doccla

Remote Patient Monitoring

# Patient/Carer App - User Manual

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# Doccla RPM Patient App - User Manual

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# Introduction

This user manual has been written for patients who must use the Doccla RPM app. The user manual has been written in a way to be thorough and understandable for patients. No prior teaching or workshop participation is necessary to understand it.

## Your health

⚠ Always be mindful of your own well being and health. If you experience any new symptoms or unexpected deterioration of existing symptoms you should seek medical attention outside the use of this app.

## Intended use

Doccla Remote Patient Monitoring (RPM) is a medical device software composed of a clinician portal and mobile applications (for patients and caregivers) that supports healthcare professionals in their remote monitoring and management of non-critical patients.

For the purpose of this document, non-critical patients are defined as adult (18 years and older) and paediatric patients (1 month to 17 years) with clinically stable chronic or post-operative conditions that do not present a risk of rapid or serious deterioration, and for whom remote monitoring is considered clinically appropriate and safe by the responsible healthcare professional.

Doccla RPM has a medical purpose to support the monitoring and management of disease, injury, or disability by enabling healthcare professionals to remotely collect, review, and assess physiological and non-physiological health data for clinical decision support.

Doccla RPM is intended to be used by patients (with caregiver assistance when required) via the mobile application to enter or transmit data, while healthcare professionals use the clinician portal to:

- Configure monitoring parameters and alert thresholds;
- Review submitted physiological and non-physiological data;
- Receive alerts when parameters deviate from thresholds set by healthcare professional-defined inputs

Doccla RPM supports clinical decision-making by providing timely information on patient status but does not perform diagnosis, prognosis, or therapeutic decision-making.

The system is intended for use with patients in non-clinical environments (e.g., patient homes, community clinics, rehabilitation centres) and low-acuity clinical environments (e.g., nursing homes, step-down facilities, outpatient follow-up units) under the supervision of qualified healthcare professionals.

## Medical indications

Doccla RPM is indicated to support the remote monitoring of **physiological and non-physiological parameters across the following categories,** either through compatible third party medical devices, manual entry or **questionnaires**. Each category includes examples (in brackets) without restricting the scope of use.

**Categories of Physiological parameters**

- **Cardiovascular parameters** *(e.g., blood pressure, heart rate, pulse waveform)*
- **Electrophysiological parameters (spot readings)** *(e.g., single-lead ECG, rhythm strips)*
- **Respiratory parameters** *(e.g., oxygen saturation ($SpO_2$), respiratory rate)*
- **Metabolic and biochemical parameters** *(e.g., glucose, ketones—where supported by compatible third party medical devices)*
- **Thermoregulatory parameters** *(e.g., body temperature)*
- **Anthropometric parameters** *(e.g., weight, BMI-related inputs)*
- **Neurological parameters** *(e.g., cognitive screening scores, neuropathic symptom questionnaires)*
- ***Musculoskeletal parameters*** *(e.g. mobility, frailty, pain evaluation)*

**Categories of Non-Physiological parameters**

- **Patient-reported outcomes** *(e.g., symptom scores, pain scales, functional assessments)*
- **Questionnaire-based metrics** *(e.g., condition-specific surveys, general health questionnaires, daily check-ins)*
- **Behavioural or contextual data** *(e.g., activity indicators, self-reported medication adherence, wellbeing checklists)*

## Main functionalities

- **Data Collection and Integration:** Acquisition of physiological and non-physiological data through compatible third party medical medical devices, manual entry, or connected systems.
- **Alert Configuration and Generation:** Allows healthcare professionals to configure thresholds and/or validated algorithms that generate alerts when patient data deviate from predefined criteria. Alerts are based solely on clinician-defined inputs and do not interpret, diagnose, or recommend treatment.
- **Data Visualisation and Trend Analysis:** Presentation of historical and current patient data to support clinical interpretation and prioritisation.

Doccla RPM supports **intermittent monitoring** only and is **not intended for real-time monitoring**.

## Benefit claims

Doccla RPM is intended to enable the early recognition of physiological changes in non-critical patients, thereby supporting timely clinical assessment, continuity of care outside hospital settings, and efficient use of healthcare resources. In short, the benefit claims for Doccla RPM are as follows:

- Doccla RPM can improve patient outcomes.
- Doccla RPM can reduce unnecessary healthcare utilisation.

These benefit claims are supported by **clinical evaluation data**, which demonstrate that Doccla RPM performs safely and effectively within its intended scope of use.

## Patient population

As defined in the Intended Use section, Doccla RPM is intended for use with **non-critical adults (18 years and older) and paediatric patients (1 month to 17 years)** who are **clinically stable** and able to participate in remote monitoring, independently or with caregiver support.

The target population includes individuals with **chronic or post-operative conditions** where remote data submission and periodic review are deemed clinically appropriate and safe by the healthcare professional.

## Intended users

Doccla RPM is intended to be used by:

- **Healthcare professionals:** For configuring monitoring parameters, reviewing patient data, and responding to alerts through the clinician portal.
- **Patients and caregivers:** For entering or transmitting data via the patient or carer mobile application.

All users must receive **appropriate training** in the safe operation of the software and any connected medical devices.

## Contra-indications

Doccla RPM must not be used for patients outside the defined non-critical population (see Section 1). The system is contraindicated for patients who are clinically unstable, at risk of rapid deterioration, or who require real-time physiological monitoring.

These contraindications apply where a patient is clinically unstable or requires real-time monitoring. A patient with a chronic or post-operative condition who develops a temporary intercurrent illness remains eligible for use, provided the responsible healthcare professional determines the patient to be clinically stable and suitable for remote monitoring.

**Unstable physiological parameters**

Patients with instability in any monitored physiological domain, including:

- **Cardiovascular instability** *(e.g., severe/symptomatic BP fluctuations, hypertensive crisis, decompensated heart failure, unstable arrhythmias)*
- **Electrophysiological instability** *(e.g., acute rhythm disturbances requiring real-time ECG/telemetry)*
- **Respiratory instability** *(e.g., acute respiratory distress)*
- **Metabolic or biochemical instability** *(e.g., recurrent severe hypoglycaemia, significant DKA risk, metabolic derangements requiring inpatient titration)*
- **Thermoregulatory instability** *(e.g., active sepsis, high-grade fever needing continuous observation)*
- **Anthropometric instability** *(e.g., rapid unexplained weight change, severe dehydration requiring close inpatient*

*monitoring)*
- ***Neurological instability*** *(e.g., real-time neurological monitoring or emergency neurological intervention)*
- ***Musculoskeletal instability*** *(e.g., acute musculoskeletal emergencies or severe functional impairment needing intensive supervision)*

**Need for real-time monitoring**

Doccla RPM must not be used where real-time monitoring is required, including:

- **ICU, HDU, CCU or similar high-acuity settings**
- **Emergency or acute presentations** *(e.g., unstable vital signs)*
- Any environment requiring real-time review of physiological parameters
- Doccla RPM is not intended to support monitoring of neonates (<1 month old) because their monitoring requirements typically necessitate real-time or high-acuity clinical observation

**Functional, cognitive, or environmental unsuitability**

Use is contraindicated where safe remote monitoring cannot be ensured (unless supported by a caregiver), including:

- **Cognitive or communication barriers** *(e.g., inability to understand/apply instructions)*
- **Physical limitations** *(e.g., inability to operate devices or collect measurements independently)*
- **Insufficient caregiver support** *(e.g., paediatric users without responsible adult supervision)*
- **Technical or connectivity limitations** *(e.g., no mobile/internet/landline access or inability to sustain regular data submission)*

**General exclusions**

- Doccla RPM does **not** diagnose, detect serious deterioration, or provide treatment recommendations.
- It must **not** replace emergency services or clinician-led acute assessment.
- Suitability must always be assessed and periodically reviewed by the responsible healthcare professional.

These contraindications have been established based on clinical evaluation and risk management considerations.

# Warning and Precautions

## ⚠ Warning

- The product may only be used by patients/and or the patient's caregivers/next of kin and healthcare personnel.
- Doccla Remote Patient Monitoring (RPM) is not to be used for any purpose outside of the scope of the intended use defined in the Instructions For Use - this includes the specific patient population that the device is indicated for use with. Use of the Doccla RPM outside of the scope of the intended use is subject to the requirements of applicable regulatory legislation regarding misuse, off-label use and obligations of importers, distributors and other persons.
- No modification of the Doccla RPM software is allowed.
- The user must keep login information confidential to others to avoid unauthorized access.
- The user must have received appropriate and adequate training from either a representative from Doccla Denmark or a colleague who has been trained by a Doccla Denmark representative.
- The user must read and fully understand the instructions for use for the medical equipment.
- Doccla RPM does not provide real-time alerts and is not intended to provide automated treatment decisions or diagnosis.
- Doccla RPM must not be used for real-time monitoring of time-critical data and emergency intervention.
- Doccla RPM platform is an information tool and must not be used as a substitute for the clinician's professional judgment when diagnosing and treating patients.
- In the case of Doccla RPM being unavailable or not working as intended, please email support@doccla.com.

## Telemedicine platform Doccla RPM

In Doccla RPM you will be using a mobile device (tablet or phone) along with an optional set of medical measurement devices: The combination of mobile device + measurement device will be referred to as an Doccla RPM kit in this user manual.

## Example kit

The example kit consists of the following (yours may vary):

- A tablet, with the Doccla RPM Patient App installed,
- a blood pressure monitor,
- a thermometer,
- a pulse oximeter.

## Supported measurements

The Doccla RPM app supports manual input of measurements as well as automatic input of measurements using Bluetooth enabled devices. The following set of devices are all supported by Doccla RPM:

### Bluetooth integrated devices

| Device type | Manufacturer | Model name | Device Image |
|---|---|---|---|
| Activity Tracker | Beurer | AS80 | |
| Blood pressure monitor | A&D | UA-651BLE | |
| Blood pressure monitor | A&D | UA-656BLE | |

| | | | |
|---|---|---|---|
| Blood pressure monitor | TeleRPM | BB2284-AE01 | |
| ECG | AliveCor | KardiaMobile6L | |
| Multi-Vital ECG Sensor | Vivalink | VV350 | |
| Multi-Vital Bracelet | Corsano | CardioWatch 287-2B | |
| Oximeter | Masimo | MightySat Rx | |
| Oximeter | Nonin | 3150BLE | |
| Oximeter | Nonin | Onyx 3230 | |
| Oximeter | Kinetik | MD300CI218R | |
| Peak Flow Meter | Vitalograph | asma-1 BT | |
| Thermometer | Kinetik | ET-100EB | |

| | | | |
|---|---|---|---|
| Weight scale | A&D | UC-352BLE | |
| Weight scale | Transtek | Body Scale GBS-2012-B | |

## Software integrated devices

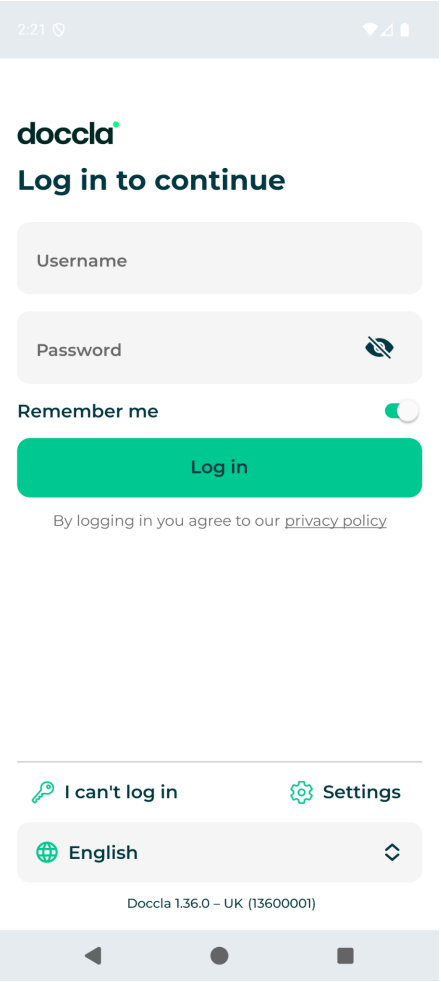
| Measurement type | Manufacturer | Model name |
|---|---|---|
| Smartphone Camera PPG | Happitech | Heart Rhythm SDK |

# App parts

The following section describes different parts of the Doccla Patient App.

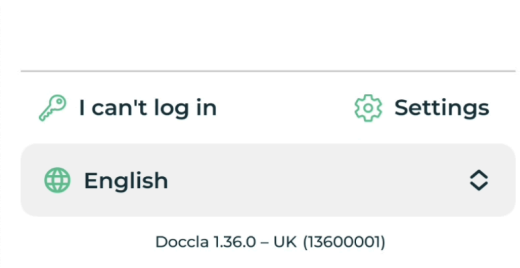
## Log on to app

When you open the Doccla app you will be presented with the login screen, enter your username and password to log in. If you check the “Remember me” checkbox, the app will remember your password and you will not need to enter your username and password again unless you explicitly log out from the app.
If using the “Remember me” function please keep in mind that personally sensitive data is visible through the app and do not share your username and password with anyone.




## Language selection

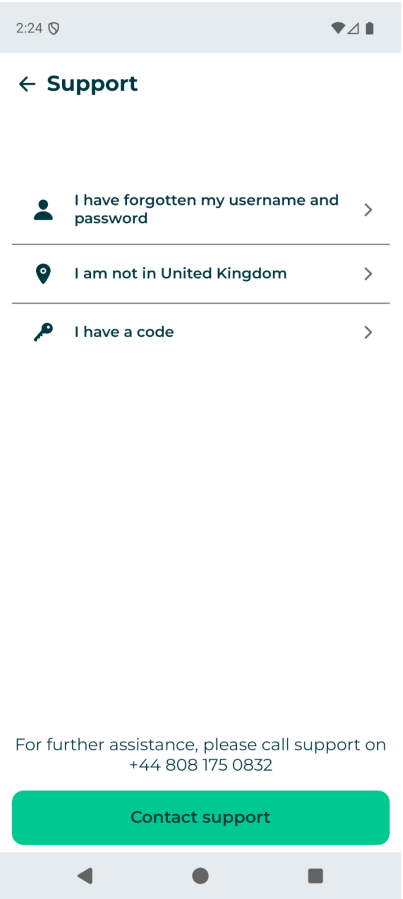
There is a language selector at the bottom of the login screen. To change the language press onto the language indicator that opens a menu of supported languages, press onto a language to select it.



# Login support - “I can’t log in”

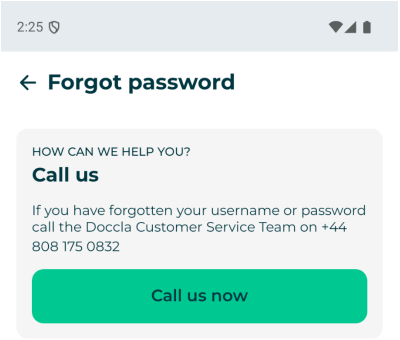
There is an option for users that are struggling to log in to the app below the “Privacy Policy”.

When pressed the user is presented with options.



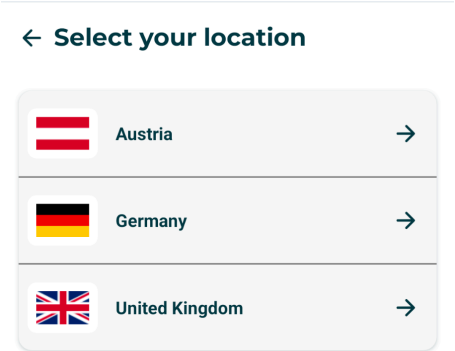

## Forgotten login or password

When “I have forgotten my username and password” is pressed the instructions to call Customer Support are displayed.



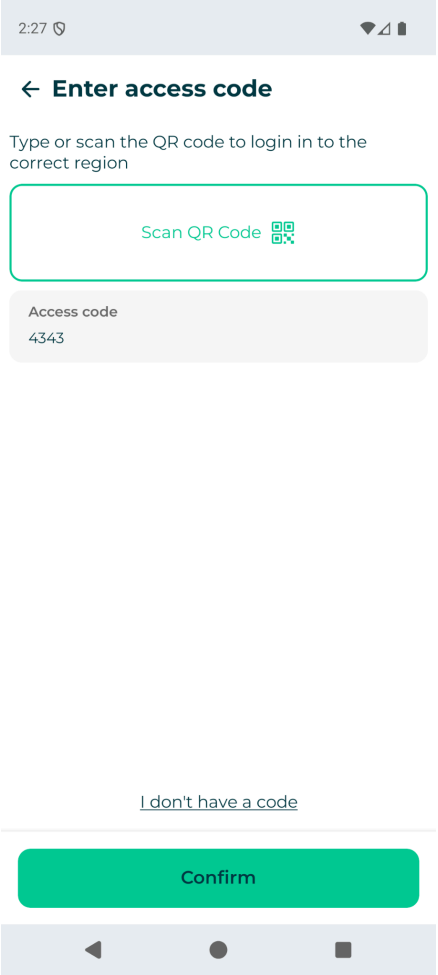

## Selecting your country

When “I am not in [country name]” is pressed the user can select which country they are based in and press “Save Location”. When “Save Location” is pressed the user is returned to the Login Screen.



## I have a code

If you have been given a QR code you can scan this and it will direct you to the login page.



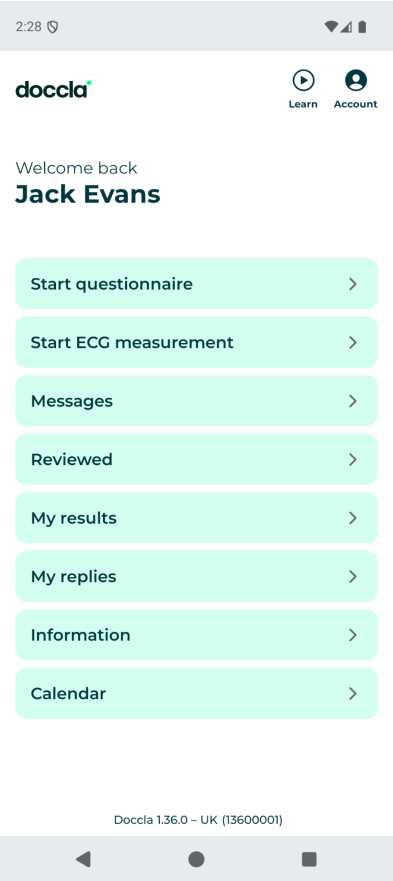
# Home menu

From the home menu you can navigate to one of the following submenus by pressing their corresponding button:

**Start questionnaire:** Press to show all questionnaires that can or need to be completed.
**Start ECG Measurement:** Press to open the ECG submission module.
**Messages:** Press to show messages between you and the healthcare professionals.
**Reviewed:** Press to show acknowledgements of your recent measurements by healthcare professionals.
**My results:** Press to show tables and graphs of measurement results previously submitted by you.
**My replies:** Press to show tables of questionnaire replies previously submitted by you.
**Information:** Press to show links to further relevant material for your condition on the web.
**Calendar:** See upcoming video conferences between you and a healthcare professional.

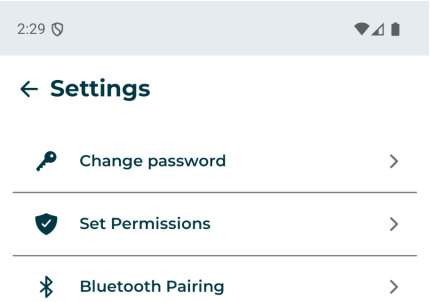
The menu items that have a blue background and a number next to the title, here **Start questionnaire (2)** and **Messages (3)**, indicate that there are questionnaires to be answered and new messages from the clinicians, respectively.

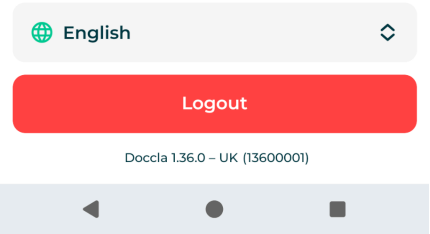
**Note:** Depending on your condition you may not necessarily see all these menu items when logging into the Doccla app.



Press the **Account** button

in the top right hand corner to access the app **Settings**.




- Press the **Change password** button to go to the change password page.
- Press the **Set Permissions** button to manage the permissions granted to the app.
- Press the **Bluetooth Pairing** button to pair a medical device from the supported device list.
- Press the **Select Language** button to change the language of the app.
- Press the **Logout** button to log out of the app.

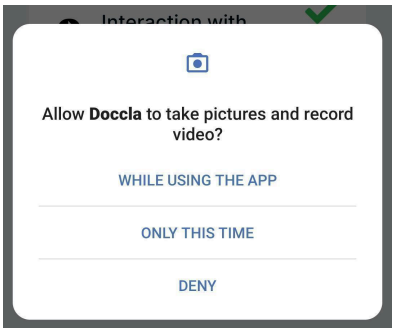
# Change Password

This menu allows you to change your password by entering your current password followed by a new password twice and pressing change.
You can always press the **back** button to return to the previous menu.

# Set Permissions

All of the permissions the app requires are listed shown with a green tick ✔ if the permission has been granted or with a red cross ✘ if the permission has not been granted.

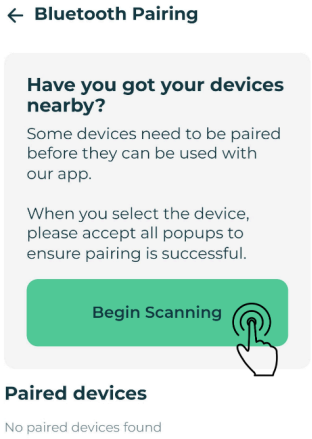
To enable a permission click on the red cross ✘ and on a pop up you can select what level of permission to grant.



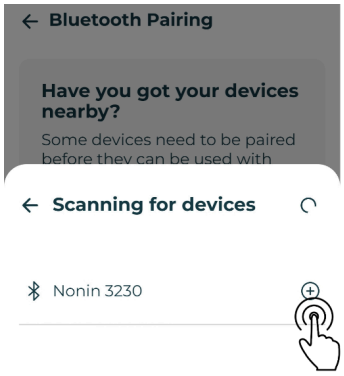
# In-app Bluetooth Pairing

The Bluetooth pairing option **only allows you to pair medical devices integrated with the Doccla app**, these devices are listed on pages 6-7 of this User Manual.

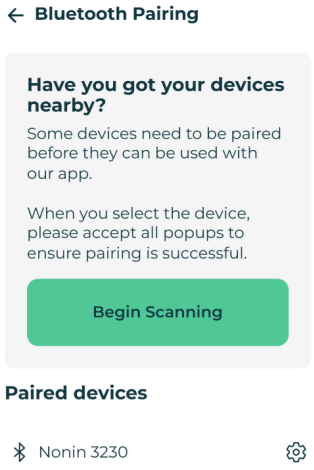
After selecting the Bluetooth pairing option the app will display any devices that are already paired with the smartphone or tablet and offer the option to “Begin Scanning” for devices that are in pairing mode.




When pressing “Begin Scanning” all nearby devices that are in pairing mode (and not already paired with the smartphone or tablet) will appear. To pair with that device select it from the list by pressing the **+** button next to the device’s name and follow the on-screen instructions.




On Android smartphones and tablets you will see that the device now appears in the “Paired devices” list. On Apple smartphones and tablets (running iOS) you will need to navigate to the smartphone/tablet’s Settings app to reviewed paired Bluetooth devices.

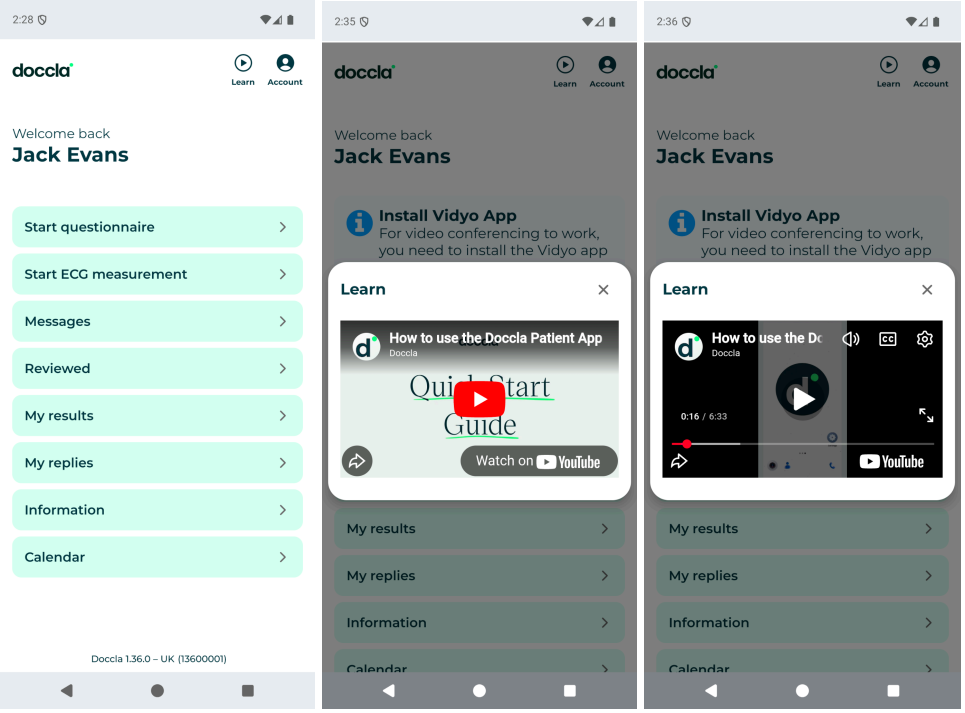


# App Navigation Guidance

Video guidance is available for how to use application features by pressing on the Learn icon

at the top of the screen, for example when inputting a blood pressure measurement in a questionnaire.

When pressed the icon will open a video window with a red play button, when this is pressed the video will start.

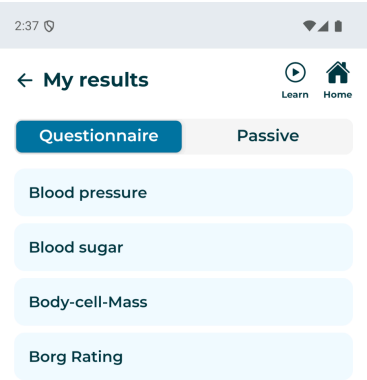



When the video has started it can be

- Made full screen by pressing the square button in the bottom right corner of the video
- Paused by pressing the two lines button in the bottom left corner of the video
- Closed by pressing the X button to the top right of the video window

# My Results

This menu allows you to see previous submitted results and measurements as tables and graphs. Press one of the measurement types in the list to see more details.

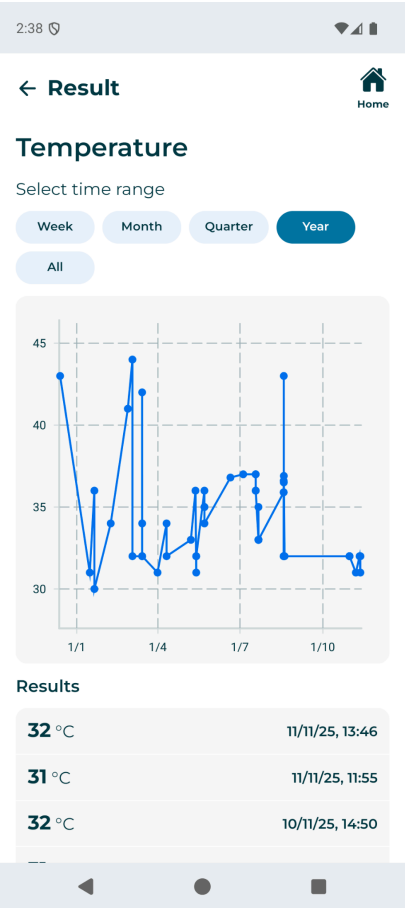



You can always press the **home** button to return to the home menu.

## My Results – Temperature

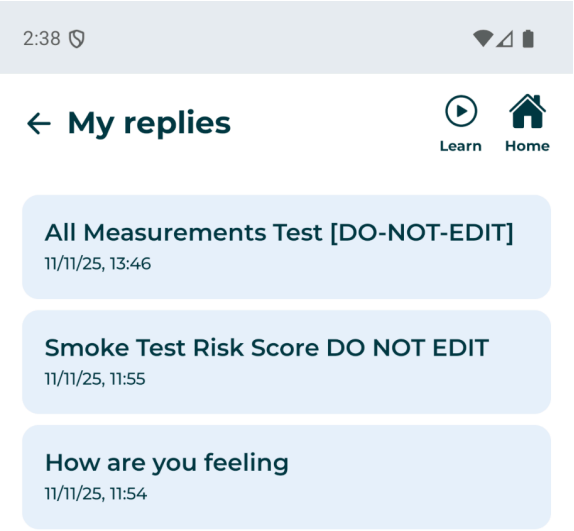
This is an example of results for a specific measurement type that was chosen in the previous **My results** menu. Here you can see a graph and a table of results, where you can filter the amount of results shown by pressing on one of the time filters at the top of the menu.

You can always press the **back** button to return to the previous menu.



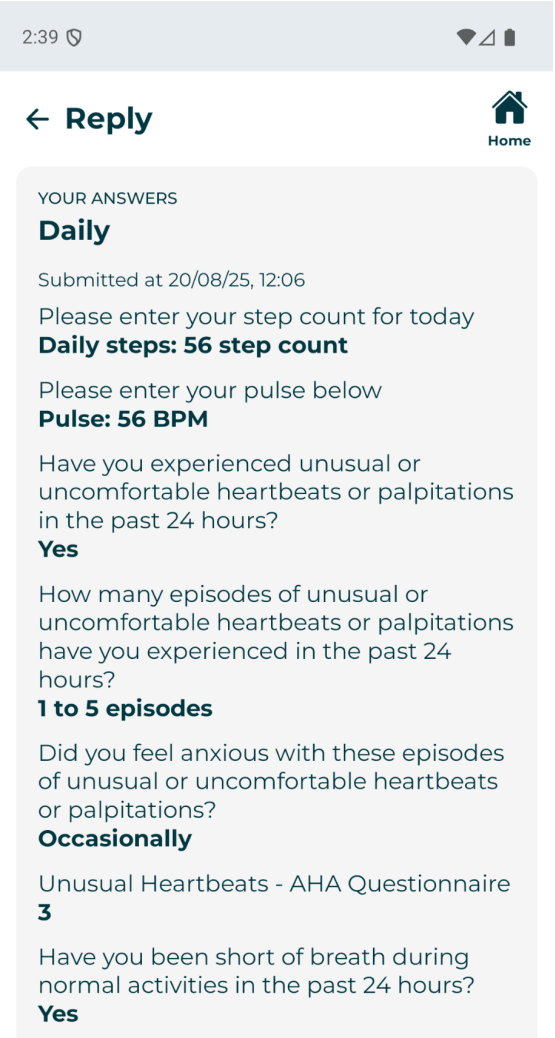
# My Replies

This menu allows you to see previous submitted questionnaire replies displayed as tables. Press one of the questionnaire replies in the list to see more details.
You can always press the **home** button to return to the home menu.




# My Replies – Daily questionnaire

This is an example of a reply for a questionnaire that was chosen in the previous **My replies** menu. Here you can see a table with a column for the **Questions** asked and the **Replies** given.
You can always press the **back** button to return to the previous menu.

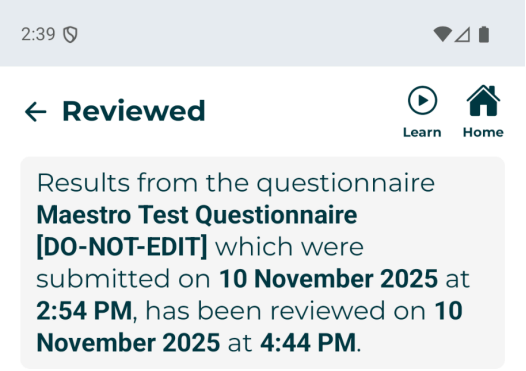


# Reviewed

This menu shows you when a healthcare professional has reviewed your most recent results. A list of messages is displayed, one for each of your recent results sent in to the healthcare professionals including the date and time at which it has been reviewed.

If there are no results reviewed yet, you will get the message “There are currently no reviewed results to show”.

You can always press the **home** button to return to the home menu.

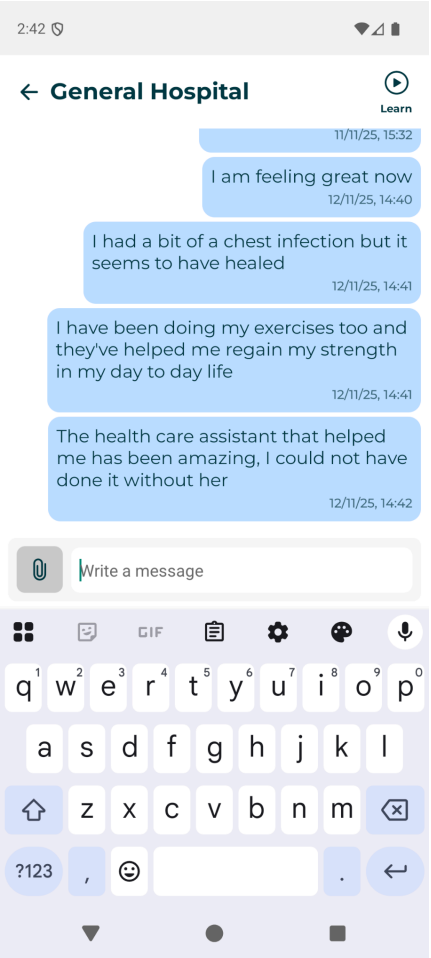



# Messages

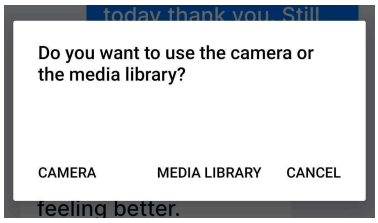
This menu shows the messages sent between you and the healthcare professionals. The newest message will be at the bottom of the screen.

At the bottom of the screen in the white input field, you can enter a message for the healthcare professionals.

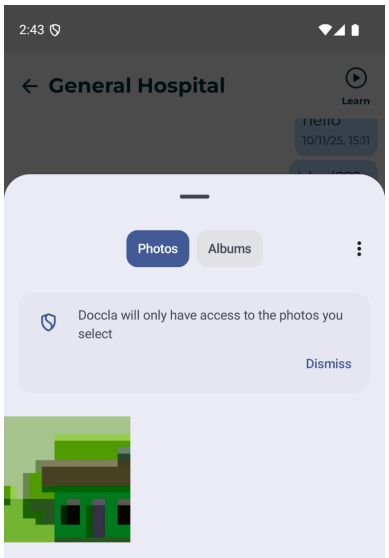
After writing the message press the button to send it to the healthcare professionals. You can always press the **back** button to return to the previous menu.

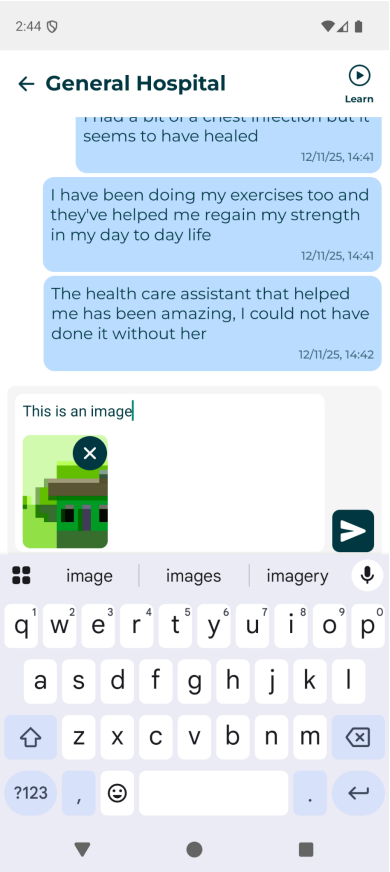


To attach an image to a message, click the button next to the send button. Depending on the mobile device, you can choose to take an image with the device's camera, or upload an existing one.




After choosing an image, a preview will be shown next to the message.



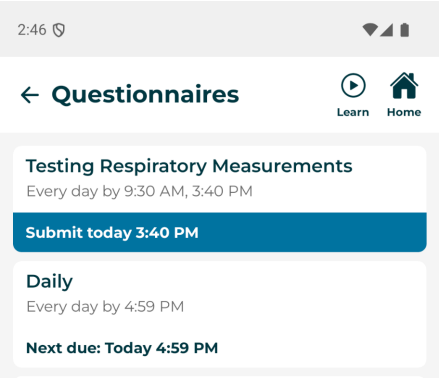



When a sent message contains an image, a thumbnail will be shown in the conversation. Click to enlarge.

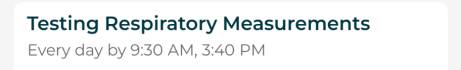
If an image is deleted, a gray placeholder will be shown instead of the original image.

# Start questionnaire

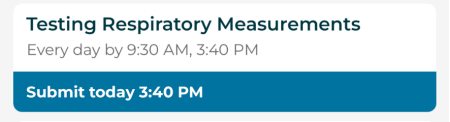
This menu shows all the questionnaires currently available for you to answer. Press one of the questionnaires in order to start completing it.
You can always press the **home** button to return to the home menu.



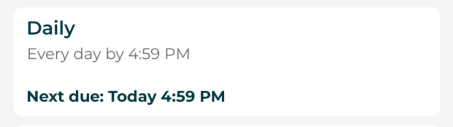

The frequency you need to submit your questionnaire will be displayed under the name of the questionnaire.




The questionnaires with a blue row indicate that these should be answered before the deadline displayed underneath the questionnaire title, e.g. the **Testing Respiratory Measurements** questionnaire has a deadline at *Today, 3:40PM*.




If a questionnaire has a visible deadline but has not been marked with a blue background yet, that means you should not complete the questionnaire just yet but wait until you get closer to the deadline.



# Answer a questionnaire

This is an example of a questionnaire that was chosen in the previous screen.

When answering a questionnaire, you are led through a series of different questions, each either showing a text, a simple input field, a measurement input field or a multiple choice question.

For each question, you navigate to the next by clicking on one of the buttons at the bottom of the screen.

The number of buttons may vary between the different screens, i.e. a **Next** button, a **No** and **Yes** button or a **Skip** and **Next** button.

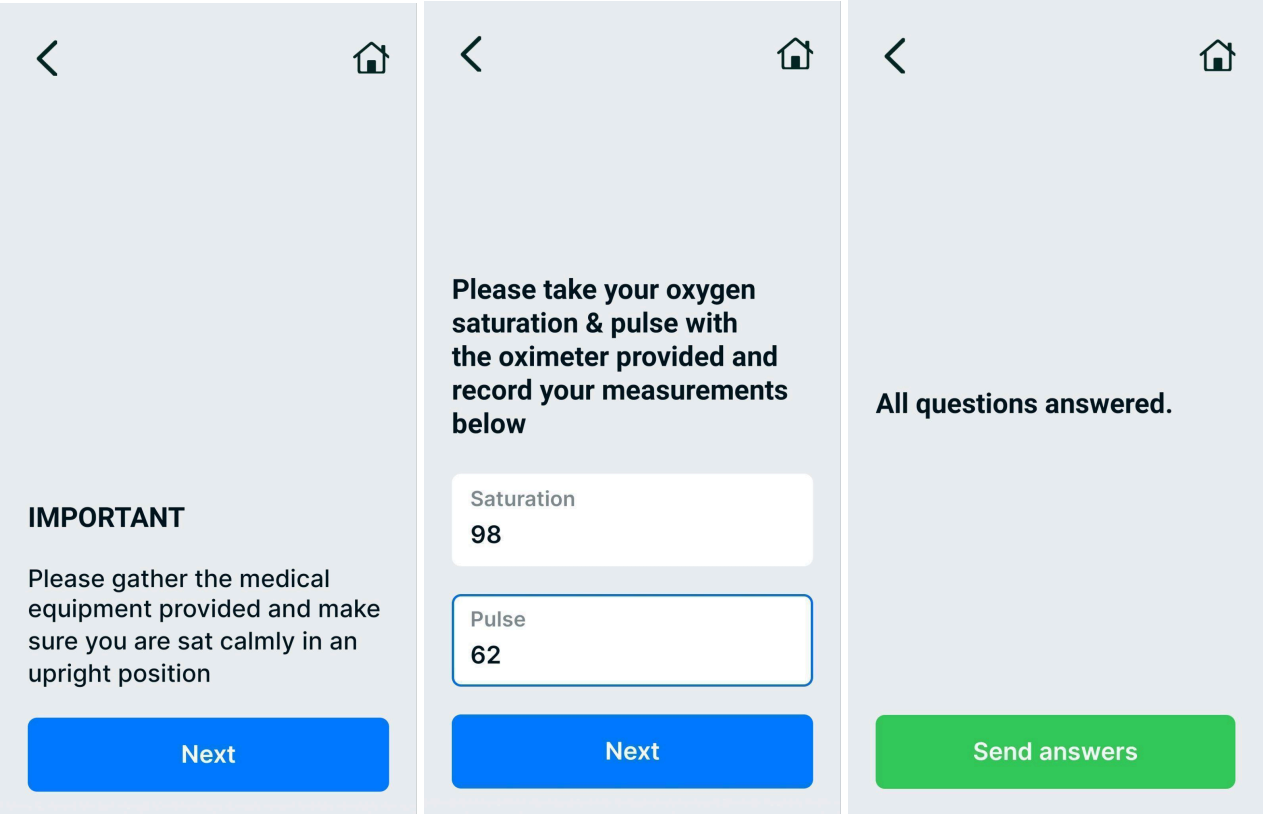
At the end of a questionnaire you must choose to either send the questionnaire results to the healthcare professionals or omit the results.

When asked to perform a measurement please find the appropriate measurement device and take a measurement. The medical devices should already have been paired with the tablet via Bluetooth allowing for automatic measurements.

If you are using devices that are not using Bluetooth, you enter the result into the questionnaire answer box.
You can always press the **back** button to go back to the previous question to choose a different answer or the **home** button to return to the home menu.

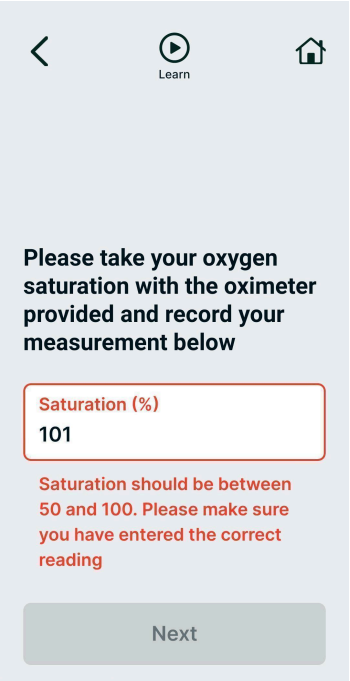
Enter the value in the input field and press **Next**. (Consult the help text if needed, shown when clicking on the Help at the top).
To send the completed questionnaire results to the healthcare professionals, press **Send answers**.

An acknowledgment is shown when the completed questionnaire is successfully received.

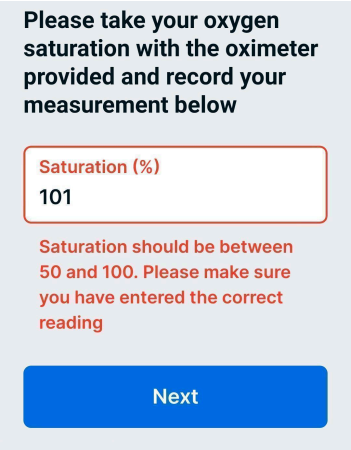


## Measurement input validation

When answering a questionnaire there is validation on the values that can be entered for measurements. If a value is input outside of the expected limits for a measurement a warning message will appear with the upper and lower limits expected for that measurement type.

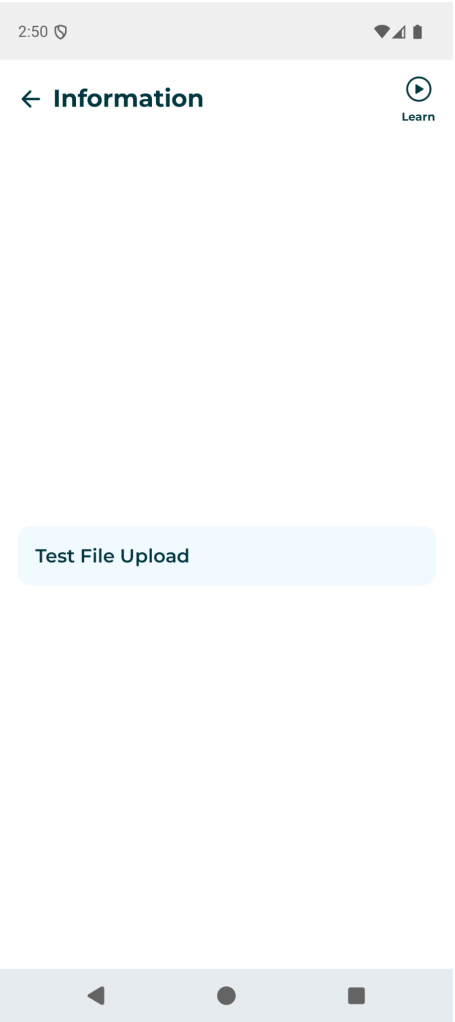


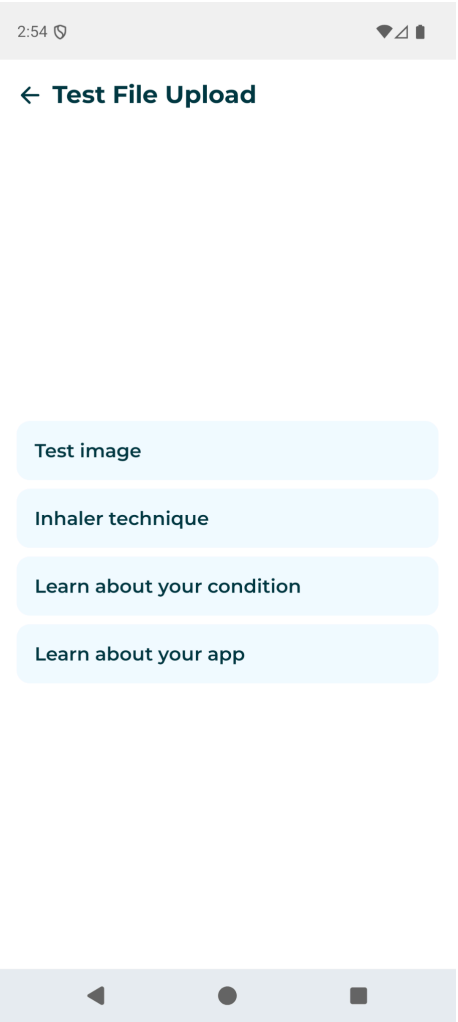

The limits are designed to screen unlikely values, so the “Next” button will be greyed out and disabled until the value is either changed or three seconds have elapsed when the “Next” button turns blue and can be pressed to progress.



# Information

This menu shows a list of links to pages, videos or documents containing further information that might help you in your treatment.

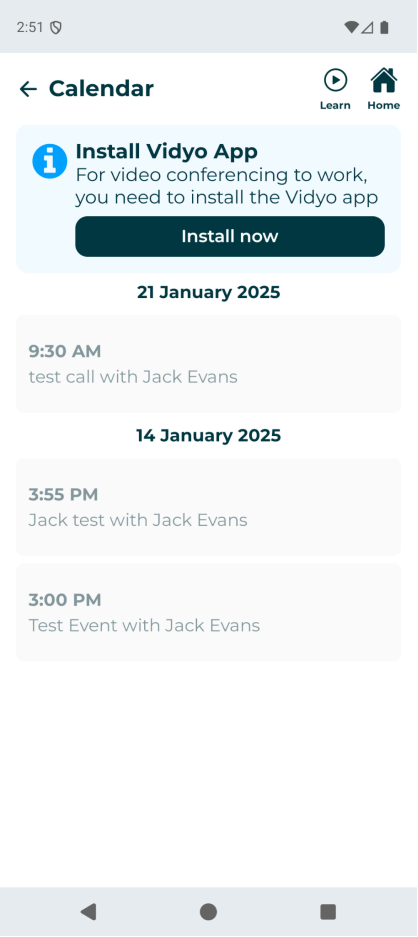



When clicking such a link be aware that you are leaving the Doccla app and opening the link in the web browser on your mobile device.

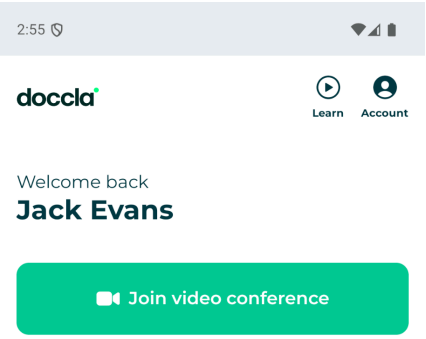
# Calendar

The menu allows you to view upcoming and past video conferences with a healthcare professional.



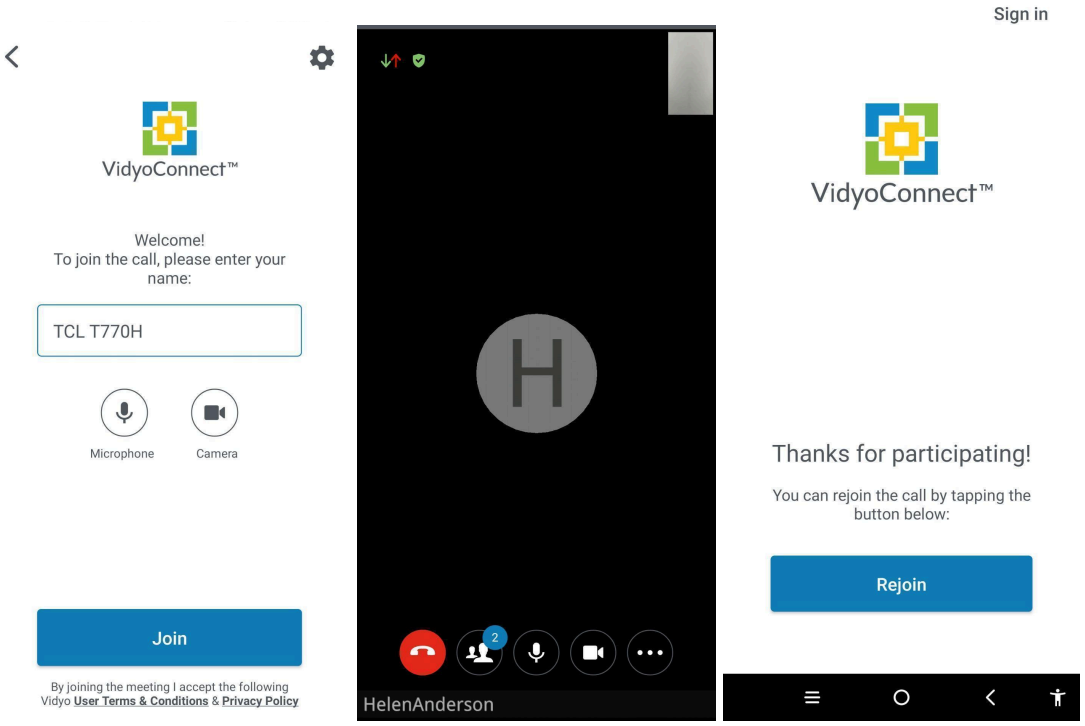

# Video conference

Your clinician can choose to start a video conference with you. They will call you up on your mobile device, after which you have to accept the call by pressing the **Join video conference** button.




- The video conference will open in the VidyoConnect app and you will need to click **Join**.
- You will see the clinician who has initiated the call in the centre of the screen and in the top right hand corner you will see a preview of yourself. You use the controls below
    - You can turn your camera on/off by pressing the button
    - You can turn your microphone on/off by pressing the button
    - You can end the call by pressing the button
    - **Do not use** the functionality of the button is not supported.
- When the call has ended you can return to the Doccla Patient App by clicking at the bottom of the

screen.


VidyoConnect™
Welcome!
To join the call, please enter your name:
TCL T770H
Microphone
Camera
Join
By joining the meeting I accept the following Vidyo User Terms & Conditions & Privacy Policy
H
2
HelenAnderson
Sign in
VidyoConnect™
Thanks for participating!
You can rejoin the call by tapping the button below:
Rejoin

# Passive Monitoring

## Overview

Passive Monitoring allows the Doccla app to automatically collect physiological data from a compatible wearable device without requiring manual input. This feature enhances patient monitoring by passively tracking key vital signs and transmitting data to healthcare professionals.

## Setting Up Passive Monitoring

1. Prepare the wearable device:
    - Ensure the wearable is charged. Plug the provided charger into a power adapter and charge the device.
2. Pairing the wearable:
    - Open the Doccla App and navigate to the home screen.
    - Press “Pair”
    - The app will search for the wearable. A message will appear:
        i. Now remove the wearable from the charger
        ii. "Bracelet found, start pairing process."
            1. If the wearable is not found, ensure Bluetooth is enabled on your mobile device.
        iii. Once found, follow on-screen instructions to complete pairing.
3. Complete pairing profile.
4. Complete wearing optimisation
    - Follow on-screen instructions
        i. Remain still and rest your arm on a flat surface while completing this step.
5. Monitoring Activation:
    - Once paired, Passive Monitoring starts automatically.
    - The app will notify you if data is not being recorded (e.g., if the bracelet is disconnected or battery is low).

## Checking Monitoring Status

- The wearable device status is displayed on the Home Screen.
    - If monitoring is active, you will see a status indicating that data is being recorded.
    - If monitoring is not active, the app will display a "Not recording!" message.
- To navigate to the wearable page in the app press on the wearable card.
- Ensure the bracelet is worn correctly.

## Data Transmission

- Data is automatically sent to healthcare professionals.
- No manual data entry is required.
- Healthcare professionals can review trends over time.

## Troubleshooting

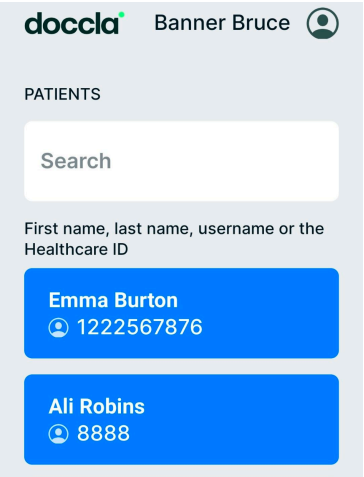
- If pairing fails:
    - Make sure the bracelet is charged.
    - Restart the bracelet by placing it back on the charger for a few seconds.
- If monitoring stops:
    - Ensure the bracelet is snug on your wrist.
    - Reconnect in the wearable device section.

## Important Notes

- Passive Monitoring is not a substitute for emergency care. If you experience symptoms, seek medical assistance.
- The bracelet does not provide real-time alerts for critical conditions.
- Always ensure the bracelet is charged and correctly positioned on your wrist.
- If the device is not on the latest firmware (“Update available” will be displayed) then press to update.

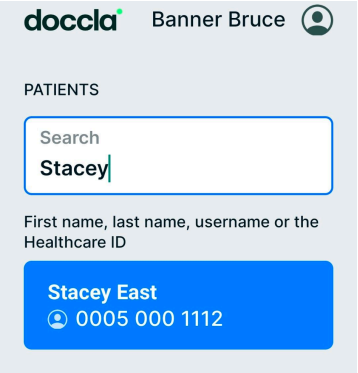
# Carer App - Patient Selection

When you have logged in you will be presented with a list of the patients that you care for.

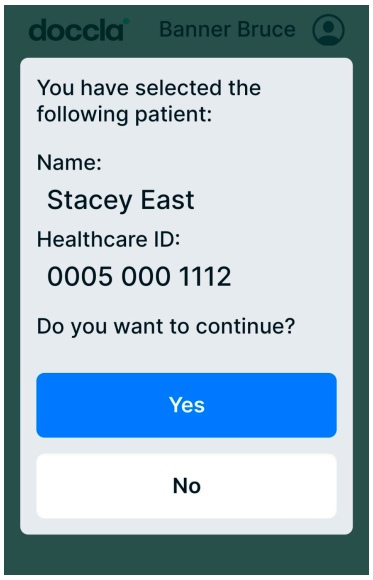



It is recommended that you search for the patient in the search box at the top of the Home Screen. You can search for patients with any of the below fields from the Clinician Dashboard -

- First name
- Last name
- Healthcare ID
- Username




You will be asked to confirm that you have selected the correct patient, it is important to check the Healthcare ID in the app matches the Healthcare ID on the Clinician Dashboard.



# Addendum

## Reporting patient incident

Any serious incident that occurred in connection with the use of Doccla RPM shall be reported to Doccla Denmark via support@doccla.com. Additionally, the serious incidents shall be reported to the competent authority of the Member State where the user and/or patient is established.

## Precautions

The information in this document is subject to change without notice.

## Legal Notices

Doccla Denmark declares that the Doccla RPM software application is placed on the market in compliance with the following legislation concerning Medical Devices:

- Council directive 93/42/EEC.
- Regulation (EU) 2020/561, which amends article 120 of Regulation (EU) 2017/745 concerning transitional provisions.

## Manufacturer

Doccla Denmark,
Søren Frichs Vej 38K, 1.
8230 Åbyhøj,
Denmark

## Manufacturer responsibility

The manufacturer is only responsible for the software of Doccla RPM itself and does therefore not take responsibility for the functionality of the measurement devices used, the tablet or other devices that the Doccla RPM app can communicate with. The manufacturer ensures compliance with the listed Bluetooth devices in this document. No parts of this document may be reproduced or translated without the prior written permission of the manufacturer.

## End of life (EOL)

The product's End of life (EOL) is 2 years after release. After EOL there is no product support. The date for EOL can be found on the product label.

The device (Doccla RPM software) works as an assisting tool and is not a replacement of treatments. It is recommended to avoid performing a measurement with moist or wet hands. A pen or other hardware tool can be used in case of touch screen challenges.