

TECHNICAL BULLETIN 935-R6

Measurement speed unmatched by any other brand saving you time and money

The DDM Series of Automatic Density Meters



——— The Simplicity of Touch Screen ——— Measurement with the Flexibility of Windows[®]

Oscillating U-Tube with Viscosity Correction and Reference

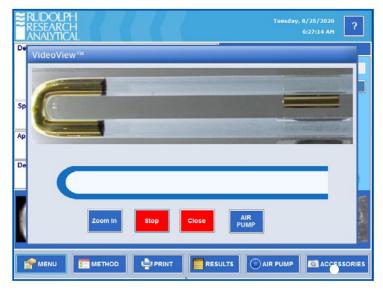
Rudolph DDM Series Density Meters utilize an oscillating U-tube with full range viscosity correction and reference oscillator that allows for long term calibration stability and measurement at all temperatures with a single calibration (Patent # 7,735,353).

Full Feature VideoView® with Automatic Scanning of Entire U-Tube

Rudolph's exclusive VideoView is protected under Patent #7,437,909 and provides superior high resolution visual bubble detection of your sample with live on-screen video viewing. Images can be saved with the sample results and may be viewed and/or printed as desired.

A full view of the entire U-tube is possible at 2X magnification. Further, the U-Tube can zoom to 6X or 10X so the user can see that the U-Tube is air bubble free. The 6X and 10X magnification are also extremely helpful in detecting the cleanliness of the glass U-tube. The clarity, magnification and resolution are the very best available in the market.

- Three magnified video assisted views of the entire cell are available, in 2X, 6X and a 10X magnifications
- Images may be saved with results for subsequent review



Windows Embedded® Operating System

- 32 gigabytes of internal memory, the biggest on the market, allows almost unlimited memory for saving measurement data. All Rudolph Density Meters are network ready. Data may be saved and exported directly to your server or to any desired directories.
- Internet access is possible directly from all Rudolph Density Meters. The disk protection feature protects the operating system against malware and virus infections in networked environments.
- 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 Rudolph instrument's internal memory.
- Copy methods, transfer concentration tables, download data, among other functions via the USB ports on the front and back of the unit.
- Five USB ports allow for quick and easy connection to a mouse, keyboard, printer, bar code scanner, or memory stick. All Rudolph Density Meters connect directly to your server or server printer without additional software or PC access.

Result View						
Menu > Met	hod Management > Results					
All Date	Manual Export			ply		
1	Data Location	C:\Density\Data				
2 🔽 3 🗆 4 🗆	Export file options	Overwrite file	Browse For Folder	adings Idings FR11		
5 🗆 6 🗆	File Types	PDF	Select a directory to store the result	FR11		
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		🔗 ок	 AlcoTest-RI AlcoTest-RI-Bubble AP4/Network/AuditTrail 			
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	JMN INGS	🕵 PREVIEW 🚺	Make New Folder OK Cancel	1		

——— The Simplicity of Touch Screen ——— Measurement with the Flexibility of Windows[®]

cGMP/GLP Calibration

- Calibrate the Rudolph DDM Series Density Meter with 2 or 3 points (e.g. NIST Traceable Standards) as calibrating with merely air and water appears inconsistent with cGMP/GLP compliance regulations
- Ability to print out complete method configuration, communication settings, as well as calibration verification and calibration adjustment data/history
- Unlimited number of customizable calibration verifications possible
- Complete History of Calibration Adjustments and Verifications are available to View, Print, and/or Export
- Set calendar reminders as to when Calibration Verifications are due
- View, print, control charts in calibration verifications
- Pass/Fail calibration verifications available

GlaxoSmithKline

Tel: (908) 293-4000

Date: 8/2020

Lot ID 2019 Temperature: 20.0 Deg C

> 8421 8421

8421

8421

842

Counts

Average SD

Maximum Minimum

Operator

No Sample ID Density

1.09803

1.09803

1.09803

1.09803

1.09803

1.0980

184 Liberty Corner Rd Warren, NJ 07059





This sample was measured on DDM 2911 PLUS serial number 20212, manufactured by

Normality

6.0092

6.0092

6.0092

6.0092

6.0092

HCL %

19.95

19.95

19.95

19.95

° Bau

12.94

12.94

12.94

12.94

Rudolph Research Analytical, Hackettstown, NJ, USA

Sp. Gravity

1.1000

1.1000

1.1000

1.1000

1.1000

do more feel better

14:20:50 PM

14:21:40 PM

14:22:30 PM

14:23:20 PM 14:24:10 PM

Ο

Versatile Communication Capability

The Rudolph Density Meter's standard communication package includes:

- 1 RS-232 port
- 1 HDMI
- 2 CAT Ethernet Ports for Network Cable Connection
- 5 USB ports -2 in the front, 3 in the back
- Allowing the capability to:
- Export measurement results with saved video view images to a thumb drive, store it locally on the C:\ drive, or easily send data to any external PC, LIMS, SAP, etc.
- Print measurement results to any local or networked printer. Most printers are supported by Windows Embedded[®] but if required the driver may be added
- Save measurement data directly to your Network/Server

cGMP/GLP Printing

Sample measurement reports are edited quickly and easily. Just import your logo to the Rudolph Density Meter and send your company's customized certificate of analysis to your server or local printer.

> Print your customized Certificate of Analysis including your company logo directly from the Density Meter

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

——— Unmatched Versatility, ——— Traceability, Compliance and Flexibility

For Highly Regulated Labs, Full 21 CFR Part 11 Instrument Level Compliance

The United States Food and Drug Administration 21 CFR Part 11 regulation establishes the FDA's requirements for electronic records and electronic signatures (ERES) to be trustworthy, reliable, and essentially equivalent to paper records and handwritten signatures. The Rudolph Density Meter user interface software's 21 CFR Part 11 features fully supports and exceeds the requirements of 21CFR Part 11. Available in embedded and PC versions.

The Rudolph Density Meter's 21 CFR 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

- PDF encrypted and password protected
- Unique and Settable User rights and privileges

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Density \	ensity Menu > Operational Parameters > Communication Settings > Export Settings						
	File Export Options	PDF	*				
	Enclose with	None	· .				
	Password Options						
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	Data Location M:\DD	M-S4-DataExport					
	Export file options						
	Create file Overwrite file Append to file						
	In-Case Of Continuous	Mode		OFF			
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1000							
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Р МІ		SAVE	CANCEL	SORIES			
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User Access Levels are set by the administrator. Ô Add / Edit User Menu > 21CFR11 > 21CFR11 Admin Options > User / Groups > Add / Edit Users > Add Density VC Add Account MAL User Name g C 1 **Full Name** C Specific Grav Password Retype Password Select Group Group ✓ User must change password at next logon CCESSORIES As Audit Trails are produced they are saved internally which can be viewed, exported or printed.

Date Filter Last 2 Days - From 8/23/2020				From 8/23/2020 To 8/25/2020		
1	All Data	Sear	ch By -			
		User Name V	Tab Name	V Des		
1		Automatic	Audit Trail	Audit Trail backup was created to C:\Density\Data\Audit_Trial_I		
2		Automatic	Audit Trail	Audit Trail backup was created to C:\Density\Data\Audit_Trial_I		
3		Administrator	Set 21CFR11	Enable Operator was changed		
4		Administrator	Set 21CFR11	Enable 21CFR11 was changed		
5		Automatic	Audit Trail	Audit Trail backup was created to C:\Density\Data\Audit_Trial_E		
6		Automatic	Audit Trail	Audit Trail backup was created to C:\Density\Data\Audit_Trial_E		
7		Administrator Set 21CFR11		Enable Operator was changed		
8		Administrator Set 21CFR11		Enable 21CFR11 was changed		
9		Automatic Audit Trail		Audit Trail backup was created to C:\Density\Data\Audit_Trial_E		
10		reviewer	Measurement	Measurement terminated by reviewer. Results file 'M:\DDM-S4-		
11		Automatic	Audit Trail	Audit Trail backup was created to C:\Density\Data\Audit_Trial_I		
4		1				



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——— Unmatched Versatility, ——— Traceability, Compliance and Flexibility



NIST Traceable Calibration Standards

Rudolph knows how important it is to calibrate with Traceable Standards and therefore, we include either a NIST or other National Physical Laboratory (NPL) traceable standard in the accessories provided with your density meter.

The Rudolph DDM Series Density Meter includes all the accessories for immediate use*:

- Quick Start Guide
- IQOQPQ Documentation
- Rinse/Sample Waste Container
- Filling Nozzles
- Connecting Fittings & Tubing
- Traceable StandardLuer Syringes
- User Manual
- Tools
- Certificate of Calibration

* Certain restrictions apply

Flexible Method Management

Factory installed measurement methods allow for immediate selection of the correct method to match the most common applications.

For unique measurement applications, easily create a sample method using an unlimited number of Concentration Tables, Formulas, and Polynomials to match the measurement methods used in your laboratory.

Method Management		<u> </u>		
Menu > Method Management				
NAME	TYPE	TYPE		
21cfr11-Density	Custom			
AOAC Ethanol	Factory			
Beer	Factory			
Beer - Tabarie	Factory			
Brix	Factory			
Crude Oil	Factory			
Density	Factory			
Density through Temperature	Factory			
Density VC	Factory			
Dilution by Volume TTB	Factory			
Dilution by Weight TTB	Factory			
Factory OC Testing	Factory	·		
O LOAD		J RENAME		
	HIDE 🏩 PRINT	CLOSE		

Customized Methods:

- Concentration D2O Heavy Water
- Ethanol Proofing
- Testing of aspartame and other artificial sweeteners
- Monomer Solutions
- Hydrogen Peroxide
- Determination of Partial Specific Volume
- ppm, Normality, Molarity, Molality
- % Toluene in Heptane
- Purity of sample testing
- Density of Gases and Aerosols
- Potassium Permanganate
- Ultracentrifugation applications
- SG of Urine
- Sodium Hydroxide

Choose the Sample Load —— Option Solution for Your Application

0.99821

1,00010

0.00

0.00 Dec 0

Vertical Load

- Sample injection is done vertically against gravity reducing air bubbles. Suitable for left and right handed operators as opposed to manual horizontal injection. Plunger is easier to push with all samples and there is more control over the syringe than with Horizontal Load.
- Gives the ability to apply more pressure to the syringe when injecting viscous samples without harming operators.
- Much easier cleaning. When a measurement is complete and the syringe is removed, gravity will force the sample down and into the waste jar. As opposed to the traditional horizontal load, if the waste tubing was bent, the sample would pour backwards and spill out on the table.
- Preserves the nozzles and nozzle bodies much better since there will not be added pressure from pushing on them when loading a sample. All the pressure will be on the top plate, thus saving in future maintenance costs.

Traditional Horizontal Load

- Samples can be easily loaded in the Density Meter by directly injecting your sample into the inlet port.
- You can watch the sample progress through the U-Tube and monitor for bubbles with a 2X magnification.
- Need a closer look? View at 6X or 10X magnification.
- When your measurement is complete simply flush the U-Tube with your choice of solvent and use the convenient built in air pump to dry the U-Tube.
- Only 1ml of sample is required.



Choose the Sample Load —— Option Solution for Your Application

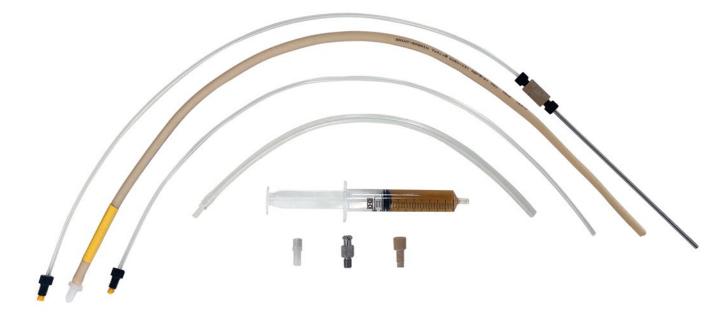
LoadAssist[™]

- Great option as there are two ways to inject a sample: by manual vertical injection or having the PeriPump pull the syringe down for you.
- Ideal for pulling the rinse solutions automatically into the system thus making the rinsing part of the operation much easier and independent.
- Pressure mode available for carbonated samples.
- Benefits customers that have multiple inexperienced users as the PeriPump will automatically inject the sample the same way every time.
- No change in instrument's performance when compared to manual injection.



LoadAssist[™] is the most versatile option

LoadAssist[™] allows multiple ways to inject the sample: automatically through supplied needle, syringe, hard and flexible tubings.



Sample handling options for high throughput laboratories

Peristaltic Pump

Combining a Peristaltic Pump with a Rudolph Density Meter makes sample loading and cleaning faster and more convenient. A Peristaltic Pump draws the sample into the Density Meter and could also load a second instrument such as a Refractometer. The user drops a tube into the sample and starts the Peri Pump from the Density Meter display. The Peristaltic Pump draws the sample through one or two instruments and then measures automatically. The measured sample is displaced to waste by the following sample.

Who Should Use this System?

Laboratories working with low viscosity samples such as beverages, food, dairy, alcohol.

Users who do not mind utilizing 30-50 ml of sample for a measurement. A larger amount of sample is needed to ensure all of the previous sample is displaced with new sample.



Sample handling options for high throughput laboratories

Automate your Laboratory with a Rudolph Autoflex® R837 or R835 Automation System

The DDM Series Density meters can be combined with various Rudolph Automation Systems and Sample Handling Accessories such as: Peristaltic Pump, ECS (Easy Clean System), Autofill[®], Autoflex[®] R835 and Autoflex[®] R837 AutoSampler. The Rudolph Research R837 AutoFlex[®] is perfect for high throughput laboratories looking to increase productivity.

The AutoFlex[®] R837 Sampler Features :

- \bullet Customizable bottle size, Test Tube size such as: Boston Rounds:10z, $^{1\!/}_{2}$ oz, virtually any size
- Customizable Rack configurations: heated and unheated on the same carousel
- Automated sample introduction
- Flexible Method Selection: Suction mode, Pressure mode, Rinse, and Hybrid Mode
- Programmable cleaning and drying
- Automatic solvent and waste level detection
- System Configuration minimal sample volume: 1.5 mL
- Fast throughput
- Automation saves operator time and increases your lab's efficiency
- An urgent-sample interruption can be made at any time

Operation is completely automatic. The sample is measured and the data recorded. Depending on how the system is configured the data may also be printed, saved as an Excel file or transferred to LIMS, SAP, or directly onto your network

The AutoFlex® R835 Sampler with powerful peristaltic pump features:

- Faster cycle times
- Higher throughput

- Lower Cost
- Draws sample through one or more instruments where measured sample is displaced to waste by the following sample.
- Many Bottle Options
 Fully automated inject
 - Fully automated injection and rinsing

Multiple parameters from one sample, with full automation including injection, cleaning and drying.

Description

Combine instruments with Automation to Measure: Refractive Index, Brix, Density, Specific Gravity, Optical Rotation, Color, Alcohol % vol/vol, pH, Proof and more from a single sample.

AutoFlex® gives you the most flexibility in sample vial selection, sample handling and instrument combinations. Please refer to Rudolph's Automation Technical Bulletin

Ideal for high throughput Flavor, Fragrance, Alcohol, Chemical, Petroleum, Food Labs who run many samples each day and want multiple parameters reported in a single sample.





—— Combine a Density Meter with a —— Refractometer for additional Measurements

Test obscured Alcohol samples with Rudolph's AlcoTest[®]-RI System.

Obscured Alcohol samples are any solutions containing alcohol, water plus anything else such as flavoring or barrel aging. This includes beer, wines, flavored spirits and many barrel aged rums, whiskeys, and Bourbons. The AlcoTest®-RI measures the sample by calculating the density of the sample and then correcting for the obscuration using refractive index. The user can measure % alcohol by volume in less than two minutes.

UAN (Urea Ammonium Nitrate) Fertilizer Analysis

Rudolph Research offers a more rapid, less complex UAN analysis method using concurrent Density and Refractive index measurements. The results yield a full analysis including concentration of Ammonium Nitrate, Urea, water, and the % of Total Nitrogen in UAN solution. The advantages of using the Rudolph UAN measurement method are speed, safety, and a reduction of technical expertise required. No user interpretation is required and there is no unusual danger to the user. Accuracy is within required results with up to 0.024% accuracy when using a Rudolph J457 Refractometer optics module and a DDM2911 Density Meter. Reproducibility is improved over existing methods due to the reduced variables utilized in the Rudolph Method and results are far less dependent upon user skill or procedure.



Accurate Determination of Sulfuric Acid concentration within the Chemical, Accumulators, Fertilizers and Plastics Industries.

As Sulfuric Acid concentration increases, density also increases. This fairly linear relationship goes from 0% concentration up to approximately 96% or 97%. However, somewhere around 93% the linear relationship starts to become a bell curve so the concentration/density relationship starts curving back on itself. As a consequence, the densities of Sulfuric Acid at these high levels have two different possible concentrations, for example, 93% and 98% Sulfuric Acid have very close density values.

In order to solve this inconvenience and be capable of analyzing beyond 90 % with total confidence Rudolph Research Analytical adds a second piece of advanced technology that determines the Refractive Index of Sulfuric Acid at high concentrations beyond 90 % such as in the J457OM-SV-H Refractometer where the behavior of the curve is stable.

A Density Meter is paired with a J457OM-SV-H Refractometer in which the sample gets either manually or automatically injected. This combination of reliable technologies provides a more rapid, less complex solution for determination of sulfuric acid concentration throughout its entire range.



—— Densitometry —

The Rudolph DDM Series of Density Meters, with high precision Peltier temperature control of sample, has the features to meet the needs of today's industrial applications.



BEVERAGES, SPIRITS, WINE

- The US TTB requires high accuracy for testing % Ethanol ABV in wine, beer, and spirits
- The DDM 2911 Plus offers 0.01% accuracy for Ethanol testing
- Direct and accurate means of °Brix determination, °Plato, °Balling, Proof, % Solids





FOOD, FLAVOR, FRAGRANCE

- Measure Density, Specific Gravity
 - Checking of raw materials and product release
 - Check batch consistency and ensure proper blending ratios
 - Add refractive index, color and optical rotation with R837 and **R835** Automation Solutions

PETROLEUM, CHEMICAL

- Measure API, Density and Specific Gravity values in compliance with ASTM D1250, ASTM D4052, ASTM D4806, ASTM D5002, ASTM D5931, ISO 12185, ISO 15212-1 and DIN 51757
- Measure in units of kg/m3, g/cm3, g/ mL, pounds/gallon, specific gravity, Baumé and more



PHARMACEUTICAL Capable of 2,3,4 or more multiple

- measurements with standard deviation, mean, min and max reading for true cGLP/GMP compliance
- Complete Factory and On Site IQ/OQ/ PQ documentation and data inventory
- 21CFR Part 11 Compliance and DATA integrity; Electronic Signature and Secure Data Storage
- Compliant with USP <841>, EP 2.2.5, JP, BP, Chinese, Brazilian, Mexican, Pharmacopeias





DDM 2911 PLUS Density Meter is Rudolph Research's TTB Approved Instrument for Alcohol Proof Testing.

The capability you need to easily test your spirits production and comply with TTB Requirements:

The DDM 2911 PLUS has built-in precision Electronic Temperature Control ensuring accurate and reproducible results. A Windows Embedded® OS allows the operator to save calibration and measurement data right to Excel[™] and PDF.

- With 0.00001 g/cm³ accuracy and 0.000001 g/cm³ resolution the DDM 2911 PLUS is an excellent choice for the Alcohol Beverage industry to measure alcohol concentration to determine alcohol proof
- Easy to Use. Easy to Validate
- Windows Embedded® OS
- Precision built-in electronic Temperature Control (via Peltier)
- Easily combined with Rudolph's R837 or R835 Automation System
- 3 Year Domestic Warranty 20 Year Service Guarantee

0.01% Alcohol Determination adding Precision to the Art of Craft Distilling

————————————————————————————————————						
	DDM 2909	DDM 2910	DDM 2911	DDM 2911 PLUS		
Accuracy	Density: 0.0001 g/cm ^{3*} Temperature: 0.05 °C	Density: 0.0001 g/cm ³ Temperature: 0.03 °C	Density: 0.00005 g/cm ³ Temperature: 0.02 °C	Density: 0.000010 g/cm ³ Temperature: 0.01 °C		
Repeatability (Standard Deviation)***	Density: 0.00002 g/cm ³ Temperature: 0.02 °C	Density: 0.00001 g/cm ³ Temperature: 0.02 °C	Density: 0.000005 g/cm ³ Temperature: 0.01 °C	Density: 0.000002 g/cm ³ Temperature Selectable: 0.001 °C		
Resolution (Standard)	Density: 0.0001 g/cm ³ Temperature: 0.01 °C	Density: 0.0001 g/cm ³ Temperature: 0.01 °C	Density: 0.00001 g/cm ³ Temperature: 0.01 °C	Density: 0.000001 g/cm ³ Temperature: 0.001°C		
Resolution (USR)**	Density: Up to 0.00001 g/cm3**	Density: Up to 0.00001 g/cm3**	Density: Up to 0.000001 g/cm3**			
Density Range	$0 \text{ g/cm}^3 \text{ to } 3 \text{ g/cm}^3 (32^\circ \text{ F} - 212^\circ \text{ F})$					
Temperature Range (controlled via Peltier)	0°C – 70°C	0°C – 100°C				
Pressure Range	0 to 10 bar (145 psi)					
Viscosity Correction		Yes, over th	ne entire range			
U-Tube Video Scanning & Magnification	Three magnified video assisted views of the entire cell are available, in 2x, 6x and a 10x magnifications with video scanning. Images may be saved with results for subsequent review.					
Automatic Bubble Detection	Automatically warns operator of bubbles					
Measurement Modes	Continuous, Single, Multiple					
Measurement Technique	Mechanical Oscillating U-Tube Method					
Minimum Sample Volume	Approx 1mL (depending on the load option)					
Wetted Materials	Borosilicate glass, Teflon PTFE ECTFE					
Operating System	Windows Embedded [®] ; write protected software safe from malware and viruses					
Measurement Time	Typically 30 - 40 seconds after thermal equilibration					
Display	Bright 10.4 inch diagonal TFT type LCD with wide viewing angle, anti-glare flat panel touch screen, 300 nits brightness, 800 x 600 pixels, chemical, scratch and spill resistant monitor, the industry's largest, most flexible, and customizable user interface					
Communication Interfaces	5 USB Ports, 2 RS232 Ports, 2 Ethernet Ports for Network Connection, 1 HDMI, Keyboard Bar Code Scanner, Mouse, Network Capabilities					
Remote Support	Troubleshooting, Diagnostics, Software Updates available via the Internet			e Internet		
Internal Memory	32 GB Non-removable Compact Flash Allowing Storage of over 100,000 Measurements					
Operating Dimensions	18.36" (L) x 11.80" (W) x 13.90" (H) 46.61 cm (L) x 29.97 cm (W) x 35.30 cm (H)					
Shipping Dimensions	24.5" (L) x 17.5" (W) x 22" (H) 62cm (L) x 44cm (W) x 56cm (H)					
Operating Weight 53 lbs (24 kg.)			s (24 kg.)			
Power Supply	100 to 240 VAC; 50 to 60 Hz					
Power Consumption	120 Watts at peak					
Country of Manufacture Ind Design / WarrantyUnited States of America (U.S.A.) 3 Year US Warranty - 1-2 Year International *Warranty varies by country and instrument model(1-3 years)				odel(1-3 years)		

When optional USR (User Selectable Resolution) is chosen * According to ISO 5725 and with USR enabled and under ideal conditions

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