RUDOLPH RESEARCH ANALYTICAL

TECHNICAL BULLETIN 946



Two Great Solutions For Pharmaceutical Applications, Research and Incoming Raw Materials

The Autopol® IV and Autopol® V



LIFETIME CELL WARRANTY

ISO 17025 ACCREDITATION

20 YEAR Service Guarantee

ISO 9001 CERTIFIED

nqa. ISO 9001 QUALITY MANAGEMENT — ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

nqa. ISO 9001 QUALITY MANAGEMENT — UKAS MANAGEMENT SYSTEMS 015

A2LA ACCREDITED
CERT #7528.01

Rudolph Research Analytical serving its customers with Integrity, Quality, and Innovation for over 50 years.

Rudolph subjects itself to a variety of industry accreditations and outside examination. Visit our website to learn how these apply to your purchase.

*Emmes Survey

Autopol® IV and V are Available in 1, 2, or 6 wavelength versions



Cerakote® Acid Resistant Cell Chamber
Ceramic Quartz Measurement Cell with Lifetime Warranty
External NIST Calibration Tools



Accessories Included With Autopol IV and V

Only Rudolph Provides:

NVLAP Accreditation
Single Rotation TempTrol™ ,
NIST Traceable Quartz
Calibration Standard.

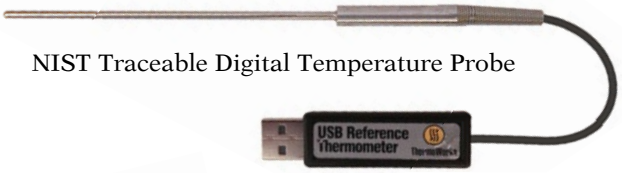




2 Lamps
Included
2,000 hours
each.

Lifetime Guarantee,
TempTrol™ Ceramic Quartz
measurement cell





NIST Traceable Digital Temperature Probe



The Rudolph FillStation™
Patent No. 9,677,995



Temperature Validation Cell

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

The Industry Standard Polarimeter

The Autopol® V has 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's quality, accuracy and reproducibility.

Autopol® V Standard Features and Accessories

- TempTrol™ – Electronic cooling & heating from 15°-35°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.
- International warranty varies by country.
- Standard Accessories: TempTrol™ NIST Traceable Quartz Standard (single rotation), TempTrol™ 100mm Polarimeter Cell, TempTrol™ Temperature Validation Cell, Built-In Sample Measurement Probe.

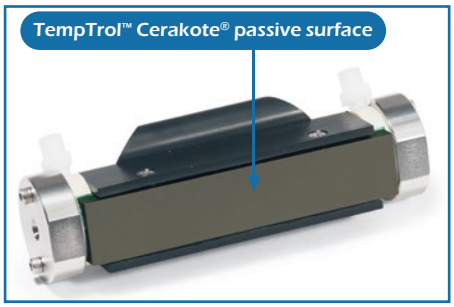
The Autopol® IV-T and V Use Rudolph's Exclusive TempTrol™ Electronic Temperature Control System

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

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

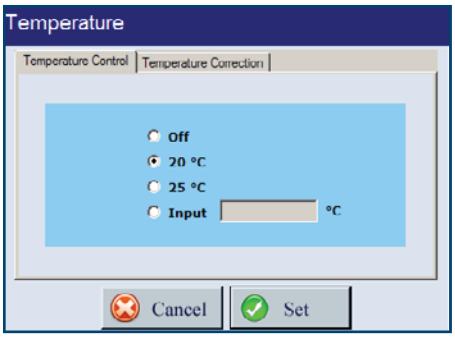
The TempTrol™ System allows push-button temperature control of your cell up to 200mm or Quartz Plate. Set the temperature, push "measure" and walk away. The Autopol® will heat or cool to a predefined temperature and then provide you with the result all in one easy step.

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

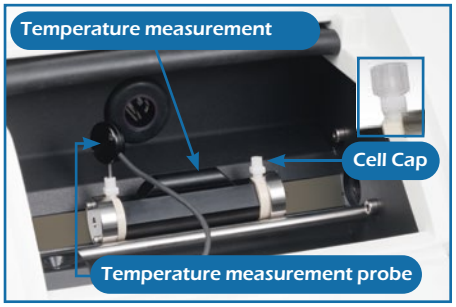


TempTrol™ cell with mating heating & cooling transfer surface manufactured with acid resistance materials: Cerakote® and Peek™.

Cerakote® is a industry leading acid resistant proprietary ceramic polymer coating providing protection against even 6M HCl.



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

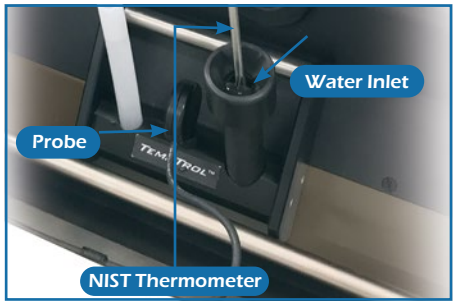


Place the TempTrol™ cell in your TempTrol™ equipped Autopol® sample chamber to measure to within ±0.2°C of the USP, EP, JP or BP specified temperature (normally 20°C or 25°C ±0.5°C).

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.



TempTrol™ heating and cooling transfer surface



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 ±0.2°C.

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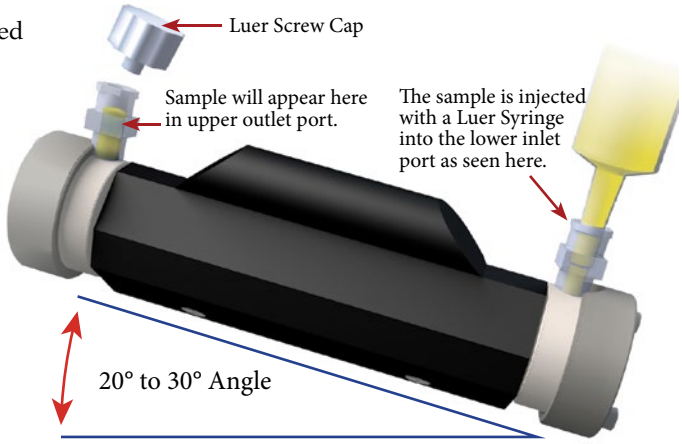
How to Fill Cells Manually

Rudolph Research Polarimeter Sample Cells

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.

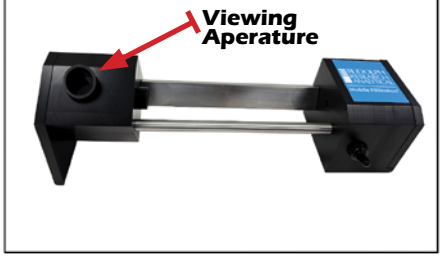
Rudolph cells are unlike other manufacturers' cells as they are uniquely designed to keep small air bubbles out of the light path. Filling the cell is as simple as holding the cell at a slight upward angle and filling from the bottom inlet using a Luer Syringe. When the sample appears near the top outlet 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.



How to use the Rudolph Research Polarimeter Cell FillStation®

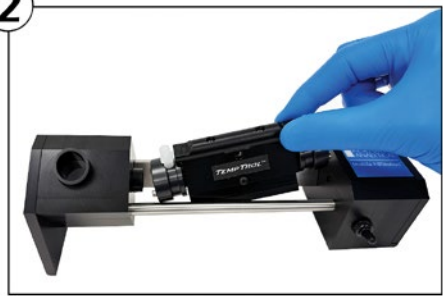
For users who prefer not to hold the cell while working with highly acidic or basic samples, the Rudolph Cell Fill Station® should be used.

1



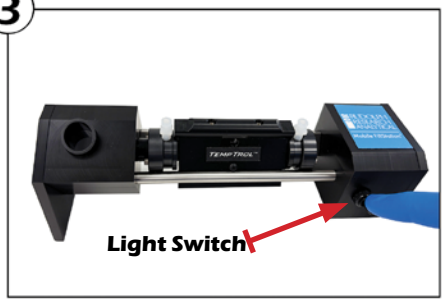
By design, the FillStation® will hold the cell at a suitable angle.

2



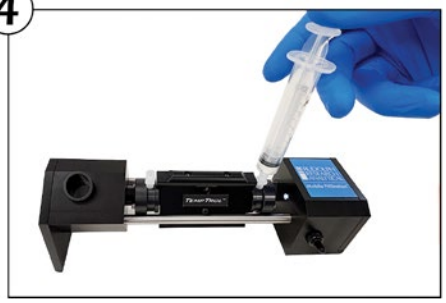
Place a Polarimeter cell into the Rudolph FillStation®.

3



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

4



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.

5



The FillStation® creates a light image that will go from darker to a bright white circle when the cell is filled and air-bubble free. A bubble free cell shows an illuminated white circle as shown on the right.



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 solution 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 Fill Station® accessory is available for all Rudolph Autopol® Polarimeters and is included free of charge with Autopol® V, Autopol®V PLUS, and Autopol® VI Polarimeter Models.

Reading Your FillStation®



Empty Cell

Cell Being Filled

Air Bubbles detected during filling process

Cell filled and free of air bubbles

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The Rudolph FillStation™

Fill Rudolph Polarimeter Cells reliably outside of the instrument

Most users prefer to load cells outside of the Polarimeter. When this procedure fits with your work flow or safety protocols, Rudolph has engineered a tool to assist you, the Rudolph Polarimeter FillStation™. Designed to sit on your laboratory bench or under your fume hood and assist you in loading your Rudolph Polarimeter cell easily and reliably, the FillStation™ holds the cell at the right angle so you always fill the cell from bottom to top. Using a syringe, you inject the sample until it begins to appear at the top port. Once filled, the monitoring light will become bright and you know you have a full cell free of air bubbles that is ready for a measurement. Cap the Top Cell Port, remove the syringe, cap the Lower Port and go!



FillStation™ Patent No. 9,677,995

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; allowing for a bubble free fill every time.
- Filling from the bottom to top pushes 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 for even inexperienced operators.
- Helps eliminate contact with strong acids like 6M HCl, 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 cGLP 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.

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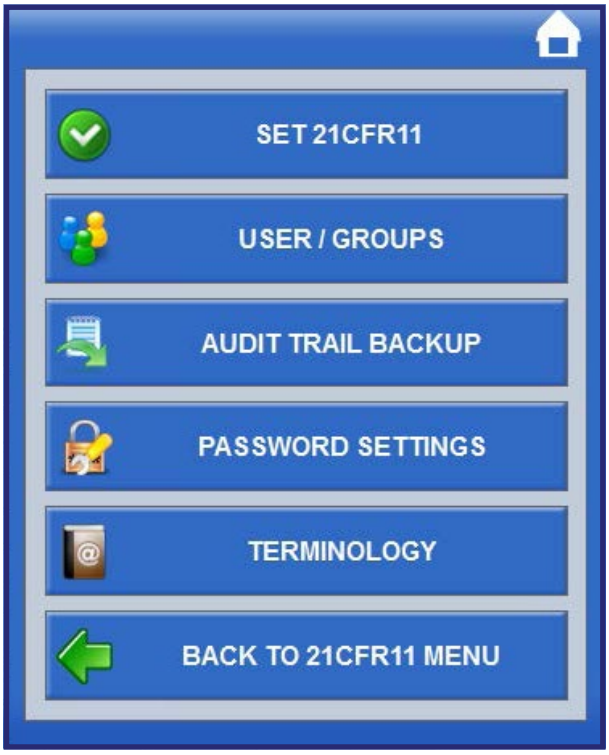
Full 21CFR Part 11 Compliance

Full 21CFR Part 11 Instrument Level Compliance

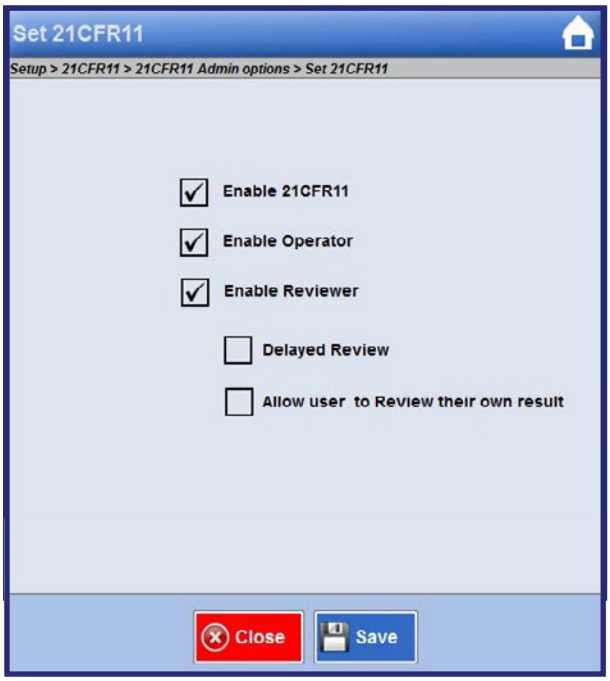
The Autopol® V 21CFR Part 11 software module is easily enabled through the user friendly touch screen. This module gives you full compliance with:

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

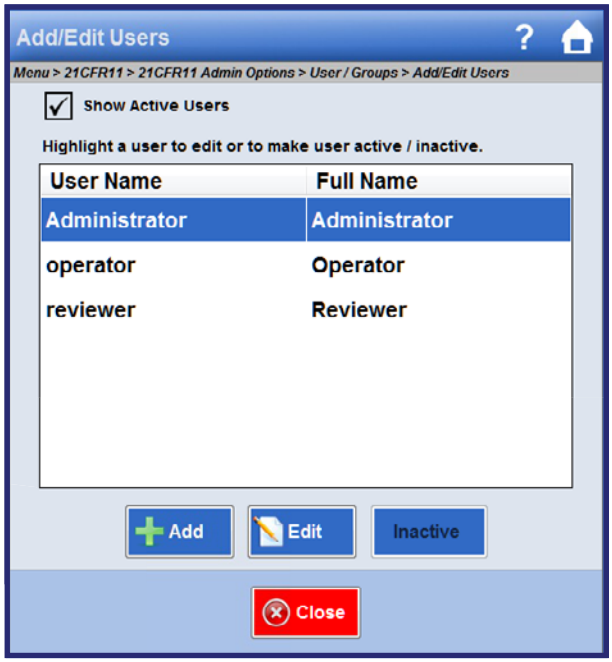
Autopol IV, 21CFR Part 11 is by external PC only











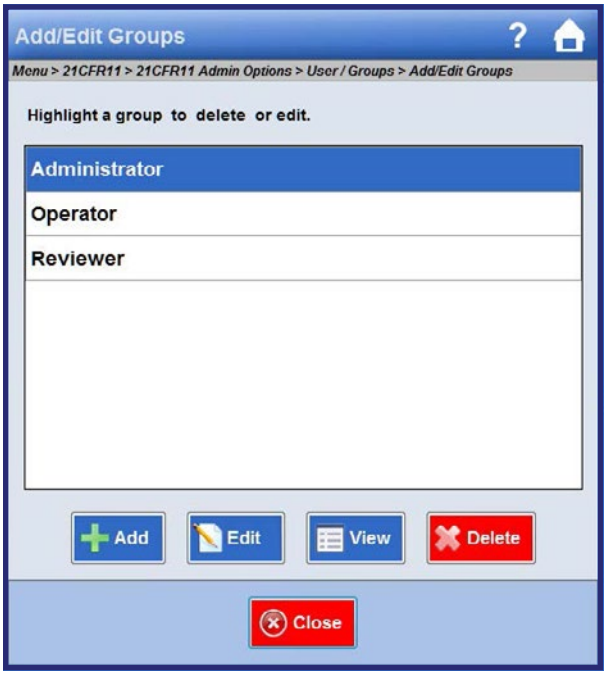
21CFR11 mode is enabled via the Set 21CFR11 button. After clicking the Enable 21CFR11 button, the user must also select to either Enable Operator, Enable Reviewer or both.

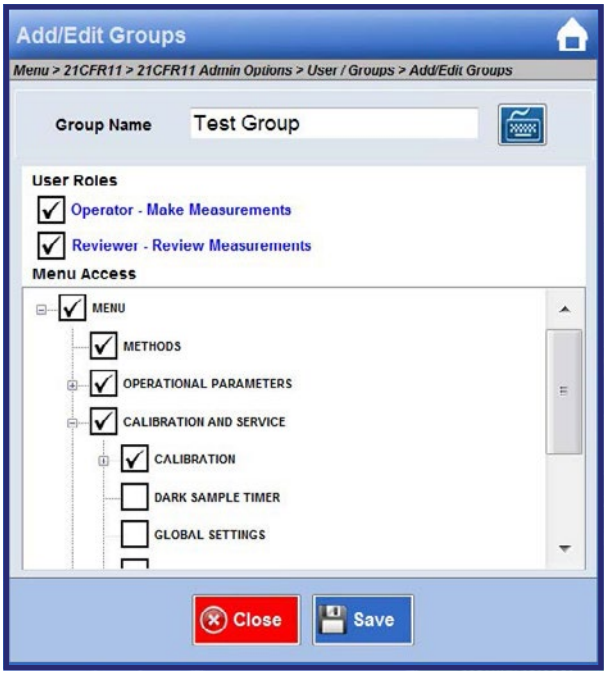


Add/Edit Users allows the creation of new 21CFR11 users, the ability to edit an existing user, and the ability to lock and unlock accounts.

Full 21CFR Part 11 Compliance

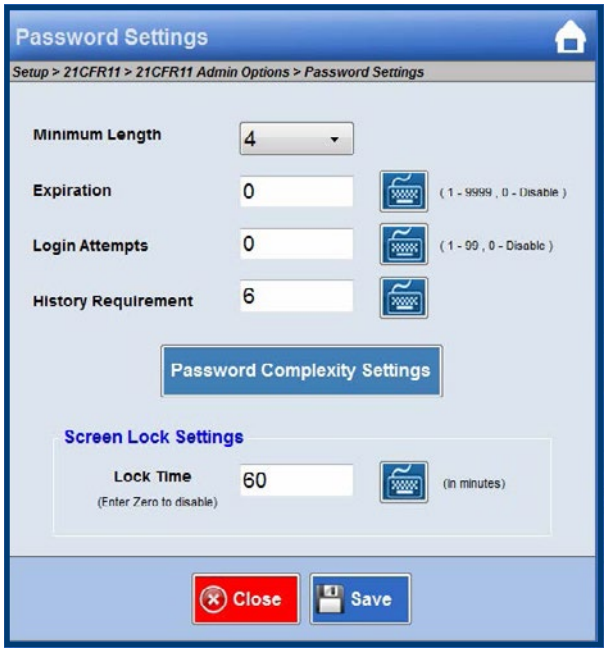
ADD / EDIT GROUPS

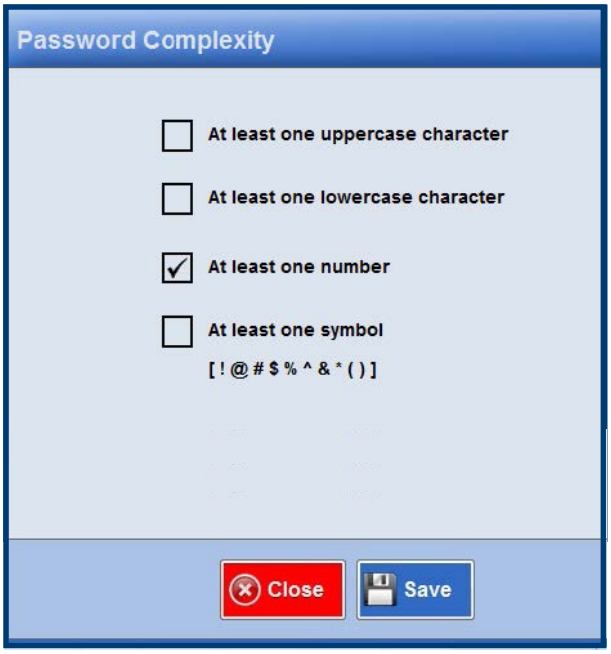




Groups are used to determine the access permissions of the 21CFR11 users. When a group is added or edited, the administrator decides what menus the group will have access to in the Setup menu and sub-menus, and the 21CFR11 Administration Options menu and sub-menus.

PASSWORD SETTINGS

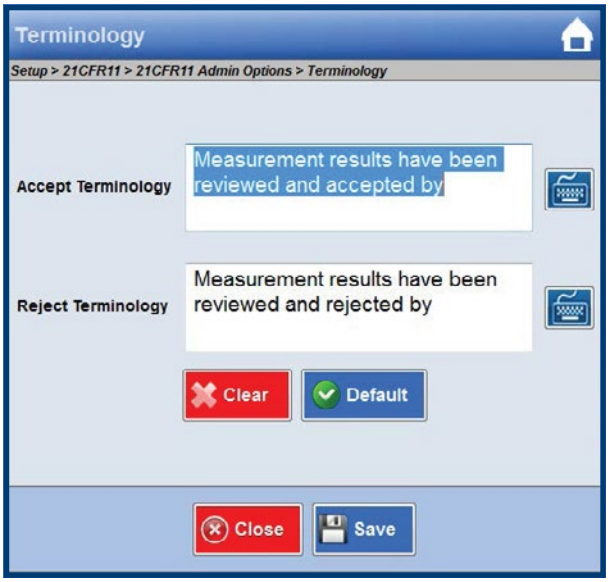




Password Settings control the password policy used by the Autopol to authenticate users and whether the screen lock function is active and how long it takes for the screen lock to turn on.

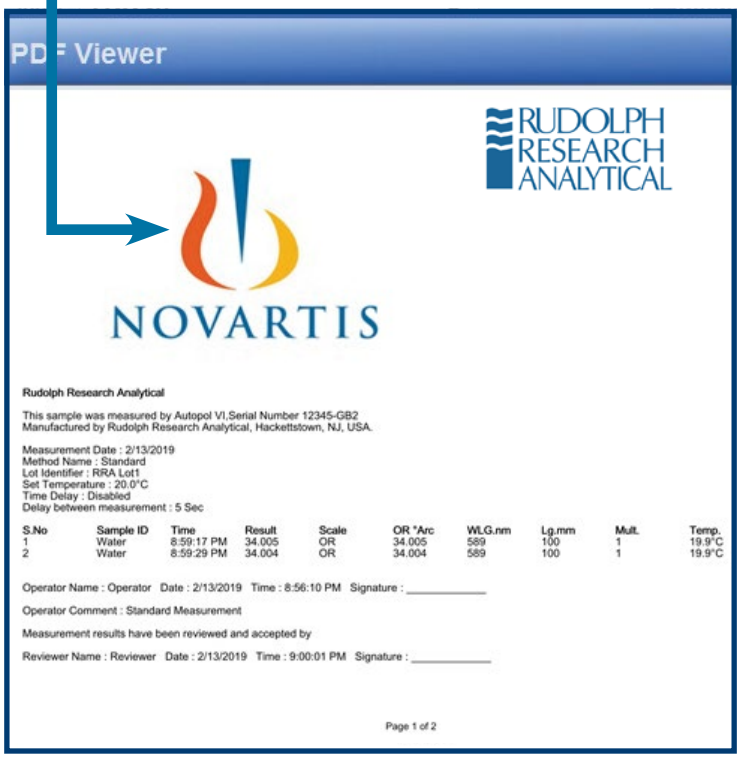
Full 21CFR Part 11 Compliance

TERMINOLOGY

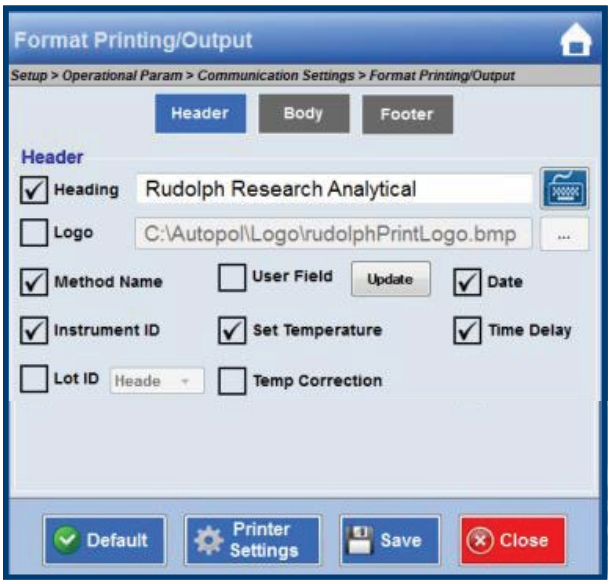


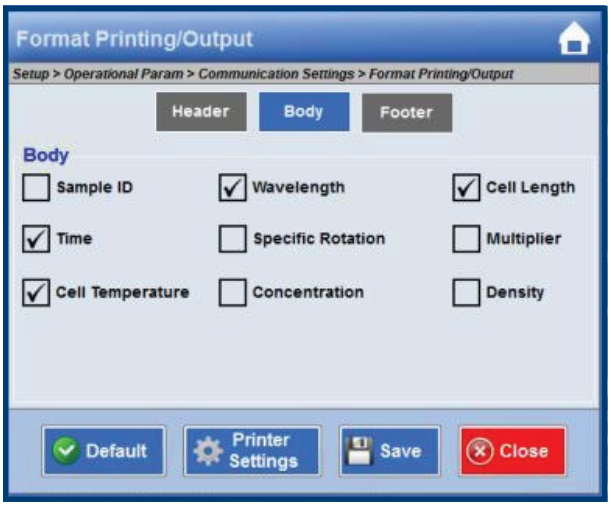
Terminology allows the Administrator to customize the language of the Accept/Reject language that appears in the measurement report reviewed by a reviewer.

Print your customized Certificate of Analysis including your company logo directly from the Autopol IV® and Autopol V® 's touch screen



FORMAT PRINTING/OUTPUT

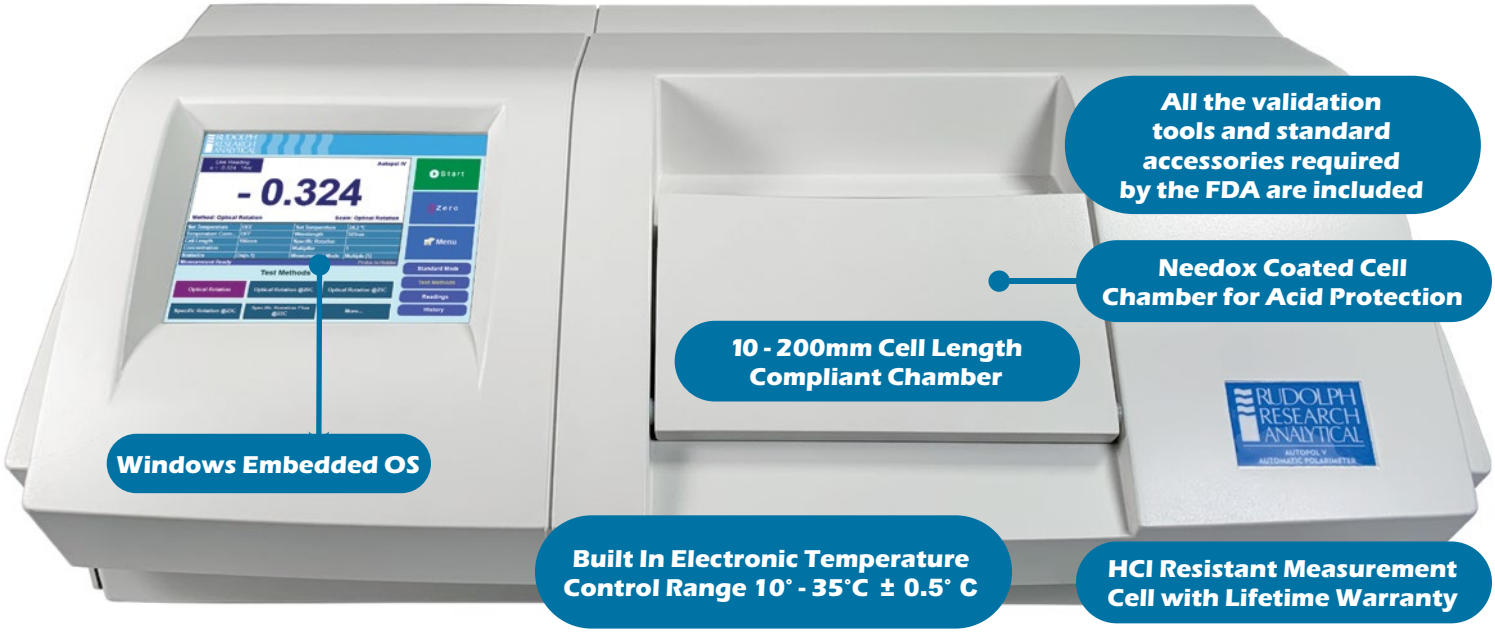




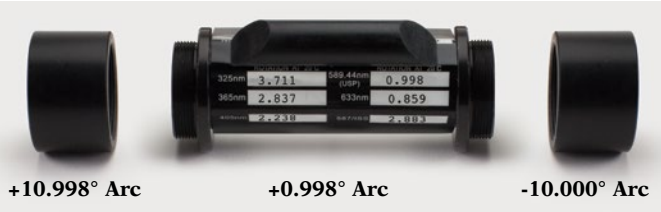


The Format Printing/Output menu lets the user control what information will be contained in the report, if the report will contain a logo image, the page orientation and margin settings and if the user will be prompted for a lot identifier and sample identifier when the measurements are being performed.

The AUTOPOL® IV and V by Rudolph – Simply the Best



The Autopol® IV and V Advantage

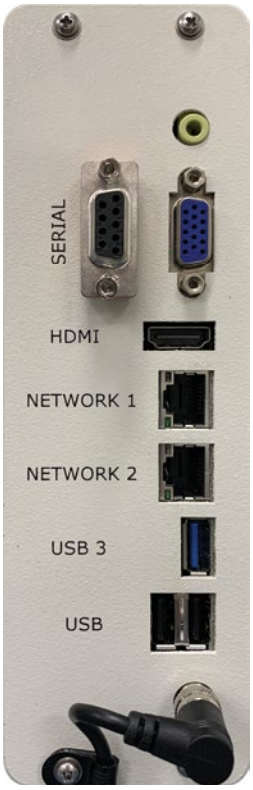


- 6m HCl acid resistance: Cerakote® coating on the chamber temperature transfer surface and a ceramic measurement cell with optional NIST certificate certifying optical path length.
- To meet the FDA's latest position on measurement bracketing, the Autopol® IV and V come with a NIST traceable quartz plate with three rotations: +0.998° Arc, +10.998° Arc, -10.000° Arc. Each rotation has a NIST certificate.



Autopol® V data connections on back of unit

- 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 internal memory.
- Available with automated sampling.
- 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 (shown left) and three USB ports are located on the back of the unit.
- 2 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.





- **Lifetime Warranty against breakage on Stainless Steel and Ceramic Quartz Cells.**
- **Acid Resistant Lifetime Warranty on Ceramic Cells.**
- **No Warranty on 14 and 14J Glass Cells.**
- **All Cell Optical Path Lengths are Accurate to ±0.02 mm.**
- **Rudolph 60T cells have Lifetime warranties against damage from acid or mishandling**

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Supporting Over 8,000 Instruments In Over 80 Countries

Austin Pharma
811 Paloma Drive
Suite C
Round Rock, Texas 78665
Phone: 866-917-2617

Dear Kathy,

I just wanted to tell everyone at Rudolph Research what a pleasure it has been working with each of you. From the customer service down to the documents provided with the instrument, everything has been top-notch. The experience Rudolph has dealing with the pharmaceutical field really shows through. Peter Marriot was here on Tuesday and did a great job getting the instrument up and running exactly the way we wanted and took the time to answer any questions I had. He also went through the qualification documents page by page and explained each test performed.

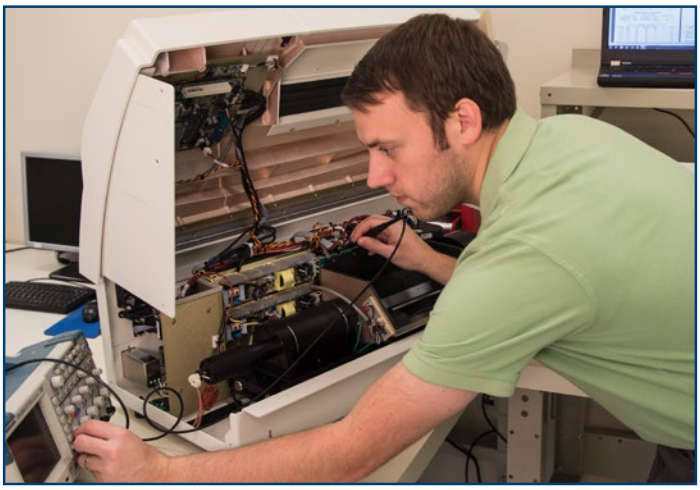
Over the past couple of years setting up a new lab I have had to deal with quite a few manufacturers and this has been one of the best experiences I've had in ordering an instrument from getting the quote to getting it qualified. To be quite honest, a lot of experiences I've had been somewhat excruciating but I won't name names. After Gary Mathurin was here about this time last year to give a demo, I was already pretty sure Rudolph was the company to go with but now I'm certain we made the right choice.

Thank you all!
Regards

Dale Smith
QA/QC Manager
Austin Pharma/Insys Therapeutics Inc.
811 Paloma Dr. Suite C
Round Rock, TX 78665

Call Us ! We Answer the Phone !

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.



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

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

Industry Leading Comprehensive Warranty Protection

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.

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

ACCREDITED
CERT #7528.01

Rudolph subjects itself to a variety of industry accreditations and outside examination.
Visit our website to learn how these apply to your purchase.

Protecting Your Investment After 30 Years



The Rudolph Service Pledge:

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

The Rudolph Service Promise:

Every new instrument purchase is backed by our commitment to a 20 year service support guaranteee and the knowledge that Rudolph is still repairing products built in the 1970's.

Specifications

Features	Autopol® IV	Autopol® V
Measuring Mode:	Optical Rotation, Specific Rotation, Specific Rotation PLUS, Concentration & User-defined Scales	
Measuring Scale:	Degrees Arc, % Concentration, °Z	
Measuring Range:	± 89.99° Arc Optical Rotation ± 999.99°Arc Specific Rotation 0-99.9% Concentration	
Resolution:	0.001° Arc Optical Rotation 0.001% Concentration 0.001° Specific Rotation	
Reproducibility / Repeatability	0.002° Arc	
Standard Model Accuracy:	0.002° up to 1°, 0.2% up to 5°, 0.01° above 5°	
AP Model Accuracy:	(546nm and 589nm): ±0.002° Arc over 0 - ⁺89.99° Arc. Accuracy for other wavelengths is the same as the standard model.	
Prism:	Glan Thompson Calcite Quartz	
Optical Wavelengths:	365nm, 405nm, 436nm, 546nm, 589nm, 633nm (other wavelengths available)	
Wavelength Selection:	Automatic by Touchscreen	
Operating System	Windows Emedded	
TempTrol™ Range:	Automatic Electronic Heating & Cooling 15°-35°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:	CAT 5 Ethernet Port for Network Connection, 3USB, Two RS232 serial ports, keyboard, printer, scanner, and mouse	
Calibration:	Automatic calibration by push-button	
Display:	7.5cm x 10cm graphics LCD, 320 x 240 dots cold fluorescent back lit	
Support Guarantee Period	20 Years	
User Interface:	Touchscreen	
Automatic Sensitivity Control:	Measures samples with transmittance as low as 0.01% (up to O.D. 4.0)	
Input Power:	100-240VAC, 50/60 Hz	
Operating Dimensions:	35”W x 10.5”H x 17”D 890mm W x 267mm H x 432mm D	
Shipping Dimensions:	43”W x 26”H x 23”D 1,025mm W x 625mm H x 625mm D	
Operating Weight:	85 lbs. (39kg)	
Shipping Weight:	115 lbs. (52kg)	