

Instructions for Use

florio® NEPHREE app

Version 1.1.x, Date 13.03.2026

Revision A



Intended purpose	florio NEPHREE is a digital support solution for people living with complement 3 glomerulopathy (C3G) or immune complex-mediated membranoproliferative glomerulonephritis (IC-MPGN) and their healthcare professionals to alleviate the daily burden of the disease. C3G and IC-MPGN are ultra rare immunological disorders. florio NEPHREE enables lay users to record and organise their health and treatment information, disease-related symptoms, medication, and diagnostic results, to support management of their condition. florio NEPHREE allows lay users and professional users to review contextualised treatment information, individual treatment outcomes, personalised trends and analyses. The application does not provide specific treatment recommendations to the user or their HCP (healthcare professional).
Indication	Complement 3 glomerulopathy (C3G) or immune complex-mediated membranoproliferative glomerulonephritis (IC-MPGN)
Contraindication	florio NEPHREE is not intended to be used by users with a disease other than complement 3 glomerulopathy (C3G) or immune complex-mediated membranoproliferative glomerulonephritis (IC-MPGN).
Patient selection criteria	Patients diagnosed with complement 3 glomerulopathy (C3G) or immune complex-mediated membranoproliferative glomerulonephritis (IC-MPGN) (≥ 12 years old)
Side effects	No side effects were identified for florio NEPHREE.
Warnings	Warnings have not been identified to date.
Precautions	Entering wrong information into the app can lead to the display of erroneous data and notifications 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. Please make sure that you have always installed the latest version of florio NEPHREE. Please, only use florio NEPHREE in accordance with its intended use. Please, make sure you keep your login credentials safe Sharing your login information with other

people may potentially compromise your personal data.

Lifetime

The expected device lifetime is 2 years

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1. About florio NEPHREE

The florio NEPHREE app enables you to document health related events conveniently via your smartphone. The app analyses and visualises data entered by you. Data logged in the florio NEPHREE app are shared with your healthcare team in real time through a web-based dashboard. This will help your healthcare team to review your treatment documentation and individual treatment outcomes. The florio NEPHREE app requires an internet connection.

2. Get started

Talk to your healthcare team to find out if florio NEPHREE is right for you. As soon as your account is enabled by your healthcare team, you're ready to use the app.

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

Follow the instructions on the screens and confirm the terms and conditions of the app. If you are below the age of majority in your country, you will be asked to hand your phone to your legal representative to accept the Terms of Use. Set-up your account by entering your email address and choosing a password. For security the app uses two factor authentication.

3. Home screen and menu

The home screen provides you the following information:

- Quick check: Find health questions, reminders to log your biomarker values or to fill in a questionnaire here.
- Your medication: See here your scheduled and logged medications
- Your trends: Pin your most important biomarker

Use the menu on the bottom to access the sections  trends,  timeline and  settings. Use the plus button to log events.

4. Treatment plan

4.1.Set up

After you created your account, you will be asked to set up your treatment plan. Follow the steps on the screens to finish the set up.

To access the section, select  settings in the menu and tap on “Treatment plan”.

4.2.Medication reminders

During the creation of your treatment plan, you can set up medication reminders. If you would like to enable them later, follow the instructions in the next section on how to edit a treatment plan. Once enabled, you will get a reminder at the time of your choice.

To receive medication reminders, you must give florio NEPHREE permission through your phone settings to send you push notifications.

Please always take your medication as prescribed by your doctor.

4.3.Edit, end or delete a treatment plan

Select  settings in the menu and tap on “Treatment plan”. Select the treatment plan you would like to edit, end or delete.

- Edit: Tap on “Edit” and change the start date, frequency, dose & time or switch on/off and edit medication reminders. If you changed the dose or frequency, to track the changes florio NEPHREE will end your current treatment plan and save a new one with your updates.
- End: Tap on “End”, select the end date and confirm.
- Delete: Only treatment plans with a start date in the future or already ended treatment plans can be deleted. Tap on “Delete this treatment plan” and confirm.

5. Record events

Tap on the plus button on the home screen and follow the instructions on the screens.

5.1.Biomarkers and symptoms

You can log symptoms - fatigue, swelling, frothy urine and blood in urine – and biomarkers - proteinuria, microscopic haematuria, eGFR, and serum albumin/creatinine. You can also log weight, height and blood pressure.

When entering values for proteinuria and serum albumin/creatinine, both SI or conventional units can be used. The system automatically converts the values. Please always log the units as stated in your lab report.

5.2.Medical events

Record your scheduled medication in florio NEPHREE from your medication reminder, by tapping on the plus button in the navigation bar, or the plus button next to your scheduled medication on your home screen or by selecting the corresponding scheduled medication in your timeline. Follow the instructions on the screens to finish logging.

You can also log one-time medication, by tapping on the plus button in the navigation bar.

Vaccinations can only be logged retrospectively. If the vaccine type “Other” is selected, you need to enter the vaccine type manually.

5.3.Questionnaires

Your treating doctor may send you applicable

questionnaires via florio NEPHREE once or on a regular basis. A message with an invitation to complete the questionnaire will appear on your home screen. Follow the instructions on the screen to complete the survey. You can also access open and completed questionnaires via settings .

5.4.Edit or delete entries

You can either edit or delete entries.

Go to the  timeline, select the log you would like to edit or delete and follow the instructions on the screens.

6. Visualise data

6.1. Timeline

The  timeline provides you with a review of your logs, future events and your scheduled and taken medications in chronological order. The filter helps you to easily see selected logs.

6.2.Trends

The  trends section visualises your logged biomarkers, displays a summary of your recorded data and shows your medication adherence. Adherence calculation is based on most recent 30 days and is only available for disease-specific medication.

7. Symbol explanation

Symbol	Explanation
	Indicates the item is a medical device
	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
	Indicates the date when the medical device was manufactured
	To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form
	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 checked or updated
	Identifies that the original medical device information has undergone a translation which supplements or replaces the original information
	To identify the control to invoke a menu for human language selection in accordance with a user's preference
	Indicates the Swiss representative (only applies for CH market)
	Navigates to the home screen
	Navigates to the trends screen
	Navigates to new logs creation
	Navigates to the settings screen
	Navigates to the timeline screen
	Filters displayed items
	Deletes item

Symbol	Explanation
	Display additional information
	Indicates a decrease
	Indicates stable trend
	Indicates an increase

8. Data protection

8.1.Data security



Take reasonable measures to protect your florio NEPHREE app from unauthorised 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 activate security features for the florio NEPHREE app in your mobile phone settings.

8.2.Data protection

Information about data protection is available in the Data Privacy Policy and Terms of Use for florio NEPHREE, available at <https://dashboard.nephree.com/v1/patient/legal-docs>

8.3.Account deletion

If you would like to delete your account, tab on  settings and tap on “Profile settings”. Tap on “Delete

account” and follow the instructions on the screens to finish the account deletion.

With account deletion you will immediately lose access to your account.

Your doctor will be informed about the deletion of your account.

You can delete the app from your device at any time.

9. Information for emergencies

9.1. Adverse events and complaints related to medication

florio NEPHREE is not a tool for reporting suspected side effects (also known as adverse events) of your medication and does not store or submit records of it. Please consult your doctor with any questions or concerns you may have regarding your health condition. Relevant contact details for the manufacturer of your medication can be found on the manufacturer’s website. If there is any defect of content or function of florio NEPHREE, please contact help@florio.com without delay.

9.2. Incidents and complaints related to florio NEPHREE

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 NEPHREE 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.

10. 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 NEPHREE please contact us at help@florio.com.

florio NEPHREE is a digital support solution for people living with complement 3 glomerulopathy (C3G) or immune complex-mediated membranoproliferative glomerulonephritis (IC-MPGN) and their healthcare professionals to alleviate the daily burden of the disease. C3G and IC-MPGN are ultra rare immunological disorders.

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The application does not provide specific treatment

recommendations to the user or their HCP.

The intended users are lay users (florio NEPHREE app) with complement 3 glomerulopathy (C3G) or immune complex-mediated membranoproliferative glomerulonephritis (IC-MPGN) and their healthcare team (florio NEPHREE dashboard). florio NEPHREE is not intended to be used in other disease areas.

11. Minimum IT requirements

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

Minimum smartphone requirements:

- iPhone: supports latest major iOS version and at least one below
- Android: version 9.0 or newer versions
- The app is built for the average smartphone screen size that is typically between 6.1 and 6.8 inches. As minimum a screen size of 5.6 inches is required. The app requires a minimum smartphone screen resolution of 1792x828 pixels.
- Landscape mode is not supported.
- The use of foldable phones may not be supported if the screen in the folded/unfolded state is larger or smaller than a regular smartphone.

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) 04260748180198 (8012) V1.1.0

Android app :
(01) 04260748180204 (8012) V1.1.0

Please, note that in case of software updates (bug fixes), the last digit of the UDI-PI (V1.1.x) may be different on the corresponding application "About" screen compared to this overview.