## APÉNDICE A: GLOSARIO DE TÉRMINOS USADOS FRECUENTEMENTE EN ESPIROMETRÍA

**ATPS**: Las letras son las iniciales en el idioma inglés de "temperatura ambiente y presión saturada con vapor de agua" (*Ambient Temperature and Pressure Saturated with water vapor*). Los volúmenes medidos directamente por el espirómetro basado en volumen (y sin conversión a BTPS) están en condiciones ATPS.

**ATS**: La Sociedad Americana de Tórax (*The American Thoracic Society*) promueve la mejoría de la espirometría mediante el uso de sus recomendaciones.

**BTPS**: Las letras son las iniciales en el idioma inglés de "temperatura corporal y presión saturada con vapor de agua (Body Temperature and Pressure Saturated with water vapor). Un volumen de gas se va a comprimir al enfriarlo. El volumen de gas exhalado de los pulmones a un espirómetro, se va a contraer debido a que los pulmones se encuentran más calientes que el espirómetro. De esa manera, es necesario ajustar los valores registrados con un factor de conversión BTPS, para determinar el volumen real de aire exhalado antes de sufrir una contracción. Este factor corrige el volumen de aire saturado con vapor de agua a la temperatura del cuerpo para varias temperaturas de los espirómetros.

**CAPACIDAD PULMONAR TOTAL (CPT)**: La suma de la capacidad vital y del volumen residual.

**CAPACIDAD VITAL (CV)**: La máxima cantidad de aire que puede ser exhalada después de de una inspiración profunda máxima. Es la suma del volumen corriente, del volumen de reserva espiratorio y del volumen de reserva inspiratorio. Puede ser medida durante la inhalación o durante la exhalación.

**CAPACIDAD VITAL FORZADA (CVF)**: El máximo volumen de aire que puede ser exhalado de manera forzada, después de una inspiración máxima. NOTA: La capacidad vital (VC) es la cantidad de aire que puede ser exhalada por un individuo después de tomar la mayor cantidad de aire, independientemente si ese aire es exhalado de manera forzada (CVF) o lentamente (CV).

**COMPLACENCIA O DISTENSIBILIDAD (*COMPLIANCE*)**: Representa la cantidad de presión necesaria para incrementar o disminuir el volumen de los pulmones. Los pulmones con enfisema tienen una distensibilidad elevada, mientras que los pulmones con enfermedad pulmonar intersticial tienen una distensibilidad baja.

**CURVA FLUJO/VOLUMEN (*FLOW/VOLUME LOOP*)**: Un trazado de la velocidad del flujo (sobre las "y", o eje vertical) contra volumen (sobre las "x", o eje horizontal), obtenido de una maniobra espiratoria forzada después de una inhalación máxima.

**ELASTICIDAD (*ELASTIC RECOIL*)**: La propiedad de los pulmones de regresar a su situación de reposo. La elasticidad natural del pulmón durante la espiración. [1]

**ENFERMEDADES PULMONARES OBSTRUCTIVAS**: Enfermedades que reducen el flujo de los pulmones. Entre estas enfermedades se incluyen asma, bronquitis crónica y enfisema.

**ENFERMEDADES PULMONARES RESTRICTIVAS**: Enfermedades que reducen la capacidad de los pulmones para expandirse plenamente, pero que no necesariamente afectan el flujo de aire. La asbestosis y la silicosis, dos de las enfermedades restrictivas más frecuentes

1 N del T la tendencia del pulmón a desinflarse.

dentro de las enfermedades ocupacionales, son causadas por el depósito de tejido fibroso en el pulmón.

**ESPIROGRAMA**: Un solo trazo o gráfica que registra las maniobras respiratorias. Se expresan estas gráficas como trazos volumen/tiempo o flujo/volumen, dependiendo del espirómetro usado.

**ESPIROGRAMA ACEPTABLE**: Una maniobra espiratoria forzada, después de una inhalación máxima, que está libre de titubeos o falsos inicios, de tos, de un final prematuro, de un esfuerzo variable o de errores de línea de base. Se deberán obtener tres maniobras aceptables antes de evaluar la variabilidad excesiva.

**ESPIRÓMETRO**: Un instrumento para medir los volúmenes pulmonares y las velocidades de flujo. Las dos principales clases de espirómetros comprenden los que detectan volúmenes y los que detectan flujos.

**ESPIRÓMETRO DE FLUJO**: Un tipo de espirómetro que mide qué tan rápido el aire se mueve hacia adentro o hacia fuera de los pulmones. Los espirómetros de flujo son habitualmente más pequeños que los espirómetros de volumen. Los ejemplos incluyen el neumotacógrafo, el anemómetro de alambre caliente y el de turbina.

**ESPIRÓMETRO DE VOLUMEN**: Un tipo de espirómetro que registra la cantidad de aire inhalado o exhalado dentro de cierto tiempo. Ejemplos de este tipo son los espirómetros de sello de agua, de sello seco y los instrumentos de fuelle.

**ESTUDIOS LONGITUDINALES**: Información obtenida del mismo individuo o grupo de individuos, a intervalos regulares, sobre un período extenso de tiempo. Los valores de las últimas pruebas son comparados con los resultados de las previas pruebas del grupo.

**EXACTA**: Una medición que se encuentra muy cercana al valor verdadero o que se encuentra libre de errores. En términos prácticos, una medición que se encuentra dentro de un rango predeterminado del verdadero valor de la medición.

**EXTRAPOLACIÓN RETRÓGRADA (*BACK EXTRAPOLATION*)**: El método para determinar el tiempo cero de un espirograma, y que es particularmente importante cuando el punto exacto de inicio de la maniobra espiratoria forzada no resulta obvio. Ya que el $VEF_1$ se ve afectado por el punto en la gráfica que se selecciona como el inicio, se debe usar un método uniforme para determinarlo.

**FACTOR DEL INSTRUMENTO**: En ciertos espirómetros de sello de agua, se refiere a la constante que indica el volumen de desplazamiento por milímetro del movimiento vertical de la campana.

**$FEF_{25-75\%}$**: Flujo meso-espiratorio forzado *(mid forced expiratory flow*) medido desde el punto en el cual se logra el 25% de la CVF, hasta el punto donde se alcanza el 75% de la CVF (durante el segmento medio de la CVF). Se abrevia como MMEF, MMFR o MMF.

**FIN DE LA PRUEBA**: El punto durante la maniobra espiratoria forzada cuando se alcanza la meseta.

**LLN**: El límite inferior (*lower limit of normal*) de lo normal es el valor por abajo del cual solamente 5% de la población “normal” de referencia deberá tener valores observables. El valor específico del LLN es dependiente de la población de estudio y de los métodos usados para derivar los valores de referencia. El LLN deberá estar disponible en la fuente de valores de referencia.

**MANIOBRA ESPIRATORIA FORZADA**: La maniobra básica y fundamental de la espirometría, y en la cual el sujeto toma aire de la manera más intensa posible, y lo expulsa a través de una boquilla tan fuerte y rápido como pueda. Se le denomina también como maniobra de capacidad vital forzada.

**MEJOR CURVA**: Un espirograma aceptable que tiene la suma más grande del $VEF_1$ y la CVF.

**PRECISO**: Capaz de dar resultados consistentes y reproducibles en sucesivas ocasiones. Un espirómetro que no está adecuadamente calibrado puede producir resultados precisos pero que no son exactos.

**PUNTO DEL TIEMPO CERO**: En la medición del $VEF_1$, es el punto que señala el inicio de la prueba y se obtiene usando una extrapolación retrógrada.

**REPRODUCIBILIDAD**: La capacidad de una prueba, de obtener el mismo resultado de un individuo cuando la prueba se repite en varias ocasiones. La reproducibilidad se determina verificando los excesos de variabilidad entre los dos valores mayores para la CVF y el $VEF_1$, obtenidos de tres espirogramas calificados como aceptables.

**RESISTENCIA AL FLUJO DE AIRE:** La facilidad con la cual el aire puede pasar a través de las vías aéreas. El número, la longitud y el diámetro de las vías aéreas, determinan la magnitud de la resistencia que existe.

**SINERGISMO**: Ocurre cuando el efecto combinado de dos o más sustancias es mayor que la suma de los efectos de cada sustancia.

**TIEMPO ESPIRATORIO**: El tiempo requerido por un sujeto para expulsar su mayor volumen (CVF). Por motivos de control de calidad, el tiempo espiratorio total es el tiempo desde el comienzo de la exhalación, hasta el final de la maniobra espiratoria del sujeto. Como regla nemotécnica, el tiempo espiratorio total deberá ser mayor de 6 segundos.

**TRAZO DE TIEMPO REAL (*REAL TIME TRACING*)**: Un espirograma que se genera conforme se lleva a cabo la maniobra espiratoria forzada.

**VALORES NORMALES ESPERADOS**: Valores esperados de varios volúmenes pulmonares y velocidades de flujo, obtenidos de sujetos sanos no fumadores. Los valores están ajustados para el sexo, la edad, la talla y la raza.

**$VEF_1$/CVF (expresado como proporción o porcentaje)**: Es el volumen espiratorio forzado en un segundo, expresado como porcentaje de la capacidad vital forzada. Se trata de la fracción del total que se exhala en el primer segundo. Es el índice de la velocidad del flujo aéreo espiratorio. Se calcula utilizando el $VEF_1$ mayor obtenido y la CVF mayor obtenida, aún cuando ambas mediciones no sean de la misma curva. Un $VEF_1$/CVF% disminuido se asocia con una obstrucción de la vía aérea.

**VERIFICACIÓN DE LA CALIBRACIÓN: (*CALIBRATION CHECK*)**. Determinación periódica de la capacidad del espirómetro para realizar mediciones exactas de volumen y tiempo (y de flujo, si resulta apropiado).

**VOLUMEN CORRIENTE, VOLUMEN TIDAL (*TIDAL VOLUMEN, TV*)**: El volumen de aire inhalado o exhalado durante una respiración tranquila y normal.

**VOLUMEN DE RESERVA ESPIRATORIA (VRE)**. La máxima cantidad de aire exhalado de una manera forzada, después de una inspiración y una espiración normal.

**VOLUMEN DE RESERVA INSPIRATORIO (VRI)**: La máxima cantidad de aire inhalado de manera forzada, después de una inhalación normal.

**VOLUMEN ESPIRATORIO FORZADO EN UN SEGUNDO ($VEF_1$)**: El volumen de aire exhalado durante el primer segundo de la maniobra espiratoria forzada. Se le puede también considerar como el flujo promedio durante el primer segundo de la maniobra de la CVF.

**VOLUMEN EXTRAPOLADO**: El volumen que fue determinado por una línea perpendicular, desde el punto de tiempo cero, hasta el punto donde intercepta la curva de la CVF. El volumen extrapolado debe ser menor de 150 ml (para una CVF menor de 3 L), o menor [2] de 5% (para aquellas CVF mayores de 3 L), para que el trazo se considere apropiado. Un volumen extrapolado elevado se debe a un comienzo lento o un titubeo al inicio de la maniobra.

**VOLUMEN RESIDUAL (VR)**: La cantidad de aire que permanece en los pulmones después de una exhalación completa. Este volumen no se puede medir en una espirometría.

2 N del T, el volumen espirado en el tiempo cero.

## APÉNDICE B. UNA REVISIÓN SOBRE RIESGOS PULMONARES OCUPACIONALES

### Tipos de riesgos pulmonares

Los contaminantes pulmonares ocupacionales se presentan de muchas formas. Algunos pueden verse, olerse o sentirse como irritantes en la nariz o la garganta. Sin embargo, otros solamente pueden detectarse con equipo especializado. La exposición a corto plazo de muchos tóxicos puede causar un daño agudo inmediato. Sin embargo, la mayoría de los contaminantes requieren de exposiciones repetidas a lo largo de meses o años para causar un daño permanente o una enfermedad. El impacto de los riesgos pulmonares se ve influenciado por la contaminación ambiental en general, por la edad, el hábito de fumar, el estado nutricional, así como otros factores menos comprendidos como los factores genéticos y el estrés.

Muchos procesos de trabajo generan varios contaminantes al mismo tiempo. Las consecuencias sobre la salud de estos riesgos pueden ser simplemente aditivas, o peor, pueden ser sinergistas. De esa manera, es esencial conocer los materiales y procesos utilizados en un lugar de trabajo, para poder evaluar, monitorear y controlar los riesgos pulmonares potenciales. Está más allá de los objetivos de esta guía el cubrir las medidas de control para dichos riesgos. Sin embargo, hay que resaltar que la mayoría de las exposiciones ocupacionales a riesgos generados en el aire del ambiente, pueden eliminarse o reducirse en una gran medida por medio de controles de ingeniería, como es el caso del mejoramiento de la ventilación, las prácticas adecuadas de trabajo y el uso de equipos personales de protección como los respiradores adecuadamente seleccionados. Refiérase a Fundamentos de Higiene Industrial para una revisión de las medidas de control (41).

Generalmente se utilizan dos enfoques para categorizar los riesgos pulmonares ocupacionales. El primer enfoque, utiliza un punto de vista médico para clasificar los riesgos de acuerdo a su impacto en el tracto respiratorio. En esta instancia, todos los riesgos que causan efectos similares se agrupan juntos, independientemente si estos riesgos comparten o no similitudes. El segundo enfoque, utiliza un punto de vista de la higiene ocupacional, para agrupar a los riesgos de acuerdo a sus propiedades comunes y los métodos por los cuales son generados. Ambos enfoques se describen a continuación:

**Riesgos clasificados de acuerdo a su impacto en el tracto respiratorio**

ASFIXIANTES: Gases que disminuyen el oxígeno de los tejidos del organismo.

Asfixiantes simples: Gases inertes que fisiológicamente desplazan al oxígeno en la sangre y a altas concentraciones causan sofocación.

Ejemplos: Nitrógeno, metano, argón, neón, helio

Asfixiantes químicos: Gases que interfieren con la capacidad del organismo de utilizar oxígeno (Ej. al fijarse con la hemoglobina o al prevenir las reacciones químicas necesarias para utilizar el oxígeno en las células).

Ejemplos: Monóxido de carbono, compuestos de cianuro, arsénico

IRRITANTES: Sustancias que irritan las vías respiratorias condicionando una constricción de las vías aéreas. Pueden provocarse síntomas asmáticos, disnea, edema pulmonar o infecciones.

Ejemplos: Cloro, ácido clorhídrico, ácido fluorhídrico, amoníaco, flúor, dióxido de sulfuro, fosgeno, óxidos de nitrógeno, ozono.

PRODUCTORES DE FIBROSIS: Sustancias que causan cambios fibróticos (cicatrices) en los tejidos asociándose con enfermedades restrictivas.

Ejemplos: Asbesto, berilio, sílice, polvo de carbón, así como otros polvos orgánicos e inorgánicos.

ALERGENOS: Sustancias que inducen una respuesta alérgica caracterizada por broncoconstricción. Esto puede ocurrir, inclusive, si en exposiciones previas no se han producido efectos adversos.

Ejemplos: Isocianatos, esporas de hongos, formaldehído, caspa animal.

CARCINÓGENOS: Sustancias que pueden causar cáncer.

Ejemplos: Asbesto, humo de cigarrillo, cromo, uranio, arsénico, emisiones de hornos de coque.

**Riesgos clasificados de acuerdo a sus propiedades**

Aunque algunos contaminantes pueden no afectar de manera adversa al pulmón, es a través de él que se puede entrar al torrente sanguíneo y dañar otros órganos, o alterar la capacidad de transporte del oxígeno. Estos tipos de efectos sobre la salud no son detectables a través de una espirometría. Sin embargo, los riesgos que producen estos efectos se incluyen, para mostrar la manera en la cual los contaminantes respirables pueden producir daño al organismo.

La información presentada abajo se adaptó de una Introducción a las Enfermedades Pulmonares Ocupacionales (44).

POLVOS

| | |
|---|---|
| Polvos minerales: | Polvos y fibras minerales formados a partir de piedras, rocas y pozos. Como ejemplos se incluyen el asbesto, los cristales de sílice y el polvo del carbón. |
| Fuentes: | Labores de minería, construcción de túneles, explosiones, fundiciones, moliendas y trabajos en molinos, etc. |
| Efectos en la salud: | La mayoría son inertes y no se descomponen o se disuelven fácilmente. Se acumulan en el pulmón una vez que han saturado los mecanismos de depuración propios del pulmón. Pueden conducir a neumoconiosis, bronquitis crónica, enfisema, complicaciones cardíacas y, asimismo, pueden iniciar otros procesos como fibrosis o cáncer. Se asocian con la clase de enfermedades pulmonares ocupacionales fibróticas llamadas neumoconiosis. |
| Polvos orgánicos: | Son polvos que se forman a partir de material vivo u orgánico (vgr. microorganismos, plantas y animales) o productos naturales como la lana o el cuero. |
| Fuentes: | Productos de las plantas (vgr. algodón, madera, granos de cereal, especias, granos de café, etc).: labores de sembradío, de cosecha, almacenamiento, transporte o procesamiento (moliendas, corte de fibras, hilado etc). Manejo de animales: excretas, pelambres, plumas, etc. |
| Efectos en la salud: | Habitualmente no se acumulan, pero sí se disuelven o se fragmentan. Pueden causar reacciones de hipersensibilidad como el asma ocupacional, la bisinosis (por algodón) o neumonitis por hipersensibilidad. Pueden conducir a una enfermedad pulmonar obstructiva permanente, o a una fibrosis pulmonar difusa. Ciertos polvos de madera se han asociado también con cáncer. |

Polvos químicos: Agentes químicos sintéticos que vienen en forma de polvo (vgr. pesticidas, agentes farmacéuticos, colorantes, agentes blanqueadores, detergentes, pinturas, etc).

Fuentes: Durante su proceso de manufactura, secado o empaquetamiento; durante su preparación para usarlos, aplicarlos, secarlos, o como resultado de su contacto con el ambiente, como es el caso de pinturas en las paredes exteriores, etc.

Efectos en la salud: Va a depender de las propiedades tóxicas de los químicos específicos. Algunos de ellos son irritantes o alergenos, otros tienen un efecto cáustico y pueden causar quemaduras químicas. Algunos son tóxicos para las células y los tejidos. Algunos penetran al cuerpo a través del pulmón y pueden causar cáncer del pulmón o de otros sitios del cuerpo.

HUMOS: Partículas sólidas muy pequeñas que se forman cuando vapores calientes (habitualmente a partir de metales o polímeros) se enfrían rápidamente y se condensan. Al mismo tiempo se pueden desprender gases tóxicos. En los pulmones, los humos actúan como los polvos de material muy fino.

Fuentes: Procesos de calentamiento a temperaturas muy elevadas (Ej. Soldaduras, fundiciones, trabajos en calderas).

Efectos en la salud: Es difícil evaluar el impacto de los materiales en forma individual ya que generalmente se presentan varios riesgos al mismo tiempo. Pueden generar fiebre por humo de metales o polímeros, enfisema y cáncer pulmonar.

NOTA: el humo no se suele clasificar aparte ya que es una mezcla de gases y partículas sólidas.

NIEBLAS Y AEROSOLES: Gotas líquidas suspendidas en el aire o en otro gas disipador o propelente.

Fuentes: Utilizados ampliamente en la industria, específicamente para aplicar sustancias en superficies difíciles de alcanzar o sustancias que pueden dañar la piel si se aplican con la mano (Ej. productos de limpieza, pesticidas, pinturas, productos cosméticos, removedores de material oxidado, etc. También productos generados por otros procesos como los aceites lubricantes en las maquinarias).

Efectos en la salud: Mientras más fino es el aerosol, más profunda es la penetración en los pulmones. Los efectos dependen del material que se está dispersando, la concentración y la temperatura. Los efectos pueden ir desde quemaduras químicas en los pulmones, hasta varias formas de cáncer.

GASES: Fluídos que se expanden llenando el espacio que los contiene. Pueden

desplazarse rápidamente desde el punto donde se originan. Muchos de ellos son altamente inflamables o explosivos al mezclarlos con aire, y también pueden ser química y fisiológicamente reactivos. Algunos de ellos son transparentes y sin olor.

Fuentes: Reacciones químicas naturales (Ej. metano de zonas carboníferas, óxidos de nitrógeno de silos de fermentación, sulfuro de hidrógeno y de metano a partir de trabajos en el tratamiento de aguas negras). Reacciones químicas artificiales (Ej. a partir de procesos industriales, ozono de la contaminación, así como interacción de productos de limpieza como el amoníaco y los blanqueadores a base de cloro). En el medio industrial, se pueden emitir gases durante los procesos de manufactura, manipulación o transporte de los mismos si no se toman medidas de protección. También se pueden producir gases durante procesos de calentamiento a altas temperaturas (Ej. soldaduras, fundiciones, calderas, secado de hornos, quemaduras, o la combustión accidental de ciertos materiales sintéticos).

Efectos en la salud: Los gases fisiológicamente inertes (Ej. metano y nitrógeno) pueden causar sofocación al desplazar al oxígeno (asfixiantes simples). Otros interfieren con la utilización del oxígeno (Ej. monóxido de carbono y cianuro) (asfixiantes fisiológicos).

Gases que son inmediatamente irritantes (Ej. amoníaco, bromo, dióxido de sulfuro, cloro). Una exposición intensa, de manera súbita, a este tipo de gases, puede causar una severa irritación que queme los pulmones o cierre la traquea. La exposición a bajos niveles puede causar constricción de las vías aéreas y agravar enfermedades pulmonares preexistentes.

Gases que no son inmediatamente irritantes (Ej. fosgeno y óxidos de nitrógeno): Estos gases penetran de una manera profunda en los pulmones causando edema pulmonar y otras complicaciones serias, sin producir sintomatología del tracto respiratorio superior.

Gases carcinogénicos (Ej. gases radioactivos, carbonilo de níquel, cloruro de vinilo). Los cánceres generados por estos gases toman habitualmente varios años para desarrollarse y puede ser difícil rastrear la causa exacta. El cáncer puede estar ubicado fuera del pulmón.

VAPORES: El término técnico para denominar a la forma gaseosa de un líquido que siempre se encuentra sobre la forma líquida. Va a ocurrir un mayor grado de vaporización conforme la temperatura del líquido alcance su punto de ebullición. Los vapores afectan el pulmón de manera similar a los gases. La principal diferencia entre los vapores y los gases es que los vapores se encuentran siempre sobre los líquidos de donde se forman,

mientras que los gases no se encuentran siempre asociados con formas líquidas.

Fuentes: Sustancias inorgánicas: La mayoría de ellas tienen puntos de ebullición muy altos y no se evaporan a temperatura ambiente. Habitualmente no se asocian con enfermedad pulmonar. Vapores orgánicos: Muchos de ellos se evaporan a temperatura ambiente. Habitualmente se les utiliza como solventes (cetonas, hidrocarburos aromáticos, alcoholes, acetatos).

Efectos en la salud: Muchos vapores orgánicos penetran al organismo a través de los pulmones. Aunque los pulmones no se dañan, puede ocurrir daño excesivo en otros órganos como es el caso de lesión cerebral y del sistema nervioso central, edema pulmonar, y traqueobronquitis (mercurio y compuestos relacionados). Reacciones de hipersensibilidad (cloruro de polivinilo), cáncer (benceno y compuestos relacionados).

RADIACIÓN: Las radiaciones no ionizantes incluyen las ondas electromagnéticas (Ej. infrarrojas, ultravioleta, microondas, láser, radar y de radiofrecuencia). La radiación ionizante incluye a los rayos alfa, beta y gamma, partículas de neutrones y rayos-X.

Fuentes: Minería en pozos radioactivos. Se usan también en medicina, material de guerra, plantas de energía, en la industria (Ej. equipos eléctricos de alta energía, láser, microondas y radares).

Efectos en la salud: Las ondas electromagnéticas no parecen lesionar al pulmón a menos de que la energía sea suficiente como para causar quemaduras térmicas. Sin embargo, pueden causar daños en los ojos. Las radiaciones ionizantes dañan los tejidos humanos y pueden conducir a varias formas de cáncer, incluyendo cáncer de pulmón.

RIESGOS BIOLÓGICOS: Bacterias, virus, hongos, ricketsias, clamidias y parásitos.

Fuentes: Instituciones de salud, asilos y guarderías, sistemas de ventilación con un mal mantenimiento, laboratorios de investigación biomédica, sitios de crianza de animales y procesamiento de sus productos.

Efectos en la salud: Dependen del tipo de riesgo. Pueden ir desde alergias menores e infecciones respiratorias, hasta enfermedades fatales del sistema nervioso central y cánceres. En algunos casos se disponen de vacunas.

## APÉNDICE C. REVISIÓN DE LA ENFERMEDAD PULMONAR OCUPACIONAL

### A. Algunas de las enfermedades pulmonares que muestran un patrón obstructivo

**Asma ocupacional**
El asma ocupacional está causada por la exposición repetida a ciertos contaminantes del aire ambiental, los cuales traen como resultado una sensibilización, conduciendo a una respuesta alérgica crónica. En las exposiciones subsecuentes, el músculo liso de los conductos respiratorios va a generar un espasmo y oclusión de las vías aéreas. También se produce un moco excesivo, que viene a agravar más el problema al producir tapones en las vías aéreas. Los síntomas más frecuentes son la tos, las sibilancias y la disnea. Una gran variedad de agentes sensibilizantes puede inducir los ataques. Estos pueden ocurrir en personas que son esencialmente normales y que quedan sensibilizadas, o en individuos con historia previa de alergias o de asma durante la infancia. (Ciertos agentes como los disocianatos son irritantes y sensibilizadores de tal potencia, que causan reacciones respiratorias en la mayoría de los individuos.) Los trabajadores pueden, en ocasiones, relacionar sus síntomas asmáticos a una exposición específica, o al menos a una zona específica de su sitio de trabajo. En muchos casos, sin embargo, los síntomas comienzan después del turno laboral y ceden para la mañana siguiente.

**Síndrome de disfunción de vías aéreas reactivas –SDVAR (*Reactive Airways Dysfunction Syndrome - RADS*)**
El Síndrome de disfunción de vías aéreas reactivas se parece al asma, pero se debe a más de un irritante que a un estímulo alergeno. Los individuos con SDVAR van a sentir una obstrucción al flujo del aire a niveles de exposición mucho más bajos de los que producirían una respuesta en un individuo no afectado.

Un caso particular de SDVAR lo constituye una respuesta exagerada al aire frío. Se sabe que en los asmáticos pueden iniciarse sus ataques por este aire frío. Otros sujetos sin historia conocida de asma, pueden desarrollar broncoconstricción y dificultad respiratoria al exponerse al aire frío, ya sea en el trabajo o durante el ejercicio. Al retirarse de la exposición, los síntomas ceden, generalmente en el transcurso de 1 a 2 horas.

**Enfisema**
La exposición crónica a sustancias irritantes, fundamentalmente al cigarrillo, puede causar enfisema. Estas exposiciones llevan a la destrucción de la elasticidad de los bronquios más pequeños. Cuando la presión en el tórax comienza a incrementarse con el inicio de la exhalación, estos bronquios se pueden colapsar, atrapando el aire adentro. Como resultado, los sacos de aire permanecen parcialmente expandidos. La disnea es un problema permanente y el intento de respirar más rápido o más profundamente, provoca solamente que mayor cantidad de aire quede atrapado adentro. Frecuentemente los pulmones quedan distendidos, generando la configuración del cuerpo de un “tórax en tonel”. La enfermedad es progresiva y el daño al corazón es una complicación frecuente.

**Bronquitis crónica**
La bronquitis crónica es causada por infecciones a repetición o por la exposición a irritantes como los humos y los polvos (incluyendo polvo de madera y fibras minerales), aerosoles de aceite, gases como el ozono y el dióxido de nitrógeno, el humo de cigarrillo y la exposición al fuego (como en la profesión de bombero). Hay inflamación, edema y un aumento en la producción de moco, predisponiendo a la infección crónica bacteriana en las vías aéreas pequeñas taponadas con moco. Los síntomas incluyen la disnea y una tos persistente y productiva.

**B. Algunas de las enfermedades pulmonares que muestran un patrón restrictivo**

**Neumoconiosis**
Las tres principales clases de neumoconiosis en los Estados Unidos son la asbestosis, la silicosis y la neumoconiosis de los trabajadores del carbón (Enfermedad de los pulmones negros). Las neumoconiosis son unas de las enfermedades ocupacionales pulmonares mejor conocidas, sin embargo, durante mucho tiempo, en las cortes judiciales, se dudó de su existencia y se rehusaban a considerarlas como enfermedades sujetas a indemnización. Las principales causas de neumoconiosis son polvos inorgánicos y fibras, con partículas menores de 5 micras. A las partículas de ese tamaño se les denomina “partículas respirables”. Ya que estas partículas son invisibles, es posible estar expuesto sin saberlo. Sin embargo, muchas de las exposiciones más intensas se acompañaban de partículas de tamaño mayor, lo que daba una imagen de “polvo” en aire del ambiente de estas industrias.

La patología del pulmón es la de una fibrosis, esto es, un depósito de tejido fibroso entre los alvéolos, lo cual interfiere con la expansión normal del pulmón. La fibrosis puede tomar dos formas: nodular y localizada alrededor de los bronquios (peribronquial) (caso típico de la silicosis), o intersticial (entre los alvéolos) y difusa (caso típico de la asbestosis). Con una exposición continua, la fibrosis aumenta, conduciendo a disnea, tos persistente, y, en estadíos avanzados, a insuficiencia cardíaca. Las neumoconiosis son prácticamente siempre enfermedades de origen ocupacional y son objeto de indemnización.

**Neumonitis por hipersensibilidad**
La neumonitis por hipersensibilidad se denomina también como alveolitis alérgica extrínseca. La enfermedad ocurre principalmente en los alvéolos y en los bronquiolos terminales, en respuesta a polvos orgánicos asociados con profesiones específicas. En algunos casos el agente detonante es un hongo, como en el caso del pulmón del granjero (Farmer lung disease) y la bagasosis. En otros casos se trata de proteínas de origen animal (como en el caso de los criadores de pájaros o la enfermedad de los peleteros) o proteínas vegetales (como la neumopatía de los cafetaleros). Estos trabajadores desarrollan una enfermedad aguda con tos, disnea, habitualmente sin sibilancias, pero sí acompañada de fiebre y escalofríos. En su primera aparición se pueden confundir con un cuadro de influenza o un cuadro gripal. Una vez que los trabajadores han quedado sensibilizados, pueden responder a dosis muy pequeñas de alergenos. El líquido se acumula en los alvéolos interfiriendo con la capacidad de difusión del oxígeno. La finalización de la exposición va a permitir que se resuelva la fase aguda a lo largo de un período de 1-2 semanas. Sin embargo, las exposiciones recurrentes pueden producir una enfermedad crónica con fibrosis intersticial y disnea severa.

**Enfermedad granulomatosa**
Los granulomas son respuestas inflamatorias que ocurren como reacción a las infecciones (Ej. tuberculosis) o a las toxinas. Hay un desplazamiento de grandes células inflamatorias que comienzan a acumularse alrededor del punto de exposición. Más tarde, hay migración de tejido fibroso que va a rodear el sitio, produciendo una masa globular que se puede observar bajo el microscopio. La beriliosis es el mejor ejemplo de enfermedad pulmonar ocupacional de esta clase.

**Otras condiciones de salud**
Varias condiciones preexistentes pueden causar patrones restrictivos. Estos incluyen el embarazo, la obesidad, ciertas anormalidades anatómicas, así como la cirugía torácica y abdominal. Aunque estas condiciones no son inducidas de una manera ocupacional, se les menciona debido a que su impacto se debe tomar en cuenta al revisar los resultados de las espirometrías.

## C. Algunas de las enfermedades pulmonares que muestran patrones obstructivos o restrictivos

**Neumonías**
Las neumonías pueden tener un efecto restrictivo debido a la acumulación de líquido y células inflamatorias en los alvéolos (semejante a una alveolitis), o un efecto obstructivo debido a la acumulación de células alrededor de los bronquios (neumonía bronquial). Las neumonías pueden aparecer como parte de un proceso tóxico, o más frecuentemente, debido a una infección. La enfermedad ocupacional de origen infeccioso ocurre fundamentalmente en trabajadores de la salud, empleados de asilos y guarderías, y en personas que trabajan con animales. Los agentes causantes pueden ser bacterias, virus, hongos y otros microorganismos. En muchos casos estas enfermedades se acompañan de fiebre y escalofríos.

**Neumoconiosis**
Aunque las neumoconiosis son primariamente enfermedades restrictivas, en los casos avanzados el tejido fibroso puede extenderse hasta el árbol traqueobronquial causando también síntomas obstructivos.

**Cáncer pulmonar ocupacional**
El cáncer pulmonar se caracteriza por una masa creciente de células que prolifera de manera no controlada. El hábito de fumar es la causa más importante y tiene un efecto sinergista con algunos otros carcinógenos ocupacionales. Algunos estudios epidemiológicos han mostrado tasas más frecuentes de cáncer pulmonar en individuos expuestos de manera repetida a: bis-clorometil éter, alquitrán de hulla, volátiles de alquitrán, gas mostaza, arsénico, asbesto, radio, petróleo, cromatos, y uranio. El cáncer pulmonar es particularmente insidioso, ya que es frecuente que los síntomas no aparezcan hasta en una etapa muy tardía para cualquier intervención médica. Dependiendo de dónde es que vaya a crecer el tumor(es), en las etapas tardías puede causar patrones obstructivo o restrictivo.

## APÉNDICE D. PROGRAMAS DE VIGILANCIA RESPIRATORIA

Los ambientes laborales donde los trabajadores están expuestos de manera potencial a riesgos pulmonares, deberán tener un programa de vigilancia respiratoria. Aunque las enfermedades pulmonares no son las enfermedades ocupacionales más frecuentes, frecuentemente resultan significativas debido a su severidad. El gasto humano y económico debido al asma ocupacional, las neumoconiosis (asbestosis, enfermedad de los pulmones negros, silicosis, etc.) y el cáncer pulmonar ocupacional son muy grandes. Estas enfermedades son causas significativas de morbilidad, incapacidad, retiro prematuro y muerte. Aún más, estas enfermedades son del todo prevenibles una vez que se reconocen sus causas. De esa manera, el reconocimiento de los riesgos asociados con la enfermedad pulmonar ocupacional debe tener una alta prioridad.

De manera idónea un programa de vigilancia respiratoria tiene cuatro objetivos primarios:

1. Reducir el sufrimiento humano y el impacto económico de la enfermedad ocupacional. La prevención como la detección temprana y el tratamiento son menos costosos tanto para la compañía como para la sociedad, que la productividad reducida, las indemnizaciones al trabajador, los litigios, las primas de seguro más caras y los gastos médicos.

2. Detectar las enfermedades pulmonares ocupacionales y no ocupacionales en sus etapas más tempranas es decir cuando hay mayor probabilidad de disminución a la exposición. Por ejemplo, la detección temprana y la remoción de alergenos presentes, reduce la posibilidad de un daño permanente para los individuos con asma ocupacional.

3. Identificar condiciones de trabajo riesgosas para que de esa manera se lleven a cabo las modificaciones de higiene industrial. De manera ideal esto no debería ser necesario. Sin embargo, la salud ocupacional no es una ciencia exacta. Conforme se aprende cada día más acerca de la relación entre las exposiciones y la enfermedad, se puede encontrar que los estándares de protección resulten ya anticuados. Además, algunos individuos desarrollan enfermedad pulmonar ocupacional con niveles de exposición por debajo de aquéllos considerados seguros.

4. Establecer como parámetro de referencia la situación actual del funcionamiento respiratorio de los nuevos empleados e identificar daños pulmonares preexistentes en los candidatos para el trabajo, de manera que se les pueda ubicar en puestos donde no se ponga en riesgo su salud. Por ejemplo, un puesto de trabajo que requiere el uso de un respirador, puede no ser lo más apropiado para alguien con enfisema (45).

La espirometría juega un papel importante en el programa de vigilancia respiratoria. La espirometría es portátil, segura tanto para el sujeto como para el técnico, no invasiva, barata y reproducible. Con un personal capacitado y con experiencia, resulta también relativamente fácil de realizar. Sin embargo, como se discutió ya anteriormente, los resultados de las pruebas espirométricas deben ser evaluados dentro del contexto de otra información médica para superar sus limitaciones. Los programas de vigilancia respiratoria deberán contener al menos los siguientes elementos programados de manera regular:

1. Una historia clínica detallada, haciendo énfasis en el hábito de fumar, enfermedades pulmonares previas así como síntomas respiratorios actuales.

2. Una detallada revisión de los antecedentes laborales, haciendo énfasis en potenciales exposiciones ocupacionales a riesgos pulmonares y en el uso de respiradores. Se deberán también investigar las potenciales exposiciones relacionadas con los pasatiempos y los empleos de medio tiempo.

3. Una exploración física completa, haciendo énfasis en la exploración torácica.

4. Radiografías de tórax (Rayos-X) cuando estén justificadas. Es importante interconsultar con radiólogos que tengan un adiestramiento especializado en los datos radiológicos de las enfermedades ocupacionales, como es el caso de los intérpretes tipo B (B-readers). Se trata de médicos adiestrados y certificados por NIOSH para interpretar radiografías de tórax, con la finalidad de detectar evidencias de neumoconiosis.

5. Espirometría.

Un programa de vigilancia respiratoria debe interactuar con un programa de higiene industrial que sea capaz de identificar y controlar riesgos pulmonares potenciales, que pueda supervisar el entrenamiento con respiradores y realizar actividades de evaluación.

La frecuencia con la cual se debe usar la espirometría para monitorizar a los trabajadores va a depender de los niveles de exposición y de la severidad del daño potencial. Sin embargo, al igual que con cualquier otro estudio médico, uno debe tener una razón justificable para realizar la espirometría, así como lineamientos para interpretar las pruebas y decidir sobre los resultados.

La vigilancia médica, por sí misma, debe usarse de manera conjunta con un monitoreo ambiental y un control de ingeniería para limitar, en la medida de lo posible, la magnitud de la exposición. En este contexto, la vigilancia médica es en realidad un procedimiento de control de calidad, diseñado para detectar si la exposición excesiva está ocurriendo a pesar de las medidas de control establecidas en el puesto.

Una vez que se han descartado factores técnicos para explicar un descenso en los valores de la función pulmonar, si se detectan anormalidades o si se detecta una reducción de la función pulmonar, comparada con estudios previos, se deberá hacer un esfuerzo para identificar la causa. Si la causa es una exposición en el sitio de trabajo, se deberán tomar las medidas necesarias para reducir la exposición y prevenir mayor daño a los pulmones de la persona. No resulta ético utilizar la espirometría para detectar a trabajadores con lesión pulmonar ocupacional, sin complementar esto con medidas para reducir la exposición, o si la información es utilizada como motivo de despido.

## APÉNDICE E. EL ESTÁNDAR DEL "COTTON DUST" DE LA OSHA

### Apéndice D de 29CFR1910.43 Estándares del funcionamiento pulmonar para los estándares del Cotton Dust

Las mediciones espirométricas de la función pulmonar deberán cumplir con los mínimos estándares descritos a continuación. Estos requisitos no impiden que se lleven a cabo estudios adicionales o métodos alternativos que puedan considerarse superiores.

I. **Aparato.**

a. El instrumento deberá tener una exactitud entre ± 50 ml o dentro del ± 3% de la lectura, cualquiera que resulte mayor de estos dos valores.

b. El instrumento deberá ser capaz de medir la capacidad vital de 0 a 7 litros BTPS.

c. El instrumento deberá tener una baja inercia y ofrecer poca resistencia al flujo de aire, de una manera en que dicha resistencia al flujo de aire de 12 litros por segundo, sea menor que 1.5 cm $H_20$/ (litros/segundo).

d. Para los propósitos de medir el tiempo del $VEF_1$, el punto cero deberá ser determinado al extrapolar, de manera retrógrada, la mayor pendiente de la curva volumen-tiempo, hasta el máximo volumen inspiratorio (1, 2, 3, 4), o por un método equivalente.

e. Los instrumentos que incorporen mediciones del flujo aéreo para determinar el volumen, deberán ajustarse al mismo grado de exactitud de volumen que se señala en el inciso (a) de esta sección, cuando el rango de flujo sea de 0 a 12 litros por segundo.

f. El instrumento, o el operador del instrumento, deberán tener los medios para corregir los valores de los volúmenes a la temperatura del cuerpo saturada con vapor de agua (BTPS), bajo aquellas condiciones donde las temperaturas ambientes del espirómetro y las presiones barométricas sean variables.

g. El instrumento utilizado deberá generar un trazo impreso, o en pantalla, de las relaciones flujo versus volumen, o del volumen versus tiempo durante toda la maniobra espiratoria forzada. Este trazo, o su imagen, son necesarios para determinar si el paciente ha ejecutado la prueba de manera adecuada. El trazo debe poder ser almacenado y estar disponible para revisiones; asimismo, deberá tener el suficiente tamaño para que se puedan hacer mediciones manuales con los requerimientos señalados en el inciso (a) de esta sección. Si se hace una impresión en papel, éste deberá tener una velocidad de al menos 2cm/seg y una sensibilidad al volumen de al menos 10.0 mm de la trama, por litro de volumen.

h. El instrumento deberá ser capaz de acumular el volumen por un mínimo de 10 segundos, y no deberá terminar de acumular este volumen antes de (1) que el cambio de volumen en un intervalo de 0.5 segundos sea menor de 25 mililitros, o (2) el flujo sea menor de 50

mililitros por segundo, en cada intervalo de 0.5 segundos.

i. Las mediciones de la capacidad vital forzada (CVF) y el volumen espiratorio forzado en 1 segundo ($VEF_1$), deberán cumplir con los requisitos de exactitud señalados en el inciso "a" de esta sección. Esto quiere decir que deberán ser medidos con una exactitud dentro de ± 50 ml o dentro de un ± 3% del valor, cualquiera que sea el mayor valor.

j. El instrumento debe tener la capacidad de poder ser calibrado en las zonas de trabajo, en relación a la CVF y al $VEF_1$. Esta calibración del $VEF_1$ y de la CVF puede ser realizada directamente, o indirectamente a través de mediciones de volumen y tiempo. La fuente de calibración del volumen deberá poder ofrecer un desplazamiento de volumen de al menos 2 litros y deberá tener una exactitud dentro de ± 30 mililitros.

## II. Técnica para la medición de la maniobra de la capacidad vital forzada

a. Se recomienda, pero no es indispensable, el uso de un clip nasal. Se deberá explicar el procedimiento al paciente en un lenguaje simple. Asimismo, se le indicará que se afloje cualquier prenda de vestir que esté ajustada y que se ponga de pie frente al aparato. El sujeto puede sentarse pero se deberá ser cuidadoso para que en ese caso, las pruebas repetidas se hagan en la misma posición, y de ser posible, con el mismo espirómetro. Se deberá poner particular atención para asegurarse de que el mentón esté ligeramente elevado y el cuello ligeramente extendido. Se deberá instruir al paciente para realizar una inspiración profunda a partir de un patrón respiratorio basal y después de eso, que lo expulse tan fuerte, rápido y completo como le sea posible. Se deberán realizar por lo menos tres maniobras espiratorias forzadas. Durante éstas, se deberá vigilar que el paciente siga las instrucciones. Se deberán verificar de manera visual los trazos de volumen-tiempo o flujo-volumen para verificar la reproducibilidad. Se considerarán inaceptables las maniobras cuando el paciente:

1. No haya logrado una inspiración completa antes de la espiración forzada.

2. No haya ejecutado un esfuerzo máximo durante toda la espiración forzada.

3. No haya continuado la espiración por al menos 5 segundos, o hasta que haya ocurrido una meseta evidente en la curva de volumen-tiempo.

4. Haya tosido o cerrado la glotis.

5. Tenga una boquilla que lo obstruya o una fuga alrededor de ella (obstrucción debido a que se haya colocado la lengua frente a la boquilla, o por el movimiento de dientes postizos frente a la misma boquilla, etc.)

6. Haya tenido un inicio de espiración no satisfactorio, uno que se haya caracterizado por titubeos (o falsos comienzos), y que por lo tanto impida la extrapolación retrógrada del tiempo 0 (el volumen extrapolado del trazo de volumen-tiempo debe ser menor del 10% de la CVF).

7. Haya tenido una excesiva variabilidad entre las tres curvas aceptables. La variación entre las dos mayores CVF y los dos mayores $VEF_1$, a partir de tres trazos satisfactorios, no deberá exceder el 10 por ciento o ± 100 mililitros, cualquiera que resulte mayor.

8. Se deberá llevar a cabo una calibración periódica de rutina del instrumento o del método usado para registrar la CVF y el $VEF_1$. Se deberá hacer ésta, utilizando una jeringa u otra fuente de volumen de por lo menos dos litros.

## III. Interpretación del espirograma

a. El primer paso al evaluar un espirograma va a ser determinar si el paciente ha ejecutado o no la prueba de manera adecuada como se describe en la sección II, más arriba. Se deberán medir y registrar la capacidad vital forzada (CVF) y el volumen espiratorio forzado en 1 segundo ($VFF_1$) a partir de los tres trazos satisfactorios. Se deberán usar tanto la CVF como el $VEF_1$ mayores, independientemente de la curva de la cual provenga cada uno.

b. Se recomiendan los siguientes lineamientos por parte de NIOSH para la evaluación y manejo de los trabajadores expuestos al polvo de algodón. Es importante señalar que los empleados que muestren una reducción de la proporción $VEF_1$/CVF, por debajo de 0.75, o reducciones en el $VEF_1$ del día lunes, del 5% o mayores con relación al examen inicial, deberán volver a ser examinados con un mes de diferencia. Aquéllos que muestren una disminución consistente en la función pulmonar, como se muestra en la siguiente tabla, deberán ser manejados de acuerdo a las recomendaciones.

## IV. Calificación del personal que realiza la prueba

Los técnicos que realizan la prueba a los trabajadores deberán tener el conocimiento básico que se requiere para obtener resultados significativos. El curso de adiestramiento de aproximadamente 16 horas deberá cubrir las siguientes áreas. Las personas que completen y pasen el curso van a ser certificadas por OSHA u otra institución incorporada.

a. Fisiología básica de la maniobra de la capacidad vital forzada y los determinantes de las limitaciones del flujo aéreo, haciendo énfasis sobre la reproducibilidad de los resultados.

b. Requerimientos del instrumental incluyendo los procedimientos de calibración, fuentes de error, así como su corrección.

c. Realización de la prueba incluyendo el asesoramiento que se le dé al sujeto evaluado, la capacidad para reconocer aquellas maniobras llevadas a cabo de manera inapropiada, y las sugerencias para corregirlas.

d. Resultados de calidad con énfasis en la reproducibilidad.

e. Uso práctico del equipo bajo condiciones supervisadas.

f. Mediciones de los trazos y cálculos de los resultados.

2. La parte 1928 del Título 29 del Código Federal de Regulaciones (Unión Americana) es corregido añadiéndole un nuevo párrafo(a) (5) a la sección 1928.21, que se lee como sigue:

Sección 1928.21. Estándares aplicables en CFR 29, parte 10.
(a) * * *
(5) Exposición al polvo del algodón en limpiadoras de algodón - Sección 1910.1046.

(Secciones 6,8, 84 OBSERVACIONES 1593, 1599(29 u.s.c. 655,657): Orden de la Secretaría del Trabajo (Unión Americana) 8-76 (41 FR 25059); CFR 29 parte 1911)
[Documento FR. 78-17233, archivado el 6-19-78; 11.53 am]

American Thoracic Society
MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

# Standardization of Spirometry

## 1994 Update

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, NOVEMBER 11, 1994

CONTENTS



The first American Thoracic Society (ATS) Statement on the Standardization of Spirometry was published 15 yr ago and was based on the Snowbird Workshop held in 1979 (1). This initial statement was updated in March 1987 (2) after 8 yr of practical experience with the initial recommendations. The state of the art of spirometry has continued to advance as a result of scientific studies that have provided additional data relating to performance of spirometry. The use of computers for spirometry measurement has become even more commonplace. New statements by the ATS (3) and the European Respiratory Society (4) also underscore the need to update the ATS statement on spirometry. This revision of the standards for spirometry reflects the changes in clinical emphasis and in available technology since the 1987 ATS spirometry update (2) was published. The changes in clinical emphasis and equipment include:

- The strong emphasis on the use of portable peak flow meters to monitor lung function in asthmatics by the National Heart, Lung, and Blood Institute's Asthma Education Program (5), the International Asthma Management Project (6), the British Thoracic Society (7), and others.
- The corresponding development of many new model peak flow monitoring devices, some purely mechanical and some electronic.
- A better understanding of the complexities of correcting spirometric values to BTPS conditions.

This statement was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. *Members of the committee:* Robert O. Crapo, M.D., Chairman, John L. Hankinson, Ph.D., Charles Irvin, Ph.D., Neil R. MacIntyre, M.D., Karen Z. Voter, M.D., and Robert A. Wise, M.D. *Spirometry Subcommittee:* John L. Hankinson, Ph.D., Subcommittee Chairman, Charles Irvin, Ph.D., Robert A. Wise, M.D. *Invited Spirometry and DLCO Workshop participants:* Brian Graham, Ph.D., Carl O'Donnell, Sc.D., Paolo Paoletti, M.D., Josep Roca, M.D., and Giovanni Viegi, M.D. *Corresponding members:* Margaret R. Becklake, M.D., A. Sonia Buist, M.D., Gary duMoulin, Ph.D., Robert L. Jensen, Ph.D., Albert Miller, M.D., and Andrea Rossi, M.D.

Am J Respir Crit Care Med Vol 152, pp 1107–1136, 1995

- A greater appreciation of the importance of the technicians and procedures in achieving good spirometric results.
- An increased concern about the risk of transmission of infectious diseases during pulmonary function testing.

We have responded to these changes by:

- Separating the standards for laboratory or diagnostic spirometers from those of devices designed to be used primarily as monitors.
- Adding BTPS testing to the testing of spirometers.
- Adding a section on performance of slow vital capacity.
- Strengthening and updating the procedural aspects of quality control, including an appendix with sample spirograms.
- Adding a section on hygiene and infection control.

A central goal of any guideline or standardization document is to improve performance and thus decrease the variability of laboratory testing. In 1979 (1), and again in 1987 (2), the perception was that the major source of variability was instrumentation. More recently, instrumentation has improved to a point where other sources of variability can be identified, in particular, procedural problems. In 1991, the ATS Statement on Lung Function Testing: Selection of Reference Values and Interpretation Strategies (3) stated: "The largest single source of within-subject variability is improper performance of the test." More recently, Enright and coworkers (8) have shown a positive impact of an extensive quality control program on spirometric results. As a consequence, there is an effort in the present statement to address issues of test performance and quality control.

The ATS statements on standardization of spirometry have had far-reaching effects on manufacturers and users of spirometers. In some cases, manufacturers have used the document as a minimum performance requirement document. We continue to be concerned with this approach and encourage manufacturers to seek excellence in design so that the state of the art for spirometers will *exceed* ATS recommendations. Some research protocols will necessitate even more stringent requirements than stated here.

Spirometry is a medical test that measures the volume of air an individual inhales or exhales as a function of time. Flow, or the rate at which the volume is changing as a function of time, may also be measured with spirometry. Spirometry, like the measurement of blood pressure, is a useful screen of general health. Like the simple measurement of blood pressure, it does not suffice in certain situations where more extensive testing is warranted. Spirometric results correlate well with morbidity and life expectancy. Spirometry is used to affect decisions about individual patients, including the nature of the defect, its severity, and the response to therapy. Table 1 lists some of the potential indications for spirometry.

Results from tests based on spirometric maneuvers can have an important effect on a person's lifestyle, standard of living, and future treatment (10). Similarly, accurate and precise spirometers are required for epidemiologic studies. Rates of improvement or deterioration of pulmonary function measured in relation to environmental exposures and/or personal characteristics may be erroneous if inaccurate spirometers are used or less sensitive if imprecise spirometers are used (11).

Maximizing the clinical usefulness of spirometry depends on a number of steps, ranging from equipment selection to interpretation, and ultimately involves clinical assessment. Figure 1 is a flow diagram of these steps.

The first step is establishing equipment performance criteria. The Snowbird Workshop (1), 1987 Update (2), and this update give recommendations for equipment used for spirometry.

The second step in the process involves validation that the spirometer design meets the minimum recommendations through the testing of a representative device. Detailed methods for performing the validation testing are outlined later in this statement. The ATS makes equipment recommendations but does not act as a certifying agency to verify compliance with these standards. Spirometer users should carefully select equipment that meets the ATS recommendations to assure that spirometry testing can be done accurately. Before purchasing a spirometer, it is wise to: (*1*) ask the manufacturer to provide summary data that demonstrates that the device being considered meets or exceeds ATS recommendations, or (*2*) review results of spirometry testing from independent testing laboratories. This statement does not mandate testing by an independent laboratory. There are many calibrated computer-driven syringes available. When an independent laboratory is not used, manufacturers should make the testing protocol, the raw data, and the summary data available to potential customers for their review.

Even after spirometers have been found to meet ATS recommendations, they (like other mechanical, electrical, or computer equipment) must be routinely checked for performance quality.

TABLE 1

INDICATIONS FOR SPIROMETRY*

- Diagnostic
  - To evaluate symptoms, signs, or abnormal laboratory tests
    - —Symptoms: dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain
    - —Signs: diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles
    - —Abnormal laboratory tests: hypoxemia, hypercapnia, polycythemia, abnormal chest radiographs
  - To measure the effect of disease on pulmonary function
  - To screen individuals at risk of having pulmonary diseases
    - —Smokers
    - —Individuals in occupations with exposures to injurious substances
    - —Some routine physical examinations
  - To assess preoperative risk
  - To assess prognosis (lung transplant, etc.)
  - To assess health status before enrollment in strenuous physical activity programs
- Monitoring
  - To assess therapeutic interventions
    - —Bronchodilator therapy
    - —Steroid treatment for asthma, interstitial lung disease, etc.
    - —Management of congestive heart failure
    - —Other (antibiotics in cystic fibrosis, etc.)
  - To describe the course of diseases affecting lung function
    - —Pulmonary diseases
      - Obstructive airways diseases
      - Interstitial lung diseases
    - —Cardiac diseases
      - Congestive heart failure
    - —Neuromuscular diseases
      - Guillain-Barré Syndrome
  - To monitor persons in occupations with exposure to injurious agents
  - To monitor for adverse reactions to drugs with known pulmonary toxicity
- Disability/Impairment Evaluations
  - To assess patients as part of a rehabilitation program
    - —Medical
    - —Industrial
    - —Vocational
  - To assess risks as part of an insurance evaluation
  - To assess individuals for legal reasons
    - —Social Security or other government compensation programs
    - —Personal injury lawsuits
    - —Others
- Public Health
  - Epidemiologic surveys
    - —Comparison of health status of populations living in different environments
    - —Validation of subjective complaints in occupational/environmental settings
  - Derivation of reference equations

* Adapted from reference 9.

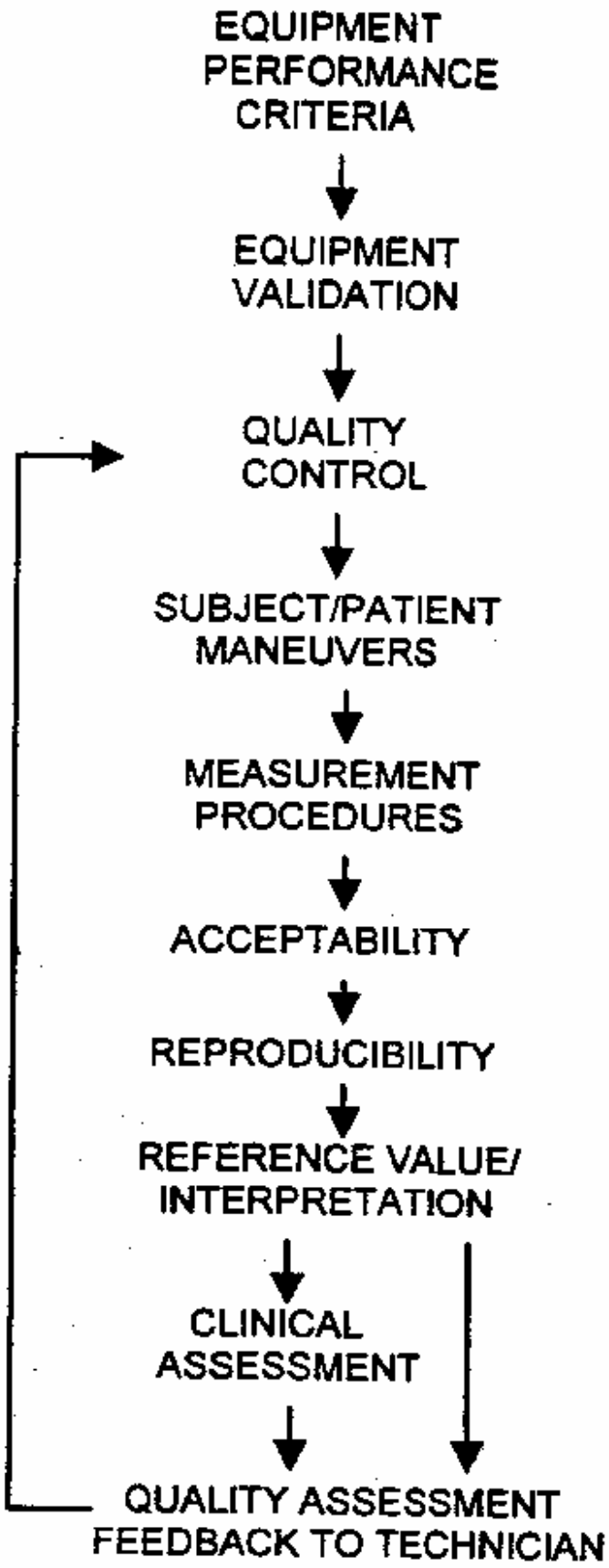



*Figure 1.* Spirometry standardization steps.

Recommendations for spirometer quality control have been developed by the ATS and are summarized in this statement.

Spirometry is an effort-dependent maneuver that requires understanding, coordination, and cooperation by the patient-subject, who must be carefully instructed. Thus, procedural recommendations are important components of testing. Part of the recommendation is to obtain a sufficient number of maneuvers of adequate quality and then determine if these acceptable maneuvers are reproducible, implying that maximal effort has been achieved. Once spirometry maneuvers have been performed, data are either measured by hand or computer. Measurement procedures are included in this article to help assure that uniform methods are used and comparable results are obtained. These recommendations include considerations such as using "back extrapolation" for determining the "start-of-test" time (zero point) for measures such as $FEV_1$ and the criteria to determine the end of the expiratory maneuver. Instruments that provide feedback to the technician in the form of checks on the adequacy of the data are clearly desirable.

The interactions between technicians and subjects are crucial to obtaining adequate spirometry, since it is such an effort-dependent maneuver. Technicians must be trained and must maintain a high level of proficiency to assure optimal results.

The spirogram tracing must be carefully scrutinized for quality. Recommendations about quality, acceptability, and reproducibility of test results are presented, as well as examples of unacceptable maneuvers (*see* APPENDIX A). After adequate results are obtained, they are usually compared with reference values to make an assessment (interpretation) of the results. The ATS 1991 Statement on Lung Function Testing: Selection of Reference Values and Interpretative Strategies provides guidelines for selecting reference values and interpreting the results. Clinical assessment should be an integral part of spirometry. Results obtained from spirometry are only one part of the much more complex patient-care relationship or research study analysis. It is the responsibility of the laboratory director to provide adequate quality control procedures to assure that an attempt to meet these recommendations and criteria has been made.

In both the original ATS statement on spirometry and the 1987 update, a rationale was provided for each recommendation. Since many of these recommendations and their rationales have not changed since the original statements, the reader is referred to the 1987 update (2) for the rationales concerning less controversial recommendations.

## DEFINITIONS

All terms and abbreviations used here are based on a report of the American College of Chest Physicians (ACCP)–ATS Joint Committee on Pulmonary Nomenclature (12).

Accuracy and precision are important terms in equipment recommendations and warrant some definition. Accuracy error is the systematic difference between the "true" and the measured value. The accuracy of a spirometer system depends on a number of factors, including linearity and frequency response of the system or processor, sensitivity to environmental conditions, calibration, and adequacy of correction factors. Its precision depends on the signal/noise ratio and on the resolution (i.e., the minimal detectable volume or flow). Precision error, usually denoted reproducibility, is the numerical difference between successive measurements (4). For example, if a volume spirometer's pen is not on zero but at 1 L, all volumes read directly from the graph would be overread by 1 L. The accuracy error would be 1 L, since the measured volume would read 3 L when the true volume is 2 L. However, the precision of the spirometer would remain unchanged, as the spirometer would consistently read 3 L each time 2 L is injected into the spirometer. For some applications, e.g., peak expiratory flow (PEF) monitoring, precision is more important than accuracy.

In several sections of this document, the terms "open circuit" and "closed circuit" technique are used. The term "open circuit" spirometry refers to the method of conducting spirometry where the subject takes a full inspiration before inserting the mouthpiece to perform the test. In this approach, the subject does not inhale from the spirometer or potentially contaminated flow sensor. The term "closed circuit" spirometry refers to the method of conducting spirometry where the subject is attached to the mouthpiece before the inspiration is begun, and often several tidal breaths are obtained. In this approach, the subject does inhale from the spirometer. There are advantages and disadvantages to both of these approaches and both are recommended procedures. For example, an advantage of the closed circuit technique is that it allows measurement of expiratory reserve volume (ERV), tidal volume (TV), and inspiratory flows.

Previous recommendations (1, 2) treated all spirometers alike whether used for clinical, diagnostic, or epidemiologic purposes. However, a new class of device has been added for monitoring purposes. Monitoring devices (portable peak flow meters, etc.) have separate recommendations from diagnostic spirometers for the recorder/display requirements as well as the accuracy requirements. In addition, precision requirements have been added for monitoring devices. Recommendations concerning monitoring devices are identified in this statement by the notation, "Monitoring." We do *not* recommend the use of monitoring devices for diagnostic purposes in the traditional diagnostic setting where one is comparing a measured value with a reference value. In this setting, monitoring instruments are likely to be inadequate because: (*1*) they may be less accurate than diagnostic instruments; (*2*) they usually cannot be calibrated or checked to assure their performance; (*3*) their graphical displays may be missing or inadequate to allow proper evaluation of the subject's effort and overall test quality; and (*4*) current PEF standards of ± 10% allow models of instruments to vary by up to 20%, adding variability to reference values derived when a monitoring instrument is used. However, monitoring instruments may be useful in diagnosing excessive variability in spirometric parameters because they tend to have excellent precision.

## EQUIPMENT RECOMMENDATIONS

Accurate results require accurate equipment. Spirometer equipment recommendations apply to all diagnostic spirometers whether used for clinical or epidemiologic purposes. Instrumentation recommendations should be followed to provide accurate spirometric data and information that are comparable from laboratory to laboratory and from one time period to another (1). The accuracy of a spirometry system depends on the resolution (i.e., the minimal detectable volume or flow) and linearity of the entire system, from volume or flow transducer to recorder, display, or processor. Errors at any step in the process can affect the accuracy of the results. For example, if the BTPS correction factor is in error, an accurate, uncorrected FVC will be corrupted when the factor is applied.

Recommendations are first provided for diagnostic spirometers, followed by recommendations for monitoring devices under the subheading, "Monitoring." For example, the equipment recommendations for diagnostic spirometry are summarized in Table 2 and for monitoring devices in Table 3. Spirometers are not required to measure all the following parameters but must meet the recommendations for those parameters that are measured. Accuracy and precision recommendations apply over the entire volume range of the instrument.

TABLE 2

MINIMAL RECOMMENDATIONS FOR DIAGNOSTIC SPIROMETRY*

| Test | Range/Accuracy (BTPS) | Flow Range (L/s) | Time (s) | Resistance and Back Pressure | Test Signal |
|---|---|---|---|---|---|
| VC | 0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater | zero to 14 | 30 | | 3-L Cal Syringe |
| FVC | 0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater | zero to 14 | 15 | Less than 1.5 cm $H_2O$/L/s | 24 standard waveforms<br>3-L Cal Syringe |
| $FEV_t$ | 0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater | zero to 14 | 1 | Less than 1.5 cm $H_2O$/L/s | 24 standard waveforms |
| Time zero | The time point from which all $FEV_t$ measurements are taken | | | Back extrapolation | |
| PEF | Accuracy: ± 10% of reading or ± 0.400 L/s, whichever is greater<br>Precision: ± 5% of reading or ± 0.200 L/s, whichever is greater | zero to 14 | | Same as $FEV_t$ | 26 flow standard waveforms |
| $FEF_{25-75\%}$ | 7.0 L/s ± 5% of reading or ± 0.200 L/s, whichever is greater | ± 14 | 15 | Same as $FEV_t$ | 24 standard waveforms |
| V | ± 14 L/s ± 5% of reading or ± 0.200 L/s, whichever is greater | zero to 14 | 15 | Same as $FEV_t$ | Proof from manufacturer |
| MVV | 250 L/min at TV of 2 L within ± 10% of reading or ± 15 L/min, whichever is greater | ± 14<br>± 3% | 12<br>to 15 | Pressure less than ± 10 cm $H_2O$ at 2-L TV at 2.0 Hz | Sine wave pump |

* Unless specifically stated, precision requirements are the same as the accuracy requirements.

**Recommendation: Vital Capacity (VC)**

VC = The maximal volume of air exhaled from the point of maximal inhalation or the maximal volume of air inhaled from a point of maximal exhalation can be measured with a slow exhalation or inhalation, respectively. This was previously called the "slow" vital capacity and has been better described as the "relaxed vital capacity" (13). The VC is expressed in liters (BTPS). BTPS is body conditions: normal body temperature (37° C), ambient pressure, saturated with water vapor. When the rebreathing technique is used, an oxygen supply may be provided and carbon dioxide absorbed to account for oxygen consumption and the production of carbon dioxide. In this case, the oxygen supply must account for the total oxygen consumed, maintaining the volume constant at functional residual capacity. If this is not done properly, an incorrect VC could be obtained. Because of this potential error, the rebreathing technique with the absorption of carbon dioxide is discouraged as a technique when only VC is to be measured.

*Rationale.* In some subjects, a slow or relaxed vital capacity provides a more accurate determination of the vital capacity than those obtained with a forced exhalation. Forced expiratory volumes are usually lower than those obtained with a slow exhalation in subjects with airways obstruction and in older subjects. With severe airways obstruction, VC values may be larger than FVC values by as much as 1 L.

TABLE 3

MINIMAL RECOMMENDATIONS FOR MONITORING DEVICES

| Requirement | FVC & $FEV_t$ (BTPS) | PEF (BTPS) |
|---|---|---|
| Range | High: 0.50 to 8 L<br>Low: 0.5 to 6 L | High: 100 L/min to ≥ 700 L/min but ≤ 850 L/min<br>Low: 60 L/min to ≥ 275 L/min but ≤ 400 L/min |
| Accuracy | ± 5% of reading or ± 0.100 L, whichever is greater | ± 10% of reading or ± 20 L/min, whichever is greater |
| Precision | ± 3% of reading or ± 0.050 L, whichever is greater | Intradevice: ≤ 5% of reading or ≤ 10 L/min, whichever is greater<br>Interdevice: ≤ 10% of reading or ≤ 20 L/min, whichever is greater |
| Linearity | Within 3% over range | Within 5% over range |
| Graduations | Constant over entire range<br>High: 0.100 L<br>Low: 0.050 L | Constant over entire range<br>High: 20 L/min<br>Low: 10 L/min |
| Resolution | High: 0.050 L<br>Low: 0.025 L | High: 10 L/min<br>Low: 5 L/min |
| Resistance | Less than 2.5 cm $H_2O$/L/s, from zero to 14 L/s | Less than 2.5 cm $H_2O$/L/s, from zero to 14 L/s |
| Minimal detectable volume | 0.030 L | — |
| Test Signal | 24 standard volume-time waveforms | 26-standard flow-time waveforms |

High = high range and low = low range devices.

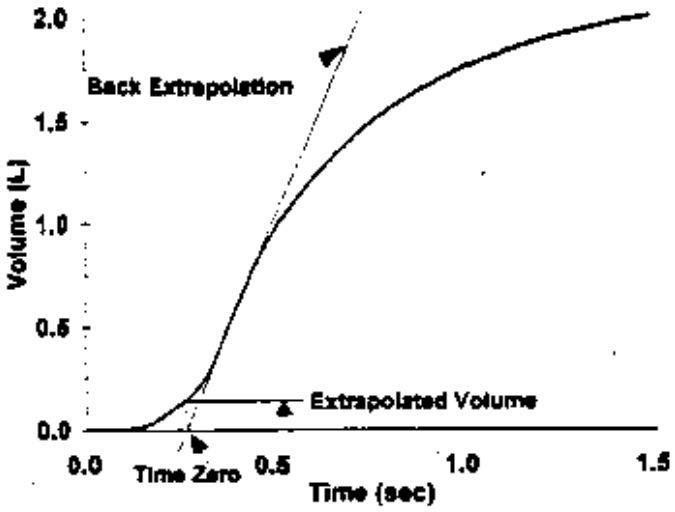



*Figure 2.* Typical subject waveform of a volume–time spirogram illustrating back extrapolation to determine "time zero." Extrapolated volume = Vext.

For measurements of VC, the spirometer must be capable of accumulating volume for *at least* 30 s. Spirometers must be capable of measuring volumes of *at least* 8 L (BTPS) with flows between zero and 14 L/s with a volume accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater.

#### Recommendation: Forced Vital Capacity (FVC)

FVC = Maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration, i.e., vital capacity performed with a maximally forced expiratory effort, expressed in liters (BTPS).

The diagnostic spirometer must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The 8-L range requirement applies to newly manufactured instruments; existing spirometers with a 7-L range may continue to be used. The spirometer must be capable of accumulating volume for *at least* 15 s, although longer times are recommended.

*Monitoring.* Monitoring devices must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices must be *at least* ± 3% of reading or ± 0.050 L, whichever is greater. The device must be capable of accumulating volume for *at least* 15 s.

#### Recommendation: Timed Forced Expiratory Volume ($FEV_t$)

$FEV_t$ = The volume of air exhaled in the specified time during the performance of the FVC, e.g., $FEV_t$ for the volume of air exhaled during the first second of FVC, expressed in liters (BTPS).

Measuring $FEV_t$ requires a spirometer capable of measuring volumes of *at least* 8 L. The spirometer must measure $FEV_t$ within an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The start-of-test for purposes of timing *must be* determined by the back extrapolation method (1, 14, 15) or a method shown to be equivalent (Figure 2). For manual measurements, the back extrapolation method traces back from the steepest slope on the volume–time curve (Figure 2) (15, 16). For computer methods of back extrapolation, we recommend using the largest slope averaged over an 80-ms period (17). The total resistance to airflow at 14.0 L/s must be less than 1.5 cm $H_2O$/L/s. The total resistance must be measured including any tubing, valves, pre-filter, etc., that may be inserted between the subject and the spirometer. Since some devices may exhibit changes in resistance due to water vapor condensation, resistance requirements must be met under ATPS conditions when up to eight successive FVC maneuvers are performed in a 10-min period.

*Monitoring.* The monitoring device must be capable of measuring $FEV_t$ up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices for $FEV_t$ must be *at least* ± 3% of reading or ± 0.050 L, whichever is greater. Resistance should be less than 2.5 cm $H_2O$/L/s and the start-of-test requirement is the same as for diagnostic spirometry.

#### Recommendation: PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/second (BTPS).

Measuring PEF requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 0.300 L/s, whichever is greater. Intra-instrument precision must be less than 5% of reading or 0.150 L/s, whichever is greater. Interdevice precision must be less than 10% or 0.300 L/s, whichever is greater.

The following or an equivalent method can be used in the determination of $FEF_{max}$ or PEF for volume–time curves. However, the method used to derive PEF may depend on the measuring instrument (18), and the final determination of compliance should be determined through testing using the standard waveforms (26 flow–time waveforms, APPENDIX D), with PEF derived from the flow–time waveform (Table D1, column 2).

Determination of PEF can be performed from the volume–time data by using a parabolic curve-fitting algorithm, which smooths the data using a least squares parabolic fit to a 40- or 80-ms segment (np = 2 or 4) of the volume–time curve, or:

$$\text{flow}(n) = \frac{\sum_{j=-np}^{np} j \cdot \text{vol}(n+j)}{2 \cdot h \cdot \sum_{j=1}^{np} j \cdot j} \qquad \text{PEF} = \text{Max (flow)}$$

where flow = an array of flow values from start to end of test; n = index of current flow data point (n = [np + 1] to index value of end of test); vol = an array of volume values; j = an index value as indicated in the equation; h = the time between samples (0.01 s in this example); np = the number of data points (for a 40-ms segment, np = 2 and for an 80-ms segment, np = 4); and PEF is the maximum value observed in the array flow.

*Rationale.* Using the 26 flow–time waveforms to define PEF is a change from the ATS 1987 Update. The PEFs for the 24 standard volume–time waveforms and the $FEF_{max}$ described in the 1987 ATS Spirometry Update used the above algorithm with an 80-ms interval. Manufacturers, through the use of mechanical simulators and the 24 standard volume–time waveforms, have been implementing this or equivalent methods through their attempts to derive PEFs similar to those defined by the 24 standard volume–time waveforms.

In addition, the National Asthma Education Program (NAEP) (5) has adopted ATS standard volume–time waveform number 24 as their standard for portable PEF meters. Hankinson and Crapo (18) have shown that reducing the time interval in the above equation from 80 to 40 ms results in as much as an 8% higher PEF for two of the 24 standard volume–time waveforms and a

5% higher PEF value for waveform number 24. Regardless of this apparent change, PEF is a flow parameter and therefore should be defined based on a flow–time waveform rather than a volume–time waveform (i.e., waveform number 24). The final determination of compliance should be determined through testing using the standard 26 flow–time waveforms (APPENDIX D) and the PEF derived from the flow–time curve (Table D1, column 2). This approach allows all of an instrument's characteristics to be considered, rather than only the PEF computational algorithm. Because PEF is more variable than FVC and $FEV_1$ and because of the confusion surrounding PEF definition, a relatively large ± 10% accuracy requirement was allowed.

#### Recommendation (Monitoring): PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/minute (BTPS).

Monitoring PEF also requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz and a resistance less than 2.5 cm $H_2O$/L/s with flows up to 14 L/s. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 20 L/min, whichever is greater, with PEFs between 60 to 400 L/min for children and from 100 to 850 L/min for adults. The lower limit range of the instrument must be less than or equal to 60 L/min for children and 100 L/min for adults. The upper limit range must be greater than or equal to 275 L/min but less than 400/L min for children and greater than or equal to 700 L/min but less than 850 L/min for adults. If manual reading of the instrument is used, the reader must be able to resolve at least 5 L/min for low range (children) and 10 L/min for high range (adults) (marked PEF intervals [graduations] no greater than 10 L/min for low range and 20 L/min for high range). Intra-instrument precision must be less than or equal to 5% of reading or 10 L/min, whichever is greater. Interdevice precision must be less than 10% or 20 L/min, whichever is greater. Data on the instrument's life span and durability must be provided by the manufacturer, specified as the typical life span over which the instrument will satisfy the requirements of this section.

In addition to the above requirements, PEF measuring devices must also provide a method of reporting values at BTPS. For portable PEF meters, BTPS correction may be accomplished by limiting the environmental operational range for the instrument in terms of barometric pressure (altitude) and ambient temperature. Portable PEF meters must meet the accuracy and precision requirements above, given the range of environmental conditions encountered with typical use. A 10% accuracy requirement, higher than the 5% for other flows, is recommended to allow for potential BTPS correction complications associated with PEF measurements. Besides providing a method of correcting PEF values to BTPS, the instrument's manufacturer must also provide a correction for the effects of altitude or other environmental conditions as appropriate.

A package insert must be provided with each portable PEF meter containing *at least*: (*1*) clear instructions (with illustrations) for use of the instrument in simple terms that are understood by the general public; (*2*) instructions concerning maintenance of the instrument and methods to recognize when it is malfunctioning; and (*3*) appropriate actions to be taken when PEF readings change appreciably (i.e., whom to contact).

*Rationale.* Concerning the requirement of a flat frequency response up to 12 Hz, Lemen and coworkers (19) have shown that the mean highest frequency (HF) with significant amplitude content was 5.06 Hz in healthy individuals and 6.4 Hz in patients and smokers. They concluded that flow measuring devices should have a frequency response that is flat up to 12 Hz. Peslin and coworkers (20) found a slightly higher HF of about 10 Hz in healthy males and 7.5 Hz in female subjects. In addition, current mechanical waveform-generating equipment generally cannot accurately produce waveforms with frequency content above 12 Hz. The accuracy recommendation is less stringent for PEF than for the FVC and $FEV_1$ (10% versus 5%) because of the higher within- and between-subject variabilities associated with PEF measurements and because of testing instrument limitations. The PEF instrument precision and intra-instrument variability recommendations are lower (5%) than the accuracy and inter-instrument variability requirements (10%) because of the need for low instrument variability in the routine use of PEF meters for serial measurements. In addition, several studies have shown PEF meters to be much more precise than accurate (21–23). These recommendations are also similar to those of the NAEP (5). The range recommendations are made with the understanding that PEF measurements are often made using portable PEF meters. With these meters, reading resolution (number of graduations) must be balanced against the range of the meter (upper and lower meter limits). Therefore, different instrument ranges for children and adults are appropriate. The range recommendations for children are not intended to preclude the use of an instrument with adult ranges if the instrument meets the resolution requirements (ease of reading) for children.

An instrument's life span and durability are difficult to determine and will be specific to an instrument. However, portable peak flowmeters are often used for extended periods of time. Therefore, the instrument manufacturer must provide information on the typical life span of their instrument as well as cleaning and other maintenance instructions. The package insert requirements recommended by the NAEP (5) are similar to those recommended in this statement.

#### Recommendation: $FEF_{25-75\%}$

$FEF_{25-75\%}$ = Mean forced expiratory flow during the middle half of the FVC. Formerly called the maximal mid-expiratory flow (MMEF), expressed in liters/second (BTPS).

The $FEF_{25-75\%}$ must be measured with an accuracy of *at least* ± 5% of reading or ± 0.200 L/s, whichever is greater, over a range of up to 7 L/s. The $FEF_{25-75\%}$ must be measured on a system that meets diagnostic FVC recommendations.

#### Recommendation: Flow ($\dot{V}$)

$\dot{V}$ = Instantaneous forced expiratory flow (except for PEF), expressed in liters/second (BTPS).

Flow may be measured electronically or manually from a flow–volume display with adequate size for hand measuring. Where flow–volume loops or other uses of flow are made, with flow in the range of −14 to 14 L/s, the flow must be measurable to within ± 5% of reading or ± 0.200 L/s, whichever is greater.

#### Recommendation: Forced Expiratory Time (FET%)

FET% = Time from the back-extrapolated "time zero" until a specified percentage of a maneuver's FVC is exhaled, expressed in seconds. For example, FET95% would be the time required to reach 95% of a maneuver's FVC. See APPENDIX A for FET% examples. FET100% would be defined as the time required to reach the FVC or the time at which the volume was observed to be at its highest level. For maneuver quality assessment purposes, the reporting of the FET99% (24) or FET100% is encouraged but not mandated. Also, the FET25–75% (mid-expiratory time) may be a useful indicator of diminished flow when VC is decreased and may be less dependent on body or lung size than other flow parameters (25).

#### Recommendation: Forced Inspiratory Vital Capacity Maneuvers

These maneuvers are inspiratory vital capacity maneuvers per-

formed with maximally forced effort from a position of maximal expiration to a position of maximal inspiration. Both volume and flow parameters are measured, which roughly correspond (except for direction) to those from the FVC maneuver. Volume measurements are expressed in liters (BTPS), flow measurements in liters/second (BTPS).

*Rationale.* Forced inspiratory maneuvers are useful in diagnosing and monitoring upper airway obstruction. They are usually performed either preceding or following the FVC maneuver but may be performed separately. Elderly or ill patients often have difficulty performing forced inspiratory and expiratory maneuvers as part of the same effort. Forced inspiratory maneuvers require the use of one of the closed circuit techniques.

For measurements of forced inspiratory spirometric parameters diagnostic spirometers must meet the corresponding range, accuracy, and precision recommendations specified for diagnostic spirometry systems (Table 2).

#### Recommendation: Maximal Voluntary Ventilation (MVV)

MVV = The volume of air exhaled in a specified period during repetitive maximal respiratory efforts, expressed in liters/minute (BTPS).

When a spirometer is used for measuring MVV, it must have an amplitude–frequency response that is flat within ± 10% from zero to 4 Hz at flow rates of up to 12 L/s over the volume range. The time for exhaled volume integration or recording must be no less than 12 s nor more than 15 s (26). The indicated time must be accurate to within ± 3%. The MVV must be measured with an accuracy of ± 10% of reading or ± 15 L/min, whichever is greater.

#### General Background: Spirometry Recorders/Displays

Paper records or graphic displays of spirometry signals are *required* and are used for:

1. Diagnostic function—when waveforms are to be used for quality control or review of the forced expiratory maneuver to determine if the maneuver was performed properly, so that unacceptable maneuvers can be eliminated.
2. Validation function—when waveforms are to be used to validate the spirometer system hardware and software for accuracy and reliability through the use of manual measurements (for example, measurement of $FEV_1$ using back extrapolation by comparing computer- and manually determined $FEV_1$).
3. Manual measurement function—when waveforms are to be manually measured for spirometric parameters (FVC, $FEV_1$, etc.) in the absence or failure of a computer.

With the continued advances in computer technology, there are many different ways to display and record spirometric waveforms. The committee continues to encourage use of computer technology.

Paper recorder requirements are the same regardless of the purpose, diagnostic, validation, or manual measurement. If no paper recorder or printer is available, then proof of validation of the accuracy and stability of the spirometer by an independent laboratory *must* be provided by the manufacturer. For these computer methods, any new software releases *must* also be validated.

#### Recommendation: Display of VC Maneuver

Either "open" or "closed" circuit technique may be used to measure the VC maneuver. Although the open circuit technique may be preferred because of hygiene concerns, this technique does not allow the monitoring (display) of the inhalation to TLC and therefore is less than optimum. Regardless of whether the open or closed circuit technique is used, a display of the entire VC maneuver must be provided. The maximal expiratory volume must be assessed to determine whether the subject has obtained a plateau in the expiratory effort. Subjects with airways obstruction usually exhibit different shaped curves at the end of their expiratory maneuver—a slope showing the nonhomogeneous emptying of lung units. Some patients with severe airways obstruction are not able to return to the level of FRC due to gas trapping (*see* APPENDIX A, VC maneuvers). In addition, important differences between inspiratory (IVC) and expiratory (EVC) maneuvers may be observed in patients with airways obstruction (27). For systems using a closed circuit with carbon dioxide absorption, a volume–time display is needed to verify baseline end-expiratory level (functional residual capacity or FRC). The graph should indicate the starting volume to evaluate the correct positioning of FRC.

#### Recommendation: Display of FVC Maneuver

Displays using flow versus volume instead of volume versus time expand the initial portions (first 1–2 s) of the forced vital capacity maneuver. Since this portion of the maneuver, particularly the peak expiratory flow, is correlated with the pleural pressure during the maneuver, the flow–volume display is useful to assess the magnitude of effort during the initial portions of the maneuver. Overlaying a series of flow–volume curves registered at apparent TLC (maximal inhalation, which may not be true TLC) is helpful in detecting a submaximal effort that may result in a large though nonreproducible $FEV_1$ as a consequence of negative effort dependence (28).

Unlike the flow–volume curve display, display of the FVC maneuver as a volume–time graph expands the terminal portions of the maneuver. Therefore, the volume–time display is useful in assessing the duration of effort and whether a plateau is achieved. Where spirometry may need to be reviewed by independent agencies, a volume–time tracing of sufficient size allows independent measurement and calculation of parameters from the FVC maneuvers. Overlaying a series of volume–time curves aligned at back-extrapolated time zero or flow–volume curves aligned at TLC is useful in evaluating reproducibility and submaximal efforts. For optimal quality control, both flow–volume and volume–time displays are useful and strongly encouraged. See APPENDIX A for illustrations of volume–time and flow–volume displays.

#### Recommendation: VC and FVC Maneuver Volume and Time Scales

Volume scale: When a volume–time curve is plotted or displayed, the volume scale must be *at least*: 10 mm/L (BTPS).

Time scale: *at least* 2 cm/s; larger time scales are preferred (at least 3 cm/s) when manual measurements are to be made (1, 29, 30). When the volume–time plot is used in conjunction with a flow–volume curve (both display methods are provided for interpretations and no hand-measurements are performed), the time scale requirement is reduced to 1 cm/s from the usually required minimum of 2 cm/s. This exception is allowed because, in these circumstances, the flow–volume curve can provide the means for quality assessment during the initial portion of the FVC maneuver. The volume–time curve can be used to evaluate the terminal portion of the FVC maneuver, and the time scale is less critical. For display of the slow VC, the volume scale may also be reduced to 1 cm/L and the time scale to 0.5 cm/s.

#### Recommendation: Flow–Volume Curves

When a flow–volume curve is plotted or displayed, exhaled flow must be plotted upwards and exhaled volume towards the right.

TABLE 4

MINIMUM REQUIRED SCALE FACTORS FOR TIME, VOLUME, AND FLOW GRAPHICS

| Parameter | Resolution Required | Scale Factor |
|---|---|---|
| Volume | 0.025 L | 10 mm/L |
| Flow | 0.100 L/s | 5 mm/L/s |
| Time | 0.20 s | 2 cm/s |

A 2:1 ratio must be maintained between the flow and volume scales, e.g., 2 L/s of flow and 1 L of exhaled volume must be the same distance on their respective axes. The flow and volume scales must be *at least* as shown in Table 4.

*Rationale.* It was the committee's unanimous opinion that the previous diagnostic recorder requirements of 5 mm/L and 1 cm/s have proven inadequate for judging the quality of an expiratory effort, e.g., terminal events are not detectable (APPENDIX A). For certain applications (for example, for disability determination and legal cases), diagnostic size displays are clearly *not* adequate (26, 30). The U.S. Cotton Dust standard requires ". . . tracings must be stored and available for recall and must be of sufficient size that manual measurements may be made . . ." (31). Also, users will customarily not be able to verify accuracy and stability of spirometers by themselves in the absence of an adequate paper recording.

#### Recommendation: Correction to BTPS

This statement recommends that diagnostic spirometric studies not be conducted with ambient temperatures less than 17° C or more than 40° C. In part, the rationale for this recommendation is based on problems with finite cooling times of gases in volume-type spirometers (32–34) and the problems of estimating BTPS correction factors for flow devices (35–37). When a subject performs an FVC maneuver, the air leaving the lungs and entering the spirometer is at approximately 33 to 35° C (38, 39) and is saturated with water vapor. Most volume-type spirometers assume instantaneous cooling of the air as it enters the spirometer. However, this is not always the case, and an error in $FEV_1$ can occur due to the incorrect assumption of instantaneous cooling of the air. For capillary and screen pneumotachometers, the gain is dependent on gas viscosity and increases with increasing temperature. Therefore, a different correction factor is needed between patients and a calibrating syringe and between inspiratory and expiratory maneuvers. In addition, the assumption is usually made that no cooling of the air occurs as the air passes through the flow sensor. This may not be the case, particularly with unheated flow sensors (35). If the expired gas is assumed to be BTPS, an error of about 1% will result. The error will increase if the flow sensor is located further from the mouth and more cooling occurs. In addition, water condensation within or on the surface of a flow sensor may alter its calibration. Depending on environmental temperature, the BTPS correction factor may be as large as 10%. Therefore, the method used to calculate or estimate the BTPS factor can potentially introduce significant errors by the application of an erroneous BTPS correction factor.

Changes in spirometer temperature can be a source of variability; therefore, spirometer temperature should be measured and not assumed to be constant, even over the course of one testing session. Johnson and colleagues (40) found that if ambient temperature was used in BTPS correction and applied to all maneuvers, $FEV_1$ and FVC measurement errors of up to 6% may occur. When using volume spirometers, they recommend that the temperature of air inside the spirometer should be measured accurately during each breathing maneuver.

#### Recommendation (Monitoring): Correction to BTPS

For operating simplicity, monitoring devices may use one BTPS correction factor for a range of barometric pressures (altitude) and environmental temperatures. However, the use of a single BTPS correction factor or direct readings at BTPS does not eliminate the requirement to meet the accuracy specifications under BTPS conditions. Therefore, manufacturers must provide appropriate labeling concerning the environmental conditions (ambient temperature and pressure) under which their device will meet the accuracy requirements. If necessary or appropriate, the manufacturer may provide several BTPS correction factors to meet the accuracy requirements over a range of environmental conditions (altitude and temperature).

## EQUIPMENT VALIDATION

#### Recommendation: FVC Validation

The diversity of FVC maneuvers encountered in clinical practice are currently best simulated by the use of the 24 standard waveforms developed by Hankinson and Gardner (17, 41). These waveforms can be used to drive a computer-controlled mechanical syringe or its equivalent for testing actual hardware and software (42, 43) or they can be put into a system in digital form to evaluate *only* the software. It is strongly recommended that spirometry systems be evaluated using a computer-driven mechanical syringe or its equivalent and that the digital forms only be used for evaluating changes in software. APPENDIX C shows the measured values for each of the 24 standard waveforms. The American Thoracic Society also provides these waveforms on floppy disks for an IBM-PC.* Appropriate corrections for using gas at ambient temperature and humidity instead of BTPS may need to be made for some mechanical syringe-spirometer combinations. In addition, precision criteria have been added, and testing of spirometry systems using heated and humidified test gas is recommended.

The accuracy validation limits (tolerance for simulator systems is included in these limits) for volume are: volume (FVC, $FEV_1$) ± 3.5% of reading or ± 0.070 L, whichever is greater; and average flow ($FEF_{25-75\%}$) ± 5.5% of reading or ± 0.250 L/s, whichever is greater. The error range is expanded from the earlier ATS spirometry recommendation to allow for errors associated with mechanical syringes (42). The precision validation limits are: volume (FVC and $FEV_1$) 3.5% (range percent) or 0.100 L, whichever is greater; and flow ($FEF_{25-75\%}$) 5.5% or 0.250 L/s, whichever is greater. Mechanical syringes used for validation must be accurate within ± 0.025 L for FVC and $FEV_1$ and ± 0.100 L/s for $FEF_{25-75\%}$.

*Rationale.* Testing of spirometry systems using heated and humidified test gas has been added to the validation criteria because of potential problems associated with BTPS correction (32–37). See APPENDIX B for further details.

#### Recommendation: PEF Validation

PEF instrument designs must be validated using a mechanically driven syringe or its equivalent, using the flow–time waveforms described in APPENDIX D. These waveforms are available on digital media from the ATS. In addition, the mechanically driven syringe must be validated (APPENDIX B) to ensure that it accurately produces these waveforms and corresponding PEFs within ± 2% of reading. The flow–time waveforms in APPENDIX D were chosen to represent a range of peak flows and flow–time signals with various times-to-PEF (time required to go from 0.200 L/s to PEF). The accuracy validation limit for PEF is ± 12% of reading or ± 25 L/min, whichever is greater.

* Available from the American Thoracic Society.

The precision (range deviation) validation limit for PEF is 6% or 15 L/min, whichever is greater.

*Rationale.* The NAEP (5) recommended the use of a mechanically driven syringe to test and validate the accuracy of peak flow measuring instruments and to assess intra- and inter-device precision. Their recommendations included the use of ATS waveform 24 with various multipliers to achieve different PEFs. One problem with using only waveform 24 is a lack of variability in the shape or rise-time in the waveforms used to test PEF meters. Therefore, the use of several waveforms in the testing and validation of PEF meters to provide a range of PEFs and times-to-PEF (rise-times) is recommended. The waveforms in APPENDIX D are flow-time waveforms and, therefore, the definition of peak flow obtained from these waveforms is simple to derive. In addition, a volume-time curve for use by the mechanically driven syringe can be obtained from a flow-time curve by simply summing the flow-time values (integrating the flow signal).

The accuracy of the mechanically driven syringe for PEF, ± 2% of reading, was chosen based on current technical feasibility. Current technology of mechanically driven syringes is not sufficient to provide greater accuracies. This is due to the dynamic aspect of peak flow—high frequency content and PEF occurs at a point in the flow-time signal where the acceleration is changing, resulting in potential "overshoot" by a mechanical syringe. In addition, insufficient data are available concerning the accuracy of PEF meters using waveforms with higher frequency content (shorter times-to-PEF). Additional detailed information concerning spirometer testing procedures is contained in APPENDICES B, C, and D.

#### Recommendation: MVV Validation

When tested with a pump producing a sinusoidal waveform, the accuracy validation limits of the spirometer used for MVV for flows up to 250 L/min, produced with stroke volumes up to 2 L, are ± 10.5% of reading or ± 20 L/min, whichever is greater. During the testing, the pressure at the mouthpiece must not exceed ± 10 cm $H_2O$. For volume spirometers, these requirements apply throughout their volume range.

## QUALITY CONTROL

Routine equipment preventive maintenance—cleaning, calibration checks, verification, and quality control—is essential to assure accurate spirometry results (44). A spirometry procedure manual is an important base for a quality assurance program. The manual should contain a quality control plan, guidelines for ordering spirometry, guidelines for performing spirometry, and guidelines for reporting spirometry results. See the document, "ATS Quality Assurance for Pulmonary Laboratories," for more details (44).

#### Recommendation: Technician's Role in Quality Control

Quality control is important to ensure that the laboratory is consistently meeting appropriate standards. In any quality control program, an important element is a procedures manual containing: calibration procedures, test performance procedures, calculations, criteria, reference values source, and action to be taken when "panic" values are observed. A notebook should be maintained that documents daily instrument calibration as well as problems encountered with the system, corrective action required, and system hardware and software upgrades. Records of anomalous events involving either patients/subjects or the technician should be documented, with the results of subsequent evaluation and responses to the event. The technician should also maintain records of continuing education and the results of evaluation and feedback provided by the medical director. Perhaps the most important component in successful spirometry is a well-motivated, enthusiastic technician. A recent study has clearly demonstrated the importance of a quality control program with feedback to technicians in obtaining adequate spirometry results (8). A quality control program that continuously monitors technician performance is critical to the collection of high-quality spirometry data. Feedback to the technicians concerning their performance should be provided on a routine basis. This feedback should include, at a minimum: (*1*) information concerning the nature and extent of unacceptable FVC maneuvers and non-reproducible tests; (*2*) corrective action the technician can take to improve the quality and number of acceptable maneuvers; and (*3*) recognition for superior performance by the technician in obtaining good maneuvers from challenging patients/subjects.

Manufacturers are encouraged to include quality control aids in their software packages for spirometers. For example, a calibration logging program may be provided that stores the time and results of routine daily calibration checks. Additionally, the program could issue a warning if an acceptable daily calibration check has not been performed.

#### Recommendation: Hygiene and Infection Control

This section has been reviewed by the Microbiology Assembly.

The major goal of infection control is to prevent infection transmission to patients/subjects and staff during pulmonary function testing. Two major types of infection transmission are:

1. Direct contact: There is potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections through direct contact. Although hepatitis and HIV contagion are unlikely via saliva, this is a possibility when there are open sores on the oral mucosa, bleeding gums, or hemoptysis. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.
2. Indirect contact: There is potential for transmission of tuberculosis, various viral infections, and, possibly, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces and proximal valves and tubing.

**Prevention:**

1. Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing or use of barrier devices (latex gloves). To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves, or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if there are any open cuts or sores on technicians' hands. Hand washing should always be performed between patients. Indications and techniques for hand washing during pulmonary function testing have been reviewed by Tablan and coworkers (45).
2. To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves, and manifolds should be disinfected or sterilized regularly. Mouthpieces, nose clips, and any other equipment coming into direct contact with mucosal surfaces should be disinfected, sterilized, or discarded (i.e., disposable mouthpieces, nose clips, etc.) after each use. The optimal frequency for disinfection or sterilization of tubing, valves, or manifolds has not been established. However, any equipment surface with visible condensation from expired air should be disinfected or sterilized before reuse. Since the use of cold sterilizing agents is not without risk, laboratory staff should take care to follow all manufacturer's recommendations regarding proper handling of these products.
3. Between subjects, spirometers using the closed circuit tech-

nique should be flushed at least five times over the entire volume range to facilitate clearance of droplet nuclei. Also, the breathing tube and mouthpiece should be decontaminated between patients. When the open circuit technique is used, only that portion of the circuit through which rebreathing occurs needs to be decontaminated between patients. For example, when a pneumotachometer system is used, either inspiration from the device should be avoided or the resistive element and tubing should be decontaminated between subjects. A disposable sensor is another alternative. When an open circuit technique is used for measurement of only the forced exhalation, without inspiration from the measuring system (either volume- or flow-type spirometers), only the mouthpiece needs to be changed or decontaminated between subjects.

It should be noted that disassembling, cleaning, and/or sensor replacement requires recalibration. If patients do not inspire through the device, there is the disadvantage that test acceptability may be more difficult to assess in the absence of an inspiratory tracing. On the other hand, disassembly, cleaning, or sensor replacement has the disadvantage that recalibration is required. Alternatively, in-line filters may be effective in preventing equipment contamination (46). However, if an in-line filter is used, the measuring system should meet the minimal recommendations for range, accuracy, flow resistance, and back pressure with the filter installed. The influence of commercially available in-line filters on forced expiratory measures, such as the FVC and $FEV_1$, has not been well characterized.

4. In settings where tuberculosis or other diseases spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air, should be used to prevent disease transmission.
5. Special precautions should be taken when testing patients with hemoptysis, open sores on the oral mucosa, or bleeding gums. Tubing and breathing valves should be decontaminated before reuse and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.
6. Extra precautions may be undertaken for patients with known transmissible infectious diseases. Possible precautions include: (*a*) Reserving equipment for the sole purpose of testing infected patients; (*b*) testing patients at the end of the day to allow time for spirometer disassembly and disinfection; and (*c*) testing patients in their own room or in rooms with adequate ventilation and easily cleaned surfaces.
7. In the absence of evidence for infection transmission during pulmonary function testing, the regular use of in-line filters is not mandated when the precautions described above are followed. However, some spirometric equipment, particularly those incorporated in multi-purpose testing systems, employ valve manifolds that are situated proximal to breathing tubes. These valving arrangements provide internal surfaces on which deposition of expired aerosol nuclei is likely. Given their complexity, they may be difficult to disassemble and disinfect between subjects. To the extent that in-line filters have been shown to remove microorganisms from the expiratory air stream and thus prevent their deposition, presumably as aerosol nuclei on spirometer surfaces (46), their use may be indicated in this setting. The economy of using in-line filters compared with tubing and valve changes depends on the PFT equipment in use. The extent to which measures such as maximum expiratory flow or other instantaneous flows are influenced by the use of in-line filters is undocumented. One study has shown that a low impedance barrier device did not have a significant impact on spirometric indices, such as the forced vital capacity and the $FEV_1$ (47). If an in-line filter is used during spirometry, interpretation of spirometric indices other than FVC and $FEV_1$ (e.g., PEF) should allow for the possibility that the filter might affect spirometer performance. The mechanical characteristics of the combined measuring device and filter should meet the minimal recommendations outlined in Table 2. Furthermore, if in-line filters are used, it is recommended that equipment be calibrated with the filter installed. The use of in-line filters does not eliminate the need for regular cleaning and decontamination of spirometric equipment.
8. Manufacturers of spirometric equipment are encouraged to design instrumentation that can be easily disassembled for disinfection.

*Rationale.* Spirometric equipment has not been directly implicated in the transmission of infections, although there is indirect evidence of infection transmission during pulmonary function testing (PFT). Organisms from the respiratory tract of test subjects can be recovered from PFT mouthpieces and from the proximal surfaces of tubing through which the subjects breathe (48, 49). There is one case report of a tuberculosis skin-test conversion after exposure to a spirometer used to test a patient with documented tuberculosis (50). Likewise, there is circumstantial evidence that contaminated PFT equipment may be implicated in the increasing prevalence of *Pseudomonas* infections among cystic fibrosis patients at one center (51). There is some evidence that pneumotachometer-based systems are less susceptible to bacterial contamination than water-sealed spirometers (52). Finally, it is well documented that community hospital water supplies can be contaminated with Mycobacteria and *Pseudomonas aeruginosa* organisms (53–55). Thus, the potential exists for both patients/subjects and health care workers to deposit microorganisms onto spirometer surfaces (including mouthpieces, nose clips, tubing, and any internal or external machine surface), which could subsequently come into direct or indirect contact with other patients. This does not seem to pose an appreciable threat to patients/subjects with competent immune systems.

It has been argued that immunocompromised patients may require only a relatively small infective dose of either opportunistic organisms or common pathogens. Concerns for the protection of immunocompromised hosts, along with increased public and provider awareness of hospital infection control issues over the past decade, has led many laboratory directors to use in-line filters routinely as a means of reassuring patients and laboratory personnel that adequate consideration has been given to protection. There is no direct evidence that routine spirometry testing poses an increased risk of infection to immunocompromised patients.

### Recommendation: Equipment Quality Control

The recommendations that follow are primarily aimed at diagnostic devices.

Attention to good equipment quality control and calibration is an important part of good laboratory practice. Log books of calibration results must be maintained. Documentation of repairs or other alterations that return the equipment to acceptable operation need to be maintained. Dates of computer software and hardware updates or changes must also be maintained.

*Volume.* The spirometer's ability to accurately measure volume must be checked *at least* daily with a calibrated syringe with a volume of at least 3 L. During industrial surveys or other studies in which a large number of subject maneuvers are done, the equipment's calibration must be checked daily, before testing, and every 4 h during use (44). In circumstances where the temperature is changing (e.g., field studies), more frequent temperature corrections may be needed. Although there is minimal day-to-day variation in volume calibration, daily calibration checking is highly recommended so that the onset of a problem can be de-

termined within 1 day, eliminating needless reporting of false values for several weeks or months and also to help define day-to-day laboratory variability. It is recommended that the calibration syringe be stored and used in such a way as to maintain the exact temperature and humidity of the testing site. This is best accomplished by keeping the syringe in close proximity to the spirometer. In the case of flow-type spirometers where a volume syringe is used to check the instrument, volume calibration checks using different flow rates are recommended. At least three trials where the flow rates are varied between 2 and 12 L/s must be performed (3-L injection times of approximately 1 s, 6 s, and somewhere in between 2 and 6 s).

*Syringe Accuracy.* The syringe used to check the volume calibration of spirometers must have an accuracy of at least 15 ml or at least 0.5% of full scale (15 ml for a 3-L syringe), and the manufacturer must provide recommendations concerning appropriate syringe calibration intervals. If the syringe has an adjustable variable stop, the syringe may be out of calibration if the stop is reset. Calibration syringes should be leak-tested periodically by trying to empty them with the outlet corked.

*Leak Test.* Volumetric spirometer systems must be evaluated for leaks on a daily basis (15, 56). The Intermountain Thoracic Society Manual (15) suggests that leaks can be detected by applying a constant positive pressure of 3 cm $H_2O$ or more with the spirometer outlet occluded. Any observed volume change of greater than 10 ml after 1 min is indicative of a leak (15) and needs to be corrected.

*Linearity.* At least quarterly, volume spirometers must have their calibration checked over their entire volume range (in 1-L increments) using a calibrated syringe (42) or an equivalent volume standard. Flow spirometers must have their linearity determined *at least* weekly and given the current software capabilities, daily linearity checks are reasonable. Flow spirometer linearity can be checked by injecting the volume from a 3-L syringe with several different flows. The linearity check is considered acceptable if the spirometer meets the volume accuracy requirements for all flows and/or volumes tested.

*Time.* Assessing mechanical recorder time scale accuracy with a stopwatch must be performed *at least* quarterly. An accuracy of within 1% must be achieved. If equipment is changed or relocated (e.g., industrial surveys), calibration checks and quality control procedures must be repeated before initiating further testing.

*PEF Meters.* Since it is difficult to perform a calibration check of portable peak flow monitoring meters, it is particularly important that the instructions from the manufacturer include information concerning typical instrument lifetimes and methods of recognizing when an instrument is malfunctioning.

*Other Quality Assurance Procedures.* In addition to calibration with physical standards, the practice of using laboratory personnel as "known subjects" and performing intralaboratory and interlaboratory testing is recommended (44). The ATS has published guidelines for quality assurance in pulmonary function laboratories (44), which can be consulted for specific details.

The use of computers to analyze spirometry has accelerated in the past 10 yr, and this trend is advantageous to obtain accurate spirometry (10, 30). However, testing of commercially available spirometers consistently shows that a major source of errors is in computer software (42). Because of the increased use of computers in pulmonary laboratories and the problems associated with them (42, 57), the ATS has published computer guidelines for pulmonary laboratories (58), which should be followed. Computer software must adhere to ATS recommendations, especially procedural recommendations, contained in this statement. Because of the tremendous improvement in the power and speed of computers and their extensive use in hospitals and clinics, manufacturers should attempt to integrate computers into their spirometry systems. Primary data should be available, allowing independent manipulation of uncorrected values by the user. Listings or descriptions of ATS algorithms should be available (end of test, back-extrapolation, etc.). In addition, some program flexibility should be available to the user, for example, allowing user selection of appropriate reference equations, including the use of user-derived reference equations.

TABLE 5

EQUIPMENT QUALITY CONTROL SUMMARY

| Test | Minimum Interval | Action |
|---|---|---|
| Volume | Daily | 3-L syringe check |
| Leak | Daily | 3 cm $H_2O$ constant pressure for 1 min |
| Linearity | Quarterly | 1-L increments with a calibrating syringe measured over entire volume range (flow spirometers simulate several different flow ranges) |
| | Weekly (flow spirometers) | |
| Time | Quarterly | Mechanical recorder check with stopwatch |
| Software | New versions | Log installation date and perform test using "known" subject |

## MANEUVER PERFORMANCE RECOMMENDATIONS

### Personnel Qualifications

The ATS has made recommendations for laboratory personnel conducting pulmonary function tests (59). High school training was recommended. In addition, the ATS encouraged but did not mandate one or more years of college or equivalent training and a strong background in mathematics. For pulmonary function laboratories, 6 mo of supervised training time is recommended for conducting spirometry. If troubleshooting is to be a part of the laboratory technician's responsibility, a training period of 1 yr is recommended. The ATS recommends that the medical directors must have appropriate training and be responsible for all pulmonary function testing (60).

For industrial/occupational testing, there are training requirements mandated by the National Institute for Occupational Safety and Health (NIOSH), industry, and the ACCP (16, 31, 61). Several excellent training manuals have been prepared for performance of spirometry (15, 16, 31, 62, 63). NIOSH approves the content of spirometry training courses under the U.S. Cotton Dust Standard (16).

### Recommendation: VC—Subject Instruction and Maneuver Performance

The VC maneuver may be considered either as an inspiratory vital capacity (IVC), where the subject inhales completely from a position of full expiration, or as an expiratory vital capacity (EVC), where the subject exhales completely from a position of full inspiration. In addition, several spirometer setups are possible using either open or closed circuit techniques with or without rebreathing.

1. A closed circuit technique *without* $CO_2$ absorption (i.e., using a rolling-sealed or water-sealed spirometer) may be used. Subjects may also rebreathe from the spirometer circuit. Rebreathing is preferable because it allows technicians to better monitor the entire vital capacity maneuver. In the absence of $CO_2$ absorption and the addition of supplemental oxygen, the maneuver should be brief—fewer tidal volumes before and after the VC maneuver.
2. A closed circuit technique *with* $CO_2$ absorption and the addition of supplemental oxygen may be used. This system allows

the subject to rebreathe for a longer period of time and establish a better FRC baseline. However, it requires precise replacement of oxygen to avoid shifting the baseline.

3. A modified closed circuit technique (i.e., flow-sensor–based systems where the subject can breathe in and out through the sensor without the need for $CO_2$ absorption) may be used.
4. An open circuit technique where the subjects may inhale completely before inserting the mouthpiece and exhaling into the spirometer may be used. This may be preferable when hygiene concerns are present.

For all systems, it is important to instruct the subject in the VC maneuver and demonstrate the appropriate technique. It is important that subjects understand they must *completely* fill and empty their lungs.

*Standard Procedure Open Circuit Technique.* The subject inhales maximally, inserts the mouthpiece just past his/her front teeth, seals his/her lips around the mouthpiece, and blows slowly and evenly until a clear plateau is seen at maximal exhalation or until end-of-test criteria (see sections on FVC and end-of-test criteria) are met. The technician must observe the subject's inhalation to ensure that it is complete and that air is not exhaled while the mouthpiece is being inserted. During the exhalation, the technician should monitor the spirometer volume–time display to ensure that a relatively constant expiratory flow and an adequate end-expiratory plateau is achieved (see APPENDIX A for examples of the VC maneuver).

*Closed Circuit Techniques.* The following procedure should be used when testing is conducted *without* $CO_2$ absorption (limited oxygen reserve available for test performance). A two-way valve may be useful, allowing the initial tidal volumes to be performed with room air before the subject is connected to the spirometer. The test is begun with quiet breathing, preferably with the subject breathing room air. No more than five tidal volumes should be recorded with the subject rebreathing from the spirometer. The subject should then perform the VC maneuver described below. When $CO_2$ absorption is not used, returning to FRC after the VC maneuver followed by three tidal volumes may be helpful but is not required.

The following procedure should be used when testing is conducted with $CO_2$ absorption and oxygen supplementation. The test is begun with quiet breathing. Several tidal volumes should be recorded (minimum of five or until a stable end-expiratory level is observed). The subject should then perform the VC maneuver described below. The end of test is reached when the subject returns to the level of FRC and performs at least three more tidal volumes.

For both procedures, the maneuver is not forced; it is performed in a relaxed manner with the subject using a mouthpiece and a nose clip. The VC maneuver is composed of the subject exhaling completely to residual volume (RV), and completely inhaling to total lung capacity (TLC), and then exhaling to residual volume again. The technician should encourage the subject to reach maximal inhaled and exhaled volumes with a relatively constant flow. Technicians should observe the subject to be certain his/her lips are sealed, that nothing obstructs the mouthpiece, that no leaks occur, and that TLC and RV are reached. The technician should check the volume display to ensure relatively linear inspiratory and expiratory volume curves and adequate maximal inspiratory and expiratory level plateaus. Oxygen should be added to the circuit to precisely counterbalance the absorption of $CO_2$.

For all techniques, a minimum of two acceptable VC maneuvers should be obtained, with a maximum of four attempts. The largest VC should be reported. Some investigators have reported that the VC is slightly higher than the FVC in normal subjects (64).

**TABLE 6**

**PERFORMANCE OF FVC MANEUVER**

- Check spirometer calibration
- Explain test
- Prepare subject
  - Ask about smoking, recent illness, medication use, etc.
- Instruct and demonstrate test to subject
  - Correct posture with head elevated
  - Inhale completely
  - Position mouthpiece (open circuit)
  - Exhale with maximal force
- Perform maneuver
  - Have subject assume correct posture
  - Attach nose clip
  - Inhale completely; the inhalation should be rapid but not forced
  - Place mouthpiece in mouth and close lips around mouthpiece
  - Exhale maximally as soon as lips are sealed around mouthpiece*
  - Repeat instructions as necessary, coaching vigorously
  - Repeat for a minimum of three maneuvers; no more than eight are usually required
- Check test reproducibility and perform more maneuvers as necessary

* D'Angelo and coworkers (65) have reported that PEF and $FEV_1$ for 13 normal subjects measured in a body plethysmograph are reduced (4% and 5%, respectively) when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. Therefore, an excessive pause at TLC should be avoided.

### Recommendation: FVC—Subject Instruction and Maneuver Performance

Instruct the subject in the FVC maneuver. The technician should demonstrate the appropriate technique (Table 6). Have the subject inhale from FRC and then, if using the open circuit method, insert the breathing tube into his/her mouth, making sure his/her lips are sealed around the mouthpiece, and begin the FVC maneuver with minimal hesitation (65). It is *imperative* that the subject have a complete inhalation before beginning the forced exhalation. Prompt the subject to "blast," not just "blow," the air from their lungs, then continue to encourage him/her to fully exhale. Throughout the maneuver, enthusiastically coach the subject by word and body language. It is particularly helpful to observe the subject and the chart recorder or computer display during the test to better ensure maximal effort. Perform a *minimum* of three acceptable FVC maneuvers. If a subject shows large variability (FVC and/or $FEV_1$) between expiratory maneuvers (> 0.2 L), reproducibility criteria may require that up to but usually no more than eight maneuvers be performed. Volume–time or flow–volume curves from the best three FVC maneuvers must be retained. See Figure 3 and the section on acceptability and reproducibility for further clarification.

### Recommendation (Monitoring): PEF—Subject Instruction and Test Performance

Since PEF is both effort- and volume-dependent, maximum subject cooperation is essential. Since an optimal peak flow is usually reached in about one-tenth of a second, patients must be encouraged to perform the expiratory maneuver as vigorously as possible. The subject should not cough and a prolonged exhalation is unnecessary (1 to 2 s is adequate).

When implementing unobserved self-administered PEF measurements, it is essential that:

1. The subject should be taught how to use the peak flow meter properly by someone skilled with the procedure. Trained personnel should observe the subject's performance both initially and on repeat visits.
2. The subject should be taught how and when to record PEF measurements, along with other pertinent information, such as symptoms.
3. The subject should be instructed about what action to take if PEF falls.

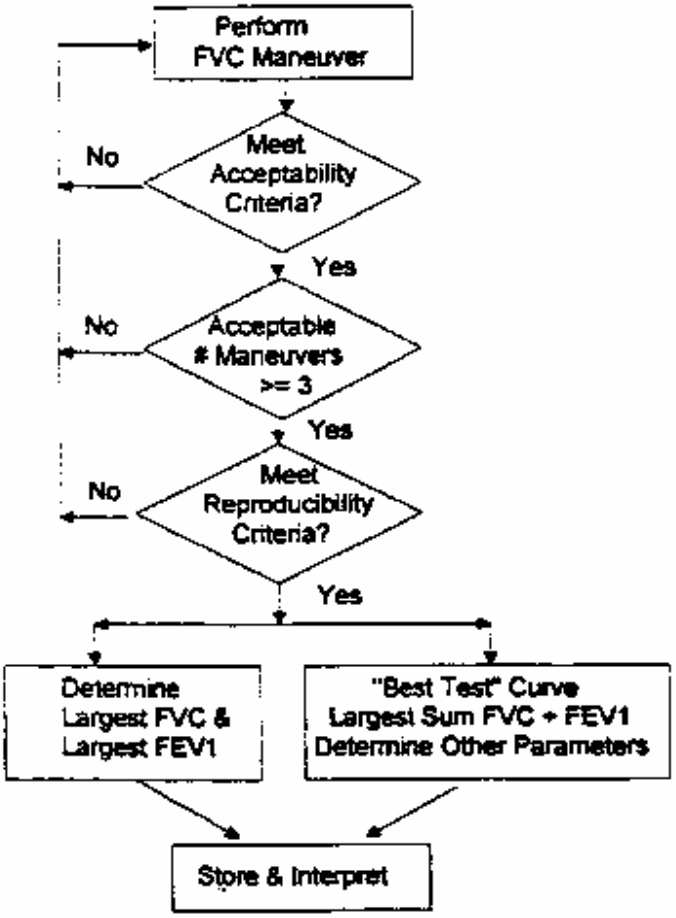



*Figure 3.* Flow-chart diagram of FVC spirometry testing.

**Recommendation: FVC—Satisfactory Start-of-Test Criteria**

To achieve accurate "time zero" and ensure that the $FEV_t$ comes from a maximal effort curve, the extrapolated volume must be less than 5% of the FVC or 0.15 L, whichever is greater. See Figure 2 for an example and explanation of back extrapolation. In the example shown, the extrapolated volume is 0.16 L or 8%. In general, back-extrapolated volume should be measured on any curve with a perceptible extrapolated volume. Provisions for rapid computerized feedback to the technician when these criteria are not met are encouraged.

The committee discussed the possible use of time-to-PEF as a measure of the subject's performance early in the FVC maneuver. However, the committee felt there were insufficient data on which to base a clear recommendation, and additional research is needed. When conducting research on assessment of the subjects' correct performance of FVC maneuvers, investigators are encouraged to measure the time-to-PEF or rise-time of peak flow in addition to other quality assessment parameters. The rise-time of peak flow is defined as the time required for expiratory flow to rise from 10% to 90% of the maneuver's peak flow. Although use of other measures of acceptable efforts have been described and may be useful (8, 66), they are not recommended at this time.

*Rationale.* A very slow start with a low peak flow will result in a greater than allowable extrapolated volume (Figure 2) (1, 67–69). In addition, the $FEV_t$ from a submaximal effort can be either smaller than those obtained when a maximal effort is performed because the subject fails to reach a maximal TLC, or larger due to less dynamic compression of airways in subjects where airways are relatively more collapsible. Recent experience in large epidemiologic studies (8) suggests that use of time-to-PEF and PEF reproducibility may minimize most of these problems in the majority of subjects. However, at this time, it is not recommended that maneuvers be eliminated because of a low PEF or PEF rise-time, but only because of an excessively large extrapolated volume.

TABLE 7

PERFORMANCE OF PEAK FLOW MANEUVER

| |
|---|
| Explain and demonstrate the test* |
| Zero the PEF monitor, if necessary |
| Stand up straight |
| Inhale completely; the inhalation should be rapid but not forced |
| Place PEF monitor in mouth and close lips around mouthpiece† |
| Exhale with maximal force‡ as soon as lips are sealed around mouthpiece§ |
| Write down results |
| Repeat two more times (three total) |
| Record all three values |

* Not necessary if at home.
† Nose clips are not necessary.
‡ Make sure subject understands to make full use of respiratory muscles, not just use the diaphragm as a "toot" or "mouth" maneuver.
§ D'Angelo and coworkers (65) have reported that PEF is reduced when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. It is not known if similar changes will be observed with portable peak flow meters.

**Recommendation: FVC—Minimum Exhalation Time**

A minimum exhalation time of 6 s (length of maximum expiratory effort), unless there is an obvious plateau in the volume–time curve display, is required to obtain maximal FVC results. There are instances (e.g., the testing of children, young adults, and some restricted patients) where shorter exhalation times are acceptable.

**Recommendation: FVC—End-of-Test Criteria**

To obtain an optimal effort, it is important that subjects be verbally exhorted to continue to exhale air at the end of the maneuver. End-of-test criteria are used to identify a reasonable FVC effort. Recommended end-of-test criteria are:

1. The subject cannot or should not continue further exhalation. Although subjects should be encouraged to achieve their maximal effort, they should be allowed to terminate the maneuver on their own at any time, especially if they are experiencing discomfort. The technician should also be alert to any indication the patient is experiencing discomfort and should terminate the test if a patient is becoming uncomfortable.

*OR*

2. The volume–time curve shows an obvious plateau. This criterion is based on no change in volume for *at least* 1 s after an exhalation time of *at least* 6 s (10 s is optimal). "No change in volume" is defined as the minimal detectable volume of the spirometer. To meet ATS criteria, the minimal detectable volume for spirometers must be 0.030 L or less.

*OR*

3. The forced exhalation is of reasonable duration. For patients with airways obstruction or older subjects, exhalation times longer than 6 s are frequently needed to reach a plateau. Many would not reach a plateau even with a 20-s exhalation. However, exhalation times greater than 15 s will rarely change clinical decisions. *Multiple* prolonged exhalations (longer than 6 s) are seldom justified and may cause lightheadedness, syncope, undue fatigue, and unnecessary discomfort. In such patients, a slow or unforced VC maneuver (previously described) may provide a more appropriate denominator for calculation

of the $FEV_t/VC\%$. Manufacturers should note that several of the 24 test waveforms have durations longer than 20 s.

Achieving an end-of-test criterion is one measure of maneuver acceptability. Maneuvers that do not meet an end-of-test criterion should not be used to satisfy the requirement of three acceptable maneuvers. However, early termination is not by itself a reason to eliminate a maneuver from further consideration. Information such as $FEV_1$ and $FEV_3$ may be valid (depending on the length of exhalation) and should be reported from these early terminated maneuvers. When the subject does not exhale completely, the volume accumulated over a shorter period of time (e.g., 4 s) may be used as an approximate surrogate for FVC. In such cases, the volume label should reflect the shorter exhalation time (e.g., $FEV_4$ for a 4-s exhalation).

#### Recommendation: VC and FVC—Maximum Number of Maneuvers

Although there may be some circumstances in which more than eight consecutive FVC maneuvers may be needed, eight maneuvers is considered a practical upper limit for most subjects. After several forced expiratory maneuvers, fatigue begins to take its toll on subjects, and thus on their spirometric parameters, so additional maneuvers would be of little added value. In addition, some subjects with asthma may exhibit spirometry-induced bronchospasm. Ferris and associates (70) and Kanner and colleagues (71) have reported that for adults and children, eight maneuvers is a practical upper limit. For VC, four is considered a practical upper limit. Because of the potential for muscular fatigue and volume history effects, it is preferable that VC maneuvers be performed before FVC maneuvers.

#### Recommendation (Monitoring): PEF—Number of Trials

The subject must perform and record a minimum of three trials.

#### Recommendation: VC and FVC—Environmental Conditions

Spirometric testing with ambient temperatures less than 17° C or more than 40° C may pose problems. Ambient temperature must *always* be recorded and reported to an accuracy of ± 1° C. In situations where the ambient air temperature is changing rapidly (> 5° C in less than 30 min), continuous temperature corrections should be made. Spirometer users should be aware of the problems with testing done at lower temperatures, which in some subjects can cause airflow limitation. Due to other technical reasons, 17° C is judged to be an acceptable and reasonable lower limit (32–38, 72) for ambient temperature. Ranges of barometric pressures that are acceptable for the spirometer must be published by the manufacturer.

*Rationale.* There is evidence that some subjects may develop airflow limitation with the inhalation of very cold air. Therefore, spirometry should not be conducted when the ambient temperature is cold enough to induce airflow limitation.

Studies also point out the problem of finite cooling times of gases in volume-type spirometers and their associated tubing (32–35) when BTPS correction techniques usually assume instantaneous cooling. In one of these studies, it was found that a 7.7 to 14% error in $FEV_1$ results if the volume-type spirometer is at an ambient temperature of 3° C and the standard BTPS correction is used. This error is less if the spirometer is warmer (nearer body temperature) (32). As a result, 17° C was judged to be an acceptable and reasonable lower limit.

Complexities related to temperature are also encountered with flow-measuring devices (34–38). Air exhaled from the mouth is estimated to be 33 to 35° C (36, 38, 39). If any connecting tubing is used between the mouthpiece and the flow sensor, the exhaled gas will experience a variable amount of cooling if the room temperature is not at approximately 33° C. Details of the cooling pattern for many types of flow spirometers have not been studied, but they may result in errors similar to those for volume devices (34–38).

Because not all spirometers are used at sea level (blood pressure = 760 mm Hg), the range of barometric pressures allowed by the spirometer and its associated computational equipment must be specified by the manufacturer.

#### Recommendation: VC and FVC—Use of Nose Clips

In most people, not wearing nose clips does not appreciably influence the FVC when using the open circuit technique. However, some people breathe through the nose and the use of nose clips is encouraged, especially when performing a slow VC maneuver. Nose clips must be used if a closed circuit technique with carbon dioxide absorption is used.

#### Recommendation: VC and FVC—Sitting Versus Standing

Testing may be done either in the sitting or standing position. Indication of position is necessary on the report (1, 73). The standing position may not be appropriate in some circumstances, such as in hospitals where many patients may not be able to tolerate the standing position, especially when making forced maneuvers. The selection of the position for testing is, therefore, an individual one. If the standing position is used, an appropriately shaped chair should be placed behind the patient/subject so he/she can be quickly and easily eased into a sitting position if he/she becomes light-headed during the maneuver.

*Rationale.* Studies by Townsend show that for adults there are significantly larger FEVs in the standing position than in the sitting position (73). The earlier ATS recommendation indicates that in children, VC is greater when standing (1).

#### Recommendation (Monitoring): PEF—Nose Clips and Subject Position

Nose clips are not necessary when using PEF meters. Although the test can be conducted while sitting, the standing position is preferred.

*Rationale.* Because the PEF is dependent on a complete inhalation and an exhalation with maximal force, the standing position is preferred.

*Bronchodilator Testing.* Spirometry is often performed before and after inhalation of bronchodilators (or bronchoconstrictors) from a metered dose inhaler (MDI) or nebulizers. Although specific recommendations are beyond the scope of this document, it should be remembered that this is a complex procedure. Factors that can significantly affect a patient's response include: (*1*) activity, dose, and airway deposition of the medication; (*2*) recent prior medication; (*3*) timing of the postmedication maneuver; (*4*) choice and variability of the measurement used to detect a response; and (*5*) the method of calculating the magnitude of change after administering the bronchodilator.

## MEASUREMENT PROCEDURES

### Measurement

Spirometric variables should be measured from a series of *at least* three acceptable forced expiratory curves.

#### Recommendation: VC and FVC—Test Result Selection/Reporting of Results

The largest VC should be reported from all acceptable curves, including the forced maneuvers (FVC). The largest FVC and the largest $FEV_t$ (BTPS) should be recorded after examining the data from all of the acceptable curves, even if they do not come from the same curve. Other measures, such as the $FEF_{25-75\%}$ and the instantaneous expiratory flows, should be obtained from the single curve (1, 2, 15) that meets the acceptability criteria and gives the largest sum of FVC plus $FEV_t$ (best test).

**Recommendation (Monitoring): PEF—Test Result/Reporting of Readings**

Although all readings are recorded, the highest reading at any testing session (minimum of three trials) should be used in trend analysis. All readings are recorded to allow the comparison of the trials to evaluate reproducibility and to detect possible maneuver-induced bronchospasm.

*Rationale.* Since the PEF is effort-dependent, the highest reading should be used. This is consistent with the current recommended selection method for FVC and $FEV_1$.

## ACCEPTABILITY AND REPRODUCIBILITY

**Recommendation: VC and FVC—Maneuver Acceptability**

For FVC measurements, acceptability must be determined by ascertaining that the recommendations outlined previously in the section on performing the FVC test are met. APPENDIX A contains examples of unacceptable volume–time and corresponding flow–volume curves. In review, these acceptability criteria are: (*1*) satisfactory start-of-test; (*2*) minimum FVC exhalation time of 6 s; and (*3*) end-of-test criteria. In addition, the technician should observe that the subject understood the instructions and performed the maneuver with a maximum inspiration, with a good start, with a smooth continuous exhalation, with maximal effort, and *without*:

1. An unsatisfactory start of expiration, characterized by excessive hesitation, false start, or extrapolated volume of greater than 5% of FVC or 0.15 L, whichever is greater (Figure 2).
2. Coughing during the first second of the maneuver, thereby affecting the measured $FEV_1$ value, or any other cough that, in the technician's judgment, interferes with measurement of accurate results (APPENDIX A, Figures 2A and 2B).
3. Early termination of expiration. A plateau in the volume–time curve should be observed, as defined by no change in volume for at least 1 s or a reasonable expiratory time. In a *normal* young subject this would be before completion of the breath—*usually* less than a 6-s maneuver. In an obstructed or older healthy subject, a longer expiratory time is required to reach a plateau (2, 74, 75) (APPENDIX A, Figures 3A and 3B). However, *multiple* prolonged exhalations (longer than 6 s) are seldom justified.
4. Valsalva maneuver (glottis closure) or hesitation during the maneuver that causes a cessation of airflow (APPENDIX A, Figures 4A and 4B).
5. A leak (APPENDIX A, Figures 5A and 5B).
6. An obstructed mouthpiece (e.g., obstruction due to the tongue being placed in front of the mouthpiece or false teeth falling in front of the mouthpiece).

For VC measurements, all of the above requirements should be met with the exception of those related to the forced nature of the effort. In addition, plateaus in the volume–time display should be reached at both the maximal inspiratory and expiratory volumes.

Computer-based systems that provide feedback to the technician when the above conditions are not met are desirable. The reporting format should include qualifiers indicating the acceptability of each maneuver. However, it cannot be overemphasized that failure to meet these criteria does not necessarily invalidate the maneuver, since for some subjects this is their best performance. Further, such maneuvers should be retained, since these maneuvers may contain useful information.

A flow chart outlining how acceptability and reproducibility criteria are to be applied is shown in Figure 3.

**Recommendation: VC and FVC—Test Result Reproducibility**

As a goal during test result performance, the largest FVC (or VC) and second largest FVC (or VC) from acceptable maneuvers must not vary by more than 0.2 L. In addition for forced exhalations, the largest $FEV_1$ and the second largest $FEV_1$ must not vary by more than 0.2 L. The 0.2 L reproducibility criteria are a change from the ATS 1987 Spirometry Statement and are intended to provide an equal assessment of test reproducibility independent of lung size. However, these criteria are only goals during data collection; therefore, an immediate change in spirometry data collection software is not warranted.

The reproducibility criteria are used as a guide to whether more than three acceptable FVC maneuvers are needed; these criteria are *not* to be used for excluding results from reports or for excluding subjects from a study. Labeling results as being derived from data that do not conform to the reproducibility criteria stated above is encouraged (especially when the data suggest that bronchospasm was triggered by the FVC maneuver). In addition, the reproducibility criteria are minimum requirements and many subjects should be able to provide FVC and $FEV_1$ reproducibility well below 0.2 L. The acceptability criteria must be applied before the reproducibility criteria (Figure 3). Unacceptable maneuvers must be discarded before applying the reproducibility criteria.

The only criterion for unacceptable subject performance is fewer than two acceptable curves. No spirogram should be rejected solely on the basis of its poor reproducibility. Reproducibility of results should be considered at the time of interpretation. Use of data from maneuvers with poor reproducibility is left to the discretion of the interpreter. In addition, use of data from unacceptable maneuvers due to failure to meet the end-of-test requirements is left to the discretion of the interpreter.

*Rationale.* Several epidemiologic studies (67–69) have shown that the elimination of data from subjects who fail to meet the ATS reproducibility criteria may result in a population bias by excluding data from subjects who have abnormal lung function. Pennock and colleagues (76) have reported that subjects with obstruction have greater coefficients of variation than do normal subjects. Therefore, these subjects are more likely to be unable to meet the ATS minimum reproducibility criteria. The reproducibility criteria have been simplified to eliminate confusion. If acceptability criteria are not applied before the reproducibility criteria, a passive exhalation maneuver will often be labeled as the best test maneuver because it may give the largest sum of FVC and $FEV_1$.

The calculation of the FVC and $FEV_1$ reproducibility presents no problem for a computer; however, the need for rapid determination of $FEV_1$ during the testing session presents a recognized logistics problem if results are hand-measured and calculated. Changing to 0.2-L criterion does simplify this calculation.

Changing the reproducibility criteria to a minimum value of 0.2-L is based on evidence that within subject variability of FVC and $FEV_1$ is not dependent on body size. The use of a 5% or 100-ml criterion has been shown to result in more individuals of short stature being classified as nonreproducible. In contrast, a 0.2-L fixed volume criterion provides a commensurable level of difficulty for all subjects, regardless of age or height (lung volume) (77). Regardless of the reproducibility criterion for FVC or $FEV_1$, it should be used as a goal during data collection. Therefore, continued use of the previous criteria (5% or 0.1 L, whichever is greater) during an interim period should have little practical impact on spirometry results.

**Recommendation: PEF—Maneuver Acceptability and Reproducibility**

PEF values for each maneuver must be recorded in the order in which they occur. This information will be useful in detecting possible test (maneuver)-induced bronchospasms.

TABLE 5
ACCEPTABILITY AND REPRODUCIBILITY CRITERIA: SUMMARY

*Acceptability criteria*
- Individual spirograms are "acceptable" if:
  - They are free from artifacts (see APPENDIX A for examples)
    - Cough or glottis closure during the first second of exhalation
    - Early termination or cutoff
    - Variable effort
    - Leak
    - Obstructed mouthpiece
  - Have good starts
    - Extrapolated volume less than 5% of FVC or 0.15 L, whichever is greater; *OR*
    - Time-to-PEF of less than 120 ms (optional until further information is available)
  - Have a satisfactory exhalation
    - 6 s of exhalation and/or a plateau in the volume–time curve; *OR*
    - Reasonable duration of a plateau in the volume–time curve; *OR*
    - If the subject cannot or should not continue to exhale

*Reproducibility criteria*
- After three acceptable spirograms have been obtained, apply the following tests:
  - Are the two largest FVC within 0.2 L of each other?
  - Are the two largest $FEV_1$ within 0.2 L of each other?
- If both of these criteria are met, the test session may be concluded.
- If both of these criteria are not met, continue testing until:
  - Both of the criteria are met with analysis of additional acceptable spirograms; *OR*
  - A total of eight tests have been performed; *OR*
  - The patient/subject cannot or should not continue
- Save at a minimum the three best maneuvers

*Rationale.* Unlike the FEV, obtained from routine spirometry, PEF measurements are more variable, and the measurement is often conducted in patients with high variability in their PEF. Although there may be some benefit from using PEF reproducibility to improve a subject effort, no specific reproducibility criterion is recommended at this time.

## REFERENCE VALUES, INTERPRETATION STANDARDIZATION, AND CLINICAL ASSESSMENT

### Clinical/Epidemiologic Considerations

Whether the spirogram results are to be used for clinical or epidemiologic purposes, the following recommendations apply.

Since the last standards were issued in 1987, a detailed statement on selection of reference values and interpretation of lung function tests has been published (3). The interpretation of spirometry involves two tasks: (*1*) The classification of the derived values with respect to a reference population and assessment of the reliability of the data; and (*2*) The integration of the spirometric values into the diagnosis, therapy, and prognosis for an individual patient. The first task is ordinarily the responsibility of the laboratory director or a designee and serves not only to communicate information to referring health care providers but also is an important aspect of laboratory quality control. The second task is ordinarily the responsibility of the physician requesting the studies and is performed within the context of patient care.

It is the responsibility of the medical director to develop explicit procedures for interpretation of spirometry and to select appropriate reference values. The procedures for interpretation and reference values may legitimately vary from laboratory to laboratory depending upon geographic location and the characteristics of the population being tested. In a setting where large numbers of healthy individuals are being screened for abnormality and the prevalence of disease is low, it is appropriate to set the threshold for abnormality at a higher level than in a setting where most individuals are referred because of symptoms or disease. In the latter case, where the prevalence of disease is high, an appropriate standard would be set to a more sensitive threshold for abnormality. The interpretative strategy should also take into consideration the consequences of false-positive and false-negative errors. Accordingly, no specific guidelines for interpretative procedures are recommended that would be applicable to all laboratories. More important, however, is that there be a consistent approach to the interpretation of lung function tests within a single laboratory. Therefore, referring physicians will not infer a change in the condition of the patient from a change in interpretation when it is the result of a change in the approach of the interpreting physician.

In providing the referring physician with an interpretation of spirometry results, it is also important to comment on deviations of the data from the guidelines for acceptability and reproducibility set forth herein. Although a spirometry session may not meet all of the guidelines, it may provide important clinical information and should be reported with appropriate qualification. Although some individuals display negative effort dependence, submaximal efforts usually lead to underestimation of the maximal effort values (28). Suboptimal efforts may be adequate to assist clinical decisions, where it can be judged that the recorded values underestimate true lung function.

*Acknowledgment:* The Committee thanks those who have provided input to this update of the Standardization of Spirometry. Special thanks go to the original participants of the Update Workshop, whose valued input was sought and used.

*External reviewers:* Scott T. Weiss, M.D., M.S., Gary R. Epler, M.D., and James R. Hansen, M.D.

## APPENDIX A

### Sample Spirograms

The sample spirograms shown in this appendix are from actual individuals and represent a few illustrations of acceptable and unacceptable maneuvers. It is imperative that the technician administering the test be capable of recognizing these anomalies and take appropriate corrective action – proper coaching. During the interpretation process, the reviewer may decide to include a maneuver that may have been considered unacceptable during test performance. As with the reproducibility criteria, some judgment must be made concerning what is an unacceptable maneuver. This decision will be based on the number of curves available, the disease pattern observed or expected for the individual, etc. However, the technician's action taken during the data collection stage of the process should almost always be to obtain additional maneuvers combined with effective coaching of the individual.

Figures A1a and A1b are volume–time and corresponding flow–volume samples that are acceptable spirograms from the draft NIOSH spirometry manual (78). In these spirograms, the individual exhibited a maximal effort for the entire maneuver, exhaling for at least 6 s with a greater than 1 s plateau in the volume–time curve. Figure A1a illustrates the relative expansion of the last portion of the FVC maneuver associated with a volume–time curve display. In contrast, Figure A1b illustrates the relative expansion of the initial portion of the FVC maneuver associated with a flow–volume curve display. Notice in the flow–volume curve (Figure A1b) it is more difficult to determine that the individual produced an acceptable plateau than in the volume–time curve display.

Figures A2a and A2b illustrate an unacceptable spirogram due to a cough during the first second of exhalation. Notice that the cough, which occurs at approximately 3.0 to 3.5 L, is very apparent in the flow–volume curve but is more difficult to detect in the volume–time curve. The anomalies seen in the volume–time curve at approximately 5.0 and 5.5 L could be slight coughs or variable effort, but occurred after the first second of exhalation.

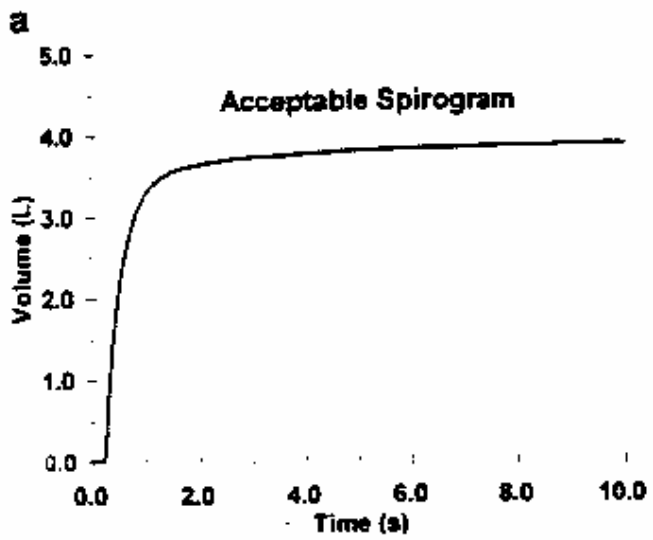



*Figure A1a.* Acceptable volume–time spirogram.

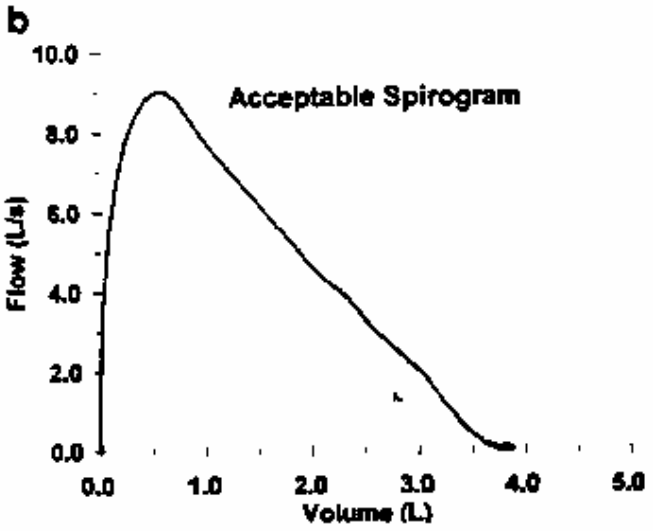



*Figure A1b.* Acceptable flow–volume spirogram.

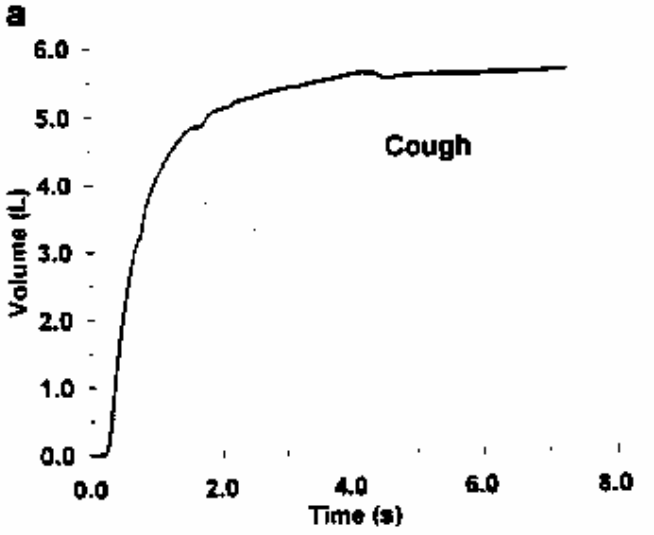



*Figure A2a.* Volume–time spirogram with a cough during the first second of exhalation.

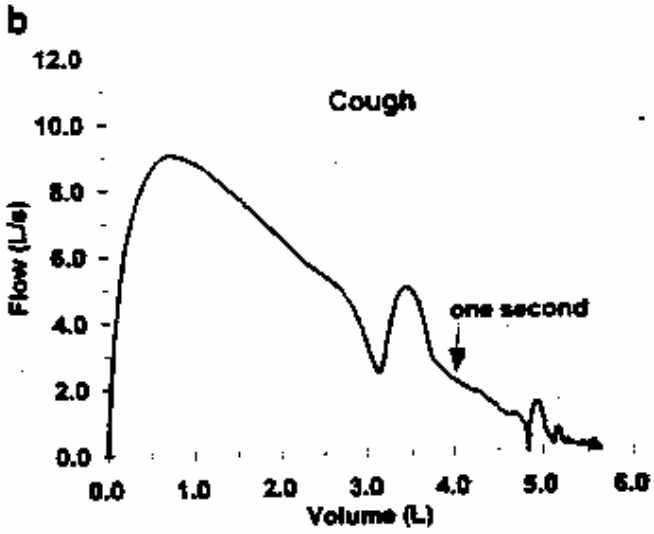



*Figure A2b.* Flow–volume spirogram with a cough during the first second of exhalation.

Although the fluctuations in flow observed in the flow–volume curve in Figure A2b are reasonably large, they may not result in a significantly different $FEV_1$. Therefore, the $FEV_1$ from this curve may be valid, particularly if all other curves are unacceptable. Regardless, when the technician observes the spirograms in Figures A2a and A2b, additional maneuvers should be obtained from the individual.

Figures A3a and A3b illustrate an unacceptable spirogram due to a variable effort or cough during the first second of exhalation and early termination of the maneuver. The anomaly observed at 1 L of exhalation is apparent on both the volume–time and flow–volume curves.

The duration of the anomaly and the fact that the flow immediately following the anomaly does not exceed the expected flow–volume envelope suggest that the anomaly is a variation in effort instead of a cough. The early termination is less apparent on the flow–volume curve. However, on the volume–time curve, it is apparent that the individual failed to exhale for 6 s and there is no 1-s plateau of the volume–time curve.

Figures A4a and A4b illustrate unacceptable sample spirograms due to an abrupt termination of flow at the end of the maneuver, possibly the result of the individual closing his/her glottis. Notice in Figure A4a that the volume–time curve plateau occurs abruptly at approximately 2.2 s where the volume remains constant for the remainder of the maneuver. In Figure A4b, the flow–volume curve exhibits an abrupt decrease in flow at the end of the maneuver.

Figures A5a and A5b illustrate unacceptable sample spirograms due to a leak in the volume-type spirometer or spirometer hose. This leak is approximately 50 ml/s and produces an approximate 300-ml loss in volume over the 6-s exhalation produced by this individual. Notice that the leak is very apparent on the volume–time curve and perhaps less apparent on the flow–volume curve. At the end of the maneuver when the leak is most

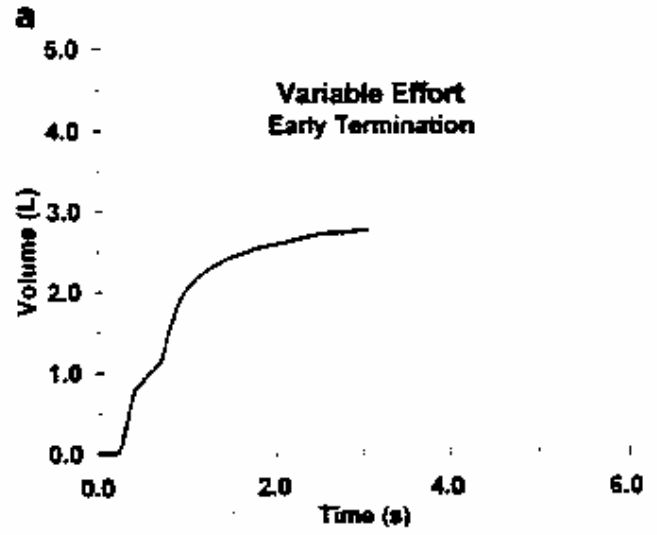



*Figure A3a.* Unacceptable volume–time spirogram due to variable effort and early termination.

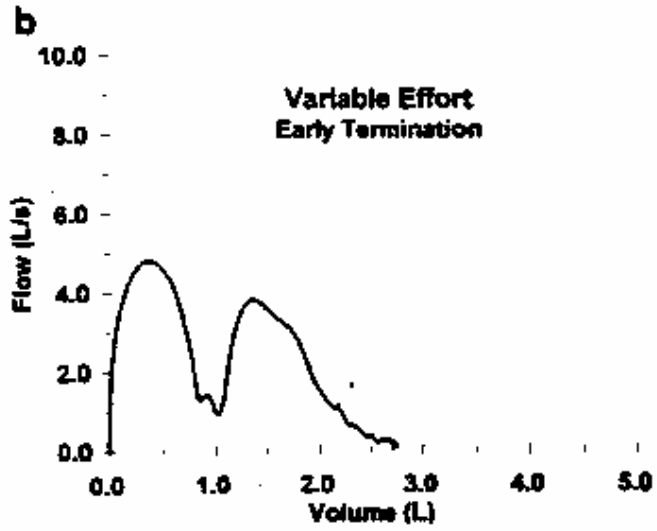



*Figure A3b.* Unacceptable flow–volume spirogram due to variable effort and early termination.

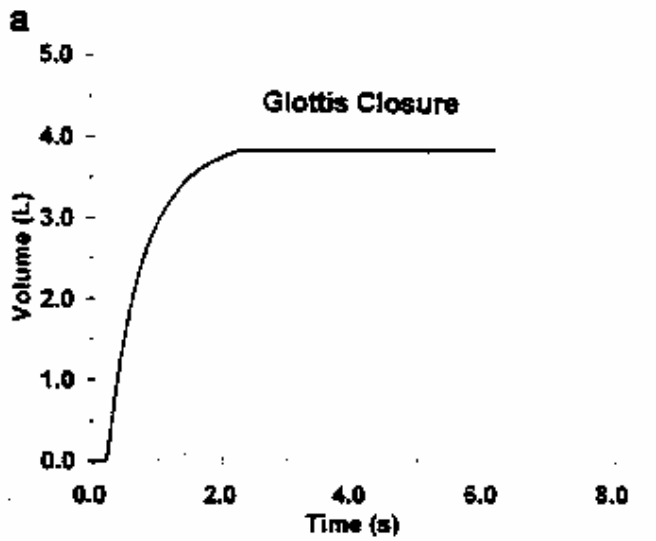



*Figure A4a.* Unacceptable volume–time spirogram due to possible glottis closure.

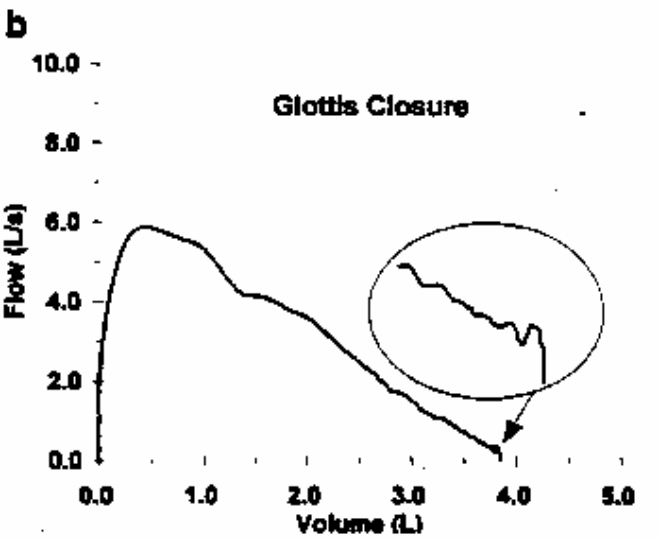



*Figure A4b.* Unacceptable flow–volume spirogram due to possible glottis closure.

apparent, the flow is slightly negative and volume is decreasing (*see* insert in Figure A5b, short line moving to the left below the zero flow line). If a spirometry system display does not display negative flows, then the leak would be even less apparent on the flow–volume curve.

Figures A6a and A6b illustrate acceptable sample spirograms for an individual with mild airways obstruction ($FEV_1/FVC\%$ = 67%). Notice the relatively small change in volume after 10 s of exhalation (Figure A6a) and the corresponding relative low flow (Figure A6b) at the end of the maneuver.

In addition to requiring three acceptable maneuvers, the reproducibility criteria for FVC and $FEV_1$ should be met as a goal during test performance. Figure A7a illustrates the volume–time curve and Figure A7b the corresponding flow–volume curve for a 22-yr-old, healthy female. In these figures, the subject did not meet the minimum reproducibility criteria for both the FVC and $FEV_1$ despite performing three acceptable maneuvers. The second largest FVC was 0.43 L (10%) lower than the largest, and the second largest $FEV_1$ was 0.37 L (12.1%) lower than the largest $FEV_1$. Therefore, at least one additional maneuver should be performed by this subject in an attempt to meet the FVC and $FEV_1$ reproducibility criteria. The most likely cause of this pattern (nonreproducible tracings but good initial effort) is a failure to achieve a maximal inhalation before performing the FVC maneuver.

Figures A8a and A8b illustrate a reproducible test with three acceptable maneuvers. Figure A8a displays the three acceptable volume–time curves, and Figure A8b displays the corresponding flow–volume curves. These maneuvers were obtained from an 80-yr-old male with an $FEV_1/FVC\%$ = 61.7%. Notice that the curves are very reproducible even though the subject required approximately 20 s to reach his final volume or FVC.

Figure A9 shows a sample VC maneuver for a normal subject. This subject starts the test with several tidal volumes through

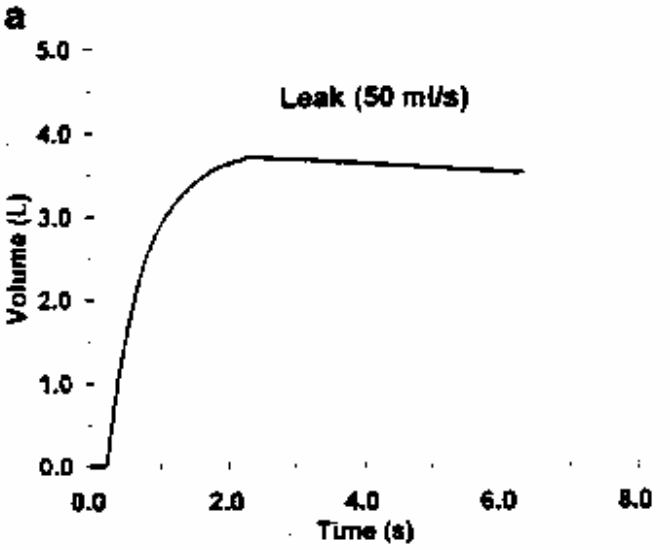



*Figure A5a.* Unacceptable volume–time spirogram due to a leak.

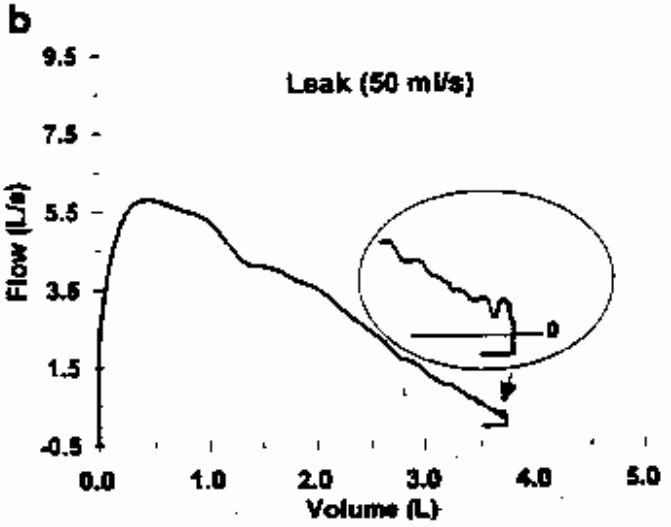



*Figure A5b.* Unacceptable flow–volume spirogram due to a leak.

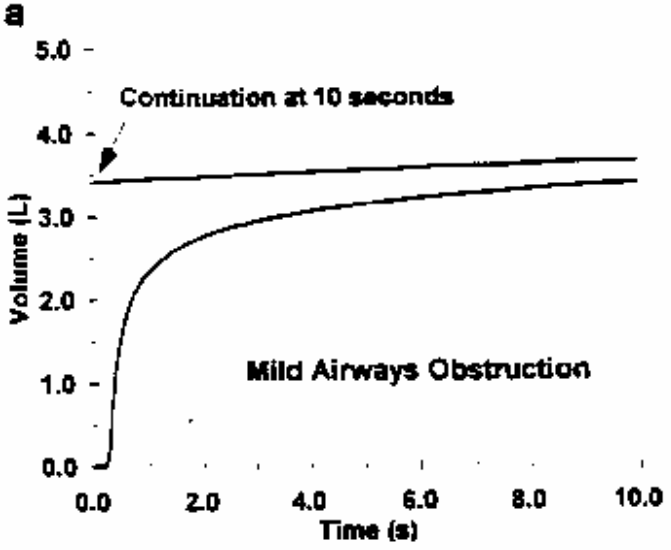



*Figure A6a.* Acceptable volume–time spirogram for an individual with mild airways obstruction.

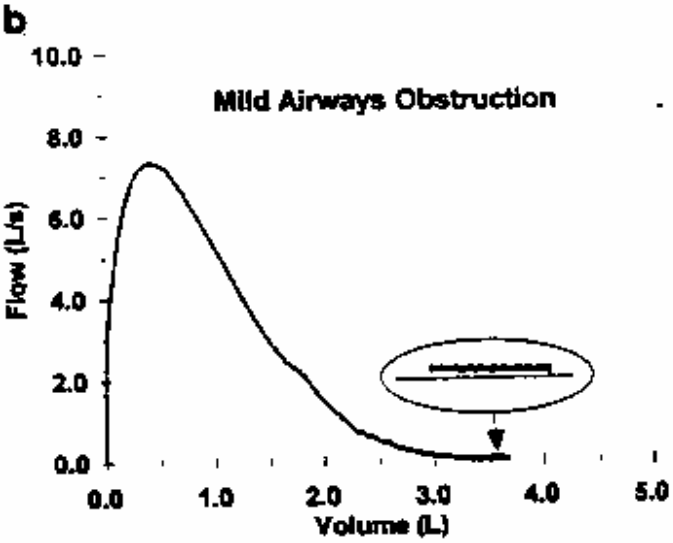



*Figure A6b.* Acceptable flow–volume spirogram for an individual with mild airways obstruction.

a valve opened to room air to become accustomed to breathing on the mouthpiece. The subject is then connected to the spirometer, where several additional tidal volumes are recorded. The subject then completely inhales to total lung capacity (TLC) and slowly exhales to residual volume (RV), making sure to completely inhale to TLC and exhale to RV. After reaching RV, the subject returns to FRC, where several tidal volumes are again obtained before the subject comes off the mouthpiece. Notice the plateaus at TLC and RV, indicating that the subject has completely inhaled and exhaled.

Figure A10 shows a sample VC maneuver for a subject with severe airways obstruction. The identical maneuver for the normal subject shown in Figure A9 is repeated for this subject with severe airways obstruction. However, the tidal volumes of the subject with severe airways obstruction are much more rapid and the subject requires a longer exhalation time to reach RV, as long as 25 s. Notice that as with the normal subject, a plateau in the volume–time curve is obtained at both TLC and RV. This indicates that the subject has completely inhaled and exhaled. Also notice that the subject has some difficulty in obtaining a stable FRC after the VC maneuver, probably due to gas trapping.

## APPENDIX B

### Spirometer Testing Guidelines

The following testing guidelines should be used when evaluating new spirometer designs and when changes have been made to spirometer hardware or software. For production testing, the use of a smaller set of test waveforms may be appropriate. The spirometer selected for testing should be a "production" model and not one that was specifically selected because of any extraordinary calibration efforts. Once testing has begun, the device be-

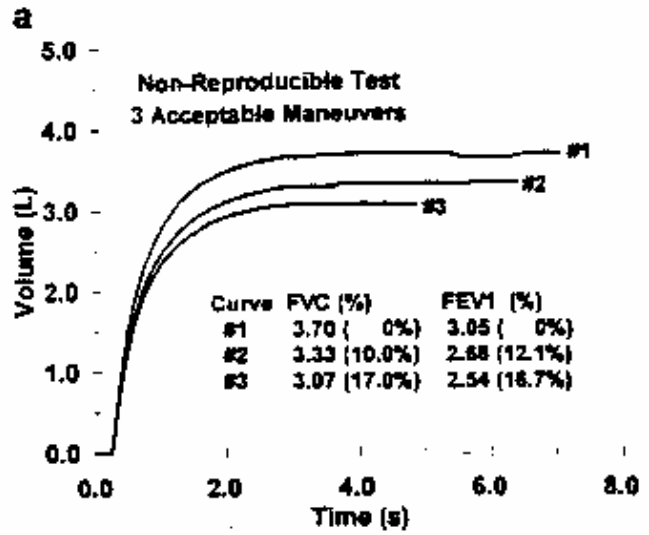



*Figure A7a.* Nonreproducible test with three acceptable volume–time curves. Percents are difference from largest value.

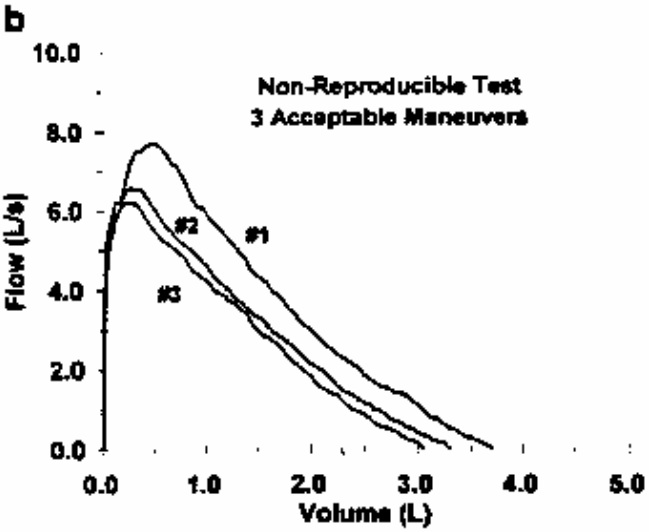



*Figure A7b.* Nonreproducible test with three acceptable flow–volume curves.

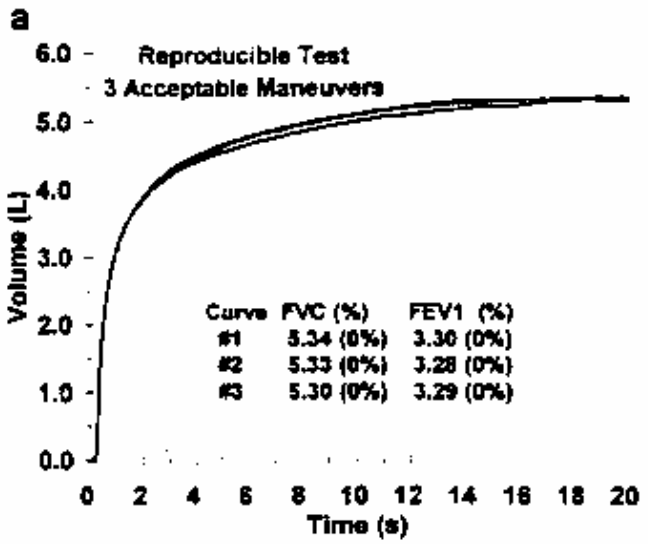



*Figure A8a.* Reproducible test with three acceptable volume–time curves. Percents are difference from largest value.

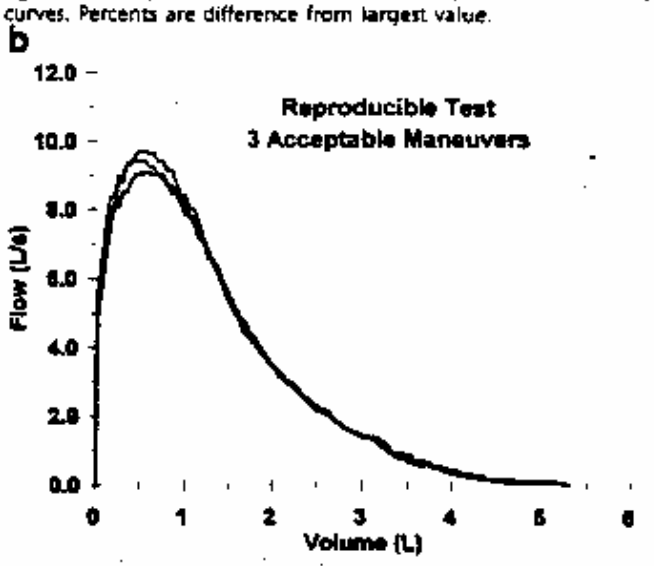



*Figure A8b.* Reproducible test with three acceptable flow–volume curves.

ing tested should not receive any adjustments or special calibration procedures that are not part of its routine operational procedures.

Volume parameters should be validated using the 24 volume-time standard waveforms described in APPENDIX C. For PEF and other flow parameters *not* based on a percentage of the FVC, the 26 flow–time standard waveforms should be used (APPENDIX D). The validation limits are provided for each parameter in the main sections of this statement. All tests should be conducted using the appropriate waveforms and a computer-controlled mechanical syringe or its equivalent (waveform generator). The accuracy of the waveform generator should be checked at least daily when in use, either using a spirometer for volume waveforms or a pneumotachometer for flow waveforms, or an equivalent method. The desired accuracy of the waveform generator for volume parameters is ± 0.5% (or ± 0.05 L, whichever is greater); ± 2% (or ± 5 L/min, whichever is greater) for flow parameters (e.g., PEF). In comparing results obtained from a particular spirometer, the tolerance limits of the waveform generator are to be considered by adding them to the accuracy requirement for the parameter under test, for example 0.5% (± 0.05 L) for volume parameters and 2% (± 5 L/min) for flow parameters. Therefore, the FVC accuracy requirement for comparisons with observed values would be ± 3.5% (performance accuracy requirement ± 3% plus waveform generator accuracy of ± 0.5%).

The accuracy and precision validation limits contained in this section assume a waveform generator accuracy of 0.5% for volume and 2% for flow parameters. The accuracy of available waveform generators has not been established; therefore, the desired 2% waveform generator accuracy for flow parameters may not be achieved. In this circumstance, the *actual* accuracy limit of the waveform generator should be added to the accuracy require-

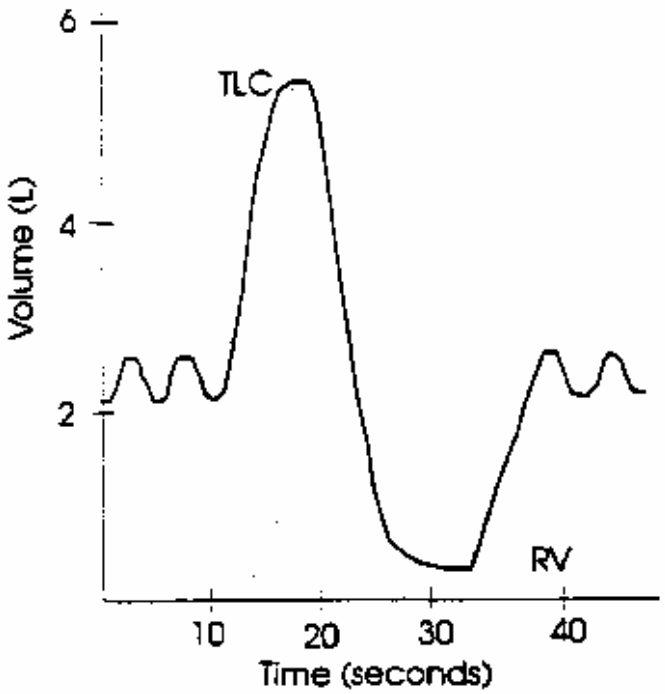



*Figure A9.* Sample relaxed VC maneuver in a normal subject.

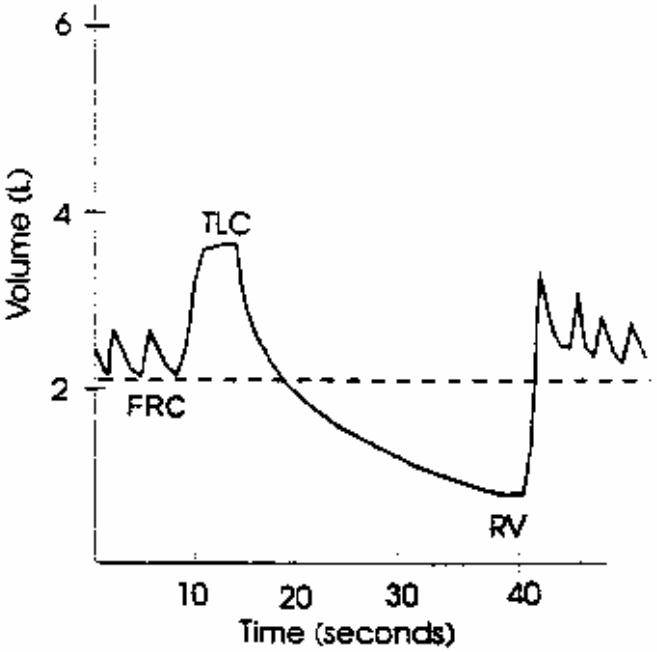



*Figure A10.* Sample VC maneuver from a subject with severe airways obstruction.

ment of the parameter under test. Every attempt should be made to improve the accuracy of waveform simulators, but in no case should the simulator accuracy limit be considered less than 0.5% for volume and 2% for flow parameters.

Spirometers or peak flow meters should be connected to the waveform generator in the same orientation used in the testing of subjects. Tubing or other connecting material may be used, but the volume associated with the connecting tubing should be less than 300 ml. For handheld devices, full testing should be conducted with the sensor in a horizontal position (the typical position with the patient at TLC about to initiate the maneuver). In addition, handheld devices should be tested with two waveforms (standard volume–time waveforms 1 and 6) at a typical FRC position (instrument at a 30° angle down from horizontal). These devices must meet diagnostic spirometer accuracy criteria for these two waveforms in the 30° down-angle position.

The instruments (diagnostic or monitoring devices) should be tested using the waveform generator under conditions similar to those present when testing human subjects. No special procedures should be followed in testing the instrument. Specifically, each waveform will be injected into the instrument within not less than 5 s or more than 1 min of the instrument being set to the ready condition. In measuring the resistance of the instrument, pressure should be measured in the side of the standard mouthpiece used by the instrument when constant flows are injected into the spirometer. If an in-line filter is to be used as part of routine testing of humans, a filter must be attached during spirometer validation and resistance testing.

Five repeats of each of the 24 waveforms should be injected into the test instrument using room air at ambient temperature. In those circumstances where the flow or volume sensor is changed between subjects (e.g., disposable flow sensor), a different sensor should be used for each of the repeat tests. The average of the five repeat values should be used for comparison with the standard values. The range and percent deviations of values from the five repeated tests should also be computed by:

$$\text{Range} = \text{maximum} - \text{minimum} \quad \text{(B1)}$$

$$\text{Range (\%)} = 100 * \frac{(\text{maximum} - \text{minimum})}{\text{average}} \quad \text{(B2)}$$

$$\text{Deviation} = \text{average} - \text{standard} \quad \text{(B3)}$$

$$\text{Deviation (\%)} = 100 * \frac{(\text{average} - \text{standard})}{\text{standard}} \quad \text{(B4)}$$

Averages are calculated as a simple n weighted average.

The five repeats of 24 waveforms should be considered a rigid testing sequence. The testing of a device should be completed by running all 24 waveforms with five repeated tests. If the device fails to accurately measure a value for a particular waveform, no additional repeats should be conducted for only one waveform.

Diagnostic devices should also be tested by injecting at least four waveforms using heated and humidified air (waveforms 1 through 4) to verify accuracy of volume parameters under BTPS conditions. Using volume-time waveforms 1 through 4, the average FVC and $FEV_1$ of three trials shall be compared to the standard values. The validation limits for testing under BTPS conditions are ± 4.5% or 200 ml, whichever is greater. Spirometers must meet these accuracy criteria for all four waveforms under BTPS conditions. Using 4.5% allows a 1.5% simulator error, necessary because of the added uncertainty when using heated and humidified air. The time between each of the three trials should be less than 2 min. The temperature of the air injected into the device under test should be within ± 1° C of 37° C and should be measured before the air is injected into the device. Waveform generators are being modified to allow BTPS testing. The BTPS testing requirement will be implemented when BTPS testing services are available.

In addition to testing using the waveform generator, the device should be tested using at least two healthy human subjects.

TABLE B1

STROKE VOLUME, VOLUME IN SPIROMETER AT START OF TEST (FOR VOLUME SPIROMETERS), RATE, AND CORRESPONDING MVV TARGET VALUES

| Test Number | Target MVV (L/min) | Stroke Volume (L) | Rate (Strokes/min) | Starting Volume (L) |
|---|---|---|---|---|
| 1 | 60 | 1.0 | 60 | 2.0 |
| 2 | 100 | 1.0 | 100 | 3.0 |
| 3 | 120 | 2.0 | 60 | 3.0 |
| 4 | 200 | 2.0 | 100 | 3.0 |

The purpose of the testing using a human subject is to verify that the instrument will function properly under conditions other than those present using a mechanical simulator. To achieve a balanced design, each subject should perform alternating maneuvers between a standard spirometer and the device being tested, performing three maneuvers on each device, for a total of six maneuvers. One subject should be randomly assigned to perform their first maneuver on the standard spirometer while the other subject's first maneuver will be performed on the device being tested, allowing the learning effect to be equally distributed across both instruments. The differences between the largest of the three trials from each device should be within ± 6% or 200 ml, whichever is greater, for FVC and $FEV_1$, and ± 15% or 30 L/min, whichever is greater, for PEF.

For validating MVV, a mechanical pump should be used with a sinusoidal waveform. The response of the device should be determined using incrementally increased flows up to a maximum of 250 L/min, produced with stroke volumes up to 2 L. The specific minimum patterns and for volume spirometers, the volume in the spirometer, are given in Table B1. The device should read the MVV within ± 10.5% of reading or ± 20 L/min, whichever is greater for all four test patterns specified in Table B1. In addition, the pressure measured at the mouthpiece should not exceed 10 cm $H_2O$ during the entire MVV maneuver. No mechanical pump testing at BTPS is required for MVV.

## DIAGNOSTIC DEVICES: TESTING FOR ACCURACY AND PRECISION WITH A WAVEFORM GENERATOR

### Accuracy Testing

Accuracy criteria: Deviation ± 3.5% or ± 0.100 L, whichever is greater, for volume measurements; ± 5.5% or ± 0.250 L/s, whichever is greater, for $FEF_{25-75\%}$; ± 12% or ± 25 L/min (± 0.420 L/s), whichever is greater, for PEF. These criteria are increased slightly from those in Table 2 to account for the waveform generator inaccuracy. For MVV testing, deviation must be less than ± 10.5% or 20 L/min, whichever is greater.

Waveforms: Twenty-four standard volume–time waveforms (APPENDIX C) for FVC, $FEV_1$, and $FEF_{25-75\%}$; 26 standard flow–time waveforms (APPENDIX D) for PEF. For BTPS testing, volume–time waveforms 1 through 4 should be used with heated and humidified air as specified in this appendix. For MVV testing, sinusoidal waveforms should be used with the patterns specified in Table B1.

Spirometer tested: One production spirometer. Spirometers should not be screened or especially calibrated before testing. If an in-line filter is to be used during the testing of humans, it should be attached for this testing. When during clinical testing, if the flow or volume sensor is changed between subjects, the sensors must be changed for each of the five repeat tests described below. The spirometer may not be recalibrated after these sensor changes unless recalibration is required after each sensor change during clinical testing.

Validation: Each spirometric waveform is to be injected into the spirometer five times. MVV patterns will be injected in duplicate. Average values will be calculated for each waveform and, along with individual values, will be used to score the spirometer. See formulas B1–B4.

Acceptable performance: For FVC and FEV, in each of the volume–time waveforms: deviation (formula B3) must be less than 0.100 L *or* deviation (%) (formula B4) must be less than 3.5%. For $FEF_{25-75\%}$ in each of the volume–time waveforms: deviation must be less than 0.250 L/s *or* deviation (%) must be less than 5.5%. For PEF in each of the flow–time waveforms: deviation must be less than 25 L/min (0.420 L/s) or deviation (%) must be less than 12%. For BTPS testing using waveforms 1–4: deviation must be less than 0.2 L or deviation (%) must be less than 4.5%. For MVV in each of the patterns: deviation must be less than 20 L/min or deviation (%) must be less than 10.5%.

An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. For testing with ambient air, acceptable performance is present if the error rate for each individual parameter (FVC, $FEV_1$, $FEF_{25-75\%}$, PEF) is less than 5% (one error for each parameter when 24 or 26 waveforms are used). For MVV testing and spirometric testing with BTPS conditions, acceptable performance is present if the error rate is zero.

### Precision Testing: Intradevice Testing

Precision criteria: See the acceptable performance criteria listed below.

Waveforms: Use data generated as part of accuracy testing. Acceptable performance: For FVC and $FEV_1$, for each of the volume–time waveforms: The range (formula B1) must be less than 0.100 L *or* range (%) (formula B2) must be less than 3.5%. For $FEF_{25-75\%}$ using each of the volume–time waveforms: The range (formula B1) must be less than 0.250 L/s or the range (%) (formula B2) must be less than 5.5%. For PEF using each of the flow–time waveforms: The range must be less than 25 L/min (0.420 L/s) or the range (%) must be less than 7%.

An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if the error rate for each individual parameter (FVC, FEV, PEF) is less than 5% (one error for each parameter if 24 or 26 waveforms are used).

## MONITORING DEVICES (PEF) TESTING CRITERIA

The range and deviations from the standard PEF values should be calculated using formulas B1 through B4.

### Accuracy Testing

Accuracy criterion: ± 12% or ± 25 L/min of target values, whichever is larger. The primary criterion is ± 10%; 2% is added to account for the inaccuracy of the waveform generator.

Waveforms: 26 flow–time curves (APPENDIX D).

Meters tested: Two production meters. Meters should be selected routinely from a production run and not be screened before validation testing.

Validation: Each meter will receive five maneuvers for each of the 26 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance is less than three errors out of the total 52 tests (26 waveforms, 2 meters).

### Precision Testing: Intradevice Testing

Criterion: Less than 6% intradevice variability or 15 L/min, whichever is greater. The primary criterion is less than 5%. One per-

TABLE C1

VALUES FOR STANDARD WAVEFORMS

| Curve | FVC (L) | $FEV_1$ (L) | $FEV_1$ (%FVC) | Vext (L) | Vext (%FVC) | $PEF_{max}$ (L/s) | $FEV_{25-75\%}$ (L/s) |
|---|---|---|---|---|---|---|---|
| 1 | 6.000 | 4.262 | 71.0 | 0.052 | 0.9 | 6.497 | 3.410 |
| 2 | 4.999 | 4.574 | 91.5 | 0.068 | 1.4 | 9.873 | 5.683 |
| 3 | 3.498 | 1.188 | 33.9 | 0.014 | 0.4 | 1.380 | 0.644 |
| 4 | 1.498 | 1.371 | 91.5 | 0.019 | 1.3 | 2.952 | 1.704 |
| 5 | 5.132 | 3.868 | 75.4 | 0.087 | 1.7 | 7.535 | 3.209 |
| 6 | 4.011 | 3.027 | 75.5 | 0.317 | 7.9 | 5.063 | 2.572 |
| 7 | 3.169 | 2.519 | 79.5 | 0.354 | 11.2 | 4.750 | 2.368 |
| 8 | 1.993 | 1.615 | 81.0 | 0.151 | 7.6 | 3.450 | 1.857 |
| 9 | 4.854 | 3.772 | 77.7 | 0.203 | 4.2 | 7.778 | 3.365 |
| 10 | 3.843 | 3.031 | 78.9 | 0.244 | 6.3 | 4.650 | 2.899 |
| 11 | 2.735 | 1.811 | 66.2 | 0.022 | 0.8 | 3.708 | 1.272 |
| 12 | 2.002 | 1.621 | 81.0 | 0.094 | 4.7 | 3.807 | 1.780 |
| 13 | 4.896 | 3.834 | 78.3 | 0.460 | 9.4 | 5.207 | 3.677 |
| 14 | 3.786 | 3.053 | 80.6 | 0.388 | 10.2 | 4.368 | 3.122 |
| 15 | 5.937 | 5.304 | 89.3 | 0.080 | 1.3 | 12.132 | 6.092 |
| 16 | 5.458 | 3.896 | 71.4 | 0.215 | 3.9 | 7.395 | 2.892 |
| 17 | 5.833 | 2.597 | 44.5 | 0.035 | 0.6 | 5.257 | 1.153 |
| 18 | 4.343 | 3.155 | 72.6 | 0.042 | 1.0 | 7.523 | 2.335 |
| 19 | 3.935 | 2.512 | 63.8 | 0.044 | 1.1 | 5.408 | 1.137 |
| 20 | 2.881 | 2.563 | 89.0 | 0.041 | 1.4 | 5.822 | 2.695 |
| 21 | 4.477 | 3.549 | 79.3 | 0.102 | 2.3 | 9.398 | 3.368 |
| 22 | 3.857 | 2.813 | 72.9 | 0.036 | 0.9 | 5.055 | 2.204 |
| 23 | 3.419 | 1.360 | 39.8 | 0.013 | 0.4 | 2.868 | 0.531 |
| 24 | 1.237 | 0.922 | 74.5 | 0.037 | 3.0 | 2.095 | 0.709 |

*Definition of abbreviations:* Vext = extrapolated volume (see Figure 2 for description).

cent or 5 L/min is added to account for the imprecision of the waveform generator.

Waveforms: Four of the 26 standard flow–time waveforms (waveforms 1, 4, 8, and 25).

Meters tested: Ten production meters.

Validation: Three flows for each waveform for each meter. For each waveform and for each meter, calculate range (formula B1) and range (%) (formula B2) for each PEF.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is six or fewer errors (error rate = 5% for 120 trials).

#### Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 25 L/min, whichever is greater. This includes 1% or 5 L/min for the imprecision of the waveform generator.

Waveforms: Same as for intradevice testing.

Meters tested: Same as for intradevice testing.

Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each meter, calculate an average PEF for each waveform. For each waveform, combine all data from the 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

TABLE D1

CALCULATED VALUES FOR 26 STANDARD FLOW–TIME WAVEFORMS (0.002-S SAMPLING INTERVAL)*

| Waveform Number | Flow PEF (L/s) | Vol-80 PEF (L/s) | Vol-40 PEF (L/s) | Rise-Time (ms) | Vext Time-to-PEF (ms) | Flow Time-to-PEF (ms) | Extr Vol (L) | %Vext (%FVC) | $FEV_1$ (L) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 7.445 | 7.243 | 7.337 | 93.5 | 86.8 | 151.7 | 0.108 | 2.5 | 3.373 |
| 2 | 10.860 | 9.905 | 10.450 | 55.7 | 46.5 | 86.6 | 0.093 | 2.2 | 3.838 |
| 3 | 4.794 | 4.372 | 4.630 | 68.3 | 53.0 | 114.7 | 0.054 | 3.3 | 1.302 |
| 4 | 4.401 | 4.240 | 4.321 | 76.0 | 65.6 | 116.3 | 0.051 | 2.9 | 1.468 |
| 5 | 3.430 | 3.564 | 3.584 | 159.5 | 170.6 | 241.0 | 0.081 | 3.0 | 2.053 |
| 6 | 3.088 | 2.728 | 2.949 | 44.5 | 36.8 | 62.7 | 0.027 | 1.3 | 1.110 |
| 7 | 2.509 | 2.237 | 2.403 | 148.0 | 67.6 | 173.6 | 0.057 | 3.7 | 1.046 |
| 8 | 2.328 | 2.048 | 2.210 | 42.4 | 35.6 | 57.6 | 0.015 | 1.0 | 0.950 |
| 9 | 5.259 | 4.923 | 5.109 | 57.0 | 47.2 | 85.4 | 0.046 | 1.8 | 2.182 |
| 10 | 4.733 | 4.657 | 4.666 | 46.7 | 93.6 | 122.2 | 0.035 | 1.5 | 2.029 |
| 11 | 6.870 | 6.472 | 6.706 | 81.1 | 67.4 | 125.6 | 0.085 | 3.1 | 2.080 |
| 12 | 10.684 | 10.528 | 10.556 | 115.3 | 139.9 | 214.1 | 0.189 | 3.4 | 4.618 |
| 13 | 4.804 | 4.706 | 4.739 | 105.3 | 121.7 | 194.9 | 0.080 | 2.7 | 2.304 |
| 14 | 3.821 | 3.756 | 3.769 | 124.7 | 127.7 | 201.8 | 0.074 | 2.5 | 2.249 |
| 15 | 7.956 | 7.814 | 7.852 | 174.9 | 152.6 | 270.4 | 0.192 | 5.0 | 3.219 |
| 16 | 5.251 | 5.100 | 5.165 | 76.3 | 80.5 | 123.7 | 0.060 | 2.1 | 2.246 |
| 17 | 5.842 | 5.721 | 5.757 | 165.1 | 163.4 | 285.1 | 0.131 | 5.0 | 2.802 |
| 18 | 8.593 | 8.404 | 8.465 | 132.9 | 126.2 | 248.7 | 0.178 | 3.6 | 4.303 |
| 19 | 6.953 | 6.651 | 6.807 | 76.5 | 63.7 | 120.2 | 0.083 | 2.2 | 3.007 |
| 20 | 7.430 | 7.274 | 7.324 | 120.9 | 143.3 | 268.4 | 0.141 | 2.5 | 4.613 |
| 21 | 3.973 | 3.745 | 3.880 | 130.3 | 88.4 | 193.1 | 0.079 | 6.0 | 1.096 |
| 22 | 3.377 | 3.316 | 3.334 | 184.2 | 157.6 | 259.6 | 0.094 | 5.0 | 1.559 |
| 23 | 8.132 | 7.954 | 8.019 | 84.8 | 83.1 | 152.1 | 0.107 | 2.4 | 3.476 |
| 24 | 4.155 | 4.028 | 4.086 | 50.3 | 52.3 | 83.7 | 0.032 | 1.2 | 1.833 |
| 25 | 14.194 | 13.896 | 13.964 | 57.9 | 53.7 | 100.3 | 0.126 | 1.9 | 5.944 |
| 26 | 11.595 | 10.446 | 11.172 | 49.6 | 42.2 | 79.1 | 0.088 | 1.7 | 4.311 |

*Definition of abbreviations:* Flow PEF = peak flow determined by obtained highest observed flow value; Vol-80 PEF = peak flow determined from volume–time curve using an 80-ms segment; Vol-40 PEF = Peak flow determined from volume–time curve using a 40-ms segment; Rise-Time = time required for the flow to rise from 10% of PEF to 90% of PEF; Flow Time-to-PEF = time required for flow to rise from 200 ml/s to maximum flow (PEF); Vext Time-to-PEF = time required for flow to rise from Vext time zero to PEF.

* Units: flow (L/s), volumes (L), and time (milliseconds). These waveforms are available on digital media from the American Thoracic Society.

## MONITORING DEVICES (FVC AND $FEV_1$) TESTING CRITERIA

### Accuracy Testing

Criterion: Deviation ± 5.5% *or* deviation (%) ± 0.1 L, whichever is larger.

Waveforms: Twenty-four standard volume–time waveforms (APPENDIX C).

Device testing: Two production devices selected routinely from a production run and not screened before testing.

Validation: Each device will receive five maneuvers for each of the 24 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance for each individual parameter is less than three errors out of the total 48 tests (24 waveforms, 2 devices).

### Precision Testing: Intradevice Testing

Criterion: Range (%) < 3.5% or range < 0.1 L, whichever is greater.

Waveforms: Four of the 24 standard volume–time waveforms (waveforms 1, 3, 6, and 11).

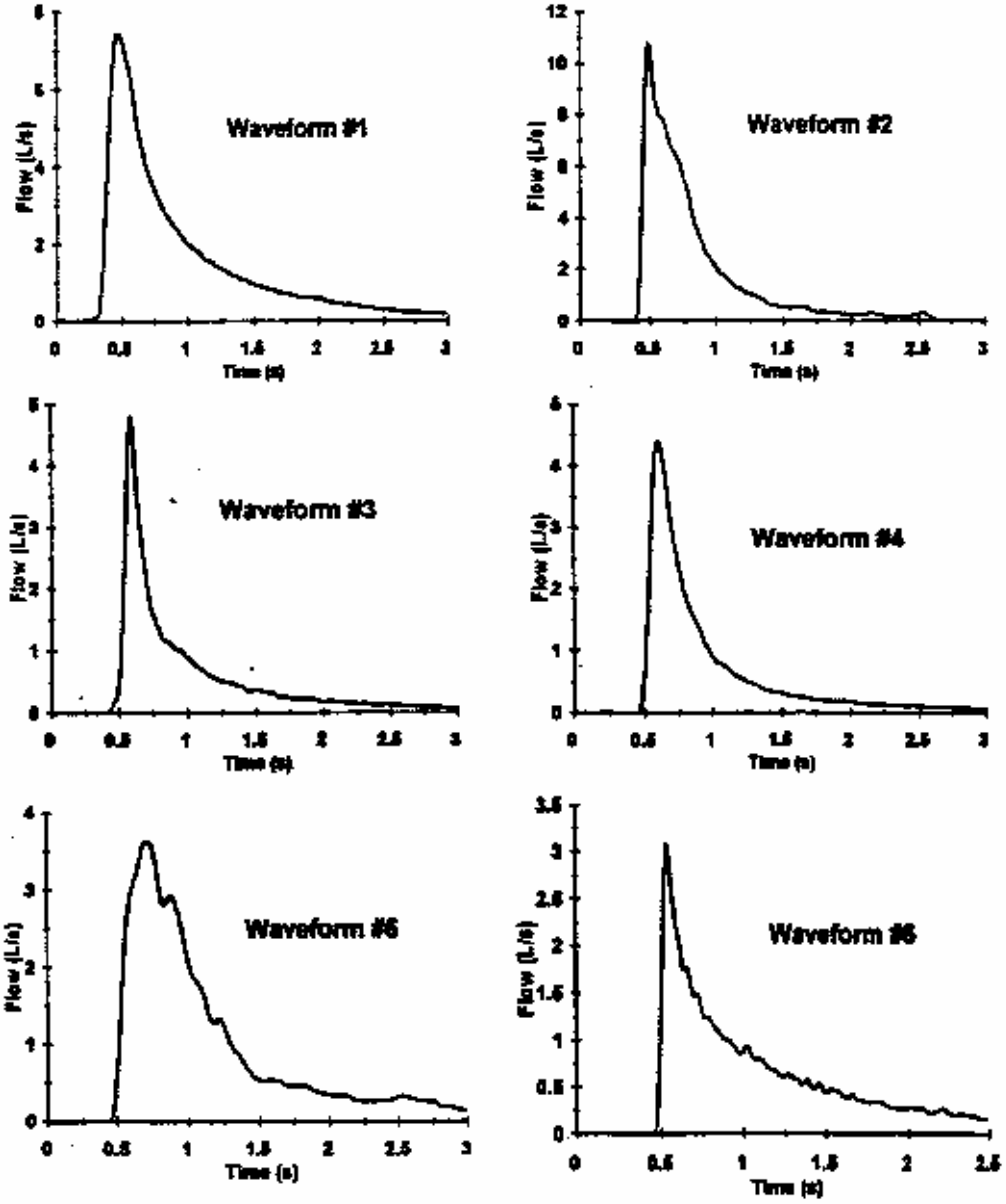
Meters tested: Ten production devices.

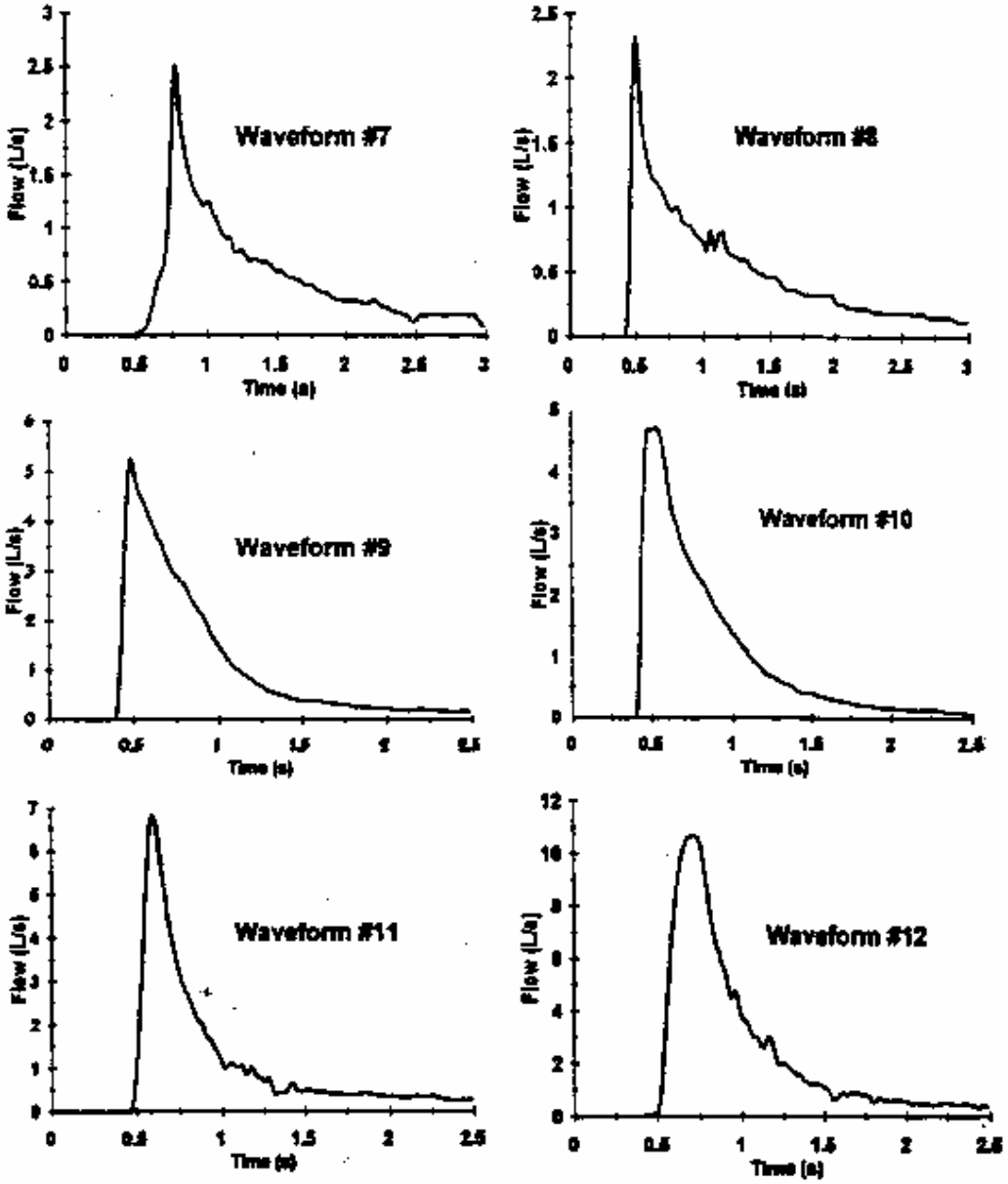
Validation: Three flows for each waveform for each device. For each waveform and for each device, calculate range (formula B1) and range (%) (formula B2) for FVC and $FEV_1$.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance for each individual parameter is six or fewer errors (error rate ± 5% for 120 trials).

### Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 0.2 L, whichever is greater.






Waveforms: Same as for intradevice testing.

Devices tested: Same as for intradevice testing.

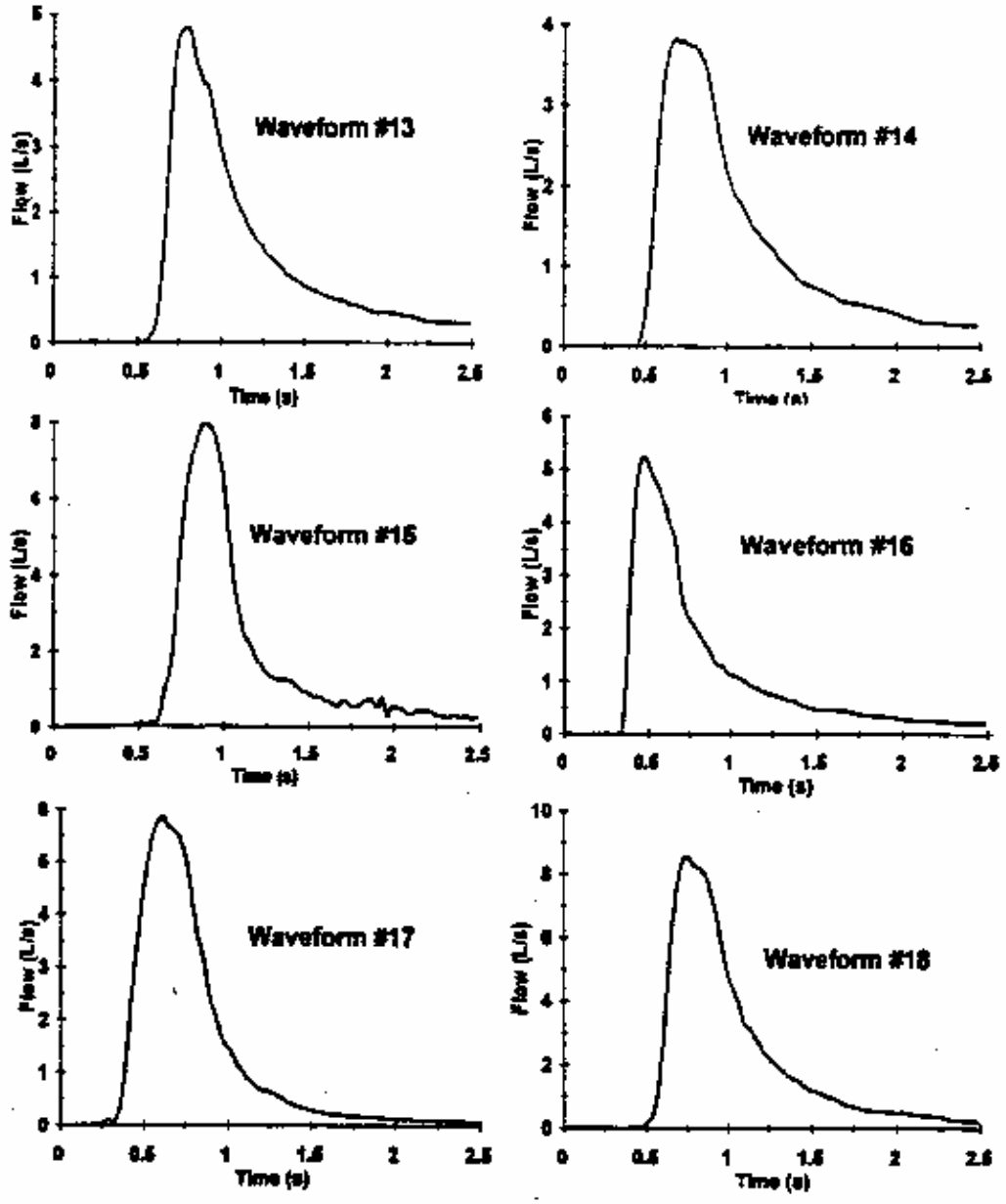
Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each device, calculate an average FVC and FEV, for each waveform. For each waveform and parameter, combine all data from 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

## APPENDIX D

### Standard Flow-Time Waveforms for Validating PEF

The following flow-time waveforms are intended primarily for testing portable PEF meters but can be used for testing other types of spirometers, especially those measuring PEF, time-to-peak flow, or rise-time. These waveforms were chosen to represent a range of PEFs and efforts (rise-times). The PEF is derived directly from the flow–time waveform–maximal observed value. To calculate the volume-determined PEF, volume is first obtained by integrating (summing) the flow values. Flow is then calculated from the volume–time waveform using the ATS 8-point smoothing function. The resulting volume PEF is usually lower than the PEF obtained from the flow–time waveform. Rise-time is defined as the time required for the flow to rise from 10% of the PEF to 90% of the PEF and is expressed in milliseconds. Other investigators have used the time-to-PEF, using the back-extrapolated technique to determine the zero time-point. Using back-extrapolation to calculate time-to-peak flow sometimes



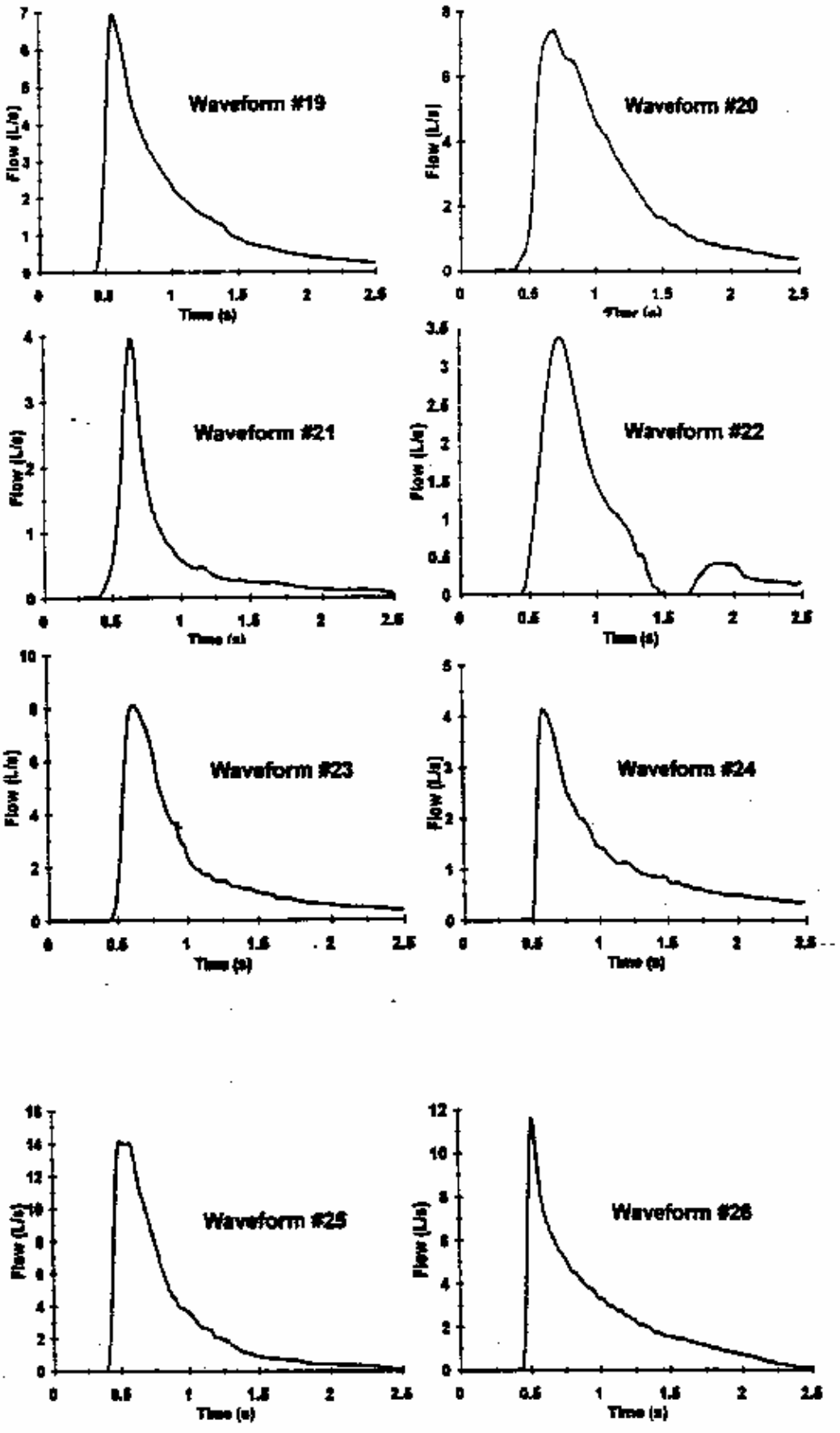

results in artificially lower time-to-PEF, as can be seen in waveform 7.

## APPENDIX E

### Signal-Processing Tutorial

Since computers have come into such common use in spirometry and since fundamental errors have been detected in recently tested commercially available hardware and software (79), a short tutorial on signal processing is presented (Figure E1).

For volume spirometers, signals are generally derived from electrical voltages from a potentiometer. Some spirometers also use optical shaft or position encoders (80). Flow devices of the Fleisch pneumotachometer variety also have electrical voltage outputs. For the volume spirometer with a potentiometer and the flow device with a flow transducer, the signal is sampled by a computer's analog to digital (A-to-D) converter. The ability of these systems to accurately measure the spirogram depends on the volume or flow transducer's linearity, the accuracy and linearity of the electrical transducer (potentiometer), and the resolution of the A-to-D converter. A resolution of 12 bits (1 part in 4,096, raw resolution from 0.003 to 0.004 L) for the A-to-D converter is recommended, although 10 bits (1 part in 1,024, raw resolution from 0.008 to 0.016 L) may be adequate for sampling volume. The sampling rate of the spirometer volume or flow is very important. Lemen and associates (19) have shown


Waveform #19
Waveform #20
Waveform #21
Waveform #22
Waveform #23
Waveform #24
Waveform #25
Waveform #26
Flow (L/s)
Time (s)

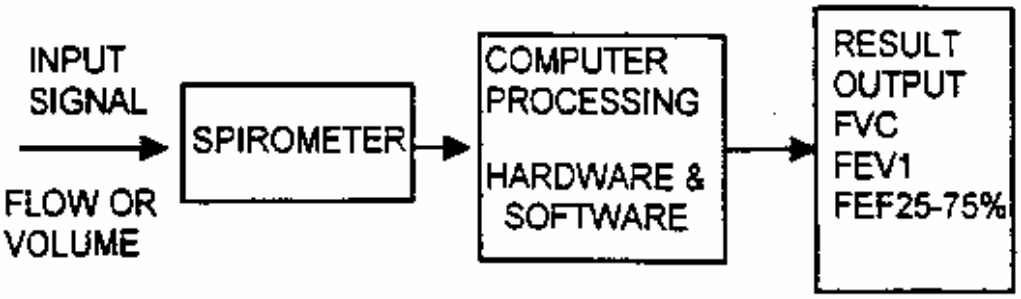



*Figure E1.* Block diagram of spirometer data acquisition.

that for both infants and adults, 95% of the signal energy in the flow–time spirogram is within a bandwidth of zero to 12 Hz. For the volume–time curve, 95% of the signal energy is contained from zero to 6 Hz. Digital sampling theory requires that samples be taken at least twice the rate of the highest frequency contained in the signal (81). Thus for volume–time spirograms, a 12-Hz sampling rate should be adequate. However, most volume–time spirograms are sampled at a 100-Hz or greater rate to make measurements easier and more accurate. Computer system developers should be aware that even with 100-Hz sampling, it may be necessary to linearly interpolate between sampling points to determine accurate $FEV_1$, $FEF_{25-75\%}$, and other similar spirometric measures.

Volume sampling techniques with optical and shaft or position encoders of the volume–time signal have been used (80). This approach measures the time interval between uniform volume intervals (for example, 0.010 L). In this case, the resolution of the time interval between measurements during rapid flow becomes a limiting factor. Ostler and associates have recently addressed these issues (80). For example, if a resolution of flow to within ± 5% of reading at 12 L/s for a system with 0.010-L resolution is required, then a clock resolution of at least 40 μs is needed (80).

## References


1. American Thoracic Society. 1979. Standardization of spirometry. *Am. Rev. Respir. Dis.* 119:831–838.
2. American Thoracic Society. 1987. Standardization of spirometry: 1987 update. *Am. Rev. Respir. Dis.* 136:1286–1296.
3. American Thoracic Society. 1991. Lung function testing: selection of reference values and interpretative strategies. *Am. Rev. Respir. Dis.* 144:1202–1218.
4. Quanjer, P. H., G. J. Tammeling, J. E. Cotes, R. Pedersen, R. Peslin, and J. C. Yernault. 1993. Lung volumes and forced ventilatory flows: report of working party, standardization of lung function tests, European Community for Steel and Coal – official statement of the European Respiratory Society. *Eur. Respir. J.* 6(Suppl. 16):5–40.
5. National Asthma Education Program. October 1992. Expert panel report on diagnosis and management of asthma. U.S. Government Printing Office, Washington, DC. NIH Publication No. 92-2113A.
6. U.S. Department of Health and Human Services. June 1992. International consensus report on the diagnosis and treatment of asthma. U.S. Government Printing Office, Washington, DC. DHHS Publication No. 92-3091.
7. 1993. Guidelines on the management of asthma: statement by the British Thoracic Society, the British Paediatric Association, the Research Unit of the Royal College of Physicians of London, the King's Fund Centre, the National Asthma Campaign, *et al. Thorax* 48(Suppl.): S1–S24.
8. Enright, P. L., L. J. Johnson, J. E. Connett, H. Voelker, and A. S. Buist. 1991. Spirometry in the Lung Health Study: methods and quality control. *Am. Rev. Respir. Dis.* 143:1215–1223.
9. Crapo, R. O. 1994. Pulmonary-function testing. *N. Engl. J. Med.* 331: 25–30.
10. Renzetti, A. D., Jr., E. R. Bleecker, G. R. Epler, R. N. Jones, R. E. Kanner, and L. H. Repsher. 1986. Evaluation of impairment/disability secondary to respiratory disorders. *Am. Rev. Respir. Dis.* 133: 1205–1209.
11. Hankinson, J. L. 1986. Pulmonary function testing in the screening of workers: guidelines for instrumentation, performance, and interpretation. *J. Occup. Med.* 28:1081–1092.
12. 1975. Pulmonary terms and symbols: a report of the ACCP-ATS Joint Committee on Pulmonary Nomenclature. *Chest* 67:583–593.
13. 1994 Topical review: guidelines for the measurement of respiratory function – recommendations of the British Thoracic Society and the Association of Respiratory Technicians and Physiologists. *Respir. Med.* 88:165–194.
14. Smith, A. A., and E. A. Gaensler. 1975. Timing of forced expiratory volume in one second. *Am. Rev. Respir. Dis.* 112:882.
15. Morris, A. H., R. E. Kanner, R. O. Crapo, and R. M. Gardner. July 1984. Clinical Pulmonary Function Testing: A Manual of Uniform Laboratory Procedures, 2nd ed. Intermountain Thoracic Society, Salt Lake City.
16. E. P. Horvath, Jr., editor. 1981. Manual of Spirometry in Occupational Medicine. National Institutes for Occupational Safety and Health, Cincinnati.
17. Hankinson, J. L., and R. M. Gardner. 1982. Standard waveforms for spirometer testing. *Am. Rev. Respir. Dis.* 126:362–364.
18. Hankinson, J. L., and R. O. Crapo. 1995. Flow-time standard waveforms for testing PEF. *Am. J. Respir. Crit. Care Med.* 696–701.
19. Lemen, R. J., C. B. Gerdes, M. J. Wegmann, and K. J. Perrin. 1982. Frequency spectra of flow and volume events for forced vital capacity. *J. Appl. Physiol.* 53:977–984.
20. Peslin, R., A. Jardin, A. Bohadana, and B. Hannhard. 1982. Harmonic content of the flow signal during forced expiration in normal man. *Bull. Eur. Physiopath. Respir.* 18:491–500.
21. Jensen, R. L., R. O. Crapo, R. I. Jackson, and S. L. Barlin. 1991. Evaluation of peak flow meter precision using a computerized pump. *Am. Rev. Respir. Dis.* 143:A347.
22. Shapiro, S. M., J. M. Hendler, R. G. Ogirala, T. K. Aldrich, and M. B. Shapiro. 1992. An evaluation of the accuracy of Assess and miniWright peak flow meters. *Chest* 99:358–362.
23. Hankinson, J. L., M. S. Fillios, K. B. Kinsley, and E. L. Petsonk. 1993. Comparison of miniWright and spirometer measurements of peak flow. *Am. Rev. Respir. Dis.* 197:A115.
24. Glindmeyer, H. W., R. N. Jones, H. W. Barkman, and H. Weill. 1987. Spirometry: quantitative test criteria and test acceptability. *Am. Rev. Respir. Dis.* 136:449–452.
25. Brown, L. K., A. Miller, M. Pilipski, and T. S. Lau. 1995. Forced mid-expiratory time: reference values and the effect of smoking. *Lung* (In press)
26. Section of pulmonary function specifications. *Federal Register.* February 12, 1973; 38:4265.
27. Hansen, L. M., O. F. Pedersen, S. Lyager, and N. Naerra. 1983. Differences in vital capacity due to the methods employed (in Danish). *Ugeskr. Laeger* 145:2752–2756.
28. Krowka, M. J., P. L. Enright, J. R. Rodarte, and R. E. Hyatt. 1987. Effect of effort on measurement of forced expiratory volume in one second. *Am. Rev. Respir. Dis.* 136:829–833.
29. Morgan, K. C. 1975. The assessment of ventilatory capacity (committee

recommendations). *Chest* 67:95–97.
30. Gardner, R. M., R. O. Crapo, R. G. Billings, J. W. Shigeoka, and J. L. Hankinson. 1983. Spirometry: what paper speed? *Chest* 84:161–165.
31. Occupational Safety and Health Administration. 1980. Pulmonary function standards for cotton dust: 29 Code of Federal Regulations: 1910. 1043 Cotton Dust, Appendix D: 808–832.
32. Hankinson, J. L., and J. O. Viola. 1983. Dynamic BTPS correction factors for spirometric data. *J. Appl. Physiol.* 44:1354–1360.
33. Hankinson, J. L., R. M. Castellan, K. B. Kinsley, and D. G. Kleinig. 1986. Effects of spirometer temperature on FEV, shift changes. *J. Occup. Med.* 28:1222–1225.
34. Pincock, A. C., and M. R. Miller. 1983. The effect of temperature on recording spirograms. *Am. Rev. Respir. Dis.* 128:894–898.
35. Hankinson, J. L., J. O. Viola, E. L. Petsonk, and T. R. Ebeling. 1994. BTPS correction for ceramic flow sensors. *Chest* 105:1481–1486.
36. Miller, M. R., and A. C. Pincock. 1986. Linearity and temperature control of the Fleisch pneumotachometer. *J. Appl. Physiol.* 60:710–715.
37. Perks, W. H., T. Sopwith, D. Brown, C. H. Jones, and M. Green. 1983. Effects of temperature on vitalograph spirometer readings. *Thorax* 38:592–594.
38. Cole, P. 1954. Recordings of respiratory air temperature. *J. Laryngol.* 68:295–307.
39. Madan, I., P. Bright, and M. R. Miller. 1993. Expired air temperature at the mouth during a maximal forced expiratory manoevre. *Eur. Respir. J.* 6:1556–1562.
40. Johnson, L. R., P. L. Enright, H. T. Voelker, and D. P. Tashkin. 1994. Volume spirometers need automated internal temperature sensors. *Am. J. Respir. Crit. Care Med.* 150:1575–1580.
41. Association for the Advancement of Medical Instrumentation. October 1980. Standard for Spirometers (draft). AAMI, Arlington, Virginia.
42. Nelson, S. B., R. M. Gardner, R. O. Crapo, and R. L. Jensen. 1990. Performance evaluation of contemporary spirometers. *Chest* 97:288–297.
43. Gardner, R. M., J. L. Hankinson, and B. J. West. 1986. Evaluating commercially available spirometers. *Am. Rev. Respir. Dis.* 134:626–627.
44. Gardner, R. M., J. L. Clausen, R. O. Crapo, G. R. Epler, J. L. Hankinson, R. L. Johnson, Jr., and A. L. Plummer. 1986. Quality assurance in pulmonary function laboratories. *Am. Rev. Respir. Dis.* 134:626–627.
45. Tablan, O. C., W. W. Williams, and W. J. Martone. 1985. Infection control in pulmonary function laboratories. *Infect. Control* 6:442–444.
46. Kirk, Y. L., K. Kenday, H. A. Ashworth, and P. R. Hunter. 1992. Laboratory evaluation of a filter for the control of cross-infection during pulmonary function testing. *J. Hosp. Infect.* 20:193–198.
47. Denison, D. M., D. S. Cramer, and P. J. V. Hanson. 1989. Lung function testing and AIDS. *Respir. Med.* 83:133–138.
48. Rutala, D. R., W. A. Rutala, D. J. Weber, and C. A. Thomann. 1991. Infection risks associated with spirometry. *Infect. Control Hosp. Epidemiol.* 12:89–92.
49. Leeming, J. P., A. H. Kendrick, D. Pryce-Roberts, D. Smith, and E. C. Smith. 1993. Use of filters for the control of cross-infection during pulmonary function testing. *J. Hosp. Infect.* 23:245–246.
50. Hazaleus, R. E., J. Cole, and M. Berdischewsk. 1981. Tuberculin skin test conversion from exposure to contaminated pulmonary function testing apparatus. *Respir. Care* 26:53–55.
51. Isles, A., I. Maclusky, M. Corey, R. Gold, C. Prober, P. Fleming, and H. Levison. 1984. *Pseudomonas cepacia* in cystic fibrosis: an emerging problem. *J. Pediatr.* 104:206–210.
52. Burgos, F., C. Martinez, and J. Torres. 1993. *Am. Rev. Respir. Dis.* 147:A400.
53. du Moulin, G. C., K. D. Stottmeier, P. A. Pelletier, A. Y. Tsang, and J. Hedley-White. 1988. Concentration of *Mycobacterium avium* by hospital hot water systems. *J.A.M.A.* 260:1599–1601.
54. von Reyn, C. F., R. D. Waddell, T. Eaton, R. D. Arbeit, J. N. Maslow, T. W. Barber, R. J. Brindle, C. F. Gilks, J. Lumio, J. Lähdevirta, A. Ranki, D. Dawson, and J. D. Falkinham III. 1993. Isolation of *Mycobacterium avium* complex from water in the United States, Finland, Zaire, and Kenya. *J. Clin. Microbiol.* 31:3227–3230.
55. Eichorn, J. H., M. L. Bancroff, H. Lassberg, G. C. du Moulin, and A. J. Saubermann. 1977. Contamination of medical gas and water pipelines in a new hospital building. *Anesthesiology* 46:286–289.
56. Townsend, M. C. 1984. The effects of leaks in spirometers on measurement of pulmonary function. *J. Occup. Med.* 26:835–841.
57. Crapo, R. O., R. M. Gardner, S. L. Berlin, and A. H. Morris. 1986. Automation of pulmonary function equipment: user beware! *Chest* 90:1–2.
58. Gardner, R. M., J. L. Clausen, D. J. Coulon, R. D. Crapo, G. R. Epler, J. L. Hankinson, and R. L. Johnson. 1986. Computer guidelines for pulmonary laboratories. *Am. Rev. Respir. Dis.* 134: 628–629.
59. Gardner, R. M., J. L. Clausen, G. Epler, J. L. Hankinson, S. Permutt, and A. L. Plummer. 1986. Pulmonary function laboratory personnel qualifications. *Am. Rev. Respir. Dis.* 134:623–624.
60. American Thoracic Society. 1978. ATS respiratory care committee position paper: director of pulmonary function laboratory. *ATS News* 4:6.
61. Make, B. 1979. Minimum criteria for training course in spirometric testing in industry. *Bull. Am. Coll. Chest Phys.* 18:24–26.
62. Enright, P. L., and R. D. Hyatt. 1987. Office Spirometry. Lea & Febiger, Philadelphia.
63. Wanger, J. 1992. Pulmonary Function Testing: A Practical Approach. Williams & Wilkins, Baltimore.
64. Paoletti, P., G. Pistelli, P. Fazzi, G. Viegi, F. DiPede, R. Predilletto, L. Carrozzi, R. Polato, M. Sastta, R. Zambon, T. Sapigni, M. D. Lebowitz, and C. Giuntini. 1986. Reference values for vital capacity and flow-volume curves from a general population study. *Bull. Eur. Physiopathol. Respir.* 22:451–459.
65. D'Angelo, E., E. Prandi, and J. Milic-Emili. 1993. Dependence of maximal flow-volume curves on time course of preceding inspiration. *J. Appl. Physiol.* 75:1155–1159.
66. Hankinson, J. L. 1993. Instrumentation for spirometry. *In* E. A. Eisen, editor. Occupational Medicine: State of the Art Reviews, Vol. 8. Hanley and Belfus, Philadelphia. 397–407.
67. Eisen, E. A., J. M. Robins, J. A. Greaves, and D. H. Wegman. 1984. Selection effects of repeatability criteria applied to lung spirometry. *Am. J. Epidemiol.* 120:734.
68. Eisen, E. A., L. C. Oliver, D. C. Christiani, J. M. Robins, and D. H. Wegman. 1985. Effects of spirometry standards in two occupational cohorts. *Am. Rev. Respir. Dis.* 132:120.
69. Kellie, S. E., M. D. Attfield, J. L. Hankinson, and R. M. Castellan. 1987. The ATS spirometry variability criteria: associations with morbidity and mortality in an occupational cohort of coal miners. *Am. J. Epidemiol.* 125:437–444.
70. Ferris, B. G., Jr., F. E. Speizer, Y. Bishop, G. Prang, and J. Weener. 1978. Spirometry for an epidemiologic study: deriving optimum summary statistics for each subject. *Bull. Eur. Physiopathol. Respir.* 14:146–166.
71. Kanner, R. E., M. B. Schenker, A. Munoz, and F. E. Speizer. 1983. Spirometry in children: methodology for obtaining optimal results for clinical and epidemiological studies. *Am. Rev. Respir. Dis.* 127:720–724.
72. Liese, W., W. J. Warwick, and G. Cumming. 1974. Water vapour pressure in expired air. *Respiration* 31:252–261.
73. Townsend, M. C. 1984. Spirometric forced expiratory volumes measured in the standing versus the sitting position. *Am. Rev. Respir. Dis.* 103:123–124.
74. Ferris, B. G. 1978. Epidemiology standardization project: recommended standardized procedures for pulmonary function testing. *Am. Rev. Respir. Dis.* 118(part 2):55–88.
75. Townsend, M. C., A. G. DuChene, and R. J. Fallat. 1982. The effects of underrecording forced expirations on spirometric lung function indexes. *Am. Rev. Respir. Dis.* 126:734–737.
76. Pennock, B. E., R. M. Rogers, and D. R. McCaffree. 1981. Changes in measured spirometric indices: what is significant? *Chest* 80:97.
77. Hankinson, J. L., and K. M. Bang. 1991. Acceptability and reproducibility criteria of the American Thoracic Society as observed in a sample of the general population. *Am. Rev. Respir. Dis.* 143:516–521.
78. National Institute for Occupational Safety and Health. August 1991. Draft Spirometry Training Guide. National Institute for Occupational Safety and Health and the Universities Occupational Safety and Health Educational Resource Center, Continuing Education and Outreach Program, University of Medicine and Dentistry of New Jersey.
79. Nelson, S. B. 1987. Commercially Available Spirometers: Performance Evaluation. University of Utah. Thesis.
80. Ostler, D. V., R. M. Gardner, and R. O. Crapo. 1984. A computer system for analysis and transmission of spirometry waveforms using volume sampling. *Comput. Biomed. Res.* 17:229–240.
81. Jerri, A. J. 1977. The Shannon sampling theorem: its various extension and applications—a tutorial review. *Proc. IEEE* 65:1565–1596.

## APÉNDICE G. LISTA DE VERIFICACIÓN DEL PROCEDIMIENTO DE LA ESPIROMETRÍA

La lista que se muestra abajo es un resumen de la unidad 4: Técnica espirométrica. Refiérase a dicha unidad para mayor información.

1. **Prepare el equipo.**
   a. Configure y limpie el equipo.
      1. Verifique si hay papel.
      2. Fije la velocidad del papel si es necesario.
      3. Verifique la posición de las plumillas.
      4. Coloque el tubo principal si el caso lo amerita.

   b. Verifique la calibración del equipo.

   c. Haga una prueba de cómo corre el papel.

   d. Verifique que tenga todo lo necesario en cantidad adecuada.

   e. Escriba el valor de la temperatura ambiente (y de la presión barométrica, si esto es necesario).

   f. Verifique que las escalas de medición de peso y talla estén funcionando adecuadamente.

2. **Prepare a la persona.**
   a. Explique el motivo de la espirometría: “Me gustaría ver qué tan fuerte y rápido puede usted sacar aire”.

   b. Determine si la espirometría debe ser pospuesta usando los criterios de su institución, o los aspectos explorados en la siguiente lista de preguntas:
      1. ¿Cómo se siente hoy?
      2. ¿Ha usted fumado cigarrillos, puro, o pipa, durante la última hora?
      3. ¿Ha usado cualquier medicamento inhalado, como un broncodilatador en aerosol, durante la última hora?
      4. ¿Qué ha comido en la última hora?
      5. ¿Ha tenido usted alguna infección respiratoria como catarro, gripe, neumonía o bronquitis, en las últimas tres semanas?
      6. ¿Ha tenido algún problema o infección en los oídos, durante las últimas tres semanas?
      7. ¿Lo han operado recientemente?
      8. ¿Si usted usa prótesis dental (dentadura postiza), se puede quitar ésta?

3. **Coloque a la persona en posición.**
   a. Verifique la posición previamente empleada (sentado o parado) y use la misma posición de ser posible. Registre en la hoja de la persona la posición que se va a usar.

b. Recomiéndele a la persona aflojarse cualquier prenda de vestir entallada e indíquele que eleve el mentón y extienda ligeramente el cuello.

c. Enséñele a la persona cómo se coloca el clip nasal y verifique que lo haga de la manera correcta.

4. **Realice la prueba.**
   a. Explíquele a la persona cómo colocar la boquilla (en la boca, sin que haya obstrucción por la lengua o dientes, y que cierre los labios alrededor, herméticamente).

   b. Explíquele y póngale el ejemplo de cómo se realiza la maniobra espiratoria forzada: "Cuando esté listo, tome todo el aire posible, coloque la boquilla en su boca y sin titubeos, sople y expulse el aire lo más fuerte, rápido y completo que pueda, sin parar, y hasta que yo le diga".

5. **Verifique los últimos detalles de la preparación.**
   a. Coloque la plumilla para imprimir en la posición apropiada sobre el papel.

   b. Comience a correr el papel al menos un segundo antes de que la persona sople en la boquilla.

6. **Asesore a la persona.**
   a. Anime a la persona de manera activa mientras esté realizando la maniobra (¡Sople, sople, sople!).

   b. Siga animándola hasta que se alcance una meseta—ATS-1994. (Polvo de algodón, *Cotton Dust*): cambio de volumen en 0.5 segundos, menor a 25 ml.

7. **Verifique la aceptabilidad de cada trazo antes de continuar la prueba.**
   a. Los espirogramas aceptables no deben tener:
      1. Titubeos o falsos inicios.
      2. Tos
      3. Esfuerzo variable.
      4. Cierre de glotis.
      5. Finalización temprana antes de alcanzar una meseta.
      6. Fugas.
      7. Errores en la línea basal.

   b. Revise con el sujeto, si es necesario, las causas de los errores.

   c. Continúe haciendo maniobras hasta que haya obtenido tres trazos aceptables, permitiéndole al sujeto que descanse entre cada una de las pruebas y no supere un máximo de 8 pruebas.

8. **Verifique el exceso de variabilidad de las dos CVF y los dos $VEF_1$ mayores. (Véase la unidad 5: Cálculos espirométricos básicos** y el **apéndice H: Esquema general de los cálculos espirométricos**, para mayor información). Haga que la persona realice todas las maniobras espiratorias forzadas adicionales que sean necesarias y que no se las prohíba una afección médica
9. **Registre la información en la hoja del paciente**. Anote, como mínimo, la siguiente información**:**
    a. Nombre,
    b. edad,
    c. sexo,
    d. talla,
    e. raza,
    f. posición de pruebas anteriores,
    g. valores esperados usados previamente,
    h. día y hora de la prueba,
    i. temperatura ambiente,
    j. presión barométrica (si es posible),
    k. resultados de la prueba,
    l. identificación del técnico.

## APÉNDICE H. ESQUEMA GENERAL DE LOS CÁLCULOS ESPIROMÉTRICOS

La lista abajo mostrada es un resumen de la unidad 5: Cálculos espirométricos básicos. Refiérase a dicha unidad para más información.

1. **Use solamente trazos que cumplan los criterios de aceptabilidad** (Véase **apéndice G. Lista de verificación del procedimiento de la espirometría** y la **unidad 4: Técnica espirométrica**, para las instrucciones).

2. **Capacidad vital forzada (CVF)**
   a. Mida la CVF a partir de la línea basal, en todos los trazos aceptables.
   b. Determine si hay un exceso de variabilidad, esto es, que la diferencia entre las dos CVF mayores sea menor de 200 ml (**Opcional**: de acuerdo a la ATS-1987 (Sociedad Americana Torácica), para las CVFs que tienen un valor de 2 litros o menos, úsese 100 ml; para CVF mayores de 2 litros, úsese 5%; Polvo de algodón - CVF menor de 1 litro, use 100 ml ó 10% para aquellas CVF mayores de un litro).
   c. Use la mayor CVF obtenida a partir de todos los trazos aceptables.
   d. Convierta a BTPS si se necesita (véase más abajo).

3. **Volumen espiratorio forzado en un segundo ($VEF_1$)**
   a. Mida el $VEF_1$ en los trazos aceptables.
   b. Encuentre los puntos t = 0 y t = 1 segundo.
   c. Haga una extrapolación retrógrada si el t = 0 no resulta obvio. La ATS recomienda hacerla en todos los cálculos del $VEF_1$. Trace una línea recta a lo largo de la porción más empinada de la curva y extienda la línea hasta interceptar la línea basal.
   d. Calcule el volumen en t = 1 segundo.
   e. Determine si hay un volumen extrapolado excesivo a nivel de t = 0. No se acepta un volumen extrapolado si es mayor del 5% de la CVF, para aquellas CVF que exceden de 3 litros - use 150 ml para aquellas CVF menores de 3 litros.
   f. Determine si hay un exceso de variabilidad. La diferencia entre los dos mayores $VEF_1$ deberá ser menor de 200 ml. Opcional: de acuerdo a la ATS-1987, use 100 ml para $VEF_1$ de 2 litros o menores; use 5% para aquéllos que sean mayores de 2 litros; Polvo de algodón - para un $VEF_1$ menor de 1 litro, use 100 ml ó 10% para $VEF_1$ mayores de 1 litro.
   g. Convierta a BTPS si es necesario (véase más abajo).

4. **El $VEF_1$ como porcentaje de la CVF**.
   a. Use la CVF y el $VEF_1$ mayores aceptables, aún cuando no provengan del mismo trazo.
   b. $VEF_1/CVF \times 100 = VEF_1/CVF\%$
   c. No convierta a BTPS, ya que el resultado es una proporción o cociente.

5. **Indice de flujo espiratorio forzado medio ($FEF_{25-75\%}$)**
   a. Use la "mejor curva" (trazo aceptable con la suma mayor de la CVF y del $VEF_1$).
   b. Calcule el 25% y el 75% de la CVF y marque dichos puntos en el trazo.
   c. Trace una línea recta a través de los puntos del 25% y del 75%.
   d. Localice dos líneas verticales de tiempo adyacentes que estén separadas por un segundo.

e. Determine el volumen para cada una de esas dos líneas verticales.
f. Determine la diferencia entre estos dos volúmenes.
g. Convierta a BTPS (véase más abajo).
h. El resultado es en litros por segundo.

6. **Conversión a BTPS**
   a. Convierta la temperatura ambiente a grados centígrados, si fuera necesario.
   b. Encuentre la temperatura ambiente y el factor de conversión correspondiente en el **nomograma de conversión a BTPS**.
   c. Multiplique la CVF, el $VEF_1$ y el $FEF_{25-75\%}$ por el factor de conversión, para obtener el volumen correcto en BTPS.

7. **Valores normales esperados**
   a. Sea consistente con la tabla de valores esperados que vaya a usar.
   b. Localice los valores esperados para el $VEF_1$ y la CVF, utilizando como indicadores la edad de la persona, su sexo, su talla y su raza.
   c. En algunas personas de raza blanca, multiplique los valores esperados por 0.85 (el factor de conversión racial).
   d. Calcule el porcentaje del valor esperado:
   CVF observada/CVF esperada x 100 = CVF% del valor normal. (Haga lo mismo para el $VEF_1$ y el $FEF_{25-75\%}$).

8. **Cambios en espirogramas de seguimiento**
   a. Calcúlelo como diferencia absoluta (vgr., CVF en el $tiempo_1$ – CVF en el $tiempo_2$ = + ó – litros de diferencia).
   b. Puede también calcularlo como cambio porcentual con relación al valor previo (Vgr.,

$$\frac{\text{CVF en el tiempo}_1 - \text{CVF en el tiempo}_2}{\text{CVF en el tiempo}_1} \times 100 + \text{ó } - \%$$

   c. Use los mismos pasos para calcular el cambio porcentual en el $VEF_1$ y en el $FEF_{25-75}$%.

## APÉNDICE I: CÁLCULOS MATEMÁTICOS BÁSICOS

**SUMA**: a + b = c

Ejemplo: 3 + 2 = 5

**RESTA**: c – b = a

Ejemplo: 5 - 2 = 3

**MULTIPLICACIÓN**: a x b = d

Ejemplo: 3 x 2 = 6

**DIVISIÓN**: $\frac{d}{b} = a$ ó d/b = a

Ejemplo: 3 x 2 = 6

**FRACCIÓN**: $a = \frac{\text{numerador}}{\text{denominador}}$ ó a/b

Ejemplo: 3/5

**DECIMALES**:

1. Los números a la izquierda del punto decimal son números enteros.
   Ejemplo 3.

2. El primer número a la derecha del punto decimal representa las décimas.

   Ejemplo .2 = 2/10

3. El segundo número a la derecha del punto decimal representa las centésimas.

   Ejemplo .05 = 5/100
   .67 = 67/100

4. El tercer número a la derecha del punto decimal representa las milésimas, etc.

   Ejemplo: .009 = 9/1000
   .872 = 872/1000

**CONVERSIÓN DE FRACCIONES A DECIMALES:**

a/b = .c

Ejemplo: 4/5 = .8

**CONVERSIÓN DE DECIMALES A FRACCIÓN:**

a.bc = abc/100
Ejemplo: 3.75 = 375/100
= 3 ¾

**CONVERTIR DECIMALES A PORCENTAJES:**

.a = a x 100 = a %
Ejemplo: .8 = 80%
(.8 x 100 = 80%)

**CONVERTIR PORCENTAJES A DECIMALES:**

a % = a %/100 = .a
Ejemplo: 80% = .8
(80/100 = .8)

## APÉNDICE J. CONVERSIONES MÉTRICAS

El sistema métrico sigue una secuencia ordenada para los prefijos que indican la unidad de medición:

| Prefijo | Unidades en | Ejemplo |
|---|---|---|
| Kilo- | miles | 1 kilolitro = 1,000 litros |
| Hecto- | cientos | 1 hectolitro = 100 litros |
| Deca- | decenas | 1 decalitro = 10 litros |
| No prefijo | unidades | |
| Deci- | décimas | 1 decilitro = 0.1 litro |
| Centi- | centésimas | 1 centilitro = 0.01 litro |
| Mili | milésima | 1 mililitro = 0.001 litro |

Se presentan las unidades de medición más frecuentes en el sistema métrico y su equivalente en unidades utilizadas en los Estados Unidos:

| Unidades Métricas | Abreviación | Equivalente aproximado de unidades usadas en USA |
|---|---|---|
| Distancia | | |
| Kilómetro | Km. | 0.62 millas |
| Metro | m | 39.37 pulgadas |
| Centímetro | cm. | 0.39 pulgadas |
| Milímetro | Mm. | 0.04 pulgadas |
| Capacidad (líquidos) | | |
| Litro | l | 1.057 cuartos de galón |
| Capacidad (material seco) | | |
| Litro | l | 0.908 cuartos de galón |
| Peso | | |
| kilogramo | Kg. | 2.2046 libras |
| gramo | g | 0.035 onzas |
| miligramo | MG | 0.015 pizcas (grains) |

| Unidades Norteamericanas | Equivalente métrico |
|---|---|
| **Distancia** | |
| 1 milla | 1.609 Km. |
| 1 yarda | 0.914 m |
| 1 pie | 30.480 cm. |
| 1 pulgada | 2.540 cm. |
| **Capacidad (líquidos)** | |
| 1 galón | 3.7851 l |
| 1 cuarto de galón | 0.946 l |
| 1 pinta | 0.473 l |
| 1 onza líquida | 29.573 ml |
| **Capacidad (material seco)** | |
| 1 medida de áridos (bushel) | 35.238 l |
| 1 cuarto de galón | 1.101 l |
| 1 pinta | 0.550 l |
| **Peso** | |
| 1 libra | 0.453 Kg. |
| 1 onza | 28.349 g |

## APÉNDICE K. OTROS FACTORES A TOMAR EN CUENTA AL CALCULAR BTPS

1. Presión ambiental. Algunos médicos prefieren usar los factores de conversión BTPS que corrijan la presión del ambiental así como la temperatura. Las fluctuaciones en la presión ambiental produce cambios de menos del 1% en las pruebas espirométricas habituales. Sin embargo, a grandes alturas o durante estudios de investigación, se deberá considerar el uso de factores de conversión para la presión ambiental.

   Para obtener la presión ambiental, use un barómetro o infórmese con el servicio meteorológico sobre la presión barométrica. Convierta las pulgadas de mercurio en milímetros de mercurio, si es necesario (1 mm = 0.04 pulgadas).

   Para tomar en cuenta la presión ambiental dentro de los cálculos de BTPS, use la siguiente fórmula:

$$V_{BTPS} = \frac{V_{ATPS} \times [310 \times (P_B - PH_20)]}{[(P_B - 47) \times (273 + T)]}$$

Pb = Presión barométrica, mmHg.

$PH_20$ = Presión del vapor de agua a la temperatura del espirómetro

T = Temperatura en grados centígrados

47 = Presión del vapor de agua a temperatura de 37°C

310 = Temperatura absoluta del cuerpo (en grados Kelvin)

2. Factor del instrumento o de campana: El factor instrumental o factor de campana se menciona ocasionalmente junto con BTPS. En ciertos espirómetros de sello de agua, se refiere a una constante que indica el volumen de desplazamiento por milímitero, del movimiento vertical de la campana. Si usted usa este tipo de espirómetro, se necesita este factor de corrección. Consulte las instrucciones en el manual del fabricante.

3. Instrumentos con gráficas en unidades BTPS: Algunos instrumentos cuentan con un papel graficado que asume que el espirómetro se encuentra a 25°C y a una presión barométrica de 760 mm de mercurio (presión barométrica a nivel del mar). Si la temperatura ambiente no es de 25°C, la información recolectada por este tipo de instrumentos debe ser corregida con el factor BTPS apropiado. Consulte las instrucciones en el manual del fabricante.

**APÉNDICE L. TABLAS DE VALORES DE REFERENCIA DEL NHANES III** (Hankinson et al.-1999)

Tabla 1. **Varones caucásicos**

| Talla | Edad | CVF | | VEF1 | | VEF1/CVF% | |
|---|---|---|---|---|---|---|---|
| | | Pred | LLN | Pred | LLN | Pred | LLN |
| 170cm | 20 | 5.10 | 4.25 | 4.30 | 3.58 | 83.9% | 74.3% |
| | 30 | 4.97 | 4.12 | 4.08 | 3.36 | 81.9% | 72.2% |
| | 40 | 4.79 | 3.94 | 3.83 | 3.11 | 79.8% | 70.1% |
| | 50 | 4.55 | 3.70 | 3.55 | 2.83 | 77.7% | 68.1% |
| | 60 | 4.26 | 3.41 | 3.23 | 2.51 | 75.7% | 66.0% |
| 180cm | 20 | 5.75 | 4.80 | 4.79 | 3.98 | 83.9% | 74.3% |
| | 30 | 5.62 | 4.67 | 4.58 | 3.77 | 81.9% | 72.2% |
| | 40 | 5.44 | 4.49 | 4.32 | 3.52 | 79.8% | 70.1% |
| | 50 | 5.21 | 4.25 | 4.04 | 3.23 | 77.7% | 68.1% |
| | 60 | 4.92 | 3.96 | 3.72 | 2.91 | 75.7% | 66.0% |
| 190cm | 20 | 6.44 | 5.38 | 5.31 | 4.41 | 83.9% | 74.3% |
| | 30 | 6.31 | 5.25 | 5.10 | 4.20 | 81.9% | 72.2% |
| | 40 | 6.13 | 5.07 | 4.85 | 3.95 | 79.8% | 70.1% |
| | 50 | 5.90 | 4.83 | 4.56 | 3.66 | 77.7% | 68.1% |
| | 60 | 5.61 | 4.54 | 4.24 | 3.34 | 75.7% | 66.0% |

**Tabla 2. Varones afro-americanos**

| Talla | Edad | CVF | | VEF1 | | VEF1/CVF% | |
|---|---|---|---|---|---|---|---|
| | | Pred | LLN | Pred | LLN | Pred | LLN |
| 170cm | 20 | 4.29 | 3.43 | 3.69 | 2.93 | 85.6% | 75.2% |
| | 30 | 4.11 | 3.25 | 3.46 | 2.70 | 83.8% | 73.3% |
| | 40 | 3.93 | 3.07 | 3.23 | 2.47 | 81.9% | 71.5% |
| | 50 | 3.75 | 2.89 | 3.00 | 2.24 | 80.1% | 69.7% |
| | 60 | 3.57 | 2.71 | 2.77 | 2.01 | 78.3% | 67.9% |
| 180cm | 20 | 4.88 | 3.91 | 4.15 | 3.30 | 85.6% | 75.2% |
| | 30 | 4.69 | 3.73 | 3.92 | 3.07 | 83.8% | 73.3% |
| | 40 | 4.51 | 3.55 | 3.69 | 2.84 | 81.9% | 71.5% |
| | 50 | 4.33 | 3.37 | 3.46 | 2.61 | 80.1% | 69.7% |
| | 60 | 4.15 | 3.18 | 3.23 | 2.38 | 78.3% | 67.9% |
| 190cm | 20 | 5.49 | 4.42 | 4.64 | 3.69 | 85.6% | 75.2% |
| | 30 | 5.31 | 4.24 | 4.41 | 3.46 | 83.8% | 73.3% |
| | 40 | 5.13 | 4.05 | 4.18 | 3.23 | 81.9% | 71.5% |
| | 50 | 4.95 | 3.87 | 3.95 | 3.00 | 80.1% | 69.7% |
| | 60 | 4.76 | 3.69 | 3.72 | 2.77 | 78.3% | 67.9% |

**Tabla 3. Varones méxico-americanos**

| Talla | Edad | CVF | | VEF1 | | VEF1/CVF% | |
|---|---|---|---|---|---|---|---|
| | | Pred | LLN | Pred | LLN | Pred | LLN |
| 170cm | 20 | 5.14 | 4.31 | 4.41 | 3.71 | 85.7% | 76.6% |
| | 30 | 4.96 | 4.13 | 4.12 | 3.41 | 83.5% | 74.4% |
| | 40 | 4.74 | 3.91 | 3.82 | 3.12 | 81.3% | 72.2% |
| | 50 | 4.49 | 3.66 | 3.53 | 2.83 | 79.1% | 70.0% |
| | 60 | 4.20 | 3.37 | 3.24 | 2.54 | 76.9% | 67.8% |
| 180cm | 20 | 5.76 | 4.83 | 4.94 | 4.15 | 85.7% | 76.6% |
| | 30 | 5.58 | 4.65 | 4.65 | 3.86 | 83.5% | 74.4% |
| | 40 | 5.36 | 4.43 | 4.35 | 3.56 | 81.3% | 72.2% |
| | 50 | 5.11 | 4.18 | 4.06 | 3.27 | 79.1% | 70.0% |
| | 60 | 4.82 | 3.89 | 3.77 | 2.98 | 76.9% | 67.8% |
| 190cm | 20 | 6.42 | 5.38 | 5.50 | 4.62 | 85.7% | 76.6% |
| | 30 | 6.24 | 5.20 | 5.20 | 4.33 | 83.5% | 74.4% |
| | 40 | 6.02 | 4.99 | 4.91 | 4.03 | 81.3% | 72.2% |
| | 50 | 5.77 | 4.73 | 4.62 | 3.74 | 79.1% | 70.0% |
| | 60 | 5.48 | 4.44 | 4.33 | 3.45 | 76.9% | 67.8% |

**Tabla 4. Mujeres caucásicas**

| Talla | Edad | CVF | | VEF1 | | VEF1/CVF% | |
|---|---|---|---|---|---|---|---|
| | | Pred | LLN | Pred | LLN | Pred | LLN |
| 150cm | 20 | 3.20 | 2.61 | 2.87 | 2.37 | 86.6% | 76.8% |
| | 30 | 3.19 | 2.61 | 2.74 | 2.24 | 84.4% | 74.6% |
| | 40 | 3.11 | 2.53 | 2.57 | 2.07 | 82.3% | 72.5% |
| | 50 | 2.96 | 2.37 | 2.35 | 1.86 | 80.2% | 70.4% |
| | 60 | 2.72 | 2.14 | 2.10 | 1.61 | 78.1% | 68.3% |
| 160cm | 20 | 3.66 | 2.99 | 3.23 | 2.66 | 86.6% | 76.8% |
| | 30 | 3.65 | 2.98 | 3.09 | 2.53 | 84.4% | 74.6% |
| | 40 | 3.57 | 2.90 | 2.92 | 2.35 | 82.3% | 72.5% |
| | 50 | 3.42 | 2.75 | 2.71 | 2.14 | 80.2% | 70.4% |
| | 60 | 3.18 | 2.51 | 2.46 | 1.89 | 78.1% | 68.3% |
| 170cm | 20 | 4.15 | 3.39 | 3.61 | 2.97 | 86.6% | 76.8% |
| | 30 | 4.14 | 3.39 | 3.47 | 2.83 | 84.4% | 74.6% |
| | 40 | 4.06 | 3.31 | 3.30 | 2.66 | 82.3% | 72.5% |
| | 50 | 3.91 | 3.15 | 3.09 | 2.45 | 80.2% | 70.4% |
| | 60 | 3.67 | 2.92 | 2.84 | 2.20 | 78.1% | 68.3% |

**Tabla 5. Mujeres afro-americanas**

| Talla | Edad | CVF | | VEF1 | | VEF1/CVF% | |
|---|---|---|---|---|---|---|---|
| | | Pred | LLN | Pred | LLN | Pred | LLN |
| 150cm | 20 | 2.76 | 2.15 | 2.49 | 1.97 | 87.6% | 76.9% |
| | 30 | 2.68 | 2.07 | 2.31 | 1.79 | 85.5% | 74.9% |
| | 40 | 2.55 | 1.94 | 2.12 | 1.60 | 83.5% | 72.8% |
| | 50 | 2.36 | 1.76 | 1.90 | 1.38 | 81.5% | 70.8% |
| | 60 | 2.13 | 1.52 | 1.66 | 1.15 | 79.4% | 68.7% |
| 160cm | 20 | 3.18 | 2.49 | 2.82 | 2.24 | 87.6% | 76.9% |
| | 30 | 3.10 | 2.41 | 2.65 | 2.06 | 85.5% | 74.9% |
| | 40 | 2.97 | 2.28 | 2.45 | 1.86 | 83.5% | 72.8% |
| | 50 | 2.78 | 2.10 | 2.24 | 1.65 | 81.5% | 70.8% |
| | 60 | 2.55 | 1.86 | 2.00 | 1.41 | 79.4% | 68.7% |
| 170cm | 20 | 3.63 | 2.85 | 3.18 | 2.52 | 87.6% | 76.9% |
| | 30 | 3.55 | 2.77 | 3.01 | 2.34 | 85.5% | 74.9% |
| | 40 | 3.42 | 2.64 | 2.81 | 2.14 | 83.5% | 72.8% |
| | 50 | 3.23 | 2.46 | 2.59 | 1.93 | 81.5% | 70.8% |
| | 60 | 3.00 | 2.22 | 2.36 | 1.69 | 79.4% | 68.7% |

**Tabla 6. Mujeres méxico-americanas**

| Talla | Edad | CVF | | VEF1 | | VEF1/CVF% | |
|---|---|---|---|---|---|---|---|
| | | Pred | LLN | Pred | LLN | Pred | LLN |
| 150cm | 20 | 3.29 | 2.69 | 2.91 | 2.40 | 87.9% | 78.5% |
| | 30 | 3.21 | 2.60 | 2.73 | 2.22 | 85.6% | 76.3% |
| | 40 | 3.07 | 2.47 | 2.54 | 2.03 | 83.4% | 74.1% |
| | 50 | 2.89 | 2.29 | 2.32 | 1.81 | 81.1% | 71.8% |
| | 60 | 2.66 | 2.06 | 2.07 | 1.56 | 78.9% | 69.6% |
| 160cm | 20 | 3.73 | 3.05 | 3.28 | 2.70 | 87.9% | 78.5% |
| | 30 | 3.65 | 2.96 | 3.11 | 2.53 | 85.6% | 76.3% |
| | 40 | 3.51 | 2.83 | 2.91 | 2.33 | 83.4% | 74.1% |
| | 50 | 3.33 | 2.64 | 2.69 | 2.11 | 81.1% | 71.8% |
| | 60 | 3.10 | 2.41 | 2.45 | 1.87 | 78.9% | 69.6% |
| 170cm | 20 | 4.20 | 3.43 | 3.68 | 3.03 | 87.9% | 78.5% |
| | 30 | 4.12 | 3.34 | 3.51 | 2.86 | 85.6% | 76.3% |
| | 40 | 3.98 | 3.21 | 3.31 | 2.66 | 83.4% | 74.1% |
| | 50 | 3.80 | 3.03 | 3.09 | 2.44 | 81.1% | 71.8% |
| | 60 | 3.57 | 2.80 | 2.85 | 2.20 | 78.9% | 69.6% |

## APÉNDICE M. TABLAS DE PATRONES OBSTRUCTIVOS Y RESTRICTIVOS

La información que se presenta abajo, representa un método para interpretar los resultados espirométricos. Este método no es el único y existen otros que se pueden usar.

### ENFERMEDADES PULMONARES Y RESULTADOS ESPIROMÉTRICOS

| **Interpretación** | **$VEF_1$/CVF%** | **CVF** | **$VEF_1$** |
|---|---|---|---|
| Persona normal | Normal | Normal | Normal |
| Obstrucción de las vías aéreas | Bajo | Normal o baja | Bajo |
| Restricción pulmonar | Normal | Baja | Bajo |
| Combinación de obstrucción/restricción | Bajo | Baja | Bajo |

Adaptado de: Chronic Obstructive Pulmonary Disease, 5th. Edition [1977]. American Lung Association (46).

### LINEAMIENTOS PARA EVALUAR EL GRADO DE COMPROMISO VENTILATORIO

| **Interpretación** | **Patrón obstructivo** | **Patrón restrictivo** |
|---|---|---|
| Normal | $VEF_1/CVF\% \geq LLN$ | $CVF \geq LLN$ |
| Limítrofe | $VEF_1/CVF < LLL$ & $VFV_1 \geq LLN$ | |
| Leve | $VEF_1 < 100$ & $\geq 70\%$ Pred | $CVF < LLN$ & $\geq 70\%$ Pred |
| Moderado | $VEF_1 < 70$ & $\geq 50\%$ Pred | $CVF < 70$ & $\geq 50\%$ Pred |
| Severo | $VEF_1 < 50\%$ Pred | $CVF < 50\%$ Pred |

Adaptado de la Sociedad Torácica Americana: Lung function testing: Selection of reference values and interpretative strategies [1991]. American Review of Respiratory Diseases 144: 1202-1218 (30).