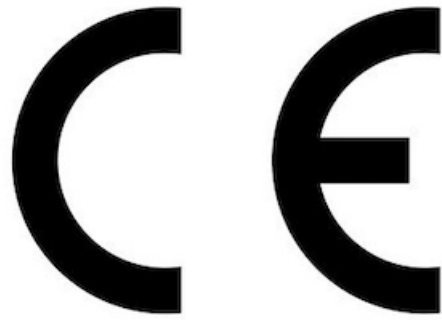




**REMOTE HEALTHCARE MADE SIMPLE**



# Table of content

---

- Introduction
  - Intended use of OTH software
- General Navigation
  - Logging in to the system
  - Menus and page layout
- Questionnaires
  - Creating a questionnaire
  - Editing a questionnaire draft
    - The questionnaire editor layout
    - Adding a measurement node
    - Adding a text node
    - Adding an input node
    - Adding a multiple choice node
    - Adding a multiple choice summation node
    - Adding a delay node
    - Adding help texts to questionnaire nodes
    - Publishing a questionnaire
    - Setting a default schedule to a questionnaire
- Questionnaire Groups
  - Creating a questionnaire group
- Message Snippets
- Info for Patients
  - Creating a new info category
- Organizations
  - Creating a new organization
- Patient groups
  - Creating a new patient group
- Patient app logging
  - Setting up app logging for a patient
- Audit log
- Thresholds
  - Thresholds overview
    - Add threshold
  - Filtering the list of thresholds
- Schedule window
  - How to edit the window of a schedule type
- Users
  - Creating a new user
- User roles
  - Creating and editing a user role
- API Clients
  - Creating and Editing an API Client
- Addendum
  - Reporting patient incident
  - Precautions

- Legal Notices
- Manufacturer
  - Manufacturer responsibility
  - End of life (EOL)

# Introduction

---

This user manual for the OTH Clinician Portal (Administrator) has been written for administrative staff. The user manual has been written in a way so that it is thorough and understandable for the administrative staff, and no prior teaching or workshop participation is necessary to understand it. All administrative staff must read this entire user manual before using the administrative menu in OTH Clinician Portal.

## Intended use of 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 software platform allows 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 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.
- OTH2 is not to be used for any purpose outside of the scope of the intended use defined in this manual - this includes the specific medical conditions that the device is indicated for use with. Use of OpenTele version 2 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 OTH2 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. OTH2 does not provide real-time alerts and is not intended to provide automated treatment decisions or diagnosis.
- OTH2 must not be used for real-time monitoring of time-critical data and emergency intervention.
- The OTH2 platform is an information tool and must not be used as a substitute for the clinician's professional judgment when diagnosing and treating patients.



## General Navigation

### Logging in to the system

1. **Visit** the OTH webpage application web site in your Internet browser. The URL is provided upon installation. The OTH clinician portal is a web based application and can be used anywhere as long as you have access to a web browser. The website functions best with Google Chrome, Mozilla Firefox, or Microsoft Edge.
2. **Type** in your username and password. Your username and initial temporary password will be provided by the administrator. Upon initial login, you will be asked to change your password. Passwords must be at least 8 alpha numeric characters in length and must contain 1 number.
3. **Click** "Login".

### Menus and page layout

The Overview page displays patients assigned to you that have pending alerts/alarms.

General navigation features are described below:

1. Overview page; this is the default page that is displayed upon login. It shows the patients with pending alarms for your organization.
2. Main Menu panel allows access to the submenus: Overview, Calendar (optional), Patient group messages (optional), Find Patient, Create Patient and All Notes for My Team pages.
3. Top menu bar displays the username you are logged in with; Administrator Menu button to access the Administrator Menu; Round button with the initials of the signed in user to change your login password, a logout button to log out of the system when desired, an About page containing the product label and access to a help site.
4. In the drop down it is possible to choose a which patient group will display.

Clicking on the **admin menu** reveals the following set of links to all the different submenus of the administrator menu. These submenus are the focus of this manual.

After navigating to one of these submenus the main menu panel to the far left will be replaced with the same administrator menu panel as seen in the dropdown.

1. Questionnaires
2. Questionnaire groups
3. Message snippets
4. Info for Patients
5. Organizations
6. Patient groups
7. Patient app logging
8. Audit log

8. Alerts
9. Thresholds
10. Schedule window
11. Users
12. User roles
13. API Clients

## Questionnaires

---

### Creating a questionnaire

---

1. **Click** on the “Questionnaires” menu and create a new Questionnaire by pressing the **+ Create Questionnaire Header** button.
2. **Enter** a name for the new questionnaire.
3. If you want all completed questionnaires of this type to be manually reviewed by a clinician check the “Requires manual control?” box. This ensures all completed questionnaires will raise an orange or higher alarm.
4. **Press** the **Create+Edit new draft** button which will navigate you to the questionnaire editor.

### Editing a questionnaire draft

---

#### The questionnaire editor layout

1. This page shows the overview of the published version of the questionnaire.
2. The current version line shows which version is currently published to patients.
3. **Press** Edit to edit the title and schedule of the questionnaire.
4. **Press** Remove Current Version to move to the last version of the questionnaire.
5. **Press** Create Draft to create a new draft of the questionnaire.
6. **Select** the version of the questionnaire you want as a template for the new draft. It is possible to choose an empty template.
7. **Press** Create and the editor will open and you are ready to edit the new draft version of the questionnaire.
8. The questionnaire builder displays. The flow chart in the questionnaire builder shows the questionnaire information coming from the one used as a template.
9. Edit the questionnaire as needed by adding or removing nodes or help texts as described later in the manual.
10. **Press** Save to save the changes or **Press** “Save and close” to save the changes and close the edit mode.
11. It’s possible to **Select** Import or Export to export/import from one OTH environment to another the questionnaire.

#### Adding a measurement node

1. **Click** on the “measurement” menu item in the Node types menu.
2. **Fill** out the form that appears with instructions to the patient, the type of measurement to be taken and whether it should be done automatically by the client software (using connected devices), or manually by the patient.
  - The ‘help text’ dropdown allows you to add a help text and image to the measurement node providing extra information to the patient.
  - The ‘allow patient comment’ checkbox allows the patient to add an optional comment to the measurement, e.g. giving some context for a higher/lower than usual value.
3. **Click** the “Create” button or **check** the “branch on patient threshold” box before **clicking** the “Create”
  - If pressing “Create” without checking the “branch on patient threshold” box, the node will be added to the drawing area with two outgoing endpoints, depending on whether the patient takes the measurement or skips it.
  - If the “branch on patient threshold” box is checked before pressing “Create”, the node will be added with an endpoint for each type of notification that can be triggered based on the patient thresholds: “red high”, “yellow high”, “yellow low”, “red low”, an endpoint if the measurement is within normal range, and finally an endpoint for if the patient chooses to skip the measurement.
4. Each of these endpoints can be connected to other nodes in the questionnaire. In the case where “branch on patient threshold” has been checked, each of the endpoints have already been assigned fixed severities based on their corresponding threshold notification trigger.

## Adding a text node

1. **Select** Text in the Node type menu.
2. **Type** a headline for the text node.
3. **Type** a text for the text node.
4. **Press** Create.
5. The node is created. Finally, each of the text node endpoints can be connected to other nodes in the questionnaire.

## Adding an input node

1. **Select** Input in the Node type menu.
2. **Type** a short description for the node.
3. **Type** the question to ask the user.
4. **Choose** Answer type (decimal number, integer, text, yes/no).
5. The node is created. Finally, each of the input node endpoints can be connected to other nodes in the questionnaire.

## Adding a multiple choice node

1. **Click** on the “Multiple choice” menu item.
2. **Fill** out the form that appears. Add the question to be given to the patient along with possible answers. Note that values entered in the ‘clinician text’ fields are only shown to the clinician as shorthands for the respective ‘patient text’ values in order to reduce noise when reviewing completed questionnaires answers and when branching on the choices.
3. **Click** the “Create” button. Optional: **check** the “branch on choices” box before **clicking** “Create”.
  - If pressing “Create” without checking the “branch on choices” box the node will be added to the drawing area with just one outgoing endpoint and works as most other nodes.
  - If checking the “branch on choices” box before pressing “Create” the node will be added with one endpoint for each choice entered into the form. Each endpoint is labeled according to the entered “clinician text” of the given choice.
4. Each of these endpoints can be connected to other nodes in the questionnaire. In the case where “branch on choices” has been checked, an endpoint is created for each possible answer. It can be assigned severities in order to trigger a notification.

## Adding a multiple choice summation node

1. **Click** on the ‘multiple choice - sum’ menu item.
2. **Fill** out the form that appears with a short description of the multiple choice series. This description is only shown to the clinician.
3. **Click** the “Create” button. Optional: **check** the “branch on sum” box before **clicking** “Create”.
  - If pressing “Create” without checking the “branch on sum” box, the node will be added to the drawing area with just one outgoing endpoint, and will work as most other nodes.
  - If checking the “branch on sum” box before pressing “Create”, a form will appear. Here you can add the different intervals on which to branch, where an endpoint is created for each of the intervals entered in form and labeled according to the entered “from” and “to” values of the given interval.
4. **Click** on the circle with a ‘+’ sign on a multiple choice node to add a question to the series of multiple choice nodes.
5. **Fill** out the form: the question given to the patient along with the possible answers and their respective value. Press “Create”.
6. In order to add more questions to the series, repeat one or more times.
7. Each of the interval branch endpoints can be connected to other nodes in the questionnaire and assigned a severity in order to trigger a notification for the clinician.

## Adding a delay node

1. **Select** delay in the Node type menu.
2. **Type** short description for the node.
3. **Type** a text for delay node to show for the users.
4. **Type** the length of the delay in second.
5. **Enter** if it has to count from 0 and up (up) or from max to 0(down).
6. The node is created. Each of the input node endpoints can be connected to other nodes in the questionnaire.

## Adding help texts to questionnaire nodes

Help texts are segments of text or images that a patient can access on a given node by clicking the question mark button.

1. Click on **Create** in the help texts menu.
2. Fill out the appearing form with a name, description (optional) and image (optional) for the help text and click **Create**.
3. Clicking on **Show all** will list all available help texts.
4. The newly created “My help text” help text will now appear in the “Add measurement node” and “Add text node” popup forms.

## Publishing a questionnaire

A questionnaire needs to be published after editing to be used by patients.

1. **Press** Publish to publish the latest version of the questionnaire (here version 5).
2. If you want to edit more **press** Edit draft.
3. If you want to delete the draft **press** Delete draft.
4. **Press** Confirm to confirm the publishing.
5. It is now possible for the patient to use the new version of the questionnaire.

## Setting a default schedule to a questionnaire

1. **Press** the Edit button on the questionnaire header.
2. **Choose** a schedule type and set the deadline(s) for when the patient should answer the questionnaire.

### Explanation of the different schedules:

- **Unscheduled:** The questionnaire can be completed at any time and as many times as you wish.
- **Weekdays - several daily measurements:** The questionnaire can be completed on specific days of the week and it is possible to make several measurements per day.
- **Weekdays - one daily measurement:** The questionnaire can be completed on specific days of the week with a single measurement per day.
- **Date(s) of the Month:** The questionnaire can be completed on specific dates of the month, e.g. the 1st and 15th of the month.
- **Every nth day:** The questionnaire can be completed on every nth day, e.g. a measurement every 3 days.
- **Specific date:** The questionnaire can be completed on a specific date.
- **Deadline at:** Questionnaire should be completed at the specified time of day. If a measurement frequency is selected with several measurements per day, multiple measurement times can be specified by clicking on the ‘+’ button.
- **Reminder at:** Reminder sent a specified number of minutes before the deadline for the questionnaire.
- **Schedule window:** Used to indicate how long before a deadline a sent in questionnaire result is registered as being the result of a questionnaire. This is used to indicate a period in which a delayed questionnaire result is not counted as an in-time result for the next questionnaire deadline.
- **Weekdays:** First, select which weeks the first measurement frequency should be, e.g. 2 weeks. Next, choose which days of the week the patient should answer the questionnaire in the first period e.g. Monday, Wednesday and Friday. Then, which weekdays in the second period, e.g. Monday and Friday, for which the patient should answer the questionnaire. The second measurement period is valid as long as this questionnaire is valid for this patient.

## Questionnaire Groups

The “Questionnaire groups” menu allows grouping a set of questionnaires to more easily assign the proper set of questionnaire to a patient or patient group.

Note that when a questionnaire group is assigned to a patient or patient group, the relation works as a link, which means that any changes made to the questionnaire group affects all patients and patient groups linked to the given questionnaire group.

## Creating a questionnaire group

1. **Click** on the “Questionnaire groups” menu and create a new questionnaire group by pressing the “Create” button.

- “Create” button.
- Enter** a name for the new questionnaire group.
- Select** a questionnaire to add to the questionnaire group and click the “+” button.
- Press** the “Delete” button to remove a specific questionnaire from the questionnaire group.
- Press** “Create” and the questionnaire group header will be created.

## Message Snippets

---

- Click** on the “Message snippets” menu button.
- Enter** the snippet title.
- Select** the organization for which the snippet should be available.
- Enter** the content of the snippet.
- Click** on the “Add” button. The snippet is now available inside the “Messages” patient menu for all clinicians in the selected organization.
- Click on **Edit** or **Delete** buttons in the “Message snippets” table to the left to update existing snippets. Sorting can be done by clicking on the different table column headers.



## Info for Patients

---

The “Info and guidance” menu is used for giving easy access to public healthcare information for patients in a specific patient group. The information is grouped into categories, e.g. one category for each condition or patient group.

### Creating a new info category

---

- Click** on the “Info for Patients” menu item in the administrator menu.
- Press** “Create Category” to create a new category of info.
- Enter** the name of the Category of the info or guidance.
- Enter** the description of the specific link.
- Enter** or copy the link to the web you want to add to the category.
- or **Press** the “Upload” button to upload a file and link to the uploaded file.
- Press** the **+** button to add the link to the category.
- Press**  or  if you want to edit or delete the link.
- Select** the Patient group.
- Press** “Create” to create the link and return to the overview of Info and Guidance.


## Organizations

---

The menu “Organizations” is used for creating and managing the different organizations in the OTH application.

### Creating a new organization

---

- Click** “Organizations” in the administrator menu.
- Press**  **Edit** to edit/change an existing organization.
- Press** “Create” to go to the create organization form.
- Enter** the name of the new organization.
- Add** any relevant metadata fields to the new organization by specifying the name and input type of the metadata field. A metadata field can describe any piece of useful metadata about each patient within a given organization. The field is then added to the basic data form when creating or editing a patient belonging to any patient group within that organization. A metadata field can either be a yes/no, whole number, decimal number, text, date, or choice input. A few examples of metadata fields could be:
  - ‘Comorbidity’ as a text input,
  - ‘COVID vaccinated’ as a yes/no input, or
  - ‘Expected discharge’ as a date input.



**Warning**

A patient metadata field should not be used for communicate time-sensitive information essential to patient health as these values are not shown in the patient overview nor require any sort of acknowledgement by a clinician, making it unclear if these values have been acted upon.

6. **Verify** that any relevant metadata fields have been added to the organization.
7. **Press** “Create” to create a new organization.

## Patient groups

The “Patient groups” menu is used for creating and managing the patient groups in the OTH application.

### Creating a new patient group

1. **Click** “Patient groups” in the administrator menu.
2. **Press** “Create” to go to the create patient group form.
3. **Enter** the name of the new patient group.
4. **Select** which organization the patient group should be associated with.
5. **Select** the questionnaire group(s) the patient group should be associated with.
6. **Check** the “Enable messaging to/from patient” box to enable the “Messages” menu in the portal and patient app for all clinicians and patients in the patient group. In addition, this checkbox also toggles whether the “Reviewed” menu in the patient app is also visible.
7. **Uncheck** the “Blue alarms enabled” box to disable blue alarms being triggered in the event where a patient misses a questionnaire deadline and the questionnaire is assigned via a questionnaire group assigned to the patient group. **Note:** that it is not possible to disable blue alarms in general for questionnaires assigned directly via a patient’s monitoring plan, only for questionnaires linked via the patient’s patient groups.
8. **Check** the “Show due date and gestational age” box if it should be possible to enter a due date in the basic data for the patient. If checked the gestational age is calculated and shown at the top of the patient menu.
9. **Press** “Create” to create the patient group.

#### **Warning**

Unchecking the “Blue alarms enabled” should only be done for patient groups for which there is no risk of deterioration in patient health if a given patient in the group misses one-or-more questionnaires, as the lack of blue alarms makes it harder to spot any patients that consistently are not answering their questionnaires.

11. **Press** “Edit” if you want to correct any data for the patient group.
12. **Press** “Delete” if you want to delete the patient group.

## Patient app logging

The “Patient app logging” menu is used for setting up app logging for a specific patient for a limited period of time in the case where some bug or odd program behavior has to be investigated.

### Setting up app logging for a patient

1. **Click** “Patient app logging” from the administrator menu.
2. **Enter** the name of the patient.
3. **Press** “Find User” to find the patient you want to set up for app logging.
4. The Audit ID for the patient is shown. This Audit ID is used for identifying the patient’s actions in the OTH system’s log files.
5. **Enter** the duration in days for which the app logging should be enabled.
6. **Press** “Add” to setup the app logging.
7. The page will show the patients for whom for which patients app logging is currently enabled. The app logging is enabled until the date in “Active until”.

# Audit log

---

In the “Audit log” menu it is possible to view the actions taken by specific users or on specific entities, optionally filtered based on time and the clinician responsible.

1. **Click** “Audit log” from the administrator menu.
2. **Enter** the filter for the search in the log. The following filters are available:
  - From date: Fetch events starting the specified **from date**.
  - To date: Fetch events until the specified **to date**.
  - Event type: Choose one or more event types to fetch, e.g. **Patient created, Threshold updated**, etc.
  - Responsible: Show only events that were triggered by the specified **responsible clinician**.
  - Entity: Show only events related to the specified entity. E.g the name of a patient, clinician, or user role.
3. **Press** “Update” to select the logs within the specified filter.
4. A list of events is shown based on the previous search terms.
5. **Click** on an event to see further details.
6. A detailed description of the event is shown.

# Thresholds

---

In the “Thresholds” menu it is possible set up threshold values for the different patient groups.

In the create patient flow, the thresholds assigned to the patient groups of the patient being created will be used as the default values for that patient. It is then possible to adjust these assigned default values as part of the flow.

## Thresholds overview

---

1. **Click** “Thresholds” from the administrator menu.
2. The list of thresholds assigned to a specific patient group, which can be inspected, edited and deleted, is shown.
3. **Click** “Add threshold” to add a new threshold to the specific patient group. (see **Add threshold** section)
4. **Click** “Delete all thresholds” to delete all thresholds for the specific patient group.
5. This page contains filtering options. (see **Filtering thresholds** section)

## Add threshold

1. Select the Measurement type for the new threshold.
2. Select the Threshold type for the new threshold. Depending on the selected measurement type there are up to four possibilities:
  - Absolute
  - Relative latest
  - Relative period
  - Lag

each of these will be described in the following.

### Absolute thresholds

An absolute threshold compares a new measurement value with a fixed set of value limits when determining its severity.

3. Enter the relevant limits of the thresholds:
  - a. Red alarm (high): values greater than this trigger a red alarm.
  - b. Yellow alarm (high): values greater than this trigger a yellow alarm.
  - c. Yellow alarm (low): values lower than this trigger a yellow alarm.
  - d. Red alarm (low): values lower than this trigger a red alarm.

**Example:** if a patient submits a blood pressure measurement where the systolic value is greater than 120 mmHg then trigger a red alarm, if it is less than 120 mmHg but greater than 110 mmHg then

130 mmHg, then trigger a red alarm, if it is less than 130 mmHg but greater than 110 mmHg, then trigger a yellow alarm, and finally if it is lower than 110 mmHg then don't trigger any alarm.

4. Press Create to create the threshold for the patient group.

### Relative latest threshold

A relative latest threshold compares a new measurement with the latest measurement received by looking at the change in value between the two measurements when determining its severity.

3. Select whether to define the threshold limits for the measurement value change as a percentage or an absolute value.
4. Enter the relevant limits of the threshold.
5. Press "Create" to create the threshold for the patient.

**Example:** if a patient submits a weight measurement where the change in value compared to the previous measurement is greater than 2.5 kg, then trigger a red alarm, if it is less than 2.5 kg but greater than 1.5 kg then trigger a yellow alarm, and finally if it is lower than 1.5 kg, don't trigger any alarm.

**Note:** Because the relative latest threshold calculates the severity based on a previously submitted measurement, the very first measurement submitted by the patient will always trigger an orange alarm, as the patient will have no prior measurements to compare it to. If an orange alarm is shown, the clinician will need to assess the patient measurement manually.

### Relative period thresholds

A relative period threshold compares a new measurement to the measurement received previously within a given time period that has the highest or lowest value, and then looks at the change in value between the two measurements when determining its severity.

3. Select whether to define the threshold limits for the measurement value change as a percentage or an absolute value.
4. Select whether to compare the measurement with the highest or lowest value received within the time period.
5. Select whether the time period should be the whole time the patient has been enrolled or a period of the last number of days. If the latter, then enter the number of days to look back in time.
6. Enter the relevant limits of the threshold.
7. Press Create to create the threshold for the patient.

**Example:** if a patient submits a weight measurement where the change in value compared to the lowest measurement received within the last 5 days is greater than 2.5 kg then trigger a red alarm, if it is less than 2.5 kg but greater than 1.5 kg, then trigger a yellow alarm, and finally if it is lower than 1.5kg don't trigger any alarm.

**Note:** Because the relative period threshold calculates the severity based on a previously submitted measurement, the very first measurement submitted by the patient will always trigger an orange alarm, because the patient will have no prior measurements to compare it to. If an orange alarm is shown, the clinician will need to assess the patient measurement manually.

### Aggregate thresholds

When adding a new patient threshold, of one of the above types, it is possible to make it *aggregate*. This means that a measurement value has to exceed the threshold for at least a certain percentage of the latest received measurements. For example, if an aggregate threshold is set to 40% of the last 5 measurements, it means that at least 2 of the latest 5 measurements, including the latest one, must exceed the threshold (be it absolute or relative). If there are not enough previous measurements to evaluate an aggregate measurement, the measurement will trigger an orange alarm.

#### Example

If we have an **absolute** weight threshold with a **Red alarm (high)** set to 100 kg with aggregation set to 40% of the latest 5 measurements we get the following set of severities:

Measurement sequence (kg)					Severity
95	95	98	99	101	OK
95	98	99	101	99	OK
98	99	101	99	102	RED ALARM
99	101	99	102	98	OK

#### Adding aggregate thresholds

On the Add threshold page:

1. Select the Measurement type for the new threshold.
2. Select the Threshold type for the new threshold.
3. Check the Aggregation checkbox to enable aggregation.
4. Enter the percentage of the looked at measurements that need to exceed a limit, and then enter the number of measurements to look at.
5. Enter the relevant limits of the threshold.
6. Press “Create” to create the threshold for the patient.

In the above example, the threshold should be read as a normal absolute threshold except that it now requires 3 (60%) of the 5 latest received measurements to exceed a limit before the measurement triggers a yellow or red alarm.

## Lag

In contrast to the previous threshold types that are used for calculating the severity of a measurement attached to a questionnaire or an external measurement. The lag threshold is used for calculating the severity of a stream of measurements being continuously submitted by a patient, e.g. in a Virtual Ward scenario where a patient has a measurement device attached to them that continuously monitor and submits their vitals. The **lag** threshold works by looking at all measurements received within the last number of minutes and then calculates whether the trend of the patient’s severity is changing, thus minimizing any false alarms in the case where a patient has a very brief spike.

3. Enter the number of minutes back in time the threshold should compare measurements.
4. Enter the relevant limits of the thresholds:
  - Red alarm (high): values greater than this trigger a red alarm.
  - Yellow alarm (high): values greater than this trigger a yellow alarm.
  - Yellow alarm (low): values lower than this trigger a yellow alarm.
  - Red alarm (low): values lower than this trigger a red alarm.

**Example:** if all pulse measurements submitted by the patient within the last 5 minutes have a value greater than 100 BPM then trigger a red alarm, if all pulse measurements submitted by the patient within the last 5 minutes have a value greater than 90 BPM then trigger a yellow alarm, etc.

5. Press Create to create the threshold for the patient group.

## Filtering the list of thresholds

The list of thresholds shown in the **thresholds overview** can be filtered in the following ways.

1. **Select** a specific patient group to hide all other patient groups in the overview, or
2. **Select** a specific measurement type to hide all patient groups without a threshold defined for the selected measurement type.
3. **Click** reset filtering to show all patient group thresholds again.

## Schedule window

The “Schedule window” menu is used for changing the number of hours/days a questionnaire can be sent in before a deadline and still be valid.

## How to edit the window of a schedule type

1. **Click** “Schedule window” from the administrator menu.
2. The list of available schedule types when defining the schedule of a questionnaire is shown with the number of hours/days before a given deadline that it is possible for a patient to submit a questionnaire for it to be considered valid.
3. **Click** on a schedule type to edit the specific type.
4. **Press** “Edit” to navigate to the edit schedule type form.
5. **Enter** the number of minutes the schedule window should have.
6. **Press** “Update” to update the schedule window.

## Users

The “Users” menu is used for creating and administrating the clinical users of the OTH application.

## Creating a new user





1. **Click** “Users” in the administrator menu.
2. It is possible to search for a user by entering the name, or part of the name, of the user you are looking for and/or to limit the users shown to users assigned a specific patient group, and then **pressing** “Search”.
3. The list of users already created is shown.
4. **Press** “Create User” to create the new user.
5. **Enter** the first name of the user.
6. **Enter** the last name of the user.
7. **Enter** the user ID.
8. **Enter** the user name (It needs to be a unique username).
9. OTH assigns the user a temporary password. It needs to be changed the first time the user is logging into the system.
10. **Enter** the telephone number of the user.
11. **Enter** the mobile phone number of the user.
12. **Enter** the email of the user.
13. **Select** one or more patient groups that the clinical user should be assigned.
14. **Select** the user role(s) for the user.
  - Access all patients: Grant access to see all patients in the system.
  - Administrator: Grant access to all administration menus.
  - Clinician: Grant access to all clinician menus (those described in the clinician user manual).
  - Video consultant: Grant access to video conferencing functionality allowing clinicians to call up patients in the app.
15. **Press** “Create” to create the user.
16. The created user is shown.
17. If any corrections are needed for the created user, **Press** “Edit”.

## User roles

The “User roles” menu is used for creating and managing the user roles in the OTH system.

**Note: Changing the settings of the default user roles can have unexpected consequences, so please consult the OTH tech support before doing so at [tech-support@opentelehealth.com](mailto:tech-support@opentelehealth.com).**

### Creating and editing a user role

1. **Click** “User roles” from the Administrator menu.
2. The list of user roles already created in the system is shown.
3. **Press**  **Edit** to edit/change an existing user role.
4. **Press** “Create” to navigate to the create user role form.
5. **Enter** the name of the new user role.
6. In “Filter permissions” it is possible to filter the user permissions below, e.g. entering “Threshold” shows all permissions with the string “Threshold” in their name.
7. The list of all permissions.
8. **Click** on the  **Add** button to add permissions to the user role.
9. The permissions are paginated at the bottom of the screen.
10. The list of permissions assigned to the role can be seen in the list.
11. The search bar for filtering is above the list and can be used to filter out specific permissions.
12. **Click** on the  **Add** button to add permissions to the user role and  **Remove** to remove an already assigned permission from the user role.
13. **Click** “Create” to complete the assignment of permissions.
14. **Click** “Update” to update the assigned permissions to the user role.
15. User roles are now updated with the new permissions.



## API Clients

The menu “API Clients” is used for allowing and administering external access to the OTH APIs, e.g. from some 3rd party integration module.

**Note: A number of built-in API Clients exist and these cannot be edited or removed, but will be shown in the list of API clients.**

## Creating and Editing an API Client

---

1. **Click** “API Clients” from the Administrator menu.
2. The list of API clients already created in the system is shown.
3. **Press**  **Edit** to edit/change an existing API Client.
4. **Press** “Delete” to remove an API Client from the system.
5. **Press** “Revoke Keys” to revoke existing credentials for the API Client and generate new credentials. The new credentials will be shown in a popup dialog and must be copied for distribution from that dialog. This can be useful if credentials are lost or compromised.
6. **Press** “Create” to create a new API Client
7. **Enter** the name of the new API Client.
8. It is possible to copy all permissions from an existing user role to this API client
9. In “Filter permissions” it is possible to filter the user permissions below, e.g. entering “Threshold” shows all permissions with the string “Threshold” in their name.
10. The list of all permissions.
11. **Click** on the  **Add** button to add permissions to the API Client.
12. The permissions are paginated.
13. **Press** “Create” to create the new API Client.
14. The “Edit” flow is very similar to the create flow. For details see how to edit User Roles in the previous section.

## 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 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. 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.