

SCANMATE FLEX

ULTRASOUND PLATFORM



OPERATOR'S MANUAL

FOR USE WITH SCANMATE v4.1.x SOFTWARE

CE 0120



THE ULTRASOUND SPECIALIST

DOCUMENT #: FLEX-INS-OMENG-R2

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WARNINGS AND CAUTIONS

All warnings and cautions listed throughout this manual are to be observed when operating the device.

WARNING: Indicates a potentially hazardous situation which, if not avoided, could cause injury or harm to the patient or erroneous results.

CAUTION: Indicates a potentially hazardous situation which, if not avoided, may result in minor injury or harm to the equipment.



GENERAL WARNINGS

WARNING: EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics, gases, mixtures or in an oxygen-rich atmosphere.

WARNING: ELECTRICAL SHOCK HAZARD. Do not open the unit. Refer servicing to qualified service personnel.

WARNING: CONTAMINATION HAZARD. Probes used must be cleaned and disinfected after each use. Follow the manufacturer's instructions when using disinfectants.

WARNING: BURN HAZARD: The Scanmate Flex does not provide protective means against burns to the patient if used with HF surgical equipment. The Scanmate Flex should not be used with HF surgical equipment.

WARNING: If the Scanmate Flex is used with other devices, current leakage may increase and electric shock may be caused. It is the user's responsibility to ensure safety when the probe is to be used with other devices. If safety cannot be ensured, use of the probe with other devices is not allowed.

WARNING: The device should only be powered using the provided AC adapter. Likewise, the computer hosting the device should only be powered using a medical grade AC/DC power supply. Use of other adapters could potentially cause harm to the system, the probe, the operator and/or the patient.

WARNING: Device contains a Lithium Ion battery. Improper service/replacement of the battery may cause damage to the device, excessive temperatures, fire or explosion. The battery is only to be serviced/replaced by qualified service personnel.

WARNING: Using non-essential software in conjunction with the system could have unknown/adverse impact on the operation of the device and is therefore not recommended.

WARNING: Due to the threat of computer viruses, it is recommended that an anti-virus program be installed on the computer running the Scanmate application and that patient records be backed up regularly.

WARNING: Electromagnetic interference may cause distortion of received ultrasonic signals. Such interference may result in distorted images or waveforms.

WARNING: Use of this equipment adjacent to or stacked with other equipment may result in improper operation and should be avoided. If such use is necessary, all equipment should be observed to verify normal operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Scanmate Flex, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Probes and cables should not be autoclaved or subjected to intense heat.



GENERAL CAUTIONS

CAUTION: Do not allow sharp objects, such as scalpels or cauterizing knives, to touch the probe or cables.

CAUTION: Disconnect the Scanmate Flex from the host computer before performing routine maintenance or cleaning. Always follow the manufacturer's instructions when cleaning and disinfecting probes.



GENERAL WARNING SIGN

[2] REF NO. W001

Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself.



TYPE B APPLIED PART

[3] REF NO. 5840

This symbol indicates the degree of protection against electric shock. The Scanmate Flex is classified as Type B Applied Part. This symbol is located on the unit label.



CLASS II EQUIPMENT

[3] REF NO. 5172

This symbol indicates that the device is an IEC Protection Class II (double insulated) device.



CONSULT INSTRUCTIONS FOR USE

[1] REF NO. 1641

Indicates the need for the user to consult the instructions for use.

REF

CATALOGUE NUMBER

[1] REF NO. 2493

Indicates the manufacturer's catalogue number so that the medical device can be identified.

SN

SERIAL NUMBER

[1] REF NO. 2498

Indicates the manufacturer's serial number so that a specific medical device can be identified.



MANUFACTURER

[1] REF NO. 3082

Identifies the device manufacturer. Adjacent to the symbol is the name and address of the manufacturer.



ATMOSPHERIC PRESSURE LIMITATION

[1] REF NO. 2621

Indicates the range of atmospheric pressure to which the medical device can be safely exposed.



HUMIDITY LIMITATION

[1] REF NO. 2620

Indicates the range of humidity to which the medical device can be safely exposed.



TEMPERATURE LIMIT

[1] REF NO. 0632

Indicates the temperature limits to which the medical device can be safely exposed.



ON (POWER)

[3] REF NO 5007

Indicates power on position for the switch.



OFF (POWER)

[1] REF NO 5008

Indicates the power off position for the switch.



STANDBY

[3] REF NO 5009

Indicates the standby status of the device (device powered on).



BATTERY CHECK INDICATOR

Indicates the button pressed to check the battery charge status of the device.



BATTERY CHARGE INDICATOR

Indicates the amount of battery charge remaining



ACTIVE CHARGING INDICATOR

Indicates that the device is charging the battery.

[1] EN ISO 7000 (5th Ed) Graphical Symbols For Use On Equipment

[2] EN ISO 7010 (2nd Ed) Graphical Symbols—Safety Color and Safety Signs—Registered Safety Signs

[3] IEC 60417:2002 DB Graphical Symbols For Use On Equipment

[4] ISO 15223-1:2012 Medical Devices—Symbols To be Used With Medical Devices Labels, Labeling, And Information To Be Supplied—Part 1: General Requirements

**USB**

Indicates a USB connection port.

18v DC
 $\overline{\overline{1.67 A}}$

DIRECT CURRENT

[3] REF NO. 5031

Indicates the connection port for the power supply. Adjacent text indicates the input current voltage and amperage.

**WEEE SYMBOL**

Indicates that the equipment consists of electronic components and other assemblies that must not be disposed of as domestic refuse. Refer to the Disposal section of this manual for more information.

**AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**

[4] REF NO. 5.1.2

Indicates the Authorized Representative in the European Community. Adjacent to the symbol is the name and address of the Authorized Representative.

[1] EN ISO 7000 (5th Ed) Graphical Symbols For Use On Equipment

[2] EN ISO 7010 (2nd Ed) Graphical Symbols—Safety Color and Safety Signs—Registered Safety Signs

[3] IEC 60417:2002 DB Graphical Symbols For Use On Equipment

[4] ISO 15223-1:2012 Medical Devices—Symbols To be Used With Medical Devices Labels, Labeling, And Information To Be Supplied—Part 1: General Requirements

TERMS AND ABBREVIATIONS

The following terms and abbreviations are used within this Operator's Manual and in the Scanmate software.

A-constant	The A-constant is a constant provided by an IOL manufacturer to be used in IOL power calculations.
ACD	Anterior Chamber Depth is defined as the measured distance from anterior vertex of the cornea and the anterior vertex of the lens.
ACD (constant)	The ACD constant is a constant provided by the IOL manufacturer to be used in Binkhorst formula IOL power calculations.
a0	The a0 constant is calculated from the manufacturer's A-constant to be used in Haigis formula IOL power calculations.
AXL	Axial Length is the distance between the anterior surface of the cornea and the anterior surface of the retina of the eye.
CL _{base curve}	The contact lens base curve is the known curvature of the plano hard contact lens.
CL _{over}	The contact lens over correction is the measured refraction with the plano lens in place.
CL _{power}	The contact lens power is the known power of the plano hard contact lens.
IOL	Intraocular Lens
IOP	Intraocular Pressure
K _{corr}	The corrected K value that should be used in IOL calculations for patients who have previously undergone refractive surgery.
K1	Flat Corneal Axis
K2	Steep Corneal Axis
LT	Lens Thickness
nc	The keratometer constant.
OD	Right Eye (Oculus Dexter)
OS	Left Eye (Oculus Sinister)
pACD	The pACD constant is calculated from the manufacturer's A-constant to be used in Hoffer Q formula IOL Power calculations.
post-K _{avg}	Average of K1 and K2 values measured after refractive surgery.
pre-K _{avg}	Average of K1 and K2 values measured before refractive surgery.
Rx	Refractive error (D)
S.E. _{post}	Refractive error measured after refractive surgery.
S.E. _{pre}	Refractive error measured before refractive surgery.
SF	The Surgeon Factor constant is calculated from the manufacturer's A-constant to be used in Holladay 1 formula IOL Power Calculations
VCD	Vitreous Chamber Depth

GENERAL DEVICE DESCRIPTION

The Scanmate Flex is a diagnostic ultrasound device used by professionals in the ophthalmic field to produce images and measurements of the eye and orbit of adult patients. The system consists of three main components: an interface module with integrated probe holder, one or more ultrasonic probes, and the Scanmate software application.

Three different probes are available, at least one of which is required for operation. The available probes include an A-scan probe, B-scan probes and a UBM probe. The probe or probes in use are plugged into the interface module, which is, in turn, connected via a USB cable to a PC running the Scanmate software. The minimum PC requirements are as follows:

Processor:	32-bit or 64-bit, 2.0 GHz
Memory:	2 GB RAM
Hard Drive:	1 GB minimum, 100 GB recommended
Ports:	(2x) USB 2.0 1 available port for USB interface 1 available port for footswitch (optional)
Display:	1024 x 768 resolution
Peripherals:	Mouse (or Touchpad), Keyboard
PC Power Supply:	AC/DC Medical Grade Transformer
Compatible OS:	Microsoft Windows 7 (32-bit or 64-bit) Microsoft Windows 8/8.1 (32-bit or 64-bit) Microsoft Windows 10 (32-bit or 64-bit) Microsoft Windows Server 2008 R2 (64-bit)* Microsoft Windows Server 2012 /2012 R2 (64-bit)* Microsoft Windows Server 2016 (64-bit)*

** Server Operating Systems only support installation of the SQL Server database. Refer to the Scanmate Installation Guide for more information.*

Refer to the Scanmate Installation Manual for information on installing and configuring the software. The installation manual also contains information on backing up and restoring the database.

DEVICE CLASSIFICATION

Device: System, Imaging, Pulsed Echo, Ultrasonic	Device: Diagnostic Ultrasonic Transducer
Panel: Radiology	Panel: Radiology
Product Code: IYO	Product Code: ITX
Device Class: II	Device Class: II
Regulation Number: 21 CFR 892.1560	Regulation Number: 21 CFR 892.1570

INDICATIONS FOR USE

The Scanmate Flex ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power. The Scanmate Flex is intended for the examination of adult patients.

CONTRAINDICATIONS

None.

 **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

OPERATOR QUALIFICATIONS

 **CAUTION:** Operators of the device should be trained medical professionals with knowledge of the use of ultrasonic imaging devices and imaging protocols.

ALARA STATEMENT

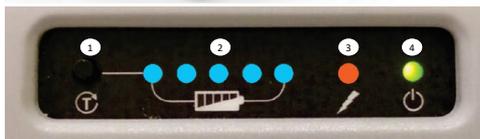
The ultrasound energy emitted by the Scanmate Flex is of low intensity and will have no adverse effects on the patient and/or operator. However, the operator is still cautioned to perform examinations using the principle of ALARA (As Low As Reasonably Achievable). All examinations should be done so that 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 performing an exam. Do not perform unnecessary exams.

SYSTEM COMPONENTS

The Scanmate Flex is capable of operating various probes. The following tables describe the Scanmate Flex device and supported probe specifications.

USB INTERFACE MODULE — FLEX-USBIM

1. Battery Charge Check Button
2. Battery Charge Indicator Lights (blue)
3. Active Charging Indicator Light (amber)
4. Power On Indicator Light (green)
5. B-Scan / UBM connector
6. A-Scan connector
7. A-Scan test block
8. USB Connector
9. Power Switch
10. AC/DC Transformer Connector



Scanmate Flex		REF Scanmate Flex
		SN XXXX
DGH TECHNOLOGY, INC. 110 SUMMIT DRIVE SUITE B EXTON, PA 19341 yyy y USA (610) 594-9100		 (01) 00857377006117 (21) XXXX
<p>WARNING: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.</p> <p>WARNING: Explosion hazard. Do not use in presence of flammable anesthetics, gases or oxygen-rich atmosphere.</p> <p>WARNING: The Scanmate Flex and the computer connected to the Scanmate Flex must be powered with a medical grade power supply.</p> <p>WARNING: Electrical shock hazard. Do not open. Refer servicing to qualified service personnel.</p> <p>WARNING: Device contains non user-replaceable Lithium-ion battery. Refer to user manual for instructions on how to disconnect the battery prior to shipping or storage.</p> <p style="text-align: right; font-size: small;">FLEX-LAB-80PNL REV 0</p>		

Bottom Panel Label

Front Panel

MAX FRAMES PER SECOND (FPS)	40 fps, 128 sectors, 2-way scan mode 20 fps, 128 vectors, 1-way scan mode 20 fps, 256 vectors, 2-way scan mode 12 fps, 256 vectors, 1-way scan mode
PIXEL COUNT	512 x 512 (4:1 oversampling)
SAMPLING FREQUENCY	80 MHz (max)
PC CONNECTION	USB 2.0
BATTERY PACK TYPE*	10.8 V, 3250 mAh Li-Ion
BATTERY LIFE	Approximately 4 hours when fully charged.
INPUT VOLTAGE	18 Vdc
INPUT CURRENT	1.67 A
POWER SUPPLY MODEL**	EMMAQ180167-P5P-IC (Medical Grade AC/DC Adapter)

* Battery only to be serviced/replaced by DGH Technology, Inc.

** Isolation from electrical supply mains provided by using the listed medical grade AC/DC adapter.

NOTE: Do not submerge housing. Device housing not sealed against water ingress.

A-SCAN PROBE— DGH 6006

1. Probe Lens w/ Fixation LED
2. Immersion Shell Stop
3. Probe Handle
4. Cord Strain Relief
5. Probe cord to cable



(01) 00857377006230
(21) #####

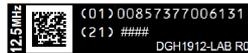
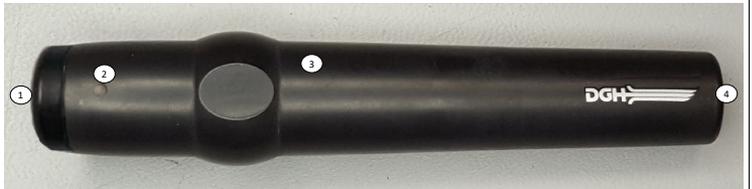
DGH 6006 Engraving

TRANSDUCER	10 MHz (nominal)
FOCAL POINT	LED brightness adjustable 0% - 100% in software.
AXL MEASUREMENT RANGE	15.0 mm — 40.0 mm
ACD MEASUREMENT RANGE	2.0 mm — 6.0 mm
LT MEASUREMENT RANGE	2.0 mm — 7.5 mm
AXL MEASUREMENT REPEATABILITY	± 0.03 mm StDev (immersion) , ± 0.10 mm StDev (contact)
AXL MEASUREMENT ACCURACY	100 microns (immersion) , 180 microns (contact)
REPLACEMENT PROBE CABLE	N/A. Permanently attached. (6'-0" length)

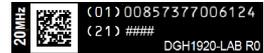
NOTE: Probe may be submerged up to the edge of the probe cord strain relief.

B-SCAN PROBES

1. Probe Lens
2. Probe Top Identifier
3. Probe Handle
4. Probe Connector



DGH1912 Label



DGH1920 Label

MODEL NUMBER	DGH1912	DGH1920
TRANSDUCER	12.5 MHz (nominal)	20 MHz (nominal)
SCAN ANGLE DISPLAYED	60 degrees	60 degrees
PROBE POSITION ACCURACY	±3 degrees	±3 degrees
FOCUS	20 mm ±2 mm	21 mm ±3 mm
DEPTH OF FIELD	15 mm—30 mm	15 mm — 30 mm
LATERAL RESOLUTION	0.5 mm ±0.1 mm	0.4 mm ±0.1 mm
AXIAL RESOLUTION	<0.35 μs at focal point	<0.13 μs at focal point
REPLACEMENT PROBE CABLE	FLEX-PCABLE (8'-0" length)	FLEX-PCABLE (8'-0" length)

NOTE: Probe may be completely submerged in liquid when disconnected from probe cable.

UBM PROBE — DGH1500*

1. Removable Transducer
2. O-Ring
3. Rubber Gasket
4. Probe Top Identifier
5. Probe Handle
6. Probe Connector



DGH1500 Label

TRANSDUCER MODEL	DGH1500-35	DGH1500-50
TRANSDUCER FREQUENCY*	35 MHz	50 MHz
SCAN ANGLE DISPLAYED	30 degrees	30 degrees
FOCAL POINT	12.8 mm (nominal)	12.8 mm (nominal)
DEPTH OF FIELD	11.5 mm—14 mm	11.5 mm—14 mm
LATERAL RESOLUTION	80 μ m (nominal)	50 μ m (nominal)
AXIAL RESOLUTION	65 μ m (nominal)	50 μ m (nominal)
REPLACEMENT PROBE CABLE	FLEX-PCABLE (8'-0" length)	FLEX-PCABLE (8'-0" length)
REPLACEMENT TRANSDUCER O-RING	C323000	C323000

* The DGH1500 probe can be used with either the 35 MHz or the 50 MHz transducer.

NOTE: Probe may be completely submerged when disconnected from probe cable.

REMOVING THE UBM TRANSDUCER

The UBM probe is capable of utilizing both a 35MHz and 50MHz transducer. This transducer can be changed/replaced by the operator or removed for cleaning. Refer to the Cleaning and Disinfection section for cleaning instructions.

! **CAUTION:** The gold surface of the transducer is very fragile. Avoid contact with this surface .

1. Gently pivot the transducer connector to one side.
2. To detach the transducer from the probe, gently grip the sides of the transducer and unscrew the transducer moving in a counter-clockwise motion.
3. To reattach the transducer to the probe, gently grip the sides of the transducer and screw on the transducer moving in a clockwise motion. When screwing on the transducer, it should be inserted far enough that the black o-ring is in complete, firm contact.



NOTE: Before reattaching the transducer, be sure that the connector interior for both the probe and transducer are completely dry (i.e. after cleaning). Also, ensure that the connector interiors are completely dry before storage.

WARNING: Device contains a Lithium Ion battery. Improper service/replacement of the battery may cause damage to the device, excessive temperatures, fire or explosion. The Lithium Ion battery is only to be serviced/replaced by qualified service personnel.

WARNING: FIRE HAZARD. Failing to disable the battery prior to shipment could result in damage to the device, excessive temperatures, fire or explosion.

CAUTION: Recharge the battery pack within 10 days of full discharge. Allowing the battery pack to fully discharge may render it unusable.

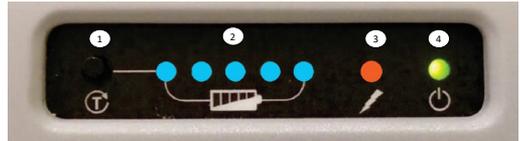
CAUTION: If the unit must be stored for an extended period of time, fully charge the battery before placing into storage. Check the batteries every 6 months and recharge as needed. Failure to do so may deteriorate the useful life of the battery.

CAUTION: Do not attempt to use the device until it has completed a first full charge. Doing so may deteriorate the useful life of the battery.

1. Locate the slot in the upper left corner of the front end-plate. This provides access to the enable/disable switch for the device battery and power. When the unit is shipped from the manufacturer, this switch is placed in the OFF position (to the left).
2. Using a pick, slide the switch to the ON position (to the right). Use only light force to slide the switch.
3. Every time the unit is shipped, (i.e. if being sent for service/repair) or being stored for extended periods of time, this switch must be placed in the OFF position (to the left).
4. Press and hold the Battery Charge Check button to see the remaining charge.



1. Battery Charge Check Button
2. Battery Charge Indicator Lights (blue)
3. Active Charging Indicator Light (amber)
4. Power On Indicator Light (green)



Front Panel

INITIAL SETUP

 **CAUTION:** Do not attempt to use the device until it has completed a first full charge. Doing so may deteriorate the useful life of the battery.

CAUTION: If it is difficult to connect the probes and/or cables, do not force the connection. Verify that alignment between connectors is correct. If proper alignment cannot be determined, contact DGH Technology, Inc. for customer assistance.

1. Remove the device from the packaging. Enable the device battery and power by sliding the switch to the ON position (to the right). See the Enabling and Disabling the Rechargeable Battery section for more information.
2. Position the device to allow for easy connection/disconnection of all cables.
3. Plug the power cord into its mating connector (labeled “18 VDC 1.6A”). Plug the transformer into a receptacle and allow the battery pack to charge for 3 hours. The green light on the front panel will illuminate, indicating the device is powered. The amber light will indicate active battery charging. The blue Charge Status lights will become illuminated indicating the battery charge level.

NOTE: Battery charge can be checked at any time by pressing the Battery Check button.

4. Once charging is complete, connect the other cables and probes. Be attentive to the alignment of connectors. All connectors on the device have alignment mechanisms to ensure that cables and probes are properly installed. Do not connect the USB cable to the computer yet.
5. Installation of the Scanmate software can be performed on desired computers. Refer to the Scanmate Installation Manual for information on installing and configuring the software.

NOTE: There are several instances during installation where the device may need to be attached /detached. It is suggested that the device be unattached to the computer when starting installation, and then only attached when prompted or instructed by the installation guide.

6. Start the Scanmate application by clicking the desktop icon or selecting it from the start menu. Probe drivers will be installed the first time the software is run. Refer to the Scanmate Installation Guide for more information.

TOUCH CONTROLS

The Scanmate software can be operated using touch controls on systems that have a touch-capable display. Buttons, sliders and combo boxes can be operated by touching the screen.

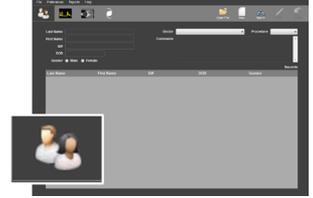
B-Scan/UBM measurement tools can be operated using touch controls. Zooming and panning of zoomed B-Scan/UBM images can also be controlled through touch input. Refer to the sections of this manual detailing B-Scan/UBM control for more information.

SOFTWARE MODES AND SYSTEM MENUS

The tabs in the upper left-hand corner allow the user to switch between modes of operation. By clicking the tabs, the user is able to navigate between the Patient Data, A-Scan, B-Scan/UBM or IOL Calculation screens.

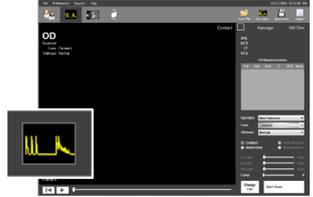
PATIENT SCREEN

When starting the program, the Patient Database Screen is presented. Clicking this tab will bring you to the patient data screen.



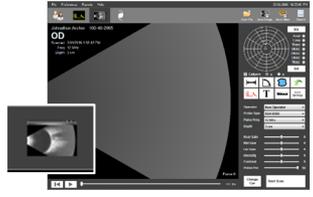
A-SCAN SCREEN

Clicking this tab will bring the operator to the A-Scan screen.



B-SCAN/UBM SCREEN

Clicking this tab will bring you to the B-Scan / UBM screen



IOL CALCULATOR SCREEN

Clicking this tab will bring you to the IOL Calculator.

Additional tools and configuration options are available through the menus which are located above the Mode Tabs.



FILE MENU

The File Menu allows the user to save measurements, images and videos. The File Menu also allows the user to import and export patient records. The Database Backup / Restore utility is accessed through this menu as well.

PREFERENCES MENU

The Preferences Menu allows individual doctor and user profiles to be created. Users can preconfigure the system according to their preferences and recall the settings at a later time. System preferences for system login and report export can be edited from this menu as well.

REPORTS MENU

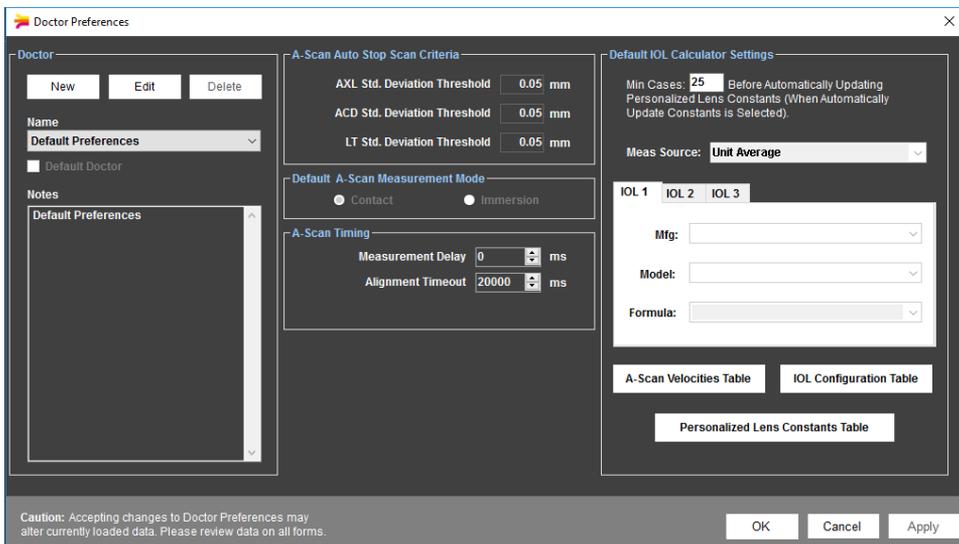
The Reports Menu allows the user to generate reports from patient records. See the corresponding section for information on creating A-Scan, B-Scan/UBM and IOL Calculator reports.

HELP MENU

The Help Menu contains a link to the user manual, software/system information and contact information for DGH Technology, Inc.

DOCTOR PREFERENCES MENU

The Doctor Preferences Menu allows the user to create, edit or delete individual doctor preferences for the device. Doctor Preferences define the default protocol for performing A-Scans and IOL Calculations.



A-SCAN AUTO STOP CRITERIA

This section allows the user to create standard deviation thresholds to use with the software Auto Stop feature. Individual threshold limits can be defined for the Axial Length (AXL), Anterior Chamber Depth (ACD) and Lens Thickness (LT). Each category of standard deviation is calculated from eight (8) A-Scan measurements. Measurements in the measurement bank must fall within the standard deviation thresholds for the system to automatically stop scanning.

MEASUREMENT DELAY

The Measurement Delay is the amount of time after alignment is detected, but before an A-Scan measurement is taken. A Measurement Delay of 0 ms will result in a measurement as soon as alignment is achieved.

ALIGNMENT TIMEOUT

Alignment Timeout is the amount of time the probe can be in contact with the eye before the software reduces or disables the alignment algorithm. If Alignment Timeout is set to 0 ms, the alignment algorithm is disabled (Estimate Mode). Refer to the Alignment Ranking System section for more information on alignment timeout.

MIN CASES

This text box allows the user to set the minimum number of procedures that must be performed before a Personalized Lens Constant is calculated for a given IOL model.

IOL 1/IOL 2/IOL 3 TABS

Allow the user to specify up to three preferred IOLs for the currently selected doctor. IOL information is saved in the system using the IOL Configuration Table.

A-SCAN VELOCITIES TABLE

Click the **[A-SCAN VELOCITIES TABLE]** button. The table displayed allows the user to view the speeds of sound for each lens and vitreous type. These values are used by the software in calculations interpreting A-Scan measurements. This screen also allows the user to enter custom speeds of sound for custom phakic, aphakic, and pseudophakic lenses.

To use custom speeds of sound to calculate measurements, the custom lens types must be selected on the A-Scan screen. Custom lens types can be selected from the 'Lens' dropdown box on the right-hand side of the A-Scan screen.

NOTE: Only one (1) set of custom velocities can be stored. Changing these values under one doctor's preferences will change them for all users.

IOL CONFIGURATION TABLE

The IOL Configuration Table allows the user to create, edit, view, or delete IOLs from the database. Fields are provided to input the IOL manufacturer, model, A-Constant, step range and type. IOL information is specific to the doctor that creates them, so each doctor must enter their own preferred IOLs.

Once information has been entered for the IOL, click the **[CALCULATE FROM MFG. A-CONST.]** button to automatically calculate and display all constants needed for the SRK®-II, SRK®-T, Hoffer® Q, Holladay 1, and Haigis formulas. These values can also be entered manually into the highlighted fields.

PERSONALIZED LENS CONSTANTS TABLE

The Personalized Lens Constants Table allows the user to manage how Personalized Lens Constants are calculated. The table displays all Pre-Operative, Post-Operative, patient, and procedure information associated with the currently selected Doctor and IOL. The IOL information table columns can be rearranged by the user. The table rows can be sorted based upon the selected column.

The Current Personalized Constants section displays lens constants that are currently being used for the selected Doctor and IOL. Textboxes within this area are read-only unless the user clicks the **[EDIT]** button. Once edit is selected, the user may manually change any of the current constant values for the selected Doctor, IOL Manufacturer and IOL Model. If a value outside of the accepted range for each variable is entered, it will be highlighted in red and must be corrected before continuing.

The New Personalized Constants section displays the lens constants as they are calculated by selecting and deselecting records in the Personalized Lens Constants table.

When the **[↑]** button is clicked, the values that are displayed within the "New Personalized Constants" section are loaded into the "Current Personalized Constants" textboxes.

Selecting the **[AUTOMATIC CONSTANTS UPDATE]** checkbox enables the Automatic Constants Update feature. This feature automatically calculates and updates the personalized lens constant for the selected doctor and lens based on the records in the table that have “Use Record” selected. The Personalized Lens Constants are also automatically recalculated when new records for the specified doctor and IOL manufacturer and model are created and the “Add to Personalized Lens Table” checkbox on the “Patient Data” Screen is checked. The number of records used to calculate the constants are also counted and stored automatically upon each recalculation. Automatically Calculated Personalized Constants are only available for use once the number of selected records exceeds the “Min Cases Before Using Personalized Constants” set in Doctor Preferences.

Min Cases: This value is displayed on the Personalized Constants table. This indicates the minimum number of cases used in calculating personalized constants and is not editable on this screen. To edit this value, go to the Doctor Preferences menu.

Selected Cases: This value is a counter that notifies the user how many records have been selected in the Use Record column. It cannot be edited on this screen, but will update automatically as records are selected or deselected for use in personalized constant calculations.

OPERATOR PREFERENCES MENU

The Operator Preferences Menu allows the user to create, edit or delete individual operators for the device. Operator preferences such as video playback speeds and auto-saving options can also be set in this menu. A field is provided for user to record notes associated with the operator. Other settings that can be adjusted are listed below.

Video Buffer Frames: The video buffer determines the amount of video that is captured before recording is stopped or overwritten. Increasing the number of frames allows the user to record longer videos. This will also result in larger file sizes.

Bidirectional Scan: If enabled, the B-Scan probe will acquire image information in both sweep directions.

Average / Interpolate: The software can be configured to use a frame-to-frame averaging and/or interpolation algorithm. Using these algorithms may improve image quality depending upon the system processor.

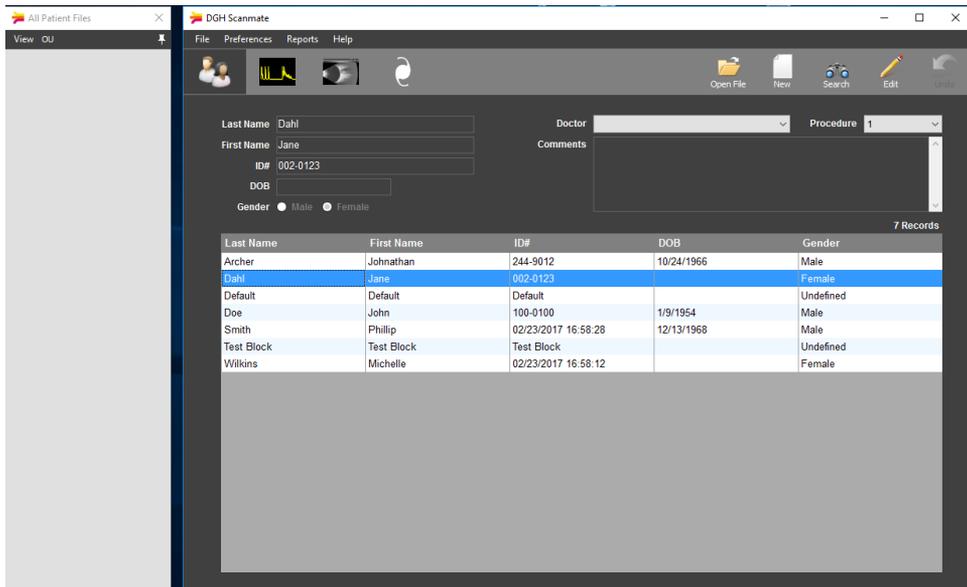
SYSTEM PREFERENCES MENU

The System Preferences Menu allows the user to set the practice identification information, date format and database login configuration. Other settings that can be adjusted are listed below.

Voice Control: Voice control can be enabled/disabled in this menu. Refer To the B-Scan/UBM Voice Control and A-Scan Voice Control sections for more information.

Default Keratometer Index (nc) The Default Keratometer Index (nc) must be set to match the nc value the keratometer used. This must be done prior to performing IOL Calculations.

The Patient Database Screen allows the user to search patients and create new or edit existing records.



Create New Patient: To create a new patient, click the **[NEW]** icon in the upper right-hand corner. The fields for entering patient information will be highlighted. Once all information is entered, click the **[SAVE]** icon in the upper right hand corner.

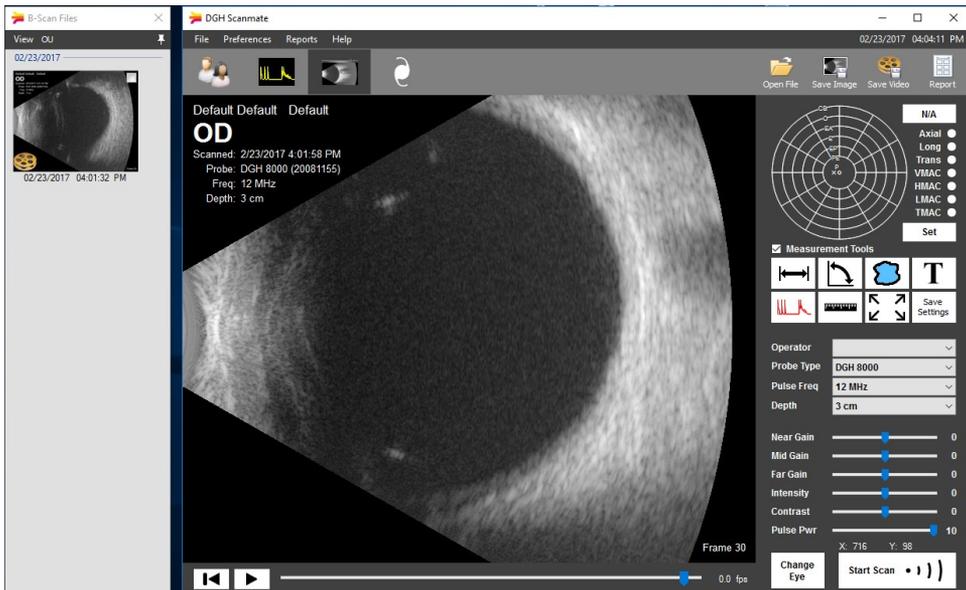
Search for Patient: To search for an existing patient, click the **[SEARCH]** icon in the upper right hand corner. The search fields will be highlighted. Type in the identifying information to perform the search. Searches can also be performed by scrolling through the patient table.

Load Existing Patient: To view an existing patient, highlight the desired patient and double click. The patient information will appear in the boxes above.

View Patient Records: Once a patient has been loaded, click the **[OPEN FILE]** icon in the upper right-hand corner. A window will appear showing all records related to this patient. Double click the record to load it.

Edit Patient Records: To edit a patient’s records, load the patient and click the **[EDIT]** icon in the upper right-hand corner. The editable fields will be highlighted. Once the information is edited, click the **[SAVE]** icon in the upper right-hand corner.

The B-Scan/UBM Screen allows the user to perform B-Scan/UBM procedures and review stored scan records.

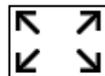


Open File: To view B-Scan/UBM images, videos and records associated with the current patient, click the **[OPEN FILE]†** button in the upper right-hand corner. Load the desired file from the window by double-clicking the corresponding icon.

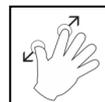
Position Map: The Position Map in the upper right-hand corner allows the user to record the probe orientation information. This information is included in the B-scan image or video. It can be set before or after scanning.

A-Scan Overlay: Enabling the A-Scan Overlay will superimpose an A-Scan waveform over the B-Scan image or video. The user can adjust the A-Scan vector by moving a slider on the right-hand side of the scan video.

Zoom: Double-click the left mouse button† to zoom in. The area clicked will be centered when zoomed. To zoom in further, double-click the left mouse button again or use the mouse scroll wheel to zoom in and out†. To reset the zoom, click the **ZOOM** icon.



If the PC running the Scanmate application has a touch-capable display, zooming may be performed using “pinch zoom” touch controls. To zoom in, place two fingers on the B-scan image being displayed and move them apart. To zoom out, place two fingers on the B-scan image being displayed and move them together.



To pan a zoomed image, place one finger on the B-scan image being displayed and move it in the desired pan direction.

†Indicates a command that may be executed through B-Scan/UBM voice controls. Refer to the B-Scan and UBM Voice Controls section.

PERFORMING B-SCANS

 **WARNING:** Before each procedure, the ultrasound probe must be cleaned and disinfected. Refer to the Cleaning and Disinfection section.

1. Select the “Patient Data” Screen and either enter a new patient or select an existing patient.
2. Select the “B-Scan/UBM” screen tab and select the eye to be measured (OD or OS) by clicking the **[CHANGE EYE]†** button.
3. Select the desired probe, frequency and depth from the drop down boxes. Select the name of the Operator performing the measurement. If the operator is not listed in the “Operator” drop-down box, add the new operator by selecting **Preferences > Operator** and clicking the **[NEW]** button.
4. Seat or recline the patient in a comfortable position. Minimize head movement during the exam. Position the Scanmate display so that it is easily visible during the examination.
5. If desired, use the Position Map to indicate the area of the eye being examined.
6. Click the **[START SCAN]†** button to begin scanning. Alternatively, pressing the **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) will also begin a scan. The software will begin recording B-Scan frames. The software will start recording over itself once the video buffer has reached the “Video Buffer Frame Size” specified in the Operator Preferences.
7. Direct the patient to look in the desired direction and gently apply the probe directly to the eye or over the eyelid. For best results, acoustic coupling gel should be used.
8. Once the desired image has been obtained, click the **[STOP SCAN]†** button, **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) to stop scanning. .
9. The image frames captured during the exam can be reviewed on the display by pressing the ← and → keys on the keyboard or by moving the slider along the bottom of the screen. The video playback controls can also be used to play back the video of the exam.
10. Save the desired image(s) by clicking the **[SAVE IMAGE]†** button or save the entire video by clicking the **[SAVE VIDEO]†** button in the upper right-hand corner. Images and videos can also be saved by going to **File > Save > B-Scan Image†** or **File > Save > B-Scan Video†**.
11. Repeat the steps above until all the desired regions of the eye have been examined.

NOTE: The Pulse Power slider adjusts the amount of energy used to pulse the transducer. Exams are typically performed at the highest Pulse Power unless the image is saturated and better definition between tissue structures is desired.

†Indicates a command that may be executed through B-Scan/UBM voice controls. Refer to the B-Scan and UBM Voice Controls section.

PERFORMING UBM SCANS

 **WARNING:** Contact between the moving transducer element and the eye will result in injury. When performing a UBM procedure, the user must visually gauge the distance of the transducer to the cornea and ensure that a safe distance between the transducer and cornea is maintained at all times.

WARNING: The DGH1500 UBM probe must be used with a ClearScan probe cover in order to reduce the risk of patient to patient infection, corneal injury due to accidental contact with the oscillating transducer and potential adverse biological responses.

WARNING: Before each procedure, the ultrasound probe and removable transducer must be cleaned and disinfected. Clearscan covers cannot be cleaned or reused. Refer to the Cleaning and Disinfection section.

1. Select the “Patient Data” Screen and either enter a new patient or select an existing patient.
2. Select the “B-Scan/UBM” screen tab and select the eye to be measured (OD or OS) by clicking the **[CHANGE EYE]†** button.
3. Select the desired probe, frequency and depth from the drop down box. Select the name of the Operator performing the measurement. If the operator is not listed in the “Operator” drop-down box, add the new operator by selecting **Preferences > Operator** and clicking the **[NEW]** button.
4. Seat the patient in a comfortable, seated position or in a reclined position if desired. Minimize head movement during the exam. Position the Scanmate display so that it is easily visible during the examination.
5. Holding the Clearscan cover with the silicone seal facing up, pour distilled, deionized or sterile water into the bag until it is approximately 75% full.
6. Insert the probe into Clearscan. As the probe enters the water, the Clearscan will pressurize and take on a “bullet-like” shape. Pressure can be adjusted by changing the depth of the probe in the Clearscan. Pressure can also be released by lightly squeezing the silicone ring of the Clearscan.
7. Click the **[START SCAN]†** button to begin scanning. Alternatively, pressing the **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) will also begin a scan. The software will begin recording scan frames. The software will start recording over itself once the video buffer has reached the “Video Buffer Frame Size” specified in the Operator Preferences.
8. Direct the patient to look in the desired direction. It may be necessary to hold back the patient’s eyelid or brow to properly expose the eye for scanning. Gently apply the Clearscan bag to the cornea.
9. The transducer must be kept far enough from the patient’s eye so that the zone of interest is within the focal range of the probe. The depth of the scan is affected by the depth of the transducer in the water. So if the cornea is the target of the scan, the transducer will be further from the eye. If the lens is target of the scan, the transducer will be closer to the eye. To change the depth of the probe in the Clearscan, remove the Clearscan from the patient’s eye. Hold the probe firmly and grip the silicone ring of the Clearscan. Slide the Clearscan along the probe, until the transducer depth is correct. If necessary, water pressure can be relieved by gently squeezing the silicone ring.

†Indicates a command that may be executed through B-Scan/UBM voice controls. Refer to the B-Scan and UBM Voice Controls section.

10. Once the desired image has been obtained, click the **[STOP SCAN]†** button, **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) to stop scanning.
11. The image frames captured during the exam can be reviewed on the display by pressing the ← and → keys on the keyboard or by moving the slider along the bottom of the screen. The video playback controls can also be used to play back the video of the exam.
12. Save the desired image(s) by clicking the **[SAVE IMAGE]†** button or save the entire video by clicking the **[SAVE VIDEO]†** button in the upper right-hand corner. Images and videos can also be saved by going to **File > Save > B-Scan Image†** or **File > Save > B-Scan Video†**.
13. Repeat the steps above until all the desired regions of the eye have been examined.

NOTE: The Pulse Power slider adjusts the amount of energy used to pulse the transducer. Exams are typically performed at the highest Pulse Power unless the image is saturated and better definition between tissue structures is desired.

NOTE: The UBM transducer should be allowed to completely dry before storage.

†Indicates a command that may be executed through B-Scan/UBM voice controls. Refer to the B-Scan and UBM Voice Controls section.

REVIEWING B-SCAN AND UBM VIDEOS

ADJUSTING SCAN IMAGES

The Gain, Intensity, Contrast and Zoom controls (available on the right-hand side of the screen) can be used to enhance the quality of the image. These settings can be adjusted before, during or after a procedure.

ADDING ANNOTATIONS

Once complete, the exam can be annotated with comments and measurements using the provided tools. To enable measurement tools and show measurement notations, click on the **[MEASUREMENT TOOLS CHECKBOX]**. To disable measurement tools and hide notations, clear the **[MEASUREMENT TOOLS CHECKBOX]**.

- Distance Measurement: To perform a distance measurement, left-click on the **[CALIPER TOOL]** then hold the left mouse button and drag across the distance to be measured. A line will appear indicating the measured distance and a measurement value will appear on at the end of the line. Multiple measurements may be performed, however the **[CALIPER TOOL]** must be selected before each measurement. Measurements can be deleted by right-clicking on a measurement line and selecting "Delete" from the drop down menu. 
- Angle Measurement: Click the **[ANGLE TOOL]**, Use single clicks of the right mouse button to designate three points to create the desired angle. 
- Area Calculation: Click the **[AREA TOOL]**. Use single-clicks of the left mouse button to designate points around the desired area. Once all points have been designated, single-click the right mouse to perform the calculation. 
- Ruler Overlay: A ruler overlay will be displayed when the **[RULER]** button is clicked. It will be hidden when the button is clicked again. The ruler overlay can also be controlled via voice commands. 

DELETING NOTATIONS

Distance, angle and area notations can be removed by right-clicking on the lines and selecting "Delete" from the menu displayed or by left-clicking on the line to select it and pressing the "Delete" keyboard key

CREATING B-SCAN/UBM REPORTS

Click the **[OPEN FILE]†** button in the upper right-hand corner. Select the images and videos to be included in the report by marking the checkbox in the upper right hand corner of the thumbnail image. Click the **[REPORT]** button in the upper right-hand corner of the screen. A B-Scan report will be generated that can be saved to the database as a PDF or printed.

Reports that had been saved to the database will be displayed in the window with patient scans. PDF versions of reports can be exported by left-clicking and dragging them to the desired location. Refer to the Exporting and Importing Data section for more information.

†Indicates a command that may be executed through B-Scan/UBM voice controls. Refer to the B-Scan and UBM Voice Controls section.

B-SCAN AND UBM VOICE CONTROLS

ENABLING VOICE CONTROL

Voice control can be enabled/disabled through the **Preferences > System** menu. Voice control can be configured to begin upon pressing the **[ENTER]** key or by a verbal command of “Hey Flex”. Voice control sensitivity can be adjusted in this menu as well.

NOTE: To use the voice control feature, the computer running the Scanmate Flex software must have a connected (or integrated) microphone that is enabled.

NOTE: If the **[ENTER]** key is not configured to initiate a voice command, pressing it while on the B-Scan Screen will automatically save an image.

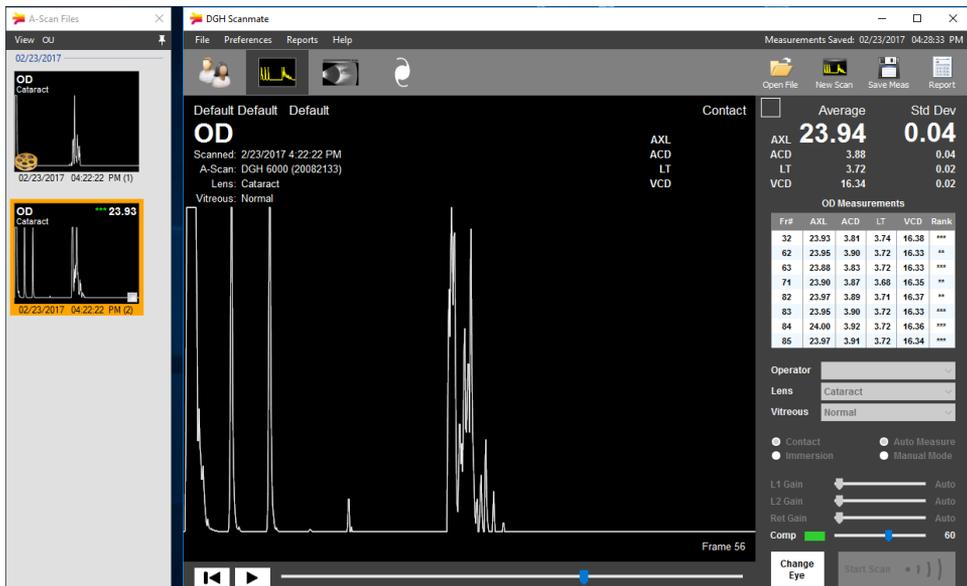
VOICE COMMANDS

The following verbal commands are recognized by the Scanmate Flex software while performing a B-Scan or UBM scan. To issue a command, the user must first say “Hey Flex” or press the **[ENTER]** key (depending upon System Configuration).

USER VERBAL COMMANDS	FLEX AUDIBLE RESPONSE	FLEX COMMAND EXECUTED
“Hey Flex”	Tone: Double-Beep	Voice control activated. The software is ready to receive verbal commands.
“Start Scan”	Verbal: “Starting Scan”	The B-Scan / UBM scan will start.
“Stop Scan” *	Verbal: “Scan Stopped”	The B-Scan / UBM scan will stop.
“Change Eye”	Verbal: “Eye changed to OD/OS.”	The eye being scanned is changed. The audible response will state if OD or OS is being scanned.
“Zoom In”	N/A	Zoom will enlarge the image or video.
“Zoom Out”	N/A	Zoom will reduce the image or video.
“Show Ruler”	N/A	The ruler overlay is shown.
“Hide Ruler”	N/A	The ruler overlay is hidden.
“Save Image”	Verbal: “Image Saved”	The currently displayed frame is saved.
“Save Video”	Verbal: “Video Saved”	The currently displayed video is saved.
“Open File”	N/A	A window is opened showing B-Scan/UBM records for the currently loaded patient.
“Yes” *	N/A	Selects ‘Yes’ for a dialog box prompts.
“No” *	N/A	Selects ‘No’ for a dialog box prompts.

* Indicates a command that DOES NOT require “Hey Flex” or an **[ENTER]** key press to be initiated.

The A-Scan Screen allows the user to perform A-Scan procedures and review a patient’s A-Scan records.



Open File: To view A-Scan videos, measurements and records associated with the current patient, click the **[OPEN FILE]** button in the upper right-hand corner. Load the desired file from the window by double-clicking the corresponding icon.

Measurement Type: If performing a new measurement, it is necessary to select the measurement type by marking the **[CONTACT]** or **[IMMERSION]** radio button.

Measurement Mode: Measurements can be taken in Manual Mode or Auto Measure Mode. In Manual Mode, the operator must manually select the measurements to be entered into the measurement bank and manually stop the scan. In Auto Measure Mode, measurements that meet alignment criteria will automatically be entered into the measurement bank, and measurement will stop once the bank has been populated with measurements that fall within Standard Deviation requirements. Refer to the A-Scan Measurement Modes section for more information.

To select the measurement mode, mark the **[AUTO MEASURE]** or **[MANUAL MODE]** radio button.

Begin New Scan: To begin a new scan, click the **[NEW SCAN]** button in the upper right-hand corner, to begin scanning click the **[START SCAN]**† button in the lower right-hand corner. To stop the scan, click the same button. To switch between the OD and OS, click the **[CHANGE EYE]**† button.

†Indicates a command that may be executed through A-Scan voice controls. Refer to the A-Scan Voice Controls section.

 **WARNING:** Exercise caution when coming into contact with a patient's eye. To avoid potential injury, use minimal pressure when applying the probe or adjusting its position. Only make minor position adjustments while in contact with the eye. If significant position adjustment is necessary, remove the probe from the eye and then reapply.

WARNING: Before each procedure, the ultrasound probe must be cleaned. Refer to the Cleaning and Disinfection section.

1. Select the "Patient Data" Screen and either enter a new patient or select an existing patient.
2. Select the "A-Scan" screen tab. Click the **[CHANGE EYE]†** button to select the eye to be measured (OD or OS).
3. Select the "Contact" radio button on the right-hand side of the screen. Select the name of the Operator performing the measurement from the drop-down box.
4. Select the correct Lens and Vitreous type for the eye to be measured.
5. Adjust the compression lockout sensitivity track bar (Comp) to the desired setting. Higher Compression Sensitivity will decrease the amount of error due to corneal compression, but will make it more difficult to obtain measurements.
6. Seat or recline the patient in a comfortable position for both the Patient and Operator. Minimize head movement during the exam.
7. Anesthetize the eye and have the patient fixate with both eyes on a spot on the ceiling or wall.
8. Press the **[START SCAN]†** button. Alternatively, clicking the **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) will also begin a scan. A waveform will be displayed on the screen, but the unit will not begin recording.
9. Stabilize the hand holding the probe. Typically this can be done by resting a palm on the cheek or forehead of the patient. This will help minimize indentation of the cornea or excessive movement.
10. Gently apply the probe tip to the cornea. Contact should be observed from a vantage point that allows the operator to look across the topography of the eye. The transducer should be perpendicular to the surface of the eye as it approaches the cornea. This method aids in seeing the exact moment when the probe contacts the cornea so indentation of the cornea will be minimized.

NOTE: Contact should be made as close to the visual axis as possible. When applying the probe, one should be particularly careful that contact is made with the center of the probe tip. An aid in this can be to point the back side of the probe at the fixation target while applying the lens of the probe to the center of the cornea.

11. At the moment of contact, the unit will start beeping. This indicates that coupling has been achieved. If the beeping stops, then the probe is no longer in contact with the eye and a slight pressure of the probe should be applied to restore contact. The device will only record waveforms and perform measurements when proper coupling is detected.

†Indicates a command that may be executed through A-Scan voice controls. Refer to the A-Scan Voice Controls section.

12. If probe alignment needs slight adjustment, keep the probe tip in stationary contact and slightly tilt the back end of the probe. This will change the angle of contact. As the probe comes closer to proper alignment, the beep rate will increase. As soon as proper alignment is achieved, measurement will begin (provided no corneal compression is detected).
13. Once the probe is in proper contact and aligned, measurements will be obtained almost instantaneously. A higher tone beep will indicate when the probe is properly aligned. The measurements for AXL, ACD and LT can be observed on the graphic display along with the corresponding echo waveform. If the unit is configured for the "Aphakic" lens type, only the axial length will be given.
14. In **Auto Measurement Mode**, each high-pitched beep indicates a successful 3-star measurement being recorded in the measurement bank. Measurements automatically placed in the bank are given a 1, 2 or 3-star alignment ranking.
In **Manual Measurement Mode**, a measurement is only recorded in the measurement bank if the user presses the **Enter** key (on the keyboard) or **Right Foot Pedal** (optional accessory). Measurements manually placed in the bank are given a "MAN" ranking.
15. Scanning is stopped as follows:
In **Auto Measurement Mode**, the scan will stop automatically as soon as eight (8) measurements are obtained that meet the alignment ranking and standard deviation requirements. Scans can also be aborted manually as described below.
In **Manual Measurement Mode**, the user must select the **[STOP SCAN][†]** button to stop the scan. Alternatively, clicking the **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) will also stop a scan.
16. After obtaining the desired measurements for the first eye (OD/OS), the operator may obtain measurements on the patient's other eye, if desired, by clicking the **[CHANGE EYE][†]** button and repeating the steps above.

IMPROPER ALIGNMENT

If a measurement is not obtained successfully upon contact and/or 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 a rapid beep rate is obtained or a measurement is taken.

CORNEAL COMPRESSION SENSITIVITY

If a low-tone beep is heard during the alignment procedure, corneal compression may be occurring. The compression lockout prohibits measurement if corneal compression is detected. The Compression Sensitivity (Comp track bar) adjusts the sensitivity of the unit in detecting corneal compression. Higher settings allow for less compression, making measurements more accurate, but also more difficult to obtain. If low-pitched beeps or a constant tone is heard, maintain the probe transducer alignment and slowly withdraw the probe from the cornea until measurements are obtained.

ALIGNMENT TIME OUT AND VIDEO BUFFER FULL ISSUES

Refer to the Alignment Ranking System and Video Buffer Full sections for information on these issues.

[†]Indicates a command that may be executed through A-Scan voice controls. Refer to the A-Scan Voice Controls section.



WARNING: Exercise caution when coming into contact with a patient's eye. To avoid potential injury, use minimal pressure when applying the immersion shell or adjusting its position. Only make minor position adjustments while in contact with the eye. If significant position adjustment is necessary, remove the probe from the eye and then reapply.

WARNING: Before each procedure, the ultrasound probe and immersion shell must be cleaned. Refer to the Cleaning and Disinfection section.

1. Select the "Patient Data" Screen and either enter a new patient or select an existing patient.
2. Select the "A-Scan" screen tab. Click the **[CHANGE EYE]†** button to select the eye to be measured (OD or OS) .
3. Select the "Immersion" radio button on the right-hand side of the screen. Select the name of the Operator performing the measurement from the drop-down box.
4. Select the correct Lens and Vitreous type for the eye to be measured.
5. Seat or recline the patient in a comfortable position so that the patient's head can be positioned in a nearly horizontal plan. Minimize head movement during the exam.
6. Gently insert the A-Scan probe into the clean and disinfected immersion shell until it reaches the auto-stop point. Verify that the transducer tip is even with the line scored on the barrel of the shell. Once the probe is properly inserted, tighten the white nylon set screw to hold the probe in place. Do not overtighten the set screw. The software cannot work if the probe is not in the proper position.
7. Connect the catheter tubing to the immersion shell filler port and to the saline reservoir (either a syringe or bottle). Place the saline reservoir in a convenient location, typically near the patient's head, on their chest or shoulder.
8. Anesthetize the eye and have the patient fixate with both eyes on a spot on the ceiling or wall. Press the **[START SCAN]†** button. Alternatively, clicking the **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) will also begin a scan. A waveform will be displayed on the screen, but the unit will not begin recording.
10. Stabilize the hand holding the probe/immersion shell. Typically this can be done by resting a palm on the cheek or forehead of the patient. This will help minimize excessive movement.
11. Direct the patient to look upward. Pull the patient's lower eye lid down and insert the flared rim inside the lid (the lower portion of the shell will make contact with the sclera while the upper part of the shell will be held away from the eye). Then direct the patient to look straight ahead with the other, uncovered eye, back toward the fixation point. Lift the patient's upper eyelid and gently pivot the upper portion of the shell into the upper 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.
12. Rest the palm of the hand holding the immersion shell on the patient's forehead to reduce shell pressure on the eye. This position allows the palm to act as a pivot point for the shell. If necessary, the operator can stabilize the shell with the other hand and make micro-adjustments. A tissue may be placed on the temporal canthus to catch any excess saline.

†Indicates a command that may be executed through A-Scan voice controls. Refer to the A-Scan Voice Controls section.

13. Use the saline reservoir to slowly inject saline into the shell. As soon as the liquid fills the shell sufficiently to reach the tip of the transducer (about 2cc), a beep rate of approximately once per second will be heard. This means that coupling has been achieved and sound pulses are being transmitted through the eye.
14. If the probe is properly aligned when saline is injected, measurements will be obtained almost instantaneously. A higher tone beep will indicate when the probe is properly aligned. The measurements for AXL, ACD and LT can be observed on the graphic display along with the corresponding echo waveform. If the unit is configured for the "Aphakic" lens type, only the axial length will be given.
15. In **Auto Measurement Mode**, each high-pitched beep indicates a successful 3-star measurement being recorded in the measurement bank. Measurements automatically placed in the bank are given a 1, 2 or 3-star alignment ranking.
In **Manual Measurement Mode**, a measurement is only recorded in the measurement bank if the user presses the Enter key (on the keyboard) or Right Foot Pedal (optional accessory). Measurements manually placed in the bank are given a "MAN" ranking.
16. Scanning is stopped as follows:
In **Auto Measurement Mode**, the scan will stop automatically as soon as eight (8) measurements are obtained that meet the alignment ranking and standard deviation requirements. Scans can also be aborted manually as described below.
In **Manual Measurement Mode**, the user must select the **[STOP SCAN]†** button to stop the scan. Alternatively, clicking the **Space Bar** (on the keyboard) or **Left Foot Pedal** (optional accessory) will also stop a scan.
17. After measurements are obtained, remove the shell from the patient's eye. Direct the patient to look straight ahead during removal. 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 out. Be prepared with a towel or tissue.
18. After obtaining the desired measurements for the first eye (OD/OS), the operator may obtain measurements on the patient's other eye, if desired, by clicking the **[CHANGE EYE]†** button and repeating the steps above.

IMPROPER ALIGNMENT

If a measurement is not obtained successfully when the saline is injected, and/or the beep rate is still low, then the probe is out of alignment. Gently move the shell around the sphere of the eye to bring the line of the probe into alignment with the visual axis. The beep rate will increase as the transducer approaches alignment with the visual axis.

ALIGNMENT TIME OUT AND VIDEO BUFFER FULL ISSUES

Refer to the Alignment Ranking System and Video Buffer Full sections for information on these issues.

†Indicates a command that may be executed through A-Scan voice controls. Refer to the A-Scan Voice Controls section.

ALIGNMENT RANKING SYSTEM

In Automatic Measurement Mode, the Scanmate Software uses a pattern recognition algorithm to determine when the probe is properly aligned. The alignment algorithm first looks for the proper pattern of reflectance peaks from each expected interface. Then the algorithm examines the retinal spike for particular signal characteristics which are produced only by retinal interfaces. Waveforms that meet the alignment criteria are ranked and put into the measurement bank.

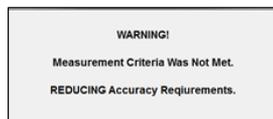
Alignment is ranked using a “star” system. As measurements enter the measurement bank, they are given a 1-star, 2-star or 3-star rank, with 3-star being the best. 3-star ranked measurements will replace those in the bank with a lower ranking.

In order to meet the measurement criteria, eight measurements must be obtained that meet the ranking (3-Star) and standard deviation requirements. Standard deviation requirements can be viewed and adjusted by selecting **Preferences > Doctor**.

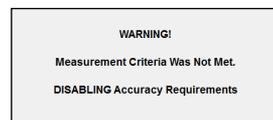
Fr#	AXL	ACD	LT	VCD	Rank
6	25.68	3.74	3.77	18.17	***
7	25.68	3.74	3.77	18.17	***
8	25.65	3.71	3.76	18.18	***
9	25.62	3.69	3.75	18.18	***
10	25.58	3.65	3.75	18.18	***
11	25.55	3.63	3.73	18.19	***
12	25.58	3.66	3.72	18.20	***
13	25.60	3.68	3.72	18.20	***

Once the measurement bank is filled with 3-star measurements, and all measurements are within the standard deviation parameters, measurement will automatically stop. The entries in the bank are used to calculate the measurement average.

If 3-star alignment is not achieved within the alignment timeout period, a warning message will appear stating that alignment accuracy requirements will be reduced. 1-star, 2-star and 3-star measurements will be accepted for calculating the average.



If alignment continues to be undetected, a warning message will appear stating that alignment accuracy requirements will be disabled, placing the system in “Estimate Mode”. All measurements, regardless of alignment, will be accepted for calculating the average.



If measurements are obtained that do not show signs of alignment, they will be given an “EST” ranking.

168	23.72	3.57	3.96	16.19	EST
-----	-------	------	------	-------	-----

Note: Measurements with an “EST” ranking do not show signs of alignment. Star ranked measurements should be given preference over “EST” ranked measurements when possible.

If eight valid measurements are not obtained prior to the video buffer expiring, the scan will time out. Two long beeps will signal that the scan has timed out.

VIDEO BUFFER FULL

If 8 valid measurements have not been obtained before the video buffer is full, the scan will time out as indicated by two long beeps. The default video duration is 1024 frames. This can be adjusted in the **Preferences > System** menu.

REVIEW WAVEFORM VIDEOS

Waveform videos captured during the exam can be reviewed frame by frame by pressing the ← and → keys on the keyboard or by moving the slider along the bottom of the screen. If the currently displayed frame is associated with a measurement in the bank, the corresponding entry in the measurement bank will be highlighted. The scan video is replayed by clicking the **[REWIND]** button and then the **[PLAY]** button in the bottom left-hand corner.

DELETING A-SCAN MEASUREMENTS

If a measurement is observed which is suspect because it does not agree with the other measurements, it may be removed or replaced with a different measurement. To delete an entry from the measurement bank, first select the **[MANUAL MODE]** radio button. Right-click on the entry to be removed and select **[REMOVE MEASUREMENT]** from the menu .

MANUAL MEASUREMENT MODE REVIEW

The Scanmate software can be placed in Manual Measurement Mode by selecting the **[MANUAL MODE]** radio button. In this mode scans must be stopped by the operator and measurements must be manually selected and entered into the measurement bank. Manual Mode scans are only stopped by user commands or if the video buffer expires. Measurements can be reviewed and deleted as described above. Users can also make gain and measurement point adjustments.

On a desired frame, the measurement points can be set by the user. In contact mode, three red arrows represent measurement points that can be selected; they represent the anterior and posterior lens surfaces (L1 and L2) and the retina (R). In immersion mode, the corneal peak is also visible in the waveform and is indicated by an additional arrow at the leftmost echo.

The red arrows can be moved horizontally by using the mouse to left click-and-hold on the arrow, then sliding it to the desired position. When a measurement arrow is released it will snap to the closest intersection of the measurement level and the displayed waveform. The measurement points can only be adjusted when the video is paused. The horizontal green line represents the measurement level. In manual mode, the measurement level can be adjusted up and down while the video is paused or playing. The three sliders control the gain at the three measurement points (L1, L2, and R). They can be adjusted independently while the video is paused or playing. The amount of gain is displayed as a percentage of the incoming waveform amplitude.

A measurement can be added to the measurement bank by right-clicking in the measurement bank and selecting **[INSERT MEASUREMENT]**. Measurements that are manually inserted are given a “MAN” rank.

SAVE A-SCAN MEASUREMENTS

Go to **File > Save > A-Scan Measurements†** to save the entries in the measurement bank for both the OD and OS. A saved A-Scan measurement will also contain the measurement average and standard deviation for the AXL, ACD, LT and VCD, as well as lens and vitreous type.

SAVE A-SCAN VIDEO

Go to **File > Save > A-Scan Video†** to save all frames of the A-Scan performed. Saving the A-Scan Video (rather than just the measurements) allows the user to review the entire measurement procedure and select manual measurement points. The user can also make adjustments to the waveform, such as gain and compression sensitivity settings. The scan video and associated measurements will remain in memory for each eye (OD and/or OS) until either a new scan is performed for that eye, or a new patient is selected.

†Indicates a command that may be executed through A-Scan voice controls. Refer to the A-Scan Voice Controls section.

A-SCAN VOICE CONTROLS

ENABLING VOICE CONTROL

Voice control can be enabled/disabled through the Preferences > System menu. Voice control can be configured to begin upon pressing the **[ENTER]** key or by a verbal command of “Hey Flex”. Voice control sensitivity can be adjusted in this menu as well.

NOTE: To use the voice control feature, the computer running the Scanmate Flex software must have a connected (or integrated) microphone that is enabled.

NOTE: If the **[ENTER]** key is not configured to initiate a voice command, pressing it while on the A-Scan Screen will automatically save a measurement file.

VOICE COMMANDS

The following verbal commands are recognized by the Scanmate Flex software while performing an A-Scan. To issue a command, the user must first say “Hey Flex” or press the **[ENTER]** key (depending upon System Configuration).

USER VERBAL COMMANDS	FLEX AUDIBLE RESPONSE	FLEX COMMAND EXECUTED
“Hey Flex”	Tone: Double-Beep	Voice control activated. The software is ready to receive verbal commands.
“Start Scan”	Verbal: “Starting Scan”	The A-scan will start.
“Stop Scan” *	Verbal: “Scan Stopped”	The A-scan will stop.
“Change Eye”	Verbal: “Eye changed to OD/OS.”	The eye being scanned is changed. The audible response will state if OD or OS is being scanned.
“Save Measurements”	Verbal: “Measurements Saved”	The currently displayed frame is saved.
“Save Video”	Verbal: “Video Saved”	The currently displayed video is saved.
“Open File”	N/A	A window is opened showing A-Scan measurements and videos for the currently loaded patient.
“Yes” *	N/A	Selects ‘Yes’ for a dialog box prompts.
“No” *	N/A	Selects ‘No’ for a dialog box prompts.

* Indicates a command that DOES NOT require “Hey Flex” or an **[ENTER]** key press to be initiated.

IOL CALCULATOR SCREEN

The IOL Calculator Screen allows the user to perform and review intraocular lens power calculations for the currently selected patient. If available, measurements and the selected lens and vitreous type are automatically loaded from the A-Scan Screen. Information from the Patient Data screen, (Patient Name, ID, Doctor) will be imported into the IOL Calculator.

Pre-Operative Data: Clicking the **[PRE-OP]** tab will present all fields necessary to perform IOL calculations. ACD, LT and AXL measurement values will automatically be imported from the patient's selected A-Scan. Other values that may be edited by the user are highlighted. Missing or out-of-range inputs are automatically marked in red. The results of the IOL calculation (Target IOL Power, Emmetropic Power, and Range of IOL Power and Refractions) are displayed for up to three (3) IOLs for each eye.

Post-Refractive Data: If the patient has previously undergone refractive surgery, select the **[POST REFRACTIVE]** checkbox for the affected eye. This will enable the Post Refractive K Calculator which can assist the user in determining the true corneal power of eyes that have undergone corneal refractive surgery. This calculator can perform Kcorr calculations using history derived, clinically derived, refraction derived, contact lens over-refraction or double-k calculation methods

Post-Operative Info: Clicking the **[POST-OP]** tab will present the Post-Operative section of the Patient Data Screen, where the user may input the stabilized surgical results for the current patient and procedure. This section of the Patient Data Screen is only editable if valid Pre-Operative Data has been entered for the selected eye.

PERFORMING IOL CALCULATIONS

NOTE: 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 post-operative results.

1. Select the “Patient Data” Screen and either enter a new patient or select an existing patient.
2. Select the “A-Scan” Screen tab and obtain A-Scan measurements for the patient. Refer to the Performing A-Scans (Contact) or Performing A-Scans (Immersion) sections for information on using the Scanmate software for these procedures. Verify that the information is correct and enter any missing Pre-Operative Data.
3. Select the Doctor that is performing the Lens Replacement Surgery using the drop down box. The preferred IOLs and formulas will automatically be loaded for the selected Doctor.
4. If the Patient has previously undergone corneal refractive surgery, select the “Post Refractive” checkbox for the affected eye or for both eyes. This will automatically open the Post Refractive Calculator. Refer to the Post Refractive Calculations section for more information.
5. Select the measurement source. Choices include A-Scan average, A-Scan Single Measurement and User Input. If user input is selected, complete the highlighted fields.
6. The Corneal Refractive Index (nc) of the keratometer used to calculate the corneal power (K1 and K2) for the current patient should be entered in this field. This field will automatically be completed with the default corneal refractive index (nc) set in System Preferences, but it can be changed by the user on this screen.

 **WARNING:** Failure to adjust the Default Keratometer Index (nc) to match the actual nc of the keratometer used to measure the eye may result in errors in the IOL Calculation .

7. If desired, modify the IOLs and formulas using the appropriate drop-down boxes. The “default” lens constant for the selected IOL and formula will be shown underneath the formula selection box.
8. If desired, select the “Personalized Constant” checkbox. This option will only be available if a personalized lens constant has been calculated for the currently selected Doctor and IOL. When selected, the personalized lens constant will replace the default lens constant. Refer to the Personalized Lens Constants section for more information.
9. Once all necessary inputs are entered, the DGH Scanmate will perform IOL calculations using the selected formula for each of the six (6) selected IOLs on the screen. Any necessary inputs for performing an IOL Power Calculation that are either missing or out of range are automatically highlighted in red.
10. Save the pre-operative data for the current patient and procedure by selecting the **[SAVE]** icon.

IOL FORMULA REFERENCES

The following IOL Power Calculation formulas are included in the Scanmate IOL Calculator. The formulas selected for inclusion are commonly used, and have been refined from earlier models. IOL power calculation formulas have evolved from the first models to become more accurate in a wider range of cases; selecting the appropriate IOL formula will be based on the individual practitioner's judgment and experience. The IOL Power Calculations are based on formulas published in peer-reviewed journals.

- BINKHORST II JEDMED Internal documents, based on Binkhorst, R.D. "Pitfalls in Determination of Intraocular Lens Power Without Ultrasound." *Ophthalmic Surgery* 7:68 (1976): 69-82.
- STORZ CompuScan LT. User Manual.
- HAIGIS Haigis, W. Personal communication, based on documents prepared July 2, 2008. Received Feb 2, 2009.
- HOFFER Q. Hoffer, K.J. "The Hoffer Q formula: A comparison of theoretic and regression formulas." *Journal of Cataract and Refractive Surgery* 19:6 (Nov 1993): 700-712.
- Errata in *Journal of Cataract and Refractive Surgery* 33:1 (Jan 2007): 2.
- Author response in *Journal of Cataract and Refractive Surgery* 33:1 (Jan 2007): 2-3.
- HOLLADAY 1 Holladay J.T., et al. "A three-part system for refining intraocular lens power calculations." *Journal of Cataract Refractive Surgery* 14:1 (Jan 1988): 17-24.
- SRK-II Sanders, D.R., et al. "Comparison of the SRK-II Formula and Other Second Generation Formulas." *Journal of Cataract and Refractive Surgery* 14:2 (Mar 1988): 136-141.
- SRK-T Retzlaff, JA et al. "Development of the SRK/T Intraocular Lens Implant Power Calculation Formula." *Journal of Cataract and Refractive Surgery* 16:3 (May 1990): 333-340.
- Errata in *Journal of Cataract and Refractive Surgery* 16:4 (Jul 1990): 528.

POST REFRACTIVE CALCULATIONS

NOTE: The corrected corneal power (Kcorr) calculated using the formulas described are *NOT to be interpreted as a suggested or recommended corneal power on the part of DGH Technology, Inc.* The calculated corrected corneal power (Kcorr) should be used as a guideline only. It is based upon the accuracy of the post refractive formula used and the data entered. The determination of the corrected corneal power (Kcorr) to use for performing IOL Power Calculations must be made by the surgeon, based on personal experiences and previous postoperative results.

1. Select the “Post Refractive” checkbox on the IOL Calculator Screen next to the eye that has previously undergone corneal refractive surgery. This will automatically open the Post Refractive Calculator.

NOTE: The Post Refractive Calculator can be opened again at any time by selecting the **[KCORR]** button on the IOL Calculator Screen. The **[KCORR]** button is inactive until the “Post Refractive” checkbox has been selected.

2. When the “Post Refractive” checkbox is selected, the Pre-Op group box on the IOL Calculator screen will change in the following ways:
 - K1 and K2 will be replaced with Kcorr or Pre Ref. K and Post Ref. K (Pre Refractive Surgery and Post Refractive Surgery) depending on the Post Refractive Method selected.
 - The values Kcorr, Pre Ref. K, and Post Ref. K are “read only”
 - K1 and K2 are entered automatically into the “Post Refractive Surgery” section of the Post Refractive Calculator

NOTE: Deselecting the “Post Refractive” checkbox returns all fields to the original configuration.

3. In the Post Refractive Calculator, select the desired eye(s) on which to perform Post Refractive calculations using the “Calculate OD” and “Calculate OS” checkboxes.
4. Select the desired Post Refractive formula using the method drop-down box. The required inputs for the selected method will then be highlighted in white.
5. Enter all known inputs. If a field is gray, that input is not required for the selected method, but can still be edited. K1 and K2 values can be entered as either mm or D, but both K values in a section must be in the same units. Pre-Surgical and Post-Surgical K values can be entered in different units.

NOTE: The refractive index (nc) displayed in the IOL Calculator will be automatically transferred to both the Pre-Surgical and Post-Surgical sections of the Post Refractive Calculator. If a different keratometer was used for Pre-Surgical measurements, the correct nc for the keratometer used must be entered in the Post Refractive Calculator.

6. Click the **[CALCULATE]** button and the corrected corneal power (Kcorr) will be calculated. If required inputs are missing, the empty field will be highlighted in red. All fields must be entered to complete the calculation. A successful calculation will display the Kcorr in the “Outputs” section of the calculator. Kcorr is given in diopters (D) using a keratometer index (nc) of 1.3375.

7. Once calculated, results will automatically be imported into the IOL Calculator Screen and used for IOL Power Calculations. Selecting the **[OK]** button without calculating will close the calculator and save the values entered, but will not import a Kcorr to the IOL Calculator.
8. Use the “K Correction Method” drop-down box on the IOL Calculator Screen to see the corrected corneal power (Kcorr) predicted by the other Post Refractive Formulas. If the new method selected requires information that has not been entered, the Post Refractive Calculator will open automatically. Once the desired Post Refractive Formula has been selected, proceed with the IOL Power Calculation.

POST REFRACTIVE FORMULAS

It has been well established that the corneal power for patients that have undergone corneal refractive eye surgery cannot be accurately measured using current keratometry or topography methods. The Post Refractive Calculator included with the Scanmate software helps predict the true corneal power for patients that have undergone corneal refractive surgery. The Scanmate software is equipped to calculate the corrected corneal power (Kcorr) using History Derived, Clinically Derived, Refraction Derived, Contact Lens Over-Correction and Double K methods. These methods have been implemented as described by Shammas, H. John. *Intraocular lens power calculations*. Slack Incorporated, 2004

HISTORY DERIVED

The History Derived method is considered to be one of the most accurate methods for determining the true post-surgical corneal power. Unfortunately, it also requires the most information about the patient – some of which may not be available. This History Derived method calculates the amount of correction that was achieved through refractive surgery and adds it to the pre-surgical corneal power. This method can be used with 3rd generation formulas (SRK/T, Hoffer Q or Holladay 1).

$$K_{\text{corr}} = \text{pre} - K_{\text{ave}} - \left(\frac{S.E._{\text{post}}}{(1 - S.E._{\text{post}})} - \frac{S.E._{\text{pre}}}{(1 - S.E._{\text{pre}})} \right)$$

Required Inputs: Pre Refractive Surgery K measurements
 Pre Refractive Surgery Spectacle Refraction (S.E.)
 Post Refractive Surgery Spectacle Refraction (S.E.)

CLINICALLY DERIVED

The advantage of this formula is that no information prior to the refractive surgery is needed. The only input required for this method is the average (post-surgical) manual keratometry measurement of corneal power. The disadvantage is that since the amount of correction achieved through refractive surgery is unknown, it is not factored into the calculation. This method can be used with 3rd generation formulas (SRK/T, Hoffer Q or Holladay 1).

$$K_{\text{corr}} = (1.14 \times \text{post} - K_{\text{ave}}) - 6.8\text{m}^{-1}$$

Required Inputs: Post Refractive Surgery K measurements

REFRACTION DERIVED

This method is useful when the pre-operative K values are unknown, but the pre-operative spectacle refraction is known.

$$K_{\text{corr}} = \text{post} - K_{\text{ave}} - 0.23 \times \left(\frac{S.E._{\text{post}}}{(1 - S.E._{\text{post}})} - \frac{S.E._{\text{pre}}}{(1 - S.E._{\text{pre}})} \right)$$

Required Inputs: Pre Refractive Surgery Spectacle Refraction (S.E.)
 Post Refractive Surgery K measurements
 Post Refractive Surgery Spectacle Refraction (S.E.)

CONTACT LENS OVER-CORRECTION (CL Over-Corr)

This method requires the doctor to place a plano hard contact lens of a known curvature on the patient's eye. If the refraction remains the same, the corneal curvature is equal to that of the contact lens. If the over-refraction results in a higher myopic error, the difference in refraction is added to the base curve value. This method can be used with 3rd generation formulas (SRK/T, Hoffer Q or Holladay 1).

$$K_{\text{corr}} = CL_{\text{base curve}} + \left(\frac{CL_{\text{over}}}{1 - 0.012\text{m} \times CL_{\text{over}}} \right) - \left(\frac{S.E._{\text{post}}}{1 - S.E._{\text{post}}} \right) + CL_{\text{power}}$$

Required Inputs: Contact Lens Base Curve
 Contact Lens Power
 Contact Lens Over-Refraction (S.E.)
 Post Refractive Surgery Spectacle Refraction (S.E.)

DOUBLE-K (SRK-T)

This method uses the pre-refractive corneal power to estimate the post-refractive anterior chamber depth (also known as effective lens position). The post-refractive corneal power is estimated using the History Derived Method. This method can be used with the SRK/T formula.

The Double K method modifies the SRK-T formula to use both pre- and post-refractive surgery K values. The pre-refractive surgery K value is used to calculate the effective lens position, and the post-refractive surgery K value is used for IOL power calculations. This method have been implemented as described by Aramberri, J. "Intraocular Len Power Calculation After Corneal Refractive Surgery: Double-K Method." *Journal of Cataract and Refractive Surgery* 29:11 (Nov 2003): 2063-2068.

Required Inputs: Pre Refractive Surgery K measurements
 Pre Refractive Surgery Spectacle Refraction (S.E.)
 Post Refractive Surgery Spectacle Refraction (S.E.)

PERSONALIZED LENS CONSTANTS



WARNING: Only A-Scan measurements performed with the Scanmate Flex should be used to calculate personalized lens constants.

WARNING: Only stabilized post operative results should be used to calculate personalized lens constants.

WARNING: Corneal power measurements used for calculating personalized lens constants should be performed using the same keratometer.

WARNING: Results for patients that have undergone corneal refractive surgery should not be used to calculate personalized lens constants

1. Select the “Patient Data” Screen and either enter a new patient or select an existing patient.

NOTE: Ensure that the nc set in System Preferences matches the corneal refractive index of the Keratometer used to measure the K values.

2. Select the “A-Scan” Screen tab and obtain A-Scan measurements for the patient. Refer to the Performing A-Scans (Contact) or Performing A-Scans (Immersion) sections for information on using the Scanmate software for these procedures.

NOTE: DGH does not recommend mixing Contact and Immersion measurement results when calculating personalized lens constants.

3. Select the IOL Calculator Screen and perform calculations as described in the Performing IOL Calculations section. Save the Pre-Operative Data used to perform the calculations by clicking the **[SAVE]** button.

4. Perform the lens replacement surgery. Record the actual lens model and power that was used.

5. Enter the Stabilized “Post-Operative” results in the IOL Calculator Screen. Review the Pre-Operative data and Post-Operative Results and decide if the Procedure should be included in the Personalized Lens Constant Calculation. If the Procedure is a good candidate, select the “Add to Personalized Constants Table” checkbox.

Selection of consistent results is the most critical step in Calculating Personalized Lens Constants. Personalized Lens Constants only compensate for consistent errors in predicting the power of the implanted IOL. For this reason, all steps used to measure the patient, calculate the IOL power and perform the lens replacement surgery should be performed as identically as possible. Ultimately it is up to the doctor to decide which results to use, but in general the following guidelines should be observed:

- Do not include results where complications occurred during the procedure.
- Only include results where the same surgical technique was used.
- Do not include results from patients that have undergone refractive eye surgery.
- Only include results where the A-Scan measurement was performed using the same technique, measurement mode (immersion or contact) and instrument.
- Only include results where the Corneal Power measurements were made with the same instrument.

6. After a large population of results has been acquired for a given doctor and IOL model, navigate to the Personalized Lens Constants Table to view the Procedures that were performed by the selected doctor using the selected lens. Review the Procedures that have “Use Record” selected and modify as necessary. See step 5 for considerations on filtering which results to use.
7. The “New Personalized Constants” group box shows the results of the Personalized Lens Constants calculation based on the Procedures that are currently selected in the table. The “Current Personalized Constants” group box displays the lens constants that are currently being used for the selected Doctor and IOL.
8. Click the [↑] button to replace the “Current Personalized Constants” with the “New Personalized Constants”. These new Personalized Lens Constants will now be available for use in future IOL power calculations.

NOTE: Automatically calculating lens constants is similar to the procedure described above except that the lens constants are recalculated as soon as “Add to Personalized Constants Table” checkbox is selected.

EXPORTING AND IMPORTING DATA

Individual measurement and video files can be exported and imported from the database to be consulted in other locations or by other practitioners. The Scanmate software must be installed on a computer to view measurement or video files.

EXPORT A-SCAN MEASUREMENT FILE

Select **File > Export > A-Scan Measurements**. The measurements currently in the measurement bank will be saved as a .meas file.

EXPORT A-SCAN VIDEO

Select **File > Export > A-Scan Video**. The images currently in the video buffer will be saved as a .vdo file. Alternatively, an .avi file (which can be opened on most PC media applications) can be exported by using the top menu bar and selecting **File > Export > A-Scan Video (AVI)**.

EXPORT B-SCAN/UBM IMAGE

Click the **[OPEN FILE]** icon to display saved images associated with the patient, and then drag-and-drop the thumbnail onto the desktop or into the appropriate folder. The image will be saved in a .jpeg format.

EXPORT B-SCAN/UBM VIDEO

Select **File > Export > B-Scan File**. The images currently in the video buffer will be saved as a video file. The user can choose to save in .bscan and .avi file formats. Alternatively, an .avi file (which can be opened on most PC media applications) can be exported by using the top menu bar and selecting **File > Export > B-Scan Video (AVI)**.

EXPORT A-SCAN/B-SCAN/UBM REPORT

Click the **[OPEN FILE]** icon to display saved reports associated with the patient, and then drag-and-drop the thumbnail onto the desktop or into the appropriate folder. The report will be saved in a .pdf format.

IMPORT A-SCAN MEASUREMENT FILE

Select **File > Import > A-Scan Measurements**. A browser window will open. Select the desired .meas file to open. The opened file will replace any information currently in the patient data fields and the measurement bank. The opened file can be saved into the database at this point.

IMPORT A-SCAN VIDEO FILE

Select **File > Import > A-Scan Video**. A browser window will open. Select the desired .vdo file to open. The opened file will replace any information currently in the patient data fields and the video buffer. The opened file can be saved into the database at this point.

IMPORT B-SCAN/UBM VIDEO FILE

Select **File > Import > B-Scan Video**. A browser window will open. Select the desired video file to open. The user can choose to import .bscan, .bs and .cini files. The opened file will replace any information currently in the patient data fields and the video buffer. The opened file can be saved into the database at this point.

Legacy B-Scan files do not contain all the necessary information to be included in the DGH-Scanmate database. When attempting to import a legacy file, a dialog window will open requesting additional information when importing these file types. Select the Patient that you would like to associate the imported file with. If the desired patient is not shown, select **[CANCEL]** and add the patient to the database. Verify that the Eye (OD or OS) and the Scan Date are correct and select **[IMPORT]**.

DATABASE MANAGEMENT—SQL SERVER DATABASE BACKUP

If a **Client PC** installation was performed, an SQL Server database is used to store patient records. Electronic records should be backed up regularly to prevent data loss. To backup the Scanmate database using the Backup / Restore tool:

1. Open the Back Up / Restore window by selecting **File > Database > Backup / Restore**.
2. Connect to the DGH Database Server by entering the system administrator username and password that was created when the DGH Database Server was installed and clicking the **[CONNECT]** button.

NOTE: This is the same username and password that were created during SQL Server prerequisite installation.

3. Select the desired database to Back Up from the combo box and select the **[BACK UP]** button
4. Once the back up process has completed, a message box will display the location of the backup file. It is recommended that the backups be performed regularly and stored in a safe location. Preferably, backup files should not be stored on the same physical drive that hosts the database.

The screenshot shows a software window titled "Server Connection" and "Back Up / Restore". The "Server Connection" section has a "Status: Connected" indicator, a "Server" dropdown menu set to "(local)\DGHSERVER", a "User Name" text box containing "sa", and a "Password" text box containing "IDGHTest1". There is a checkbox for "Use Windows Authentication" which is unchecked, and a "Connect" button. The "Back Up / Restore" section shows "Last Back Up: None", a "Database" dropdown menu set to "DGH-Scanmate", and two buttons: "Back Up" and "Restore". A "Done" button is located at the bottom right of the window.

DATABASE MANAGEMENT—SQLITE DATABASE BACKUP

If a **Single PC** installation was performed, a SQLite database is used to store patient records. Electronic records should be backed up regularly to prevent data loss. To backup the database using the Backup / Restore tool:

1. Open the Back Up / Restore window by selecting **File > Database > Backup / Restore**.

2. The combo box shows the default location where the backup file will be created. If a different location is desired, click the **[...]** button. A dialog window will open and allow a different location to be selected.

The screenshot shows a software window titled "Back Up / Restore". It displays "Last Back Up: None" and a "Backup File Path" text box containing the path "C:\Users\Win7_x64\Desktop\DGH_Scanmate\BackUp\DGH_Scanmate.db". There are "Back Up" and "Done" buttons.

3. Once the desired backup location is selected, click the **[BACK UP]** button.
4. Once the back up process has completed, a message box will display the location of the backup file. Click the **[OK]** button. It is recommended that the backups be performed regularly and stored in a safe location. Preferably, backup files should not be stored on the same physical drive that hosts the database.

DATABASE MANAGEMENT—RESTORING AND TROUBLESHOOTING

Additional procedures for database management, restoring and troubleshooting are available in the DGH Scanmate Installation Guide.

CLEANING AND DISINFECTION

WARNING: Cleaning and disinfection of all patient contact surfaces of the device and accessories must be performed prior to beginning any biometry procedure. To avoid cross contamination, follow all infection control policies established for the office, department or hospital as they apply to personnel and equipment.

WARNING: Probes and cables should not be autoclaved or subjected to intense heat.

WARNING: DGH Technology, Inc. makes no claims about the biological effectiveness as a disinfectant of any of the products/solutions listed below. Furthermore, DGH Technology, Inc. makes no claims regarding the effectiveness of any product for killing any known or unknown bacteria, virus, or other microorganism. DGH Technology, Inc. only claims that the products listed, when used as described, will not harm the device.

DISINFECTANT ^a	CONCENTRATION ^a	PROBE TYPE		
		A-SCAN ¹	B-SCAN ²	UBM ²
Cavicide Solution	(10-20%) Isopropyl Alcohol and (1-5%) Ethylene Glycol Monobutyl Ether	soak ≤1hr		
Cavicide Wipe	(10-20%) Isopropyl Alcohol and (1-5%) Ethylene Glycol Monobutyl Ether	wipe		
Cidex	2.55% (w/w) Glutaraldehyde	soak ≤1hr	soak ^e 20 min	soak ^e 20 min
Cidex OPA	6.2% by (w/w) Ortho-Phthalaldehyde (1,2 – benzenedicarboxaldehyde)	soak ≤1hr		
Isopropyl Alcohol	70% (v/v) Isopropyl Alcohol	soak ≤1hr	soak ^d 5-10 min	soak ^d 5-10 min
Household Bleach	0.6% (w/w) Sodium Hypochlorite	soak ≤1hr	soak ^d 5 min	soak ^{d,xx} 5 min
Hygeol 1-20	0.2% Sodium Hypochlorite and distilled water	soak ≤1hr	soak ^d 10 min	soak ^d 10 min
Hydrogen Peroxide	3% (w/w) H ₂ O ₂	soak ≤1hr		
Hydrogen Peroxide	6% (w/w) H ₂ O ₂	soak ≤1hr	soak ^d 10 min	soak ^d 10 min
Milton	2% (w/w) Sodium Hypochlorite	soak ≤1hr		

a Disinfectants listed were found to be compatible with the probe tip material at concentrations shown, however DGH Technology, Inc. makes no claims regarding the effectiveness of these products as a disinfectant or for the killing of any known or unknown bacteria, virus, or other microorganism. DGH only claims that these products, when used properly, will not harm the device.

xx This method of disinfection is most severe and will shorten the life of the UBM transducer. It is only recommended when other methods are unavailable or not suited to the disinfection requirements.

e After soaking in Cidex, rinse with ethyl alcohol, then rinse thoroughly with distilled water (de-ionized or sterile water may also be used).

d After soaking, rinse thoroughly with distilled water (de-ionized or sterile water may also be used)

1 Probe may be submerged up to probe cable strain relief

2 Probe may be completely submerged when disconnected from probe cable.

 **CAUTION:** The USB interface housing is not water tight. Do not saturate or immerse the housing in liquid.

The USB Interface Module's plastic housing can be cleaned using a soft cloth dampened with 70% (v/v) Isopropyl Alcohol.

A-SCAN PROBE (DGH6006)—GENERAL CLEANING AND DISINFECTION

 **CAUTION:** Do not submerge the A-Scan probe in liquid beyond the cord strain relief. Care must be taken to prevent liquids from entering the probe housing from the cord-side or from coming into contact with the probe connector.

NOTE: Disinfection should be performed after general cleaning.

NOTE: Wear protective gloves when performing general cleaning or disinfection.

GENERAL CLEANING: Disconnect the probe from the USB interface module. Dampen a soft cloth with 70% isopropyl alcohol (70% IPA). Wipe the probe tip, housing and cord (if necessary) to remove any body fluids or particulate matter present. Wipe with a water-dampened cloth (using distilled, sterile or de-ionized water) to remove any residue and then wipe dry with a soft, dry cloth.

DISINFECTION: Immerse approximately 1/4" of the probe tip in a solution of 70% isopropyl alcohol (70% IPA). If it is desired that more of the probe housing be disinfected, the probe may be immersed as far as the beginning of the probe cord strain relief. Allow the probe to soak for no more than 1 hour. Rinse using distilled, sterile or de-ionized water. Thoroughly dry the probe using sterile gauze.

A-SCAN IMMERSION SHELL (P-102)—GENERAL CLEANING AND DISINFECTION

 **WARNING:** The catheter tubing used with the immersion shell can not be reused.

CAUTION: The immersion shell cannot be autoclaved.

The A-Scan immersion shell is not sold sterile, and must be cleaned and disinfected before each use. Clean and disinfect the immersion shell using FDA and EPA approved cleaning and disinfection products. The solutions must be compatible with polycarbonate and Kynar plastic. Follow the instructions on the cleaning and disinfectant labels. Refer to the immersion shell manufacturer's instructions for more information.

UBM PROBE (DGH1500) AND TRANSDUCERS (1500-35, 1500-50)—GENERAL CLEANING AND DISINFECTION

 **CAUTION:** Contaminants in tap water will corrode the metal surfaces of the UBM probe and transducer. Only use distilled, deionized or sterile water when cleaning. If tap water is inadvertently used, thoroughly rinse the probe using distilled, deionized or sterile water.

CAUTION: Extreme care must be taken to avoid scratching or otherwise damaging the gold surface of the transducer. Never use a coarse or abrasive cloth/tissue/brush when wiping the transducer surface. A soft gauze should be used when it is necessary to wipe the transducer surfaces.

CAUTION: Exposure to Sodium Hypochlorite (bleach) solutions will shorten the life of the UBM transducer.

NOTE: Disinfection should be performed after general cleaning.

NOTE: The transducer may be disconnected from the probe and cleaning may be performed separately if desired.

NOTE: Wear protective gloves when performing cleaning or disinfection.

GENERAL CLEANING: Disconnect the probe from the probe cable. When cleaning, special care must be taken not to damage the gold surface of the transducer. Surfaces of the probe may be cleaned using 70% isopropyl alcohol (70% IPA) to remove contaminants. The transducer may be cleaned using a soft gauze while only applying light pressure. When cleaning the rubber gasket, use a soft cloth or soft bristle brush (with light pressure). Hard plastic surfaces of the probe may be scrubbed using a cloth or soft bristle brush. Rinse the probe in distilled, sterile or deionized water. The transducer surface should be gently dabbed dry using a camera lens cleaning cloth or soft gauze. Hard surfaces of the probe may be dried with a soft towel or gauze. The probe should be allowed to completely dry prior to storage.

DISINFECTION: Immerse the transducer (if attached) plus approximately 2 cm of the probe cover in the desired solution. Allow the probe to soak for the necessary amount of time. The UBM probe is hermetically sealed and may be completely immersed in the disinfecting solution if necessary. However, this should be reserved for rare cases where it is judged by the clinician that the entire probe has been contaminated. Rinse the probe in distilled, sterile or de-ionized water. Thoroughly dry the probe using sterile gauze. The transducer surface should be gently dabbed dry using a soft, sterile gauze. The probe should be allowed to completely dry prior to storage.

UBM CLEARSCAN

 **CAUTION:** The Clearscan is provided sterile. An expiration date is located on each Clearscan package. Verify that the Clearscan has not expired before use.

Clearscan covers cannot be reused. Dispose of the Clearscan cover after use.

NOTE: Disinfection should be performed after general cleaning.

NOTE: Wear protective gloves when performing general cleaning or disinfection.

GENERAL CLEANING: Disconnect the probe from the probe cable. Using 70% isopropyl alcohol (70% IPA) and a cloth or soft bristle brush, scrub the hard plastic surfaces of the probe. Rinse the probe in distilled, sterile or deionized water. Surfaces of the probe may be dried with a soft towel or gauze.

DISINFECTION: Immerse the portion of the probe that has been in contact with the patient, plus approximately 2 cm of the probe cover in the desired solution. Allow the probe to soak for the necessary amount of time. The B-Scan probe is hermetically sealed and may be completely immersed in the disinfecting solution if necessary. However, this should be reserved for rare cases where it is judged by the clinician that the entire probe has been contaminated. Rinse the probe in distilled, sterile or de-ionized water. Thoroughly dry the probe using sterile gauze. The probe should be allowed to completely dry prior to storage.

ROUTINE MAINTENANCE — PHYSICAL INSPECTION

 **WARNING:** Routine maintenance should not be performed while the device is in use with the patient. Physical Inspection should be performed prior to use of the device.

WARNING: Physical inspection is required to ensure that the device and probe housings have not been damaged/compromised. Liquid ingress into the device or probes may cause damage and/or result in an electrical hazard.

Inspection of the device and its accessories is required to identify wear or damage that may be the result of routine use or accidental misuse. If the device or one of its components looks compromised, contact DGH Technology, Inc. for information on replacement components.

USB INTERFACE MODULE (FLEX-USBIM)

The USB Interface Module should be routinely inspected for dents, cracks and other forms of damage. Connectors should be inspected for cracks, deformation, damaged/bent pins, etc.

DEVICE CORDS (FLEX-PCABLE)

All device cords (probe cords, power cords, USB cords, etc.) should be routinely inspected for bends, cuts, abrasions and other forms of damage. Cord connectors should be inspected for cracks, abrasions, deformation, damaged/bent pins, etc.

A-SCAN PROBE (DGH6006)

The A-Scan probe housing should be routinely inspected of cracks, splitting, dents, sharp edges, projections, deformation and other forms of damage. Special attention should be paid to the probe tip that contacts the patient's eye, ensuring that the surface is smooth and without cracks, dents or blemishes.

The B-Scan probe housing should be routinely inspected for cracks, splitting, dents, sharp edges, projections, deformation and other forms of damage. B-Scan probes should also be inspected for leaks of the internal transmission fluid. Special attention should be paid to the probe tip that contacts the patient's eye, ensuring that the surface is smooth and without cracks, dents or blemishes.

UBM PROBE (DGH1500) AND TRANSDUCERS (DGH1500-35, DGH1500-50)

The UBM probe housing should be routinely inspected of cracks, splitting, dents, sharp edges, projections, deformation and other forms of damage. Special attention should be paid to check for damage/deformation that may allow water ingress. The black o-ring seals between the transducer and probe should be checked for damage that may allow water ingress. If the o-ring is damaged, it can be replaced with the manufacturer provided substitutes.

IMMERSION SHELL (P-102)

The A-Scan Immersion shell should be regularly checked for chips, cracks, abrasions, deformation and other physical damage. If damage is found, the shell should be discarded and replaced.

ROUTINE MAINTENANCE — VERIFYING A-SCAN CALIBRATION

 **WARNING:** Verifying calibration should not be performed while the device is in use with the patient. Verifying calibration should be performed prior to use of the device.

A-Scan calibration should be verified routinely. The software must be placed into a test mode to check calibration on a standardized polystyrene block (provided with unit). The following procedure describes entering test mode and verifying unit calibration.

1. Navigate to the Patient Data Screen by selecting the "Patient Data" tab. In the "Last Name" drop-down box, select "Test Block".
2. Navigate to the A-Scan Screen by selecting the "A-Scan" tab. The current eye should be displayed as "Test Block" in the waveform display screen, and the lens type drop-down box should be frozen, displaying "Test Block".
3. Place the arm of the Flex unit in the down position. Apply a small drop of water to the top of the reference test block.
4. Apply the probe tip to the center of the reference test block.
5. Measurement of the test block should begin almost instantaneously. If not, move the probe tip slightly until a measurement is obtained.
6. Observe axial length measurements to be 12.60 mm +/- 0.1 mm. Readings outside these limits do not necessarily indicate the device is out of calibration. If an erroneous reading is obtained, verify that the following fault conditions are not present and repeat the measurements on the reference test block:
 - A. Ensure excessive water is not on the reference test block. 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, the water depth may be measured causing longer axial length measurements.
 - B. The reference test block is sensitive to temperature. The block must be stabilized at 72°F ±10°F before measurements are taken.

7. If the reference block readings are outside the limits stated, it is possible that the unit is defective and needs repair. Refer to the Repairs and Customer Support section (below) for information on contacting DGH Technology.

REPAIRS AND CUSTOMER SUPPORT

All repairs/replacements/modifications are to be performed by DGH Technology, Inc. If you feel there is a problem with the device, please contact DGH Technology, Inc.

Customers within the United States can contact DGH Technology, Inc. at the address and phone number listed below. Customers outside of the United States should contact an authorized DGH distributor to arrange service/repair.

DGH TECHNOLOGY, INC.
110 SUMMIT DRIVE, SUITE B
EXTON, PA 19341 USA

PHONE: 610 594-9100
FAX: 610-594-0390
WEB: DGHTECHNOLOGY.COM

If shipping a device to for service or repair, the battery must be disabled. To disable the battery, use a pick to slide the battery disable switch to the "Off" position. Refer to the Enable and Disable the Rechargeable Battery section for information on enabling/disabling the device battery.

 **WARNING:** Device contains a Lithium Ion battery. Improper service/replacement of the battery may cause damage to the device, excessive temperatures, fire or explosion. The Lithium Ion battery is only to be serviced/replaced by qualified service personnel.

ULTRASONIC EMISSIONS INFORMATION

The following Acoustic Output Reporting Tables show the average outputs of the samples tested. These results include the pressure-time waveform, the Fourier transform, the pulse intensity integral and the waveform analysis taken at the derated spatial peak location ($z_{m_{PII.3}}$).

The Statistical Analysis of Measurement Data tables show the results of a statistical analysis was performed on the data to examine the upper output limits, based on a one-sided tolerance limit approach. The mean and standard deviation of the Spatial-Peak, Time-Average Intensity and Mechanical Index were found, and the upper output limits were calculated from the following formula:

$$X = \bar{x} + K * S_x$$

where X is the upper output parameter limit, \bar{x} is the average of the measured output parameter, S_x is the standard deviation of the measured output parameter, and K is a factor from Reference 11, Table A-7 (of *M.G.Natrella, Experimental Statistics, NBS Handbook 91, October 1963*). A value of K was chosen which corresponds to a 90% probability that 90% of all probes would fall below the calculated limits X. Table notation definitions listed below:

MI Mechanical Index	Z at max. $I_{pi.\alpha}$ derated spatial peak location
TIS Soft Tissue Thermal Index	$I_{spta.3}$ derated spatial-peak pulse-average intensity
TIB Bone Thermal Index	A_{aprt} Active aperture area
TIC Cranial Bone Thermal Index	F_c center frequency (in MHz).
P output power (in mW)	p_r peak rarefactional pressure (in MPa)
T_d pulse duration	F_{awf} acoustic working frequenc (in MHz)
	$I_{pi.\alpha}$ derated pulse intensity integral

STATISTICAL ANALYSIS OF MEASURMENT DATA

Mode / Model:	B-Mode: 12.5 MHz (B-Scan) DGH1912		B-Mode: 20 MHz (B-Scan) DGH1920		A-Mode: 10 MHz (A-Scan) DGH6006	
	MI (Unitless)	$I_{SPTA.3}$ (mW/cm ²)	MI (Unitless)	$I_{SPTA.3}$ (mW/cm ²)	MI (Unitless)	$I_{SPTA.3}$ (mW/cm ²)
Sample Size	3.00	3.00	3.00	3.00	5.00	5.00
K	4.258	4.258	4.258	4.258	2.742	2.742
Mean (x)	0.149	0.105	0.169	0.155	0.133	0.522
StdDev (Sx)	0.0154	0.0260	5.20E-3	7.24E-3	3.24E-3	0.0258
Limit (X)	0.215	0.216	0.191	0.185	0.142	0.593

Mode / Model:	B-Mode: 35 MHz (UBM) DGH1500-35		B-Mode: 50 MHz (UBM) DGH1500-50	
	MI (Unitless)	$I_{SPTA.3}$ (mW/cm ²)	MI (Unitless)	$I_{SPTA.3}$ (mW/cm ²)
Sample Size	3.00	3.00	3.00	3.00
K	4.258	4.258	4.258	4.258
Mean (x)	0.177	0.0799	0.113	0.0262
StdDev (Sx)	3.61E-3	0.0116	8.72E-3	3.50E-3
Limit (X)	0.192	0.129	0.150	0.0411

Index Label		MI	TIS			TIB	TIC
			Scan	Non-Scan		Non-scan	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} > 1\text{cm}^2$		
Maximum index value		0.133	#	6.72E-4	-	1.17E-3	(a)
Associated Acoustic parameter	$P_{r,a}$ (MPa)	0.406					
	P (mW)		#	0.0151		0.0151	#
	Min of $[P_{\alpha}(z_s), I_{t\alpha,\alpha}(z_s)]$ (mW)				-		
	z_s (cm)				-		
	z_{bp} (cm)				-		
	z_b (cm)					-	
	Z at max. $I_{pi,\alpha}$ (cm)	1.30					
	$d_{eq}(z_b)$ (cm)					-	
	f_{awf} (MHz)		#	9.35	-	9.35	#
	Dim of A_{aprt}	X (cm)		#	0.350	-	0.350
Y (cm)			#	0.350	-	0.350	#
Other Information	Td (μsec)	0.0960					
	prr (Hz)	768					
	P_r at max. I_{pi} (MPa)	0.618					
	D_{eq} at max. I_{pi} (cm)					0.126	
	$I_{pa,3}$ at max. MI (W/cm^2)	7.09					
Operating Control Conditions	XMT = 100V						

Note 1: Information need not be provided for any formulations of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic use.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

ACCOUSTIC OUTPUT REPORTING TABLE

Transducer Model: DGH1912

Operating Mode: B-Mode

Index Label		MI	TIS			TIB	TIC
			Scan	Non-Scan		Non-scan	
				$A_{\text{aprt}} \leq 1\text{cm}^2$	$A_{\text{aprt}} > 1\text{cm}^2$		
Maximum index value		0.149	4.76E-3	-	-	-	@
Associated Acoustic parameter	$P_{r,a}$ (MPa)	0.524					
	P (mW)		0.0706	-		-	#
	Min of $[P_{\alpha}(z_s), I_{t\alpha,\alpha}(z_s)]$ (mW)				-		
	z_s (cm)				-		
	z_{bp} (cm)				-		
	z_b (cm)					-	
	Z at max. $I_{pi,\alpha}$ (cm)	1.67					
	$d_{eq}(z_b)$ (cm)						-
	f_{awf} (MHz)	12.4	12.4	-	-	-	#
	Dim of A_{aprt}	X (cm)		0.600	-	-	-
Y (cm)			0.600	-	-	-	#
Other Information	Td (μsec)	0.128					
	prr (Hz)	2560					
	P_r at max. I_{pi} (MPa)	1.07					
	D_{eq} at max. I_{pi} (cm)					-	
	$I_{pa,3}$ at max. MI (W/cm^2)	10.4					
Operating Control Conditions	10 Hz scan rate						
	60 degree scan angle						
	256 lines per scan						

Note 1: Information need not be provided for any formulations of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic use.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

Index Label		MI	TIS			TIB	TIC
			Scan	Non-Scan		Non-scan	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} > 1\text{cm}^2$		
Maximum index value		0.169	0.0112	-	-	-	@
Associated Acoustic parameter	$P_{r,a}$ (MPa)	0.640					
	P (mW)		0.163	-		-	#
	Min of $[P_{\alpha}(z_s), I_{t\alpha,\alpha}(z_s)]$ (mW)				-		
	z_s (cm)				-		
	z_{bp} (cm)				-		
	z_b (cm)					-	
	Z at max. $I_{pi,\alpha}$ (cm)	1.67					
	$d_{eq}(z_b)$ (cm)					-	
	f_{awf} (MHz)	14.4	14.4	-	-	-	#
	Dim of A_{aprt}	X (cm)		0.560	-	-	-
Y (cm)			0.560	-	-	-	#
Other Information	Td (μsec)	0.107					
	prr (Hz)	2560					
	P_r at max. I_{pi} (MPa)	1.47					
	D_{eq} at max. I_{pi} (cm)					-	
	$I_{pa,3}$ at max. MI (W/cm^2)	17.1					
Operating Control Conditions	10 Hz scan rate						
	60 degree scan angle						
	256 lines per scan						

Note 1: Information need not be provided for any formulations of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic use.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

Index Label		MI	TIS			TIB	TIC
			Scan	Non-Scan		Non-scan	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} > 1\text{cm}^2$		
Maximum index value		0.177	1.43E-3	-	-	-	@
Associated Acoustic parameter	$P_{r,a}$ (MPa)	0.800					
	P (mW)		0.0147	-		-	#
	Min of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$ (mW)				-		
	z_s (cm)				-		
	z_{bp} (cm)				-		
	z_b (cm)					-	
	Z at max. $I_{pi,\alpha}$ (cm)	1.00					
	$d_{eq}(z_b)$ (cm)						-
	f_{awf} (MHz)	20.4	20.4	-	-	-	#
	Dim of A_{aprt}	X (cm)		0.700	-	-	-
Y (cm)			0.700	-	-	-	#
Other Information	Td (μsec)	0.0497					
	prr (Hz)	2560					
	P_r at max. I_{pi} (MPa)	1.62					
	D_{eq} at max. I_{pi} (cm)						-
	$I_{pa,3}$ at max. MI (W/cm^2)	14.0					
Operating Control Conditions	10 Hz scan rate						
	20 degree scan angle						
	256 lines per scan						

Note 1: Information need not be provided for any formulations of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic use.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

ACCOUSTIC OUTPUT REPORTING TABLE

Transducer Model: DGH1500-50

Operating Mode: B-Mode

Index Label		MI	TIS			TIB	TIC
			Scan	Non-Scan		Non-scan	
				$A_{aprt} \leq 1 \text{cm}^2$	$A_{aprt} > 1 \text{cm}^2$		
Maximum index value		0.113	4.44E-4	-	-	-	@
Associated Acoustic parameter	$P_{r,a}$ (MPa)	0.500					
	P (mW)		5.85E-3	-		-	#
	Min of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$ (mW)				-		
	z_s (cm)				-		
	z_{bp} (cm)				-		
	z_b (cm)					-	
	Z at max. $I_{pi,\alpha}$ (cm)	1.07					
	$d_{eq}(z_b)$ (cm)						-
	f_{awf} (MHz)	19.6	19.6	-	-	-	#
	Dim of A_{aprt}	X (cm)		0.700	-	-	-
Y (cm)			0.700	-	-	-	#
Other Information	Td (μsec)	0.0437					
	prr (Hz)	2560					
	P_r at max. I_{pi} (MPa)	1.02					
	D_{eq} at max. I_{pi} (cm)					-	
	$I_{pa,3}$ at max. MI (W/cm^2)	6.33					
Operating Control Conditions	10 Hz scan rate						
	20 degree scan angle						
	256 lines per scan						

Note 1: Information need not be provided for any formulations of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic use.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

ELECTROMAGNETIC IMMUNITY AND EMISSIONS

The Electro Magnetic Interference and Compatibility testing of the Scanmate Flex was performed to determine compliance with emissions and immunity requirements set forth by the European Community under the requirements of the EMC Directive (2004/108/EC). The system complied with the radiated emissions requirements throughout the test.

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

The Scanmate Flex is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanmate Flex should assure that it is used in such an environment.

Immunity Test Basic Standard	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) Immunity IEC 61000-4-2	Indirect Applications ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV Contact Direct Applications ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV Contact ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV, ± 15 kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electric Fast Transient / Burst Immunity IEC 61000-4-4	2 kV for AC Mains 1 kV for signal I/O lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge Immunity IEC 61000-4-5	± 0.5 , ± 1 kV, ± 2 kV line(s) to line(s) ± 0.5 kV, ± 1 kV for AC Mains	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips and Interruptions IEC 61000-4-11	0% U_T (100% reduction from U_T) for 0.5 cycle 40% U_T (60% reduction from U_T) for 6 cycles 70% U_T (30% reduction from U_T) for 30 cycles 5% U_T (95% reduction from U_T) for 300 cycles @ 100V/60Hz For 250 cycles @ 230V/50Hz	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Scanmate Flex requires continued operation during power mains interruptions, it is recommended that the Scanmate Flex be powered from an uninterruptible power supply or battery.
Power Frequency Magnetic Field Immunity IEC 61000-4-8	30 A/m at 50 Hz 30 A/m at 60Hz	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the AC mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

The Scanmate Flex is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanmate Flex should assure that it is used in such an environment.

Immunity Test	Test Level	Compliance level	Electromagnetic environment - guidance
Conducted RF Immunity IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz for AC Mains	Complies	Portable and mobile RF communications equipment should be used no closer to any part of the Scanmate Flex, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_i} \right] \sqrt{P}$ 150 kHz—80 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz—800MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz—2.5 GHz
	6 Vrms 150 kHz to 80 MHz for signal I/O lines	Complies	
Radiated RF Immunity IEC 61000-4-3:2006 A1:2007 A2:2010	3 V/m 80 MHz to 1000 MHz	Complies	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
	3 V/m 1000 MHz to 2000 MHz		
	3 V/m 2000 MHz to 2500 MHz		

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies

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

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

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m

Recommended separation distances between Portable and mobile RF communications equipment and the Scanmate Flex

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

Rated maximum output power of transmitter in Watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

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

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

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

NOTE 3 Values used for calculations above are $V_1 = 3$ Vrms (150 kHz to 80 MHz), $E_1 = 3$ V/m (80 MHz to 800 MHz), $E_1 = 3$ V/m (800 MHz to 2.5 GHz).

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC EMISSIONS

The Scanmate Flex is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanmate Flex should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
Radiated Emissions, Class A CISPR 11	Complies	The Scanmate Flex uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted Emissions, Class A CISPR 11	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Harmonic Current Emissions IEC 61000-3-2: 2005 +A1: 2008 +A2: 2009	Complies	
Voltage Fluctuations & Flicker IEC 61000-3-3: 2012	Complies	

ENVIRONMENTAL CONDITIONS

The Scanmate Flex is capable of operating between temperatures of:

Temperature: 18°C to 40°C

The Scanmate Flex is capable, while packed for transport or storage, of being exposed for a period not exceeding 15 weeks to environmental conditions within the following ranges:

Temperature: -10°C to 50°C

Relative Humidity: 20% to 80% (non-condensing)

Atmospheric pressure: 70 kPa to 106 kPa

When the Scanmate Flex is not being used, it should be stored in a clean, dry area. To prevent damage to the Scanmate Flex, do not store in areas where it might be exposed to excessive vibration, excessive dust and dirt, liquids or condensation or impact.

SHELF-LIFE / LIFETIME

The shelf-life / lifetime indicated for this device is 10 years with proper care and maintenance.

The shelf-life/lifetime indicated for the 35 MHz UBM transducer element (DGH1500-35) is 1 year with proper care and maintenance.

The shelf-life/lifetime indicated for the 50 MHz UBM transducer element (DGH1500-50) is 1 year with proper care and maintenance.

DISPOSAL



This product should not be treated as household waste. Disposal should be done in accordance with all relevant country, state and local laws. By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste-handling of this product.

For more information concerning the return and recycling of this product, please contact DGH Technology, Inc.

UNABLE TO CONNECT—DGH DATABASE SERVER

Error Message/Indicator: “Error while opening database” message.

“An exception occurred while opening a report.” message.

“Save unsuccessful.” message.

“An exception occurred while testing the connection to the database. Error while opening database.” message.

“Unable to update the procedure record in the database.” message

Unable to open the database software.

Unable to view/edit patient information while using the software.

- Confirm that the location (computer name) and password for connecting to the database server are correct.
- If connecting to a database over the network, verify that the computer hosting the database is powered ON and that all network cables are connected. Verify that the firewall on the database host computer is configured to allow access to SQL Server (refer to the Scanmate Installation Guide for more information on configuring the firewall).
- Verify that both computers are in the same WORKGROUP or DOMAIN..
- Confirm that the “SQL Server (DGHSERVER)” instance is running in SQL Server 2012.
 1. Launch SQL Server Configuration Manager on the computer hosting the database. Configuration Manager can be found in the Windows Start Menu by selecting Programs > Microsoft SQL Server 2012 > Configuration Tools > SQL Server Configuration Manager.
 2. In the SQL Server Configuration Manager’s left-hand column select SQL Server Configuration Manager > SQL Server Services
 3. The software will populate a list in the right-hand column. Confirm that the item labelled SQL Server (DGHSERVER) state is “Running”. If this item is listed as “Stopped”, right-click and select “Start” from the drop-down menu.
- If the system administrator password for SQL Server has been lost or forgotten, it will be necessary to reset it using Management Studio.
 1. Launch SQL Server Management Studio on the computer hosting the database. Management Studio can be found in the Windows Start Menu by selecting Programs > Microsoft SQL Server 2012 > SQL Server Management Studio.
 2. Select “Windows Authentication” instead of “SQL Server Authentication”.
 3. Navigate to Security > Logins and right-click on the “sa” User Account, then select Properties.
 4. Enter and confirm a new password for the “sa” User Account.

USB CONNECTION NOT DETECTED

Error Message/Indicator: “No A-Scan Attached” message

“No B-Scan Attached” message

- Confirm that the drivers have been installed for the USB 2.0 port the module is currently connected to.
- Confirm that the USB cable is fully inserted and firmly seated in the USB interface module/probe.
- Connect the USB Interface Module to a various USB ports on the PC. Confirm that the USB cable is fully inserted and firmly seated in the USB connector on the PC.

UNABLE TO ACQUIRE AN A-SCAN MEASUREMENT

Error Message/Indicator: While attempting measurement, the A-scan video is playing, but measurement acquisition is not initiated.

- Verify that the correct measurement mode (Immersion / Contact) and “Eye Type” has been selected.
- If performing a Contact measurement, it may be necessary to adjust the Compression Sensitivity (Comp).
- If performing an Immersion measurement, verify that the transducer is properly inserted in the Prager Shell.

POOR QUALITY B-SCAN VIDEO

Error Message/Indicator: During video acquisition the B-Scan image looks grainy, show decreased contrast between structures and/or display lines radiating from the narrow side of the image.

- Verify that the probe is connected directly to the computer (no USB extender cord in use).
- Verify that the probe cable is properly connected to the probe and the USB port of the PC.
- Connect the B-Scan to other USB ports on the computer. Test for a firm connection/seating with the port.
- Verify that there are no emitters of high-powered electromagnetic disturbances nearby (i.e. HF surgical equipment, MRI machines, etc.)

PATIENT DATA NOT LOADED

Error Message/Indicator: “Can not save. No patient loaded.” message
 “With no patient loaded, data will be lost” message

- Verify that a patient has been selected from the Patient Data screen. Scans/measurements cannot be saved unless the corresponding patient is select. If the patient does not exist in the database, a new patient must be created. (Refer to the Patient Screen section for information on creating a new patient.)

PROBE KEY EXPIRED

Error Message/Indicator: “Probe key has expired.” message

- The A-Scan USB Interface Module and/or B-Scan probe must be detected by Scanmate application 1 time for every 20-hours of use. If these devices are disconnected for more than 20 hours, the software will lock until the device is connected and detected by the application
- If connecting the device does not reset the Probe Key, try the steps described in “USB Connection Not Detected” of this troubleshooting table.

NEW PROBE KEY REQUIRED

Error Message/Indicator: “Enter the key for the given probe and then press save.” message

- Contact DGH Technology Inc. in order to request a new probe key.

WARRANTY

DGH Technology, Inc. warrants that new devices and the accompanying accessories (hereinafter called "Equipment") are to be free from defects in material and workmanship according to the warranty certificate provided with the equipment at the time of purchase.

Warranties do 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. The cost of servicing replaceable and expendable 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.

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 changes.

The warranty provided with the device at the time of purchase 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 or 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 .



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