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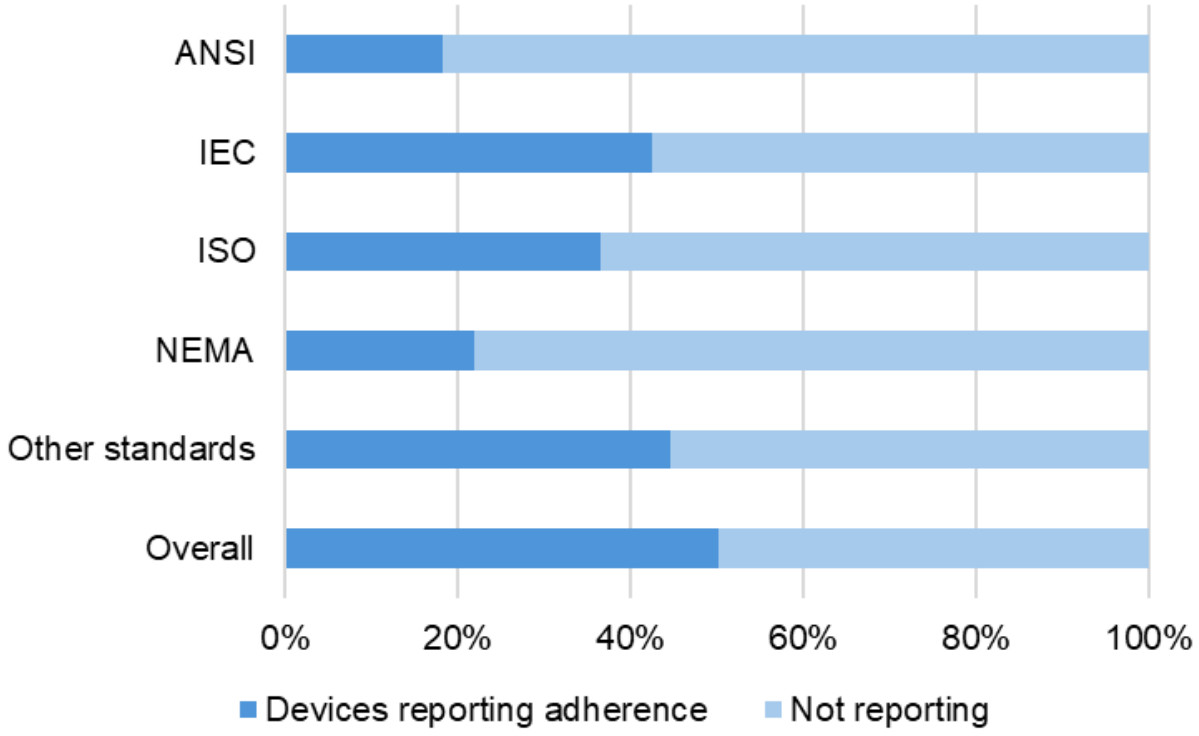
ETable 1: Classification System for Study Designs for AI/ML Devices

Study Design	Description
Comparative	Studies that directly compare two or more similar groups to analyze differences in outcomes or effects.
Cohort	Studies that follow a group of individuals over a period of time to observe the development of certain outcomes based on exposures or interventions.
Case-Control	Studies that compare individuals with a particular condition (cases) to those without the condition (controls) to identify potential factors associated with the condition.
Cross-Sectional	Studies that analyze data collected from a population at a single point in time to examine relationships between variables or characteristics.
Software Validation	Process of ensuring that software meets specified requirements and functions correctly according to its intended purpose.
RCTs	Randomized Controlled Trials: Studies in which participants are randomly assigned to different groups to compare the effects of treatments or interventions.

EFigure 1: Safety Standards Reported by FDA-Cleared AI/ML Devices



AI/ML, artificial intelligence/machine learning; FDA, Food and Drug Administration.

ETable 2: Safety Risks of AI/ML Devices Reported in Decision Summaries

Safety Risk	**# of devices**	**Examples**
Algorithm Errors	30	Device failure or delay, data corruption, false positives/negatives
User Errors	32	Improper dosing, device misuse, misinterpretation of results
Physical Harm	17	Adverse tissue reaction, electrical shock, eye hazard or injury
Other Risks	3	Data breaches caused by insecure transmission of data, interference with other devices

ETable 3: Characteristics of Recalls of AI/ML Medical Devices

Device Name	Number of Recalls	Reason for Recall	Patient harm (Yes/No)	Recall Details
Device A	1	Device Failure	No	Low battery life
Device B	1	Device Failure	No	Internal failure of the vertical/horizontal tilt adjustment mechanism
Device C	2	Device Failure	Yes	Improperly formulated and released fluorescence in situ hybridization (FISH) probes resulting in false positives
Device D	10	Software and Device Failure	Yes	Complaints due to compromised HGB chamber, optical degradation may potentially cause a delay in reporting results
Device E	1	Device Failure	No	Issue with locking mechanism preventing scanning
Device F	2	Device Failure	No	Issue with locking mechanism preventing scanning
Device G	4	Physical Harm, Software, and Device Failure	Yes	Elevated acoustic noise during scanning, potentially leading to hearing loss.
Device H	1	Device Failure	No	lubricating grease may cause visible, dot- or lineshaped, fat-isointense artifacts during head examinations
Device I	1	Device Failure	No	lubricating grease may cause visible, dot- or lineshaped, fat-isointense artifacts during head examinations
Device J	27	Software and Device Failure	No	Issue with propagation of treatment course information, software error resulting in local underestimation of expected dose, issues applying pitch/roll correction

Device K	1	Device Failure	No	Initial delivery positions will be set incorrectly despite calibration
Device L	2	Device Failure	No	System operator is able to bypass the SmokeDetector Interlock system locking mechanism after a smoke detection
Device M	8	Software and Device Failure	No	Potential for Incorrect Image Orientation resulting images may be flipped or reversed result in misdiagnosis, incorrect treatment of a condition, or additional radiation exposure if a rescan is required
Device N	9	Software and Device Failure	No	Dosing errors and duplication, software issues resulting in incorrect data transmission and patient care planning
Device O	1	Device Failure	No	probe handle may crack
Device P	1	Device Failure	No	Potential for amplified noise and/or overall signal reduction, which may interfere with intended recordings of heart rhythms
Device Q	2	Software and Labeling	No	default reference ranges are incorrectly displayed, resulting in incorrect readings
Device R	1	Labeling	No	Missing precautionary statemetns
Device S	7	Physical Harm and Software	Yes	Potential for composed images to be flipped, resulting in misdiagnosis
Device T	1	Software	No	Low sensitivity, resulting in delays in diagnosis and treatment
Device U	2	Software	No	wrong calculation of the dose/minute for fluoroscopy exams
Device V	6	Software	No	May bring up another patient when comparing scans

Device W	1	Software	No	Insufficient documentation of quality procedures
Device X	1	Software	No	Data transmission issues
Device Y	1	Software	No	Inability to boot up in timely fashion
Device Z	1	Software	No	Inability to boot up in timely fashion
Device AA	1	Software	No	duplicate logging of a blood glucose level reading
Device AB	2	Software	No	Inconsistent configuration
Device AC	1	Software	No	Data not properly transmitted
Device AD	1	Software	No	Partial electrical reset results in inability to detect and report Brady and Pause events
Device AE	2	Software	No	incorrect dosing or dose applied to the wrong location
Device AF	1	Software	No	Incorrect measurements
Device AG	1	Software	No	CT scan failing resulting in rescanning and reinjection of contrast medium.
Device AH	1	Software	No	unintended video frames being included, resulting in incorrect estimates
Device AI	1	Software	No	diagnostic imaging system failing resulting in rescanning and reinjection of contrast medium
Device AJ	1	Software	No	Potential for data loss
Device AK	1	Software	No	potential interruption of data communication

Device AL	1	Software	No	Issues with terminating scan, resulting in treatment delay
Device AM	1	Software	No	Misleading and out-of-sync display