EVIDENCE Checklist

Table 1. EVIDENCE (EValuating connecteD sENsor teChnologiEs) Checklist

This checklist is intended for studies of which the primary outcomes are the evaluation of a digital measurement product.

Legend:

White/Blank=Required, Grey=Preferred, Black=Not Required

Identify the evaluation type: _____

Section/Topic	#	Importance	Checklist Item	Proof of Concept	Verification	Analytical Validation	Clinical Validation	Utility & Usability	Page #
TITLE									
Title	1	Preferred	Explicitly identify the study as proof of concept, verification, analytical validation, clinical validation, and/or utility and usability. If limited by journal specified word length, it is recommended to include the evaluation type as key words.						
ABSTRACT									
Structured Summary	2	Required, individual elements as applicable	Provide a structured summary including the following items, as applicable to the study: evaluation type (proof of concept, verification, analytical validation, clinical validation, and/or utility and usability), study objectives, concept of interest and outcomes measured, description of patient population, digital measurement products used, wear location, reference standard, sample size, and key results.						

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INTRODUCTION									
Rationale	3	Required	Define study rationale in the context of what is already known and any existing gaps in the field.						
Objectives	4	Required	Clearly state the research question and study aims.						
METHODS									
Ethics and Informed Consent	5	Required	Include a statement that Institutional Review Board (IRB) approval or Ethics Committee review of the study documentation was completed. Indicate whether a written consent was obtained from the study participants.		[redacted]				
Protocol and Registration	6	Preferred	When evaluation studies are conducted as part of an interventional clinical trial, document the clinical trial's registration number and whether or not the protocol can be accessed.		[redacted]				
Participants	7	Required	Define the recruitment strategy, inclusion, and exclusion criteria of study participants.		[redacted]				
Sample Size	8	Required	Indicate how the sample size was determined. In cases of N-of-1 studies, authors may describe the sample size based on number of measurements rather than the number of participants.		[redacted]				
Connected Sensor Technology	9								
Make and Model	9a	Required	State the make and model of the connected sensor technology used						
Selection Rationale	9b	Preferred	Describe why the connected sensor technology was chosen for the study.						

Product Availability/ Maturity	9c	Preferred	Describe if the connected sensor technology is a custom prototype or a product that is currently on the market, available for purchase.						
Sensor Characteristics	9d	Required	Describe the sensor modality(ies) and sample level data characteristics (ex. units, sampling rate, etc.) used for data collection in as much detail as possible.						
Form Factor and Wear Location	9e	Required	Describe the form factor (physical shape) and wear location (precise anatomic position of sensor)						
Software	10								
Algorithm Description	10a	Required	Describe in as much detail as possible the algorithm used for data analysis in the study. If a new algorithm is being created, describe in as much detail as possible the procedure for building the algorithm. Procedures used for validating the algorithm can be included in the statistical analysis section.		[redacted]			[redacted]	
Version Number and Manufacturer	10b	Required	State the version number and manufacturer of any software used for data collection and analysis where possible.		[redacted]			[redacted]	
Outcome Assessed	11	Required	Clearly identify the outcomes to be measured.						
Data Collection Protocol	12	Required	Describe experimental procedures to collect data.						
Wear Time	13	Preferred	Determine the minimum wear time for sufficient data capture and a meaningful data set used in analysis.		[redacted]				
Reference Standard	14	Required	Describe the standard to which the performance of the connected sensor technology is being compared.						

Statistical Analysis	15	Required	Describe relevant statistical analyses to perform verification, analytical and/or clinical validation of the solution utilized in research.						
Training for Staff and/or Participants	16	Preferred	Describe any training given to study participants and/or staff for how to properly use the connected sensor technology.		[redacted]				
RESULTS									
Participant Flow	17	Required	A diagram similar to a CONSORT flowchart is strongly recommended to show numbers for participant recruitment to study completion.		[redacted]				
Participant Demographics	18	Required	Describe the participant demographics that are minimally necessary for the study.		[redacted]				
Numbers Analyzed/ Findings	19	Required	Describe the study's findings, including missing data.						
Utility and Usability	20								
Technical Problems	20a	Preferred	Describe any technical problems that impacted the study results		[redacted]				
Adverse Events	20b	Required	Describe unintended effects of technology causing physical or psychological harms		[redacted]				
Feedback from Participants and Study Staff	20c	Preferred	Describe any feedback from participants and study staff and/or findings from satisfaction surveys.		[redacted]				
DISCUSSION									
Summary of Findings	21	Required	Summarize the main findings and relevance for the patient population and its clinical application as						

			appropriate.						
Comparison to Existing Literature	22	Required	Compare results to similar studies and describe potential reasons for any major differences observed.						
Limitations	23	Required	Discuss limitations of study methods and/or the connected sensor technology used.						
Conclusions	24	Required	Provide interpretation of findings and implications for future research.						
OTHER									
Funding and Competing Interests	25	Required	Describe sources of funding or other support received for work.						