



**Patient user manual
for the Maela web platform and
mobile application (iOS/Android)**

Manufacturer information



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Product information

REF Maela® Platform

Product version: V4.4.14

Certification and declaration of conformity

  The Maela® platform is a class I medical device marked CE in 2019.

This device complies with the essential requirements of Council Directive 93/42/EEC of 14 June 1993 relating to medical devices.

This device complies with the general safety and performance requirements of Regulation (EU) 2017/745.

Disclaimer regarding warranties and limitations of responsibilities

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Modifications

The information given in this document is subject to change without prior notice. We have made our best efforts to ensure the accuracy of the information given in this document. If any changes are made to this manual, the new version of this manual will be provided to users.

If you identify incorrect information, please contact us at this email address: contact-mns@careside.care

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1. Introduction

1.1. Purpose of the document

This user manual presents the Maela® platform, which is a medical device designed by the Maela® company for the **remote monitoring** of patients.

This manual contains step-by-step descriptions of how to use the platform. It is intended for patients who are admitted to a healthcare institution that holds a contract with Maela®.

By request only, it can also be made available in paper format.



Read this manual carefully before using the Maela® platform.

1.2. Abbreviations and definitions

| Abbreviations and terms | Description |
|--------------------------------|---|
| Medical device | A tool, device, piece of equipment, machine, implant, reagent for <i>in vitro</i> use, software, hardware or other similar or related items that are intended for use alone or operated by humans for a specific medical purpose or a range of medical purposes. |
| Prevention | According to the World Health Organization, prevention is the set of measures aimed at avoiding or reducing the number and severity of illnesses, accidents and disabilities. |
| Pathway model | The highest entity level in the Maela® platform. A care pathway model includes key dates, monitoring protocols and screening surveys. |
| Remote monitoring | A tool that is used for remote medical monitoring of the patient. It can be operated through specific platforms such as Maela®. |
| Healthcare professional | A person who uses his or her skills and judgement to provide a service related to maintaining or improving people's health, or treats injured, sick, disabled or infirm people by providing them with care and treatment. |
| Protocol | A Maela® protocol is made up of various types of content that may (or may not) be scheduled over time. A protocol corresponds to a specific follow-up that is included in a care pathway, such as a surgical episode as part of an oncology pathway. A Maela® protocol is made up of follow-up surveys, documents, links, educational content, analyses or even treatment follow-up. It also includes useful information for healthcare professionals so that they can provide support for any side effects that the patient may experience. A protocol has a start date and an end date. |
| serious incident | Any incident which has directly or indirectly resulted in, is likely to have resulted in or is likely to result in: |

| | |
|-----------------------------|--|
| | <ul style="list-style-type: none"> a) the death of a patient, user or any other person b) a serious deterioration, temporary or permanent, in the state of health of a patient, user or any other person c) a serious threat to public health |
| ERAS | Enhanced Recovery After Surgery. ERAS is a comprehensive patient management approach that promotes early recovery of the patient's abilities after surgery. |
| Caregiver | A person who can help or supervise a patient throughout his or her daily activities. |
| Psychomotor disorder | A disorder that affects the relationship between brain activity and the way the body moves (psychomotor function). It may or may not be associated with brain damage. This type of disorder may be caused by genetic or nervous system issues, or by factors related to the individual's development, environment or mood. |
| To-do list | Allows the user to manage the tasks in the care pathway. These tasks must be performed in a certain order. |
| Timeline | A detailed view of the patient's care pathway. All the content in the pathway will be displayed in this timeline. A timeline consists of events positioned along a time arrow, and shows the order in which the events take place. |
| Key date | A date on which content is scheduled. |
| Pop-up | A window that opens in front of the main window. |
| Scheduled content | Scheduled content in Maela® refers to all the follow-up surveys, educational content, measures, tasks, reminders or analyses that are planned within a pathway or a protocol. |
| Alert | A signal that warns of a danger or risk to the patient. It also allows information to be transmitted based on the patient's responses. |
| OTP | One-Time Password. This acronym refers to the code sent by SMS or email to secure your Maela® account. |

2. Indications and symbols

2.1. Description of symbols

The following table describes all the symbols used in this user manual and on the product itself.

| | |
|---|--|
|  | <p>Warning: This symbol is used to alert the user to a potential risk regarding the use of the product which could have consequences for the safety of the patient or user.</p> |
|---|--|

| | |
|---|--|
|  | Recommendation: This symbol is used to make a recommendation to the user regarding the use of the product without any consequences for the safety of the patient or user. |
|  | Read the user manual |
|  | Manufacturer's name |
|  | Product reference |
|  | Medical Device |

2.2. Precautions

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

- The content (questionnaires, educational content, documents, links and reminders), protocols and pathway offered to patients are validated by the referring care team. If the questions are not precise enough or if inappropriate content is shown, it is the professionals' responsibility to update the pathway.

2.3. Warnings

| | |
|---|---|
|  | <ul style="list-style-type: none"> - All users must be trained before using the product. - When updating the platform, users must clear their browser's cache and update their mobile application. These notices are sent to Maela® users during each update, indicating the process to follow. |
|---|---|

2.4. Malfunction

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

If it is not possible to identify or eliminate the cause of the malfunction with the help of this document, switch off the device and call our support centre on +44 (0)1923205184 (United Kingdom) or +353 (0)91750797 (Ireland).

3. Product description

3.1. Indication

The solution developed by Maela® is a **medical device** intended for healthcare professionals to ensure the medical follow-up of patients throughout their care pathway. This solution allows the care team and practitioners to determine treatment journeys that are suited to their specialism and patient base.

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

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

3.2. Target patient group

Patients who are accepted into a healthcare institution that holds a contract with Maela® can use Maela® for their follow-up care.

The patient should:

- Have an Internet connection at home (over Wi-Fi or mobile data)
- Have a mobile phone
- Be over 12 years old

3.3. Target users

The intended users are:

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

3.4. Clinical benefits

- Improvement in the quality of life and satisfaction of patients
- Improvement in the medical services provided
- Early detection and more effective management of complications
- Better monitoring of **ERAS protocols** (Agri F., Hahnloser D., Desmartines N., Hubner M. (2020) Gains and limitations of a connected tracking solution in the

perioperative follow-up of colorectal surgery patients. *Colorectal Dis.* 2020 Aug;22(8):959–966)

- Increased survival rate (Basch E., Deal A.M., Dueck A.C., et al. (2017) Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. *JAMA.* 2017;318(2):197–198)

3.5. Safety information

In the event of a worrying state of health, please contact your referring healthcare professionals or the emergency department, especially if the platform is unavailable.

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

3.5.1. Contraindications

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

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

3.6. Browsers and download

The Maela® web platform is designed and tested for use with the two latest major versions of the browsers that are integrated with Windows and MacOS, as well as with Google Chrome and Firefox. As the web platform has a responsive interface, it is also compatible with Android and iOS, and is designed and tested for use with the latest versions of the browsers that are supplied with these operating systems (Google Chrome and Safari respectively).

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

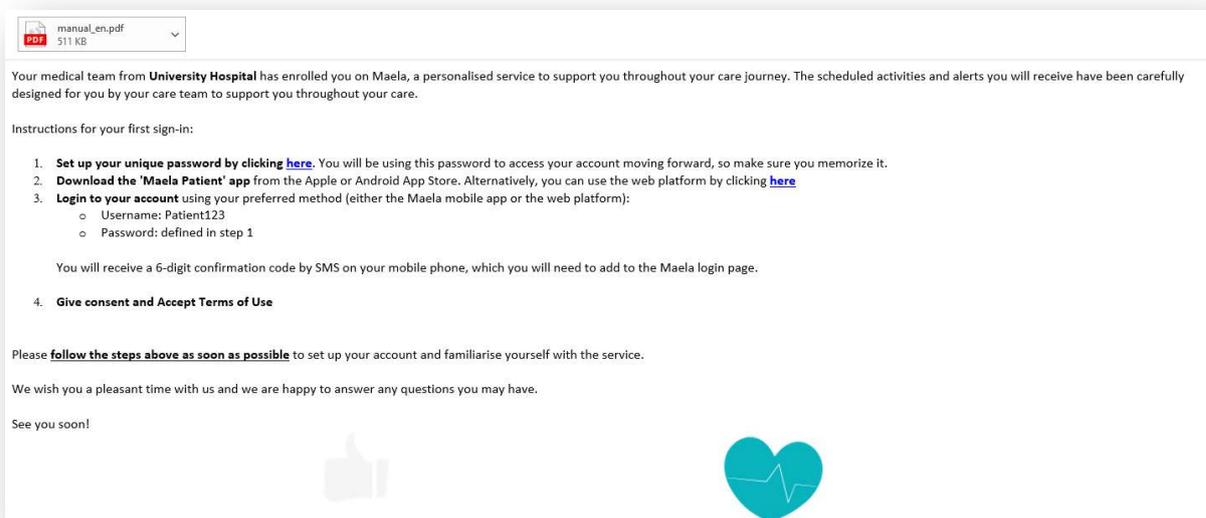
Web platform and mobile application

4. Your first login

The authentication process described in this section may vary depending on how the platform is configured by your healthcare institution.

4.1. Check your email

Once your healthcare team has enrolled you in the program, you will receive an email from the Maela digital platform. The email will contain your username and a link to create your unique password.



Note: The email may take several minutes to arrive. If you have problems finding it in your inbox, please check your junk or spam folders.

4.2. Create a password

Click on the link to create your password. This will take you to a page inviting you to set up your unique password.

Instructions for your first sign-in:

1. Set up your unique password by clicking [here](#). You will be using this password to access your account moving forward, so make sure you memorize it.

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 (!"#\$%&'()*+,-./:;<=>?@[\\]^_`{|}~)

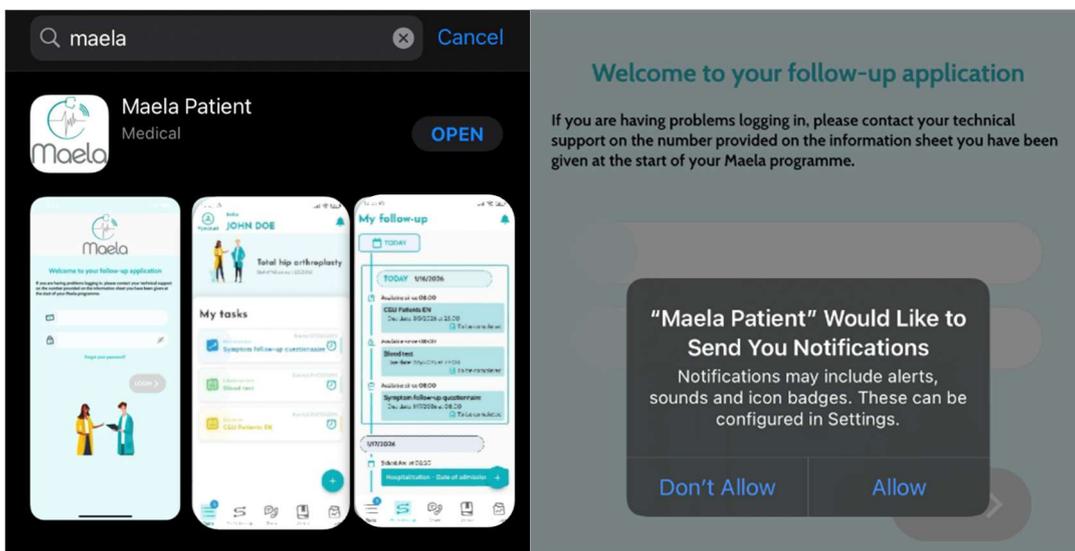
You will use this password to access your account in future, so make sure you memorise it.

Note: This step needs to be done within a few days of receiving the welcome email, or the link will expire. If the link takes you to a webpage that says the link has expired, please go to the login page and click on “Forgotten password” to receive a new link to set your password.

4.3. Download the mobile app or use the web platform

Once you have set your password, you can access your account using your preferred method: the Maela mobile app or the web platform.

Download the “Maela Patient” app from the Apple App Store or Google Play Store (Android). When opening the app for the first time, it is recommended that you allow Maela Patient to send you notifications to ensure that you do not miss any messages or tasks.



The web platform can be accessed in two ways:

- Using the link in the welcome email
- Visiting the Maela website <https://www.maela.fr/en-gb/> and clicking on the “Patient Login” button

Maela - the benchmark solution for remote patient management

With Maela, prepare for your arrival at the hospital and benefit from professional health monitoring.

[Patient login](#)

[Professional login](#)



4.4. Log in to your account

When you log in for the first time and depending on your hospital you might receive a 6-digit one-time password (OTP) by SMS or e-mail. Enter the Maela OTP on the Maela login page and press “Confirm”. Note: The OTP must be entered within 5 minutes. If this time has passed, you can request a new OTP from the app by pressing “Generate new code”.

Note: Every time you access the app from a different device or browser, the OTP will be sent again and you will need to enter it. This is to ensure that your account is kept secure from unauthorised access.

By default, on the mobile application, the preselected localization country appears according to the language and country configured in the phone.

4.5. Give consent and accept the Terms of Use

When you log in for the first time, or if the documents are updated, you will be asked to:

- i. Give consent for Maela patient engagement and remote monitoring
- ii. Review and accept the Terms of Use and Privacy Notice

Once you accept these, you will be fully logged into your account.

5. Homepage

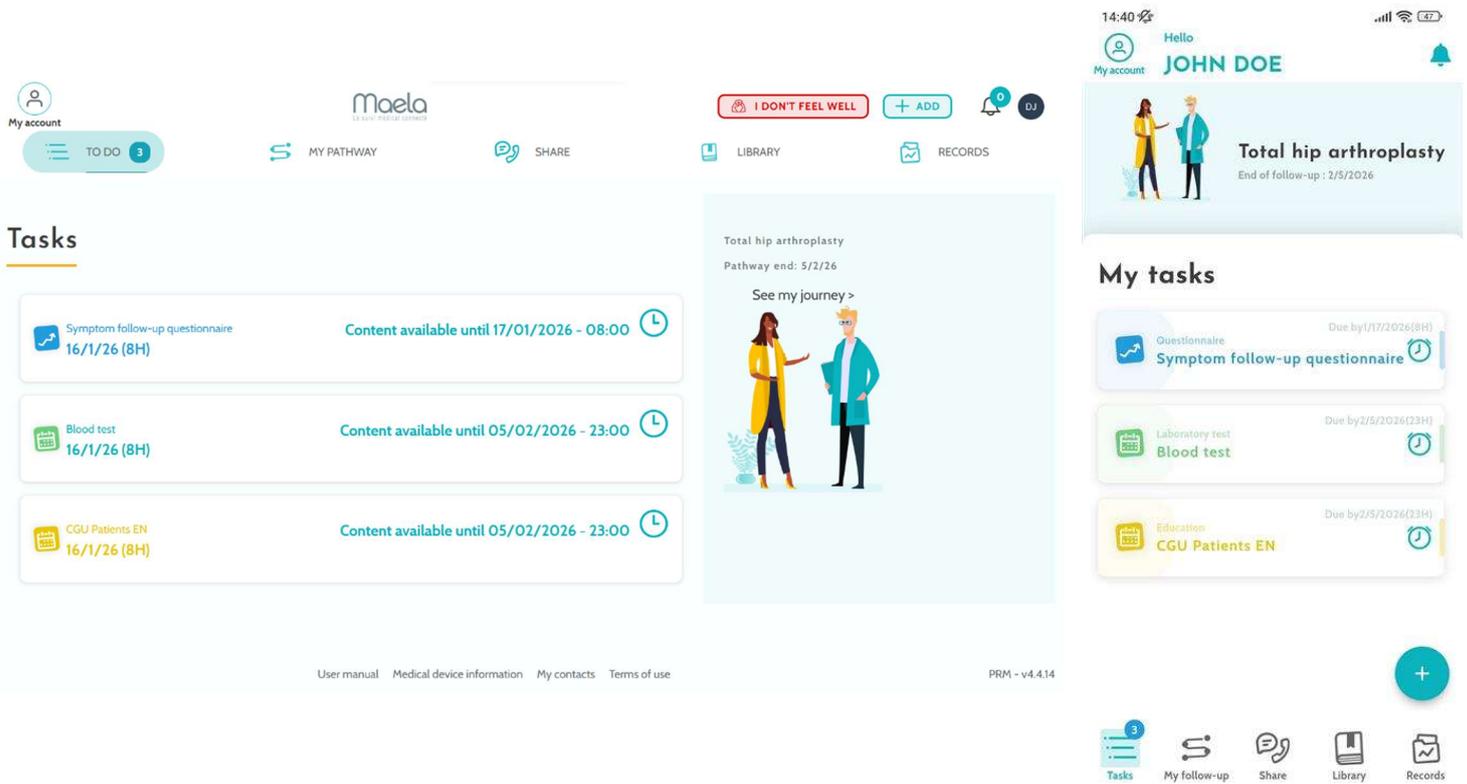
Once your account is set up, you will be redirected to the homepage of your patient portal. The Maela® platform has five main functions: To-do list, Journey, Share, Library and Records.

5.1. To Do

The To-do list contains your tasks for the day as well as your overdue tasks. If you click on a task, you will see the title and description. Click on “**Done**” to complete a task. Click on “**Cancel**” if you just want to close the page without completing the task.

Once a task is completed, the title will appear greyed out and struck through at the end of the to-do list.

There are several types of tasks. Each type of task is displayed with a specific icon and a specific colour: treatment tasks, questionnaires, measurements, educational content, task reminders, alerts and laboratory tests.



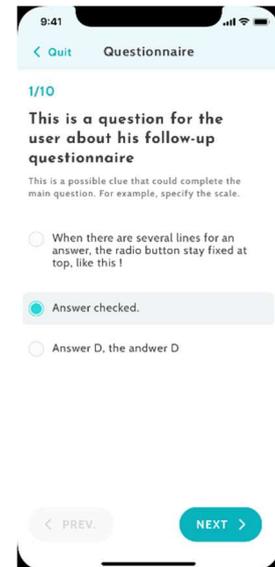
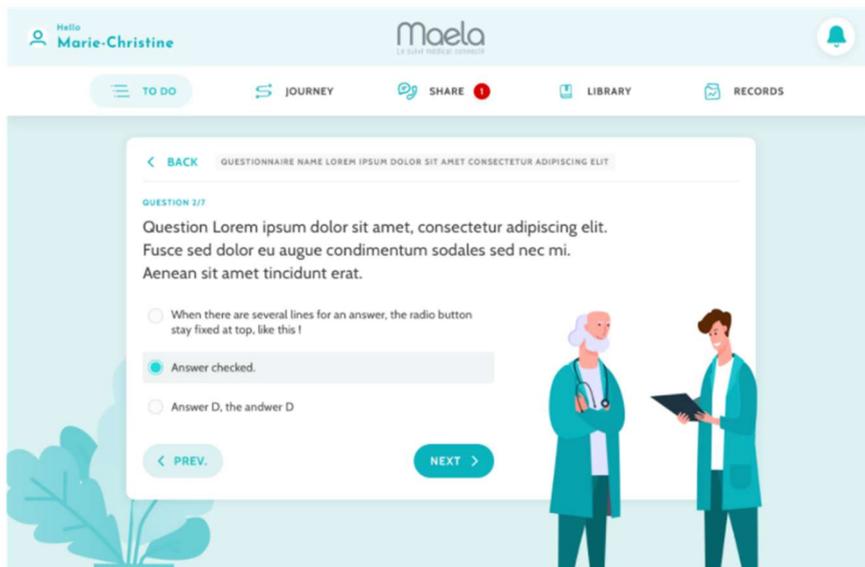
5.1.1. Treatment tasks

This type of task will ask you to confirm whether you have taken specific medication that has been prescribed to you during your pathway.

When you click on the task, you will see the title and description, as well as the date and time of the next intake. Click on the “**Done**” button to confirm the intake.

NB: Tasks can only be carried out during your establishment's opening hours
If your healthcare institution is closed you will not be able to access the platform

5.1.2. Questionnaires



Questionnaires are sets of questions with a choice of answers set by your care team. They are used to follow up on your status and to gather information about your health and experience.

When you click on a questionnaire task, you will see one question per screen. You can move between questions by clicking on “**Previous**” and “**Next**”. If a question is mandatory, it will be outlined in red, and you will not be able to proceed until it is answered. Once you have finished, click on “**Save**” to send the answers.

5.1.3. Measurements

This type of task will ask you to input specific parameters that are relevant to your monitoring (for example your temperature, weight or blood pressure)

Click on the task to fill in the requested value and click on “**Send**” to transfer the data to your care team.

5.1.4. Educational content

Educational content refers to articles that can contain text, images, videos and/or links related to your pathway.

Click on the task to open and navigate the educational content. You can confirm that you have read it by clicking on “**Confirm**” at the bottom. Educational content will always be available in the library in case you wish to revisit it.

5.1.5. Laboratory tests

A laboratory test task will enable you to send the results of laboratory tests requested by your care team. If you have a paper copy of your test results, you will need to digitalise it by scanning the document or taking a picture of it.

Click on the task to open it and then click on “**Add**” to search for documents among the files on your computer/smartphone. The document must **NOT** be over 19 MB and must be in the

following formats only: PDF, images (JPEG, PNG, GIF, TIFF), Microsoft Office (DOC, DOCX, XLS, XLSX, PPT, PPTX), videos (MP4, AVI), webpages (HTML), simple text files (TXT) and RTF.

Enter the date of the scan, the name of the scan and a description if necessary. Remember to tick the “**Notify care team**” box at the bottom of the pop-up. To close the pop-up, slide your finger from the top to the bottom.

5.2. Alerts

An alert is a notification set by your care team to provide you with information. Alerts may also ask you to act on a given situation related to your condition or care pathway. Alerts with a high importance level are shown on the to-do list.

The bell icon on the top-right will have a red notification showing the number of alerts that have not yet been acknowledged. Click on it to access your alerts, which will be sorted by importance:

- **Danger**
- **Warning**
- **Messaging**
- **Information**
- **Non-entry**

By clicking on an alert, you will see title, date and time, a message and the importance level. Read it carefully and click on “**Acknowledge**” once you are done to remove it from the list. Alerts that you have not acknowledged will also appear on your to-do list and timeline.

WARNING: We strongly advise you always to check your alerts and to acknowledge them systematically to avoid any misunderstandings with your care team.

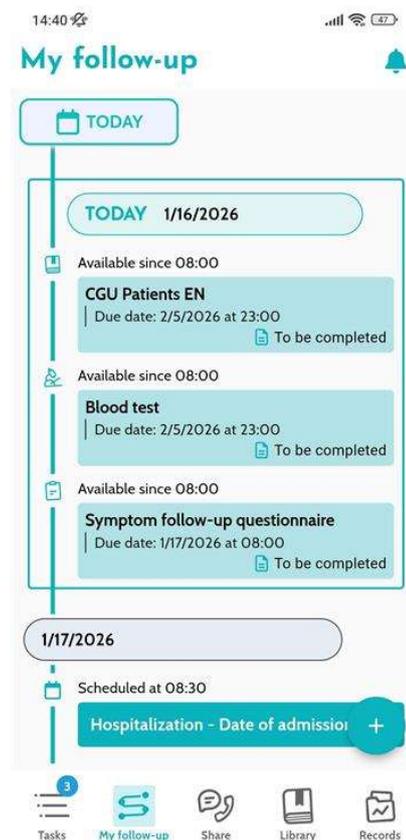
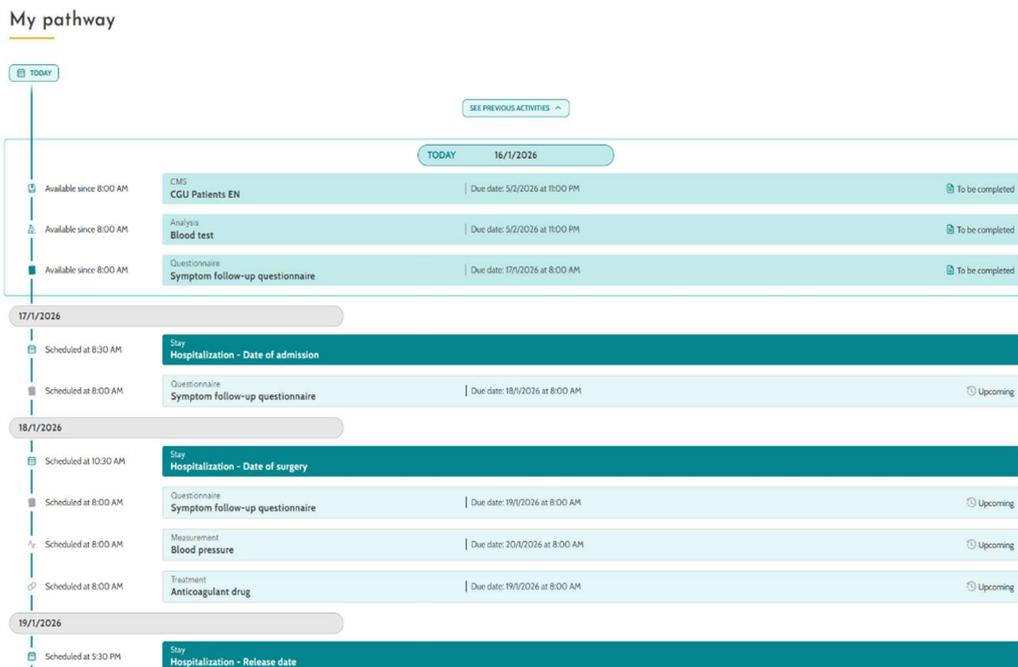
5.3. Quick actions



The "Add" button, located at the top right of the screen, enables you to complete selected content, tasks or submit documents at any time. The list of available contents depends on the configuration made by your institution.

The "I don't feel well" button will display content to complete, show your local emergency number, and send an alert to your care team. However, please note that Maela is not an emergency service.

6. My Pathway



The Pathway tab provides an overview of the key steps in your care journey, with all the relevant dates, completed steps, missing steps and future scheduled items. For each contents, you can see the date since when the contents is available, the due date, type of contents and title.

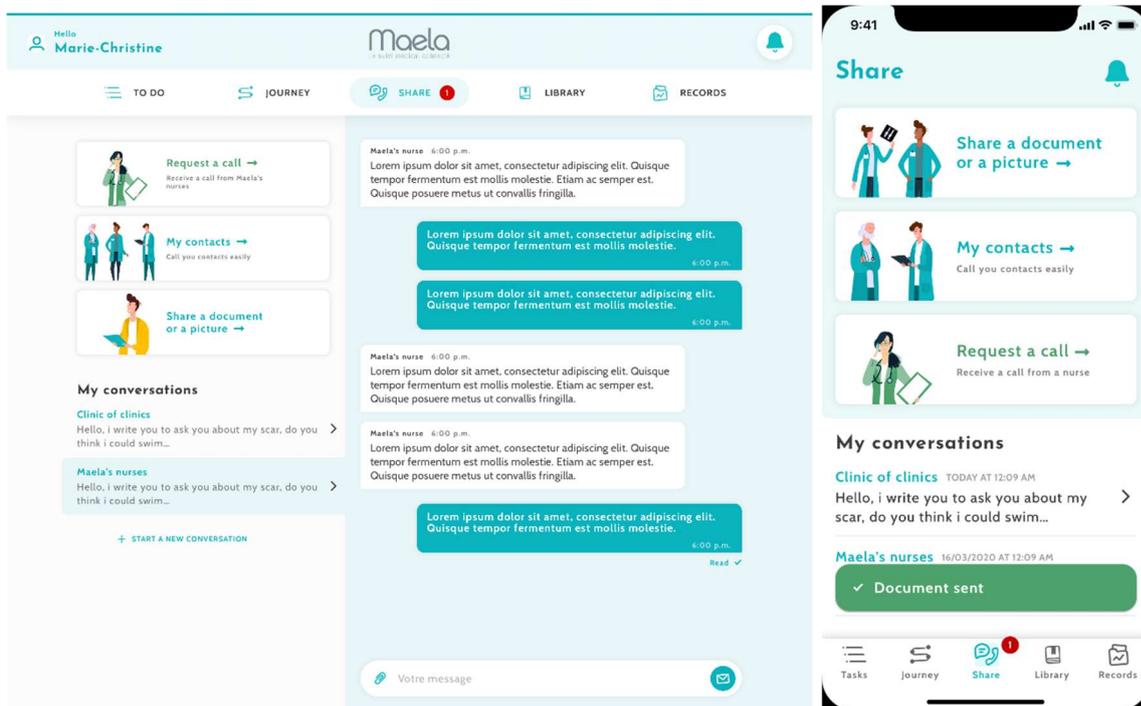
In the web or mobile app, you will see a timeline on the screen showing the date and contents available for today. The timeline contains the different phases of your journey, arranged in chronological order and showing the corresponding dates.

You can only provide answers for overdue content or today's content. All content to be entered at a future date will be greyed out and will not be clickable until the scheduled date has been reached.

Once a task is done, the title of the task will appear greyed out and the status is changed by "completed".

7. Share

The "Share" function allows you to exchange information with your care team using the features detailed below:



7.1. Share a document or a picture

This feature allows you to share pictures and documents with your care team at any time. When you click on “**Send**”, you can attach a document or a picture.

If you are using the mobile app, you can take a picture directly using the camera on your smartphone/tablet. You can retake the shot, and when you are happy with it, you can insert a comment before clicking on “**Send**”.

For security reasons, when a photo is taken from the app, the photo is stored only on the app; it will not be available in your smartphone's library.

Documents and pictures must **NOT** be over a size of 19 MB and must be in the **following formats only**: PDF, images (JPEG, PNG, GIF, TIFF), Microsoft Office (DOC, DOCX, XLS, XLSX, PPT, PPTX), videos (MP4, AVI), webpages (HTML), simple text files (TXT) and RTF.

7.2. My contacts

In this section, you can find relevant contact details provided by your care team. For example, contact details of your healthcare institution, your follow-up medical team and your practitioner.

7.3. Request a call

If this feature is activated by your healthcare institution, you will have the option to request a call from the care team in charge of your follow-up. You can cancel your request at any time by clicking on “**Cancel request**”.

7.4. My conversations

If your healthcare institution has activated it, this feature allows you to exchange written messages, including attachments, securely with the care team in charge of your follow-up.

Click on “**Start a new message**” to open a conversation with your healthcare team. Enter the title and the text, and when you are happy with it, click on “**Send**”. Once this is done, the conversation will immediately appear in the “**My messages**” section, together with the date and time of the last message. When a message is read, a double blue tick will appear next to it.

It is possible to close or archive a discussion. Closing a discussion is irreversible. When discussions are closed or archived, messages can only be visualised.

8. Library

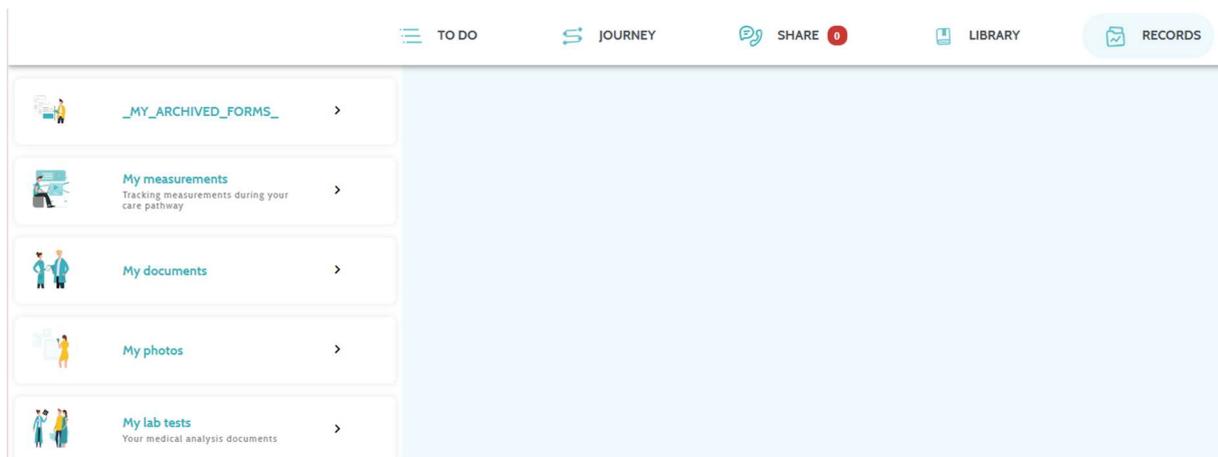
The screenshot shows the Moela application interface. The top navigation bar includes 'Hello Sophie Martin', the Moela logo, and a notification bell with '47'. Below the navigation bar are tabs for 'TO DO', 'JOURNEY', 'SHARE', 'LIBRARY', and 'RECORDS'. The main content area is divided into a sidebar and a main table. The sidebar lists 'My Condition' (7 Document), 'My Pathway' (2 Document), 'My Lifestyle' (5 Document), and 'General Information' (3 Document). The main table displays a list of documents with columns for 'TYPE', 'TITLE', 'STATUS', 'DUE DATE', and 'ACTIONS'. The table is organized into three sections: 'Definition 0/2', 'Causes and risk factors 0/2', and 'Treatment and management 0/3'. The 'My library' inset on the right shows progress indicators for 'My Condition' (0/6 Documents read), 'My Pathway' (0/2 Documents read), 'My Lifestyle' (0/5 Documents read), and 'General Information' (0/1 Documents read). The bottom navigation bar includes icons for 'Tasks', 'Journey', 'Share', 'Library', and 'Records'.

Inside “**Library**”, you will find all the content related to your pathway, divided into several categories and subcategories:

- Educational articles containing text, images, videos and/or links related to your pathway
- Static documents
- Links

9. Records

The “**Records**” tab contains four types of record:



9.1 My archived questionnaires

This menu lets you view your questionnaires and associated alerts.

They are organized by month.

9.2 My measurements

This function contains graphs and tables showing the various scheduled measurements within your pathway.

You can choose what data is displayed on your graph by selecting the past week, the past month or the past three months.

9.3 My lab tests

This feature allows you to view the laboratory test result files that are shared with your care team.

There are two tabs available:

- Sent: laboratory tests sent to your care team during your follow-up
- Received: laboratory test results received from your care team

You can click on the lab test entries if you wish to download and view them.

9.4 My documents and photos

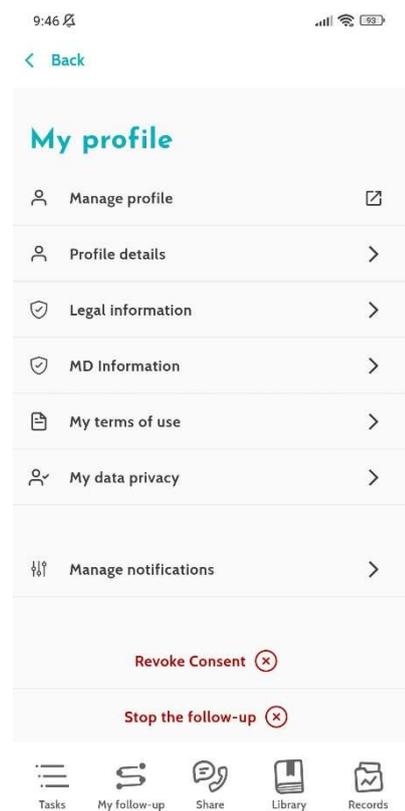
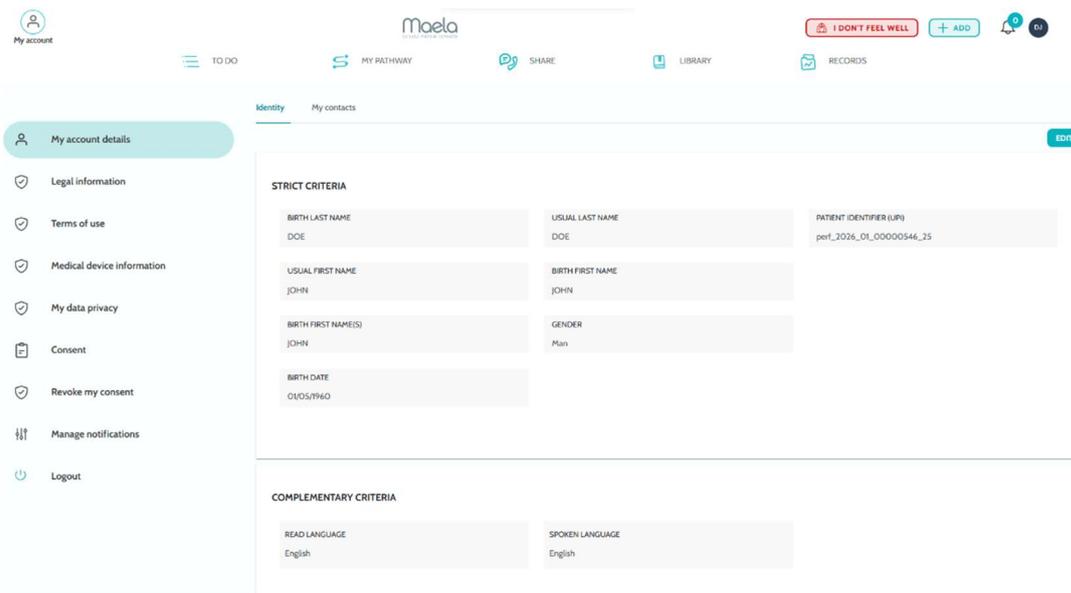
This feature allows you to view the documents and photos shared with your care team.

You can click on the entries if you wish to download and view them.

There are two tabs available:

- Sent: documents and photos sent to your care team during your follow-up
- Received: documents and photos received from your care team

10. My profile



The “**My profile**” menu is

displayed at the top-left side of the homepage when you click on the icon



My account

In this menu, you can access the following sections:

1. Your personal information, as well as the language from “**My account**”. You can edit all this information if necessary. You can also see the list of your useful contacts and add new contacts.
2. The associated legal documents by accessing the sections: “**Legal information**”, “**My terms of use**” and “**My data privacy**”.
3. The “**Manage notifications**” menu, where you can configure how you want to be alerted (email, SMS or push notification from the app) of the following events:
 - Daily reminders: A reminder is sent at **8.25 am** if you have uncompleted tasks on your to-do list.
 - Messages sent by your care team
4. The “**Revoke my consent**” and “**Stop the follow-up**” options will terminate your Maela® follow-up. This option is inside “**Consent**” on the web platform.

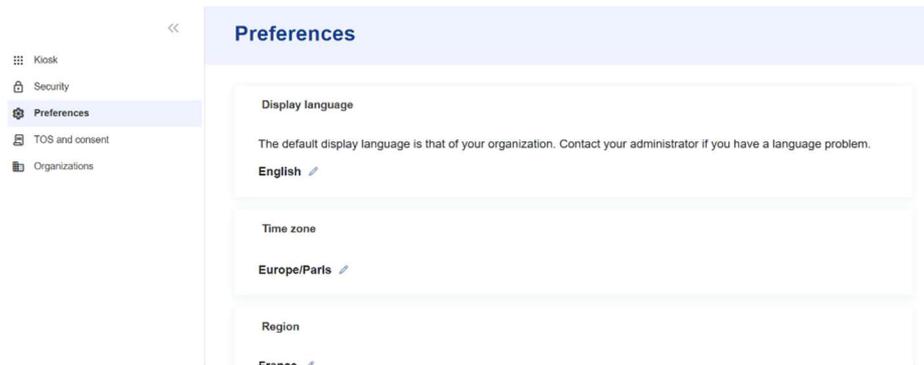
Please note that this action is not recommended. We strongly advise you to contact your care team before stopping your follow-up.

5. The option “Logout” allows you to exit the application.

From mobile app, when you click on “my profile” or from web app when you click on the



“bubble” icon in the top right, you will open a new web window where you can access your language preferences or time zone settings, and set up the two-factor authentication.



11. Installation check

Before launching Maela®, the deployment manager will configure all of the journeys required by the healthcare institution and will then suggest performing a patient test to check the configuration.

Once the healthcare professional has tested several pathways with the test patient, the device will be ready to be assigned to real patients.

12. 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.

Still haven't found the answer to your question? Having technical issues?

**Please contact our technical support team on
+44 (0)1923205184 (United Kingdom) or +353 (0)91750797 (Ireland).**

We wish you all the best for your follow-up and a speedy recovery.

The Maela® team