

# RELEASE NOTES

Clinical Decision Support Platform  
1.2.0  
August 23, 2026

## Supported Medical Devices

### ADNEX2

- [ADNEX2 electronic Instructions for Use \(eIFU\)](#)

### IETA

- [IETA electronic Instruction for Use \(eIFU\)](#)

### EPC

- [EPC electronic Instruction for Use \(eIFU\)](#)

## New Features / Enhancements

### Support for ADNEX2

The platform now supports the updated ADNEX2 model.

### US Market Readiness (FDA Non-Device CDS Compliance)

Pursuant to Section 520(o)(1)(E) of the FD&C Act and the FDA Clinical Decision Support Software Guidance Document, the following changes have been implemented to ensure the platform meets Non-Device CDS criteria for the US market.

- **Instructions for Use (IFU) update:** The IFU has been revised to include labeling content required under criterion 4 of the FDA CDS Guidance, applicable to US-market users.
- **Input parameter traceability:** A direct link from the report page to the corresponding case detail page has been added, enabling users to review the exact input parameters that produced the displayed result.
- **Applicability test skip acknowledgment:** When a user enables the "skip applicability assessment" setting, an explicit acknowledgment flow is triggered, confirming the user accepts responsibility for verifying applicability criteria independently. On the case detail page, a disclaimer is shown for cases where the applicability test was skipped, listing the unanswered questions for reference.

## Support for EPC v1.0.1

The platform now supports the updated EPC module, which includes a corrected minimum boundary for the initial hCG input (25 IU/L).

## Improvements / Bug fixes

PWA sync error on user settings update: Resolved an issue where the PWA sync process triggered errors when attempting to update user settings that were already present in the database. The settings creation flow now correctly handles pre-existing records.

## Known issues

No known issue identified

## Security Updates

All third-party libraries have been upgraded to their latest versions.