RUDOLPH RESEARCH ANALYTICAL

TECHNICAL BULLETIN 922

For the Most Demanding cGLP/GMP Laboratories

The DDM 2911 Automatic Density Meter

United States Department of Commerce
National Institute of Standards and Technology

NVLAP

NVLAP LAB CODE: 200898-0
Accreditation to ISO/IEC 17025:2005

Densitometry

Applications

The DDM 2911 Density Meter, with high precision Peltier temperature control of sample, has the features to meet the needs of today's industries.

PETROLEUM

- Measure API Values in accordance with ASTM D1250, ASTM D4052, ASTM D5002 and DIN 51757
- QC incoming raw materials
- Research new products and additives
- Withstands harsh and heavy use environments
- Calibrate using petroleum standards

CHEMICAL

- Measure in units of Kg/m^3, g/cm^3, g/ml, pounds/gallon, specific gravity, Baumé and more
- Determine concentrations in: %, molarity, normality, mole fraction, ppm, and more
- Check batch consistency and ensure proper blending ratios
- Wetted materials compatible with the most aggressive chemicals

PHARMACEUTICAL

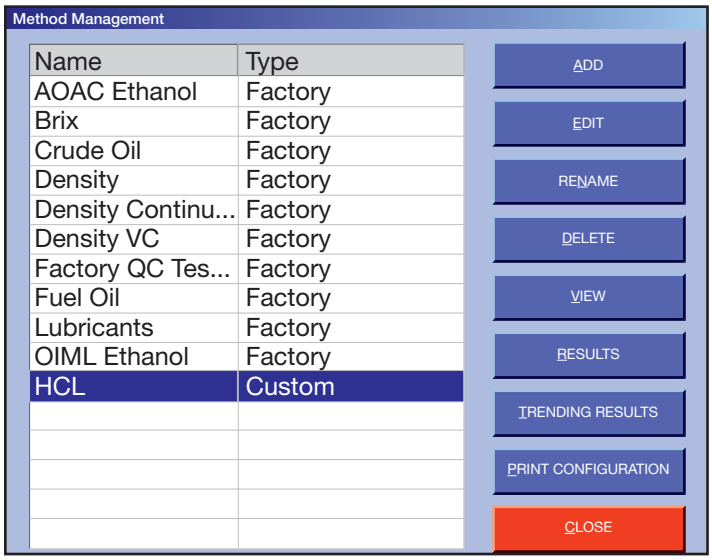
- Capable of 2,3,4 or more multiple measurements with standard deviation, mean, min and max reading for true cGLP/GMP compliance
- Complete IQ/OQ/PQ documentation
- Checking of raw materials and product release
- 21CFR11 Compliance; Electronic Signature and Secure Data Storage
- Compliant with USP 29<841>, JP, BP and EP

BEVERAGE

- Measure both alcoholic and non-alcoholic beverages with easy bubble detection using VideoView™
- Direct and accurate means of °Brix determination, °Plato, °Balling, % Solids
- Use apparent density function for proper filling volume monitoring

Flexible Method Management

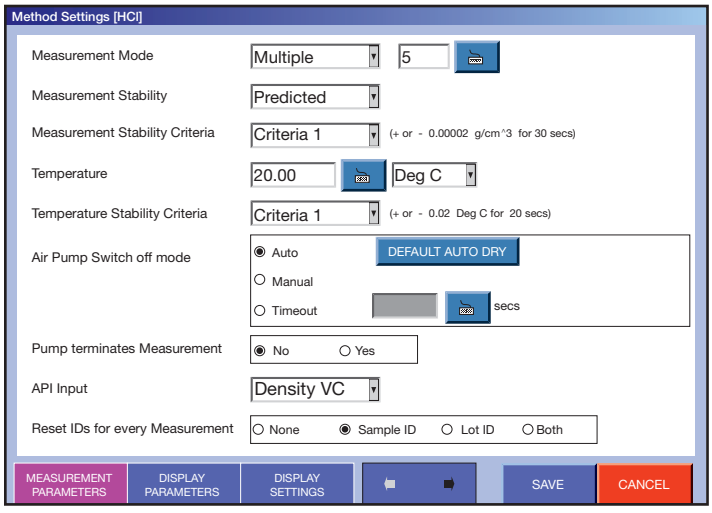
Factory installed measurement methods allow for immediate selection of the correct method to match the most common applications.



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

- Concentration D_2O – Heavy Water
- Baumé of Hydrochloric Acid
- Normality of Sulfuric Acid
- Density of Gasses and Aerosols
- Drug to Propellant Ratio
- Lead Content
- ppm Gold in Acid
- % Toluene in Heptane
- Fat in Lubricant
- Mole Fraction of Methanol
- % HNO_3
- Monomer Solutions
- Potassium Permanganate
- Hydrogen Peroxide
- Molar Solutions of EDTA
- SG of Urine
- Sweeteners
- Sodium Hydroxide

Setting up your custom method is as simple as filling out a few screens like the one below.



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

Versatile Communication Capability

The DDM 2911's standard communication package includes:

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

Allowing the capability to:

- Export measurement results to a thumb drive, store it locally on the C:\ drive, or easily send data to any external PC, LIMS, etc.
- Print measurement results to a local or networked printer. Use any printer; just load the proper printer driver as you would with any PC
- Save measurement data direct to your Network/Server

cGMP/GLP Printing

Sample measurement reports are edited quickly and easily. Just import templates from Word® or Excel® to the DDM 2911 Density Meter and print your company's customized "C of A" directly.

Print your customized Certificate of Analysis including your company logo directly from the DDM 2911 touch screen

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Hackettstown, NJ 07840 USA

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Date: February 19, 2011

This sample was measured on DDM 2911 serial number 20212, manufactured by Rudolph Research Analytical, Hackettstown, NJ, USA.

Lot ID 2019

Temperature: 20.0 Deg C

No	Sample ID	Density	Sp. Gravity	Normality	HCL % wt	° Baume	Time
1	8421	1.09803	1.1000	6.0092	19.95	12.94	14:20:50 PM
1	8421	1.09803	1.1000	6.0092	19.95	12.94	14:21:40 PM
1	8421	1.09803	1.1000	6.0092	19.95	12.94	14:22:30 PM
1	8421	1.09803	1.1000	6.0092	19.95	12.94	14:23:20 PM
1	8421	1.09803	1.1000	6.0092	19.95	12.94	14:24:10 PM

Counts	:	5
Average	:	1.0980
SD	:	0.0000
Maximum	:	1.0980
Minimum	:	1.0980

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

NIST Traceable Calibration Standards

Rudolph knows how important it is to calibrate with Traceable Standards and therefore, we include either a NIST or UKAS standards in the accessories provided with your density meter. The DDM 2911 standard accessories include:

- Quick Start Guide
- Rinse/Sample Waste Container
- Connecting Fittings & Tubing
- Manual
- IQOQPQ Documentation
- Filling Nozzles
- Traceable Standard
- Luer Syringes

The Simplicity of Touch Screen Measure

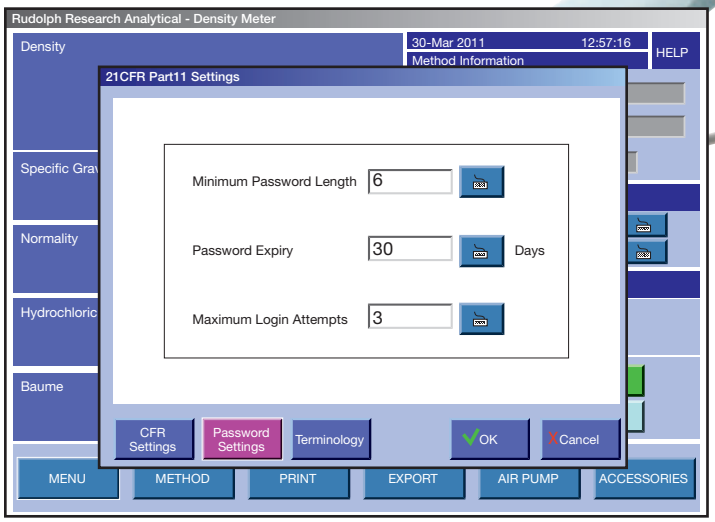
VideoView™ Bubble Detection

No more straining to see small difficult-to-detect air bubbles in your sample with live on-screen video viewing. On-screen bubble detection is made possible utilizing Rudolph's exclusive VideoView™ (Patent # 7,437,909) with 10X magnification.

Full 21CFR Part 11 Instrument Level Compliance

The DDM 2911'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



Oscillating U-Tube with Viscosity Correction and Reference Oscillator

(Patent # 7,735,353)

The DDM 2911's oscillating U-tube with full range viscosity correction and reference oscillator allows long term calibration stability and measurement at all temperatures with a single calibration.

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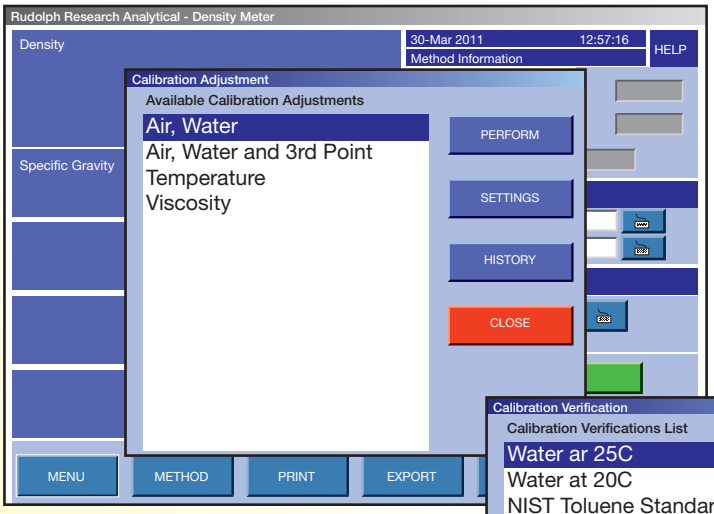
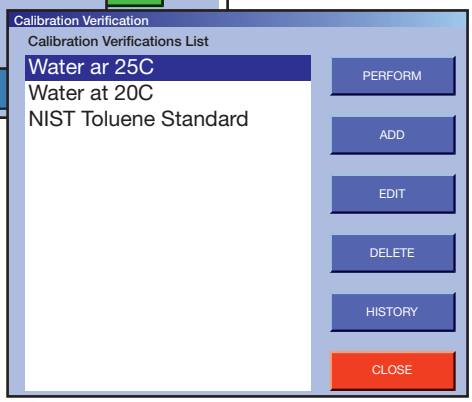
ement with the Flexibility of Windows®





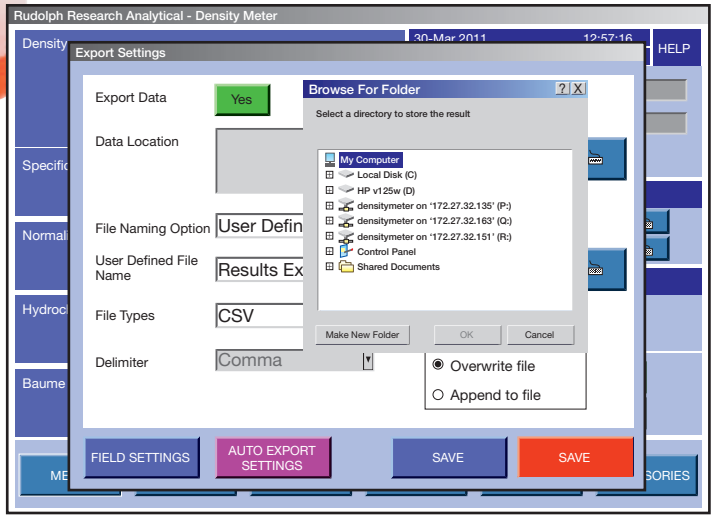
cGMP/GLP Calibration

- Calibrate the DDM 2911 with 2 or 3 NIST Traceable Standards – calibrating with merely air and water appears inconsistent with cGMP/GLP compliance regulations. (see H&D Fitzgerald's recommendations at www.density.co.uk)
- Can print out complete method configuration, communication settings, as well as calibration verification and calibration adjustment data/history.
- Measured values can be shown continuously as temperature stability is being reached or, at the discretion of the user, measured values will only be displayed once the final answer is reached and completely stable.

- Unlimited number of customized calibration adjustments and calibration verifications possible.
- Complete History of Calibration Adjustments and Verifications are available to View, Print, and/or Export
- Possible to set calendar reminders as to when Calibrations are due

Computer Windows Based Flexibility

- 8 gigabytes of internal memory allow almost unlimited capacity for saving measurement data. The DDM 2911 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 DDM 2911's touch screen. Disk Protection feature protects the operating system against malware 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 DDM 2911's internal memory.
- Copy methods, transfer concentration tables, download data, etc., via a USB port on front of unit.
- Three USB ports allow for quick and easy connection to a mouse, keyboard, printer, bar code scanner, or memory stick.



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Automation Flexibility

- Rudolph's AutoSampler can be loaded with up to 240 samples
- Combine density and specific gravity measurements with a polarimeter, refractometer, and colorimeter for simultaneous measurements of:
  - Refractive Index
  - Color
  - pH
  - Optical Rotation/ Specific Rotation
- Up to three different rinse solvents available for use; fully programmable
- Two sample loading modes; pressurized and suction; for optimized sample transfer and measurement
- Customer's unique sample bottles may be used to eliminate the need to transfer samples into special sized test tubes.
- Emergency samples measured at any time without stopping the AutoSampler or moving sample vials.

Specifications of the DDM 2911

Measurement Ranges:	**Density:** 0 to 3 g/cm³ **Temperature:** 0 °C to 90 °C (controlled via Peltier) **Pressure:** 0 to 10 bars
Measurement Modes:	Continuous, Single, Multiple
Measurement Technique:	Mechanical Oscillator Method
Accuracy:	**Density:** 0.00005 g/cm³ **Temperature:** 0.03 °C
Repeatability:	**Density:** 0.00001 g/cm³ **Temperature:** 0.01 °C
Resolution:	**Density:** 0.00001 g/cm³ **Temperature:** 0.01 °C
Minimum Sample Volume:	Less than 1ml
Wetted Materials:	Borosilicate glass, Teflon (PTFE, ECTFE)
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
Video & Magnification:	Video assisted view of cell, capable of approximately 10X magnification
Internal Memory:	8 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:	70 lbs. (31.75 kg)
Power Supply:	85 to 260 VAC; 48 to 62 Hz
Power Consumption:	150 – 200 Watts

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