



Operating Instructions

UM-102 (EN)

tSDR-3000

Digital Refractor



Operating Instructions for Digital Refractor TSDR-3000

Rev. 1

Language - English (EN)



SCIENCETERA Co., Ltd.



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Index

1 General information.....	1
1.1 Device Outline	1
1.2 Device name and model.....	1
1.3 Manufacturer	1
1.4 Qualification of the product as a medical device	2
1.4.1 Rationale for qualification	2
1.4.2 Not an accessory	4
1.4.3 Classification and regulatory implication	5
1.5 Device classification and justification	6
1.5.1 Risk class.....	6
1.5.2 Justification for classification	6
1.5.3 Non applicability of other rules.....	8
1.6 Regulatory mark	9
1.7 Authorised Representative	9
1.8 Unique Device Identification (UDI).....	10
2 Information.....	11
2.1 Intended purpose.....	11
2.2 Intended environment	11
2.3 Intended user	13
2.3.1 Segmentation of occupation.....	13
2.3.2 User characteristics	13
2.4 Residual risks	14
2.5 Indications	14
2.6 Contra-indications.....	14
2.7 Patient target groups.....	15
2.7.1 Patient-contacting components	15
2.8 Undesirable side-effects.....	15

2.9 Operating principle.....	16
2.9.1 Mode of action.....	16
2.9.2 Scientific basis.....	16
3 Safety information	18
3.1 Reporting of Serious Incidents.....	22
4 Labels and symbols.....	23
4.1 Refractor head.....	25
4.2 Junction box	26
5 Device description.....	27
5.1 Refractor head.....	27
5.2 Junction box	29
5.3 Tablet controller.....	30
5.4 Accessories.....	31
6 Installation and setup	33
6.1 Unpacking and inspection	33
6.2 Installation requirements	33
6.3 Mounting the Refractor head	34
6.4 Connecting the Refractor head.....	35
6.5 Connection to External Ophthalmic Devices (Optional).....	37
6.6 Connection to Visual Acuity Chart System (Optional).....	38
6.7 Bluetooth configuration.....	39
6.8 Initial system start-up	39
6.9 System initialization	40
6.10 Functional verification.....	40
6.11 Daily start-up check.....	41
7 Operation.....	42
7.1 Starting the Application	42
7.1.1 Powering on the system.....	42
7.1.2 Main screen.....	42

7.2 Patient management.....	57
7.2.1 Creating a new patient record.....	57
7.2.2 Opening an Existing Patient Record	58
7.2.3 Modifying Patient Information	59
7.2.4 Saving Examination Results.....	59
7.3 Bluetooth configuration.....	60
7.3.1 Opening the Bluetooth menu.....	60
7.3.2 Connecting the Refractor head.....	61
7.3.3 Connecting a Visual Acuity Chart System (Optional)	63
7.3.4 Connecting a printer (Optional).....	65
7.3.5 Disconnecting a device	67
7.4 Loading examination data	67
7.4.1 Loading received data.....	68
7.4.2 Manual data entry	69
7.4.3 Applying loaded data	70
7.5 Near vision chart.....	71
7.5.1 Opening the Near vision chart	71
7.5.2 Selecting the chart type.....	72
7.5.3 Adjusting the Examination Distance.....	73
7.5.4 Closing the Near vision chart.....	74
7.6 System settings	75
7.6.1 OPTION settings	76
7.6.2 LENS settings.....	78
7.6.3 TEST settings.....	80
7.6.4 TEST ENVIRONMENT settings.....	82
7.6.5 PRINT settings	84
7.6.6 LENS CLEANING	86
7.6.7 INFORMATION	87
7.7 Custom charts	88

7.7.1 Overview	88
7.7.2 Opening Custom Edit.....	88
7.7.3 Creating a custom chart.....	89
7.7.4 Custom chart parameters.....	90
7.7.5 Deleting a custom chart	91
7.8 Examination programs	92
7.8.1 Overview.....	92
7.8.2 Opening Program Edit	92
7.8.3 Creating an examination program.....	93
7.8.4 Program parameters.....	94
7.8.5 Executing an examination program.....	95
7.8.6 Deleting an examination program	95
8 Examination functions	96
8.1 Subjective refraction workflow	96
8.2 Pupillary distance (PD) adjustment.....	97
8.2.1 Purpose	97
8.2.2 Procedure	97
8.2.3 Verification	99
8.3 Vertex distance (VD) adjustment	100
8.3.1 Purpose	100
8.3.2 Procedure	100
8.3.3 Recommended vertex distance	101
8.4 Sphere power adjustment.....	102
8.4.1 Purpose	102
8.4.2 Selecting the eye.....	102
8.4.3 Adjusting sphere power.....	102
8.4.4 Available adjustment steps.....	104
8.4.5 SHIFT function	104
8.4.6 Fogging.....	104

8.5 Cylinder power adjustment.....	105
8.5.1 Purpose	105
8.5.2 Selecting the eye	105
8.5.3 Adjusting cylinder power	105
8.5.4 Cylinder Sign Convention.....	106
8.5.5 Cylinder Adjustment Step.....	107
8.6 Axis adjustment	108
8.6.1 Purpose	108
8.6.2 Selecting the eye	108
8.6.3 Adjusting the Axis	108
8.6.4 Axis range	109
8.6.5 Axis control functions	110
8.7 Jackson Cross Cylinder (JCC) examination.....	112
8.7.1 Purpose	112
8.7.2 Starting the JCC test.....	112
8.7.3 Axis refinement.....	113
8.7.4 Cylinder power refinement	114
8.7.5 Cross Cylinder lens selection	115
8.8 Prism adjustment.....	116
8.8.1 Purpose	116
8.8.2 Prism types	116
8.8.3 Horizontal prism adjustment (BI-BO).....	117
8.8.4 Vertical prism adjustment (BD-BU)	119
8.8.5 Prism display formats.....	121
8.8.6 Prism adjustment functions	121
8.9 Near vision examination	122
8.9.1 Purpose	122
8.9.2 Adjusting the ADD power	122
8.9.3 ADD adjustment step.....	123

8.9.4 Working distance (WD)	123
8.9.5 Age setting (AGE).....	123
8.9.6 ADD OFF function	124
8.10 Binocular balance test.....	125
8.10.1 Purpose.....	125
8.10.2 Starting the binocular balance test.....	125
8.10.3 Examination procedure	126
8.10.4 Examination notes	126
8.11 Near addition tests	127
8.11.1 Near Add Cross Grid test	127
8.11.2 Near Add Visual Acuity test.....	129
8.12 Duochrome test	131
8.12.1 Purpose.....	131
8.12.2 Procedure.....	131
8.12.3 Expected endpoint.....	133
8.13 Astigmatism tests.....	134
8.13.1 Cross Grid test (Distance)	134
8.13.2 Clock Dial test (Cylinder Axis and Power test).....	136
8.14 Binocular vision tests	137
8.14.1 Worth Four Dots test.....	137
8.14.2 Stereo test.....	140
8.14.3 Minutes Stereo test.....	142
8.15 Phoria tests	144
8.15.1 Horizontal Von Graefe test	144
8.15.2 Vertical Von Graefe test	146
8.15.3 Horizontal Maddox test	148
8.15.4 Vertical Maddox test	150
8.16 Fusion and Coincidence tests.....	152
8.16.1 Schober test.....	152

8.16.2 Horizontal Coincidence test.....	154
8.16.3 Vertical Coincidence test.....	156
8.16.4 Cross test with Fixation Point	158
8.17 Special tests	160
8.17.1 Polarized Red/Green test	160
8.17.2 Dominant eye test.....	162
9 Maintenance and service.....	164
9.1 Routine cleaning.....	164
9.1.1 General precautions	164
9.1.2 Cleaning of exterior surfaces.....	165
9.1.3 Cleaning of optical lenses through measuring windows	165
9.1.4 Cleaning and disinfection of forehead rest and face shields.....	166
9.1.5 Inspection After Cleaning	166
9.2 Inspection before use.....	167
9.2.1 Exterior Inspection.....	167
9.2.2 Power Supply Inspection.....	167
9.2.3 Optical System Inspection.....	168
9.2.4 Functional Inspection.....	168
9.2.5 Patient-contact surface inspection	168
9.2.6 Inspection Result.....	169
9.3 Functional verification after service.....	170
9.3.1 Verification procedure	170
9.3.2 Verification result.....	171
9.3.3 Service record	171
9.4 Fuse replacement.....	172
9.4.1 General precautions	172
9.4.2 Fuse specification.....	172
9.4.3 Fuse replacement procedure.....	173
9.4.4 Verification after replacement.....	173

9.5 Storage and transportation	174
9.5.1 Storage conditions	174
9.5.2 Transportation conditions	175
9.5.3 Transportation precautions.....	175
9.5.4 Inspection after transportation	176
9.5.5 Condensation precaution	176
9.6 Disposal Information	177
10 Troubleshooting	178
10.1 Troubleshooting guide.....	178
10.2 Service required.....	179
11 Technical specifications.....	180
11.1 Measurement range	180
11.2 Auxiliary lenses.....	181
11.3 Hardware specifications	181
11.4 Electrical specifications	181
12 IT and Cybersecurity information.....	182
12.1 Minimum hardware requirements.....	182
12.2 Wireless communication security	182
12.3 IT Network requirements	183
12.4 IT Security measures	183
13 Regulatory and compliance information.....	184
14 EMC information	186
15 Revision history.....	188

1 General information

1.1 Device Outline

The Digital Refractor Model TSDR-3000 is an automated subjective refraction system intended for determination of refractive errors and binocular vision assessment.

The system consists of:

- Refractor head
- Control tablet
- Junction box
- Near Vision rod
- External thermal printer

The device may receive measurement data from compatible Auto Refractometers and Visual Acuity Chart Systems.

1.2 Device name and model

- Device name: Digital Refractor
- Model: TSDR-3000
- Rating: 100-240 V~, 50/60 Hz, 50 VA
- Software: Android 9.0.0
- Serial Number: See Marking plate.

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

– *in accordance with MDR Annex II Section 1.1 (e)*

1.4.1 Rationale for qualification

The TSDR-3000 Digital Refractor is qualified as a medical device under Regulation (EU) 2017/745, Article 2 (1), which defines a medical device as:

‘medical device’ means any instrument, apparatus, appliance, software implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevent, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- product specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1 (4) and of those referred to in the first paragraph of this point.

The TSDR-3000 is intended to be used by ophthalmologists, optometrists, opticians and other qualified eye-care professionals during subjective refraction procedures.

The device allows the examiner to:

- Determine refractive errors such as myopia, hyperopia and astigmatism
- Evaluate binocular vision functions
- Assess accommodative and vergence functions

- Determine the corrective lens prescription required by the patient
- Support clinical diagnosis and management of visual disorders

The device automatically positions ophthalmic lenses before the patient's eyes and enables controlled presentation of optical stimuli during the refraction process.

The examination results obtained using the device are used directly by eye-care professionals for clinical decision making and vision correction.

Therefore, the intended purpose of the TSDR-3000 contributes directly to the diagnosis and assessment of visual function and ocular refractive status.

Accordingly, the TSDR-3000 fulfills the definition of a medical device under Article 2(1) of Regulation (EU) 2017/745.

1.4.2 Not an accessory

The TSDR-3000 is not considered an accessory according to Article 2(2) of Regulation (EU) 2017/745.

Although the device may communicate with compatible Auto Refractometers, Visual Acuity Chart Systems, Lensmeters and other ophthalmic equipment, it does not merely enable another medical device to be used in accordance with its intended purpose.

The TSDR-3000 performs an independent medical function by:

- Presenting ophthalmic lenses during subjective refraction
- Supporting determination of refractive correction
- Performing binocular vision assessments
- Assisting clinical evaluation of visual performance

The device remains fully functional as a stand-alone system and provides a direct diagnostic contribution regardless of whether external devices are connected. Therefore, the TSDR-3000 shall be regarded as an independent medical device rather than an accessory.

1.4.3 Classification and regulatory implication

Based on its intended purpose, mode of operation, and technological characteristics, the TSDR-3000 Digital Refractor is classified as a medical device under Regulation (EU) 2017/745 – MDR.

Medical Device – Class I
according to MDR Annex VIII, Chapter III, Rule 13

The TSDR-3000 is an active, non-invasive ophthalmic instrument intended to support subjective refraction procedures and binocular vision assessments performed by qualified eye-care professionals.

As a Class I medical device, the TSDR-3000 is subject to the applicable requirements of Regulation (EU) 2017/745, including:

- General Safety and Performance Requirements (Annex I)
- Technical Documentation Requirements (Annex II)
- Post-Market Surveillance Requirements (Annex III)
- UDI Requirements
- CE Marking Requirements

The conformity assessment procedure applicable to this device is the Class I conformity assessment route in accordance with Article 52 of Regulation (EU) 2017/745.

The rationale for the classification of the device is provided in section 1.5.

1.5 Device classification and justification

– *in accordance with MDR Annex II Section 1.1 (f)*

1.5.1 Risk class

The TSDR-3000 Digital Refractor is an active medical device intended to support subjective refraction procedures and binocular vision assessments performed by qualified eye-care professionals. Accordingly, the device is classified as Class I Medical Device in accordance with Regulation (EU) 2017/745 – MDR, Annex VIII, Chapter III, Rule 13.

1.5.2 Justification for classification

1.5.2.1 Applicable rule

MDR Annex VIII, Chapter III Classification Rules
6. ACTIVE DEVICES
6.5. Rule 13
Other active devices are classified as class I

The device does not independently measure or calculate physiological parameters and therefore does not fall within Rule 10.

1.5.2.2 Rationale

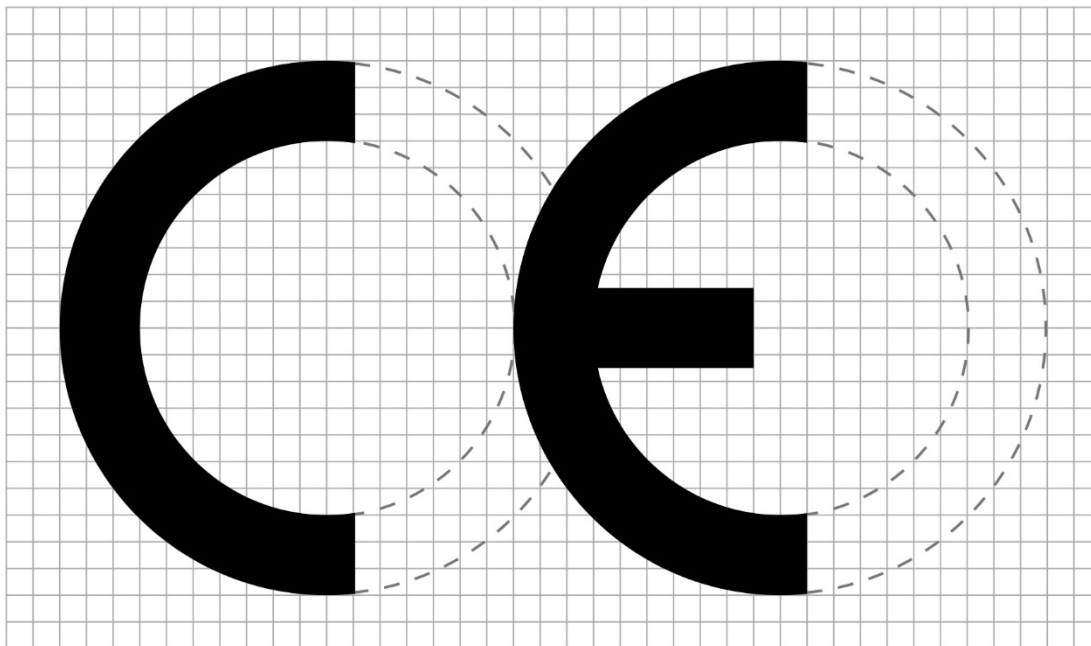
- a) The TSDR-3000 is an active medical device because it uses electrical energy to control and position ophthalmic lenses during subjective refraction procedures.
- b) The device is intended to support determination of refractive correction and binocular vision assessment by qualified healthcare professionals.
- c) The device is non-invasive and does not introduce energy, substances, or materials into the human body.
- d) The device does not administer therapeutic energy and does not exchange energy with the patient.
- e) The device does not monitor physiological parameters and does not provide automated diagnosis.
- f) The device does not independently measure physiological or optical parameters. Clinical findings and refractive prescriptions are determined by the examiner based on patient responses during subjective testing.
- g) The device serves as an examination instrument that presents ophthalmic lenses under controlled conditions and supports professional clinical judgement.
- h) As the device does not meet the conditions described in Rules 9, 10, 11, or 12 of MDR Annex VIII, it falls within the scope of Rule 13.

Accordingly, the TSDR-3000 is classified as a Class I Medical Device.

1.5.3 Non applicability of other rules

No.	Rule summary	A or N/A	Reason for non-applicability
Rule 9	Active devices intended to deliver energy to or exchange energy with the human body for diagnosis or therapy	N/A	Administer or exchange energy with the human body.
Rule 10	Active devices intended for monitoring or measurement of vital physiological parameters	N/A	The device does not monitor physiological parameters.
Rule 11	Software intended for processing or interpretation of medical data	N/A	The software controls lens positioning and examination functions only. Diagnostic conclusions remain the responsibility of the examiner.
Rule 12	Active devices intended to emit or exchange energy absorbed by the body	N/A	The device does not administer energy for therapeutic or diagnostic absorption by the body.
Rule 13	All other active devices not covered by the above rules	A	Active ophthalmic examination device intended to support subjective refraction and binocular vision assessment.

1.6 Regulatory mark



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

1.7 Authorised Representative

EU Representative

Advena Ltd.

Tower Business Center, 2nd Flr.,
Tower Street Swatar BKR 4013 Malta

UK Responsible Person

Advena Ltd. UK

Pure Offices Plato Close Warwick CV34 6WE United Kingdom

1.8 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 Information

2.1 Intended purpose

The TSDR-3000 Digital Refractor is intended to be used by qualified eye-care professionals to perform subjective refraction and binocular vision assessment for determination of refractive correction.

2.2 Intended environment

Item	Description
Location	Specialized medical institutions such as medical offices, refraction room, etc. in hospitals
Lighting	Indoor lighting 80 to 320 cd/m ² 200 cd/m ² recommended
Noise	Used in relatively quiet conditions to allow conversation with the patients
Space	Sufficient space for safe installation and examination
Power supply	AC 100-240V 50/60Hz fixed outlet required
Buildings or infrastructures	Professional healthcare facility environment Hospitals, medical institutions, and treatment facilities; Hospitals except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging
Operating environment	Temperature: -10 °C to +40 °C Humidity: 10 to 90 % (non-condensing) Atmospheric pressure: 80 kPa to 106 kPa

	This device is intended for use only in professional healthcare facility environments, such as hospitals, clinics, and optometry offices. Do not use in non-clinical or home environments.
	Do not operate this device in close proximity to active high-frequency (HF) surgical equipment, as excessive electromagnetic interference (EMI) may cause malfunction or incorrect chart display.
	This device must not be used inside or adjacent to the RF shielded room of an ME system for magnetic resonance imaging (MRI). Strong electromagnetic fields in such environments can lead to device failure and potential hazards.

2.3 Intended user

2.3.1 Segmentation of occupation

User group	Description
Doctor	A doctor who tests, diagnoses and prescribes a patient's vision in hospital
Optometrist	Specialized medical technician who specializes in eyesight test in hospitals, etc.
Optician	A medical technician who performs an eyesight test for prescription of eyeglasses or contact lenses
medical professional, technician or relevant qualifying holder	A person who assists the test according to the doctor's instructions

2.3.2 User characteristics

- healthcare qualified professionals with relevant qualifications
- a secondary level of education, at least
- receive minimal training or instruction before using the product
- possibility of elderly users or user unfamiliar with digital devices

2.4 Residual risks

The following residual risks remain after implementation of risk control measures:

- Temporary visual discomfort during subjective refraction procedures
- Temporary eye fatigue during prolonged examinations
- Inaccurate examination results due to incorrect operation
- Inaccurate examination results due to improper patient positioning
- Minor discomfort caused by contact with the forehead rest or face shields

The benefits of the device outweigh the identified residual risks.

2.5 Indications

The device is indicated for patients requiring:

- Subjective refraction
- Determination of spectacle prescription
- Evaluation of refractive errors
- Assessment of binocular vision status
- Assessment of accommodation and vergence functions
- Follow-up evaluation of visual performance

2.6 Contra-indications

There are no known absolute contraindications for use of this device.

However, testing should be avoided or performed with caution in patients who:

- Are unable to provide reliable subjective responses
- Cannot maintain stable fixation
- Have severe cognitive impairment preventing cooperation
- Experience significant discomfort during ophthalmic examination

If unusual symptoms occur during examination, testing should be discontinued.

2.7 Patient target groups

The device is intended for:

- Adults requiring vision examination
- Children capable of responding to subjective refraction procedures
- Patients with refractive errors
- Patients requiring binocular vision assessment

The device is not intended for:

- Unconscious patients
- Patients unable to communicate responses
- Patients requiring fully automated objective refraction measurements

2.7.1 Patient-contacting components

The forehead rest and face shields are intended for temporary contact with intact skin only (<24 h).

No other patient-contacting parts are provided.

2.8 Undesirable side-effects

No known physiological side effects are associated with normal use of this device.

Some patients may experience:

- Temporary visual fatigue
- Temporary eye strain
- Temporary discomfort during prolonged testing

These effects are generally mild and transient.

2.9 Operating principle

The TSDR-3000 Digital Refractor operates by automatically positioning ophthalmic lenses before the patient's eyes during subjective refraction procedures. The examiner adjusts spherical power, cylindrical power, axis, addition power, prism values, and auxiliary lenses while evaluating the patient's responses to visual stimuli presented by a compatible visual acuity chart system. The device enables rapid and precise lens presentation and supports binocular vision examinations through automated lens control and synchronized examination functions.

2.9.1 Mode of action

The device does not act on the human body and does not produce a therapeutic effect. Its mode of action consists of controlled presentation of ophthalmic lenses that alter the optical conditions under which visual stimuli are observed. The examiner evaluates the patient's responses and determines the appropriate refractive correction.

2.9.2 Scientific basis

The operation of the TSDR-3000 is based on internationally recognized principles of subjective refraction and binocular vision assessment used in ophthalmic and optometric practice.

The device supports established clinical examination methods including:

- Subjective refraction using spherical, cylindrical, axis, and addition lens adjustments
- Jackson Cross Cylinder (JCC) testing
- Duochrome (Red/Green) testing
- Binocular balance testing
- Prism and phoria assessment
- Accommodation and vergence testing
- Stereopsis evaluation

These examination methods are widely accepted in clinical ophthalmology and optometry and are used for determination of refractive correction and evaluation of binocular visual function. The examiner determines the final clinical result based on patient responses and professional judgement.



This device shall be operated only by qualified healthcare professionals with appropriate training in visual acuity testing procedures.



Elderly users or those unfamiliar with digital devices may require additional instruction or supervised use to avoid operational errors.



The device is not intended for patient self-testing or layperson use. Any use outside the defined professional user group may compromise patient safety and test reliability.

3 Safety information

	This device is intended for use only in professional healthcare facility environments, such as hospitals, clinics, and optometry offices. Do not use in non-clinical or home environments.
	Do not operate this device in close proximity to active high-frequency (HF) surgical equipment, as excessive electromagnetic interference (EMI) may cause malfunction or incorrect chart display.
	This device must not be used inside or adjacent to the RF shielded room of an ME system for magnetic resonance imaging (MRI). Strong electromagnetic fields in such environments can lead to device failure and potential hazards.
	This device shall be operated only by qualified healthcare professionals with appropriate training in visual acuity testing procedures.
	Elderly users or those unfamiliar with digital devices may require additional instruction or supervised use to avoid operational errors.
	The device is not intended for patient self-testing or layperson use. Any use outside the defined professional user group may compromise patient safety and test reliability.
	Use only power cord specified by the manufacturer. Use of other adapters may cause malfunction or damage.
	Do not install the product using a wall mount bracket not specified by the manufacturer. Improper installation may cause the device to fall, resulting in product damage or personal injury.
	- Request for specialist's help as needed. - Contact manufacturer or authorized local distributor when any problem occurs during installation
	- Never operate the device while installation. - Do not touch the device with wet hands in order to avoid electric shock.
	- Do not use the device if physical damage is observed. - If any damage or missing items are identified, contact the manufacturer or authorized local distributor before use.
	- Ensure that all mounting screws are fully tightened before use. - Improper installation may result in equipment instability or patient injury.

	- Do not use the device if excessive movement or looseness is observed.
	- Ensure that the functional ground connection is securely fastened before operating the device. - Do not apply power to the system until all connectors and grounding connections have been completed. - Improper grounding may result in malfunction or electromagnetic interference.
	- Only compatible devices approved by the manufacturer shall be connected. - Communication settings such as baud rate, parity, stop bits, and data format shall match the requirements of the connected device. - Refer to the communication compatibility list for supported models and interface specifications.
	- Always connect or disconnect the Bluetooth communication module with the power turned OFF. - Connecting the module while power is applied may result in electrical damage or communication malfunction. - Ensure that the retaining screws are securely tightened before operating the system.
	Do not move the Refractor head manually during initialization.
	Do not use the device if any abnormal condition is observed.
	Use the CLEAR and INITIALIZATION functions carefully. Saved patient records are not affected, but unsaved examination data displayed on the current screen may be cleared.
	If the connection fails, verify that the Junction box is powered on and that the selected serial number corresponds to the connected Refractor head.
	Verify that the correct Bluetooth device is selected before establishing the connection.
	Connecting to an unintended Bluetooth device may result in communication failure or improper system operation.

	Verify that the selected Bluetooth device corresponds to the intended printer.
	Communication may be interrupted by distance, obstacles, or electromagnetic interference.
	Bluetooth communication may be interrupted by distance, obstacles, or electromagnetic interference.
	Always verify proper communication before starting an examination.
	The examiner is responsible for verifying the accuracy and suitability of all loaded or manually entered data before applying them during an examination.
	The Near Vision Chart is intended to assist qualified eye care professionals during near vision examinations. The examiner is responsible for selecting the appropriate examination distance and chart type.
	Lens cleaning should only be performed by qualified personnel.
	Do not use excessive force when cleaning optical components.
	Use only approved lens cleaning materials and procedures.
	Deleted custom chart items cannot be recovered unless a backup copy is available.
	Changes are not stored until the Save button is pressed.
	Deleted examination steps cannot be recovered unless a backup copy is available.
	Incorrect PD settings may induce unwanted prism effects and may affect the accuracy of the examination results.
	The Near Point Illuminator flashes when the patient's forehead is temporarily separated from the forehead rest. This indication alerts the examiner that the patient's head position may have changed. For accurate examination results, ensure that the patient's forehead remains in contact with the forehead rest throughout the examination.

	Do not apply excessive force when adjusting the forehead rest. Excessive pressure may cause patient discomfort and may affect examination accuracy.
	Do not clean the device while power is applied.
	Do not allow liquids to enter any openings or connectors.
	Do not use excessive force during cleaning.
	Never use organic solvents such as thinner, benzene, acetone, or alcohol-based industrial cleaners.
	Do not spray liquids directly onto the device.
	Scratches or contamination of optical surfaces may affect examination performance.
	Cleaning and disinfection shall be performed after each patient to reduce the risk of cross-contamination.
	Do not spray liquid directly onto the device.
	Do not allow cleaning fluids to enter the interior of the instrument.
	Do not use abrasive cleaners or solvents that may damage plastic surfaces.
	Repeated use of disinfectants other than 70% isopropyl alcohol may discolor or damage plastic components.
	Do not use the device if any mechanical damage is observed.
	Do not use damaged power cords or adapters.
	Contaminated optical surfaces should be cleaned before use.
	Disconnect the power cord from the AC outlet before replacing the fuse.

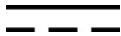
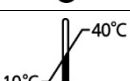
	Replace the fuse only with a fuse of the specified type and rating.
	Use of an incorrect fuse may result in fire, electric shock, or equipment damage.
	If the replacement fuse fails repeatedly, discontinue use and contact qualified service personnel.
	Improper packaging may result in damage to optical, mechanical, or electronic components.
	Condensation inside the device may result in malfunction or electrical hazards.
	Do not power ON the device until all condensation has completely evaporated.

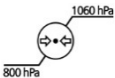
3.1 Reporting of Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is located.

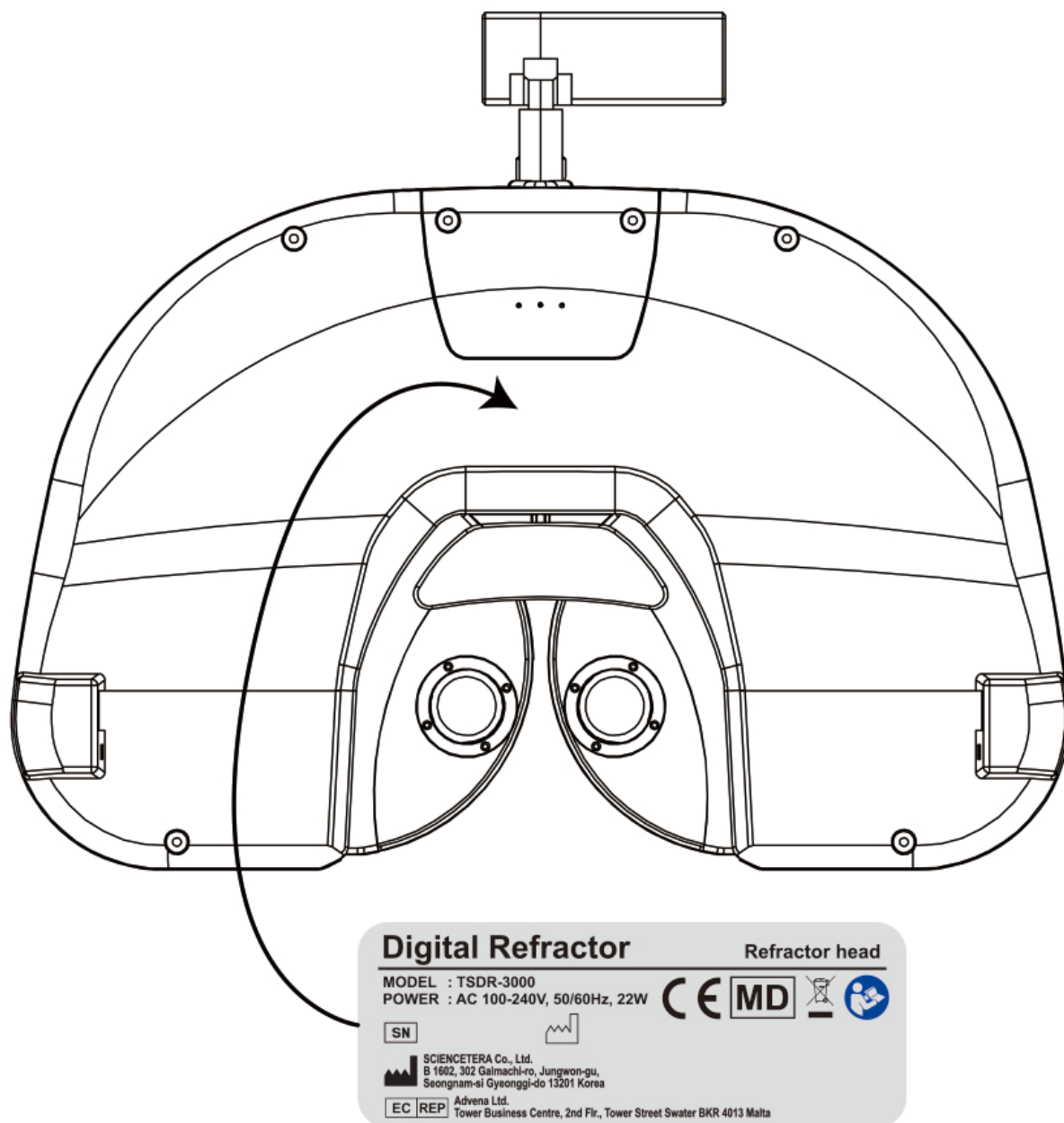
4 Labels and symbols

To call attention to operators, some labels and indications are provided on the device. If labels are curling up or characters are fading and becoming barely legible, contact manufacturer or authorized local distributor.

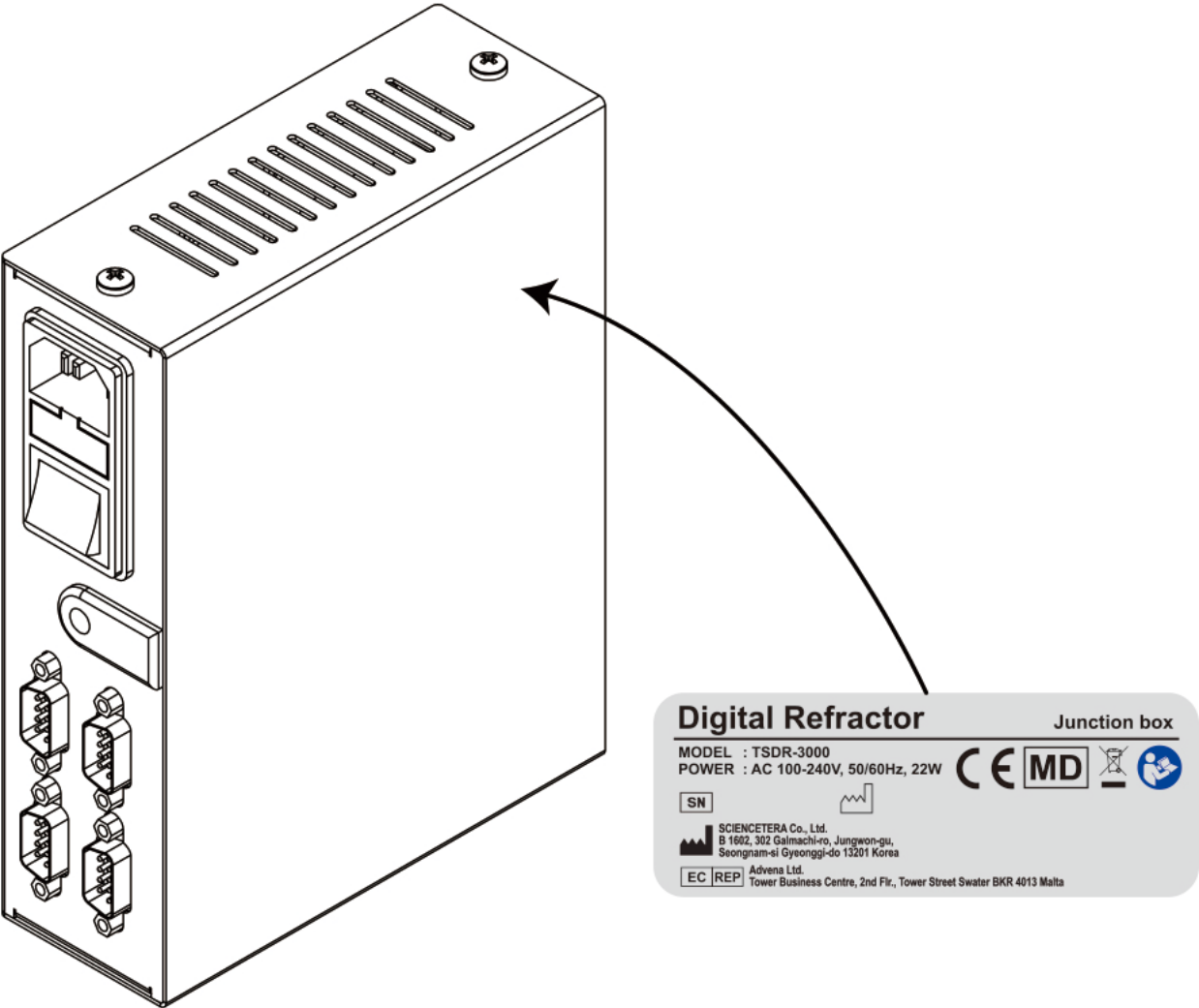
Symbols	Description	Reference
	CE Marking of Conformity	Regulation (EU) 2017/745 Annex V
	Medical Device	Regulation (EU) 2017/745 Article 2 (1)
	Authorised Representative in the European Community	Regulation (EU) 2017/745 Article 11
	Operating instructions	ISO 7000:2019-1641
	Caution	ISO 7000:2019-0434A
	General prohibition sign and template for constructing a prohibition sign	ISO 7010:2019-P001
	Direct current	IEC 60417:2025-5031
	Alternating current	IEC 60417:2025-5032
	Refer to instruction manual/ booklet	ISO 7010:2019-M002
	Date of manufacture	ISO 7000:2019-2497
	Manufacturer	ISO 7000:2019-3082
	Serial number	ISO 7000:2019-2498
	Keep away from rain	ISO 7000:2019-0626
	Use no hook	ISO 7000:2019-0622
	Temperature limit	ISO 7000:2019-0632
	Humidity limitation	ISO 7000:2019-2620

	Atmospheric pressure limitation	ISO 7000:2019-2621
	Waste electrical and electronic equipment	Directive 2012/19/EU ANNEX IX

4.1 Refractor head



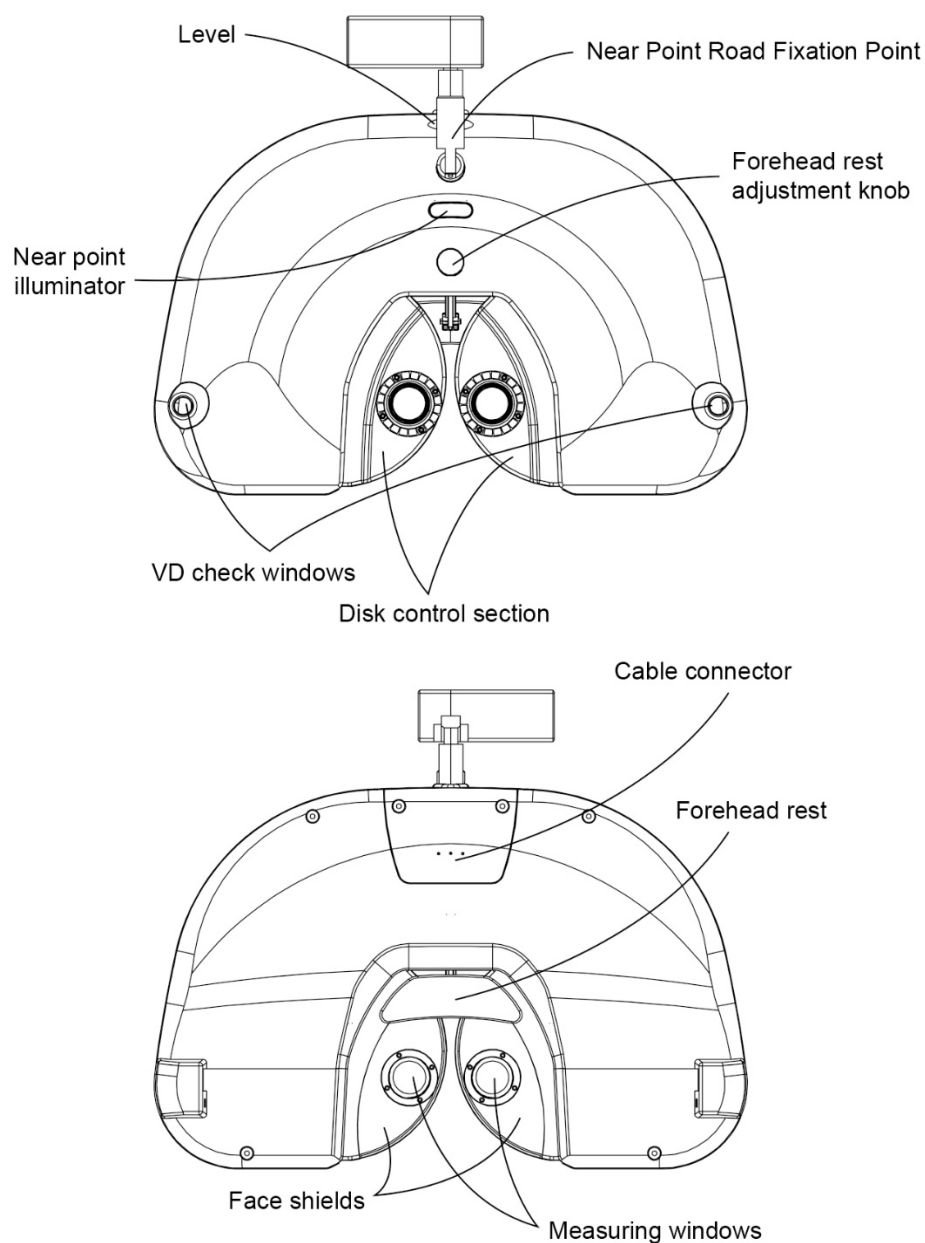
4.2 Junction box



5 Device description

5.1 Refractor head

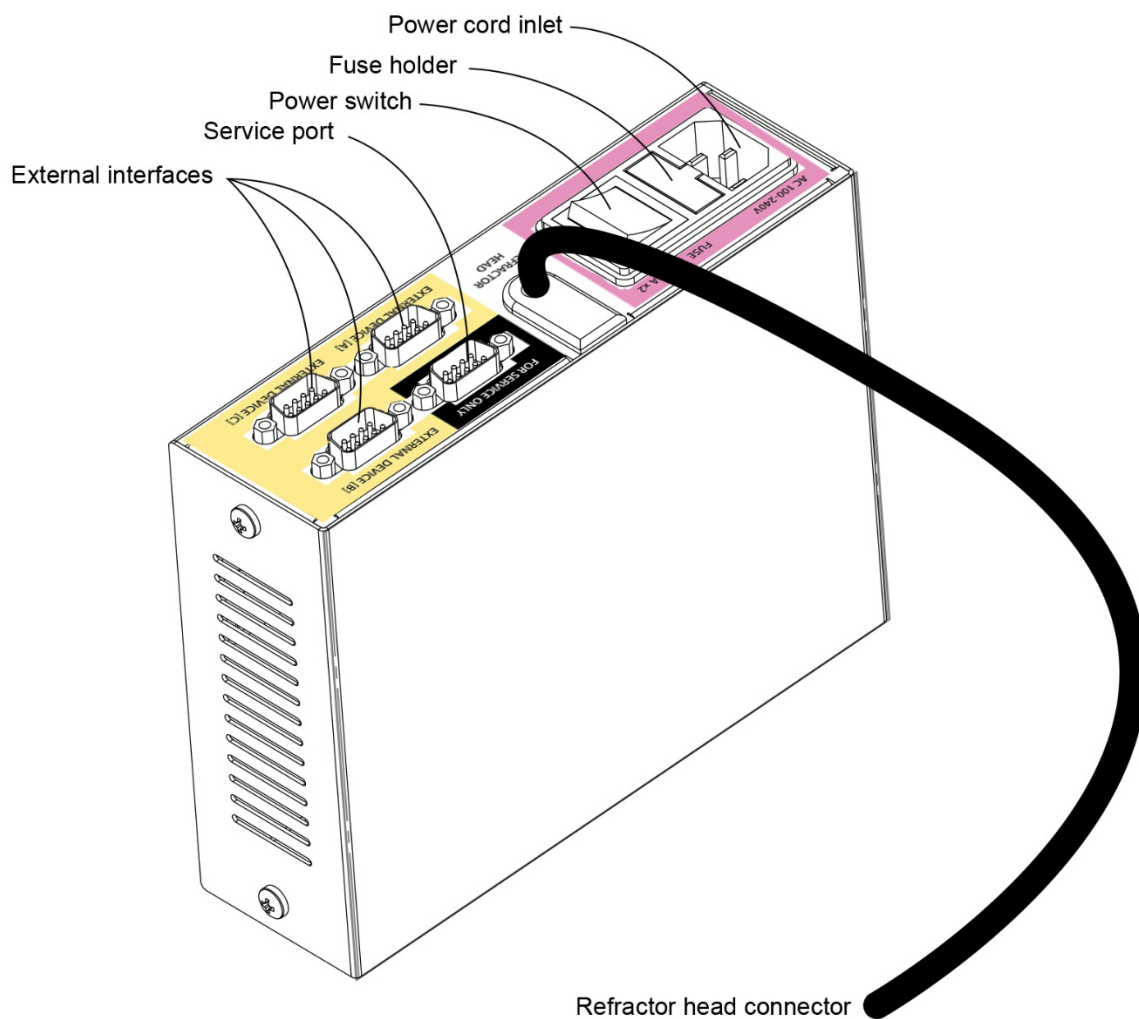
The Refractor head is the primary examination component of the TSDR-3000 system. It automatically positions ophthalmic lenses before the patient's eyes during subjective refraction and binocular vision examinations. The device incorporates spherical, cylindrical, prism, auxiliary, and binocular vision testing lenses that are automatically controlled through the tablet application.



Description	Function
Level	Used to verify that the refractor head is level.
Near Point Rod Fixation Point	Attachment point for the near vision rod.
Forehead rest adjustment knob	Used to adjust vertex distance (VD).
Near point illuminator	Provides illumination for near vision testing.
VD check windows	Used to verify vertex distance between the cornea and lens plane.
Disk control part	Controls lens disks and lens positioning.
Cable connector part	Connection point for communication and power.
Forehead rest	Stabilizes patient position during examination.
Face shields	Assist proper patient alignment and positioning.
Measuring windows	Viewing apertures through which the patient observes visual targets.

NOTE	The forehead rest and face shields are intended for temporary contact with intact skin only (< 24 h). No contact with breached skin, mucosal membranes, or sterile body areas is intended.
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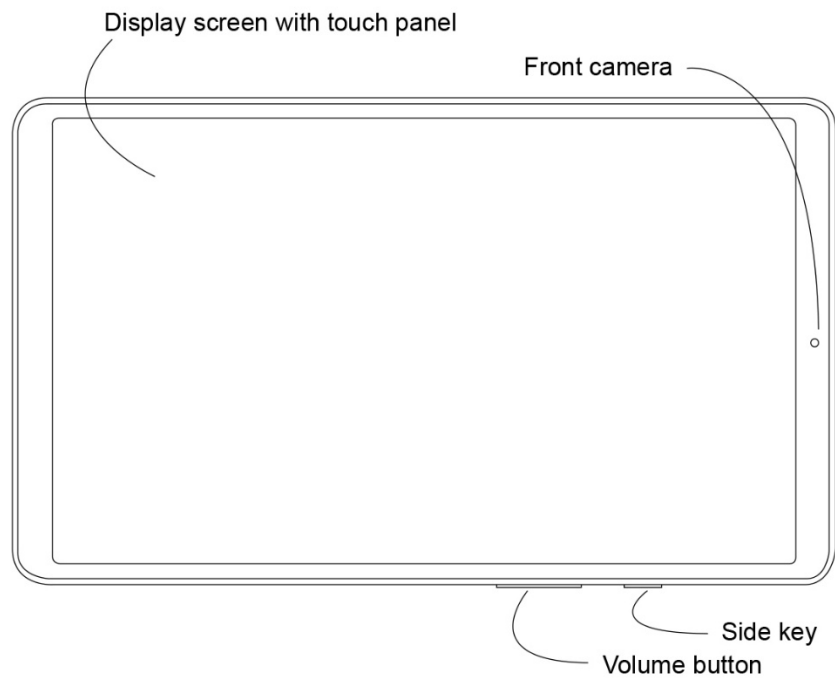
5.2 Junction box



Description	Function
Power cord inlet	Connection for AC power.
Fuse holder	Provides over-current protection.
Power switch	Turns system power ON and OFF.
Service port	Used for service and maintenance activities.
External interfaces	Communication ports for external devices.
Refractor head connector	Connection to the refractor head.

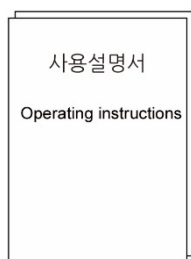
5.3 Tablet controller

The Tablet Controller provides the primary user interface for operation of the TSDR-3000 system. The tablet application allows control of lens positioning, examination procedures, patient records, binocular vision tests, communication settings, and print functions.



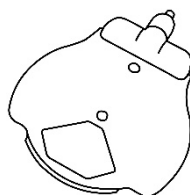
Description	Function
Display Screen with Touch Panel	Displays examination data and allows user interaction with the TSDR-3000 application.
Front Camera	Built-in camera of the tablet device. Not required for normal operation of the TSDR-3000.
Side Key	Tablet control key used for screen activation and system functions.
Volume Button	Tablet control button used for volume adjustment and operating system functions.

5.4 Accessories



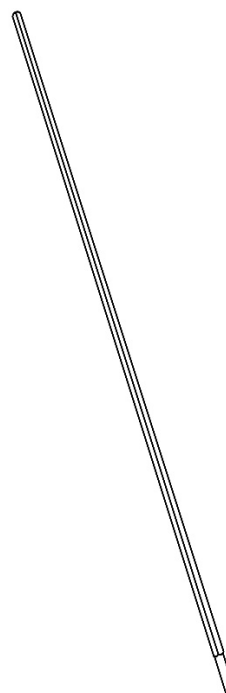
Operating instructions

UM-102



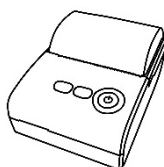
Near Chart

D1-P01



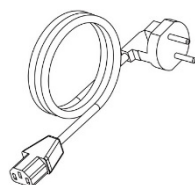
Near Point Rod

D1-P02



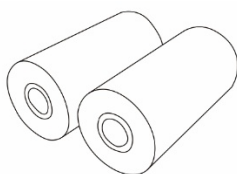
External thermal printer

D1-E01



Power cord

KKP/30/KKS-16A



Roll papers

D1-E02



Dust cover

D1-E03

NOTE	The Operating instructions are provided in English or Korean as standard. For other languages, please contact your local distributor upon request.
NOTE	According to International Civil Aviation Organization – ICAO and IATA Dangerous Good Regulations – DGR, the transport of batteries may be restricted or prohibited on certain airlines or in specific countries. Therefore, some accessories of this product may be shipped without batteries included.
	Use only power cord specified by the manufacturer. Use of other adapters may cause malfunction or damage.
	Do not install the product using a wall mount bracket not specified by the manufacturer. Improper installation may cause the device to fall, resulting in product damage or personal injury.

6 Installation and setup

	- Request for specialist's help as needed. - Contact manufacturer or authorized local distributor when any problem occurs during installation
	- Never operate the device while installation. - Do not touch the device with wet hands in order to avoid electric shock.

6.1 Unpacking and inspection

Upon receipt of the device, inspect the packaging and contents for signs of damages. Verify that all components and accessories listed in section 5.

	- Do not use the device if physical damage is observed. - If any damage or missing items are identified, contact the manufacturer or authorized local distributor before use.
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6.2 Installation requirements

The TSDR-3000 is intended to be installed on a compatible ophthalmic unit equipped with a refractor arm.

Before installation, verify that:

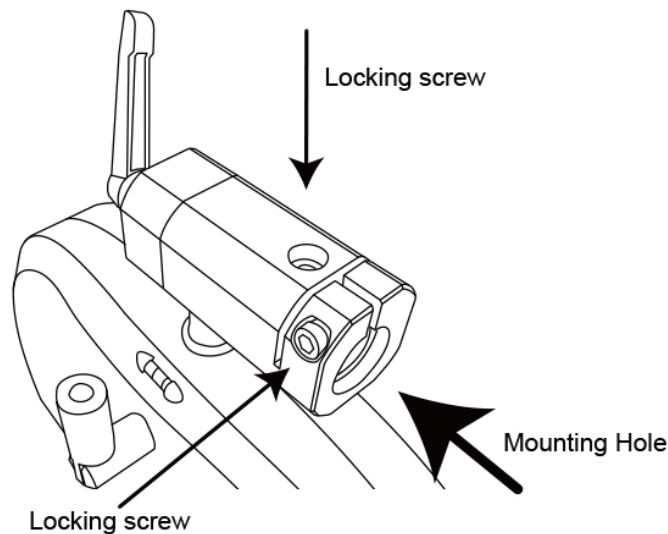
- The ophthalmic unit is stable and properly assembled.
- The refractor arm is suitable for the weight and dimensions of the TSDR-3000.
- The installation area provides sufficient space for examination and operator access.
- The environmental conditions comply with section 2.2.

Installation shall be performed by qualified service personnel or trained personnel.

6.3 Mounting the Refractor head

The refractor head shall be mounted securely onto the refractor arm of the ophthalmic unit.

- (1) Position the refractor arm in its installation position.
- (2) Insert the mounting shaft of the refractor arm fully into the mounting hole of the refractor head.
- (3) Adjust the orientation of the refractor head as required.
- (4) Secure the assembly by tightening the locking screws as below.



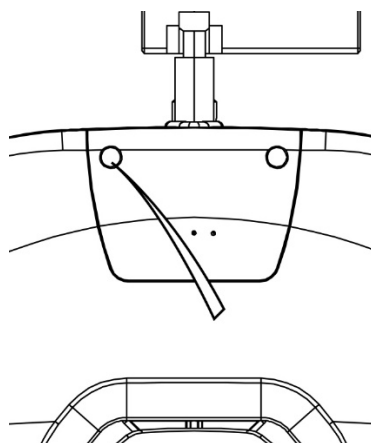
- (5) Verify that the Refractor head is firmly attached.
- (6) Move the refractor arm through its full operating range and confirm smooth movement.



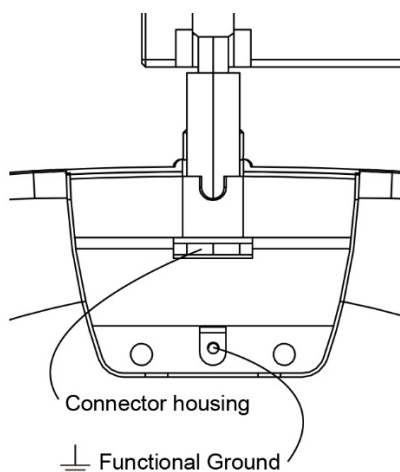
- Ensure that all mounting screws are fully tightened before use.
- Improper installation may result in equipment instability or patient injury.
- Do not use the device if excessive movement or looseness is observed.

6.4 Connecting the Refractor head

- (1) Place the Junction box in a safe location where accidental contact by the patient or operator is unlikely.
- (2) Remove the rubber cap from the cable connection compartment of the Refractor head using a suitable pointed tool.



- (3) Remove the two fixing screws located beneath the rubber cap and remove the cable connection compartment cover.
- (4) Connect the Refractor head connector from the Junction box to the connector inside the cable connection compartment as show below.



- (5) Securely attach the circular ground terminal (functional ground) of the Refractor head connector to the functional ground point using the supplied screw.
- (6) Verify that both the connector and grounding terminal are securely fastened. Reinstall the cable connection compartment cover, tighten the two fixing screws, and close the rubber cap properly.



- Ensure that the functional ground connection is securely fastened before operating the device.
- Do not apply power to the system until all connectors and grounding connections have been completed.
- Improper grounding may result in malfunction or electromagnetic interference.

6.5 Connection to External Ophthalmic Devices (Optional)

The TSDR-3000 may be connected to compatible ophthalmic devices capable of transmitting examination data through a supported communication interface. Examples of compatible devices include:

- Auto Refractometers
- Auto Lensmeters
- Auto Refkeratometers
- Other compatible ophthalmic instruments

- (1) Turn off the power of both devices before making any connections.
- (2) Connect a D-Sub 9-pin communication cable to one of the External Interface ports on the Junction box.
- (3) Connect the opposite end of the cable to the communication port of the external device.
- (4) Secure the connectors by tightening the retaining screws on both sides of the D-Sub connector.
- (5) Turn on both devices.
- (6) Verify that communication is established and that examination data can be transferred correctly.

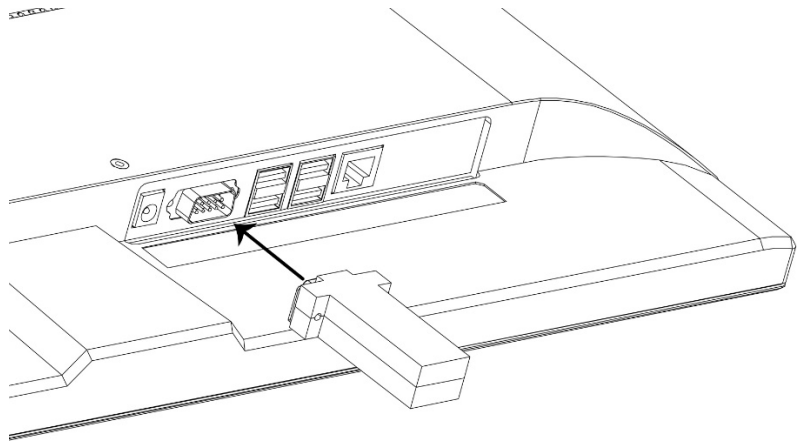


- Only compatible devices approved by the manufacturer shall be connected.
- Communication settings such as baud rate, parity, stop bits, and data format shall match the requirements of the connected device.
- Refer to the communication compatibility list for supported models and interface specifications.

6.6 Connection to Visual Acuity Chart System (Optional)

The TSDR-3000 may communicate with a compatible Visual Acuity Chart System through a Bluetooth communication module.

- (1) Ensure that the Visual Acuity Chart System is powered OFF.
- (2) Insert the Bluetooth communication module into the RS-232C port of the Visual Acuity Chart System.



- (3) Secure the Bluetooth communication module by tightening the retaining screws on both sides of the module.
- (4) Verify that the module is firmly attached and cannot be loosened unintentionally.
- (5) Turn on the Visual Acuity Chart System.
- (6) Establish Bluetooth communication according to the instructions provided in the TSDR-3000 application.

	- Always connect or disconnect the Bluetooth communication module with the power turned OFF. - Connecting the module while power is applied may result in electrical damage or communication malfunction. - Ensure that the retaining screws are securely tightened before operating the system.
NOTE	- Use only Bluetooth communication modules supplied or approved by the manufacturer. - Compatibility may vary depending on the model and software version of the connected Visual Acuity Chart System.

6.7 Bluetooth configuration

The TSDR-3000 uses Bluetooth communication between Tablet controller, Refractor head, and optional peripheral devices. Bluetooth configuration is normally required during initial installation, after replacement of the tablet controller, or when connecting a new peripheral device.

Device	Function
Refractor head	Control and communication with the TSDR-3000
Visual Acuity Chart System (Optional)	Remote chart control
Auto Lensmeter (Optional)	Receiving refractive data
External printer (Optional)	Printing examination results

NOTE

Bluetooth communication performance may be affected by electromagnetic interference from nearby equipment, wireless transmitters, or other radio-frequency sources. If communication becomes unstable, reduce the distance to the connected device, remove potential sources of interference, and verify proper operation before continuing use.

6.8 Initial system start-up

After all electrical and communication connections have been completed:

- (1) Turn on the Junction box.
- (2) Turn on the Tablet controller. The TSDR-3000 application is launched automatically.
- (3) Verify the Bluetooth communication with the Refractor head is established.
- (4) Confirm that no communication errors are displayed.

6.9 System initialization

When communication has been established successfully, the TSDR-3000 performs an automatic initialization procedure.

During initialization:

- Lens disks are moved to their reference positions.
- Internal position sensors are checked.
- Communication status is verified.

Wait until initialization has been completed before starting an examination.



Do not move the Refractor head manually during initialization.

6.10 Functional verification

Before first use, verify that:

- The Refractor head is securely mounted on the refractor arm.
- The locking screw is tightened securely.
- All connectors are properly connected.
- Functional grounding is connected correctly.
- Bluetooth communication is operating normally.
- Lens movement is smooth and normal.
- No abnormal noise, vibration, or error message is present.

If any abnormality is detected, discontinue use and contact qualified service personnel.

6.11 Daily start-up check

Before examining patients each day:

- Verify secure mounting of the Refractor head.
- Verify normal communication between system components.
- Verify normal operation of lens controls.
- Verify correct operation of connected peripheral devices, if used.



Do not use the device if any abnormal condition is observed.

7 Operation

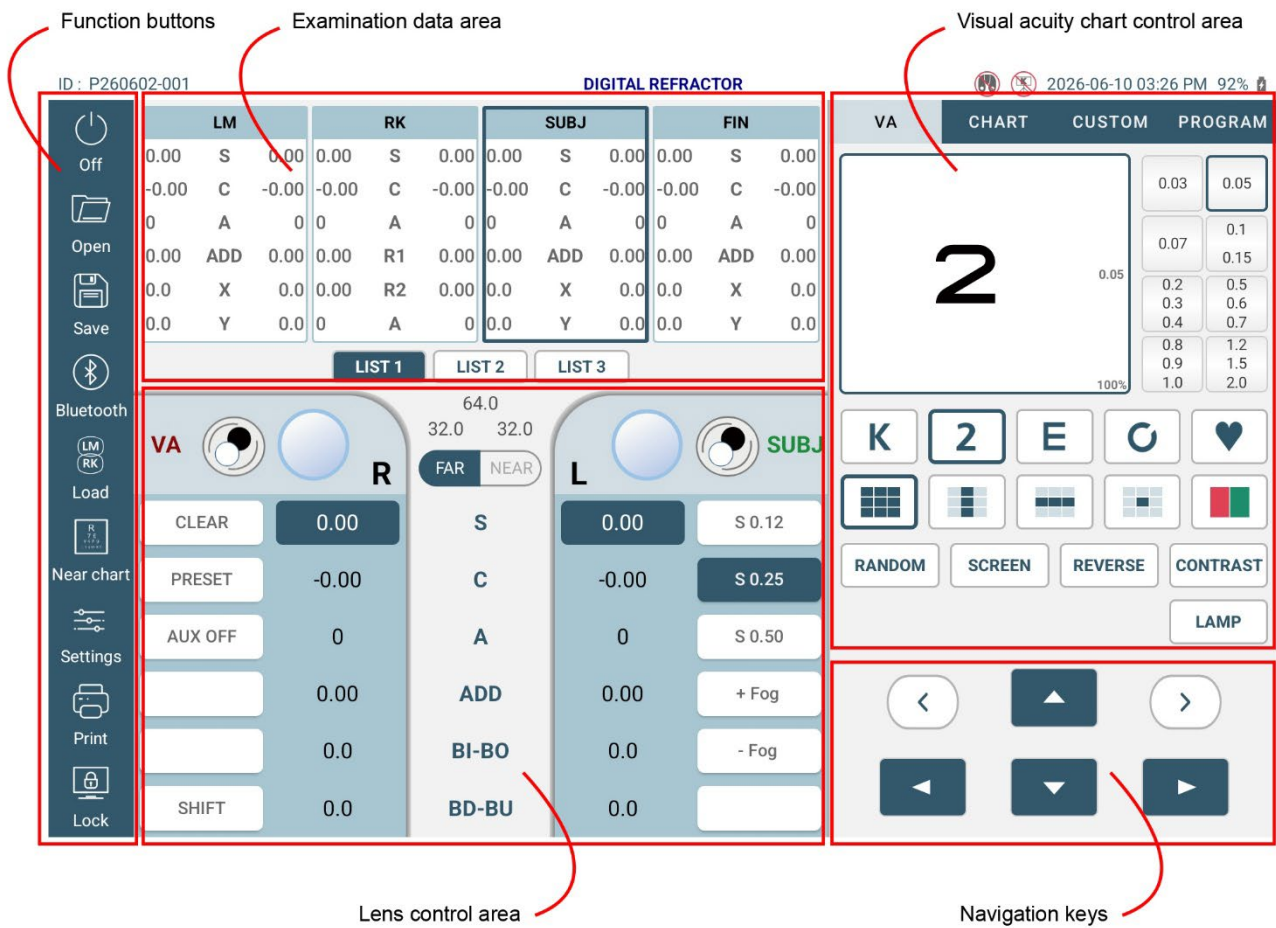
7.1 Starting the Application

7.1.1 Powering on the system

- (1) Turn on the Junction box.
- (2) Turn on the Tablet controller. The TSDR-3000 application is launched automatically.
- (3) Wait until communication with the Refractor head is established.
- (4) Verify that no error messages are displayed.

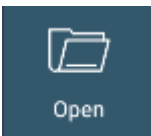
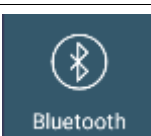
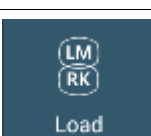
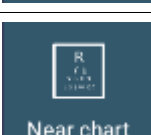
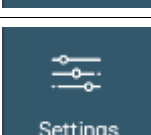
7.1.2 Main screen

After start-up, the main screen is displayed.



7.1.2.1 Function buttons

The Function buttons provide access to frequently used system functions and settings.

Button	Function
	Exits the TSDR-3000 application.
	Opens an existing patient record or creates a new patient record.
	Saves the current examination results to the patient database.
	Opens the Bluetooth configuration menu for communication with the Refractor head and optional peripheral devices.
	Loads measurement data received from compatible external ophthalmic devices.
	Opens the Near Vision Chart for near vision examinations.
	Opens the system configuration menu.
	Prints examination results using a connected printer.
	Temporarily disables touchscreen operation to prevent unintended input.

NOTE

Some functions may require optional accessories or compatible external devices to be connected before use.

7.1.2.2 Examination data area

The Examination data area displays patient examination data and allows comparison of measurements obtained from different examination methods. The displayed data are organized into three lists.

LIST 1 – Refraction data

LIST 1 displays refractive data obtained during the examination process.

LM			RK			SUBJ			FIN		
0.00	S	0.00	0.00	S	0.00	0.00	S	0.00	0.00	S	0.00
-0.00	C	-0.00	-0.00	C	-0.00	-0.00	C	-0.00	-0.00	C	-0.00
0	A	0	0	A	0	0	A	0	0	A	0
0.00	ADD	0.00	0.00	R1	0.00	0.00	ADD	0.00	0.00	ADD	0.00
0.0	X	0.0	0.00	R2	0.00	0.0	X	0.0	0.0	X	0.0
0.0	Y	0.0	0	A	0	0.0	Y	0.0	0.0	Y	0.0
LIST 1LIST 2LIST 3											

Category	Description
LM	Refractive data imported from a compatible lensmeter.
RK	Objective refractive data imported from a compatible auto refractometer or auto refractor-keratometer.
SUBJ	Refractive data obtained through subjective refraction performed using the TSDR-3000.
FIN	Final refractive values selected by the examiner for prescription purposes.

The examiner may compare the displayed data to evaluate differences between objective measurements, subjective findings, and the final prescription.

Any displayed data set may be selected and temporarily applied to the Refractor head. This function allows rapid comparison of lens values obtained from different examination methods during the refraction procedure.

LIST 2 – Binocular vision data

LIST 2 displays results obtained from binocular vision and accommodation examinations.

FAR		BLUR	BREAK	RECOVERY	Dominant Eye : NONE NPC : NPA BIN : R : L : Fusion : Stereo : Min.Stereo :
NRC		0.0	0.0	0.0	
PRC		0.0	0.0	0.0	
SUPRA			0.0	0.0	
INFRA			0.0	0.0	
NRA	R	0.00		0.00	
	OU	0.00		0.00	
	L	0.00		0.00	
PRA	R	0.00		0.00	
	OU	0.00		0.00	
	L	0.00		0.00	

LIST 1
LIST 2
LIST 3

Depending on the examination performed, the displayed information may include:

- Near Point of Convergence (NPC)
- Positive Relative Accommodation (PRA)
- Negative Relative Accommodation (NRA)
- Fusional Vergence Measurements
- Accommodation and Vergence rest results

LIST 3 – Prism and special test data

LIST 3 displays prism values and results obtained during special binocular vision examinations.

FAR	X Δ		Y Δ	
	R	L	R	L
Schober	0.0	0.0	0.0	0.0
Coincidence	0.0	0.0	0.0	0.0
Maddox, Rod	0.0	0.0	0.0	0.0
Phoria	0.0	0.0	0.0	0.0
Von Graefe	0.0	0.0	0.0	0.0
Phoria with Fixation	0.0	0.0	0.0	0.0

LIST 1

LIST 2

LIST 3

The displayed information may include results from:

- Maddox Rod test
- Von Graefe test
- Schober test
- Coincidence test
- Phoria measurements

These values assist the examiner in evaluating binocular vision status and determining appropriate prism correction when required.

NOTE	The available data fields may vary depending on the examination performed and the connected external devices.
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7.1.2.3 Lens control area

The Lens control area is used to control the optical configuration of the Refractor head during subjective refraction and binocular vision examinations.

Refractive lens adjustment

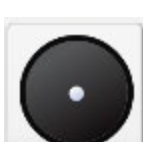
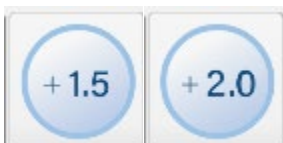
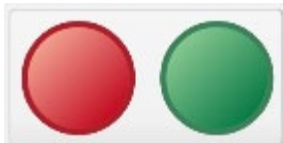
The following refractive parameters may be adjusted:

Parameter	Description
S (Sphere)	Adjusts spherical lens power.
C (Cylinder)	Adjusts cylindrical lens power.
A (Axis)	Adjusts cylinder axis orientation.
ADD	Adjusts near addition power.
BI-BO	Adjusts horizontal prism power.
BD-BU	Adjusts vertical prism power.

The current values are displayed separately for the right eye (R) and left eye (L).

Auxiliary lens control

Auxiliary lenses may be inserted into or removed from the optical path as required for specific examination procedures.

Auxiliary lens	Applied to	Description
	R / L	[Open aperture] No auxiliary lens is inserted in the optical path.
	R / L	[Occluder] Blocks vision in the selected eye during monocular examinations.
	R / L	[Pinhole lens] Reduces the effect of refractive error and assists in visual acuity assessment.
	R: Horizontal L: Vertical	[Maddox rod] Converts a point light source into a line image for evaluation of ocular deviation and phoria.
	R / L	[Retinoscopy lens] Used during retinoscopy procedures to compensate for the examiner's working distance.
	R / L	[Cross cylinder lens] Used for refinement of cylinder power and axis during subjective refraction.
	R: 45° / L: 135° and R: 135° / L: 45°	[Polarizing filter] Used for binocular vision and stereopsis examinations requiring polarized separation of images.
	R: Red / L: Green	[Red / Green filter] Used for binocular balance and dissociation tests.

	R / L	[PD verification lens] Assists in verification of patient alignment and pupillary distance settings.
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Pupillary Distance controls

Used to adjust the interpupillary distance (PD) according to the patient's anatomical characteristics and examination requirements. Separate right and left PD values may be displayed and adjusted.

Examination distance controls

Used to select the examination distance.

Button	Description
FAR	Distance examination mode
NEAR	Near examination mode

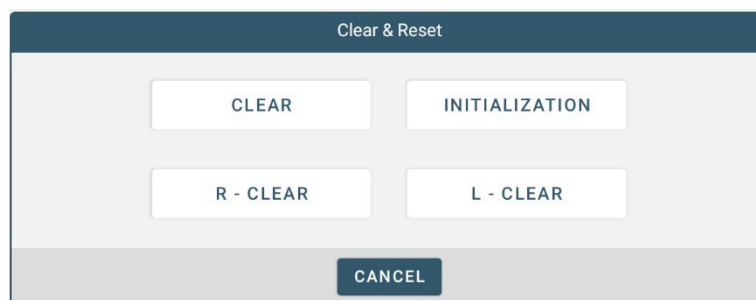
When Near mode is selected, the system automatically applies the near examination configuration.

Lens control functions

Function	Description
CLEAR ¹⁾	Opens the Clear & Reset menu. The examiner may clear all measurement data, initialize all lenses, or clear data for the right or left eye only.
PRESET	Temporarily holds lens changes without immediately applying them to the Refractor head. When released, the prepared lens values are applied simultaneously.
AUX OFF	Temporarily removes auxiliary lenses from the optical path. When deactivated, the previously selected auxiliary lenses are restored.
SHIFT	Increases the adjustment step for selected lens parameters to allow faster changes.
Step and Fog ²⁾	provides step buttons for changing the adjustment increment during lens operation.

CLEAR Function ¹⁾

When the CLEAR button is touched and held, the Clear & Reset menu is displayed.



Button	Function
CLEAR ¹⁾	Opens the Clear & Reset menu. The examiner may clear all measurement data, initialize all lenses, or clear data for the right or left eye only.
INITIALIZATION	Clears measurement data and performs lens initialization for both eyes.
R-CLEAR	Clears measurement data for the right eye only.
L-CLEAR	Clears measurement data for the left eye only.
CANCEL	Closes the Clear & Reset menu without applying changes.



Use the CLEAR and INITIALIZATION functions carefully. Saved patient records are not affected, but unsaved examination data displayed on the current screen may be cleared.

Step and Fog Controls ²⁾

The Lens Control Area provides step buttons for changing the adjustment increment during lens operation.

Button	Description
S 0.12	Sets the sphere adjustment step to 0.12 D.
S 0.25	Sets the sphere adjustment step to 0.25 D.
S 0.50	Sets the sphere adjustment step to 0.50 D.
S 1.00	Sets the sphere adjustment step to 1.00 D. (It shows when SHIFT activates)
S 2.00	Sets the sphere adjustment step to 2.00 D. (It shows when SHIFT activates)
+ Fog	Adds plus power for fogging during subjective refraction or binocular balance procedures.
- Fog	Reduces fogging power or removes previously applied fogging power.

The available step values may vary depending on system settings.

NOTE	Detailed procedures for lens adjustment, auxiliary lens selection, PD adjustment, prism adjustment, and examination distance selection are described in section 8.
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7.1.2.4 Visual acuity chart control area

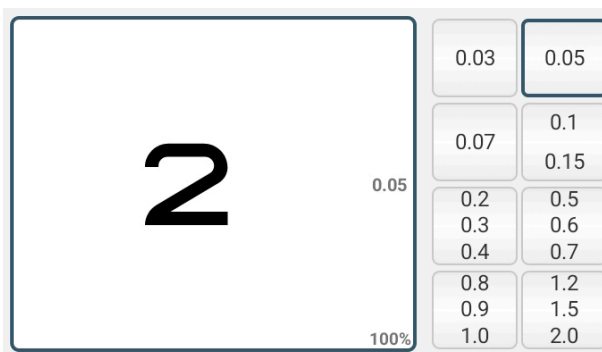
The visual acuity chart control area is used to control the connected Visual Acuity Chart System during refraction and binocular vision examinations. This area allows the examiner to select visual acuity charts, special examination charts, custom charts examination programs, chart presentation modes, and chart display settings.

Chart categories

Function	Description
VA	Displays standard visual acuity charts used for subjective refraction examinations.
CHART	Displays special examination charts used for binocular vision and visual function testing.
CUSTOM	Displays user-defined charts configured by the examiner.
PROGRAM	Executes predefined examination sequences stored in the system.

Visual acuity selection

The visual acuity buttons are used to directly select the optotype size displayed on the connected Visual Acuity Chart System. Available visual acuity levels may vary according to chart type and examination configuration.



Optotype selection

Button	Description
	Letters (Alphabet Optotypes)
	Number Optotypes
	Tumbling E Optotypes
	Landolt Ring Optotypes
	Pediatric Optotypes

Masking controls

Masking functions may be applied during monocular visual acuity examinations. Available masking modes may include:

- Vertical mask
- Horizontal mask
- Single Optotype mask
- Isolation mask

The available masking patterns depend on the connected Visual Acuity Chart System.

Display controls

Function	Description
RANDOM	Randomizes the optotype sequence to reduce memorization effects.
SCREEN	Changes the chart presentation or masking mode.
REVERSE	Reverses the display orientation of the chart.
CONTRAST	Adjusts chart contrast for contrast sensitivity examinations.
LAMP	Controls chart illumination or near-vision illumination when supported by the connected system.

NOTE	Available chart types and functions may vary depending on the connected Visual Acuity Chart System and software version. Detailed procedures for visual acuity testing and special examination charts are provided in section 9.
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7.1.2.5 Navigation keys

The Navigation Keys are used to navigate examination charts, control program sequences, and adjust the position of selected test targets. The available functions depend on the currently selected examination mode.

Button	Description
	Moves the selected target or chart position upward.
	Moves the selected target or chart position downward.
	Moves the selected target or chart position to the left.
	Moves the selected target or chart position to the right.
	Returns to the previous chart, program step, or test position.
	Advances to the next chart, program step, or test position.

The Navigation keys may also be used during special examinations such as binocular vision tests, stereopsis tests, and custom examination programs.

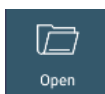
NOTE	The function of each Navigation key may vary depending on the active chart, examination mode, or program configuration.
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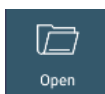
7.2 Patient management

The TSDR-3000 allows patient information and examination results to be stored, retrieved, and managed through the patient database. Patient records may be created before an examination and updated after completion of the examination.

7.2.1 Creating a new patient record

To create a new patient record:



(1) Touch  button.

(2) Touch the NEW button.

ID	Name	Phone number	Age	Gender	Test date
P260609-001					

(3) Enter the required patient information.

Patient Information

ID

P260610-001

Name

Age

Phone number

Gender

MALE

FEMALE

SAVE

CANCEL

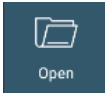
(4) Confirm the entered information.

(5) Save the patient record.

7.2.2 Opening an Existing Patient Record

Previously stored patient records may be retrieved from the database.

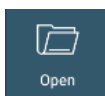
To open an existing patient record:

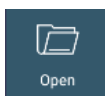


- (1) Touch button.
- (2) Search for the desired patient record.
- (3) Select the patient from the displayed list by OPEN button.
- (4) Confirm that the patient information is displayed correctly.

7.2.3 Modifying Patient Information

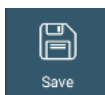
Patient information may be edited when necessary.

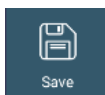


- (1) Touch  button.
- (2) Search for the desired patient record.
- (3) Select the patient from the displayed list by EDIT button.
- (4) Confirm that the patient information is displayed correctly.

7.2.4 Saving Examination Results

After completing the examination:



- (1) Touch  button.
- (2) Verify the displayed examination results.
- (3) Confirm the save operation.

The examination results are stored in the patient database and may be retrieved later.

NOTE

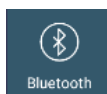
The availability of patient information fields may vary depending on software version and regional requirements.

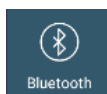
7.3 Bluetooth configuration

The TSDR-3000 uses Bluetooth communication to connect the Tablet Controller with the Refractor head and optional peripheral devices. Bluetooth configuration is normally required during initial installation, after replacement of the tablet controller, or when connecting a new peripheral device.

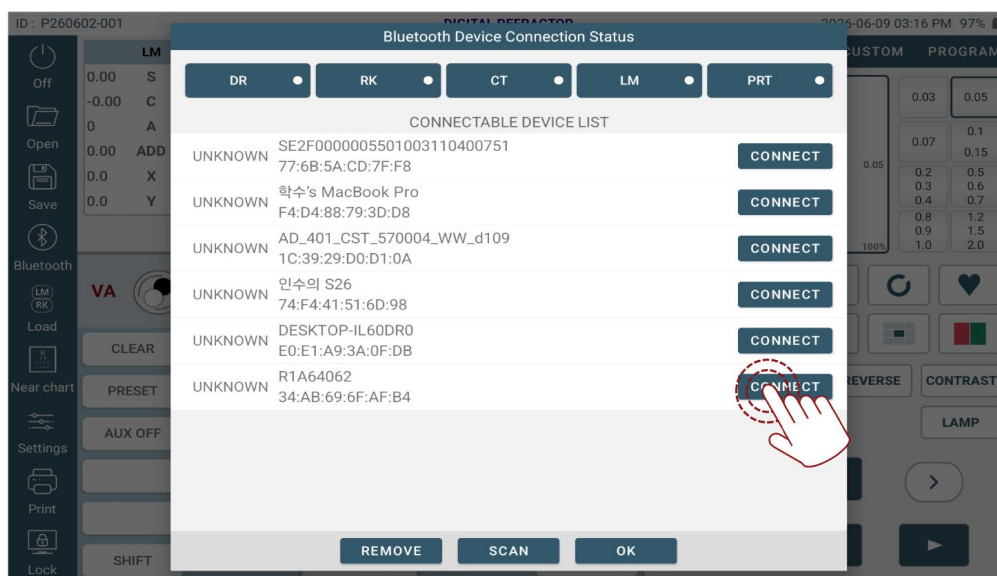
7.3.1 Opening the Bluetooth menu

To Open the Bluetooth configuration menu:



(1) Touch  button on the function buttons.

(2) The Bluetooth configuration window is displayed.



(3) Select the device type to be configured.

Available device types may include:

- Refractor head
- Visual Acuity Chart System
- External printer

Additional device type such as Auto Refractometer and Auto Lensmeter may become available in future software releases. Available depends on software version and system configuration.

7.3.2 Connecting the Refractor head

The Refractor head must be connected before the TSDR-3000 can be operated.

To connect the Refractor head:

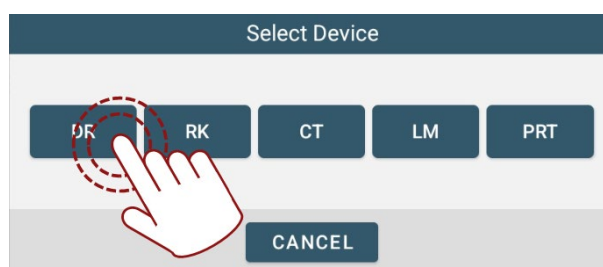
- (1) Turn on the Junction box.



- (2) Touch  to open the Bluetooth configuration menu.

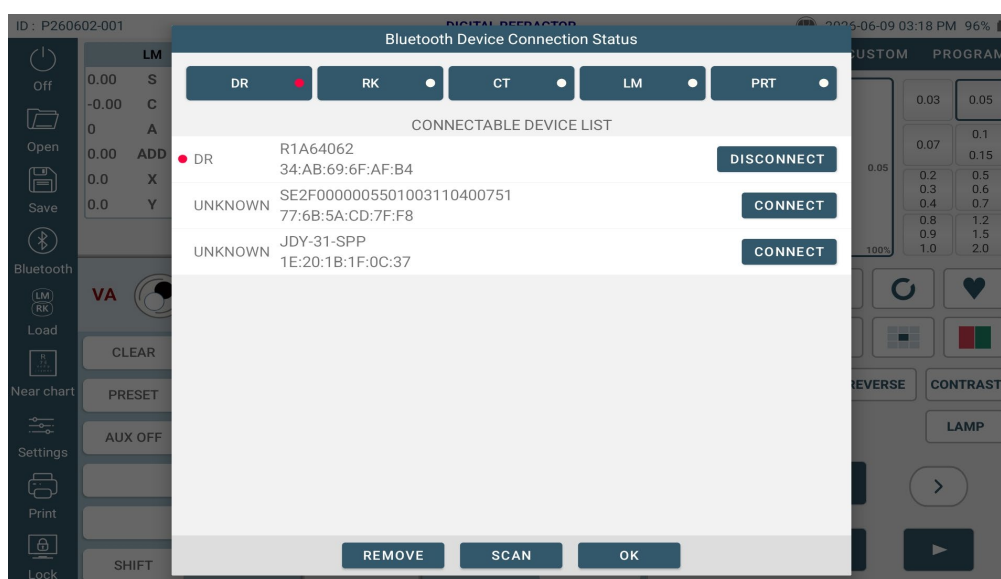
- (3) Select the device corresponding to the serial number of the Refractor head and touch CONNECT button.

- (4) When the Selected Device window appears, select DR.



- (5) When the Bluetooth pairing request window is displayed, enter the PIN code 1234 and confirm the pairing request.

- (6) When a red indicator is displayed on the DR button as shown below, the connection has been established successfully.



- (7) Touch OK button to complete the procedure.

NOTE	The serial number of the Refractor head is displayed on the product label attached to the device.
	If the connection fails, verify that the Junction box is powered on and that the selected serial number corresponds to the connected Refractor head.

7.3.3 Connecting a Visual Acuity Chart System (Optional)

A compatible Visual Acuity Chart System may be connected to the TSDR-3000 to allow remote control during examinations. Before attempting to connect, ensure that a manufacturer-approved Bluetooth communication module is properly installed in the Visual Acuity Chart System.

To connect a Visual Acuity Chart System:

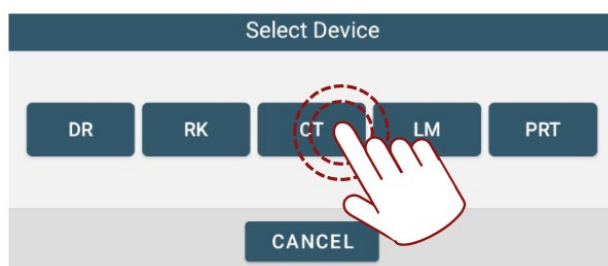
- (1) Turn on the Visual Acuity Chart System.



- (2) Touch  to open the Bluetooth configuration menu.

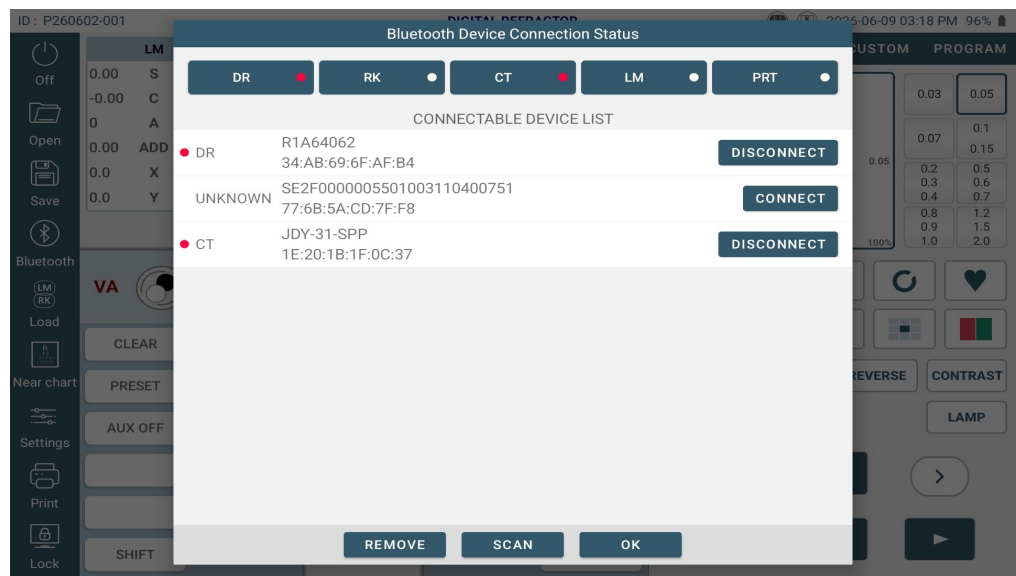
- (3) Select the Bluetooth device whose name begins with "JDY" and touch CONNECT button.

- (4) When the Selected Device window appears, select CT.



- (5) When the Bluetooth pairing request window is displayed, enter the PIN code 1234 and confirm the pairing request.

(6) When a red indicator is displayed on the CT button as shown below, the connection has been established successfully.



(7) Touch OK button to complete the procedure.

NOTE	A Bluetooth communication module must be installed in the Visual Acuity Chart System before Bluetooth communication can be established. Bluetooth device names may vary depending on the Bluetooth module version.
	Verify that the correct Bluetooth device is selected before establishing the connection.
	Connecting to an unintended Bluetooth device may result in communication failure or improper system operation.

7.3.4 Connecting a printer (Optional)

A compatible Bluetooth printer may be connected to the TSDR-3000 for printing examination results and prescription information. To connect a printer:

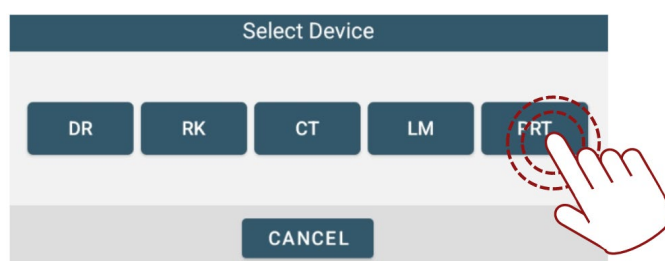
(1) Turn on the printer.



(2) Touch  to open the Bluetooth configuration menu.

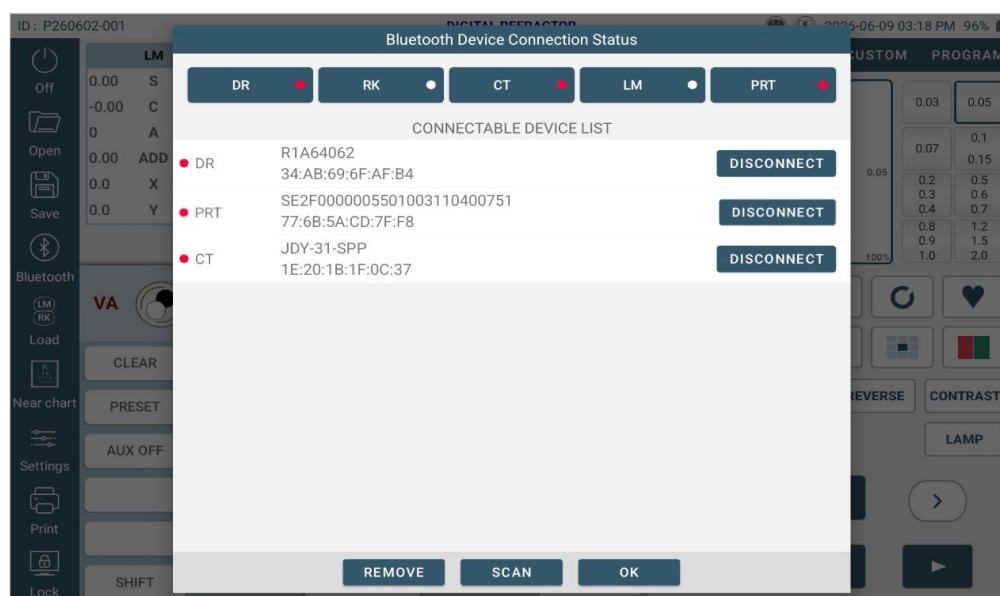
(3) Select the Bluetooth device name shown under DEVICE NAME on the printer label and touch CONNECT.

(4) When the Selected Device window appears, select PRT.



(5) When the Bluetooth pairing request window is displayed, enter the PIN code 0000 and confirm the pairing request.

(6) When a red indicator is displayed on the PRT button as shown below, the connection has been established successfully.

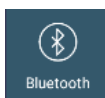


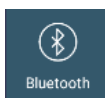
(7) Touch OK button to complete the procedure.

NOTE	The printer shall be powered on and placed within the effective Bluetooth communication range before attempting to establish a connection. Bluetooth device names may vary depending on the printer model.
	Verify that the selected Bluetooth device corresponds to the intended printer.
	Communication may be interrupted by distance, obstacles, or electromagnetic interference.

7.3.5 Disconnecting a device

To disconnect a Bluetooth device:



- (1) Touch  to open the Bluetooth configuration menu.
- (2) Selected the connected device.
- (3) Touch DISCONNECT button.
- (4) Verify that the connection status changes to disconnected.



Bluetooth communication may be interrupted by distance, obstacles, or electromagnetic interference.



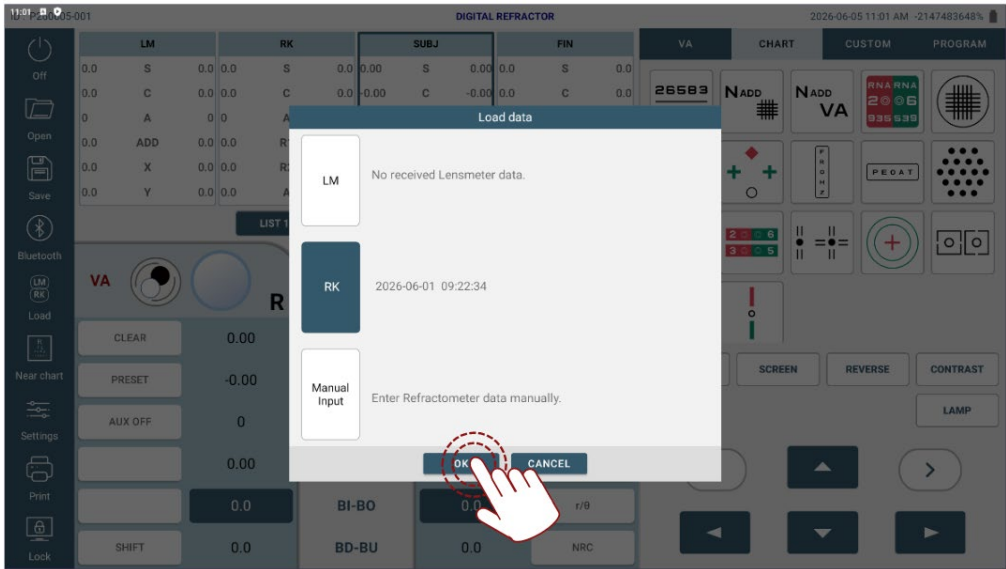
Always verify proper communication before starting an examination.

7.4 Loading examination data

The TSDR-3000 can receive examination data from compatible external ophthalmic devices or allow manual entry of measurement data. Received or manually entered data may be loaded into the Examination data area and used as a reference during subjective refraction.

7.4.1 Loading received data

When measurement data are transmitted from a compatible external device, the Load Data window is displayed automatically.



To load received data:

- (1) Select the desired data source.

Device	Description
LM	Auto lensmeter data
RK	Auto Refractometer / Auto RefKeratometer data

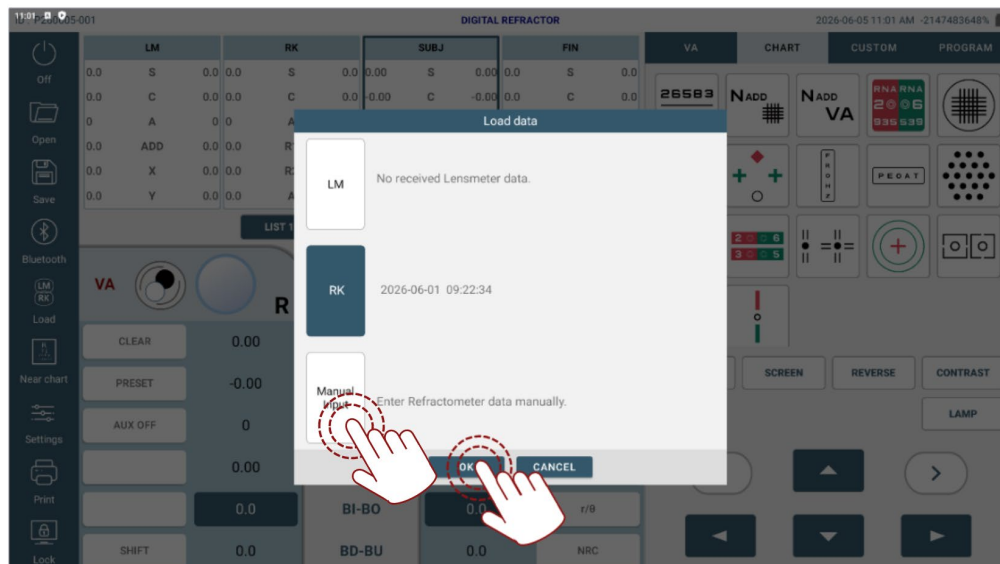
- (2) Verify the displayed measurement information.
- (3) Touch OK button.
- (4) The selected data are loaded into the Examination data area.

NOTE	The Load Data window is displayed automatically when compatible measurement data are received from an external device.
------	--

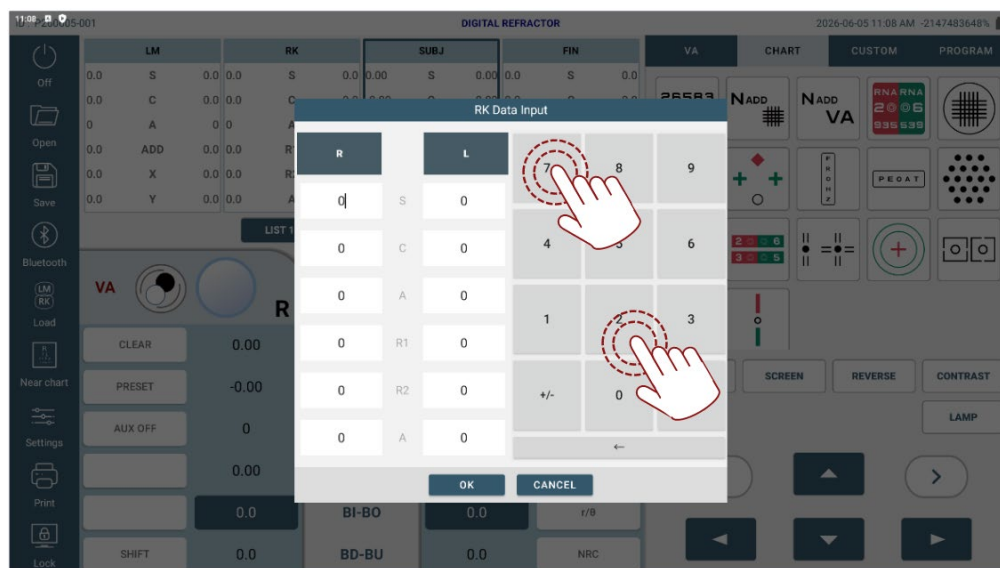
7.4.2 Manual data entry

If external measurement data are unavailable, refractive data may be entered manually. To enter data manually:

(1) In the Load Data window, select Manual Input.



(2) The RK Data Input window is displayed.



(3) Enter the measurement values for the right eye (R) and left eye (L).

(4) Touch OK button.

(5) The entered data are displayed in the Load Data window.

(6) Touch OK button again to load the data into the Examination data area.

NOTE	Manually entered data are treated in the same manner as externally received measurement data after loading.
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7.4.3 Applying loaded data

Loaded data may be used as a starting point for subjective refraction.

The examiner may compare:

Abbreviation	Meaning	Description
LM	Auto Lensmeter Measurement	Refractive data obtained from a lensmeter.
RK	Auto RefKeratometer Measurement	Objective refractive data obtained from an auto refractometer or auto refractor-keratometer.
SUBJ	Subjective Refraction	Refractive values determined through subjective refraction performed using the TSDR-3000.
FIN	Final Prescription	Final refractive values selected by the examiner.

Any displayed data set may be selected and temporarily applied to the Refractor head for comparison during the examination.

	The examiner is responsible for verifying the accuracy and suitability of all loaded or manually entered data before applying them during an examination.
---	---

7.5 Near vision chart

The TSDR-3000 provides a Near vision chart function for near vision examinations. The Near vision chart is displayed on the Tablet controller and may be used during near vision testing, presbyopia assessment, and near addition determination.

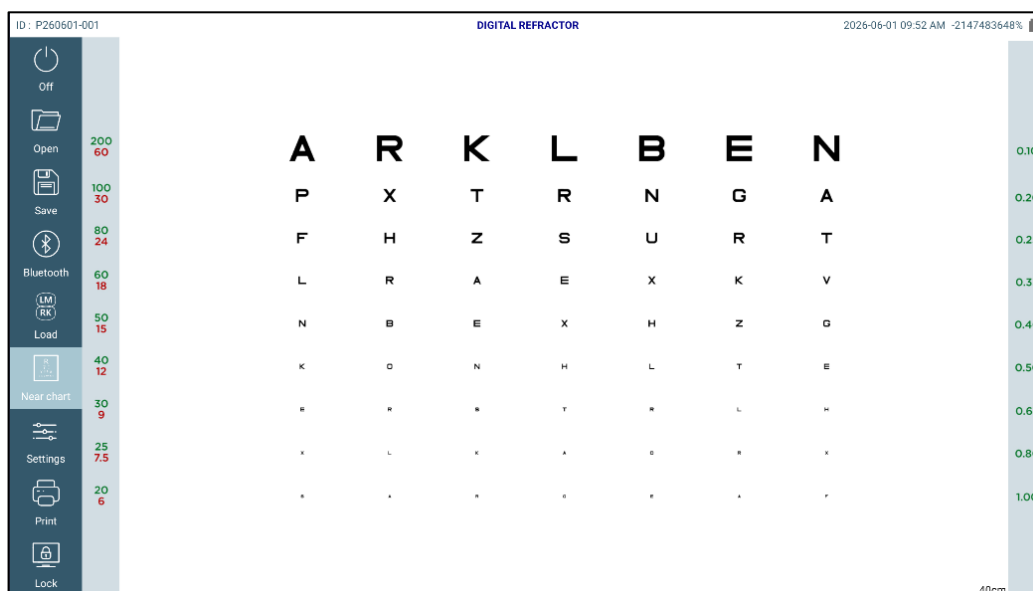
7.5.1 Opening the Near vision chart

To open the Near vision chart:



(1) Touch **Near chart** button on the function buttons.

(2) The Near vision chart window is displayed.



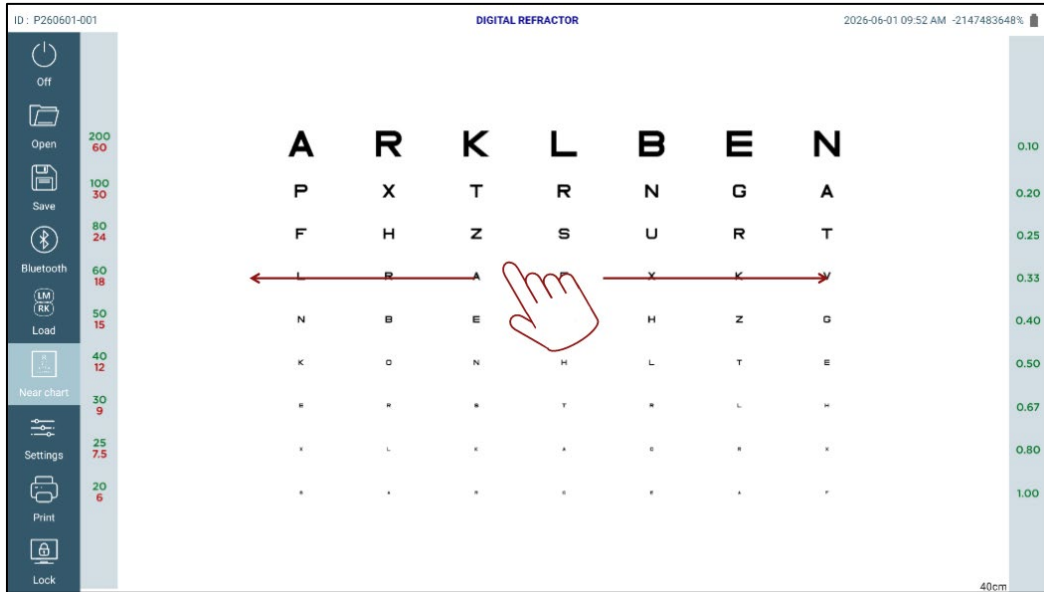
(3) Select the desired chart type.

(4) Position the tablet at the required examination distance.

7.5.2 Selecting the chart type

The displayed near vision chart can be changed by dragging the chart area horizontally.

- Drag left or right to select a different chart type.



- Available chart types include:

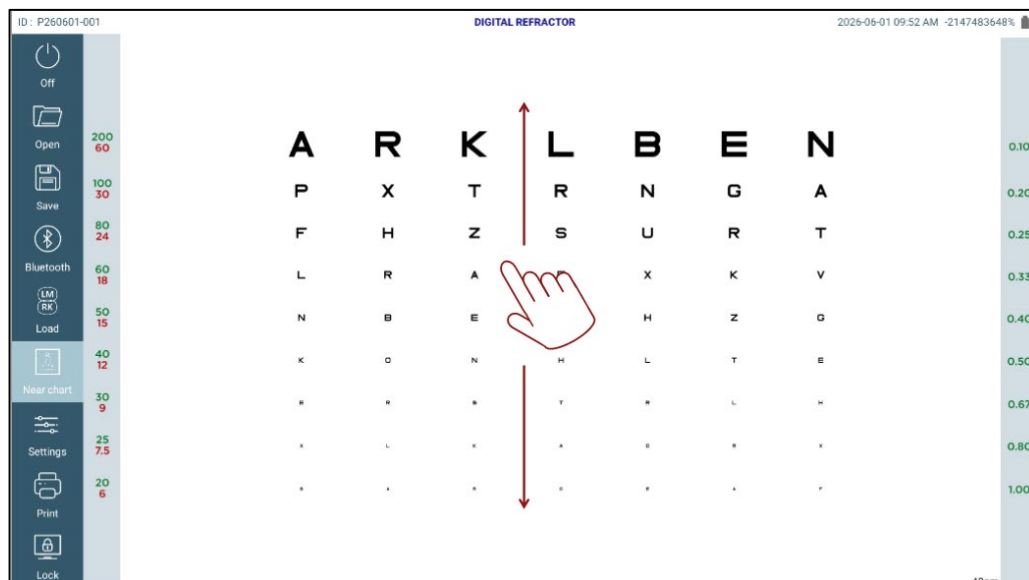
- Alphabet
- Number
- Tumbling E
- Landolt Ring

The selected chart type is displayed immediately.

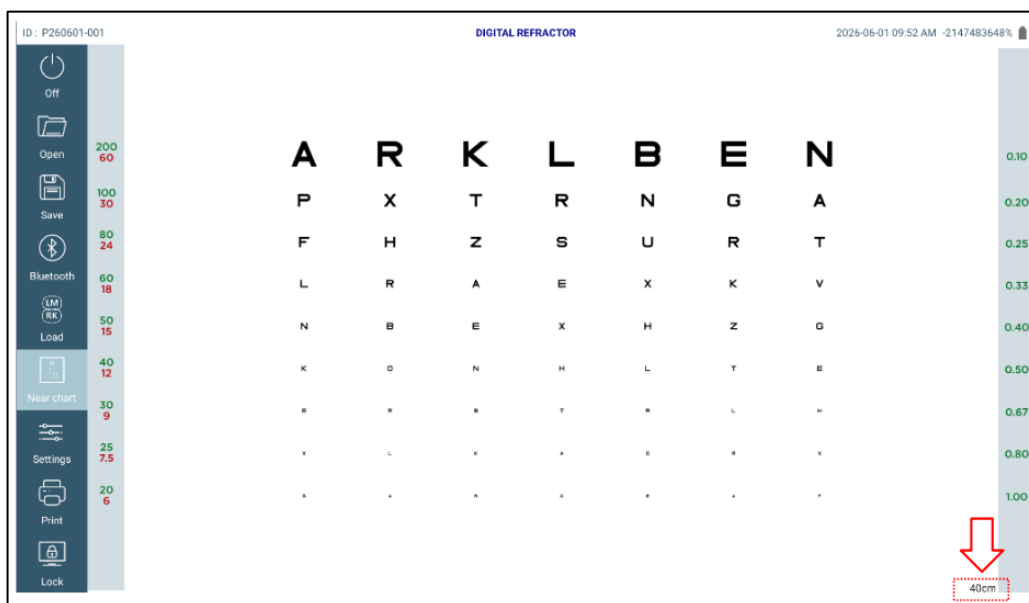
7.5.3 Adjusting the Examination Distance

The examination distance can be adjusted by dragging the chart area vertically.

- Drag upward or downward to change the examination distance.



- The examination distance can be adjusted from 35 cm to 70 cm.



The currently selected examination distance is displayed in the lower-right corner of the screen. The optotype size is automatically adjusted according to the selected examination distance.

7.5.4 Closing the Near vision chart

To close the Near vision chart:



(1) Touch  button on the function buttons.

(2) The system returns to the Main screen.



The Near Vision Chart is intended to assist qualified eye care professionals during near vision examinations. The examiner is responsible for selecting the appropriate examination distance and chart type.

7.6 System settings

The system setting menu allows configuration of system parameters and operating preferences. Setting should only be modified by qualified personnel who are familiar with the operation of the TSDR-3000.

To open the system settings menu:



- (1) Touch **Settings** button on the function buttons.
- (2) The Settings menu displayed
- (3) Select the desired setting category.

The System Settings menu is organized into the categories shown below:

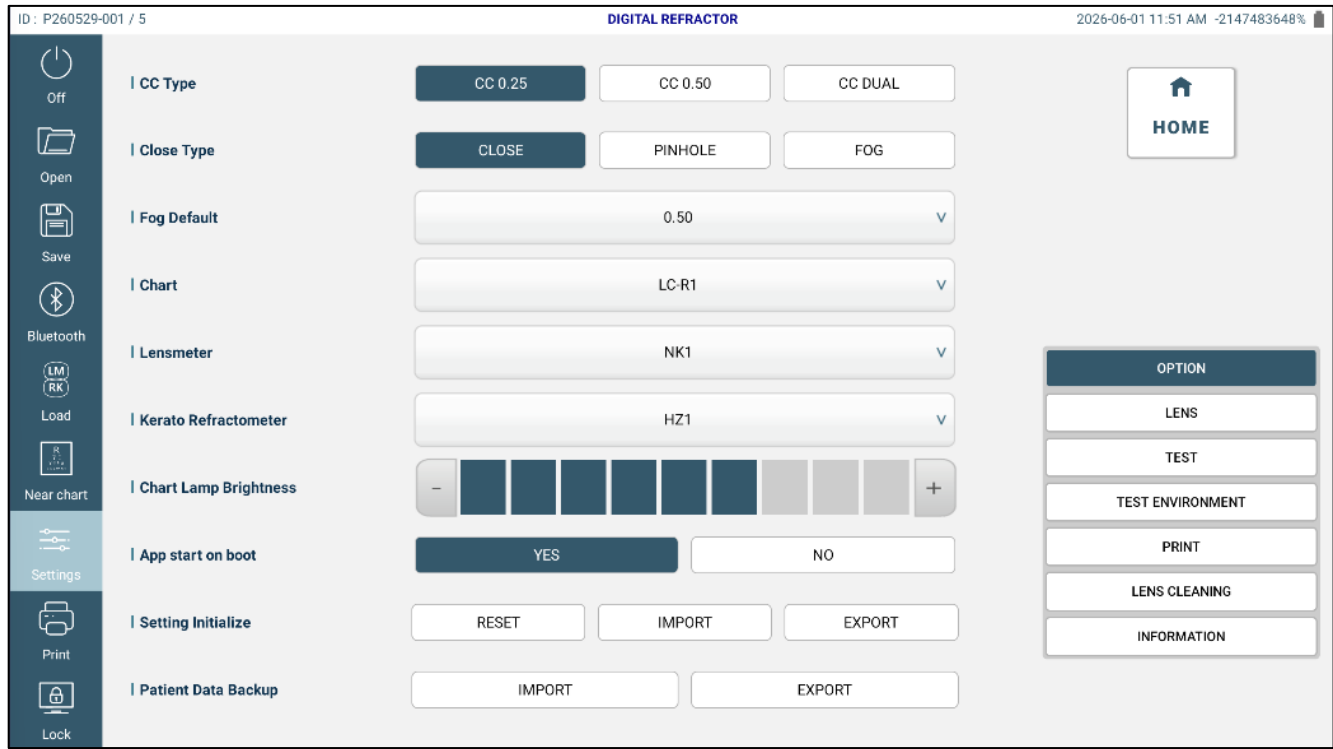
Category	Description
OPTION	Configures examination defaults, connected device settings, communication protocols, and application behavior.
LENS	Configures lens adjustment increments, cylinder notation, prism display format, and lens operation behavior.
TEST	Configures examination-related functions, automatic chart selection, PD settings, and fogging parameters.
TEST ENVIRONMENT	Configures user interface behavior, language settings, device connection preferences, and operating environment options.
PRINT	Configures printout contents, header and footer messages, and printing behavior.
LENS CLEANING	Provides access to the lens cleaning mode, allowing individual lens disks to be positioned for inspection and cleaning.
INFORMATION	Displays software version, firmware version, serial number, and other system information.

NOTE

Changes to system settings may affect device operation and examination procedures. Verify all settings before performing patient examinations.

7.6.1 OPTION settings

The OPTION settings menu allows configuration of connected devices, examination defaults, and application behavior.



Setting	Description	
CC Type	Selects the Jackson Cross Cylinder lens type (± 0.25 D, ± 0.50 D, or Dual Cross Cylinder).	
	CC 0.25	Uses a ± 0.25 D Jackson Cross Cylinder lens.
	CC 0.50	Uses a ± 0.50 D Jackson Cross Cylinder lens.
	CC DUAL	Uses a Dual Cross Cylinder configuration.
Close Type	Selects the method used for automatic occlusion (Occluder, Pinhole, or Fogging).	
	CLOSE	Uses an occluder for automatic occlusion.
	PINHOLE	Uses a pinhole lens for automatic occlusion.
Fog Default	FOG	Uses fogging instead of physical occlusion.
	Sets the default fogging power.	
Chart	Selects the connected Visual Acuity Chart System model.	
	LC-R1	Compatible with TSLC-2000 systems.

	LC-R1P	Compatible with TSLC-2000P systems.
	LC-R1N	Compatible with TSLC-2000 systems running software version 244 or later.
	LC-R1NP	Compatible with TSLC-2000P systems running software version 244 or later.
Lensmeter	Selects the communication protocol for a compatible lensmeter	
	NK1	Communication protocol for compatible NIDEK lensmeters.
	HZL1	Communication protocol for compatible HUVITZ lensmeters.
Kerato Refractometer	Selects the communication protocol for a compatible auto refractometer or auto refractor-keratometer.	
	HZ1	Communication protocol for compatible HUVITZ devices.
	EW1	Communication protocol for TSRK-3000.
	NRK1	Communication protocol for compatible NIDEK devices.
	TC8	Communication protocol for TOPCON KR-8100.
	TC8900	Communication protocol for TOPCON KR-8800 and KR-8900.
	TR1	Communication protocol for TSRK-1000P.
	RK-F1	Communication protocol for compatible CANON devices.
Chart Lamp Brightness	Adjusts chart illumination brightness.	
App start on boot	Automatically launches the application when the tablet starts.	
Setting Initialize	Resets, imports, or exports system settings.	
	RESET	Restores factory-default settings.
	IMPORT	Imports previously saved settings.
	EXPORT	Exports current settings for backup purposes.
Patient Data Backup	Imports or exports patient data.	
	IMPORT	Imports patient records from external storage.
	EXPORT	Exports patient records for backup or transfer purposes.

7.6.2 LENS settings

The Lens Settings menu allows configuration of lens adjustment increments, display formats, and lens operation behavior.



Setting	Description	
SPH Step	Sets the adjustment increment used when changing sphere power.	
CYL Step	Sets the adjustment increment used when changing cylinder power.	
CYL Sign	Selects plus-cylinder (+) or minus-cylinder (-) notation.	
AXIS Step	Sets the adjustment increment used when changing cylinder axis.	
ADD Step	Sets the adjustment increment used when changing addition power.	
Prism Step	Sets the adjustment increment used when changing prism power.	
	X / Y	Displays horizontal and vertical prism components separately.
	r / θ	Displays prism values using polar coordinates (magnitude and angle).
Prism Display	Selects the prism display format.	
S.C: Auto Occlusion	Enables or disables automatic occlusion while lens power is changing. During lens	

	power changes, temporary image blur may occur while the lens disks rotate. When S.C Auto Occlusion is enabled, the eye is automatically occluded during lens movement to reduce patient discomfort and visual disturbance. <table> <tr> <td>YES</td><td>Automatic occlusion enabled.</td></tr> <tr> <td>NO</td><td>Automatic occlusion disabled.</td></tr> </table>	YES	Automatic occlusion enabled.	NO	Automatic occlusion disabled.
YES	Automatic occlusion enabled.				
NO	Automatic occlusion disabled.				
C.C: Auto Occlusion	Enables or disables automatic occlusion during large axis changes in cross-cylinder examinations. During cross-cylinder examinations, large axis changes may cause visual discomfort. When C.C Auto Occlusion is enabled, the eye is temporarily occluded while the axis is being changed. <table> <tr> <td>YES</td><td>Automatic occlusion enabled.</td></tr> <tr> <td>NO</td><td>Automatic occlusion disabled.</td></tr> </table>	YES	Automatic occlusion enabled.	NO	Automatic occlusion disabled.
YES	Automatic occlusion enabled.				
NO	Automatic occlusion disabled.				
Preset Von Graefe	Selects automatic or manual prism insertion during Von Graefe testing. Determines how prisms are inserted during Von Graefe testing. <table> <tr> <td>AUTO</td><td>Preset prism values are inserted automatically.</td></tr> <tr> <td>MANUAL</td><td>Prism values are selected manually by the examiner.</td></tr> </table>	AUTO	Preset prism values are inserted automatically.	MANUAL	Prism values are selected manually by the examiner.
AUTO	Preset prism values are inserted automatically.				
MANUAL	Prism values are selected manually by the examiner.				

7.6.3 TEST settings

The TEST settings menu allows configuration of examination-related functions and default testing parameters.

ID : P260529-001 / 5

DIGITAL REFRACTOR

2026-06-01 02:55 PM -2147483648%

Off

Open

Save

Bluetooth

Load

Near chart

Settings

Print

Lock

Blur / Break / Recovery

VA Auto Set

Working Distance

Pupil Distance

PD Auto Set

Input Coincidence

Fog : Balance

Fog : Red / Green

YES

NO

YES

OFF

40

64

RK

LM

OFF

YES

NO

0.50

0.50

HOME

OPTION

LENS

TEST

TEST ENVIRONMENT

PRINT

LENS CLEANING

INFORMATION

Setting	Description						
Blur / Break / Recovery	Enables or disables function keys used during NRC and PRC horizontal prism testing.						
VA Auto Set	Automatically selects an appropriate visual acuity chart based on imported examination data.						
Working Distance	Sets the default working distance used during examinations.						
Pupil Distance	Sets the default pupillary distance (PD).						
PD Auto Set	Automatically applies PD values received from external measurement devices. <table><tr><td>RK</td><td>Automatically applies PD values received from an auto refractometer.</td></tr><tr><td>LM</td><td>Automatically applies PD values received from a lensmeter.</td></tr><tr><td>OFF</td><td>Automatic PD application disabled.</td></tr></table>	RK	Automatically applies PD values received from an auto refractometer.	LM	Automatically applies PD values received from a lensmeter.	OFF	Automatic PD application disabled.
RK	Automatically applies PD values received from an auto refractometer.						
LM	Automatically applies PD values received from a lensmeter.						
OFF	Automatic PD application disabled.						
Input Coincidence	Enables or disables function keys used during aniseikonia examinations.						

80 / 188

Rev. 1 (SEP 15, 2026)

Fog: Balance	Sets the default fogging value used during binocular balance testing. The fogging value may be selected from 0.25 D to 2.00 D in 0.25 D increments.
Fog: Red / Green	Sets the default fogging value used during red-green balance testing. The fogging value may be selected from 0.25 D to 2.00 D in 0.25 D increments.

7.6.4 TEST ENVIRONMENT settings

The TEST ENVIRONMENT settings menu allows customization of user interface behavior, device operation, and examination workflow preferences.



Setting	Description				
Screen Auto Off	Sets the period of inactivity after which the tablet display is automatically turned off. This function helps reduce power consumption when the system is not in use.				
Beep Sound	Selects the notification sound used by the application. Different sound types may be available depending on the software version.				
Language	Selects the display language. Changes take effect immediately after selection.				
Device Connect	Selects automatic or manual connection of the Refractor head at application startup.				
Step Increase Direction	Defines the direction used to increase or decrease refractive values during drag operations. <table><tr><td>DEFAULT</td><td>Dragging right (or upward) increases minus power. Dragging left (or downward) increases plus power.</td></tr><tr><td>OPPOSITE</td><td>Dragging left (or downward) increases minus power.</td></tr></table>	DEFAULT	Dragging right (or upward) increases minus power. Dragging left (or downward) increases plus power.	OPPOSITE	Dragging left (or downward) increases minus power.
DEFAULT	Dragging right (or upward) increases minus power. Dragging left (or downward) increases plus power.				
OPPOSITE	Dragging left (or downward) increases minus power.				

		Dragging right (or upward) increases plus power.
Unit Step Direction	Defines the drag direction used for lens value adjustment.	
	VERTICAL DRAG	Lens values are adjusted using left and right drag movements.
	HORIZONTAL DRAG	Lens values are adjusted using up and down drag movements.
Program	Selects the examination program used by the system.	
	STANDARD	Uses the default examination sequence.
	Custom Edit	Modifies user-defined examination sequences.
	Program Edit	Creates or edits examination programs.
Text Size	Adjusts the size of text displayed on the screen to improve readability.	
Firmware	Selects the firmware profile used for communication and device operation. This setting should only be changed by qualified service personnel or according to manufacturer instructions.	

NOTE

Changes to TEST ENVIRONMENT settings may affect system behavior and examination workflow. Verify the selected settings before performing patient examinations.

7.6.5 PRINT settings

The PRINT settings menu allows configuration of printed examination reports and prescription printouts.

ID : P260529-001 / 5

DIGITAL REFRACTOR

2026-06-01 02:54 PM -2147483648%

Off

Open

Save

Bluetooth

LM
RK

Load

Near chart

Settings

Print

Lock

| Print Header Message

| Print Footer Message

| Print Subjective

| Print Objective

| Auto Clear

| Preview List

ALL

ALL

YES

NO

YES

NO

HOME

OPTION

LENS

TEST

TEST ENVIRONMENT

PRINT

LENS CLEANING

INFORMATION

Setting	Description
Print Header Message	Allows the user to enter a custom message that will be printed at the top of each report. Typical examples include: - Clinic name - Hospital name - Examiner name - Contact information
Print Footer Message	Allows the user to enter a custom message that will be printed at the bottom of each report. Typical examples include: - Disclaimer statements - Follow-up instructions - Clinic contact information
Print Subjective	Determines which subjective refraction data are included in the printout.

	ALL	Prints all available subjective refraction and visual acuity data.
	W/O UNAIDED VA	Prints all data except unaided visual acuity results.
	W/O BIN VF	Prints all data except binocular vision examination results.
	SUBJ & FIN ONLY	Prints only Subjective Refraction (SUBJ) and Final Prescription (FIN) data.
	OFF	Subjective refraction data are not printed.
Print Objective	Determines which objective measurement data are included in the printout.	
	ALL	Prints all available objective measurement data.
	LM ONLY	Prints only lensmeter measurement data (LM).
	RK ONLY	Prints only auto refractometer measurement data (RK).
	OFF	Objective measurement data are not printed.
Auto Clear	Determines whether examination data are automatically cleared after a successful print operation.	
Preview List	Determines whether a print preview window is displayed before printing.	

7.6.6 LENS CLEANING

The Lens Cleaning menu allows individual lens disks inside the Refractor head to be positioned for inspection and cleaning. This function is intended to assist maintenance personnel when cleaning optical components.

	Lens cleaning should only be performed by qualified personnel.
	Do not use excessive force when cleaning optical components.
	Use only approved lens cleaning materials and procedures.

Lens selection

Button	Description
L	Select the left-eye optical system.
R	Select the right-eye optical system.
OPEN	Moves the selected optical system to the open position for inspection and cleaning.

Disk selection

Button	Description
DISK1 to DISK6	Selects the lens disk to be positioned for inspection or cleaning.

Disk movement

Button	Description
<	Rotates the selected disk to the previous position.
>	Rotates the selected disk to the next position.

The currently displayed position number indicates the active rotational position of the selected lens disk.

Cleaning procedure

- (1) Open the LENS CLEANING menu.
- (2) Select L or R to choose the eye to be serviced.
- (3) Select the desired lens disk (DISK1 – DISK6).
- (4) Use the navigation arrows to rotate the disk until the target lens is accessible.
- (5) Carefully clean the lens surface using approved optical cleaning materials.
- (6) Repeat the procedure for additional lens disks if required.
- (7) When cleaning is complete, return to the HOME screen.

NOTE	The Lens Cleaning function only changes the position of internal lens disks and does not modify examination settings or patient data.
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7.6.7 INFORMATION

The Information menu displays identification and version information for the TSDR-3000. This information may be required when contacting the manufacturer, requesting technical support, performing software updates, or reporting service issues.

NOTE	The information displayed on this screen is read-only and cannot be modified by the user.
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7.7 Custom charts

7.7.1 Overview

The TSDR-3000 allows the examiner to create and store user-defined custom charts. Custom charts may contain visual acuity charts, special examination charts, or other examination targets arranged according to the examiner's preferences. Custom charts can be used independently or incorporated into examination programs.

NOTE	The availability of custom charts functions may vary depending on software version and system configuration.
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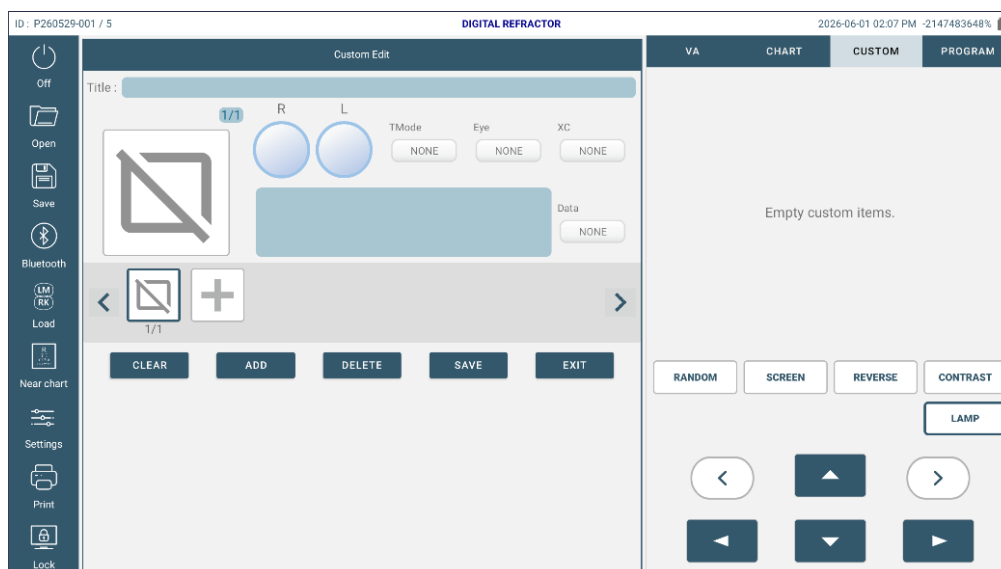
7.7.2 Opening Custom Edit



- (1) Touch **Settings** button on the function buttons.
- (2) Select TEST ENVIRONMENT.
- (3) Touch the Custom Edit button.

7.7.3 Creating a custom chart

(1) Open the Custom Edit window.



(2) Enter a title for the custom chart.

(3) Select a chart from the VA or CHART category.

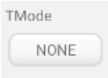
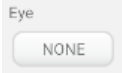
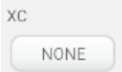
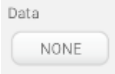
(4) Configure desired examination parameters.

(5) Touch  button to insert the chart into the custom chart sequence.

(6) Repeat the procedure as require.

7.7.4 Custom chart parameters

The following parameters may be configured for each custom chart item.

Parameter	Description
	Specifies the name of the custom chart.
	Displays the selected chart.
	Selects the auxiliary lens that will be inserted automatically when the custom chart is displayed.
	Selects the examination distance (Far or Near).
	Selects the eye condition (Right, Left, or Binocular).
	Selects the Cross Cylinder type (0.25 D, 0.50 D, or Dual).
	Selects the examination data associated with the chart item.
	Removes all settings from the current chart item.
	Adds a new chart item.
	Deletes the selected chart item.
	Saves the custom chart.
	Closes the Custom Edit window.

7.7.5 Deleting a custom chart

- (1) Open the Custom Edit window.
- (2) Select the chart item to be deleted.
- (3) Touch  button.
- (4) Save the changes.



Deleted custom chart items cannot be recovered unless a backup copy is available.

7.8 Examination programs

7.8.1 Overview

The TSDR-3000 allows the examiner to create customized examination programs. An examination program consists of a predefined sequence of visual acuity charts, special examination charts, and custom charts that are displayed automatically in a specified order during an examination. Examination programs help standardize examination procedures and improve workflow efficiency.

NOTE	The availability of program functions may vary depending on software version and system configuration.
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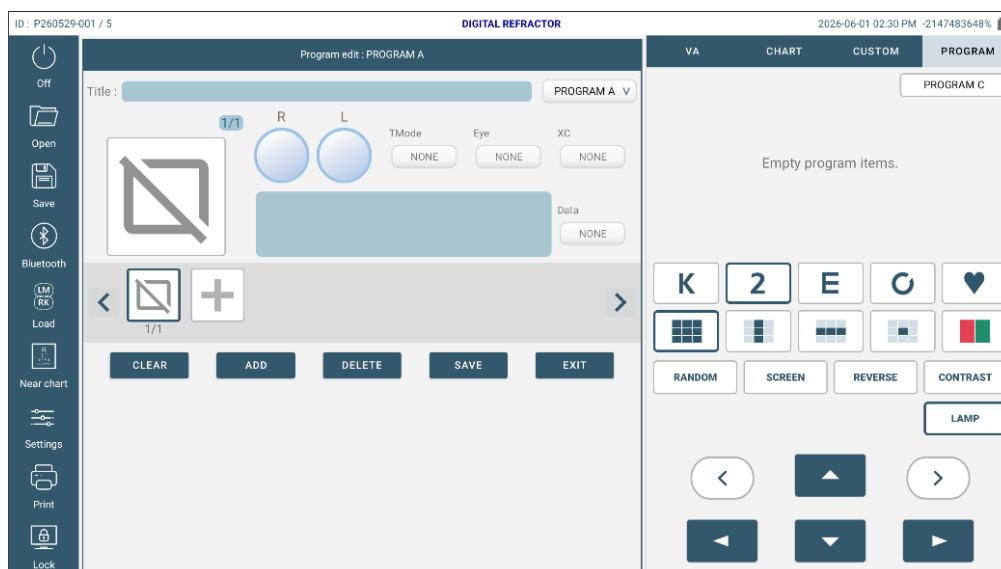
7.8.2 Opening Program Edit



- (1) Touch  button on the function buttons.
- (2) Select TEST ENVIRONMENT.
- (3) Touch the Program Edit button.

7.8.3 Creating an examination program

(1) Open the Program Edit window.



(2) Enter a title for the program.

(3) Select the desired program location.

(4) Select a chart from the VA or CHART category.

(5) Configure desired examination parameters for each chart item.

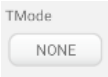
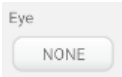
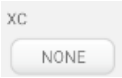
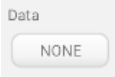
(6) Touch  button to insert the chart into the custom chart sequence.

(7) Repeat the procedure as require.

(8) Touch  to store the examination program.

7.8.4 Program parameters

The following parameters may be configured for each custom chart item.

Parameter	Description
	Specifies the name of the examination program.
	Selects the program to be edited. Up to ten programs (PROGRAM A to PROGRAM J) may be stored.
	Displays the selected chart.
	Selects the auxiliary lens that will be inserted automatically when the examination step is displayed.
	Selects the examination distance (Far or Near).
	Selects the eye condition (Right, Left, or Binocular).
	Selects the Cross Cylinder type (0.25 D, 0.50 D, or Dual).
	Selects the examination data associated with the chart item.
	Removes all settings from the current chart item.
	Adds a new chart item.
	Deletes the selected chart item.
	Saves the examination program.
	Closes the Program Edit window.

7.8.5 Executing an examination program

- (1) Touch the PROGRAM tab in the Visual acuity chart control area.
- (2) Select the desired examination program.
- (3) The charts stored in the selected program are displayed sequentially.
- (4) Use the navigation keys to move between examination steps.

Any auxiliary lenses, examination distance settings, eye conditions, or cross-cylinder settings associated with the selected step are applied automatically.

7.8.6 Deleting an examination program

- (1) Open the Program Edit window.
- (2) Select the examination step to be removed.
- (3) Touch  button.
- (4) Save the changes.



Changes are not stored until the Save button is pressed.



Deleted examination steps cannot be recovered unless a backup copy is available.

8 Examination functions

This section describes the examination functions provided by the TSDR-3000 and the general procedures used during subjective refraction and binocular vision examinations. The actual examination sequence may vary depending on the clinical protocol, examiner preference, and patient condition.

8.1 Subjective refraction workflow

The TSDR-3000 supports a complete subjective refraction procedure. A typical examination sequence is as follows:

- Load objective measurement data from a compatible Auto Refractometer (optional)
- Adjust pupillary distance (PD)
- Verify vertex distance (VD)
- Determine sphere power
- Determine cylinder axis
- Determine cylinder power
- Perform duochrome (Red/Green) balancing
- Perform binocular balance test
- Determine near addition power (if required)
- Save and print examination results

The examiner may modify the sequence according to clinical preference.

8.2 Pupillary distance (PD) adjustment

8.2.1 Purpose

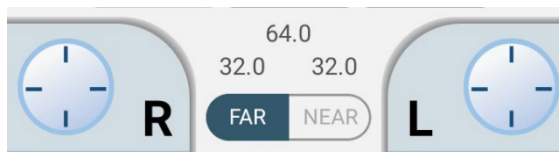
The pupillary distance (PD) shall be adjusted to align the optical centers of the refractor lenses with the patient's visual axes. Incorrect PD settings may result in prism effects and inaccurate examination results.

8.2.2 Procedure

- (1) Position the patient correctly at the refractor head.
- (2) Touch the PD display area on the main examination screen.



- (3) Verify that the PD verification lenses are automatically inserted into the measurement windows.



- (4) Select the desired PD adjustment step and choose whether to adjust the Right Eye (R), Left Eye (L), or Both Eyes (OU).



- (5) Drag the area indicated below to move the PD verification lens horizontally until the cross mark is aligned with the center of the patient's pupil.



- (6) Repeat the procedure for both eyes as required until proper alignment is achieved.

- (7) Touch **SAVE** button to store the adjusted PD values.

8.2.3 Verification

The PD verification lenses may be used to confirm proper alignment of the patient's pupils with the optical centers of the refractor head.

NOTE	For accurate examination results, ensure that the center of each pupil is aligned with the cross mark displayed by the PD Verification Lens before proceeding with subjective refraction.
	Incorrect PD settings may induce unwanted prism effects and may affect the accuracy of the examination results.

8.3 Vertex distance (VD) adjustment

8.3.1 Purpose

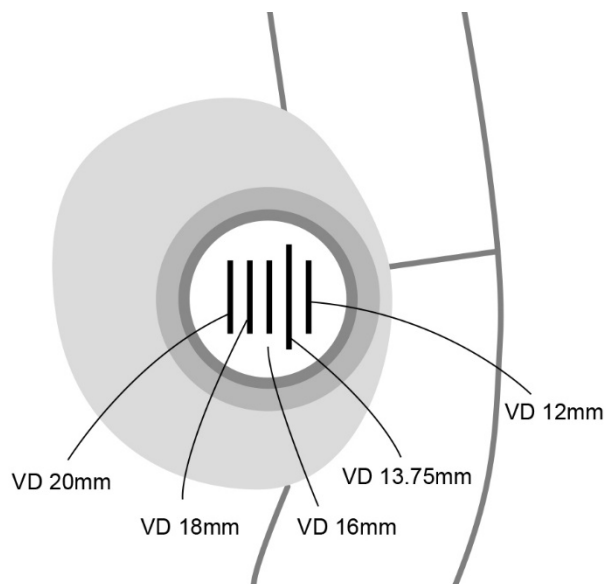
Vertex distance (VD) is the distance between the back surface of the corrective lens and the apex of the cornea. Proper VD adjustment is important to ensure accurate refractive measurements, particularly when high-power prescriptions are involved.

8.3.2 Procedure

- (1) Position the patient comfortably at the Refractor head.
- (2) Adjust the forehead rest so that the patient maintains a stable head position throughout the examination.
- (3) Observe the patient's eye through the VD check windows.
- (4) Rotate the Forehead rest adjustment knob until the corneal apex is aligned with the VD reference mark visible in the VD check windows.
- (5) Repeat the procedure for the other eye if necessary.
- (6) Confirm that the patient's forehead remains in contact with the forehead rest and that the VD is correctly adjusted before starting the examination.

8.3.3 Recommended vertex distance

The optimum vertex distance may vary depending on the patient's facial anatomy and the examiner's clinical judgment. A vertex distance of 12 mm is commonly used as a reference value in Korea and several other Asian countries. The examiner may adjust the vertex distance as clinically appropriate.



NOTE	Changes in vertex distance may affect the effective refractive power, particularly when examining patients with high spherical or cylindrical corrections. For accurate examination results, verify the vertex distance before performing subjective refraction.
	The Near Point Illuminator flashes when the patient's forehead is temporarily separated from the forehead rest. This indication alerts the examiner that the patient's head position may have changed. For accurate examination results, ensure that the patient's forehead remains in contact with the forehead rest throughout the examination.
	Do not apply excessive force when adjusting the forehead rest. Excessive pressure may cause patient discomfort and may affect examination accuracy.

8.4 Sphere power adjustment

8.4.1 Purpose

Sphere adjustment is used to determine the spherical component of the patient's refractive correction. The spherical power may be adjusted independently for the right eye (R) and left eye (L).

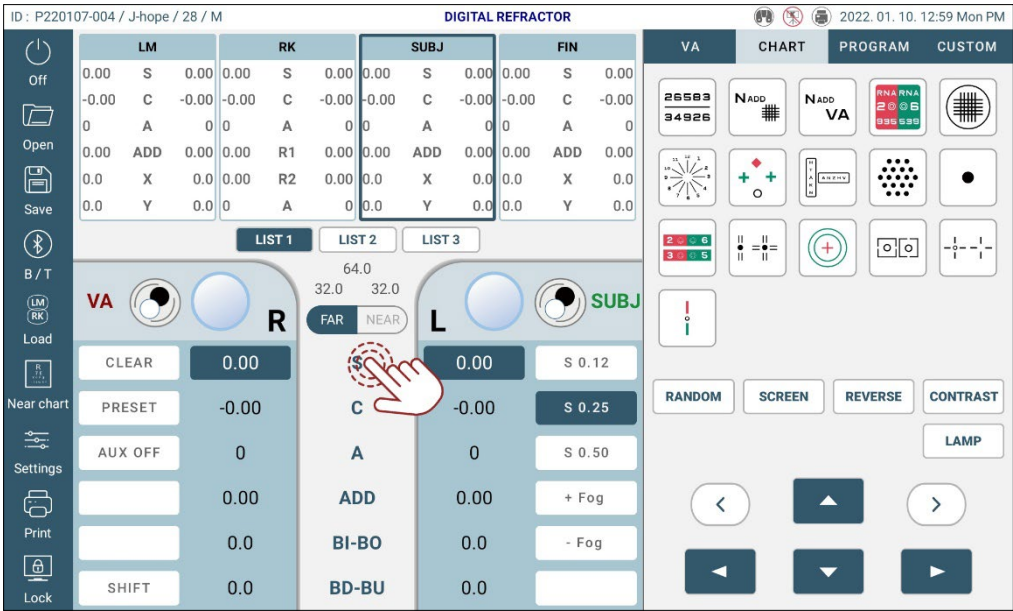
8.4.2 Selecting the eye

Before adjusting the sphere power, select the eye to be examined.

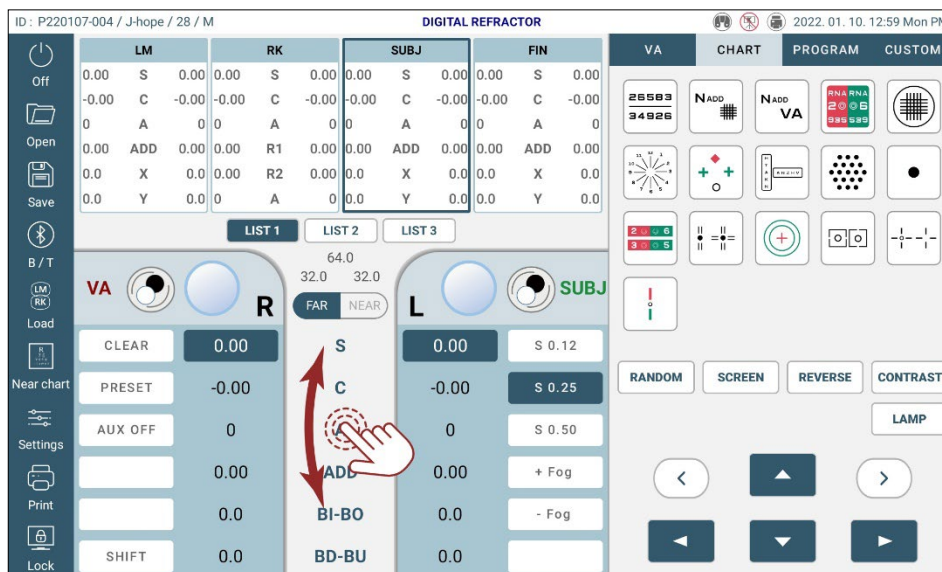
Button	Description
R	Adjusts the right eye only.
L	Adjusts the left eye only.
R/L	Adjusts both eyes simultaneously.

8.4.3 Adjusting sphere power

- (1) Select the eye to be adjusted.
- (2) Touch the Sphere (S) value displayed in the Lens control area.



(3) Drag the control area upward or downward to change the spherical power.



(4) Continue the adjustment while observing the patient's responses.

(5) Repeat until the desired spherical power is obtained.

The current sphere value is displayed continuously on the screen.

8.4.4 Available adjustment steps

Button	Description
S 0.12	Sets the sphere adjustment step to 0.12 D.
S 0.25	Sets the sphere adjustment step to 0.25 D.
S 0.50	Sets the sphere adjustment step to 0.50 D.
S 1.00	Sets the sphere adjustment step to 1.00 D (SHIFT mode).
S 2.00	Sets the sphere adjustment step to 2.00 D (SHIFT mode).

Smaller steps provide finer control, while larger steps allow rapid changes.

8.4.5 SHIFT function

The SHIFT function temporarily increases the adjustment increment to allow faster lens changes. When SHIFT mode is activated:

- Larger sphere adjustment steps become available.
- Rapid changes of refractive power can be performed.
- Fine adjustment should be performed after returning to normal step sizes.

8.4.6 Fogging

Fogging may be applied during subjective refraction or binocular balance procedures.

Button	Description
+ FOG	Adds plus spherical power for fogging.
- FOG	Reduces or removes previously applied fogging power.

Fogging helps control accommodation during refraction procedures.

NOTE	The actual examination sequence and refraction technique may vary according to the examiner's clinical preference and established examination protocol.
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8.5 Cylinder power adjustment

8.5.1 Purpose

Cylinder power adjustment is used to determine the magnitude of astigmatic correction required by the patient.

The cylinder value may be adjusted independently for the right eye (R) and left eye (L).

8.5.2 Selecting the eye

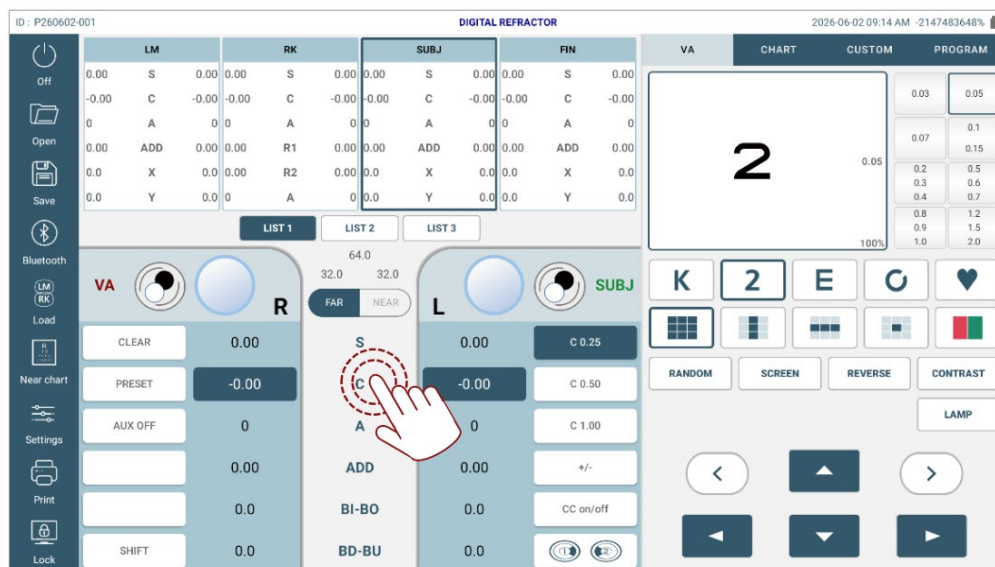
Before adjusting the cylinder power, select the eye to be examined.

Button	Description
R	Adjusts the right eye only.
L	Adjusts the left eye only.
R/L	Adjusts both eyes simultaneously.

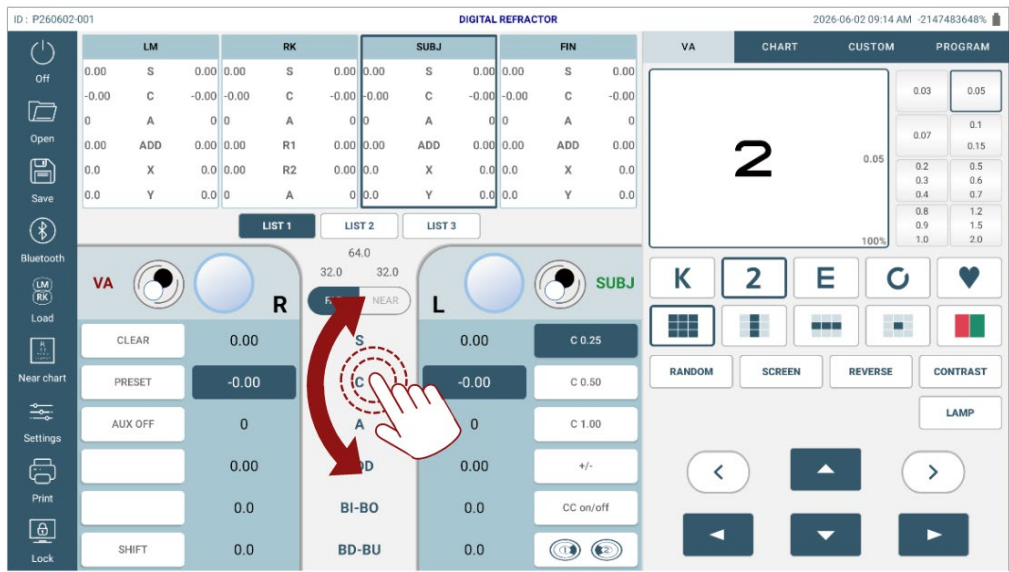
8.5.3 Adjusting cylinder power

(1) Select the eye to be adjusted.

(2) Touch the Cylinder (C) value displayed in the Lens control area.



(3) Drag the control area upward or downward to increase or decrease the cylinder power.



(4) Observe the patient's responses and continue adjustment as required.

(5) Repeat the procedure until the desired cylinder power is obtained.

The current cylinder value is displayed continuously on the screen.

8.5.4 Cylinder Sign Convention

The TSDR-3000 supports both plus-cylinder and minus-cylinder notation.



The notation may be selected in: Settings >> LENS >> CYL Sign

Option	Description
+	Plus-cylinder notation
-	Minus-cylinder notation

Changing the cylinder notation does not change the optical correction. Only the displayed representation is changed.

8.5.5 Cylinder Adjustment Step

The cylinder adjustment increment may be configured in the LENS settings menu. Smaller increments provide finer control during subjective refraction, while larger increments allow faster adjustments.

NOTE	Cylinder power and cylinder axis are closely related parameters. After modifying cylinder power, additional axis refinement may be required to obtain the optimum refractive correction.
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8.6 Axis adjustment

8.6.1 Purpose

Axis adjustment is used to determine the orientation of astigmatic correction. The axis value defines the meridian along which the cylindrical correction is applied and is expressed in degrees.

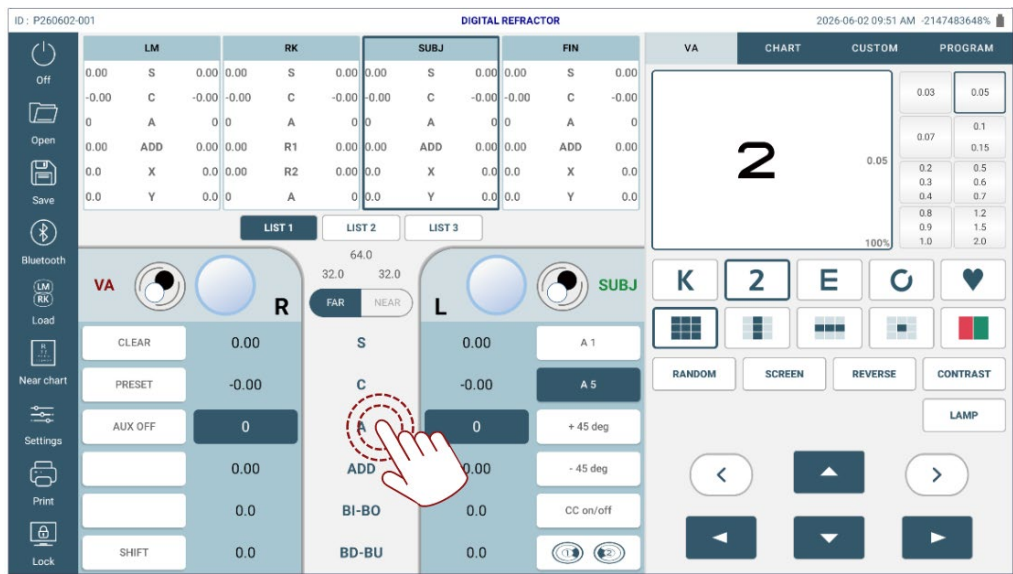
8.6.2 Selecting the eye

Before adjusting the axis value, select the eye to be examined.

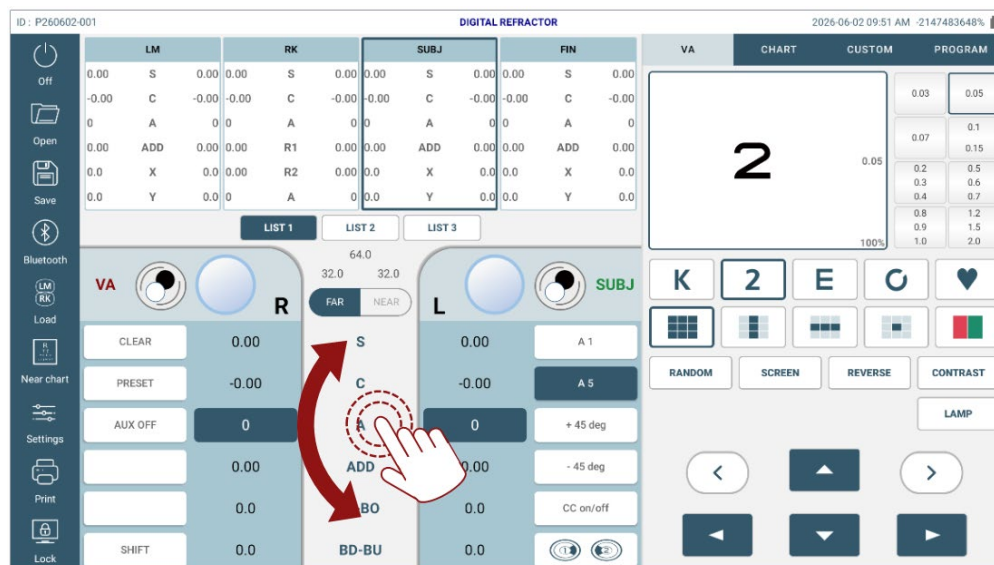
Button	Description
R	Adjusts the right eye only.
L	Adjusts the left eye only.
R/L	Adjusts both eyes simultaneously.

8.6.3 Adjusting the Axis

- (1) Select the eye to be adjusted.
- (2) Touch the Axis (A) value displayed in the Lens control area.



(3) Drag the control area upward or downward to rotate the cylinder axis.



(4) Observe the patient's responses and continue adjustment as required.

(5) Repeat the procedure until the optimum axis position is obtained.

The current axis value is displayed continuously on the screen.

8.6.4 Axis range

The cylinder axis may be adjusted within a range of 0° to 179° . Since 0° and 180° represent the same meridian, the TSDR-3000 uses a continuous axis scale from 0° to 179° . When the limit of the adjustment range is reached, the value automatically wraps around.

8.6.5 Axis control functions

The TSDR-3000 provides several functions for efficient axis adjustment during subjective refraction.

Axis adjustment step

The axis adjustment increment may be selected according to the examination requirements.

Button	Description
A 1	Adjusts the axis in 1° increments.
A 5	Adjusts the axis in 5° increments.
A 15	Adjusts the axis in 15° increments. Available when SHIFT mode is enabled.
A 30	Adjusts the axis in 30° increments. Available when SHIFT mode is enabled.

Smaller increments are recommended for final refinement, while larger increments allow rapid adjustment during the initial stages of examination.

45-degree rotation buttons

Button	Description
+ 45 deg	Rotates the axis by +45°.
- 45 deg	Rotates the axis by -45°.

These buttons are useful when large axis changes are required during subjective refraction.

Cross Cylinder Control

The Cross Cylinder lens may be inserted or removed immediately using the dedicated control button.

Button	Description
CC on/off	Inserts or removes the Cross Cylinder lens.

This function allows the examiner to quickly switch between normal viewing and Cross Cylinder testing without changing the current examination mode.

NOTE	For precise astigmatic refinement, use smaller axis adjustment steps and the Cross Cylinder lens as appropriate.
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8.7 Jackson Cross Cylinder (JCC) examination

8.7.1 Purpose

The Jackson Cross Cylinder (JCC) test is used to refine the cylinder axis and cylinder power during subjective refraction. The TSDR-3000 provides a dedicated JCC test mode that assists the examiner in determining the optimum astigmatic correction.

8.7.2 Starting the JCC test

(1) Complete the preliminary subjective refraction and obtain an approximate cylinder correction.



(2) Touch button on the visual acuity chart control area.

(3) The JCC test screen appears and the selected Cross Cylinder lens is automatically inserted.

8.7.3 Axis refinement

Before performing axis refinement, slight overcorrection of cylinder power is recommended. A cylinder overcorrection of approximately -0.25 D to -0.50 D may improve sensitivity during the JCC procedure.

- (1) Select the Axis (A) parameter.
- (2) Present Position 1 and Position 2 using the JCC control.
- (3) Ask the patient: "Which is clearer, 1 or 2?"
- (4) Adjust the axis according to the patient's response.

Patient Preference	Description
	[Position 1 clearer] Increase axis value
	[Position 2 clearer] Decrease axis value
-	[No difference] Axis refinement completed

- (5) Repeat until no significant preference is reported.

8.7.4 Cylinder power refinement

After completing axis refinement:

- (1) Select the Cylinder (C) parameter.
- (2) Activate the Cross Cylinder lens.
- (3) Present Position 1 and Position 2.
- (4) Ask the patient: "Which is clearer, 1 or 2?"
- (5) Modify cylinder power according to the response.

Patient Preference	Description
	[Position 1 clearer] Increase minus cylinder power
	[Position 2 clearer] Decrease minus cylinder power
-	[No difference] Cylinder refinement completed

- (6) Repeat until no significant preference is reported.

8.7.5 Cross Cylinder lens selection

The following Cross cylinder lens types are available.

Lens type	Description
CC 0.25	± 0.25 D Jackson Cross cylinder lens.
CC 0.50	± 0.50 D Jackson Cross cylinder lens.
CC Dual	Dual cross Cylinder lens configuration.

NOTE	The TSDR-3000 provides guidance for JCC testing; however, interpretation of patient responses and determination of the final prescription remain the responsibility of the examiner.
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8.8 Prism adjustment

8.8.1 Purpose

Prism adjustment is used to introduce horizontal or vertical prism during binocular vision examinations and other specialized procedures. The TSDR-3000 supports both horizontal and vertical prism adjustment.

8.8.2 Prism types

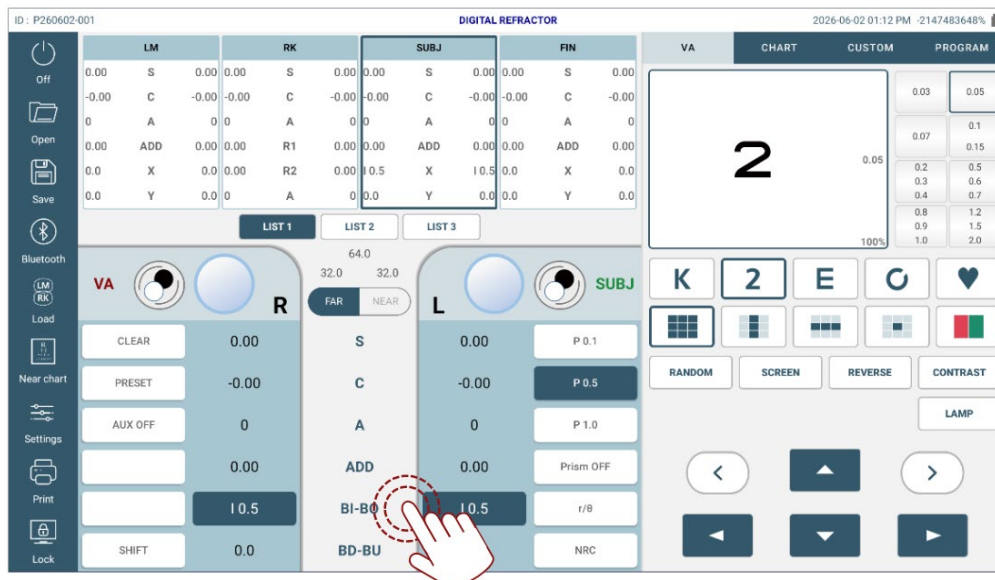
The following prism types are available.

Parameter	Description
BI-BO	Horizontal prism adjustment.
BD-BU	Vertical prism adjustment.

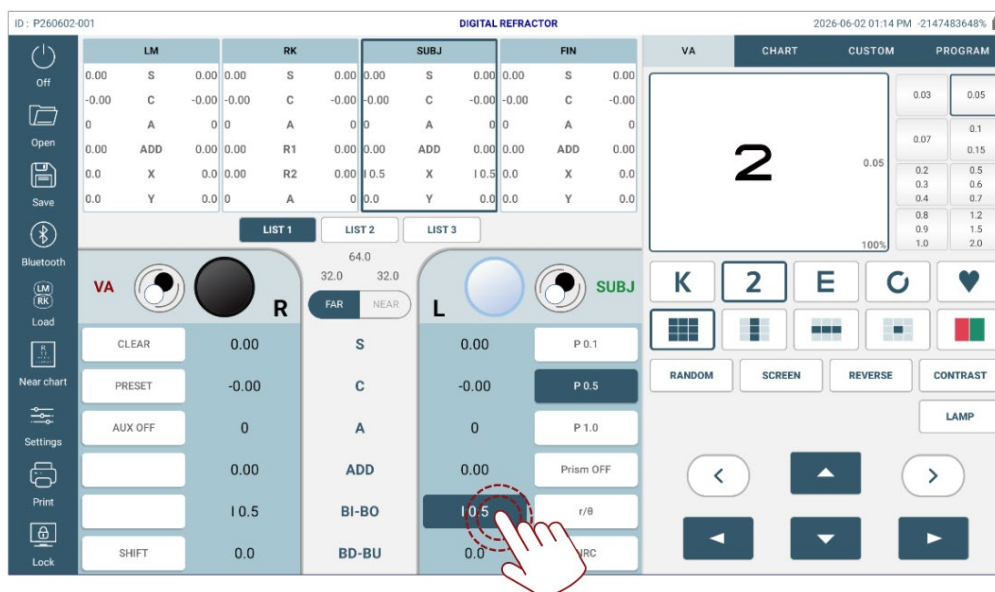
8.8.3 Horizontal prism adjustment (BI-BO)

The BI-BO parameter controls horizontal prism power.

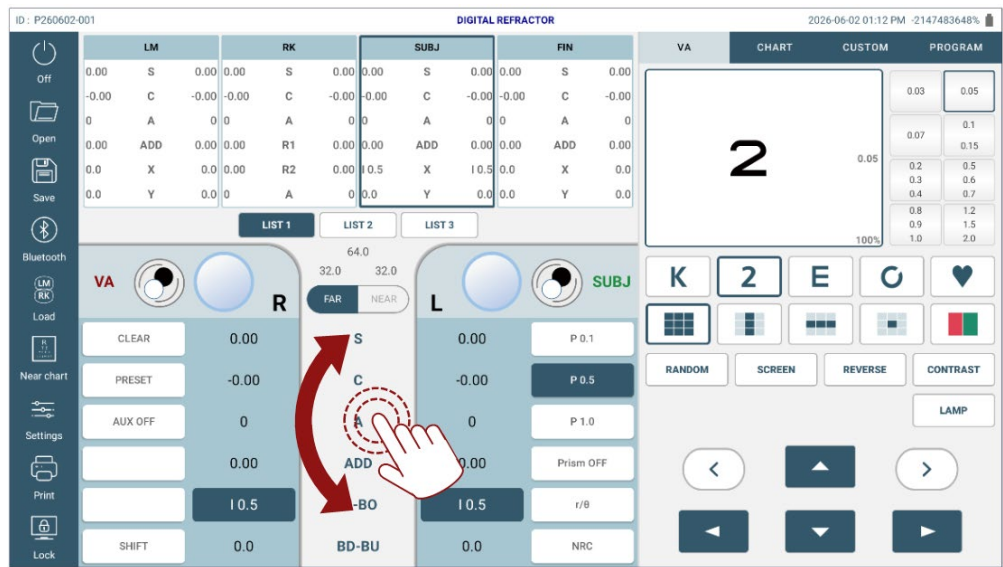
(1) Select BI-BO in the Lens control area.



(2) Select the eye to be adjusted.



(3) Adjust the prism value as required.



Positive and negative values are displayed as:

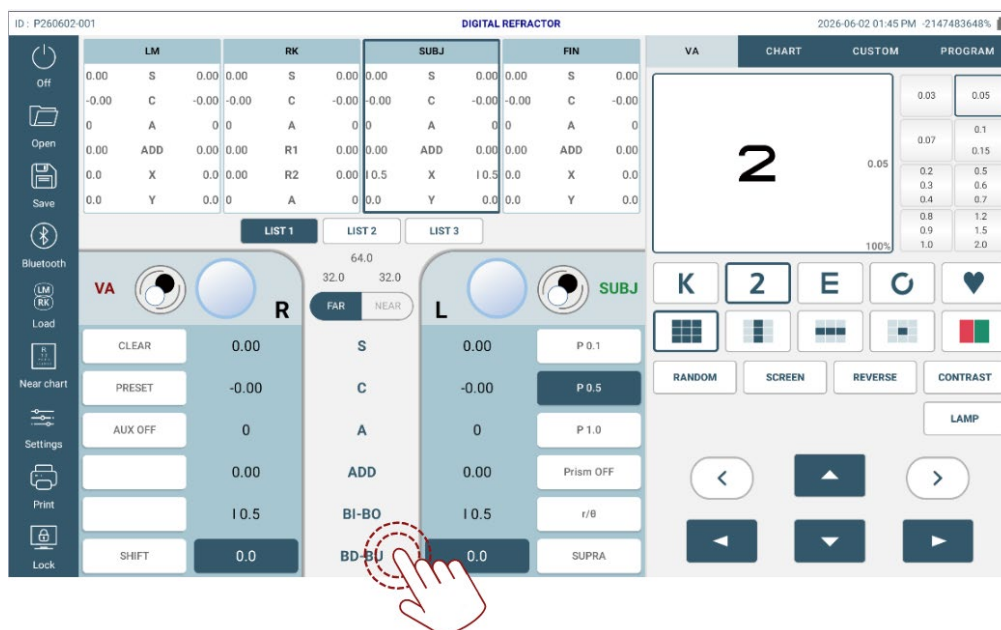
Direction	Description
BI	Base In
BO	Base Out

The current prism value is displayed continuously on the screen.

8.8.4 Vertical prism adjustment (BD-BU)

The BD-BU parameter controls vertical prism power.

(1) Select BD-BU in the Lens control area.



(2) Select the eye to be adjusted.



(3) Adjust the prism value as required.



Prism direction is displayed as:

Direction	Description
BD	Base Down
BU	Base Up

The current prism value is displayed continuously on the screen.

8.8.5 Prism display formats

The prism value may be displayed in one of the following formats.

Format	Description
X / Y	Displays horizontal and vertical prism components separately.
r / θ	Displays prism magnitude (r) and prism angle (θ) using polar coordinates.

To change the display format:

- (1) Select a prism parameter (BI-BO or BD-BU).
- (2) Touch the r / θ button.
- (3) The display format toggles between X / Y and r / θ .

This function allows the examiner to select the most appropriate prism representation for the examination.

8.8.6 Prism adjustment functions

The TSDR-3000 provides multiple prism adjustment increments for efficient prism control.

Button	Description
P 0.1	Adjusts prism power in 0.1 Δ increments.
P 0.5	Adjusts prism power in 0.5 Δ increments.
P 1.0	Adjusts prism power in 1.0 Δ increments.
P 2.0	Adjusts prism power in 2.0 Δ increments. Available when SHIFT mode is enabled.
P 3.0	Adjusts prism power in 3.0 Δ increments. Available when SHIFT mode is enabled.
Prism OFF	Removes the prism lens from the optical path.

NOTE	Prism values are expressed in prism diopters (Δ). The available adjustment increments may vary depending on the selected prism mode and examination settings.
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8.9 Near vision examination

8.9.1 Purpose

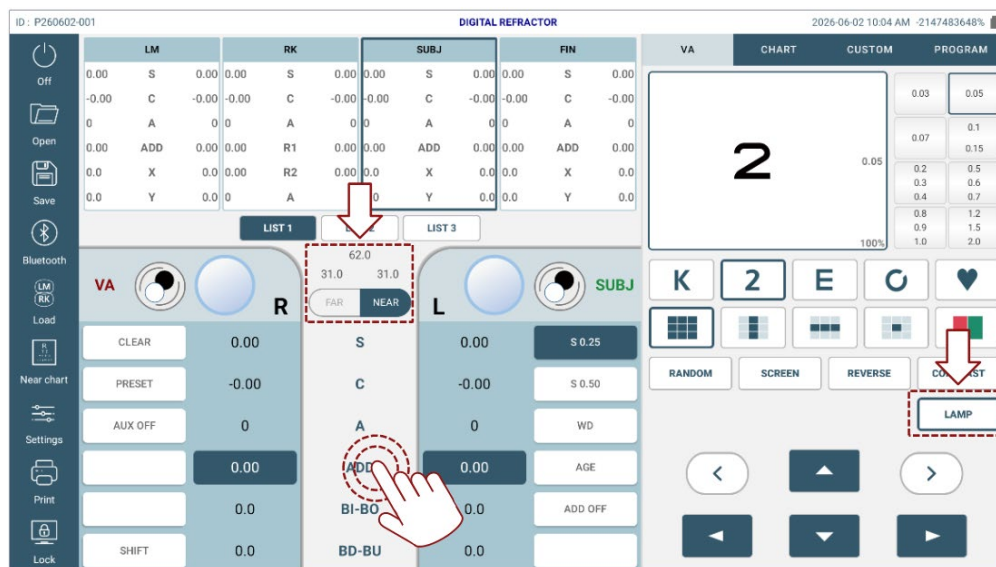
Near vision mode is used to determine the appropriate near addition (ADD) power and to perform near visual acuity examinations. Touch the NEAR button to activate Near Vision mode.

When Near Vision mode is activated:

- The programmed ADD value is applied.
- Near vision charts become available.
- Additional near vision functions are enabled.
- The Near point illuminator is automatically illuminated.

8.9.2 Adjusting the ADD power

- (1) Select the eye or eyes to be adjusted.
- (2) Touch the ADD parameter in the Lens control area.



- (3) Drag the control area upward or downward to increase or decrease the ADD value.
- (4) Observe the patient's responses while viewing a near target.
- (5) Continue adjustment until the optimum near vision correction is obtained.

The current ADD value is displayed continuously on the screen.

8.9.3 ADD adjustment step

The ADD adjustment increment may be selected using the step buttons.

Button	Description
S 0.25	0.25 D adjustment step
S 0.50	0.50 D adjustment step
S 1.00	1.00 D adjustment step Available when SHIFT mode is enabled.
S 2.00	2.00 D adjustment step Available when SHIFT mode is enabled.

The selected step size is highlighted on the screen.

8.9.4 Working distance (WD)

The working distance may be adjusted according to the patients' near working requirements.

- (1) Touch the WD button.
- (2) Drag the control Area upward or downward.
- (3) Set the desired working distance.

The working distance may be adjusted from 35 cm to 70 cm. (5 cm step)

8.9.5 Age setting (AGE)

The AGE function provides a reference value for near vision examinations

- (1) Touch the AGE button.
- (2) Drag the control area upward or downward.
- (3) Set the patient's age.

The age may be adjusted from 0 to 100 years.

8.9.6 ADD OFF function

The ADD OFF button temporarily removes the ADD power from the optical system. This function allows the examiner to compare distance and near correction conditions without changing the stored ADD value. Touch ADD OFF again to restore the previously selected ADD value.

NOTE	The AGE and WD functions are intended as examination aids. Final determination of the ADD value should be based on the patient's visual requirements, working distance, and the examiner's clinical judgment.
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8.10 Binocular balance test

8.10.1 Purpose

The Binocular Balance test is used to equalize the accommodative stimulus between the right and left eyes after monocular subjective refraction has been completed. The TSDR-3000 automatically inserts the required red/green filters and displays the binocular balance chart.

8.10.2 Starting the binocular balance test

- (1) Complete the monocular subjective refraction for both eyes.



- (2) Touch  button in the Visual acuity chart control area.

- (3) The TSDR-3000 automatically inserts the required red/green filters and displays the binocular balance test chart.



8.10.3 Examination procedure

- (1) Instruct the patient to observe the chart binocularly.
- (2) Ask the patient: "Which numbers appear clearer, the upper numbers or the lower numbers?"
- (3) Evaluate the patient's response.
 - If the upper numbers appear clearer, Increase the spherical power (S) of the left eye.
 - If the lower numbers appear clearer, increase the spherical power (S) of the right eye.
- (4) Repeat the procedure until the patient reports equal clarity between the upper and lower numbers.

8.10.4 Examination notes

The binocular balance test should be performed after completion of monocular subjective refraction. The TSDR-3000 automatically inserts the required dissociation lenses for this examination. Small spherical adjustments may be required to achieve balanced binocular vision. Final refractive values should be determined according to the examiner's clinical judgment.

NOTE	The goal of the binocular balance test is to obtain equal visual perception between the right and left eyes under binocular viewing conditions.
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8.11 Near addition tests

8.11.1 Near Add Cross Grid test

8.11.1.1 Purpose

The NearAdd Cross Grid test is used to determine the appropriate near addition (ADD) power by comparing the clarity of horizontal and vertical grid lines.

8.11.1.2 Procedure

- (1) Complete the distance subjective refraction.
- (2) Set the Near vision chart to the desired working distance (default: 40 cm).



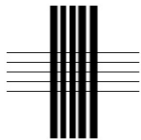
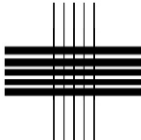
- (3) Touch  button in the Visual acuity chart control area.

- (4) The TSDR-3000 automatically configures the required examination conditions and displays the Near Add Cross Grid test screen.



- (5) Ask the patient whether the horizontal lines or vertical lines appear darker or clearer.
- (6) Adjust the ADD value as required.

Patient response	Action
Vertical lines appear darker or clearer	Decrease the ADD value.

	
Horizontal lines appear darker or clearer 	Increase the ADD value.
Both appear equally clear	Appropriate ADD value obtained.

(7) Repeat the procedure until the patient reports equal clarity of both line groups.

NOTE	The Near Add Cross Grid test should be performed at the patient's intended working distance whenever possible.
-------------	--

8.11.2 Near Add Visual Acuity test

8.11.2.1 Purpose

The Near Add Visual Acuity test is used to record the patients' near visual acuity after the appropriate ADD value has been determined.

8.11.2.2 Procedure

(1) Select the desired examination condition:

- Distance corrected
- Near corrected
- Monocular (Right or Left Eye)
- Binocular

(2) Set the near vision chart to the desired working distance (default: 40 cm).



(3) Touch  button in the Visual acuity chart control area.

(4) The Near Add Visual Acuity test screen is displayed.



- (5) Select the eye to be evaluated:
- Right Eye
 - Left Eye
 - Binocular
- (6) Present the near visual acuity chart and determine the patient's visual acuity.
- (7) Drag the control area to select the appropriate visual acuity result.

8.11.2.3 Available Results

Result	Description
NLP	No Light Perception.
LP	Light Perception.
LPJ	Light Projection. The patient can identify the direction of the light source.
HM	Hand Motion. The patient can detect movement of a hand in front of the eye.
CF	Counting Fingers. The patient can count the examiner's fingers.
0.03~2.0	Visual acuity measured using the near vision chart.

NOTE	Near visual acuity should be recorded using the patient's final near correction and the intended working distance.
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8.12 Duochrome test

8.12.1 Purpose

The Duochrome test is used to verify the spherical power endpoint by comparing the clarity of optotypes displayed on red and green backgrounds.

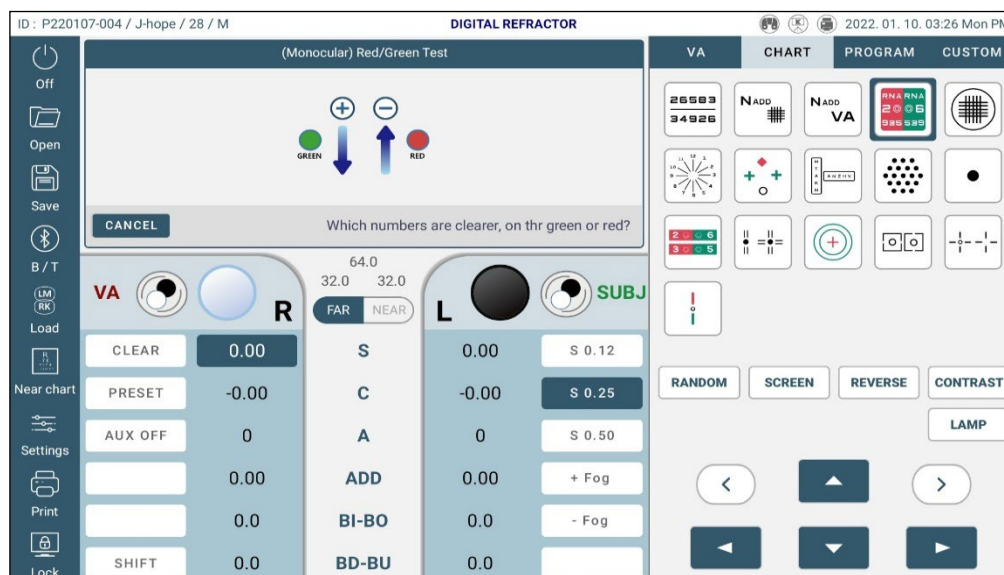
8.12.2 Procedure

- (1) Complete the monocular subjective refraction and determine the tentative spherical correction.



- (2) Touch  button in the Visual acuity chart control area.

- (3) The TSDR-3000 automatically displays optotypes on red and green backgrounds.



- (4) Ask the patient: "Which side appears clearer, the red side or the green side?"

(5) Adjust the spherical power according to the patient's response.

Patient response	Action
Red side clearer 	Add minus (-) sphere power.
Green side clearer 	Add plus (+) sphere power.
Both sides equally clear	Correct spherical endpoint achieved.

(6) Repeat the comparison until the patient reports equal clarity on both sides.

NOTE	The Duochrome test should be performed after obtaining the best visual acuity through subjective refraction.
NOTE	Small spherical changes (typically 0.25 D steps) are recommended during the refinement process.
NOTE	The test is based on the eye's longitudinal chromatic aberration and should be interpreted together with visual acuity findings.

8.12.3 Expected endpoint

The final spherical correction is considered appropriate when the patient reports that the optotypes on the red and green backgrounds appear equally clear.

8.13 Astigmatism tests

Astigmatism tests are used to determine and refine cylinder power and axis during subjective refraction. The TSDR-3000 provides several charts and test modes to assist in astigmatism evaluation.

8.13.1 Cross Grid test (Distance)

8.13.1.1 Purpose

The Cross Grid test is used to evaluate residual spherical error and to assist in determining whether additional spherical correction is required before proceeding with cylinder refinement.

8.13.1.2 Procedure

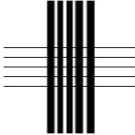
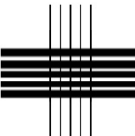


(1) Touch button in the Visual acuity chart control area.



(2) Ask the patient: "Which lines appear clearer, the horizontal lines or the vertical lines?"

(3) Adjust the spherical power according to the patient's response.

Patient response	Action
Vertical lines appear darker or clearer 	Increase minus sphere power.
Horizontal lines appear darker or clearer 	Increase plus sphere power.
Both appear equally clear	Spherical correction is considered balanced.

(4) Repeat the comparison until the patient reports equal clarity in both directions.

8.13.2 Clock Dial test (Cylinder Axis and Power test)

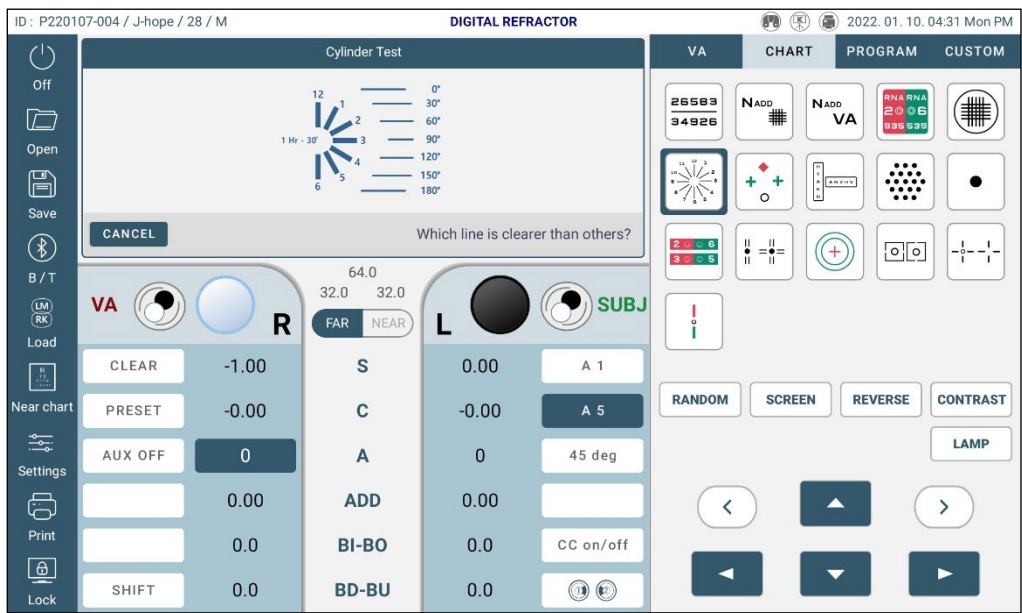
8.13.2.1 Purpose

The Clock Dial test is used to determine the presence and approximate axis of astigmatism.

8.13.2.2 Procedure



(1) Touch button in the Visual acuity chart control area.



(2) Ask the patient: "Which line or group of lines appears darkest or clearest?"

(3) If all lines appear equally clear, significant astigmatism may not be present.

(4) If one or more lines appear darker than the others, determine the corresponding axis direction.

(5) Adjust the cylinder axis and cylinder power according to the patient's response.

(6) Repeat the procedure until the patient reports that all clock dial lines appear equally clear.

NOTE	The Clock Dial test provides an approximate cylinder axis and should be followed by a Jackson Cross Cylinder test for refinement.
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8.14 Binocular vision tests

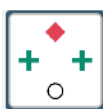
Binocular vision tests are used to evaluate sensory fusion, stereopsis, ocular dominance, and binocular coordination. The TSDR-3000 provides several binocular vision tests to assist in the assessment of binocular function.

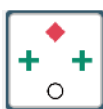
8.14.1 Worth Four Dots test

8.14.1.1 Purpose

The Worth Four Dot test is used to evaluate binocular fusion, ocular suppression, and diplopia under binocular viewing conditions.

8.14.1.2 Procedure

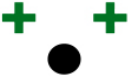
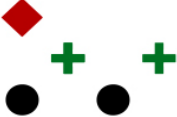


- (1) Touch  button in the Visual acuity chart control area.
- (2) The TSDR-3000 automatically presents the appropriate red and green filters required for the test.



- (3) Ask the patient: "How many dots do you see?"

(4) Record the patient's response and interpret the result according to the table below.

Patient response	Action
Four dots are visible 	Normal binocular fusion
Three dots are visible 	Right eye suppression
Two dots are visible 	Left eye suppression
Five dots are visible 	Diplopia
Five dots alternating or flashing	Alternating suppression

8.14.1.2 Additional interpretation

When four dots are visible:

- If the central dot appears red, the right eye is dominant.
- If the central dot appears green, the left eye is dominant.

When five dots are visible:

- If the red dot appears to the left of the green dots, the patient has esophoria/esotropia tendency.
- If the red dot appears to the right of the green dots, the patient has exophoria/exotropia tendency.

NOTE	The Worth Four Dot test evaluates sensory fusion rather than stereopsis.
NOTE	Alternating suppression may occur in patients with intermittent strabismus or significant interocular refractive differences.
NOTE	Test results should be interpreted together with other binocular vision assessments.

8.14.2 Stereo test

8.14.2.1 Purpose

The Stereo test is used to evaluate the patient's ability to perceive relative depth using binocular vision.

8.14.2.2 Procedure

(1) Perform the test after completing the distance refractive correction.



(2) Touch button in the Visual acuity chart control area.

(3) The TSDR-3000 automatically inserts the polarization filters required for the examination.



(4) Ask the patient: "Which bar appears closer to you, the upper bar or the lower bar?"

(5) Record the patient's response.

(6) If the patient reports that the upper bar appears closer, touch OK.

(7) If the patient reports that the lower bar appears closer, or cannot determine which bar appears closer, touch NG.

(8) The examination result is displayed and recorded automatically.

8.14.2.3 Interpretation

Result	Description
OK	Stereopsis is present.
NG	Stereopsis could not be confirmed.

NOTE	The Stereo test is a screening test for stereopsis and does not provide a quantitative stereoacuity value.
NOTE	For quantitative measurement of stereoacuity, perform the Minutes Stereo test described in section 8.14.3.
NOTE	Accurate binocular alignment and appropriate refractive correction are recommended before performing the test.

8.14.3 Minutes Stereo test

8.14.3.1 Purpose

The Minutes Stereo test is used to quantitatively evaluate stereopsis and determine the patient's stereoacuity level.

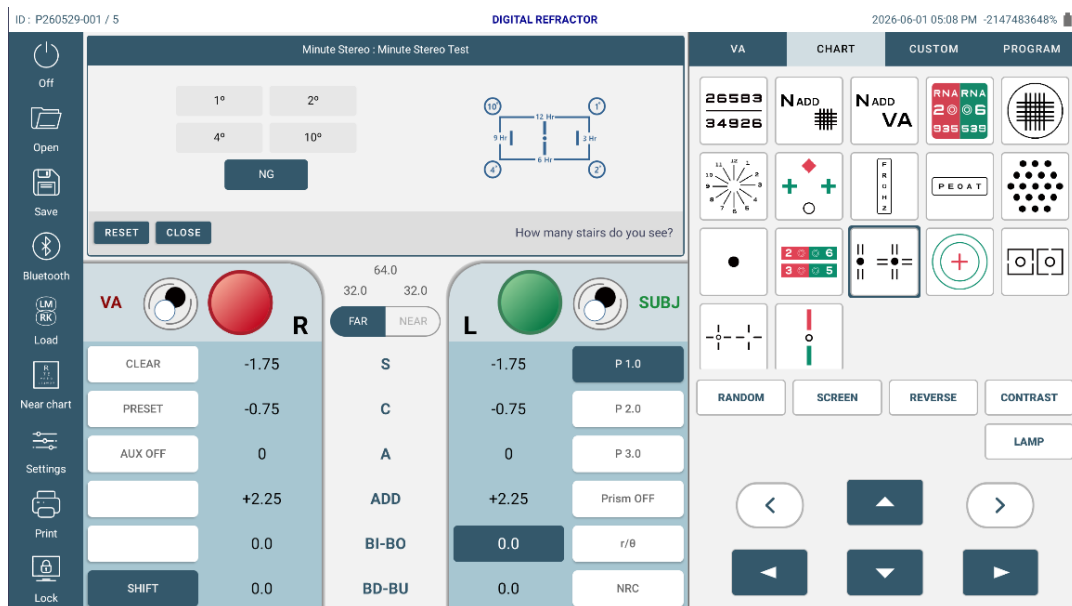
8.14.3.2 Procedure

(1) Perform the test after completing distance refractive correction.



(2) Touch button twice in the Visual acuity chart control area.

(3) The TSDR-3000 automatically inserts the polarization filters required for the examination.



(4) Ask the patient: "Do any of the bars at the 12Hr, 3Hr, 6Hr, or 9Hr positions appear closer or stand out in depth?"

(5) Record the patient's response according to the table below.

Patient response	Action
Bars at 12Hr and 3Hr appear stereoscopic	Select 1° button.
Bars at 3Hr and 6Hr appear stereoscopic	Select 2° button.
Bars at 6Hr and 9Hr appear stereoscopic	Select 4° button.
Bar at 12Hr appears stereoscopic	Select 10° button.
No stereoscopic effect can be identified	Select NG button.

(6) Touch the corresponding button to record the result.

8.14.3.3 Interpretation

Result	Stereoacuity
1°	1 minute of arc
2°	2 minutes of arc
4°	4 minutes of arc
10°	10 minutes of arc
NG	Stereopsis not detected

NOTE	Smaller values indicate better stereoacuity.
NOTE	The test should be performed with appropriate refractive correction and stable binocular fixation.
NOTE	If the patient cannot reliably identify any stereoscopic target, record the result as NG.
NOTE	The Minutes Stereo test provides a quantitative assessment of stereopsis, whereas the Stereo test described in section 8.14.2 provides only a qualitative screening result.

8.15 Phoria tests

This section describes the phoria measurement functions available in the TSDR-3000. These tests are used to evaluate latent ocular deviations under dissociated viewing conditions.

8.15.1 Horizontal Von Graefe test

8.15.1.1 Purpose

The Horizontal Von Graefe test is used to measure horizontal phoria (esophoria or exophoria).

8.15.1.2 Procedure



(1) Touch  button in the Visual acuity chart control area.

(2) When the test starts, the TSDR-3000 automatically inserts:

- Right eye: 6Δ Base Up
- Left eye: 12Δ Base In



(3) Ask the patient whether two separate targets are visible.

(4) If only one target is visible, increase the horizontal prism until the patient reports two separate targets.

(5) Ask the patient: "Is the upper target to the right or left of the lower target?"

(6) Adjust the horizontal prism while observing the patient's response until the two targets appear vertically aligned.

(7) When alignment is achieved, record the horizontal prism value displayed on the screen.

(8) Press SAVE to store the test result.

8.15.1.3 Expected endpoint

The endpoint is reached when the patient reports that the upper and lower targets are positioned directly above one another without any horizontal displacement.

8.15.1.4 Interpretation

- Base In (BI) value indicates exophoria.
- Base Out (BO) value indicates esophoria.
- A value close to zero indicates minimal horizontal phoria.

NOTE	The results of the Von Graefe test should be interpreted together with other binocular vision test results and the examiner's clinical judgment.
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8.15.2 Vertical Von Graefe test

8.15.2.1 Purpose

The Vertical Von Graefe test is used to measure vertical phoria.

8.15.2.2 Procedure



(1) Touch  button in the Visual acuity chart control area.

(2) When the test starts, the TSDR-3000 automatically inserts:

- Right eye: 6 Δ Base Up
- Left eye: 12 Δ Base In



- (3) Ask the patient whether two separate targets are visible.
- (4) If only one target is visible, increase the vertical prism until two separate targets are perceived.
- (5) Ask the patient: "Is the target on the right positioned above or below the target on the left?"
- (6) Adjust the vertical prism while observing the patient's response until both targets appear horizontally aligned.
- (7) When alignment is achieved, record the vertical prism value displayed on the screen.
- (8) Press SAVE to store the test result.

8.15.2.3 Expected endpoint

The endpoint is reached when the patient reports that the two targets are located at the same height without any vertical displacement.

8.15.1.4 Interpretation

- Base Up (BU) or Base Down (BD) values indicate the magnitude and direction of vertical phoria.
- A value close to zero indicates minimal vertical phoria.

NOTE	The prism values displayed and saved by the TSDR-3000 represent the phoria measurement obtained during the test and may be used as reference data for binocular vision assessment.
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8.15.3 Horizontal Maddox test

8.15.3.1 Purpose

The Horizontal Maddox test is used to measure horizontal phoria by dissociating the eyes with a Maddox rod and determining the prism amount required to align the perceived line and fixation light.

8.15.3.2 Procedure



(1) Touch button in the Visual acuity chart control area.

(2) The TSDR-3000 automatically inserts the Maddox rod and displays a fixation light.



(3) Ask the patient: "Is the vertical red line passing through the fixation light, or is it located to the right or left of the light?"

(4) Adjust the BI/BO prism until the vertical line and fixation light are aligned.

(5) Interpret the patient's response as follows:

Patient response	Adjustment
Vertical line appears to the right of the fixation light	Increase BO prism (Esophoria)
Vertical line appears to the left of the fixation light	Increase BI prism (Exophoria)

(6) Continue adjusting the prism until the patient reports that the vertical line passes directly through the fixation light.

(7) Record the prism value displayed on the screen and press SAVE.

8.15.3.3 Expected endpoint

The endpoint is reached when the patient reports that the vertical Maddox line and the fixation light are perfectly aligned.

8.15.3.4 Interpretation

Result	Interpretation
BI prism required for alignment	Exophoria
BO prism required for alignment	Esophoria
0Δ	Orthophoria

8.15.4 Vertical Maddox test

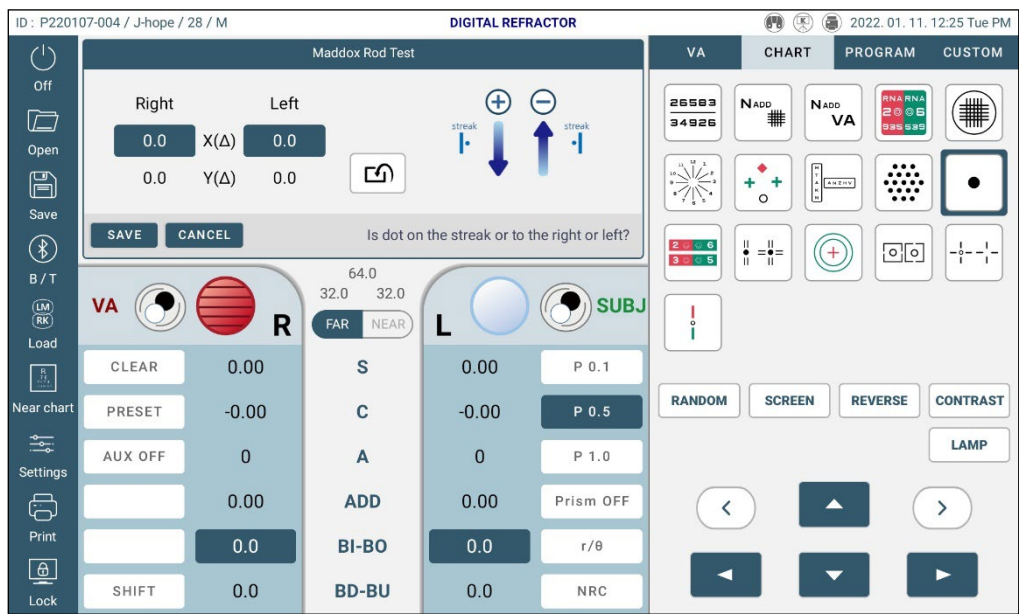
8.15.4.1 Purpose

The Vertical Maddox test is used to measure vertical phoria by aligning a horizontal Maddox line with a fixation light using vertical prism.

8.15.4.2 Procedure



- (1) Touch button twice in the Visual acuity chart control area.
- (2) The TSDR-3000 automatically inserts the Maddox rod and displays a fixation light.



- (3) Ask the patient: "Is the horizontal line above or below the fixation light?"
- (4) Adjust the BD/BU prism until the horizontal line and fixation light become aligned.
- (5) Interpret the patient's response as follows:

Patient response	Adjustment
Horizontal line appears below the fixation light	Add BD prism to the right eye (Right Hyperphoria)
Horizontal line appears above the fixation light	Add BU prism to the right eye (Right Hypophoria)

(6) Continue adjusting the prism until the patient reports that the horizontal line passes directly through the fixation light.

(7) Record the prism value displayed on the screen and press SAVE.

8.15.4.3 Expected endpoint

The endpoint is reached when the patient reports that the horizontal Maddox line and fixation light are located at the same height.

8.15.4.4 Interpretation

Result	Interpretation
BU prism required for alignment	Right Hypophoria
BD prism required for alignment	Right Hyperphoria
0Δ	Orthophoria

NOTE

The Maddox test provides a highly dissociated phoria measurement and is particularly useful for detecting small horizontal and vertical deviations under monocular dissociation conditions.

8.16 Fusion and Coincidence tests

Fusion and Coincidence tests are used to evaluate the patient's ability to maintain binocular fusion and to determine the presence and magnitude of ocular deviation. These examinations assist the examiner in assessing binocular alignment and sensory fusion status.

8.16.1 Schober test

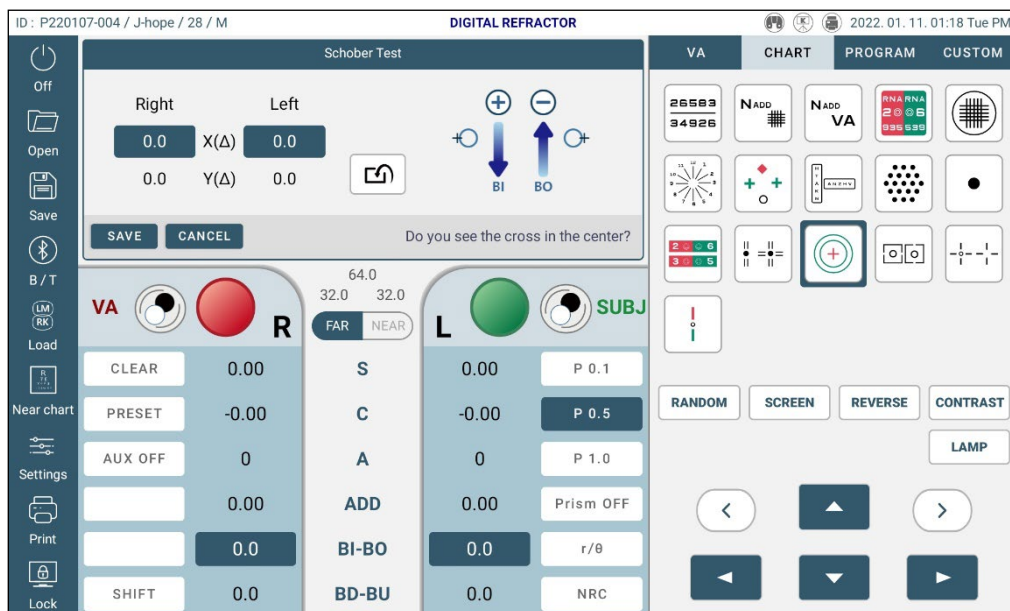
8.16.1.1 Purpose

The Schober test is used to evaluate binocular fusion and coincidence and to estimate horizontal and vertical phoria by prism neutralization.

8.16.1.2 Procedure



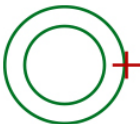
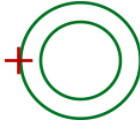
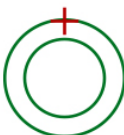
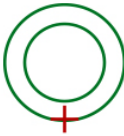
- (1) Touch  button in the Visual acuity chart control area.
- (2) The Schober target consists of a green circular ring and a red fixation cross presented under binocular dissociation conditions.



- (3) Ask the patient: "Do you see the red cross in the center of the green circle?"
- (4) If the patient reports that the red cross is located in the center of the green circle, binocular alignment is considered normal and the examination may be completed.

- (5) If the red cross is not centered, ask the patient whether the cross appears to the right, left, above, or below the center of the circle.
- (6) Adjust the prism value until the patient reports that the red cross is positioned in the center of the green circle.

8.16.1.3 Interpretation and prism neutralization

Patient's view	Interpretation	Prism neutralization
	Esophoria	Apply BO prism binocularly
	Exophoria	Apply BI prism binocularly
	Right Hypophoria or Left Hyperphoria	Apply BU prism to the right eye or BD prism to the left eye
	Right Hyperphoria or Left Hypophoria	Apply BD prism to the right eye or BU prism to the left eye

8.16.1.4 Recording the result

Record the horizontal and/or vertical prism value required to align the red cross with the center of the green circle.

8.16.2 Horizontal Coincidence test

8.16.2.1 Purpose

The Horizontal Coincidence Test is used to evaluate horizontal binocular alignment and to determine the amount of horizontal phoria required for binocular coincidence.

8.16.2.2 Procedure



(1) Touch button in the Visual acuity chart control area.

(2) Ask the patient whether two square targets are visible and whether the upper and lower squares are horizontally aligned.



(3) If the targets are not aligned, adjust the horizontal prism value (BI-BO) until the patient reports that the upper and lower squares are vertically aligned.

(4) After alignment is achieved, ask the patient whether the two squares appear to be the same size.

(5) Record the prism value required to achieve alignment.

8.16.2.3 Interpretation

Patient's response	Diagnosis	Prism adjustment
Upper square appears to the right of the lower square	Esophoria	Increase BO prism
Upper square appears to the left of the lower square	Exophoria	Increase BI prism
Upper and lower squares are aligned	Horizontal alignment achieved	Record prism value
Squares are aligned but appear different in size	Aniseikonia suspected	One line difference corresponds to approximately 3.5% image-size difference

8.16.3 Vertical Coincidence test

8.16.3.1 Purpose

The Vertical Coincidence test is used to evaluate vertical binocular alignment and to determine the amount of vertical phoria required for binocular coincidence.

8.16.3.2 Procedure



- (1) Touch button three times in the Visual acuity chart control area.
- (2) Ask the patient whether two square targets are visible and whether the right and left squares are vertically aligned.



- (3) If the targets are not aligned, adjust the vertical prism value (BD-BU) until the patient reports that the two squares are horizontally aligned.
- (4) After alignment is achieved, ask the patient whether the two squares appear to be the same size.
- (5) Record the prism value required to achieve alignment.

8.16.3.3 Interpretation

Patient's response	Diagnosis	Prism adjustment
Red square appears higher than green square	Right Hypophoria or Left Hyperphoria	Increase BU prism OD or BD prism OS
Green square appears higher than red square	Right Hyperphoria or Left Hypophoria	Increase BD prism OD or BU prism OS
Squares are vertically aligned	Vertical alignment achieved	Record prism value
Squares are aligned but appear different in size	Aniseikonia suspected	One line difference corresponds to approximately 3.5% image-size difference

8.16.4 Cross test with Fixation Point

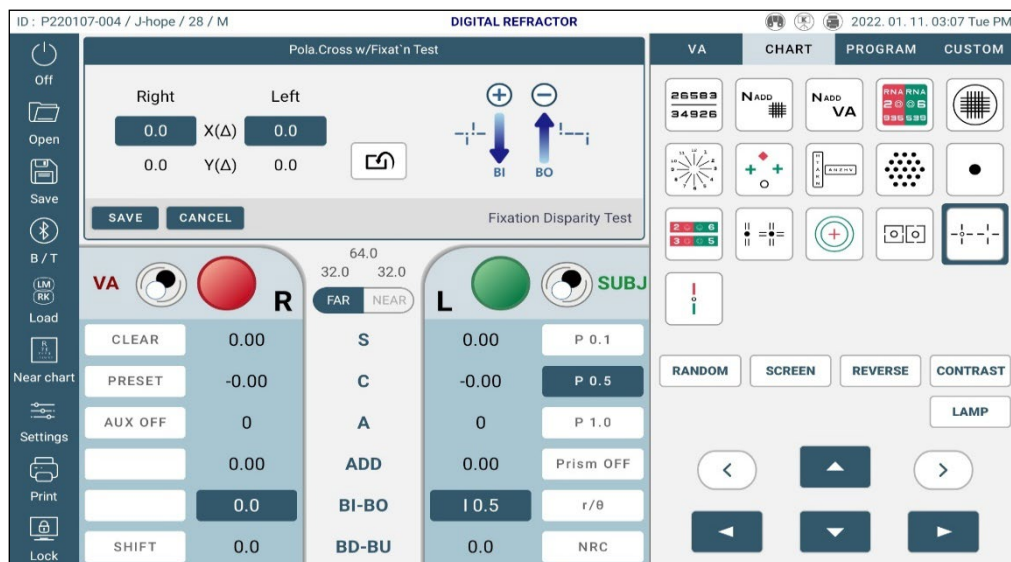
8.16.4.1 Purpose

The Cross test with Fixation Point is used to evaluate horizontal and vertical phoria simultaneously using polarized fixation targets. The test allows rapid identification of binocular alignment abnormalities and determination of the prism correction required for alignment.

8.16.4.2 Procedure

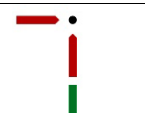
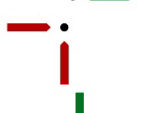
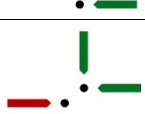
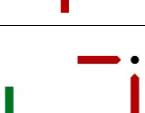


- (1) Touch  button in the Visual acuity chart control area.
- (2) Ask the patient whether the red and green line segments form a complete cross.



- (3) If the patient reports that the cross is complete and properly aligned, binocular alignment is considered normal.
- (4) If the cross is not aligned, determine whether the horizontal or vertical components are displaced.
- (5) Adjust the horizontal prism (BI-BO) and/or vertical prism (BD-BU) until the patient reports that the red and green line segments form a complete cross.
- (6) Record the prism values required to achieve alignment.

8.16.4.3 Interpretation

Patient's view	Interpretation	Prism Neutralization
	Esophoria	Increase BO prism until alignment is achieved.
	Exophoria	Increase BI prism until alignment is achieved.
	Right Hyperphoria (Left Hypophoria)	Adjust BD-BU prism until alignment is achieved.
	Right Hypophoria (Left Hyperphoria)	Adjust BD-BU prism until alignment is achieved.
	Esophoria + Right Hypophoria	Increase BO prism and adjust BD-BU prism until alignment is achieved.
	Esophoria + Right Hyperphoria	Increase BO prism and adjust BD-BU prism until alignment is achieved.
	Exophoria + Right Hypophoria	Increase BI prism and adjust BD-BU prism until alignment is achieved.
	Exophoria + Right Hyperphoria	Increase BI prism and adjust BD-BU prism until alignment is achieved.

8.17 Special tests

The tests described in this section provide additional information regarding binocular balance, ocular dominance, and subjective refraction.

8.17.1 Polarized Red/Green test

8.17.1.1 Purpose

The Polarized Red/Green test is used to evaluate binocular balance and refine the spherical correction of each eye under binocular viewing conditions.

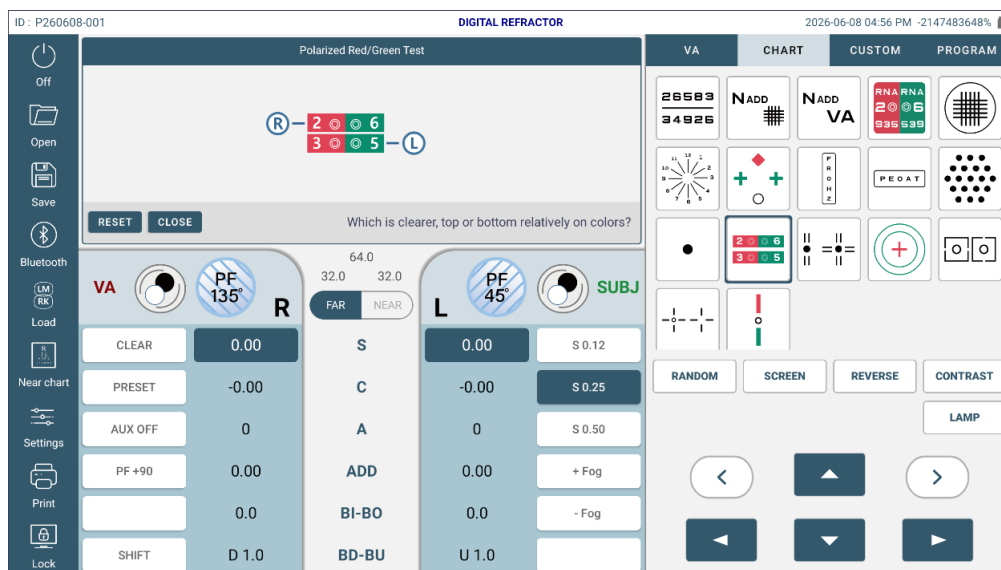
IMPORTANT

The Polarized Red/Green test functions correctly only when used with a compatible polarized chart system, such as the TSLC-2000P. Standard LCD chart systems without polarization capability cannot be used for this test.

8.17.1.2 Procedure



- (1) Touch  button in the Visual acuity chart control area.
- (2) Confirm the patient's dominant eye before beginning the test.



(3) Compare the red and green characters in the upper target and adjust the right-eye spherical power according to the table below.

Patient response (Upper target)	Adjustment
Red-side characters appear clearer	Increase the right-eye spherical power in the minus direction
Green-side characters appear clearer	Increase the right-eye spherical power in the plus direction

(4) Compare the red and green characters in the lower target and adjust the left-eye spherical power according to the table below.

Patient response (Lower target)	Adjustment
Red-side characters appear clearer	Increase the left-eye spherical power in the minus direction
Green-side characters appear clearer	Increase the left-eye spherical power in the plus direction

(5) Compare the upper target and lower target and adjust binocular balance according to the table below.

Patient response	Adjustment
Upper target appears clearer	Increase the right-eye spherical power in the plus direction
Lower target appears clearer	Increase the left-eye spherical power in the plus direction
Upper and lower targets appear equally clear	Binocular balance achieved

8.17.1.3 Expected endpoint

The red and green targets appear equally clear, and the upper and lower targets appear equally clear under binocular viewing conditions.

8.17.2 Dominant eye test

8.17.2.1 Purpose

The Dominant Eye test is used to determine the patient's sensory dominant eye for binocular balancing procedures.

8.17.2.2 Procedure



(1) Touch button in the Visual acuity chart control area.

(2) Ask the patient to identify which colored bar the fixation point appears to follow.



(3) If the fixation point follows the red bar, record the right eye as the dominant eye.

(4) If the fixation point follows the green bar, record the left eye as the dominant eye.

(5) Save the result.

8.17.2.3 Interpretation

Patient response	Dominant eye
Fixation point follows the red bar	Right eye dominant
Fixation point follows the green bar	Left eye dominant

NOTE	The dominant eye identified by this test may be used as a reference during binocular balance procedures.
NOTE	In cases where binocular balance cannot be fully achieved, the final prescription may be biased toward the dominant eye.

9 Maintenance and service

9.1 Routine cleaning

9.1.1 General precautions

To maintain proper performance and prolong the service life of the TSDR-3000, routine cleaning shall be performed regularly. Before cleaning:

- (1) Turn OFF the Junction box power switch.
- (2) Turn OFF the Tablet controller.
- (3) Disconnect the power cord from the AC outlet.
- (4) Ensure that all system components are completely powered down.

	Do not clean the device while power is applied.
	Do not allow liquids to enter any openings or connectors.
	Do not use excessive force during cleaning.
	Never use organic solvents such as thinner, benzene, acetone, or alcohol-based industrial cleaners.

9.1.2 Cleaning of exterior surfaces

The exterior surfaces of the Refractor head, Junction box, and Tablet controller may be cleaned using a soft dry cloth. If necessary:

- (1) Slightly moisten a soft cloth with water or a mild neutral detergent solution.
- (2) Wipe the contaminated surface carefully.
- (3) Remove any remaining moisture with a dry cloth.



Do not spray liquids directly onto the device.

9.1.3 Cleaning of optical lenses through measuring windows

The measuring windows and observation apertures shall be kept clean to ensure accurate examination results.

- (1) Remove dust using a blower or soft brush.
- (2) Wipe the optical surfaces gently using a lint-free optical cleaning cloth.
- (3) Inspect the surfaces for fingerprints, dust, or smudges.



Scratches or contamination of optical surfaces may affect examination performance.

9.1.4 Cleaning and disinfection of forehead rest and face shields

The forehead rest and face shields come into direct contact with the patient during examination and shall be cleaned and disinfected after each patient.

- (1) Wipe the forehead rest and face shields using a soft cloth or disposable wipe moistened with 70% isopropyl alcohol (IPA).
- (2) Ensure that all patient-contact surfaces are thoroughly cleaned.
- (3) Allow the surfaces to air dry completely before the next examination.
- (4) Inspect the surfaces for contamination, damage, or excessive wear.

	Cleaning and disinfection shall be performed after each patient to reduce the risk of cross-contamination.
	Do not spray liquid directly onto the device.
	Do not allow cleaning fluids to enter the interior of the instrument.
	Do not use abrasive cleaners or solvents that may damage plastic surfaces.
	Repeated use of disinfectants other than 70% isopropyl alcohol may discolor or damage plastic components.

9.1.5 Inspection After Cleaning

After cleaning:

- Verify that all surfaces are dry.
- Verify that no cleaning materials remain inside the device.
- Verify that all optical windows are clean and unobstructed.
- Verify normal operation before returning the device to clinical use.

9.2 Inspection before use

The operator shall perform the following inspection before using the TSDR-3000 to ensure safe and proper operation. If any abnormality is detected, discontinue use and contact qualified service personnel.

9.2.1 Exterior Inspection

Inspect the exterior condition of the system. Verify that:

- The Refractor head is free from visible damage.
- The Junction box enclosure is not cracked or deformed.
- The Tablet controller screen is free from excessive damage.
- The forehead rest and face shields are securely attached.
- No loose parts are present.



Do not use the device if any mechanical damage is observed.

9.2.2 Power Supply Inspection

Inspect the power supply components before use. Verify that:

- The power adapter is free from damage.
- The power cord insulation is intact.
- The AC plug is not damaged.
- All connectors are securely connected.



Do not use damaged power cords or adapters.

9.2.3 Optical System Inspection

Verify that the optical components are clean and unobstructed. Check for:

- Dust or contamination on observation windows.
- Scratches on optical surfaces.
- Obstructions within the viewing path.



Contaminated optical surfaces should be cleaned before use.

9.2.4 Functional Inspection

Power ON the system and verify normal operation. Confirm that:

- The Tablet controller starts normally.
- Communication between the Tablet controller and Refractor head is established.
- Lens movement operates normally.
- Occluders operate normally.
- Near-point illumination operates normally.
- Examination charts are displayed correctly.
- All control buttons respond properly.

9.2.5 Patient-contact surface inspection

Before each patient examination, verify that:

- The forehead rest is clean and disinfected.
- The face shields are clean and disinfected.
- No cracks, sharp edges, or excessive wear are present.

NOTE

If contamination is observed, clean and disinfect the surfaces according to section 9.1 before use.

9.2.6 Inspection Result

The device may be used only when all inspection items have been completed successfully. If any abnormality is detected during inspection:

- Stop using the device.
- Disconnect the power if necessary.
- Contact qualified service personnel or the manufacturer.

9.3 Functional verification after service

After completion of any repair, adjustment, software update, component replacement, or maintenance activity, the service personnel shall perform a functional verification before returning the device to clinical use. The purpose of this verification is to confirm that the TSDR-3000 operates according to its intended performance and that no abnormalities have been introduced during the service procedure.

9.3.1 Verification procedure

Item	Verification
Power supply	Verify that the system powers ON and OFF normally.
Refractor head	Verify normal initialization and operation of the refractor head.
Lens movement	Verify proper movement and positioning of spherical, cylindrical, and auxiliary lenses.
Occluders	Verify correct operation of the right and left occluders.
Near-point unit	Verify proper movement and positioning of the near-point unit.
Near-point illumination	Verify that the near-point illumination turns ON and OFF normally.
Tablet controller	Verify normal startup and operation of the tablet controller.
Touch-screen operation	Verify correct response of all touch controls.
Communication	Verify communication between the tablet controller, junction box, and refractor head.
Examination functions	Verify normal operation of examination charts and test functions.
Bluetooth functions	Where applicable, verify communication with connected Bluetooth devices.
Printer functions	Where applicable, verify proper operation of the connected printer.
Display indicators	Verify that all status indicators are displayed correctly.
Mechanical condition	Verify that covers, brackets, screws, and internal components are securely installed.

9.3.2 Verification result

The device may be returned to clinical service only if all verification items are completed successfully. If any abnormality is detected:

- (1) Remove the device from service.
- (2) Identify and correct the cause of the abnormality.
- (3) Repeat the verification procedure.
- (4) Return the device to clinical use only after successful completion of all verification items.

9.3.3 Service record

The manufacturer recommends maintaining a service record that includes:

- Date of service
- Description of service performed
- Parts replaced (if applicable)
- Software version (if updated)
- Verification result
- Name of service personnel

Maintaining service records facilitates traceability and supports preventive maintenance activities.

9.4 Fuse replacement

9.4.1 General precautions

The Junction box is equipped with a replaceable fuse to protect the system against excessive current conditions.

Replace the fuse only when it is confirmed that the fuse has failed.

	Disconnect the power cord from the AC outlet before replacing the fuse.
	Replace the fuse only with a fuse of the specified type and rating.
	Use of an incorrect fuse may result in fire, electric shock, or equipment damage.
	If the replacement fuse fails repeatedly, discontinue use and contact qualified service personnel.

9.4.2 Fuse specification

Item	Specification
Fuse type	Time-delay (Slow-blow) fuse
Rated current	2 A
Rated voltage	250 V AC
Fuse size	5 x 20 mm
Quantity	2

Replace only with a fuse of the same type, current rating, voltage rating, and dimensions as the original fuse.

9.4.3 Fuse replacement procedure

- (1) Turn OFF the Junction box power switch.
- (2) Disconnect the power cord from the AC outlet.
- (3) Locate the fuse holder on the rear panel of the Junction box.
- (4) Open the fuse holder using an appropriate tool if necessary.
- (5) Remove the blown fuse.
- (6) Verify that the replacement fuse matches the specified type and rating.
- (7) Install the replacement fuse into the fuse holder.
- (8) Reinstall and secure the fuse holder.
- (9) Reconnect the power cord.
- (10) Turn ON the Junction box and verify normal operation.

9.4.4 Verification after replacement

After replacing the fuse:

- Verify that the system powers ON normally.
- Verify that communication with the Refractor head is established.
- Verify normal lens operation.
- Verify that no abnormal noise, odor, or overheating is present.

If any abnormality is observed, immediately disconnect the power and contact qualified service personnel.

NOTE	A blown fuse may indicate an internal electrical fault. If the replacement fuse fails again, do not continue replacing fuses. The device should be inspected by qualified service personnel before further use.
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9.5 Storage and transportation

9.5.1 Storage conditions

When the device is not in use for an extended period, store it under the following environmental conditions:

Item	Condition
Temperature	-10 °C to +40 °C
Relative Humidity	10 % to 90 % (non-condensing)
Atmospheric pressure	80 kPa to 106 kPa

When storing the product, ensure that the following conditions:

- It shall not be splashed with water.
- Store the product away from environments where air pressure, temperature, humidity ventilation sunlight, dust, salty/sulfurous air, etc. could cause damage.
- Do not store the instrument where chemicals are stored or gas is generated.

9.5.2 Transportation conditions

During transportation, the device shall remain in its original packaging or equivalent protective packaging.

Environmental conditions during transportation:

Item	Condition
Temperature	-10 °C to +40 °C
Relative Humidity	10 % to 90 % (non-condensing)
Atmospheric pressure	80 kPa to 106 kPa

Avoid exposure to:

- Excessive shock or vibration
- Direct rain or water ingress
- Excessive heat
- Strong magnetic fields
- Stacking loads exceeding package specifications

9.5.3 Transportation precautions

Before transportation:

- (1) Turn OFF the system.
- (2) Disconnect the power cord and all accessories.
- (3) Secure all movable components.
- (4) Pack the Refractor head, Junction box, Tablet controller, and accessories separately using protective cushioning materials.
- (5) Use the original shipping carton whenever possible.



Improper packaging may result in damage to optical, mechanical, or electronic components.

9.5.4 Inspection after transportation

After transportation:

- (1) Inspect the packaging for visible damage.
- (2) Verify that all components are present.
- (3) Inspect the device for signs of mechanical damage.
- (4) Perform the inspection procedure described in section 9.2 before use.
- (5) Verify normal operation before placing the device into service.

9.5.5 Condensation precaution

If the device has been transported or stored under significantly different temperature conditions, allow the system to stabilize at room temperature before use.

	Condensation inside the device may result in malfunction or electrical hazards.
	Do not power ON the device until all condensation has completely evaporated.

9.6 Disposal Information

The TSDR-3000 contains electrical and electronic components that shall be disposed of in accordance with applicable local regulations for Waste Electrical and Electronic Equipment (WEEE) or equivalent national requirements.

- Do not dispose of the device as unsorted municipal waste.
- Electronic components, cables, power adapters, and optional accessories shall be collected separately for recycling or environmentally responsible disposal.
- If the supplied tablet computer contains a rechargeable battery, dispose of the battery in accordance with local battery disposal regulations.
- The device contains no biological materials, hazardous patient-contacting substances, or infectious components requiring special biomedical waste handling.
- Prior to disposal, remove any patient information stored in the system in accordance with local data protection requirements.

For additional information regarding disposal and recycling, contact the manufacturer or authorized distributor.

10 Troubleshooting

If the device does not operate as expected, refer to the following table before contacting service personnel. If the problem persists after performing the recommended corrective action, discontinue use and contact the manufacturer or qualified service personnel.

10.1 Troubleshooting guide

Event	Possible cause	Recommended action
Device does not power ON	Power cord disconnected	Verify power cord connection.
	AC outlet has no power	Verify AC power supply.
	Fuse is blown	Inspect and replace the fuse as described in section 9.4.
Tablet controller does not start	Battery discharged	Charge the tablet controller.
	System software error	Restart the tablet controller.
No communication between Tablet controller and Refractor head	Communication cable disconnected	Verify cable connections.
	Junction box not powered	Verify Junction box power status.
	Internal communication error	Restart the system.
Lens does not move properly	Internal mechanical obstruction	Restart the system and repeat initialization.
	Drive mechanism failure	Contact service personnel.
Occluder does not operate	Internal mechanism error	Restart the system.
	Drive mechanism failure	Contact service personnel.
Near-point unit does not move	Positioning mechanism error	Restart the system.
	Mechanical failure	Contact service personnel.
Near-point illumination does not operate	Illumination disabled	Verify illumination settings.
	LED failure	Contact service personnel.
Bluetooth device cannot connect	Bluetooth disabled	Verify Bluetooth settings.
	Device out of range	Move the Bluetooth device closer to the

		system.
	Pairing failure	Repeat the pairing procedure.
Printer does not print	Printer power OFF	Verify printer power.
	Bluetooth connection failure	Reconnect the printer.
	Paper exhausted	Replace paper roll.
	Battery discharged	Charge the printer.
Examination chart not displayed correctly	Software malfunction	Restart the application.
	Display communication error	Restart the system.

10.2 Service required

Immediately discontinue use and contact qualified service personnel if any of the following conditions occur:

- Smoke, unusual odor, or abnormal heat is observed.
- Liquid has entered the device.
- The device has been dropped or subjected to severe impact.
- The enclosure is cracked or damaged.
- Repeated fuse failure occurs.
- Normal operation cannot be restored after troubleshooting.

11 Technical specifications

11.1 Measurement range

Item	Specification
Spherical Lens	-29.00 D to +26.75 D (Regular) -19.00 D to +16.75 D (Cross Cylinder or Prism tests)
Sphere Step	0.12 / 0.25 / 0.50 / 1.00 / 2.00 / 3.00 D
Cylinder Lens	0.00 D to ±8.75 D
Cylinder Step	0.12 / 0.25 / 0.50 / 1.00 / 2.00 / 3.00 D
Cylinder Axis	0° to 179°
Axis Step	1° / 5° / 15° / 30° / 45°
Pupillary Distance (PD)	48 mm to 80 mm
PD Step	0.5 mm / 1.0 mm
Near PD	50 mm to 74 mm
Near Working Distance	35 cm to 70 cm
Rotary Prism Lens	0Δ to 20Δ
Prism Step	0.1 / 0.2 / 0.5 / 1 / 2Δ
Cross Cylinder	±0.25 D, ±0.50 D
Dual Cross Cylinder	±0.25 D Prism Split Lens
Retinoscopic Lens	+1.5 D, +2.0 D

11.2 Auxiliary lenses

Item	Specification
Occluding Aperture	Provided
Pinhole Lens	Ø 2 mm
Maddox Rod	Right Eye (Red, Horizontal) / Left Eye (Red, Vertical)
Red/Green Filter	Right Eye (Red) / Left Eye (Green)
Polarizing Filter	Right Eye (135°, 45°) / Left Eye (45°, 135°)
Split Prism	Right Eye: 6Δ BU Left Eye: 10Δ BI, 0–5Δ Complement
PD Check Lens	Provided
Fixed Cross Cylinder Lens	±0.50 D (Axis fixed at 90°)
Visual Field	40° (VD = 12 mm)

11.3 Hardware specifications

Item	Specification
Refractor head	343(W) × 105(D) × 277(H) mm, 2.8 kg
Junction box	142(W) × 180(D) × 51(H) mm, 0.8 kg
Tablet controller	Samsung Galaxy Tab Series 257(W) × 168(D) × 7(H) mm, 0.5 kg
Portable printer	75(W) × 105(D) × 45(H) mm, 0.2 kg

11.4 Electrical specifications

Item	Specification
Power Input	AC 100-240V, 50/60Hz
Consumption	50 VA
Fuse	5 × 20 mm Time-delay Fuse

12 IT and Cybersecurity information

12.1 Minimum hardware requirements

- Use only the Digital Refractor head, junction box, tablet computer, power adapter, printer, and accessories supplied or approved by the manufacturer.
- Do not modify the operating system, application software, firmware, or hardware components.
- Ensure a stable AC power supply of 100–240 Vac, 50/60 Hz.
- Use only manufacturer-approved replacement parts and accessories.

12.2 Wireless communication security

The device uses Bluetooth wireless communication for connection with compatible peripherals. Bluetooth communication performance may be affected by electromagnetic interference from nearby equipment. Reliable operation cannot be guaranteed in environments with excessive radio-frequency interference.

12.3 IT Network requirements

- The TSDR-3000 is intended to operate as a stand-alone medical device and does not require network connectivity during normal clinical use.
- If network connectivity is used for software updates, service support, or data transfer, use a secure network environment.
- Avoid connection to public or unsecured wireless networks.
- Access to the device should be restricted to authorized personnel.

12.4 IT Security measures

- Install only software updates supplied or approved by the manufacturer.
- Do not install third-party applications on the tablet computer used with the device.
- Protect the device against unauthorized access, modification, or tampering.
- If patient data are stored on the system, appropriate local data protection requirements shall be followed.
- Maintain physical security of the device and associated tablet computer.

13 Regulatory and compliance information

Category	Applicable standard / regulation	Scope	Test / Certification Reference	Status
Safety	IEC 60601-1:2005 +A1:2012 +A2:2020	Medical electrical equipment – General requirements for basic safety and essential performance	Test Report issued by Standard Bank Co., Ltd.	Compliant (Pass)
EMC	IEC 60601-1-2:2014 +A1:2020	Electromagnetic compatibility (emissions / immunity)	Test Report issued by Standard Bank Co., Ltd.	Compliant (Pass)
Usability	IEC 60601-1-6:2020	Collateral standard: Usability	Test Report issued by Standard Bank Co., Ltd.	Compliant (Pass)
Ophthalmic instrument	ISO 15004-1:2020	Fundamental requirements and test method	Test Report issued by Standard Bank Co., Ltd.	Compliant (Pass)
Usability engineering	IEC 62366-1:2015 +A1:2020	Usability engineering process	Usability Engineering File TSC-UE-002	Compliant
Software validation	IEC 62304:2006 +A1:2015 (Class A)	Medical device software life cycle processes	Software Validation Report TSC-SVVP- 002	Compliant
Risk management	ISO 14971:2019	Risk management for medical devices	Risk Management File TSC-RMF-002	Compliant
Biocompatibility	ISO 10993-1:2025	Biological evaluation of medical devices	Biocompatibility File TSC-BCF-001	Compliant
Quality Management	ISO 13485:2016	Quality management systems for medical	QMS Certificate No. 25-b-1983	Certified

system		devices	Rev.0	
EU regulation	[MDR] Regulation (EU) 2017/745	Class I medical device	Declaration of Conformity	CE Marking
Korean regulation	Medical Device Act	Medical device approval	Registry No. 26- 697	Approved
Environmental directives	[WEEE] Directive 2012/19/EU	Waste electrical and electronic equipment	WEEE Symbol applied	Compliant
	[ROHS] Directive 2011/65/EU	Restriction of hazardous substances	Material Declaration	Compliant

14 EMC information

Precaution to be taken to prevent adverse events to the patient and the operator due to Electromagnetic

Disturbances are listed in the column “Electromagnetic environment – guidance” in the tables below.

A. Manufacturer announcement – electromagnetic waves trouble

Electromagnetic waves trouble	
The TSDR-3000 should be used in the below mentioned electromagnetic wave environment.	
The TSDR-3000 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		
TSDR-3000 is to be used in the below mentioned electromagnetic wave environment. TSDR-3000 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

15 Revision history

No.	Date	Contents
0	2026.06.12	- Initial
1	2026.09.15	- The power rating was revised based on the test results provided by the testing laboratory.