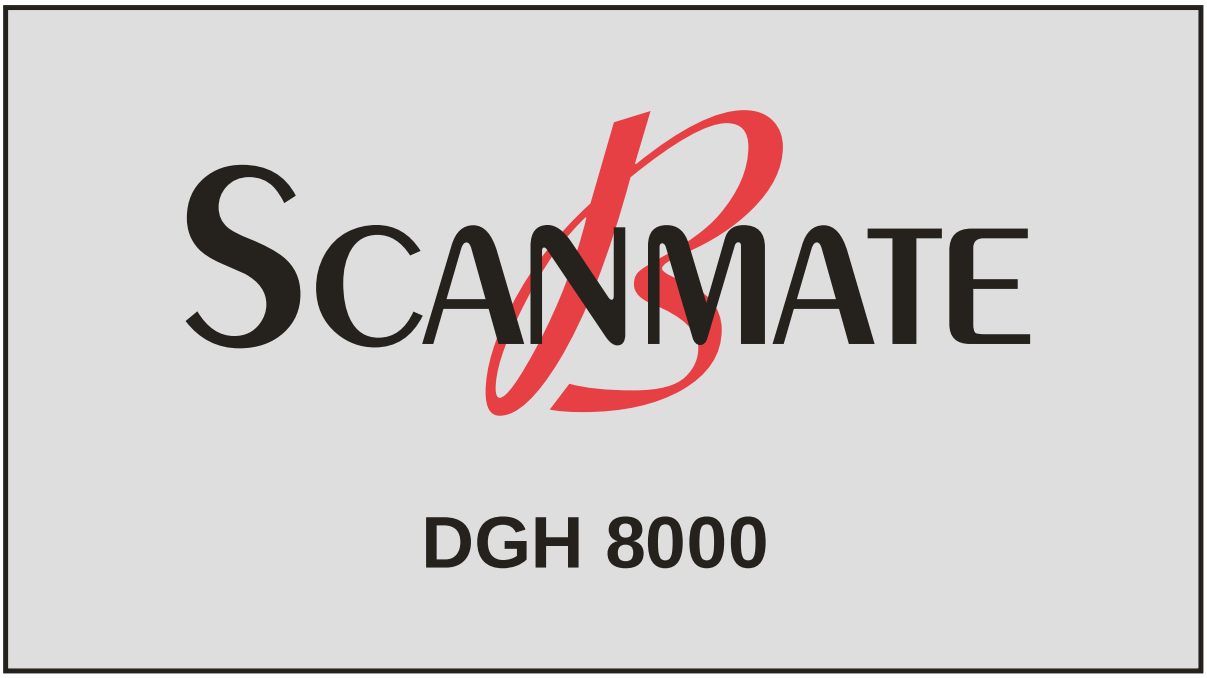
DGH 8000 (SCANMATE-B)
ULTRASONIC B-SCAN



OPERATOR'S MANUAL

For Use with Scanmate Software v4.2

Equipment Manufactured By

DGH TECHNOLOGY, INC.
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1 General Device Description

The DGH 8000 is a diagnostic ultrasound device used by professionals in the ophthalmic field to produce cross-sectional images of the eye and orbit. The probe is comprised of a 12 MHz, single element transducer that is mechanically oscillated to perform a 60-degree sector scan of the eye. The probe hand piece contains the electronics used to pulse the transducer as well as to measure, filter and amplify the resulting echoes from intraocular and orbital tissue. The probe is powered and controlled via a USB 2.0 cable, which must be connected to a PC or Laptop running the Scanmate software. The Scanmate software interprets the digital signals transmitted by the probe and displays a "Brightness Scan" that shows the relative magnitude of the echo spikes received by the transducer. The software allows the user to adjust the scan rate of the probe (12 or 15 MHz) as well as the gain, contrast, intensity, and depth of the displayed image. Once the exam is complete, the application allows the user to save video(s), image(s) or create a report to document the results.

2 Device Classification

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

3 Indications for Use

The DGH 8000 Scanmate-B is an ultrasonic device used by professionals in the ophthalmic field to perform a "Brightness Scan" of the eye. The main function of the device is to produce cross-sectional images of the eye and orbit and to serve as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria.

4 Warnings and Cautions

4.1 Meaning of Signal Words

In this manual, the signal words "Warning" and "Caution" are used to highlight important safety and usage instructions. All users of the DGH 8000 must understand the meanings of these signal words.

Signal Word	Meaning
WARNING	Indicates a potentially hazardous situation which if not avoided could cause injury or harm to the equipment or erroneous results.
CAUTION	Indicates a potentially hazardous situation which if not avoided may result in minor injury or harm to the equipment.

4.2 Description of Symbols

This symbol indicates the degree of protection against electric shock. The DGH 8000 Scanmate-B is classified as type BF equipment.

This symbol instructs the operator to read the operating manual.

This mark indicates that Notified Body 0120 (SGS United Kingdom Ltd) has certified the management system of DGH Technology, Inc. meets the requirements applicable requirements of 21 CFR 1010 (Performance Standards for Electronic Products: General) and 21 CFR 1050 (Performance Standards for Sonic, Infrasonic, and Ultrasonic Radiation-Emitting Products). The device also conforms to the following International Standards:

- EN 60601-1: Medical electrical equipment – Part 1: General requirements for safety – IEC 60601-1
- EN 60601-1-2: Medical electrical equipment – Part 1: General requirements for safety. Collateral standard: Electromagnetic compatibility requirements and tests. IEC 60601-1-2
- NEMA Standard Publication UD-2: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA Standard Publication UD-3: Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

This symbol indicates that Emergo Europe is the European Authorized Representative for this device.

This symbol indicates that DGH Technology, Inc. is the manufacturer of the DGH 8000 Scanmate-B device. The YYYY under the symbol indicates the year the device was manufactured.

REF This symbol indicates that the model number of this device is DGH 8000.

SN This symbol indicates the serial number of the device. YYYY indicates the year of manufacture and XXXX indicates the unit number.

This symbol located on the DGH 8000 indicates that the equipment consists of electronic assemblies and other components that may be subject to Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC of the European parliament, which advises that electrical and electronic devices must not be disposed of as normal domestic refuse. In order to prevent environmental risks or endangerments by non-professional disposal, the disposal of this product, including any accessories, must comply with valid practices as outlined in Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC and local regulations. All electronic components and systems should be returned to Original Manufacturer for disposal.

4.3 General Cautions and Warnings

CAUTION

The probe must be cleaned after each use. Cleaning the probe is an essential step prior to effective disinfection. Follow the manufacturer's instructions when using disinfectants.

WARNING

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

WARNING

Equipment not suitable for use in the presence of flammable mixtures.

WARNING

If the device is used in conjunction with other devices, current leakage may increase and electric shock may be caused. It is the user's responsibility to ensure safety when the device is to be used in conjunction with other devices. If safety cannot be ensured, the simultaneous use of devices is not allowed.

WARNING

The use of a "Non-Medical" grade AC Adapter could potentially cause harm to the system, the probe, the operator and/or the patient.

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

Electromagnetic interference may cause distortion of received ultrasonic signals. Such interference may result in distorted images.

WARNING

Use of accessories 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

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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5 Prescription Device Statement

CAUTION

The DGH 8000 is a prescription device and is only to be used by, or under the supervision of, a licensed physician.

6 Operator Qualifications

This DGH 8000 is intended to be used by trained medical professionals. The medical professional operating the DGH 8000 must have a general knowledge of the use of ultrasonic imaging devices and imaging protocols.

7 Use of Ultrasound in Ophthalmic Devices

Ultrasound offers a non-invasive method to examine the interior of solid objects. Ultrasonic pulses consist of sound waves of a frequency level too high to be heard by the human ear. When a sound impulse strikes an interface, some sound is reflected, and some sound is transmitted. Because some sound will pass through the surface and be reflected by the next surface, complex structures can be examined with ultrasound. When ultrasound penetrates an object with several interfaces, the reflected ultrasound can be observed on a display as a "Brightness Scan" that shows the relative position and magnitude of the echo spikes received by the transducer.

Note: Ultrasound cannot travel through air because air is not dense enough for the high frequency waves to propagate. Ultrasonic measurements must therefore be performed by direct contact or through a denser medium such as coupling gel or water.

8 Ultrasonic Exposure and Intensities

8.1 Tissue Exposure to Ultrasound Energy

The ultrasound energy emitted by the DGH 8000 is 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.

8.2 Ultrasonic Intensities

See Appendix B of this manual for acoustic measurements.

9 Biometric Imaging Capabilities

The following table shows the resolution for the DGH 8000 Scanmate-B.

Parameter	Electronic	Clinical
Resolution	0.015 mm	< 0.1mm

10 Installation and Configuration of Scanmate Software

Refer to the Scanmate Installation Manual for information on installing and configuring the software.

11 Starting the Scanmate Software

11.1 Launching the Application

Once installed, the “Scanmate” shortcut appears on the Windows desktop and in the start menu. Click on the desktop icon to start the DGH Scanmate application.

11.2 Splash Screen

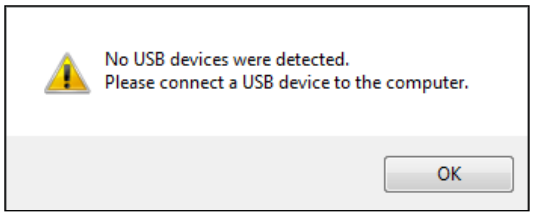
The Scanmate splash screen will appear while the application loads.

11.3 Login Screen

A single username and password is used to gain access to the software and database for all users. By default, the Scanmate software is set to automatically log in when the application is started using the username and password specified in **System Preferences**. To change this setting, uncheck the "Automatic Login" preference in the **System Preferences** menu. If a login is requested, enter the username and password created during software installation.

11.4 No USB Devices Detected Warning

If the USB probe is not attached, a warning box will appear.



Clicking "OK" will complete the log-in and allow the Scanmate software to be used without the USB probe. Although no scans can be completed, the software can still be used to review B-Scan images, videos and reports.

If the Scanmate software is being used without the DGH 8000 probe attached, the software will require probe key authentication before using, and after every 20 hours of use. Warnings will appear every hour after 15 hours of use. To provide authentication, plug a DGH 8000 probe into a USB port; authentication will complete in a few seconds.

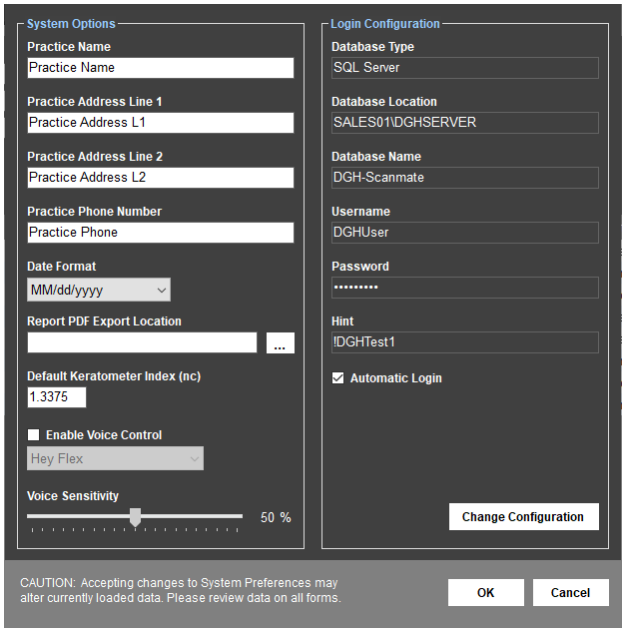
11.5 Touch Controls

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. Measurement tools can be operated using touch controls (see Sections 15.11 through 15.15). Zooming and panning of zoomed images can also be controlled through touch input (see Section 15.16).

12 Configuring the Scanmate Software

12.1 System Preferences

The "System Preferences" window provides controls to set various configuration items for the system. The System Preferences window can be accessed by selecting **Preferences → System** from the Menu Bar.



Note: Refer to the DGH 6000 Scanmate-A or the Scanmate Flex User Guide for instructions on configuring A-Scan related System Preferences.

The **Practice Name**, **Practice Address Line 1**, **Practice Address Line 2** and **Practice Phone Number** textboxes allow the user to enter practice information that will appear on reports generated by the software.

The **Date Format** textbox allows the user to select either MM/dd/yyyy or dd/MM/yyyy date format for the software.

The **Automatic Login** checkbox allows the user to select if login is required upon system startup or if the user is automatically logged in. By default, this checkbox is enabled, indicating that the username and password will be entered automatically.

The **Report PDF Export Location** setting allows the user to specify the default directory that pdf reports will be exported. The default directory can be any local or mapped network drive.

The **Enable Voice Control** checkbox allows the user to enable or disable voice control. If voice control is enabled, the user can select how to initiate voice commands from the textbox below. Voice commands may be configured to be initiated by pressing the Enter

key or by a verbal command of “Hey Flex”. Voice control sensitivity can be adjusted in this menu as well.

The **Database Type** textbox lists the database type currently being used by the Scanmate software. For more information on database types, refer to the Scanmate Installation Guide.

The **Database Location** textbox specifies the location of the DGH Database Server hosting the DGH-Scanmate database. To change the Database Location for the DGH Scanmate application, select the “Change Configuration” button and follow the prompts. For more information on configuration of the software, refer to the Scanmate Installation Guide.

The **Database Name** textbox displays the name of the DGH-Scanmate database. The default database name is created automatically when installing the system and is not user configurable.

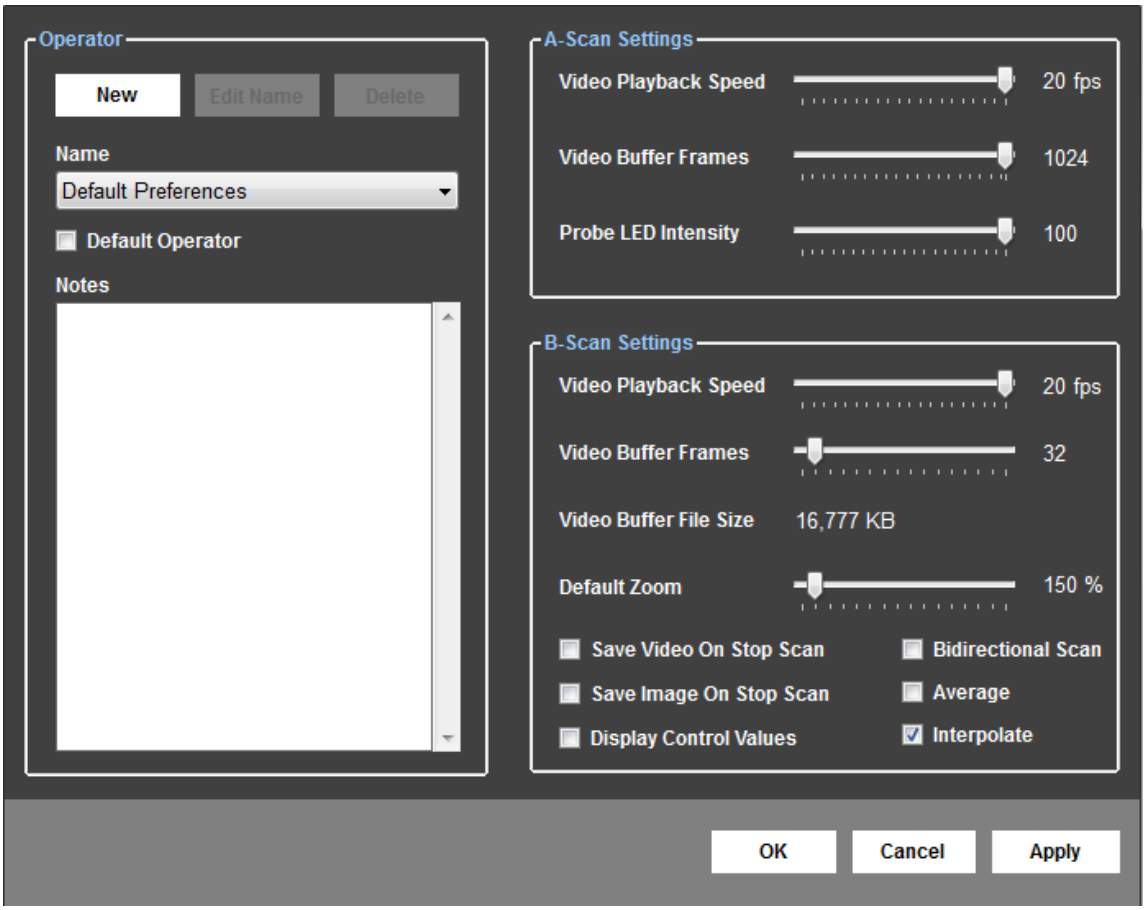
The **Username** textbox displays the username that the Scanmate application uses to connect to the database. To change the Username for the DGH Scanmate application, select the “Change Configuration” button and follow the prompts. For more information on configuration of the software, refer to the Scanmate Installation Guide.

The **Password** textbox displays the password that the Scanmate application uses to connect to the database. To change the Password for the DGH Scanmate application, select the “Change Configuration” button and follow the prompts. For more information on configuration of the software, refer to the Scanmate Installation Guide.

The **Hint** textbox allows the user to enter a hint for the password. If a user is logging in manually, clicking the “Show Hint” button at log-in will display the hint text. To change the Hint that the DGH Scanmate application displays, select the “Change Configuration” button and follow the prompts. For more information on configuration of the software, refer to the Scanmate Installation Guide.

12.2 Operator Preferences

The "Operator Preferences" window provides controls to identify Operators and configure their preferences. The Operator Preferences window can be accessed by selecting **Preferences → Operator** from the Menu Bar.

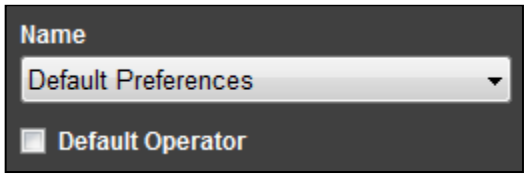


Note: Refer to the DGH 6000 Scanmate-A or the Scanmate Flex User Guide for instructions on configuring A-Scan related Operator Preferences.

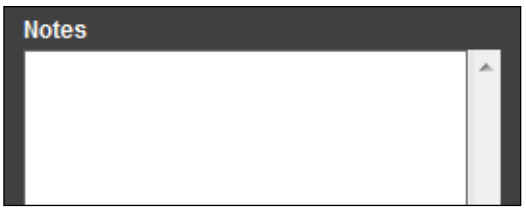
The **New** button allows the user to create new operators and assign preferences to the newly created operator.

The **Edit Name** button allows the user to make changes to an existing operator's preferences. To change an operator's preferences, click the "Edit" button while the desired operator's name is selected in the "Name" combo box. Changes to operator preferences are saved by clicking the "Apply" button, or can be discarded by clicking "Cancel". The "OK" button will save the current settings and close the "Operator Preferences" window.

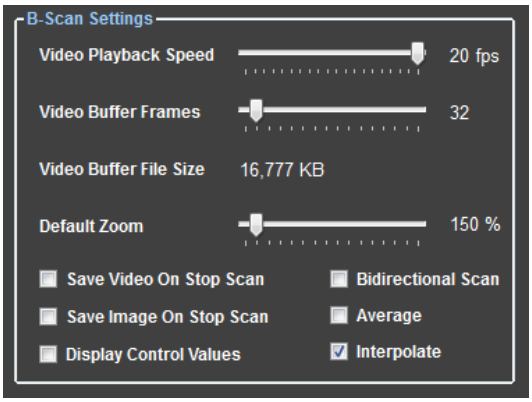
The **Delete** button will delete an operator from the system. When clicked, the user is prompted for confirmation prior to deleting the operator's preferences.



The **Name** combo box selects an existing operator from the database to view, edit, or delete their preferences. Selecting an operator's name will display that operator's preferences on the screen. The **Default Operator** checkbox selects which operator's preferences will be automatically loaded when the software is started.



The **Notes** textbox allows the user to associate notes to an operator's preferences.



The B-Scan **Video Playback Speed** slide bar adjusts the frames per second (fps) that the B-Scan video is played for the currently selected operator. The speed of video playback can be adjusted from 1 to 20 fps.

The B-Scan **Video Buffer Frames** slide bar adjusts the size of the buffer used when capturing B-Scan video. Moving the slide bar from left to right increases the number of frames stored in the buffer. Increasing the number of frames that can be stored in the buffer allows the user to determine the amount of video that is captured before it begins to overwrite itself. The video buffer can be configured to store from 16 to 256 frames.

The B-Scan **Default Zoom** slide bar adjusts the amount of magnification applied to the image or video when the zoom button is pressed.

When the **Save Video On Stop Scan** checkbox is selected, the B-Scan video will automatically be saved when the scan is stopped.

When the **Save Image On Stop Scan** checkbox is selected, the last B-Scan frame will automatically be saved when the scan is stopped.

The **Display Control Values** checkbox allows the user to select whether or not the Gain, Intensity and Contrast control values are displayed in the B-Scan image window.

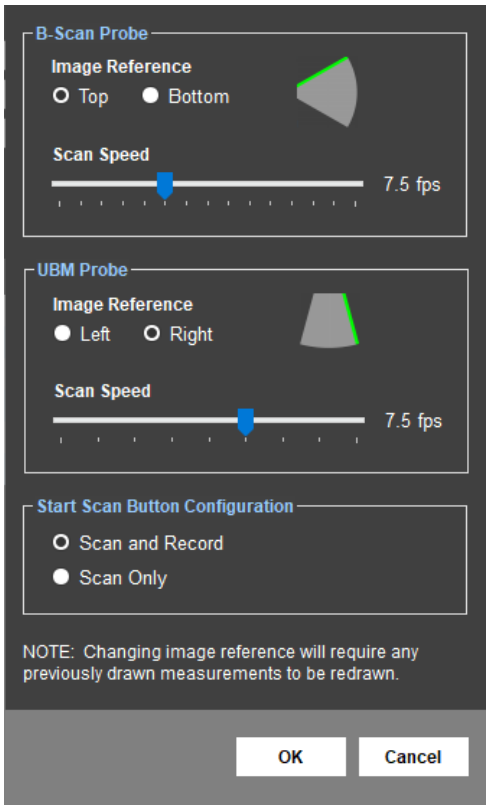
When the **Bidirectional Scan** checkbox is selected, the B-Scan probe will acquire image information in both sweep directions.

The **Average** preference turns on the frame-to-frame B-Scan averaging algorithm. For slower processors, averaging can be turned off to improve display performance at the expense of image quality.

The **Interpolate** preference enables or disables the linear interpolation algorithm. For slower processors, interpolation can be turned off to improve display performance at the expense of image quality.

12.3 B-Scan Page Preferences

The B-Scan Page Preferences allow the user to adjust image reference, scan speed and scan/record settings.



The green line of the **Image Reference** setting indicates the side of the image/video that will correspond to the top position on the probe.

Note: Changing the image reference setting will change the orientation of the images stored in the database. If this reference is changed after images have been acquired, any measurements overlaying the image will need to be redrawn.

The **Scan Speed** setting determines the number of frames that are acquired per second during a scan.

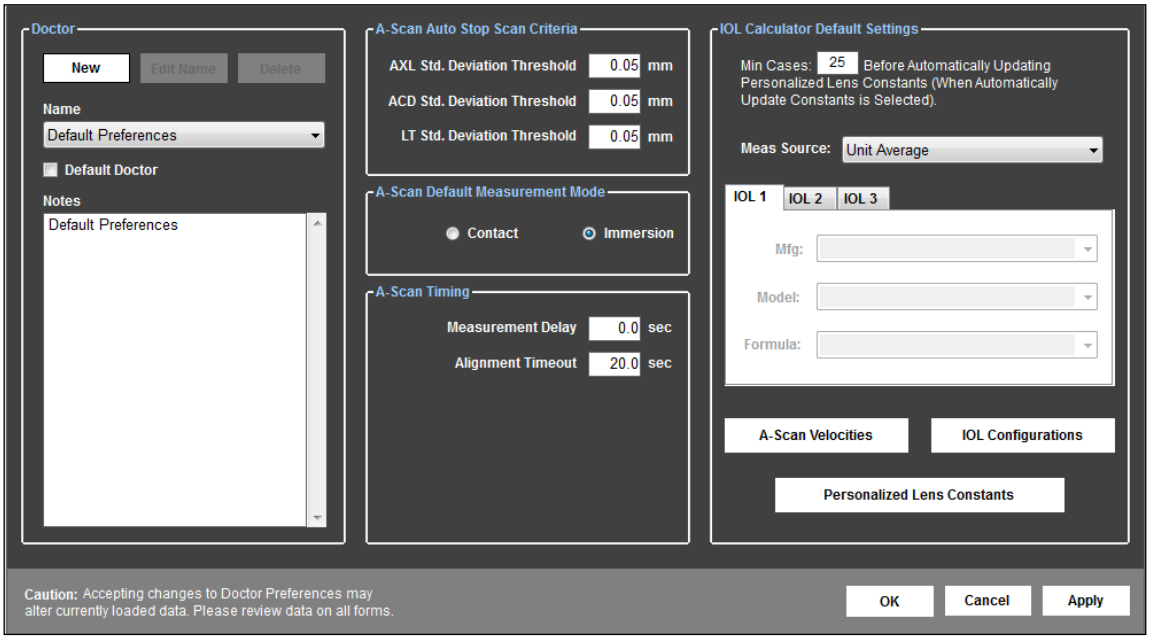
The Start Scan Button Configuration setting determines how the **Scan** and **Record** buttons on the B-Scan page can be configured to operate together or independently.

Scan and Record: When the **Start Scan** button is clicked to start a scan, the software will automatically record video. Recording will stop when the scan is stopped.

Scan Only: When the **Start Scan** button is clicked, the scan will start; however, video will not be recorded until the **Record** button is clicked. Recording can be toggled on/off as needed during a scan.

12.4 Doctor Preferences

The "Doctor Preferences" window provides controls for the user to identify Doctors and configure their preferences. Doctor Preferences define the default protocol for performing A-Scans and IOL Calculations. The Doctor Preferences window can be accessed by selecting **Preferences → Doctor** from the Menu Bar.



Note: Refer to the DGH 6000 Scanmate-A or the Scanmate Flex User Guide for instructions on configuring A-Scan related Doctor Preferences.

The **New** button allows the user to create new doctor profiles and assign preferences to the newly created doctor.

The **Edit Name** button allows the user to make changes to an existing doctor's preferences. The user can change a doctor's preferences by clicking this button while the desired doctor's name is selected in the "Name" combo box.

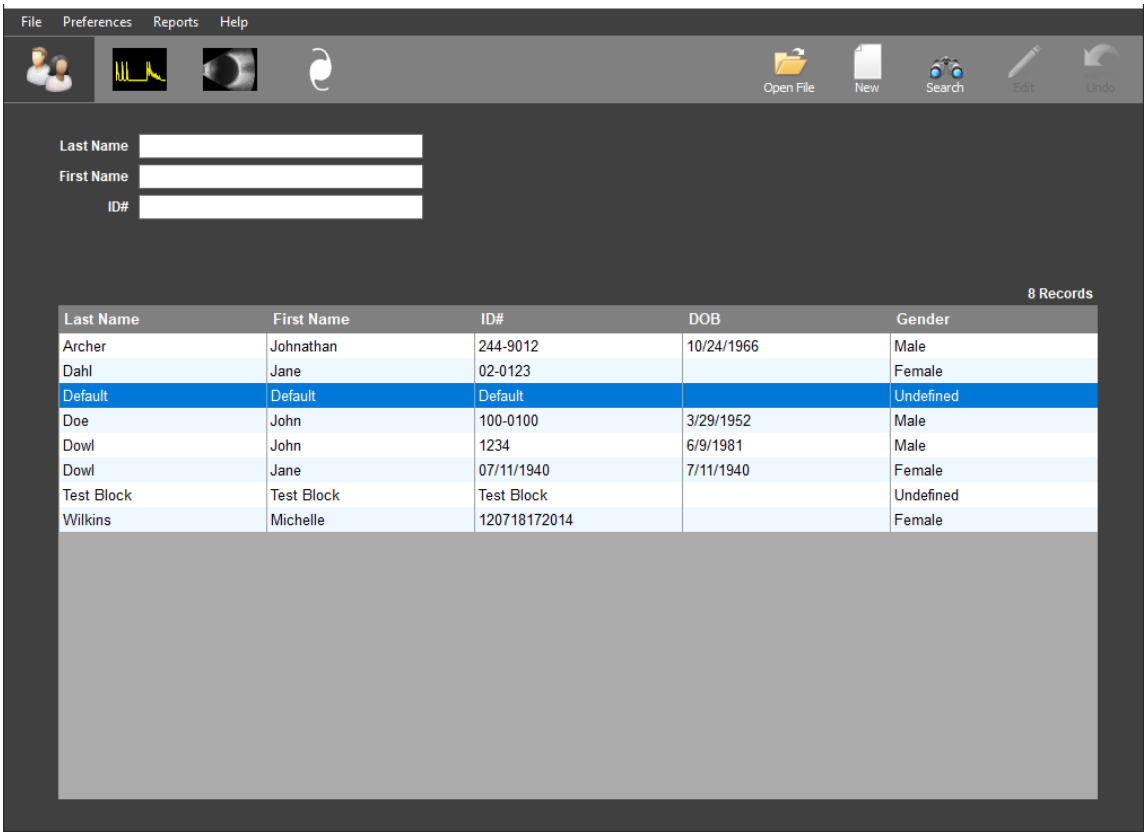
The **Delete** button deletes a doctor from the system. When clicked, the user is prompted for confirmation prior to deleting the doctor's preferences. Once deleted, the doctor will still exist in the database, but will be marked as inactive.

The **Name** combo box selects an existing doctor from the database to view, edit, or delete their preferences. The **Default Doctor** checkbox selects which doctor will be automatically placed on the Patient Data and IOL Calculator Screens. If only one doctor exists, that doctor is automatically set as the default doctor.

The **Notes** text box is provided to allow the user to associate notes to a doctor's preferences.

13 The Patient Data Screen

Upon startup, the Scanmate application will automatically open to the Patient Data Screen in Search Mode. The Patient Data Screen allows the user to Search, Create, Review and Edit patient records.



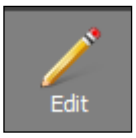
13.1 Patient Data Screen Controls

The Patient Data Screen operates in three distinct modes of operation: “Search and View”, “Edit / Save Data”, and “New Patient.” The action buttons on the top right-hand side of the screen change availability depending on the current mode of the Patient Data screen. The patient data screen buttons include:

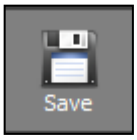
- Open File
- New
- Search
- Edit / Save
- Undo

The **New** button is used to enter new patients in the DGH-Scanmate database. When clicked, the “Last Name”, “First Name”, and “ID#” combo boxes change to plain text boxes and allow the user to enter a new patient.

The **Search** button is used to search for patients in the DGH-Scanmate database. When selected, the “Patient Info” controls are closed for editing and all combo boxes become auto-suggest fields.

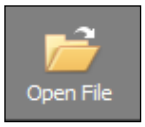


The **Edit** button is used to edit patient records in the DGH-Scanmate database. When selected, the “Patient Info” and “Pre-Operative” controls become enabled for editing. The Pre-Operative and Post-Operative data is only needed for performing IOL power calculations.



The **Save** button saves New or Modified patient records to the DGH-Scanmate database.

The **Undo** button allows the user to undo the last changes that were made to the Patient’s Record. All fields will revert to the most recent saved state.



The **Open File** button allows the user to open a window to review all records associated with the selected patient.

13.2 Entering a New Patient

Select the "New” button and enter the following required fields:

- Last Name
- First Name
- ID Number

The ID Number must be unique for each patient. The Scanmate Software will prevent a new patient from being saved to the database if a patient with the same ID Number already exists. A default unique ID number is created based on the date and time the new patient is entered; this can be replaced with any other numbering system desired. The Patient’s Last Name, First Name and ID Number are required fields and must be entered before the record can be saved.

The following optional fields can also be entered at this time:

- Patient Date of Birth
- Patient Gender
- Doctor
- Comments

- K1 and K2 (K1 and K2 values for OS and OD may be entered from the IOL Calculator Screen and are only needed for IOL Calculations)
- Desired Refraction (Desired Refraction for OS and OD may be entered from the IOL Calculator Screen and are only needed for IOL Calculations)

Select the **Save** button once all of the desired fields have been entered.

13.3 Searching for a Patient

Select the **Search** button to search for a patient record that has been saved in the database. Patients can be searched for by Last Name, First Name, or by ID Number.

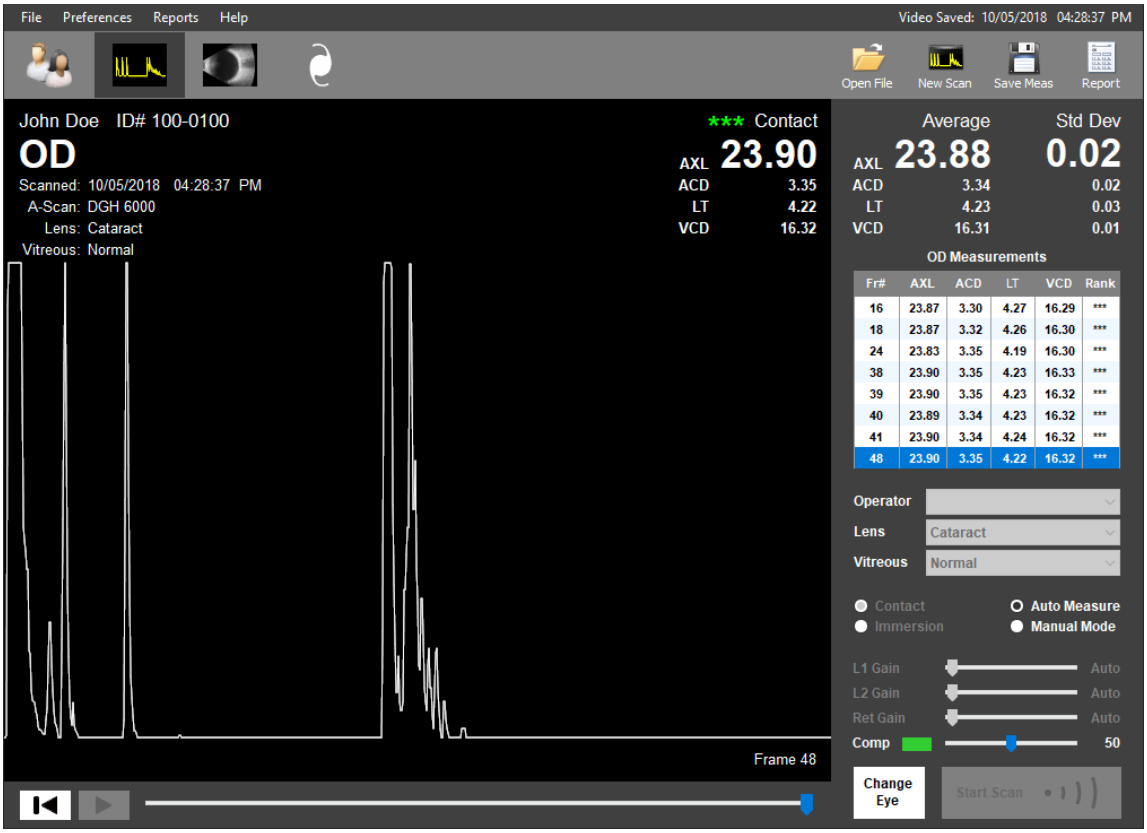
To search by Last Name, First Name or ID Number, begin typing in the field you wish to search. The software will automatically update the patient table to show all the results that match what has been typed. The desired patient can then be selected from this patient list.

13.4 Editing a Patient Record

Select the desired patient record to be edited following the steps described in Section 13.3. Once the patient record has been loaded, select the **Edit** button. All of the editable fields will change from read-only fields to white, editable text boxes. Once the desired changes have been made, select the **Save** button to save the changed record.

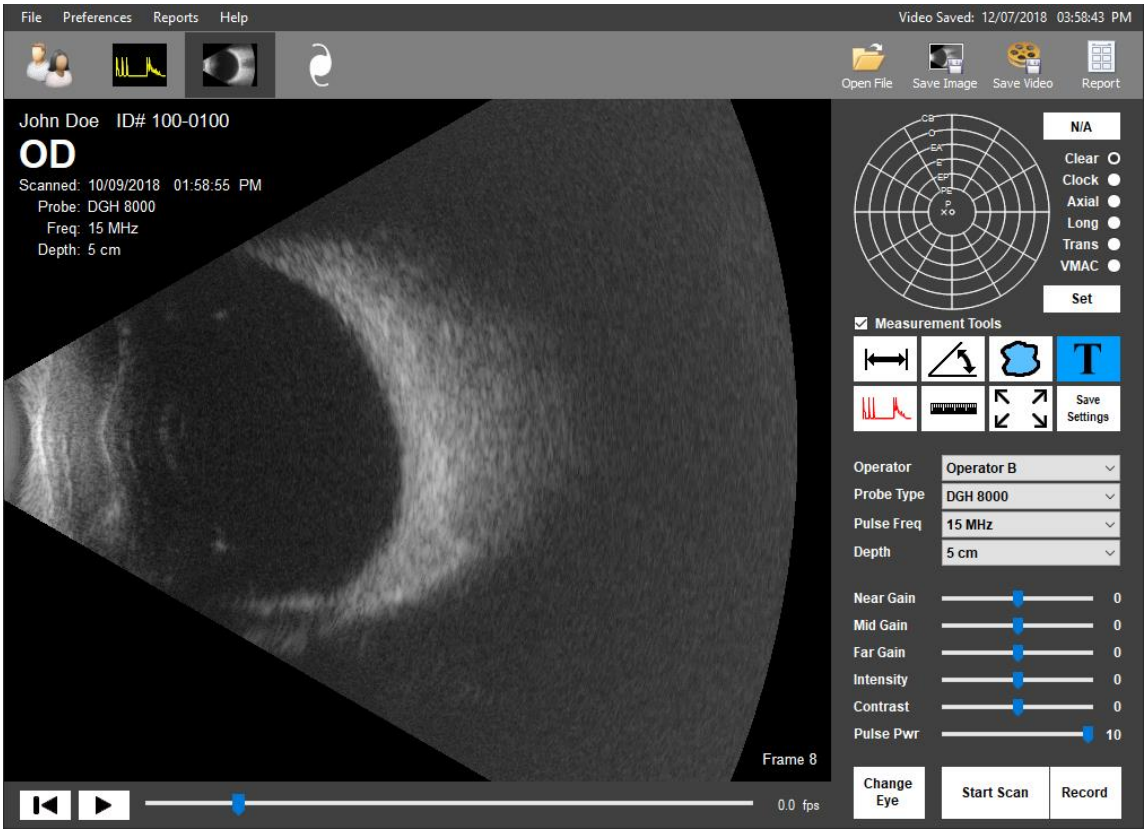
14 The A-Scan Screen

The A-Scan Screen allows the user to perform and review A-Scan Measurements for the currently selected patient. Refer to the DGH 6000 Scanmate-A or the Scanmate Flex User Guide for instructions on using the A-Scan features of this program.



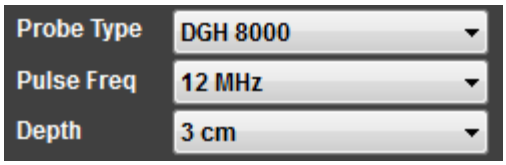
15 The B-Scan Screen

The B-Scan Screen allows the user to perform and review B-Scan exams for the currently selected patient. Refer to Section 13 for details on how to load or create patient records.



The default settings for this page are dependent on the currently selected Operator. The default settings can be changed by selecting **Preferences → Operator**.

15.1 Selecting the Probe



Select the desired probe from the list of available probes in the **Probe Type** combo box. The available **Pulse Frequencies** will be displayed for the selected probe. The **Depth** selection adjusts the depth of the displayed B-Scan image.

Note: Pulse Frequency is the rate that the probe is electronically pulsed. It is not the resonant frequency of the transducer crystal.

15.2 Adjusting Pulse Power

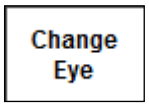
The **Pulse Pwr** slider adjusts the amount of energy used to pulse the transducer element in the probe. Adjusting the pulse power allows the user to distinguish between tissues with different acoustic densities. Exams are typically performed at the highest Pulse Power unless the image is saturated and better definition between tissue structures is desired.

15.3 Selecting the Operator

The name of the Operator performing the measurement can be selected using the Operator dropdown box at right. If the operator is not listed in the drop-down box, add the new operator by selecting **Preferences → Operator** and clicking the **New** button.

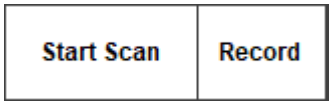
15.4 Selecting OD or OS

The eye currently being examined (OD or OS) can be selected by pressing the **Change Eye** button. The currently selected eye is shown in the top left-hand corner of the B-Scan display.



15.5 Scanning and Recording

IF the software is configured as Scan and Record (**Preferences > B-Scan Page**), the software will begin recording as soon as the scan is started.



IF the software is configured as Scan Only (**Preferences > B-Scan Page**), the software will begin scanning but will not start or stop recording until prompted.

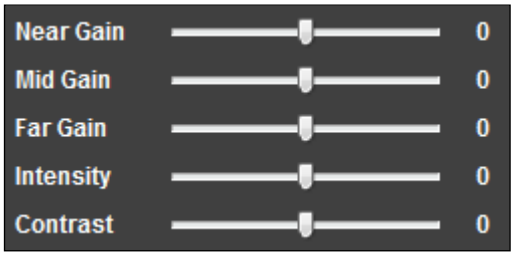
To Start scanning†:
- Click the **Start Scan** button; or
- Press the **Blue Button** (on probe); or,
- Press the **Space Bar** (keyboard); or
- Press the **Foot Pedal** (Single Pedal accessory); or
- Press the **Left Foot Pedal** (Double Pedal accessory).

To Start / Stop recording:
- Click the **Record** button; or
- Press the **Enter Key** (keyboard); or
- Press the **Right Foot Pedal** (Double Pedal accessory)

To Stop scanning†:
- Click the **Stop Scan** button; or
- Press the **Blue Button** (on probe); or,
- Press the **Space Bar** (keyboard); or
- Press the **Foot Pedal** (Single Pedal accessory); or
- Press the **Left Foot Pedal** (Double Pedal accessory).

15.6 Adjusting Image Controls

The three **Gain Controls** allow you to adjust the near, middle or far field gain of the displayed image. These sliders control gain in the imaging software, not the probe itself.

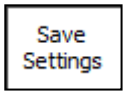


Intensity Control adjusts the overall intensity, or brightness, of the image.

Contrast Control adjusts the overall contrast of the image. Adjust this control to increase or decrease the amount of contrast between light and dark areas of the image

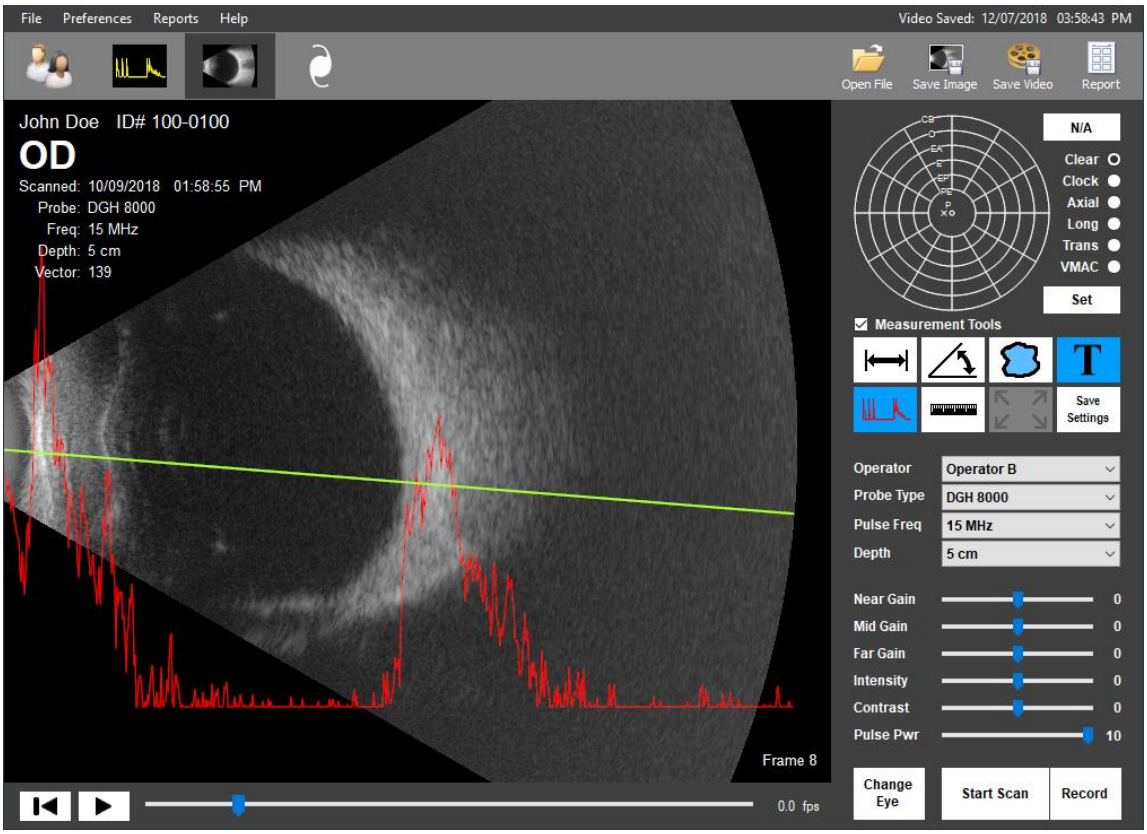
15.7 Saving Operator Settings

The current image control settings (Gain, Intensity, Contrast) can be saved to the active operator by selecting the **Save Settings** button. Whenever the operator is selected, the image controls will default to the saved settings.



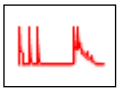
15.8 Video Controls

Use the video controls to review the scan. When paused, use the slider bar to sweep through the video manually, or use the keyboard arrow keys to move frame by frame.



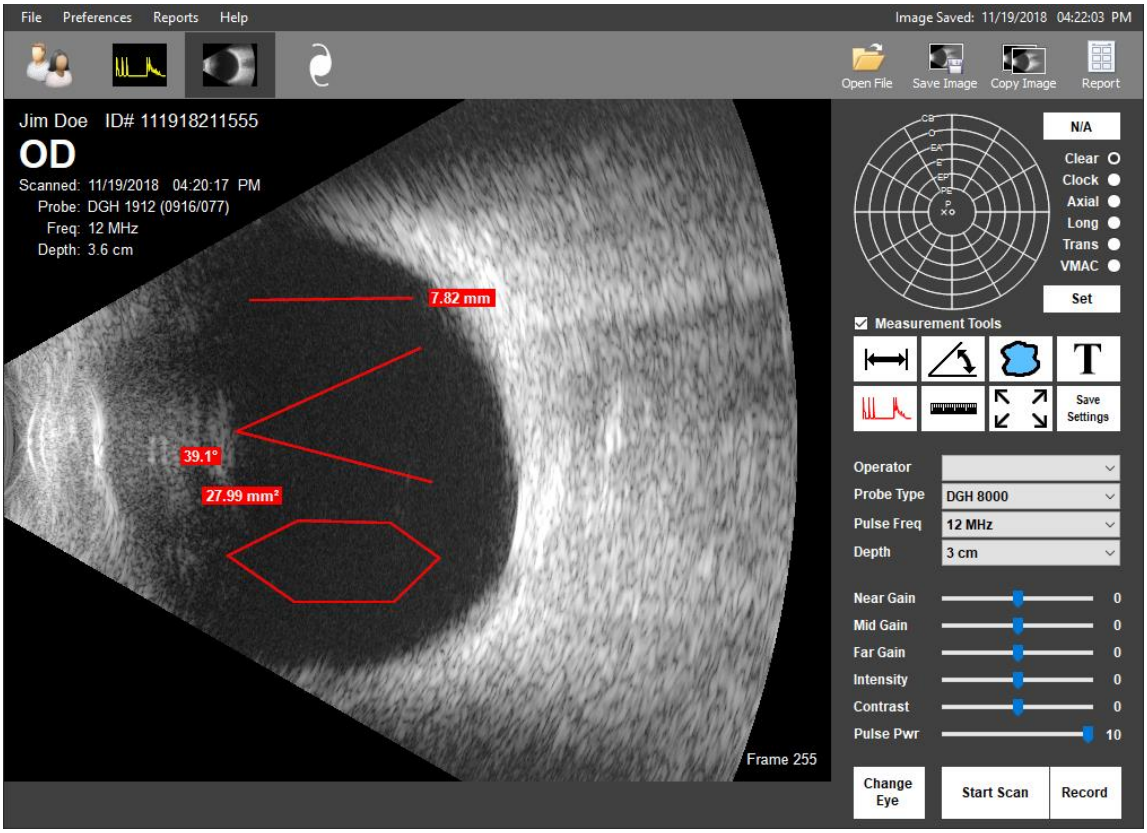
15.9 Diagnostic A-Mode

Select the **A-Mode** button to enable the diagnostic A-Scan overlay. Enabling the A-Scan Overlay will superimpose an A-Scan waveform over the B-Scan image or video. Use a left-click to place the vector in the desired position.



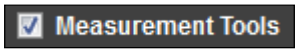
15.10 Adding Exam Comments

Select the **Comments** button to enter comments. The comments box can be dragged to any location on the image.



15.11 Measurement Tools

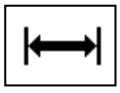
Mark the **Measurement Tools** check box to enable the use of the Caliper Tool, Angle Tool and Area Tool.



Note: Measurement notations made with the Caliper Tool, Angle Tool and Area Tool are only saved on still image records, not on videos.

15.12 Caliper Tool

Select the **Caliper Tool** button to take distance measurements. Left-click hold and drag the mouse across the image. Additional measurement can be added by clicking the button again and dragging additional caliper lines. This can also be performed using touch controls.

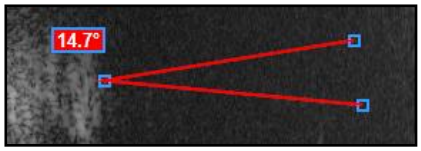


The caliper measurement values are displayed near the caliper line. Caliper lines can be adjusted and moved by left-clicking the line and dragging the control nodes to the desired position.

Caliper 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.

15.13 Angle Tool

Select the **Angle Tool** button to take angle measurements. Left-click hold and drag the mouse across the image to produce the first side of the angle, then left-click hold and drag again to produce the second side. This can also be performed using touch controls.

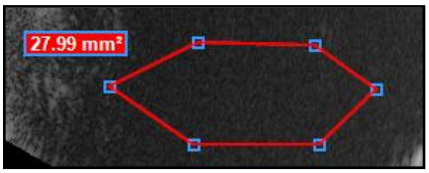


Angle measurements can be adjusted and moved by left-clicking the line and dragging the control nodes to the desired position.

Angle 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.

15.14 Area Tool

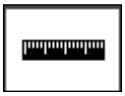
Select the **Area Tool** button to take area measurements. Left-click hold and drag the mouse across the image to produce the first side of the desired area, then repeat left-click hold and drag to produce additional sides of the desired area. This can also be performed using touch controls.



Once the area is encompassed, a measurement will be displayed showing the measurement in mm^2. Area measurements can be adjusted and moved by left-clicking the line and dragging the control nodes to the desired position.

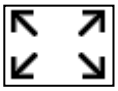
Area notations can be removed by right-clicking on the lines and selecting “Delete” from the menu displayed or by left-clicking on the line to select it and pressing the “Delete” keyboard key.

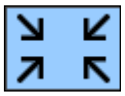
15.15 Ruler Overlay



A ruler overlay will be displayed when the **Ruler** button is clicked. The ruler overlay can also be controlled via voice commands. Refer to Section 15.25 for more information regarding voice commands.

15.16 Zoom

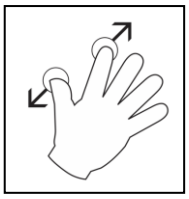




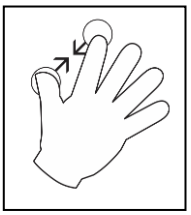
Double left-click on the image, or select the **Zoom** button to magnify the image. Additional double left-clicks on the image will continue magnification. The amount of zoom is displayed in the bottom left corner of the display. Left-click the **Normal Zoom** button to return the image to normal resolution. Zoom can also be controlled via voice commands. Refer to Section 15.25 for more information.

If the PC running the Scanmate application has a touch-capable display, zooming may be performed using "pinch zoom" touch controls.

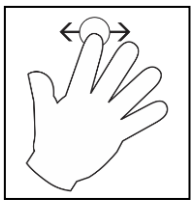
To zoom in, place two fingers on the B-scan image being displayed and move them apart.



To zoom out, place two fingers on the B-scan image being displayed and move them together.

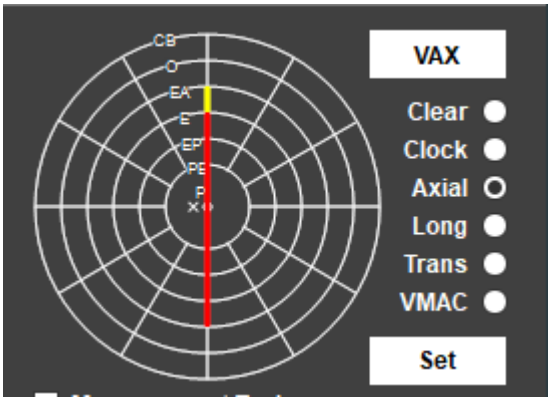


To pan a zoomed image, place one finger on the B-scan image being displayed and move it in the desired pan direction.



15.17 Selecting Probe Orientation

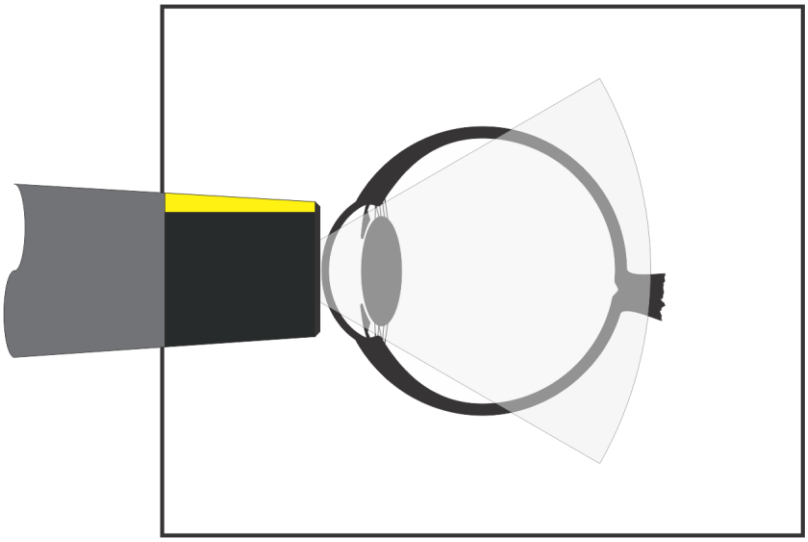
The position map allows the user to easily record the probe orientation of standardized probe positions or general clock positions. Notations are saved with the B-Scan image or video.



CB	Cilary Body
O	Ora
EA	Equator Anterior
E	Equator
EP	Equator Posterior
PE	Posterior to the Equator
P	Posterior Pole
o	Optic Nerve
x	Macula

The images produced by the DGH 8000 represent a 60 degree cross-sectional slice of the globe and orbit. The position map indicates the area of the eye being imaged, not the position of the probe. The marker on the black membrane covering the tip of the probe (as well as the blue start / stop button) corresponds to the top of the displayed image. By convention, the marker is generally aimed either superiorly or nasally.

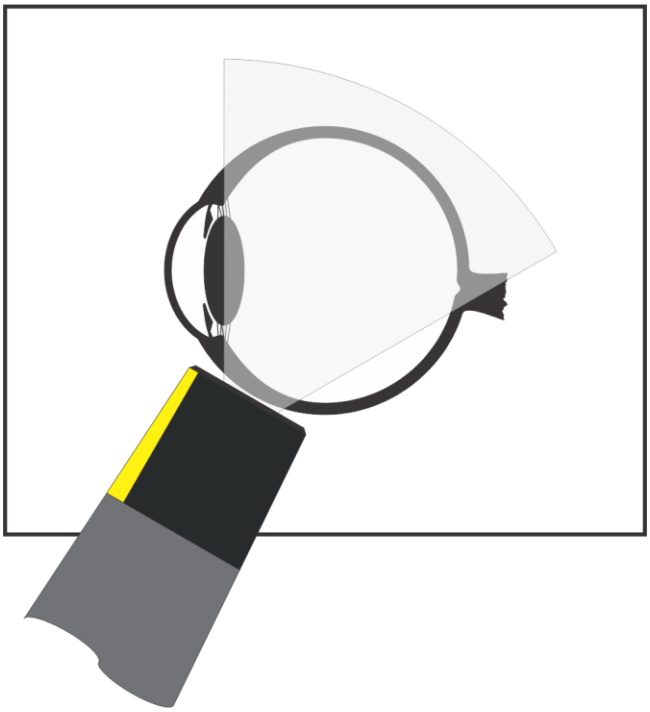
Axial Probe Positions – An axial scan provides an image of the posterior globe, with the optic nerve centered on the right side of the image. The probe is positioned so that it is centered on the cornea while the patient is looking forward. When properly aligned, the optic nerve will be centered on the right side of the image.



Example of 12:00 AX (VAX) Scan

Use the selection tool to indicate the meridian being scanned, where the yellow marker matches the orientation of the marker on the tip of the probe. Once the desired position has been selected, use the "Set" button to save the orientation to the current B-Scan Image or Video.

Longitudinal Probe Positions – Longitudinal scans provide a radial image from the posterior pole to the anterior periphery. The probe is positioned on the sclera, perpendicular to the limbus, while the patient is looking toward the area of the eye being examined. The probe marker is pointed towards the limbus, causing the optic nerve to be towards the bottom of the image.

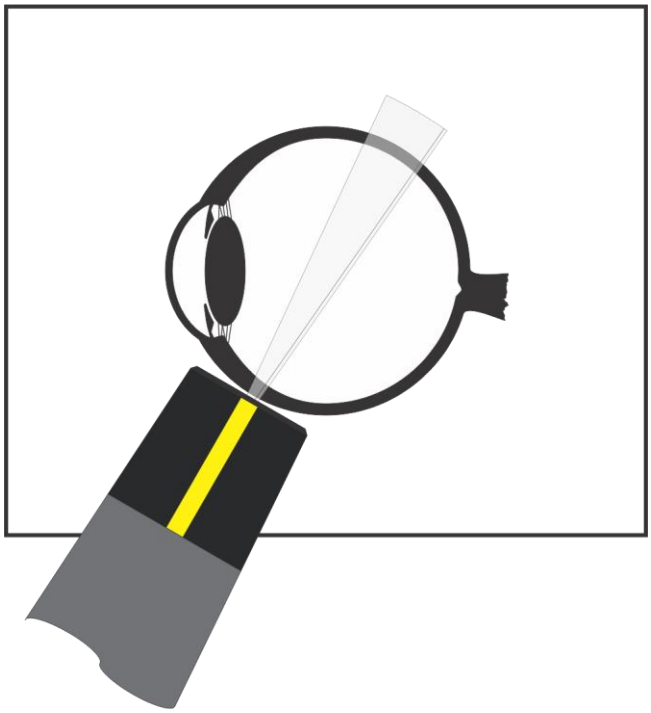


Example of 12:00 L Scan

For a 12:00 Longitudinal scan, the marker on the tip of the probe is pointed toward the area being examined at 12:00. The probe is positioned at 6:00, which is opposite of the area being examined.

Use the selection tool to indicate the meridian being scanned. Once the desired position has been selected, use the “Set” button to save the orientation to the current B-Scan Image or Video.

Transverse Probe Positions – Transverse scans provide a lateral image of the globe that traverses several clock hours. The position of the transverse scan is indicated by the center of the clock hours in the scan as well as the portion of the globe being examined (P for Posterior Pole, E for Equator, EA for Anterior to the Equator, etc.).



Example of 12:00 EP Scan

The probe is positioned on the sclera, parallel to the limbus, while the patient is looking toward the area of the eye being examined. The probe marker is held parallel to the limbus and pointed superiorly during vertical and oblique scans. For horizontal scans (6:00 and 12:00 positions), the marker is pointed nasally to keep it parallel to the limbus.

For a 12:00 EP scan, the probe is positioned at 6:00 with the marker parallel to the limbus and pointed nasally. The probe is pointed toward the Equator Posterior at 12:00.

Use the selection tool to indicate the area of the globe being scanned. Once the desired position has been selected, use the “Set” button to save the orientation to the current B-Scan Image or Video.

Macula Scans

HMAC – A horizontal macula scan (HMAC) is a horizontal axial scan where the probe has been aligned so that it is pointed directly at the macula. The marker on the tip of the probe should be pointed nasally (3:00 OD or 9:00 OS). The optic nerve shadow will be shifted towards the top of the display.

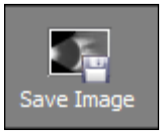
VMAC – A vertical macula scan (VMAC) is a vertical axial scan where the probe has been aligned so that it is pointed directly at the macula. The marker on the tip of the probe should be pointed in the superior (12:00) position.

LMAC – A longitudinal macula scan (LMAC) is a longitudinal scan through the macula where the marker on the tip of the probe is pointed temporally (3:00 OS or 9:00 OD).

TMAC – A transverse macula scan (TMAC) is a vertical transverse scan where the probe has been aligned so that it is pointed temporally (3:00 OS or 9:00 OD), directly at the macula.

15.18 Saving B-Scan Images

B-Scan Images can be saved by selecting the **Save Image** Button on the upper right-hand corner of the B-Scan Screen. This will also save all changes that have been made to the Patient Data since the last save.



Alternatively, the currently loaded image can be saved using the toolbar at the top of the screen by selecting **File → Save → B-Scan Image**.

An image loaded from the database can be duplicated by clicking the **Copy Image** button.

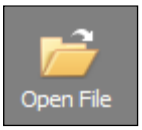
15.19 Saving B-Scan Videos

B-Scan Videos can be saved by selecting the **Save Video** Button on the upper right-hand corner of the B-Scan Screen. This will also save all changes that have been made to the Patient Data since the last save.

Alternatively, the currently loaded video can be saved using the toolbar at the top of the screen by selecting **File → Save → B-Scan Video**.

15.20 Reviewing B-Scan Exams

Saved B-scan files can be opened by clicking the **Open File** button. This will open a window that shows all saved images and videos for the current patient.



Double-clicking any image or video will open the file in the scan view window.

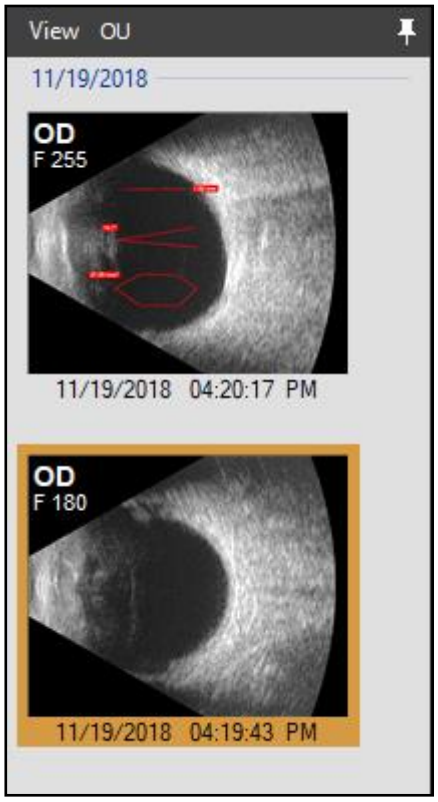
The **Push Pin** allows the user to pin the scan view window to the left-hand side of the Scanmate application window so that both windows can be moved together. Alternatively, the windows can be unpinned, so that they can be moved independently.

The window can be configured to show saved records for both eyes **(OU)** or to only show records for the right **(OD)** or left **(OS)** eye.

Records can be deleted by Right-clicking and selecting **Delete** from the context menu.

The **Aspect Ratio** of the window (vertical vs. horizontal) can easily be changed.

The presence of an orange highlight means the video/image is currently being displayed.



15.21 Saving B-Scan Images as Jpegs

It is possible to convert saved B-Scan Files to .jpg images so that they can be shared with EMR systems or practitioners that do not have the Scanmate Software. To do this, select the **Open File** button on the B-Scan screen and drag the image thumbnail(s) to the desired location.

Note: Jpeg files cannot be imported back into the Scanmate program. See Section 19 and 19.1 for other import / export options.

15.22 Saving B-Scan Videos as AVI Files

The Scanmate software can convert saved B-Scan videos to AVI files so that they can be used outside of the Scanmate program.

To create an AVI file, first load a B-Scan video from the Scanmate database and select **File → Export → B-Scan Video (AVI).**

Note: AVI files cannot be imported back into the Scanmate program. See Section 19 and 19.1 for other import / export options.

15.23 Creating Reports

Click the **Report** button to quickly create a B-scan report. The report will include the patient information, doctor, operator, and date. A window with all the saved images and videos for the current patient will open. Use the checkboxes in the bottom right corner of each image to include them in the report. The selected images will be shown inserted in a report preview window. Clicking the **Add Comments** button in the report preview will open a comment box for text entry. Reports can be sent to a printer, saved in the database, or saved as PDF files. For more information on creating reports, see Section 17 "Creating Reports".

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 Section 17.4 for more information.

15.24 Performing a B-Scan Exam

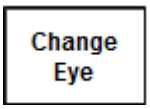
The ultrasound probe must be cleaned and disinfected before each biometry procedure. (See Section 21 for Cleaning and Disinfection Instructions.)

Note: † Indicates a command that may be executed through B-Scan voice controls. Refer to Section 15.25 for more information.

1. Launch the Scanmate Software Application as described in Section 11.

2. Create a new patient or select an existing patient on the **Patient Data Screen**.

3. Select the B-Scan Screen tab. If necessary, click the **Change Eye†** button to change the eye being measured (OD or OS).



4. Select the desired probe, frequency and depth from the drop-down box.

5. 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.)

6. Seat or recline the patient in a comfortable position. Use a firm, comfortable head rest to prevent unwanted head movement. Position the DGH Scanmate display so that it is easily visible during the examination.

7. If desired, use the Position Map to indicate the area of the eye being examined.

8. To Start scanning†:

   - Click the **Start Scan** button; or
   - Press the **Blue Button** (probe); or,
   - Press the **Space Bar** (keyboard); or
   - Press the **Foot Pedal** (Single Pedal accessory); or
   - Press the **Left Foot Pedal** (Double Pedal accessory).

9. IF the software is configured as Scan and Record (**Preferences → B-Scan Page**), the software will begin recording as soon as the scan is started.

   IF the software is configured as Scan Only (**Preferences → B-Scan Page**), the software will begin scanning but will not start or stop recording until prompted.

   To Start / Stop recording:
   - Click the **Record** button; or
   - Press the **Enter Key** (keyboard); or
   - Press the **Right Foot Pedal** (Double Pedal accessory)

10. 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, an acoustic coupling gel (such as GenTeal) should be used.

11. Once the desired image has been obtained, to Stop scanning†:

    - Click the **Stop Scan** button; or
    - Press the **Blue Button** (probe); or,
    - Press the **Space Bar** (keyboard); or
    - Press the **Foot Pedal** (Single Pedal accessory); or
    - Press the **Left Foot Pedal** (Double Pedal accessory).

12. The image frames captured during the exam can be reviewed on the display by pressing the → or ← cursor keys. The video playback controls can also be used to play back the video of the exam. Alternatively, the slider below the B-Scan display can be used to move through the video frame by frame.

13. Use the Gain, Intensity, Contrast and Zoom controls to enhance the quality of the image. If desired, annotate the exam with comments or use the A-Mode, Area, Angle and Caliper Tools.

14. To save images†, click the **Save Image** button (upper right-hand corner) or select **File → Save → B-Scan Image**.

    To save videos†, click the Save Video button (upper right-hand corner) or select **File → Save → B-Scan Video**.

N**ote**: If the software is configured so that the **Enter** key initiates voice commands, an image will not be saved when the **Enter** key is pressed.

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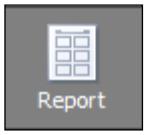
15. Repeat the steps above until all the desired regions of the eye have been examined.

16. When the exam is complete, reports may be created by selecting the **Report** button.



15.25 Voice Controls

Some controls can be operated via verbal commands from the user. 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. The following verbal commands are recognized by the Scanmate software while performing a B-Scan.

User Verbal Commands	**Software Audible Response**	**Software 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 will start.
"Stop Scan" *	Verbal: "Scan Stopped"	The B-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 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.

16 The IOL Calculator Screen

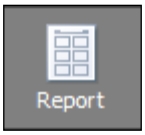
The IOL Calculator Screen allows the user to perform and review intraocular lens power calculations for the currently selected patient. Refer to the DGH 6000 Scanmate-A or the Scanmate Flex User Guide for instructions on using the IOL Calculator.

17 Creating Reports

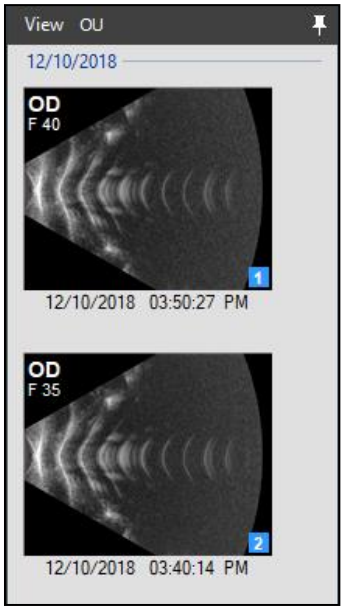
Reports can be created for viewing from the Menu Bar. The DGH Scanmate software can produce IOL Calculator Reports, A-Scan Short Reports, A-Scan Custom Reports and B-Scan Reports. Reports can be printed out, saved as PDF files and added to the patient record database. All reports are created with a header that includes the Patient's Name, ID Number, Doctor and Operator. The revision number of the DGH Scanmate software used to generate the report is located in the footer of the report.

17.1 B-Scan Report

Click the **Report** button on the B-Scan Screen to quickly create a B-scan report. A window with all the saved images and videos for the current patient will open.



Mark the checkboxes in the bottom right corner of each image to have them included in the report. Images are inserted into the report in the order they are selected.

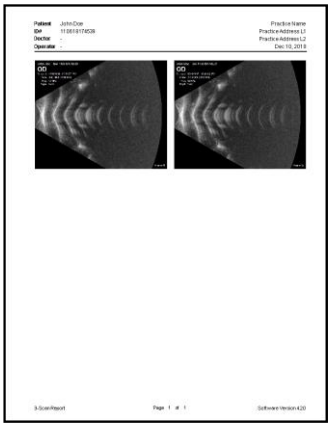


The selected images will be shown inserted in a report preview window.

Clicking the **Add Comments** button in the report preview will open a comment box for text entry.

Select the desired number of images per page using the **Image/Page Radio Buttons.**

The colors of the images can be inverted by selecting the **Invert Colors** checkbox. This helps conserve ink / toner when printing images.

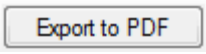


17.2 Using Reports

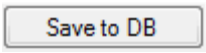
All types of reports can be printed, browsed, and saved in the same ways.

Clicking the small printer icon in the top left corner will send the report to the printer.

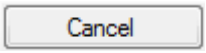
The arrows and magnifier icon–next to the printer icon will navigate through the report.



The **Export to PDF** button will save the report as a PDF to the Default Data Directory specified in System Preferences. A browser window will open to allow the user to select the save location and name of the PDF created. PDFs can also be exported as explained in Section 17.4



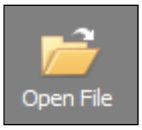
The **Save to DB** button will add the report to the DGH-Scanmate database. Once saved, the report can be retrieved by searching the patient's name or ID number.



Clicking **Cancel** will exit the report and return to the Scanmate application.

17.3 Opening Reports

To view a previously saved report, select the patient through the Patient Data screen search. Using the Menu Bar, go to **File → Open** or click the **Open File** button.



This will open a window that shows all saved images, videos and reports for the current patient. Each report is automatically given a unique name consisting of the type of report, the date it was created, and the time it was created.

17.4 Exporting B-Scan PDF Reports

It is possible to convert B-Scan reports saved in the Scanmate database to PDF files so that they can be shared with EMR systems or practitioners that do not have the Scanmate Software. To do this go to **File → Open** or click the **Open File** button.

This will open a window that shows all saved images, videos and reports for the current patient. Left-click and drag the report thumbnail(s) to the desired location. A PDF version of the report will be automatically generated.

18 Database Management

Patient data, scan images, measurements, video files, and reports created by the Scanmate application are saved in an DGH-Scanmate database. The database allows patient records to be shared, centralized, or accessed remotely, according to the needs of each biometry department. For example, several operators in a large practice could use several Scanmate Flex, DGH 6000 or DGH 8000 units simultaneously, but all patient records would be stored in a central database. Or, a doctor could perform scans in an examination room, then later access patient records from an office computer.

Refer to the Scanmate Installation Guide for information on backing-up and restoring, migrating, or deleting a database.

19 Importing and Exporting Data

B-Scan Image and Video files can be imported or exported from the DGH-Scanmate database to be consulted in other locations or by other practitioners.

If both locations have the Scanmate Software (v3.0.0 or later) installed, the best way to exchange B-Scan files is to use the .bscan file format. This format includes all the necessary information to completely identify the patient and to re-create the record in the database. It is also possible to export .jpg images or .avi movies to share with practitioners that do not have the Scanmate Software. See Section 15.21 and 15.22 for more details on exporting these file types.

To export a .bscan file, select **File → Export → B-Scan File.** The currently loaded B-Scan Image or Video will be saved to the selected location.

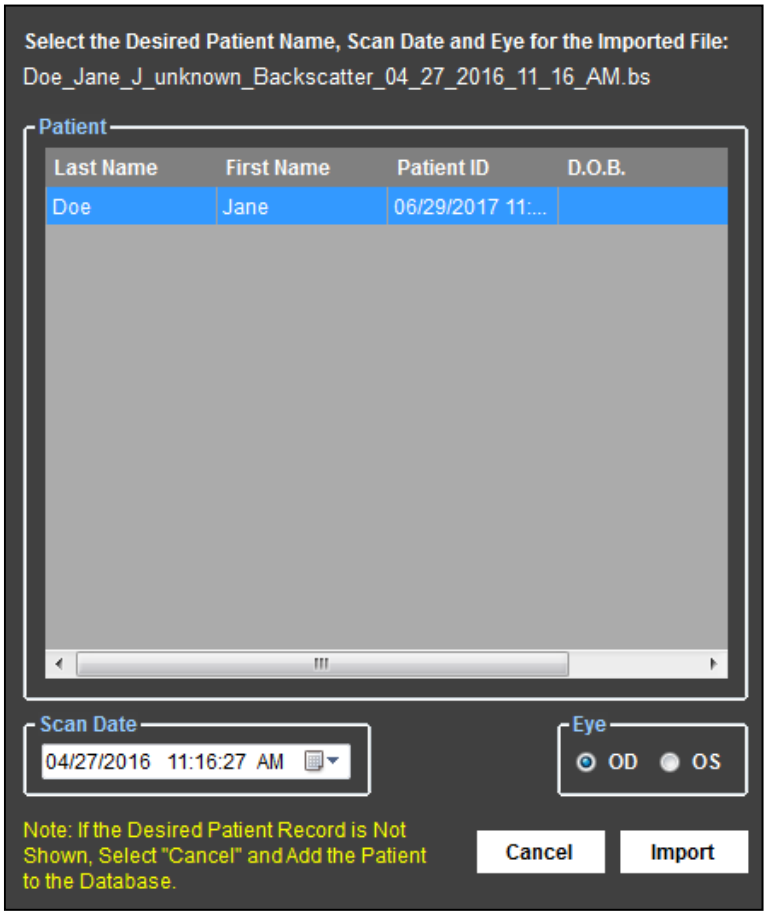
To export a B-Scan video as a .avi file (which can be opened on most PC media applications), select **File → Export → B-Scan Video (AVI).** The currently loaded B-Scan Video will be saved to the selected location.

To import a .bscan file, select **File → Import → B-Scan File**. A browser window will open to select a .bscan file to open. Once opened, the file will load the Patient Data and B-Scan information into the Scanmate program. The opened file can be saved in the database at this point.

19.1 Importing Legacy Files (.bs or .cini)

It is possible to import .bs and .cini files from prior versions of the Scanmate-B software. To import a .bs or .cini file, select **File → Import → B-Scan File**.

A browser window will open to select a .bs or .cini file to open. Because these files do not contain all the necessary information to be included in the DGH-Scanmate database, 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**.

Once opened, the file will load the Patient Data and B-Scan information into the Scanmate program. The opened file can be saved in the database at this point.

20 Electromagnetic Compatibility

Like other medical equipment, the DGH 8000 Scanmate-B requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the DGH 8000 must be installed and operated according to the EMC information provided in this manual.

The DGH 8000 has been designed and tested to comply with EN 60601-1-2 requirements for EMC with other devices.

CAUTION

Portable and mobile RF communications equipment may affect the normal function of the DGH 8000 Scanmate-B.

CAUTION

Do not use cables or accessories other than those provided with the DGH 8000 Scanmate-B, as they may result in increased electromagnetic emissions or decrease immunity to such emissions.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The DGH 8000 Probe is intended for use in the electromagnetic environment specified below. The customer or the user of the USB Ultrasound Probe should ensure that it is used in such an environment.

Emissions Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A Group 1 150 kHz to 30 MHz	Complies	The device uses RF energy for its internal function. Nearby electronic equipment may be affected.
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A Group 1 30 MHz to 1 GHz	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
Harmonics IEC/EN 61000-3-2:2006 /A2:2014	Class A Device	Complies Per Clause 5 of the Standard	
Flicker IEC/EN 61000-3-3:2013	Per Clause 5 of the Standard	Complies Per Clause 5 of the Standard	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The DGH 8000 Scanmate-B is intended for use in the electro-magnetic environment specified below. The customer or the user of the DGH 8000 should ensure that it is used in such an environment.

Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, armature 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 DGH 8000 is used exceeds the applicable RF compliance level, the DGH 8000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DGH 8000.

Test Type	Test In Accordance to	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge IEC/EN 61000-4-2	IEC/EN 60601-1-2: 2014 (4th Ed.)	±8 kV contact discharge ±2, 4, 8 &15kV air discharge	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated Immunity IEC/EN 61000-4-3	IEC/EN 60601-1-2: 2014 (4th Ed.)	80 MHz - 6 GHz 3 V/m & 10 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	Complies	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity field from RF wireless communications equipment IEC 61000-4-3	IEC/EN 60601-1-2: 2014 (4th Ed.)	See Section 6.17.3.1 Or Table 9 of standard	Complies	
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	IEC/EN 60601-1-2: 2014 (4th Ed.)	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	Complies	
Electrical Fast Transients (AC Power) IEC/EN 61000-4-4	IEC/EN 60601-1-2: 2014 (4th Ed.)	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz &100 kHz	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC/EN 61000-4-5	IEC/EN 60601-1-2: 2014 (4th Ed.)	±1 kV Line to Line ±2 kV Line to Ground	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic Immunity IEC/EN 61000-4-8	IEC/EN 60601-1-2: 2014 (4th Ed.)	30 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

21 Cleaning and Disinfection

WARNING

Users of the DGH 8000 Scanmate-B have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies established for the office, department or hospital as they apply to personnel and equipment.

WARNING

Always disconnect the DGH 8000 from the host computer before performing maintenance or cleaning.

Always follow the manufacturer's instructions when cleaning and disinfecting probes.

Do not use a surgeon's brush when cleaning probes. Even the use of soft brushes can damage the probe.

21.1 Probe Cleaning

1. Wear protective gloves when performing the cleaning process.
2. Disconnect the probe from the system.
3. Use a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any particulate matter or body fluids that remain on the probe or cable.
4. To remove remaining particulates, rinse with water up to the blue strain relief where the USB cable enters the probe. Do not immerse the strain relief or USB cable.
5. Wipe with a dry cloth; or wipe with a water-dampened cloth to remove soap residue, and then wipe with a dry cloth.

21.2 Probe Disinfection

The following disinfectants are recommended due to their biological effectiveness as well as their chemical compatibility with the DGH 8000 materials.

Solutions	Country	Type	Active ingredient	FDA 510(k)
Cidex®	USA	Liquid	Gluteraldehyde	K934434
Cidex Plus®	USA	Liquid	Gluteraldehyde	K923744

1. Wear protective gloves when performing the disinfecting procedure.
2. Check the expiration date on the solution that is being used. Use only solutions that are within the expiration date.
3. Mix the disinfection solution compatible with the probe according to label instructions for solution strength. A disinfectant qualified by the FDA 510(k) process is recommended.
4. Immerse the tip of the probe approximately 1.5 cm in the disinfection solution. Avoid immersion beyond the membrane / probe interface.
5. Follow the instructions on the disinfection label for the duration of probe immersion.
6. Using the instructions on the disinfectant or sterilization label, rinse the probe up to the point of immersion, and then air dry or towel dry with a clean cloth.
7. Examine the probe for damage such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the probe and contact a customer service representative.

WARNING

DGH makes no claims about the biological effectiveness as a disinfectant of any of the products listed above. Furthermore, DGH makes no claims regarding the effectiveness of any of these products for killing any known, or unknown, bacteria, virus, or other micro-organisms. DGH only claims that these products, when used properly, will not harm the probe tip.

WARNING

It is the responsibility of the user to remain current with the latest information from the relevant disinfectant manufacturer concerning instructions, effects, necessary concentrations, immersion times and rinse requirements.

22 Care and Maintenance

22.1 Care of the USB Probe

The USB probe is a completely sealed unit. The probe may be submersed in water up to the cable during normal use.

WARNING

Do Not Attempt To Open the Probe Housing

The probe should be cleaned after every use. See the "Cleaning and Disinfecting" section for more details.

WARNING

Using a non-recommended disinfectant, incorrect solution strength, or immersing the probe tip deeper than described in step #4 (above), or for a period longer than recommended can damage or discolor the probe and will void the probe warranty.

Do not immerse the probe tip for longer than one hour. The probe may be damaged by longer immersion times.

Disinfect the probe tip using only the liquid solutions. Using autoclave, gas (EtO), or other non DGH Technology approved methods will damage the probe and void the warranty.

Regularly check the front face of the probe for cracks, as this may cause a loss of fluid, which would impair the performance of the probe.

Be sure to keep the USB connector dry at all times.

Regularly check the USB cables for cuts cracks and kinks. The presence of these defects can impair the performance of the device.

WARNING

Do Not Attempt to Disconnect or Remove USB Cable from the Probe

22.2 Maintenance of the USB Probe

Periodic testing and maintenance of the USB Ultrasound Probe is NOT required.

22.3 Operating Conditions

The DGH 8000 (Scanmate-B) should be operated within the following conditions:

- Max operating temperature 40°C (104°F)
- Min operating temperature 10 °C (50 °F)
- Operating humidity range 20 - 80% non-condensing

22.4 Storage

When the DGH 8000 is not being used, it should be stored in a clean, dry area.

To prevent damage to the DGH 8000, do not store in areas where it might be exposed to:

- Excessive vibration
- Excessive dust and dirt
- Liquids or condensation
- Impact

Store the DGH 8000 under the following ambient conditions:

- Temperature: -10°C to 50C° (14°F to 122°F)
- Relative Humidity: 20% to 80% (no condensation)
- Atmospheric pressure: 70 kPa to 106 kPa

22.5 Transportation

Never carry the DGH 8000 by the USB cable.

Never bend the USB cable in a tight radius. This could result in damage to the cable.

Transport the DGH 8000 under the following ambient conditions:

- Temperature: -10°C to 50C° (14°F to 122°F)
- Relative Humidity: 20% to 80% (no condensation)
- Atmospheric pressure: 70 kPa to 106 kPa

When transporting the DGH 8000 to a different field location or when returning it for repair or maintenance, use the original DGH 8000 packing enclosure.

If the original package is not available, pack in such a way that the DGH 8000 is protected.

22.6 Disposal

Contact DGH Technology, Inc. before disposing of the DGH 8000.

Concerning the WEEE label, the following information is for EU member states:

The use of this symbol indicates that this product should not be treated as household waste. 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 consult DGH Technology, Inc.

23 Troubleshooting

Refer to the Scanmate Installation Guide for troubleshooting instructions related to the installation and configuration of the Scanmate software. The installation guide also contains information on backing up, restoring and moving the patient database.

24 Warranty

DGH Technology, Inc. “DGH” warrants each new DGH 8000 and its accompanying accessories (hereinafter called “Equipment”) to be free from defects in material and workmanship for twelve (12) months from the date of delivery to the original purchaser. This warranty is not applicable to any defect that is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than DGH. This warranty does not apply if the Equipment has not been operated and maintained in accordance with the operating and maintenance manuals and instructions or bulletins issued in respect thereof by DGH. 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.

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

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

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

25 Lifetime / Shelf-life

The shelf-life / lifetime indicated for this device is 5 years.

26 Customer Service

If you are having problems with this unit, please refer to the appropriate sections of this manual. Most service calls result from a misinterpretation of the operation of the instrument. The instructions in this manual have been carefully reviewed to ensure error-free performance of the DGH 8000.

However, if you feel there is a problem with the unit or a transducer, please contact the Customer Service Department at the address below. DGH Technology, Inc. can also be contacted via our website at www.dghtechnology.com. When contacting us, please provide the model and serial number for the unit. The model number and serial number are located on the side of the USB probe and can also be viewed on the display by selecting the “About” button found on the “Help” toolbar.

Manufactured by:

DGH TECHNOLOGY, INC.

110 SUMMIT DRIVE
SUITE B
EXTON, PA 19341
USA (610) 594-9100

DGH TECHNOLOGY, INC.

Authorized European Representative:

EMERGO EUROPE

EC REP

Prinsessegracht 20
2514 AP, The Hague
The Netherlands

APPENDIX A COMPUTER SYSTEM SPECIFICATIONS

System Requirements

	Minimum	Recommended	
Processor:	2.0 GHz	3.0+ GHz	
Architecture:	32-bit or 64-bit	64-bit	
Memory:	2 GB RAM	4 GB RAM	
Hard Drive:	HDD or SSD	SSD	
Storage Space:	128 GB	500 GB	
Display:	1024 x 768 resolution[A]		
Peripherals:	Mouse/Touchpad, Keyboard		
Ports:	(2x) USB 2.0[B]		
PC Power Supply:	AC/DC Medical Grade Transformer[C]		
Compatible OS:	Microsoft Windows 7		(32-bit / 64-bit)
	Microsoft Windows 8.1		(32-bit / 64-bit)
	Microsoft Windows 10		(32-bit / 64-bit)
	Microsoft Windows Server 2008 R2[D]		(64-bit)
	Microsoft Windows Server 2012 / 2012 R2[D]		(64-bit)
	Microsoft Windows Server 2016[D]		(64-bit)

[A] *The 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] *1 port used for USB interface, 1 port used for footswitch.*

[C] *PCs connected to DGH devices must be isolated from ground using a medical grade power supply.*

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

WARNING

The use of a "Non-Medical" grade AC Adapter could potentially cause harm to the system, the probe, the operator and/or the patient.

WARNING

Using "Non-Essential" Software in Conjunction with the Scanmate 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.

APPENDIX B SUMMARY OF ACOUSTIC OUTPUT (12.0 MHz Probe)

Index	MI	TIS	TIS	TIS	TIB	TIB	TIC
Mode	-	Scanning	Non-scanning	Non-scanning	Scanning	Non-scanning	-
			A_{aprt} =1 cm²	A_{aprt} >1 cm²			
Acoustic working frequency (MHz)	10.4	10.4	NA	NA	10.4	NA	NA
Output power (mW)	0.173	0.173	NA	NA	0.173	NA	NA
Bounded output power (mW)	0.173	0.173	NA	NA	0.173	NA	NA
Attenuated output power (mW)	0.056	0.056	NA	NA	0.056	NA	NA
Spatial-peak temporal-average intensity (mW/cm2)	1.26	1.26	NA	NA	1.26	NA	NA
Attenuated spatial-peak temporal-average intensity (mW/cm2)	0.41	0.41	NA	NA	0.41	NA	NA
Peak-rarefactional acoustic pressure (MPa)	1.14	1.14	NA	NA	1.14	NA	NA
Attenuated peak-rarefactional acoustic pressure (MPa)	0.65	0.65	NA	NA	0.65	NA	NA
-1 2 dB output beam area (cm2)	0.28	0.28	NA	NA	0.28	NA	NA
Equivalent aperture diameter (cm)	0.60	0.60	NA	NA	0.60	NA	NA
Depth for *TIS* (cm)	0	0	NA	NA	0	NA	NA
Depth for *TIB* (cm)	0	0	NA	NA	0	NA	NA
Depth at max. attenuated pulse-intensity integral (cm)	1.57	1.57	NA	NA	1.57	NA	NA

Supplementary information:

B-Mode only with 60 degree scan angle, 15 Hz scan rate and 256 lines per scan

APPENDIX C SCANMATE-B SPECIFICATIONS

Imaging mode	- B Scan with Vector A-mode
Functions	- Standard USB Port (2.0) connectivity - Multiple freeze method: button on probe, keyboard, or soft key on screen - Zoom with enhanced resolution using 4 times over sampling - Auto Image saves on Freeze
Resolution	- Electronic, 0.015 mm; Clinical, < 0.1 mm
Gray shades	- True 256 (8 bits) shades of gray
Sector Size	- 60 degree sector
Transducer	- High Bandwidth, single element: 12 MHz & 15 MHz
Depth selections	- 3 cm, 6 cm (12 MHz); 5 cm, 10 cm (15 MHz)
Measurements	- 2 calibers for distance measurements
Signal processing	- Image Post-processing - TGC control's, near, mid and far - Contrast and Image Intensity controls - Frame averaging - Interpolation
Archive functions	- Exam data: Patient name and comments - Video buffer range up to 512 frames or 34 seconds - Open system architecture
Power Requirements obtained from the USB2 port	- 5.0 VDC (+/- 5%) - 500mA (maximum) - 2.5 watts (maximum)
Environmental	- Max operating temperature 40°C (104°F) - Min operating temperature 10 °C (50 °F) - Operating humidity range 20 - 80% non-condensing
Storage Temperature	- 10°C to 50C° (14°F to 122°F)