INSTRUCTIONS FOR USE

ADNEX V1.0.1

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Label

Device Name	ADNEX
UDI	(01) 05430004729006 (8012) v1.0.1
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Contents	Instructions for use of ADNEX release v1.0.1
	Hyperlink to the electronic instructions for use

Symbols

Explanation of symbols

UDI	Unique Device Identifier = UDI-DI +UDI PI
	UDI-PI = Software version
	Date of manufacture / release date
	Manufacturer
eIFU indicator	Consult instructions for use
MD	Medical Device

Device description

Intended Purpose	ADNEX is intended for use by trained healthcare professionals as an aid in the assessment and triage of women with adnexal masses. Based on selected clinical and ultrasound parameters, it provides probability estimates for outcome categories (benign, borderline, stage I invasive, stage II–IV invasive, and secondary metastatic). The outputs are intended to support, but not replace, established clinical management protocols and professional judgment. The device does not provide a diagnosis or treatment recommendation."
Intended user	Trained health care professionals holding current Gynaia IOTA ovarian classification training and certification" certificate
Patient target group	Non-pregnant women aged 18 years and older presenting with an adnexal mass
Contra indications	Pregnancy, age < 18 years
Use in combination with other devices and software	N/A
Limitations of use	ADNEX is designed to support clinical decision for patient triage and is not intended for diagnostic purposes.
Warnings, precautions and/or measures to be taken	Use of the ADNEX application is contingent on the user receiving appropriate training and holding current Gynaia IOTA ovarian mass classification certification. Access to the app will not be permitted to untrained users. When evaluating an adnexal mass, if it is not possible to use the ADNEX model, patient management should not be delayed, and we advise that an alternative approach be used. We recommend using IOTA Simple Rules with expert evaluation of adnexal masses when the rules cannot be applied. Information on IOTA Simple Rules and how to use them can be found on the Gynaia learning management system and in the open access publication by Timmerman *et al.* (https://doi.org/10.1002/uog.5365).

Operating instructions
Minimum System Requirements

Supported Browsers and System Requirements

Our medical device is accessed through a web application (the platform) that is compatible with a range of modern browsers on both desktop and mobile devices. This web application can also be installed on a personal device for a native-app-like experience. To ensure proper functionality, security, and the best user experience, it is essential to use a supported browser with the minimum required version. The platform will check to ensure it only works on supported devices.

Supported Browsers

The following browsers are supported for use with our medical device. Older versions of these browsers are not supported, and you must update to the specified version or higher.

- **Chrome (Desktop & Mobile)**: Version 82 or higher.
- **Edge (Desktop & Mobile)**: Version 82 or higher.
- **Firefox (Desktop & Mobile)**: Version 77 or higher.
- **Safari (Desktop & Mobile)**: Version 12 or higher.
- **Chromium-based browsers**: Any browser built on the Chromium engine (e.g., Brave, Opera) that is based on Chromium version 82 or higher should be supported, though official testing is limited to Chrome and Edge.

Browsers that have reached their "end-of-life" and are no longer receiving security updates, such as Internet Explorer, are not supported.

Hardware Requirements

The performance of the application is dependent on the hardware of your device. The following are general minimum system requirements to run the supported browsers and our application correctly on a desktop/laptop or a mobile phone.

Desktop/Laptop:

- **Processor:** A processor with support for SSE3 instructions (e.g., Intel Pentium 4 or newer) is a general requirement for modern browsers.
- **RAM:** 2GB for 64-bit browsers is the minimum, but 4GB or more is recommended for optimal performance.
- **Operating System:** An actively supported operating system such as Windows 10 or higher, macOS 12 (Monterey) or higher, or a recent version of a Linux distribution.
- **Screen Resolution:** A minimum resolution of 1024 x 768 is required.

Mobile Devices:

- **Operating System:** A modern mobile operating system that supports the latest versions of the browsers listed above (e.g., Android 10 or later, iOS 12 or later).
- **RAM:** 3GB RAM is recommended for optimal performance.

Installation

The application can be installed on a mobile device as a PWA (progressive web app) for quick access from the home screen, similar to a native app. The installation process varies slightly between operating systems.

On iPhone (iOS) using Safari:

1. Open the web application in the Safari browser.
2. Tap the **Share** button (a square with an arrow pointing upwards) at the bottom of the screen.
3. Scroll down and select **Add to Home Screen**.
4. You will be prompted to customize the name of the application. Tap **Add** in the top right corner to confirm.
5. The application icon will now appear on your home screen.

On Android using Chrome:

1. Open the web application in the Chrome browser.
2. An "Install app" prompt may appear automatically. If it does, follow the on-screen instructions.
3. If no prompt appears, tap the **three-dot menu** in the top-right corner of the browser.
4. Select **Add to Home screen** from the menu.
5. A pop-up will appear where you can customize the app's name. Tap **Add** to confirm.
6. The application icon will now be on your home screen and in your app drawer.

Performance characteristics

Performance

ADNEX Clinical Performance	Performance endpoint/measure
1. ADNEX is able to give probabilities to distinguish between benign and malignant masses	The AUC for discrimination between benign and malignant masses is 0.94 (0.93 to 0.95) for ADNEX with CA125. For ADNEX without CA125 the AUC is 0.93 (0.92 to 0.94)..
2. ADNEX is able to give probabilities to distinguish different subclasses of malignant tumors (borderline, stage 1 invasive, stage 2-4 invasive and secondary metastatic tumors)	AUCs between malignant subtypes varied between 0.71 and 0.95 for ADNEX with CA125. For ADNEX without CA125, AUCs between malignant subtypes varied between 0.59 and 0.97
The risks predicted by ADNEX both with and without CA125 are well calibrated [1]	ADNEX with CA125 has an overall calibration intercept of 0.19 (95% confidence interval −0.01 to 0.40) and a slope of 1.11 (0.98 to 1.25) ADNEX without CA125 has an overall calibration intercept of 0.19 (95% confidence interval −0.04 to 0.42) and a slope of 1.12 (0.98 to 1.26)

[1] **Calibration**: the degree to which the risk probabilities predicted by ADNEX correspond to the actual observed outcomes in patients.

Maintenance

No maintenance is required.

For both security and technical performance reasons (including speed, user experience, and accurate risk visualization) it is strongly recommended to use the latest available version of the operating system and browser on the device running the ADNEX application.

Risks - Information for Safety

No risks are associated with installing and operating the software.

	Incorrect data entry, including misinterpretation of ultrasound features or incorrect entry of clinical variables may potentially impact the risk estimation
	Use by untrained users, potentially leading to incorrect entry of clinical variables and/or misinterpretation of results
	Inappropriate use in populations where the application has not been validated, namely patients under the age of 18 and pregnant patients. Risks may also increase if users bypass or ignore warnings and applicability checks embedded in the software
	Cybersecurity risks, such as unauthorized access or misrepresentation of user identity (e.g., accessing the software using another person's credentials). These may be mitigated by access controls and using secure, up-to-date browsers and devices.
	The ADNEX risk calculation is only indicative to support physicians in selecting patients for appropriate management within established management protocols. It is not
	intended to be used to establish a diagnosis. Even though ADNEX has a high level of performance, users should be aware that false positive and false negative results can rarely occur
	Calbration performance is very heterogenous and is based on a large multicenter study. Performance in individual centers can differ from the reported calibration.

Manufacturer

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Incidents and Support

For technical support or questions contact Gynaia support team via support@gynaia.com.

Serious incidents should be reported immediately to Gynaia and to the competent authority of the Member State in which the user/patient is established or the incident took place.

Document Version

Version	Issue date	Description of modification
1.0	13 August 2025	New document
2.0	18 August 2025	Clarification of risk section
3.0	09 September 2025	Update intended purpose Update clinical performance Update UK Rep