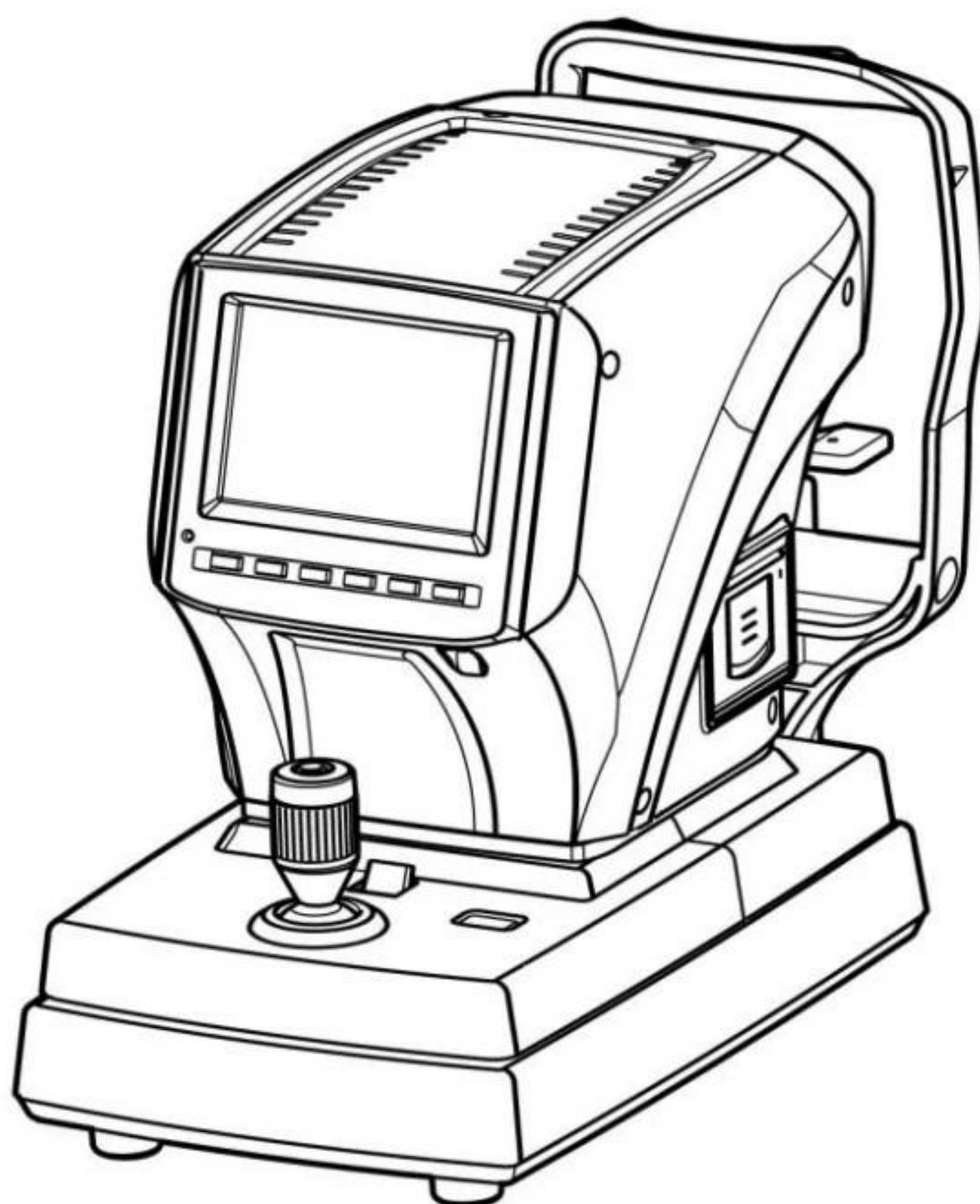


User's Manual

Auto Ref/Keratometer ERK-9100



IMPORTANT NOTICE



WARNING

Potential electromagnetic or other interference between medical equipment's and other devices being operated together in the same environmental may exert an adverse influence on functioning of the medical equipment. Non-medical equipment's not in compliance with the requirements of EN 60601-1 and EN 60601-1-2 should not be used together in the same environmental as the medical equipment's.

This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2005. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Power Cord

For use of equipment in rated voltage less than 125Vac, minimum 6A, Type SJT or SVT, 18/3AWG, 10A, and max 3.0m long: One end with Hospital Grade Type, NEMA 5-15P Other end with appliance coupler. For use of equipment in rated voltage less than 250Vac, minimum 6A, Type SJT or SVT, 18/3AWG, 10A, max 3.0m long: One end terminated with blade attachment plug (HAR) Type, NEMA 6-15P.

This product may malfunction due to electromagnetic waves caused by portable personal telephones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as, which affect this product, brought near the product.

The information in this publication has been carefully checked and is believed to be entirely accurate at the time of publication. EZER assumes no responsibility, however, for possible errors or omissions, or for any consequences resulting from the use of the information contained herein.

EZER reserves the right to make changes in its products or product specifications at any time and without prior notice, and is not required to update this documentation to reflect such changes.

All rights are reserved. Under copyright laws, this manual may not be copied, in whole or in part, without the prior written consent of EZER TM

9000ENG0033-A

Ver 0.0 (2017.01)



©2004 - 20017 - Huvitz Co., Ltd

38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

Contents

1. Introduction	6
1.1. Overview	6
1.2. Classification	6
2. Safety Information	7
2.1. Overview	7
2.2. Safety Symbol	8
2.3. Environmental Considerations	11
2.4. Safety Precaution	13
3. Characteristics	15
4. Note for Use	16
5. Names and functions of each part	17
5.1. Main parts.....	17
5.2. Explanation on Switches in Front.....	20
6. Installation of Equipment & Preparation of Measurement.....	21
7. Exercise through Model Eye.....	23
8. Measurement	26
8.1. Refractometry (REF Mode).....	28
8.1.1. Manual Measurement Mode	29
8.1.2. Auto Measurement Mode.....	35

8.2.	Keratometry (KER Mode).....	38
8.2.1.	Manual Measurement Mode	38
8.2.2.	Auto Measurement Mode.....	41
8.3.	Corneal Curvature / Refractive Power Measurement Mode (K&R Mode)	41
8.3.1.	Manual Measurement Mode	42
8.3.2.	Auto Measurement Mode.....	45
8.3.3.	Diverse Indications	46
8.4.	Keratometry Peripheral Measurement (KER-P Mode).....	47
8.5.	Measurement of Contact Lens Base Curve (CLBC Mode)	51
8.6.	Intraocular Lens (IOL) Measurement Mode (IOL Mode)	53
8.7.	Retro-ILLUM Measurement Mode (Retro-ILLUM Mode).....	54
8.7.1.	Adjustment of Array and Focus	54
8.7.2.	Observation on Retro-Illum	57
8.7.3.	Storage.....	58
8.7.4.	Examination on the other eye	58
8.7.5.	Call for Stored Image.....	59
8.7.6.	Return to measurement mode	60
9.	Other Modes.....	61
9.1.	Acuity Map Mode (Z-MAP Mode).....	61
9.1.1.	Composition of Window	

5	Auto Ref/Keratometer ERK-9100	
9.5.	Power saving Function	80
10.	Self diagnosis & Maintenance	80
10.1.	Before calling for serviceman.....	80
10.2.	Replacement	82
10.2.1.	Printer paper.....	82
10.2.2.	Chin rest paper	83
10.2.3.	Replacing Fuse.....	83
10.3.	Cleaning and Disinfection Equipment	85
10.4.	As changing the installation place of the equipment.....	87
10.5.	Disposal	87
11.	Main Specifications	88
12.	Accuracy	89
13.	Accessories	91
14.	EMC Information	92
15.	Service Information	98

1. Introduction

1.1. Overview

Auto Ref/Keratometer ERK-9100 is the equipment to provide the information of Spherical, Cylindrical and Axis while measuring the refraction of examinee's eyes. Auto Ref/Keratometer ERK-9100 is the equipment that can measure the corneal curvature of examinee. In addition, it can measure PD (=distance in between pupils) and pupil size. Especially, as its peripheral (=corneal peripheral curvature) measurement is possible as measuring the corneal curvature of examinee, it is possible to know the information on the corneal peripheral curvature as well as the corneal core curvature, which enables the exact prescription for the examinee.

This equipment shall provide the optimal optometry information with the functions of IOL (=measuring intraocular lens) and Retro-Illumination (=observing retro-illumination) to obtain an optimal figure of the eyes' state of examinee. CLBC (Contact Lens Base Curve) measurement is also a basic function of this product.

1.2. Classification

1. Classification of product:
 - EU - Class I with a measuring function according to Annex IX (Rule 12) of the Medical Device Directive 93/42/EEC
 - KFDA – Class II
2. Resistance against electric shock: Class I (earthed)
3. Protection class against electric: Type B
4. Protection against harmful ingress of water: Ordinary, IPX0
5. Degree of safety in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide: Not suitable for use in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide.
6. Mode of operation: Continuous

2. Safety Information

2.1. Overview

Safety is everyone's responsibility. The safe use of this equipment is largely dependent upon the installer, user, operator, and maintainer. It is imperative that personnel study and become familiar with this entire manual before attempting to install use, clean, service or adjust this equipment and any associated accessories. It is paramount that the instructions contained in this manual are fully understood and followed to enhance safety to the patient and the user/operator. It is for this reason that the following safety notices have been placed appropriately within the text of this manual to highlight safety related information or information requiring special emphasis. All users, operators, and maintainers must be familiar with and pay particular attention to all Warnings and Cautions incorporated herein.

WARNING

"Warning" indicates the presence of a hazard that could result in severe personal injury, death or substantial property damage if ignored.

NOTE

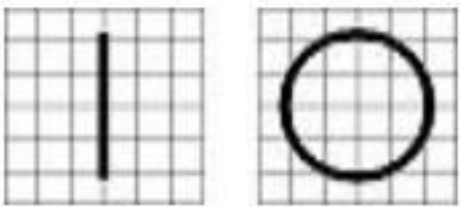
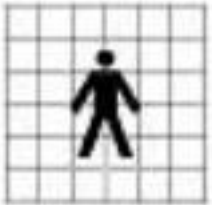
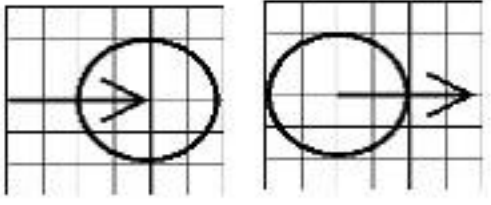
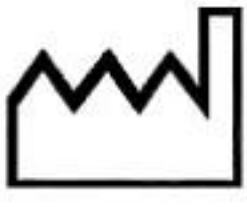
"Note" describes information for the installation, operation, or maintenance of which is important but hazard related if ignored.

CAUTION

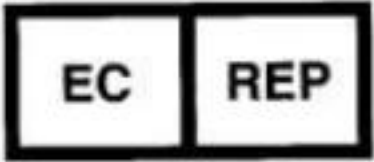
"Caution" indicates the presence of a hazard that could result in minor injury, or property damaged if ignored.

2.2. Safety Symbol

The International Electro technical Commission (IEC) has established a set of symbols for medical electronic equipment, which classify a connection or warn of any potential hazards. The classifications and symbols are shown below.

	I and O on power switch represent ON and OFF respectively.
	Type B Isolated patient connection.
	It indicates the connection of signal input/output.
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual.
	It indicates the year of manufacture and the manufacturer.

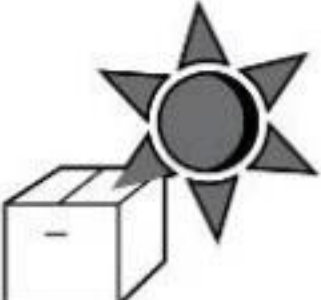
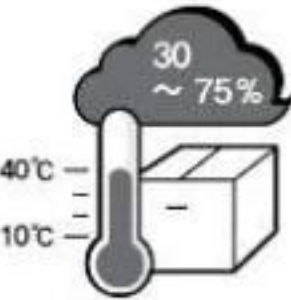
9 Auto Ref/Keratometer ERK-9100 -----

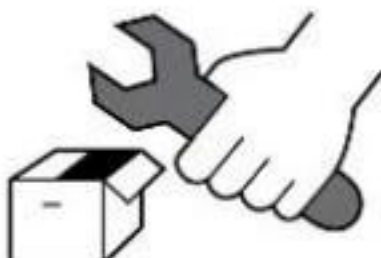
	Authorized Representative in the European Community
	Identifies the point where the system safety ground is fastened to the chassis. Protective earth connected to conductive parts of Class I equipment for safety purposes.
	Hot surface.
	Temperature Limitation
	Keep DRY
 UL60601-1 CAN/CSA C22.2 NO.601.1	 MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, AND CAN/CSA C22.2 NO.601.1

	<u>Disposal of your old appliance</u> When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. 4. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product.
	Alternating Current

2.3. Environmental Considerations

Please avoid the environment below for the operation and storage of the equipment.

	Where the equipment is exposed to water vapor. Don't operate the equipment with wet hands.
	Where the machine is exposed directly to the sunlight.
	Where the temperature changes frequently (Normal temperature for operation of the machine is at the range of 10°C ~ 40°C, and the humidity is at the range of 30%~75%).
	Where any heaters are at the close distance to the machine.
	

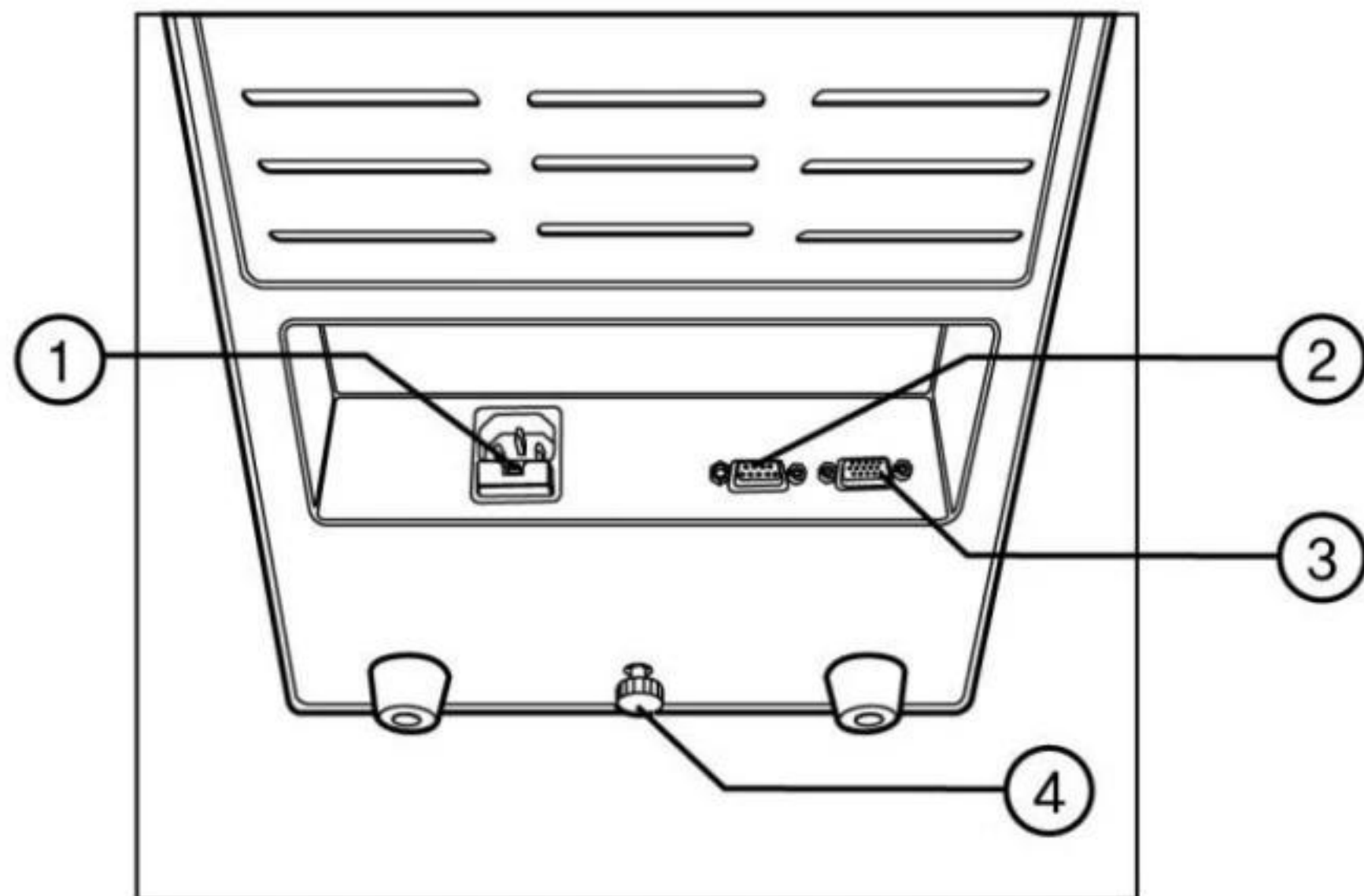
	Where the machine can be exposed to the chemical or flammable substances.
	Please keep the equipment out of dust and do not let inserted any metal parts such as coins, clips, etc.
	Do not disassemble or open the machine. The manufacture shall have no responsibility for any problems caused by these.
	Do not connect the AC power plug into the outlet while not putting the parts of machine together completely. It can harm the equipment.
	Do not pull the plug out of outlet while holding the cord.

For the normal operation of the machine, please keep the ambient temperature is 10℃ ~ 40℃, humidity is 3

7. The manufacturer is not liable for damage caused by unauthorized tampering with the device(s). Such tampering will forfeit any rights to claim under warranty.
8. The equipment may only be used together with accessories supplied by EZER's. If the customer makes use of other accessories, use them only if there is usability under technical safety aspects has been proved and confirmed by EZER or the manufacturer of the accessory.
9. Only persons who have undergone proper training and instructions are authorized to install, use, operate, and maintain this equipment.
10. User's manual or service manual should be kept in the place where the persons in charge of operation and maintenance can access easily any time.
11. Do not force cable connections. If a cable does not connect easily, be sure that the connector (plug) is appropriate for the receptacle (socket). If you cause any damage to a cable connector(s) or receptacle(s), let the damage(s) be repaired by an authorized service technician.
12. Please do not pull on any cable. Always hold on to the plug when disconnecting cables.
13. This equipment may be used for the international application related to Refractometry and Keratometry according to this manual.
14. Before every operation, proceed with visual inspection on the equipment exterior to seek any mechanical damage(s) to ensure the proper functioning.
15. Do not obstruct any ventilation outlet for proper heat dissipation.
16. In case of any presence of smoke, spark or
17. or abnormal noise/smell from the machine, please power off immediately and pull out the plug.

3. Characteristics

1. It is possible to measure the refractive power and corneal curvature with one (1) set of the machine: Refractometry and Keratometry
2. As the measurement range of refractive power is wide from -30D to +25D, it can measure the severe myopia.
3. As measuring the curvature, the minimum measurable pupil diameter is Ø2.0mm.
4. The equipment can measure the peripheral part of cornea so that user can see the value of curvature and eccentricity of each point while consecutively measuring the curvature of peripheral part around cornea to the direction of 90° degree to the upper/below/right/left from the core of cornea.
5. The refractive error can be showed in the form of Zernike topographic map.
6. The fogging technique, which is applied to the internal fixed target, is to make the more accurate measurement possible while letting the eyes of patient at the natural and comfortable state.
7. It is possible to select the display type of Refractometry and Keratometry.
8. It is possible to measure the distance in between pupils (PD).
9. Through the retro-illumination, the ERK-9100 can observe the eyes' condition of cataract patients or the scratches on the surface of contact lenses. It can store the two (2) images for each eye, and show the patients displaying them on the monitor screen.



[Figure 3. Bottom Section]

-
1. **Power Supply Socket:** A socket connecting to exterior power plug
 2. **Serial Interface Connector:** A terminal connecting to the exterior equipment
 3. **Exterior Monitor Connection Connector:** Connecting into the exterior monitor
 4. **Clamping Bolt:** Fixing the system stage

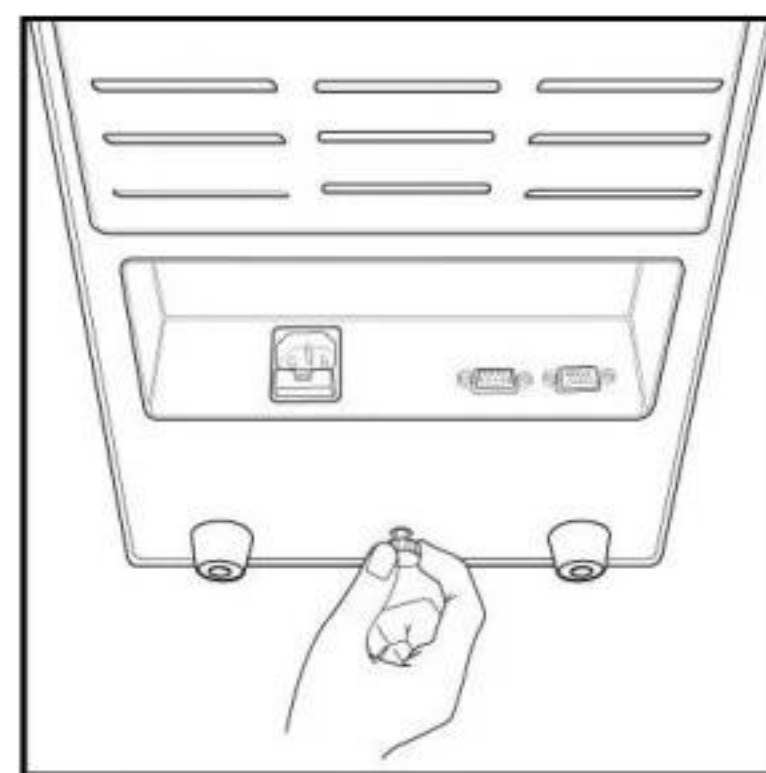
NOTE

As connecting to exterior monitor, noise can appear on the monitor owing to the length or kind of cable, and the quality of monitor.

6. Installation of Equipment & Preparation of Measurement

1. Release of Lock on Stage Section

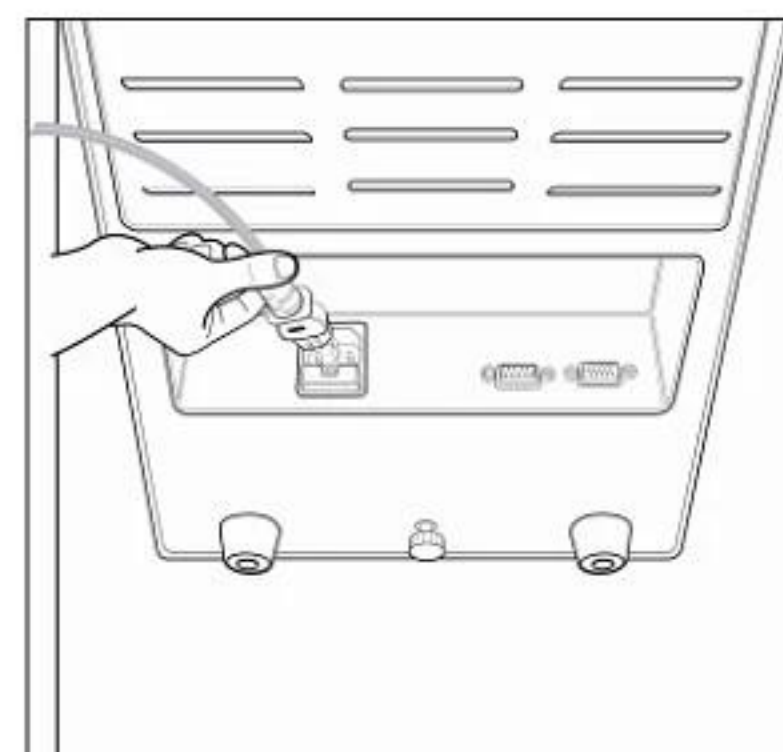
Unlock the clamping bolt at the bottom part of Chin-rest of the machine by rotating it counterclockwise, and change the stage fixing lever behind the joystick to the direction of UNLOCK.



[Figure 5. Release of Lock on Stage Section]

2. Connection of Power Cable

- Put ERK-9100 on the table.
- Insert the power cable into power connector At the bottom of the main body.
- After checking that the power of the machine is off, insert the power plug into the AC outlet (socket).



[Figure 6. Connection of Power Cable]

4. Installation of Printing Paper

Please refer to section 10.2.1 regarding the sequence of installation of printing paper.

5. Input of Message

Input the contents desirable to be printed such as name or address of hospital, etc. in the memory of message editing monitor in advance at all times.

6. Check of Setup

As for setup of corneal vertex distance, indication of CYL, unit of SPH/CYL, indication type of corneal measurement, corneal equivalent curvature, date, etc., please checks them in SETUP mode.

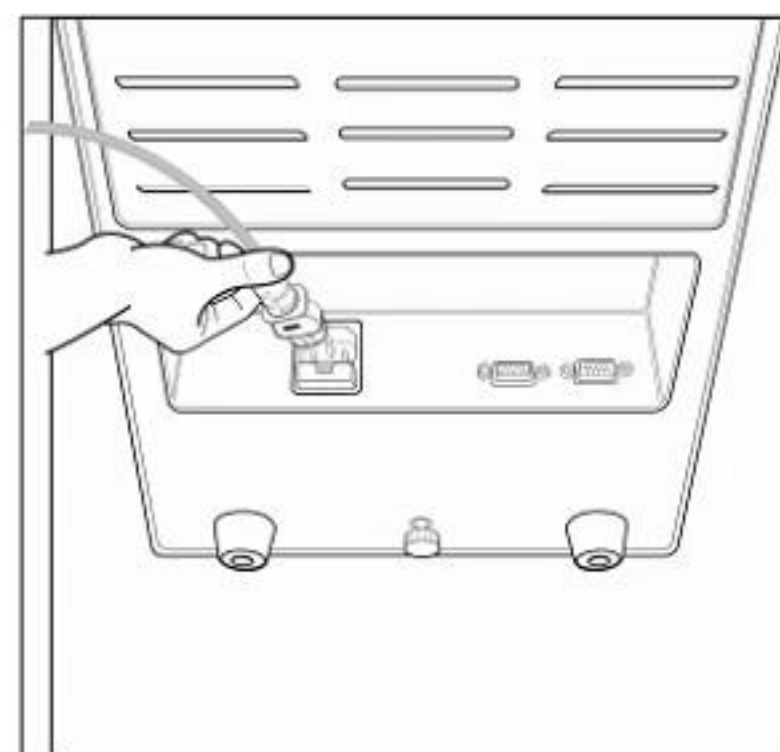
7. Transmission to Other Machines

In case of transmitting the measured results to other machines, prepare other machines while connecting the cable into the interface connector of this machine. You can select the transmitting speed in the user's SETUP mode. Please contact to the agent where you bought this machine for details.

7. Exercise through Model Eye

1. Power On of Main Body

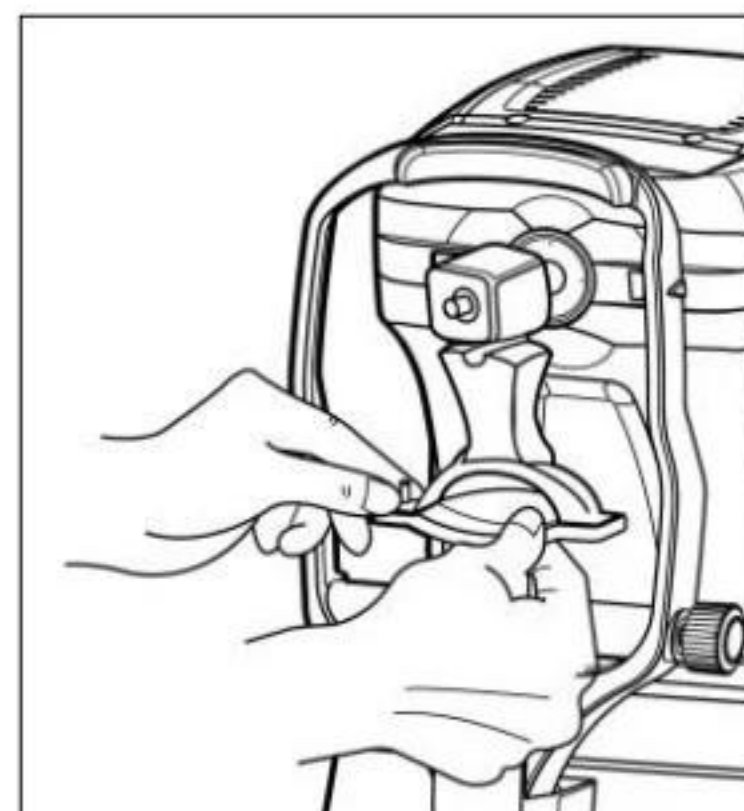
- Connect the power plug appropriately as shown in the picture.
- Let the power switch on.
- Measuring screen appears as system check is completed.



[Figure 8. Power Cable Connection]

2. Installation of Model Eye

- As removing the chin-rest paper, insert the pushing pins after adjusting the lower hole of model eye to the hole of chin-rest.



[Figure 9. Model Eye Installation]

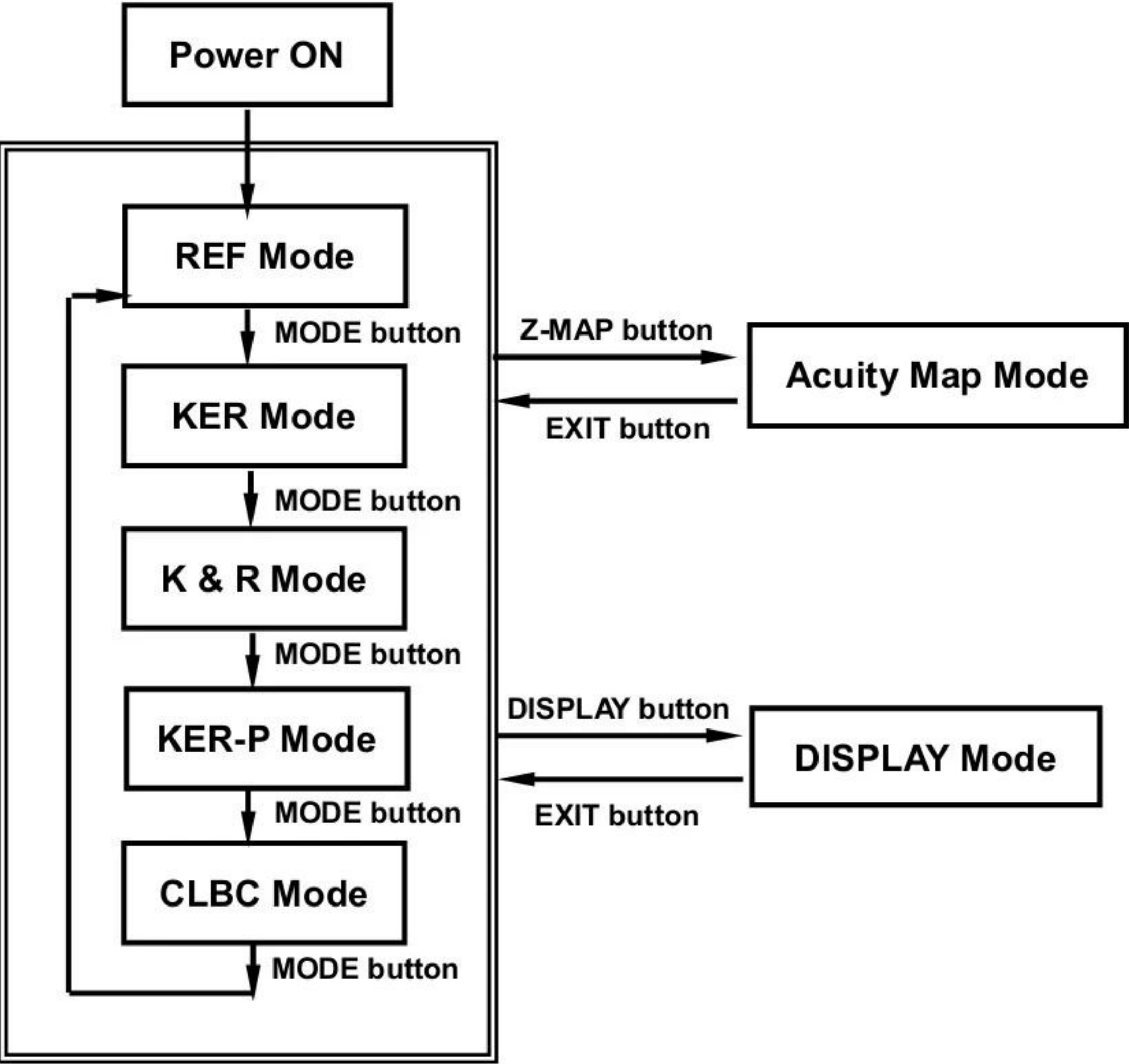
3. Release of Lock to Stage Section

- Release the clamping bolt at the lower cover of chin-rest of the machine by rotating it counterclockwise, and convert the stage fixing lever behind the joystick to the direction of UNLOCK.



NOTE

As the equipment does not operate for over 3 minutes while the power switch is at the state of "ON", the power saving mode is to be performed. If you push any buttons in the power saving mode, it is changed to the mode of measurement preparation.

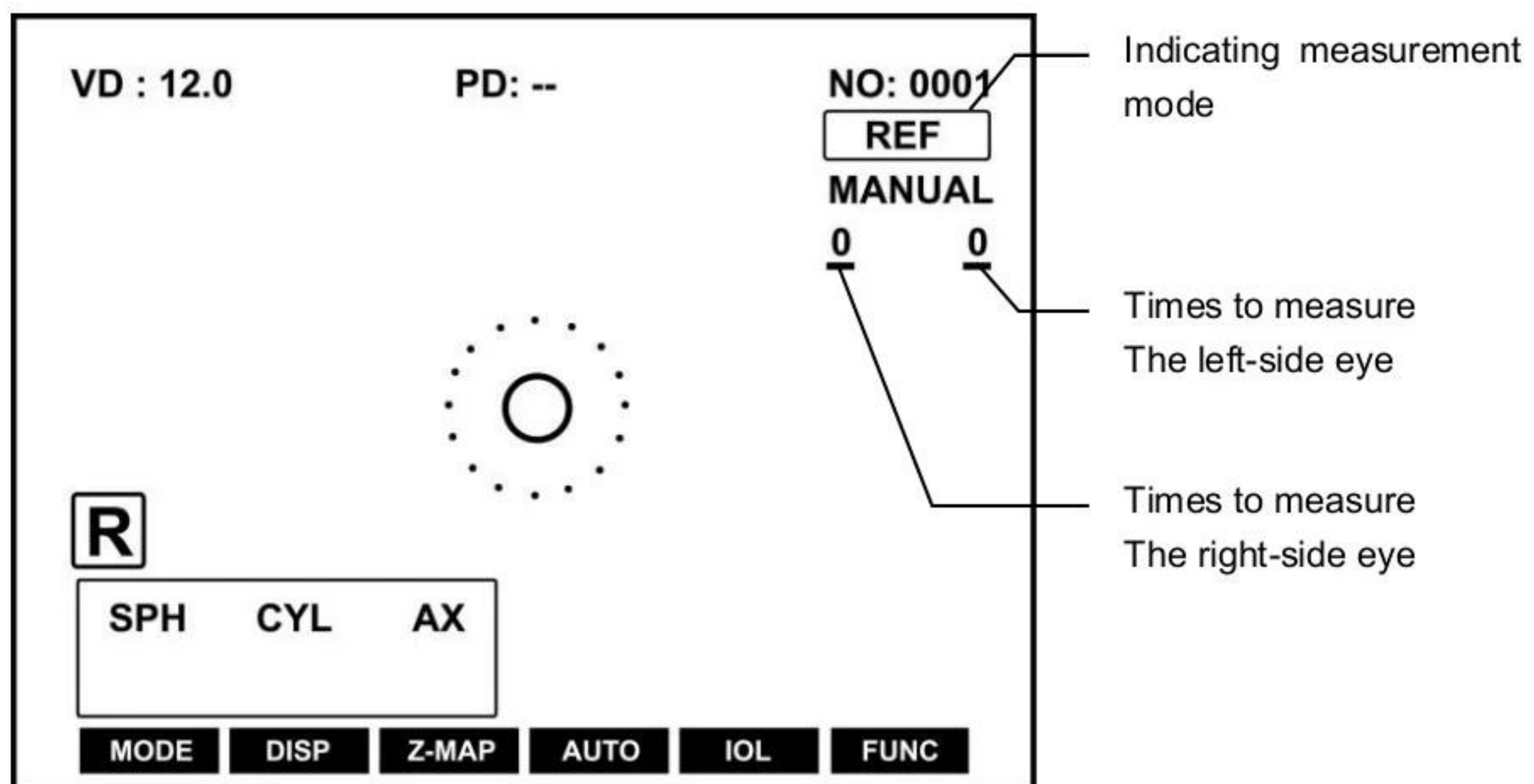


[Figure 12. Relation between each button and measurement mode]

8.1. Refractometry (REF Mode)

It is the mode to measure the refractive power solely.

1. Let the power switch "ON".
 - The measurement window as shown in the picture below appears on the screen of monitor as system check is completed.



[Figure 13. REF Mode Screen]

2. Check the measurement screen appeared on the monitor.

NOTE

- If the measurement screen as shown in the above picture does not appear on the monitor screen, let the power switch "ON" again in 10 seconds after switching it off. If the measurement screen continues not to appear either, please contact to the agents of EZER.
- If the image of measurement screen is dark, adjust the brightness by using the brightness-adjustment switch.

③ Measurement of Another Eye

- Measure the left eye according to the same procedure by moving the stage to the right side.
- As the measurement to both eyes is completed, the value of PD is to be indicated automatically on the screen of monitor.

④ Print

- Push the PRINT button in case that the measurement is conducted to the one eye only.
- In case of selecting the condition of A-Print as "ON" in Setup mode (refer to section 9.4), the measured result is to be printed automatically as the measurement of both eyes is completed.
- The message selected in Setup mode is to be printed together with the measured data.

8.2. Keratometry (KER Mode)

It is the mode to measure the corneal curvature solely.

Do not measure the base curve of hard contact lens in this mode. Please refer to CLBC mode in section 8.5 regarding the base curve of hard contact lens.

1. Check whether or not the screen of monitor is in measurement mode.
2. KER Mode Selection
 - Push MODE button until "KER" is to be indicated on the upper right side of the screen.
3. Perform the same 2, 3 procedure of consecutive measurement of refractive power

8.2.1. Manual Measurement Mode

1. Perform the adjustment of array and focus as like in the procedure of section 8.1.1.
2. Measurement
 - Push the measurement button.
 - The measurement continues to be performed as you keep pushing the measurement button.
 - As the measurement is completed, the measured result is to be indicated on the screen of monitor. In case of the consecutive measurement, the result of previous measurement is to be indicated.

