



User Manual

BAYOOCARE

MyIUS-App

Release Date: 2021-12-03



PP-KYL-ZA-0114-1

Table of content

1	Symbols	5
2	Table of acronyms & definitions	6
3	Introduction	7
3.1	Legal manufacturer	7
3.2	Scope	7
3.3	Contraindications	7
4	Expected clinical benefit	8
5	Precautionary measures / safety instructions	9
6	Quick start	10
6.1	App icon	10
6.2	Splash screen	10
6.3	Menu & toolbar	11
6.4	Main navigation	12
6.5	General warnings	13
6.6	Info screens	14
6.7	Pop-ups	14
6.8	Terms of use	15
6.9	Data privacy	15
7	First time use	16
7.1	Operating system (OS) check	16
7.2	Authorisation	17
7.2.1	Accepting terms of use	19
7.2.2	Accepting data privacy	19
7.3	Start setup configuration	20
7.4	Alias	21
7.5	Setup introduction	22
7.6	Introduction videos	23
7.7	Baseline parameters	24
7.7.1	Birth Date	25
7.7.2	Country	26
7.7.3	Your body	27
7.7.4	Previous contraceptive method	28
7.7.5	Pregnancy & births	29
7.7.6	Prevention Check-Up	30
7.8	Placement date of your IUS	31

7.9	After confirming the placement data screen	32
8	Export/Import of App-Data	33
8.1	Export	33
8.2	Import.....	34
8.2.1	Import Scanner	34
8.2.2	Successful Scanning	35
8.2.3	Failed Scanning.....	35
9	Home screen	37
9.1	Progress area.....	38
9.2	Weekly calendar screen	38
9.3	Monthly calendar screen.....	39
9.4	How to add or edit bleeding patterns	41
9.4.1	Bleeding pattern before prediction.....	42
9.4.2	Bleeding pattern after prediction.....	42
9.5	Prediction	43
9.5.1	Preconditions for a prediction.....	43
9.5.2	Prediction without missing days	44
9.5.3	Prediction with missing days	45
9.5.4	Prediction not allowed	46
9.5.5	Ask for a prediction	47
9.5.5.1	Step 1.....	47
9.5.5.2	Step 2.....	48
9.5.5.3	Step 3.....	49
10	Profile screen.....	50
11	Settings screen	52
11.1	How to set a notification	52
12	Notifications	53
12.1	System notifications	54
12.2	App internal notifications.....	54
12.2.1	Warnings about data.....	55
12.2.2	Warnings about app usage.....	55
12.3	Reminders	56
13	Your report.....	58
14	Gems	62
15	Media	65
16	FAQ	66
16.1	About your IUS	67
16.2	Before and after placement	67
16.3	Living with your IUS.....	67
16.4	How to use MyIUS.....	68
17	Support	69

17.1	Email.....	70
17.2	Hotline.....	70
17.3	App user manual	70
17.4	IUS user manual	70
17.5	Give feedback.....	71
18	Legal notice	74
18.1	Terms of use.....	74
18.2	Data privacy.....	75
18.3	Imprint.....	75

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
kg	Kilogram is a unit of mass used in the metric system

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

BAYOOCARE GmbH

Europaplatz 5

64293 Darmstadt

Tel: +49(0) 61 51 - 86 18 -0

E-Mail: info@bayoocare.com

Web: bayoocare.com

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 total.

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® or 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 artificial intelligence (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 IUSs:

- Kyleena®
- 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 Splash screen

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

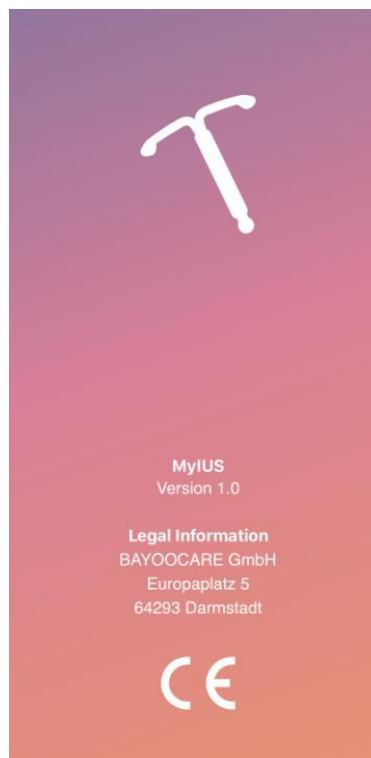




Figure 2: Splash screen at app start

6.3 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

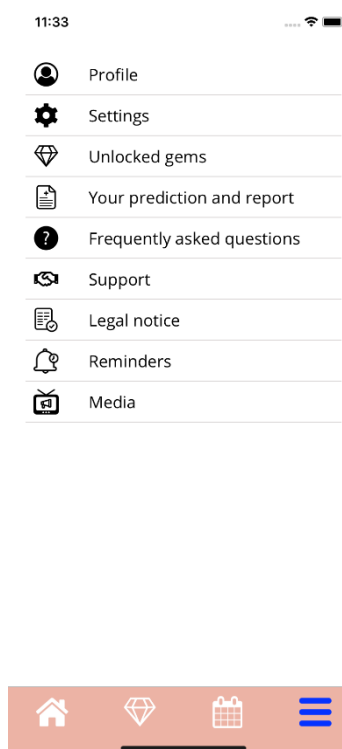


Figure 3: Burger menu

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.

6.4 Main navigation

You can navigate only from one screen further to the next one. The app does not allow you to come back to the previous screen, except for the screens belonging to the Baseline parameters. All these screens have a white arrow button on the left, as displayed in Figure 4.

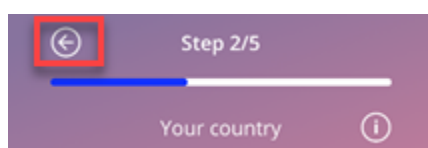


Figure 4: Back icon

By pressing on the back button from a Baseline parameter screen (except Age screen), you can go back to the previous parameter screen.

6.5 General warnings

Warning pop-ups, such as the one displayed in Figure 5 will inform you about any issues with the App or with your data.

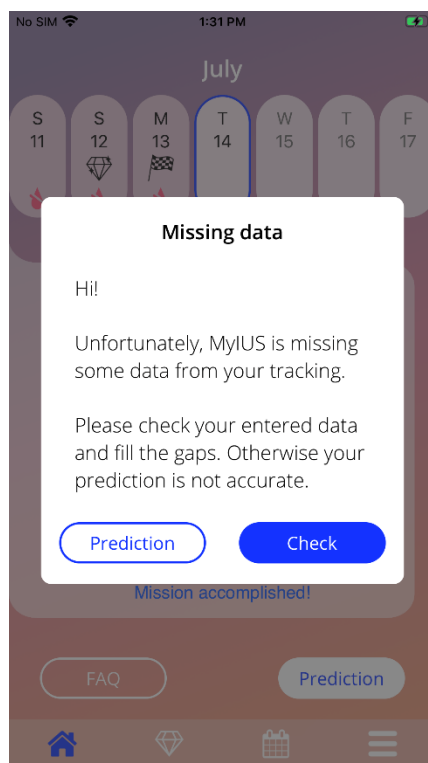


Figure 5: Warning message

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.

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 realised further

6.6 Info screens

The Progress Area on the Home Screen and all the screens of Baseline parameters have a white information icon as displayed in Figure 6.

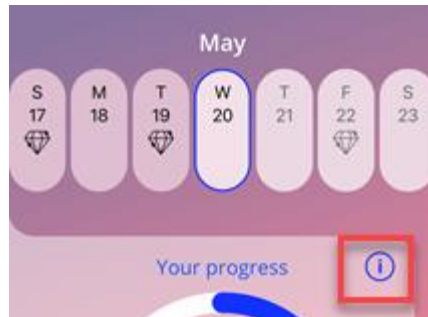


Figure 6: Information icon

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

You can close this screen by pressing again on the information icon.

6.7 Pop-ups

Pop-up, as the one displayed in Figure 7, 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 used are accessed
- When the privacy statement is accessed
- When consents for further usage are needed

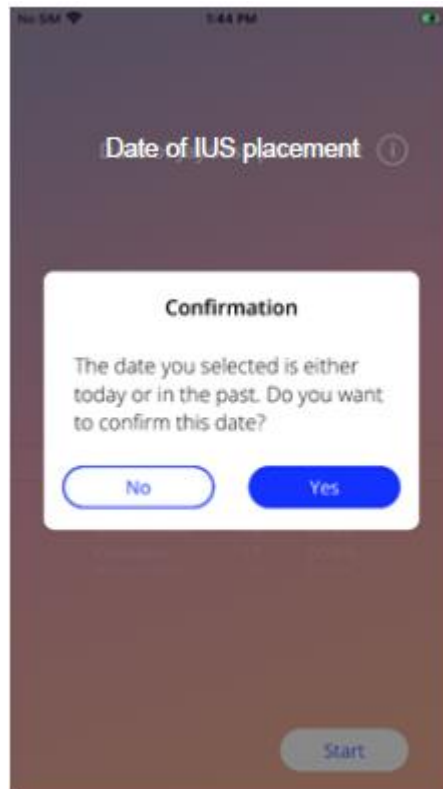


Figure 7: Pop-up message

6.8 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 Authorisation 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.

6.9 Data privacy

The Data Privacy Statement can be read and download as PDF file, by pressing on the blue link “Data Privacy Statement” on the Authorisation screen (Figure 10). The Data Privacy Statement will be provided according to the region and the language set on the smartphone. If these are not supported, an English version from Great Britain of the Data Privacy Statement will be displayed.

7 First time use

7.1 Operating system (OS) check

Every time the app is launched, the operating system 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.

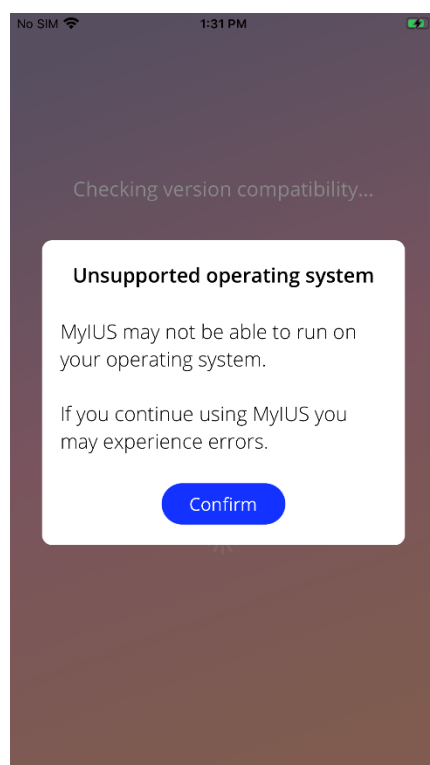


Figure 8: Pop-up message

In case the OS is not supported because it is too new, the app can be further used after giving your consent on your own risk.



Note:

If this is the case, certain functionalities might not react in the expected behavior.

In case the OS is not supported because it is too old, the app cannot be used at all.

7.2 Authorisation

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 Authorisation screen (Figure 10).

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

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



Note:

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



Advice:

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

If authorisation is successful, then this screen will not be displayed anymore next time when you start the app and the app will be considered “unlocked”.

In case of a failure, a pop-up message will appear telling you that the introduced code is not correct (Figure 9).

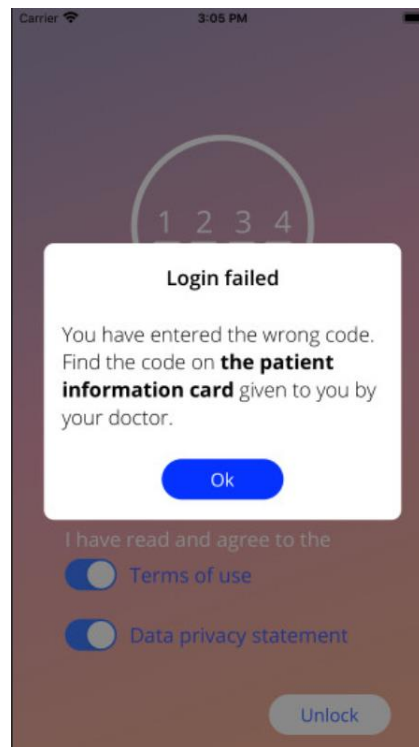


Figure 9: Login failed



Note:

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

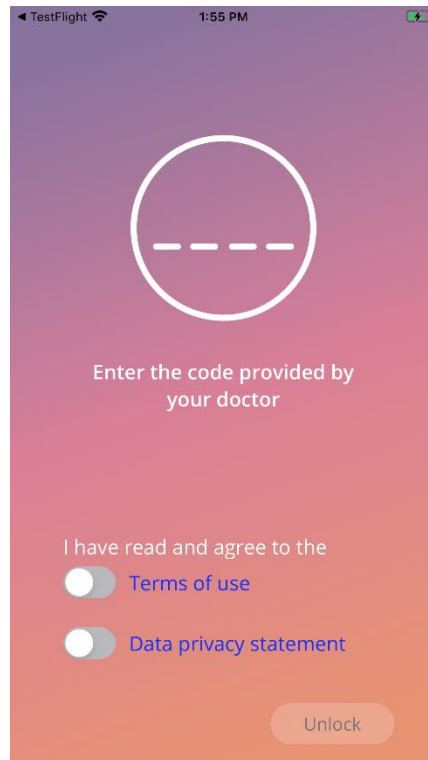


Figure 10: Authorisation screen

7.2.1 Accepting terms of use

In order to proceed to the next screen, the Terms of Use must be read and accepted by pressing on the first 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 Accepting data privacy

In order to proceed to the next screen, the Data Privacy Statement must be read and accepted by pressing on the second toggle from Figure 10. Additionally, the Data Privacy Statement can be read and can be downloaded as PDF file, by pressing on the blue link “Data Privacy Statement”.

7.3 Start setup configuration

After successful authorisation, the First Time Use wizard provides information about the IUS and the usage of the app. It starts with the Setup screen (Figure 11).

On this screen, the First Time Use setup can be skipped by pressing on “Skip” button from the bottom left part of the screen. In this case the Start Setup screen will be displayed again at the next app launch unless you will get to the Home Screen. You can complete your data later by accessing the Profile section.

The button “Start” from Figure 11 opens the Alias screen (Figure 12).

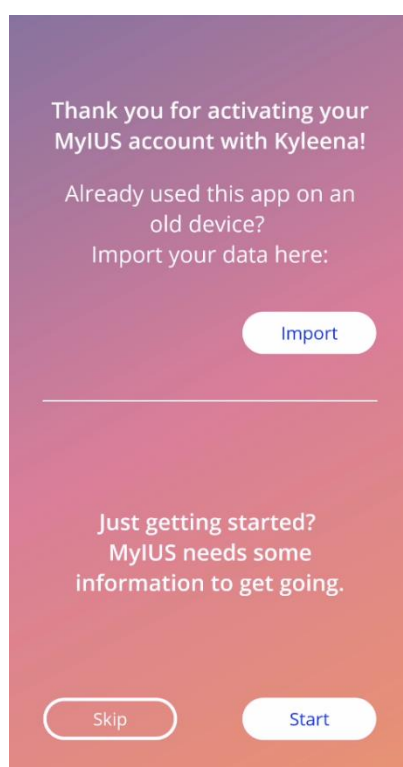


Figure 11: Start setup screen

7.4 Alias

The Alias screen (Figure 12) allows you to enter a username of maximum 15 characters. If the desired username has more than 15 characters, 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 from the Profile section. The “Continue” button is enabled in this case and you can also skip this screen.

The button “Continue” opens the Introduction screen (Figure 13).

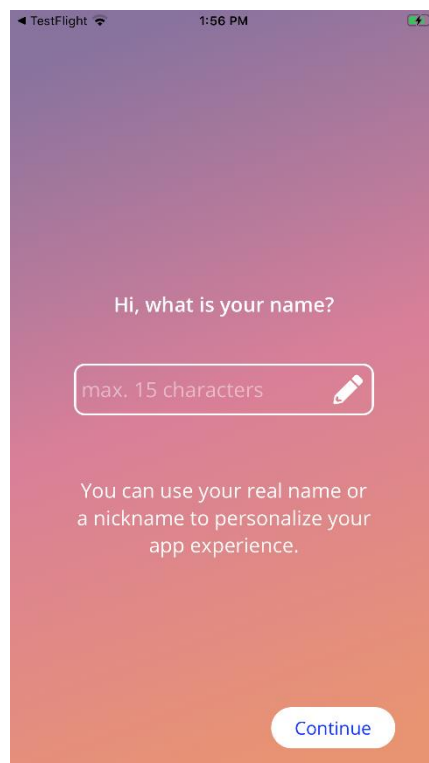


Figure 12: Alias screen

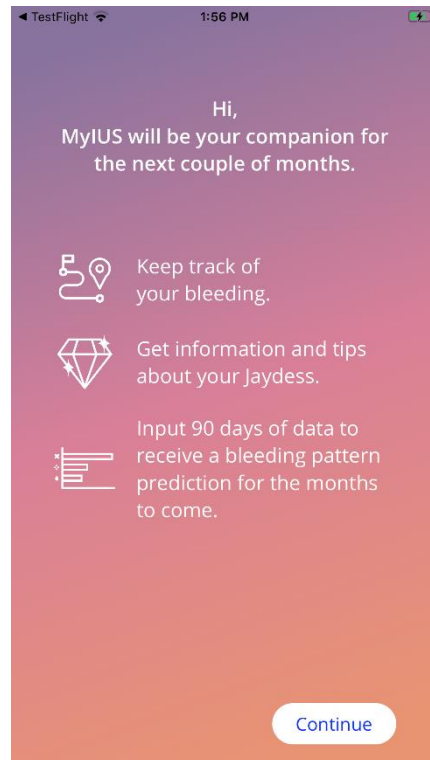


Figure 13: Introduction screen

7.5 Setup introduction

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

The “Continue” button opens the Video screen (Figure 14).

7.6 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 white arrow in the upper right corner of the screen opens the Start Baseline screen (Figure 15).



Figure 14: Video screen

7.7 Baseline parameters

In order to get an accurate prediction of your future bleeding, the app needs some information about you (Baseline parameters). Further is a questionnaire consisting of 5 or 6 steps, depending on the country you have selected, and starts with the Start Baseline screen (Figure 15).

The Baseline questionnaire can be also skipped by pressing the “Skip” button. When pressing on “Skip”, you will be forwarded to 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 this 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 baseline parameters needed for your future prediction is visible in the unlocked gems section. You will be able to display this gem also when you complete your baseline parameters at a later point in time from the Profile section.

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

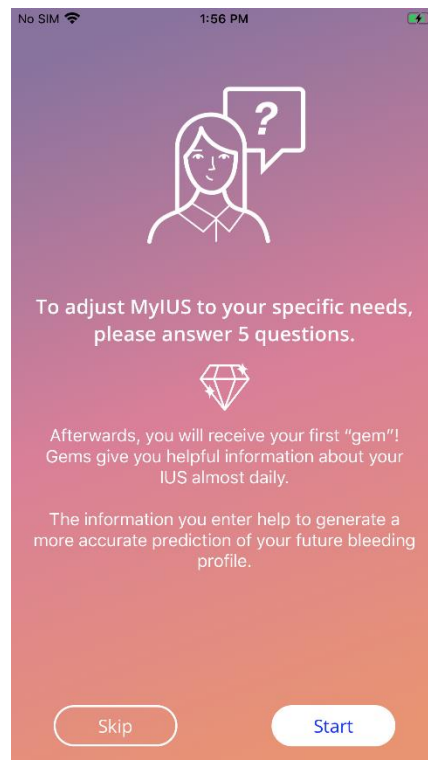
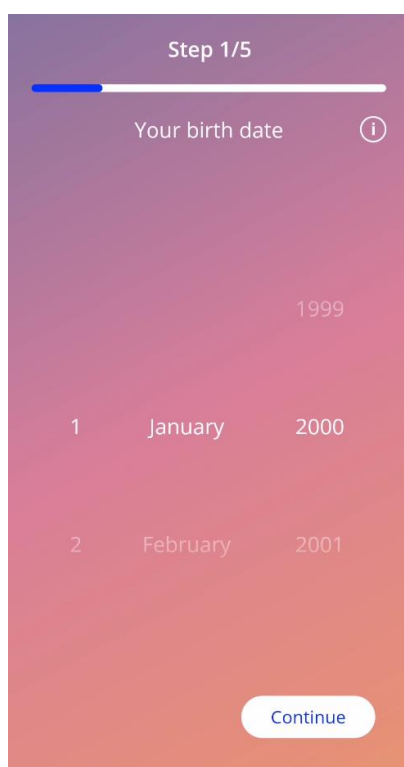


Figure 15: Start baseline screen

7.7.1 Birth Date

This is the first screen of the questionnaire. You are asked to enter your birth date. The ages supported are between 16 and 60 years. The default date is 01.01.2020.

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 16: Birth date screen

7.7.2 Country

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

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

By pressing on the back button (white arrow), you can go back on the Age 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.

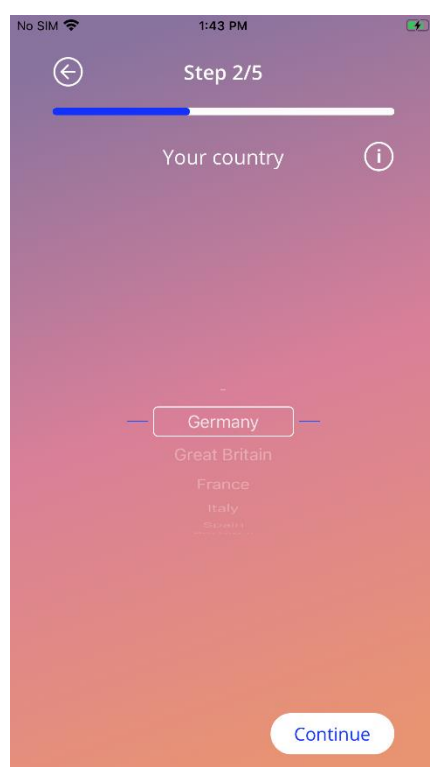


Figure 17: Country screen

7.7.3 Your body

In this screen you are asked to enter your weight, in kg or lbs. and your height in cm or ft. In order to enable the “Continue” button and to proceed to the next screen you will have to select the value from the two pickers. By default, there is no value preselected.

You can get detailed information about how the body size parameters affect the prediction of your future bleeding, 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 'Step 3/5' titled 'Your Body'. It features two vertical pickers for 'Weight kg' and 'Height cm'. The 'Weight kg' picker has values from 63 to 71, with 67 selected. The 'Height cm' picker has values from 165 to 173, with 169 selected. A 'Continue' button is at the bottom right. The screen is titled 'Step 3/5' and 'Your Body'.

Weight kg	Height cm
63	165
64	166
65	167
66	168
67	169
68	170
69	171
70	172
71	173

Figure 18: Body screen

7.7.4 Previous contraceptive method

The app needs also to know which contraceptive method was previously used. At least one option should be selected in order 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 method” is selected.



Note:

If you already have selected other options than “No method” and after this you select this option, the previous selected options will be automatically unselected.

“No method” option cannot be used in combination with other option.

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

By pressing on the back button, you can go back on the “Your body” screen.

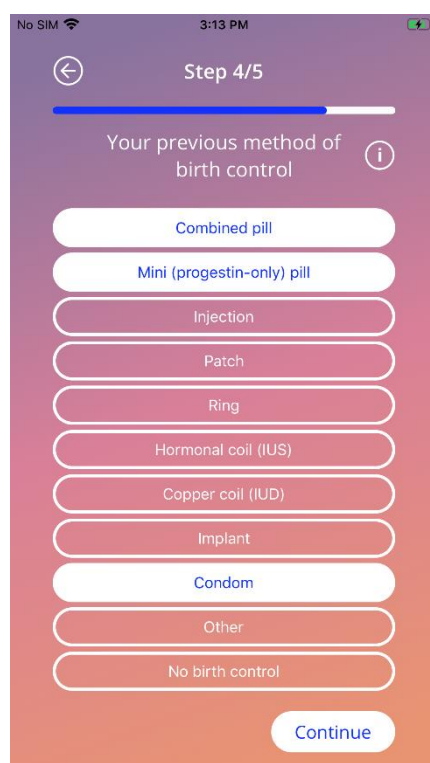


Figure 19: Contraceptive method screen

7.7.5 Pregnancy & births

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



Note:

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

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

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

Figure 20: Pregnancy screen

7.7.6 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 21). The default date is today's date.



Note:

You cannot enter future screenings.

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.

← Schritt 6/6

Letzte Vorsorge ⓘ

27 September 2019

28 Oktober 2020

29 November

Weiter

Figure 21: Last prevention check-up screen

7.8 Placement date of your IUS

The next screen, after the questionnaire containing the baseline parameters is the Placement date screen.

In order to get a prediction of future bleeding, the app needs to know the exact placement date of your IUS. You can set also a date in the past, up to a maximum of 90 days in the past. In this case, you will be asked in a pop-up right away to confirm the placement date or to change it by cancelling the pop-up.

By default, the “today” date will be preselected.

The placement date set can be also skipped and re-accessed or edited through the Profile section of the Main Menu.

When the placement date is reached or passed, the app asks the user at launch to confirm the placement date or, alternatively, to select another date.

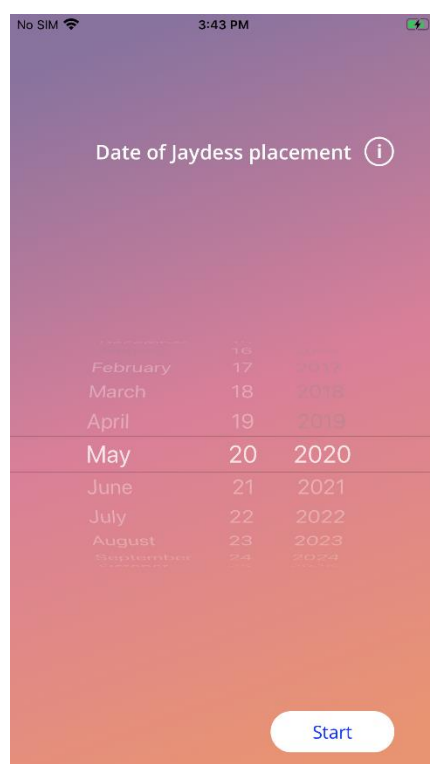


Figure 22: Placement date screen

7.9 After confirming the placement data screen

After setting a placement date and confirming it, the following screen will appear.

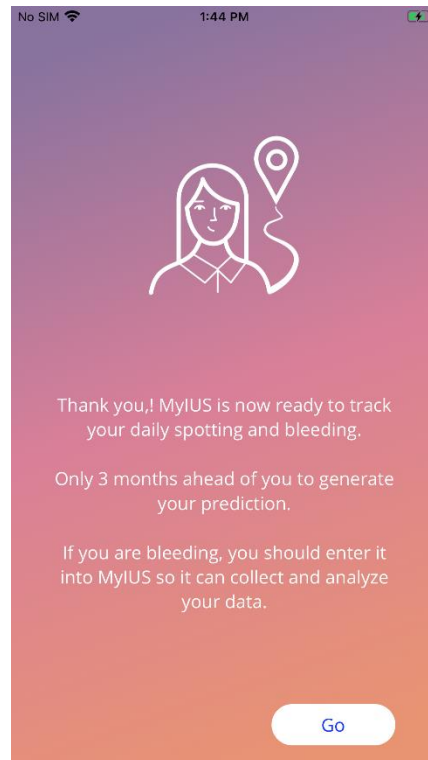


Figure 23: After confirming the placement data screen

By pressing on “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 click upon the menu icon and select settings, the app displays the button to export user data to another device. When clicked upon the “**Export button**”, the export process is initiated.

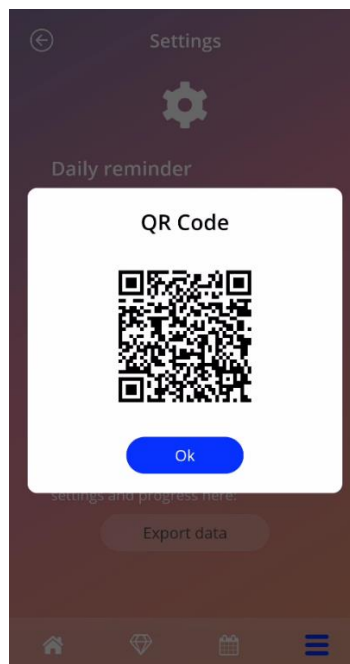


Figure 24: Export Screen

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 utilised by another end-device in order to import all relevant user data. It shall be granted that the brightness of the displaying end-device needs to be high enough, in order to guarantee 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 have to 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 before you are being asked to enter baseline information, the app provides the option to import your data. Click the “**Import-Button**” to initiate the import-process.

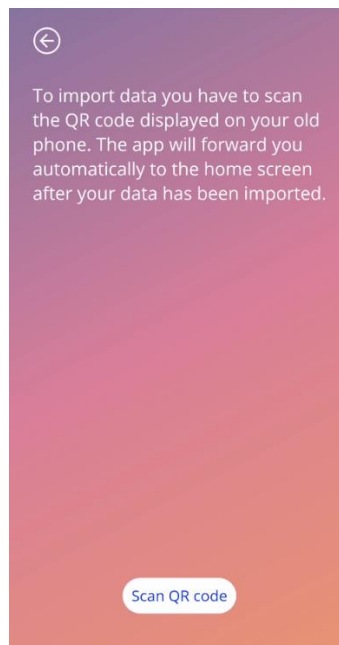


Figure 25: Import Screen

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, the app will automatically open the devices camera and use it as a QR-code-scanner. To access a camera, you must first allow the app to do so. You can change this in the system settings of your device if you have previously denied it.

Position your mobile device and your camera in a way, that the to be read QR-code is visible within the camera feed. 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 was successful or failed, the app will give you a feedback about the state of the scanning. Should no feedback be displayed although the camera was opened, 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 has a correct format and 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.

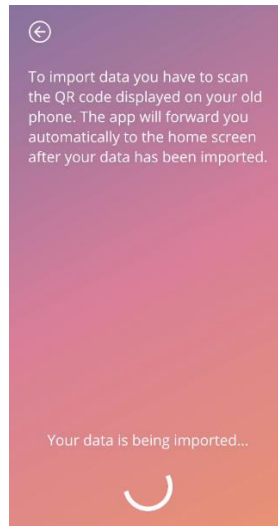


Figure 26: Scanning Successfull Screen

8.2.3 Failed Scanning

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

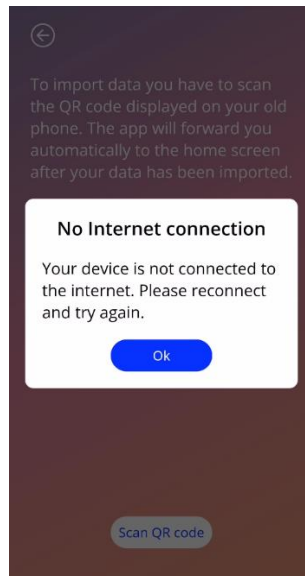


Figure 27: Scanning Failed Screen

9 Home screen

The Home screen is the main screen of the app. Here you will be forwarded every time you will start the app, after configuration.

The Home screen (Figure 28) consists of three sections:

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

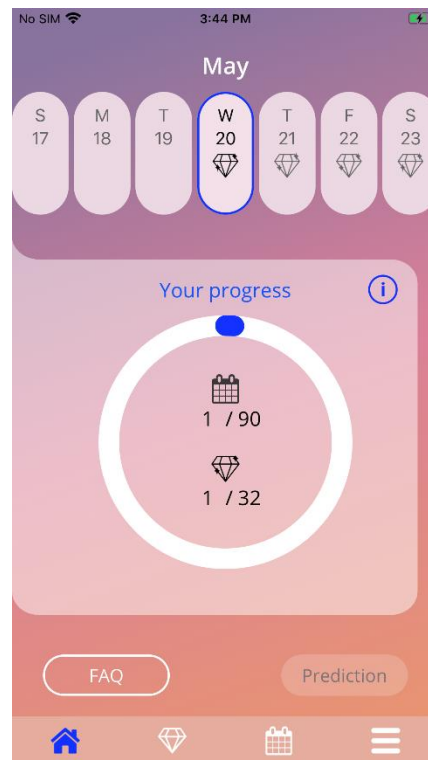


Figure 28: Home screen

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.

Every day, a new proportion of the arc of the circle will become blue, taking the day number that you are in into consideration.

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 0.

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

- The day number that you are in after your IUS placement date from the 90 days
- The number of the unlocked gems from the total available

9.2 Weekly calendar screen

The week extract having the “today” day in the middle is displayed on the top of the Home Screen. Each day might show information related to the already introduced bleeding patterns, the prediction date and the possible gems.

Swiping to the left and right is also possible in the weekly extract with exceptions:

- When no placement date is set, the swiping functionality left, and right is disabled and only the current extract is visible showing the “today” date in the middle
- When reaching the week of the placement date, swiping to the right is not possible anymore
- Swiping left dates in the future is not possible
- When one or more days are selected without having a bleeding value set

By selecting one or more days from the weekly extract will allow you to 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 in the future are not selectable and are also greyed out.

The gem icon display means that there is possible to receive one gem. Please see the conditions of receiving a gem in chapter 13 Gems.

9.3 Monthly calendar screen

The Monthly calendar screen (Figure 29) shows by default the current month. You can access it by pressing on the “Calendar” icon on the Navigation Toolbar from the Home Screen. When pressed, the calendar opens at the current month. Each day shows information related to already introduced bleeding profile, the prediction date and the possible gems.

In this case swiping functionality is possible in the past and in the future with no limits.

By selecting one or more days from the weekly extract will allow 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 and keeping the days from the previous one selected is not possible.

The days in the future are not selectable and are also greyed out.

The gem icon display means that there is a gem available. Please see the conditions of receiving a gem in chapter 14 Gems.

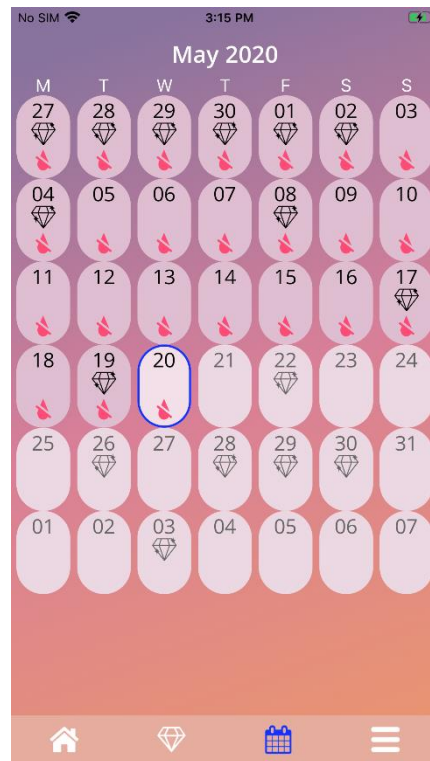


Figure 29: Monthly calendar screen

9.4 How to add or edit bleeding patterns

You can add or edit an existing bleeding pattern by pressing on one or more days at the same time on the weekly calendar or on the monthly calendar. When you select more days in the same time, the same selected bleeding pattern will be entered for all the selected days.

Three patterns can be selected:

- No bleeding
- Spotting
- Bleeding

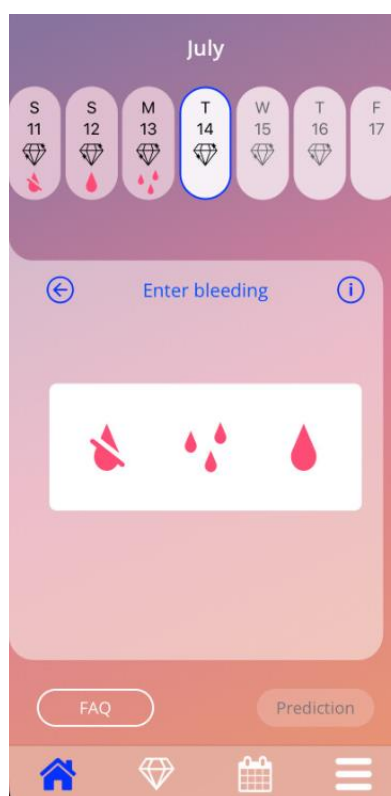


Figure 30: Bleeding pattern on home screen

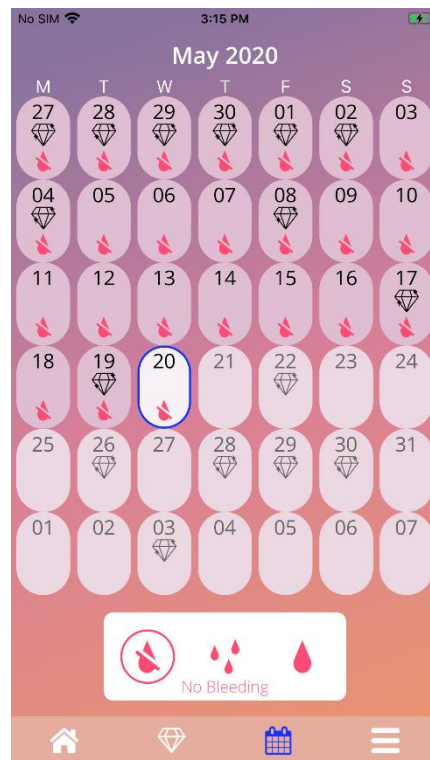


Figure 31: Bleeding pattern on monthly calendar screen

9.4.1 Bleeding pattern before prediction

In case no prediction of future bleeding is received, you can add or edit bleeding patterns only if a placement date is entered and confirmed. The selected days must be between the placement date and the current day.

9.4.2 Bleeding pattern after prediction

In case a prediction of future bleeding is received, and you have confirmed the app usage after the prediction received, 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.

9.5.1 Preconditions for a prediction

You can ask for a prediction if the following preconditions are met, in addition to the condition on the number of bleeding patterns entered:

- All the baseline parameters are set
- No previous prediction was received
- At least 90 days have passed since the placement date

90 days after the confirmed placement date and the bleeding pattern for this day is set, the app shall enable the “Prediction” button from the Home Screen (Figure 28).

9.5.2 Prediction without missing days

You can ask for a prediction for future bleeding if the preconditions in 4.5.1 are met and a bleeding profile is set for each day of the 90 days after the placement date.

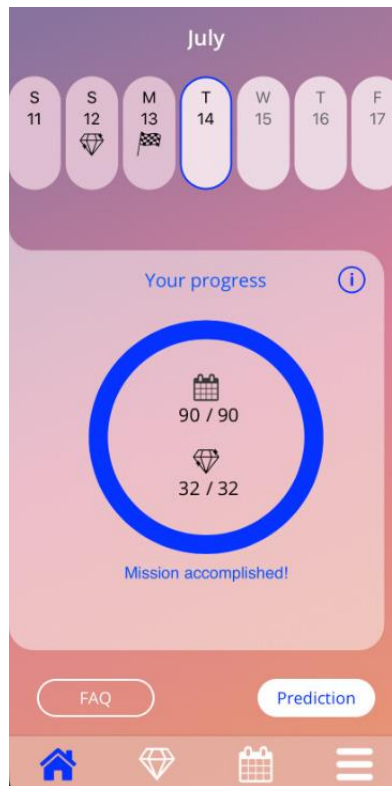


Figure 32: Prediction available screen

9.5.3 Prediction with missing days

You can ask for a prediction if at most 2 bleeding entries are missing, provided that the pre-conditions in 4.5.1 are met and the missing entries are not within the same 30 day time period over the 90 days post placement date.

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

You can enter the missing days by clicking on the “Check” button and then ask again for a prediction by following the whole workflow by pressing on “Prediction” button on Home Screen (Figure 28). By pressing on “Fill gaps” button, the monthly calendar will open at the month containing the first missing bleeding data starting from the confirmed placement date.

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



Note:

In this case, your prediction will not be as accurate as in the case of having the whole data completed and you will not be able to change the already introduced data afterwards or add the missing data at a later point in time.

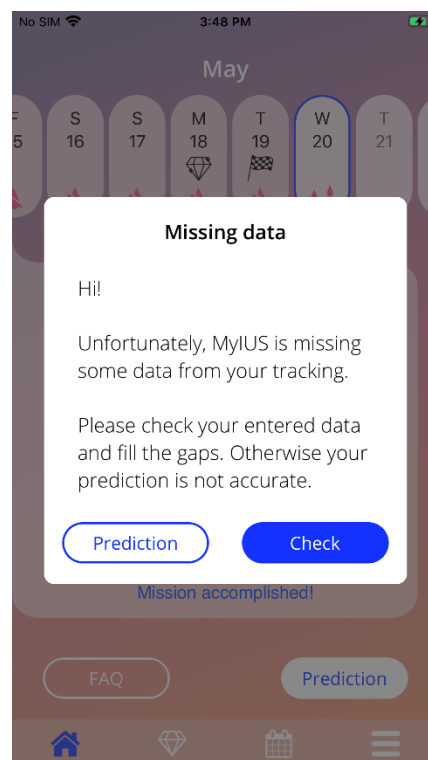


Figure 33: Missing day pop-up

9.5.4 Prediction not allowed

If within the 90 day period post the confirmed placement date, more than two bleeding patterns are missing, per 30 days, a pop-up, a pop-up is displayed, allowing you only to enter the missing bleeding patterns by opening the monthly calendar at the month containing the first missing bleeding data starting from the confirmed placement date.

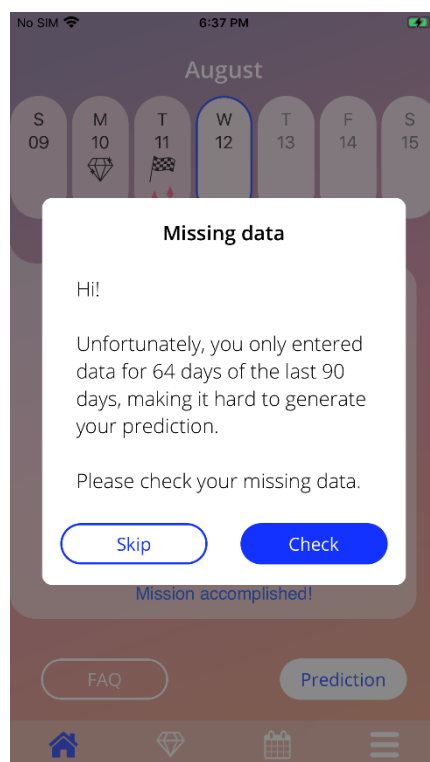


Figure 34: Too many missing data

9.5.5 Ask for a prediction

If the conditions for asking a prediction are met, you can ask for it by pressing on “Prediction” button on the Home screen (Figure 28).

9.5.5.1 Step 1

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

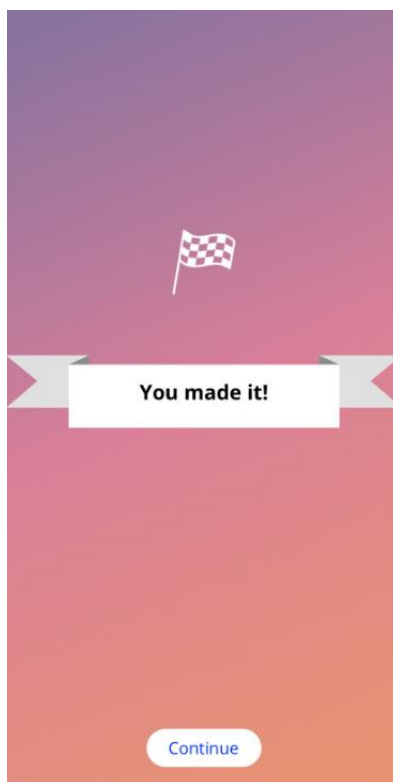


Figure 35: Prediction step 1

9.5.5.2 Step 2

This screen allows you to ask for the prediction, pressing on the “Generate your prediction” button.

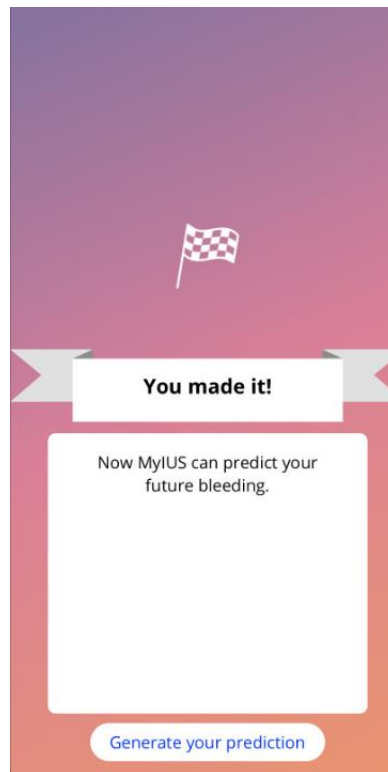


Figure 36: Prediction step 2

9.5.5.3 Step 3

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

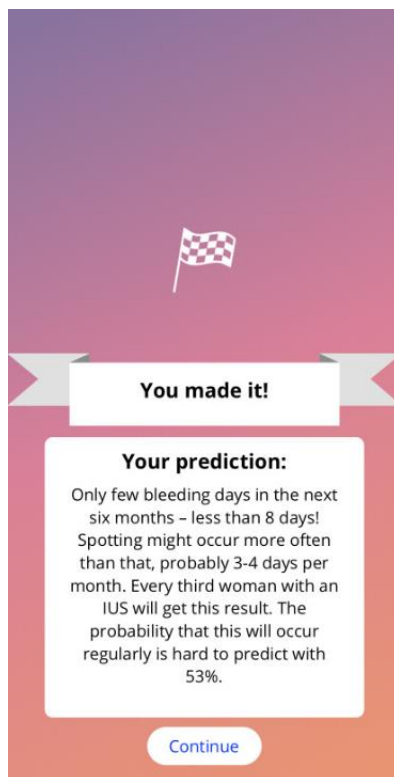



Figure 37: Prediction step 3

After receiving the prediction, the 90 days data used for it cannot be changed .

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

10 Profile screen

The Profile screen (Figure 33) is accessible from the Main Menu , pressing on the item “Profile”. It contains three sections:

- Username
- The placement date
- The baseline parameters

You can set or modify your username by selecting the proper textbox, set or modify the placement date (please refer to 3.8) and set or modify the baseline parameters (pressing on the pencil icon).

When accessing the Baseline parameters, the whole questionnaire will start again with the birth date screen (Figure 16). In case the data was already completed, it will be preselected and the “Continue” buttons will be enabled on all the screens.



Note:

You will have to go through all the screens from the questionnaire again in order to access the Profile screen again.

Profile options

Your chosen name

Jane Doe

Your IUS placement date


12/11/2020

Setup questions:

Your birth date	01/01/2000
Your body	30kg / 60cm
Your country	Great Britain
Your previous birth control	Ring
Your pregnancies and births	0/0

Figure 38: Profile screen

11 Settings screen

The Settings screen (Figure 39) is accessible from the Main Menu , by pressings on the item “Settings”.

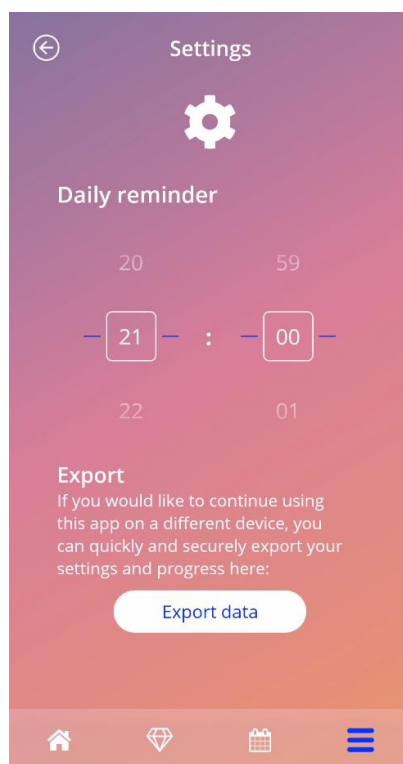


Figure 39: Settings screen

It allows you to set the time for the daily reminder related to entering the bleeding patterns and to export your data in order to import it in another app from another mobile phone.

11.1 How to set a notification

You can change the default reminder for the daily bleeding pattern (set by default to 9:00 PM), acting on the time picker on the screen. This reminder cannot be disabled, and the notification will appear on your mobile phone every day starting from the confirming of placement date until the prediction day at the set hour on this screen.

12 Notifications

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

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

The app can display system notifications and internal notifications.

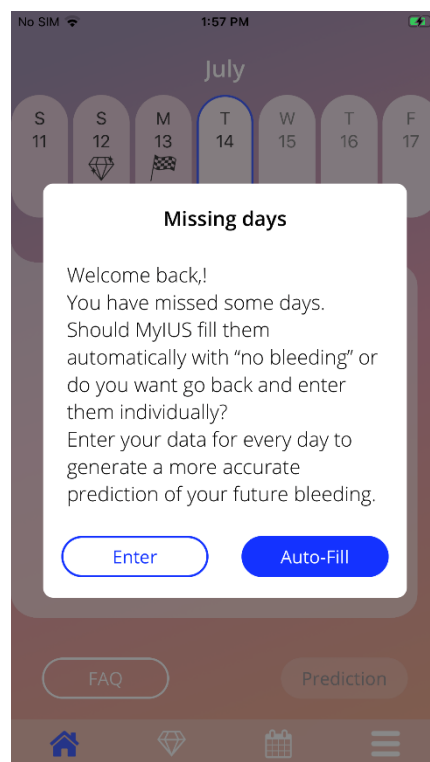


Figure 40: Reminder pop-up

12.1 System notifications

System notifications are reminders for:

- Follow-up appointment – triggers after 30 days from the confirmed placement date at 8 PM
- Planned IUS placement – triggers 1 day before planned placement date at 8.30 PM
- Daily bleeding pattern – triggers daily after confirmed placement date at 9 PM



Note:

You may not be able 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 re-start. 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 in the end not be accurate as you expect.

12.2.1 Warnings about data

These warnings inform you that you have missing information or that an action will happen that has an impact on your data/prediction.

They are displayed when:

- 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)
- placement date reached or passed
- edit of confirmed placement date that deletes the introduced daily bleeding patterns and unlocked gems
- acceptance for further usage of the app after a prediction

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)
- Authorisation code incorrect
- No internet connection (when QR Code is generated, when importing data, when sending feedbacks)
- 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 is supported, 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 it. Based on this information, the app provides you with further reminders for these check-ups:

- Early detection of genital cancer
- Early detection of breast cancer

The overview of these reminders can be found on the reminder screen (Figure 41).

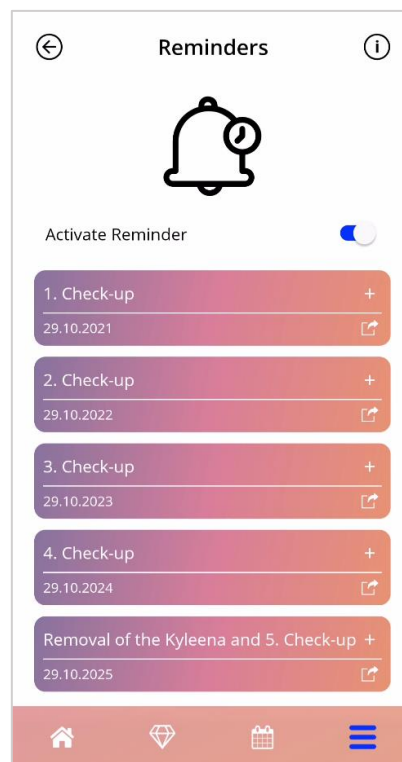
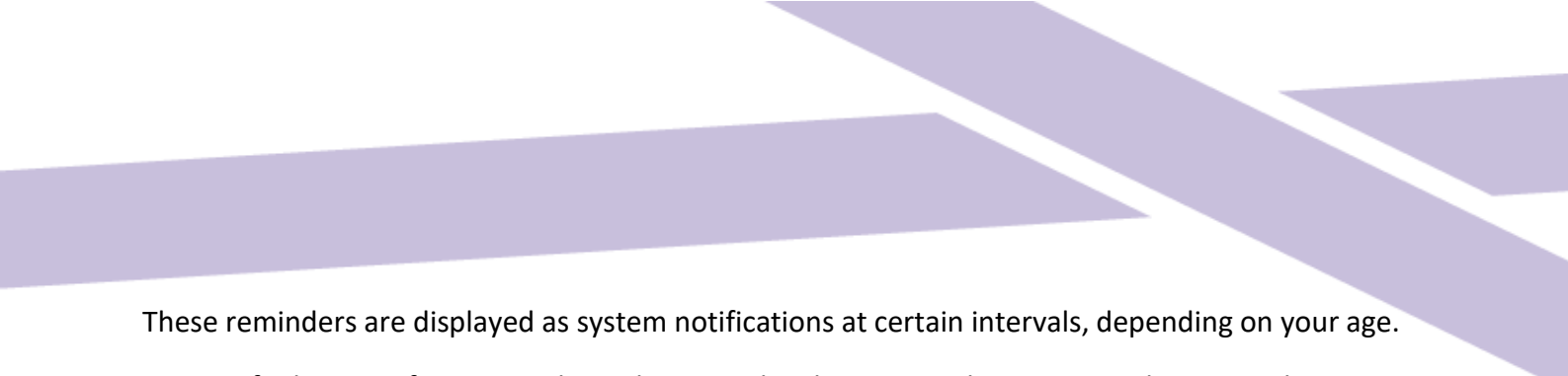


Figure 1: Reminders for check-ups




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

You can find more information about the reminders by tapping the corresponding reminder to open it or by tapping the information icon.

You can also export these reminders, as events in your device calendar. To export a reminder, press the proper export button for each reminder item 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 also deactivate the reminders by switching off the toggle button.

13 Your report

After you get your prediction, you can generate your report. By accessing the item “Your Prediction and report” from the Main Menu , the report screen in Figure 42 will be displayed.

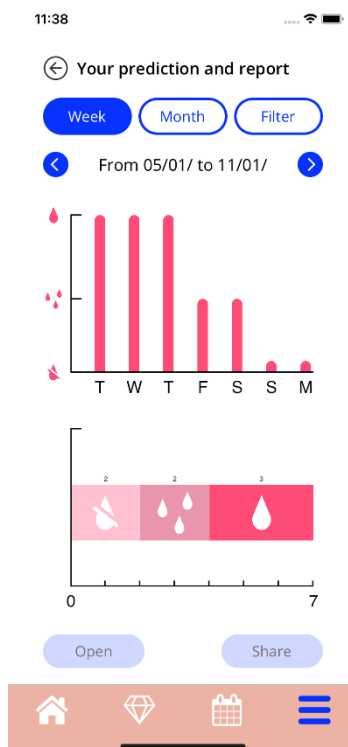


Figure 42: Report screen

This screen will present the data you have entered within two different graphs.

The upper graph shows the course of your bleeding days and on which days you have inserted which bleeding pattern. The graph below displays the number of days you have inserted for each of the three bleeding patterns. You can choose the time span of the graphs by selecting one of the buttons on the top of the screen. You can choose either 7 or 30 days or you can choose "Filter" to specify a time period you prefer.

To have a look at an overall report, including your baseline entries and all your bleeding pattern, you press on the “Open” button from the bottom left side of the screen and a PDF report will be generated.



Note:

The two buttons will only be enabled after receiving your prediction.

After the report is generated, the generated report file will be displayed within an in-app PDF viewer.

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

- your name, export date, placement date, prediction date and IUS type

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

Figure 43: Report header

- baseline parameters and BMI

Your basic entries:

Date of birth:	01/01/2000	Height:	60 cm	Previous pregnancies:	0
Country:	Spain	BMI:	83.3	Births:	0
Weight:	30 kg	Previous contraceptive method:	Ring.		

Figure 44: Report baseline parameters

- collection of daily bleeding patterns for the 90 days before and 180 days after the prediction, displayed in 9 rows, each of them representing a 30 days period. Each row is divided into the date and bleeding pattern value.

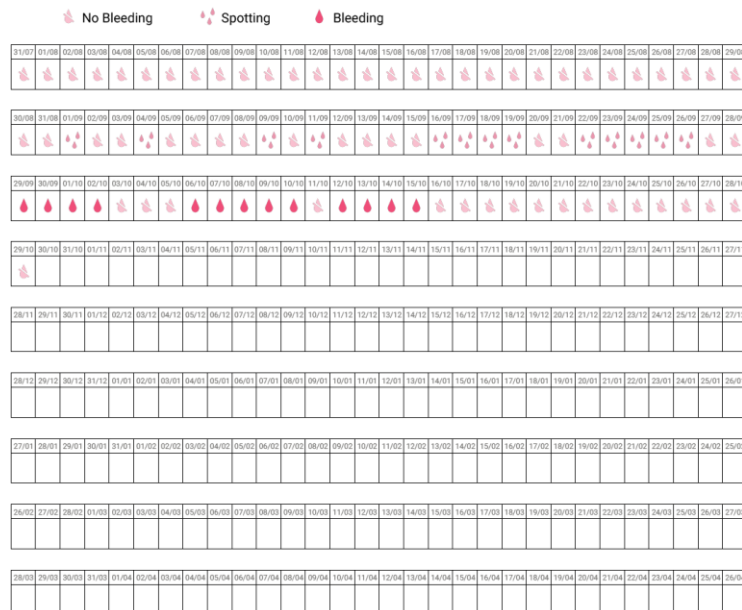


Figure 45: Report everyday pattern



Note:

In case there is no bleeding pattern stored for one day, the field for the “Data” will remain empty.

- 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.

Your Summary:

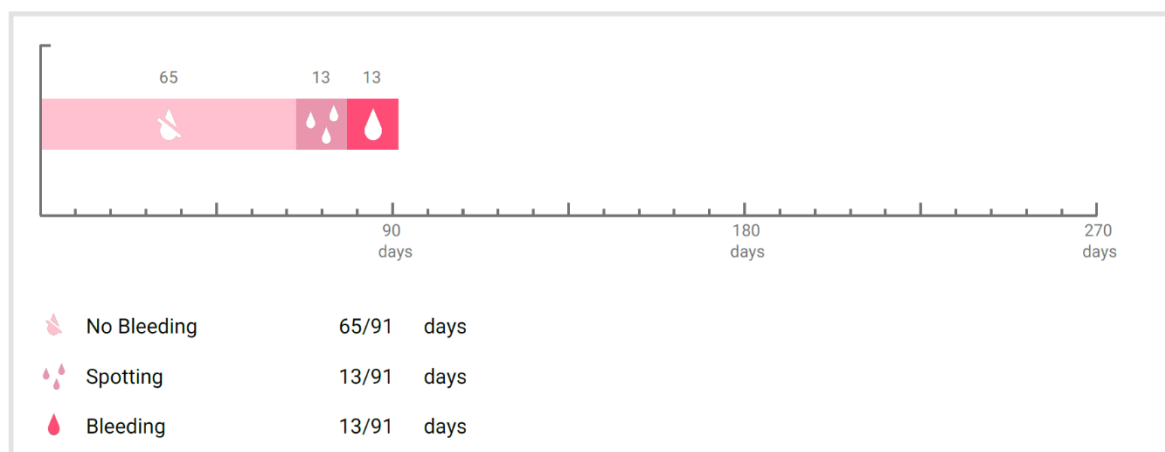
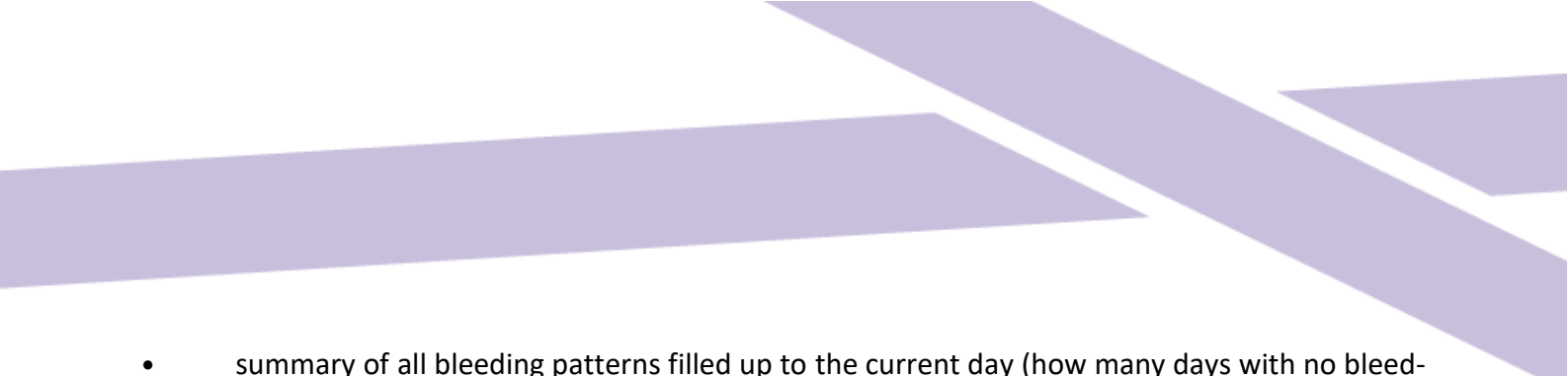



Figure 46: Report charge

- 
- summary of all bleeding patterns filled up to the current day (how many days with no bleeding, how many days with spotting and how many days with bleeding)
 - prediction of future bleeding profile
 - placeholder for comments

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

You can also print it and send it via email, using the smartphone features by pressing on “Share PDF” button.

14 Gems

The Gems screen (Figure 47) is accessible from the Main Menu  and the toolbar by pressing on the item “Unlocked Gems”.

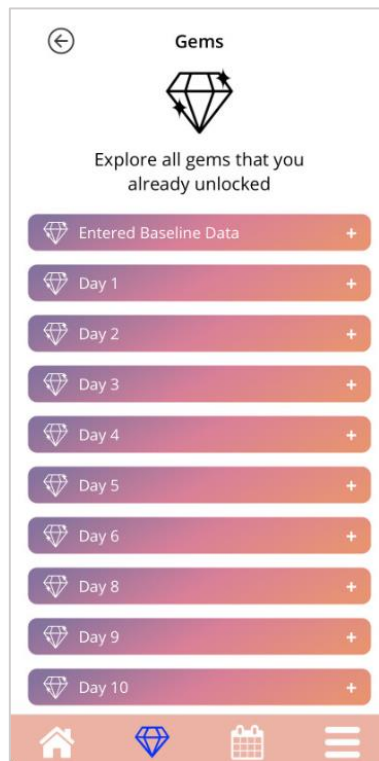


Figure 47: Gems screen

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

An informational gem is a reward that becomes available on a fixed time basis as preconfigured in the app.

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

- the day with the reward is reached or passed
- at most 1 daily bleeding pattern is missing in this 30-day period until the current day
- all previous rewards of this 30-day period are unlocked
- a daily bleeding pattern for the current day is introduced

In the Gems screen you can see for each unlocked gem the day number on which it was available, and a part of the informational text related to the gem. You can display more detailed information by tapping on the “+” symbol of a day.



Note:

Not every “diamond” displayed on the monthly and weekly calendar means you have unlocked that gem. There are displayed only the days for which gems are available.

There is a special gem related to baseline parameters. This will be received automatically after completing the baseline questionnaire and will be available on top 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 48) with the following content:

- a “diamond” icon
- an informational text related to the unlocked gem or a default text
- a button for closing the pop-up
- a button to navigate to the Gems screen (Figure 47).

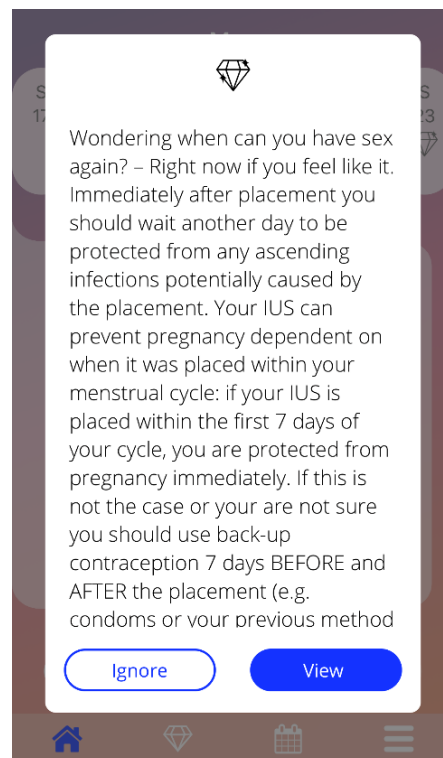


Figure 48: Informational gem pop-up

You can also receive motivational messages on a fixed time basis, depending on a constant bleeding pattern insertion. When you unlock one or more motivational gems at once, the app will open a pop-up like the one in Figure 49 having the following content:

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

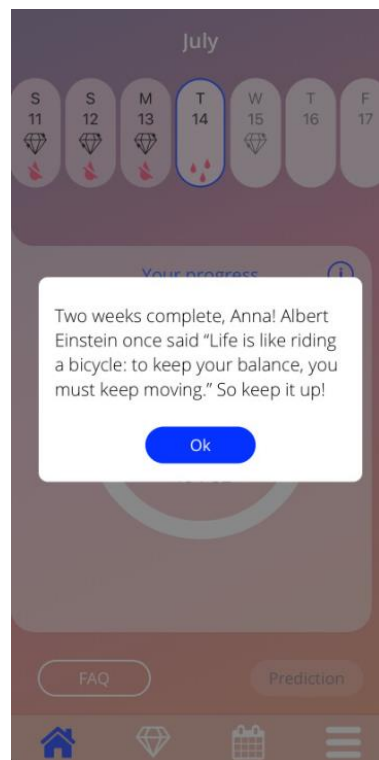


Figure 49: Motivational gem pop-up

15 Media



The Media screen (Figure 50) is accessible from the Main Menu , by pressings on the item “Media”.



Figure 50: 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 and it 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 FAQ

The FAQ screen (Figure 52) is accessible from the Main Menu , by pressing on the item “Frequently asked questions” or from the buttons area from the Home screen by pressing on “FAQ” button from the bottom left side of the screen.

You can access four categories:

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

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.

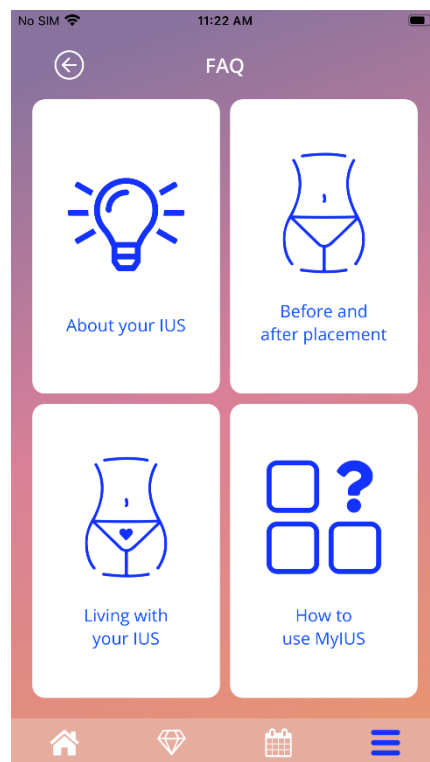


Figure 52: FAQ screen

16.1 About your IUS

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

- What is an IUS?
- How does the IUS work?
- For how long does the IUS work?
- How effective is the IUS?
- Will the IUS affect my hormonal cycle?
- What are the common 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?

16.2 Before and after placement

This section contains questions about the placement of the IUS, as the following:

- 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?

16.3 Living with your IUS

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

- (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 the 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?

16.4 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 enter 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 placement?
- How do I reset the app settings?

17 Support

The Support screen (Figure 53) is accessible from the Main Menu , by pressing on the item “Support”. This screen shows the contact information of the technical support, the App user manual and a link to your IUS user manual. You can also provide us feedback about the app, if you already received a prediction

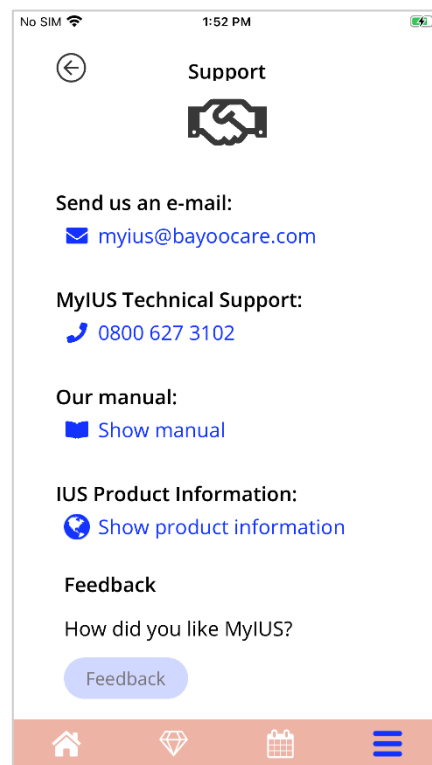


Figure 53: Support screen



Note:

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

17.1 Email

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

17.2 Hotline

If you press on the given number, the phone calling feature of your smartphone will open, with the phone number already set up.

17.3 App user manual

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

17.4 IUS user manual

The IUS user manual can be accessed by pressing on the link. The IUS user manual will be provided in the language set on the smartphone, when supported.

17.5 Give feedback

Through the Support screen, you could send your feedback about the app, if you have 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 54).

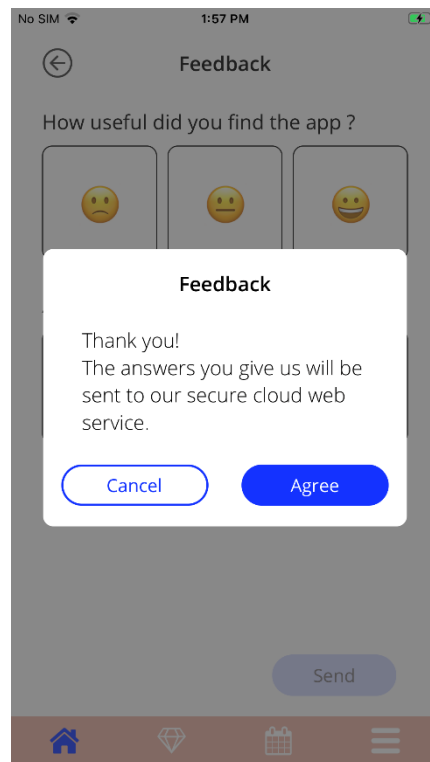


Figure 54: Feedback Consent

By pressing on the “Agree” button, the app will open the Feedback questionnaire (Figure 55). If you press on the “Cancel” button, the pop-up will close.

No SIM 2:10 PM

Feedback

How useful did you find the app ?

Are you confident in your prediction?

Send

Figure 55: Feedback Questionnaire

On the Feedback questionnaire you are asked to answer 2 questions, choosing between three different answer options, displayed as a smiley icon on the pop-up.

You can also cancel the questionnaire, by pressing on the “Cancel” button. This action closes the pop-up without sending any feedback.

If you press on the “Send” button, your answer will be uploaded in the cloud. If during the upload something goes wrong, a pop-up informing you about the failure will open (Figure 56).

The app may ask you to give your feedback not only on the Support screen, but also by displaying a pop-up after you receive your bleeding prediction. If you press on the “Give feedback” button, the consent pop-up (Figure 54) will open, and you are able to open the Feedback questionnaire (Figure 55) by pressing on the “Agree” button.

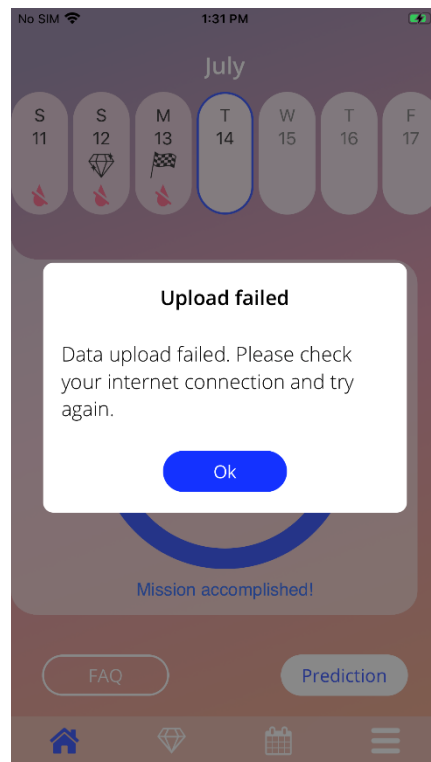



Figure 56: Upload failed pop-up

18 Legal notice

The Legal notice screen (Figure 57) is accessible from the Main Menu , by pressing on the item “Legal notice”. You can access the Terms of use, the data privacy statement and the Imprint about the manufacturer.

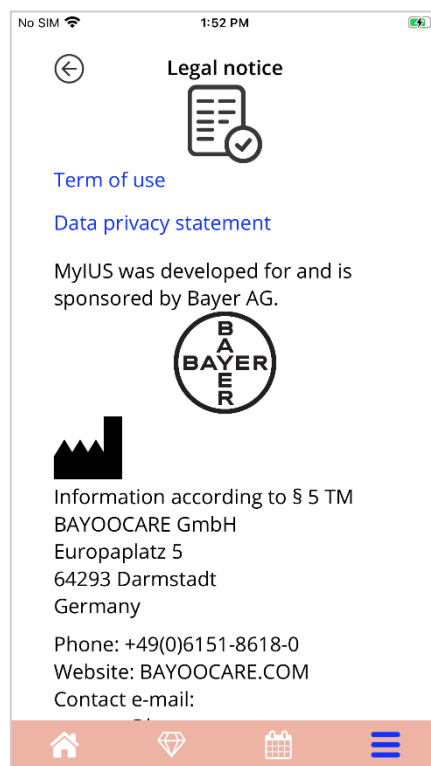


Figure 57: Legal notice screen

18.1 Terms of use

The Terms of Use can be read and downloaded as PDF file, by pressing on the link “Term of Use”. 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.

18.2 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 these are not supported, an English version from Great Britain of the Data Privacy Statement will be displayed.

18.3 Imprint

The Imprint section will be further displayed and contains the following information:

- app release information
- approval numbers app texts
- approval numbers app video
- app license agreement
- MyIUS CE Marking
- License information of used libraries where applicable

Contact information about all locations of the legal manufacturer including street, city, postal code, country. The Imprint will be provided for the region set on the smartphone. If the region is not supported by the app, the Imprint valid for Great Britain will be displayed.

PP-KYL-ZA-0114-1