

TECHNICAL BULLETIN 926

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For The Most Demanding High Accuracy Applications

The Autopol[®] VI Automatic Polarimeter

United States of America





NVLAP LAB CODE: 200898-0 accreditation to ISO/IEC 17025:200

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

AUTOPOL[®] VI

The Autopol[®] VI Automatic Polarimeter was developed for the most demanding analytical laboratories. If you are a high performance lab, the Autopol[®] VI has the features you must have.

Standard Features And Accessories

- \bullet 0.0003 accuracy for low rotation samples of $\pm 1^\circ Arc$
- TempTrolTM Electronic cooling & heating from $15^{\circ}-35^{\circ}C$
- Six Standard Wavelengths: 365nm, 405nm, 436nm, 546nm, 589nm and 633nm
- 21CFR11 Compliance: Electronic Signature and secure local electronic data storage
- Domestic 3-year warranty and 20-year support guarantee
- Standard Accessories: TempTrol[™] NIST Traceable Quartz Standard, TempTrol[™] 100mm Polarimeter Cell, TempTrol[™] Temperature Validation Cell, Built-In Sample Measurement Probe, 3 USB ports



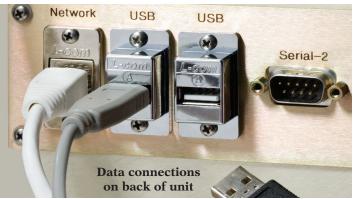
Versatile Communication Capability

The Autopol® VI's standard communication package includes:

- Ethernet Port for Network Cable Connection
- 3 USB ports
- 2 RS 232 ports

Allowing the capability to:

- Connect directly to Rudolph's service department for remote testing and diagnostics via Internet connection.
- 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



TempTrol[™] Electronic Temperature Control System

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

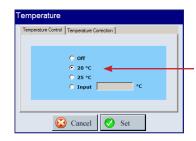
Whatever your temperature control needs are, the Autopol[®] VI's **exclusive TempTrolTM System (Patent No. 2778542)** makes your measurement in seconds without a waterbath or any type of water circulation.

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[®] VI 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:



TempTrol heating and cooling transfer surface









TempTrol cell with mating heating & cooling transfer surface manufactured with acid resistance materials: Hastelloy™ and Peek™.

Temperature is selected via touch screen. Temperature selection of 20°C shown left.

Place the TempTrol cell in your TempTrol equipped Autopol® sample chamber to measure to within ±0.2°C of the USP, EP, JP or BP specified temperature (normally 20°C or 25°C ±0.5°C)

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

Rudolph Research Analytical 55 Newburgh Road, Hackettstown, NJ 07840 USA • Phone: 973-584-1558 • Fax: 973-584-5440 • E-mail: info@rudolphresearch.com • Internet: www.rudolphresearch.com

Full cGMP/GLP Compliance

Setup				
Temp Stability Measurement Mode Methods	Operational Param In	strument Calibrat	ion Service	
QCP Calibration QCP Coefficients Temperature Calibration Change Password				
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You are in Setup->Instrument Calibration->QCP Calibration				

Validation and Calibration

Rudolph Research Analytical knows that you must be able to validate your instrument's operating performance regularly. Therefore, the Autopol® VI comes standard with the accessories, validation tools and automatic calibration functions necessary to ensure that the temperature control, temperature measurement and optical measurement processes are working accurately and reproducibly. All functions are accessed simply and conveniently through the Autopol® VI liquid sealed touchscreen.

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."

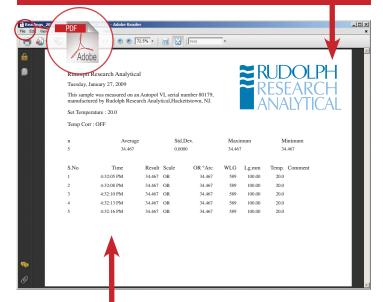
Alan Davis - Rockwell Medical Technologies

cGMP/GLP Printing

Measurement reports can be saved as an Excel or PDF file and edited quickly and easily. You can import logos and print your company's customized "C of A" directly.

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



Capable of making multiple measurements on a single sample and reporting complete statistical data and all measurement results

— Rudolph's Most Advanced Polarimeter — Offering 0.0003 Accuracy & Interface Flexibility



Unmatched Accuracy

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 .

Rudolph Analytical Resea	·ch			×			
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ANALYTICAL				04:32:11 PM			
Optical Rotation	onα						
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α = 0.4467 °Arc							
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Intuitive Windows® Based Interface

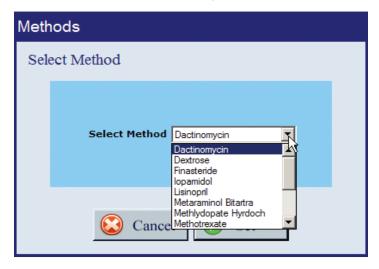
- 2 gigabytes of internal memory allow almost unlimited capacity for saving measurement data. The Autopol[®] VI is network ready and data may also be saved directly to your server or to any directory desired.
- Internet access is possible directly from the Autopol® VI's touch screen. This feature allows 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[®] VI's internal memory.
- Three 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 (shown below) and two USB ports are located on the back of the unit (shown left).



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Flexible Method Management

Install your own measurement methods for immediate selection of the correct method to match your most common tests. Setting up your custom method is as simple as filling out a few screens like the one shown to the right.



Full 21CFR Part 11 Instrument Level Compliance

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

21 CFR Part 11

Password Settings

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Set 21CFR11 | Add Account | Edit Account | Password Settings | Terminology | • •

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- Electronic signature
- Access levels
- Internal write protected storage
- Unique passwords
- Write protected documents sent directly to server
- Audit trail

Audit Trail

User Name	User Level	Tab Name	Changes	
smith	Operator, Reviewer	Temperature Cali	Temperature calibration was	🕐 ок 🔞 😧 с
smith	Operator, Reviewer	Temperature Cali	Temperature calibration was	
Administrator	Admin	Edit Account	For jsmith account, Passwor	
Administrator	Admin	Add Account	jane.doe account was added	21 CFR Part 11
Administrator	Admin	Add Account	jdoe account was added	Password Settings Terminology File Export Option Aud
Administrator	Admin	File Export Option	Path was changed	Audit Trail
Administrator	Admin	File Export Option	File Export Format was chan	
Administrator	Admin	File Export Option	File Export Format was chan	
Administrator	Admin	Set 21CFR11	Enable Review was changed	To view 21CFR11 audit information, c
Administrator	Admin	Methods	Sucrose method was added	
Administrator	Admin	Add Account	jqpublic account was added	
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Administrator	Admin	Terminology	RejectTerminology was cha	
Administrator	Admin	Terminology	RejectTerminology was cha	
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Administrator	Admin	Password Settings	Expiration was changed	
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Administrator	Admin	Password Settings	Login Attempts was changed	0 3
Administrator	Admin	Add Account	jsmith account was added	
Administrator	Admin	Set 21CFR11	Enable Review was changed	Disabled Enabled

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w	avelength	546 💌 nr	n Set 1	Гетр	30.0		С	
M	ode	Sp. Rot.	Tem	p Correct	Off		•	
S	pecific Rotatio	n	Resp	oonse Time	2	•	Sec	
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	Add
	OK Cancel Apply
21 CFI	R Part 11
Set 21CF	FR11 Add Account Edit Account Password Settings Terminology
Edit	Account



Rudolph Research Analytical – still protecting your investment after 30 years.



Today our Service Technicians have access to state of the art diagnostic tools and have a depth of knowledge that often lets them solve problems right over the phone. Our customers really appreciate the same day phone call by a real technical service person who wants to solve their problem. Our customers also know that they can expect this support for many years to come as Rudolph is still repairing instruments which were built in the 70's.

Contact us! A customer service representative is waiting to serve you!

Phone: 973-584-1558 E-mail: service@rudolphresearch.com Fax: 973-584-5440

Specifications of the AUTOPOL® VI

Measuring Mode:	Optical Rotation, Specific Rotation, Concentration & User-defined Scales
Measuring Scale:	Degrees Arc, % Concentration
Measuring Range:	±89° Arc Optical Rotation, ±999.99° Arc Specific Rotation and 0-99.9% Concentration

Performance between -1° Arc and +1° Arc

Resolution:	0.0001° Arc Optical Rotation
	0.0001% Concentration
	0.0001° Specific Rotation
Reproducibility:	0.0002° Arc Optical Rotation
Accuracy:	0.0003° Arc Optical Rotation
Wavelengths:	589 nm

Performance outside of ±1° Arc

Resolution:	0.001° Arc Optical Rotation 0.001% Concentration 0.001° Specific Rotation	
Reproducibility:	0.002° Arc Optical Rotation	
Accuracy:	0.002° up to 1°, 0.2% from 1° to 5°, 0.01° above 5°	
Wavelengths:	365nm, 405nm, 436nm, 546nm, 589nm, 633nm	
Prism:	Glan Thompson calcite quartz	
Optical Wavelengths:	365nm, 405nm, 436nm, 546nm, 589nm, 633nm (other wavelengths available)	
Wavelength Selection	Automatic by push-button	

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TempTrol [™] Range:	Automatic Electronic Heating & Cooling 15°-35°C
TempTrol [™] Accuracy	: ±0.2°C
Temp. Probe Range:	10°- 40°C
Temp. Probe Accuracy	r:±0.1°C
Acid Resistance:	Hastelloy™ measurement cell and Silco Steel™ sample chamber
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
Display:	10.4 inch diagonal, 800-600 pixels, color, Flat Panel Monitor with Resistant Touch Screen Interface, 200 nits brightness, gasketted for spill protection
Communication Interface:	Touch Screen User Interface 3 – USB Ports 2 – RS232 Ports Ethernet Port for Network Connection Keyboard, Bar Code Scanner, Mouse, Network Capabilities
Internal Memory:	2 GB Non-removable Compact Flash
Shipping Dimensions:	36 in. (L) x 19 in. (W) x 18 in. (H) 91.44 cm (L) x 48.26 cm (W) x 45.72 cm (H)
Shipping Weight:	105 lbs. (31.75 kg)
Power Supply:	85 to 260 VAC; 48 to 62 Hz
Power Consumption:	150 – 200 Watts