



User Manual

FlowCyclo®

Release Date: 2022-03-17

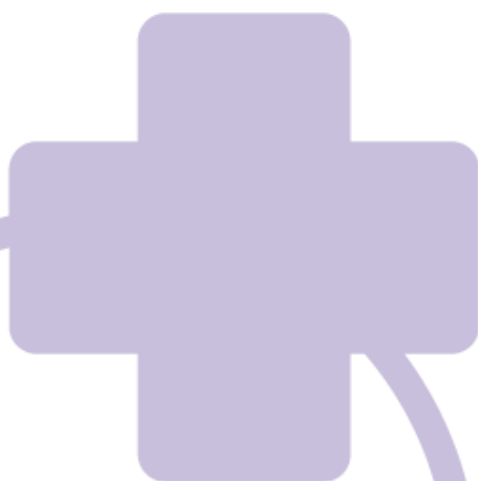


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1 Icons



Conforms with relevant EU Directives.



Observe the instructions for use!



Medical device manufacturer

2 Definitions of terms

Bleeding length:

Number of days that menstrual bleeding lasts

Bleeding status:

Value that identifies whether you are currently within your period

FAQ - Frequently Asked Questions:

Common user questions with answers provided.

Calculation:

The calculation of a result based on user input, such as the calculation of the next cycle start or the calculation of the total bleeding amount

Menorrhagia:

Periods that are too strong and too long

Pictogram:

Validated, stylised representation of hygiene products with different blood intensities

Quantification:

Indication of blood intensity as a numerical value in millilitres

3 General Information

3.1 Medical device 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 Purpose of use

Women who find that their menstrual bleeding is abnormally strong can measure their blood loss with the FlowCyclo® App. A cycle report enables users to have an informed discussion with their doctor about the volume of blood loss and the possible need for therapeutic measures.

3.3 Contraindications

FlowCyclo® is only for use by women of reproductive age who experience menstrual bleeding. Consequently, the app is not suitable for:

- Men
- Women outside reproductive age
- Women who do not experience menstrual bleeding

4 Expected clinical use

FlowCyclo® enables you to quantify blood loss during your period on the basis of information entered by you. The app can quantify and calculate the bleeding amount during a cycle by using two different quantification methods.

The results produced enable a better assessment of the actual bleeding amount compared to the subjective feeling of the user.

The quantified bleeding amount can help doctors detect any possible abnormalities or irregularities. In particular, any possible menorrhagia can be identified using the values.

5 Precautions / safety instructions

FlowCyclo® is a clinically validated medical product that meets the basic requirements of EU guideline 93/42/EEC and/or its national enforcement measures.

If you use pads, they must be viewed from the underside in order to ensure a correct comparison with the pictograms provided.

Quantification via pictograms is only validated for the following products and sizes:

- Always Ultra®:
 - Normal
 - Long
 - Night
- o.b.® ProComfort®:
 - Mini
 - Normal
 - Super
 - Super Plus

The two quantification methods "bleeding diary" and "quantification via pictograms" cannot be combined within one cycle.

The FlowCyclo® app may only be used on smartphones and operating systems validated for it.

The current version of the FlowCyclo® app must always be used.

The FlowCyclo® app may not be changed without the manufacturer's consent.

The FlowCyclo® app is not designed to serve as the sole basis for diagnoses/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.

FlowCyclo®

6 Overview

6.1 Scope of application

FlowCyclo® quantifies bleeding data entered by women who may have abnormally heavy menstrual bleeding.

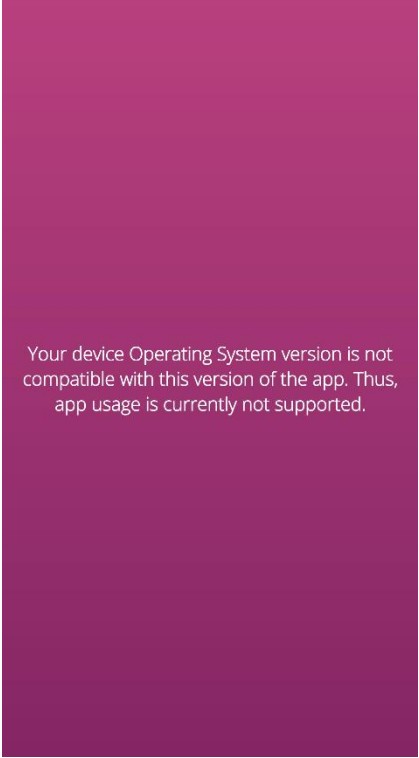
You can enter your bleeding and its intensity into the app during your period. FlowCyclo® quantifies the data entered and calculates the total amount of blood loss during a cycle.

With the help of a report that visualises all the data entered by the user, the quantified bleeding amount can help doctors determine deviations from the norm or irregularities such as menorrhagia.

6.2 App overview

6.2.1 Checking the operating system

Every time you start FlowCyclo®, the operating system on your smartphone is checked. If the app cannot function on your operating system, you will see a pop-up informing you of this (Figure 1): “You cannot use FlowCyclo® with your current operating system”.



Your device Operating System version is not compatible with this version of the app. Thus, app usage is currently not supported.

Figure 1 Operating system check – operating system not supported

In the event that the app is not validated for your operating system, you can still use the app. As a medical device that helps with a monitoring your blood loss, we cannot guarantee the proper user-experience and full functionality if the system is not compatible (Figure 2).

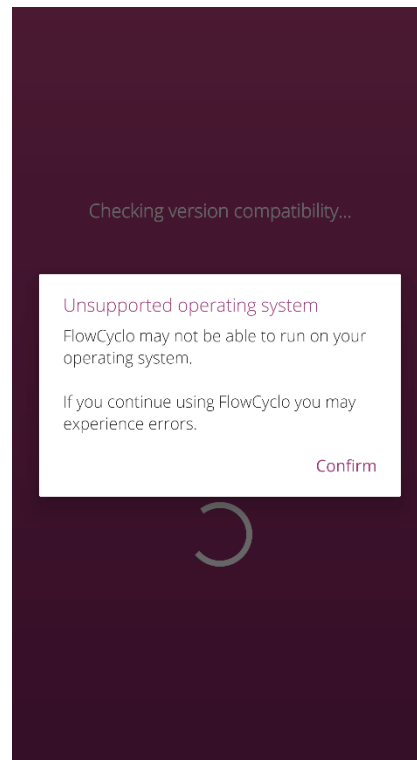


Figure 2 Operating system check – Consent required



Note:

If you use the app on a non-validated operating system, certain functions may not behave as expected.

The following operating systems are validated for the current version of FlowCyclo®:

- Android 8.0 or higher
- iOS 13 or higher

6.2.2 Navigation

After setting up the FlowCyclo® app a navigation bar will appear at the bottom of the screen with four icons, a Home icon, a Report icon, a FAQ icon and a Menu icon.

Tapping on the Menu icon of the navigation bar opens the menu.



Figure 3 Navigation bar

In addition to the navigation bar, further app functionalities can be accessed via the open menu. The structure and function of each individual menu point are described in detail in the following chapters.

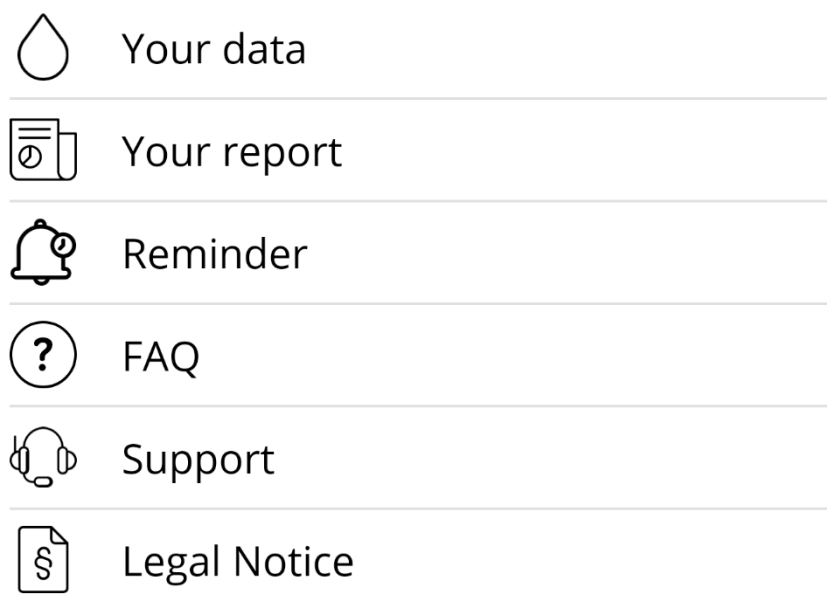


Figure 4 Menu

6.2.3 Information button

FlowCyclo® provides you with further information on various screens. To bring this additional information up on a screen, tap the Information icon (Figure 5).



Figure 5 Information button

Tapping this icon opens a pop-up with further information on the current screen. You can close the pop-up by tapping the Ok-button.

6.3 Instructions for use

The instructions for use can be accessed via the "Support" menu item (Figure 4).

If you tap on the "Support" menu item, you will see all support options as shown in Figure 6. Under "FlowCyclo® manual", you will find the instructions for using FlowCyclo®.

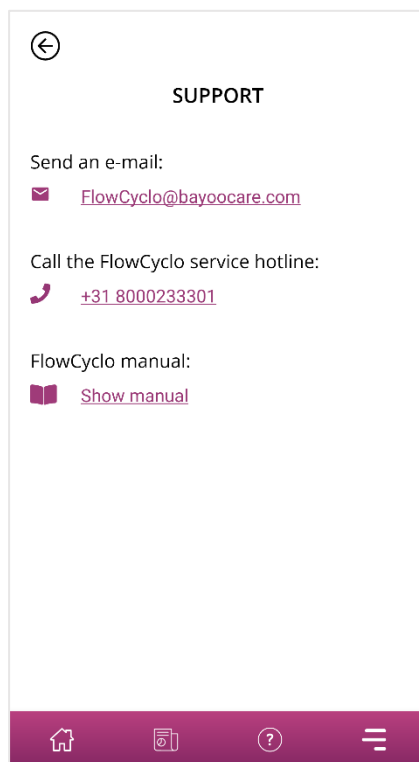


Figure 6 Support Screen

If you tap on "Show manual", you will see your smartphone's standard app for opening PDF files. Here you can select your preferred app in which you want to open the PDF "Instructions for Use".

Installation

7 Using the app for the first time

7.1 Acceptance of terms of use

When you use FlowCyclo® for the first time after installation, there is a brief introduction to how the app works. You will also be asked to answer some cycle and bleeding-related questions.

When using the app for the first time, you need to accept the terms of use. You can open the terms of use by tapping on the respective words (Figure 7).



Note:

Please read the terms of use before agreeing to them.

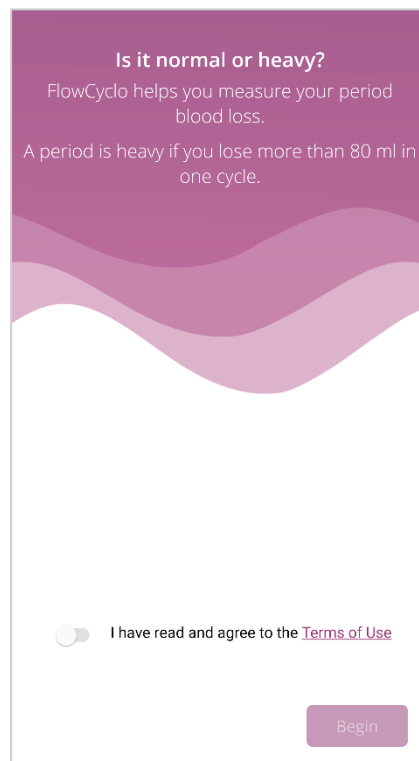


Figure 7 Home screen when using the app for the first time (ToU)

You can only continue to use the app once you agree to the terms of use. To continue after acceptance, tap the button in the lower right corner.

7.2 Acceptance of privacy policy

Once you accepted the Terms of Use, you will be asked to accept the Data privacy statement. When you read and scrolled down the entire statement, the button to accept it will enable. You can download the data privacy statement as PDF by tapping on the left button (Figure 8).



Note:

Please read the data privacy statement before agreeing to it.

DATA PRIVACY STATEMENT

Scroll down to read the privacy policy

Privacy Policy
Last updated: February 2021

STATEMENT OF CONSENT TO THE PRIVACY POLICY FOR THE FlowCyclo app.
By consenting to the processing of my health data, I declare my agreement to the data processing associated with the use of the FlowCyclo app in accordance with the privacy notices and terms of use applicable in this context.
I can revoke my consent at any time with effect for the future. To exercise my right of withdrawal, I only need to delete the app from my smartphone.

PRIVACY POLICY FOR USING THE "FlowCyclo" APP
With this privacy notice, we would like to inform you about the basis on which and the purposes for which we process personal data that we collect from you or that you provide to us or third parties when you use the "FlowCyclo" app. In addition, we would like to inform you about your data protection rights.
In order to ensure the basic security requirements of the "FlowCyclo" app, only usage data about the use of the app is collected and passed on to third parties, respectively third countries (see 3.2. of this privacy notice).
All other collected data remains locally in the protected area of the app on the smartphone. The data is used to quantify the blood loss and the corresponding output as a PDF report for possible forwarding to the attending physician. This forwarding of the PDF report is solely at the discretion of the app user.
In addition, we process your data only for contractual or legal purposes and also only with your (also implied) consent.
The app "FlowCyclo" is a medical device classified for the European Economic Area and meets the essential requirements of Directive 93/42/EEC or its national implementations.
Further information can be found in the terms of use.
"FlowCyclo" will process your personal data confidentially and

Save PDFAgree

Figure 8 Data Privacy screen when using the app for the first time

You can only continue to set up the app once you agree to the data privacy statement. To continue after reading the privacy statement, tap the button in the lower right corner.

7.3 Tracking Data

The following screen, after accepting the Data Privacy Statement, informs you about the collection and sending of tracking data (Figure 9). You have the option to enable the tracking of analytical data

by tapping on the right button “Agree”, or to deny the tracking data by tapping the left button “Not now”. The collection and sending of tracking data are not mandatory but will help us to improve the app.

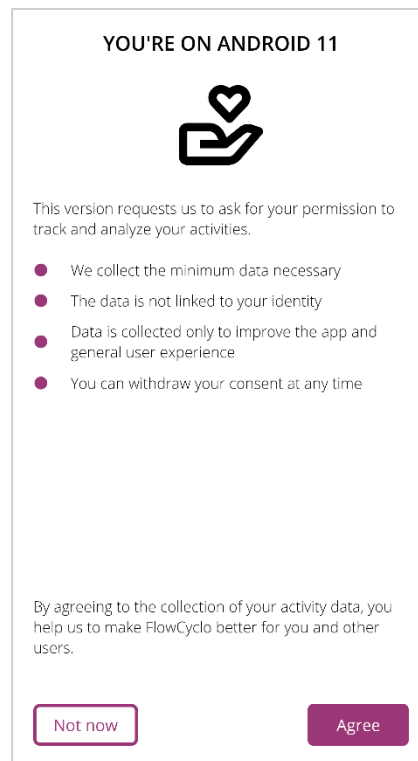


Figure 9 Data Privacy screen when using the app for the first time

7.4 Introduction to the FlowCyclo® app

After agreeing to the terms of use and the privacy policy, you will be taken to the thematic introduction to the FlowCyclo® app.

The possible quantification methods are explained on three screens:

- Quantification using pictogram (Figure 10)
- Bleeding diary (Figure 11)

You will also receive information about the report (Figure 12) that you can generate for each cycle.

On this screen, you will learn about the differences between the two methods and the Input needed for each method. The selection criteria depend on which pad/and or tampon brand you are using. The quantification method can be changed after each cycle.

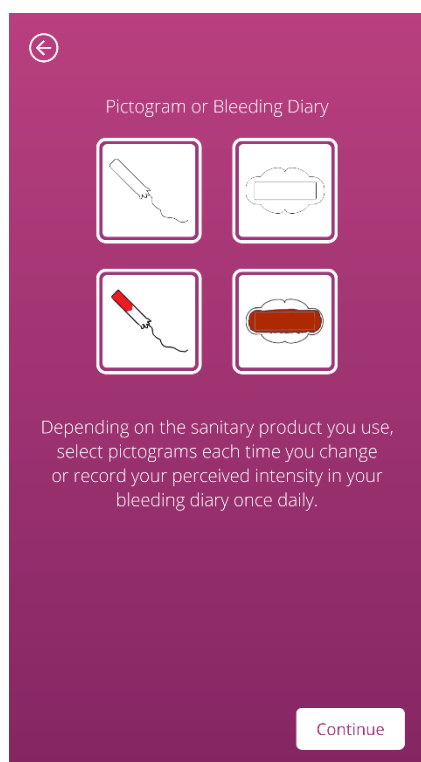


Figure 10 Introductory Screen - pictogram quantification

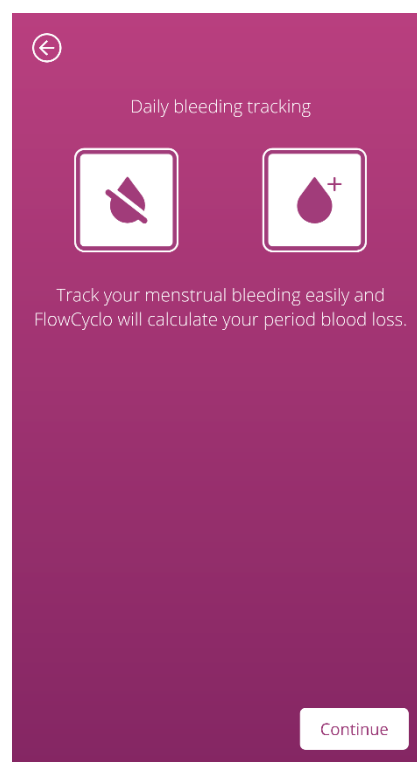


Figure 11 Introductory Screen - bleeding diary

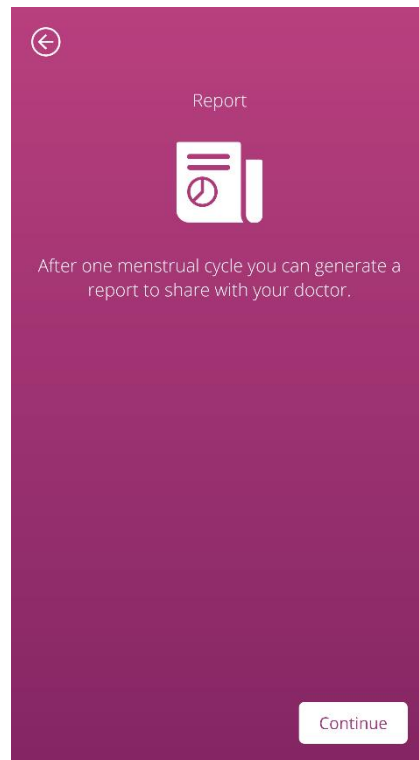


Figure 12 Introductory Screen - report

After reading through an introductory screen, you can continue by tapping the button in the lower right corner.

Basic entries

8 Questionnaire on first use

8.1 Questionnaire

When using FlowCyclo® for the first time, you will be asked to answer five questions after the introductory screens. These basic questions are relevant, for example, when calculating the start of a new cycle.

You can access additional information about each of the five questions. You can find this information under the Information button next to the progress bar (Figure 13).

Tapping this icon opens a pop-up with further information on the current screen. Tap the Ok-button close the pop-up.

Tap the button in the lower right corner to navigate to the next screen of the questionnaire. Tap the button in the upper left corner to navigate back to the previous screen.



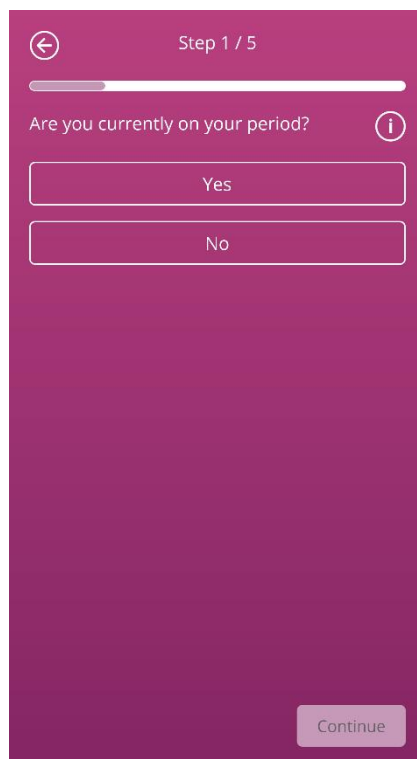
Note:

You can only switch to the next screen of the questionnaire if you have answered all questions on the current screen. If a question remains unanswered, the app will prevent you from continuing with the next question.

The only exception is the question about your contraceptive method, this is optional and can be skipped.

8.2 Question – Bleeding status

The first question of the questionnaire asks if you are bleeding on the day you first use the app (Figure 13). You can answer this with "yes" or "no".



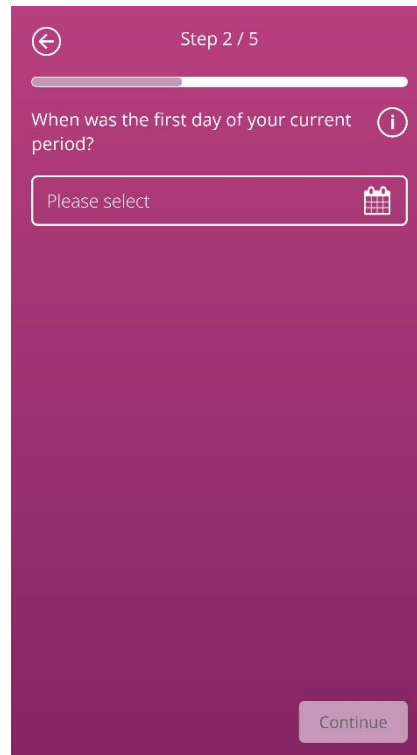
The screenshot shows a mobile application interface for a questionnaire. At the top, there is a back arrow icon and the text "Step 1 / 5". Below this is a progress bar. The main question is "Are you currently on your period?", followed by an information icon (i). There are two large, rounded rectangular buttons: "Yes" and "No". At the bottom right, there is a "Continue" button.

Figure 13 Question 1 – Bleeding status

8.3 Question – Start of period

When asked about the first day of your current or last period (Figure 14) you can choose a date from a calendar (Android) or using the date picker (iOS).

If your period has already started, please state the first day of your current menstrual cycle. Otherwise, please state the start of your last menstrual cycle here. Please note that you cannot select a date in the future.

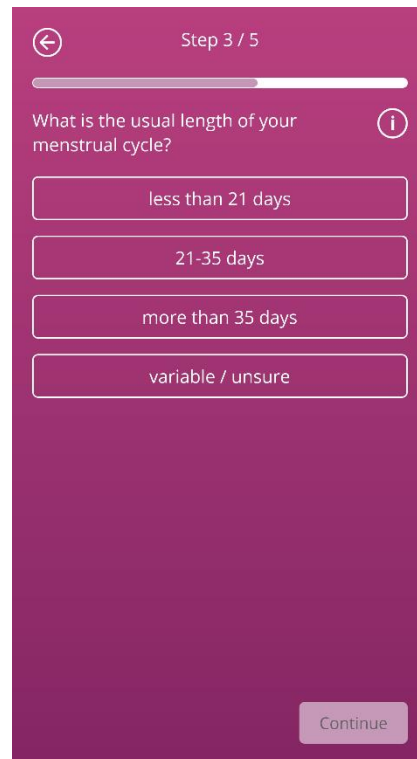


The screenshot shows a mobile application interface with a purple background. At the top, there is a back arrow icon and the text 'Step 2 / 5'. Below this is a progress bar. The main question is 'When was the first day of your current period?' with an information icon (i) to its right. Below the question is a date picker input field with the placeholder text 'Please select' and a calendar icon. At the bottom right, there is a 'Continue' button.

Figure 14 Question 2 – First day of period

8.4 Question – Cycle length

After answering the second question, you will be asked about the length of your cycle. You can choose from three different time periods (Figure 15). If you cannot find your cycle length in the specified time periods because your cycle length varies or you are not sure, you can also select this here.

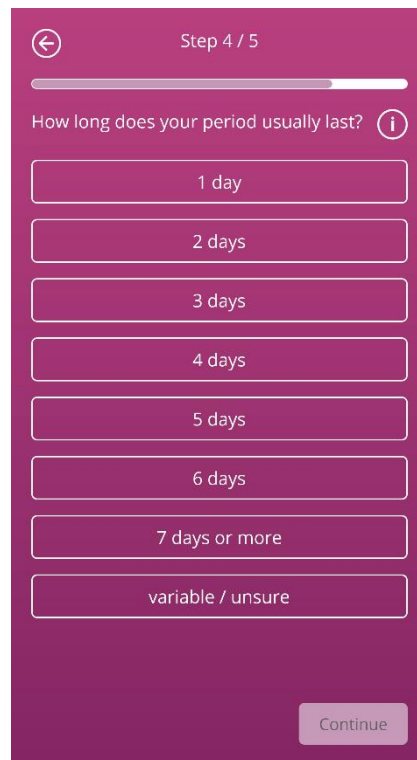


The screenshot shows a mobile application interface with a purple background. At the top, there is a back arrow icon and the text "Step 3 / 5". Below this is a progress bar. The main question is "What is the usual length of your menstrual cycle?" with an information icon (i) to its right. There are four selectable options, each in a rounded rectangle: "less than 21 days", "21-35 days", "more than 35 days", and "variable / unsure". At the bottom right, there is a "Continue" button.

Figure 15 Question 3 – Cycle length

8.5 Question – Bleeding length

In addition to the length of your menstrual cycle, FlowCyclo® also asks you the length of your period, when you use the app for the first time (Figure 16). Here, you have the choice between different menstrual lengths, specified in days. Select the average length of your period here. If your period varies or if you are unsure about your exact number of bleeding days, you can also indicate this here.



The screenshot shows a mobile app interface with a purple background. At the top, there is a back arrow icon and the text 'Step 4 / 5'. Below this is a progress bar. The main question is 'How long does your period usually last?' followed by an information icon. There are nine buttons stacked vertically, each with a white border and text: '1 day', '2 days', '3 days', '4 days', '5 days', '6 days', '7 days or more', and 'variable / unsure'. At the bottom right, there is a 'Continue' button.

Figure 16 Question 4 – Bleeding length

8.6 Question – Contraception

The last question of the questionnaire relates to your current method of contraception (Figure 17). You can select multiple contraceptive methods here if you use multiple methods concurrently. Please indicate all methods you currently use.



Step 5 / 5

What is your method of birth control? ⓘ

- Pill
- Injection
- Patch
- Ring
- Hormonal coil (IUS)
- Copper coil (IUD)
- Implant
- Condom
- Other

Continue

Figure 17 Question 5 – Contraceptive methods



Note:

Even if you are not currently using a contraceptive method, select one for this question.

Answering this question completes the questionnaire and takes you to the final screen (Figure 18). If you leave this screen, you will reach the Home screen of the app and can now use all the functionalities of FlowCyclo®.

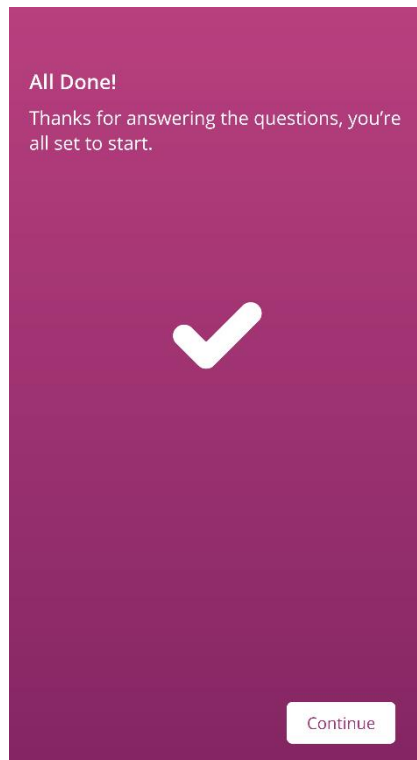


Figure 18 Final screen

9 Selection of product brand

When using FlowCyclo® for the first time and at the beginning of each new cycle, you will be asked to choose the brand of your tampon and / or pads. You can choose between “Supported products” and “Other products” (Figure 19). FlowCyclo® shows you all supported product brands here.

Choosing the product brand determines the quantification method that the app uses for one cycle. Choosing the correct product brand ensures that your entered values are quantified using the correct method and that you can receive a reliable calculation. You can choose which products to use in each cycle.

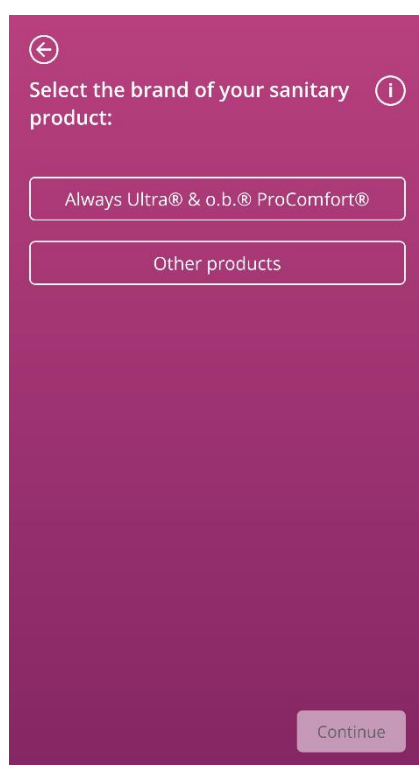


Figure 19 Brand selection



Note:

You cannot change this selection during an ongoing cycle. The quantification method used based on the product brand is fixed for one cycle. However, you have the option of choosing a different product brand and thus a different quantification method at the beginning of a new cycle.



Note:

If you have chosen “Always Ultra® and / or o.b.® ProComfort®”, please only use these products. Failure to keep to a product will affect the accuracy of your calculation.

The absorption properties of other products may differ from “Always Ultra® and / or o.b.® ProComfort” and result in a different blood distribution in the product. In this case, the visual correspondence between your product and the pictogram may be lost and the actual bleeding amount may differ from the calculated one.

Home Screen

10 Elements of the Home screen

On the Home screen (Figure 20) you will see different elements which are explained in brief here.

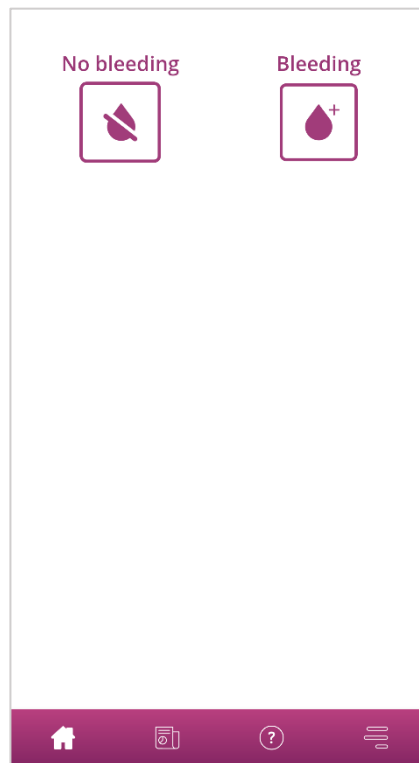


Figure 20 Home screen

10.1 Bleeding button

With the Blood Entry button (Figure 21), you can enter the bleeding amount.



Figure 21 Bleeding button

Tapping the button takes you to the input process for the respective quantification method.

To find out how such an entry process works and what steps it contains, please refer to Chapters 11 Quantification using pictogram and 12 Bleeding diary.

10.2 No bleeding button

With the "No bleeding" button (Figure 22) you can transfer information to the app for periods in which you have not had any bleeding.



Figure 22 No bleeding button

By tapping the button, you can enter a bleeding-free phase in the app.

You can find more information in Chapter 13 Entering days without bleeding.

10.3 List of recent entries



Note:

When you open FlowCyclo® for the first time, you will not see a list of recent entries on the Home screen.

As soon as you have created an entry, you can see all entries that you have added or edited in the last 24 hours in the list on your Home screen. The app quantifies every entry you make. The app

converts each of your entries to a rounded millilitre value. FlowCyclo® shows you the date of the entries and the corresponding millilitre figure in the list (Figure 23) on the Home screen.



Figure 23 Entry list

As long as there is an entry in the list, you can edit or delete it. You can find further information in Chapters 11 Quantification using pictogram and 12 Bleeding diary.

10.4 Representation of blood loss



Note:

When you open FlowCyclo® for the first time, you will not see any blood loss on the Home screen.

The representation of blood loss in the form of rising waves (Figure 24) only appears after you have made your first entry.



Figure 24 Representation of blood loss

The app quantifies the bleeding amount from every entry you make. The app converts each of your entries to a millilitre value. The quantified millilitre values are added up and displayed to you as a total in the form of waves. You can find the exact total value on the scale on the left.



Note:

Please note that the displayed values are rounded.

You can find out how your quantified values are calculated in Chapter 14 Quantification methods.

Record Blood Entries

11 Quantification using pictogram

If you have chosen the product brand “Always Ultra® and / or o.b.® ProComfort®”, you can make several entries every day. Your daily bleeding amount is calculated and quantified by entering the product used and its size, as well as the bleeding amount based on pictograms. It is important that you enter every product change in the app.



Note:

To ensure that your information is as accurate as possible, it is advisable to make the entry immediately after the change.

You can obtain additional information about each of the individual steps in the input process. You can find this under the Information button next to the question (Figure 25).

Tapping the Info icon opens a pop-up with further information on the current screen. Tap the Ok-button to close the pop-up.

Tap the button in the lower right corner to navigate to the next screen. Tap the button in the upper left corner to navigate back to the previous screen.



Warning:

If you navigate back to a previous screen, your current settings are not saved.



Note:

As soon as you have created an entry, the app remembers the entry of the last product used and its size and uses these entries as a pre-selection for the next entry.

11.1 Pictogram entry – Add entry

To add an entry to your bleeding diary, tap the "Enter Bleeding" button on the Home screen (Figure 20). This starts the entry process.

11.1.1 Select date and sanitary products

In the first step of each entry FlowCyclo® asks you to select the date for which you wish to enter bleeding information and the sanitary product you have used (Figure 25).

As before, a calendar (Android) or a date picker (iOS) opens with which you can select the date for the entry.

To select a hygiene product, tap on it. You can select two hygiene products at the same time, as long as they are not of the same type.

You can only proceed once you have selected a day and your sanitary products.



← Select the date ⓘ

17-3-2022 ⓘ

Which sanitary product did you use? ⓘ

Pads

Always Ultra®

Tampons

o.b.® ProComfort®

Continue

Figure 25 Data selection



Note:

You can only make entries for your current cycle. Therefore, the earliest possible date that you can choose is the first day of your current cycle.



Note:

If you wish to enter two hygiene products, please select one hygiene product first. As soon as you have entered this, the process for the previously unselected article is started automatically. Here, you can only make entries for two different hygiene products that you have used at the same time.

If you have used two pads, then please make two separate entries.

The simultaneous use of two tampons is not supported by FlowCyclo®.

11.1.2 Hygiene product – Size

Depending on which hygiene product you have selected, you can choose from various product sizes. You can only select one product size at a time to enter it.

If you have previously selected an “o.b.® ProComfort®” tampon, you will be presented with the four product sizes that are available, as shown in Figure 26.

With an “Always Ultra®” pad, you have the choice between three different product sizes, as shown in Figure 27.

What is the size of your tampon? ⓘ

mini

normal

super

super plus

Continue

Figure 26 Product sizes – o.b.® ProComfort® tampons

What is the size of your pad? ⓘ

normal

long

night

Continue

Figure 27 Product sizes – Always Ultra® pad

Please select the size of the hygiene product you are using.



Note:

You can usually find the size of the product you are using on the packaging of the product.

11.1.3 Pictogram selection

11.1.3.1 Pictogram selection – Always Ultra® pad

If you have selected an “Always Ultra®” pad, you will be presented with six different pictograms after selecting a product size (Figure 28). These also represent different bleeding intensities. Turn to the back of your pad and compare your used product with the pictograms and select the pictogram that most closely resembles your product.

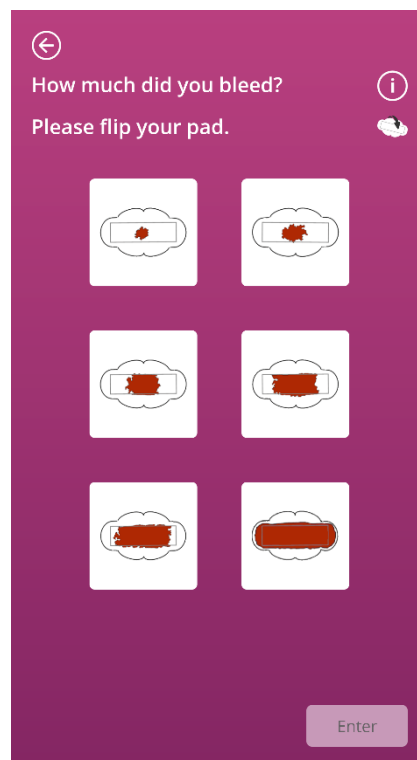


Figure 28 Pictograms – Always Ultra® pad



Note:

If you use an “Always Ultra®” pad, it is important to turn it over before comparing it with the pictograms. It is important that you use the **back of the pad** for comparisons, otherwise inaccuracies may result.

After selecting a pictogram, you can complete the entry by confirming your entries.

The app takes you to the Home screen and you can see your entry or entries in the list on the Home screen. You can also see the increase in waves that represent the total bleeding amount in the current cycle. The millilitre value that you can see in the scale on the left is the sum of your quantified entries.



Warning:

You can make entries retrospectively without limitation by selecting a past date. Please note, however, that retrospective amounts of bleeding entered from memory may be inaccurate and thus affect the accuracy of your calculation.

11.1.3.2 Pictogram selection – o.b.[®] ProComfort[®] tampon

If you have used an o.b.[®] ProComfort[®] tampon, and you enter it, after selecting a product size, you will be shown four different pictograms which represent different bleeding intensities (Figure 29).

Please compare your product with the pictograms and choose the pictogram that most closely resembles your product.

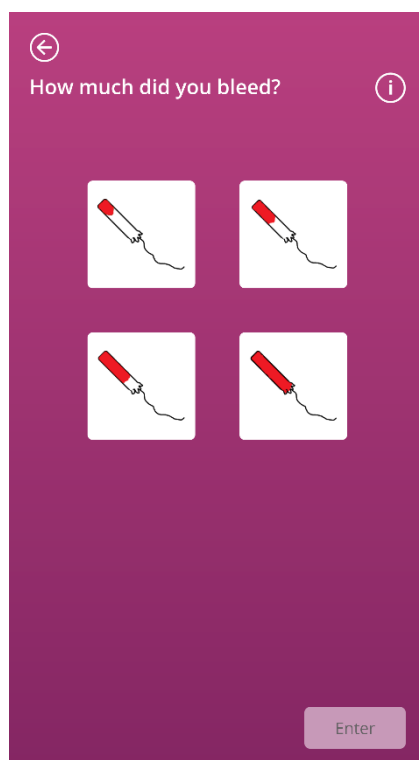


Figure 29 Pictograms – o.b.[®] ProComfort[®] tampon

After selecting a pictogram, you can complete the entry by confirming your entries.

The app takes you to the Home screen and you can see your entry or entries in the list on the Home screen. You can also see the increase in waves that represent the total bleeding amount in the current cycle. The millilitre value that you can see in the scale on the left is the sum of your quantified entries.



Warning:

You can make entries retrospectively without limitation by selecting a past date. Please note, however, that retrospective amounts of bleeding entered from memory may be inaccurate and thus affect the accuracy of your calculation.

11.1.4 Use of two products

If you have selected two products for entry, the process currently ongoing is repeated a second time with the product that has not yet been entered. Once you have entered this, you can confirm your entries and end the process.

11.2 Pictogram entry – Change entry

All entries made in the last 24 hours are shown in the list (Figure 23) on the Home screen. To edit one of the entries in the list, tap the Edit icon (Figure 30) behind the desired entry.



Figure 30 Edit icon

The selections you made during the entry process are highlighted for you. Go through the change process and input process and confirm your updated entry. Start the change process by selecting the product, followed by the product size, and finally changing the previously selected pictogram.



Note:

If you also want to change the date, delete the entry as described below and create a new entry.



Note:

It is only possible to change entries for a limited time - within 24 hours of the entry. Only entries in the list on the Home screen can be changed. If an entry can no longer be found in the list, it can no longer be changed.

11.3 Pictogram entry – Delete entry

To delete one of the entries from the list, tap the Delete icon (Figure 31) behind the desired entry.



Figure 31 Delete icon

You will then be asked to confirm the deletion. If you do this, the selected entry will be deleted.



Note:

It is only possible to delete entries for a limited time - within 24 hours of the entry. Only those in the list on the Home screen can be deleted. If an entry can no longer be found in the list, it can no longer be deleted. You cannot restore a deleted entry.

12 Bleeding diary

If you have chosen "Other Products", your daily bleeding amount will be calculated and quantified using a bleeding diary. You enter your bleeding intensity for the entire day once a day. To do this, the app needs an indication of the day for which you want to make an entry and the bleeding intensity of the selected day.

You can obtain additional information about each of the individual steps in the input process. You can find this information under the Information button next to the progress bar (Figure 32).

Tapping this icon opens a pop-up with further information on the current screen. Tap the Ok-button to close the pop-up.

Tap the button in the lower right corner to navigate to the next screen. Tap the button in the upper left corner to navigate back to the previous screen.

12.1 Bleeding diary – Add entry

To add an entry to your bleeding diary, tap the "Enter Bleeding" button on the Home screen (Figure 20). This starts the entry process.

12.1.1 Select date

In the first step of each entry FlowCyclo® asks you to select the date for which you wish to enter bleeding information (Figure 32). As before, a calendar (Android) or a date picker (iOS) opens with which you can select the date for the entry. You can only proceed once you have selected a day.

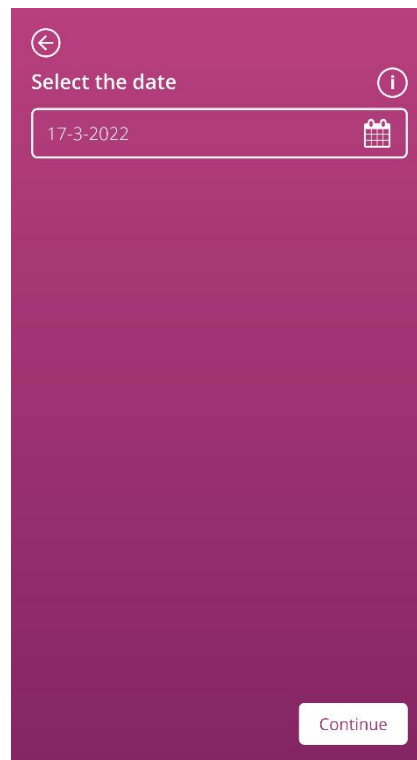


Figure 32 Date selection

12.1.2 Select bleeding intensity

In the next step you will be asked about the bleeding intensity on the selected day. The bleeding intensity describes the total severity of all bleeding that occurred during the day. You have five different bleeding intensities to choose from; these can be found in Figure 33.

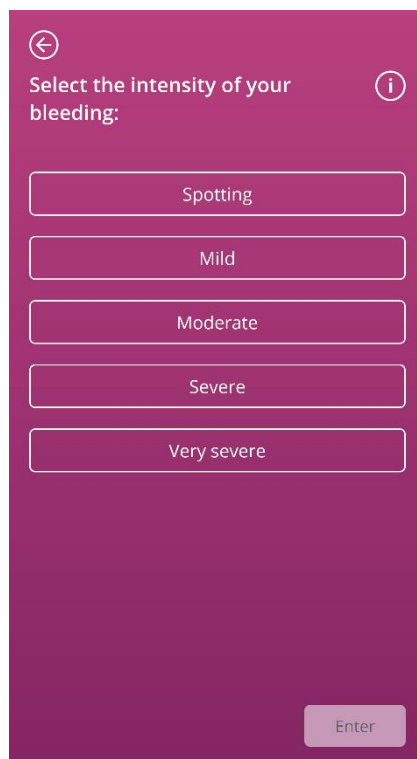


Figure 33 Bleeding intensities

Please select the intensity that corresponds to your bleeding on the selected day. You can only choose one bleeding intensity per day.

If you have selected a bleeding intensity, you can confirm the entry with the button in the lower right corner.

You will return to the Home screen and can see your entry in the list on the Home screen. In the list on your Home screen, you can see all entries that you have added or edited in the last 24 hours. You can edit or delete all entries that are displayed in this list.

You can also see the increase in waves that represent the total bleeding amount in the current cycle. The millilitre value that you can see in the scale on the left is the sum of your quantified entries.



Warning:

You can make entries retrospectively without limitation. Please note, however, that retrospective amounts of bleeding entered from memory may be inaccurate and thus affect the accuracy of your calculation.



Note:

You can only choose one bleeding intensity per day. This intensity then corresponds to your bleeding amount on the selected day. If you wish to modify an entry already made, a pop-up appears with a query as to whether you want to overwrite the entry for this day. If you confirm this, the entry of the selected day will be overwritten by the new entry.

12.2 Bleeding diary – Change entry

All entries made in the last 24 hours are shown in the list (Figure 23) on the Home screen. To edit one of the entries in the list, tap the Edit icon (Figure 34) behind the desired entry.



Figure 34 Edit icon

The app then takes you to the input process and the selection of the bleeding intensity. There you can change your entry by selecting a different bleeding intensity and saving this selection. The entry is updated and displayed in the list on the Home screen.

12.3 Bleeding diary – Delete entry

To delete one of the entries from the list, tap the Delete icon (Figure 35) behind the desired entry.



Figure 35 Delete icon



Note:

It is only possible to delete entries for a limited time - within 24 hours of the entry. Only entries in the list on the Home screen can be deleted. If an entry can no longer be found in the list, it can no longer be deleted. You cannot restore a deleted entry.

13 Entering days without bleeding

If you find that you have not had any bleeding in a day or for a certain period of time, you can also record this in FlowCyclo®, regardless of your current quantification method.

To enter a period without bleeding, tap the "No Bleeding button" (Figure 22), which is on the Home screen. If you tap this, the app marks the period from your last entry until the moment you tap the button as "period without bleeding".

If the period without bleeding was entered successfully, the appearance of the button changes, as can be seen in Figure 36.



Figure 36 No Bleeding button - confirmation

Quantification of Bleeding Amount

14 Quantification methods

The total amount of your blood loss is calculated differently depending on which products you use.



Note:

Both methods of quantification are based on scientific studies. However, quantification using the pictograms can give you more precise values than making entries in the bleeding diary. In order to obtain the most accurate values possible, it is therefore recommended to use the quantification method of the pictogram entries.

14.1 Quantification of pictogram entries

If you use “Always Ultra® or o.b.® ProComfort®” products, select a product, its size and the pictogram which most closely resembles your product after changing.

FlowCyclo® contains a validated value for every product size and every pictogram. After each entry, this validated value is added to the previous values, if available, and you get the total value of your bleeding in a cycle.

Further information on making entries can be found in Chapter 11 Quantification using pictogram.

14.2 Quantification of bleeding diary entries

If you use “Other products”, choose the bleeding intensity for one day.

FlowCyclo® contains a validated value for every bleeding intensity. After each entry, this validated value is added to the previous values, if available, and you get the total value of your bleeding in a cycle.

Further information on making entries can be found in Chapter 12 Bleeding diary.

Your Data

FlowCyclo® provides you with an overview of all your blood loss data that you have entered during the current cycle.

15 Your Data

15.1 Access „Your data“

You can access your data via the menu item "Your data" (Figure 4).

When you tap on the "Your data" menu item, you will be redirected to the data overview screen (Figure 37).

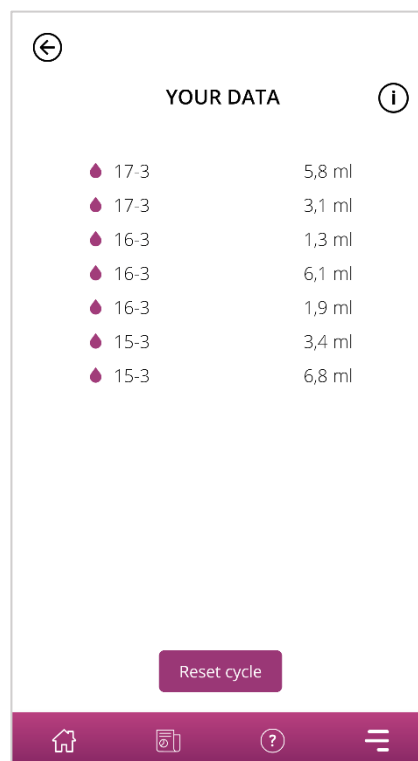


Figure 37 Data overview

15.2 Delete „Your data“

You can delete the data of your current cycle in the overview. To do so, tap on the "Delete" button on the screen. When you confirm the deletion process, all your data of the current cycle will be irrevocably deleted from the app.

Your Report

FlowCyclo® provides you with a report to help you evaluate your data.

The report contains all the data that you have entered while using the app. In addition to the entries for your blood loss, this also includes the answers to the questionnaire that you completed when using FlowCyclo® for the first time. As soon as you have made at least one entry, you can generate such a report at any time.

For example, you can present the report to your doctor at your next appointment. The quantified values of the app can make it easier for your doctor to assess blood loss during menstruation and could give indications of menorrhagia.

16 Your report

16.1 Access „Your report“

You can access the report via the menu item "Your report" (Figure 4). When you tap on the "Your report" menu item, you will be taken to the report.

On the overview screen for "Your report", you will first see the in-app report providing the graph for the last seven days of your current period. It displays the accumulated blood loss for each day. Furthermore, you can find information like the total blood loss and - if you chose to enter your blood losses via pictograms for the currently viewed period - the number of products that you used (Figure 38).

By clicking on the arrows atop of the graph, you can switch between different phases. Also, by clicking on the buttons "7 Days" or "Full cycle", you can switch the view between the seven day display (Figure 38) and the complete cycle display (Figure 39).

The button "Open" beneath the graph enables you to download the generated report as a PDF. Reports are automatically generated for all menstrual cycles you have previously entered. A one-page report is created for each cycle, summarised in a PDF file. The reports are sorted in ascending order by date, which means that the report on your current cycle is displayed first.

When FlowCyclo® has generated your report, you will see your smartphone's standard app for opening PDF files. You can select your preferred app to open the PDF report.

The button "Share" enables you to share the report as a PDF with others via applications on your smartphone.

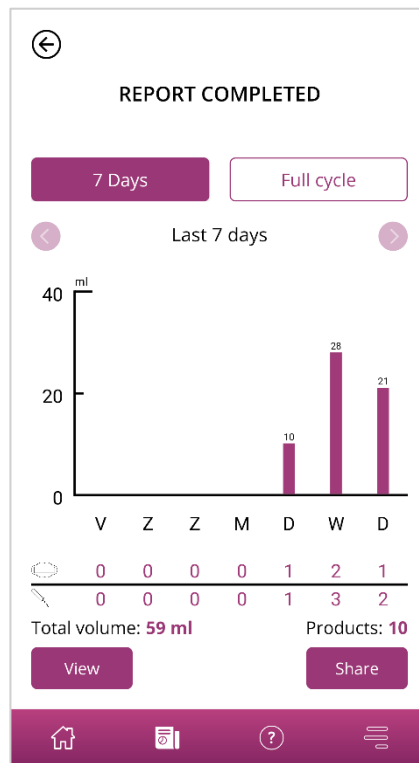


Figure 38 Report Graph (7 Days)

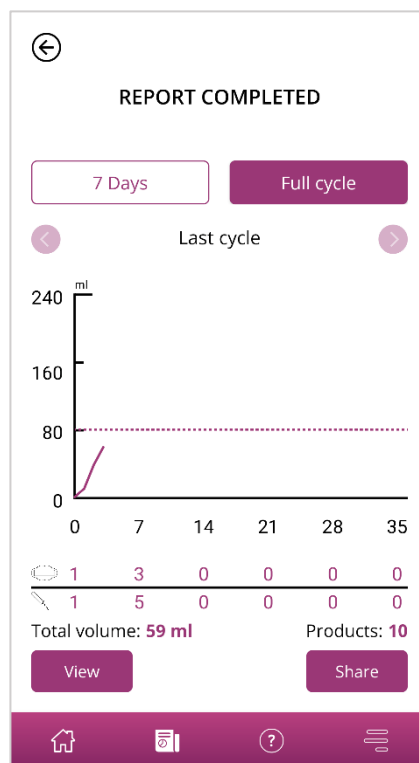


Figure 39 Report Graph (Full cycle)

16.2 Report – Content

16.2.1 Questionnaire parameters

The upper area of the report shows the information you entered when using FlowCyclo® for the first time, as well as the start and end of the cycle (Figure 40).

Your basic information:

Length of cycle:	21-35 days	Length of period:	5 days
On period when tracking started:	Yes	Contraceptive method/s:	Condom,
First day of cycle:	15-3-2022	Pill	
Last day of cycle:	-		

Figure 40 Questionnaire parameters

16.2.2 Summary

The summary of your data depends on the quantification method you have chosen based on the hygiene products you use.

16.2.2.1 Summary - Quantification using pictogram

If you have quantified your cycle using pictograms (“study products”), the summary shows different values (Figure 41).

Your summary:

Total volume*:	59 ml	 Tampons	6	 Pads	4	 Products	10
----------------	-------	---	---	--	---	--	----

Your chart:

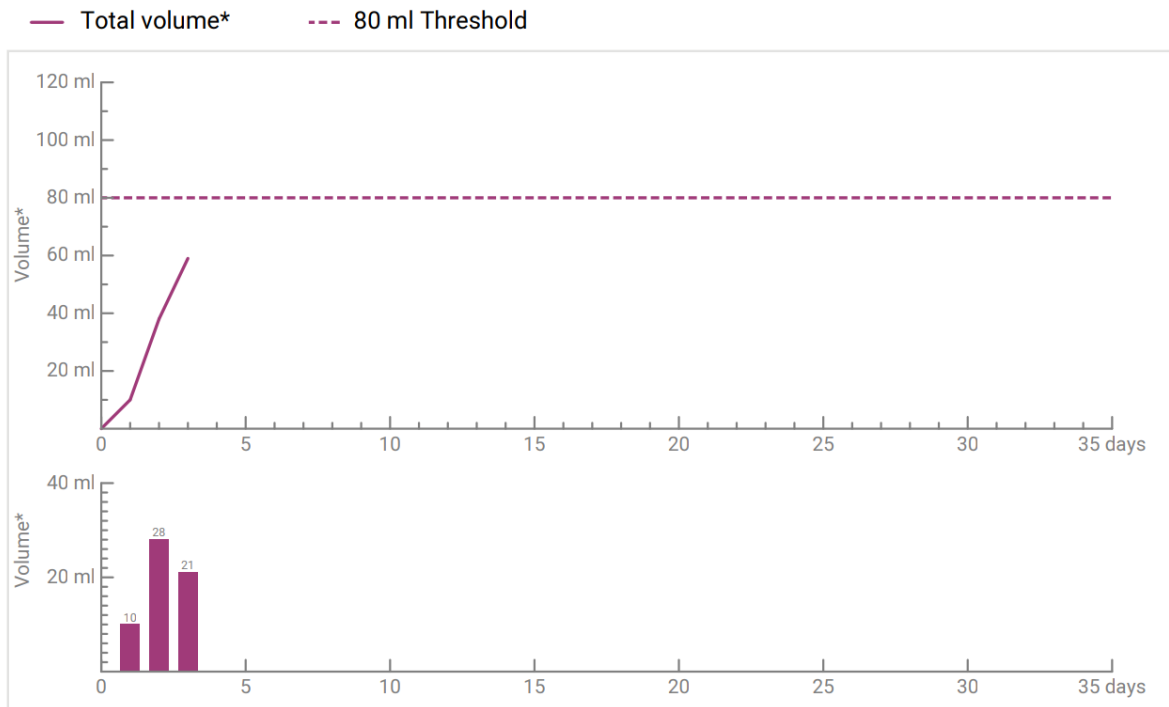


Figure 41 Summary - Quantification using pictogram

You can see the total bleeding amount of your cycle in the summary. You can also see the total number of hygiene products used, as well as the number of products used in total (Figure 42).

Your summary:

Total volume*:	59 ml	 Tampons	6	 Pads	4	 Products	10
----------------	-------	---	---	--	---	--	----

Figure 42 Total values - Quantification using pictogram

The graphs below show the progression and spread of the bleeding days during your cycle. The legend (Figure 43) tells you what the individual indicators mean.

Your chart:

— Total volume* - - - 80 ml Threshold

Figure 43 Legend - Quantification using pictogram

The first of the two graphs represent the total bleeding amount throughout your cycle (Figure 44). The horizontal axis shows the days of the cycle and the vertical axis the bleeding amount in millilitres.

The dashed line shows you the 80 ml limit - any monthly blood loss above this is categorised as high. The purple curve shows your blood loss over a cycle.

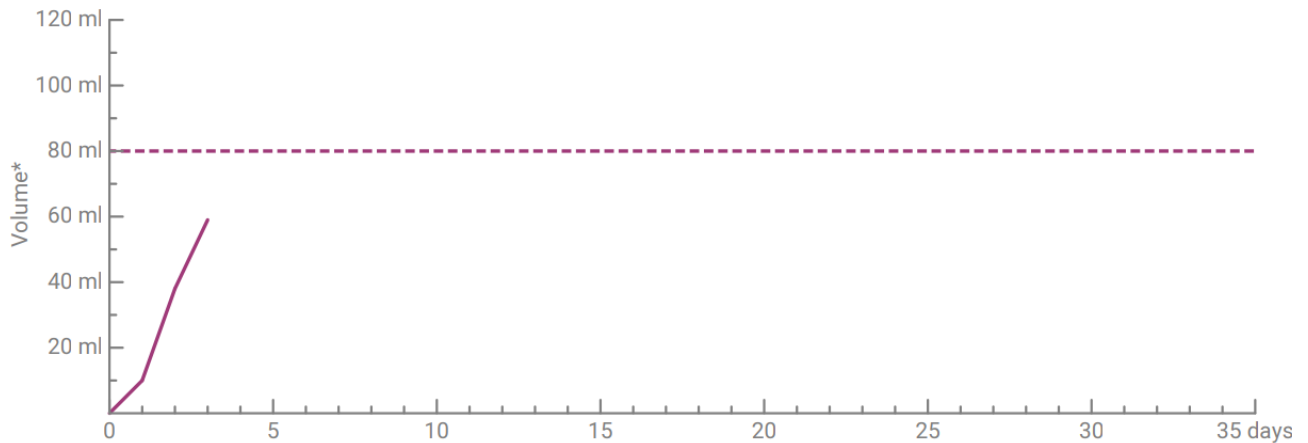


Figure 44 Curve - Quantification using pictogram

The graph below shows your daily bleeding amount (Figure 45). The horizontal axis shows the days of the cycle and the vertical axis the bleeding amount in millilitres.

The number above indicates the rounded millilitre value of the daily bleeding amount.

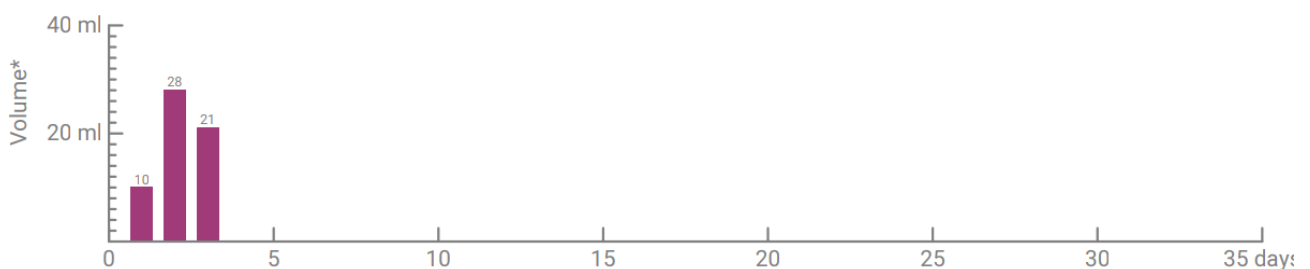


Figure 45 Bleeding amount per day

16.2.2.2 Summary – Quantification using bleeding diary

If you have quantified your cycle using the bleeding diary (“other products”), you will receive the following summary (Figure 46):

Your summary:

Total volume: 100 ml

Your chart:

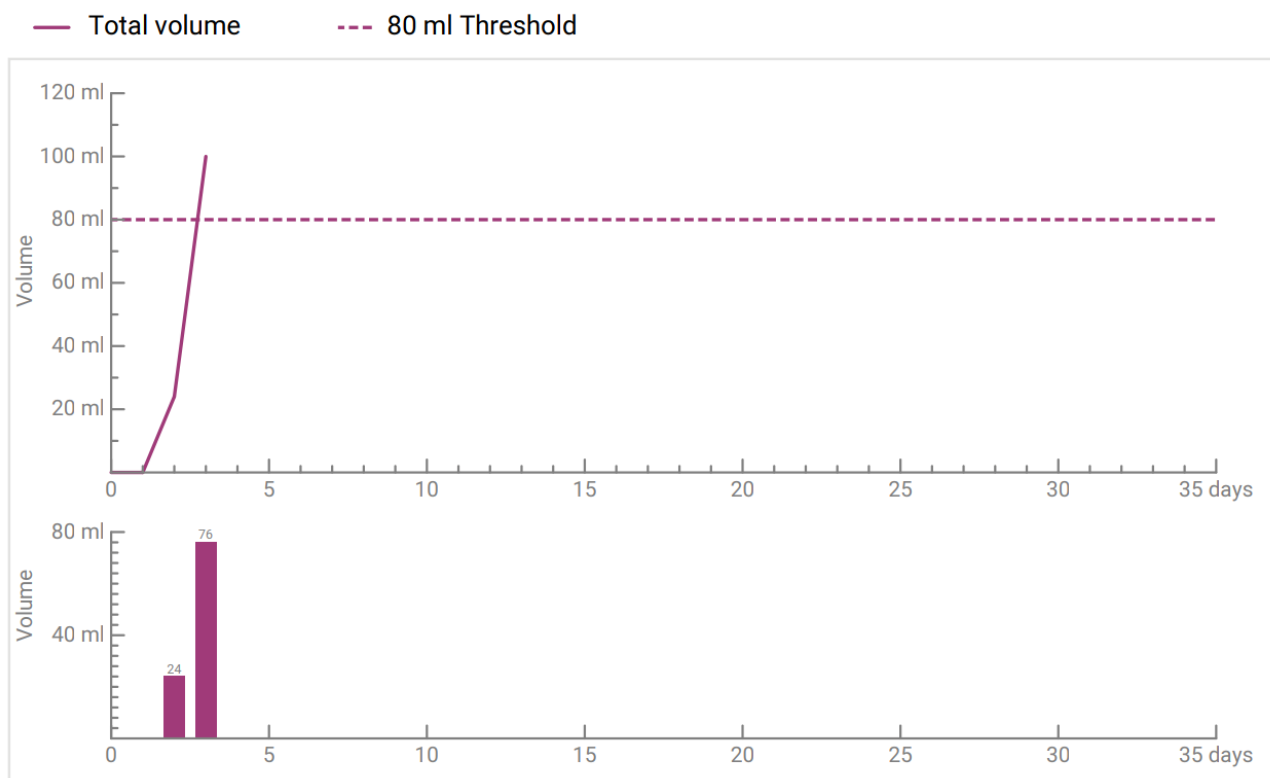


Figure 46 Summary - Bleeding diary

The total bleeding amount from your cycle is shown in the summary(Figure 47).

Your summary:

Total volume: 100 ml

Figure 47 Total values - bleeding diary

Below are two graphs that show your cycle in more detail.

The first of the two graphs represent the total bleeding amount throughout your cycle (Figure 48). The horizontal axis shows the days of the cycle and the vertical axis the bleeding amount in millilitres.

The dashed line shows you the 80 ml limit - any monthly blood loss above this is categorised as high. The purple curve shows your blood loss over a cycle.

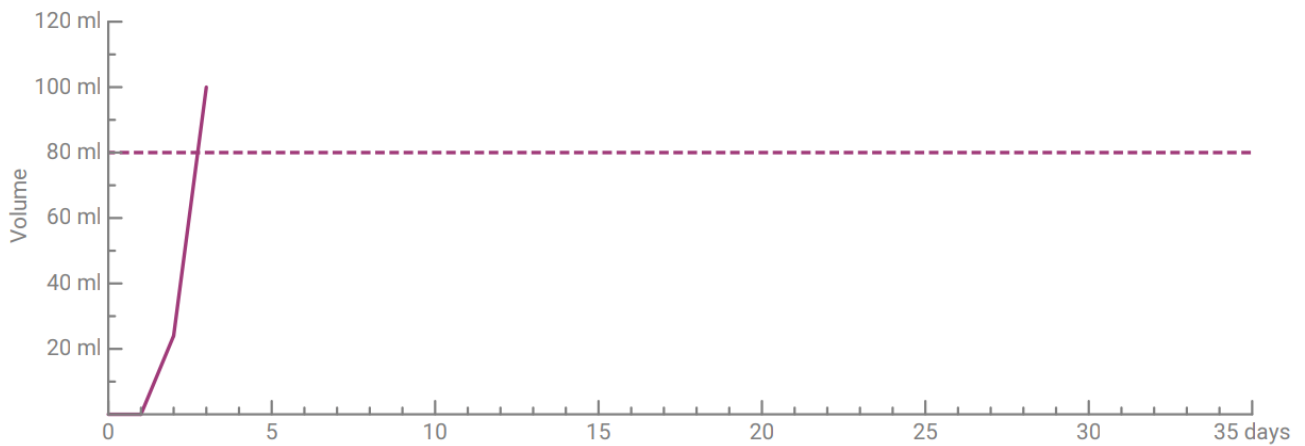


Figure 48 Curve - Bleeding diary

You can see your daily bleeding amount in the lower graph (Figure 49). The horizontal axis shows the days of the cycle and the vertical axis the bleeding amount in millilitres.

The number above indicates the rounded millilitre value of the daily bleeding amount.

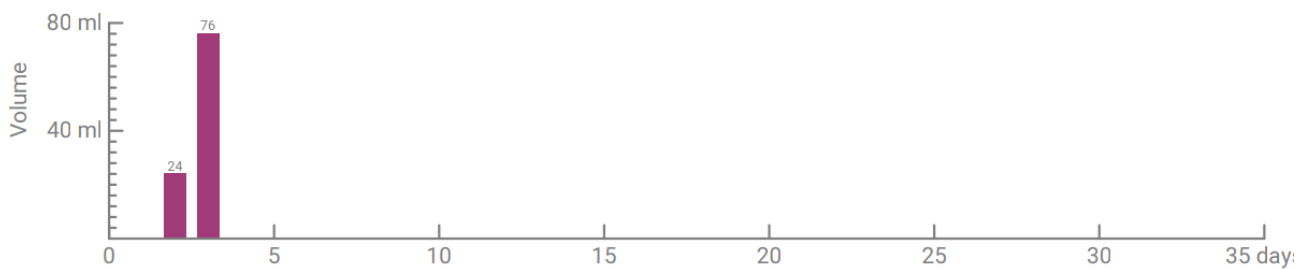


Figure 49 Bleeding amount per day

16.2.3 Results field

In the results field (Figure 50) you will be shown a text evaluating your personal bleeding within your cycle.

Your result:

You have exceeded a level of 80 ml which is considered to be an indicator for heavy menstrual bleeding even though you might perceive this differently. Usually, monthly bleeding is only in the range of 30-40 ml. Your result does not need to be a cause for concern! Please discuss it openly with your doctor.

Figure 50 Results field

16.2.4 Notes field

In the notes field (Figure 51) you can write down additional notes or comments for your doctor on the printed report.

Your notes:

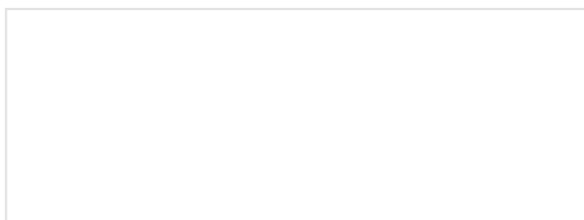


Figure 51 Notes field

Blood Loss of more than 80 ml

17 Exceeding the 80 ml limit

As soon as you have exceeded a bleeding amount of 80 ml in one cycle, FlowCyclo® will inform you.

You will receive a message (Figure 52) on the Home screen that you have lost over 80 ml of blood during your current period as a result of your last entry. The message informs you of what exceeding the 80 ml limit means in real terms.

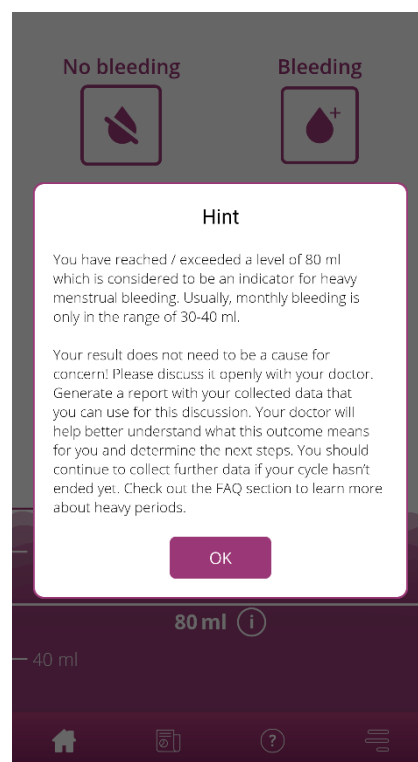


Figure 52 80 ml message

Tap the Ok-button to close the pop-up.

After closing the message, you get to the Home screen, which then shows the 80 ml limit violation as shown in Figure 53. You can also see your current blood loss and the exact millilitre value.

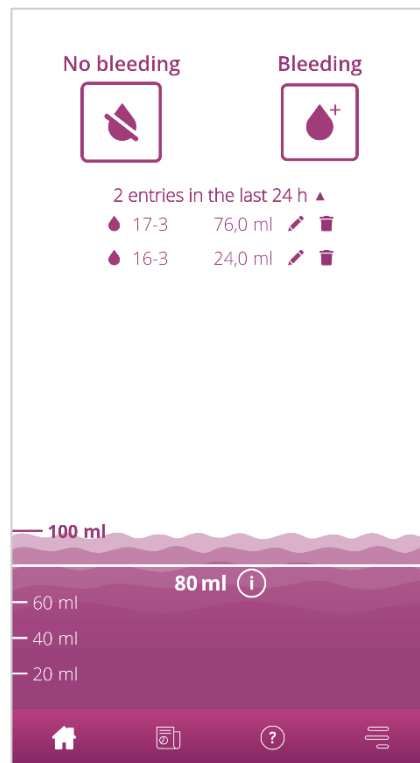


Figure 53 Home screen - 80 ml exceeded

The white line with the inscription "80 ml" shows you the value at which the blood loss is critical. If this value is exceeded, you will also see an Information button. If you tap this, the message that was displayed at the time of the limit violation opens again.



Note:

You can and should continue to enter bleeding for the cycle despite exceeding 80 ml. Only if you enter all bleeding from the cycle can the calculation correspond to the exact values of your blood loss.

Start a New Cycle

18 Start of a new cycle

Using your cycle length and bleeding length information, FlowCyclo® calculates the start of a new cycle.

18.1 Confirm cycle start

As soon as you have reached the calculated start of a new cycle with FlowCyclo®, the app will ask you whether the entry belongs to a new cycle (Figure 54).

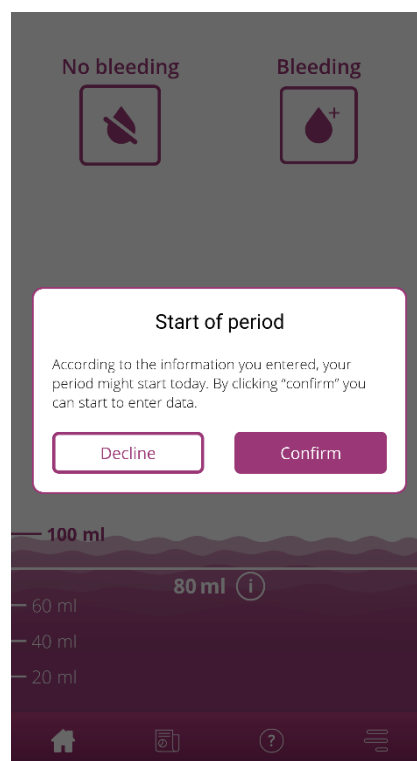


Figure 54 Start of a new cycle

If you have no bleeding when asked, you can answer this question with a "no". The app will then ask you again within a defined time frame whether your new cycle has started.

Only when you confirm the start of a new cycle will the app stop asking and the previous cycle, if available, will be closed. The new cycle is only started once you confirm. This means that you can no longer make any changes or entries for the previous cycle.

18.2 First day of menstruation in a new cycle

If you have confirmed the start of a new cycle, you will then be asked about the first day of bleeding (Figure 55). As before, you enter this via a calendar (Android) or date picker (iOS).

Please note that you cannot select a date in the future.

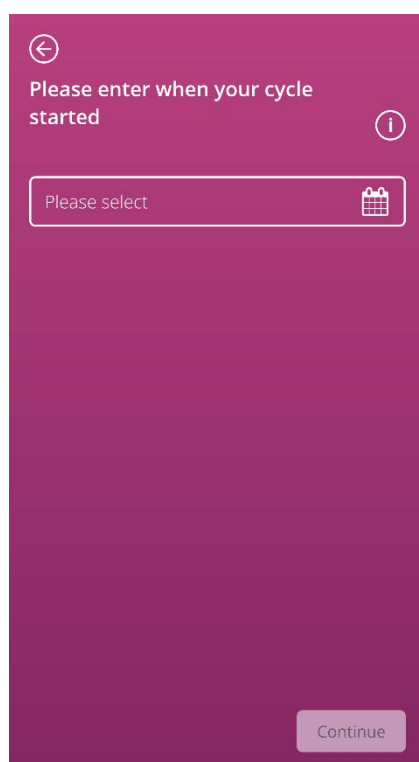
The screenshot shows a mobile application interface with a dark purple background. At the top left is a white back arrow icon. Below it, the text "Please enter when your cycle started" is displayed in white. To the right of this text is a white information icon (a lowercase 'i' inside a circle). Below the text is a white rectangular input field containing the text "Please select" and a white calendar icon on the right side. At the bottom right of the screen is a light purple button with the word "Continue" in white.

Figure 55 Start of a new cycle - date

18.3 Brand selection for a new cycle

When you have answered the two questions about the start of the cycle and the first day of menstruation of the new cycle, FlowCyclo® enables you to make a new selection of product brands for the new cycle. You can only choose one of the two product brands. The product brands used determine the quantification method that is used for the cycle. You can find more information on this in Chapter 9 Selection of product brand.



Note:

You cannot change this selection during an ongoing cycle. The quantification method used based on the product brand is fixed for one cycle. However, you have the option of choosing a different product brand and thus a different quantification method at the beginning of the next cycle.

Irregular Cycle

19 Irregular cycle

When you used FlowCyclo® for the first time, you were asked how many days your cycle lasts (8.4 Question – Cycle length). You had to choose from four different answers:

- < 21 days
- 21 – 35 days
- > 35 days
- Variable / irregular

If you have chosen a variable or irregular cycle length, the app will ask you to enter all days with and without bleeding for 35 days. This should record all bleeding that occurs in your irregular cycle and make it evaluable. After the 35 days, a new cycle begins, which continues for another 35 days, during which you can continue to enter your bleeding.

If you have selected a cycle length of less than 21 days or more than 35 days, the app will treat your cycle like an irregular cycle. Since a cycle length of less than 21 days or more than 35 days is unusual, FlowCyclo® will try to record as much bleeding data as possible from you.

If you have a cycle of less than 21 days, FlowCyclo® will ask you to enter all bleeding data for a period of 35 days. If you enter your bleeding data for 35 days, it is possible to record your cycle beyond its supposed duration. This can give your doctor important information about your bleeding behaviour.

If you have a cycle length of more than 35 days and specify this in the app, the app will still end your cycle after 35 days. However, you will be asked to enter another cycle in the app. You can enter additional cycles of up to 35 days each in the app. By recording several cycles, you help your doctor gain important insights into your long-term bleeding behaviour.

Notifications

20 Notifications

FlowCyclo® has a range of notifications to remind you to enter your bleeding data. You will receive notifications after opening the app and system notifications when you have closed the app. The purpose of the notifications is to ensure that the data you have entered is complete and correct.

20.1 In-App notifications

FlowCyclo® shows you two different types of notifications in the app.

20.1.1 Missing entries

The app reminds you to enter your bleeding into the “app” if you have not made any entries for a significant period of time.

You will be notified when you open the app. You can close the notification by tapping the “Close” button.

20.1.2 Start of a new cycle

As soon as the app has calculated the start of a new cycle based on your entries, the app will show you a notification. This will ask you if your new cycle has already started. If you answer this question by tapping the "No" button, the notification will repeat itself until you confirm the start of a new cycle.

If you confirm the start of the new cycle by tapping the "Yes" button, you will be asked further questions about the first day of your new cycle and your hygiene product brand. More information about this process can be found in Chapter 18 Start of a new cycle.

If you have specified a cycle length of less than 21 days or more than 35 days or an irregular cycle length, the app automatically ends your cycle after 35 days and starts a new cycle. You will not be asked for the first day of your bleeding. However, you can choose the brand of your hygiene products at the beginning of each new cycle.

20.2 System notifications

FlowCyclo® provides various notifications when the app is closed.



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 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.

20.2.1 Missing entries

The app reminds you to complete your data if you have not made any entries for a long period of time, even if you do not currently have the app open. Tapping the notification takes you straight to the app and you can add your missing data.

20.2.2 Start of a new cycle

As soon as the app has calculated the start of a new cycle based on your entries, the app will display a system notification if you do not currently have the app open.

If you tap the system notification, the app opens and you will see the question about the start of a new cycle, as discussed in 18 Start of a new cycle.

20.3 Customizing the reminder time

The app allows you to customize the interval or time for the missing entries reminders.

You can either set a reminder frequency, such as every eight hours. To do this, select the Frequency button and set the time in hours between your reminders (Figure 56).

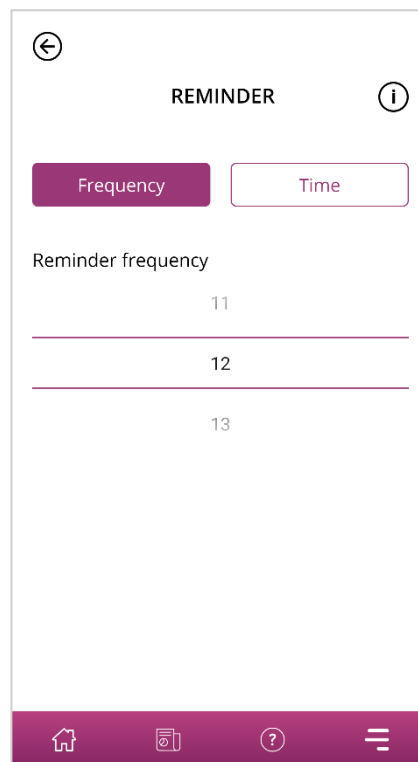


Figure 56 Set frequently reminder

You can also set a fixed time for your reminders. To do this, tap the "Time" button and set your preferred time for the daily reminder in the spinner (Figure 57).

←

REMINDER

ⓘ

Frequency

Time

Daily reminder time

11	59
12	00
13	01

🏠

📅

?

☰

Figure 57 Set reminder time

FAQ

21 Frequently Asked Questions (FAQ)

If you have any questions about menstrual bleeding, the app or how it works, you can find more information in the app.

You can find information like this in the FAQ. Frequently asked questions can be accessed via the "FAQ" menu item (Figure 4).

21.1 FAQ categories

If you tap on the "FAQ" menu item, you will be taken to the associated FAQ screen (Figure 58). On this screen you will find the current question categories.

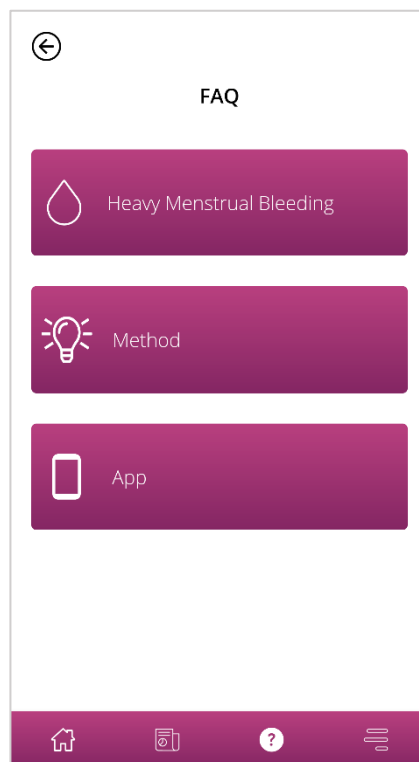


Figure 58 FAQ – Categories

There are three different categories to choose from, each with different questions. To open one of the categories, tap it.

21.2 FAQ categories – Questions

Tapping a category takes you to the respective category screen, which shows all questions of the selected category as shown in the example in Figure 59.

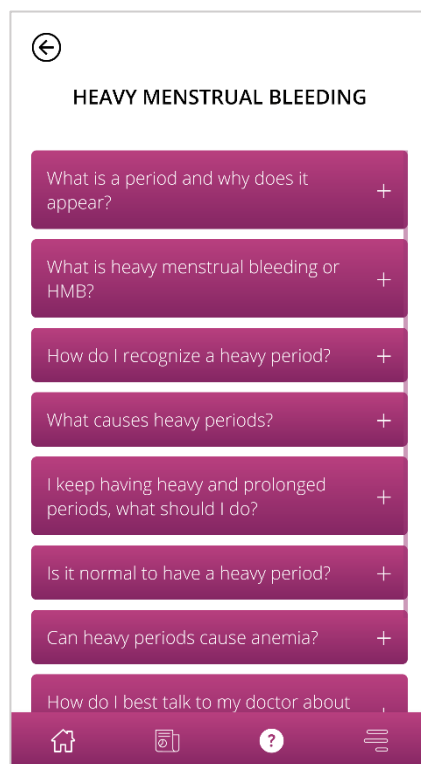


Figure 59 FAQ – Questions

If you would like to see the answer to a question, you can open it by tapping the question. This will open the answer to the question (Figure 60).

Tapping the question again closes the answer.

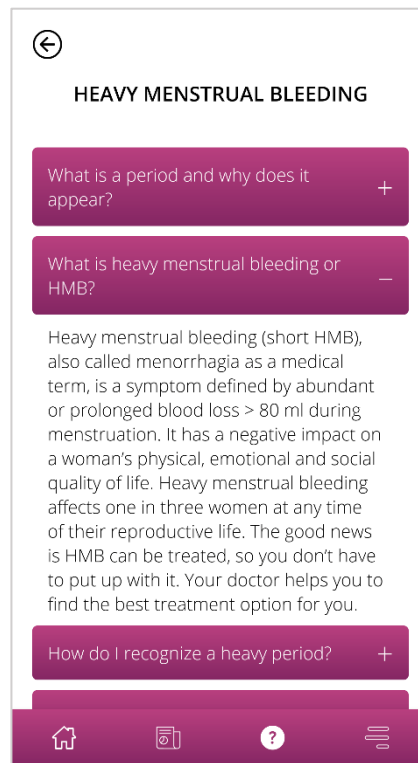


Figure 60 - FAQ – Question and answer

If you have further questions that are not included in the FAQs, you can go to the technical support. This is explained in the following chapter.

Additional Information

22 Support

You can access the various support options by tapping the "Support" menu item, as described in Chapter 6.3 Instructions for use.

This takes you to Support (Figure 6), which shows you all the support options that the app offers.

22.1 Email support

If you would like to send a support request by email, tap the email address on the support screen (Figure 61). The email app on your smartphone opens and you can write a request.

Send an e-mail:

 FlowCyclo@bayoocare.com

Figure 61 Email address

22.2 Hotline support

If you would like to clarify a support request using the support hotline, tap the hotline phone number on the support screen (Figure 62). The phone app on your smartphone opens and you can call the hotline.

Call the FlowCyclo service hotline:

 [+31 8000233301](tel:+318000233301)

Figure 62 Hotline phone number

22.3 Instructions for use

"Instructions for use" covers everything you need to know on how to use FlowCyclo®. If you tap on the Instructions for Use (Figure 63) your smartphone's standard app for opening PDF files will be displayed. Here you can select your preferred app in which you want to open the PDF "Instructions for Use".

FlowCyclo manual:



Figure 63 Instructions for Use

22.4 Feedback

Once you have entered at least one complete cycle into FlowCyclo®, you are welcome to rate the app by giving feedback. To do so, tap the feedback option that will be displayed once you have completed a cycle.



Note:

Until you have entered a full cycle in FlowCyclo®, you cannot provide feedback. Accordingly, no feedback option will be displayed.

You will be redirected to the feedback screen, which displays various questions that you can rate by selecting one of the rating icons.



Note:

If you have already given feedback for the previous cycle, you cannot give further feedback during the current cycle.

23 Legal notice

You can access the legal details of the app by tapping the menu item "Legal Notice" (Figure 4).

This takes you to the Legal Information screen (Figure 64), which displays the links for the Privacy Policy and the Terms of Use, and the Manufacturer Information contained on the app. You can also set your preference towards tracking of analytical data.

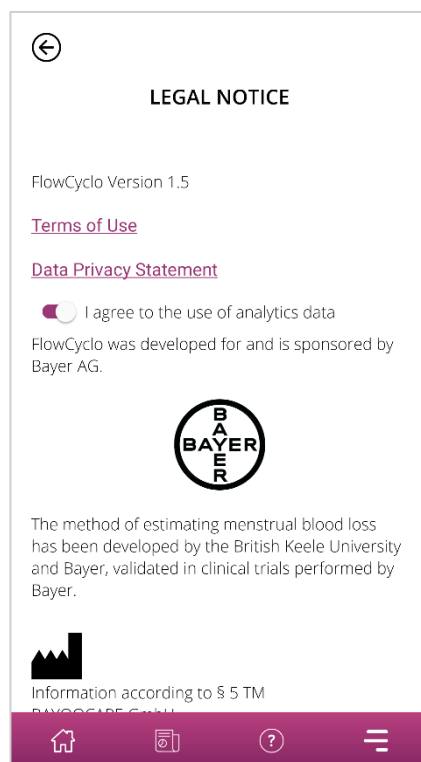


Figure 64 Legal notice

23.1 Terms of use

To read the terms of use, tap "Terms of Use". You will be shown your smartphone's standard app for opening PDF files. Here you can select your preferred app in which you want to open the PDF "Terms of Use".

23.2 Privacy policy

To read the privacy policy, tap "Privacy Policy". You will be shown your smartphone's standard app for opening PDF files. Here you can select your preferred app in which you want to open the PDF "Privacy Policy".

23.3 Manufacturer information

The manufacturer information contains information on the legal manufacturer of the product.

23.4 Data Tracking

You can set your preference for the tracking of analytical data, which is used for the improvement of FlowCyclo®, anytime. When 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.