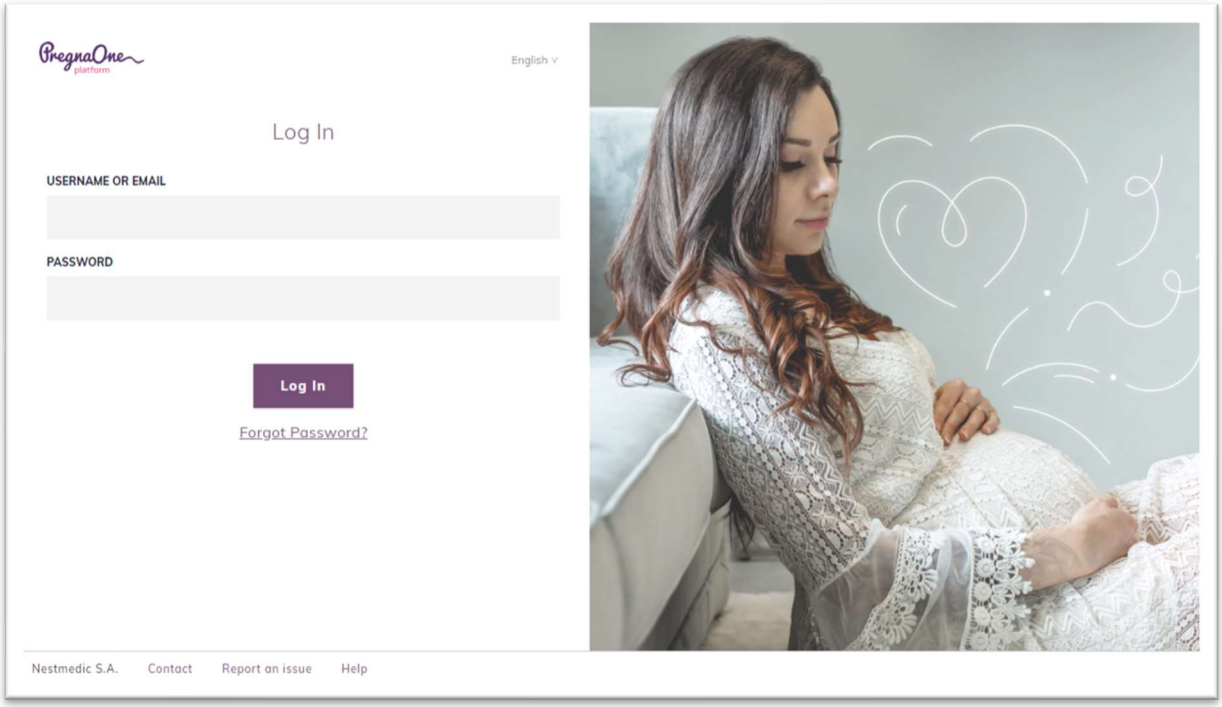
The User is obliged to read these Instructions for Use before using the device.

Please read these instructions carefully, as they contain important information regarding the safe and appropriate use of the device, as well as guidance on how to optimize work with the program.

PregnaOne Platform
Instructions for use for Patient



Manufacturer:
Nestmedic S.A.
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office@nestmedic.com
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CE 0197

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Important Information

Before you start using the PregnaOne Platform, review this document and the documents concerning software operation which are listed in the additional resources section. Users are obliged to review the requirements of the applicable terms of use of the Platform.

Activities which involve the provision and management of data must be performed in accordance with the applicable code of conduct and laws.
Under no circumstances shall Nestmedic S.A. be responsible for any indirect or direct damages resulting from inappropriate use or employ of the PregnaOne Platform.

The examples and diagrams in these instructions are for illustrative purposes only.

Introduction

These Instructions for Use contain detailed information about the PregnaOne medical device which constitutes medical software used to monitor fetal wellbeing with the Pregnabit or Pregnabit Pro devices during the last trimester of pregnancy based on the CTG traces recorded by medical devices which transmit the following 4 data sets to PregnaOne:

- Time [ms]/mother's pulse rate value [bpm] point set
- Time [ms]/fetal heart rate value [bpm] point set
- Time [ms]/uterine contraction value [%] point set
- Time [ms]/fetal movement event point set

The current version of the Instructions for Use of the device is available at:
https://pregna.one/pregnaone-ifu-patient-en/

The current version of the device label is available at:
https://pregna.one/pregnaone-label-current/

The Instructions contain the necessary information required for the use of the device by the User – the Patient. The instructions for use for the Professional User constitute an integral part of this version of Instructions for Use.

The Instructions include the most important features of the PregnaOne medical device, as well as warnings and messages that may be useful when using the device.
Review the entire contents of these Instructions before use.

These Instructions should primarily be reviewed by:

- Patients who create an account on the PregnaOne Platform individually and individually order the teleCTG device and the remote fetal wellbeing monitoring service (teleCTG examination interpretation) through the order form available on the PregnaOne Platform (online patients).
- Patients whose account on the PregnaOne Platform is associated with the medical facility providing the teleCTG device during an appointment at the facility (in-person patients).

PregnaOne does not substitute medical visits at a medical facility or in-patient treatment if indicated due to the patient's medical condition.

In the event of deterioration of medical condition or wellbeing, the Patient should immediately consult a physician or midwife, go to the nearest hospital or call the 112 emergency number.

Who are these Instructions for Use intended for?

The Instructions are intended for the Platform Users – the Patients who use the PregnaOne medical device to review their examination results and to communicate with medical personnel to guarantee response times adequate for an identified case.

Indications:
The PregnaOne medical device is intended for use by medical personnel and patients in the third trimester of pregnancy, particularly in the case of:

- post-term pregnancy
- changes in the nature of fetal movements felt by the patient
- patient's diseases: arterial hypertension, diabetes, kidney diseases, liver diseases, heart defects, thyroid diseases, anti-phospholipid syndrome or others
- pregnancy complications: placental insufficiency, umbilical cord circulation disorders, oligohydramnios, polyhydramnios, intrauterine fetal growth abnormalities, serological conflict, diabetes, pregnancy-induced arterial hypertension and others
- history of intrauterine fetal demise
- pregnant women aged above 40 years
- abnormalities identified on previous CTG examinations.

Contraindications:
No contraindications for the use of the PregnaOne medical device have been identified.
PregnaOne supports files in the Pregnabit format; therefore, its potential use is currently limited by contraindications for the use of the Pregnabit series mobile CTG devices.

Expected clinical benefits:
- Increased patient safety due to prioritization of examination results subject to evaluation by medical personnel.
- Reduced time to diagnosis (reduced risk associated with a late detection of abnormalities in the course of pregnancy).
- Increased chance of avoiding fetal harm due to existing pathologies, in particular hypoxia resulting from fetal hypoxemia.
- A chance to detect potential fetal development and pregnancy pathologies much earlier.
- Improved access to specialized care in areas with limited access to medical care.
- Improved feeling of safety in patients.

The knowledge obtained using PregnaOne based on traces transmitted by CTG machines, especially mobile ones for home use, is used by medical personnel to detect the potential risks early, to diagnose abnormalities and to take appropriate medical action.

Summary of the medical device risk profile and associated IT security objectives:
- This medical device processes sensitive data, including medical data and personal data.
- The Instructions for Use contain the operating system requirements.
- The actions required to ensure software integrity and validation are performed without end-user intervention.
- The end user is required to complete training on the use and operation of this medical device.
- The Instructions for Use specify the minimum requirements for the workstation on which this medical device may be used.
- The User shall be responsible for ensuring that the workstation software is up-to-date, i.e. for installing newer versions and security patches.
- The expected medical device use environment is the home environment.
- Use outside of the expected use environment may lead to inadequate medical conclusions.
- Maintaining additional safeguards in the form of antivirus and antimalware software on the workstations on which the medical device is used is recommended.
- The processes of security backup and system recovery from these backups, if required, are performed without end-user intervention.

Legal issues

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Warranty
The product is covered by the manufacturer's warranty.

Complaints
Complaints should be submitted using the REPORT ISSUE button located in the PregnaOne Platform bottom menu or by contacting the Manufacturer whose details are provided below.

Contact:
Nestmedic S.A.
ul. Pasymska 20
01-993 Warszawa
Polska
www.pregnabit.com
complaints@nestmedic.com

How does the teleCTG service using the PregnaOne and Pregnabit Pro devices work?

1. A patient account on the PregnaOne Platform may be set up by medical personnel or individually by the Patient.
2. Medical personnel or the Patient provides pregnancy data and medical data.
3. Medical personnel issues qualifications for CTG services.
4. Medical personnel/service provider assigns the Pregnabit Pro device to the Patient and rents it to the Patient according to the placed order.

5. The Patient performs examinations using the device.
6. Medical personnel evaluates the examination and provides information to the Patient by telephone or by sending a report to the Patient.
7. After the end of pregnancy, the Patient returns the Pregnabit Pro device to the service provider.

How to use the Platform?

What is required to use the Platform?

The software available on the PregnaOne Platform operates correctly on most devices such as tablets, smartphones, desktop computers, laptops, as well as on Windows, Android and iOS systems. The software does not require installing additional applications and is accessed only via a browser. Correct operation requires the use of browsers and operating systems listed below.

Computers:
• Minimum 4 GB RAM for Patient users
• Minimum 8 GB RAM and a monitor with 1366-pixel horizontal resolution for non-Patient users

Browsers:
• Google Chrome - version 88.0.4324 and higher versions from stable channels

Operating systems:
• Microsoft Windows - versions 7, 8, 8.1, 10 and higher
• Apple macOS - version 10.12 and higher
• Linux - distributions with a graphical user interface, operating on kernel version 4.0 and later from stable branches.

Mobile devices (for mobile mode)
• with at least 4.5-inch display and with minimum 320-pixel horizontal resolution

Mobile operating systems (for mobile mode):
• Android - version 7.0 (Nougat) or later
• iOS - version 13.0 or later

Additional software:
Installed PDF viewer software (also applicable to mobile mode).

Operating environment:
• Antivirus software recommended
• Antimalware software recommended
• Firewall use recommended
• SSL-capable network

Account registration and activation

Completing the registration process is required in order to use the Platform resources. You can initiate the registration process by clicking the activation link sent by e-mail to the address provided during Patient account set up by the medical personnel, or by using the link provided directly by the service provider. Then follow the instructions on the screen.

If the medical personnel did not register a Patient account, the Patient can set up an account individually. For this purpose, an institution code should be obtained from the service provider. The code consists of four digits, a dash and another four digits.

To complete the registration process using the code:
• Enter the Patient's first name, last name and e-mail address. Important information about the Platform will be sent to the e-mail address indicated during registration. It is important that it is real and active.
• Select a phone type and enter a phone number – this number will be verified. If this is a cell phone, a confirmation text message will be sent to the provided number. If a landline number is provided, a health care professional will contact the User to confirm that the number is correct. It is important that this number is real
and active.
• Select a country of residence (i.e. the country where the services will be physically provided) from the drop-down list.
• Enter and confirm a password. The password must contain at least 8 characters, including one lowercase and one uppercase letter, one digit and one special character (e.g. *, &, !, # etc.). The system indicates with icons which password correctness conditions are not met.
If the User has received a code from the institution medical personnel, the following checkbox should be selected: *I have an institution code*.
At this point, an additional panel is activated where the code may be entered. If a correct code is entered, the system automatically displays the Institution name assigned to the activation code. To confirm the account setup in the institution, press *Confirm and create account*.

First log-in, password and account recovery

In the log-in panel, enter the e-mail address provided during registration and the password.
If the Patient forgets the password, it may be changed by selecting Forgot password. This selection will initiate sending an e-mail to the e-mail address provided during registration that will enable the change.
! Troubleshooting – if you need to recover the e-mail address with which the account was registered, contact the manufacturer/service provider.

Two-step authorization

When logging in for the first time, you can choose whether to use one-time access or add the device to trusted devices. One-time access is intended for all situations when you are not sure who has access to the device you are using. If you routinely use a specific device in a safe manner, you can add it to trusted devices.

One-time access

If "one-time access" is selected, an access code will be sent to the provided e-mail address. Enter it in the field below and confirm. If you choose one-time access, when logging in again, you will need to complete the same second log-in step again.

Adding a device to trusted devices

In order to skip the second stage of logging in, i.e. providing the code, in the future, add the device (browser) you use to trusted devices. Assign a name to the device you use and then enter the access code that will be sent to the provided e-mail address in the field below and confirm.

Your account, data and profile

The Patient account and all data collected within it are always the Patient's property.
The account may be:

- Suspended by the Patient. When suspended, the Patient has access to all historical data but is unable to order or use any services. Suspension means opting out from receiving notifications from the Platform to the e-mail address indicated during registration.
- Restored by the Patient at any time.
- Deactivated by the Platform administrator. Deactivation prevents initiation of new services or entering data on a new pregnancy. The Patient continues to have access to all historical data collected on the Platform.

The Patient's profile contains all data entered during registration.

Training and assistance with Platform use

The system has a contextual help feature – guidance concerning select essential functionalities and three videos which include basic platform information, a description of the qualification process, order placing instructions. The videos may be accessed by clicking the *Training* button at the bottom of the screen. The grey marker indicates where the additional explanation is placed. Training is available both from the main menu and from the sections it concerns. Confirming the completion of all parts of training is required when placing an order for the online service or when the medical personnel initiates an order.

Main Platform interface elements

The following sections are available in the system:

- Main panel: the screen which displays the main actions (e.g. form completion) that should be performed by the Patient, as well as the most important notifications. These actions take you directly to the interface sections where they can be performed. To go to the main panel, click the PregnaOne logo.
- Pregnancy: the page where medical data on pregnancy and the qualification request status information are collected.
- Services: the page where the status of the assigned service access can be reviewed.
- My examinations: the page where all examinations performed at each facility are accessible.
- Top bar, other navigation elements: notifications, profile and logging-out from the service.

Account settings

Clicking the User Profile button enables entering/editing profile data such as first name, last name, e-mail address, phone number. Notification settings can be adjusted. The User can decide whether notifications will be using the e-mail address, by phone or via the Platform notification system.

Entering basic pregnancy data

The main panel will indicate that it is necessary to enter medical data to help make a decision regarding qualification. Entering all of the required data is recommended.

Select the following from the drop-down list:

- Pregnancy type: single or multiple
- Pregnancy course: normal or pathological

Pathological pregnancy is a pregnancy with an abnormal course, a high risk pregnancy due to significant obstetric history.
Enter:

- Number of previous pregnancies – include all pregnancies regardless of the outcomes
- Number of deliveries – include all deliveries: vaginal, cesarean section etc.
- Enter body weight before pregnancy.
- Date of your last menstrual period (i.e. the first day of the last menstrual period).
- Menstrual cycle length.
- All of the medical data required further in the questionnaire.

Service status

After an order is placed online or initiated by medical personnel, the individual order processing steps can be monitored on the service page. Not all medical facilities require payment for this service.

- Placed: this means that the order has been placed by medical personnel and a device has been assigned to it.
- Shipment: the device has been sent.
- Examination initiation: the device has been delivered to the Patient and the Patient has logged in to the device.
- Completed: the service provision period has ended. The device must be returned to the medical facility.

The panel also contains information on the order duration and number. If contact with the service provider is necessary, refer to the order number.

Service provision

Examination is performed using the Pregnabit or Pregnabit Pro medical device. The Platform has the following features to support service provision:

- Chat tool available during examination interpretation. It is recommended that this feature is used on a mobile device.
- Option to provide tips regarding the examination – e.g. how to use the device, how to prepare for the examination etc. These tips are distributed via an internal notification system. Additionally, the medical personnel can use the CTG examination interpretation field in the report to communicate with the Patient.
- Examination report storage, viewing and sharing.

Access to examination results

In order to receive the results of examinations performed, the Patient should find and click the examination of interest on the list available in *My examinations* tab. A screen will be displayed with information about the examination status and a report download link if a report was generated by the medical personnel.

Pregnancy summary

Once the pregnancy ends, it should be summarized in the system. To do this, click the Summarize Pregnancy button on the Pregnancy subpage.
The system displays a panel where the pregnancy end date and (optionally) pregnancy outcome should be entered by selecting from the drop-down list. The data is not mandatory; however, it may be relevant for result interpretation during the next pregnancy if it is performed on the PregnaOne Platform.

Summarizing the pregnancy results in a cancellation of all services that have been order ordered and are currently being provided.

Explanation of symbols on the PregnaOne medical device label


Manufacturer


Date of manufacture

Catalog no.


Refer to the Instructions for Use

Medical device