

More than algorithms: an analysis of safety events involving ML-enabled medical devices reported to the FDA.

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<https://psnet.ahrq.gov/issue/more-algorithms-analysis-safety-events-involving-ml-enabled-medical-devices-reported-fda>

[Patients](#) and healthcare providers rely on devices that use artificial intelligence or machine learning in diagnostics, treatment, and monitoring. This study utilizes adverse event reports submitted to the [FDA's](#) Manufacturer and Use Facility Device Experience (MAUDE) database for machine learning-enabled devices. [Mammography](#) was implicated in 69% of reports, and the majority were near-miss events.