

Orla Etämittaus INR Patient Guide

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Orla DTx Oy

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1. Accessibility

The Orla Etämittaus 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 \rightarrow Accessibility \rightarrow Keyboards \rightarrow 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 \rightarrow Accessibility \rightarrow Keyboards \rightarrow Full Keyboard Access \rightarrow Commands.

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

You can contact us in accessibility related matters via email at <u>saavutettavuus@orladtx.com</u>. The accessibility statement for the service is available from <u>https://orladtx.com/fi/saavutetta-vuusseloste-inr/</u> (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 <u>privacy@orladtx.com</u>. More information about our privacy policy is available from <u>https://orladtx.com/privacy/</u>.



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 Etämittaus 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.





4. Setup

To function, Orla Etämittaus requires the following setup:

- Phone
- Etämittaus application The latest version of the application can be downloaded from the phone's app store.
- Measurement device (incl. the device's manual)
- Etämittaus 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 Etämittaus application to your phone:

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





Figure 2

Figure 3

11.01 🖬

4

8 🗑 🕾 al 28 al 85% 🕯

Q :

- 3. Select the Orla Etämittaus application by clicking the icon. (Figure 4).
- 4. Start the installation by clicking *Install* (Figure 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.
- When you open the application for the first time, Orla Etämittaus will request access to necessary destinations (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.

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



- 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

 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.



5.3. Phone settings

To function in a reliable way, the Orla Etämittaus application requires that certain settings of the **phone's operating system** are according to the instructions in this document. Orla DTx cannot guarantee a full functionality of the application if the phone's settings are not in accordance with the instructions provided in this document.

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.

It is recommended that you lock the phone with a password, security code, or pattern. This way, your phone, and the Orla Etämittaus application are protected against improper use.

5.3.3. Airplane mode

Airplane mode cannot be enabled.



5.3.4. 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.

5.3.5. Date and time

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

5.3.6. 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 which case the measurement results are transferred the next time a data connection is available.



6. Pairing measurement device and phone

6.1. Android

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

- 1. Using an Android phone, go to *Settings* \rightarrow *Bluetooth*
- 2. If you have previously had another CoaguChek[®] INRange device paired to your phone, the old pairing needs to be forgotten. The device will be visible on the list of paired devices. Next to the device, click the cog (Figure 13). By doing this, you will be able to click *Forget* or *Unpair*, and the pairing will be undone. If there is not any previously paired CoaguChek[®] INRange devices you can skip this step and return to Bluetooth-settings.

< в	luetooth	Stop :
On		
	sure the device you want pairing mode. Your pho is currently visi s.	ne
Paired	devices	
£	CoaguChek	\$
	Figure 13	

- 3. Turn on the CoaguChek® INRange- device.
- 4. Go to Settings \rightarrow Data Transfer \rightarrow choose Bluetooth and Save.
- 5. The device will ask: "Do you want to pair?", answer *Yes*. If the device asks: "Delete pairing and pair with another device?", answer *Yes*.
- 6. The phone's Bluetooth screen will show the device CoaguChek on the list of Available devices (Figure 14). Click on the device, and click *OK*, and the pairing will be made. The device will move to the list of Previously connected devices/Paired devices. The measurement device will also show that the pairing was successful.

Available devices	Available devices
🗭 CoaguChek	CoaguChek
	Bluetooth pairing request
	Pair with CoaguChek?
	Cancel OK
	Figure 14

7. The pairing is done, and you can start measuring.



The devices will automatically connect for the following measurement, and hence this step is not necessary hereafter.

6.2. iOS

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 forgotten. The old pairing can be undone by going to *Settings* \rightarrow *Bluetooth*, choose CoaguChek and click *Forget this device*.

- Begin the pairing by opening the Orla Etämittaus application. Go to Settings (can be find 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, and hence this step is not necessary hereafter, unless the phone changes.



Figure 15



7. Preparing to measure

- 1. Wash your hands with warm water and dry them well.
- 2. Take out the lancing device, the test strips, measurement device, smart phone, and 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).

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





8. Beginning to measure

- 1. Open the Etämittaus 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 receive the updated program by swiping your finger from the top of the page downwards.

MEASUREMI	ENTS	SETTINGS	INFO
٥	Next r Wedne The IN to con measu your p record	EASUREMENT neasurement: esday April 28 IR measurement res trol warfarin dosag urement results are ersonal Warfarin Ca essonal Warfarin Ca s. If needed, a nurs ct with you during o	e. Your transmitted to ard and health e may be in
	Ν	MEASURE NOW	
	MEAS	UREMENT HIS	TORY
	W	ARFARIN CARE)

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 have their own chip that needs to be changed whenever the jar of test strips changes.







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).



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 capillary 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).





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.





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

	INR measurement		INR measurement
	ssible causes of the changed INR value ect from the options below and click Continu	ie.	Additional Information
1220014	nporary change		
0	Natural remedies	(j	
0	Change in diet	(i)	Selected causes Temporary illness
	Forgotten or extra dose of warfarin	()	FINISH
0	Operation or procedure	()	FINISH
۲	Temporary illness	()	5/ 00
0	Change in other medication	()	Figure 29
0	Planned change of warfarin dose	(i)	
0	Use of alcohol	()	
Per	manent or long term change		
0	New primary disease	(i)	
0	Change in lifestyle	(i)	
0	Negative change in primary disease	()	
0	Change in other long term medication	()	
	CONTINUE		



11. Warfarin card

11.1. Self-measurement

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 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*.



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 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*.





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 with, 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 everyday by selecting *Use same dosage daily*.

Lastly, accept the changes made by pressing Save.



SAVE	
CANCEL	



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, that is, how often the application reminds you to do the measurement.

Lastly, press *Save* to accept the changes.

y of the n	neasur	emen	nt
	y of the n		y of the measuremer

• Every four weeks

Every six weeks

Every eight weeks

SAVE	
CANCEL	1



11.3. The warfarin card data page

By pressing the *i*-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 Wa	arfarin card data
Symbol legend	s
3 mg tablet	
🖲 5 mg tablet	
O Next measu	rement
Target level of treatment:	2.00 - 3.00
Treatment indicati	ons: Atrial fibrillation

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
- coughing blood or throwing up blood abnormal menstrual or genital bleeding increased sensitivity to bruising or bleed
- increased sensitivity to bruising or bleeding from the slightest scratches
 your general condition worsens



12. Finishing the measurement

Remove the used lancet from the lancing device and place it in the 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.

ieasurements SETTINGS INFO	< Measur.	Warfarin card	í
3/31/2021 12:57 PM Your medication has been changed. Check the data on the Warfarin card.	3/31/2021 Medication	12:57 PM changed. New medication is starting 3,	/31/2021
		OK]
Next measurement: Wednesday April 28	<	3/29 - 4/4/2021	>
The INR measurement result is used to control warfarin dosage. Your measurement results are transmitted to your personal Warfarin Card and health	3/29 Mon		0.00 tb
records. If needed, a nurse may be in contact with you during office hours.	3/30 Tue		0.00 tb
MEASURE NOW	0 /01 \\		0.00.4
MEASUREMENT HISTORY	3/31 Wed		2.00 tb
WARFARIN CARD	4/1 Thu		1.00 tb
Elauro 25	4/2 Fri		1.00 tb
Figure 35	4/3 Sat		2.00 tb
	4/4 Sun		1.00 tb
	Weekly do	se:	21 mg



14. 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.

