SCORECARD · SIMPLIFIED PREVIEW

The Clinical UX Safety & Access Scorecard

Seven dimensions, fifty-six criteria, built for evidence a regulator will accept.

This is the simplified printable version of the instrument inside the kit. The full workbook computes every figure live from your evidence: dimension scores, the weighted profile and the headline figure. Use this page to see how the method thinks before you buy.

DIMENSION	WEIGHT	CRITERIA	SCORE 0–4	WEIGHTED
Clinical task fit	18%	8	—	—
User coverage	14%	8	—	—
Representation & comprehension	15%	8	—	—
Function & error resilience	16%	8	—	—
Alert quality & cognitive load	12%	8	—	—
Access & inclusion	13%	8	—	—
Safety governance & traceability	12%	8	—	—
HEADLINE FIGURE	**100%**	**56**		**— / 100**

SCORE	BAND	WHAT IT MEANS FOR THE ENGAGEMENT
85-100	Safe & accessible	Sustain. Move to surveillance and incremental improvement.
70-84	Sound with gaps	Close the specific hazards before the next release.
55-69	Conditional	Do not ship the affected tasks without mitigation and monitoring.
40-54	At risk	Redesign the affected tasks. Escalate to the safety committee.
0-39	Unsafe	Stop. Treat as a patient-safety defect, not a UX backlog item.

The normalisation. Dimension score = (sum of criterion scores / (4 x criteria scored)) x 100. Safety-weighted health = weighted mean of the seven dimensions, **capped at 69 if clinical task fit, error resilience or safety governance scores below 2.0**. **The coverage gate:** no headline figure is published below 70% coverage, and no summative claim is made with fewer than 15 participants per distinct user group.

CRITERIA 1–56 OF 56

The 56 criteria

Score each 0–4. Write the evidence reference beside it.

ID	CRITERION	0	1	2	3	4	EVIDENCE REF
CT1	The primary clinical task is completable within the time the workflow actually allows	☐	☐	☐	☐	☐	
CT2	The interface reflects the real sequence of care, not the database schema	☐	☐	☐	☐	☐	
CT3	Interruptions and resumption are supported without losing entered data	☐	☐	☐	☐	☐	
CT4	Hand-off between roles preserves context and state	☐	☐	☐	☐	☐	
CT5	Duplicate or redundant data entry is eliminated where the record allows	☐	☐	☐	☐	☐	
CT6	Task steps are minimised against a measured baseline	☐	☐	☐	☐	☐	
CT7	Workarounds clinicians already use are documented and treated as findings	☐	☐	☐	☐	☐	
CT8	The task is completable under the worst realistic staffing condition	☐	☐	☐	☐	☐	
UC1	Every distinct user group is identified, including non-clinical staff	☐	☐	☐	☐	☐	
UC2	Each group has representative participants in evaluation	☐	☐	☐	☐	☐	
UC3	Novice and expert performance are measured separately	☐	☐	☐	☐	☐	
UC4	Summative validation includes at least 15 participants per distinct user group	☐	☐	☐	☐	☐	
UC5	Participants are drawn from the real setting, not a convenience pool	☐	☐	☐	☐	☐	
UC6	Accessibility needs of the user population are represented in the sample	☐	☐	☐	☐	☐	
UC7	Language and literacy variation is represented in the sample	☐	☐	☐	☐	☐	
UC8	The training level the design assumes is stated and verified	☐	☐	☐	☐	☐	
RC1	Clinical terminology matches the vocabulary of the intended user	☐	☐	☐	☐	☐	
RC2	Units, ranges and precision are unambiguous at the point of entry	☐	☐	☐	☐	☐	
RC3	Numeric and temporal data are displayed in the form the decision requires	☐	☐	☐	☐	☐	
RC4	Risk and status are conveyed by more than colour alone	☐	☐	☐	☐	☐	
RC5	Abbreviations are expanded wherever ambiguity carries clinical risk	☐	☐	☐	☐	☐	
RC6	Content is written to the health literacy of the population served	☐	☐	☐	☐	☐	
RC7	Critical values are distinguishable at a glance under time pressure	☐	☐	☐	☐	☐	
RC8	Layout survives the smallest supported display and the busiest real state	☐	☐	☐	☐	☐	
FE1	Error messages state cause, consequence and the corrective action	☐	☐	☐	☐	☐	
FE2	High-consequence actions require confirmation proportionate to potential harm	☐	☐	☐	☐	☐	

ID	CRITERION	0	1	2	3	4	EVIDENCE REF
FE3	Destructive actions are reversible or recoverable within the record's rules	☐	☐	☐	☐	☐	
FE4	The system prevents the error rather than reporting it wherever possible	☐	☐	☐	☐	☐	
FE5	Default values are safe defaults, not convenient ones	☐	☐	☐	☐	☐	
FE6	System state is recoverable after failure, timeout or session expiry	☐	☐	☐	☐	☐	
FE7	Automation presents its reasoning and its confidence	☐	☐	☐	☐	☐	
FE8	Clinicians can override automation, and the override is recorded	☐	☐	☐	☐	☐	
AL1	Alerts are tiered by consequence, with a distinct interruptive tier	☐	☐	☐	☐	☐	
AL2	Alert volume per clinician per shift is measured	☐	☐	☐	☐	☐	
AL3	Override rates are measured and reviewed as a design signal	☐	☐	☐	☐	☐	
AL4	Duplicate and low-value alerts are suppressed by rule	☐	☐	☐	☐	☐	
AL5	Alert content names the patient, the problem and the required action	☐	☐	☐	☐	☐	
AL6	Cognitive load is measured - NASA-TLX or equivalent - not assumed	☐	☐	☐	☐	☐	
AL7	Information density is tuned to the task, not to the size of the screen	☐	☐	☐	☐	☐	
AL8	Alert fatigue is treated as a safety hazard with a named owner	☐	☐	☐	☐	☐	
AI1	The critical path is completable by keyboard alone	☐	☐	☐	☐	☐	
AI2	Focus is visible, ordered and never trapped	☐	☐	☐	☐	☐	
AI3	Contrast meets WCAG 2.2 AA - 4.5:1 for text, 3:1 for non-text	☐	☐	☐	☐	☐	
AI4	Target size meets the 24x24 CSS pixel minimum	☐	☐	☐	☐	☐	
AI5	Screen-reader names, roles and states are correct and announced	☐	☐	☐	☐	☐	
AI6	The interface works at 200% zoom and reflows without loss	☐	☐	☐	☐	☐	
AI7	Content is available in the languages the population requires	☐	☐	☐	☐	☐	
AI8	Assistive technology is tested with real users, not simulated	☐	☐	☐	☐	☐	
SG1	A use-related risk analysis exists and names the interface as a potential cause	☐	☐	☐	☐	☐	
SG2	Formative evaluation is documented against that risk analysis	☐	☐	☐	☐	☐	
SG3	Summative validation is documented per user group and per hazard	☐	☐	☐	☐	☐	
SG4	Use errors are logged, classified and traced to a design decision	☐	☐	☐	☐	☐	
SG5	The interface is under change control consistent with IEC 62304	☐	☐	☐	☐	☐	
SG6	Post-market surveillance feeds back into the design backlog	☐	☐	☐	☐	☐	
SG7	Regulatory claims are supported by evidence held on file	☐	☐	☐	☐	☐	
SG8	The safety case is reviewable by someone outside the project team	☐	☐	☐	☐	☐	

Score 0 = absent or actively unsafe. 1 = emerging - works only for expert users in ideal conditions. 2 = functional - works, with known workarounds. 3 = strong - documented, tested, consistent. 4 = exceptional - validated with representative users and under load. Every rating carries an evidence reference: a session ID, a timestamp, a hazard log entry.

METHOD & SOURCES

Every dimension and criterion in this instrument is derived from a published framework, standard or study. The kit documents the mapping so a reviewer can trace any score back to its source.

Zhang & Walji	TURF: A framework for EHR usability - Tasks, Users, Representations, Functions. Journal of Biomedical Informatics 44(6), 2011	doi:10.1016/j.jbi.2011.08.005
Carayon et al.	Work system design for patient safety: the SEIPS model. Quality & Safety in Health Care 15(Suppl I):i50-i58, 2006; SEIPS 2.0 (2013) and 3.0 (2020)	doi:10.1136/qshc.2006.018390
IEC	IEC 62366-1:2015+AMD1:2020 - Application of usability engineering to medical devices	webstore.iec.ch
U.S. FDA	Applying Human Factors and Usability Engineering to Medical Devices (2016) - including the 15-participants-per-user-group expectation for summative validation	fda.gov/media/80481
European Union	Regulation (EU) 2017/745 on medical devices (MDR)	eur-lex.europa.eu
IEC	IEC 62304:2006+AMD1:2015 - Medical device software life cycle processes	webstore.iec.ch
W3C	Web Content Accessibility Guidelines (WCAG) 2.2, W3C Recommendation, 5 October 2023	w3.org/TR/WCAG22
Creative Navy	Healthcare UX: Why User Experience Is a Patient Safety Imperative (2026) - evidence base for the prevalence and cost figures	creativenavy.com
Brooke, J.	SUS: A quick and dirty usability scale (1996); Hart & Staveland, NASA-TLX (1988)	-