ULTRASONIC A/B SCAN
FOR OPHTHALMOLOGY
GRU−7000

USER’S MANUAL
1st edition

Gilras,
FL, US
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WARNINGS
Do not make any modification to the Device without authorization.
The manufacturer won't be responsible for any damage or injury caused by any failure of following the instructions in this manual.

The manufacturer reserves the right to modify equipment characteristics without previous notice under FDA Laws and MDD (93/42/EEC) Regulation.

The quality guarantee of GRU-7000 will be invalid if the equipment is opened (even partially), modified or repaired in any way by anyone who is not authorized by the manufacturer

---------------------------------------------

WARNING:
This device is not intended for fetal use.

WARNING:
Disconnect AC power before cleaning the case.

WARNING:
While plugging in the probe, make sure the red mark on the probe align with the red mark on the socket.
While plugging off the probe, please be sure you are pulling the connector in stead of the cable.
**Do not scratch the surface of the probe.**
**Do not drop probes.**

For any question, please contact the Manufacturer or Local Distributor:

**Manufacturer: Gilras**
Address: 9990 NW 14 ST Suite 105 Doral, FL 33172
Phone: +1-305-722-7321
Fax:+1- 786-664-3347
Email: info@gilras.com
HOW TO PREVENT CROSS-INFECTION:

Between uses on different patients the probes must be cleaned to prevent cross-infection. Manufacturer advocates a preventive action and a cleaning procedure in Chapter 5: CLEANING, STERILIZATION AND MAINTENANCE OF PROBE

CAUTION:

The GRU-7000 IOL calculator will calculate negative IOL values if such is predicted by the data entered. These are displayed with a minus sign (-). Do not ignore this sign.

CAUTION:

To preserve the equipment, avoid using any abrasive cleaner. If possible, clean spots before they dry.

TISSUE EXPOSURE TO ULTRASOUND ENERGY:

The GRU-7000 unit is designed for use in ophthalmology only.

While the manufacturer is not aware of any reports of adverse effects from using ophthalmologic ultrasound scanner, even at FDA pre-enactment levels, no other use is intended or implied.

The system controls limit of the output energy within the parameters specified for its intended purpose. Please refer to APPENDIX B of User’s Manual.

No control of ultrasound energy is available to the user other than the duration of exposure, considering the current concern for possible unknown hazards, and despite the extremely low output intensities used in this ultrasound system.

The manufacturer recommends that patients exposure time during measurement be minimized.
## INDICATORS

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### POWER INPUT
- AC 100–240V Power Input

### POWER OUTPUT
- AC 100–240V Power Output
  - Power On
  - Power Off

### FOOTSWITCH
- Footswitch Socket

### VIDEO OUT
- Video Signal Output
  - Type B
  - Refer to User’s Manual

### VGA
- VGA Signal Output plug, for LCD connection
  - 100V–120V: 2 fuses of 4A, 200V–240V: 2 fuses of 2A,
  - Slow Blow Fuse, Dimensions: 5×20 mm.

### FUSE
- CE Mark

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Note ①: Only for SONY/MITSUBISHI Video Printer and manufacturer’s Image Workstation.
1. INTRODUCTION

GRU-7000 Ultrasonic A/B Scanner for Ophthalmology is an ultrasonic imaging instrument specialized in ophthalmological diagnosis. It consists of the main unit, LCD monitor, 10MHz mechanical sector B-scan probe, and 10MHz A-biometric probe.

The product is used for ophthalmological ultrasonic diagnosis and measurement.

Eyelid trauma and severe eye infection patients are prohibited to use B scan and cornea trauma, inflammation or infection patients are prohibited to use A-biometric scan.

Notes:

The instrument should be operated by trained doctors.

Please read the manual carefully before installation and operation.

Please refer to Chapter 5 for CLEANING, STERILIZATION AND MAINTENANCE OF PROBE to avoid cross-infection while using.

Unplug power supply before cleaning.

Other notice please refer to Chapter 6.

Manufacturer: Gilras

Address: 9990 NW 14 ST Suite 105 Doral, FL 33172
Phone: +1-305-722-7321
Fax: +1-786-664-3347
Email: info@gilras.com
2. SPECIFICATIONS

2.1 Working Conditions

Environmental temperature: 5°C~40°C, relative humidity not more than 80%.
Power supply: AC 100V~240V, 50/60Hz.

2.2 B Mode

Ultrasonic frequency: 10MHz.
Scanning method: mechanical sector scan.
Gain control: 98dB.
TGC: -30dB – 0 dB dynamic, manually adjusted (5 scopes).
Display mode: B, B+B, B+A, A.
Scanning scope: depth 34mm-60mm, scanning angle: 53°.
Pixel capacity: 640×512×8×64 bits.
Number of image saved: 8.
Dynamic review: 5.6sec/56 images, single or multiple.
Gray scale: 256.
Pre-image processing: frame even.
Post-image processing: 4 groups of curves (liner, logarithmic, exponential, S).
Colour Display: 8 colour modes.
Electronic caliper: electronic cursor for multiple distance measurement,
   Accuracy no less than 0.25mm.
Area measurement: Accuracy no lower than ± 0.0625mm².
Delayed depth control: 0mm~15mm.
Built-in Calendar & Clock.
Patient information input: name, sex, age.
Continuous scanning will be automatically stopped to protect the probe if it is over 10 minutes.
30 minutes of power on but unused will lead to screen safeguard, which prolongs life of LCD monitor. Press any key to recover.

2.3 A Mode:

Ultrasonic frequency: 10MHz.
Biometry accuracy: ± 0.06mm.
Resolution: 0.01mm.
Measuring range (AL): 16-40mm.
Total gain: 98dB, user adjustable gain range: 0-55dB.
Measuring parameter: anterior chamber depth, lens thickness, vitreous length and axial length.
Measuring method: immersion, contact.
IOL calculation: SRK-T, SRK-II, BINK-II, HOLLADAY, HOFFER-Q, HAIGIS. Any two calculations can be compared and displayed on the same screen.
Calculation of 8 groups' average with standard deviation (S.D.).
50 groups of results saved permanently.
4 groups of IOL constants can be saved.

2.4 Safety:

In accordance to IEC 60601-1 and IEC 60601-2-37
3. INSTALLATION

3.1 Packing List

Please check the components in the package according to the following list.

* Main Unit   1
* LCD Monitor 1
* B Probe     1
* A Probe     1
* Foot Switch 1
* Cable       1
* Fuse        2 *(2A for 200V-240V, or 4A for 100V-120V respectively)
* Test Object 1
* User’s Manuel 1
* Eye cup     Optional

3.2 Main Parts of the Instrument

The instrument consists of: main unit, LCD Monitor, 10MHz mechanical sector B probe and 10MHz A biometric probe. The configuration is as follows:
3.3 Environmental Requirements

The scanner should be operated in clean, dry and air-conditioned environment.

The power socket used must be with good grounding, otherwise it increases the risk of noise as well as creepage.

Do not use the equipment in locations subject to intense electric and/or magnetic fields. Avoid excessive shock (e.g. tooth drill) and direct sunlight.

The equipment should be placed on a stable worktable. Leave certain space around the instrument and avoid soft object below it for ventilation.

3.4 Connection

This is the rear panel of the main unit:

![Rear Panel of Main Unit]

- **VGA**: LCD Connector
- **Foot Switch**: Foot Switch Socket
- **Power Output**: Power Output socket
- **Fuse**: Fuse socket
- **Video Out**: Video Output Connector
- **Power Input**: Power Input socket
- **Power**: Power Switch

1) Plug the footswitch cable to [Footswitch] socket on the rear panel.
2) Plug the power cable to the [Power Input] socket on the rear panel and the other end to a proper grounded power supply socket.
3) Plug the LCD’s power cable to the [Power Output] socket of the main unit or a proper grounded power supply socket, and the signal cable to the [VGA]
4) Plug B probe into [B-Probe] socket on the right panel. And put B probe into B probe holder safely.
5) Plug A probe into [A-Probe] socket on the right panel. And put A probe into A probe holder safely.
Note: 1) While plugging the probe, make sure the red mark on the probe aligns with the red mark on the socket.

2) The probe should be placed in the probe holder. Do not put it on table or other supporters. Do not scratch the surface of the probe.

3) While unplugging the probe, please hold the connector. Do not pull the cable.

4) If the probe drops while using or moving, please check the surface and shell carefully. If any of them is broken, then stop using it immediately and contact the manufacturer or local distributor for repairment.

6) If a video printer is available, connect the video cable to Video In of the printer, and the other end to Video Out on the rear panel of the main unit.

3.5 Disassemble of Accessories/ Replacement of Consumables

No part can be disassembled inside the main unit. Do not open the housing.

The probe and video printer should be disconnected from the main unit and put into its original package in case of moving.

Normal water-based high-molecule ultrasonic coupling gel for ultrasound scanners is required to be used.

For replacement of printing paper, please refer to the User Manual of the printer.

The gel bottle is made of polythene, and the remaining gel is water-soluble. Heavy metal contents meet the requirements of cosmetic standard. The treatment of the empty bottle should conform to the local environmental protection regulations. It can be treated together with disposable plastics such as syringe
4. OPERATION

4.1 Keyboard Description

The instrument can be operated by both keyboard and soft keys on the screen. There are alphabetic keys, numeric keys and functional keys on the keyboard. The soft keys are controlled by the trackball and its left and right keys. Following is the configuration of the keyboard.

4.1.1 Alphabetic and numeric keys

- **Letter, Number**: The alphabetic and numeric keys are used to input characters in the place of the cursor.
- **ㆍㆍ******: Press them to input corresponding arrows in the place of the cursor.
- **عكس**: Backspace key. Press it to place the cursor one space back. At the same time the character will be erased.
- **SPACE**: Space key. To move the cursor to the right.
- **Enter**: Enter key. It is used to finish the current line and go to the next line, or finish the current item and go to the next one.
- **+ -**: to adjust the threshold of A-scan measurement under A-Mode; while under IOL or SETUP, can be used as just plus and minus.

4.1.2 Functional keys

- **Menu**: Menu key. Press it to enter the main menu.
- **B**: Press it to enter single B scan mode.
**B+A**: Press it to enter B+A mode.

**B1**  **B2**: Press them to enter double B scans, and switch between the images of B1 and B2.

**Clor**: Colour mode selection key. Press it to change the colour coding of B image; such function can also be activated by clicking on the gray scale bar on the left side of the screen with left key of the track ball.

**Proc**: Post-image processing key. There are four processing modes: linear (LINE), logarithmic (LOG CURVE), exponential (EXP CURVE) and S (S CURVE).

**Dist**: Distance measuring key. Press it to enter the distance measuring mode and use the trackball to measure the distance between two points.

**Text**: Text input key. Press it to enter the full screen labeling status; use trackball to locate the cursor and enter text.

**Cls**: Clear the text labeling of the image under B mode. Clear measuring results and start a new measurement under A scan.

**Gain**: Gain control key. Set to 60 dB automatically when instrument is started at B Mode. Press this key to activate the gain control and press  

↑  ↓  to adjust.

**Zoom**: Scanning Depth control. Press it to enter B scanning depth adjustment status from 34~60mm.

**A**: **A**: A-Sampling line moving key. It is used to move the A scan sampling line under B+A mode.

**OD/OS**: Indicate right or left eye. Press it to switch between left eye and right eye.

**Mark**: Mark key. It marks the clock position of the probe with an arrow, which is used to tell the direction and position of the scanning sector.

**Ascan**: Scan control key. Press it to enter A scan’s automatic measuring mode.

**Auto**: Automatic measuring key. Under A scan’s automatic measuring status, press this key to switch among NORM, APHA, SPEC, CATA.

- **NORM**: NORMAL EYES.
- **APHA**: APHAKIC EYES.
- **SPEC**: SPECIAL EYES.
- **CATA**: DENSE CATARACT EYES.
**MANL**: Manual key. Press it to enter the manual measurement mode of A scan.

**IOL**: Press it to enter IOL calculation where calculation parameters can be input. From A-Mode to IOL, the average axial length can be automatically put in AL box; while if an appointed AL from 8 groups of results is necessary, press [AL]. Refer to [AL] below.

**AL**: In A scan mode, press it to automatically load the axial length appointed by “→” into IOL calculation.

**CAL**: In IOL mode, press it to calculate the IOL after the constants are input correctly.

<← ↑ → ↓>: Cursor control/function switch key. Use it to move cursor or change functions.

**Del**: Delete the measuring results of automatic A scan.

**Func**: Press it to switch to the function status under B mode.

**Sure**: Exit the function under B mode.

**PgUp**, **PgDn**: Under B mode, press them to turn the image up and down and save the images. 8 pages can be saved, labeled as P1-P8. Under A mode, press them to display the automatic measured wave appointed by “→”. In IOL calculation, press them to retrieve the saved information such as axial length, cornea curvature, etc.

**Freez/Scan**: Scan/Freeze control key. Press it, the instrument shifts from Start Scan to Freeze Image or from Freeze Image to Start Scan. The probe is frozen automatically after 10 minutes continuous scanning to protect the probe.

**Setup**: System setting key for system parameter setting, including IOL Constants, Spec (Velocity), Time, etc.

**About**: Display the product information (Manufacture use only).

4.1.3 Trackball Operation

The trackball can be used to move the cursor on the screen. Press left key to activate the functions where the cursor is; in B-Mode, press right key to display or hide the function menu on the right side of the screen.

4.1.4 Gain Control

Press [Gain] key and then the ↑, ↓ keys to adjust the gain. The change of gain is displayed on the screen at the same time: GN = XX dB.
4.1.5 Foot Switch

In B mode and A mode scans, the foot switch has the same function as [SCN], i.e., controls the start-up of the probe. When it is started, SCN is on the screen: in B mode, the probe waves and the image is displayed dynamically; in A mode, the probe indicator is on. When it is frozen, FRZ is on the screen: in B mode, the probe stops and the image is still; in A mode, the probe indicator is off.

4.2 B Scan

In mode menu, SB: single B mode; B1,B2: image 1 and image 2 of the double B mode; B+1/A+B: B mode and A mode, both B image and A waves displayed. Click the function keys or the left key of the trackball to enter the corresponding work mode. The screen displays as following:

Single B Mode

B1 and B2 Mode

The upper one is B1 and the lower one is B2. Select one of them and active it, then you can scan, freeze, adjust the gain, label the eye and save.
B+A Mode

Press $A^\uparrow$, $A^\downarrow$ keys to move the Sample taking Line and A curve changes accordingly.

4.2.1 Direction and Position Analysis

There is a white dot on one side of the probe end. This dot always corresponds to the upper part of the sector image. For instance, if the dot is above the eye, marked as “↑”, the image on the screen is the vertical section of that eye. The top of the sector corresponds to the upper part of the eye, and the bottom of the sector corresponds to the lower part of the eye. Another example: if the dot is on the nose side of the right eye, marked as “→”, the image on the screen is the horizontal section of the eye. The top of the sector is the nose side of the eye, and the bottom of the sector is the temporal side of the eye.

Move the cursor with the trackball to the probe position marker, press left key of the trackball, the marker will rotate clockwise; it rotates 45° every time it is pressed. It has the same function by pressing the [MARK] key.

4.2.2 B Scan Steps

a) Select B mode.
b) Input patient information at the bottom of the screen.

NAME: 13 digits of letters or numbers.
SEX: 6 digits of letters or numbers.
AGE: 3 digits of letters or numbers.
c) Label the eye to be examined. Press OD key for right eye; press OS key for left eye.

d) Let the patient lie on his/her back, slightly close the eyes.

e) Put some acoustic gel on eyelid; gently place the B probe on the eyelid.

f) Push down the footswitch or press FRZ/SCN key, the probe starts scanning. The real time ultrasonic sectional view of the eye will appear on the screen.

g) Adjust the total gain knob to make the focus clear and get a satisfactory image. Push down the footswitch again or press FRZ/SCN to freeze the image. The collection of ultrasonic B image is completed.

Note: Adjustment of gain control is one of the key operations that affecting B mode imaging quality. For different conditions and diagnostic requirements, the gain adjustment is different. Make sure do not fix the gain, however it is also not the case that the larger the gain, the better the image.

h) Press PgUp PgDw keys to save the current image and turn the page up and down. Mark the images with P1, … P8. 8 images can be saved at most.

i) Dynamic Replay: when scan is activated, an image is saved every 100 millisecond, and 56 images from the previous 5.6 seconds can be frozen. Activate RPLY function, press the FRZ/SCN key to review the images continuously or pause, or press ← → keys to review page by page. “Page= xx” on the right upper screen shows the current page number. RPLY is in the functional menu. Press the right key of the trackball to show the function menu, and select it with left key of the trackball.

4.2.3 Functional Menu

In B mode, press the right key of the trackball to show the functional menu; press any key again to hide it. Select the functions with the trackball’s left key.

a) ZOOM Depth control key. To change the scanning scope. 6 depths are available to be adjusted. They are showed on the right upper screen as:

DEPTH = 34 mm
DEPTH = 39 mm
DEPTH = 45 mm
DEPTH = 50 mm
Press \[ \leftarrow \rightarrow \] to adjust the depth. It is effective after scanning is activated.

b) **TGC** Time Gain Control. To adjust gain within the range of 30dB. **DEFAULT** on the right upper screen is set by the manufacturer. Press \[ \rightarrow \] to enter **CUSTOM** -- to customize the gain part by part.

c) **RPLY** Dynamic replay. When scan is activated, an image is saved every 100 millisecond, and 56 images from previous 5 seconds can be frozen and saved temporarily. Activate the REPLAY function, press \[ \text{FRZ/SCN} \] key to review the images continuously or pause, or press the \[ \leftarrow \rightarrow \] key to review page by page. “Page= xx” on the right upper screen shows the current page number.

d) **DLV** Delayed depth control. Delayed depth is the distance from the surface of the probe to the end of the displayed image. Press \[ \leftarrow \rightarrow \] key to move the image horizontally. “DELAY = . MM” is showed on the right upper screen.

e) **PROC** Post-image processing key. There are four post processing modes: linear (LINE), logarithmic (LOG CURVE), exponential (EXP CURVE) and S (S CURVE).
f) **TEXT** Full screen text labeling key. Move the cursor with the left key of trackball and enter text to label the image.

g) **DIST** Distance measuring key. When double cursor distance measuring status is activated, a “✚” appears on the screen. Move the “✚” with the trackball to the position where you want to start measuring, then press the left key of the trackball, the current “✚” will be locked. Move the trackball again, another “✚” is shown up. Move it to the terminal of measuring, and press left key again to complete the measurement. The distance between two “✚” will be shown on the screen. The unit is “mm”. If another measurement is needed, repeat the above procedure.

h) **AREA** Area measuring key. Move the cursor with trackball and press left key to fix a start point and draw the outline of an area with the trackball. Press left key again to get the complete area measurement.

i) **CLRS** To clear all the labels and measuring results on the image.

j) **NEW** Clear the previous patient’s information, temporarily save ultrasonic B images and get prepared for the next examination.

k) **EXIT** To exit the functional menu or exit the function currently activated, such as Dist, Area, Rply, Text, etc.

### 4.3. A Scan

Ultrasonic A Biometry is used to measure the anterior chamber depth, lens thickness, vitreous length and to calculate the axial length according to these measurements. To ensure the accuracy, the ultrasound should go into the eye from the vertex of the cornea as close as possible and superpose with the axis.

Automatic and manual modes can be selected for the measurement. Automatic mode is suitable for normal, aphakic, dense cataract and other conditions, where radiation velocity is known.

According to whether the probe is contacted with cornea, there are two kinds of the measuring methods: contact and immersion.

For contact method, A probe is contacted with the cornea vertex directly. This method is simple and easy to control. But the cornea can be injured and slightly distorted, therefore affecting the results. So the operator should operate very carefully and not press the cornea. The contact method applies to both the auto and manual mode.
For immersion method, A probe works through a coupling medium and does not contact the cornea directly. Fix an eye cup between upper and lower eyelids and add some saline in as the coupling medium. Immerse A probe into the saline without contacting the cornea. Approach the cornea with the probe until the distance is 2mm~6mm, start the auto measuring.

When A Scan is selected, it enters the following screen.

![Screen with options]

- **NORM**: Normal Eye, Auto
- **APHA**: Aphakic, Auto
- **SPEC**: Special Eye, Auto
- **CATA**: Dense Cataract, Auto
- **MANL**: Manual
- **CONT / IMME**: Contact/Immersion
- **COR**: Thickness of Cornea
- **AC**: Anterior Chamber Depth
- **LENS**: Thickness of Lens
- **VITR**: Vitreous Length
- **AL**: Axial Length
- **AV**: Average Measuring Result
- **SD**: Standard Deviation
4.3.1 Automatic Measuring Steps

1. Press **A** to enter A scan automatic measuring mode (NORM).
2. Click **CONT** with the left key of the trackball to select the measuring method, Contact or Immersion.
3. Select the type of eye among NORM, APHA, SPEC, CATA.
4. Let the patient lie on his/her back and open both eyes. Anaesthetize the eye to be measured.
5. Sterilize the front part of A probe with chloramphenicol eyedrop.
6. Push down the footswitch or press the **FRZ/SCN** to start scanning.
   - * If contact method is selected, let the patient stare at the probe and place the probe on the cornea vertex gently.
   - * If immersion method is selected, immerse the probe in the eye cup and approach the cornea until it is 2mm–6mm. Then start auto measuring.
7. Adjust the gain control to get the satisfactory wave.
8. When you hear a series of beep sound, the result comes out and is displayed on the screen. If the beeps are not heard, move the probe slightly until beeps heard and the measuring is completed. Measuring is undertaken one by one automatically until eight groups of data are achieved or it can be stopped when **FRZ/SCN** is pressed to freeze the image. Eight groups of data can be achieved from each patient at most, and the operator decides how many groups of data are needed.

*Note: Since the auto measuring result is calculated by averaging multiple operations, the operator needs to handle the probe gently and stably. The image can be frozen and the probe be taken away only after the beeps stop and the result appears on the screen.*

Check the results & Delete unreliable data: If the measuring result is obviously unreliable, delete it. Press **PgUp** **PgDn** keys to move the cursor.
“→” to the line that needs to be deleted, and click **DEL** with the trackball’s left key. The next line moves up and average value is recalculated.

Please delete the results in the following situations:

a) Position marker does not correspond with the top of the wave.

b) The retina wave is not sharp.

c) There is a big difference between the result and the average.

(9) Label the eye. **OS** for left eye; **OD** for right eye.

(10) Clear the current result and start a new measurement, click **NEW** with the left key of the trackball or press **Cls**.

4.3.2 **Manual Measuring Steps**

In some circumstances, it is difficult to get the result by automatic biometry or patients have difficulties to cooperate with the operator. In these cases, manual biometry is selected; otherwise, it is not preferred. Press **MANL** to enter manual measurement.

Operating steps are similar to the automatic measurement. Press **FRZ/SCN** to start scanning, adjust gain control and get a satisfactory wave. Press **FRZ/SCN** again to freeze the wave and measure it with the trackball. The operation refer to Five-Point Marking Method in chapter 4.4.

Manually Measured Waves
4.4 Five-Point Marking Method

When a bundle of ultrasonic goes through optic axial, we can get ultrasonic reflex from five different layers (Figure One), including: (1) cornea vertex; (2) back of cornea; (3) front of lens; (4) back of lens; (5) retina

Due to the specialty of eye structure, ultrasonic velocity becomes different when going through different tissues as follows:

- Velocity of cornea: \( V_{cor} = 1620 \text{ m/s} \) \( (1)-(2) \)
- Velocity of anterior chamber: \( V_{ac} = 1532 \text{ m/s} \) \( (2)-(3) \)
- Velocity of lens: \( V_{len} = 1641 \text{ m/s} \) \( (3)-(4) \)
- Velocity of vitreous: \( V_{vitr} = 1532 \text{ m/s} \) \( (4)-(5) \)

Axial length: \( AL = V_{cor} \times (t_2-t_1) + V_{ac} \times (t_3-t_2) + V_{len} \times (t_4-t_3) + V_{vitr} \times (t_5-t_4) \). \( (1.1) \)

As long as the five special points can be marked precisely, we can then figure out accurate axial length according to (1.1). This is what we called Five-Point Marking method for axial length measurement.

4.4.1 Use of Five-Point marking method under B+A mode for axial length measurement

1. Press \( B+A \) key to enter B+A mode, see Figure Two.
2. Select immersion method, scan the eyeball, then freeze it once satisfied image is obtained;
(3) Move trackball, press \[ \text{area on screen with } {\text{L}} \] key of the trackball, then enter Five-Point marking stage;

(4) Move the cursor to A curve at the bottom of the screen, press \[ \text{key of the trackball} \] to mark the five points, (if it is hard to recognize vertex and back of cornea, points (1) and (2) can both be put on (1));

(5) After marking the 5th point, the result of axial length will be shown on top of the screen.

Note: Velocity between points can be set up in SETUP menu (press \[ \text{SPEC} \], input velocity of cornea, lens and vitreous, then click on \[ \text{SAVE} \]).

Figure Two

4.4.2 Use of Five-Point marking method under A mode for axial length measurement

(1) Press \[ \text{A} \] to enter A mode;

(2) Choose measuring mode: (NORM, APHA, SPEC, CATA);

(3) Place A probe onto patient’s cornea, start foot switch and undertake an automatic measurement;

(4) When standard deviation, S.D, is not clinically satisfied, Five-Point marking can be corrected.

   (a) Press \[ \text{PgUp} \quad \text{PgDw} \] key to see A scan waves, remark the ones are not satisfied;

   (b) Move trackball, press \[ \text{area on screen with } {\text{L}} \] key then enter Five-Point marking stage;

   (c) Move the cursor to A curve at the bottom of the screen, press \[ \text{key of the trackball} \] to mark the five points, (if it is hard to recognize vertex and back of cornea,
points (1) and (2) can both be put on (1));
(d) After marking the 5th point, the measurement result, average of axial length and S.D will all be recalculated according to the new marking. See Figure Three.

![Figure Three](image)

**Note:** Velocities under different measuring modes:

**NORM (Normal):**
- Velocity of cornea: $V_{cor} = 1620 \text{ m/s}$ \((1) \rightarrow (2)\)
- Velocity of anterior chamber: $V_{ac} = 1532 \text{ m/s}$ \((2) \rightarrow (3)\)
- Velocity of lens: $V_{len} = 1641 \text{ m/s}$ \((3) \rightarrow (4)\)
- Velocity of vitreous: $V_{vitr} = 1532 \text{ m/s}$ \((4) \rightarrow (5)\)

**CATA (dense cataract):**
- Velocity of cornea: $V_{cor} = 1620 \text{ m/s}$ \((1) \rightarrow (2)\)
- Velocity of anterior chamber: $V_{ac} = 1532 \text{ m/s}$ \((2) \rightarrow (3)\)
- Velocity of lens: $V_{len} = 1629 \text{ m/s}$ \((3) \rightarrow (4)\)
- Velocity of vitreous: $V_{vitr} = 1532 \text{ m/s}$ \((4) \rightarrow (5)\)

Velocities under modes of SPEC (special), MANL (manual), APHA (aphakic) can be set up in the SETUP menu.

After reset the velocities, press $<<<$ under A mode, the results will be recalculated accordingly.

$+\quad -$ can be used to adjust the threshold of A-scan measurement.
4.5 IOL Calculation

4.5.1 Velocity Setup

The velocity refers to the radiation velocity within the eye. This instrument has four eye modes: NORM (normal), APHA (aphakic), SPEC (special) and CATA (dense cataract). The parameters are as follows:

<table>
<thead>
<tr>
<th>Unit</th>
<th>m/s</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Anterior Chamber (AC)</th>
<th>NORM</th>
<th>APHA</th>
<th>SPEC*</th>
<th>CATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1532</td>
<td>-</td>
<td>1532*</td>
<td>1532</td>
<td>1532</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lens V(LEN)</th>
<th>1641</th>
<th>-</th>
<th>PMMA: 2718</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acrylic: 1946</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Silicone: 1050</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1629</td>
</tr>
</tbody>
</table>

Vitreous Body V(VITR) | 1532 | 1532* | 1532 |

*: To modify the velocity in the parameter setup function, refer to 4.6.
**: Provided by IOL manufacturer.

4.5.2 Constants in different Formulae

6 groups of IOL calculation formulae are provided: SRK_II, SRK_T, BINK_II, HOLLADAY, HOFFER_Q, HAIGIS. Different constants are used for different formula, recorded as A, or ACD, or SF, which are provided by IOL manufacturers. They can be modified and saved in the parameter setup function SETUP. For more detail, please refer to Chapter 4.6.

BINK-II and HOFFER_Q use ACD, i.e., the desired anterior chamber depth constant. ACD can also be calculated from constant A:

\[
ACD = \frac{\left[\left( A \times 0.5663 \right) - 65.60 \right] + 3.595}{0.9704}
\]

or

\[
ACD = \frac{SF + 3.595}{0.9704}
\]

HOLLADAY uses SF, can also be calculated from constant A:

\[
SF = \left( A \times 0.5663 \right) - 65.60
\]

or

\[
SF = \left( ACD \times 0.9704 \right) - 3.595
\]

The shift from A to SF is completed automatically after constant A is entered.

SRK-II and SRK-T use A, which can be calculated from the following formula:

\[
A = \frac{SF + 65.60}{0.5663}
\]

or

\[
A = 109.49 + \left( 1.71358 \times ACD \right)
\]

HAIGIS uses three constants: a0, a1, a2, can be calculated from A:

\[
a0 = (0.62467 \times A) - 72.434
\]

\[
a1 = 0.40
\]

\[
a2 = 0.10
\]
4.5.3 IOL Calculation Steps

a) Press [IOL] to enter the calculation mode.

b) Select formula with the left key of the trackball.

c) Enter parameters.

   \[ AL = \text{Axial Length}, \ K1, K2 = \text{Keratometry}, \ DR = \text{desired Refraction} \]

   When enter calculation mode, the average of axial length calculated is put in AL. Press [AL] key to input the axial length from the line where the cursor \( \rightarrow \) is located.

   Move the cursor \( \_ \_ \) with arrow key and enter key to input numbers required.

d) Modify and save constants A or ACD in the parameter setup function [SETUP]. See 4.6.

   * IOL type needs to be selected for formula BINK-II: anterior or posterior. Click [ANTI] or [POST] with left key of the trackball.

   * Anterior chamber depth AC needs to be input for formula HAIGIS. The automatically calculated average anterior chamber depth is put in AC when calculation status is entered. Press [AL] key, the anterior chamber length from the line where the cursor \( \rightarrow \) is located is input. If it is required to enter manually, move cursor \( \_ \_ \) to AC and enter the numbers.

e) Enter patient information, label the eye.

f) Press [CAL], the calculation results are as follows:

   \[
   \begin{align*}
   \text{DEM} & \quad \text{Diopter of emmetropia, Unit (D)} \\
   \text{DAM} & \quad \text{Diopter of ammetropia, Unit (D)} \\
   \text{IOL} & \quad \text{Diopter of IOL (D)} \\
   \text{REFR} & \quad \text{Refraction after implant (D)}
   \end{align*}
   \]

   Each group of AL, K1, K2, REFR, etc. can be calculated by two formula in order to compare with each other.

g) The parameters and measured results can be saved as a record by click [SAVE] with left key of the trackball. “REC= XX” is showed at the right upper corner of the screen. Use [PgUp] [PgDw] to review the records. 50 records can be saved.
4.6. Parameter Setup

Click **MENU** on the upper left corner of the screen with the left key of the trackball, select **SETUP** to enter.

Move the cursor “_” with arrow key and enter key to enter the numbers where the “_” is.

Click **IOL CONST** with left key of the trackball to setup IOL constants: A and ACD. There are two groups, as group 1 and group 2. LEFT and RIGHT for left and right side IOL calculation respectively. The number after CURRENT tells which group is active. DR is desired refraction after surgery.

The constants setup by the manufacturer are:

<table>
<thead>
<tr>
<th>Side</th>
<th>Group</th>
<th>A</th>
<th>ACD</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFT</td>
<td>1</td>
<td>115.3</td>
<td>3.39</td>
</tr>
<tr>
<td>RIGHT</td>
<td>1</td>
<td>116.6</td>
<td>4.15</td>
</tr>
<tr>
<td>LEFT</td>
<td>2</td>
<td>117.9</td>
<td>4.91</td>
</tr>
<tr>
<td>RIGHT</td>
<td>2</td>
<td>118.7</td>
<td>5.37</td>
</tr>
</tbody>
</table>

CURRENT = 1

Click **SPEC** with left key of the trackball to set the velocity. When automatic measuring the aphakic (APHA) or special (SEPC) eyes, the velocity of the anterior chamber, lens and vitreous body can be set manually. For the velocity of IOL, consult its manufacturer.

V(A) : velocity in anterior chamber (m/s)
V(L) : velocity in lens (m/s)
V(V) : velocity in vitreous body (m/s)

After setup, press **SAVE** to save permanently. The parameters will be effective when the instrument is turned on next time.

Click on **TIME** with left key of the trackball to set time. The format is mm-dd-yy, hh-mm with 24-hour system. Click **TIME** again to save.
4.7 Image Printing

If a video printer is available, all images and characters on the screen can be printed by simply pressing **PRINT** key on the printer. Please read the user’s manual of the printer for details.
5. CLEANING, STERILIZATION AND MAINTENANCE OF PROBE

5.1 How to prevent Cross-Infection

The surface of the probe must be always clean, which can be cleaned with soft tissue after each use.

Front part of the probe may be washed with distilled water, physiological saline water, alcohol, chloramphenicol eye drop or Cidex liquid disinfectant, which are usually found in hospitals. Other FDA-cleared disinfectants may also be used.

The probe can be immersed.

Do not immerse the connector.

Do not autoclave the probes.

After cleaning, rinse the end of the probe thoroughly with clean water to remove all traces of the liquid used.

Follow the instruction on the label of commercial disinfectants.

The surface should then be dried with lint-free cloth.
5.2 Sterilization Procedure – Pre-sterilization and Sterilization of the Probes

Forward:
---- Operator should use standard method to ensure satisfactory sterilization of the probe after use.
---- Operator should use risky-patient protocol to ensure satisfactory sterilization of the probe every time after use on a patient where there is a risk of infection of Creutzfeld-Jacob disease.

OPERATOR’S CLOTHING
---- One-off overall.
---- Disposable gloves, sterile for sterilization.
---- Glasses and anti-rejection masks.

EQUIPMENT
---- Soft silk brush (surgical nail brush)
---- 3 × 500 ml stainless steel (or plastic), autoclavable-soaking trays.
---- One-off hand cloths.
---- Distilled water.

PRODUCTS
   The products must be diluted at 0.5% with warm water (25 °C-30 °C) from the tap or distilled water.
   The contents of the tray must be changed every day.°C
---- Disinfectant type Alkacide ® (Company ALKAPHARM).
   The product must be changed diluted at 5% with distilled water.
   The solution must be changed every day.
---- 6 Chlorometric degree solution of sodium hypo chloride at 20 °C.
   The contents of the tray must be changed after each use.
---- Demineralized or distilled water.

NOTES:
---- Please disconnect the probes from the machines. Please be sure machine is TURNED OFF before disconnecting probes.
---- Avoid splashing liquids onto probe connectors (end of the cable, which is connected to the machine).
5.3 PREPARATION OF STERILIZATION AGENTS

A) STERILIZATION-PREDISINFECCION

---- Proteolytic enzyme based agents (2 possibilities)

1-0.5% Alkazyme solution in water (20g sachet)

a) Pour in 1L warm clean water (25-30°C)
b) Put in the unopened sachet.
c) Wait for 1 minute.
d) Pour in 4 L water and stir it.

The Alkazyme solution can be used within 8 days if kept in sealed flasks. The solution can also be made up in a 4L recipient using demineralized or distilled water fill up the soaking tray from there.

OR:

---- 1-0.5% Aniozyme solution in water (25g sachet):

a) Pour in 1L warm water (25-30°C)
b) Put into the unopened sachet.
c) Wait for 1 minute
d) Pour in 4L warm water and stir.

B) Sterilization Agnet

---- 1-0.5% Alkacide solution in water:

a) Pour 5L distilled in flask
b) Pour in the Alkacide
c) Stir it

The Alkacide solution can be used within 8 days if kept in sealed flask.
Please pour in soaking tray (500ml) when sterilization is necessary.

C) Replacing Contents Of soaking trays

For frequent use, the contents of the trays should be replaced at the beginning of the morning and beginning of the afternoon.
Wait 10 minutes after the last sterilization before emptying out the Alkazyme or Aniozyme solutions.
STANDARD METHOD

NOTES:
Please disconnect the probes from the machines. Machines must be turned off first.
Please avoid splashing any liquid onto the electrical connectors.

Sector scan “B” type probe          “A scan” type probe

A) Decontamination-Predisinfection

1. Immerse the probe and the cable (except the connector) in the solution of Alkazyme or Aniozyme for 5 to 15 minutes depending on the perceived level of risk.

2. Clean the probe and the cable in the solution with the brush for 1 minute.

3. Clean the rest of the probe body and the cables using a swab lightly dampened with the same solution. Do not wet the connectors.

Dry
B) Rinsing

4. Rinse the end of the probe in demineralized or distilled water. Do not wet the connectors.

5. Dip the probe up to a maximum of 5 cm in the Alkacide solution for 5 to 20 minutes depending on the estimated level of risk. Do not wet the connectors.

6. Clean the probe body and the cable that were not soaked using a wipe lightly dampened with the Alkacide solution. Keep the connectors dry.

D) Rinsing

4. Immerse the probe and the cable in the Alkacide solution for 5 to 20 minutes depending on the estimated level of risk. Please keep the connectors dry.

5. Rinse the end of the probe with demineralized or distilled water. Keep the connectors dry.

6. Dry it with a sterile compress.

7. The A probe is ready for use.

8. Dry it with a sterile compress.

9. The B probe is ready for use.
METHOD FOR HIGH RISK PATIENTS

NOTES:
Please disconnect the probes from the machines. Machines must be turned off first.
Please avoid splashing any liquid onto the electrical connectors.

<table>
<thead>
<tr>
<th>Sector-scan “B” type probe</th>
<th>“A scan” type probe</th>
</tr>
</thead>
</table>

A) Decontamination –Predisinfection

1. Immerse the first 5 cm maximum in a solution of either Alkazyme or Aniozyme for 5 to 15 minutes depending on the perceived level of risk.

2. Clean the end of the probe in the chosen solution for 1 minute using the brush.

3. Clean the rest of the probe body and the cables using a swab lightly dampened with the same solution. Do not wet the connector.

B) Rinsing

4. Rinse the end of the probe in demineralized or distilled water. Do not wet the connectors.
C) Inactivation

4. Immerse the probe and the cable (except connector) in a 6 chlorometric degree solution hypochloride for 60 min. at 20°C ensuring the connectors are kept dry.

6. Clean the probe body and the cable that were not soaked using a wipe lightly dampened with the Alkacide solution.

D) Rinsing

5. Rinse the probe and the cable with demineralized or distilled water.

E) Disinfection

8. Dip the probe up to a maximum of 5 cm in the Alkacide solution for 15 min.

6. Dry with a sterile compress if the rinsing water was sterile.

9. Clean the probe body and the cable that were not soaked using a wipe lightly dampened with the Alkacide solution. keep the connectors dry.
F) Rinsing

10. Rinse the end of the probe with demineralized or distilled water. 7. Rinse the probe end with demineralized or distilled water keeping the connectors dry.

11. Dry with a sterile compress or a single use dry wipe if the rinsing water was sterile 8. Dry with a sterile compress if the rinsing water was sterile

12. The B probe is ready for use 9. The A probe is ready for use.
6. MAINTENANCE AND TROULE SHOOTING

6.1 Maintenance of the Instrument

* Main power supply must be with good grounding.
* The main unit of the instrument should not be used for a long time, normally not more than 4 hours continuously. While no measurement is performing, the instrument should be in the state of freezing.
* Avoid collision and falling of the probe. Keep the top surface of the probe clean.
* None corrosive detergent is allowed to clean the housing. Avoid water and liquid getting into the housing and external keyboard. Only a mild detergent may be used with soft cloth.
* In humid area and/or season, if the instrument is not used for a long time, it should be power-on for two hours per month.
* Don’t shake and fall off the instrument when moving.
* All parts should be put into the original package in case of moving, especially the probe. Therefore, the original package should be kept properly.

6.2 Biometric Test

There is a test object available with each equipment which imitates four acoustic reflect interfaces of human eyes and used to test the biometric measuring.

Fill the object with distilled water. Be sure that there is no air bubble in the water. Gently put the A probe onto the highest stage perpendicularly in the object (see left drawing). Press A to enter A-scan and MANL to enter manual mode. Click on FRZ/SCN to start scanning; move the probe gently, adjust the gain properly to make the start wave and 3 reflected waves clear and sharp as shown in the figure below.
At this time, press AUTO key, the result will be seen automatically.

Keep the position of the probe, press A and then FRZ/SCN, the test can be restarted.

If the measuring results are repeatable, it means A-biometric scan is working properly.

### 6.3 Trouble Shooting

1) Light indicator of the power supply is not on and the instrument doesn’t work.
   * Check if the power supply plug and socket are well connected.
   * Pull off the plug and check if the fuse is burnt out.
     The fuse is 2A for 200V~240V or 4A for 100V~120V. Be always sure to use the same standard product.

2) Main unit is working, but the monitor is not active or not displayed correctly.
   * Check if the probe is well connected.

   If above operation is not effective, please don’t open the housing without authorization.
   Contact the supplier immediately. Explain the problems in detail for proper and in time support.

   The scanner is a high-tech product designed elaborately. Only qualified trained engineers are authorized to repair the instrument. We are not responsible for problems caused by any kind of unauthorized repair.

   If required, we can provide the complete maintenance and repair manual to the authorized qualified engineers.
APPENDIX A  SUPPORT INFORMATION

Warranty

1. The product has a warranty of one year from the date of purchasing, on the premise of using in accordance with this Manual.

2. If the instrument does not work properly, please contact the warrantor immediately.

3. Following repairs are charged within warranty period:
   (1) Problems caused by accidents and man-made damages.
   (2) Damages caused by unauthorized repair;
   (3) Damages caused by inappropriate operation.

4. We provide continuous maintenance and repair after warranty period with certain charges.

The Specifications of Accessories and Consumables & Supply Information

Acoustic Gel    All that approved by FDA/EC can be used.

<table>
<thead>
<tr>
<th>Fuse</th>
<th>Voltage Range</th>
<th>Spec.</th>
<th>Breaking Capacity</th>
<th>Testing Current / Blow Time</th>
<th>Dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100V～120V</td>
<td>4A</td>
<td>200A at 250 V AC</td>
<td>100% - 4h 135% - 1h 200% - 120s</td>
<td>5×20 mm</td>
</tr>
<tr>
<td></td>
<td>200V～240V</td>
<td>2A</td>
<td>100A at 250 V AC</td>
<td>100% - 4h 135% - 1h 200% - 120s</td>
<td>5×20 mm</td>
</tr>
</tbody>
</table>

Please contact local distributor or Manufacturer if other parts are needed.
### APPENDIX B  The acoustic output information

**Transducer Mode:** GRU-7000 B-Probe  
**Operating:** B-Mode

**Application:** Ophthalmic

<table>
<thead>
<tr>
<th>Acoustic Output</th>
<th>MI</th>
<th>ISPTA,3 (mW/cm²)</th>
<th>ISPPA,3 (mW/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global Maximum Value</strong></td>
<td>0.097</td>
<td>0.0375</td>
<td>3.50</td>
</tr>
</tbody>
</table>

**Associated Acoustic Parameter**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P_{r,3}$ (MPa)</td>
<td>0.315</td>
</tr>
<tr>
<td>$W_0$ (mW)</td>
<td>0.0186</td>
</tr>
<tr>
<td>$f_c$ (MHz)</td>
<td>10.6</td>
</tr>
<tr>
<td>$Z_{sp}$ (cm)</td>
<td>2.10</td>
</tr>
<tr>
<td>Beam dimensions $x_6$ (cm)</td>
<td>0.0658</td>
</tr>
<tr>
<td>$y_6$ (cm)</td>
<td>0.0662</td>
</tr>
<tr>
<td>PD ($\mu$ sec)</td>
<td>0.138</td>
</tr>
<tr>
<td>PRF (Hz)</td>
<td>2760</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Beam Associated Acoustic dimensions</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$x_6$ (cm)</td>
<td>1.80</td>
</tr>
<tr>
<td>$y_6$ (cm)</td>
<td>1.80</td>
</tr>
</tbody>
</table>

**Operating Control Conditions**

Non-Autoscanning Mode

**Transducer Mode:** GRU-7000 A-Scan  
**Operating:** A-Mode

**Application:** Ophthalmic

<table>
<thead>
<tr>
<th>Acoustic Output</th>
<th>MI</th>
<th>ISPTA,3 (mW/cm²)</th>
<th>ISPPA,3 (mW/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global Maximum Value</strong></td>
<td>0.160</td>
<td>0.0136</td>
<td>11.2</td>
</tr>
</tbody>
</table>

**Associated Acoustic Parameter**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P_{r,3}$ (MPa)</td>
<td>0.525</td>
</tr>
<tr>
<td>$W_0$ (mW)</td>
<td>6.18E-4</td>
</tr>
<tr>
<td>$f_c$ (MHz)</td>
<td>10.8</td>
</tr>
<tr>
<td>$Z_{sp}$ (cm)</td>
<td>1.40</td>
</tr>
<tr>
<td>Beam dimensions $x_6$ (cm)</td>
<td>0.133</td>
</tr>
<tr>
<td>$y_6$ (cm)</td>
<td>0.121</td>
</tr>
<tr>
<td>PD ($\mu$ sec)</td>
<td>0.121</td>
</tr>
<tr>
<td>PRF (Hz)</td>
<td>10.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Beam Associated Acoustic dimensions</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$Az$ (cm)</td>
<td>0.00</td>
</tr>
<tr>
<td>EBD</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**Operating Control Conditions**
The GRU-7000 ULTRASONIC A/B SCAN FOR OPHTHALMOLOGY is intended for use in the electromagnetic environment specified below. The customer or the user of the GRU-7000 should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>compliance</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The GRU-7000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The GRU-7000 is suitable for use in all establishments, other than domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>flicker emissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Guidance and manufacturer's declaration - electromagnetic immunity

The GRU-7000 ULTRASONIC A/B SCAN FOR OPHTHALMOLOGY is intended for use in the electromagnetic environment specified below. The customer or the user of the GRU-7000 should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrostatic fast transient/burst</td>
<td>± 2 kV for power supply lines ± 1 kV for input/output lines</td>
<td>± 2 kV for power supply lines ± 1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV differential mode ± 2 kV common mode</td>
<td>± 1 kV differential mode ± 2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5% U_T (≥95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles &lt;5% U_T (≥95% dip in U_T) for 5 cycles</td>
<td>&lt;5% U_T (≥95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles &lt;5% U_T (≥95% dip in U_T) for 5 cycles</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the GRU-7000 requires continued operation during power mains interruptions, it is recommended that the GRU-7000 be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Note: U_T is the a.c. mains voltage prior to application of the test level.
The GRU-7000 ULTRASONIC A/B SCAN FOR OPHTHALMOLOGY is intended for use in the electromagnetic environment specified below. The customer or the user of the GRU-7000 should assure that it is used in such an environment.

### Guidance and manufacturer’s declaration—electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment—guidance test level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>1 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the GRU-7000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150kHz to 80MHz</td>
<td></td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>3 V/m</td>
<td>( d = 3.5 \sqrt{P} )</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>80MHz to 2.5GHz</td>
<td>80MHz to 800MHz</td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>800MHz to 2.5GHz</td>
<td>( d = 2.3 \sqrt{P} )</td>
</tr>
</tbody>
</table>

where \( P \) is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and \( d \) is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

![Electromagnetic symbol]

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GRU-7000 is used exceeds the applicable RF compliance level above, the GRU-7000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GRU-7000.

b Over the frequency range 150KHz to 80 MHz, field strengths should be less than 1 V/m.
**Recommended separation distances between portable and mobile RF communications equipment and the GRU-7000 ULTRASONIC A/B SCAN FOR OPHTHALMOLOGY**

The GRU-7000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GRU-7000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GRU-7000 as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (w)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150kHz to 80MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.35</td>
</tr>
<tr>
<td>0.1</td>
<td>0.11</td>
</tr>
<tr>
<td>1</td>
<td>3.5</td>
</tr>
<tr>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>100</td>
<td>35</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \( P \) is the maximum output power rating of the transmitter in watts (m) according to the transmitter manufacturer.

**NOTE 1:** At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
APPENDIX D: IOL FORMULA

Six formulae are used in GRU-7000, they are:

SRK-II  
SRK-T  
BINKHOST-II  
HOLLADAY  
HOFFER-Q  
HAIGIS

Please refer to REFERENCES for further information.

REFERENCES:


