

PT100

Portable Non-Contact Tonometer

User's Guide



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

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Warnings & Cautions

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

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

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



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

WARNING: ANY REPAIR OR SERVICE TO THIS INSTRUMENT MUST BE PERFORMED BY EXPERIENCED PERSONNEL OR DEALERS WHO ARE TRAINED BY REICHERT SO THAT CORRECT OPERATION OF THIS INSTRUMENT IS MAINTAINED.

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

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

WARNING: TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH OR DAMAGE TO THE PT100 AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: THIS INSTRUMENT CONTAINS A LITHIUM ION BATTERY INSIDE THE REPLACEABLE BATTERY HANDLE. REPLACE THE BATTERY WITH REICHERT PART (P/N 13851-873) ONLY. USE OF ANOTHER BATTERY MAY CAUSE FIRE OR EXPLOSION.

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

Warnings & Cautions (Continued)

WARNING: DO NOT USE THIS INSTRUMENT IF THERE IS EVIDENCE OF FLUID LEAKING FROM THE BATTERY HANDLE. BATTERIES AND OTHER ELECTRONIC DEVICES MAY CONTAIN FLUIDS THAT ARE HAZARDOUS TO YOUR HEALTH. DIRECT CONTACT WITH SUCH FLUIDS MAY CAUSE BURNS, BLINDNESS, OR DEATH.

WARNING: USE ONLY THE CHARGING DEVICE PROVIDED WITH THIS INSTRUMENT. USE OF ANY OTHER CHARGING DEVICE COULD RESULT IN DAMAGE TO THE INSTRUMENT AND/OR SERIOUS PERSONAL INJURY.

WARNING: DO NOT ALLOW THIS INSTRUMENT TO BE USED BY CHILDREN OR UNTRAINED PERSONS WHO ARE UNFAMILIAR WITH ITS OPERATION AND FUNCTIONS. DAMAGE TO THE UNIT AND OR SERIOUS INJURY MAY OCCUR IF IMPROPERLY USED.

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

WARNING: THIS INSTRUMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURES SUCH AS OXYGEN OR NITROUS OXIDE.

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: ENSURE THAT THE VOLTAGE APPLIED TO THE UNIT IS THE SAME AS THE VOLTAGE THAT IS INDICATED ON THE DATA PLATE OR DAMAGE TO THE UNIT MAY OCCUR.

WARNING: THE INSTRUMENT MUST BE PLUGGED INTO AN OUTLET WITH AN EARTH GROUND. DO NOT REMOVE OR DEFEAT THE EARTH GROUND CONNECTION ON POWER INPUT CONNECTOR OR THE UNIT'S POWER CORD OF THIS INSTRUMENT OR DAMAGE TO IT AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

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 EXPOSE THE BATTERIES TO TEMPERATURES ABOVE 140°F, DISASSEMBLE THE BATTERIES, OR 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 PHYSICIAN.

Warnings & Cautions (Continued)

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



CAUTION: THE INTERNAL CIRCUITRY OF THE INSTRUMENT CONTAINS ELECTROSTATIC DISCHARGE SENSITIVE DEVICES (ESDS) THAT MAY BE SENSITIVE TO STATIC CHARGES PRODUCED BY THE HUMAN BODY. DO NOT REMOVE THE COVERS WITHOUT TAKING PROPER ESDS PRECAUTIONS.

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 USE ANY SOLVENTS OR STRONG CLEANING SOLUTIONS ON ANY PART OF THIS INSTRUMENT OR DAMAGE TO THE UNIT MAY OCCUR.

CAUTION: MEDICAL ELECTRONIC EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED AND PUT INTO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THE ACCOMPANYING DOCUMENTS.

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.

Symbol Information

The following symbols appear on the instrument:



Caution symbol indicating important operating and maintenance instructions that are included in this User's Guide



Alternating Current Power



Protective Earth Connection



ON / OFF



Manufacturer



Date of Manufacture

2016

REF

Catalog Number

SN

Serial Number



Waste of Electrical and Electronic Equipment



Compliance to Medical Device Directive 93/42/EEC

0120



Authorized to mark given by Intertek ETL Semko for conformance with electrical standards



Consult Instructions for Use



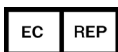
Fragile Contents in Shipping Container - handle with care



Keep Dry - Package shall be kept away from rain.



This Way Up - Indicates correct upright position of package



Authorized Representative in European Community

Introduction



Congratulations on the purchase of your new PT100 Portable Non-Contact Tonometer.

The PT100 is the world's first completely portable, cordless, Non-Contact Tonometer. The measurement head is fully self contained, utilizing a rechargeable battery. Additionally, the unit features an infrared data port for wireless transmission of measurement data. Properly trained eyecare professionals such as ophthalmologists, optometrists, opticians and eye care technicians should operate this instrument.

This User Guide is designed as a training and reference manual. We recommend that you read it carefully prior to use and follow the steps outlined in this guide to ensure optimum performance from your new instrument.

Please retain this manual for future reference and to share with other users. Additional copies can be obtained from your authorized Reichert Dealer or from the Reichert Customer Service Department. Contact information is provided at the end of this guide.

Indications for Use

The PT100 is a hand-held non-contact tonometer intended to measure the intra-ocular pressure of the eye.

Contraindications:

None

System Components

PT100 System (P/N 13850)

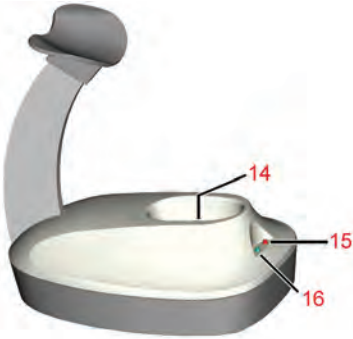
1. Charging Base
2. Transport Case
3. Battery Handle
4. PT100 Measurement Head



PT100 Measurement Head (P/N 13851)

7. Display and Controls
8. Nosepiece
9. Infrared Data Window
10. Battery Handle
11. Charging Contacts
12. On/Off Switch
13. Eyepiece

System Components (Continued)



Charging Base (P/N 13852)

- 14. Charging Contacts
- 15. Charging Indicator (amber)
- 16. Power Indicator (green)

Accessories:

- PT100 Carrying Case (13850-300)
- Battery Handle (13851-853; Without ON/OFF Button)
(13851-873; With ON/OFF Button)
- Slit Lamp Holder (13854) - Optional
- Wrist Strap (13851-096)
- Dust Cover (13850-001)
- User's Guide (13850-101)
- Quick Reference Card (13850-104)
- Eye Guard (13851-021)
- Thermal Printer (13853) - Optional
- Paper - Thermal (12441)
- Power Cord (WCBL 10018, for 110 VAC)
(WCBL 10027, for 220 VAC)

Installation, Features, and Functions

PT100 Setup

The PT100 is supplied in a convenient carrying case for easy and safe transportation to remote locations. To setup the PT100, remove all of the components and follow these instructions.

WARNING: POSITION THE PT100 SO THAT IT IS NOT DIFFICULT TO OPERATE THE DISCONNECTION DEVICE (PLUG).

WARNING: CARE MUST BE TAKEN TO ARRANGE THE CABLES FOR THE ACCESSORIES SUCH THAT THEY DO NOT PRESENT A TRIPPING HAZARD TO THE EXAMINER OR A DANGER TO THE PATIENT.

Full charging of the battery is required before using the PT100.

- Plug the female end of the power cord into the connector on the underside of the charging base and press the cord neatly into the cord-retainer channel.
- Plug the male end of the cord into a power outlet (100 to 240 VAC @ 50 to 60 Hz).

The green LED will illuminate to indicate that the base has power and the amber LED will flash to indicate the base is in standby mode.

- Place the PT100 into the charging base, making sure that it is seated properly and that the **ON/OFF** switch is placed in the **OFF** position. The Amber light will illuminate. It will take about 3 hours to fully charge the battery. A full charge will ensure maximum battery life.

Note: The instrument will charge in the **ON** position, however, the process is slower and it will take longer to achieve a full charge.

- When the PT100 is fully charged the amber LED will go out. If the PT100 is in the charging base and the amber LED is blinking, the unit is not fully seated.
- Once charged, the instrument has an operational usage of approximately 350 individual measurements before recharging is required. Operational usage will vary depending on the use of features such as IR data transmission and patient illumination. In order to conserve the charge, users should keep the power switch on the handle to the OFF (O) position.

Note: If the PT100 is not used for extended periods of time, the battery should be removed and placed in its location in the carrying case..

Power Cord



Installation, Features, and Functions (Cont'd)

On/Off Switch

The PT100 is equipped with an On/Off switch located on the lower left side of the handle. To power on the instrument, slide the switch toward the **I** symbol, which indicates the **ON** position. To power off the instrument, slide the switch toward the **O** symbol, which indicates the **OFF** position.

PT100 Initiation

The PT100 utilizes a user-friendly icon-based operating system to ensure ease of use. To initiate the system, simply press any of the function buttons on the control panel.

Battery Indicator

The PT100 has a battery indicator located in the upper right-hand corner of the display. The amount of charge is indicated by the black fill inside the battery icon. The battery is fully charged when the icon is completely black.



The black fill moves from right to left (towards the “head” of the battery) while charging. During instrument use, the black fill moves from left to right to indicate the amount of charge remaining.

Sleep Mode

To conserve battery power, the PT100 has a sleep mode that activates after 2 minutes of inactivity. Press any button to bring the instrument out of sleep mode. The LCD screen will turn on and the instrument will be ready for use. In addition to the display being on, the blue alignment crosshair, viewed through the eyepiece, indicates that the instrument is on. If the crosshair is not visible the PT100 is in sleep mode. When bringing the instrument out of sleep mode, be careful to press a button only once. Pressing a button more than once may inadvertently turn an instrument function on or off.



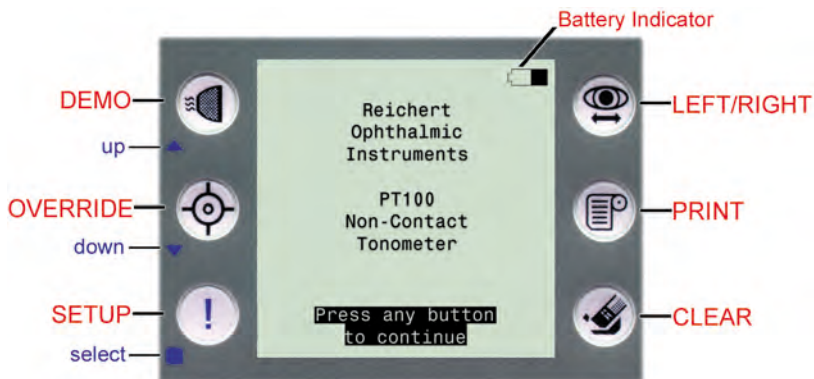
Optional Printer Setup (available, but not included)

The printer available for the PT100 system is a battery powered, wireless, infrared printer. Batteries are included. Remove the printer from its packaging and follow the instructions provided in the communication section of this manual.

Installation, Features, and Functions (Cont'd)

Control Panel Functions

The illustration below identifies the control panel icons and button functions. Press any button to proceed to the measurement screen.



Function Icons

- DEMO** Press to allow patient to feel demonstration air puff.
- OVERRIDE** Permits quicker measurement of difficult patients.
- SETUP** Enables access to the setup menu of the instrument.
- LEFT/RIGHT** Press to select the patient's left or right eye.
- PRINT** Transmits measurement data to printer or IR device.
- CLEAR** Erases current measurement data from display screen.

Setup Icons

- up** In setup mode, moves up through menu options.
- down** In setup mode, moves down through menu options.
- select** In setup mode, activates the selected setting.

Installation, Features, and Functions (Cont'd)

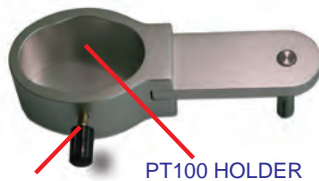
Optional Slit Lamp Mount (available, but not included)

The PT100 can be used with a Reichert optional slit lamp mount. The slit lamp mount can be used in conjunction with any slit lamp to aid in the alignment and measurement of a patient. The mount can be inserted into the hole that traditionally accommodates the focusing rod on the slit lamp. Insert the shaft of the mount into the focusing rod hole and place the PT100 into the holder. Tighten the set screw to hold the PT100 in place and utilize the controls of the slit lamp to take measurements.

Slit Lamp Mount Bottom View



Slit Lamp Mount Top View



SET SCREW

Disconnection of Input Power

1. At any time, the power switch can be set to OFF. The unit does not have a power down sequence. To terminate operation of this instrument, slide the ON / OFF switch to the OFF position (O).
2. If this instrument is intended to be OFF for an extended period of time, the battery can be removed from the hand held unit and the charging base can be disconnected from power by detaching the power cord from its receptacle.

Setup Mode

Setup Menu

The PT100 comes configured with the most commonly used instrument settings. Default settings can be changed in the setup mode. Once changes are made, they will remain set until further changes are made.



To enter the SETUP mode press the **SETUP** button on the lower left side of the control panel. Once the instrument is in SETUP mode, the operator can navigate and activate menu options by using the **UP**, **DOWN**, and **SELECT** buttons. The arrow, to the left of the menu choices on the display, will move up or down indicating the option to be selected. To activate selected options simply press the **SELECT** button.

The following options can be set by the operator:

Tonometer Menu

This menu option allows operators to choose the output format of the measurement results. The available options are mmHg (millimeters of mercury) and KPa (kilopascals). Current instrument settings are indicated by highlighting around the characters. Use the **UP**, **DOWN**, and **SELECT** buttons to navigate and activate the options. The factory default is mmHg.



Setup Mode (Continued)

Contrast Menu

This menu option allows operators to adjust the contrast of the LCD display. The range of adjustment is from -5 (lighter) to +5 (darker). Current instrument settings are indicated by highlighting around the characters. Use the **UP**, **DOWN**, and **SELECT** buttons to navigate and activate the options.



Illumination Menu

This menu option allows operators to turn the patient eye illumination On or Off. Patient eye illumination is helpful when using the PT100 in low light environments. Current instrument settings are indicated by highlighting around the characters. Use the **UP**, **DOWN**, and **SELECT** buttons to navigate and activate the options. The factory default is Off.



Setup Mode (Continued)

Communications Menu

This menu option allows operators to choose the type of device to which data are transmitted when the print button is pressed, and to access the Date and Time submenus. Operators can select Printer to send IR data to the optional wireless printer, or IR COM to send data to an IR enabled device (contact Reichert Technical Support for more information). Current instrument settings are indicated by highlighting around the characters. Use the **UP**, **DOWN**, and **SELECT** buttons to navigate and activate the options. The factory default is Printer.



Date Submenu

The Date submenu enables operators to choose the date format and set the current date. Available date formats are mdy, dmy, and ymd (d = day, m = month, y = year).

To access the Date submenu, from within the Communications menu select Date. Current instrument settings are indicated by highlighting around the characters. Use the **UP**, **DOWN**, and **SELECT** buttons to navigate and activate the options. The factory default setting for the date format is mdy.



Setup Mode (Continued)

To set the current date, move the arrow to the bottom line and press select. The first two characters will be highlighted. Use the UP and DOWN buttons to change the characters. Press SELECT when the desired setting has been attained. Repeat this procedure until all date fields (year, month, and day) are set. Upon completing the last field the operator will be returned to the main SETUP menu.

Time Submenu

The Time submenu enables operators to select the time format and set the current time. Available time formats are AM/PM and 24 hour.

To access the Time submenu, from within the Communications menu select Time. Current instrument settings are indicated by highlighting around the characters. Use the UP, DOWN, and SELECT buttons to navigate and activate the options. The factory default setting for the time format is AM/PM.

To set the current time, move the arrow to the bottom line and press SELECT. The first two numbers will be highlighted. Use the UP and DOWN buttons to change the numbers. Press SELECT when the desired setting has been attained. Repeat this procedure until all time fields are set. Upon completion of the last field the operator will be returned to the main SETUP menu.



Setup Mode (Continued)

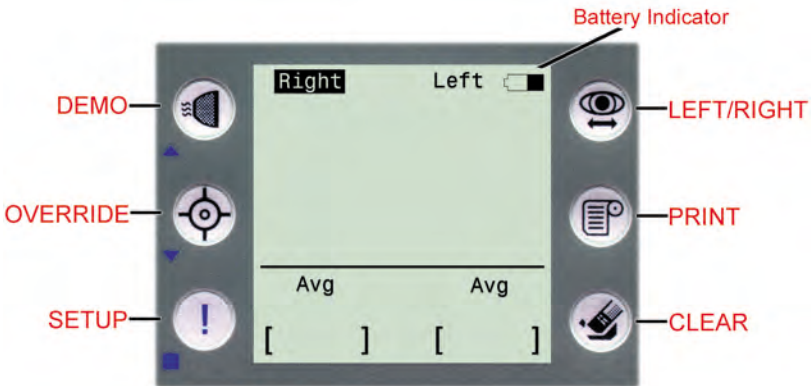
Language Menu

This menu option allows operators to choose the language that will be displayed on the screen and on printouts. Operators can select from Eng (English), Fra (French), Deu (German), Esp (Spanish), Ita (Italian), and Por (Portuguese). Current instrument settings are indicated by highlighting around the characters. Use the **UP**, **DOWN**, and **SELECT** buttons to navigate and activate the options. The factory default setting is English.



Measurement Mode

In order to take a measurement the PT100 must be in the measurement mode. To bring up the measurement mode screen, select Exit from the SETUP mode or press any button to bring the instrument out of sleep mode. The illustration below depicts the measurement mode screen.



Alignment System

The PT100 features an alignment system that guides the user to the correct position on the patient's cornea. Once properly aligned, the instrument automatically takes an IOP measurement. The alignment system is viewed through the instrument's eyepiece and utilizes a series of easy to follow visual indicators. A varying-diameter blue circle indicates distance from the eye and a crosshair is used to obtain proper directional alignment. When the PT100 is moved within the required working distance from the eye (approximately 12 mm or 1/2 inch), the alignment indicators become superimposed over the patient's eye. The illustration below shows the components of the alignment system indicators and their significance.



Measurement Mode (Continued)

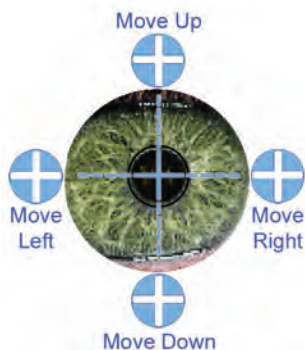
Taking an IOP Measurement

Operators should hold the PT100 with two hands. Place one hand on the handle and the other between the top-front of the instrument and the patient's brow. This will help stabilize the instrument and serves as a good starting point for establishing correct distance from the eye.



Press the **LEFT/RIGHT** button to select the eye to be measured. Using the two-handed method described above, position the PT100 in front of the patient. Look through the eyepiece and move the PT100, positioning the blue crosshair over the pupil. Instruct the patient to open their eyes wide and look at the green fixation spot. Slowly move the PT100 towards the eye until the alignment system activates. The working distance is approximately 12mm (1/2") from the eye.

The operator will see the alignment crosshair in the center of the eyepiece. The circular distance indicator will appear in the field of view. Initially, the operator should use the distance indicator to establish the correct distance from the eye. Move the PT100 either closer to the eye or further from the eye, following the cues given by the indicator. Correct distance has been achieved when the indicator displays a cross.

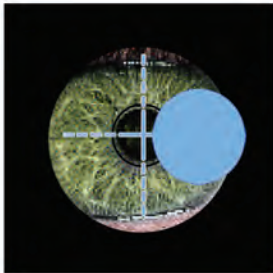


Once the correct distance has been established, simply move the PT100 to position the crosshair over the centering target. As the operator attempts to align the crosshair, the distance indicator may change position and size. Continue to move the instrument until the crosshair is positioned directly over the centering target at the correct distance.

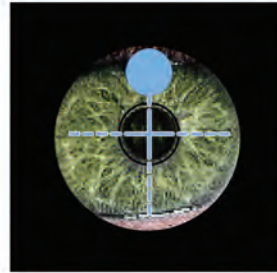
Measurement Mode (Continued)

Proper alignment requires slow, steady movements. Operators will find that the instrument becomes much easier to use with practice. Inexperienced users may take up to 30 seconds to achieve applanation. Proficient operators routinely obtain an accurate IOP measurement in 10 seconds or less. A large number of distance indicator / directional indicator combinations are possible. Some examples are illustrated below:

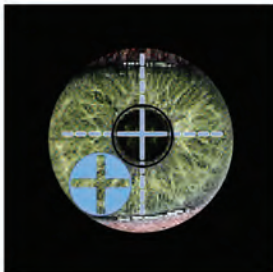
**Much Too Close
Move Right & Away**



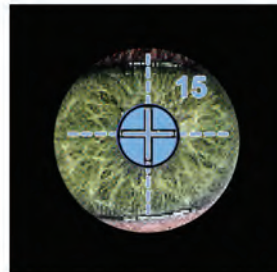
**Too Far
Move Up & Closer**



**Correct Distance
Move Down & Left**



Applanation Achieved



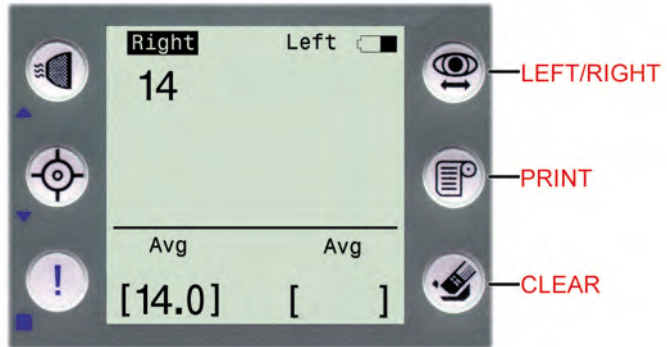
Once the correct alignment has been reached, the PT100 will automatically take an IOP measurement. The operator will hear the air puff and see the IOP measurement value briefly displayed in the eyepiece view. Values that appear followed by an asterisk indicate that the measurement is “low confidence” (see page 21). A reading of ** indicates a “no applanation” condition has occurred (see page 23).

Additional measurements can be taken in rapid succession if the instrument is kept in position and the patient is able to continue fixating on the green fixation spot.

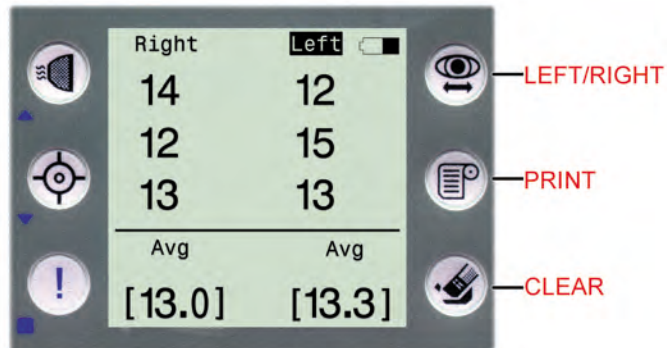
Measurement Mode (Continued)

Measurement Results

Once the measurement is taken the reading will be displayed on the screen under the Right or Left column, depending upon which eye was selected.



Reichert recommends taking three readings per eye to obtain an accurate average IOP. After taking three measurements on the first eye, press the **LEFT/RIGHT** button and take three measurements on the other eye.



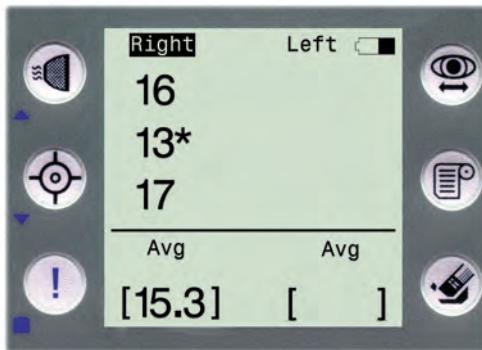
Operators can take more than three measurements per eye, but the PT100 will only display and average the last three readings. Only the measurements visible on the screen are used in the average IOP computation and will appear on the printout. Results can be cleared from the screen at anytime by pressing the **CLEAR** button or can be printed at anytime by pressing the **PRINT** button. See the communications instructions for further information. When the PT100 is not in use, place it back in the charging base to ensure that the battery maintains an adequate charge.

Measurement Mode (Continued)

Low Confidence Readings

During the measurement process, the PT100 may detect certain conditions that result in a low confidence reading. Depending on the situation, low confidence readings will be indicated by an asterisk next to the reading or by brackets around the reading. Low confidence readings can strongly skew average IOP computations. In order to obtain an accurate average IOP, Reichert recommends that operators continue to take measurements until only high confidence readings appear on the screen.

Asterisk readings can result from a sudden movement by the patient, a blink, or interference from a patient's eyelashes. The instrument's sophisticated software senses that the reading may not be correct and indicates this by displaying an asterisk after the measurement result. If an asterisk reading is displayed on the screen it is used in the computation of the average IOP and will also appear on the printout.



The asterisk reading will remain on the screen until a fourth measurement is taken. If the fourth measurement produces a high confidence reading it will automatically replace the asterisk reading.

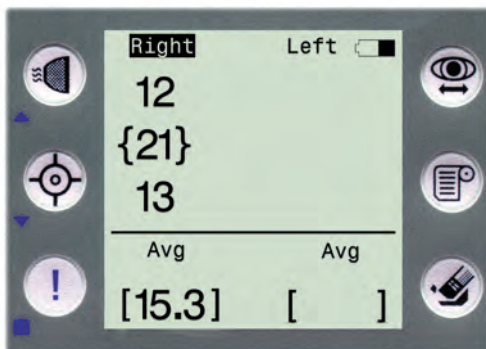
(Continued on next page)

Measurement Mode (Continued)

Low Confidence Readings (Continued)

Bracket readings will only appear on the screen after 3 measurements have been taken on the same eye. The PT100 compares all three measurements, looking for a reading that is more than 4 mmHg higher or lower than the other two.

PT100 measurements are made in milliseconds and occur at random to the cardiac-related ocular pulse. As a result, measurement fluctuations of 2 - 4 mmHg should be considered normal. However, certain situations, such as sudden movements or blinks, may cause larger measurement fluctuations. When a fluctuation of more than 4 mmHg occurs, the reading will be bracketed. If a bracketed reading is displayed on the screen it is used in the computation of the average IOP and will also appear on the printout.



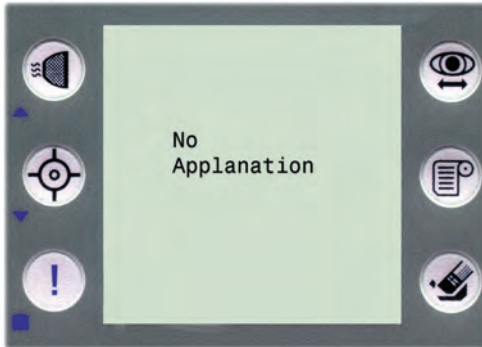
A bracketed reading will remain on the screen until a fourth measurement is taken. If the fourth measurement produces a high confidence reading, the bracketed reading will be automatically replaced by the new measurement.

Note: Brackets will not appear in the heads-up display as seen through the eyepiece, since only single measurement values are displayed here. Bracketed values only appear on the LCD screen in connection with other significantly different measurement values.

Measurement Mode (Continued)

No Applanation

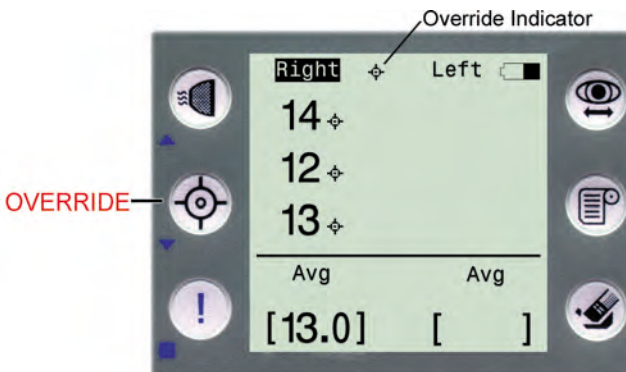
During the measurement process, the PT100 may detect certain conditions that cause “No Applanation” to be displayed on the screen. No Applanation readings can occur for various reasons including sudden movements, blinks, and corneal disorders.



If a No Applanation reading occurs, the message will be displayed on the screen for only three seconds and has no impact on any previous or future measurement results. After the message disappears the instrument will revert to the measurement screen.

Override

Some patients may be difficult to measure due to an inability to fixate, corneal scarring, or corneal disorders (for example, Fuchs Dystrophy). If an experienced operator is having a difficult time achieving applanation on such a patient, the override function may help. Pressing the **VERRIDE** button enables easier measurement by widening the instrument's auto-measurement zone. However, the results obtained with override may be less accurate. The override symbol will appear on the screen and on the printout next to any override measurements.



Communications

The PT100 uses infrared data transmission to send measurement data to the optional printer or user-supplied IR enabled devices (contact Reichert Technical Support for more information). Measurements that appear on the screen can be printed at anytime by pointing the IR window of the PT100 at the IR window on the printer and pressing the **PRINT** button. An hourglass symbol will appear at the top of the PT100 display during data transmission. Operators should continue to point the PT100 towards the printer until the hourglass disappears (approximately 3 seconds).



After transmission the screen will clear. If the data do not print properly press the **PRINT** button again even though the readings no longer appear on the screen. The PT100 retains data in memory until a new measurement is taken or **CLEAR** is pressed.

Name _____	
01/31/2002	03:31 pm
Right	Avg
13 14 13	13.3
Left	Avg
14 13 12	13.0

Always make sure the printer is on and not in sleep mode. According to the printer manufacturer's instructions, the PT100 should be no more than 18 inches from the printer and should be in line with the printer's IR window within 30 degrees left or right of center and no more than 20 degrees above or 10 degrees below the printer. Please review the instruction manual supplied with the printer for more information.

Helpful Tips for Using the PT100

As with most new instruments, operator training and technique are essential to achieving accurate results quickly. Reichert recommends that PT100 operators spend at least 30 minutes familiarizing themselves with the instrument before attempting to use it on patients. Once operators have mastered the technique, the PT100 is very easy to use.

In order to become proficient with the PT100, Reichert recommends the following:

Use both hands when operating the PT100. One to hold the instrument and the other to act as a support between the patient's forehead and the top-front of the instrument. On the grip-hand, operators should extend their index finger along the underside of the unit to provide additional stabilization.

When aligning the PT100, use very slow movements. The sophisticated alignment system responds very quickly to even the slightest movements.

It may be difficult to measure a patient whose head is significantly higher or lower than the operator's. Use whatever means are available to achieve near eye-level positioning (chairs, stools, etc).

If the patient is seated, stabilize their head using the headrest on the chair if one is available.

Ask the patient to hold their eye wide open and try not to blink. Some patients have a tendency to close the eye not being tested. Instruct patients to keep both eyes open during the measurement process. This will enable a wider opening of the eye being tested.

Use the patient's pupil as an initial alignment guide when centering the instrument.

After taking the first measurement, instead of pulling the PT100 away to look at the results, keep it in position for the next measurement. Operators will find that they are able to take a second and third reading in rapid succession.

In order to provide increased stability when standing, the operator and the patient should position their legs approximately shoulder width apart, bend the knees slightly, place one foot further forward than the other, and lean towards each other.

Maintenance

Due to its advanced design, the PT100 requires very little routine maintenance. Periodic cleaning of the nosepiece and display screen, infrequent battery replacement, and possible fuse replacement are all that may be required. If you have any questions about maintenance of the PT100, contact your local dealer or Reichert Customer Service at the address shown on the rear cover of this guide.

Cleaning

Do not use alcohol, methanol, acetone, or any other solvents when cleaning the PT100. Damage could occur causing possible malfunctions.

Clean the end of the nosepiece with a clean, lint-free cloth that is very lightly dampened with a mild soap solution (2 cc of liquid soap to 1 liter of distilled water). The frequency of cleaning will depend on the conditions and amount of use. Clean as required.

Battery Replacement

Eventually the battery will no longer hold a charge for an acceptable length of time. This is an indication that the battery should be replaced. New battery handle assemblies are available from your Authorized Reichert Dealer or Reichert Customer Service.

Replace the battery with Reichert part (P/N 13851-873) only. Use of another battery may cause fire or explosion. The battery may explode if mistreated. Do not disassemble or dispose of the battery in a fire.

To replace the battery:

- Insert a flat-blade screwdriver into the slot at the bottom of the patient's side of the battery handle.
- Lightly press down on the handle of the screwdriver so that the blade pushes up and releases the locking clip of the battery handle.
- Pull the battery handle out of the unit and disengage the wire connector from the PT100.
- Insert the connector of the new battery into the receptacle and position the replaceable battery handle into the PT100 measurement head.
- Press the assembly into place, ensuring that the locking clip properly secures the replaceable battery handle.



Note: If the PT100 is not used for extended periods of time, the battery should be removed and placed in its location in the carrying case.

Maintenance (Continued)

Fuse Replacement

Fuses are located on the bottom of the charging base near the power cord receptacle. If required, replace with fuses as indicated in the Specifications section of this manual.

WARNING: ANY REPAIR OR SERVICE TO THIS INSTRUMENT MUST BE PERFORMED BY EXPERIENCED PERSONNEL OR DEALERS WHO ARE TRAINED BY REICHERT SO THAT CORRECT OPERATION OF THIS INSTRUMENT IS MAINTAINED.

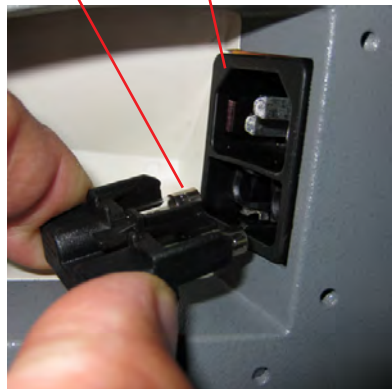
To remove the fuses:

- Disconnect input power to the charging base.
- Press down on the release tab of the Fuse Holder. When the tab is pushed down and has released, the Fuse Holder will disengage from the Power Input Module.
- Remove the fuse holder from the of the Power Input Module.
- Replace the fuses and then push the Fuse Holder back into the Power Input Module.



Tab Fuse Holder

Fuses Power Input Module



Troubleshooting

POWER	
Screen blank	- Instrument switch in Off position or in sleep mode - push any button
Charging base LED's off	- Check fuses and power input
Amber LED flashing Rapidly	- Short in battery or charging base - unplug immediately*
Battery will not charge	- Battery not plugged in properly - check connection - Damaged battery - replace
MEASUREMENT	
Does not take reading	- Instrument not aligned correctly, attempt measurement again. - Position instrument away from bright lights - Instruct patient to open eyes wide and fixate on green target - Dirty nosepiece - refer to maintenance section
PRINTER (optional, but not included)	
Will not print	- Printer not turned on or asleep - Communication menu set to IR COM - change in Setup mode. - Printer out of paper - replace paper. - PT100 battery too low to send data - recharge battery - Printer batteries dead - replace the batteries.
Paper feeds but no characters print	- Paper in backwards - refer to printer manual - Printer head damaged - contact Reichert for assistance
Paper jams in printer	- Remove jammed paper - refer to printer manual
Date / time incorrect on printout	- Enter Setup mode to set date / time
* If your problems persist, contact Reichert or your local Reichert Dealer.	

Product Specifications

PT100 Measurement Head

Height.....	10 in. (2.5 cm)
Width.....	4¾ in. (12 cm)
Depth.....	7¾ in. (20 cm)
Weight, unpacked.....	2.7 lbs. (1.3 kg)
Lithium Ion Battery Voltage.....	3.7 VDC

Charging Base

Input Voltage.....	100 VAC to 240 VAC
Input Current.....	124 mA max
Input Frequency.....	50 Hz to 60 Hz
Output Voltage.....	3.5 VDC to 4.0 VDC
Output Current.....	1.0 ADC max
Output Current.....	1.0 ADC max
Fuses	T250V 800ma

Measurement Range..... 0 mmHg to 60 mmHg
Ambient Operating Temperature Range..0°C (32°F) to +45°C (113°F)

Measurement Accuracy

Accuracy by Artificial Eye (95% Confidence)
IOP ± 0.75 mmHg (7-60 mmHg)

Environmental:

The environmental conditions are as follows:

Operating:

Temperature

10° C (50° F) to 35° C (95° F)

Relative Humidity:

30% to 75%

Atmospheric Pressure:

80 kPa (23.6 in. Hg) to
106 kPa (31.3 in. Hg)

Transportation & Storage:

Temperature

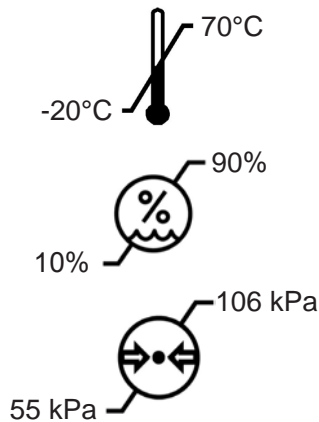
-20° C (-4° F) to +70° C (158° F)

Relative Humidity: (non-condensing)

10% to 90%

Atmospheric Pressure:

55 kPa (16.2 in. Hg) to
106 kPa (31.3 in. Hg)



Exposure to extreme temperature conditions indicated above must not exceed 15 weeks.

Product Specifications (Continued)

Disposal

This product and the lithium ion battery inside it do not generate any environmentally hazardous residues. At the end of the product life, follow local laws and ordinances regarding proper disposal.

Software Revision

The software revision can be obtained by contacting Reichert Technologies. The serial number identifies the manufacture date and will provide access to the software version.

Classification

According to the type of protection against electrical shock:
The PT100 recharging unit is classified as: Class 1 Equipment.
The PT100 measurement head is classified as: Internally Powered Equipment.

According to the degree of protection against electrical shock:
The PT100 is classified as Class B Equipment.

According to the degree of protection against harmful ingress of water:
The PT100 is classified as IPX0 Equipment.

According to the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide:
The PT100 is not suitable for use in the presence of the above flammable mixtures.

Parts and accessories used in this product meet the requirements of the applicable IEC601 series.

Guidance Tables

Table 201 – Guidance and Manufacturer’s Declaration Electromagnetic Emissions All Equipment and Systems		
Guidance and Manufacturer’s Declaration – Electromagnetic Emissions		
The PT100 is intended for use in the electromagnetic environment specified below. The customer or user of the PT100 should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance -
RF Emissions CISPR 11	Group 1 Class B	The PT100 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.
Harmonics IEC 61000-3-2	N/A	The PT100 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.
Flicker IEC 61000-3-3	N/A	


Notes: The table above contains guidance for the PT100 while in battery operation.

Guidance Tables (Continued)

Table 202 – Guidance and Manufacturer’s Declaration Electromagnetic Immunity All Equipment and Systems			
Guidance and Manufacturer’s Declaration – Electromagnetic Immunity			
The PT100 is suitable for use in electromagnetic environment specified below. The customer or user of the PT100 should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical residential, commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical residential, commercial or hospital environment. If the user of the PT100 requires continued operation during power mains interruptions, it is recommended that the PT100 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical residential, commercial or hospital environment.

Notes: The table above contains guidance for the PT100 while in battery operation.

Guidance Tables (Continued)

Table 204 – Guidance and Manufacturer’s Declaration Electromagnetic Immunity Equipment and Systems that are NOT Life-supporting			
Guidance and Manufacturer’s Declaration – Electromagnetic Immunity			
The PT100 is intended for use in the electromagnetic environment specified below. The customer or user of the PT100 should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	NA	Portable and mobile RF communications equipment should be no closer to any part of the PT100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80 MHz to 2.5 GHz @ 3V/m	(E1)=3V/m	Recommended Separation Distance: $d=(3.5/V1)(\text{Sqrt } P)$ $d=(3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz $d=(7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 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. Interference may occur in the vicinity of equipment marked with the following symbol. 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
* 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 re-orienting 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.			

Notes: The table above contains guidance for the PT100 while in battery operation.

Guidance Tables (Continued)

Table 206 – Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the PT100 for ME Equipment and ME Systems that are NOT Life-supporting. Guidance and Manufacturer’s Declaration - Electromagnetic Immunity			
Recommended Separation Distances for between Portable and Mobile RF Communications Equipment and the PT100			
The PT100 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the PT100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the PT100 as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power of Transmitter (W)	Separation (m) 150kHz to 80 MHz $d=(3.5\sqrt{V1})(\text{Sqrt } P)$	Separation (m) 80 to 800 MHz $d=(3.5/E1)(\text{Sqrt } P)$	Separation (m) 800MHz to 2.5GHz $d=(7/E1)(\text{Sqrt } P)$
0.01	N/A in Battery Mode	0.1166	0.2333
0.1	N/A in Battery Mode	0.3689	0.7378
1	N/A in Battery Mode	1.1666	2.3333
10	N/A in Battery Mode	3.6893	7.3786
100	N/A in Battery Mode	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.			

Notes: The table above contains guidance for the PT100 while in battery operation.

Warranty

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

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

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

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

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

Warranty (Continued)

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.

CLAIMS FOR SHORTAGES

We use extreme care in selection, checking, rechecking and packing to eliminate the possibility of error. If any shipping errors are discovered:

1. Carefully go through the packing materials to be sure nothing was inadvertently overlooked when the unit was unpacked.
2. Call the dealer you purchased the product from and report the shortage. The materials are packed at the factory and none should be missing if the box has never been opened.
3. Claims must be filed within 30 days of purchase.





CLAIMS FOR DAMAGES IN TRANSIT

Our shipping responsibility ceases with the safe delivery in good condition to the transportation company. Claims for loss or damage in transit should be made promptly and directly to the transportation company.

If, upon delivery, the outside of the packing case shows evidence of rough handling or damage, the transportation company's agent should be requested to make a "Received in Bad Order" notation on the delivery receipt. If within 48 hours of delivery, concealed damage is noted upon unpacking the shipment and no exterior evidence of rough handling is apparent, the transportation company should be requested to make out a "Bad Order" report. This procedure is necessary in order for the dealer to maintain the right of recovery from the carrier.



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