or procedure that, if not performed correctly, might result in minor or moderate injury. Strict compliance with these instructions is required.
	**NOTE** A note indicates an action or procedure that, if not performed correctly, can result in incorrect operation or damage to the device or trigger an unexpected response on the part of the instrument. Strict compliance with the instructions is required.
	**HINT** Hints indicate tips and tricks for a successful handling of the device and its parameters.

1.4.2 Symbols used on labels

On product labeling certain icons (symbols) are used. Their meaning is explained in Table 4.

Table 4: Symbols used on labels

Symbol	Description
	**Attention** Follow instructions for use.
	**Electrical shock** Type B patient-applied part
	**Waste Electronic and Electrical Equipment** Symbol is based on European Union Directive 2012/19/EC. The disposal to municipal waste is prohibited for electronic equipment Subject to this directive; this equipment must be collected separately and treated or recycled.
	**Certification mark** Test symbol of MET with approval for USA and Canada
	**Certification mark** European certificate of conformity
	**Manufacturer** Name and address of the manufacturer
REF	**Catalogue Number** Manufacturer's catalogue number
SN	**Serial Number** Manufacturer's serial number
Mains	**Mains**
Power	**Power**
Fuse	**Fuse**
Weight	**Weight**
Input	**Input**

1.4.3 List of abbreviations

Table 5 summarizes all abbreviations used in this Manual.

Table 5: List of abbreviations

Abbreviation	Description
ACD	Anterior Chamber Depth
AL	Axial Length
AQD	Aqueous Depth
CT	Corneal Thickness
CCT	Central Corneal Thickness
CMS	Corneal Measurement System
EBR	Eyeball Reader
EMC	Electromagnetic Compatibility
ESD	Electrostatic discharge
HD	Hard Disk / Hard Disk drive
HOA	Higher Order Aberration
IEC	International Electrotechnical Commission
LT	Lens Thickness
ME system	Medical Electrical system
OCT	Optical Coherence Technology
RF	Radio Frequency
ROI	Region of Interest
RWS	Remote Workstation
SD specified	Specified repeatability as defined by the mean Standard Deviation
SD measured	Measured repeatability as estimated by the mean Standard Deviation
SimK	Simulated Keratometry
SimKf	Simulated Keratometry Flat
SimKs	Simulated Keratometry Steep
SLED	Superluminescent Light Emitting Diode
TCP	Total Corneal Power
W	Watt
WTW	White-to-White

2 SAFETY INSTRUCTIONS

CAUTION: Personal injury or property damage due to improper operation: To assure safe operation, it is imperative that the instrument is used according to the instructions in this manual. Familiarity with the content of the instructions for use before operating the system is required.

WARNING: Personal injury or property damage due to equipment modifications that could jeopardize safety: No modification may be made to this device without the permission of the manufacturer. Access or modification to the electrical system can lead to death. Only ZIEMER service and authorized dealers are allowed to modify the device or the associated lifting table.

2.1 General

Do not use the GALILEI without having a thorough understanding of the operation, functions, controls and limitations of the system.

2.2 User Qualification

- Make certain that the GALILEI is used only in clinics and by eye specialists and opticians. It must be used in the area designated for carrying out examinations.
- For this reason, the device may only be operated by personnel instructed to do so, who, with appropriate professional education, careful study of this Operator Manual, professional expertise and practical experience, are able to ensure proper handling of the device.

2.3 Transportation and Storage

NOTE: The internal components are sensitive to any vibration, jarring, bumping, dust/dirt and extreme temperatures. If you need to move the equipment to another location, please take special care when moving the measurement unit. Re-calibration may be necessary after a move.

- To avoid re-calibration, ensure that the measurement unit is protected by using the packaging material it was originally shipped in or ensure that it is well protected from physical mishandling, bumping or any similar disruptions.
- Before moving the device, the table must be lowered to its lowest position.
- To move the device over a step, approach the step with the measurement head side first. Gently lift the table on or off the step. Approach the step with the back wheels, and then lift the table at this side.
- Do not sit on or lean against the table.
- After relocation of the device all breaks of the GALILIEI table must be locked.

2.4 Setup and Connections

- Only ZIEMER or an authorized dealer is allowed to set up and to connect the GALILEI.
- Do not setup and operate the GALILEI in areas at risk of moisture or high humidity. Keep it away from water that may drip, splash, or spray on it to ensure that no moisture can penetrate the instrument. Also, do not place any containers filled with fluids near the instrument.

- Do not setup and operate the GALILEI in areas where there is risk of extreme temperatures, and in the presence of flammable liquids including anesthetics or volatile substances such as alcohol, benzine or similar products.
- Set up the GALILEI so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.
- When connecting the power cable, ensure that the pins and socket match. Always use a three-pole power cable. Ensure that the grounding of the wall outlet is properly connected to the power network's grounding. If there is any resistance and it is impossible to make a connection, then check whether the power cable plug pins fit into the socket. If you have any questions, contact your authorized dealer or our service department.

NOTE: The GALILEI and a connected computer form a medical electrical system (ME system) according to DIN EN 60601-1. If you connect additional devices (refer to Section 3.3.4 Optional peripheral devices, accessories, and software packages) to the analog or digital interfaces of the GALILEI, such as, for example a printer, those devices become part of the ME system. Make sure that all configurations comply with pertinent EN / IEC specifications and conform to standard IEC 60601-1.

2.5 Operation of the System

- Only operate the device after you have read and understood the operating instructions.
- Only operate the device if the system has been maintained and cleaned as instructed.
- Before first use: Let ZIEMER or an authorized dealer train you in the operation of the GALILEI.
- Never operate a damaged GALILEI. If the device is defective, it must not be used and the company from whom the device was purchased should be contacted.
- Only operate the device with the original components supplied by ZIEMER and only if the unit is in good working condition.
- Do not cover any computer ventilation holes in the table and computer housing.
- Do not touch any electrical contacts on the PC housing.
- Make sure that the device cannot tip over by leaning against it, sitting on it or placing additional weight onto the GALILEI table.
- The motor for lowering and raising the table has a 1/10 intermittent duty cycle (operating time 1 min, cooling time 9 min). It is not intended for continuous operation. When moving the table up or down, make sure that operator and patient are clear of the column due to crushing hazard.

2.6 Measurement Environment and Precaution

CAUTION: Aphakic photochemical light hazard may exist under the following conditions: Repeated use of the GALILEI and/or combined use of the GALILEI with other light emitting instruments.

- While no acute optical radiation hazards have been identified for slit lamps, it is recommended that the amount of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakic patients and patients with diseased eyes may be at greater risk. The risk may also be increased if the person being examined has had any exposure with 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 subject to retinal photography.

- In an aphakic eye with a dilated pupil of 7 mm EN-ISO 15004-2:2007 the guideline for retinal exposure of an eye is 10 J/cm^2 per 24 hours. Following this guideline not more than 12 measurement should be performed on an eye.
- To ensure that the measurement precision is not affected, the GALILEI must be operated in an appropriate environment. The operating conditions are specified in Sections 4.1.1 Preparations and conditions for system setup and 8.1 Technical Data.
- The GALILEI G6 belongs to Laser Class I under IEC Standard EN 15004-2:2007 and all functionalities and instructions are compliant with EN 15004-2:2007. The limit values of the Optical Coherence beam as specified for Class I laser devices to EN 60825-1:2014 will be observed if the device is operated as intended.

2.7 Disassembly and Disposal

- When disconnecting the electrical power cords, always grasp the outside of the plug end to disconnect and avoid pulling directly on the cables.
- Dispose of the device according to legal regulations. (refer to Section 8.4 Disposal)

2.8 Electrical Safety

- Use of a multiple socket extension cord
- Electromagnetic Compatibility (EMC) / Cables (refer to Section 9.1 Manufacturer's Electromagnetic Compatibility (EMC) Declaration)

3 DEVICE DESCRIPTION

3.1 Intended Use

3.1.1 Intended use

The GALILEI is designed to take images of the anterior segment of the eye, which includes cornea, iris, pupil, anterior chamber, and crystalline lens. To evaluate:

- Corneal shape
- Pachymetry (corneal thickness)
- Position of the cornea relative to iris and lens
- Anterior and posterior opacity
- Anterior chamber angle
- Anterior chamber depth
- Volume of the anterior chamber
- White-to-white distance
- Pupil size
- Condition and position of implants (e.g. IOL, phakic IOLs, intracorneal rings)
- Location of cataracts (nuclear, sub capsular and/or cortical), using cross slit imaging with densitometry
- Condition of the lens (opaque crystalline lens)
- Lens shape
- Crystalline lens thickness

The GALILEI G6 Lens Professional is designed to additionally evaluate:

- Axial length

The GALILEI also performs calculations to assist physicians in determining the power of an intraocular lens for implantation.

3.1.2 Indications for use

The GALILEI is indicated for preoperative and postoperative evaluation of the anterior segment and axial length.

3.1.3 Contraindications

None known

3.2 Device Description

Figure 1: GALILEI G6 Lens Professional system (Example)

The GALILEI is a non-invasive, non-contact optical system designed for the analysis of the anterior segment of the eye based on processed optical images from an integrated rotating Dual-Scheimpflug and Placido tomography system. The GALILEI G6 (Figure 1) additionally provides axial length measurement (optical A-scan) using low coherence interferometry.

While rotating the measurement head, the GALILEI captures Placido and Dual-Scheimpflug images of the anterior eye segment at varying angles. The images created during an examination are transmitted to a connected PC.

The integration of these images is the basis to calculate a three-dimensional 3D model of the anterior segment and based on it to generate values. At the same time, any eye movements are recorded and taken into account with a patented iris-based eye-motion detection, and automatic realignment to the Purkinje reflection. A quality specification allows assessment of the quality of the measurement taken. The 3D model provides the basis for all subsequent analyses. Standard displays are automatically generated.

The GALILEI provides measurement information only; it does NOT make a diagnosis.

CAUTION: Ziemer Ophthalmic Systems AG shall not be liable in any form for further use of the data recorded and processed by a GALILEI.

3.3 System Components

3.3.1 Scope of delivery

The following components are delivered with the GALILEI:

- Measuring head, mounted on a height-adjustable instrument table with locking wheels, which also includes the control unit, containing the PC, and power supply. The GALILEI G6 additionally includes an EBR low coherence interferometry module for measuring axial length.
- Head and chinrest, as well as disposable chinrest paper
- Wide-screen monitor
- Keyboard and wireless mouse
- Power cable (EU and US)
- Dust cover for measuring head
- System and application software:

  - CMS application software (GALILEI G4, GALILEI G6)
  - EBR application software (GALILEI G6)
  - For details on standard and optional software modules, refer to the according application manual.
- Operator and application manual(s)
- Quick Guide to taking successful measurements

HINT: We reserve the right to change the scope of delivery in line with ongoing technical development.

3.3.2 System overview

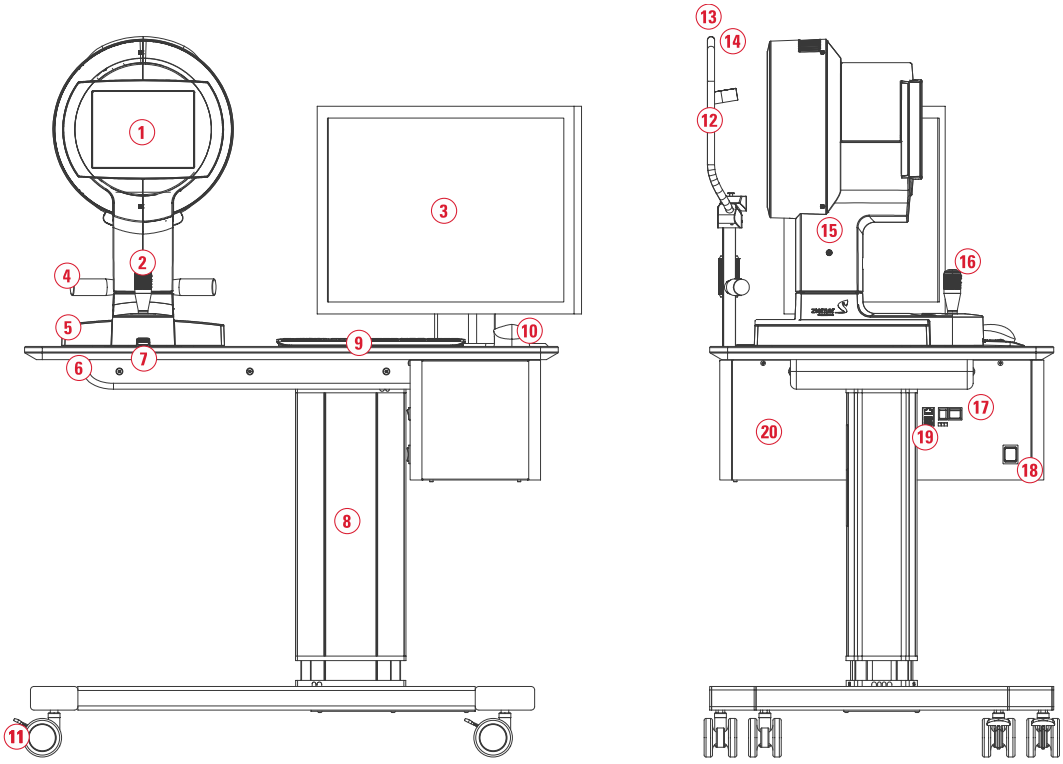


Figure 2: GALILEI system: (left) front view, (right) side view

Front view

1 Measurement head with built-in device monitor
2 Measurement head locking bolt (front)
3 Free standing system monitor
4 Handle bars attached to the headrest
5 OS / OD eye alignment guide
6 Table cover (secured with 6 screws)
7 Thumb wheel for immobilizing measurement head during transport / storage
8 Height adjustable table column
9 Keyboard
10 Wireless mouse
11 Locking wheels

Side view

12 Head and chinrest with disposable chinrest paper
13 Headrest
14 Forehead band
15 Measurement locking bolts (left and right)
16 Joystick for positioning the measurement unit
17 USB connectors
18 Height-adjustment switch for instrument table
19 Power ON / OFF (green) and system START / REBOOT (black) switches
20 Housing for computer, power supply, and cables. The GALILEI G6 additionally includes an EBR low coherence interferometry module for measuring AL.

3.3.3 System component details

Table and computer housing

On the measurement table surface near the cross-slide, there are two cross marks labeled “OD” and “OS” for indicating the approximate starting position when aligning the measurement head in front of the patient’s left or right eye. By moving the slide so that the thumbwheel for immobilizing the cross-slide is aligned with the appropriate mark, the patient’s eye can be easily aligned. For more details, refer to the application manual or follow the steps displayed on the auxiliary device monitor. The OS / OD label of the eye will be visible on the monitor once the eye is visible for measurement. Refer also to the Quick Guide (refer to Section 1.3 Supporting Documentation).

Several switches are located on the computer housing (refer to Section 3.3.2 System overview):

- A green power ON / OFF switch on the inner side of the PC housing (refer to item 19).
- A black system START / REBOOT switch next to the green power switch (refer to item 19).
- A toggle switch for moving the table up and down is located on the inside of the computer housing (refer to item 18).

Measurement head and device monitor

Figure 3: GALILEI measurement head (left: patient interface; right: operator interface)

The patient side of the device includes the Placido disk, which will rotate 180 degrees during a measurement. The operator interface includes the device monitor. This monitor is used for aligning the measurement head to the patient’s eye. In addition, it displays a short checklist for the set-up process. The joystick can be used to move the cross-slide and the measurement head left/right and back/forth, and also up/down (by turning the joystick). (Figure 3)

System monitor

The system monitor turns on automatically when the PC is on. Should it fail to do so, push the on/off button on the lower right of the monitor case.

Wireless mouse

The wireless mouse, used as the primary screen navigation tool, has an on / off toggle switch on the bottom side. When “on”, an automatic battery life saving feature is activated that switches the mouse off after a period of inactivity. To reactivate the mouse, simply click it.

Changing batteries: The battery compartment is located on the bottom of the mouse. Use one AA battery.

Keyboard

A US keyboard is supplied with the device. If the keyboard is wireless, you must insert batteries. If you received a wired keyboard, it must be plugged in to the back of the PC. The cable can be run through the cable duct in the table top.

3.3.4 Optional peripheral devices, accessories, and software packages

Printers

Printer drivers for a variety of USB printers are pre-installed in the GALILEI system software. For more details, refer to Section 4.1.5 Printer installation.

Exchangeable hard disk drive

An exchangeable hard disk drive (HD) for data storage and archiving is available.

NOTE: The hard drive must be configured by Ziemer Group in order to function. Replacement hard drives can be ordered separately.

To exchange the disk, the GALILEI must be turned off. Remove the screw beneath the front of the PC case. Slide the silver button to the right and the HD holder will open. Carefully remove the HD and replace it with the replacement device. If two exchangeable hard drives are installed, the database disk is located in the bottom slot.

Add-on Software Packages

For the GALILEI separately sold software modules are available. They require a license key. For details on available options, refer to the according Application Manual.

4 INSTALLATION AND COMMISSIONING

4.1 Setup and Connections

The GALILEI will be setup and put into operation by ZIEMER Customer Service or an authorized dealer.

4.1.1 Preparations and conditions for system setup

The following details are provided for assistance at the clinic location.

Installation of the device requires:

- Access to power supply outlets
- Ethernet connectivity for remote service access
- Surge protection (recommended)
- Backup power supply (recommended) and
- An additional external hard drive for routine and frequent backup of data (recommended, refer to Section 4.4 Backing up the Database).

When selecting a location for your device, consider the room light, temperature and airflow conditions to optimize GALILEI measurement success. The following measures will help optimize the quality of acquired data:

- The device should be placed in a darkened room and external light sources minimized and prevented from shining directly into the measurement head on the patient's side (e.g. avoid direct light sources behind the patient from another device, including a bright monitor, direct reflection of light from a mirror or an open door or window). This provides better image contrast, which can improve the image analysis algorithms that rely on high contrast optical images.
- The device should not be placed directly below an overhead air conditioning or heating unit, which may lead to condensation on the measurement head glass panel from the patient's breath or negatively affect the patient's tear film.
- Lock the brakes on the table's wheels before an exam to stabilize the table.
- Verify that the table can be raised and lowered by testing the switch on the right side of the table.
- Select a chair or stool for the patient that provides a comfortable position, adjustable height that is within range of table height adjustment, stability when subject is sitting, and the ability to allow patients to position their chin properly into the headrest.

4.1.2 Software installation

The GALILEI system is equipped with pre-installed system and application software.

4.1.3 Connecting to an existing network

The GALILEI can be connected to an existing network (intranet). Please contact ZIEMER Customer Service for further instructions. ZIEMER Customer Service may need to communicate directly with the local IT specialist for software permissions (for example, when working with a firewall) and for recommendations to minimize any software conflicts.

NOTE: Do not install any software without contacting ZIEMER Customer Service. Any attempts to install third party software without ZIEMER's consent will void any warranty.

CAUTION: The integration of a Programmable Electronic Medical System into an IT-network involving other devices may lead to risks for patients, operators or others that were previously unknown. The organization in charge must determine, analyze, evaluate and manage such risks. IEC 80001-1:2010 contains instructions on how the organization in charge may address these risks. Modifications to the IT network that may lead to risks and require analysis include: Changes to the configuration of the IT network, connection of additional elements to the IT network, removal of elements from the IT network, update of devices that are connected to the IT network, upgrade of devices that are connected to the IT network.

4.1.4 Connecting supplementary equipment

The operator of the GALILEI is responsible for compliance with the standard IEC 60601-1-1 or IEC 60601-1 (3rd) whatever is applicable according to local law when any supplementary equipment is connected to the analog or digital interfaces of the GALILEI system. Supplementary equipment may include a printer or external hard drive.

4.1.5 Printer installation

A select number of printer drivers are pre-installed on the GALILEI.

A PDF printer driver (labeled “ZIOS”) is also pre-installed and required for all printing. Do not remove this printer driver or any other pre-installed printer drivers. Printing using this PDF printer (labeled ZIOS) enables the user to preview and verify the report before it is printed. This printing process also helps to avoid over-spooling to the local printer.

NOTE: Do not uninstall any existing printers, including the PDF printer.

Installing a local printer

Connect the printer to the device and turn the power on. If the device recognizes the printer, you may then print. For further assistance installing a printer, please contact your authorized dealer or Customer Service.

Installing a network printer

Installation of a network printer requires administrator-level assistance. Please contact your authorized dealer or Customer Service for assistance.

4.1.6 Antivirus software

The Microsoft Windows default antivirus software is pre-installed and activated on the GALILEI.

- Default antivirus software for devices with Windows 7: Microsoft Security Essentials (https://support.microsoft.com/en-my/help/14210/security-essentials-download)
- Default antivirus software for devices with Windows 10: Windows Defender (https://support.microsoft.com/en-my/hub/4099151/windows-security-help)

Antivirus software is updated via Windows security updates. The GALILEI has not been tested with other antivirus software.

NOTE: If you install additional or alternate virus protection software, ZIEMER will thereafter not be responsible for the proper functioning of the device.

4.1.7 Remote workstation

The GALILEI application software features a remote workstation (RWS) capability for use through a separate networked PC. The RWS software license allows:

- Read-only access to the software and database from a separate PC.
- Full access and analysis of the measurements that are in the patient database of the GALILEI via a network connection.
- May be used for analyzing and presenting measurement data, and for printing reports, even while the device itself is operated by another user.

HINT: The RWS is an optional accessory and requires a separate license. The remote workstation has options for multiple, concurrently running remote workstations. For more information or to purchase a license, please contact your authorized dealer or ZIEMER Customer Service.

4.2 System Startup and Shutdown Procedure

To switch on the system:

1. Turn the system on with the green power switch located on the inside of the table.
2. To turn the computer on with the black start/reboot switch (next to the power switch). The first screen will be the data base management screen. Note: If the green power switch is already on, use the black start/reboot switch (next to the power switch) to startup the computer.

To switch off the system:

1. Terminate the GALILEI software by clicking on the closing icon [X] in the upper right corner.
2. Shut down the computer by clicking “Start > Shut Down” in the lower left corner of the Windows screen.
3. After the computer is shut down, turn off the green power switch located on the inside of the table.

4.3 Measuring Procedure

The measuring procedure consists of the following steps:

1. Enter the patient data
2. Position and instruct the patient
3. Perform the measurement
4. Check the quality of the measurement
5. Save the measurement

Certain clinical conditions, including but not limited to severe keratoconus for axial length measurement, and cataract and high hyperopia for white to white measurement, may result in the need for repeated measurements using the GALILEI. The physician should always take care to ensure that repeated measurements do not exceed the recommended maximum number of daily measurements (12) to protect ocular safety.

For more details on the measuring procedure, please refer to the Application Manuals GALILEI Topography/Tomography and/or GALILEI Biometry (Section 1.3 Supporting Documentation).

WARNING: The performance of the GALILEI device has not been established in subjects with severe keratoconus and prior crosslinking.[1]

4.4 Backing up the Database

Please refer to the GALILEI Topography / Tomography Application Manual for more details (Section 1.3 Supporting Documentation).

NOTE: We recommend that the database be backed up regularly, and particularly before a software update or a restore.

[1] Due to a too small sample size within the GALILEI G6 FDA registration study, no valid device performance conclusions for this intended use population can be drawn.

5 DATA COMPUTATION, DEFINITIONS AND PRINCIPLES

HINT: For your convenience, clicking the "i" or "information" button at the right hand side of the parameter bar will display help or text about the specific parameter.

5.1 Cornea Dimensions

The GALILEI displays different indices about the cornea. The definitions of these indices are detailed below.

Indices of refraction

For historical reasons, SimK parameters are calculated from anterior curvature using the so-called keratometric index of 1.3375. This refractive index is lower than that of the cornea (1.376) and allows estimation ("simulation") of total corneal power as if the cornea were a single refractive surface. Parameters calculated with the keratometric index are denoted the addition "Sim": SimKf (flat SimK), SimKs (steep SimK), etc.).

Posterior parameters (Posterior Curvature) are calculated with the indices of refraction of the cornea (1.376) and aqueous humor (1.336).

Anterior axial curvature: SimK

This parameter, shown as "SimK", is the arithmetic mean or average of the steep (SimKs) and flat (SimKf) axis and is being calculated as:

$$SimK = \frac{SimKf + SimKs}{2}$$

The axis or angle of each meridian is displayed in degrees.

Anterior curvature SimKf and SimKs

SimKs and SimKf are calculated from the pair of meridians 90° apart with the greatest difference in average power, from 0.5 to 2.0 mm distance from the center.

This maximizes the astigmatism parameter, which is the difference between SimKf and SimKs.

The corresponding radii of curvature values (in mm) are displayed to the right for each dioptric value.

Curvature K (in diopters) and radius of curvature r (in mm) are in general related as follows:

$$K = \frac{1000\ (n_2 - n_1)}{r}$$

n_1 = index of refraction of the first medium (air, n=1)

n_2 = index of refraction of the second medium (keratometric index for simulated anterior curvatures)

r = radius of curvature in mm

Anterior curvature: Astigmatism (Astig)

As mentioned above, the astigmatism value equals the difference between SimKf and SimKs.

Anterior curvature: Axis

The axis parameter is the direction of the meridian of the steepest axis (SimKs), and therefore shows the orientation of the astigmatism. The axis is displayed to the right of the astigmatism, in degrees.

Anterior and Posterior curvature: Eccentricity

Eccentricity 'ε' is reported as its square ε2. This term is one of four parameters by which the shape of a conic section can be described: Q (asphericity), p value and E (corneal shape factor) are the others. These terms are mathematically related by the following equation:

$$\epsilon^2 = E = 1 - p = -Q$$

Eccentricity can also be directly calculated:

$$\epsilon^2 = \frac{(R * R_0^2)^{\frac{2}{3}} - R_0^2}{x^2}$$

R = Instantaneous radius of curvature

R_0 = Average central instantaneous radius of curvature

x = Radial position

GALILEI calculates the eccentricity ε^2 (-Q) of the surface within a central diameter of 8 mm averaged over all meridians. This is done for the anterior and posterior surface.

Posterior curvature: Mean K, Flat K, Steep K, Cylinder, Axis, Eccentricity

These parameters are essentially the same as the ones from the anterior surface. The only difference is that the K values are not simulated, but calculated with the real indices of refraction of the cornea and the aqueous humor.

Kmax and its location

Kmax is the maximum curvature on the anterior axial curvature map. The value is determined from within the maximum curvature spot zone as identified with the cone location magnitude index CLMI algorithm. The location of Kmax is displayed in x,y coordinates relative to the center of the map (0,0). Kmax can be used to describe the severity of the cone and to monitor progression.

Central, Mid (paracentral) and Periph (peripheral) zones

- Central zone diameter = 0 – 4 mm
- Paracentral zone diameter = 4 – 7 mm
- Peripheral zone diameter = 7 – 10 mm

Pachymetry: Thinnest and Central (CCT)

The thinnest pachymetry value (in µm) and location in x,y coordinates relative to the map center are displayed. The location can be overlaid on the map as a small circle. The average central corneal thickness (CCT) is calculated across the central 2 mm zone.

Corneal Volume

The corneal volume is calculated over a diameter of 8 mm.

WTW (Limbus): Nasal-Temporal

The limbus is fit to a best-fit ellipse in the reference top view image. The maximum length in horizontal direction of the ellipse (not the ellipse long or short axis) is taken as the nasal-temporal limbus parameter white-to-white (WTW). Due to differences in white-to-white measurement between devices from various manufacturers, it is not recommended to use instruments interchangeably in clinical practice.

WTW (Limbus): Superior-Inferior (on display only)

The limbus is fit to a best-fit ellipse in reference to the top view image. The maximum length in vertical direction of the ellipse (not the ellipse long or short axis) is taken as the superior-inferior limbus parameter.

Kappa distance

The angle Kappa distance, in mm, denotes the apparent distance from the center of the reflection of the 4 Purkinje dots (approximate location of the visual axis in the pupil plane) and the pupil center.

Pupil: Average diameter (Pupil Diam)

The pupil is fit to a best-fit circle in the reference top view image. The average diameter parameter is then taken from this circle.

Pupil center location (x, y)

The center of the best-fit circle to the pupil is given as the pupil center relative to the center of the map (0, 0).

CLMIaa, PPK

Cone Location Magnitude Index Anterior Axial Curvature and probability value associated with abnormal corneal shape and asymmetry.

5.2 Anterior Chamber Dimensions

Dimensions of the Anterior Chamber (AC) are defined by several parameters, namely Anterior Segment Length (ASL), Anterior Chamber Depth (ACD), Aqueous Depth (AQD), Anterior Chamber Volume (ACV), and Anterior Chamber Angle (ACA). The definitions of these parameters are detailed below and illustrated in Figure 4 and Figure 5.

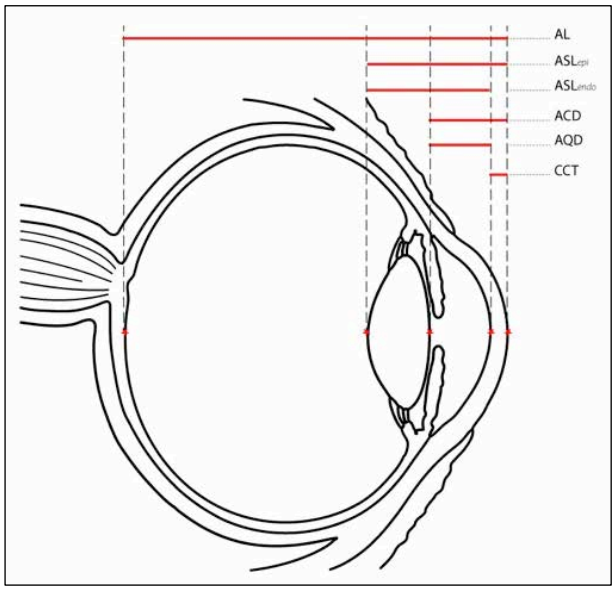


Figure 4: Definitions of Anterior Chamber dimensions indices

AL	Axial Length (measured by GALILEI G6 only)
ASL_{epi}	Anterior Segment Length from epithelium to posterior lens surface
ASL_{endo}	Anterior Segment Length from endothelium to posterior lens surface
ACD	Anterior Chamber Depth from epithelium to anterior lens surface
AQD	Aqueous Depth from endothelium to anterior lens surface
CCT	Central Corneal Thickness

AL is the central distance between the anterior surface of the cornea and the retina. It can only be measured with the A-scan modality of the GALILEI G6 Lens Professional.

ASL_{epi} is the axial distance between the anterior surface of the cornea (epithelium) and the posterior surface of the lens measured perpendicularly to the lens surface. The distance is averaged over all measured Scheimpflug scans after correction for optical effects.

ASL_{epi} = ACD + crystalline lens thickness = ASL_{endo} + CCT

ASL_{endo} is the axial distance in mm between the posterior surface of the cornea (endothelium) and the posterior surface of the lens measured perpendicularly to the lens surface. The distance is averaged over all measured Scheimpflug scans after correction for optical effects. The average anterior segment length (ASL) is used in dilated eyes only.

ASL_{endo} = AQD + crystalline lens thickness

GALILEI software measures and displays either ASL_{endo} or ASL_{epi} depending on the user preference. Set your preference in the “Settings” screen. Refer to the Topography / Tomography Application Manual for more information.

HINT: ASL can only be measured with a dilated pupil.

ACD is the distance between the anterior lens surface and the anterior cornea (epithelium). The average anterior chamber depth is measured in mm along the central normal line between the outer iris edge. The displayed value is the average of measurements for all Scheimpflug images. ACD includes the central corneal thickness.

ACD = AQD + CCT

AQD is the distance between the crystalline lens and the posterior cornea (endothelium). The average anterior chamber depth is measured along the central normal line between the outer iris edge. The displayed value is the average of measurements for all Scheimpflug images.

GALILEI software measures and displays either ACD or AQD depending on user selected preference. Set preferences in the “Settings” screen. Refer to the Topography / Tomography Application Manual.

HINT: The IOL Calculator performs all calculations with the value ACD.

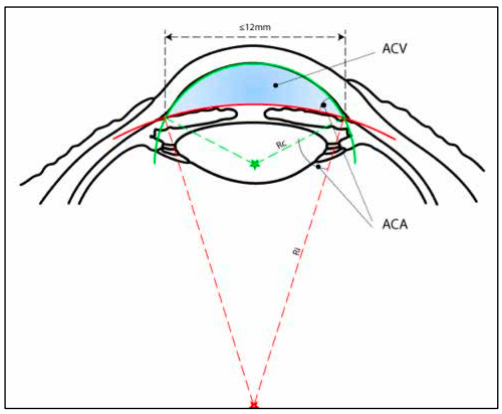


Figure 5: Definitions of Anterior Chamber volume and angle indices

ACV Anterior Chamber Volume

Rc Radius of circular fit to posterior cornea surface (green circle segment)

Ri Radius of circular fit to anterior iris edge (red circle segment)

ACA Anterior Chamber Angle (angle of intersection between green and red circle segments); equal to angle between Rc and Ri)

ACV is the volume of the anterior chamber, defined by the posterior surface of the cornea (approximated by a circular fit, along each Scheimpflug segment, to the detected posterior edges) and the anterior edge of the iris (approximated by a circular fit to the detected edges). The anterior chamber volume is calculated over a diameter of 12 mm.

ACA is the angle formed by the posterior surface of the cornea and the anterior edge of the iris at the intersection point of the two lines. The average anterior chamber angle generated from the 3D model is displayed in degrees.

For details on the methods of computation for ACV and ACA, refer to Section 5.8.4 Calculation of Anterior Chamber Angle and Volume.

5.3 Axial vs. Instantaneous Curvature

Curvature in general is mathematically defined as the rate of change of the tangent vector to the curve with respect to the arc length of the curve (Figure 6).

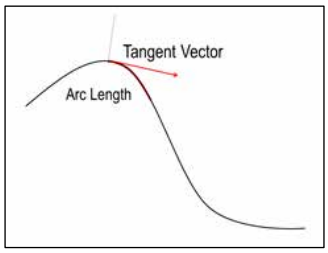


Figure 6: Definition of curvature

$$K = \frac{\frac{d^2y}{dx^2}}{\left[\left[1 + \left(\frac{dy}{dx}\right)\right]^2\right]^{\frac{3}{2}}}$$

K = curvature

y = f(x) = equation of curve

A circle with radius of curvature r described by the equation $x^2 + y^2 = r^2$. In this case, the above expression for curvature reduces to K = 1/r. When r is entered in meters (m), the unit of K is diopters (D).

In the central and para-central regions of a spherical surface separating air (refractive index = 1) from a medium of refractive index = n, refractive power in diopters (D) can be approximated as

$$D = \frac{1000\ (n - 1)}{r}$$

where r is the instantaneous radius of curvature in millimeters.

With the GALILEI, two different types of curvature are computed, axial curvature and instantaneous curvature, that are based on two different definitions of the radius of curvature as illustrated in Figure 7.

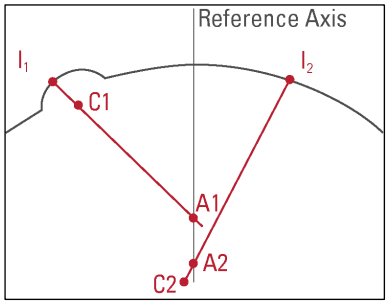


Figure 7: Axial vs. Instantaneous Curvature

At intersection points I_1 and I_2, spheres with centers C1 and C2, respectively, are best-fitted to the curve Instantaneous curvature at I_1 and I_2 is calculated as the reciprocal of the radius of curvature to C1 and C2, respectively. Axial curvature at I_1 and I_2 is calculated as the reciprocal of the radii of curvatures that are extended to a reference axis. Axial curvature is a smoothened representation of corneal shape by underestimating areas of relatively high curvature and overestimating areas of relatively low curvature. Instantaneous curvature represents a more detailed display of corneal shape than axial curvature, but may exaggerate small irregularities.

HINT: Axial curvature is also referred to as sagittal curvature. Instantaneous curvature is also referred to as tangential curvature.

5.4 Refractive Power

Refractive power is obtained by tracing rays from a distant object through the anterior corneal surface using Snell's law and the keratometric index of 1.3375, as if the cornea were a single refractive surface, determining the distance f' to the focal point F', and taking the reciprocal of f' (Figure 8). Corneal curvature as measured by topographic devices and refractive power correspond in the central and para-central regions[2], but not in peripheral regions.

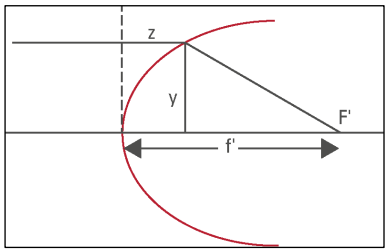


Figure 8: Refraction of light ray through a single refracting surface, coming to a focus at F' at the posterior focal distance f'

Construction for specifying refractive power as illustrated on a single refracting surface: For an off-axis ray at height "y", the focal length "f" is calculated from ray-tracing using Snell's law. For details on ray tracing, refer to Section 5.5.1 Ray-tracing. The distance "z" represents corneal sagittal depth.

5.5 Total Corneal Power (TCP; ray-traced)

5.5.1 Ray-tracing

Light rays are refracted while passing through the interfaces between two different media. Accurate scaling of an image as observed through such an interface can be challenging as a result. Therefore, to ensure accurate manual measurements of Scheimpflug images, ray-tracing is required to take into account the refraction due to the anterior and posterior corneal surfaces as well as the separation between the corneal surfaces.

Ray-tracing is a method of modeling the power of a lens by tracing initially incident parallel rays of light through an optical system, e.g. the corneal surfaces, using Snell's law to calculate the angle of refraction at each surface by means of the angle of incidence. Ray-tracing considers the curvature of the corneal surfaces and the transitions between indices of refraction at each surface, which affects how light rays are refracted.

[2] Roberts C. The accuracy of power maps to display curvature data in corneal topography systems. Invest Ophthalmol Vis Sci. 1994; 35:3525-3532.

5.5.2 Definition of TCP

Total Corneal Power (TCP) is the overall power of the cornea, considering the measured shape of the anterior and posterior corneal surfaces as well as their measured separation. TCP indices and TCP map are calculated by tracing virtual, parallel incident light rays from a distant object through the anterior and posterior corneal surfaces (refer to Section 5.5.1 Ray-tracing).

The angle of incidence θ_1 of a light ray relative to the normal at the anterior corneal surface is determined (Figure 9: Ray-tracing through the anterior and posterior corneal surfaces). The angle of refraction θ_2 is then calculated with Snell's law using $n_1 = n_{air} = 1$ and $n_2 = n_{cornea} = 1.376$. This angle of refraction θ_2 is thereafter used to determine the angle of incidence θ_1 of the light ray relative to the normal at the posterior corneal surface. The angle of refraction θ_2 is again calculated with Snell's law, but this time using $n_2 = n_{cornea} = 1.376$ and $n_3 = n_{aqueous} = 1.336$, which then determines the intersection F' of the refracted ray with the optical axis, analogous to the situation displayed in Figure 8, F' representing the posterior focal point of the cornea for this light ray. The reciprocal of the focal distance f' to F' multiplied by the refractive index of the medium in which the ray propagates is equal to TCP: TCP = n/f'.

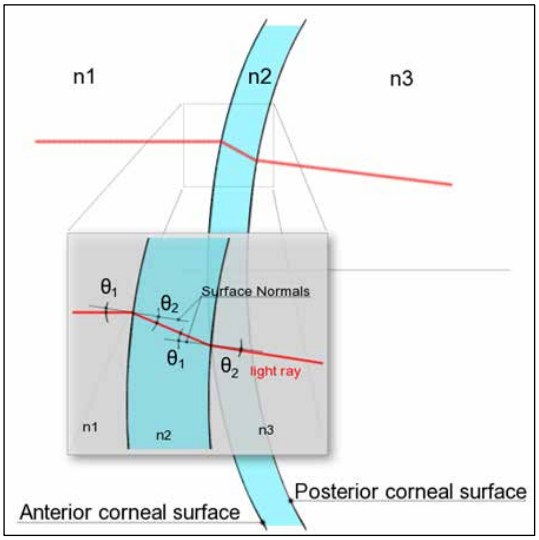


Figure 9: Ray-tracing through the anterior and posterior corneal surfaces
using indices of refraction: n1 = n_{air} = 1, n2 = n_{cornea} = 1.376, n3 = $n_{aqueous}$ = 1.336

TCP is calculated in this fashion at every point on the anterior corneal surface for determining the TCP map. Determining the greatest difference between perpendicular axes allows determination of Flat TCP, Steep TCP and Mean TCP:

- **Flat TCP** and **Steep TCP** are calculated from the pair of meridians 90° apart with the greatest difference in total corneal power, from 0.5 to 2.0 mm radius, similar to Flat SimK and Steep SimK.
- **Mean TCP** is the mean of Flat TCP and Steep TCP.

Averaging TCP over defined central, mid-peripheral and peripheral areas allows determination of indices Central, Mid and Periph.

HINT: TCP cannot be calculated by simply adding anterior corneal power to posterior corneal power because the separation of the two surfaces, i.e. corneal thickness, considerably affects overall corneal power, as dictated by Gullstrand's equation for the overall optical power D of two refractive elements with powers D_1 and D_2, separated a distance d and a medium of index n: $D = D_1 + D_2 – (d/n)D_1D_2$.

5.5.3 Using TCP

Three different TCP types (TCP_1, TCP_2, TCP_{IOL}) are calculated with the GALILEI. They differ in the refractive index n that is used in the equation TCP = n/f' and in the reference plane (anterior or posterior corneal surface) from where f' is measured to F'.

- **TCP_1**: is calculated using the corneal index of refraction (n_{cornea} = 1.376), and f' is referenced to the anterior corneal surface.
- **TCP_2**: is calculated using the aqueous index of refraction ($n_{aqueous}$ = 1.336), and f' is referenced to the anterior corneal surface, as is the case with TCP_1.
- **TCP_{IOL}**: is calculated using the aqueous index of refraction ($n_{aqueous}$ = 1.336), and f' is referenced to posterior corneal surface.

CAUTION: TCP cannot be calculated by simply adding the central anterior K value as re-computed from SimK to the posterior K value.

5.5.4 Relationship of TCP to SimK

While both TCP and SimK represent measures of overall corneal power, they are different in a number of ways:

- TCP is calculated using measured anterior and posterior corneal surface data, whereas SimK estimates overall corneal power based on the power of the anterior corneal surface, the constant relationship between anterior and posterior corneal curvature of Gullstrand's model eye, and the application of the keratometric index.
- TCP provides information over the entire cornea, whereas SimK provides information within the central area of the cornea only.
- The limitation of SimK to the central corneal area comes from the small-angle approximation that is employed when calculating SimK using radius of curvature:

  $$SimK = \frac{1000\ (n_k - 1)}{r}$$

  where r is the radius of curvature in millimeters, 1 stands for the index of refraction of air, and n_k represents the keratometric index. In peripheral corneal regions, the small-angle approximation is no longer valid, and the assumption that refractive power equals curvature no longer holds true.

5.5.5 Using GALILEI TCP in IOL formulae

For corneas without prior refractive surgery, the SimK values may be used in standard IOL formulae that were empirically developed based on SimK data.

For eyes with prior refractive surgery, TCP takes the modified relationship between anterior and posterior curvature into account. The ASCRS website (http://iolcalc.ascrs.org) offers a formula to calculate the post-refractive IOL power using GALILEI TCP. The average TCP can be calculated over any zone. The ASCRS formula was developed for the values of the average central TCP1 and TCP2, defined as the central 0- to 4-mm zone. Refer to the use of TCP_1, TCP_2, and TCP_{IOL} in Section 5.5.3 Using TCP.

CAUTION: GALILEI TCP is not intended for direct insertion into existing IOL power formulas which are designed for SimK. Refer to Sections 5.5.4 Relationship of TCP to SimK and Section 5.5.5 Using GALILEI TCP. SimK should be used in IOL power formulae developed for SimK, while TCP should be used in formulae developed for TCP.

5.5.6 Related References

- Wang, Li, Ashraf Mahmoud, Betty Anderson, Douglas Koch, Cynthia Roberts. Total corneal power estimation: Ray tracing method vs. Gaussian optics formula. Invest. Ophthalmol & Vis. Sci., November 2010, http://www.iovs.org.
- The ASCRS website to Calculate IOL Power in Eyes with Prior Refractive Surgery (http://iolcalc.ascrs.org)

5.6 Elevation

Elevation is defined as the vertical distance in micrometers of the corneal surface above or below a best-fitted spherical surface (BFS), a best-fitted aspherical surface (BFA) or a best-fitted aspherical-toric surface (BFTA). It is displayed by means of anterior and posterior BFS, BFA and BFTA maps.

5.7 Wavefront Aberrations and Equivalent Defocus

5.7.1 Wavefront Aberrations

Ocular aberrations induce differences in the optical path-length between a plane wavefront as referenced at the pupil plane and the wavefront of light exiting the eye from a point source on the retina. Such differences in the optical path-length are typically expressed in µm. On the left part of the GALILEI wavefront display, under the title “Total Corneal Wavefront”, the measured, aberrated wavefront is depicted as a map (Figure 10), representing the path-length differences in µm at various positions.

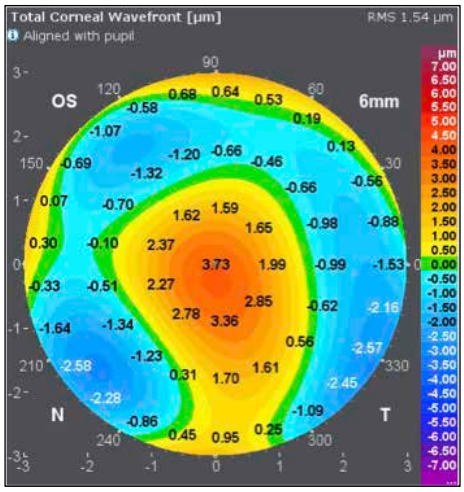


Figure 10: Measured wavefront aberrations depicted as a map

Aberrated wavefronts can also be described as a Zernike expansion which is a weighted sum of Zernike polynomials $Z_n^m(r,\varphi)$, where the weight C_n^m applied to each polynomial is the corresponding aberration coefficient, ‘n’ is the radial order and ‘m’ is the angular frequency. The GALILEI wavefront display indicates Zernike coefficients from the 2nd to the 8th order (Figure 11) at the upper left, where individual values within the 5th to 8th orders are summarized in one total value. Aberrations consisting of piston (0th order), vertical/horizontal prism (1st order), defocus, and vertical/horizontal astigmatism (2nd order) can be corrected by traditional means (sphere and cylinder) and make up about 85 percent of all aberrations in an eye.[3]

[3] Thibos LN, Applegate RA, Schwiegerling JT, Webb R (2002) Standards for reporting the optical aberrations of eyes. Journal of Refractive Surgery **18** (5):652-660.

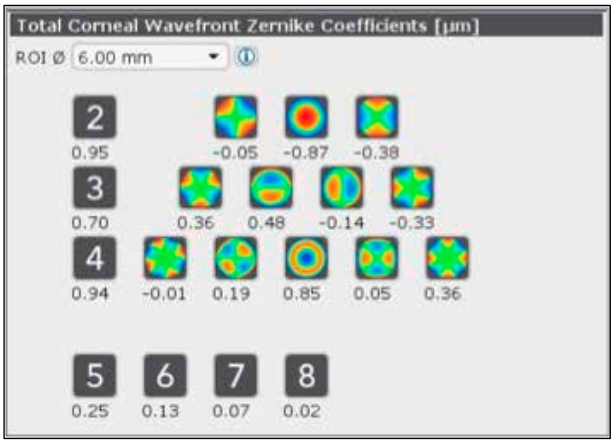


Figure 11: Indication of Zernike coefficients for 2nd to 8th orders

5.7.2 Equivalent Defocus

The idea of an equivalent defocus was created to assist in the interpretation of the magnitude of higher order wavefront aberrations. Equivalent defocus has been defined as the amount of defocus required to produce the same wavefront variance as produced by one or more higher-order Zernike modes.

HINT: "Equivalent Defocus" is different from "Total (Ocular) Defocus". The latter requires input of the axial length.

Equivalent Defocus can be expressed in an explicit formula because the absolute value of any Zernike coefficient may be interpreted as the root-mean-squared (RMS) wavefront error produced by the corresponding aberration mode:

$$M_e = 4\pi\sqrt{3}\frac{RMS}{A_p} = \frac{4\pi\sqrt{3}}{A_p}\sqrt{\sum_{m,n}(C_n^m)^2}\,,[D]$$

Where 'A_p' is the pupil area and 'C_n^m' some selected normalized Zernike coefficients of the wavefront error. If both the pupil radius and the RMS error are measured in mm, the value for equivalent defocus will be in diopters [D]. The pupil area may be replaced by the area 'pR^2' of a circle with the radius 'R' (mm) of the region of interest (ROI) of the Zernike expansion, which results in;

$$M_e = \frac{4\sqrt{3}}{R^2}\sqrt{\sum_{m,n}(C_n^m)^2}\,,[D]$$

Defocus values equivalent to selected Zernike coefficients are depicted in the upper part of the right wavefront display (Figure 12). Note: the diameter of the ROI is displayed, not the radius.

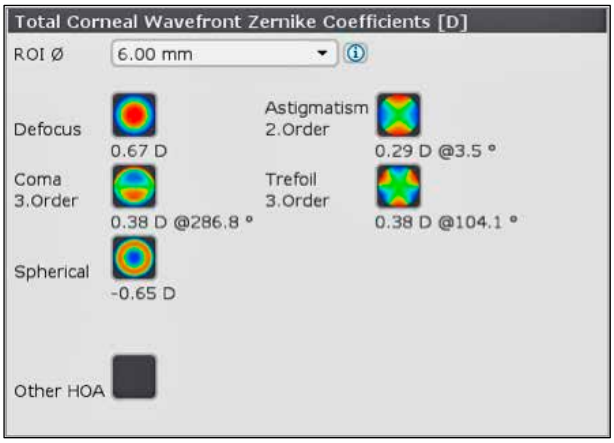
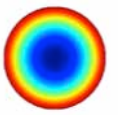
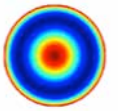
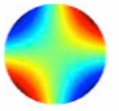
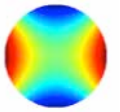
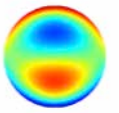
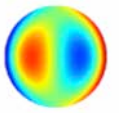
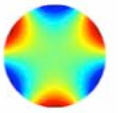
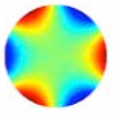


Figure 12: Defocus values equivalent to selected Zernike coefficients

Table 6: The following equations explain the indices for the equivalent defocus on this display

HOA	Zernike coefficient		Equivalent defocus
Defocus	 C_2^0		$M_e = \frac{4\sqrt{3}}{R^2}\sqrt{C_2^0}$
Spherical	 C_4^0		$M_e = \frac{4\sqrt{3}}{R^2}\sqrt{C_4^0}$
Astigmatism (2nd order)	 C_2^{-2}	 C_2^2	$M_e = \frac{4\sqrt{3}}{R^2}\sqrt{(C_2^{-2})^2 + (C_2^2)^2}$
Coma (3rd order)	 C_3^{-1}	 C_3^1	$M_e = \frac{4\sqrt{3}}{R^2}\sqrt{(C_3^{-1})^2 + (C_3^1)^2}$
Trefoil (3rd order)	 C_3^{-3}	 C_3^3	$M_e = \frac{4\sqrt{3}}{R^2}\sqrt{(C_3^{-3})^2 + (C_3^3)^2}$

The last three indices of Table 6 consist of oriented Zernike polynomials making it possible to compute an orientation of the index. The following equations explain the computation of this angle (atan2 is a function that computes the four-quadrant inverse tangent):

- Astigmatism: ϕ_A = { [atan2(C_2^{-2},C_2^2) / π+180] modulo 360 } / 2 [°]
- Coma: ϕ_C = { [atan2(C_3^{-1},C_3^1) / π+180] modulo 360 } [°]
- Trefoil: ϕ_T = { [atan2(C_3^{-3},C_3^3) / π+180] modulo 360 } / 3 [°]

5.7.3 Equivalent Defocus Maps

The definition of Equivalent Defocus is converted to a new form to transform the optical path-length differences of the wavefront aberrations into diopters. Rather than take the variance, the wavefront path-difference d is taken.

$$M_e = \frac{4\sqrt{3}}{R^2} d, [D]$$

Every point on the "Total Corneal Wavefront" map (Figure 13) is transformed into diopters using this equation. The result is depicted on the right bottom part of the GALILEI wavefront display.

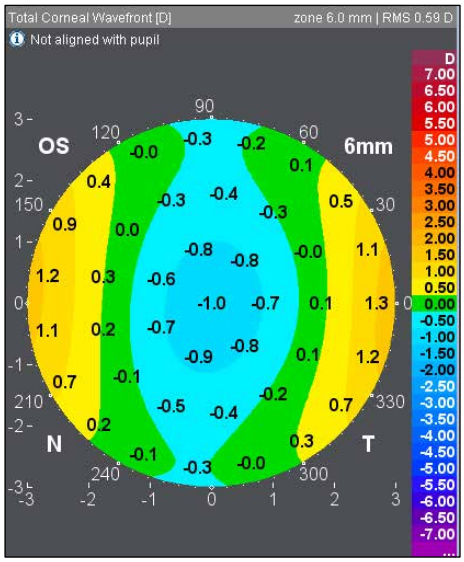


Figure 13: Total Corneal Wavefront map in [D]

5.8 How Does GALILEI Treat Data?

The scanning process acquires a series of Scheimpflug (SPF) images (meridians) and two Placido TopView images at 90 degrees apart.

From the SPF images the edges are detected (anterior cornea, posterior cornea, anterior lens and iris). On the Placido images the ring edges are detected. In a separate process, the limbus and pupil are detected from a TopView image. The limbus and pupil do not influence any other calculations performed by the system.

From the SPF edges, height data is determined. The slope data from the Placido images are transformed into conforming height data. Now the data are ready to be merged. The combined height data are then used to create a surface fit. From that surface fit, indices are calculated and maps are generated.

5.8.1 Significance of the Red Zones in the Eye Metrics

The red zones within the SPF image indicate areas where edges were not detected reliably and ray tracing was therefore not possible.

Example 1 Example 2 Example 3

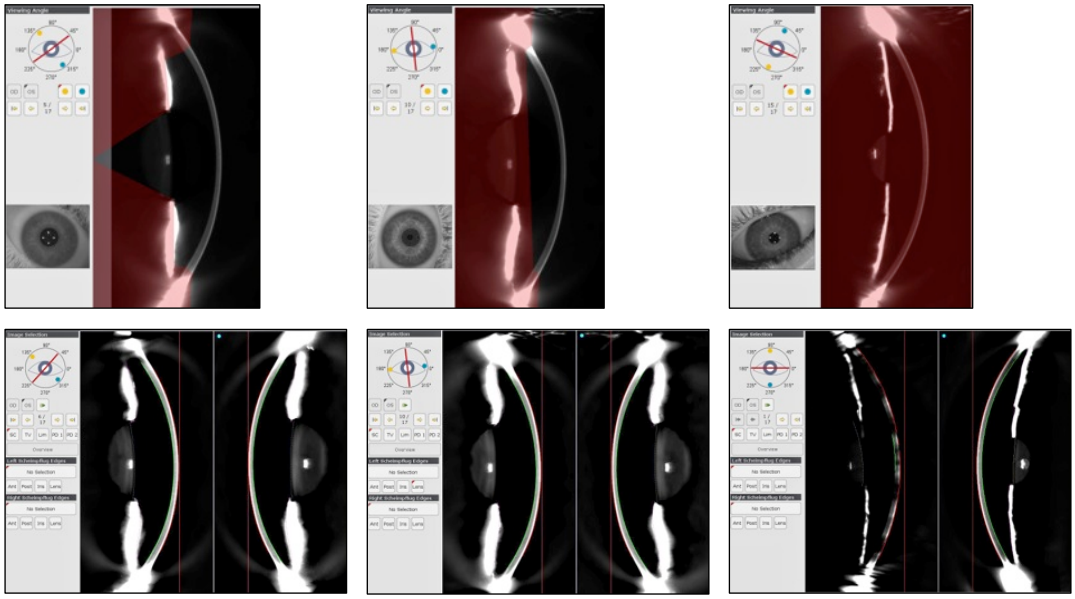


Figure 14: Red zones in the "Eye Metrics" Scheimpflug images

Three typical “red zone” examples are depicted in the top row of Figure 14 and the bottom rows correspond to the SPF images from the “Verify” screen.

- Example 1 has a minimal red zone and the edges have been detected correctly except for the bottom part of the cornea in the right SPF image (marked with a blue dot in the upper left corner). This explains why the red zone covers more of the chamber angle on the bottom than on the top of the image.
- In example 2, the lens is unavailable for manual measurements. This is because the lens edge has not been recognized in the left SPF image (yellow dot).
- Example 3 is completely red because in the right SPF image (blue dot), the corneal edges have not been found at all because of eyelashes in the Scheimpflug view.

Inspection of the below quality percentages within the “Analysis Report” (Figure 15) reveals that the percentage for SPF is just above the recommended value, whereas that of the Placido image is below the recommended value. If quality percentages are below recommended values, the measurement should be repeated.

The example shown belongs to example 3 from Figure 14.

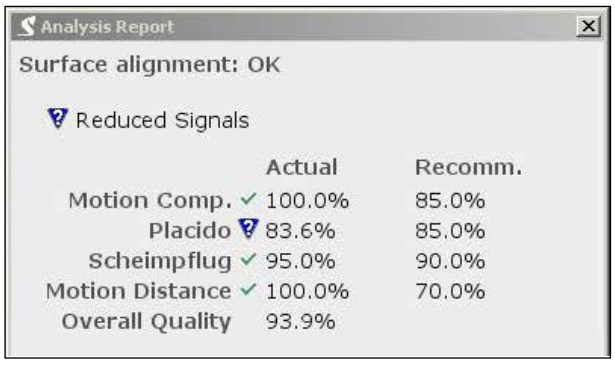


Figure 15: Example of "Analysis Report" where measurement should be repeated

5.8.2 Dual Scheimpflug and Accuracy

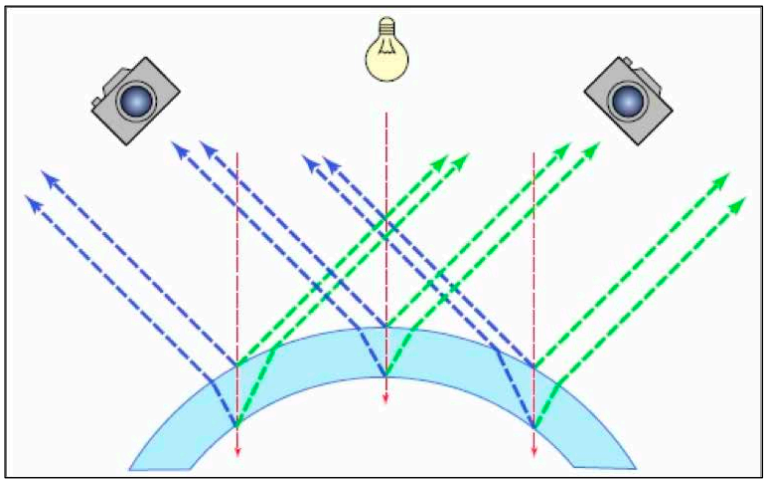


Figure 16: Eye motion affecting the image seen by a Scheimpflug camera

Figure 16 illustrates how eye motion during a measurement can affect height data of the posterior surface (which also affects pachymetry, as pachymetry is determined from anterior and posterior height data). When the slit light is centered on the apex and when there is no motion, both left and right cameras view the same thickness (the blue or green line in the cornea). When the eye moves, the two cameras shift to the left or right side. In this configuration, the left and right viewing camera will see a different thickness. Note, the difference in separation of the blue and green line pairs depend on the angle of the camera and the direction of displacement from the center of the cornea.

Combining the two camera views using ZIEMER's patented Dual Scheimpflug solution, the systematic error in the original captured image is automatically corrected by averaging the two opposed camera images. Averaging the two images corrects the decentration error caused by eye motion or misalignment, making the measurement of the posterior edge independent of eye motion, allowing for accurate pachymetry and elevation data.

Accurate anterior surface calculations technically require only one of the two SPF images, along with the Placido image. However, for posterior surfaces, both SPF images are needed to compensate for decentration due to eye motion. Therefore, accurate determination of corneal pachymetry, anterior chamber depth and posterior corneal surface requires complete dual SPF images. Loss of one of the two means that the corresponding image will be discarded and the Scheimpflug quality percentage will drop accordingly.

5.8.3 Central Anterior Curvature Accuracy: Placido vs. Scheimpflug

Placido topography is the gold standard for central anterior curvature assessment because it measures corneal slope, which is directly related to corneal curvature. However, data from inside the first (most central) Placido ring is not available because that area is used for capturing an image of the reflected rings with the top view camera. With the GALILEI, the projected size of the central ring is approximately 1 mm in diameter.

Scheimpflug tomography measures height data directly. The relation between height data and curvature data as illustrated in Table 7 reveals that a 0.25 D difference in curvature is easier to detect in the periphery than in the center.

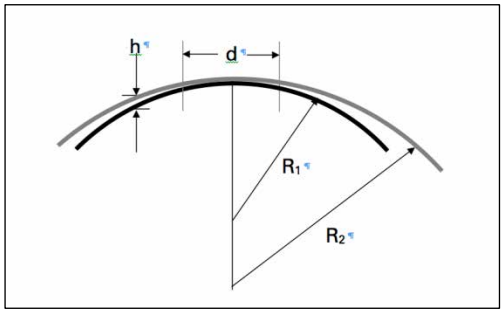


Figure 17: Surfaces with radius R_1 = 7.46 mm / power 45.25 D (black) and R_2 = 7.5 mm / power 45.00D (grey). The difference in height h increases with increasing diameter d.

Table 7: Relation between difference in height data and curvature

d	h
1 mm	0.1 µm
2 mm	0.4 µm
3 mm	0.9 µm
4 mm	1.6 µm
5 mm	2.5 µm

At d = 3 mm, for example, an approximate diameter over which keratometers typically measure corneal curvature, it takes a height difference of 0.9 µm for detecting a curvature difference of 0.25 D. This reaches or exceeds the resolution of a Scheimpflug based device or any other device that measures height for determining curvature. Thus, curvature measurement in the periphery is more accurate with Scheimpflug, whereas curvature measurement in the center is more accurate with Placido. In combination, the GALILEI allows for accurate curvature measurement in both areas.

5.8.4 Calculation of Anterior Chamber Angle and Volume

Due to Scheimpflug imaging limitations, the sulcus cannot be precisely detected (Section 5.8.1 Significance of the Red Zones in the Eye Metrics). For calculations of anterior chamber angles, the posterior corneal surface (green line) and the smoothed surface of the iris (red line), are extrapolated to the point where the two curves intersect. The angle of intersection is determined and is taken as the anterior chamber angle (mean angle). This process is repeated for all Scheimpflug images at all available meridians. (Figure 18)

The Anterior Chamber Volume (ACV) is computed from the area between the two fitted circular lines at each meridian. If the intersection points are spaced more than 12 mm apart, then the volume calculation will be truncated at 12 mm.

The computed values for ACV and mean angle are displayed in the index section of the “Eye Metrics” display.

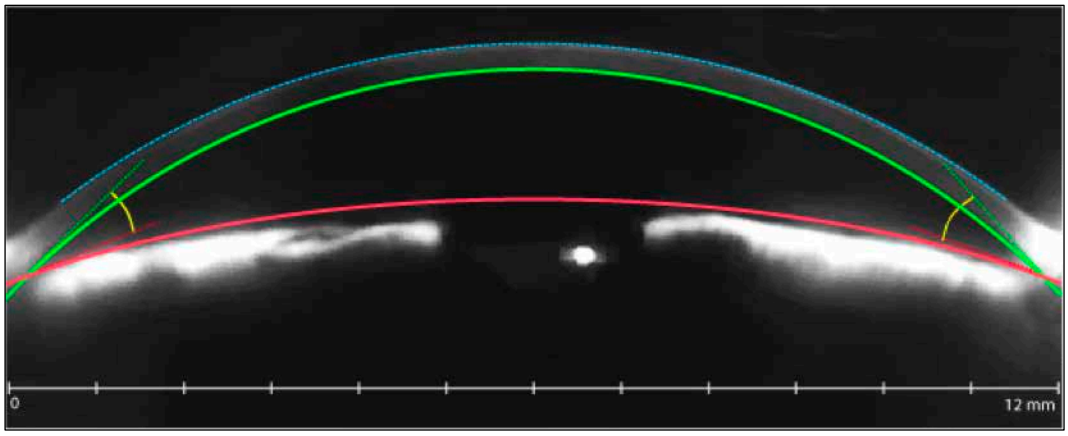


Figure 18: Illustration of computation of anterior chamber angle and volume

6 CARE AND MAINTENANCE

CAUTION: Before maintenance and cleaning of the GALILEI, always carefully disconnect the power cord from the wall socket. Also, disconnect all other equipment, which is attached to the GALILEI, e.g. a printer.

6.1 Cleaning and Disinfection

All patient contact surfaces should be disinfected by users and operators by following the directions below (Table 8).

Table 8: Cleaning and disinfection instructions

Purpose	The purpose of this procedure is to establish a consistent method by which users may clean and disinfect the patient contact surfaces as a routine operation to help reduce the potential for infection.
Materials required	• Disinfecting agent such as an anti-germicide or isopropyl alcohol • Cloth or paper towels
Procedure	• Dampen the cleaning cloth or towel in disinfecting agent and wipe the surfaces that come in contact with the patient. • Take the cleaning cloth used in the previous step and wipe the exposed surfaces of the chin rest. • The Placido disc is best cleaned with pure alcohol without any additives. • Do not pour or spray liquid onto the instrument.
Frequency	• Repeat this procedure following each exam.

It is recommended that a new standard chinrest paper (available from ophthalmic disposables suppliers) be used for every patient.

6.2 Maintenance

This GALILEI is a high-precision product containing sophisticated optics. In order to ensure accurate results and safe operation, service inspections must be performed according to the service plan of Ziemer Ophthalmic Systems AG.

For this reason, to ensure satisfactory and reliable operation, we strongly recommend that you have the GALILEI checked every year or after 10,000 measurements (whichever comes first) by ZIEMER Customer Service or an authorized dealer. The device will prompt the user to arrange for a maintenance service. Upon successful maintenance and testing, the service technician will release the system for another use cycle.

6.2.1 Replacement of Fuses

Before removing the fuses, disconnect the system from the mains plug and wait 5 minutes.

The system is equipped with two fuses of the same kind. To access the fuse holders, unplug the power cable from the system plug.

Using a screwdriver, remove the fuse holder. Remove the fuses from the holder and identify the broken fuses. Replace the broken fuses with new ones.

Fuse type: T 6.3A H

7 WARRANTY AND CUSTOMER SERVICE INFORMATION

No part of the GALILEI may be serviced by users. All service must be carried out by a ZIEMER Customer Service specialist or an authorized service provider. Modifications to the GALILEI made by unauthorized persons may void warranty.

Only spare parts, components, accessories and disposables obtained from ZIEMER may be used with the GALILEI. Use of any non-ZIEMER parts will void all warranties.

7.1 Customer Service Information

For questions or problems, first contact the distributor from whom the instrument was sold. A list of distributors can be found at:

http://www.GALILEI.ziemergroup.com

International contact address of Customer Service:

Ziemer Ophthalmic Systems AG
a Ziemer Group company
Allmendstrasse 11
2562 Port (Switzerland)
Phone: +41 848 943 637
Email: support@ziemergroup.com
www.ziemergroup.com

Local contact address of Customer Service in the USA and Canada:

Ziemer USA, Inc.
a Ziemer Group company
620 E 3rd St.
Alton, Illinois 62002 (USA)
Phone: 866-708-4472
Email: supportusa@ziemergroup.com

Local contact address of Customer Service in Germany:

Ziemer Ophthalmology (Deutschland) GmbH
a Ziemer Group company
Im Hausgrün 15
79312 Emmendingen (Germany)
Phone: +49 7641 9333 860
Email: supportde@ziemergroup.com

7.2 Remote Support

Each GALILEI is equipped with a software tool that allows remote access through the internet so that a support engineer can resolve issues quickly and efficiently to reduce device down time.

The “Remote Support Tool” requires that the GALILEI can be connected to the internet. An Ethernet cable plug connection is located on the side of the computer box (refer to Figure 2: GALILEI system: (left) front view, (right) side viewFigure 2), directly below the table. The device can be connected to a network or directly to a cable / ADSL modem.

When connected to the internet, start the Team Viewer software. Locate the software in GALILEI by left clicking on the Windows Start Menu.

When the TeamViewer software is started, the below displayed pop-up will appear (Figure 19). Please record your ID number that is shown in the window and communicate it to the service engineer. The device must be left on with the TeamViewer software running during the remote support process. The ZIEMER or distributor’s service engineer will guide the rest of the process.

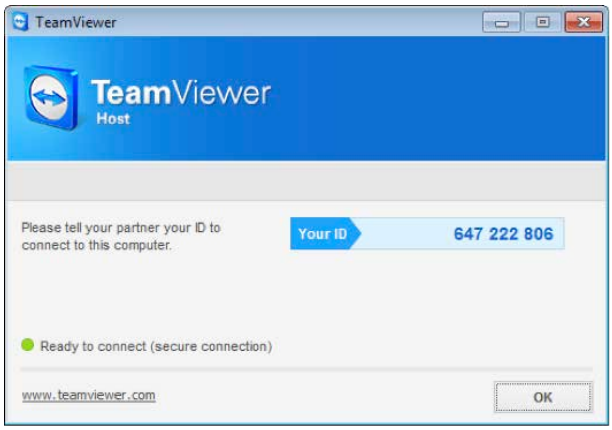


Figure 19: TeamViewer pop-up window

8 TECHNICAL DEVICE SPECIFICATIONS

8.1 Technical Data

Classification according to IEC 60601-1

- Type of protection against electric shock Protection: Class 1
- Degree of protection against electric shock: Type B Applied part
- Degree of protection against damaging penetration of water: IP20

Electrical conditions

- Mains: 100 – 240 V / 50…60 Hz
- Power: 400 W
- Fuse: 2x T6, 3A H, 250 V

Dimensions

- System footprint: 900 mm (L) × 580 mm (W)
- System height: 1226 – 1501 mm
- Table height: 692 – 967 mm
- Table weight: 69 kg (with Computer; without Measurement Unit)
- Measurement head weight: 13 kg
- System weight: 82 kg

Optical characteristics

- Placido disc: 20 rings
- Measurement time: 60 images in less than 1 second
- Number of measurement points – Scheimpflug / Placido: up to 100 000 measurement points
- Displayed map coverage: max. 10 mm
- Keratometry: 25 – 75 D (4.5 – 13.5 mm)
- Central Corneal Thickness: 250 – 800 µm
- Pupillometry: 0.5 – 10 mm
- White-to-White: 6 – 14 mm
- Anterior Chamber Depth: 1.5 – 6.5 mm
- Lens Thickness: 0.5 – 6.5 mm
- Axial Length: 14 – 40 mm (default 18 – 35 mm)

Units of measured parameters

- Curvature: Diopters [D]
- Pachymetry, Elevation: microns [um]
- Pupil, WTW, AL, ACD, LT: millimeters [mm]

Operating conditions

- Temperature: +15° C to +35° C
- Relative humidity: 30 % to 75 % no condensation
- Pressure: 690 to 1060 hPa (+3000 to -420 mASL)

Transport and storage conditions

- Ambient temperature: 0° C to +50° C, 32° F to +122° F
- Relative humidity: 10 % to 95 % no condensation
- Halfsinus shock: 30 g, duration 6 ms
- Halfsinus shock, continuous: 10 g, duration 6 ms
- Vibrations: 10 – 500 Hz 0.5 g/Hz

Measurement unit characteristics

- Measuring principle: Rotational scan of Dual-Scheimpflug slit images merged with Placido Disc and TopView images
- Observation illumination: Infrared LED 810 nm
- Flash output illumination: Blue LED Light (UV-free) 470 nm
- Cameras: 3 cameras
- Number of images per scan: 7 – 30
- Measuring principle: Optical A-scan based on optical coherence technology (OCT)
- OCT illumination: SLED (Class 1 Laser product), CW, 880 nm, max. 0.6 mW

Table 9: Measurement repeatability (for software CMS V6.2.0 and higher)

Parameter	SD specified	SD measured
SimK	≤ 0.25 D	0.05 D
Angle of flattest meridian	≤ 10° for astigmatism > 0.5 D	2.9°
CCT	≤ 3.00 µm	1.2 µm
Pupillometry	≤ 50 µm	6 µm
WTW	≤ 50 µm	16 µm
ACD	≤ 50 µm	15 µm
LT	≤ 100 µm	29 µm
AL	≤ 50 µm	17 µm

To establish and verify measurement precision and repeatability, a prospective, non-randomized comparative, internal study was conducted as described below. The measured standard deviations (SD) listed in Table 9 were established in a clinical study with the following design:

- A total of 24 normal eyes in 12 subjects were included, age range 26 – 53 years.
- Each eye was measured three consecutive times by the same operator, according to the measurement procedure described in the GALILEI Application Manual(s). Between measurements the subject removed the head from the chinrest.
- The specified repeatability refers to in vivo measurements in normal eyes for all parameters.
- A measurement was repeated when automated quality checks rejected a measurement or indicated poor measurement quality.
- Repeatability in the measured parameters was estimated by the mean standard deviation of consecutive measurements averaged over all subjects and eyes.

Product Life

The GALILEI system has a lifecycle expectancy of up to 5 years provided it was serviced and used according to our recommendations and instructions.

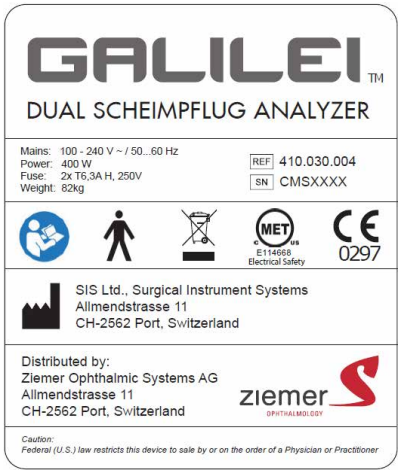
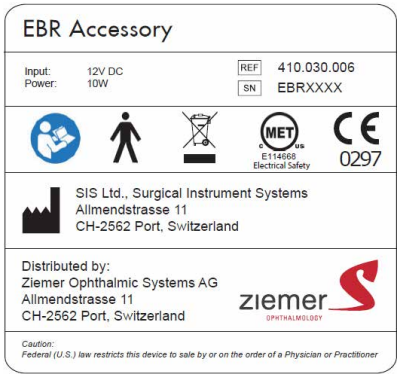
8.2 Hardware Interfaces

USB connectors are provided on the inside panel of the measurement table to connect external hard drives. A wireless mouse and a wireless keyboard are provided.

NOTE: The operator of the GALILEI is responsible for compliance with the standard IEC 60601-1 if supplementary equipment is connected to the analog or digital interfaces of the GALILEI system.

8.3 Device Labels

Table 10: Device labels

Label No.	Label definition	Label name
1		**Main identification label** (front side of the Height adjustable table column)
2		**EBR Accessory identification label (only GALILEI G6 model)** (front side of the Height adjustable table column)

8.4 Disposal

In accordance with Directive 2012/19/EU of the European Parliament and the Council of 4th July 2012 on waste of electrical and electronic equipment (WEEE) with EEA relevance, and in accordance with Swiss law governing marketing, return and environmentally compatible disposal of used electrical and electronic devices, such as appliances must be recycled and may not be discarded as household waste.

Dispose the GALILEI in a compliant manner.

9 APPENDIX

9.1 Appendix A: Manufacturer's Electromagnetic Compatibility (EMC) Declaration

Changes or modifications to this system not expressly approved by SIS AG could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulations regarding EMC and needs to be installed and put into service according to the EMC information stated in the tables below.

Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The **GALILEI** is intended for use in the electromagnetic environment specified below. The customer or user of the **GALILEI** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **GALILEI** uses RF energy for its internal function only. As such, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **GALILEI** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage 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 is an equipment/system of Class B according to CISPR 11. 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 **GALILEI** or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2, 4, 8, 15 kV air	+/- 8 kV contact +/- 2, 4, 8, 15 kV air	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 61000-4-4	+/- 2 kV for power supply lines 100 kHz	+/- 2 kV for power supply lines 5 kHz & 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field immunity test IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25 cycles 0 % UT for 250 cycles	0 % UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25 cycles 0 % UT for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **GALILEI** requires continued operation during power mains interruptions, it is recommended that the **GALILEI** be powered from an uninterruptible power supply or a battery.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz; 3 V rms ISM bands; 6 V rms	10 V rms 10 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the **GALILEI**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 * sqrt(P) d = 2.3 * sqrt(P) for 800MHz – 2.5GHz where P is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, and should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	80MHz to 2.7GHz 385 MHz 450 MHz 710, 745, 780MHz 810, 870, 930MHz 1720, 1845, 1970MHz 2450 MHz 5240, 5500, 5785 MHz	10 V/m; AM, 1 kHz, 80 % 27 V/m; PM, 18 Hz 28 V/m; FM, ±5 kHz 9 V/m; PM, 217 Hz 28 V/m; PM, 18 Hz 28 V/m; PM, 217 Hz 28 V/m; PM, 217 Hz 9 V/m; PM, 217 Hz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the **GALILEI** is used exceeds the applicable RF compliance level above, the **GALILEI** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **GALILEI**.
[b] over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the GALILEI

The **GALILEI** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **GALILEI** can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **GALILEI** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P) W	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz d= 1.2 sqrt(P)	80 MHz to 800 MHz d= 1.2 sqrt(P)	800 MHz to 2.5 GHz d= 2.3 sqrt(P)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.2 Appendix B: Internal Precision Testing

An internal clinical study was conducted to evaluate precision in terms of repeatability (intra-device, intra-operator) and reproducibility (inter-device, inter-operator) of the GALILEI G6 Lens Professional for repeated measurements.

Repeatability in this study was defined as the variation in measurements within the GALILEI G6 across 3 repeated measurements for a given device and operator. The values in Table 11 illustrate that expected differences when taking another measurement by the same operator using the same device are less than 1%, except for *CC* (8.79%) and *A flat* (3.79%), which indicates high repeatability for most parameters.

Table 11: Repeatability and reproducibility with the GALILEI G6 in normal eyes

Measure	Number of subjects	Mean	Repeatability		Reproducibility	
			SD	CV [%]	SD	CV [%]
***AL* [mm]**	12	23.91	0.02	0.08	0.02	0.08
***CCT* [um]**	12	578	4.50	0.78	6.79	1.17
***R flat* [mm]**	12	7.84	0.02	0.21	0.02	0.28
***R steep* [mm]**	12	7.62	0.02	0.21	0.02	0.27
***Rm* [mm]**	12	7.72	0.01	0.16	0.02	0.24
***CC* [D]**	12	1.27	0.11	8.79	0.11	8.98
***A flat* [deg]**	12	90	3.40	3.79	3.44	3.85
***ACD* [mm]**	12	3.54	0.03	0.85	0.03	0.86
***WtW* [mm]**	12	12.26	0.03	0.21	0.03	0.24

NOTES

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OPHTHALMOLOGY

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