INSTRUCTIONS FOR USE EPC

M6/PUL model V1.0.0 and PUV
model V1.0.0

Label

Device Name	EPC
UDI	(01) 05430004729020 (8012) v1.0.0
	Gynaia Belgium Naamsevest 88, B-3000 Leuven, Belgium
Contents	Instructions for use of EPC release v1.0.0
elFU indicator	Hyperlink to the electronic instructions for use

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Symbols

MD	CE 2797	UK CA

Explanation of symbols

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

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Device description

Intended Purpose	The EPC device, containing the M6/PUL and PUV model, is intended for use by trained healthcare professionals as an aid in the triage of pregnancies of unknown location (PUL) and the assessment of pregnancies of uncertain viability (PUV). Based on selected biochemical and clinical variables, M6/PUL provides probability estimates for ectopic pregnancy (EP). In case of intrauterine pregnancy, based on selected clinical and sonographic parameters, PUV provides probability estimates of a viable pregnancy or miscarriage. 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. The PUV model is not intended for, and should not be used in, the diagnosis of miscarriage.
Intended user	Trained health care professionals holding current Gynaia "Early Pregnancy training and certification" certificate
Patient target group	Applicable to women of reproductive age For PUL: women in early pregnancy for whom the pregnancy cannot be located on ultrasound scan For PUV: normally sited pregnancy inside the uterus, but with uncertainty about the viability (absence of an embryo or heartbeat)
Contra indications	For PUL: initial β-hCG ≤ 25 IU/L For PUV: multiple pregnancies
Use in combination with other devices and software	N/A
Limitations of use	EPC 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 EPC application is contingent on the user receiving appropriate training and holding current Gynaia Early Pregnancy certification. Access to the app will not be permitted to untrained users.

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	When evaluating an early pregnancy, and in the rare case you don't have access to the EPC application due to technical issues, patient management should not be delayed, and we advise that an alternative approach be used. In this case, expert evaluation (or repeated ultrasound examination every 48 hours) could be considered to determine further management

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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.

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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.

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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.

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Performance characteristics

Clinical Benefits

EPC Clinical Benefit	Clinical Outcome Parameter
The M6/PUL model allows to select women requiring close monitoring for a potential EP.	Net Benefit for threshold probabilities of EP between 3% and 10% showed superior clinical utility of M6/PUL compared to the default strategies (treat all (closely monitor all women) and treat none (closely monitor no-one))
The use of the PUV model is limited to patient counseling purposes and does not imply a clinical benefit.	NA

Clinical Performance

EPC Clinical Performance	Performance endpoint/measure
The M6/PUL model is able to give probabilities to differentiate between pregnancies at high and low risk of ectopic pregnancy.	The AUC to differentiate between pregnancies at high and low risk of ectopic pregnancy is 0.89 for internal-external cross-validation and 0.84–0.88 for temporal external validation. Calibration performance is good overall, but with heterogeneity between centers.
The PUV model is able to give probabilities for initial (7-14 days) and first trimester (11-14 days) viability.	The AUC for viability at 7-14 days is 0.837 (95% CI, 0.791-0.884) in the training set and 0.821 (0.756-0.885) in the test set, and at 11-14 weeks 0.788 ((0.734-0.842) and 0.774 (0.701-0.848), respectively.

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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 EPC 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
	Risks may 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 risk calculation of the M6/PUL-PUV model 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 the M6/PUL-PUV model has a high level of performance, users should be aware that false positive and false negative results can rarely occur
	Calibration performance is very heterogenous and is based on a large multicenter study. Performance in individual centers can differ from the reported calibration.

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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 *immediate* 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 **t**o 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.

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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	15 January 2026	New document

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