

Ruma Digital-System



CE Ruma® Digital-System (Pro) is a CE marked medical device

Ruma Digital-System (Pro) instructions for use

Ruma Digital-System (Pro) is a class I medical device in accordance with MDR 2017/745. These instructions for use ensure the correct application of Ruma Digital-System (Pro). Please read this information carefully and follow the instructions contained therein. The detailed manual and the Ruma support team during regular business hours are also available for any questions that may arise.

INTENDED USE

Ruma Digital-System (Pro) supports relapse management alongside therapy of addiction patients with mental and behavioural disorders due to psychotropic substances (ICD-10 Code F10-F19).

Ruma Digital-System (Pro) allows urine sample collection for the purpose of abstinence monitoring on the patient's own responsibility and independent of location. Through the intake of a urine marker substance, documented in a video recording, urine samples are positively matched to the patient. The behaviour of the patient during application of the Ruma Digital-System provides additional action-specific parameters such as calm and composure during the process, shaking hands etc. that can be included in the assessment of therapy progress. Support in coping with every-day life and time saving effects increase therapy readiness, motivation and adherence.

Ruma Digital-System (Pro) is structured in two modules that are only functional in combination: Ruma Digital-System (patient module) and Ruma Digital-System Pro (medical office module). Using the medical office module (Ruma Digital-System Pro) individually labeled urine marker substances are logged and assigned to patients. Through an integrated messaging feature urine sample provision is timed flexibly and in a manner that cannot be anticipated by the patients. Additionally, the app supports the asynchronous validation of the transmitted intake videos.

The patient module (Ruma Digital-System) prompts the patients via the messaging feature to provide a urine sample without prior notice. Afterwards the patient module verifies the security features of the urine marker substance as well as the correct assignment and allows, upon successful matching, the documentation of intake of the urine marker substance on the patient's own responsibility. The execution is comprehensibly described in the form of an instruction video. The video recording is encrypted and transmitted to the treating physicians. A validation of the regular execution is performed. Validation by laboratory analysis of the urine marker substance can thus verify potential concomitant use.

By avoiding medical office visits for such urine tests additional freedom is created for participation in social and working life, active support is provided for reaching the set therapy goals of adherence and personal responsibility is increased. In the event of pandemics no contact is necessary.

WORKING PRINCIPLE

The application Ruma Digital-System (Pro) is structured in two modules. The medical office module **Ruma Digital-System Pro** allows the treating physician to register and assign individually identified urine marker substances as well as the asynchronous evaluation of retransferred information in particular regarding willingness for therapy, therapy adherence, ability to reason and motivation.

The patient module **Ruma Digital-System** allows demonstration of urine marking performed on the patient's own responsibility by using and matching dedicated identification features. These include the individual urine marker substances as well as the recording of the intake of these marker substances in a video. After successful verification of the security features as well as encryption of the video sequence the video is transmitted to the treating physician for evaluation.

Communication between the two modules is realized on a non-public blockchain and is end-to-end encrypted.

Any urine marker substance can be utilized that is equipped with individual security features that can be processed by Ruma Digital-System (Pro).

REQUIREMENTS FOR USE

The app Ruma Digital-System (Pro) is structured in two modules. The module Ruma Digital-System is designed for patients. The module Ruma Digital-System Pro is used by physicians. To use the App Ruma Digital-System (Pro) it is necessary that the treating physician has a tablet with installed app Ruma Digital-System Pro available and that the smartphone of the patient is paired with the physician's tablet.

Patients download the App Ruma Digital-System themselves from Google app store (Play Store) or Apple App Store to their smartphone. The smartphone needs to have at least 100 MB of temporary storage space available. Physicians download the app Ruma Digital-System Pro themselves from Google app store (Play Store) or Apple App Store to their tablet. The tablet or smartphone, respectively, needs to have at least a 720P camera (both front and rear). The operating system needs to be at least Android 5.0 or iPadOS 12.3 (Ruma Digital-System Pro) or iOS 14.1 (Ruma Digital-System), respectively.

Participating physicians receive their invitation code for the activation of the software from the manufacturer. Patients activate the app by pairing their smartphone with their physician's tablet.

FIELD OF APPLICATION

Therapy of mental and behavioural disorders due to psychotropic substances in accordance with ICD-10 Code F10-F19.

WHEN should Ruma Digital-System (Pro) NOT BE USED (CONTRAINDICATIONS)?

Ruma Digital-System (Pro) should not be used in the event of manifest non-adherence and increased risk of relapse within the context of addiction therapy. There are no medical contraindications in accordance with ICD-10 regarding the application Ruma Digital-System (Pro).

FORM AND DURATION OF USE

The duration of use is determined by the respective treating physician in accordance with the individual patient's course of therapy.

NOTES

Ruma Digital-System (Pro) does not serve diagnostic or therapeutic purposes. Ruma Digital-System (Pro) has its effect alongside therapy.

For further information regarding safety and clinical performance of urine marking within the context of relapse management please visit <https://www.marker-test.de/en/literature>. Additional studies on the app Ruma Digital-System (Pro) will be published upon completion.

FREQUENCY OF USE

A suitable frequency of use is specified by the physician and may change during the course of therapy.

AGE LIMITATION

18 to 70 years of age.

SIDE EFFECTS

It is possible that not every patient benefits from the system which may cause feelings of disappointment. Contact your physician if necessary. Should side effects occur within the context of using Ruma Digital-System (Pro) please notify your physician immediately or contact Ruma.

INTERACTIONS

No interactions are known so far.

Be advised that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CONTACT INFORMATION

To protect your personal data all possible steps have been taken so that the identity of the using patients is never revealed to the manufacturer. Any exchange of data through the app between physician and patient happens within the blockchain and cannot be accessed by third parties.

Should you, as a user, need to contact the manufacturer by phone neither your name nor your contact data will be stored. Therefore, please be advised that it will not be possible to return your call. Data provided to the manufacturer via the contact form at <https://www.marker-test.de/en/contact> will be deleted immediately after the message has been processed.

MANUFACTURER

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Fax: +49 221/ 3990 11 20
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www.marker-test.de

VERSION OF THE SOFTWARE

Please find the current software version of Ruma Digital-System (Pro) in the menu at the upper right corner of the respective application.

If available updates can be downloaded via the respective app store. Updates will be installed automatically on devices that have automatic updates activated in their settings.

VERSION OF INFORMATION

Ruma Digital-System 1.1.0

UDI-DI 111820761225

2023-01-19

☞ Ruma® Digital-System (Pro) is a CE marked medical device

1 Ruma Digital-System

Ruma has developed an app system that allows patients autonomous urine labeling through intake of a marker capsule.

Correct intake of the marker substance required to do so is video documented with the help of the app.

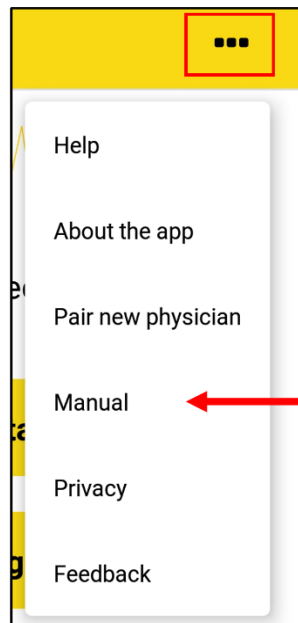
The urine marker is taken in the form of a marker capsule. The intake is documented within the app in an encrypted video that can be up to 120 seconds long. This video is then sent in another layer of encryption to the treating physician who assesses and evaluates it for correct intake and confirms adherence.

2 Downloading and activating the app

In order to install and use Ruma Digital-System, your smartphone requires an internet connection. The system requirements are at least Android 5.0 or iOS 14.1 as operating system and a camera with at least 720pixels (both front and rear camera). Please download the app from the respective store. Search for "Ruma Digital-System".

Updates can also be downloaded from the respective store, if available. If you have activated automatic updates in your settings, the updates will be installed automatically.

You can also access this manual through the app in digital form. To do so, open the menu in the upper right corner and select "Manual". You will be directed to the Ruma website where you can download the manual.



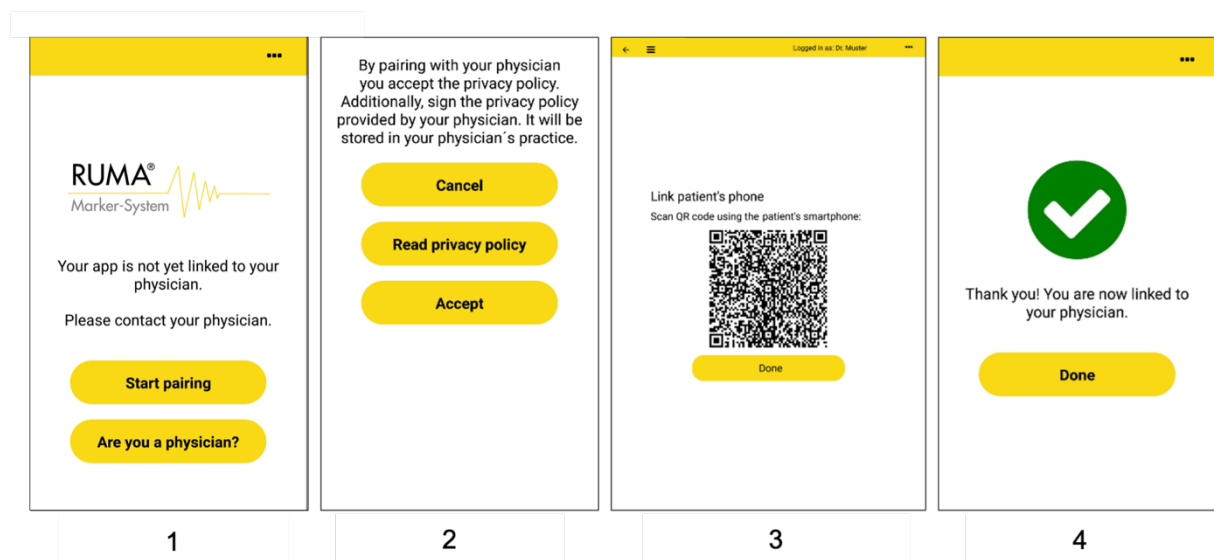
Your smartphone needs to be paired once with the tablet of the treating physician and thus activated in order to use the app and record videos. After this step, your physician will automatically receive the encrypted videos.

Please carry out the following steps together with a staff member of your medical practice:

- 1) Start the app and select **“Start pairing”**. At this point you have to accept the privacy policy. You can read it by selecting **“Read privacy policy”**. After accepting the privacy policy by selecting **“Accept”** the camera of your smartphone will be activated. Should you intend to use the app not as a patient but as a physician, then the button **“Are you a physician?”** will direct you automatically to the appropriate download site for Ruma Digital-System Pro for your operating system.
- 2) Now scan the QR pairing code with your camera that is displayed on your physician's tablet.
- 3) Successful pairing is confirmed with a green checkmark. Select **“Done”**.

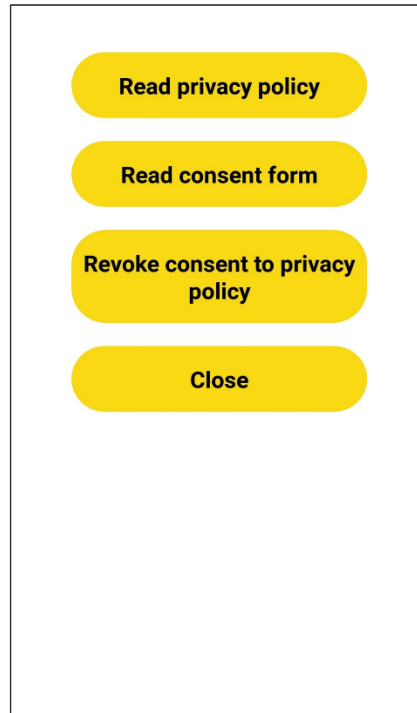
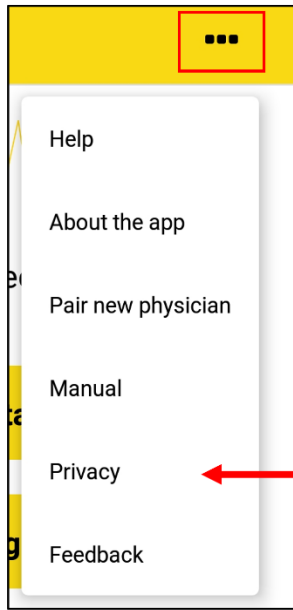
You will then get to the home screen.

The app is now activated to record marker intakes.



1: Start pairing with physician; 2: Reading and accepting of the privacy policy; 3: QR code displayed on the physician's tablet that needs to be scanned by the patient; 4: Confirmation of successful pairing.

You can revoke your consent to the processing of your data at any time. By doing so the pairing with your physician will be cancelled and you can no longer use the app until you pair your smartphone with your physician again. Open the menu in the upper right corner and select **“Privacy”**. This opens a new window where you can read the privacy policy or the consent form and revoke your consent.



3 Features in Ruma Digital-System

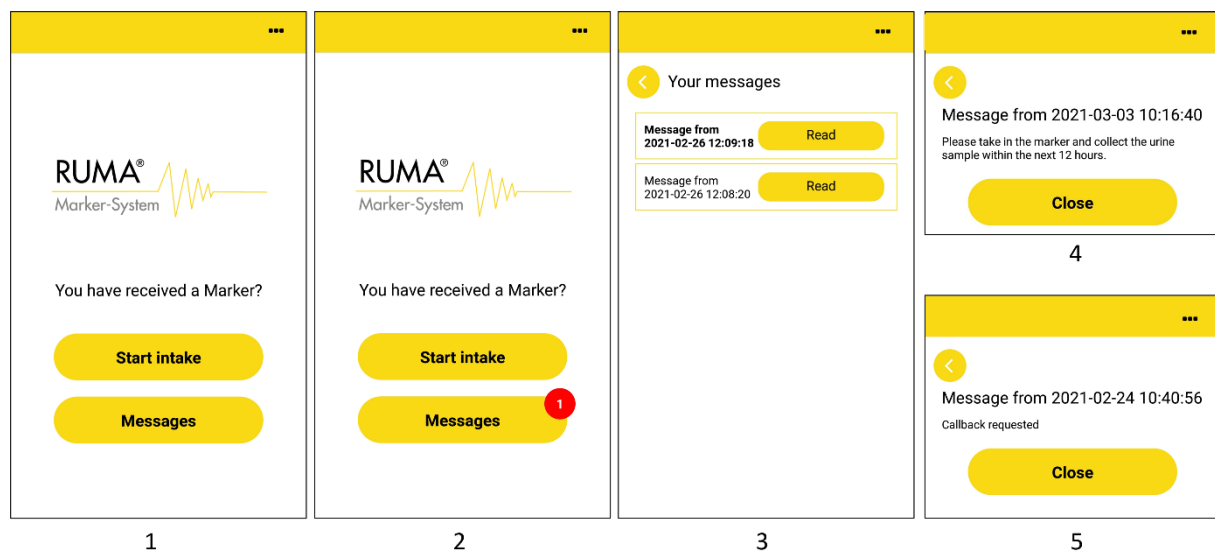
3.1 Marker and Messages

Once your smartphone is paired with the tablet of your treating physician you can use the app independent of location for marker intake, sample identification and prove of therapy adherence.

You can start the process by clicking the button **“Start intake”** on the home screen.

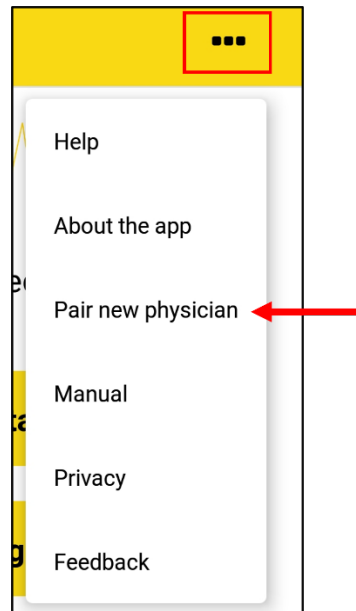
The **“Messages”** button gives you access to messages that your physician has sent you. New messages are displayed as white numbers on red background. Messages received while the app is switched off will also be shown when the app is started. Please check periodically whether your physician sent you a new message. Additionally, please make sure that push notifications are switched on so that you can receive the messages even when the app is not active.

Selecting **“Messages”** shows an overview of the messages you received so far. Unread messages are displayed in bold font. A **“Read”** button is displayed next to every message to access the actual text of the message. Your physician can send you only two types of messages. A request to carry out urine sample collection within the next 12 h or a request for callback.



1: Home screen after pairing with physician; 2: New message notification; 3: Overview of received messages; 4: Request to carry out urine sample collection; 5: Request for callback.

If you want to switch physicians, open the menu in the upper right corner and select **“Pair new physician”**. You will then be directed to the start screen. You can pair your smartphone to the tablet of your new physician as described in chapter 2.

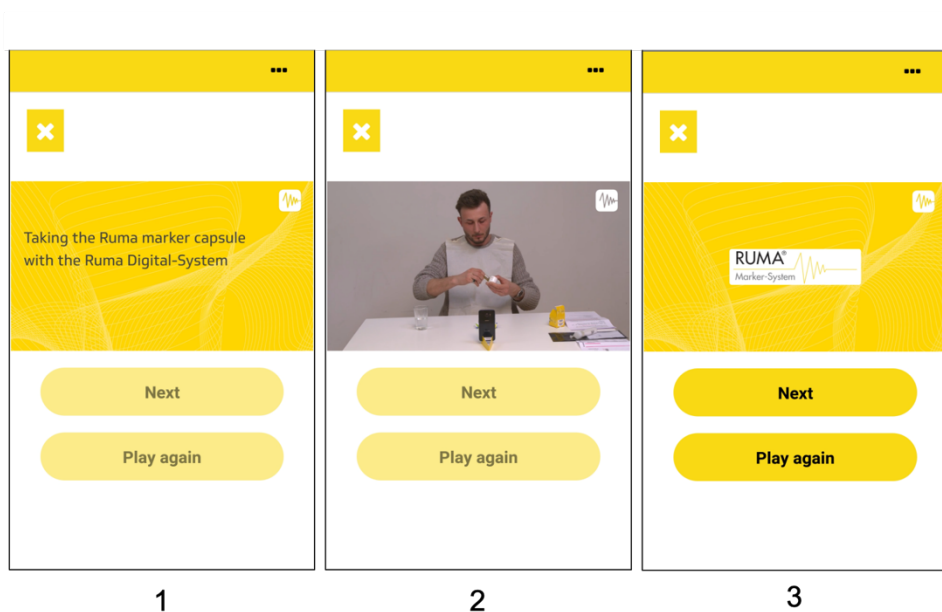


Before you proceed with the marker intake please read the provided intake protocol carefully and perform all preparations for the actual intake of the capsule.

3.2 The introductory video

For marker intake or to start recording, respectively, start the app and select **“Start intake”**. You are shown an introductory video that explains the intake procedure. This video needs to be downloaded once prior to first use. By design it cannot be skipped when you use the app for the very first time. Therefore, the buttons **“Next”** and **“Play again”** are not active when watching the video for the first time. At any subsequent start of the app, the video can be skipped by clicking **“Next”**. Use **“Play again”** to review the video from the beginning. By clicking on the video you can activate the playback options that allow you to pause, fast-forward or rewind the video (not possible when video is watched the first time).

The yellow cross at the top left of the screen allows you to abort the process. You will then return to the start screen. This option is available until you start to record your intake video.



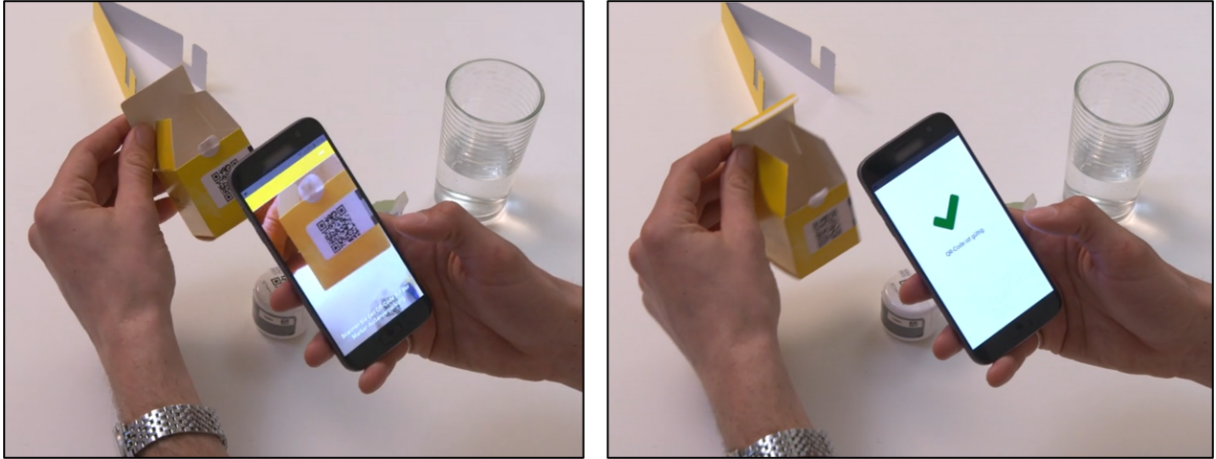
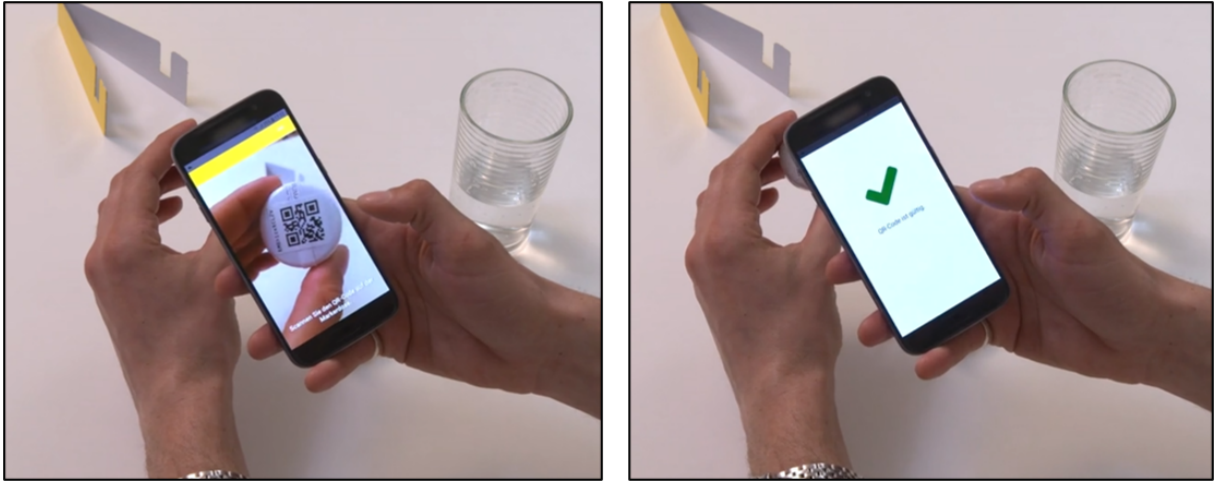
1: The introductory video will play automatically after “Start intake” was selected; 2: Introductory video for marker intake; 3: Only after the video has been watched completely at least once you can proceed with marker intake.

3.3 The intake procedure

Please follow the intake protocol for marker intake provided with every marker set. The marker intake has to be carried out exactly as described in the intake protocol. Any deviations might lead to an incorrect and thus invalid marker intake.

Preparation for marker intake and video recording:

- To set up your phone and to record the video you need a free space such as a table, a desk, a countertop or something similar.
- Make sure that there is sufficient lighting so that you and your actions are clearly visible in the video.
- Your smartphone needs to be charged at at least 25%.
- When filming, your forearms must be bare. Roll up your sleeves if necessary.
- Have a clear glass of water ready (volume approx. 200-300 mL/7-10 oz). Then open the (yellow) marker box and place the marker dish that's in it and the sherbet candies unwrapped on the table before you.
- Remove any other objects from the recording area that may obstruct or obscure your actions.
- Please put on the neutral bib and attach it.
- Start the app, select "Start intake" and follow the instructions below.

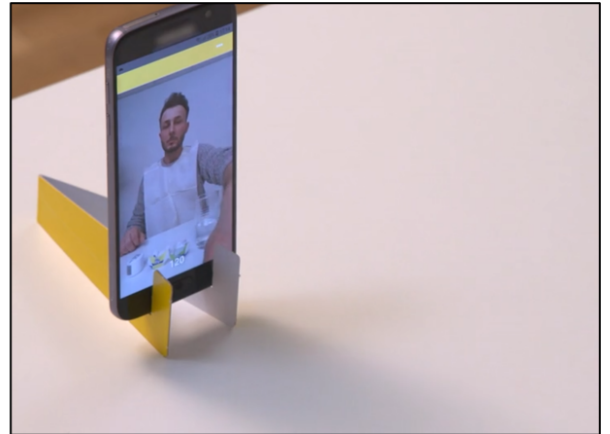
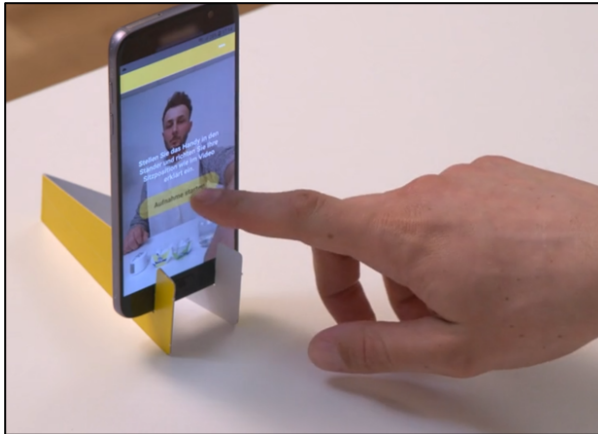
No.	Step by step instructions for marker intake with video recording
1	<p>Scan the QR-Code of the outer packaging Scan the QR code of the outer packaging (yellow box) by showing the code to the rear camera until you see a green check mark on the display for confirmation. You can now put the outer packaging aside, it is no longer needed.</p> 
2	<p>Scan the QR-Code of the marker dish Scan the QR code of the marker dish by showing the code to the rear camera until you see a green check mark on the display for confirmation.</p> 
3	<p>Align camera Place the phone upright in the provided holder with the display to your seating position. Put on the protective bib. Use the live image on the display to align your phone and seating position. The camera should capture the free table top, your bare forearms and hands (wrap up sleeves if necessary), as well as your upper body and face. The white marker dish, the glass of water and the unwrapped sherbet candies must also be clearly visible on the table in the video.</p>



Start video recording

Press "Start recording" on the display. You will now see a timer at the bottom of the screen, counting down the remaining recording time. You have 120 seconds to complete intake of the marker capsule. You can stop recording after 60 seconds at the earliest.

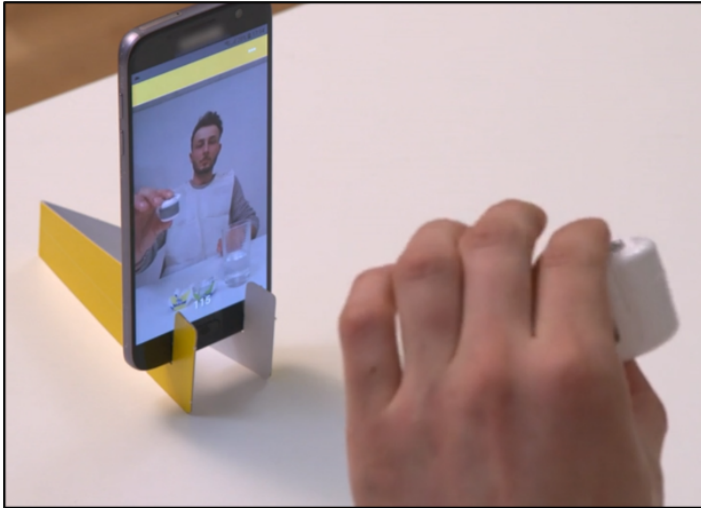
4



5

Take out capsule

Show all undamaged stickers of the marker dish to the camera. Next, peel off the grey security sticker. After that, open the dish in front of the camera. When the dish is open, place the palm of one hand on top of the open dish. Now turn your hand with the dish so that the capsule drops onto the palm of your hand. Put the dish aside and show your hand with the capsule on it to the camera.


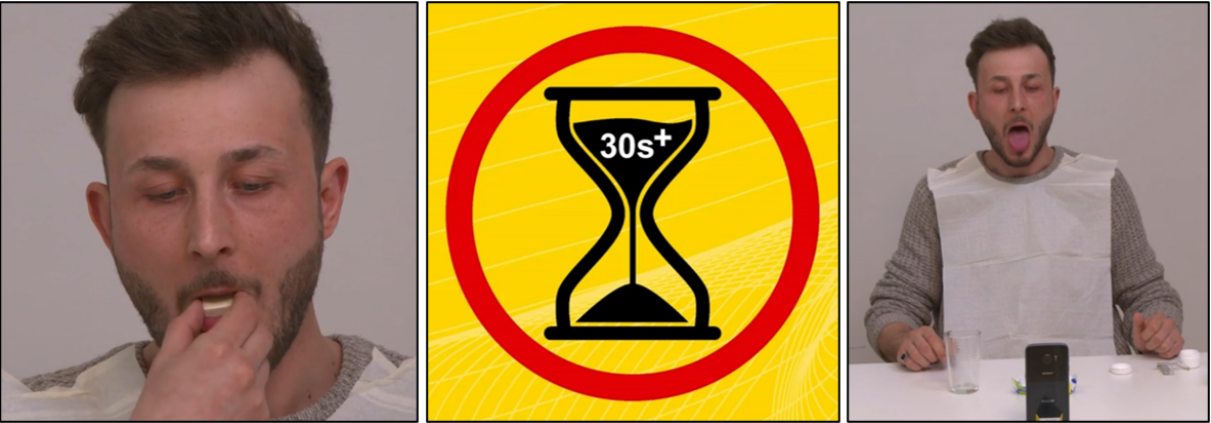


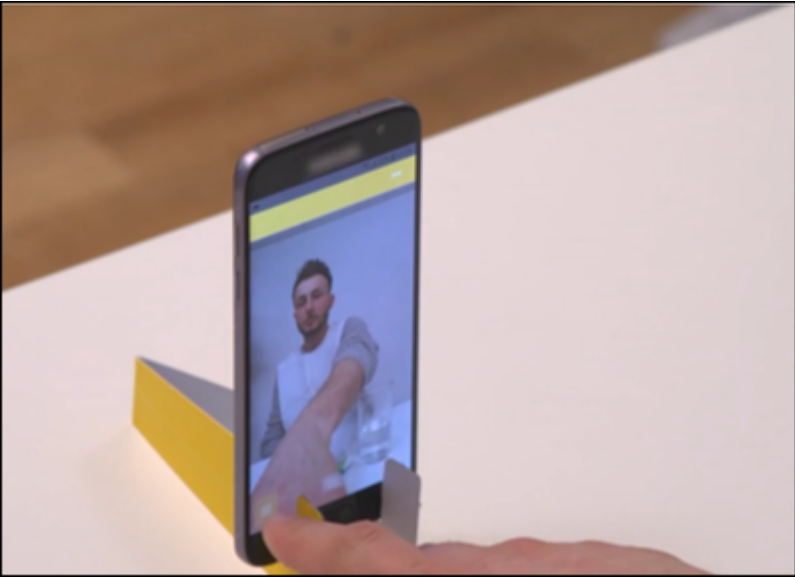
Show capsule and place on tongue

Take the capsule between thumb and forefinger of the other hand and show the capsule to the camera. Stick out your tongue and place the capsule on your tongue. Make sure to move your arm slightly to the side so it won't obstruct the camera's view on the capsule. Show the capsule on your tongue to the camera and take your tongue back into your mouth.

6



7	<p>Swallow capsule Now drink the water and swallow the capsule. Put the water glass back on the table in front of the camera after you swallowed the capsule. Then open your mouth wide and stick out your tongue.</p> 
8	<p>Chew sherbet candy Chew the two sherbet candies one after the other for at least 30 seconds with your mouth open until you can swallow them. Then stick your tongue out with your mouth wide open. It must not be blue.</p> 
9	<p>End recording Press the stop button (symbol on the lower left side of the screen) on the display of your phone to stop recording. Else, recording stops automatically at the end of the 120 second time frame.</p>

	
	<p>Note: The marker capsule dissolves in the mouth if not swallowed. If the capsule is not swallowed it will color the inside of your mouth and your tongue blue because the food colorant contained in the capsule is released.</p>

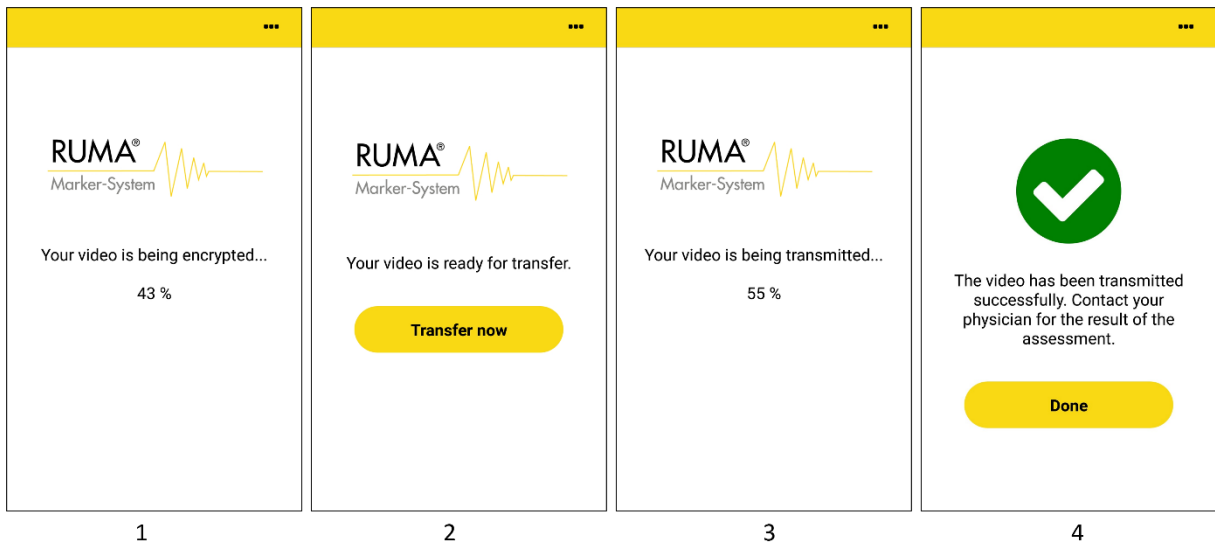
Incoming phone calls during recording of the intake video may interrupt recording depending on operating system and smartphone provider. Answering incoming calls will interrupt the video recording in any case. Therefore, do not answer any calls.

During recording the app may not be closed or the smartphone be turned off since this aborts recording. Aborting a video recording will be interpreted as a failed attempt.

Each marker can only be used once.

3.4 Transmitting the intake video

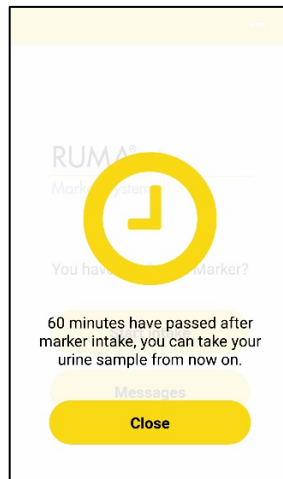
After recording has been stopped the video will be automatically encrypted. The progress of encryption is displayed in percent. Afterwards, the recorded video has to be sent to the physician. To do so, click **“Transfer now”**. The progress of transfer is again displayed in percent. Successful transfer will be confirmed with a green check mark. The video recording process is now completed. Select **“Done”**. You will be directed to the home screen.



1: Encryption of the video; 2: Prompt to send the video to the physician; 3: Video transfer; 4: Confirmation of successful transfer.

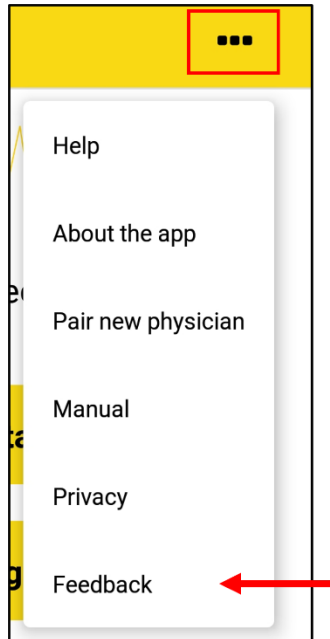
4 Collection of the urine sample

After the waiting period of 60 minutes has passed you will receive a message with the following text: "60 minutes have passed since marker intake. You can now collect your urine sample." Please follow the instructions for the steps after marker intake.



5 Feedback

Should you want to comment on the app or have technical problems using it you can send us anonymous feedback directly through the app. To do so, open the menu in the upper right corner and select "Feedback".



In the following window you can choose between three topics to give feedback on: technical problems, questions regarding use and comments on design or structure of the app. Select the category you want by tapping the circle located right in front of it.

Feedback

Here you can provide your feedback to the app entirely anonymously and in private.

I have feedback regarding the following issue:

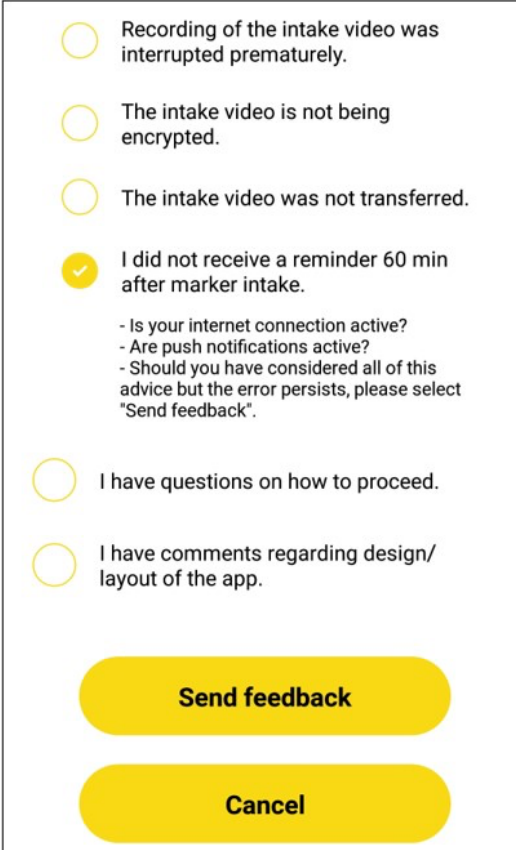
- I have a technical problem.
- I have questions on how to proceed.
- I have comments regarding design/layout of the app.

Send feedback

Cancel

Selecting "I have a technical problem" opens a list where you can pick the applicable issue you want to give feedback on.

Select the item you had a problem with. Additional tips and suggestions regarding your problem will be displayed. Should you have considered all suggestions but your problem persists, please select "send feedback". Please note that the button is only activated after you selected an item for processing.



The screenshot shows a list of six radio button options. The fourth option, "I did not receive a reminder 60 min after marker intake.", is selected, indicated by a yellow checkmark inside the radio button. Below this option are three bullet points: "- Is your internet connection active?", "- Are push notifications active?", and "- Should you have considered all of this advice but the error persists, please select 'Send feedback'". At the bottom of the list are two yellow buttons: "Send feedback" and "Cancel".

- Recording of the intake video was interrupted prematurely.
- The intake video is not being encrypted.
- The intake video was not transferred.
- I did not receive a reminder 60 min after marker intake.
 - Is your internet connection active?
 - Are push notifications active?
 - Should you have considered all of this advice but the error persists, please select "Send feedback".
- I have questions on how to proceed.
- I have comments regarding design/layout of the app.

Send feedback

Cancel

Selecting "I have questions on using the app" does not allow you to send feedback. In this case the button "send feedback" remains inactive. For questions on how to use the app, please read the instructions, watch the introductory video again, or contact your physician.

I have feedback regarding the following issue:

I have a technical problem.

I have questions on how to proceed.

- Please consult the instructions first. They can be accessed through the menu or on the Ruma homepage.
- Watch the introductory video again that is played after you select "Start intake". You can also find the video on the Ruma homepage.
- If you cannot find the answer to your question in either the instructions or the introductory video, please contact your physician.

I have comments regarding design/layout of the app.

Send feedback

Cancel

Selecting the topic "I have comments regarding the design/structure of the app" opens another selection with additional items. Pick the item you want to give feedback on and select "send feedback". The button only becomes available after you selected an item.

I have comments regarding design/layout of the app.

The buttons are too small.

The font size is too small.

Something doesn't show right on my phone.

The app is unclear and/or confusing.

The intake video is not clear.

Marker intake is too complicated.

Send feedback

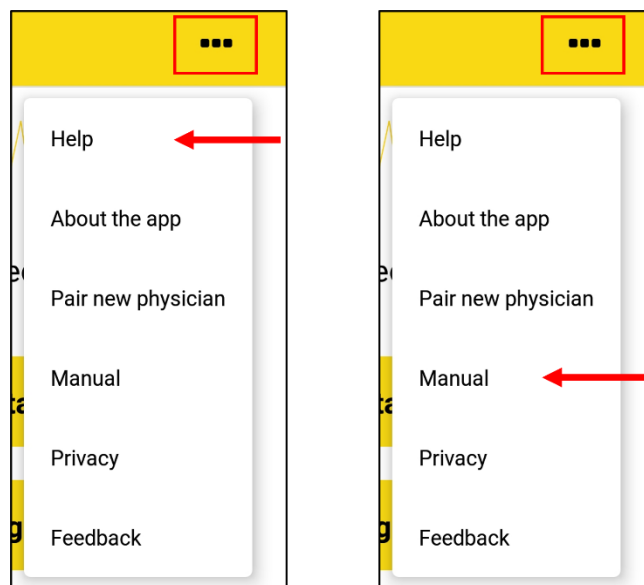
Cancel

For any comments regarding the app that are not covered by the feedback, please contact your physician.

6 Help and further information

6.1 Help with questions

If you have question during the use of the app you can access the instructions for use/manual as well as the FAQ regarding the app via the app. Open the menu in the upper right corner and select "**Manual**" or "**Help**". This will automatically download the instructions for use/manual as pdf. For the FAQ you will then be directed to the Ruma website.



For any questions that are not covered by the FAQ or should you require the instructions for use/manual as paper copy please contact

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Website: www.marker-test.de

6.2 Error messages and troubleshooting

In the following chapters list possible problems and error messages. Please contact your physician or Ruma for any problems not listed below (see 6 Support).

No internet connection

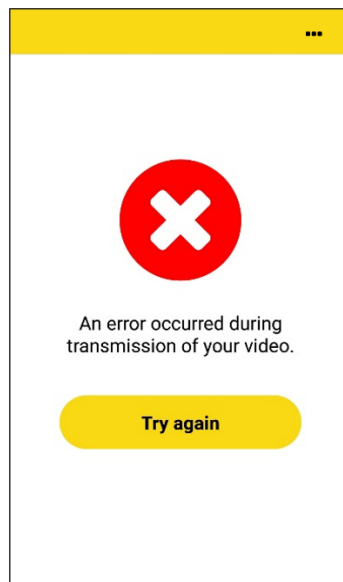
If your smartphone does not have an internet connection the following message is displayed in the app.



Please ensure that you have a stable internet connection throughout the whole process.

Transfer of intake video failed

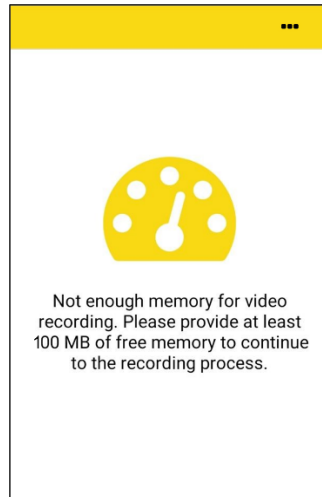
If the transfer of the intake video fails (e.g. due to a missing internet connection) the following message is displayed.



By selecting „Try again“ the transfer is repeated.

Not enough memory

If there is not enough memory available for temporary storage and encryption of the intake video prior to recording the following message is displayed.



Please ensure that you have enough free memory (approx. 100 MB) for video recording. After the video is sent to the physician it is automatically deleted from your device.

The QR code on the outer packaging cannot be scanned or is identified as invalid

Cause	Solution
You are using the wrong camera to scan the QR code.	Make sure to use the rear camera to scan the QR code.
The lighting conditions are unsuitable to scan the QR code.	Make sure there is enough light and scan again.
<ul style="list-style-type: none"> The QR code has been destroyed after it has been successfully assigned by the physician. The marker has not been assigned to you by the physician. 	Please contact your physician and return the marker in question. Have your physician assign you a new marker.

The QR code on the inner packaging cannot be scanned or is identified as invalid.

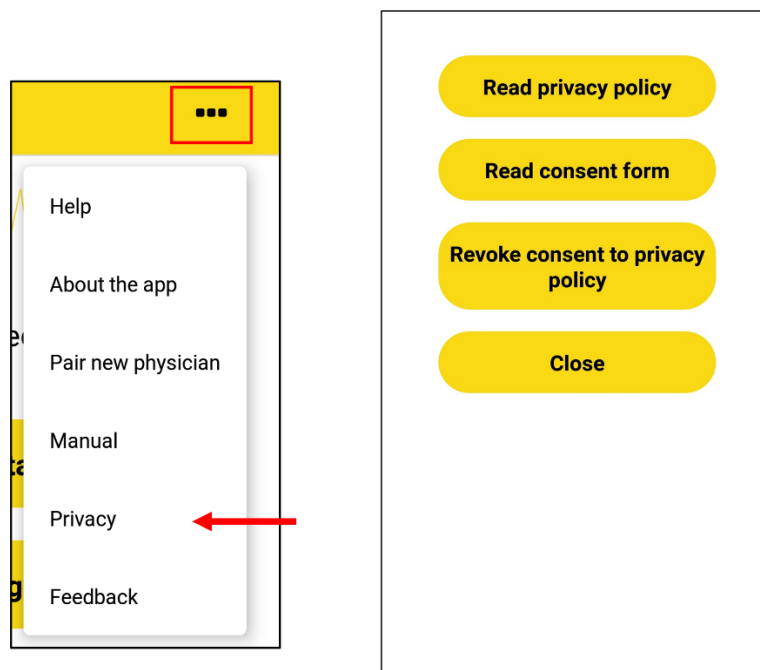
Cause	Solution
You are using the wrong camera to scan the QR code.	Make sure to use the rear camera to scan the QR code.
The lighting conditions are unsuitable to scan the QR code.	Make sure there is enough light and scan again
<ul style="list-style-type: none"> The QR code is damaged. The QR code on the inner packaging does not correspond with the QR code on the outer packaging. 	If the QR code is not scanned within 10 s a button with the text “QR code cannot be scanned?” is displayed. Press this button to access a text box for the manual input of the RMB code (above the QR code). If the process still does not work please contact your physician and return the marker in question. Have your physician assign you a new marker.

The smartphone does not fit the provided holder.

Depending on the cover you use your smartphone may be too big. If necessary, remove the smartphone cover.

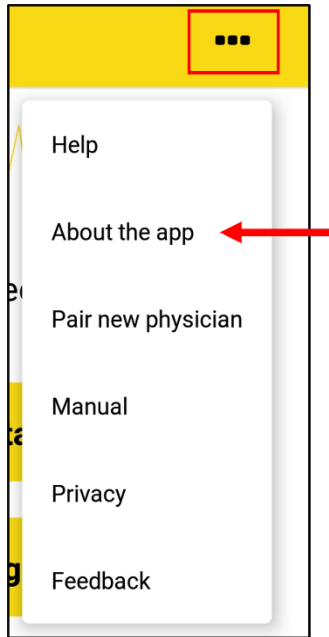
6.3 Privacy policy

You can always access our privacy policy and the consent form you agreed to when you started using the app via the app. Open the menu in the upper right corner and select **“Privacy”**. A new window opens where you can access our privacy policy or the consent form. Furthermore, you can also revoke your consent to our privacy policy through this menu. This will cancel the pairing with your physician and you can no longer use the app until you pair your smartphone with your physician again.



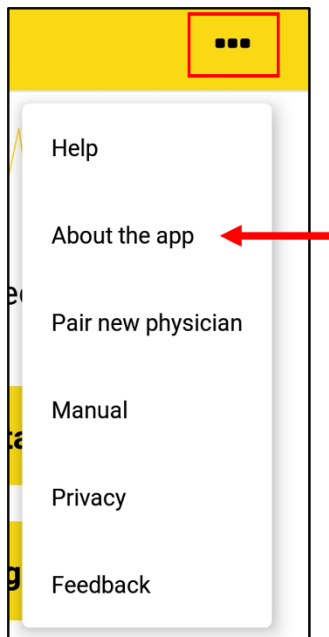
6.4 Show version of app

To see the current software version, open the menu in the upper right corner and select **“About the app”**.



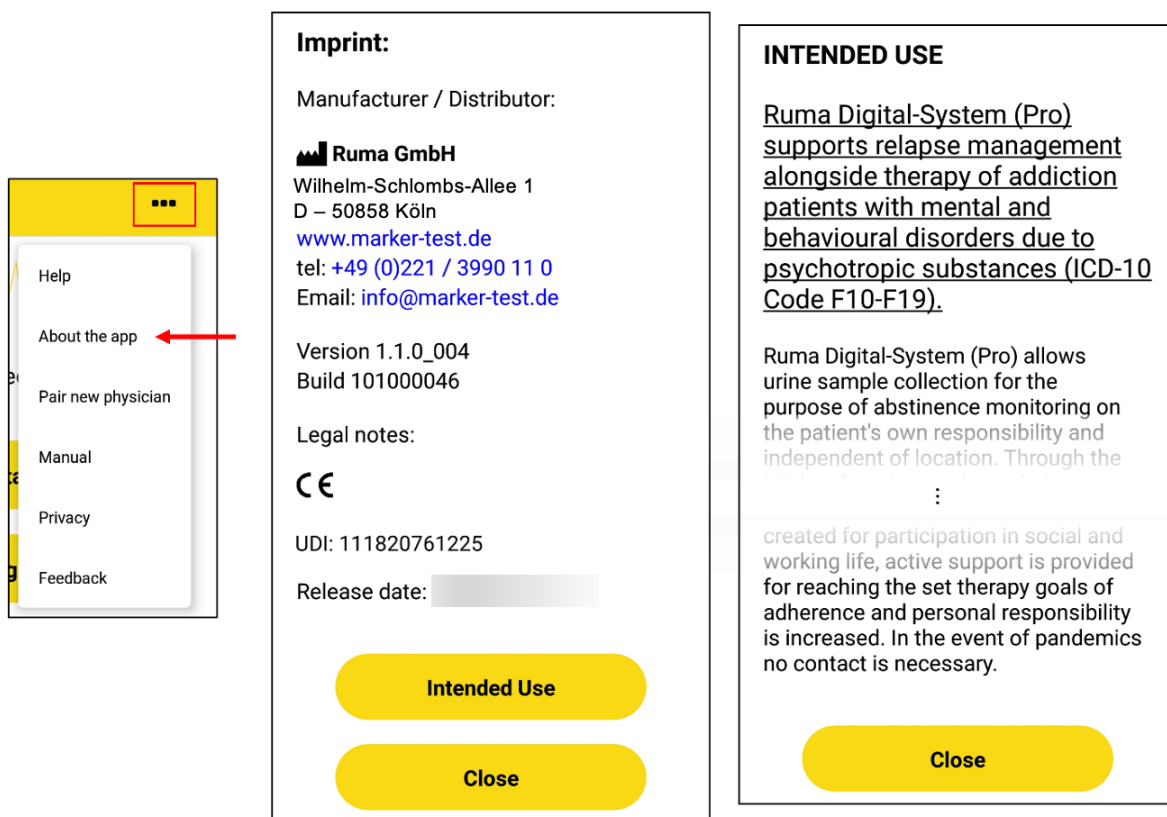
6.5 Show manufacturer and distributor

To see information regarding manufacturer and distributor, open the menu in the upper right corner and select **“About the app”**.



6.6 Accessing the intended use of this medical device

In order to access the intended use of the app, please open the menu in the upper right corner and select **“About the app”**. This opens the legal information regarding the app. The button "Intended use" is located below the information on the manufacturer / distributor and the legal information. Selecting this button opens the intended use. You will need to scroll down in order to read the full text. At the end of the intended use you find the button "Close" which returns you to the legal information.



6.7 App language setting

The language Ruma Digital-System uses depends on the settings in the smartphone's operating system. When the system language of the smartphone is German, for example, the language of Ruma Digital-System will also be German. The table below lists the currently available language versions.

System language of the tablet	Language of Ruma Digital System
German	German
English	English
Finnish	Finnish
All other languages	English

6.8 Deinstallation of the app

Should you no longer wish to use the app you can delete it as stipulated by your operating system. No video data remain on your smartphone after deinstallation of the ap. Please note that your blockchain privacy key, your private key for the encryption of video files, will also be removed from your device. If you want to use the app again the phone needs to be paired again. The data transferred to the physician are subject to legal provisions regarding medical documentation requirements.

7 Support

In the event of any errors occurring during the use of the app please contact your physician or

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