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1 General information

1.1 Device Outline

The TSRK-1000P is an ophthalmic ref-keratometer intended to objectively measure the refractive power of the eye and the radius of curvature of the cornea. The device uses an optical measurement system and a CCD-based imaging system to acquire reflected optical information from the eye and calculate refractive and keratometric parameters. The device supports refractometry, keratometry, simultaneous refraction/keratometry, contact-lens base-curve measurement, pupil/corneal diameter measurement, retro-illumination imaging, stored-data display and printed output.

1.2 Device name and model

- Device name: Auto Refkeratometer
- Model: TSRK-1000P
- Rating: 100-240 V~, 50/60 Hz, 100 VA

1.3 Manufacturer

SCIENCETERA Co., Ltd.

B1602, 302, Galmachi-ro Jungwon-gu Seongnam-si Gyeonggi-do 13201 KOREA

Phone +82-31-778-8670

1.4 Qualification of the product as a medical device

The TSRK-1000P is intended for objective ophthalmic measurement used to support clinical refraction and corneal assessment.

The device provides objective measurement information concerning the refractive state of the eye and the curvature of the cornea. The resulting information is used by qualified eye-care professionals during ophthalmic and optometric examination.

Accordingly, the TSRK-1000P is considered a medical device within the meaning of Article 2(1) of Regulation (EU) 2017/745 because it is intended to provide information for the diagnosis and assessment of physiological conditions of the human eye.

The device is electrically powered and therefore meets the definition of an active device.

1.5 Device Classification and Justification

1.5.1 Risk Class

Under Regulation (EU) 2017/745, the TSRK-1000P is classified as:

Class IIa Medical Device
in accordance with Annex VIII, Chapter III, Rule 10

1.5.2 Applicable Classification Rule

Rule 10 – Active devices intended for diagnosis and monitoring

The TSRK-1000P is an active diagnostic device that directs optical energy toward the patient's eye and analyzes the optical signal returned from ocular structures for the purpose of obtaining refractive and keratometric measurement information.

The device is not merely intended to illuminate the patient's body in the visible spectrum.

Its optical measurement system is used to obtain diagnostic measurement information concerning the refractive condition of the eye and the curvature of the cornea.

Therefore, classification under Rule 10 as Class IIa is considered appropriate.

1.5.3 Classification Rationale

Consideration	TSRK-1000P
Active device	Yes
Intended for diagnosis / measurement	Yes
Optical energy supplied to the eye	Yes
Returned optical signal analyzed	Yes
Objective refractive measurement	Yes
Corneal curvature measurement	Yes
Rule 10 applicable	Yes
MDR Classification	Class IIa

The residual active-device classification under Rule 13 is not considered appropriate because the TSRK-1000P performs an active diagnostic measurement function specifically addressed by Rule 10.

1.6 EU Regulatory Status – Legacy Device

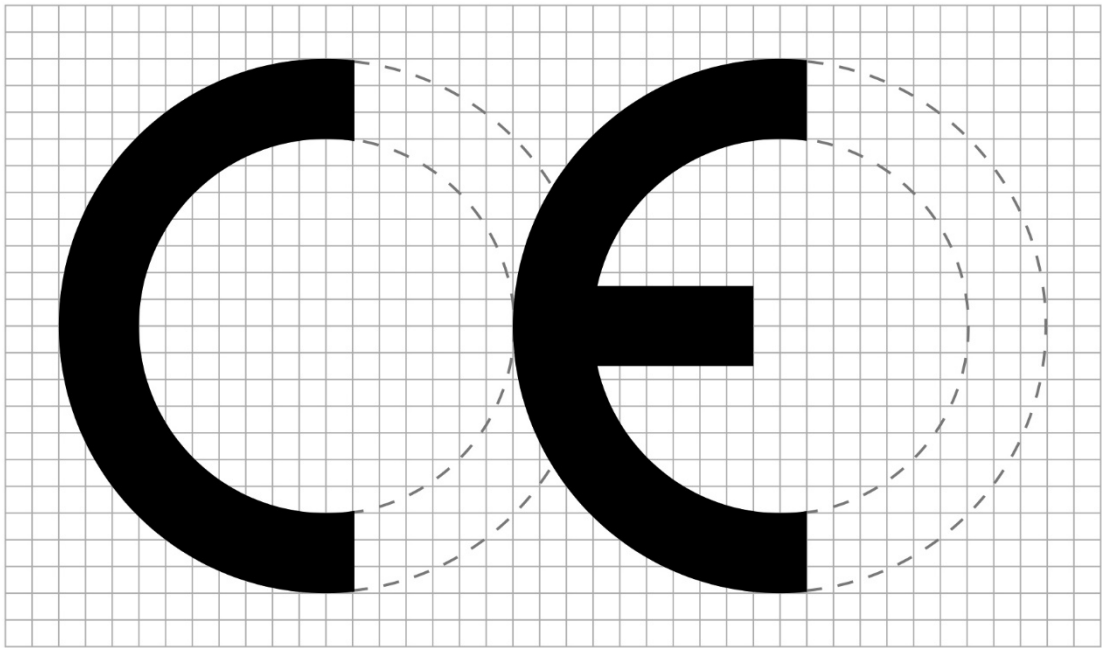
The TSRK-1000P was certified under Council Directive 93/42/EEC (MDD).

The manufacturer currently maintains the device as an MDD legacy medical device while MDR conformity assessment is in progress. Continued placing on the EU market is subject to the transitional provisions of Article 120 of Regulation (EU) 2017/745, as amended by Regulation (EU) 2023/607.

For a Class IIa legacy device, the applicable transitional period may continue until 31 December 2028, provided that all applicable conditions under Article 120 are fulfilled. During the transitional period, applicable MDR requirements relating to post-market surveillance, vigilance, market surveillance, and registration of economic operators and devices shall apply as required by Article 120.

IMPORTANT
The CE marking and Notified Body information appearing on the product shall correspond to the legally applicable conformity-assessment status of the device at the time the device is placed on the market. The MDR conformity assessment currently in progress shall not be represented as completed until the applicable MDR certificate has actually been issued.

1.7 Regulatory mark



[REGULATION (EU) 2017/745 – ANNEX V CE MARKING OF CONFORMITY]

1.8 Authorised Representative

EU Representative
Advena Ltd. Tower Business Center, 2nd Flr., Tower Street Swatar BKR 4013 Malta

1.9 Unique Device Identification (UDI)

The device label contains a Unique Device Identifier (UDI) in accordance with Regulation (EU) 2017/745.

The UDI consists of:

- Basic UDI-DI
- UDI-DI
- Production Identifier (PI)

The UDI carrier is provided in machine-readable and human-readable formats on the product of label.

2 Intended purpose and clinical information

2.1 Intended purpose

The TSRK-1000P is intended to objectively measure refractive parameters of the human eye and corneal curvature parameters for use by qualified eye-care professionals during ophthalmic and optometric examination.

2.2 Intended users

The TSRK-1000P is intended to be operated by qualified and appropriately trained eye-care professionals, including ophthalmologists, optometrists, opticians where permitted by applicable national regulations, and other qualified personnel trained in objective refraction and keratometry. The device is not intended for patient self-testing or unsupervised home use.

2.3 Intended environment

The device is intended for use in professional healthcare environments, including ophthalmology clinics, hospitals, optometry practices, refraction rooms, optical examination rooms, and other professional eye-care facilities. The device shall be placed on a stable ophthalmic instrument table. The mains supply shall provide protective earth connection. The device is not intended for outdoor use or use in environments subject to excessive moisture, dust, vibration, corrosive gas, or strong electromagnetic interference.

2.4 Patient target group

The TSRK-1000P may be used for patients requiring objective refractive or keratometric examination, provided that the patient can be appropriately positioned at the chinrest and foreheadrest and sufficient ocular alignment and fixation can be achieved. Reliable measurement may be difficult when the patient cannot maintain fixation, when alignment cannot be achieved, when the pupil is too small, or when ocular media conditions prevent acquisition of an adequate optical measurement signal

2.5 Indications

The device is intended to provide objective measurement information for assessment of refractive error, including spherical and cylindrical refractive power and cylinder axis. The device is also intended to measure corneal curvature and corneal astigmatism and to provide supporting measurement information used during refraction, keratometry, contact-lens fitting and related ophthalmic examination

2.6 Contraindications and limitations

No absolute device-specific contraindication is identified for normal use of the TSRK-1000P.

However, measurement results may be unreliable or measurement may not be possible where adequate alignment or fixation cannot be achieved, the pupil is insufficient for optical acquisition, significant ocular media opacity interferes with the measurement beam, excessive eye movement or blinking occurs, or the device repeatedly indicates a measurement error. Measurement results shall be interpreted by a qualified eye-care professional and shall not be used as the sole basis for diagnosis or prescription without appropriate professional evaluation.

2.7 Undesirable side effects

No significant physiological side effects are expected during normal use of the device.

Temporary discomfort may occur due to contact with the chinrest or foreheadrest, prolonged fixation, repeated measurement or exposure to the internal fixation target. The examination should be stopped if the patient experiences unusual discomfort.

2.8 Operating principle

The TSRK-1000P projects an optical measurement pattern toward the patient's eye and receives reflected optical information through its measurement system. The reflected information is detected by the internal optical and CCD imaging system and processed to calculate objective refractive parameters. For keratometry, reflected optical information from the corneal surface is analyzed to calculate corneal curvature parameters. The device uses a fogging method during refractive measurement to reduce the influence of accommodation. The device may automatically initiate measurement after appropriate alignment and focusing conditions have been achieved.

3 Safety information

3.1 Safety classifications

Item	Classification
Protection against electric shock	Class I
Applied Part	Type BF
Patient-contacting parts	Chinrest and Foreheadrest
Flammable anesthetic environment	Not suitable
Liquid ingress	Ordinary equipment; no special ingress protection stated in legacy documentation
Mode of Operation	Continuous Operation

3.2 Patient-Contacting Parts and Materials

Patient-contacting part	Material	Contact
Chinrest	ABS resin	Intact skin, limited contact
Foreheadrest	VMQ (Vinyl Methyl Silicone Rubber)	Intact skin, limited contact

The chinrest and foreheadrest are the patient-contacting applied parts of the TSRK-1000P. Both parts contact intact skin only and are used for a limited duration during ophthalmic examination. The foreheadrest is manufactured from VMQ (Vinyl Methyl Silicone Rubber). The chinrest uses an ABS resin material consistent with the material system used for the corresponding patient-contact component of SCIENCETERA's TSDR device.

Patient-contact materials shall be evaluated and controlled in accordance with the manufacturer's biological safety and risk-management procedures

3.3 General Warnings and Cautions

The equipment is Class I medical electrical equipment. Connect the device only to a mains supply with protective earth.

	Do not operate the device with wet hands.
	Do not use the device if the power cord, plug, mains inlet or enclosure is damaged.
	Disconnect the AC power cord before servicing the device or replacing the fuse.
	No modification of this equipment is allowed without authorization from the manufacturer.
	Unauthorized modification may affect safety, performance and regulatory compliance.
	Do not use the equipment in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.
	Do not place hands or fingers between the moving stage and base.
	Do not place hands or fingers beneath the motorized chinrest while it is moving.
	Keep the examination window clean.
	Dust, fingerprints, oil or other contamination on the optical surface may affect measurement accuracy.
	Do not operate the device in direct sunlight or under excessive external illumination that may interfere with the optical measurement system.
	Equipment connected to the RS-232C, USB or video output interfaces shall comply with applicable safety requirements.
	Where interconnected equipment forms a medical electrical system, the complete system shall comply with the applicable requirements of IEC 60601-1.

3.4 Cleaning of Patient-Contacting Parts

The chinrest and foreheadrest shall be cleaned and disinfected before use with each patient. Wipe the patient-contacting surfaces using an appropriate alcohol-based disinfectant wipe or alcohol swab.

	Do not pour or spray liquid directly onto the device.
	Do not allow cleaning liquid to enter openings, moving mechanisms or electrical components.
	Allow the contact surfaces to dry before positioning the next patient.

3.5 Reporting of Serious Incidents

Any serious incident that has occurred in relation to the TSRK-1000P shall be reported to:

SCIENCETERA Co., Ltd.

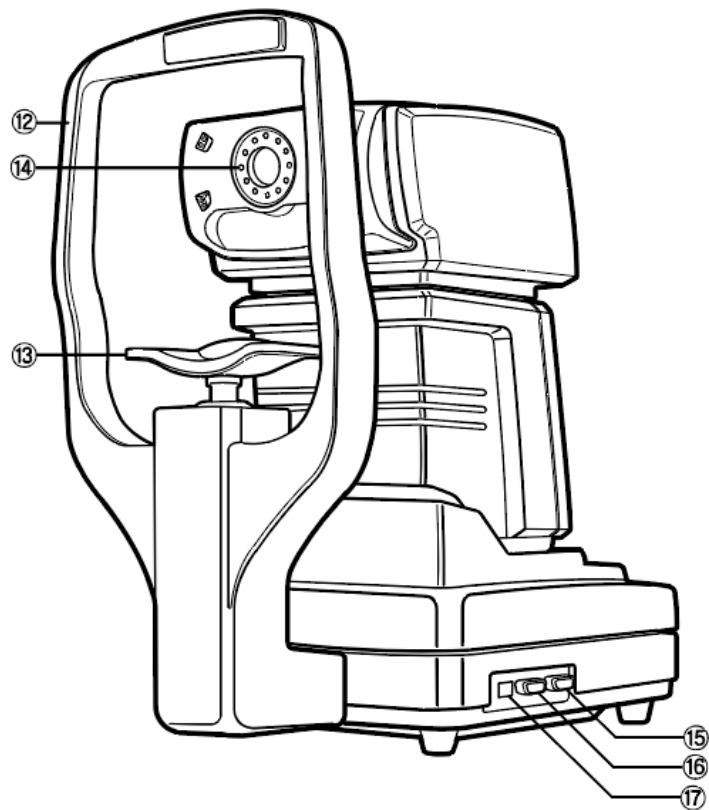
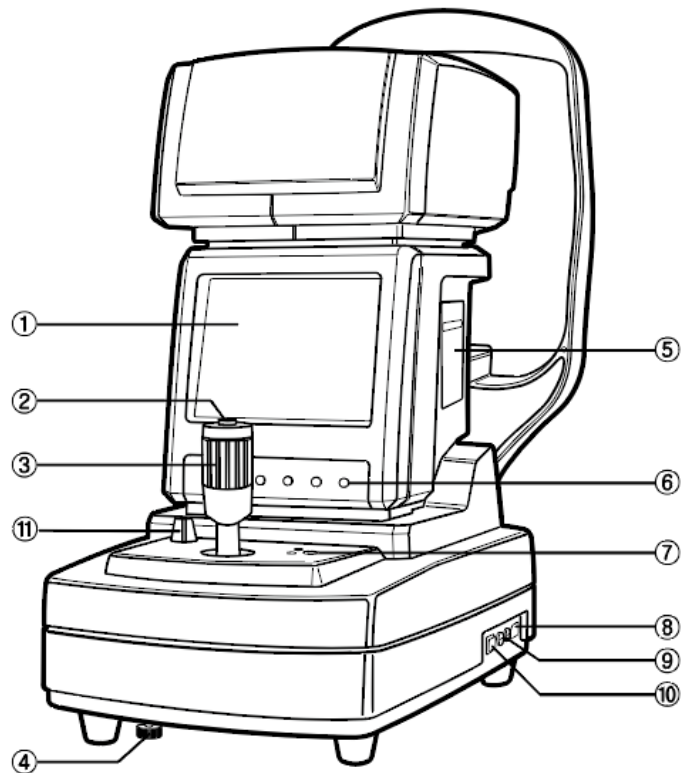
and to the competent authority of the Member State in which the user and/or patient is established, where required by applicable European medical-device legislation.

4 Device Description

4.1 General Description

The TSRK-1000P consists of a main body, optical measurement system, patient-positioning system, color LCD monitor, operation controls, built-in printer, and external communication interfaces. The patient is positioned using the chinrest and foreheadrest, and the operator aligns the measurement system with the patient's eye using the operation stick. The measurement result and alignment information are displayed on the built-in LCD monitor. The instrument provides automatic and manual measurement functions and supports refractometry, keratometry, simultaneous refractometry and keratometry, contact-lens base-curve measurement, pupil/corneal diameter measurement, and retro-illumination imaging.

4.2 Main Parts



No.	Part	Function
1	Monitor screen	Displays alignment information, measurement status, setup information and measurement results
2	Measurement button	Starts a measurement and confirms certain operations
3	Operation Joystick	Used to move the measurement stage, align the instrument with the patient's eye and adjust focus
4	Clamping bolt	Locks or releases the movable stage, mainly for transportation or installation
5	Built-in printer	Prints measurement results
6	Operation buttons	Used to select measurement modes and other functions
7	Chinrest UP/DOWN button	Raises/Lowers the chinrest
8	Power supply connector	Connects the instrument to the AC power supply
9	Fuse holder	Contains the protective mains fuse
10	Power switch	Turns the main power ON or OFF
11	Clamping handle	Locks or releases movement of the measurement stage
12	Foreheadrest	Supports and positions the patient's forehead
13	Chinrest	Supports and positions the patient's chin
14	Measurement window	Optical window through which the measurement beam is directed toward the patient's eye
15	RS-232C interface	Provides serial communication with compatible external equipment
16	Video / VGA output	Provides video output to a compatible external monitor
17	USB interface	Provides connection to compatible USB devices/functions

4.3 Operation Buttons

The operation buttons located below the monitor are used to select measurement modes and control frequently used functions.

Control	Function
MODE	Selects the measurement mode
AUTO START	Selects automatic or manual measurement start
IOL	Activates the IOL measurement function
RETRO / ILLUM	Activates the retro-illumination function
SIZE	Activates pupil / corneal diameter measurement
DISPLAY	Displays stored measurement data
CHINREST UP	Raises the chinrest
CHINREST DOWN	Lowers the chinrest
PRINT	Prints the measurement results

MODE Button

Press the MODE button to select the required measurement mode.

The available principal measurement modes are:

- K/R – Simultaneous Keratometry and Refractometry
- REF – Refractometry
- KER – Keratometry
- CLBC – Contact Lens Base Curve Measurement

4.4 Patient Positioning Parts

The TSRK-1000P incorporates two patient-contacting positioning parts:

Chinrest
The patient places the chin on the chinrest to stabilize the vertical and horizontal position of the head during measurement.
Foreheadrest
The patient places the forehead against the foreheadrest to stabilize the head and maintain a suitable measurement position.

Both parts are classified as Type BF Applied Parts.

The foreheadrest is made of:

VMQ (Vinyl Methyl Silicone Rubber)

The chinrest is made of:

ABS resin

The chinrest and foreheadrest shall be cleaned and disinfected before examination of each patient.

4.5 Measurement Window

The measurement window contains the optical path used for refractive and keratometric measurement.

The operator shall keep the measurement window clean and free from:

- dust,
- fingerprints,
- oil,
- moisture, and
- other contamination.

Contamination of the optical window may interfere with alignment or adversely affect measurement accuracy.

Do not touch the optical surface directly with fingers.

4.6 Built-in Printer

The TSRK-1000P is equipped with a built-in thermal printer. The printer can output measured refractive and keratometric data.

If the printer paper is depleted, the device displays:

NO PAPER

Replace the printer paper in accordance with the maintenance instructions in this manual.

4.7 External Interfaces

The TSRK-1000P provides the following external interfaces:

Interface	Intended Function
RS-232C	Serial communication and measurement-data transfer
Video / VGA	Connection to an external display
USB	Connection to compatible USB equipment/functions

	Only compatible equipment specified or approved by the manufacturer should be connected.
	When another electrical device is connected to the TSRK-1000P, the resulting system shall comply with the applicable medical electrical system safety requirements.

5 Installation and Connections

5.1 Installation

Install the TSRK-1000P on a stable ophthalmic instrument table in a location suitable for professional eye examination. Before installation, make sure that the instrument and its accessories have not been damaged during transportation.

Follow the procedure below.

- 1) Place the TSRK-1000P securely on the instrument table.
- 2) Turn the clamping bolt located underneath the operation stick in the counterclockwise direction to release the stage lock.
- 3) Connect the required power cable to the instrument.
- 4) Make sure that the main power switch is in the OFF position before connecting the power cord to the mains supply.
- 5) Connect the power cord to a properly grounded AC outlet.
- 6) Turn the main power switch ON.
- 7) Allow the instrument to complete initialization.
- 8) Before patient examination, confirm basic measurement operation using the supplied model eye where appropriate.

	Install the instrument on a stable and level surface.
	An unstable installation may result in inaccurate measurement, unintended movement or damage to the equipment.

5.2 AC Power Connection

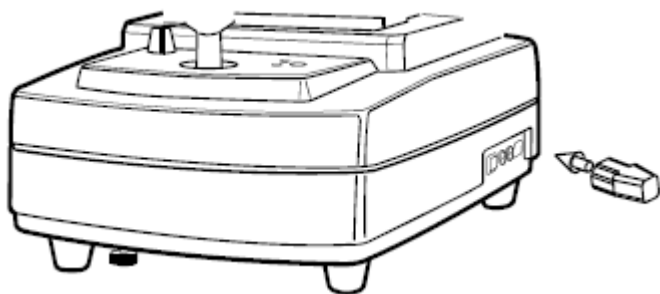
The TSRK-1000P is Class I medical electrical equipment and requires a protective-earth connection.

Before connecting the power supply:

- Make sure that the power switch is OFF.
- Check the power cord and plug for visible damage.
- Use only a mains supply within the rated voltage and frequency range of the device.
- Connect the power cord only to a grounded outlet.

Connection Procedure

- 1) Confirm that the main power switch is OFF.
- 2) Connect the AC power cord to the power inlet of the TSRK-1000P.
- 3) Insert the mains plug into a properly grounded AC outlet.
- 4) Turn the main power switch ON.



	Do not touch the AC power cord or plug with wet hands.
	The device must be connected to a mains outlet with protective earth.
	Do not use the equipment with an ungrounded or improperly grounded power supply.

5.3 Initial Functional Check

After installation and power-up, verify the basic operating condition of the device before patient use.

Check the following:

- The instrument powers on normally.
- The LCD display operates correctly.
- The measurement stage moves smoothly.
- The chinrest moves up and down correctly.
- The operation stick moves and focuses properly.
- No unusual noise, odor, vibration or error indication is present.
- The built-in printer operates correctly, if used.
- The measurement function can be confirmed using the supplied model eye.

If abnormal operation is detected, discontinue use and contact the manufacturer or an authorized service representative.

5.4 Model Eye Check

The supplied model eye may be used to confirm that the measurement function is operating normally.

To perform the check:

- 1) Attach or position the model eye at the chinrest area as specified for the device.
- 2) Adjust the instrument position so that the model eye is aligned with the measurement window.
- 3) Select the appropriate measurement mode.
- 4) Perform measurement.
- 5) Confirm that a measurement result is obtained without abnormal error messages.

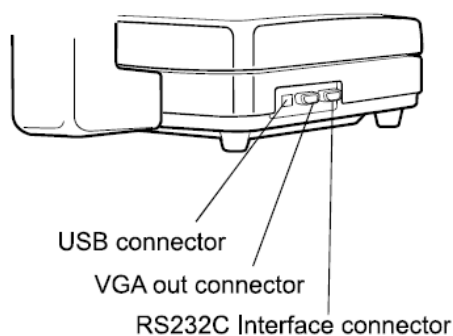
The model-eye check is intended as a functional verification and does not replace formal calibration or servicing procedures.

5.5 External Connections

The TSRK-1000P provides external connection interfaces for compatible equipment.

The available interfaces are:

- RS-232C
- Video / VGA output
- USB



The actual function of each interface shall be used only as supported by the installed hardware and software configuration.

5.5.1 RS-232C Connection

The RS-232C interface is used for serial communication and transfer of measurement data to compatible external equipment.

The legacy manual describes the RS-232C connection as a DATA IN / data communication interface and indicates that data may be transferred to a connected PC or other compatible device.

Connection Procedure

- 1) Turn off the TSRK-1000P and the external equipment before connection.
- 2) Connect the appropriate RS-232C communication cable to the RS-232C connector.
- 3) Secure the connector where applicable.
- 4) Connect the opposite end to the compatible external device.
- 5) Turn on the equipment.

6) Confirm that the communication settings of both devices are compatible.

Communication settings may include:

- Baud rate
- Data bits
- Stop bits
- Parity
- Communication protocol



Incorrect serial communication settings may prevent data transfer or result in incorrect communication.

5.5.2 Video / VGA Output Connection

The TSRK-1000P provides a video/VGA output for connection to a compatible external monitor.

Connection Procedure

- 1) Turn off the TSRK-1000P and the external monitor.
- 2) Connect the VGA/video cable to the output connector of the TSRK-1000P.
- 3) Connect the opposite end to the compatible external display.
- 4) Turn on the external monitor and the TSRK-1000P.
- 5) Confirm that the image is displayed correctly.

Only compatible monitors and cables should be used.

5.5.3 USB Connection

The TSRK-1000P is equipped with a USB connector. The USB interface shall be used only for functions supported by the specific device configuration.



The USB interface shall be used only with functions, accessories or service procedures specified or approved by SCIENCETERA Co., Ltd.

5.5.4 Connection of External Electrical Equipment

External equipment connected to the TSRK-1000P shall meet the applicable electrical safety requirements. Equipment connected to analog or digital interfaces should comply with the relevant IEC or ISO standards applicable to that equipment. Where connected equipment forms a medical electrical system, the resulting system shall comply with the applicable requirements of IEC 60601-1.



Do not connect unspecified or incompatible electrical equipment to the TSRK-1000P.



Connection of non-approved equipment may affect electrical safety, electromagnetic compatibility or data communication performance.

5.6 Installation Environment

Install and use the device under the operating environmental conditions specified in this manual. Avoid installation in locations subject to:

- direct sunlight,
- excessive humidity,
- condensation,
- excessive dust,
- oil mist,
- corrosive gas,
- strong vibration or shock,
- unstable mains voltage, or
- strong electromagnetic interference.

If the instrument is moved from a cold environment to a warmer room, allow sufficient time for the instrument to reach room temperature and for any condensation to disappear before use.

6 Measurement Procedure

6.1 Preparation Before Measurement

Before measuring a patient, confirm that the instrument is correctly installed and operating normally.

Follow the procedure below.

- 1) Turn the main power switch ON.
- 2) Allow the instrument to complete initialization.
- 3) Adjust the height of the instrument table so that the patient can be positioned comfortably.
- 4) Use the chinrest UP/DOWN controls to approximately align the patient's eye height with the measurement window.
- 5) Ask the patient to place the chin on the chinrest and the forehead against the foreheadrest.
- 6) Confirm that the patient's head is positioned securely and comfortably.
- 7) Check that the measurement window is clean and free from dust, fingerprints, oil, or other contamination.
- 8) Select the desired measurement mode.
- 9) Instruct the patient to look at the internal fixation target during measurement.

	Before each patient measurement, clean and disinfect the chinrest and foreheadrest.
	Do not allow the patient to place hands or fingers beneath the moving chinrest mechanism.
	Do not place hands or fingers between the movable stage and the base.

6.2 Patient Positioning

Correct patient positioning is important for obtaining stable and reproducible measurement results.

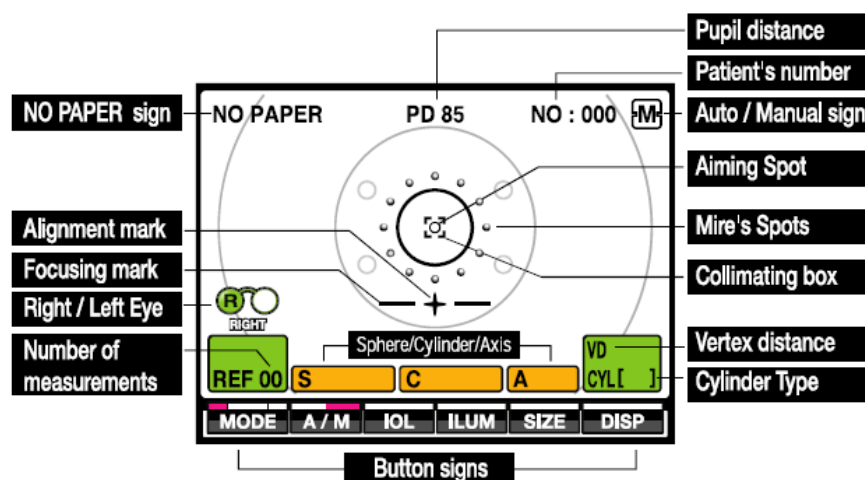
The patient should:

- sit comfortably,
- place the chin firmly on the chinrest,
- place the forehead against the foreheadrest,
- keep both eyes open unless otherwise instructed,
- look at the internal fixation target, and
- remain as still as possible during measurement.

Adjust the chinrest height until the patient's eye is approximately aligned with the height of the measurement window. The forehead should remain in contact with the foreheadrest during measurement.

6.3 Manual Start Measurement

In Manual Start mode, the operator controls the timing of measurement.



Procedure

- 1) Select the required measurement mode.
- 2) Move the instrument toward the patient's eye using the operation stick.
- 3) Adjust the horizontal and vertical position until the patient's eye appears near the center of the measurement screen.
- 4) Adjust focus using the operation stick.
- 5) Confirm that the alignment and focusing indicators indicate an acceptable measurement condition.
- 6) Ask the patient to look at the fixation target and remain still.
- 7) Press the MEASUREMENT button.
- 8) The device performs the measurement and displays the measured data on the monitor.
- 9) Repeat the measurement when necessary.
- 10) Measure the opposite eye in the same manner.

The operator should align and focus the patient's eye before pressing the measurement button, after which the result is displayed on the monitor.

6.4 Auto Start Measurement

The Auto Start function allows the device to begin measurement automatically when an acceptable alignment and focus condition has been achieved.

Procedure

- 1) Select the desired measurement mode.
- 2) Activate AUTO START.
- 3) Move the instrument toward the patient's eye.
- 4) Adjust the position and focus using the operation stick.
- 5) Observe the alignment and focusing indicators on the monitor.
- 6) When the instrument determines that the eye is correctly aligned and focused, the measurement starts automatically.
- 7) The measured result is displayed on the monitor.
- 8) Repeat the measurement if necessary.
- 9) Move the instrument to the opposite eye and repeat the procedure.

The operator may switch between Auto Start and Manual Start using the applicable control.

6.5 Alignment and Focusing

The measurement screen provides information to help the operator align and focus the patient's eye. Typical displayed indicators include:

- Right / Left eye indication
- Alignment mark
- Focusing mark
- Collimating / target box
- Aiming spot
- Mire spots
- Measurement count
- Pupil distance
- Vertex distance
- Cylinder notation
- Measurement mode
- Auto / Manual indication

Alignment
Move the instrument so that the eye is centered within the alignment area. Use the operation stick to adjust: - horizontal position, - vertical position, and - forward / backward position.
Focusing
Adjust the forward/backward position until the focusing indicator shows that the eye is within the acceptable focus range.

Measurement should be performed only when the alignment and focusing condition is satisfactory.

6.6 Measurement Sequence

For routine refraction or keratometry:

- 1) Position the patient.
- 2) Select the desired measurement mode.
- 3) Align and focus the right eye.
- 4) Perform the required number of measurements.
- 5) Move the instrument to the left eye.
- 6) Align and focus the left eye.
- 7) Perform the required number of measurements.
- 8) Review the measurement results.
- 9) Print or transfer the measurement data when required.

The existing manual indicates that repeated measurements may be performed and averaged depending on the selected mode and setup.

6.7 Measurement Messages

During measurement, the device may display messages indicating that the measurement is outside the supported range or that the measurement condition is not acceptable.

6.7.1 Refractometry Messages

Message	Meaning
+OVER	Spherical refractive value exceeds the positive measurement range
-OVER	Spherical refractive value exceeds the negative measurement range
C OUT	Cylindrical refractive value exceeds the supported cylinder range

6.7.2 Keratometry Messages

Message	Meaning
+OVER	Corneal curvature is outside the supported range in one direction
-OVER	Corneal curvature is outside the supported range in the opposite direction
C OUT	Corneal astigmatism exceeds the supported range

6.7.3 TRY AGAIN

TRY AGAIN may be displayed when the device cannot obtain a stable measurement.

Possible causes described in the legacy manual include:

- the eye moves during measurement,
- the difference between repeated measurements is excessive,
- alignment is inadequate,
- the refractometry signal is weak,
- measurement is performed under an IOL or low-reflection condition,
- the pupil is too small, or
- the measurement condition is otherwise unstable.

Recommended Action

- 1) Reposition the patient if necessary.
- 2) Confirm correct alignment.
- 3) Re-focus the eye.
- 4) Ask the patient to fixate steadily.
- 5) Repeat the measurement.

If the message continues to appear, check the instrument using the model eye.

6.7.4 ERROR

ERROR indicates that the measurement could not be completed normally.

Possible causes may include:

- patient blinking,
- excessive eye movement,
- poor alignment,
- insufficient optical signal, or
- abnormal instrument condition.

Recommended Action

- 1) Repeat the measurement.
- 2) Check the measurement window for contamination.
- 3) Check patient positioning and fixation.
- 4) Perform a measurement using the supplied model eye.
- 5) If the error persists with the model eye, discontinue patient measurement and contact an authorized service representative.

6.7.5 NO PAPER

NO PAPER indicates that printer paper is not loaded or has been depleted. Load the specified printer paper before printing.

6.8 Repeated Measurements

For improved repeatability, more than one measurement may be performed for each eye.

If repeated results differ significantly, check:

- patient fixation,
- alignment,
- focusing,
- blinking,
- pupil size,
- movement of the patient,
- cleanliness of the examination window, and
- measurement mode.

The operator should use professional judgment when deciding whether additional measurements are required.

6.9 Completion of Measurement

After measurement:

- 1) Review the measurement results.
- 2) Confirm that the right and left eye data are correctly identified.
- 3) Print or transfer the results as required.
- 4) Allow the patient to move away from the instrument.
- 5) Clean and disinfect the chinrest and foreheadrest before examination of the next patient.

7 Measurement Modes

The TSRK-1000P provides several measurement modes for refractive and keratometric examination.

Press the MODE button to select the desired measurement mode. The selected mode is displayed on the monitor.

The principal measurement modes are:

Mode	Description
K/R	Simultaneous Keratometry and Refractometry
REF	Refractometry
KER	Keratometry
CLBC	Contact Lens Base Curve Measurement

7.1 K/R Mode

The K/R mode performs refractometry and keratometry during the same examination sequence.

Procedure

- 1) Press the MODE button until K/R is displayed on the monitor.
- 2) Position the patient correctly at the chinrest and foreheadrest.
- 3) Align and focus the patient's eye.
- 4) Perform the measurement using Manual Start or Auto Start.
- 5) The device measures refractive and keratometric parameters.
- 6) Repeat the measurement as necessary.
- 7) Measure the opposite eye in the same manner.
- 8) Press the PRINT button if a printed result is required.

The K/R mode is intended to provide both refractive and corneal curvature information efficiently during routine ophthalmic examination.

7.2 REF Mode

The REF mode performs objective refractive measurement only.

Procedure

- 1) Press the MODE button until REF is displayed on the monitor.
- 2) Position the patient.
- 3) Align and focus the patient's eye.
- 4) Perform the measurement.
- 5) The refractive measurement result is displayed on the monitor.
- 6) Repeat the measurement when necessary.
- 7) Measure the opposite eye.
- 8) Press the PRINT button if a printed result is required.

The principal refractive parameters include:

- Sphere
- Cylinder
- Axis

The supported measurement ranges are described in Section 14, Technical Specifications.

7.3 KER Mode

The KER mode performs keratometric measurement only.

Procedure

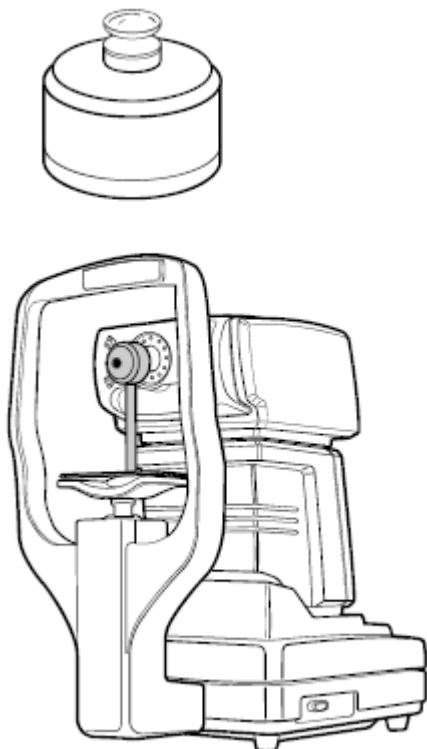
- 1) Press the MODE button until KER is displayed on the monitor.
- 2) Position the patient.
- 3) Align and focus the patient's eye.
- 4) Perform the measurement.
- 5) The keratometric result is displayed on the monitor.
- 6) Repeat the measurement when necessary.
- 7) Measure the opposite eye.
- 8) Press the PRINT button if a printed result is required.

The keratometric measurement may provide information including:

- Corneal curvature radius
- Corneal refractive power
- Corneal astigmatism
- Axis

7.4 CLBC Mode

The CLBC mode is used to measure the base curve of a contact lens. A contact lens holder supplied or approved for the TSRK-1000P shall be used for this measurement.



7.4.1 Preparation of Contact Lens

- 1) Press the MODE button until CLBC is displayed on the monitor.
- 2) Prepare the contact lens holder.
- 3) Fill the concave part of the contact lens holder with clean water as specified in the operating procedure.
- 4) Place the contact lens onto the holder with the concave side facing upward.
- 5) Make sure that:
 - the contact lens is correctly seated,
 - the lens is not tilted,
 - no air bubbles remain between the lens and the holder.
- 6) Attach the contact lens holder securely to the chinrest fixture.
- 7) Remove the chinrest paper if it interferes with attachment of the holder.
- 8) Position the lens surface toward the measurement window.

7.4.2 Measurement Procedure

- 1) Select CLBC mode.
- 2) Confirm that the contact lens holder is correctly installed.
- 3) Move the measurement head toward the contact lens.
- 4) Align the measurement system with the center of the contact lens.
- 5) Adjust focus.
- 6) Perform the measurement.
- 7) Repeat the measurement if necessary.
- 8) Review the measured base-curve result.
- 9) Press the PRINT button if a printed result is required.

7.4.3 Precautions for CLBC Measurement

	Make sure that the contact lens is correctly positioned on the holder before measurement.
	Air bubbles, incorrect lens orientation or tilting of the contact lens may cause inaccurate measurement.
	Use only the contact lens holder specified or approved by SCIENCETERA Co., Ltd.

After measurement, remove the contact lens and clean the holder as appropriate.

7.5 Selection of Measurement Mode

The measurement mode may be changed before starting an examination. The selected mode shall be confirmed on the monitor before measurement. Incorrect mode selection may result in measurement data being obtained or displayed in a form different from that intended by the operator.



Always confirm the selected measurement mode before performing the examination.

7.6 Measurement Results

Depending on the selected mode, the measurement results may include refractive, keratometric or contact-lens-related parameters.

Results may be:

- displayed on the monitor,
- stored in the internal measurement memory,
- printed using the built-in printer, or
- transferred through a supported communication interface.

The measurement result shall be interpreted by a qualified eye-care professional.

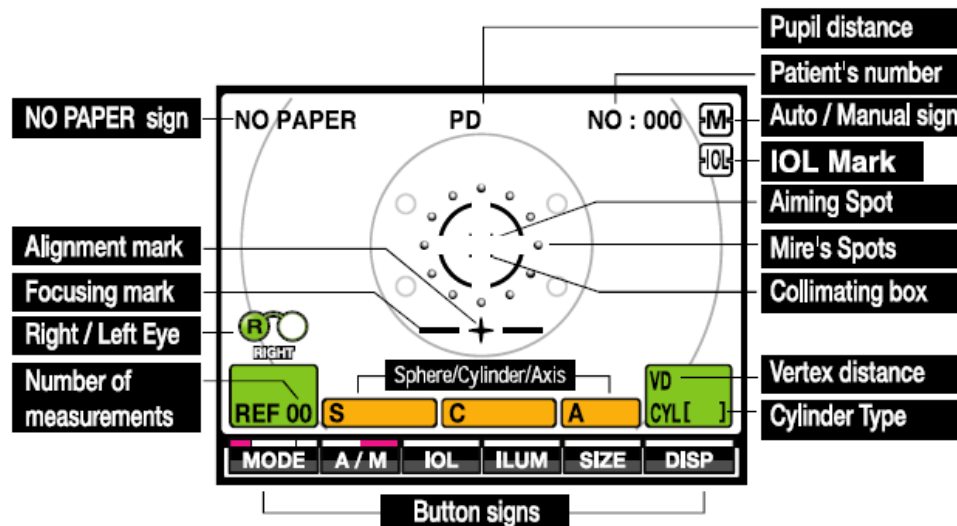
8 Other Measurement Functions

In addition to the standard refractometry and keratometry modes, the TSRK-1000P provides additional functions for specific examination conditions and for reviewing stored measurement data.

8.1 IOL Mode

Intraocular Lens Measurement

The IOL Mode may be used when standard refractive measurement is difficult, for example in an eye with an intraocular lens (IOL), unclear crystalline lens, small pupil, or other condition producing a weak or unstable measurement signal.



Procedure

- 1) Perform refractive measurement using the normal measurement procedure.
- 2) Check the measurement result and measurement screen.
- 3) If measurement errors repeatedly occur, or if the low-confidence mark (*) is displayed together with the measurement result, press the IOL button.
- 4) Confirm that the IOL mark appears on the measurement screen.
- 5) Realign and focus the patient's eye if necessary.
- 6) Perform the measurement again.
- 7) Repeat the measurement when required.

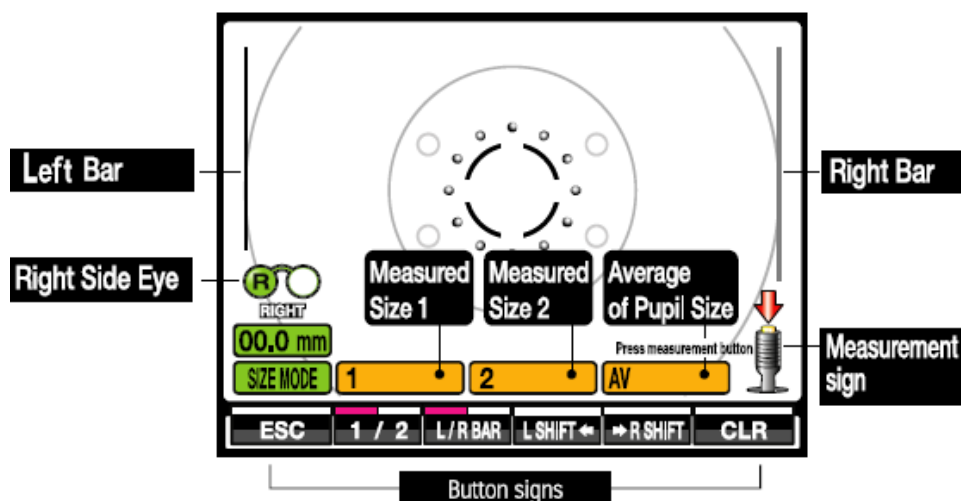
Display Indication

When IOL Mode is active, an IOL mark is displayed on the measurement screen.

NOTE	IOL Mode should be used when normal measurement is difficult or when the device indicates a low-confidence measurement condition.
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8.2 Size Mode

The Size Mode is used to measure the diameter of the cornea. The measured corneal diameter may be used as supporting information for contact-lens fitting.



Procedure

- 1) From the measurement screen, press the SIZE button.
- 2) Use the operation stick to align the patient's eye with the measurement screen.
- 3) Press the MEASUREMENT button to freeze the image.
- 4) Press the L/R BAR button to select the measurement bar to be moved.
- 5) Use the L SHIFT or R SHIFT control to move the selected measurement bar to the desired position.
- 6) The measured value is displayed on the monitor.
- 7) Press the L/R BAR button again to select the opposite measurement bar.
- 8) Use the L SHIFT or R SHIFT control to position the second measurement bar.
- 9) Confirm the measured value on the monitor.
- 10) Press the MEASUREMENT button to release the frozen image.
- 11) Repeat the alignment and measurement procedure as required.
- 12) Move the measurement stage to the opposite eye and perform the measurement in the same manner.

8.2.1 Measurement Screen

The Size Mode screen displays information including:

- Right / Left eye
- Left measurement bar
- Right measurement bar
- Measured Size 1
- Measured Size 2
- Average of pupil/corneal size
- Measurement indication



Position the measurement bars carefully at the intended corneal boundaries. Incorrect placement of the bars may result in an incorrect diameter value.

8.3 Retro-Illumination Mode

The Retro-Illumination Mode allows the operator to observe ocular features visible under retro-illumination, including visible opacity or other observable features.

Procedure

- 1) From the measurement screen, press the ILLUM button.
- 2) Ask the patient to look at the red fixation target.
- 3) Align the patient's eye.
- 4) Select the desired light source.
- 5) Adjust the illumination level as necessary to obtain a clear image.
- 6) Press the MEASUREMENT button.
- 7) The displayed image is captured and frozen.
- 8) Press the MEASUREMENT button again to save the captured image into memory.
- 9) To cancel the captured image without saving, use the applicable cancel control.
- 10) Repeat the procedure when additional images are required.

8.3.1 Illumination Controls

The Retro-Illumination screen provides selectable light-source controls.

The existing display identifies:

Display	Function
REF	Refraction-related light source
ILM	Retro-illumination light source
TAG	Fixation-target light
SHIFT	Selects the light source to be adjusted
+1	Increases the selected light level
-1	Decreases the selected light level
DISP	Displays stored captured images
ESC	Exits Retro-Illumination Mode

The illumination level can be adjusted individually to obtain a suitable image.

8.3.2 Reviewing Retro-Illumination Images

Press the DISP button while in the Retro-Illumination function to display images stored in memory.

The display may include:

- captured image,
- date,
- time,
- patient number,
- sub-number,
- measurement mode,
- Right / Left eye indication.

Stored images are displayed as thumbnails and may be selected for enlarged viewing.

Control	Function
ESC	Exit
REAL SIZE	Displays the selected image at real-size magnification
DOUBLE SIZE	Displays the selected image at increased magnification
NEXT	Moves the image-selection cursor
CLR	Clears the selected stored image

8.4 Display Mode

The Display Mode allows measurement data stored in memory to be reviewed on the monitor.

The legacy manual specifies that up to 10 measurements for each eye can be displayed in this mode.

Procedure

- 1) Press the DISP button from the measurement screen.
- 2) The first display page shows stored refractometry data.
- 3) Press NEXT to move to the second page.
- 4) The second page displays stored keratometry data.
- 5) Press NEXT again to move to the third page.
- 6) The third page displays stored CLBC data.
- 7) Press NEXT again to return to the first display page.

8.4.1 REF Data Display

The refractometry display includes measured data for the right and left eyes. Typical parameters include:

- SPH
- CYL
- AX
- Average measurement
- PD
- VD

8.4.2 KER Data Display

The keratometry display includes right-eye and left-eye measurement data. Typical displayed parameters include:

- R1
- R2
- Axis
- Average value
- PD
- Corneal refractive index setting

8.4.3 CLBC Data Display

The CLBC display shows the stored contact-lens base-curve measurement data.

8.4.4 Clearing Stored Measurement Data

To clear the stored measurement data, press the CLR button while in Display Mode.



Confirm that stored measurement data are no longer required before clearing them.

8.4.5 Exiting Display Mode

Press the ESC button from any Display Mode page to return to the measurement screen.

9 Printed and Stored Data

9.1 General

The TSRK-1000P can display, store, print and, where supported, communicate measurement data obtained during examination. The built-in thermal printer can print refractive and keratometric results. Stored measurement data can also be reviewed using Display Mode. The exact format of displayed or printed data may depend on the selected measurement mode and setup configuration.

9.2 Printed Measurement Data

Press the PRINT button after completing the required measurements. The built-in printer prints the available measurement results according to the current print settings.

The legacy manual shows that the printed data may include:

- Date and time
- Patient number
- Vertex distance
- Cylinder notation
- Right-eye refractometry data
- Left-eye refractometry data
- Averaged refractometry data
- Keratometry data
- Corneal curvature values
- Corneal refractive power
- Corneal astigmatism
- Axis
- Pupillary distance

The exact printed format may vary depending on the selected setup configuration.

9.3 Refractometry Printout

The refractometry section of the printout may include measurements for the right and left eyes.

Typical displayed or printed parameters include:

Parameter	Description
SPH	Spherical refractive power
CYL	Cylindrical refractive power
AX	Cylinder axis
AVE	Averaged measurement result
PD	Pupillary distance
VD	Vertex distance

Where multiple measurements are performed, individual measurements and/or an averaged value may be printed according to the current setup.

9.4 Keratometry Printout

The keratometry section may include:

Parameter	Description
R1	Corneal curvature measurement in one principal meridian
R2	Corneal curvature measurement in the second principal meridian
AX	Axis associated with the keratometric measurement
AVE	Average corneal curvature / refractive value as displayed by the device
CYL	Corneal astigmatism value
PD	Pupillary distance, where included

9.5 Averaged Measurement Data

When multiple measurements are obtained for the same eye, the device may calculate and display an average value. The average value is identified by AVE on the display or printout where applicable. The operator should review the individual measurements as well as the average value, particularly when there is significant variation between repeated measurements.



An averaged value should not be relied upon without reviewing measurement consistency and clinical plausibility.

9.6 Right and Left Eye Identification

Measurement data are identified separately for the:

- Right eye (R)
- Left eye (L)

Before printing or transferring data, the operator should confirm that the measurement results correspond to the correct eye.



Verify the right/left eye identification before using printed or transferred measurement data for clinical evaluation.

9.7 Patient Number

The TSRK-1000P allows a patient number to be associated with measurement data. The patient number may be entered or managed through the applicable setup function.

The entered patient number may appear on the:

- measurement screen,
- stored-data display, and
- printed report.



Verify the patient number before examination when patient identification is used.

9.8 Stored Measurement Data

Measured data are temporarily stored in the internal memory for review in Display Mode.

Stored data may include:

- refractometry data,
- keratometry data, and
- CLBC measurement data.

The exact stored information depends on the measurement modes used during the examination.

9.9 Reviewing Stored Data

Press the DISP button to enter Display Mode.

The stored data are displayed on separate pages according to measurement type. Typical page sequence:

- 1) Refractometry data
- 2) Keratometry data
- 3) CLBC data

Press NEXT to move between the available pages.

Press ESC to return to the measurement screen.

9.10 Clearing Stored Data

Stored measurement data may be cleared using the CLR function in Display Mode.



Confirm that the stored data are no longer required before clearing the measurement memory.

The legacy manual confirms the CLR function but does not describe an additional confirmation step, so I would avoid adding one to the revised IFU unless it is verified on the current software.

9.11 Printing Corneal Size Results

When Corneal Size Mode is used, the measured result may be printed using the built-in printer.

The legacy manual identifies the corresponding printed result as:

<CORNEA SIZE>

The result is generated after completion of the corneal diameter measurement procedure.

9.12 Printing CLBC Results

Measurement data obtained in CLBC Mode may also be printed using the built-in printer.

The operator should confirm that the correct measurement mode and data are displayed before printing.

9.13 Printer Example

TSRK-1000P				[KER DATA]			
2007-01-01 AM 00:00				Index: 1.3375			
NAME : _____				<R> R1 R2 AX			
[REF DATA]				7.85 7.81 10			
VD: 12.00 CL: [-]				7.84 7.81 12			
<R> SPH CYL AX				7.86 7.82 12			
0.25 0.00				AVE 7.85 7.81 11			
0.00 0.00				CYL -0.25			
I 0.00 0.00				<L> R1 R2 AX			
AVE 0.00 0.00				7.75 7.70 120			
<L> SPH CYL AX				7.74 7.69 122			
-1.25 -0.50 35				7.76 7.71 122			
-1.25 -0.50 37				AVE 7.75 7.70 121			
-1.50 -0.25 33				CYL -1.00			
AVE -1.25 -0.50 36				PD = 63mm			
				SCIENCETERA CO., LTD.			

10 User Setup

10.1 General

The User Setup function allows the operator to configure measurement, display, printing, communication and other operating parameters of the TSRK-1000P.

The Setup Mode consists of five pages:

- 1) Displaying & Printing Format 1
- 2) Displaying & Printing Format 2
- 3) Message for Internal Printer
- 4) Correction of Measured Data
- 5) Display

10.2 Entering Setup Mode

To enter Setup Mode:

- 1) From the measurement screen, press the DISP button to enter Display Mode.
- 2) Activate the hidden SET-UP function assigned to the applicable soft key.
- 3) The first page of Setup Mode is displayed.

Control	Function
NEXT	Moves to the next Setup page
CHANGE	Changes the setting item
SHIFT	Selects the item or setting field
▲ / ▼	Changes the selected setting value
SAVE	Saves the edited settings
ESC	Exits Setup Mode and returns to measurement mode
CLR	Initializes the patient number only, where applicable

NOTE

The CLR button in the first Setup page is used to initialize the patient number only. It does not initialize all device settings.

10.3 Setup Page 1

The first Setup page contains general patient-number, date/time, printing and measurement-start settings. The available items shown in the legacy interface include the following:

Setting	Function
COUNT	Patient number ON / OFF
[NO.]	Patient number
DATE TYPE	Selects the date display format
DATE & TIME	Sets the internal date and time
BEEP	Turns the audible beep ON / OFF
REF-PRINT	Selects refractometry print format
KER-PRINT	Selects keratometry print format
EYE	Eye-image printing ON / OFF
PRINTING ORDER	Selects the order of printed results
AUTO / MANUAL	Selects automatic or manual measurement start
AUTO COUNT	Sets the number of measurements in Auto Start mode
POWER SAVE	Sets the power-saving time

10.3.1 Date Type

The available date formats include:

- YMD – Year / Month / Day
- MDY – Month / Day / Year
- DMY – Day / Month / Year

10.3.2 REF-PRINT and KER-PRINT

The print format for refractometry and keratometry may be configured.

Available options shown in the existing system include:

- ALL DATA
- AVERAGE
- OFF

When ALL DATA is selected, individual measurement data are printed.

When AVERAGE is selected, averaged measurement data are printed.

When OFF is selected, the corresponding measurement results are not printed.

10.3.3 Printing Order

The printout order may be configured according to the operator's preference.

The existing UI provides options relating to:

- REF / KER
- RIGHT / LEFT

The selected setting determines the order in which measurement information is printed.

10.3.4 Auto Count

AUTO COUNT specifies the number of measurements performed in Auto Start mode.

The operator shall select an appropriate number of repeated measurements according to the examination procedure.

10.4 Setup Page 2

The second Setup page contains measurement display, step-size, communication and keratometry-related settings. The available settings include:

Setting	Function
VD	Vertex distance
CYL	Cylinder notation / type
STEP REF	Increment of sphere and cylinder values
STEP KER	Increment used for keratometric display
mm / D	Keratometry display format
AUTO FOCUS	Auto-focus-related setting
RS 232C	RS-232C communication speed
INDEX	Applied keratometric refractive index
PRINT	Selects output destination / behavior
MODE	Defines measurement-mode order

10.4.1 Vertex Distance – VD

The device provides selectable vertex-distance settings.

The existing interface shows:

- 0.0 mm
- 12.0 mm
- 13.5 mm
- 15.0 mm

The selected VD setting affects the displayed or printed refractive values where vertex-distance conversion is applicable.



Confirm that the selected vertex distance is appropriate for the examination and reporting procedure.

10.4.2 Cylinder Notation – CYL

The cylinder display type can be selected. The available settings include:

- Minus cylinder
- Plus cylinder
- Mixed

The selected cylinder notation affects how refractive cylinder values are displayed and printed.

10.4.3 STEP REF

The refractive measurement display increment can be selected. The existing interface provides step settings including:

- 0.125 D
- 0.250 D

The selected value determines the increment used for sphere and cylinder display.

10.4.4 STEP KER

The keratometry display increment can be selected from the values provided in the installed software.

The setting affects the displayed increment of keratometric values.

10.4.5 Keratometry Display Format

The keratometric measurement may be displayed using the supported format selected in Setup Mode.

The existing UI includes display options associated with:

- mm
- D
- averaged keratometric presentation where applicable.

10.4.6 RS-232C Setting

The RS 232C setting defines the serial communication speed used when measurement data are transferred to compatible external equipment.



The communication parameters of the TSRK-1000P and the connected external device must match. Incorrect settings may result in communication failure.

10.4.7 Keratometric Refractive Index – INDEX

The INDEX setting specifies the refractive index used for conversion of corneal curvature into keratometric refractive power. The existing interface provides selectable index values.

The legacy screen shows examples including:

- 1.3375
- 1.3320
- 1.3360



Changing the keratometric refractive index affects the calculated keratometric diopter value.
Confirm the appropriate setting before interpreting or comparing measurement results.

10.4.8 Output Setting – PRINT

The PRINT setting controls the output behavior of measurement data.

The existing interface provides settings associated with:

- Internal printout
- RS-232C data output
- Printing and RS-232C output

The exact behavior shall follow the selected device configuration.

10.4.9 Measurement Mode Order – MODE

The order of available measurement modes can be configured.

The principal modes are:

- REF
- KER
- REF/KER
- CLBC

The selected configuration determines the sequence in which modes appear when the MODE button is pressed.

10.5 Setup Page 3

The third Setup page allows the user to edit the text printed by the internal printer.

The text may be used for information such as:

- clinic name,
- company name,
- telephone number, or
- other short identification information.

Control	Function
→	Moves the editing cursor
←	Moves the editing cursor
DEL	Deletes a character
UP / DOWN	Selects or edits characters
SAVE	Saves the edited printer label
ESC	Exits the editing screen

10.6 Setup Page 4

The fourth Setup page provides correction values for refractometry and keratometry.

The available correction parameters are shown in the legacy interface as:

Parameter	Description
REF DSTS	Sphere correction (D)
REF DSTC	Cylinder correction (D)
REF DSTA	Axis / angle correction (degree)
KER DSTS	Keratometry sphere / radius correction
KER DSTC	Keratometry cylinder correction
KER DSTA	Keratometry axis / angle correction

The correction value is changed using the applicable +COUNT / -COUNT controls.

	Measurement correction values shall not be changed during normal clinical use unless specifically instructed by SCIENCETERA Co., Ltd. or authorized service personnel.
	Incorrect correction values may cause systematic measurement error.

10.7 Setup Page 5

The fifth Setup page provides display adjustment parameters.

The available parameters are:

Setting	Function
LCD LIGHT	Adjusts LCD backlight level
BRIGHTNESS	Adjusts screen brightness
CONTRAST	Adjusts display contrast
GAMMA	Adjusts display gamma

These settings affect only the display appearance. Adjust the display so that alignment indicators, measurement information and images can be clearly viewed under the intended clinical lighting conditions.

	Avoid extreme display settings that make alignment indicators or measurement information difficult to distinguish.
---	--

10.8 Saving Setup Changes

After changing a setting:

- 1) Confirm the selected value.
- 2) Press SAVE.
- 3) Verify that the setting has been stored.
- 4) Press ESC to return to the measurement screen.

If the user exits without saving, the edited value may not be retained.

11 Inspection and Maintenance

11.1 General

Regular inspection and appropriate maintenance are necessary to maintain the safety and performance of the TSRK-1000P. Before use, visually inspect the device and confirm that no abnormal condition is present. If an error message is displayed or abnormal operation occurs, follow the instructions in this section. If the problem cannot be resolved, discontinue use of the device and contact SCIENCETERA Co., Ltd. or an authorized distributor/service representative.

	Do not open, modify or repair the device unless specifically authorized by SCIENCETERA Co., Ltd.
	Disconnect the AC power cord before performing maintenance involving the fuse holder or other electrical parts.

11.2 Before Requesting Service

If a problem occurs during operation, an error message may be displayed on the monitor.

First check the displayed message and follow the recommended action.

11.2.1 Internal Error Messages

Message	Possible Cause	Recommended Action
System Error	Internal error	Turn the power OFF. Wait approximately 10 seconds, then turn the power ON again.
EEPROM Data Error	Internal error	Turn the power OFF. Wait approximately 10 seconds, then turn the power ON again.
EEPROM Error	Internal error	Turn the power OFF. Wait approximately 10 seconds, then turn the power ON again.
Motor Error	Internal error / motor-related abnormality	Turn the power OFF. Wait approximately 10 seconds, then turn the power ON again.
Printer Error	Internal printer-related error	Turn the power OFF. Wait approximately 10 seconds, then turn the power ON again.

If the same error message appears repeatedly after restarting the device, discontinue use and contact an authorized service representative.

11.2.2 Measurement-Related Messages

Message	Meaning	Recommended Action
+OVER	Measurement exceeds the supported positive measurement range	Measurement cannot be completed within the specified range
-OVER	Measurement exceeds the supported negative measurement range	Measurement cannot be completed within the specified range
C OUT	Astigmatic / cylindrical value exceeds the supported measurement range	Measurement cannot be completed within the specified range
TRY AGAIN	Alignment or measurement condition is not appropriate	Realign and repeat the measurement
NO PAPER	Printer paper is not loaded	Load printer paper

For detailed information concerning measurement-related messages, refer to Section 6.7 Measurement Messages.

11.3 Functional Check After an Error

If measurement errors continue to occur:

- 1) Check that the patient is correctly positioned.
- 2) Check the measurement window for dust, fingerprints or contamination.
- 3) Confirm proper alignment and focusing.
- 4) Repeat the measurement.
- 5) If necessary, check the measurement function using the supplied model eye.
- 6) If abnormal operation also occurs with the model eye, discontinue use and contact authorized service personnel.

11.4 Replacement of Printer Paper

When NO PAPER is displayed or the printer paper has been depleted, replace the paper roll.

Procedure

- 1) Open the printer cover.
- 2) Remove the empty or remaining paper roll.
- 3) Insert a new printer paper roll.
- 4) Pull the leading edge of the paper through the printer cover slot.
- 5) Make sure that the paper is correctly aligned.
- 6) Close the printer cover.
- 7) Perform a print operation to confirm correct paper feeding.



Use printer paper suitable for the built-in thermal printer.



Do not pull or force the paper while the printer is operating.

11.5 Fuse Replacement

The TSRK-1000P uses mains fuses for electrical protection.

The current available IEC 60601-1 report identifies two mains fuses, 250 Vac, 2 A.

Fuse Specification – Rating: 250 V, 2 A

Use only the specified fuse type and rating.

Replacement Procedure

- 1) Turn the main power switch OFF.
- 2) Disconnect the AC power cord from the instrument.
- 3) Using a suitable flat-head screwdriver, gently press the fuse holder and turn it counterclockwise.
- 4) Remove the fuse holder.
- 5) Remove the defective fuse.
- 6) Replace it with a new fuse of the specified rating.
- 7) Reinsert the fuse holder.
- 8) Gently press and turn the fuse holder clockwise until it is securely seated.
- 9) Reconnect the AC power cord.
- 10) Turn the device ON and verify normal operation.

	Disconnect the AC power cord before removing or replacing the fuse.
	Do not connect the device to the AC mains while the fuse holder is removed.
	Use only the specified fuse rating. Use of an incorrect fuse may result in electric shock, fire or equipment damage.
	If a replacement fuse opens again, do not replace the fuse repeatedly. Discontinue use and contact authorized service personnel.

11.6 Daily Check

Perform the following checks before or during routine use.

Check that:

- the enclosure is not damaged,
- the power cord and plug are not damaged,
- the connectors are securely installed,
- the measurement stage moves normally,
- the operation stick operates normally,
- the chinrest moves normally, and
- no abnormal noise, odor or vibration is present.

11.6.1 Examination Window

The examination window is an important part of the optical measurement system. Keep the examination window free from:

- dust,
- fingerprints,
- oil,
- moisture, and
- other contamination.

	Do not touch the optical window directly with fingers.
	Contamination of the examination window may adversely affect alignment or measurement.

11.6.2 Protection from Dust

When the device is not in use:

- 1) Turn the power OFF.
- 2) Disconnect the mains power if appropriate for long-term storage.
- 3) Cover the instrument with the supplied dust cover.

Avoid exposing the device to excessive dust.

11.6.3 Mechanical Shock

Do not subject the instrument to strong impact, shock or vibration.

If the device has been dropped or subjected to significant impact, discontinue use until its condition and measurement performance have been checked.

11.7 Condensation

If the instrument is moved from a cold environment to a warm environment, or if the room temperature increases rapidly, condensation may form on the optical components. Condensation may cause the examination window or internal optical system to become cloudy.

If condensation occurs:

- 1) Do not perform measurements immediately.
- 2) Allow the instrument to remain at room temperature.
- 3) Wait until the condensation has disappeared naturally.
- 4) Confirm that the optical window is clear before measurement.

Do not attempt to remove internal condensation by opening the instrument.



Do not attempt to remove internal condensation by opening the instrument.

11.8 Conditions Requiring Service

Stop using the TSRK-1000P and contact SCIENCETERA Co., Ltd. or an authorized service representative if any of the following occurs:

- an internal error message repeatedly appears,
- measurement cannot be performed using the model eye,
- the instrument does not power on normally,
- abnormal motor operation occurs,
- the measurement stage or chinrest does not move normally,
- the printer repeatedly malfunctions,
- the fuse repeatedly opens,
- the power cord or electrical parts are damaged,
- liquid has entered the instrument,
- the device has been dropped or significantly impacted, or
- abnormal noise, odor, smoke or heat is detected.



If smoke, unusual odor or abnormal heat is detected, turn the power OFF immediately, disconnect the AC power cord, and discontinue use.

11.9 Maintenance by Authorized Personnel

Internal adjustment, calibration, electrical repair, optical adjustment and replacement of internal components shall be performed only by personnel authorized or trained by SCIENCETERA Co., Ltd. The user shall not change service-level measurement correction values unless specifically instructed by the manufacturer.

12 Cleaning and Disinfection

12.1 General

Proper cleaning and disinfection are necessary to maintain the hygiene, safety and performance of the TSRK-1000P. The patient-contacting surfaces shall be cleaned and disinfected between patients.

Before cleaning the instrument:

- 1) Turn the main power switch OFF.
- 2) Disconnect the AC power cord when cleaning areas near electrical components or openings.
- 3) Use only cleaning materials compatible with the surfaces of the device.
- 4) Prevent liquid from entering the instrument.

	Do not clean the instrument while it is connected to the mains power if there is a possibility that liquid may enter the equipment.
	Do not pour or spray cleaning or disinfecting liquid directly onto the instrument.

12.2 Patient-Contacting Parts

The patient-contacting parts of the TSRK-1000P are:

- Chinrest
- Foreheadrest

These parts contact intact skin during normal examination. Both surfaces shall be cleaned and disinfected before use with each new patient.

12.2.1 Chinrest

Wipe the chinrest using an ethanol-based disinfectant wipe or an ethanol-moistened soft cloth.

Remove visible contamination before disinfection.

After wiping:

- 1) Allow the surface to remain visibly wet for the contact time specified for the disinfectant, where applicable.

- 2) Allow the surface to dry before positioning the next patient.
- 3) Make sure that no liquid enters the chinrest moving mechanism.

If disposable chinrest paper is used, replace it when contaminated and in accordance with the clinic's infection-control procedure.

	Do not saturate the chinrest or allow disinfectant to enter the motorized chinrest mechanism.
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12.2.2 Foreheadrest

The foreheadrest is made of:

VMQ (Vinyl Methyl Silicone Rubber)

Wipe the foreheadrest with an ethanol-based disinfectant wipe or ethanol-moistened soft cloth before each patient examination. After disinfection, allow the surface to dry before contact with the next patient.

	Do not immerse the foreheadrest in liquid.
	Do not use sharp tools, abrasive materials or aggressive solvents that could damage the silicone-rubber surface.

12.3 Cleaning Frequency

Part	Recommended Frequency
Chinrest	Before each patient
Foreheadrest	Before each patient
Measurement window	Whenever dust, fingerprints or contamination are visible
LCD / monitor surface	As necessary
External housing	As necessary
Operation controls	Regularly and when visibly contaminated

12.4 Examination / Measurement Window

The examination window is part of the optical measurement system and shall be kept clean.

Contamination such as:

- dust,
- fingerprints,
- oil,
- moisture, or
- residue

may adversely affect image quality, alignment or measurement performance.

If dust is present:

- 1) Use a suitable air blower to remove loose particles.
- 2) Do not wipe loose abrasive particles directly across the optical surface.

If fingerprints or oil are present:

- 1) Remove loose dust first.
- 2) Use clean optical gauze or a suitable lens-cleaning cloth.
- 3) Apply a small amount of suitable optical lens cleaner to the cloth, if required.
- 4) Wipe the optical surface gently.

	Do not touch the examination window directly with fingers.
	Do not apply excessive pressure to the optical surface.

12.5 External Housing

For routine cleaning of the external enclosure:

- 1) Turn the device OFF.
- 2) Use a clean, soft and dry cloth.
- 3) If necessary, use a slightly dampened cloth.
- 4) Wipe the surface gently.
- 5) Make sure the instrument is dry before use.

	Do not allow liquid to enter: - ventilation openings, - connectors, - switches, - printer opening, - USB / RS-232C / video connectors, or - moving mechanisms.
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12.6 LCD Monitor

Clean the monitor using a clean, soft, lint-free cloth.

- Do not use excessive pressure.
- If necessary, lightly dampen the cloth with a cleaning agent suitable for display surfaces.

	Do not spray cleaning solution directly onto the monitor.
	Do not use rough paper, abrasive pads or sharp objects on the display surface.

12.7 Prohibited Cleaning Agents and Methods

Do not use:

- benzene,
- paint thinner,
- strong organic solvents,
- abrasive cleaners,
- abrasive pads,
- excessive amounts of liquid, or
- cleaning methods that may allow liquid to enter the device.

The existing manual specifically prohibits benzene, thinner and chemical-containing dustcloths for cleaning the instrument.

Do not immerse the device or any electrical part in liquid.

Do not sterilize the complete instrument by steam, heat or other sterilization methods unless specifically approved by SCIENCETERA Co., Ltd.

12.8 After Cleaning and Disinfection

After cleaning:

- 1) Check that all cleaned surfaces are dry.
- 2) Check that no cleaning liquid has entered the instrument.
- 3) Inspect the chinrest and foreheadrest for damage, cracking or deterioration.
- 4) Check that the measurement window is clean.
- 5) Reconnect power only after the instrument is completely dry.
- 6) Confirm normal operation before patient use.

If a patient-contacting part is damaged or deteriorated, discontinue use of the affected part and replace it with an approved replacement component.

12.9 Infection-Control Considerations

The chinrest and foreheadrest come into direct contact with the patient's intact skin. Therefore, cleaning and disinfection between patients are required to reduce the possibility of cross-contamination. The facility using the TSRK-1000P should also follow its applicable institutional infection-control procedures.

13 Standard Accessories

13.1 Standard Accessories Supplied

The following accessories are normally supplied with the TSRK-1000P.

Accessory	Quantity	Purpose
Power Cable	1	Connection to the AC mains supply
Model Eye	1	Functional check of the measurement system
Dust Cover	1	Protection of the instrument from dust when not in use
Fuse	2	Replacement mains fuse
Printer Paper	2	Printing measurement results
Chinrest Paper	1	Disposable covering for the chinrest
Instructions for Use / Operation Manual	1	Operating and safety information

The available IEC 60601-1 documentation also identifies the equipment configuration as including the main body, model eye, printer paper, power supply components and dust cover.

13.2 Power Cable

Use only a power cable that is suitable for the mains supply and applicable electrical requirements of the country where the device is used. The power cable shall provide a protective-earth connection appropriate for the Class I equipment.

	Do not use a damaged power cable.
	Do not use an adapter or connection method that defeats the protective-earth connection.

13.3 Model Eye

The supplied model eye is intended for checking the basic measurement operation of the TSRK-1000P.

It may be used when:

- the instrument is installed,
- measurement performance is in doubt,
- repeated patient measurement errors occur, or
- a basic functional check is required before contacting service personnel.

The model eye is intended for a functional check and is not a substitute for formal calibration or verification using appropriate reference equipment.

13.4 Dust Cover

Use the supplied dust cover when the instrument is not in use for an extended period.

Before fitting the dust cover:

- 1) Turn the device OFF.
- 2) Allow the instrument to cool if necessary.
- 3) Make sure that the instrument is dry.
- 4) Fit the dust cover over the device.

Do not cover the instrument while it is operating.

13.5 Replacement Fuse

The device uses two mains fuses.

The existing IEC 60601-1 report identifies the mains fuse rating as:

250 Vac, 2 A

with two fuses provided.

Use only the fuse type and rating specified for the device.

	Disconnect the AC power cord before replacing a fuse.
	If a replacement fuse opens repeatedly, discontinue use and contact authorized service personnel.

13.6 Printer Paper

Use thermal printer paper suitable for the built-in printer.

Incorrect paper type, width or installation may cause:

- poor print quality,
- paper-feed problems, or
- printer malfunction.

Replace the printer paper as described in Section 11.4 Replacement of Printer Paper.

13.7 Chinrest Paper

Disposable chinrest paper may be installed on the chinrest for patient use.

The chinrest paper does not replace the requirement to maintain the chinrest in a clean and hygienic condition.

Replace the chinrest paper:

- when visibly contaminated,
- when damaged, or
- according to the facility's infection-control procedure.

The underlying chinrest shall still be cleaned and disinfected as required.

13.8 Replacement Accessories and Parts

Use only accessories, replacement parts and consumables that are specified or approved by SCIENCETERA Co., Ltd.

Use of incompatible parts may affect:

- device safety,
- measurement performance,
- electromagnetic compatibility, or
- mechanical operation.

For replacement accessories or parts, contact SCIENCETERA Co., Ltd. or an authorized distributor.

14 Technical Specifications

Refractometer Mode	
Sphere	-25.00D ~ +22.00D
Cylinder	0 ~ ±10D
Axis	1° ~ 180°
Keratometer Mode	
Corneal Curvature	R5.0mm ~ R10.0mm
Corneal Refraction	67.5D ~ 33.75D
Corneal Astigmatism	0 ~ ±10D
Axis Angle	1° ~ 180°
Other Measurement Mode	
Pupil Distance	10 ~ 85mm
Pupil Diameter	2 ~ 12mm
CLBC	R5.0mm ~ R10.0mm
IOL Calculation	Supported
Retro-illumination	Supported
General	
Measurement Start	Auto / Manual
Display	6.4-inch TFT Color LCD
Printer	Built-in 57mm thermal printer
Interface	RS-232C, USB and Video output
Power Supply	AC 100 ~ 240V, 50/60Hz, 100VA
Dimensions	242(W) × 467(D) × 465(H) mm
Weight	13.6 kg

15 Transport and Storage

15.1 General

The TSRK-1000P shall be transported and stored under environmental conditions that prevent damage to the optical, mechanical and electrical components of the device.

During transport and storage:

- protect the device from excessive shock and vibration,
- protect the device from moisture and condensation,
- keep the device away from corrosive gases and excessive dust,
- avoid direct sunlight and excessive heat,
- keep the device in a stable orientation, and
- use the original or equivalent protective packaging whenever possible.

15.2 Transport Conditions

Condition	Specification
Temperature	-40 °C to 70 °C
Relative Humidity	10% to 95% RH
Atmospheric Pressure	500 to 1060 hPa

15.3 Storage Conditions

Condition	Specification
Temperature	-10 °C to 55 °C
Relative Humidity	35% to 75% RH
Atmospheric Pressure	700 to 1060 hPa

15.4 Preparation for Transport

Before transporting the device:

- 1) Turn the main power switch OFF.
- 2) Disconnect the AC power cord.
- 3) Disconnect all external cables.
- 4) Remove or secure loose accessories.
- 5) Secure the movable measurement stage using the clamping mechanism provided for transport.
- 6) Protect the measurement window and other optical surfaces.
- 7) Pack the device securely to prevent movement or impact during transport.

	Do not transport the device with the movable stage unsecured.
	Do not lift or carry the device by the monitor, foreheadrest, chinrest or other movable parts.

15.5 Storage Before Use

When the device is stored for an extended period:

- turn the power OFF,
- disconnect the mains power,
- install the dust cover,
- keep the device in a dry and clean area,
- avoid areas subject to strong vibration,
- avoid exposure to oil mist, corrosive gas or excessive dust.

15.6 Condensation

If the TSRK-1000P is moved from a cold environment to a warm environment, condensation may form on the optical components. The existing manual notes that in winter or in a cold region the instrument lenses may become cloudy and that measurement should not begin until the lens has become clear naturally.

If condensation is suspected:

- 1) Do not perform patient measurement.
- 2) Leave the instrument at room temperature.
- 3) Allow the device to reach thermal equilibrium.
- 4) Wait until all visible condensation or optical clouding has disappeared.
- 5) Confirm that the measurement window is clear.
- 6) Perform a functional check before use if necessary.



Do not attempt to remove internal condensation by opening the instrument or applying external heat.

15.7 After Transportation

After transport, inspect the instrument before patient use.

Check:

- the outer enclosure,
- the power cord and connectors,
- the measurement window,
- the movable stage,
- the operation stick,
- the chinrest movement,
- the LCD display,
- and the built-in printer.

If the device has been exposed to strong impact, abnormal vibration or environmental conditions outside the specified limits, do not use it until normal operation has been confirmed.

Where necessary, use the supplied model eye to perform a basic measurement check.

15.8 Environmental Conditions During Operation

For reference, the normal operating conditions are:

Condition	Specification
Temperature	10 °C to 40 °C
Relative Humidity	30% to 75% RH
Atmospheric Pressure	700 to 1060 hPa

16 Regulatory and Compliance Information

16.1 European Regulatory Framework

The TSRK-1000P was originally placed on the European market in conformity with Council Directive 93/42/EEC concerning medical devices (MDD). The device is currently undergoing conformity assessment for transition to Regulation (EU) 2017/745 on medical devices (MDR).

Until completion of the MDR conformity assessment, the device is managed as an MDD legacy device in accordance with the transitional provisions of Article 120 of Regulation (EU) 2017/745, as amended by Regulation (EU) 2023/607.

NOTE	The MDR conformity assessment is currently in progress. The presence of MDR-related information in this Instructions for Use does not indicate that an MDR certificate has already been issued.
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16.2 MDD Legacy Device Status

The TSRK-1000P is covered by conformity assessment documentation issued under Directive 93/42/EEC.

During the applicable MDR transitional period, the device may continue to be placed on the market or put into service as a legacy device, provided that all applicable conditions of Article 120 of Regulation (EU) 2017/745 continue to be fulfilled.

These conditions include, as applicable:

- continued compliance with Directive 93/42/EEC;
- no significant change in the design or intended purpose;
- continued compliance with applicable MDR transitional requirements; and
- fulfilment of the required MDR conformity-assessment transition arrangements.

For eligible Class IIa legacy devices, the transitional period under Regulation (EU) 2023/607 extends to 31 December 2028, subject to fulfilment of the applicable conditions.

16.3 MDR Device Classification

Under Regulation (EU) 2017/745, the TSRK-1000P is classified as:

- Class IIa according to Annex VIII, Chapter III, Rule 10

Rule 10 applies to active devices intended for diagnosis and monitoring where, among other criteria, the device supplies energy that is absorbed by the human body, except for devices intended solely to illuminate the patient's body in the visible spectrum.

16.3.1 Classification Rationale

The TSRK-1000P is an active diagnostic medical device.

The device:

- uses electrical energy for operation;
- directs optical energy toward the patient's eye;
- receives reflected optical information from ocular structures;
- processes the returned optical information; and
- objectively determines refractive and keratometric parameters.

The device is not intended solely to illuminate the patient's body in the visible spectrum.

Therefore, classification under Rule 10 as Class IIa is considered appropriate.

16.4 No Significant Change During Legacy Transition

During the legacy-device transitional period, no significant change shall be made to the design or intended purpose that would invalidate the applicable transitional provisions.

The current TSRK-1000P maintains the established:

- intended purpose,
- measurement principle,
- measurement functions,
- basic design,
- patient-contact configuration, and
- principal technical specifications.

Regulation (EU) 2023/607 expressly requires that eligible legacy devices continue to comply with the applicable Directive and have no significant change in design or intended purpose.

16.5 CE Marking and Notified Body

During the applicable legacy-device transitional period, the CE marking and Notified Body identification shall correspond to the legally applicable MDD conformity-assessment documentation and approved labeling.

The legacy TSRK-1000P labeling identifies **CE 0123** associated with the existing MDD conformity-assessment status.

16.6 Existing Electrical Safety Evidence

Existing electrical-safety documentation for the TSRK-1000P includes:

- Report No.: BWS-20-SC-0046
- Standard: EN 60601-1:2006 + A1:2013
- Date of issue: 18 August 2020

The report identifies the test item as:

- Ophthalmic Ref-Keratometer – AXIS (TSRK-1000P)

with an electrical rating of:

- 100–240 V~, 50/60 Hz, 100 VA.

The same report identifies the Chin and Forehead as Type BF applied parts.

16.7 Existing EMC Evidence

Existing EMC test documentation includes:

- Test Report No.: CPSC01220818 / TRECEE18-0106
- Product: Auto Ref-Keratometer
- Model: TSRK-1000P

The report identifies the following standards:

- EN 60601-1-2:2015
- EN 61000-3-2:2014
- EN 61000-3-3:2013

with a positive / compliant test result.

16.8 Applicable Standards

The standards applicable to the current regulatory submission shall be defined and controlled in the TSRK-1000P technical documentation.

Existing legacy conformity evidence includes, but is not limited to:

- IEC / EN 60601-1 – Medical electrical equipment – General requirements for basic safety and essential performance
- IEC / EN 60601-1-2 – Electromagnetic disturbances
- applicable ophthalmic instrument standards
- applicable usability requirements
- applicable risk-management requirements
- applicable biological-safety requirements for patient-contacting materials

NOTE	The exact editions and amendments applicable to the final MDR technical documentation shall be updated following completion of the planned new safety and EMC testing.
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16.9 Post-Market Surveillance and Vigilance

During the MDR transitional period, applicable MDR requirements concerning post-market surveillance, vigilance, market surveillance, and registration continue to apply to legacy devices under Article 120.

Any serious incident associated with the TSRK-1000P shall be reported to:

- SCIENCETERA Co., Ltd.; and
- the competent authority of the Member State concerned, where required.

Complaints, adverse events and safety-related information shall be handled in accordance with the manufacturer's post-market surveillance and quality-management procedures.

16.10 Regulatory Information Control

The following information shall be maintained consistently across the applicable regulatory documents and labeling:

- Manufacturer name and address
- EU Authorized Representative
- Device name
- Model
- Intended purpose
- Risk classification
- UDI
- CE marking
- Notified Body identification
- Electrical rating
- Applied-part classification
- Patient-contacting materials
- applicable warnings and precautions

Where a regulatory record or certificate is revised, the manufacturer shall assess whether corresponding labeling or IFU updates are required.

17 EMC information

Precautions to prevent adverse events to the patient and the operator due to electromagnetic disturbances are provided in the tables below.

A. Manufacturer announcement – electromagnetic waves trouble

Electromagnetic waves trouble	
TSRK-1000P should be used in the below mentioned electromagnetic wave environment.	
TSRK-1000P purchaser or user needs to confirm whether it is used in this type of environment.	
Trouble test	Question of appropriateness
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker IEC 61000-3-3	Complies

B. Manufacturer announcement – electromagnetic waves tolerance

Electromagnetic waves tolerance		
TSRK-1000P is to be used in the below mentioned electromagnetic wave environment. TSRK-1000P purchaser or user needs to confirm whether it issued at this environment.		
Tolerance test	IEC 60601 test conditions	Appropriateness level
Electrostatic discharge (ESD) IEC 61000-4-2	contact ± 8 kV in the air ± 15 kV	contact ± 8 kV in the air ± 15 kV
Electric rapid transients/burst IEC 61000-4-4	power supplying line ± 2 kV input/output line ± 1 kV	power supplying line ± 2 kV input/output line ± 1 kV
Surge IEC 61000-4-5	between lines ± 1 kV between line and grounding ± 2 kV	differential mode ± 1 kV common mode ± 2 kV
Voltage dip, instantaneous interruption, voltage fluctuation at the power input line IEC 61000-4-11	for 0.5 cycle < 5% UT (UT's >95% decrease) for 5 cycle 40% UT (UT's 60% decrease)	for 0.5 cycle < 5% UT (UT's >95% decrease) for 5 cycle, 50% UT (UT's 60% decrease)

	for 25 cycle 70% UT (UT's 30% decrease) for 5 seconds < 5% UT (UT's > 95% decrease)	for 25 cycle, 70% UT (UT's 30% decrease) for 5 seconds, <5% UT (UT's > 95% decrease)
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30A/m
Other UT is the a.c. power voltage for before approving the test level.		
Conductivity RF electromagnetic field IEC 61000-4-6	3 Vrms 150 kHz – 80 Mhz 5 Vrms in ISM band 6.765 MHz to 6.795 MHz 13.553 MHz to 13.567 MHz 26.957 MHz to 27.283 MHz 40.66 MHz to 40.70 MHz	3 Vrms 6 Vrms
Radioactivity RF electromagnetic field tolerance IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz scope	3 V/m

18 Revision history

No.	Date	Contents
0	2026.10.07	- Initial issue