

INSTRUCTIONS FOR USE IETA

IETA model V1.0.0

Label

Device Name



Contents



IETA
(01) 05430004729013 (8012) v1.0.0
Gynaia Belgium Naamsevest 88, B-3000 Leuven, Belgium
Instructions for use of IETA release v1.0.0
Hyperlink to the electronic instructions for use

Symbols



Explanation of symbols

	<p>Unique Device Identifier = UDI-DI +UDI PI</p>
	<p>UDI-PI = Software version</p>
	<p>Date of manufacture / release date</p>
	<p>Manufacturer</p>
	<p>Consult instructions for use</p>
	<p>Medical Device</p>

Device description

<i>Intended Purpose</i>	<p>IETA is intended for use by trained healthcare professionals as an aid in the assessment and triage of women with endometrial pathology. Based on selected clinical and ultrasound parameters, it provides probability estimates for potential endometrial pathology in women, including endometrial cancer, endometrial atrophy, focal pathology, or diffuse endometrial conditions.</p> <p>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.</p>
<i>Intended user</i>	Trained health care professionals holding current Gynaia “IETA uterine training and certification” certificate
<i>Patient target group</i>	Non-pregnant women aged 18 years and older presenting with Abnormal uterine bleeding or presenting for ultrasonography for other indications
<i>Contra indications</i>	Pregnancy, during post partum phase (<3 months after delivery or miscarriage), age < 18 year
<i>Use in combination with other devices and software</i>	N/A
<i>Limitations of use</i>	IETA is designed to support clinical decision for patient triage and is not intended for diagnostic purposes.
<i>Warnings, precautions and/or measures to be taken</i>	<p>Use of the IETA application is contingent on the user receiving appropriate training and holding current Gynaia IETA uterine certification. Access to the app will not be permitted to untrained users.</p> <p>When evaluating a suspected endometrial lesion, and in the rare case you don’t have access to the IETA application due to technical issues, patient management should not be delayed, and we advise that an alternative approach be used.</p> <p>In this case, expert evaluation could be considered to determine further management, potentially including tissue sampling or hysteroscopy, if indicated.</p>

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

Clinical Benefits

IETA Clinical Benefit	Clinical Outcome Parameter
<p>IETA can be used to decide which patients should undergo urgent office endometrial sampling (i.e., office sampling without delay with request for a quick reply by the pathologist, and if the histology result does not indicate malignancy, further testing to exclude a missed lesion).</p>	<p>Clinical Utility (Net Benefit) of an increased malignancy risk according to the IETA model to decide which patients should undergo urgent office endometrial sampling was superior to office endometrial sampling in all women, if one is willing to perform a maximum of 20 urgent office biopsies to detect one malignancy in (presumed) postmenopausal women.</p>

Clinical Performance

IETA Clinical Performance	Performance endpoint/measure
<p>IETA is able to give probabilities to differentiate between benign and malignant endometrial lesions</p>	<p>The AUC for discrimination between benign and malignant endometrial lesions is 0.88 (95% CI: 0.85-0.91)</p>
<p>IETA is able to give probabilities to distinguish between: (1) endometrial atrophy, (2) endometrial polyp or intracavitary myoma, (3) endometrial malignancy or atypical hyperplasia, (4) proliferative/secretory changes, endometritis, or hyperplasia without atypia</p>	<p>The model discriminated well between all categories (polytomous discrimination index 0.67, 95% CI: 0.63–0.75) with AUCs ranging from 0.76 (95% CI: 0.74–0.79) for polyp or myoma versus proliferative or secretory endometrium to 0.94 (95% CI: 0.92–0.96) for atrophy versus malignancy</p>

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 IETA application.

Risks - Information for Safety

No risks are associated with installing and operating the software.

	<p>Incorrect data entry, including misinterpretation of ultrasound features or incorrect entry of clinical variables may potentially impact the risk estimation</p>
	<p>Use by untrained users, potentially leading to incorrect entry of clinical variables and/or misinterpretation of results</p>
	<p>Inappropriate use in populations where the application has not been validated, namely patients under the age of 18 and pregnancy during the post partum phase. Risks may also increase if users bypass or ignore warnings and applicability checks embedded in the software</p>
	<p>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.</p>
	<p>The IETA 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.</p>
	<p>Even though IETA has a high level of performance, users should be aware that false positive and false negative results can rarely occur</p>
	<p>The IETA model can over- or underestimate risks for certain outcomes in some centers.</p>

Data Security

Area	Physician Responsibility (Duty of Care)
Active Use & Logout	NEVER leave the application logged in and unattended. After every consultation or period of use, you must securely log out (or rely on the system's <i>immediate</i> automatic log-off feature).
Screen Privacy (Public View)	ENSURE Visual Privacy while using the application. Position your screen (PC, smartphone, tablet) so that it cannot be viewed by unauthorized persons.
Device Security	Your device must be secured with a strong PIN, password, or biometrics (fingerprint/face ID). Ensure the device's operating system and the application are updated to the latest security versions.
Data Transmission	Only use the application over trusted, encrypted networks (e.g., your clinic's secured Wi-Fi or a trusted VPN).
Personal Data Export	Do not download or take screenshots of Protected Health Information (PHI) to your personal device's local storage unless absolutely necessary and immediately secure or delete the file after use.

DISCLAIMER

The manufacturer is not responsible for security breaches, data loss, or system compromise resulting from the user's failure to adhere to the security and data protection responsibilities outlined in this IFU, including but not limited to, the use of weak passwords, the use of unapproved operating environments, or failure to apply recommended software updates.

Instructions for Use for this product are provided electronically (eIFU). No paper Instructions for Use are supplied by default.

Paper copies of the Instructions for Use are available upon request. Printed copies are considered uncontrolled documents. Users are responsible for verifying that the version in use is the current and applicable version.

Manufacturer

Contact details:

Gynaia Belgium
Naamsevest 88
B-3000 Leuven - Belgium
T: +32 497 79 89 99
E: support@gynaia.com
SRN: BE-MF-000048109

UK – Responsible Person Ltd UK

Qarad UK Ltd
8 Northumberland Ave, Westminster, London WC2N 5BY, United Kingdom

ukrp@qbdgroup.com

Registration number: 13004437 and with VAT Number GB364 2759 75.

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	15 January 2026	New document