Recommended measurement sequence for examination prior surgery
Table of Contents

1 GENERAL INFORMATION ................................................................................................. 3
  1.1 Device Identification Data .......................................................................................... 3
  1.2 Notes on the Short Manual, Purpose and Scope .......................................................... 4
  1.3 Intended Use .................................................................................................................. 4

2 RECOMMENDED MEASUREMENT SEQUENCE FOR EXAMINATION PRIOR SURGERY ................................................................................................................... 5
1 GENERAL INFORMATION

1.1 Device Identification Data

**Product name:** SCHWIND SIRIUS

**Product description:** System combination consisting of a lifting table with Panel PC (Workstation) and a diagnostic device SCHWIND SIRIUS (rotating Scheimpflug camera and a Placido disc topographer).

- **SCHWIND SIRIUS** - “two in one system” combining a rotating Scheimpflug camera with a Placido disc topographer
  - **Application:** Topography measurements, Pupillometry

- **SCHWIND WORKSTATION** - Hardware platform for system combination of approved diagnostic medical devices and medical software for measurement, evaluation and planning of diagnostic results of ophthalmological diagnostic devices.

**Software version:** Phoenix 3.7.01 and higher (SCHWIND SIRIUS)

**Medical Device Class:**
- Im (SCHWIND SIRIUS)
- I (SCHWIND WORKSTATION)

**CE labelling of the manufacturer:**
- CE 0051 (C.S.O Srl) (SIRIUS)
- (SCHWIND WORKSTATION)

**Approved device combination:** Only products specified by SCHWIND eye-tech-solutions acc. to Declaration of Conformity EWG 12 for system combination:
- Combi / Single Workstation
- SCHWIND PERAMIS
- Corneal Wavefront Analyzer (OPTIKON Keratron Scout)
- SCHWIND CAM

**Manufacturer:**

- **SIRIUS**
  C.S.O. Srl – Costruzione Strumenti Oftalmici
  Via degli Stagnacci 12/E – 50010 Badia a Settimo, Firenze
  [www.csophthalmic.com](http://www.csophthalmic.com)

- **SCHWIND WORKSTATION**
  SCHWIND eye-tech-solutions GmbH
  Mainparkstrasse 6-10
  63801 Kleinostheim, Germany

**System intergration and delivery:** SCHWIND eye-tech-solutions GmbH or authorized distributor
1.2 Notes on the Short Manual, Purpose and Scope

This Short Manual is the basis for treatment planning and SCHWIND case analysis. It contains the instructions for the effective use of SCHWIND SIRIUS Single Workstation. The purpose of the user manual is to familiarize operator(s) of the SCHWIND SIRIUS with the topic mentioned above. This document addresses users, operators, clinic’s technical servicing people.

**IMPORTANT NOTE**

This Short Manual does not contain all information which is necessary for safe and effective operation and application of the SCHWIND SIRIUS according to its intended use. Refer to the related SIRIUS and PERAMIS documents as listed in the SCHWIND Short Manual “PERAMIS-SIRIUS Measurement Evaluation” and in the SCHWIND User Manual “WORKSTATION”, chapter 1.3. Do not use the SCHWIND PERAMIS and/or SCHWIND SIRIUS before reading the documents listed in the “Short Manual SIRIUS-PERAMIS Measurement Evaluation”! Follow all instructions and notes, which cover the regulatory requirements. Keep the Short Manual and all related documents close to the medical device(s). Always allow any user access to this user manual at all times, store it readily available.

**IMPORTANT NOTE**

The present manual contains the ORIGINAL INSTRUCTIONS, which are legally binding. Translations of these must bear the words “Translation of the Original Instructions”.

1.3 Intended Use

Refer to the CSO manual “Instructions for Maintenance and Use”. Refer to the SCHWIND Workstation User Manual, chapter 3.1 “Intended Use of the Product”.
2. **RECOMMENDED MEASUREMENT SEQUENCE FOR EXAMINATION PRIOR SURGERY**
   (Basis for treatment planning and SCHWIND case analysis)

1. **Pupillometry:**
   - Let the patient adapt to the dark room conditions for several minutes, start with scotopic for OD & OS, continue with mesopic OD & OS and finish with photopic pupil measurement (normally only scotopic pupil necessary for selection of OZ)
   - Printout OD/OS

2. **Scheimpflug measurements:**
   - Perform minimum 3 Scheimpflug measurements
     → Cover the fellow eye and advise patient to fixate the target correctly
     → To improve the Placido ring recognition – turn and tilt the head of the patient according to the video demonstration ([https://youtu.be/4poCnxVdrRo](https://youtu.be/4poCnxVdrRo))
   - Reprocess all measurements
   - Preselect the best measurement with function “statistics of acquisition” and check for quality and repeatability as follows:

   ![Keratoscopy quality](image)

   - **Keratoscopy quality** ( green mark = good quality; red mark = bad quality)
Recommended Measurement Sequence for Examination prior Surgery

- **Placido coverage [%]** (OK, when no attention sign like 🟢 or 🟠 is displayed)
  - in case 🟢 or 🟠 is displayed, perform new measurements with eyes wide open
  - ideally the highest value in %

- **Section (Scheimpflug) coverage [%]** (OK, when no attention sign like 🟢 or 🟠 is displayed)
  - in case 🟢 or 🟠 is displayed, perform new measurements with eyes wide open
  - ideally the highest value in %

- **Check SCC (Static Cyclotorsion Control)**
  - SCC shall be suitable ( ✓ green mark) in case the cylinder refraction >1.25D and for customized treatments

- **Check Meridians 3mm (Avg) [D]**
  - max. SD (standard deviation) 0.25D

- **Check Meridians 3mm (Cyl) [D]**
  - in case cylinder >1.25D the max. deviation in axis 10°

- **Check CCT [µm]** (Central Corneal Thickness)
  - max. SD 10µm

- **Pupil center [mm]**:
  - **Check Offset**: the crosses shall be inside the yellow dotted circle and as close together as possible
  - prefer the smallest offset

- **Keratoscopy center [mm]**:
  - should be within the yellow dotted circle

- Based on the above mentioned points set the best chosen measurement as favorite with yellow star
- Double click to open the summary page of the favorite and go to comparison to confirm your selection
Recommended Measurement Sequence for Examination prior Surgery

✓ Check homogeneity of tangential maps
   ➔ exclude unstable tearfilm and eyelid artefacts

✓ Check Offset values ➔ when the Offset ≥ 0.50mm repeat measurements and take care to cover the fellow eye and advise patient to fixate the target correctly

✓ Check Keratoconus Summary

• Go to Export:
  ✓ Check amount of full Placido rings
     ➔ Ideally ≥14 full Placido rings are available for customized treatments

✓ Check correct pupil detection (red circle fits with pupil size)

✓ Check correct limbus detection (red half circles fit with limbus)

• Printout via “File” ➔ “Print”

End of manual