ACCUTOME

AccuPen® Handheld Tonometer

User's Guide

24-3002 Rev. E

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 manual, 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 and 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 from that to which the receiver is connected
- Consult Accutome Ultrasound, 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 Ultrasound, Inc. could void the FCC compliance and negate your authority to operate the product.

Authorized Representative in Europe (for regulatory affairs only):

CE
0086

EC REP
EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

Manufactured in the USA by:
Accutome, Inc.
3222 Phoenixville Pike
Malvern, Pennsylvania 19355
USA

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1 Introduction

AccuPen Overview

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

Figure 1: AccuPen® Tonometer

Features

The AccuPen 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 you assure accurate measurements. Reliable design and efficient manufacturing provide fiscal value. Upgradeable software protects your investment. The AccuPen lets you accomplish even the complex simply.

The AccuPen provides the following general features:

- Multisegment 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 (7.25" X 1.25" X 1.25" 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 CCT (Central Corneal Thickness) and provides Adjusted IOP based on manually entered corneal thickness measurements
- The body of the AccuPen 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
- Display of measured IOP, entered corneal thickness, Corrected IOP, and average for all stored measurements
- Capture and store up to nine measurements along with the running average of all measurements taken

Measurements

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

- High-resolution, real-time waveform analysis
- High-speed signal digitalization which acquires many date points per measurement in a continuous acquisition until strict criteria are recognized
- Automatic offset control to acquire the optimum signal
- Sampling of the pressure signal is at a 1KHz rate
- Unit correlates matching (or multiple) readings to insure accuracy
- Uses a highly precision machined probe

- Has Adjusted IOP feature to correct for varying CCTs
- Uses proprietary pressure waveform analysis algorithm

About this Manual

This manual is a guide for technicians, optometrists, and opthalmologists who are experienced in intraocular pressure measurement techniques.

This manual is organized as follows:

Section 2	Safety	Summarizes safety precautions, warnings, symbols and terms.
Section 3	Getting Started	Provides assembly instructions, overview of AccuPen basic operation.
Section 4	Maintenance	Provides general maintenance instructions
Section 5	Specifications	Provides AccuPen physical and operational specifications
Section 6	Warranty and Repairs	Describes AccuPen warranty information and repair procedures.

Having read this manual you will be able to set up the AccuPen, take measurements, and enter and calculate Adjusted IOP.

Safety Information

The section lists:

- Safety Precautions associated with the AccuPen
- Safety Precautions of a general nature

Safety Issues to Consider When Using the AccuPen

The AccuPen is non-invasive. The strain gauge sensor probe tip, covered with a single-use latex disposable, touches the surface of the anesthetized cornea during the scanning process.

Indications for use

This instrument is used for measuring the intraocular pressure (IOP) of the eye. It is to be used in a medical setting, and only by physicians, optometrists, and technicians who are experienced in IOP measurement techniques.

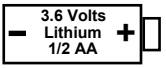
CAUTION: General indications for use of the AccuPen include on external, structurally intact areas of the eye globe and orbit only.

Symbol Definitions for the AccuPen

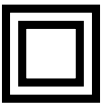
Statements, graphics and symbols listed below are used on components of the AccuPen. Descriptions and meanings are listed to the right of the symbols.

"Attention! Consult Instruction Manual."

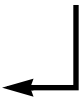
Type B Medical Device



Battery Replacement



Class II Insulation



Action Control Button

Disposal of Product within EU

Safety Precautions

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

The AccuPen 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.

Maintenance

Remove AccuTip tonometer tip cover and dispose.

Clean the sensor with optical quality compressed gas before the first use each day, prior to storage and in the event of suspect readings.

Spray the compressed gas into the sensor for approximately 2 seconds. Wait 3 minutes to allow the instrument to thermally stabilize and place a new AccuTip tonomter tip cover over the tip.

Disinfection and Cleaning

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 officer for the latest information and disinfection techniques.

WARNING! DO NOT AUTOCLAVE!

WARNING! DO NOT IMMERSE THE ENTIRE AccuPen IN ANY LIQUID.

Cleaning

Keep the surfaces of the AccuPen free of dust and dirt and store the instrument in a dry and cool place so as not to adversely affect any electronic parts. No specific cleaning interval is recommended.

CAUTION: No abrasive or harsh cleaning solutions should be used while cleaning the AccuPen.

When the unit needs cleaning, use only a damp, soft, lint-free cloth. Do not pour or spray any liquids or cleaners onto the unit at any time. The damp, lint-free cloth may contain mild soap if necessary. Gently wipe down the instrument surfaces. Allow the unit to completely dry before using again.

If the probe tip needs cleaning, it may be wiped with a damp, soft, lint-free cloth as needed.

Electrical Hazard and Safety

The AccuPen 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 AccuPen, 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 AccuPen without protective covers.

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

Avoiding Equipment Damage

No peripheral equipment may be connected to the AccuPen.

The AccuPen 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.

Overview

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

Unpacking Instructions

Upon receiving the AccuPen:

1. Remove the AccuPen® Tonometer case from the protective shipping materials. Save the shipping materials for use if return or repair becomes necessary.
2. Check for missing items. The AccuPen® Tonometer, this manual, a battery, a bag of 100 AccuTip single-use latex tip covers and a lanyard should be included inside the case.
3. Visually inspect the AccuPen® Tonometer for damage.

CAUTION: AccuTips contain natural rubber latex which may cause allergic reactions. Question patients about allergies to latex before examining them with the AccuPen.

Figure 2: AccuPen® Unpacked

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

Battery Specification and Installation

The power source for the AccuPen is 3.6 V Lithium battery. The battery is included with the AccuPen and must be installed before use.

Battery Specification

Use only one (1) 3.6 volt, XENO model XLP-050F Lithium battery, or an equivalent.

CAUTION: Use only the style and type of battery specified. Using another 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 AccuPen:

1. Locate the battery compartment (as shown in Figure 3) on the bottom of the AccuPen and open the compartment by unscrewing the 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.

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 over tighten the screw.

Figure 3: Battery Insertion

Instructions for Use

CAUTION: DO NOT AUTOCLAVE THE AccuPen® TONOMETER.

Initial AccuPen Tonometer Setup

The followiing steps outline the basic setup of the AccuPen.

1. If the battery is not installed in the AccuPen, install the battery as described in "Battery Installation" on page 11 and 12 of this manual.
2. To return to the Measurement screen, press and hold the Action Control Button for 2 to 3 seconds until the Measurement screen appears.

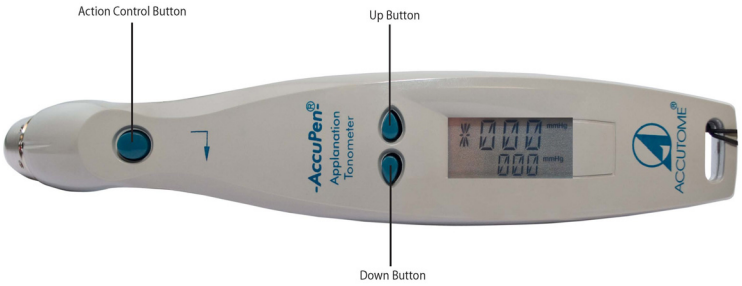


Figure 4: Control Buttons and LCD

Calibration

The AccuPen is calibrated during the manufacturing process, so there is no need to calibrate unit prior to using the AccuPen. The AccuPen does NOT require further calibration.

Recalibration of the unit is recommended only after the unit has been dropped or mishandled. The steps to recalibrate the AccuPen are as follows.

1. With the AccuPen powered on, press and hold *Main* button and *Up* button simultaneously for 5 seconds. Probe will enter calibration mode and *"PROB HORZ"* will be displayed on LCD as shown in Figure 5.

2. Hold AccuPen, so the probe is horizontal and press *Main* button as shown in Figure 5.

Figure 5: Calibration Probe Horizontal Position

3. Wait for beep and then hold AccuPen, so that the probe is straight up in a vertical position and press *Main* button as shown in Figure 6. "*PROB UP*" will be displated on the LCD.

Figure 6: Calibration Probe Up Position

4. Wait for beep again and then hold AccuPen, so that the probe is straight down in a vertical position and press *Main* button as shown in Figure 7. "*PROB DOWN*" will be displayed on the LCD.

Figure 7: Calibration Probe Down Position

5. Wait for beep, a calibration number will be displayed on LCD.
6. Press *Main* button again to exit calibration mode and store calibration number.
7. If "*No Calc*" is displayed on LCD the calibration process was not performed correctly.

Basic Operation

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

1. Power on the AccuPen instrument.
2. Take up to nine measurements.
3. Enter the measured CCT (Central Corneal Thickness) and calculate the AIOP (Adjusted IOP) for each eye.
4. Record the data in the Patient Record,

How to Power On the AccuPen

1. With the battery installed, the AccuPen is always powered. However, after a period of non-use, 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.

2. The Product Information Screen is briefly shown and then the Measure Screen is displayed.

How to Start a New Patient

To start a new Patient:

1. Hold the Up and Down control buttons on the AccuPen simultaneously for two to three seconds.
2. A single beep from the instrument will indicate that all IOP measurements, averages, CCT entries and Calculations are set to zero.

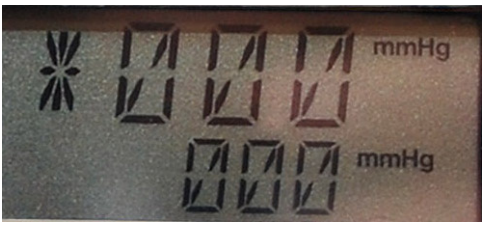


Figure 8: Measure Screen Starting New Patient

WARNING! The AccuTip cover must be replaced before taking any measurements on a new patient.

How to Take a Measurement

To take a patient measurement:

1. Touch and hold the Up and Down control buttons on the AccuPen simultaneously for two to three 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 AccuPen is ready to take a reading.
3. Gently tap the sensor tip on the patient's eye.
4. The AccuPen will automatically proceed to the next empty measurement if it is available.
5. The AccuPen will emit a high pitched chirp (beep) when you have automatically acquired a measurement.
6. The AccuPen will emit three high pitched chirps (beeps) when the 9th measurement has been taken, or if the measurement time expires.

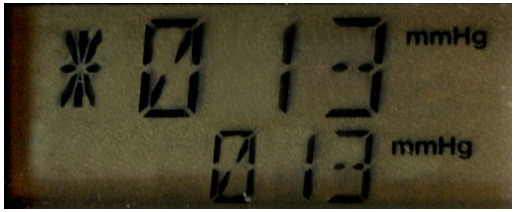


Figure 9: Capturing a Measurement

Notes

1. The AccuPen can take up to 9 measurements and provide the average of those measurements. This average is the number used when calculating the Adjusted Intraocular Pressure (AIOP).
2. The * symbol by a measurement indicates the reading which is furthest 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 Calculate Adjusted IOP

After you have completed a Patient's measurements you can calculate the Adjusted IOP for the Patient. You can perform the calculation from the MCCT (Manual Central Corneal Thickness) Screen.

To calculate Adjusted IOP:

1. From the Measurement Screen, select the MCCT screen by pressing and holding the Action Control button for two to three seconds. 530µm will appear as default.
2. Enter the measured CCT by pressing the Up and Down control buttons until the proper measured CCT is displayed. If you make a mistake, just reselect the correct value.
3. The Adjusted IOP based on the average of the measurements taken is displayed below the measured IOP.
4. Return to the Measurement Screen. by pressing and holding the Action Control button until the Measurement Screen appears.

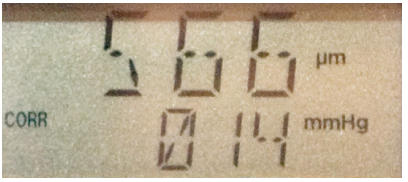


Figure 10: Adjusted IOP Screen

Table 1 below provides the IOP correction values.

Table 1: IOP Correction Values

Corneal Thickness (micrometers)	Correction Values (mm Hg)
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, Pages 88, 89, 90.	

WARNING! CCT Adjustments are not supported by performance data.

4 Maintenance, Storage and Troubleshooting

General Maintenance

Maintenance that should be performed on the AccuPen 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 effect electronic parts.

Refer to Chapter 2, page 7 through page 8 for details on sterilization, disinfection and cleaning before doing any sterilization, disinfection, or cleaning of the AccuPen.

CAUTION: No abrasives or harsh cleaning solutions should be used while cleaning the AccuPen.

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

Maintenance and Cleaning

Clean the AccuPen Tonometer by wiping everything except the tip with a clean, lint-free, non-abrasive cloth and alcohol.

Clean the AccuPen Tonometer tip by wiping the tip with alcohol 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 Section 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 disposal of used batteries in the trash is forbidden. Disposal can be done through non-profit 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 the cells 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 licensed waste carrier. A recycler in US 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 the proper disposal or recycling.

In accordance with these directives the AccuPen® 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 US

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 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 authorized, professional disposal company which has the knowledge in the requirements of the Federal, the State and the Local authorities regarding hazardous materials, transportation and waste disposal. ***In any case it is recommended to contact the local EPA office.***

PROPER SHIPPING NAME: Waste lithium Batteries

UN NUMBER: 3090

LABEL REQUIREMENTS: MISCELLANEOUS, HAZARDOUS WASTE

DISPOSAL CODE: D003

Following is a suggestion for battery recycler and collector in the US:

ToxCo Inc.

3200E Frontera, Anaheim, California 92806

Contact Person- David Miller,

Email- DMiller320@aol.com

Tel- (714) 879 2076, Fax (714) 441 0857

www.Toxco.com

Storage

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

Troubleshooting

Refer to Table 2 for information in identifying and correcting problems that can occur with the AccuPen.

Table 2: AccuPen Troubleshooting Information

Symptom	Probable Cause	Correction
A. "LOW BATT" displayed	A. Battery is low	A. Replace battery (See Section 3.)
B. Multiple variable readings	B.1. Improper technique	B.1. Review measurement technique
	B.2. Battery is low	B.2. Replace battery (See Section 3.)
	B.3. Mechanical or electronic damage	B.3. Arrange for repair through Accutome Technical Service Group (See Section 9.)
C. No beep and/ or no display upon activation	C.1. Action Control Button not held down long enough	C.1. Hold down Action Control Button longer
	C.2. Incorrect battery installation	C.2. Check battery
	C.3. Battery is low	C.3. Replace battery (See Section 3.)
	C.4. Mechanical or electronic damage	C.4. Arrange for repair through Accutome Technical Service Group (See Section 6.)
D. No readings	D.1. Improper technique	D.1. Review measurement technique
	D.2. Incorrect battery installation	D.2. Check battery

	D.3. Battery is low	D.4. Replace battery (See Section 3.)
	D.4. Mechanical or electronic damage	D.5. Arrange for repair through Accutome Technical Service Group (See Section 9.)
E. “NO CALC” displayed	E. Out of calibration	E. Recalibrate unit (See Section 3.)
F. "ERR 0" displayed	F. Measurable range out of tolerance	F. Arrange for repair through Accutome Technical Service Group (See Section 9.
G. "ERR 1" displayed	G. Measurable range out of tolerance	G. Arrange for repair through Accutome Technical Service Group (See Section 9.
H. "ERR 2" displayed	H. Measurable range out of tolerance	H. Arrange for repair through Accutome Technical Service Group (See Section 9

Overview

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

Physical Specifications

Table 3 below lists the physical specifications of the AccuPen instrument and associated peripherals.

Table 3: AccuPen Physical Specifications

Main Unit	
Dimensions	18.4 cm X 3.2 cm X 3.2 cm (7.25" X 1.25" X 1.25")
Weight	85 g (3 oz.)
Display	
Type	Multi Segment Monochrome Liquid Crystal Display (LCD)
Size	28.6 mm (1.13") Diagonal Viewable Area
Distal Tip	300 Series Stainless Steel
Sampling Rate	1 KHz
Safety	
Meets EN 60601-1 Series electrical standards for medical equipment	

Environmental Specifications

Table 4 below lists the AccuPen system operating and storage values for temperature and humidity.

Table 4: Environmental Specifications

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

Measurement Accuracy

Table 5 below lists the AccuPen accuracy.

Table 5: Measurement Accuracy

Measurement	IOP
Sampling of Pressure Signal	1 KHz
Range	7 - 60 mmHG
Accuracy	+/-2 mmHG

EMC Compliance Information

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual

Portable and mobile RF communications equipment can affect Medical Electrical Equipmentl

Table 6: Guidance and manufacturer's declaration - electromagnetic emissions

The AccuPen is intended for use in the electromagnetic environment specified below. The customer or the user of the AccuPen should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11*	Group 1	The AccuPen 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 11*	Class B	The AccuPen 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 IEC61000-3-3	Complies	

Table 7: Guidance and manufacturer's declaration - electromagnetic immunity

The AccuPen is intended for use in the electromagnetic environment specified below. The customer or the user of the AccuPen should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6kV Contact +/- 8kV Air	+/- 6kV Contact +/- 8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) 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 8: Guidance and manufacturer's declaration - electromagnetic immunity

The AccuPen is intended for use in the electromagnetic environment specified below. The customer or the user of the AccuPen 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 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the AccuPen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz 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 metres (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AccuPen is used exceeds the applicable RF compliance level above, the AccuPen should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AccuPen
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m

Table 9: Recommended separation distances between portable and mobile RF communications equipment and the AccuPen

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

Rated maximum output power of transmitteer W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHZ to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Warranty

Accutome, Inc. 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 one year 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 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 Accutome, Inc. will result in immediate loss of 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 USA):	1-800-979-2020
Tech Service:	1-610-889-0200
Fax:	1-610-889-3233

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

All Other Returns

Returns for non-service 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 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 10: Accutome Replacement Parts

Description	Accutome Part No.
Standard Parts	
Battery	24-5101
AccuTip Tonometer Probe Caps, Sanitized	AX9950
Proparacaine, 15 ml	AX0500