iPac® Pachymeter

Instructions for Use



Reichert
AMETEK

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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 and Cautions



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

WARNING: UNITED STATES FEDERAL LAW AND EUROPEAN REGULATIONS REQUIRE THAT THIS DEVICE BE PURCHASED ONLY BY A PHYSICIAN OR A PERSON ACTING ON BEHALF OF A PHYSICIAN. ONLY USERS TRAINED IN THE USE OF OPHTHALMIC INSTRUMENTS THAT CONTACT THE EYE SHOULD USE THIS DEVICE. REICHERT TECHNOLOGIES CANNOT BE HELD RESPONSIBLE FOR ANY DAMAGE OR INJURY THAT RESULTS FROM A FAILURE TO FOLLOW DIRECTIONS IN THE USER'S MANUAL. PLEASE ENSURE THAT YOU ARE ENTIRELY FAMILIAR WITH THE CORRECT PROCEDURES FOR OPERATING THE INSTRUMENT BEFORE USE.

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

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: AFTER EACH PATIENT, PERFORM THE CLEANING INSTRUCTIONS AS INDICATED IN THE CLEANING SECTION OF THIS MANUAL.

WARNING: DO NOT USE THE IPAC PACHYMETER IF THE MEASUREMENT TIP IS CRACKED, CHIPPED OR SHOWS ANY IRREGULARITY OF THE SURFACE, TO PREVENT PATIENT INJURY AND OR INACCURATE READINGS.

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

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

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.

Warnings and Cautions (continued)

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

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

WARNING: IN ORDER TO PREVENT PATIENT-TO-PATIENT TRANSFER OF INFECTION, AFTER EACH USE DISINFECT THE MEASUREMENT TIP FOLLOWING ACCEPTED LOCAL CLINICAL PROCEDURES REGARDING THE USE OF DISINFECTANTS. ANY CLINICALLY APPROVED CHEMICAL DISINFECTANT CAN BE USED.

WARNING: MEASUREMENTS SHOULD NOT BE ATTEMPTED WHEN OCULAR INTEGRITY IS QUESTIONABLE. THE HANDHELD TRANSDUCER MUST TOUCH THE EYE DURING OPERATION. CONSEQUENTLY, THE USER NEEDS TO EXHIBIT CARE IN MANIPULATING THE TRANSDUCER. FORCE SHOULD NOT BE EXERTED AGAINST THE EYE – THE TRANSDUCER TIP ONLY NEEDS TO LIGHTLY TOUCH THE CORNEA.

WARNING: TO ENSURE PATIENT ISOLATION FROM HIGH ELECTRICAL POTENTIAL, DO NOT USE THE IPAC ON A PATIENT WHEN THE INSTRUMENT IS CHARGING. IPAC CHARGING MUST ONLY TAKE PLACE AT A DISTANCE OF AT LEAST 1.5 M FROM THE PATIENT.

WARNING: IT IS PRUDENT TO MINIMIZE THE PATIENT'S EXPOSURE TO ULTRASOUND ENERGY TO A LEVEL AS LOW AS REASONABLY ACHIEVABLE (ALARA) BY REDUCING THE NUMBER OF SCANS NEEDED TO BE PERFORMED. ADVISE THE PATIENT OF WHAT TO EXPECT DURING A SCAN TO REDUCE REPETITIVE SCANS. THE AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE (AIUM) HAS A PUBLICATION "MEDICAL ULTRASOUND SAFETY" (1994) WHICH HAS MORE INFORMATION ON THIS TOPIC.

WARNING: USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT AND RESULT IN IMPROPER OPERATION.

WARNING: PORTABLE RF COMMUNICATIONS EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF THE IPAC, 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 THE IPAC PACHYMETER IN FLUIDS OR DAMAGE TO THE ELECTRONICS MAY OCCUR.

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.

Warnings and Cautions (continued)

CAUTION: DO NOT ATTEMPT TO MODIFY THE IPAC PACHYMETER OR PATIENT INJURY, AND/OR INACCURATE READINGS MAY OCCUR.

CAUTION: THIS DEVICE HAS NOT BEEN TESTED IN CONJUNCTION WITH HF SURGICAL (E.G. ELECTROCAUTERY) EQUIPMENT AND SHOULD NOT BE USED WITH SUCH EQUIPMENT.

CAUTION: THIS INSTRUMENT IS NOT INTENDED TO BE CONNECTED TO EQUIPMENT OUTSIDE THE CONTROL OF REICHERT INC. OR MUST BE TESTED TO AN APPLICABLE IEC OR ISO STANDARDS.

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

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 INTERNAL STERILIZATION OF IPAC OR DAMAGE TO THE ELECTRONICS MAY OCCUR.

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

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 THE PERFORMANCE OR SERVICE LIFE OF THIS INSTRUMENT. IF INTERFERENCE IS PRESENT, TURN OFF OTHER ELECTRONIC DEVICES, OR REMOVE THEM FROM THE IMMEDIATE AREA WHILE OPERATING THIS INSTRUMENT.

CAUTION: ALWAYS ENSURE THE IPAC IS CHARGED SUFFICIENTLY OR ERRATIC READINGS MAY OCCUR. USE ONLY THE SUPPLIED CHARGER PROVIDED WITH THE UNIT. IT IS RECOMMENDED THAT THE IPAC BE ATTACHED TO ITS CHARGER (OR CHARGING BASE) WHEN NOT IN USE TO ENSURE PROPER OPERATION.

CAUTION: DO NOT ATTEMPT TO CHARGE THE IPAC OR POWER THE CHARGING CRADLE USING THE USB PORT OF A COMPUTER OR DAMAGE TO THE IPAC OR COMPUTER MAY OCCUR.

CAUTION: 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.

CAUTION: IF THE IPAC IS EXPOSED TO EMC INTERFERENCE NOT LISTED IN THE EMC TABLE SECTION, THE INSTRUMENT MAY NOT MEASURE AND DISPLAY CORRECT READINGS, THE DISPLAY MAY NOT SHOW NORMAL SCREENS AS FOUND IN THE USER GUIDE. IF THE INSTRUMENT IS FUNCTIONING ERRATICALLY AFTER EMC EXPOSURE, PLEASE CONTACT REICHERT.

Symbol Information



Caution



Protective Earth - Indicates that a protective earth ground is connected where the symbol is located.

REF Catalog Number

SN Serial Number



Manufacturer



Date of Manufacture



Waste of Electrical and Electronic Equipment



Compliance to Medical Device Directive 93/42/EEC



Consult Instructions for Use - Indicates that important operating and maintenance instructions are included in this User's Guide.



Authorized Representative in European Community



Fragile Contents in Shipping Container - handle with care



Keep Dry - Package shall be kept away from rain.



Type BF Product Classification.



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



C-Tick mark for ACMA in Australia Trade Marks Act 1995 and RSM in New Zealand under section 47 of the New Zealand Trademarks Acts.

Introduction

Congratulations on your purchase of the AMETEK Reichert® iPac® Pachymeter.

This Instructions for Use is designed as a training and reference manual for operation, maintenance, and troubleshooting. We recommend that you read it carefully prior to use and follow the instructions in the guide to ensure optimum performance of your new instrument. If used properly, the iPac Pachymeter will provide you with fast, accurate and reliable measurements for many years. Properly trained eyecare professionals such as ophthalmologists, optometrists, opticians and eye care technicians should operate this instrument.

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

Intended Use
The iPac Pachymeter is intended to measure thickness of the cornea in the human eye using ultrasound energy.

Indications for Use
The indications for use is to measure the thickness of the cornea.

Contraindications
None.

Device Description
The iPac Pachymeter is an ergonomic, hand-held Pachymeter that measures central corneal thickness. The body of the instrument is designed to fit comfortably in the user's hand, facilitating fast and accurate measurements. The tip of the Pachymeter contains a sensor which measures central corneal thickness. The electronics housed in the ergonomic iPac Pachymeter body process and analyze the waveforms produced by each measurement of the corneal thickness of the eye. These are used to produce an averaged pachymetry measurement. The measurement is displayed on the Organic Light Emitting Diode (OLED) display.

A rechargeable battery is used in the iPac Pachymeter and consists of a lithium ion battery.

-continued-

Features

The iPac Pachymeter has the following features:

- Easy to Use - corneal thickness can be measured accurately by medical eye care professionals.
- Portable - The iPac Pachymeter weighs just 3.53 oz. (100 g) and is rechargeable.
- Versatile - The iPac Pachymeter may be used easily with the patient in any position, making the instrument suitable for the office, in clinics, at the hospital bedside, and in remote locations.
- OLED Color Display - Intuitive graphical display for ease of use.

Device Regulatory Classification

- Insulation Protection Class II
- Ingress Protection IPX1
- Applied Part Type BF
- Operation Mode Continuous

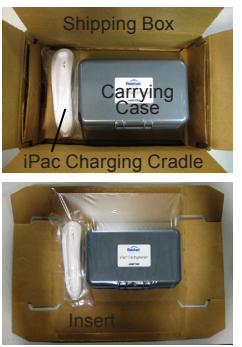
Instrument Setup

Unpacking Instructions

Great care has been taken to deliver your iPac Pachymeter to you. The packaging was specifically designed to transport this instrument. Please retain the packaging for future use in case transportation is required.

Removing the iPac Pachymeter

1. Lift the insert that contains the Carrying Case and iPac Charging Cradle out of the box.
2. Unfold the insert and slide the Carrying Case and iPac Charging Cradle out of the insert.
3. Open the carrying case, remove the Instructions for Use and read the instructions carefully.
4. Remove the iPac from the case, and charge the instrument according to the Charging the iPac Pachymeter section.
5. Store the box and insert in a safe place so that if it is needed for future shipping, it will be available.



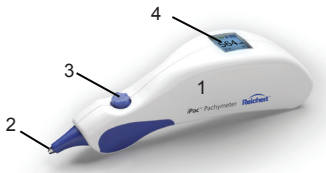
Shipping Box & Insert

The items listed below should be included in the iPac Pachymeter packaging:

- Carrying Case
  - iPac Pachymeter
  - Lanyard
  - Tip Cover
  - Instructions for Use
  - Battery (in the iPac)
  - A/C Adapter w/ Mini USB
- iPac Pachymeter Charging Cradle

Note: If any of these items are missing, please contact the Reichert Customer Service Department. Contact information can be found on the back cover of this manual.

Instrument Setup (continued)



iPac Pachymeter

Parts Identification

1. Pachymeter
2. Measurement Tip
3. Control button
4. OLED Display
5. iPac Pachymeter Charging Cradle



iPac Pachymeter Charging Cradle

Accessories & Spare Parts

Instructions for Use (P/N 16040-101)
Carrying Case (P/N 16040-380)
Lanyard (P/N 13851-096)
Measurement Tip Cover (P/N 16040-027)
iPac Rechargeable Lithium Ion Battery (P/N 16042)
iPac Pachymeter Charging Cradle (P/N 16041)
A/C Adapter w/ Mini USB (P/N 16040-430) Including Country Specific Pin Connector:

- North America (P/N 16040-410-001)
- Australia (P/N 16040-410-002)
- United Kingdom, Hong Kong, Singapore (P/N 16040-410-003)

Note: When ordering a replacement A/C Adapter, the corresponding Country Specific Pin must be ordered as well.

Instrument Setup (continued)

Icon Description



Move the Control button **forward** to go UP



Move the Control button **back** to go DOWN



Move the Control button **left** to go LEFT



Move the Control button **right** to go RIGHT



Press and hold the Control button for the indicated time



Press the Control button once and then release it



Export Data



Clear

Battery Requires Charging

Battery Low Power

Battery Fully Charged

Battery Charging

Charging the iPac Pachymeter

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.

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

CAUTION: USE ONLY THE SUPPLIED CHARGER PROVIDED WITH THE UNIT. IT IS RECOMMENDED THAT THE IPAC BE ATTACHED TO ITS CHARGER (OR CHARGING BASE) WHEN NOT IN USE TO ENSURE PROPER OPERATION.

CAUTION: DO NOT ATTEMPT TO CHARGE THE IPAC OR POWER THE CHARGING CRADLE USING THE USB PORT OF A COMPUTER OR DAMAGE TO THE IPAC OR COMPUTER MAY OCCUR.

The iPac can be charged directly with the Charging Cradle or the A/C adaptor. In either case, it is important to be sure that the Mini USB Plug is correctly oriented to the Mini USB Port, either on the iPac or the Charging Cradle.

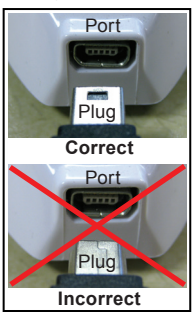
With a Charging Cradle

Note: Initially charge the unit for 10 hours.

Note: The Mini USB Port and the Mini USB Plug have a flat side and a curved side. The flat side of the Plug has a small rectangular cutout visible from the flat side. When connecting the Plug to the Port, be sure that the flat side of the Plug is lined up with the flat side of the Port.

CAUTION: IF THE MINI USB PLUG IS NOT ALIGNED PROPERLY WITH THE MINI USB PORT, THE PORT MAY BREAK OFF AND THE PLUG MAY BECOME DAMAGED.

Note: It is important to initially charge the iPac Pachymeter for the recommended period of time to ensure correct operation.



With Charging Cradle

Note: The iPac comes with a mini USB port cap installed in the mini USB port hole. This should remain in the iPac to help ensure the iPac properly sits on the cradle.

1. Plug the A/C Adaptor with Mini USB into an appropriately volted outlet.
2. Connect the Mini USB charging cord to the Charging Cradle.
3. Place the iPac on the Charging Cradle.

-continued-

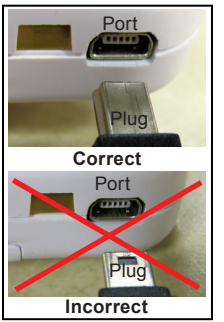
Charging the iPac Pachymeter (continued)

Without a Charging Cradle

Note: Initially charge the unit for 10 hours.

Note: The Mini USB Port and the Mini USB Plug have a flat side and a curved side. The flat side of the Plug has a small rectangular cutout visible from the flat side. When connecting the Plug to the Port, be sure that the flat side of the Plug is lined up with the flat side of the Port.

CAUTION: IF THE MINI USB PLUG IS NOT ALIGNED PROPERLY WITH THE MINI USB PORT, THE PORT MAY BREAK OFF AND THE PLUG MAY BECOME DAMAGED.



Without Charging Cradle

Note: It is important to initially charge the iPac Pachymeter for the recommended period of time to ensure correct operation.

Note: The iPac comes with a mini USB port cap installed in the mini USB port hole. This needs to be removed before charging directly.

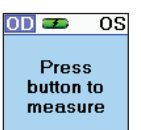
1. Plug the A/C Adaptor with Mini USB into an appropriately volted outlet.
2. Connect the Mini USB charging cord to the iPac Pachymeter.

Power Up Mode

Pressing the Control button initiates the iPac, the display will show “Press button to measure,” after about one minute of inactivity, the iPac will go into sleep mode, the display will turn off. To wake up the iPac press the control button and the display will light up.

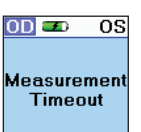
Measurement Mode

In this mode the iPac has about 15 seconds to start the measurement process, if no measurements are taken then the display will show “Measurement Timeout” and then revert back to the “Press button to measure” display.



Sleep Mode

The iPac will automatically go into a power saving sleep mode after a period of inactivity, the display will turn off. Press the control button to exit the sleep mode and resume operation. There is no ON/OFF switch on this instrument.



iPac Setup Menu

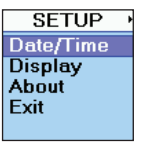
The iPac setup menu enables the user to select the options that are preferred when using the pachymeter. Press and hold (Hold) the Control button for three seconds to display the Setup menu.

At the top of the Display is a menu title (e.g., SETUP). If there is a small arrow on the left or right, moving the Control button LEFT or RIGHT will navigate through the menu screens in accordance with the arrows. Selecting the LEFT arrow displays the previous menu screen. Selecting the RIGHT arrow displays the highlighted selection.

Selecting options in the menu screens is performed by moving the Control button UP, DOWN, LEFT, or RIGHT until the desired option is selected (highlighted). Press (Press) the Control button to activate the desired option.

The iPac SETUP screens are the following:

- Date/Time
- Display
- About
- Exit



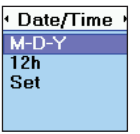
In the Setup menus there are options that will have specific colored indicator icons. The colors are:


Green Icon - Indicates this option is turned On.


Gray Icon - Indicates this option is turned Off.

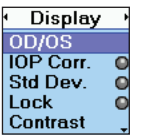
Instrument Setup (continued)

iPac Setup Menu (continued)



Date/Time

The Date/Time menu is used to change the date and time format and also to set the current date and time, this will be printed with the measurement data.



Display

The display menu options are:

- The eye can be set to either OD/OS or Right/Left (R/L).
- IOP Correction can be set ON or OFF.
- Standard Deviation can be set ON or OFF.
- Locks the screen viewing orientation.
- Sets the contrast on the display.
- Sets the operating language.

Note: Move the control button down to access the language option.



About

The About screen displays the following information:

- Serial - displays the serial number of the unit.
- Revision - Provides the revision of the operating software of the iPac.

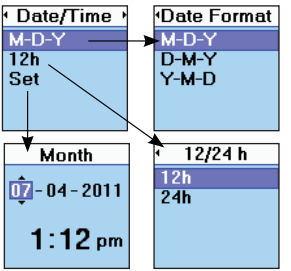
Exit

Exits the Setup menu and returns to the Measure screen.

iPac Menu Options (continued)

Date/Time
The Date and Time format can be changed in Setup.

- **Date Format**
  Sets the month, day and year format.
- **12 or 24**
  Sets the option to display the hours in 12 hour or 24 hour format.
- **Set**
  Allows the user to set the current date and time.



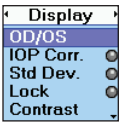
To make changes to the Date/Time:

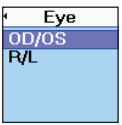
1. Highlight the option you want to change with the control button, move up (Up) and down (Down) the menu screen.
2. Press (Press) the control button and the display will change to show the available options.
3. Highlight the new option, moving up (Up) and down (Down) the menu.
4. To select the new option press (Press) the control button in and the option is selected and the display will return to the main Date/Time screen.
5. To make changes to the date and time value use the control button up (Up) and down (Down) function and then move to the next value by using the right (Right) or left (Left) function. Once all changes are made, press (Press) the control button in and the display will return to the main Date/Time menu.

iPac Menu Options (continued)

Display

The Display screen allows changes to the following options:





- **Eye:**
  Displays the selected eye as OD/OS or R/L.
  OD = Right Eye.
  OS = Left Eye.



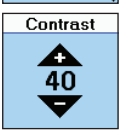
- **IOP Corr:**
  IOP Correction value is displayed if the Option is set ON. The option is indicated by a green or gray icon next to the option (Gray is OFF, Green is ON). An IOP adjustment table is shown in Appendix A.



- **Std Dev:**
  Displays the standard deviation for the CCT measurement. f this option is set OFF, then no standard deviation is displayed
  (Gray is OFF, Green is ON).



- **Lock:**
  The display will change orientation as the instrument is rotated if this option is OFF. If the option is ON, the orientation of the display remains the same even if the instrument is rotated (Gray is OFF, Green is ON).



- **Contrast:**
  Sets the contrast level of the display. Use the UP and DOWN Control button function to change the contrast of the screen.



- **Language:**
  Sets the language of the instrument. Languages available are: English, German, French, Spanish, Portuguese, Italian.

Instrument Operation

Measurement Screen

In the measurement mode the display will have the following information displayed.

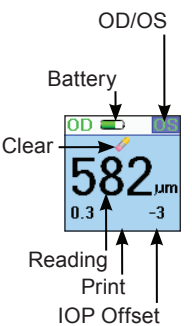
OD/OS: This represents the patient's eye. The highlighted option is the eye selected to be measured. The iPac always defaults to the right eye at the beginning of the measurement process. Move the control button right or left to select the eye you wish to measure.

Battery: The battery symbol indicates how much battery life is available. The battery symbol changes from green (full) to yellow to red (empty). When the battery symbol is red, it is time to re-charge the battery.

Clear: Move the control button UP and hold it until the display shows "Measurement cleared" All data will be cleared and a new measurement can be started.

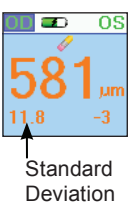
Readings: This number represents the CCT measurement for the selected eye. To review the measurement of the opposite eye, move the control button right or left.

Export: Measurement data may be transferred to an EMR system when device is connected with a USB cable (not supplied). Move the control button down to send the measurement data. To clear the data after exporting move the button up and all the measurement data will be cleared.



IOP Offset: The number on the lower right is the IOP Offset number that is associated with the pachymetry reading. Refer to Appendix A for the IOP adjustment chart.

Std. Dev: The number in the lower left of the screen is the standard deviation of the CCT measurement. The standard deviation is how much variation or "dispersion" there is from the average measured value.



Note: If the CCT measurement is displayed in orange then the standard deviation is greater than 10 (σ > 10). This is an indication that another set of measurements should be taken.

Measurement Screen (continued)

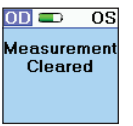


Asterisks

When the instrument is ready to take measurements, three asterisks (***) are displayed on the screen. After five or more measurements are acquired the asterisks will change and display the average value. The number of measurements are displayed below the asterisks (e.g., 6/25). If it is difficult to get measurements from a patient, fewer than 25 measurements can be taken, the average will be based on the fewer measurements.

Clearing Data

To clear data on the display, move the Control button up (Up) for about 2 seconds, until the display indicates that the measurements have been cleared.



Operation

CAUTION: IT IS PRUDENT TO MINIMIZE THE PATIENT'S EXPOSURE TO ULTRASOUND ENERGY TO A LEVEL AS LOW AS REASONABLY ACHIEVABLE (ALARA) BY REDUCING THE NUMBER OF SCANS NEEDED TO BE PERFORMED. ADVISE THE PATIENT OF WHAT TO EXPECT DURING A SCAN TO REDUCE REPETITIVE SCANS. THE AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE (AIUM) HAS A PUBLICATION "MEDICAL ULTRASOUND SAFETY" (1994) WHICH HAS MORE INFORMATION ON THIS TOPIC.

Operational Check

Measure the patient according to the following procedure and precautions.

WARNING: DO NOT USE THE IPAC PACHYMETER IF THE MEASUREMENT TIP IS CRACKED, CHIPPED OR SHOWS ANY IRREGULARITY OF THE SURFACE, TO PREVENT PATIENT INJURY, AND/OR INACCURATE READINGS.

1. Before using, visually inspect the Pachymeter's sensor for cracks, chips or other irregularities. Do not use the pachymeter if the tip is cracked, chipped, or shows any kind of irregularity of its surface.
2. Press and release the control button (

) to activate the iPac.

Note: The instrument will automatically enter the power OFF sequence after inactivity of approximately one minute.

3. Check the battery icon to ensure that the battery is fully charged. If the iPac needs charging, plug in the charger until the icon indicates that it is fully charged, or place it in the iPac Charging Cradle.

CAUTION: ALWAYS ENSURE THE IPAC IS CHARGED SUFFICIENTLY OR ERRATIC READINGS MAY OCCUR.

Patient Preparation

1. Advise the patient of the measuring process and what to expect before taking measurements.
2. Have the patient sit comfortably and install a drop of topical anesthetic into the eye to be examined.

CAUTION: DO NOT PUT ANESTHETIC DROPS ON THE MEASUREMENT TIP. THIS MAY RESULT IN INACCURATE READINGS. TIP SHOULD BE DRY BEFORE TAKING MEASUREMENTS.

3. Give the patient the appropriate time for the anesthetic to start working.

Measurement Process

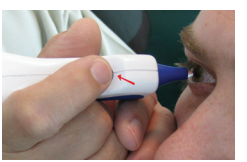


4. Instruct the patient to look straight ahead at a fixation target (e.g., ear, nose, distant object) to minimize eye movement, with eyes fully open to prepare for a measurement.
5. Hold the iPac Pachymeter as you would a pencil and to enable viewing of the sensor and the patient's cornea where contact will be made. For normal corneas, central corneal contact is highly recommended.

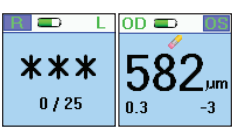


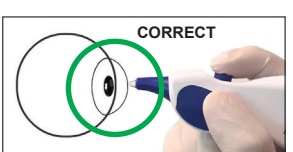
Note: The corneal surface needs only to be contacted for a short time. Indentation or additional pressure is not required and may lead to injury to the eye.

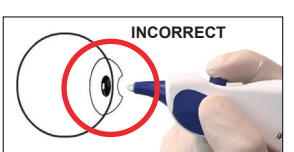
Note: Do not 'tap' the iPac on the cornea. Hold it steadily against the cornea.



6. Support the iPac with your hand, and if necessary, stabilize the movement of the iPac by resting your hand against the patient.
7. Press and release the Control button, one time (Press). The iPac will initiate the measurement process and beep once. After the beep, three asterisks are displayed.
8. Minimizing the time the Pachymeter is touching the eye, lightly touch the center of the cornea until the iPac completes a series of beeps followed by a single beep.
9. After the series of beeps and the final beep, remove the iPac from the eye. The iPac will display the average reading.







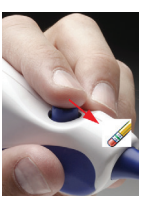
Measurement Process (continued)

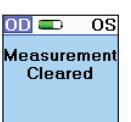
10. Move the Control button to the right (Right) or left (Left) as needed to acquire measurements on the other eye and repeat the above process.
11. To review the measurement data, you can “toggle” between the right and left eye by moving the control button right (Right) or left (Left).
12. To clear the measurement data, move the control button up (Up) and hold it until the display shows “measurement cleared.”
13. Perform the cleaning instructions in the Cleaning and Disinfection section of this manual.



Note: If you are unable to take 25 measurements, the average will be displayed for the number of measurements that were taken. Either press the control button down once or wait for about 15 seconds and the display will change to show the print and clear icon.







Cleaning and Disinfection

iPac Cleaning Instructions

Perform the following procedure when cleaning the outside of the iPac Pachymeter.

CAUTION: DO NOT IMMERSE THE INSTRUMENT IN LIQUIDS OR AUTOCLAVE OR DAMAGE TO THE ELECTRONICS OF THE PACHYMETER WILL OCCUR.

1. After using the iPac Pachymeter, we recommend wiping the outside of the instrument with a soft, cotton cloth lightly moistened with one of the following approved cleaning solutions:
    - Soap and Water
    - 70% Isopropyl Alcohol
    - 5.25% Bleach and Water Solution
    - 7.5% Hydrogen Peroxide and Water Solution
    - Sani-cloth* Prime Germicidal Wipes (Didecyl Dimethyl Ammonium Chloride, isopropyl alcohol and ethyl alcohol.)
2. After cleaning, wipe the outside of the instrument with a soft, cotton cloth lightly moistened with sterile distilled water.
3. Dry the unit with a lint free cloth or tissue.

Note: Always store the pachymeter in its case when not being used for an extended period of time.

Measurement Tip Cleaning Instructions

Perform the following procedure when cleaning and disinfecting the iPac measurement tip.

WARNING: DO NOT ATTEMPT TO USE THE IPAC IF THERE IS ANY INDICATION THE MEASUREMENT TIP HAS BEEN DAMAGED AND/OR THEIR PHYSICAL INTEGRITY HAS BEEN COMPROMISED. IF THE MEASUREMENT TIP HAS MADE CONTACT WITH ANYTHING BETWEEN APPLANATIONS, CLEAN THE TIP ACCORDING TO THE MEASUREMENT TIP CLEANING INSTRUCTIONS OR SERIOUS INJURY MAY OCCUR.

1. After each patient, we recommend wiping the measurement tip with a cotton swab soaked in 70% isopropyl alcohol.

* Sani-Cloth is a registered trademark of PDI, Inc., Woodcliff Lake, NJ.

CAUTION: DO NOT IMMERSE THE INSTRUMENT IN LIQUIDS EXCEPT FOR ONLY THE MEASUREMENT TIP OF THE PACHYMETER OR DAMAGE TO THE ELECTRONICS OF THE PACHYMETER WILL OCCUR.

2. Immerse only the measurement tip for 10 minutes in 70% isopropyl alcohol or an equivalent locally approved disinfectant.
3. After cleaning, rinse the end of the measurement tip thoroughly with sterile distilled water.
4. Dry the measurement tip with a lint free cloth or tissue.

Note: Always store the pachymeter in its case when not being used for an extended period of time.

Measurement Tip High Level Disinfection Instructions

Perform the following procedure when cleaning and high-level disinfecting the iPac measurement tip.

This procedure may be indicated if 70% isopropyl alcohol is deemed insufficient.

WARNING: DO NOT ATTEMPT TO USE THE IPAC IF THERE IS ANY INDICATION THE MEASUREMENT TIP HAS BEEN DAMAGED AND/OR THEIR PHYSICAL INTEGRITY HAS BEEN COMPROMISED. IF THE MEASUREMENT TIP HAS MADE CONTACT WITH ANYTHING BETWEEN APPLANATIONS, CLEAN THE TIP ACCORDING TO THE MEASUREMENT TIP CLEANING INSTRUCTIONS OR SERIOUS INJURY MAY OCCUR.

1. After each patient, thoroughly wipe the measurement tip with a cotton swab soaked in 70% isopropyl alcohol.
2. Rinse residual alcohol and soil from the device using clean tap water.

CAUTION: DO NOT IMMERSE THE INSTRUMENT IN LIQUIDS EXCEPT FOR ONLY THE MEASUREMENT TIP OF THE PACHYMETER OR DAMAGE TO THE ELECTRONICS OF THE PACHYMETER WILL OCCUR.

-continued-

Measurement Tip High Level Disinfection Instructions (continued)

3. Immerse only the measurement tip for 10 minutes in freshly (daily) constituted solution (or minimum effective concentration monitored solution) of one of the following high level disinfectants used in accordance with the solution manufacturer's instructions:
    - 5.25% Bleach and Water Solution
    - 7.5% Hydrogen Peroxide and Water Solution

4. After cleaning, rinse the end of the measurement tip thoroughly with sterile distilled water.
5. Dry the measurement tip with a lint free cloth or tissue.
6. Visually inspect the iPac for cleanliness and integrity.
7. The iPac can be stored in the iPac case with a new lint free cloth or tissue over the tip if not to be used for an extended period of time.

Note: Always store the Pachymeter in its case when not being used for an extended period of time.

Maintenance and Storage

General Maintenance

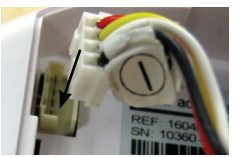
This instrument performs an internal check of the unit just before the unit indicates that it is ready to measure. If the unit displays that it is ready to measure, then the system check was successfully completed and the unit is ready for use.

Battery

Replace the iPac Battery when it stops holding a charge.

Battery Replacement:

1. On the back of the iPac is the battery door. Open it by pushing the latch towards the door and lifting the door.
2. Disconnect the battery harness from the iPac.
3. Replace the battery and connect the battery harness to the iPac.



Battery Harness

Note: Be sure that the battery is oriented correctly so that the door can close properly. If the battery is oriented incorrectly, the harness may become damaged and the door may not close. If the battery harness becomes damaged, the battery will need to be replaced. The battery should connect at the harness, the wires should lay flat along the side of the battery compartment, and then attach to the battery at the bottom. If the wires are bunched up at the top, near the point of connection to the iPac, then the battery is oriented incorrectly.



Correct



Incorrect

Battery Orientation

4. Attach the door and ensure that it latches closed.
5. Charge the battery for approximately 10 hours before using.

Note: Refer to Disposal section of this manual for your local laws and ordinances regarding the proper disposal of the battery.

Storage

If the instrument is to be stored for an extended period or prepared for transportation, remove the iPac battery to avoid possible damage to the instrument due to battery leakage.

Troubleshooting

The table below provides a guide for troubleshooting some basic iPac Pachymeter operational problems. If a problem persists after using this guide contact Reichert for further assistance.

SYMPTOM	PROBABLE CAUSE	CORRECTION
Will not turn on.	Unsuccessful boot.	Remove the battery, wait 10 seconds, re-install the battery.
	Battery is drained.	Attach the charger to the iPac and fully charge the battery.
	Battery is defective.	Replace Battery.
Battery symbol low.	Low iPac battery capacity.	Attach the charger to the iPac and charge it until the icon indicates full.
Multiple inaccurate readings.	Improper technique.	Review “Measurement” Section of this manual.
	Debris on tip.	Clean sensor tip.
	Mechanical or electronic damage.	Arrange for service through Reichert Technical Service Group.
No beeps when measuring.	Control button not properly pressed.	Press Control button.
	Battery is drained.	Attach the charger to the iPac and charge it until the icon indicates full.
	Mechanical or electronic damage.	Arrange for service through Reichert Technical Service Group.
Battery will not charge.	Defective battery.	Replace iPac battery pack
	Battery is too low to charge on the cradle.	Charge the iPac directly with the power cord until the unit is responsive (screen turns on). Then charge with the cradle until battery is full.
Error Code Displayed.	Software anomaly.	Remove and install the battery pack to reset hardware.
	Malfunction of the iPac.	Contact the Reichert Technical Service Group for technical support and provide error message.

Specifications

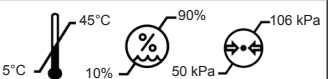
PHYSICAL DIMENSIONS

Size

Length: 7.05 in. (179 mm)
Width: 1.46 in. (37.0 mm)
Height: 2.20 in. (56.0 mm)

Weight: 3.53 oz.(100 g)

Measurement Tip Diameter:
.08 in. (2.0 mm)



RANGE OF MEASUREMENTS

200 to 1000 µm, ±5 µm

ENVIRONMENTAL REQUIREMENTS

Operational Environment

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

Relative Humidity range:
20 to 80% RH

Atmospheric Pressure range:
70 to 106 kPa (20.7 to 31.6 in.Hg)

Transport and Storage Environment

Ambient Temperature range:
41°F to 113°F (5 °C to 45°C)

Relative Humidity range:
10 to 90% RH (non-condensing)

Atmospheric Pressure range:
50 to 106 kPa (14.8 to 31.6 in.Hg)

ELECTRICAL

Measurement tip Ultrasound Frequency: 10.5 MHz Straight Probe
Battery Pack Voltage: 3.7V LI-ION Battery Pack
A/C Adaptor Input Voltage: 100-240 Vac, 50-60 Hz, 0.16 A max
A/C Adaptor Output: 5Vdc, 1.2A max

Disposal

This product does not generate any environmentally hazardous residues. At the end of its product life, follow your local laws and ordinances regarding the proper disposal of this equipment.

Software Revision

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

Guidance & Manufacturer's Declaration

Table 201 – Guidance and Manufacturer's Declaration

Electromagnetic Emissions

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The iPac is intended for use in the electromagnetic environment specified below. The customer or user of the iPac 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	The iPac 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	The iPac 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	

Table 202 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The iPac is suitable for use in electromagnetic environment specified below. The customer or user of the iPac should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%.
Electrical Fast Transients / Bursts IEC 61000-4-4	±2kV Mains Power Lines ±1kV I/O Lines 100kHz repetition frequency	±2kV Mains Power Lines N/A, I/O Lines	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 N/A, 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 the iPac requires continued operation during power mains interruptions, it is recommended that the iPac 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.

Table 204 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The iPac is intended for use in the electromagnetic environment specified below. The customer or user of the iPac 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	6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 KHz	(V1) = 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 KHz	Portable and mobile RF communications equipment should be no closer to any part of the iPac, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: d=(3.5/V1)(√P) d=(3.5/E1)(√P) 80 to 800 MHz d=(7/E1)(√P) 800 MHz to 6.0 GHz Where P is the max output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF Electromagnetic Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	(E1) = 3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz (E1) = 3 V/m 80 MHz to 6 GHz 80% AM at 1kHz	
	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	N/A	

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. The measured field strength in the location in which the ME Equipment or ME System should be observed to verify normal operation. If abnormal performance is observed, additional measures many be necessary, such as re-orienting or relocating the ME Equipment or ME System.

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

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

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Recommended Separation Distances for between Portable and Mobile RF Communications Equipment and the iPac

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

Max Output Power of Transmitter (W)	Separation (m) 150kHz to 80 MHz Outside ISM Bands d=(3.5/V1)(√P)	Separation (m) 150kHz to 80 MHz In ISM Bands d=(10/3)(3.5/V1)(√P)	Separation (m) 80 to 800 MHz d=(3.5/E1)(√P)	Separation (m) 800MHz to 6.0GHz d=(7/E1)(√P)
0.01	0.1166	0.1944	0.1166	0.2333
0.1	0.3689	0.6149	0.3689	0.7378
1	1.1666	1.9444	1.1666	2.3333
10	3.6893	6.1489	3.6893	7.3786
100	11.6666	19.4444	11.6666	23.3333

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note 3: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 6.0 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.

Table 9 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Immunity to Proximity Fields from RF Wireless Communications Equipment

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	IEC 60601Test Level					Compliance Level	Electromagnetic Environment -Guidance-
	Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	Immunity Test Level (V/m)	Compliance Level	
Radiated RF IEC 61000-4-3	385	380 to 390	TETRA 400	Pulse Modulation[b] 18 Hz	27	27 V/m	d = 6/E √P where d = Minimum separation distance in meters E = Immunity test level in V/m P = Maximum power in Watts (W)
	450	430 to 470	GMR 460, FRS 460	FM[c] ±5 kHz deviation 1 kHs sine	28	28 V/m	
	710 745 780	704 to 787	LTE Band 13, 17	Pulse Modulation[b] 217 Hz	9	9 V/m	
	810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation[b] 18 Hz	28	28 V/m	
	1 720 1 845 1 970	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation[b] 217 Hz	28	28 V/m	
	2 450	2 400 to 2 570	Bluetooth WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation[b] 217 Hz	28	28 V/m	
	5 240 5 500 5 785	5 100 to 5 800	WLAN 802.11 a/n	Pulse Modulation[b] 217 Hz	9	9 V/m	

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

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

[c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

Table 11 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Immunity to Proximity Magnetic Fields in the Frequency Range of 9kHz to 13,56 MHz

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The iPac is intended for use in the electromagnetic environment as specified below related to proximity magnetic fields.

Immunity Test	IEC 60601Test Level			Compliance Level
Radiated Magnetic Fields IEC 61000-4-39	Test Frequency	Modulation	Immunity Test Level (A/m)	Compliance Level
	30 kHz [a]	CW	8	8 A/m
	134,2 kHz	Pulse Modulation [b] 2,1 kHz	65 [c]	65 A/m
	13,56 MHz	Pulse Modulation [b] 50 kHz	7,5 [c]	7,5 A/m

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

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

[c] r.m.s., before modulation is applied.

Acoustic Output

Typical Acoustic Output
(Non- Autoscanning Mode)

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value				0.117	1.93	3.70
Associated Acoustic Parameter	$p_{r.3}$		(MPa)	0.390		
	W_0		(mW)		0.0242	0.0242
	f_c		(MHz)	11.1	11.1	11.1
	Z_{sp}		(cm)	0.300	0.300	0.300
	Beam Dimensions	X_{-6}	(cm)		0.128	.0128
		y_{-6}	(cm)		0.113	0.113
	PD		(µsec)	0.111		0.111
	PRF		(Hz)	4680		4680
	EBD	Az.	(cm)		0.250	
		Ele.	(cm)		0.250	
Operating Control Conditions	There are no operator controls that alter the acoustic output power.					

Uncertainties in the above values are reported as ±1 standard deviation. The derated intensities were derived from those measured in water based on the measured center frequency of the acoustic signal (fc, MHz) and the distance from the transducer to the point at which the intensity was measured (d, cm) using the formula: Derated Intensity = Measured Intensity *e-0.069*fc*d.

In compliance with FDA's preamendments acoustic output exposure levels for an Ophthalmic device, the derated spatial-peak temporal-average intensity (Ispta.3) is less than 17 mW/cm², the derated spatial -peak pulse-average intensity (Isppa.3) is less than 28 W/cm², and the mechanical index (MI) is less than 0.23.

Definitions
ISPTA.3 - derated spatial-peak temporal-average intensity (milliwatts per square centimeter).
ISPPA.3 - derated spatial-peak pulse-average intensity (watts per square centimeter).
MI - Mechanical Index.
pr.3 - derated peak rarefactional pressure (megapascals) associated with the transmit pattern giving rise to the value reported under MI.
Wo - ultrasonic power (milliwatts). For the operating condition giving rise to ISPTA.3, Wo is the total time-average power. For the operating condition giving rise to ISPPA.3, Wo is the ultrasonic power associated with the transmit pattern giving rise to the ISPPA.3 value.

Acoustic Output (continued)

Definitions (Continued)
fc - center frequency (MHz). For MI and ISPPA.3, fc is the center frequency associated with the transmit pattern giving rise to the global maximum value of the respective parameter.
zsp - axial distance at which the reported parameter is measured (centimeters).
x-6, y-6 - are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where zsp is found (centimeters).
PD - pulse duration (microseconds)
PRF - pulse repetition frequency (Hz)
EBD - entrance beam dimensions for the azimuthal and elevational planes (centimeters).

Tissue Exposure To Ultrasound Energy

The ultrasound energy emitted by the iPac is of low intensity and will have no adverse effects on the patient and/or user. However, the user is still cautioned to perform examinations using the principle of ALARA (As Low As Reasonably Achievable). All examinations should be done so that the patient receives as little ultrasound radiation as possible. Do not hold the measurement tip against the eye or other tissue with the system activated except when making a measurement. Do not make unnecessary measurements.

Ultrasonic Intensities

The iPac has only one mode, and ultrasonic intensity settings are not under the control of the user. Thus, the values below are the values to be expected for a typical transducer.
In Water In the Eye
I SPTA, mw/cm2 1.74, 1.93, 1.68
I SPPA, W/cm2 3.39, 3.70, 3.34
MI(unitless) 0.114, 0.117, 0.112

Since the iPac is a contact instrument, the energy will always be attenuated by the tissue when used as recommended. However, since the focal length (point of maximum intensity) is very short (1 mm), and thus penetration into the eye is limited, the water values are effectively the same as the tissue values, for all practical purposes. If more accuracy is desired, the intensity in the eye at the transducer focus (corresponding to maximum intensity) may be calculated according to the formula recommended by the FDA:

$It = Iw \times e^{(-0.069 \times f \times z)}$

where It is the estimated in situ intensity, Iw is the measured intensity in water at the focus of the transducer, f is the ultrasonic frequency, and z is the distance from the face of the measurement tip to the transducer focus, which is the point of measurement (1mm). The nominal frequency of these transducers is 10.5 MHz. The actual frequency of a particular transducer may vary from this value. The tissue calculations above were done with the measured frequency of the transducer used for the tests.

Warranty

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

Appendix A

The IOP correction value is based on data of Ehlers et al (1975), modified from Stodmeister (1998). Mean of corneal thickness in healthy subjects; 545µm (Doughty and Zaman 2000) See adjustment chart indicated below for more information.

Corneal Thickness (um)	Correction Value (mmHg)
445	+7
455	+6
465	+6
475	+5
485	+4
495	+4
505	+3
515	+2
525	+1
535	+1
545	0
555	-1
565	-1
575	-2
585	-3
595	-4
605	-4
615	-5
625	-6
635	-6
645	-7

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