

Lindera Mobility Analysis

Instructions for use

App Version 10



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PART A: General Information

1. Information about the user manual

This user manual describes the application and functions of Lindera Mobility Analysis.

The user manual is made up of three parts. The first part contains all the basic information about the user manual itself and the way the product works. The second part describes how to use Lindera Mobility Analysis. The third part is aimed at expert users.

Additional information about Lindera Mobility Analysis can be found on the Lindera website <https://www.lindera.de/>. You can also download the latest version of the user manual there or call +49 30 12085471 (Monday through Friday 9:00 a.m. to 5:00 p.m.) to order a printed paper version of the user manual free of charge (7-day delivery period within the EU).

If you have any questions or uncertainties when using the app, please contact your Customer Success Manager or the Lindera service team at service@lindera.de or by phone at +49 30 1208 5471 (Monday through Friday 9 a.m. to 5 p.m.).

2. Symbols

This manual and the associated product use the following symbols (color and dimensions may vary):

Symbol	Description
	CE marking (Communauté Européenne). A product that has this marking meets the requirements of the relevant EU Directive, i.e., the applicable European standard.
	Observe user manual

	Manufacturer
	Date of manufacture
	Warning Warnings are always relevant to safety.
	Note A note gives you important information about the safe and correct use of the product.
	Information

3. Manufacturer information



Lindera GmbH

Diana Heinrichs
Kottbusser Damm 79
10967 Berlin, Germany
Charlottenburg District Court (Berlin)
HRB 190227 B
VAT ID No. DE310129466

Lindera Service team

Email: service@lindera.de
Phone: +49 30 12085473
Service times: Monday through Friday 9 a.m. to 5 p.m.



Lindera Mobility Analysis is a Class 1 medical device following Directive 93/42/EEC Annex IX Rule 12.

4. Product description

Lindera Mobility Analysis analyzes fall risks and gives personalized recommendations to decrease risk factors. The assessment takes place on the Lindera Mobility Analysis App in two steps: 1.) a video is recorded of the patient's gait and then evaluated by an AI-based algorithm and 2.) a questionnaire is filled out regarding other fall risk factors. For the analysis, only the integrated camera on the smartphone or tablet is required. The analysis results will be presented and explained in a fall risk report, including the overall risk score (the Lindera fall risk score) and the underlying fall risk factors and individual recommendations for risk reduction and fall prevention. This report is provided in a PDF file format.

Lindera Mobility Analysis is based on verified clinical evidence and guidelines, e.g., in line with the expert standard of accidental falls, and is intended to be utilized repeatedly. The development of fall risk factors over time is shown in the Mobility Analysis App and all fall prevention recommendations are updated with every new mobility analysis that is conducted, based on the current risk profile and previous recommendations.

There is one account available for lay users and a professional account is provided for medical personnel. Both accounts can be linked to each other. When an account has been linked, specialists can see their patient's profile and access the associated data.

4.1 Intended purpose

Information regarding proper use

Lindera Mobility Analysis was developed to identify and monitor fall risk factors with the assistance of an AI-based video recording analysis of the gait of the person in need of care and a digital questionnaire. The objective is to reduce the identified risk factors by giving the patient evidence-based recommendations for fall prevention.

Field of application and target group	<p>The intended group: people of any gender aged 60 or above with limited mobility and/or a potential fall risk.</p> <p>Persons in need of care must be able to get up from a chair walk forward 3 meters, turn, return to the chair and sit down, either alone or with the support of a walking aid or a third person.</p>
User groups	<p>Intended users include healthcare professionals e.g., doctors, nurses, geriatric nurses or physiotherapists, as well as persons in need of care as defined in the intended group above. In accordance with the user manual, persons in need of care must be supported by medical professionals, or laypersons and caregivers when necessary.</p>
Operational environment	<p>The application is designed to be used in the healthcare sector and/or in a home environment, in compliance with the safety information described in the app and the user manual.</p>
Contraindications	<p>There are no known or expected contraindications if the medical device is used as intended.</p>
Side effects	<p>There are no known or expected side effects if the medical device is used as intended.</p>

4.2 How it works (detailed)

The Lindera Mobility Analysis is constructed on established mobility tests and analyzes the individual fall risk based on an algorithm-supported evaluation of a video recording of a patient’s gait, using a smartphone or tablet camera, and a questionnaire on other fall risk factors.

To analyze the gait, a person is filmed getting up from a chair, walking a short distance of 3 meters, turning 180°, walking back to the chair, and sitting down again. The high-precision AI-based algorithm analyzes risk-relevant gait parameters from this video, such as the angle of the upper body forward lean

and/or tilt to either left or right, the step length, step time, walking speed, step height and cadence.

Lindera Mobility Analysis also incorporates information, in addition to these gait parameters, from a multidisciplinary questionnaire to identify other evidence-based fall risk factors. This includes questions about the following topics:

- Impaired mobility and gait
- Impaired sensory perception and cognition
- Diseases and medications that can cause syncope [loss of consciousness]
- Excretory habits
- Fear of falling
- Fall history
- Extrinsic risk factors (i.e., environmental hazards, unsuitable footwear, walking aids/tools)

The analysis risk factors are displayed in the App and summarized in a comprehensive fall risk report. The personalized report contains, among other things, evidence-based recommendations to reduce every risk factor and can also be viewed on the app.

The identified risk factors are weighted and then summarized to deduce the overall risk score – the Lindera fall risk score. The fall risk score ranges from 0 to 100%. The more risk factors are identified, the higher the fall risk score. The fall risk score is not intended to predict the occurrence of a fall, but rather serves as an indication of the number and severity of identified fall risk factors.

4.3 Clinical benefit

The Lindera Mobility Analysis determines individual fall risk factors on the basis of a precise gait parameter analysis and digital questionnaire. The Lindera Mobility Analysis provides the patient with evidence-based recommendations to reduce identified risk factors to support fall prevention and maintain mobility.

4.4 Recommended frequency of use

It is advised that Lindera Mobility Analysis be repeated every two months to review treatment success and get new recommendations. The manufacturer additionally recommends carrying out the mobility analysis again after the following events:

- If there is an acute change to the physical condition
- If there is a change to the medication
- If the patient moves in or out of a home, or there are changes to the living environment
- If the need for care increases
- If the care plan is revised
- After a fall

4.5 Product configuration

The Lindera Mobility Analysis is available in different configurations as shown in the table below.

- **Account type:** There is an account for private use of Lindera Mobility Analysis (supported by healthcare professionals and other lay users, as described in the user manual). In addition, a special account for third parties involved in care is offered, which contains functions that contribute to the support of (several) persons in need of care. This account can be used, for example, to carry out mobility analyses for persons in need of care **and to allow third parties involved in care to view the results of these analyses.**
- **Additional modules:** An additional group prevention module is offered through which individual offers can be planned.
- **System interfaces:** Lindera can be integrated into care documentation or patient management systems.
- **Language options:** DE, EN
- **Distributed in:** DE, AT

4.6 Product service life

A minor update of the app (changes to the second or third section of the version number) is a recommended update; however, previous versions remain functional. The manufacturer reserves the right to restrict the functioning of older

versions or even block all access in the event of major updates (changes to the first section of the version number) or important safety updates. When updating the software to the latest version, data from older versions are automatically migrated. The manufacturer reserves the right to limit data migration to the two latest major updates.

5. Important safety information

Please observe the following warning and safety information before using Lindera Mobility Analysis. So that warning and safety instructions can be more easily understood, some instructions in the product are slightly shortened and combined with image elements. For other specific information that is only related to certain contexts of use, said information is only stated at the appropriate place in the product itself (example: information appears if a recommendation has been planned for over six months but has yet to be implemented).

5.1 Warnings

The following warnings are for people in need of care. However, also if you are a caregiver or relative of the patient, please read them carefully and make sure that they are observed.



Only record the video with the assistance of another person (e.g., relative or caregiver).



Be sure to use your usual walking aids (e.g., walking stick, walker, support from another person).



Please make sure that the designated walking distance is free of any tripping hazards.



This analysis does not replace a medical diagnosis or treatment. Please discuss the risk factors and recommendations we have provided with your physician, physiotherapist, or nurse.

5.2 Safety information

For persons in need of care

-  If you need assistance answering health-related questions, only use the Linder app with the support of a relative or caregiver (e.g., doctor, nurse).
-  If you use a walker, please remove or empty attached bags or baskets before recording the video.
-  The fall risk score is not intended to predict the occurrence of a fall, but rather serves as an indication of the number and severity of identified fall risk factors.

For relatives and specialists

-  The video subject must walk a distance of 3, turn and walk back. Mark a spot on the floor 3 meters from the chair, at which the video subject will later turn around. Mark a spot 5 m away from the chair, from which you will later record the person in need of care.
-  While recording, stay on the 5 m mark. Ensure that all body parts are completely in view during the recording.
-  Hold the smartphone or tablet in portrait (vertical) mode while recording.
-  Ensure that there is sufficient lighting and avoid having bright light sources in the background (such as a large and bright window).
-  If the video subject receives assistance when walking, make sure that the seated subject is alone in the picture for the first 2-3 seconds of the recording and that the patient is always in the center/focus of the picture while recording.



Note for caregivers when using the group prevention module: This module is used by caregivers to organize group prevention measures. The Linder algorithm pre-sorts patients into groups based on their risk profile. Caregivers can process this selection and supplement it with specific measures. Please note: Using this module requires specialist expertise – the manufacturer cannot assume any liability for reviewing and implementing the measures.

Please also observe the safety information for persons in need of care as stipulated at the beginning of this chapter.

6. Data privacy and data security

The data are stored on Telekom servers in Germany. The data path between the app and our server is encrypted with SSL. The personal data collected by Linder are stored until expiry of the statutory retention period (10 years from the end of the calendar year in which the order was terminated) and then deleted, unless Linder is obligated to store them for a longer period in accordance with GDPR Article 6 Paragraph 1 Page 1 Item c on the basis of retention or documentation obligations under tax or commercial law (resulting from the German Commercial Code (HGB), German Penal Code (StGB), or German Tax Code (AO)), or if you have consented to longer storage in accordance with GDPR Article 6 para. 1 sentence 1 lit. a GDPR. The parameters collected from the videos as well as the data from the psychosocial tests are stored, after your consent has been given, anonymously for further statistical purposes. No conclusions on the person of the user can be drawn from these.

- After the data transmission to Linder, no personal data will be stored on the user smartphone. The data are stored on the smartphone in an encrypted manner until transmission.
- The patient has the right to request
 - access to their personal data (§15 GDPR);
 - rectification of their personal data (§16 GDPR);
 - erasure of their personal data (§17 GDPR).

Our website, the Linder Mobility Analysis App and the associated products are equipped with security features to ward off threats against your data. In particular, we carry out the following measures:

- We constantly endeavor to improve our security standards. Furthermore, we continuously adapt the anonymization of personal data according to state-of-the-art technical standards.
- Internal access to personal data is restricted to those who absolutely need access.

You can find more information under:

<https://www.lindera.de/wp-content/uploads/legal/dataprotection-english.pdf>.

7. Installing the app

7.1 Mobile application of the Lindera Mobility Analysis App

We recommend that, as a minimum, you use a version of the operating system (iOS/Android) for which the manufacturer provides security updates. These are usually the latest and current version of iOS as well as both the current version of Android and its two predecessors. This helps ensure that your app delivers the highest possible level of security and functionality.

The app can be used with both common smartphones and tablets. The app is installed directly from the system's own app store.

 If you do not have a user account for iTunes or Google Play Store yet, here are instructions on how to set up a user account:

- iTunes (iOS): <https://support.apple.com/en-us/HT204316>
- Google Play (Android):
<https://support.google.com/accounts/answer/27441?hl=en>

You can uninstall the app from your device at any time. However, your account remains active if you uninstall the app. If you want to delete your account, you must do so before uninstalling the app. You can find the option to delete your account in the advanced settings section.

7.2 Optional: Lindera Dashboard web application (chapter 14.1)

Lindera Dashboard can be used in modern web browsers with compatible operating systems (recommended: Chrome 71, Edge 87, Safari 11.0 or newer versions). Older versions may also be supported, but the manufacturer does not recommend using these.

- ① Please note that Lindera Dashboard is only used to display information and is not part of the medical device. All the information displayed on the dashboard can also be found in the app.

PART B: Using the Lindera Mobility Analysis App

This part of the user manual explains how to use the Lindera Fall Prevention App.

8. Registration

8.1 Creating a user account

When using the app for the first time, you must first register as a user.

Registering via the Lindera Fall Prevention App:

- Install the Lindera Fall Prevention App on your smartphone or tablet (see Chapter 7.1)
- Open the app and select the button that says *No account yet? Register here* and then select the role *Private person*.
- If you have received an activation code from your carer, you can enter or scan it. If not, you can skip this step.
- In the next step, please enter your email address and a password that you will use to log in later.

Once you have set your access data, you must now complete your profile.

After registration, you must confirm your email address. To do so, click on the confirmation link in the welcome email. You will be taken back to the application. Note that you need an internet connection for these steps. You can then use your login details to log in (see Chapter 8.2)

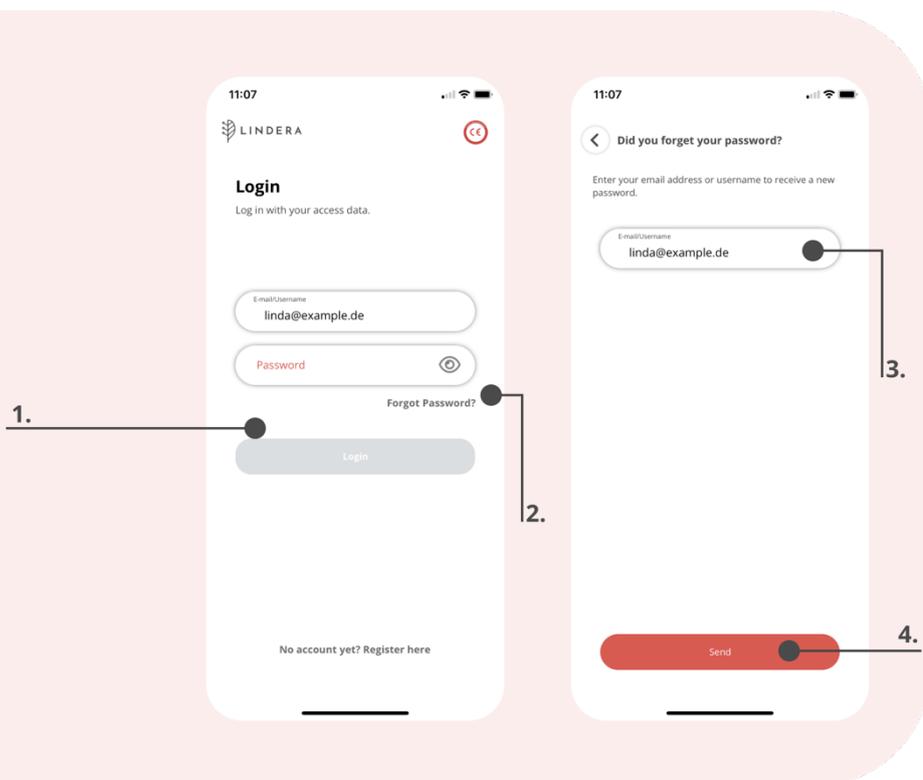
8.2 Logging into the Lindera Fall Prevention App

You must have the Lindera Mobility Analysis App installed on your smartphone or tablet in order to be able to carry out the Lindera Mobility Analysis (see Chapter 7.1). Enter your email address and your password and click on *Login* (1) to log in.

- ⓘ After more than 15 minutes of inactivity, you must re-enter your password to authenticate yourself for security reasons.

If you have forgotten your password:

- Click on *Did you forget your password?* (2)
- Check your email address (3)
- Click on *Send* (4)
- You will receive an email: Now click on the link to reset your password and create a new password



9. Home screen of the Mobility Analysis App

You can access two areas of the application via the navigation at the bottom of the screen.

- **My profile:** Here you can check your profile information and adjust it if necessary. You can also view your recommendations as well as new and past evaluations or start a new analysis. In addition, you can link your account to a caregiver from here. The time until your next analysis and the current fall risk score can be viewed in the upper area.
- **More:** In the More tab you will find more information and settings related to the Lindera App. If you have problems with the app, you can contact the support here and access the user manual.

If you need further help, select the *Help?* button in the lower right area of some pages. An explanation of the current page will be displayed.

10. Carrying out a Lindera Mobility Analysis

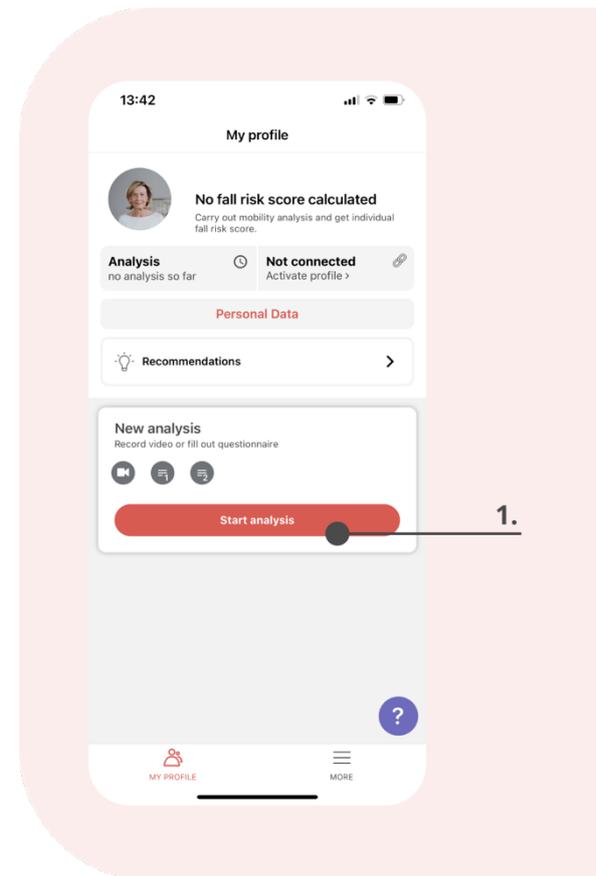
10.1 Preparing the device

Please make sure your device is sufficiently charged before starting an analysis. You do not need an Internet connection at any step of the mobility analysis (video recording and questionnaire). An Internet connection is only necessary when you upload the video and completed questionnaire.

10.2 Start mobility analysis

- On the profile, click on *New Analysis* or *Follow-up Analysis*. Alternatively.
- Confirm the information in your *Profile* (1)
- If you need to make changes to the listed data, click on *Edit* and then correct your data.

For the first analysis, the type of questionnaire must also be selected. Further information on the questionnaires can be found in chapter [10.4](#).



10.3 Video recording for gait analysis

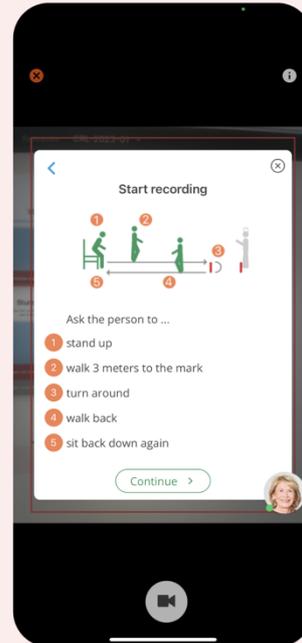
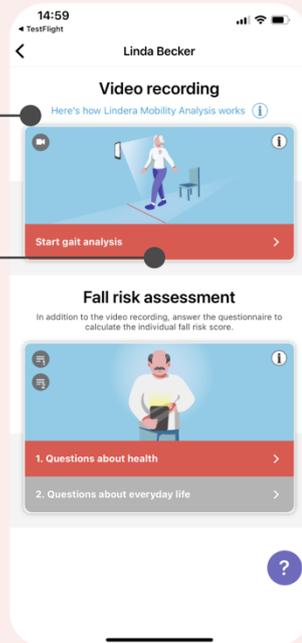
A part of the mobility analysis entails an analysis of the gait pattern by means of a video recording. Before starting to record, please watch the video instructions (1)

You need the following for the analysis:

- A chair
- About 5 meters of space
- Two markings (e.g., colored tape that you can stick on the floor)
- A person who will assist you with the recording (hereinafter “person recording”)
- If need be, walking aids, or another person who can assist you with the gait analysis. You should move in the gait analysis exactly as you do in everyday life, i.e., with the corresponding walking aids.

1.

2.



Preparing for the video recording:

- Please read the following sections together with the person recording
- Place the chair, or ask someone else to place it, at about 5 m distance

i Ask the person recording to mark the spot at which you will later turn around. This should be about 3 m away from the chair. Then ask the person recording to also mark a spot 5 m away, at which the person recording will record the video.

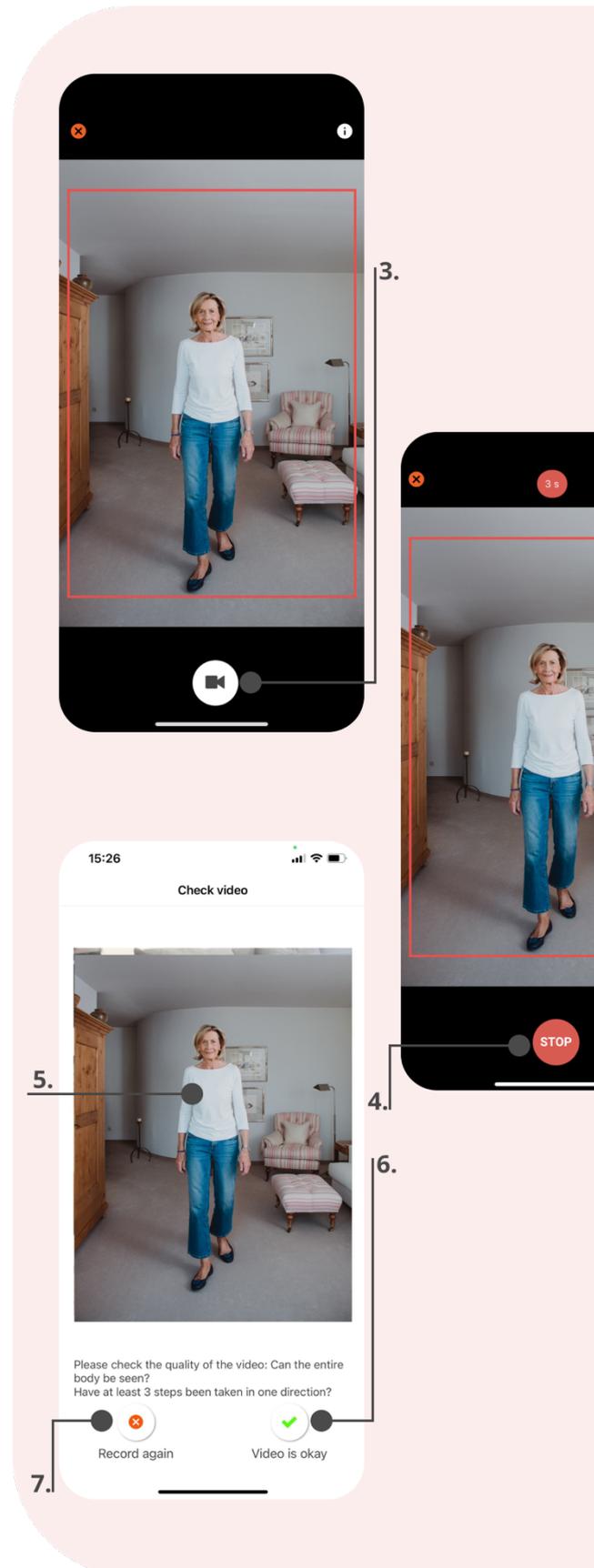
- Sit down on the chair
- Ask the person recording to stand on the 5 m mark and turn towards you with the camera



Please observe the safety instructions and warnings on safely and correctly carrying out the video analysis (see Chapter 5)

Instructions for the person recording the video:

- Click on *Start gait analysis* (2)
- A recording window with a red frame will appear. Please make sure that the video subject's entire body is fully visible within this red frame for the duration of the recording.
- Click on the camera icon (3) to start the video
- Instruct the video subject to stand up from the chair, walk to the marked spot, turn around, walk back to the chair, and sit down again (*see illustration above*)
- During the recording, be sure to walk at the same speed that you normally do. It is not about walking fast. There is no time restriction for the video recording.
- After completing the recording, click on the stop symbol (4)
- Afterwards, you are shown the video once more to review it (5)
- Please check to make sure that...
 - ... the lighting is suitable
 - ... the person is in the frame from head to toe for the entire recording and that they are not covered by other persons or items
- If the system detects that the video might not be of the required quality, a notification will pop up (image to the right)
- In this case, please check the video with particular care
- If the video meets all necessary criteria, you can still upload it (6)
- If the video is inadequate, please make a new recording (7)
- Once you have successfully uploaded the video, you are shown the successful upload (8)



- The video is now evaluated and the gait parameters are sent to you as an intermediate result in the app.

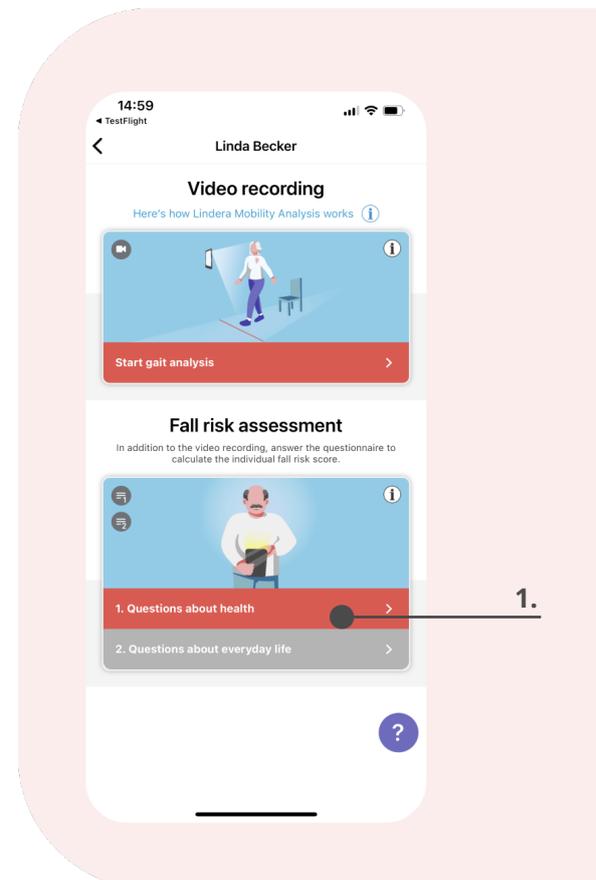
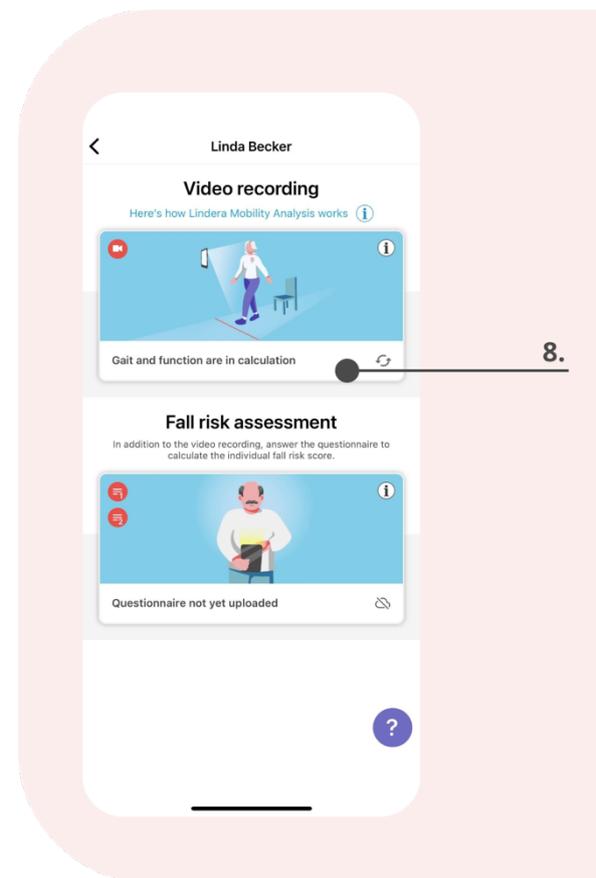
- ① If you carry out the analysis in offline mode, i.e. without an Internet connection, the video will only be uploaded later and will be saved on your device encrypted until the upload is complete (see Chapter 10.5).

10.4 Filling out the fall risk questionnaire

- The second part of the analysis entails the completion of the questionnaire (1).
- You have two versions of the questionnaire available to choose from:
- The fall risk assessment covers a basic assessment of the elementary risk factors.
- The advanced assessment is used to assess elementary risk factors as well as a short psychological profile.

- ① If you have indicated in your profile that there are cognitive restrictions, a simplified version of the questionnaire will automatically be selected.

- Each questionnaire is divided into two parts. The first part is primarily about health-related aspects such as medication, diagnoses, and any history of falls. The second part contains questions about everyday life, such as the living environment and well-being.
- The first part of the questionnaire must be completed first.
- Now answer the remaining questions of the questionnaire by choosing the answer and confirm your answer by pressing *Continue*.

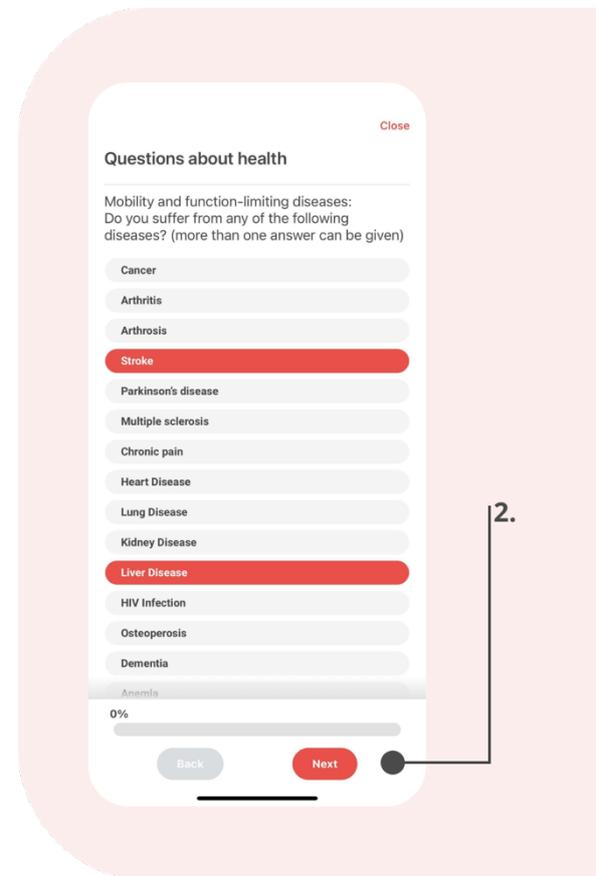


- If you want to correct an answer, you can navigate back to the previous question clicking *Back*.
- The bar at the bottom of the screen displays your progress (2).
- There are two types of questions:
- **Single selection** (*example on the left*): There is always just one response you may select. If you have already selected a response and then click on another response, the previous answer is deactivated.
- **Multiple selection** (*example on the right*): You may select more than one response. If you wish to undo a selection, simply click on it again.

i You may only click on *Continue* after making a selection.

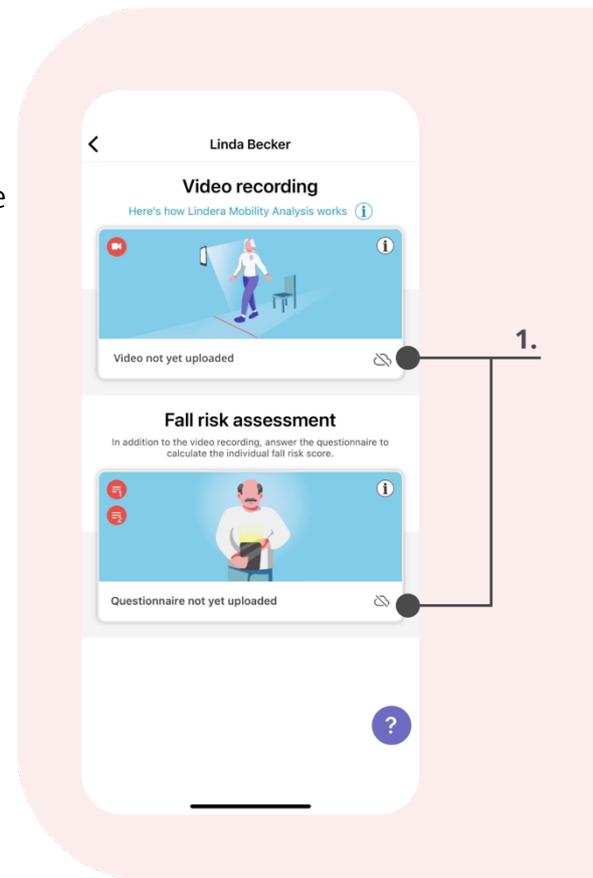
- Each questionnaire is divided into two parts. The first part is primarily about health-related aspects such as medication, diagnoses, and any history of falls. The second part contains questions about everyday life, such as the living environment and well-being.
- If both modules (video and questionnaire) have already been completed, the degree of fall and all other results will be determined. You will receive a notification as soon as the evaluation is available.

i Alternatively, you can also fill out the questionnaire in offline mode. See Chapter 10.5 on offline mode.



10.5 Carrying out the analysis in offline mode

- If you temporarily do not have an Internet connection, you may carry out the analysis offline and upload it later.
- If you have any analyses stored offline but have not uploaded them yet, they are shown on the home screen (1).
- As soon as you're connected to the Internet again, the system will automatically try to synchronize your data and upload offline data. However, you may also start this process manually by clicking *Upload* on the home screen.
- You will always see the status of the video and questionnaire. If data is cached on your device, you will see an icon with a crossed-out cloud(2).



10.6 Continue analysis or start again

- ① An analysis that has been started is only available for 14 days.
- Analyses that have already been started and have either a video or questionnaire, can be completed via the profile. To do so, click on *Complete*.
- You also have the option to start a new analysis. The following steps are from Chapter 10.2, Starting a mobility analysis.

11. Carrying out a follow-up analysis

In line with the expert standard for the prevention of accidental falls, we recommend repeating the analysis regularly. To carry out a follow-up analysis, simply follow the steps explained to you in Chapter 10 and conduct the analysis again. The evaluation not only shows the current results, but also the developments since the previous analysis, and you will receive new and updated recommendations.

12. Results of the Linder Analysis

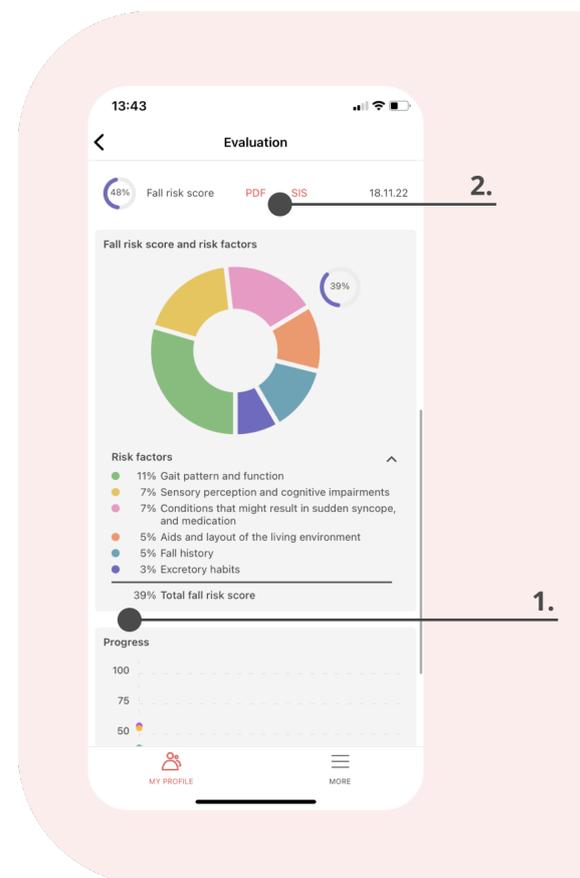
You will receive the analysis evaluation after uploading the analysis, within a few minutes to hours, but at the most within one working day, and you will be notified as soon as the evaluation is ready.

You will receive the calculated gait parameters from the video recording as an intermediate result. The values can be found under gait pattern and function in the profile.

By clicking on the profile an overview of your fall risk score, risk factors, and their progression (1). You can also view your entire evaluation report in your profile, including detailed explanations (2), so that you can share it with your doctor or caregiver.

If you have already carried out several analyses, the results are listed chronologically in your profile.

In the upper part of the profile you can view your recommendations for action, click on *Recommendations* for this.



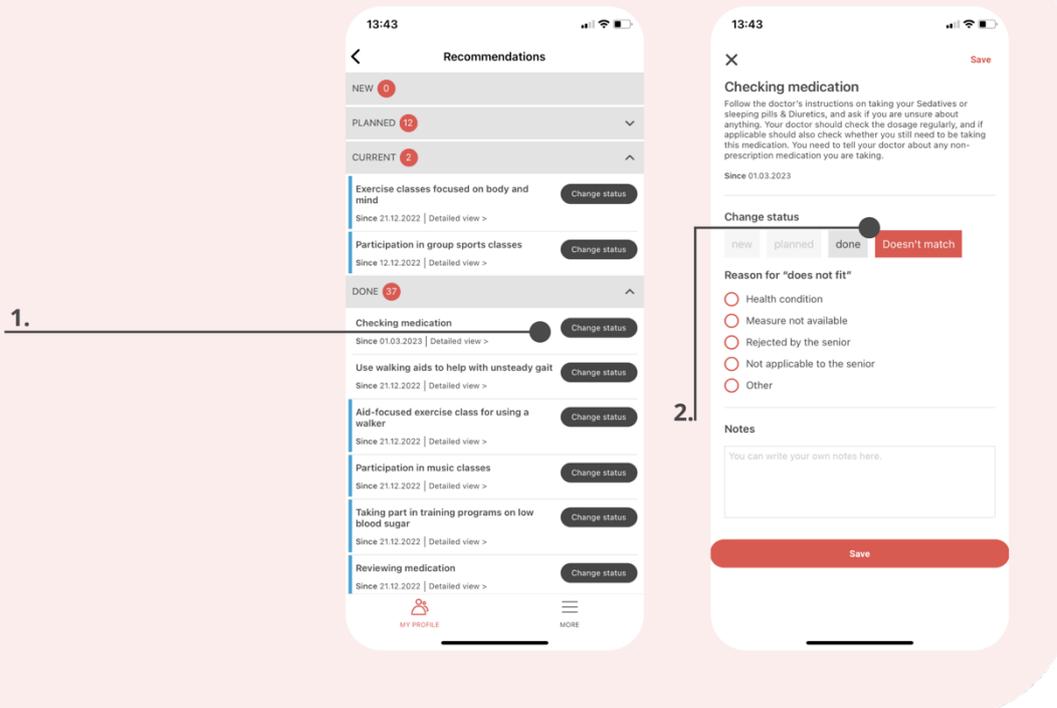
13. Recommended measures

You will receive recommended measures in addition to your analysis results. These are put together for you individually based on the gait analysis results and the responses given in the questionnaire.

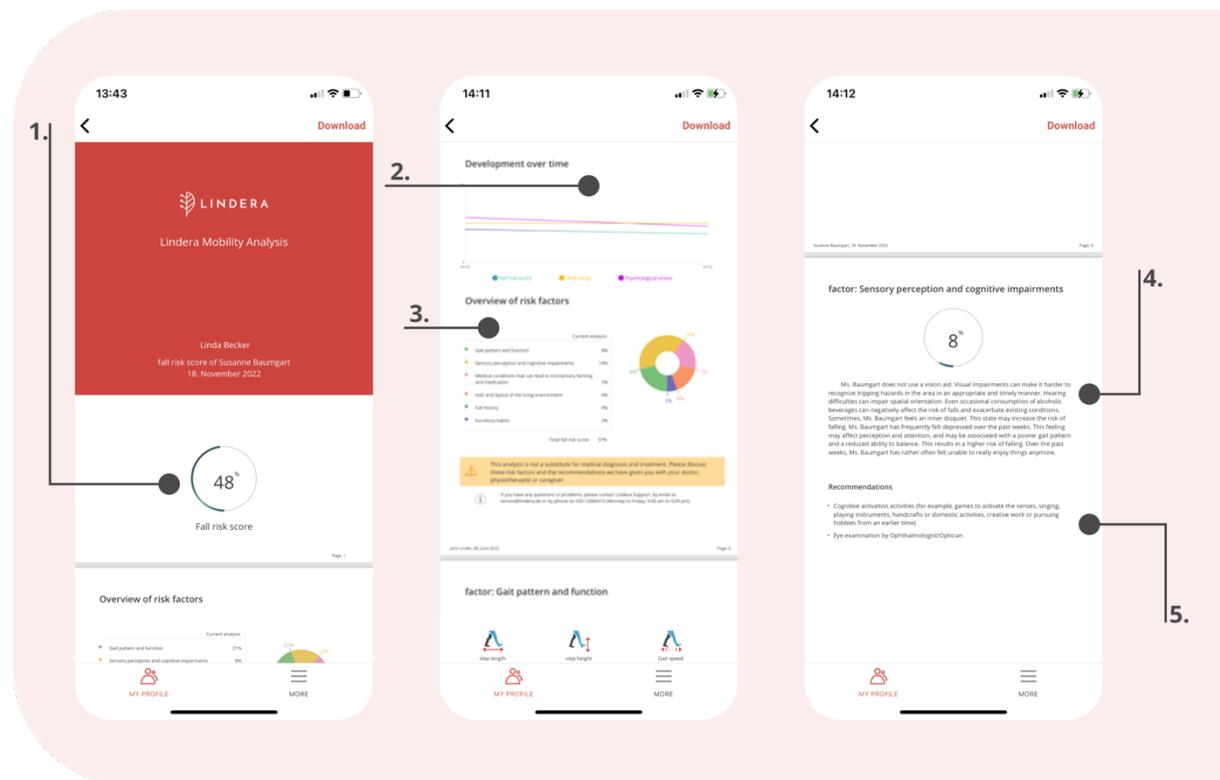
The recommendations are divided into different sections based on their status:

- New: Your new recommendations are displayed here
- Planned: Your planned recommendations are displayed here
- Current: You can keep track of your current recommendations here
- Implemented: Your already implemented recommendations are displayed here
- Does not match: You can see the measures that you turned down here

You can change the recommendation status yourself via the *Change status* (1) button. If you do so, the detailed recommendation view will open (image to the right), which contains a brief informative text and the option to select a different status. You can also record individual notes (such as appointments) in the note field. If you do not want to follow a recommendation, you can change the status to “Does not match” and state a reason (2).



14. Evaluation of the Lindera Gait Analysis



The evaluation of the mobility analysis includes the following elements:

- **(1) Fall risk score:** The more risk factors are present, the higher the fall risk score.
- **(2) Development over time:** Shows how the fall risk score, the patient's well-being, and the psychological stress have changed from one analysis to the next (is only displayed from the second analysis onwards, which must be carried out at a minimum interval of 3 months).
- **(3) Risk factors:** Shows the risk factors that make up the fall risk score.
- **(4) Detailed description of the individual risk factors:** A description of the effect and weight of each risk factor on the person in need of care is given.
- **(5) Recommendations:** Recommended preventive measures are given for each risk factor to help reduce it.



Please observe the safety instructions and warnings to safely handle the evaluation and recommendations (see Chapter 5)

14.1 Optional: Registration on Lindera Dashboard

Lindera offers an additional web application – Lindera Dashboard. This web version is optional and can be used on any device via the browser. The dashboard

provides all the information (analysis results, recommendations, group prevention measures, etc.), that is also available via the mobile application.

- ① Please note that Lindera Dashboard is only used to display information and is not part of the medical device. All the information displayed on the dashboard can also be found in the app.

14.2 Optional: Link user account with account of a third person involved in the care

If you would like direct support by a third person, such as a relative a professional, such as your doctor or nurse, when using Lindera Mobility Analysis and want to share your data, you can link your profile to another account. The requirement for this is that the third person involved in the care has their own Lindera supporting account. Refer to Part C of this user manual for more information. To link your account, go to the “My Profile” tab in the app and then navigate to “Link account.” Next, ask your third person involved in your care to give you their personal Lindera link code. Enter this code in the respective field. You can remove this link again at any time in your profile.

PART C: Use of the application by persons involved in care

As a person involved in providing care (e.g., doctor, physiotherapist or nurse) you can use the application in two ways:

1) Support the person in need of care in using their own account

Depending on the user's needs, this could mean that you...

- discuss the evaluation of the mobility analysis with the the person in need of care;
- support the the person in need of care in recording the video for gait analysis;
- provide additional assistance when required.

You can find the most important information on how to use the patient account in chapter 10.

2) Open your own supporting account

If you want to work more intensively with Lindera Mobility Analysis, you can also set up your own Lindera professional account. The professional account is specifically tailored to the needs of supporting persons and offers some additional functions, such as summarized statistics and the option of planning group preventive measures.

To request a user account, contact our Customer Success Team or use the contact form at <https://www.lindera.de/>. After you have received your login information, use the description in the welcome email to change your temporary password. You can then log into the mobile Fall Prevention App with your login information.

14.3 Functionalities in the supporting account

You have all the functionalities available to you in the Lindera professional account, they have only been slightly adapted to the conditions of persons involved in providing care. For example, the home screen of the Mobility Analysis App shows a status overview of the current analyses.

Group prevention measures or individual measures can be planned via an additional module in the Lindera internet application. Our Customer Success Team can give you a detailed explanation of these functionalities. Your personal Lindera contacts will provide you with all the relevant information.

