

User Manual

BAYOOCARE

MyIUS-App

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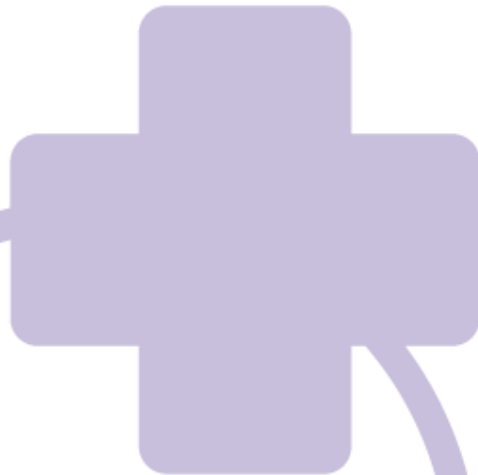


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1 Symbols



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
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

3 Introduction

The current document is the user manual for MyIUS software and contains instructions for safe and effective use of the system according to its intended purpose. The app is intended to be used by persons employing specific Levonorgestrel Intrauterine System (LNG-IUS) contraception systems produced by BAYER AG (Kyleena® and Mirena®). 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 Intended Use

3.2.1 Intended Use Statement

MyIUS is an application for women with occurring regular or even irregular menstrual periods who are using or want to use contraception with a levonorgestrel intrauterine system (LNG-IUS). The application was designed to cover the period from IUS prescription through insertion and up to three months thereafter. It provides information and the ability to obtain a prediction of the future bleeding profile.

3.2.2 Indication for Use

Bleeding might be affected by LNG-IUS. Therefore, MyIUS app is able to provide a most likely future bleeding profile with respect to intensity and/or regularity in order to raise user satisfaction. The intended usage of the MyIUS application starts with the prescription of the IUS and ends ideally after providing a most likely future bleeding profile with the removal of the LNG-IUS or upon decision of the user. The application itself is a patient support tool or a so-called “digital companion” to be used by women applying Kyleena®, and Mirena®.

3.2.3 Patient Population

The target patient population includes persons with menstrual cycles which use or are planning to use Levonorgestrel Intrauterine System (LNG-IUS) contraception systems produced by BAYER AG. However, only the products Kyleena® and Mirena® are validated for use in combination with the

application. The system is intended to be used by persons without any specific knowledge or training on contraception or data tracking.

Blind and visual restricted persons as well as men and women not having a prescription for or not already using an intrauterine system produced by BAYER AG are excluded.

3.2.4 Intended Use Environment and Users

The intended use environment entails daily routine environment as no specific conditions are required to use the app.

Users are expected to be familiar with basic functionalities of smart phone devices and apps (either Android or iOS).

A basic knowledge of the female cycle (e.g. for determining cycle length, cycle end) and birth prevention is expected.

The ability to read and understand one of the supported languages is expected.

3.2.5 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:

- Persons not having a prescription for or not using an intrauterine system from BAYER AG
- Persons 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 persons using Kyleena® and 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 the user expedient 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,
- 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 2017/745 regulation or its national implementations.

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

- Kyleena®
- Mirena®

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 Installation

MyIUS app is developed for two different operating systems, Android and iOS. To make the app available to as many potential users as possible, MyIUS is published on two different platforms, one for each operating system.

- For iOS, the operating system running on Apple devices, the app is available in the Apple App Store.
- For Android devices, the app can be downloaded from Google Play Store.

Both platforms are usually pre-installed on the devices. It is necessary to be registered at the platform to be able to download apps.

MyIUS can be found under the name "MyIUS" in the Apple App Store and Google Play Store. The application is free for all devices.

By selecting the download option in one of the platforms, the latest version of the app can be downloaded and installed on the device.

Updates of the MyIUS application will be provided in the dedicated stores.

7 Quick start

7.1 App Icon

After installing the app, it places an application icon on the smartphone. The default icon is shown in Figure 1.




Figure 1: App icon


The procedure how to change the app icon is described in chapter 14.2.

7.2 Menu & toolbar

The menu toolbar on the bottom contains the following five elements, that navigates you to the related sections:

- Home
- Report
- Track
- Guide
- More

The More Menu icon , that is displayed on the right of menu toolbar, provides additional options to navigate through the app.

By pressing on  ten options will be displayed and each of them navigates to one of the following sections:

- Profile
- Settings
- Reminders
- User Manual
- Technical Support
- About your IUS
- Give Feedback
- Imprint
- Terms and Conditions
- Data Privacy

7.3 Main navigation

You can navigate freely once you completed the setup of the application.

The menu toolbar and the More Menu 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 an arrow button on the left, as displayed in Figure 2, in order to navigate to a previously displayed screen.

Some overlays can also be closed by the "X" button on the top left corner.



Figure 2: Back Icon

7.4 General warnings

Warning pop-ups, such as the one displayed in Figure 3, will inform you about any issues with the app or with your data. You can close the pop-up by selecting the displayed button.

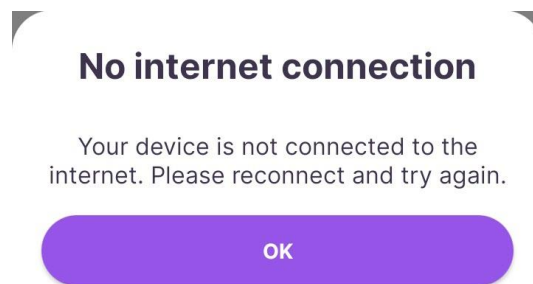


Figure 3: Warning message

7.5 Pop-ups

Pop-ups, as the one displayed in Figure 4, will appear in different cases. The pop-ups provide you the option to decide between two or more options.

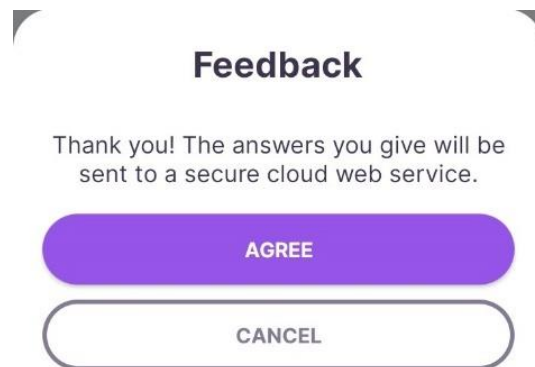


Figure 4: Pop-up message

8 First time use

8.1 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 will inform you about it.

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 for example, 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 MyIUS:

- Android 8.0 or higher
- iOS 13 or higher

8.2 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 5).

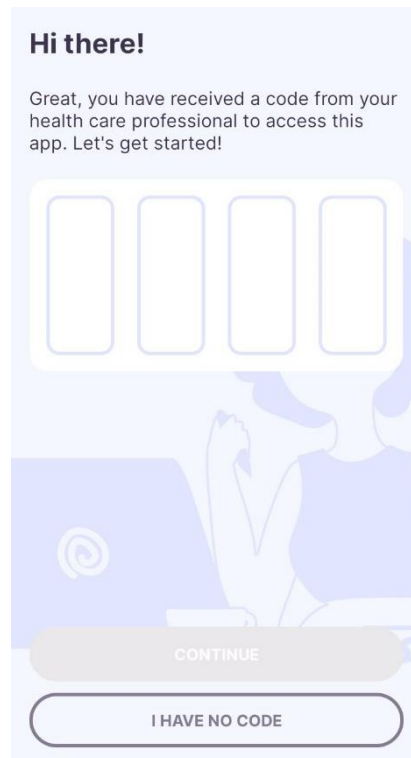


Figure 5: Authorization screen

The authorization is mandatory. Before starting to use the app, you must enter the authorization code consisting of four digits, received from your doctor.

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



Note:

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

8.2.1 I have no code

If you do not have a code, please tap on “I have no Code” button. A new screen will be opened (Figure 6) informing you about the help-process and the available support options. When you select one of the options, the app will redirect you to the corresponding service.

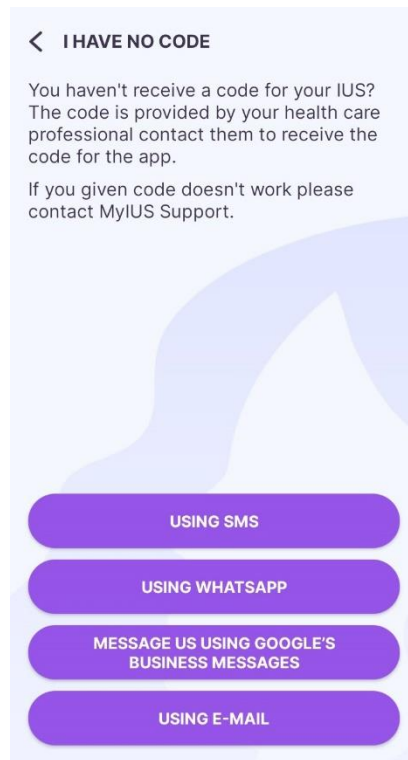


Figure 6: I have no code screen

8.3 Data Privacy Statement

After the successful authorization via code, the Data Privacy Statement must be accepted after reading it and scrolling down the statement and selecting the corresponding check box” on the Data Privacy Statement screen (Figure 7).

Additionally, the Terms and Conditions must also be accepted. Press on the “terms and conditions” link to open and to read the terms of use.

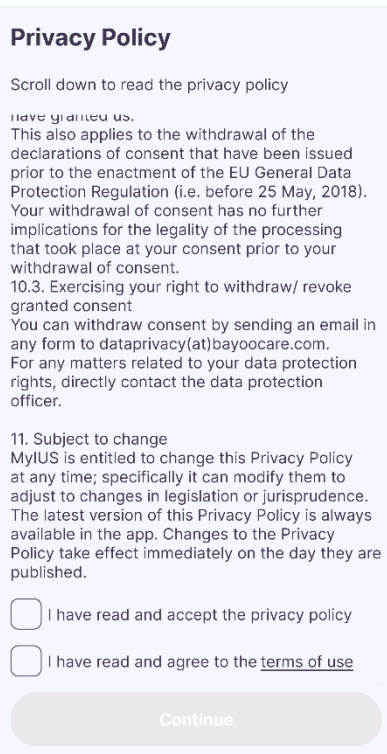


Figure 7: Data Privacy screen

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 “unlocked”.

8.3.1 Accepting data privacy and terms and conditions

In order to proceed to the next screen, the Data Privacy Statement and the Terms and Conditions must be read and accepted by selecting the check box.



Note:

In case the Data Privacy Statement and the Terms and Conditions are not accepted by selecting the check boxes, the Continue button remains disabled.



Advice:

Please read the Data Privacy Statement and the Terms and Conditions before accepting them.

8.4 Tracking Data

The following screen informs you about the collection and sending of tracking data.

You have the option to enable or disable the tracking of analytical data by selecting the dedicated option. .

The collection and sending of tracking data are not mandatory but will help us to improve the app.

8.5 Start setup configuration

After successful authorization, the First Time Use wizard starts with the Setup screen (Figure 8).

The button “Let’s do it” starts the setup process and opens the nickname screen.

The button “Import old data” allows you to import application data from another end-device (e.g. your previously used phone) as further described in chapter 9.2.

The First Time Use setup can be skipped by pressing on “Skip configuration” option on the bottom of the screen. The application skips the baseline questionnaire. You can complete your data later by accessing the Profile section.

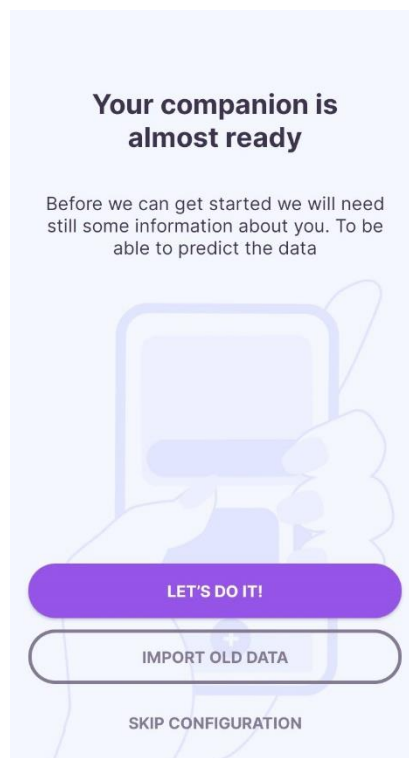


Figure 8: Start setup screen

8.6 Baseline parameters

To get an accurate prediction of your future bleeding, the app needs some information about you (Baseline parameters). Depending on the country you have selected, the number of questions in the questionnaire varies. 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 and the option to skip each parameter individually to navigate to the next part of the questionnaire. You can press the back arrow on the top left to go to the previous question. To skip a question, you have to select the “I’ll do it later” option from the bottom of each screen. Missing information can be completed in the profile screen, later.

8.6.1 Nickname

The Nickname screen allows you to enter a username of maximum 15 characters. The button “Continue” opens the Country screen.

8.6.2 Country

In order to predict future bleeding, the app also needs to know your current 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.

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

8.6.3 Birth Date

On this screen you are asked to enter your date of birth. Ages below 60 years are supported by the MyIUS app. The default date is the 01.01.2000.

8.6.4 Height

In this screen you are asked to enter your height in cm or ft. By default, 160 cm are preselected. Please select your personal values for the future prediction to be personalized for your body. You can increase or decrease the displayed number by selecting the “+” and “-” buttons or tap in the middle of the field and enter the value directly.

Furthermore, you can change the unit by selecting the “cm” or “ft/in” button.

8.6.5 Weight

In this screen you are asked to enter your weight in kg or lbs. By default, 60 kg are preselected. Please select your personal values for the future prediction to be personalized for your body. You can increase or decrease the displayed number by selecting the “+” and “-” buttons or tap in the middle of the field and enter the value directly.

Furthermore, you can change the unit by selecting the “kg” or “lbs” button.

8.6.6 Pregnancy & births

This screen is about the number of pregnancies and the number of births. You can increase or decrease the displayed number by selecting the “+” and “-” buttons or tap in the middle of the field and enter the value directly.



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.

8.6.7 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.

8.6.8 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.



Note:

You cannot enter future screenings.

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

8.7 Placement date of your IUS

The next screen following the baseline parameter questionnaire, is the Placement date screen (Figure 9).

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 placement date is more than 90 days ago, predicting bleeding patterns 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, when opening the selection calendar.

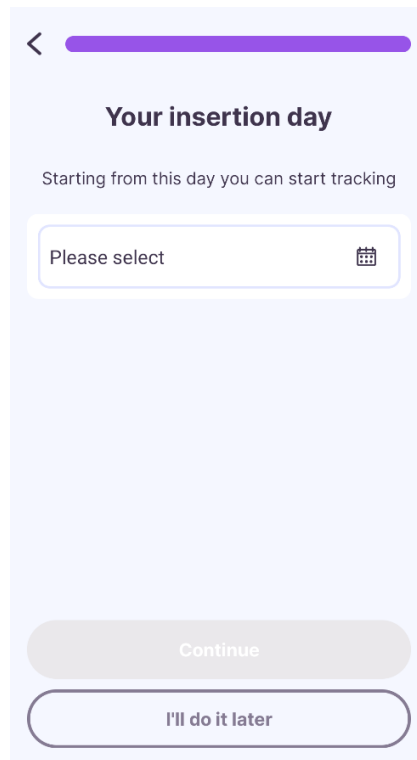



Figure 9: Placement date screen

Setting the placement date can also be skipped and re-accessed or edited through the Profile section of the More Menu .

If your placement date is older than 90 days, the app will inform you about this and require you to confirm the insertion date. 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.

Nonetheless, if your insertion date is in the past or today and you press the “Continue” button, the baseline parameter entries are completed. By pressing the “Get started” button on the last screen, you will be forwarded to the Home Screen.

The app will show you a short introduction to the six main features on the Home Screen:

- Tracking / Wellbeing Switch: Switch between your insights for bleeding / spotting / no bleeding events and your tracked wellbeing data.
- Progress circle: Access your progress since IUS placement day and see when your prediction for the upcoming months will be unlocked.
- Add Tracking: Start tracking daily bleeding / spotting and no bleeding events and optionally wellbeing insights.
- Bottom menu: Switch between home screen, exportable report of your insights, useful articles and further menu items in “more”.
- Did you know section: Receive useful information and articles depending on your progress since insertion day. Those can be accessed anytime in the section “Guide” as well.
- +: Use the + button to start tracking wherever you are within the MyIUS app.

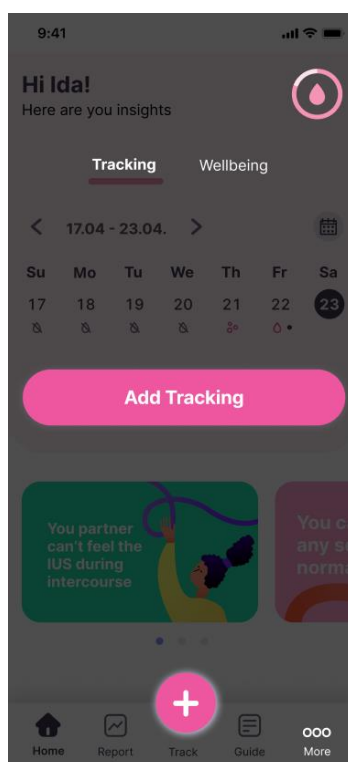


Figure 10: Placement date screen

This introduction is only shown once. You can navigate between the items by selecting the “Next” button. If you select the “Skip” button, the introduction is closed.

9 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 and wellbeing entries. If another end-device shall be used, the export feature can be used to transfer your data.

9.1 Export

1. Access the Export Screen via the Settings screen (Figure 27).
2. Press the button to export your data to another device. When you press on the “Export data” button, the export process is initiated.
3. A unique QR-code is generated and displayed by the MyIUS app.
4. Scan this displayed QR-code (Figure 11) with 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. The MyIUS app will automatically encrypt all above mentioned data and transfer it to a server.

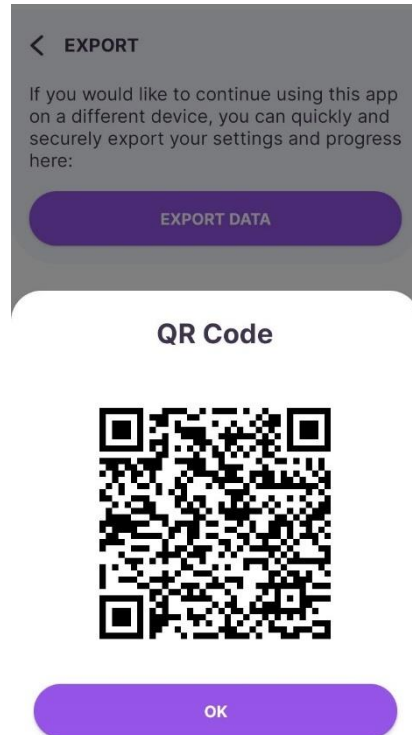


Figure 11: Export screen



Note: Your uploaded data will be deleted after the transmission was successful, or after 24 hours have passed. If data from the same app shall be transmitted after more than 24 hours, or another transmission of the same data shall be executed, you must initiate a new export process.

A new QR Code needs to be regenerated if you haven't used the previous one in 24 hours.

An active internet connection is mandatory for the export feature to work.

9.2 Import existing data from another device

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 8). Press the “Import” button to initiate the import-process, described in 8.2.1.

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 uninstalled and then installed again, in order to select the import feature after the first start of the app.

9.2.1 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.

1. 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.
2. Scanning is executed automatically once the camera detects a QR-code.
3. When the scanning either succeeded or failed, the app will give you feedback about the state of the scanning.
4. 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.

9.2.2 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 and a pop-up is displayed informing about the successful import. It is not necessary to restart the app.

9.2.3 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.

10 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 12) consists of the following sections:

- two tabs for switching between tracking and wellbeing
- a Weekly Calendar extract
- an information part

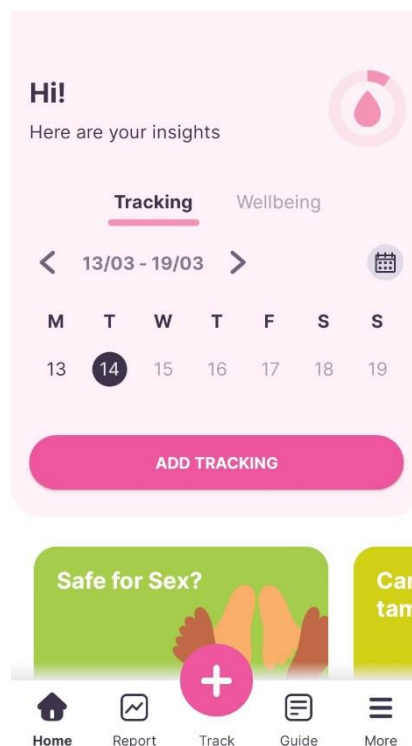


Figure 12: Home screen

10.1 Tracking and Wellbeing Tabs

To switch between the tracked bleedings and wellbeing, you can select one of the tabs.

You can directly add your bleeding patterns on the Tracking tab by selecting the “Add tracking” button or your wellbeing on the Wellbeing tab by selecting the “Add wellbeing” button. Further information about the adding of bleeding patterns and wellbeing can be found in chapter 10.4 How to add or edit bleeding patterns and wellbeing.

When you select a day, which has already a bleeding or wellbeing entry, the button will change from “Add” to “Edit”.

10.2 Weekly calendar

The weekly calendar extract is displayed on the top of the Home Screen. It shows the whole week at the top and the current day is highlighted. Each of the displayed days may show information related to the already introduced bleeding patterns or additional information about your mood and wellbeing that you entered previously.

You can navigate through the calendar extract by pressing on the arrows on the left or the right. Days prior to the placement date and future days are greyed out.

After you selected one day from the weekly calendar extract you may set the bleeding profile for this day.

10.3 Monthly calendar

You can extend the weekly calendar to the monthly calendar by pressing on the “Calendar” icon on the top right of the Home Screen. When pressed, the calendar opens for the current month. Each day shows information related to already given bleeding entries or additional information about your wellbeing that you entered previously.

To navigate through the months on the monthly calendar screen, you can simply navigate through the calendar by using the arrows atop of the calendar.

Selecting one day in the calendar allows you to set the bleeding profile for this day.

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

10.4 How to add or edit bleeding patterns and wellbeing

10.4.1 Add or edit bleeding patterns

You can add a new bleeding entry or edit an existing bleeding entry by selecting one day on the weekly calendar and pressing the “Add bleeding” or “Edit bleeding” button. The tracking screen will open, and you can select one or more days and a bleeding icon for the selected time.

When multiple days are selected, the same bleeding pattern will be set for all selected days. You can choose between three bleeding patterns:

- Bleeding
- Spotting
- No bleeding

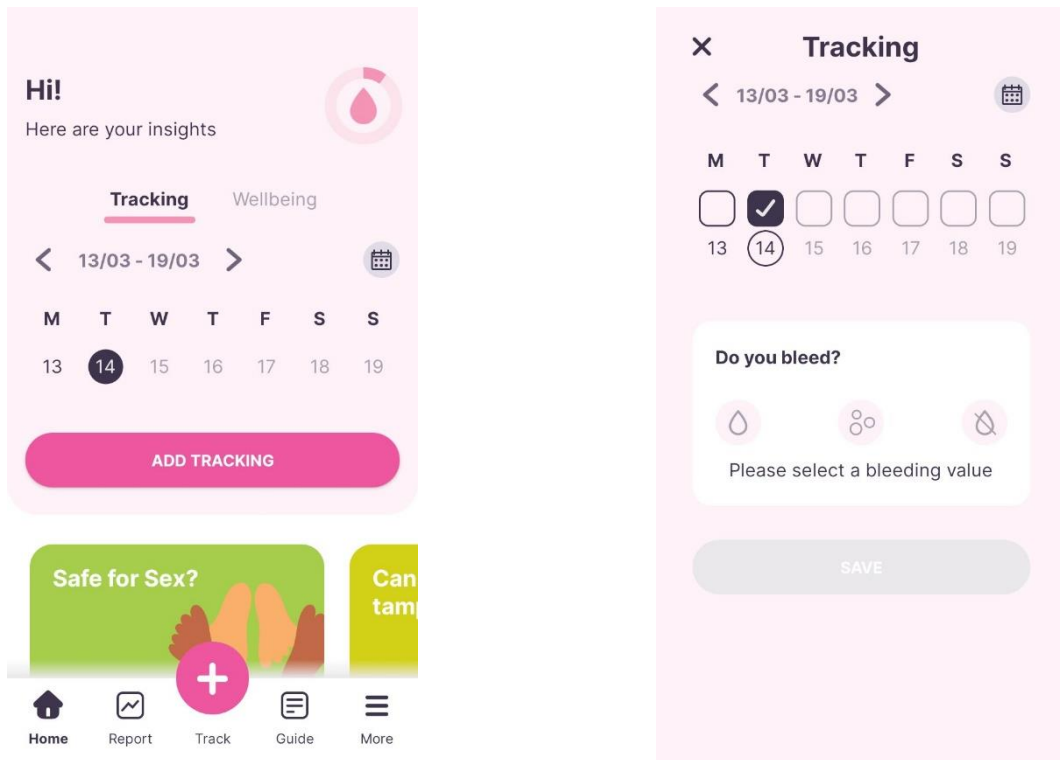


Figure 13: Bleeding pattern tracking



Note:

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



Note:

When editing existing data or adding data for multiple days including days with entries, the app will ask you to confirm the changes if you overwrite existing entries. Accidentally overwriting existing entries may affect your future prediction.

10.4.2 Add or edit wellbeing

Furthermore, you can document your wellbeing, feelings and mood. Therefore you have to switch to the wellbeing tab, select a day and press the “Add wellbeing” button or the “Edit wellbeing” button, when wellbeing is already available for the selected day. After adding a bleeding pattern, the app will also ask you if you want to add additional wellbeing information.

A new screen will open providing you the option to add or edit:

- Moods
- Wellbeing
- Notes

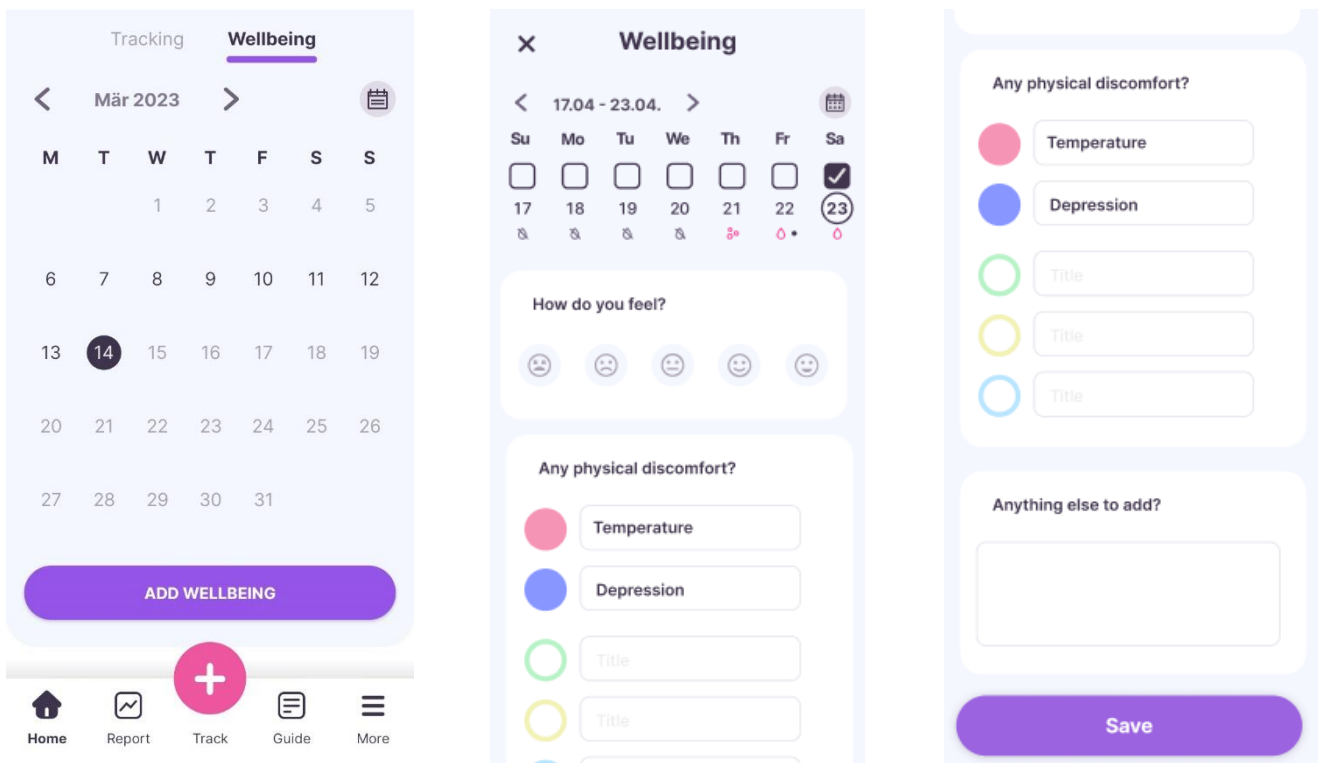


Figure 14: Wellbeing and mood tracking

You can select one of five icons for indicating today's mood.

To enter a discomfort, you have to select a color and enter a description of your personal discomfort in the input field. After adding the name of a discomfort, you can tap on the item to be selected for the day and placed at the top. The new discomfort will be available for selection when adding or editing a wellbeing entry. When you edit the description of the discomfort, it will be edited on the selected day, the days you added it previously will remain as you configured it before.

Additionally, you can also enter up to 200 characters to describe any of your wellbeing notes and feelings on the bottom of the wellbeing screen (Figure 14).

The “Save” button needs to be pressed to save the wellbeing entry for the selected day.

Once you provided any inputs about your wellbeing for a day, or entered a note, the calendar extract or the monthly calendar will mark that day with a dot below the date.

10.4.3 Bleeding pattern and wellbeing entries before prediction

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

10.4.4 Bleeding pattern and wellbeing entries after prediction

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

10.5 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.

10.5.1 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
- When starting to add bleeding entries,, 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 “Prediction” icon on the top right corner of the Home Screen (Figure 12) changes to a button (Figure 15) and allows you to open or ask for your prediction.

10.5.2 Prediction without missing days

You can ask for a prediction for future bleeding if the preconditions in 10.5.1 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 15: Prediction available button

10.5.3 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 10.5.1 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 will notify you by displaying a screen when the previous conditions are met.

You can enter missing days after pressing on the “Enter Manually” button by yourself or let the app set all missing days as “non-bleeding” when selecting “Auto-Complete”. Afterwards you can ask for a prediction again by pressing on the “Prediction” button on Home Screen (Figure 15). By pressing on the “Enter Manually” button, the monthly calendar will open at the month containing the first missing bleeding data.



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.

10.5.4 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, 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.

10.5.5 Ask for a prediction

If the conditions for a prediction are met, you can receive the prediction after the 90th entry or request it by pressing on the “Prediction” button on the Home screen (Figure 15).

10.5.5.1 Generate prediction

This screen tells you that you have reached the goal (Figure 16). You can press on the “Get prediction” button to receive your personal prediction. The prediction will be generated and displayed. Please ensure that you have an active internet connection.

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

The button “Prediction” will always display the received prediction when you select it.

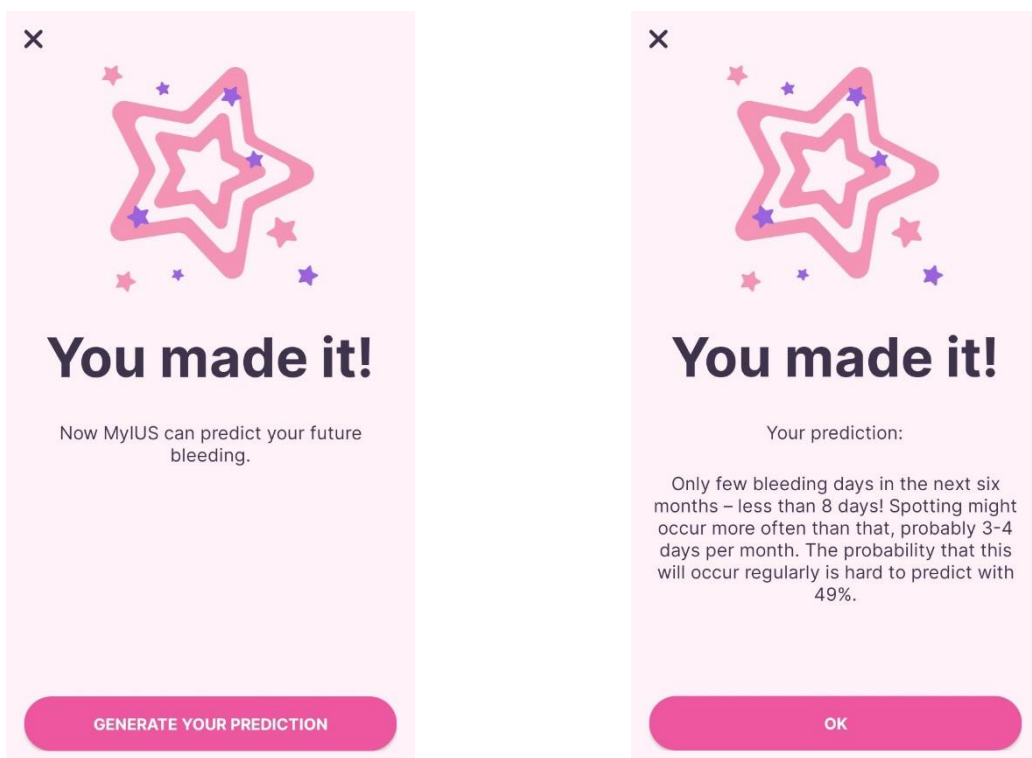


Figure 16: Prediction Example

11 Your report

You can generate your report any time. By accessing the item “Report” from the menu toolbar, the Report screen will be displayed (Figure 17).

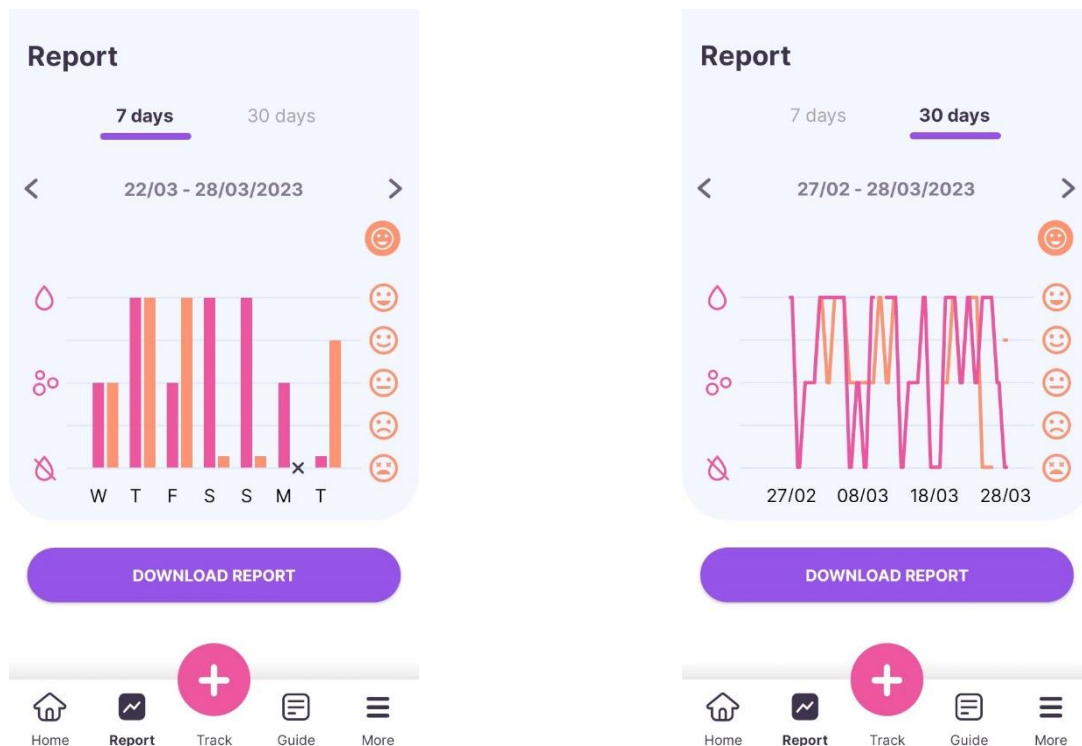


Figure 17: Report screen

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

The left graph shows your bleeding entries for each day within pink, and the right bar shows your mood entries in an orange.

You can display or hide the mood entries that you made by pressing the colored mood icon on top of the five mood icons, as you can see on Figure 17.

You can choose the time span of the graphs by pressing one of the tabs on the top of the screen. You can switch between 7 or 30 days. When selecting the “30 days” time span, the bars will turn into line graphs, but the legend of the colors remains the same as before.

To have a look at an overall report, including your baseline entries and all your bleeding entries, you can press on the “Download report” button on the bottom of the screen. Before a PDF report will be generated, you will be asked whether you want to include the wellbeing entries in the report. After the report is generated, the 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 18)

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

Figure 18: Report header

- baseline parameters and BMI (Figure 19)

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 19: 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 20). If you included the mood entries in the report, each monthly column is split between bleeding entries and mood entries.

No Bleeding		Spotting		Bleeding		Excellent		Alright		Feel bad	
Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar			
1	1	1	1	1	1	1	1	1			
2	2	2	2	2	2	2	2	2			
3	3	3	3	3	3	3	3	3			
4	4	4	4	4	4	4	4	4			
5	5	5	5	5	5	5	5	5			
6	6	6	6	6	6	6	6	6			
7	7	7	7	7	7	7	7	7			
8	8	8	8	8	8	8	8	8			
9	9	9	9	9	9	9	9	9			
10	10	10	10	10	10	10	10	10			
11	11	11	11	11	11	11	11	11			
12	12	12	12	12	12	12	12	12			
13	13	13	13	13	13	13	13	13			
14	14	14	14	14	14	14	14	14			
15	15	15	15	15	15	15	15	15			
16	16	16	16	16	16	16	16	16			
17	17	17	17	17	17	17	17	17			
18	18	18	18	18	18	18	18	18			
19	19	19	19	19	19	19	19	19			
20	20	20	20	20	20	20	20	20			
21	21	21	21	21	21	21	21	21			
22	22	22	22	22	22	22	22	22			
23	23	23	23	23	23	23	23	23			
24	24	24	24	24	24	24	24	24			
25	25	25	25	25	25	25	25	25			
26	26	26	26	26	26	26	26	26			
27	27	27	27	27	27	27	27	27			
28	28	28	28	28	28	28	28	28			
29	29	29	29	29	29	29	29	29			
30	30	30	30	30	30	30	30	30			
31	31	31	31	31	31	31	31	31			

Figure 20: 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 21)

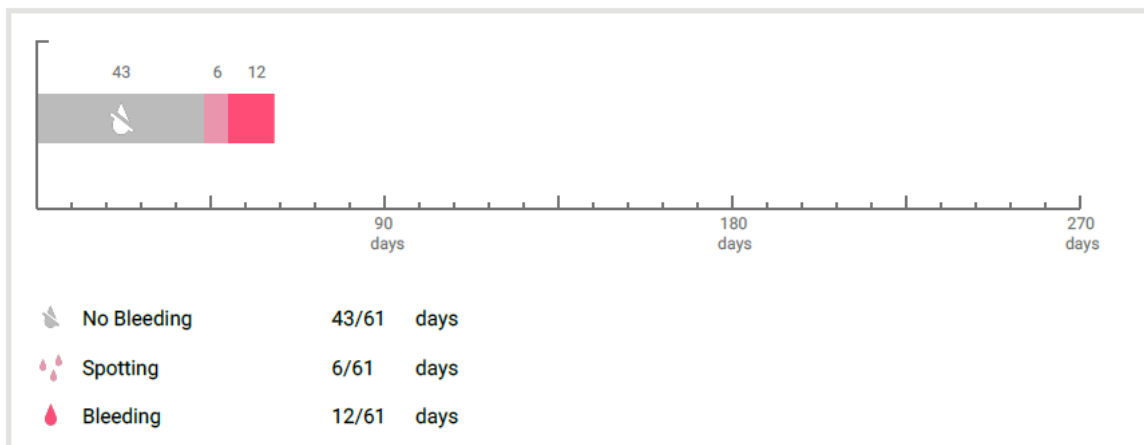


Figure 21: Report chart

- 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.

12 Guide

The Guide section (Figure 22) is accessible from the menu toolbar by pressing on the item “Guide” or from the Home screen by pressing on one of the Guide Element buttons on the bottom of the screen.

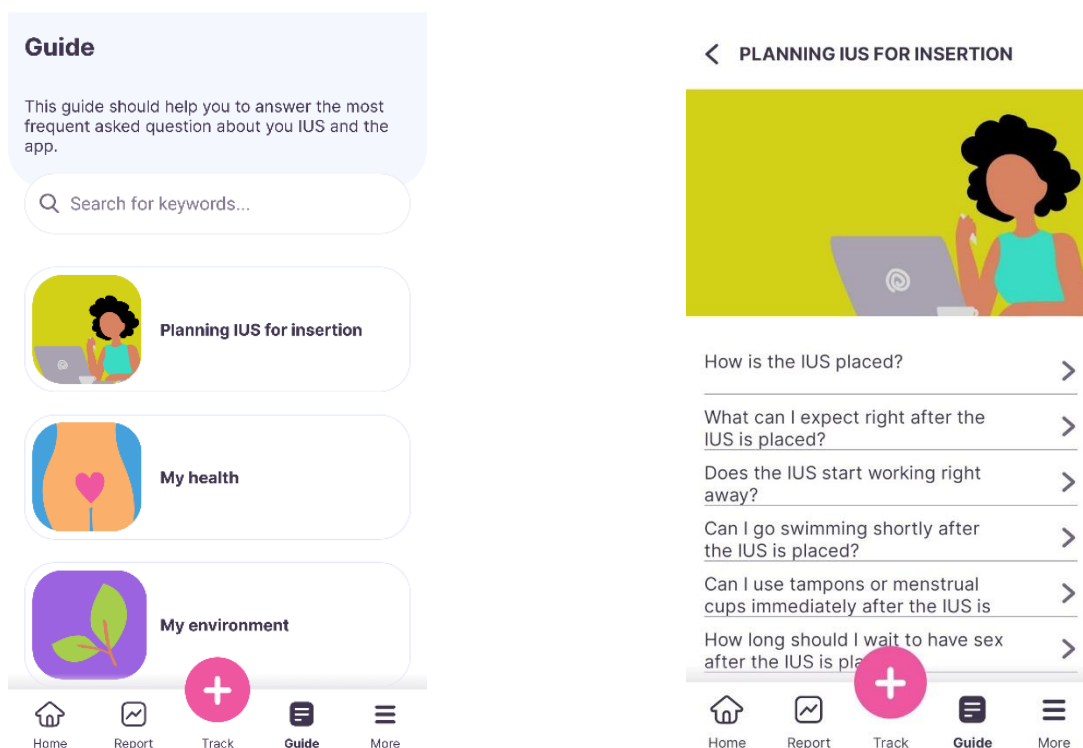


Figure 22: Guide section

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. Furthermore some answers include videos and links for additional information. Those videos or links will navigate you out of the app. Therefore you have to confirm the opening of the video or link.

12.1 Searching in the Guide section

Atop of your guide categories, you can find a search bar. You can enter terms to easily find information.

As soon as you tap on the search bar in, you can enter your desired search term and the results will be displayed below immediately as long as at least three characters have been entered (Figure 23).

In case that no results were found for the entered 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 guide topics, simply tap on the little “x” within the search bar or in case that no results were found on the text link.

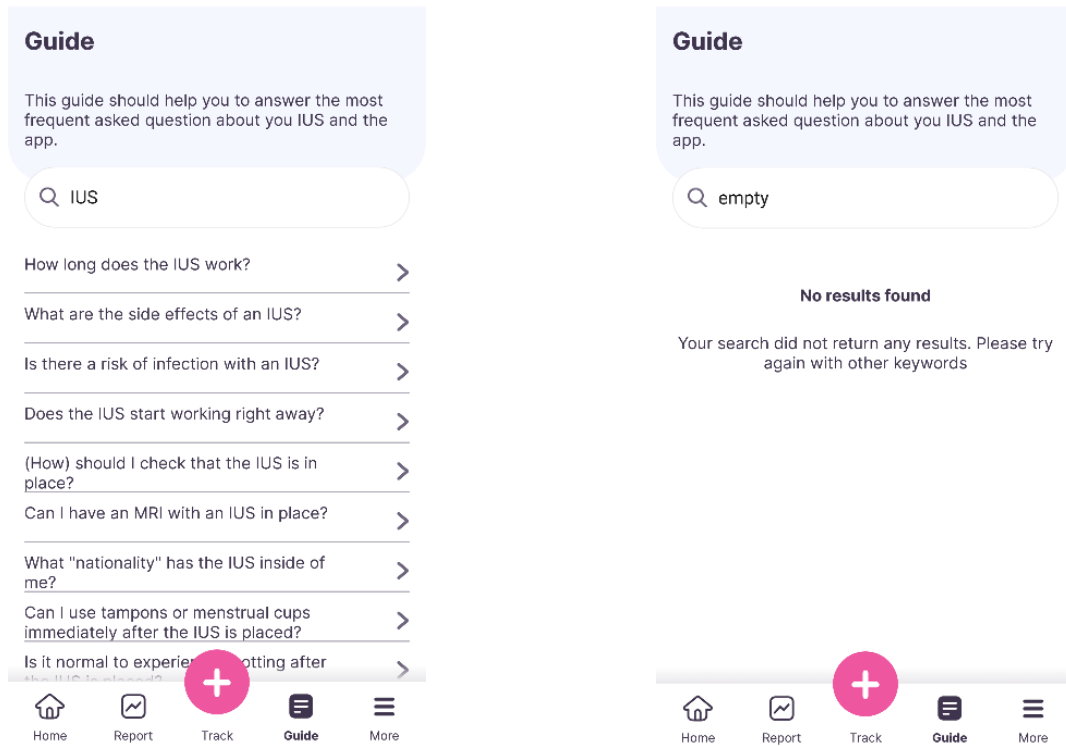


Figure 23: Search results

13 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 from 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.



Note:

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

13.1 Scan via QR-Code

By default, the MyIUS app will start with the process “Scan via QR-Code”. The app will open a screen, where you can initiate the scanning by pressing on the “Scan code” button. 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.

If you allowed the access to your phone’s camera, you could see the camera feed of the MyIUS Card setup screen to scan the QR code on your IUS folding box (Figure 24).



Figure 24: 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.

13.2 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.

1. By pressing on “Enter Batch number manually” at the bottom of the MyIUS Card setup screen, the app will forward you to the MyIUS Card manual screen.
2. 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 25.
3. 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.
4. 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.



Figure 25: Batch number on folding box pop-up

13.3 Create MyIUS Card

If you press on the button “MyIUS Card” on top of the More Menu  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).

13.3.1 MyIUS Card Overview

You can access the overview via the Profile screen by pressing on the button “MyIUS Card”. The app will display the MyIUS Card screen (Figure 26). Your MyIUS Card shows your IUS, the batch number and the placement and removal dates.

Your IUS is shown according to the entered code during the authentication after the first launch of the app.

When you select the edit option on the MyIUS Card, the app will direct you to the profile screen, where you can edit the batch number. The latest day of removal is automatically provided according to your IUS and your placement date and cannot be adjusted manually.

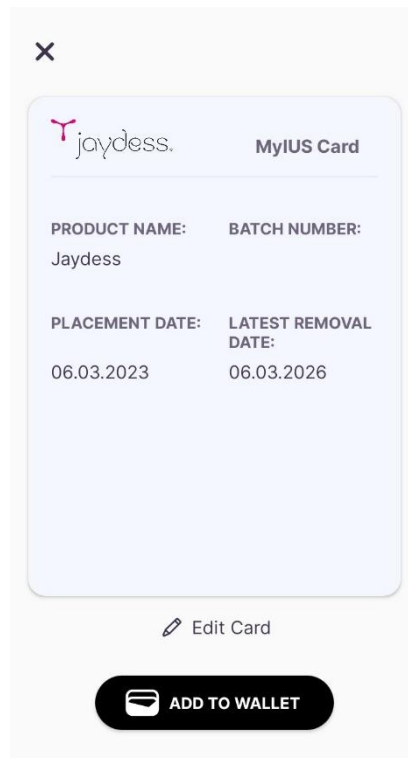



Figure 26: MyIUS Card screen

13.3.2 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 26) 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.

14 Profile screen

The Profile screen is accessible from the More Menu  by pressing on the item “Profile”.

The Profile screen contains the following information and options:

- Username
- IUS Placement date
- Batch number
- Date of Birth
- Weight
- Height
- Country
- Previous contraception
- Pregnancies
- Births

You can set or modify your profile information by selecting a profile field. The settings will automatically be saved when you tap outside the field.


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 13 for more information about the processes.



Note:

You can also edit the placement date on the profile screen. If you want to change the placement date, you have to confirm the change. When you confirm to set a new placement date, all of your previously set data will be deleted.

15 Settings

The Settings screen (Figure 27) is accessible from the More Menu , by pressing on the item “Settings”.

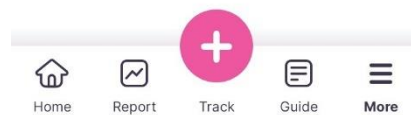


Figure 27: Settings screen

15.1 How to export data

Further details about how to export your data can be found in the chapter Export/Import of App-Data.

15.2 How to change the app icon

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). 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.

16 Reminders

Notifications can be reminders or warnings displayed by the app. The app can display system notifications and internal notifications.

The app allows you to set the time for the daily reminder for bleeding entries on the “Reminder” screen, which can be accessed via the More Menu ☰.

16.1 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 reminder screen on the daily tab (Figure 28). 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.

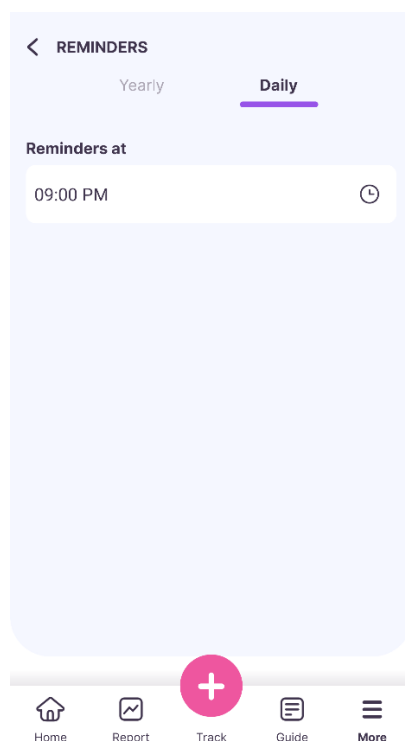


Figure 28: Reminders screen – Daily Reminders



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.

16.2 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.

16.3 Checkup 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 gynecological cancer
- Early detection of breast cancer

The overview of these reminders can be found on the Reminder screen for checkup reminders (Figure 29).

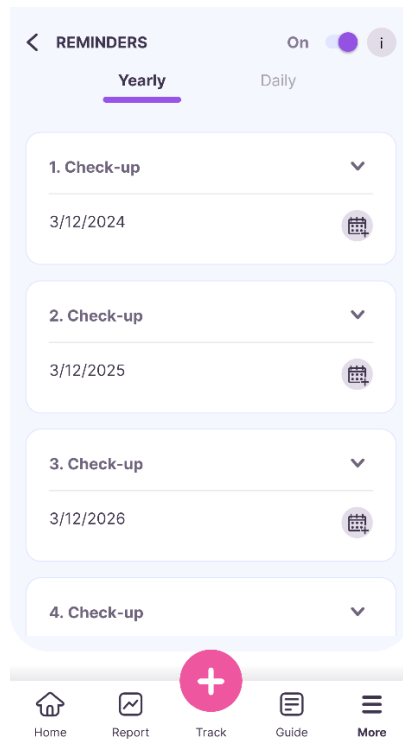


Figure 29: Reminders for check-ups

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.

16.3.1 Additional Information

The checkup reminder section has an information icon (Figure 30) displayed on the top right.



Figure 30: Information icon

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


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

17 User Manual

The app's user manual can be read and downloaded as PDF file, by pressing on the "User Manual" item on the More Menu.

The user manual will be provided in the language set on the smartphone, if supported.

18 Technical Support

The Support screen (Figure 31) is accessible from the More Menu  by pressing on the item "Technical Support". This screen shows the contact information of the technical support.

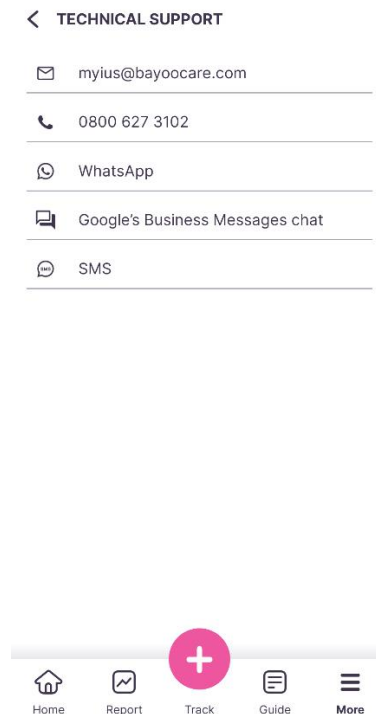


Figure 31: Support screen



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 About your IUS screen.

18.1 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.

18.2 Hotline

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

18.3 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.


18.4 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.

18.5 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.

19 About your IUS

The About your IUS screen (Figure 32) is accessible from the More Menu  by pressing on the item “About your IUS”. This screen shows the IUS product information, the patient brochure, if available in the country, and the option to report IUS side effects.

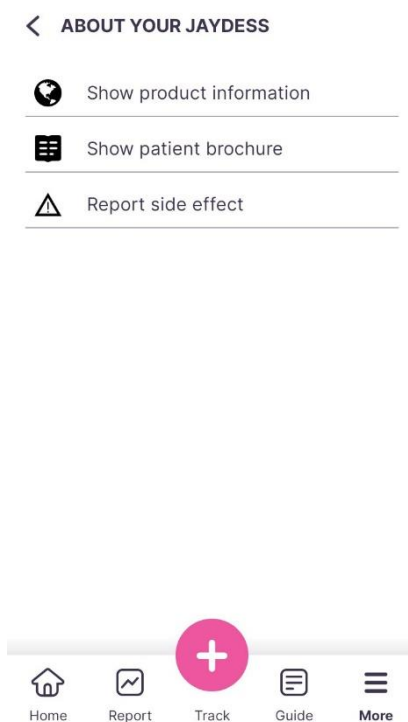


Figure 32: About your IUS screen

19.1 IUS product information

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

19.2 Patient brochure


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

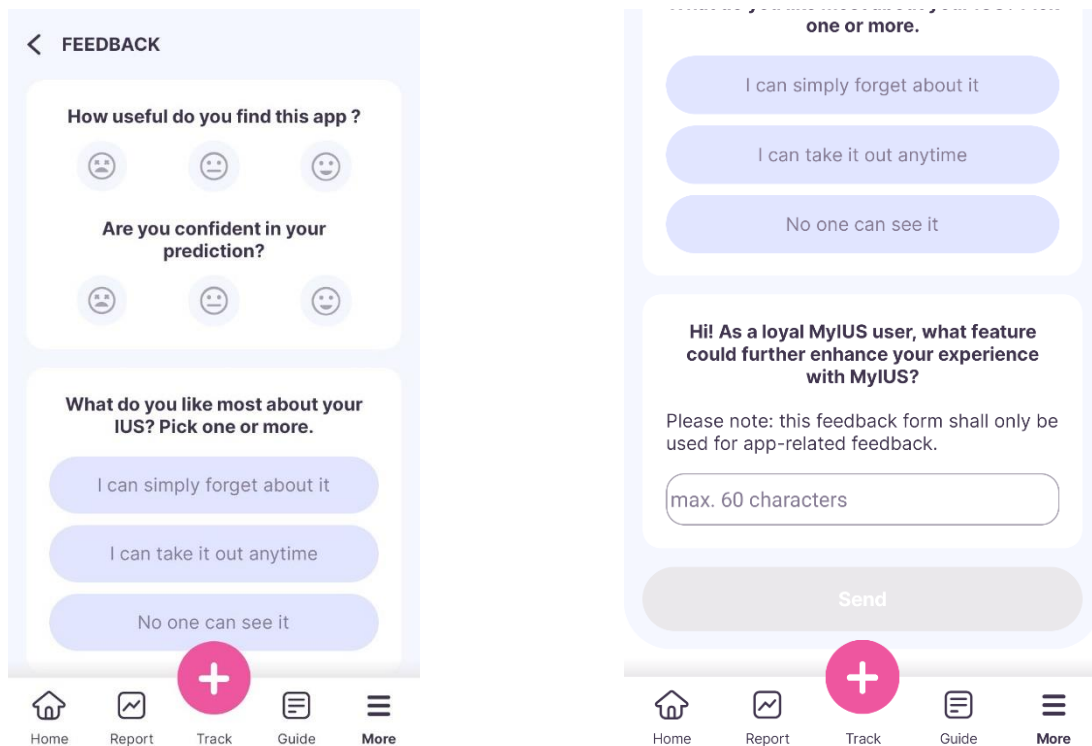
19.3 Reporting a side effect (Pharmacovigilance)

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. 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.

20 Give feedback

The Feedback screen (Figure 33) is accessible from the More Menu  by pressing on the item “Feedback”.



FEEDBACK

How useful do you find this app ?

Are you confident in your prediction?

What do you like most about your IUS? Pick one or more.

I can simply forget about it

I can take it out anytime

No one can see it

Hi! As a loyal MyIUS user, what feature could further enhance your experience with MyIUS?

Please note: this feedback form shall only be used for app-related feedback.

max. 60 characters

Send

Home Report Track Guide More

Figure 33: Feedback Questionnaire


Four questions can be answered on the Feedback screen, each providing different answer options, displayed as smileys, multiple choice buttons or a free-text field.

You can add maximum 60 characters into the feedback field, the app shows you the remaining characters while typing in.

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.

21 Imprint

The Imprint screen (Figure 34) is accessible from the More Menu  by pressing on the item “Imprint”. You can access the Imprint about the manufacturer.

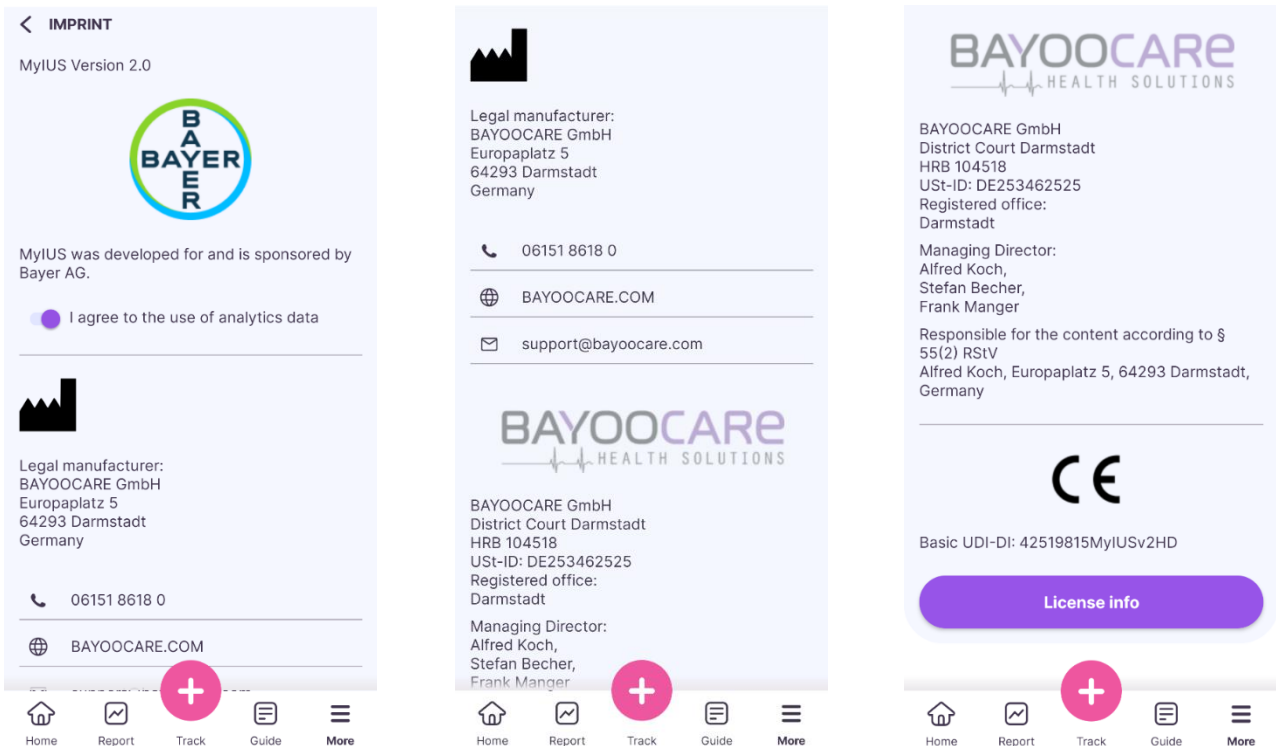


Figure 34: Imprint screen

21.1 Imprint

The Imprint section displays the following information:

- App version
- App sponsor logo and information
- Legal Manufacturer logo and information
- Approval numbers
- MyIUS CE Marking
- UID number
- License information of used libraries as applicable

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.

22 Terms of use

The Terms of use can be read 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.

23 Data privacy

The Data Privacy Statement can be read 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.



Note:

When the data privacy policy is updated in your country, the app will request you to renew your consent.

Without the consent, the app is no longer usable.

23.1 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.