Consumer **Technology Association**°



September 2022

Monitors

NOTICE

Consumer Technology Association (CTA)™ Standards, Bulletins and other technical publications are designed to serve the public interest through eliminating misunderstandings between manufacturers and purchasers, facilitating interchangeability and improvement of products, and assisting the purchaser in selecting and obtaining with minimum delay the proper product for his particular need. Existence of such Standards, Bulletins and other technical publications shall not in any respect preclude any member or nonmember of the Consumer Technology Association from manufacturing or selling products not conforming to such Standards, Bulletins or other technical publications, nor shall the existence of such Standards, Bulletins and other technical publications preclude their voluntary use by those other than Consumer Technology Association members, whether the standard is to be used either domestically or internationally.

Standards, Bulletins and other technical publications are adopted by the Consumer Technology Association in accordance with the American National Standards Institute (ANSI) patent policy. By such action, the Consumer Technology Association does not assume any liability to any patent owner, nor does it assume any obligation whatever to parties adopting the Standard, Bulletin or other technical publication.

This document does not purport to address all safety problems associated with its use or all applicable regulatory requirements. It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations before its use.

This document is copyrighted by the Consumer Technology Association (CTA)[™] and may not be reproduced, in whole or part, without written permission. Federal copyright law prohibits unauthorized reproduction of this document by any means. Organizations may obtain permission to reproduce a limited number of copies by entering into a license agreement. Requests to reproduce text, data, charts, figures or other material should be made to the Consumer Technology Association (CTA)[™].

(Formulated under the cognizance of the CTA **R11 Health, Fitness & Wellness Technology Committee.**)

Published by

©CONSUMER TECHNOLOGY ASSOCIATION 2022

Technology & Standards Department

www.cta.tech

All rights reserved

FOREWORD

This standard was developed by the Consumer Technology Association's R11 Health, Fitness & Wellness Technology Committee.

(This page intentionally left blank.)

TABLE OF CONTENTS

1	Scope and Disclaimer	1
2	References	4
2.1	Informative References	4
2.2	Compliance Notation	5
2.3	Definitions	5
2.4	Symbols and Abbreviations	5
3	Definitions, Indicators, and Calculations	6
A: Ge	eneral Terms Describing the Temporal Surrounding a Sleep Episode	6
A.1 (I	Elemental): TATS Start Time	6
A.2 (I	Elemental): TATS End Time	6
A.3 (I	Elemental): TIB Start Time	6
A.4 (I	Elemental): TIB End Time	7
A.5 (I	Derived) Total TATS Duration	7
A.6 (I	Derived) Total TIB Duration	7
B: Ge	eneral Terms Describing Basic Features of Wakefulness and Sleep	7
B.1 (E	Elemental): Awake (Wake)	8
B.2 (E	Elemental): Asleep (Sleep)	8
B.3 (E	Elemental): Awakening from Sleep	8
B.4 (E	Elemental): Brief Awakening	9
B.5 (E	Elemental): Brief Moment of Sleep (Dozing)	9
B.6 (I	Derived): Total sleep period duration (TSPD)	9
B.7 (I	Derived): Total sleep time (TST)	9
B.8 (I	Derived): Sleep maintenance percentage	9
B.9 (I	Derived): Total wakefulness duration	9
B.10	(Derived): Wakefulness duration after initial sleep onset	0
B.11	(Derived): Number of awakenings1	0
B.12	(Derived): Number of brief awakenings 1	0
B.13	(Derived): Awakening rate per hour1	0
B.14	(Derived): Sleep fragmentation rate 1	0

B.15 (Derived): Number of dozing episodes	. 10
C: Terms Derived from Basic Features of Wakefulness and Sleep As They Relate to the Episode and Temporal Surround	•
C.1 (Elemental): Initial Sleep Onset Time	. 11
C.2 (Elemental): Final Awakening Time	. 11
C.3 (Derived): Latency to sleep onset	. 11
C.4 (Derived): Latency to arising	. 11
C.5 (Derived): Sleep efficiency percentage	. 12
D. Specific Terms Describing Processes Occurring During Sleep Based on Polysomnogr	
D.1 (Elemental): REM Sleep	. 12
D.2 (Elemental): N1	. 12
D.3 (Elemental): N2	. 13
D.4 (Elemental): N3	. 13
D.5 (Elemental): CNS Arousal	. 13
D.6 (Derived): Number of CNS arousals	. 13
D.7 (Derived): CNS arousal rate per hour	. 13
D.8 (Derived): REM sleep duration, percentage, latency from sleep onset, and latency TATS start time	
D.9 (Derived): N1 Sleep duration, percentage, latency from sleep onset, and latency from start time	
D.10 (Derived): N2 Sleep duration, percentage, latency from sleep onset, and latency start time	
D.11 (Derived): N3 Sleep duration, percentage, latency from sleep onset, and latency start time	
E: Terms used to describe the sleep-wake cycle over time periods exceeding 7 days	. 15
E.1 (Elemental): Sleep-Wake Regularity	. 15
E.2 (Elemental): Sleep-Wake Fragmentation	. 16
Alternative Definition: None	. 16
E.3 (Elemental): Sleep-Wake Amplitude	. 16
Alternative Definition: None	. 17
E.4 (Elemental): Circadian Phase (phi)	. 17
F.5 (Flemental): Circadian Phase Angle (psi)	.17

E.6 (Elemental): Circadian Period length (tau)	17
E.7 (Elemental): Circadian Amplitude	17

(This page intentionally left blank.)

Definitions and Characteristics for Wearable Sleep Monitors

1 SCOPE AND DISCLAIMER

This voluntary standard defines terms used to describe sleep and indicates, where appropriate, the functionality necessary in a consumer sleep measuring device to measure those characteristics. This standard provides definitions of sleep features terminology recommended for wearable sleep monitoring consumer products. This standard does not provide operational definitions for terminology used for medical devices. Furthermore, it is acknowledged that not all compliant products will include features to meet every use case, but the ones that it does claim such will meet the respective requirements.

Terminology covered in this document falls into five general categories (A-E) as shown on the Table 1.

Table 1 - Sleep Terminology Categorization

	Terminology Category	Elemental Measure	Derived Measures
A	General terms describing the temporal surround of a sleep episode	<u>Time when individual began</u> <u>Attempting/Intending To Sleep (TATS):</u> 1. TATS Start Time (A.1) 2. TATS End Time (A.2) <u>Time In Bed (TIB):</u> 3. TIB Start Time (A.3) 4. TIB End Time (A.4)	5. Total TATS Duration (A.5) 6. Total TIB Duration (A.6)
В	General terms describing basic features of wakefulness and sleep	1. Awake (Wake) (B.1) 2. Asleep (Sleep) (B.2) 3. Awakening from sleep (B.3) 4. Brief awakening (B.4) 5. Brief moment of sleep (dozing) (B.5)	 Total sleep period duration (TSPD) (B.6) Total sleep time (TST) (B.7) Sleep maintenance Percentage (B.8) Total wakefulness duration (B.9) Wakefulness duration after initial sleep onset (B.10) Number of awakenings (B.11) Number of brief awakenings (B.12) Awakening rate per hour (B.13) Sleep fragmentation rate (B.14) Number of dozing episodes (B.15)
С	Terms calculated from basic features of wakefulness, sleep as they relate to the sleep episode and its surround	 Initial sleep onset time (C.1) Final awakening time (C.2) 	 Latency to sleep onset (C.3) Latency to arising (C.4) Sleep efficiency Percentage (C.5)
D	Specific terms describing processes occurring during sleep based on polysomnography	1. REM Sleep (D.1) 2. N1 (D.2) 3. N2 (D.3) 4. N3 (D.4) 5. CNS Arousal (D.5)	6. Number of CNS arousals (D.6) 7. CNS arousal rate per hour (D.7) Duration, percentage (of TST), and latency from sleep onset for each of the following: 8. REM (D.8) 9. N1 (D.9) 10. N2 (D.10)

				11. N3 (D.11)
E	Terms used to describe the sleep-wake cycle over time periods exceeding 7 days	1. 2. 3. 4. 5. 6. 7.	Sleep-Wake Regularity (E.1) Sleep-Wake Fragmentation (E.2) Sleep-Wake Amplitude (E.3) Circadian Phase (E.4) Circadian Phase Angle (E.5) Circadian Period Length (E.6) Circadian Amplitude (E.7)	

- **Terms in Category A:** We begin by defining terms describing a sleep episode's context. These are general terms related to the sleeper's intention and their position in the environment. Because a person may be in bed without an intention to sleep, this leads to the distinction between these two elements. There are no systematic reviews published on terms and definitions such as time in bed (TIB) for this category and for these arguments in accessible journals. Therefore, it was decided to introduce new definitions here. This is "Time when individual began Attempting/Intending To Sleep (TATS)". The definition includes the TATS start time and the TATS end time. The difference between the two will be TATS duration. Commonly used in sleep laboratories and sleep reports is the term "Time in Bed (TIB)". Often, in sleep medicine and sleep research, TIB is perceived as TATS. However, as a consequence of the above argument, that a person might want to spent time in bed without intending to sleep, especially in the home environment, there is a need to distinguish the conditions with and without sleep intention. Therefore, TIB will be greater than or equal to TATS, according to these definitions. Time away from the bed in this interval (e.g., to use the restroom) would not be included in either definition.
- Terms in Category B: Terminology in category B consists of terms used to describe the general sequence of events once there is an intention to sleep. Some amount of wakefulness followed by eventual sleep will occur. Furthermore, once sleep has occurred, there can be awakenings. If a person has a very brief sleep episode surrounded by wakefulness, a dozing episode can be considered. It should be noted that some of the terms in category B have both general and laboratory definitions. However, terms such as wakefulness may not require polysomnographic comparison to verify (e.g., I am awake while I am typing this document). Such terms have and can be defined using other criteria. Such terms include, but are not limited to wakefulness, sleep, and awakening. Once sleep and wakefulness episodes are detected, many parameters can be calculated (e.g., total sleep period duration, total sleep time, and number of awakenings). For the general definitions of terms, no systematic reviews are published in accessible journals. For the laboratory definitions, of terms, the definitions are linked to the specific study. Some studies (most historic studies) are observational. Other studies use simple surrogates such as movement monitoring (by camera or other noncontact monitoring, by movement sensors in the bed or linked to the bed, or by body worn sensors) for describing the basic features of sleep and wakefulness. Lately other indirect surrogate sensing such as changes in vital signs accessible to easy monitoring

- (body temperature, pulse wave, respiration) are used for a general monitoring of wakefulness, sleep, and awakenings.
- **Terms in Category C:** Once the initial sleep and final wakefulness episode has been detected, it is possible to calculate several important metrics based on the relationship between these measures and the temporal surround. These include latency to sleep onset, latency to arising, and sleep efficiency.
- Terms in Category D: Standards for sleep features shown in category D are defined in the "AASM manual for the scoring of sleep and associated events: rules, terminology and technical specifications. 1st edition" (Iber et al, 2007) and updated in the "American Academy of Sleep Medicine. The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications, Version 2.6 (Berry et al., 2020) and following updates. This sleep feature nomenclature is well established and widely used by sleep researchers and sleep medicine practitioners. These standards are based on polysomnographic (electroencephalogram, electrooculogram, and electromyogram) correlates derived from normal human subjects. To avoid creating linguistic ambiguity, these terms should concord with standardized definitions and will not be redefined here. It should be noted that the Standardized Manual also defines abnormal respiratory, movement, and cardiac events used in diagnostic practice. Definitions for these sleep pathophysiologies are beyond the scope of this document and should concord with existing nomenclature.
 - There are other terms that may be used in sleep tracking devices other than what is currently considered standard staging terminology (e.g., N1, N2, N3, REM, and Wake). If such terminology is used it should be defined in a methodological manner, and the device manufacturer should indicate whether and how the new terminology related to standard staging terminology to avoid confusion.
- Terms in Category E: Terminology used to describe circadian rhythms is included here.
 Actigraphs, using accelerometers usually worn on the wrist and resembling a
 wristwatch, have long been used in circadian rhythm research. Such devices are
 currently being used in the Human Sleep Genome Project. Each actigraph differs with
 respect to their precision and accuracy and should be evaluated for its performance
 characteristics. Recommended terminology and definitions are provided herein.

The terminology provided herein reflects the consensus of the Consumer Technology Association™ Health, Fitness and Wellness Technology Committee's knowledge of terminology used by manufacturers of consumer devices that track sleep as a feature as of the time of publication. This document should not be construed as all-inclusive.

2 REFERENCES

2.1 Informative References

The following references contain provisions that, through reference in this text, constitute informative provisions of this standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below.

- 1. Iber C, Ancoli-Israel S, Chesson A, Quan SF for the American Academy of Sleep Medicine. The AASM manual for the scoring of sleep and associated events: rules, terminology and technical specifications. 1st ed. Westchester, Ill: American Academy of Sleep Medicine; 2007.
- 2. Berry RB, Brooks R, Gamaldo CE, Harding SM, Lloyd RM, Marcus CL, Vaughn BV. The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications. WWW. AASM. ORG. Darien, IL: American Academy of Sleep Medicine, 2020.
- 3. Orem J, Barnes CD (Eds). Physiology in Sleep. New York: Elsevier 2012.
- 4. Sleep Research Society. Basics of Sleep Behavior. Los Angeles, CA: UCLA and Sleep Research Society; 1993.
- 5. Hirshkowitz M, Sharafkhaneh A. The physiology of sleep. In: Guilleminault C (Ed). Handbook of Clinical Neurophysiology- Clinical Neurophysiology of Sleep Disorders. Philadelphia: Elsevier, 2005; 3-20.
- 6. Avidan AY. Normal Sleep in Humans. In: Kryger MH, Avidan AY, Berry RB (Eds). Atlas of Clinical Sleep Medicine (2nd Edition). Philadelphia, PA: Elsevier; 2014, 70-97.
- 7. Witting W, Kwa IH, Eikelenboom P, Mirmiran M, Swaab DF. Alterations in the circadian rest-activity rhythm in aging and Alzheimer's disease. Biol Psychiatry. 1990 Mar 15;27(6):563-72. doi: 10.1016/0006-3223(90)90523-5. PMID: 2322616.
- 8. Phillips AJK, Clerx WM, O'Brien CS, Sano A, Barger LK, Picard RW, Lockley SW, Klerman EB, Czeisler CA. Irregular sleep/wake patterns are associated with poorer academic performance and delayed circadian and sleep/wake timing. Sci Rep. 2017 Jun 12;7(1):3216. doi: 10.1038/s41598-017-03171-4. PMID: 28607474; PMCID: PMC5468315.
- 9. Cornelissen G. (2014). Cosinor-based rhythmometry. *Theoretical biology & medical modelling*, 11, 16. https://doi.org/10.1186/1742-4682-11-16
- 10. Marler MR, Gehrman P, Martin JL, Ancoli-Israel S. The sigmoidally transformed cosine curve: a mathematical model for circadian rhythms with symmetric non-sinusoidal shapes. Stat Med. 2006 Nov 30;25(22):3893-904. doi: 10.1002/sim.2466. PMID: 16381069.
- 11. Duffy JF, Dijk DJ. Getting through to circadian oscillators: why use constant routines? J Biol Rhythms. 2002 Feb;17(1):4-13. doi: 10.1177/074873002129002294. PMID: 11837947.
- 12. Kleitman N., Sleep and Wakefulness, September 1987.

2.2 Compliance Notation

CTA defines the following compliance terms for use in its documents:

shall This word indicates specific provisions that are to be followed

strictly (no deviation is permitted).

shall not This phrase indicates specific provisions that are absolutely

prohibited.

should This word indicates that a certain course of action is preferred but

not necessarily required.

should not This phrase means a certain possibility or course of action is

undesirable but not prohibited.

may This phrase indicates that a certain course of action is optional.

2.3 Definitions

Two types of terms will be defined in this document: (1) Elemental terms and (2) derived terms. *Elemental terms* are those that are determined directly from self-declaration, visual observation, ongoing phenomena, or biosensors. By contrast, *derived terms* are calculated directly from elemental terms and require no indicators other than those required by the elemental terms used to make the calculation.

For the purpose of this document, the follow format will be used for defining each term:

Primary Definition: General Meaning of the term used. These are consumer-friendly

definitions applicable to normal healthy sleepers.

Indicators: For each elemental term, the types of signs or measures that may

be used to determine whether an individual meets criteria are provided (e.g., self-declaration, visual observation, detectable

phenomena, and/or biosensor signals).

Calculation: For each **derived term**, the method or formula used to calculate

the parameter is provided.

Alternative Definition: Definitions used in sleep research and sleep medicine.

2.4 Symbols and Abbreviations

ANS Autonomic Nervous System

BP Blood Pressure

EDA Electrodermal Activity

EEG Electroencephalogram

ANSI/CTA/NSF-2052.1-A

EMG Electromyogram

EOG Electrooculogram

HR Heart Rate

NREM Non-Rapid Eye Movement

REM Rapid Eye Movement

3 DEFINITIONS, INDICATORS, AND CALCULATIONS

A: General Terms Describing the Temporal Surrounding a Sleep Episode

This section defines terms describing a sleep episode's temporal surround. These are general terms related to the sleeper's intention and the environment, because a person may be in bed without an intention to sleep, leads to the distinction between these two elements. The main parameters related to the <u>Time</u> when individual is <u>Attempting To Sleep</u> (TATS) and the <u>Time</u> when the individual is <u>In Bed</u> (TIB). For the purpose of this document, the use of "Time" is equivalent to "Timestamp".

A.1 (Elemental): TATS Start Time

Primary Definition: Time at which the individual is in bed and begins attempting to sleep.

Indicators: Indicators may include but are not limited to self-declared intention to sleep (e.g., indicator button on a device), closing of the eyes while an individual is in bed.

Alternative Definition: None.

A.2 (Elemental): TATS End Time

Primary Definition: Time at which the individual is in bed and is no longer attempting to sleep.

Indicators: Indicators may include but are not limited to self-declared intention to remain awake (e.g., indicator button on a device), increased motion/mobility for a certain amount of time, opening of the eyes.

Alternative Definition: None.

A.3 (Elemental): TIB Start Time

Primary Definition: The time that an individual gets into bed.

Indicators: Indicators may include but are not limited to: Self-declared status that an individual has gotten into bed, visual observation, sensors indicating an individual is horizontal, and bed or room sensors indicating that a person has gotten into bed.

Alternative Definition: In the sleep laboratory this term is actually used to designate TATS Start Time. It is also sometimes called "Lights Out Time" in the sleep lab. This term comes from the

concept that there should not be any light in the bedroom in the sleep laboratory when the subject is studied for her or his sleep under controlled conditions.

A.4 (Elemental): TIB End Time

Primary Definition: The time that an individual gets out of bed.

Indicators: Indicators may include but are not limited to: Self-declared status that an individual has gotten out of bed, visual observation, sensors indicating an individual is not horizontal, and bed or room sensors indicating that a person has gotten out of bed.

Alternative Definition: Same as primary definition; however, in the laboratory this term is actually used to designate TATS End Time. It is also sometimes called "Lights On Time".

A.5 (Derived) Total TATS Duration

Primary Definition: Total time duration that the individual is in bed and is attempting to sleep excluding time in bed not intending to sleep (watching TV, reading a book, etc.).

Calculation: The amount of time from TATS Start Time to TATS End Time.

Alternative Definition: None.

A.6 (Derived) Total TIB Duration

Primary Definition: The total duration of time that an individual is in bed.

Calculation: The total amount of time from TIB Start Time to TIB End Time.

Alternative Definition: Same as primary definition; however, in the laboratory this term is

actually used to designate Total TATS Duration.

B: General Terms Describing Basic Features of Wakefulness and Sleep

Terminology in this section is used to describe events once there is an intention to sleep. Some of the terms in this section have both general and laboratory definitions. Terms such as "sleep" existed long before polysomnographic procedures were applied to investigate the neurophysiology, psychophysiology, and general physiology of sleep. These terms include (but are not limited to): Awake, asleep, and awakening from sleep. Additionally, other sleep measures can be derived from these parameters (e.g., total sleep time and number of awakenings). This section defines such terms.

It is worth noting that actigraphs, using accelerometers, usually worn on the wrist and resembling a wristwatch, have long been used in sleep research. Sleep features commonly derived from actigraphic devices include Total sleep period, total sleep time, sleep latency, sleep efficiency (or sleep maintenance), and awakening rate per hour. Each actigraph differs with respect to their precision and accuracy and should be compared to a reference standard to determine its performance characteristic if it is being used as a clinical or medical device. Actigraphy algorithms commonly have high sensitivity but low specificity for sleep, which

means derived features like TST will appear more accurate the higher the sleep efficiency, and less accurate the lower the sleep efficiency. For some use cases, such accuracy trade-offs may be reasonable, such as when long-term tracking is undertaken in healthy populations.

B.1 (Elemental): Awake (Wake)

Primary Definition: Moments when one is not asleep. Usually accompanied by consciousness and/or awareness. Can also be accompanied by purposeful movements.

Indicators: Wakefulness may include but is not limited to cognitive awareness and/or consciousness, responsiveness to environmental cues, EEG beta and/or alpha waves, sustained movement, eyes open, voluntary eye movements, eye blinks, EMG increases on the chin, heart rate increase, respiration increase, blood pressure increase, slow core body temperature increase (and will drop again if sleep begins or resumes), increased electrodermal activity, increased blood flow.

Alternative Definition: Wakefulness can be polysomnographically defined typically as a 30-second epoch in which eyes are open and low-voltage, mixed frequency EEG activity is present. If eyes are closed and the subject is not engaged in strenuous mental activity, EEG occipital alpha activity is present in approximately 90% of the population.

B.2 (Elemental): Asleep (Sleep)

Primary Definition: A period when one is less responsive to the environment and relatively immobile, but it is a rapidly reversible state. It usually includes a lack of alertness and consciousness. Sleep is associated with multiple bodily functions and benefits.

Indicators: In healthy individuals, indicators of sleep may include but not limited to: reduced mobility; eyes closure; eyes twitches; disengagement from environment; lack of response to stimuli (that is rapidly reversible); loss of consciousness; decline in heart rate; increased R-R variability; decline in body temperature; decline in respiration; reduction in alpha EEG waves; increase in EEG theta and delta waves; decline in oxygen saturation; decline in blood pressure; recumbancy.

Alternative Definition: Sleep can be polysomnographically defined as any epoch meeting scoring criteria for N1, N2, N3, or REM sleep as defined in Section D.

B.3 (Elemental): Awakening from Sleep

Primary Definition: To cease sleeping the sleeper may or may not be aware of this sleep disturbance.

Indicators: Same indicators as for term <u>Awake</u> but must follow immediately after sleep was present.

Alternative Definition: Polysomnograhic criteria for an awakening is the same as for being awake for more than 15 seconds if it follow immediately after sleep was present.

B.4 (Elemental): Brief Awakening

Primary Definition: An awakening of which the sleeper is typically not aware.

Indicators: Same indicators as for term Awakening.

Alternative Definition: A brief awakening defined by polysomnographic criteria is called a central nervous system (CNS) arousal. A disruption of sleep that lasts between 3-15 seconds. Arousals from REM sleep require 3-15 seconds of sustained frequency shift in the EEG (usually to a higher frequency – alpha/beta) and, when in REM sleep, a greater-than-1-second increase in submentalis EMG activity.

B.5 (Elemental): Brief Moment of Sleep (Dozing)

Primary Definition: A brief transition from wakefulness to sleep (e.g.,3-30 seconds) with a subsequent return to wakefulness. The individual may be unaware of the brief sleep episode.

Indicators: Same indicators as for term <u>Asleep</u> but must be contiguous (before and after) with the presence of wakefulness.

Alternative Definition: None.

B.6 (Derived): Total sleep period duration (TSPD)

Primary Definition: The duration of time from initial sleep onset time to final awakening time.

Calculation: Usually reported in hours and minutes or total number of minutes. This measure includes time awake occurring after the initial sleep onset and before the final awakening.

Alternative Definition: The same calculation is used for polysomnographic data.

B.7 (Derived): Total sleep time (TST)

Primary Definition: The total amount of time spent asleep.

Calculation: Sum of all asleep time within a sleep period.

Alternative Definition: The same calculation is used for polysomnographic data.

B.8 (Derived): Sleep maintenance percentage

Primary Definition: The amount of time spent asleep as a percentage of the sleep period. This measure is sometimes called the sleep maintenance index.

Calculation: (TST/TSPD)*100.

Alternative Definition: The same calculation is used for polysomnographic data.

B.9 (Derived): Total wakefulness duration

Primary Definition: The amount of time spent awake during time attempting to sleep.

Calculation: The amount of time spent awake from TATS start time until TATS end time.

Alternative Definition: Polysomnographically, total wakefulness duration from lights out to lights on.

B.10 (Derived): Wakefulness duration after initial sleep onset

Primary Definition: The amount of time spent awake during a sleep period.

Calculation: The amount of time spent awake from initial sleep onset until final awakening.

Alternative Definition: The same calculation is used for polysomnographic data and the

resulting metric is called wake after sleep onset (WASO).

B.11 (Derived): Number of awakenings

Primary Definition: The number of times an individual transitions from sleep to wakefulness during the total sleep period.

Calculation: Sum of awakenings occurring during a sleep period.

Alternative Definition: The same calculation is used for polysomnographic data.

B.12 (Derived): Number of brief awakenings

Primary Definition: The number of brief awakenings from sleep during the total sleep period.

Calculation: Sum of brief awakenings during a sleep period.

Alternative Definition: The same calculation is used for polysomnographic data.

B.13 (Derived): Awakening rate per hour

Primary Definition: The number of awakenings per hour in a sleep period.

Calculation: [(number of awakenings)/TST in min]*60).

Alternative Definition: The same calculation is used for polysomnographic data.

B.14 (Derived): Sleep fragmentation rate

Primary Definition: The rate at which sleep is disturbed by awakenings and brief awakenings.

Calculation: [(number of awakenings + number of brief awakenings)/TST in min]*60.

Alternative Definition: The same calculation is used for polysomnographic data.

B.15 (Derived): Number of dozing episodes

Primary Definition: Number of brief moments of sleep (dozing) in any stated time frame.

Calculation: Sum of the number of dozing episodes.

Alternative Definition: There are no equivalent polysomnographic terms currently defined.

C: Terms Derived from Basic Features of Wakefulness and Sleep As They Relate to the Sleep Episode and Temporal Surround

C.1 (Elemental): Initial Sleep Onset Time

Primary Definition: Time of the first occurrence of sleep after TATS start time.

Indicators: Indicators may include but are not limited to: loss of consciousness; cessation of responding to environmental stimuli; decreased muscle activity (tone); decreased body temperature; heart rate slowing; decreased muscle activity; slow rolling horizontal eye movements; upward rolling eye movements; cessation of blinking; reduction in alpha EEG activity; general slowing of EEG to theta frequencies; appearance of vertex sharp waves, sleep spindles, or K complexes; increased event related potential amplitude; electrodermal response habituation; slowing in respiratory rate.

Alternative Definition: Polysomnographically, the initial sleep onset is defined as the first epoch meeting scoring criteria for N1, N2, N3, or REM sleep.

C.2 (Elemental): Final Awakening Time

Primary Definition: Time immediately after the final occurrence of sleep before TATS end time.

Indicators: Indicators may include but are not limited to: consciousness; responding to environmental stimuli; speaking, reading, purposeful movement, increased muscle activity (tone); increased body temperature; increased heart rate; increased muscle activity; appearance of alpha or beta EEG activity; electrodermal response dishabituation; increase in respiratory rate.

Alternative Definition: Polysomnographically, the final awakening time is the first epoch of wake after the final epoch of sleep meeting scoring criteria for N1, N2, N3, or REM sleep.

C.3 (Derived): Latency to sleep onset

Primary Definition: The amount of time it takes to achieve sleep after there is an intention to sleep.

Calculation: Time from TATS start time to initial sleep onset time.

Alternative Definition: In the laboratory, latency to sleep onset is the duration of the interval from lights out to the initial sleep onset time. There are multiple ways that Sleep Onset can be defined; precise definition should be given.

C.4 (Derived): Latency to arising

Primary Definition: The amount of time from the final awakening until there is no longer intention to sleep.

Calculation: Time from final awakening time to TATS end time.

Alternative Definition: Polysomnographically defined, this is the time from final awakening until lights on time.

C.5 (Derived): Sleep efficiency percentage

Primary Definition: Total sleep time as a percentage of the total amount of time there was an intention to sleep.

Calculation: (TST/TATS)*100.

Alternative Definition: (TST/TIB)*100. This is more frequently used in insomnia trials where there is an active effort to reduce time spent in bed without the intention of sleeping

D. Specific Terms Describing Processes Occurring During Sleep Based on Polysomnography

The terminology in this category evolved from the psychophysiological study of sleep using polysomnography. These terms were adopted by sleep medicine and are defined in the "American Academy of Sleep Medicine. The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications, Version 2.6 (Berry et al., 2020 and following updates. For terms in this category, the primary definition is a polysomnographic definition.

D.1 (Elemental): REM Sleep

Primary Definition: REM sleep is characterized by low-voltage, mixed-frequency EEG activity. Rapid-eye-movements are present (or are present in contiguous epochs not classified as NREM stages), EMG activity recorded from submentalis muscle (chin) is very much diminished or absent.

Indicators: EEG low-voltage mixed frequency activity, sometimes including saw-tooth theta activity; rapid eye movements; nearly absent submentalis muscle tone; global somatic muscle atonia; vivid dream mentation; penile/clitoral tumescence; ANS (RR and HR) irregularity/instability.

Alternative Definition: None.

D.2 (Elemental): N1

Primary Definition: N1 Sleep is characterized by low voltage, mixed frequency EEG activity, slow rolling eye movements, and decreased muscle tone. Any 30-second epoch that meets criteria for sleep but does not meet specific criteria for N2, N3, or REM sleep, is classified as N1 sleep.

Indicators: low-voltage, mixed frequency EEG activity with less than 15 seconds of alpha activity in a 30-second epoch; possible vertex sharp waves; no sleep spindles or K complexes; possible slow rolling eye movements; diminished submentalis EMG activity.

Alternative Definition: None.

D.3 (Elemental): N2

Primary Definition: N2 sleep is characterized by sleep spindles and/or K complexes.

Indicators: Sleep spindle activity; K complex activity; absence of eye movements; diminished

submentalis EMG activity.

Alternative Definition: None.

D.4 (Elemental): N3

Primary Definition: N3 Sleep is characterized by a 30-second epoch containing 6 or more seconds of slow wave activity (low frequencies in the EEG delta activity spectrum). EEG delta activity is characterized by a frequency of 4 Hz or less (slow waves are usually 2 Hz, or less. In humans, a minimum amplitude criteria for slow waves to count toward meeting N3 criteria is $75 \, \mu V$ (peak-to-peak).

Indicators: High amplitude, slow wave EEG activity.

Alternative Definition: None.

D.5 (Elemental): CNS Arousal

Primary Definition: Score arousal during sleep stages N1, N2, N3, or R where there is an abrupt shift of EEG frequency including alpha, theta and/or frequencies greater than 16 Hz (but not spindles) that lasts at least 3 seconds, with at least 10 seconds of stable sleep preceding the change. Scoring of arousal during REM requires a concurrent increase in submental EMG lasting at least 1 second."

Indicators: EEG alpha activity; sometimes EEG beta activity; possible changes in submentalis EMG activity.

Alternative Definition: None.

D.6 (Derived): Number of CNS arousals

Primary Definition: The number of CNS arousals in the total sleep period.

Calculation: Sum of CNS arousals in total sleep period.

Alternative Definition: None.

D.7 (Derived): CNS arousal rate per hour

Primary Definition: The number of CNS arousals per hour of sleep.

Calculation: [(number of CNS arousals/TST (in minutes))*60).

Alternative Definition: None.

D.8 (Derived): REM sleep duration, percentage, latency from sleep onset, and latency from TATS start time

Primary Definition: REM sleep duration is the sum of the number of minutes scored as REM sleep; percentage is the percentage of total sleep time; latency from sleep onset is the duration interval between sleep onset and the first epoch scored as REM sleep; and latency from TATS start time is the duration interval between TATS start time to the first epoch scored as REM sleep.

Calculation: Duration- Sum of the time spent in REM sleep.

Percentage- Percent of TST.

Latency from sleep onset- Amount of time from sleep onset to first epoch scored

as REM sleep.

Latency from TATS start time- Amount of time from TATS start time to first

epoch scored as REM sleep.

Alternative Definition: None.

D.9 (Derived): N1 Sleep duration, percentage, latency from sleep onset, and latency from TATS start time

Primary Definition: N1 sleep duration is the sum of the number of minutes scored as N1 sleep; percentage is the percentage of total sleep time; and latency is the duration interval between lights out and the first epoch scored as N1 sleep.

Calculation: Duration- Sum of the time spent in N1 sleep.

Percentage- Percent of TST.

Latency from sleep onset- Amount of time from sleep onset to first epoch scored

as N1 sleep.

Latency from TATS start time- Amount of time from TATS start time to first

epoch scored as N1 sleep.

Alternative Definition: None.

D.10 (Derived): N2 Sleep duration, percentage, latency from sleep onset, and latency from TATS start time

Primary Definition: N2 sleep duration is the sum of the number of minutes scored as N2 sleep; percentage is the percentage of total sleep time; and latency is the duration interval between lights out and the first epoch scored as N2 sleep.

Calculation: Duration- Sum of the time spent in N2 sleep.

Percentage- Percent of TST.

Latency from sleep onset - Amount of time from sleep onset to first epoch scored as N2 sleep.

Latency from TATS start time- Amount of time from TATS start time to first epoch scored as N2 sleep.

Alternative Definition: None.

D.11 (Derived): N3 Sleep duration, percentage, latency from sleep onset, and latency from TATS start time

Primary Definition: N3 sleep duration is the sum of the number of minutes scored as N3 sleep; percentage is the percentage of total sleep time; and latency is the duration interval between lights out and the first epoch scored as N3 sleep.

Calculation: Duration- Sum of the time spent in N3 sleep.

Percentage- Percent of TST.

Latency from sleep onset - Amount of time from sleep onset to first epoch

scored as N3 sleep.

Latency from TATS start time- Amount of time from TATS start time to first

epoch scored as N3 sleep.

Alternative Definition: None.

E: Terms used to describe the sleep-wake cycle over time periods exceeding 7 days

Circadian rhythms are near 24-hour oscillations that can only be examined under very specific controlled conditions in which elements that could obscure or otherwise influence the underlying oscillation are not present or are accounted for mathematically. While daily patterns (e.g., movement, sleep, heart rate, temperature) are all influenced by the central circadian clock, located in the brain, they are also influenced by many other aspects of behavior, environment, and physiology and are therefore, in an of themselves, are unreliable markers of the underlying rhythm under ambulatory circumstances. Multiday sleep-wake cycles, which are significantly influenced by the circadian clock can be described and may provide insight into the robustness of the underlying circadian rhythms.

E.1 (Elemental): Sleep-Wake Regularity

Primary Definition: The variability in the timing of the main daily sleep period over an extended (1 week or more) period.

Calculation: There are many different ways, both parametric and non-parametric, to calculate regularity of extended patterns of sleep and wake. Included among these are the following. (1) Standard deviation of the onset, offset, or midpoint of the main sleep period. (2) Interdaily stability [Ref 7]: normalized 24-hour value of a X² periodogram of movement (e.g., accelerometry) data [Interdaily Stability = $\frac{n\sum_{h=1}^{p}(\overline{X_h}-\bar{X})^2}{p\sum_{i=1}^{n}(X_i-\bar{X})^2}$, such that n = total number of samples, p = samples per day, \overline{X}_h =hourly means, \overline{X} = average of all data, and x_i = activity at a single time point]. (3) Sleep Regularity Index [Ref 8]: the average likelihood (probability) of an individual being in the same state (wake or sleep) at any two time points 24 hour apart [Sleep Regularity Index = $-100 + \frac{200}{M(N-1)} \sum_{j=1}^{M} \sum_{i=1}^{N-1} \delta(s_{i,j}, s_{i+1,j})$, such that M=number daily epochs, N=number days, $s_{i,j}$ =0 for sleep and 1 for wake, $\delta(s_{i,j}, s_{i+1,j})$ =1 if $s_{i,j}$ = $s_{i+1,j}$ and 0 otherwise].

Alternative Definition: None.

E.2 (Elemental): Sleep-Wake Fragmentation

Primary Definition: The degree of consolidation of bouts of activity (wake) and inactivity (sleep) over an extended (1 week or more) period.

Calculation: There are many different ways, both parametric and non-parametric, to calculate fragmentation of extended patterns of sleep and wake. Included among these are the following. (1) Intradaily variability [Ref 7]: the ratio of the mean square of the difference between successive activity (e.g., accelerometry) values to the mean square of the difference between individual values and overall average values [Interdaily Variability = $\frac{n\sum_{i=2}^{n}(X_i-X_{i-1})^2}{(n-1)\sum_{i=1}^{n}(X_i-\bar{X})^2}$, such that n=1 total number of samples, p=1 samples per day, p=1 average of all data, and p=1 activity at a single time point]. (2) Sleep Regularity Index [Ref 8]: see F.1.

Alternative Definition: None.

E.3 (Elemental): Sleep-Wake Amplitude

Primary Definition: The difference between activity levels at night and during the daytime over an extended (1 week or more) period.

Calculation: There are many different ways, both parametric and non-parametric, to calculate activity amplitude. Included among these are the following. (1) Amplitude of a cosinor fit to activity (e.g., accelerometry) data [$[Y(t) = M + Acos\left(2\pi\frac{t}{\tau} + \phi\right) + e(t)$, such that M = midline estimating statistic of rhythm (rhythm-adjusted mean), A = amplitude (% peak to M distance), $\Phi = \text{time of the peak}$, $\tau = \text{period length of one cycle}$, and e(t) = error estimate][Ref 9] or extended cosinor function [cosinor modified by either a Hill function, anti-logistic, or arctangent [Ref 10]], (2) Relative Amplitude: ratio of the average activity during the 10 most active contiguous hours to the average activity during the 5 least active contiguous hours [Relative Amplitude = $\frac{(M10-L5)}{(M10+L5)}$, such that M10 = average activity occurring in the 10

consecutive hours with the most activity and *L5* = average activity occurring in the 5 consecutive hours with the least activity].

Alternative Definition: None.

E.4 (Elemental): Circadian Phase (phi)

Primary Definition: Any readily definable time point in a circadian oscillation.

Indicators: Indicators may include but not limited to minimum of core body temperature on a constant routine [Ref 11]; onset or midpoint of melatonin (saliva, blood) when light levels are adequately (<5 lux) low; peak of urinary melatonin metabolite (6-MT); timing of the circadian clock imputed through ambulatory light measurements.

Alternative Definition: None.

E.5 (Elemental): Circadian Phase Angle (psi)

Primary Definition: The temporal relationship between either two circadian phases or between one circadian phase and either a behavior or external event.

Indicators: Indicators may include but not limited to time between core body temperature minimum and melatonin onset on a constant routine; time between melatonin onset and onset of sleep; time between melatonin midpoint and wake time.

Alternative Definition: None.

E.6 (Elemental): Circadian Period length (tau)

Primary Definition: The duration of one complete circadian cycle under free-running conditions.

Indicators: Indicators may include but not limited to core body temperature or specific endocrine variations (e.g., cortisol, melatonin) on a forced desynchrony protocol [Ref 12] in which the timing of the circadian clock is disambiguated from the 24-hr day.

Alternative Definition: None.

E.7 (Elemental): Circadian Amplitude

Primary Definition: (1) The mathematical representation of the strength of the circadian oscillation. (2) The contribution of the circadian clock to the magnitude of a daily oscillation.

Indicators: (1) Two indicators have been validated: the amplitude of core body temperature on a constant routine, the duration of nocturnal melatonin release. Both are relative, within-person measures and not valid as absolute measures. (2) Under conditions (e.g., forced desynchrony or constant routine protocols) in which the contributions of the circadian clock can be isolated from other influences (e.g., sleep, activity, stress), indicators may include but not limited to core body temperature, cortisol, melatonin.

ANSI/CTA/NSF-2052.1-A

Alternative Definition: None.



Consumer Technology Association Document Improvement Proposal

If in the review or use of this document a potential change is made evident for safety, health or technical reasons, please email your reason/rationale for the recommended change to standards@CTA.tech.

Consumer Technology Association Technology & Standards Department 1919 S Eads Street, Arlington, VA 22202 FAX: (703) 907-7693 standards@CTA.tech

Consumer Technology Association[™]