OKKO HEALTH

Instructions for Use		
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Instructions For Use are supplied electronically, paper format is available at no additional cost on request at support@okkohealth.com

OKKO Health
Adults App (Version DCADULT_1.0.0)

Instructions for Use (Lay User)

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1. Product Description

The OKKO Health App is an adjunct to clinical care and the purpose of the product is two-fold:

- Collecting vision data by capturing screen interactions with presented images, the OKKO Health App derives a score based upon the responses. The OKKO Health App presents this score data longitudinally in a graphical format. This is visualised within the mobile device OKKO Health App itself, but can also be shared and visualised with the eye care professional.

- Providing relevant educational material to promote the patient's health literacy and empowerment about their eye condition. The app provides push notifications that the patient can click on in order to engage in relevant content.

1.1 Indication for use

The OKKO Health App is software designed to acquire and visualise objective quantifiable data related to visual function, used as an adjunct to inform decision making and to assist communication between the patient and their eye care professional. As a companion tool, this software also has a treatment diary function and an education module. It is intended to be used on a tablet or smartphone.

Data related to visual function includes:

- Visual acuity

The OKKO Health App is intended to be used in adults with or at risk of macular degeneration. Common medical indications include:

- Degenerative disorder of the macula and disorder of the macula of the retina including Age-related macular degeneration

1.2 Contraindications

The **OKKO Health App** may **not** be used for the following indications:

- Retinal detachment
- Conditions where the visual acuity in both eyes is expected to be worse than 0.67 logMAR (approximately 6/30)
- Congenital blindness

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The **OKKO Health App** data is not intended to replace any aspect of the clinical examination.

1.3 Warnings

- Do not use for diagnosis of new or existing eye problems

- Do not use if your screen/screen protector is damaged as this may affect results

- Make sure screen modes on your device that affect the screen brightness and/or colours are switched off, as they may affect results - find instructions on how to turn off these screen modes here.

- Do not use screen magnification or increased screen contrast or have screen colour modifications enabled while using the app, as this may affect results

- Do not use your account on more than one device (choose one device you'd like to use for the OKKO Health app)

- Do not allow others to use your account as this will affect your health results

- Do not use the app if you do not meet the criteria stated in the Indications for Use section above

- Do not use the app to replace appointments with your eye care professional

- Do not let advice in the app override advice provided by your eye care professional

1.4 Precautions

- Consult your eye care professional if you feel your vision has deteriorated, regardless of the app results.

- This device is non-interventional and non-decision making.

- This device does not act as a replacement for appointments with eye care professionals.

- This device app requires a compatible, functioning mobile device with a compatible iOS or Android operating system (see list of compatible devices and operating systems here.)

- Ensure you have read and understood these Instructions for Use and follow all in-app instructions on how to play correctly.

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2. Recommendations

2.1 Guidelines for use

The OKKO Health App can be used anywhere that it is safe to use your mobile phone, at any time when you have enough free time to use the application without getting distracted.

It is recommended that patients use the OKKO Health App in a well-lit environment with minimal distractions. If a patient typically wears glasses to read, they are asked to wear these during the evaluation period. Patients are asked to play the OKKO Health App at 35cm distance from the screen.

If there is no internet connection, a measurement can still be performed, but the measurement analysis will only be available after the connection has been restored as the information must be sent to the cloud for proper analysis. If offline data is stored in the app, the next time the patient visits the Home Screen they are prompted to send unsubmitted data to the server. If the patient's device is connected to the internet, the data will be sent successfully. If it is not connected to the internet, patients will continue being prompted to send unsubmitted data until there is no offline data stored.

2.2 Intended Users

OKKO Health App is intended to be used by:

- Patients over the age of 18 years,

- Patients who are regularly under the care of an eye care professional and require monitoring over time,

- Patients who do not have a prohibited indication (as defined above),

- Patients who are familiar with smartphones or tablets and who are able to tap on the screen and interact with the mobile device application.

3. Compatibility

3.1 OKKO Health Mobile Application

The OKKO Health mobile app is designed for use on smartphones or tablets that:

- Have screen pixel density of at least 250 pixels per inch, but below 600 pixels per inch, and a screen resolution width of at least 750 pixels and physical width of at least 5.5cm

- Have a physical screen brightness within a usable and comfortable range within typical environments.

- Do not have screen magnification or increased screen contrast/screen colour modifications enabled while using the app.

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3.2 OKKO Health Web Application

The OKKO Health mobile app is not designed for web applications.

4. Set up your personal Account

4.1 Download the OKKO Health App

If you have an Apple device, open the App Store

If you have an Android device, open the Play Store

1. Search for "OKKO Health"
2. Tap to download the app
3. Once downloaded, open the app and login, or create a new account following the instructions below.

The OKKO Health app contains a pop up feature to let you know when an update is available. If you have automatic updates turned on, the app will update automatically.

4.2 Setting up your personal account using an activation code

1. Open the OKKO Health app
2. Tap 'Create Account'
3. If you were given a code by your eye care professional, or OKKO Health, enter it now (if you don't have a code, please contact support@okkohealth.com for more information)
4. Read and confirm that you understand the Privacy Policy and Terms & Conditions
5. Enter your email address, and create a password
6. Create a profile
7. Follow instructions to Setup Secure Access,to protect your health data (See 4.3 for details)
8. You are now signed up
9. If your eye care professional, or someone else helped you create your OKKO Health account, using your personal email, but with a temporary password, ensure you reset this password upon first login.

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4.3 Setup Secure Access

Setting up Secure Access will allow you to quickly and safely access your OKKO Health account every time opening the app; this means that you don't have to logout after every time you have used the app. Should you be inactive for more than 30 days, you will be automatically logged out and will need to sign-in manually again.

1. During account creation, you will be prompted to Setup Secure Access - this will allow for an extra layer of security/protection of your health data

2. Enter a 4-digit code of your choice, and then repeat it. Tap 'Confirm'

3. You will now get the choice to setup Biometric Login - this means setting up Face ID/Fingerprint ID, and allows for quick access to your account. *You will be asked to follow the standard device instructions to do this.*

4. You can choose to not setup Biometric Login, in which case you will need to enter your 4-digit pin upon every time opening the OKKO Health app.

5. You can reset your Secure Access pin code should you forget it. You can reset your pin by tapping 'Forgot pin code?'. Following these scenarios, you are prompted to log out of your OKKO Health account, and sign back in. Upon signing in, you will be asked to create a new 4-digit pin code.
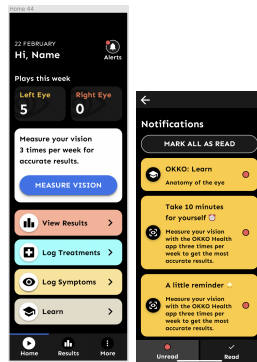
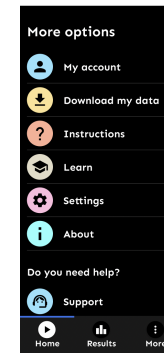| Instructions for Use		
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5. Home Screen and Navigation in app
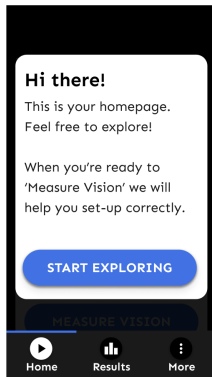
The first time logging into the OKKO Health app, you will be presented with a pop-up message. Continue by tapping 'Start Exploring'.

This is your **Home Screen**. Here you can see how many sessions you have completed this week. Tap 'Measure Vision' to complete a new session. There are also shortcuts to other features, such as the notification screen.
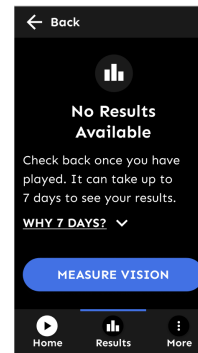
Use the navigation bar at the bottom to see your **Results Screen**. Here you will be able to view your vision results over time. The Results Screen is updated once per week with your weekly averaged results.

Use the navigation bar at the bottom to see your **More Option** menu. Here you are able to re-read instructions of use, log treatments, change settings, log out and more.

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5.1 Start Measurement

When choosing to complete your first measurement in the OKKO Health app, you will be provided with detailed instructions on how to do so accurately and comfortably. See Section 6.1 First time setup for measurement (face recognition) and Section 6.2 First time setup for measurement (no face-recognition) for instructions related to starting measurement.

5.2 My Results

When you have completed a few measurements in the OKKO Health app, you will be provided with average results/scores for these sessions. See section 6.3.1 for explanation of result classifications, and section 6.3.2 for information on how to interpret your results.

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5.3 Help

5.3.1 Support Tickets

If you have a question related to the OKKO Health app, contact support@okkohealth.com or raise a ticket on
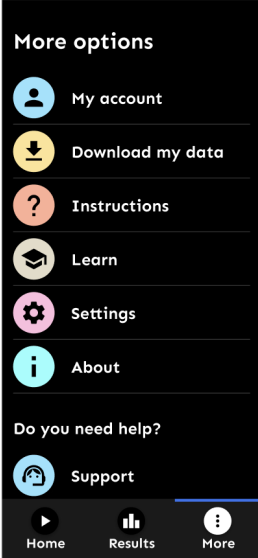https://okkohealth.com/en-gb/support/.

If you have a question whilst in the app, then tap 'More', 'Support', and you will then be taken to OKKO Health's website where a support ticket can be raised.
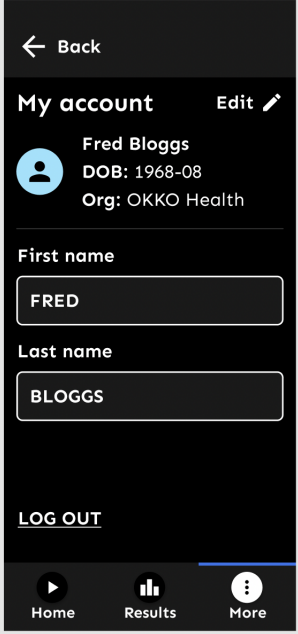
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5.4 More Options

| 5.4.1 More options | Tap 'More' to see the More Options screen | **On the More Options screen, you have a few actions available**
- My account
- Download my data
- Instructions*
- Learn*
- Settings
- About

*Instructions and Learn are shortcuts to the full *First Time Setup Course* (see section 6.1) and the *Educational Module* (see section 7) | |
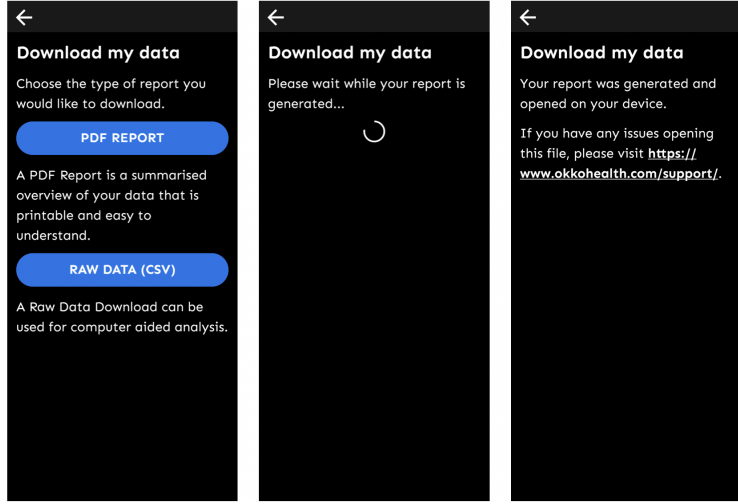
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| 5.4.2 My account | Tap 'My account' to see details about your account | **On 'My account', you can view and edit details about yourself.** Tap 'Edit' to change your first and last name. You can only edit details about your month and year of birth and organisation* by contacting support@okkohealth.com.

 *Your organisation is determined depending on the **5-digit code** you entered upon sign-up. This code should have been given to you by your eye care professional, or OKKO Health, and is a unique identifier to a specific clinic, project etc.

 Tap 'Log out' to log out of your account**.

 Please note: we recommend not logging out unless absolutely necessary. The 'secure access' feature (see section 4.2) allows you to safely and quickly access your OKKO Health account, and so prevents you from having to login/log out every time you open the app. | ← Back
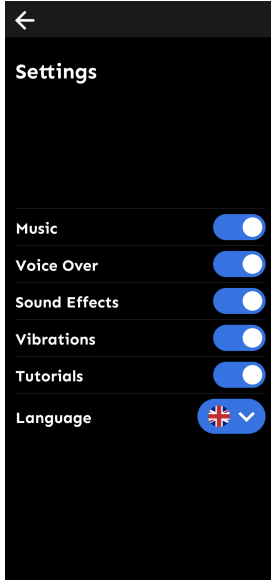
My account   Edit ✏️

Fred Bloggs
DOB: 1968-08
Org: OKKO Health

First name
FRED

Last name
BLOGGS

LOG OUT

▶ Home   📊 Results   ⋮ More |

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5.4.3 Download my data	Tap 'Download my data' to export a CSV or PDF report of your all-time OKKO Health data	**By clicking 'Download my data', you can export a report of your all-time data.** This report can be exported either as - A PDF or - Raw Data (CSV)	
5.4.4 Instructions		This is a shortcut to the First Time Measurement Course. See Section 6.1 for full instructions.	
5.4.5 Learn		This is a shortcut to the Education Module. See Section 7 for full instructions.	
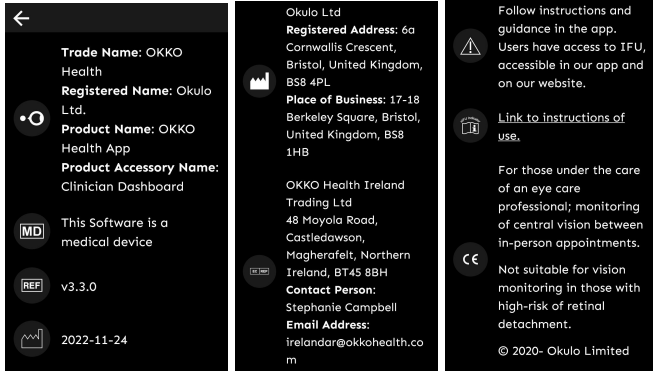
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5.4.6. Settings		**Click 'Settings' to change the following functions:** - Music (On/Off) - Voice Over (On/Off) - Sound Effects (On/Off) - Vibrations (On/Off) - Tutorials (On/Off) - Language	

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5.4.7 About		On the 'About' screen, you can find shortcuts to the following: - Support page on OKKO Health's website (https://okkohealth.com/en-gb/support/) - OKKO Health's Privacy Policy - OKKO Health's Terms & Conditions You will also find detailed company information about OKKO Health, such as company address, app version number, link to Instructions for Use (this document), etc.	
5.4.8 Support		This is a shortcut to the Support Page. See Section 5.3.2 for full instructions.	
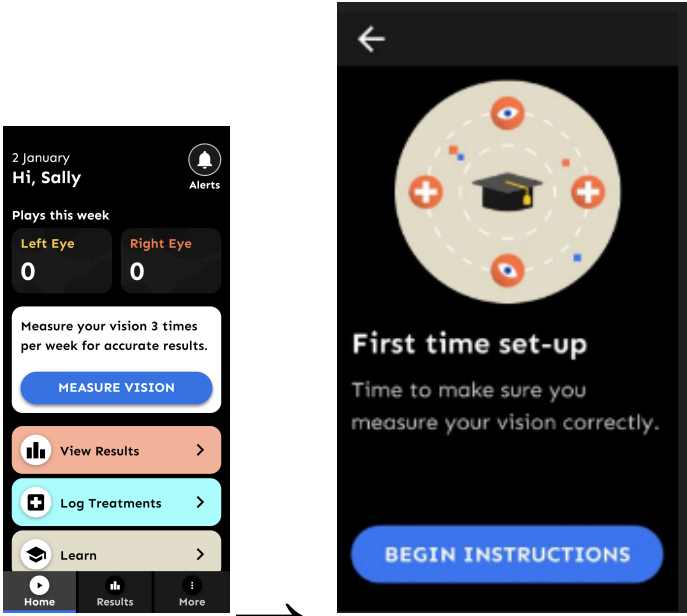
6. OKKO Health Measurement

6.1 First time setup for measurement (face-recognition)
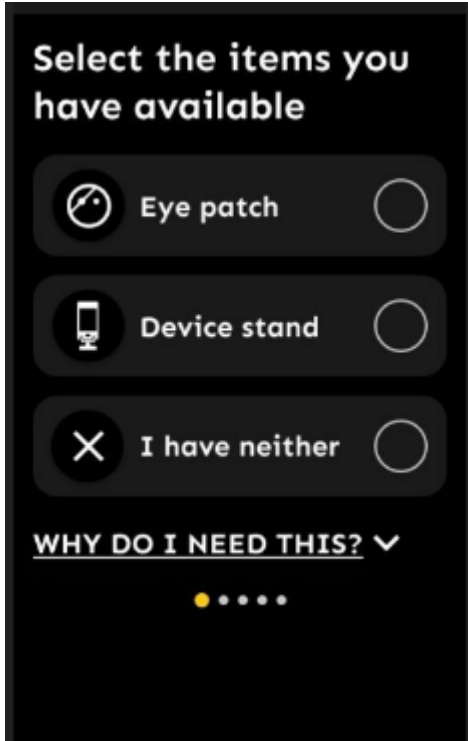
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1.	Tap 'MEASURE VISION' to start 'First time set-up' Course	**These instructions are only relevant if your device has got face-recognition.** It is important that you are properly set-up when completing a measurement in the OKKO Health app to ensure comfort and accurate results. You need to successfully complete the in-app instructions ('First time Set-up' Course) in full before being able to do your first measurement in the OKKO Health app. You can always rewatch the 'First time Set-up' course in the app by tapping 'Instructions' in the menu or following the instructions in this document.	

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2	Select the items you have available	By letting us know the details of your situation, we will be able to give you suitable instructions. It is recommended to use an eye patch and/or device stand during measurement to ensure comfort and more accurate results. A device stand, or something to prop your phone up is required if you don't have an eye patch, as it will be difficult to cover an eye with one hand and hold the device and engage with the game mode with the other hand.	
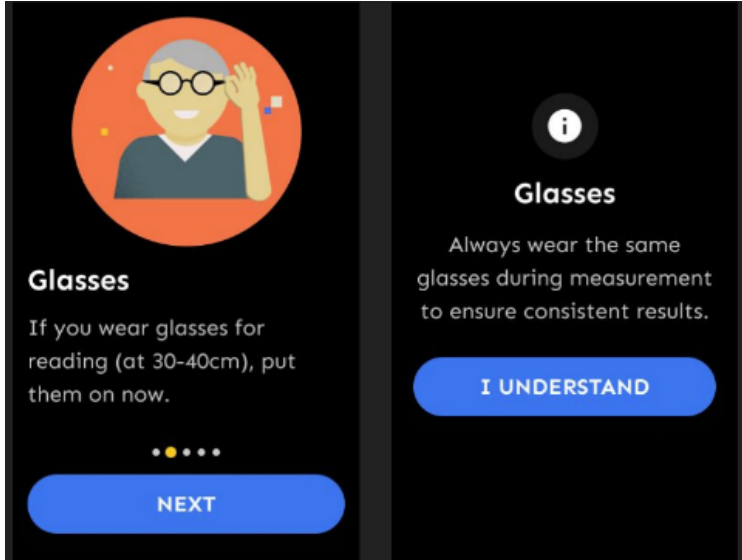
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3	Eye patch/no eyePatch	If you only selected **device stand**, an alert will appear which recommends you to purchase or make your own eye patch before continuing. If you selected **I have neither**, you will also be recommended to grab a stack of books as a substitute for a device stand. If you selected **eye patch** or **eye patch and device stand,** you will go straight to the next step (Glasses screen). →	

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4	Glasses	If you wear reading glasses, put them on now. Always wear the same glasses during your OKKO Health measurements.	

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5a	Camera Access	The front-facing camera helps us measure how far away you are from the screen during measurement, like a ruler. This is important to calculate accurate results. We never take photos or collect images of your face. Tap **'TRY THE CAMERA'**, and then **'OK'** to allow camera access.	
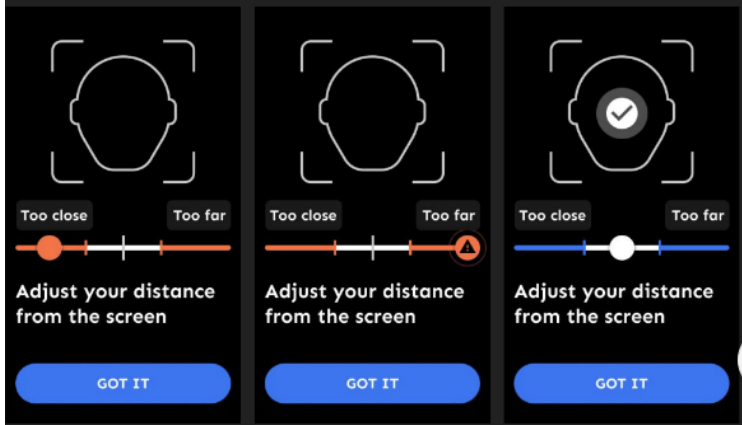
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| 5b | Denied Camera Access | Should you tap **'Don't Allow'** when asked for camera access, you will be presented with the following screen.

Denied camera access means that we cannot measure your distance from the screen, which will affect your vision results. You can allow camera access in device settings: click **'HOW TO ALLOW CAMERA ACCESS IN MY SETTINGS'**. This will take you to an article on your internet browser which provides instructions on how to allow camera access on your device.
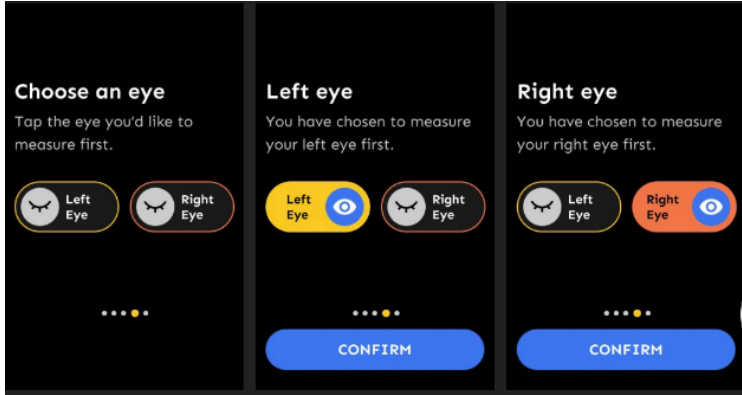
If you tap **'CONTINUE ANYWAY'**, you will be pushed to a different instruction flow: *6.2. First time Set-up for measurement (no face-recognition)*. | |

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6	Distance Tracking Tool	Once you have allowed Camera Access, you will be asked to adjust your distance from the screen, using the distance tracking tool as reference. The orange dot will move along the slider as you move closer/further away from the screen. Once the dot has reached the middle of the slider, you can tap **'GOT IT'** to continue.	

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7	Choose an eye	You complete each measurement in the OKKO Health app using one eye at a time. Select the eye you'd like to start with and tap **'CONFIRM'** when you are ready to continue.	
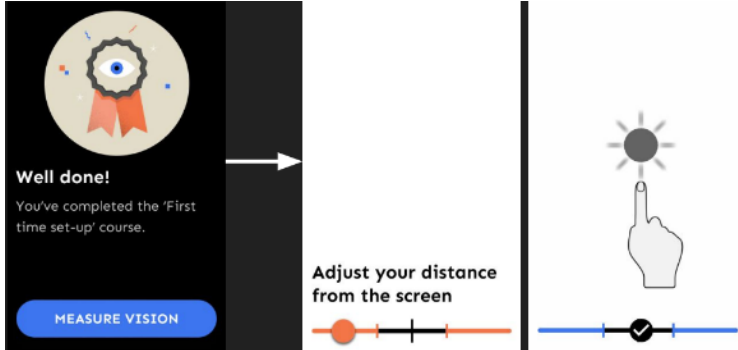
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8	Cover other eye	Once you have selected an eye, you will be asked to cover the other eye. If you selected to measure the left eye, you will be asked to cover the right eye, and vice versa. The instructions are dependent on your previous selections (in Step 2): If you selected eye patch/eye patch and device stand in step 2, then you will first be asked to cover your other eye (the one you are not measuring) with the eye patch. If you selected 'I have neither' in step 2, you will be asked to prop up your device and cover the eye you're not measuring with your hand. Tap 'DONE!' when you're ready.	

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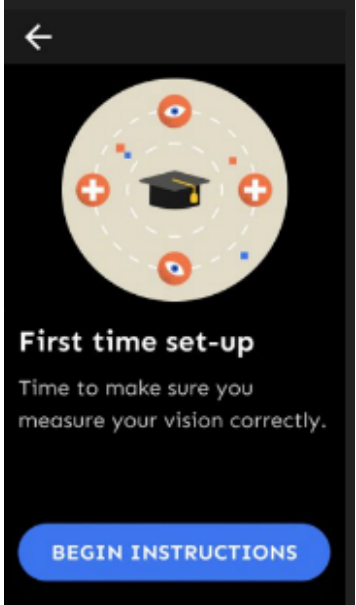| Document Title	Document Description	Revision No.
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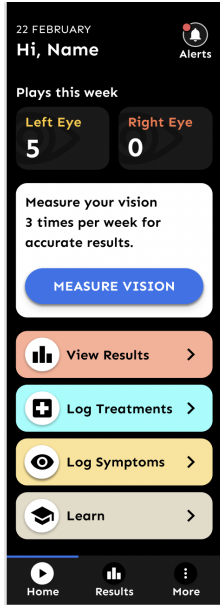
9	Course Completed!	You have now completed your *'First time set-up course'* and are ready to complete the first measurement. Tap 'MEASURE VISION'. You will quickly be reminded to adjust your distance from the screen to ensure accurate results. Once you are at a correct distance, the measurement will start.	

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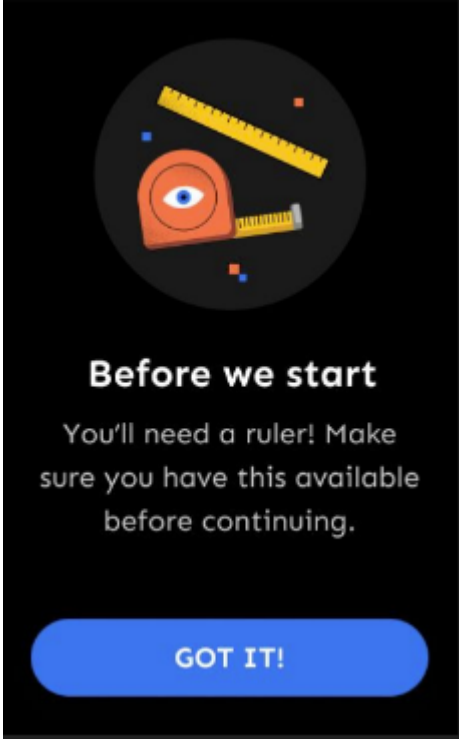
6.2 First time setup for measurement (no face-recognition)

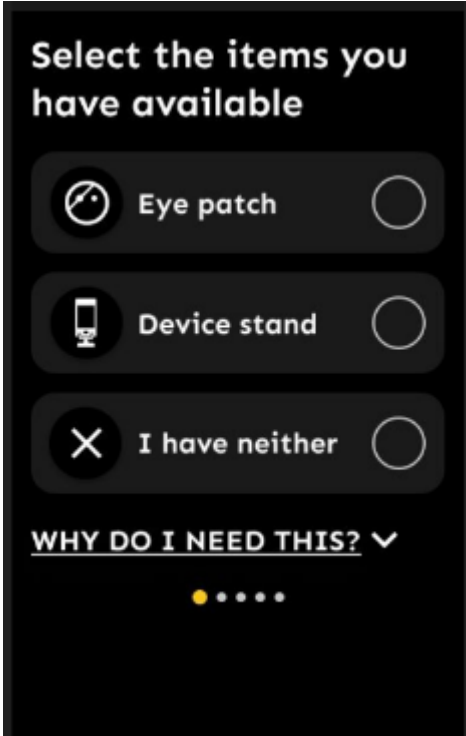|			
1.	Tap 'MEASURE VISION' to start 'First time setup' Course	**These instructions are only relevant if your device does not have face-recognition, or if you have denied camera access.** It is important that you are properly set-up when completing a measurement in the OKKO Health app to ensure comfort and accurate results. You need to successfully complete the in-app instructions ('First time Setup' Course) in full before doing your first measurement in the OKKO Health app. You can always rewatch the 'First time Set-up' course in the app, by tapping 'Instructions' on the menu or following the instructions in this document.	

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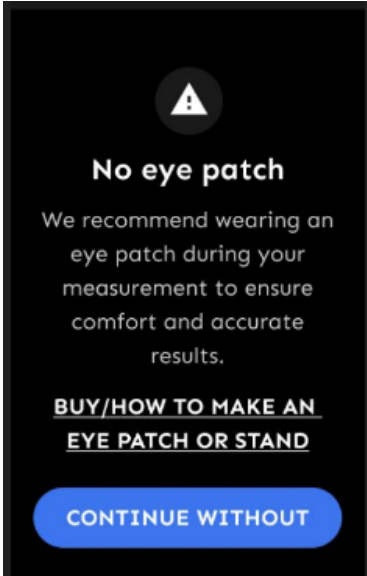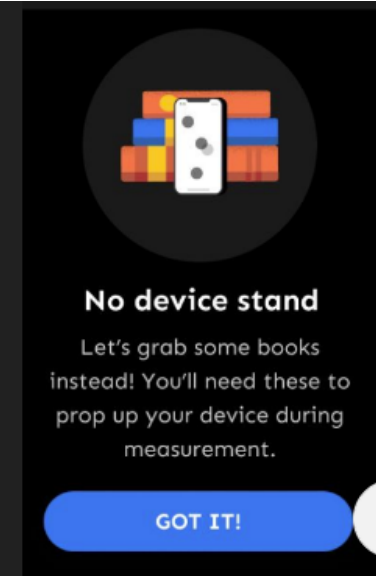| 2.	Ruler	To ensure accurate results during measurement, you need to be at a specific distance from the screen. Make sure you have a ruler available before starting the measurement to help you in gauging the correct distance.	

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3.	Select the items you have available	By letting us know the details of your situation, we will be able to give you suitable instructions. It is recommended to use an eye patch and/or device stand during measurement to ensure comfort and more accurate results. A device stand, or a stack of books, is required if you don't have an eye patch, as it will be difficult to cover an eye with one hand and hold the device and engage with the game mode with the other hand.	
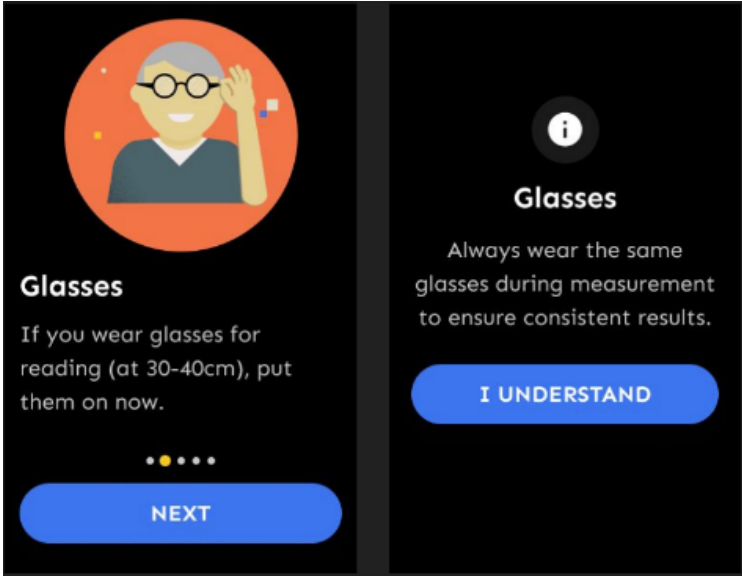
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4.	Eye patch/no eye patch	If you only selected **device stand**, an alert will appear which recommends you to purchase/make your own eye patch before continuing. If you selected **I have neither**, you will also be recommended to grab a stack of books as a substitute for a device stand. If you selected **eye patch** or **eye patch and device stand,** you will go straight to the next step (Glasses screen). →	

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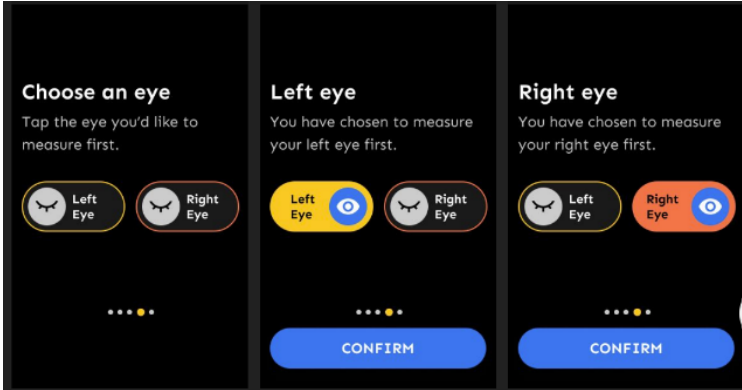
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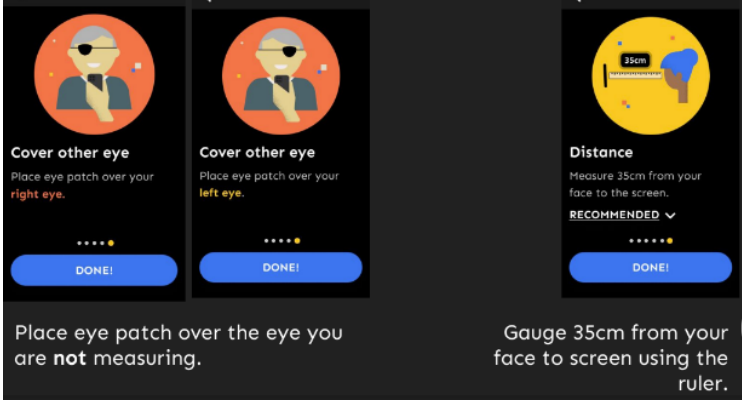| 5.	Glasses	If you wear reading glasses (at 30-40 cm), put them on now. Always wear the same glasses during your OKKO Health measurements.	

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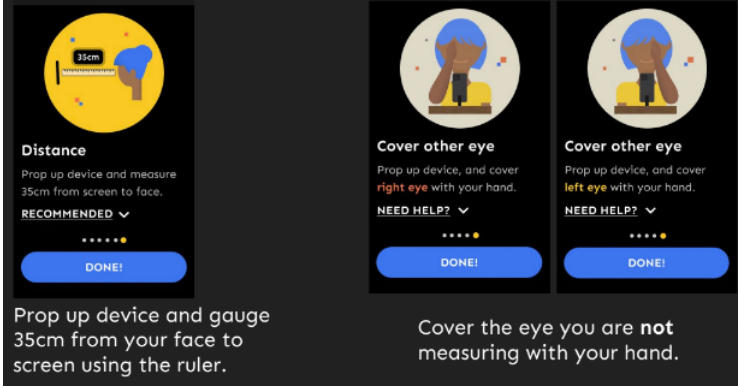| 6.	Choose an eye	You complete each measurement in the OKKO Health app using one eye at a time. Select the eye you'd like to start with, and tap **'CONFIRM'** when you are ready to continue.	

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| 7a. | Cover other eye and measure distance - Eye Patch/Eye patch and Device Stand | If you selected eye patch/eye patch and device stand in step 3, then you will first be asked to cover your other eye (the one you are not measuring) with the eye patch. Tap 'DONE!' when you're ready.

You will then be asked to gauge 35 cm (roughly) from your face to the screen using the ruler. Tap '**DONE!**' when you are ready. | |
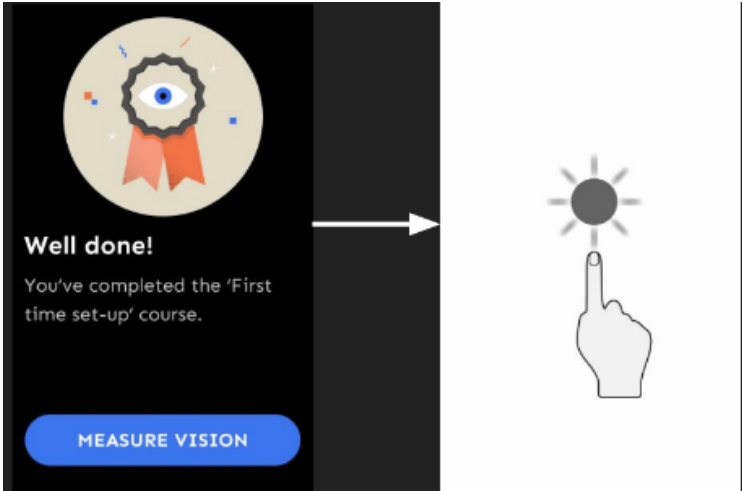
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| 7b. | Cover other eye and measure distance - **No Eye Patch** | If you only selected **'device stand'/'I have neither'** in step 3, then you will first be asked to prop up your device and gauge 35 cm (roughly) from your face to the screen, using the ruler. Tap **'DONE!'** when you're ready.

You will then be asked to cover your other eye (the one you are not measuring) with your hand. Tap **'DONE!'** when you are ready. | |

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8.	Course Completed!	You have now completed your 'First time set-up course' and are ready to complete first measurement. Tap '**MEASURE VISION**'. Remember to try and keep the 30-40cm distance during your measurement.	

6.3 Result Screen

The Result Screen in the OKKO Health app displays your weekly average scores in each game mode (visual function test), for each eye. Your scores are displayed in graphs so that you can quickly and intuitively make an evaluation of your progress in the last 4 weeks but you can also learn more in-depth about each score point should you wish (more details about this in section 6.3.2 How to Interpret Result).

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Please note: The scores on the Results Screen are an indication of your performance in the game modes in the OKKO Health app, and should not be used as a way to diagnose new or existing issues in your vision. If you are worried about your eye health, contact your eye care professional directly.

6.3.1 Explanation of Result classifications

The OKKO Health App collects information from within the app about how the patient interacts with the visual function tests (for example, whether they have tapped on certain shapes on the screen to indicate that they saw them). This information is sent to a server (the "OKKO Health Platform") where scores are calculated using scientifically recognised and experimentally validated algorithms. One score is calculated per visual function test. This means that the scores are:
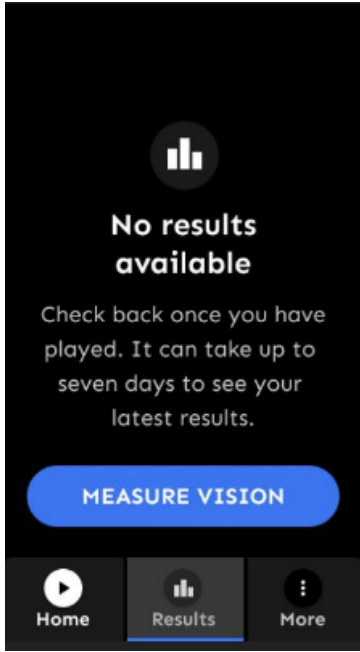
- Visual acuity, scored in logMAR

Visual acuity, scored in logMAR, is measured clinically using a logMAR chart in adults.

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6.3.2 How to Interpret Results

1.	Results Screen - No Results Available	In the Results Screen, you are able to view your weekly averaged results in the OKKO Health app. This is where you will be able to monitor your vision over time. The first few times you enter the app, there will be no results available. Once you have completed your first measurement, it can take up to 7 days to view your latest results. The Results Screen is usually updated every Monday.	
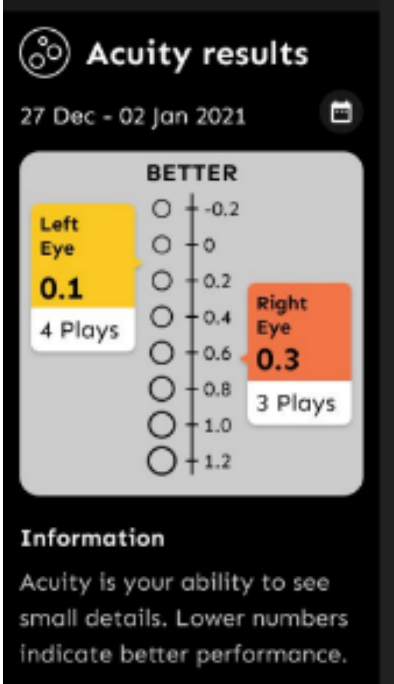
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2.	First set of Results	After a few days of having completed one or more measurements in the app, you will be able to see your first set of weekly averaged results. When you go to the Results Screen, you will first be prompted to read a disclaimer, which explains that the results you are about to see are an indication of your eye health, meaning that you should **always contact your eye care professional if you are worried about your vision.** Your latest set of weekly averaged results is now on the graph. Tap the dot for detailed results and more information.	

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3.	Weekly Detailed Results	Once you have tapped on a dot, you will see the detailed results for that particular week and for that particular game mode. Here you will see your weekly average scores for the eye(s) you're measuring and how many plays you have completed. Each game mode is measured differently - Acuity is measured in LogMAR	

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| 4. | Results Over Time | When you have played for a while, a graph will start taking shape. A graph pointing upwards means that your results are improving, a graph pointing downwards means that your results are declining. Should you have a drastic and/or continuous change/drop in data, please contact your eye care professional. Data varies naturally, so minor changes shouldn't be a cause for concern. If you are confused or worried about your results, then tap the link below the graph **'WORRIED ABOUT YOUR VISION/RESULTS?'** which will take you to an article explaining what is normal, and when you should contact your doctor.

You can choose to view the left eye or right eye on its own, or both eyes at the same time. | |

OKKO HEALTH

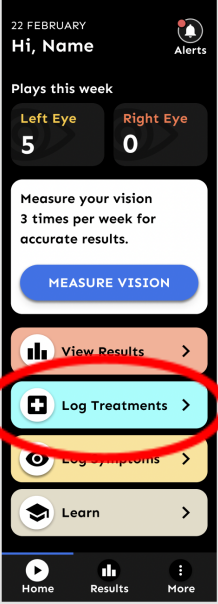| Instructions for Use		
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5.	Incomplete Week(s)	If you enter the Results screen and have played less than 3 times at least one week in the last 4 weeks, you will be prompted with a pop-up alert explaining that you have one or more *Incomplete weeks*. When you then tap a dot to see detailed results, you will again be prompted if you have insufficient plays on at least one eye that week. Eyes with less than 3 plays will be presented with an outlined scoring box, rather than a filled in one. This is to make sure that you are aware that the score/results for that eye might not be fully accurate due to insufficient plays.	

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6.4 Treatments

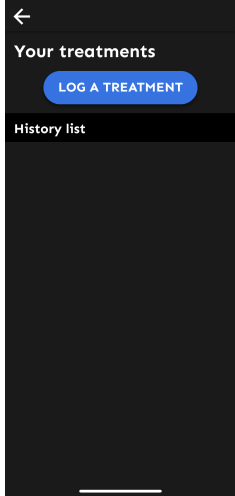|			
1.	Where to log treatments	The Treatment Diary is there for you to keep track of recent injections, operations and change of prescription glasses. All these events may affect your results in the OKKO Health app, and to tag them is therefore important for the interpretation of your results. Open the OKKO Health app and tap 'Log Treatments' on the Home Screen to go to the Treatment Diary.	
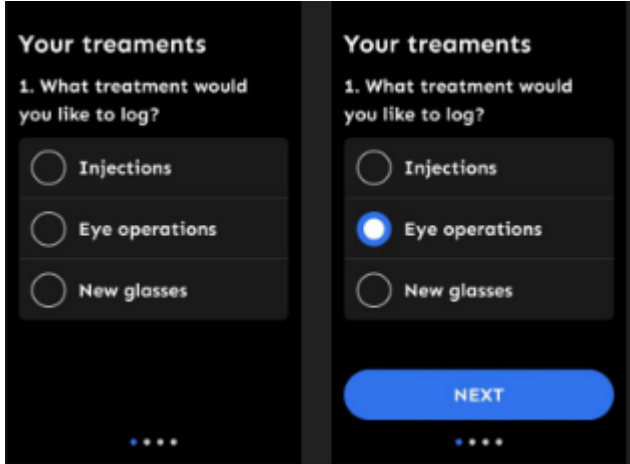
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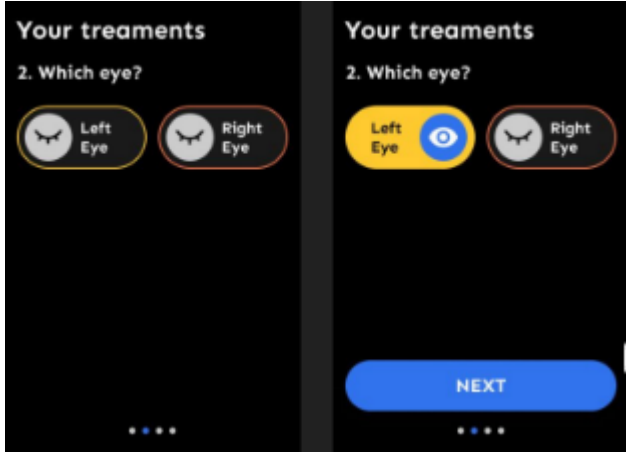| 2.	Logging a treatment	If you've never logged a treatment before, you will be presented with the following screen (History List will be empty). Tap 'LOG A TREATMENT' to get started. Make sure you have the type of treatment, which eye it is regarding and date of treatment ready.	

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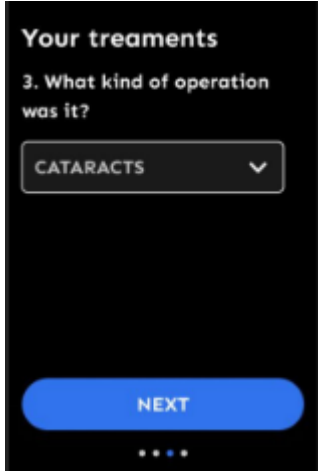|			
3.	Logging a treatment - *Treatment*	First, select the type of treatment it's regarding - injections, eye operation or new prescription glasses? For example, let's assume you have had an eye operation. Once selected, tap 'NEXT' to continue.	

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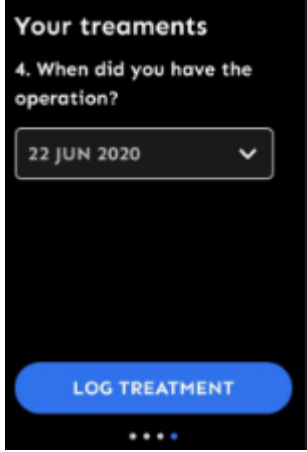| 4.	Logging a treatment - *Left, right or both eyes?*	Now, select which eye the treatment was done to. If both eyes are involved, then select both left eye and right eye. For example, let's assume it's regarding your left eye. Once selected, tap 'NEXT' to continue.	

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5.	Logging a treatment - *Additional Details*	If you selected 'Eye Operations' in step 3, you will now be asked to give additional details about what type of operation. If you selected **injection or new glasses**, you will go straight to step 6 after step 4. The dropdown menu includes a list of various common eye operations. If your operation is not on the list, then please select 'other'. For example, let's assume that you have had a cataracts operation. Once selected, tap 'NEXT' to continue.	**Your treaments** 3. What kind of operation was it? CATARACTS ⌄ NEXT • • • •

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5.	Logging a treatment - *Date of treatment*	Tap the drop-down menu to select the date of your treatment. For example, let's assume it was on the 22nd June 2020. Once selected, tap 'LOG TREATMENT' to save and add the treatment to your history list.	

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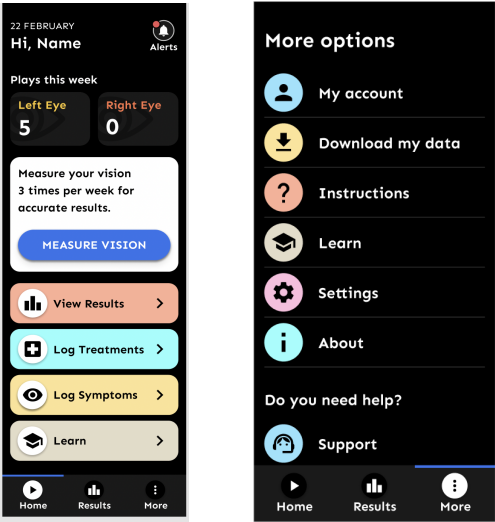| Document Title	Document Description	Revision No.
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	Logging a treatment - *Date of treatment*	You have now successfully logged your first treatment in the treatment diary. You will be able to see all logged treatments in your History List. The more treatments you log, the longer the list will be. You can also change details about a logged treatment, or remove it completely, by tapping the 'Edit' button next to the treatment you'd like to adjust.	

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7. Education Module

1.	Where to find the Learn section	The Learn section (OKKO Health's Educational Module) in the OKKO Health app can be found a) via the Home screen, or b) via the 'More' screen. If you have allowed notifications from the OKKO Health app on your device, you will also be sent alerts about specific articles that we think may interest you. These notifications will take you directly to the relevant article.	

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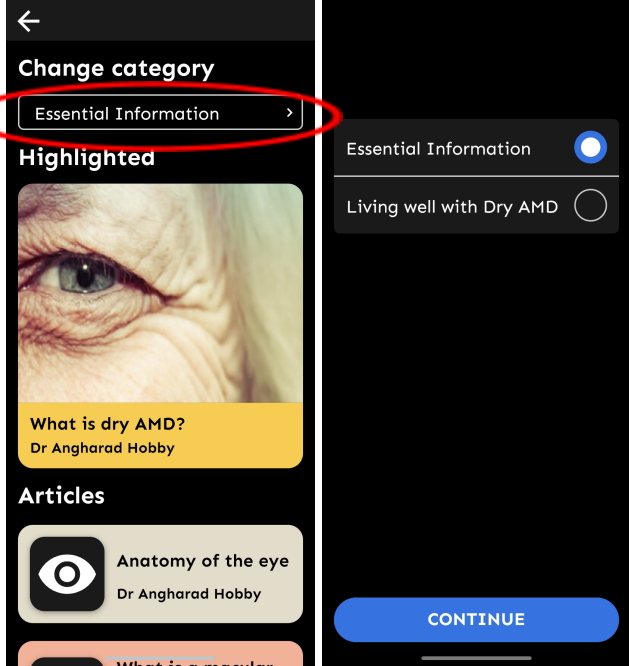| 2. | Learn section
Navigating through categories | Once in the Learn Section, you will be presented with a few article categories to choose from. In the example to the right, the user has selected the category 'OKKO Health', in which there are articles about OKKO Health, the OKKO Health app, home-monitoring and how it can help you.

You can also change category whilst you are in one, by tapping the dropdown menu at the top of the screen (underneath 'Change category'). | |

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| 3. | Learn section
Navigating through categories/subcategories | Some categories have subcategories, for example, the category **'Eye conditions'** has got a few subcategories for different eye conditions. In the example to the right, the user has selected **'Eye conditions'**, and then the subcategory **'Late Dry AMD'**. Here there are more categories to choose from Once the user has decided which category they are interested in, they can read the articles in that category. | |

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4.	Learn section *Navigating through categories/subcategories*	Whilst in a category/subcategory, you can tap the dropdown menu to change to another category/subcategory, for quick navigation.	

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8. Renewal and Disposal
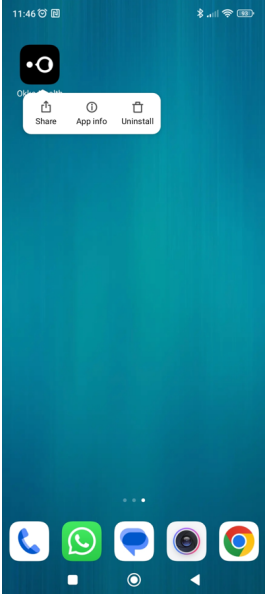
8.3 Delete OKKO Health account

Unfortunately at this stage, there isn't a function in the OKKO Health app which allows you to delete your account. If you would like to delete your account, please get in touch with your eye care professional to make sure this is the correct course of action. Once confirmed, contact us and we will make sure to help you in this matter.

support@okkohealth.com

If you have chosen to delete your OKKO Health account, we are so sorry to see you leaving! If you have any issues or concerns with OKKO Health, please don't hesitate to get in touch. We are here to help:
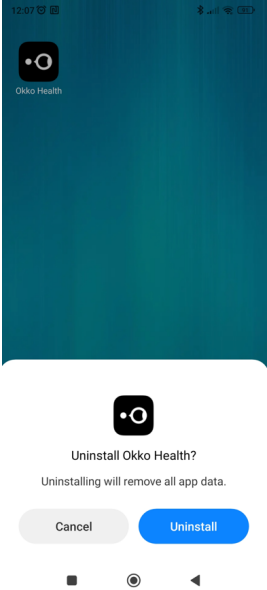
https://okkohealth.com/support

8.4 Delete OKKO Health App - Android

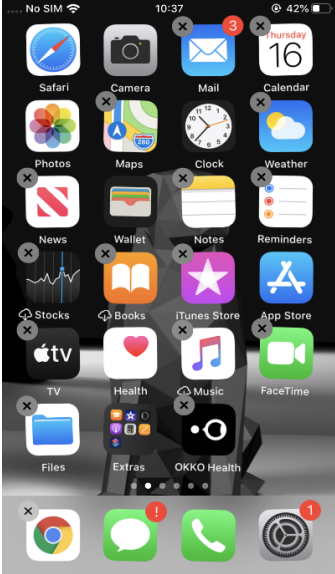| 1.	Find the OKKO Health App on the home screen of your device. Once you have found it, hold your finger down lightly on it for approximately five seconds. A speech bubble will open with the options for 'Share', 'App info' and 'Uninstall' . (Please see example to the right)	

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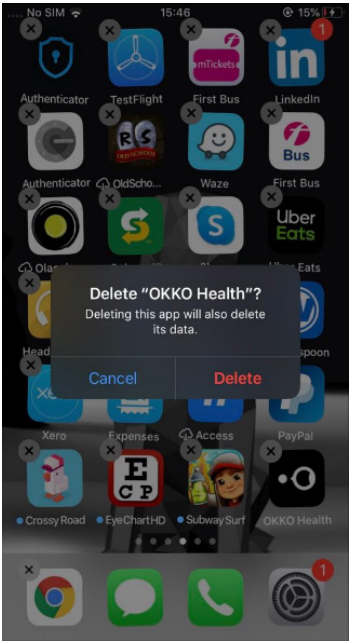| 2.	Tap 'Uninstall' in the speech bubble. A pop up window will appear and ask you if you are sure that you want to uninstall the app. Now tap the blue "Uninstall" button, and the application will be removed from your device.	

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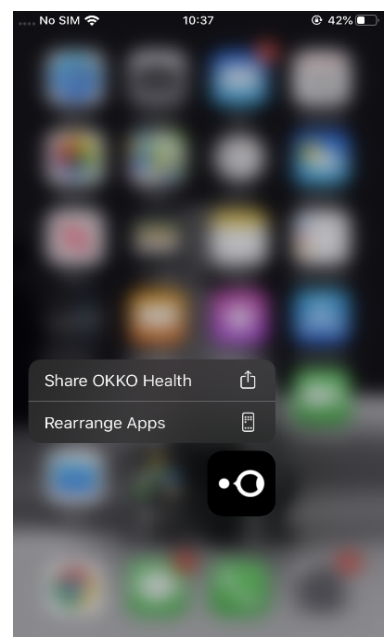### 8.5 Delete OKKO Health App - ios

1.	Find the OKKO Health App on the home screen of your device. Once you have found it, hold your finger down lightly on it for approximately five seconds. Eventually, all of your applications will wiggle on the spot as well as showing a small 'X' symbol in the top left corner. (Please see example to the right)	

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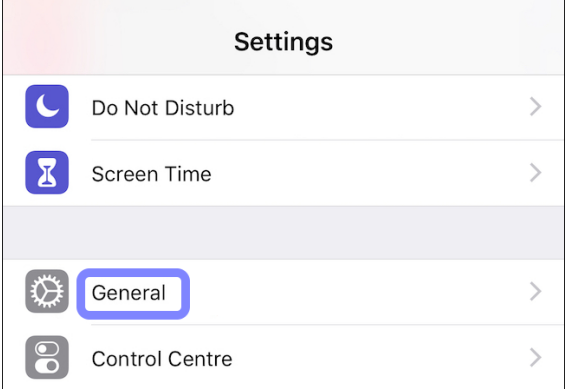| Document Title	Document Description	Revision No.
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2.	Tap the 'X' symbol on the OKKO Health App. A pop up window will appear and ask you if you are sure that you want to delete the app. Now tap "Delete", and the application will be removed from your device.	

If you have followed the steps above, and a different popup appears unexpectedly (see image to the right), follow these steps instead:
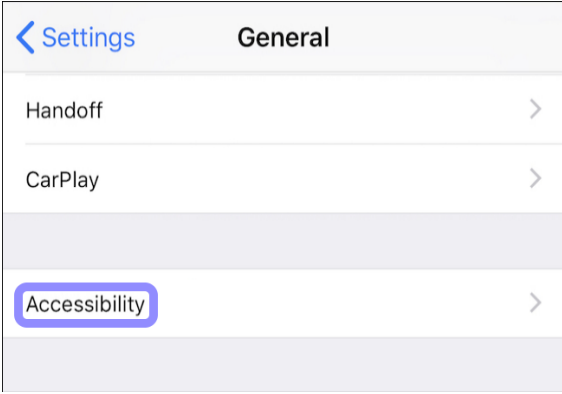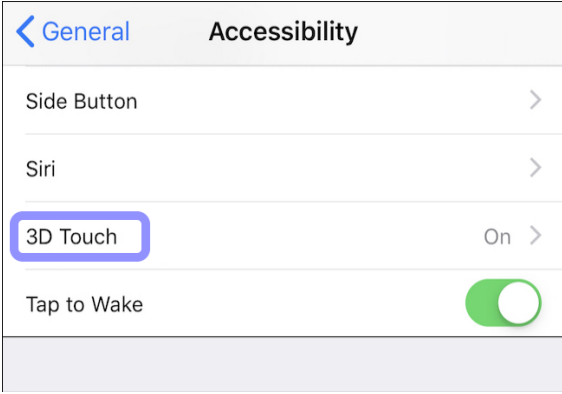
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1.	Find your settings application on your mobile device home screen and tap to open it. (Circled in blue)	
2.	Select the "General" option. (Circled in blue)	
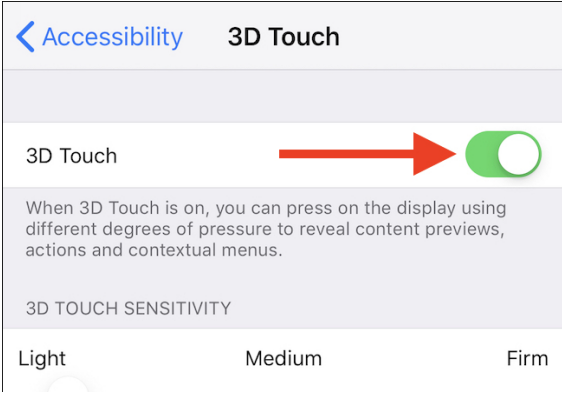
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3.	Select the "Accessibility" option. (Circled in blue)	
4.	Select the "3D Touch" option. (Circled in blue)	

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5.	Finally, toggle off the 3D Touch by tapping the green slider. The slider should be *grey*. Now that you have turned off the "3D Touch" feature, retry the first steps demonstrated in the sections above.	**❮ Accessibility 3D Touch** 3D Touch When 3D Touch is on, you can press on the display using different degrees of pressure to reveal content previews, actions and contextual menus. 3D TOUCH SENSITIVITY Light Medium Firm

9. Hygienic Maintenance

The OKKO Health App is a software downloaded onto a mobile device (smartphone/tablet) and does not interact with the body in any way. As a result, there are no special cleaning measures required for OKKO Health. However, general hygiene should be maintained during use of the mobile device. Importantly, measurements should not be performed when the camera lens or screen is unclean, or the device is damaged in any way.

10. Cybersecurity

OKKO Health uses industry-standard encryption protocols to secure data in transit and at rest. We have strong physical security measures (we are ISO 27001 certified) and digital security measures (we have CyberEssentials Plus certification), which are reviewed at independent security reviews. We take regular automatic backups of data.

OKKO Health does its utmost to guarantee your data safety. For you as an OKKO Health user, it is very important to keep in mind the following recommendations:

- Never share your OKKO Health credentials;
- Use a secured Internet connection;
- Only use compatible devices;
- Do not use rooted or jailbroken devices;
- Do not use simulators/ emulators.

At any point, you can request your data to be deleted by emailing dpo@okkohealth.com, please refer to OKKO Health's Privacy Policy for full details
https://okkohealth.com/en-gb/privacy/
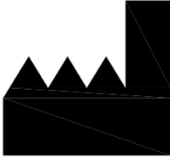
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11. Applicable Symbols

11.1 Software Label - EU MDR

OKKO HEALTH

MD

REF

Trade Name: OKKO Health

Registered Name: Okulo Ltd.

Product Name: OKKO Health App

Product Accessory Name: Clinician Dashboard

This Software is a medical device

Software Release Number: DCADULT_1.0.0

Software Release Date: 2023-01-13

Okulo Ltd

Registered Address: 6a Cornwallis Crescent, Bristol, United Kingdom, BS8 4PL

Place of Business: 17-18 Berkeley Square, Bristol, United Kingdom, BS8 1HB

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EC | REP

OKKO Health Ireland Trading Ltd

48 Moyola Road, Castledawson, Magherafelt, Northern Ireland, BT45 8BH

Contact Person: Stephanie Campbell

Email Address: irelandar@okkohealth.com

Follow instructions and guidance in the app.

Users have access to IFU, accessible in our app and on our website.

https://okkohealth.com/en-gb/instructions-for-use-patients/

https://okkohealth.com/en-gb/instructions-for-use-clinicians/

https://okkohealth.de/de/anweisungen-laien/

https://okkohealth.de/de/anweisungen-klinik/

UDI

Basic UDI-DI: 5065012821OKKO0014Q

OKKO Health App - ios UDI: 5065012821000

OKKO Health App - android UDI: 5065012821017

OKKO Health Clinician Dashboard UDI: 5065012821024

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$$CE$$ 2797

BSI Notified Body Number: 2797

12. Contact Details

For more information or questions, please contact us at support@okkohealth.com.

Any incidents (including Data Protection breaches) that have occurred in relation to the device shall be reported to:

(1) the legal manufacturer via support@okkohealth.com

(2) the local Competent Authority

12.1 Manufacturer

OKULO LIMITED (trading as OKKO HEALTH)

Company number: 11251527

Registered Address: 6a Cornwallis Crescent, Bristol, United Kingdom, BS8 4PL

12.2 EU Rep

OKKO HEALTH IRELAND TRADING LTD

Company number NI679335

Registered Address - 48 Moyola Road, Castledawson, Magherafelt, Northern Ireland, BT45 8BH

REVISION HISTORY

Version number	Author	Details of update
0	Sally von Hofsten	New Document
1		

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2		
3		