



INSTRUCTIONS FOR USE

Tono-Vera™ Vet

Tonometer

©2020 AMETEK, Inc.

Reichert and Reichert Technologies are registered trademarks of Reichert, Inc.

Tono-Vera, Ocu-Dot, ActiView, and ReichertSync are trademarks of Reichert, Inc.

AMETEK is a registered trademark of AMETEK, Inc.

All other trademarks are properties of their respective owners.

The information contained in this document was accurate at time of publication. Specifications subject to change without notice. Reichert, Inc. reserves the right to make changes in the product described in this manual without notice and without incorporating those changes in any products already sold.

ISO 13485 Certified – Reichert products are designed and manufactured under quality processes meeting ISO 13485 requirements.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, recording, or otherwise, without the prior written permission of Reichert, Inc.

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

Table of Contents

Warnings and Cautions	4
Symbol Information	5
Introduction	6
Unpacking Instructions	7
In the Box	8
Tono-Vera™ Vet Tonometer Starter Kit - Rechargeable 16309	8
Tono-Vera Vet Tonometer Starter it - AA Battery 16308	8
Tono-Vera Vet Tonometer Identification	9
Instructions for Use	10
Installing the Batteries.....	10
Rechargeable Battery Model	10
AA Battery Model.....	10
Set Up Base	11
Install Wrist Strap.....	11
Turning Tono-Vera Vet On and Off.....	11
Menu.....	12
Ocu-Dot™ Probe Installation	13
Measurement Screen	14
Positioning.....	15
Device Orientation	15
Aligning.....	16
Measuring	17
Understanding Results	18
Data Transfer	19
Connecting Ton-Vera Vet to the PC	19
Transferring Data to the PC.....	19
Tono-Vera Vet Training Aid.....	20
Cleaning & Maintenance	21
Probe Chamber	21
Cleaning Tono-Vera Vet	22
Battery.....	22
Storage.....	22
Disposal.....	22
Troubleshooting	23
Specifications	25
Guidance Tables	27
Warranty	33

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 veterinarian or a person acting on behalf of a veterinarian.

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 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: 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 60°C (140°F) 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 Vet 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: 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: 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 Tono-Vera 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 immerse Tono-Vera Vet 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 Vet 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 Vet Tonometer or Tono-Vera Vet Li-Ion Rechargeable Battery Pack or damage to the device may occur.

CAUTION: Do not store Tono-Vera Vet 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 Vet 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
-  Waste of Electrical and Electronic Equipment
-  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
-  Compliance with relevant EU requirements
-  Refer to Instructions for Use
-  Authorized Representative in the European Community

Symbols for Ocu-Dot Tonometer Probes only

-  Do not reuse. Single-Use
-  Batch Code
-  Use-by Date

Introduction

Congratulations on your purchase of the Tono-Vera™ Vet Tonometer, a handheld veterinary tonometer.

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

NOTE: Tono-Vera Vet Tonometer is not approved for use on humans.

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 Vet 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 additional copies of this manual or questions related to Tono-Vera Vet Tonometer, contact your local authorized Reichert® distributor or contact Customer Service directly at:

Phone: +1-716-686-4500

Toll Free (US Only): 888-849-8955

Fax: +1-716-686-4555

Email: reichert.information@ametek.com

Indications for Use

The indications for use include measuring of intraocular pressure of animal eyes for the purpose of aiding in the diagnosis and monitoring of glaucoma.

Contra-Indications

None.

Device Description

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

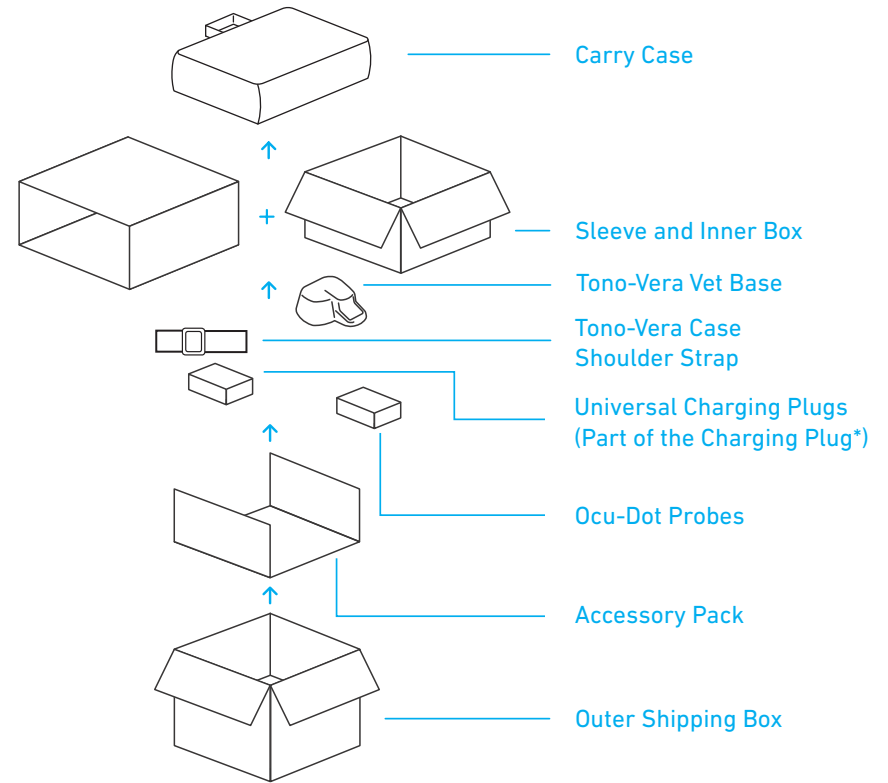
Our ActiView™ Positioning System (patent pending) guides the operator to proper alignment on the apex of the cornea with the Ocu-Dot™ Tonometer Probe (hereinafter referred to as Ocu-Dot Probe). When set to ActiView Auto Measure mode (recommended), Tono-Vera Vet automatically takes IOP measurements once properly aligned, providing a high confidence measurement in as few as three measurements. When set to ActiView Manual Measure mode or Manual Measure mode, Tono-Vera Vet takes measurements only when the Manual Measure Button is pressed.

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

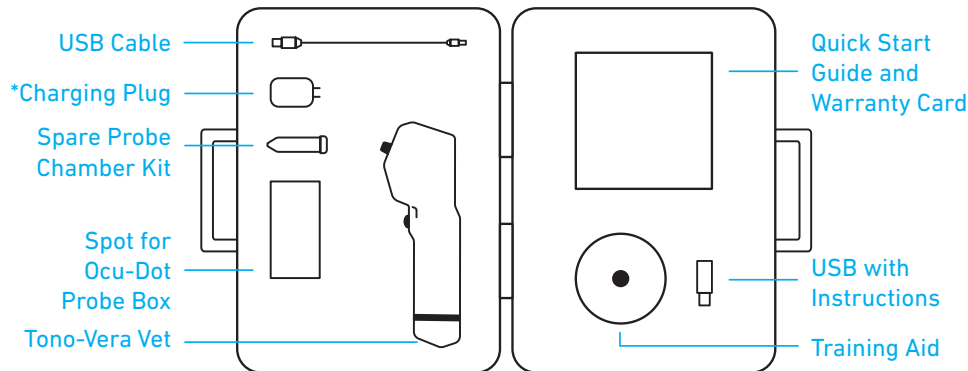
Introduction (continued)

Unpacking Instructions

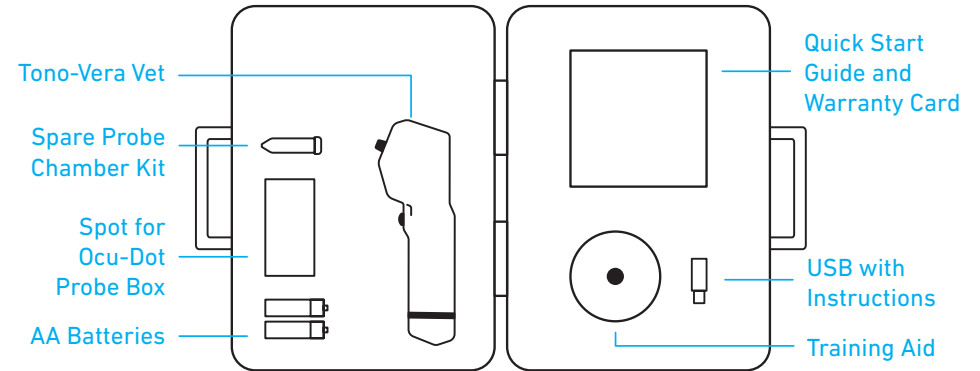
- 1 Retain original packaging to use if future transportation is required.
- 2 Open the Outer Shipping Box and remove the Inner Box.
- 3 Slide the Sleeve off the Inner Box.
- 4 Remove the Carry Case from the Inner Box.
- 5 Remove the Accessory Pack beneath the Inner Box.
- 6 Verify that all parts and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



Tono-Vera Vet Tonometer Starter Kit - Rechargeable



Tono-Vera Vet Tonometer Starter Kit - AA Battery



In the Box

Tono-Vera Vet Tonometer Starter Kit - Rechargeable 16309



Tono-Vera™ Vet Tonometer
16308-800

+



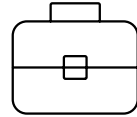
Tono-Vera™ Vet Li-Ion
Rechargeable Battery Pack
16317



Wrist Strap
13851-096



Tono-Vera™ Vet Charging Base
16316



Tono-Vera™ Vet Carry Case
16305-399



Tono-Vera™ Case
Shoulder Strap
16305-131



Tono-Vera™ Vet Quick Start Guide
16308-105



Tono-Vera™ Vet Training Aid
16308-878



Ocu-Dot™ Tonometer
Probes - 100 Count
16307



Tono-Vera™ Vet USB with Instructions
16308-106



Warranty Card
16305-111



Tono-Vera™ Spare Probe
Chamber Kit
16305-877



USB-C Charging Cable
16305-405



Charging Plug
16305-404

Tono-Vera Vet Tonometer Starter Kit - AA Battery 16308

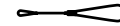


Tono-Vera™ Vet Tonometer
16308-800

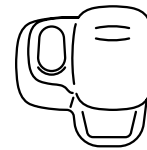
+



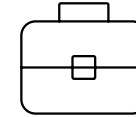
Tono-Vera™ Vet AA Battery Pack
16315



Wrist Strap
13851-096



Tono-Vera™ Vet Base
16314



Tono-Vera™ Vet Carry Case
16305-399



Tono-Vera™ Case
Shoulder Strap
16305-131



Tono-Vera™ Vet Quick Start Guide
16308-105



Tono-Vera™ Vet Training Aid
16308-878



Ocu-Dot™ Tonometer
Probes - 100 Count
16307



Tono-Vera™ Vet USB with Instructions
16308-106



Warranty Card
16305-111



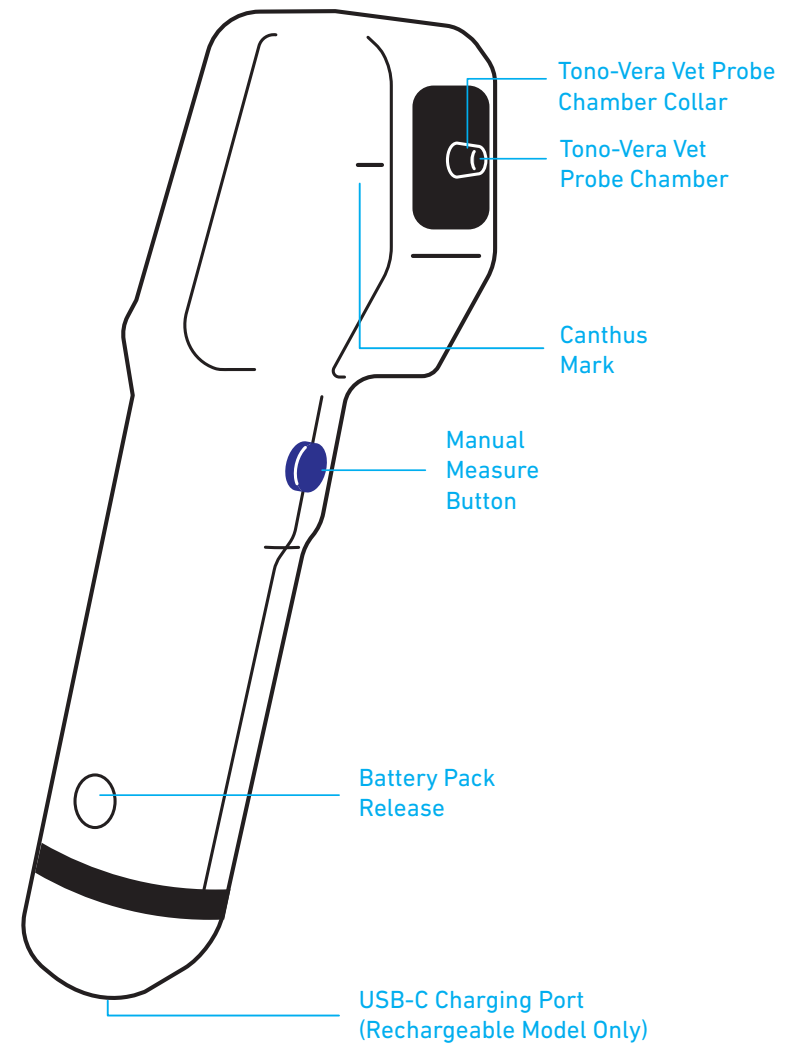
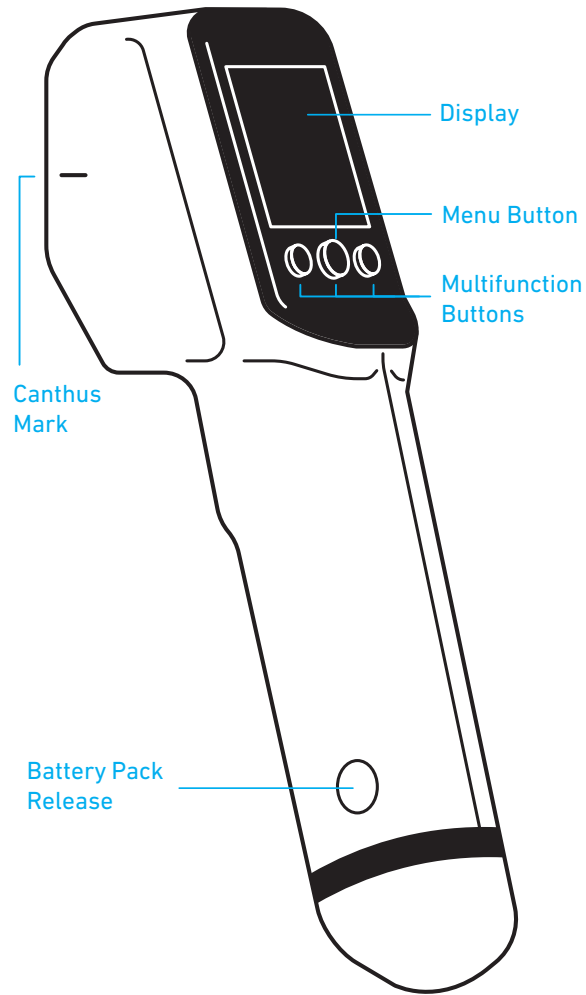
Tono-Vera™ Spare Probe
Chamber Kit
16305-877



Pack of Four AA Batteries
16305-097

In the Box (continued)

Tono-Vera Vet Tonometer Identification



Instructions for Use

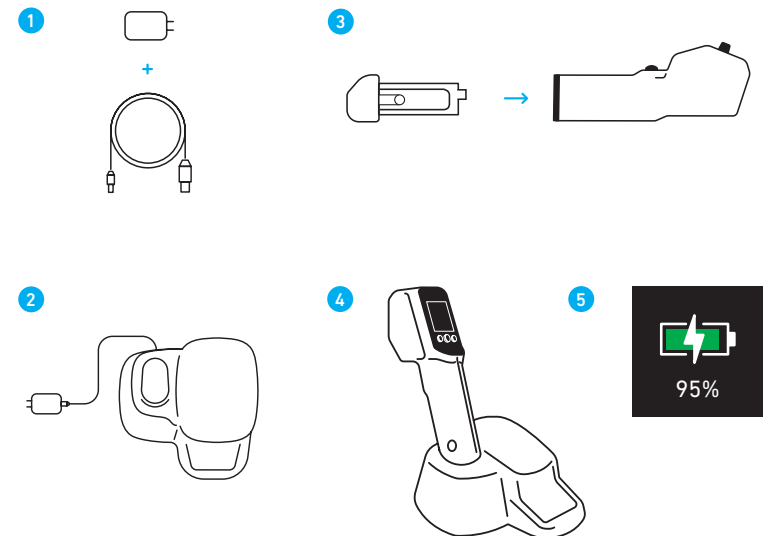
Installing the Batteries

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

Rechargeable Battery Model

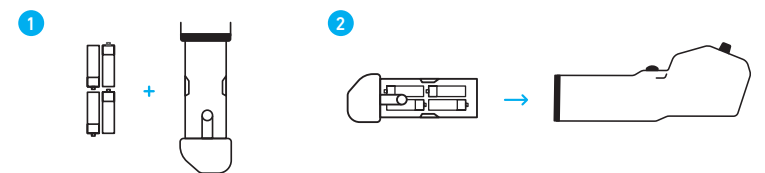
- 1 Install the country-specific adaptor to the Charging Plug. Insert one end of the USB-C Charging Cable into the Charging Plug, and the other end into the back of the Tono-Vera Vet Charging Base.
- 2 Connect the Tono-Vera Vet Charging Base to an AC wall outlet.
- 3 Slide the Tono-Vera Vet Li-Ion Rechargeable Battery Pack into Tono-Vera Vet until the Battery Pack Releases click into place.
- 4 Place Tono-Vera Vet into the Tono-Vera Vet 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 percentage 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 Vet.



AA Battery Model

- 1 Insert the four AA batteries into the Tono-Vera Vet 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 Vet AA Battery Pack into Tono-Vera Vet until the Battery Pack Releases click into place.

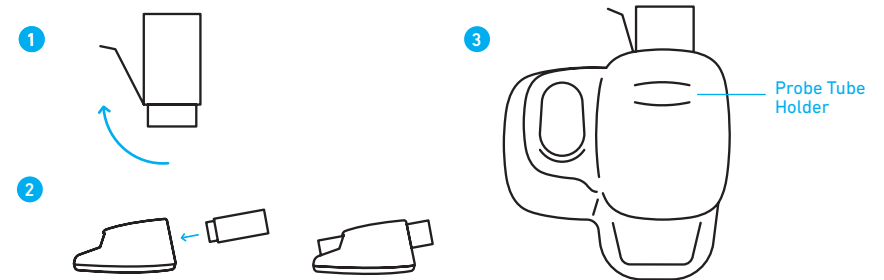


Instructions for Use (continued)

Set Up Base

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

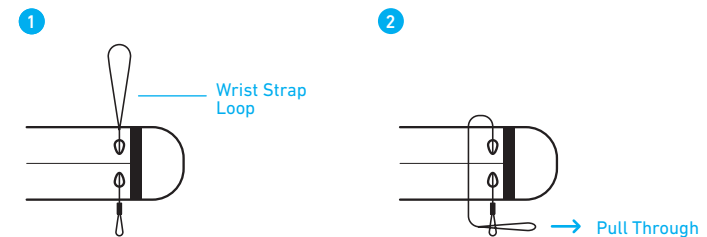
- 1 Open the box and fold the flap back along the side.
- 2 Insert the Ocu-Dot Probe box with the tray into the back of the Base with the opening facing forward. The box will stop halfway down. Push the plastic Ocu-Dot Probe tray all the way forward by inserting your finger into the circular cutout at 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 Vet to prevent the device from being dropped.

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

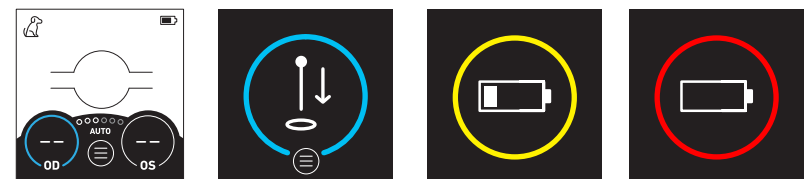


Turning Tono-Vera Vet On and Off

Press any button to turn Tono-Vera Vet on. The screen will display the Reichert and Tono-Vera Vet logos. After startup, the load probe notification will be displayed if a probe is not already loaded. Once a probe is loaded, the measurement screen will appear.

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

To turn off, press and hold the center Multifunction Button for three seconds.

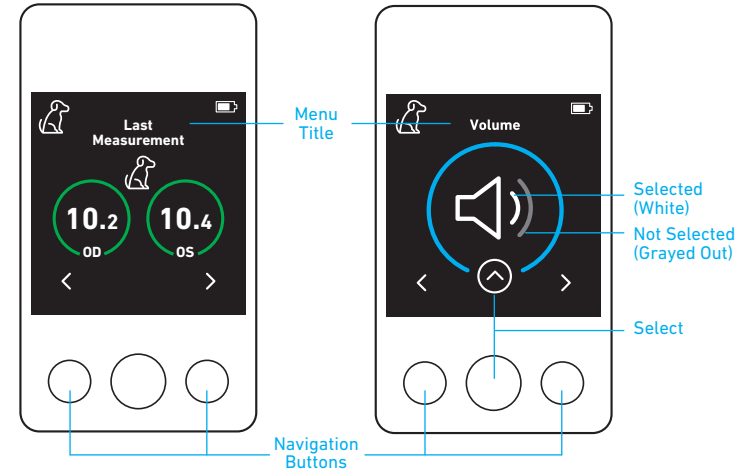


Instructions for Use (continued)

Menu

Press the Menu 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.



	<p>Species Dog, Cat, Horse, or Rabbit.</p>		<p>Measurements 1: (Quick) Provides a reliable IOP result in one fast measurement. 3+: Takes multiple measurements (minimum 3 / maximum of 6) for instances when a higher-confidence IOP result is desired.</p>		<p>Bluetooth On: Device can connect to a computer to transfer measurements to an EMR system. Off: Bluetooth off.</p>		<p>Last Measurement Displays the species and results of the previous measurement. These values can be exported via Bluetooth.</p>
	<p>Measure Mode-ActiView Auto Measure: Device automatically takes measurements when ActiView Positioning System is properly aligned to the eye.</p>		<p>Brightness Low, medium, or high screen brightness settings available.</p>		<p>Language English, German, French, Spanish, Italian, or Portuguese.</p>		
	<p>Measure Mode-ActiView Manual Measure: ActiView Positioning System is on, but device will only take measurements when blue Manual Measure Button is pressed.</p>		<p>Volume Off, low, or high volume settings available.</p>		<p>System Info Displays Software Version, the serial number, and the device name.</p>		
	<p>Measure Mode-Manual Measure: ActiView Positioning System is off. Device will only take measurements when blue Manual Measure Button is pressed.</p>		<p>Sleep 30, 60, or 90 second sleep timer available.</p>		<p>Exit Exit the menu.</p>		

Instructions for Use (continued)

Ocu-Dot Probe Installation

- 1 Pull off the Tono-Vera Vet Protective Probe Chamber Cover from the Tono-Vera Vet Probe Chamber. Take a new Ocu-Dot Probe Tube from the box and remove the cap.
- 2 Insert the open end of the Ocu-Dot Probe Tube into the Probe Chamber.
- 3 Rotate Tono-Vera Vet up so the Ocu-Dot Probe can slide into the Probe Chamber.
- 4 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 the Probe Tube for disposal.
- 5 You may store the empty Ocu-Dot Probe Tube in recess on base.

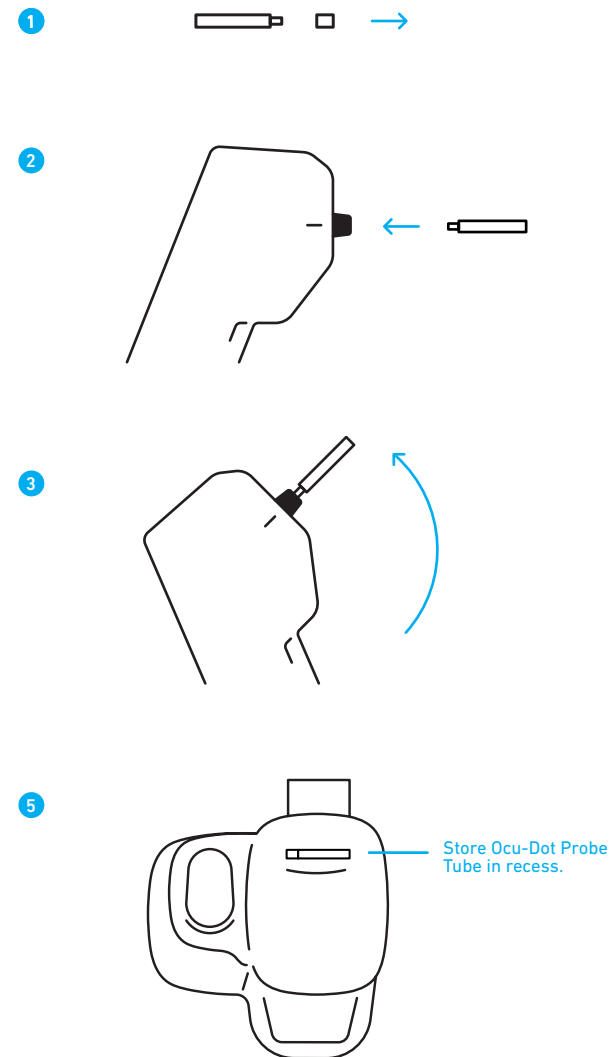
If Tono-Vera Vet is on, the tonometer will automatically secure the Ocu-Dot Probe. If it is not, press any button to turn the device on and secure the Ocu-Dot Probe.

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: 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.

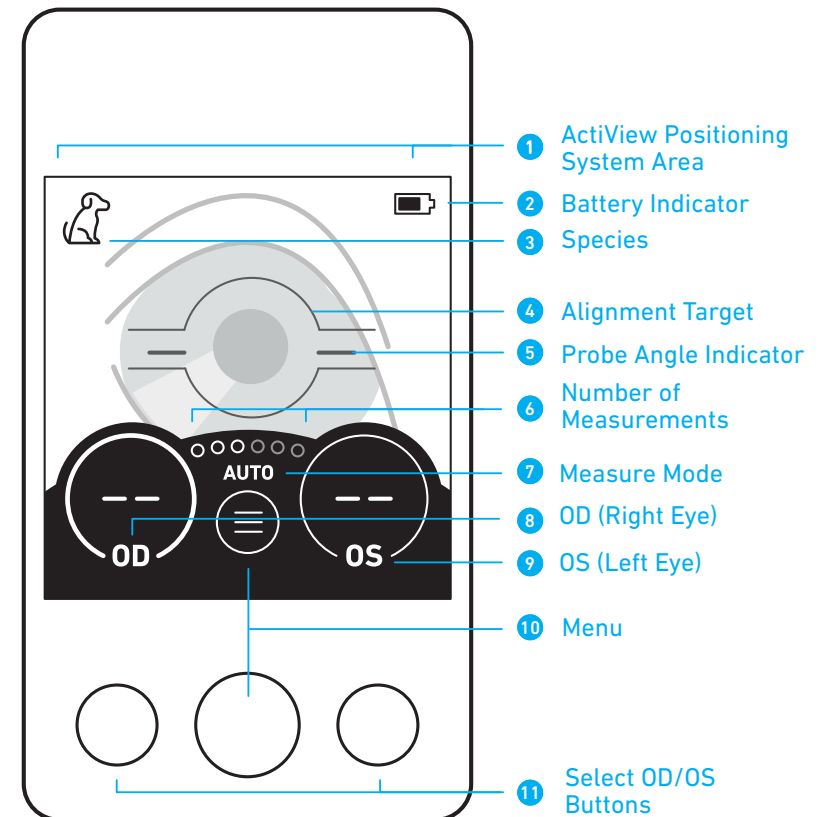
WARNING: When Tono-Vera Vet turns off, the probe will be ejected.



Instructions for Use (continued)

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 Species:** The species selected. Options are Dog, Cat, Horse, or Rabbit.
- 4 Alignment Target:** The alignment area, consisting of a circular center target and level indicators.
- 5 Probe Angle Indicator:** Two colored marks (green or yellow) appear on each side of the Alignment Target, indicating the probe angle of the device.
- 6 Number of Measurements:** The dots indicate the measurements required and completed (1 or 3+). An empty white dot indicates a required measurement. A solid yellow dot indicates an unreliable measurement. A solid blue dot indicates a completed, reliable measurement.
- 7 Measure Mode:** If AUTO is illuminated, device will automatically measure when properly aligned. If AUTO is grayed out (ActiView Manual Measure or Manual Measure modes), then the Manual Measure Button must be pressed to take a measurement. Pressing and holding the blue Manual Measure Button will take continuous measurements.
- 8 OD:** Right eye. The circle will be blue if selected.
- 9 OS:** Left eye. The circle will be blue if selected.
- 10 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, 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.
- 11 Select OD/OS Buttons:** Select OD or OS by pressing the corresponding button.



Instructions for Use (continued)

Positioning

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

The default Measure Mode is ActiView Auto Measure which enables automatic measurements upon correct alignment. Canthus marks on the outside of the device also aid with alignment.

- 1 Turn Tono-Vera Vet on by pressing any button.
- 2 Install a new Ocu-Dot Probe.
- 3 OD (right eye) will automatically be selected, indicated by a blue circle.

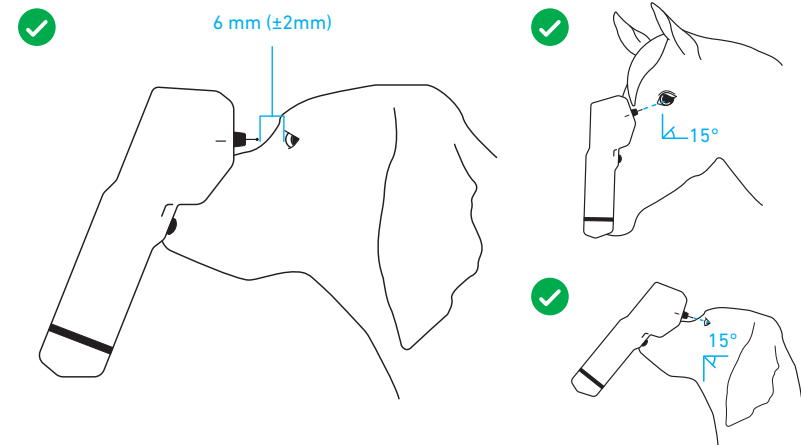
NOTE: To start on the OS (left eye), press the button beneath the OS area to select the left eye.

- 4 Position the device so that the two canthus marks located at the front of Tono-Vera Vet (one on each side) are level with the patient's canthus. Tono-Vera Vet is able to measure at a probe angle of $\pm 15^\circ$, but the Ocu-Dot Probe must remain perpendicular to the eye.
- 5 The correct working distance is 6 mm (± 2 mm) from the eye.

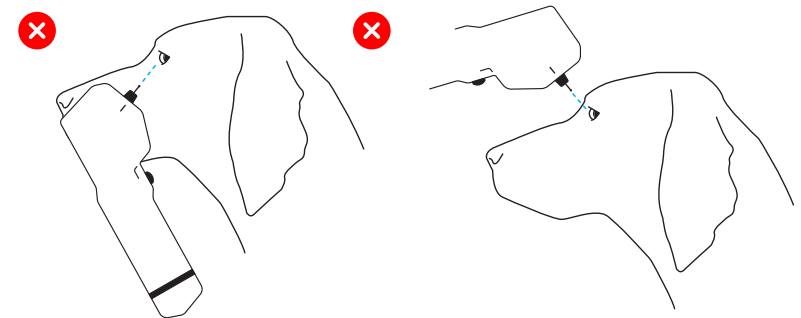
Device Orientation

Tono-Vera Vet 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 $\pm 15^\circ$ probe angle range.

Correct Probe Angle



Incorrect Probe Angle



Device Orientation



Instructions for Use (continued)

Aligning

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

NOTE: Tono-Vera Vet is able to measure at a probe angle of $\pm 15^\circ$, 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 if the probe is outside of the $\pm 15^\circ$ probe angle range.

- 2 Using the ActiView Positioning System, slowly align Tono-Vera Vet so the device is centered over the pupil and the Ocu-Dot Probe is approximately 6 mm from the apex of the cornea.
- 3 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.

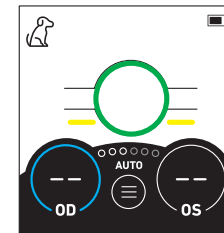
Large Red Ring

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

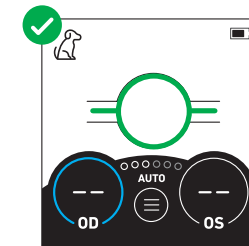
Large Red Stop Sign

STOP! Device is too close. Move the device further away from the eye.

Probe Angle ($\pm 15^\circ$)

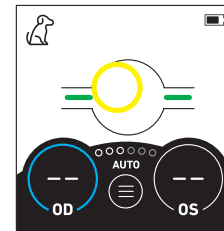


Yellow Probe Angle Indicators:
Probe Angle Too High

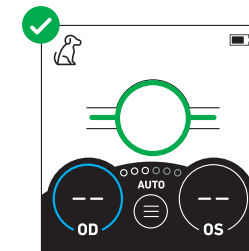


Green Probe Angle Indicators:
Proper Probe Angle Alignment

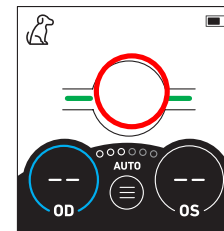
Distance & Centration (Approx. 6 mm)



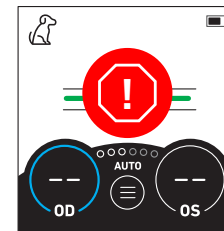
Yellow Ring:
Too Far and/or Off-Center



Green Ring:
Proper Distance and Centration



Large Red Ring:
Too Close
Beep Will Sound



Large Red Stop Sign:
Too Close
Beep Will Sound

Instructions for Use (continued)

Measuring

- 1 If Measure Mode is set to ActiView Auto Measure, measurements will be taken automatically when Tono-Vera Vet is aligned correctly. If Measure Mode is set to ActiView Manual Measure or Manual Measure, press the blue Manual Measure Button to measure upon correct alignment.

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 $\pm 15^\circ$ probe angle range.

- 2 The measurement dots indicate the number of 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. A solid yellow dot indicates an unsuccessful measurement which must be retaken.

When Measurements are set to 1 (Quick), only one measurement will be needed to obtain a high-confidence IOP result. When set to 3+, measurements will be taken until a high-confidence IOP result is obtained, a minimum of three measurements and a maximum of six. If more than three measurements are required, an empty gray dot will turn white, indicating another measurement is required.

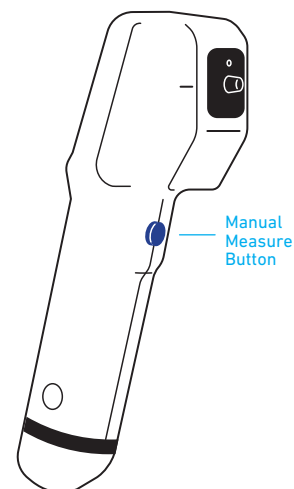
NOTE: When measurements are completed, the IOP will be displayed in a large colored ring on the screen. Refer to the Understanding Results section of this manual for detailed information.

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

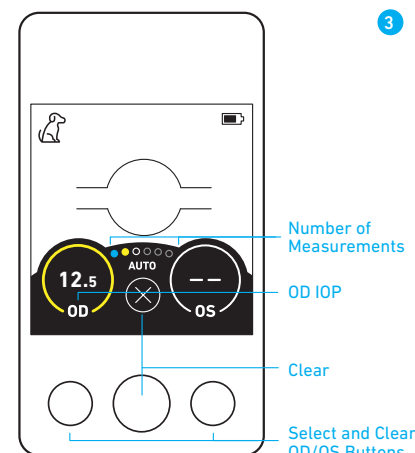
WARNING: If the device takes a measurement while the patient blinks, the probe could potentially become caught by the patient's eyelashes. If this occurs, simply dispose of the probe and begin the examination again with a new probe.

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.

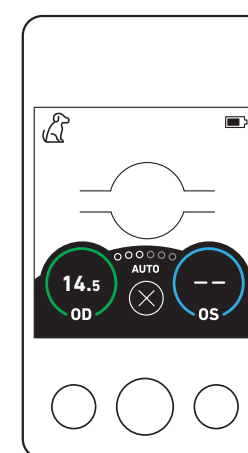
1



2



3



Instructions for Use (continued)

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

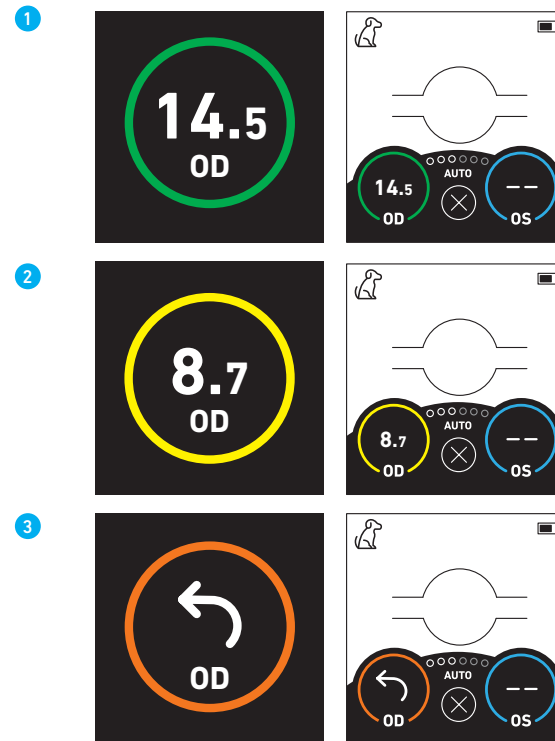
If the Manual Measure Button was pressed during ActiView Auto Measure Mode, the Final IOP Result will be briefly displayed in a yellow ring. After, the measurement screen will reappear and the corresponding OD or OS circle will have a yellow ring around it.

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 Retake Measurement arrow will not appear when Measurement Mode is set to 1 (Quick).



Instructions for Use (continued)


Data Transfer

Tono-Vera Vet is capable of transmitting data via Bluetooth® to EMR, using ReichertSync™ Software. To successfully transmit data, Tono-Vera Vet must be paired with a PC that has ReichertSync installed on it. To obtain a copy of ReichertSync, contact the Reichert Technical Support Group at the contact information at the back of this manual.

Connecting Tono-Vera Vet to the PC

1 Install ReichertSync on your PC. Refer to the ReichertSync Instructions for Use to set up Tono-Vera Vet 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 Vet and the PC. When Bluetooth is enabled, a Bluetooth icon will appear in the upper right corner beneath the Battery Indicator. This indicates the status of the Bluetooth connection.



No Dots:
Not Connected



Green Dots:
Connected and Able to
Transfer Data

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

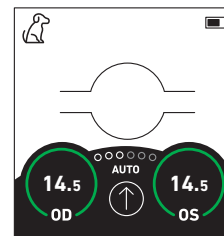
5 To disable Bluetooth, navigate to the Bluetooth screen in the Menu and press the Select Button. The large Bluetooth icon will turn gray and the small Bluetooth icon in the upper right will disappear.

Transferring Data to the PC

1 After obtaining Final IOP Results, press the center Multifunction Button to transfer data to the PC. 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 (continued)

Tono-Vera Vet Training Aid

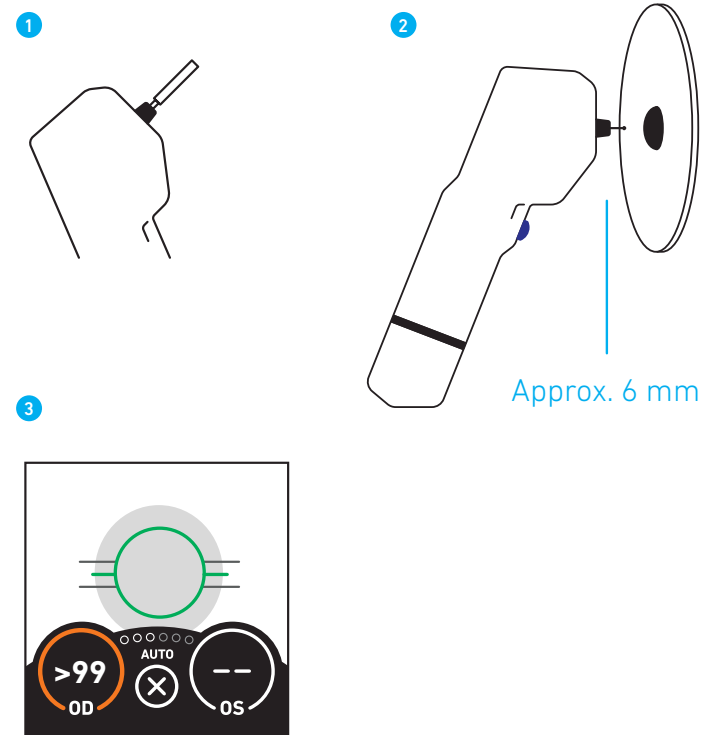
The included Training Aid allows users to become familiar with the operation of Tono-Vera Vet. The Training Aid is designed to simulate the experience of aligning the device using the ActiView Positioning System to take measurements.

- 1 Turn Tono-Vera Vet on and install a new Ocu-Dot Probe.
- 2 Hold the Training Aid in the palm of your hand. Using the on-screen ActiView Positioning System, slowly align Tono-Vera Vet so the Ocu-Dot Probe tip is centered over the training eye, and at the correct distance. The alignment ring and level indicators will turn green when the device is properly aligned for both distance, centration, and probe angle. Refer to the Positioning, Aligning, and Measuring sections of this manual for detailed instructions.
- 3 After a successful measurement, the Final IOP Result will read “>99” and briefly appear in a large orange ring, indicating a successful Training Aid measurement. After, the orange ring and “>99” will appear in the selected eye as the Final IOP Result for that eye.

NOTE: The Training Aid eye is a hard material, and the IOP value will always read as greater than 99. Any IOP measurement over 99 will appear as “>99” and appear in an orange ring.

- 4 At any point, measurements can be cleared by pressing Clear (×).
- 5 Practice taking IOP measurements with the Training Aid as many times as desired.
- 6 After practice measurements are finished, dispose of the Ocu-Dot Probe by ejecting it into the Probe Tube. Refer to the Ocu-Dot Probe Installation section of this manual for more detailed instructions on disposing the Ocu-Dot Probe.

NOTE: The Training Aid may not work well in very bright environments.



Cleaning and Maintenance

Probe Chamber

A replacement Probe Chamber is included with the Tono-Vera Vet so that the device can be used while the Probe Chamber is being cleaned.



Cleaning

Clean the Probe Chamber every six months, or anytime the Clean icon appears.

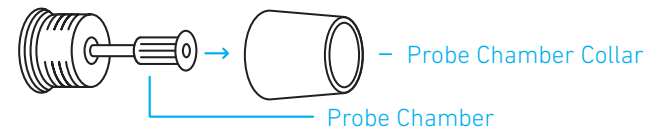
- 1 Press and hold the center Multifunction Button for three seconds to turn the power off.
- 2 Unscrew the Probe Chamber Collar by hand, turning it counterclockwise, and place in a safe location.
- 3 Slide the Probe Chamber out.
- 4 Place the Probe Chamber in the Cleaning Vial that was provided with the device.
- 5 Fill the Cleaning Vial with 70% isopropyl alcohol and close the top of the vial.
- 6 Let the Probe Guide 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.

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

Replacement

Replace the Probe Chamber every twelve months or anytime cleaning does not resolve any measuring issues.

- 1 Remove the Probe Chamber.
- 2 Insert a new Probe Chamber into Tono-Vera Vet.
- 3 Secure the Probe Chamber by installing the Probe Chamber Collar. Turn the Probe Chamber Collar clockwise until it is fully seated.



Cleaning and Maintenance (continued)

Cleaning Tono-Vera Vet

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

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

The outer surfaces of Tono-Vera Vet and Tono-Vera Vet Base, including the charging contacts, 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 three 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 Vet batteries when needed. Only replace with new AA batteries or the Reichert Tono-Vera Vet Lithium-Ion Rechargeable Battery Pack. Energizer® or Duracell® batteries are recommended to be used with this device. Alternative brands may impact device measurement longevity.

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

Storage


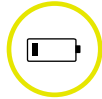
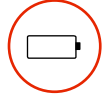

If the device is to be stored for an extended period, remove the AA batteries or the rechargeable battery pack to avoid possible damage to the device due to battery leakage. The device may be stored on the Tono-Vera Vet Base or in the Tono-Vera Vet Carry Case.

Disposal

Tono-Vera Vet, Ocu-Dot Probes, and Tono-Vera Vet 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 Vet 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 Vet 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 Vet Charging Base.	Clean the contacts. Refer to the Cleaning & Maintenance section of this manual.
	Missing or bent charging contacts in the Tono-Vera Vet 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 (continued)

SYMPTOM	PROBABLE CAUSE	CORRECTION
Will not take a measurement.	ActiView Auto Measure not selected in Measure Mode.	Select ActiView Auto Measure in Measure Mode.
	Manual Measure Button not pressed when Measure Mode is set to either ActiView Manual Measure or Manual Measure mode.	Press the Manual Measure Button when the device is properly aligned.
	Device is outside the probe angle range ($\pm 15^\circ$)	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.
	Correct species is not selected.	Select the correct species in the Menu.
Inaccurate measurements.	The Manual Measure Button was pressed while in ActiView Auto Measure mode.	Do not press the Manual Measure Button when measuring in ActiView Auto Measure mode.
	Measure Mode set to either ActiView Manual Measure or Manual Measure mode.	Change Measure Mode to ActiView Auto Measure.
	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 Vet Bluetooth is not on.	Turn Bluetooth on in the Menu.
	Tono-Vera Vet is not paired with computer or Bluetooth connection not setup properly.	Connect the Tono-Vera Vet 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 the Tono-Vera Vet. Contact the Reichert Technical Support Group for further assistance.

Specifications

PHYSICAL DIMENSIONS		ENVIRONMENTAL REQUIREMENTS							
<p>TONO-VERA VET</p> <p>Size: 19.8 x 6.6 x 3.0 cm (7.8 x 2.6 x 1.2 in)</p> <p>Weight: 113.4g (4.0 oz) (without batteries)</p>	<p>DISPLAY DIMENSIONS</p> <p>Size: 2.8 x 2.8 cm (1.1 x 1.1 in)</p>	<p>Operational Environment Ambient Temperature range: 10° to 35°C (50° to 95°F)</p> <p>Relative Humidity range: 30 to 90%</p> <p>Atmospheric Pressure range: 80 kPa to 106 kPa (23.6 to 31.3 in.Hg)</p> <p>Transport and Storage Environment Ambient Temperature range: -10° to 55°C (14° to 131°F)</p> <p>Relative Humidity range: 10 to 95% (non-condensing)</p> <p>Atmospheric Pressure range: 70 kPa to 106 kPa (20.7 to 31.3 in.Hg)</p>							
<p>ELECTRICAL</p> <p>Tono-Vera Vet Li-Ion Rechargeable Battery Pack Voltage: 3.7V Li-Ion</p> <p>Battery Pack A/C Adaptor Input Voltage: 100-240 Vac, 50-60 Hz, 0.16 A max</p> <p>A/C Adaptor Output: 5Vdc, 1.2A max</p> <p>Input Voltage - New AA Batteries: (4 x AA non-rechargeable batteries**) 1.5 V alkaline LR6</p> <p>*Only use the Tono-Vera Vet Li-Ion Rechargeable Battery Pack from Reichert. Do not use another brand of rechargeable battery with the device.</p> <p>** Energizer® or Duracell® batteries are recommended to be used with this device. Alternative brands may impact battery life.</p>		<p>RANGE OF IOP MEASUREMENTS</p> <p>Measurement range 1-99 mmHg Accuracy by manometric measurements (95% confidence)</p> <table border="1"> <thead> <tr> <th>Measurement (mm Hg)</th> <th>Accuracy (mm Hg)</th> </tr> </thead> <tbody> <tr> <td>5-19</td> <td>± 1.2</td> </tr> <tr> <td>20-60</td> <td>± 2.2</td> </tr> </tbody> </table>	Measurement (mm Hg)	Accuracy (mm Hg)	5-19	± 1.2	20-60	± 2.2	<p>MEASUREMENT DISTANCE</p> <p>6 MM (±1.5 MM)</p>
Measurement (mm Hg)	Accuracy (mm Hg)								
5-19	± 1.2								
20-60	± 2.2								
<p>OCU-DOT TONOMETER PROBES – 100 COUNT</p>		<p>Biocompatible polymer tipped wire.</p>							
<p>SOFTWARE REVISION</p>		<p>The software revision can be found under the System Info section of the Menu.</p>							

Specifications (continued)

Device Regulatory Classification

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

Compliance

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

The LMX9838 has been tested and approved to be compliant to the following regulatory standards:

CE Compliance

IEC 60601-1 Edition 3.1
Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 Edition 3.1
Medical electrical equipment –
Part 1-6: General requirements for basic safety and essential performance – Collateral Standard:
Usability

IEC 60601-1-2 Edition 4.0
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 \leq 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 \leq 16A per phase and not subject to conditional connection

Radio Equipment Directive (RED) 2014/53/EU

ETSI EN 300 328:2016 Ed. V2.1.1
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 301 489-17:2017-03 Ed. V3.2.2
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-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: MIC Notification No. 88 Annex 43
Certificate No: JN0834 i02

Guidance Tables

FCC Bluetooth RF Transmitter Characteristics

- Contains FCC ID: WAP3028
- Contains IC: CYBT-423028-02
 - Frequency 2402-2480 MHz, Spread Spectrum

IC Bluetooth RF Transmitter Characteristics

- License: IC: 7922A-3028
 - Frequency 2402-2480 MHz, Spread Spectrum

MIC Japan Bluetooth RF Transmitter Characteristics

- Certification No. 203-JN0834

FCC/IC Statements

This device complies with Part 15 of the FCC Rules. 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 FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter, except in accordance with FCC test procedures. This transmitter is considered as mobile device.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

The minimum separation distance to human body is 40 mm. RF exposure or SAR evaluations is not required when the separation distance is 40 mm or more.

Guidance Tables (continued)

Table 201 – Guidance and Manufacturer’s Declaration

Electromagnetic Emissions

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

Tono-Vera Vet is intended for use in the electromagnetic environment specified below. The customer or user of Tono-Vera Vet 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 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.
Conducted and Radiated RF Emissions CISPR 11	Class B	Tono-Vera 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	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	

Guidance Tables (continued)

Table 202 – Guidance and Manufacturer’s Declaration

Electromagnetic Immunity

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

Tono-Vera Vet is suitable for use in electromagnetic environment specified below. The customer or user of Tono-Vera 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 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, ±1kV Line-to-line ±0.5kV, ±1kV, ±2kV Line-to-ground	±0.5kV, ±1kV Differential Mode ±0.5kV, ±1kV, ±2kV Common 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 Vet requires continued operation during power mains interruptions, it is recommended that Tono-Vera 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°	0% Ut, 1.0 cycle and 70% Ut, 25/30 cycles Single phase: at 0°	
Voltage Interruptions IEC 61000-4-11	0% Ut, 250/300 cycles	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 (continued)


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

Tono-Vera Vet is intended for use in the electromagnetic environment specified below. The customer or user of Tono-Vera 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	(V1) = 3 Vrms 150 kHz to 80 MHz (V1) = 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	(V1) = 3 Vrms 150 kHz to 80 MHz (V1) = 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	<p>Portable and mobile RF communications equipment should be no closer to any part of Tono-Vera Vet, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance:</p> $d = (3.5/V1)(\sqrt{P})$ $d = (3.5/E1)(\sqrt{P})$ 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 frequency range. <p> Interference may occur in the vicinity of equipment marked with the following symbol.</p>
Radiated RF Electromagnetic Fields IEC 61000-4-3	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	(E1) = 3 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 than [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 (continued)

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 Tono-Vera Vet.

Tono-Vera Vet is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of Tono-Vera Vet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and Tono-Vera Vet 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 $d = (3.5/V1)(\sqrt{P})$	Separation (m) 150 kHz to 80 MHz In ISM Bands $d = (10/3)(3.5/V1)(\sqrt{P})$	Separation (m) 80 to 800 MHz $d = (3.5/E1)(\sqrt{P})$	Separation (m) 800 MHz to 2.7 GHz $d = (7/E1)(\sqrt{P})$
0.01	0.1166	0.1944	0.1166	0.2333
0.1	0.3689	0.6149	0.3689	0.7378
1	1.1666	1.9444	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.

Guidance Tables (continued)

Table 9 – Guidance and Manufacturer’s Declaration

Electromagnetic Immunity

Immunity to Proximity Fields from RF Wireless Communications Equipment

Guidance and Manufacturer’s Declaration - Electronic Immunity

Tono-Vera 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
Radiated RF IEC 61000-4-3	Test Frequency (MHz)	Band (MHz)	Service (MHz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level	$d = 6/E \sqrt{P}$ where d = Minimum separation distance in meters E = Immunity test level in V/m P = Maximum power in Watts (W)
	385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27 V/m at 0.3 m	
	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	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9 V/m at 0.3 m	
	745								
	780								
	810	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	
	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 at 0.3 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 at 0.3 m	
	5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9 V/m at 0.3 m	
5500									
5785									

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:



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

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

Authorized European Repair Center
AMETEK GmbH
Business Unit Reichert
Email: info.reichert-de@ametek.com
Tel: +49 (89) 315 89 110

Authorized European Representative
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

ISO-13485 Certified



16308-101 Rev. A

2020-10-21

