

PachPen® Handheld Pachymeter



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 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):

Emergo Europe P.O. Box 18510 2502 EM The Hague The Netherlands

Tel: (31) 70 345 8570 Fax: (31) 70 346 7299



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PachPen Overview

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

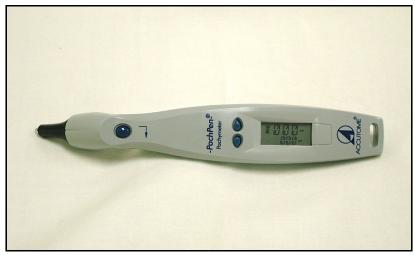


Figure 1 PachPen® Pachymeter

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

The PachPen 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 (71/4" X 11/4" X 11/4 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 settable 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

Introduction Features

Measurements

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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 4000 points per signal waveform
- Automatic gain control to acquire the optimum signal
- Highly sensitive 10.5MHz composite probe
- 20 individual signals acquired and analyzed to produce each measurement

About This Manual

This manual is a guide for technicians, optometrists, and opthalmologists who are experienced in ultrasonic biometric 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 PachPen basic operation.
Section 4	Maintenance	Provides general maintenance instructions
Section 5	Specifications	Provides PachPen physical and operational specifications
Section 6	Warranty and Repairs	Describes PachPen warranty information and repair procedures.

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



Safety Information

The section lists:

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

Safety Issues to Consider When Using the PachPen

The PachPen is non-invasive. 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 opthalmologists who are experienced in ultrasonic biometric techniques.

CAUTION:

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

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

Safety Precautions

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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.

Sterilization

Sterilization issues are confined to the PachPen probe that comes in contact with the patient's eye. 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 sterilization techniques.

The probe tip should be sterilized or disinfected before use on each patient.

The recommended sterilization technique is to immerse the probe tip (and only the probe tip) in an antibacterial solution. Follow the manufacturer's written protocol when using any antibacterial solution.

Disinfection and Cleaning

Disinfection issues are confined to the PachPen probe that comes in contact with the patient's eye. 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.

The probe tip should be sterilized or disinfected before use on each patient.

The recommended disinfection technique is to gently wipe the probe tip with isopropyl alcohol (and no other substance). It is imperative that the alcohol be given

time to evaporate before applying a probe to the patient's eye.

WARNING!

DO NOT AUTOCLAVE!

WARNING!

DO NOT IMMERSE THE ENTIRE PachPen IN ANY LIQUID. ALLOW TO DRY BEFORE USE.

Cleaning

Keep the surfaces of the PachPen 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 PachPen.

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 and component cables as needed. 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. Disinfect the probe after cleaning.

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 3.6 V lithium battery.

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.

ALARA Principle

This instrument has no user operated controls or settings that affect the acoustic output.

When using the device, the ALARA (As Low As Reasonably Achievable) principle should be followed. This principle is used to reduce unnecessary, potentially hazardous exposure to individuals, by keeping doses and test repetition As Low As Reasonably Achievable to achieve the required diagnostic information.

Accutome PachPen User Guide



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:

- 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 2 PachPen® 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 PachPen is 3.6 V Lithium battery. The battery is included with the PachPen and

must be installed before use.

Battery Specification

Use only one (1) 3.6 volt, TADIRAN model TL-5902/S 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:

- Locate the battery compartment (see Figure 3 below) on the bottom 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 Tadiran model TL-5902/S Lithium battery, or an equivalent, into the battery compartment as shown in Figure 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 PachPen® PACHYMETER.

Initial PachPen Pachymeter Setup

The steps below outline the basic setup of the PachPen.

- If the battery is not installed in the PachPen, install the battery as described in "Battery Installation" on page 13 of this manual.
- 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.

3. 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



Figure 5 Speed of Sound Screen

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

- 1. Power on the PachPen instrument.
- **2.** Take up to nine measurements.
- **3.** Enter the measured IOP and calculate the corrected IOP for each eye.
- 4. 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 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.

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



Figure 6 Measure Screen Displayed

How to Start a New Patient

To start a new Patient:

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



Figure 7 Measure Screen Starting New Patient

WARNING!

The probe tip must be properly sterilized or disinfected before taking any measurements on a new patient.

How to Take a Measurement

To take a patient measurement:

 Touch and hold the Up and Down control buttons on the PachPen 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 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.
- The PachPen will emit a high pitched chirp (beep) when you have automatically acquired a measurement.
- The PachPen will emit three high pitched chirps (beeps) when the 9th measurement has been taken, or if the measurement time expires.

Notes

- 1. The PachPen can take up to 9 measurements and provide the average of those measurements. This average is the number used when calculating the True IntraOccular Pressure (TIOP).
- 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 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:

- From the Measurement Screen, select the MIOP screen by pressing and holding the Action Control button for two to three seconds.
- 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.
- the True 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 8 True 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.



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 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 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

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Clean the PachPen Pachymeter by wiping everything except the tip with a clean, lint-free, non-abrasive 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 Section 3 for battery specification and installation.

Battery Disposal

Follow the procedure outlined below for proper disposal of lithium batteries

Instructions for Disposal

- 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 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.

The state of the state of the state of

 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.
- 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 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 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

<u>LABEL REQUIREMENTS:</u> 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

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

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Troubleshoot- Refer Table 2 below for information in identifying and correcting problems that can occur with the PachPen.

Table 2 PachPen Troubleshooting Information

Symptom	Probable Cause	Correction		
A. "LOW BATT" displayed	A. Battery is low	A. Replace battery (See Section 3.)		
B. Multiple vari- able 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 tech- nique	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.)		



Overview This section provides the physical and operational

specifications of the PachPen.

Physical Specifications

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

Table 3 PachPen Physical Specifications

Main Unit				
Dimensions	18.4 cm X 3.2 cm X 3.2 cm (71/4" X 11/4" X 11/4")			
Weight	85 g (3 oz)			
Display				
Туре	Multi Segment Monochrome Liquid Crystal Display (LCD)			
Size	28.6 mm (1.13") Diagonal Viewable Area			
Probe Frequency	10.5 MHz, Composite			
Sampling Frequency	65 MHz			
Safety				
Meets EN 60601-1 Series electrical standards for medical equipment				

Environmental Specifications

Table 4 below lists the PachPen 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 PachPen accuracy.

Table 5 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 6 Operating Mode(s)

Clinical Application	A	В	М	PWD	CWD	CD	Com- bined (Specify)	Other† (Specify)
Ophthalmic	Х							
Fetal Imaging & Other*								
Cardiac, Adult &								
Pediatric								
PeripheralVes- sel								

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

[†] Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

Acoustic Output

Table 7 below provides the acoustic output reporting for the following:

System: PachPen

Transducer Model A-Mode Probe

Operating Mode: A-Mode

Application(s): Ophthalmic

Table 7 Acoustic Output Reporting Table for Track 1
Non-Autoscanning Mode

Acoustic Output			MI	I _{SPTA.3} (mW/cm ²)	I _{SPPA.3} (W/cm ²)
Maximum Value			0.182	0.022	15.34
	P _{r.3} (MPa)		0.656		
Associ- ated Acoustic Parame- ters	W ₀	(mW)		0.000256	0.000256
	f _c (MHz)		12.93	12.93	12.93
	z _{sp} (cm)		0.3	0.3	0.3
	Beam dimen- sions	x ₋₆ (cm)		0.124	0.124
		y ₋₆ (cm)		0.124	0.124
	PD	(ìS)	0.071		0.071
	PRF	(Hz)	20		20
	EBD	Az (cm)		0.224	
		Ele. (cm)		0.224	
Operating Control Conditions					



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.

263 Great Valley Pkwy

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 8 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 8 Accutome Replacement Parts

Description	Accutome Part No.			
Standard Parts				
Battery	24-5101			

Accutome PachPen User Guide