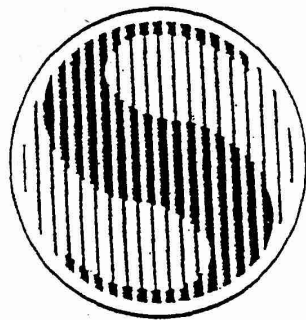


CORNEO-GAGE™ PLUS 1

USER'S MANUAL



SONOGAGE, INC.

V4.1
4/2/01

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SONOGAGE, INC.

26650 RENAISSANCE PKWY.
SUITE 3
CLEVELAND, OHIO 44128
U.S.A.

800/798-1119
216/464-1119
216/831-3444 (FACSIMILE)

LOCAL REPRESENTATIVE: _____
DATE RECEIVED: _____ / _____ / _____
MODEL TYPE: CORNEO-GAGE PLUS™1/2
SERIAL NUMBER: _____ / _____

PLEASE COMPLETE AND MAIL THE FOLLOWING REGISTRATION FORM
(PAGE iii) IN ORDER TO VALIDATE YOUR WARRANTY.



CORNEO-GAGE PLUS USER'S MANUAL


LIST OF ILLUSTRATIONS


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CHAPTER ONE

1.0 Precautions and Warnings

Several **WARNINGS**  and **PRECAUTIONS**  are used throughout this manual to alert the user to potential hazards and/or failures that may occur if the instructions provided are not followed completely.

WARNINGS  in this manual are used to alert you of a condition which can endanger either the patient or operator.

PRECAUTIONS  in this manual are used to alert you of conditions that can result in damage to the device.

Special attention must be given to each **PRECAUTION** and **WARNING** as it appears in this manual.

CHAPTER TWO

2.0 Introduction and General Information

The Sonogage, Inc. Corneo-Gage™ Plus is a modular designed, upgradable ultrasonic pachometer offering state-of-the-art high frequency technology to provide accurate, reproducible corneal thickness measurements.

Multi-function modality permits the user to select from radial keratotomy (RK), automated lamellar keratoplasty (ALK), laser keratectomy (LK), or the optional PachKnife™ (PK) modes in which the devices' electronics determine and set the parameters for signal processing and data presentation.

By properly placing the probe on the patient's cornea, the appropriate parameters can be achieved to obtain highly accurate, averaged measurements.

Measurements are continuously taken and stored by the device in memory.

Stored measurements can be reviewed and printed by the built-in dot matrix printer.

The goal of this manual is to guide the user through the intended and recommended uses of the Corneo-Gage™ Plus 1.

2.1 Corneo-Gage Plus™ 1 Features Include:

- RK measurement mode
- Range: 0.300-2.00 mm
- Probe with 50 Mhz transducer in Sight™ Handle
- Averages 1000 measurements
- Automatic measurement storage
- Measurement review
- Expanded memory (99 locations)
- Automatic calibration verification
- Self test routines at start-up
- Large LCD display
- Membrane keypad
- Battery Powered
- Battery level indicator
- 'Continuous read'
- Upgradable to ALK, LK, and PachKnife™ modes
- Dot-matrix printer

2.2 Clinical Applications

The Corneo-Gage Plus ultrasonic pachometer is intended for use by properly trained physicians and technicians for ophthalmic examination. This device is not intended for examination of any other anatomical site.

The objective of ophthalmic examination utilizing the Corneo-Gage Plus™ ultrasonic pachometer is to measure and monitor corneal thickness.

Corneal thickness is important for: keratorefractive surgery, astigmatic keratometry in cataract surgery, monitoring Fuch's Dystrophy, monitoring corneal edema after cataract surgery, monitoring daily and extended contact lens wearers, and monitoring early failure of corneal grafts.

The Corneo-Gage Plus is intended to be utilized with Sonogage, Inc. accessories only (e.g. probes and chargers). No substitutions of any kind are permitted.

CHAPTER THREE

3.0 Corneo-Gage Plus 1 Description (Fig. A)

- The device consists of three (3) components
- Pachometer with built-in printer
- Probe with 50 Mhz transducer in Sight™ handle
- Recharger transformer

3.1 Corneo-Gage Plus Control Panel (Fig. B)

PRECAUTION: Do not depress keypads with sharp objects.

The Corneo-Gage Plus Features:

- A 14 position calculator-style numerical keypad (0-9, -, +, ENTER, CE)
- A 4 function keypad (READ, RECALL, PRINT, RESET)
- 2 Operational keys (MODE, ON)

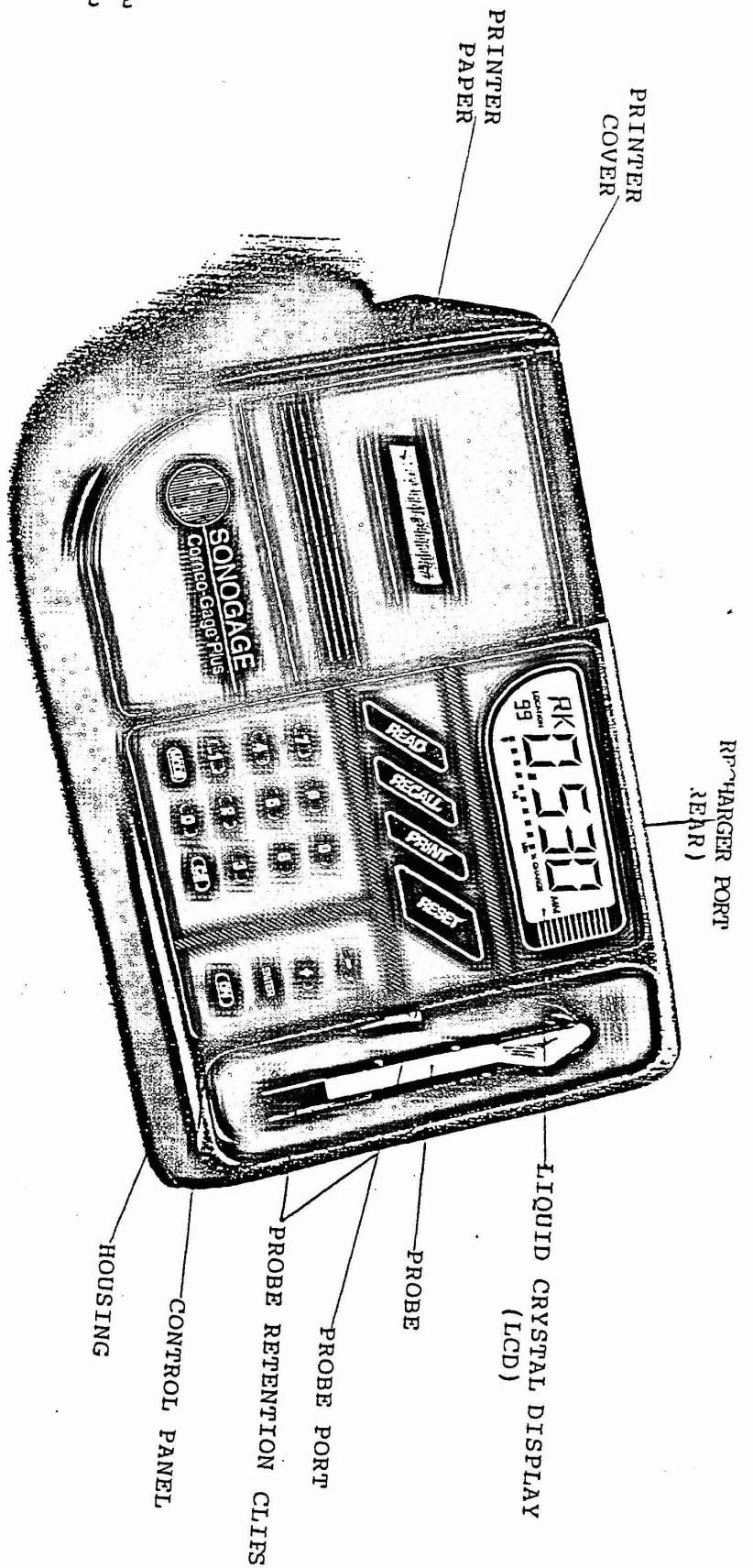
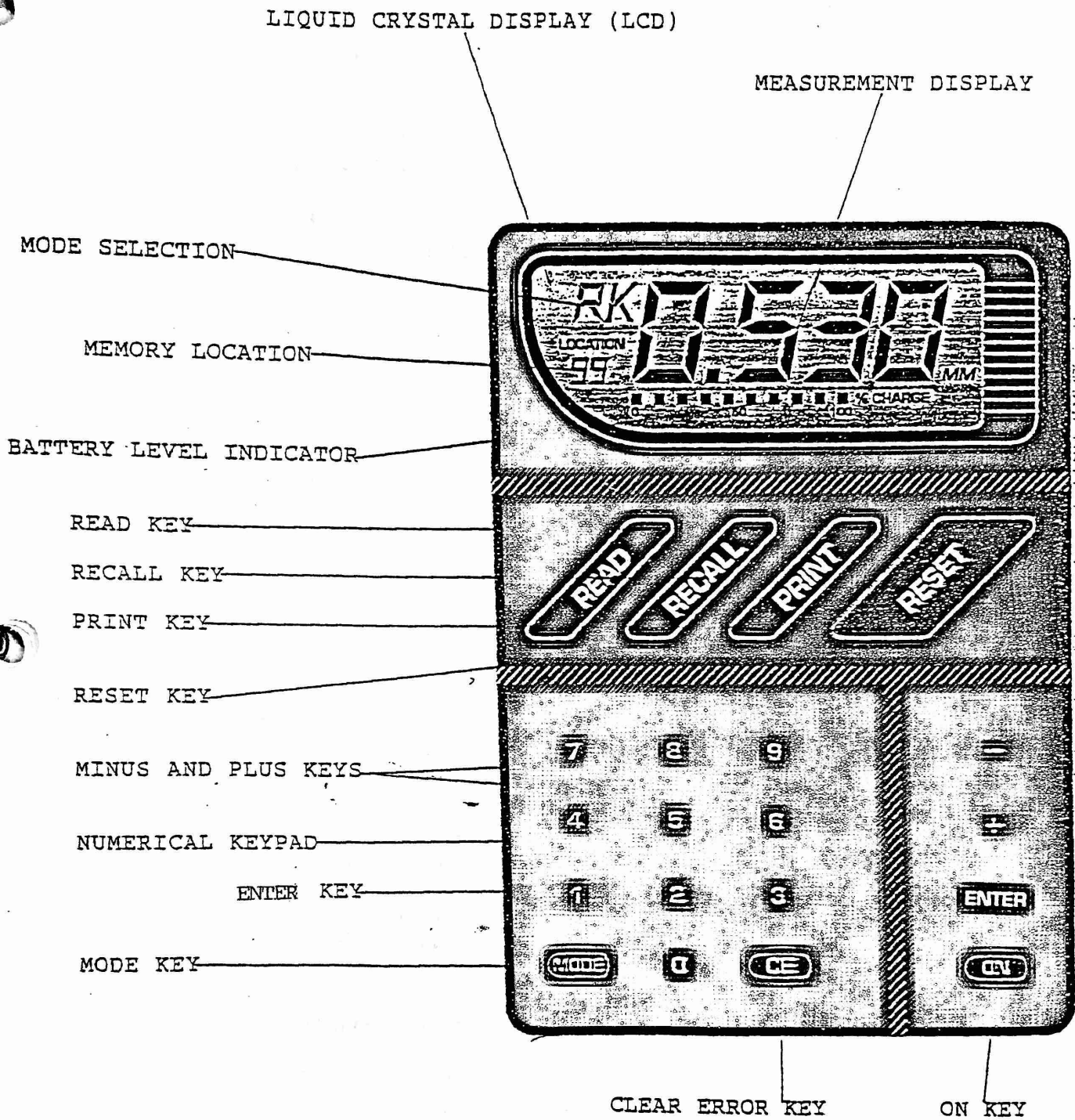


FIG. A
 CORNEO-GAGE™ PLUS
 Ultrasonic Pachometer

FIG. B

CONTROL PANEL



3.2 OPERATIONAL CONTROLS

MEMBRANE KEYPAD (Fig. B)

KEYPAD FUNCTION DESCRIPTION

READ

Depressing the READ key initiates a calibration verification test and then allows measurement.

RECALL

Depressing the RECALL key after taking measurements accesses stored measurements in memory.

PRINT

Depressing the PRINT key activates the printer which provides hardcopy printout of stored measurements.

RESET

Depressing the RESET key clears the mode selection and clears memory.

NUMERICAL KEYS

Numerical keys 0 through 9 are used to input measurement values in the ALK mode.

MINUS (-)

Selection of the - key allows backwards scrolling in memory recall.

PLUS (+)

Selection of the + key allows forwards scrolling in memory recall

ENTER

Depressing the ENTER key after inputting measurement values in the ALK and PK modes enters those values.

Also depressing the ENTER key advances the paperfeed when 'PF' is displayed and turns the device off when 'OFF' is displayed.

ON

Depressing the ON key activates the device.

CLEAR ENTRY (ce)

Depressing the CE key will clear entry when in the ALK mode.

MODE

Depressing the MODE key will select alternative modes RK, ALK, LK, PF, and OFF.

MODES

RK (CG PLUS ONE AND TWO)

RK mode is selected for radial keratotomy and astigmatic keratotomy cases.

Allows continuous readings for overall corneal thickness measurement.

ALK (CG PLUS TWO ONLY)

ALK mode is selected for automated lamellar keratoplasty cases. Prompts the user to input values relative to the ALK methodology and automatically calculates and prints cap, stromal bed, and lenticle values.

LK (CG PLUS TWO ONLY)

LK mode is selected for laser keratectomy procedures. Permits exclusive measurement of corneal epithelium.

PF (PLUS ONE AND TWO)

PF mode is selected to advance the printer paper.

OFF (ALL VERSIONS)

OFF mode is selected to turn the device off.

NOTE: Corneo-Gage™ Plus 1 is RK measurement mode capable only.
Contact Sonogage for update and pricing information.

CHAPTER FOUR

4.0 Environmental Conditions That Affect Use



PRECAUTION: Static electricity, lightning, and power surges can cause damage to the device. The device should be used with same care as your computer.



PRECAUTION: Do not operate the device in a wet environment. Electronics are sensitive to dampness. Operation in a wet environment may cause damage.

CHAPTER FIVE

5.0 Device Set-Up

5.1 Unpacking and Inspection

5.2 Device Components

Your Corneo-Gage Plus pachometer includes:

1. Corneo-Gage Plus unit
2. Sight™ probe (and dual transducer handpiece with the optional PP/PK mode)
3. Recharger
4. User's Manual

NOTE: Contact Sonogage immediately if any components are missing or damaged.

5.3 Device Placement

Place the device on a flat surface within range of the patient (e.g. on a Mayo stand)

5.4 Set-up Instructions



PRECAUTION: Incorrect set-up may result in damage to the device.



PRECAUTION: Failure to store the probe in the retaining clips with the rubber tip on may result in probe damage.



PRECAUTION: Gently remove white rubber protective cover from the probe. Probe damage can occur with rough handling.

1. Remove probe from the white probe shipping box.
2. Uncoil the probe cord.
3. Plug the gold probe connector into the probe port (Fig. A).
4. Wind the probe cord clockwise two turns below the probe retaining clips (Fig. A).
5. Store the probe in the retaining clips with the white rubber protective cover on the clear probe tip.
6. Press the ON button and observe the battery level indicator (Fig. B) for power level. If the battery power level is less than 50% charging is recommended. See chapter 10 for charging instructions.
7. Set-up is complete. Turn the device off by pressing the MODE button until 'OFF' is displayed. Press the ENTER button to switch the device off.

If you encounter any problems or have any questions regarding set-up, contact Sonogage.

CHAPTER SIX

6.0 Device Check-Out

6.1 Visual Inspection

Visually inspect the device for loose connections, adequate battery power level, and printer paper. Inspect the clear probe tip for scratches, dents or cracks.



WARNING: Do not attempt to take readings if the probe tip is scratched, dented or cracked as these conditions can injure cornea.



PRECAUTION: Scratched, dented, cracked or otherwise damaged probe tips may provide inaccurate readings.

6.2 Calibration

Calibration is not required by the user. The device performs an automatic calibration check upon power up and activation. Calibration is confirmed by the 'CAL' display prior to taking readings.

If the unit cannot calibrate, an error message will be displayed.

If this occurs, contact Sonogage.

6.3 Functional Test

A step-by-step procedure to check for proper function of the necessary parts of the device.

NOTE: A credit card and drop of water or saline is required for this test.

1. Place a drop of water or saline on a credit card.
2. Press the ON button (unit will defer to RK mode).
3. Press the READ button (CAL will display).
4. Gently depress the probe tip on the credit card through the water droplet. Hold the probe perpendicular to the credit card.
5. Readings will be continuously displayed as long as contact and orientation is maintained. Three beeps will be heard each time a reading is taken.
6. Remove the probe from the water drop, dry the clear tip with a tissue, wipe down the entire handpiece and tip with alcohol, air-dry, and replace protective white rubber tip and return handpiece to the probe holder clips.
7. Press the PRINT button for the printout.
8. When the printout is completed, press the RESET button.
9. Press the MODE button until 'OFF' displays.
10. Press the ENTER button to switch the device off.



Functional test should be performed 2-3 days before cases to insure operation and/or to allow adequate repair time if the device is not operating properly.

If the device does not perform the functional test as described, contact Sonogage.

CHAPTER SEVEN

7.0 Operation

7.1 Patient Preparation

Apply a drop of topical anesthetic to the eye that is to be measured.



WARNING: Anesthetize the eye before attempting pachometry. Pachometry without anesthesia may result in corneal trauma.

The patient can be either seated upright or reclined in a comfortable position.

7.2 Device Preparation

Gently remove the white protective rubber tip cover and cleanse the clear probe tip and white handle with Pantasept or an equivalent antiseptic.

7.3 Step-By-Step Operation (RK mode)

Step	Result
1. Press the ON key	Display illuminates and device defers to RK mode.
2. Press the READ key	'CAL' is displayed. You now have 20 seconds to position the probe on the cornea. If you do not do so, the unit will emit a long tone signaling a pause. To re-activate device, press the READ button again.
3. Hold the probe like a pencil, use the fifth finger on the patients' cheek or forehead to steady your hand. Instruct the patient to fixate on a target with the companion eye. Approach the cornea slowly and indent the cornea so as to see the indent reflection around the probe tip.	Readings display continuously and are stored automatically in memory provided the proper parameters are met. Each stored measurement is accompanied by a quick 3 beep tone.

NOTE: The device allows a 5 degree angulation margin to permit only the best measurements. If you are not within 5 degrees of perpendicular, you may not get readings.

- | | |
|--|--|
| 4. Hold the probe steady and maintain corneal indentation. Do not move or remove the probe tip between measurements. | Allows continuous measurement. The device can store up to 99 consecutive measurements. |
| 5. Take 5-7 consecutive measurements then remove the probe tip from the cornea. Cap and store probe in holder if finished. | Take measurements |
| 6. Press RECALL then depress the + key to advance sequentially through the stored measurements (Depress the - key to scroll backwards)
OR | Reviews stored measurements. |
| 7. Press the PRINT key. | For Printout (Fig. C) |
| 8. Clean and relocate the clear probe tip and repeat steps 2-7 to measure additional locations. | Additional testing. |
| 9. Press MODE key until ' OFF ' is displayed then press the ENTER key. | Switches device off. |

FIG. C

PRINTOUT EXAMPLES

Patient _____
Date / /
OD OS

Loc#	mm
1	0.557
2	0.562
3	0.557
4	0.562
5	0.561
6	0.561

(RK AND LK MODE)

ALK PACHOMETRY
Patient _____
Date / /
MYOPIA _____
OD OS
HYPEROPIA _____
OD OS

PRE-OP = 0.560 mm

STROMAL BED - 1st CUT
= 0.390 mm
CAP = 0.170 mm

(ALK -- HYPEROPIA)

ALK PACHOMETRY
Patient _____
Date / /
MYOPIA _____
OD OS
HYPEROPIA _____
OD OS

PRE-OP = 0.560 mm

STROMAL BED - 1st CUT
= 0.400 mm
CAP = 0.160 mm

STROMAL BED - 2nd CUT
= 0.310 mm
LENTICLE = 0.090 mm

(ALK -- MYOPIA)

CHAPTER EIGHT

8.0 SONOGAGE PACHOMETRY TECHNIQUE

8.1 ADVANTAGES OF CONTINUOUS READ

- Eliminates erroneous cornea measurement caused by tear film
- Avoids corneal trauma caused by repeated applanations
- A series of 5 quick readings reveals an aberrant measurement
- Choosing the smallest measurement of a series increases on-axis accuracy

8.2 TECHNIQUE

- Apply topical anesthetic
- Press READ button
- Hold probe like a pencil
- Use 5th finger on cheek or forehead to steady the hand
- Instruct the patient to fixate on a target with the other eye
- Approach the cornea slowly and indent the cornea so as to see a light reflex (halo effect) around the probe tip.
- Maintain indentation and perpendicular orientation to allow 4-5 additional measurements.
- Remove probe from cornea.



WARNING: NEVER LOOK AWAY FROM THE EYE UNTIL THE PROBE IS COMPLETELY REMOVED FROM THE CORNEA.

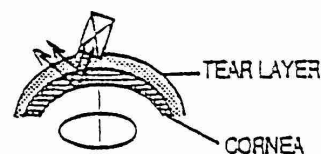
8.3 INTERPRETATION OF READINGS

- The first reading may be higher than the rest because it is a tear film plus the corneal reading--disregard it.
- Accuracy is assumed if 3 of 4 readings are grouped within .005 mm (e.g. 542, 543, 541, 410).
- Choose the smallest reading in the group since the probe angle was most perpendicular to the corneal surface during that reading (e.g. 542, 543, 541, 410: choose 541).

8.4 ERRORS AND ARTIFACTS IN ULTRASONIC PACHOMETRY

a. Misalignment Error

If the probe is not absolutely perpendicular to the cornea, an error of increased thickness will result. Corneo-Gage™ Plus allows only a 5 degree angulation margin to permit the best measurements. If you are not within this margin, you will not get readings.



b. Wet Probe Error

If the probe tip is wet, a false reading of the water (tear) droplet may occur before the cornea is indented and upon removal.



WATER DROPLET

CHAPTER NINE

9.0 MAINTENANCE

9.1 Routine Maintenance


Maintenance should be performed on a regular basis so that the device is always operating in a safe and reliable manner. Visual inspection of all components 2-3 days prior to use is a good practice and should minimize downtime.


9.2 General Inspection

- Visually inspect the device and its components for any defects or damage, loose or damaged connectors, frayed or broken cables, dented/broken or otherwise damaged probe tips.
- Verify adequate battery levels. If the battery level on the display indicator (Fig. 2) is less than 50 percent, charge the device.
- Verify that the paper is extending slightly from the printer so that it does not jam.

9.3 Cleaning

- The Corneo-Gage Plus housing should be cleaned periodically with a slightly detergent dampened cloth.
- The probe and cord should be routinely cleaned and disinfected with alcohol, Pantasept, Cidex or an equivalent antiseptic agent.

 **PRECAUTION:** Never use solvents such as acetone, thinner, benzine or abrasive cleaners on the housing and probe tip as these will damage the device.

 **PRECAUTION:** Do not soak the probe in saline solution, alcohol, or hydrogen peroxide as these will damage the device.

Contact Sonogage with any questions regarding cleaning procedures or agents.

9.4 PRINTER MAINTENANCE

9.4.1 Paper Replacement

The Corneo-Gage Plus incorporates an internal dot matrix printer that is accessed through the printer cover (Fig. A). The printer uses 2¼ inch plain paper.

Step-by-Step Paper Roll Replacement (Refer to Fig. D)

1. Remove printer cover as in Fig. 1 & 2).
2. Remove the spindle and empty paper spool from printer. Discard the paper spool.
3. Slide the spindle through the spool of the new roll of printer paper (Fig. 3)
4. Orient the roll of paper so that the paper feeds from under the roll and towards the front of the instrument (Fig. 4). Mount the spindle with the paper roll into the printer by inserting the mounting tips (located at each end of the spindle (Figs. 5 & 6).
5. Insert the end of the paper through the horizontal slot located under the printer cartridge (Fig. 7).
6. Press the ON key.
7. Press the mode key repeatedly until 'PF' is displayed. Then press the = key to advance the paper until approximately 2-3 inches emerges from the exit slot (Figs. 8 & 9).
8. Thread the paper through the bottom of the printer cover/cutter slot (Fig. 10).
9. Replace the printer cover (Fig. 10).

9.4.1 Printer Cartridge Replacement

Step-by-Step Printer Cartridge replacement (Refer to Fig. D & E)

1. Remove the printer cover as in Fig. D-1.
2. Press the left side of the printer cartridge to leverage it off the drive gear (Fig. D).
3. Remove cartridge.
4. Replace with new cartridge and snap in place.

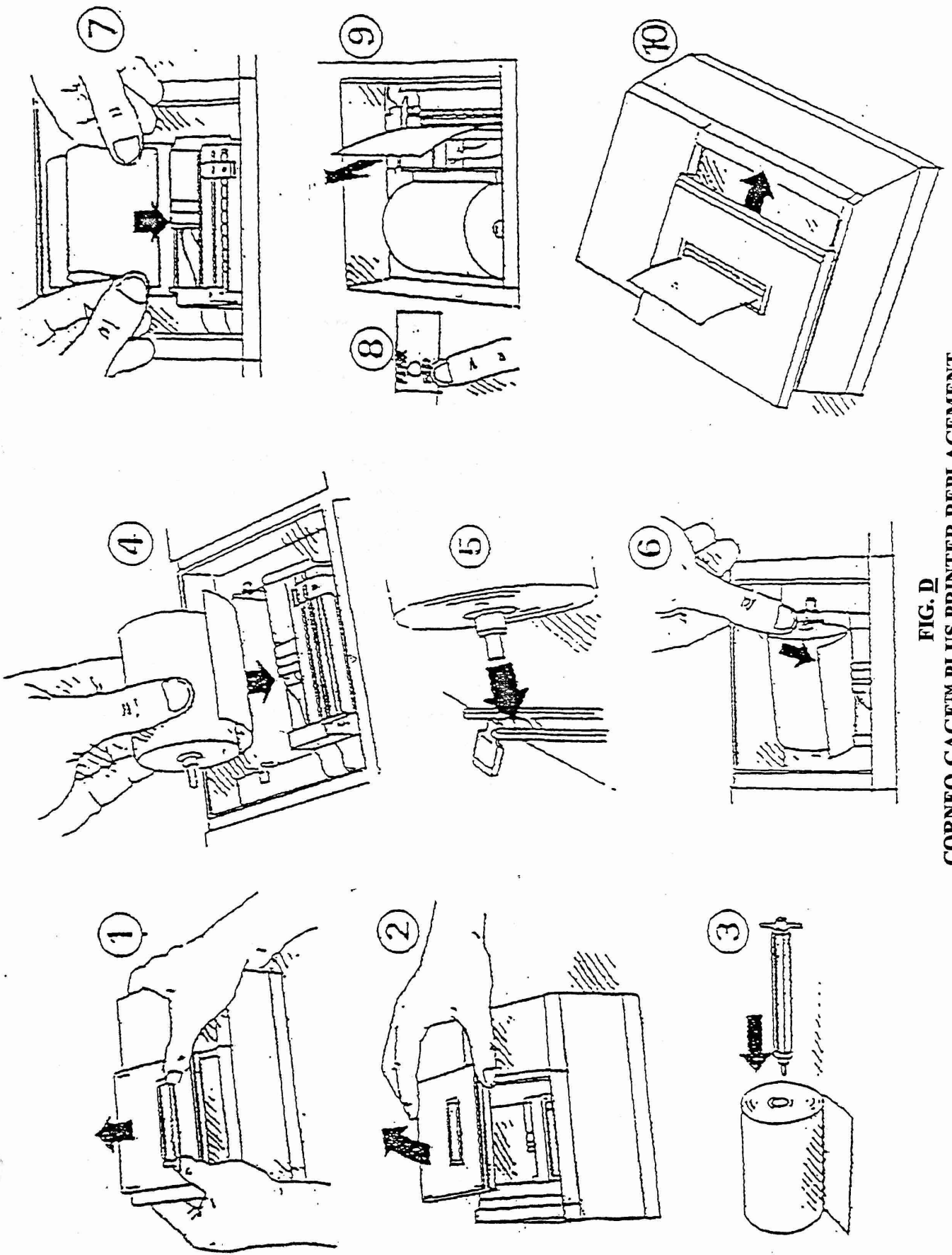
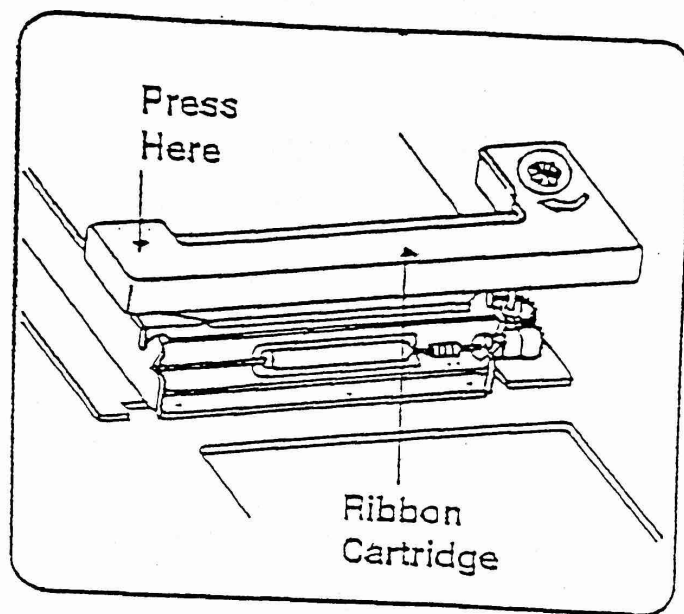


FIG. D
CORNEO-GAGE™ PLUS PRINTER REPLACEMENT

FIG. E
PRINTER CARTRIDGE REPLACEMENT



CHAPTER TEN

10.0 BATTERY RECHARGING

The device is internally equipped with a rechargeable 12 volt lead acid battery. This battery should last the life of the device.

A fully charged battery will typically provide between 1-3 weeks service depending on usage.

Battery load is indicated on the display (Fig. A).

Charge the device when the load level approaches 50%. Frequent charging will not harm the device or affect the battery. Lead acid type batteries do not retain a memory as other types do.

10.1 Step-By-Step Recharging Instructions

1. Plug transformer portion of the Sonogage recharger into a wall or strip outlet.
2. Plug recharger jack into the recharger port located on the rear of the unit.
3. Charge overnight for maximum load. The device will flash "CHARGING" on the display (Fig. A) while recharging. **The device will not operate while recharging.**
4. Upon completion, of recharging, disconnect recharger from the device and the wall or strip outlet and store the recharger.

PRECAUTION: Do not use a substitute recharger unless approved by Sonogage. Unapproved rechargers can cause severe damage to the device.

Contact Sonogage with any questions regarding the recharging procedure or device.

CHAPTER ELEVEN

11.0 LONG TERM STORAGE

If the device is not to be used for an extended period of time, it is advisable to still charge the device once a month and to keep it covered to prevent dust and debris from entering the system.

Store the device where it is protected from temperature extremes and humidity which can cause damage to the electronics.

The probe should be removed and stored in its shipping box.

CHAPTER TWELVE

12.0 WARRANTY AND SERVICE

Sonogage, Inc. warrants to the original instrument purchaser the Sonogage Corneo-Gage Plus ultrasonic pachometer system to be free of defects in workmanship and material under recommended normal usage and servicing for twelve (12) months from date of invoice.

During the warranty period, the obligation of Sonogage, Inc. shall be limited to repair or replacement of the defective parts(s).

The following terms and conditions must be met in order to receive any warranty service.

1. Sonogage, Inc. shall be immediately notified of problems encountered during the warranty period.
2. Sonogage, Inc. must be notified no later than five (5) working days after said warranty has expired.
3. In order to obtain warranty service, permission must be obtained from Sonogage, Inc. U.S.A. at 216/464-1119, prior to returning the unit for repair.
4. The following information shall accompany all returned units:
 - A. Your name, address, telephone number, fax number
 - B. List of equipment and Serial Numbers
 - C. Description of the problem
 - D. Proof of the date of purchase and Invoice Number

Ship or otherwise return the product, transportation cost prepaid to:

Sonogage, Inc.
26650 Emery Industrial Pkwy.
Suite 3
Cleveland, Ohio 44128
U.S.A.

CHAPTER THIRTEEN

13.0 TROUBLESHOOTING GUIDE

<u>SYMPTOM</u>	<u>ACTION</u>
Strange looking display	<ul style="list-style-type: none">* Take reading: if persists;* Call Sonogage
No power	<ul style="list-style-type: none">* Plug in charger* Call Sonogage
Scratched, dented, or broken probe tip.	<ul style="list-style-type: none">* Call Sonogage
No readings	<ul style="list-style-type: none">* Check Probe connection* Review Sonogage Technique* Dry eye > Have patient blink to distribute tears.* Not perpendicular > Re-orient probe.
Wide variance in readings	<ul style="list-style-type: none">* Review Sonogage Technique* Do not come off eye between readings.* Indent cornea when applanating.* Call Sonogage.
Difficulty in getting peripheral readings	<ul style="list-style-type: none">* Dry eye > Have patient blink.* Not perpendicular > re-orient probe.* Call Sonogage
Won't work with charger plugged in.	<ul style="list-style-type: none">* Call Sonogage
No buzzer noise	<ul style="list-style-type: none">* Call Sonogage
Reads off the eye	<ul style="list-style-type: none">* Clean tip and dry* Call Sonogage
Printer won't work	<ul style="list-style-type: none">* Recharge device* Call Sonogage
Paper jam/won't feed	<ul style="list-style-type: none">* Unjam printer--see Fig. D* Call Sonogage
Print copy light	<ul style="list-style-type: none">* Replace print cartridge--see Fig. E.

13.1 ERROR CODES

The Corneo-Gage™ Plus displays error codes on the display (Fig. A) should an operational fault occur.

User applicable Error Codes:

<u>Code</u>	<u>Definition</u>	<u>Action</u>
E0	Bad probe port connection	Check connection
E7	No read allowed while charging	Complete charging cycle
E8	Low battery level	Recharge unit

All other error codes should be promptly reported to Sonogage (216.464.1119—tele or 216.831.3444—fax).

CHAPTER FOURTEEN

14.0 SPECIFICATIONS

PHYSICAL

Size: 13.75 inches wide
8.50 inches deep
6.75 inches high
Weight: 5 lbs.

POWER

Lead/acid Battery: 12 VDC 600 mA
6 hour recharge cycle

Recharger: In - 120 VAC
Out - 12 VDC @ 300 mA

ENVIRONMENTAL

Operating Temperature: 41°F (5°C) - 104°F (40°C)

DISPLAY

Type: LCD

PRINTER

Type: Dot Matrix Impact

PAPER

Type: Plain white roll
Width: 2.25 inches
Roll Diameter: 1.65 inches

MEASUREMENT RANGE

Corneo-Gage Plus™ Plus 1 : 0.025 mm - 2.000 mm
Corneo-Gage Plus™ Plus 1A: 0.025 mm - 2.000 mm
Corneo-Gage Plus™ Plus 2 : 0.025 mm - 2.000 mm

MEASUREMENT ACCURACY

50 Mhz
Electronic: +.0004 mm
Clinical: +.001 mm

MEMORY CAPACITY

Measurements: 99 sets

PROBE TIP SIZE

50 Mhz: 1.50 mm diameter

VELOCITY

1636 m/SEC

MEASUREMENT METHOD

Average of 1000 readings

14.1 OPTIONS

Corneo-Gage™ Plus 1

- ALK, LK Mode Update

Corneo-Gage™ Plus 1A

- ALK, LK Mode Update
- Printer Upgrade

(One, Two or Three year Service Plans)

14.2 ACCESSORIES

- Additional 50 Mhz Probe in Sight™ Handle
- Corneo-Gage™ Plus carrying case
- Additional 120 VAC charger
- 220 VAC charger

14.3 SUPPLIES

Printer paper (5 packs)
Printer cartridge

**CALL SONOGAGE CUSTOMER SERVICE 800/798-1119 TO ORDER OPTIONS,
ACCESSORIES, AND SUPPLIES.**