MAKERS OF RESPIRATORY VALVES SINCE 1938
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Data Sheet

RUDOLPH VOLUME CALIBRATION SYRINGES

Series 5520, 5510, 5550, 5540, 5530, 5570, 4900

PRODUCT DESCRIPTION

The Hans Rudolph Calibration Syringes deliver a known calibrated air volume as a standard for a reliable method of calibrating and measuring the accuracy of respiratory volume measuring equipment in the field on a regular basis to satisfy your quality assurance program.

The 3 Liter size syringe with an accuracy of 0.5% FS is specified for use for the calibration of Spirometers in the "Standardization of Spirometry 2019 Update" An official American Thoracic Society and European Respiratory Society Technical Statement and ISO 26782:2009(E) "Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans".

PRODUCT FEATURES

- Calibrated syringes range in full stroke volumes of 10 ml through 7000 ml.
- Precision bore cylinders are either finely honed hard anodized aluminum or machined and polished cast acrylic
- Sealing elements are either proprietary high wear lubricated rubber or machined flat spring loaded virgin Teflon jacket type
- Piston rods are ground aluminum with black anodize or injection molded long glass filled nylon
- Piston rod graduations are either lathe cut (machined) or laser marked
- Outlet ports available in standard and custom sizes
- Adjustable sliding positive stop collars for different delivered volumes include tightening wrench
- Plugs available for leak testing the syringe in the field
- Each syringe volume certified and leak tested
- Recalibration, repair services and rentals available
- Handle assembly available for 3L Syringes

GENERAL INFORMATION

INTENDED USE AND PATIENT POPULATION

Volume Calibration Syringes are designed for testing and calibrating flow and volume measurement devices use in the respiratory device market. The Calibration Syringes are manually operated by actuating the piston rod in and out of the cylinder assembly. The outlet port of the syringe assembly shall be attached to the device under test. Hans Rudolph provides custom outlet ports to mate any of the spirometric devices on the market. The Calibration Syringe when actuated shall deliver known volumes of air into the flow or volume measurement device. The operator compares the calibration syringe volume delivered with the volume results obtained from the device under test to determine the accuracy.

INDICATIONS AND ENVIRONMENT FOR USE

The Calibration Syringes are indicated for use for the calibration of respiratory flow meters and volume displacement type spirometers. These devices are typically part of spirometry systems and pulmonary function testing systems. The Calibration Syringes are used in pulmonary function test laboratories, bio-medical engineering calibration laboratories, private physician offices, universities, research centers and manufacturers of respiratory systems. The syringes are used by persons trained in the calibration procedures of the equipment under test.

SPECIFICATIONS

Model Series		5520	5510	5550	5540	5530	5570	4900
Accuracy ±0.5% FS	ml	±0.05	±0.5	±2.5	±5.0	±15.0	±15.0	±35.0
Total Volume	ml	10	100	500	1000	3000	3000	7000
Smallest Graduation	ml	2	20	50	50	100	3000	100
Full Volume Stroke	in	3	5	6.25	12.38	14.75	14.75	15
	cm	7.6	12.7	15.8	31.5	37.5	37.5	38.1
Cylinder Bore Diameter	in	0.50	1.25	2.50	2.50	4.0	4.0	6.0
	cm	1.27	3.17	6.35	6.35	10.16	10.16	15.24
Weight	lb	.17	.39	1.7	2	3.7	3.6	10
	gm	75	175	771	907	1690	1655	4536



Volume Calibration Syringes



Syringe Validator

MATERIALS

Model Series	5520	5510	5550	5540	5530	5570	4900
Cylinder	Acrylic Plastic		Aluminum Hard Anodized				
Piston Rod	Aluminum Black Anodized				Nylon Long Glass Filled		Aluminum Black Anodized
Sealing Element	Teflon Jacket with Stainless Steel Spring		Proprietary Molded Nitrile Rubber Lubricated U-Cup				
Piston	PET				POM (Acetal)		PET
End Plate (2)	PET				POM (Acetal)		PET
Outlet Adapter	PET				PET (threaded type) & POM (end plate integral type)		PET
Lubri-cant	PTFE		Silicone Grease				
Plug	Silicone Rubber						

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Recommendations from Rudolph and the ATS/ERS Standards of Spirometry for Syringe Calibration methods

1. Rudolph recommends that our syringes be checked at a minimum one time per year for accuracy from a 3rd party laboratory capable of checking the volume delivery of the syringe. Rudolph offers this service.
2. The syringe should be maintained at the same temperature as the spirometer under test for use during spirometer calibration or verification.
3. Do not hold the syringe body (cylinder) during use as the heat transfer can raise the temperature of the air delivery contributing to a measurement error.
4. Operators should be aware that a syringe with adjustable stop(s) may be out of calibration if the stop is reset or accidentally moved. In our syringes there is also an internal fixed stop for the "ZERO" datum graduation visible at the end plate when the piston rod is pulled all the way out. If the ZERO graduation is not aligned directly with the end plate then the syringe should be returned to RUDOLPH for recalibration. Recommend daily checks of the stops position.
5. Calibration syringes should be leaked tested at several volumes monthly using PLUGS in the outlet while attempting to empty or fill the syringe. Rudolph has plugs available.
6. Daily checks for smooth operation of the syringe with no sticking or catching.
7. A dropped or damaged syringe should be considered out of calibration until it is checked.
8. Spirometer calibration verifications should be undertaken at least daily using a 3-L syringe cycled at least three times to give a range of flows varying between 0.5 and 12 L/s (with 3-L injection times between 0.5 and 6 sec).
9. If an in-line filter is used in spirometry testing, then it must be used during recalibrations or verifications

Cleaning and Disinfection

- These products are packaged clean, non-sterile
- For cleaning care refer to our Instructions for Use 691203

Caution

Federal law restricts this device to sale by or on the order of a physician.

Warnings and Risks

Refer to the Instructions for Use 691203

Ambient Conditions

- Temperature: 5ºC to 40ºC
- Relative Humidity: 0% to 95% (non-condensing)

Reference

1. How to use a Volume Calibration Syringe for calibration checks of Volume Spirometers. Refer to Chapter 8, Calibration, of the book titled "Office Spirometry, A Practical Guide to the Selection and Use of Spirometers", by Paul L. Enright and Robert E. Hyatt, published by Lee & Febiger, Philadelphia PA USA 1987.
2. Standardization of Spirometry 2019 Update, An official American Thoracic Society and European Respiratory Society Technical Statement, American Journal of Respiratory Care Medicine, Volume 200, Number 8, October 15, 2019.
3. International Standard, ISO 26782:2009 (E) First Edition, 2009-07-15, "Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans", Sec 8.2.



Handle for 3L Syringes (US Design Patent and EC Design Registrations Pending)

Ordering Information

Order Part Number	Series	Description
201824	5530, 5570	Handle Assy for Rudolph 3L Syringe
201825	N/A	Handle Assy for Vyaire 3L Syringe
201834	5530, 5570	Handle Assy Installed on Rudolph 3L Syringe
201835	N/A	Handle Assy Installed on Vyaire 3L Syringe

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Ordering Information

Order Part Number	Series	Description (Total Volume & Smallest Graduation)	Outlet Port Size	Outlet Port Type (A) Threaded removable (B) Integral to End Plate
112380	5520	10 ml Syringe (2 ml graduations)	15mm OD Medical Taper 10.5mm ID	A
112381	5520	10 ml Syringe (2 ml graduations)	22mm OD Medical Taper 15mm ID Medical Taper	A
112378	5510	100 ml Syringe (20 ml graduations)	15mm OD Medical Taper 10.5mm ID	A
112379	5510	100 ml Syringe (20 ml graduations)	22mm OD Medical Taper 15mm ID Medical Taper	A
112742	5550	500 ml Syringe (50 ml graduations)	1.375" (35mm) OD 1.125" (28.6mm) ID	A
112743	5550	500 ml Syringe (50 ml graduations)	1.75" (44.5mm) OD x 1.125" (28.6mm) OD Long OD Taper	A
112744	5550	500 ml Syringe (50 ml graduations)	22mm OD Medical Taper 15mm ID Medical Taper	A
112745	5550	500 ml Syringe (50 ml graduations)	2.0" ID O-ring Slip-Fit (mates 2" OD)	A
112746	5550	500 ml Syringe (50 ml graduations)	1.125" (28.6mm) OD 22mm ID Medical Taper	A
112706	5540	1000 ml Syringe (50 ml graduations)	1.375" (35mm) OD 1.125" (28.6mm) ID	A
112707	5540	1000 ml Syringe (50 ml graduations)	1.75" (44.5mm) OD x 1.125" (28.6mm) OD Long OD Taper	A
112708	5540	1000 ml Syringe (50 ml graduations)	22mm OD Medical Taper 15mm ID Medical Taper	A
112709	5540	1000 ml Syringe (50 ml graduations)	2.0" ID O-ring Slip-Fit (mates 2" OD)	A
112710	5540	1000 ml Syringe (50 ml graduations)	1.125" (28.6mm) OD 22mm ID Medical Taper	A
112028	5530	3000 ml Syringe (100 ml graduations)	1.375" (35mm) OD 1.125" (28.6mm) ID	B
112231	5530	3000 ml Syringe (100 ml graduations)	1.75" (44.5mm) OD x 1.125" (28.6mm) OD Long OD Taper	A
112232	5530	3000 ml Syringe (100 ml graduations)	22mm OD Medical Taper 15mm ID Medical Taper	A
112233	5530	3000 ml Syringe (100 ml graduations)	2.0" ID O-ring Slip-Fit (mates 2" OD)	A
112567	5530	3000 ml Syringe (100 ml graduations)	1.125" (28.6mm) OD 22mm ID Medical Taper	B
113391	5570	3000 ml Syringe (Pre-Set at 3000 ml Volume – NO adjustment)	1.375" (35mm) OD 1.125" (28.6mm) ID	B
113638	5570	3000 ml Syringe (Pre-Set at 3000 ml Volume – NO adjustment)	1.75" (44.5mm) OD x 1.125" (28.6mm) OD Long OD Taper	A
113611	5570	3000 ml Syringe (Pre-Set at 3000 ml Volume – NO adjustment)	22mm OD Medical Taper 15mm ID Medical Taper	A
113392	5570	3000 ml Syringe (Pre-Set at 3000 ml Volume – NO adjustment)	1.125" (28.6mm) OD 22mm ID Medical Taper	B
113568	5570	3000 ml Syringe (Pre-Set at 3000 ml Volume – NO adjustment)	1.125" (28.6mm) OD 22mm ID Medical Taper	A
112092	4900	7000 ml Syringe (100 ml graduations)	1.375" (35mm) OD 1.125" (28.6mm) ID	A
112234	4900	7000 ml Syringe (100 ml graduations)	1.75" (44.5mm) OD x 1.125" (28.6mm) OD Long OD Taper	A
112235	4900	7000 ml Syringe (100 ml graduations)	22mm OD Medical Taper 15mm ID Medical Taper	A
112236	4900	7000 ml Syringe (100 ml graduations)	2.0" ID O-ring Slip-Fit (mates 2" OD)	A
112568	4900	7000 ml Syringe (100 ml graduations)	1.125" (28.6mm) OD 22mm ID Medical Taper	A

REPLACEMENT OUTLET PORT ADAPTERS

Order Part Number	Description	Syringe Series	Syringe Size
200271	15mm OD Medical Taper 10.5mm ID	5520	10ml
200272	22mm OD Medical Taper 15mm ID Medical Taper		
200269	15mm OD Medical Taper 10.5mm ID	5510	100ml
200270	22mm OD Medical Taper 15mm ID Medical Taper		
200264	1.375" (35mm) OD 1.125" (28.6mm) ID	5550 5540 5530 4900	500ml 1000ml 3000ml 7000ml
200265	1.75" (44.5mm) OD x 1.125" (28.6mm) OD Long OD Taper		
200266	22mm OD Medical Taper 15mm ID Medical Taper		
200267	2.0" ID O-ring Slip-Fit (mates 2" OD)		
200268	1.125" (28.6mm) OD 22mm ID Medical Taper		

REPLACEMENT PARTS

Order Part Number	Description	Syringe Series	Syringe Size
171171	"T" Allen Wrench	5520 5510	10ml 100ml
171125	"T" Allen Wrench	5550 5540 4900	500ml 1000ml 7000ml
171129	"T" Allen Wrench	5530	3000ml
200232	Setting Collar with Ball Plunger	5520 5510	10ml 100ml
171115	Setting Collar	5550 5540 4900	500ml 1000ml 7000ml
171119	Setting Collar	5530	3000ml
171168	Knob	5520 5510	10ml 100ml
171127	Knob	5550 5540 4900	500ml 1000ml 7000ml

Recalibration & Dead Space Measurements Services

Contact HRI for Return Authorization Number (RAN)

Order Part Number	Description
955039	Recalibration 5520 Series 10ml Syringe
955038	Recalibration 5510 Series 100ml Syringe
955037	Recalibration 5550 Series 500ml Syringe
955036	Recalibration 5540 Series 1000ml Syringe
955035	Recalibration 5530 Series 3000ml Syringe
955052	Recalibration 5570 Series 3000ml Syringe
955034	Recalibration 4900 Series 7000ml Syringe
955051	Dead Space Measurement of New Syringe (all series)
955050	Dead Space Measurement of returned syringe. Standard recalibration required before deadspace measurement

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In-Coming Calibration on returned syringe

Contact HRI for Return Authorization Number (RAN)

Order Part Number	Description
955307	In-Coming Calibration 5520 series 10ml Syringe
955308	In-Coming Calibration 5510 series 100ml Syringe
955309	In-Coming Calibration 5550 series 500ml Syringe
955310	In-Coming Calibration 5540 series 1000ml Syringe
955311	In-Coming Calibration 5530 series 3000ml Syringe
955315	In-Coming Calibration 5570 series 3000ml Syringe
955312	In-Coming Calibration 4900 series 7000ml Syringe

Certificate of Calibration (Traceable to NIST)

Order Part Number	Description
955301	Certificate of Calibration 5520 series 10ml Syringe
955302	Certificate of Calibration 5510 series 100ml Syringe
955303	Certificate of Calibration 5550 series 500ml Syringe
955304	Certificate of Calibration 5540 series 1000ml Syringe
955305	Certificate of Calibration 5530 series 3000ml Syringe
955316	Certificate of Calibration 5570 series 3000ml Syringe
955306	Certificate of Calibration 4900 series 7000ml Syringe

PLUGS for Leak Testing (Silicone Rubber)

Order Part Number	Outlet Port Size of Syringe ID Range in (mm)
602151	.60 (15) – .70 (18)
602152	.75 (19) – .90 (23)
602153	.95 (24) – .1.03 (26)
602154	1.07 (27) – 1.11 (28)
602155	1.12 (28.5) – 1.17 (29.5)
602156	1.18 (30) – 1.25 (31.8)
602157	1.26 (32) – 1.35 (34)
602158	1.36 (34.5) – 1.50 (38)

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