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.1. Introduction

.1.1. Purpose of the document

This user manual presents the Careside® platform, and the **Cortex Alert Engine** module, a medical device (MD) designed by the company MN Santé Holding for remote patient monitoring.

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

The detailed instructions for use of **Cortex Alert Engine** are given in section .3 (MD) Cortex Alert Engine instructions for use.

N.B.: All patient or professional identities visible in the screenshots used to illustrate the features are purely fictitious.



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

.1.2. Abbreviations and definitions

Abbreviation or term	Description
Administrator	Establishment administrator or Careside® administrator profile with user management rights and privileges for performing various functions on Careside®.
Alert	Signal that warns of a danger or risk to the patient. Allows information to be transmitted based on the patient's response.
Contents sent by SMS (Ambulight)	Simplified patient follow-up using SMS over a short period around an episode of care or hospital event.
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.
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.
Carelink	Carelink is the brand of connected insulin pumps from which you can collect measures.
Care pathway	Highest level entity in the Careside® platform. A pathway model includes key dates, follow-up protocols and screening questionnaires.
CMS	Content Management System. Careside® has chosen to link its platform to WordPress for the management of educational content and GDPR-related documents.
Criticality	Determination and prioritisation of the degree of importance of an alert that is sent to healthcare professionals or patients.
CSV	Coma Separated Values file.
Data extraction	The act or process of retrieving data from data sources for further data processing or data storage (data migration).

Abbreviation or term	Description
GDPR	European General Data Protection Regulation.
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.
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.
IoT	Internet of Things. Abbreviation corresponding to connected devices.
Licence	Subscription to the Careside® platform.
MAC address	Physical identifier of a connected device.
Medical device	Instrument, apparatus, equipment, machine, device, implant, reagent for <i>in vitro</i> 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.
OTP	Only Time Password. Abbreviation corresponding to the code sent by SMS or email to secure a Careside® account.
Planned content	The planned content of Careside® correspond to all the follow-up questionnaires, educational content, measurements, tasks and reminders that are planned within a care pathway or protocol.
Pop-up	Window that opens on top of the main window.
Protocol	Careside® 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 Careside® 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.
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.
Remote monitoring protocol	A remote monitoring 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.
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).
Screening	Screening is a type of questionnaire that makes it possible to personalise a patient's protocols inside the pathway.

Abbreviation or term	Description
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.
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).

.2.Careside® platform instructions for use

.2.1. Product description

The Careside® solution developed by MN Santé Holding is 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 Careside® solution consists of a web platform. Patients have access to the Careside® 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 Careside® licence can benefit from the Careside® platform.

The Careside® solution contains the **Cortex Alert Engine** module. It is a medical device intended for the remote monitoring of patient. All information related to **Cortex Alert Engine** can be found in section .3 (MD) Cortex Alert Engine instructions for use.

.2.2.Permission matrix

The application has a set of **permissions** (or rights), each corresponding to a specific action or access on a given feature or module (view, create, modify, delete, export, administer, etc.).

These permissions are never assigned individually to each user. They are grouped into **profiles** (or roles). A profile is a specific combination of permissions, generally corresponding to a business function (e.g., *Administrator, Manager, Consultant, Read-only*).

Each user is assigned one or more profiles, which determines the set of actions they can perform within the application.

The functions highlighted in blue are part of **Cortex Alert Engine**. They are detailed in section .3 (MD) Cortex Alert Engine instructions for use.

Module	Functionality	Read	Create	Update	Delete	Translate	List
Back office	Profile	X	X	X	X	X	X
	Role	X	X	X	X	X	X
	Institution management	X	X	X	X		X
	Professional management	X	X	X	X		X
	Indicator management	X	X	X	X	X	X
	RPM configuration model	X	X	X	X	X	X
	Variable and question concept	X	X	X		X	X
	Prescription template	X	X	X	X	X	X
	Pathway template	X	X	X	X	X	X
	Protocol template	X	X	X	X	X	X
	Questionnaire template	X	X	X	X	X	
	Content template	X	X	X	X	X	X
	Anchor point template	X	X	X	X	X	
	Prescription line management	X	X	X	X	X	X
Alert management (CAE)	Threshold management	X	X	X	X	X	X
	Alert rules	X	X	X	X		
	Alert management	X		X			X
Planification	Content scheduling	X	X	X	X		X
	Protocol scheduling	X	X	X	X		
	Indicator scheduling	X	X	X	X		

Patient file management	Patient file	X					X
	Enrolment	X					
	Questionnaire	X	X	X	X		X
	Files / Analysis	X	X	X	X		X
	Visio	X	X	X	X		X
	Treatments	X	X	X	X		X
	Note	X	X	X	X		X
	Messaging	X	X	X	X		X
	Indicator	X	X	X	X		X
	Care team	X	X	X	X		X
	IoT reports	X					X
	Educational content	X	X	X	X		
	Pathway	X	X	X	X		X
	Prescription	X	X	X	X		X
	SMS patient	X	X	X			
	Screening	X	X	X	X		X
	Event (anchor point)	X	X	X	X		X
	PRM notifications	X	X	X	X		
	Task	X	X	X	X		X
	Measurement	X					X
KPIs	Data export	X					
	Dashboard	X					
Measurement management	Pairing	X	X				

FUNCTIONS

.2.3. Institution management

Careside Environnement administrateur MAELA | Administrator Maela

Professionals Healthcare providers Administration ▾ Dashboard

Healthcare provider list

[Import a healthcare institution](#)

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_EL_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
Salut Saint Briec - 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**”, “**Healthcare providers**”, “**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 Careside® 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 contract¹	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 institution¹	Choose the type of institution: follow-up, healthcare or technical institution.	Careside® and Medtronic administrators
Type of follow-up¹	Choose the type of follow-up allowed in the institution: Classic (Careside®), Contents sent by SMS (Ambulight) follow-up or both.	Careside® and Medtronic administrators

Category	Field	Accessibility
Follow-up institution	If applicable, select one or more follow-up institutions to link to the healthcare unit or geographical entity you are creating.	Careside® 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).	Careside® and Medtronic administrators only, for “Healthcare” institution type
Opening days¹	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.	All administrators
SMS management	Configure SMS follow-up settings.	Careside®, Medtronic and healthcare administrators, if Ambulight follow-up type selected
Personalization	Customize the content of e-mails and SMS messages sent to institution users.	Careside® and Medtronic administrators only
Indicators	Tab for activating the indicators you want to appear on the patient list.	All administrators

¹ Mandatory field to be able to save

Professionals	Domains	Healthcare providers	Administration ▾	Dashboard
---------------	---------	----------------------	------------------	-----------

Healthcare providers > Edit

[BACK TO LIST](#)
[SAVE](#)
[DELETE](#)

Edit a healthcare provider

General Personalisation **Indicators**

PLUG INTO MY ENTITIES

Indicator label	Short label	Color	Source	Activate	Actions
Préopératoire	Préopératoire		MAELA	☐	
Postopératoire	Postopératoire		MAELA	☐	
(Re)hospitalisé	(Re)hospitalisé		MAELA	☐	
Relance effectuée	Relance effectuée		MAELA	☐	
Alerte en attente	Alerte en attente		MAELA	☐	
À surveiller	À surveiller		MAELA	☐	
Category 1	Category 1		MEDTRONIC	☒	
Category 2	Category 2		MEDTRONIC	☒	
Category 3	Category 3		MEDTRONIC	☒	
Category 4	Category 4		MEDTRONIC	☒	
Category 5	Category 5		MEDTRONIC	☒	
Category 6	Category 6		MEDTRONIC	☒	

12 results on 12

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.

.2.4. Professional account management

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

- **Careside® 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 Careside® or Medtronic admin
- their identifier type: for example, professional license 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 ²	All
	Birth name	All
	First name ²	All
	Profile ²	Depending on your profile, you can create user types
	Telephone ²	All
	Private number	Doctor, medical secretary, social actor and nurse coordinator

Category	Field	Profile
	Email ²	All
	Address	All
	ID Type and Practitioner's ID	All
Authentication	Username ²	All
	OTP phone number ²	All
Institution	Institution ²	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 ²	All
	Time zone ²	All
Secretaries management	Search a secretary	Admins only
	Secretaries list	Admins only
Other	Other	All

² Mandatory fields

.2.5.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

.2.5.1. 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 Careside® administrators, and the professional himself will see the number.

.2.5.2. Password and security

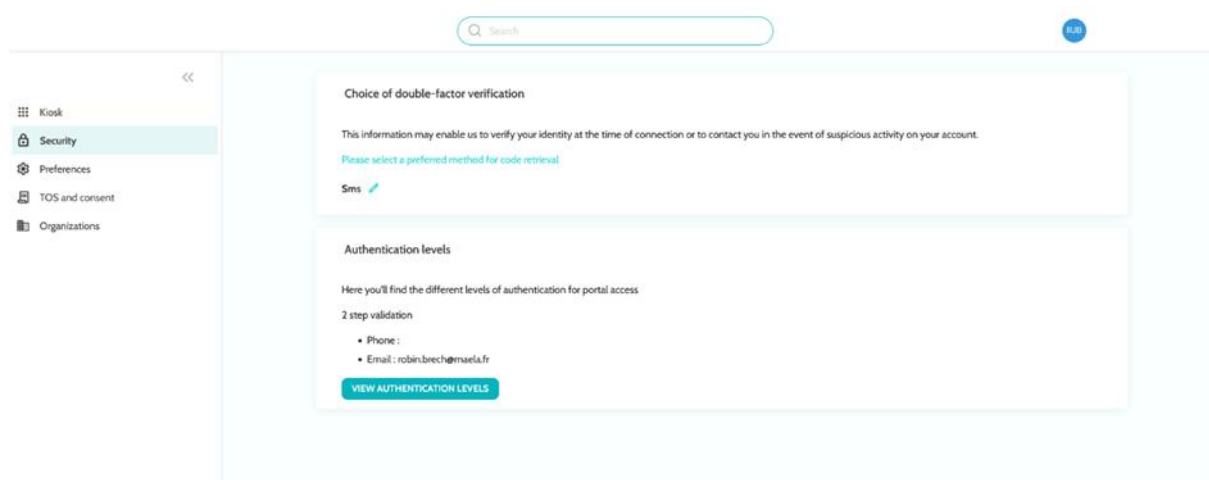
To change your password, click on your initials and a menu will appear. Click on “**Manage my account**”, then on the left-hand security menu and finally on “**Password**”. You can now change your password.

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

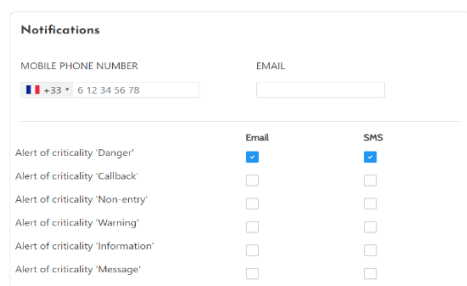
- At least 8 characters
- At least 1 number
- At least 1 uppercase letter and 1 lowercase letter
- At least 1 special character (!"#\$%&'()*+,-./:;<=>?@[\\]^_`{|}~)

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.



.2.5.3. Notifications management



	Email	SMS
Alert of criticality 'Danger'	☒	☒
Alert of criticality 'Callback'	☐	☐
Alert of criticality 'Non-entry'	☐	☐
Alert of criticality 'Warning'	☐	☐
Alert of criticality 'Information'	☐	☐
Alert of criticality 'Message'	☐	☐

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.

.2.5.4. Secretaries

Only practitioners can authorize secretaries in their user profile. The authorized secretary profiles can enroll patients. They have the same rights as the practitioner for the patient file except for the functionality that manages authorizations of other practitioners and institutions. They also won't receive notifications.

.2.5.5. Replacing practitioners

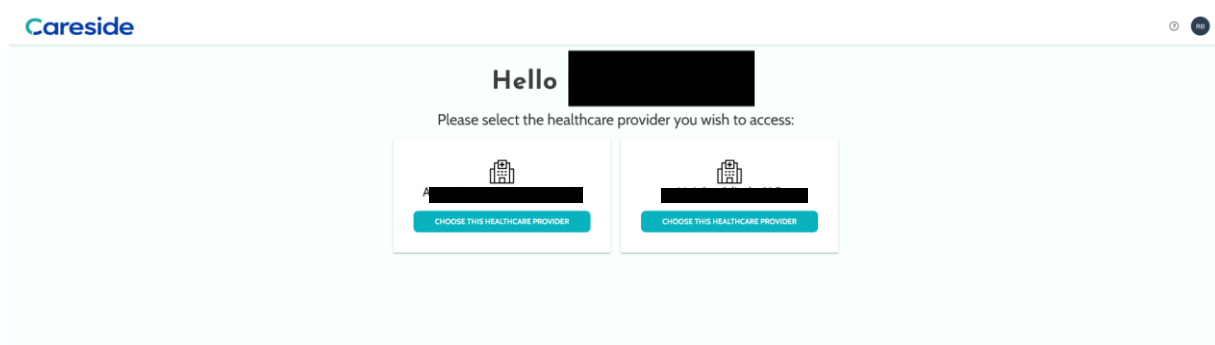
Only practitioners can give access to all their patient files for a defined period to another practitioner in Careside®. The start and end dates of the replacement period must be set. During this time, the primary practitioner can access the account normally, but notifications are sent to the replacement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

.2.5.6. 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.



.2.6. Patient enrolment

Patients are added to the **Patient List** by selecting the “**Add a patient**” button. A new page is then displayed, allowing the patient’s identity to be searched and, if necessary, created. Enrollment in a remote monitoring pathway is carried out through several onboarding steps.

.2.6.1. Identity search

An identity search is used to verify whether the patient already exists in the platform. Mandatory fields must be completed before selecting the “**Search**” button. If the patient is already registered, their details are displayed in the table below the search fields. If no match is found, the “**Create**” button becomes available to initiate registration.

.2.6.2. Identity creation

During the identity creation step, the “**Patient consent**” checkbox must be selected in order to proceed with the remote monitoring enrollment process. All mandatory fields, marked with an asterisk, must be completed.

The “**Next**” button then becomes available to move to the following step. In case of an error (such as missing information or unchecked consent), an error message is displayed in the top right corner of the screen.

1 Recherche d'identité 2 Identité 3 Parcours 4 Données d'inclusion 5 Validation

PRÉCÉDENT SUIVANT

☐ En cliquant sur cette case, vous certifiez que le patient a donné son consentement pour être inclus dans un parcours de télé-suivi pouvant lui transmettre des SMS de manière automatisée pour suivre son état de santé *

TRAITS STRICTS

Nom de naissance * Bernard

Prénom utilisé

Prénom(s) de naissance ⓘ

Date de naissance * jj/mm/aaaa

Code postal du lieu de naissance

Pays de naissance

Nom utilisé

1er Prénom de naissance *

Sexe *

Ville de naissance

Code lieu de naissance (Code INSEE)

DOMAINE D'IDENTITÉ

DOMAINE D'IDENTITÉ
DI CENTRE HOSPITALIER METROPOLE SAVOIE

VALIDATION D'IDENTITÉ

JUSTIFICATIF D'IDENTITÉ ⓘ

INDICATEURS

Indicateurs

.2.6.3. Pathway

The **Pathway** step allows the appropriate remote monitoring pathway to be selected, along with the associated dates for the patient's enrollment.

Additional dates may be entered for events related to the selected pathway.

Liste Patient Validation Administration ▾ Tableau de bord

1 Recherche d'identité 2 Identité 3 Parcours 4 Données d'inclusion 5 Validation

🏠 BERNARD Jean

Née le : 27/06/2025 (0 an)

IPP : SAVOIE_2025_06_00000005_73

Dd-ID : 2025-06-27

Nom de naissance : BERNARD

HORS SUIVI SUIVANT

Nom * Parcours Centre gériatriques / neurologiques

Description * 20

Date de début du parcours * 27/6/25

Date de fin du parcours

Nombre d'éléments sur la vue parcours * ⓘ 20

Durée automatique du suivi : 15 jours après Début du parcours ☐ Parcours activant le compte patient ⓘ

Événements

.2.6.4. Inclusion data

The **Inclusion Data** section is displayed only if the selected pathway includes pre-inclusion content. If no pre-inclusion content is configured, this step is skipped automatically.

.2.6.5. Validation

The **Validation** step provides an overview of the information entered during the previous steps. The patient's identity and inclusion data are displayed for review. Selecting the “**Confirm**” button finalizes the enrollment.

Once confirmation is completed, the **Patient List** is displayed, including the newly enrolled patient.

.2.7. Patient enrolment with 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.

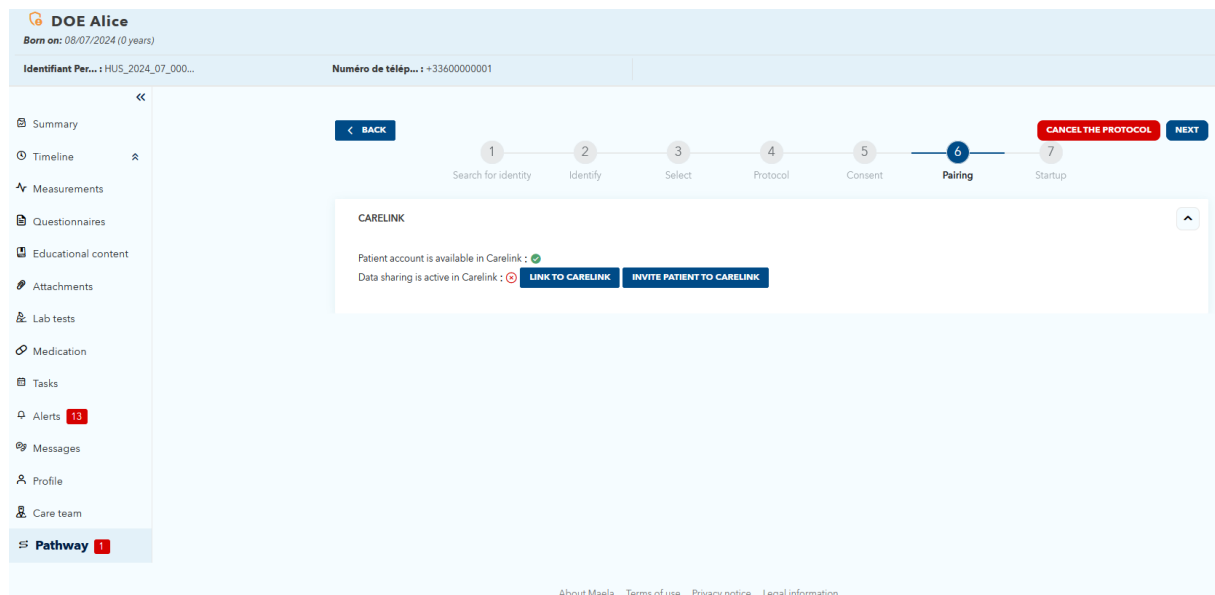
Please note that if you add content to the telemonitoring protocol, it will be available in all the other languages of the protocol template, but displayed by default in the language of the logged-in user who added it.

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.

.2.7.1. 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.

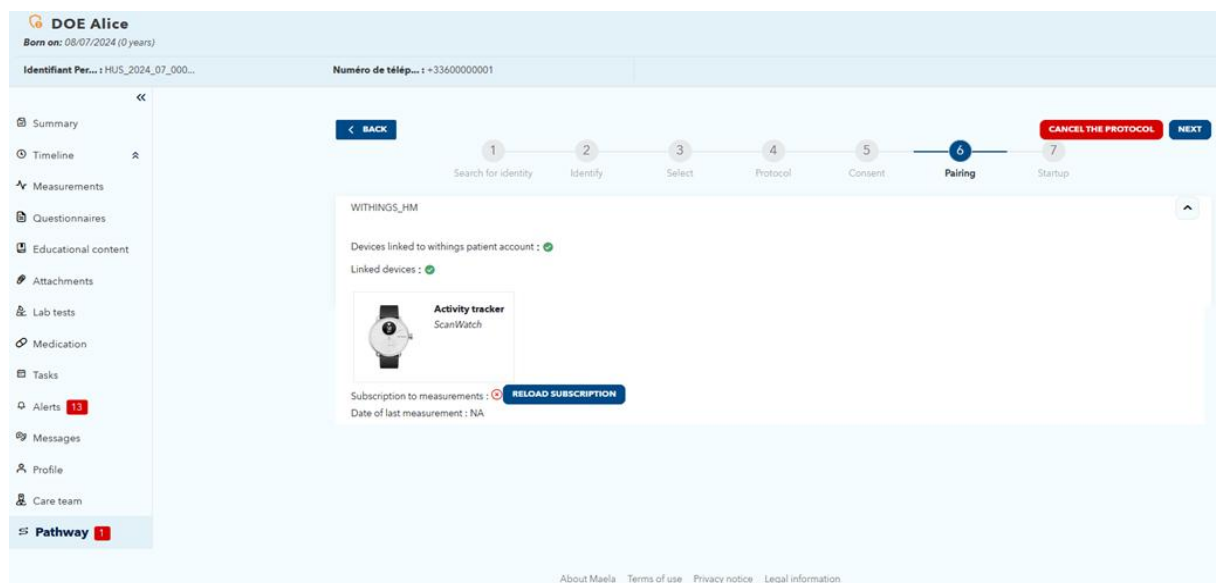
- **Patient invitation:** If the patient has not yet created an account on Carelink, you can send him/her an invitation with the steps to follow. Click on the “**Invite patient**” button, then enter the patient's e-mail address so that the patient receives the instructions.
- **Patient link:** If the 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 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 enrolment process.

.2.7.2. 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.

.2.7.3. Withings SIM

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 the 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.

.2.7.4.Startup

To finalize enrolment, 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 enrolment has been completed, whether partial or total, the patient's status is displayed on the dashboard.

.2.8.The patient list

The screenshot shows the 'Patient list' interface. At the top, there's a navigation bar with links: Patient list, Remote monitoring, Validation, Scheduled content, Administration, and Dashboard. Below this, a header indicates '6 patient(s)' and includes a 'RESET SEARCH' button and an 'ADD A PATIENT' button. A filter bar shows categories: J-1 ADMISSION, J-1 ADMISSION, J-1-4 ADMISSION, CATEGORY A, CATEGORY B, CATEGORY C, CATEGORY D, CATEGORY E, and CATEGORY F. Below the filter bar, there's a section for 'Patients with no active pathway' and three buttons: CRITICAL 3, WARNING 4, and NON-INPUT 6. The main table lists patients with columns: Alert manag, LAST NAME First, Phone number, Pathway, Hospital admission, Procedure, Discharge date, Indicator, and Last entry date. The table contains 6 rows of patient data, each with an alert icon and a status indicator.

Alert manag	LAST NAME First	Phone number	Pathway	Hospital admission	Procedure	Discharge date	Indicator	Last entry date
55	MOLTI CHRIS	+33649318992	Parcours MEP V3 à 23/06/2025 → 05/06/2025	24/06/2025				23/06/2025 15:00
187	FOISON ANNIC	+33600000000	Parcours MEP V3 à 17/06/2025 → 29/06/2025	17/06/2025				04/06/2025 15:00
40	LEMARQUAND	+33600000000	Parcours alertes à c 22/06/2025 → 29/06/2025	25/06/2025				
42	TNR F PATIENT	+33600000000	Parcours quest 15/06/2025 → 30/06/2025	21/06/2025	21/06/2025			17/12/2024 15:00
39	DYLAN DYLAN	+33605409176	Parcours MEP V3 à 18/06/2025 → 30/06/2025	18/06/2025				
1	ALIX ALICE (O)	+33649318992	non saisie 23/06/2025 → 25/06/2025					

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 authorization. Patients are ordered by status, meaning that the patients with the highest criticality statuses are displayed first.

3 buttons are available: Critical, Warning and No input with the alert number of each type in the patient list. When clicking on the button, it filters the patient list to show only the patients with the alert type selected.

Alerts column shows the icon of the most critical alert of the patient with the total number of all the alerts detected for a patient. You can click on them to open a right panel which will display the alert details and the last care team exchange (note).

Status list in order of criticality: Critical, Warning, Call request, Messaging, No input, Information and No alerts.

The screenshot shows the 'Patient list' interface with a detailed view of a patient's alerts and BMI data. The patient list table is visible, showing 6 results. The patient 'LEMARQUAND Vincent' is highlighted. To the right, a panel shows the patient's details, including name, birth date, phone number, and email. Below this, there are sections for 'Alerts' and 'SMS'. The 'Alerts' section shows a 'Critical' alert with the message 'Alerte non saisie 1 j après pro' and a 'Warning' alert with the message 'Alerte non saisie 1 h après les deux'. The 'SMS' section shows a 'Warning' alert with the message 'Alerte non saisie 1 h après les deux'. The 'BMI data' section shows a 'Critical' alert with the message 'Alerte non saisie 1 j après pro' and a 'Warning' alert with the message 'Alerte non saisie 1 h après les deux'. The 'BMI data' section also shows a 'Warning' alert with the message 'Alerte non saisie 1 h après les deux'.

The order of alert severity is as follows: **Danger, Warning, Information**, No input, Call request, Discussion and messages, and No alerts. Alerts can be clicked to display the latest note and view all alerts.

A messaging icon may also appear in the alert column. It allows the right-hand panel to open directly in the SMS tab, if this feature is enabled for the medical unit.

The “**Intervention**” column displays the intervention date closest to the current day in the case of patients with multiple hospital stays, along with the intervention time.

The “**Appointment**” column highlights the date and time of the patient’s appointment if defined in the pathway, and the “**Discharge Date**” column displays the hospital discharge date. These columns can be shown or hidden in the patient list using the column settings.

The “**Reason for Intervention**” column allows the reason for the patient’s hospitalization to be viewed directly in the patient list. This information is also visible in the right-hand panel when viewing alerts or the SMS conversation.

The “**Indicator**” column shows the labels assigned to each patient case, either manually or automatically, based on predefined criteria. To assign a label to a patient, open the patient file and select the desired “Patient Case Indicator” in the “Summary” tab.

Some indicators can be automatically assigned to define stages in the patient’s care pathway. This requires scheduling the indicator in a pathway template (for example, an indicator calculated from the pathway start date to the intervention date for the preoperative phase), and automatically removing it from the patient once the planned period is completed.

The “**Pathway Status**” column displays the current status of the patient’s pathway:

- Ongoing – green label
- Pre-included – yellow label – clicking redirects to the pre-inclusion content
- Not Started – blue label

The “**Patients Outside Monitoring**” button displays patients whose pathway is completed, not started, or not assigned, but whose file has already been created.

Note: For care coordination nurses, a calendar icon indicates when the patient’s healthcare facility is closed, thereby blocking the patient’s access to the platform.

.2.9.Validation list

This menu is only available if the health Institution uses protocols with contents sent by SMS (Ambulight).

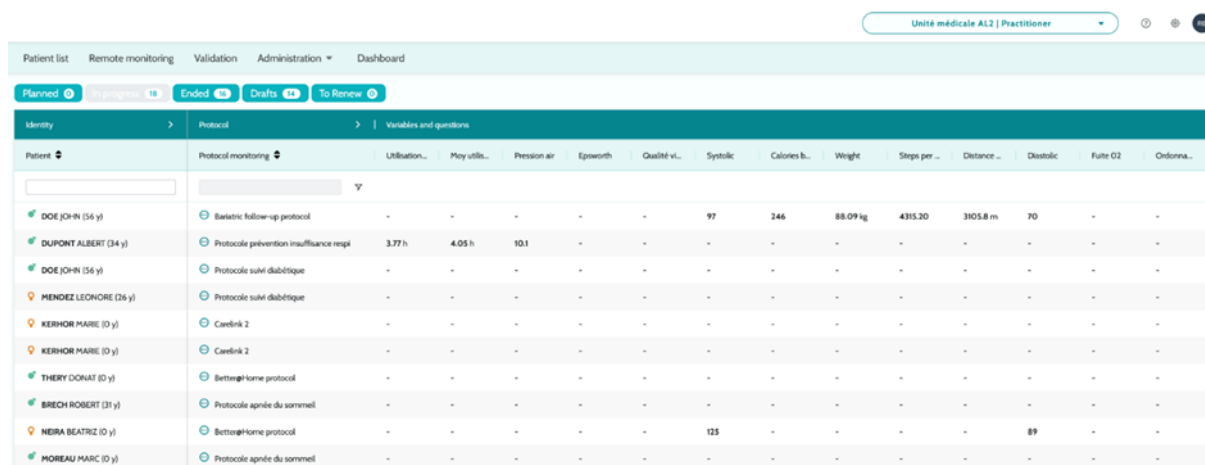
It allows you to validate the identity of patients when they respond to questionnaires directly via secure links sent to them by SMS. This is a mandatory identity check measure and is only requested for patients with a content sent by SMS (Ambulight) protocol who respond directly via that secure link 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.

.2.10. Remote monitoring list

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

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



Unité médicale AL2 Practitioner													
Patient list Remote monitoring Validation Administration Dashboard													
Planned In progress Ended Drafts To Renew													
Identity	Protocol	Variables and questions											
Patient	Protocol monitoring	Utilisation...	Play utilis...	Pression air	Egworth	Qualité vi...	Systolic	Calories b...	Weight	Steps per ...	Distance ...	Diastolic	Fuite O2
DOE JOHN (56 y)	Statistic follow-up protocol	-	-	-	-	-	97	246	88.09 kg	4315.20	3105.8 m	70	-
DUPOINT ALBERT (34 y)	Protocole prévention insuffisance respi	3.77 h	4.05 h	10.1	-	-	-	-	-	-	-	-	-
DOE JOHN (56 y)	Protocole suivi diabétique	-	-	-	-	-	-	-	-	-	-	-	-
MENDEZ LEONORE (26 y)	Protocole suivi diabétique	-	-	-	-	-	-	-	-	-	-	-	-
KERHON MARIE (0 y)	Carelink 2	-	-	-	-	-	-	-	-	-	-	-	-
KERHON MARIE (0 y)	Carelink 2	-	-	-	-	-	-	-	-	-	-	-	-
THERY DONAT (0 y)	Better@home protocol	-	-	-	-	-	-	-	-	-	-	-	-
BRECH ROBERT (31 y)	Protocole après du sommeil	-	-	-	-	-	-	-	-	-	-	-	-
NEIRA BEATRIZ (0 y)	Better@home protocol	-	-	-	-	-	125	-	-	-	-	89	-
MOREAU MARC (0 y)	Protocole après du sommeil	-	-	-	-	-	-	-	-	-	-	-	-

- 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 finalized.
- 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, No input, Call request and Discussion and messages.

.2.11. Scheduled contents list

This menu can be setup and activated for some Health Institution; it is not always available.

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 customize the date range to view historical or upcoming information.

Patient list

Remote monitoring

Validation

Scheduled content

Administration ▾

Dashboard

Scheduled content

SMS

Period

From

23/06/2025

×

To

23/06/2025

×

🕒

Alerts

Patient >

Pathway >

Content >

Alerts 🗲	LAST NAME First nai	Telephone no. 🗲	Indicator	Pathway 🗲	Name 🗲	Format 🗲	Status	Scheduled date 🗲	Entry d
	▽	▽	▽			▽	▽	j/mm/aaaa 🗲	j/mm
⚠	MOLTI Christophe (€	+33 6 49 31 89 92		Parcours MEP V3 à c...	Digicop One Page V3	Questionnaires	Replied	23/06/2025	23/06/
⚠	MOLTI Christophe (€	+33 6 49 31 89 92		Parcours MEP V3 à c...	Digicop One Page V2	Questionnaires	Replied	23/06/2025	23/06/
⚠	MOLTI Christophe (€	+33 6 49 31 89 92		Parcours MEP V3 à c...	Digicop 1 champ par...	Questionnaires		23/06/2025	23/06/
⚠	MOLTI Christophe (€	+33 6 49 31 89 92		Parcours MEP V3 à c...	Digicop 1 champ par...	Questionnaires	Replied	23/06/2025	23/06/
⚠	MOLTI Christophe (€	+33 6 49 31 89 92		Parcours MEP V3 à c...	Digicop Questionna...	Questionnaires		23/06/2025	23/06/
ℹ	LEMARQUAND Vinc	+33 6 00 00 00 00		Parcours alertes à ch...	TTT A NE PAS REM...	Treatment	Late	23/06/2025	
ℹ	LEMARQUAND Vinc	+33 6 00 00 00 00		Parcours alertes à ch...	ANALYSE A NE PAS ...	File Analysis	Late	23/06/2025	
ℹ	LEMARQUAND Vinc	+33 6 00 00 00 00		Parcours alertes à ch...	TÂCHE A NE PAS R...	Task	Late	23/06/2025	
ℹ	LEMARQUAND Vinc	+33 6 00 00 00 00		Parcours alertes à ch...	Questionnaire A NE ...	Questionnaires	Late	23/06/2025	
ℹ	LEMARQUAND Vinc	+33 6 00 00 00 00		Parcours alertes à ch...	Données IMC	Measurement	Late	23/06/2025	
🔗	MOLTI Christophe (€	+33 6 49 31 89 92		Parcours MEP V3 à c...	Digicop 1 champ par...	Questionnaires	Late	23/06/2025	

The “SMS” menu displays the SMS questionnaires sent and answered by patients.

Patient list
Remote monitoring
Validation
Scheduled content
Administration ▾
Dashboard

Scheduled content

SMS

Period

From 23/06/2025

To 23/06/2025

Alerts

Patient >

Pathway >

Content

Group

Alerts

LAST NAME First r

Telephone no.

Indicator

Pathway

Status

Confirmation présence, répondez par oui "Oui" par "Non" (1/1)

MOLTI Christophe

+33 6 49 31 89 92

Parcours MEP V3 ...

Response rec

1 results

<< < 1 > >>

25 ▾

Questionnaire SMS GS

Completed on 23/06/2025 at 11:05 by CHRISTOPHE MOLTI

Bonjour Confirmation présence, répondez par oui "Oui" par "Non"

SENT

Oui

RECEIVED

Nous avons bien pris en compte votre présence

SENT

Please note that it is forbidden to include health data in SMS messages sent to your patients.

.2.12. Dashboard

The “**Dashboard**” menu offers you data insights on your use of the Careside® 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) Careside® 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) Careside® administrator Medtronic administrator	Possibility to download the responses provided in Careside® 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.

.2.13. 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.

.2.13.1. Header

The header banner displays patient information for DUPONT Albert, born 05/28/1990 (34 years old). It includes a 'Protocol' section for 'Protocol: Protocol prevention insa...' with a 'In progress' status. The banner is divided into four columns showing various patient metrics and identifiers.

Permanent ident...	Email address :	May Pressure:	Variation points:
AtLqgi_000000...	robin.brochgar...	10.40	79.00 %
Phone number : +33612345678		Utilisation PPC: 3.77 h	Pressure air: 10.10

The patient banner consists of four 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 below, 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.

.2.13.2. Summary

The summary dashboard provides a comprehensive overview of the patient's data, organized into several key sections:

- Pathway information:** Displays details for the 'SAVR DEMO' pathway, including start (10/01/2023), procedure (17/01/2023), and end (10/04/2023) dates. It also lists 'Last entry' events like 'Baseline assessment' and 'date order bug.png'.
- Patient contact information:** Shows personal details such as phone number (+33600000000) and email address (beatriz.neira@medtronic.com).
- Care team contact:** Identifies the responsible practitioner as Dr. Prof Dr Max Meyer, along with their contact information.
- Notes:** A section for consultation notes, currently showing a note from Prof Dr Max Meyer dated 10/1/2023.
- Patient connectivity:** Tracks the last connection via web (1/10/23, 12:20 PM) and mobile.
- Organisation contact:** Lists Medtronic Demo EMEA with associated mobile and email addresses.

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.

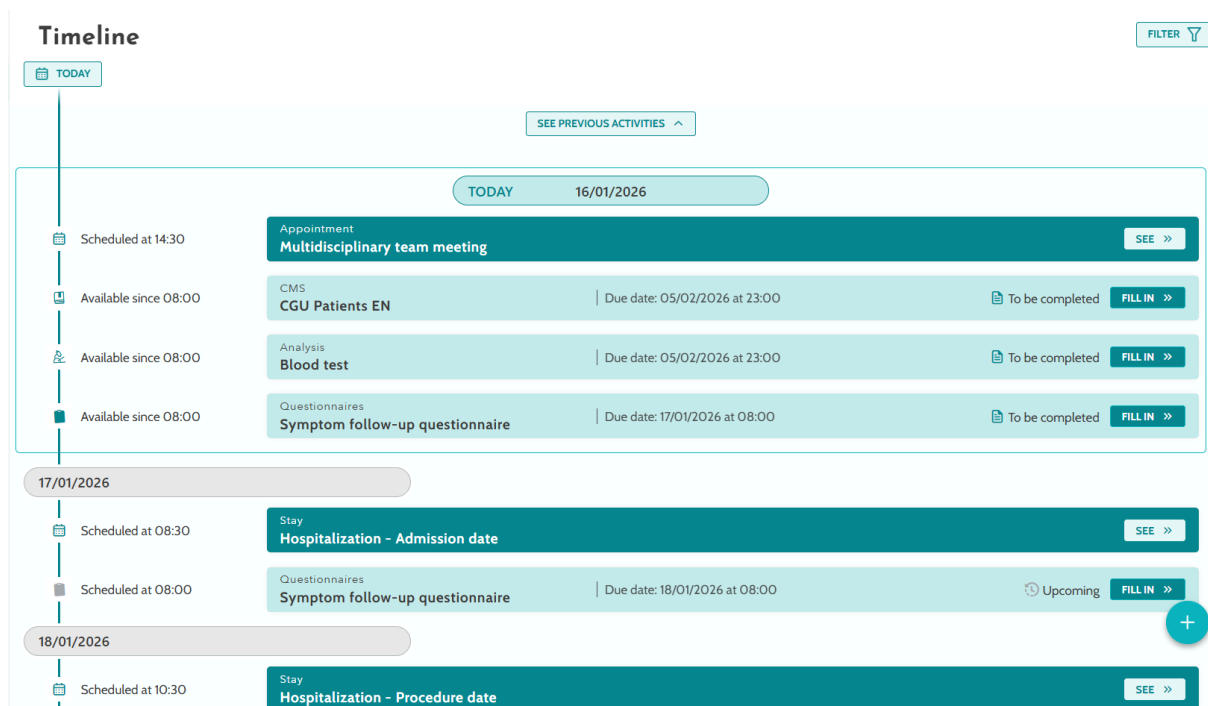
The “**Patient indicators**” dropdown contains all the indicators added to the patient file, even if they are not activated in the organization where you work.

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.

2.13.3. 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 anchor points, planned content and alerts for the patient's care pathway. The items are organized 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.

The button “X event(s) to schedule” open the right-side panel and leads to plan the anchor points date which were not mandatory at the enrolment time. It is also possible to edit and modify these dates from the Timeline clicking on the event.

The screenshot shows a panel titled "Event(s) to schedule" with a close button in the top right. It contains three expandable sections, each for a different hospitalisation event:

- Hospitalisation - Admission date**: Includes fields for "Anchor point date" (with a calendar icon) and "Event time" (with a clock icon). A teal "DONE" button is at the bottom.
- Hospitalisation - Intervention date**: Includes fields for "Anchor point date" and "Event time". A teal "DONE" button is at the bottom.
- Hospitalisation - Discharge date**: Includes fields for "Anchor point date" and "Event time". A teal "DONE" button is at the bottom.

A “**Filter**” button can be used to filter the timeline, around a specific date, on content type or specific event.

The screenshot shows a panel titled "Filters" with a close button in the top right. It includes the following elements:

- A "Filter around the date:" field with a calendar icon.
- A "Filter by content type:" section with a grid of buttons:
 - ALL TYPES OF CONTENT (highlighted in teal)
 - EVENT(S)
 - ALERT(S)
 - QUESTIONNAIRE(S)
 - MEASUREMENT(S)
 - TASK(S)
 - TREATMENT(S)
 - ANALYSIS
 - PRESCRIPTION(S)
 - CMS
 - VIDEOCONFERENCE(S)
 - ATTACHMENT(S)
- At the bottom, there are two buttons: "RESET ALL FILTERS" and "FILTER" (highlighted in teal).

.2.13.4. Measurements

.2.13.4.1. Constant tab

A 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.

.2.13.4.2. 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.

We can also see on the graph or in the report the limits defined on every variable. These limits are displayed depending on colors selected in the protocol.

The “modify threshold” button’s behaviour is described in section .3.3.4 Modify a threshold.

.2.13.5. 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.

For the “Lowenstein” acquisition mode, a “**Restart subscription**” button can be used to start retrieving patient measurements from the Lowenstein respiration.

.2.13.6. 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 protocols.

.2.13.7. 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 are used to trigger one or more protocols, depending on the responses provided. Screening questionnaires can only be completed once and cannot be modified later.

Default questionnaires can be entered multiple times and edited by the healthcare professional.

Click on **"Generate report"** to download the PDF questionnaire with associated alerts. The social actor does not have the rights for this last action.

.2.13.8. 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.

.2.13.9. 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.

.2.13.10. 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.

.2.13.11. 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.

.2.13.12. 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.

The screenshot displays the 'Timeline' view of a patient's medical record. On the left, a sidebar lists various patient data categories: Summary, Timeline (selected), Measurements, Questionnaires, Educational content, Files, Medication, Tasks, Video meetings, Alerts, Messages, Profile, Care team, and Pathway. The main timeline area shows a vertical timeline for 'TODAY' (16/01/2026). Key events include:

- Scheduled at 14:30:** Appointment 'Multidisciplinary team meeting' with a 'SEE' button.
- Available since 08:00:** CMS 'CGU Patients EN' with a due date of 05/02/2026 at 23:00, marked 'To be completed' with a 'FILL IN' button.
- Available since 08:00:** Analysis 'Blood test' with a due date of 05/02/2026 at 23:00, marked 'To be completed' with a 'FILL IN' button.
- Available since 08:00:** Questionnaires 'Symptom follow-up questionnaire' with a due date of 17/01/2026 at 08:00, marked 'To be completed' with a 'FILL IN' button.
- Available since 14:00:** Videoconference 'Un contenu de Visioconférence' with a due date of 16:00, marked 'To be completed' with a 'JOIN' button.

On the right, a panel titled 'Un contenu de Visioconférence' provides details:

- Appointment information:**
 - REASON: Un contenu de Visioconférence
 - DATE OF THE VIDEO: 16/01/2026
 - START TIME: Now
 - DURATION: -
 - STATUS: In progress
- Access to video meetings:** A 'PARTICIPATE' button.
- Report:** A text area for notes.

Alerts

Alerts

Criticality	Creation date	Measurement date	Title	Message	Type	Acknowledgement date	Author of the acknowledgement	Content
Recall	29/04/2025 10:47	29/04/2025 10:47	Callback request	Callback	Classic follow-up			
Information	29/04/2025 10:46	29/04/2025 10:46	Lab test	Add lab test	Care protocol			Assurance mutuelle (An...
Warning	29/04/2025 10:12	29/04/2025 10:12	Follow-up stopped / co...	Follow-up stop / consen...	Care protocol			Assurance mutuelle (An...
Information	13/02/2025 15:28	13/02/2025 15:28	Lab test	Add lab test	Care protocol			Assurance mutuelle (An...

In this section, you find all the alerts and notifications generated during the care pathway. The management of alerts is detailed in section .3.3.2 Alerts acknowledgement.

By default, only unacknowledged alert and notifications are displayed with the criticality, date and time triggered, title and message body, and associated content. The checkbox “**Show acknowledged alerts**” displays the alerts and notifications that have been acknowledged. In this list, we display the medical alerts and the administrative notifications.

Notifications follow this color code:

- Dark blue: Non-input
- Turquoise blue: Callback request
- Green: Discussion and messages

You can configure a notification as the criticality danger, warning or information.

You can choose to acknowledge one or multiple notifications, 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).

.2.13.13. Messages

Messages

Criticality	Creation date	Measurement date	Title	Message	Type	Acknowledgement date	Author of the acknowledgement	Content
Recall	29/04/2025 10:47	29/04/2025 10:47	Callback request	Callback	Classic follow-up			
Information	29/04/2025 10:46	29/04/2025 10:46	Lab test	Add lab test	Care protocol			Assurance mutuelle (An...
Warning	29/04/2025 10:12	29/04/2025 10:12	Follow-up stopped / co...	Follow-up stop / consen...	Care protocol			Assurance mutuelle (An...

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

The “**Discussion**” 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.

.2.13.14. 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's contact details 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 Careside® is connected to the hospital information system and electronic medical records. It contains the list of the patient's hospital stays. In the “**Type**” column, the letter “**H**” refers to hospitalization, 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.
- “**Family/Social Connections**” allows the entry of the patient's useful contacts (persons to be called in case of emergency).

.2.13.15. Care team

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

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

“**Authorize 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 authorization at any time by clicking on the bin icon.

.2.13.16. Pathway

NEIRA Beatriz
Born 24/06/2024 (2 years)
Identifiant Per...: AirLiq_000000...
Email address: beatriz.nesigm...
Numéro de télép...: +33600000000

Protocol: Better@Home protocol in progress

Pathway + ADD A PATHWAY

Active Archives

PATHWAY 1: BETTER@HOME Active START: 24/06/2024 END: 24/07/2024

Name	Specialty	Origin	Type	Author	Start date	End date	Status	Actions
Manual start/stop	General medicine	Manual	Care	Brech Robin	24/06/2024	Manual		
Better@Home Maeda prot...	General medicine	Scheduled	Care	Brech Robin	24/06/2024	24/07/2024		
Better@Home protocol	General medicine	Scheduled	Remote monitoring	Brech Robin	24/06/2024	24/07/2024		

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.

.2.13.16.1. Active pathway

The active tab displays all the patient's pathways, 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 enrolment 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.

.2.13.16.2. 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.

.2.14.Administration

Careside® and Medtronic administrators, as well as the institution administrators, have access to a list of submenus inside “**Administration**”

.2.14.1. Non-medical content

Careside® 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 Careside® 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.

.2.14.2. 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. Careside® and Medtronic administrators can view and edit all the existing content templates in the solution. Both Careside® 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 Careside® 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.

Template Type	Category	Description
	SMS	Questionnaire sent by SMS which the patient can answer directly by SMS. The choice of question types is limited.
Task	Default	Used to configure a task of any type to set a reminder for example.
Medication	Default	Enables you to set a medication reminder.
Technical task	Default	This content is used to send a planned SMS notification to a patient like an appointment reminder, pre-operative instructions, information... It can be planned in the protocol like other contents.

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.

Access rights to the content template created can then be managed for a specific user or healthcare facility, with permissions such as: view, share, translate, or edit.

Modifications made to a content template at the administrator level apply to all facilities using that template within a protocol.

Modifications made to a content template at the facility administrator level apply to all protocols within that facility that use the template.

.2.14.2.1. 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” 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 non-input notifications, which are described in more detail below.

2.14.2.2. 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.*

Condition

Group of "OR" conditions 1

cognition1 ▾

= ▾

Existing option X ▾

Oui X ▾

+ OR

+ AND

Dynamic value

Existing option

CLEAR ALL

SAVE

CANCEL

.2.14.2.3. 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.

Edit score

Question: Radio buttons 2

Choice 1:

▴ ▾

 point

Choice 2:

▴ ▾

 point

Choice 3:

▴ ▾

 point

SAVE

CLOSE

1 Add a score to a field

Formula

Formula

Variable scores

- SUM OF SCORES
- COGNITION2 (RADIOGROUP)
- NUT2 (RADIOGROUP)
- NUT3 (RADIOGROUP)
- MOT1 (TEXT)
- MOT2 (TEXT)

Keyboard

+	π		
x~y	+	-	x
√()	/	(	)
LOG()	1	2	3
LN()	4	5	6
EXP()	7	8	9

CANCEL

SAVE

2 Create a calculated score

.2.14.2.4. Notification for non-input

This is the type of notification 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 notification (Information, Warning or Non-input) and plan the notification conditions and finally the visibility (patients, practitioners or both).

The form for creating a notification for non-input includes the following fields and options:

- Title***: A text input field.
- Message***: A larger text input area.
- Importance**: A dropdown menu with "Information" selected.
- Alert created**: A radio button that is selected.
- 1 days before planned date**: A configuration for the alert timing.
- At the planned input time**: A radio button.
- An hour after the planned input time**: A radio button.
- Visible to patients**: A toggle switch that is turned on.
- Visible to practitioners**: A toggle switch that is turned off.

.2.14.2.5. Screening questionnaires

The **screening questionnaire** allows the patient to be assigned to a specific protocol (among several), based on their responses.

To configure this type of questionnaire, all questions, answers, and variables must first be defined.

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.

.2.14.3. 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. Careside® and Medtronic administrators can view and edit all the existing protocols in the solution. Both Careside® 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.

General information

Name

Protocol complete test

Specialty

Cardiac Surgery

Type of follow-up

☒ Maela
 ☐ Ambulight

Follow-up institution

-

Template language

English

☐ Add the SMS questionnaire channel

Information

Planned content

QUESTIONNAIRES

MEASUREMENTS

LABORATORY TESTS, DRUG THERAPIES AND TASKS

EDUCATIONAL CONTENT

Questionnaires

CREATE A NEW QUESTIONNAIRE

Add a questionnaire

+ ADD

TEMPLATE DEFAULT QUESTIONNAIRE TEST ("Questionnaires")

No scheduling rules linked to this content

No alert rule associated with this content.

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 whether the content should be sent the day before or after the scheduled date if it falls on a day when the facility is closed
- 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.

Scheduling

Authorised days:

If a content is planned on an unavailable day, it is automatically rescheduled for the next available day.

☒ Monday
 ☒ Tuesday
 ☒ Wednesday
 ☒ Thursday
 ☒ Friday
 ☒ Saturday
 ☒ Sunday

Planning number	Hour start	Hour remind	Hour end	Actions
Scheduling 1				
Hour start 10:00 AM				
Recall After this period, the content will be replaced by "delay" This time is used for sending non-entry alerts 1 Hours X before after Start of current planning X at 11:00 AM X				
End If an end is defined, the content can no longer be entered by the patient after this period 1 Hours X before after Reminder of current planning X at 12:00 PM X				
CANCEL DONE				

CANCEL

ADD AN ITERATION

SAVE

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 Careside® 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.

.2.14.4. RPM IoT protocols templates

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 **"Alert rules"**. All mandatory fields are highlighted in yellow and marked with an asterisk.

2.14.4.1. General information

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.

2.14.4.2. 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 file 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).

.2.14.4.3. Setting non-input notifications in the protocol model

The “Alerts” section allows you to define the conditions for triggering no-input notifications.

Add no input notification rule

Title *

Content to trigger *

No input notification X

Importance is required

Message *

Importance *

Rule origin

Visibility

Patient visibility X Pro visibility X

Duration validity ⓘ

Conditions group

>

0

Day(s)

CANCEL ADD

No-input notifications 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, set the criticality to “No input”, the origin, the validity period, the visibility and the triggering conditions.

The visibility determines whether the patient and/or healthcare professional should see the notification when it is triggered. Patients will be notified of the alert and must acknowledge that they have seen it.

For the alert setting, please refer to section .3.3.3 Setting alert rules in the protocol model.

.2.14.4.4. Status of protocol template

The protocol templates created are in 'draft' status by default. To associate them with a patient, authorized 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.

.2.14.5. 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. Careside® and Medtronic administrators can view and edit all the existing pathways in the solution. Both Careside® 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.

Pathway language *
English

☐ Pathway activates patient account ⓘ
This option allows activation of the patient account as well as visibility of the journey by the patient after enrollment

Name * Description * Duration * Anchor points *

Pathway code + ADD

Anchor points
Protocols
Screening
Pre-inclusion

Format	Category	Name	Niveau	Mandatory	Actions
File	Attachment	alademande	Pathway		
File	Attachment	Pièce jointe avec ...	...		

2 results

<< < 1 > >>

25

CANCEL + DONE

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)
Careside® key date	There exist four types of Careside® 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 a content sent by SMS (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 pathway model. Click on "Remote monitoring protocol" to open the list of protocol models proposed by your organization.

.2.14.6. Translation

For each type of template (content, protocol and pathway), there is a colored flag.

If it is 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.

.2.15. Dashboard

The “**Dashboard**” menu offers you data insights on your use of the Careside® 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) Careside® 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) Careside® administrator Medtronic administrator	Possibility to download the responses provided in Careside® 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.

.2.15.1. General information

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.

.2.15.2. 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 file 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).

.2.15.3. Status of protocol template

The protocol templates created are in 'draft' status by default. To associate them with a patient, authorized 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.

.3.(MD) Cortex Alert Engine instructions for use

Manufacturer's information



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Main product information



Cortex Alert Engine

Product Version: V1.0



(01)3770027995012(8012)1.0.62

Certification and declaration of conformity



Cortex Alert Engine, which is a software component of the Careside® platform, is a Class IIa **medical device** CE marked in YYYY/MM/DD¹.

This device complies with the General Safety and Performance Requirements of Medical Device Regulation 2017/745.

Availability of the instructions for use

This user manual could be provided on paper form on demand by the user, within 7 days.

Exclusions of warranties and limitations of liability

MN Santé Holding makes no express or implied warranties regarding this manual or its quality, performance or suitability for any specific type of procedure. In addition, this manual is subject to change by the company without notice and without implying any obligation or liability on the part of the company.

¹ This information will be completed when the CE mark is obtained.

Trademarks (if applicable)

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Modifications

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 significant changes are made to this manual concerning the medical device module, the Notified Body will be informed.

If a user identifies incorrect information, please contact us at this email address contact@careside.care.

Revision history

Release date global instructions for use: 28/09/2026

Cortex Alert Engine

Instruction for use version	Release date	Revision for safety reason?
1	08/01/2026	☐ Yes ☒ No
2	28/09/2026	☐ Yes ☒ No

.3.1. Indications and symbols

.3.1.1. Description of symbols

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

	CE mark and notified body number
	Caution: 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.
	Consult electronic instructions for use https://cms.mae.la.care/83319

	Manufacturer
	Reference number
	Medical device
	Unique Device Identifier

.3.1.2. 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.

.3.1.3. Warnings

	• All users must be trained before using the product. • When updating the platform, users must clear their browser's cache. These notices are sent to Careside® users during each update, indicating the procedure to follow.
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.3.1.4. Residual risks

.3.1.4.1. General

- **Cortex Alert Engine** is not an emergency monitoring service. Alerts are reviewed exclusively during the days and hours defined by the remote monitoring operator and are not interpreted instantaneously. It must not be used as a substitute for continuous bedside monitoring or emergency response pathways.
- **Cortex Alert Engine** supports clinical decision-making but does not replace the clinical judgement of the healthcare professional. Users must not over-rely on alerts generated by the device to the exclusion of other clinical assessment methods.
- Any serious incident in which **Cortex Alert Engine** was or may have been a contributory cause must be reported to the manufacturer and to the relevant national competent authority, in accordance with MDR Article 87.

.3.1.4.2. Configuration and alert management

- All users must be trained before using **Cortex Alert Engine**. Training is provided by MN Santé at deployment. Untrained users must not configure or manage alerts.
- Alert rules and thresholds must be carefully configured by authorised healthcare professionals. Incorrect configuration may result in alerts not being triggered when clinically required.

- Alert criticality levels are indicated by symbols and colour codes. Users must be familiar with these indicators to avoid misinterpretation.
- Acknowledged alerts are no longer visible in the active alert list. Users must verify that an alert has been appropriately addressed before acknowledging it. An acknowledgement cancellation function is available.

.3.1.4.3. Technical environment

- **Cortex Alert Engine** requires a stable internet connection. Inadequate network conditions may prevent access to the platform and disrupt patient monitoring.
- Users must access **Cortex Alert Engine** via a compatible and supported web browser. Use of unsupported browsers may result in degraded functionality.
- During scheduled platform updates, **Cortex Alert Engine** may be temporarily unavailable. Users are notified in advance via newsletter and platform pop-up. Monitoring pathways must account for potential periods of unavailability.

.3.1.4.4. Data and security

- Access credentials must be kept confidential. Users must not share their login details. Multi-factor authentication is required.
- User accounts must be deactivated promptly when a professional is no longer authorised to access the platform.
- Patient health data stored in **Cortex Alert Engine** is subject to applicable data protection regulations. Decommissioning of patient data must be carried out in accordance with applicable regulations.

.3.1.5. 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 center at **+441923205184** (United Kingdom) or **+35391750797** (Ireland).

.3.2. Product description

.3.2.1. Indications for use

Cortex Alert Engine is indicated for use in remote patient monitoring for adult and pediatric patients (under supervision of a legal guardian) across all medical specialties, when monitoring of physiological or declarative parameters is clinically relevant.

Cortex Alert Engine is specifically indicated to assist healthcare professionals in:

- Detecting early signs of clinical deterioration or deviation from pre-established physiological thresholds, based on data transmitted from connected medical devices, patient-reported outcomes, or interoperable health information systems;
- Triggering configurable clinical alerts enabling timely review and intervention by a qualified healthcare professional;
- Supporting the organization and prioritization of remote monitoring workload through a structured, rule-based alert management interface.

Cortex Alert Engine is indicated for use in settings where an organized remote monitoring care pathway is established, including but not limited to:

- Post-surgical and perioperative follow-up (defined worst-case scenario for clinical evaluation purposes);
- Chronic disease management (cardiology, chronic respiratory insufficiency, diabetology, etc.);

- Home hospitalization and ambulatory care;
- Oncology supportive care;
- Prevention of frailty in older adults;
- Post-discharge monitoring following acute episodes, including post-stroke follow-up.

Cortex Alert Engine is intended to support clinical decision-making.

Cortex Alert Engine is relying on deterministic algorithms.

Cortex Alert Engine is not intended to replace clinical decision-making. The interpretation of alerts and any resulting clinical action remain the sole responsibility of the healthcare professional.

Cortex Alert Engine is not indicated as an emergency monitoring system. Alerts are processed during scheduled monitoring windows defined by the remote monitoring operator.

Cortex Alert Engine is not intended to replace continuous bedside monitoring or emergency response systems.

Cortex Alert Engine is not based on artificial intelligence models, does not perform autonomous diagnosis, therapeutic recommendation, or any form of treatment initiation.

.3.2.2. Intended use

Cortex Alert Engine is a medical device software intended for remote patient monitoring throughout different stages of their care.

It allows healthcare professionals to set customizable rules for detecting health risks and triggering alerts based on patient data. The system is highly configurable, supporting clinical decision-making by enabling early detection of potential risks.

The remote monitoring via **Cortex Alert Engine** is not an emergency service and the recorded data or alerts are not read and interpreted instantaneously but only during the days and the times set by the remote monitoring operator.

.3.2.3. Patient population

Cortex Alert Engine is intended for remote monitoring of patients of all age groups, including pediatric patients under the supervision of a legal guardian, across all medical specialties as described in section .3.2.1 Indications for use.

Some patient populations are subject to restrictions on use, as described in section .3.2.8 Security information and contraindications:

- Children, except in the presence of a legal guardian;
- Visually impaired patients, except in the presence of a caregiver able to provide the required follow-up;
- Patients with significant psychomotor disorders of the upper limbs, except in the presence of a caregiver;
- Patients with memory disorders, except in the presence of a caregiver;
- Patients without an internet connection, except in the presence of a caregiver;
- Non-consenting patients.

These restrictions reflect the indirect nature of Cortex Alert Engine's interaction with patients: the device does not interact with patients directly, but the monitoring pathway depends on patient-generated data. Inability to generate reliable data, whether due to age, disability, or lack of connectivity, must be mitigated by caregiver involvement. Otherwise, the device is inappropriate for use.

.3.2.4. Intended users

Cortex Alert Engine module is intended to be used by:

- Healthcare professionals who can use digital tools
- Administrative professionals (medical secretaries, health executives and site managers)

We recommend to give the permission on the **Cortex Alert Engine** only to healthcare professional or at least having the validation of an healthcare professional on the **Cortex Alert Engine** configuration.

.3.2.5. Use environment

Cortex Alert Engine is intended for use at medical facilities by healthcare and administrative professionals.

The user environment shall meet certain requirements, as its characteristics can affect user interactions with the device leading to performance issues or software malfunctions. The minimum requirements are:

- A stable internet connection
- Using the recommended Web Browsers: Latest versions of Google Chrome and Firefox on Windows and macOS and Google Chrome and Safari on Android and iOS, respectively.

.3.2.6. Clinical benefits

The clinical benefits of **Cortex Alert Engine** are expected to apply across all indicated specialties, with demonstrated or clinically plausible evidence assessed in the context of the perioperative worst-case scenario:

- Reduction of complications through early detection of physiological deterioration;
- Reduction of unplanned readmissions and length of hospitalization;
- Improved adherence to outpatient care plans and home treatments;
- Optimization of healthcare professional workload through prioritized alert management.

.3.2.7. Performance characteristics

The technical performances of **Cortex Alert Engine** are summarized in the following table.

Technical performance	Objective	Action threshold
Availability of the RPM production endpoints (front and API, both hosting regions)	≥ 99.5%, excluding scheduled maintenance	Endpoint unavailable on two consecutive probes
Validity of the TLS certificates of these endpoints	No certificate reaching expiry in service	7 days before expiry
New exceptions on the RPM API application role	No new unhandled exception in production	Any new exception
New exceptions on the RPM scheduler application role	No new unhandled exception in production	Any new exception

Technical performance	Objective	Action threshold
RPM operations whose average duration exceeds the operational threshold	No operation above threshold, or documented justification	Any operation above 5,000 ms average duration
Trend of the average duration of RPM operations	No upward drift between two consecutive periods	Degradation against the previous period
Availability of the database serving the engine	No unplanned unavailability	Any failed health check
Number of alerts sent per day, by criticality	Volume consistent with the active patient base, no unexplained drop	50% drop against the preceding comparable period, or abnormal growth

.3.2.8. Security information and contraindications

Any serious incident occurring in connection with the **Cortex Alert Engine** module must be notified to the manufacturer using the following contact detail:

Address: MN Santé Holding, 56 rue Saint-Jean-de-Dieu, 69007 Lyon, France

Email: materio-mns@careside.care

Phone: +33 (0)4 81 68 25 26

and to the relevant national competent authority of the Member State in which the user is established.

The use of the **Cortex Alert Engine** module is not recommended in:

- Children, except in the presence of a legal guardian;
- Visually impaired patients, except in the presence of a caregiver able to provide the required follow-up;
- Patients with significant psychomotor disorders of the upper limbs, except in the presence of a caregiver;
- Patients with memory disorders, except in the presence of a caregiver;
- Patients without an internet connection, except in the presence of a caregiver;
- Non-consenting patients.

.3.2.9. Recommended configuration and browsers

Workstation requirements. The platform must be accessed from a device managed by your organization, running an operating system version still supported by its publisher and receiving security updates, with anti-malware protection active, full-disk encryption enabled, and automatic screen locking after a period of inactivity. Access from a public or shared computer is not permitted. Date & time of the device must be set to the official and correct local date & time of its user.

Connectivity requirements A stable and high-speed internet connection is essential for accessing Careside®. A minimum download and upload speed of 10Mbit/s is recommended.

Ensure that network firewall and security settings allow access to the Careside® web application. Careside® requires outbound HTTPS access on port 443 to the domains provided to your organization; no other inbound or outbound flow is necessary. Interception or decryption of this traffic by a network security appliance is not supported and prevents the platform from operating securely.

Avoid untrusted networks such as open public Wi-Fi; where remote access is required, and use the secure connection provided by your organization.

Browser version requirements 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. Browser versions that are no longer maintained by their publisher must not be used, as they no longer receive security corrections.

Ensure that network firewall and security settings allow access to the Careside® web application. Careside® requires outbound HTTPS access on port 443 to the domains provided to your organisation; no other inbound or outbound flow is necessary. Interception or decryption of this traffic by a network security appliance is not supported and prevents the platform from operating securely.

What Careside® protects, and where your responsibility begins. Careside® authenticates every user through the centralised identity provider using the OpenID Connect standard, encrypts all exchanges between your browser and the platform, restricts access through role-based permissions limited to what each role requires, terminates inactive sessions automatically, and records access and security events for traceability. Platform security updates are deployed by Careside® and require no installation on your part. These measures protect the platform and the data in transit; they cannot protect the workstation you use, your credentials, or the network your organisation provides.

Account and session use. Use your own individual account. Accounts must never be shared between professionals, even within the same care team: traceability of access to patient data depends on it. Never communicate your credentials, including to a colleague or to a person presenting themselves as Careside® support — Careside® never asks for your password. Log out when you leave the workstation and lock the screen even for a short absence; automatic session expiry is a safety net, not a substitute. Be aware of your surroundings when patient data is displayed, and do not export patient data to unencrypted removable media or transmit it through unsecured messaging.

Access rights. Access rights are assigned by the administrator designated within your organisation, which is responsible for requesting account creation, for keeping assigned roles aligned with actual duties, and for requesting the immediate deactivation of an account when a professional leaves or changes duties.

Reporting a security event. Report without delay, to your organisation's IT contact and to Careside® support, any unexpected connection or activity on your account, any authentication code received without having requested it, any message asking for your credentials or directing you to a page resembling Careside®, any unexplained modification or disappearance of data, and any loss or theft of a device used for access. A suspicion is sufficient to report; establishing that an incident occurred is not for you to do.

No measure can compensate for a compromised workstation, a disclosed credential, or an account left active after a departure. The conditions above are those under which the protection of the platform remains effective.

.3.3. Use of Cortex Alert Engine features

.3.3.1. Right and authorization

The rights below are linked to **Cortex Alert Engine**.

Rights and authorization Module	Functionality	Read	Create	Update	Delete	Translate	List
Alert management (CAE)	Threshold management			X			
	Alert rules	X	X	X	X		
	Alert management	X		X			

.3.3.2. Alerts acknowledgement

When you want to acknowledge an alert, you have two options:

- **Acknowledge a single alert.** In this case, screenshot 1 below opens.
- **Acknowledge several alerts at once.** In this case, screenshot 2 below opens with the details of each alert. The acknowledgment reason will apply to all selected alerts.

Alert detail

TITLE	Add photo
MESSAGE	Photo
CREATION DATE	11/05/2026 14:51
MEASUREMENT DATE	11/05/2026 14:51

Acknowledgement

Reason *

Error / False alert / False measurement

Acknowledgement message

 CANCEL

 ACKNOWLEDGE

Multiple acknowledgements

Criticality	Creation date	Measurement date	Title	Message	Type
Warning	04/09/2026 11:27	04/09/2026 11:27	Follow-up stopped / conse...	Follow-up stop / consent re...	Classic follow-up
Warning	15/07/2026 14:55	15/07/2026 14:55	Follow-up stopped / conse...	Follow-up stop / consent re...	Classic follow-up
Warning	11/05/2026 14:52	11/05/2026 14:52	Follow-up stopped / conse...	Follow-up stop / consent re...	Classic follow-up

3 results

Reason *

Error / False alert / False measurement

Acknowledgement message

CANCEL ACKNOWLEDGE

3.3.3. Setting alert rules in the protocol model

The “Alerts” section allows you to define the conditions for triggering value alerts.

Add alert rule

Title *

Fever

Content to trigger *

Alert

Message *

patient has fever

Importance *

Warning

Rule origin

Visibility

Patient visibility Pro visibility

Duration validity

Timeout

Conditions group

temp ≥ Enter a value

38

AND OR

CANCEL ADD

Value alerts inform the user that the value of one or more variables or the answer to a question is unusual.

You need to enter the title, the message, the criticality of the alert (Information, Warning, Danger), 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 timeout (the expiration time is the time after which the alert is automatically acknowledge), the visibility of the alert (you can select among the profile available) and the triggering conditions.

The visibility of the alert determines whether the patient and/or healthcare professional should see the alert when it is triggered. Patients will be notified of the alert and must acknowledge that they have seen it.

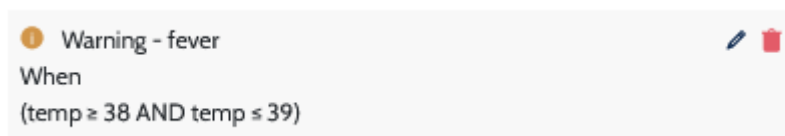
To enter a condition for triggering an alert:

- 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
- Comparison value for value alerts can be:
 - Either selected from the limits defined in the selected variable;
 - Either on another variable/question from the protocol;
 - Either a manually entered value.

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

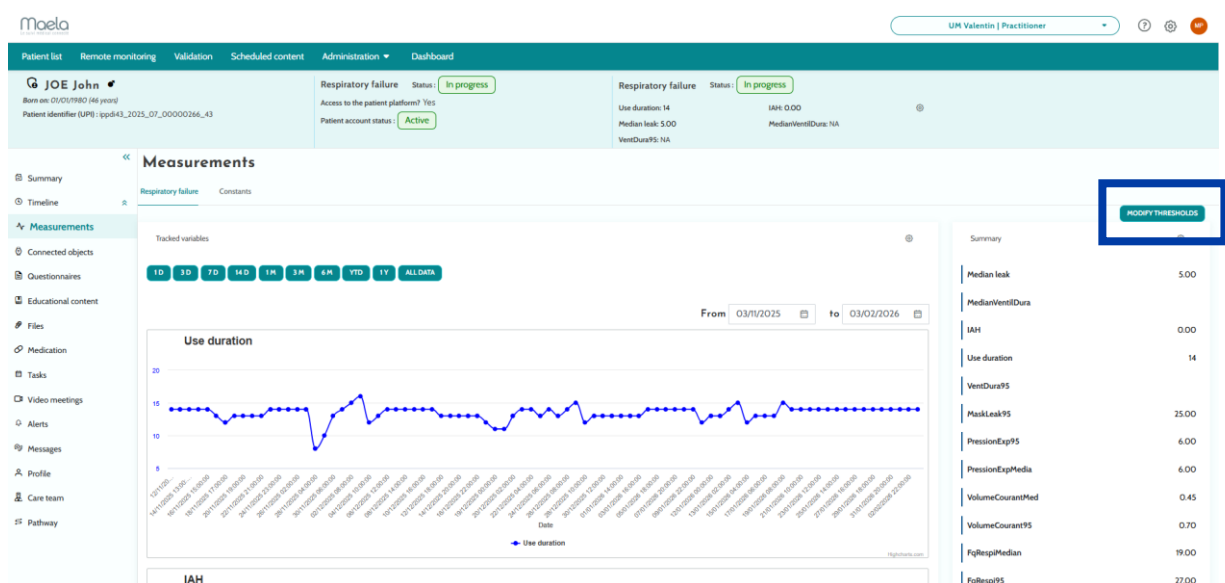
Alerts are triggered when measurements are received that meet the condition(s). They are displayed in the patient file.

The alert rule configured are display with a pen icon to edit the alert rule, and a trash icon in order to remove the alert rule.



3.3.4. Modify a threshold

In the measurement tab (see .2.13.4 Measurements), a button “modify threshold” allows to quickly modify the limits values set-up.



By clicking on the button “modify threshold”, you open a modal that allow you to edit the threshold already configure in the protocol.

Modify threshold values

Glycémie

Minimum threshold

Threshold label	Threshold value *
Min threshold 1	70

Maximum threshold

Threshold label	Threshold value *
Max threshold 1	130

Glycémie moyen

Minimum threshold

Threshold label	Threshold value *
Min threshold 1	70

Maximum threshold

Threshold label	Threshold value *
Max threshold 1	130

CANCEL **SAVE**

.3.4. Installation check and access to Cortex Alert Engine

.3.4.1. Checks to perform before using Cortex Alert Engine

- Verify that your web browser is one of the supported versions listed in section .3.2.9 Recommended configuration and browsers.
- Ensure a stable internet connection is available (minimum 5-10 Mbit/s recommended).
- Ensure that your institution's network firewall and security settings allow access to the Careside® web application.
- Ensure your user account has been created and activated.
- Ensure you have received training on **Cortex Alert Engine** before first use.

Please note that since Careside and, consequently, **Cortex Alert Engine** are available as Software as a Service, no action is required on your part when an update is released. However, if you notice a problem following an update, please clear your browser cache.

The export and deletion of data are managed by the manufacturer. It is performed at the end of the contract, as explained in section .3.7 Withdrawal of the device, or at the request of the data owner.

.3.4.2. Accessing Cortex Alert Engine

1. Open your supported web browser.
2. Navigate to <https://maela.cortex-care.io/>.
3. Enter your username and password on the login page.
4. Complete multi-factor authentication (MFA) by entering the one-time code received by SMS or email. This double authentication depends on your security domain. Depending on your security domain, other way to connect could be available (such as Pro Santé Connect in France).
5. Upon successful authentication, you are directed to the web application. The Cortex Alert Engine functions are accessible in the protocol template details and the Alerts section of each patient file.

.3.4.3. Installation check before first use

Before launching Careside®, which includes **Cortex Alert Engine**, the deployment manager configures all the pathways required by the healthcare institution, including but not limited to alert and threshold settings.

The manufacturer strongly recommends that at least one person from the care team performs a test with a fictitious patient for all configured pathways. The deployment manager will suggest this test for each pathway configuration.

Once the healthcare professional has validated the configuration, the device is ready to be used for real patients.

.3.5. Troubleshooting

If you encounter a problem while using the platform, refer to the table below. If the problem persists after applying the proposed solution, contact the support (see "Assistance contacts" at the end of this section).

.3.5.1. Application problems

Problem	Possible cause	Proposed solution
The platform does not load, or pages display incorrectly.	Unsupported or outdated browser.	Use a supported browser in its current version (see .3.2.9 Recommended configuration and browsers) and update it.
The platform loads but behaves erratically (empty screens, outdated data).	Corrupted local cache or cookies.	Clear the browser cache and cookies for the platform's address, or try in a private browsing window.
The platform is unreachable from the facility's workstations only.	The facility's network (proxy, firewall) blocks access to the platform.	Contact your facility's IT department and ask them to authorize the platform's address.

.3.5.2. Connection problems

Problem	Possible cause	Proposed solution
Unable to log in: "invalid credentials" message.	Incorrect username or password, or password expired (passwords must be changed every 90 days).	Use the "Forgot password" link to reset your password. Check that the username is your professional account identifier.
Unable to log in: account locked or access denied.	The account has been deactivated or the authorization has been withdrawn by the account manager of your healthcare facility.	Contact the account manager of your healthcare facility to verify the status of your account.
The two-factor authentication code is not received.	Incorrect or no phone number or email address in your profile, or delivery delay from the operator.	Wait one minute and request a new code. If the problem persists, verify your contact details with your account manager or contact the support.

Problem	Possible cause	Proposed solution
You are logged out unexpectedly during use.	Automatic session logout after X minutes (configured depending of your security domain) of inactivity (security mechanism).	This is the expected behavior. Log in again. Save your entries regularly when configuring alert rules.

.3.5.3. Alerts that do not trigger

Problem	Possible cause	Proposed solution
An expected alert was not raised for a patient.	The corresponding measurement was not recorded or not transmitted to the platform. Or one of the measures used in the alert rule was not valid anymore	Check that the measurement is present in the patient record. If it was entered by the patient, check with the patient that the entry was completed. Verify the measurement status
An expected alert was not raised although the measurement is present.	The alert rule is disabled, or the thresholds are not adapted to the patient (patient-level thresholds override protocol defaults). Or one of the measures used in the alert rules was not valid anymore	Review the alert rule configuration and the patient-level thresholds for the monitored variable. Verify the measurement status
No alert is ever raised for a monitored variable.	The variable monitored by the rule does not match the variable of the patient's protocol. We receive the measures too late and the measures is automatically unactivate	Verify that the alert rule is attached to the correct protocol variable. Contact the support if the configuration appears correct.
Measurements from a connected device are missing.	Synchronization failure between the device and its manufacturer's service, or between that service and the platform.	Check the device pairing and synchronization in the device's companion application. Ask the patient to synchronize the device. If measurements remain missing, contact the support.

.3.5.4. Errors when configuring alert rules

Problem	Possible cause	Proposed solution
An error message is displayed when saving a rule or a threshold.	A mandatory field is missing, or the values are inconsistent (e.g. lower threshold greater than upper threshold).	Correct the highlighted fields and check the consistency of the threshold values, then save again.
A threshold modification does not seem to be applied.	A patient-level threshold overrides the protocol-level value, or the modification targets the wrong variable.	Check whether a patient-level adaptation exists for this patient, and that the modification targets the intended protocol variable.

Problem	Possible cause	Proposed solution
The rule is saved but never evaluated.	The rule is attached to a variable that is not part of the patient's monitoring protocol.	Verify that the monitored variable belongs to the patient's protocol. Contact the support if the configuration appears correct.

.3.5.5. Assistance contacts

For any problem not resolved by this section, or for any actual or suspected anomaly or failure of the software, contact the manufacturer's support:

Channel	Contact	Availability
Email	rs.maelasupport@medtronic.com	Business days

Guaranteed response times, according to the severity of the reported problem:

Severity	Definition	Guaranteed response time
Critical	Platform unavailable, or alerts not being raised or displayed.	30 minutes
High	A major function is degraded but patient monitoring remains possible.	1 hour
Medium	A minor function is degraded but patient monitoring remains possible.	4 hours
Minor	Cosmetic problem or request for information.	No SLA

When contacting the support, indicate: your facility, your username (never your password), the date and time of the problem, the patient record concerned if applicable, and the exact error message displayed.

.3.6.Communication process

The manufacturer informs users and distributors of any anomaly and of any approved device update (bug fix, vulnerability resolution, or following an incident report) through the following channels and within the following timeframes:

- **Channel:** distribution list (e-mail) covering all registered users and distributors of the device.
- Notification timelines:
 - **Discovery of an anomaly**
 - **Critical anomaly** (cybersecurity incident, data breach, complete loss of alert functionality): initial notification sent within **24 hours** following discovery, informing users of the identified anomaly and, where applicable, any precautionary measures to be taken.
 - **Significant anomaly** (partial degradation of performance, non-critical bug affecting usability): initial notification sent within **5 business days**, informing users of the identified anomaly and, where applicable, any precautionary measures to be taken.
 - **Minor anomaly** (cosmetic bug, non-impacting issue): notification included in the next scheduled release note.
 - **Publication of the fix:** a follow-up notification is sent as soon as the fix has been **delivered and validated in production**, confirming resolution of the anomaly and detailing, if necessary, any actions required on the user's side.

- **Functional evolution** (new feature, planned improvement, non-corrective): notification is sent at least **15 calendar days** before deployment to production.
- **Notification content:** nature of the anomaly or update, potential impact on use, and any required user actions, as applicable.

These notifications may take the form of warnings, digital Field Safety Notices (FSNs), or bug/patch release notes, depending on the nature and criticality of the update.

.3.7. 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.

The expected lifetime of **Cortex Alert Engine** is 2 years. MN Santé Holding maintain compatibility with browsers and handsets supported by their manufacturers. MN Santé Holding performs an annual review of the SOUPs (Software of Unknown Provenance) and annual penetration tests.