Reichert
AMETEK

Tono-Vera®

Tonometer

INSTRUCTIONS FOR USE

Scan for additional information and languages:

CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician. Rx only.

Table of Contents

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, or if instrument is not used in accordance with its Instructions for Use.

⚠ 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 Instructions for Use guide. The safety of the operator and the performance of the instrument cannot be guaranteed if used in a manner not specified by Reichert.

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: Use the wrist strap to prevent dropping the device. If the device is dropped, check for damage before using the device.

WARNING: Inspect the device for damage before use.

WARNING: Do not use an Ocu-Dot Tonometer Probe on more than one patient to help prevent cross contamination. Do not clean or disinfect a probe and then use it. Probes are single-use only.

WARNING: To prevent contamination, do not touch the bare Ocu-Dot Tonometer Probe. Do not use a probe if it touches a non-sanitized surface like a table or a floor. Properly dispose of a touched or dropped probe (e.g. in a container for disposable needles).

WARNING: Always keep Ocu-Dot Tonometer Probes out of the reach of infants, animals, and young children. The probes can become a choking hazard.

WARNING: Do not expose the battery to temperatures above 60ºC (140ºF) or disassemble the batteries. Damage to this unit and/or serious personal injury may result.

WARNING: If an unusual rise in temperature on the handle of the instrument occurs, remove the battery pack and batteries and contact Reichert Technical Support. Contact information is at the back of this manual.

WARNING: Do not carry Tono-Vera Li-Ion Rechargeable Battery Pack 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: Take care when handling the Lithium-Ion Rechargeable Battery Pack. If it becomes too hot, do not use and contact Reichert Technical Support. Contact information is at the back of this manual.

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: 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 doctor.

WARNING: Take care not to pinch any fingers when installing a battery pack.

WARNING: The use of any power adapter, other than the one supplied, should not be used with Tono-Vera instrument or docking station.

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, decreased immunity, or over-Voltage 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: Only use Ocu-Dot probes with Tono-Vera for accurate IOP measurements. Use of probes from other manufactures will cause inaccurate IOP measurements.

WARNING: The wireless module within a Tono-Vera operates above the regulatory limits for radio frequency exposure. It is recommended to maintain a minimum distance of 15 mm from the user's body and upper half of the instrument when operating the features of the wireless module. This distance will be maintained when the instrument is held by the lower handle and during normal patient use. Prolonged exposure to RF radiation may pose potential health risks.

CAUTION: An instruction that draws attention to the risk of damage to the product.

CAUTION: Do not immerse Tono-Vera Tonometer in fluids or damage to the electronics may occur.

CAUTION: Do not bump, jar, or drop the device because damage to the electronics may occur. If the device is dropped, carefully inspect the device for damage.

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 Tono-Vera Tonometer or damage to the electronics may occur.

CAUTION: Do not use solvents on any part of this instrument as damage to the unit may occur. See maintenance section for detailed cleaning instructions

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 Tono-Vera Tonometer or Tono-Vera Li-Ion Rechargeable Battery Pack or damage to the device may occur.

CAUTION: Do not store Tono-Vera Tonometer without the probe cover or debris may enter the unit 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 affect Medical Electrical Equipment.

CAUTION: This instrument is not to be used near high-frequency emitting surgical equipment.

CAUTION: Ocu-Dot Tonometer Probes should be stored between -10°C and 55°C (14°F-131°F).

CAUTION: If liquid is spilled on the device, remove the battery and return Tono-Vera to Reichert for service. Liquid may damage the electronics.

Symbol Information

The following symbols appear on the device.

 Caution

 Catalog Number

 Serial Number

 Date of Manufacture

 Manufacturer

 Consult Instructions for Use

 Fragile Contents in Shipping Container—Handle with Care

 Do not get Shipping Container Wet

 This Side Up

 Type BF Applied Part

 Refer to Instructions for Use

 Authorization to mark given by QPS Evaluation Services for conformance with electrical standards

Symbols for Ocu-Dot Tonometer Probes only

 Do not reuse. Single-Use

 Batch Code

 Use-by Date

 Do Not Use if Package is Damaged

 Sterilized using irradiation

Introduction

Congratulations on your purchase of Tono-Vera® Tonometer.

Tono-Vera Tonometer is a prescription-only device intended for measuring intraocular pressure (IOP) during routine eye examinations or when increased IOP is suspected by properly trained eyecare professionals such as ophthalmologists, optometrists, opticians, and eye care technicians.

This Instructions for Use 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 device. If used properly, Tono-Vera Tonometer will provide you with fast, accurate, and reliable measurements for many years.

Please retain this manual for future reference and to share with other users. For questions related to Tono-Vera Tonometer, contact your local authorized Reichert® distributor or contact Reichert Technical Support directly at:

Phone: +1-716-686-4500
Toll Free (US and Canada Only): 888-849-8955
Fax: +1-716-686-4555
Email: reichert.information@ametek.com

Any serious incident associated with this device should be reported to Reichert and to your national health agency.

Indications for Use

The intended use of the device is to measure the intraocular pressure (IOP) of the human eye.

Contra-Indications

None.

Device Description

Tono-Vera Tonometer (hereinafter referred to as Tono-Vera) is a handheld tonometer which allows IOP to be measured accurately, rapidly, and without an anesthetic.

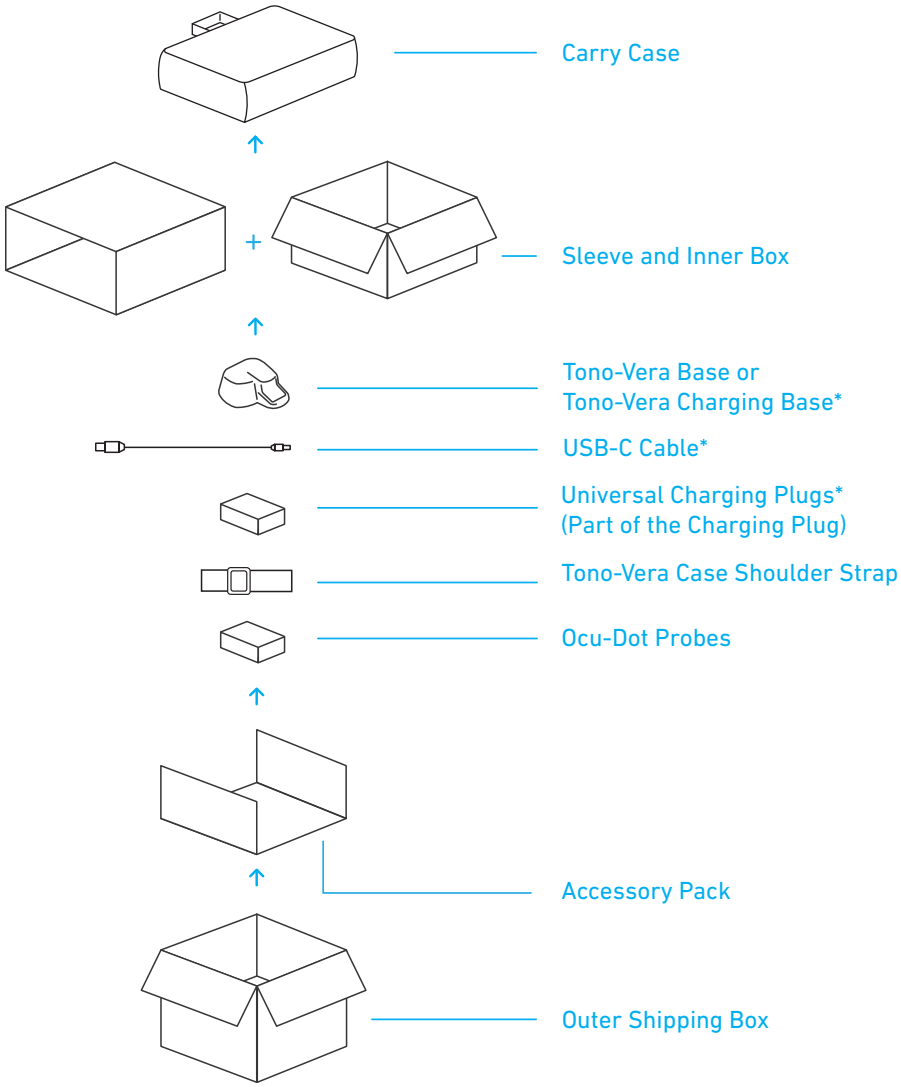
The patented ActiView™ Positioning System guides the operator to proper alignment on the apex of the cornea. When ActiView Auto Measure Mode is ON (recommended), Tono-Vera automatically takes IOP measurements once properly aligned, providing a high confidence measurement in as few as three measurements. When ActiView Auto Measure Mode is OFF, Tono-Vera takes measurements only when the Manual Measure Button is pressed. Measurements are made using Ocu-Dot Tonometer Probes (hereinafter referred to as Ocu-Dot Probes) which are sanitized, and single use.

Reichert Tono-Vera incorporates Bluetooth® which provides wireless communication to transfer data to an EMR system.

Introduction

Unpacking Instructions

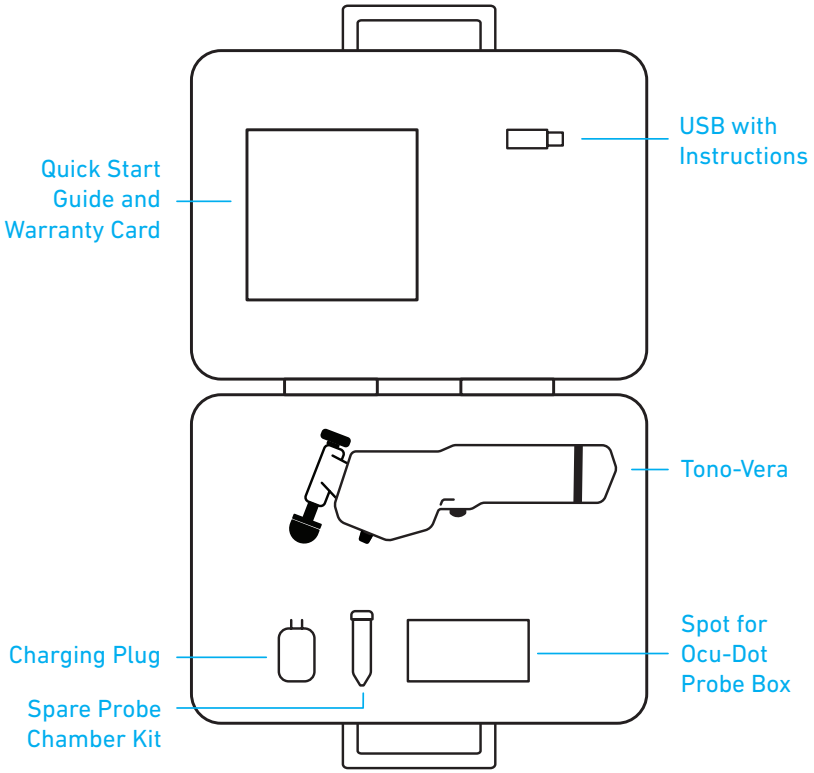
1. Retain original packaging to use if future transportation is required.
2. Open the Outer Shipping Box and remove the Inner Box.
3. Slide the Sleeve off the Inner Box.
4. Remove the Carry Case from the Inner Box.
5. Remove the Accessory Pack beneath the Inner Box.
6. Verify that all parts and accessories are included.
7. If anything is missing, contact Reichert at the contact information located on the last page of this manual.



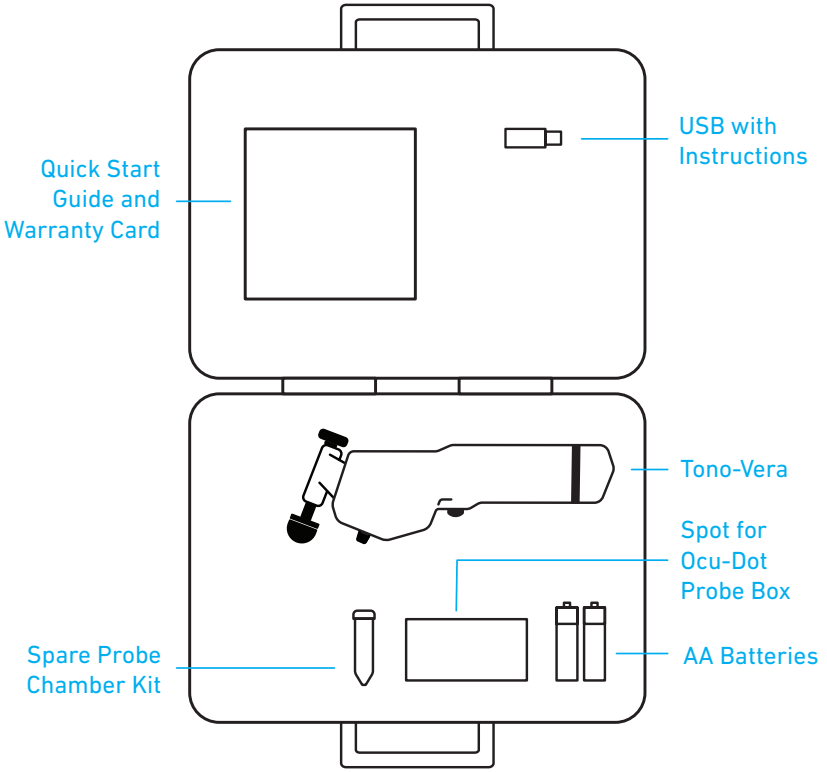
* Tono-Vera Tonometer Rechargeable Version Only (PN 16306)

In the Box

Tono-Vera Tonometer Starter Kit - Rechargeable

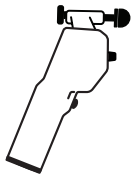


Tono-Vera Tonometer Starter Kit - AA Battery



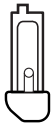
In the Box

Tono-Vera Tonometer Starter Kit - Rechargeable 16306



Tono-Vera® Tonometer
16325-800

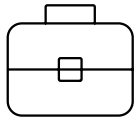
+



Tono-Vera® Li-Ion
Rechargeable Battery Pack
16313

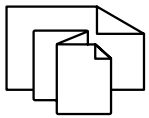
Wrist Strap
13851-096

Tono-Vera® Charging Base
16312



Tono-Vera® Carry Case
16305-866

Tono-Vera® Case
Shoulder Strap



Tono-Vera® Quick Start Guide
16305-105 &
Tono-Vera® Instructions for Use
16325-101

Protective Cap
16305-098

Ocu-Dot® Tonometer
Probes - 100 Count
16318

Tono-Vera® USB with Instructions
16325-106

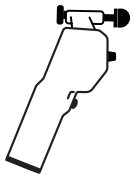
Warranty Card
16305-111

Tono-Vera® Spare Probe
Chamber Kit
16305-877

USB-C Charging Cable
16305-405

Charging Plug
16305-404

Tono-Vera Tonometer Starter Kit - AA Battery 16305



Tono-Vera® Tonometer
16325-800

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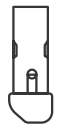
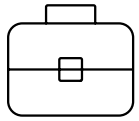


Tono-Vera® AA Battery Pack
16311

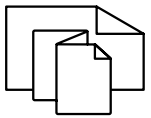
Wrist Strap
13851-096

Tono-Vera® Base
16310



Tono-Vera® Carry Case
16305-866

Tono-Vera® Case
Shoulder Strap



Tono-Vera® Quick Start Guide
16305-105 &
Tono-Vera® Instructions for Use
16325-101

Protective Cap
16305-098

Ocu-Dot® Tonometer
Probes - 100 Count
16318

Tono-Vera® USB with Instructions
16325-106

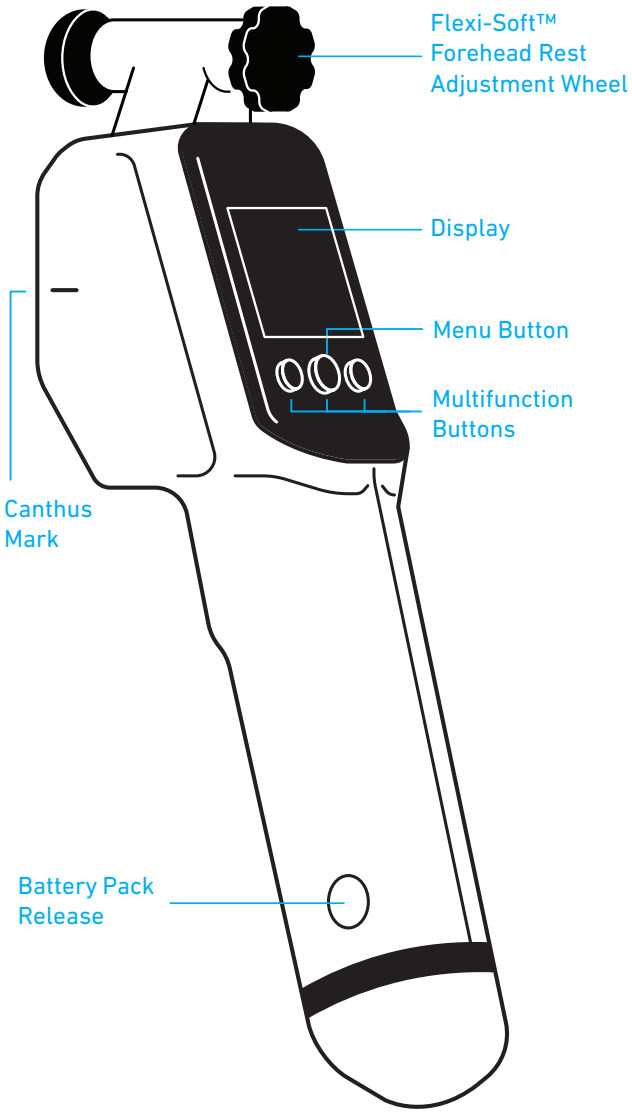
Warranty Card
16305-111

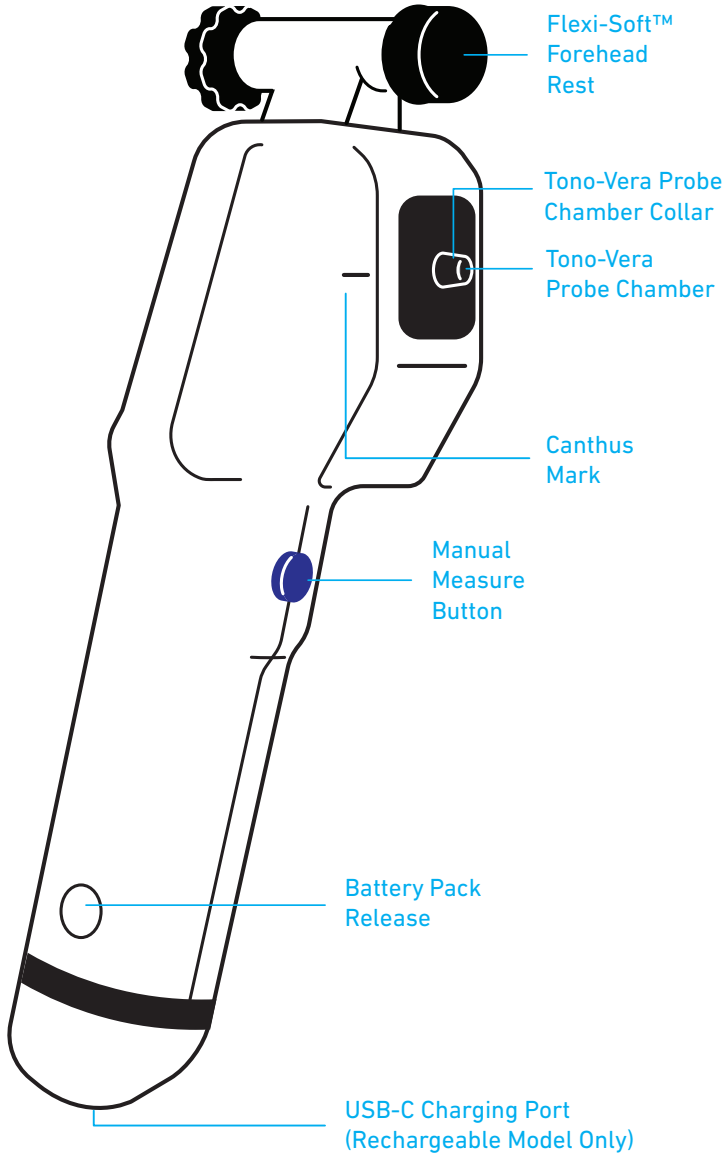
Tono-Vera® Spare Probe
Chamber Kit
16305-877

Pack of Four AA Batteries
16305-097

In the Box

Tono-Vera Tonometer Identification





Instructions for Use

Installing the Batteries

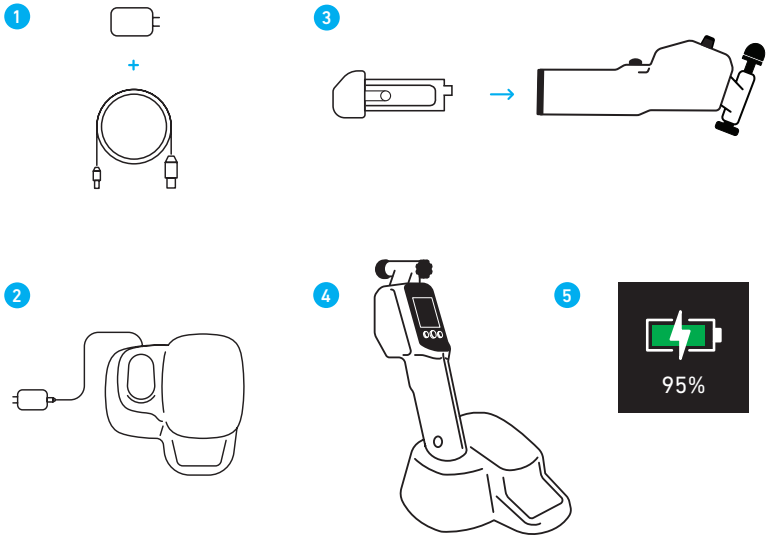
CAUTION: Use only the battery type specified in technical specification section of this manual.

Rechargeable Battery Model

1. Install the country-specific adaptor to the Charging Plug. Insert one end of the USB-C Charging Cable into the Charging Plug, and the other end into the back of the Tono-Vera Charging Base.
2. Connect the Tono-Vera Charging Base to an AC wall outlet.
3. Slide the Tono-Vera Li-Ion Rechargeable Battery Pack into Tono-Vera until the Battery Pack clicks into place.
4. Place Tono-Vera into the Tono-Vera Charging Base with the screen facing the user.
5. When the device is properly docked, a beep will sound and the battery charging symbol and the percent charged will briefly appear on the screen.

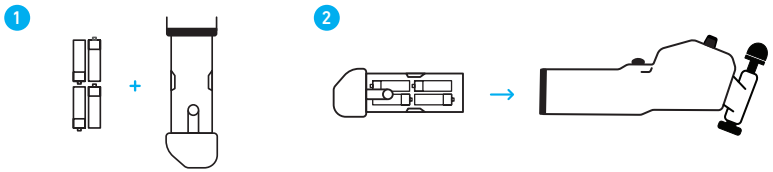
   NOTE: The device may also be charged using the USB-C Charging Cable and the Charging Plug by inserting one end of the USB-C Charging Cable into the USB-C Charging Port at the bottom of Tono-Vera.

   CAUTION: Re-install the Protective Cap onto the Probe Chamber Collar when charging Tono-Vera.



AA Battery Model

1. Insert the four AA batteries into the Tono-Vera AA Battery Pack. Be sure to install the batteries so the positive and negative ends are aligned according to the inscription on the holder.
2. Slide the Tono-Vera AA Battery Pack into Tono-Vera until the Battery Pack clicks into place.

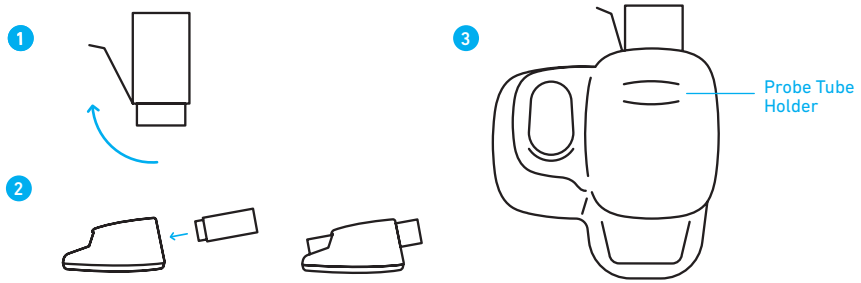


Instructions for Use

Set Up Base

The Tono-Vera Base features a convenient dispenser for Ocu-Dot Probes and also includes a recess to hold the empty Probe Tube while taking a measurement.

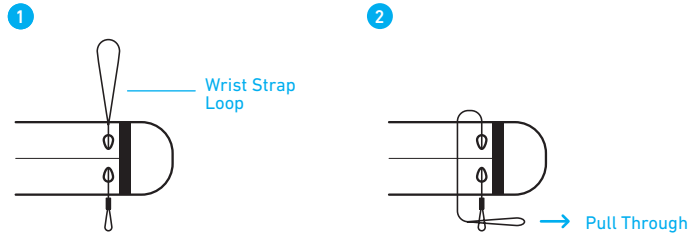
1. Open the box and fold the flap back along the side.
2. Insert the Ocu-Dot Probe box with the tray into the back of the Base with the opening facing forward. The box will stop halfway down. Push the plastic Ocu-Dot Probe tray all the way forward by inserting your finger into the circular cutout at the back of the box.
3. Use the recess carved into the top of the base to hold an Ocu-Dot Probe Tube.



Install Wrist Strap

It is recommended that you always use the included Wrist Strap when using Tono-Vera to prevent the device from being dropped.

1. Insert the loop of the Wrist Strap into the opening at the base of Tono-Vera.
2. Pull the other end of the Wrist Strap through the loop until the Wrist Strap is secured in place.

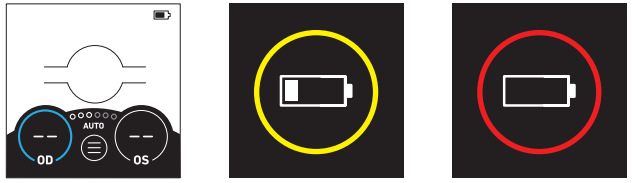


Turning On and Off

Press any button to turn Tono-Vera on. The screen will display Reichert and Tono-Vera logos, followed by the Measure Screen.

If the batteries are low, a low battery warning will briefly appear. If the batteries are depleted, a dead battery warning will appear and Tono-Vera will shut off.

To turn off, press and hold the center Multifunction Button for approximately five seconds. A countdown will appear before the device turns off.



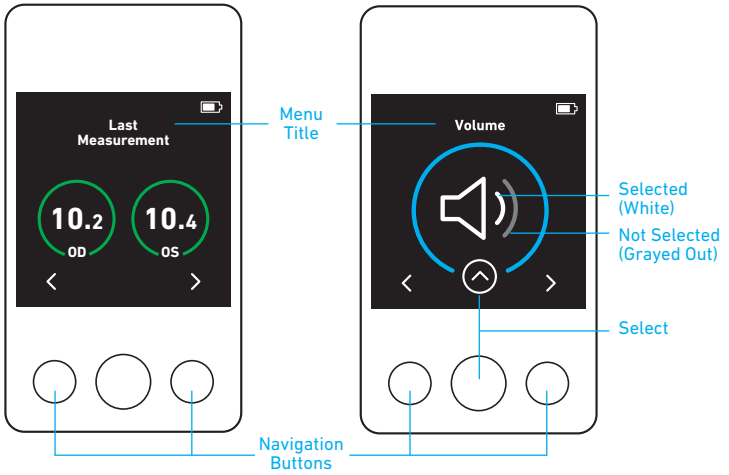
Measure Screen | Low Battery | Dead Battery

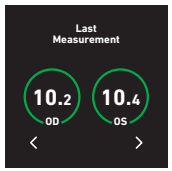
Instructions for Use

Menu

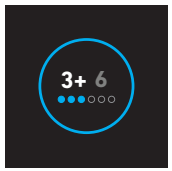
Press the center Multifunction Button to access the Menu. Press the left and right Navigation Buttons to access the different menu screens. Press the Select Button to change the current setting/ selection. The highlighted option is the active selection.

To exit the Menu, navigate to the Exit screen and press the Select Button, or press the Manual Measure Button at any time.





Last Measurement
Displays the results of the previous measurement. These values can be exported via Bluetooth.



Measurements
3+: (Quick) Will take the fewest measurements necessary to get a high confidence IOP result.
6: Takes 6 IOP measurements.

Sleep
30, 60, or 90 second sleep timer available.

System Info
Displays Software Version, the serial number, and the device name.

Practice:
Enter Practice mode to practice aligning and measuring with Tono-Vera without using an Ocu-Dot Probe.

Brightness
Low, medium, or high screen brightness settings available.

Bluetooth
On: Device can connect to a computer to transfer measurements to an EMR system.
Off: Bluetooth off.

Exit
Exit the menu.

ActiView Auto Measure Mode-
On: Automatically takes measurements when ActiView Positioning System is properly aligned.
Off: Must press Manual Measure Button to take a measurement.

Volume
Off, low, or high volume settings available.

Language
English, German, French, Spanish, Italian, or Portuguese.

Instructions for Use

Ocu-Dot Probe Installation

1. Tono-Vera indicates that Ocu-Dot Probe needs to be inserted.
2. Remove the protective rubber cover from the front of the Probe Chamber on Tono-Vera Tonometer. Take a new Ocu-Dot Probe Tube from the box and remove the cap.
3. Insert the open end of the Ocu-Dot Probe Tube into the Probe Chamber.
4. Rotate Tono-Vera up so the Ocu-Dot Probe can slide into the Probe Chamber.
5. To remove the Ocu-Dot Probe, press and hold the center Multifunction Button for three seconds to turn the device off and eject the Ocu-Dot Probe. It is recommended to eject the used Ocu-Dot Probe directly into an empty Probe Tube for disposal.
6. You may store the empty Ocu-Dot Probe Tube in recess on base.

If Tono-Vera is on, the tonometer will automatically secure the Ocu-Dot Probe. If it is off, press any button to turn the device on and secure the Ocu-Dot Probe. If Tono-Vera is not on, the Probe will not be secured and could fall out.

NOTE: The Probe Tube can be used to dispose of the probe, which may be placed in a sharps container to prevent any injury.

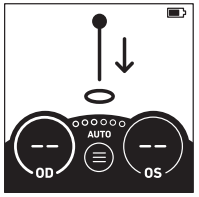
WARNING: Visually inspect the probe before use. Do not use a probe with any signs of defects or damage.

WARNING: To prevent contamination, do not touch the bare Ocu-Dot Probe. Do not use a probe if it touches a non-sanitized surface like a table or a floor. Properly dispose of a touched or dropped probe (e.g. in a container for disposable needles).

WARNING: Do not use an Ocu-Dot Probe on more than one patient to prevent cross contamination.

WARNING: Only use Ocu-Dot probes with Tono-Vera for accurate IOP measurements. Use of probes from other manufactures will cause inaccurate IOP measurements.

1

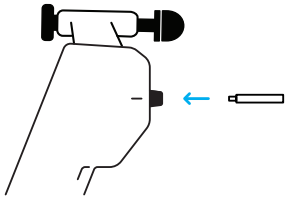


Tono-Vera indicates that Ocu-Dot Probe needs to be inserted.

2

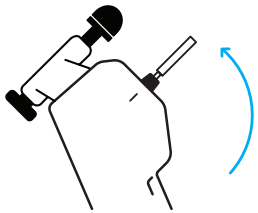
Remove Ocu-Dot Probe Tube Cap.

3



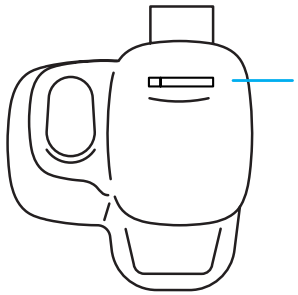
Insert Ocu-Dot Probe Tube into Probe Chamber.

4



Rotate the unit so the Ocu-Dot Probe slides into the Probe Chamber.

6



Store Ocu-Dot Probe Tube in Tono-Vera Base recess.

Instructions for Use

Measurement Screen

1. **ActiView Positioning System Area:** The full-color area on screen where the eye is aligned to the device.

2. **Battery Indicator:** The battery icon indicates the battery level.

3. **Alignment Target:** The alignment area, consisting of a circular center target and level indicators.

4. **Probe Angle Indicator:** Two colored marks (green or yellow) appear on each side of the Alignment Target, indicating the probe angle.

5. **Number of Measurements:** The dots indicate the measurements required and completed (3+ or 6). An empty white dot indicates a required measurement. A solid blue dot indicates a reliable, completed measurement.

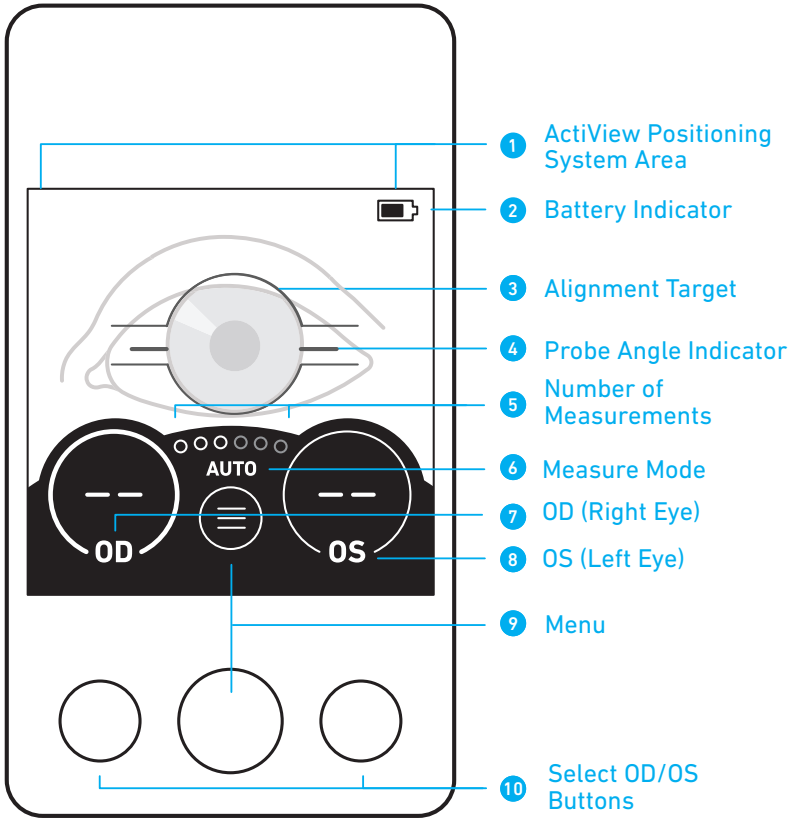
6. **ActiView Auto Measure Mode:** If AUTO is illuminated, Tono-Vera will automatically measure when properly aligned. If AUTO is grayed out (Manual Measure Mode), then the Manual Measure Button must be pressed to take a measurement. Pressing and holding the blue Manual Measure Button will take continuous measurements.

7. **OD:** Right eye. The circle will be blue if selected.

8. **OS:** Left eye. The circle will be blue if selected.

9. **Menu:** To access the Menu, press the center button beneath the Menu icon. Refer to the Menu section of this manual for details. If an X icon appears where the Menu icon is depicted, measurements have been taken. Press the button beneath the X to clear out all measurements. If Bluetooth is activated and connected, an export icon (up arrow) will appear after measurements are taken. Press the button beneath the arrow to transfer the data to an EMR system.

10. **Select OD/OS Buttons:** Select OD or OS by pressing the corresponding button.



Instructions for Use

Positioning

To obtain quick, easy, and accurate IOP results, Tono-Vera features the ActiView Positioning System to guide users to proper alignment.

The default ActiView Auto Measure Mode setting is ON, which enables automatic measurements upon correct alignment. Canthus marks on the outside of the device along with the Flexi-Soft Forehead Rest also aid with alignment.

CAUTION: To prevent cross contamination, clean the Flexi-Soft Forehead Rest between patients with alcohol. Refer to the Cleaning and Maintenance section for more information.

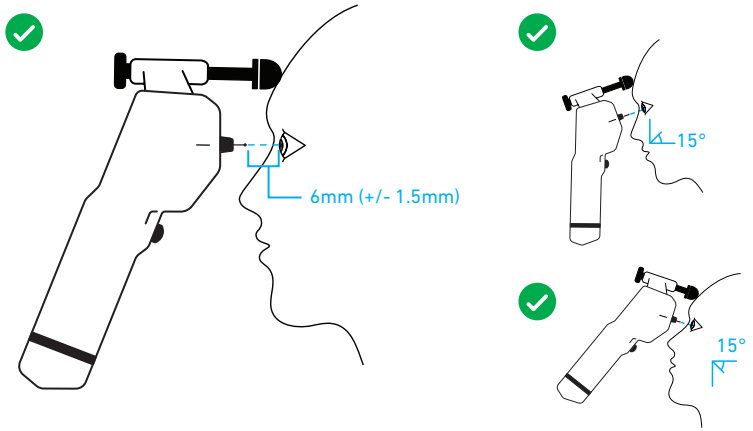
1. Adjust the Flexi-Soft Forehead Rest by turning the Flexi-Soft Forehead Rest Adjustment Wheel.
2. Turn Tono-Vera on by pressing any button.
3. Install a new Ocu-Dot Probe.
4. OD (right eye) will automatically be selected, indicated by a blue circle.

   NOTE: To start on the OS (left eye), press the button beneath the OS area to select the left eye.
5. Position the device so that the two canthus marks located at the front of Tono-Vera (one on each side) are level with the patient's canthus. Tono-Vera is able to measure at a probe angle of ±15°, but the Ocu-Dot Probe must remain perpendicular to the eye. The Flexi-Soft Forehead Rest allows for fine-tune adjustments.
6. The correct working distance is 6mm (+/- 1.5mm) from the probe tip to the eye.

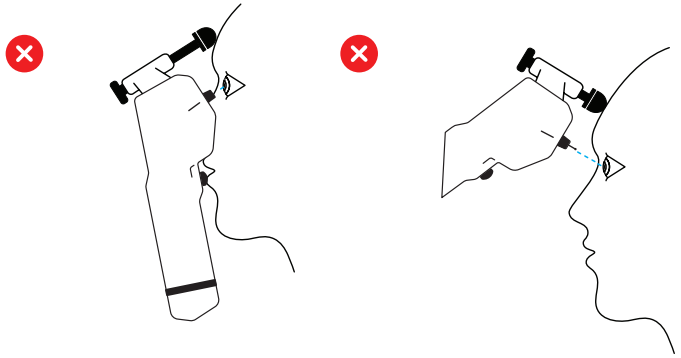
Device Orientation

Tono-Vera can be rotated a full 360° around the axis of the Ocu-Dot Probe, as long as the probe is kept parallel to the ground, within the ±15° probe angle range. Therefore, reclined or recumbent patients can be measured by positioning their head to the side, then rotating Tono-Vera to the proper alignment as described in step five of Positioning.

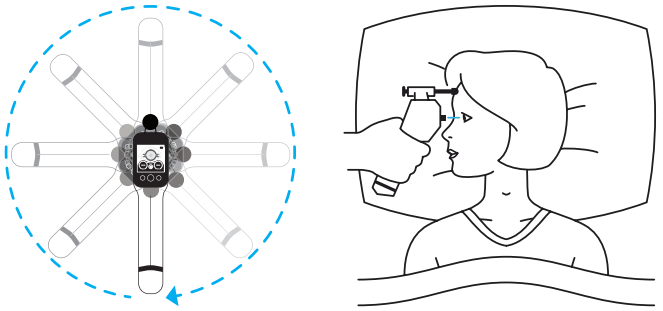
Correct Probe Angle



Incorrect Probe Angle



Device Orientation



Instructions for Use

Aligning

1. Using the ActiView Positioning System, slowly align Tono-Vera following the alignment cues on the screen, so the device is centered over the pupil and the Ocu-Dot Probe is approximately 6 mm from the apex of the cornea.

2. A colored ring will appear when the device detects the eye. The size, color, and position of the ring indicate alignment and distance.

   The goal is to obtain a green ring directly over the central alignment target. This indicates proper distance and proper alignment.

   Yellow Ring
   Device is too far away or off-center. Move closer or more centered on the eye.

   Green Ring
   Proper alignment and distance obtained.

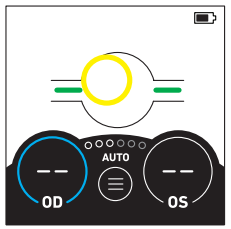
   Large Red Ring
   Device is getting too close. Move the device further away from the eye.

   Large Red Stop Sign
   STOP! Device is too close. Move the device further away from the eye.

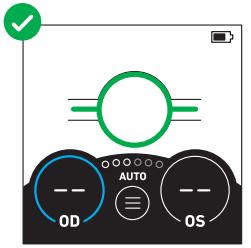
3. Using the ActiView Positioning System, slowly align Tono-Vera so the device is level with the eye.

   NOTE: Tono-Vera is able to measure at a probe angle of ±15°, but the Ocu-Dot Probe must remain perpendicular to the eye. The Probe Angle Indicators located on the left and right side of the positioning target will help with the probe angle. The Probe Angle Indicators will be yellow if the probe angle is too high or too low, and will be green when the probe is within the correct probe angle range. The device will not measure, and the probe angle indicators will flash accompanied by an audible tone, if the probe is outside of the ±15° probe angle range.

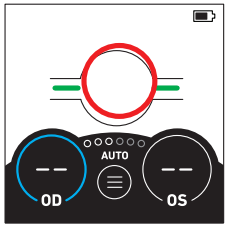
Distance & Centration (6 mm (+/- 1.5 mm))



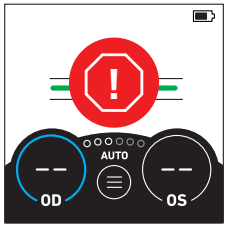
Yellow Ring:
Too Far and/or Off-Center



Green Ring:
Proper Distance and Centration

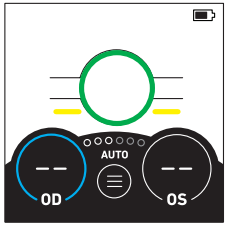


Large Red Ring:
Too Close
Beep Will Sound

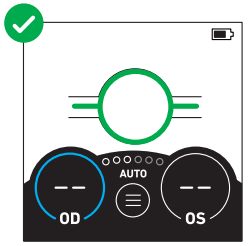


Large Red Stop Sign:
Too Close
Beep Will Sound

Probe Angle (±15°)



Yellow Probe Angle Indicators:
Probe Angle Too High



Green Probe Angle Indicators:
Proper Probe Angle Alignment

Instructions for Use

Measuring

1. If ActiView Auto Measure Mode is ON, measurements will be taken automatically when Tono-Vera is positioned correctly. If ActiView Auto Measure Mode is OFF, press the blue Manual Measure Button to measure upon correct positioning.

   NOTE: The blue Manual Measure Button can be pressed at any time if the operator wishes to override the auto measurement system. However, this may result in less reliable measurements. Measurements will only be taken if the device is within the ±15° probe angle range.

2. The measurement dots indicate the number and status of measurements needed to obtain the Final IOP Result.

   Each empty white dot indicates a required measurement. A solid blue dot indicates a successful measurement.

   When the Menu setting for Measurements is set to 3+ (Quick), a minimum of three measurements will be needed to obtain a high-confidence IOP result. If more than three measurements are required, an empty gray dot will turn white, indicating another measurement is required. When set to 6, six measurements will be taken for a high-confidence IOP result.*

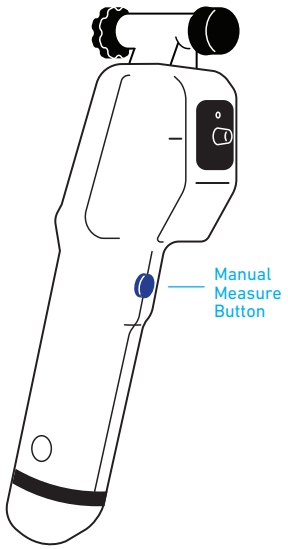
   NOTE: When measurements are completed, the IOP will be displayed in a large colored ring on the screen. Refer to the Understanding Results section of this manual for detailed information.

3. After measuring the first eye, the device will automatically select the next eye to measure.

   WARNING: If the device takes a measurement while the patient blinks, the probe could potentially become caught by the patient's eyelashes. If this occurs, simply dispose of the probe and begin the examination again with a new probe.

   CAUTION: Do not place device on a surface with the Ocu-Dot Probe or Probe Chamber facing down. This may damage the device and Ocu-Dot Probe. Place device on its side if the device must be laid down on a surface.

1



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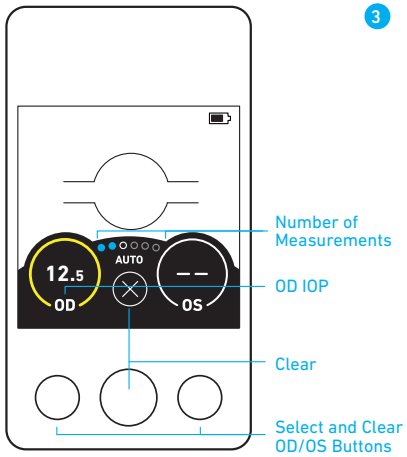

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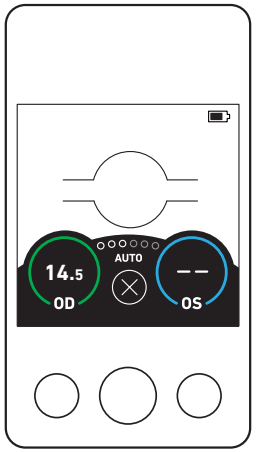


*The 6 Measurement option may provide better repeat measurement variability versus the 3+ (Quick) Measurement option.

Instructions for Use

Probe Notifications

Probe Did Not Deploy
Tono-Vera attempted to take a measurement, but the probe did not deploy. Attempt the measurement a second time. If the error occurs again, dispose of the existing probe and replace it with a new one.

Clean Probe Base
See “Cleaning and Maintenance” section.

Too Far From Eye
Tono-Vera attempted to take a measurement, but the probe did not contact the eye. Use the ActiView Positioning System to maintain ~6mm distance from the eye while measuring.

Probe Did Not Deploy | Clean Probe Base | Too Far from Eye

Understanding Results

1. **High Confidence Final IOP Result**
   Once enough measurements are taken for a high confidence Final IOP Result, the Final IOP Result will be briefly displayed in a large green ring. After, the measurement screen will reappear and the corresponding OD or OS circle will have a green ring around it.

2. **Low Confidence Final IOP Result**
   If the Manual Measure Button was pressed when ActiView Auto Measure Mode is ON, the Final IOP Result will be briefly displayed in a yellow ring. After, the measurement screen will reappear and the corresponding OD or OS circle will have a yellow ring around it.

   If the other eye is selected before sufficient measurements were taken to obtain a High Confidence Final IOP Result, the corresponding OD or OS circle will appear in yellow.

3. **Retake Measurement**
   If there is a high variability between measurements (high standard deviation) the Retake Measurement arrow will appear with a large orange ring around it. Retake the measurement to obtain a reliable Final IOP Result.

NOTE: The 3+ (Quick) or 6 Measurements option is selected by the operator in the device menu. When the 6 Measurement option is selected, Tono-Vera always uses 6 probe activations to calculate the IOP for each eye. The median of all 6 measurements is determined, then the final IOP is calculated as the mean of all measurements within +/-10% of that median value. Any measurements outside of +/-10% of the median are excluded from calculation of the final IOP. To be considered valid, the final IOP value must have been calculated using a minimum of 4 measurements.

When the 3+ (Quick) Measurement option is selected, Tono-Vera uses a minimum of 3 and a maximum of 6 probe activations to calculate the IOP for each eye. After each probe activation, the median of the measurements is determined, then the IOP is calculated as the mean of all measurements within +/-10% of the that median value. Any measurements outside of +/-10% of the median are excluded from calculation of the final IOP. To be considered valid, the final IOP value must have been calculated using at least three measurements after 3, 4, or 5 probe activations, or at least four measurements after 6 probe activations.

CAUTION: Tono-Vera was tested on only 2 subjects with corneal astigmatism > 3 diopters and IOP ≥ 23 mmHg. The ANSI Z80.10 (2014) standard requires testing of at least 10 subjects in this corneal astigmatism and pressure subcategory with Tono-Vera and GAT. Therefore, it is uncertain if Tono-Vera measurements will agree with GAT measurements to within the standard's required measurement pair difference of ± 5.0 mmHg for eyes in this subcategory.

Instructions for Use

Data Transfer

Tono-Vera is capable of transmitting measurements via Bluetooth to a PC with a Windows 10 or higher operating system. These measurements are received by ReichertSync software, which makes them available to a medical records (EMR/EHR) application running on the same PC. Tono-Vera takes a number of cybersecurity precautions, including encrypted data transmission and the use of passcodes during pairing. No Protected Health Information is present in any data transmission.

To begin data transmission, download ReichertSync from the Reichert website and install, following the setup and cybersecurity guidance in the ReichertSync instructions. Note the range of Bluetooth is generally limited to 10 meters and will work best at 3 meters or less.

If you have any questions, cybersecurity concerns, or notice any unusual or suspicious activity, please contact the Reichert Technical Support Group by phone or via the Reichert website.

Connecting to the Computer

1. Install ReichertSync on your computer. Refer to the ReichertSync Instructions for Use to set up Tono-Vera in ReichertSync.

2. Navigate to the Bluetooth screen in the Menu.

3. 

   Press the Select Button to enable Bluetooth. The Bluetooth icon will turn white when Bluetooth is enabled.

4. Follow the directions in ReichertSync to pair Tono-Vera to the computer. When Bluetooth is enabled, a Bluetooth icon will appear in the upper left corner. This indicates the status of the Bluetooth connection.

No Dots:
Not Connected

Green Dots:
Connected and Able to Transfer Data

NOTE: After Tono-Vera is paired to the computer, the Bluetooth connection will automatically reconnect when the device is powered up. If Tono-Vera does not automatically reconnect to the computer, refer to the Troubleshooting section of this manual.

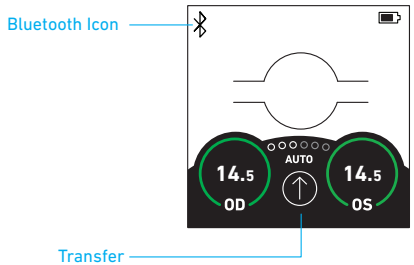
5. To disable Bluetooth, navigate to the Bluetooth screen in the Menu and press the Select Button. The large Bluetooth icon will turn gray and the small Bluetooth icon in the upper left will disappear.

Transferring Data to the Computer

1. After obtaining Final IOP Results, press the center Multifunction Button to transfer data to the computer. A countdown may appear indicating that data is transferring.

2. Once the data has been transferred, a Bluetooth icon in a green ring will briefly appear on the screen. The IOP measurements will clear out and the device will be ready to take a new measurement.

NOTE: If an error occurs, the Bluetooth symbol will appear in an orange ring. Refer to the Troubleshooting section of this manual.



Instructions for Use

Practice

Tono-Vera provides a Practice feature to help users become familiar with the ActiView Positioning System. Practice allows a user to experience aligning the device to a patient's eye without using a probe.

1. Navigate to the Practice screen in the Menu and click the center Multifunction Button to enter Practice mode.

2. If an Ocu-Dot Probe is installed, a notification will be displayed indicating that the probe should be removed. Remove the probe to continue with Practice.

3. Using the on-screen ActiView Positioning System, slowly align Tono-Vera so the Tono-Vera Probe Chamber is centered over the subject's eye, and at the correct distance. The alignment ring and level indicators will turn green when the device is properly aligned for distance, centration, and angle. Refer to the Positioning, Aligning, and Measuring sections of this manual for detailed instructions.

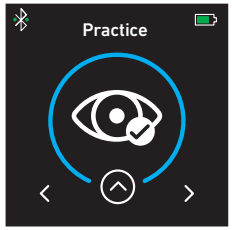
4. As simulated measurements are performed, the OD/OS circles will display how many measurements have been taken. After the full set of measurements are complete, the OD/OS circles will display a checkmark.

5. At any point, measurements can be cleared by pressing the center Multifunction Button.

6. Practice taking IOP measurements as many times as desired.

7. After measurements are cleared, press the center Multifunction Button again to end Practice and resume normal operation.

1



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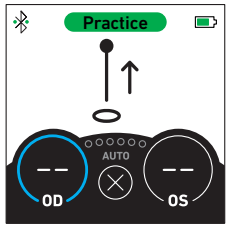

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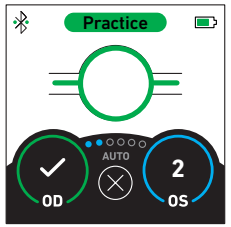


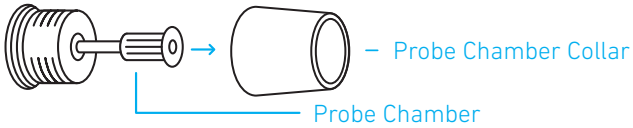
Cleaning and Maintenance

Probe Chamber

A replacement Probe Chamber is included with Tono-Vera so that the device can be used while the Probe Chamber is being cleaned. Over time, dirt, dust, and debris may enter the Probe Chamber, so cleaning of the Probe Chamber is necessary for the proper functioning of the device.

Cleaning
Clean the Probe Chamber every 15 days, or anytime the Clean icon appears.

1. Remove the Battery Pack.
2. Unscrew the Probe Chamber Collar by hand, turning it counterclockwise, and place in a safe location.
3. Slide the Probe Chamber out.



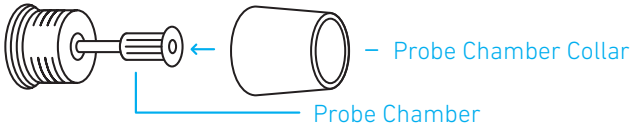
4. Place the Probe Chamber in the empty Cleaning Vial that was provided with the device.
5. Fill the Cleaning Vial with 70% isopropyl alcohol and close the top of the vial.
6. Let the Probe Chamber soak for five minutes, occasionally shaking the vial.
7. Remove the Probe Chamber and rinse with water.
8. Shake residual water and alcohol out of the Probe Chamber. Place on paper towel or tissue and allow to dry for 24 hours. Alternately, you may use canned air to force dry the inside of the Probe Chamber.

Installation and Replacement

1. Insert a new or clean Probe Chamber into Tono-Vera.

   WARNING: It is essential that the Probe Chamber be completely dry inside before reinstalling into the device.

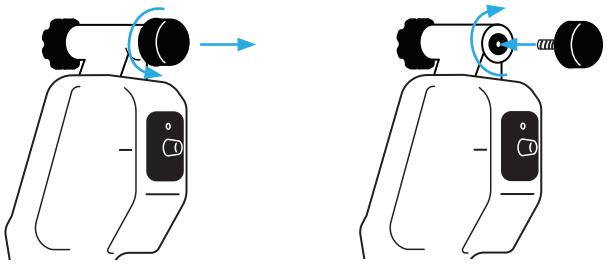
2. Secure the Probe Chamber by installing the Probe Chamber Collar. Turn the Probe Chamber Collar clockwise until it is fully seated.



Flexi-Soft Forehead Rest

Replace Flexi-Soft Forehead Rest (PN 16305-876) when needed.

1. Remove the Flexi-Soft Forehead Rest by turning it counterclockwise (when Forehead Rest is facing you).
2. Install a new Flexi-Soft Forehead Rest by screwing it on clockwise.



Cleaning and Maintenance

Cleaning Tono-Vera Exterior

CAUTION: Do not immerse Tono-Vera in fluids. This will cause damage to the electronics and void the warranty.

WARNING: Do not spray, pour, or spill liquid onto Tono-Vera, its accessories, connectors, switches, or openings in the body. Remove any liquid appearing on the surface of Tono-Vera immediately.

The outer surfaces of Tono-Vera and Tono-Vera Base, including the charging contacts and the Flexi-Soft Forehead Rest, may be safely cleaned with the following:

- 7.5% hydrogen peroxide and water solution
- 5.25% bleach and water solution (sodium hypochlorite at least 5000 parts per million (ppm) diluted at 1/4 unit volume 5.25% bleach to 2.25 unit by volume distilled water)
- 70% isopropyl alcohol
- Quaternary ammonium compounds

1. Press and hold the center Multifunction Button for approximately five seconds to turn the power off.
2. Dampen a soft cloth with one of the approved solutions, or use one of the approved products.
3. Lightly wipe the surfaces.
4. Remove residual fluid using a soft, dry cloth.

Battery

Replace Tono-Vera batteries when needed. Only replace with the Reichert Tono-Vera Lithium-ion Rechargeable Battery Pack or with new AA batteries.

Energizer® or Duracell® batteries are recommended to be used with the AA version. Alternative battery brands may impact device measurement longevity.

NOTE: Only use new batteries. Never mix new and old batteries together.

Storage

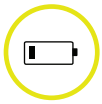
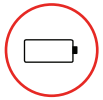
If the device is to be stored for an extended period, remove the AA batteries or the rechargeable battery pack to avoid possible damage to the device due to battery leakage. The device may be stored on the Tono-Vera Base or in the Tono-Vera Carry Case.

Disposal

Tono-Vera, Ocu-Dot Probes, and Tono-Vera Lithium-Ion Cartridge 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 the device.

Troubleshooting

The table below provides a guide for troubleshooting some basic Tono-Vera Tonometer operational problems.
If a problem persists after using this guide, contact the Reichert Technical Support Group. Contact information is on the last page of this manual.

SYMPTOM	PROBABLE CAUSE	CORRECTION
Device will not turn on.	Button not pressed.	Press any button.
	Depleted batteries in device.	Replace or recharge the batteries.
	Mechanical or electronic damage.	Arrange for service through the Reichert Technical Service Group.
	Batteries not installed correctly (AA model).	Ensure batteries are installed according to the diagram on the AA Battery Pack.
Battery will not charge. (For Tono-Vera Li-Ion Rechargeable Battery Pack only)	Charging Base is not properly plugged in.	Plug in the Charging Base, ensuring both ends of the USB-C Charging Cord are fully inserted into both the Charging Plug and the Charging Base.
	Battery is too hot or too cold (higher than 45°C (113° F) or lower than 0°C (32° F)).	Allow battery to either warm up or cool down so it is between 45°C (113° F) and 0°C (32° F) then charge the battery.
	Incorrect voltage to electrical outlet.	Check the voltage to the electrical outlet.
	Dirty charging contacts on the Tono-Vera Charging Base.	Clean the contacts. Refer to the Cleaning & Maintenance section of this manual.
	Missing or bent charging contacts in the Tono-Vera Charging Base.	Arrange for service through the Reichert Technical Support Group.
	A foreign object is blocking the charging contacts in the Charging Base.	Remove the foreign object to allow for proper charging.
This symbol appears on screen: 	Battery is hotter than 45°C (113° F) or colder than 0°C (32° F).	Allow battery to either warm up or cool down so it is between 0°C (32° F) and 45°C (113° F). If the battery is between these temperatures and is still displaying this symbol, contact the Reichert Technical Support Group.
	Battery charge is low.	Device will need to have batteries replaced or recharged soon.
	Battery has no charge. Device will shut down.	Replace batteries with new batteries if using AA model. Charge battery if using rechargeable model. If symbol reappears after replacing the batteries or charging the rechargeable battery, contact the Reichert Technical Support Group.
Error Code appears on screen:  ERROR 0xXXXX	Internal system error.	Device will power off. Restart device. If error occurs again, contact the Reichert Technical Support Group.

Troubleshooting

SYMPTOM	PROBABLE CAUSE	CORRECTION
Will not take a measurement.	ActiView Auto Measure Mode not ON.	Set ActiView Auto Measure Mode to ON.
	Manual Measure Button not pressed when ActiView Auto Measure Mode is OFF.	Press the Manual Measure Button when the device is properly aligned.
	Device is outside the probe angle range (±15°)	Ensure the device is at the correct probe angle.
	Patient blinking while taking the measurement and Ocu-Dot Probe not contacting the eye.	Have the patient focus on a focal point and retake the measurement.
	Ocu-Dot Probe not installed.	Install a new Ocu-Dot Probe.
	Bad Ocu-Dot Probe.	Install a new Ocu-Dot Probe.
	Dirty Probe Chamber.	Clean the Probe Chamber.
	Bad Probe Chamber.	Replace the Probe Chamber.
Inaccurate measurements.	The Manual Measure Button was pressed while ActiView Auto Measure Mode was ON.	Do not press the Manual Measure Button when ActiView Auto Measure Mode is ON.
	ActiView Auto Measure Mode is OFF.	Set ActiView Auto Measure Mode to ON.
	Bent or damaged Ocu-Dot Probe.	Replace the Ocu-Dot Probe.
	Measurements are outside the measurement range (>99).	Device is operating correctly. Measurements greater than 99 mmHg will always appear in an orange circle.
	Mechanical or electronic damage.	Arrange for service through the Reichert Technical Support Group.
Data not transferring to EMR	Tono-Vera Bluetooth is not on.	Turn Bluetooth on in the Menu.
	Tono-Vera is not paired with computer or Bluetooth connection not setup properly.	Connect Tono-Vera to the PC. Refer to the Data Transfer section of this manual. Contact the Reichert Technical Support Group for further troubleshooting.
	PC does not have Bluetooth enabled.	Enable Bluetooth on the PC.
	Bluetooth driver not installed on PC.	Install or update the Bluetooth driver on your PC.
	ReichertSync is not running on the PC.	Run the ReichertSync software.
	ReichertSync settings are incorrect.	Refer to the ReichertSync Instructions for Use to properly set up Tono-Vera. Contact the Reichert Technical Support Group for further assistance.

Specifications

PHYSICAL DIMENSIONS

TONO-VERA

Size: 21.25 x 6.6 x 3.0 cm
(8.4 x 2.6 x 1.2 in)

Weight: 120.3g (4.2 oz)
(without batteries)

DISPLAY DIMENSIONS

Size: 2.8 x 2.8 cm
(1.1 x 1.1 in)

ENVIRONMENTAL REQUIREMENTS

Operational Environment
Ambient Temperature range: 10° to 35°C (50° to 95°F)

Relative Humidity range: 30 to 90%

Atmospheric Pressure range: 80 kPa to 106 kPa (23.6 to 31.3 inHg)

Transportation Environment
Ambient Temperature range: -40° to 70°C (-40° to 158°F)

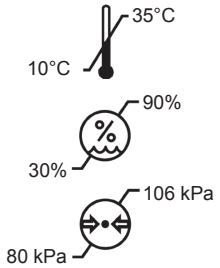
Relative Humidity range: 10 to 95% (non-condensing)

Atmospheric Pressure range: 50 kPa to 106 kPa (14.8 to 31.3 inHg)

Storage Environment
Ambient Temperature range: -10° to 55°C (14° to 131°F)

Relative Humidity range: 10 to 95% (non-condensing)

Atmospheric Pressure range: 70 kPa to 106 kPa (20.7 to 31.3 inHg)



ELECTRICAL

Battery Pack
Tono-Vera Li-Ion Rechargeable Battery Pack Voltage: 3.7V Li-Ion*
Input: 5.0 Vdc, 1.2 A

A/C Adaptor:
A/C Adaptor Input: 100-240 VAC, 50-60 Hz,0.32-0.19 A max
A/C Adaptor Output: 5.1 VDC, 2.4 A

Input Voltage - New AA Batteries:
(4 x AA non-rechargeable batteries**) 1.5 V alkaline LR6

* Only use the Tono-Vera Li-Ion Rechargeable Battery Pack from Reichert. Do not use another brand of rechargeable battery with the device.

** Energizer® or Duracell® batteries are recommended to be used with this device. Alternative brands may impact battery life.

RANGE OF IOP MEASUREMENTS

Measurement range 5-60 mmHg

(Display range 1-99 mmHg)

Accuracy by bench testing (95% confidence)

Measurement (mm Hg)	Accuracy (mm Hg)
5-20	± 1.0
21-60	± 2.0

Tono-Vera complies with the ISO 8612:2009 Ophthalmic instruments — Tonometers standard

Repeatability (coefficient of variation): <3.6%

MEASUREMENT DISTANCE

6 MM (±1.5 MM)

OCU-DOT TONOMETER PROBES – 100 COUNT

Biocompatible polymer tipped wire.

SOFTWARE REVISION

The software revision can be found under the System Info section of the Menu.

Specifications

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

Compliance
Tono-Vera complies with:
IEC 60601-1 (Edition 3.2)
IEC 60601-1-2 (Edition 4.1)

CE Compliance
IEC 60601-1 Edition 3.2
Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 Edition 3.2
Medical electrical equipment –
Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

IEC 60601-1-2 Edition 4.1
Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

CISPR 11
Industrial, scientific and medical equipment –
Radio-frequency disturbance characteristics – Limits and methods of measurement

IEC/EN 61000-3-2
Electromagnetic compatibility (EMC) –
Part 3-2: Limits – Limits for harmonic current emissions (equipment ≤ 16A per phase)

IEC/EN 61000-3-3
Electromagnetic compatibility (EMC) –
Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16A per phase and not subject to conditional connection

Radio Equipment Directive (RED) 2014/53/EU

ETSI EN 300 328 V2.2.2 (2019-07)
Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

ETSI EN 301 489-1:2019-11 Ed. V2.2.3
Electromagnetic Compatibility (EMC) standard for radio equipment and services;
Part 1: Common technical requirements; Harmonized Standard for Electromagnetic Compatibility

ETSI EN 301 489-17:2020-09 Ed. V3.2.4
Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard for Electromagnetic Compatibility

AS/NZS 4268:2017
Radio equipment and systems –
Short range devices – Limits and methods of measurement

Method of compliance per standard above and RSS-Gen

FCC Compliance
FCC 47 CFR Part 15 Subpart B – Class B Digital Device – Unintentional Radiators

FCC 47 CFR Part 15 Subpart C 15.247 Operation within the bands 902-928 MHz, 2400-2483.5 MHz, 5725-5850 MHz
(Approved Module Spurious Emission Verification)

ANSI C63.4:2014
American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

IC (INDUSTRY CANADA):
ISED ICES-003:2016 Ed. 6
ISED ICES-001, Issue 5, Class B – Industrial, Scientific and Medical (ISM) Equipment
ISED ICES-003, Issue 6, Class A – Information Technology Equipment (Including Digital Apparatus) – Limits and methods of measurement
Compliance is suggested by ISED Canada as CAN ICES-3 (A) / NMB-3 (A)

Method of compliance per each standard above and ANSI C63.4:2014

MIC Japan Compliance
Low power data communications in the 2.4GHz band - Radio Equipment
Radio Law: Law No. 131, 1950 and Amendments
Standards: Equipment Radio Regulations: 2008 (including amendments)
Certificate No: 201-210665 /00

Performance

Results from ANSI Z80.10-2014 / ISO 8612-2009 clinical trial:

A study was designed in accordance with ANSI Z80.10-2014 and ISO 8612-2009 guidelines for tonometer comparison. Intraocular Pressure (IOP) was measured by the reference tonometer (Goldmann Applanation; GAT) and the test tonometer (Tono-Vera; TV) on 160 eyes of 160 subjects. Bland-Altman plots, total least squares regression analysis, and simple linear regression were used to evaluate agreement between the tonometers. The results are summarized in Table 1 and in Figures 1-3 below. While there are slight differences in the ANSI and ISO standards, Tono-Vera meets the primary requirements of both.

	IOP RANGE (mmHg) DEFINED BY GAT	ASTIGMATISM	N EYES	AVERAGE GAT IOP (mmHg)	AVERAGE TV IOP (mmHg)	MEASUREMENT PAIR DIFFERENCE > ± 5 mmHg	% OF MEASUREMENT PAIR DIFFERENCES > ± 5 mmHg
LOW	7 TO 16	≤3D	49	12.7	13.3	0	0.00%
MEDIUM	>16 TO <23	≤3D	43	19.6	19.1	1	2.27%
HIGH	≥23	≤3D	45	27.4	26.7	1	2.17%
LOW	7 TO 16	>3D	11	13.1	12.9	0	0.00%
MEDIUM	>16 TO <23	>3D	10	19.4	18.2	0	0.00%
HIGH	≥23	>3D	2	27.0	26.3	0	0.00%
TOTAL			**160**	**19.2**	**19.0**	**2**	**1.25%**

Table 1: ANSI Z80.10-2014 data

Notes: ANSI Z80.10 and ISO 8612 require 40 eyes in each of the three IOP categories. Test and reference tonometer measurements must be +/- 5 mmHg in 95% of matched-pairs. ANSI Z80.10 requires 10 additional eyes per IOP category with greater than 3D astigmatism. The investigators were unable to recruit 10 patients with >23 IOP and >3D astigmatism eyes. Tono-Vera was used in 6-measurement mode.

Performance

Figure 1: Total Least Squares Regression of Tono-Vera vs GAT for all 160 eyes with best fit line.

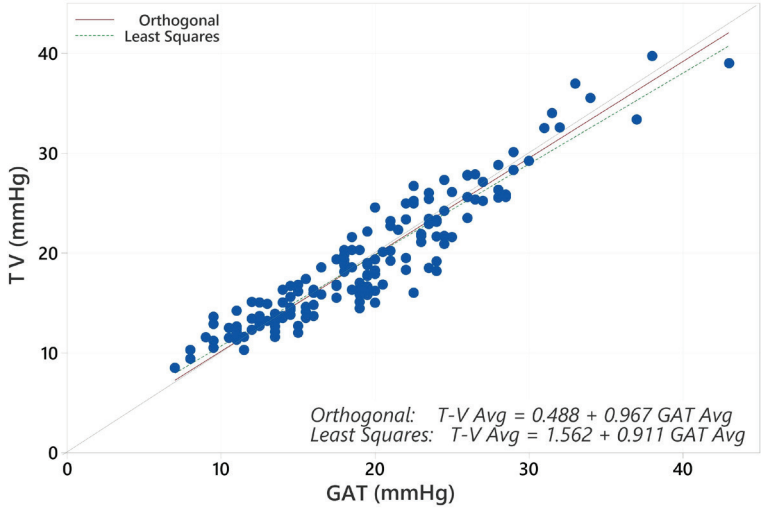


Figure 2: Bland-Altman Comparison of Tono-Vera to GAT for 137 eyes with <3D corneal astigmatism.

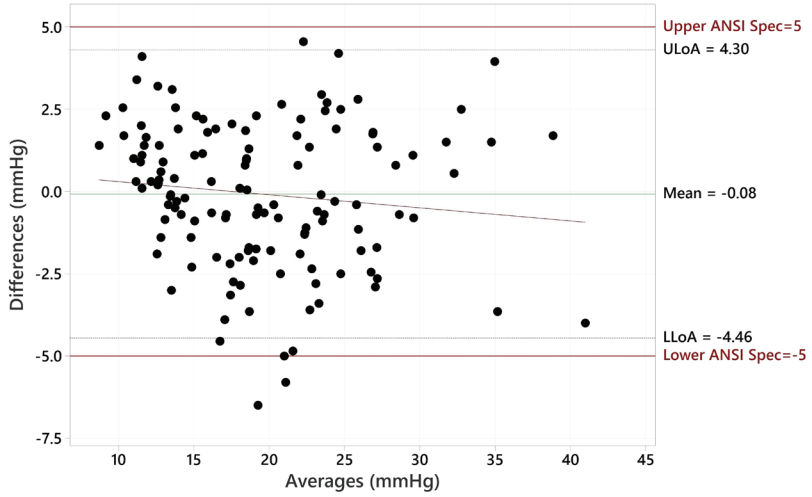
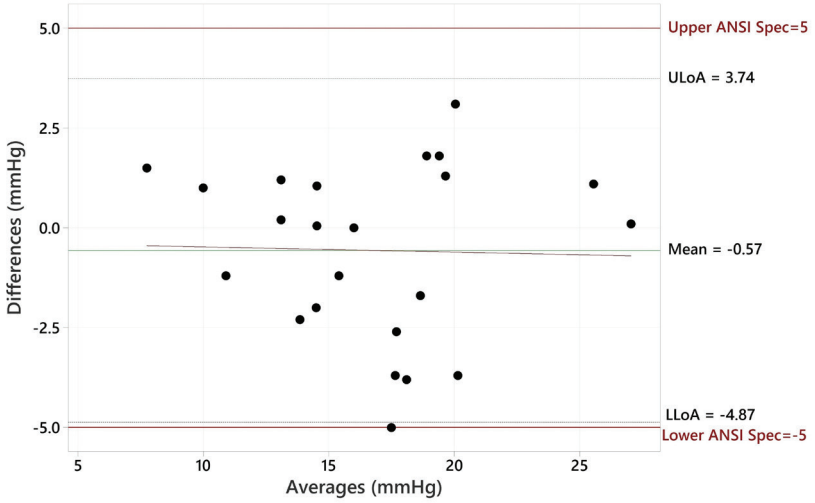


Figure 3: Bland-Altman Comparison of Tono-Vera to GAT for eyes with >3.0D corneal astigmatism.



Performance

Clinical Validation of 3+ (Quick) Measurement Option

Clinical data was used to demonstrate the equivalence of IOP results obtained using the 6 Measurement option and the 3+ (Quick) Measurement option. 60 eyes of 32 subjects with corneal astigmatism ≤ 3 diopters were measured using the 6 Measurement option. Individual IOP readings from each probe activation were recorded using ReichertSync software. Individual IOP readings taken with the 6 Measurement option were retrospectively analyzed using our 3+ (Quick) algorithm to calculate the 3+ (Quick) IOP measurement values in order to compare the IOP values from the two measurement options. Table 1 below provides an overview of the results. The 3+ (Quick) Measurement option has not been clinically evaluated in subjects with corneal astigmatism of > 3 diopters.

RANGE (mmHg)		NUMBER OF EYES	3+ MEAN (mmHg)	6 TAP MEAN (mmHg)	3+ Stdev (mmHg)	6 TAP Stdev (mmHg)
LOW	7 TO 16	23	17.1	16.9	2.7	2.7
MEDIUM	>16 TO <23	16	22.1	22.0	3.1	2.5
HIGH	≥23	21	28.4	28.3	6.4	6.5
TOTAL		60				

Table 1: Result Summary; Corneal Astigmatism ≤ 3.0D

Guidance Tables

RF Wireless Module Certifications

FCC RF Transmitter Characteristics

- Contains FCC ID: WAP3072
- Frequency 2402-2480 MHz, Spread Spectrum

IC RF Transmitter Characteristics

- License IC: 7922A-3072
- Frequency 2402-2480 MHz, Spread Spectrum

MIC Japan RF Transmitter Characteristics

- Certification No. 201-210665 / 00

FCC/IC Statements

FCC Statement

The device complies with Part 15 of the FCC Rules and meets the requirements for modular transmitter approval as detailed in FCC public Notice DA00-1407.

Operation 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.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part B of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful 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 into an outlet on a circuit different from that to which the receiver is connected.
- Consult Reichert or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow specific operating instructions for satisfying RF exposure compliance. The instrument must not be co-located or operated in conjunction with any other antenna or transmitter, except in accordance with FCC test procedures. This transmitter is considered a mobile device.

ISED Statement

The device complies with Canada RSS-GEN Rules. The device meets the requirements for modular transmitter approval as detailed in RSS-GEN. This device complies with Innovation, Science and Economic Development (ISED) Canada license-exempt RSS standard(s).

Operation 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.

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 15 mm between the radiator and your body.

Guidance Tables

Guidance and Manufacturer's Declaration – Electromagnetic Emissions
Professional Healthcare Facility Environment

Electromagnetic Emissions

All Medical Electrical Equipment and Medical Electrical Systems

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

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE -
Conducted and Radiated RF Emissions CISPR 11	Group 1	Tono-Vera 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.
Conducted and Radiated RF Emissions CISPR 11	Class B	Tono-Vera 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	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	

Guidance Tables

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
Professional Healthcare Facility Environment

Electromagnetic Immunity

All Medical Electrical Equipment and Medical Electrical Systems

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

IMMUNITY TEST	IEC 60601-1-2 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 100 kHz repetition frequency	±2kV Mains Power Lines ±1kV I/O Lines 100 kHz repetition frequency	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surges IEC 61000-4-5	±0.5kV, ±1.0kV Line-to-line	±0.5kV, ±1.0kV Differential Mode	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°	0% Ut, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Mains power quality should be that of a typical residential, commercial or hospital environment. If the user of Tono-Vera requires continued operation during power mains interruptions, it is recommended that Tono-Vera be powered from an uninterruptible power supply or battery.
	0% Ut, 1.0 cycle 70% Ut, 25/30 cycles for 50Hz and 60Hz respectively Single phase: at 0°	0% Ut, 1.0 cycle 70% Ut, 25/30 cycles for 50Hz and 60Hz respectively Single phase: at 0°	
Voltage Interruptions IEC 61000-4-11	0% Ut, 250/300 cycles for 50Hz and 60Hz respectively Single phase: at 0°	0% Ut, 250/300 cycles	
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.

Guidance Tables

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
Professional Healthcare Facility Environment

Electromagnetic Immunity

All Medical Electrical Equipment and Medical Electrical Systems

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

Immunity Test	IEC 60601-1-2 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 and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz	(V1) = 3 Vrms 150 kHz to 80 MHz (V2) = 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be no closer to any part of Tono-Vera, 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(√P) 150kHz to 80 MHz d = (10/3)(3.5)/V2(√P) 150kHz to 80 MHz in ISM bands d = 3.5/E1(√P) 80 to 800 MHz d = 7/E1(√P) 800 MHz to 6.0 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 6.0 GHz 80% AM at 1kHz	(E1) = 3 V/m 80 MHz to 6.0 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 may be necessary, such as reorienting 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.

Guidance Tables

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Professional Healthcare Facility Environment

Recommended Separation Distances between

Portable and Mobile RF Communications Equipment from Medical Equipment and Medical Electrical Systems

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and Tono-Vera.

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

Max Output Power of Transmitter (W)	Separation (m) 150 kHz to 80 MHz Outside ISM Bands $d = 1.2(\sqrt{P})$	Separation (m) 150 kHz to 80 MHz In ISM Bands $d = 1.9444(\sqrt{P})$	Separation (m) 80 to 800 MHz $d = 1.2(\sqrt{P})$	Separation (m) 800 MHz to 6 GHz $d = 2.3(\sqrt{P})$
0.01	0.1166	0.1944	0.1166	0.2333
0.1	0.3689	0.6149	0.3689	0.7378
1	1.1666	1.1944	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.

Guidance Tables

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
Professional Healthcare Facility Environment

Electromagnetic Immunity

Immunity to Proximity Fields from RF Wireless Communications Equipment

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

Immunity Test	IEC 60601-1-2 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	$d = 6/E\sqrt{P}$ 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 kHz sine	2	0.3	28	28 V/m	
	710	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9 V/m	
	745								
	780								
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28	28 V/m	
	870								
	930								
	1720	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	
	1845								
	1970								
	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	
	5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9 V/m	
	5500								
	5785								

Guidance Tables

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
Professional Healthcare Facility Environment

Electromagnetic Immunity

Immunity to Proximity Magnetic Fields in the Frequency Range of 9 kHz to 13.56 MHz

Tono-Vera is intended for use in the electromagnetic environment as specified below related to proximity magnetic fields.

Immunity Test	**IEC 60601-1-2 Test Level**			**Compliance Level**
Radiated Magnetic Fields IEC 61000-4-39	**Test Frequency**	**Modulation**	**Immunity Test Level (A/m)**	**Compliance Level**
	30 kHz [a]	CW	8	N/A
	134.2 kHz	Pulse Modulation [b] 2.1 kHz	65 [c]	65 A/m
	13.56 MHz	Pulse Modulation [b] 50 kHz	7.5 [c]	7.5 A/m

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) r.m.s. before modulation is applied.

Warranty

This product is warranted by Reichert, Inc. against defective material and workmanship under normal use for a period of two years 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, batteries, 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.

Notes:

Notes:

Notes:

Notes:

Notes:

Manufactured by
Reichert, Inc.
3362 Walden Ave.
Suite 100
Depew, NY 14043
USA

Toll Free (US and Canada Only): 888-849-8955
Phone: +1 716-686-4500
Fax: +1 716-686-4555
Email: reichert.information@ametek.com
reichert.com
reichert.com/support

ISO-13485 Certified

16305-101 Rev. C

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