Selecting Spirometers for Home Testing

Kevin McCarthy

Monitoring Spirometry at Home

The last several years have seen a large increase in the interest in telehealthcare. Some of this interest is driven by the lower costs of managing patients in their homes; some by the recent implementation of penalties for rehospitalization of patients after hospital discharge; and some driven by a mobile-centric population and the development of technology that makes this possible.

Spirometry has been used for decades for monitoring patients with pulmonary disease at home with varying success.[1] The intention for the monitoring has been mostly focused on following the progression of the disease, the effectiveness of patient treatment and most hopefully, for forecasting acute exacerbation.

Unfortunately, the promise of home monitoring of lung function has not fully lived up to its expectations. The data from home monitoring studies have been mixed, as to the quality of the measurement, the clinical outcomes and the economic impact.[2] Without the guidance and coaching of trained pulmonary technologist, the ability of patients to perform to ATS/ERS standards is questionable.[4] In a recent manuscript, spirometry reports from 17 private physician offices were collected and analyzed for acceptability to ATS/ERS standards.[3] Of those studies, 40 percent did not meet the acceptability requirements even though these tests were performed with supervision. If there is low quality of tests performed in physician offices, the likelihood of good quality data from self-administered tests would be anticipated to be even less.

The second aspect that affects the value of testing is the accuracy of the measurement devices themselves. Again, in that same publication of tests performed in physician offices, 94% of the spirometers failed to meet the ATS definition of acceptable performance when they were taken to a validation laboratory and tested on a certified waveform generator running the ATS waveform series. If the accuracy of devices is poor in the physician's office, the likelihood of accurate data coming from patient's home is not promising. The accuracy is not only affected by the spirometer's technology and its calibration process, but can be affected by where the calibration is performed if it is different than where the spirometer is used. If home spirometry is to be successful, then it is important to consider the different technologies used for home spirometric measurements in the decision making process for instrumentation selection.

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Spirometers

There are several measurement technologies that are typically used for spirometers provided to patients for self-testing at home. These include:

Differential Pressure Pneumotachs

Figure 1 is a representative illustration of a differential pressure (DP) pneumotach. These flow sensors consist of a low resistance element that creates a pressure drop across the element (typically a screen, a plastic post or flap, or a Fleisch design with a set of laminar flow capillary tubes) with a differential pressure transducer that measures that pressure drop. As flow increases, there is a predictable, but not necessarily linear, change in pressure as it relates to the change in flow. The integration of the instantaneous flows in finite time periods enables the spirometer to calculate the volume passing through the spirometer in that period.

While there are usually no moving parts in DP pneumotachs, there are potential performance limitations related to changes to the resistor element (contaminants on the screen or in the capillary tubes) that will change the pressure-flow relationship. They are also sensitive to changes in temperature, humidity and altitude. Any of these changes would cause errors in flow measurements and the resultant volume calculations. In addition, pressure transducers are known to drift over time. For these reasons, frequent or even daily calibration of a DP

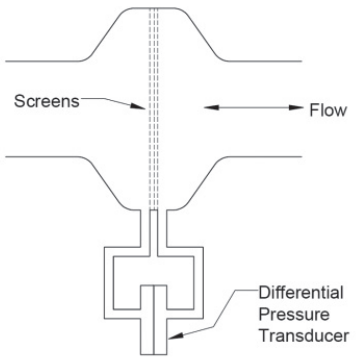

Figure 1. Differential Pressure Pneumotach

pneumotach is required in order to meet ATS/ERS standards for diagnostic spirometry.

Ultrasonic Flow Meters

Figure 2 is a representative illustration of an ultrasonic flow meter. Ultrasonic flow meters work by locating two ultrasonic transducers on either side of the breathing path. The transducers emit and receive sound in alternating directions. When air is flowing in the tube, sound pulses that travel against the flow are slowed down and take a longer time to reach the opposite transducer. When a pulse is traveling with the flow it travels faster and takes a shorter time to reach the opposite transducer. The transit-time of each sound pulse is precisely measured with a digital clock. The air flow through the breathing path is calculated from the upstream and downstream transit-times and integrated into volume.

Because there are no moving parts, no mechanical components to catch sputum and no flow-resistive elements that can change with use, ultrasonic flowmeters have demonstrated long-term calibration stability. The ultrasonic flow measurement is independent of gas composition, pressure, temperature, and humidity thus eliminating errors due to these variables. This technology eliminates most problems associated with traditional methods of flow measurement making ultrasonic flow meters extraordinarily fast, reliable, and accurate.

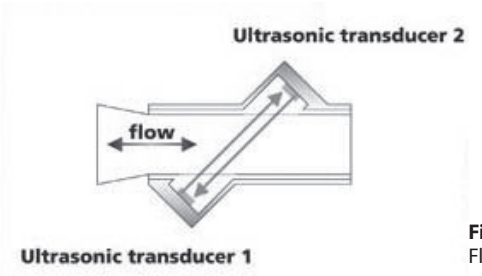

Figure 2. Ultrasonic Flow Meter

Turbine Flow Meters

Figure 3 is a representative illustration of a turbine flow meter. Turbine flow meters work by locating a low inertial vane behind a swirl plate (or between two if bidirectional flow is measured) with the post of the vane rotating in a jeweled, low-friction bearing. The swirl plates deflect the air entering the flow path and convert the linear airflow into a helical flow past the vane. This angular velocity therefore becomes proportional to the flow and is detected by the interruption of a pair of infrared beams by the vane twice per rotation. The frequency of these interrupted pulses is therefore proportional to the flow and the number of pulses proportional to the volume. This binary light/no-light measurement is the most reliable method of measuring flow as light doesn't drift.

Similar to ultrasonic flow meters, turbine flow meters measure exhaled air directly at B.T.P.S. (body temperature and pressure with saturated water vapor) and have no requirement for temperature correction on exhalation and are not affected by humidity, temperature or altitude. Bidirectional turbine flow meters have electronic temperature sensors to correct inspired volumes and flow. These characteristics also make the turbine spirometer extremely stable and obviate the need for frequent calibration. The main limitation of many turbine flow meters (horizontal operation) is the difficulty it has with the measurement of extremely low flows so as to meet the ATS/ERS requirement down to 0.025 L/sec.

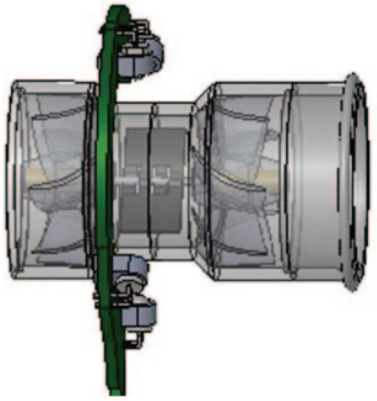

Figure 3. Turbine Flow Meter

Differentiating spirometers, depending on the need for hospital accuracy at home.

If spirometric measurements are to be meaningful, assuming that all technology on the market has been reviewed by the FDA, then the following specific characteristics are important when considering for home use:

- The spirometer should not require daily calibration in a patient's home and still meet ATS/ERS performance requirements.
- The spirometer should be able to measure full flow volume loops (inspiratory and expiratory).
- The spirometer should be able to meet the ATS/ERS standard for low flows
- The spirometer should be able to inform the patient if they performed the test according to ATS/ERS requirements.

Calibration

As discussed in the previous section, calibration requirements for diagnostic measurements are heavily dependent on the basic technology in the spirometer. These requirements can be significantly loosened for screening devices that do not measure Forced Vital Capacity and whose results are confirmed by an institutional diagnostic measurement. Long term calibration stability has been explored for both ultrasonic and turbine spirometers following long term use and they appear to remain within 1-2 percent over periods exceeding 2 years of use.[6,7]

Full Flow Volume Loops

Many of the spirometers placed in home settings are exhalation only measurement systems and therefore require patients to take a deep inspiration, raise the spirometer to their mouth, get a good seal and then forcefully exhale. This coordination requirement, particularly difficult for older patients, can potentially take several seconds. As reported by D'Angelo, a pause at end inspiration can reduce flows by as much as 20-40%, and FEV1 by 8%.[8] The importance of this is emphasized in the ATS/ERS Standardization of Spirometry statement that "the FVC manoeuvre should be begun with minimal hesitation. Reductions in PEF and FEV1 have been shown when inspiration is slow and/or there is a 4-6 s pause at total lung capacity (TLC) before beginning exhalation. It is, therefore, important that the preceding inspiration is fast and any pause at full inspiration be minimal (ie, only for 1-2 s)." Therefore the importance of the ability to transition from a deep inspiration to an immediate forced exhalation is not minimal, as it would improve the

Common Spirometers Used for Telehealthcare Applications

Manufacturer	Model	Measurement Technology	Screening or Diagnostic[1]	Full FV Loop	Approved for Home Use	Meets ATS/ ERS Low Flow Requirement	Test Quality Feedback (see Quality discussion below)
ERT	AM-1	Horizontal Turbine	Screening	No	Yes*	No	No
ERT	AM-3	Horizontal Turbine	Screening	No	Yes*	No	No
CareFusion	Micro 1	Horizontal Turbine	Diagnostic	No	Yes*	No	Yes
CoHero	SpiroThor	Ultrasonic	Diagnostic	Yes	No	NA	No
Ganshorn	SpiroScout	Ultrasonic	Diagnostic	Yes	No	Yes	No
MedChip	SpiroConnect	Vertical Turbine	Diagnostic	Yes	No	Yes	Yes
MIR	Spirobank	Horizontal Turbine	Diagnostic	Yes	Yes*	No	Yes
MIR	Spirotel	Horizontal Turbine	Diagnostic	Yes	Yes*	No	Yes
Monitored Therapeutics	GoSpiro	Vertical Turbine	Diagnostic	Yes	Yes	Yes	Yes
NDD	EasyOne	Ultrasonic	Diagnostic	Yes	No	Yes	Yes
PMD Healthcare	SpiroPD	Horizontal Turbine	Diagnostic	No	Yes*	No	6 Sec Timer Only
SDI	Astra300	Horizontal Turbine	Diagnostic	Yes	Yes*	No	No
Vitalograph	6300 Micro	Fleisch DP	Diagnostic	No	Yes*	No	No
Vitalograph	Asma-1	Horizontal Turbine	Screening	No	Yes*	No	Cough, TPF (120 ms)

*Indicates the spirometer was approved without being tested to meet current Home-Use requirements.

likelihood of more accurate measurements recorded at home and therefor provide the interpreting physician with more relevant data.

Low Flow Requirements

The ATS/ERS Standard requires that spirometers record flows as low as 0.025 l/sec.[5] This is important for accurate measurement of FVC. However, when spirometers are tested to the ATS waveforms, they don't specifically test at that low a flow. Therefore, many spirometers that pass the ATS waveform test and are FDA cleared for sale, don't really meet **all** of the ATS/ ERS standards. This is a particular problem with many turbine spirometers that fail to meet this requirement. While turbine flow meters rotate on a jeweled bearing, because they are usually used in a horizontal position, they don't rotate exclusively on the point of the vane spindle, but also on the side of the spindle (See Figures 4a, b, c). This horizontal position causes minimal drag on the vane rotation, but sufficiently enough to prevent rotation at low flows. Only two manufacturers produce vertical turbines (MedChip's SpiroConnect and MTI's GoSpiro) that allow the vane to rotate on the tip of the spindle, enabling measurements at these low flows to meet the ATS/ERS standard.

Video of the low flow performance of the turbines tested can be seen at http://respiratorytherapy.ca/videos/spirometers.

Quality Problems with Self-Measurements

In the same review of spirometry measurements in physician offices discussed earlier, they evaluated the quality of the measurements collected by "trained" office assistants, nurses or the physician themselves. Of the 153 tests reviewed, 40% did not meet the minimum ATS/ERS standards for spirometry. If trained individuals can't encourage a patient to perform a spirometry test correctly, how would a patient testing themselves at home know if they performed it right? According to the ATS/ERS standards, there are five important requirements for a good test. These include 1) that the patient exhaled for at least six seconds (3 seconds in children <10 years of age); 2) that the back extrapolated exhaled volume is less than the larger of 5%

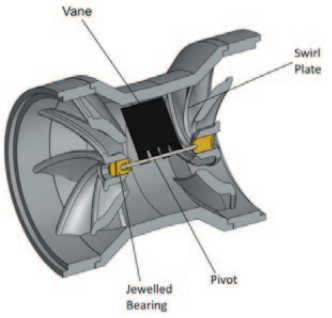

Figure 4a.

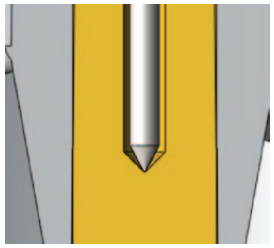

Figure 4b.

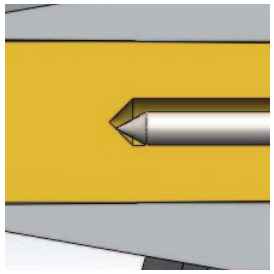

Figure 4c.

of the FVC or 150 mL; 3) that the time to peak flow occurs is minimal (estimated at less than 300 milliseconds); 4) that the exhaled flow at the end of exhalation is less than 0.025 liters per second; and 5) that there is no cough during the first second that could affect the measured FEV1. While most spirometers provide feedback as to the difference between the measured values and either previous or predicted values, only a few provide feedback as to the actual quality of the test. The MIR series of spirometers as well as the MTI GoSpiro, MedChip SpiroConnect, and the CareFusion Micro 1 measure and report all five quality parameters to the patient so that they know whether they need to repeat the measurement due to the poor quality of the maneuver.

Home Use Specific

Between 2014 and 2016, new ISO standards and FDA requirements were developed for medical devices used in the

home.[9,10] These standards were driven by the recognition that environmental exposure in the home could have a greater effect on medical devices than when used in the hospital setting. These new standards raise the safety margins for electromagnetic interference, radio frequency immunity and coexistence, environmental exposures (particularly water ingress) as well as electrical safety and usability (labeling and instructions). This means that among other requirements, that they meet the ISO 60601-1-11:2015 for electronic devices for use in patient's home and the FDA Guidance Document, Design Considerations for Devices Intended for Home Use. While there are many spirometers that have FDA clearance to be sold for use in a patient's home, only the MTI GoSpiro has been actually designed for patient use at home and has passed these more stringent test requirements.

Conclusions

There are many spirometers that are used to monitor patient lung function at home. The differences between some of these devices are considerable as to their characteristics and operational performance. If the purpose of monitoring these patients is to be more than just going through the motions and to obtain meaningful data that guides their care and prognosis, then careful thought should go into the selection of spirometers used to monitor them.

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