Instructions for Use

florio® HAEMO app
for
People with haemophilia

Version 4.1.0, Date 30.10.2024

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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.
Patient selection criteria	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.
Warnings	Warnings have not been identified to date.
Precautions	Entering wrong information into the app can lead to the display of erroneous data in the app. This can also be caused by connectivity issues, application errors or cyber-attacks. If you feel that the information displayed in the app is not in line with your prescribed treatment, please stick to the prescribed treatment and consult your doctor. Underdosing of medication can lead to a reduced efficacy of prophylaxis. Engaging in activities with a too low factor level might increase the risk of bleeding. Please make sure that you have always installed the latest version of florio HAEMO.
	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

Content

1. About florio HAEMO

The florio HAEMO app enables you to document haemophilia-related events intuitively, quickly and conveniently via your smartphone. Data logged in the florio HAEMO app are shared with your healthcare team in real time through a web-based dashboard. This will help your healthcare team to monitor your treatment. As a caregiver, you can use the caregiver mode to record and view data on behalf of patients in your care.

florio HAEMO does not provide medical advice.

The florio HAEMO app requires an internet connection.

2. Get started

Download the florio HAEMO app from the Apple App Store or Google Play. Make sure not to use any other source for downloading.

Follow the instructions on the screens and confirm the terms and conditions of the app. Set-up your account by entering your email address and choosing a password. For users below 12 years of age, the app will automatically switch to caregiver mode.

3. Home screen

The Home screen displays your current estimated plasma factor level or the number of days without any bleedings, depending on your treatment type. You can also see information about your injections. Use the plus

button to log events.

4. Menu

You will find the menu symbol in the top left corner of the Home screen.

The menu provides you with access to the sections Timeline, Trends, Stock, Surveys, Settings, FAQs and About.

5. Record events

You will need an internet connection to log events like injections, bleeds and pain. People with haemophilia and caregivers should log events in a timely manner. Tap on the plus button on the Home screen and follow the instructions on the screens.

5.1. Injections

Record your injections in florio HAEMO from your Home screen or the plus button. Please be aware that the time of injection is critical to display your estimated plasma factor level accurately (where available).

5.2. Bleeds

Tap on the plus button on the Home screen to log bleeds. While a bleed is ongoing, you are able to log other bleeds, log injections, activity and pain.
If a bleed has resolved tap on "End bleed"

If florio HAEMO displays your factor level, you can only set a date that is later than your last documented injection in florio HAEMO when logging a bleed. In case you want to enter a bleed event that occurred prior, please manually delete this injection in the Timeline. Now enter the bleed and afterwards enter the injection again.

If your bleed is ongoing your current estimated plasma factor level will not be displayed on the Home screen (availability dependent on Treatment Plan).

5.3. Injection reminders

You can set reminders for your scheduled injections based on your treatment plan. The injection reminder requires your permission for florio HAEMO to send notifications to you.

5.4. Physical activity data

You can log physical activities manually or record them automatically from a smart watch or fitness tracker, by connecting florio HAEMO to either HealthKit (Apple iOS) or Health Connect (Google Android).

1) Set up HealthKit or Health Connect on your mobile phone.
2) Set up your wearable device for data sharing with your mobile phone.
3) Select "Settings" from the florio HAEMO menu, select "Activity Data" and connect to HealthKit

or Health Connect.

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.

In addition, you may manually log physical activity data in the florio HAEMO app.

6. Edit or delete entries

You can either edit or delete entries.

If florio HAEMO displays your factor level, you can only delete or edit your latest prophylactic injection and your latest bleed. Pain events and activities can be edited and deleted at any time.

Further information on bleeds can be found in section 5.2.

7. Stock

In the Stock section, you can review your available stock and the estimated number of remaining prophylactic injections based on your total stock. Depending on your selected treatment, florio HAEMO calculates the estimated number of prophylactic injections.

To save new stock, navigate to the menu and select "Stock". Follow the instructions on the screens to add stock manually or automatically. You can edit your

stock entries by tapping on the stock information.

<u>The automatic factor recording provided by pharmacies (for Germany only)</u>
The automatic factor entry by pharmacies enables factor deliveries of your pharmacy to be automatically entered and displayed in florio HAEMO.
For information on automatic factor recording via pharmacies, navigate to the menu, tap Stock and select "Stock additions via pharmacies?".

8. Visualise data
8.1. Estimated plasma factor level

The app shows your current and predicted estimated plasma factor level on the Home screen (availability depending on your treatment type, please consult your doctor for additional information).
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 your actual current 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 your estimated factor levels from McMaster PopPK after each prophylaxis logged by you in florio HAEMO. Florio GmbH has no control over the estimate and cannot

guarantee the accuracy of the estimate provided by McMaster PopPK.

You can view your estimated future factor levels by using the factor level predictor. Tap the icon next to the current estimated factor level on the Home screen.

The factor level predictor does not provide medical advice; you must follow the instructions of your doctor when planning your activities.

8.2. **Treatment plan**

Your personal treatment plan is provided by your doctor and only your doctor can modify it. Please contact your healthcare team for any questions about your treatment plan.

Please reach out to the healthcare team immediately if the treatment plan discussed with your doctor does not match the treatment plan displayed in florio HAEMO.

8.3. **Timeline**

The Timeline provides you a review of your recorded events:

- Injections
- Bleed treatments
- Bleeds
- Pain events
- Activities
- Daily steps

If you need to edit or delete an event, select the respective event and select the edit or delete option.

8.4. **Trends**

The Trends section displays a summary of your recorded data:

- Adherence score (only available for patients using prophylaxis)
- Bleed trends
- Pain trends
- Activity trends
- Daily steps trends

8.5. **Surveys**

Your treating physician may send you a health questionnaire via florio HAEMO once or on a regular basis. A message with an invitation to complete the survey will appear on your Home screen. Follow the instructions on the screen to complete the survey. If you close the survey before sending it your entered data will not be stored. You will be prompted once again to complete the survey.

9. **Caregiver mode**

9.1. **Record data in caregiver mode**

In caregiver mode you can log injections, activities, bleeds and pain events on behalf of up to four patients in your care. The currently active profile of the patient

in your care is shown as an icon in the top right corner of the app.

To switch to another profile or add a new profile for a patient in your care tap on the profile icon in the top right corner. You can access the caregiver mode of a person in your care on several smartphones.

9.2. Link florio HAEMO in caregiver mode to florio HAEMO Kids

This product may not be available in your country. Please check your Application Store for availability. florio HAEMO Kids is a separate app and not part of florio HAEMO. It is not a medical device .

1) Download florio HAEMO Kids from the Apple App Store, Google Play or Amazon App store either to the device where you run florio HAEMO or to the child's mobile phone or tablet.
2) Follow the instructions on the screens.
3) In florio HAEMO, open the patient profile you want to connect to florio HAEMO Kids, navigate to the Menu and select "Settings"
4) Select the florio HAEMO Kids banner on the bottom of the page. Select "Connect (patient name) to florio HAEMO Kids", then click "Next" and you will see a QR code and a numeric code.
5) Either scan the QR code with the florio HAEMO Kids app or enter the numeric

code in the florio HAEMO Kids app manually.

6) The connection to florio HAEMO Kids is now complete.

10. Symbol explanation

Symbol	Explanation
MD	Medical device
$C\epsilon$ 2797	The CE mark indicates conformity to the Medical Device Regulation (EU) 2017/745 with the notified body identification number
▲▲	Indicates the medical device manufacturer as defined in Medical Device Regulation (EU) 2017/745
UDI	Unique Device Identifier
(1↑)	Indicates a medical device that may be used multiple times on a single patient
☑	Symbol to indicate that the system needs to be updated
A→文	Identifies that the original medical device information has undergone a translation which supplements or replaces the original information

11.   Data protection

Take reasonable measures to protect your florio HAEMO app from unauthorized access, e.g. perform software updates timely and regularly, set up password protection or biometric authentication of your phone and use device encryption.

You can access the in-app privacy settings by navigating to the Menu. Select Settings and then Privacy.

You can also activate security features for the florio HAEMO app in your mobile phone settings.

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/patient

The deletion of data entered in florio HAEMO, also including user profiles, can be requested by contacting Florio GmbH at help@florio.com. You can delete the app from your device at any time.

12.   Connection to external partners

Your doctor may ask you to share your data with specifically evaluated partners. Examples may include haemophilia registries or clinical information systems used by treatment centres (a computerised system used for clinical patient data).You will be asked to give explicit consent.

13. Information for emergencies
13.1. 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. You should consult your healthcare provider with any questions or concerns you may have regarding your health condition.

13.2. Incidents and complaints related to florio HAEMO

In case of medical emergency, please contact your doctor or dial the emergency number. 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.

14. Product disclaimer

The app is not intended to be used in place of advice from your physician or other healthcare professionals. Should you have any health-related issues contact your

physician or other healthcare professional promptly. Should you have any questions on florio HAEMO please contact us at help@florio.com.

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The intended users are lay users (florio HAEMO app) and healthcare professionals (florio HAEMO dashboard). florio HAEMO is not intended to be used by users with a disease other than haemophilia.

15.   Minimum IT requirements

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.
- The minimal supported resolution is 1136 × 640 Pixel. Note: Use of foldable phones may not be supported if the screen in the folded/unfolded state is larger or smaller than a regular smartphone.

Minimum smartwatch requirements:

- Support Apple Watch running on latest OS version and one below paired to an iPhone

For requests, enquiries and technical questions or if you would prefer a printed version of the instructions for use, please send an email to help@florio.com.

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iOS app:
(01) 04260748180136 (8012) V4.1.0
Android app :
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