

Instructions for Use

florio[®] HAEMO dashboard for doctors and healthcare teams

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Information about florio HAEMO

Intended purpose	florio HAEMO is a software intended to monitor treatment of haemophilia, a rare haematologic disorder, and its outcomes. Lay users can record haemophilia-related events and view personalised data trends and analyses that help them manage their condition. These personalised data trends and analyses can be used to support treatment decision-making by HCPs.
Indication	Congenital Haemophilia A and B
Contraindication	florio HAEMO is not intended to be used by users with a disease other than haemophilia.
Target group	All patients receiving treatment for their haemophilia with clotting factors or bispecific antibodies mimicking the function of clotting factor VIII. Patient Mode: Patients diagnosed with haemophilia (≥ 12 years old) Caregiver Mode: Patients diagnosed with haemophilia (< 12 years old)
Side effects	No side effects were reported for florio HAEMO to date
Warnings	Warnings have not been identified to date.
Precautions	Entering wrong information into the app or dashboard can lead to the display of erroneous data in the app or the dashboard. This can also be caused by connectivity issues, application errors or cyber-attacks. If the information displayed in the app or the dashboard is not in line with the treatment information for this patient or does not match the reported data by the patient, please do not consider this information for treatment adjustment. Underdosing of medication can lead to a reduced efficacy of prophylaxis. Using florio HAEMO by users with contraindications for florio HAEMO may lead to reduced efficacy of prophylactic treatment.
Lifetime	The expected lifetime is 1 year

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1. About florio HAEMO

The florio HAEMO dashboard provides doctors with the possibility to review data entered by their patients or their caregivers via their florio HAEMO app in context and in real time. The florio HAEMO app enables patients to document haemophilia-related events intuitively, quickly and conveniently via their smartphone. Doctors can review summaries of patients' recorded events to monitor and potentially adjust haemophilia treatment.

florio HAEMO does not provide medical advice. The florio HAEMO app and dashboard require an internet connection.

2. Get started

When you are a new user, you can log-in via the email you got from us confirming the successful account creation. Otherwise log-in at <https://live.florio.app/pro>. Follow the instructions on the screens and confirm the terms and conditions of the dashboard.

3. Home screen

The Home screen of the florio HAEMO dashboard shows a tabular list of your patients registered for florio HAEMO. Select "View HTC Summary" on the Home screen to see summarised key data of your patients in a tabular form. To add a patient, click on the "Add patient" button.

4. Menu

The menu provides you with access to the sections Home, Export Data, About, Notifications (bell symbol), Language selection and Logout.

5. Activate a patient in florio HAEMO

Click on “Add patient” on the Home screen. Enter the requested patient information and follow the instructions on the screens.

If you want to enable a PK guided prophylaxis for a patient, see section 7 “Treatment plan”.

No demo accounts can be created.

Each florio HAEMO profile requires a unique email address. If a caregiver needs an additional address for a dependants’ profile add a + sign and a number before the @ sign (e.g. name+1@domain.com). florio HAEMO invites will go to the original email account (e.g. invites sent to “name+1@domain.com” will be automatically forwarded to “name@domain.com”).

6. Review data reported by patients

By selecting the Patient ID on the Home screen you will be provided a summary of the reported information, the treatment timeline, details on the reported bleeds and pain, physical activity, survey results, stock and consumption.

6.1. Patient summary

The top of the page shows a summary of patient information and key parameters like adherence or the number of bleeds.

6.2. Treatment timeline

The Treatment Timeline shows summarised contextualised information of reported events, like injections, bleeds, pain, steps and physical activity over time.

Depending on the treatment plan the Treatment Timeline shows the patient's estimated plasma factor level. It will not be shown during an ongoing bleed. The factor level percentage shown in florio HAEMO represents an estimate only and is not a result of actual measurement. The estimated factor level may not correspond to the patients actual factor level. It is calculated and supplied by a third-party service (McMaster PopPK, operated by McMaster University, Canada, <https://www.mcmasterpoppk.org>) and not by Florio GmbH. florio HAEMO retrieves the estimated factor levels from McMaster PopPK after each prophylaxis logged by your patient in florio HAEMO. Florio GmbH has no control over the estimate and cannot guarantee the accuracy of the estimate provided by McMaster PopPK.

6.3.Bleeds and pain

Details on reported bleed and pain events are shown below the treatment timeline. Additional information can be found when clicking on the arrow in the respective event line.

6.4.Physical activity

Patients can log physical activities manually or record them automatically from a smart watch or fitness tracker. Activities per activity type and day are shown as reported. This section is empty if a patient is not recording activities.

Data on physical activity is supplied to florio HAEMO by third party providers HealthKit (Apple iOS) and Health Connect (Google Android). Florio GmbH does not have control over this data and cannot guarantee the accuracy of such data.

The accuracy of this data depends on the patients input and is used and managed in their own responsibility.

6.5.Surveys

The florio HAEMO dashboard supports sending the EQ-5D-5L Health Questionnaire to the florio HAEMO app. Click on “Edit survey” and choose the time interval or if you want the survey to be sent once.

6.6.Stock

Stock information over the last 12 months is shown. The stock information is based on the data entered by the patient. The graph shows the reported stock at the end of each week.

The automatic factor recording provided by pharmacies (for Germany only)

florio HAEMO supports the automatic factor recording provided by pharmacies. After linking the App with a pharmacy, factor deliveries from this pharmacy are automatically recorded in florio HAEMO and displayed in the app and in the dashboard.

6.7.Consumption

The weekly consumption summarises the prophylactic injections and/or bleed treatments reported by the patient over the last 12 months.

7. Treatment plan

The functionality of florio HAEMO is based on an accurate patient treatment plan. Therefore please keep the treatment plan up to date at any time.

7.1.Edit treatment plan

You can edit treatment plans by clicking on the pen symbol next to Treatment Plan in the patient summary. Follow the instructions on the screen to finish the set

up. Patients get notifications about a treatment plan change.

7.2.Enable PK guided prophylaxis

To enable a PK guided prophylaxis for a patient follow the steps below. For more detailed information go to the FAQs available in the Support-section.

1. Create a patient profile in McMaster PopPK (MPPK). Make sure you have informed your patient about entering their data into the MPPK system. Set up a PK study and a treatment plan in MPPK. Make sure to select the treatment plan as “current” in the system. Select florio HAEMO as the app for your patient.
2. Create a user profile in florio HAEMO. During the set-up select “Prophylaxis” as treatment and finish the profile set up.
3. To connect the florio HAEMO patient profile to MPPK:
 - a. Click on the pen symbol next to Treatment Plan in the florio HAEMO patient summary.
 - b. Select “Enable PK guided prophylaxis” in the pop up window.
 - c. Depending on your last log-in at MPPK, you will be asked for authentication by signing in again.
 - d. Follow the instructions on the screens to

finish the connection.

- e. The patient will receive a consent request for the connection with MPPK.
- f. After the patients' consent, you and the patient will see estimated plasma factor levels in florio HAEMO.

If your patient declined the connection to MPPK, click on the arrow next to "MPPK ID" in the florio HAEMO patient summary, and resend the consent or disconnect the profile.

8. Export data

You can export individual patient data or data of all patients in your treatment center which are linked to your account using florio HAEMO. Please click on "Export" in the Menu at the top of the page to start the data export and follow the instructions on the screens. The file will be downloaded to your computer's default download location, using a secure internet connection.

9. PDF report







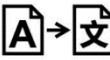
The PDF report is a printer friendly report summarising all the data for an individual patient as shown on the dashboard. This report may include a listing of all injections, bleeds and pain entries, depending on your choice. To create a PDF report go to patient summary, click on the drop down icon next to the patient ID and select "Print report".

The report will be downloaded to your computer's default download location, using a secure internet connection.

10. Activate/deactivate a patient

To activate or deactivate a patient in florio HAEMO, go to the patient page, click on the arrow next to the patient ID and select "Edit profile". Switch toggle to enable or disable patient profile. Disabling a patient means, that the patient can no longer use florio HAEMO. An disabled patient can be enabled again by switching the toggle.

11. Symbol explanation

Symbol	Explanation
	Medical device
	Indicates conformity with notified body identification number as defined in Medical Device Regulation (EU) 2017/745
	Indicates the medical device manufacturer as defined in Medical Device Regulation (EU) 2017/745
	Unique Device Identifier
	Indicates a medical device that may be used multiple times on a single patient
	Symbol to indicate that the system needs to be updated
	Identifies that the original medical device information has undergone a translation which supplements or replaces the original information

12. Data protection

Take reasonable measurements to protect your account from unauthorized access, e.g. perform software updates timely and regularly, set up password protection or biometric authentication of your laptop and use device encryption. Please log out at the end of

each session.

Information about data protection is available in the Data Privacy Policy and Terms of Use for florio HAEMO, available at <https://live.florio.app/legal/physician>.

The deletion of data entered in florio HAEMO, also including user profiles, can be requested by contacting Florio GmbH at help@florio.com.

13. Connection to external partners

florio HAEMO maintains an interface through which your patient's data can be shared with specifically evaluated partners, such as haemophilia registries and clinical information systems. You will be notified in the florio HAEMO dashboard in case connections are available for your country or treatment centre. During your activation of the connection your patients will be asked for their explicit consent, Please check the FAQs at "Support" for more information.

14. Adverse events and complaints

14.1. Adverse events and complaints related to haemophilia medication

florio HAEMO is not a tool for reporting suspected side effects (also known as adverse events) of medicine and does not store or is under responsibility to submit adverse event reports to pharmaceutical manufacturers. Relevant contact details of the

manufacturers can be found on the respective manufacturers' websites and any medicine package or package leaflet.

14.2. Incidents and complaints related to florio HAEMO

If there is any defect as to the content of florio HAEMO or suspected security events the manufacturer should be contacted without delay at help@florio.com. For serious incidents, please contact the manufacturer via help@florio.com as well as your local competent authority.

15. Minimum IT requirements

The florio HAEMO dashboard may be accessed via tablets (in landscape mode), laptops and PCs. The recommended screen size is 1024 pixels and shall be accessed through the latest browser version of Google Chrome, Mozilla Firefox, Edge or Safari.

The florio HAEMO app works on smartphones operating iOS and Android operating systems.

Minimum smartphone requirements:

- iPhone: supports latest major iOS version and at least one below, or
- Android: version 9.0 or newer versions.

Minimum smartwatch requirements:

- Apple Watch running WatchOS 6 or newer

versions (Apple iOS), or

- Android watches integrating Health Connect (Google Android).

The Florio team is available for requests and enquiries at help@florio.com.



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