Keeler
– A world without vision loss –

UBM Plus & B-Scan Probe

NON-STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT:

This document is designed to assist in using the UBM & B-Scan Probe. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

DESCRIPTION:

The UBM Probe & B-Scan device is designed as a high frequency ultrasound B-Scan, which uses pulsed echo ultrasound to image the anterior segment of the eye.

The B-Scan utilized an eye-contact probe, and the UBM Probe utilized a non-contact probe via a contact Scleral shell, to generate and receive the ultrasound pulses, and provides a graphic display of returning pulse echoes to indicate the various structures.

Imaging and play back provided with the ease of plugging into any Window's based computer in the world, using either Microsoft Windows® XP (SP2) or later. The UBM & B-Scan Probe also has many additional features that allow multiple methods of viewing, diagnosing and printing acquired images.

INDICATIONS FOR USE:

This instrument is used for the imaging of the internal structure of the eye including opaque media and anterior segment pathology, for the purpose of diagnosing pathological or traumatic conditions of the eye.

Side Effects

There are no known side effects associated with the use of the UBM/B-Scan ultrasound imaging devices. Any side effects associated with the use of the UBM/B-Scan Probe are related to the topical anesthetic chosen by the physician to anesthetize the eye of the patient. Please consult the warning labels of the chosen topical anesthetics for further information.

Contraindications

There are no known contraindications associated with the use of the UBM/B-Scan Probe.

CAUTION: General indications for use of the UBM & B-Scan Probe include on external, structurally intact areas of the eye globe and orbit only.

WARNING! THE UBM & B-Scan Probe IS NOT INTENDED FOR FETAL USE!

SAFETY INFORMATION:

The UBM/B-Scan Probe has no user-operated controls or settings that affect the acoustic output. The UBM/B-Scan Probe is noninvasive. The ultrasonic probes touch the surface of the anesthetized cornea during the scanning process. Energy in the form of ultrasound is transmitted into the eye. The maximum power allowed to be set by the application software and/or by the user is below the FDA, Health Canada, and EU maximum power limits.

Disposal in Europe

The European Community (EC) has issued two directives; 91/157/EEC and 93/86/EEC. These directives are implemented by each member country in a different way. Thus, in each country, the manufacturers, importers, and users are responsible for the proper disposal or recycling.

EU directives and national regulations currently in force at the time of marketing prohibit the disposal of the UBM/B-Scan Probe and associated probes specified on the delivery note in domestic waste of by municipal waste disposal companies. If the associated probes or components are resold, the seller has the duty to notify the buyer that the product must be disposed of in accordance with currently valid national regulations.

Disposal in the United States

The UBM/B-Scan contains electronic components. At the end of its useful life it must be properly disposed of incompliance with local regulations.

Electrical Hazard and Safety

The UBM/B-Scan Probe is an electrical device. Reasonable care should be taken when making an electrical connection and handling electrically powered devices. Avoid the use of damaged electrical equipment or frayed electrical cords. If repair or maintenance is to be performed on the UBM/B-Scan Probe and/or any attachments, the equipment must be turned off and the power cord disconnected.

Use only the provided probes and footswitch. Be sure the cable and the connectors are in good condition. Inspect the probe before each use to ensure that there are no breaks, cracks, or other damage.

Avoiding Equipment Damage

The UBM/B-Scan Probe and associated probes provide no explosion protection from static discharge or arcing components. Do not operate the instrument in the presence of explosive gases such as flammable mixtures of anesthetic and air, or nitrous oxide.

CAUTION:

Before each patient procedure, inspect the probe to ensure that there are no breaks or cracks in the outside shell.

To avoid possible loss of patient data stored in the PC, ensure that the data is backed up on a device external to the PC.

CLEANING AND MAINTENANCE:

CAUTION: No abrasive or harsh cleaning solutions should be used while cleaning the UBM/B-Scan Probe.

In order to prevent the transmission of disease, medical authority(ies) having jurisdiction guidelines are referenced for proper control of sterilization issues. These guidelines are frequently updated so be sure to contact your local disease-control agency for the latest information and disinfection techniques.

To clean the UBM/B-Scan Probe, perform the following steps:

CAUTION: DO NOT WIPE THE PROBE END; IT MAY RESULT IN DAMAGE TO THE CRYSTAL.

Clean the probe handle with a damp cloth. Use appropriate products to clean the computer, keyboard and monitor. Cables may be cleaned with a soft cloth and alcohol. The probe holder should be washed with warm water and mild detergent. Probe and Transducer: The user must use the following procedure to clean the transducer and probe daily: Keep the transducer and probe connected, soak/rinse the transducer and probe end thoroughly with distilled water.

• Inspect all surfaces carefully for debris or build up.

• If there is still debris, soak/rinse the transducer and probe tip end with distilled water again. Repeat until all debris is gone.

• Let the transducer and probe air dry.

Disinfection of the Probes with Alcohol

One recommended disinfection technique is to clean the probe assemblies with 70% isopropyl alcohol.

NOTE: A 5-10-minute exposure is recommended. It is imperative that the alcohol be given time to evaporate before applying a probe to a patient's eye. Do not completely immerse the probe or cable; only the tip of the probe should be placed in the solution.

After cleaning, rinse the end of the probe thoroughly with distilled water to remove all traces of alcohol.

Probe surfaces should be dried with a lint-free cloth.

High-Level Disinfection of the Probe

If high-level disinfection is required by your facility, the probe may be cleaned using an FDA-cleared high-level disinfectant, such as Cidex OPA Activated Dialdehyde Solution.

If your facility is located in the EU, Mikrozid wipes are a compatible method of high-level disinfection.

NOTE: Be sure to follow the disinfectant manufacturer's written protocol when using any antibacterial solution, including high-level disinfectants.

Cleaning and Disinfection of Immersion and Sclera Shells

After applying new gloves, soak the shell for 10 minutes in Cidex of 10% bleach solution. Thoroughly rinse the device with sterile water, allowing to air-dry. Do not use heat or gas.

WARNING! DO NOT WIPE THE PROBE END OF THE UBM/B-SCAN PROBE; IT MAY RESULT IN DAMAGE TO THE CRYSTAL.

WARNING! DO NOT IMMERSE THE PROBE'S CABLES OR METAL CONNECTORS, ALLOW TO AIR DRY. DO NOT IMMERSE THE PROBE TIPS IN TAP WATER AS THE FLUORIDE CAN DAMAGE THE CRYSTAL, USE DISTILLED WATER FOR CLEANING AND DISINFECTION.

WARNING! DO NOT AUTOCLAVE! DO NOT IMMERSE THE ENTIRE UBM/B-SCAN PROBE IN ANY LIQUID.

WARNING! THE UBM/B-SCAN PROBE AND ASSOCIATED PROBES ARE NOT INTENDED FOR FETAL USE!

CAUTION: CARDIAC RHYTHM DISTURBANCES DURING PERFUSION STUDIES USING GAS ULTRASOUND CONTRAST AGENTS HAVE BEEN OBSERVED IN THE DIAGNOSTIC RANGE OF MECHANICAL INDEX (MI) VALUES.

WARNING! THE PROBE TIP OF THE UBM IS NEVER TO COME IN CONTACT WITH THE PATIENT'S EYE, AS IT MAY RESULT IN A CORNEAL ABRASION OR SIMILAR TYPE INJURY.

WARNING! OPERATING OR STORING THE UBM/B-SCAN PROBES BEYOND THE ENVIRONMENTAL RANGES MAY RESULT IN ERRONEOUS READINGS AND/OR PREMATURE FAILURE OF THE DEVICE.

WARNING! UBM/B-SCAN PROBES ARE ONLY TO BE USED WITH A COMPUTER USING MEDICAL GRADE POWER SUPPLY COMPLIANT WITH IEC60601-1.

WARNING! THE USE OF THE ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED BY THE MANUFACTURER MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE UBM/B-SCAN PROBE

WARNING! THE UBM/B-SCAN PROBE SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE UBM/B-SCAN PROBE SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION.

WARNING! SELECTING THE WRONG TISSUE MATERIAL WILL RESULT IN SERIOUS MEASUREMENT ERRORS.

STORAGE:

This device is intended for use in a controlled environment only; it is not intended for outdoor use.

WARNING! OPERATING OR STORING THE UBM/B-SCAN PROBES BEYOND THE ENVIRONMENTAL RANGES MAY RESULT IN ERRONEOUS READINGS AND/OR PREMATURE FAILURE OF THE DEVICE.

WARRANTY:

Keeler, warrants its new equipment to be free from defects in workmanship or materials. Any product that is proven to be defective will be repaired or replaced, at our discretion, free of charge, up to three years from the date of purchase by the initial user of the equipment from Keeler, or any of its authorized distributors.

This warranty covers all repairs and servicing of parts that proved defective by manufacture and not by misuse or mishandling. This type of service will be handled by our trained sales force, or, if necessary, in our home office. Shipping charges for returns or repair of non-warranted items will be the responsibility of the customer. Alteration, repair, or modification of any product that is performed by persons not authorized by Keeler USA will immediately void the warranty.

PRODUCT RETURNS:

Service and Repair

Before returning instruments for service or repair, contact the Keeler Product Specialist Group for troubleshooting assistance, or our Customer Service Team for a Return Authorization (RA) number.

Toll Free (800) 523-5620
Phone (610) 353-4350
Fax (610) 353-7814

After receiving authorization, print the RA number on the outside of the package and send the instrument to:

Technical Service
Keeler USA
3222 Phoenixville Pike
Malvern, PA 19355 USA

All Other Returns

Returns for nonservice-related reasons must be authorized by the Keeler Customer Service Department. Please contact Customer Service for an RA number.

Merchandise returned within 30 days of date of invoice will be credited as follows:

- Full credit for all merchandise returned in resalable condition

Nonreturnable Merchandise

Keeler USA, will not authorize a return for merchandise held longer than 30 days.

PRODUCT COMPLAINTS:

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance, should notify Keeler or its representative. Moreover, if a device has malfunctioned, Keeler or its representative must be advised immediately.

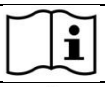
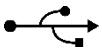
If a Keeler product has ever worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor or Keeler Representative must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please include the device name, reference number, lot number of the component(s), your name and address, and an exhaustive description of the event to help Keeler understand the causes of the complaint. See below for contact information.

For further information or complaints, please contact:

Keeler USA 3222 Phoenixville Pike Bldg. 50 Malvern PA, 19355	**Customer Support Phone:** 800.523.5620
Product Complaints: Complaints@KeelerUSA.com	**Customer Service Fax:** 610.353.7814
Website: www.KeelerUSA.com	**General Information:** Customerservice@KeelerUSA.com

The below symbols may be found on the package label:

	Manufacturer		Disposal of product within the EU
	Manufacture Date		Caution, see instructions
	Non-Sterile		Consult instructions for use
	Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner		Type B medical device
	Attention! Consult instruction manual		Class II insulation
	Electrical Shock Hazard		CE Mark
	USB Connector		No User Serviceable Parts
	Do Not Use Near Flammable Gases