

TECHNICAL BULLETIN 928-R2



For the Most Demanding High Accuracy Applications

The Autopol® V PLUS and Autopol® VI



The brand of polarimeter used in more labs than any other.*











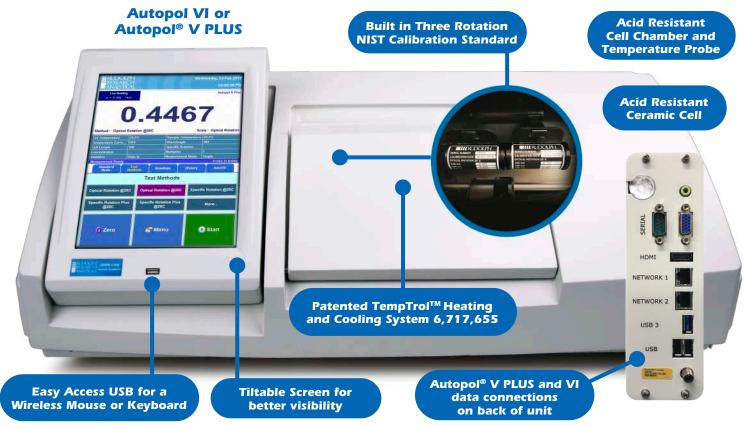








=The most stringent pharmaceutical requirements ——



Unmatched Accuracy: ± 0.0003° Arc

For Racemic Solutions and very low concentration samples, the Autopol® VI provides unmatched 4th decimal optical rotation accuracy of $\pm 0.0003^\circ Arc$ over $\pm 1^\circ Arc$. Instrument performance for readings between -1 and 1° Arc is: Resolution ± 0.0001 , Reproducibility ± 0.0002 , and Accuracy ± 0.0003 .

The Industry Standard Polarimeter

The Autopol® V PLUS and Autopol® VI have the validation tools and features to satisfy today's global pharmaceutical companies, including: instrument level 21CFR Part 11 compliance, NIST traceable calibration standards and a global list of installations. Rudolph Research has thousands of satisfied customers who praise the Autopol® V PLUS and Autopol® VI quality, accuracy and reproducibility.

Autopol® V PLUS and Autopol VI Standard Features and Accessories

- TempTrolTM Electronic cooling & heating from 15°- 40°C
- Six Standard Wavelengths: 365nm, 405nm, 436nm, 546nm, 589nm and 633nm
- 21CFR11 Compliance: Embedded or by a separate PC
- Domestic 3-year warranty and 20-year support guarantee
- International warranty varies by country
- Standard Accessories: TempTrol™ NIST Traceable Quartz Standard (3 rotation), TempTrol™ 100mm Polarimeter Cell, TempTrol™ Temperature Validation Cell, Thermoprobe, and Built-In Sample Measurement Probe

NIST Traceable Measurement Calibration Accessories Included With Instrument Purchase



3 Rotation TempTrol™ NIST Traceable Quartz
Calibration Standards For Hands Free Internal Optical
Rotation Measurement Validation

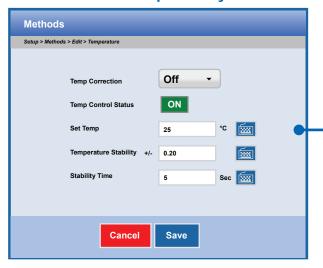
The Autopol® V PLUS and Autopol® VI Use Rudolph's Exclusive TempTrol™ Electronic Temperature Control System

The USP <781> requires optical rotation measurements at 25°C ± .5°C (unless another temperature is specified). The (EP)European Pharmacopoeia requires optical rotation measurements made at 20° ± .5°C (unless another temperature is specified).

Whatever your temperature control needs are, the Autopol® VI and the Autopol® V PLUS' exclusive TempTrol™ System (Patent No. 6,717,665) makes your measurement in a few minutes without a water bath or any type of water circulation.

The TempTrol™ System allows push-button temperature control of your 100mm cell, 200mm cell or Quartz Plate. Set the temperature, push "measure" and walk away. The Autopol® will heat or cool to a predefined temperature and then provide you with the result all in one easy step.

Patented TempTrol[™] Technology Eliminates the Need for a Water Bath. Here is How the TempTrol[™] System Works:



Temperature is selected via touch screen. Temperature selection of 25°C shown above.

Temp $Trol^{TM}$ cell with mating heating & cooling transfer surface manufactured with acid resistant materials: Cerakote® and Peek TM below.

TempTrol™ active surface with Cerakote® coating



For improved temperature performance or when working with acids (HCl) use the measurement port in the body of the cell. This also allows the inlet and outlet ports to be capped to avoid evaporation, fumes and spillage.



Cerakote® Coated Temperature measurement probe

Place the TempTrolTM cell in your TempTrolTM equipped Autopol® sample chamber to measure to within $\pm 0.2^{\circ}$ C of the USP, EP, JP or BP specified temperature (normally 20°C or 25°C $\pm 0.5^{\circ}$ C).

To Validate Temperature Performance

Rudolph provides a temperature validation cell with every TempTrol^ $^{\text{TM}}$ system. The temperature validation cell along with an optional NIST traceable Thermo Probe is designed to validate the temperature control performance of the polarimeter and cell to $\pm 0.2^{\circ}\text{C}$.

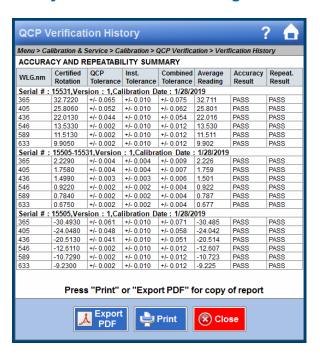


-Automatic Measurement Validation

The only self contained and automatically loaded quartz control plates.

- Calibrate your Rudolph Autopol® V PLUS and Autopol® VI Polarimeter right from the user friendly touch screen.
- The Quartz Control plates stored in the instrument are automatically positioned and the calibration is performed for you. Results are recorded and you are finished. Calibration results can be stored on the local hard drive or printed for future reference.
- Rudolph's 3 rotation Quartz Standard is Traceable to NIST and certified by an internationally recognized accreditation body (NVLAP).
- Labs must use multiple rotations to comply with FDA rulings a Single Rotation Quartz Control Plate has been ruled non-compliant by the FDA.
- Rudolph strongly encourages Ccalibration with 3 rotational values to comply with the latest FDA rulings.

Your history of calibration is stored right in the instrument.





2 Quartz Plates are stored within the instrument, ready for automatic calibration. Rudolph is the only Polarimeter manufacturer in the world producing certified 3 rotation Quartz Calibration Standards accredited by NVLAP and traceable to NIST, with an accuracy of \pm 0.002 degrees Optical Rotation.



Each Quartz plate is positioned for calibration by the instrument right from the touch screen. Calibration is thus fully automated and requires no handling of the Quartz Control Plate.



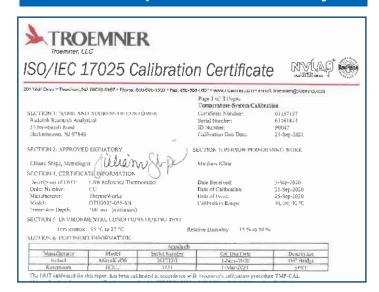
Rudolph strongly encourages Quartz Calibration Standards with 3 rotational values above, below and near the sample under test to comply with FDA rulings related to "Sample Bracketing" and EP's most recent calibration guidelines on linearity. Each Quartz Standard is certified by an accredited independent body (NVLAP) and traceable to NIST.

=Accredited to NVLAP and Traceable to NIST=

Optical Rotation Traceability



External Temperature Probe Traceability





- Rudolph supplies Ceramic Quartz Cells as standard on Autopol V, V PLUS and VI polarimeters
- Cells are resistant to 6 Molar HCL Ceramic Quartz Cells are impervious to acids and transfer heat quickly and evenly.
- Rudolph's exclusive, patented TempTrol[™] cells use an acid resistant Cerakote[®] coated transfer surface to mate with the Cerakote[®] coated TempTrol[™] active heating and cooling transfer surface.
- Rudolph Polarimeter cells are easy to handle, lightweight, easy to fill and easy to clean. Cell ends are removable for thorough cleaning.
- Rudolph Cells are light and have a large thermal transfer surface so they come to temperature quickly and evenly across the cell.
- Cell apertures are smaller than the internal bore diameter, therefore, small air bubbles do not impact sample measurement.



Lifetime Warranty on Cells

Only Rudolph provides a Lifetime Guarantee on its Ceramic Quartz Polarimeter cells covering breakage and damage caused by acids*.

*According to all available marketing resources at time of printing.

The Rudolph AutoFill™:

Filling a Polarimeter Cell has never been easier.

Rudolph Research Analytical developed AutoFill™, Patent No. 10,101,353, a simple and easy way to allow fast and reliable polarimeter cell loading. Polarimeter sample cells are filled without bubbles, using Rudolph propriatary BubbleInspect™ technology, sample vapors are contained, and cleaning and drying is automated. Manual cell handling, cleaning and loading is eliminated.

The AutoFill™ (Patent No. 10,101,353) is available as an option with BubbleInspect™ on the Autopol V Plus and Autopol VI Polarimeters.



Engineered for perfect fills every time.

Operation is as simple as opening the AutoFillTM lid, pouring in your sample, closing the lid and pressing start. The sample will be advanced into the Polarimeter cell and stopped once full. The cell is now loaded and the measurement will automatically begin after BubbleInspectTM approves the measurement. When the measurement is complete the operator is prompted to open the AutoFillTM chamber and add a solvent. The AutoFillTM lid is closed and the solution is flushed through the cell to waste. Air drying will automatically begin and end.

You are now ready for your next measurement.

AutoFill™ reduces sample loading and cleaning time

- No need to inject samples with syringes. Samples are easily poured in the AutoFillTM sample well.
- Eliminate contact with acids and bases.
- Air dry is run for the correct amount of time to fully dry the cell.
- Cleaning is made effortless.
- A perfect cell load is guaranteed every time with Rudolph's exclusive Optical Rotation Homogeneity Inspection Solution.

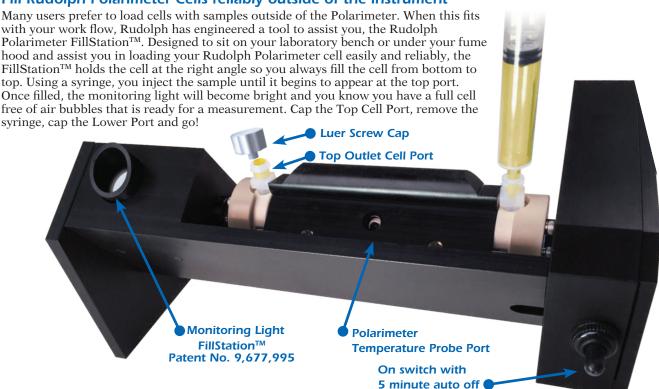
When Acids and Open Samples are Allowed in the Instrument Measurement Area

- Sample is easily poured into the large AutoFillTM well.
- All wetted parts are made to stand up against the most aggressive samples including 6 Molar HCl
- All Materials are Teflon, Peek, and Kalrez[®].
- You may choose to clean with a single solvent or a combination of solvents.



The Rudolph FillStation™

Fill Rudolph Polarimeter Cells reliably outside of the instrument



Advantages of using the Rudolph FillStation™

- The cell is held at the right angle and filled from the bottom just the way Rudolph cells were designed to be filled. Perfect every time.
- Filling from the bottom to top moves any air with the potential to cause a bubble up and out of the cell.
- Once you see the monitoring light go to bright there is no question that the cell is properly filled.
- Verification of air free sample loading even for inexperienced operators.
- Helps eliminate contact with acids, bases, or any sample the user does not want to come in contact with.
- Less experienced operators can learn to reliably fill cells with minimal training.

The FillStation[™] (Patent No. 9,677,995) is included standard with all Rudolph Autopol V, Autopol V PLUS, and VI Polarimeters.



Today's laboratories and cGMP procedures demand that noxious fumes, strong acids and other caustic materials are filled in a designated safe area where a fume hood is used and there is minimal operator exposure. Instruments are now located in clean areas or a laboratory separate from the wet area. Rudolph addresses these concerns with its FillStation™ so that cells can be easily filled and capped inside the safe wet area.

■ How to use the FillStation™

For users who prefer not to hold the cell while working with highly acidic or basic samples, the Rudolph Cell FillStationTM is simple and easy to use, just follow the steps below:



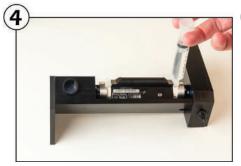
By design, the FillStationTM will hold the cell at a suitable angle.



Place a 2.5mm or 5.0mm bore Polarimeter cell into the Rudolph FillStation TM .



Turn the FillStation TM light on. The light will turn off automatically after a few minutes.



Make sure the cell is always clean and dry. Use compressed air and acetone for this process. Fill the cell from the lower inlet port with a Luer Syringe only.

As the cell becomes filled and sample begins to appear at the upper inlet, cap off the upper, then lower inlet port. Your cell is now filled and air bubble free.



The FillStation[™] creates a light image that will go from darker to a bright white circle when the cell is filled and airbubble free. A bubble free cell shows an illuminated white circle as shown below.

Please Note:

Filling a Rudolph Polarimeter cell is easy and you can be assured of an air bubble free sample cell. It is important to note that when using highly acidic or basic solutions samples the cell should not be filled in the Polarimeter. Doing so may allow spillage into the instrument which, over time, may damage the instrument.

The Rudolph Polarimeter Cell FillStation[™] accessory is available for all Rudolph Autopol Polarimeters and included free of charge with Autopol V, Autopol V PLUS, and Autopol VI Polarimeter Models.

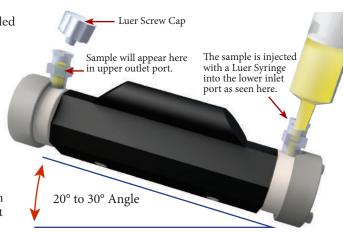


Designed for syringe loading

Rudolph Research Polarimeter Sample Cells are designed to be easily filled and cleaned with a Luer syringe.

When held at the correct angle and filled using the lower inlet port, the cell is filled with almost no possibility of leaving an air bubble in the cell. Filling from the lower inlet port forces any air bubbles up and out of the upper outlet port.

Rudolph cells are unlike other manufacturers cells as they are uniquely designed to keep small air bubbles out of the light path. Filling the cell is as simple as holding the cell at a slight upward angle and filling from the bottom inlet using a Luer Syringe. When the sample appears near the top outlet port, simply place the Luer cap on the upper port and then lower port. Your cell is now filled, capped and air bubble free. Cells must be clean and dry to ensure proper filling with minimum sample.



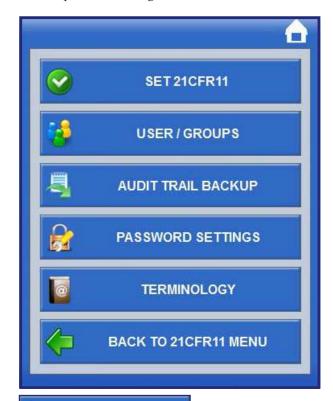
Full 21CFR Part 11 Compliance

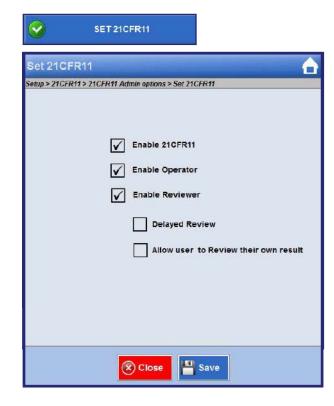
Full 21CFR Part 11 Instrument Level Compliance

The Autopol® V PLUS and VI's 21CFR Part 11 software module is easily enabled through the user friendly touch screen. This module gives you full compliance with:

- Electronic signature
- Access levels
- Internal write protected storage

- Unique passwords
- Write protected documents sent directly to server
- Audit trail









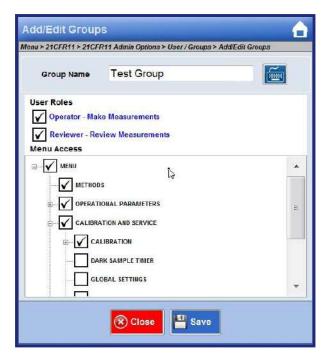
21CFR11 mode is enabled via the Set 21CFR11 button. After clicking the Enable 21CFR11 button, the user must also select to either Enable Operator, Enable Reviewer or both.

Add/Edit Users allows the creation of new 21CFR11 users, the ability to edit an existing user, and the ability to lock and unlock accounts.

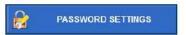
= Full 21CFR Part 11 Compliance =

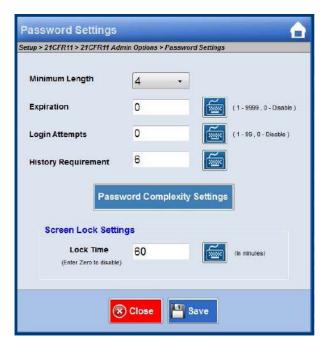






Groups are used to determine the access permissions of the 21CFR11 users. When a group is added or edited, the administrator decides what menus the group will have access to in the Setup menu and sub-menus, and the 21CFR11 Administration Options menu and sub-menus.



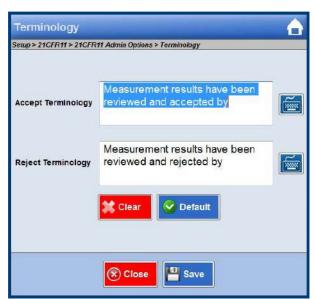




Password Settings control the password policy used by the Autopol to authenticate users and whether the screen lock function is active and how long it takes for the screen lock to turn on.

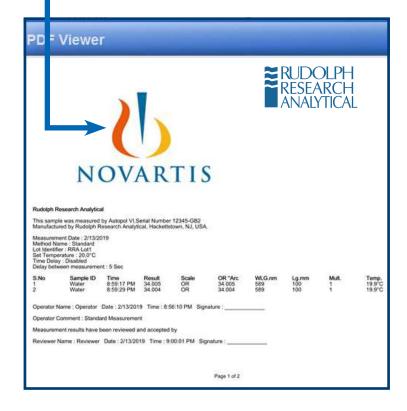
=Full 21CFR Part 11 Compliance=

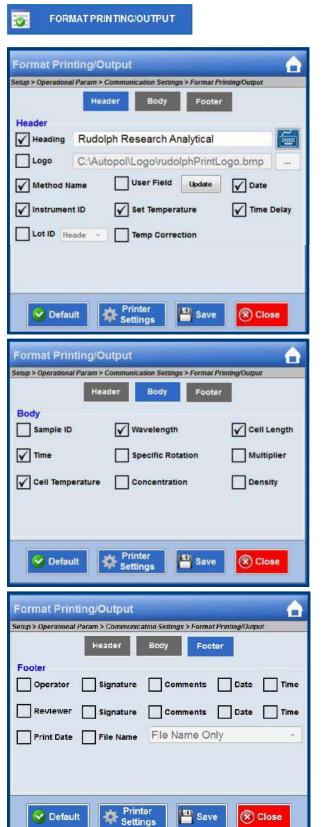




Terminology allows the Administrator to customize the language of the Accept/Reject language that appears in the measurement report reviewed by a reviewer.

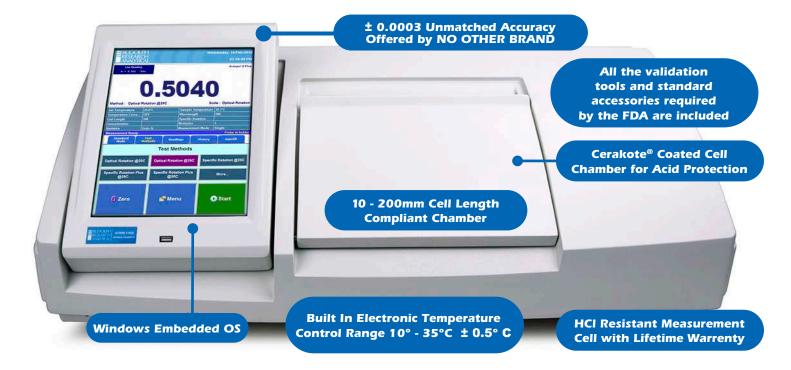
Print your customized Certificate of Analysis including your company logo directly from the Autopol VI® touch screen





The Format Printing/Output menu lets the user control what information will be contained in the report, if the report will contain a logo image, the page orientation and margin settings and if the user will be prompted for a lot identifier and sample identifier when the measurements are being performed.

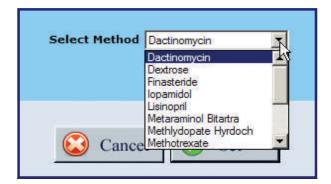
The AUTOPOL® VI by Rudolph – Simply the Best =

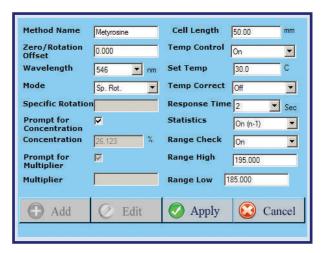


Rudolph Exclusive Features

Flexible Method Management

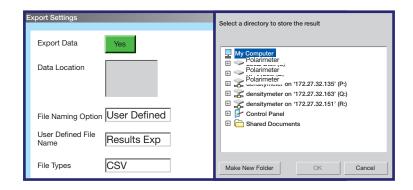
Install your own Test Methods for immediate selection of the correct method to match your most common tests.





Intuitive Windows® Based Interface

- 32 gigabytes of internal memory allow almost unlimited capacity for saving measurement data. The Autopol® V PLUS and Autopol® VI are network ready and data may also be saved directly to your server or to any directory desired.
- Internet access is possible directly from the Autopol® V PLUS and Autopol® VI's touch screens. This feature allows real time contact with Rudolph Research Analytical's Service and Technical Support Team who can access your instrument remotely to assist in Window navigation, method setup and trouble shooting.
- Windows based navigation architecture is so intuitive that most operators will never read the manual. But should you wish to reference the manual, it is stored right on the Autopol® V PLUS and Autopol® VI's internal memory.
- Four USB ports allow quick and easy connection to a mouse, keyboard, printer, bar code scanner, or memory stick. One USB port is located on the front of the unit and two USB ports are located on the back of the unit.



=Accessories Included With Autopol V PLUS and VI= Rudolph Provides: Lifetime Guarantee,



=The AUTOPOL® V PLUS and AUTOPOL® VI Advantage =

- 6 Molar HCl acid resistance: Cerakote® coating on the chamber, temperature transfer surface, cell surface, and temperature probe slot.
- To meet the FDA's latest position on measurement bracketing, the Autopol® V PLUS and VI come with two NIST traceable quartz plates with three rotations: +0.998° Arc, +10.998° Arc, -10.000° Arc. Each Quartz Plate comes with a NIST Traceable Certificate and NVLAP Accreditation document.
- Measurement validation is completely automated. 2 Quartz Control Plates are stored right in the instrument for a 3 rotation validation, all accomplished right from the touch screen and held in the internal QCP history database.
- Temperature validation cell to ensure compliance to USP/EP 25°C ± 0.5°C and 20°C ± 0.5°C
- Windows based navigation architecture is so intuitive that most operators will never read the manual. But should you wish to reference the manual, it is stored right on the Autopol® V PLUS and VI internal hard drive.
- Rudolph's Exclusive FillStation™ (Patent No. 9,677,995) is a standard accessory.
- Four USB ports allow quick and easy connection to a mouse, keyboard, printer, bar code scanner, or memory stick. One USB port is located on the front of the unit and two USB ports are located on the back of the unit.
- Ethernet Port for Network Cable Connection.
- Internet access allowing connection to Rudolph's service department for remote testing and diagnostics .
- Connect to any Windows® based printer via USB or direct to the server via Windows® Print Library.
- Save measurement data direct to your Network/Server- LIMS or SAP (No PC or special software needed).
- Windows embedded software cannot be written to, thus virus proof.
- Only Rudolph provides a lifetime guarantee on breakage and HCl resistance on its ceramic quartz sample cells.
- Only Rudolph commits to servicing your instrument for 20 years or more.
- Most of the polarimeters Rudolph has manufactured in the past 10, 20 and 30 years are still being used in labs today.
- Rudolph sells more polarimeters than the next two manufacturers combined.

=Supporting over 8,000 Instruments in over 80 Countries=



















































































ROCKWELL



Abbott











































































abbvie

Just listen to our customers

"We have the AUTOPOL V from Rudolph Research Analytical (RRA)... I have used numerous polarimeters and this is by far the best. We have had it for 1-1/2 years and have had zero problems, the original lamp is still in the instrument. I recommend it over other instruments. RRA installed, trained and performed the IQOQ... It is one piece of equipment that you never worry about."

Alan Davis - Rockwell Medical Technologies

Rudolph Research Analytical Service Guarantee

The Rudolph Service Pledge:

Earning your loyalty everyday, through our commitment to exceptional service and attentive customer focus.

Integrity, Quality, and Innovation with a Global Reach.

Rudolph Research Analytical manufactures automatic Density Meters, Refractometers, Polarimeters, Saccharimeters and Automation Solutions for a wide variety of industries. With over 8,000 laboratory instruments installed in demanding applications worldwide and thousands still in use which were manufactured in the 70s, 80s and 90s, Rudolph Research Analytical has established itself as a premier vendor well known for its quality, reliability and innovation.

Rudolph's entire line of instruments carry its exclusive 20 Year Service and Support Guarantee.

Rudolph Research Analytical offers a comprehensive range of Preventive Maintenance and Service Programs. Rudolph has demonstrated a commitment to its customers by keeping installed instruments operational, not only for 20 years, but in some cases for over 40 years. This long-term commitment to keeping our instruments running makes the cost of ownership, over the life of a Rudolph Instrument, one of the lowest in the laboratory market segment. At the date this document was published, there is no other laboratory instrument manufacturer guaranteeing service and technical support for 20 years.



Christina Says:

"Maximize your up time with a preventative maintenance plan designed for the way you work."

Heidi Says:

"Our Customer Support team is dedicated to providing you with an exceptional customer experience."



Rudolph stands behind each instrument purchase with a 20 year support guarantee. Rudolph is still repairing instruments it manufactured in the 1970s.

Specifications =

Features	Autopol® V PLUS	Autopol® VI
Measuring Mode:	Optical Rotation, Specific Rotation,	Concentration & User-defined Scales
Measuring Scale:	Degrees Arc, % Concentration	
Measuring Range:	±89.9° Arc Optical Rotation, ±999.99° Arc Specific Rotation and 0-99.9% Concentration	
Resolution	0.001° Arc Optical Rotation 0.001% Concentration 0.001° Specific Rotation	0.0001° Arc Optical Rotation 0.0001% Concentration 0.0001° Specific Rotation
USR Resolution	0.0001° Arc Optical Rotation 0.0001% Concentration 0.0001° Specific Rotation	Not Applicable
Standard Repeatability:	0.002° Optical Rotation (OR)	
Standard Accuracy:	0.002° up to 1°, 0.2% up to 5°, 0.01° above 5° (° in OR)	
High Accuracy Mode: @589nm between +1°1°	Not Available	Accuracy: 0.0003° Optical Rotation (OR) Repeatability: 0.0002° Optical Rotation (OR)
AP High Accuracy Option	Autopol V Plus Single: ±0.002° Arc over ±89.9° Arc. Autopol V Plus Six Wavelength (546nm and 589nm): ±0.002° over ±89.9° Arc. Accuracy for other wavelengths is the same as the standard model.	Not Applicable
Prism:	Glan Thompson Calcite Quartz	
Optical Wavelengths:	365nm, 405nm, 436nm, 546nm, 589nm, 633nm (other wavelengths available)	
Wavelength Selection:	Automatic by Touch Screen	
TempTrol™ Range:	Automatic Electronic Heating & Cooling 10°-40°C	
TempTrol™ Accuracy:	±0.2°C	
Temp. Probe Range:	10°- 40°C	
Temp. Probe Accuracy:	±0.1°C	
Acid Resistance:	Ceramic Quartz measurement cell and Cerakote® sample chamber (standard)	
Measurement Time:	4°/sec. slew rate and 5 sec. nominal settling time	
Light Source:	Tungsten-halogen 6V, 20W, avg. 2,000 hour life	
Sample Chamber:	Accepts sample tubes up to 200mm	
Data Storage/Internal Memory:	32 GB Non-removable Compact Flash	
Communication Interface:	Touch Screen, 3 – USB Ports, 2 – RS232 Ports, Ethernet Port for Network Connection, Keyboard, Bar Code Scanner, Mouse, Network Capabilities	
Calibration:	Automatic calibration by push-button	
Operating System	Windows Embedded	
Display:	10.4 inch diagonal, 800-600 pixels, color, Flat Panel Monitor with Resistant Touch Screen Interface, 200 nits brightness, gasketted for spill protection	
User Interface:	Touchscreen	
Automatic Sensitivity Control:	Measures samples with transmittance as low as 0.01% (up to O.D. 4.0)	
Input Power:	85 – 260 VAC; 48 – 62 Hz, 150 – 200 Watts consumption	
Operating Dimensions:	32"W x 11.5"H x 18"D 81.28cm W x 29.21cm H x 45.72cm D	
Shipping Dimensions:	37"W x 24"H x 26"D 94cm W x 61cm H x 66cm D	
Operating Weight:	90 lbs. (41kg)	
Shipping Weight:	105 lbs. (48kg)	