Evaluating Commercially Available Spirometers[1-5]

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Summary

This study was designed to: (*1*) determine the performance characteristics of available spirometers; (*2*) assess the practicality and applicability of the American Thoracic Society's (ATS) Snowbird Workshop recommendations on Standardization of Spirometry; and (*3*) determine whether spirometer testing could be done with room air. Nineteen spirometers were tested with 16 different forced vital capacity waveforms. Fourteen spirometers met the ATS forced vital capacity requirements. Three of these 14 spirometers had difficulties in determining the end of expiration. Fourteen of the devices tested met the requirements for forced expiratory volume in one second. Ten of 13 devices tested for maximal voluntary ventilation were satisfactory. The standards recommended by ATS were believed to be applicable and practical. The testing methods recommended by ATS need to be expanded to include more patient waveforms. Testing with room air is easier and simpler and, for most devices, just as effective as heated and humidified air.

We conclude that most available spirometers can faithfully record forced spirograms and that if a spirometer meets the ATS requirements, it makes no difference on which device the spirogram is recorded.

Introduction

Proliferation of commercially available spirometers has resulted from the wide use of spirometers for evaluation of patients with respiratory complaints, for screening examinations, for epidemiologic studies, and for research. Standards of spirometer performance are needed regardless of their application. Accordingly, performance criteria have been recommended by the American Thoracic Society (ATS) (1) (table 1) and the American College of Chest Physicians (ACCP) (2).

This study had 3 objectives: (*1*) to measure the performance characteristics of commercially available spirometers, (*2*) to assess the practicality and applicability of the ATS Snowbird Workshop criteria and testing methods, and (*3*) to determine the difference between testing with room air and heated and humidified air.

Methods

A list of 35 manufacturers who marketed spirometers in January 1976 was obtained from the Bureau of Medical Devices of the Food and Drug Administration (3). These manufacturers were invited to submit their spirometers for testing. Thirteen spirometers from 13 manufacturers were submitted for testing. Six additional instruments were purchased on the open market, which brought the total to 19. (Initial testing was completed by October 1977.) For most devices, only the spirometer and recorder were tested. When a spirometer did not include a recorder or computer, a fast-response X-Y recorder was used (Hewlett-Packard 7046A; slew speed,

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TABLE 1

SUMMARY OF ATS RECOMMENDATIONS

	FVC	FEV_1	MVV
Volume			
Range/Accuracy, BTPS	7 L ± 3 % of reading or 50 ml, whichever is greater for flows of 0 to 12 L/s	7 L ± 3 % of reading or 50 ml, whichever is greater for flows of 0 to 12 L/s	2 L maximal tidal volume for flows up to 12 L/s
Recorder	Volume Time or Volume Flow Record		
Time base	for volume time record—FVC, minimum of 10 s at paper speed of at least 2 cm/s		12 to 15 s, ± 3 %
Sensitivity	volume: at least 10 mm/L, BTPS flow: at least 4 mm/L/s, BTPS		
Frequency response			flat ± 10 % for sine wave up to 4 Hz for minute ventilation up to 250 L/min
Resistance and back pressure		Less than 1.5 cm H_2O/L/s at flow of 12 L/s	

Definitions of abbreviations: FVC = forced vital capacity; FEV_1 = forced expiratory volume in one second; MVV = maximal voluntary ventilation.

76 cm/s). For some models, the entire system had to be tested because of the design of the spirometer.

Methods used for evaluating a spirometer's ability to measure the forced vital capacity (FVC) maneuver are an expansion of those recommended by the ATS (1) and are somewhat different from those recommended by others (4–11). There were 6 test methods available at the time of this evaluation: (*1*) subject testing using 100 people on the test spirometer and the "standard spirometer" (4–6); (*2*) simultaneous comparison of a large number of subjects with spirometers connected in series (7); (*3*) sinusoidal linearity and frequency response testing (8); (*4*) explosive decompression, using gas at an increased pressure released through an orifice (9); (*5*) hand-driven syringe, using syringes with volumes of 3 L or more, with injection of the volume at varying flow rates (10); (*6*) power driven syringes with waveform "templates." These syringes use either motor- or spring-driven plungers to produce simulated FVC waveforms (11, 12).

Each of the methods described has some limitations that may be categorized into 4 areas: (*1*) The logistical problems of getting 100 people to test multiple devices. The large number of subjects and tests needed make serious testing of multiple devices impractical. (*2*) Waveform reproducibility, whether due to subject variability or mechanical limitations, eliminates several techniques. Even with trained subjects there is a variability of ± 3 % in FVC and forced expiratory volume in one second (FEV_1) (1). Long-term variability (months or years) is an even more serious problem. (*3*) The application of waveforms that do not simulate the FVC maneuver may not be applicable to all devices. Because the testing is done to determine the ability of the device to measure

TABLE 2

SUMMARY OF FVC TEST METHODS AND THEIR LIMITATIONS

	Limitations			
	Logistics of Testing 100 People	Reproducibility Limitations	Does Not Simulate FVC or Not Applicable to All Devices	Limited No. of Waveforms
1. Subject testing of 100 Subjects	X	X		X
2. Simultaneous comparison	X	X	X	X
3. Sinusoidal			X	
4. Explosive decompression		?	?	X
5. Hand-driven syringe		X		X
6. Power-driven syringe				X

the FVC maneuver, other types of waveform testing may lead to nonlinearities and patterns that cannot be applied to all devices. (*4*) The availability of a wide variety of waveforms, because spirometers must measure over a large range of volumes and flows. It is difficult to get a representative cross section of waveforms, either with subjects or devices. The methods and their limitations are outlined in table 2.

Because of the limitations of available testing methods, an air-moving hydraulic 6-L syringe with servocontrol was designed and constructed. (Novatek Inc., Burlington, Mass., CDC/NIOSH Contract no. 210-76-0103). The air-mover consists of a cylinder and a piston that gives a displacement proportional to applied input voltage with an accuracy of ± 30 ml. The Novatek syringe accuracy was determined by measuring the physical dimensions of the cylinder and monitoring the piston displacement as a function of applied input voltage. Because the position of the piston is monitored by a linear variable differential transformer (LVDT) as part of the hydraulic feedback control system, static and dynamic displacements are accurately controlled. Comparison of actual piston displacement, measured with the LVDT output and the known input voltage, is shown in figure 1, in which it is also demonstrated that the Novatek syringe is incapable of following the input signal exactly at flow rates greater than 12.3 L/s. This velocity limitation is known as the "slew rate" limit. The slightly lower flow rates seen in the spirometer output at high flow is caused by gas compression. Even with the high flow rate and large volume of waveform no. 1, it is noteworthy that by 0.5 s the curves are superimposed. Shown in figure 2 is the excellent repeatability

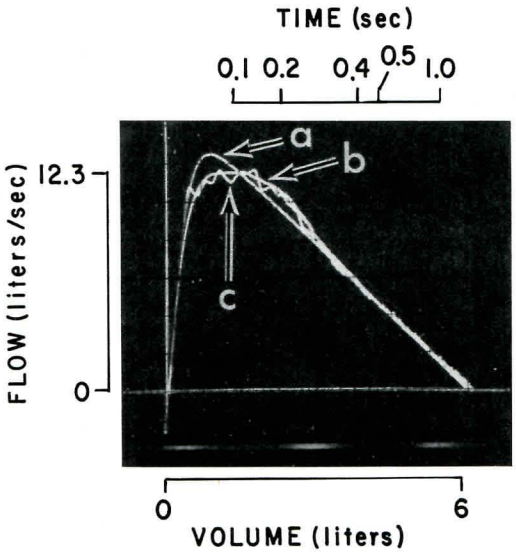

Fig. 1. Flow-volume loop recording of waveform no. 1 showing (*a*) input signal low pass filtered at 16 Hz with a 2-pole filter, (*b*) the Novatek linear variable differential transformer (LVDT) signal, and (*c*) the Ohio 840 spirometer output signal.

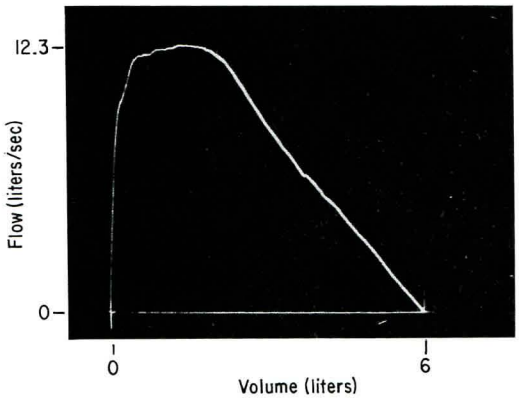

Fig. 2. Flow-volume curve for waveform no. 1 repeated 10 times showing excellent repeatability of Novatek testing syringe.

of the syringe reproducing the same waveform. Excellent results obtained from the Stead-Wells spirometer, which has been used as a "standard" spirometer, further verified the Novatek syringe accuracy.

A digital computer was programmed to generate the testing waveforms. The Novatek syringe was connected to the computer by a 12-bit digital-to-analog converter. Most of the tests were performed with the syringe filled with room air. Water-filled spirometers were tested using fully saturated air (ATPS) from the spirometer bell. A few select instruments were tested with air heated to 37° C and saturated with water vapor.

All spirometers were tested using simulated FVC signals (table 3). Each spirometer was tested by applying a single sequence of each of the 16 FVC signals. Those spirometers capable of measuring maximal voluntary ventilation were tested with sinusoidal signals (table 4). The simulated FVC signals were computer-generated "exponentials" described by the following equation (figure 3): $V(t) = FVC\,(1 - e^{-t/\tau})$, where FVC = forced vital capacity (final volume), t = time, and τ = time constant.

In addition to the mathematically derived sets of FVC test signals (signals 1 to 12, table 3), 4 signals were derived from 2 normal subjects and 2 subjects with airways obstruction (figure 4, table 3). This was achieved by digitizing the data from analog tape recordings of FVC maneuvers. These human curves were obtained from an Ohio 840 Rolling Seal spirometer.

Resistance of the spirometer to air flow was measured by inserting an 18-gauge needle at the hydraulic syringe output port. This needle was directly attached to a Validyne MP 45-1 (± 20 cm H_2O) pressure transducer. Pressure in cm H_2O was recorded using a Validyne CD-19 carrier amplifier and a Gulton Industries TR 444 Hot Stylus recorder. The resistance measurement was made only for test signal no. 1 (FVC = 6.0 L, τ = 0.4 s). Although the calculated peak flow for this signal was 15 L/s, the actual peak flow measured was 12.3 L/s because of "slew rate" limitations. Resistance was calcu-

TABLE 3

FORCED VITAL CAPACITY (FVC) TESTING SIGNALS

Test	Volume (*ml*)	Time Constant (*s*)	Values		
			Calculated Peak Flow (*L/s*)	FEV_1* (*ml*)	FEV_1/FVC (%)
1	6,000	0.4	15.00	5,507	91.8
2	6,000	0.8	7.50	4,281	71.4
3	6,000	2.4	2.50	2,045	34.1
4	5,000	0.4	12.50	4,590	91.8
5	5,000	0.8	6.25	3,567	71.4
6	5,000	2.4	2.08	1,704	34.1
7	3,500	0.4	8.75	3,213	91.8
8	3,500	0.8	4.38	2,497	71.3
9	3,500	2.4	1.46	1,193	34.1
10	1,500	0.4	3.75	1,377	91.8
11	1,500	0.8	1.88	1,070	71.3
12	1,500	2.4	0.63	511	34.1
13	4,638	Normal patient		3,788	81.7
14	5,188	Normal patient		4,075	78.5
15	2,675	Obstructed patient		1,300	48.6
16	5,613	Obstructed patient		3,413	60.8

* Forced expiratory volume in one second.

lated by dividing the peak pressure by the measured peak flow of 12.3 L/s.

All measurements and calculations were performed independently by 2 investigators. Differences greater than ± 30 ml were remeasured until agreement was obtained.

We conducted tests on several configurations of a Stead-Wells water seal spirometer and the Ohio 840 rolling seal spirometer, to help resolve the issue of whether heated and humidified air should be used for testing. The Novatek syringe was filled with 100 % humidified air and heated to 37° C before each FVC trial.

Results

The top of table 5 shows the actual FVC values followed by the maximal and minimal value (± 3 % or ± 50 ml, whichever is greater). Results for each device are then presented with differences (Δ ml) between measured and syringe volumes, with

TABLE 4

MAXIMAL VOLUNTARY VENTILATION (MVV) TEST SIGNALS

Test	Rate (*Hz*)	Tidal Volume (*ml*)	Approximate Volume in Spirometer (at End Inspiration) (*ml*)	MVV (*L/min*)
1	0.05	4,000	2,000	12.0
2	0.1	4,000	2,000	24.0
3	0.2	4,000	2,000	48.0
4	0.5	4,000	2,000	120.0
5	0.1	2,000	4,000	12.0
6	0.2	2,000	4,000	24.0
7	0.5	2,000	4,000	60.0
8	1.0	2,000	4,000	120.0
9	2.0	2,000	4,000	240.0
10	0.1	1,000	5,000	6.0
11	0.2	1,000	5,000	12.0
12	0.5	1,000	5,000	30.0
13	1.0	1,000	5,000	60.0
14	2.0	1,000	5,000	120.0
15	3.0	1,000	5,000	180.0
16	0.5	500	6,000	15.0
17	1.0	500	6,000	30.0
18	2.0	500	6,000	60.0
19	3.0	500	6,000	90.0
20	4.0	500	6,000	120.0

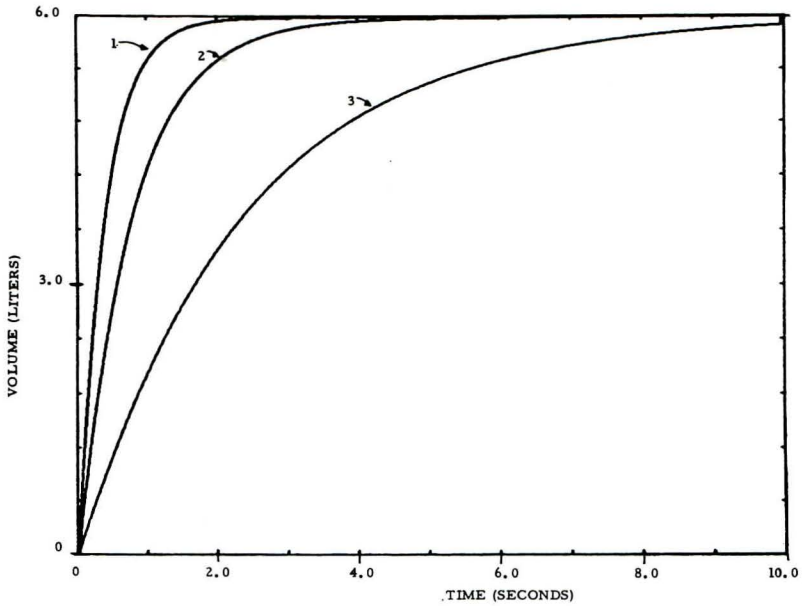

Fig. 3. Exponential forced vital capacity waveforms no. 1, 2, and 3 used for testing.

the error shown in per cent (% Δ), or in volume, if the 50-ml limit applies. The 2 columns on the right show the largest volume error and the largest percentage error, or ml error if the 50-ml limit applies. All rolling seal, bell, 2-bellows spirometers, and the Med Science spirometer were within the accuracy range recommended by the ATS for all 16 test signals. The Vitalor volume device and the Vanguard, Donti, Ultrasonic, and Pneumoscan flow devices did not meet the accuracy requirements. Three flowmeter-type spirometers (Hewlett-Packard, Cybermedic, and SRL) had difficulty in detecting the end of expiration because of "noise" in the waveform. These spirometers per-

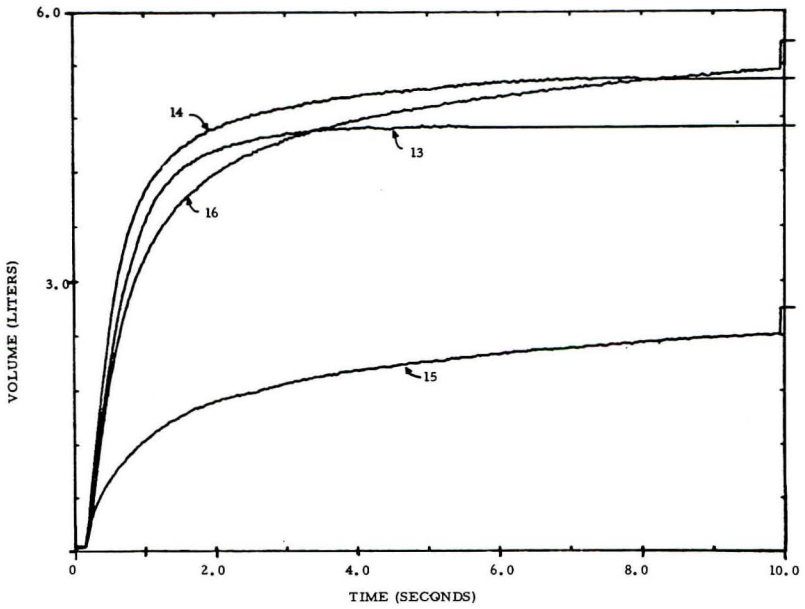

Fig. 4. Patient forced vital capacity waveforms from 2 normal subjects (*13* and *14*) and 2 patients with airway obstruction (*15* and *16*).

formed well with the exponential waveforms but had difficulty with the patient waveforms. The patient waveforms had "noise" in them as a result of the data collection and recording process. The "noise" usually triggered a premature termination of the waveform and as a consequence decreased FVC. Because of the noise in the waveform and the fact that all of these devices were tested as complete systems rather than just as transducers, the Hewlett-Packard, Cybermedic, and SRL were given qualified acceptance for measurement of FVC.

Shown in table 6 are the results for one-second forced expiratory volume (FEV_1) testing in a format similar to that of table 5. The Med Science and all the rolling seal and bell spirometers except

TABLE 5
FVC TEST RESULTS

	Test # →	1	2	3	4	5	6	7	8	9	10	11	12	13@	14@	15@	16@	Largest ΔVOL	Largest % Error or ml Error if 50 ml applies	Meet ATS Recommendations
	Actual FVC ml	6,000	6,000	6,000	5,000	5,000	5,000	3,500	3,500	3,500	1,500	1,500	1,500	4,638	5,188	2,675	5,613			
	Max ml	6,180	6,180	6,180	5,150	5,150	5,150	3,605	3,605	3,605	1,550	1,550	1,550	4,777	5,344	2,755	5,781			
Allowable	Min ml	5,820	5,820	5,820	4,850	4,850	4,850	3,395	3,395	3,395	1,450	1,450	1,450	4,499	5,032	2,595	5,445			
1	CPI	6,062	6,062	6,062	5,006	5,006	5,006	3,460	3,460	3,460	1,509	1,509	1,509	4,651	5,203	2,614	5,664			
	Rolling Seal Δ	+62	+62	+62	+6	+6	+6	−40	−40	−40	+9	+9	+9	+13	+15	−61	+51	62		
	% Δ	1.0	1.0	1.0	-	-	-	-	-	-	-	-	-	-	-	2.3	0.9		2.3	Y
2	OHIO	6,070	6,070	6,060	5,000	5,000	5,000	3,482	3,482	3,482	1,494	1,494	1,494	4,614	5,181	2,636	5,641			
	Rolling Seal	70	70	60	0	0	0	−18	−18	−18	−6	−6	−6	−24	−7	−39	+28	70		
		1.2	1.2	1.0	-	-	-	-	-	-	-	-	-	-	-	-	-		1.2	Y
3	COLLINS	6,090	6,080	6,090	5,030	5,030	5,030	3,540	3,530	3,520	1,540	1,540	1,520	4,650	5,220	2,680	5,680			
	Rolling Seal	+90	+80	+90	+30	+30	+30	+40	+30	+20	+40	+30	+20	+12	+32	+5	+67	90		
		1.5	1.3	1.5	-	-	-	-	-	-	-	-	-	-	-	-	1.2		1.5	Y
4	STEAD-WELLS	5,955	5,955	5,955	4,973	4,973	4,973	3,469	3,469	3,469	1,513	1,513	1,513	4,597	5,098	2,624	5,516			
	Bell	−45	−45	−45	−27	−27	−27	−31	−31	−31	+13	+13	+13	−41	−90	−51	+3	90		
		-	-	-	-	-	-	-	-	-	-	-	-	-	1.7	1.9	-		1.9	Y
5	COLLINS	6,018	5,976	5,850	4,973	4,931	4,868	3,489	3,448	3,406	1,525	1,504	1,442	4,597	5,182	2,675	5,558			
	13.5L Plastic	+18	−24	−150	−27	−69	−132	−11	−52	−94	+25	+4	−58	−41	−6	0	−55	150		
		-	-	2.5	-	-	2.6	-	1.5	2.7	-	-	−8ml	-	-	-	1.0		2.7	Y
6	COLLINS	6,090	6,090	5,970	5,010	5,010	5,000	3,520	3,540	3,500	1,530	1,550	1,550	4,660	5,180	2,670	5,670		−8ml	
	Survey	+90	+90	−30	+10	+10	0	+20	+40	0	+30	+50	+50	+22	−8	−5	+67	90		
		1.5	1.5	-	-	-	-	-	-	-	-	-	-	-	-	-	1.2		1.5	Y
7	COLLINS	5,976	5,955	5,934	4,962	4,942	4,931	3,500	3,469	3,458	1,525	1,510	1,515	4,597	5,192	2,643	5,600			
	9L Metal Bell	−24	−45	−66	−38	−58	−69	0	−31	−42	+25	+10	+15	−41	−16	−32	−13	69		
		-	-	1.1	-		1.4	-	-	-	-	-	-	-	-	-	-		1.4	Y
8	MED SCI	6,000	6,000	6,000	4,962	4,962	4,950	3,488	3,488	3,488	1,513	1,513	1,513	4,644	5,184	2,679	5,622			
		0	0	0	−38	−38	−50	−12	−12	−12	+13	+13	+13	+6	−4	+4	+9	50		
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		1.0	Y
9	JONES	6,013	6,013	6,013	5,009	5,009	5,009	3,540	3,540	3,540	1,500	1,500	1,500	4,718	5,289	2,614	5,715			
	Bellows	+13	+13	+13	+9	+9	+9	+40	+40	+40	0	0	0	+80	+101	−61	+102	102		
		-	-	-	-	-	-	-	-	-	-	-	-	1.7	1.9	2.3	1.8		2.3	Y
10	VITALOGRAPH	6,130	6,070	5,960	5,040	5,000	4,950	3,480	3,470	3,430	1,470	1,470	1,470	4,570	5,090	2,550	5,470			
	Bellows	+130	+70	−40	+40	0	−50	−20	−30	−70	−30	−30	−30	−68	−98	−125	−143	143		
		2.2	1.2	-	-	-	-	-	-	1.2	-	-	-	1.5	1.9	4.7	2.5		4.7	Y
11	BREON	6,060	6,060	6,060	5,020	5,020	5,000	3,530	3,530	3,530	1,570	1,570	1,510	4,690	5,230	2,730	5,700			
	Bellows	+60	+60	+60	+20	+20	0	+30	+30	+30	+70	+70	+10	+52	+42	+55	+87	87		
		1.0	1.0	1.0	-	-	-	-	-	-	+20ml	+20ml	-	1.1	-	2.1	1.5		2.1	Y
12	VITALOR							3,370	3,422	3,283	1,348	1,326							+20ml	
	Bellows							−130	−78	−217	−152	−174						217		
								3.7	2.2	6.2	−102ml	−124ml							6.2	*
13	HP	5,950	5,940	6,050	4,960	4,980	5,050	3,480	3,510	3,610	1,540	1,550	1,580	4,510	4,830	2,690	5,340		−124ml	
	Pneumotach	−50	−60	+50	−40	−20	+50	−20	+10	110	+40	+50	+80	−128	358	+15	−273	358		
		-	1.0	-	-	-	-	-	-	3.1	-	-	+30ml	2.8	6.9	-	4.9		6.9	YQ
14	CYBERMEDIC	6,230	6,030	6,040	5,090	5,000	4,960	3,520	3,500	3,470	1,510	1,550	1,380	4,520	4,890	1,950	4,640		+30ml	
	Pneumotach	+230	+30	+40	+90	0	+40	+20	0	−30	+10	+50	−120	−120	−300	−730	−970	970		
		3.83	-	-	1.80	-	-	-	-	-	-	-	−70ml	2.5	5.7	27.1	17.3		27.1	YQ
15	LIFE SUPPORT	6,000	5,859	5,564	4,974	4,872	4,615	3,449	3,390	3,128	1,500	1,462	1,231	4,603	5,154	-	5,538		−70ml	
	EQUIP. Pneumotach	0	−141	−436	−26	−128	−385	−51	−110	−372	0	−138	−269	−35	−34	-	−75	436		
		-	2.3	7.3	-	2.6	7.7	1.5	3.1	10.6	-	−88ml	−219ml	-	-	-	1.3		10.6	*
16	SRL	5,820	6,000	6,040	4,880	4,980	4,900	3,480	3,500	3,410	1,540	1,530	1,540	4,800	5,450	2,950	6,360		−219ml	
	Hot Wire	−180	0	+40	−120	−20	−100	−20	0	−90	+40	+30	+40	+162	+262	+275	747	747		
		3.0	-	-	2.4	-	2.0	-	-	2.6	-	-	-	3.49	5.05	10.3	13.3		13.3	YQ
17	DONTI	5,239	5,484	5,337	4,502	4,535	4,387	3,241	3,208	3,110	1,391	1,342	1,244	4,109	4,338	1,506	4,256			
	Hot Wire	−761	−516	−663	−498	−465	−613	−259	−292	−390	−109	−158	−256	−529	−850	−1,169	−1,357	1,357		
		12.7	8.6	11.1	10.0	9.3	12.3	7.4	8.3	11.1	−59ml	−108ml	−206ml	11.4	16.4	43.7	24.2		43.7	*
18	KL ENGINEERING	5,800	5,800	5,800	4,900	4,800	4,800	3,400	3,400	3,400	1,600	1,500	1,300	5,100	6,000	4,200	7,900		252ml	
	Rotameter	−200	−200	−200	−100	−200	−200	−100	−100	−100	+100	0	−200	462	812	1,525	2,287	2,287		
		3.3	3.3	3.3	2.0	4.0	4.0	2.9	2.9	2.9	2.9	-	−150ml	10.0	15.7	57.0	40.7		57.0	*
19	PROTOTYPE	6,310	6,150	6,000	5,150	5,070	5,040	3,600	3,480	3,430	1,510	1,490	1,340	4,660	5,000	1,960	5,010		−150ml	
	Ultrasonic	+310	+150	0	+150	+70	+40	+100	−20	−70	+10	−10	−160	+22	−188	−715	−563	715		
		5.2	2.5	-	3.0	1.4	-	2.9	-	2.0	-	-	−110ml	-	3.6	26.7	10.0		26.7	*
																			−110ml	

@ Tests from magnetic tape recordings of human data. Contained "noise" which may not be representative of actual patient waveform (see text).
Y Yes—met recommendations.
YQ Qualified yes—meet ATS recommendations.
* Does not meet ATS recommendations.

TABLE 6
FEV, TEST RESULTS

	Test # →	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	Largest ΔVOL	Largest % Error	Meet ATS Rec.
	Actual FEV, ml	5,507	4,281	2,045	4,590	3,567	1,704	3,213	2,497	1,193	1,377	1,070	511	3,788	4,075	1,300	3,413			
	Max ml	5,672	4,409	2,106	4,728	3,674	1,755	3,309	2,572	1,243	1,427	1,120	561	3,902	4,197	1,350	3,515			
Allowable	Min ml	5,341	4,152	1,984	4,452	3,460	1,653	3,117	2,422	1,143	1,327	1,020	461	3,674	3,953	1,250	3,311			
1	CPI	5,497	4,221	2,037	4,540	3,509	1,669	3,166	2,435	1,141	1,362	1,055	491	3,804	4,086	1,257	3,399			
	Rolling Seal Δ	−10	−60	−8	−50	−58	−35	−47	−62	−52	−15	−15	−20	+14	+11	−43	−14	62		
	% Δ	-	1.4	-	-	1.6	-	-	2.5	−2m	-	-	-	-	-	-	-		2.5	Y
2	OHIO	5,470	4,193	2,060	4,518	3,494	1,663	3,173	2,446	1,145	1,361	1,048	494	3,711	4,048	1,252	3,373		−2 ml	
	Rolling Seal	−37	−88	+15	−72	−73	−41	−40	−51	−48	−16	−22	−17	−77	−27	−48	−40	88		
		-	2.1	-	1.6	2.0	-	-	2.0	-	-	-	-	2.0	-	-	-		2.1	Y
3	COLLINS	5,480	4,240	2,080	4,550	3,520	1,660	3,180	2,480	1,150	1,390	1,060	450	3,800	4,080	1,280	3,400			
	Rolling Seal	−27	−41	+35	−40	−47	−44	−33	−17	−43	+13	−10	−61	+12	+5	−20	−13	61		
		-	-	-	-	-	-	-	-	-	-	-	−11ml	-	-	-	-		−11ml	Y
4	STEAD-WELLS	5,516	4,263	2,090	4,555	3,573	1,731	3,197	2,445	1,170	1,337	1,045	543	3,800	4,072	1,336	3,362			
	Bell	+9	−18	+45	−40	+6	+27	−16	−52	−23	−40	−25	+32	+12	−3	+36	−51	52		
		-	-	-	-	-	-	-	2.1	-	-	-	-	-	-	-	1.5		2.1	Y
5*	COLLINS	5,558	4,304	2,006	4,576	3,531	1,672	3,197	2,445	1,149	1,379	1,045	522	3,782	4,095	1,295	3,364			
	13.5L Plastic	+51	+23	−39	−14	−36	−32	−16	−52	−44	+2	−25	+11	−6	+20	−5	−49	52		
		-	-	-	-	-	-	-	2.1	-	-	-	-	-	-	-	-		2.1	Y
6	COLLINS	5,490	4,190	2,010	4,600	3,530	1,660	3,230	2,490	1,180	1,390	1,060	520	3,830	4,140	1,330	3,480			
	Survey	−17	−91	−35	+10	−37	−44	+17	−7	−13	+13	−10	+9	+42	+65	+30	+67	91		
		-	2.1	-	-	-	-	-	-	-	-	-	-	-	1.6	-	2.0		2.1	Y
7	COLLINS	5,265	4,053	2,048	4,471	3,406	1,672	3,239	2,528	1,160	1,421	1,081	522	3,871	4,210	1,295	3,479			
	9L Metal Bell	−242	−228	+3	−119	−161	−32	+26	+31	−33	−44	+11	+11	+83	+135	−5	+66	242		
		4.4	5.3	-	2.6	4.5	-	-	-	-	-	-	-	2.2	3.3	-	1.9		5.3	*
8	MED SCI	5,463	4,263	2,075	4,538	3,525	1,688	3,163	2,463	1,163	1,363	1,063	513	3,812	4,102	1,300	3,438			
		−44	−18	+30	−52	−42	−16	+50	−34	−30	−14	−7	+2	+24	+27	0	+25	52		
		-	-	-	1.1	-	-	-	-	-	-	-	-	-	-	-	-		1.1	Y
9	JONES	5,499	4,093	1,983	4,567	3,486	1,629	3,155	2,464	1,142	1,364	1,083	511	3,756	4,069	1,262	3,389			
	Bellows	−8	−188	−62	−23	−81	−75	−58	−33	−51	−33	+12	0	−32	−6	−48	24	188		
		-	4.4	3.0	-	2.2	4.4	1.8	-	1ml	-	-	-	-	-	-	-		4.4	Y
10	VITALOGRAPH	5,650	4,390	2,090	4,670	3,570	1,700	3,200	2,480	1,190	1,350	1,050	540	3,790	4,100	1,250	3,380		−1 ml	
	Bellows	+143	+109	+45	+80	+3	+4	+13	−17	−3	27	+20	+29	+2	+25	−50	−33	143		
		2.6	2.5	-	1.7	-	-	-	-	-	-	-	-	-	-	-	-		2.6	Y
11	BREON	5,530	4,300	2,050	4,620	3,550	1,700	3,240	2,530	1,200	1,420	1,100	520	3,860	4,100	1,300	3,460			
	Bellows	+23	+9	+5	30	−17	−4	27	33	+7	-	-	+9	+72	+25	0	+47	47		
		-	-	-	-	-	-	-	1.3	-	-	-	-	1.9	-	-	1.4		1.9	Y
12	VITALOR							3,150	2,435	1,130	1,283	913	478							
	Bellows							−63	−62	−63	−94	−157	−33					157		
								2.0	2.5	−13ml	−44ml	−107ml	-						2.5	*
13	HP	5,390	4,150	2,040	4,490	3,460	1,670	3,140	2,440	1,170	1,390	1,080	530	3,690	3,980	1,270	3,330		−107ml	
	Pneumotach	−117	−131	−5	−100	−107	−34	−73	−57	−23	+13	+10	+19	−98	−95	+30	−83	131		
		2.1	3.1	-	2.2	3.0	-	2.3	2.3	-	-	-	-	2.6	2.3	−30	2.4		3.1	Y
14	CYBERMEDIC	5,680	4,210	2,030	4,620	3,470	1,650	3,190	2,430	1,160	1,390	1,080	530	3,750	4,100	1,290	3,380			
	Pneumotach	173	−71	+15	30	−97	−54	−23	−67	−33	+13	+10	+19	−38	+25	−10	−33	173		
		3.1	1.7	-	-	2.7	3.2	-	2.7	-	-	-	-	-	-	-	-		3.2	Y
15	LIFE SUPPORT	5,447	4,169	2,006	4,533	3,451	1,622	3,638	2,455	1,173	1,367	1,042	501	5,707	4,022	-	3,234			
	EQUIP. Pneumotach	−10	−112	−39	−57	−126	−82	+425	−42	−20	−10	−28	−10	−81	−53	-	−89	425		
		-	2.6	-	1.2	3.5	4.8	13.2	-	-	-	-	-	2.1	1.3	-	2.6		13.2	*
16	SRL	5,290	4,200	2,100	4,450	3,570	1,700	3,150	2,440	1,160	1,340	2,050	491	3,795	4,040	1,317	3,415			
	Hot Wire	−217	−81	+55	−144	+3	−4	−58	−57	−33	−37	−20	−20	+7	−35	+17	+2	144		
		3.9	1.9	2.7	3.1	-	-	1.8	2.3	-	-	-	-	-	-	-	-		3.9	Y
17	DONTI	4,813	4,797	1,899	4,125	3,258	1,539	2,979	2,292	1,064	1,310	1,015	507	3,503	3,765	1,211	3,110			
	Hot Wire	−694	+516	−146	−465	−309	165	−234	−205	129	−67	−55	−4	−285	−310	89	303	694		
		12.6	12.1	7.1	10.1	8.7	9.7	7.3	8.2	−79ml	−17ml	−5ml	-	7.5	7.6	−39ml	8.9		12.6	*
18	KL ENGINEERING	5,200	4,000	2,000	4,300	3,300	1,600	3,000	2,300	1,100	1,400	1,000	500	3,600	-	1,300	3,200		−39ml	
	Rotameter	−307	−281	−45	−290	−267	−104	−213	−197	−93	−123	−70	−11	−188	-	−213	−213	307		
		5.6	6.6	-	6.3	7.5	6.1	6.6	7.9	−43ml	-	−20ml	-	5.0	-	6.2	6.2		7.9	*
19	PROTOTYPE	DID NOT RUN																	−43ml	
	Ultrasonic																			

one met the criteria for FEV_1 accuracy. Only the 1961 model Collins 9-L metal bell spirometer, which is no longer marketed, did not meet the accuracy criteria. Of the bellows spirometers, only the Vitalor failed to meet the FEV_1 criteria. The Vitalograph and Breon required "back extrapolation" and adjustment of the 1-s time line before they met the accuracy requirement, because neither device had the paper moving before the exhalation began, as required by the ATS recommendations. Flowmeter-type spirometers, Hewlett-Packard, SRL, and Cybermedic met the criteria.

All of the results are summarized in table 7. Six spirometers did not have a recorder or did not record the FVC for the recommended 10 s. Only 2 devices, the 9-L Collins metal bell and the Vitalor, had excessive resistance. Of the 13 devices capable of measuring MVV, only the 9-L Collins metal bell and 2 bellows spirometers failed to stay within the ± 10 % limits for the signals outlined in table 4.

The effects of heated and humidified air on volume spirometers were observed to determine how rapidly warm humidified gases were cooled. When the Stead-Wells spirometer was tested with heated (37° C) and humidified air (100 %) at the fastest rate possible (12.3 L/s) for a 6-L volume,

TABLE 7
SUMMARY OF RESULTS

	Brand Model	Year Manufactured	Type	Device Tested	FVC Accuracy	FVC Time Base	FEV_1 Accuracy	FEV_1 Resistance $cmH_2O^1/(L/s)$ @ 12L/s	MVV Met Criteria	Recorder Type	Recorder Paper Speed mm/s	Recorder Volume 3 Sensitivity mm/L
1	CPI 220	1977	Volume Rolling Seal	Spirometer with our X-Y recorder	Y	YR	Y	0.72	Y	VT	25.4 YR	YR
2	OHIO 840	1976	Volume Rolling Seal	Spirometer with our X-Y recorder	Y	YR	Y	0.54	Y	VT	25.4 YR	29.5 YR
3	COLLINS 06500	1977	Volume Rolling Seal	Spirometer with our X-Y recorder	Y	YR	Y	0.70	Y	VT	25.4 YR	29.5 YR
4	COLLINS P1400 Stead-Wells 06041	1972	Volume Bell	Spirometer with self contained recorder	Y	Y	Y	1.18	Y	VT	32.0	38.7
5	COLLINS P1300 13.5 Liter 06003	1972	Volume Bell (Plastic)	Spirometer with self contained recorder	Y	Y	Y	0.69	Y	VT	32.0	38.7
6	COLLINS P1350 Survey 06031	1977	Volume Bell	Spirometer with self contained recorder	Y	Y	Y	1.10	Y	VT	32.0	38.7
7	COLLINS 9L P900 (Old) Metal Bell	1961	Volume Bell	Spirometer with self contained recorder	Y	Y	N*	1.84*	N*	VT	32.0	77.3
8	MED SCIENCE 570	1977	Volume	Spirometer with our X-Y recorder	Y	YR	Y	0.50	Y	VT VF	25.4 YR	23.7 YR
9	JONES Pulmonar II	1970	Volume Bellows	Spirometer with self contained recorder	Y	Y	Y	1.16	N*	VT	25.4	15.9
10	VITALOGRAPH 20.00	1977	Volume Bellows	Spirometer with self contained recorder	Y	6.0*	YQ (BE)	0.92	N*	VT	30.0 6 sec only*	30.0
11	BREON 2400	1977	Volume Bellows	Spirometer with self contained recorder	Y	6.0* 12.0	YQ (BE)	0.62		VT	25.4 or 12.7*	17.6
12	VITALOR	1977	Volume Bellows	Spirometer with self contained recorder	N*	6.0*	N*	2.40*		VT	20.0	20.4
13	HEWLETT-PACKARD 47804A	1977	Flow/Bi-directional Pneumotach	Digital System Complete	YQ	Y	Y	0.35	Y	VT VF	20.0	15.0
14	CYBERMEDIC MEDISTOR	1977	Flow/Bi-directional Pneumotach	Digital System Complete	YQ	YQ	Y	0.16		None*	None*	None*
15	LIFE SUPPORT EQUIP. VANGUARD DS500	1977	Flow/Bi-directional Pneumotach	Digital System Complete	N*	N*	N*	0.20		VT	20.0	10.0
16	SRL M-10	1977	Flow/Uni-directional Hot Wire	Digital System Complete	YQ	Y	Y	1.20	Y	VT VF	25.4 YR	29.5 YR
17	DONTI PA 75	1977	Flow/Uni-directional Hot Wire	Digital System Complete	N*	N*	N*	0.60		VT	25.4	15.8
18	KL ENGINEERING PNEUMOSCAN	1977	Flow/Uni-directional Rotameter	Digital Display Only	N*	N*	N*	1.36	Y	VT	20.0	10.0
19	PROTOTYPE Not Marketed	1977	Flow/Uni-directional Ultrasonic	Digital Display	N*			1.04		VT VF	25.4 YR	20.0
ATS Recommendations					±3% or ± 50 ml Table 4	10 s at 2 cm/s	±3% or ± 50 ml Table 5	Less than 1.5	See Table 1		20 mm/s	10 mm/L

Y = Yes—met recommendations.
YR = Yes but dependent on external recorder.
N = No—did not meet recommendations.
* = Does not meet ATS recommendations.
YQ = Qualified yes—see text.
VT = Volume time record.
VF = Volume flow record.
BE = Back extrapolation.
Blank = Not available on instrument or did not run.

there was an overshoot (over-reading); this amounted to 200 ml when 2 input hoses were used and was 250 ml when 1 hose was used. As the air cooled to room temperature and the water vapor "rained" out, the volumes corrected by the BTPS factor were within 1 % of the known volume. The time-constant of this cooling was approximately 0.9 s for the 2-hose system and 1.4 s for the single-hose system. Maximal overshoot for the fastest FVC signals (nos. 1, 7, and 10) was then observed on the Stead-Wells and the Ohio 840 spirometer. The maximal overshoot was with waveform no. 1 and was 100 ml (1.7 %); this occurred at about 1.5 s. The largest FEV_1 overshoot for each of the 3 curves was 2.0 %.

Our observations indicate that gas entering volume-measuring devices cools very rapidly and that maximal errors in FEV_1, caused by failure of the gas to cool instantaneously, are approximately 2 %. We also noticed that cooling was more rapid and overshoot was diminished if both tubes of the Stead-Wells were connected or a long tube was attached to the Ohio spirometer.

Discussion

Several investigators have studied the perfor-

mance of spirometers (5–12), and medical device legislation has been enacted to protect consumers (13). Using the ATS criteria and an expansion of the recommended testing waveforms (1), we evaluated 19 commercially available spirometers.

Testing with the expanded waveform set revealed that some spirometers marketed in October 1977 had marginal or poor performance. It was noteworthy (tables 5 and 6) that even if the accuracy criteria for FVC and FEV_1 had been relaxed to ± 5 %, no additional spirometers would have met the requirements.

We have recommended to several manufacturers that corrections be made in their spirometers, and most have responded positively. Manufacturers should now be encouraged to meet the ATS recommendations as a minimal goal.

Spirograms with "false" starts and extended expirations due to airway obstruction caused difficulty in some spirometer systems. The Vitalograph and Breon required back extrapolation beyond the "zero" timeline before they met FEV_1 accuracy criteria. All of the spirometers that were tested as complete systems (devices 13, 14, 15, 16, 17, 18, and 19) also had problems in recording correct FVC, especially on waveforms from patients with airway obstruction. The test methods and waveforms proposed by the ATS are adequate for comparing spirometers; however, they are not comprehensive enough to qualify the spirometers. Therefore, we recommend that additional patient waveforms, which would test the adequacy of beginning and end of test criteria, be added to the exponential waveforms suggested by ATS. These waveforms will not only test the spirometer as a transducer, but will also evaluate the pattern recognition algorithms of spirometer systems.

The ATS recommendations did not specify whether testing should be done with room air or heated and humidified air. Based on our experience, we advise that testing be done with room air. We recommend that manufacturers of volume devices install thermometers in their spirometers, because a 1 % error in volume results for each 2° C of temperature change. In addition, flowmeter manufacturers are encouraged to provide correction factors that will permit testing with room air.

From our testing experience and results, we drew the following conclusions: (*1*) the spirometry criteria recommended by ATS are not too severe and are readily applicable to existing spirometers; (*2*) many commercially available spirometers currently meet the ATS recommendations; (*3*) most volume-measuring devices met the ATS recommendations, whereas most flow devices had difficulties. This resulted from the fact that (*a*) testing was primarily for volume measures (FVC and FEV_1), and (*b*) all flow devices were tested as complete systems, whereas with the volume devices only the transducer was tested; (*4*) the ATS recommendations will not have a major economic impact because many devices that meet the criteria cost less than $1,000 (14); (*5*) the testing methods established by the ATS are a good starting point but are inadequate for testing spirometry systems. A spirometer system includes the spirometer transducer *and* the recording or computer system; (*6*) testing of volume spirometers with heated and humidified air shows that rapid cooling occurs and this is not of major concern in spirometer testing; (*7*) testing with room air is simple and adequate for spirometer evaluation; (*8*) finally and probably most important, results obtained on any spirometer meeting the ATS requirements are interchangeable. So long as the device meets the requirements and methods of testing are as outlined by the ATS, it makes no difference which spirometer is used.

References

1. Gardner RM et al. ATS statement. Snowbird workshop on standarization of spirometry. Am Rev Respir Dis 1979; 119:831–8.
2. Permutt S, chairman. Office spirometry in clinical practice. Chest 1978; 74:298.
3. Baker CD, Couvillon LA Jr, Yates WG. An evaluation of safety and performance characteristics of electronic spirometers; final report Utah Biomedical Test Laboratory, TR 165-007, 31 January 1976, prepared for the Food and Drug Administration, Contract 223-74-5253.
4. Morgan KC, chairman (committee recommendations). The assessment of ventilatory capacity. Chest 1975; 67:95–7.
5. Glindmeyer HW, Anderson ST, Diem JE, Weill H. A comparison on Jones and Stead-Wells spirometers. Chest 1978; 73:596–602.
6. Hudson LD, Petty TL, Baidwan B, Stark K. Clinical evaluation of new office spirometer. JAMA 1979; 240:2754–5.
7. Shanks DE, Morris JF. Clinical comparison of two electronic spirometers with a water-seal spirometer. Chest 1976; 69:461–6.
8. McCall CB, Hyatt RE, Noble FW, Fry DC. Harmonic content of certain respiratory flow phenomena in normal individuals. J Appl Physiol 1957; 10:215–18.
9. Ferris BG. Epidemiology standarization project: recommended standardized procedure for

pulmonary function testing. Am Rev Respir Dis 1978; 118 (Suppl 2:55–88).
10. Fitzgerald MX, Smith AA, Gaensler EA. Evaluation of "electronic" spirometers. N Engl J Med 1973; 289:1283–8.
11. Clausen JL, Tisi GM, Moser KM. Methods of evaluation of accuracy of spirometers and pneumotachographs, Med Instrum 1974; 8:117.
12. Bouhuys A, Virgulto JA. Calibration of flow-volume curves. Lung 1978; 155:123–30.
13. Public Law 94–295, "Medical Device Amendment of 1976."
14. Wickware P. Is spirometry practical in your office? Patient Care 1978; 12:136–60.