AccuPach VI
Tabletop Pachymeter

AccuPach VI User's Guide

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

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

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

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

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

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

The AccuPach VI is manufactured and trademarked by:
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Introduction

AccuPach VI Overview

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

Figure 1.1 - AccuPach VI

Features

The AccuPach VI is designed for easy access to all screens and functions. The unsurpassed ease of use of the touchscreen, and the straightforward Graphical User Interface guide you through every operation.

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

The AccuPach VI provides the following general features:
- 128 X 64 high-resolution LCD screen with touchscreen to provide an intuitive user interface
- External, universal input, worldwide power supply
- 10" X 10" X 2 3/4" size makes the unit very portable
- Synthesized voice output of each measurement for ease of use
- Allows entry of Intraocular Pressure (IOP) and provides Corrected IOP based on corneal thickness measurements
- Adjustable handle/stand allows viewing at different angles
- User-settable speed of sound
- Display of measured corneal thickness, entered IOP, Corrected IOP, and average and standard deviation for all stored measurements

- Automatically or manually capture and store up to nine measurements for each eye, along with the running average of all measurements taken

Measurements

- The high accuracy of the AccuPach VI measurements is provided by the following:
- High-resolution, real-time waveform analysis
- High-speed signal digitalization that acquires over 4,000 points per signal waveform
- Automatic gain control to acquire the optimum signal
- Highly sensitive 10.5 MHz composite probe
- 20 individual signals acquired and analyzed to produce each measurement

Components

The components that are standard with each AccuPach VI instrument are:

- Ultrasonic probe
- Keyboard
- USB flash drive

Optional Components

There are also several components that further simplify the use of the AccuPach VI:

- Footswitch
- User-supplied computer
- User-supplied external printer

About This Manual

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 AccuPach VI basic operation.
Chapter 4 - Maintenance
Provides general maintenance instructions.
Chapter 5 - Specifications
Provides AccuPach VI physical and operational specifications.
 Chapter 6 - Warranty & Repairs
Describes AccuPach VI warranty information and repair procedures.

After reading this manual, you will be able to set up the AccuPach VI, take measurements, enter and calculate Corrected IOP, and print and save patient records.

2 Safety

Safety Information
The section lists:
- Specific safety precautions associated with the AccuPach VI
- General safety precautions

Safety Issues to Consider When Using the AccuPach VI
The AccuPach VI is noninvasive. The ultrasonic biometry probe touches the surface of the anesthetized cornea during the scanning process.

Contraindications
There are no known contraindications for the AccuPach VI device.

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 AccuPach VI include on external, structurally intact areas of the eye globe and orbit only.

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

Disposal of the Product within the EU
EU directives and national regulations currently in force at the time of marketing prohibit the disposal of the AccuPachVI specified on the delivery note in domestic waste or by municipal waste-disposal companies. If the AccuPach Vi or its components are resold, the seller has the duty to notify the buyer that the product must be diposed of in accordance with currently valid national regulations.

Safety Precautions
There are several areas in the use of the above AccuPach VI that require special attention, as they may pose a safety threat.

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

Symbol Definitions for the AccuPach VI

Attention! Consult Instruction Manual

Type B Medical Device

No User Serviceable Parts

Do Not Use Near Flammable Gases

Single Phase Alternating Current

Disposal of Product within the EU

Keyboard Connector

Footswitch Input Connector

Electrical Shock Hazard

Fuse

Ultrasound Probe Connector

Accessories such as the extension handle or Goldman Tonometer Adapter that might come in contact with eye fluids should be cleaned with an FDA-cleared high-level disinfectant.

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

Warnings

DO NOT AUTOCLAVE THE PROBES OR CONNECTORS.

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

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

Cleaning Procedure at Point of Use

1. Wear protective gloves when performing the cleaning process.
2. Disconnect the probe from the system.
3. Use a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any particulate matter or body fluids that remain on the probe or cable.
4. To remove remaining particulates, rinse with a distilled water–dampened cloth to remove soap residue, and then wipe with a dry cloth.

Disinfection of the Probes with Alcohol

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

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

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

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

High-Level Disinfection of the Probe

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

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

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

CAUTION: No abrasive or harsh cleaning solutions should be used while cleaning the AccuPach VI or any of its components.

Electrical Hazard and Safety

The instrument, footswitch, and probe of the AccuPach VI are electrical/electronic devices. Reasonable care should be taken when making an electrical connection and handling electrically powered devices. Avoid the use of damaged electrical equipment or frayed electrical cords. If repair or maintenance is to be performed on the AccuPach VI, the equipment must be turned off and the power cord disconnected.

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 AccuPach VI without protective covers.

The system is intended to operate from a power source of 100-240 VAC, 47-63 Hz. Protective earth grounding through the grounding connection in the power cord is essential for safe system operation.

Use only a hospital-grade power cord and the connectors supplied with the AccuPach VI. Also, be sure the power cord and connector are in good condition.

Note: The power switch on the AccuPach VI device will not completely issolate the device from power. In order to safely isolate the unit from power, the AccuPach VI must be unplugged.

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

WARNING! THE ACCUPACH VI PRODUCT IS ONLY TO BE USED WITH A MEDICAL-GRADE POWER SUPPLY.

WARNING! DO NOT POSITION THE ACCUPACH VI IN A WAY THAT WILL MAKE IT DIFFICULT TO OPERATE THE DICONNECTION DEVICE WHEN AN APPLIANCE COUPLER OR SEPARABLE PLUG IS USED AS ISOLATION MEANS.

WARNING! THE ACCUPACH VI DEVICE CONTAINS A POTENTIAL EQUALIZATION CONDUCTOR THAT PROVIDES A CONNECTION BETWEEN EQUIPMENT AND THE POTENTIAL EQUILIZATION BUSBAR OF THE ELECTRICAL INSTALLATION. THIS CONDUCTOR TERMINAL IS REQUIRED BY 60601-1:2005 TO BE ACCESSIBLE TO THE OPERATOR WITH THE ME EQUIPMENT IN ANY POSITION OF NORMAL USE AND SHALL ALLOW THE CONDUCTOR TO BE DETATCHED WITHOUT THE USE OF A TOOL. THE RISK OF ACCIDENTAL DISCONNECTION SHALL BE MINIMIZED IN NORMAL USE.

Avoiding Equipment Damage

The only peripheral equipment that may be connected to an AccuPach VI is a printer that has been selected and installed in compliance with EN60601-1 requirements.

The AccuPach VI 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.

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

Avoiding Electromagnetic and Other Interference

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

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

WARNING! THE ACCUPACH VI SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE ACCUPACH VI SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

3 Getting Started

Assembling the AccuPach VI

The AccuPach VI is designed to be used in multiple medical settings and can be rested on a surface, such as a counter or desk. The AccuPach VI requires little assembly. All components, standard and optional, can be quickly and easily connected.

What You Need

For a complete AccuPach VI setup, you will need the following:

- AccuPach VI instrument including display
- Ultrasonic Probe
- Keyboard
- Power Cord
- USB Flash Drive
- Footswitch - Optional Accessory
- Computer and Printer- User Supplied

Figure 3.1 - AccuPach VI Components

Probe

The probe provided with the AccuPach VI is an essential component of the AccuPach VI. No other probes should be used with the instrument.

Keyboard

The keyboard is not required for operation but provides convenience for entering alphanumeric data when saving a patient report to the USB Flash Drive.

Footswitch

The footswitch can be used to capture measurements.

Note: The footswitch is ONLY to be used on the floor and only actuated by the operator's foot. It is never to be operated as a handheld switch

USB Flash Drive
The USB Flash Drive is used to store patient data, which can be transferred to a computer for storage, or printed.

Placing the AccuPach VI
The AccuPach VI is designed to be placed on a surface, such as a counter or a desk.

Connecting the Components
All of the connectors for the AccuPach VI components, except for the probe and USB Flash Drive, are located on the back of the instrument.

Connecting the Footswitch
To connect the footswitch:
1. Locate the footswitch connector on the back of the instrument.
2. Insert the connector of footswitch cable into the footswitch connector.

Connecting the Keyboard
To connect the keyboard:
1. Locate the keyboard connector on the back of the instrument.
2. Insert the connector of keyboard cable into the keyboard connector.

Figure 3.2 - Footswitch and Keyboard Connector

Connecting the Probe
The AccuPach VI probe connector is located on the front of the instrument.
To connect the probe:
1. Locate the probe connector on the front of the instrument.
2. Insert the probe.

Figure 3.3 - Probe Connector (front of unit)

Figure 3.4 - Probe Connected

Connecting the Power

To connect the power:

1. Locate the power entry connector on the back of the instrument (see figure below).
2. Insert the power cable provided with the AccuPach VI into the power connector.
3. Connect the power cable to the power mains.

Figure 3.5 - Component Connectors (back of instrument)

How to Set Preferences

There are several features of the AccuPach VI that you can set to your own preferences:

- Speed of sound
- Readings captured automatically or with the footswitch
- Instrument clock
- LCD presentation
- Annunciator to provide voice output

Note: The AccuPach VI uses an LCD with a touchscreen as the user interface. To make selections, touch and release the appropriate box displayed on the LCD.

After setting up the AccuPach VI, set the instrument preferences by turning the unit on and selecting the Util box on the touchscreen. The AccuPach VI will then display the preferences screen.

Setting the Speed of Sound

To set the speed of sound:

1. The current setting for the speed of sound is displayed along with Up and Down boxes (default factory setting is 1640).
2. Select either Up or Down to change the speed of sound as you wish. When finished, select Done to return to the Util screen.

Setting the Method for Capturing Readings

The AccuPach VI is designed so that you can take readings automatically or manually by using the footswitch. The factory default is automatic readings and is displayed as Read Auto.

To change the method for capturing readings:

1. The Read selection toggles between Auto and Manual. If you wish to use the footswitch to trigger readings, select Read Auto and it will change to Read Manual.
2. If you wish to switch from the footswitch to auto capture, select Read Manual and it will change the unit to Read Auto.

Setting the Clock

There is a date/time stamp printed on every patient record. When you first receive the AccuPach VI, you will need to correctly set the instrument clock.

To set the clock:

1. Activate the clock setting by selecting Set Clock.
2. Set the day of the week by selecting Up or Down.
3. Select Next to set the next part of the date and time. Continue selecting Up or Down to change the values and Next to set the next part of the date and time.
4. Select Done when finished to return to the Util screen.

Setting the LCD Presentation

The AccuPach VI allows you to adjust the LCD display and brightness with the Screen function.

To set the LCD presentation:

1. Set the LCD presentation by selecting Screen. This will allow you to change the screen presentation from Normal (factory default) to Reverse (inverse video) by selecting the appropriate box.
2. Screen brightness can be changed by selecting Up or Down. When finished, select Done to return to the Util screen.

Setting the Annunciator

The AccuPach VI has an annunciator to provide a voice output of the measurements taken. The factory default is to have this voice output on.

If you wish to change the voice volume level:

1. Select the Util box on the LCD.
2. Select the Speech box on the LCD.
3. Select the Up box to increase the volume of the voice.
4. Select the Down to decrease the volume of the box.
5. Select Done box to return to Util screen.

Note: The volume levels are 1 thru 7. Each time the volume is increased or decreased, the voice will repeat "Accutome AccuPach VI" at the selected volume.

If you wish to turn the voice output off:
1. While in Speech screen, select Mode On box to turn the voice off.
2. To turn the voice back on, select Mode Off.
3. Select Done to return to Util screen.

Returning to the Measure Screen
When finished setting the unit preferences, select Meas to return to the measurement screen.

Basic Operation
The basic operation of the AccuPach VI consists of the following steps:
1. Power on the AccuPach VI instrument.
2. Adjust the LCD display contrast.
3. Take up to 9 measurements per eye.
4. Enter the measured IOP and calculate the corrected IOP for each eye.
5. Save the Patient Record.
6. Print the Patient Record (if printer is connected).

How to Power On the AccuPach VI
To power on the AccuPach VI:
1. Press the "I" on the power rocker switch. When you power on the AccuPach VI, a splash screen will appear. The AccuPach VI will go through an initialization process and when completed will display the Measure screen.
2. The first screen you see will be the Measure screen.

Figure 3.6 - Measure Screen Displayed

Using the Test Block
The AccuPach VI is equipped with a test block, located on the top of the instrument. The test block is provided as a way to test the basic
operation of the AccuPach VI and the probe.
To test the AccuPach VI and probe:
1. Apply some immersion fluid (water or BSS) to the test block.
2. Place the probe on the test block.
3. You should receive a measurement in the Measure screen.

Figure 3.7 - AccuPach VI Test Block (top of instrument)

Note: If you cannot detect a waveform, call the Accutome Service Group at (610) 889-0200.

WARNING! DO NOT USE THE TEST BLOCK AND THEN TAKE A PATIENT MEASUREMENT. DISINFECT THE PROBE TIP AFTER USING THE TEST BLOCK AND BEFORE TAKING A PATIENT MEASUREMENT.

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How to Start a New Patient

To start a new Patient:
1. Touch and release the New Patient box on the LCD.
2. When you start a new patient, the AccuPach VI will set all measurements, averages, IOP entries, and calculations to zero.

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

Figure 3.8 - Measure Screen Starting New Patient

How to Take a Measurement

To take a patient measurement:
1. Select the New Patient box on the LCD display to reset all measurements, averages, and IOP information to zero.
2. Choose the appropriate eye by selecting the OD or OS box on the LCD. Selecting this box again returns it to the other eye.
3. Apply the probe to the patient's eye.
4. If the AccuPach VI is not in the Auto Read mode, press the footswitch to take the measurement. The AccuPach VI will automatically proceed to the next empty measurement if it is available.
5. The AccuPach VI will emit a high-pitched chirp when you have automatically acquired a measurement.

Notes

1. The AccuPach VI can take up to nine measurements for each eye and provide the average of those measurements. This average is the number used when calculating the True IntraOccular Pressure (TIOP).
2. The * symbol by a measurement indicates the reading for that eye that is furthest away from the average for that eye.
3. You can review the measurements taken by selecting (touching and releasing) the measurement value.
4. You can delete any measurement taken by touching and holding the measurement value (until the unit emits a high-pitched chirp). After deleting a measurement, the unit will automatically recalculate the average of the measurements.

How to Perform a Calculation

After you have completed a patient's measurements, you can calculate the true IOP for the patient. You can perform the calculation from the MIOP Screen.
To calculate True IOP:
1. Select the Miop box on the LCD.
2. Enter the measured IOP by selecting the digits of the measurement. For example, if the measured IOP is "17", select "1", then select "7". If you make a mistake, just reselect the correct digits.
3. Select the Calc box on the LCD and the True IOP will then be displayed.

4. Select Meas and return to the Measurement screen. 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.

How to Save a Record

After you have completed a patient exam, you may want to save the record to a USB flash drive. Using the flash drive allows the user to save and print a patient's record to/from any computer.

To save a record:

1. Select the Util box on the LCD.
2. Select the Save Ready box on the LCD.

Figure 3.9 - USB Flash Drive

Note: A USB flash drive must be plugged into the USB port, otherwise "Save No Disk" will be displayed. The USB flash drive can be plugged into the port at any time to activate the Save Ready function.

3. Begin typing on the keyboard if you wish to rename the file. The name of the file automatically defaults to the date.
4. Tab to Patient Name field to enter patient's name.

Note: The Tab button can be used to maneuver between the File Name and Patient Name fields.

Note: Any text entered in the Patient Name field will be displayed at the top of the Patient Record when opened. The record will be in .TXT format.

5. Select Save to save patient exam to USB flash drive.
6. Select Done to return to Util screen.

Note: If Done is selected prior to Save, the record will not be saved. The record can still be saved by simply running through the process again.

7. Remove USB flash drive from AccuPach VI unit to save or print record to/ from a computer.

How to Print a Record

In order to print a record, you will first need to save the record to the USB flash drive.
To print a record:
1. Follow the steps outlined in How to Save a Record on page 13.
2. Remove the USB flash drive from the Pach VI unit and plug it into any computer.
3. Access the USB flash drive as you would any external storage peripheral.
4. Open the exam (.TXT File) to be printed.
5. Click File and select Print

Figure 3.10 - Example of Patient Record Printout

4 Maintenance

General Maintenance

Maintenance that should be performed on the AccuPach VI 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 for details on sterilization, disinfection, and cleaning before doing any sterilization, disinfection, or cleaning of the AccuPach VI.

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

Regularly check the probe, footswitch, and mains power cable for cracked or frayed insulation or any other damage.

WARNING! DO NOT USE ANY PROBE, FOOTSWITCH, OR MAINS CABLE THAT HAS BEEN DAMAGED OR HAS CRACKED OR FRAYED INSULATION.

See Warranty & Repairs on page 21 of this manual for user-replaceable parts.

5 Specifications

Overview

This section provides the physical and operational specifications of the AccuPach VI.

Physical Specifications

The table below lists the physical specifications of the AccuPach VI instrument and associated peripherals.

Table 5.1 - AccuPach VI Physical Specifications

Main Unit	
Dimensions	25.4 cm X 25.4 cm X 6.35 cm (10" X 10" X 2.5")
Weight	1.4 kg (3.1 lb.)
Input Voltage	100-240 VAC, 47-63 Hz
Current	300 mA
Fuses	Littlefuse 218.001 (250V, 1A, Type T, 5 X 20 mm) T1AL, 250 V
Display	
Type	Monochrome Liquid Crystal Display (LCD)
Size	73.75 mm (2.9") Diagonal Viewable Area
Resolution	128 X 64 pixels, 16 shades of gray
External I/O Connectors	
Footswitch	3.5 mm mono phone jack
Probe (Use only Accutome PN 24-5001)	
Frequency	10.5 MHz, Composite
Dimensions	0.64 cm (0.25") diameter X 4.45 cm (1.75") length
Cable Length	1.52 m (5 ft.)
Keyboard (Use only Accutome PN 24-4003)	
Dimensions	29.19 X 13.21 X 2.29 cm (11.1" x 5.2" x 0.9")
Number of Keys	83
Footswitch (Use only Accutome PN 24-4004) - Optional Accessory	
Dimensions	8.9 cm (3.5") x 6.6 cm (2.6") x 2.5 cm (1")
Weight	0.2 kg (7 oz.)
Environmental	IP20, IP68

Table 5.1 - (Continued) AccuPach VI Physical Specifications

USB Flash Drive (Any USB Flash Drive can be used)
Safety
Meets EN 60601-1 Series electrical standards for medical equipment

Environmental Specifications

The table below lists the AccuPach VI 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

The table below lists the AccuPach VI accuracy.

Table 5.3 - Measurement Accuracy

Measurement	Corneal Thickness
Clinical Accuracy (1 Sigma)	+/- 5 Micrometers
Electronic Resolution (@1640 m/sec)	+/- 1 Micrometer
Range	300—999 Micrometers

Operating Modes

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

Table 5.4 - Operating Mode(s)

Clinical Application	A	B	M	PWD	CWD	CD	Combined (Specify)	Other** (Specify)
Ophthalmic	X							
Fetal Imaging & Other*								
Cardiac, Adult &								
Pediatric								
Peripheral Vessel								

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional), Musculo-Skeletal (superficial)
**Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

Acoustic Output

The table below provides the acoustic output reporting for the following:

System: AccuPach VI
Transducer Model: A-Mode Probe (S/N 0604-5651)
Operating Mode: A-Mode
Application(s): Ophthalmic

Table 5.5 - Acoustic Output Reporting Table for Track 1 Nonautoscanning Mode

Acoustic Output			MI	ISPTA.3 (mW/cm2)	ISPPA.3 (W/cm2)
Global Maximum Value			0.182	0.022	15.34
Associated Acoustic Parameter	Pr.3 (MPa)		0.656	---	---
	Wo (mW)		---	0.000256	0.000256
	Fc (MHz)		12.93	12.93	12.93
	Zsp (cm)		0.3	0.3	0.3
	Beam Dimensions	x-6 (cm)	---	0.124	0.124
		y-6 (cm)	---	0.124	0.124
	PD (msec)		0.071	---	0.071
	PRF (Hz)		20	---	20
	EBD	Az. (cm)	---	0.224	---
		Ele. (cm)	---	0.224	---

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 equipment.

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

The AccuPach VI is intended for use in the electromagnetic environment specified below. The customer or the user of the AccuPach VI should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11*	Group 1	The AccuPach VI 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 AccuPach VI is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

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

The AccuPach VI is intended for use in the electromagnetic environment specified below. The customer or the user of the AccuPach VI should assure 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 5.8 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the AccuPach VI, 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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [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: (((·ᵢ)))

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 AccuPach VI is used exceeds the applicable RF compliance level above, the AccuPach VI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AccuPach VI.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

6 Warranty & Repairs

Warranty

Accutome, Inc., warrants its new equipment to be free from defects in workmanship or materials. Any 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 nonwarranted items will be the responsibility of the customer. Alteration, repair, or modification of any product that is performed by persons not authorized by Accutome, Inc., will 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 US):	(800) 979-2020
International:	(610)-889-0200
Fax:	(610) 889-3233

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

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

All Other Returns

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

Merchandise returned within 30 days of date of invoice will be credited as follows:
• Full credit for all merchandise returned in resalable condition

Nonreturnable Merchandise

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

- Merchandise held longer than 30 days

Replacement Parts

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

Table 6.1 - Accutome Replacement Parts

Description	Accutome Part No.
Standard Parts	
Probe	24-5001
Keyboard	24-4003
Footswitch	24-4004
USB Flash Drive	24-6210
Power Supply Cable (US)	9510-1100