
**Health informatics — Personal health
device communication —**

**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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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.

Contents

1. Overview	1
1.1 Scope	1
1.2 Purpose	2
1.1 Context	2
2. Normative references.....	2
3. Definitions, acronyms, and abbreviations	3
3.1 Definitions	3
3.2 Acronyms and abbreviations	4
4. Introduction to ISO/IEEE 11073 personal health devices standards	5
4.1 General	5
4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs	5
4.3 Compliance with other standards.....	6
5. SABTE device concepts and modalities.....	7
5.1 General	7
5.2 Compliance monitoring	10
5.3 Efficacy monitoring	11
5.4 Service monitoring	13
5.5 Device settings.....	14
5.6 Therapy settings.....	14
6. Sleep apnoea breathing therapy equipment domain information model.....	18
6.1 Overview	18
6.2 Class extensions.....	18
6.3 Object instance diagram	19
6.4 Types of configuration.....	21
6.5 Profile	21
6.6 Medical device system object.....	23
6.7 Numeric objects.....	29
6.8 Real-time sample array objects.....	48
6.9 Enumeration objects	50
6.10 PM-store objects	60
6.11 Scanner objects	65
6.12 Class extension objects	68
6.13 SABTE information model extensibility rules	69
7. SABTE service model	69
7.1 General	69
7.2 Object access services.....	69
7.3 Object access event report services	72
8. SABTE communication model.....	73
8.1 Overview	73
8.2 Communications characteristics	73
8.3 Association procedure	73
8.4 Configuring procedure.....	75
8.5 Operating procedure	78
8.6 Time synchronization	79

9. Test associations	79
9.1 Behavior with standard configuration.....	79
9.2 Behavior with extended configurations	79
10. Conformance	80
10.1 Applicability	80
10.2 Conformance specification	80
10.3 Levels of conformance	80
10.4 Implementation conformance statements	81
Annex A (informative) Bibliography	86
Annex B (normative) Any additional ASN.1 definitions	87
B.1 Efficacy annotations bit mapping.....	87
B.2 Compliance annotations bit mapping.....	88
B.3 PHD DM status bit mapping	88
B.4 Autostart/-stop bit mapping	89
Annex C (normative) Allocation of identifiers.....	90
C.1 General	90
C.2 Definitions of terms and codes.....	90
C.3 Systematic derivations of terms and codes	93
Annex D (informative) Message sequence examples	101
Annex E (informative) Protocol data unit examples	103
E.1 General	103
E.2 Association information exchange	103
E.3 Configuration information exchange.....	106
E.4 GET MDS attributes service	109
E.5 Data reporting.....	110
E.6 Disassociation	111

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.