

Ruma Digital-System



1. Ruma Digital-System

Ruma has developed an app system that allows patients autonomous urine labeling by intake of a marker capsule. The intake is carried out independently of location, and the correct intake is video documented through the app.

The urine marker is taken in the form of a marker capsule. The intake is documented in a video that can be up to 120 seconds long. This video is then sent encryptedly to the treating physician who assesses and evaluates it for correct intake and confirms the willingness for therapy.

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 10 as operating system and a camera with at least 720pixels (front and rear camera). Please download the app from the respective store. Search for “Ruma Digital-System” or use the following links:

For Google Play Store (Android):

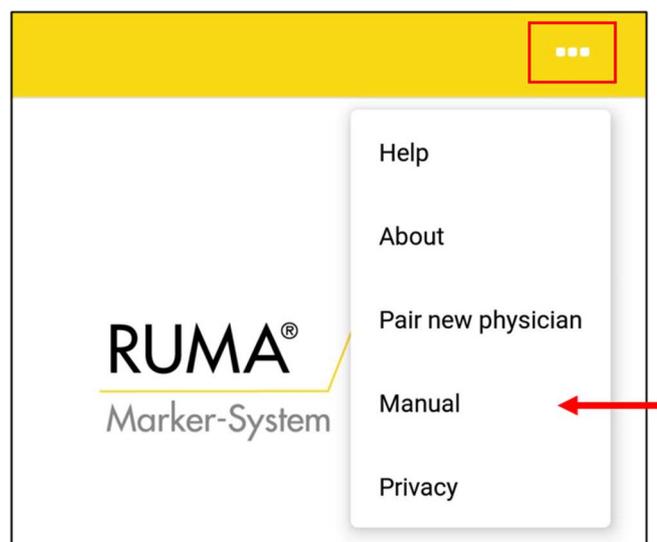
https://play.google.com/store/apps/details?id=de.marker_test.patient_app

For Apple Store (iOS)

<https://apps.apple.com/us/app/ruma-digital-system/id1510736352>

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. 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.

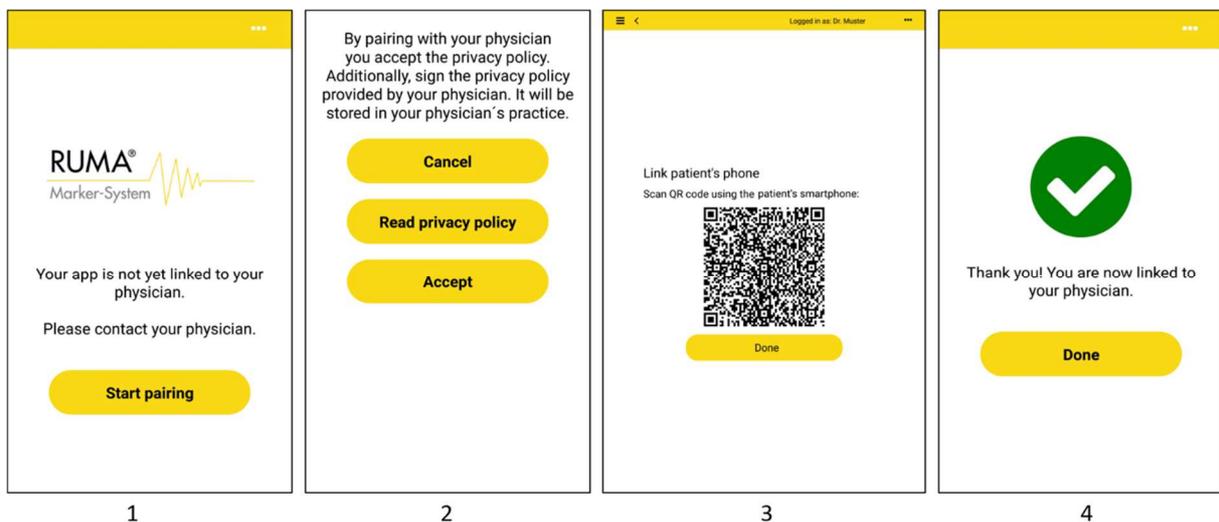


Your smartphone needs to be paired once with the tablet of the treating physician and thus activated in order to use the app and record videos. Afterwards, your physician will automatically receive the encrypted videos.

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

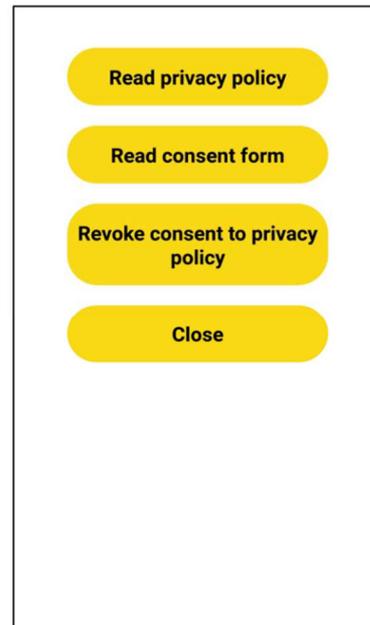
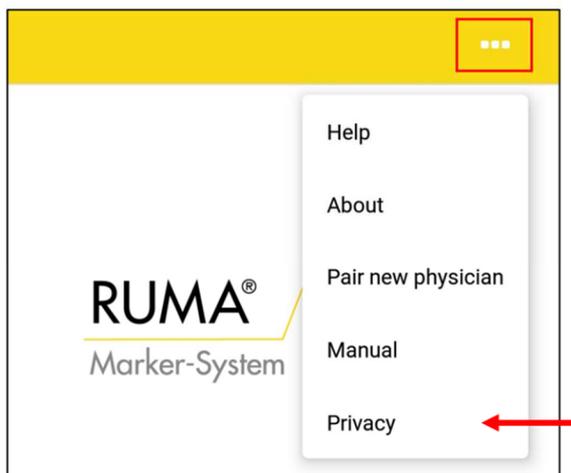
- 1) Start the app and select “Start pairing”. At this point you have to accept the privacy policy. You can read it by selecting “Read privacy policy”. After accepting of the privacy policy by selecting “Accept” the camera of your smartphone will be activated.
- 2) Scan the “pairing code” with your camera provided to you by your physician.
- 3) Successful pairing is confirmed with a green checkmark. Select “Done”.

You will then get to the home screen. The app is now activated for marker intake.



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 always have the possibility to object the data processing. By doing that 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 in which you have the option to read the privacy policy or the consent form and revoke your consent.



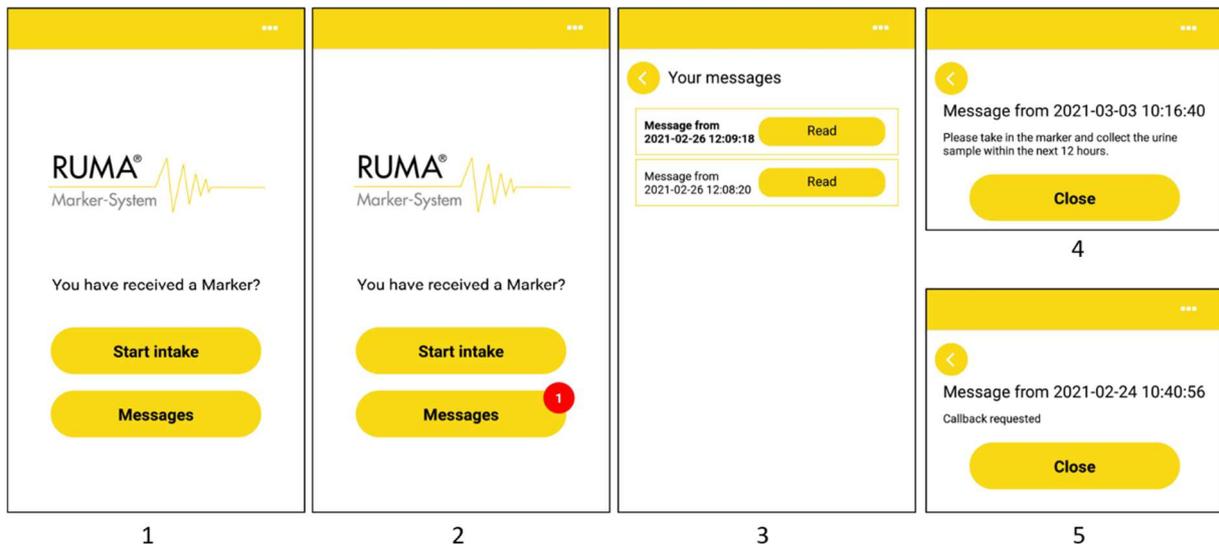
3. Functions in Ruma Digital-System

3.1. Markers and messages

Once your smartphone is paired with the tablet of your treating physician you can use the app independently of location for marker intake, sample identification and prove of willingness for therapy. You can start the process by clicking the button **“Start intake”** on the home screen.

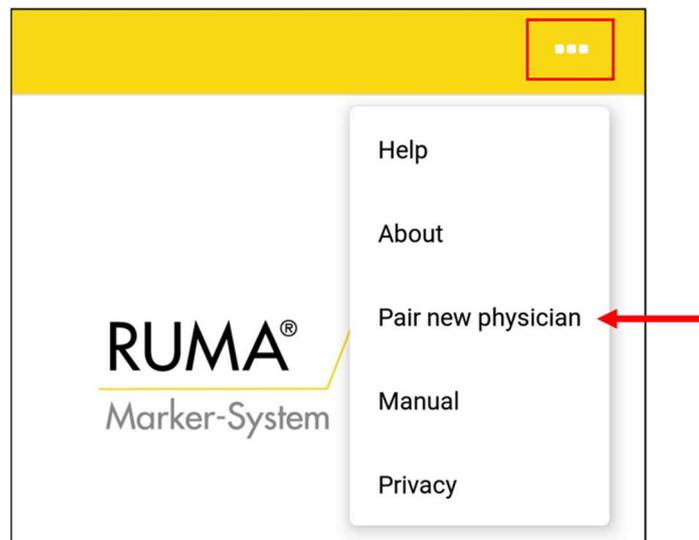
The **“Messages”** button gives you access to messages that your physician has sent you. New messages are displayed as white numbers on red ground. Messages received while the app is switched off will be shown when the app is started as well. Please check periodically if your physician sent you a new 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. In general, your physician can send you two types of messages. A request to carry out marker intake and urine sample collection within the next 12 hours 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 the marker intake and 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 new physician as described in chapter 2.

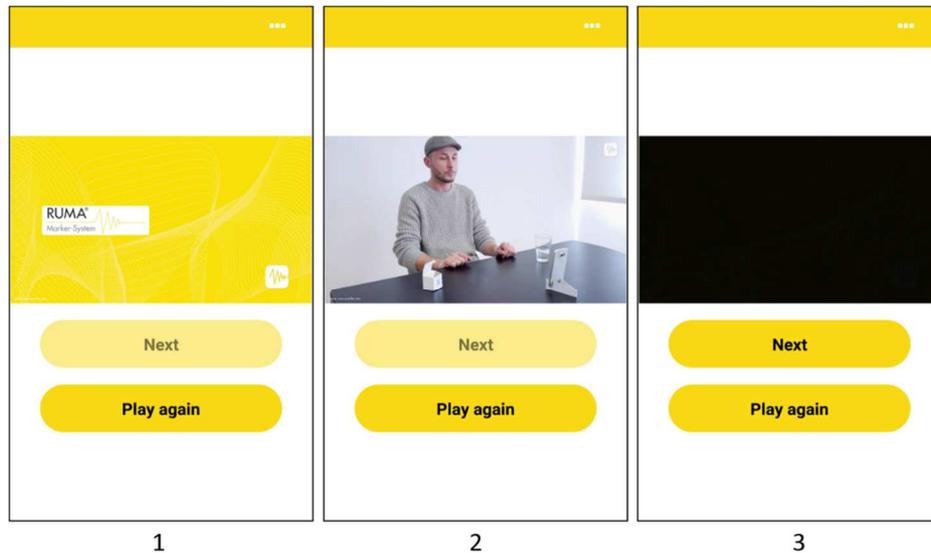


Before you proceed with the marker intake please read the provided intake protocol carefully and perform all preparations as described.

3.2. The introductory video

For marker intake or to start recording, respectively, start the app and select “Start intake”. You will now see an introductory video that explains the intake procedure. The video must be downloaded once prior to first use of the app. This video cannot be skipped the first time the app is started. 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).



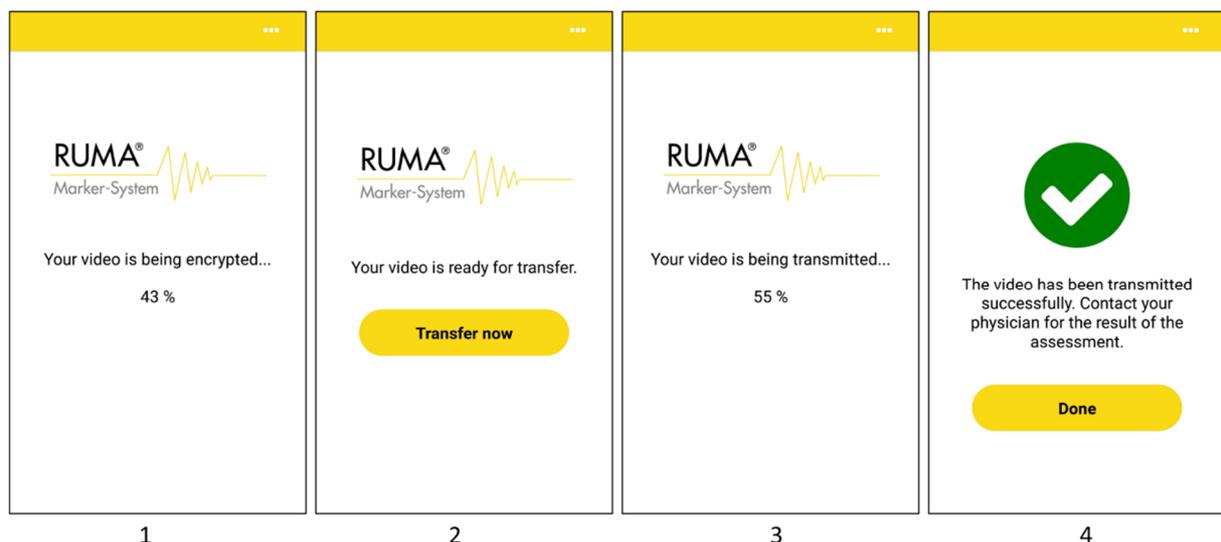
1: The introductory video will play automatically after “Start intake” was selected; 2: Introductory video for marker intake; 3: The video needs to be watched completely at least once before you can proceed to the next steps.

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.

3.4. Sending of 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 intake 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 after marker intake, you can take your urine sample from now on." Please follow the instructions for the steps after marker intake.



5. Help and further information

5.1. Help with questions

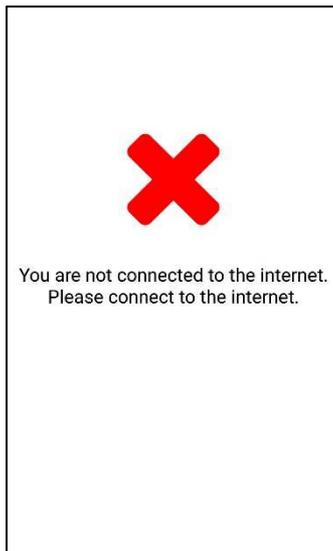
If you have question during the use of the app you can access the FAQ via the app. Open the menu in the upper right corner and select „Help“. You will then be directed to the FAQ on the Ruma website.

5.2. Error messages and troubleshooting

The following chapter lists possible problems and error messages. Please contact your physician or Ruma for any problems not listed below (see 6 Support).

No internet connection

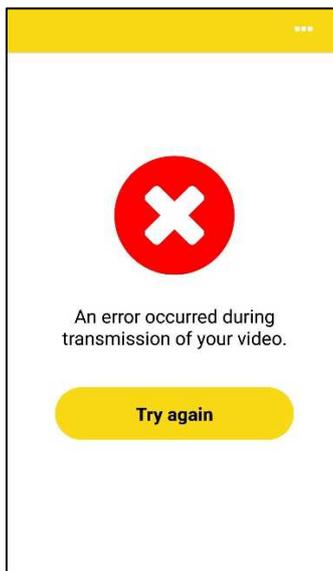
If your smartphone does not have an internet connection the following message is displayed.



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 at the beginning of recording the following message is displayed.



Please ensure that you have enough free memory (approx. 200 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.	Please use the rear camera to scan the QR code.
The lighting conditions are unsuitable for scanning of 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 successful assignment of the marker by the physician. You received a marker that has not been assigned to you by the physician. 	Please contact your physician and return the marker in question. You will receive a new marker from your physician. If you still have another marker carry out the urine sample collection with the marker on hand.

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

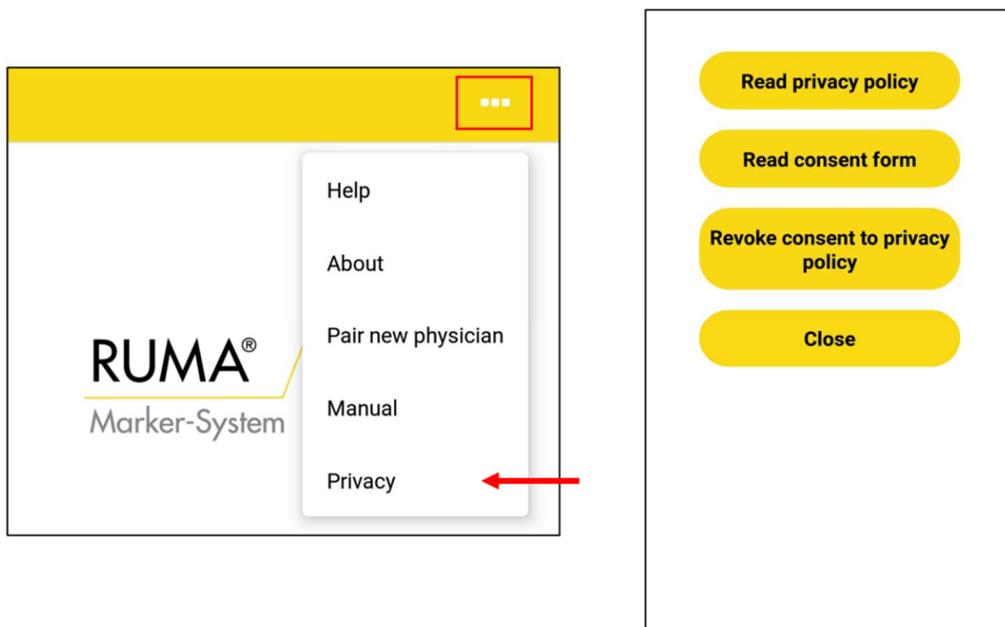
Cause	Solution
You are using the wrong camera to scan the QR code.	Please use the rear camera to scan the QR code.
The lighting conditions are unsuitable for scanning of the QR code.	Make sure there is enough light and scan again
<ul style="list-style-type: none"> The QR code is damaged. The QR code on the outer packaging does not correspond with the QR code on the inner 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. You will receive a new marker from your physician. If you still have another marker carry out the urine sample collection with the marker on hand.

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.

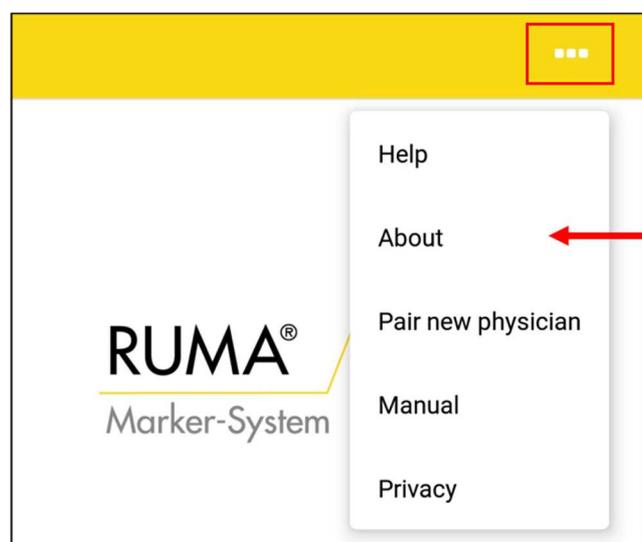
5.3. Privacy policy

You can always access our privacy policy and the consent form you agreed to 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.



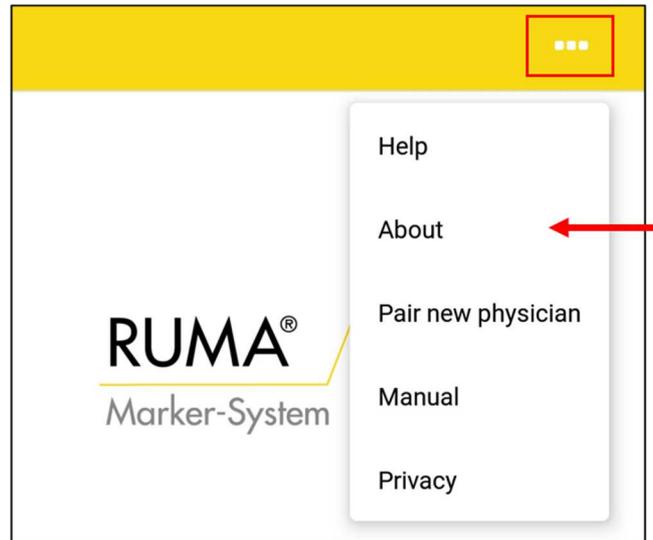
5.4. Show version of app

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



5.5. Show manufacturer and distributor

To see information regarding manufacturer and distributor, open the menu in the upper right corner and select "About".



5.6. 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 Pro
German	German
English	English
Finish	Finish
All other languages	English

6. Support

If any errors occur during the use of the app please contact your physician or

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