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Zdravotnická informatika – Komunikační zařízení pro osobní zdravotní péči – Část 10424: Specializované zařízení – Zařízení pro léčbu krátkodobé zástavy dechu během spánku (SABTE)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11073-10424:2016/AC

January 2018
Janvier 2018
Januar 2018

ICS 35.240.80

English version
Version Française
Deutsche Fassung

Health informatics - Personal health device communication - Part 10424: Device specialization - Sleep apnoea breathing therapy equipment (SABTE) - Technical Corrigendum 1 (ISO/IEEE 11073-10424:2016/Cor 1:2018)

Informatique de la santé - Communication entre dispositifs de santé personnels - Partie 10424: Spécialisation de dispositif - Équipement de thérapie respiratoire de l'apnée du sommeil (SABTE) - Rectificatif technique 1 (ISO/IEEE 11073-10424:2016/Cor 1:2018)

This corrigendum becomes effective on 24 January 2018 for incorporation in the official English version of the EN.

Ce corrigendum prendra effet le 24 janvier 2018 pour incorporation dans la version anglaise officielle de la EN.

Die Berichtigung tritt am 24. Januar 2018 zur Einarbeitung in die offizielle Englische Fassung der EN in Kraft.

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Ref. No.:EN ISO 11073-10424:2016/AC:2018 E

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European foreword

The text of ISO/IEEE 11073-10424:2016/Cor 1:2018 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-10424:2016/AC:2018 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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INTERNATIONAL STANDARD

ISO/IEEE 11073-10424

First edition
2016-06-15

Corrigendum 1
2018-01

Health informatics — Personal health device communication —

Part 10424: Device specialization — Sleep apnoea breathing therapy equipment (SABTE)

TECHNICAL CORRIGENDUM 1

Informatique de la santé — Communication entre dispositifs de santé personnels —

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

RECTIFICATIF TECHNIQUE 1

Reference number
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IEEE Std 11073-10424™-2014/Cor 1-2017
(Corrigendum to
IEEE Std 11073-10424-2014)

Health informatics—Personal health device communication

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

Corrigendum 1

Sponsor

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

Approved 23 March 2017

IEEE-SA Standards Board

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 IEEE Std 11073-10424-2014. 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. IEEE Std 11073-10424-2014 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. This corrigendum corrects errors that have been identified in IEEE Std 11073-10424-2014 to make it easier to implement the standard in an interoperable fashion.

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

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Introduction

This introduction is not part of IEEE Std 11073-10424-2014/Cor 1-2017, IEEE Standard for Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE)—Corrigendum 1.

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, IEEE Std 11073-10424-2014 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. IEEE Std 11073-10424-2014 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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Contents

Health informatics—Personal health device communication

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

Corrigendum 1

NOTE—The editing instructions contained in this **corrigendum** define how to merge the material contained therein into the existing base standard and its amendments to form the comprehensive standard.

The editing instructions are shown in ***bold italic***. Four editing instructions are used: change, delete, insert, and replace. ***Change*** is used to make corrections in existing text or tables. The editing instruction specifies the location of the change and describes what is being changed by using ~~strikethrough~~ (to remove old material) and underscore (to add new material). ***Delete*** removes existing material. ***Insert*** adds new material without disturbing the existing material. Insertions may require renumbering. If so, renumbering instructions are given in the editing instruction. ***Replace*** is used to make changes in figures or equations by removing the existing figure or equation and replacing it with a new one. Editing instructions, change markings, and this NOTE will not be carried over into future editions because the changes will be incorporated into the base standard.

6. Sleep apnoea breathing therapy equipment domain information model

6.7 Numeric objects

6.7.3 Apnoea hypopnoea index (AHI)

Change the last word in the following sentence as shown:

The Type attribute is used to distinguish the modality of particular AHI between total AHI (i.e., MDC_SABTE_AHI_TOTAL), uAHI (i.e., MDC_SABTE_AHI_UNCLASS), oAHI (i.e., MDC_SABTE_AHI_OBSTRUC), or cAHI (i.e., MDC_SABTE_AHI_CENTRAL).

Change Table 7 as shown:

Table 7—AHI numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_SABTE_AHI_TOTAL} or {MDC_PART_PHD_DM, MDC_SABTE_AHI_UNCLASS} or {MDC_PART_PHD_DM, MDC_SABTE_AHI_OBSTRUC} or {MDC_PART_PHD_DM, MDC_SABTE_AHI_CENTRAL}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-acc-manager-initiated, mss-acc-agent-initiated, mss-cat-calculation.	M
Unit-Code	MDC_DIM_EVT_PER_HR	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

6.7.4 Therapy Pressure

Change Table 9 and the text immediately following it as shown:

Table 9—Therapy pressure numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_SABTE_PRESS_INSTANT} or ~~{MDC_PART_PHD_DM, MDC_SABTE_PRESS_MIN}~~ ~~or~~ {MDC_PART_PHD_DM, MDC_SABTE_PRESS_MAX} or {MDC_PART_PHD_DM, MDC_SABTE_PRESS_MIN} or {MDC_PART_PHD_DM, MDC_SABTE_PRESS_MEAN} or {MDC_PART_PHD_DM, MDC_SABTE_PRESS_P50} or {MDC_PART_PHD_DM, MDC_SABTE_PRESS_P90} or {MDC_PART_PHD_DM, MDC_SABTE_PRESS_P95}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-manager-initiated, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_HECTO_PASCAL	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

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

The Type attribute is used to distinguish the modality of particular therapy pressure between instantaneous value (i.e., MDC_SABTE_PRESS_INSTANT), ~~minimum of a usage session (i.e., MDC_SABTE_PRESS_MIN),~~ maximum of a usage session (i.e., MDC_SABTE_PRESS_MAX), minimum of a usage session (i.e., MDC_SABTE_PRESS_MIN), arithmetic mean of a usage session (i.e., MDC_SABTE_PRESS_MEAN), 50th percentile of a usage session (i.e., MDC_SABTE_PRESS_P50), 90th percentile of a usage session (i.e., MDC_SABTE_PRESS_P90), or 95th percentile of a usage session (i.e., MDC_SABTE_PRESS_P95).

6.7.5 Leakage

Change Table 10 and the text immediately following it as shown:

Table 10—Leakage numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM MDC_SABTE_VOL_LEAK_INSTANT} or ~~{MDC_PART_PHD_DM, MDC_SABTE_VOL_LEAK_MIN}~~ ~~or~~ {MDC_PART_PHD_DM, MDC_SABTE_VOL_LEAK_MAX} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_LEAK_MIN} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_LEAK_MEAN} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_LEAK_P50} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_LEAK_P90} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_LEAK_P95}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-manager-initiated, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_L_PER_MIN	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

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

The Type attribute is used to distinguish the modality of particular leakage between instantaneous value (i.e., MDC_SABTE_VOL_LEAK_INSTANT), ~~minimum of a usage session (i.e., MDC_SABTE_VOL_LEAK_MIN),~~ maximum of a usage session (i.e., MDC_SABTE_VOL_LEAK_MAX), minimum of a usage session (i.e., MDC_SABTE_VOL_LEAK_MIN), arithmetic mean of a usage session (i.e., MDC_SABTE_VOL_LEAK_MEAN), 50th percentile of a usage session (i.e., MDC_SABTE_VOL_LEAK_P50), 90th percentile of a usage session (i.e., MDC_SABTE_VOL_LEAK_P90), or 95th percentile of a usage session (i.e., MDC_SABTE_VOL_LEAK_P95).

6.7.6 Respiratory rate

Change Table 11 and the text immediately following it as shown:

Table 11—Respiratory rate numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_INSTANT} or ~~{MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_MIN}~~ ~~or~~ {MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_MAX} or {MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_MIN} or {MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_MEAN} or {MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_P50} or {MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_P90} or {MDC_PART_PHD_DM, MDC_SABTE_RESP_RATE_P95}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-manager-initiated, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_RESP_PER_MIN	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

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

The Type attribute is used to distinguish the modality of particular respiratory rate between instantaneous value (i.e., MDC_SABTE_RESP_RATE_INSTANT)~~, minimum of a usage session (i.e., MDC_SABTE_RESP_RATE_MIN)~~, maximum of a usage session (i.e., MDC_SABTE_RESP_RATE_MAX), minimum of a usage session (i.e., MDC_SABTE_RESP_RATE_MIN), arithmetic mean of a usage session (i.e., MDC_SABTE_RESP_RATE_MEAN), 50th percentile of a usage session (i.e., MDC_SABTE_RESP_RATE_P50), 90th percentile of a usage session (i.e., MDC_SABTE_RESP_RATE_P90), or 95th percentile of a usage session (i.e., MDC_SABTE_RESP_RATE_P95).

6.7.7 Tidal volume

Change the Table 12 and the text immediately following it as shown:

Table 12—Tidal volume numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_INSTANT} or ~~{MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_MIN}~~ ~~or~~ {MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_MAX} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_MIN} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_MEAN} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_P50} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_P90} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_TIDAL_P95}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-manager-initiated, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_MILLI_L	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

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

The Type attribute is used to distinguish the modality of particular tidal volume between instantaneous value (i.e., MDC_SABTE_VOL_TIDAL_INSTANT), ~~minimum of a usage session (i.e., MDC_SABTE_VOL_TIDAL_MIN),~~ maximum of a usage session (i.e., MDC_SABTE_VOL_TIDAL_MAX), minimum of a usage session (i.e., MDC_SABTE_VOL_TIDAL_MIN), arithmetic mean of a usage session (i.e., MDC_SABTE_VOL_TIDAL_MEAN), 50th percentile of a usage session (i.e., MDC_SABTE_VOL_TIDAL_P50), 90th percentile of a usage session (i.e., MDC_SABTE_VOL_TIDAL_P90), or 95th percentile of a usage session (i.e., MDC_SABTE_VOL_TIDAL_P95).

6.7.8 Respiratory minute volume

Change Table 13 and the text immediately following it as shown:

Table 13—Respiratory minute volume numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_INSTANT} or ~~{MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_MIN}~~ ~~or~~ {MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_MAX} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_MIN} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_MEAN} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_P50} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_P90} or {MDC_PART_PHD_DM, MDC_SABTE_VOL_MINUTE_P95}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-manager-initiated, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_L_PER_MIN	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

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

The Type attribute is used to distinguish the modality of particular respiratory minute volume between instantaneous value (i.e., MDC_SABTE_VOL_MINUTE_INSTANT), ~~minimum of a usage session (i.e., MDC_SABTE_VOL_MINUTE_MIN),~~ maximum of a usage session (i.e., MDC_SABTE_VOL_MINUTE_MAX), minimum of a usage session (i.e., MDC_SABTE_VOL_MINUTE_MIN), arithmetic mean of a usage session (i.e., MDC_SABTE_VOL_MINUTE_MEAN), 50th percentile of a usage session (i.e., MDC_SABTE_VOL_MINUTE_P50), 90th percentile of a usage session (i.e., MDC_SABTE_VOL_MINUTE_P90), or 95th percentile of a usage session (i.e., MDC_SABTE_VOL_MINUTE_P95).

6.7.9 I:E ratio

Change Table 14 and the text immediately following it as shown:

Table 14—I:E ratio duration numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_INSTANT} or ~~{MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_MIN}~~ ~~or~~ {MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_MAX} or {MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_MIN} or {MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_MEAN} or {MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_P50} or {MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_P90} or {MDC_PART_PHD_DM, MDC_SABTE_RATIO_IE_P95}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-acc-manager-initiated, mss-acc-agent-initiated, mss-cat-calculation.	M
Unit-Code	MDC_DIM_PERCENT	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

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

The Type attribute is used to distinguish the modality of particular I:E ratio between instantaneous value (i.e., MDC_SABTE_RATIO_IE_INSTANT)~~, minimum of a usage session (i.e., MDC_SABTE_RATIO_IE_MIN)~~, maximum of a usage session (i.e., MDC_SABTE_RATIO_IE_MAX), minimum of a usage session (i.e., MDC_SABTE_RATIO_IE_MIN), arithmetic mean of a usage session (i.e., MDC_SABTE_RATIO_IE_MEAN), 50th percentile of a usage session (i.e., MDC_SABTE_RATIO_IE_P50), 90th percentile of a usage session (i.e., MDC_SABTE_RATIO_IE_P90), or 95th percentile of a usage session (i.e., MDC_SABTE_RATIO_IE_P95).

6.8 Real-time sample array objects

6.8.1 General

Change the first sentence in 6.8.1 as shown:

The SABTE DIM for metric objects (see Figure 5) contains two three RT-SA objects for therapy pressure, leakage, and airflow waveform data.

Annex C

(normative)

Allocation of identifiers

C.1 Definitions of terms and codes

Change the code value of MDC_DEV_SPEC_PROFILE_SABTE as shown:

```
#define MDC_DEV_SPEC_PROFILE_SABTE      4121~~1~~0    /*                  */
```

Change the Reference ID of MDC_SABTE_AHI_CENT as shown:

```
#define MDC_SABTE_AHI_CENTRAL           22196   /*                  */
```

Change the definitions of multiple nomenclature codes, starting from MDC_SABTE_PRESS through MDC_SABTE_VOL_TIDAL_INSTANT, as shown:

```
#define MDC_SABTE_PRESS                 22336   /*                  */
#define MDC_SABTE_PRESS_INSTANT         22336   /*                  */
#define MDC_SABTE_PRESS_MAX             22337   /*                  */
#define MDC_SABTE_PRESS_MIN             22338   /*                  */
#define MDC_SABTE_PRESS_MEAN            22339   /*                  */
#define MDC_SABTE_PRESS_P50             22343   /*                  */
#define MDC_SABTE_PRESS_P90             22345   /*                  */
#define MDC_SABTE_PRESS_P95             22346   /*                  */
#define MDC_SABTE_PRESS_TARGET          22352   /*                  */
#define MDC_SABTE_PRESS_CPAP_SET        22356   /*                  */
#define MDC_SABTE_PRESS_CPAP_AUTO_MAX_SET 22360 /*                  */
#define MDC_SABTE_PRESS_CPAP_AUTO_MIN_SET 22364 /*                  */
#define MDC_SABTE_PRESS_IPAP_SET        22368   /*                  */
#define MDC_SABTE_PRESS_EPAP_SET        22372   /*                  */
#define MDC_SABTE_PRESS_RAMP_START_SET  22376   /*                  */
#define MDC_SABTE_RESP_RATE_INSTANT     22384   /*                  */
#define MDC_SABTE_RESP_RATE_MAX         22385   /*                  */
#define MDC_SABTE_RESP_RATE_MIN         22386   /*                  */
#define MDC_SABTE_RESP_RATE_MEAN        22387   /*                  */
#define MDC_SABTE_RESP_RATE_P50         22391   /*                  */
#define MDC_SABTE_RESP_RATE_P90         22393   /*                  */
#define MDC_SABTE_RESP_RATE_P95         22394   /*                  */
#define MDC_SABTE_RESP_RATE_SET         22480   /*                  */
#define MDC_SABTE_RATIO_IE_INSTANT      22400   /*                  */
#define MDC_SABTE_RATIO_IE_MAX          22401   /*                  */
#define MDC_SABTE_RATIO_IE_MIN          22402   /*                  */
#define MDC_SABTE_RATIO_IE_MEAN         22403   /*                  */
```

```
#define MDC_SABTE_RATIO_IE_P50                  22407   /*                  */
#define MDC_SABTE_RATIO_IE_P90                  22409   /*                  */
#define MDC_SABTE_RATIO_IE_P95                  22410   /*                  */
#define MDC_SABTE_RATIO_IE_SET                  22484   /*                  */
#define MDC_SABTE_VOL_LEAK                      22432   /*                  */
#define MDC_SABTE_VOL_LEAK_INSTANT              22432   /*                  */
#define MDC_SABTE_VOL_LEAK_MAX                  22433   /*                  */
#define MDC_SABTE_VOL_LEAK_MIN                  22434   /*                  */
#define MDC_SABTE_VOL_LEAK_MEAN                 22435   /*                  */
#define MDC_SABTE_VOL_LEAK_P50                  22439   /*                  */
#define MDC_SABTE_VOL_LEAK_P90                  22441   /*                  */
#define MDC_SABTE_VOL_LEAK_P95                  22442   /*                  */
#define MDC_SABTE_VOL_MINUTE_INSTANT            22448   /*                  */
#define MDC_SABTE_VOL_MINUTE_MAX                22449   /*                  */
#define MDC_SABTE_VOL_MINUTE_MIN                22450   /*                  */
#define MDC_SABTE_VOL_MINUTE_MEAN               22451   /*                  */
#define MDC_SABTE_VOL_MINUTE_P50                22455   /*                  */
#define MDC_SABTE_VOL_MINUTE_P90                22457   /*                  */
#define MDC_SABTE_VOL_MINUTE_P95                22458   /*                  */
#define MDC_SABTE_VOL_TIDAL_INSTANT             22464   /*                  */
#define MDC_SABTE_VOL_TIDAL_MAX                 22465   /*                  */
#define MDC_SABTE_VOL_TIDAL_MIN                 22466   /*                  */
#define MDC_SABTE_VOL_TIDAL_MEAN                22467   /*                  */
#define MDC_SABTE_VOL_TIDAL_P50                 22471   /*                  */
#define MDC_SABTE_VOL_TIDAL_P90                 22473   /*                  */
#define MDC_SABTE_VOL_TIDAL_P95                 22474   /*                  */
```

Change the format of units to superscript, for the nomenclature codes MDC_DIM_L_PER_MIN and MDC_DIM_EVT_PER_HR, as shown:

```
/**************************************************************************
* From Dimensions (MDC_PART_DIM) (4)
**************************************************************************/
#define MDC_DIM_L_PER_MIN                       3072    /* l min-1 ~~-1~~   */
#define MDC_DIM_EVT_PER_HR                      4732    /* event h-1 ~~-1~~ */
```

C.2 Systematic derivations of terms and codes

Change the code value of MDC_DEV_SPEC_PROFILE_SABTE in Table C.1 as shown:

Table C.1—Infrastructure nomenclature and codes (MDC_PART_INFRA)

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Profile | Device | SABTE	Sleep apnoea breathing therapy equipment	SABTE	Profile of SABTE device specialization.	MDC_DEV_SPEC_PROFILE_SABTE	4121~~0~~

Change the Reference ID of MDC_SABTE_AHI_CENT in Table C.2 as shown:

Table C.2—Personal Health Device Disease Management nomenclature and codes (MDC_PART_PHD_DM)

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Index | Ratio (Number, Duration) | Apnoea, Hypopnoea, Central | SABTE	Central apnoea hypopnoea index	cAHI	Total number of all central apnoea and central hypopnoea events occurring during a usage session divided by the hours of sleep. See 5.3.1 and 6.7.3.	MDC_SABTE_AHI_CENTRAL	22196

Replace the definitions of multiple nomenclature codes in Table C.2, starting from MDC_SABTE_PRESS through the end of the table, as shown:

Table C.2—Personal Health Device Disease Management nomenclature and codes (MDC_PART_PHD_DM)

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Pressure | | Gas | SABTE	Therapy pressure waveform		Sequence of therapy pressure samples. See 5.3.3 and 6.8.2.	MDC_SABTE_PRESS	22336
Pressure | Instantaneous | Gas | SABTE	Instantaneous therapy pressure	P	Instantaneous value of delivered therapy pressure. See 5.3.2 and 6.7.5.	MDC_SABTE_PRESS_INSTANT	22336
Pressure | Maximum | Gas | SABTE	Maximum therapy pressure	P max	Maximum delivered therapy pressure during a usage session. See 5.3.2 and 6.7.5.	MDC_SABTE_PRESS_MAX	22337
Pressure | Minimum | Gas | SABTE	Minimum therapy pressure	P min	Minimum delivered therapy pressure during a usage session. See 5.3.2 and 6.7.5.	MDC_SABTE_PRESS_MIN	22338
Pressure | Mean | Gas | SABTE	Mean therapy pressure	P mean	Mean delivered therapy pressure during a usage session. See 5.3.2 and 6.7.5.	MDC_SABTE_PRESS_MEAN	22339

Table C.2—Personal Health Device Disease Management nomenclature and codes (MDC_PART_PHD_DM) *(continued)*

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Pressure | P50 | Gas | SABTE	50th percentile of therapy pressure	P50	50th percentile of delivered therapy pressure during a usage session. See 5.3.2 and 6.7.5.	MDC_SABTE_PRESS_P50	22343
Pressure | P90 | Gas | SABTE	90th percentile of therapy pressure	P90	90th percentile of delivered therapy pressure during a usage session. See 5.3.2 and 6.7.5.	MDC_SABTE_PRESS_P90	22345
Pressure | P95 | Gas | SABTE	95th percentile of therapy pressure	P95	95th percentile of delivered therapy pressure during a usage session. See 5.3.2 and 6.7.5.	MDC_SABTE_PRESS_P95	22346
Pressure | Target | Gas | SABTE	Target therapy pressure waveform		Sequence of target therapy pressure samples. See 5.3.3 and 6.8.2.	MDC_SABTE_PRESS_TARGET	22352
Pressure | CPAP, Setting | | SABTE	CPAP pressure set	P CPAP set	Setting of target therapy pressure in CPAP mode during a therapy session. See 5.6.7.1 and 6.7.18.	MDC_SABTE_PRESS_CPAP_SET	22356
Pressure | CPAP, Auto, Maximum, Setting | | SABTE	Auto-CPAP maximum pressure set	Pmax APAP set	Setting of maximum target therapy pressure in Auto-CPAP mode during a therapy session. See 5.6.8.2 and 6.7.20.	MDC_SABTE_PRESS_CPAP_AUTO_MAX_SET	22360
Pressure | CPAP, Auto, Minimum, Setting | | SABTE	Auto-CPAP minimum pressure set	Pmin APAP set	Setting of minimum target therapy pressure in Auto-CPAP mode during a therapy session. See 5.6.8.1 and 6.7.19.	MDC_SABTE_PRESS_CPAP_AUTO_MIN_SET	22364
Pressure | IPAP, Setting | | SABTE	IPAP pressure set	P IPAP set	Setting of target inspiration therapy pressure in BiLevel PAP mode during a breath cycle. See 5.6.9.1 and 6.7.21.	MDC_SABTE_PRESS_IPAP_SET	22368
Pressure | EPAP, Setting | | SABTE	EPAP pressure set	P EPAP set	Setting of target expiration therapy pressure in BiLevel PAP mode during a breath cycle. See 5.6.9.2 and 6.7.22	MDC_SABTE_PRESS_EPAP_SET	22372
Pressure | Start, Setting | Ramp | SABTE	Ramp start pressure set		Setting of length of the sleep ramp. See 5.6.4.1 and 6.7.15.	MDC_SABTE_PRESS_RAMP_START_SET	22376
Rate | Instantaneous | Breath | SABTE	Instantaneous respiration rate	RR	Instantaneous value of respiration rate. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_INSTANT	22384
Rate | Maximum | Breath | SABTE	Maximum respiration rate	RR max	Maximum respiration rate during a usage session. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_MAX	22385
Rate | Minimum | Breath | SABTE	Minimum respiration rate	RR min	Minimum respiration rate during a usage session. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_MIN	22386
Rate | Mean | Breath | SABTE	Mean respiration rate	RR mean	Mean respiration rate during a usage session. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_MEAN	22387

Table C.2—Personal Health Device Disease Management nomenclature and codes (MDC_PART_PHD_DM) *(continued)*

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Rate | P50 | Breath | SABTE	50th percentile of respiration rate		50th percentile of respiration rate during a usage session. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_P50	22391
Rate | P90 | Breath | SABTE	90th percentile of respiration rate		90th percentile of respiration rate during a usage session. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_P90	22393
Rate | P95 | Breath | SABTE	95th percentile of respiration rate		95th percentile of respiration rate during a usage session. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_P95	22394
Rate | Setting | Breath | SABTE	Respiratory rate set	RR set	Instantaneous value of respiration rate. See 5.3.7 and 6.7.7.	MDC_SABTE_RESP_RATE_SET	22480
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), Instantaneous | Gas | SABTE	Instantaneous I:E ratio	TI/TE	Setting of target breathing frequency in BiLevel PAP mode during a therapy session. See 5.6.9.3 and 6.7.23.	MDC_SABTE_RATIO_IE_INSTANT	22400
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), Maximum | Gas | SABTE	Maximum I:E ratio	TI/TE max	Instantaneous value of I:E ratio. See 5.3.10 and 6.7.10.	MDC_SABTE_RATIO_IE_MAX	22401
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), Minimum | Gas | SABTE	Minimum I:E ratio	TI/TE min	Minimum I:E ratio during a usage session. See 5.3.10 and 6.7.10.	MDC_SABTE_RATIO_IE_MIN	22402
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), Mean | Gas | SABTE	Mean I:E ratio	TI/TE mean	Maximum I:E ratio during a usage session. See 5.3.10 and 6.7.10.	MDC_SABTE_RATIO_IE_MEAN	22403
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), P50 | Gas | SABTE	50th percentile of I:E ratio		Minimum I:E ratio during a usage session. See 5.3.10 and 6.7.10.	MDC_SABTE_RATIO_IE_P50	22407
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), P90 | Gas | SABTE	90th percentile of I:E ratio		Mean I:E ratio during a usage session. See 5.3.10 and 6.7.10.	MDC_SABTE_RATIO_IE_P90	22409

Table C.2—Personal Health Device Disease Management nomenclature and codes (MDC_PART_PHD_DM) *(continued)*

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), P95 | Gas | SABTE	95th percentile of I:E ratio		95th percentile of I:E ratio during a usage session. See 5.3.10 and 6.7.10.	MDC_SABTE_RATIO_IE_P95	22410
Ratio | Duration(InspirationPhase), Duration(ExpirationPhase), Setting | Gas | SABTE	I:E ratio set	TI/TE set	Setting of target ratio between duration of the inspiration to the duration of the expiration in BiLevel PAP mode during a breath cycle. See 5.6.9.4 and 6.7.24.	MDC_SABTE_RATIO_IE_SET	22484
Volume | | Leakage | SABTE	Leakage waveform		Sequence of leakage samples. See 5.3.5 and 6.8.3.	MDC_SABTE_VOL_LEAK	22432
Volume | Instantaneous | Leakage | SABTE	Instantaneous leakage		Instantaneous value of leakage. See 5.3.4 and 6.7.6.	MDC_SABTE_VOL_LEAK_INSTANT	22432
Volume | Maximum | Leakage | SABTE	Maximum leakage		Maximum leakage during a usage session. See 5.3.4 and 6.7.6.	MDC_SABTE_VOL_LEAK_MAX	22433
Volume | Minimum | Leakage | SABTE	Minimum leakage		Minimum leakage during a usage session. See 5.3.4 and 6.7.6.	MDC_SABTE_VOL_LEAK_MIN	22434
Volume | Mean | Leakage | SABTE	Mean leakage		Mean leakage during a usage session. See 5.3.4 and 6.7.6.	MDC_SABTE_VOL_LEAK_MEAN	22435
Volume | P50 | Leakage | SABTE	50th percentile of leakage		50th percentile of leakage during a usage session. See 5.3.4 and 6.7.6.	MDC_SABTE_VOL_LEAK_P50	22439
Volume | P90 | Leakage | SABTE	90th percentile of leakage		90th percentile of leakage during a usage session. See 5.3.4 and 6.7.6.	MDC_SABTE_VOL_LEAK_P90	22441
Volume | P95 | Leakage | SABTE	95th percentile of leakage		95th percentile of leakage during a usage session. See 5.3.4 and 6.7.6.	MDC_SABTE_VOL_LEAK_P95	22442
Volume | OneMinute, Instantaneous | Gas | SABTE	Instantaneous respir. minute volume	RMV	Instantaneous value of respiratory minute volume. See 5.3.9 and 6.7.9.	MDC_SABTE_VOL_MINUTE_INSTANT	22448
Volume | OneMinute, Maximum | Gas | SABTE	Maximum respir. minute volume	RMV max	Maximum respiratory minute volume during a usage session. See 5.3.9 and 6.7.9.	MDC_SABTE_VOL_MINUTE_MAX	22449
Volume | OneMinute, Minimum | Gas | SABTE	Minimum respir. minute volume	RMV min	Minimum respiratory minute volume during a usage session. See 5.3.9 and 6.7.9.	MDC_SABTE_VOL_MINUTE_MIN	22450
Volume | OneMinute, Mean | Gas | SABTE	Mean respir. minute volume	RMV mean	Mean respiratory minute volume during a usage session. See 5.3.9 and 6.7.9.	MDC_SABTE_VOL_MINUTE_MEAN	22451

Table C.2—Personal Health Device Disease Management nomenclature and codes (MDC_PART_PHD_DM) *(continued)*

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Volume | OneMinute, P50 | Gas | SABTE	50th percentile of respir. minute volume		50th percentile of respiratory minute volume during a usage session. See 5.3.9 and 6.7.9.	MDC_SABTE_VOL_MINUTE_P50	22455
Volume | OneMinute, P90 | Gas | SABTE	90th percentile of respir. minute volume		90th percentile of respiratory minute volume during a usage session. See 5.3.9 and 6.7.9.	MDC_SABTE_VOL_MINUTE_P90	22457
Volume | OneMinute, P95 | Gas | SABTE	95th percentile of respir. minute volume		95th percentile of respiratory minute volume during a usage session. See 5.3.9 and 6.7.9.	MDC_SABTE_VOL_MINUTE_P95	22458
Volume | Instantaneous | Lung, Tidal | SABTE	Instantaneous respir. tidal volume	VT	Instantaneous value of respiratory tidal volume. See 5.3.8 and 6.7.8.	MDC_SABTE_VOL_TIDAL_INSTANT	22464
Volume | Maximum | Lung, Tidal | SABTE	Maximum respir. tidal volume	VT max	Maximum respiratory tidal volume during a usage session. See 5.3.8 and 6.7.8.	MDC_SABTE_VOL_TIDAL_MAX	22465
Volume | Minimum | Lung, Tidal | SABTE	Minimum respir. tidal volume	VT min	Minimum respiratory tidal volume during a usage session. See 5.3.8 and 6.7.8.	MDC_SABTE_VOL_TIDAL_MIN	22466
Volume | Mean | Lung, Tidal | SABTE	Mean respir. tidal volume	VT mean	Mean respiratory tidal volume during a usage session. See 5.3.8 and 6.7.8.	MDC_SABTE_VOL_TIDAL_MEAN	22467
Volume | P50 | Lung, Tidal | SABTE	50th percentile of respir. tidal volume		50th percentile of respiratory tidal volume during a usage session. See 5.3.8 and 6.7.8.	MDC_SABTE_VOL_TIDAL_P50	22471
Volume | P90 | Lung, Tidal | SABTE	90th percentile of respir. tidal volume		90th percentile of respiratory tidal volume during a usage session. See 5.3.8 and 6.7.8.	MDC_SABTE_VOL_TIDAL_P90	22473
Volume | P95 | Lung, Tidal | SABTE	95th percentile of respir. tidal volume		95th percentile of respiratory tidal volume during a usage session. See 5.3.8 and 6.7.8.	MDC_SABTE_VOL_TIDAL_P95	22474

Annex E

(informative)

Protocol data unit examples

E.4 GET MDS attributes service

Change the subclause number from E.4.1.1 to E.4.1 as shown:

~~E.4.1.1~~ E.4.1 General

Change the subclause number from E.4.1.2 to E.4.2 as shown:

~~E.4.1.2~~ E.4.2 Get all medical device system attributes request

Change the subclause number from E.4.1.3 to E.4.3 as shown:

~~E.4.1.3~~ E.4.3 Get response with all MDS attributes

Change the line starting with "0x10 0x19" as shown:

```
0x10 0x1~~9~~8                    type = MDC_DEV_SPEC_PROFILE_SABTE
```

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Vaše názory, podněty a připomínky týkající se technických norem a zájmu o možnou účast v procesech technické normalizace lze zaslat na e-mailovou adresu info@agentura-cas.cz.

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