Performance Criteria and Testing Protocols for Breathing Parameters

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(This document was produced by CTA's **R11 Health, Fitness & Wellness Committee**.)

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FORWARD

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

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Performance Criteria and Testing Protocols for Breathing Rate

1 SCOPE

This standard establishes definitions and performance criteria for consumer technology measuring breathing parameters including Breathing Rate (BR). Specifically, the standard provides a process for the evaluation of respiration monitoring solutions at rest and during physical activity.

1.1 Purpose

The purpose of this document is to provide organizations who want to test consumer grade BR monitoring devices with a standard process that ensures the device meets the basic standard for BR accuracy as defined by the CTA.

1.2 Stakeholders

The stakeholders for this document include:

- Wearable device companies who want to understand what guidelines need to be adhered to in order to meet a basic standard for BR monitoring accuracy.
- Wearable device companies who want to make sure that consumers or media who test their device for BR accuracy have a clear standard to test against so outcomes can be reported accurately.
- Consumers who want to know if a specific device meets the minimum standards for BR accuracy.
- Media who want to test the accuracy of a BR monitor for a specific device.
- Researchers who want to know if a specific device meets the minimum standards for BR accuracy.
- Organizations recommending devices to their employees or end-consumers.

1.3 Other Considerations

This standard was produced to examine performance of devices that measure BR. Participant characteristics, test conditions, and protocols were chosen to include a range of conditions that allow for examination of BR from devices utilizing varying techniques. It is acknowledged that current and future methods for monitoring BR may benefit from additional analysis beyond that recommended in this document. For example, optical techniques may be affected by ambient light, inertial techniques may be affected by non-breathing motion, and audio techniques may be affected by ambient noise. Additionally, sensor location on the body may be more or less suited for particular protocols.

This standard focuses on testing healthy adults where the solution is in the consumer space. There are a number of use cases for testing BR in higher risk situations (e.g., allergy trigger monitoring, guided relaxation) that extend to clinical applications (e.g., asthma attack detection, sleep disorder) that are not considered within scope of this document.

With that in mind the following considerations are noted as potentially important while not accounted for in the current standard.

- Participant characteristics: specific age ranges, body composition, cardiopulmonary health status.
- Test conditions: variable ambient light (e.g., direct, indirect, and sun/shadow transitions), wide ranging temperatures (cold and warm), wide range of ambient noises, incorporation of clothing that may have the potential to interfere with devices (e.g., tightness, thickness, or that which restricts ideal wearing of device), body or wrist positions during certain protocols (e.g., for cycling applications: bent wrist or straight arms), position of device on the body, electrical interference from outside sources, potential for signal loss between the measurement device and data repository (e.g., mobile app or other).

2 REFERENCES

2.1 Normative References

The following standards contain provisions that, through reference in this text, constitute normative provisions of this standard. At the time of publication, the editions indicated were 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 editions of the standards listed here.

2.2 Normative Reference List

1. Fitzpatrick, T. B. "Soleil et peau" [Sun and skin]. *Journal de Médecine Esthétique* (in French), (2), 33–34 (1975).

2. Thomas, S., Reading, J., Shephard, R.J. “Revision of the Physical Activity Readiness Questionnaire (PAR-Q)”. *Can J Sport Sci.*, 17(4), 338-45 (1992).

3 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.

4 DEFINITIONS, SYMBOLS AND ABBREVIATIONS

4.1 Definitions

Breathing Rate (BR): BR, sometimes referred to as respiratory rate or respiration rate, measures the number of breaths, typically per minute, exhibited.

Breathing Rate Monitoring Device (BRMD): The BRMD is the wearable device to be tested.

Body Mass Index (BMI): BMI is a person's weight in kilograms (kg) divided by the squared of his or her height in meters.

Electrocardiogram (ECG): An electrocardiogram is a record or display of a person's heartbeat produced by electrocardiography.

Participant (Subject): The participant is the human test subject.

Refresh Time Offset: The refresh time offset is the amount of time between a BR data point being collected and the data being made available. This is sometimes referred to as data refresh latency.

Running/Jogging: Running/Jogging is the act of raising and lowering each foot, with a period of time where neither foot is in contact with the ground, with the express purpose of locomotion.

Tester (tester instructor): The tester is the research investigator who is obtaining data from the Participant.

Test Condition: The test condition is a subpart of a test protocol.

Test Protocol: The test protocol is a set of test conditions to be tested on a Participant as a single unit.

Walking: Walking is the act of raising and lowering each foot, with at least one foot in contact with the ground at any given time, with the express purpose of locomotion.

5 TECHNOLOGY APPLICATIONS

Below are examples of technologies that can be used in the detection of BR. This is not an exhaustive list.

- Contact: Photoplethysmogram (PPG), Electrocardiogram (ECG), Ballistocardiogram (BCG), Inertial Measurement Unit (IMU), acoustic, Inductive Plethysmography, Box Plethysmography, pressure sensor
- Contactless: Radio Frequency (RF)/acoustic/wifi, video, Functional Near-Infrared Spectroscopy (FNIRS), Forward-Looking Infrared (FLIR), Near-Infrared (NIR)

Placement/form-factor:

- Contact: watch, ring, patch/band, chest strap, earbuds/headphones, glasses, headband, mask, clothing tag

- Contactless: camera/radar

6 TESTING CONDITIONS

The following clauses address the conditions by which testing shall be conducted. Testing is intended to be performed on Breathing Rate Monitoring Devices (BRMD) that measure BR.

6.1 Participant Considerations

Testing shall include at least 30 Participants based on the inclusion criteria outlined in this section and the Participants shall be representative as specified across the characteristics listed in the following subsections.

6.1.1 Skin Tones

Using the Fitzpatrick Scale when applicable for technology, at a suggested minimum the following number of Participants shall have skin tones in the range specified:

- At least 25% of Participants lighter skin range (1-3 on Fitzpatrick Scale) and
- At least 25 % of Participants darker skin range (4-6 on Fitzpatrick Scale).

6.1.2 BMI – Range

Using BMI, at a suggested minimum the following percentage of Participants shall be within the range specified:

- At least 10% of Participants below 20 kg/m^2,
- At least 20% of Participants between 20kg/m^2 and 25kg/m^2, and
- At least 10 % of Participants above 25 kg/m^2.

6.1.3 Age

All Participants shall be at least 18 years of age and physically capable of completing the prescribed tests[1].

6.1.4 Sex

At least 40% of participants shall be male. At least 40 % of participants shall be female.

[1] Thomas, S., Reading, J., Shephard, R.J. "Revision of the Physical Activity Readiness Questionnaire (PAR-Q)". Can J Sport Sci., 17(4), 338-45 (1992).

6.2 Testing Environment

The ambient light levels in the testing area shall consist of typical lighting conditions for indoor environment for optical sensing. For acoustic sensing, the environment should be quiet since breathing sound can be obfuscated by the environmental noise.

6.3 Control Device

The tester shall identify a control device to be used and record the control device name and properties as outlined in the Test Report (Section 8). The control device should be either a FDA approved handheld device that measures tidal breathing rate, pneumotachogram, capnography, or respiratory inductive plethysmography band (thoracic, abdominal or combination thereof). A device that is scientifically validated and reported in a peer reviewed scientific publication published in a relevant journal may also be used.

6.3.1 Control Device Configuration

The control device should be updated with the latest commercial firmware version, calibrated, and settings adjusted, if appropriate, per the manufacturer's specifications prior to testing.

6.3.2 Control Device Setup

The control device shall be worn by the Participant at the preferred body position as recommended by manufacturer including device and Participant preparation. It is recommended that the control device has a known accuracy.

6.4 Breathing Rate Monitoring Device

There is no restriction on the type of device or sensor that can be used as the BRMD as outlined in Section 5.

6.4.1 Breathing Rate Monitoring Device Configuration

BRMD to be tested shall be updated with the latest commercial firmware version, calibrated, and settings adjusted, if appropriate, per the manufacturer's specifications prior to testing. Any future changes to the underlying algorithm or firmware that significantly affects performance shall require retesting. This includes changes to how BR data is collected, computed or stored and changes that affect the BRMD's power consumption, memory consumption or battery voltage.

6.4.2 Breathing Rate Monitoring Device Setup

BRMD to be tested shall be worn by the Participant at the preferred body position as recommended by manufacturer for the use of the BRMD. The Participant shall be correctly fitted with the test BRMD taking special care that the sensor is not obstructed or hindered by the test setup. The BRMD should also be set to the appropriate "mode," if required, to collect BR data.

Special considerations shall be taken when a chest-based BRMD is assessed. The BRMD should be fitted at least one (1) inch from the control device. Caution shall be exercised to avoid physical contact between the devices. If devices are intended for the same location causing devices to be placed next to each other the relative positions of the devices shall be randomized across Participants.

7 TESTING PROTOCOL

The testing protocol for this standard has been divided into two sections. The mandatory testing shall be conducted by all devices to claim compliance with the standard. The optional section provides additional protocols that can be conducted by devices that make the correlating claims. All test conducted and association results shall be included in the Test report (as outlined in Section 8).

7.1 Mandatory Testing Protocol: Breathing Rate while Resting

The Participant shall assume the at rest position of the Tester's choosing. This may include seated on a chair, lying supine, or standing. Tester shall maintain consistency regarding the at-rest position for all tests executed. Participant shall remain still for the duration of the test, with hands, legs, and head not moving. Participant shall refrain from talking during the test and testing shall be conducted in a quiet environment. Tester shall monitor Participant's comfort during the protocol and shall carry out safety checks about comfort level prior to when breathing pace is increased according to the protocol. Tester should allow rest periods between breathing exercises. Guidance should not interfere with the measurement. Note: one minute (60 seconds) is the minimum suggested duration for the breathing measurement.

7.1.1 Protocol

Perform data collection utilizing the following protocol:

- Participant is to stay in an at-rest position and instructed to breathe normally for at least 1 minute.
- Participant is to breathe following the guidance of repetitive visual, auditory or haptic cues:
    - Execute for breathing guidance frequencies including 5, 10, 15, 20, 25, 30, 35 breaths per minute in the order at the discretion of the Tester:
        - Participant is to breathe following the guidance for a period of minimally 60 seconds.
        - Participant is to breathe freely until a comfortable breathing rate is achieved. This is to prepare the subject for the next cue. Data collected in this step is not used for evaluation of the BRMD.

This represents the end of the testing protocol.

7.2 Optional Testing Protocol(s)

There are a variety of circumstances and activities that may alter breathing rate, rate detection, and breathing patterns. These include speech, sleep, activity, and others. While comprehensive assessments across all stats and conditions are out of scope for this standard, below are optional protocols to operationalize physical activity respiration assessments.

- physical activity:
  - walking
  - running/jogging

7.2.1 Breathing Rate while Walking Protocol

Perform data collection utilizing the following protocol:

- 1 minute (0:00-1:00) of standing quietly on treadmill
- 10 minutes (1:00-11:00) on a Treadmill walking at a comfortable pace and at minimal incline but not less than 0% (i.e., between 0%-1%). The pace should be comfortable and align with the CDC definition of Moderate Intensity[2] throughout the duration of the protocol.
- 3 minutes (11:00-14:00) of standing quietly on treadmill.
- After 14 minutes have elapsed, data collection should end.

7.2.2 Breathing Rate while Running/Jogging Protocol

Perform data collection utilizing the following protocol:

- 1 minute (0:00-1:00) of standing quietly on treadmill
- 15 minutes (1:00-16:00) of jogging/running on a Treadmill at a comfortable pace and at minimal incline but not less than 0% (i.e., between 0%-1%). The pace should be comfortable for the duration of the test and align with the CDC definition Vigorous Intensity[2].
- 10 minutes (16:00-26:00) on treadmill running/jogging or walking at a slower pace.
- After 26 minutes has elapsed, data collection should end.

8 DATA

The following performance criteria must be met for all mandatory protocols in order to meet this standard.

For evaluation of performance four components of data are considered. These areas are data output rate, availability, data accuracy, and delay in presenting data. The investigator is responsible for

[2] https://www.cdc.gov/physicalactivity/basics/measuring/index.html

ensuring the quality of the data collection for both the testing device and the reference device as poor data acquisition and quality can impact these domains. It is also the case that shift in the time domain can occur between devices and should be accounted in analysis. Ideally, time-shift can be aligned for each breathing cycle when morphological features are extracted. However, alignment of the data minute by minute using aggregated statistics (such as mean and standard deviation) should be acceptable.

- Data accuracy:
    - A BRMD or BRMD derived reference rate is considered accurate if the overall mean absolute error (MAE) +/-2 breaths/min
    - Accuracy per task should be calculated and reported
    - While the cutoff of MAE of +/- 2 breaths/min is often thought of as adequate, there may be challenges in starting and stopping times and at the extremes of respiratory rates that should be addressed in analysis.
        - Analysis using Bland-Altman and other techniques are suggested to assess level-of-agreement (LOA) between the test device and the reference device and to assess for the fixed bias and proportional bias.

8.1 Validation

Offline analysis of the collected BR data (control device and the breathing rate monitoring device, BRMD) should be carried out as follows:

- Data output rate temporal averaging
    - The two synchronized BR time series (reference and BRMD) should follow the same temporal averaging that the BRMD uses in providing BR data to the user. For example, if the BRMD provides BR data every second, based on a sliding window of 5 seconds, then the reference BR time series should undergo the same temporal averaging.
- Inspection of control device data
    - Visual inspection of the collected data is strongly encouraged as a first step of analysis. High quality of reference data is of utmost importance for meaningful results, and the reference BR data should be checked for any errors such as spikes which do not represent stable physiological signal, and which should be either removed in post-processing or excluded from analysis. The amount of reference data corrected and/or excluded should be reported in percentage. The amount of reference data corrected and/or excluded (including the exclusion of entire data sets) should be reported as a percentage.
    - The BRMD estimates may lag behind the reference BR values for a number of reasons, including the time required for computation and the nature of the algorithm used to estimate BR. To compensate for this lag, the timestamps of the BRMD estimated values may be adjusted by a constant amount of time to increase ‘synchronization’ with the reference BR values. This synchronization time constant is referred to as the ‘refresh time offset’ and must be kept constant within a given validation (i.e., it must be the kept

same for each activity tested). The BRMD timestamps may be moved in time up to the maximum refresh time offset.)

- Data availability or coverage
  - Calculation of data availability determined and reported as percentage of overall data.
- Calculation of the error metric values
  - The error metrics (MAE) should be calculated from each respiratory rate estimate using the synchronized reference and BRMD time series for each Participant.

Mean absolute error (MAE) is a quantity used to measure how close an estimate is to the true value and the equation for the MAE calculation is given below:

$$MAE = \frac{1}{N}\sum_{i=1}^{N}|T_i - E_i|$$

Where T_i is the true value (obtained from the Control Device) and E_i is the estimate value (obtained from the BRMD), and N is the number of estimate values (i.e., for each test protocol).

- Calculate accuracy = (number of data points whose MAE $\leq$ 2 breaths per minute) / N. This metric will help ignore some of the estimated values affected by motion or other artifacts. The test device or algorithm should have >80% accuracy based on this metric.

9 TEST REPORTING

A Test Report shall be generated documenting the test configuration and setup of the BRMD and the test results for the BRMD.

The Test Report shall include the following test configuration and setup aspects.

1. The properties of the BRMD including:
   a. Model number
   b. Update/revision number (if applicable)
   c. Firmware version number
   d. Sensing modality (for example: optical, electrical)
   e. Update rate (how frequently the device updates collected data)
   f. Refresh Time Offset before newly collected data is visible/available
   g. If sensitivity settings are available report each setting that device was in and if multiple are available recommended to test in all

2. The properties of the Control Device including:
   a. Make and Model number
   b. Update/revision number (if applicable)
   c. Firmware version number

d. Modality (for example: 5 lead ECG, electrode-based chest worn device)
e. Update rate
f. Refresh Time Offset
g. Values of any adjustable settings
h. Date of most recent calibration

3. Report the exclusion and/or inclusion criteria used for selecting Participants

4. Description of the characteristics of each Participant including:
a. Gender
b. Age
c. Weight
d. Height
e. BMI
f. Health status and relevant characteristics (e.g., physical conditions)
f. Skin tone Fitzpatrick score (if applicable)
g. Artifacts or other salient features (if applicable)
h. Indication that PAR Q questionnaire completed (Y/N).

5. Detailed description of each Test Protocol including:
a. Deviations, if any from the mandatory protocol specified in Section 8.1
b. For the Baseline Task, the time duration and details of what is required to establish the Device Baseline, if the Device Baseline is performed, as well as the method used to establish the Participant Baseline for Participants
c. Equipment used for each test condition, if any
d. Participant activity within each test condition (resting, walking, running, etc.)
e. Setting of testing equipment (e.g., incline and speed of treadmill)
f. Wearing (body) position of the BRMD on Participants.
g. If the BRMD has multiple wearability settings (for example a strap with multiple holes to vary tightness on a wrist-worn BRMD) a description of how the BRMD was properly fitted to the Participants should be included

6. For Data Section, any Participant data acquired but not included in the calculation of performance metrics

7. The Test Report shall include the following test results for each Test Protocol defined in the subsections of Section 8:
a. Data output rate from both the BRMD and control device
b. Mean and standard deviation of BR for each Participant from the BRMD
c. Mean and standard deviation of BR for each Participant from the Control device
d. Mean and standard deviation of BR for all Participants
e. Refresh time offset correction if utilized
f. MAE or accuracy of BR for the BRMD.

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.

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