REMOTE HEALTHCARE MADE SIMPLE

Patient App - User Manual

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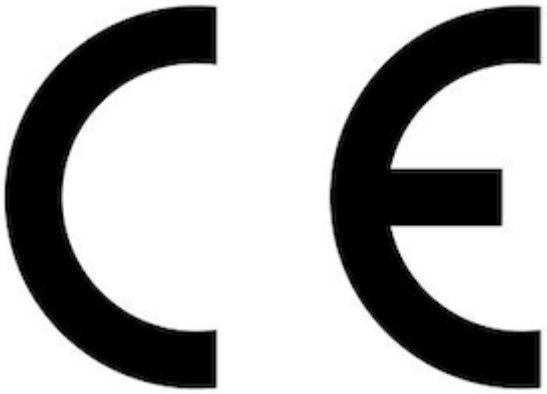

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Introduction

This user manual has been written for patients who must use OTH app. The user manual has been written in a 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 OTH 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 (HCPs) to remotely monitor patients’s 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 HCPs 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.

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.
- In the case of OpenTele version 2 being unavailable or not working as intended, please email tech-support@opentelehealth.com.

Telemedicine platform OTH

In OTH 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.

Supported measurement

The OTH 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 OTH:

Measurement type	Manufacturer	Model name
Activity tracker	Beurer	AS98
Blood pressure monitor	A&D	UA-651BLE
Blood pressure monitor	A&D	UA-656BLE
Blood pressure monitor	Xim	Lifelight
Blood pressure monitor + ECG	Beurer	BM96
ECG	Bittium	Faros-180
ECG	Savvy	Savvy
Glucometer	Contour	Next One

Measurement type	Manufacturer	Model name
Oximeter	Nonin	Onyx 3230
Spirometer	Vitalograph	4000
Thermometer	FORA	IR-20b
Thermometer	A&D	UT-201BLE-A
Weight scale	A&D	UC-352BLE
Weight scale	Marsden	M430

Remember to keep Bluetooth switched on

Automatic input of measurements requires that Bluetooth is enabled. Do not turn off Bluetooth. If you turn off Bluetooth measurements can no longer be collected from the devices automatically.

App parts

The following section describes different parts of the OTH app.

Log on to app

When you open the OTH 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 logout from the app.

Please keep in mind that personally sensitive data is visible through the app. Do not share your username and password with anyone. If using the “Remember me” function, it is important that access to your device is protected by some other means (pin-code, fingerprint reader etc.).

Main menu

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

- **Start visit:** All questionnaires that can or need to be completed.
- **Messages:** Messages between you and the healthcare professionals.
- **Reviewed:** Acknowledgements of your recent measurements by healthcare professionals.
- **My results:** Tables and graphs of measurement results previously submitted by you.
- **My replies:** Tables of questionnaire replies previously submitted by you.
- **Information:** Links to further relevant material for your condition on the web.
- **Calendar:** Upcoming video conferences between you and a healthcare professional.

Depending on your condition you may not necessarily see all these menu items when logging into the OTH app.

Press the **logout** button ⍈ button in the upper right corner to log out of the app.

Menu items that have a highlighted background and a number next to the title indicate that there are questionnaires to be answered or new messages from the clinicians.

Profile menu

Depending on your condition you may not necessarily see the profile menu. You can enter the profile menu by pressing the in the header. This will fold out the profile menu. From the profile menu you can navigate to one of the following sub menus by pressing their corresponding button:

- **Product information** View product information and instructions for use.
- **Change password** Change your own password .
- **Download data** Download a report containing your data.

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To close or unfold the profile menu, press .

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.

Download data

This menu allows you to download a PDF-report containing information about you such as: Basic data, messages and questionnaire answers. Press the ‘Download data’-button to download this pdf.

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

My Results

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

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

My Results – Specific measurement

After choosing a measurement type to view in the previous My results menu, you can see a graph (on tablet) and a table of results (both tablet and mobile). 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 or the **home** button ⌂ to return to the main 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 navigate to newer or older questionnaire replies using the **Newer** and **Older** buttons at the bottom of the screen.

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

My Replies – Specific questionnaire

After choosing a questionnaire in the previous My replies menu, 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 or the **home** button ⌂ to return to the main menu.

Reviewed

This menu shows you when a healthcare professional has reviewed your most recent results. A list is displayed, an entry 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 **back** button ←

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 paper airplane Send 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.

When the picture is enlarged, a **Delete** button appears. Clicking it twice will delete the image permanently. You can only delete your own image.

Once 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 **back** button ← to

The questionnaires with a highlighted background indicate that these should be answered before the deadline displayed underneath the questionnaire title. If a questionnaire has a visible deadline but has not been marked with a highlighted background yet, that means you should not complete the questionnaire just yet but wait until you get closer to the deadline.

Answer a questionnaire

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 main menu.

Enter the value in the input field and press **Next**. (Consult the help text if needed, shown when clicking on the **?** in the top right corner)

To send the completed questionnaire results to the healthcare professionals, press **Yes**.

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

Information and guidance

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

When clicking such a link a popup is shown ensuring that you are aware that you are leaving the OTH app and opening the link in the web browser on your mobile device.

Calendar

The menu allows you to view upcoming video conference 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 **OK** button.

Use the app as a guardian

A patient can have one or more guardians assigned to act on the patients behalf. All guardians have their own username and password, which can be used to log in to the app.

When logged in the guardian user is presented with a menu where the guardian can choose to act on behalf of the patient being assigned to the guardian. Also it is possible for the guardian to change the current password or log out of the app again.

When selecting to act on behalf of the patient, the guardian is redirected to the normal patient main menu, and can perform the same actions as if it was the patient being logged in.

Addendum

Reporting patient incident

Any serious incident that occurred in connection with the use of OpenTele version 2 shall be reported to OpenTeleHealth ApS via tech-support@opentelehealth.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 are 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, which amends 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 OTH 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 (OTH 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.