Testing Spirometers – ATS Standards*

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As a follow-up to the Snowbird Workshop on the Standardization of Spirometry, 35 manufacturers were invited to send spirometers for testing. From this invitation we received and tested 17 devices for compliance with the American Thoracic Society draft spirometer standards. There were two purposes in testing: (*1*) To determine if spirometers could be tested with the general test signals proposed in the standard. (*2*) To establish whether devices currently on the market would be able to meet the specifications or if the specifications were too stringent and none of the devices would meet them. These results are not to be used by manufacturers as a certification by the American Thoracic Society, the federal government, or others that their device meets the American Thoracic Society specifications.

Personal experience, literature review, and discussion at the Snowbird Workshop indicated that testing spirometers would be a difficult task. To make the testing as simple as possible we decided to test only the spirometer itself rather than entire systems. Because spirometers are generally used in systems, the systems will also need to be tested eventually.

A mechanical stimulator of some kind is necessary to provide reproducible test signals because patients and even trained subjects have more variability than the 3 per cent error desired and because subjects are not readily available to simulate a variety of pathologic conditions. Therefore, the air moving syringe system designed by Novatek Inc. and constructed under an NIOSH contract was used. The air mover consists of a cylinder and a piston, which gives a displacement proportional to applied input voltage with an accuracy of approximately ± 30 ml. Accuracy measurements were determined by measuring the physical dimensions of the cylinder and monitoring the piston displacement as a function of applied input voltage. The linearity of this hydraulically driven system is limited only by the displacement transducer, which measures actual piston displacement for use in the feedback control system. A digital computer was then programmed to generate the waveforms outlined in table 1. The air moving system was connected to the computer through a 12-bit digital-analog converter. Test signals 1 through 12 are exponential signals generated mathematically by the computer with the volumes and time constants indicated. Signals 13 through 16 are for human subject data, which were digitized from an analog tape recording of actual patient data from the volume spirometer. These final 4 test signals are representative of a varity of patient types, and the "artifact" in the human data provided a more realistic testing signal. Tests 15 and 16 obtained from obstructed patients were especially demanding and actually exceeded the requirements of the ATS draft standards. One of the tests required an expiration time of 17 sec. In fairness to the manufacturers whose devices were tested and in the spirit of investigative science, it must be stated that the testing methods and signals are not perfect; however, they were uniformly applied to each device.

Preliminary results are shown in table 2, which shows results of forced vital capacity (FVC) testing. Specifically reported are resistance, FVC and 1-sec forced expiratory volume. Not reported are instantaneous flow and results from maximal voluntary ventilation testing. Of the devices tested, 8 met the

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specifications for FVC, 2 were borderline, and 7 did not meet the specifications. We invited manufacturers to retest their instruments if they had not met the specifications. Some of the manufacturers took this opportunity. As a result of this retest, some devices moved from the "no" category to the "yes" category.

The preliminary results presented in table 2 show that (*1*) the ATS specifications are reasonable and can be met by many current spirometers; (*2*) testing of spirometers can be carried out to the accuracy needed to verify that the instrument meets ATS specifications. Note that most volume measurement instruments had little difficulty meeting the ATS specifications, which are in this case the volume specifications, whereas most flow-measuring devices had difficulty. It is possible that the flow-measuring devices would have outperformed the volume devices if flow measurements had been carefully tested. The question of how to test for flow characteristics and resolve the complex, dynamic characteristics of flow signals requires further study.

Miscellaneous Observations during Testing

The problems of temperature and humidity and their effect on the results are extremely important with all of the devices. For the volume-measuring device, temperature measurement and equilibration together with compensation for water vapor is extremely important. Based on the testing results, we recommend that every spirometer be equipped with a thermometer. The subtle differences in testing of dry versus wet spirometers within room air can cause errors of 1 to 2 per cent. Testing with heated and humidified air driven into a volume spirometer indicated time constants varying from 4 and one-half sec to 15 sec and volume errors of approximately 80 ml in a simulated 6-liter forced expiration. The shorter time constants were with longer interconnecting tubing and the longer time constants were with shorter interconnecting tubing, indicating that the most rapid heat loss is in the tubing.

Flow sensors that are both temperature and humidity sensitive were especially difficult to test and evaluate. These problems are also manifested in clinical situations where patients may not be at 37° C but may be 38 or 36° C.

TABLE 1

Forced Vital Capacity (FVC) Testing Signals

Test	Volume *(ml)*	Time Constant *(sec)*	Values: Calculated Peak Flow *(liter/sec)*	Values: 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

*1-sec forced expiratory volume.

TABLE 2

*Preliminary Findings of Spirometer Testing**

Device No.	Type	Meets ATS FVC, FEV_1 Specs	Resistance *cm H_2O liter/sec @ 12.0 liter/sec)*	FVC Maximal Error *(%)*	FEV_1 Maximal Error *(%)*
1	Volume	Yes	0.72	1.2	1.8
2	Volume	Yes	0.54	1.5	1.4
3	Volume	Yes	0.70	1.5	2.6
4	Volume	Yes	0.92	1.7	2.7
5	Volume	Yes	0.64	2.6	2.4
6	Volume	Yes? ?	1.84	1.7	4.5
7	Volume	Yes	0.50	1.0	2.2
8	Volume	Yes?	1.16	3	~4
9	Volume	No	0.92	6.2	11.6
10	Volume	No	2.4	10	15
11	Flow	No	1.04	~10	~10
12	Flow	Yes	1.20	3	3
13	Flow	No	0.60	~10	~7
14	Flow	Yes	0.35	~3	3
15	Flow	No	0.16	6.2 → 29	3.8 → 10.3
16	Flow	No	0.20	0 → 7.7	0 → 5.7
17	Flow	No	1.36	Up to 60	7.8
		8 Yes 2 Yes? 7 No			

Definition of abbreviations: FVC = forced vital capacity; FEV_1 = 1-sec forced expiratory volume.

*Results are reported in abbreviated form because for each device at least 16 tests were run. Maximal errors are indicated in most cases, but in some cases ranges of error are given to show variability. Because testing and measurement errors may result from our errors we have given the device the benefit of the doubt in some cases.

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The International Union Against Tuberculosis (IUAT) invites those interested in presenting papers at its XXIV Conference in Brussels, Belgium, September 3-9, 1978, to submit abstracts of their proposed presentations.

The Conference will include four themes. The first theme, tuberculosis, includes these topics: (*1*) Epidemiology, natural history, surveillance; (*2*) Immunology and bacteriology: Case finding and diagnostic methods; (*3*) Chemotherapy: Controlled clinical trails; (*4*) Prevention: Chemoprophylaxis and BCG; (*5*) Socio-economic aspects.

The second theme covers these topics: (*1*) Chronic obstructive lung disease: (bronchitis, emphysema, asthma); (*2*) Lung fibrosis; (*3*) Pathogenesis and pathophysiology; (*4*) Environmental factors: tobacco, smoking, air pollution, occupational exposure; (*5*) Host factors: Lung defense mechanisms, genetics; (*6*) Screening tests and new diagnostic methods; (*7*) Treatment and rehabilitation; (*8*) Prevention: Public health and community aspects.

Leprosy is the third theme; the topics are epidemiology, chemotherapy, and combined programs for tuberculosis, leprosy, and other diseases. The fourth theme is primary health care—promotion of health, training.

IUAT requests you to write your abstract in English or French, limiting it to 300 words and submit five copies in time for arrival September 30, 1977. Send abstracts to International Union Against Tuberculosis, 3 Rue Georges Ville, 75 116 Paris, France.

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