

User Manual

BAYOOCARE

MyIUS-App

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1 Symbols



Conform with the relevant EU guidelines.



Follow the instructions!



Medical device manufacturer

2 Table of acronyms & definitions

Abbreviation	Description
FTU	First Time Use
IUS	Intrauterine system
IFU	Instructions for use
OS	Operating System
FAQ	Frequently Asked Questions
app	MyIUS application
BMI	Body Mass Index
cm	Centimeter
ft	Feet
lb(s)	Pound (symbol: lb) is a unit of mass used in the imperial and US system
kg	Kilogram is a unit of mass used in the metric system
RWE	Real World Evidence

3 Introduction

This document is the user manual that must be read prior to using the App. These instructions will also help and guide the user regarding the correct usage and understanding of the functionalities of the App.

3.1 Legal manufacturer

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3.2 Scope

MyIUS is an application designed for persons with cycles using or planning to use Levonorgestrel Intrauterine System (LNG-IUS) contraception systems. The application is intended to accompany these users on their journey from IUS prescription over placement up to the succeeding three months and providing educational material and the option to get a prediction of future bleeding patterns. Furthermore, the application allows to record further data up to 270 days in sum.

3.3 Contraindications

MyIUS is an application designed for persons with cycles using or planning to use Levonorgestrel Intrauterine System (LNG-IUS) contraception systems. This makes the app not suitable for:

- Men
- Women not having a prescription for or not using an intrauterine system from BAYER AG
- Women suffering from Heavy Menstrual Bleeding (Menorrhagia)

4 Expected clinical benefit

As changes in bleeding profile are common to LNG-IUS users, the lack of awareness of possible bleeding changes with IUS can affect user satisfaction and further usage of this method in real world. The intended usage of the application starts with the prescription of the IUS and ends ideally after providing a most likely future bleeding profile with respect to intensity and/or regularity.

The application itself is a patient support tool or a so-called “digital companion” to be used by women using Kyleena®, Jaydess®, Mirena®. The targets of the application are the following:

- Accompanying the user from the prescription, over placement of the IUS to at least 90 days after the placement offering her useful information,
- Collecting one-time baseline parameters and continuously daily bleeding diary for at least 90 days after placement of IUS,
- Providing a prediction of bleeding profile with respect to intensity and regularity based on the collected data,
- Depending on location, collecting data beyond 90 days to improve and validate the prediction in a real-world setting
- Facilitating the communication with the HCP by providing a report comprising the daily bleeding diary and prediction.

The prediction is based on an AI model which provides the most likely future bleeding profile after the placement of the IUS. Without entering the requested information about baseline parameters and daily bleeding pattern the prediction is not available.

5 Precautionary measures / safety instructions

The app MyIUS is a clinically validated medical device and complies with the essential requirements of the 93/42/EEC directive or its national implementations.

The prediction of the bleeding pattern is only validated for the following IUS:

- Kyleena®
- Jaydess®
- Mirena®

The MyIUS app may only be used on validated smartphones and operating systems.

The current version of the app MyIUS should always be used.

The app MyIUS may not be modified without permission of the manufacturer.

The app MyIUS is not intended to be used as the sole basis for diagnosis / therapy decisions.



Note:

If you use a rooted device, the Android security mechanisms can be bypassed. Therefore, rooted smartphones are not supported for using the app, regardless of the version of the operating system.

6 Quick start


6.1 App icon

After installing the app, it shall have an application icon on the smartphone, as shown in Figure 1.



Figure 1: App icon

6.2 App Icon Change

The MyIUS application provides the option to change the MyIUS app icon. You can select an inconspicuous app icon instead of the default app icon (Figure 1) in the settings section of the application, accessible from the main menu . You will see alternative app icons at the bottom of the screen (Figure 53). The currently selected and applied icon will be highlighted. You can tap on any of the provided icons to change the MyIUS app icon. Only one icon can be selected at a time.



Note:

Please be advised, that the icon change will not happen immediately and that a restart of the app might be required for the application icon change to be applied.

6.3 Splash screen

When the app is started, a splash screen containing the logo and the installed version of the software and the legal manufacturer info will be displayed (Figure 2).

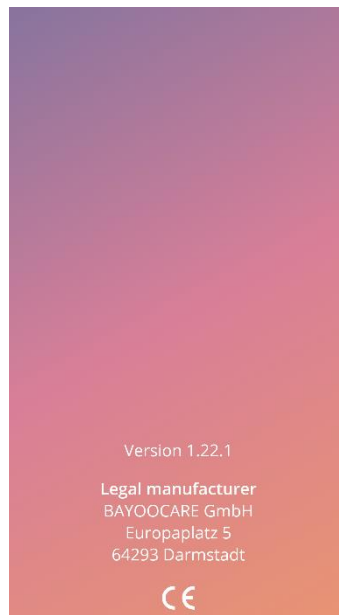




Figure 2: Splash screen at app start

6.4 Menu & toolbar

The menu  icon is displayed on the bottom right of each of the main screens.

By pressing on  nine options will be displayed and each of them navigates to one of the following sections (Figure 3):

- Profile
- Settings
- Unlocked gems
- Your Prediction and report
- Frequently asked questions
- Support
- Legal notice
- Reminders
- Media

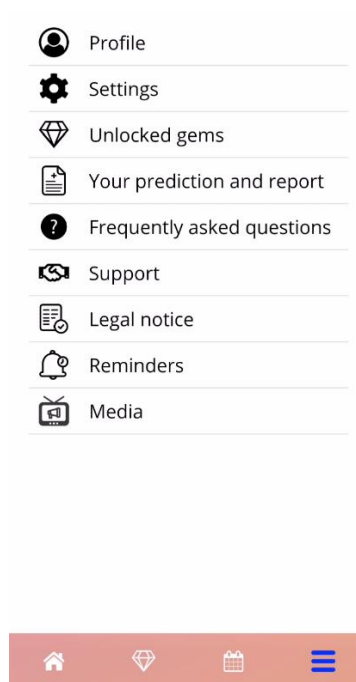


Figure 3: Burger menu

Once you accepted the invitation to the MyIUS Study (as described in chapter 16.1) the additional entry “MyIUS Study” will appear in the Main Menu (Figure 4: Burger menu).

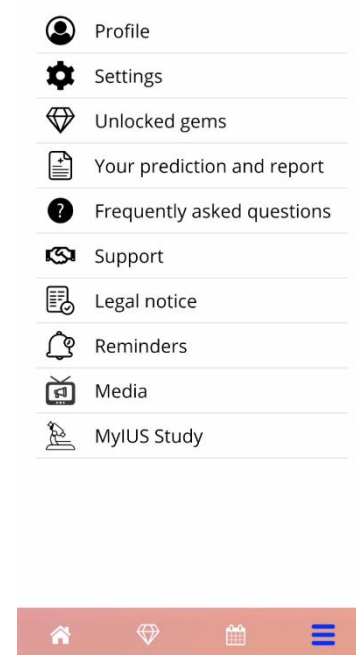


Figure 4: Burger menu (MyIUS Study)

When accessing one of the sections from the Main Menu, the toolbar is also visible and contains four buttons: Home screen, unlocked Gems screen, Calendar screen and Menu icon.

6.5 Main navigation

You can navigate freely once you completed the setup of the application. The Home screen (Figure 33) and the Main Menu (Figure 3) allow you to navigate to the application's features by pressing on the respective items. Furthermore, the MyIUS application provides buttons to navigate between screens that follow each other. Most of these screens have a blue or white arrow button on the left, as displayed in Figure 5, in order to navigate to a previously displayed screen. When you start a workflow, usually you cannot navigate back via such a button but have to abort the workflow by pressing a "Cancel" button in order to go back to the main menu. To continue to the next screen of a sequence, you have to press a button like "Continue" or "Skip".

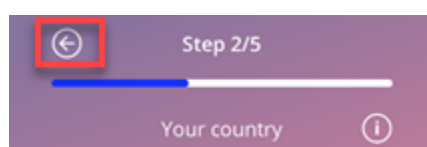


Figure 5: Back Icon

E.g., by pressing on the back button from a Baseline parameter screen, you can go back to the previous parameter screen. The first screen of the Baseline parameter questionnaire (Age screen) does not have a back button.

6.6 General warnings

Warning pop-ups, such as the one displayed in Figure 6 will inform you about any issues with the app or with your data.

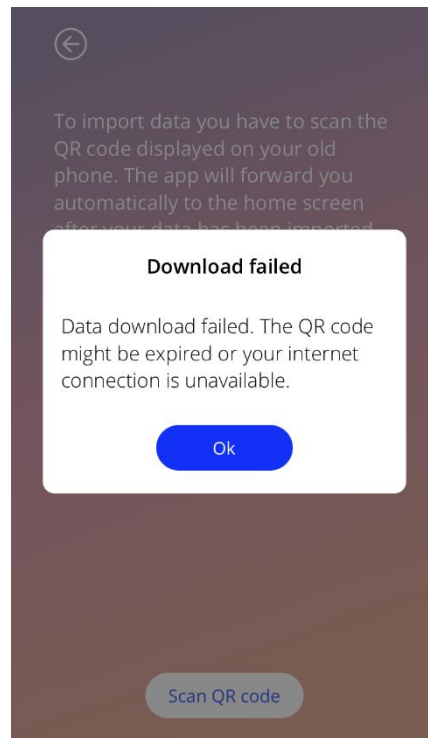


Figure 6: Warning message

Warnings will appear in the following cases:

- Upload and store of app data
- Missing baseline entries
- Missing bleeding data
- When the app is started, and the operating system of your mobile phone is not supported
- Failed export of reminders to your calendar
- Denied camera access
- PIN for authorization is incorrect
- Your E-Mail application cannot be reached in case of a support E-Mail
- Changing of the IUS insertion date
- Reminders are not available for your country

The warning pop-ups have the following content:

- a title
- a message describing the problem that occurred
- one or two buttons representing the actions that can be realized further

6.7 Information pop-up

The Progress Area on the Home Screen and all the screens of Baseline parameters have a blue or white information icon as displayed in Figure 7.

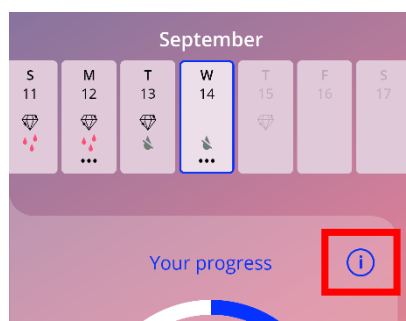


Figure 7: Information icon

When pressing on the information icon, a new pop-up will be displayed, containing detailed information about the selected section.

You can close these pop-ups by pressing the “Close” button.

6.8 Pop-ups

Pop-up, as the one displayed in Figure 8, will appear in the following cases:

- When a reminder or notification is triggered
- When a gem is unlocked or received
- When motivational messages are provided
- When placement date is “today” or in the past and needs confirmation
- When you can confirm your placement date
- When you receive motivational messages
- When you access informational screens
- When you give feedback about the app
- When the terms of use are accessed
- When the privacy statement is accessed
- When consents for further usage are needed
- When a reminder is successfully exported to your calendar

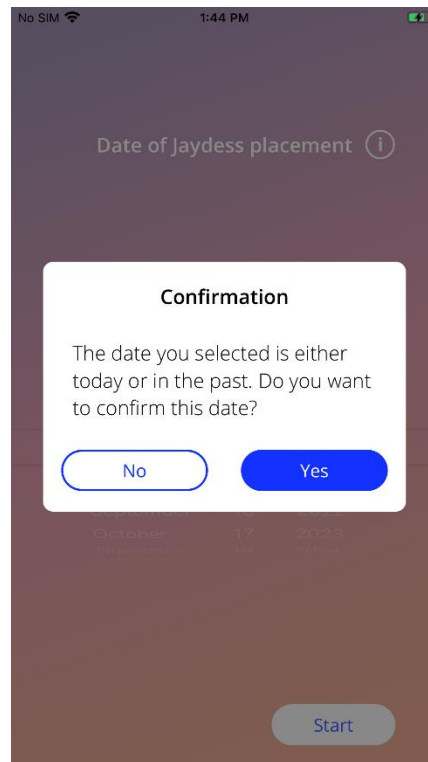


Figure 8: Pop-up message

6.9 Terms of use

The Terms of Use can be read and downloaded as PDF file, by pressing on the blue link “Terms of Use” on the Authorization screen (Figure 10). The Terms of Use will be provided according to the region and the language set on the smartphone. If the language is not supported, an English version of the Terms of Use will be displayed.

6.10 Data privacy

The Data Privacy Statement can be read on the Data Privacy screen (Figure 13) and be downloaded as PDF file, by pressing on the button “Save PDF” on the Data Privacy screen (Figure 13). The Data Privacy Statement will be provided according to the region and the language set on the smartphone. If these are not supported, the Data Privacy Statement will be displayed in English.

7 First time use

7.1 Operating system check

Every time the app is launched, the operating system version of your mobile is checked. In case the operation system of your mobile phone is not supported by the app version, a pop-up like the following will inform you about it.

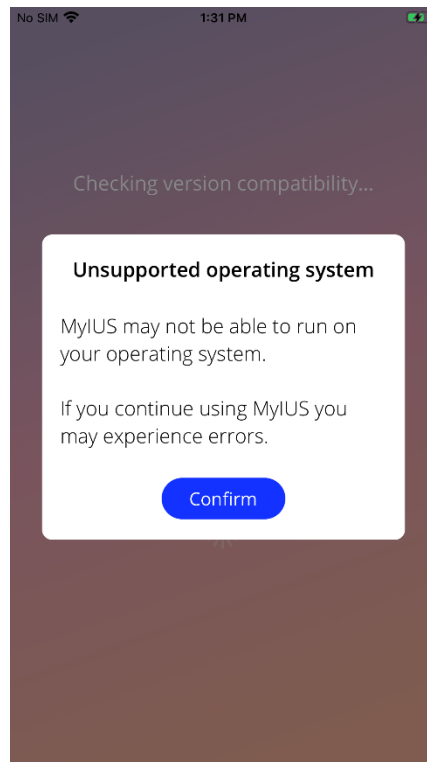


Figure 9: Operating System Check - Operating System not supported

In most cases when the OS is not supported, the app can be further used after giving your consent on your own risk. In case the OS is blocked because it is too old, the app cannot be used at all.



Note:

If the warning pop-up appears, certain functionalities might not react in the expected behavior.

The following operating systems are supported for the current version of MylUS:

- Android 8.0 or higher
- iOS 13 or higher

7.2 Authorization

Once the installation has been completed and the app is launched, the “First-Time-Use” (FTU) wizard starts.

The initial screen of the FTU is the Authorization screen (Figure 10).

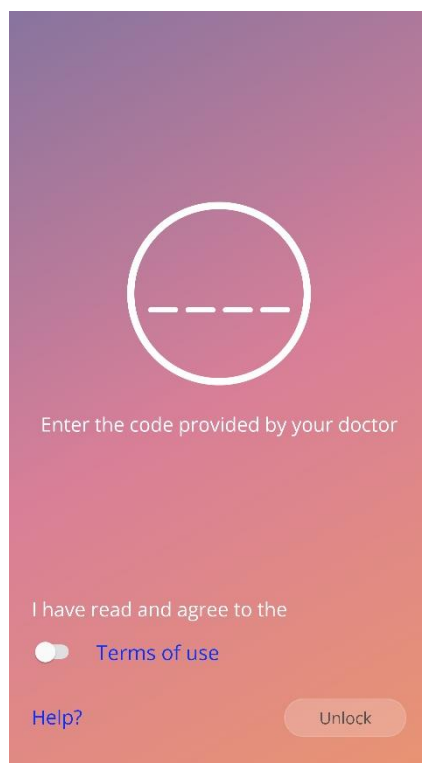


Figure 10: Authorization screen

The authorization is mandatory. Before starting to use the app, you must follow these steps:

1. enter the authorization code consisting of four digits received from your doctor
2. read and accept the Terms of Use
3. press on the “Unlock” button.



Note:

In case the Terms of Use is not accepted by switching on the proper toggle, the Unlock button remains disabled.



Advice:

Please read the Terms of Use before accepting it.

In case of a failure, a pop-up message will appear telling you that the introduced code is not correct (Figure 11).

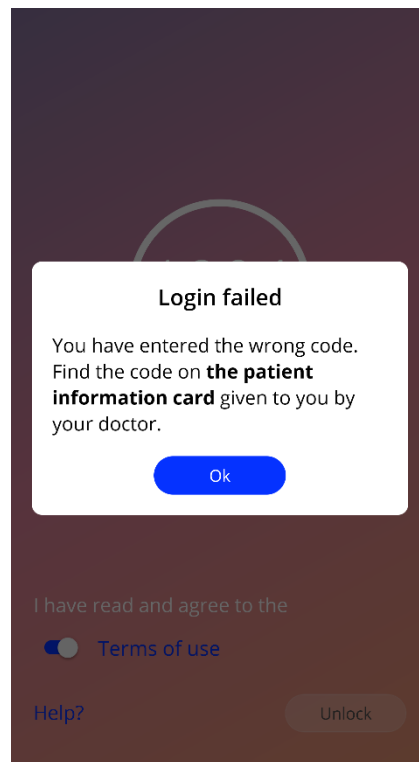


Figure 11: Login failed



Note:

In order to further use the app, you will have to enter the correct code.

7.2.1 Accepting terms of use

To proceed to the next screen, the Terms of Use must be read and accepted by pressing on the toggle from Figure 10. Additionally, the Terms of Use can be downloaded and can be read as PDF file, by pressing on the blue link “Terms of Use”.

7.2.2 Need Help?

If you require further information or help with the authorization process, please tap on the link “Help?” from the bottom of the page (Figure 10). A pop-up will appear informing you about the help-process (Figure 12). If you press on the button “Ok”, your default E-Mail app will open pre-set with our E-Mail address and a default message. Please overwrite the square brackets and the placeholder text within with your IUS type and your name. The service team will provide you with the necessary information to authenticate. Please feel free to ask us for any further support that you might need.

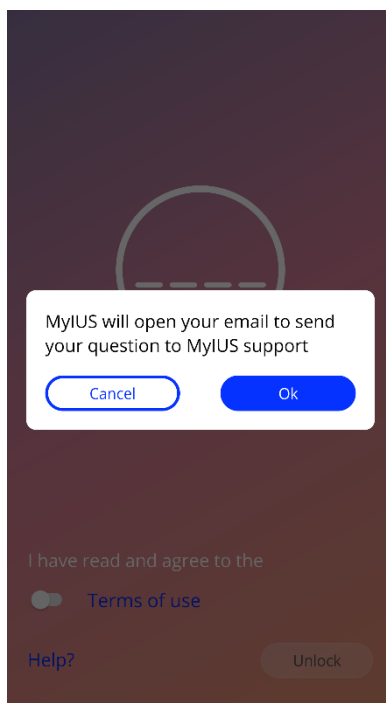


Figure 12: Authentication Help Pop-Up

7.3 Data Privacy Statement

After the successful authorization via code, the Data Privacy Statement must be accepted after reading and scrolling down the statement and pressing on the button “Agree” on the Data Privacy Statement screen (Figure 13).

If the authorization was successful, then the Authorization screen and the Data Privacy Statement screen will not be displayed anymore the next time when you start the app, and the app will be considered as “unlocked”.

7.3.1 Accepting data privacy

In order to proceed to the next screen, the Data Privacy Statement must be read and accepted by pressing on the right button from Figure 13. Additionally, the Data Privacy Statement can be read and downloaded as PDF file, by pressing on the left button.



Note:

In case the Data Privacy Statement is not scrolled down completely, the Accept button remains disabled.



Advice:

Please read the Data Privacy Statement before accepting it.

Privacy Policy

[Scroll down](#) to read the privacy policy

Last updated: October 2020

STATEMENT OF CONSENT TO THE PRIVACY POLICY FOR THE MyIUS app.

By consenting to the processing of your health-related data, I hereby grant my consent to the processing of my data when using the MyIUS app in accordance with the applicable Privacy Policy and Terms and Conditions for Use.

I can withdraw my consent for future data processing at any time. To exercise my right to withdraw consent, I must simply delete the app from my smartphone.

PRIVACY POLICY FOR USING THE "MyIUS" APP

Through this Privacy Policy, we wish to inform you of the legal grounds and purposes for which we process personal data that we collect from you or that you provide to us when using the MyIUS app. We also wish to inform you of your rights under data protection law.

For specific categories of data processing, additional privacy policy provisions may apply; for example, when using the MyIUS app to participate in a study. The MyIUS app is classified as a medical product within the European Economic Area and meets the

[Save PDF](#)

[Agree](#)

Figure 13: Data Privacy screen

7.4 Tracking Data

The following screen, after accepting the Data Privacy Statement, informs you about the collection and sending of tracking data (Figure 14). You have the option to enable the tracking of analytical data by tapping on the right button “Agree”, or to deny the tracking data by tapping the left button “Not now”. The collection and sending of tracking data are not mandatory but will help us to improve the app.

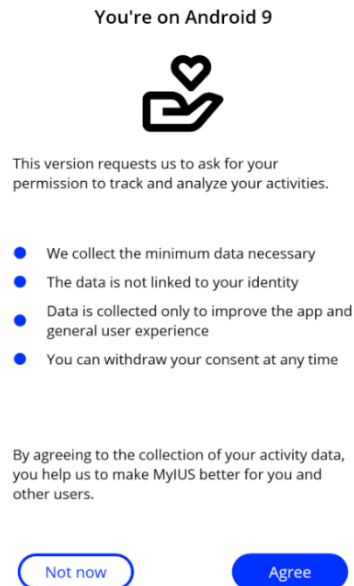


Figure 14: Tracking Data screen

7.5 Start setup configuration

After successful authorization, the First Time Use wizard provides information about the IUS and the usage of the app. It starts with the Setup screen (Figure 15).

On this screen, the First Time Use setup can be skipped by pressing on “Skip” button from the bottom left part of the screen. The application skips the baseline questionnaire and displays the Placement date screen (Figure 26), where you can enter the date of the placement of your IUS. You can complete your data later by accessing the Profile section.

The button “Start” from Figure 15 opens the Alias screen (Figure 16). The button “Import” allows you to import application data from another end-device (e.g. your previously used phone) as further described in chapter 8.2.

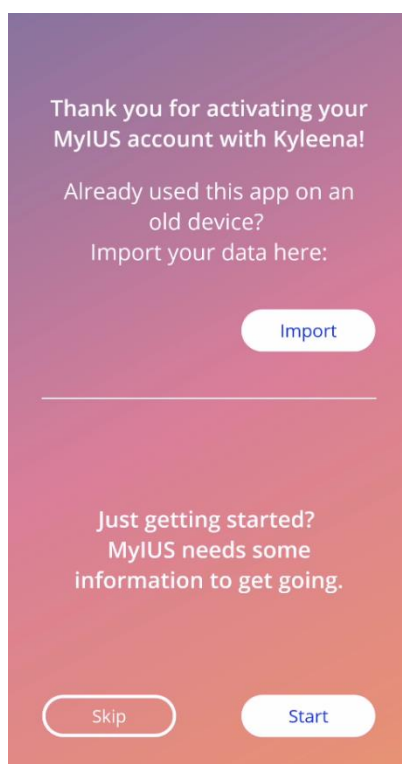


Figure 15: Start setup screen

7.6 Alias

The Alias screen (Figure 16) allows you to enter a username of maximum 15 characters. If the desired username has more than 15 characters, it will be truncated to the first 15.

If the textbox for the username is left empty or you would like to change the previously set one, it can be changed later in the Profile section. In the latter case, the “Continue” button would be enabled, allowing you to skip the screen.

The button “Continue” opens the Introduction screen (Figure 17).

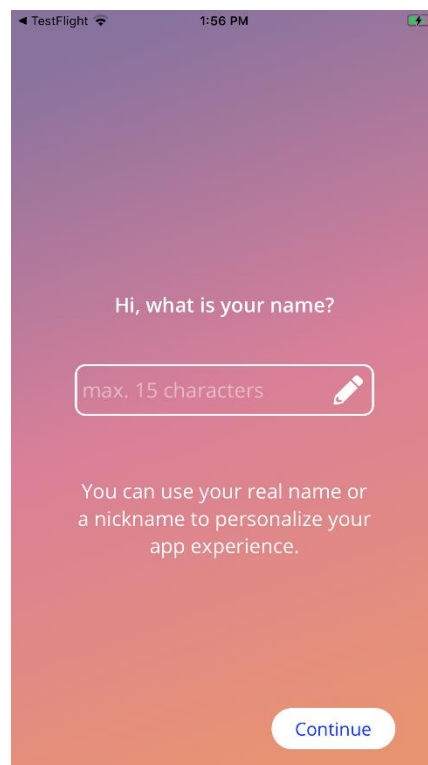


Figure 16: Alias screen

7.7 Setup introduction

The next screen provides a short introduction text to the app usage.

The “Continue” button opens the Video screen (Figure 18).

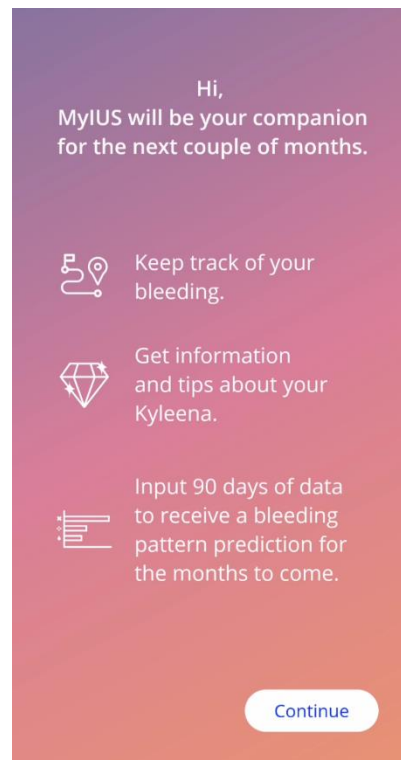


Figure 17: Introduction screen

7.8 Introduction videos

This screen provides a Media section including three short full screen videos introducing the app usage. The videos can be opened within the app.

The “Continue” button in the lower right corner of the screen opens the Start Baseline screen (Figure 19).

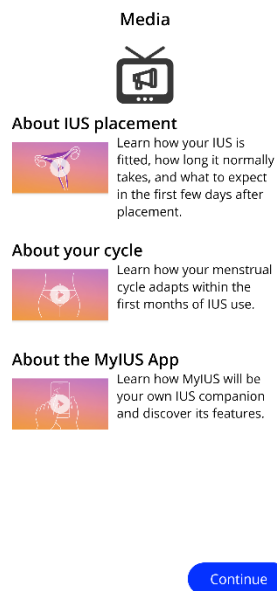


Figure 18: Video screen

7.9 Baseline parameters

To get an accurate prediction of your future bleeding, the app needs some information about you (Baseline parameters). A questionnaire will start with the Start Baseline screen (Figure 19). Depending on the country you have selected the questionnaire consists of 5 or 6 steps.

The Baseline questionnaire can be also skipped by pressing the “Skip” button. When pressing on “Skip”, you will be forwarded to the placement date screen.

The user can start the questionnaire also from the Profile section of the Main Menu. Also, from the Profile screen you will have the possibility to change the values that you set for these parameters. Each screen related to the baseline parameters gives you the possibility to return to the previous screen of the questionnaire.

Only after completing the questionnaire, you will be rewarded with a gem, as mentioned on this screen. The gem received for completing the questionnaire is visible in the Unlocked gems section. You will also be able to display this gem once you completed your questionnaire at a later point in time. You can access the questionnaire via the Profile section.

All the screens belonging to the questionnaire will have the “step number” as a progress displayed on top of the screen.

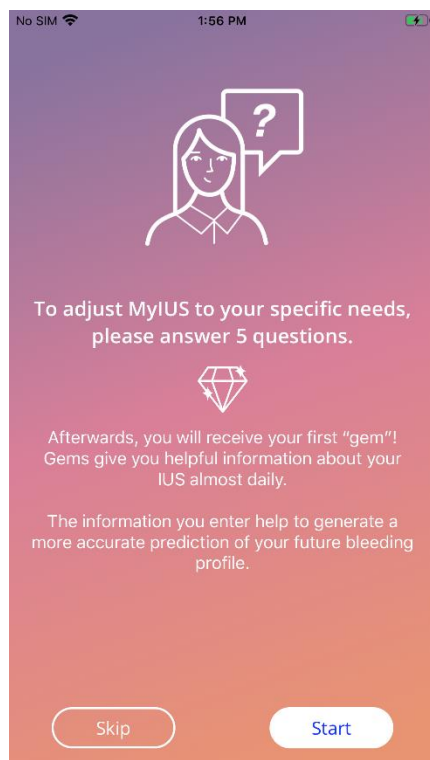


Figure 19: Start baseline screen

7.9.1 Birth Date

This is the first screen of the questionnaire. You are asked to enter your birth date. The ages supported must be below 60 years. The default date is the current date.

You can get detailed information about how the birth date parameter affects the prediction of your future bleeding by pressing on the information icon.

Step 1/5

Your birth date ⓘ

1999

1 January 2000

2 February 2001

Continue

Figure 20: Birth date screen

7.9.2 Country

In order to predict future bleeding, the app also needs to know your country. In case the region set on your mobile phone is supported by the app, the country will automatically appear as preselected.

You can get detailed information about how the country parameter affects the prediction of your future bleeding by pressing on the information icon.

By pressing on the back button (white arrow), you can go back to the Birth date screen.

In order to enable the “Continue” button and to proceed to the next screen you will have to select a value from the picker.

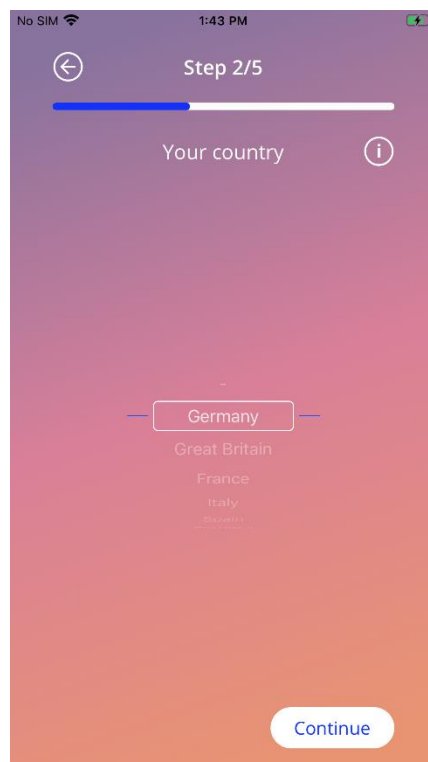


Figure 21: Country screen

7.9.3 Weight and Height

In this screen you are asked to enter your weight in kg or lbs and your height in cm or ft. By default, 60kg and 160cm are preselected. Please select your personal values for the future prediction to be personalized for your body.

You can get detailed information about how the body size parameters affect the prediction of your future bleeding by pressing on the information icon. By pressing on the back button, you can go back to the Country screen.

The screenshot shows a mobile app interface for entering body parameters. At the top, there's a status bar with 'No SIM', signal strength, time '1:43 PM', and battery level. Below is a navigation bar with a back arrow, 'Step 3/5' with a progress bar, and the title 'Your Body' with an information icon. The main area has two columns: 'Weight kg' and 'Height cm'. Each column has a list of values with a selected value highlighted. The selected weight is 67 kg and the selected height is 169 cm. At the bottom right is a 'Continue' button.

Weight kg	Height cm
62	165
64	166
65	167
66	168
67	169
68	170
69	171
70	172
71	173

Figure 22: Body screen

7.9.4 Previous contraceptive method

The app also needs to know which contraceptive method you previously used. At least one option should be selected to enable the “Continue” button and to proceed to the next screen. More than one option can be selected on this screen, except when “No birth control” is selected.



Note:

The option “No birth control” cannot be used in combination with other options. If you select “No birth control”, any previously selected options will be deselected.

You can get detailed information about how this parameter affects the prediction of your future bleeding by pressing on the information icon.

By pressing on the back button, you can go back to the Body screen.

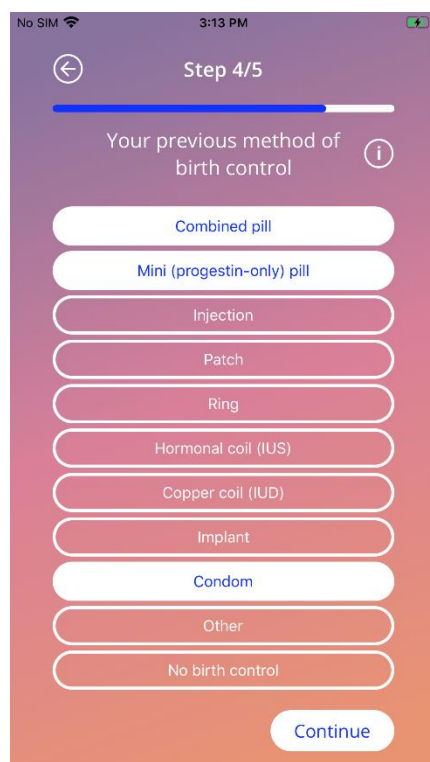


Figure 23: Contraceptive method screen

7.9.5 Pregnancy & births

This screen is about the number of pregnancies and the number of births. In order to enable the “Continue” button and proceed to the next screen, values for both parameters must be selected.



Note:

The values from the two pickers are interdependent and the number of pregnancies can only be greater or equal to the number of births.

You can get detailed information about how this parameter affects the prediction of your future bleeding by pressing on the information icon.

By pressing on the back button (white arrow), you can go back to the Previous contraceptive method screen.

Figure 24: Pregnancy screen

7.9.6 Prevention Check-Up

If you are using the app in a country that supports prevention check-ups, you will be asked for the date of your last check-up as the last screen of the questionnaire (Figure 25). The default date is today's date.



Note:

You cannot enter future screenings.

Depending on your country, the count of screens differs between five and six screens in total as indicated atop of each of the baseline screens.

You will get detailed information about why this parameter is needed by tapping on the information icon.

By tapping the back button (white arrow) you return to the Pregnancies and Births screen.

Figure 25: Last prevention check-up screen

7.10 Placement date of your IUS

The next screen following the baseline parameter questionnaire, is the Placement date screen (Figure 26).

In order to get a prediction of future bleeding, the app needs to know the exact placement date of your IUS. You can also set a date in the past. If the date of entry is more than 90 days ago, predicting bleeding patterns, providing feedback and participating in the study is disabled. In this case, you will be warned by a pop-up.



Note:

You can enter a placement date that lies in the past, but keep in mind, that the prediction of your future bleeding pattern can only be created if your placement date is not older than the last 90 days. If your placement date was prior to the 90 days past, please enter your correct date to use the app to track your bleeding patterns on your own.

By default, the current date will be preselected.

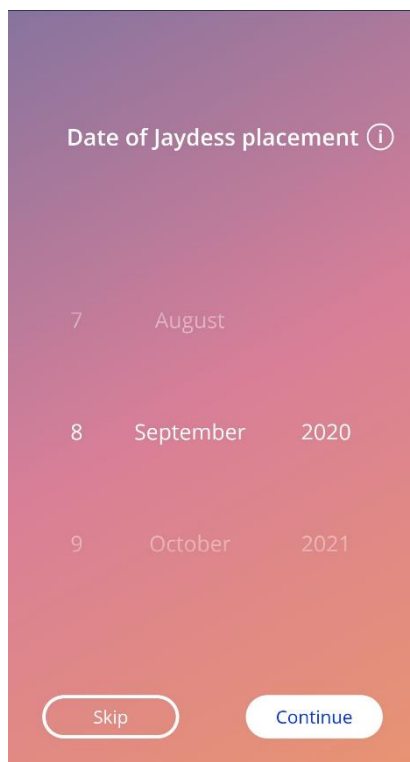
A screenshot of the 'Date of Jaydess placement' screen. The title is 'Date of Jaydess placement' with an information icon. Below the title, there are three rows of date selection: '7 August', '8 September 2020', and '9 October 2021'. At the bottom, there are two buttons: 'Skip' and 'Continue'.

Figure 26: Placement date screen

Setting the placement date can also be skipped and re-accessed or edited through the Profile section of the Main Menu. If you edit the placement day accessed via the Profile screen, then the “Skip” button will not be visible. If you skip here by pressing the “Skip” button or if you entered an insertion date that is in the future and you press the “Continue” button, the app will display the Home screen.

If your placement date is older than 90 days, the app will inform you about this and require you to confirm the insertion date (Figure 27). If you accept the insertion date, you will notice that on the Home Screen, all elements are already filled. This is because the prediction of a bleeding pattern is only available for insertion dates that happened in the past 90 days. Nevertheless, you can use the app to track your bleeding patterns.

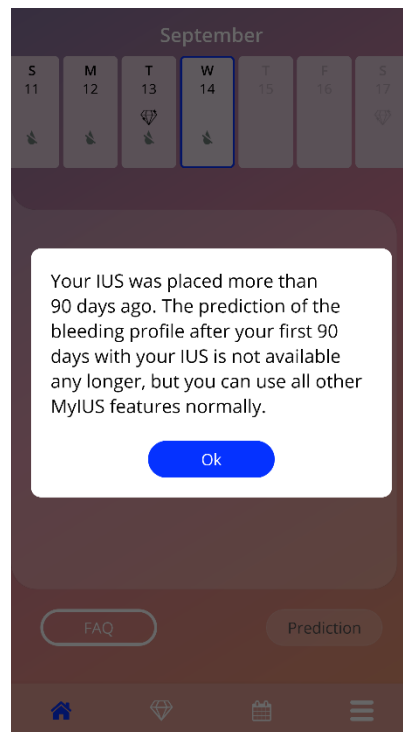


Figure 27: Confirm placement prior 90 days

Nonetheless, if your insertion date is in the past or today and you press the “Continue” button, the app will display the following screen:

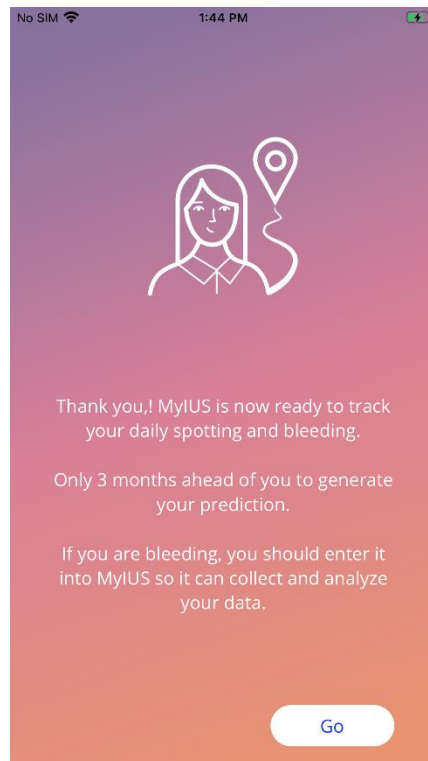


Figure 28: After placement data screen

By pressing the “Go” button, you will be forwarded to the Home Screen.

8 Export/Import of App-Data

The app provides you with the possibility to transfer app-data from one end-device to another end-device. Both end-devices need to have the MyIUS app installed. App-data consist out of all your entered data such as the base information or entered bleeding pattern entries. If another end-device shall be used, the export feature can be used to transfer your data.

8.1 Export

If you access the Settings screen via the Main Menu, the app displays the button to export user data to another device. When you press on the “Export data” button, the export process is initiated.

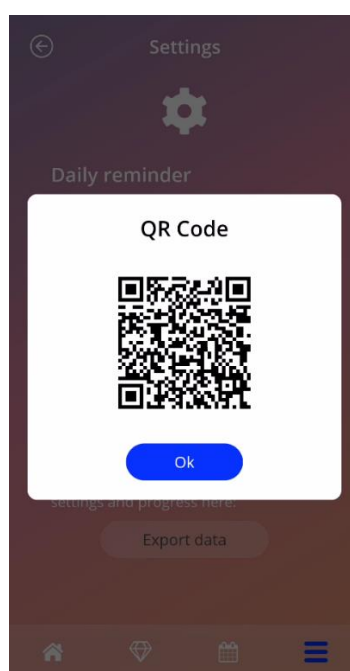


Figure 29: Export screen

The MyIUS app will automatically encrypt all required data and transfer it to a server. Thereafter, a unique QR-code is generated and displayed by the MyIUS app. This displayed QR-code can be scanned by another end-device in order to import all relevant user data. You should adjust the brightness of the displaying end-device to guarantee better visibility of the QR-code.

An active internet connection is mandatory for the export feature to work. Your uploaded data will be deleted after the transmission was successful, or after 24 hours have passed. If data of the same app shall be transmitted after 24 hours, or another transmission of the same data shall be executed, you must initiate a new export process.

8.2 Import

In order to apply your app data to the current end-device, the app must be installed. After the app is started, and prior to being asked to enter baseline information, the app provides the option to import your data (Figure 15). Press the “Import” Button to initiate the import-process.

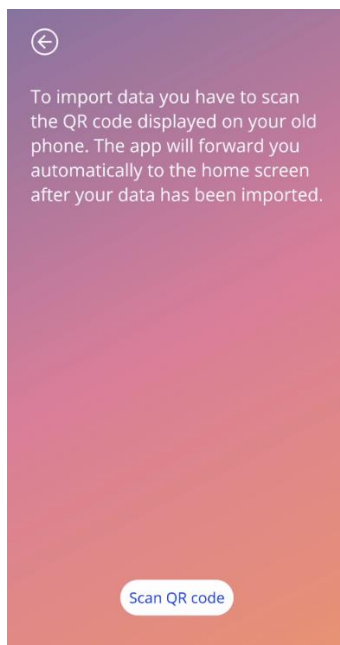


Figure 30: Import screen

The feature to import data can only be selected before any base information is entered by the user. In order to import data anew, the app needs to be deinstalled and then installed again, in order to select the import feature after the first start of the app.

8.2.1 Import Scanner

When the import-process is initiated, and you granted access right to your device’s camera, the app will automatically open the camera and use it as a QR-code-scanner. You can change the access right in the system settings of your device if you have previously denied it.

Adjust the camera feed until the QR-code is fully visible on your screen. Complete visibility of the QR-code and a sufficient brightness of the displaying end-device is necessary for the code to be readable. Scanning is executed automatically once the camera detects a QR-code. When the scanning either succeeded or failed, the app will give you feedback about the state of the scanning. Should no feedback be displayed while the camera is open, the QR-code must be aligned within the camera feed or the brightness of the displaying end-device needs to be increased.

8.2.2 Successful Scanning

When the QR-code was scanned successfully by the MyIUS app, all your data will automatically be downloaded and applied to the local app. Afterwards you will be redirected to the app’s main screen. It is not necessary to restart the app.

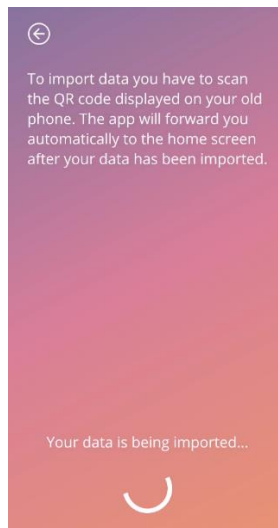


Figure 31: Scanning Successful screen

8.2.3 Failed Scanning

It is possible for the scanning or for the download of data to fail. This can have several reasons, for instance an inactive internet connection, not being able to find the data (e.g. they were deleted after 24 hours) or a QR-code with an invalid format. In these cases, the app will inform you about the error.

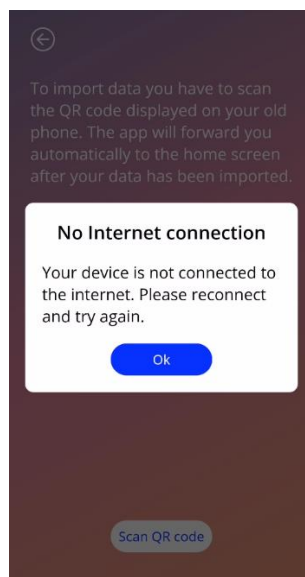


Figure 32: Scanning Failed screen

9 Home screen

The Home screen is the main screen of the app. This screen will be displayed once you start the app after you have answered the baseline questions.

The Home screen (Figure 33) consists of three sections:

- a Weekly Calendar extract
- a Progress Area and
- a buttons area

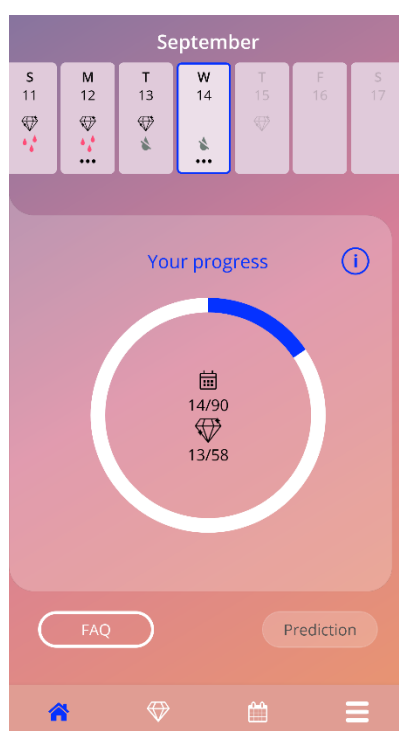


Figure 33: Home screen

9.1 Progress area

The Progress Area shows your progress related to the number of days passed since your placement date and the number of collected gems.

The progression bar (blue circle) will fill according to the number of days you have been using the app.

By pressing on the information icon, you will get detailed information about the progress area.



Note:

This area will update only after setting and confirming your placement date of the IUS. When no placement date is set and confirmed, the number will remain at 0.

In the middle of the progress area there is a summary representing:

- The number of days you use the app after your IUS placement date out of the 90 days total
- The number of unlocked gems out of the total available gems

When you complete the 90 days and receive your Prediction, and don't participate in the RWE Study, the progress area will be hidden (Figure 34). This is also the case if your placement date was more than 90 days in the past when you entered it – see 7.10.

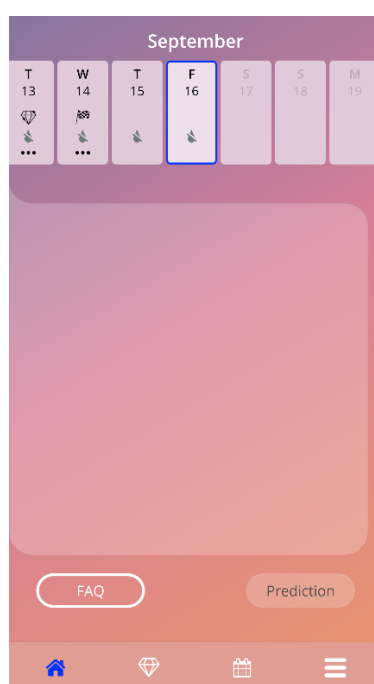


Figure 34: Home screen with progress area hidden

9.2 Weekly calendar screen

The weekly calendar extract is displayed on the top of the Home Screen. It shows the current month at the top and the current day is shown in the center. Each of the displayed days may show information related to the already introduced bleeding patterns, the prediction date, the possible gems or additional information about your mood that you entered previously. You can swipe the calendar extract to the left or to the right in order to navigate through the weeks. The following conditions apply:

- Swiping is disabled if no placement date has been set, only the current week is displayed
- Days prior to the placement date are not shown
- Swiping to display more days in the future is not possible
- Swiping while you have selected one or more days on the weekly calendar extract is not possible

After you selected one or more days from the weekly calendar extract you may set the bleeding profile for those days.



Note:

When adding data for more than one day, you should be as accurate as possible as this may affect your future prediction.



Note:

Selection of more days is possible only in the current visible weekly extract. Swiping to weeks in the past and keeping the days selected is not possible.

The days of the current week that lie in the future are not selectable and are greyed out. The days prior to the placement date are not visible.

When the gem icon is displayed, it is possible to receive a gem on that day. Please see the conditions of receiving a gem in chapter 14 Gems.

9.3 Monthly calendar screen

You can access the monthly calendar screen (Figure 35) by pressing on the “Calendar” icon on the Navigation Toolbar on the Home Screen. When pressed, the calendar opens for the current month. Each day shows information related to already given bleeding entries, the prediction date, the potential gems or additional information about your mood that you entered previously.

To navigate through the months on the monthly calendar screen, you can simply swipe the calendar to the left or right or use the arrows atop of the calendar as seen in Figure 35. By pressing on the month in between the navigational arrows, you can directly select a desired month of a desired year, or additionally switch between the years on the following pop-up.

Selecting one or more days in the calendar allows you to set the bleeding profile for those days.



Note:

Selection of more than one day is possible only in the currently selected month. Swiping to another month while keeping the selection not possible.

The days in the future and prior to the placement date are not selectable and greyed out.

When the gem icon is displayed, it is possible to receive a gem on that day. Please see the conditions of receiving a gem in chapter 14 Gems.

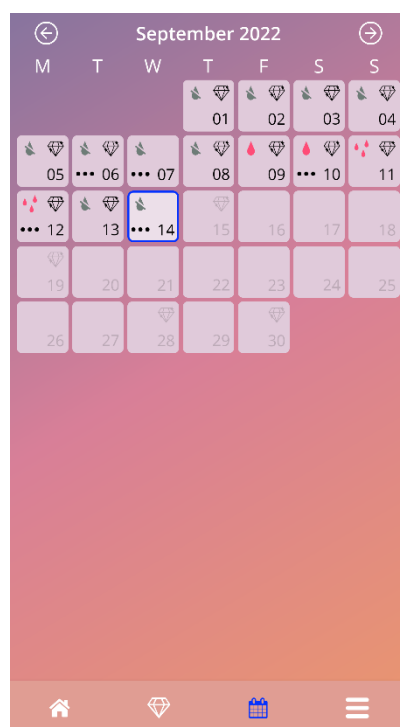


Figure 35: Monthly calendar screen

9.4 How to add or edit bleeding patterns

You can add a new bleeding entry or edit an existing bleeding entry by pressing on one or more days on the weekly calendar (Figure 36) or on the monthly calendar (Figure 37). When you select a bleeding pattern for multiple selected days, the same bleeding pattern is set for all of the selected days.

You can choose between three bleeding patterns:

- No bleeding
- Spotting
- Bleeding

Furthermore, you can document your feelings and mood by selecting from three smileys, displayed below the bleeding pattern. You can also enter up to 200 characters to describe any of your symptoms and feelings. Once you provided any inputs about your mood for a day, or entered a note, the calendar extract or the monthly calendar will mark that day with three dots (Figure 36).

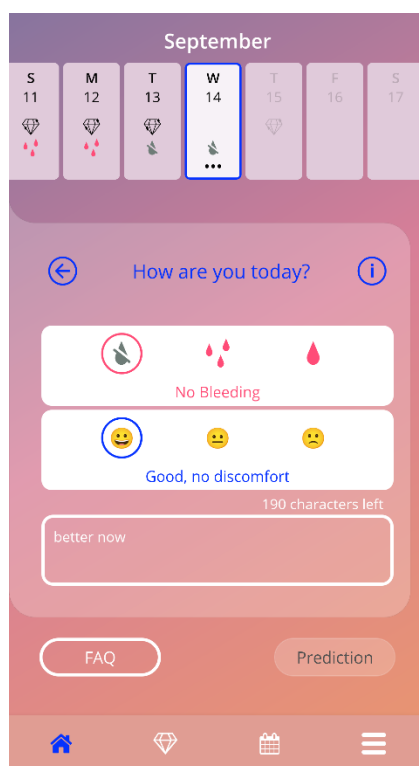


Figure 36: Bleeding pattern on home screen

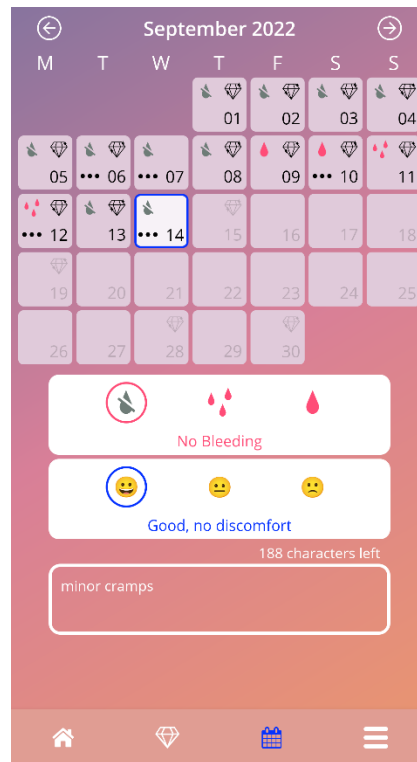


Figure 37: Bleeding pattern on monthly calendar screen

9.4.1 Bleeding pattern before prediction

After the placement date was entered, you can add or edit bleeding patterns until you receive the future bleeding prediction. The selected days must be between the placement date and the current day.

9.4.2 Bleeding pattern after prediction

After you received the prediction of future bleeding it is possible to add or edit bleeding patterns between the prediction day and the current day.

9.5 Prediction

The request for a prediction for future bleeding depends on various factors, including the number of bleeding patterns entered as further described in the following chapters.

9.5.1 Preconditions for a prediction

In addition to the condition of the number of bleeding patterns entered, you can request your prediction once the following preconditions are met:

- All the baseline parameters are set
- At the start of data entry, the insertion date was no more than 90 days in the past
- No prediction has yet been received
- At least 90 days have passed since the placement day

When the 90th day after the confirmed placement date is reached and the bleeding pattern for that day is set, the app enables the “Prediction” button from the Home Screen (Figure 33).

9.5.2 Prediction without missing days

You can ask for a prediction for future bleeding if the preconditions in 9.5.1 are met and a bleeding entry is set for each of the 90 days after the placement day.



Note:

This prediction will provide you with the most accurate result.

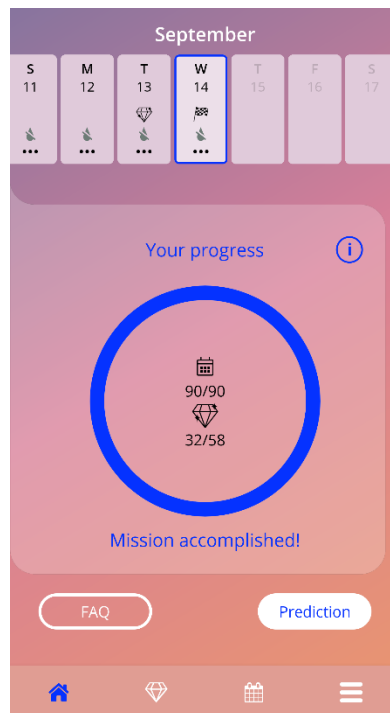


Figure 38: Prediction available screen

9.5.3 Prediction with missing days

You can also ask for a prediction if a few daily bleeding patterns are missing, provided that the pre-conditions in 9.5.1 are met and only two bleeding entries in total are missing per 30 days and no bleeding entries are missing consecutively within the total 90 days.

The app shall notify you by displaying a pop-up when the previous conditions are met.

You can enter missing days after pressing on the “Check” button. Afterwards you can ask for a prediction again by pressing on the “Prediction” button on Home Screen (Figure 38). By pressing on the “Check” button, the monthly calendar will open at the month containing the first missing bleeding data.

You can also ask for a prediction without entering the missing days by pressing on the “Prediction” button on the pop-up (Figure 39).



Note:

In this case, your prediction will not be as accurate as in the case of having a completed dataset and you will not be able to edit or add bleeding entries after you received your prediction.

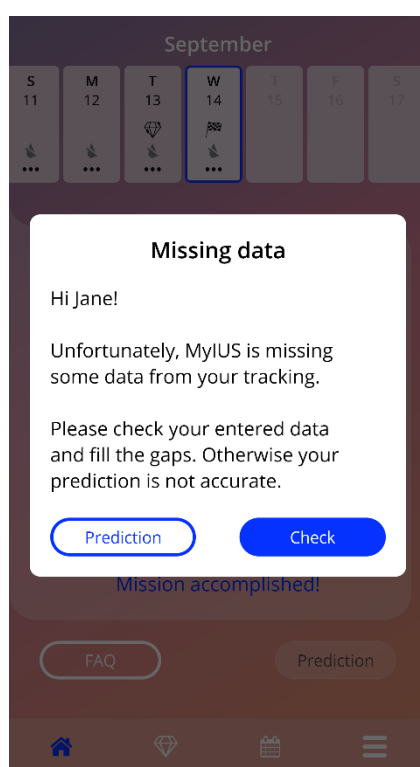


Figure 39: Missing day pop-up

9.5.4 Prediction not allowed

When more than two bleeding patterns per 30 days are missing, or when more than two entries are missing consecutively within the total 90 days, a pop-up is displayed (Figure 40), providing you the options to navigate to the monthly calendar to add missing entries and to skip the entering of missing bleeding entries for now.



Note:

In this case, it is not even possible to generate an inaccurate prediction for you. You will have to enter missing bleeding entries in order to receive a prediction.

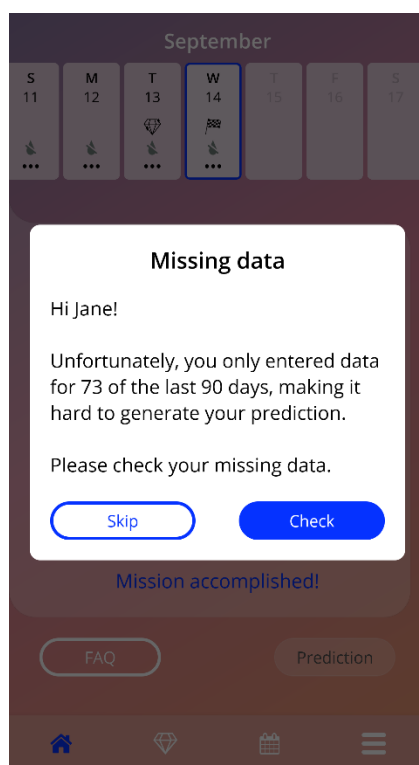


Figure 40: Too many missing data

9.5.5 Ask for a prediction

If the conditions for a prediction are met, you can request it by pressing on the “Prediction” button on the Home screen (Figure 38).

9.5.5.1 Step 1

This screen tells you that you have reached the goal (Figure 41). You can press on the “Continue” button to go to the step 2.

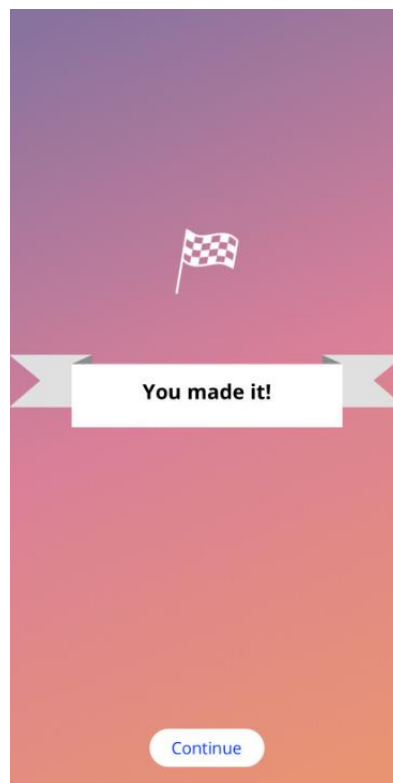


Figure 41: Prediction step 1

9.5.5.2 Step 2

This screen allows you to ask for the prediction by pressing on the “Generate your prediction” button (Figure 42).

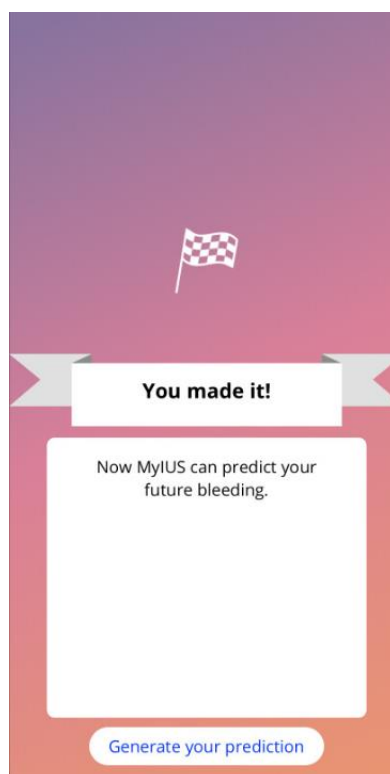


Figure 42: Prediction step 2

9.5.5.3 Step 3

This screen shows you your prediction (Figure 43). After that, you can go to the Home screen by pressing on the “Continue” button.

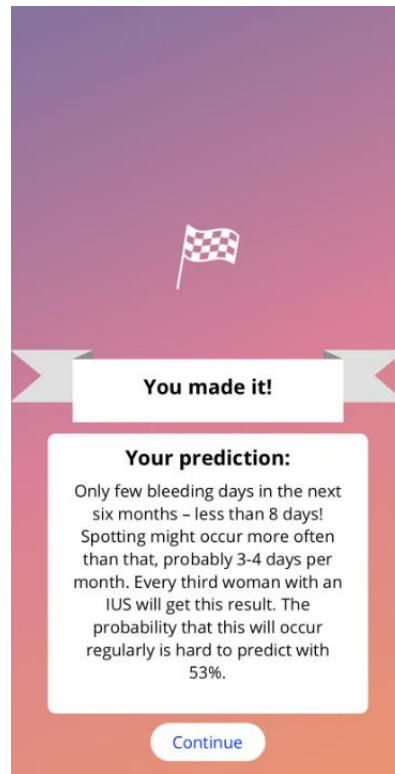


Figure 43: Prediction step 3

After receiving the prediction, the bleeding entries used for its calculation cannot be changed anymore.

The button “Prediction” will remain enabled on the Home screen and will always display the initially received prediction from this step.

9.6 Update of new features

The MyIUS app is updated regularly. To not lose track of any new features the app will inform you about these features upon app start. Once you open the app, you will be presented with a pop-up that gives you information about the latest feature change or add (Figure 44). These pop-ups will only be shown to you once. Furthermore, the main menu will indicate where to find any new feature with a red dot (Figure 45). These will disappear respectively once you accessed a new feature.

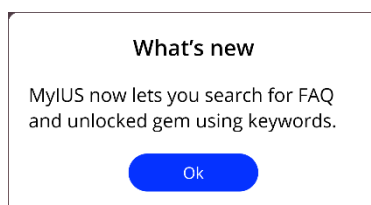


Figure 44: What's new pop-up

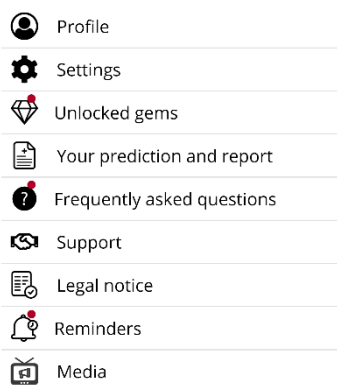


Figure 45: Main menu (new feature indication)

10 Profile screen

The Profile screen (Figure 47) is accessible from the Main Menu  by pressing on the item “Profile”.

When you access the profile screen and did not previously provide the batch number of your IUS, the app will ask you to provide this information. Please refer to the following instructions on how to enter your batch number. If you do not wish to be reminded again when accessing the profile screen, you can select the toggle “Don’t remind me again” on the pop-up shown in Figure 46.



Note:

We recommend entering your batch number. It can help you if you encounter any side effect while using the IUS.

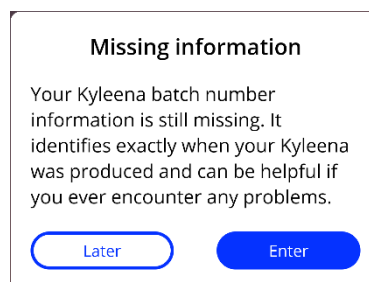


Figure 46: Batch number reminder pop-up

The Profile screen contains the following information and options:

- Username
- Your IUS
- Batch number
- IUS Placement date
- Latest date for removal
- Baseline parameters
- Create MyIUS Card

You can set or modify your username by selecting the textbox “Your chosen name”.

Your IUS is shown according to the entered code or the selection you have made during the authentication after the first launch of the app. You cannot change your IUS type belatedly.

The batch number is shown in case you already provided it. You can access the process to provide the batch number of your IUS by pressing on the textbox “Batch number”. Please refer to chapter 10.1 for more information about the processes.

You can set or modify the placement date (please refer to 7.10) by pressing the textbox “Your IUS placement date”.

The latest day of removal is automatically provided according to your IUS and your placement date and cannot be adjusted manually.

You can set or modify the baseline parameters by pressing the first row of the “setup questions” or the pencil icon. When accessing the baseline parameters, the whole questionnaire will start again with the Birth date screen (Figure 20). When the questionnaire was already completed, your previous entries are preselected and the “Continue” buttons are enabled on all the screens.

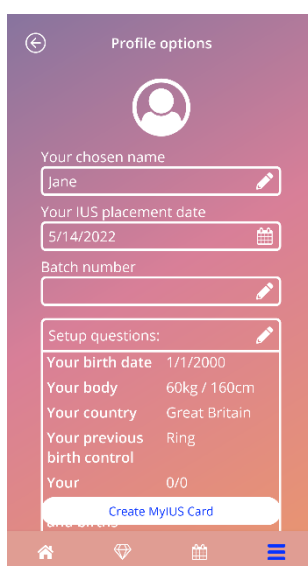


Figure 47: Profile screen

10.1 Providing the IUS Batch Number

Once you pressed on the textbox “Batch number” on the Profile screen you will automatically enter the process for providing the batch number of your IUS package. You will have two options to provide the batch number;

- Scan via QR-Code
- Manually enter the number

The following subchapters will guide you through either process. Once you provided your batch number, you can always edit the number by going through either process via the Profile screen as described above.

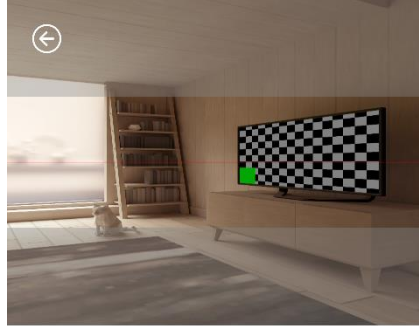
10.1.1 Scan via QR-Code

By default, the MyIUS app will start with the process “Scan via QR-Code” (Figure 48). The app would like to access your phone’s camera for the QR code scan.



Note:

You can deny the access to your camera for the MyIUS app either when first accessing the MyIUS Card setup process or in your phone's settings.



Scan the QR code on the folding box



[Enter Batch number manually](#)

Figure 48: MyIUS Card setup screen

If you allowed the access to your phone's camera, you can see the camera feed of the MyIUS Card setup screen to scan the QR code on your IUS folding box (Figure 49).



Figure 49: QR code on folding box

In case the MyIUS app cannot identify the scanned QR code correctly, the app will inform you by displaying a warning pop-up. You can try to scan the QR code as many times as you like.

In case the MyIUS app scanned and identified the QR code successfully, the app will inform you by displaying a confirmation pop-up. After pressing on “Ok” the app will forward you back to the Profile screen. You will notice that your batch number was automatically entered in the proper text box.

10.1.2 Manual Batch Number

If you do not want to use your camera and enter the batch number via the QR code or the scan fails, you can setup the MyIUS Card by manually entering the batch number. By pressing on “Enter Batch number manually” at the bottom of the MyIUS Card setup screen (Figure 48), the app will forward you to the MyIUS Card manual screen (Figure 50).

At the top of the screen, you can enter the batch number in the textbox “Batch number”. You can find the batch number as shown in Figure 51. You can navigate back to the MyIUS Card setup screen via QR Code scan by pressing on the link “Scan code to enter batch number” at the bottom of the MyIUS Card manual screen.

Once you entered the code you can return to the profile screen by pressing on the back button atop of the MyIUS Card manual screen. The just entered batch number will be displayed in your profile from now on.

←

Batch number

Save

The batch number is on the folding box and on your patient information card

PC: 05010605180507
SN: 001188180748
Lot: T10039p3
Exp: 09.2024

Kyleena is used for the prevention of pregnancy (contraception) for up to five years.

Patient's name
Doctor's name and phone number
Date of insertion Latest date of removal

T10039p3
Lot

[Scan code to enter batch number](#)

Figure 50: MyIUS Card manual screen



Kyleena is used for the prevention of pregnancy (contraception) for up to five years.

Patient's name

Doctor's name and phone number

Date of insertion Latest date of removal

LOT TU039P3

Figure 51: Batch number on folding box pop-up

10.2 Create MyIUS Card

If you press on the button “Create MyIUS Card” on the Profile screen, the app will forward you to the MyIUS Card. Here you can see the details of your card and add your MyIUS Card to your Apple Wallet (iOS) or your installed Wallet application (Android).

10.2.1 MyIUS Card Overview

You can access the overview via the Profile screen by pressing on the button “Create MyIUS Card”. The app will display the MyIUS Card screen (Figure 52). Your MyIUS Card shows your IUS, the batch number and the placement and removal dates. Additionally, you can access the reporting feature by pressing on the text link “Report a side effect” at the bottom of the card. Please refer to chapter 0 for more information about reporting a side effect.

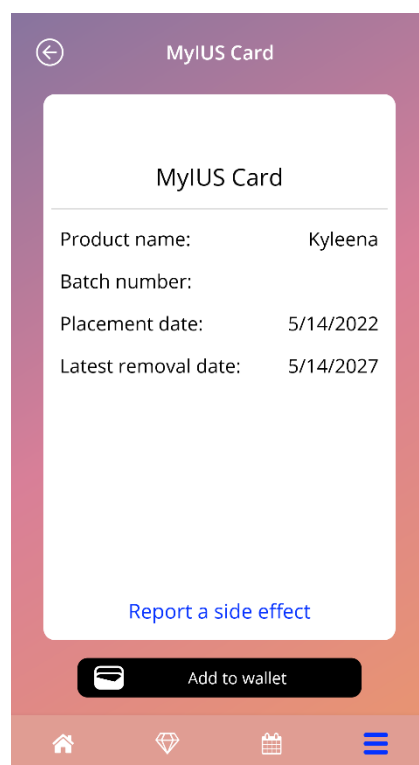



Figure 52: MyIUS Card screen

10.2.2 Digital Wallet

The MyIUS Card can be added to your wallet application on your smartphone. If you tap on the button at the bottom the MyIUS Card Screen (Figure 52) you will be asked to “Add” the card, or to “Cancel” the process. If you accept, your MyIUS Card will automatically be added to your smartphone’s wallet. In case that you cancel the process, you will return to the MyIUS Card screen.

11 Settings screen

The Settings screen (Figure 53) is accessible from the Main Menu , by pressing on the item “Settings”.

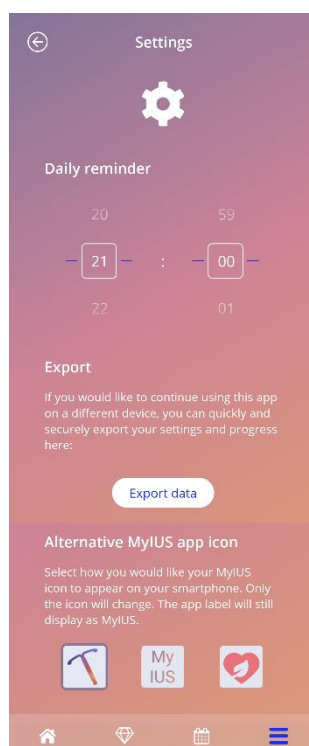


Figure 53: Settings screen

It allows you to set the time for the daily reminder for bleeding entries and to export your data to another mobile phone as described in chapter 8. Also, you can change your App Icon here, as described in chapter 6.2

11.1 How to set a notification

You can change the default reminder for the daily bleeding pattern (set to 9:00 PM or 21:00 by default), by scrolling the time pickers on the screen. This reminder cannot be disabled, and the notification will appear on your mobile phone every day at the set hour on this screen, starting on the placement date.



Note:

Depending on the settings on your smartphone, the setting of the reminder time is displayed as the 24h- or 12h-format. If your phone uses the 12h-format, you are able to select between am and pm for your chosen time.

12 Notifications

Notifications can be reminders or warnings displayed by the app via pop-ups. The general appearance of a notification pop-up consists of:

- A title
- A text
- A button to close the pop-up

The app can display system notifications and internal notifications.

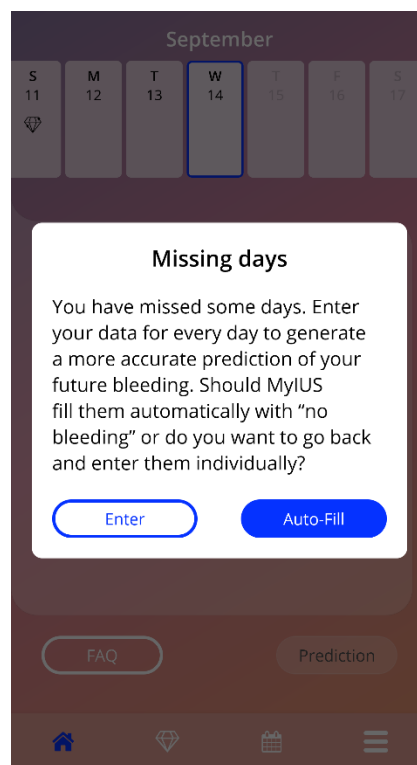


Figure 54: Reminder pop-up

12.1 System notifications

System notifications are reminders for:

- Follow-up appointment: triggers after 30 days from the confirmed placement day at 8 PM
- Planned IUS placement: triggers 1 day before planned placement day at 8.30 PM
- Daily bleeding pattern: you can set the trigger to a specific time yourself



Note:

You may be unable to see system notifications. This can have different causes, depending on your operating system.

If you are using an Android smartphone, notifications may not be displayed after a restart. To activate the notifications again, you have to create an entry in the app. The notifications will then be displayed as before.

If you are using an iOS smartphone, you must allow the app to display notifications in your device settings. Unless you allow it, you will not see system notifications outside the app.

12.2 App internal notifications

App internal notifications are mainly related to warnings about missing data or app usage. These warnings will be displayed when the app is started or comes to the foreground. You will always have the possibility to add your missing data or to close the notification.



Note:

Missing data can always lead to inconsistencies and your prediction might not be as accurate as you expect in the end.

12.2.1 Warnings about data

These warnings inform you that you have either missed bleeding entries or that your actions have an impact on your data/prediction.

They are displayed in case of:

- missing baseline parameters entries – when parameters have not been set, starting 10 days after placement date
- missing daily bleeding patterns – 10 days or more with no introduced data
- missing data on prediction day (in accepted range or not acceptable for algorithm)
- edit of confirmed placement date that deletes your daily bleeding entries and unlocked gems

12.2.2 Warnings about app usage

These pop-ups warn the user that something is wrong with the app and this can lead to not being able to use the app anymore or having to redo some actions.

They are displayed in case of:

- OS not supported (too new OS version or too old OS version)
- Authorization code incorrect
- No internet connection (e.g. when QR Code is generated, when importing data, when sending feedback)
- Unexpected error that affects the app and needs your interaction
- Invalid QR Code
- Export or import data error
- QR Code scan error

12.3 Reminders

The app offers you the possibility to remind yourself of various preventive medical checkups.

If your country supports them, the app shows you the following reminders:

- Check-up for hormonal contraception
- Spiral removal and control examination

If you are using the app in a country that supports prevention check-ups, you were also asked for the date of your last health check-up when you first used the app. Based on this information, the app provides you with further reminders for these check-ups:

- Early detection of gynaecological cancer
- Early detection of breast cancer

The overview of these reminders can be found on the Reminder screen (Figure 55).

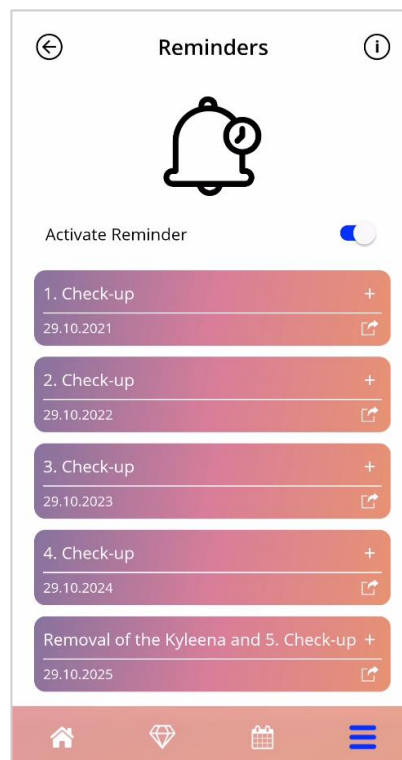
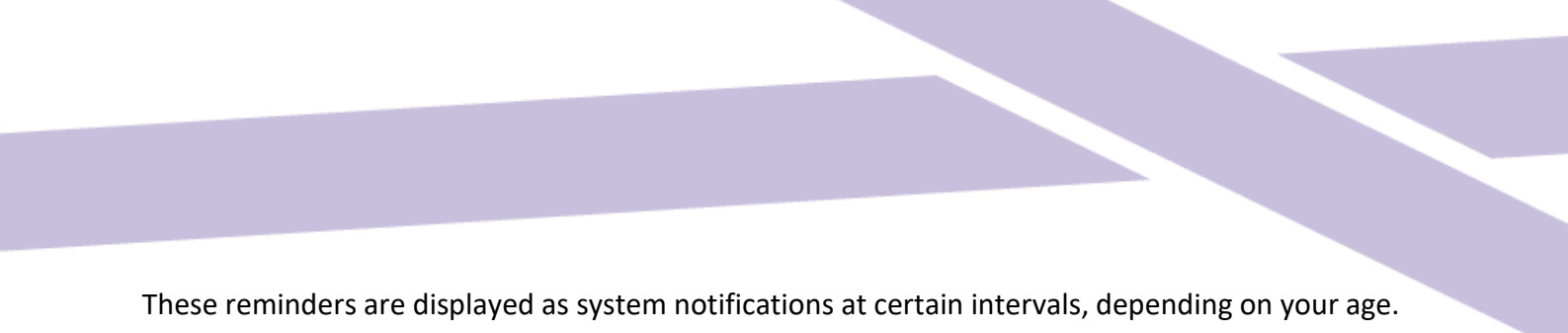


Figure 55: Reminders for check-ups




These reminders are displayed as system notifications at certain intervals, depending on your age.

You can find more information about the reminders by tapping on the corresponding reminder or by tapping the information icon.

You can also export these reminders as events to your device calendar. To export a reminder, press the export button for the respective reminder in the list. If the export was successful, you will see a pop-up and you can find the reminder in your device calendar. If the export was not successful, you will get a notification that the export failed.

By default, all reminders are activated. However, you can deactivate the reminders by switching the toggle button off.

13 Your report

You can generate your report any time. By accessing the item “Your Prediction and report” from the Main Menu , the Report screen will be displayed (Figure 56).

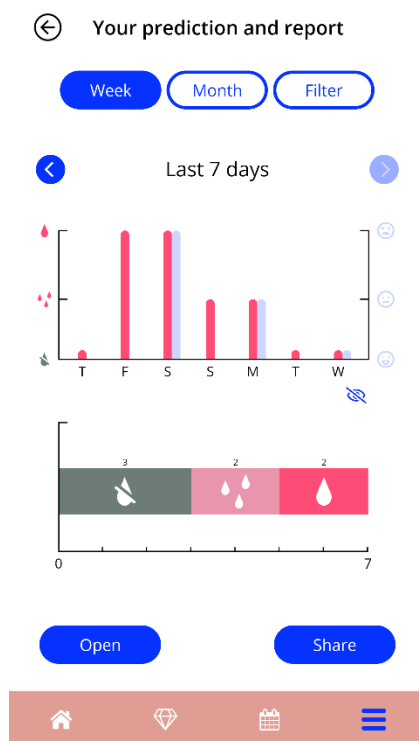


Figure 56: Report screen

This screen will provide the data you have entered within two different kinds of graphs.

The upper graph shows your bleeding entries for each day with a red graph and the mood entries in a light blue graph. You can display or hide the mood entries that you made by pressing the eye icon on Figure 56. The lower graph shows the total numbers of days for each of the three bleeding patterns. You can choose the time span of the graphs by pressing one of the buttons on the top of the screen. You can either choose 7 or 30 days or you can choose "Filter" to individually specify a time period of your preference.

To have a look at an overall report, including your baseline entries and all your bleeding entries, you press on the “Open” button on the bottom left of the screen. Before a PDF report will be generated, you will be asked whether you want to include the mood entries in the report. After the report is generated, the report file will be downloaded.

The generated report is a PDF file, with the following content:

- your name, export date, placement date, prediction date and IUS type (Figure 57)

Name:	Export date:	Placement date:	Prediction date:	Product:
	29/10/2020	31/07/2020	28/10/2020	Kyleena

Figure 57: Report header

- baseline parameters and BMI (Figure 58)

Your basic entries:

Date of birth:	07/04/1998	Height:	165 cm	Previous pregnancies:	0
Country:	Great Britain	BMI:	22.8	Births:	0
Weight:	62 kg	Previous contraceptive method:	Combined pill, Ring, Condom		

Figure 58: Report baseline parameters

- collection of daily bleeding patterns for the 90 days before and 180 days after the prediction, displayed in a column for each month. Each column is split in date and bleeding pattern value (Figure 59). If you included the mood entries in the report, each monthly column is split between bleeding entries and mood entries.

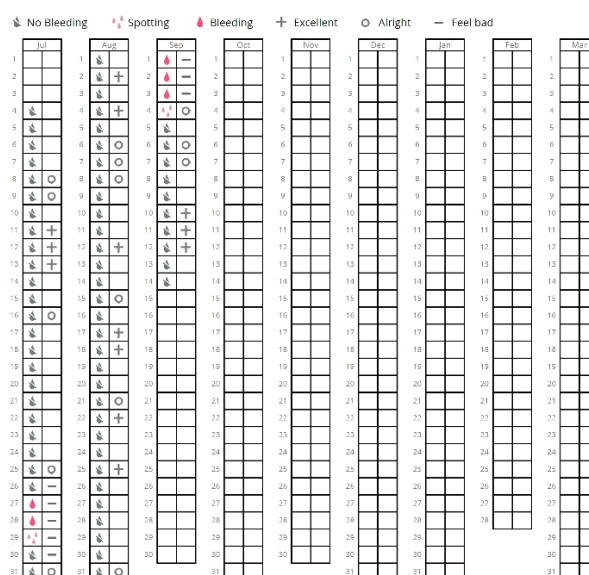


Figure 59: Report everyday pattern



Note:

If no bleeding entry is available for a day, the field for that day remains empty.



Note:

If no data is entered at all, your report can still be generated but will contain empty sections.

- 270-day bar chart of each of the possible values of the entered data for the 90 days before and 180 days after the prediction (Figure 60)

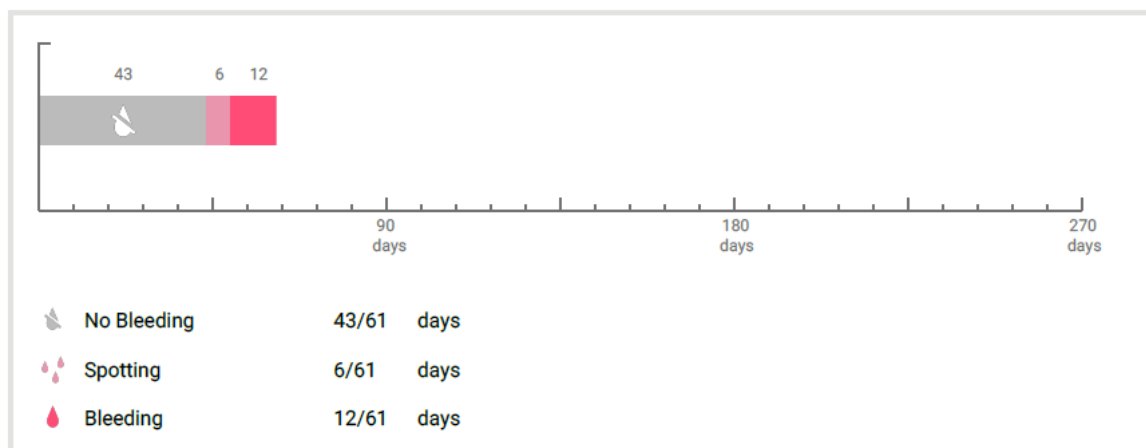



Figure 60: Report chart

- summary of all bleeding entries up to the current date (how many days with no bleeding, how many days with spotting and how many days with bleeding)
- prediction of future bleeding
- placeholder for comments
- your entered notes

The report can be downloaded as a PDF file, by pressing on the “Open” button.

You can also print and send the Report via E-Mail, using the features of your operating system by pressing on the “Share” button.

14 Gems

The Gems screen (Figure 61) is accessible from the Main Menu  and the toolbar by pressing on the Gems-Symbol.

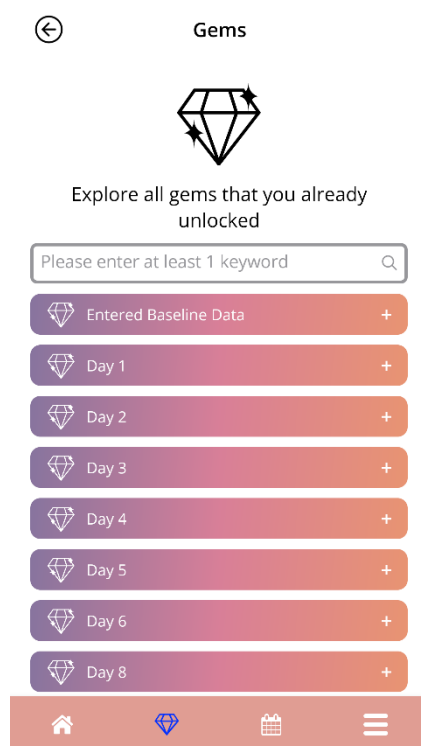


Figure 61: Gems screen

On this screen, you can explore the “unlocked” informational gems.

An informational gem is a reward that becomes available on certain days as preconfigured in the app.

You can “unlock” an informational gem when all of the following conditions are met:

- the day of the reward is reached or was passed
- at most 2 daily bleeding patterns are missing in this 30-day period until the current day but not consecutively
- all previous rewards of this 30-day period are unlocked (if you missed one or two days, these gems will unlock)
- a daily bleeding pattern for the current day is entered

You can see the day’s number for each unlocked gem. You can display detailed information by tapping on the “+” symbol of a day.



Note:

Not every diamond-icon displayed on the monthly and weekly calendar means you have unlocked that gem. The display only shows you for which days gems are available for unlocking.

There is a special gem related to baseline parameters. This will be received automatically after completing the baseline questionnaire and will be shown atop of the list in the Unlocked gems section.

When you unlock one or more informational gems at once, the app will open a pop-up (Figure 62) with the following content:

- informational text related to the unlocked gem or a default text
- the “Ignore” button for closing the pop-up
- the “View” button to navigate to the Gems screen (Figure 61).
-

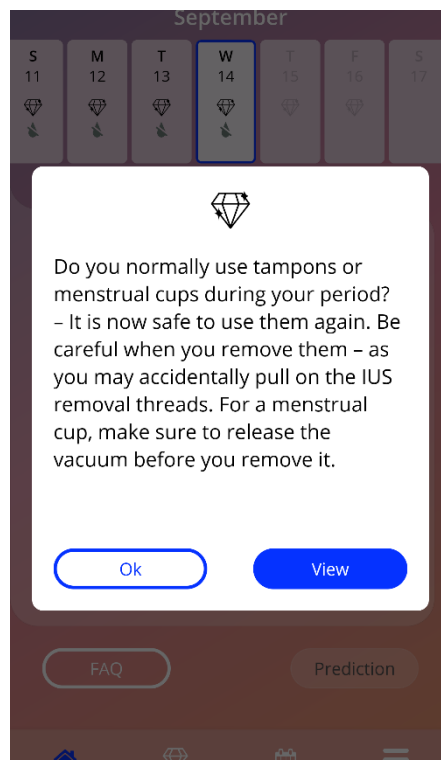


Figure 62: Informational gem pop-up

You can also receive motivational messages on certain days, depending on a consistent entering of bleeding patterns. When you unlock one or more motivational gems at once, the app will open a pop-up like the one in Figure 63 having the following content:

- a motivational text related to your consistent data entering
- a button for closing the pop-up

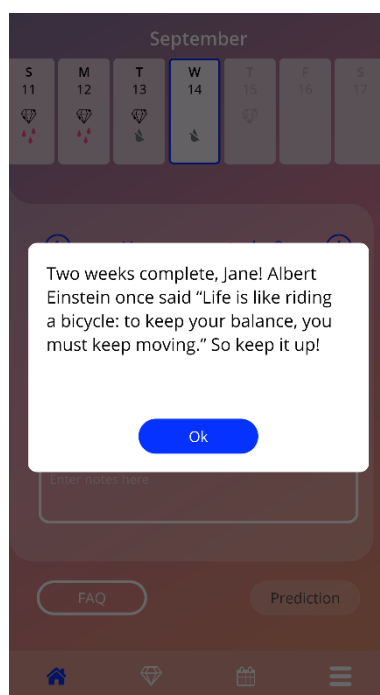


Figure 63: Motivational gem pop-up

14.1 Searching in Gems

Atop of your unlocked gems, you can find a search bar. You can enter terms to easily find or back-track previously received gems. As soon as you tap on the search bar in Figure 61, you can enter your desired search term and the results will be displayed below immediately. Primarily, the found gems related to your search term are displayed atop, and secondarily further search results from the FAQ section are displayed below (Figure 64). In case that no results were found for the search term you will be informed. You can restart a search with a new search term anytime. To go back to the initial listing of your gems, simply click on the little x within the search bar - or in case that no results were found - on the text link as shown in (Figure 65).

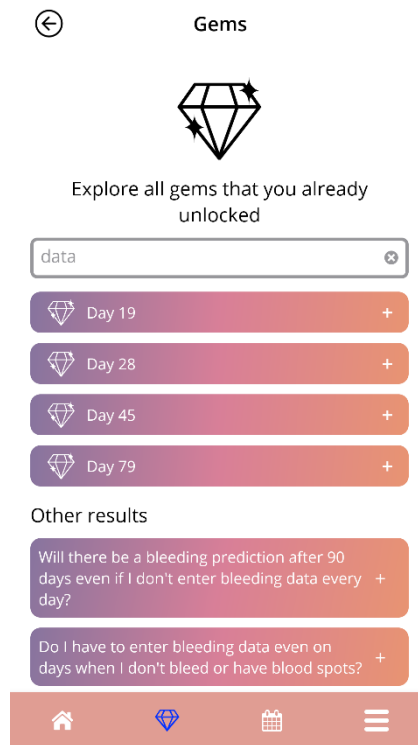


Figure 64: Search results (Gems)

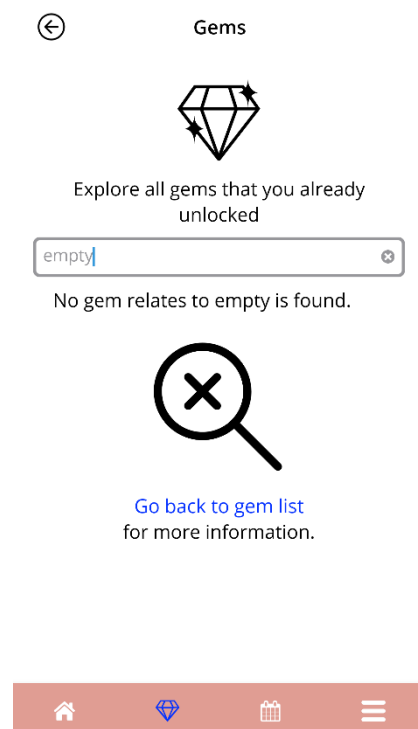


Figure 65: No search results (Gems)

14.2 Extraordinary Gems

Some gems contain extraordinary information and services or ask for your feedback. The following subchapters provide a brief overview of the types of these gems and how you can interact with them.



Note:

Not every gem is available for each country. Depending on your location, some gems might not be available for you.

14.2.1 App Store Rating

When you unlock certain gems, the displayed pop-up might ask for your app-rating for the Google Play Store or the Apple Appstore. When you tap on the respective button in the pop-up, a pop-up of your app store will automatically appear. If you do not wish to rate the app, feel free to simply close the gem pop-up.

14.2.2 FAQ

Some unlocked gems contain references to questions and answers from the FAQ section of the MyIUS application. You can find the respective button to access the FAQ in the displayed pop-up as well as in the displayed information for the gem in the Gems section. If you tap on the button “Learn more”, the app will automatically display the respective question and answer in the FAQ section for you.

14.2.3 Feedback

If the MyIUS app asks for your feedback in an unlocked gem, you can select one or multiple options in the displayed gem pop-up. If you wish to send your selection to us, you can tap the “Send” button afterwards. If you do not wish to provide us with feedback, simply tap on the “Ignore” button in the pop-up.

It is also possible that you are asked to provide feedback by entering a small phrase of your choice in a text field of the displayed pop-up of an unlocked gem. You can enter up to 15 characters of a feature or section of the app, which you think could be further improved or what you miss in the app in general. After you entered a term, you can send the feedback by tapping the “Send” button. You can also ignore the sending of feedback by tapping on the “Ignore” button.

14.2.4 IUS brand information

If an unlocked gem provides you with further insight into your IUS brand, you can tap on a button in the respective pop-up. The MyIUS app will automatically open your web browser for product information about your IUS. This information is also accessible anytime in the Support section (chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

14.2.5 Reminder

If you deactivated reminders for future screenings and other medical appointments, you might receive gems that will provide the hint and possibility to reactivate these reminders. This will help you to keep track of appointments. If you tap on the “Activate” button in the respective pop-up of the unlocked gem, the app will navigate you to the Reminder section (chapter 12.3).

15 Media

The Media screen (Figure 66) is accessible from the Main Menu  by pressing on the item “Media”.

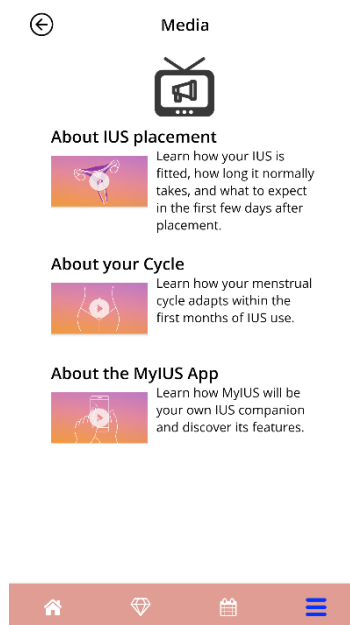


Figure 66: Media Screen

The media screen contains different videos about your IUS and the app usage. To watch a video, you can press on the play icon. The video will start within the app. You can return to the app from the in-app video viewer by pressing the back button in the upper left corner.

16 MyIUS Study

The MyIUS study is a real-world evidence study conducted by Bayer to further improve the algorithm and effectiveness of the IUS bleeding prediction. The study is conducted in multiple countries worldwide and solely accessible via the MyIUS app.

If you want to take part in the MyIUS Study, you must confirm your participation. When you take part, you simply have to track your bleeding patterns for further 180 days. Your app data, consisting out of your anonymized baseline information and the bleeding entries, will be sent to a secure server for evaluation afterwards.

Depending on your country, you may receive rewards once you reach the conditions for completing the study participation. The countries support vouchers and donations to external organizations. However, rewards are prohibited in some countries.

16.1 MyIUS study invitation

After you entered your bleeding patterns for 90 days and you received a prediction, the app might invite you to participate in the MyIUS Study (Figure 67).



Note:

The number of participants is limited for each country. Therefore you may not receive an invitation for the MyIUS study.

You can receive further information about this study on the study introduction screens that will be displayed after you press the “Learn more” button. The first screens will lead you through all necessary information regarding the task at hand, the study goal, and possible rewards.

If you are not interested in taking part in the MyIUS study, you can tap on the “No, thanks” button. The app will navigate to the Home screen and you can further use the app as before.

If you are unsure about participating or want to decide later, you can tap on the “Later” button. The app will navigate to the Home screen and ask for your participation again.



Note:

If you postponed the initial invite, the app would ask for your participation again after 24 hours. Beware that this second time, you only have the option to either participate or to deny the invitation. You will not be asked again.

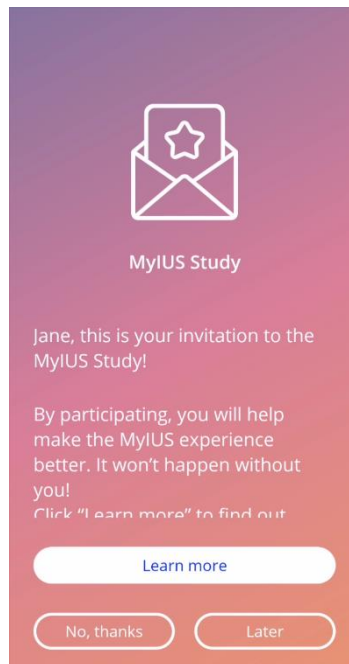


Figure 67: MyIUS Study invitation

16.2 MyIUS study consent

After you informed yourself about the MyIUS study on the first informational screens of the invitation, you are required to give your informed consent to the Data Privacy Statement of the MyIUS study. The Consent screen (Figure 68) provides you with all the information regarding data handling while enrolled in the MyIUS study.

After you read the complete Data Privacy Statement and scrolled down the entire screen, you can give your consent by pressing on the “Accept” button on the right.

If you don’t want to consent to the Data Privacy Statement, you need to decline the invitation for the MyIUS study entirely by pressing on “Deny” button on the left (Figure 69).



Note:

Please be advised that the Data Privacy Statement, that you agreed to when first setting up the app, covers the general use of the app, while the Data Privacy Statement here handles data protection matters regarding the MyIUS study. You can accept or deny this study’s Data Privacy Statement and withdraw your consent for the study regardless of and without implications for the initial Data Privacy Statement.

← Informed Consent Form

This form describes in detail how the study works and your role in it. Your signature means you understand and agree to participate.

Before you sign, you should know

① WHAT IS THE AIM OF THE MYIUS STUDY?

The principal aim of the MyIUS study is to validate that the algorithm for the MyIUS bleeding profile prediction, works also in the home-use environment, so-called real-world setting. The MyIUS study will also help to expand the functionalities of and/or otherwise improve the MyIUS app in the future. This can be done with the data that you collect and share

Figure 68: MyIUS Study consent (top of the screen)

← Informed Consent Form

- Right to restriction of processing (Article 18 GDPR)
- Right to data portability, i.e. the right to request that your stored personal data be sent to you or a third party in a commonly used format (Article 20 GDPR)
- Right to lodge a complaint with a supervisory authority (Article 77 GDPR in combination with Article 19 BDSG [German Federal Data Protection Act])


In order to comply with your right of access, your MyIUS study participant ID will be required in order to be able to match your pseudonymously processed data to you. Please send this via email to dataprivacy@bayoocare.com.

Deny Accept

Figure 69: MyIUS Study consent (bottom of the screen)

Once you consent, you can take part in the study by using the application as before and enter your daily bleeding patterns for the next 180 days. The app will regularly inform you, if something went wrong with your data entries and that the intended participation and thus entry of bleeding patterns might lead to an insufficient study participation result.

16.3 Study and Consent Management

At any time, you have the possibility to manage your given consent. The Study Management screen (Figure 70) is accessible from the Main Menu  by pressing on the item “MyIUS Study” once you enrolled in the MyIUS study. You will be able to see how many women have already enrolled in the MyIUS Study as a text display and as a graphical display (the circle will fill as more women are enrolled). Furthermore, you can see information about your own data privacy consent.



Note:

The displayed participant ID is important! Only you can see your personal participation ID. If you want to contact the data privacy officer and handle legal regards with us, you will have to refer to your personal ID in order for us to handle your requests compliant to data privacy laws.

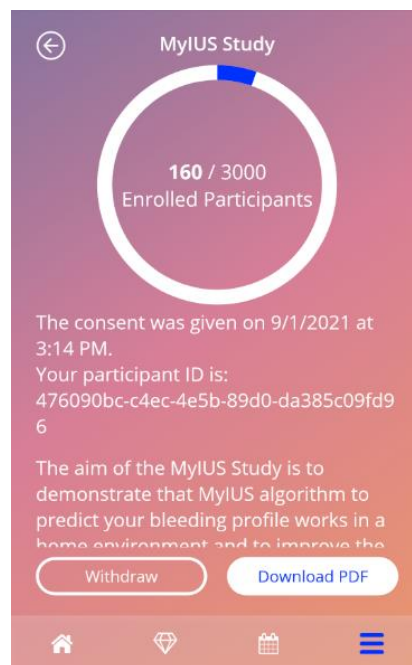


Figure 70: MyIUS Study Management

By pressing on the button “Download PDF” (Figure 70), the data privacy statement will be downloaded and provided to you. If you should change your mind and wish to withdraw your consent, you can press on the “Withdraw” button on the left. Afterwards, you will have to confirm your withdrawal in the just opened pop-up. No further data will be sent to the secure server once you withdrew your consent. Keep in mind, that once withdrawn, you will not be able to take part in the study again!

16.4 MyIUS Study reward

Some countries support monetary incentives. This might either be a monetary donation to a good cause, or you receive a coupon. Depending on your country, you will be informed about the amount and the kind of rewards that you would receive after a successful study participation before you enrol in the MyIUS study.

Once your final study data is uploaded successfully to the secure cloud web servers, the MyIUS app will congratulate you for the successful participation and provide you with further information how to receive the reward in case the reward is a coupon (Figure 71).

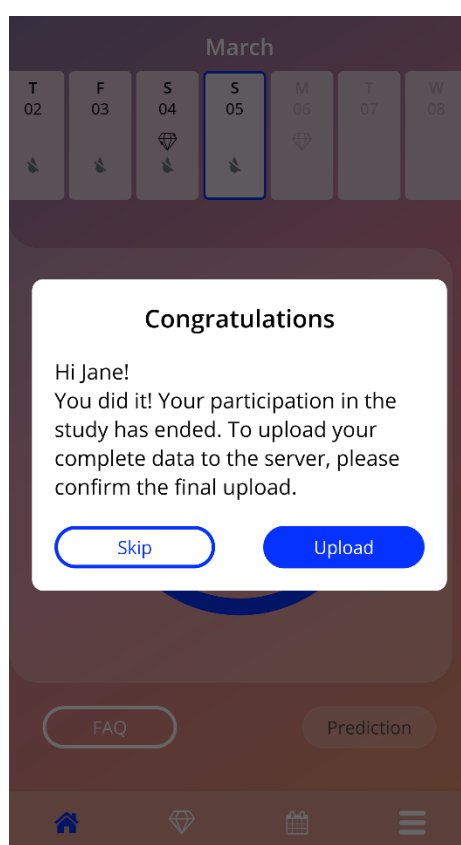



Figure 71: Final Study Data Upload Pop-up

17 FAQ

The FAQ screen (Figure 72) is accessible from the Main Menu  by pressing on the item “Frequently asked questions” or from the Home screen by pressing on the “FAQ” button on the bottom left side of the screen.

You can access the following categories:

- About your IUS
- Before and after placement
- Living with your IUS
- How to use MyIUS
- MyIUS Study



Note:

There are only four categories available any time. The sections “Before and after placement”, “Living with your IUS” and “How to use MyIUS” are always accessible. Once you enrolled in the MyIUS study, as further described under chapter 16, the section “About your IUS” will be replaced with the section “MyIUS Study” (Figure 73). Should you withdraw your consent for the study, the section “About your IUS” will be accessible again.

You can open a category by pressing on the related button. Each category shows a list of questions about the selected topic. You can view the complete text of the answer linked to each question by pressing on the arrow button next to the question.

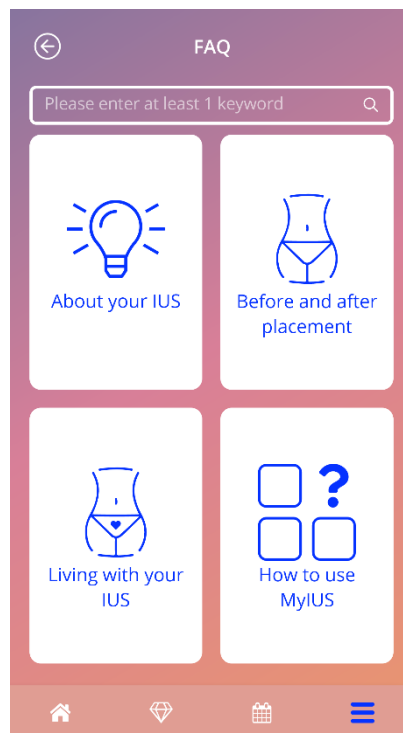


Figure 72: FAQ screen

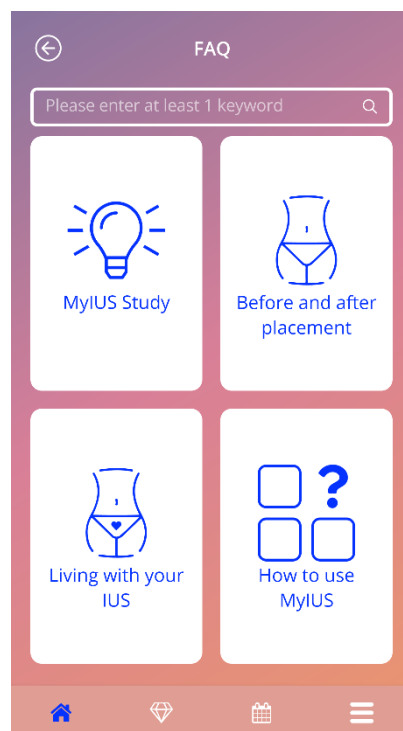


Figure 73: FAQ screen after enrollment in MyIUS study

17.1 Searching in FAQ

Atop of your FAQ categories, you can find a search bar (Figure 72). You can enter terms to easily find FAQs. As soon as you tap on the search bar in Figure 72, you can enter your desired search term and the results will be displayed below immediately. Primarily, the found FAQs related to your search term are displayed atop, and secondarily further search results found in the Gems are displayed below (Figure 74). In case that no results were found for the search term you will be informed. You can restart a search with a new search term anytime. To go back to the initial listing of your FAQ topics, simply tap on the little x within the search bar or in case that no results were found on the text link as shown in (Figure 75).

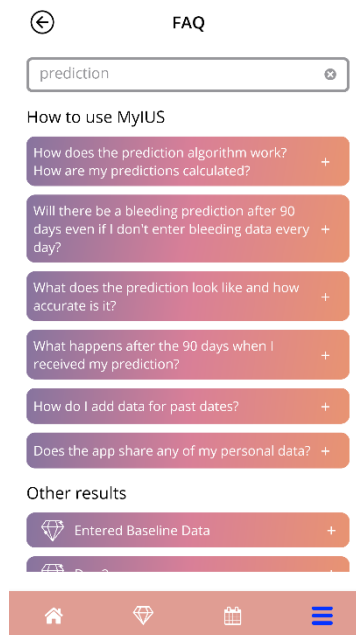


Figure 74: Search results (FAQ)

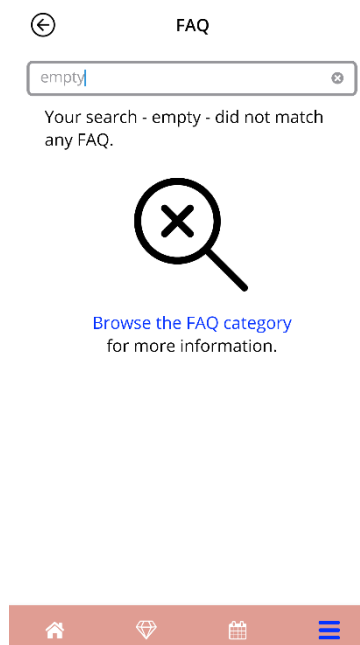


Figure 75: No search results (FAQ)

17.2 About your IUS

This section contains general questions about the IUS:

- What is an IUS?
- How does the IUS work?
- How long does the IUS work?
- How effective is the IUS?
- Will the IUS affect my hormonal cycle?
- What are the side effects of an IUS?
- Can certain drugs (such as antibiotics) interfere with the contraceptive effect of an IUS?
- Can the IUS affect my weight?
- Is there a risk of infection with an IUS?
- How will the IUS change my periods?

17.3 Before and after placement

This section contains questions about the placement of the IUS:

- How do I prepare for the placement of an IUS?
- How is the IUS placed?
- What can I expect right after the IUS is placed?
- Can I go swimming shortly after the IUS is placed?
- Can I use tampons or menstrual cups immediately after the IUS is placed?
- Does the IUS start working right away?
- How long should I wait to have sex after the IUS is placed?
- Is it normal to experience spotting after the IUS is placed?
- What kind of pain is normal after the IUS is placed?

17.4 Living with your IUS

This paragraph answers questions about what happens after the IUS placement:

- (How) should I check that the IUS is in place?
- Can I feel the IUS in my body?
- Can I have an MRI with an IUS in place?
- For what and how often are medical IUS assessments required?
- What if I change my mind and want to try to get pregnant?
- When do I need to replace IUS?
- Does the IUS affect my sex drive?
- Will my partner be able to feel my IUS during sex?
- Can I use a vibrator or other sex toys?
- Is it possible to displace the IUS during sex or other intense physical activity?

17.5 How to use MyIUS

This section contains general questions about the app, as the following:

- How does the prediction algorithm work? How are my predictions calculated?
- Will there be a bleeding prediction after 90 days even if I don't enter bleeding data every day?
- What does the prediction look like and how accurate is it?
- Do I have to enter bleeding data even on days when I don't bleed or have blood spots?
- Can I change my profile name?
- Can multiple people use the app on the same device?
- Can I transfer my data to another device?
- How do I add data for past dates?
- Does the app share any of my personal data?
- How can I delete my data?
- Where can I find and manage my language settings?
- What happens after the 90 days when I received my prediction?
- How can I change the start date of my IUS use?
- How do I reset the app settings?


17.6 MyIUS study

Once you were invited to participate in the MyIUS study and accepted the invite, the FAQ section will update and display the “MyIUS study” category instead of the “About your IUS” category.

This section contains general questions about the MyIUS study, as the following:

- What are the MyIUS Study procedures?
- Who can participate in the MyIUS study and with what equipment?
- Are there benefits to participating in the MyIUS study?
- What risks or discomforts should I expect from being in the MyIUS Study?
- What happens if I want to withdraw from the MyIUS Study?
- What data will be collected?
- What will happen with my data?
- Is there an opportunity for commercial gain by participating in the MyIUS Study?
- Who can answer my questions about the MyIUS Study?

18 Support

The Support screen (Figure 76) is accessible from the Main Menu  by pressing on the item “Support”. This screen shows the contact information of the technical support, the App’s user manual and a link to your IUS’s user manual. You can also provide feedback for us about the app, once you received a prediction.

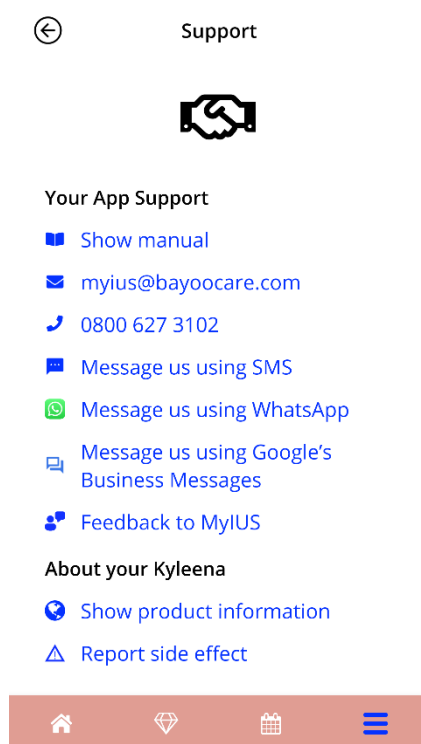


Figure 76: Support screen



Note:

No medical support will be received by using any of this contact information methods (email or phone). These contacts provide technical support related to the app.

In case of a side effect while using an IUS, please contact the dedicated provider responsible in your country directly by pressing on the link “Report side effect” on the Support screen.

18.1 App user manual

The App's user manual can be read and downloaded as PDF file, by pressing on the link "Show manual". The user manual will be provided in the language set on the smartphone, if supported.

18.2 Email

If you press on the given E-Mail address, the default E-Mail app of your smartphone will open, with the recipient's address already set up.

18.3 Hotline

If you press on the given number, the phone of your smartphone will open with the phone number pre-dialled.

18.4 SMS

If you press on the SMS link, a pop-up will open asking you to enter the phone number at which you would like to be contacted. After entering and confirming your phone number, you will be contacted via SMS.

18.5 WhatsApp

If you press on the WhatsApp link, your browser will forward you to WhatsApp, opening a new chat window with the technical support for MyIUS. You need to have WhatsApp installed for this to work.

18.6 Google / iOS Business Chat

If you press on your platforms business messages link, your browser will forward you to Google Business Messages or iOS Business Chat, respectively. A new chat window with the technical support for MyIUS will then be opened.

18.7 Give feedback

Through the Support screen, you can send your feedback about the app, once you received your bleeding prediction. If you press on the "Feedback" button, a pop-up asking for your consent to send your feedback to the cloud will open (Figure 77).

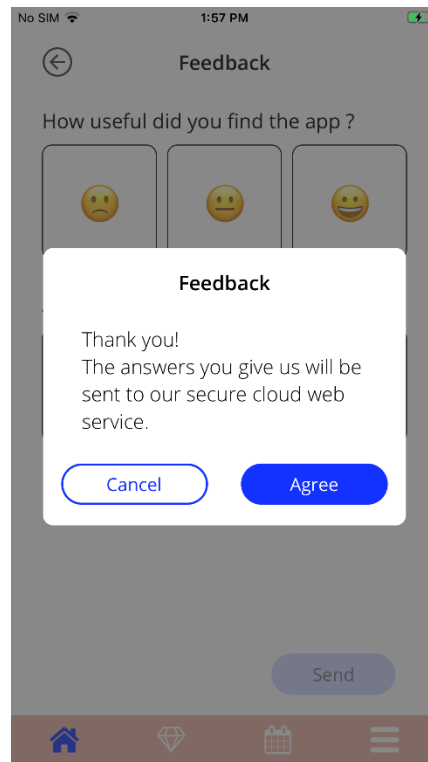


Figure 77: Feedback Consent

By pressing on the “Agree” button, the app will open the Feedback questionnaire (Figure 78). If you press on the “Cancel” button, the pop-up and the feedback screen will close.

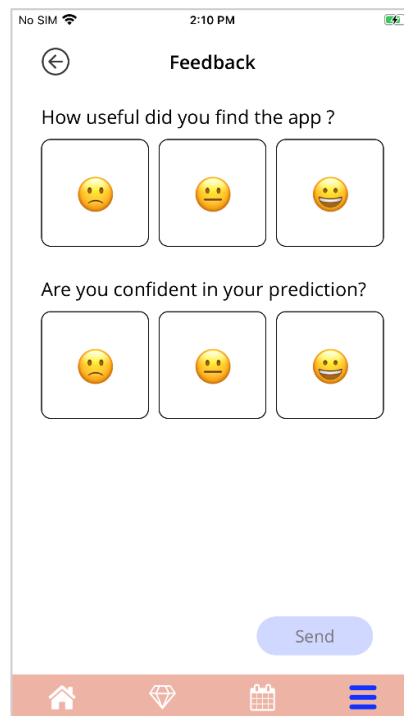


Figure 78: Feedback Questionnaire

Two questions can be answered on the Feedback screen, each providing three different answer options, displayed as smileys.

You can also cancel the feedback process, by pressing on the “Back” button in the top left corner of the screen. This action closes the screen without sending feedback.

If you press on the “Send” button, your answers will be uploaded to the cloud. If something goes wrong during the upload, a pop-up informing you about the failure will open (Figure 79).

The app asks you automatically to give your feedback by displaying a pop-up right after you received your bleeding prediction. If you press on the “Feedback” button, the consent pop-up (Figure 77) will open, and you are able to open the Feedback questionnaire (Figure 78) by pressing on the “Agree” button.

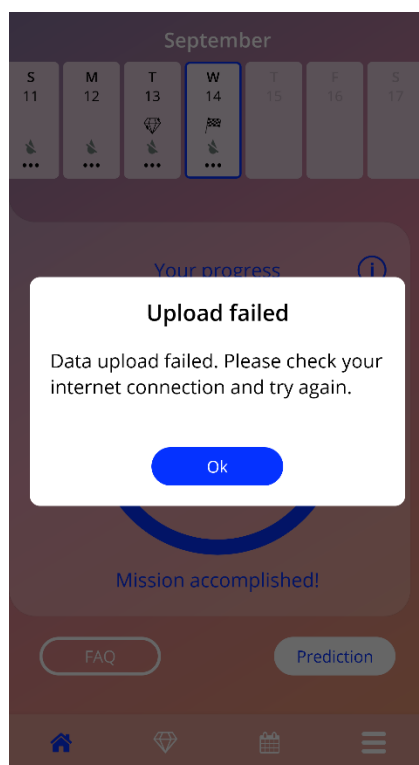


Figure 79: Upload failed pop-up

18.8 IUS user manual

The IUS’s user manual can be accessed by pressing on the link “Show product information”. The IUS user manual will be provided in the language set on the smartphone, if supported.

18.9 Reporting a side effect (Pharmacovigilance)

If you suffer from a side effect while using an IUS, please use the contact feature provided by the officially dedicated provider responsible in your country. You can access the contact feature by pressing on the link on the Settings screen “Report side effect”. The app will provide further information regarding the reporting process on the next screen (Figure 80). By pressing on the button “Start” the dedicated contact form will open in your native web-browser outside of the MyIUS application. In case that no dedicated provider is available for your country, your E-Mail application will open with a pre-defined E-Mail address and text that you can use to report your side effects.

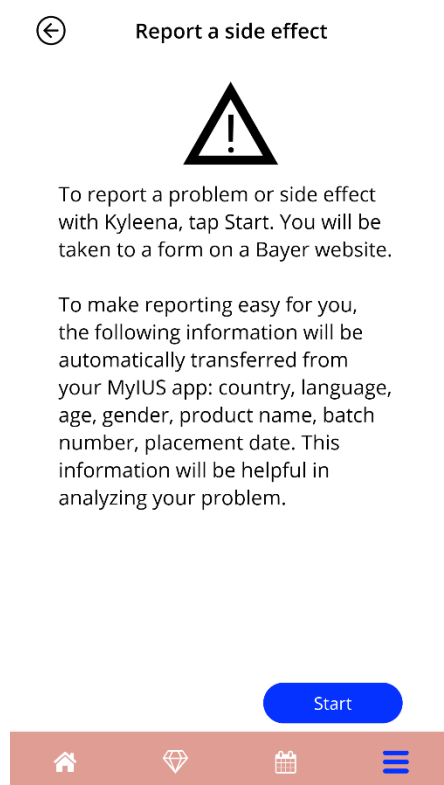



Figure 80: Report side effect

19 Legal notice

The Legal notice screen (Figure 81) is accessible from the Main Menu  by pressing on the item “Legal notice”. You can access the Terms of use, the Data Privacy Statement, the Imprint about the manufacturer and the option to set your preference regarding the tracking of analytical data.

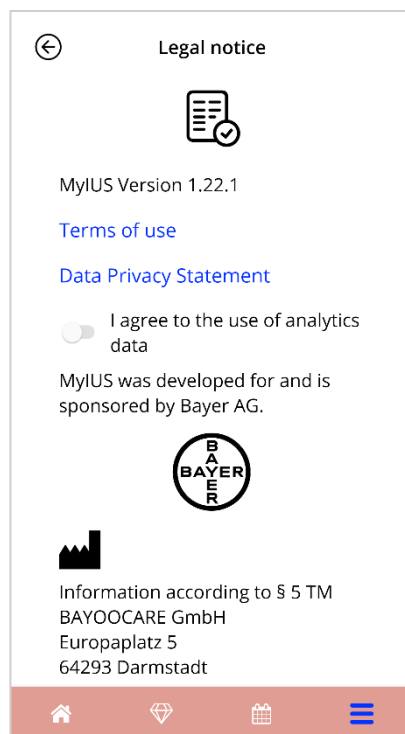


Figure 81: Legal notice screen

19.1 Terms of use

The Terms of use can be read and downloaded as a PDF file, by pressing on the link “Terms of use”. The Terms of use will be provided according to the region and the language set on the smartphone. If they are not supported, the Terms of use will be displayed in English.

19.2 Data privacy

The Data Privacy Statement can be read and downloaded as PDF file, by pressing on the link “Data Privacy Statement”. The Data Privacy Statement will be provided according to the region and the language set on the smartphone. If they are not supported, the Data Privacy Statement will be displayed in English.

19.3 Imprint

The Imprint section displays the following information:

- App release information
- Approval numbers of app texts
- Approval numbers of app videos
- App license agreement
- MyIUS CE Marking
- License information of used libraries as applicable
- Contact information of the legal manufacturer

The Imprint will be provided for the region set on the smartphone. If the region is not supported by the app, the Imprint will be displayed in English.

19.4 Data Tracking

You can set your preference for the tracking of analytical data, which is used for the improvement of the app, anytime. If you accepted the tracking of analytical data at the first start of the app, the toggle for your preference will be enabled - otherwise disabled. By tapping on the toggle your preference will be automatically applied.