From: COMPUTERS IN CRITICAL CARE AND PULMONARY MEDICINE, Vol. 3
Edited by Sreedhar Nair, Omar Prakash, and Richard P. Imbruce
(Plenum Publishing Corporation, 1983)

SIGNAL PROCESSING FOR COMPUTERIZED SPIROMETRY

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Spirometry is one of the most important and frequently used diagnostic tests of pulmonary function. It is performed with relatively simple instruments and involves straightforward techniques. In 1846 Hutchinson described the first spirometer and established reference or "normal" values for test populations[1]. The Hutchinson device was a counterweighted water seal spirometer which measured only the vital capacity. Volume was measured on a graduate scale at the side of the instrument, temperature was also measured so that corrections for ambient conditions could be made. It was not until the late 1940's and early 1950's that the timed vital capacity, now known as the forced vital capacity maneuver (FVC), came into general use [2,3]. At that time the water seal spirometer was still the most popular device, although it had dynamic response limitations. Stead and Wells[4] outlined these limitations and their investigations eventually led to the development of the Stead-Wells spirometer[5]. Other devices developed and marketed since that time include the wedge spirometer, the rolling seal spirometer, the bellows spirometer, and a variety of flow measuring devices which use pneumotachometers. Each of these instruments has a characteristic to recommend it such as small size, low cost, operating convenience, etc.

The most common parameters measured from the spirogram are[6]

FVC (Forced Vital Capacity)

The maximum volume of air exhaled from the point of maximum inspiration performed with a maximally forced expiratory effort.

FEV_1 (Forced Vital Capacity in One Second)

(FEV_1 continued) The volume of air exhaled in one second during the performance of the forced vital capacity

$\underline{FEF_{25-75\%}}$ Mean forced expiratory flow during the middle half of the FVC.

Other flow measures are sometimes considered, especially those derived from flow-volume curves[7]. For purposes of this discussion, however, only the three parameters described above will be considered.

Several attempts have been made to standardize spirometric terminology and the methods of measurement. Standards have been written for equipment as well as for operational techniques[8,9,10]. The most comprehensive of these recommendations emerged from the American Thoracic Society's Snowbird Conference[10]. At this workshop several recommendations were made to ensure equipment accuracy. In addition, standardized methods for measurement of start and end of test times, as well as standards for minimal patient reproducibility, were also recommended. Some of the recommendations are summarized in Table 1.

Table 1.
ATS Recommendations - Summary

Specification	FVC	FEV_1
Range Volume/Accuracy BTPS	7 L ±3% of Reading or ±50 ml, whichever is greater for flows of 0 to 12 L/sec	7 L ± 3% reading or ±50 ml. whichever is greater for flows of 0 to 12 L/sec
Recorder	Volume-Time or Flow-Volume	
Time Base	Volume-Time 10 sec at paper speed of at least 2 cm/sec	
Sensitivity	Volume: at least 10 mm/L BTPS Flow: at least 4 mm(L/sec)BTPS	

Also emanating from the Snowbird Workshop were methods to test equipment which were applicable to all existing spirometers. Up to that time there were six test methods in common use. The first used

100 subjects who breathed into a "gold standard" device, then the subjects breathed into the spirometer being tested. This method suffered from logistical difficulties, problems of patient reproducibility, and the fact that there were a limited number of waveform varieties. The second method connected two devices in series (device under test and the "gold standard") and allowed simultaneous comparison of both records. This method had the same limitations as did the 100-subject comparison test and was not applicable to many spirometers. The third method used sine wave testing. This test did not have application to all of the devices and had some severe theoretical limitations because sine waveforms are not identical to the forced spirogram[14]. The fourth procedure used explosive decompression. Exponential waveforms were generated which had the same form as the FVC waveform, but did not have characteristics at the beginning and end of the test which are typical of patients. This method also had limited waveform reproducibility[11,12]. The fifth method using a precision calibrated syringe, had the advantage of being inexpensive, but it failed to reproduce FVC waveforms. The sixth method used a motorized syringe with a limited number of waveforms[13].

Because of the limitations of each of the available testing methods an air-moving 6 liter hydraulic servo-controlled syringe was obtained to test spirometers[14]. A digital computer was programmed to generate testing waveforms using actual patient waveforms and simulated exponential waveforms. Nineteen different spirometers were tested using this computer-controlled hydraulic syringe. Results are summarized in Table 2.

Table 2. Summary of Spirometry Testing Results (Adapted from(14)

Volume Devices (12)	OK (10/12)	BAD (2/12)
Rolling Seal	3	0
Bell	3	1
Wedge	1	0
Bellows	3	1
Flow Devices (7)	3/7	4/7
Pneumotach	2	1
Hot Wire	1	1
Other	0	2
Total	13/19	6/19

This study showed that 13 out of 19 spirometers in the marketplace met the ATS criteria and that the majority of these were volume-measuring devices. One of the complicating factors of this testing was the assessment and evaluation of different elements in a spirometer system (See Figure 1). Some devices contained only a volume measuring transducer and self-contained recorder while other devices had waveform processing hardware and/or software. Since with some devices it was impossible to separate the transducer from the computer processing better testing methods were sought. Since the recommendations of the American Thoracic Society (ATS)[10] and the Association for the Advancement of Instrumentation (AAMI)[15] are based on performance requirements representative patient FVC waveforms were selected[16]. Twenty-four standard waveforms have been selected which have known spirometric parameters. These 24 waveforms are now available for testing and qualifying spirometers[16].

At the Snowbird Conference, and subsequently at AAMI meetings[15] where standards for spirometers were under discussion, the committee was tempted to establish strict engineering specifications. Specification of design parameters such as sampling rates, A-to-D conversion resolution, and pattern recognition criteria could have been outlined. However, in order to encourage innovation and motivate improvement of devices, the set of 24 standard patient waveforms was adopted.

Based on these standard test waveforms, the criteria of the Snowbird Workshop and our own testing experience several things have become apparent. (1) The ATS recommended methodology for determination of "time zero" of back extrapolation is essential. Smith and Gaensler have shown that by using this method the FEV_1 is approximately 180 ml greater than when the Kory method is used[17]. Back extrapolation determination of "time zero" is demonstrated in Figure 2. The extrapolated volume should be less than 10% of the forced vital capacity to qualify as a good test[10]. (2) The accuracy of a spirometer system depends on the resolution and linearity of the entire system. Figure 3 shows a typical rolling seal spirometer with potentiometer attached. The voltage output from the potentiometer would normally go to an Analog to Digital(A-to-D) converter for computer sampling. The ability of the system to determine the FVC accurately then depends on the linearity and accuracy of the rolling seal spirometer, the linearity of the potentiometer and its coupling to the spirometer, the amplifier stability, and the bit resolution of the A-to-D converter. For most systems at least 10 bits of A-to-D is desirable - a bit A-to-D usually gives a resolution of about $\pm$20 ml. (3) The sampling rate at which samples of spirometric values are measured is a very important consideration. Lemen and his associates[18] have shown that for both infants and adults 95% of the signal in the flow-time curve is available if one limits the bandwidth to DC to 12 Hz. For volume-time curves, 95% of the signal is contained in DC to 6 Hz frequency. Digital sampling

theory requires that samples be taken at twice the highest frequency, i.e., 24 Hz for the flow-time curve or 12 Hz for the volume-time curve, in order to give adequate results. However, most spirometric analysis is done with sampling rates of at least 50 Hz.

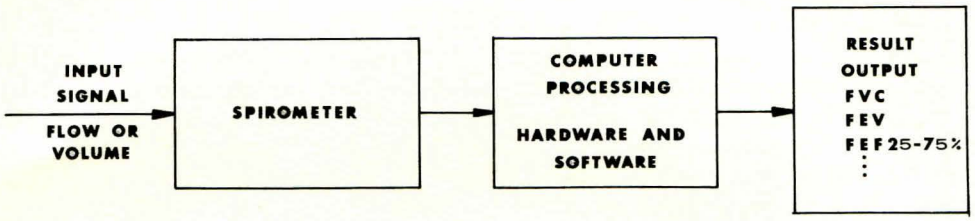

Figure 1. Block diagram of elements contained in a spirometer system.

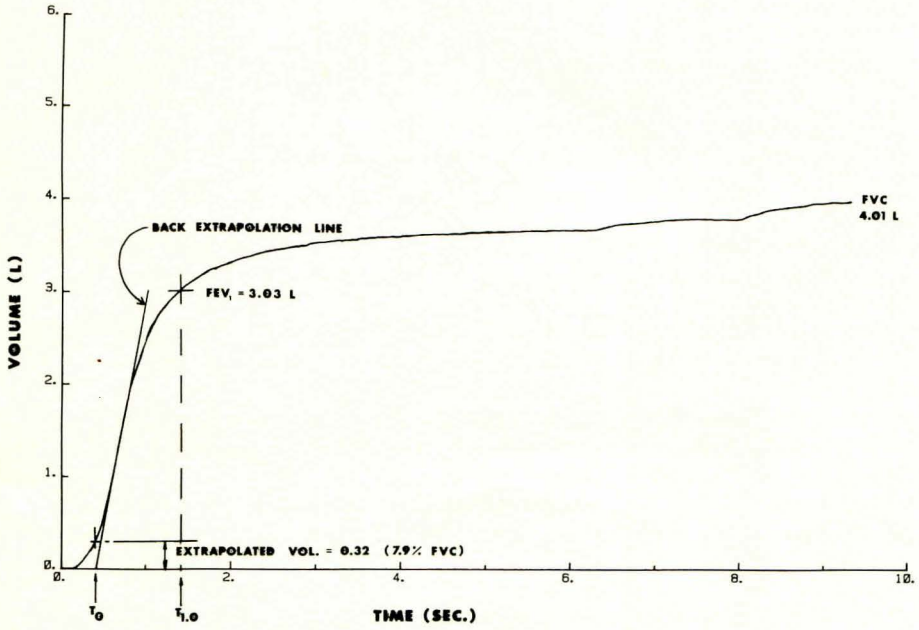

Figure 2. Typical patient waveform of a volume-time spirogram with back extrapolation method illustrated.

Some computer systems sample the spirogram at rates up to 1000 Hz, but it is doubtful that additional information can be

gained at sampling rates greater than 100 Hz. Recently some investigators[19] and some manufacturers have switched from time sampling to volume sampling. Figure 4 illustrates a typical patient waveform which is time sampled while Figure 5 shows the same waveform which is volume sampled. The volume sampled signal uses a shaft encoder which generates pulses for each increment in volume (Figure 6) rather than using the potentiometer (Figure 3). The pulses which occur at volume increments of 10 ml are timed and stored in the computer memory. The time sampled analysis (Figure 4) provides many samples in the slow part of the forced expiratory curve, whereas the volume sampled(Figure 5) method gives uniform data at varying time intervals. The volume sampled technique gives many more sample points during the rapid starting time of the forced spirogram than at the end, since volume sampling uses an optical digital transducer. The transducer puts the signal in digital form immediately and does not wear out or drift limitations of potentiometers and time sampled data.

CONCLUSIONS

The following conclusions are drawn from the data outlined.

1. The ATS criteria are appropriate and applicable to spirometers. They have resulted in an upgrading of devices in the marketplace.

2. As a group, volume spirometers are more accurate than flow measuring devices.

3. Test waveforms of real patient data with known characteristics are the best tools to test and qualify spirometers.

4. Performance testing criteria give more design flexibility and allow for innovation when compared to requiring meeting detailed engineering specifications. The volume sampling device is a good illustration which could not have happened if sampling rate and number of bits of A-to-D had been specified.

5. Finally any future spirometric testing must include all the elements in the system(Figure 1) since they can interact. Accuracy of the entire system is the most important measure. Waveform pattern recognition techniques and other software elements will become more and more important in qualifying future spirometers.

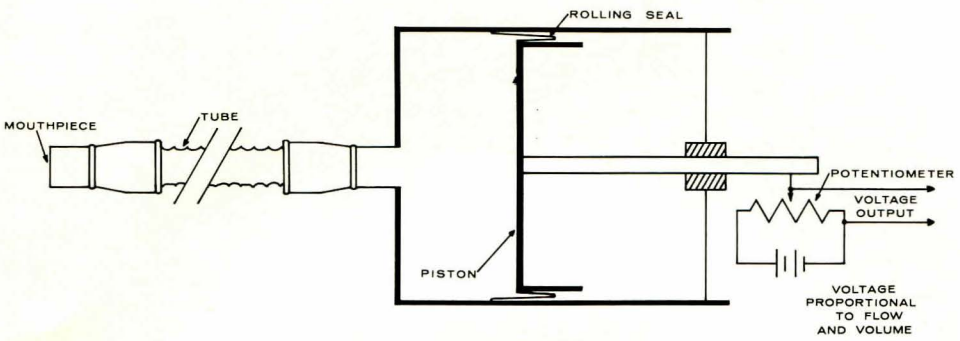

Figure 3. Rolling seal spirometer with a linear potentiometer attached to give voltage output proportional to volume.

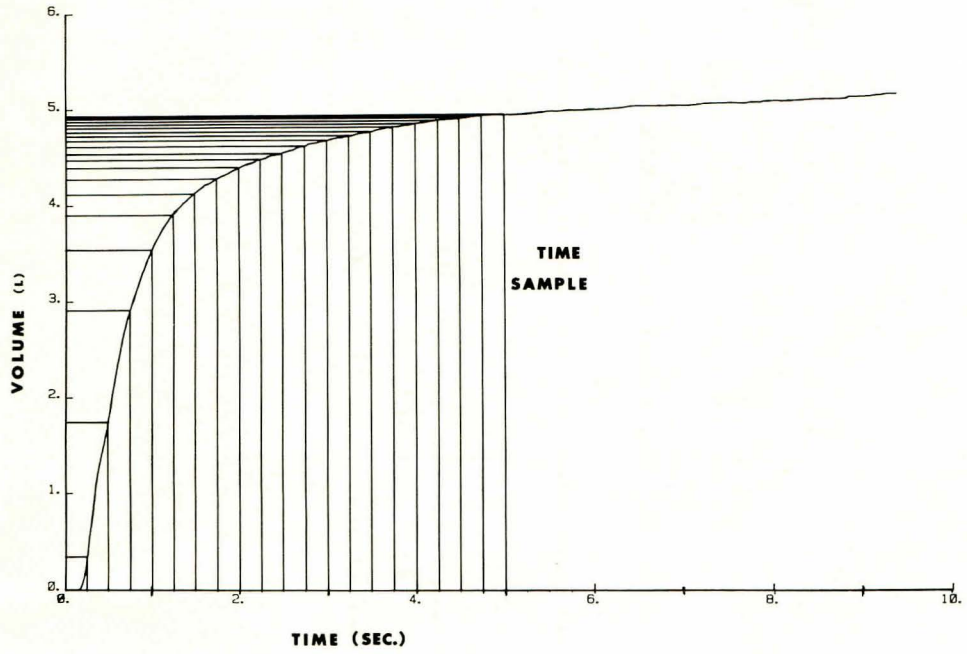

Figure 4. Illustration of time sampling of a volume-time forced spirogram. This example shows the volume sample values (vertical axis) which would be obtained if the curve were sampled at a 4 Hz rate. Note the large volume differences in the rapid first segment of the curve and the small volume changes at the end of the curve.

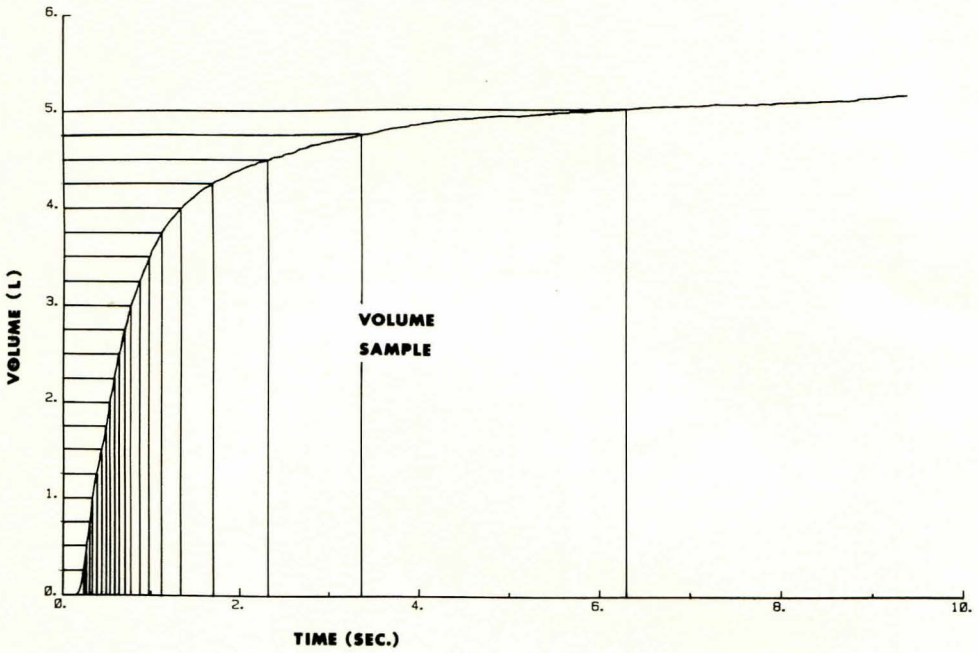

Figure 5. Illustration of a volume samples spirogram. Volume intervals of 250 ml were taken. Note the small time intervals in the rapidly changing first segment of the curve and the long time intervals at the end of the curve.

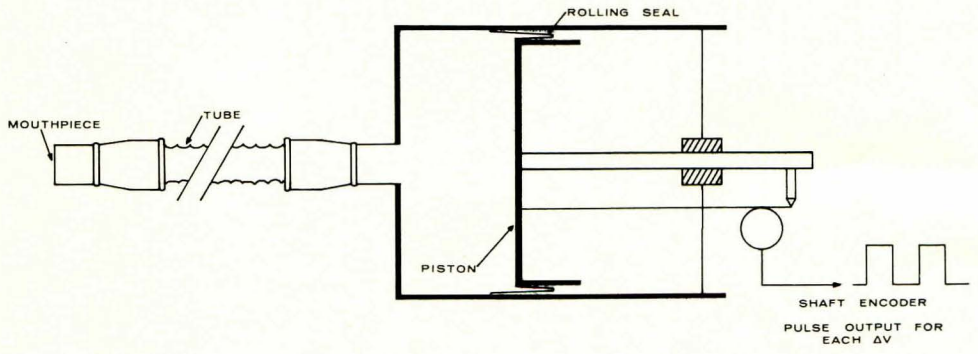

Figure 6. Rolling seal spirometer with a linear shaft encoder attached to give pulse outputs for each 10 ml change in volume.

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