

Target product profile: Digital TBI assessment tool

ATTRIBUTE	ESSENTIAL	IDEAL
General capability description	A mobile medical app or other digital health technology to aid in the rapid detection of traumatic brain injury (TBI)	A mobile medical app or other digital health technology to aid in the rapid detection of traumatic brain injury (TBI)
Intended use	- Aid in the assessment of TBI in those with suspected head injury, within 24 hours of injury event - May be limited to patients without other traumatic injury - Output rules need for imaging or other advanced assessment methods - For use by providers with some medical training (e.g., first responders)	- Aid in the assessment and management of TBI in those with suspected head injury, within 72 hours following the injury event - For patients with or without other traumatic injury - Output classifies TBI severity without other advanced assessment methods - No medical or other training required for use (e.g., may be self-administered for telehealth use)
Target population being tested	Limited age population (e.g., pediatric or adult)	All ages
Use setting	Extended prehospital care setting with limited or no access to imaging and lab equipment	Extended prehospital care setting with limited or no access to imaging and lab equipment
Specimen or data collected	- Physical response data collected using only sensors and image capture capabilities integrated in commonly available consumer technologies (e.g., smartphones, wearables, EEG-headbands) - May include user data entry (e.g., symptoms, medical history and behaviors); may also include common neurocognitive assessment batteries	Only uses physical response data collected with sensors and image capture capabilities integrated in commonly available consumer technologies (e.g., smartphones and wearables)
Description of system and device architecture	- Mobile medical application running on commonly available consumer technologies (e.g., smartphones and wearables) - Auxiliary components permitted for prototypes - Compatible with popular operating systems and available for download via app stores	- No auxiliary components required - Ability to perform all steps and generate results without internet connection - Interoperability with Electronic Medical Record (EMR) systems
Clinical performance characteristics	For moderate-severe TBI: - Diagnostic sensitivity >80% - Diagnostic specificity >60% - NPV >95% - PPV >30%	For all TBI severities: - Diagnostic sensitivity >80% - Diagnostic specificity >60% - NPV >95% - PPV >30%
Time to result	Evaluation and results in less than 5 minutes	Evaluation and results in less than 2 minutes
Regulatory and quality	FDA clearance/approval	FDA clearance/approval