tucuvi

# Instructions For Use (IFU)

## Tucuvi Health Manager (THM)

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# 1. Introduction

Tucuvi Health Manager is a software for automated follow-up of patients at home based on structured questionnaires called protocols. These protocols are composed of conversational flows (e.g., symptoms, state of well-being, vital signs, etc.) and rule conditions considered as alerts (e.g., fever over X degrees, saturation below X%, presence of dyspnea, etc.) that can be personalized for each individual patient.

Healthcare professionals build the protocols by combining the Tucuvi Portfolio conversational flows and configuring the different alerts that will be triggered depending on the patient responses. Healthcare professionals set the periodicity of the follow-ups through Tucuvi Dashboard or Tucuvi API. A virtual assistant, called LOLA, has a conversation with patients using Natural Language Processing (NLP) algorithms that follow the conversational flows that are part of the protocol. It collects and structures the information so that the alert system is triggered, and all the information is then visible through Tucuvi Dashboard (accessible via a web URL with personal, non-transferable credentials) or through their Electronic Health Record (EHR) when integrated through Tucuvi API. Healthcare professionals can be notified by email or SMS when alerts are triggered.

Tucuvi Health Manager is a Class I CE-marked medical device in accordance with the Medical Device Directive (MDD), Directive 93/42/EEC.
Tucuvi has implemented the measures to fulfil the requirements of Regulation (EU) 2016/679 (GDPR).

We recommend that you read the manual carefully before using the product. Please read the precautions with symbols carefully to ensure that the device is used safely and under optimum conditions.

## 1.1. Intended purpose

Tucuvi Health Manager (THM) is a medical device software (MDSW) intended for the automation of clinical conversation between LOLA, a virtual assistant, and patients at home using Conversational AI. It serves as an aid to Healthcare Professionals (HCPs) in the follow-up and management of patients' chronic diseases and acute care processes. THM analyses and structures patients' symptoms and health status collected during the

conversation into clinical concepts, triggering alerts for healthcare professionals when predefined risk conditions, configured by them in Tucuvi Dashboard, are met. This alert configuration is done at a protocol level and can be personalized for each individual patient. The information analyzed and structured is presented to healthcare professionals through Tucuvi Dashboard or Tucuvi FHIR API. Additionally, alerts are sent via email and/or SMS.

## 1.2. Intended users and qualifications and training required

Tucuvi Health Manager is designed to be used only by qualified personnel (healthcare professionals) to automate the follow-up and management of patients' chronic diseases and acute care processes.

Patients are not direct users of THM, but interact with the software while having the conversation with LOLA to provide information about their health status. This information is then provided to the HCPs.

Required training:

- Healthcare professionals, in addition to their medical training such as a degree in medicine or nursing, will receive a one-hour training session on how to use the Tucuvi Health Manager platform. This training is to ensure safe use of the platform before they begin using the product. The platform is not intended for non-professional users. For each clinical site where the device will be used, Tucuvi will be responsible for conducting the training, activating the specific Work Unit according to customer requirements, and providing support and follow-up.
- Patients do not require any specific training as they only need to answer a normal phone call and enter into a normal conversation.

## 1.3. Clinical benefits

- Tucuvi Health Manager improves patients' quality of life as it improves the clinical management of patients by the healthcare professional. By automating clinical conversations and triggering alerts following predefined rules, it allows HCPs to prioritize actions such as manually calling the patient, changing medication,

scheduling a clinical test, anticipating a clinical procedure, transferring the patient to another HCP, etc.

- Tucuvi Health Manager provides accurate medical information about patients' responses.
- Tucuvi Health Manager performs its intended function with the implication being that there is a clinical benefit to doing so.

In summary, the clinical benefits of Tucuvi Health Manager is the positive impact related to its function to automate the clinical conversations with patients at home for the follow-up and clinical management of chronic patients and acute care processes, providing accurate information regarding patients' symptoms and health status which can be used as an aid in the clinical management of the patient.

## 1.4. Warnings and cybersecurity

While Tucuvi Health Manager is highly adaptable, it is not recommended for use with patients who have severe speech or hearing impairments, or severe mental disorders unless the protocols are specifically tailored to accommodate these patients. This ensures that all patient interactions through the software are effective and sensitive to the specific needs of the patient population.

The software should only be used in combination with devices that meet the minimum requirements specified in section 3.1.

Cybersecurity user instructions:

- Cybersecurity

Tucuvi uses industry-standard controls to protect Tucuvi Health Manager software on Cloud. Our database integrates an authentication system to verify user identities before granting access to data. It implements security rules for tailored access control based on user authentication and data attributes. Additionally, it utilizes Transport Layer Security (TLS) to encrypt all data transmitted between clients and database servers, guaranteeing secure communication channels. Encryption of data at rest is also implemented, automatically encrypting data stored and thereby protecting it from unauthorized access. Data is automatically backed up and protected by encryption. In addition, Tucuvi regularly applies security patches for Tucuvi Health Manager.

Tucuvi has 2 different user roles: user and administrator. Administrators will have permission to create credentials and edit the alert protocols configuration.

Specific IT configuration requirements such as firewall rules are defined in Annex 1. Technical requirements EU (EN) (see section 3.1)

- Device Security

It is the responsibility of the authorized user to ensure that access to THM is not left unsecured when not in use to prevent non-authorized users from gaining access.

- User Responsibility

Usernames or passwords must not be shared with colleagues or others.
Users have access to patients' ePHI and must not take snapshots, screenshots, or pictures (e.g., using another device) of any information viewed through the device.

- Reporting Device Security or Privacy Breaches

Users must contact Tucuvi if they suspect or confirm any compromised user accounts or other privacy or security breaches.

- Recovery from Compromised Accounts or Devices

When accounts are considered compromised, credentials are lost, or unauthorized access is discovered or suspected, the user must contact Tucuvi's support team so that they can suspend and modify the user login criteria and issue new login credentials for the user to access their account securely.

- Unavailable Service

Users should report unavailable services or prohibited access to information to Tucuvi's support team.

## 1.5. Indications and patient population

Tucuvi Health Manager provides templates for common Chronic Care Management and Acute Care pathways and other Care Processes:

- Chronic Care Management: Chronic Obstructive Pulmonary Disease (COPD),

Heart Failure, Hypertension, Diabetes, Acute Asthma, Chronic Kidney Disease, Lupus, Multiple Sclerosis, Dermatological Disorders, Oncology, Arthritis, Arthrosis, Sleep Apnea, Complex/Multipathology Chronic Patient.

- Acute Care Management and Other Care Processes: Includes post-discharge follow-up, stroke prevention, digestive pathologies and alterations, bowel obstruction in ovarian cancer, psychological wellbeing assessment, surgery and clinical tests preparations (pre-anesthesia forms, endoscopy, instructions pre-surgery, etc.), post-cardiac surgery follow-up (TAVI/pacemakers), post-outpatient surgery follow-up, post-emergency visit follow-up, acute infections follow-up, post-infiltration follow-up, medical equipment needs assessments.

Those templates are always designed by Tucuvi's clinical team based on clinical guidelines and are ready to be used without any adaptations. However, our clients can adapt those templates during the implementation phase to fully meet their patient populations' needs. Some examples are the following:

- Follow-up of medication, CPAP
- Questionnaires to collect information for referral to a specialized service (e.g., using symptoms flows for collecting patient health status)

In addition, the software is set to handle non-clinical pathways such as cancer prevention campaigns (e.g., outreach for screening mammograms for women over 50), vaccination campaigns, scheduling consultations, etc. However, it should be noted that these are non-clinical pathways and do not fall under the classification of medical procedures.

The list of protocols including the questions and the alerts configured can be consulted by the user in the "Settings" menu at any time (see section 4.10).

Our main target populations are chronic patients of the aforementioned pathologies, patients that are in the middle of different acute care pathways such as a surgery or hospital discharge, and patients that undergo care processes where follow-up is needed.

The characteristics of age, weight, race, as well as the health condition (different to the

condition targeted by the protocol) are not relevant. The software is intended to use in patients of age >= 12 years, which are considered patients with adult speech and comprehension ability. Nevertheless, as we accept people answering on behalf of the patient (whether it be a caregiver, son, daughter, parents, etc.), patient age restrictions are not in place. We request that individuals answering the phone are at least 12 years old to ensure they are a suitable person to respond on behalf of the patient.

# 2. Conformity of use

The use of this device is strictly reserved for medical practitioners, or for use under their direct supervision. Any form of inappropriate usage is strictly prohibited. Users are required to:

- Abstain from altering or modifying the software.
- Uphold the safety and well-being of patients, other individuals, operators, assistants, and themselves by taking necessary precautions to prevent harm.

Prior to each usage, users are obligated to verify the security of the session and the operational condition of the devices. In this regard, it is essential to ensure that one is logged in with their personal account and possesses appropriate access to their designated patients. Subsequently, logging out at the end of Tucuvi Dashboard usage is imperative. This practice safeguards against unauthorized access to patient data and prevents any unauthorized alterations to patient tracking.

# 3. Technical specifications

## 3.1. Requirements for THM access

THM can be accessed on Cloud or integrated via API:

- Access requirements for Tucuvi Dashboard (Annex 1. A3-SOP-10_Technical requirements): This document is given to our client's IT departments to make sure that they take the necessary steps when it comes to networking and firewall perimeters to allow HCPs to enter Tucuvi Dashboard through Google Chrome in its latest version:
    - For the installation of Google Chrome, a free web browser, the professional must

first check whether it is compatible with their operating software and whether it meets the system requirements.
    - System requirements and installation guides for Windows, Ubuntu, and MacOS can be found here.
    - The use of the Tucuvi Dashboard is ensured with the latest version of Google Chrome available at that time. The current guaranteed version is v124.
    - It is recommended to set the Zoom in Google Chrome to 100% for optimal use of the platform. Higher Zoom levels may require the use of scroll bars to navigate the platform.
- The FHIR API is compatible with the FHIR standard. For the use of the FHIR API follow the documentation provided in Tucuvi FHIR API Reference.

### 3.1.1. Credentials

The healthcare professional must login to Tucuvi Dashboard using their personal credentials (email address and password), provided by Tucuvi. After the first login, the user must change their password. This must have a minimum of 8 characters, including 1 number and a special character (,._-;¿?¡!*{}).

Every user has the ability to access profiles associated with their work unit via Settings (refer to the icon in section 4.2), see Figure 1. Additionally, administrators of each work unit not only have the privilege of viewing these profiles but are also authorized to manage access for other healthcare professionals within their unit via the “New credentials” screen in Settings (Figure 2). Through this interface, administrators are granted permission to create or deactivate profiles as needed.

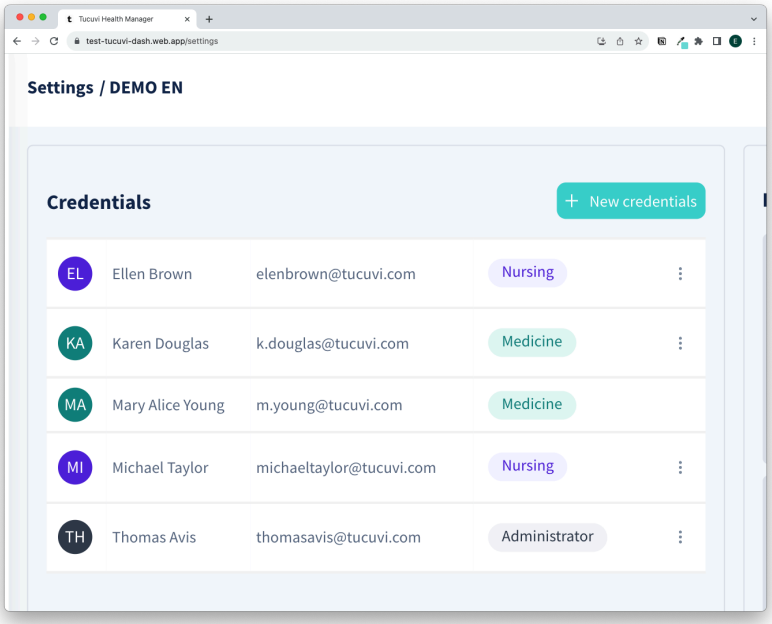



*Figure 1. Settings - Credentials screen.*

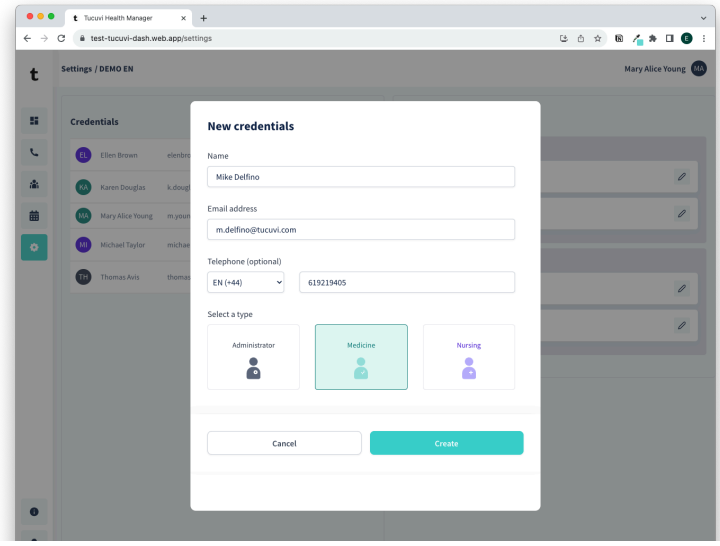



*Figure 2. Settings - New credentials screen.*

### 3.1.2. Credentials removal

When it is necessary to remove the access of a professional, it can be done through the credentials screen mentioned above. If you require any support during this process contact Tucuvi, who will proceed with permanent deletion of the credentials.

## 3.2. Interaction of Tucuvi Health Manager with the patient

The patient will receive phone calls via LOLA, Tucuvi Health Manager's Virtual Assistant. For this interaction, the following instructions should be provided:

- The patient should have available their landline or cellphone with a good signal.
- The patient should have a normal conversation with LOLA.
- LOLA will introduce itself during the first call indicating its purpose and the frequency of the calls.

# 4. Advanced features

In the following we will detail the functionalities and views the user interface contains to provide a better and efficient management of the software.

## 4.1. Login

User credentials for each professional will be generated by Tucuvi upon request from the head of the medical team. This request will include the practitioner's full name, surname, and the email address associated with Tucuvi Dashboard access. Once this information is entered into the authentication system, an automated email notification will be dispatched to inform the user that Tucuvi Dashboard access has been authorized.

If the user forgets the password, they can use the "Change Password" option on the login screen. They will receive an email with the instructions to follow in order to reset the password.

## 4.2. Navigation

| | |
|---|---|
|  | **Working list (optional)**. See section 4.4. |

| | |
|---|---|
|  | **Call list**. See section 4.3. |
|  | **Patient list**. See section 4.5. |
|  | **Statistics (optional)**. See section 4.11. |
|  | **Calendar**. See section 4.12. |
|  | **Settings**. See section 4.10. |
|  | **Software information**. See section 4.14. |
|  | **Logout button** |
|   | **Professional profile**. See section 4.13. |

*Table 1. Navigation icons.*

## 4.3. Call List

The **Call List** screen serves as the primary interface that is accessible immediately upon successful credential verification. It provides an overview of all calls, arranged from the most recent to the least recent, both answered and unanswered. They can be filtered by assignee, protocol, date and alert severity. There is also a search filter to locate the calls associated by ID or name.

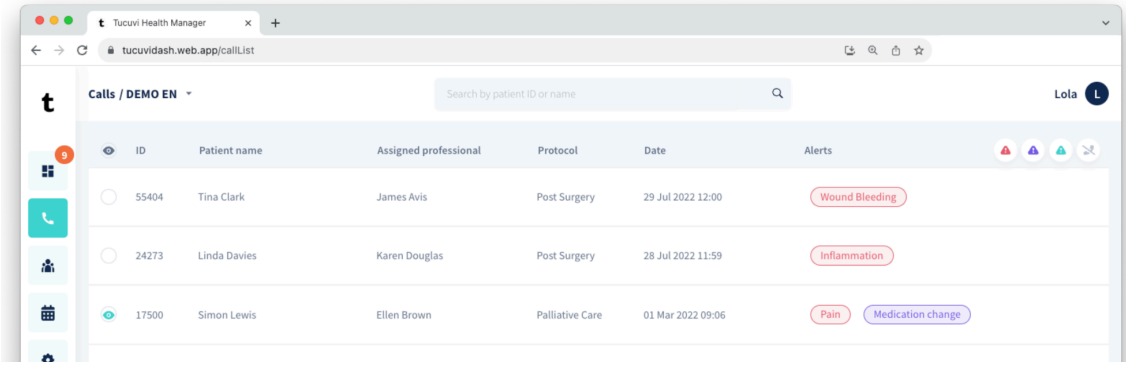



*Figure 3. Call List view.*

Calls are presented in the list in one of two ways, contingent upon whether they have undergone review by a healthcare professional. The ideal situation is that all calls are marked as reviewed as soon as possible.

| | |
|---|---|
|  | Review icon and filter. |
|  | Indicates that the call has already been reviewed. |
|  | Indicates that the call has not been reviewed yet. |

*Table 2. Call review status icons.*

The call list displays different types of information arranged in columns:

| | |
|---|---|
| **ID** | Entered manually at the time of the patient's inclusion in the user interface; a required field in the Personal Data section. |
| **Patient's name and surname** | The name and surname of the patient who has received the call. As there may be more than one patient with this identical information, the use of the Clinical ID field is recommended to verify the identity. |
| **Assigned professional** | The professional in charge of the patient's monitoring, who will be notified in the event Tucuvi Health Manager detects any alert in the patient's call. |
| **Protocol** | The protocol that the patient has responded to in the call. |
| **Call date** | The date and time the patient was called. |

| | |
|---|---|
| **Alerts** | All the alerts in each call, color-coded by severity. For every call, two alerts are presented, and if additional exist, they are consolidated under a "+number" notation. Hovering over the button will display all.<br><br>General wellbeing  Dyspnoea  +4 |

*Table 3. Columns in Call List view.*

### 4.3.1. Quick call filters

Located in the top right corner. These filters can be deactivated by clicking on them.

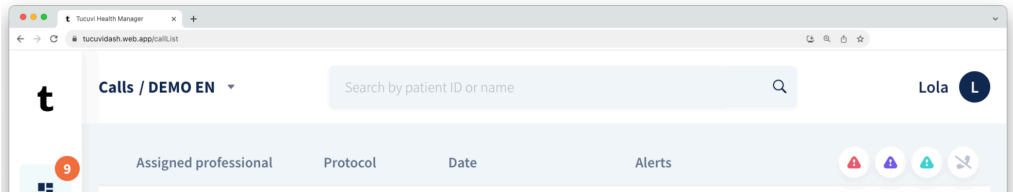



*Figure 4. Quick call filters.*

| | |
|---|---|
| | Only calls with at least one **severe alert** are shown. |
| | Only calls with at least one **medium alert** are shown. |
| | Only calls with at least one **mild alert** are shown. |
| | Unanswered calls are hidden. Only answered calls are shown. |

*Table 4. Description of Quick Call filters.*

## 4.4. Working list (optional)

This is an optional view that can be enabled per unit. It has 2 blocks:

- **Pending calls to review**: provides a filtered list of calls that meet predefined conditions, such as specific alerts, answered calls only, calls from the last week,

among others. The information displayed for each call is the same as in the "**Call List**". This allows healthcare professionals to prioritize their review by focusing on the most relevant calls.
The filters to be applied are initially defined by the Unit Manager, but they can be modified by clicking the "+" button located above the call list and configuring the desired filters. The icon in the side-menu indicates the number of calls present in the filtered list, providing an overview of pending tasks.

- **Ongoing conversations:** shows the calls that LOLA, the virtual assistant, has scheduled for the day, as well as the time at which these calls will be made.

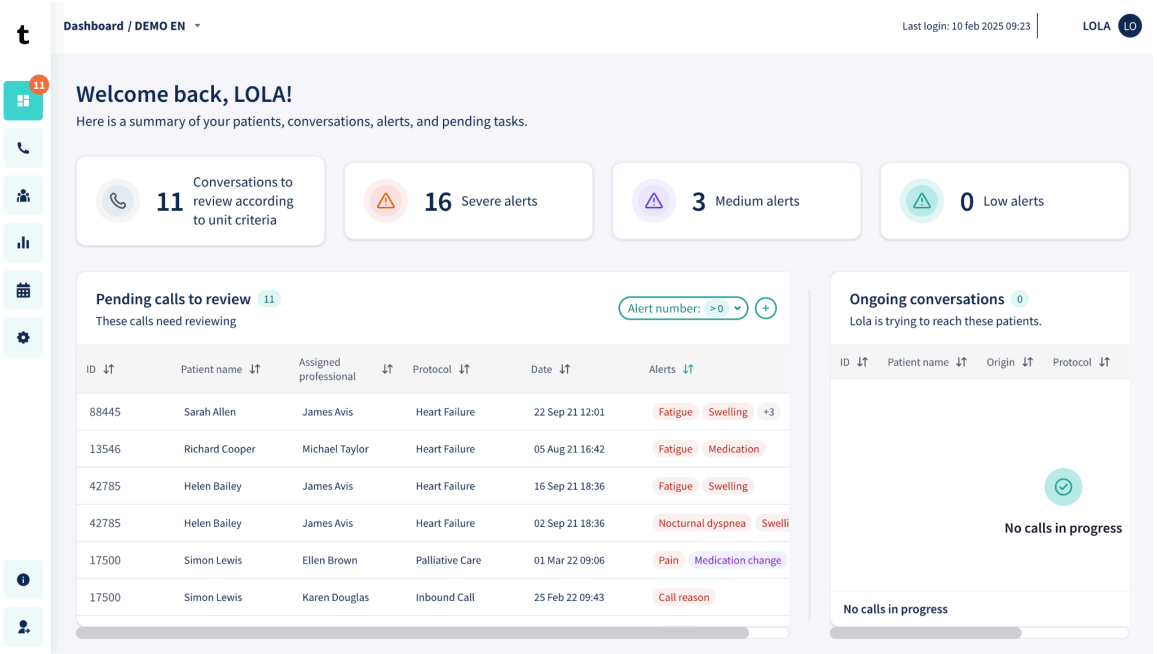



*Figure 5. Working list view.*

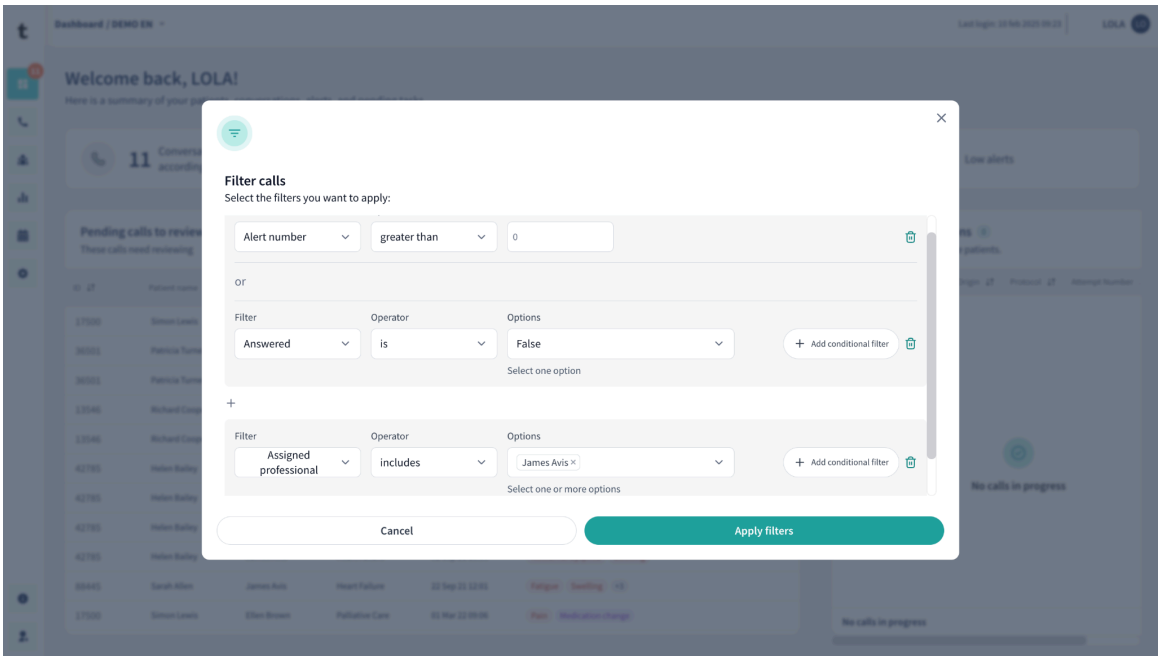



*Figure 6. Configuration of Working list view*

# 4.5. List of patients

The **Patients** screen displays all patients who are included in Tucuvi Health Manager. The list of patients is sorted so that recently added patients appear at the top and the patients added first appear at the bottom. There is also a search engine that allows you to locate them by name, surname or ID. The list of patients displayed shows all that match the data provided.

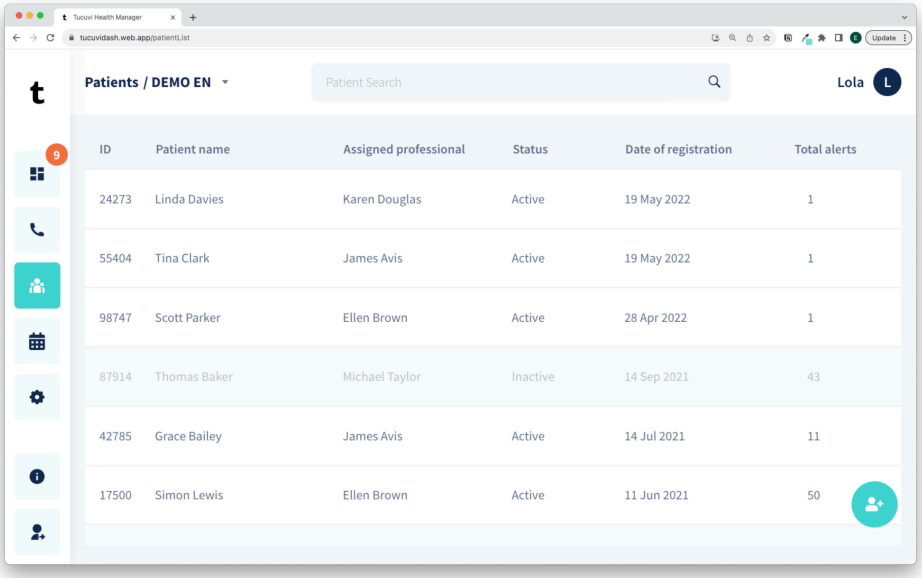


*Figure 7. List of patients view.*

The list of patients is arranged in a similar way to the call list, but displays different information. Some is the same as the information in the call list, but others are specific to this section.

| | |
|---|---|
| **ID** | Entered manually at the time of the patient's inclusion in Tucuvi Health Manager, a required field in the Personal Data section. |
| **Patient's name and surname** | The name and surname of the patient who has received the call. As there may be more than one patient with this identical information, the use of the Clinical ID field is recommended to verify the identity. |
| **Assigned professional** | The professional in charge of the patient's monitoring, who will be notified if Tucuvi Health Manager detects any alert in a patient's call. |
| **Status** | This indicates whether the patient is currently active (so receiving calls) or inactive. Inactive patients are highlighted in light grey. |
| **Date of registration** | The date when the patient was registered in Tucuvi Health Manager, providing information on how long the patient has been in the software. |
| **Total alerts** | The total number of alerts in all the patient's calls. |

*Table 5. Columns in the list of patients.*

## 4.6. Add patient

To create a new patient, select the **Add patient** icon, located in the bottom right corner, and enter the relevant data. Once completed, the patient is saved and registered in Tucuvi Dashboard.

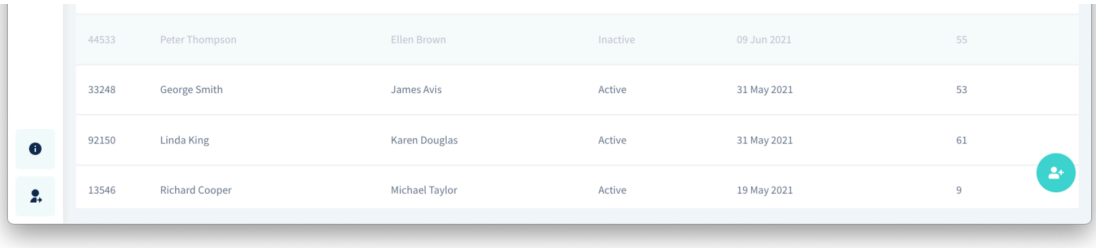



*Figure 8. Add patient icon.*

Upon clicking this button, a window will be opened, allowing you to enter the details. There are several fields, whose data will be common to all calls and protocols that are activated for the patient.

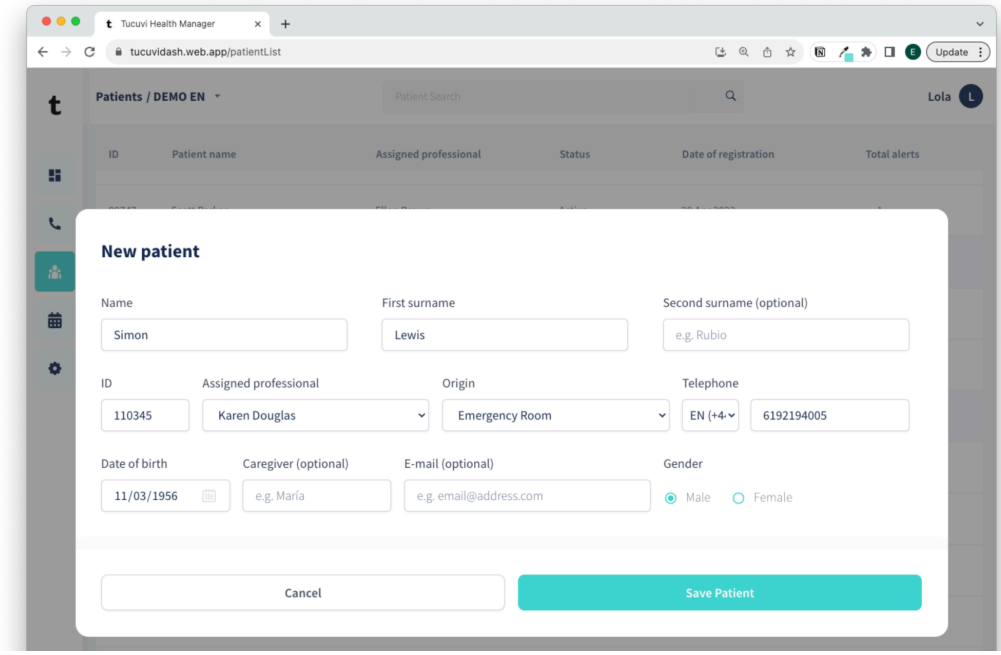



*Figure 9. Create a new patient view.*

| | |
|---|---|
| **Name and surname** | The name and surname of the patient. |
| **ID** | Unique, personal and non-transferable for each patient. It might correspond to the associated clinical history code. |
| **Date of birth** | Entered via the keypad in format dd/mm/yyyy or via calendar. |

| | |
|---|---|
| **Assigned professional** | The professional in charge of the patient's monitoring, who will be notified if Tucuvi Health Manager detects any alert in a patient's call. |
| **Telephone** | The phone number where the patient wishes to be reached. It is advised that the chosen phone line is both easily accessible to the patient and uncomplicated for them to use. This mitigates potential errors during calls, such as unexpected hang-ups or not knowing how to answer the call. The line must remain operational for as long as the software is being used. Users must check the validity of the telephone number. |
| **Gender** | Gender pronouns are used during the call. The one the patient identifies with should be chosen to personalize the call. |
| **Origin** | The origin of this new patient, such as the hospital unit. |

*Table 6. Create new patient fields.*

All mandatory fields must be completed. If any field is incomplete, the edges will be highlighted in red and no saving will be allowed. Upon creation, you'll be redirected to the patient record.

### 4.6.1. Bulk Loading (optional)

This discretionary feature allows the creation of multiple patients at the same time by uploading a CSV file. A downloadable template is provided for this purpose. Instructions are displayed on the screen to guide users through the process.

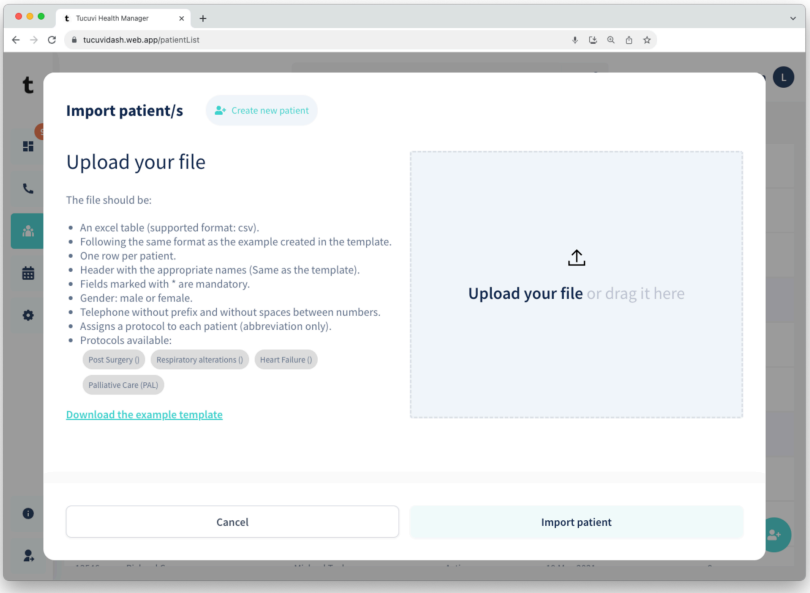



*Figure 10. Import patients through a CSV file view.*

## 4.7. Setting up calls

To schedule calls for a protocol, it is necessary to open the patient record.

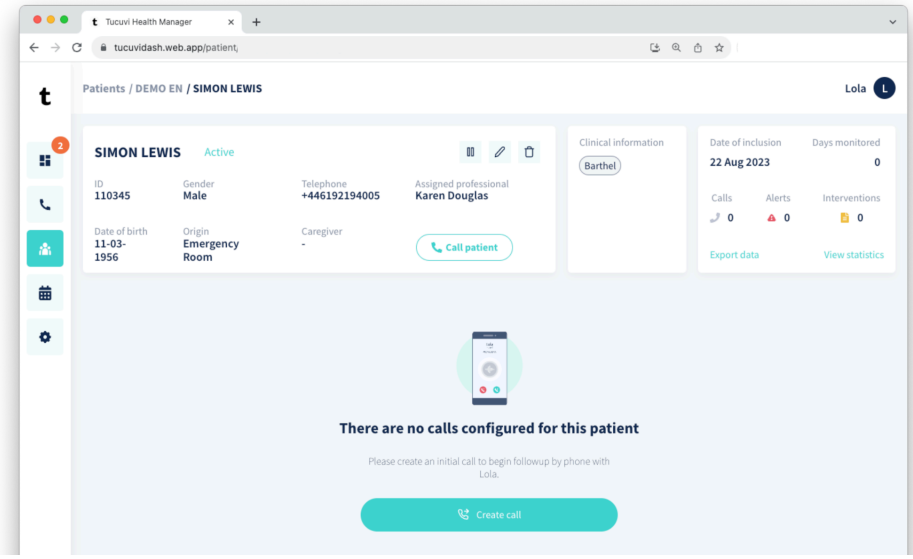



*Figure 11. Patient record view.*

Only the protocols agreed with the customer will be available for selection in their unit. There are several fields that must be completed:

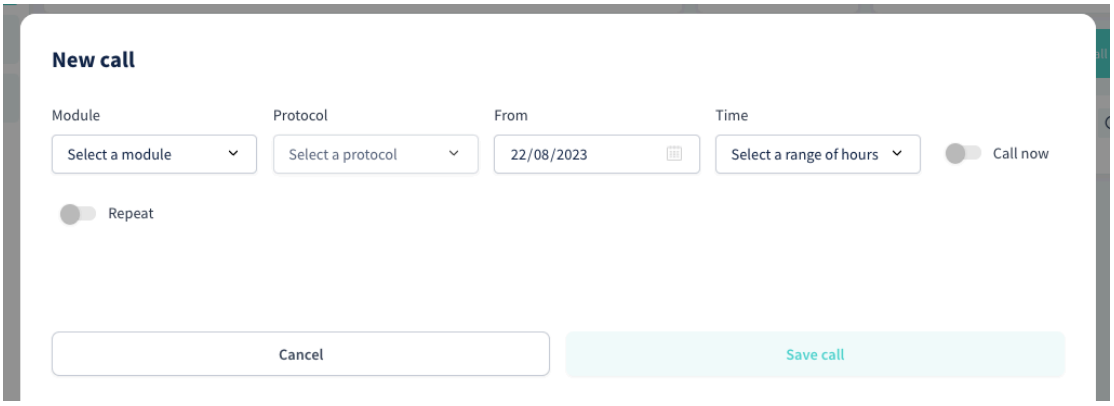
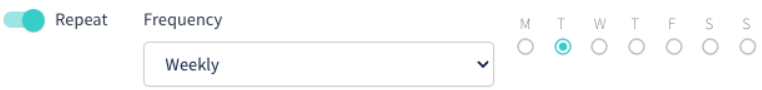



*Figure 12. Create a new call view.*

| | |
|---|---|
| **Module** | Required to specify the protocol, as they are grouped by this field. |
| **Protocol** | For each module, drop-down menu with the associated protocols. |
| **Start date (From)** | The date the first call will be launched, always in the future. Can be entered via keypad in format dd/mm/yyyy or via calendar. |
| **Time** | The designated time range during which the patient should receive the call. It is recommended that the time is chosen by the patients themselves, within the medical indications necessary for each protocol, to improve the answering rate. |
| **Repeat** | In the case of a single, one-off call, this selector shall be set to "off" mode. Thus, the call will only be made on the date and time previously indicated, with no repetition. Conversely, if you wish to make this call periodically, this button must be “on” and an additional section will appear.<br>  |
| **Frequency** | How often the calls will be scheduled:<br>• Daily: every day matching the days of the week selected.<br>• Weekly: every 7 days.<br>• Fortnightly: every 14 days.<br>• Monthly: every calendar month.<br>• Quarterly: every 3 calendar months.<br>If daily periodicity is selected, the call will be configured from |

| | |
|---|---|
| | Monday to Sunday by default, but the days of the week are completely customizable, so you can select between 2 and 7 days a week to schedule the call. This call will always take place at the same time.<br><br>For the other options, there is only one day of the week, so if Tuesday is selected and it is weekly, the call will be made every Tuesday; in the case of fortnightly, every other Tuesday; and in the case of monthly it will be every four (or five) Tuesdays, depending on the month's duration. |

*Table 7. Schedule a call fields.*

### 4.7.1. Add, edit and pause calls

If the patient needs to receive several calls (i.e. several protocols), all these calls can be created with the "**Create call"** button. Should there be a need to temporarily halt or modify a call, such actions can be accomplished by selecting the icons located in the upper-right corner of the respective call box.

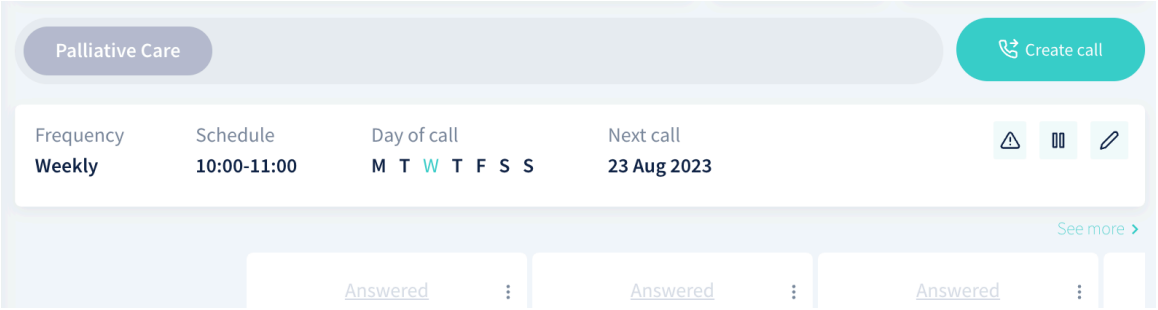



*Figure 13. Create a call button view.*

| | |
|---|---|
| Create call | Used to create a new call. |
|  | Used to edit an existing call. Fields are the same in *4.7. Setting up calls.* |
|  | Used to pause an existing call. |
|  | Used to resume a paused call. Fields are the same in *4.7. Setting up calls.* |

| | |
|---|---|
| ⚠ | Used to personalize alerts. See *4.10.2. Alert per patient (optional)* |

*Table 8. Add, edit and/or pause calls options.*

## 4.8. Patient record

Each patient has a personal screen where both their personal data and the information collected in every call, grouped by protocols, are collected. The upper section contains personal data, clinical information and statistics, and the lower section displays the list of calls made.

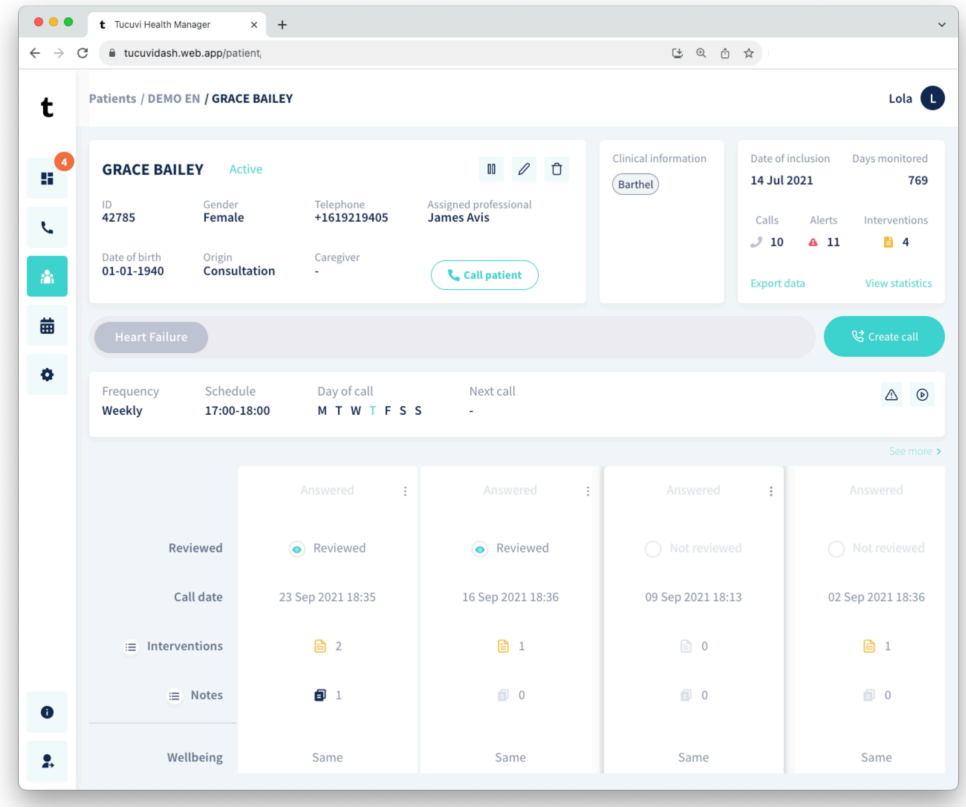
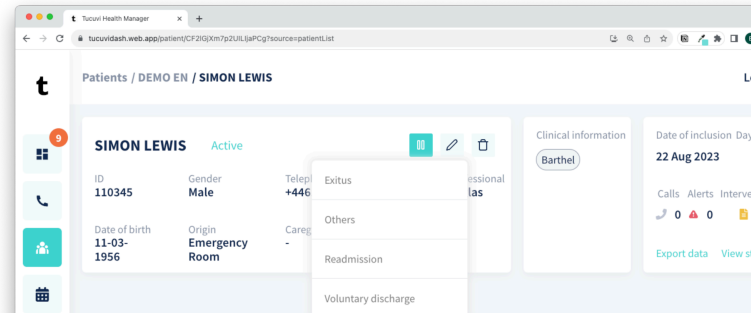
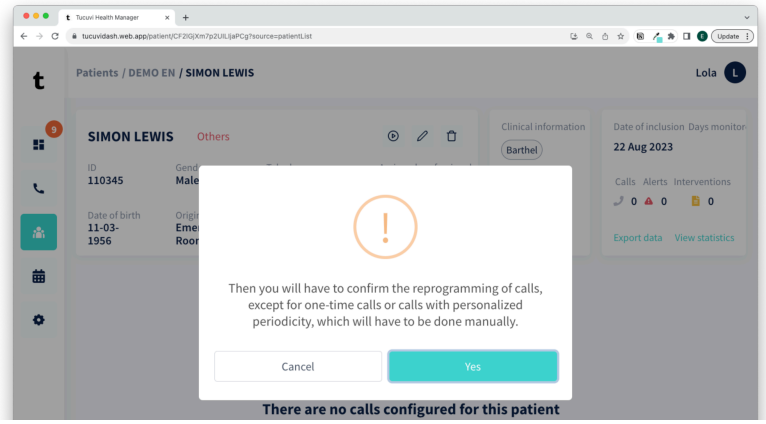



*Figure 14. Patient record and calls view.*

### 4.8.1. Edit and inactivate patients

In the top right corner of the patient block:

| | |
|---|---|
|  | It allows you to edit a patient. Fields are the same shown in *4.6. Add patient.* |
|  | Inactivates the patient. The cause of the discharge must be selected in the drop-down menu. The patient will not receive more calls, but all information is stored in Tucuvi Dashboard.<br>  |
|  | Used to reactivate a patient who had been previously inactivated. Follow the instructions in Tucuvi Dashboard to also resume calls.<br>  |

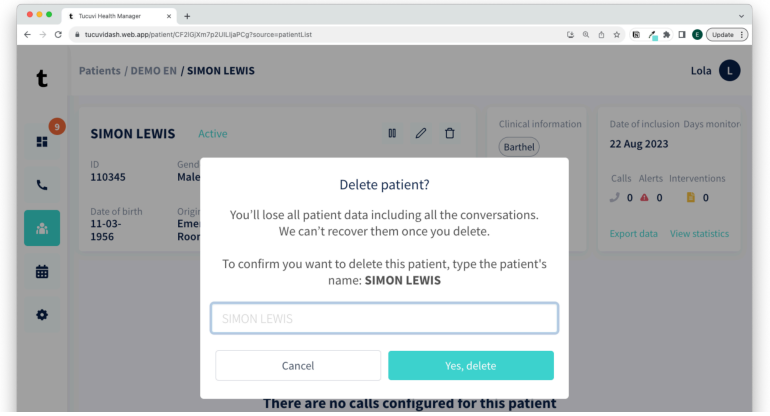
| | |
|---|---|
|  | **This button is optional, hidden unless requested.** It allows the deletion of a patient permanently, including personal data and all conversations. This action cannot be undone once confirmed.<br>  |

*Table 9. Actions on patients screen.*

## 4.8.2. View patient statistics

It provides a summary of patient data: date of inclusion, days monitored, number of calls and distribution of alerts and interventions.

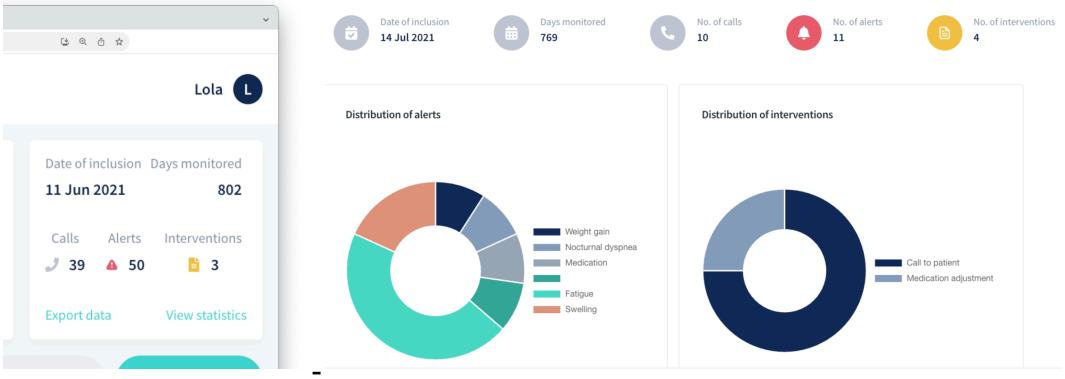



*Figure 15. Patient statistics view.*

## 4.9. Conversation columns

Below the patient data, you will find all the information about the calls received, grouped by protocol. Each protocol displays the information related to the scheduling (frequency, days of the week and time) and all the calls made.

Every call is shown with its date, whether it has been reviewed, the notes and

interventions added by healthcare professionals after reviewing the symptoms and answers gathered. The questions made by the assistant are displayed upon clicking on the symptom name.

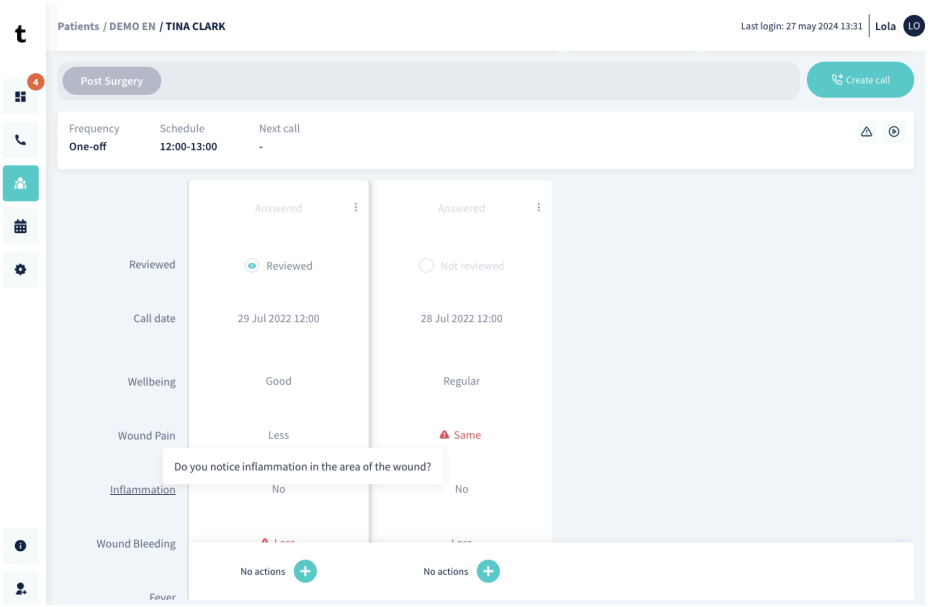



*Figure 16. Conversation details view.*

| | |
|---|---|
| Not reviewed | Indicates the call has not been reviewed yet. |
| Reviewed | Indicates the call has been reviewed. |
| Patient hung up | If the conversation is incomplete, where the patient hung up.<br>31 Ago 2021: 0, 0, Worse, No<br>26 Ago 2021: 0, 0, Patient hung up, -<br>14 Ago 2021: 0, 0, Better, No |

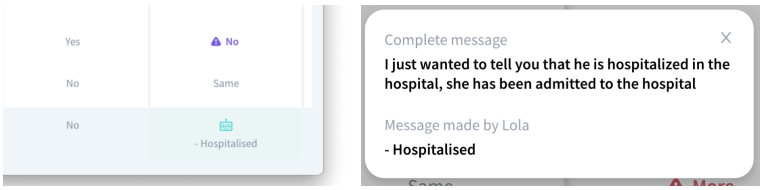
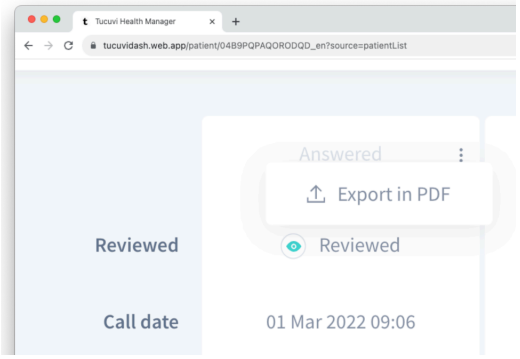
| | |
|---|---|
| **Smart summarization** | Clicking on it shows the whole patient transcript and the summary made by LOLA.<br>  |
|  <br>**Review button** | When clicking on the Review button a new view is opened (see section 4.9.1.) |
| **More options icon** | **This is optional**. It shows more actions, like export PDF.<br>  |

*Table 10. Conversation details meaning.*

### 4.9.1 Conversation review

- **Create a Care Plan**

In this view, users can create a Care Plan for the patient. It allows the healthcare professional to review in detail the information collected from the patient's call and the alerts created and note any action taken on the right. Once the review is completed, they can click on Save and proceed to store the review.

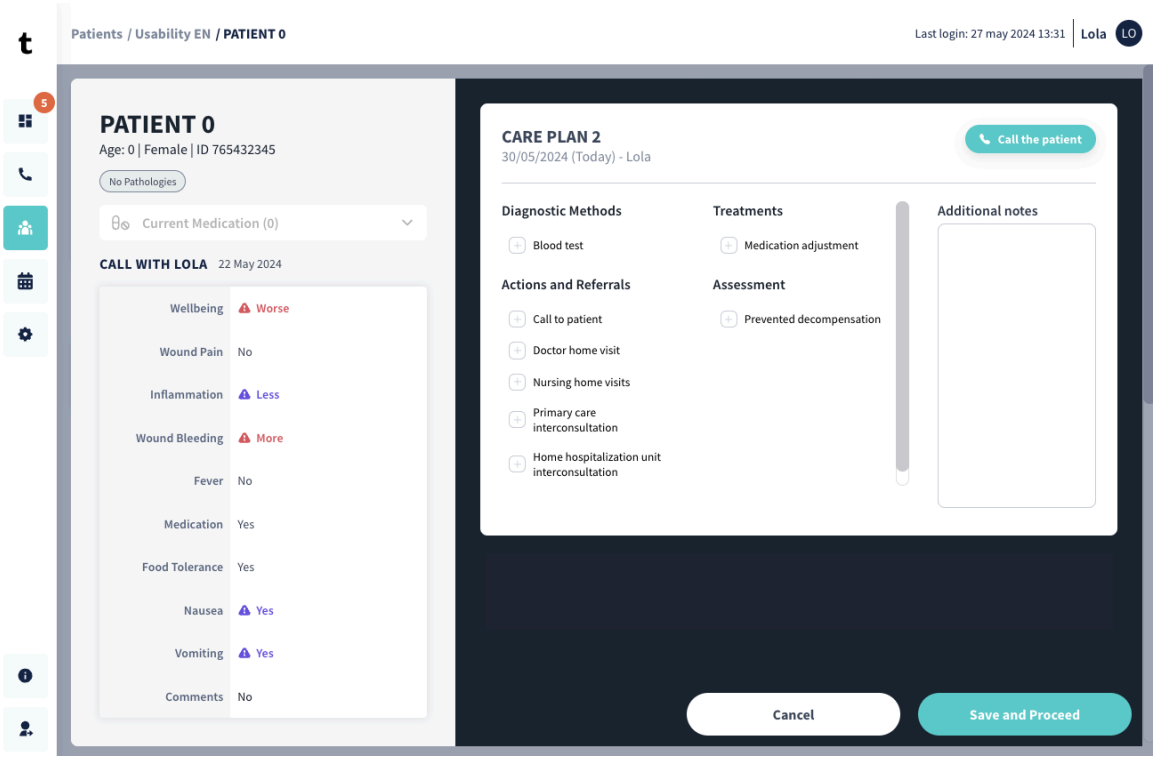



*Figure 17. Review panel.*

- **Phone Visit with Scribe**

The user may call the patient while reviewing the call clicking on “Call the patient”. Once the conversation between the healthcare professional and the patient is finished, an automatic summary is created.

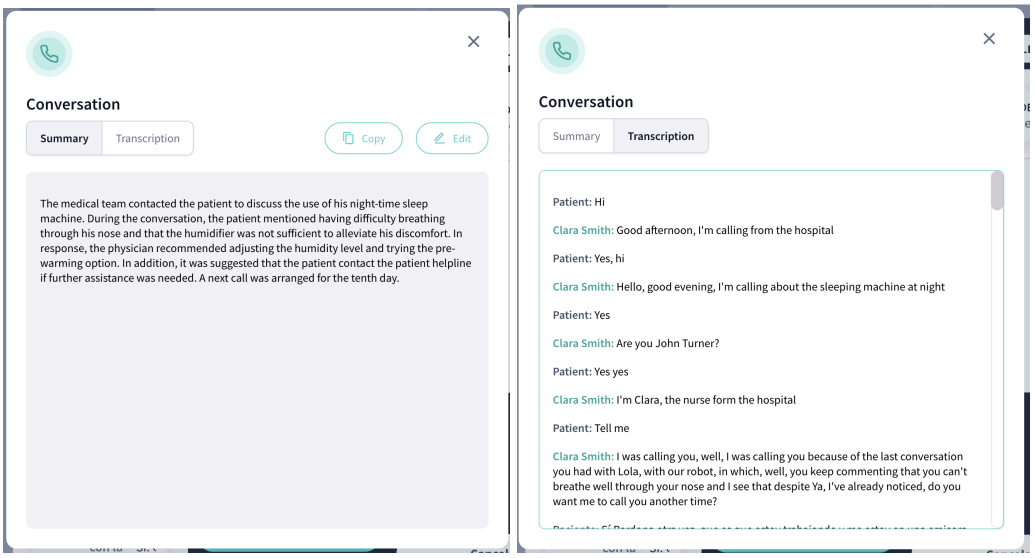
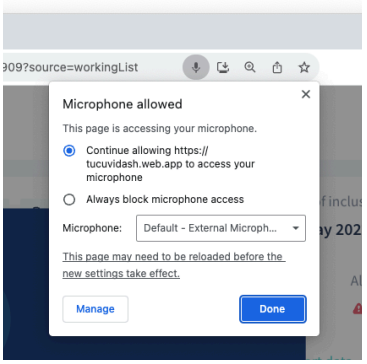



*Figure 18. Phone visit with Scribe.*

**Important Consideration: Microphone Access**

To enable audio communication during the call, ensure that your web browser has permission to access the computer's microphone. Modern web browsers typically prompt users to grant access to their microphone when initiating a call.




# 4.10. Settings - Protocols and Alerts

The principal objective of patient calls is identification of potential alerts. To this end, a series of alerts have been defined during the protocols' developmental phase. Protocols are structured around conversational flows (such as dyspnea, pain, temperature, etc.). For each of them, specific responses are cataloged as alerts (increased dyspnea, exacerbated pain, temperature surpassing a designated threshold, etc.).

Patient responses categorized as alerts are colored in the patient record. They are categorized into 3 groups sorted by urgency: severe (red), medium (purple) and mild alerts (blue).

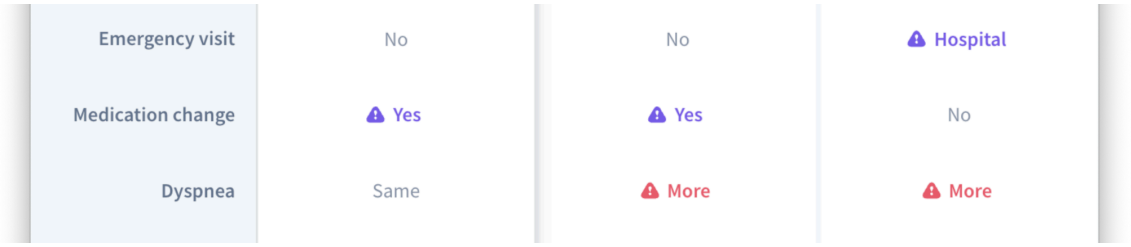



*Figure 19. Alerts in conversations view.*

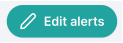
| | | |
|---|---|---|
| Severe alert. | Medium alert. | Low/mild alert. |

*Table 11. Alert icons meaning.*

The configuration of alerts is accessible through the **Settings** screen. In this screen, the users can review the complete list of questions included in each of the protocols and the associated alerts configured in their unit.

**Alerts Customization:**

The following configurations can be edited by the user using the “Edit alerts” button




1. **Enable/Disable Alerts:**
    a. **Enabled Alerts**  **:** When an alert is enabled, it means that the alert is active. If a patient’s response matches the defined condition (e.g., temperature surpassing a threshold), the alert will be triggered.
    b. **Disabled Alerts**  **:** When an alert is disabled, it means that the alert is inactive. Even if a patient’s response matches the defined condition, no alert will be triggered for any patient.
2. **Severity Adjustment:** The urgency level of alerts can be modified by clinicians. Alerts are classified into:
    a. **Severe** (red)
    b. **Medium** (purple)
    c. **Mild** (blue)
3. **Occurrences:** Clinicians can define the number of consecutive times a condition must be met before activating the alert. This provides flexibility to minimize unnecessary notifications while maintaining patient safety.

**Types of Alerts:**

- **Categorical Alerts:** These are based on specific conditions reported by the patient, such as "the pain has increased" or "the mucus is green".
- **Numerical Alerts:** These rely on measurable values, such as "saturation below x%" or "fever over X degrees". Numerical alerts have additional attributes:
    - **Threshold:** This determines the value at which the condition triggers an alert. Thresholds can be assessed through:
        - The value extracted during the current conversation.
        - Comparison with the previous call.
        - Comparison with the patient's baseline value.
    - When comparing values, the change can be:

- A **relative change** (percentage increase or decrease).
- An **absolute change** (specific increase or decrease in value).

By default, exclusive authorization to edit alerts is vested in the head of the unit. However, in response to specific requests, this permission can be extended to other designated profiles.

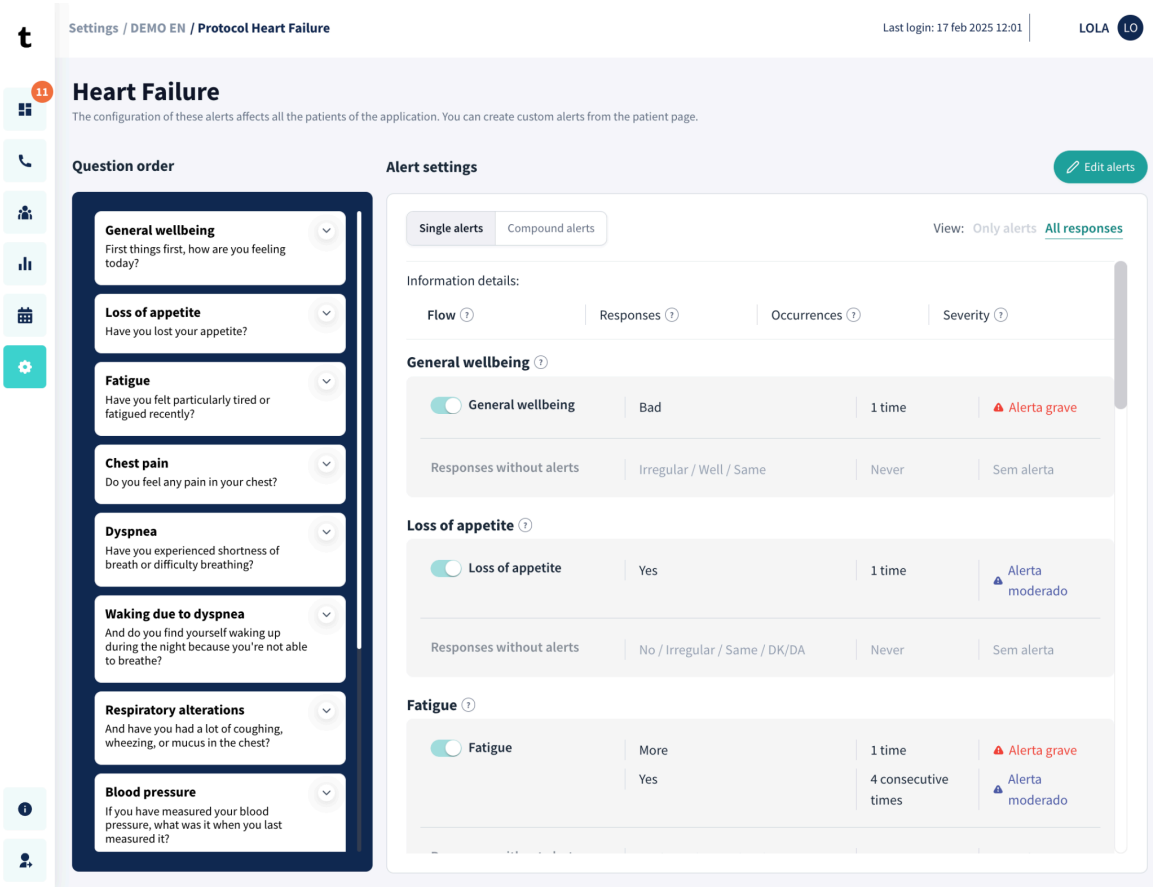



*Figure 20. Configuration of alerts view.*

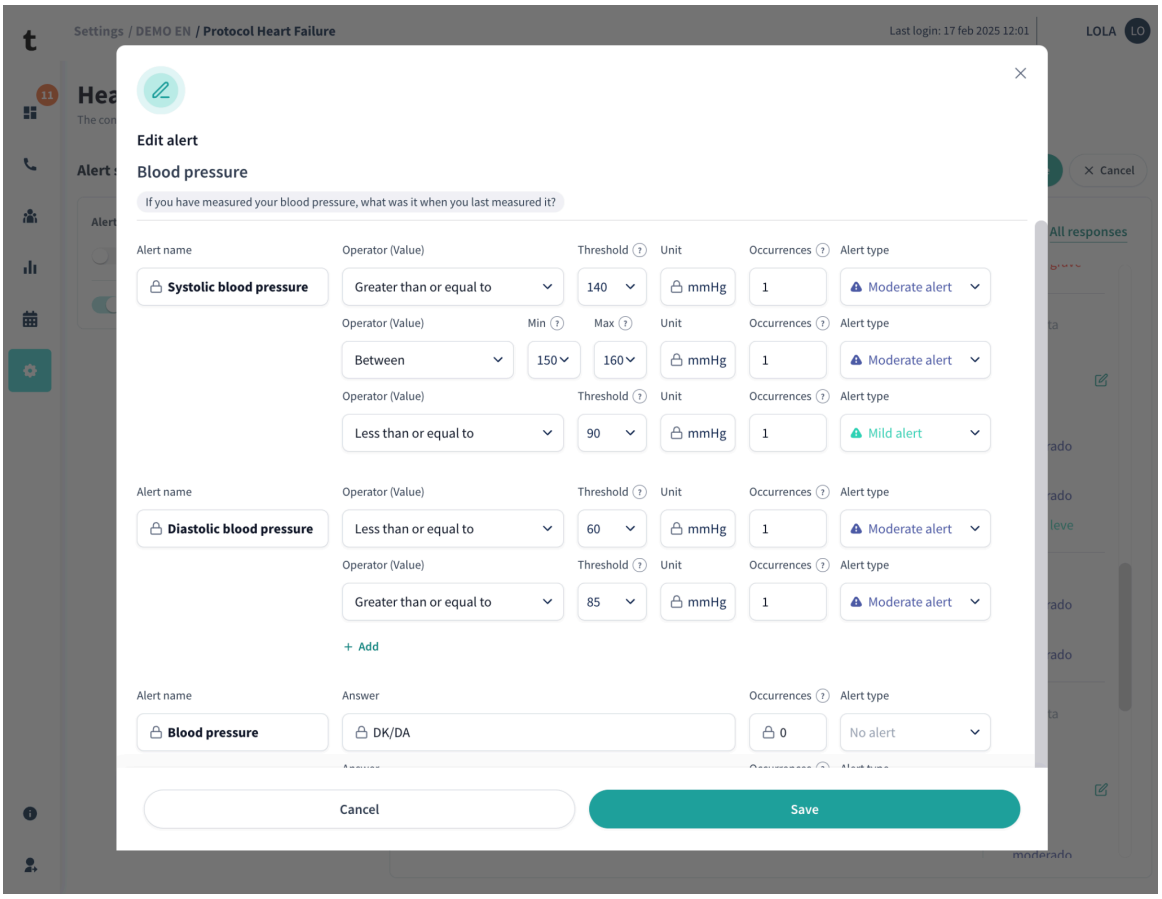



*Figure 21. Example of a single alert configuration.*

## 4.10.1. Alert notification to professionals

See section *4.13.3 Notifications*.

## 4.10.2. Alert per patient (optional)

This discretionary feature can be activated on a per-unit basis. Upon activation, the parameters that are modifiable in the *Settings* section can also be edited within the patient record. This can be accomplished via the alert icon, which shows how many personalized alerts the patient has.

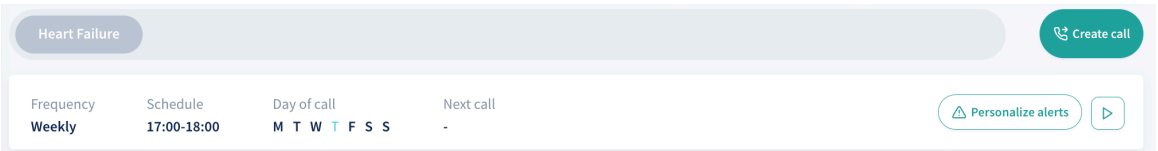



*Figure 22. Alert per patient button.*

Clicking this icon will open a pop up window to tailor alerts to the patient's specifics. Likewise, alerts can be reset to the default settings, negating any personalizations previously applied.

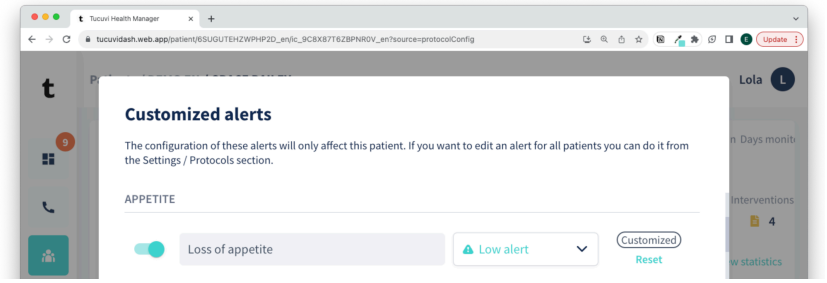
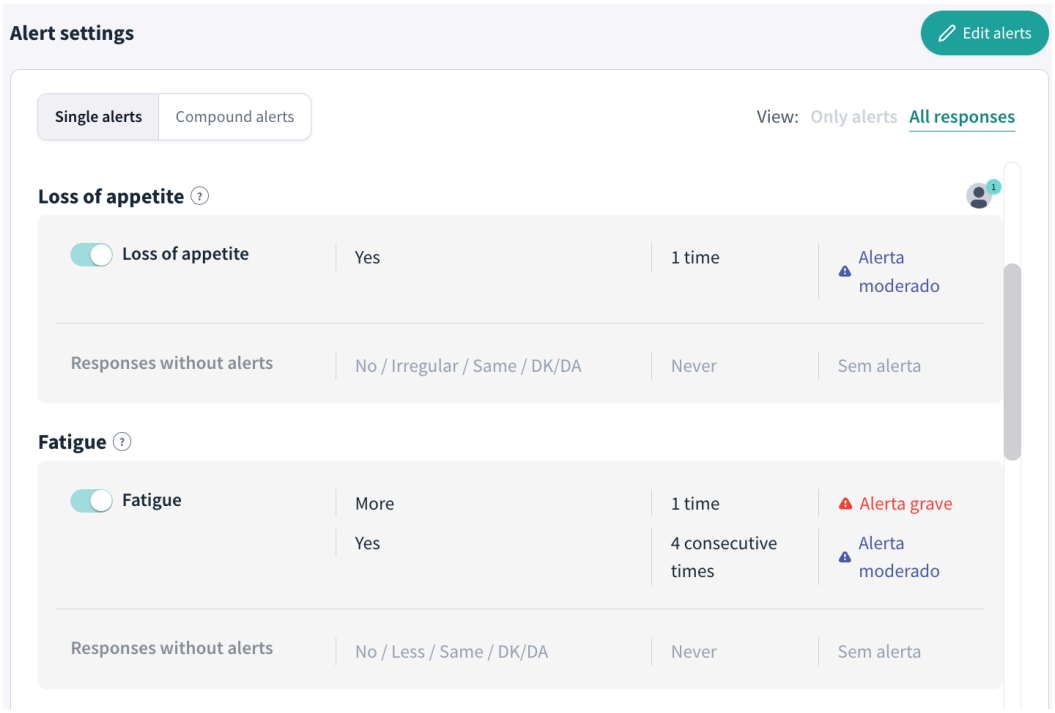



*Figure 23. Alert per patient configuration view.*

In the general settings it can be seen immediately if there is a personalized alert for any patient. **In the event that personalized alerts have been established for any patient, it's important to note that modifying alerts in this general settings screen will not impact these patient-specific configurations.** This ensures that alterations made in the general settings will not inadvertently alter personalized alert settings for individual patients.



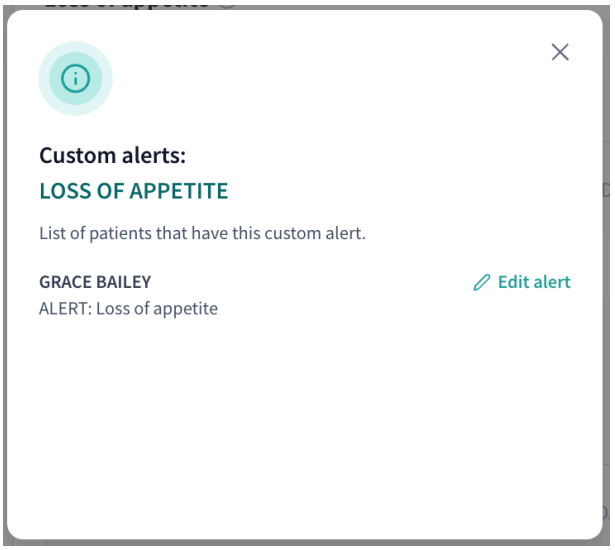



*Figure 24. General alert settings view.*

## 4.11. Statistics (optional)

This optional view can be activated per Work Unit. It provides a comprehensive compilation of data pertaining to patients, calls, alerts, and interventions, spanning a designated time frame. On the left side of the interface, an array of filters is presented, encompassing elements like the time period, patient demographics, and call variables, inclusive of alerts and protocol names. These filters collectively serve as a mechanism to extract and scrutinize pertinent information relevant to the specified parameters.

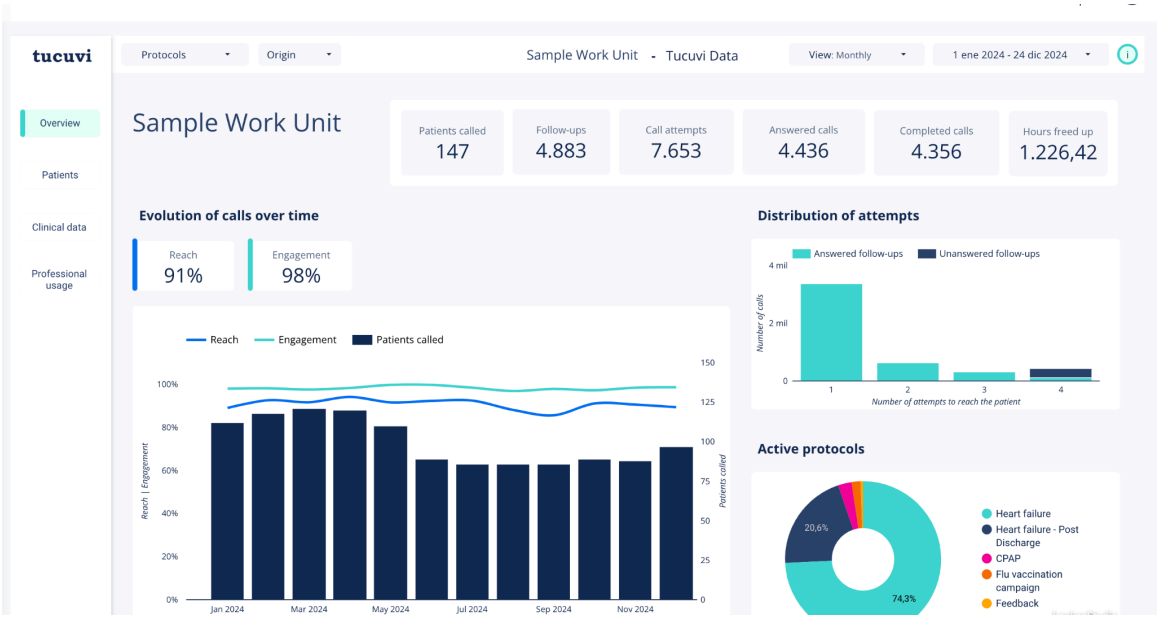


*Figure 25. Statistics.*

# 4.12. Calendar

The **Calendar** interface serves as a visual representation of all scheduled patient calls.

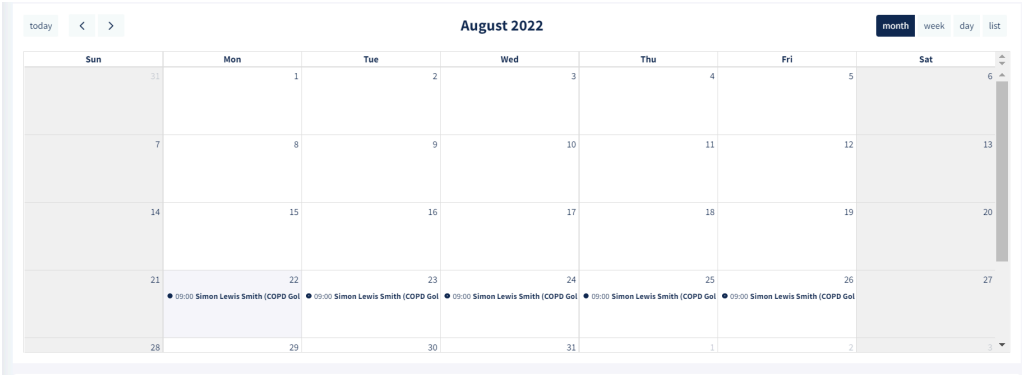



*Figure 26. Calendar view.*

Within this interface, managers possess the ability to effectuate call rescheduling, which is contingent upon the nature of the call:

- **One-off calls**. One can simply employ the drag-and-drop technique. Utilize your cursor to relocate the desired call to the preferred day on the calendar. If you intend to modify the call's timing, execute this adjustment within either the week or day view, adhering to the permissible time range indicated by a white background.

- **Daily calls.** Rescheduling daily calls directly through the calendar is not feasible. Alterations to the day and/or time must be made in the patient record. Upon accessing the patient record, you can initiate modifications to the call, wherein any changes made will be automatically synchronized with the calendar.

- **Periodic call**. The rescheduling options are twofold. You can either reschedule an individual instance of the call or opt to reschedule the entirety of the scheduled calls.

# 4.13. Professional profile

Located in the top right corner, you will see an icon with your name and initials. This icon serves as the gateway to access your personal profile as a healthcare professional.

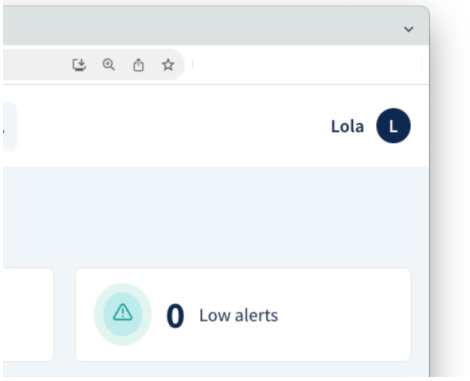



*Figure 27. Professional profile icon.*

## 4.13.1. Personal Details

This section contains your name, email address, and telephone number (for potential SMS notifications). The name and number can be edited.

## 4.13.2. Password

The password feature enables you to initiate a password change request. Upon initiating this request, an email will be dispatched containing instructions guiding you through the process.

## 4.13.3. Notifications

You have the option to configure the notifications delivered via email or SMS. The default configuration activates all, which can be personalized to align with your preferences.

**a. Email Notifications:** When activated, you will receive emails corresponding to conversations assigned to you that entail specified alerts. Each email will provide a direct link to the patient's record in Tucuvi dashboard, facilitating immediate review.

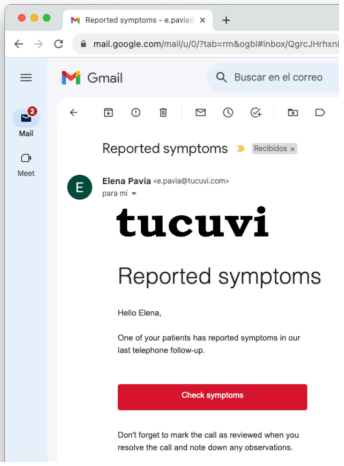



*Figure 28. Example of email sent to the healthcare professional.*

**b. SMS Notifications:** Activation of this feature ensures that you receive SMS notifications corresponding to conversations assigned to you with specific alerts. Each SMS will encompass the clinical ID of the patient associated with the alerts.

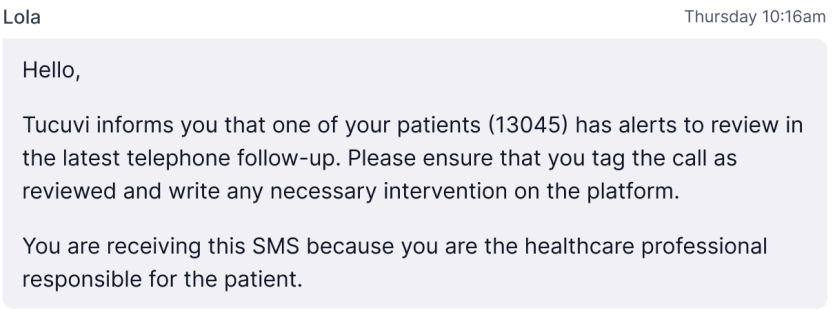



*Figure 29. Example of SMS sent to the healthcare professional.*

## 3.13.4. Aggregate Data

In this section, you are able to download aggregate data (available as a .csv file) and access and download monthly reports that contain comprehensive data about the activities conducted throughout the respective month.

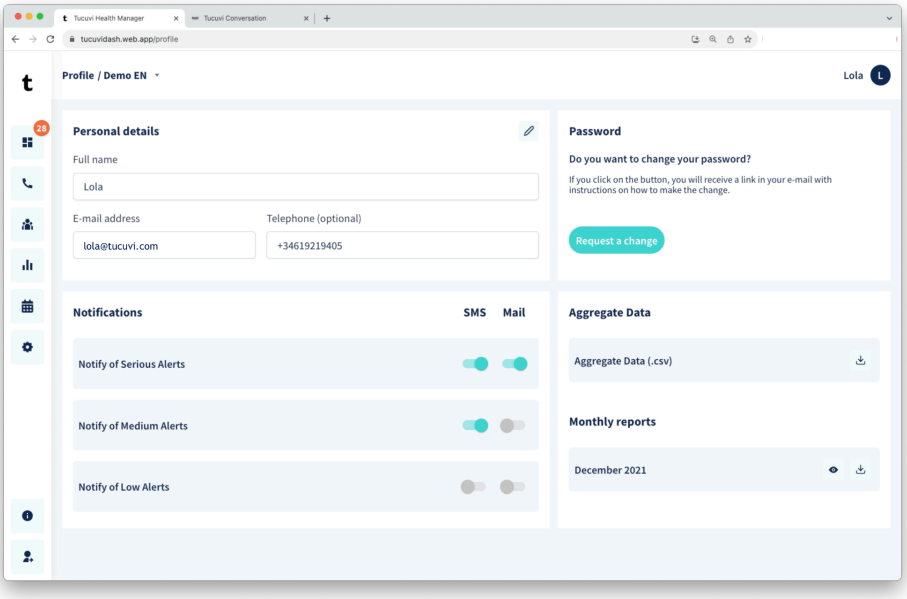



*Figure 30. Aggregate data screen.*

## 4.14. Software information

Within the **Software Information** interface, a repository of software-related information is at your disposal. This repository contains informative documents, such as this user manual, together with scales employed in specific protocols, and other pertinent documents conducive to proficient use of the Tucuvi Health Manager. It also includes the label of the medical device at the bottom of the interface.

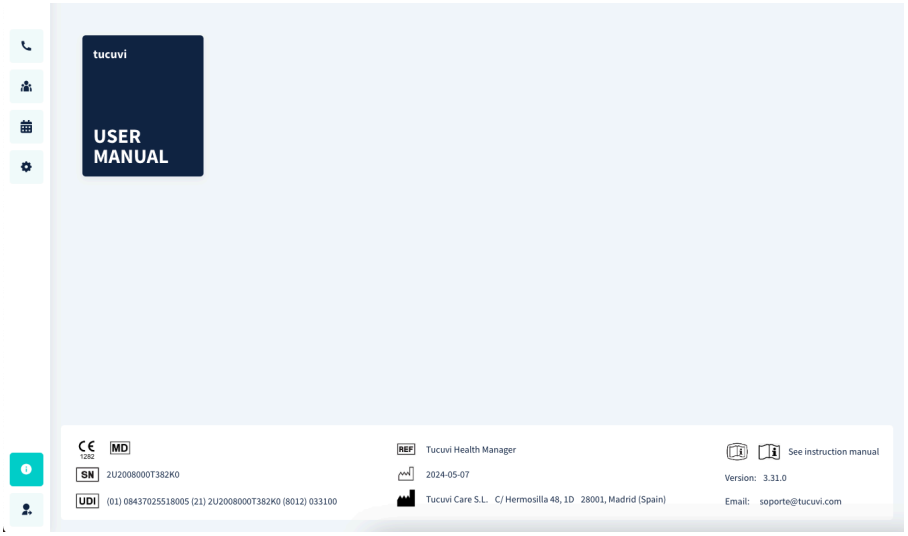



*Figure 31. Software information view.*

# 5. Troubleshooting

In the event of a malfunction:

- Cease usage of the device promptly.
- Endeavor to ascertain or eliminate potential causes by referring to the information provided within this section.

Should the inability to pinpoint or mitigate the issue persist despite consulting this document, it is imperative to discontinue Tucuvi Health Manager usage and promptly initiate contact with Tucuvi's technical service. Refer to Section 8 for the requisite contact details.

## 5.1. Malfunction of the device and Troubleshooting

In this section, we present a comprehensive outline of prevalent issues that may impede the seamless functionality of the medical software. Please adhere to the following recommendations to ensure optimal operation:

1. **Outdated Software Versions:**

Using an outdated version of the software could result in the absence of critical improvements and new features, thereby potentially giving rise to operational issues. To safeguard against this, it is imperative to consistently access Tucuvi Dashboard by initiating a new browser tab, thereby ensuring the adoption of the most recent version of the software.

2. **Incompatibility with Mobile Devices:**
   Tucuvi Dashboard is purposefully tailored for web-based usage. Consequently, accessing it via a mobile device might compromise screen displays and certain functionalities. Hence, it is strongly advised against using Tucuvi Dashboard on mobile devices due to potential function impairment.

3. **Browser Compatibility:**
   For optimal software performance, we strongly recommend using the Google Chrome web browser. The use of alternative browsers may introduce errors that hinder seamless operation.

4. **Internet Connectivity Requirement:**
   A stable internet connection is indispensable for accessing the software through a web browser. Failure to establish an internet connection will render Tucuvi Dashboard access unattainable.

5. **Effects of Weak Internet Connectivity:**
   The efficacy of certain functionalities, such as data loading and data-modifying processes, may be compromised by inadequate internet connectivity. To mitigate such issues, it is advisable to use a well-connected computer and assess the connection speed to ensure optimal performance.

6. **Alert Detection Irregularities:**
   Instances of misclassification in alert indicators, whether erroneously triggering alerts that are not warranted or neglecting to notify alerts to medical professionals, can have severe consequences. Should any such discrepancies arise during patient monitoring, it is imperative to promptly notify both the designated responsible individual and the Tucuvi team for immediate rectification.

7. **Screen too maximized:**
   It is recommended to set the Zoom in Google Chrome to 100% for optimal use of the platform. Higher Zoom levels may require the use of scroll bars to navigate the platform.

By heeding these guidelines, users can significantly enhance the reliability and functionality of the Tucuvi Health Manager. Should you encounter any persisting issues beyond those listed in this manual, do not hesitate to contact our support team for comprehensive assistance.

The user must report any serious incident concerning the medical device to the manufacturer and the competent authority of the Member State in which the user is established .

# 6. Labelling symbols

Both the label and electronic Instructions for Use (eIFU) are accessible via Tucuvi Dashboard in the “Software information” icon on the left-hand side of the screen, as explained in *Section 4.14*.

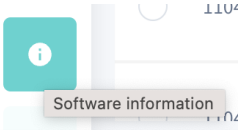



*Figure 32. Label information icon.*

Description of symbols:

| Symbol | Description |
|---|---|
| MD | Medical Device |
| CE | CE marking medical devices |

| | |
|---|---|
| REF | Name of the device |
|  | Manufacturer details |
| Version | Version of the software |
|  | Date of manufacturing (date of version release) |
| UDI | Unique device identifier |
| SN | Serial Number |
|  | Please refer to the instruction manual |
|  | Instructions for Use are provided in electronic format |

*Table 13. Label: Description of symbols.*

# 7. Legal notices

In compliance with the duty of information set out in Article 10 of Law 34/2002, of July 11, on Information Society Services and Electronic Commerce (LSSICE), the owner of the software informs you of the following:

## 7.1. Exemption from liability

Tucuvi Health Manager serves as a tool designed to facilitate patient management. In this capacity, it assumes no responsibility for the ultimate diagnosis of patients or any potential alteration to their state of health that might occur during the course of the clinical conversations.

Tucuvi Health Manager is not intended as a substitute for expert clinical judgement and decision making. Clinicians should always use clinical judgement to determine the

patient's suitability for the product.

## 7.2. Company data

Company Name: Tucuvi Care, S.L
TAX ID: B95969705
Address: C/Hermosilla, 48, 1ºD, 28001 - Madrid (Spain)

# 8. Manufacturer’s contact details

Tucuvi Care, S.L.
C/ Hermosilla 48, 1ºD, 28001, Madrid, Spain
+34 617759326 / +34 692547670
support@tucuvi.com