ASSESSING HEAT STRAIN THROUGH PHYSIOLOGICAL MONITORING

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LIMITATIONS TO PHYSIOLOGICAL MONITORING

Cost

- Individual devices
- Cost of work
 associated with
 data collection,
 interpretation,
 and management

User Acceptance

- "Opt in"
- Informed consent
- Agreements on use of data
- No penalties for additional rest dictated by physiological monitoring system

Data Analysis, Interpretation, Management

- Team approach with small numbers
- Data analyst familiar with physiological effects of heat on the human body
- Case-by-case review of data

Data Privacy

- Concerns with ownership of data, sharing data, and using data to make employment decisions
- Consider privacy agreements and consulting legal and regulatory professionals

LIMITATIONS TO PHYSIOLOGICAL MONITORING

HOW VALID IS THE METHOD?

- Is it measuring what it's intended to measure?
- Is it accurate?



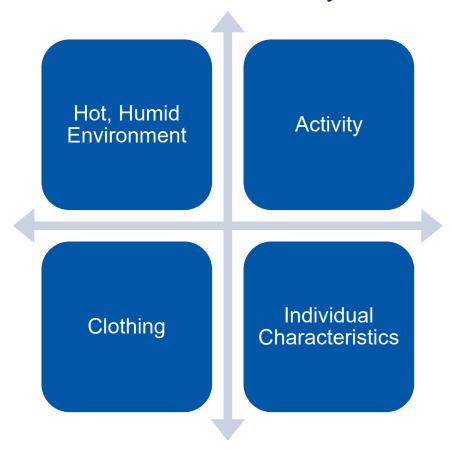


Invalid and/or not reliable?



Can lead to false positives or false negatives

Factors that influence validity assessment



QUESTIONS TO ASK WHEN LOOKING AT VALIDITY STUDIES

Who?

Were participants reflective of populations who work in the heat? (Age, biological sex, fitness, health status)

Where?

Field or lab study? Work setting?

What?

Environmental conditions?

Attire? PPE?

Type of work being performed? Simulated or actual work?

Exercise intensity and duration?

How hot did the participants get?

99.5 - 103.1°F range with the assumption that workers will no longer be in that exposure before they reach 104 °F

Valid?

What was the gold-standard device for comparison? HOW different from gold-standard?

Conclude after review:

Is the device "fit for purpose" to be deployed within a specific heat stress management program?

Table 3. Operational Definitions and Relevant Examples of Reliability, Validity, Sensitivity, and Specificity Related to the Monitor System and Its Decision Performance*

Term	Operational Definition	Relevant Example
Reliability	The ability to (re)produce a decision in accordance with expected dynamics.	A core body temperature monitoring device that can provide consistent, reproducible estimates of core body temperature at the decision threshold (or over a reasonable range of core body temperatures).
Validity - Decision	The degree to which a decision is likely to a produce a result similar to a gold standard.	When comparing an estimated core temperature measure to a gold standard assessment at the decision threshold, the absolute mean difference of repeated trials is near zero (accuracy or bias) and the precision (standard deviation of the differences) is small.
Validity – Method	The degree to which a measurement is likely to produce a result similar to a gold standard over a range of relevant values.	When comparing an estimated core temperature measure to a gold standard assessment between 37 and 40 °C, the absolute mean difference between methods is near zero (accuracy or bias) and the precision (standard deviation of the differences) is small (say less than 0.05 °C).
Sensitivity	The ability of a decision to yield a positive result for a person that has that condition; that is, "True Positive." Sensitivity is calculated as the number of True Positive observations divided by all the gold standard positive observations.	With a definition of hyperthermia as above 38.5°C (101.3°F), the estimated core body temperature monitoring device can confirm that the individual's core temperature is over the 38.5°C (101.3°F) threshold (e.g., hyperthermic) when the gold standard assessment confirms they are hyperthermic
Specificity	The ability of the test or instrument to obtain normal range or negative results for a person who does not have a that condition; that is, True Negative. Specificity is calculated as the number of True Negative observations divided by all the gold standard negative observations.	With a definition of hyperthermia as above 38.5°C (101.3°F), the estimated core body temperature monitoring device can confirm that the individual's core temperature is below the 38.5°C (101.3°F) threshold (e.g., not hyperthermic) when the gold standard assessment confirms they are not hyperthermic

DISCLAIMER: The diagnosis of a heat-related illness, specifically exertional heat stroke (a medical emergency), presents with central nervous system dysfunction in conjunction with a clinically assessed rectal temperature of over 104/105°F (40/40.5°C). It cannot be diagnosed with a surrogate method like a wearable device.







leither reliable Reliable, but no nor valid valid

Valid

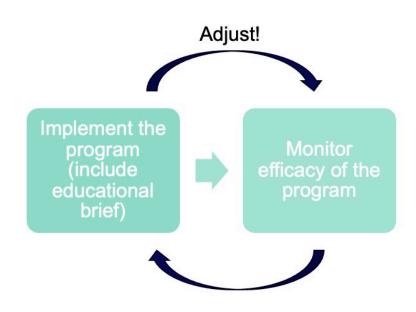
^{*} These definitions and relevant examples are specific to the physiological variables discussed in this white paper

YOUR ASSESSMENT TEAM: WHO'S INVOLVED?

Assessment Team Role	Job Title
Device Creator and Manufacturers	•Engineers •Sales representatives
Subject matter experts / stakeholders/	 Health, Safety, Medical/Healthcare professionals and on-site clinical staff Quality assurance / data analysts Procurement specialists Physiologists Workers Consultants Human resources
Team Lead	Health and Safety Specialists Industrial Hygienists Project / Program Managers
Executive Sponsor	•Leadership / Site Management Team
End user representatives	•Field operations •Technicians
Data Analysts	PhysiologistsMedical professionals (e.g., physicians, nurses, athletic trainers)Consultants

KEY STEPS TO BUILDING ASSESSMENT TEAM

- 1. Establish the assessment purpose and objectives
 - Write it down
- 2. Determine team members and their roles/responsibilities
 - Clearly define
- 3. Develop the wearable physiological monitoring program as a supplement to an existing heat stress management plan
 - Includes plans for: training, communication, implementation, monitoring, assessment, data analysis
- 4. Develop clear guidelines on using the data to modify or stop work
 - Write it down
- 5. Implement, monitor, adjust! Technology is always evolving



SUMMARY



- Physiological monitoring to assess heat strain can be done in real-time, continuously, and for each individual worker
 - Can account for intra- and inter-variability in response to the same heat load
- Core body temperature, heart rate, and PSI are common variables to assess;
 many emerging variables exist
 - Use data for risk management, decision making, and assessing efficacy of heat mitigation interventions
- Limitations: cost, user acceptance, data analysis/management, data privacy
 - Do your homework and have documented plan!
- Validity of a selected method is vital to its implementation and use
- It takes a village build a team!



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White Paper

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