Tono-Pen AVIA Vet®

Veterinary Tonometer

User's Guide



AMETEK®
ULTRA PRECISION TECHNOLOGIES

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Table of Contents

Warnings and Cautions 4
Symbols..... 8
Introduction..... 9
- Indications for Use 9
- Contraindications 9
- Device Description 10
- Features..... 10
- Parts Identification.....11
- Accessories.....11
- Available Accessories 11

Instructions for Use 12
- Tono-Pen AVIA Vet Tonometer Modes 12
- Tono-Pen AVIA Vet Tonometer Verification 13
- Tono-Pen AVIA Vet Tonometer Tones..... 15
- Battery Installation and Replacement 16
- Liquid Crystal Display - User Interface..... 17
- Tono-Pen AVIA Vet Tonometer Preparation 19
- Verification Mode..... 20
- Performing IOP Measurements..... 21
- Applanation 22
- Interpreting the IOP Measurement..... 23

Cleaning & Maintenance 24
- Cleaning Instructions..... 24
- Battery..... 26
- Storage..... 26
- Disposal 26

Troubleshooting..... 27
Specifications 28
Guidance & Manufacturer's Declaration 30
Warranty..... 35

Warnings and Cautions

Reichert Technologies (Reichert) is not responsible for the safety and reliability of this instrument when:

- Assembly, disassembly, repair or modification is made by unauthorized dealers or persons.
- Instrument is not used in accordance with its User's Guide.

WARNING: AN INSTRUCTION THAT DRAWS ATTENTION TO RISK OF INJURY OR DEATH.

WARNING: UNITED STATES FEDERAL LAW AND EUROPEAN REGULATIONS REQUIRE THAT THIS DEVICE BE PURCHASED ONLY BY A PHYSICIAN OR A PERSON ACTING ON BEHALF OF A PHYSICIAN.

WARNING: DO NOT REPAIR OR SERVICE THIS INSTRUMENT WITHOUT AUTHORIZATION FROM THE MANUFACTURER. ANY REPAIR OR SERVICE TO THIS INSTRUMENT MUST BE PERFORMED BY EXPERIENCED PERSONNEL OR DEALERS WHO ARE TRAINED BY REICHERT OR SERIOUS INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: THIS INSTRUMENT SHOULD BE USED IN STRICT ACCORDANCE WITH THE INSTRUCTIONS OUTLINED IN THIS USER'S GUIDE. THE SAFETY OF THE OPERATOR AND THE PERFORMANCE OF THE INSTRUMENT CANNOT BE GUARANTEED IF USED IN A MANNER NOT SPECIFIED BY REICHERT TECHNOLOGIES.

WARNING: MODIFICATIONS TO THIS INSTRUMENT ARE NOT ALLOWED. ANY MODIFICATION TO THIS UNIT MUST BE AUTHORIZED BY REICHERT OR SERIOUS INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: IF THIS INSTRUMENT IS MODIFIED, APPROPRIATE INSPECTION AND TESTING MUST BE CONDUCTED TO ENSURE CONTINUED SAFE USE OF THIS INSTRUMENT.

WARNING: DO NOT USE THE TONO-PEN AVIA VET TONOMETER ON A PATIENT WITHOUT AN OCU-FILM + TIP COVER OR INACCURATE READINGS MAY BE OBTAINED.

WARNING: DO NOT USE AN OCU-FILM + TIP COVER ON MORE THAN ONE PATIENT TO HELP PREVENT CROSS CONTAMINATION.

WARNING: IT IS IMPERATIVE THAT A FRESH OCU-FILM + TIP COVER BE USED FOR EACH PATIENT FOR THE PROTECTION OF THE EYE AND THE TRANSDUCER ASSEMBLY. THE TRANSFER OF INFECTION IS THUS PREVENTED. REPLACE OCU-FILM + TIP COVERS AFTER EXAMINATION OF EACH PATIENT.

WARNING: DO NOT USE EXCESSIVE PRESSURE DURING APPLANATION OR EYE INJURY MAY OCCUR.

Warnings and Cautions (continued)

WARNING: DO NOT USE THE TONO-PEN AVIA VET TONOMETER IF THE TRANSDUCER ASSEMBLY IS CRACKED, CHIPPED OR SHOWS ANY IRREGULARITY OF THE SURFACE, TO PREVENT PATIENT INJURY, AND/OR INACCURATE READINGS.

WARNING: THE CORNEAL SURFACE NEEDS ONLY TO BE MOMENTARILY CONTACTED. INDENTATION OR ADDITIONAL PRESSURE AFTER THE AUDIO "CHIRP" TONE IS HEARD IS NOT REQUIRED AND MAY LEAD TO DAMAGE TO THE EYE. IF MEASUREMENT PROCESS CAUSES PATIENT DISCOMFORT, DEVICE DOES NOT SHOW A MEASUREMENT, OR IF DEVICE REQUIRES MULTIPLE ATTEMPTS TO OBTAIN A MEASUREMENT, STOP THE EXAMINATION AND REFER TO THE TROUBLESHOOTING SECTION OF THIS MANUAL.

WARNING: OCU-FILM + TIP COVERS CONTAIN NATURAL LATEX WHICH MAY CAUSE ALLERGIC REACTIONS. QUESTION PATIENTS ABOUT ALLERGIES TO LATEX BEFORE MEASURING THEM WITH THE TONO-PEN AVIA VET TONOMETER.

WARNING: DO NOT CARRY THE TONO-PEN AVIA VET POWERCEL BATTERY IN A POCKET, OR CLOSE TO YOUR PERSON, AS A BURN INJURY MAY RESULT.

WARNING: THE BATTERY SHOULD ONLY BE REPLACED WITH THE BATTERY SPECIFIED IN THIS MANUAL. USE OF ANOTHER BATTERY MAY CAUSE FIRE OR AN EXPLOSION.

WARNING: DO NOT PLACE A SHORTING DEVICE BETWEEN THE BATTERY TERMINALS, OR ALLOW THE BATTERY TO BECOME WET. MISUSE OR IMPROPER DISPOSAL OF THIS BATTERY MAY CAUSE IT TO BECOME VERY HOT, IGNITE OR EXPLODE. DAMAGE TO THIS UNIT AND/OR SERIOUS PERSONAL INJURY MAY RESULT.

WARNING: DO NOT RECHARGE THE BATTERY. THE BATTERY IS NOT DESIGNED TO BE CHARGED BY ANY ELECTRICAL SOURCE. CHARGING COULD GENERATE GAS AND INTERNAL SHORT-CIRCUITING, LEADING TO DISTORTION, LEAKAGE, OVERHEATING, EXPLOSION OR FIRE.

WARNING: NEVER ALLOW LIQUID LEAKING FROM THE BATTERY TO GET IN YOUR EYES OR MOUTH AS THIS LIQUID COULD CAUSE SERIOUS PERSONAL INJURY. IF IT COMES IN CONTACT WITH YOUR EYES OR MOUTH, FLUSH THEM IMMEDIATELY WITH PLENTY OF WATER AND CONSULT A PHYSICIAN.

WARNING: DO NOT EXPOSE THE BATTERY TO TEMPERATURES ABOVE 140ºF, DISASSEMBLE THE BATTERIES, OR DAMAGE TO THIS UNIT AND/OR SERIOUS PERSONAL INJURY MAY RESULT.

-CONTINUED-

Warnings and Cautions (continued)

WARNING: ALWAYS KEEP BATTERIES OUT OF THE REACH OF INFANTS AND YOUNG CHILDREN TO PREVENT THEM FROM BEING SWALLOWED. IF SWALLOWED, CONSULT A PHYSICIAN IMMEDIATELY.

WARNING: THE USE OF ACCESSORIES OR CABLES OTHER THAN THOSE SPECIFIED, WITH THE EXCEPTION OF THOSE SOLD BY THE MANUFACTURER AS REPLACEMENT PARTS FOR INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE EQUIPMENT OR SYSTEM.

WARNING: USE OF THIS EQUIPMENT ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS EQUIPMENT AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.

WARNING: PORTABLE RF COMMUNICATIONS EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF THE TONO-PEN AVIA VET, INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS EQUIPMENT COULD RESULT.

CAUTION: AN INSTRUCTION THAT DRAWS ATTENTION TO THE RISK OF DAMAGE TO THE PRODUCT.

CAUTION: DO NOT USE THE TONO-PEN AVIA VET TONOMETER WITHOUT AN OCU-FILM + TIP COVER TO PREVENT DAMAGE TO THE TRANSDUCER ASSEMBLY.

CAUTION: DO NOT TOUCH THE TRANSDUCER ASSEMBLY WITHOUT AN OCU-FILM + TIP COVER APPLIED OR DAMAGE TO THE TRANSDUCER ASSEMBLY MAY RESULT.

CAUTION: DO NOT BUMP, JAR OR DROP THE DEVICE BECAUSE DAMAGE TO THE ELECTRONICS OR TRANSDUCER MAY OCCUR. IF THE DEVICE IS DROPPED, CAREFULLY INSPECT THE DEVICE TIP FOR DAMAGE.

CAUTION: DO NOT IMMERSE THE TONO-PEN AVIA VET TONOMETER IN FLUIDS OR DAMAGE TO THE ELECTRONICS MAY OCCUR.

CAUTION: USE OF AMMONIA BASED CLEANERS ON THE LIQUID CRYSTAL DISPLAY (LCD) MAY CAUSE DAMAGE TO THE DISPLAY. SEE MAINTENANCE SECTION FOR DETAILED CLEANING INSTRUCTION.

CAUTION: DO NOT ATTEMPT TO STERILIZE THE TONO-PEN AVIA VET TONOMETER OR DAMAGE TO THE ELECTRONICS MAY OCCUR.

CAUTION: DO NOT USE SOLVENTS OR STRONG CLEANING SOLUTIONS ON ANY PART OF THIS INSTRUMENT AS DAMAGE TO THE UNIT MAY OCCUR. SEE MAINTENANCE SECTION FOR DETAILED CLEANING INSTRUCTION.

Warnings and Cautions (continued)

CAUTION: DO NOT AUTOCLAVE OR DISINFECT USING HIGH TEMPERATURES EXCEEDING THE RECOMMENDED TEMPERATURES INDICATED IN THE SPECIFICATIONS SECTION OF THIS MANUAL OR DAMAGE TO THE UNIT MAY OCCUR.

CAUTION: DO NOT ATTEMPT TO MODIFY THE TONO-PEN AVIA VET TONOMETER OR THE TONO-PEN AVIA VET POWERCEL BATTERY OR DAMAGE TO THE DEVICE MAY OCCUR.

CAUTION: DO NOT STORE THE TONO-PEN AVIA VET TONOMETER WITHOUT AN OCU-FILM + TIP COVER OR DEBRIS MAY ENTER THE TRANSDUCER ASSEMBLY AND CAUSE MALFUNCTIONS.

CAUTION: 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.

CAUTION: ELECTROMAGNETIC INTERFERENCE FROM OTHER DEVICES MAY AFFECT THIS INSTRUMENT. IF INTERFERENCE IS PRESENT, TURN OFF OTHER ELECTRONIC DEVICES, OR REMOVE THEM FROM THE IMMEDIATE AREA WHILE OPERATING THIS INSTRUMENT.

CAUTION: PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT CAN EFFECT MEDICAL ELECTRICAL EQUIPMENT.

CAUTION: THIS INSTRUMENT IS NOT TO BE USED NEAR HIGH-FREQUENCY EMITTING SURGICAL EQUIPMENT.

CAUTION: OCU-FILM + TIP COVERS SHOULD BE STORED BETWEEN 35° AND 80° FAHRENHEIT (2°-27° CELSIUS).

CAUTION: EACH BOX OF HIGH QUALITY OCU-FILM + TIP COVERS HAS A “USE BEFORE” DATE STAMPED ON THE BOX. WE SUGGEST USE OF OUR OCU-FILM + BEFORE THIS DATE TO GUARD AGAINST THE POSSIBILITY OF SHELF WEAR. THE LATEX MATERIAL USED IN THE OCU-FILM + TIP COVERS CAN DEGRADE. A DEGRADED FILM MAY RESULT IN LEAKAGE OF WETTING SOLUTION AND INSTRUMENT DAMAGE. EXAMINE EACH OCU-FILM + TIP COVER FOR YELLOWING, CRACKS, OR A STICKY TEXTURE PRIOR TO USE.

CAUTION: IF LIQUID IS SPILLED ON THE DEVICE, REMOVE THE BATTERY AND RETURN THE TONO-PEN AVIA VET TO REICHERT FOR SERVICE. LIQUID MAY DAMAGE THE ELECTRONICS.

Symbols


Caution, See Instructions for use

REF Catalog Number

SN Serial Number



Date of Manufacture


Manufacturer


Waste of Electrical and Electronic Equipment


Low Voltage Directive 2014/35/EU and EMC Directive 2014/30/EU


Consult Instructions for Use



Authorized Representative in European Community


Fragile Contents in Shipping Container - handle with care


Do not get Shipping Container wet


Type BF Applied Part

SYMBOLS FOR OCU-FILM + TIP COVERS ONLY


Do not reuse. Single Use


Use By

LOT Lot Number



Contains natural rubber latex

Introduction

Congratulations on your purchase of the Tono-Pen AVIA Vet® veterinary tonometer.

The Tono-Pen AVIA Vet tonometer is a prescription only device intended for measuring intraocular pressure (IOP) during routine eye examinations or when increased intraocular pressure is suspected by properly trained eyecare professionals such as veterinarians, and veterinary technicians.

Note: The Tono-Pen AVIA Vet is not approved for use on humans.

This User's Guide is designed as a training and reference manual for operation, maintenance, and troubleshooting. We recommend that you read it carefully prior to use and follow the instructions in the guide to ensure optimum performance of your new instrument. If used properly, the Tono-Pen AVIA Vet tonometer will provide you with fast, accurate and reliable measurements for many years. Properly trained eyecare professionals such as veterinarians, and veterinary technicians should operate this instrument.

Please retain this manual for future reference and to share with other users. For additional copies of this manual or questions related to the Tono-Pen AVIA Vet tonometer, contact your local authorized Reichert® dealer or contact our Customer Service department directly at:

Tel: 716-686-4500
Toll Free: 888-849-8955
Fax: 716-686-4555
E-mail: reichert.information@ametek.com

Indications for Use

The indications for use include measuring intraocular pressure (IOP) for suspected glaucoma, or when increased intraocular pressure is suspected.

Contraindications

None.

Device Description

The Tono-Pen AVIA Vet tonometer is an ergonomic, hand-held tonometer that measures intraocular pressure. The body of the instrument is designed to fit comfortably in the user's hand, facilitating fast and accurate measurements. The tip of the tonometer contains a sensor that houses a transducer assembly which converts applied force into an electrical signal. The electronics housed in the ergonomic Tono-Pen AVIA Vet tonometer body process and analyze the waveforms produced by each applanation of the corneal surface of the eye. These are used to produce an averaged IOP measurement. The measurement is displayed on the Liquid Crystal Displays (LCDs).

A replaceable battery compartment houses the Tono-Pen AVIA Vet POWERCEL® battery pack, consisting of two Lithium Manganese Dioxide batteries.

Features

The Tono-Pen AVIA Vet tonometer has the following features:

- Easy to use - IOP can be measured reliably by veterinary professionals.
- Portable - The Tono-Pen AVIA Vet tonometer weighs just 71 g (2.4 oz) and is battery operated.
- Accurate - The measurements from the Tono-Pen AVIA Vet tonometer correlate strongly with Goldmann applanation tonometry and direct measurements of IOP.
- Versatile - The Tono-Pen AVIA Vet tonometer may be used easily with the patient in any position, making the instrument suitable for the office and in remote locations.

Parts Identification

A. Tip – location of sensor.
B. Transducer Assembly - housing for sensor.
C. LCD - displays the IOP in mmHg, number of applanations collected, statistical confidence indicator, and battery life status.
D. LED - green light on in Applanation Mode.
E. Power Supply - Tono-Pen AVIA Vet POWERCEL battery pack.
F. Activation Button - Applanation Mode select button.

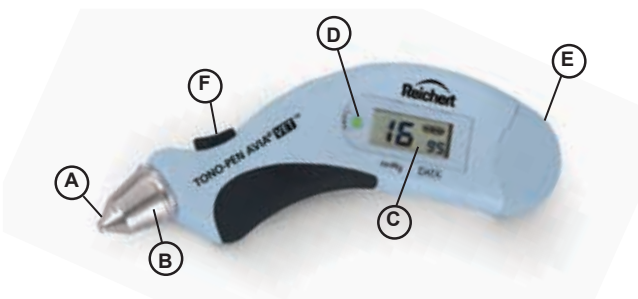


Figure 1. Key Features

Accessories

230751	Tono-Pen AVIA Vet POWERCEL™ Battery
230651	Ocu-Film® + Tip Covers (150 per box)
68C1334	Carrying Case
230750-101	User's Guide
230750-104	Quick reference Guide

Available Accessories

230651	Ocu-Film + Tip Covers (150 count per box)
230653	Ocu-Film + Tip Covers (600 count bulk bag)

Tono-Pen AVIA Vet Tonometer Modes

Power Up Mode

Pressing the activation button initiates the battery life, LCD, Transducer Assembly, and electronic self-test. A successful power-up puts the device automatically into applanation mode.

Applanation Mode

The user will have 15 seconds after pressing the activation button to obtain the first applanation. 2-6 applanations are needed to acquire an IOP value. During applanation mode, the LCD will display the IOP and number of applanations collected. After 6 applanations are collected, the LCD will display the final OP along with a statistical confidence indicator. After 25 seconds, the device will automatically go into a sleep mode. If the activation button is pressed again the data will be cleared and the unit will be ready to start another measurement sequence.

Verification Mode

Pressing and holding the activation button for 5 seconds initiates an electronic self test mode. See Tono-Pen AVIA Vet Tonometer Verification section for details.

Sleep Mode

A power-saving mode automatically activates after 25 seconds of non-use. Pressing the activation button will initiate a power-up mode.

Tono-Pen AVIA Vet Tonometer Verification

If suspect readings are observed, a verification test should be performed. This will ensure that the Transducer Assembly and electronics are performing correctly.

Verification

1. Hold the Tono-Pen AVIA Vet tonometer with the Transducer Assembly end pointing down towards the floor.
2. Press and hold the activation button for 5 seconds - a beep will sound at one second intervals.
3. At the end of the 5 second button hold, the display will show **[dn]**.
4. Keep the pen vertical, with the Transducer Assembly pointing down towards the floor, for a total of 15 seconds.
5. At the end of this period, a beep will sound and the display will show **[UP]**.
6. Immediately point the Transducer Assembly straight up and wait for the next beep (within 3 seconds).



Figure 2. Tono-Pen AVIA Vet Verification Procedure

-continued-

Verification (continued)

7. A properly functioning Tono-Pen AVIA Vet tonometer will display **[PASS]**. Pressing the activation button will now put the device into Applanation Mode.



Figure 3. Tono-Pen AVIA Vet Verification Pass

8. Verification test will need to be repeated if the display shows **[FAIL]**. A single press of the Activation button will re-start the verification test.

Note: The Tono-Pen AVIA Vet tonometer will remain in the Verification mode until it passes verification test.

9. The most common cause for failure is debris in the tip of the Transducer Assembly. Follow the instructions for cleaning the tip in the “Maintenance & Storage” section before re-performing the verification test.
10. If this is unsuccessful, please contact the Reichert Technical Service Department.

Tono-Pen AVIA Vet Tonometer Tones

The Tono-Pen AVIA Vet tonometer generates two different tones.
A “BEEP” will sound when:

- Power Up Mode fails
- Verification Mode fails
- Applanation Mode starts
- IOP testing is completed
- IOP values are out of range (>99)
- At various points during the verification test.

A “CHIRP” will sound when:

- A valid IOP measurement has been taken during applanation.

Battery Installation and Replacement

The Tono-Pen AVIA Vet tonometer is supplied with a Tono-Pen AVIA Vet POWERCEL Battery that needs to be installed prior to use. The Tono-Pen AVIA Vet POWERCEL Battery is the only replacement battery that can be used with this device.

1. Insert the Tono-Pen AVIA Vet POWERCEL Battery into the base of Tono-Pen AVIA Vet tonometer until fully seated. The Battery is “keyed” for correct installation.
2. Press the Activation Button.
3. Check that the battery symbol in the LCD has all segments displayed.
4. Check that the Self-Test is initiated.
5. Dispose of used Batteries in accordance with local regulations.



Figure 4. Tono-Pen AVIA Vet POWERCEL Battery Installation and Replacement

Liquid Crystal Display - User Interface

POWER UP MODE - USER INTERFACE SEQUENCE OF EVENTS		
	User Interface LCD/Battery Test	LED Off Passed Battery Life Test/Passed LCD Test

(SEE APPLANATION MODE)

POWER UP MODE - USER INTERFACE ERROR CODES		
	User Interface Error Code	LED Off Battery Level Critical (when low, symbol will flash)
	User Interface Error Code	LED Off Failed Self Test

APPLANATION MODE - USER INTERFACE SEQUENCE OF EVENTS		
	User Interface Ready to Measure	LED On, 1 Beep Ready to Begin IOP Testing (15 seconds for testing before Time Out)
	User Interface Testing Display	LED On During Test, screen shows number of applanations achieved (in this case 4 of 10) Each applanation taken equals 1 Chirp
	User Interface Test Complete	LED Off, 1 Beep Test Complete Patient has an IOP of 16 with a statistical confidence indicator of 95

Liquid Crystal Display - User Interface (continued)

APPLANATION MODE - USER INTERFACE ERROR CODES		
	User Interface Error Code	LED Off Error - IOP value Under Range (<5mm Hg)
	User Interface Error Code	LED Off Error- IOP Value Over Range (>99mm Hg)
	User Interface Error Code	LED Off Timeout - not enough IOP values collected

VERIFICATION MODE - SEQUENCE OF EVENTS		
	User Interface Begin Verification Mode	Hold Tono-Pen AVIA Vet tonometer with transducer down towards floor (LED Off)
	User Interface Invert Pen	Invert Tono-Pen AVIA Vet tonometer (LED Off)
	User Interface Successful Verification	Successful Tono-Pen AVIA Vet tonometer verification (LED Off)

VERIFICATION MODE - USER INTERFACE ERROR CODE		
	User Interface Error Code	Unsuccessful Tono-Pen AVIA Vet tonometer verification (LED Off)

Tono-Pen AVIA Vet Tonometer Preparation

1. Allow the instrument to thermally stabilize to room temperature for approximately 30 minutes prior to use.
2. Remove the storage Ocu-Film + tip cover from the Transducer Assembly.
3. Visually inspect the Transducer Assembly for cracks, chips or other irregularities. Do not use if these conditions are present.
4. Slide an Ocu-Film + Tip Cover onto the Transducer Assembly until the ridge is seated, taking care not to apply the tip cover too tightly or too loosely. Make certain that the rubber is flat across the tip, but not taut.



Figure 5. Tono-Pen AVIA Vet Tonometer Preparation

Note: Use of the Ocu-Film + Tip Cover is required under original Tono-Pen instrument warranty and service contract terms.

Note: Corneal topical anesthetic is required with tonometry.

Verification Mode

A verification test may be initiated if suspect readings are observed. (See Tono-Pen AVIA VET Tonometer Verification section for details.)

If the verification test resulted with the LCD displaying **[FAIL]**, repeat the verification test, or reference the troubleshooting section for potential causes for test failure.

Note: The Tono-Pen AVIA Vet tonometer will remain in the Verification mode until it passes verification.

Performing IOP Measurements

WARNING: OCU-FILM + TIP COVERS CONTAIN NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS. QUESTION PATIENTS ABOUT ALLERGIES TO LATEX BEFORE MEASURING THEM WITH THE TONO-PEN AVIA VET TONOMETER.

WARNING: DO NOT USE AN OCU-FILM + TIP COVER ON MORE THAN ONE PATIENT TO HELP PREVENT CROSS CONTAMINATION.

Note: Refer to the Reichert website for instructional videos.

1. Instill a drop of topical anesthetic into the eye to be examined.
2. Position the patient, seated or supine, in front of a fixation target.

Note: The Tono-Pen AVIA Vet tonometer will function in any orientation.

3. Where possible, instruct the patient to look straight ahead at the fixation target (i.e. ear, nose, distant object) to minimize eye movement, with eyes fully open.
4. Hold the Tono-Pen AVIA Vet tonometer as you would a pencil and position yourself to allow viewing of the Transducer Assembly and the patient's cornea where contact will be made. For normal corneas, central corneal contact is recommended.
5. The corneal surface needs only to be momentarily contacted. **Indentation or excessive force is not required and may lead to inaccurate readings or patient injury.** Refer to Figure 6.



Figure 6. Corneal Applanation

6. Brace the heel of your hand on the patient's cheek for stability while holding The Tono-Pen AVIA Vet tonometer perpendicular to and within approximately 1.3 cm (1/2") of the patient's cornea.

Note: In the unlikely event an Electrostatic Discharge (ESD) occurs, the Tono-Pen AVIA Vet tonometer may display inaccurate data. Simply re-press the Activation button and start the measurement again.

Applanation

1. Press and release the activation button once to initiate the applanation mode.
2. A brief display of **[88888]** will flash on the LCD, a double row of dashes **[===]** will be displayed, the green LED will turn on, and a “beep” tone will sound, indicating the Tono-Pen AVIA Vet tonometer is ready to measure intraocular pressure.
3. Tap very lightly and briefly on the corneal surface. The device will chirp and the IOP measurement will be displayed in the mmHg field on the LCD, and the DATA field will increment for each valid IOP reading obtained.
4. When another beep tone is heard, indicating 6 applanations have been read, the green LED will turn OFF, and the averaged IOP measurement will appear above the mmHg field, and the statistical confidence indicator will appear above the DATA field on the LCD.

Note: If at least 2 applanations were read, the avergae IOP will be displayed after a 4 second delay, along with the statistical confidence indicator.

Note: After pressing the Activation button, do not shake the Tono-Pen AVIA Vet tonometer as it may register a reading. If this occurs simply re-press the Activation button and start the measurement again.

The user will have 15 seconds after pressing the activation button to obtain the first applanation before the Tono-Pen AVIA Vet tonometer will initiate the Sleep Mode, indicated initially by the display of a single row of dashes **[---]**, followed by a blank display. The applanation mode may be initiated by pressing the activation button.

If any error codes appear on the LCD after the final beep, the applanation procedure must be repeated.

Interpreting the IOP Measurement

During the measurement, the LCD shows the cumulative number of applanations detected. Once 10 applanations are achieved, the LCD will display the IOP in millimeters of mercury (mm Hg), along with a statistical confidence indicator.

A statistical confidence indicator of 95 means that the standard deviation of the valid measurements is 5% or less of the number shown. The higher the statistical confidence indicator, the more reliable the measurement.

If the statistical confidence indicator is 80 or 80-, a repeat measurement is recommended.



Figure 7. LCD showing an IOP measurement of 16 and statistical confidence indicator of 95

Cleaning Instructions

The Tono-Pen AVIA Vet tonometer may have difficulty taking measurements or display **[FAIL]** after a verification when its tip is dirty and requires cleaning. When the Transducer Assembly of the tonometer has dirt and contaminants in the tip, cleaning of the tip is necessary. When the tip contains contaminants, it cannot move freely and the Tono-Pen AVIA Vet may have erratic readings and then show a **[FAIL]** verification.



Figure 17 - Cleaning the Tip

1. Remove Ocu-Film + tip cover from the tonometer, if one is installed.
2. Using canned air, place the outlet of the canned air firmly against the Transducer Tip of the Tono-Pen AVIA Vet to inject air into the tip as shown in Figure 17.
3. Blow canned air directly into the tip of the tonometer for approximately 3 seconds to push out any contaminants embedded in the tip of the Tono-Pen AVIA Vet.

Note: Try to get a good seal between the canned air and the Tono-Pen AVIA Vet tip to blow any contaminants stuck in the tip of the Tono-Pen AVIA Vet safely into the internal cavity of the Tono-Pen AVIA Vet.

4. After cleaning the tip with compressed air, the Transducer Assembly will be cold. Allow the Transducer Assembly to warm to room temperature.
5. Wipe the outside of the Tono-Pen AVIA Vet with a clean, dust-free, cotton cloth dampened with an approved cleaning solution* and distilled water, or an approved cleaning wipe**. Refer to Figure 18.
6. Perform the tonometer verification as indicated in the Verification Procedure section of this manual.

Note: If the tonometer does not calibrate **[Pass]**, then repeat the above cleaning instructions as needed. If the Tono-Pen AVIA Vet has been cleaned 3 times in a row and it still does not pass the verification, request an RMA (http://www.reichert.com/service.cfm) to return of the Tono-Pen AVIA Vet for repair.



Figure 18 - Wiping Down the Tip

Cleaning Instructions (continued)

7. Install a new Ocu-Film tip cover as indicated in the User Guide.

Note: DO NOT use the Tono-Pen AVIA Vet tonometer on a patient without a new Ocu-Film tip cover installed.

Note: ALWAYS store the Tono-Pen AVIA Vet tonometer in its case with a new Ocu-Film tip cover installed to protect the tonometer tip from dirt and contaminants.

Note: Ocu-Film + tip covers are the only manufacturer approved covers for use with the Tono-Pen AVIA Vet tonometer. Use of any other type of branded tip cover may affect readings or may void your warranty.

Suggested Cleaning Schedule

Number of Patients per Week	Number of Days Between Cleaning
10	30
100	15
300	7
600	1

Tono-Pen AVIA Vet Body

CAUTION: DO NOT USE EXCESS ALCOHOL ON OR AROUND THE LCD SCREEN AS THIS MAY DAMAGE IT.

CAUTION: DO NOT IMMERSE TONO-PEN AVIA VET BODY IN FLUIDS. THIS WILL CAUSE DAMAGE TO THE ELECTRONICS AND VOID THE WARRANTY.

Avoid any shock or excessive vibration which will damage the unit. Clean with a non-abrasive, dry cloth. When cleaning between patients is required, the body may be wiped down with a paper towel or soft cloth lightly moistened with an approved cleaning solution*, or an approved cleaning wipe**. Refer to Figure 19.



Figure 19 Wiping Down the Body

* 70% isopropyl alcohol, 7.5% Hydrogen Peroxide solution, 5.25% Bleach solution.

** Clorox[1] Bleach Germicidal Wipes (0.55% sodium hypochlorite), Sani-Cloth[2] Prime Germicidal wipes (Didecyl Dimethyl Ammonium Chloride, isopropyl alcohol and ethyl alcohol)

Battery

Replace the Tono-Pen AVIA Vet POWERCEL Battery when:

- The battery indicator shows low battery after depressing the activation button.
- There are no beeps, the LCD remains blank after pressing the activation button, or a noticeable slowing occurs when activating the device.

Note: Replace the battery with PN 230751.

Storage

- Cover the tip with an Ocu-Film + tip cover for protection.
- If the Tono-Pen AVIA Vet tonometer is not to be used until a subsequent day, the instrument and accessories should be placed in the storage case provided.
- If the instrument is to be stored for an extended period, remove the Tono-Pen AVIA Vet POWERCEL Battery to avoid possible damage to the instrument due to battery leakage.

Disposal

The Tono-Pen AVIA Vet, Ocu-Film, and Tono-Pen AVIA Vet POWERCEL do not generate any environmentally hazardous residues. At the end of its product service life, follow your local laws and ordinances regarding the proper disposal of this equipment.

[1] Clorox is a registerd trademark of the Clorox Company, Oakland, CA.
[2] Sani-Cloth is a registered trademark of PDI, Inc., Woodcliff Lake, NJ.

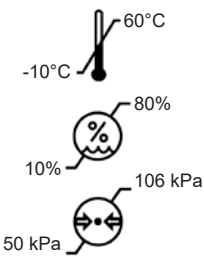
Troubleshooting

The table below provides a guide for troubleshooting some basic Tono-Pen AVIA Vet tonometer operational problems. If a problem persists after using this guide contact Reichert technical services.

SYMPTOM	PROBABLE CAUSE	CORRECTION
Battery symbol flashes	Low Tono-Pen AVIA Vet POWERCEL Battery capacity	Replace Tono-Pen AVIA Vet POWERCEL Battery
Multiple inaccurate readings	Improper technique (Example: too much or too little force used, taps too long, device not held perpendicular to the patient's eye)	Review "APPLANATION" Section of this manual
	Old or improperly applied Ocu-Film + tip cover being used, or non-Reichert tip cover being used	Replace Ocu-Film tip cover
	Debris in tip	Clean tip
	Mechanical or electronic damage	Arrange for service through Reichert Technical Service Group
No beeps and/or no dashes upon activation	Activation button not properly pressed	Press Activation button
	No Tono-Pen AVIA Vet POWERCEL Battery capacity	Replace Tono-Pen AVIA Vet POWERCEL Battery
	Mechanical or electronic damage	Arrange for service through Reichert Technical Service Group
Verification Failure	Debris in tip	Clean tip
	Compressed air cleaning has lowered the temperature of the instrument	Allow Tono-Pen AVIA Vet tonometer unit to warm to room temperature

Specifications

Catalog Number: 230650V

PHYSICAL DIMENSIONS Size: 16 x 2 x 4.4 cm (6 1/4" x 3/4" x 1 3/4") Weight: 71 g (2.4 oz)  	**ENVIRONMENTAL REQUIREMENTS** **Operational Environment** Ambient Temperature range: 15° to 35°C (59° to 95°F) Relative Humidity range: 30 to 75% Atmospheric Pressure range: 80 kPa to 106 kPa (23.6 to 31.3 in.Hg) **Transport and Storage Environment** Ambient Temperature range: -10° to 60°C (14° to 140°F) Relative Humidity range: 10 to 80% (non-condensing) Atmospheric Pressure range: 50 kPa to 106 kPa (14.8 to 31.3 in.Hg)
RANGE OF IOP MEASUREMENTS 5-99 mmHg	**ELECTRICAL** Input Voltage (Tono-Pen AVIA Vet POWERCEL Battery) 2 x 3V Lithium Manganese Dioxide batteries ($LiMnO_2$)
OCU-FILM + TIP COVER	Contains natural rubber latex
SOFTWARE REVISION	The software revision can be obtained by contacting Reichert Technologies. The serial number identifies the manufacture date and will provide access to the software version

Device Regulatory Classification

Insulation Protection	Internally Powered (6 V battery)
Ingress Protection	IPX0
Applied Part Type	BF
Operation Mode	Continuous

Compliance

The Tono-pen AVIA Vet complies with:
IEC 60601-1:2005 + A1:2012 (Edition 3.1)
IEC 60601-1-2:2014 (Edition 4)

Guidance & Manufacturer's Declaration

Table 201 – Guidance and Manufacturer's Declaration

Electromagnetic Emissions

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Tono-Pen AVIA Vet is intended for use in the electromagnetic environment specified below. The customer or user of the Tono-Pen AVIA Vet should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance -
Radiated RF Emissions CISPR 11	Group 1	The Tono-Pen AVIA Vet uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated RF Emissions CISPR 11	Class B	The Tono-Pen AVIA Vet is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building for domestic power.
Harmonic Distortion IEC 61000-3-2	N/A	
Voltage Fluctuations and Flicker IEC 61000-3-3	N/A	

Table 202 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Tono-Pen AVIA Vet is suitable for use in electromagnetic environment specified below. The customer or user of the Tono-Pen AVIA Vet should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%.
Electrical Fast Transients / Bursts IEC 61000-4-4	±2kV Mains Power Lines ±1kV I/O Lines 100kHz repetition frequency	N/A	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surges IEC 61000-4-5	±0.5kV, ±1kV Line-to-line ±0.5kV, ±1kV, ±2kV Line-to-ground	N/A	Mains power quality should be that of a typical residential, commercial or hospital environment.
Voltage Dips IEC 61000-4-11	0% Ut; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	N/A	Mains power quality should be that of a typical residential, commercial or hospital environment. If the user of the Tono-Pen AVIA Vet requires continued operation during power mains interruptions, it is recommended that the Tono-Pen AVIA Vet be powered from an uninterruptible power supply or battery.
	0% Ut; 1.0 cycle and 70% Ut; 25/30 cycles Single phase: at 0°	N/A	
Voltage Interruptions IEC 61000-4-11	0% Ut, 250/300 cycles	N/A	
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30A/m 50 Hz or 60 Hz	30A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be that of a typical residential, commercial or hospital environment.

Table 204 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Medical Electrical Equipment and Medical Electrical Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Tono-Pen AVIA Vet is intended for use in the electromagnetic environment specified below. The customer or user of the Tono-Pen AVIA Vet should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 KHz	N/A	Portable and mobile RF communications equipment should be no closer to any part of the Tono-Pen AVIA Vet, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d=(3.5/V1)(\sqrt{P})$ $d=(3.5/E1)(\sqrt{P})$ 80 to 800 MHz $d=(7/E1)(\sqrt{P})$ 800 MHz to 2.7 GHz Where P is the max 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 transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels in each frequence range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF Electromagnetic Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	(E1) = 3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	
	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	N/A	

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.

* 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. The measured field strength in the location in which the ME Equipment or ME System should be observed to verify normal operation. If abnormal performance is observed, additional measures many be necessary, such as re-orienting or relocating the ME Equipment or ME System.

* Over the frequency range 150 kHz to 80 MHz, field strengths should be less then [V1] V/m.

* The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz, to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 206 – Recommended Separation Distances between Portable and Mobile RF Communications Equipment for ME Equipment and ME Systems that are NOT Life-supporting.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Recommended Separation Distances for between Portable and Mobile RF Communications Equipment and the Tono-Pen AVIA Vet.

The Tono-Pen AVIA Vet is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Tono-Pen AVIA Vet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Tono-Pen AVIA Vet as recommended below, according to the maximum output power of the communications equipment.

Max Output Power of Transmitter (W)	Separation (m) 150kHz to 80 MHz Outside ISM Bands d=(3.5/V1)(√P)	Separation (m) 150kHz to 80 MHz In ISM Bands d=(10/3)(3.5/V1)(√P)	Separation (m) 80 to 800 MHz d=(3.5/E1)(√P)	Separation (m) 800MHz to 2.7GHz d=(7/E1)(√P)
0.01	0.1166	0.1944	0.1166	0.2333
0.1	0.3689	0.6149	0.3689	0.7378
1	1.1666	1.9444	1.1666	2.3333
10	3.6893	6.1489	3.6893	7.3786
100	11.6666	19.4444	11.6666	23.3333

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.

Note 3: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.

Table 9 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Immunity to Proximity Fields from RF Wireless Communications Equipment

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Tono-Pen AVIA Vet is intended for use in the electromagnetic environment as specified below related to proximity fields from RF wireless communications equipment.

Immunity Test	IEC 60601 Test Level							Compliance Level	Electromagnetic Environment - Guidance
	Test Frequency (MHz)	Band (MHz)	Service (MHz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level	
Radiated RF IEC 61000-4-3	385	380-390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27	27 V/m at 0,3 m	d = 6/E √P where d = Minimum separation distance in meters E = Immunity test level in V/m P = Maximum power in Watts (W)
	450	430-470	GMR 460, FRS 460	FM ±5 kHz deviation 1 kHs sine	2	0,3	28	28 V/m at 0,3 m	
	710 745 780	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0,2	0,3	9	9 V/m at 0,3 m	
	810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 18 Hz	2	0,3	28	28 V/m at 0,3 m	
	1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0,3	28	28 V/m at 0,3 m	
	2450	2400-2570	Bluetooth WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0,3	28	28 V/m at 0,3 m	
	5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0,2	0,3	9	9 V/m at 0,3 m	

Warranty

This product is warranted by Reichert, Inc. against defective material and workmanship under normal use for a period of one year from the date of invoice to the original purchaser. (An authorized dealer shall not be considered an original purchaser.) Under this warranty, Reichert's sole obligation is to repair or replace the defective part or product at Reichert's discretion.

This warranty applies to new products and does not apply to a product that has been tampered with, altered in any way, misused, damaged by accident or negligence, or which has had the serial number removed, altered or effaced. Nor shall this warranty be extended to a product installed or operated in a manner not in accordance with the applicable Reichert instruction manual, nor to a product which has been sold, serviced, installed or repaired other than by a Reichert factory, Technical Service Center, or authorized Reichert Dealer.

Lamps, bulbs, charts, cards and other expendable items are not covered by this warranty.

All claims under this warranty must be in writing and directed to the Reichert factory, Technical Service Center, or authorized instrument dealer making the original sale and must be accompanied by a copy of the purchaser's invoice.

This warranty is in lieu of all other warranties implied or expressed. All implied warranties of merchantability or fitness for a particular use are hereby disclaimed. No representative or other person is authorized to make any other obligations for Reichert. Reichert shall not be liable for any special, incidental, or consequent damages for any negligence, breach of warranty, strict liability or any other damages resulting from or relating to design, manufacture, sale, use or handling of the product.

PATENT WARRANTY

If notified promptly in writing of any action brought against the purchaser based on a claim that the instrument infringes a U.S. Patent, Reichert will defend such action at its expense and will pay costs and damages awarded in any such action, provided that Reichert shall have sole control of the defense of any such action with information and assistance (at Reichert's expense) for such defense, and of all negotiation for the settlement and compromise thereof.

PRODUCT CHANGES

Reichert reserves the right to make changes in design or to make additions to or improvements in its products without obligation to add such to products previously manufactured.

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