

# PachPen

Handheld Pachymeter



## PachPen User's Guide

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

**FEDERAL COMMUNICATIONS COMMISSION (FCC)  
UNINTENTIONAL EMITTER PER FCC PART 15**

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in an office installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions in the user's guide, may cause harmful interference to radio or television reception. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a different circuit than the receiver is connected to.
- Consult Accutome, Inc., or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation of this product is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**CAUTION: Changes or modifications not expressly approved by Accutome, Inc., could void the FCC compliance and negate your authority to operate the product.**

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# 1

# Introduction

## PachPen Overview

The Accutome PachPen pictured below has all the features that make it easy to obtain extreme accuracy and improved patient outcomes.



Figure 1.1 - PachPen Pachymeter

## Features

The PachPen is designed for easy access to all screens and functions. The unsurpassed ease of use of the control buttons and the straightforward graphical user interface guide you through every operation.

What you can't see on the surface is also important. Industry-leading signal acquisition and processing helps ensure accurate measurements. Reliable design and efficient manufacturing provide fiscal value. Upgradable software protects your investment. The PachPen lets you accomplish even the complex simply.

The PachPen provides the following general features:

- Multi-segment high-resolution LCD screen with control buttons to provide an intuitive user interface
- Long-lasting lithium battery power source
- 18.4 cm x 3.2 cm x 3.2 cm (7 1/4" X 1 1/4" X 1 1/4") size, and 85 g (3 oz.) weight make the unit very portable
- Ergonomic design that fits comfortably into the hand for fast and accurate measurements
- Allows entry of Intraocular Pressure (IOP) and provides Corrected IOP based on corneal thickness measurements
- The body of the PachPen is angled from the probe tip, and both the body and the tip have sighting lines that allow easy visualization of the cornea, facilitating both centration and perpendicularity
- User controlled speed of sound
- Display of measured corneal thickness, entered IOP, Corrected IOP, and average for all stored measurements
- Automatically or manually capture and store up to nine measurements, along with the running average of all measurements taken

## Measurements

The high accuracy of the PachPen measurements is provided by the following:

- High-resolution, real-time waveform analysis
- High-speed signal digitalization that acquires over 4,000 points per signal waveform
- Automatic gain control to acquire the optimum signal
- Highly sensitive 10.5 MHz composite probe
- 20 individual signals acquired and analyzed to produce each measurement

## About This Manual

This manual is a guide for technicians, optometrists, and ophthalmologists who are experienced in ultrasonic biometric techniques.

This manual is organized as follows:

### **Chapter 2 - Safety**

Summarizes safety precautions, warnings, symbols, and terms.

### **Chapter 3 - Getting Started**

Provides assembly instructions and overview of PachPen basic operation.

### **Chapter 4 - Maintenance, Storage & Troubleshooting**

Provides general maintenance, storage and troubleshooting instructions.

### **Chapter 5 - Specifications**

Provides PachPen physical and operational specifications.

### **Chapter 6 - Warranty and Repairs**

Describes PachPen warranty information and repair procedures.

After reading this manual, you will be able to set up the PachPen, take measurements, and enter and calculate Corrected IOP.

# 2

# Safety

## Information

The section lists:

- Specific safety precautions associated with the PachPen
- General safety precautions

## Safety Issues to Consider When Using the PachPen

The PachPen is noninvasive. The ultrasonic biometry probe touches the surface of the anesthetized cornea during the scanning process.

## Indications for Use

This instrument is used for measuring the corneal thickness of the eye. It is to be used in a medical setting and only by technicians, optometrists, and ophthalmologists who are experienced in ultrasonic biometric techniques.

**CAUTION: General indications for use of the PachPen include external, structurally intact areas of the eye globe and orbit only.**

## Disposal Requirements

### Disposal of the product within the EU

The PachPen contains electronic components. At the end of its useful life, it must be properly disposed of in compliance with local regulations.

EU directives and national regulations currently in force at the time of marketing prohibit the disposal of the PachPen specified on the delivery note in domestic waste or by municipal waste disposal companies. If the PachPen or its 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.

## Symbol Definitions for the PachPen

Statements, graphics, and symbols listed below are used on components of the PachPen. Descriptions and meanings are listed to the right of the symbols.



Attention! Consult Instruction Manual



Type B Medical Device



Battery Replacement



Class II Insulation



Action Control Button



Disposal of Product within the EU



## Safety Precautions

There are several areas in the use of the PachPen that require special attention, as they may pose a safety threat.

The PachPen has an enclosure rated Degree of Protection of IP32. The enclosure provides protection for objects larger than 2.5 mm and dripping water. In the event of a spill contacting the unit, wipe the unit completely dry before returning it to service.

## Disinfection and Cleaning

Disinfection issues are confined to the Accutome probe that comes in contact with the patient's eye. In order to prevent the transmission of disease, refer to the OSHA and CDC guidelines for proper control of disinfection. These guidelines are frequently updated so be sure to contact OSHA, CDC, or your local disease control agency for the latest information and disinfection technique.

The probe must be cleaned between patients to prevent patient-to-patient transfer of infection. It is the user's responsibility to ensure that the relevant standards are maintained and that the products and procedures are effective and appropriate for ophthalmic applications. The following information is provided for the guidance of users, and specific products are mentioned for illustration only. Accutome does not endorse the use of these or any other product. Products must be used in accordance with the manufacturer's instructions.

## Warnings

DO NOT AUTOCLAVE THE PROBES OR CONNECTORS.

DO NOT IMMERSE THE PROBE'S CABLES OR METAL CONNECTORS. ALLOW TO DRY BEFORE USE.

DO NOT IMMERSE THE PROBE TIPS IN TAP WATER. USE DISTILLED WATER FOR CLEANING AND DISINFECTION

## Cleaning Procedure at Point of Use

1. Wear protective gloves when performing the cleaning process.
2. 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.
3. To remove remaining particulates, rinse with a distilled water—dampened cloth to remove soap residue, and then wipe with a dry cloth.

## Disinfection of the Probes with Alcohol

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

A 5 to 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, Mikrozyd wipes are a compatible method of high-level disinfection for Accutome probes.

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

## Electrical Hazard and Safety

The PachPen is an electrical/electronic device. Reasonable care should be taken when making an electrical connection and handling electrically powered devices. Avoid the use of damaged electrical equipment. If repair or maintenance is to be performed on the PachPen, the equipment must be turned off and the battery removed.

The device covers must not be removed except by qualified personnel. There are no user controls inside the unit. To avoid injury, do not operate the PachPen without protective covers.

The system is intended to operate from a 3.6V lithium battery.

**WARNING! BEFORE EACH PATIENT PROCEDURE, INSPECT THE PROBE TO ENSURE THAT THERE ARE NO BREAKS OR CRACKS IN THE OUTER SHELL.**

## Avoiding Equipment Damage

No peripheral equipment may be connected to the PachPen.

The PachPen provides 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: Dropping the PachPen can result in damage to the housing or other parts of the device. To prevent unwanted damage to the device, be sure to use the lanyard provided when handling the unit.**

**WARNING! OPERATING OR STORING THE DEVICE BEYOND THE ENVIRONMENTAL RANGES IN THE SPECIFICATIONS CHAPTER MAY RESULT IN ERRONEOUS READINGS AND/OR PREMATURE FAILURE OF THE DEVICE.**

### Avoiding Electromagnetic and Other Interference

Do not use a cellular telephone or other device not compliant with EMC Class B requirements, as its signals may cause the equipment to malfunction. The effect of radio signals on medical devices is dependent on various factors and therefore unpredictable. To avoid electromagnetic interference, the device must be installed and operated in accordance with the user's manual and using the components supplied by Accutome.

**WARNING! THE USE OF ACCESSORIES, TRANSDUCERS, AND CABLES OTHER THAN THOSE SPECIFIED BY THE MANUFACTURER MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY.**

# 3

## Getting Started

### Overview

The PachPen is designed to be used in multiple medical settings and can be rested on a surface, such as a counter or desk. The PachPen requires no assembly.

### Unpacking Instructions

Upon receiving the PachPen:

1. Remove the PachPen Pachymeter case from the protective shipping materials. Save the shipping materials for use if return or repair becomes necessary.
2. Check for missing items. The PachPen Pachymeter, this manual, and a lanyard should be included inside the case. The additional openings in the case foam are for storing alcohol prep pads and a bottle of ophthalmic anesthetic, if you wish.
3. Visually inspect the PachPen Pachymeter for damage.



Figure 3.1 - PachPen Unpacked

### Accessories Included with the PachPen

1. [1] XENO 3.6V Lithium Battery
2. [1] User's Guide
3. [1] Screwdriver
4. [1] Lanyard

**Note: Notify Accutome, Inc., immediately if any components are missing or damaged. See chapter 6 of this manual for contact information.**

### Battery Specification and Installation

The power source for the PachPen is a 3.6V lithium battery. The battery is included with the PachPen and must be installed before use.

### Battery Specification

Use only one [1] 3.6V, XENO model XLP-050F lithium battery, or an equivalent.

**CAUTION: USE ONLY THE STYLE AND TYPE OF BATTERY SPECIFIED. ANY OTHER STYLE OR TYPE OF BATTERY MAY CAUSE DAMAGE TO THE PRODUCT AND INVALIDATE THE WARRANTY.**

### Battery Installation

**CAUTION: THE BATTERY IS POLARIZED SO THAT IT ONLY FITS INTO THE BATTERY COMPARTMENT ONE WAY. CHECK TO BE SURE THAT THE BATTERY IS INSTALLED CORRECTLY, AND DO NOT FORCE THE BATTERY INTO PLACE. INCORRECT BATTERY INSTALLATION COULD CAUSE SEVERE DAMAGE TO THE PRODUCT AND INVALIDATE THE WARRANTY.**

To install the battery in the PachPen:

1. Locate the battery compartment on the underside of the PachPen and open the compartment by unscrewing the captive battery door screw. The battery door is hinged to the bottom of the handle and should not be removed from the product.
2. Insert the XENO model XLP-050F lithium battery, or an equivalent, into the battery compartment as shown in Figure 3.2.
3. Close the battery compartment door and screw the captive battery door screw back into position to firmly hold the battery compartment door in a closed position. Do not overtighten the screw.



Figure 3.2 - Battery Insertion

### Instructions for Use

**CAUTION: DO NOT AUTOCLAVE THE PACHPEN PACHYMETETER.**

#### Initial PachPen Pachymeter Setup

The steps below outline the basic setup of the PachPen.

1. If the battery is not installed in the PachPen, install the battery as described in "Battery Installation" above.
2. If you wish to change the speed of sound setting for the unit, press and hold the Action Control Button for 2 to 3 seconds until the Speed of Sound

screen is shown on the LCD display. Then release the Action Control Button and use the Up and Down Control Buttons to set the speed of sound desired.

- To return to the Measurement screen, press and hold the Action Control Button for 2 to 3 seconds until the Measurement screen appears.



Figure 3.3 - Action Control Buttons and LCD



Figure 3.4 - Speed of Sound Screen



Figure 3.5 - Measurement Screen

## Basic Operation

The basic operation of the PachPen consists of the following steps:

- Power on the PachPen instrument.
- Take up to nine measurements.
- Enter the measured IOP and calculate the corrected IOP for each eye.
- Record the data in the Patient Record.

### How to Power On the PachPen

- With the battery installed, the PachPen is always powered. However, after a period of nonuse, the unit turns off sections of the electronics, including the LCD, to conserve power.
- To restore the unit to full power, press any control button.
- The Product Information Screen is briefly displayed, and then the Measurement Screen is displayed.

### How to Start a New Patient

- Hold the Up and Down Control Buttons on the PachPen simultaneously for 2 to 3 seconds.

2. A single beep from the instrument will indicate that all measurements, averages, IOP entries and calculations are set to zero.



Figure 3.6 - Measurement Screen Starting New Patient

**WARNING! THE PROBE TIP MUST BE PROPERLY DISINFECTED BEFORE TAKING ANY MEASUREMENTS ON A NEW PATIENT.**

## How to Take a Measurement

1. Touch and hold the Up and Down Control Buttons on the PachPen simultaneously for 2 to 3 seconds to reset all measurements, averages, and IOP information to zero.
2. Press and release the Action Control Button. Two high pitched chirps (beeps) and a rotating line to the left of the average in the display indicate that the PachPen is ready to take a reading.
3. Apply the probe to the patient's eye.
4. The PachPen will automatically proceed to the next empty measurement if it is available.
5. The PachPen will emit a high-pitched chirp (beep) when you have automatically acquired a measurement.
6. The PachPen will emit three high-pitched chirps (beeps) when the ninth measurement has been taken, or if the measurement time expires.

## Notes

1. The PachPen can take up to nine measurements and provide the average of those measurements. This average is the number used when calculating the True IntraOcular Pressure (TIOPI).
2. The \* symbol by a measurement indicates the reading which is farthest away from the average.
3. You can review the measurements taken by pressing the Up and Down Control Buttons.
4. You can delete any measurement taken by touching and holding either the Up or Down Control Button for several seconds (until the unit emits a high-pitched chirp). After deleting a measurement, the unit will automatically recalculate the average of the measurements.

## How to Perform a Calculation

After you have completed a patient's measurements, you can calculate the True IOP for the patient. You can perform the calculation from the MIOP Screen.

To calculate True IOP:

1. From the Measurement Screen, select the MIOP screen by pressing and holding the Action Control Button for 2 to 3 seconds.
2. Enter the measured IOP by pressing the Up and Down Control Buttons until the proper measured IOP is displayed. If you make a mistake, just reselect the correct value.
3. The True IOP based on the average of the measurements taken is displayed below the measured IOP.



Figure 3.7 - True IOP Screen

4. Return to the Measurement Screen by pressing and holding the Action Control button until the Measurement Screen appears.

Table 3.1 below provides the IOP correction values.

Table 3.1 - IOP Correction Values

| Corneal Thickness (micrometers) | Correction Values (mmHg) |
|---------------------------------|--------------------------|
| 405                             | 7                        |
| 425                             | 6                        |
| 445                             | 5                        |
| 465                             | 4                        |
| 485                             | 3                        |
| 505                             | 2                        |
| 525                             | 1                        |
| 545                             | 0                        |
| 565                             | -1                       |
| 585                             | -2                       |
| 605                             | -3                       |
| 625                             | -4                       |
| 645                             | -5                       |
| 665                             | -6                       |
| 685                             | -7                       |
| 705                             | -8                       |

Correction Values according to corneal thickness of 545 micrometers. These correction values are modified from the work of Doughty and Zamen. This chart was reproduced from the *Review of Ophthalmology*, July 2002. Leon Herndon, MD, Duke University, Glaucoma Service, pp. 88–90.



# 4

## Maintenance, Storage & Troubleshooting

### General Maintenance

Maintenance that should be performed on the PachPen consists of activities such as keeping surfaces free of dust and dirt and storing in a dry and cool place so as to not adversely affect electronic parts.

Refer to pages 4 and 5 for details on disinfection and cleaning before doing any disinfection or cleaning of the PachPen.

**CAUTION: NO ABRASIVES OR HARSH CLEANING SOLUTIONS SHOULD BE USED WHILE CLEANING THE PACHPEN.**

**Note:** The unit does not contain any user replaceable parts other than the battery.

### Maintenance and Cleaning

Clean the PachPen Pachymeter by wiping everything except the tip with a clean lint-free, nonabrasive cloth and alcohol.

Clean the PachPen Pachymeter tip by dipping only the first ¼" of the tip into alcohol or in an ultrasonic cleaner and allowing it to air-dry.

**Do not drop the device.** Avoid any shock or excessive vibration as this may damage the unit.

**Do not immerse the device in any fluid.** This will damage the electronics and invalidate the warranty.

**Note:** See chapter 3 for battery specification and installation.

### Battery Disposal

Follow the procedure outlined below for proper disposal of lithium batteries.

#### Instructions for Disposal

1. Guidelines for the disposal of lithium batteries are continually under review. Waste-management companies can provide assistance in the disposal of these cells and batteries.
2. Disposal should be done in accordance with applicable regulations, which vary from country to country. In most countries, trashing of used batteries is forbidden and disposal can be done through nonprofit organizations mandated by local authorities or organized by professionals.
3. Cells and batteries should not be incinerated unless suitable procedures are followed and appropriate precautions have been taken by qualified handlers. Exposure of these cells to high temperatures or fire can cause them to vent and/or rupture.

4. Used batteries should be shipped with the same regulations as those for new lithium/thionyl chloride batteries.
5. Accutome recommends that cells and batteries for disposal should be collected, transported, and disposed of in a manner that will prevent short-circuit (the terminals taped).
6. Handling of used cells and batteries should be done according to the safety instructions of fresh cells.
7. Recycling of the cells and batteries should be done in authorized facilities, through a licensed waste carrier. A recycler in the United States is listed below.

### 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 proper disposal or recycling.

In accordance with these directives, the PachPen Lithium cells do not contain dangerous substances. The reaction products are inorganic and do not represent environmental hazards, once the decomposition or neutralization process has terminated.

### Disposal in the United States.

Lithium batteries are neither specifically listed nor exempted from the federal Environmental Protection Agency (EPA) hazardous waste regulations, as conveyed by the Resources Conservation and Recovery Act (RCRA). The only metal of possible concern in the cell is the lithium metal that is not listed or characterized as a toxic hazardous waste. Significant amount of spent cells and batteries that are untreated and not fully discharged are considered as reactive hazardous waste. Thus, hazardous waste of spent cells and batteries can be disposed of after they are first neutralized through an approved secondary treatment prior to disposal (as required by U.S. Land Ban Restriction of the Hazardous and Solid Waste Amendments of 1984).

Disposal of spent batteries should be performed by an authorized, professional disposal company that is familiar with the requirements of the federal, state, and local authorities regarding hazardous materials, transportation, and waste disposal.

**In any case, it is recommended that you contact your local EPA office.**

|                              |                                |
|------------------------------|--------------------------------|
| <b>PROPER SHIPPING NAME:</b> | Waste lithium Batteries        |
| <b>UN NUMBER:</b>            | 3090                           |
| <b>LABEL REQUIREMENTS:</b>   | MISCELLANEOUS, HAZARDOUS WASTE |
| <b>DISPOSAL CODE:</b>        | D003                           |

Following is a battery recycler and collector in the United States:

**ToxCo, Inc.**

3200E Frontera, Anaheim, California 92806

**Contact Person:** David Miller • **Email:** DMiller320@aol.com

**Phone:** (714) 879-2076 • **Fax:** (714) 441-0857 • **www:** www.Toxco.com

## Storage

1. When not in use, the PachPen Pachymeter and all accessories should be placed in the storage case.
2. If the PachPen Pachymeter is not to be used for an extended period of time, remove the battery from the device.

## Troubleshooting

Refer to Table 4.1 below for information in identifying and correcting problems that can occur with the PachPen.

Table 4.1 - PachPen Troubleshooting Information

| Symptom  | Probable Cause                                  | Correction  |
|--|---|---|
| <b>“LOW BATT” Displayed</b>                      | Battery is low                                  | Replace battery (see chapter 3)   |
| <b>Multiple variable readings</b>                | Improper technique                              | Review measurement technique  |
|  | Battery is low                                  | Replace battery (see chapter 3)   |
|  | Mechanical or electronic damage                 | Arrange for repair through Accutome Technical Service Group (see chapter 6) |
| <b>No beep and/or no display upon activation</b> | Action Control Button not held down long enough | Hold down Action Control Button longer                                      |
|  | Incorrect battery installation                  | Check battery installation  |
|  | Battery is low                                  | Replace battery (see chapter 3)   |
|  | Mechanical or electronic damage                 | Arrange for repair through Accutome Technical Service Group (see chapter 6) |
| <b>No Readings</b>                               | Improper technique                              | Review measurement technique  |
|  | Incorrect battery installation                  | Check battery installation  |
|  | Battery is low                                  | Replace battery (see chapter 3)   |
|  | Mechanical or electronic damage                 | Arrange for repair through Accutome Technical Service Group (see chapter 6) |

# 5

# Specifications

## Overview

This section provides the physical and operational specifications of the PachPen.

## Physical Specifications

Table 5.1 below lists the physical specifications of the PachPen instrument and associated peripherals.

Table 5.1 - PachPen Physical Specifications

| Main Unit               |  |
|-------------------------|--|
| Dimensions              | 18.4 cm x 3.2 cm x 3.2 cm (7 1/4" x 1 1/4" x 1 1/4")               |
| Weight                  | 85 g (3 oz.)   |
| Display                 |  |
| Type                    | Multi-Segment Monochrome Liquid Crystal Display (LCD)              |
| Size                    | 28.6 mm (1.13") Diagonal Viewable Area                             |
| <b>Probe Frequency</b>  | 10.5 MHz, Composite  |
| <b>Sample Frequency</b> | 65 MHz   |
| <b>Safety</b>           | Meets EN 60601-1 Series electrical standards for medical equipment |
| <b>Applied Parts</b>    | PachPen pachymeter probe   |

## Environmental Specifications

Table 5.2 below lists the PachPen system operating and storage values for temperature and humidity.

Table 5.2 - Environmental Specifications

| Temperature          |                        |
|----------------------|------------------------|
| Operating            | +10°—40°C (50°—104°F)  |
| Storage              | -20°—60°C (-4°—140°F)  |
| Relative Humidity    |                        |
| Operating            | 20—80% (noncondensing) |
| Storage              | 15—90% (noncondensing) |
| Atmospheric Pressure |                        |
| Operating            | 700—1060 hPa           |
| Storage              | 500—1060 hPa           |

## Measurement Accuracy

Table 5.3 below lists the PachPen accuracy.

Table 5.3 - Measurement Accuracy

| Measurement                         | Corneal Thickness   |
|-------------------------------------|---------------------|
| Clinical Accuracy [1 Sigma]         | +/- 5 Micrometers   |
| Electronic Resolution [@1640 m/sec] | +/- 1 Micrometer    |
| Range                               | 300–999 Micrometers |

## Operating Modes

The following table summarizes the mode/application possibilities for each system/transducer combination.

Table 5.4 - Operating Modes

| Clinical Application       | A | B | M | PWD | CWD | CD | Combined (specify) | Other <sup>†</sup> (specify) |
|----------------------------|---|---|---|-----|-----|----|--------------------|------------------------------|
| Ophthalmic                 | X |   |   |     |     |    |                    |                              |
| Fetal Imaging & Other*     |   |   |   |     |     |    |                    |                              |
| Cardiac, Adult & Pediatric |   |   |   |     |     |    |                    |                              |
| Peripheral Vessel          |   |   |   |     |     |    |                    |                              |

\* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional), Musculo-Skeletal (superficial)

<sup>†</sup>Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

## Acoustic Output

Table 5.5 below provides the acoustic output reporting for the following:

|                          |              |
|--------------------------|--------------|
| <b>System:</b>           | PachPen      |
| <b>Transducer Model:</b> | A-Mode Probe |
| <b>Operating Mode:</b>   | A-Mode       |
| <b>Application(s):</b>   | Ophthalmic   |

Table 5.5 - Acoustic Output Reporting Table for Track 1 Non-Autoscanning Mode

| Acoustic Output                     |                   | MI       | ISPTA.3<br>(mW/cm <sup>2</sup> ) | ISPPA.3<br>(W/cm <sup>2</sup> ) |       |
|-------------------------------------|-------------------|----------|----------------------------------|---------------------------------|-------|
| Global Maximum Value                |                   | 0.154    | 0.0145                           | 8.53                            |       |
| Associated<br>Acoustic<br>Parameter | Pr.3 (MPa)        | 0.555    | ---                              | ---                             |       |
|                                     | Wo (mW)           | ---      | 1.49E-4                          | 1.49E-4                         |       |
|                                     | Fc (MHz)          | 13.0     | 13.0                             | 13.0                            |       |
|                                     | Zsp (cm)          | 0.400    | 0.400                            | 0.400                           |       |
|                                     | Beam<br>Dimension | x-6 (cm) | ---                              | 0.979                           | 0.979 |
|                                     |                   | y-6 (cm) | ---                              | 0.103                           | 0.103 |
|                                     | PD (iS)           | 0.948    | ---                              | 0.848                           |       |
|                                     | PRF(Hz)           | 20       | ---                              | 20                              |       |
| EBD                                 | Az. (cm)          | ---      | 0.267                            | ---                             |       |
|                                     | Ele. (cm)         | ---      | 0.267                            | ---                             |       |
| Operating<br>Control<br>Conditions  |                   |          |                                  |                                 |       |

Table 5.6 - Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

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

| <b>Emissions Test</b>                                | <b>Compliance</b> | <b>Electromagnetic Environment Guidance</b>  |
|--|-------------------|--|
| RF Emissions CISPR II*                               | Group I           | The PachPen uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.   |
| RF Emissions CISPR II*                               | Class B           | The PachPen is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2                     | N/A               |  |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies          |  |


Table 5.7- Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

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

| <b>Immunity Test</b>                                    | <b>IEC 60601 Test Level</b> | <b>Compliance Level</b> | <b>Electromagnetic Environment Guidance</b>  |
|---|-----------------------------|-------------------------|--|
| Electrostatic Discharge (ESD)                           | +/- 6kV Contact             | +/- 6kV Contact         | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| IEC 61000-4-2   | +/- 8kV Air                 | +/- 8kV Air             |  |
| Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 | 3 A/m                       | 3 A/m                   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.      |

Table 5.8 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

| Immunity Test              | IEC 60601 Test Level      | Compliance Level | Electromagnetic Environment Guidance   |
|----------------------------|---------------------------|------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 0.15 MHz to 80 MHz | N/A              | Portable and mobile RF communications equipment should be used no closer to any part of the PachPen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ 800 MHz to 2,5 GHz  |
| Radiated RF IEC 61000-4-3  | 3 V/m 80MHz to 2,5 GHz    | 3 V/m            | where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:<br> |

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

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

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

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.



# 6

# Warranty & Repairs

## Warranty

Accutome, Inc., warrants its new equipment to be free from defects in workmanship or materials. Any PachPen 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 Accutome, Inc., or any of its authorized distributors.

This warranty covers all repairs and servicing of parts that prove 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 nonwarranted items will be the responsibility of the customer. Alteration, repair, or modification of any product that is performed by persons not authorized by Accutome, Inc., will immediately void the warranty.

## Product Returns

Follow the instructions given below to return products to Accutome, Inc.

## Service and Repair

Before returning instruments for service or repair, contact the Accutome Technical Service Group for a Return Goods Authorization (RGA) number.

|                    |                |
|--------------------|----------------|
| Toll-Free (in US): | (800) 979-2020 |
| International:     | (610)-889-0200 |
| Fax:               | (610) 889-3233 |

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

Technical Service Group  
Accutome, Inc.  
3222 Phoenixville Pike  
Malvern, PA 19355 USA

## All Other Returns

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

Merchandise returned within 60 days of date of invoice will be credited as follows:

- Full credit for all merchandise returned in resalable condition

## Non-Returnable Merchandise

Accutome, Inc., will not authorize a return for:

- Merchandise held longer than 60 days

## Replacement Parts

Table 6.1 below lists items that are available from Accutome, Inc. or from your local sales representative. Please be sure to use the Accutome part number for the item when placing an order.

Table 6.1 - Accutome Replacement Parts

| Description           | Accutome Part No. |
|-----------------------|-------------------|
| <b>Standard Parts</b> |                   |
| Battery               | 24-5101           |



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