AccuPen

Handheld Tonometer

AccuPen User's Guide

IFU-24-3000 REV-A

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 Keeler 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 Keeler could void the FCC compliance and negate your authority to operate the product.

The AccuPen is manufactured and trademarked by:

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Malvern, PA 19355 USA
Toll Free (800) 523-5620
Phone (610) 353-4350
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CE 2797

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1 Introduction

AccuPen Overview

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

Figure 1.1 - AccuPen Tonometer

Features

The AccuPen is designed for easy access to all screens and functions.
The easy use of the control buttons and 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. Upgradeable software protects your investment.

The AccuPen provides the following general features:

- Multisegmented 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 that acquires many data 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 1 KHz rate
- Unit correlates matching (or multiple) readings to ensure 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 ophthalmologists who are experienced in intraocular pressure measurement 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 AccuPen basic operation.
Chapter 4 - Maintenance, Storage & Troubleshooting
Provides general maintenance, storage, and troubleshooting instructions.
Chapter 5 - Specifications
Provides AccuPen physical and operational specifications.
Chapter 6 - Warranty & Repairs
Describes AccuPen warranty information and repair procedures.

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

2 Safety

Safety Information

The section lists:

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

Safety Issues to Consider When Using the AccuPen

The AccuPen is noninvasive. 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.

Battery Disposal

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

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 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 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. Keeler 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 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 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 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 number 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 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 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 battery recycler and collector in the United States:

Battery Solutions
4930 Holtz Drive, Wixom, MI 48393
E: customerservice@batterysolutions.com
P: (800) 852-8127
W: www.batterysolutions.com

Symbol Definitions for the AccuPen

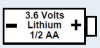
Statements, graphics, and symbols listed below are used on components of the AccuPen. Descriptions and meanings are listed to the right of the symbols.

Safety Precautions

There are several areas in the use of the AccuPen that require special attention,


Attention! Consult Instruction Manual


Type B Medical Device



Battery Replacement


Action Control Button


Disposal of Product within the EU

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 tonometer tip cover over the tip.

Disinfection

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.

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.

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,

Sensor Cleaning Instructions

The AccuPen tonometer may have difficulty taking measurements or display an "Error Message" when its tip is dirty and requires cleaning. When the tip of the tonometer has dirt and contaminants in the airspace between the sensor and the housing, cleaning of the tip is necessary. When the airspace contains contaminants, the sensor cannot move freely and the tonometer may have erratic readings and then display an "Error Message."

NOTE: It is recommended that this procedure be performed on a daily basis to prevent buildup of powder or dirt in the sensor.

To clean the AccuPen, perform the following steps:

1. Remove AccuTip cover from the tonometer, if one is installed.

2. Submerge the tip of the AccuPen in Isopropyl Alcohol to loosen any debris that may have accumulated in the sensor housing

NOTE: Allow the tip of the AccuPen to soak in the Isopropyl Alcohol for two to three minutes, frequently moving the tip in the solution to aid in the loosening of debris.

WARNING! DO NOT SUBMERSE THE ENTIRE TIP IN ISOPROPYL ALCOHOL, AS THIS WILL DAMAGE COMPONENTS IN THE SENSOR.

3. Using compressed air, place the sensor end of the tonometer against the outlet of the canned air as shown in figure 2.1.
4. Blow the canned air into the tip of the tonometer for approximately 3 seconds.

Figure 2.1 - Clean with Canned Air

NOTE: It is necessary to blow canned air directly into the tip, so that the contaminants are pushed out of the airspace between the sensor and the housing.

5. After cleaning the tip of the tonometer with compressed air, the tip will be cold. Allow the tip of the tonometer to warm to room temperature.
6. Perform the calibration procedure as listed in User Manual.

NOTE: If the tonometer does not pass verification, then repeat the above cleaning instructions. Do not clean more than 3 times in a row. If the tonometer still will not pass verification, contact Keeler.

NOTE: Always store the AccuPen tonometer with an AccuTip cover installed to protect the tonometer tip from dirt and contaminants.

WARNING! NEVER USE THE ACCUPEN TONOMETER WITHOUT AN ACCUTIP COVER INSTALLED.

Warnings

DO NOT AUTOCLAVE!

DO NOT IMMERSE THE ENTIRE ACCUPEN IN ANY LIQUID.

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.

3 Getting Started

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 guide, a battery, a screwdriver, a box 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.

Figure 3.1 - AccuPen Unpacked

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

Accessories Included with the AccuPen

1. (2) XENO 3.6V Lithium Battery
2. (1) User's Guide
3. (1) Screwdriver
4. (1) Lanyard
5. (1) Box of AccuTips

Note: Notify Keeler 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 AccuPen is a 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 V, XENO model XLP-050F lithium battery.

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 3.2) 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, 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 over tighten the screw.

Figure 3.2 - Battery Insertion

Instructions for Use

CAUTION: Do not Autoclave the AccuPen Tonometer.

Initial AccuPen Tonometer Setup

The following 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 9, above.
2. To return to the Measurement screen, press and hold the up and down buttons for 2 to 3 seconds until the Measurement screen appears.

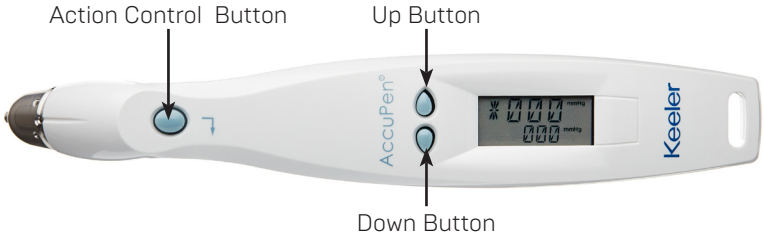


Figure 3.3 - Action Control Buttons and LCD

Calibration

The AccuPen is calibrated during the manufacturing process, so calibration is not required, but is recommended prior to first use.

Recalibration of the unit is recommended after each time the unit is cleaned or if 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 the Action Control 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 3.4.
2. Hold AccuPen, so the probe is horizontal and press and release Action Control button as shown in Figure 3.4.

Figure 3.4 - Calibration Probe Horizontal Position

3. Wait for a beep and then hold the AccuPen so that the probe is straight up in a vertical position. Press and release the Action Control button as shown in Figure 3.5. "PROB UP" will be displayed on the LCD.

Figure 3.5 - Calibration Probe Up Position

4. Wait for a beep again and then hold the AccuPen so that the probe is straight down in a vertical position. Press and release the Action Control button as shown in Figure 3.6. "PROB DOWN" will be displayed on the LCD.

Figure 3.6 - Calibration Probe Down Position

5. Wait for a beep, then a calibration number will be displayed on the LCD.
6. Press the Action Control button again to exit calibration mode and store calibration number.
7. If "No Calc" is displayed on the LCD, the calibration process was not performed correctly. Contact Keeler for help if needed.

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

How to Start a New Patient

1. Hold the Up and Down control buttons on the AccuPen simultaneously for 2 to 3 seconds.
2. A single beep from the instrument will indicate that all IOP measurements, averages, CCT entries, and calculations are set to zero.

Figure 3.7 - Measurement Screen Starting New Patient

WARNING! THE ACCUTIP COVER MUST BE REPLACED BEFORE TAKING ANY MEASUREMENTS ON A NEW PATIENT.

How to Take a Measurement

Figure 3.8 - Capturing a Measurement

1. Touch and hold the Up and Down control buttons on the AccuPen simultaneously for 2 to 3 seconds to reset all measurements, averages, and IOP information to zero.
2. In measurement position, 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 emit short chirps (beep) and then a longer chirp (beep) when you have automatically acquired a measurement.
5. The AccuPen will emit three high-pitched chirps (beeps) when the ninth measurement has been taken, or if the measurement time expires.

Notes

1. The AccuPen can take up to nine 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 that 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:

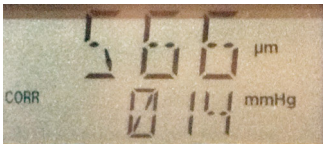


Figure 3.9 - Adjusted IOP Screen

1. From the Measurement screen, select the MCCT screen by pressing and holding the Action Control button for 2 to 3 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 releasing 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, Pages 88, 89, 90.

WARNING! CCT ADJUSTMENTS ARE NOT SUPPORTED BY PERFORMANCE DATA.

4 Maintenance, Storage & 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 affect electronic parts.

Refer to page 3 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 Chapter 2 for detailed cleaning instructions and see Chapter 3 for battery specification and installation.

Storage

1. When not in use, the AccuPen Tonometer and all accessories should be placed 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 4.1 below for information on identifying and correcting problems that can occur with the AccuPen.

Table 4.1 - AccuPen Troubleshooting Information

Symptom	Probable Cause	Correction
"LOW BATT" displayed	Battery is low	Replace battery (see Chapter 3)
Multiple variable readings	Improper technique	Review measurement technique

Table 4.1 - Continued AccuPen Troubleshooting Information

Symptom	Probable Cause	Correction
Multiple variable readings	Battery is low	Replace battery (see Chapter 3)
	Mechanical or electronic damage	Arrange for repair through Keeler Technical Service Group (see Chapter 6)
No beep and/ or no display upon activation	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 Keeler Technical Service Group (see Chapter 6)
No readings	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 Keeler Technical Service Group (see Chapter 6)
"NO CALC" displayed	Out of calibration	Recalibrate unit (see Chapter 3)
"ERR 0" displayed	Measurable range out of tolerance	Arrange for repair through Keeler Technical Service Group (see Chapter 6)
"ERR 1" displayed	Measurable range out of tolerance	Arrange for repair through Keeler Technical Service Group (See Chapter 6)
"ERR 2" displayed	Measurable range out of tolerance	Arrange for repair through Keeler Technical Service Group (See Chapter 6)

5 Specifications

Overview

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

Physical Specifications

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

Table 5.1 - 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	
Tip	300 Series Stainless Steel
Sampling Rate	
Rate	1KHz
Safety	
Meets EN 60601-1 Series electrical standards for medical equipment.	

Environmental Specifications

Table 5.2 below lists the AccuPen 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 AccuPen accuracy.

Table 5.3 - 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 guide. Portable and mobile RF communications equipment can affect medical electrical equipment.

Table 5.4 - 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 ensure 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	N/A	

Table 5.5 - 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 ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
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 5.6 - 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 ensure 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 $d = 1.2\sqrt{P}$ 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a]should be less than the compliance level in each frequency range. [b]Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 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 reorienting or relocating the AccuPen.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 5.7 - 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 Transmitter W	**Separation Distance According to Frequency of Transmitter m**		
	150 kHz to 80 MHz d = 1.2√P	80 MHZ to 800 MHz d = 1.2√P	800 MHz to 2,5 GHz d = 1.2√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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher-frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

6 Warranty & Repairs

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 one year 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 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 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

Follow the instructions given below to return products to Keeler.

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 Material Authorization (RMA) number.

Toll Free	(800) 523-5620
Phone	(610) 3534350
Fax	(610) 353-7814

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

Product Specialist Group
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 RGA 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 will not authorize a return for:

- Merchandise held longer than 30 days

Replacement Parts

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

Table 6.1 - Keeler Replacement Parts

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

Keeler
3222 Phoenixville Pike
Building 50
Malvern, PA 19355 USA
Toll Free: 1-800-523-5620
Tel: 610-353-4350
Fax: 610-353-7814
Email: customerservice@keelerusa.com
Website: www.keelerusa.com

Keeler Ltd.
Clewer Hill Road, Windsor
Berkshire, SL4 4AA, UK
Tel: +44 (0) 1753 857177
Fax: +44 (0) 1753 827145
Email: info@keeler.co.uk
Website: www.keeler.co.uk

Keeler
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