neuro ventis

Neuroventis Platform 1.x.x

Version date: 2021-03-17

Instructions for Use

Language version: English

Instructions for use are supplied electronically, paper format is available on request at support@neuroventis.care.

New in this version of the IFU:
- New company name
- New email address for contact
- Update of the intended use of the Neuroventis Platform
- Update of the device description to be aligned with the new intented use
- Error message or warning message are described

1. Applicable symbols

Symbol	Detail
CE	European conformity mark
	Electronic instructions for use are available in the Neuroventis Platform by clicking on this symbol
	Neuroventis BV Groeneweg 35A 3090 Overijse Belgium
⚠	This symbol is to indicate an important warning in these Instructions for Use. This symbol can vary in size.

2. Product description

Neuroventis is a software platform that consists out of the Neuroventis Dashboard for the healthcare professionals and Neuroventis Applications for the patients. For the healthcare professionals, the Neuroventis dashboard is intended to monitor, understand and manage patients with neurological disorders. On advice of the healthcare professional, the patient can use the Neuroventis Application to self-manage and understand their disorder. Together with the Neuroventis Dashboard, each Neuroventis Application is specific for a particular neurological disorder:

- The Neuroventis Dashboard and Helpilepsy Application are intended to provide digital tools for patients and healthcare professionals intended to manage the patient's epilepsy.
- The Neuroventis Dashboard and the MigraineManager Application are intended to provide digital tools for patients and healthcare professionals intended to manage the patient's headache disorder.
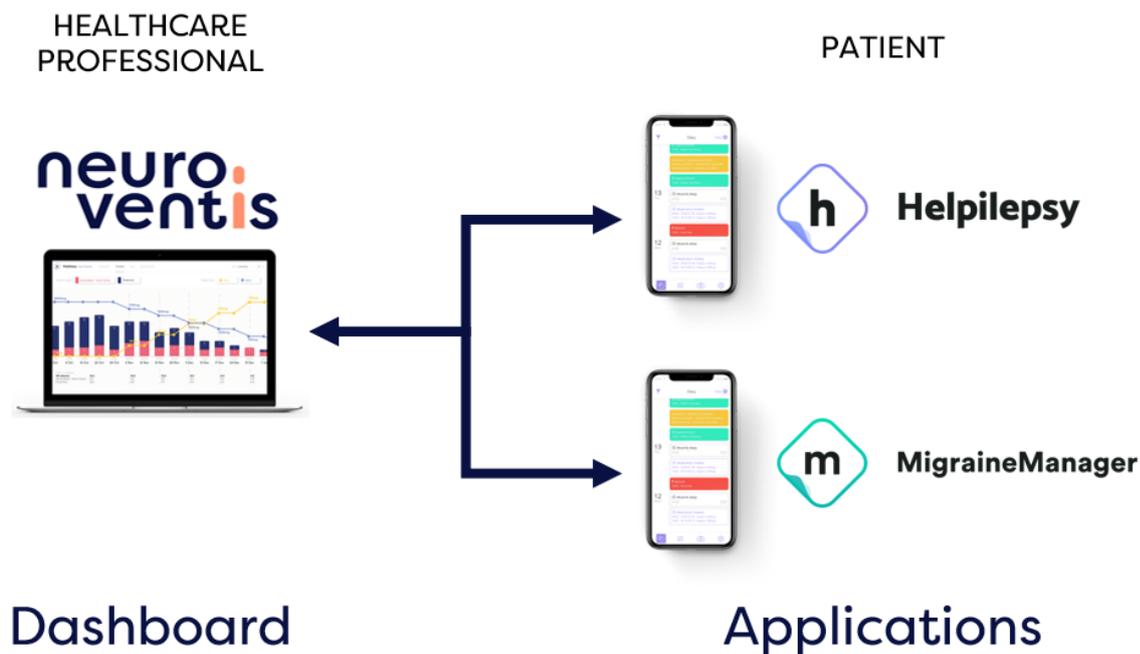
Figure 1: Graphical representation of the Neuroventis Platform consisting of two Neuroventis Applications (Helpilepsy and MigraineManager) and the Neuroventis Dashboard.

GENERAL DESCRIPTION

The Neuroventis Applications are mobile applications that the patients use to track their disorders, to learn about their health and to manage it.

The patients automatically (upon consent) share their data with their healthcare professional.

The healthcare professional can access the patient's health data through the Neuroventis Dashboard. There, the healthcare professional can monitor the patient's health evolution, understand it and manage it through different tools.

The Neuroventis Platform is focused on patients with neurological disorders. Currently, epilepsy and headache disorder are supported, through the Helpilepsy Neuroventis Application and the MigraineManager Neuroventis Application respectively.

INTENDED USE

The Neuroventis platform is a medical device software that provides digital tools for patients and healthcare professionals intended to manage neurological disorders.

Through an application, patients self-manage and understand the disorder, as well as share their data with their healthcare professionals.

Through a dedicated software, the healthcare professionals monitor, understand and manage patients' neurological disorders.

Note: this medical device is no substitution for normal care or practice. The data displayed is informative but may be useful to the doctor to support treatment decision. A doctor should always be contacted in case of any symptoms that are not within the expectations

USERS

The Neuroventis Applications Helpilepsy and MigraineManager are used by the patients and their caregivers, while the Neuroventis Dashboard is used by the patients' healthcare professional.

3. Steps for use

NEUROVENTIS DASHBOARD

In this chapter, you can read the guidelines on how to use the Neuroventis Dashboard, intended for healthcare professionals.

Setting up your physician account

You need a personal account to monitor and manage the health of your patients. Go to the Neuroventis Dashboard and use the "Create new account"-form.
Important: To create a "healthcare professional" account, you need to have received an Activation Code. To request one, contact us at support@neuroventis.care.
After this, follow the instructions presented.

Inviting a patient to use the Neuroventis Applications

To invite a patient, go to the "My patients"-page and click on the "Add a new patient"-button. Fill in the required and optional fields. Once the patient is added, he/she will receive an invitation E-Mail to start using the Neuroventis Application Helpilepsy or MigraineManager and will be prompted to accept sharing his/her data with you.

If the patient hasn't created an account yet or has denied the data sharing, you can prompt again your patient to do so by clicking "Resend invite" or "Ask to share data" in the list of patients in the "My patients"-page.

Monitoring the data of your patient

In the "My patients"-page, tap on a patient in the list of patients to go to that patient's dashboard. In there, you have access to several views:
- Treatments: This page shows the comparison between different treatments and the effect on the patient.
- Timeline: This page shows the data of the patient in a timeline view, in different frequencies.
- Seizures / Headaches: This page shows the logs of seizures / headaches logged by the patient.
- Appointments: This page shows a summary of information between appointments.
- Medications: This page shows the list of medications used by the patient.
- Forms: This page shows scheduled and answered forms of the patient.
- Videos: This page shows a list of seizure videos of the patient connected to a specific seizure event.
- (optional) NightWatch: This page shows the logs of the NightWatch device used by the patient.
- (optional) Specific study pages: This page shows the details of the patient in the context of specific clinical study.

Sending a questionnaire / form to your patient

As a healthcare professional, you can send questionnaires / forms to your patient. These can be related to quality of life, comorbidities, side effects, symptoms, appointment preparations, etc.
To send them, go to a patient in the "Forms"-page and click on "Send a new form".
If you would like to add new questionnaires / forms in the list, contact us at support@neuroventis.care.

Adding a (video) appointment to a patient

As a healthcare professional, you can add appointments with your patient through the Neuroventis Dashboard. To do this on an existing patient, go in "My patients"-list and click on the "+" icon next to the patient. Fill in the form.
If you select a video appointment, your patient will receive an invitation link to join the video appointment. To manage and join your video appointments, click on "My video appointments"-page and join/edit appointments.

Important: The video appointments do not work on the browser Microsoft Internet Explorer. Please use an alternative like Google Chrome, Mozilla Firefox or Microsoft Edge.

To invite a patient not using the Neuroventis Applications yet, you need to wait that he created his account or invite him for a video appointment (in that case, he will receive the link to the video consultation without having to create his account).

⚠️ If you are using video appointments in the Neuroventis Dashboard, verify the identity of the patient before sharing confidential information.

Participating to a study

Via "My studies"-page you can access the studies to which you are participating. Your own studies can also be configured. For more information, contact us at support@neuroventis.care.

NEUROVENTIS APPLICATIONS HELPILEPSY & MIGRAINEMANAGER

In this chapter, you can read the guidelines on how to use the Neuroventis Applications Helpilepsy and MigraineManager.

Setting up your personal account

You need a personal account to monitor and manage your health with the Neuroventis Applications Helpilepsy & MigraineManager. Setting up an account can be done in 2 steps. Follow the step-by-step instructions below to successfully create an account.

i. Downloading the Helpilepsy or MigraineManager application

If your physician invited you to use the Application, you will find a link in the invitation email to download the application on the App Store from Apple or the Play Store from Android. Download the app and open it.

If your physician provided you with his Email Account, go to the App Store from Apple or the Play Store from Android and search "Helpilepsy" or "MigraineManager", download the app and open it.

ii. Registering your personal account

Go through the short tutorial screens and then tap on the "Create new account"-button. Fill in the registration form.
Important: If you were invited by your physician, please use the same email address on which he invited you! You can find this email address in the invitation email you received.

After this, follow the instructions presented.

An important step is the sharing of your data with your physician that invited you:
- If you were invited by your physician via email, you will be prompted to approve the data sharing with your physician, accept it (after having controlled it is the right physician name displayed).
- If your physician provided you his email address for you to add in the Application, add that email address in the appropriate step during the registration procedure.

Adding health-related events & answering questionnaires

It is recommended to add daily health-related events in the Application. You can do this by tapping the "Add +"-button on top-right of the "Home" and "Diary" screens. You can add several types of events:
- Seizure (Helpilepsy) or Headache episode (MigraineManager)
- Appointments

- Side effects
- Notes/events: General event to add any noteworthy event related to your health. In case of doubt, please add it.
- Daily mood & sleep quality

For each event, several fields are optional, however it is recommended to document for each event as much details as possible to use the full potential of the product.

Depending on your physician, you will be prompted once in a while to answer questionnaires. For this you will receive notifications. Tap on them to answer the questionnaires.

Self-management /eLearning module

If you are linked to a self-management or eLearning module then we recommend following this module with specific knowledge content (eLearning sections) and patient reported outcome questionnaires. Therefore, you are going to receive notifications on which you can tap to take action. An extra menu will appear for this, where you can find more information and review your progress on your self-education.

Study

If you are linked to a study, then specific questionnaire or input regarding health-related events could be asked. For this you will receive notifications on which you can tap to take action. An extra menu will appear for this, where you can find more information and review the progress of the study.

Setting up your medication & medication reminders

It is recommended to report all your medication, not only linked with epilepsy or headaches, in the Application. For this, go to the "Treatments"-page and tap "Add new treatment". From there, follow the step-by-step instructions.

Take care to record the right information as this will support the medical appointment and the decisions related to medication intake.

Several fields are optional, however it is recommended to document for each medication as much details as possible to use the full potential of the product.

You can also setup or deactivate medication intake reminders: tap on "Edit intake hours & reminders" in the "Treatments"-page.

iii. Removing your personal account and uninstall the Application

If needed, it is possible to remove your account. For this, go to the "Settings"-page and tap my profile, scroll down and tap there on "Remove account".
If you want to remove the Application from your smartphone you can uninstall it.
NOTE: Uninstall the application not only deletes the app, but also all of its data on the device.

4. Important safety information

GENERAL SAFETY INFORMATION FOR ALL USERS

To use the Neuroventis Platform, each user should:
- Have an email address
- Have basic computer and internet knowledge
- Be willing to use the Neuroventis Platform

GENERAL SAFETY INFORMATION FOR NEUROVENTIS APPLICATIONS USERS

When using the Neuroventis Applications Helpilepsy and MigraineManager, keep these points in mind:

- It is recommended to set the settings in the App Store and Play Store so that the Application is automatically updated when a new update becomes available. If not, please update to the newest version as soon as possible.
- The Application is not intended to replace the physician, so in case of any question or emergency, please consult your treating physician.
- We recommend filling in daily information about your health (e.g. attacks, symptoms, medication (reminders), sleep quality, optional self-management module) and use it for a minimum of 12 weeks.
- User needs to be able to operate a smartphone.

GENERAL SAFETY INFORMATION FOR NEUROVENTIS DASHBOARD USERS

When using the Neuroventis Dashboard, keep these points in mind:

- When inviting patients, please ensure that they fit the usage requirements (see "Users" in "2. Product Description").
- When inviting a patient, please be aware of the risk for photosensitive patients and the use of the Neuroventis Application.

PERFORMANCE ISSUES

If you experience error messages or slow loadings, verify that your internet connection is stable. If the problem persists, contact the Neuroventis team via support@neuroventis.care and stop relying on the device till the Neuroventis team resolved the issue.

ERROR AND WARNING MESSAGES

The Neuroventis Platform will show an error message or warning message when there is an issue. The error and warning massages can be grouped in the following four categories:

- When the user didn't fill all the required details for an event or action
- When the user didn't fill in the correct input
- When there is no internet connection
- When there is a performance issue with the server

The message will explain the user what is wrong to help to resolve the issue and will contain a title "Warning" or "Error".

DATA PROTECTION & DATA SECURITY

Neuroventis uses industry-standard encryption protocols to secure all products and data in transfer and at rest. The data is only stored on secure, encrypted servers and not on the device of the user. A continuous backup system is used to make sure all data is secure. Other technical and organizational measures exist within Neuroventis to keep the data safe and accessible.

You, as a user, can also improve the safety of your data, or your patients' data. For this, it is very important to keep in mind the following recommendations:

- Use a complex and unique password for your login:
  - For Neuroventis Applications users, we recommend minimum 8 characters, with at least 1 digit, 1 capital letter and 1 special character;
  - For Neuroventis Dashboards users, you are requested to use a password with minimum 8 characters, with at least 1 digit, 1 capital letter and 1 special character;
- If you use the Neuroventis Dashboard, we recommend setting up 2-factor-authentication. This can be done in the "My settings"-page of the Dashboard;
- Be careful to never share your credentials;
- When using a smartphone from someone else for the Neuroventis Applications, don't forget to log out of them;
- When using a public computer, don't forget to log out of your Neuroventis session;
- Use a secured Internet connection

Furthermore, as a user, you have several rights with regards to your data. These rights are explained in our Privacy Notice. For all questions and concerns regarding the security of your data, please contact us at privacy@neuroventis.care.

VERIFYING CORRECT INSTALLATION

Neuroventis Dashboard

To verify you are using the latest version of the Neuroventis Dashboard, on the home page of the Neuroventis Dashboard, you can check the version number, which should fit with the version reported in these Instructions for Use.

Neuroventis Applications Helpilepsy & MigraineManager

To verify you are using the latest version of an Neuroventis Application (Helpilepsy or MigraineManager), go to the App Store from Apple or the Play Store from Google and check the application if an update is available. If up to date, you can see in the home page (or in the Settings-page of the app) the version number, which should fit with the version reported in these Instructions for Use.

CONNECTED DEVICES

The Neuroventis Platform can be connected to third party devices.

For now, only the NightWatch from LivAssured, a medical device under European regulation, can be connected. Please note that we are not responsible for this device. For more information about this device, please go to https://www.nightwatchepilepsy.com.

5. Compatibility

NEUROVENTIS DASHBOARD

Software compatibility

The Neuroventis Dashboard, an online tool for the Healthcare Professional, is compatible with:
- Google Chrome (83 or higher)
- Internet Explorer (11 or higher) (! Except the Video Appointments module)
- Mozilla Firefox (76 or higher)
- Apple Safari (13 or higher)
- Microsoft Edge (83 or higher)

Users will always have access to the latest version of the Neuroventis Dashboard since it's a secured website. They will be notified of minor and major updates.

Hardware compatibility

In order to use the Neuroventis Dashboard, the device must be constantly connected to the Internet and meet the following minimum hardware requirements:
- 1.3 GHz CPU
- 1GB RAM
- 8GB Internal Storage

NEUROVENTIS APPLICATIONS HELPILEPSY AND MIGRAINEMANAGER

Software compatibility

The minimum system requirements for the Neuroventis Applications Helpilepsy and MigraineManager are an Android operating system with minimal software version Android 5.1 or an iOS operating system with minimal software version iOS 11.0.

Neuroventis users will be notified when an update is available. The update of the Neuroventis Applications can be found in the App Store/ Play Store.

Hardware compatibility

In order to use the Neuroventis Applications, the device must be constantly connected to the Internet and meet the following minimum hardware requirements:
- 1.3 GHz CPU
- 1GB RAM
- 8GB Internal Storage

6. Support

If you have any questions or if you found a problem about the Neuroventis Platform, including the Neuroventis Applications Helpilepsy and MigraineManager, please contact us at support@neuroventis.care.

In the event of a serious incident related to the use of this medical device, you can contact Neuroventis customer service desk (via support@neuroventis.care) as well as the responsible local authority.

7. Manufacturer

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Belgium
support@neuroventis.care