



DGH 5000e
ULTRASONIC A-SCAN
OPERATOR'S MANUAL

Sys: SBH Doc: 5000E-INS-OMENG Rev: 1

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I. INTRODUCTION

Ultrasound is sound of a frequency level too high to be heard by the human ear. However, sensitive equipment can send and receive ultrasonic impulses as well as analyze information about anything these impulses strike along their route of travel. Every time a sound impulse strikes an interface, some sound is reflected (bounces off), and some sound is refracted (passes through). The amount of reflected and refracted sound varies with the density of the interface it strikes. Reflected sound acts much like a rubber ball being thrown at a wall. Sound hitting an interface perpendicularly will reflect back along the same path that it approached (Figure I-A). Sound hitting an interface at an angle will reflect at an angle away from the source (Figure I-B). The refracted sound will continue on at a lesser amplitude because of reflected energy lost at the interface.

By means of sophisticated equipment, sound impulses can be projected into a non-uniform material, causing reflections (or echoes) to be produced whenever the impulses strike an interface. These echoes can be observed on a graphic display as a two dimensional waveform with spikes that are related to the positions of the interfaces. By looking at the height (intensity) of the spike, one can determine the angle at which the sound is striking it (Figures I-A & I-B).

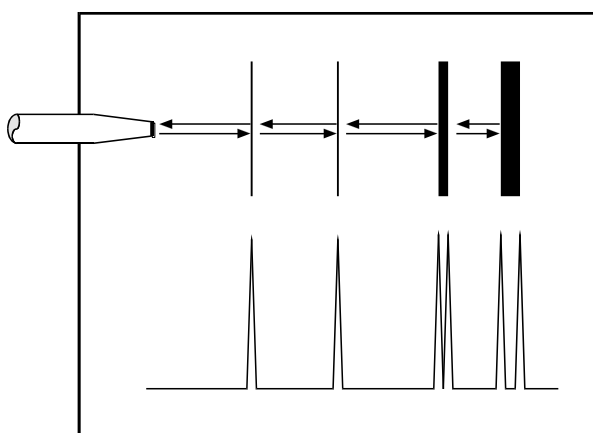


Figure I-A *Sound hitting an interface perpendicularly.*

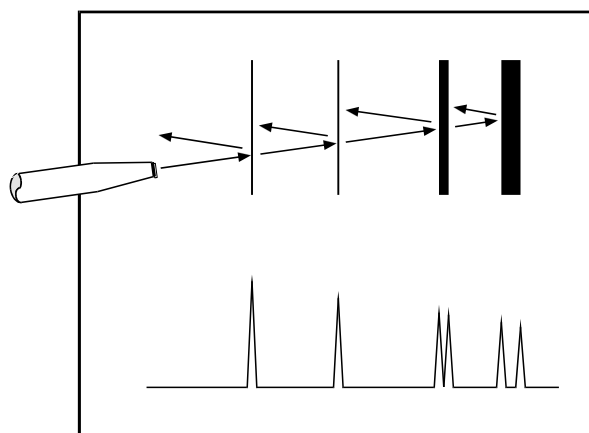


Figure I-B *Sound hitting an interface at an angle.*

Taking into consideration the above properties and applying them to ophthalmology, the alignment of an ultrasound beam through the eye can be determined. This alignment is crucial to the accuracy of measurements that will be used for IOL calculations. Figure

I-C illustrates an ultrasonic pattern typical when alignment along the visual axis is met. Please note the two high spikes representing the anterior lens and posterior lens interfaces, along with a strong spike representing the retinal interface. Conversely, Figure I-D illustrates a pattern representing misalignment. Improper measurements could be obtained with this incorrect alignment. Most older A-Scans require the operator to decide when proper alignment has been met. This is normally done by the operator looking at a display to view the spikes relating to the anterior lens, posterior lens, and retinal interfaces. This is very difficult to master when the operator's attention must be moved from the patient to the equipment. Reproducible results are particularly difficult between two or more operators.

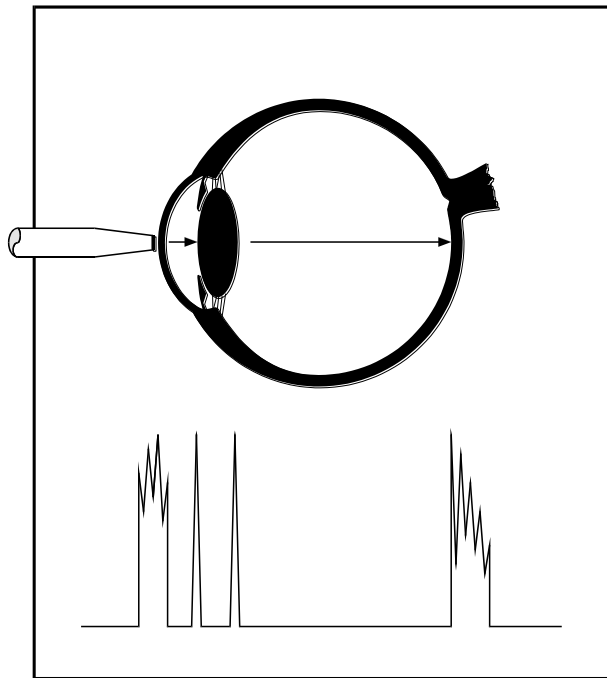


Figure I-C *Correct alignment along the visual axis.*

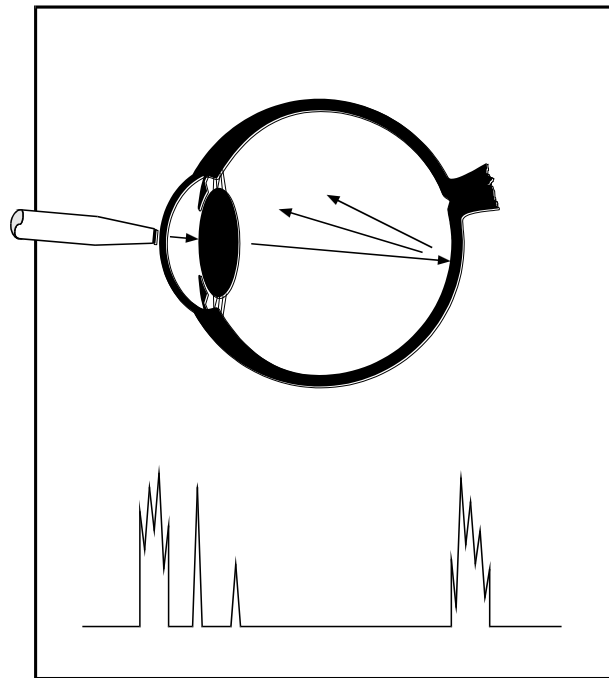


Figure I-D *Incorrect alignment along the visual axis.*

The DGH 5000e A-Scan incorporates a very sophisticated pattern recognition program that automatically checks for proper alignment. It looks for the proper pattern of spikes as well as going a major step further by looking at the retinal spike for particular signal characteristics which are produced only by retinal interfaces. This recognition is accomplished very quickly and does not remove your attention from the patient.

An important property of ultrasound is that it cannot travel through air. It must have a medium of substantial mass for transmission. Liquids or substances containing large amounts of water conduct ultrasound very well. This agrees with the fact that the speed of sound is faster in materials that are more dense. Figure I-E shows a list of the established speeds of sound for ophthalmic structures.

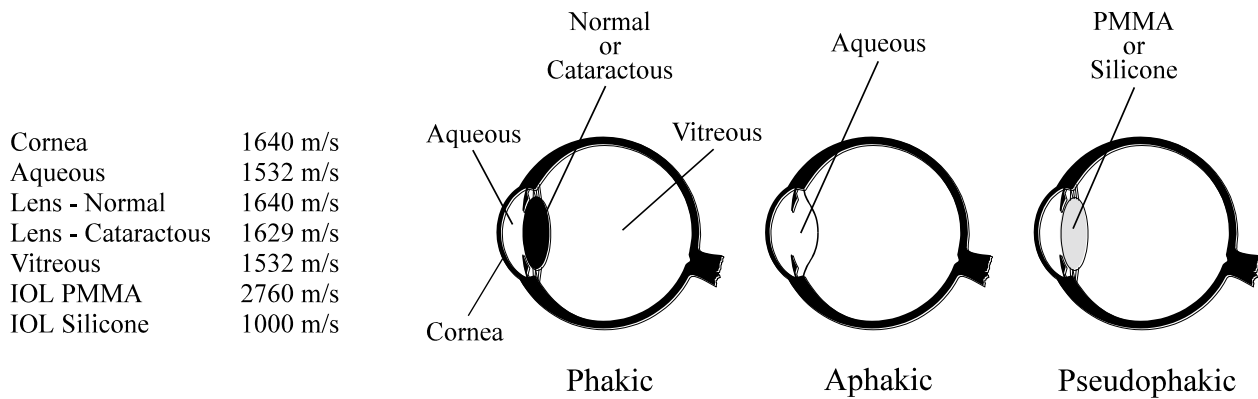


Figure I-E *Speeds of sound for ophthalmic structures.*

Using the relationship between the density of a material and the speed of sound, Ophthalmic A-Scans obtain distances in the eye by performing a two step process. First, a pulse of sound is timed as it travels through the eye, reflects off the retina, and returns to the transducer. Second, a length is calculated by analyzing the travel time in comparison to the speed of sound through the eye. Most ophthalmic ultrasonic units use an average speed of sound of 1550 m/s for phakic eyes and 1532 m/s for aphakic eyes. The DGH 5000e is programmed to automatically use the proper speed for the eye you wish to read.

Another important area of concern in obtaining accurate A-Scan measurements is corneal indentation. Logic would dictate that if you indent the very thing you are measuring, a false or shortened value will be obtained. Logic also dictates that as soon as you touch something that is soft, you will immediately indent it. This is true of the eye when an ultrasonic probe comes in direct contact with the cornea. The DGH 5000e has a pattern recognition program that rejects any measurement which contains a significant amount of corneal indentation. So, through a simple and fast technique, accurate ultrasonic measurements can be obtained.

For an even greater degree of accuracy, the DGH 5000e can be equipped with the optional Water Immersion mode. This option completely eliminates corneal indentation because the probe never touches the cornea.

The only important measurement obtained via an A-Scan for IOL calculations is the axial length (Figure I-F). Dimensions of other structural entities of the eye can prove useful; however, only a few A-Scans on the market are able to produce these. The DGH 5000e displays values for the anterior chamber, lens thickness, and axial length automatically each time a reading is made. These readings can be entered into the patient's permanent record via the integrated printer or the optional computer link.

Obtaining accurate measurements for the axial length of the eye is only part of the challenge of predicting the correct IOL power for a patient. Many factors play roles in the procedure. Several of the most common factors are described in the following sections.

Axial Length

Axial length measurement is the most important factor affecting IOL power calculations. An error of 1.0 mm affects the postoperative refraction by approximately 2.5 diopters.

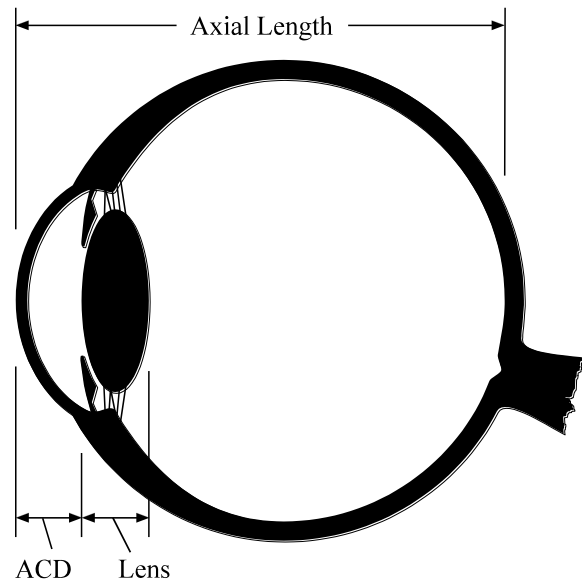


Figure I-F Axial length of the eye.

Corneal Power

Corneal power is the second most important factor affecting IOL power calculations. A keratometer is an instrument that measures the central 3.3 mm of the anterior curvature of the cornea in its two meridians. The readings are called K-readings.

There are two potential sources of error in keratometry. First, failure to calibrate the instrument can cause all readings to be in error by as much as 0.2 mm or 1.0 D. A second source of error is hidden in the dioptric scale of any keratometer. No keratometer measures the refracting power of the cornea in diopters. Keratometers measure the radius of curvature of the anterior corneal surface and then convert this millimeter measurement into diopters. The dioptric scale used for this conversion is based on an assumption, a fictitious refractive index. The true refractive index of the cornea is 1.376, but to obtain an approximation of the true refracting power of the cornea from only the radius of the anterior surface, a fictitious refractive index has to be used. This index varies with the make of keratometer. Common values are:

- 1.3375 (Haag-Streit, Bausch and Lomb)
- 1.336 (American Optical)
- 1.332 (Gambs)

A radius of 7.8 mm will thus read 43.27, 43.08, or 42.56 D respectively, depending on which keratometer is used. These differences may not be of much importance in contact lens fitting or the determination of corneal astigmatism. However, these differences are significant when calculating IOL power, which is a new application for the established discipline of keratometry.

Any IOL power calculation formula which features the dioptric power of the cornea is subject to this source of error. With the same data, one may calculate IOL powers varying almost a diopter depending on the make of the keratometer used.

With both potential sources of error in mind, consider that an error of 1 diopter in the measurement of the corneal power produces an error of about 1 diopter in the post-operative refraction.

Postoperative Anterior Chamber Depth

The anterior chamber depth is the least important factor affecting IOL power calculations. An error of 1.0 mm affects the postoperative refraction by approximately 1.0 diopter in a myopic eye, 1.5 diopter in an emmetropic eye, and up to 2.5 diopters in a hyperopic eye.

Preoperative measurement of the anterior chamber depth is of little value, and the actual position of the IOL after surgery cannot be accurately predicted so an estimate has to be used.

Surgical Technique

Changes in corneal curvature are often noted postoperatively. This fact as well as differences between actual placement and predicted placement of the IOL can produce an error. An intraocular lens placed in the posterior segment requires a stronger power, and inserting the implant with the convex side backwards necessitates an even stronger lens.

Implant Power

The implant power is measured differently by different manufacturers. This can result in variations between IOL companies.

Formulas Used

There are basically two classifications of IOL formulas - Theoretical and Regression. All THEORETICAL formulas work on optical formulas based on a two lens system, the cornea and pseudophakic lens focusing images on the retina. REGRESSION formulas are derived empirically from retrospective computer analysis of data on a great many patients who have undergone surgery. Although similar results are obtained between regression and theoretical formulas for eyes that are considered average in length (23.5 mm), results may vary for eyes on the shorter and longer side of average.

An ideal IOL prediction formula would be one that is derived empirically from a retrospective analysis of data on patients operated on by the same surgeon, using the same IOL, and obtaining measurements from the same equipment. This would be a personalized regression formula.

Summary

Predicting preoperatively the IOL power is a combination of science and art. Accurate axial length and keratometry measurements must be obtained. These measurements must then be applied to the prediction formula that works best for the surgeon. With the majority of accuracy based on correct axial length readings, the importance of a simple, fast and accurate ultrasonic A-Scan is increased.

II. FEATURES

The DGH 5000e Ultrasonic A-Scan is manufactured with high quality components that are designed and built using the latest technological concepts. The result is an advanced and powerful unit that offers practicality and reliability. The following features are just a sample of the characteristics and capabilities of this unique unit.

- Simple to use. No complicated setup procedures to follow - very user friendly.
- Solid transducer tip, 3.0 mm in diameter, for ease of appplanation and visualization.
- Graphic display simultaneously shows the axial length, anterior chamber depth, lens thickness, and a waveform of the echo amplitudes.
- Front panel keypad permits programming and data entry.
- Storage of measurement data for review.
- Operator feedback. An audible signal indicates when the probe is properly aligned and when a valid measurement is complete.
- An A-Scan pattern recognition program that yields accurate, reproducible measurements in a fraction of a second.
- Built in printer documents the A-Scan measurements and IOL power calculations generated by the unit.
- Multiple doctor configurations. Allows personalized IOL configurations and printer settings for 5 different doctors. This information is permanently stored even when the unit is turned off.
- Water Immersion (Optional). This feature completely eliminates corneal indentation and also provides a measurement technique that is much more consistent. As a result, both precision and accuracy are increased.

III. GENERAL DESCRIPTION

Front Panel

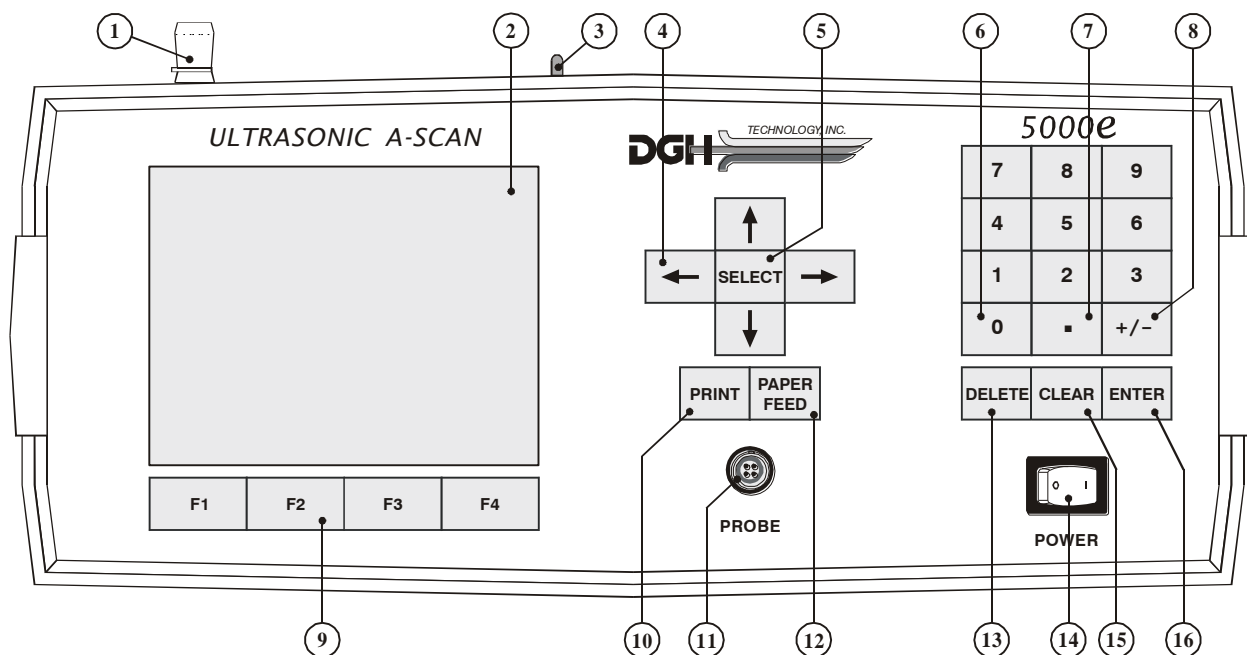


Figure III-A DGH 5000e front panel layout.

- ① **Paper Door Latch**
When the thermal printer paper needs replacing, this latch is used to gain access to the thermal graphics printer. The printer provides the operator with a permanent record.
- ② **Graphic Display**
The display is used to present both text and graphic information to the operator.
- ③ **Paper Release Lever**
This lever releases the thermal paper from the printer platen.
- ④ **“ ↑ ↓ ← → ” - Cursor Keys**
These keys are used to position the cursor for data entry. The cursor keys are also used for scrolling through menu options, acquired axial measurements, or IOL calculations.

- ⑤ **“SELECT”**
This key is used to select lettered parameter values in all configuration screens, or to select menu items from any pop-up menus. Also, if the Water Immersion option is enabled, this key is used to start or stop the measurement sequence.
- ⑥ **“0” thru “9” - Digits**
Used to input appropriate numbers for A-Scan setup and IOL calculations.
- ⑦ **“.” - Decimal Point**
Used to provide fractional data for IOL calculations.
- ⑧ **“+/-” - Sign Change**
Used to change the sign of a number appearing on the display.
- ⑨ **“F1” thru “F4” - Function Keys**
Depending on the current state of the unit, these four keys will take on different functions. A label for each function key will be provided by the graphic display.
- ⑩ **“PRINT”**
Initiates print out.
- ⑪ **A-Scan Probe Interface**
Connector located on the front panel which mates to the A-Scan probe.
- ⑫ **“PAPER FEED”**
Allows the printer paper to be advanced.
- ⑬ **“DELETE” - Delete Measurement**
Used to delete an undesired measurement or to erase unwanted keystrokes when entering data
- ⑭ **Power Switch**
Rocker switch located on the lower right hand corner of the front panel.
- ⑮ **“CLEAR”**
Used to clear A-Scan measurements and/or Patient Data from memory.
- ⑯ **“ENTER”**
Used to enter data or to accept options presented on the display.

Back Panel

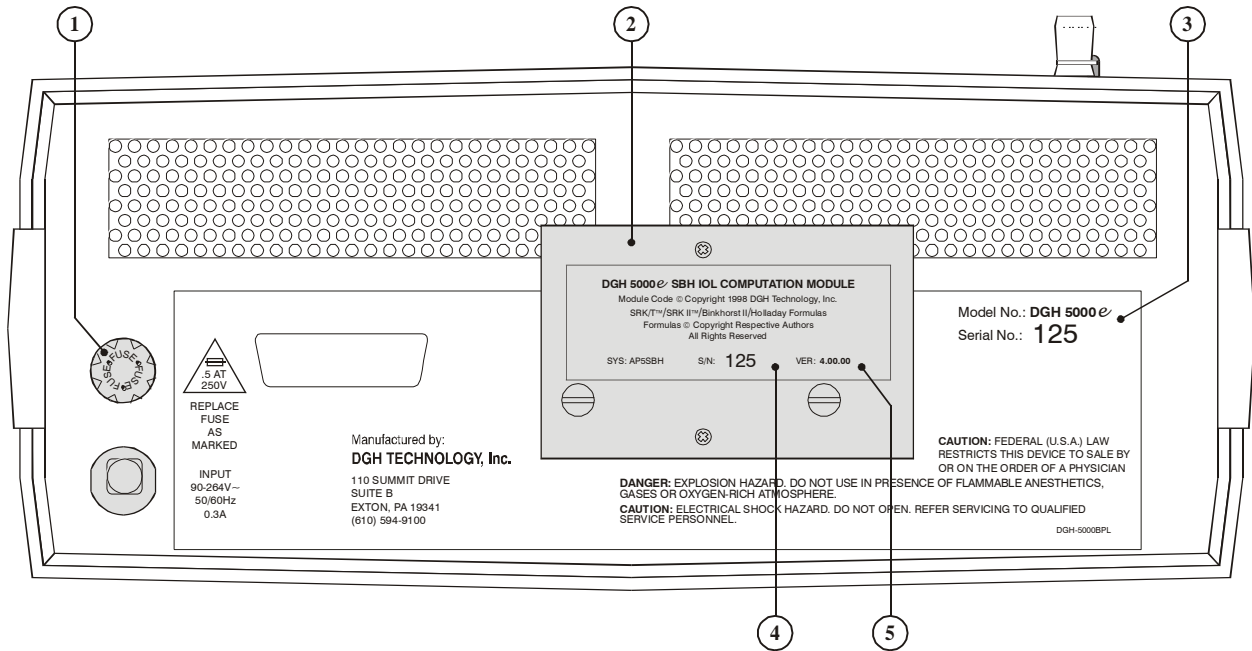


Figure III-B *DGH 5000e back panel layout.*

- ① **Fuse Holder**
Contains the AC line fuse.
- ② **IOL Calculation Firmware Module**
Firmware module where the IOL calculation formulas are stored.
- ③ **Unit Model Number & Serial Number**
Location of the model number and serial number for the DGH 5000e. These numbers are used to identify the unit.
- ④ **IOL Calculation Firmware Module Serial Number**
Location of the serial number for the IOL calculation firmware module.
- ⑤ **IOL Calculation Firmware Module Revision Number**
Location of the revision number for the IOL calculation firmware module.

Calibration Standard

The DGH 5000e uses a polystyrene test block (Figure III-C) to check the A-Scan calibration. This block simulates an aphakic axial length of 23.90 ± 0.25 mm. Refer to section IX on page 43 for instructions on using the test block.

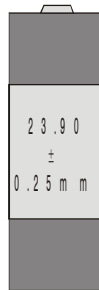


Figure III-C *Polystyrene test block*

IV. PRELIMINARY INFORMATION

Conventions Used In This Manual

- Keys on the keypad are always shown in bold uppercase letters. For example, **DELETE**, **SELECT**, and **ENTER**.
- Function key labels are shown in bold uppercase letters and are immediately followed by the function key number. For example, **ASCAN (F2)**, **IOL (F3)**, and **SETUP (F4)**.
- Menu items, which are found on a pop-up menu, are shown in bold letters. For example, **Printout...**, and **Display...**
- Parameters, which are found on the setup pages, are shown in small capital letters. For example, DEFAULT POWERUP SCREEN, MEASUREMENT TIMEOUT, and PATIENT NUMBER.
- Parameter values, which are found on the setup pages, are shown in quotes. For example, "Patient Data", "Cataract", and "Meas".

Function Keys

Function keys are located directly underneath the graphic display. The purpose of each key may change or become inactive if it is not needed. Any Function key that is active will have a label displayed directly above it. The label will describe the purpose of the function key at the appropriate time.

Inputting Data and Changing Parameters

On the DGH 5000e, inputting data and/or changing setup parameters is accomplished by accessing the appropriate input or setup page. On these pages, a highlighted cursor identifies exactly which data/parameter can be modified. To advance from one data/parameter to the next, use one of the cursor keys (↑, ↓, ←, or →). Once the desired data/parameter is highlighted, the operator can make the appropriate changes.

Any data/parameters that have a numeric value can be entered by using the numeric keypad. If a wrong number is accidentally entered, it can be erased by pressing the

DELETE key. For any data/parameters that have a lettered value, press the **SELECT** key repetitively to cycle through the available options.

The Default Power Up Screen

Whenever the DGH 5000e is powered up, the unit performs an internal self-test function, and then displays either the “Patient Data” page (Figure IV-A) or the “A-Scan” mode (Figure IV-B). Which screen the unit will display is determined by a parameter called the DEFAULT POWERUP SCREEN. At the factory, this parameter is programmed so that the patient data page will appear whenever the unit is turned on. If the operator prefers to have the A-Scan mode appear instead, the DEFAULT POWERUP SCREEN can be changed by accessing the A-Scan Setup page as described in section V.A on page 17.

PATIENT DATA		04 / 12 / 01
Doctor Number	■
Operator Number	0
Patient Number	0
A-Scan Info		
		* OD OS
Lens Type	Cataract	Cataract
K1	0	0
K2	0	0
Desired Refraction	0	0
AXL Length Source	Meas	Meas
AXL Length Average	0	0
A-SCAN		IOL SETUP

Figure IV-A Patient Data page.

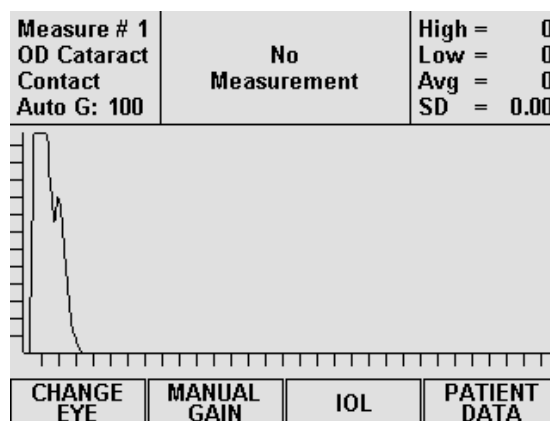


Figure IV-B A-Scan mode.

Patient Data Page

The patient data page is the home base of the DGH 5000e. From this page the operator can either input patient information or access one of three major sections of the unit. These sections are: (1) The A-Scan mode, (2) the IOL calculator, and (3) the Setup menu. To access any one of these sections, press the appropriate function key located underneath the display. The **ASCAN** (F2) key switches the unit to the A-Scan mode so that the operator can obtain axial length measurements. The **IOL** (F3) key initiates IOL power calculations provided that all necessary data has been entered into the DGH 5000e. The **SETUP** (F4) key displays the setup menu which permits the operator to access several different pages. These pages are designed for customizing the

DGH 5000e, for entering IOL configuration data, or for checking A-Scan calibration. To select an item from the setup menu, use the ↑ or ↓ cursor keys to highlight the item, and then press either **SELECT** or **ENTER**. To exit the setup menu without selecting any item, press the **SETUP** (F4) key again.

Clearing the DGH 5000e

It is recommended that the DGH 5000e be cleared whenever the operator has finished with the current patient. By doing so, the unit will be ready to obtain measurements on the next patient. Clearing the DGH 5000e erases A-Scan measurements, IOL calculations, or patient data from the memory of the unit. The operator can choose exactly which information should be erased by pressing the **CLEAR** key and then selecting one of the available on-screen options. The selection of on-screen options will differ depending upon which mode is currently active.

When the patient data page is active (Figure IV-A), pressing **CLEAR** causes the following options to appear: **Clear Patient Data**, **Clear A-Scan**, **Clear All**, or **Cancel**. Selecting **Clear Patient Data**, or **Clear A-Scan** will only clear the appropriate section. Selecting **Clear All** will clear the entire unit. Selecting **Cancel** will abort the clear procedure and remove the clear prompt.

If the A-Scan mode is active (Figure IV-B), pressing **CLEAR** causes the following options to appear: **Clear A-Scan**, **Clear OD**, **Clear OS**, or **Cancel**. Selecting **Clear OD**, or **Clear OS**, will only clear the appropriate section. Selecting **Clear A-Scan** will clear both the OD and OS sections. Selecting **Cancel** will abort the clear procedure and remove the clear prompt.

Note Whenever the DGH 5000e is powered up, all of the above memory sections are automatically cleared.

V. SETTING UP THE DGH 5000e

The DGH 5000e has been designed to allow the operator to set up certain default parameters so that the A-Scan can be tailored to meet one's needs. These parameters can be changed by accessing one of the following setup pages: (1) A-Scan Setup, (2) Printout Format, and (3) Display Appearance. In the sections that follow, procedures are given that explain how to access these setup pages and make changes to the default settings. Changed parameters are permanently stored in memory so that they will be automatically recalled each time the unit is powered up.

In addition to changing default parameters, the unit has also been designed to accept specific patient data that is necessary for IOL calculations. Section V.B explains the correct procedure for entering a patient's data.

V.A. The A-Scan Setup Page

The A-Scan Setup page contains velocity and thickness parameters for the most common types of lenses. Other parameters also available on this page are the DEFAULT POWERUP SCREEN, MEASUREMENT TIMEOUT, and MEASUREMENT MODE. Descriptions for all the A-Scan setup parameters are given in Table 1 on page 18. Use the following procedure to access the A-Scan Setup page and modify these parameters.

1. On the Patient Data page, press **SETUP** (F4) and then use the \uparrow cursor key to highlight **A-Scan...** (Figure V-A).

PATIENT DATA		04 / 12 / 01
Doctor Number	1
Operator Number	0
Patient Number	0
A-Scan Info		
Lens Type	Cat	Service...
K1	Test A-Scan...
K2	IOL...
Desired Refraction	A-Scan...
AXL Length Source	Display...
AXL Length Average	Printout...
		SETUP

Figure V-A Accessing the A-Scan Setup page from the setup menu.

A-SCAN SETUP		04 / 12 / 01
Default Powerup Screen	Patient Data
Measurement Timeout	5 sec
Measurement Mode	Direct Contact
Lens Type	Vel (m/s)	Thick (mm)
Normal	1640	N/A
Cataract	1629	N/A
Aphakic (Aqu/Vitr)	1532	N/A
PMMA	2760	0.70
Silicone	1000	0.90
Acrylic	2120	0.70
		OK
		CANCEL
		DEFAULTS

Figure V-B A-Scan Setup page.

2. Press either **SELECT** or **ENTER** to display the A-Scan Setup page (Figure V-B).
3. Highlight the value of the parameter to be modified by using the cursor keys.
4. Use the numeric keypad to change any parameters that have a numeric value. If a wrong number is accidentally entered, it can be erased by pressing the **DELETE** key. For any parameters that have a lettered value, use the **SELECT** key to choose one of the available options.
5. Press **OK** (F2) to exit the A-Scan Setup page. If any parameters were modified, the operator will be prompted to save the changes. Answer the prompt by highlighting either YES or NO and then press **SELECT**. All saved parameters are retained in memory even when power is removed from the unit.

Other Function Keys

CANCEL (F3) - exits the A-Scan Setup page without saving any changes.
DEFAULTS (F4) - resets all parameters back to their original factory settings.

Table 1 *Parameters On The A-Scan Setup Page*

Parameter	Default Value	Value Range	Description
Default Powerup Screen	Patient Data	Patient Data or A-Scan	Determines which screen will appear when the DGH 5000e is initially powered up.
Measurement Timeout	5 sec	0 - 30 sec (0 disables timeout)	Length of time that the probe may be applanated to the cornea before a time-out message appears.
Measurement Mode <i>(Only visible if the Water Immersion option is installed.)</i>	Direct Contact	Direct Contact or Water Immersion	Direct Contact – to obtain measurements the probe must touch the cornea. Water Immersion – to obtain measurements the probe must be held above the eye in a water bath.
Normal Velocity	1640 m/s	1000 - 1999 m/s	Speed of sound in a natural lens.
Cataract Velocity	1629 m/s	1000 - 1999 m/s	Speed of sound in a cataractous lens.
Aphakic (Aqu/Vitr) Velocity	1532 m/s	1000 - 1999 m/s	Speed of sound in the aqueous/vitreous.
PMMA Velocity	2760 m/s	1000 - 3999 m/s	Speed of sound in a PMMA lens.
Silicone Velocity	1000 m/s	1000 - 3999 m/s	Speed of sound in a silicone lens.
Acrylic Velocity	2120 m/s	1000 - 3999 m/s	Speed of sound in an Acrylic lens.
PMMA Thickness	0.70 mm	0.10 - 2.99 mm	Thickness of the PMMA lens.
Silicone Thickness	1.20 mm	0.10 - 2.99 mm	Thickness of the Silicone lens.
Acrylic Thickness	0.70 mm	0.10 - 2.99 mm	Thickness of an Acrylic lens.

V.B. The Patient Data Page

Patient data for the DGH 5000e consists of the following information:

- Doctor number
- Operator number
- Patient number
- Type of lens in the eye
- Keratometer readings (K1 and K2)
- Desired postoperative refraction
- Averaged axial length

This information is used for both patient identification and the calculation of IOL powers. To input a patient’s data into the DGH 5000e, use the procedure described below. This data is deleted from the unit’s memory whenever power is removed. Therefore, if a permanent record is desired, a hard copy should be printed before the power switch is turned off.

Entering Patient Data

Whenever the unit is turned on, the patient data page is automatically displayed and the unit is ready to accept data (Figure V-C),. If the A-Scan mode or IOL calculator is currently being used, the patient data page can be accessed by pressing the **PATIENT DATA** (F4) key. Descriptions for all patient data are given in Table 2 on page 21. Use the following procedure to enter the data.

1. If a date is desired on the printout, press the **↑** key and then enter the date. Two digit numbers are used to represent the month, day, and year. After each two digit number, press **ENTER** to advance to the next number.
2. Enter a doctor number (1 - 5) and then press **ENTER**. This number is used to associate a personalized group of IOL configurations (formulas, constants, etc.) and printer settings with a doctor.

PATIENT DATA		04 / 12 / 01
Doctor Number	█
Operator Number	0
Patient Number	0
A-Scan Info		
		* OD OS
Lens Type Cataract Cataract
K1 0 0
K2 0 0
Desired Refraction 0 0
AXL Length Source Meas Meas
AXL Length Average 0 0

A-SCAN

IOL

SETUP

Figure V-C Patient Data page.

Note To setup an IOL configuration(s)

or change printer settings for the current doctor, press **SETUP** (F4) and then select the appropriate item from the setup menu.

3. For operator identification, enter an operator number and then press **ENTER**.
4. For patient identification, enter a patient number and then press **ENTER**.
5. The LENS TYPE for the OD eye should now be highlighted. Before taking A-Scan measurements, the proper type of lens should always be selected (Cataract is the default). If only the OS eye will be measured, use the **→** key to highlight the OS LENS TYPE.
6. Choose the proper LENS TYPE by using the **SELECT** key and then press **ENTER**.
7. If IOL powers need to be calculated, enter both K readings, and the desired postoperative refraction. Follow each entry with the **ENTER** key.
8. The AXL LENGTH SOURCE should now be highlighted. If axial length measurements will be obtained with the DGH 5000e, the source should be “Meas” (measured). However, if only IOL calculations need to be performed and the patient’s axial length is already known, then the source should be changed to “Input”. Changing the source from “Meas” to “Input” allows the operator to enter a known axial length for the AXL LENGTH AVERAGE parameter.
9. Choose the desired AXL LENGTH SOURCE by using the **SELECT** key and then press **ENTER**.
10. If AXL LENGTH SOURCE was set to “Input”, then the AXL LENGTH AVERAGE parameter will be highlighted. Input the patient’s axial length and then press **ENTER**.
11. If taking measurements and/or performing IOL calculations on both eyes, patient data for the OD eye should now be completed. Repeat steps 6 thru 10 (as appropriate) for the OS eye.
12. After all patient data has been entered, proceed with A-Scan measurements, IOL calculations, or one of the setup pages.

Clearing Patient Data

When finished with the current patient, all of the patient’s data should be erased from the memory of the DGH 5000e before starting with a new patient. Patient data is erased by pressing the **CLEAR** key and then selecting an appropriate on-screen option. The **Clear Patient Data** option erases all patient data that was entered by the operator, but it does not erase the “Measured” axial length average. This axial length is the result of

A-Scan measurements that were obtained in the A-Scan mode. To erase the measured axial length average, select either the **Clear A-Scan** or the **Clear All** option.

Table 2 *Parameters On The Patient Data Page*

Data Parameter	Default Value	Value Range	Description
Date	00 / 00 / 00	Month: 1 to 12 Day: 1 to 31 Year: 0 to 99	The current date. If the date is entered, it will appear on the printout.
Doctor Number	1	1 to 5	A number used to associate personalized IOL configurations and printout settings with a doctor.
Operator Number	0	0 to 9999999999	A 10 digit number used to identify the operator of the DGH 5000e.
Patient Number	0	0 to 9999999999	A 10 digit number used to identify the patient.
Lens Type	Cataract	Cataract, Normal, Aphakic, PMMA, Silicone, Acrylic.	The type of lens associated with the patient's eye that is being measured.
K1	0	30 to 60 D	The first keratometer reading. This value must be entered in diopters (337.5 / mm of radius = diopters).
K2	0	30 to 60 D	The second keratometer reading. This value must be entered in diopters (337.5 / mm of radius = diopters).
Desired Refraction	0	-9.00 to + 9.00	The desired postoperative refraction.
AXL Length Source	Meas	Meas or Input	Source of the patients axial length. The source can either be "Meas" (measured by using the A-Scan mode) or "Input" from the patient's previous record.
Axl Length Average	0	15 to 36 mm (Source = Input)	Averaged axial length obtained with the DGH 5000e, or a length entered by the operator from the patient's previous record.

V.C. The Printout Format Page

The DGH 5000e includes a 38 column thermal printer for generating a permanent record of all A-Scan measurements and IOL calculations. From the factory, the printout format parameters of the DGH 5000e are configured to print in a manner that will be satisfactory for most situations. However, if a printout which includes more or less

information is desired, then the Printout Format page can be used to customize the printout format parameters.

Changing The Printout Format Parameters

Descriptions for all the printout format parameters are given in Table 3 on page 23. Use the following procedure to access the Printout Format page and make changes to these parameters.

1. On the Patient Data page, press **SETUP** (F4) and the **Printout...** menu item will be highlighted (Figure V-D).

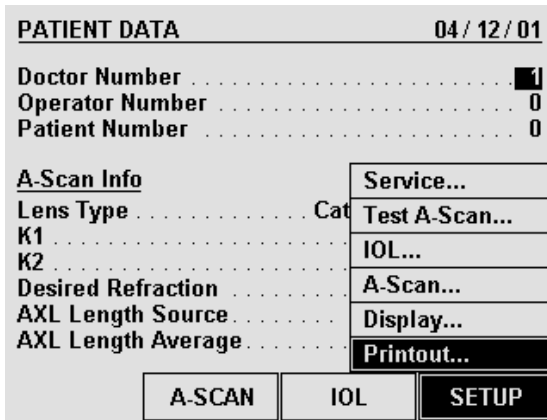


Figure V-D Accessing the Printout Format page from the setup menu.

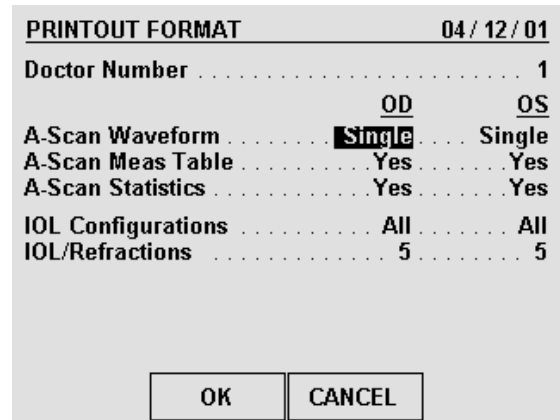


Figure V-E Printout Format page.

2. Press **SELECT** or **ENTER** to display the Printout Format page (Figure V-E).
3. Highlight the value of the parameter to be changed by using the cursor keys.
4. For parameters that have a lettered value, use the **SELECT** key to choose one of the available options. Parameters that have a numeric value can be changed by using the numeric keypad. If a wrong number is accidentally entered, it can be erased by pressing the **DELETE** key.
5. Press **OK** (F2) to exit the Printout Format page. If any parameters were modified, the operator will be prompted to save the changes. Answer the prompt by highlighting either YES or NO and then press **SELECT**. All saved parameters are retained in memory even when power is removed from the unit.

Other Function Keys

CANCEL (F3) - exits the Printout Format page without saving any changes.

Table 3 *Parameters On The Printout Format Page*

Parameter	Default Value	Selection Choices	Description
A-Scan Waveform	Single	Single, All, None	Determines how many graphic waveforms will be printed. If set to “Single”, only the measurement that is currently being displayed will be printed.
A-Scan Meas Table	Yes	Yes or No	If enabled (“Yes”), the printout will include a short table of all obtained measurements.
A-Scan Statistics	Yes	Yes or No	If enabled (“Yes”), the printout will include statistical data for the obtained measurements.
IOL Configurations	All	Single, All, None	Determines how many IOL configurations will be printed. If set to “Single”, only the IOL configuration that is currently being displayed will be printed.
IOL/Refractions	5	3 to 21 (odd numbers only)	Determines how many IOL/Refraction combinations will be printed.

V.D. The Display Appearance Page

Under different lighting conditions, it is possible that the graphic display may appear either too light or too dark. Exactly how the display should look really depends upon the operator’s taste. Therefore, the DGH 5000e has been designed so that the operator can adjust the appearance of the graphic display. There are three parameters that can be varied in order to change how the display will look: BACKGROUND COLOR, BRIGHTNESS, and CONTRAST. To change any of these parameters, the operator must first access the Display Appearance page. Use the following procedure to gain access to this page and then change the appearance of the display.

1. On the Patient Data page, press **SETUP** (F4) and then use the **↑** cursor key to highlight **Display...** (Figure V-F).
2. Press **SELECT** or **ENTER** to access the Display Appearance page (Figure V-G).
3. Use the **SELECT** key to set the BACKGROUND COLOR to either “Black” or “White” (“Black” is the default).
4. To change the BRIGHTNESS or CONTRAST, use the **↑** or **↓** cursor keys to highlight the appropriate word, and then use the **←** or **→** cursor keys to make an adjustment.

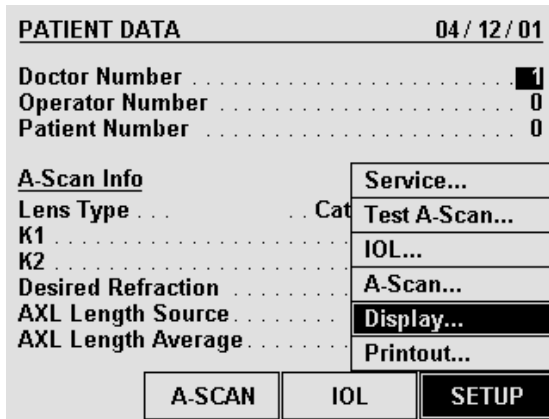


Figure V-F Accessing the Display Appearance page from the setup menu.

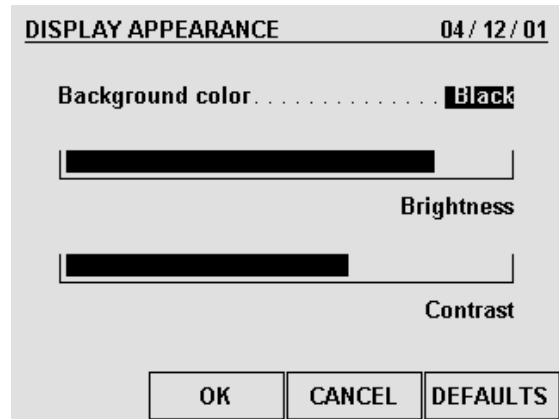


Figure V-G Display Appearance page.

5. Press **OK** (F2) to exit the Display Appearance page. If any parameters were modified, the operator will be prompted to save the changes. Answer the prompt by highlighting either YES or NO and then press **SELECT**. All saved parameters are retained in memory even when power is removed from the unit.

Other Function Keys

CANCEL (F3) - exits the Display Appearance page without saving any changes.
DEFAULTS (F4) - resets the appearance of the display back to its original factory setting.

VI. POWER UP AND PROGRAMMING SEQUENCE

Use the following procedure to prepare the DGH 5000e for taking measurements:

1. Plug the AC cord into a three prong outlet.
2. Verify that the A-Scan probe is connected to the front panel.

***** CAUTION *****

When power is applied to the unit, the DGH 5000e will automatically set the internal gain of the unit to comply with the probe sensitivity. This is how the unit maintains consistent performance throughout the life of a transducer. Therefore, it is **imperative** that the probe tip be **clean and dry before** the unit is turned on. Also, the temperature of the probe should be stabilized to within $\pm 10^{\circ}\text{F}$ of the temperature at which the probe will actually be used. **Never** turn on the unit with the probe attached after the probe has just been exposed to an extremely cold or hot environment. **Always** allow time for the probe to stabilize at room temperature.

3. Turn on the unit by using the power switch located on the front panel.
4. The unit will perform an internal self-test function, and then the display will indicate whether or not an IOL Firmware Module is installed.
5. The Patient Data page will appear on the display (Figure IV-A on page 14).
6. Enter the patient's data as described in section V.B on page 19.
7. Press **A-SCAN** (F2) to access the A-Scan mode (Figure IV-B on page 14).
8. In the A-Scan mode, the upper left portion of the display will indicate "OD" (right eye) and the selected LENS TYPE will also be displayed. The operator may now begin taking A-Scan measurements on the OD eye as described in the next section.
9. If the OS eye is to be measured, press **CHANGE EYE** (F1). The operator may now begin taking A-Scan measurements on the OS eye as described in the next section.

VII. OBTAINING A-SCAN MEASUREMENTS

A basic DGH 5000e obtains A-Scan measurements by using the “Direct Contact” measurement mode. Direct contact means that the ultrasonic probe must be applanated to the cornea. This method is the quickest and most convenient way of taking measurements, but since the cornea is indented, the obtained axial length may be shorter than its actual value. To improve accuracy, the DGH 5000e has a pattern recognition program that rejects any measurement which contains a significant amount of corneal indentation; however, some degree of indentation may still exist. To completely eliminate corneal indentation, the optional “Water Immersion” mode should be used.

When using the Water Immersion mode, measurements are obtained in a column of water while the probe is suspended above the eye. Since the probe does not actually touch the eye, corneal indentation can not occur. As a result, both measurement accuracy and precision are increased.

Two procedures are given below for obtaining A-Scan measurements. The first procedure describes the Direct Contact measurement mode, and the second describes the Water Immersion mode. Follow the appropriate procedure for the measurement mode that will be used. If the Water Immersion option is installed, the operator can switch between Direct Contact and Water Immersion mode by accessing the A-Scan setup page (see section V.A on page 17).

VII.A. Direct Contact Measurement Mode

1. Perform the Power Up and Programming Sequence as described in the previous section.
2. Position the unit for easy visibility during patient examination.
3. Seat or lay the patient in a comfortable position so that the head can be positioned in almost a horizontal plane. Use a firm, comfortable head rest to prevent unwanted head movement.
4. Anesthetize the cornea and ask the patient to fixate with their fellow eye on a spot on the ceiling or wall.
5. Hold the probe in such a way that you can stabilize your hand on the cheek or forehead of the patient. This will help prevent indentation of the cornea or excessive movement.

6. The probe can now be applanated to the cornea. Applanation should be observed from a vantage point that allows the operator to look across the topography of the eye. This method aids in seeing the exact moment when the probe touches the cornea so indentation of the cornea will be minimized. Applanation should be made as close to the visual axis as possible. An aid in this can be to point the back side of the probe at the fixation target while touching the front portion to the center of the cornea.

Note When applanating the probe, one should be particularly careful that contact is made with the center of the probe tip.

***** IMPORTANT *****

In order to obtain measurements, the probe must be in proper alignment. The audible feedback from the unit is a key element to achieving proper alignment. Measurements are most readily obtained by concentrating on the audible feedback while viewing the probe as it is applanated to the cornea. (It is not recommended that the operator view the waveforms on the graphic display during the actual measurement cycle.) The significance of the audible tones that are emitted during the measurement cycle are explained below.

7. At the moment of applanation, the unit will start beeping at a rate of approximately one beep per second. This means that proper coupling has been achieved and sound pulses are being transmitted through the eye. If the beeping stops, then the probe is no longer applanated to the eye and a slight pressure of the probe should be applied.
8. If the probe is in proper alignment when applanation occurs, a measurement will be obtained almost instantaneously as indicated by three short, successive beeps. The axial length measurement can be observed on the graphic display along with its echo waveform. Figure VII-A shows how a typical measurement will be displayed for the “Cataract” LENS TYPE. Measurements for the anterior chamber length and lens thickness are also given. If the unit is configured for a “PMMA”, “Silicone”, or “Acrylic” LENS TYPE, only an anterior chamber length will appear above the axial length. And for the “Aphakic” LENS TYPE, only the axial length will be given.

9. If a measurement is not obtained instantaneously when applanation occurs and the beep rate is still very low, remove the probe from the cornea and position the probe at a slightly different location or angle. Repeat this probe removal and repositioning procedure until either a measurement or a very high beep rate is obtained.

10. At the higher beep rate, measurements can be obtained by slightly tilting the back end of the probe while the tip remains stationary and applanated at the same location. As soon as proper alignment is achieved, the measurement will be obtained - provided that there is no corneal indentation present.

11. If the beep rate reaches a constant tone during the alignment procedure, cornea indentation may be occurring. The DGH 5000e uses special circuitry that prohibits any measurements from being obtained if the cornea is significantly indented. If a constant tone is obtained, maintain the probe alignment and slowly withdraw the probe from the cornea until a measurement is obtained.

12. If a measurement is not obtained after a preset time period of probe applanation, the unit will time out as indicated by two long beeps. The display will show a message indicating why the measurement could not be obtained. For an explanation of all possible messages that can appear when no measurement is obtained, refer to section VIII on page 37. At this point the operator should take the corrective action indicated by the display and reattempt taking a measurement.

Note The time duration allowed for a measurement cycle is preset at the factory for 5 seconds. This time can be changed to meet the operator's needs. Refer to section V.A on page 17 for the procedure used to change this time duration.

13. After obtaining and storing an acceptable measurement as "Measure 1", the unit will be ready to take a second measurement. When the unit senses that the probe is being applanated to the cornea a second time, the display will advance to "Measure 2". At this point, the probe applanation and alignment procedures described in steps 5 through 11 should be repeated until another measurement is taken.

14. The acquisition and storage of up to eight different measurements can be obtained for each eye. Whenever eight measurements are obtained, the unit emits a short-long beep combination and displays a message to indicate that the measurement set is completed. For each group of readings, the unit records the highest, lowest, and

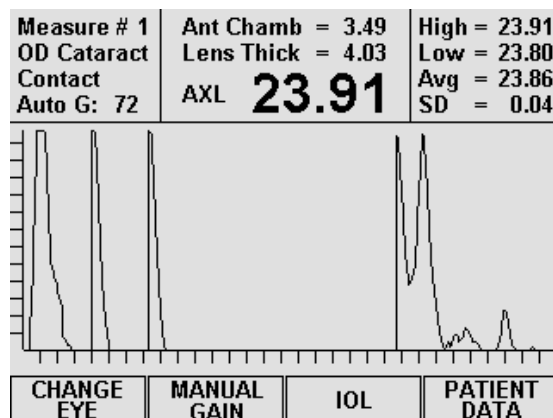


Figure VII-A Typical contact measurement with the "Cataract" lens type.

average measurement, and also calculates the standard deviation. This information is visible in the upper right hand corner of the display, and it is updated after each measurement. The operator can use this information to evaluate just how many measurements are necessary for consistency and repeatability.

15. All measurements and their echo waveforms can be reviewed on the display by pressing the \uparrow or \downarrow cursor keys.
16. If during the data review a reading is observed which is suspect because it does not agree with the other measurements, the measurement data in that particular memory location may be replaced with a new measurement as follows:
 - a) Scroll through the measurement data using the \uparrow or \downarrow cursor keys until the data which you desire to replace with a new measurement appears on the display.
 - b) Press the **DELETE** key to erase the measurement from memory. A message will appear prompting the operator for confirmation. Use the \leftarrow or \rightarrow cursor keys to highlight the appropriate answer and then press **SELECT**.
 - c) Repeat the measurement sequence of steps 5 through 11 above until a new measurement is obtained.
17. After obtaining the desired measurements for the first eye (“OD” or “OS”), the operator may obtain measurements on the same patient’s other eye, if desired, by pressing **CHANGE EYE** (F1) and repeating the measurement sequence of steps 5 through 11.

Note The measurement data for the first eye will remain stored in memory while measurements are being obtained on the second eye.

18. After measurements have been taken, the operator may obtain a permanent record by pressing the **PRINT** key. The unit will print out the following:
 - a) A header with the unit model number and software version number
 - b) Patient Data
 - i) Current date (if input by the operator)
 - ii) Doctor number
 - iii) Space to write the operator’s name and an operator ID number
 - iv) Space to write the patient’s name and a patient ID number
 - v) Type of lens in the eye
 - vi) Keratometer readings (K1 and K2)
 - vii) Desired postoperative refraction
 - viii) Averaged or input axial length measurement
 - c) A-Scan measurement data

- i) Current measurement mode.
- ii) Aqueous/Vitreous velocity and lens velocity.
- iii) Table of the actual ocular measurements including axial length, anterior chamber depth, and lens thickness where applicable. Up to eight (8) measurements for each eye may be printed out (Optional).
- iv) Graphic waveform of one or all measurements (Optional).
- v) Statistical information which includes the high, low, mean, and standard deviation from all axial length measurements (Optional).

Note Optional data can be included or excluded on the printout by enabling or disabling the associated parameter on the Printout Format page as described in section V.C on page 21.

19. All measurements remain in memory until either the A-Scan is cleared or the unit is turned off. To clear A-Scan measurements from memory, press the **CLEAR** key and then select the appropriate on-screen prompt.

***** CAUTION *****

When the **CLEAR** key is pressed and the **Clear A-Scan** prompt is selected, the DGH 5000e will automatically set the internal gain of the unit to comply with the probe sensitivity. Therefore, it is **imperative** that the probe tip be **clean and dry before** the unit is cleared. Also, the temperature of the probe should be stabilized to within $\pm 10^{\circ}\text{F}$ of the temperature at which the probe will actually be used. **Never** clear the unit with the probe attached after the probe has just been exposed to an extremely cold or hot environment. **Always** allow time for the probe to stabilize at room temperature.

VII.B. Water Immersion Measurement Mode

Before each biometry procedure, be sure that both the ultrasound probe and the immersion shell have been cleaned. Besides the normal asepsis procedure employed with a biometry probe (which is commonly a wipe-down with an alcohol prep), there is the necessity to clean the immersion shell itself. This is best accomplished by removing the catheter tubing and then washing the shell, using a bactericidal liquid soap followed by a thorough hot water flush; some practitioners insure asepsis by including a soak in hydrogen peroxide, or alcohol, or in Cydex. We suggest that you use fresh saline for each patient. It is recommended that a busy biometry department acquires two or three shells, allowing one or more shells to be in the cleaning cycle while another one is in use.

1. Perform the Power Up and Programming Sequence as described in section VI.
2. Position the unit for easy visibility during patient examination.
3. Seat or lay the patient in a comfortable position so that the head can be positioned in almost a horizontal plane. Use a firm, comfortable head rest to prevent unwanted head movement.
4. Insert the biometry probe into the shell with the probe cord oriented in line with the filler port. One can easily gauge the correct position of the probe within the shell by advancing the probe until its tip is even with the line scored in the barrel of the shell. Once the correct position has been found, simply tighten the white nylon set screw to hold the probe in place. The software will work only if the probe is in the proper position. Sometimes it may be necessary to move the probe slightly beyond the scribed line toward the flared rim.
5. Fill a syringe (5cc or 10cc size) with saline or BSS and then connect it to the catheter tubing.
6. Administer routine topical anesthesia to the patient's eye.
7. Place a towel on the patient's shoulder and rest the syringe on the towel. Hold onto the probe/shell in preparation for the insertion, with the filler port and probe cord oriented in a position that is comfortable for the operator and patient (we suggest that the filler port and probe cord be oriented downward, toward the patient's feet).
8. Press **SELECT** to start the measurement sequence. The unit will start beeping at a rate of one beep per second.
9. Direct the patient to look downward, toward their feet; then lift the patient's upper eye lid and insert the flared rim underneath the lid (the upper portion of the shell will make contact with the sclera while the lower part of the shell will be held

away from the eye); then direct the patient to look straight ahead with the other, uncovered eye, toward the fixation spot. Pull the patient's lower eyelid down and gently pivot the lower portion of the shell into the lower fornix, making sure by close inspection that it is in the fornix and not atop a fold in the conjunctiva. This pivotal motion avoids contact with the cornea and insures centration of the device around the limbus.

10. Rest the left hand/palm on the patient's forehead to reduce shell pressure on the eye. Moreover, the palm acts as the fulcrum or pivot point for the shell. Sometimes you can stabilize the shell with the right hand and make micro-movements. With practice you will usually hold the shell with just the left hand resting on the forehead. The right hand is free to make instrument adjustments, if necessary. A Kleenex may be placed on the temporal canthus to catch any excess saline.
11. Pick up the syringe from its place on the patient's shoulder and slowly inject the saline into the shell. As soon as the liquid fills the shell sufficiently to reach the tip of the probe (about 2cc) the beep rate will increase. This means that proper coupling has been achieved and sound pulses are being transmitted through the eye.

***** IMPORTANT *****

In order to obtain measurements, the probe must be in proper alignment. The audible feedback from the unit is a key element to achieving proper alignment. Measurements are most readily obtained by concentrating on the audible feedback while viewing the probe/shell as it is aligned with the visual axis. (It is not recommended that the operator view the waveforms on the graphic display during the actual measurement cycle.) The significance of the audible tones that are emitted during the measurement cycle are explained below.

12. If the probe is in proper alignment when the saline is injected, a measurement will be obtained almost instantaneously as indicated by three short, successive beeps. The axial length measurement can be observed on the graphic display along with its echo waveform. Figure VII-B shows how a typical measurement will be displayed for the "Cataract" LENS TYPE. Measurements for the anterior chamber length and lens thickness are also given. If the unit is configured for a "PMMA", "Silicone", or "Acrylic" LENS TYPE, only an anterior chamber length will appear above the axial length. And for the "Aphakic" LENS TYPE, only the axial length will be given.

13. If a measurement is not obtained instantaneously and the beep rate is still very low, then the probe is too far out of alignment. Move the shell around the sphere of the eye in a manner that brings the line of the probe closer to the visual axis. The beep rate will increase as the probe gets closer to the visual axis.
14. As soon as proper alignment is achieved, a measurement will be obtained as indicated by three short, successive beeps.
15. If a measurement is not obtained after a preset time period, the unit will time out as indicated audibly by two long beeps. The display will show a message indicating why the measurement could not be obtained, and then the unit will attempt the measurement again. While reattempting the measurement, the operator should take the corrective action that was indicated by the message. For an explanation of all possible messages that can appear when no measurement is obtained, refer to section VIII on page 37.

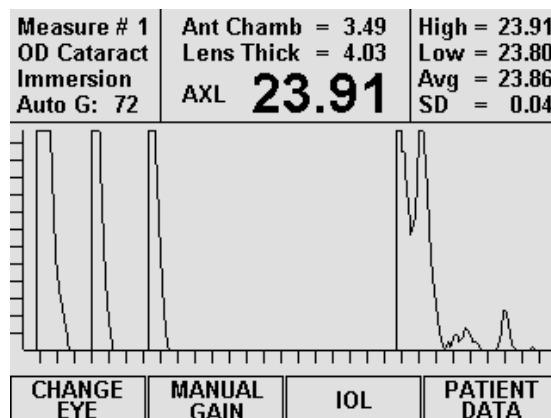


Figure VII-B Typical immersion measurement with the "Cataract" lens type.

Note The time duration allowed for a measurement cycle is preset at the factory for 10 seconds. This time can be changed to meet the operator's needs. Refer to section V.A on page 17 for the procedure used to change this time duration.

16. After obtaining the first measurement, the unit will immediately begin to take more measurements as long as the probe/shell is held in the proper alignment. If the unit has trouble obtaining any one measurement, then the probe alignment procedure described in steps 13 - 15 should be repeated until the measurement is obtained.
17. Up to eight different measurements can be obtained for each eye. Whenever eight measurements are obtained, the unit emits a short-long beep combination and displays a message to indicate that the measurement set is completed. For each group of readings, the unit records the highest, lowest, and average measurement, and also calculates the standard deviation. This information is visible in the upper right hand corner of the display, and it is updated after each measurement. The operator can use this information to evaluate just how many measurements are necessary for consistency and repeatability.
18. All measurements and their echo waveforms can be reviewed on the display by pressing the \uparrow or \downarrow cursor keys.
19. If during the data review a reading is observed which is suspect because it does not agree with the other measurements, the measurement data in that particular

memory location may be replaced with a new measurement as follows:

- a) Scroll through the measurement data using the ↑ or ↓ cursor keys until the data which you desire to replace with a new measurement appears on the display.
 - b) Press the **DELETE** key to erase the measurement from memory. A message will appear prompting the operator for confirmation. Use the ← or → cursor keys to highlight the appropriate answer and then press **SELECT**.
 - c) Obtain a new measurement.
20. After measurements are obtained and reviewed, remove the shell from the patient's eye. Raise the patient's upper eyelid, which releases the top part of the shell from under the eyelid. Then pivot the shell downward, directing the patient to continue to look straight ahead. Then pull the shell away from the eye without contacting the cornea. Upon the initial release, the remaining contents of the shell (1-3cc of liquid) will spill down the patient's cheek. Be prepared with a towel or Kleenex.
21. After obtaining the desired measurements for the first eye ("OD" or "OS"), the operator may obtain measurements on the same patient's other eye, if desired, by pressing **CHANGE EYE** (F1) and then repeating the measurement procedure.

Note The measurement data for the first eye will remain stored in memory while measurements are being obtained on the second eye.

22. After measurements have been taken, the operator may obtain a permanent record by pressing the **PRINT** key. The unit will print out the following:
- a) A header with the unit model number and software version number
 - b) Patient Data
 - i) Current date (if input by the operator)
 - ii) Doctor number
 - iii) Space to write the operator's name and an operator ID number
 - iv) Space to write the patient's name and a patient ID number
 - v) Type of lens in the eye
 - vi) Keratometer readings (K1 and K2)
 - vii) Desired postoperative refraction
 - viii) Averaged or input axial length measurement
 - c) A-Scan measurement data
 - i) Current measurement mode.
 - ii) Aqueous/Vitreous velocity and lens velocity.
 - iii) Table of the actual ocular measurements including axial length, anterior chamber depth, and lens thickness where applicable. Up to eight (8) measurements for each eye may be printed out (Optional).

- iv) Graphic waveform of one or all measurements (Optional).
- v) Statistical information which includes the high, low, mean, and standard deviation from all axial length measurements (Optional).

Note Optional data can be included or excluded on the printout by enabling or disabling the associated parameter on the Printout Format page as described in section V.C on page 21.

23. All measurements remain in memory until either the A-Scan is cleared or the unit is turned off. To clear A-Scan measurements from memory, press the **CLEAR** key and then select the appropriate on-screen prompt.

* * * CAUTION * * *

When the **CLEAR** key is pressed and the **Clear A-Scan** prompt is selected, the DGH 5000e will automatically set the internal gain of the unit to comply with the probe sensitivity. Therefore, it is **imperative** that the probe tip be **clean and dry before** the unit is cleared. Also, the temperature of the probe should be stabilized to within $\pm 10^{\circ}\text{F}$ of the temperature at which the probe will actually be used. **Never** clear the unit with the probe attached after the probe has just been exposed to an extremely cold or hot environment. **Always** allow time for the probe to stabilize at room temperature.

VIII. EXPLANATION OF DISPLAY MESSAGES

The DGH 5000e provides feedback to the operator in the form of messages on the front panel display. These messages will appear if the operator has not been able to obtain a measurement after the probe has been applanated to the cornea for a preset time period. An audible feedback of two long beeps will prompt the operator to remove the probe from the cornea and observe the display. The next section describes the messages that can appear when trying to take A-Scan measurements.

Display Message Descriptions

1. This type of message has several variations. Each message will report which of the echo amplitudes was either too low or too high. The message indicates that the probe was far out of alignment with the visual axis. The operator should make a major adjustment in probe orientation and attempt another measurement.

Measurement failed due to Lens 1 Amplitude too low, Lens 2 Amplitude too low, Check probe alignment. Reattempt measurement.
2. This message appears after the next measurement attempt when two previous attempts have resulted in messages of type 1 (above). The message usually means that, due to certain physiological conditions, the Auto Gain feature is having trouble optimizing the heights of the echo amplitudes. The operator may need to adjust the gain manually in order to obtain a measurement.

Auto Gain may not be able to optimize echo amplitudes. If measurement difficulty persists, use Manual Gain.
3. This message appears if the operator was close to having correct alignment but needed just a minor adjustment in probe orientation when the measurement time expired. The operator should reattempt the measurement with the probe oriented as close as possible to the final position of the previous measurement attempt.

Measurement failed due to Bad Lens Echo Signature(s). Reattempt measurement.

4. This message appears if the operator was close to having correct alignment but needed just a minor adjustment in probe orientation when the measurement time expired. The operator should reattempt the measurement with the probe oriented as close as possible to the final position of the previous measurement attempt.

**Measurement failed due to
Bad Retinal Echo Signature.
Reattempt measurement.**

5. This message appears when the probe is properly aligned, but due to certain physiological conditions (blood in the vitreous, detached vitreous, cupping of the retina, etc.), the retinal echo does not meet the normal retina signature requirements. After this message appears, the operator has 5 seconds to press the **ENTER** key which will relax the retina signature requirements, i.e., it should be much easier to get a measurement. The display will then indicate that the retina signature requirements have been relaxed and prompt the operator to attempt another measurement. If the operator does not intervene within the five second waiting period, the DGH 5000e will prompt the operator to reattempt the measurement using the normal retina signature requirements.

**Measurement failed due to
Bad Retinal Echo Signature.
To relax the retina signature
requirements, press "ENTER".**

*** * * CAUTION * * ***

When the retina signature requirements are relaxed to allow measurements to be obtained more easily, it also increases the probability of obtaining a false measurement (measuring the distance to the sclera instead of the retina, measuring off axis, etc.). It is highly recommended that multiple measurements be obtained and the results evaluated to assure all readings fall within approximately ± 0.2 mm. Measurements outside this range should be repeated so as not to be included in the measurement averaging. In any case, measurements obtained with the retina signature requirements relaxed should only be considered estimates!

6. This message indicates that the operator was pressing too hard on the cornea, possibly causing corneal compression or indentation when the measurement time expired. The operator should reattempt the measurement being careful not to press too hard on the cornea.

**Measurement failed due to
Corneal Compression.
Reattempt measurement.**

Note While attempting to take a measurement, a constant audible tone indicates that corneal indentation may be occurring. This tone and the above message are not applicable when using the Water Immersion option.

7. This message is displayed when corneal compression occurs again immediately after the first corneal compression message. At this point the operator has 5 seconds to override (disable) the test for corneal compression by pressing the **ENTER** key. The display will then indicate that the compression test is overridden and prompt the operator to attempt another measurement. If the operator does not intervene within the 5 second waiting period, the display will prompt the operator to reattempt the measurement with the compression test still enabled.

Measurement failed due to Corneal Compression. Press "ENTER" to override the compression test.

Note When a measurement has been obtained with the compression test disabled, the DGH 5000e will automatically re-enable the compression test for the next measurement cycle. This message does not apply when using the Water Immersion option.

***** CAUTION *****

When the compression test has been overridden, the probability of obtaining a short axial length measurement due to corneal compression or indentation is increased. It is highly recommended that multiple measurements be obtained and the results evaluated to assure all readings fall within approximately $\pm 0.2\text{mm}$. Measurements outside this range should be repeated so as not to be included in the measurement averaging. In any case, measurements obtained with the compression test overridden should only be considered estimates!

8. This message appears when a set of 8 measurements have been obtained. The operator may review the measurements on the display, print a hardcopy of the measurements, or perform IOL calculations.

Measurement set completed. Use cursor keys to review measurements.

9. When using the optional Water Immersion mode, this message will appear if the probe is positioned too close to the eye. The probe should be pulled back out of the Prager shell

Probe too close to the eye. Reposition the probe and then reattempt measurement.

(about 1 mm from its current position) and then the measurement should be reattempted.

10. When using the optional Water Immersion mode, this message will appear if the probe is positioned too far away from the eye. The probe should be inserted further into the Prager shell (about 1 mm from its current position) and then the measurement should be reattempted.

**Probe too far away from eye.
Reposition the probe and
then reattempt measurement.**

11. When using the optional Water Immersion mode, this message is used to prompt the operator how to begin and/or end a measurement sequence. Pressing **SELECT** begins the measurement sequence (up to 8 measurements may be taken). To terminate the sequence early, press the **SELECT** key again.

**Press SELECT to start or
stop taking measurements.**

12. This message occurs when: (1) the A-Scan probe is not properly mated to the "PROBE" connector on the front panel, (2) there was water or other foreign substance on the probe tip during power-up, or (3) the A-Scan probe is defective.

!!! PLUG IN ASCAN PROBE !!!

IX. MANUAL GAIN ADJUSTMENT

The DGH 5000e has an Auto Gain feature that is designed to optimize echo amplitudes for both measurement accuracy and ease of measurement. This feature is adequate for obtaining measurements on most patients. However, under certain physiological conditions (such as an extremely dense cataract) the Auto Gain may prove to be inadequate. In this case, the operator can elect to adjust the gain manually.

There are 3 gain parameters that can be used to enhance the A-Scan waveform: the anterior lens echo (or Lens 1) gain, the posterior lens echo (or Lens 2) gain, and the Retina gain. Use the following procedure to modify these gains.

Procedure For Adjusting Gain Manually

1. With the DGH 5000e in the A-Scan mode (see Figure IV-B on page 14), press the **MANUAL GAIN** (F2) key to access the Manual Gain page (Figure IX-A).

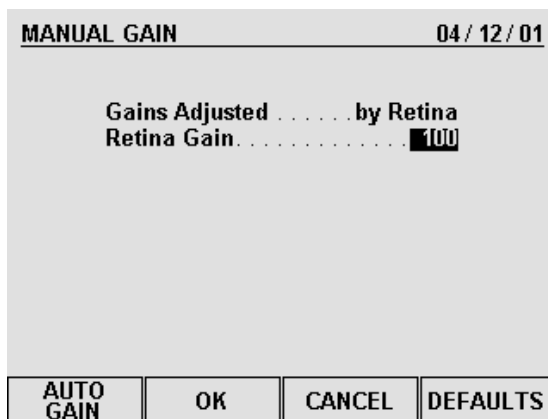


Figure IX-A Manual Gain page.

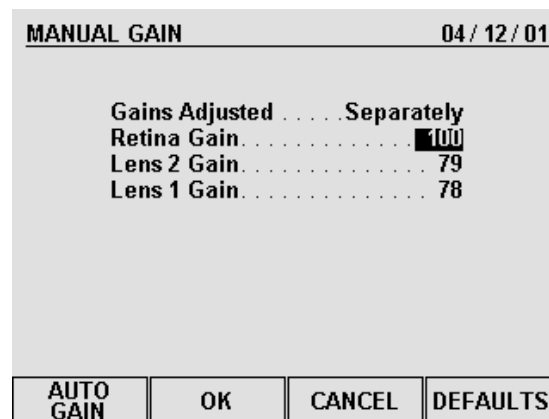


Figure IX-B Gains adjusted separately.

2. A default value will be shown for the retina gain. It is suggested that you try this gain setting first, and then come back and readjust if necessary.
3. To change the retina gain, use the numeric keypad to enter a new value (only values in the range of 40 to 120 are valid). When the retina gain is changed, the gains for lens 1 and 2 are automatically changed based on the new retina setting.

If it becomes necessary to change the lens gains separately from the retina,

highlight “by Retina” and then press **SELECT**. All gains may now be adjusted individually (see Figure IX-B).

4. Press **OK** (F2) to save the changes and return to the A-Scan mode.

5. When the unit is back in the A-Scan mode and the manual gain is active, the text “Manl G:” with a gain number will be visible in the upper left section of the display (Figure IX-C). In addition, the F2 function key label will now display the words “**ADJUST GAIN**”.

6. Attempt measurements with the manual gain settings. If a measurement can not be obtained because an echo amplitude is too low, press the **ADJUST GAIN** (F2) key, increase the appropriate gain, and then reattempt the measurement.

Likewise, if an echo amplitude is too high, lower the appropriate gain setting and then reattempt the measurement.

7. Once the manual gain has been set, the DGH 5000e will begin all subsequent measurement attempts at the gain entered by the operator. The unit will continue to use the manual gain setting until the operator re-enables the Auto Gain feature, the A-Scan is cleared, or the power is switched off and then back on again.

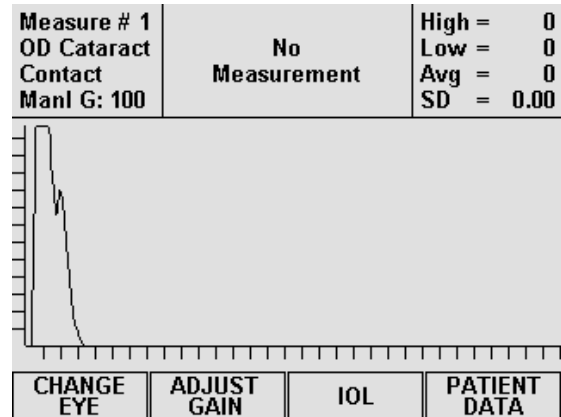


Figure IX-C A-Scan mode with a manual gain setting of 100.

Other Function Keys

AUTO GAIN (F1) – returns to A-Scan mode and re-enables the Auto Gain.

CANCEL (F3) - returns to A-Scan mode without saving any changes.

DEFAULTS (F4) - resets the gains back to the factory default values.

X. TEST MODE

The DGH 5000e uses a pattern recognition algorithm that looks for unique characteristics of the human retina to obtain true probe alignment. Therefore, it is not possible to simulate the echo response of the human eye using the standard multiple plastic interface phantoms. For this reason, the DGH 5000e must be placed into a test mode to allow measurement of a polystyrene block that is used to check calibration. The procedure for entering the test mode and verifying proper calibration of the unit is described below.

Test Mode Procedure

1. On the Patient Data page, press **SETUP** (F4) and then use the ↓ cursor key to highlight **Test A-Scan...** (Figure X-A).

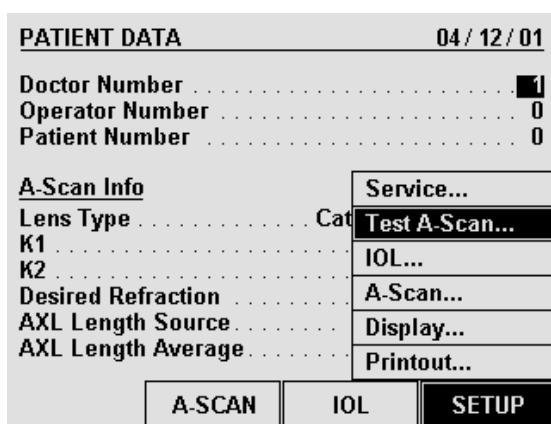


Figure X-A Accessing the A-Scan Test Mode from the setup menu.

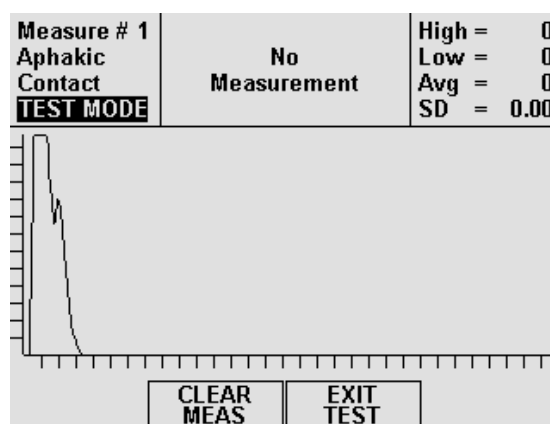


Figure X-B A-Scan Test Mode.

2. Press **SELECT** or **ENTER** and then choose YES from the on-screen prompt. The unit will indicate that the test mode is active by displaying the words **TEST MODE** in the upper left portion of the screen (Figure X-B). The DGH 5000e is now ready to measure the polystyrene reference block that came with the unit (see Figure III-C on page 12).
3. Apply a small drop of water to the smaller diameter end of the reference block.
4. Appanate the probe tip to the center of the reference block. Note that the probe tip

and reference block have equal diameters to facilitate positioning.

5. The DGH 5000e should measure the reference block almost instantaneously. If not, move the probe tip slightly until a measurement is obtained.
6. Observe axial length measurements of $23.90 \pm 0.25\text{mm}$.
7. Readings outside these limits do not necessarily indicate the DGH 5000e is out of calibration. Erroneous measurements may be due to the following:
 - a) During the test mode, the algorithm does not preclude measurement of tear film as it does during normal operation. Therefore, if excessive water was placed on the reference block, it could be measured causing longer axial length measurements.
 - b) The polystyrene reference block is sensitive to temperature. The block must have stabilized at $72^{\circ}\text{F} \pm 10^{\circ}\text{F}$ before measurements are taken.

If an erroneous reading is obtained, verify that these fault conditions are not present and repeat the measurements on the reference block.

8. If the reference block readings are outside the limits stated above, it is possible that the unit is defective and needs repair. Contact the Customer Service Department of DGH Technology, Inc. at (610) 594-9100 to arrange for repair.
9. When the calibration verification procedure is completed, the operator must exit the test mode and return the unit back to the normal operating mode before attempting to take any measurements on the eye. To exit the test mode, press **EXIT TEST** (F3).

Note The test mode will also be canceled if the power is removed from the unit.

***** CAUTION *****

Upon completion of the calibration verification procedure, the unit **must** be returned to the **normal** operating mode. **Never** attempt to take measurements on the eye when the unit is still in the test mode. This could result in erroneous measurements.

XI. DIAGNOSTIC INFORMATION

The DGH 5000e has the unique capability to provide diagnostic information to the operator and/or service personnel. Two types of diagnostic information exist: (1) Diagnostic Data and (2) A Diagnostic Waveform. The Diagnostic Data can be used as feedback for service personnel in the event that a problem should develop with the DGH 5000e. The Diagnostic Waveform can be used by the operator in two ways:

- As an aid to verify readings that may be suspect, such as readings on a pseudophakic eye where reduplication echoes may be present and be confused with the actual retinal echo.
- As documentation of the actual ultrasonic echoes received by the unit.

Printing Diagnostic Information

Diagnostic information can be printed for the currently displayed measurement (or measurement attempt) by pressing and holding in the print key until the printout begins. Approximately 4 inches of diagnostic Powerup Data will be printed first. This information is mostly numerical data that is organized into 5 columns, but it also includes a small graphic printout. Diagnostic measurement data is printed next. Numeric data associated with the measurement comes first followed by a diagnostic waveform.

The Diagnostic Waveform is a high resolution graphic of the actual ultrasonic waveform that the measurement was based on. The X-axis of this graphic printout is scaled for axial length in millimeters, allowing the operator to identify the retinal echo pattern and obtain an axial length measurement. Every diagnostic waveform is approximately 15 inches long which does consume a little paper. To terminate the graphic printout at any time, press the **CLEAR** key.

XII. IOL CALCULATIONS

When equipped with the external firmware module SYS: AP5SBH, the DGH 5000e is capable of calculating IOL powers for four different IOLs simultaneously. For each IOL, one of the following IOL formulas can be used: SRK/T™, SRK II™, Binkhorst II, or Holladay Dioptrimum™. These four IOL formulas have been proven over the years to have a high degree of accuracy in yielding the correct power of implant for individual eyes. Instructions for calculating IOL powers are given in section XII.B on page 51. However, before any computations can be performed, several types of information must be entered into the DGH 5000e. This information can be categorized into two main areas:

- Patient Data
- An IOL Configuration

Patient data required for IOL calculations consists of the following information: keratometer readings, the desired postoperative refraction, and a valid axial length. All of this information can be entered into the DGH 5000e by accessing the Patient Data page as described in section V.B on page 19.

Note If the patient's axial length is already on file, it can be input directly into the Patient Data page. Otherwise, an axial length measurement should be obtained with the DGH 5000e. Refer to section VII on page 27 for instructions on taking axial length measurements.

An IOL configuration contains parameters that are associated with an IOL. These parameters are explained in the next section.

XII.A. IOL Configuration Parameters

Before calculating IOL powers, the following information about the IOL must be entered into the DGH 5000e:

- IOL Type
- IOL Calculation Formula
- IOL Constant

These 3 parameters are referred to as an "IOL configuration". The DGH 5000e can store four different IOL configurations for each of 5 doctors. This feature allows 5

different doctors to be able to use the same unit for calculating IOL powers, and each doctor can have his or her own personal IOL configurations retained. All IOL configuration parameters are permanently stored in memory so that they can be automatically recalled whenever the unit is powered up. To input the IOL configuration parameters, the operator should access the IOL Configurations page as explained below.

Accessing The IOL Configurations Page

Descriptions of all the IOL configuration parameters are given in Table 4 on page 50. Use the following procedure to access the IOL Configuration Setup page and enter these parameters.

1. On the Patient Data page, enter the doctor number (1 – 5) that will be associated with the IOL configurations that are being setup.

The screenshot shows the 'PATIENT DATA' screen with the date '04/12/01'. Fields include Doctor Number (1), Operator Number (0), and Patient Number (0). The 'A-Scan Info' section is expanded, showing options like Service..., Test A-Scan..., IOL..., A-Scan..., Display..., and Printout... The 'IOL...' option is highlighted. At the bottom, there are buttons for 'A-SCAN', 'IOL', and 'SETUP'.

Figure XII-A Accessing the IOL Configurations page from the setup menu.

The screenshot shows the 'IOL CONFIGURATIONS' screen with the date '04/12/01'. The 'Doctor Number' is set to 1. Below is a table with columns: #, Type, Formula, and Constant. The table contains four rows of data. At the bottom, there are buttons for 'PSF', 'OK', 'CANCEL', and 'CLEAR ALL'.

#	Type	Formula	Constant
1	Pos	None	—
2	Pos	None	—
3	Pos	None	—
4	Pos	None	—

Figure XII-B IOL Configurations page.

2. Press **SETUP** (F4) and use the \uparrow cursor key to highlight **IOL...** (Figure XII-A).
3. Press **SELECT** or **ENTER** to access the IOL Configurations page (Figure XII-B).
4. Highlight the value of the parameter to be changed by using the cursor keys.
5. Use the **SELECT** key to choose the IOL TYPE and the IOL FORMULA. Use the numeric keypad to enter a valid formula CONSTANT. If a wrong number is accidentally entered, it can be erased by pressing the **DELETE** key.

Values for the A-constant, ACD, and Surgeon Factor (A, ACD, and SF) can be

obtained either from the lens manufacturer or Table 5 on page 51.

Note At least one IOL configuration must be completed in order to perform IOL calculations.

6. After the parameters have been entered, press **OK** (F2) to exit the IOL Configurations page. If any parameters were modified, the operator will be prompted to save the changes. Answer the prompt by highlighting either YES or NO and then press **SELECT**. All saved parameters are retained in memory even when power is removed from the unit.

Other Function Keys

PSF (F1) – Accesses the Holladay Personalized Surgeon Factor calculator.

CANCEL (F3) - exits the IOL Configurations page without saving any changes.

CLEAR ALL (F4) - resets all lens types to “Posterior”, all formulas to “None”, and all constants to zero.

Table 4 *Parameters On The IOL Configurations Page*

Parameter	Default Value	Selection Choices	Description
Type	Pos	Pos	Posterior chamber lens position.
		Ant	Anterior chamber lens position.
Formula	None	None	No formula selected.
		SRK/T	The SRK/T™(SRK/Theoretical) formula combines the optical theoretic formula elements of the Hoffer-Colenbrander and Binkhorst formulas with physiologic iris plane estimation and use of the familiar SRK™A-Constants as lens descriptors.
		SRK II	The Sanders, Retzlaff, Kraff SRK II™formula is a regression formula based on the observed relationship between the preoperative variables (keratometer readings and axial length) and the actual implant power required to achieve emmetropia.
		Binkhorst	Binkhorst II - a theoretical formula that will correct for variations in postoperative anterior chamber depth due to axial length.
		Holladay	The components of the three-part Holladay system are: (1) data screening criteria to identify improbable axial length and keratometry measurements, (2) the modified theoretical formula which predicts the effective position of the IOL based on the axial length and the average corneal curvature, and (3) a Personalized Surgeon Factor (PSF) that adjusts for any consistent bias in the surgeon's results, from any source, based on a reverse solution of the Holladay formula.
Const	0	A 110 to 125	A-Constant - A numeric value, provided by the lens manufacturer, that must be entered for the particular lens being used.
		ACD 0.3 to 9	Anterior Chamber Depth - A numeric ACD value must be entered for the particular lens being used. Obtain the ACD which corresponds to the lens A-Constant from Table 5 on page 51.
		SF -3.5 to + 5.25	Surgeon Factor - A numeric value for the surgeon factor must be entered for the particular lens being used. Obtain the Basic Surgeon Factor from the IOL manufacturer or from Table 5 on page 51, or calculate the Personalized Surgeon Factor (PSF) as described in section XII.C on page 55. Note If a zero (0) surgeon factor is entered, it will not work with the IOL calculator. This is a form of error checking, and it assures that the operator must enter a surgeon factor. If a zero (0) surgeon factor is actually desired, use a small value such as 0.01. The difference between 0 and 0.01 will be insignificant for IOL calculations.

Table 5 *Corresponding Values for the A-Constant, ACD, & Surgeon Factor*

A	ACD	Surgeon Factor	A	ACD	Surgeon Factor	A	ACD	Surgeon Factor
114.0	2.63	-1.04	116.0	3.80	0.09	118.0	4.97	1.22
114.1	2.69	-0.99	116.1	3.86	0.15	118.1	5.02	1.28
114.2	2.75	-0.93	116.2	3.91	0.20	118.2	5.08	1.34
114.3	2.81	-0.87	116.3	3.97	0.26	118.3	5.14	1.39
114.4	2.86	-0.82	116.4	4.03	0.32	118.4	5.20	1.45
114.5	2.92	-0.76	116.5	4.09	0.37	118.5	5.26	1.51
114.6	2.98	-0.70	116.6	4.15	0.43	118.6	5.32	1.56
114.7	3.04	-0.65	116.7	4.21	0.49	118.7	5.37	1.62
114.8	3.10	-0.59	116.8	4.27	0.54	118.8	5.43	1.68
114.9	3.16	-0.53	116.9	4.32	0.60	118.9	5.49	1.73
115.0	3.21	-0.48	117.0	4.38	0.66	119.0	5.55	1.79
115.1	3.27	-0.42	117.1	4.44	0.71	119.1	5.61	1.85
115.2	3.33	-0.36	117.2	4.50	0.77	119.2	5.67	1.90
115.3	3.39	-0.31	117.3	4.56	0.83	119.3	5.72	1.96
115.4	3.45	-0.25	117.4	4.62	0.88	119.4	5.78	2.02
115.5	3.51	-0.19	117.5	4.67	0.94	119.5	5.84	2.07
115.6	3.56	-0.14	117.6	4.73	1.00	119.6	5.90	2.13
115.7	3.62	-0.08	117.7	4.79	1.05	119.7	5.96	2.19
115.8	3.68	-0.02	117.8	4.85	1.11	119.8	6.02	2.24
115.9	3.74	0.03	117.9	4.91	1.17	119.9	6.07	2.30

XII.B. Instructions For Calculating IOL Powers

When using the DGH 5000e to perform IOL calculations, IOL powers can be computed for up to four different IOLs simultaneously. For each IOL, a patient's data and an IOL configuration are used to calculate a "Target IOL" power. An implanted lens with the Target IOL power should produce the desired postoperative refraction.

If lenses could be obtained with any conceivable power, then an IOL could be selected having a power that exactly matches the Target IOL. However, since IOLs are only manufactured with powers that are in half-diopter increments, an IOL must be selected having a power that comes closest to the Target IOL. To aid the operator in selecting an IOL with the best power, the DGH 5000e computes all of the following information:

- An IOL power that predicts emmetropia.
- A target IOL power that is based on the desired postoperative refraction.
- A selected IOL having a power that comes closest to the target IOL power.
- A postoperative refraction predicted by using the selected IOL power.
- Postoperative refractions predicted by using IOL powers that are within five powers above and below the selected IOL power (in half-diopter increments).

All IOL calculations can be observed on the graphic display and a hard copy can also be printed. The content of the IOL printout can be customized as described in section V.C on page 21.

When calculations are completed, 5 IOL/refraction combinations for a single IOL will be visible on the display. The selected IOL/refraction pair will be highlighted. In addition, 16 other IOL/refraction combinations are also available to the operator. All of these combinations will be listed by IOL power (in half-diopter increments) five powers above and below the selected IOL power. The operator may observe these IOL/refraction combinations by using the \uparrow and \downarrow cursor keys.

If more than one IOL configuration has been set up, the operator may see the calculated powers for the next IOL by pressing the **CHANGE IOL #** (F2) key on the IOL calculations page.

***** IMPORTANT *****

The calculated IOL powers are *NOT to be interpreted as suggested or recommended implant powers on the part of DGH Technology, Inc.* The calculated IOL should be used as a guideline only. It is based upon the accuracy of the IOL formula used and the data entered. The final IOL implant power selection must be made by the surgeon, based on personal experiences and previous postoperative results.

Obtaining IOL Calculations

In order to obtain IOL calculations, a patient's data must be entered into the DGH 5000e for either one or both eyes. Also, at least one valid IOL configuration (formula, constant, etc.) must be setup. The steps for entering this information and obtaining IOL calculations are as follows:

1. Turn on the DGH 5000e and wait for the Patient Data page to be displayed (see Figure IV-A on page 14).
2. Enter the patient’s data as described in section V.B on page 19.
3. If an IOL configuration needs to be set up for one or more IOLs, press **SETUP** (F4) and then select **IOL...** (see section XII.A on page 47). When finished, press **OK** (F2) to return to the Patient Data page.
4. If A-Scan measurements need to be taken, press **A-SCAN** (F2). Obtain and review A-Scan measurements on either one or both eyes by following the steps of section VII on page 27 (no printout is required).

A-Scan measurements may be obtained on either eye by pressing the **CHANGE EYE** (F1) key. If measurements are taken on both eyes, the printout will include the average axial length for each eye. **Measuring both eyes is recommended as an effective screen for suspect axial length measurements.**

5. Press the **IOL** (F3) key to perform IOL calculations.
6. Figure XII-C shows how the calculations will be displayed. The top half of the screen provides the patient’s data and current IOL configuration which were used to generate the IOL powers. The bottom half of the screen shows the computed results. The “Target IOL” is the IOL power that predicts the desired postoperative refraction. A selected IOL power that comes closest to the target IOL will be highlighted. If desired, use the **↑** and **↓** cursor keys to review the five IOL powers (in half-diopter increments) above and below the selected IOL power.

IOL CALCULATIONS		04 / 12 / 01	
Eye	OD	IOL #	1
K1	44.00	Type	Posterior
K2	45.25	Formula	SRK/T
AXL	23.45	A	118.00
Des Refrac	- 0.50		
Computed Results		IOL	Refrac
Emmetr IOL = 19.10		19.00	0.07
Target IOL = 19.81		19.50	- 0.28
		20.00	- 0.64
		20.50	- 0.99
		21.00	- 1.35
CHANGE EYE	CHANGE IOL #	A-SCAN	PATIENT DATA

Figure XII-C Results of IOL power calculations.

7. If more than one IOL configuration has been setup, the calculations for the next IOL may be reviewed by pressing the **CHANGE IOL #** (F2) key.
8. If patient data for both eyes has been entered, press the **CHANGE EYE** (F1) key to calculate IOL powers for the other eye.

***** CAUTION *****

Reviewing the calculated IOL powers on the display should be used as a preliminary screen only. Be sure to check all data against the Holladay data screening criteria as described in section XII.C on page 60.

9. Press the **PRINT** key to obtain a complete printout of the IOL calculations and associated data. The following outline is a description of the printout. This outline is presented in the order that the data is printed.
 - a) A header with the unit model number and software version number
 - b) Patient Data
 - i) Current date (if input by the operator)
 - ii) Doctor number
 - iii) Space to write the operator's name and an operator ID number
 - iv) Space to write the patient's name and a patient ID number
 - v) Type of lens in the eye
 - vi) Keratometer readings (K1 and K2)
 - vii) Desired postoperative refraction
 - viii) Averaged or input axial length measurement
 - c) A-Scan measurement data (Optional).
 - d) IOL calculations for one or all IOL configurations (Optional). The printout of each IOL configuration will include the following:
 - i) IOL Configuration number
 - ii) Type of IOL (anterior or posterior)
 - iii) Selected IOL formula and constant
 - iv) Emmetropic IOL power.
 - v) Target IOL power, i.e., the IOL power required to produce the desired postoperative refraction.
 - vi) Table of IOL/refraction combinations calculated by using the selected IOL formula. This table includes the selected IOL/refraction combination (highlighted) plus other combinations above and below the selected IOL power (in half-diopter increments). The number of printed IOL/refraction combinations is selectable.

Note Optional data can be included or excluded on the printout by modifying the proper parameters on the Printout Format page as described in section V.C on page 21.

10. All measurements, patient data, and IOL calculations will remain in memory until either the information is cleared or the unit is turned off. To clear the information go to the patient data page, press the **CLEAR** key, and then select the appropriate on-screen prompt.

XII.C. The Holladay Formula And The Personalized Surgeon Factor

Dr. Jack Holladay's article entitled, "A Three-Part System for Redefining Intraocular Lens Power Calculations" gives the theory of the formula and also describes the study showing the improved accuracy of the formula. (Copies of this article are available upon request from DGH Technology, Inc.)

As stated in the article, the three parts of the system are as follows:

1. The Holladay formula using the "Basic Surgeon Factor".
2. Calculation of the "Personalized Surgeon Factor". This is the advanced method which requires inputting patient refractions.
3. A data screening method developed to prevent over 90% of the "surprises".

Surgeon Factors

The "surgeon factor" is represented as the distance, in millimeters, from the aphakic (or pseudophakic) anterior iris plane to the effective optical plane of the implanted intraocular lens.

Basic Surgeon Factor can be calculated from the A-Constant provided by the lens manufacturer.

Personalized Surgeon Factor (PSF) is the final step in making the Holladay calculation as accurate as possible. The proper method for arriving at this optimum constant is to solve the Holladay formula in reverse using preoperative corneal and axial length measurements, implanted IOL power, and stabilized postoperative refraction. If this is done on at least ten patients, the factor will be personalized and reflect any consistent biases from any source.

Calculating The Personalized Surgeon Factor (PSF)

Calculating the Holladay PSF is a simple two step procedure in which the only requirement is that all aspects of the surgery must be kept constant. The A-Scan, keratometer, surgical procedure, and IOL must all be the same for any given set of data used to calculate the PSF. You can calculate a maximum of four PSF values, one for each IOL configuration.

STEP 1 Collect Data

Using a minimum of ten cases, make a table of the following data collected from patient files:

- PATIENT NO.
- K1
- K2
- AXIAL LENGTH
- IOL POWER
- SPHERE
- CYLINDER

(A blank page of this table is provided at the end of this section)

K1, K2, and AXIAL LENGTH are the values used preoperatively to calculate the IOL power. The IOL POWER is the power of the lens actually implanted, irrespective of the degree of ametropia that you may have chosen to produce. SPHERE and CYLINDER are from the postoperative refraction. These should be stabilized results with a 20/40 or better acuity.

STEP 2 Enter Data Into The Holladay PSF Calculator

1. On the Patient Data page, press **SETUP** (F4) and then use the \uparrow cursor key to highlight **IOL...** (Figure XII-D).
2. Press **SELECT** or **ENTER** to display the IOL Configurations page (Figure XII-E).
3. Press **PSF** (F1) to access the Holladay PSF calculator (Figure XII-F)
4. The top portion of the Holladay PSF calculator indicates the current IOL number and surgeon factor. If a different IOL configuration is desired for this particular set of data, press the **CHANGE IOL #** (F2) key. Each time the key is pressed, the next IOL

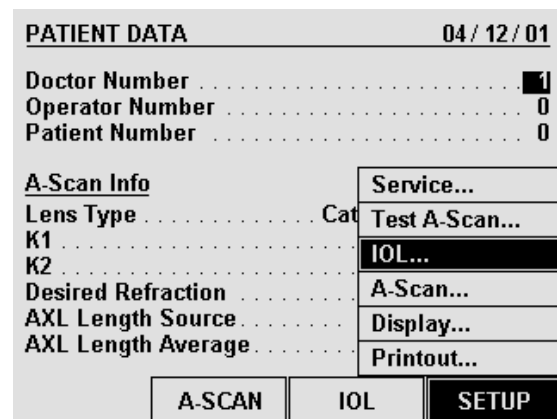


Figure XII-D Selecting the IOL Configurations page from the setup menu.

IOL CONFIGURATIONS				04 / 12 / 01
Doctor Number				1
#	Type	Formula	Constant	
1	Pos	SRK/T	A = 118.00	
2	Pos	SRK II	A = 118.00	
3	Pos	Binkhorst	ACD = 4.97	
4	Pos	Holladay	SF = 1.22	
PSF		OK	CANCEL	CLEAR ALL

Figure XII-E The IOL Configurations page.

Holladay PSF Calculator								
IOL # 4							Current SF:	1.22
No.	K1	K2	AXL	IOL	SPH	CYL	SF	
1								
2								
3								
4								
5								
6								
7								
PSF Data Base Summary								
Data Base	# incld	# excld	PSF	SEM				
New Cases	0	0						
Prev Cases	0							
Combined	0							
ENTER CASES	CHANGE IOL #	DATA BASE OPTIONS	EXIT					

Figure XII-F The Holladay PSF calculator.

configuration will be selected. In Figure XII-F, IOL #4 was chosen which has a current surgeon factor of 1.22.

5. Press the **ENTER CASES** (F1) key to begin entering the table of data with K1 for case #1 (Figure XII-G). Use the numeric keypad to input the data.
6. Enter the remaining data for case #1, and then input data for the other cases. Use the cursor keys to advance through the data table.

Note Although only 7 cases are visible on the display at a given time, the operator can input data for as many as 25 cases in one session. By using the cursor keys, the operator can view and/or input data for all 25 cases.

7. After the table of data has been entered, check to be certain that there are no errors. Use the cursor keys to review the data on the display.

If a single error is found, use the cursor keys to highlight the error and then input the correct number with the keypad. If an entire case is suspect, it can be removed from the calculator by positioning the cursor on any data of the suspect case and then pressing **CLEAR CASE** (F1).

8. Once the table of data has been checked, press **COMPUTE PSF** (F2). The computed PSF will appear at the bottom of the calculator in the PSF Data Base Summary. This summary displays the results of three individual data

Holladay PSF Calculator								
IOL # 4							Current SF:	1.22
No.	K1	K2	AXL	IOL	SPH	CYL	SF	
1	0.00							
2								
3								
4								
5								
6								
7								
PSF Data Base Summary								
Data Base	# incld	# excld	PSF	SEM				
New Cases	0	0						
Prev Cases	0							
Combined	0							
CLEAR CASE	COMPUTE PSF	PRINT	SAVE/ABORT					

Figure XII-G Entering the table of data into the Holladay PSF calculator.

bases:

New Cases - PSF calculations using data from the current session.

Previous Cases - PSF calculations from any previous session(s).

Combined - PSF calculations using data from the current and previous sessions.

Each of the above data bases holds the following information:

- # incld - Number of cases included in the PSF calculation.
- # excld - Number of cases excluded from the PSF calculation.
- PSF - The calculated Personalized Surgeon Factor.
- SEM - Standard Error of the Mean.

Note If the surgeon factor from any case is statistically out of range, the case data will be excluded from the final PSF calculation. Excluded cases will be identified on the display by drawing a line through the middle of the case data.

9. If a hard copy of the PSF calculations is desired, press the **PRINT** (F3) key.
10. At this point, you may either “Save” or “Abort” the new cases that were entered into the PSF calculator. Saving these cases will add the new data to the permanently stored data base. Assuming that all data entries are correct, press **SAVE/ABORT** (F4) and answer YES when prompted to save. Answering NO will abort the procedure and erase all data entered during the current session.

After saving the new case data and calculated PSF, the operator will be prompted to replace the current IOL configuration Surgeon Factor with the new Personalized Surgeon Factor. If YES is selected, the “Current SF” in the upper right hand corner of the display will be updated with the new PSF. If the operator wishes to change the calculated PSF (based on surgical experience), a new number can always be input by accessing the IOL Configurations page as described in the beginning of this procedure.

Note Pressing the **SAVE/ABORT** (F4) key may also cause two other prompts to appear. A warning prompt will be produced if the total number of saved cases in the permanent data base is less than 10. Using fewer than 10 cases to compute a PSF is NOT recommended. In addition, if a hard copy of the new cases was not printed before saving, a prompt will appear asking if a printout is desired.

11. Press **EXIT** (F4) to leave the Holladay PSF calculator and switch back to the IOL Configurations page. If at a later time the operator wishes to add more cases to an IOL configuration, repeat the above procedure. The new cases will be added to the existing data in a statistically correct manner.

Data Base Options On The Holladay PSF Calculator

The Holladay PSF calculator contains several options that can be used to manipulate the PSF data bases between IOL configurations. These options are accessed by pressing the **DATA BASE OPTIONS** (F3) key (Figure XII-H). An explanation of each option is given below:

Merge Data - Merge allows the operator to combine case information from two PSF data bases. As a result, a new PSF is calculated from the combined data. When this option is selected, the operator is prompted to enter a source and destination IOL configuration number. The PSF data base from the source IOL configuration is added, in a statistically correct manner, to the PSF data base in the destination IOL configuration.

Clear Data - Clear allows the operator to erase a PSF data base from the selected IOL configuration. This option would be used if a lens is abandoned and the IOL configuration is needed for a new lens.

Copy Data - Copy allows the operator to make a duplicate PSF data base from an existing one. When this option is selected, the operator is prompted to enter a source and destination IOL configuration number. The PSF data base from the source IOL configuration is copied to the destination IOL configuration.

Move Data - Move allows the operator to transfer a PSF data base from one IOL configuration to another. When this option is selected, the operator is prompted to enter a source and destination IOL configuration number. The PSF data base from the source IOL configuration is moved to the destination IOL configuration.

Note When using the Move or Copy functions, if the destination IOL configuration already contains a PSF data base, it will be overwritten by the data from the source IOL configuration.

Holladay PSF Calculator								
IOL # 4		Current SF: 1.22						
No.	K1	K2	AXL	IOL	SPH	CYL	SF	
Data Base		PSF D	Merge Data...					
		# incl	Clear Data...					SEM
New Cases		0	Copy Data...					
Prev Cases		0	Move Data...					
Combined		0						
ENTER CASES		CHANGE IOL #	DATA BASE OPTIONS					EXIT

Figure XII-H Accessing the Data Base Options on the Holladay PSF calculator.

Explanation Of The Printout From The Holladay PSF Calculator

Each case that you have entered will be listed on the printout. In addition, the Surgeon Factor for each case will be shown. If one or more of the cases were statistically out of range, it will be excluded and will be marked EXCLUDED.

The PSF Data Base Summary will also be included on the printout. This summary is composed of three data bases: (1) New cases entered, (2) Previous cases entered, and (3) Combined cases. For each of these data bases, the following information is provided: the total number of included cases, the total number of excluded cases, the calculated PSF, and the standard error of the mean (SEM). As explained in the article by Dr. Holladay, the SEM for the Surgeon Factor should be less than 0.20 as a 0.20 corresponds to an error in the calculated IOL power of 0.5 D. The way to reduce the SEM for the Surgeon Factor is to include more cases.

Data Screening To Prevent Surprises

Dr. Holladay's article has a section titled "Data Screening Criteria", which states that routine data screening is an essential ingredient for accurate IOL calculation. This screening identifies the majority of large refractive surprises preoperatively. Therefore, it is strongly recommended that the operator double check all input data and A-Scan measurements for statistically unlikely values.

The purpose of this screening is to alert the operator that the values being entered are suspect. The values may be correct, but they are out of the norm and should be repeated either because they are statistically unlikely or because there is an unlikely variation between both eyes.

Definitions Of Statistically Unlikely Data

K Values --- Repeat Measurement

Suspect K values are measurements that are substantially different from those of an average eye (less than 40 D or greater than 47 D).

When the difference in the K values between the OD and OS eyes is equal to or greater than 1 D, the measurements should be repeated.

Axial Length --- Repeat Measurement

Suspect axial lengths are measurements that are less than 22.0 mm or greater than 25.0 mm. Both long and short eyes have a greater possibility of error than average eyes and should be re-measured.

When the difference in the axial length between the OD and OS eyes is equal to or greater than 0.3 mm, the measurements should be repeated.

Emmetropic IOL --- Repeat both K and Axial Length Measurements

If the calculated IOL power for emmetropia is substantially different (greater than 3 D) from the average for a specific lens style, it should be considered suspect. According to Holladay's article, the average emmetropic IOL power for a specific lens style is calculated using the corresponding "surgeon factor," corneal power of 43.81 D, and axial length of 23.5 mm.

When the difference in the emmetropic IOL power between the OD and OS eyes is equal to or greater than 1 D, the measurements should be repeated.

IOL Parameters --- Cross Check

A suspect IOL parameter is a value for an A-Constant, ACD, or Surgeon Factor that is not in agreement with the others. Check the numbers entered for these parameters and enter the correct values.

XIII. CARE AND MAINTENANCE INFORMATION

XIII.A. Cleaning Instructions

Keep the probe tip clean. To prevent patient-to-patient infection, after each patient wipe the probe with a Q-tip soaked in 70% isopropyl alcohol, and then immerse the probe tip for 10 minutes in 70% isopropyl alcohol. The tip should be rinsed in sterile distilled water before using.

*** * * CAUTION * * ***

The probe should **NEVER** be autoclaved or subjected to intense heat. As a general rule, the above cleaning instructions are sufficient to disinfect the probe in ordinary use.

The electronic console can be cleaned by wiping with a damp cloth with mild soap. Do not immerse in water.

XIII.B. Storage And Operating Conditions

The DGH 5000e electronic console and probe may be stored in temperatures between -35°C to +75°C.

The DGH 5000e should be operated between the temperatures of +18°C to +40°C.

XIII.C. Loading Paper Into The Printer

1. When the printer paper is almost exhausted, a colored stripe will appear on the paper. This stripe reminds the operator to change the paper before it reaches the end of the roll.

*** * * CAUTION * * ***

A possible loss of data could occur if the paper runs out while the unit is printing. Never try to print if there is not enough paper on the roll. Always install a new roll of paper *immediately* when the colored stripe first appears.

2. To change the paper, loosen the paper door latch and raise the door.
3. Pull the paper release lever all the way forward to lift the print head off of the rubber platen. The lever is completely forward when it latches in the direction that is opposite from the normal/rest position.
4. Grab the old roll of paper and remove it from the unit. The paper beneath the platen should slide out easily.
5. Remove the plastic paper spool from the old roll of paper and then insert the spool through the center of the new roll of paper.
6. Install the spool/paper roll assembly into the slotted brackets in the instrument with the loose end of the paper coming from underneath the paper roll. Push the paper roll assembly all the way down until it bottoms.
7. Insert the leading edge of the paper below the rubber platen, and push gently with a side-to-side motion until the edge of the paper appears on top of the rubber platen. Grasp the end of the threaded paper and pull approximately six (6) inches of paper through the thermal head area.
8. At this point, ensure that the paper is centered on the rubber platen and aligned properly. When correct alignment has been confirmed, grasp the leading edge of the paper and hold it toward the front of the instrument. Close and secure the paper door.
9. Return the paper release lever to the normal/rest position.
10. Confirm that the paper is feeding correctly by pressing the “PAPER FEED” key. When you are satisfied that threading has been satisfactorily accomplished, excess paper may be removed by using the paper tearing edge.

***** IMPORTANT *****

In the event the paper does run out during a printout, the message “PRINTER ERROR DETECTED, OUT OF PAPER” will appear on the display. The operator then has two choices:

1. Press the “CLEAR” key which will clear the unit from the print mode and return the unit to the state it was in prior to printing.
2. Install a new roll of paper as described in steps 2 through 9 above. Upon completion of step 9 (returning the paper release lever to the normal/rest position), the printer will immediately continue printing from the point prior to running out of paper.

XIII.D. Warranty

DGH Technology, Inc. “DGH” warrants each new DGH 5000e and its accompanying accessories (hereinafter called “Equipment”) to be free from defects in material and workmanship for twelve (12) months from the date of delivery to the original purchaser. This warranty is not applicable to any defect which is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than DGH. This warranty does not apply if the Equipment has not been operated and maintained in accordance with the operating and maintenance manuals and instructions or bulletins issued in respect thereof by DGH. It is further understood that the cost of servicing replaceable and expandable items including parts and labor made in connection with the routine maintenance services as described in such Operator’s Manual is not covered under this warranty and is the responsibility of the purchaser.

This warranty is strictly limited to replacement or repair of the part which is found to be defective in material and workmanship. At the option of DGH, said part shall be replaced or repaired free of charge, F.O.B. our factory by DGH.

DGH reserves the right to make changes in the design and material of Equipment without incurring any obligations to incorporate such changes in Equipment already completed on the effective date of any such change or changes.

This is the only warranty of this product and is expressly in lieu of all other warranties, expressed or implied by law or otherwise, including any implied warranties of merchantability and of fitness for a particular purpose. Without regard to the alleged defect, DGH does not, under any circumstances, assume any responsibility for the loss

of time, inconvenience or other consequential damages, including but not limited to, loss of damage of personal property, or loss of revenue. DGH has neither assumed nor authorized any other person (including any distributor authorized to sell its Equipment) to assume for it any other liability in the connection with the sale of Equipment.

XIII.E. Service

If you are having problems with this unit, please refer to the appropriate sections of this manual. Most service calls result from a misinterpretation of the operation of the instrument, as described in the manual.

However, if you feel there is a problem with the unit or a probe, please contact the Customer Service Department at the address below. DGH Technology, Inc. can also be contacted via our web page at www.dghkoi.com. When contacting us, please provide the model and serial number for the unit. These numbers are located on the right hand side of the back panel. They can also be obtained from the graphic display by pressing the **SETUP** (F4) key on the patient data page, and then selecting **Service...**

DGH Technology, Inc.
110 Summit Drive, Suite B
Exton, PA 19341
Phone: (610) 594-9100
Fax: (610) 594-0390



XIV. IMPORTANT NOTES

XIV.A. Prescription Device

The DGH 5000e is a prescription device and is to be used only by or under the supervision of a licensed physician.

XIV.B. Tissue Exposure To Ultrasound Energy

Perform examinations using the principle of ALARA (As Low As Reasonably Achievable). All examinations should be done so that the patient receives as little ultrasound radiation as possible. Do not hold the probe against the eye or other tissue with the system activated except when making a measurement. Do not make unnecessary measurements.

**** WARNING ****

This device is not intended for fetal use.

XIV.C. Ultrasonic Intensities

The DGH 5000e does not have ultrasonic intensity settings that are under the control of the operator. Thus, the values below are the values to be expected for a typical transducer.

<u>Maximum Acoustic Output (In-situ)</u>	<u>A-Scan Mode</u>
I SPTA(mW/cm ²)	1.66
I SPPA(W/cm ²)	2.76

XV. SPECIFICATIONS

Shipping Weight	15 pounds
Weight	12 pounds
Height.....	5.5 inches
Width	12.5 inches
Depth	12.0 inches
Power	90-264 VAC, 50-60 Hz

Table 7 *Biometric Measurement Capabilities*

Direct Contact	Range	Accuracy	Display Resolution
Axial Length	18.5 - 34.0	± 0.1	0.01
Anterior Chamber Depth	2.0 - 4.8	± 0.1	0.01
Lens Thickness	2.0 - 7.5	± 0.1	0.01
Water Immersion			
Axial Length	18.5 - 32.0	± 0.1	0.01
Anterior Chamber Depth	2.0 - 5.7	± 0.1	0.01
Lens Thickness	2.0 - 7.5	± 0.1	0.01

All values are given in millimeters (mm)

