

tucuvi

User Manual

Tucuvi Health Manager (THM)

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1. Introduction

Tucuvi Health Manager (THM) is a software that allows, by means of automatic phone calls, the automation of the follow-up of patients at home for different pathologies and care processes. It collects relevant information about their health status, structures it, and alerts healthcare professionals when predefined conditions are met.

Tucuvi Health Manager performs a follow-up of patients at home for different pathologies based on predefined protocols. Protocols are composed of conversational flows (e.g. symptoms, state of well-being, constants, etc.) and well-described situations considered as alerts (eg: fever above X degrees, saturation below X%, etc.) that can be personalised on a per-patient basis. The user interface of THM, called Tucuvi Dashboard, allows professionals to choose which protocols to use with their patients and to define their frequency. On the other hand, it allows them to visualise their responses, both individually for each patient as well as in aggregate form by groups of patients. It also facilitates the annotation of interventions by the professionals derived from the visualisation of the results of the calls, i.e. in the call to a patient it has been recorded that oxygen saturation is below 90% and this information has resulted in a call by the nursing team.

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 the best conditions.

1.1. Intended use and Intended purpose

Intended use: The intended use of Tucuvi Health Manager is the automation of patient follow-up through conversational AI and reporting of gathered data to healthcare professionals.

Intended purpose: Tucuvi Health Manager is intended for the automation of patient follow-up for various pathologies and care processes based on modular protocols, including predefined alerts, that can be personalized on a per-patient basis. This information is structured and returned to healthcare professionals via a dashboard or an API.

1.2. Warnings and precautions

Tucuvi Health Manager is not recommended for patients who experience speech or hearing impairments, as the clinical follow-up facilitated by the software may be significantly compromised. Additionally, the inclusion of patients with mental disorders in Tucuvi Health Manager, is advised only within protocols explicitly designed to accommodate these specific conditions.

1.3. Forecast of use

The construction of protocols or care pathways involves the amalgamation of a series of conversational flows utilizing an internal platform. These conversational flows encompass an array of elements, including symptoms (fever, dyspnoea, fatigue, pain, etc.), scales (ranging from 1-5, 1-10, color scales, etc.), situations (emergency visits, hospitalization), and wellbeing assessments, among others. Our medical team utilizes these flows to formulate follow-up protocols for various chronic ailments, aligning with established clinical guidelines, or to automate the follow-up processes tailored to distinct healthcare facilities.

It is imperative that professionals select the appropriate protocol and frequency of calls for each patient during their inclusion into the software. Once the monitoring commences, healthcare professionals can review the categorized responses of the user, as well as the detected alerts. For protocols involving periodic follow-ups, the professional holds the responsibility of pausing or halting the follow-up when deemed necessary through Tucuvi Dashboard.

The target demographic encompasses patients characterized by healthcare professionals within the protocols, or individuals undergoing care processes and need remote follow-up, such as preparation for clinical examinations, post-surgery care, post-emergency visit monitoring, etc. The software is designed for utilization solely by qualified personnel (healthcare professionals) with the intention of automating the remote follow-up of patients in a home-based setting.

2. Conformity of use

The utilization 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 after completing Tucuvi Dashboard usage is imperative. This practice safeguards against unauthorized access to patient data and prevents any unauthorized alterations to patient tracking.

3. Installation and uninstallation

The access to Tucuvi Dashboard will be done through a web browser, always using the Google Chrome browser and personal and non-transferable credentials.

3.1. Installation procedure

3.1.1. Installing Google Chrome

For the installation of Google Chrome, a free web browser, the professional must first check whether it is compatible with his or her 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 v116.

3.1.2. Credentials

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

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

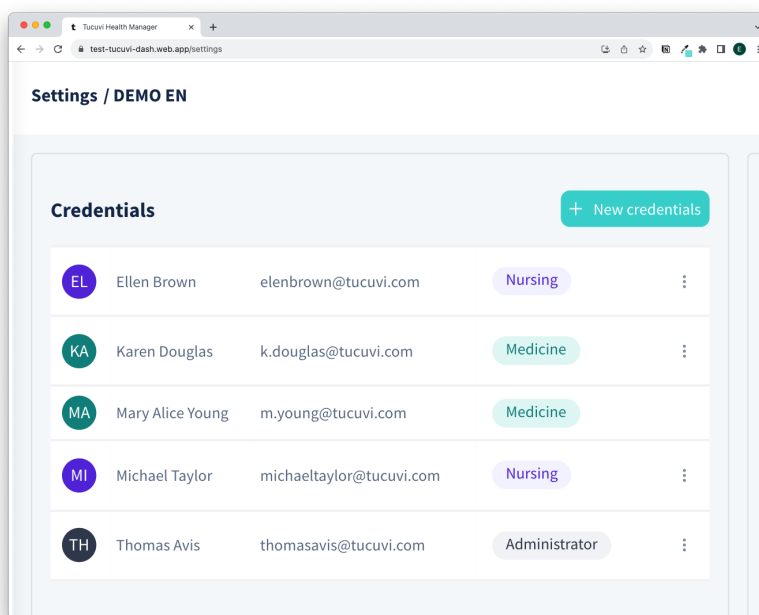


Figure 1. Settings - Credentials screen.

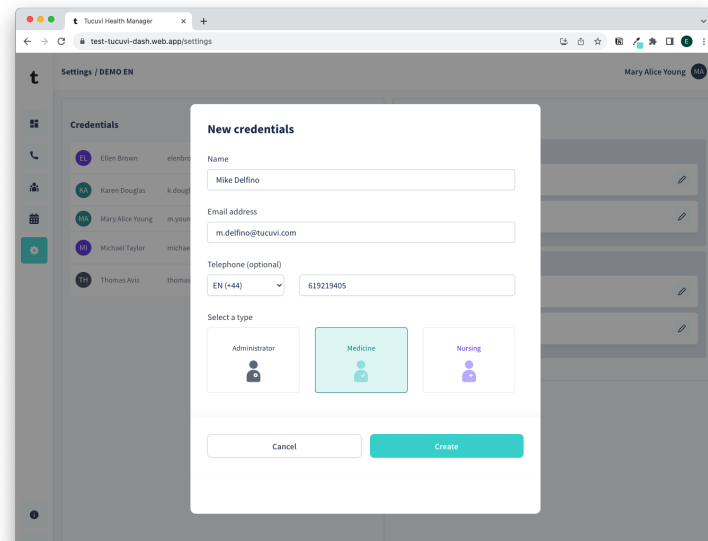


Figure 2. Settings - New credentials screen.

3.2. Uninstallation procedure

When it is necessary to remove the access of a professional, contact Tucuvi, who will proceed to remove their credentials permanently.

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. Log in

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 symbols.

4.3. List of calls

The **Calls** 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.

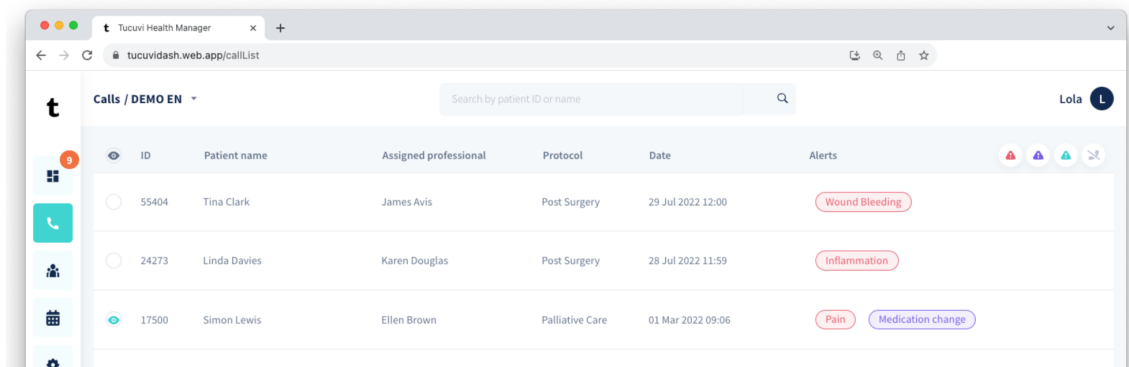


Figure 3. List of calls view.

Calls are presented in the list in one of two distinct manners, 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. Calls review status symbols.

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.

<p>Alerts</p>	<p>All the alerts in each call, colored 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.</p> <div style="text-align: right; margin-top: 20px;"> General wellbeing Dyspnoea +4 </div>
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Table 3. Columns in list of calls view.

4.3.1. Quick call filters

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

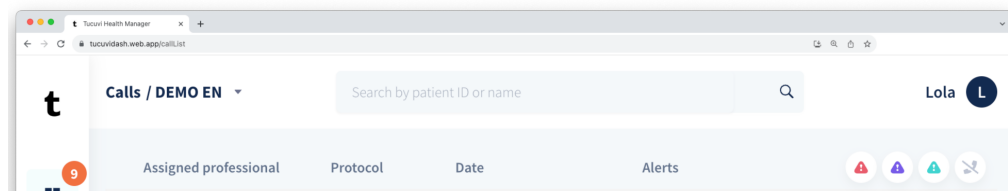


Figure 4. Quick call filters.



	<p>Only calls with at least one severe alert are shown.</p>
	<p>Only calls with at least one medium alert are shown.</p>
	<p>Only calls with at least one mild alert are shown.</p>
	<p>Unanswered calls are hidden. Only answered calls are shown.</p>

Table 4. Quick call filters meaning.

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 the list of calls that meet predefined conditions, such as having specific alerts, only answered calls, calls from the last week, etc. The information displayed for each call is the same as in “Calls list”. This provides the healthcare professional with a filtered view of the calls, allowing them to prioritise their review. The filters to be applied are initially defined by the Unit Manager. The icon in the lateral menu shows the number of calls in the list.
- **Ongoing conversations:** shows the calls that the virtual assistant, which is called LOLA, has due today, as well as the time at which these calls will be made.

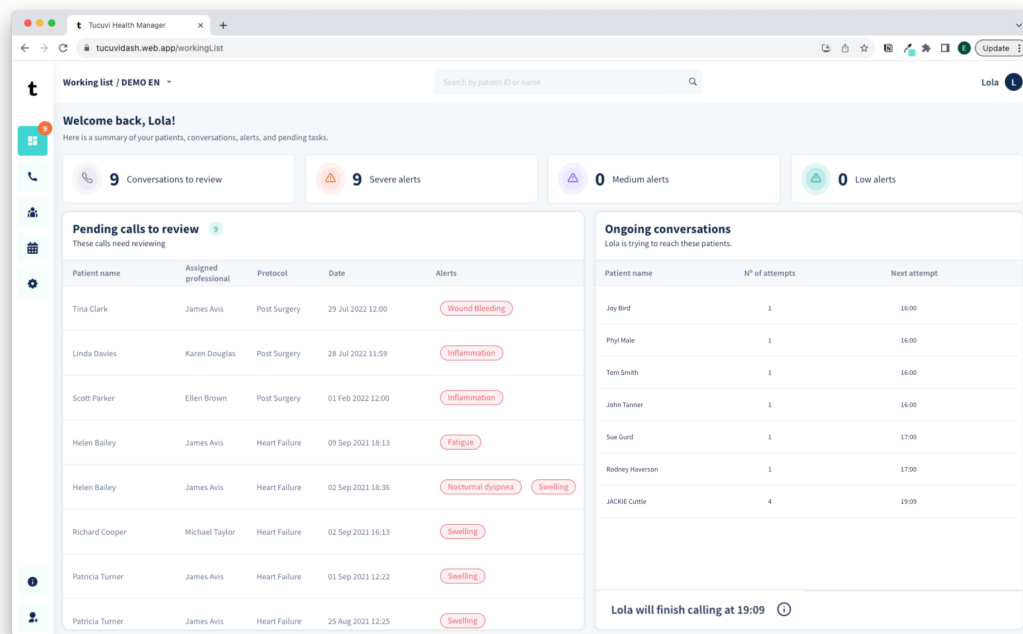


Figure 5. Working list view.

4.5. List of patients

The **Patients** screen displays all patients who are included in Tucuvi Health Manager. Patient roster is sorted so that recently added patients appear at the top and the oldest patients 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 that will appear will show those that match the data provided.

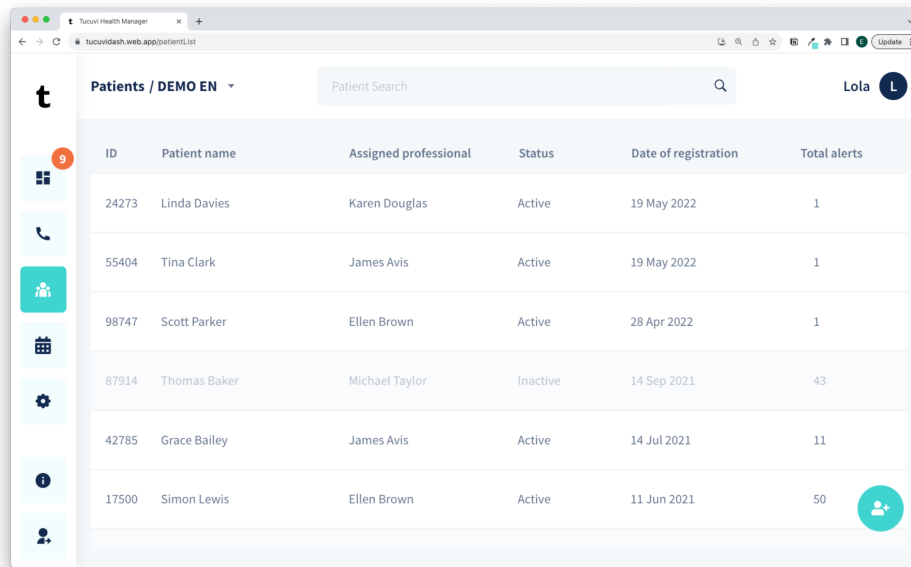


Figure 6. List of patients view.

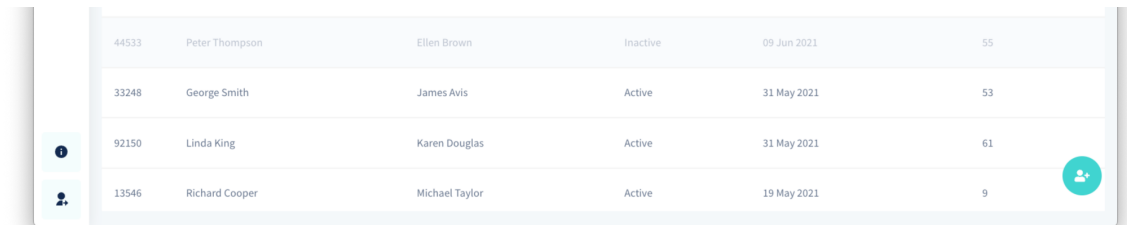
The list of patients is arranged in a similar way to the list of calls, but shows different information. Some are common to the call list, but others are specific to this section.

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	It indicates whether the patient is currently active (so receiving calls) or inactive. Inactive patients are shown in light grey rows.
Date of registration	The date when the patient was registered in Tucuvi Health Manager, thus allowing to know 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 a patient

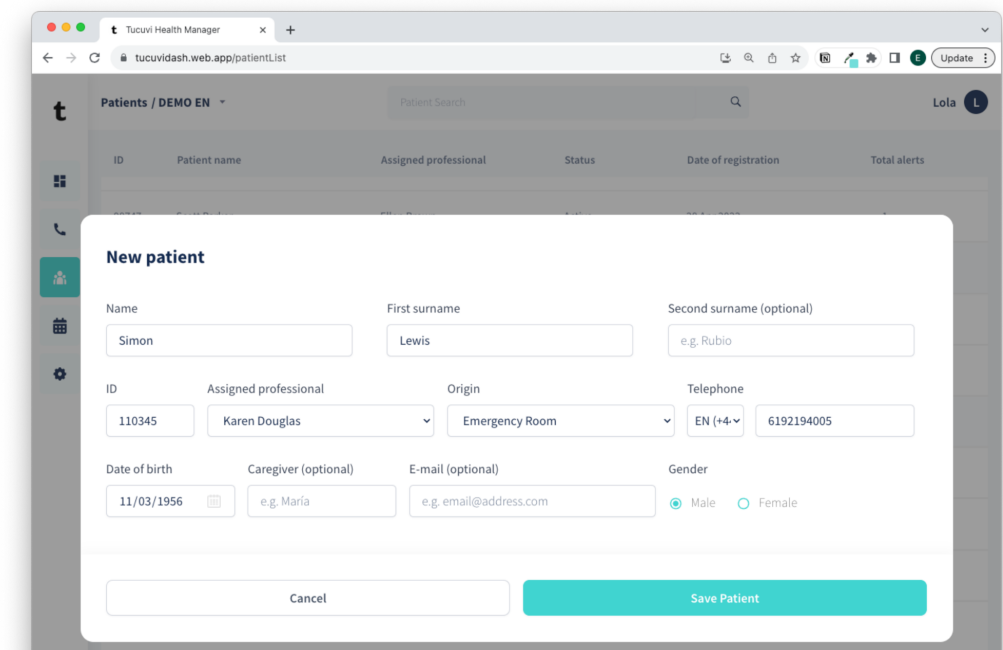
To create a new patient, select the **Add patient** icon, located at the bottom right corner, and fill in the data. Once completed, the patient is saved and registered in Tucuvi Dashboard.



44533	Peter Thompson	Ellen Brown	Inactive	09 Jun 2021	55
33248	George Smith	James Avis	Active	31 May 2021	53
92150	Linda King	Karen Douglas	Active	31 May 2021	61
13546	Richard Cooper	Michael Taylor	Active	19 May 2021	9

Figure 7. Add a patient button.

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.



New patient

Name: Simon

First surname: Lewis

Second surname (optional): e.g. Rubio

ID: 110345

Assigned professional: Karen Douglas

Origin: Emergency Room

Telephone: EN (+4) 6192194005

Date of birth: 11/03/1956

Caregiver (optional): e.g. María

E-mail (optional): e.g. email@address.com

Gender: Male Female

Buttons: Cancel, Save Patient

Figure 8. 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 throughout the software's utilization. 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 personalise 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 filled in. 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 conveyed on the screen guiding users through the process.

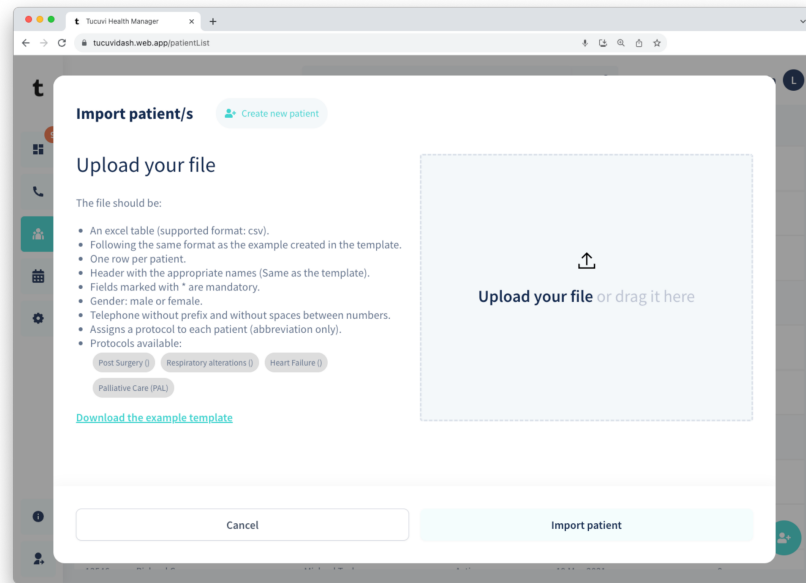


Figure 9. Import patients through a CSV file view.

4.7. Setting up calls

To schedule calls for a protocol, one must open the patient record.

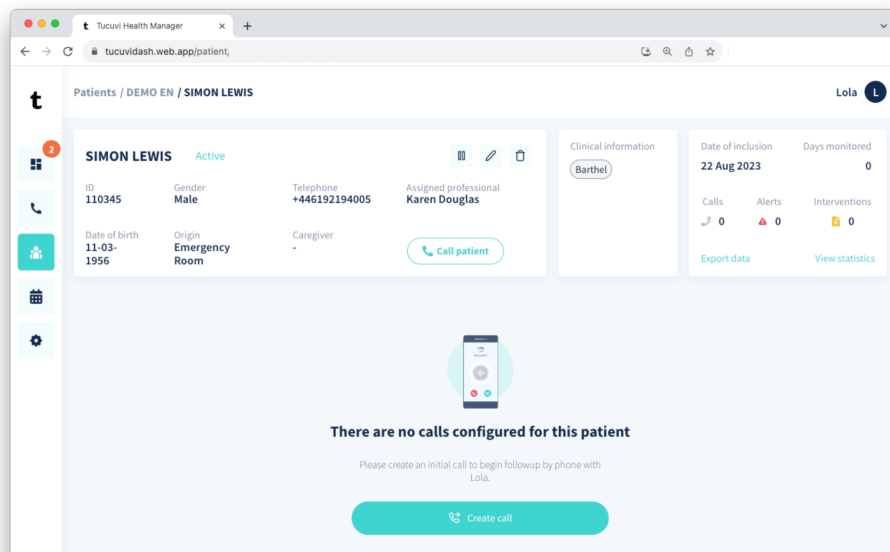


Figure 10. Patient record view.

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

New call

Module: Select a module (dropdown)
 Protocol: Select a protocol (dropdown)
 From: 22/08/2023 (calendar icon)
 Time: Select a range of hours (dropdown)

Call now

Repeat

Cancel Save call

Figure 11. 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	<p>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.</p>
Frequency	<p>How often the calls will be scheduled:</p> <ul style="list-style-type: none"> • Daily: every day matching the days of the week selected. • Weekly: every 7 days. • Fortnightly: every 14 days. • Monthly: every 1 calendar month. • Quarterly: every 3 calendar months. <p>If daily periodicity is selected, the call will be configured from</p>

	<p>Monday to Sunday by default, but the days of the week are completely customisable, 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.</p> <p>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.</p>
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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.

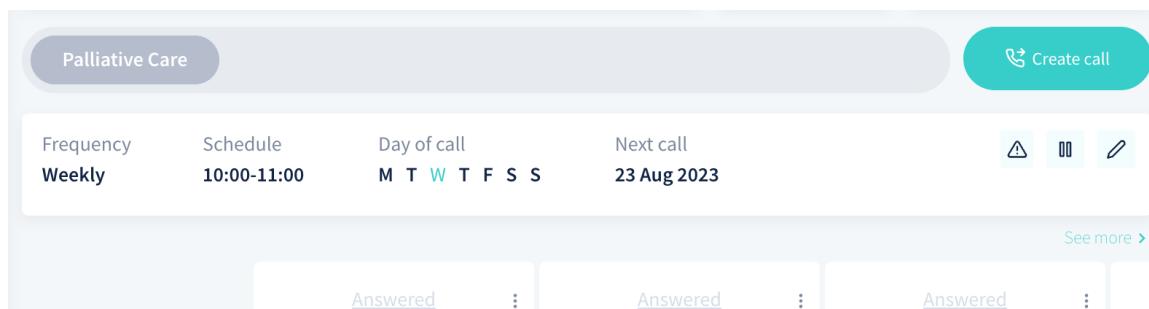


Figure 12. Create a call button view.

	Used to create a new call.
	Used to edit an existing call. Fields are the same in 4.7. <i>Setting up calls.</i>
	Used to pause an existing call.
	Used to resume a paused call. Fields are the same in 4.7. <i>Setting up calls.</i>


	Used to personalize alerts. See 4.10.2. <i>Alert per patient (optional)</i>
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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 allocates personal data, clinical information and statistics, and the lower section displays the list of calls made.

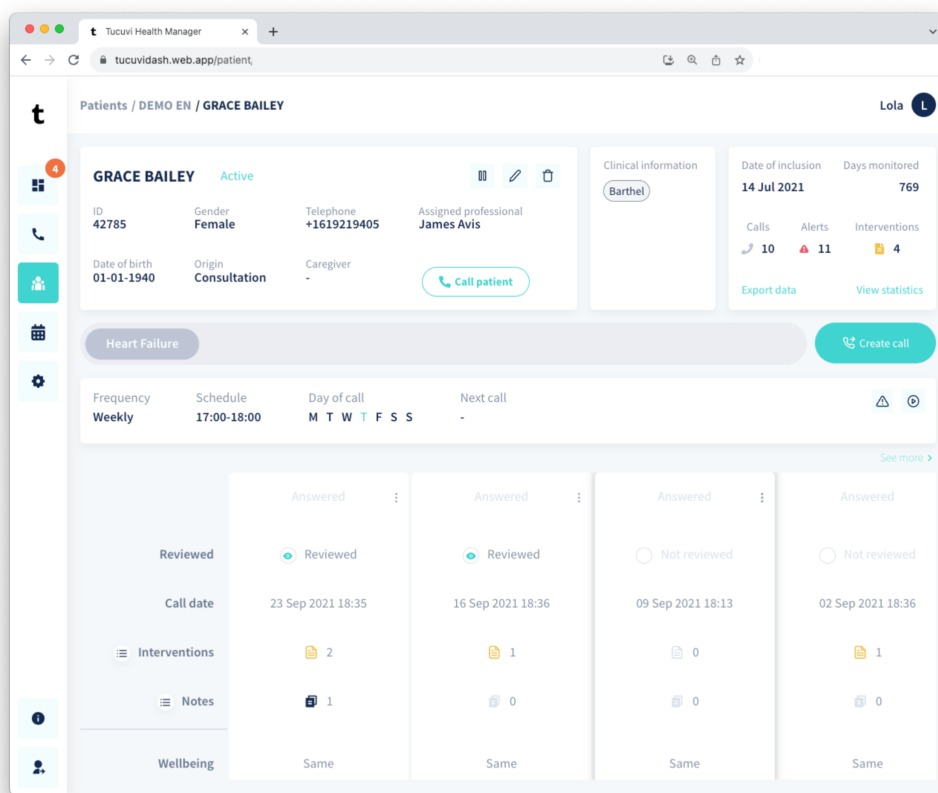


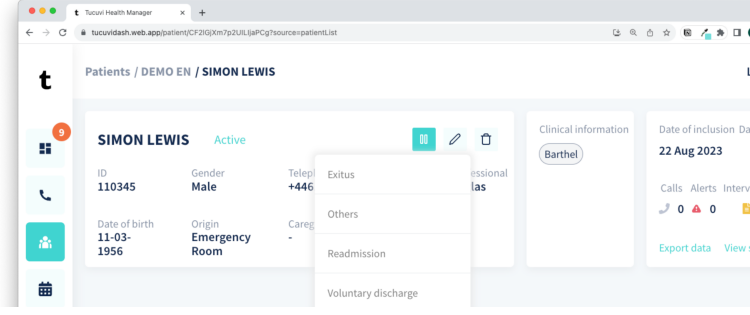

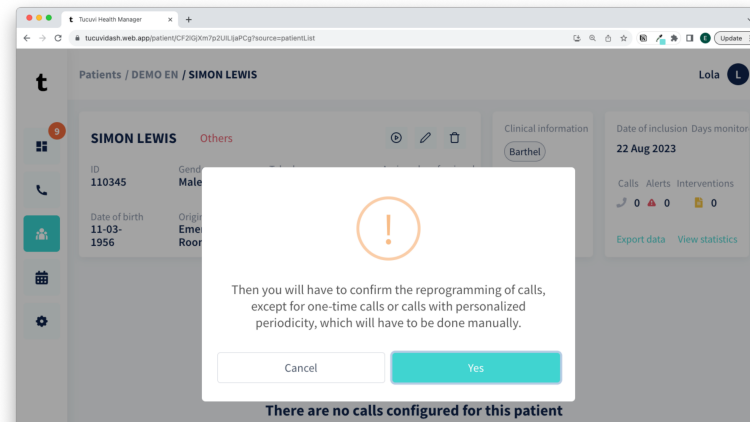


Figure 13. Patient record and calls view.

4.8.1. Edit and inactivate patients

In the top right corner of the patient block:

	<p>It allows you to edit a patient. Fields are the same shown in 4.6. <i>Add patient.</i></p>
	<p>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.</p> 
	<p>Used to reactivate a patient who had been previously inactivated. Follow the instructions in Tucuvi Dashboard to also resume calls.</p> 

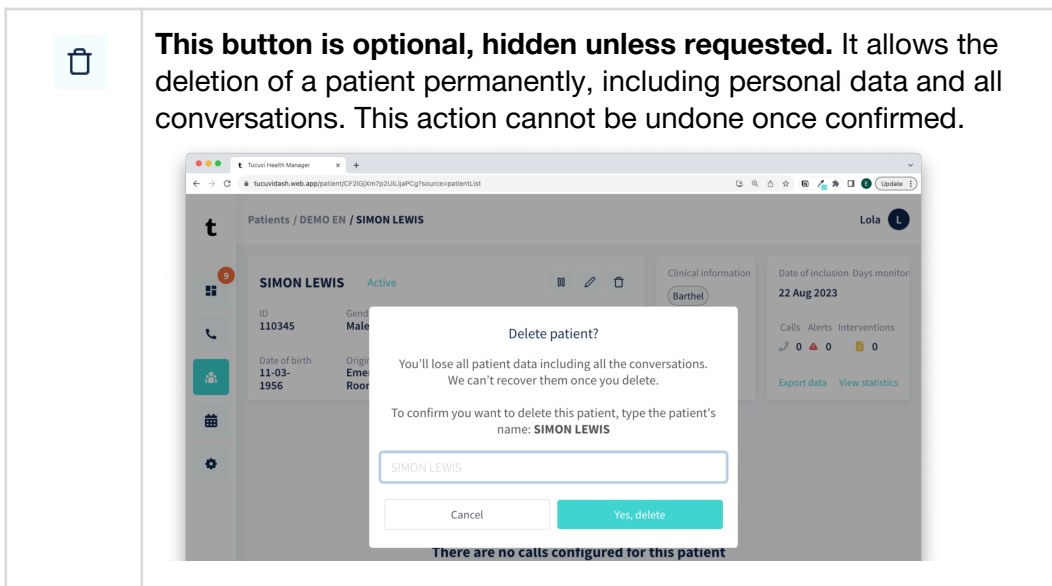


Table 9. Actions on patients buttons.

4.8.2. View patient statistics

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

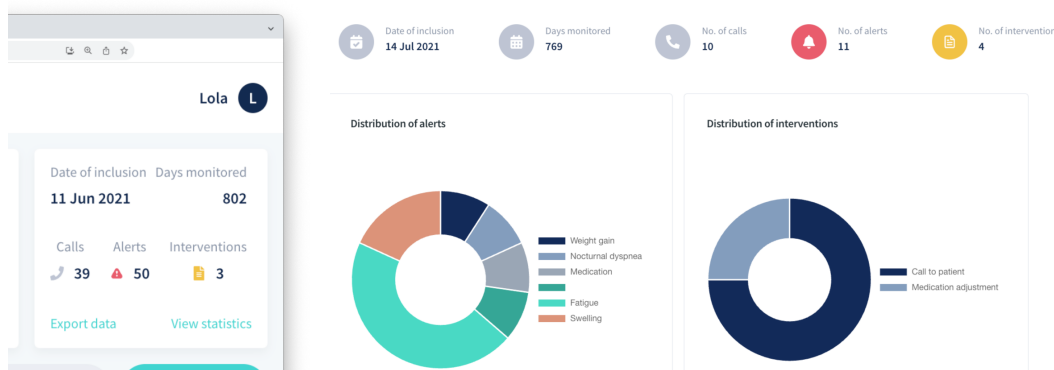


Figure 14. Patient statistics view.

4.8.3. Call from dashboard (optional)

This feature enables healthcare professionals to initiate a real-time audio call with patients directly from their computer, within the patient's record.

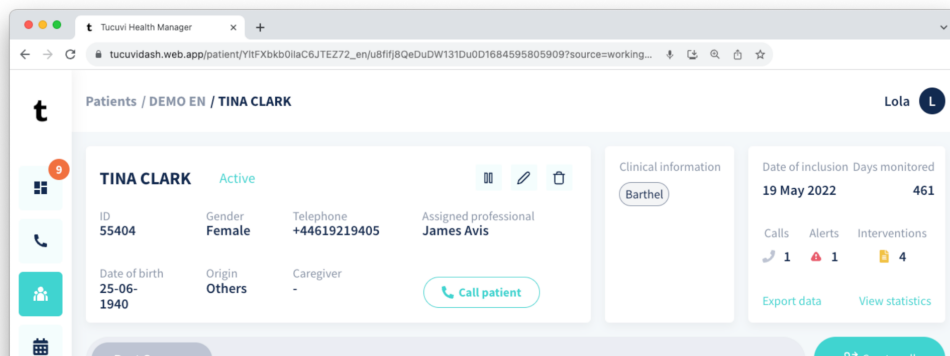


Figure 15. Call the patient from the dashboard option.

How to Use

1. **Access the patient record** and locate the "Call Patient" button, at the bottom right corner of the patient data block. A pop-up window will appear for confirmation.
2. **Initiate call:** Once the call is initiated, the patient will receive a call from the same phone number that LOLA uses for launching the follow-up calls.

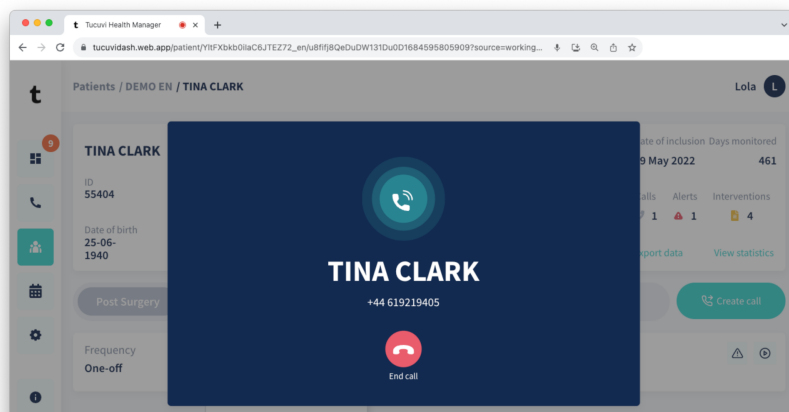
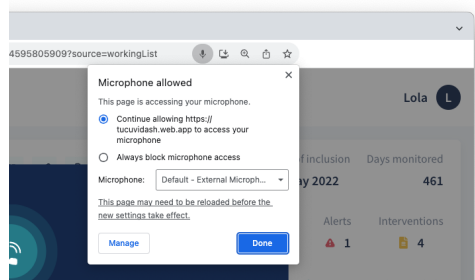


Figure 16. Initiating a call from dashboard view.

3. **End Call:** After the call is concluded, both you and the patient have the option to end the call from your respective ends.

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.



4.9. 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.

For every call, It is shown 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.

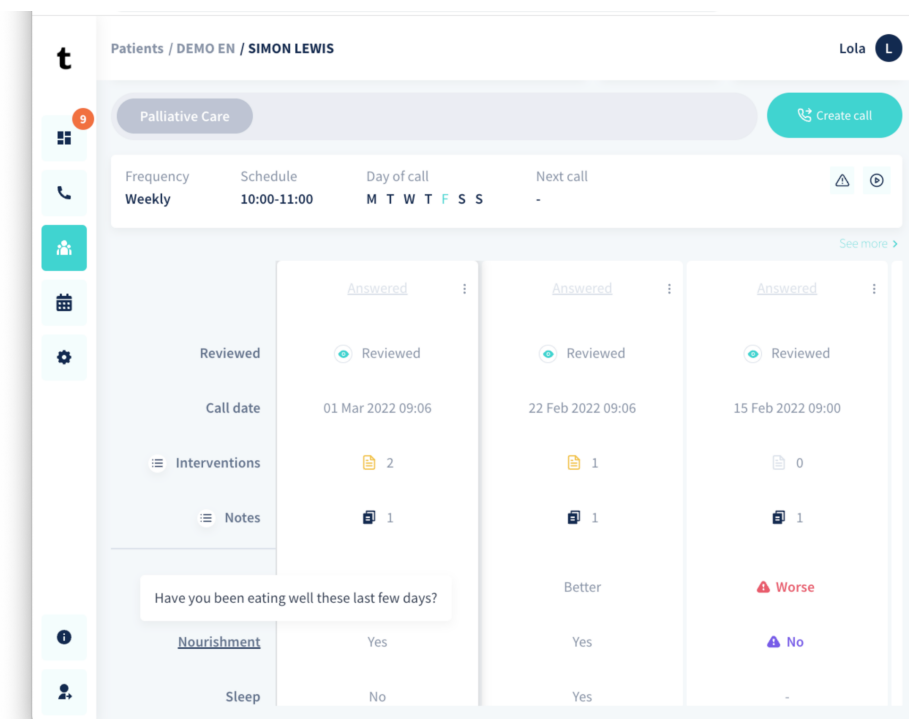


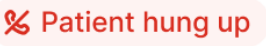
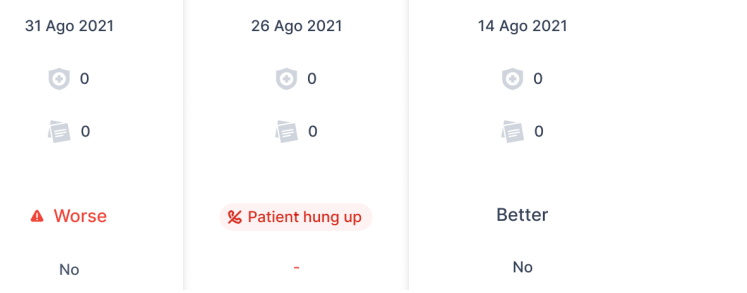

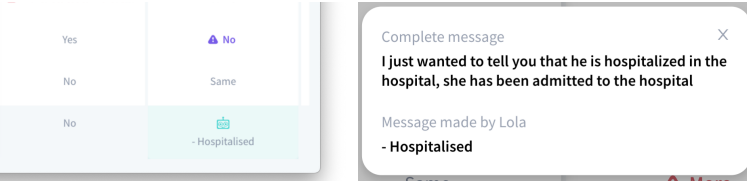

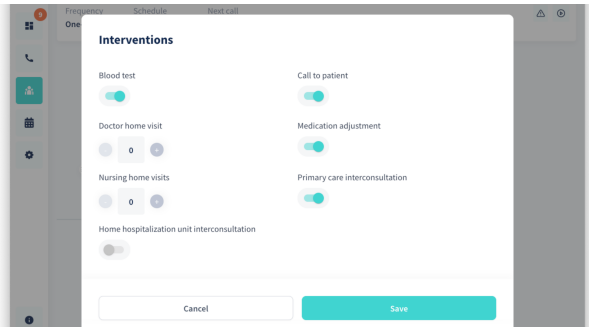


Figure 17. Conversation details view.

 Not reviewed	<p>Indicates the call has not been reviewed yet.</p>
 Reviewed	<p>Indicates the call has been reviewed. Based on the patient's answers, professionals may take any necessary measures.</p>
 Patient hung up	<p>If the conversation is incomplete, where the patient hung up.</p> 
 <p>Smart summarization</p>	<p>Clicking on it shows the whole patient transcript and the summary made by LOLA.</p> 
 <p>Interventions button</p>	<p>Clicking on it opens a pop-up window to complete the interventions performed on the patient based on the patient's responses. They are defined by the Unit Manager.</p> 


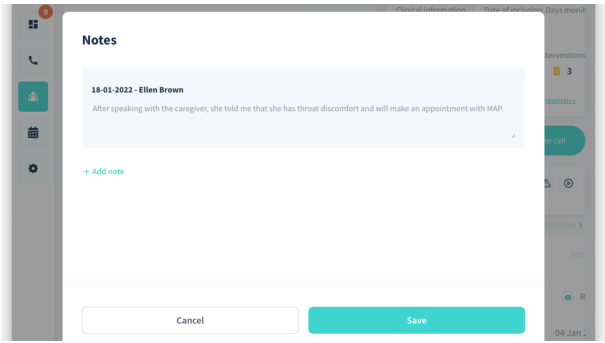

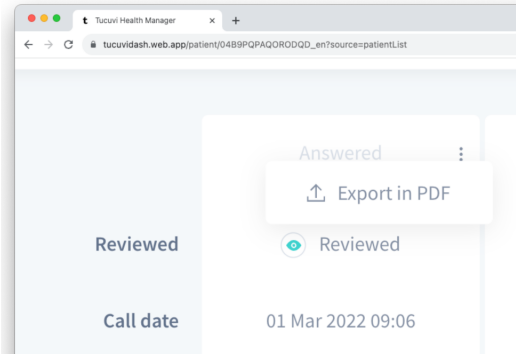
 <p>Notes button</p>	<p>Clicking on it opens a pop-up window to write unstructured free text after the call has been reviewed.</p> 
 <p>More options button</p>	<p>This is optional. It shows more actions, like export PDF.</p> 

Table 10. Conversation details meaning.

4.10. Settings - Alerts

The principal objective of patient calls resides in the 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 dyspnoea, pain, temperature, etc.). For each of them, specific responses are cataloged as alerts (increased dyspnoea, 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).

Emergency visit	No	No	⚠ Hospital
Medication change	⚠ Yes	⚠ Yes	No
Dyspnea	Same	⚠ More	⚠ More

Figure 18. 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. 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.

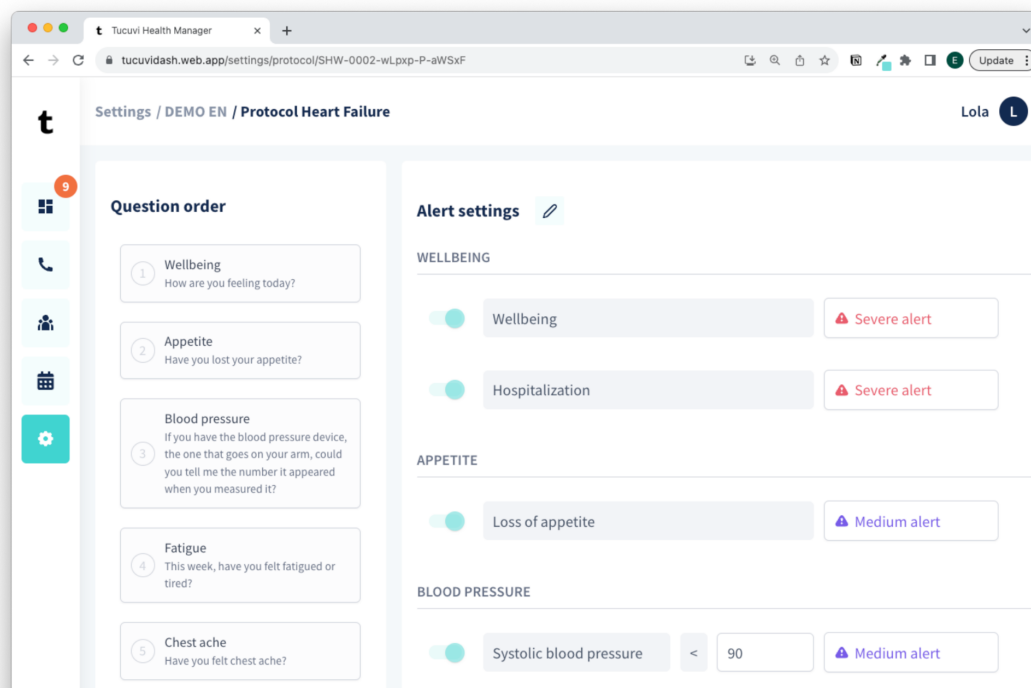


Figure 19. Configuration of alerts view.




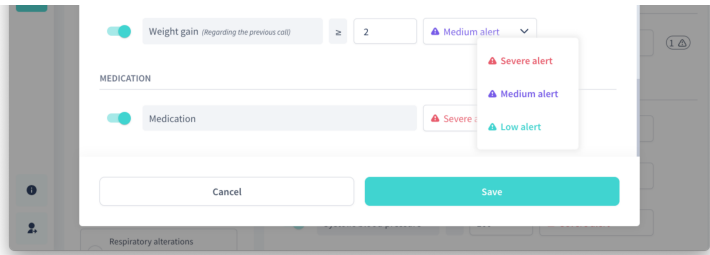
	<p>Indicates that the alert is activated, i.e. if patient response matches the defined condition, an alert will be triggered.</p>
	<p>Indicates that the alert is deactivated, i.e. if patient response matches the defined condition, no alert will be triggered in any patient.</p>
	<p>It allows to edit the configuration:</p> <ul style="list-style-type: none"> - Alerts can be turned ON and OFF - The severity can be adjusted (e.g. from low to medium) - Thresholds can be modified (e.g. saturation below 94% to 92%) <p>Alerts cannot be added or deleted. Likewise, numerical operators —greater than ($>$), \geq), less than ($<$), \leq) or equal to ($=$)— remain unalterable.</p> 

Table 12. Configuration of alerts options.

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 20. 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.

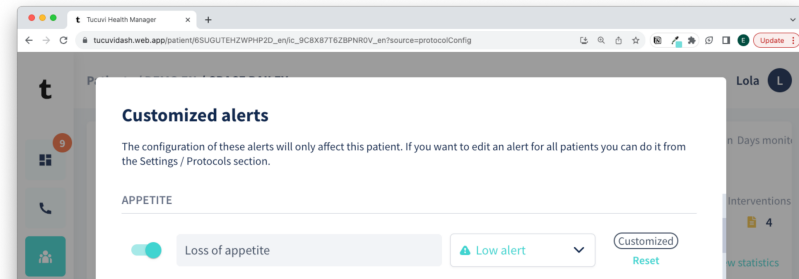


Figure 21. Alert per patient configuration view.

In the general settings it can be visualized at a glance if any alert is personalized in 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 demarcation ensures that alterations made in the general settings arena will not inadvertently alter personalized alert settings for individual patients.

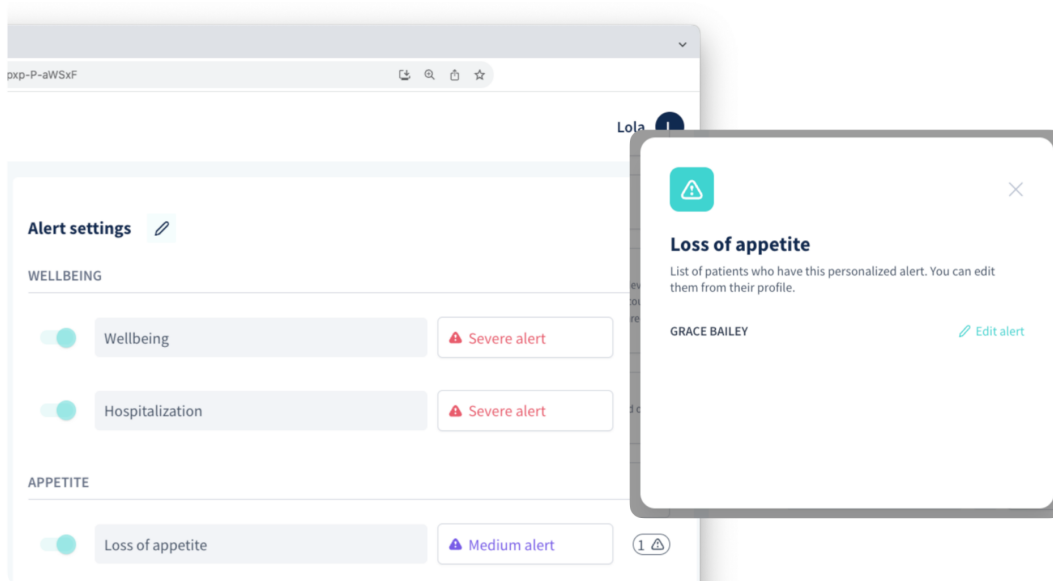


Figure 22. General alert settings view.

4.11. Statistics (optional)

This optional view can be activated per Work Unit. It furnishes 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.

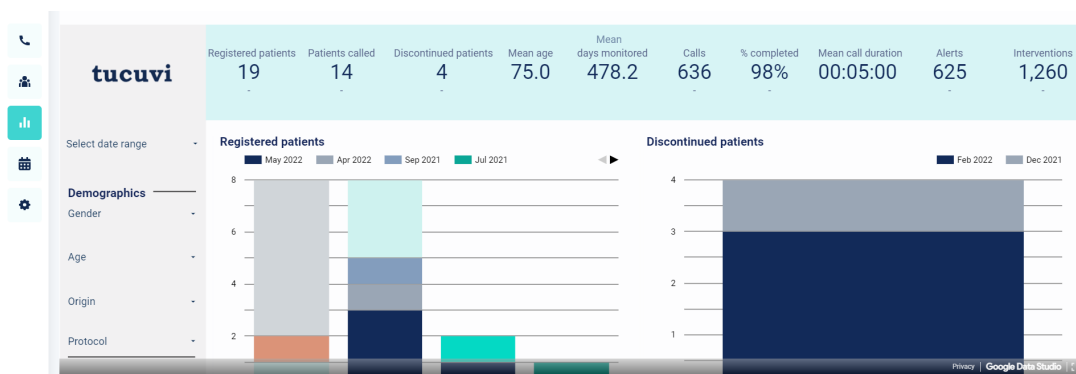


Figure 23. Statistics view.

4.12. Calendar

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

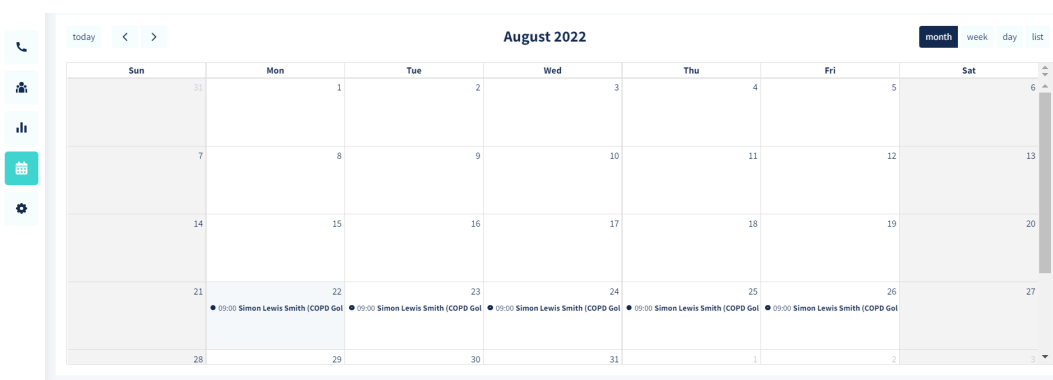


Figure 24. Calendar view.

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. To effect alterations to the day and/or time, this must be undertaken from 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 upper-right corner, you will encounter an icon bearing your name and initials. This icon serves as the gateway to access your personal profile as a healthcare professional.

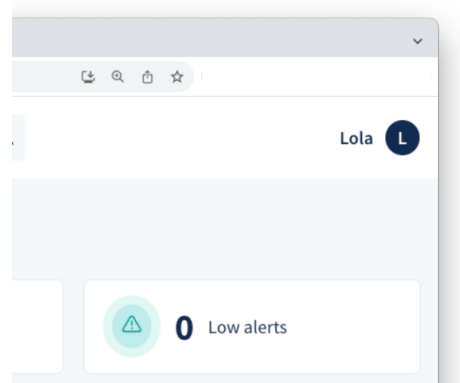


Figure 25. Professional profile button.

4.13.1. Personal Details

This section encapsulates your name, email address, and telephone number (for potential SMS notifications). Notably, the name and number are open to editing.

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 are empowered 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.

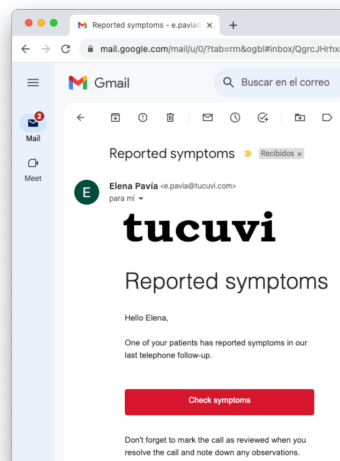


Figure 26. Example of email sent to the healthcare professional.

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 clinic ID of the patient associated with the alerts.

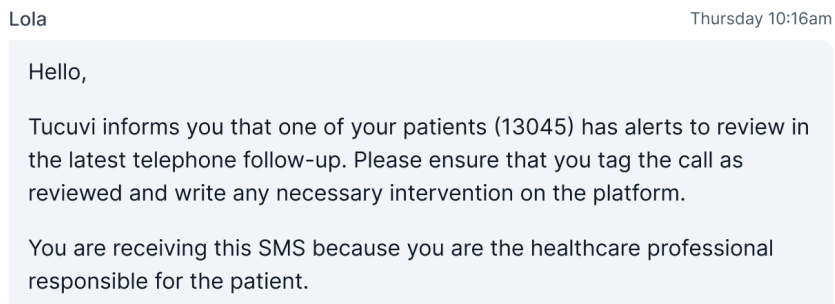


Figure 27. Example of SMS sent to the healthcare professional.

3.13.4. Aggregate Data

Within this segment, you are afforded to download aggregated data (available as a .csv file) and access and download monthly reports that contain comprehensive data about the activities conducted throughout the respective month.

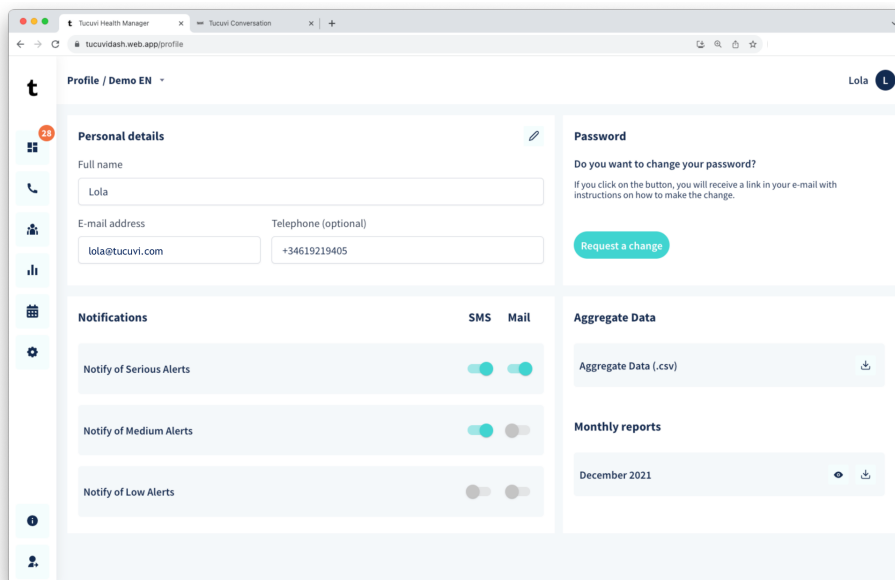


Figure 28. Aggregate data button.

4.14. Software information

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

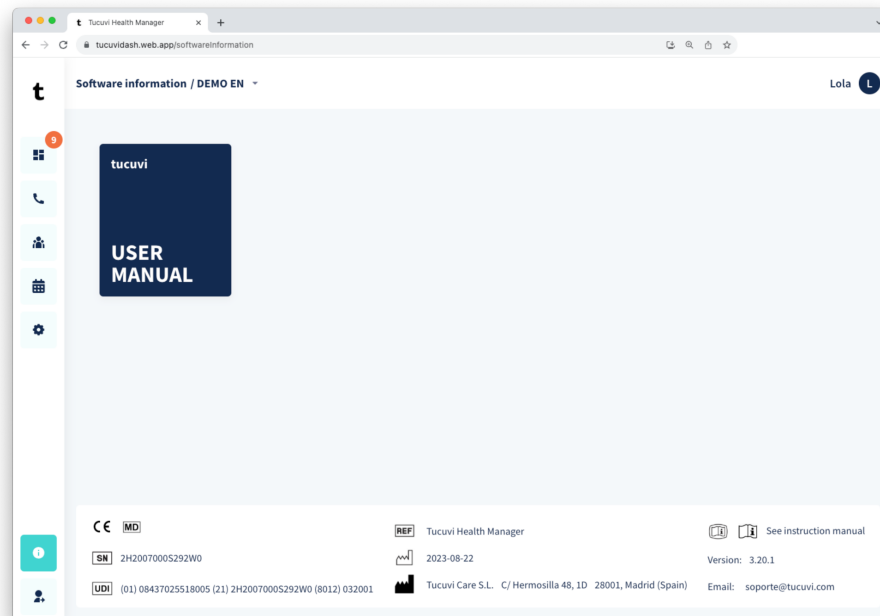


Figure 29. Software information view.

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. 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. Utilizing Outdated Software Versions:

Employing 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 software iteration.

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 employing Tucuvi Dashboard on mobile devices due to potential functionality impairment.

3. Browser Compatibility:

For optimal software performance, we strongly recommend employing the Google Chrome web browser. The utilization 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 employ 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.

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 herein, do not hesitate to reach out to 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. Symbols on labelling

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

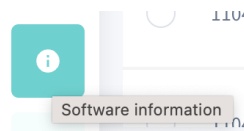


Figure 30. Labelling information button.

Symbols explanation:










Symbol	Explanation
	Medical Device
	CE marking medical devices
	Name of the device
	Manufacturer details
Version	Version of the software
	Date of manufacturing (date of version release)
	Unique device identifier
	Serial Number
	Please refer to the instruction manual
	Instructions for Use are provided in electronic format

Table 13. Labelling symbols explanation.

7. Legal notices

In compliance with the duty of information set out in article 10 of Law 34/2002, of 11 July, 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 monitoring. In this capacity, it assumes no responsibility for the ultimate diagnosis of patients or any potential modifications to their state of health that might occur during the course of monitoring.

7.2. Personal data

Company Name: Tucuvi Care, S.L

TAX ID: B95969705

Address: C/Hermosilla, 48, 1ºD, 28001 - Madrid (Spain)

8. Manufacturer's contact details



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