



Orla Etämittäus

INR Patient Guide

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1. Accessibility

The Orla Etämittaust application has been assessed for accessibility and can e.g. be used via the screen reading capabilities of the phone. To ensure correct function, the language setting of the phone must be the same as the language set in the application.

The accessibility assessment of the service is focused on the use of the mobile application. The suitability of the measurement devices connected to the service must be assessed for patients separately.

The software platform used by the application does not support the Focus Order feature on phones using the Android operating system. On phones using the iOS operating system, this feature works. On phones using the Android operating system, we recommend using the screen reader's Explore feature where you slowly drag one finger around the screen and the screen reader announces the item currently under your finger.

In order to use an external keyboard on phones using the iOS operating system, Full Keyboard Access must be switched on: Settings → Accessibility → Keyboards → Full Keyboard Access.

When using an external keyboard for navigation, the following keys (among others) are available:

Command	iOS	Android
Move forwards	Tab	Tab
Move backwards	Shift-Tab	Shift-Tab
Move to next item	Ctrl-Tab	Alt-Shift-Left Arrow
Move to previous item	Shift-Ctrl-Tab	Alt-Shift-Right Arrow
Move in a direction	Arrow keys	Arrow keys
Activate	Space	Enter

On phones that use the iOS operating system, the Move to next item command is in particular needed for accessing the Measure Now button in the main view and for changing the medicine strength in the Warfarin Card view.

More information on key commands available on phones using the iOS operating system is available from the phone settings: Settings → Accessibility → Keyboards → Full Keyboard Access → Commands.

More information on key commands available on phones using the Android operating system is available from the phone settings: Settings → Accessibility → Screen reader → Settings → Keyboard shortcuts. There is also additional information available on the Web: <https://support.google.com/accessibility/android/answer/6110948?hl=en>.

You can contact us in accessibility related matters via email at saavutettavuus@orladtx.com. The accessibility statement for the service is available from <https://orladtx.com/fi/saavutettavuusseloste-inr/> (in Finnish).

2. Privacy Policy

We process your data only in accordance to our agreements with the healthcare providers and as directed by the healthcare providers. We protect your data with appropriate security measures and store it until the healthcare provider instructs us to delete it.

Since we only process patient and professional user data on behalf of healthcare providers, you cannot directly exercise your data rights through us. Rather, you should contact your healthcare provider, who will then instruct us to take the necessary actions.

You can contact us in privacy and security related matters via email at privacy@orladtx.com. More information about our privacy policy is available from <https://orladtx.com/privacy/>.

3. About measuring

You now have the CoaguChek® INRange measurement device (Figure 1) at your disposal. It is used for measuring how long it takes for your blood to clot. After each measurement, the Orla Etämittäus application automatically sends the values from your phone to a health care professional to provide information. Handle the device and the phone with care.

Make sure the phone battery is sufficiently charged, and always keep your phone turned on. Ensure that the Bluetooth connection of your phone is on.

Please note that the device is intended for your personal use only. All measurements completed with the device will be entered into your health care file. Use the device in exact accordance with the instructions and ensure children do not gain access to it.

To take a measurement, you must follow the instructions provided by the phone. With the help of these guidelines as well as the instructions given by your phone you will be able to measure your INR-value. Carefully read the separate instructions for the CoaguChek® INRange- device as well as the information about the test strips.



Figure 1

4. Setup

To function, Orla Etämittaust requires the following setup:

- Phone
- Etämittaust application
The latest version of the application can be downloaded from the phone's app store.
- Measurement device (incl. the device's manual)
- Etämittaust manual (this document)

5. Preparing the phone

5.1. Android

Please note that your phone must use the operating system version *Android 7.0* or newer. You can verify the version used in *Settings / General / Device information / Android version*.

Downloading the Orla Etämittaust application to your phone:

1. Turn on the phone and unlock it. From the start screen(s), search for *Play Store* and press the icon (Figure 2).
2. Type *Orla Etämittaust* into the search field that in the upper corner of the screen. After this, click the magnifying glass. (Figure 3).

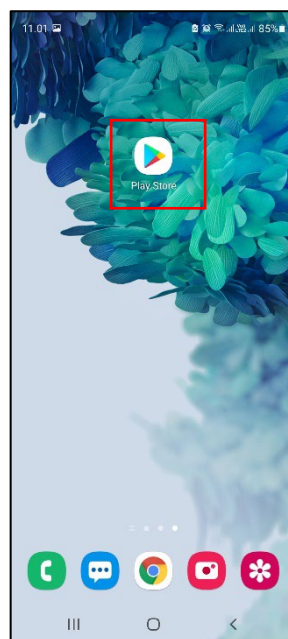


Figure 2

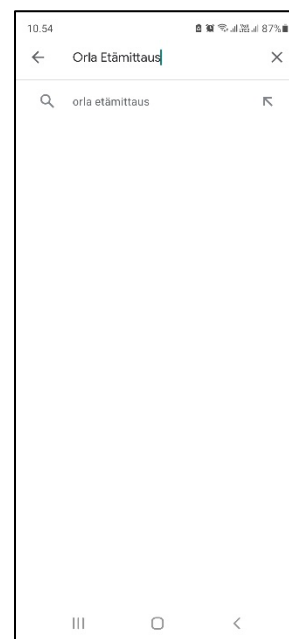


Figure 3

3. Select the *Orla Etämittaust* application by clicking the icon. (Figure 4).
4. Start the installation by clicking *Install* (Figure 5).

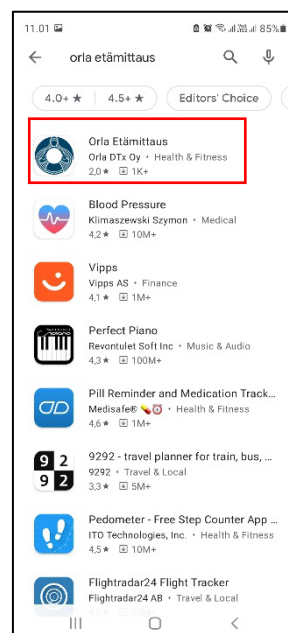


Figure 4

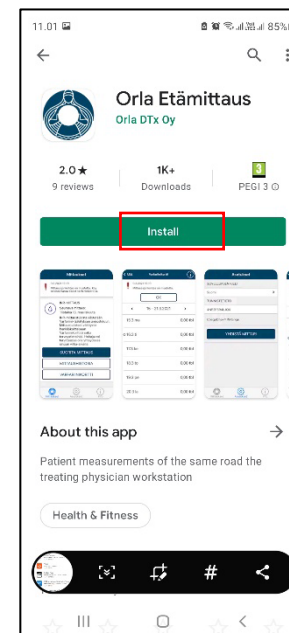


Figure 5

5. The installation is complete when the text Open appears on the screen (Figure 6). Please note that the installation may take a while (depending on the speed of the internet connection).
6. You can now open the Orla Etämittaus application or exit by pressing the *Home Menu* button.
7. When you open the application for the first time, Orla Etämittaus will request necessary access rights (Location, Images/media/files, Bluetooth connection). Click Allow/While using this app to install the application (Figure 7). Please note that Orla Etämittaus will not use your images and media files, or your location. However, the transfer of measurement results between the phone and the measurement device is permitted under these categories.

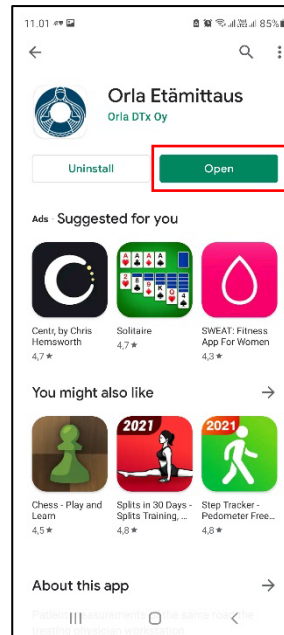


Figure 6

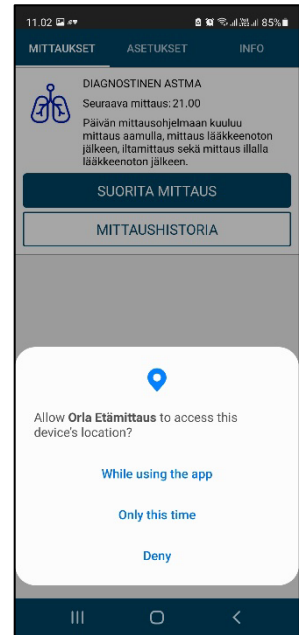


Figure 7

5.2. iOS

Please note that your phone must use the operating system version *iOS 9.0* or newer. You can verify the version used in *Settings / General / Information / Version*.

Downloading the Orla Etämittaus application to your phone:

1. Turn on the phone and unlock it. From the start screen(s), search for *App Store* and click the icon. (Figure 8).
2. Click the *magnifying glass* icon (Figure 9) and type *Orla Etämittaus* into the search field that opens in the upper corner of the screen. Then press *Search*.



Figure 8

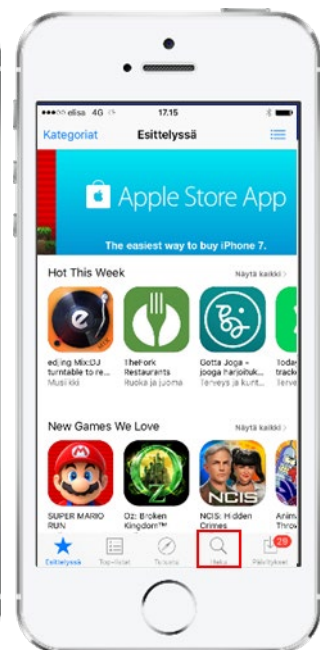


Figure 9

3. Download Orla Etämittaus application by clicking the download button (Figure 10). The application is installed automatically. Please note that the installation may take a while (depending on the speed of the internet connection).
4. The installation is complete when the text *Open* appears on the screen. (Figure 11). You can open the Orla Etämittaus application or exit by pressing the *Home Menu* button.

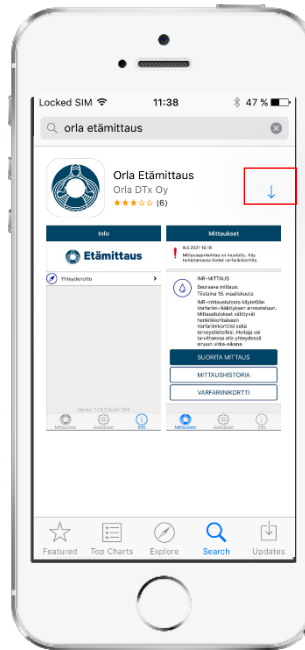


Figure 10

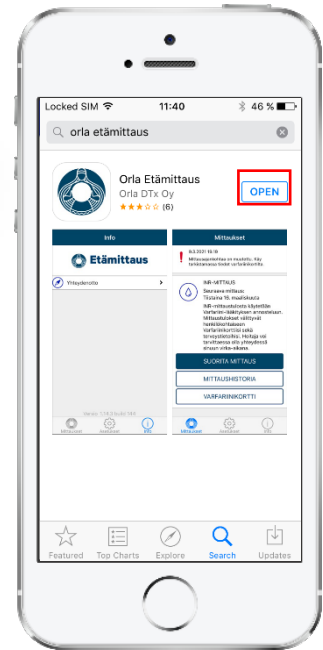


Figure 11

5. When you open the application for the first time, allow the application to send you notifications by clicking *OK* (Figure 12). If you do not allow notifications, alerts reminding you of a measurement etc. will be omitted.

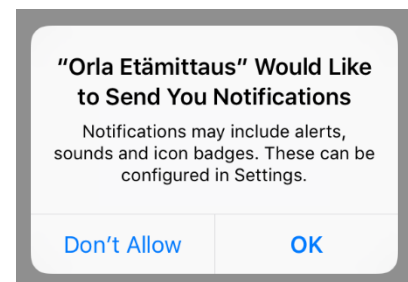


Figure 12

5.3. Phone settings

To function in a reliable way, the Orla Etämittaus application requires that certain phone settings are set as instructed below. Orla DTx cannot guarantee full functionality of the application if the phone's settings are not correct.

5.3.1. Bluetooth

The phone's Bluetooth connection must be enabled. Without a Bluetooth connection, communication between the phone and the measurement device will not work.

5.3.2. Lock screen

The maximum possible timeout should be set for the phone screen. The smallest compatible timeout is 5 minutes.

5.3.3. Phone security

Set a screen lock on your phone using a password, security code, or pattern. This way, your phone and the Orla Etämittäus application are protected from unauthorized use.

Your phone must be encrypted to protect your data. On new Android phones with Android version 10 or later, data is automatically encrypted. If you have an earlier Android version, it is possible (depending on the phone model) that phone encryption must be enabled separately in the phone settings. Check your phone settings. If necessary, contact Orla customer support.

On all supported iOS versions, data is automatically encrypted.

5.3.4. Airplane mode

Airplane mode must not be enabled.

5.3.5. Power saving

Power saving must be disabled. When power saving is enabled, the texts in the application can be difficult to read due to a dim screen. As a result of power saving, the phone may also fail to alert you to take a measurement.

5.3.6. Date and time

For monitoring and reporting the measurement results, it is important that the phone's date and time have been set correctly.

5.3.7. Network connection

For the transfer of the measurement results, it is important that a data connection is available. Measurements can also be taken without a data connection. In this case, the measurement results are transferred the next time a data connection is available.

6. Pairing measurement device and phone

Before the first measurement, the CoaguChek® INRange device needs to be paired to your phone using Bluetooth.

If the phone has previously been paired with another CoaguChek® device, the old pairing needs to first be removed. The old pairing can be undone by going to *Settings* → *Bluetooth*, choose CoaguChek and choose *Unpair* (Android) / *Forget this device* (iOS).

1. Begin the pairing by opening the Orla Etämittaust application. Go to Settings (can be found at the bottom of the page). (Figure 15)
2. Click Pair Meter. Hereafter, the phone will give you detailed instructions for pairing the devices (Figure 16).

The devices will automatically connect for the following measurement. Pairing is not necessary hereafter, unless the phone changes.

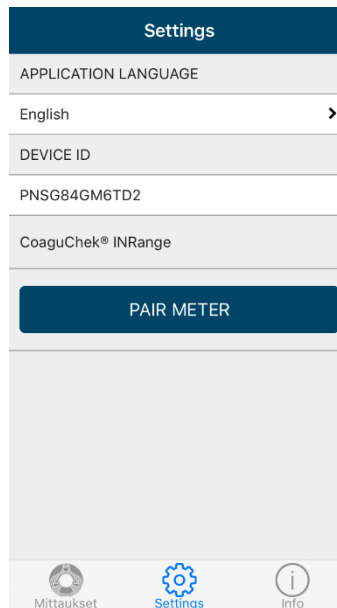


Figure 15

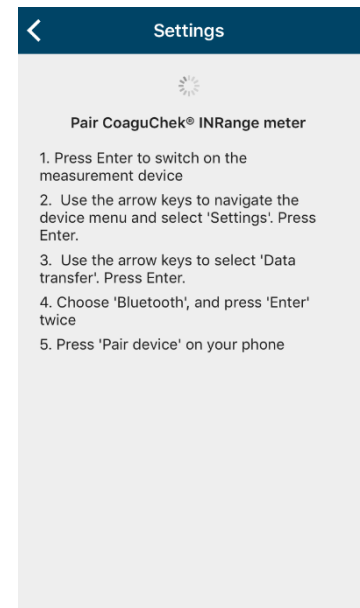


Figure 16

7. Preparing to measure

1. Wash your hands with warm water and dry them well.
2. Take out the following:
 - lancing device
 - the test strips
 - measurement device
 - smart phone
 - a tissue paper (and plaster)
3. Open the lancing device and place the lancet. Close the lancing device and adjust the depth of the lancet by turning the head of the lancing device. The bigger the number, the deeper the needle will go (Figure 17).

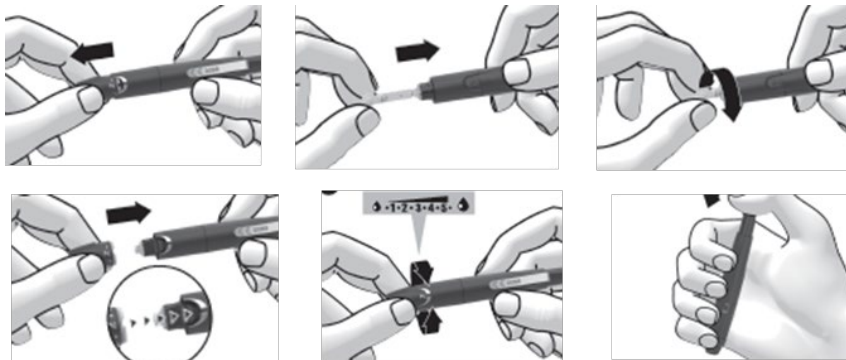


Figure 17

of the lancet by turning the head of the lancing device. The bigger the number, the deeper the needle will go (Figure 17).

Remember that the lancet is disposable and must be changed before every measurement!

8. Beginning to measure

1. Open the Etämittaust application by pressing the icon on the phone's screen, or by pressing the application's notification.
2. When the measurement program has been updated to the phone, the *Measurement* page will show the information of the measurement program. Start measuring by pressing *Measure now* (Figure 18).

If the health care professional has made changes to your measurement program, you can download the updated program by pressing the Update Information button.

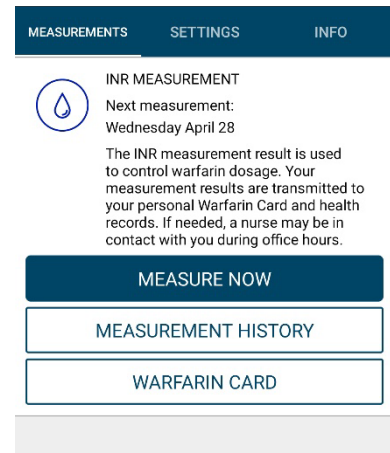


Figure 18

3. Turn on the measurement device by inserting a test strip (Figure 19). Remember to close the jar with test strips immediately when you have taken one out. If you have not already inserted the chip belonging to the jar of test strips, insert it now (Figure 20). Every jar of test strips has its own chip that needs to be changed whenever the jar of test strips changes.



Figure 19



Figure 20

9. Taking blood sample

1. Stick the side of a dry and warm fingertip with the lancing device (Figure 21). When the screen of the measurement device shows a countdown of seconds starting at 180, and an image of a test strip and a blood drop, you have three minutes to add a blood drop to the test strip (Figure 22).



Figure 21



Figure 22

2. Place the first blood drop to the test strip within 15 seconds of the stick. Make sure that the blood drop is about the size of a lingonberry (8 microliter). The test strip absorbs the blood drop through capillary action at the dosage spot of the test strip. Add the blood drop to the test strip by "sliding" the test strip under the blood drop (Figure 23).



Figure 23

3. The measurement device gives a sound and an indication on the screen when the blood is being analyzed (Figure 24). Lastly, the result is shown on the screen (Figure 25).

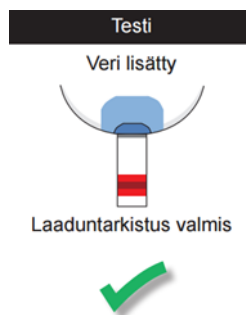


Figure 24



Figure 25

10. Results

1. Transfer the result to your smart phone by pressing Transfer data (Figure 26). Wait until the result is shown on the screen of your phone.



Figure 26

2. If your result is within the reference value, end the measurement by pressing *Finish* on the phone's application.
3. If your result is below the reference value, considerably below the reference value (Figure 27), above the reference value or considerably above the reference value, press *Continue* to give further information.

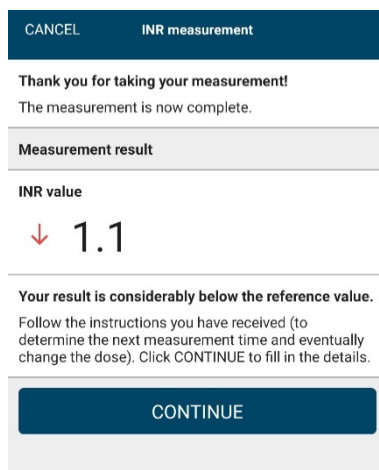


Figure 27

4. Choose one or several of the given alternatives in the app (Figure 28) as the likely reason for the change in your INR-value and press *Continue*. On the following page you can in your own words write further information about the possible causes (Figure 29). Press *Finish*.

INR measurement

Possible causes of the changed INR value
Select from the options below and click Continue

Temporary change

☐

 Natural remedies

☐

 Change in diet

☐

 Forgotten or extra dose of warfarin☐☒☐☐☐

Permanent or long term change

☐☐☐☐

CONTINUE

Figure 28

INR measurement

Additional Information

Selected causes
Temporary illness

FINISH

Figure 29

11. Warfarin card

11.1. Self-measurement

When the measuring is done, you move on to the warfarin card. On the warfarin card you find information about your medication as well as the following measurement date (Figure 30).

If you are a self-measurement patient, the health care professional will make the necessary changes to your medication and the following measurement time based on your results. This information is always visible on the warfarin card. You can scroll through both past and coming weeks of medication at the top of the warfarin card by pressing the arrows either left or right.

You can get to the warfarin card directly from the frontpage of the application as well by pressing *Warfarin card*.



Figure 30

11.2. Self-care

When the measuring is done, you move on to the warfarin card, where you find information about your medication as well as the following measurement time (Figure 31).

If you are a self-care patient, you can change your medication and the next measurement time, based on your results. You can scroll through both past and coming weeks of medication at the top of the warfarin card by pressing the left and right arrows.

You can also get to the warfarin card directly from the frontpage of the application by pressing *Warfarin card*.

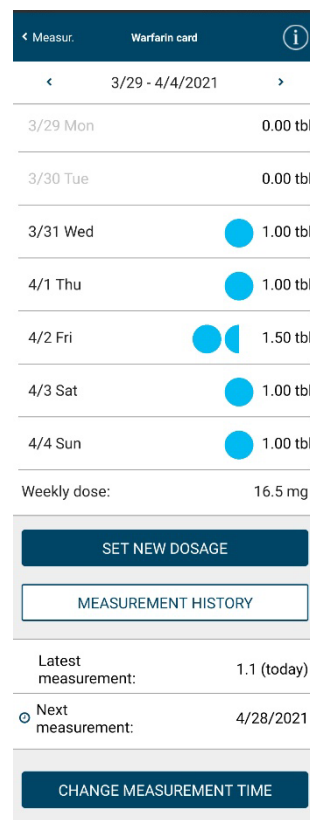


Figure 31

11.2.1. Changing the dosage

By choosing *Set new dosage* from the warfarin card, the page changes and you can change your dosage.

To start, choose the start date and the strength of the medicine (Figure 32).

Secondly, you can adjust the daily dosage by pressing the **+** and **-** buttons. You can also choose the same dosage for every day by selecting *Use same dosage daily*.

Lastly, accept the changes made by pressing *Save*.

Change dosage

Select start date
3/31/2021

Define dosage
Use same dosage daily

Select medicine strength
☒ 3 mg / ☐ 5 mg

Define dosage

Monday 1 tbl	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Tuesday 1.5 tbl	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Wednesday 1 tbl	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Thursday 1 tbl	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Friday 1.5 tbl	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Saturday 1 tbl	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Sunday 1 tbl	<input type="radio"/> <input type="radio"/> <input type="radio"/>

Total weekly dosage 8 tbl / 24 mg

SAVE

CANCEL

Figure 32

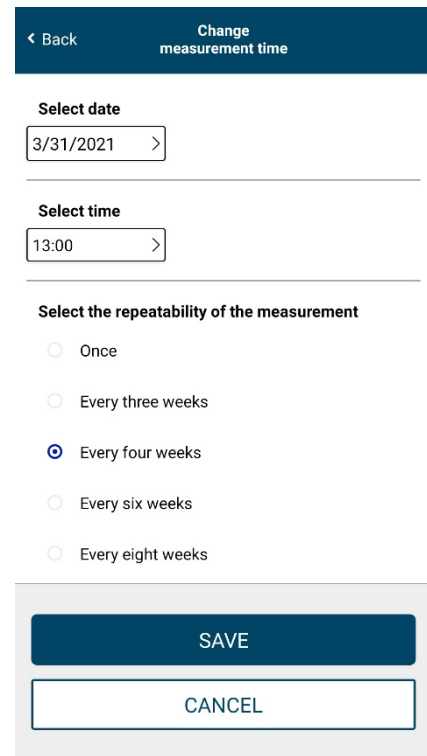
11.2.2. Changing the measurement time

By choosing *Change measurement time* from the warfarin card, the page changes and you can set a new measurement time (Figure 33).

First, choose the day and time when you want the next measurement to take place.

Secondly, you can choose the repeatability of the measurement. Repeatability means how frequently the measurement is automatically repeated.

Lastly, press *Save* to accept the changes.



The screenshot shows a mobile application interface for changing measurement time. At the top is a dark blue header with a back arrow and the text 'Change measurement time'. Below this, there are three sections: 'Select date' with a date picker showing '3/31/2021', 'Select time' with a time picker showing '13:00', and 'Select the repeatability of the measurement' with five radio button options: 'Once', 'Every three weeks', 'Every four weeks' (which is selected), 'Every six weeks', and 'Every eight weeks'. At the bottom of the form are two buttons: a dark blue 'SAVE' button and a white 'CANCEL' button with a dark blue border.

Figure 33

11.3. The warfarin card data page

By pressing the *Back* button at the upper right corner of the warfarin card, you are transferred to the information page of the warfarin card (Figure 34). The page explains

- The symbols on the warfarin card
- The reference values of your treatment
- The indication of your treatment
- The duration of your program
- Basic information about using the warfarin card

By pressing *Back* you return to the warfarin card.

◀ Back Warfarin card data

Symbol legends

- 3 mg tablet
- 5 mg tablet
- Next measurement

Target level of treatment: 2.00 - 3.00

Treatment indications: Atrial fibrillation

Program duration: 3/31/2021 - 3/31/2022

The doctor records basic information on the card at the beginning of Warfarin treatment. The information is reviewed and updated by the nurse/doctor during annual check-ups or as needed. The current tablet strength, the dose in tablets per day, the weekly dose in milligrams, the INR results and the time of the next INR control are all recorded in the dosage section. Any required dosage adjustments are calculated towards the total weekly dose, which is translated into a standard daily dose, if possible. For more information on the Warfarin card, see [Antikoagulaatiohoidon käsikirja](#)

If you experience any of the following symptoms, contact your healthcare provider or emergency room immediately:

- feces turns black or urine becomes bloody
- severe abdominal pain, weakness, headache or balance problems
- bleeding from the gums or the nose or coughing blood or throwing up blood
- abnormal menstrual or genital bleeding
- increased sensitivity to bruising or bleeding from the slightest scratches
- your general condition worsens

Figure 34

12. Finishing the measurement

Remove the used lancet from the lancing device. Place the lancet in a container for sharp waste. Remove the used test strip from the measurement device and throw it in the garbage bin.

Exit the program with the Home button or -gesture on the phone. The application will notify you again when it is time to perform the next measurement. The measurement device switches off automatically after two minutes. Do not close the application from the application manager, let it run in the background.

The application sends the measurement data to the health care professional for review as soon as the measurement is completed. If a network connection is not available, the application will continue to try sending the data until the transmission is successful. In the measurement history, sent measurements are marked with a green checkmark and measurements still waiting to be sent are marked with a red exclamation mark. You can view your measurement history by tapping the Measurement History button on application main page. We recommend that you check from time to time that all measurements have been sent successfully.

13. Notifications regarding changes

If the health care professional makes changes to your INR measurement program, such as the medication dosage and/or the next measurement time, you will receive a notification about the change to your phone.

The notification is also visible on the front page of the application (Figure 35). More specific information about the changes are found on the warfarin card (Figure 36). The notifications disappear when pressing *OK*.

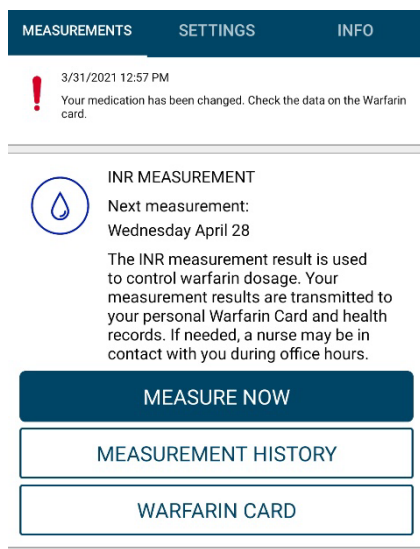


Figure 35

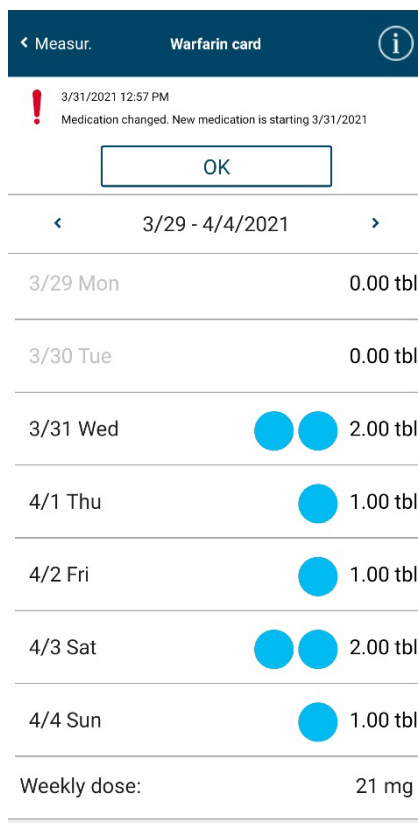


Figure 36

14. Error Messages and Troubleshooting

If none of the suggested solutions solve your problem, contact Orla patient support (see Contact Information section).

14.1. Error Messages

Error Message	Solution
Measurement program was cancelled, or it is already complete.	Please contact your nursing staff. Possibly the end date of the measurement program has been set too early.
Measurement cannot be cancelled.	Finish the measurement process. It is not possible to cancel a measurement once the measurement result has been received from the measurement device.
Location permission denied. Measurement program can not be started.	Enable location permissions in the phone's application settings.
Measuring not possible, because bluetooth is not enabled!	Enable Bluetooth in the phone settings.
An error occurred. Please verify that your phone's network connection is switched on and try again.	Do as instructed under "Measurement program fetching error."
Measurement cannot be taken because location is not switched on!	Enable location information in phone settings.
An error occurred in the application. Please try again. If the error persists, please contact your nursing personnel.	Close the application through the phone's application manager and try again. If this does not help, restart the phone and try again.
Error initiating the message server. Notifications sent by the server cannot be received. Please contact your nursing personnel.	Communication with the message server is not working. This may be a temporary networking problem. Close the application through the phone's application manager and try again after a while. If the problem persists, contact Orla patient support (see Contact Information section).
Measurement program fetching error.	Attempt the following solutions, in order: 1. Verify with your phone browser (e.g. by making a Google search) that you have a working Internet connection. If you do not have a working Internet connection, the problem might be with your local Wi-Fi network. Try switching off the Wi-Fi on your phone to force use of the cellular network. If your cellular network connection does not work, resolve the problem with your cellular operator. 2. Reboot your phone and try again.
INR medicine sending error.	Do as instructed under "Measurement program fetching error."
INR schedule sending error.	Do as instructed under "Measurement program fetching error."
Communication error - Error in communication with Bluetooth device.	Attempt the following solutions, in order: 1. Switch Bluetooth off for a moment, then switch it on again, and try again. 2. Restart both your phone and the measurement device, and try again. 3. Remove the Bluetooth pairing from your phone, pair the devices again according to the instructions in this manual, and try again.

Error Message	Solution
Communication error - Please verify the encryption key value ...	Check the encryption key value as instructed. If the encryption key does not match, contact Orla patient support (see Contact Information section).
Wrong device.	The connected CoaguChek device is not the same as the currently paired device. Check that devices have not been switched by mistake.
Error in communication with CoaguChek.	Try again. If the transfer of measurements is still not working, do as instructed under "Communication error - Error in communication with Bluetooth device."
Failed to establish a connection to the meter.	Make sure that the meter is turned on and try again.
Error in sending the measurement results.	Do as instructed under "Measurement program fetching error."
Authentication error, the device ID was not recognized.	Either measurement program has not been created yet or it has the wrong phone ID. Contact Orla patient support (see Contact Information section).

14.2. Troubleshooting

Problem	Solution
I have a new phone, and now I cannot make INR measurements or see my measurement program information in the mobile application.	<p>The phone identifier of the Orla Etämittaust application changes when the phone changes, which means that the phone identifier should be changed in your measurement program information. Please report the phone identifier of the new phone to your healthcare professional or to Orla Etämittaust patient support (the phone identifier can be found on the Settings page of the Etämittaust application).</p> <p>When your phone identifier has been changed, your measurement program needs to be downloaded to the phone. To do this, press the "Update Information" button on the main page of the application. When your measurement program has been downloaded to your phone, a new pairing must be done before you can make new measurements. See the instructions for pairing devices in this manual, according to your phone model.</p>
I am making measurements and there is problem with the Bluetooth connection between my phone and measurement device.	<p>Attempt the following solutions, in order:</p> <ol style="list-style-type: none"> 1. Ensure you have started the measurement on the phone (pressed the "Measure Now" button) before attempting to send a measurement from the measurement device. The application is not able to receive measurements before the "Measure Now" button has been pressed. 2. Switch Bluetooth off for a moment, then switch it on again, and try again. 3. Restart both your phone and the measurement device, and try again. 4. Remove the Bluetooth pairing from your phone, pair the devices again according to the instructions in this manual, and try again.
My measurement device does not accept test strips.	Your test strip container has probably changed. Please change the chip card in your INR measurement device. The chip card is always "per container" and should be changed when a new test strip container is taken into use. The chip for the new container can be found in the packaging of the container.
My INR results have not been transferred to the phone, but I can see the result on the measurement device.	If this happens, you can later transfer your results from the measurement device to your phone. First, you press "Measure Now" in the application on the phone. Then you go to "My Results" on the INR measurement device and select "Transfer Data". Your latest result is transferred to your phone and you then continue the process as normal to transfer the result to a healthcare professional.
My INR results are not being transferred from phone to a healthcare professional, the measurement history shows a red error symbol instead of a green checkmark.	<p>Attempt the following solutions, in order:</p> <ol style="list-style-type: none"> 1. Verify with your phone browser (e.g. by making a Google search) that you have a working Internet connection. If you do not have a working Internet connection, the problem might be with your local Wi-Fi network. Try switching off the Wi-Fi on your phone to force use of the cellular network. If your cellular network connection does not work, resolve the problem with your cellular operator. 2. Reboot your phone and try again.

15. Decommissioning

When you no longer need the mobile application, uninstall it to ensure that all your measurement data is removed from your phone. Before you uninstall the application, please make sure that all your measurements have been transferred to a healthcare professional. You can verify this in your measurement history, all measurements should have a green checkmark next to them indicating a successful transfer.

16. Contact information

If your problem is related to your health or medication, please contact your nursing staff.

Do not make any changes to your treatment without discussing with a health care professional.

The nurse's contact information:

Name: _____

Phone: _____

Email: _____

If you are experiencing problems with the Etämittaus Application, please contact:

Patient's technical support

Phone: +358 50 435 2071

Email: potilastuki@orladtx.com

For problems with the measuring instrument, see the instruction manual for the instrument itself.

Any serious incidents should be reported to the manufacturer and to the competent authority.