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Part 10424: Device Specialization — Sleep Apnoea Breathing Therapy Equipment (SABTE)

Informatique de santé — Communication entre dispositifs de santé personnels

Partie 10424: Spécialisation de dispositif — Équipement de thérapie respiratoire de l'apnée du sommeil (SABTE)



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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between sleep apnoea breathing therapy equipment (SABTE) devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes), in a manner that enables plug-and-play interoperability, is established in this standard. 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 SABTE. In this context, SABTE is defined as a device that is intended to alleviate the symptoms of a patient who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the patient. SABTE is primarily used in the home health-care environment by a lay operator without direct professional supervision.

Keywords: IEEE 11073-10424™, medical device communication, personal health devices, sleep apnoea breathing therapy equipment (SABTE)

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This introduction is not part of IEEE Std 11073-10424-2014, Health informatics—Personal Health Device Communication—Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE).

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between sleep apnoea breathing therapy equipment (SABTE) devices (agents) 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 SABTE. In this context, SABTE is defined as a device that is intended to alleviate the symptoms of a patient who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the patient. SABTE is primarily used in the home health-care environment by a lay operator without direct professional supervision.

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Health informatics—Personal health device communication

Part 10424: Device Specialization— Sleep Apnoea Breathing Therapy Equipment (SABTE)

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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 sleep apnoea breathing therapy equipment 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 sleep apnoea breathing therapy equipment. In this context, sleep apnoea breathing therapy equipment are defined as devices that are intended to alleviate the symptoms of a patient who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the patient. Sleep apnoea breathing therapy equipment are primarily used in the home health-care environment by a lay operator without direct professional supervision.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

1.1 Context

See IEEE Std 11073-20601a™-2010 for an overview of the environment within which this standard is written.¹

This standard defines the device specialization for the SABTE, 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 11073-20601a-2010, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B9] and ISO/IEEE 11073-20101:2004 [B10].² The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601a-2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B8] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601a-2010, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.³

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601a-2010, where zz can be any number from 01 to 99, inclusive.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

ISO/IEEE 11073-20601:2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.⁴

IEEE Std 11073-20601a™-2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol—Amendment 1.^{5, 6}

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

¹ Information on references can be found in Clause 2.

² The numbers in brackets correspond to those of the bibliography in Annex A.

³ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

⁴ ISO/IEEE publications are available from the ISO Central Secretariat (<http://www.iso.org/>). ISO/IEEE publications are also available in the United States from The Institute of Electrical and Electronics Engineers (<http://standards.ieee.org/>).

⁵ IEEE publications are available from The Institute of Electrical and Electronics Engineers (<http://standards.ieee.org/>).

⁶ The IEEE standards or products referred to in this clause are trademarks of The Institute of Electrical and Electronics Engineers, Inc.

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.⁷

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

airflow: Volume of air per minute that flows through the SABTE system, tubing, connectors, etc.

apnoea: An abnormal pattern of breathing characterized by a strong reduction of airflow compared to baseline.

apnoea hypopnoea index (AHI): An index of sleep apnoea severity that denotes the average number of apnoea and hypopnoea events per hour.

Cheyne-Stokes respiration (CSR): An abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in an apnoea.

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

compliance: A patient's adherence to a recommended course of treatment.

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

efficacy: Indicates the capacity for beneficial change (or therapeutic effect) of treatment with SABTE.

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

hypopnoea: An abnormal pattern of breathing characterized by a moderate reduction of airflow compared to baseline associated with an oxygen desaturation.

I:E ratio: Ratio between duration of the inspiration to the duration of the expiration during a breath cycle.

leakage: Volume of air lost per minute by unintentional and intentional leakage in SABTE system, tubing, connectors, etc.

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 computer system.

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**.

personal health device (PHD): A device used in personal health applications.

⁷*IEEE Standards Dictionary Online* subscription is available at:
http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html.

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

therapy pressure: Breathing system pressure delivered by the SABTE.

tidal volume: Volume of air moved into or out of a patient's lung during breathing.

3.2 Acronyms and abbreviations

AcSV	anti-cyclic servo ventilation
AHI	apnoea hypopnoea index
APAP	automatic positive airway pressure
APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
BiLevel PAP S	bi-level positive airway pressure spontaneous breathing
BiLevel PAP ST	bi-level positive airway pressure spontaneous-timed breathing
BiLevel PAP T	bi-level positive airway pressure timed breathing
BPAP	bi-level positive airway pressure
cAHI	central apnoea hypopnoea index
CPAP	continuous positive airway pressure
CSR	Cheyne-Stokes respiration
DIM	domain information model
EPAP	expiratory positive airway pressure
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statements
IPAP	inspiratory positive airway pressure
MDC	medical device communication
MDER	medical device encoding rule
MDS	medical device system
MOC	managed object class
oAHI	obstructive apnoea hypopnoea index
OID	object identifier
OSA	obstructive sleep apnoea
P	pressure
P50	50th percentile
P90	90th percentile
P95	95th percentile
PAP	positive airway pressure
PDU	protocol data unit

PHD	personal health device
RR	respiratory rate
RT-SA	real-time sample array
SABTE	Sleep Apnoea Breathing Therapy Equipment
SATD	Sleep Apnoea Therapy Device
uAHI	unclassified apnoea hypopnoea index
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices standards

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 11073-20601a-2010 for a description of the guiding principles for this series of ISO/IEEE 11073 PHD standards.

IEEE Std 11073-20601a-2010 supports the modeling and implementation of an extensive set of PHDs. This standard defines aspects of the SABTE device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD SABTE agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601a-2010 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601a-2010, are normatively defined in Annex C.

4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601a-2010, 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 11073-20601a-2010 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 11073-20601a-2010.

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 11073-20601a-2010 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 11073-20601a-2010.

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 optional 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 will comply with the IEC 60601-1:2007 [B2] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B3] and ISO/IEC 80601-2 [B7] series of standards. Software aspects may apply through standards such as IEC 62304:2006/EN 62304:2006 [B4].

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. Some relevant examples are ISO 14971:2007 [B6] and IEC 80001-1:2010 [B5]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

The definitions of sleep and associated events are based on the AASM Manual Version 2.0 [B1].

5. SABTE device concepts and modalities

5.1 General

This clause presents the general concepts of sleep apnoea breathing therapy equipment (SABTE). In the context of PHDs in the ISO/IEEE 11073 family of standards, SABTE is intended to alleviate the symptoms of patients who suffer from sleep apnoea by delivering a therapeutic breathing pressure to the patient. Sleep apnoea is the clinically significant intermittent absences of normal respiration occurring during sleep indicated by apnoea and hypopnoea events.

An apnoea (also known as *apnea* and *apnœa*) event is defined according to the AASM Manual [B1] as a reduction of airflow of $\geq 90\%$ compared to baseline during ≥ 10 s (see Figure 1). It can be caused by obstruction of the upper airway, resulting in *obstructive sleep apnoea* (OSA), or by a failure of the brain to initiate a breath, called *central sleep apnoea* (CSA), and is typically associated with heart failure patients. Fairly common are mixed apnoea, which consists of central and obstructive components. Often, co-morbidities are present in patients with OSA, which can contribute to their earlier onset including hypertension, heart failure, and diabetes if left untreated. It can cause and worsen other medical conditions, including hypertension, heart failure, and diabetes.

An hypopnoea (also known as *hypopnea* and *hypopnœa*) event is defined according to the AASM Manual [B1] as a reduction of airflow $\geq 30\%$ compared to baseline during ≥ 10 s and associated with an oxygen desaturation of $\geq 3\%$ from pre-event baseline (see Figure 1). Hypopnoeas are less severe than apnoeas (which is a more complete loss of airflow). It can likewise result in a decreased amount of air movement into the lungs and can cause oxygen levels in the blood to drop. Like apnoeas, hypopnoeas come in the three varieties: obstructive, central, or mixed. But it is more commonly due to partial obstruction of the upper airway.

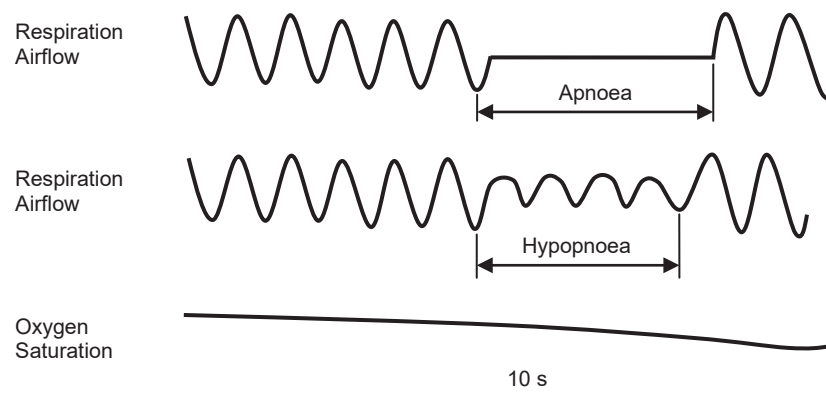


Figure 1—Apnoea and hypopnoea event

Cheyne-Stokes respiration (CSR) is defined according to the AASM Manual [B1] as a cyclic crescendo and decrescendo change in the breathing amplitude with duration of at least at least 10 consecutive minutes (see Figure 2). The pattern repeats usually with each cycle taking 30 s to 2 min.

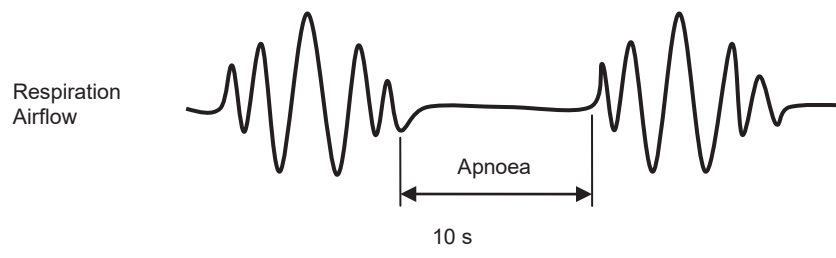


Figure 2—Cheyne-Stokes respiration

Dependent on severity of the sleep apnoea, different device types are used to treat the absences of normal respiration during sleep. This standard supports three types of sleep apnoea therapy devices (SATD) as follows:

- Continuous positive airway pressure (CPAP) device: The most common SATD used for obstructive sleep apnoea treatment is a CPAP device. This type of device is commonly used for people who are suffering from moderate or severe sleep apnoea. In general, this device uses a special mask that is customized to fit over a person's nose. It works by gently blowing air into the entry and passage of air into the airways. Through this action, air is pressed against the airway wall. At the same time, pressure of air is also set so it would be just enough to stop and prevent blockage and narrowing of airways during sleep.
- Auto-CPAP (APAP) device: For a CPAP device this therapy pressure is adjusted by a health-care professional normally in a sleep laboratory during the first nights and afterwards fixed. An Auto-CPAP device automatically adjusts the therapy pressure while the patient is sleeping to his current needs between limits given by the health-care professional.
- Bi-level positive airway pressure (BiLevel PAP) device: This device is commonly used for those unable to be adapted to using CPAP and Auto-CPAP, or for central sleep apnoea sufferers who need assistance for a weak breathing pattern. It provides more pressure during the inhalation phase, less during the exhalation phase. There are three sub-modes of BiLevel PAP: spontaneous breathing "S," timed breathing "T," and spontaneous-timed breathing "ST."
- Auto-Bi-level positive airway pressure (Auto-BiLevel PAP) device: Like the Auto-CPAP this type of SATD automatically adjusts the BiLevel PAP settings to the patient needs within given limits of a health-care professional.
- Anti-cyclic Servo Ventilation (AcSV) device: AcSV mode of therapy has been introduced to attempt to manage complex sleep apnoea and CSR.

Typically more complex devices support also the therapy modes of lower class devices. For example a BiLevel PAP device could also support the therapy modes Auto-CPAP and CPAP, whereas an Auto-CPAP device also supports the therapy mode CPAP. The combination of a SATD, mask, tube, and different accessories are called *sleep apnoea breathing therapy equipment* (SABTE) as shown in Figure 3.

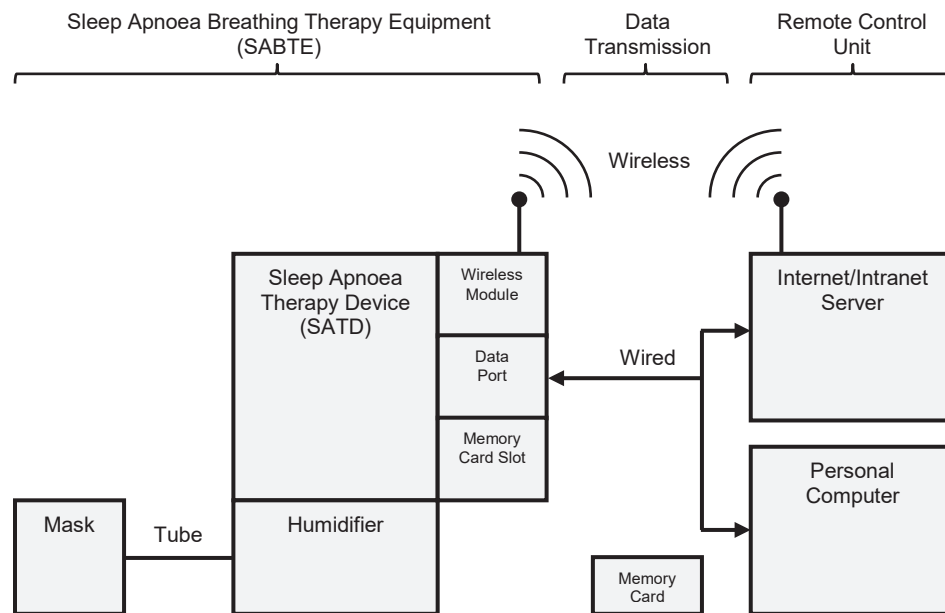


Figure 3—SABTE Interfaces

SABTE provide, detect, and store data for device handling and later analysis by health-care professionals, health-care service providers, payers, and patients. This standard supports reading out of the following:

- Device identification: Information identifying the device.
- Compliance monitoring: Accumulated data provided as a set of information on an off-line basis providing evidence of patient compliance with the sleep apnoea therapy.
- Efficacy monitoring: In addition to compliance monitoring data, providing parameters related to the effectiveness of the treatment.
- Service monitoring: Indicators relating to preventative and corrective maintenance of the device and its accessories.
- Device settings: Configuration of the SATD behavior and usage.
- Therapy settings: Configuration of the different therapy modes provided by SATD.

The data of compliance and efficacy monitoring is only generated during a therapy session (i.e., SATD is in device mode = therapy). A therapy session starts typically in the evening when the patient gets into bed and stops in the morning when the patient leaves the bed. During a therapy session the SATD might detect if a patient is using the device (e.g., via breathing patterns in the respiration airflow). If a SATD could not detect real patient usage then usage session is equal therapy session. Epochs and events according to the efficacy annotations could only occur during usage sessions. The difference between epochs and events are that epochs may overlap with events and epochs of other types (i.e., snoring or CSR epochs); events may overlap with epochs but not with other events (i.e., hypopnoea or apnoea events). Figure 4 provides an illustration of sessions, epochs, events, and their annotations.

IEEE Std 11073-10424-2014
Health informatics—Personal Health Device Communication—Part 10424: Device Specialization—Sleep Apnoea
Breathing Therapy Equipment (SABTE)

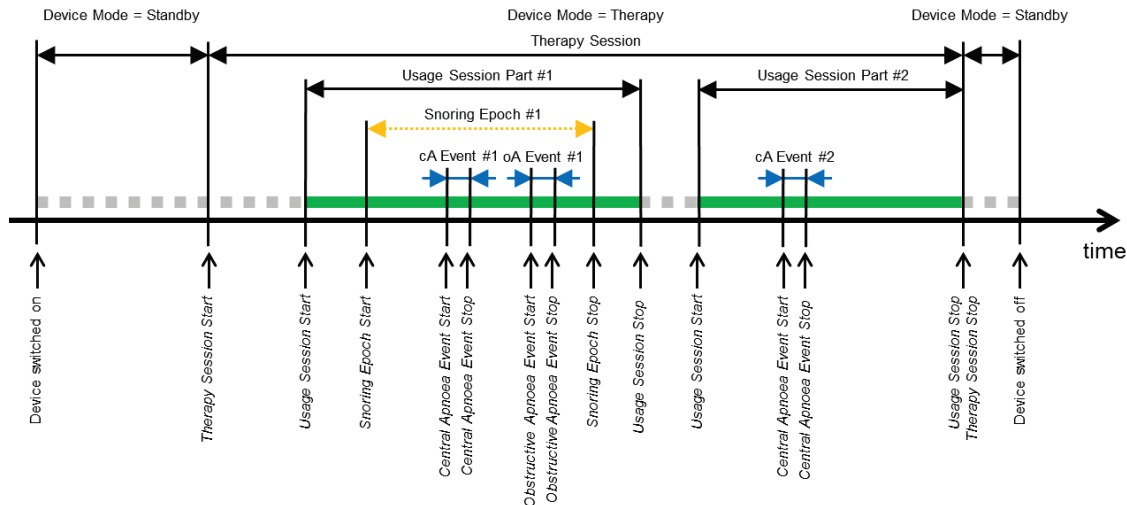


Figure 4—Sessions, epochs, events, and annotations

SABTE devices are used in different locations and by different users. There are three typical scenarios for the data transfer between a SABTE (i.e., agent) and a remote control unit (i.e., manager) as follows:

- In a non health-care environment (e.g., patient home) stored data is automatically transferred (e.g., once a day, week, month) via an attached remote control unit (e.g., mobile station with cellular network connection or modem with land line connection) to Internet server. Normally the data transfer happens after device usage and no user interaction is necessary.
- In a health-care office (e.g., service provider or physician office) stored data is requested by a remote control unit (e.g., personal computer, tablet). The remote control unit is controlled by health-care service provider or professional. Normally the data transfer happens during (e.g., mask fitting) or after (e.g., therapy control) device usage and the user selects the data to be transferred.
- In a clinic environment (e.g., sleep laboratory) current data is automatically transferred (e.g., as data stream) to a remote control unit (e.g., via Intranet server to a personal computer in a control room). The remote control unit is controlled by health-care professional. Normally the user only selects when the data transmission should be started or stopped.

This standard is not applicable to home health-care environment ventilators, ventilatory support equipment, emergency and transport ventilators, anesthetic ventilators, high-frequency jet ventilators, critical care ventilators, or high-frequency oscillatory ventilators.

5.2 Compliance monitoring

This clause describes the accumulated data as a set of information providing evidence of patient compliance (also known as *adherence*, *capacitance*, or *concordance*) with the sleep apnoea therapy.

5.2.1 Duration of patient use

The “duration of patient use” (also known as *compliance*) is the time period where SABTE was providing therapy to the patient (i.e., was used by the patient) during a usage session measured in minutes. It could be three distinct duration values, as follows:

- With attached humidifier
- Without attached humidifier
- Total duration

5.2.2 Compliance annotations

The “compliance annotations” indicate by time stamps the start and stop of a therapy session, usage session, and undetermined session.

5.3 Efficacy monitoring

In addition to the compliance monitoring data, this clause describes parameters related to the effectiveness of the treatment.

5.3.1 Apnoea hypopnoea index (AHI)

The *apnoea hypopnoea index* (AHI) is the total number of all apnoea and hypopnoea events occurring during a usage session divided by the hours of sleep.

Apnoea and hypopnoea events could be classified as obstructive, central or mixed based on the pattern of respiratory effort. If an event could not be classified it is named unclassified.

Based on this definition the *central apnoea hypopnoea index* (cAHI) is the total number of all central apnoea and central hypopnoea events occurring during a usage session divided by the hours of sleep. The *obstructive apnoea hypopnoea index* (oAHI) counts all mixed and obstructive events. All unclassified apnoea and hypopnoea events are summarized in the *unclassified apnoea hypopnoea index* (uAHI).

For further details see AASM Manual, Version 2.0 [B1].

5.3.2 Therapy pressure

“Therapy pressure” is the pressure delivered by the SABTE at the patient interface (e.g., mask) measured in hPa. It could be the instantaneous value or a statistical parameter of a usage session (i.e., minimum, maximum, arithmetic mean, P50, P90 and P95).

The instantaneous value is often fluctuating and is therefore filtered (e.g., moving average) reducing higher frequency content for the purpose to display a number.

The percentile therapy pressure is the pressure at which the patient was supplied that percent of time at or below. For instance, if the data show a 90 percentile therapy pressure (P90) of 11 hPa, it means that 90% of the time the patient was using the SABTE the patient was receiving a breathing system of 11 hPa or less.

5.3.3 Therapy pressure waveform

There are applications where it is desired to visualize the sequence of samples related to the time-varying therapy pressure as a waveform. It could be distinct in target therapy pressure (i.e., what is the aim of the therapy algorithm) and the current therapy pressure (i.e., what is physically possible, for example, because of high leakage). The unit of “therapy pressure waveform” is hPa. The waveform is typically used to display a curve.

5.3.4 Leakage

The “leakage” (also known as *leak*) is the volume of air lost per minute by unintentional and intentional leakage in SABTE system, tubing, connectors, etc. measured in L/min. Intentional leakage is that leak normally due to the use of a vented mask. Unintentional leakage is that due to other circumstances such as poor mask fit or similar issues. It could be the instantaneous value or a statistical parameter of a usage session (i.e., minimum, maximum, arithmetic mean, P50, P90 and P95).

The instantaneous value is often fluctuating and is therefore filtered (e.g., moving average) reducing higher frequency content for the purpose to display a number.

The percentile leakage is the air escaping that percent of time at or below. For instance, if the data show a 90 percentile leakage (P90) of 5 L/min, it means that 90 percent of the time the leakage was of 5 L/min or less.

5.3.5 Leakage waveform

There are applications where it is desired to visualize the sequence of samples related to the time-varying leakage as a waveform. The unit of the “leakage waveform” is L/min. The waveform is typically used to display a curve.

5.3.6 Airflow waveform

There are applications where it is desired to visualize the sequence of samples related to the time-varying airflow (also known as *airway flow wave*) as a waveform. It could be distinct in total device airflow (i.e., respiration airflow, purge flow and leakage), device airflow without purge flow (i.e., respiration airflow and leakage) and the respiration airflow. The unit of the “airflow waveform” is L/min. The waveform is typically used to display a curve.

5.3.7 Respiratory rate

The “respiratory rate” (RR, also known as *ventilation rate*, *respiration rate*, *breathing rate*, *breathing frequency*, and *respiratory frequency*) is the number of breaths a patient takes during one minute measured in breaths per minute (bpm). It could be the instantaneous value or a statistical parameter of a usage session (i.e., minimum, maximum, arithmetic mean, P50, P90 and P95).

The instantaneous value is often fluctuating and is therefore filtered (e.g., moving average) reducing higher frequency content for the purpose to display a number.

5.3.8 Tidal volume

The “tidal volume” (VT, also known as *respiratory tidal volume*) is the volume of air moved into or out of a patient’s lung during breathing measured in ml. It could be the instantaneous value or a statistical parameter of a usage session (i.e., minimum, maximum, arithmetic mean, P50, P90, and P95).

The instantaneous value is often fluctuating and is therefore filtered (e.g., moving average) reducing higher frequency content for the purpose to display a number.

5.3.9 Respiratory minute volume

The “respiratory minute volume” (RMV or $\dot{V}$, also known as *minute ventilation* and *expired minute volume*) is the volume of air inhaled or exhaled from a patient’s lung per minute measured in L/min. It could be the instantaneous value or a statistical parameter of a usage session (i.e., minimum, maximum, arithmetic mean, P50, P90, and P95).

The instantaneous value is often fluctuating and is therefore filtered (e.g., moving average) reducing higher frequency content for the purpose to display a number.

5.3.10 I:E ratio

The “I:E ratio” (TI/TE, Ti/T, or TiT) is the ratio between duration of the inspiration to the duration of the expiration during a breath cycle measured in percentage. In normal spontaneous breathing, the expiratory time is about twice as long as the inspiratory time. This gives an I:E ratio of 1:2 and is read “one to two.” But the value is stored and transmitted as 50%. It could be the instantaneous value or a statistical parameter of a usage session (i.e., minimum, maximum, arithmetic mean, P50, P90, and P95).

The instantaneous value is often fluctuating and is therefore filtered (e.g., moving average) reducing higher frequency content for the purpose to display a number.

5.3.11 Snoring duration

The “snoring duration” is the time period where snoring occurs during a usage session measured in minutes. It is the total sum of all snoring periods during a therapy session.

5.3.12 CSR duration

The “CSR duration” is the time period where CSR occurs during a usage session measured in minutes. It is the total sum of all CSR periods during a therapy session.

5.3.13 Efficacy annotations

The “efficacy annotations” indicates by time stamps the start and stop of an artifact breathing epoch, spontaneous breathing epoch, timed breathing epoch, snoring epoch, CSR epoch, undetermined epoch, flow limitation event, unclassified hypopnoea event, obstructive hypopnoea event, central hypopnoea event, unclassified apnoea event, obstructive apnoea event, mixed apnoea event, central apnoea event, and undetermined event during a usage session.

5.4 Service monitoring

This subclause describes indicators relating to preventative and corrective maintenance of the device and its accessories.

5.4.1 Duration of flow generation

The “duration of flow generation” (also known as *operating hours counter*) is the time period where the SABTE was powered on and was providing airflow measured in minutes. It is the sum of duration of all operating periods (e.g., therapy, mask fitting, and drying periods) during the lifetime of the flow generator.

5.4.2 PHD DM status

The “PHD DM status” allows generic notification handling for PHDs. It indicates by time stamps the raising of info, warning, error, service, and undetermined messages.

5.5 Device settings

This subclause describes the configuration of the SATD behavior and usage.

5.5.1 Device mode set

The “device mode set” is the current active setting of the SABTE device state. It is a selection out of the following:

- Standby
- Therapy
- Mask fitting
- Drying
- Exporting
- Undetermined

The mode “standby” means that the SATD is powered on, the flow generation is off, and the SATD is ready to use. The mode “therapy” means that the flow generation of the SATD is on and the SABTE is providing therapy to a patient. The mode “mask fitting” is a special device mode that is used to check if the mask position is O.K. and the leakage is in a normal range. The mode “drying” is a special device mode that is used to dry the breathing system part like turbine and tube. The mode “exporting” is a special device mode for devices that are not capable of exporting data during other modes. It is used to indicate that the SATD is currently busy with storing data for example on a memory card or is transmitting data via wire or wireless. If the current device mode could not be detected or is not supported by this standard, the mode “undetermined” is used.

5.6 Therapy settings

This subclause describes the configuration of the different therapy modes provided by SATD.

5.6.1 Therapy mode set

The “therapy mode set” is the current active setting of the SABTE therapy state. It is a selection out of the following:

- CPAP
- Auto-CPAP
- BiLevel PAP S
- BiLevel PAP T
- BiLevel PAP ST
- Auto-BiLevel PAP S
- Auto-BiLevel PAP T
- Auto-BiLevel PAP ST
- AcSV
- Undetermined

The mode “CPAP” stands for Continuous Positive Airway Pressure, which means fixed therapy pressure during a therapy session. In the mode “Auto-CPAP” (also known as *APAP*) the therapy pressure is a fixed therapy pressure level but the level will be automatically adapted during a therapy session to the patient needs. The mode “BiLevel PAP” (also known as *BPAP* or *Bi-Level*) means that the therapy pressure is switched between two levels. There are three sub-modes of BiLevel PAP: spontaneous breathing “S,” timed breathing “T,” and spontaneous-timed breathing “ST.” In addition, Auto-BiLevel PAP automatically adapt the therapy pressure levels during a therapy session to the patient needs. The mode “AcSV” (also known as *Anti-cyclic Servo Ventilation* or *Adaptive Servo Ventilation*) is a form of closed-loop mechanical ventilation, pressure preset, and volume or flow cycled. If the current therapy mode could not be detected or is not supported by this standard, the mode “undetermined” is used.

Therapy modes apply when the “device mode set” is “therapy” (see 5.6.5, 5.6.8, and 5.6.9).

5.6.2 Humidifier level set

“Humidifier level set” is a comfort feature of a SATD. If a humidifier is attached and filled with water, it allows increasing the humidity of the breathing air.

The “humidifier level set” is the current active setting of the SABTE humidifier level set as a percentage of the maximum possible setting. It could be one or more settings of the following:

- Humidifier relative stage (e.g., heater power)
- Humidifier relative air output temperature
- Humidifier relative humidity

A value of 0% means minimal possible humidifier level (i.e., disabled, relative stage of 0% = “off,” relative temperature of 0% = 0 °C, relative humidity of 0 %). A value of 100% means maximal possible humidifier level (i.e., automatically adjusted, relative stage of 100% = “maximum,” theoretically relative temperature of 100% = 100 °C, theoretically relative humidity of 100%).

5.6.3 Autostart/-stop set

“Autostart/-stop set” is a comfort feature of a SATD. It allows starting the therapy without pushing a button only via breathing into the mask.

The “Autostart/-stop set” is the current active setting of the SABTE autostart and autostop feature. It is a selection out of the following:

- Autostart off and autostop off
- Autostart off and autostop on
- Autostart on and autostop off
- Autostart on and autostop on

“Autostart on” means that if the “device mode set” is “standby” and a patient starts using the SABTE, the SATD detects it and automatically switches into device mode “therapy.” “Autostop on” means that if the “device mode set” is “therapy” and the patient stops using the SABTE, the SATD automatically switches into device mode “standby.” “Autostart off” or “autostop off” mean that this feature is disabled.

5.6.4 Ramp settings

“Ramp” is a comfort feature on a SATD. The ramp function increases the pressure gradually until it reaches the prescribed therapy pressure.

5.6.4.1 Ramp start pressure set

The “ramp start pressure set” is the therapy pressure at the start of the sleep ramp set in hPa.

This setting is normally used in combination with “ramp duration set” (see 5.6.4.2).

5.6.4.2 Ramp duration set

The “ramp duration set” is the length of the sleep ramp set in minutes. A value of 0 min means that the sleep ramp is disabled.

This setting is normally used in combination with “ramp start pressure set” (see 5.6.4).

5.6.5 Pressure adaption settings

“Pressure adaption” is a comfort feature of a SATD. It reduces the pressure during expiration used as exhalation relief.

5.6.5.1 Pressure adaption level set

The “pressure adaption level set” (also known as *pressure reduction level*) is the current active setting of the pressure adaption during expiration and/or inspiration set as a percentage of the maximum setting. A value of 0% means minimal possible pressure adaption level (e.g., disabled), whereas a value of 100% means maximal possible pressure reduction (e.g., automatically adjusted).

This setting is normally used in combination with “pressure adaption freeze set” (see 5.6.5.2).

5.6.5.2 Pressure adaption freeze set

The “pressure adaption freeze set” is the current active setting of the pressure adaption freeze feature. It is a selection between “on” or “off.” A value “off” means that the patient could change the setting of the “pressure adaption level” setting. A value “on” means that only a health-care professional could change the setting of the “pressure adaption level.”

This setting is normally used in combination with “pressure adaption level set” (see 5.6.5.1).

5.6.6 Inspiration pressure rise set

The “inspiration pressure rise set” (P Rise) is the current active setting of the pressure rise during inspiration set as a percentage of the maximum setting. A value of 0% means minimal possible inspiration pressure rise (e.g., disabled), whereas a value of 100% means maximal possible inspiration pressure rise (e.g., automatically adjusted).

5.6.7 CPAP settings

The “CPAP settings” contain the setting of “P CPAP Set.”

Typically in CPAP mode also the comfort features “humidifier level set,” “autostart/-stop set,” “ramp start pressure set,” “ramp duration set,” “pressure adaption level set” and “pressure adaption freeze set” are available.

5.6.7.1 P CPAP Set

The “P CPAP Set” is the target therapy pressure during a therapy session set in hPa.

5.6.8 Auto-CPAP settings

The “auto-CPAP settings” contain the setting of “Pmin APAP Set,” “Pmax APAP Set,” and “inspiration pressure rise set.” These are atomic settings that mean that only all values together have a useful meaning.

Typically in Auto-CPAP mode also the comfort features “humidifier level set,” “autostart/-stop set,” “ramp start pressure set,” “ramp duration set,” “pressure adaption level set,” and “pressure adaption freeze set” are available.

5.6.8.1 Pmin APAP set

The “Pmin APAP set” is the lower bound of the target therapy pressure during a therapy session set in hPa.

5.6.8.2 Pmax APAP set

The “Pmax APAP set” is the upper bound of the target therapy pressure during a therapy session set in hPa.

5.6.9 BiLevel PAP S / T / ST settings

The “BiLevel PAP settings” contain the setting of “P IPAP set,” “P EPAP set,” “respiratory rate set,” “I:E ratio set,” “trigger sensitivity set” and “inspiration pressure rise set.” These are atomic settings, which means that only all values together have a useful meaning.

Typically in BiLevel PAP S / T / ST mode also the comfort features “humidifier level set,” “auto-start/-stop set,” “ramp start pressure set” and “ramp duration set” are available.

5.6.9.1 P IPAP set

The “P IPAP set” is the target inspiration therapy pressure during a breath cycle set in hPa.

5.6.9.2 P EPAP set

The “P EPAP set” is the target expiration therapy pressure during a breath cycle set in hPa.

5.6.9.3 Respiratory rate set

The “respiratory rate set” (RR set) is the target breathing frequency during a therapy session set in breaths per minute (bpm) (see 5.3.7).

5.6.9.4 I:E ratio set

The “I:E ratio set” is the target ratio between duration of the inspiration to the duration of the expiration during a breath cycle set in percentage (see 5.3.10).

5.6.9.5 Trigger sensitivity set

The “trigger sensitivity set” is the target inspiratory and expiratory trigger sensitivity set in percentage of the maximum setting. A value of 0% means minimal possible trigger sensitivity (e.g., disabled), whereas a value of 100% means maximal possible trigger sensitivity (e.g., automatically adjusted).

6. Sleep apnoea breathing therapy equipment domain information model

6.1 Overview

This clause describes the domain information model of the sleep apnoea breathing therapy equipment (SABTE).

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601a-2010.

6.3 Object instance diagram

The object instance diagram of the SABTE domain information model, defined for the purposes of this standard, is shown in Figure 5.

The objects of the DIM, as shown in Figure 5, are described in 6.5 through 6.10. This includes the medical device system (MDS) object (6.5), the numeric objects (6.6), the RT-SA objects (6.7), the enumeration objects (6.8), the PM-store objects (6.9), and the scanner objects (6.10). Subclause 6.11 specifies the rules for extending the SABTE information model beyond elements as described in this standard. Each subclause that describes an object of the SABTE 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 11073-20601a-2010.
- 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 mean: M—Attribute is mandatory, C—Attribute is conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601a-2010 is referenced, then it contains the conditions), R—Attribute is recommended, NR—Attribute is not recommended, and 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. For attributes with qualifiers set to R or NR, underlying requirements stated in the Remark and Value column in IEEE Std 11073-20601a-2010 shall be followed.

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.

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Breathing Therapy Equipment (SABTE)

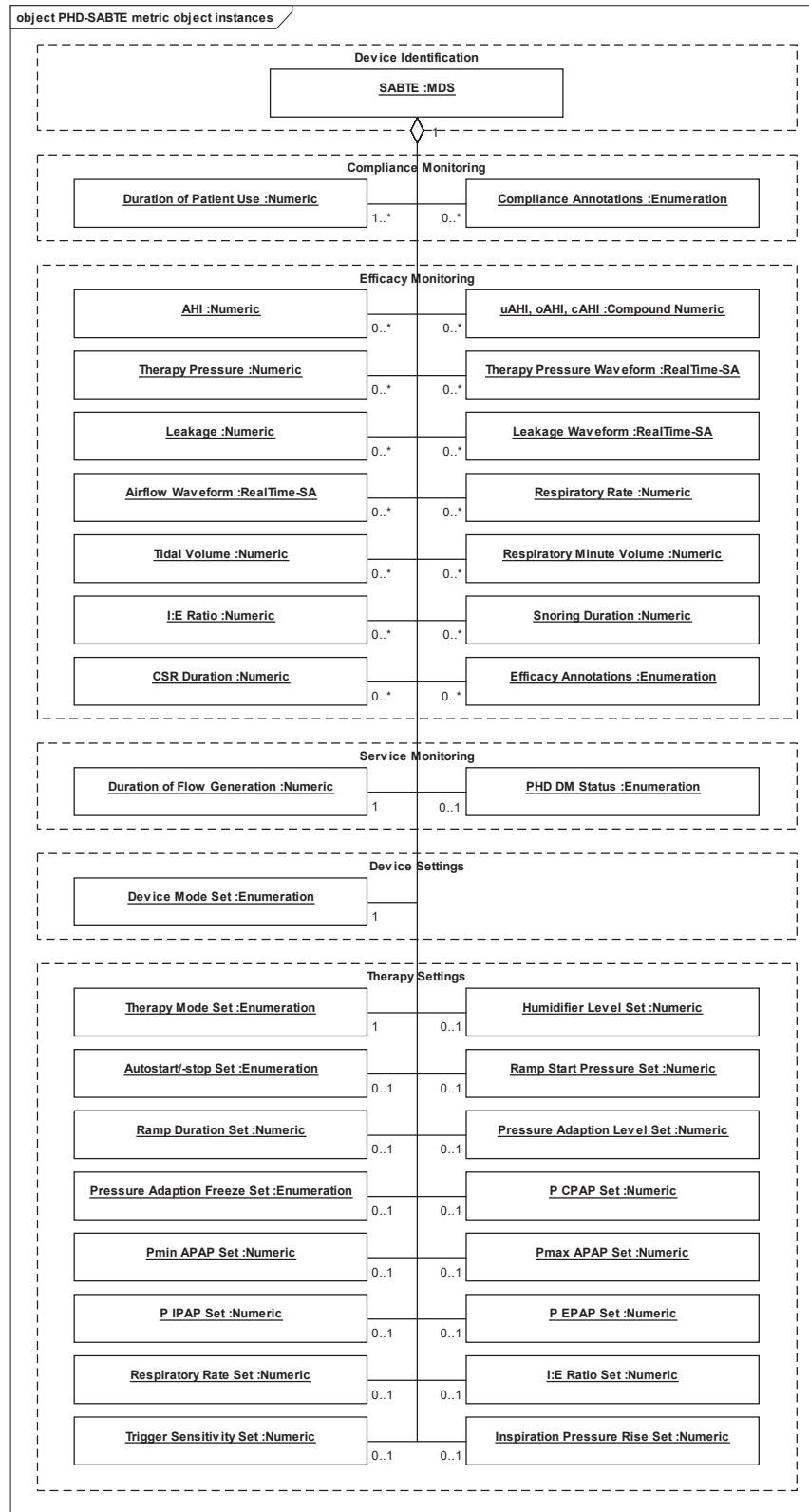


Figure 5—SABTE—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601a-2010, 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 (such as this standard) 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.

One standard configuration is defined in this standard. The standard configuration 2400 (0x0960) contains the SABTE objects “duration of patient use (total)” (see 6.7.2), “duration of flow generation” (6.7.13), “device mode set” (see 6.9.5), and “therapy mode set” (see 6.9.6).

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.

6.5 Profile

6.5.1 General

A profile further constrains the objects, services, and communication model of a specialization. By profiling the device specialization, the standard provides more guidance on the specific mandatory objects that shall be implemented, the objects that are optional, and the objects that are not required. This standard defines three profiles: the CPAP profile (see 6.5.2), the Auto-CPAP profile (see 6.5.3), and the BiLevel PAP profile (see 6.5.4). A SABTE device may implement one or more of these three profiles.

6.5.2 CPAP profile

The metric object instance diagram of the CPAP profile domain information model is shown in Figure 6. A SABTE device implementing the CPAP profile shall implement in addition to the standard configuration objects (see 6.4) the object “P CPAP set.” The objects “Pmin APAP set,” “Pmax APAP set,” “P IPAP set,” “P EPAP set,” “respiratory rate set,” “I:E ratio set,” “trigger sensitivity set,” and “inspiration pressure rise set” are not required. The nomenclature code to identify the CPAP profile is MDC_DEV_SUB_SPEC_PROFILE_CPAP. For the CPAP profile, currently no standard configuration is defined.

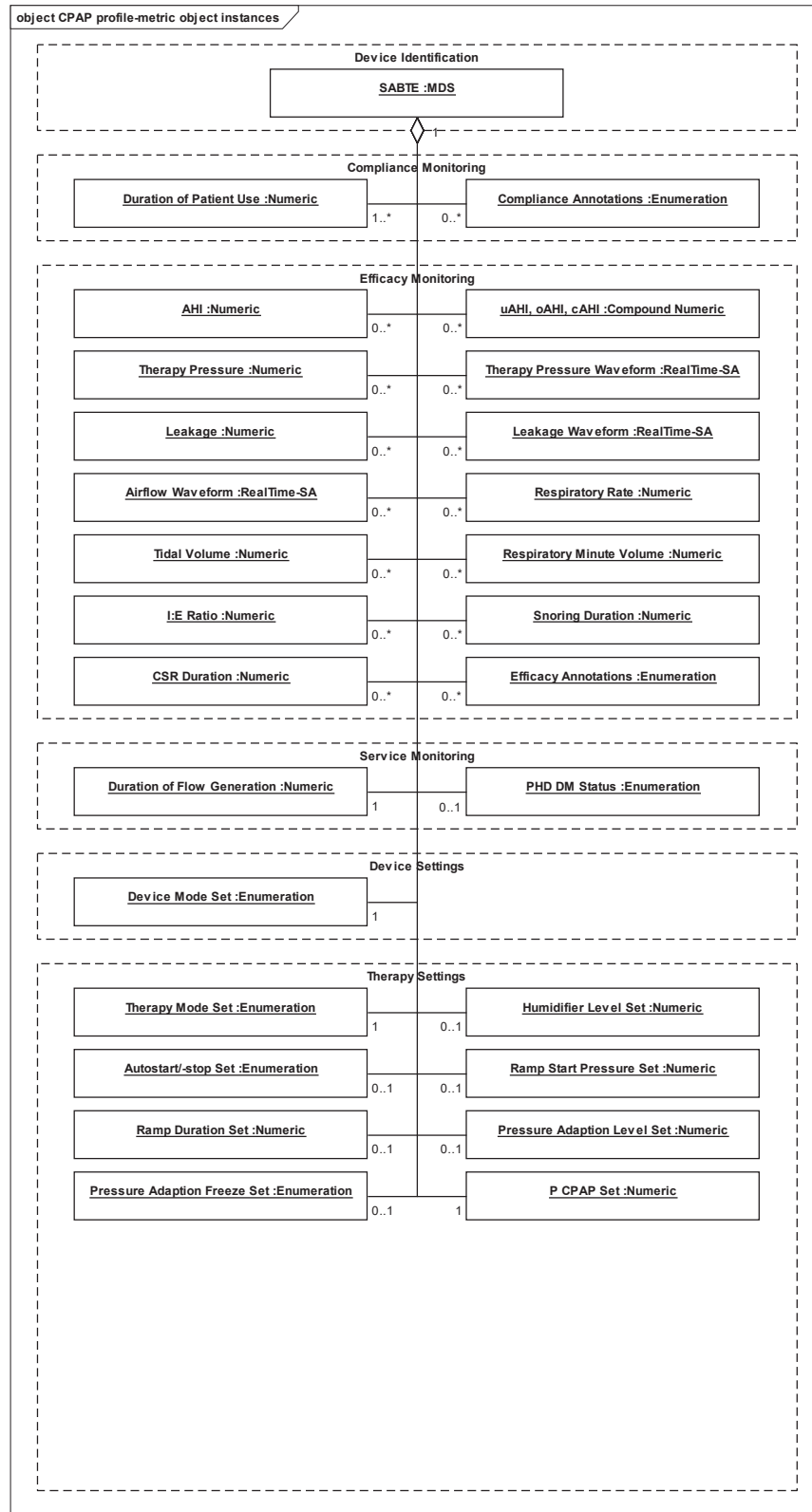


Figure 6—CPAP profile—metric objects

6.5.3 Auto-CPAP profile

The metric object instance diagram of the Auto-CPAP profile domain information model is shown in Figure 7. A SABTE device implementing the Auto-CPAP profile shall implement in addition to the standard configuration objects (see 6.4) the objects “Pmin APAP set” and “Pmax APAP set.” The objects “P CPAP set,” “P IPAP set,” “P EPAP set,” “respiratory rate set,” “I:E ratio set,” and “trigger sensitivity set” are not required. The nomenclature code to identify the Auto-CPAP profile is MDC_DEV_SUB_SPEC_PROFILE_CPAP_AUTO. For the Auto-CPAP profile, currently no standard configuration is defined.

6.5.4 BiLevel PAP profile

The metric object instance diagram of the BiLevel PAP profile domain information model is shown in Figure 8. A SABTE device implementing the BiLevel PAP profile shall implement in addition to the standard configuration objects (see 6.4) the objects “P IPAP set” and “P EPAP set.” The objects “pressure adaption level set,” “pressure adaption freeze set,” “P CPAP set,” “Pmin APAP set,” and “Pmax APAP Set” are not required. The nomenclature code to identify the BiLevel PAP profile is MDC_DEV_SUB_SPEC_PROFILE_BPAP. For the BiLevel PAP profile, currently no standard configuration is defined.

6.6 Medical device system object

6.6.1 MDS object attributes

Table 1 summarizes the attributes of the SABTE MDS object. The nomenclature code to identify the MDS class is MDC_MOC_VMS_MDS_SIMP.

Table 1—MDS object attributes

Attribute name	Value	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601a-2010.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_SABTE, 1} and Profile value: {MDC_DEV_SUB_SPEC_PROFILE_CPAP, 1}, {MDC_DEV_SUB_SPEC_PROFILE_CPAP_AUTO, 1} or {MDC_DEV_SUB_SPEC_PROFILE_BPAP, 1}	M
System-Model	{“Manufacturer,” “Model”}.	M
System-Id	Extended unique identifier (64-bits) (EUI-64) See IEEE Std 11073-20601a-2010.	M
Dev-Configuration-Id	Standard config: 0x0960 (2400) Extended configs: 0x4000-0x7FFF.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Production-Specification	See IEEE Std 11073-20601a-2010.	M
Mds-Time-Info	See IEEE Std 11073-20601a-2010.	C
Date-and-Time	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time	See IEEE Std 11073-20601a-2010.	R

Table 1—MDS object attributes (*continued*)

Attribute name	Value	Qual.
Relative-Time	See IEEE Std 11073-20601a-2010.	C
HiRes-Relative-Time	See IEEE Std 11073-20601a-2010.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601a-2010.	C
Power-Status	See IEEE Std 11073-20601a-2010.	O
Battery-Level	See IEEE Std 11073-20601a-2010.	O
Remaining-Battery-Time	See IEEE Std 11073-20601a-2010.	O
Reg-Cert-Data-List	See IEEE Std 11073-20601a-2010.	O
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

In the response to a Get MDS Object command, only implemented attributes and their corresponding values are returned.

See IEEE Std 11073-20601a-2010 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

If an agent implements multiple IEEE 11073-104zz specializations, System-Type-Spec-List is a list of type/version pairs, each referencing the respective device specialization and version of that specialization. For a SABTE agent, a specialization value of MDC_DEV_SPEC_PROFILE_SABTE shall be included in the System-Type-Spec-List attribute as shown in Table 1. Additionally, the value(s) for the supported profile(s) shall be included in the System-Type-Spec-List attribute. The profile value for a SABTE agent supporting the CPAP profile shall be set to MDC_DEV_SUB_SPEC_PROFILE_CPAP. The profile value for a SABTE agent supporting the Auto-CPAP profile shall be set to MDC_DEV_SUB_SPEC_PROFILE_CPAP_AUTO. The profile value for a SABTE agent supporting the BiLevel PAP profile shall be set to MDC_DEV_SUB_SPEC_PROFILE_BPAP.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a SABTE agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601a-2010) as shown in Table 1.

The agent sends the Dev-Configuration-Id during the Associating state (see 8.3) to identify its configuration for the duration of the association. If the manager already holds the configuration information relating to the Dev-Configuration-Id, it recognizes the Dev-Configuration-Id and the Configuring state (see 8.4) is skipped, and the agent and manager then enter the Operating state. If the manager does not recognize the Dev-Configuration-Id, the agent and manager enter the Configuring state.

Agents following this device specialization shall include a component to the Production-Specification attribute with the spec-type field set to serial-number and the prod-spec field set to the serial number of the device. Furthermore they shall include a component to the Production-Specification MDS-object attribute with the spec-type field set to fw-revision and the prod-spec field set to the firmware identifier of the device (see ISO/IEC 80601-2-70 [B7]).

SABTE should use Base-Offset-Time to handle daylight saving time and time-zone traveling.