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REMOTE HEALTHCARE MADE SIMPLE

Patient App - User Manual

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OpenTele version 2 RN Patient App - User Manual

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Introduction

This user manual has been written for patients who must use the OpenTele version 2 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 of the OpenTele version 2 software

Intended use

OpenTele version 2 is a software platform consisting of two integrated parts, a web application and a mobile device application. The software platform is intended to provide patient information from the patient to a remote healthcare team through relevant network technology.

OpenTele version 2 is intended for booking and management of appointments, patient interaction through video consultation and text messaging, capture of electronic questionnaires, aggregation, storage and management of clinical data, as well as information management of independent external physiological measurement devices connected either directly to the mobile device application or through digital communication technologies such as USB, Bluetooth or Bluetooth Low Energy (LE).

Product claims

The OpenTele version 2 software platform allows healthcare professionals to remotely monitor patients' vital signs through questionnaires and/or forms requesting the patient to report on their health status and/or perform measurements. This combination of objective data and subjective responses enables healthcare professionals to make informed, timely decisions for patients.

OpenTele version 2 enables the healthcare professional to design and distribute individualized or generic electronic questionnaires and/or forms. The healthcare professional may add threshold values for reference when reviewing reported information in the web application.

Indication for Use

OpenTele version 2 is indicated for use by patients and by healthcare professionals for collection and reviewing of data from patients who are capable and willing to engage in the use of OpenTele version 2.

Warning and Precautions



Warning

- The product may only be used by patients and healthcare personnel.
- No modification of the OpenTele version 2 software is allowed and the following points are mandatory.
- 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 OpenTeleHealth ApS or a colleague who has been trained by an OTH representative.
- The user must read and fully understand the instructions for use for the medical equipment.
- The remote residual risk refers to situations where a clinician neglects good clinical practice and trusts the outcome

of the medical device, potentially leading to a life-threatening situation. OpenTele version 2 does not provide real-time alerts and is not intended to provide automated treatment decisions or diagnosis.

- OpenTele version 2 must not be used for real-time monitoring of time-critical data and emergency intervention.
- The OpenTele version 2 platform is an information tool and must not be used as a substitute for the clinician's professional judgment when diagnosing and treating patients.
- Do not turn off bluetooth when using the OpenTele version 2 app.

Telemedicine platform OTH

In OpenTele version 2 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 OTH kit in this user manual.

Example kit

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

- A tablet, with the OpenTele version 2 RN Patient App installed,
- a blood pressure monitor,
- a thermometer,
- a pulse oximeter.







Supported measurement



The OpenTele version 2 RN Patient App app supports manual input of measurements as well as automatic input of measurements using software or Bluetooth enabled devices. The following set of devices are all supported by OpenTele version 2 RN Patient App:

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	
ECG	AliveCor	KardiaMobile6L	

Multi-Vital ECG Sensor	Vivalink	VV350	
Oximeter	Masimo	MightySat Rx	
Oximeter	Nonin	3150BLE	
Oximeter	Nonin	Onyx 3230	
Oximeter	Kinetik	MD300CI218R	
Peak Flow Meter	Vitalograph	asma-1 BT	
Weight scale	A&D	UC-352BLE	

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 app.

Log on to app

When you open the 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 on the login screen, below the “Remember me” checkbox.

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 two options: “I have forgotten my username and password” and “I am not in [country name]”.

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.

Home menu

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

Start visit: 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 visit (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 app.

Press the **Profile** button  in the top right hand corner to access the **Patient profile**.

- Press the **Select Language** button  to change the language of the app.
- 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 **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.




App Navigation Guidance



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

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 visit

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 **Covid - Severe** questionnaire has a deadline at *Today, 2:30PM*.

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  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 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.

1. The video conference will open in the VidyoConnect app and you will need to click **Join**.
2. 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

- a. You can turn your camera on/off by pressing the button 
- b. You can turn your microphone on/off by pressing the button 
- c. You can end the call by pressing the button 
- d. **Do not use** the functionality of the button  is not supported.

3. When the call has ended you can return to the OpenTele version 2 RN Patient App by clicking  at the bottom of the screen.

Passive Monitoring

Disclaimer

This feature is to be used exclusively for clinical investigation.

When a patient has been referred for passive monitoring they will be given a bluetooth enabled medical device and this device will transmit vital sign measurements from the device to the patient app.

After logging into the app you will see the “Monitoring” section.

Pressing the “Pause” button will pause the monitoring and you will need to confirm they want to initiate the pause.

1. “Paused” - The device will not be recording and therefore not sending any vital sign measurements.
 - a. Pressing the “Start” button will reactivate the monitoring.
2. A card is displayed with the name of the medical device for passive monitoring e.g. “Chest Patch”, its status and an expandable “More info” section
3. The status of the connected device is shown under the name of the medical device. These statuses can be -
 - a. “**Searching**” - The application is scanning for the medical device.
 - b. “**Connecting**” - The application has found the medical device and is connecting to it.
 - c. “**Not positioned**” - The application has connected to the medical device but the device isn’t correctly positioned on your body.
 - d. “**Recording**” - The application is receiving vital sign measurements from the medical device and is sending them to the clinical team.
 - e. “**Not sending**” - The application is connected to the medical device and is receiving vital sign measurements, but is not able to send them to the clinical team.
 - f. “**Not recording**” - The application is connected to the medical device but is not receiving vital sign measurements.
 - g. “**Disconnected**” - The application is not connected to the medical device.
 - h. “**Needs charging**” - The medical device needs to be charged.
 - i. “**Charging**” - The medical device is charging.
 - j. “**Paused**” - The passive monitoring has been paused.
4. “More info...” is a clickable dropdown that will expand to give you more information about the passive monitoring status.
 - a. Vital sign measurements
 - i. You will see the measurement type and the measurement value.
 - b. “Last sent” - You can see the last time that the vital sign measurements were sent from the application to the clinical team.
 - c. “How to charge” - When clicked you will see expanded instructions for charging the medical device.
 - d. “How to position” - When clicked you will see expanded instructions for positioning the medical device on your body.

Addendum

Reporting patient incident

Any serious incident that occurred in connection with the use of OpenTele version 2 must be reported to OTH and 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

OpenTeleHealth declares that OpenTele version 2 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 and Regulation (EU) 2023/607, which amend article 120 of Regulation (EU) 2017/745 concerning transitional provisions.

Manufacturer

OpenTeleHealth ApS,
Toldbodgade 8, 1., 8000
Aarhus C, Denmark



Manufacturer responsibility

The manufacturer is only responsible for the software of OTH itself and does therefore not take responsibility for the functionality of the measurement devices used, the tablet or other devices that the OpenTele version 2 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 (OpenTele version 2 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.