florio®
ITP

Instructions for Use

florio® ITP App

Version: 5.1, Date: 18.07.2023

MD $\quad$ **CE** 2797

Table of Contents

The first part of the document (item 1-18) describes technical details about florio ITP, in which people with ITP are partly addressed directly and partly referred to as user or patient.
From point 19 onwards, the functions and use of the app are described and people with ITP are addressed as "you".

1. Contact

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

2. Manufacturer

Florio GmbH
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80807 München
Germany
www.florio.com

3. Product name

MD   florio® ITP

UDI   iOS App   (01) 04260748184004 (8012) V5.1.0
          Android App   (01) 04260748180037 (8012) V5.1.0

4. Intended purpose

florio ITP is a software intended to monitor treatment of immune thrombocytopenia (ITP), a rare haematologic disorder, and its outcomes.
Lay users can record ITP-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.

5. Classification and CE mark

CE 2797

florio ITP is a CE-marked medical device Class IIa as defined in Medical Device Regulation (EU) 2017/745.

6. Functionality

florio ITP enables intuitive, simple and fast documentation and monitoring of ITP-related data. The visualization of the entered data in the App and the display of trends can help with the self-management of the disease.

People with ITP can summarize data from florio ITP in a clear report and easily share it with their healthcare team using the florio ITP app. The information from the report can help the healthcare team to better understand the health situation and monitor therapy success.

florio ITP provides the user with the following features:

- Recording of platelet counts
- Recording of events such as bleeds, bruises and petechiae
- Recording of fatigue, activity levels, mood and wellbeing
- Recording of treatment plans
- Setting reminders to take medication, and/or to follow dietary restrictions required for medications
- Recording and viewing of upcoming appointments
- Completion of pre-appointment surveys to track progress prior to medical appointments
- Displaying trends from the data recorded in the application across platelet counts, important events, fatigue and activity levels
- Optional sharing of a summary report on recorded data with the healthcare team

7. Intended users

Intended users for the florio ITP app are patients that have been diagnosed with immune thrombocytopenia (ITP) who have reached the age of majority within their respective country and healthcare professionals.

8. Patient selection criteria

All patients diagnosed with immune thrombocytopenia, who have reached the age of majority within their respective country.

9. Field of application

florio ITP is intended for use by patients who have been diagnosed with immune thrombocytopenia (ITP).

florio ITP is not intended to administer or exchange energy with the human body and is not intended to administer or remove substances. It is furthermore not intended for direct diagnosis or to monitor vital physiological parameters, e.g., heart rate. florio ITP does not control any other devices which may do so.

10. Type and duration of use

florio ITP is intended to be used frequently by users in their typical everyday social environment. florio ITP can be used for a long period of time.

11. Frequency of use

florio ITP should be used as often as necessary in order to accurately and timely log all relevant ITP events, such as bleeds, fatigue and treatment details.

12. Device lifetime

The expected lifetime of florio ITP is one year. Within the product lifetime, there might be maintenance updates. Their type and frequency depend on maintenance input. The user shall keep the software version up to date. It is recommended to always use the latest software version. If an older version of the instructions for use is needed, please contact us at help@florio.com.

13. Contraindications (when the product is not intended to be used)

florio ITP is not intended to be used by patients with a disease other than ITP. Additionally, the patient must not be classified as a minor which is defined as those who have not reached the age of majority in the jurisdiction in which they reside.

14. Side effects

No side effects were reported for florio ITP.

15. Interactions

florio ITP does not have known interactions.

16. Warnings and precautions

CAUTION	Entering wrong information into the app can lead to the display of erroneous data in the app which can lead to underdosing, overdosing or to reduced efficacy of your medication. This can also be caused by connectivity issues, application errors, unauthorized access 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. Sharing incorrect data with your HCP via the health report may lead to inaccurate data being taken into account when making potential treatment adjustments. Please make sure that you have always installed the latest version of florio ITP.
CAUTION	Please make sure florio ITP is only used in accordance with its intended use. Using florio ITP for other indications may lead to incorrect treatment decisions.
CAUTION	Please make sure you double check the email address if you share your health report. Sharing the health report with the wrong recipient may potentially compromise your personal data.
CAUTION	Please make sure you keep your login credentials save. Sharing your login information with other people may potentially compromise your personal data.

Warnings have not been identified to date.

17. 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 ITP please contact us at help@florio.com.

florio ITP is not a tool for reporting suspected side effects (also known as adverse events) of your medicine and does not store or submit adverse event reports. Please consult your healthcare professional with any questions or concerns you may have regarding your health condition. Relevant contact details for the manufacturer can be found on the manufacturers' website which should be on any medicine packaging. If there is any defect as to the content or function of florio ITP, you should contact help@florio.com without delay.

18. Minimum IT requirements

18.1. Principles of operation

florio ITP requires either of the following minimum operating systems:

- iPhone: supports latest major iOS version and at least one below, or
- Android 9.0 (SDK v28) and above.

18.2. Other

The florio ITP App requires an internet connection. For protection against unauthorized access the user should refer to section "Sign-up and log in", as well as "Data protection". Florio GmbH has implemented comprehensive measures to protect personal health data based on state-of-the-art technology. If you want to learn more about data protection at Florio, please check the Privacy Policy. The Privacy Policy can be accessed by tapping on "About" in the main menu, then select "Privacy Policy".

19. Get started with florio ITP

19.1. Sign-up and log in

You can download florio ITP from the Apple App Store or the Google Play Store. Make sure not to use any other source for downloading.

1) Install florio ITP on your mobile phone.
2) Open florio ITP, and you will be guided through a few short steps that provide information about the App.
3) Tap on "Create an account".
4) To set your account details complete all fields on the account registration form. After all fields

are successfully entered tap on "Create an account".

5) You will be asked to provide your consent for the use of florio ITP, based on florio ITP's terms of use and data privacy policy. Please carefully read these documents, which you can retrieve from the provided links.

6) florio ITP will now send a confirmation code to the email address entered on the account registration form. Input the code from this email into the confirmation code field within florio ITP.

7) florio ITP is now ready to be used.

19.2. Main menu

You can access the main menu by tapping on the menu symbol on the top left corner of the home screen. The menu provides you with quick access to "Home", "Trends", "Treatment plan", "Appointments", "Profile", "Support", and the "About" sections.

19.3. Home screen

The home screen displays your last entered platelet count, and a summary of your personal logs added to florio ITP from the last 30 days.

20. Record data in the florio ITP App

20.1. Treatment plan

20.1.1. Create a treatment plan

You can enter the medication(s) and other treatments you are currently taking by navigating to the treatment plan screen via the main menu. On the treatment plan screen you can add a new treatment by tapping the "Add treatment" button. Next, select the type of treatment you wish to add. For each treatment you will be asked to supply a "start date" (when you will begin the treatment). For most treatments you will also be asked to specify:

- "frequency" (how often you take the treatment)
- "usual time" (the time of day you normally take the treatment)
- "dosage" (the amount of medication you take each time)

You can optionally assign a colour to treatments, to make it easier to identify.

florio ITP does not provide recommendations to the user to alter a previously prescribed treatment or therapy.

20.1.2.   Set medication and dietary restriction reminders

When creating certain treatments, you can choose to enter the time of day you usually take the medication (usual time). Within that same area you can set medication reminders. Once enabled, you will get a reminder at the time, you usually take your medication. Medication reminders are currently only available for the following treatment types:

- TPO-RA
- Corticosteroids
- Platelet Destruction Inhibitor

Some ITP medications require dietary restrictions to be respected around the time that you take your dose. If you take such kind of medication you can set dietary restriction reminders. They can be found in the same area where the medication reminders are set. Dietary restriction reminders can be set to be displayed between four hours before and until two hours after the time, you usually take your medication.

Please note that in order to use medication and dietary restrictions reminders, you must give florio ITP permission to send you push notifications on your phone through your phone settings.

20.1.3.   End treatment

When you have stopped taking a specific treatment you can "End" the treatment in your treatment plan. At the "Treatment plan" screen tap "…" next to the treatment you wish to end. From the options that appear, select "End treatment" and select end date.

20.1.4.   Delete treatment plan

If you have made a mistake while adding a treatment it may be best to simply delete that treatment from your treatment plan. At the "Treatment plan" screen tap "…" next to the treatment you wish to delete. From the options that appear, select "Delete treatment".

20.2. Appointments and surveys

20.2.1. Create and delete an appointment

To add an upcoming appointment, navigate to the "Appointments" screen via the main menu:

- If you have never added an appointment before, there will be a prompt shown on the home screen to create one. Tap on it and the appointments screen will open. Tap now on the "Add appointment" button to continue.
- Otherwise, open the main menu and tap on "Appointments". From this screen, tap on the green "+" button to continue.

Select the appointment type from the available list and fill in the required fields. After all mandatory fields are complete you can save the appointment, and it will appear within your list of upcoming or past appointments within the appointments screen.

If you have erroneously entered an appointment, you can delete it from the appointment list. From the appointments screen tap "..." next to the appointment you wish to delete. From the options that appear, select "Delete".

20.2.2. Complete a pre-appointment survey

If you have created a consultation appointment, you can complete a pre-appointment survey within 48 hours before the appointment. To complete the survey, you can tap on the pre-appointment survey prompt from either:

- the „Home" screen.
- the "Appointments" screen, which can be accessed via the main menu.

After accessing the survey, you will then be guided through a series of short questions to gather information about the impact of ITP on your daily life. For each question, simply select the response that describes best your situation. Once the survey is complete, you can create a health report and optionally share the report with your doctor or healthcare team. If you wish to view your answers of the survey, you can do this via the health report prompts from either:

- the „Home" screen.
- the "Appointments" screen, which can be accessed via the main menu.

These prompts will appear until the day after the scheduled date of your consultation appointment.

20.3. Event logging

20.3.1. Log medication as taken

You can use florio ITP to keep track of your taken medications that are part of your treatment plan:
1) On the home screen, tap the "+" button
2) Tap "Log medication"
3) If your treatment plan contains more than one current medication, select the medication you wish to log now.
4) Enter the "Date and time taken"
5) Tap "Save"

20.3.2. Log platelet counts

You can log platelet counts from the home screen:
- If you have never logged a platelet count before and are using florio ITP for the first time, tap the "Add platelet count" button.
- Otherwise, tap the green "+" sign at the bottom right corner of the home screen and select the "Platelet Count" button to log a new platelet count.

Enter the platelet count and fill in all required fields. Then tap on "Done".

20.3.3. Log personal logs

You can log bleed, bruise, petechiae, or fatigue via the home screen by tapping the green "+" at the bottom right corner of the screen.

1) Select what you wish to log (bleed, bruise, petechiae, or fatigue).
2) Enter the required information.
3) If you want to add a severity (optional), move the severity slider by tapping on the value that best describes your log.
4) Tap "Save".
5) You can now either tap "Done" to complete the flow and return to the home screen or tap "Log another" to start logging another event.

20.3.4. Delete logs

If you have entered any of the logs in error, you can delete these via the timeline screen. Tap on an event in the timeline to view more information about it, from this view you can also delete the event.

20.4. Visualise data in florio ITP

20.4.1. Trends

To access the "Trends" screen, navigate to the main menu and tap on "Trends". At the top of the "Trends" screen you can select the time frame (30 days, three months, or six months). The "Trends" screen shows you a summary of your recorded data.

In the 30-day time frame you can also view your medication adherence. "Adherence" expresses how well you follow your treatment plan. For example, if you are directed by your doctor to take your medication daily for the last 30 days, and you logged your doses only 20 times in florio ITP, your adherence score will show 66% (20 out of 30).

In the three- or six-month time frames a timeline graph is shown. If you switch to landscape view you can tap on a month to see a detailed breakdown of the logs within that month.

20.4.2. Display activity data

If you have a wearable device, such as a smartwatch or fitness tracker, you can record activity data from such devices in florio ITP. For florio ITP to access your physical activity data, you must:

1) Install and set up Apple HealthKit (iOS phones) or Google Fit (Android phones) on your mobile phone
2) Set up your wearable device for data sharing with your mobile phone
3) Open florio ITP and navigate to the "Trends" screen via the main menu
4) Scroll to the bottom of the "Trends" screen and tap on the "connect activity" banner to authorise florio ITP to connect to Apple HealthKit (iPhone) or Google Fit (Android)
5) You will be directed to a confirmation area to complete the data sharing with florio ITP.

After completion, your activity data will be synced with florio ITP and shown within the activity section of the "Trends" screen.

Data on physical activity is supplied to florio ITP by third party providers (Google Fit or Apple Health Kit). Florio GmbH does not have control over this data and cannot guarantee the accuracy of such data.

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

20.4.3.   Create and share a health report PDF

Your health report is a six-month summary of your recorded data including the results of your latest pre-appointment survey, if completed. You can generate a health report by navigating to the "Trends" screen and tapping on the upper right button "Generate report". When generating your health report, you can enter an optional name to appear on the report. You can choose to either "View health report" or "Share health report" securely. If you choose to view your report, you will be shown an in-App PDF.

If you choose to share your health report securely, you will see a pop-up with icons that show the possible communication applications to share a link to your report. When sharing the report via florio ITP, there will be an auto-generated message which can be edited if required, however please do not remove, or alter the web-link and password as the recipient will need these to access a copy of your health report. The recipient of your health report (e.g., your doctor) should open the report by clicking on the link they receive and entering the associated password. The web-link will only work when opened from a desktop browser, not a mobile phone or tablet.

21.   Data protection

The processing of personal data in florio ITP is in accordance with the European General Data Protection Regulation, the UK General Data Protection Regulation and the German Federal Data Protection Act. Florio GmbH uses industry best practices to protect your data from attack and loss. More information about data protection is available in the "Privacy Policy" and the "Terms of Use" for florio ITP, available at https://florio-itp.com/legal. You can delete the App from your device at any time. The deletion of data entered in florio ITP, also including user profiles, can be requested by contacting Florio GmbH at help@florio.com.

21.1.   Protect your data

Take reasonable measurements to protect your florio ITP 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.

21.2.   Data Governance Board

Aiming to improve ITP care, your non-identifiable data may contribute to medical research. This information will be used for medical research purposes only and is governed by an independent external Data Governance Board, consisting of international medical experts and patient association representatives.

22.   Emergencies and complaints

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 ITP or suspected security events the manufacturer should be contacted without delay at help@florio.com.

23.   Symbol explanation

Symbol	Explanation
MD	Medical device
CE 2797	Indicates conformity with notified body identification number as defined in Medical Device Regulation (EU) 2017/745
(manufacturer symbol)	Indicates the medical device manufacturer as defined in Medical Device Regulation (EU) 2017/745
UDI	Unique Device Identifier
(single patient multiple use symbol)	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

24. Status of the software

The current software version of florio ITP can be found in the App under the menu item "About".

25. Last update of the information

18.07.2023.

26. Further information

For technical questions or if you would prefer a printed version of the instructions for use, please send an e-mail to help@florio.com.