Professional side user manual

Maela web platform

Manufacturer's information

MN Santé Holding

Adresse: 9 rue du Colonel Pierre Avia, 75015 Paris

Telephone: +33(0)481682526

Email: contact@careside.care

Website: www.maela.fr/en

Distributed by

Medtronic International Trading SARL, Route du Molliau 31, 1131 Tolochenaz, Switzerland

Main product information

REF Maela® Platform

Product Version: V4.3.10

Certification and declaration of conformity

CE MD The Maela® platform is a Class I ***medical device*** CE marked in 2019.
This device complies with the essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
This device complies with the general safety and performance requirements of Regulation 2017/745.

Exclusions of warranties and limitations of liability

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Trademarks (if applicable)

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Modifications

The information in this document is subject to change without notice. We have made our best efforts to ensure the accuracy of the information provided in this document. If changes are made to this manual, the latest version will be provided to users.
If a user identifies incorrect information, please contact us at this email address contact@careside.care.

Release date: 27/02/2025

Table of Content

1. Introduction

1.1. Purpose of the document

This user manual presents the Maela® platform, a medical device designed by the company MN Santé for remote patient monitoring.

It contains descriptions explaining the use of the platform step by step. It is intended for professionals authorised to use the Maela® platform.

Please read this manual carefully before using the Maela® platform.

1.2. Abbreviations and definitions

Abbreviation or term	Description
Medical device	Instrument, apparatus, equipment, machine, device, implant, reagent for *in vitro* use, software, material or other similar or related item that the manufacturer intends to use alone or in combination in humans for one or more specific medical purposes.
Prevention	The World Health Organization defines prevention as all measures aimed at avoiding or reducing the number and severity of diseases, accidents and disabilities.
Healthcare professional	Person who exercises skill and judgement, provides a service related to the maintenance or improvement of the health of individuals or the treatment of injured, sick, disabled or infirm individuals by providing care and therapy.
Administrator	Establishment administrator or Maela administrator profile with user management rights and privileges for performing various functions on Maela.
Psychomotor disorder	Disorder that is not necessarily associated with a neurological lesion. It concerns a psychomotor function, i.e. a function that has a genetic and neurological origin as well as developmental, environmental and emotional dimensions in the history of the patient.
ERAS	Enhanced Recovery After Surgery. *ERAS* is a multimodal perioperative care pathway designed to achieve early recovery in patients undergoing major surgery.
Care pathway	Highest level entity in the Maela platform. A pathway model includes key dates, follow-up protocols and screening questionnaires.
Planned content	The planned content of Maela® correspond to all the follow-up questionnaires, educational content, measurements, tasks and reminders that are planned within a care pathway or protocol.
Ambulight	Simplified patient follow-up using SMS over a short period around an episode of care or hospital event.

Abbreviation or term	Description
Protocol	Maela protocol consisting of different types of content that may be scheduled over time. A protocol corresponds to a specific episode of care, such as a surgical episode within an oncology pathway. A Maela protocol consists of follow-up questionnaires, monitoring of measurements, documents, links, educational content, lab analyses, treatment follow-up and useful information for the medical professional to properly manage possible adverse reactions that the patient may encounter. A protocol has start and end dates.
Remote monitoring protocol	A telemonitoring protocol is a set of variables and associated alert rules that enable healthcare professionals to assess a patient's state of health remotely, over a defined period, and to decide what action to take.
Identification	Process establishing a user's identity. The user has an individual identity in the solution. They are assigned a unique username to access the solution.
Authentication	Process of proving a user's identity. This takes place after the identification process. The user uses an authenticator or “secret code” that is only sent to them.
Criticality	Determination and prioritisation of the degree of importance of an alert that is sent to healthcare professionals or patients.
Data extraction	The act or process of retrieving data from data sources for further data processing or data storage (data migration).
Alert	Signal that warns of a danger or risk to the patient. Allows information to be transmitted based on the patient's response.
Timeline	Detailed view of a patient's care pathway. All the content configured in the pathway is displayed in this timeline. A timeline is a linear representation of events positioned on a line representing time; it associates events with their chronological positions in time along a graduated scale.
Pop-up	Window that opens on top of the main window.
Licence	Subscription to the Maela platform.
Identity-checking	In the hospital context, a *“system for monitoring and managing risks and errors related to patient identification”* to *“move from an administrative identity for billing purposes to a culture of clinical identification as part of a global approach and project for quality and safety of care”.*
OTP	Only Time Password. Abbreviation corresponding to the code sent by SMS or email to secure a Maela account.
IoT	Internet of Things. Abbreviation corresponding to connected devices.
Mac address	Physical identifier of a connected device.
Withings	Withings is a manufacturer of connected everyday devices. The connected devices can either be used with the Withings application (healthmate) or they are connected via cellular (SIM).
Carelink	Carelink is the brand of connected insulin pumps from which you can collect measures.
Screening	Screening is a type of questionnaire that makes it possible to personalise a patient's protocols inside the pathway.
Responsive site	Website whose design offers comfortable browsing on screens of various sizes. The user can thus view the same website through different types of devices (tablet, computer, smartphone).

Abbreviation or term	Description
CMS	Content Management System. Maela® has chosen to link its platform to WordPress for the management of educational content and GDPR-related documents.
GDPR	European General Data Protection Regulation.
National identification number	A unique patient number at the national or regional level.
CSV	Coma Separated Values file.
Cache	Cache memory is, in computer science, memory that temporarily stores copies of data from a source to reduce the time it takes for computer equipment to access the data later.

2. Indications and symbols

2.1. Description of symbols

The following table describes all the symbols used in this user manual, as well as on the product.

	**Warning:** alerts the user to a potential risk regarding the use of the product, which could have consequences for the safety of the patient or user.
	Read the user manual
	Manufacturer's name
REF	Product reference
MD	Medical device

2.2. Precautions

Please carefully read the instructions below to ensure that the device is used in the best and the safest possible conditions.

The content (questionnaires, educational content, documents, links, reminders), protocols and pathways offered to patients are validated by the referring care team. In the event of imprecise questions or inappropriate content, it is the professional's responsibility to update their pathway.

2.3. Warnings

- **All users must be trained before using the product.**
- **When updating the platform, users must clear their browser's cache and update their mobile app. These notices are sent to Maela® users during each update, indicating the procedure to follow.**

2.4. Malfunction

In the event of a malfunction, stop using your device immediately.

If it is not possible to identify or eliminate the cause with the help of this document, switch off the device and call our support centre at **+441923205184** (United Kingdom) or **+35391750797** (Ireland).

3. Product description

3.1. Indication

The solution developed by MN Santé is a ***medical device*** intended for ***healthcare professionals*** to ensure the medical follow-up of patients throughout their ***care pathways***. This solution allows care teams and practitioners to determine care pathways for their specialties and their patients.

The Maela® device consists of a web platform and a mobile app. Patients have access to the Maela® solution via the mobile app and web platform, while healthcare professionals only have access to the web platform.

Only healthcare institutions that have purchased a Maela® licence can benefit from the Maela® platform.

3.2. Target patient group

Patients accepted into a co-contracting health institution can benefit from the Maela® follow-up.

Patients must:

- Have an internet connection at home (over Wi-Fi or mobile data)
- Have a mobile phone
- Be aged over 18 years, or be accompanied by a legal representative.

3.3. Target users

The intended users are:

- **Healthcare professionals**: doctors, nurses, health facilities, pharmacists
- **Social actors**
- **Administrative professionals of facilities**: executives, medical secretaries, directors, Data Protection Officer (DPO)
- **Adult patients monitored for the planned indications**
- **Caregivers of monitored patients who do not have the necessary capacities or autonomy, as well as caregivers of patients who are minors.**

3.4. Clinical benefits

- Improvement in patient quality of life and satisfaction
- Improvement in the medical service provided
- Early detection of complications and better management of complications
- Better monitoring of ***ERAS protocols*** *(Agri, F. Hahnloser, D. Desmartines, N. Hubner, M. (2020) Gains and limitations of a connected tracking solution in the perioperative follow-up of colorectal surgery patients. Colorectal Dis. 2020 Aug; 22(8): 959–966.)*
- Increased survival rate (Basch, E. Deal, A.M. Dueck, A.C. *et al.* (2017) *Overall Survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment*. JAMA. 2017; 318(2): 197–198.)

3.5. Security Information

Any serious incident occurring in connection with the Maela® platform must be notified to the manufacturer and the national competent authority.

3.5.1. Contraindications

The use of the Maela® platform is not recommended in:

- Children
- Except in the presence of a **caregiver** who can provide the follow-up:
  - Visually impaired patients
  - Patients with significant psychomotor disorders of the upper limbs
  - Patients with memory disorders
  - Patients without a mobile phone number
  - Patients who do not have an internet connection
- Non-consenting patients

3.6. Browsers and download

The product is designed and tested to be compatible with the two latest and major versions of the Windows and macOS integrated browsers as well as Google Chrome and Firefox. Thanks to responsive web design, the web platform is also available on Android and iOS on which it is designed and tested to be compatible with the latest versions of their incorporated browsers (Google Chrome and Safari, respectively).

The latest version of the Product mobile app is also available to download on Android and iOS devices from their corresponding app stores (Google Play store for Android and the Apple App Store for iOS).

4. User rights matrix

The matrix below defines all the possible user roles and their specific rights and functions. You can refer to this matrix to verify whether a specific section of this document concerns your user role.

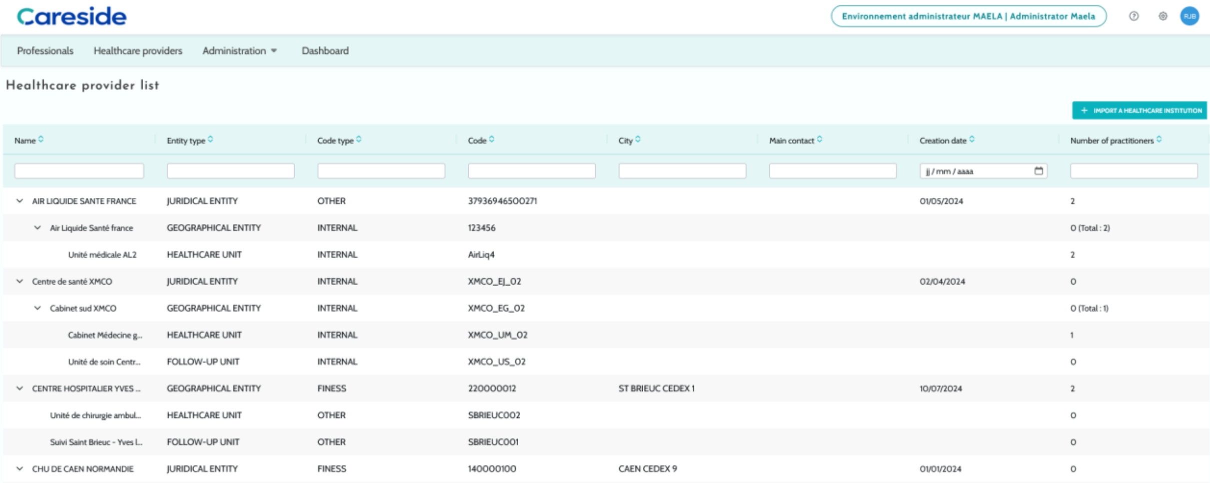
Function	Maela administrator	Medtronic administrator	Health institution administrator	Practitioner	Medical secretary	Social actor	Nurse coordinator	Data manager	Technical support
General access									
Connect to professional site	X	X	X	X	X	X	X	X	X
Institution management									
Create/edit institution: Maela	X		X						
Create/edit institution: Medtronic	X	X	X						
View full institution list: Maela	X								
View full institution list: Medtronic	X	X							
Personalization e-mail and SMS	X	X							
Professional accounts management									
Create/edit professional accounts: Maela	X		X						
Create/edit professional accounts: Medtronic	X	X	X						
View full institution list: Maela	X								
View full institution list: Medtronic	X	X							
Self-manage professional accounts	X	X	X	X	X		X	X	X
Patient enrolment									
Identity management				X	X	X			X
Manual pathway assignment				X	X	X			
Patient management									
Patient list				X	X		X		X
Validation				X	X		X		
General information				X	X		X		
Summary				X	X		X		
Timeline				X	X		X		
Alerts				X	X		X		
Messages				X	X		X		
Profiles				X	X		X		
Care teams				X					
Pathway content				X	X	X			
Pathway dates				X	X	X	X		
Pathways									
Create/edit pathway	X	X	X	X					

Function	Maela administrator	Medtronic administrator	Health institution administrator	Practitioner	Medical secretary	Social actor	Nurse coordinator	Data manager	Technical support
Create/edit protocol	X	X		X					
Create/edit content	X	X		X					
Push pathway, protocol, content	X	X							
Pull pathway, protocol, contents	X	X		X					
Dashboard									
Dashboard MAELA	X								
Dashboard MEDTRONIC	X	X							
Dashboard Institution			X						
Dashboard HCP				X					
Data extraction									
Standard questionnaires extraction			X	X				**X**	
Managing variables and questions									
Create/modify a variable/question in the concept store	X	X	X						
Display list of variables/questions in the concept warehouse	X	X	X						
Activate/deactivate a variable/question	X	X	X						
Protocol model management									
Creating/modifying/duplicating a protocol template	X	X	X	X					
Protocol model validation				X					
Publication of the protocol model (push towards an organisation)	X	X	X						
Display list of protocol templates	X	X	X	X					
Archiving a protocol model	X	X	X						
Enrolment									
Identity creation and selection in IMS + protocol model association				X	X				
Protocol customisation				X	X				
Consent				X	X				
Pairing				X	X				
Protocol start-up				X	X				
Dashboard and protocol file									
Access to patient record AND dashboard display - PRE INCLUDED				X	X				
Patient record access AND dashboard display AND alert lists - IN PROGRESS				X	X	X			
Access to patient record AND dashboard display AND alert lists - COMPLETED				X	X	X			
Access to patient file AND dashboard display AND alert lists - TO BE RENEWED				X	X	X			

Function	Maela administrator	Medtronic administrator	Health institution administrator	Practitioner	Medical secretary	Social actor	Nurse coordinator	Data manager	Technical support
Modification of a protocol in progress				X	X				
Protocol renewal				X	X				
Stopping or cancelling a protocol				X	X				

FUNCTIONS

5. Institution management



Name	Entity type	Code type	Code	City	Main contact	Creation date	Number of practitioners
AIR LIQUIDE SANTE FRANCE	JURIDICAL ENTITY	OTHER	37936946500271			01/05/2024	2
Air Liquide Santé france	GEOGRAPHICAL ENTITY	INTERNAL	123456				0 (Total : 2)
Unité médicale AL2	HEALTHCARE UNIT	INTERNAL	AirLiq4				2
Centre de santé XMCO	JURIDICAL ENTITY	INTERNAL	XMCO_EJ_02			02/04/2024	0
Cabinet sud XMCO	GEOGRAPHICAL ENTITY	INTERNAL	XMCO_EG_02				0 (Total : 1)
Cabinet Médecine g...	HEALTHCARE UNIT	INTERNAL	XMCO_UM_02				1
Unité de soin Centr...	FOLLOW-UP UNIT	INTERNAL	XMCO_US_02				0
CENTRE HOSPITALIER YVES ...	GEOGRAPHICAL ENTITY	FINESS	220000012	ST BRIEUC CEDEX 1		10/07/2024	2
Unité de chirurgie ambul...	HEALTHCARE UNIT	OTHER	SBRIEUC002				0
Suivi Saint Brieuc - Yves L...	FOLLOW-UP UNIT	OTHER	SBRIEUC001				0
CHU DE CAEN NORMANDIE	JURIDICAL ENTITY	FINESS	140000100	CAEN CEDEX 9		01/01/2024	0

When you log in as Administrator, you have access to the following tabs: "**Professionals**", "**Institutions**", "**Administration**" and "**Dashboard**".

To change the institution configuration, click on the pencil under the "**Action**" column.

You can create a new institution by clicking on the "**Import a Health institution**" button.

First you have to search the institution by:

- its type: (juridical entity, geographical entity, follow-up unit, healthcare unit, medical-technical unit
- Its country: (if you are a Maela or Medtronic admin)
- its code type: for example, a FINESS number or an internal ID number
- Its code value

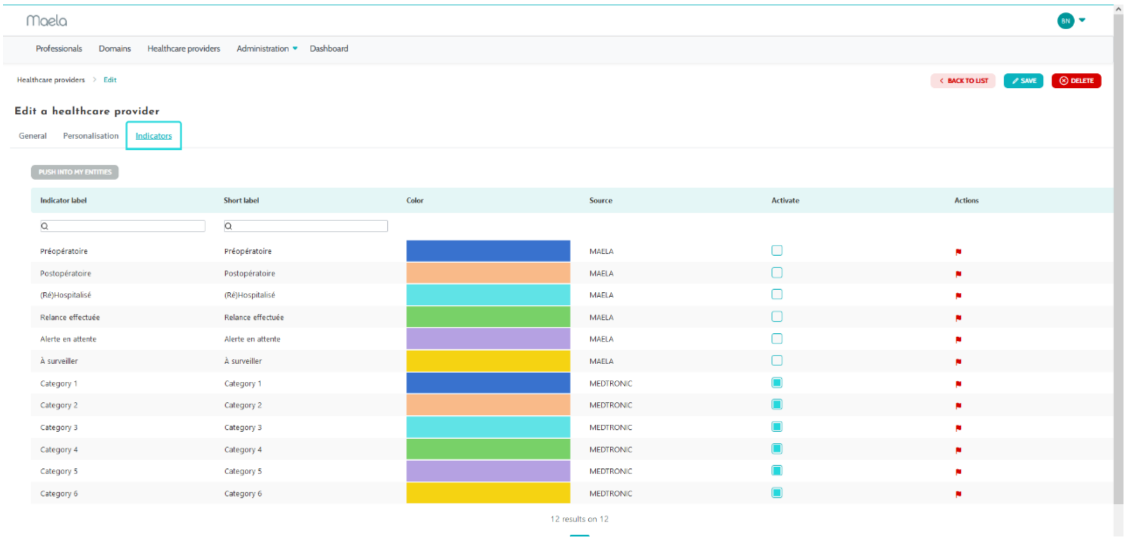
That allows us to research in our resources directory and import the information if it is available.

Both options open the institution create/edit page, which is divided into the categories below:

Category	Field	Accessibility
Healthcare provider code	Type and value (already completed with research information)	All administrators
Group contract*	Enter the name, country, type, short name, start date, identity domain of the institution, the users' creation realm.	All administrators
General information	Enter the address, email, phone number of the institution.	All administrators

Type of institution*	Choose the type of institution: follow-up, healthcare or technical institution.	Maela® and Medtronic administrators
Type of follow-up*	Choose the type of follow-up allowed in the institution: Maela®, Ambulight follow-up or both.	Maela® and Medtronic administrators
Follow-up institution	If applicable, select one or more follow-up institutions to link to the healthcare unit or geographical entity you are creating.	Maela® and Medtronic administrators only, for "Healthcare" institution type
Technical institution	If applicable, select one technical institution from the drop-down menu that lists the existing ones. (only for geographical entities and medical units)	Maela® and Medtronic administrators only, for "Healthcare" institution type
Opening days*	Choose the opening days/hours of the institution	All administrators
Channel configuration - Request a call channel	Check this option to activate the "request a call" functionality.	All administrators
Channel configuration - Messaging channel for patients	Check this option if you want patients and professionals to be able to exchange information via secure messaging.	All administrators
Languages	Choose all the languages needed.	All administrators
Time zone	Set the preferred time zone.	All administrators
Enable two-factor authentication	Enable secure dual authentication	All administrators
Document configuration	Select the correct legal content for your institution, which should be created at the CMS.	All administrators
Single link	Select a validity duration for the password creation link	Maela®, Medtronic and healthcare administrators
SMS management	Configure SMS follow-up settings	Maela®, Medtronic and healthcare administrators, if Ambulight follow-up type selected
Personalization	Customize the content of e-mails and SMS messages sent to institution users.	Maela® and Medtronic administrators only
Indicators	Tab for activating the indicators you want to appear on the patient list	Maela®, Medtronic and healthcare administrators

* Mandatory field to be able to save



When editing a healthcare institution, all the indicators configured in the indicator warehouse are displayed. Activating an indicator enables healthcare professionals to use this new indicator on patient files and to have a new quick filter.

6. Professional account management

6.1. Management of the Professional's list

When you click on "**Professionals**", what you see depends on your administrator profile:

- **Maela administrator**: you can manage all the professional accounts of the application
- **Medtronic administrator**: you can only manage professionals of your institutions
- **Health institution administrator:** you can manage all the professionals assigned to your health institution

To edit a user, click on the user line and then click on the "**Edit a professional**" button. You can create a new user by clicking on the "**Add a professional user**" button.

First you have to search the professional by:

- their country: (if you are a Maela or Medtronic admin)
- their identifier type: for example, RPPS number (national identifier) or a local ID number
- their ID number

That allows us to research in our resources directory and import the information if it is available.

Both options open the institution create/edit page, which is divided into the categories below:

Category	Field	Profile
General information	Surname*	All
	Birth name	All
	First name*	All
	Profile*	Depending on your profile, you can create user types

Category	Field	Profile
	Telephone*	All
	Private number	Doctor, medical secretary, social actor and nurse coordinator
	Email*	All
	Address	All
	ID Type and Practitioner's ID	All
Authentication	Username*	All
	OTP phone number*	All
Institution	Institution*	Depending on your profile, you can view and assign specific institutions
	Phone number of secretary's office	Practitioners only
	Phone number of the department	Practitioners only
Preferences	Language*	All
	Time zone*	All
Secretaries management	Search a secretary	Admins only
	Secretaries list	Admins only
Other	Other	All

* Mandatory fields

6.2. Self-management pro account

By clicking on your initials located on the top right of the platform, a drop-down list of links leading to configuration pages appears. Depending on your profile, you have access to various sections defined in the table below.

Section	User profile
My account	All profiles except for the notification section, which can only be viewed by practitioners.
Secretaries	Practitioners only
Replacing practitioners	Practitioners only
Password	All profiles
View my verified devices	All profiles

6.2.1. Account details

When you click on the "**My account**" section, you open the page in consultation and edit mode. You can modify and edit some of the fields such as language, time zone, address; phone numbers. The professional's institution can also be modified. For the practitioner profile, there are two additional sections: "**Notification**" and "**Institution**".

For the healthcare practitioner, medical secretary, social actor and nurse coordinator profiles, the "**Private Number**" checkbox allows the number to be hidden from other users. Only the institution administrator, Medtronic and Maela administrators, and the professional himself will see the number.

6.2.2. Password and security

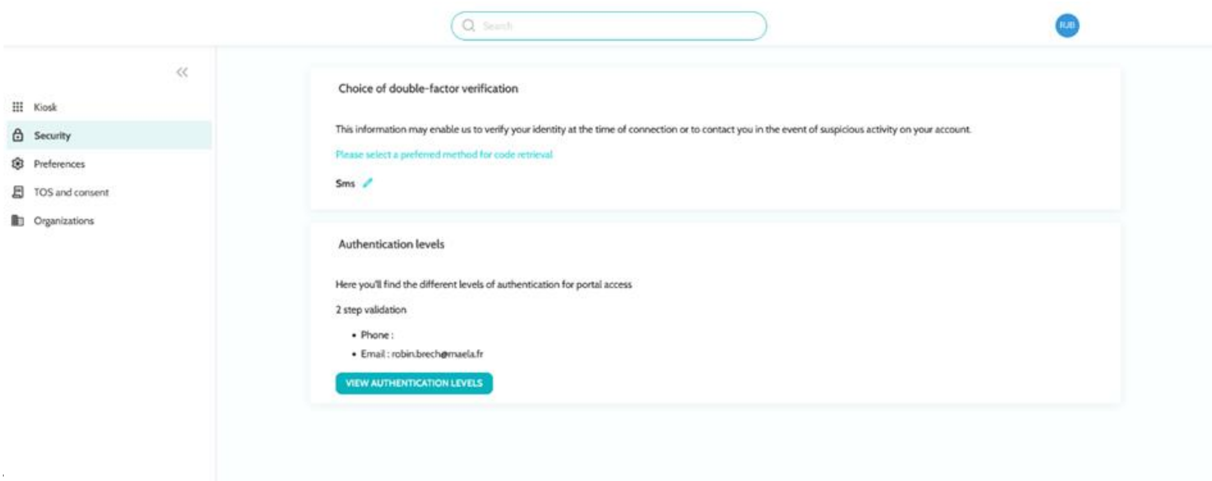
To change your password, click on your initials and a menu will appear. Click on “Manage my account”, then on the left-hand security menu and finally on “Password”. You can now change your password.

In this menu, you can change your current password. For security reasons, the password must contain:

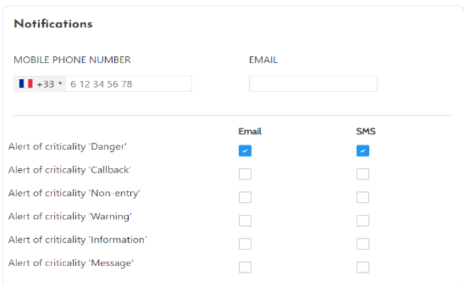
- At least 8 characters
- At least 1 number
- At least 1 uppercase letter and 1 lowercase letter
- At least 1 special character (!"#$%&'()*+,-./:;<=>?@[\]^_`{|}~)

The criteria must be followed to be able to save.

From the same “Security” menu, you can choose how your identity will be verified at login: by receiving a one-time code by e-mail or SMS.



6.2.3. Notifications management



Only practitioners have this option. Notifications can be sent by SMS and/or email, and practitioners can choose the criticality of the alerts they want to receive.

6.2.4. Secretaries

Only practitioners can authorise secretaries in their user profile. The authorised secretary profiles can enrol patients. They have the same rights as the practitioner for the patient file except for the functionality that manages authorisations of other practitioners and institutions. They also won’t receive notifications.

6.2.5. Replacing practitioners

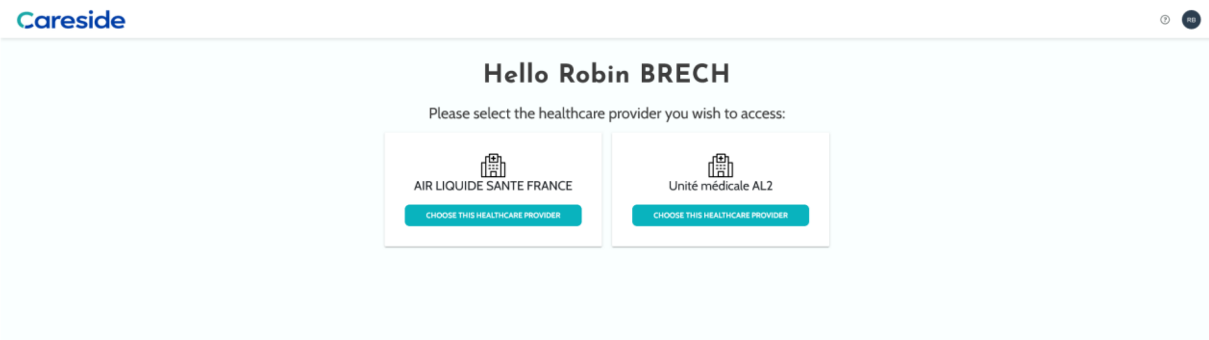
Only practitioners can give access to all their patient files for a defined period to another practitioner in Maela®. The start and end dates of the replacement period must be set. During this time, the primary practitioner can access the account normally, but notifications are sent to the replacement practitioner until the replacement period ends.

6.2.6. Multi profiles

Your account may give you access to several work contexts, for example depending on:

- Your role: You can be a practitioner and an administrator for the same establishment.
- Your facility: You can be a practitioner for several sites

If your identifiers have been entered in the same way for the different profiles, you will have a single account (login and password) and will be able to choose your working context when you log in, and change it at any time once you are logged in.



7. Patient enrolment

7.1. Identity management

Patients can be added to the "**Patient list**" by clicking on the "**Add a patient**" button. A new page opens making it possible to search for the corresponding patient identity. For the "Social actor" profile, the first page corresponds to this identity search. If the identity already exists, click on the desired search result to open the patient identity page and verify the patient details. Click on "**Validate**" once you finish to move on to the pathway assignment.

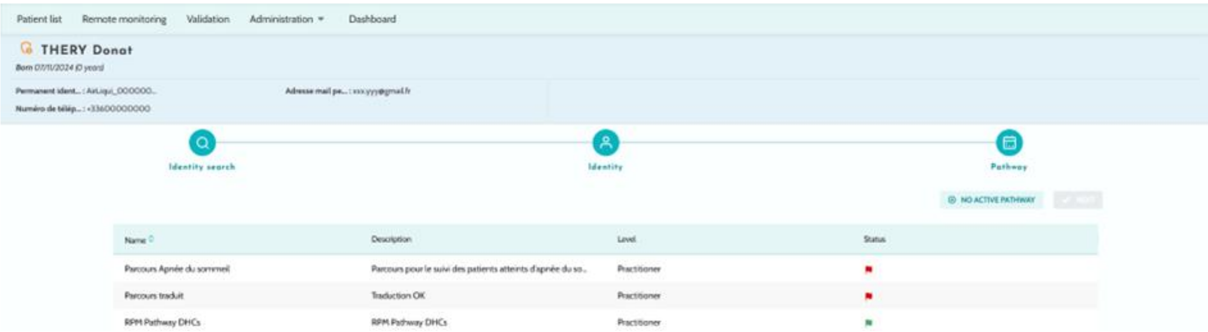
If the identity does not exist, the button "**Create new identity**" appears and another page opens asking you to fill in the following mandatory fields:

- First name
- Surname
- Date of birth
- Personal phone number
- Email address
- Patient username
- OTP phone number

Click on "**Validate**" once you finish to move on to the pathway assignment.

If the connection identifier is already in use (patient being treated in another health establishment), a pop-up window will appear offering you a new connection identifier other than the email address.

7.2. Pathway assignment



When the identity is validated, a patient record is created. Once the patient record has been created, the pathway to be assigned to the patient must be selected. The flags displayed to the right of the pathway templates indicate the translation status of the pathway in relation to the patient's language:

- Red: pathway not translated into the patient's language.

- Green: pathway translated into the patient's language.

The pathway templates available to you correspond to the templates in your personal library and to the templates you share with other practitioners in the same department.

Only one pathway can be assigned at a time. There are two scenarios when assigning a pathway:

1. **When onboarding a new patient:** After the identity is created or retrieved, you can add a pathway to your patient. Choose the pathway you need to assign from a closed list.
2. **If the patient already exists**: Open the patient file and "**Pathway**" tab. Click on "**Add a new pathway**" and choose the pathway you need to assign.

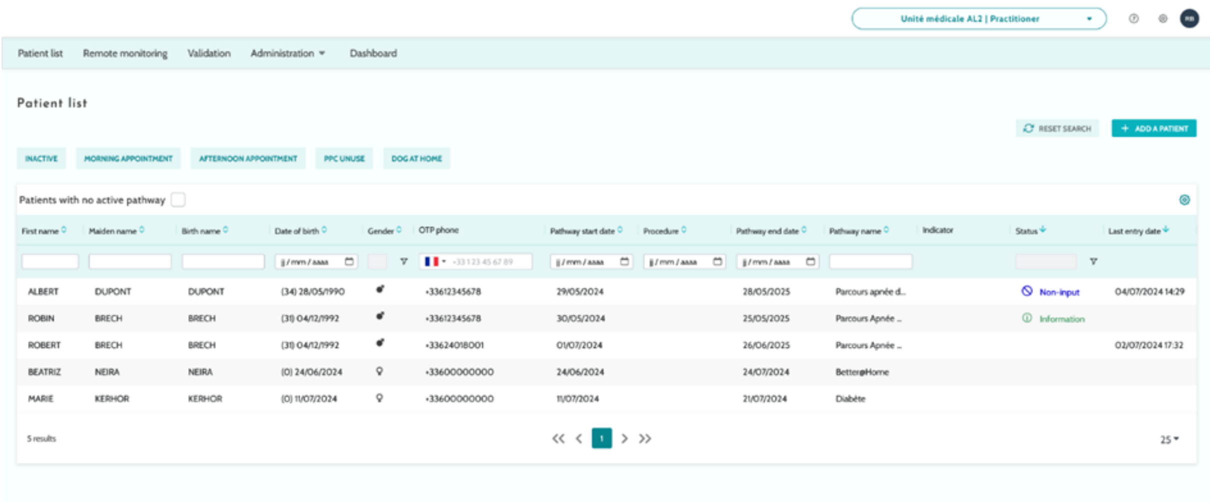
In both scenarios, with a practitioner or medical secretary profile, you can create it from scratch by clicking on "**Create a new pathway**".

The next step is to complete the mandatory fields to finalise the pathway assignment process.

You must determine whether the pathway enables the activation of a patient account, allowing the patient to access the application.

You can also fill in event dates, if known. These dates can be used to activate content for the patient, so we strongly advise you to keep them up to date. If you wish to modify any information in the course, click on "**Edit pathway**".

8. The patient list



The patient list appears to practitioners, medical secretaries and nurses.

This is the default home page that is displayed directly after your log-in. You see the list of active patients for whom you have authorisation. Patients are ordered by status, meaning that the patients with the highest criticality statuses are displayed first.

Status list in order of criticality: Danger, Warning, Call-back, Messaging, No input, Information and No alerts. You can click on them to open a right pane which will display the alert details and the last care team exchange (note).

Case management statuses are displayed in colours that can be assigned to patients to facilitate classification and filtering. To assign a colour to a patient, open the patient file and select the desired colour on the "**Summary**" list.

The "**Patients out of follow-up**" button displays the patients whose pathway has ended, has not started or has no assigned pathway.

For follow-up institutions only, a calendar logo allows to visualise if a healthcare institution is closed or not for the patient.

9. Validation

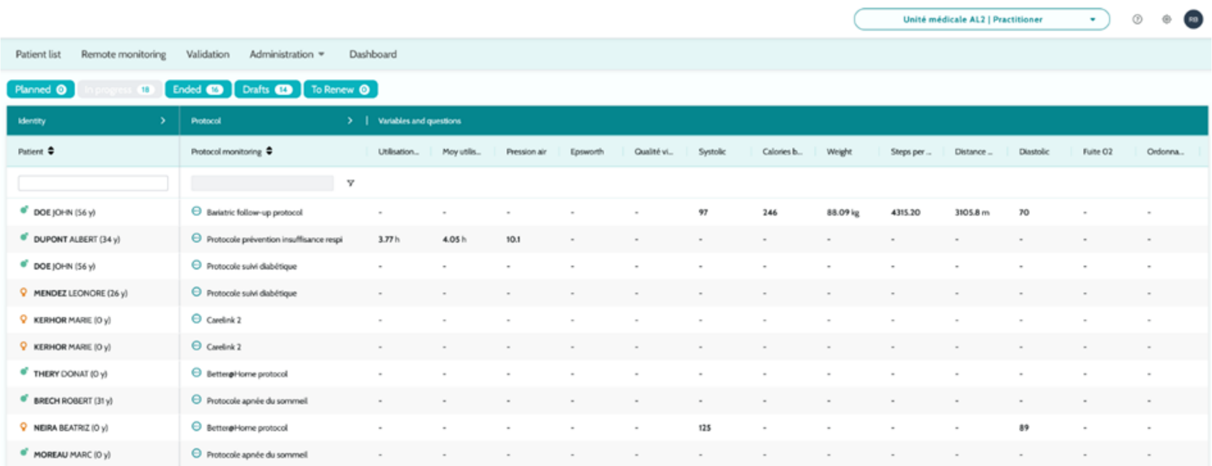
This menu allows you to validate the identity of patients when they respond to questionnaires directly via secure links sent to them by SMS. This is a mandatory identity check measure and is only requested for patients with an Ambulight protocol who respond directly via that secure link sent by SMS. Only patients who have not entered a surname and first name that are exactly the same as the birth surname and first name registered on the platform will appear in this menu.

For security purposes, regardless of the validation process being completed, as soon as the patient has responded to the questionnaire or measurement content, any alerts triggered by the responses are directly available in the patient file.

10. Remote monitoring menu

The remote monitoring menu is displayed for practitioner, medical secretary and nurse profiles. In this list you will find the patients whose pathways contain telemonitoring protocols for which you have access authorisation.

Depending on the status of enrolment, the telemonitoring protocol is displayed on the dashboard with a status indicating this.



- In progress: patient whose telemonitoring protocol has started: start date is greater than or equal to today's date.
- Terminated: patient for whom the protocol has been terminated for a reason to be entered.

- Pre-included: patient whose enrolment has not yet been finalised.
- To be renewed: patient whose telemonitoring protocol is in progress but whose end date is approaching or has passed.

Protocols are ranked in order of alert criticality, with those containing a danger alert at the top of the list.

List of alert criticalities in order of priority: Danger, Warning, Information, Not entered and No alert.

11. Patient file

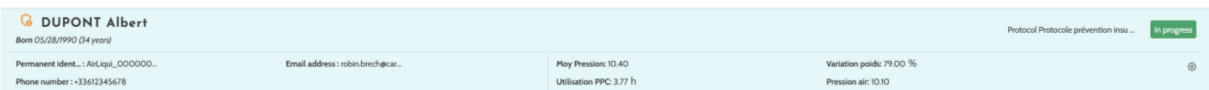
To open a patient file, click on the desired patient line in the patient list. By default, this action opens the patient's summary menu.

The patient file menu consists of **sixteen** modules:

- Summary
- Pathway view
- Measurement
- Connected device
- Reports
- Questionnaires
- Educational content
- Attachments
- Analysis
- Treatment
- Tasks
- Alerts
- Messages
- Profile
- Care team
- Pathway

The Social Actor will only see three modules: Questionnaires, Profile and Pathway.

11.1. Patient headband

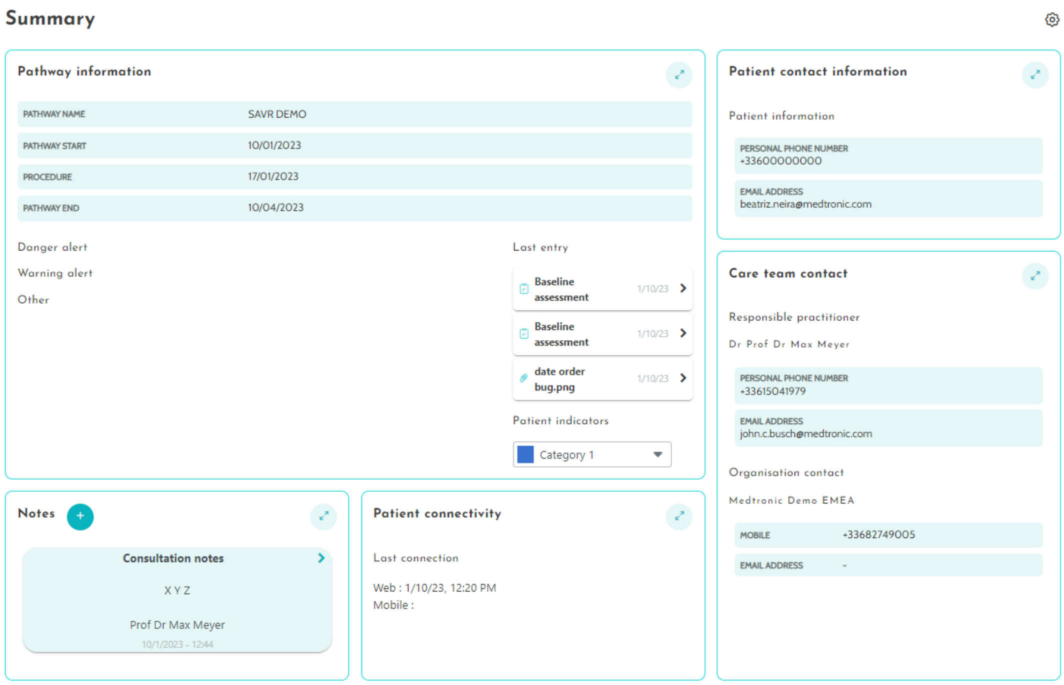


The patient banner consists of three parts:

- The mandatory identity data section, with the patient's birth name, surname, first name, identity status, date of birth, calculated age and gender.
- The configurable identity widget, in which your administrator has configured the information to be displayed (telephone number, email address, permanent patient identifier, etc.).

- The information pathway and patient account widget in which you can find the pathway name and status, and also information about patient account (access to the platform and account status).
- The variables and questions widget, which is only displayed if the remote monitoring package is activated. This widget contains the different variables (CRP, temperature, blood glucose, etc.) or questions (smoking patient, polypathology patient, etc.) that you wish to view at any time.

11.2. Summary



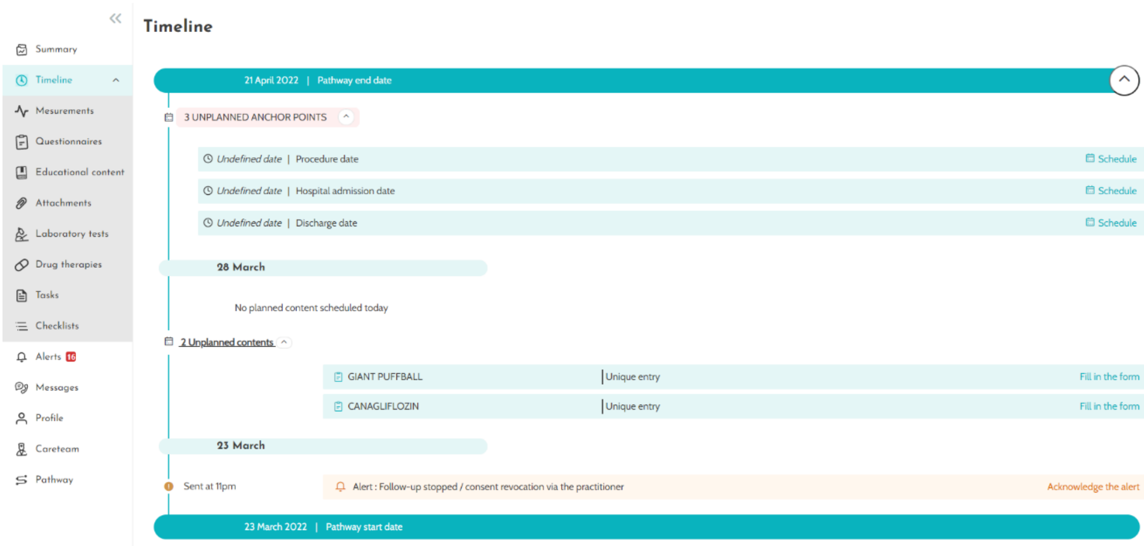
On the summary tab, the following sections are present:

- **Pathway information**, which contains the pathway name, start and end dates and unacknowledged alerts. The alerts are sorted by criticality and by the date and time they were triggered. Alerts can be acknowledged by clicking on them.
  The "**Patient indicators**" dropdown contains all the indicators added to the patient file, even if they are not activated in the organization where you work.
  Finally, the "**Last data**" section shows the last time the patient made an entry, responded to a questionnaire or sent a document.
- **Notes**, which contains the last three notes exchanged between the care team, this section allows creating, reading and replying to notes.
- **Patient contact information**, which contains the patient's email and phone number. There is also information about the patient's trusted person(s).
- **Adherence information**, which displays information about the patient's last connection: date and time as well as device type used.
  Care team contact, which contains the contact details (name, phone number and email) of the healthcare institution and responsible practitioner. For this last one, the contact details are shown only if the box "**Private number**" is unchecked.

A banner is displayed below the menu if the patient's institution is closed indicating that the patient cannot log in.

11.3. Follow-up

11.3.1. Timeline



The complete care pathway can be viewed under the "**Timeline**" menu. This menu contains submenus giving direct access to patient measurements, questionnaires, educational content, files (attachments, laboratory tests, pictures), drug therapies and tasks.

The timeline includes all key dates, planned content and alerts for the patient's care pathway. The items are organised in reverse chronological order, with the option to expand or collapse the menus. By default, the expanded menu with all details is the one the patient is currently in.

When you click on a timeline item, a side panel opens allowing you to perform review, complete and validate actions

11.3.2. Measurements

a. Constant tab

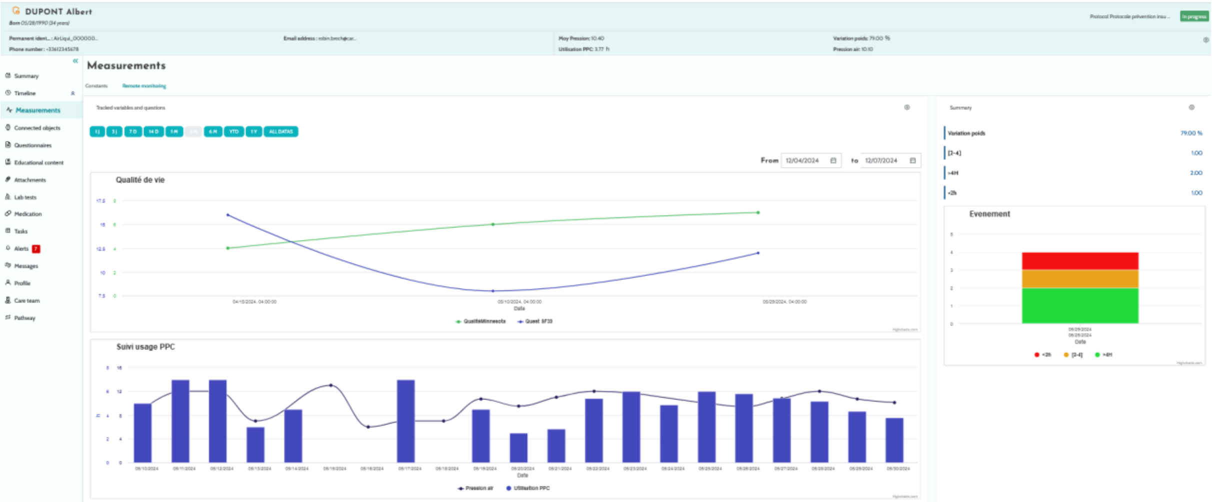
RA point on a graph corresponds to data entered by the patient (or by the practitioner on behalf of the patient). By moving the cursor over a point on the graph, you can display the detailed results or edit them.

b. E-monitoring tab

This tab shows the graphical evolution (curves and/or histograms) of the measurements of the variables in the remote monitoring protocols.

A point on the graph of a variable corresponds to a measurement collected for the patient. Hovering the mouse over a point on the graph displays a tooltip with details of the measurement (date, time, and source). The cogwheel icon lets you change the order of the variables.

This section also contains a summary view of the latest measurements of the variables and questions monitored for the patient. In the protocol, you define the variables and questions you wish to display in the summary (no limit on variables/questions). Hovering the mouse over a variable in the summary displays a tooltip with details of its last five measurements (date, time and source of each measurement). The cogwheel icon lets you change the order of the variables and questions.



11.3.3. Connected device

This sub-menu displays the link status of the protocol to the various activated automatic measurement acquisition modes.

The notches indicate that the link is still active, and the red crosses indicate that the link has been interrupted.

For the “Carelink” acquisition mode, a “Synchronise” button can be used to manually start retrieving patient measurements from the Carelink application.

For the “Withings HM” and “Withings SIM” acquisition modes, a “Restart subscription” button reactivates access to measurements collected by Withings connected devices.

11.3.4. Reports

This section shows all the connected devices reports available in the context of remote patient monitoring. Reports showed depend on acquisition mode set up in the protocol. You can download these reports on your computer.

Today, only Carelink and Lowenstein reports are available if you use Carelink or Lowenstein acquisition mode in your RPM protocols.

11.3.5. Questionnaires

This section shows the list of completed questionnaires with the date and author. Click on each line to check the details of the responses. The questionnaire can be completed by the patient, the professional or both regular questionnaires can be input an unlimited number of times and modified (creating a new version). Screening questionnaires can only be completed once and cannot be modified later.

Click on “Generate report” to download the pdf questionnaire with associated alerts. The social actor does not have the rights for this last action.

11.3.6. Educational content

This section contains the full list of educational content assigned to the patient, the professional or both with their categories, subcategories, due dates and read dates. If the content is not scheduled, “**NC**” is displayed in the date column. Clicking on a line opens a preview.

11.3.7. Files

This sub-menu contains all the documents exchanged between the patient and/or professionals. It displays documents entered, to be entered, those to be entered in the future and archived documents.

The profile column indicates who can view and/or enter the file.

You can enter a new file using the “Add attachment” button at the top right of your screen.

This section displays a list of all the documents added to the patient file. These attachments can be shared either by the patient or healthcare professional. Privately shared attachments have a padlock beside them. Finally, the three dots allow you to perform the following actions: delete, edit and download.

Drug therapies

This section displays all the medicinal products assigned to the patient, and for each medicinal product, you can acknowledge and see:

- Treatment description
- Dates of the last dose and the next dose

Clicking on the eye displays the patient dosing history with the dates and times

11.3.8. Tasks

This section includes the list of all tasks completed and pending assigned to the patient, the professional or both. Each task has an assigned status:

- **Green checkbox**: task completed
- **Red box**: user has not yet completed the task
- **Orange line**: user is late completing the task

When you open a task entry, the side panel appears with the name and description, as well as the validation option if it is not yet completed.

11.3.9. Video Conferencing

Once your institution subscribes to the video conferencing service, you will be able to initiate a video conference with your patient from various sections of their patient file:

- An active message conversation
- The timeline view
- The video conferencing page

Clicking the video conferencing icon will open a pop-up window, enabling you to start an instant video conference. The patient will be notified immediately via both email and SMS.

To join the video conference, navigate to either the video conferencing page or the timeline view and click "Join the video conference." The video conferencing module will open in a pop-up window, separate from the main platform.

A stable connection is required for both the patient and the professional. The professional will be automatically connected if they are already logged in to the platform.

Within the video conferencing module, the patient banner is available to call the patient if they are late, assist them with connecting, and verify their identity.

11.4. Alerts

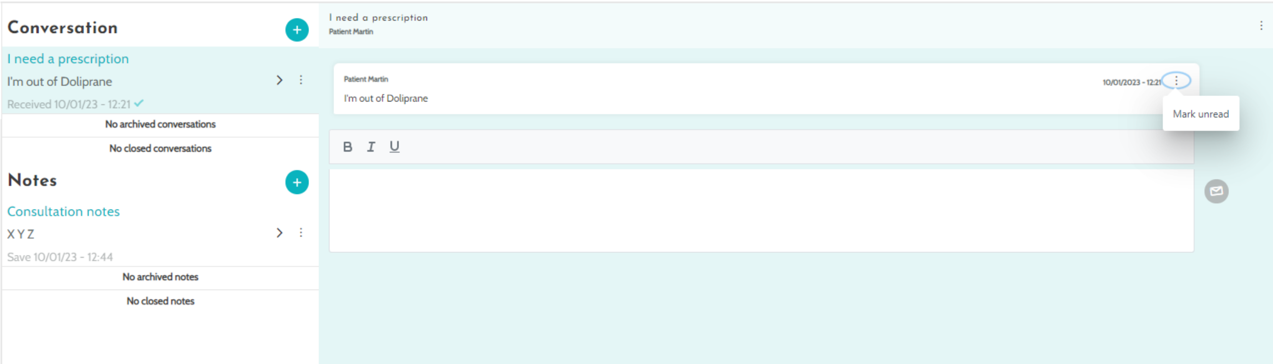
In this section, you find all the alerts generated during the care pathway. By default, only unacknowledged alerts are displayed with the criticality, date and time triggered, title and message body, and associated content. The checkbox "**Show acknowledged alerts**" displays the alerts that have been acknowledged.

Alerts follow a simple colour code:

- Red: Danger
- Orange: Warning
- Blue turquoise: Callback request
- Green: Discussion and messages
- Dark blue: Non-input
- Light blue: Information

You can choose to acknowledge one or multiple alerts, and then a pop-up lets you choose a **reason** for the acknowledgement from a drop-down list (mandatory) and enter a **message** in the text box below (optional).

11.5. Messages



In this section, the healthcare professionals authorised in the patient file can view all conversation threads and notes.

The “Conversations” option can be activated or deactivated in the healthcare institution's settings. It creates a channel of communication between the healthcare professional and patient. Clicking on an open conversation displays a side chat with the conversation title, date and time, as well as the last message status (unread, read and when it was read). Messages can be marked as unread. This will unacknowledged the associated alert.

It is also possible to share files between healthcare professionals and patients through a conversation with the dedicated icon.

The “Notes” functionality creates a channel of communication between the healthcare professionals only.

For both functionalities it is possible to archive and close a thread.

11.6. Profile

This module contains the patient personal information registered during account creation.

The module is divided into five tabs:

- “**Identity**” contains the patient's first name, surname, birth of date and gender, among other patient identifiers. It also contains the patient contacts and postal address. As a healthcare professional, you can edit the information.
- “**Account**” contains information on the patient's user account (username, e-mail address, telephone number, and languages). From this tab, it is possible to regenerate a password or to send the password renewal link to the patient.
- “**Visit**” is available when Maela® is connected to the hospital information system and electronic medical records. It contains the list of the patient hospital stays. In the “**Type**” column, the letter “**H**” refers to hospitalisation, the letter “**R**” to recurrent, the letter “**U**” to emergency and the “**A**” to ambulatory.
- “**Consent**” contains the legal documents approved by the patient and the dates of the endorsements. Patient consent can be revoked.
- “**History**” allows you to consult the patient's identity modification history.

11.7. Care team

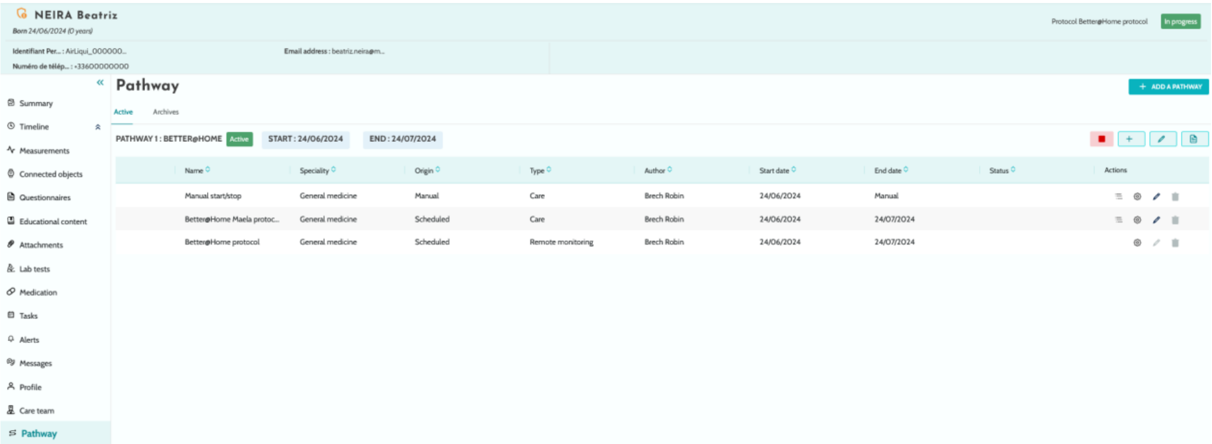
The “**Care team**” menu lists the professionals or services authorised to access a patient file. Via this menu, you can do the following:

“**Authorise a practitioner**” allows you to provide access to the specific patient file to other practitioners. You can filter and search the available practitioners list.

“**Authorise an entity**” enable another entity and its health professionals to have access to a specific patient file. You can filter and search the entities list.

You can revoke an authorisation at any time by clicking on the bin icon.

11.8. Pathway



The “**Pathway**” tab inside the patient file lists the current active pathway as well as the Archived pathways on another tab. Only one pathway can be active at a time, so while a pathway is ongoing, the “**Add a pathway**” button is disabled.

For a given protocol, when you click on the three dots that say “Details and recommendations” a lateral menu opens with the protocol information. If you click on the pencil, the protocol edition page appears.

Finally, if you click on the upper pencil edit button the pathway edition page opens.

For the “**Practitioner**” profile, a “**Stop pathway**” button will be available at the end of the current pathway line. This button allows you to force the end of the pathway before its end date.

WARNING: Forcing the end of a pathway is not recommended. It is preferable to wait for the pathway to end or for the patient to stop it.

An “**Export**” button can be used to generate a zip file for a patient's pathway, which contains the files loaded in this pathway (attachments, analyses, prescriptions), the end- of-follow-up report and the csv of measurements collected if there is a remote monitoring protocol.

a. Active pathway:

The active tab displays all the patient's courses, with different statuses: pre-included, active or started.

A pre-included pathway is a pathway that contains at least one pre-inclusion criterion that has not been completed. An icon on the left indicates whether actions need to be taken on a protocol. For example, if a telemonitoring protocol requires additional information to enroll the patient, you'll need to click on the “little man” icon to open the various enrollment stages. Other times it might be content that needs to be input, which you can enter by clicking on “Finalize pre-inclusion”.

The “stop”, “edit”, “add protocol” and “generate report” buttons are used to launch actions on the pathway. The pathway displays all the protocols attached to it in a table, which can be care or remote monitoring protocols.

b. Archived:

The archived tab displays all pathways in stopped, completed and archived status.

Archived pathways do not offer the user the possibility of taking any action, unlike completed and stopped pathways, where actions on protocols, in particular, are still possible. In fact, protocols can become active again if the schedule is modified.

c. Enrolling in an IoT/RPM protocol

Clicking on this icon opens the personalization step, which allows you to customize the remote monitoring protocol for your patient: for example, customize the alert trigger thresholds.

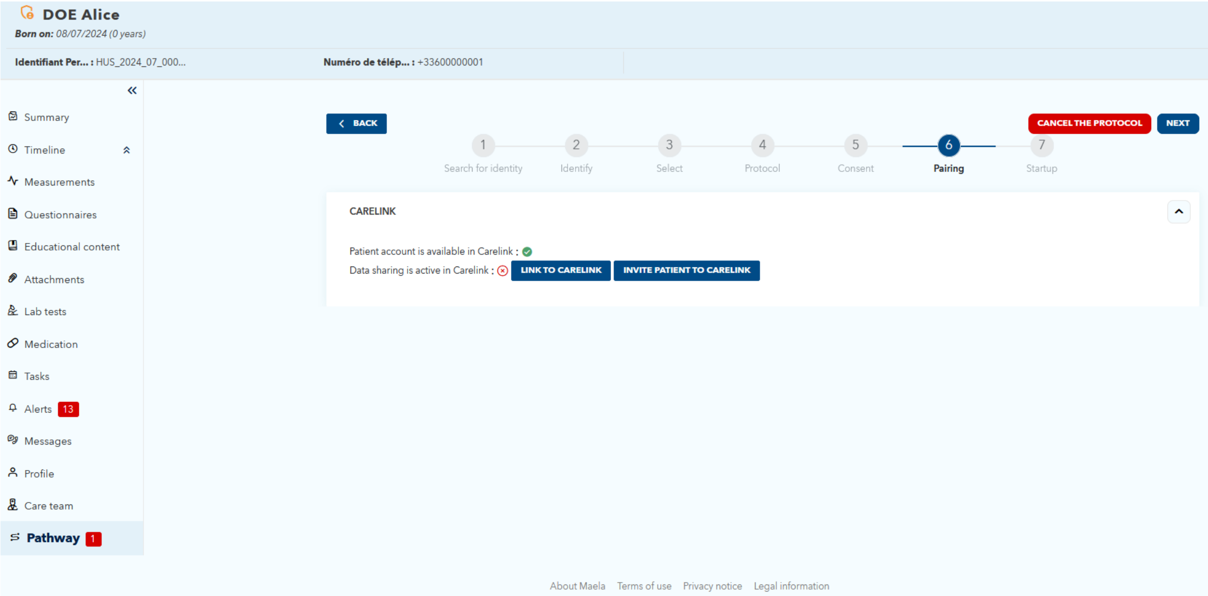
Please note that if you add content to the telemonitoring protocol, it will be available in all the other languages of the protocol template, but displayed by default in the language of the logged-in user who added it.

Once you have customized the telemonitoring protocol for your patient, you can click on Next to collect the patient's consent. A checkbox at the end of the consent details allows you to validate that the patient has agreed to be included in a telemonitoring protocol, and to save the date of this agreement.

Depending on the acquisition modes selected, you can then link the various devices connected to the patient's telemonitoring protocol, in order to collect the various measurements via these connected devices.

d. Carelink

Once you have selected the “Carelink” acquisition mode in the protocol, pairing is a 3-step process:



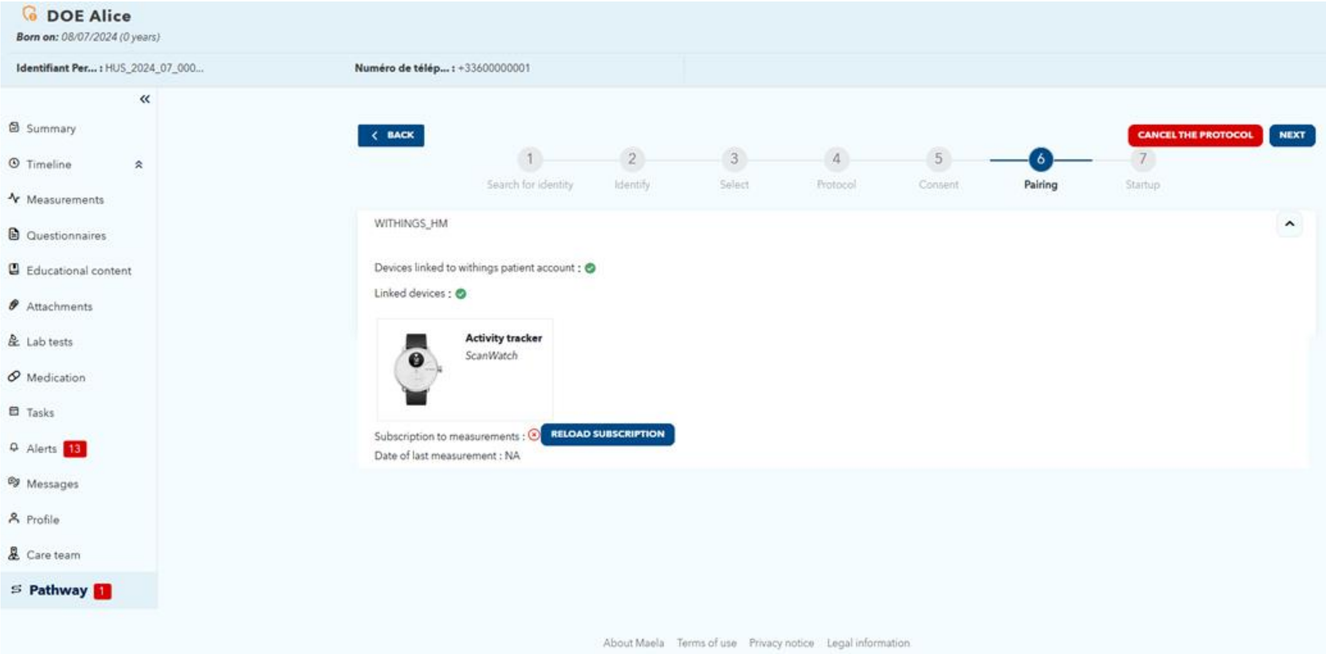
- **Creating a Carelink account**: You need to create an account for the patient in the Carelink application by clicking on the "Create patient" button. A confirmation message appears when the account is created, and a green notch is displayed to signify that the patient account is available.
- **Patient invitation**: If the patient has not yet created an account on Carelink, you can send him/her an invitation with the steps to follow. Click on the "Invite patient" button, then enter the patient's e-mail address so that the patient receives the instructions.
- **Patient link**: If the patient has already created a Carelink space, you need to link the patient space to the Carelink account. To do this, you have two options after clicking on the "Link to Carelink" button:
    - Send a sharing request to the patient by entering his or her username. The patient. The patient receives an e-mail to make the link.
    - Activate live sharing by entering the patient's Carelink username and password.

Green notches in front of a pairing step indicate that the step has been successfully completed. Red crosses, on the other hand, show that the step has not yet been completed.

Note that if you don't select an automatic measurement acquisition mode, then you skip this step in the enrollment process.

e. Withings Health Mate (HM)

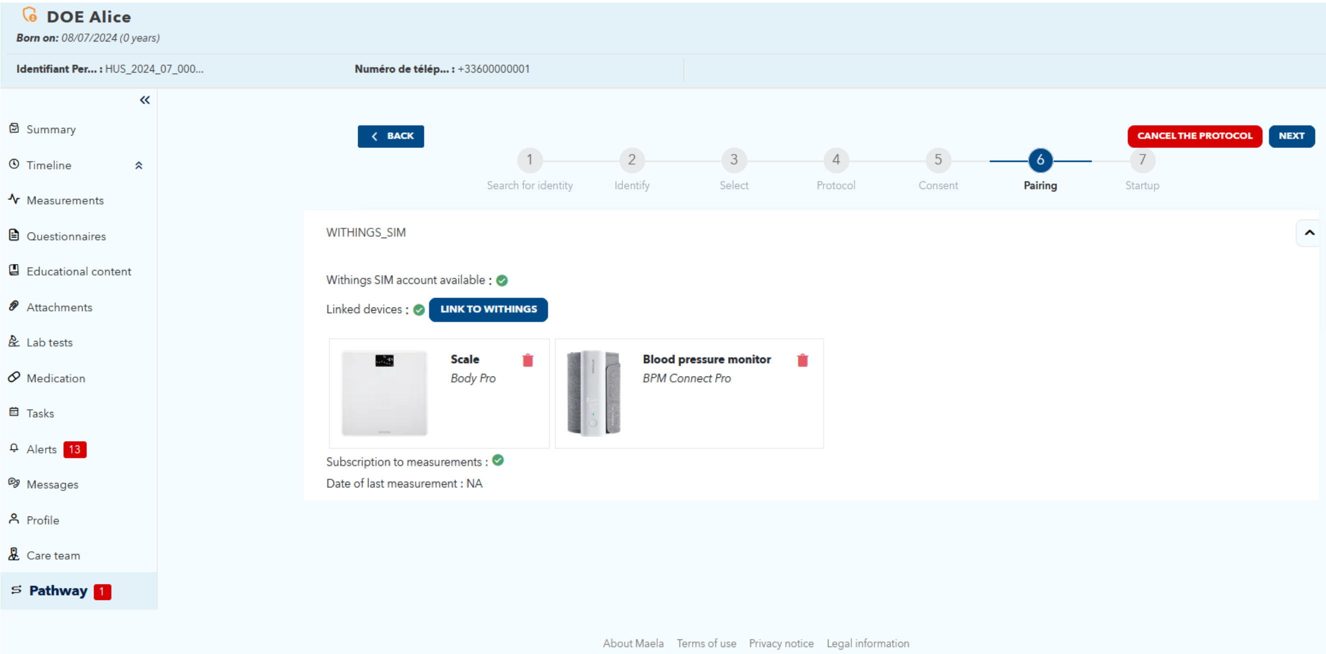
Withings Health Mate concerns patients using connected devices from the Withings range that require their application to function. When you have chosen the "Withings HM" acquisition mode in the protocol, then for pairing you need to link the protocol to the patient's account on the Withings application.



By clicking on the “Link to withings” button, a pop-up window opens, allowing authentication with the patient's withings account credentials. Once authentication has been successfully completed, the connected devices linked to the patient's withings account are automatically displayed in the pairing screen.

f. <u>Withings SIM</u>

Withings SIM concerns patients using connected objects with a SIM from the Withings range without their application. Once you have chosen the “Withings SIM” acquisition mode in the protocol, you will need to activate a technical account in order to access the data from the connected devices.

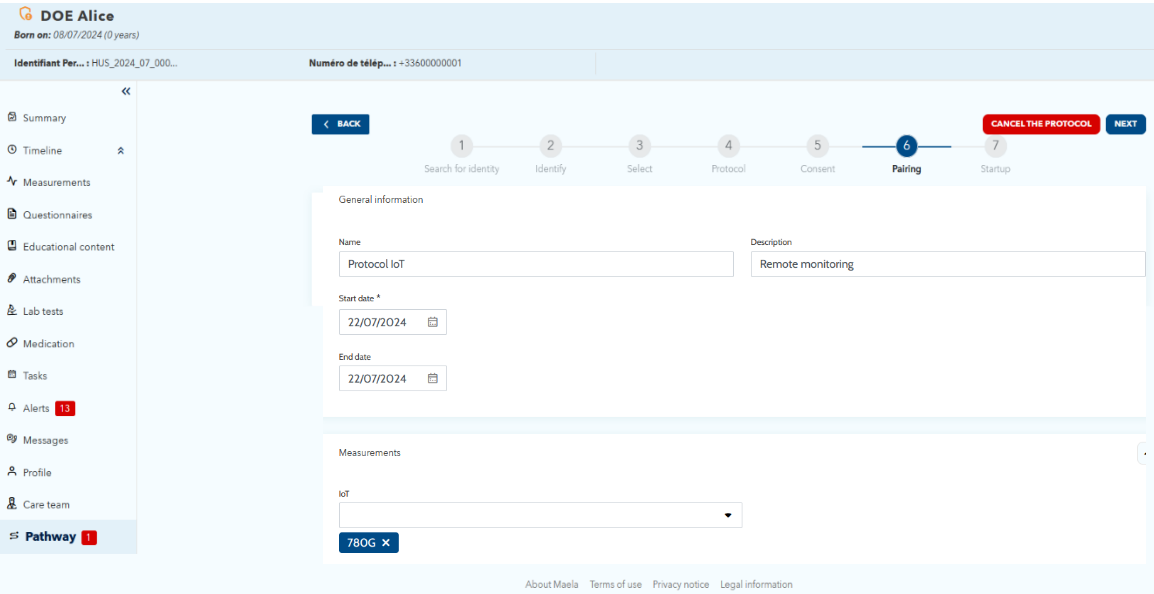


Click on the **'Activate'** button to display a pop-up window where you can enter your height, weight and the MAC addresses of the connected objects available to the patient, which will be used for remote monitoring.

Once activation is successful, the pairing screen automatically displays the connected devices corresponding to the MAC addresses entered.

A “**Link to Withings**” button opens a pop-up window for entering the MAC addresses of connected devices to be used in addition in the remote monitoring protocol.

g. Startup



To finalize enrollment, you need to enter the start and end dates of the telemonitoring protocol, as well as the measurements of the pre-inclusion variables, if configured.

NB: Many protocols can be associated with the same patient in parallel.

Once enrollment has been completed, whether partial or total, the patient's status is displayed on the dashboard.

12. Non-medical content

Maela® and Medtronic administrators, as well as the institution administrators, have access to a submenu inside “**Administration**” called “**Content**”. This section allows you to create quality questionnaires.

The quality questionnaires created by a Maela® or Medtronic administrator are seen by all patients enrolled in the solution.

The quality questionnaires created by an institution administrator are seen by all patients enrolled in the solution who are under treatment in that specific institution.

13. Scheduled contents

A dedicated tab at the header menu displays all planned content, including statuses (scheduled/completed) along with planned and entry dates.

The worklist also displays any triggered alerts in the first column, helping you track and manage alerts related to specific content items.

By default, the worklist is filtered to display today's data, but you can customise the date range to view historical or upcoming information.

14. Content templates

Content templates can be accessed via the "**Administration**" tab or directly via protocols and pathways both at the administration level and in the patient file. At the practitioner level, this page lists all the content templates you have created or imported.

Click on "**Add a template**" to access the templates available at your level or to create your own content templates. Maela® and Medtronic administrators can view and edit all the existing content templates in the solution. Both Maela® and Medtronic, as well as institution administrators, can push each item to specific institutions.

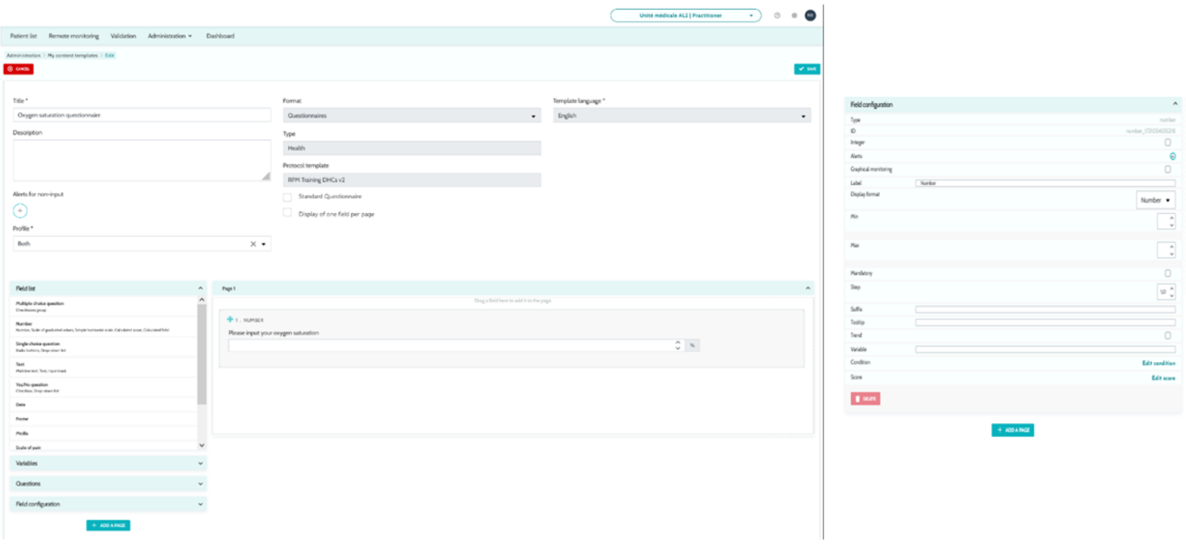
When creating a new content template, you can select different types:

Template Type	Category	Description
Educational content	Default	This type of template creates a link between Maela and a content management system called WordPress. It can be completed by the patient, the professional or both.
Document	Default	This content type can be uploaded from the computer in the following formats: PDF, PNG, JPG, Microsoft Office, MP4, AVI, HTML, TXT, RTF.
Files	Lab test	Enables you to configure a task for the patient to submit a lab test.
	Attachment	Enables you to configure a task for the patient to submit an attachment.
Questionnaire	Default	Questionnaire builder that allows you to create and configure questions, possible responses, conditional rules, scoring and alerts. It can be completed by the patient, the professional or both.
	Screening	Special questionnaire also configured using the questionnaire builder. Depending on the user responses, different protocols can be triggered in the patient pathway. It can be completed by the patient, the professional or both and it can only be completed once.

	SMS	Questionnaire sent by SMS which the patient can answer directly by SMS. The choice of question types is limited.
Task	Deafult	Used to configure a task of any type to set a reminder for example.
Medication	Deafult	Enables you to set a medication reminder

When configuring “Documents”, “Links” and “Educational content”, there is an option to select under which category and subcategory of the patient library the content template must be displayed.

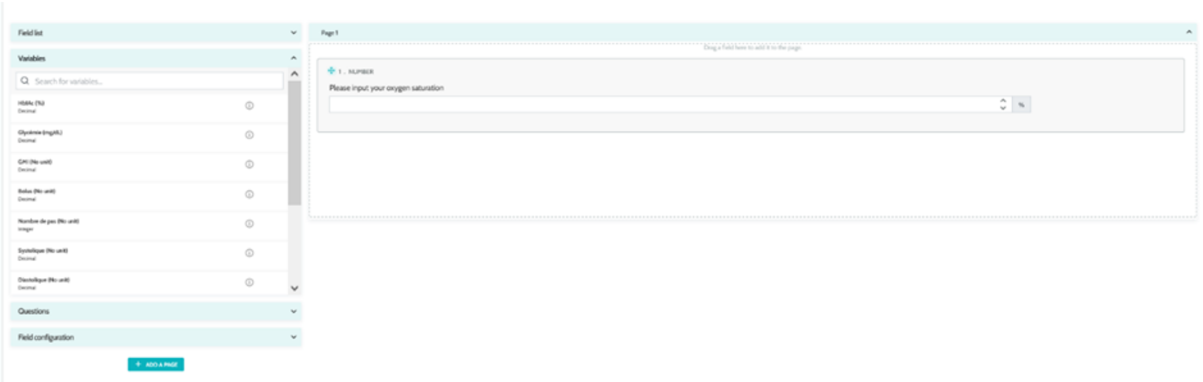
Questionnaire builder



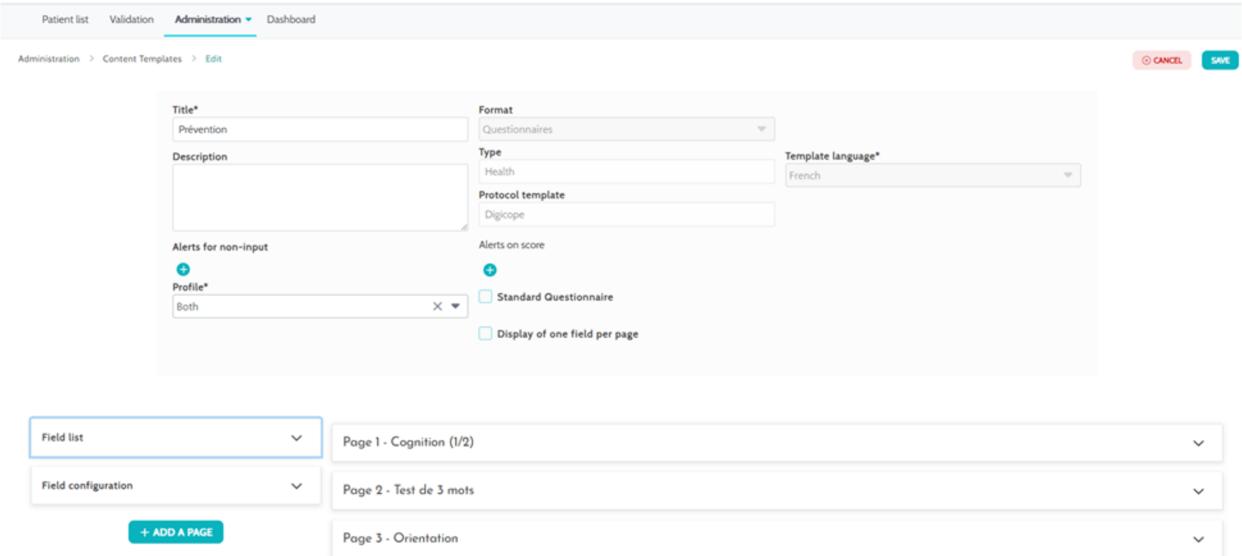
When selecting “**Questionnaire**” or “**Screening**” as content types, the questionnaire builder appears. A “**Field list**” allows you to “drag and drop” the field types and configure them. Configuration actions include the following: choosing your question label, possible responses, adding tooltips, variables, making a question mandatory, delimiting the maximum and minimum input values for numerical field types etc.

The fields in the “variables” and “questions” accordions correspond to the variable templates and question templates configured in the IoT module. These templates allow you to simplify the configuration of your questionnaire, as they feature pre-filled fields such as the unit and question wording.

/!\ We advise you to use variables and questions that have already been set up, as by default they have a potentially translated question label, unit and response options.



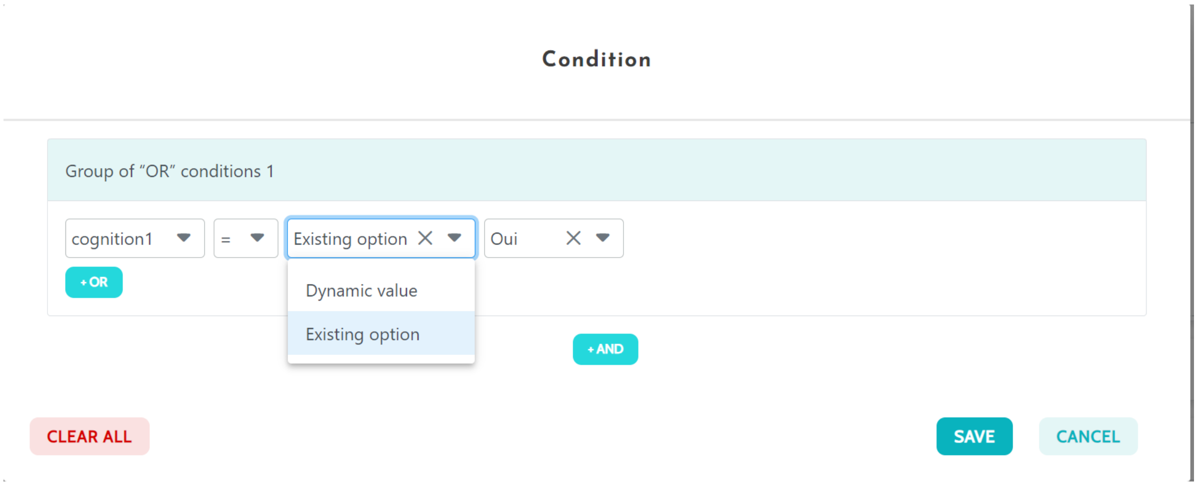
You can choose the questionnaire view for the user. Select the "Display of one field per page" option, to display a single field on a page. Or by adding pages, in order to have more fields on the same page. This display will be visible to patient and healthcare professional.



Other more complex configurations include creating conditional fields, adding scoring and setting alerts, which are described in more detail below.

Conditional fields

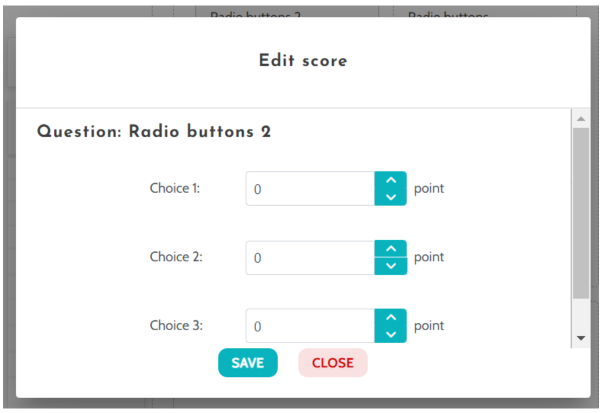
Allows you to add conditions for the appearance of a specific field, i.e. the field is only available and appears for input if the defined conditions are followed. The variable can be a defined response, or a dynamic variable like day, year or month of questionnaire entry. *Used, for example, to identify disorientation.*



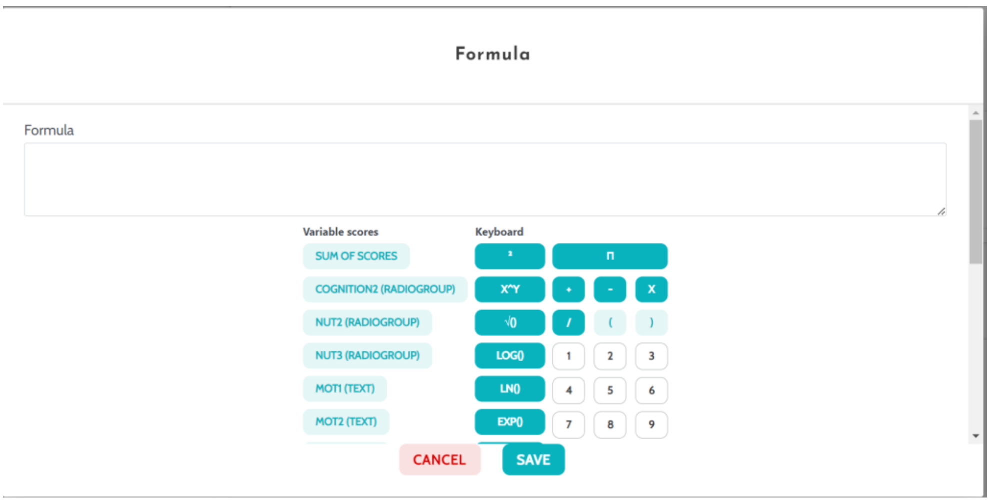
Scoring questionnaires and calculated score

When you edit the score of a question, the questionnaire becomes a scoring questionnaire. For each response possibility, you can assign a positive score.

This score can be used to calculate the overall score (the sum of the individual scores), or for more complex calculations, using the "Calculated score" field. This calculated score may or may not be visible to patients.



1 Add a score to a field

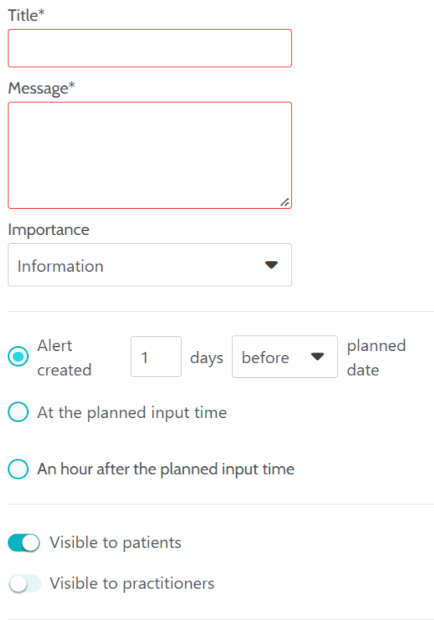


2 Create a calculated score

Alert for non-input

This is the type of alert that can be added to content to notify a user that the content has not been completed or viewed.

It is necessary to select the importance of the alert (Information, Warning, Danger or Non-input) and plan the alert conditions and finally the visibility (patients, practitioners or both).



Input alert

These can be added as an option if users wish to be notified when content has been validated.

Alert on value

These alerts are configured to notify the user that a certain field has been completed with an unusual value.

It is necessary to fill in the title, message, importance of the alert (Information, Warning, Danger), a comparison operator (which depends on the questionnaire field), a comparison value and visibility (patients, practitioners or both).

Screening questionnaires

To configure this type of questionnaire, you must first set all the questions, responses and variables. Then click on "**Linked protocols**" and fill in the name of the condition, select the variable and indicate the response(s) that launch a linked protocol. Finally, add the protocol(s) that are triggered if the condition is fulfilled.

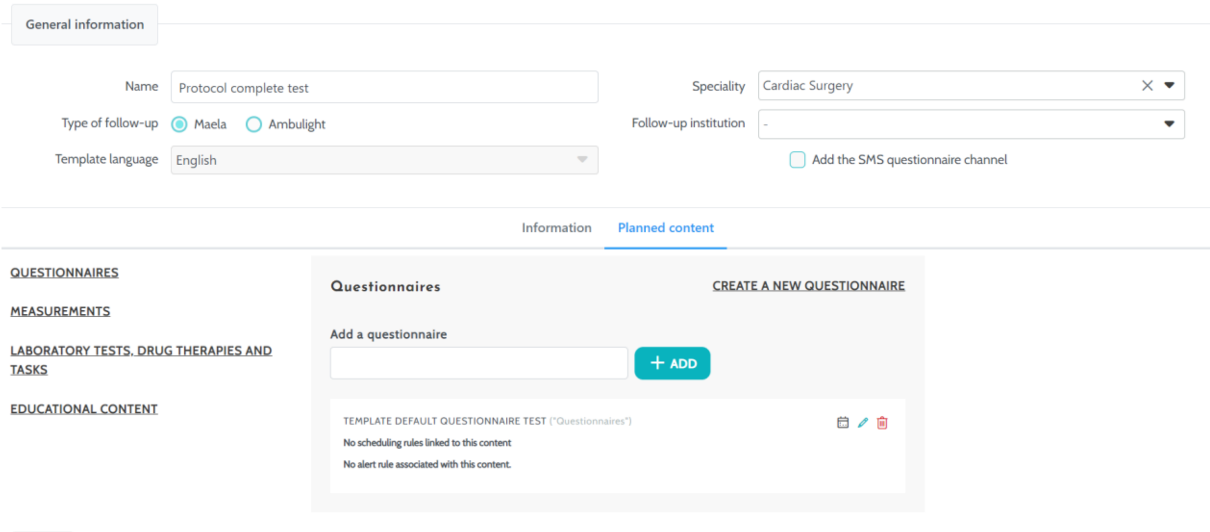
15. Protocols templates

Protocols can be accessed via the "**Administration**" tab or directly via pathways both at the administration level and in the patient file. At the practitioner level, this page lists all the standard protocols you have created or imported.

Click on "**Add a standard protocol**" to access the protocols available at the institution level or to create a new standard protocol. Maela® and Medtronic administrators can view and edit all the existing protocols in the solution. Both Maela® and Medtronic can push protocols to specific institutions.

The form for creating or editing a protocol template is separated into three parts: "General information", "Information" and "Planned content". All mandatory fields are highlighted in gold.

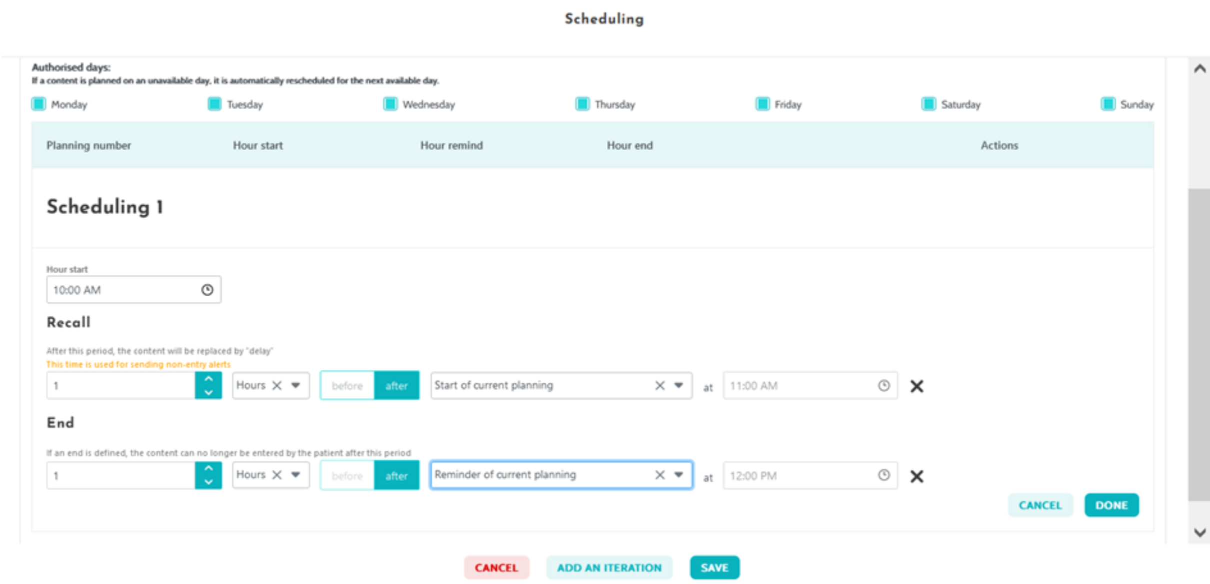
The "**Planned content**" section allows you to add the content templates available in your library as well as measurements, tasks, drug therapies and laboratory tests.



A calendar icon allows to set scheduling rules for all these items. There are two possibilities: "One-time" planning and "Recurrent" planning, and you can:

- Define the date(s) and start time(s) of the content
- Define when the content should be framed in red with the "Delayed" label
- Define the end date and time of a content. After this end date, the content will expire and the patient will be no longer able to complete it. If no end date is input, the content will be available until the end of the protocol like today.

A check box allows you to chain the schedules by defining the end of each schedule as the start of the next schedule.



Non-input alerts and value alerts for measurements should be configured at this stage. Non-input alerts for tasks, drug therapies and laboratory tests are also configured at this point.

The protocol type can be Maela® or Ambulight. An Ambulight protocol sends content templates (except educational content) by SMS to the patient.

The renewal planning feature allows for files with an expiration date to define the first occurrence of the file, and the expiration date will be requested from the user who enters the content. An alert will be sent one week before the expiration date to prompt for new content entry.

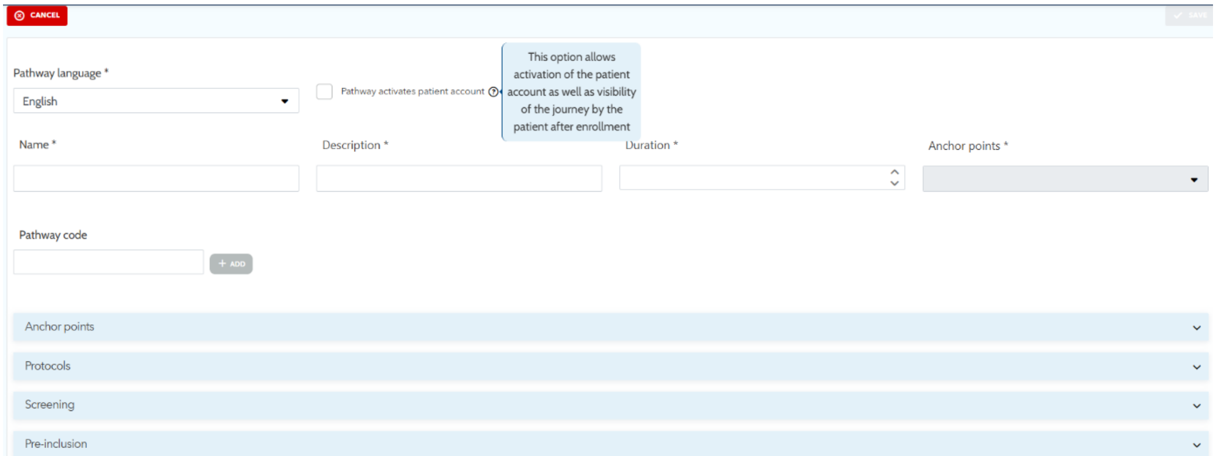
The free planning option allows for adding content that is available throughout the patient's journey. It is possible to configure a single input, for content that only needs to be input once or multiple inputs, which allows to submit multiple entries of a specific content item, which is particularly beneficial for use cases such as diaries, pain reporting, and similar scenarios.

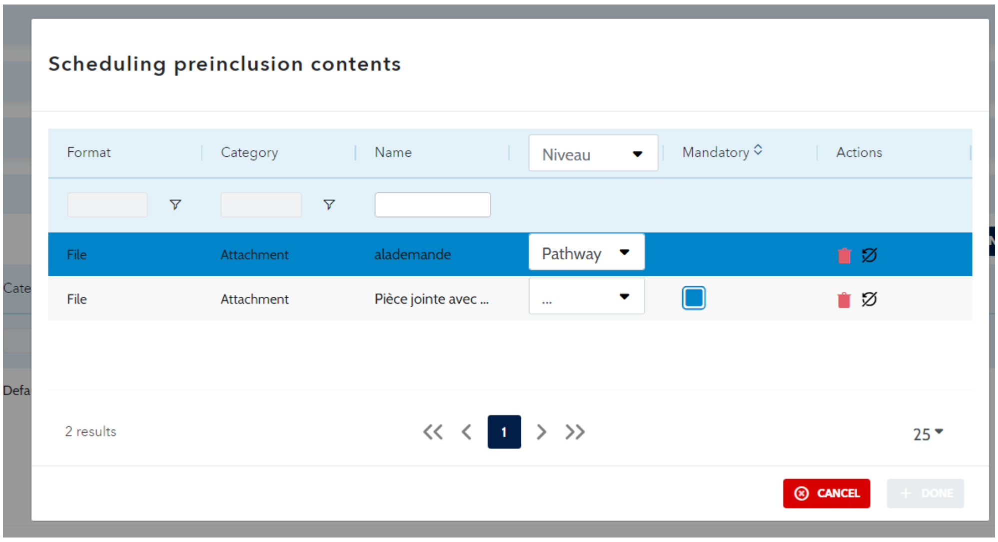
16. Pathways templates

Pathways can be accessed via the "**Administration**" tab or directly in the patient file. At the practitioner level, this page lists all the pathway models you have created or imported.

Click on "**Add a pathway model**" to access the pathways available at the institution level or to create a new pathway model. Maela® and Medtronic administrators can view and edit all the existing pathways in the solution. Both Maela® and Medtronic administrators can push pathways to specific institutions.

The form for creating or editing a pathway model is divided into the following: Information, Key dates, Protocols and Screening questionnaires. All mandatory fields are highlighted in gold.





In the *Pathway Information* section, a checkbox allows you to specify whether the pathway template leads to the creation of a patient account upon enrolment.

If this checkbox is selected, enrolling the patient in the pathway will automatically create their account, granting them access to the patient web or mobile app.

Conversely, if the checkbox is not selected, no patient account will be created after enrolment in the pathway. As a result, the patient will not receive any communications or notifications from the application (e.g., alerts, or messages).

The pathway key dates serve as anchor points to schedule the different protocol items: content templates, measurements, tasks, drug therapies and laboratory tests. There are different types of key dates:

Key date	Description	Mandatory (when assigning the pathway)
Maela® key date	There exist four types of Maela® key dates: hospital admission date, procedure date,discharge date and custom date.	No
Pathway date	Pathway start date and Pathway end date	Yes
Patient key date	Custom key dates, that can be entered by the patient or healthcare professional.	No
Ambulight key date	Key dates that appear only if the pathway contains an Ambulight protocol. For each protocol, the hospital admission date and the procedure date are displayed.	No

Inside pathways, protocols and screening questionnaires can be added. The general protocols and the protocols inside the screening questionnaires are planned according to the configured anchor points, matching the start and end dates of the pathway; they can also be manual. The screening questionnaires are planned according to the configured anchor points.

The pre-inclusions section allows for adding content templates that are prerequisites for launching a protocol or journey (if they are mandatory with a journey level, the journey cannot be initiated without the required documents). If this content is not entered, the patient will not be able to start their follow-up with the platform. This content can only be entered by a professional.

Renewal can be activated or deactivated for pre-inclusion content for prescription and attachment types.

IoT module integration:

If you have subscribed to the IoT offer, you can integrate IoT protocols into your path model. Click on “Remote monitoring protocol” to open the list of protocol models proposed by your organization.

17. Translation

For each type of template (content, protocol and pathway), there is a coloured flag. If its Green, the translation is complete in all the configured languages at your institution; otherwise, it is red. Hovering over the flag symbol displays the missing language(s).

Clicking on a flag opens the translation management page. You can directly input the missing translations at your level using this page or you can download the strings in CSV format. Once the strings are translated, you can import them back. You can add media via the web interface.

18. Dashboard

The “**Dashboard**” menu offers you data insights on your use of the Maela® platform as well as other statistics collected from the results of both quality and standard questionnaires.

Depending on the profile connected, the menus available inside of the “**Dashboard**” menu differ:

Menu	Accessibility	Description
Statistics	Healthcare administrator (only for their institution) Maela® administrator Medtronic administrator	This menu provides the following data: • Total number of patients, number of patients in follow-up. • Number of patients created per month, number of protocols per month, number of pathways per month and accumulated number of monitoring days. • Total number of alerts sent per month and over the current year. • Total number of SMS sent.
Quality questionnaires	Healthcare administrator (only for their institution) Maela® administrator Medtronic administrator	Possibility to download the responses provided in Maela® quality questionnaires in CSV format.
Standard questionnaires	Healthcare administrator (access to all standard questionnaire responses of patients inside the institution) Practitioner (access to standard questionnaire responses of the patients they created)	Possibility to view a graphical display and download the responses provided in standard questionnaires in CSV format.

19. Configuration IoT protocols templates (RPM)

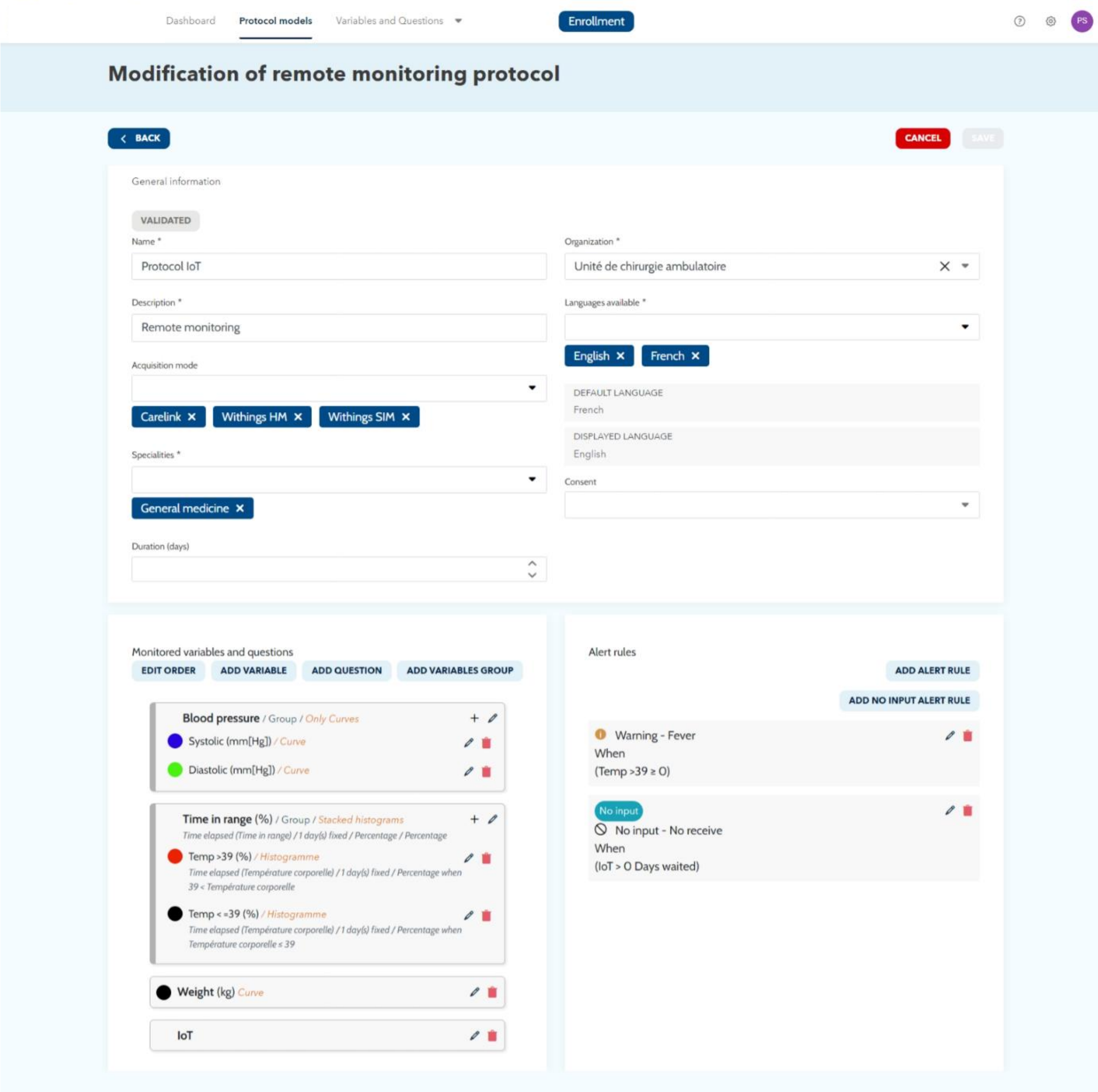
If you have the IOT /RPM option activated in your organization, you need to connect to this RPM module (https://iam.cortex-care.io/) to create the telemonitoring protocol templates to be added to the itinerary or pathway model.

A telemonitoring protocol template is a set of variables, questions and alert rules associated with these variables/questions, enabling healthcare professionals to remotely assess a patient's state of health over a defined period, and to decide on the course of action to be taken.

The list of telemonitoring protocol templates can be accessed via the "**Protocol templates**" list.

Click on "New protocol" to create a new protocol template, or click on the line of an existing template to modify it.

The form for creating or editing a protocol template is divided into three parts: “**General information**”, “**Variables and monitored variables and questions**” and “Alerts”. All mandatory fields are highlighted in yellow and marked with an asterisk.



19.1. General informations

The “General information” section allows you to enter the general data for the protocol model as well as the automatic acquisition mode(s) for measurements of variables and questions.

The automatic acquisition modes available are Carelink and Withings. Carelink is used for patients with the same brand of insulin pump. Withings offers a wide range of connected medical devices such as scales, watches and connected blood pressure monitors.

The duration defined in the protocol template is the default time during which patients will be monitored. This duration can be modified according to each patient.

19.2. Setting variables and questions monitored in the protocol model

The “Variables and questions monitored” section allows you to add the variables and questions to be monitored as part of the protocol.

Variables can be added in raw form or calculations such as averages, variation, time spent in data ranges over periods (fixed or rolling) can be configured.

Example:

- Fixed 1-year period: 1 January to 31 December of the same year

- Period of 1 sliding year: 26 June 2024 to 26 June 2025

The evolution over time of the measurements of the added variables is represented on graphs (in the form of histograms or curves) as detailed in the Dossier section of the protocol.

In the “variables and questions monitored” section, it is possible to associate numerical variables in the same group. This association allows you:

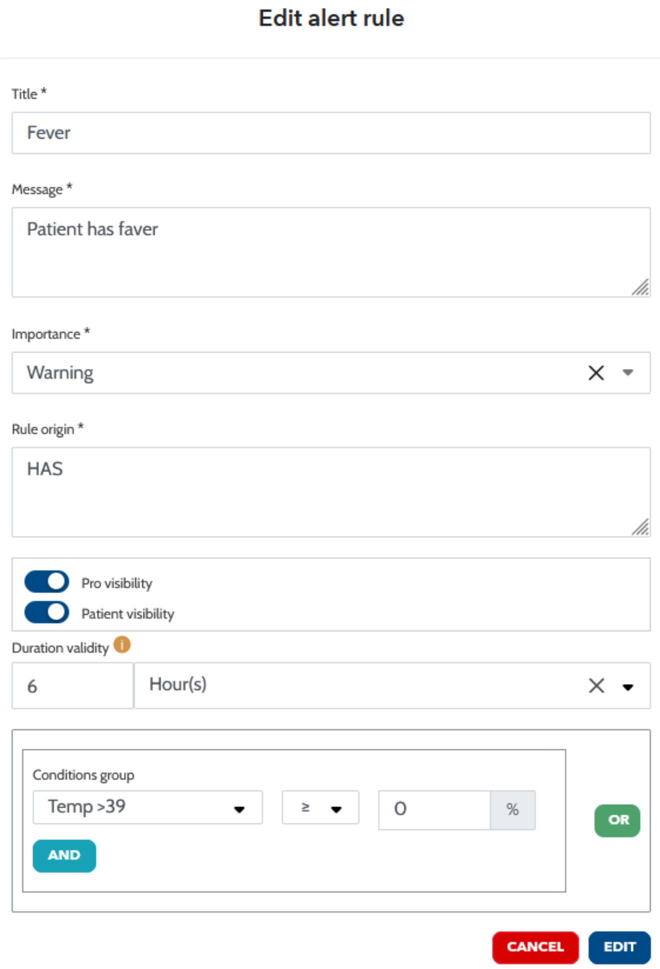
- Either display the curves and/or histograms of these variables in the same graph,

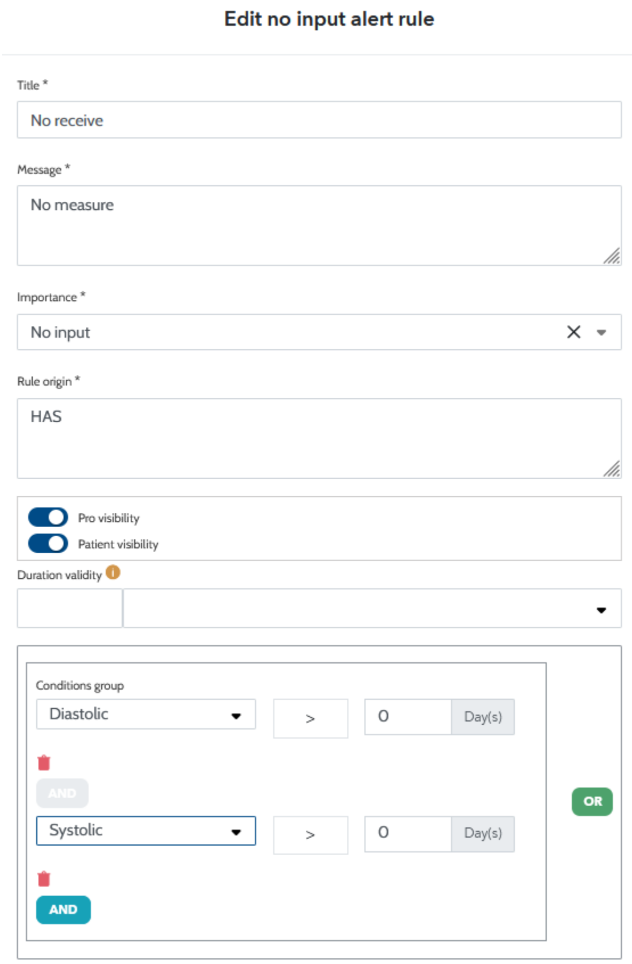
- Or to display these variables as stacked histograms.

It is also in this section that you define for each variable where its value will be displayed (on the dashboard, in the widget, in the graphical monitoring, in the summary) and whether the measurement is required to start the protocol (pre-inclusion variable).

19.3. Setting alert rules in the protocol model

The “Alerts” section allows you to define the conditions for triggering value alerts and/or non-receipt alerts.





- Value alerts inform the user that the value of one or more variables or the answer to a question is unusual.
- Non-receive alerts inform a user that the value of a variable or question has not been entered for a defined period.

You need to enter the title, the message, the criticality of the alert (Information, Warning, Danger, Not entered), the origin of the alert, the validity period (the period during which the alert is not re-triggered even if values respect the conditions), the visibility of the alert and the triggering conditions.

- To enter a condition for triggering an alert:
- Select a variable or question from the list of variables and questions added to the protocol model,
- A comparison operator is applied to this variable/question,
- Then enter the comparison value according to the format of the variable or question.

You can also enter several conditions linked by logical AND/OR operators to trigger an alert.

Alerts are triggered when measurements are received that meet the condition(s). They are displayed in the patient file.

19.4. Status of protocol template

The protocol templates created are in 'draft' status by default. To associate them with a patient, authorised profiles (administrator and practitioner) must validate them. Protocol templates that are no longer required can also be archived.

/ ! \ Only protocols with 'Validated' status can be added to pathway templates.

20. Installation check

Before launching Maela®, the deployment manager configures all the pathways required by the healthcare institution and then suggests performing a patient test to check its configuration.
Once the healthcare professional has tested various pathways with the test patient, the device is ready to be assigned to real patients.

21. Withdrawal of the device

Once the license agreement between your facility and MN Santé Holding has expired, your facility recovers your data within one month to meet its own regulatory obligations. Access to the platform is closed, and the data collected is deleted.