Technology performance considerations for selection of devices measuring nocturnal scratch

Measurement performance

Specification	Definition	Considerations ★★★
Accuracy	The degree to which a measurement agrees with a reference standard	The environment for data capture (for example, temperature) can affect mobile technology accuracy. Technology accuracy may also vary across the measurement range and with battery charge. Levels of accuracy shall be provided by the technology vendor based on analytical validation.
Precision	Reproducibility of the measurement over time in a single device and across multiple devices.	Precision should be considered over time in a single mobile technology and across like technologies. Levels of precision shall be provided by the technology vendor based on analytical validation.
Sampling frequency	The number of samples per second (or per other unit) taken from a continuous signal to make a discrete or digital signal.	Two levels of sampling frequency to consider for scratching measurement: 1. Sample level data (e.g. accelerometer sampling frequency) 2. Output data: Minimum measurable length of the scratching bout (usually in seconds) For a successful analysis by your selected algorithm to detect scratching movements, ensure that sufficient frequency of accelerometer sample level data is collected.

Resolution	The smallest absolute amount of change that can be detected by a measurement.	What is the smallest/finest scratching movement the technology can detect? Remember there will be a tradeoff between sensitivity of the measure and noise. Additionally, establish if the technology can measure only hand-scratching behavior, or also non-hand scratching behavior.

Operational specifications

Specification	Definition	Considerations ★★★
Firmware	Firmware is permanent software programmed into the mobile technology that serves as its operating system.	Updates to firmware can change all aspects of functionality, including security features and how the sensor data is processed. Inquire with the technology vendor about firmware update procedures and how they may affect collection, processing, or upload of data. Ensure that 1) data equivalence is maintained throughout the trial and 2) data security is optimized during the firmware updates.
Failure rate	The frequency with which the technology, or a component of the technology, fails.	Impacts of technology failure may include missing data, participant and investigator dissatisfaction, and potentially increased dropout rates from the trial.
Battery life	Run time of the mobile technology on full charge.	Battery life is determined by both the power available on a full charge and the power consumption of the mobile technology. There will be a tradeoff between power consumption and technical performance.
Setup & use	Activities required for the patient to start using the device and continue using it correctly.	Evaluate required level of technology setup & maintenance - both in-clinic and at home. Consider actions required to be performed by the patient, such as connecting to Wi-Fi, charging, connecting to a data hub/app on a phone, or cleaning the device. Opt for the least possible overhead on patients as possible. Where appropriate, feasibility studies examining the acceptability and usability of the technology should be conducted with the participant population of interest.

Unit and measurement uniformity	All units of the DHT should conform to the same performance, operational, and communication standards and descriptions as provided by the manufacturer.	Evaluate the manufacturer's evidence about uniformity of the units, such as repeatability and reproducibility of the measurement, updates to the latest firmware or OS, or conformity in the form factor. Are the DHT's measurements consistent across a range of factors (e.g., body morphology, skin color, variation in sensor placement) that may introduce variability into measurements?
Conditions of use	For some DHTs and investigations, it may be appropriate to identify the conditions (e.g., temperature range) under which the DHT functions reliably.	Consider whether the measurement performance and operational standards are met and reproducible over a range of environmental conditions (such as temperature, nearby electronics, humidity, etc.).
Cost & availability of devices	Costs and need for a specific number of units may differ based on the study scope and phase.	Based on your study needs, think about the number of units needed in the study (consider also re-using the same unit by multiple patients in case of a shorter study wear time). Calculate the costs and inquire about availability of sufficient device units with the vendor.

Technology communication and data transfer

For additional considerations regarding subject privacy assurance, data collection, and study monitoring please refer to the following resource of this toolkit: *Recommendations for subject privacy assurance, data collection, and study monitoring in clinical studies utilizing digital measurement of nocturnal scratch*

Specification	Definition	Considerations ★★★
Connectivity	Wearables and remote sensors not embedded in participants' smartphones typically pair via Wi-Fi or Bluetooth to an app prior to transmission to a central server.	Define how the device is set up and connected. This can be performed either at the site during the initial visit, or at home by the patient or study personnel. In both cases, provide materials and support to ensure successful connection of the device to the remote server.
Transfer to data gathering platform	The transfer of individual participant data to a central server or other data gathering platform for the trial.	Data is typically transferred to the technology manufacturer's servers prior to transfer to the final data storage servers. As such, technology selection should also consider 1) if any intermediary technology, such as a mobile app, is required for data transfer 2) strategies for handling unreliable data streams and 3) the specifications of the technology manufacturer servers, if relied upon.
21 CFR Part 11 Compliance (US)	Regulations in Part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11) apply to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in FDA regulations.	While data management processes may be outsourced to electronic service providers, sponsors remain ultimately responsible for the authenticity, integrity, and confidentiality of data generated by mobile technologies.

GDPR compliance (EU)	GDPR regulation covers aspects of security and data rights, privacy, and governance, such as principles and conditions for the processing of personal data, individual's rights, data transfers, and breach reporting.	In the EU, the phrase "personal data" has a wider interpretation that covers data where individuals can be differentiated but not named, so even pseudonymised (de-identified) data remains personal data. Health data is considered a special category of data under GDPR and is subject to additional controls.

Data processing and analysis

Specification	Definition	Considerations ★★★
Data Processing	Operations performed on a given set of data to extract the required information in an appropriate form.	Several levels of data processing may occur. Ask the technology manufacturer for a data processing diagram from raw (e.g. accelerometer) data to final measurement output (e.g. total scratching duration).
Algorithm	A set of instructions embedded in a software used for solving a problem or accomplishing a task, e.g. calculating a movement from a portion of accelerometer data.	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, together with its versioning and processes of continuous improvements (if applicable). In case the algorithm is 'learning' or improving over time, describe this design as well.
Metadata	Data that describes and gives information about other data.	Metadata is required to provide context for the data captured by digital technologies, allow the data to be readily interpreted, and determine the data's clinical meaningfulness. Minimal requirement for metadata is timestamp or time-alignment. Additional metadata can provide information about the device or the system (e.g. battery use in time, connection status, etc.), or about environment of the measurement (e.g. humidity, temperature, etc.)

Data Attribution	A link between each data point and one specific study participant.	Ensure that all collected data are attributed to one specific participant in the study. Consider disruption in data attribution, e.g. capturing motion of other people in the room (for non-wearable sensors), changing behaviors (e.g. usually occupied bedside), or other people using the device (manipulation when the device is taken off, use of a wearable device by another member in the household).
Availability of raw data	Raw data is data that has not been processed or altered after their initial generation by the sensors.	Consider if you will require raw data from the device or sensor manufacturer (such as accelerometer readout) for your analysis. This data may be needed if using a standalone algorithm to identify scratching movements from sensor data. Other options are to obtain pre-processed, processed, or aggregated data from the device manufacturer.
Real time overview	View in real time on data collection, storage, processing or analysis.	Discuss with the technology manufacturer or vendor whether it is possible to offer for the sponsor or the study team an option for real-time monitoring of data that is being collected, stored on a remote server, processed, or analyzed.

Examples of technology performance trade-offs between technologies measuring nocturnal scratching

IR Video Camera

Description: A camera device recording in the infrared light spectrum. Often accompanied by polysomnography (PSG) measurement in a sleep lab.

Pros	Cons
+ No attachment to skin - no risk of skin irritation + Possibility to observe movements of the whole body	- Automated analysis still difficult - usually requires a human rater and labeling is expensive - Requires trained technical professionals to set up (often happens in a sleep lab outside of the patients' homes) - Scratching movements might be difficult to read if hands are hidden (e.g. under a blanket) - Difficult to scale to large clinical studies - Privacy concerns when used in home environments

Non-wearable room sensor device

Description: A room-installed sensor using Wi-Fi or other wave technology for spatial and movement sensing.

Pros	Cons
+ No attachment to skin - no risk of skin irritation + Possibility to observe movements of the whole body + Automated analysis better developed than other	- Automated analysis may incorporate risk of false positives - identifying other body movements as scratches - Potential to incorporate false positives generated by other persons in the household. Data attribution is not straightforward

technologies, e.g. IR videography + Additional sensors may be part of the device (e.g. measuring ambient temperature, ambient light, etc.) + Low overhead for patients once installed (typically no charging, remembering to put on or take off, etc.)	(signal can come from other people or pets) - Not yet as widespread a technology as wearables

Wearable technology - wrist-worn device

Description: A wristwatch like accelerometer-based device that may or may not include a watch face. It is worn on the wrist of one or both hands.

Pros	Cons
+ Easy to use in home setting and over many consecutive nights + Ease of setup & wear + Ubiquitous technology that has been well received and accepted for research use + Additional sensors may be part of the device (e.g. measuring temperature, heart rate, ambient light, etc.) + Usually good battery life (days or weeks)	- A tendency to incorporate false positives - identifying other body movements (e.g., turning over while sleeping, etc.) as scratches - May not capture scratching movements generated by other parts of the body (e.g. legs, torso) - May not capture fine scratch movements (e.g. finger-only scratching) - Requires skin contact - may irritate the skin

Wearable technology - patch device

Description: A patch-like accelerometer-based device that adheres directly to the patient's skin.

Pros	Cons
+ Can be positioned anywhere on	- Adhesives of the patch may

the body + Easy to use in home setting + Ability to capture fine scratching movements (e.g. finger-only scratching) + Additional sensors may be part of the device	irritate the skin - Smaller form-factor and use of connectivity & accelerometer measurement may require more frequent battery charging - A tendency to incorporate false positives - identifying other body movements (e.g., turning over while sleeping, etc.) as scratches

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Additional Relevant Resources

- The Playbook: An evaluation framework for fit-for-purpose digital sensing products
- The Playbook: Tech considerations (slides 75-149)
- DiMe EVIDENCE checklist
- CTTI: Framework of Specifications to Consider During Mobile Technology Selection
- 21 CFR Part 11