

RELEASE NOTES

ADNEX 1.0.0 August 22, 2025



New Features / Enhancements

Authentication & Authorization

- Login and logout functionality to prevent access by unauthorized users.
- **Permission management** to prevent unauthorized access to the ADNEX medical device.
- Secure user sessions with automatic timeout.
- Single sign-on (SSO) with a single Gynaia user account.
- Supports two versions: training mode and medical device mode.

Dashboard

- ADNEX model selection card
 - o Includes all required regulatory labels (version, UDI number, release date, mode)
 - o Allows users to view and download instructions for use (IFU).
- Gynaia contact information
- User information

Applicability Test

- A dynamic, step-by-step **applicability assessment questionnaire** with supporting information, such as descriptions and example images or icons, for clarity.
- Context-aware question progression.
- Provides clear outcomes: ADNEX applicable or not applicable.
- Navigates to the ADNEX model based on the assessment result.

Input

- An **intuitive input form** with validation on submission.
- Extensive validation on all fields.
- Labels with info icons to clearly explain what is expected in each field.
- A warning page to explain the consequences of using the optional CA-125 serum field on model performance.



ADNEX Calculator

- ADNEX version 1
- Calculates the probability and relative risk for aggregated results of benign and malignant tumors.
- Calculates the probability and relative risk for borderline tumors, stage I ovarian cancer, stage II-IV ovarian cancer, and metastatic cancer of the adnexa.
- Correctly rounds probability and relative risk values.

Reporting

- Visualizes the probability and relative risk calculated by the ADNEX calculator in both a tabular format and a bar chart.
- Provides probability and relative risk in both summary and detailed modes.
 - o **Summary mode** sums results to benign and malignant.
 - o **Detailed mode** shows results for each of the four stages.
- Mapping between malignant risk score and O-RADS classification and visualization of O-RADS classification.

Progressive Web Application (PWA)

- Can be installed on mobile and desktop devices for quick access.
- Optimized for all screen sizes.
- Fast loading by caching essential files on the device instead of relying on network requests



Improvements / Bug fixes

First version of the ADNEX medical device application.

Known issues

Security penetration testing identified a **medium-risk vulnerability** related to our Content Security Policy (CSP). Essentially, a misconfiguration could allow a malicious user to perform a **cross-site scripting (XSS) attack** by injecting malicious code, typically JavaScript, into the application. We are actively working on a fix for this issue in an upcoming release.

Security Updates

First version of the ADNEX medical device application.