



Health Informatics—Device Interoperability

**Part 10429: Personal Health Device
Communication—Device
Specialization—Spirometry**

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE 11073™ Standards Committee

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Health Informatics—Device Interoperability

Part 10429: Personal Health Device Communication—Device Specialization—Spirometry

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

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IEEE SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, in this standard, a normative definition of the communication between personal telehealth spirometry devices and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes) is established in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors are specified in telehealth environments restricting optionality in base frameworks in favor of interoperability. A common core of communication functionality for personal telehealth spirometry is defined in this standard.

Keywords: device interoperability, IEEE 11073-10429™, personal health devices communication, spirometry

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Introduction

This introduction is not part of IEEE Std 11073-10429-2022, Health Informatics—Device Interoperability—Part 10429: Personal Health Device Communication—Device Specialization—Spirometry.

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal telehealth spirometry devices and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth spirometry.

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Health Informatics—Device Interoperability

Part 10429: Personal Health Device Communication—Device Specialization—Spirometry

1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal telehealth spirometry devices and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth spirometry.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes).

1.3 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).^{6,7}

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

⁶ The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.

⁷ The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

1.4 Context

See IEEE Std 11073-20601™ for an overview of the environment within which this standard is written.⁸

This standard defines the device specialization for the spirometer, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601.⁹ The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601.

The object classes and attributes in this standard are referenced using nomenclature codes. Each code is identified by a reference identifier (RefID). By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. This standard leverages the existing nomenclature codes in ISO/IEEE 11073-10101™. Meanwhile, it defines specialized nomenclature codes that will be collected in future revisions of ISO/IEEE 11073-10101. Between this standard, ISO/IEEE 11073-10101, IEEE Std 11073-20601, and other IEEE Std 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective action will be published as corrigenda.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601, where zz can be any number from 01 to 99, inclusive.¹⁰

2. Normative references

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IEEE Std 11073-20601™, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.^{11,12}

ISO/IEEE 11073-10101, Health informatics – Device interoperability – Part 10101: Point-of-care medical device communication – Nomenclature.¹³

See Annex A for all informative material referenced by this standard.

⁸ Information on normative references can be found in Clause 2.

⁹ The numbers in brackets correspond to the numbers of the bibliography in Annex A.

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3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.¹⁴

agent: A node that collects and transmits personal health data to an associated manager.

class: In object-oriented modeling, a class describes the attributes, methods, and events that objects instantiated from the class utilize.

compute engine: *See:* **manager**.

device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

forced expiration start time: The time zero for a forced expiratory maneuver, determined from the volume-time graph using the back extrapolation method.

forced expiratory volume in 1 s: The expiratory volume of a subject under forced conditions at 1 s, measured from the forced expiration start time. Often denoted by FEV1.

forced expiratory volume in 6 s: The expiratory volume of a subject under forced conditions at 6 s, measured from the forced expiration start time. Denoted by FEV6 and often used as a surrogate for forced vital capacity on simpler devices.

forced vital capacity: The total volume of air expired by a subject performing a forced maneuver.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set-top box, or a computer system.

maneuver: The process whereby a patient exhales or inhales into a spirometer. The most common type of maneuver is the forced exhalation where the patient inhales as deeply as possible and exhales as fast as possible until the lungs are depleted. A typical test session consists of multiple maneuvers.

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

obj-handle: *See:* **handle**.

observation: An AttributeChangeSet (see IEEE Std 11073-20601) that has only one of the following attributes:

- Compound-Simple-Nu-Observed-Value
- Basic-Nu-Observed-Value
- Compound-Basic-Nu-Observed-Value

¹⁴ *IEEE Standards Dictionary Online* is available at: <https://dictionary.ieee.org>. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

- Nu-Observed-Value
- Compound-Nu-Observed-Value
- Simple-Sa-Observed-Value
- Enum-Observed-Value-Simple-OID
- Enum Value -Observed-Value-Simple-Bit-Str
- Enum-Observed-Value- Basic-Bit-Str
- Enum-Observed-Simple-Str
- Enum-Observed-Value

which is combined with the associated static and dynamic attributes.

peak expiratory flow: Maximum flow measured at the mouth during an expiration delivered with maximal force starting immediately after achieving maximum lung inflation.

peak expiratory flow monitor: A medical device used to measure the respiratory function of those managing respiratory conditions such as asthma. A peak flow monitor specialization is defined in IEEE Std 11073-10421.

personal health device: A device used in personal health applications.

personal telehealth device: *See:* **personal health device.**

predicted average peak flow: The value of peak expiratory flow that is calculated based on the user's age, height, and sex to serve as a benchmark for the user's measurements.

session: A set of sequential maneuver subsessions used to measure lung function.

subsession: A maneuver or calibration.

summary measurement: A value that is derived from measurement[s] in previous maneuver subsessions.

time zero: In the context of this document, time zero is the instant determined from the volume-time graph using the back extrapolation method at which a forced expiratory maneuver starts.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
FEV	forced expiratory volume
FEV1	forced expiratory volume in 1 s
FEV6	forced expiratory volume in 6 s
ICS	implementation conformance statements
MDC	medical device communication
MDER	medical device encoding rules

MDS	medical device system
MOC	managed object class
OID	object identified
PDU	protocol data unit
PEF	peak expiratory flow
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See IEEE Std 11073-20601 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the spirometer device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 spirometer agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B12]. Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601, are normatively defined in Annex D, with systematic names and descriptions being given in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601 for a detailed description of the modeling constructs.

4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in IEEE Std 11073-20601.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601. The security of this communication is largely determined by, but not limited to, the physical security of the device along with the inherent security of the underlying transports. Additional security may be defined by future revisions of IEEE Std 11073-20601.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed.

Typically, medical devices should comply with the IEC 60601-1 [B6] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B7] series of standards. Software aspects may apply through standards such as IEC 62304 [B8]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Relevant examples include ISO 14971 [B9] and IEC 80001-1 [B9]. The requirements of such risk assessment, risk management, and conformance are outside the scope of this standard. The applicable versions of the referenced safety-related standards may differ by country.

5. Spirometry device concepts and modalities

5.1 General

This subclause presents the general concepts of spirometry devices. This specialization presents an extensive set of quantitative measurements. However, only a subset of these measurements will be supported by any given spirometer and only a subset is commonly used in clinical care.

A spirometer is a device that measures expired and inspired airflow, and air volume of an individual, providing measurements that are clinically useful to monitor those with respiratory conditions such as asthma and COPD. In general, spirometers provide measurements that are based on measuring airflow during a forced expiratory maneuver and also during an inspiratory maneuver. The spirometer is then able to provide measurements that include the volume exhaled at various time points during the forced expiration (e.g., forced expiratory volume at 1 s (FEV_1); the start of forced expiration is determined by back-extrapolation from the volume-time graph). Forced vital capacity (FVC) is the total volume exhaled from the start to the end of forced expiration.

FEV_1 , FVC, and FEV_1/FVC ratio are the most commonly used spirometry measurements. The forced expiratory maneuvers required to measure these measures are not natural. Those being tested need to inhale as much air as they can into the chest and then blow out as hard and as fast as they can until air flow stops, or they can no longer maintain the expiratory maneuver (maximum length of expiratory maneuver is 15 s). As the quality of this maneuver can greatly affect results, assessment of the quality of a spirometry test is very important. Optimally, a spirometry test session includes three acceptable forced expiratory maneuvers with values recorded for each maneuver. There are established criteria to determine if a forced expiratory maneuver is acceptable. The values used for clinical purposes from a spirometry test session are drawn from the three acceptable forced expiratory maneuvers. The largest FEV_1 and the largest FVC are used, even if they come from different forced expiratory maneuvers. Many other measures may be derived from the single maneuver with the greatest sum of $FEV_1 + FVC$. In general, spirometry measures are taken under the supervision of a healthcare professional to verify maximal effort and correct procedure; however, there is an increase in the number of devices available for personal use and certain criteria can be used to assess the quality of personal spirometry obtained in personal health settings.

Children under five years of age are often unable to achieve expiration beyond 1 s, and so measurements of air exhaled at 0.5 s ($FEV_{0.5}$) and at 0.75 s ($FEV_{0.75}$) after the start of forced expiration are used in this age group.

Spirometers use several types of sensors to measure airflow and determine measures; the most common methods include pressure sensors, mechanical turbines, and piezo-electric crystals. The subject follows a defined protocol for expiration and inspiration into a mouthpiece that channels the air to the sensor.

Spirometry measurements are typically interpreted relative to expected values that are calculated from reference equations for the individual subject. Many reference equations are used worldwide. These equations use parameters including age, height, race or ethnicity, and sex (such as sex assigned at birth) to calculate expected values.

Spirometers require other data to provide accurate measurements. This includes ambient temperature and barometric pressure to standardize results to BTPS (body temperature, ambient barometric pressure, saturated with water vapor). Details about how a study is performed, for example if nose clips were worn or if the study was performed in sitting or standing position, can affect results and so information on these details is important. Other data (name, date and time of study, etc.) is also needed.

This standard is designed to be flexible. A simple agent may record only a few measures in a session consisting of a single or multiple maneuvers and perform no assessment analysis. The standard also supports agents that come close to acute Point-of-Care Devices used in hospital settings that may support

interactions with a medical professional and generate not only an extensive set of measurements but assessment diagnostics. Thus, the number of measurement objects in this standard is large, but the advantage is that agents following this standard will represent these measurements in a consistent fashion.

5.2 Spirometry tests

A spirometry test comprises a number of maneuvers that make a repeated measure of a lung function. Multiple maneuvers are recommended to ensure consistency in measurements. The measurements taken in each maneuver are normally reported after a maneuver. Summary and statistical measures may be reported after the final maneuver to compare the ratio of specific measures from different maneuvers, and to compare measures against predicted outcomes for a patient.

Figure 1 illustrates a spirometry test sequence.

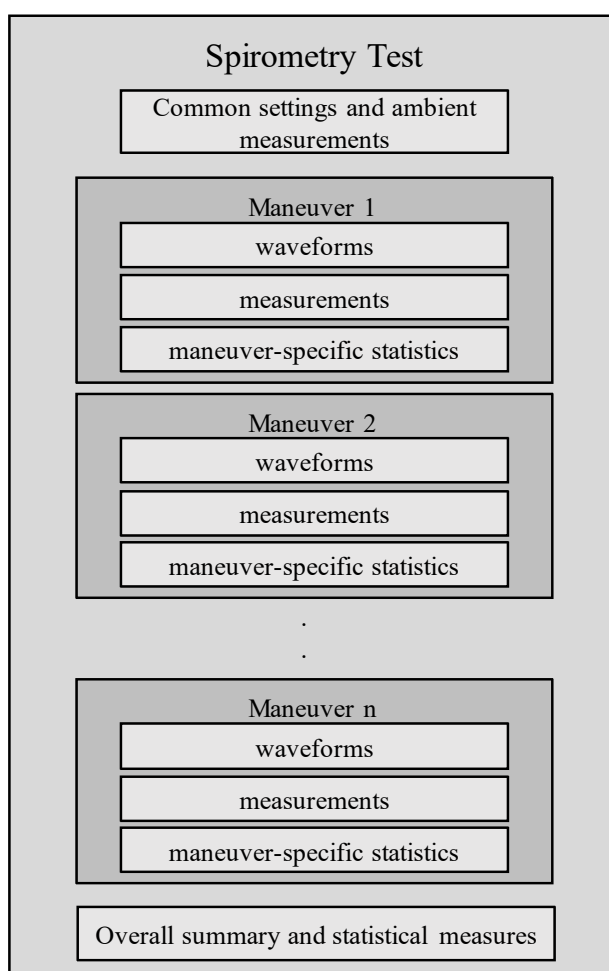


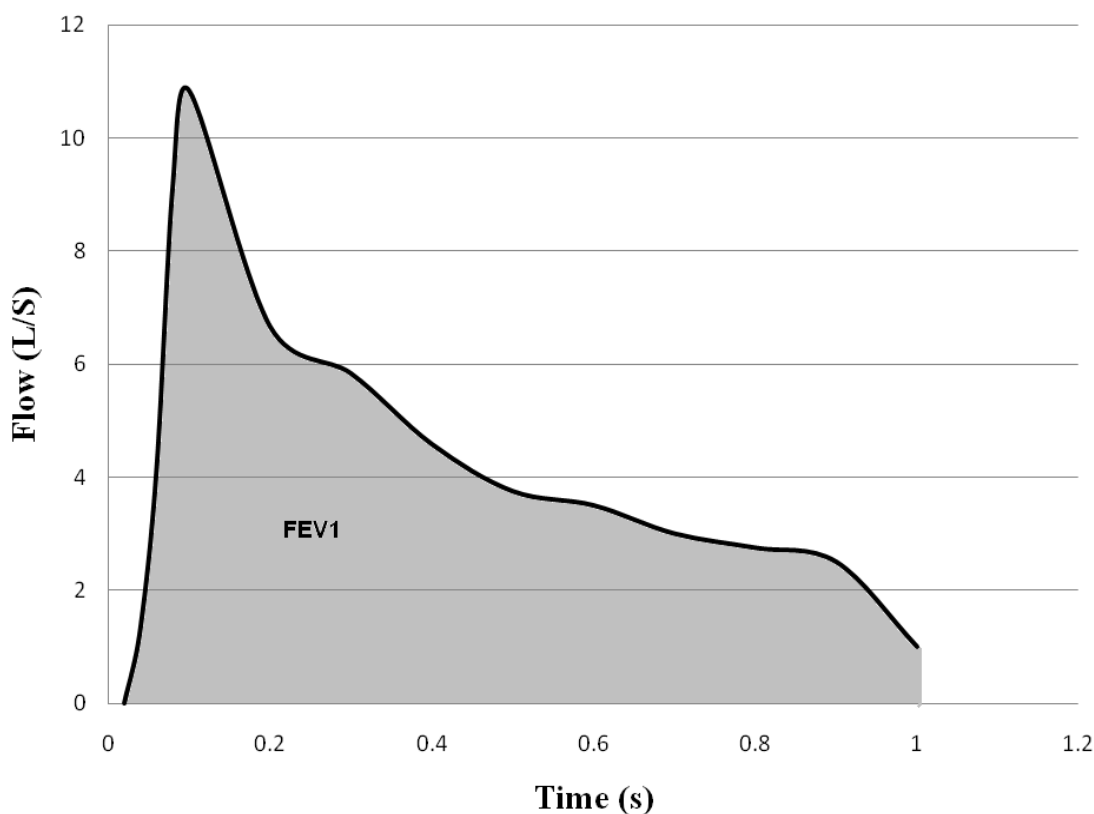
Figure 1—A spirometry test

5.3 Home spirometry measures

The measures in this subclause are also defined for peak expiratory flow in IEEE Std 11073-10421. They are also contained in this standard as they form a subset of spirometry measures.

5.3.1 Forced expiratory volume in 1 s (FEV₁)

FEV₁ is a measure of forced expiratory volume. It is measured during a forced expiratory maneuver when a subject blows out as hard and as fast as they can after inhaling as much air as they can into the chest. It measures expiratory volume of a subject under these forced conditions at 1 s, measured from time zero (time at which subject starts the expiration determined by back-extrapolation from the volume-time graph). At the point of peak expiratory flow (PEF) on the volume-time graph, a tangent is drawn with a slope equal to PEF, and its intersection on the abscissa defines time zero). FEV₁ is measured in liters. Figure 2 shows a typical pulmonary flow-time waveform where FEV₁ is the total volume of air and would be calculated as the area under the curve between 0 s and 1 s. Typically, between 3 and 8 individual FEV₁s are measured during a test session. Ideally, each value should be retained. The best value from an acceptable forced expiratory maneuver is reported as the final value.

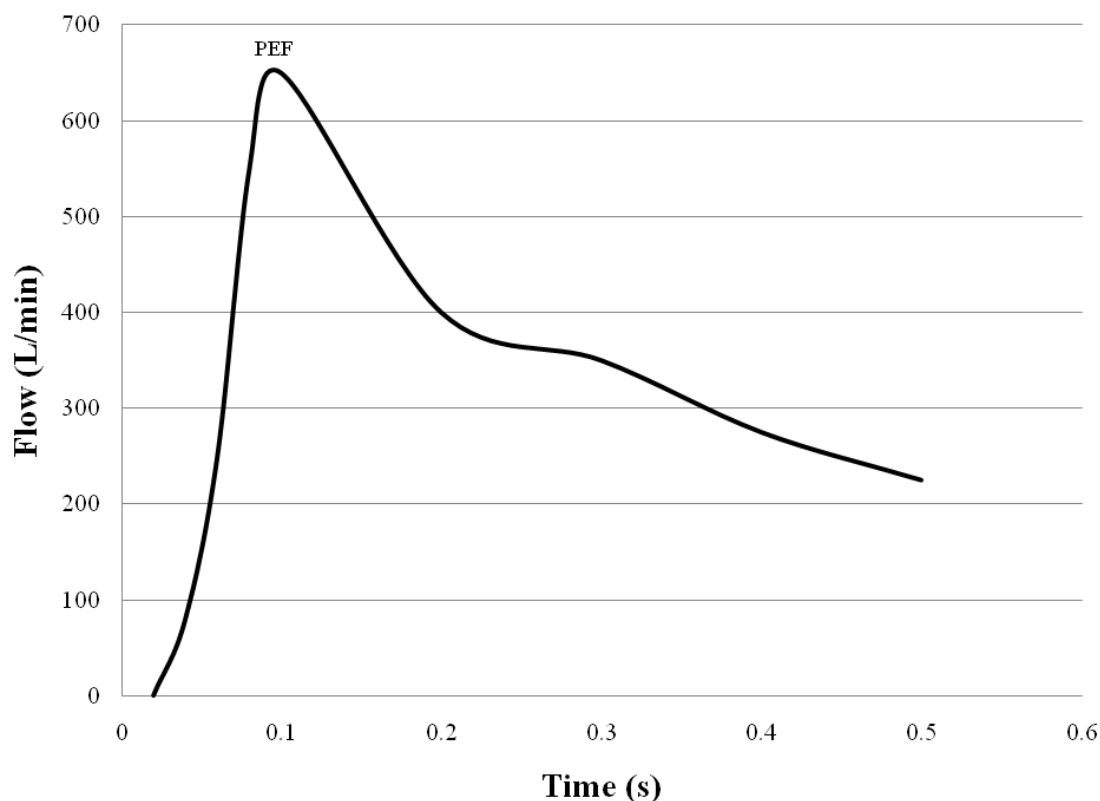


NOTE—This figure is a representation and does not correspond to real values.

Figure 2 —FEV₁ flow-time waveform

5.3.2 Peak expiratory flow (PEF)

PEF is a measure of the greatest flow rate that an individual can push air out of their lungs during a maximal forced expiration after taking a maximal inspiration. Figure 3 shows the typical rate of flow during the measurement of PEF with the maximal value at around 0.1 s. PEF is measured in liters per minute.



NOTE—This figure is a representation and does not correspond to real values.

Figure 3—PEF waveform

5.4 Common spirometry measures

This subclause defines the most common measures of spirometry. The most important single measurement is FEV_1 (see 5.3.1). Other important measurements commonly used in spirometry are forced vital capacity (FVC) and the ratio of FEV_1/FVC (see 5.6.1). The European Respiratory Society (ERS) and the American Thoracic Society (ATS) recommend routinely reporting forced expiratory time (FET) for quality assessment (described in 5.8) [B1].

5.4.1 Forced vital capacity

FVC is a measure of forced expiratory volume. It is measured during a forced expiratory maneuver when a subject blows out as hard, as fast, and for as long as they can after inspiring as much air as they can into the chest. It measures the total volume of air expired by subject under these forced conditions, measured from time zero (time at which subject starts the expiration defined by back-extrapolation as described in 5.4.1) until the end of forced expiration (defined as an expiratory plateau [≤ 0.025 L in the last 1 s of expiration] or expiratory time ≥ 15 s) or, in those who cannot expire long enough to achieve a plateau, if the FVC is greater than, or within the repeatability tolerance of the largest FVC observed before a maneuver in that testing set. FVC is measured in liters. Typically, between three and eight individual FVCs are measured during a test session. Ideally, each individual value should be retained. The best value from an acceptable forced expiratory maneuver is reported as the final value [B2].

5.4.2 Slow vital capacity (SVC)

SVC is a measure of slow (not forced) expiratory volume. It is measured during a slow, complete expiratory maneuver performed after inspiring as much air as possible into the chest and expiring until no more air can be expired. It measures the total volume of air expired from time zero (as previously described) until the end of slow expiration. More than one SVC may be measured during a test session. Ideally, each individual value should be retained. The best value from an acceptable expiratory maneuver is reported as the final value. SVC is measured in liters.

5.4.3 Forced expiratory volume in six seconds (FEV₆)

FEV₆ is a measure of the forced expiratory volume of a subject under forced conditions at 6 s measured from time zero. FEV₆ is measured in liters. Typically, between three to eight individual FEV₆ measurements are made during a test session. Ideally, each individual value should be retained. The best value from an acceptable forced expiratory maneuver is reported as the final value.

5.5 Spirometry measures used for children

This subclause defines measures used for spirometry in children under six years of age, who are often able to exhale to nearly their total FVC in the first second.

5.5.1 Forced expiratory volume in 0.5 s (FEV_{0.5})

FEV_{0.5} is a measure of the forced expiratory volume of a subject under forced conditions after one-half second measured from time zero. FEV_{0.5} is measured in liters.

5.5.2 Forced expiratory volume in 0.75 s (FEV_{0.75}).

FEV_{0.75} is a measure of the forced expiratory volume of a subject under forced conditions after three quarters of a second measured from time zero. FEV_{0.75} is measured in liters.

5.6 Spirometry measures normalized to FVC, SVC, and FEV₆

This subclause defines measures normalized to FVC, SVC, and FEV₆.

5.6.1 Ratio of forced expiratory volume in 1 s/FVC (FEV₁/FVC)

The ratio FEV₁/FVC gives a measure of the amount of air expired after 1 s compared with the total amount of air expired during a forced maneuver. The best values of FEV₁ and FVC obtained during a session are used for this ratio, even if they come from different acceptable forced expiratory maneuvers. The ratio has been measured as a percent, but current recommendations are to express the value as a decimal fraction to two decimal places.

5.6.2 Ratio of forced expiratory volume in 1 s/SVC (FEV₁/SVC)

The ratio FEV₁/SVC gives a measure of the amount of air expired after 1 s compared with the total amount of air expired during an unforced maneuver. The measure requires two separate types of expiratory maneuvers (forced and slow). The ratio has been measured as a percent, but current recommendations are to express the value as a decimal fraction to two decimal places.

5.6.3 Ratio of Forced Expiratory Volumes in 1 s and 6 s (FEV_1/FEV_6)

This ratio is sometimes used as an alternative to FEV_1/FVC , as FEV_6 is less demanding technically to measure accurately. The best values of FEV_1 and FEV_6 obtained during a session are used, even if they come from different acceptable forced expiratory maneuvers. The ratio has been measured as a percent, but current recommendations are to express the value as a decimal fraction to two decimal places.

5.6.4 Ratio of forced expiratory volume in 0.5 s/FVC ($FEV_{0.5}/FVC$)

The ratio $FEV_{0.5}/FVC$ gives a measure of the amount of air expired after one-half second to the total amount of air expired during a forced maneuver. The ratio has been measured as a percent, but current recommendations are to express the value as a decimal fraction to two decimal places.

5.6.5 Ratio of forced expiratory volume in 0.75 s/FVC ($FEV_{0.75}/FVC$)

The ratio $FEV_{0.75}/FVC$ gives a measure of the amount of air expired after three quarters of a second to the total amount of air expired during a forced maneuver. The ratio has been measured as a percent, but current recommendations are to express the value as a decimal fraction to two decimal places.

5.7 Spirometry measures related to forced expiratory flow

This subclause defines measures related to forced expiratory flow. These are typically reported for each maneuver performed during a session. The final expiratory values are determined from the single expiratory maneuver with the greatest sum of $FEV_1 + FVC$.

5.7.1 Forced expiratory flow at 25 % of FVC (FEF_{25})

FEF_{25} gives the flow rate at the moment when 25 % of the FVC has been exhaled. The measure is in liters per second.

5.7.2 Forced expiratory flow at 50 % of FVC (FEF_{50})

FEF_{50} gives the flow rate at the moment when 50 % of the FVC has been exhaled. The measure is in liters per second.

5.7.3 Forced expiratory flow at 75 % of FVC (FEF_{75})

FEF_{75} gives the flow rate at the moment when 75 % of the FVC has been exhaled. The measure is in liters per second.

5.7.4 Forced expiratory flow between 25 % and 75 % of FVC (FEF_{25-75})

Maximal mid-expiratory flow rate, traditionally known as MMEF, FEF_{25-75} is the average flow rate between the 25 % level and 75 % level of the observed FVC (e.g., with an observed FVC of 4.0 L the 25 % level is at 1.0 L and the 75 % level is at 3.0 L. The slope of a line drawn through these points on the volume-time graph of the FVC curve will be considered the average flow rate). The FEF_{25-75} is calculated from the single acceptable forced expiratory maneuver obtained during a test session with the greatest sum of $FEV_1 + FVC$. FEF_{25-75} is measured in liters per second.

5.8 Spirometry measures related to forced inspiration

This subclause defines measures related to forced inspiration. These are typically measured for each inspiratory maneuver performed during a session.

5.8.1 Forced inspiratory vital capacity (FIVC)

FIVC is a measure of forced inspiratory volume. It is measured during a forced inspiratory maneuver when a subject inspires as hard and as fast as they can to fill the chest to its maximum after a full exhalation. It measures the total volume of air inhaled by subject under these forced conditions, measured from time zero (time at which subject starts the inhalation) until the end of forced inhalation. FIVC is measured in liters.

5.8.2 Forced inspiratory volume in 1 s (FIV₁)

FIV₁ is a measure of forced inspiratory volume. It is measured during a forced inspiratory maneuver when a subject inspires as hard and as fast as they can to fill the chest to its maximum after a full exhalation. It measures the total volume of air inhaled by subject under these forced conditions, measured from time zero (time at which subject starts the inhalation) after one second. FIV₁ is measured in liters.

5.8.3 Forced inspiratory flow at 25 % of FIVC (FIF₂₅)

FIV₂₅ is a measure of forced inspiratory flow at the moment when 25 % of FIVC has been obtained. It is measured during a forced inspiratory maneuver when a subject inspires as hard and as fast as they can to fill the chest to its maximum after a full exhalation. FIV₂₅ is measured in liters per second.

5.8.4 Forced inspiratory flow at 50 % of FIVC (FIF₅₀)

FIV₅₀ is a measure of forced inspiratory flow at the moment when 50 % of FIVC has been obtained. It is measured during a forced inspiratory maneuver when a subject inspires as hard and as fast as they can to fill the chest to its maximum after a full exhalation. FIV₅₀ is measured in liters per second.

5.8.5 Forced inspiratory flow at 75 % of FIVC (FIF₇₅)

FIV₇₅ is a measure of forced inspiratory flow at the moment when 75 % of FIVC has been obtained. It is measured during a forced inspiratory maneuver when a subject inspires as hard and as fast as they can to fill the chest to its maximum after a full exhalation. FIV₇₅ is measured in liters per second.

5.8.6 Peak inspiratory flow (PIF)

PIF is the maximum flow rate obtained during forced inspiration. PIF is measured in liters per second.

5.9 Spirometry measures related to volume during unforced breathing

This subclause defines measures related to volume measured during unforced breathing. SVC (5.4.2) is already described and not repeated in this subclause. These may be measured more than once during a single test session.

5.9.1 Tidal volume (TV)

The tidal volume is the volume of inspired and expired air during normal, restful breathing. Its typical value is about 500 mL = 0.5 L. The magnitude of the TV depends on the size of the individual and their metabolic state. The TV usually varies from breath to breath. TV is measured in liters.

5.9.2 Inspiratory capacity measured from tidal volume (IC)

IC is the maximum amount of air that can be inspired after the patient has expired during a normal tidal breathing cycle. It is measured in liters. The remaining volume of air in the lungs after a normal tidal breathing expiration is referred to as the functional residual capacity (FRC). FRC cannot be directly measured via spirometry. IC is measured in liters.

5.9.3 Expiratory reserve volume (ERV)

The expiratory reserve volume is the additional volume of air that can be expired after a normal or tidal expiration. A typical value is about 1100 mL for a young adult male. ERV is measured in liters.

5.9.4 Inspiratory reserve volume (IRV)

The inspiratory reserve volume is the additional volume of air that can be inspired at the end of a normal or tidal inspiration. The typical value for a young adult male of normal size is about 3000 mL. IRV is measured in liters.

5.9.5 Inspiratory vital capacity measured from maximal exhalation (IVC)

Inspiratory vital capacity is the maximum volume of air inspired from the point of maximum expiration. The maneuver is unforced. IVC is measured in liters.

5.10 Spirometry measures related to BTPS correction, calibration verification/check, and technical factors

This subclause defines measures that are used to correct measurements for body temperature, ambient pressure, water vapor saturated condition of exhaled air, calibration verification/check to evaluate that a spirometer is functioning properly, and to document certain technical factors that might affect results.

5.10.1 Body temperature-pressure-saturated (BTPS) correction factor

The BTPS correction factor is used to convert flow and volume measured at ambient conditions to the conditions within the lungs. Ambient conditions are the current temperature and pressure in the room where the test is being performed and called ATP (ambient temperature, pressure). The conditions within the lungs are called BTPS (body temperature, pressure, water vapor saturated).

5.10.2 Ambient air pressure

The ambient air pressure is the atmospheric pressure in the room where the test is being performed.

5.10.3 Ambient room temperature

The ambient room temperature is the room air temperature where the test is being performed. It needs to be recorded with an accuracy of ± 1 °C.

5.10.4 Patient-immediate ambient relative humidity

The patient-immediate ambient relative humidity is the relative humidity of the ambient air in the vicinity of the patient.

5.10.5 Date/Time of last calibration verification/check session

The date/time that the most recent calibration verification/check session was performed.

5.10.6 Last calibration verification/check session, number of calibration verifications

Number of calibration verifications performed by injecting air using a 3-L syringe (usually cycled at least three times to give a range of flows varying between 0.5 L/s and 12 L/s (with 3-L injection times between 0.5 s and 6 s).

5.10.7 Last calibration verification/check session, volumes measured

Volume in liters measured after each syringe injection for calibration verification.

5.10.8 Last calibration verification/check session, number of failed calibration verifications

Number of failed calibration verifications (not meeting the accuracy requirement of $\pm 3\%$).

5.10.9 History of calibration verification/check sessions

The dates and times of previous calibration verification/check sessions, and whether the device passed or failed the check.

5.10.10 Testing position

Standing or sitting.

5.10.11 Nose clips

With or without nose clips.

5.10.12 Bronchodilator

Pre-bronchodilator or post-bronchodilator.

5.11 Spirometry measures related to test quality assessment

5.11.1 Forced expiratory time (FET)

FET is measured for each expiratory maneuver in a session. It is the time measured in seconds from the start of forced expiration (time zero) to the end of the expiratory plateau, or the beginning of inspiration after maximal forced expiration, or the time at which the patient comes off the mouthpiece, whichever is shortest. The FET does not include any period of zero flow at the end of expiration. The FET from the maneuver with the largest FVC is reported on the clinical report. $FET \geq 15$ s is one criterion for acceptability of a forced expiratory (FVC) maneuver.

5.11.2 Back-extrapolated volume (BEV, EVOL, Vext)

The back-extrapolated volume is measured for each forced expiratory maneuver in a session. It is the volume of air expired before time zero in a forced maneuver, as determined by the back-extrapolated volume method. Time zero is determined by drawing a line with a slope equal to the peak flow through the

point of maximum peak flow on the volume–time curve and setting Time 0 to the point where this line intersects the time axis. The back-extrapolated volume is equal to the volume of gas exhaled before time zero and reflects the hesitation in performing a forced maneuver. Back-extrapolated volume needs to be $\leq 5\%$ of FVC or 0.100 L, whichever is greater. If the extrapolated volume is larger than allowed, that FVC maneuver is considered invalid.

5.11.3 Achievement of end of forced expiration (EOFE)

Achievement of EOFE is determined for each forced expiratory maneuver in a session. To be acceptable, a maneuver needs to achieve one of three EOFE indicators: expiratory plateau (≤ 0.025 L in the last 1 s of expiration); expiratory time ≥ 15 s; or FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC. FVC repeatability tolerance for those more than six years old is that the difference between the two largest FVC values needs to be ≤ 0.150 L. FVC repeatability tolerance for those six years or less is that the difference between the two largest FVC values needs to be ≤ 0.100 L or 10 % of the highest value, whichever is greater. Achievement is reported as yes/no for each forced expiratory maneuver.

5.11.4 FIVC-FVC

FIVC-FVC is determined for each maneuver in a session that is a combined expiratory/inspiratory maneuver. If the maximal inspiration after EOFE is greater than FVC, then FIVC-FVC needs to be ≤ 0.100 L or 5 % of FVC, whichever is greater. If the FIVC-FVC difference is greater, the maneuver is considered invalid.

5.11.5 Point at which expiratory flow ceases

Point at which expiratory flow ceases is used in pediatrics to assess for early termination of the forced expiratory maneuver. It is measured for each expiratory maneuver in a session and expressed as the percent of PEF at which expiratory flow ceases. If cessation of flow occurs at greater than 10 % of peak flow, then this maneuver should be classified as showing premature termination. It may be possible to report timed expiratory volumes from such a maneuver, but FVC and forced expiratory flows cannot be reported.

5.11.6 Individual FVC maneuver acceptability

This is determined for each forced expiratory maneuver in a session. An individual FVC maneuver that meets criteria for acceptability is reported as yes or no.

5.11.7 Number of acceptable FVC maneuvers

Number of acceptable FVC maneuvers obtained in a test session. Optimally, at least three acceptable FVC maneuvers meeting reproducibility criteria should be obtained during a session. Typically, a maximum of eight FVC maneuvers are attempted in order to obtain three acceptable maneuvers.

5.11.8 Between-maneuver FVC reproducibility

The difference between the two largest FVC values obtained during a test session in liters. To meet acceptability criteria, needs to be ≤ 0.150 L in those older than six years or ≤ 0.100 L or 10 % of the highest FVC value, whichever is greater, in those six years and younger.

5.11.9 Between-maneuver FEV₁ reproducibility

The difference between the two largest FEV₁ values obtained during a test session in liters. To meet acceptability criteria, this needs to be ≤ 0.150 L in those older than six years or ≤ 0.100 L or 10 % of the highest FEV₁ value, whichever is greater, in those six years and younger.

5.11.10 FVC quality grade

Letter grade assigned based on the criteria in Table 1.

Table 1—FVC quality grade

Grade	Number of measurements	Repeatability	
		Age > 6 years	Age < 6 years
A	≥3 acceptable	Within 0.150 L	Within 0.100 L ^a
B	2 acceptable	Within 0.150 L	Within 0.100 L ^a
C	≥2 acceptable	Within 0.200 L	Within 0.150 L ^a
D	≥2 acceptable	Within 0.250 L	Within 0.200 L ^a
E	≥2 acceptable	>0.250 L	>0.200 L ^a
	OR 1 acceptable	N/A	N/A
U	0 acceptable AND ≥1 usable	N/A	N/A
F	0 acceptable and 0 usable	N/A	N/A

^a Or 10 % of the highest value, whichever is greater; applies for age six years or younger only.

5.11.11 FEV₁ quality grade

Letter grade assigned based on the criteria in Table 2.

Table 2—FEV₁ quality grade

Grade	Number of Measurements	Repeatability	
		Age > 6 year	Age ≤ 6 year
A	≥3 acceptable	Within 0.150 L	Within 0.100 L ^a
B	2 acceptable	Within 0.150 L	Within 0.100 L ^a
C	≥2 acceptable	Within 0.200 L	Within 0.150 L ^a
D	≥2 acceptable	Within 0.25 L	Within 0.200 L ^a
E	≥2 acceptable	>0.250 L	>0.200 L ^a
	OR 1 acceptable	N/A	N/A
U	0 acceptable AND ≥1 usable	N/A	N/A
F	0 acceptable and 0 usable	N/A	N/A

^a Or 10 % of the highest value, whichever is greater; applies for age 6 years or younger only.

5.12 Spirometry waveform measures

This subclause defines waveform measures.

5.12.1 Volume-time waveform (VT)

The VT curve shows the total volume expired or inspired as a function of time. Data samples to generate these curves should be taken at a sample rate of at least every 10 ms. VT waveform data should be provided as an array of time and volume values, with times adjusted to ‘Time 0’ using the back-extrapolation method. Ideally, VT data is retained for each forced expiratory-inspiratory or expiratory-only maneuver performed in a spirometry test session.

5.12.2 Flow-time waveform (FT)

The FT curve shows the flow rate as a function of time during inspiration or expiration. Data samples to generate these curves should be taken at a sample rate of at least every 10 ms. FT waveform data should be provided as an array of time and flow values, with times adjusted to ‘Time 0’ using the back-extrapolation method. Ideally, FT data is retained for each forced expiratory-inspiratory or expiratory-only maneuver performed in a spirometry test session.

5.13 Interpretive spirometry measures

This subclause defines measures used to interpret spirometry measures.

5.13.1 Reference equations

Reference equations are used to determine predicted values, lower limits of normal (LLN), and z-scores for FEV₁, FVC, FEV₁/FVC, and other spirometry measures based on the sex, age, height, and racial/ethnic group of a patient. Examples of widely used contemporary reference equations are GLI-2012 [B2], NHANES-III [B13], and ECSC [B2], although many other reference equations are used around the world. The reference equation used for interpretation should be identified.

Examples of pediatric reference equations include Eigen et al. [B3], Nystad et al. [B14], Zapletal and Chalupova [B16], and Viložni et al. [B15].

There are also many other pediatric reference equations used around the world.

5.13.1.1 Assigned sex at birth

Male or female.

5.13.1.2 Gender Identity

Male, female, or other gender identity.

5.13.1.3 Age

Age in years to one decimal place.

5.13.1.4 Height

Height in centimeters without shoes to one decimal place.

5.13.1.5 Weight

Wearing indoor clothes; to nearest 0.5 kg.

5.13.1.6 Body mass index

Calculated as kilograms per square meter (kg/m²).

5.13.1.7 GLI-2012 racial/ethnic group

Racial/ethnic group needed to use the GLI-2012 reference equation. The groups are as follows: Caucasian, African-American, Northeast Asian, Southeast Asian, or Mixed Ethnic Origins.

5.13.1.8 NHANES-III racial/ethnic group

Racial/Ethnic group needed to use the NHANES-III reference equation. The groups are as follows: Caucasian, African-American, or Mexican-American. Asian is also included by applying an adjustment factor to the Caucasian equation.

5.13.2 LLN FEV₁

Specifies reference equation and lower limit of normal for FEV₁ calculated as lower fifth percentile from the reference equation. Expressed in liters.

5.13.3 LLN FVC

Specifies reference equation and lower limit of normal for FVC calculated as lower fifth percentile from the reference equation. Expressed in liters.

5.13.4 LLN FEV₆

Specifies reference equation and lower limit of normal for FEV₆ calculated as lower fifth percentile from the reference equation. Expressed in liters.

5.13.5 LLN SVC

Specifies reference equation and lower limit of normal for SVC calculated as lower fifth percentile from the reference equation. Expressed in liters.

5.13.6 LLN FEV_{0.5}

Specifies reference equation and lower limit of normal for FEV_{0.5} calculated as lower fifth percentile from the reference equation. Expressed in liters.

5.13.7 LLN FEV_{0.75}

Specifies reference equation and lower limit of normal for FEV_{0.75} calculated as lower fifth percentile from the reference equation. Expressed in liters.

5.13.8 LLN FEV₁/FVC

Specifies reference equation and lower limit of normal for FEV₁/FVC calculated as lower fifth percentile from the reference equation. Expressed as a percentage.

5.13.9 LLN FEV₁/FEV₆

Specifies reference equation and lower limit of normal for FEV₁/FEV₆ calculated as lower fifth percentile from the reference equation. Expressed as a percentage.

5.13.10 LLN FEV₁/SVC

Specifies reference equation and lower limit of normal for FEV₁/SVC calculated as lower fifth percentile from the reference equation. Expressed as a percentage.

5.13.11 Z-score FEV₁

Specifies reference equation and displacement of the FEV₁ from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted FEV₁. The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.12 Z-score FVC

Specifies reference equation and displacement of the FVC from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted FVC. The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.13 Z-score FEV₆

Specifies reference equation and displacement of the FEV₆ from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted FEV₆. The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.14 Z-score SVC

Specifies reference equation and displacement of the SVC from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted SVC. The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.15 Z-score FEV_{0.5}

Specifies reference equation and displacement of the FEV_{0.5} from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted FEV_{0.5}. The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.16 Z-score FEV_{0.75}

Specifies reference equation and displacement of the FEV_{0.75} from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted FEV_{0.75}. The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.17 Z-score FEV₁/FVC

Specifies reference equation and displacement of the FEV₁/FVC from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference

equation predicted FEV_1/FVC . The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.18 Z-score FEV_1/FEV_6

Specifies reference equation and displacement of the FEV_1/FEV_6 from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted FEV_1/FEV_6 . The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.19 Z-Score FEV_1/SVC

Specifies reference equation and displacement of the FEV_1/SVC from the predicted value in standard deviation units. In this case, the z-score is the number of standardized residuals away from the reference equation predicted FEV_1/SVC . The z-score can be positive or negative. A z-score of -1.645 is equivalent to a value at the LLN (lower fifth percentile from prediction equation).

5.13.20 Percent predicted FEV_1

Specifies reference equation and percentage calculated by dividing the observed FEV_1 determined from the test session by the predicted FEV_1 determined from the reference equation and multiplying by 100.

5.13.21 Percent predicted FVC

Specifies reference equation and percentage calculated by dividing the observed FVC determined from the test session by the predicted FVC determined from the reference equation and multiplying by 100.

5.13.22 Percent predicted FEV_6

Specifies reference equation and percentage calculated by dividing the observed FEV_6 determined from the test session by the predicted FEV_6 determined from the reference equation and multiplying by 100.

5.13.23 Percent predicted SVC

Specifies reference equation and percentage calculated by dividing the observed SVC determined from the test session by the predicted SVC determined from the reference equation and multiplying by 100.

5.13.24 Percent predicted $FEV_{0.5}$

Specifies reference equation and percentage calculated by dividing the observed $FEV_{0.5}$ determined from the test session by the predicted $FEV_{0.5}$ determined from the reference equation and multiplying by 100.

5.13.25 Percent predicted $FEV_{0.75}$

Specifies reference equation and percentage calculated by dividing the observed $FEV_{0.75}$ determined from the test session by the predicted $FEV_{0.75}$ determined from the reference equation and multiplying by 100.

5.14 Graphical representation of some spirometry measures

5.14.1 Spirometry volumes

Figure 4 shows the spirometry volume relations.

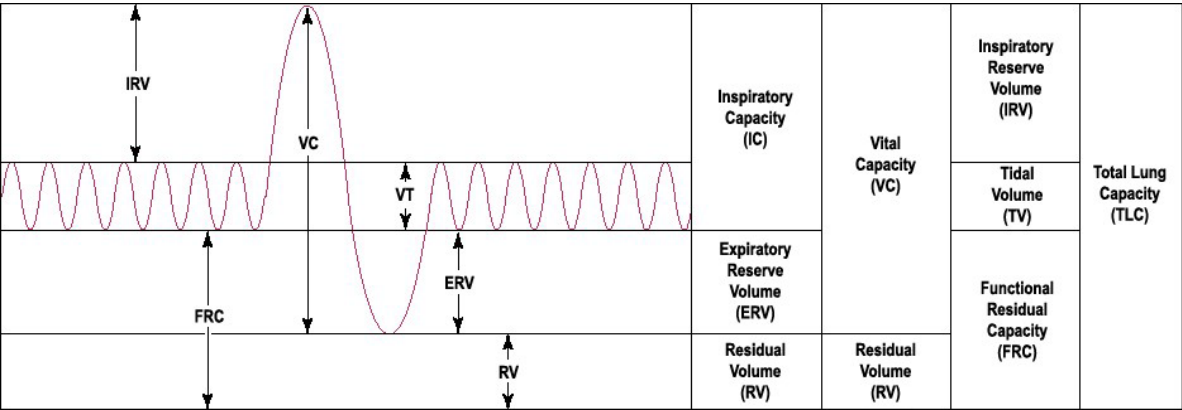


Figure 4—Spirometry volume relations

5.14.2 Spirometry volume-time curve

Figure 5 shows the spirometry maneuver volume-flow curve.

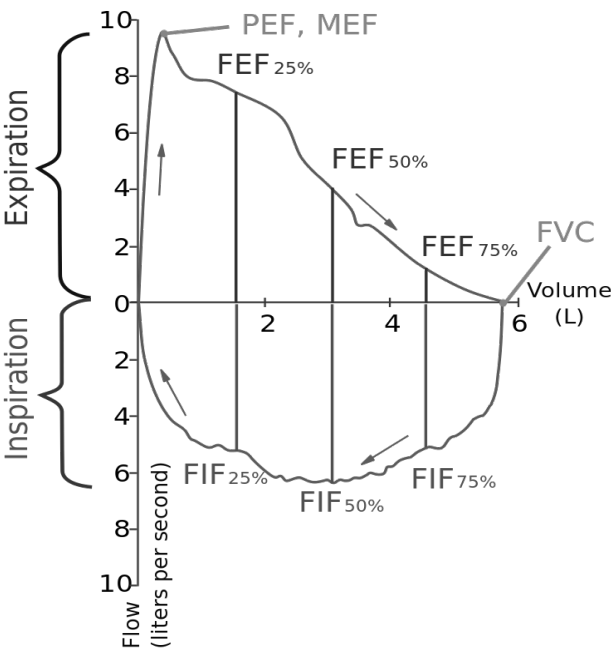


Figure 5—Spirometry maneuver volume-flow curve

5.14.3 Prediction equations and Z-score

Figure 6 shows the bell-curve representing the distribution of results around the predicted value of the given measurement. A Z-Score of 0 means the actual measured value was equal to the predicted value. Positive values are above normal and negative values are below. A value of -1.64 is the lower limit of normal at 5 %. A result that is above the LLN value is generated by 95 % of the population.

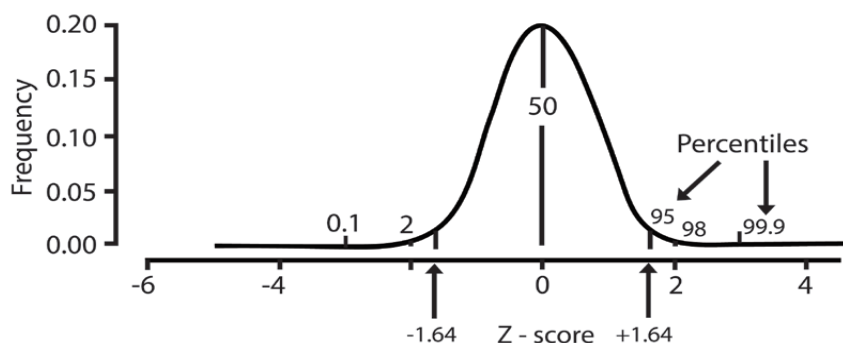


Figure 6—Z-score population distribution curve

5.14.4 Back extrapolated volume (BEV)

Figure 7 shows the derivation of the BEV and test start by finding the point where the line with the slope of the volume-time curve at the point of peak flow intersects the time axis. The point of intersection is the start of the test. The BEV is the exhaled volume recorded at this new start time. The BEV is caused by hesitancy and is not part of the test measurements.

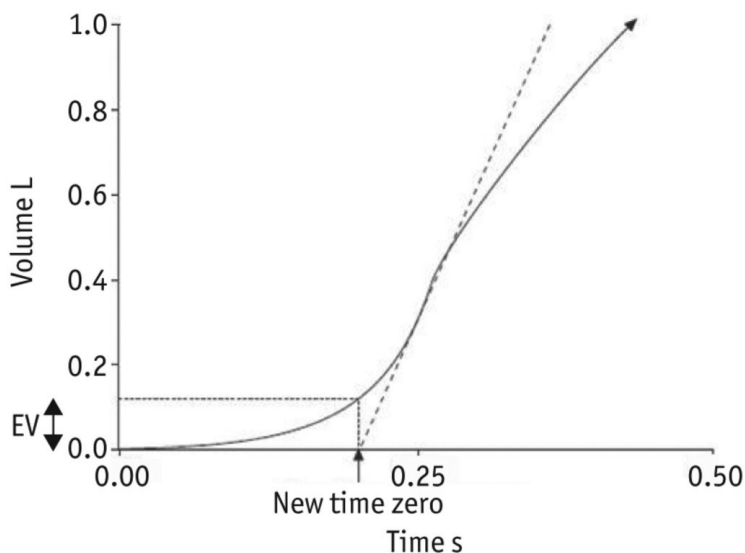


Figure 7—Determination of back extrapolated volume

6. Spirometer domain information model

6.1 Overview

This subclause describes the domain information model of the spirometer.

6.2 Class extensions

In this standard, the Metric Class adds two attributes, the Observation-Id and Observation-Ref-List.

6.3 Object instance hierarchy

The objects of the DIM are described in 6.5 through 6.10. This includes the medical device system (MDS) object (6.5), the numeric objects (6.6), the real-time sample array objects (6.7), the enumeration objects (6.8), the PM-store objects (6.9), and the scanner objects (6.10). Subclause 6.11 describes the rules for extending the spirometer information model beyond elements as described in this standard. Each subclause that describes an object of the spirometer contains the following information:

- The nomenclature code used to identify the class of the object. One example where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.
- The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601.
- The methods available on the object.
- The potential events generated by the object. The data are sent to the manager using events.
- The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers are as follows:

- M: Attribute is Mandatory
- C: Attribute is Conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601 is referenced, then it contains the conditions)
- R: Attribute is Recommended
- NR: Attribute is Not Recommended
- O: Attribute is Optional

Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented by the agent.

The attributes can be either static, meaning that they shall remain unchanged after the configuration is agreed upon, or dynamic, meaning that the attribute may change at some point after configuration.

A summary of the many objects defined in this standard are listed as follows:

- MDS object
 - Numeric objects
 - Forced expiratory volumes (FEV_n) after N seconds
 - Peak expiratory flow (PEF)
 - Forced vital capacity (FVC)
 - Slow (unforced) vital capacity (SVC)
 - Ratio of FEV₁/FEV₆
 - Ratio of FEV_n/FVC
 - Forced expiratory flow mean from *x* to *y* percent of FVC
 - Forced expiratory flow (FEF_{*x*}) at *x* percent of FVC
 - Peak inspiratory flow (PIF)
 - Forced inspiratory vital capacity (FIVC)
 - Forced inspiratory volume after 1 s (FIV₁)
 - Forced inspiratory flow at *x* percent of FIVC (FIF_{*x*})
 - Tidal volume (TV)
 - Inspiratory capacity from tidal volume (IC)
 - Expiratory reserve volume (ERV)
 - Inspiratory reserve volume (IRV)
 - Inspiratory vital capacity from maximum exhalation (IVC)
 - Forced expiratory time (FET)
 - Back extrapolated volume (BEV, EVOL, Vext)
 - Adjusted temperature-pressure-saturated factor (BTPS)
 - Ambient air temperature
 - Ambient relative humidity
 - Ambient air pressure
 - Slow expiratory vital capacity from maximum inhalation (EVC)
 - Maximal expiratory flow (MEF)
 - Forced expiratory flow mean from 0.2 L to 1.2 L (FEF_{0.2-1.2})
 - Tidal breathing expiratory time (Tex)
 - Tidal breathing inspiratory time (Tin)
 - Ratio of Tin/Tex
 - Forced inspiratory flow mean from *x* to *y* percent (FIF_{*x-y*}) of FIVC
 - Ratio of forced inspiratory volume after 1 s to FIVC (FIV₁/FIVC)
 - Maximal voluntary ventilation in 12 s (MVV₁₂)
 - Maximal voluntary ventilation in 15 s (MVV₁₅)
 - Mean expiratory time at 25 % to 75 % of FVC (MET_{25_75})
 - Time to peak expiratory flow (TPEF)
 - Mean tidal flow (VT/TI)

- Ratio of forced expiratory flow after 1 s to slow vital capacity (FEV1/SVC)
- Z-scores
- Lower limit of normal (LLN)
- Percent predicted
- Numeric settings
 - Age
 - Body weight
 - Body height
 - Calibration
- Real-time-sample-array (RTSA) objects
 - Flow-time waveform (FT)
 - Volume-time waveform (VT)
- Enumeration objects
 - Diagnostic session
 - Diagnostic subsession
 - Enumeration settings
 - Ethnicity
 - Birth sex
 - ERS/ATS quality grade
 - Maneuver status

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the IEEE 11073-104zz specializations and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at association time between the agent and the manager. If the manager recognizes and selects to operate using the configuration, then the agent can send measurements immediately. If the manager does not recognize the configuration, the agent provides the configuration prior to transmitting measurement information.

This specialization does not define any standard configurations.

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines the objects, attributes, and values that will be used in a configuration and assigns a configuration identifier. When the agent associates with a manager, an acceptable configuration is negotiated. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send its configuration information as a configuration event report. If, however, the manager recognizes the configuration, either because it was preloaded in some way or the agent had

previously associated with the manager, then the manager responds that the configuration is known, and no further configuration information needs to be sent.

6.4.4 Spirometry sessions

In spirometry, the source of all measurements is the maneuver. The maneuver is that period where the subject expires and/or inspires air through the mouthpiece and then detaches. The European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines require that the most commonly used spirometry measurements, the forced expiratory volume in 1 s (FEV₁) and forced vital capacity (FVC), each be the single best measurement from at least three acceptable forced maneuvers. In some cases, such as ambulatory monitoring, a spirometry measurement might be obtained from a session consisting of just one maneuver, even though this would not be consistent with international guidelines for measurement of FEV₁ and FVC.

To support the many possible scenarios a spirometry test may take, this specialization defines a session object that designates the start and end of the test effort to organize the supporting data and maneuvers. All the non-calibration objects reported within a session are from a single patient. The diagnostic session object defines a test or optional calibration session. The test session may consist of one or more maneuvers, where each maneuver is delineated by a subsession object with start and end values. A spirometry test typically, but not always, involves at minimum three, and up to a maximum of eight, maneuvers. How these session and subsession start and end points are identified is left up to the application. It may be a button push or detected. However, an application shall send all maneuver real time and evaluation data before the corresponding maneuver subsession object with the end value. Likewise, any measurements that require input from multiple maneuvers shall be reported after the last maneuver subsession object with the end value and before the diagnostic test session object with the end value.

Note the difference between a diagnostic session and maneuver subsessions. A patient may have a session with three maneuver subsessions and sometime later (after sufficient rest) have a second session with three maneuver subsessions. Again, how these sessions and subsessions are detected is left up to the application.

A clinical spirometer should be compliant with the ERS/ATS guidelines. If a spirometer is compliant with the ERS/ATS guidelines, then it shall be capable of supporting multiple maneuvers during a session.

An example diagnostic test session with three maneuvers is shown as follows:

- Session test start
 - Settings and ambient conditions common to all maneuver subsessions
 - Maneuver subsession 1 start
 - Settings and ambient conditions unique to maneuver subsession 1
 - Flow and volume data

In most cases where RTSAs are used one is reporting continuously streaming waveform data and therefore the data is sent in a sequence of scan event reports with N samples in each report until the association is terminated. An ECG is a good example of such a device. In the spirometry case, the duration of a maneuver is short enough that the entire set of samples could be sent in a single scan event report and not exceed the 20601 APDU size limit of 63K. However, this standard continues to follow 20601 and the number of samples sent per Scan Event Report is left up to the application. Regardless of how the application chooses to send the flow data, no more flow data from this maneuver shall be sent after the subsession with the end designator is sent.
 - Maneuver evaluation data (FEV₁, FEV₆, FVC, FEV₁/FVC, Z-score, etc.)
 - Maneuver subsession 1 end (no more maneuver data from subsession 1, including RTSAs)
 - Maneuver subsession 2 start

- Settings and ambient conditions unique to maneuver subsession 2
 - Flow and volume data (perhaps sent in 1-s segments)
 - Maneuver evaluation data (FEV1, FEV6, FVC, FEV1/FVC, Z-score, etc.)
 - Maneuver subsession 2 end (no more maneuver data from subsession 2)
 - Maneuver subsession 3 start
 - Settings and ambient conditions unique to maneuver subsession 3
 - Flow and volume data
 - Maneuver evaluation data (FEV1, FEV6, FVC, FEV1/FVC, Z-score, etc.)
 - Maneuver subsession 3 end (no more maneuver data from subsession 3)
- If there are no more maneuver subsessions, summary data (if any) is now reported:
- Session Evaluation measures whose input requires data from different subsessions (ratios like FEV1/FVC where FEV1 comes from maneuver n and FVC comes from maneuver m , Z-scores picking the best result, ERS/ATS Quality, etc.).
 - Session test end (no more data shall come from this session)

An ambulatory monitoring test session could also be as simple as the following, recognizing that the FEV₁ measurement would not be obtained in a way consistent with ERS/ATS guidelines:

- Session test start
 - Maneuver subsession 1 start
 - Maneuver evaluation data FEV1
 - Maneuver subsession 1 end (no more single maneuver data from subsession 1)
- Session test end

The most likely situation where a spirometer agent would report multiple sessions during an association is if the agent stores data.

6.4.4.1 Observation-Id and Observation-Ref-List attributes

This standard defines two attributes of the Metric Object, the Observation-Id and the Observation-Ref-List. Both are Observational. The Observation-Id value is a number which is unique for each observation (see definitions in 3.1). For this specialization, the uniqueness of the values shall extend across all observations within an association. The uniqueness includes any stored data delivered during the association.

The Observation-Ref-List attribute is used to reference one or more observations. If a reported object references one or more other reported observations, the referenced observations shall be reported before the observation containing the references. For example, the FEV1 and FVC observations must be sent prior to the FEV1/FVC ratio or occur before the FEV1/FVC ratio within the Scan Event Report if sent in the same Scan Event Report.

There is no requirement that an observation which reports an Observation-Id must be referenced by another observation.

6.4.4.2 Measurement references

In addition to scoping measurement delivery by the Session objects with the start and end designators, the observations scoped by a session contain references pointing to the scoping session. The Session and Subsession objects with the start designator have an Observation-Id attribute. The maneuver Subsession observations with the start designator and Session observation with the end designator have an Observation-Ref-List attribute containing the Observation-Id attribute value of the Session observation with