

VOCERA ENGAGE PLATFORM

EMDAN 3.0.0

Compliance Training

Engage Medical Device Alarm Notification: what it is, why it is regulated, and how to work with it safely

Objectives

By the end of this training, you will be able to explain:

What EMDAN is

Its role inside the Vocera Engage platform and how it is packaged

What EMDAN does

How it receives medical device data and routes alarms to clinicians

How data flows

From incoming integrations to the clinician's mobile device

Why EMDAN is regulated

510(k) clearance, sensitive data, and who may change its configuration

FDA software function classification

No medical purpose

Non-medical software. No FDA enforcement.

Administrative support, wellness apps with no diagnostic function, electronic patient records.

Enforcement discretion

Non-device CDS and MDDS.

Tools that transfer, store, convert, or display data, or that give recommendations a clinician reviews and decides on.

FDA enforcement

Software as / in a medical device, device CDS, and mobile medical apps.

Software that analyzes or interprets medical device data, like **EMDAN alarms**.

Every software product falls somewhere on this spectrum. Where a feature lands decides how it must be built, released, and supported.

KEY DISTINCTION

Alarms, alerts, and notifications

	Alarms (EMDAN)	Alerts (Engage)	Notifications (Engage CDS)
What it is	A signal that a potential or actual hazard exists, generated by a medical device such as a patient monitor, ventilator, or IV pump	A signal that a hazard may exist, generated by nurse call systems or EHR orders and labs, not by medical devices	Combined patient information a clinician uses as a reference when making decisions under hospital policy
Examples	Alarms from patient monitors, ventilators, and IV pumps	Code Blue, patient in pain, STAT blood draw order	Bed exit protocol not set, bed out of compliance
Who configures	Only Vocera staff	Customer administrators	Customer administrators

HOW IT WORKS

How EMDAN receives and routes data



If an input system is a medical device, its data **must** be stored in the Clinicals dataset, and the entire pathway it travels must use EMDAN's controlled configuration.

Why EMDAN is important

510(k)

Cleared Class II medical device

Regulatory requirements apply, including validating the training on how it is used.

PHI

Sensitive data

The Clinicals dataset stores patient and alarm information that needs permission-based protection.

Rules

Influence on clinicians

Whoever configures message delivery shapes what clinicians see, so access is tightly limited.

Three levels of configuration access

Level 1

Vocera staff

Full read and write access to all alerts and alarms

Level 2

Customer administrator

Full access to alerts, view-only access to clinical alarms

Level 3

Charge nurses and staff

View-only access to how alert delivery is configured

Permissions are granted to **groups**, so every member of a group inherits its access. Confirm group membership before granting administration rights.

How EMDAN is released and labeled

Controlled release process

Because EMDAN is FDA regulated, each new release follows a documented change process.

Internal change request steps: [REDACTED]

Regulatory labeling in the product

An "About" screen in the Administrator Console shows:

- Engage and EMDAN version numbers
- Unique Device Identifier
- Manufacturer address and site-specific labeling

Internal package locations and system links have been removed from this sample.

SUMMARY

Key takeaways

- EMDAN is a 510(k)-cleared Class II medical device inside Vocera Engage
- Alarms come from medical devices; only Vocera staff configure them
- Medical device data must flow through the regulated Clinicals pathway
- Grant administration access to groups carefully