

CE






## **MOOV CARE<sup>®</sup> Lung**

**Medical device for monitoring lung cancer**

**Version 3.8.8 (API 3.8.8)**

# **User manual for Health professionals**



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All trademarks are the property of their owners.

Date of CE marking: July 2017

**Please read this entire instruction manual carefully before using MOOV CARE<sup>®</sup> Lung, class I medical device, because it contains important information.**

You must always use MOOV CARE<sup>®</sup> Lung software medical device by scrupulously following the information provided in this leaflet.

- Keep this notice. You may need to refer to it later.
- For any technical assistance, you can contact us at any moment via email at [support@moovcare.com](mailto:support@moovcare.com) and we will make sure to respond to you within 24 hours.
- Contact us by telephone on 09 72 57 22 10 (free call) Monday to Friday from 9:00 a.m. to 12:00 p.m. and from 2:00 p.m. to 5:00 p.m. (French time)

The user guide can be requested in paper version, at no additional cost, by simply sending an e-mail to [support@moovcare.com](mailto:support@moovcare.com) with your full address (response within 7 working days).

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## 1. CONCEPT

MOOV CARE<sup>®</sup> Lung is a class I, autonomous and non-invasive medical device which allows the early detection of relapses or complications of lung cancer.

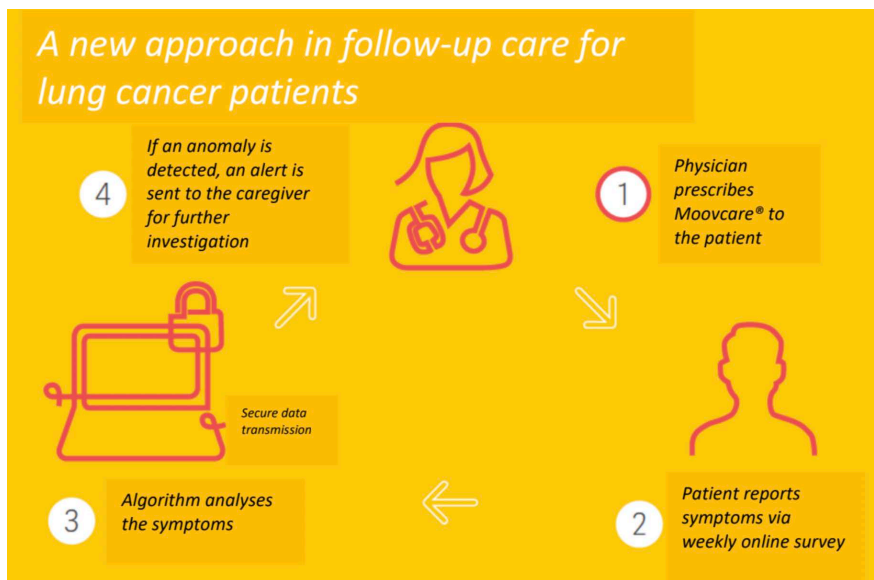
Its operation is based on software containing an algorithm (set of formulas and calculations) analysis of the evolution of clinical symptoms. It allows active, individual and remote monitoring of patients by their doctors during their surveillance for lung cancer.

### In practice :

MOOV CARE<sup>®</sup> Lung sends the patient (via a clickable link on their personal email address) a weekly questionnaire to complete on a computer. Patients do not have access to the history of the data entered.

MOOV CARE<sup>®</sup> Lung analyzes the responses and automatically generates alerts e-mail and/or SMS to the patient's referring specialist physician if a risk of relapse or complication is detected. The alerts issued and the results of the questionnaires will be accessible and analyzed by the referring physician and/or the medical staff of the selected center who will adapt the course of action for the patient, if necessary. A secure personal space is accessible and offers functionalities adapted according to the type of healthcare professional user/care establishment (registration, monitoring of patient progress, etc.).

MOOV CARE<sup>®</sup> Lung is a web application that can be used on the internet and accessible by any browser. It does not require downloading via the stores or any special installation. It can be used on computer, smartphone or tablet.



## 2. THERAPEUTIC INDICATION AND BENEFITS

The indication for MOOV CARE Lung device is the early detection of relapses or complications for patients over 16 years of age with non-progressive lung cancer after the last medical treatment, regardless of the histological type of the tumor.

MOOV CARE Lung requires a medical prescription, only the referring physician or the medical staff of the selected center can register the patient. The latter will receive an explanation of the functionalities of MOOV CARE Lung by the healthcare professional who registered them.

MOOV CARE Lung can be used with maintenance treatment.

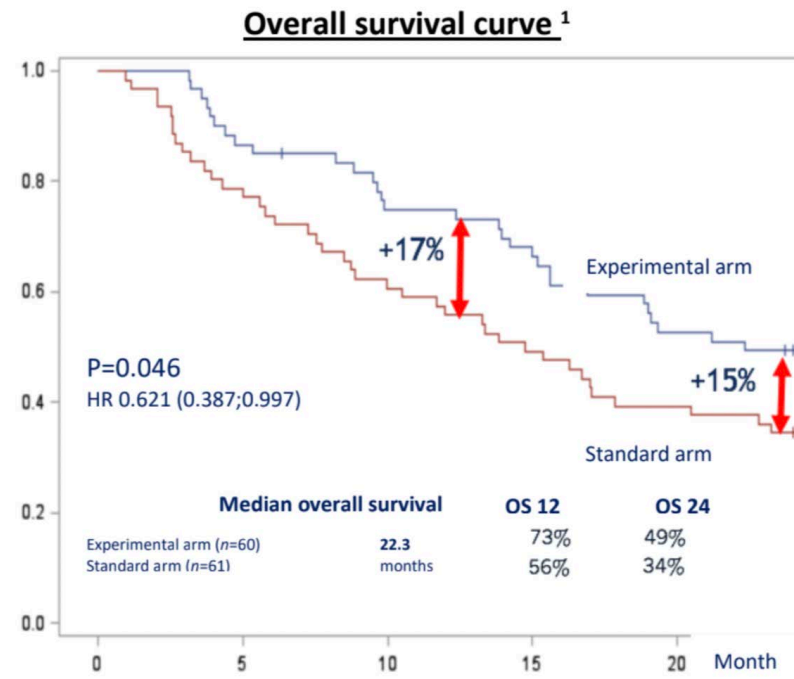
MOOV CARE Lung has been designed to follow patients **minimally symptomatic**. An eligibility test is required. This test makes it possible to calculate a score based on clinical symptoms when the patient is registered by the practitioner in their personal space (score strictly less than 7 **based on 5 clinical symptoms** rated from 0 to 3: fatigue, loss of appetite, cough, shortness of breath, pain).

MOOV CARE<sup>®</sup> Lung has undergone rigorous clinical development.

The Phase III clinical study<sup>1</sup> demonstrated the following benefits compared to conventional monitoring. MOOV CARE<sup>®</sup> Lung:

- has proved the early detection of relapses or complications of lung cancer,
- reduces the risk of death by 3,
- increases the overall survival of patients by 7.6 months, with an improvement in overall survival of 17% at 1 year and 15% at 2 years, significantly HR=0.62; p=0.048,
- allows optimal treatment of patients with recurrence with better access to subsequent treatments,

- allows a reduction in imaging examinations of around 50%/patient/year,
- improves the quality of life of patients at 6 months,
- improves the general condition of patients.



in

<sup>1</sup> Denis F, Basch E, Septans AL, Bennouna J, Urban T, Dueck AC et al. Final overall survival results of a trial comparing web-mediated follow-up via patient-reported outcomes vs. routine surveillance following treatment for lung cancer. *JAMA* 2019;321(3) :306-307

### 3. INSTRUCTIONS FOR USE

#### 3.1. Preliminary instructions for use and description of users

MOOV CARE<sup>®</sup> Lung medical device can only be used on medical prescription and registration by the specialist doctor or the medical staff of the mandated care center, after verification of the patient's state of health.

MOOV CARE<sup>®</sup> Lung does not replace a diagnosis established by a health professional. Patients should notify their physician or healthcare professional in case of:

- appearance of new symptoms, not collected by the questionnaire, and occurring during their monitored by MOOV CARE<sup>®</sup> Lung.

*Please note: The patient has a free text window at the end of their questionnaire. This free text window allows him to indicate any strictly additional medical information or new symptoms (e.g.: skin rashes, diarrhea or others).*

- unable to answer a questionnaire (no internet access, hospitalization, etc.).

**Personalized tracking-** With MOOV CARE<sup>®</sup> Lung, patients have personalized monitoring. The referring doctor maintains a continuous link with his patient. He can, on his secure personal space, follow the responses to the weekly questionnaires. He receives alerts about e-mail and or SMS in the event of an anomaly detected. Their personal space is accessible via their preferred medium (computer, smartphone or tablet).

**No installation required-** MOOV CARE<sup>®</sup> Lung is a web application that does not require installation or any configuration before use. However, it is sometimes necessary to check accessibility by configuring the firewalls of the medium used (computer). Healthcare professionals do not need to download the application from download platforms. However, all users (health professionals and patients) must have an internet connection and a mailbox. mail to use it. MOOV CARE<sup>®</sup> Lung being a web-application, at any time, users navigate to the latest current validated version without necessary updating.

MOOV CARE<sup>®</sup> Lung can be used on internet browsers from the following versions (ensuring SSL compatibility): Firefox 134, Chrome 132, Internet Explorer 11, Safari 17, Edge 132 and provided that the browsers are used on the following operating systems from versions: Android 15; Windows 10/11 ; iOS 18; OSX 14.



**Data security** : The transmission of recorded data is secure. Anonymized data is stored in a secure and audited data center, with ISO 27001 Health Data Hosting certification and meeting the French public health code (Article L1111-8).

**Answers to the weekly questionnaire:**

Patients cannot use MOOV CARE Lung medical device if they have not been registered by their referring doctor or the care staff of the mandated center (cancer nurse, coordinating nurse, advanced practice nurse with delegation of tasks ). A medical collaborator, attached to the referring physician, to the possibility of pre-registering the patient by completing only the administrative part to facilitate patient registration.

**To be able to prescribe MOOV CARE Lung**, the referring doctor must check **beforehand** that there are no contraindications and that the eligibility criteria are respected, in particular the initial state of the patient regarding his symptoms. When registering a patient, a functionality allows the referring doctor to directly calculate an initial symptom score which will also be displayed in their personal space.

During follow-up, patients must answer 12 simple questions, some yes/no, others assessing the severity of symptoms (no problem, minor problem, moderate problem, major problem). Weight and temperature are numerical answers with decimal places. Patients have an optional free comment window. It is **strictly reserved** for providing medical information such as a change in state of health, a new phenomenon, or the appearance of a symptom not taken into account by the questionnaire. **The patient is constantly informed in the questionnaire that in the event of sudden chest pain associated (or not) with dyspnea (shortness of breath), they must immediately contact a doctor or go to the emergency services.**

**Processing alerts:** The physician or prescribing nursing staff at the healthcare center receives an alert in the event of an anomaly detected by MOOV CARE Lung and must, if they deem it necessary, contact their patient to verify the accuracy of the information provided, then discuss their health condition and adapt the behavior to be taken.

If the prescribing physician is unable to manage the alerts received by e-mail, MOOV CARE Lung allows the referring physician to designate specialist doctors or healthcare personnel mandated by the healthcare establishment, who have access to the application in order to take over from time to time in the event of an alert received for a given patient .

Despite the ease of use of MOOV CARE Lung application, the prescribing healthcare staff must provide their patients with initial training and check that they have understood all aspects of the operation, particularly the completion of the weekly questionnaire. When validating the installation of the device and creating an administrator account for a healthcare center, training in the use of MOOV CARE® Lung is dispensed by the manufacturer or its authorized representative with the presentation of the device.

During this training, the following points are covered:

- the concept of remote monitoring of lung cancer patients and key clinical benefits published
- the indication, prescribing conditions, eligibility criteria, contraindications and conditions of use/precautions for use, confidentiality and security of data and warnings;
- the selection of the medical team using MOOV CARE® Lung and identification of different responsibilities
- how MOOV CARE works® Lung and the different types of users:
  - the different access rights and functionalities per user (health professionals and patient)
  - description of the screens that the patient will be able to view,
  - description of the main screens of healthcare professionals and legends (dashboard, historical data table, historical clinical data),
  - demonstration of the registration of health professionals,
  - demonstration of patient registration,
  - demonstration of how to manage an alert and recommendations on what to do in the event of an alert,
  - detailed explanation of the questionnaire and the elements to be indicated to patients, - information and access to technical supports,
  - presentation of the material made available to users.

**MOOV CARE® Lung users :**

Access and functionalities of MOOV CARE® Lung user profiles in a healthcare center can be customized according to different healthcare facility organizations. These rights must be validated and selected by the entire medical team in agreement with Sivan Innovation. All access to patient health data must be reserved for qualified medical personnel and validated by the care center. The pre-configured profiles will be presented in this user manual:

MOOV CARE user profiles® Lung	Definition of user profiles	Creation and editing of accounts by	Data visualization medical patients	Visualisation profiles users
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The administrator (administration function assigned to a care center profile)	The centralizing actor of MOOV CARE® Lung Medical Device in a health center	MOOV CARE® Lung Service	The administrator functionalities will be assigned to the nursing staff selected by the medical team using Moovcare at the healthcare centre.	At least the medical team
referring physician / prescriber	Physician in charge of monitoring cancer patients	The center administrator	Yes	Patients and medical team of the center
Secondary practitioner	Physician(s) appointed as substitute physician to the referring physician for the follow-up of cancer patients	Appointed by the referring physician	Yes	Patients and medical team of the center
Patient	Person being monitored by MOOV CARE® Lung for his bronchial cancer	Referring physician and profiles designated by the medical team	No	No
Close, trusted person or Caregiver at residence	Person designated by the patient who can help them with their follow-up	Referring doctor and profiles designated by the medical team	No	No
<b>Profile to configure (access and functionalities can be personalized according to the specific requests of the care center)</b>				
medical assistant	Persons designated by the administrator and the medical team to help monitor patients who use MOOV CARE® Lung Medical Device	Administrator	No	Care center health professionals
Nurse	Persons designated by the administrator and the medical team to help monitor patients who use MOOV CARE® Lung	Administrator	No	Care center health professionals

You have the possibility, as for patients, to request instructions for previous versions of MOOV CARE® Lung by sending your request to: [contact@moovcare.com](mailto:contact@moovcare.com). You can also consult them on the site <https://www.moovcare.com/fr/instructions/>

## 3.2. Managing a healthcare professional account

### 3.2.1. Initialize your account

To access your MOOV CARE<sup>®</sup> Lung personal space, it is necessary that an account be created for you:

Your account can only be created by the person designated by the medical team within your care center who has administrator rights.

The creation and activation of a “health professional” account is the same regardless of the health professional user profile created by the healthcare center. Only the access rights and functionalities during use will be different. These 2 parameters will be determined by the medical team when creating the center in collaboration with the Sivan Innovation representative.

Creating an account can only be done by the healthcare center administrator.

Find out within your establishment whether MOOV CARE<sup>®</sup> Lung is available or contact Sivan Innovation customer service by sending an email to [contact@sivan-innovation.com](mailto:contact@sivan-innovation.com).

### ○Activation of your account

Once your account is created, you will receive once an e-mail confirming your registration. This e-mail, titled “Moovcare Email Verification”, contains your first and last name. It allows you to authenticate your email address, activate your account and log in to your personal space.

To activate your account, simply follow the following steps:

- Click on the link received by e-mail
- Choose a password (at least 12 characters, letters, numbers and special characters accepted)
- Log in by entering your password and e-mail address
- Read and accept the General Conditions of Use (CGU)
- Enter the security code that you will receive by SMS on your mobile

When creating your password, you will be informed of the strength of the password you choose.

### 3.2.2. Access your account (after activation)

Go directly to the site <https://dashboard.moovcare.com>.

As MOOV CARE is available in several countries, you may need to select your country to help us direct you to the correct login page.

You can enter your address-mail and password and by clicking on “connection” you can access your personal space. If you have trouble signing in, make sure the username, password, and country selected are correct. You can change the country by selecting another country from the drop-down menu. For security reasons, the number of connection attempts is limited to 10 per hour. If you tried to enter your password 10 times without success, this will happen:

- A pop-up window will appear, suggesting contacting support for help.
- An email will be sent to your inbox with the option to reset the password.
- If you do not recognize attempts to change your password, you can, in e-mail received, click on a link to reset the password and enter a code received on your mobile phone.
- Another email will be sent to let you know that your password has been successfully changed.

#### Other connection methods:

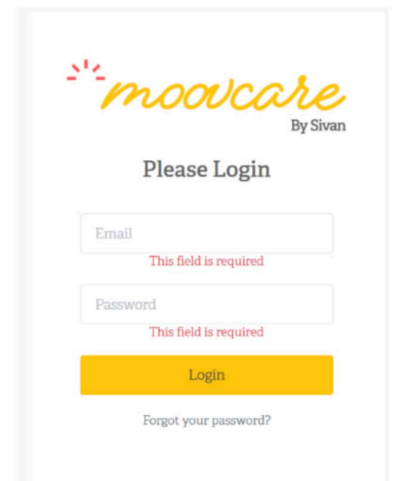
In France, you have the option to connect via “Pro Sante Connect”. This tool is a federation of identity providers using the OpenID standard, allowing you to easily authenticate on all e-health services with the identification method of your choice.

You also have the option of simply providing your RPPS number instead of your email to log in (in France only.)

### 3.2.3. Forgot your password

If you have forgotten your password, please follow the following steps:

1. Click “Forgotten Password” on the connexion page
2. You will then be asked to verify your number phone by entering the code sent to your mobile phone.



3. After verification, you will receive an email in your inbox which will allow you to modify Your password.
4. When you receive this email, click on the password recovery link. You will need to create a new password which must be different from the previous three passwords, then log in again with your credentials and this new password.

**Attention :** If your email address is invalid, you will not receive the email allowing you to change your password. The following red message will then appear on your screen: “Sorry, we could not find this email address”.

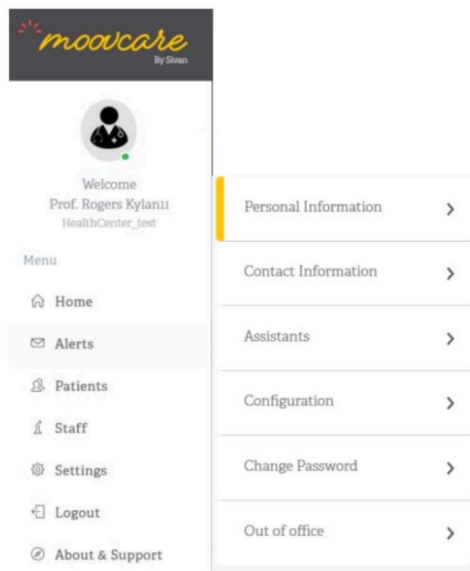
If you do not receive a verification code on your mobile phone, it may mean that it is not updated in the Moovcare® system, please contact your administrator to update it.

We recommend that you set a new password if you believe your account or password has been compromised.

#### 3.2.4. Configure your personal space

The default settings of your MOOV CARE® personal space (language, calendar, units of measurement) are automatically determined by the country entered by your center administrator of care. In your personal space, inside the menu you have the possibility to modify the parameters following:

- Personal data: Title, First name, Last name, Gender
- Contact data: Email address, Mobile number, Landline, how would you like to receive alerts (about E-mail. You can add the SMS option if you wish) Assistant: Named the assistant (only for doctor profile)
- Manage my absences
- Configuration of tracking parameters: Language, Temperature unit, Weight unit
- Change your password



**Note: The format of the telephone numbers to use corresponds to the international format and includes the country code. The default code is France (+33).**

If you want to change your mobile number, make sure the "SMS" button is checked. This will allow the number to be changed. You can then uncheck "SMS". If you have a problem saving your changes, make sure all fields mandatory have been up to date.

### 3.2.5. Login session expired

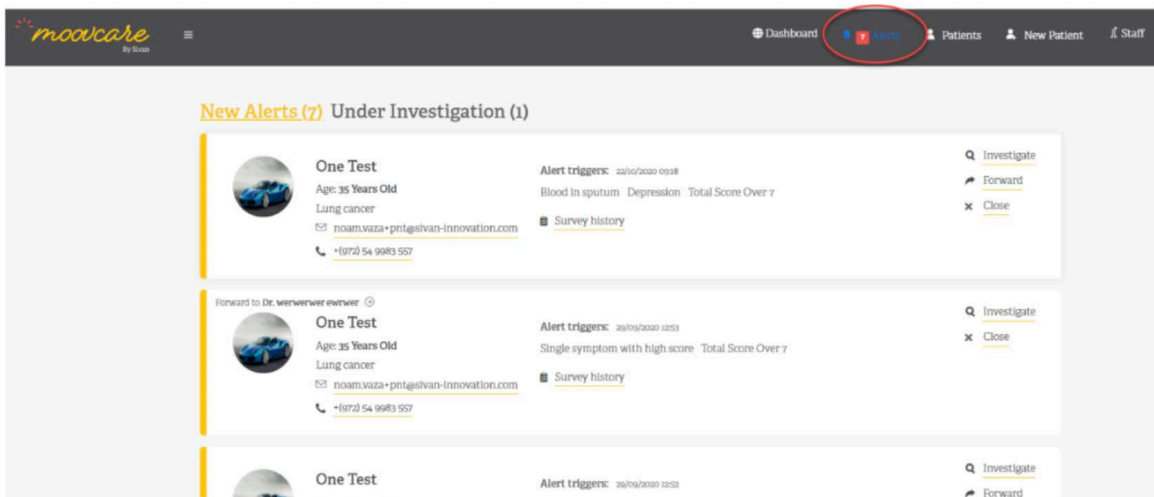
For data quality and privacy purposes, the login session timeout dashboard is 30 minutes after session inactivity. 2 minutes before disconnection automatically, a window will appear asking you if you wish to continue this session. If there is no response, you will be automatically disconnected.

The automatic message is "Your session will expire soon, would you like to continue your navigation? If not, you will be automatically disconnected and you will have to reconnect to your account." Then use the button: "I would like to continue using my session".

## 3.3. Patient's referring practitioner and qualified and selected healthcare staff (with access rights)

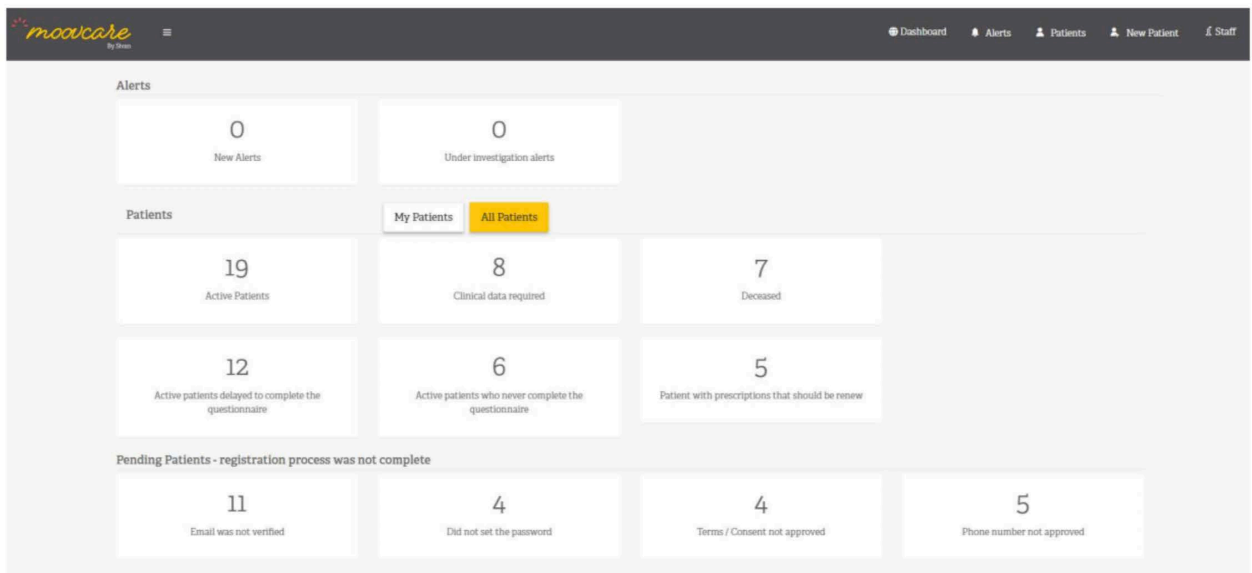
### 3.3.1. Main screens of your personal space and functionalities

- **Screen A:** Alerts:



*This screen displays new and searched alerts. At the top right, the user has access to different interfaces. In the menu at the top left, he can access his personal settings and log out.*

● **Screen B: Dashboard**



*This new screen will summarize important data and help you better manage patients and alerts. You can see there:*

- *the number of new alerts in the last 24 hours*
- *alerts processed*
- *the number of active patients*
- *patients waiting for an eligibility test*
- *deceased patients*
- *active patients late in completing the weekly questionnaire*



- active patients who have never completed the weekly questionnaire
- patients whose prescription must be renewed
- patients who did not complete the registration process, and the stage at which they stopped.

By selecting one of the buttons, a list of patients filtered based on the selection is displayed.

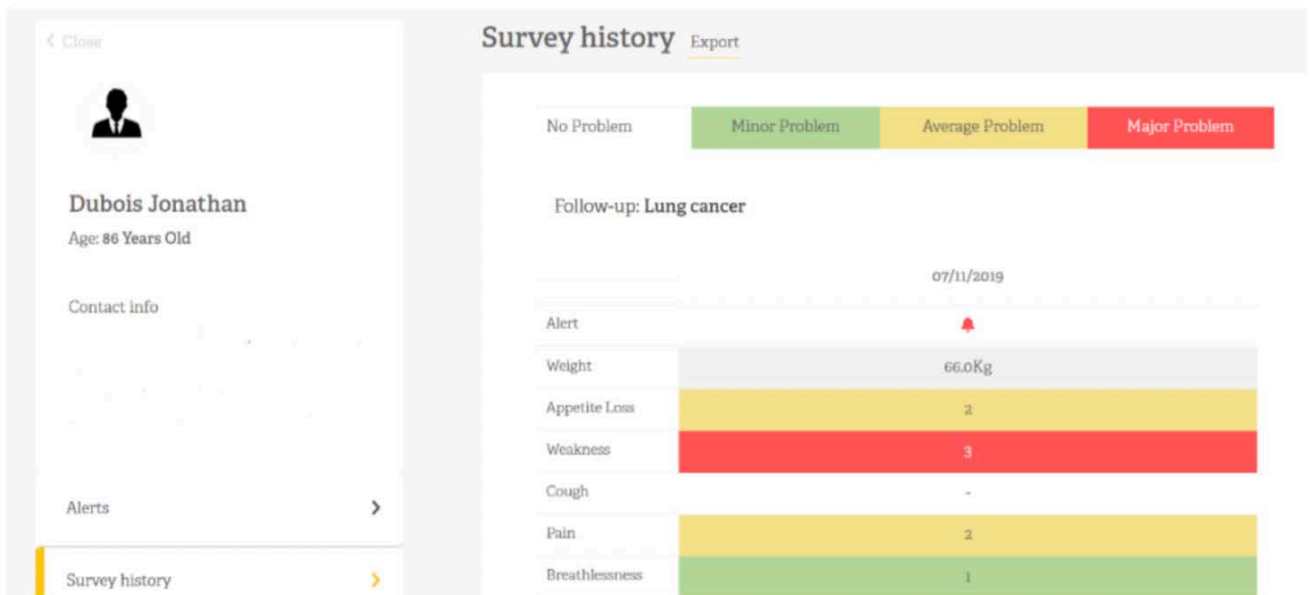
You can view all patients in your hospital or just your patients. Clicking on “Eligibility Test Required” will display the list of patients awaiting eligibility screening with a link to complete eligibility.

- **Screen C:** Screen allowing you to view a patient’s file:

Aucun problème	Problème mineur				Problème modéré				Problème majeur			
	22/06/2022	22/06/2022	22/06/2022	22/06/2022	23/06/2022	01/07/2022	01/07/2022	01/07/2022	01/07/2022	01/07/2022	01/07/2022	27/12/2022
Alerte												
Poids	80.0Kg	80.0Kg	80.0Kg	80.0Kg	80.0Kg	77.0Kg	79.0Kg	81.0Kg	78.0Kg	78.0Kg	77.0Kg	80.0Kg
Appétit	-	-	-	1	2	1	1	1	-	-	-	-
Faiblesse	-	-	-	2	2	3	1	1	-	-	1	-
Toux	-	-	-	2	2	2	1	1	2	1	-	-
Douleur	-	-	-	2	2	1	1	1	-	2	-	3
Essoufflement	-	-	-	1	2	3	1	1	1	-	1	-
Déprime	-	-	-	3	2	-	2	2	-	2	-	-
Fièvre	-	-	-	-	-	-	-	-	-	39.0°C	-	-
Oedème visage	Non	Non	Non	Oui	Oui	Oui	Oui	Non	Non	Non	Non	Non
Nodule	Non	Non	Non	Oui	Non	Non	Non	Non	Oui	Non	Non	Non
Dysphonie	Non	Non	Non	Oui	Non	Non	Non	Oui	Oui	Oui	Non	Non
Hémoptysie	Non	Non	Non	Oui	Non	Non	Non	Non	Non	Non	Non	Non
Commentaire	-	-	-	-	-	-	-	-	-	-	-	-

Each patient has a personal file in which the designated care staff can have access to the patient's clinical and personal data, as well as to the actions available to manage the patient's follow-up if the rights have been assigned to them.

- **Screen D:** Screen allowing you to view the history of responses to a patient's questionnaire



- **Screen E** :Space present on all pages of your personal space allowing access in particular to technical supports/documentations.

À Propos	Über	información	About	Informazioni
France	Deutschland	España	USA	Italia
Moovcare® Poumon : dispositif médical de classe I	Moovcare® Lunge: Medizinprodukt der Klasse 1	Moovcare® pulmón: producto sanitario de clase I	Moovcare® Lung: Decision support tool compliant with the FDA classification for Mobile Medical Devices section VB.	Moovcare® Polmone: Strumento di supporto decisionale conforme alla classificazione FDA per la sezione VB dei Dispositivi Medici Mobili.
Web-application de télésurveillance personnalisée des patients atteints d'un cancer du poumon	Web-Applikation für das personalisierte Telemonitoring von Lungenkrebspatienten	Aplicación web para la telemonitorización personalizada de pacientes con cáncer de pulmón	Web-application for personalized telemonitoring of lung cancer patient	Applicazione web per il telemonitoraggio personalizzato dei pazienti affetti da cancro ai polmoni.
<a href="#">Guide d'utilisation des patients</a>	<a href="#">Patienten Benutzerhandbuch</a>	<a href="#">Guía de usuario del paciente</a>	<a href="#">Patients user guide</a>	<a href="#">Manuale d'uso per pazienti</a>
<a href="#">Guide d'utilisation des médecins</a>	<a href="#">Benutzerhandbuch für Ärzte</a>	<a href="#">Guía del usuario para médicos</a>	<a href="#">Physicians user guide</a>	<a href="#">Manuale d'uso per Professionisti sanitari</a>
<a href="#">Conditions Générales d'Utilisation</a>	<a href="#">Nutzungsbedingungen</a>	<a href="#">Términos de servicio</a>	<a href="#">Terms of service</a>	<a href="#">Termini di servizio</a>
<a href="#">Mentions légales</a>	<a href="#">Impressum</a>	<a href="#">Menciones legales</a>	<a href="#">Legal Mentions</a>	<a href="#">Menzioni legali</a>
<a href="#">Politique de confidentialité</a>	<a href="#">Datenschutzbestimmungen</a>	<a href="#">Política de privacidad</a>	<a href="#">Privacy policy</a>	<a href="#">Politica sulla privacy</a>

### 3.3.2. Patient profile management

#### 3.3.2.1. Register a new patient and obtain their consent

In the main menu, you can add a patient by clicking on “New Patient”.

You will be asked to enter certain administrative information in order to be able to register your patient in the MOOV CARE® system. In some healthcare organizations, the file can be completed by a medical assistant or caregiver. Adding the following patient data to the system is a minimum requirement.

- First name(s) (at birth)
- Last name (at birth)
- First name at birth
- Date of birth
- Sex
- Place of birth
- Place of birth - INSEE code
- Mail address
- Patient's cell phone number
- Referring physician - The referring physician is the one who will receive alerts if an anomaly is detected. detected

The other fields are optional:

- First name used
- Name used
- Patient landline number
- Patient Social Security Number
- Internal patient number
- Secondary Referring Physicians – Secondary referring physicians will receive the alerts if the referring physician has not responded to the alert within 24 hours. All secondary doctors on the list will be alerted.

When assigning a doctor, their status may appear as absent in the application. If this is the case, please ensure that this doctor is available to see this new patient. This will have no impact on the new patient registration.

*Patient consent to receive assistance* : obtain authorization from the patient so that a representative can contact him/her to offer technical and professional assistance. This will help the patient to complete their registration easily and quickly. It is important to clarify that we will not use the patient's data for any other purpose, and that if the patient wishes to withdraw consent, he or she will be able to do so on their account after registration, or by contacting us by e-mail or telephone. Once the patient has given consent, be sure to check the box.

**Please note: the email entered will be the email on which the patient will receive their link to activate**

their profile and on which they will receive their weekly questionnaire each week. We advise the patient to use a Gmail email account to receive MOOV CARE® emails and notifications®.

**Please note: The mobile phone number entered here will be the number on which the patient will receive the SMS authentication code necessary to activate their account.**

### **Pathology and eligibility check**

Only the specialist physician or healthcare personnel designated by the medical team can carry out this step. In order to be able to prescribe MOOV CARE® to a patient, you must select the “Lung” pathology.

### **Eligibility Check**

**Ask the patient these 5 questions** assessing the severity of the following 5 symptoms: loss of appetite, asthenia (feeling of weakness), pain, cough, shortness of breath (dyspnea). You will ask him to answer according to the 4 answer choices: “no problem” (score=0), “minor problem” (score=1), “moderate problem” (score=2), “major problem” (score=3 ).

Based on this questionnaire, the score calculation is automatic. If the patient presents a score below a defined threshold (<7), you can create its file. If the score obtained is too high and the patient is too symptomatic, the patient cannot be followed by MOOV CARE® Lung and you will not be able to validate the registration. The score will then be recorded to remind you of the rule.

Note: the total score is a sum of the scores for each symptom. The results of the initial eligibility test will also appear in the patient file in the clinical data tab.

Please note: if a patient is not eligible for MOOV CARE® Lung because its score is too high, its administrative file will be kept in the list of patients and its status marked as “**Not eligible.**” You will be able to return to his administrative file later if his condition stabilizes in order to have him take the eligibility questionnaire again by clicking in the patient file “**Perform a new eligibility test**”.

**When you have finished entering the required information, click “Create Patient” to finalize the registration.**

**The patient will receive an email containing a link to activate their profile.**

*Recommendation: if the patient has the possibility of consulting their email box during registration, it is advisable to check with them that they have received their activation email.*

*For optimal effectiveness, it is essential to properly train the patient in monitoring by MOOV CARE<sup>®</sup> Lung by reminding him of the importance of completing his questionnaires accurately once a week and by explaining each item in the questionnaire.*

*Don't forget to recall the information for weight gain (always use the same scale, in the morning, on an empty stomach, without clothes) and temperature measurement (use the same type of thermometer and indicate the rectal temperature or temperature equivalent if an infrared thermometer is used). We also invite you to warn the patient that in the event of sudden pain associated with dyspnea (shortness of breath) or not, it is important that the patient goes to a doctor or to the emergency room.*

*Once the patient activates his account, in your interface it will change to “active” status. He will therefore be able to receive his weekly questionnaires. Otherwise, their status will be notified “Pending”, they will not receive a questionnaire. (To help a patient activate their account, we invite you to consult chapter 3.3.4.4. Case of non-active patients).*

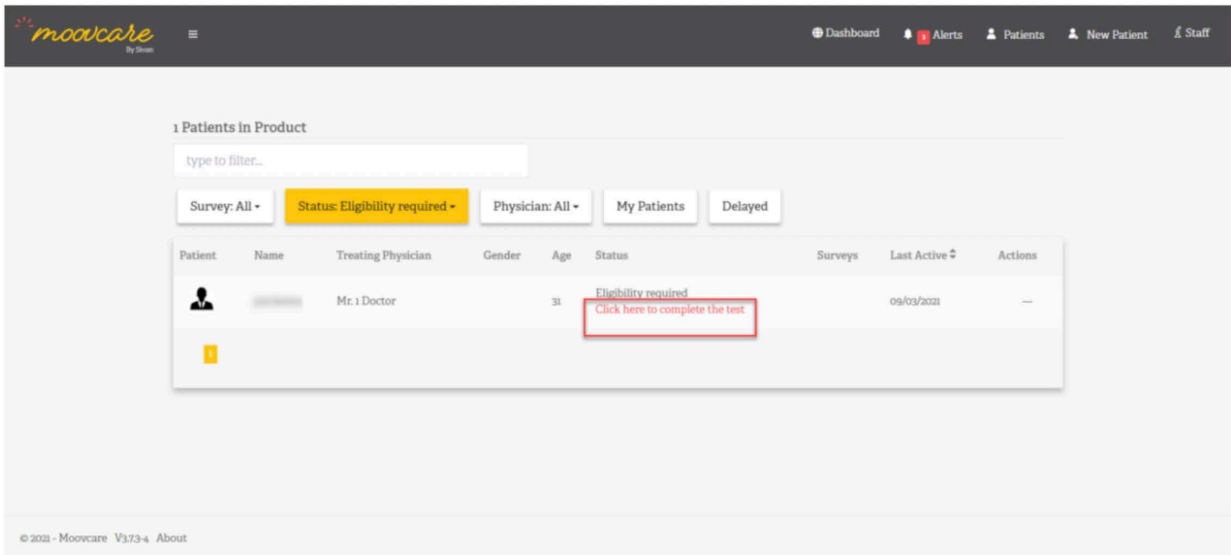
## **Updating Patient Eligibility**

Step 1 :

Patients who have not passed the eligibility test will have the status “Eligibility required”.

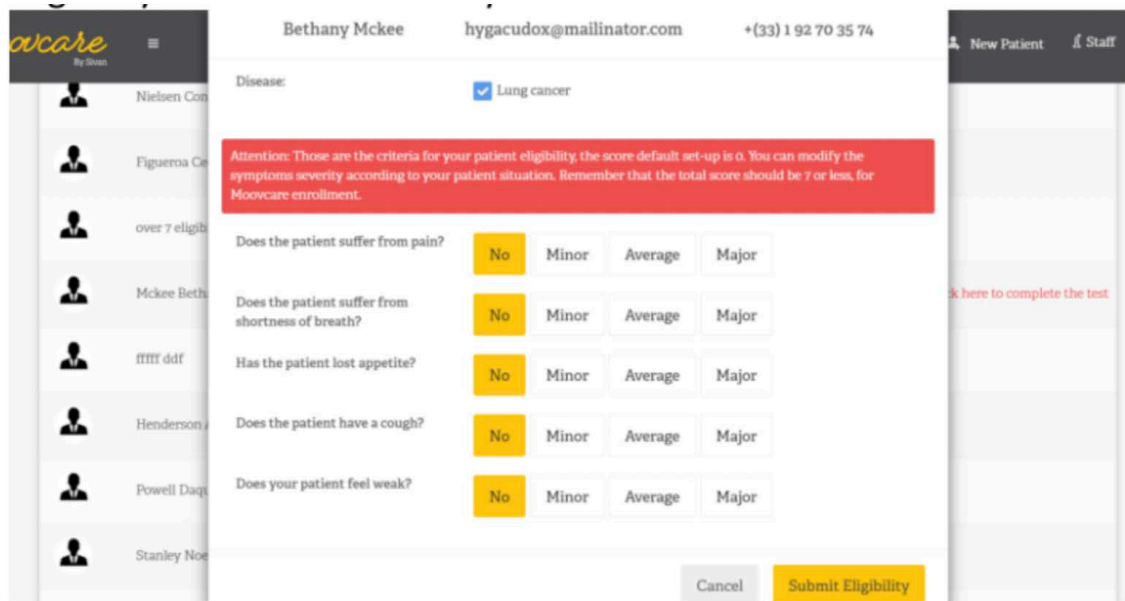
Eligibility can be entered by selecting patients from the main menu and filtering for “Eligibility Required” status.

Eligibility can be determined by clicking on the “Take Test” link.



2nd step :

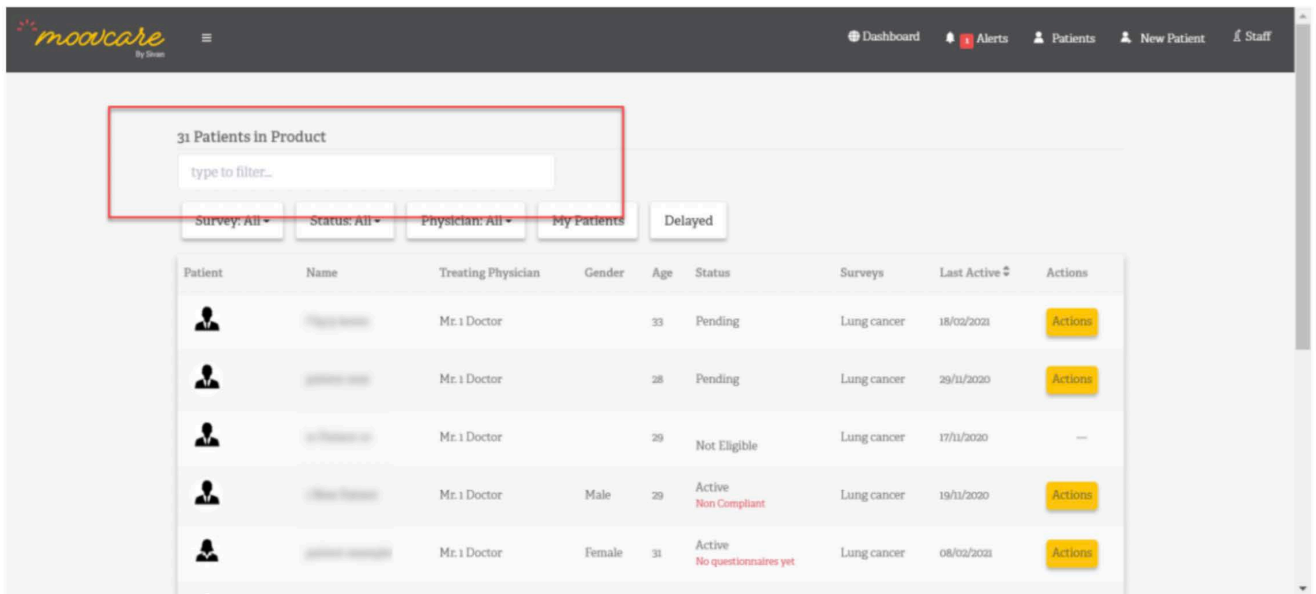
Eligibility can be determined and submitted easily.



### Change a patient's eligibility

If the patient's eligibility has changed, it can be updated as follows:

Step 1 :

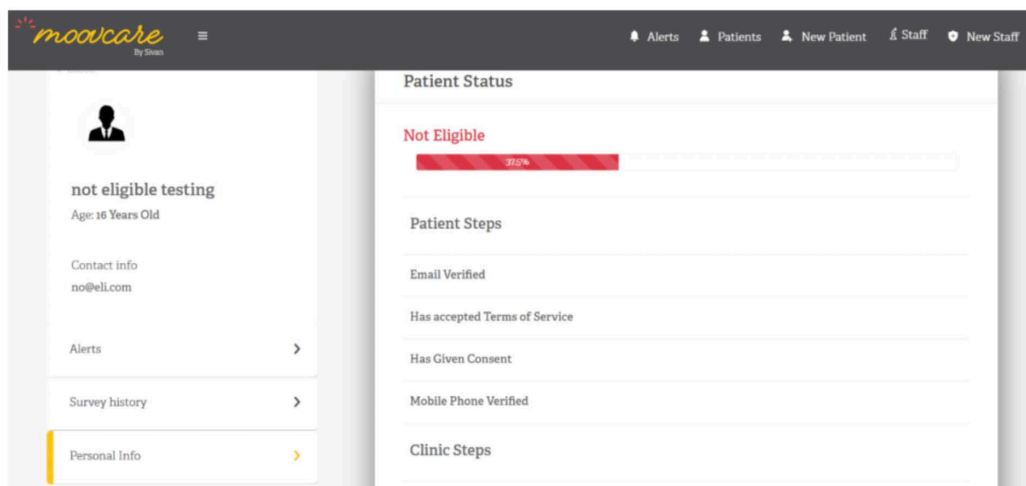


Click on “Patients” and search for the patient by name using the search bar.

Step 2: Select the patient by clicking on their name

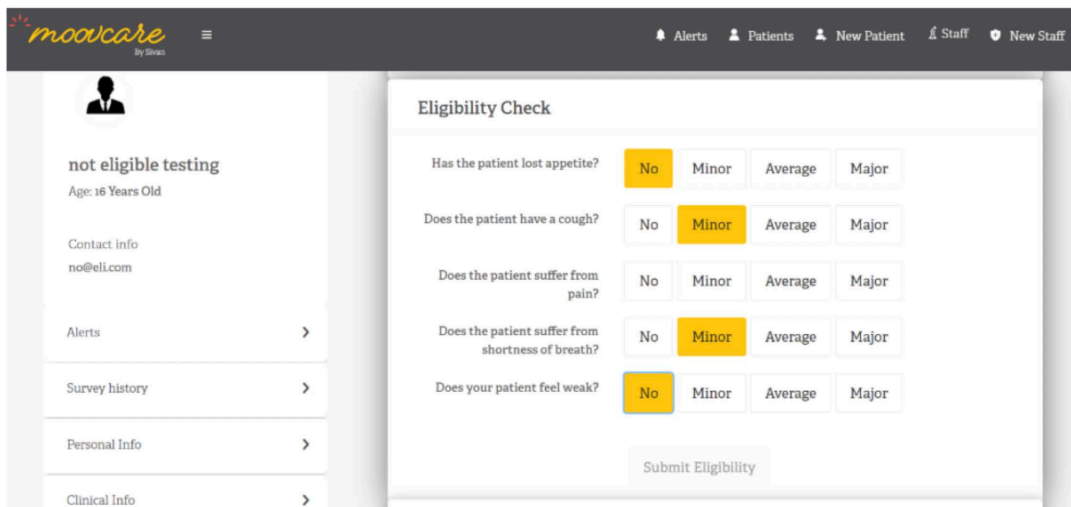
Then click on the “Personal data” menu (menu on the left)

You can see that the patient's status is: “Not eligible” (in red).



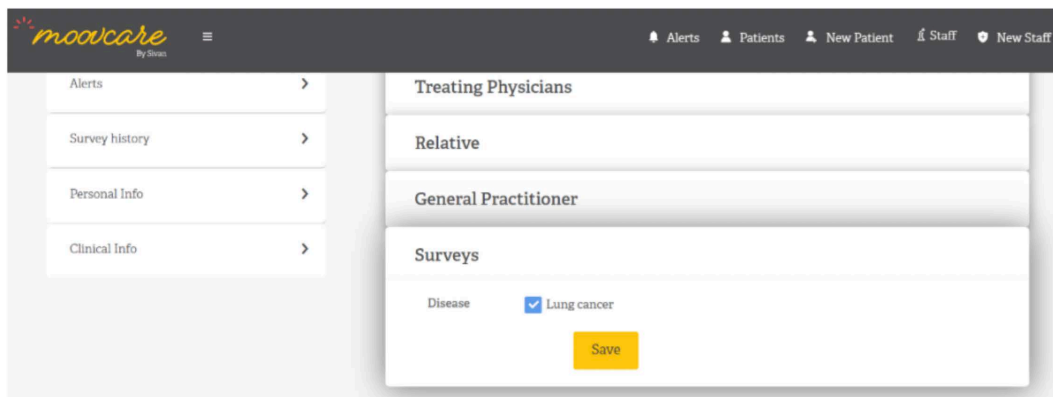
Step 3: Click on “Eligibility Check” (link on the right side) Then fill out the eligibility

questionnaire and click on “Create patient”.



Step 4: Click on Questionnaire (at the bottom of the same page)

Check the patient's pathology, then click Save.



Step 5: Verify that the patient's registration is complete:

Return to the top of the same page, then click "Stop tracking":

- Check that the patient is indeed waiting



- Check that the patient's prescription has been entered correctly with the green check mark

### 3.3.2.2. Edit a patient's administrative information

In your personal space, by clicking on the patient's first or last name you can access their file. You can modify the information under the heading “Personal information” by clicking on the corresponding tab. In this tab you can edit profile data and contact details by clicking “Edit”. You also have the possibility of changing the referring doctor and the secondary referring doctor in the follow-up of care with MOOV CARE®.

**Be sure to click the “Save” button after making the change to ensure the change is effective.**

*Please note: Changes to the mobile number will result in a change in the patient's monitoring status. The tracking status will change from “Active” has “On hold”, as a security measure, while waiting for the patient to reactivate their account. In fact, he will no longer receive a questionnaire during this period and he will receive an SMS asking him to authenticate his contact details.*

#### Email modification case:

*If the patient wants to change their email address, go to the patient's file, click "Edit" and change the email address by entering the new information and clicking the "Save" button. He will receive a new email with a link. They will have to click on the link to confirm their new email address. Until the new email is validated, the patient can continue to log in using the old email address. Once validated, only the new email address can be used for login.*

#### Case of modification of the mobile number:

*If the patient wants to change their cell phone number, go to their file, click on the "Edit" button and change the cell phone number by entering the new information and clicking on the "Edit" function and don't forget to click on “Save”. The next time they log in to their environment with their email address and password, the patient will receive an SMS to their new mobile number after login. This SMS contains a 6-digit security code that the patient must enter in MOOV CARE® interface. Following validation, his account will be reactivated and will change to “Active” status again in your environment. He will be able to receive his questionnaire again every week.*

**Please note: The patient himself has the possibility of changing his email or mobile phone number from his own interface.**

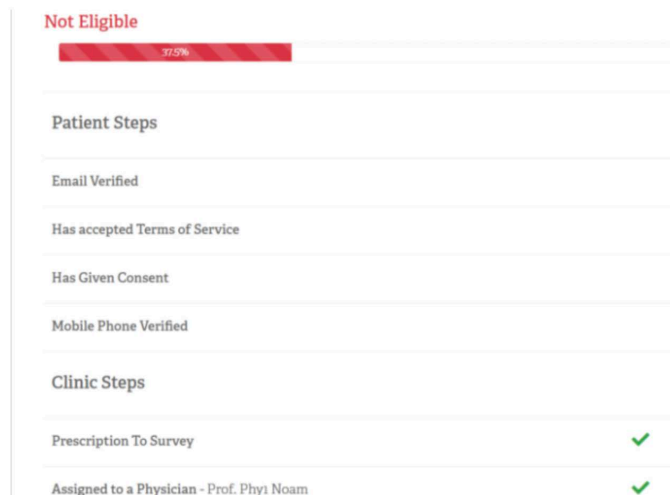
### 3.3.2.3 What to do if the patient's status is "pending" at registration?

At registration, if the patient's status remains pending even though the patient is eligible, it is because the patient has not completed one of the steps.

This can occur when:

- He did not confirm his email address; It is then advisable to look in your SPAMs.
- The patient forgot his password. If this happens during the registration process, it needs you to reset its password.

You can also go to the patient file in Moovcare® and check at which stage the patient is stuck:



To resolve these issues:

click on **"Personal data / Actions"**

You will then be able to:

- "Send verification email" to start the registration process again;
- Or "Send reset email password" if the patient forgot their password. There will then be no request to enter a code sent by SMS.

In this version, the patient can advance in their registration process without entering the prescription date or uploading a photo of their prescription. However, this will eventually become a mandatory step. You also have the possibility of doing it directly from a professional interface to facilitate patient registration.

**If the patient is waiting at another stage, we invite you to contact them to discuss Moovcare® follow-up with them** : it is either a problem with the entry of personal data, or consent not given or the conditions of use not accepted.

#### **3.3.2.4. Stop tracking by MOOV CARE® Lung for a patient**

You have the option to stop monitoring MOOV CARE® system for a patient according to different reasons.

To do this, go to the patient file in the **"Personal data"** and the sub tab **"Actions"**.

Under the title **Patient Status** you have the possibility to stop monitoring the patient by selecting one of the reasons offered. If the patient:

- is hospitalized
- died
- must have their account canceled

**Simply click on the reason and validate your choice.**

The status of the patient will therefore have a **"Disabled"** following your validation.

Please note: In their environment, the patient has the possibility of withdrawing their consent. In its menu, by clicking on **"Settings"** the patient can withdraw their consent in order to no longer be followed by MOOV CARE®.

In your user space its status will therefore be **"Disabled"**.

If the patient wishes to be followed again by MOOV CARE®, he can reactivate his account by entering his email address and his last password on his personal access <https://patient.moovcare.com>. He will have to give his consent again and will be able to complete his weekly questionnaires.

If the patient confirms that he no longer wishes to be followed by Moovcare®, we advise you to establish a new type of monitoring of his pathology. You will then need to archive the data for this patient, so that the latter is no longer visible on the dashboards.

### **To archive patient data:**

Go to the tab “**Personal data**» go to «**actions** ».

If the patient has not withdrawn their consent themselves, you can stop the follow-up by choosing one of the options offered. After 30 days, you can then return to “**Personal data**», « **actions** » and click on the button «**archive**» to archive this patient's data.

If the patient has withdrawn their consent on their own, they no longer receive an email but their account is still present in the patient list. You should then do the following, as soon as you have confirmation of the withdrawal of consent:

In “**Personal data**», « **actions** », « **enable tracking**» then cancel the patient account. You will then be able to archive this patient's data after 30 days.

Note: If a patient withdrew consent before archiving, you will not be able to archive the patient. Please contact us at support@moovcare.com to complete the process. To proceed with the patient's right to erasure, you must contact your processing subcontractors (SIVAN Innovation and ATE), the erasure of patient data is done with the healthcare provider.

### **3.3.2.5. Re-activate monitoring by MOOV CARE<sup>®</sup> Lung for a patient**

You can easily reactivate a patient by going to their file. In the tab “**Actions**” you can click on “**Activate account**” in order to follow the patient again. Its status will be “**On hold**”, while the patient activates their account.

### **3.3.2.6 Case of an ineligible patient**

If a patient appears to be ineligible for MOOV CARE<sup>®</sup> (eligibility score  $\geq 7$ ), their form will be recorded in the system but the patient will not be followed up (no questionnaire sent). Their administrative information will be kept until they are eligible for follow-up. If the patient's symptoms improve, you have the option of administering the eligibility questionnaire again by selecting their form from your patient list.

### 3.3.3. Questionnaire management

Patients will receive a reminder by email each week of their questionnaire to complete as part of their follow-up. The questionnaire consists of a minimum of 12 questions to be completed and an optional free field:

-6 questions assess the severity of a symptom and require responding with “no problem”, “minor problem”, “moderate problem”, “major problem”.

*This symptom severity scale is a universal scale used by learned societies. This scale has also been validated during clinical studies of MOOV CARE®. Its aim is to help the patient “self-care”-evaluate” during the questionnaire. It is necessary to educate the patient on the different symptoms as well as the severity scale when prescribing it.*

- Loss of appetite
  - Feeling weak
  - Pain
  - Cough
  - Shortness of breath
  - Depressed...
- 5 questions assess the presence of a symptom and require a yes or no answer.
    - Fever at least equal to 38.2°C
    - Sudden swelling of the face
    - Appearance of a lump under the skin
    - Voice change
    - Appearance or increase of blood in sputum
  - The weight and temperature must be entered following the instructions below: the answers are numerical answers with decimal places.
    - The weight in kilograms entered in each questionnaire must be collected by

the same scale, in the morning, on an empty stomach, without clothing.

- The temperature in degrees Celsius must be entered if it is above 38.2°C. It must be taken with the same thermometer at each seizure, either with a rectal thermometer or an infrared thermometer, noting the temperature equivalence of a rectal thermometer. If the patient notices a fever of at least 38.2°C, a window will appear allowing them to enter their temperature.
- 1 optional free comment window strictly reserved for providing medical information such as a change in the patient's state of health or a new phenomenon.
- An information sentence informs the patient that in the event of sudden associated pain dyspnea (shortness of breath) or not, it is necessary to immediately contact a doctor or go to the emergency room.
- Before validation and sending, the patient must check his answers and can modify them if necessary
- When the patient validates his answers, he receives confirmation of recording of their responses by e-mail.

**1/13 What is your current weight?**

Please use the same scale, in the morning, on an empty stomach, without your clothes

Weight should be between 40-200 kg

**2/13 Are you experiencing a loss of appetite?**

**3/13 Are you feeling weak?**

**4/13 Do you have a cough?**

5/13 Are you suffering from pain?

6/13 Are you breathless?

9/13 Is your face swollen?

10/13 Have you noticed a lump under your skin?

### 3.3.3.1. Configure the sending of questionnaires to patients

From the patient's file, and after activation of their account, **you can define with your patient the day and time** fixed time at which he will receive his weekly questionnaire. By default, delivery will be made on Monday at 8:00 a.m. (or the following day if it is a public holiday).

In their personal space, the patient has the possibility to modify the day and time of their questionnaire themselves.

### 3.3.3.2. Patient late in completing their questionnaire

If a patient does not respond to their questionnaire after 24 hours, the patient (or their designated relative) will receive reminders until they have responded, by email or SMS, within the following time limits: 3 days late, 10 days late and 17 days late. Two types of alerts, visible in the "patients" tab, may be displayed for patients who are late in completing a questionnaire.

1. Active, with an alert "late" – this patient has not responded to the questionnaire for more than a week
2. Active, with an alert "non-compliant" – this patient has not completed a questionnaire for more than 24 days. In such a case, this patient will no longer receive an email from Moovcare.

After 10 days of delay (i.e. two uncompleted questionnaires in a row), you will also receive an e-mail informing you that your patient is late in completing the questionnaires. If you notice a delay or non-compliance in a patient, we recommend that you contact them, or update their status in Moovcare if necessary.

### 3.3.3.3. Send a new questionnaire to a patient

The patient can re-enter their questionnaire at any time before the scheduled receipt of the questionnaire for the following week if they notice an entry error or if they notice a change or the appearance of a symptom. or for any other reason.

As a reminder, the patient has the possibility to enter a new questionnaire using the link present in the last e-mail received, by connecting to their interface or to request the sending of a questionnaire to their medical team.

To send a new questionnaire to a patient, go to the **“Profile”** of the patient file and in the **“Actions”** tab click on **“Resend the questionnaire»**.

### 3.3.3.4. Other functionality

#### - Understanding patient status

In a patient’s file, in the **“tab”Profile”** you will find the sub tab **“Patient Status”**. Patient status will inform you of the patient's follow-up status. In the event that the patient has a status **“On hold”** you will be able to understand those step your patient is blocked if his status is not activated.

If the email is not validated, you can in the sub-tab **“Actions”**, to click on **“Send verification email (email)”** by MOOV CARE<sup>®</sup>.

If the patient does not receive an email, check their email address.

If the patient has forgotten his password, he can be blocked: You have the possibility in the sub-tab **“Actions »** to click on **“Send reset password email”** to help the patient.

Otherwise, contact MOOV CARE<sup>®</sup> technical support. Our assistance will be able to resolve any technical problem and assist you in its use.



### - Register a loved one, a trusted person or a home caregiver to help the patient

In a patient's file, in the "Profile" tab you will find the sub tab "Close". If the patient wishes to be helped by a person, you can register this person. The latter will not receive the questionnaire. He will only be alerted by e-mail if the patient is late in completing his questionnaire. When registering, the loved one must activate their profile by email and validate the general conditions of use.

### - Register a GP

You can save the contact information of the general practitioner for a given patient, in order to contact them if necessary. Please note the general practitioner is only recorded for information purposes, he will under no circumstances be contacted by the MOOV CARE<sup>®</sup> system or informed of the patient's condition.

### - Edit pathology

In the patient file, within the "Questionnaire", you can modify the pathology tracked (only one is currently available).

### - Clinical data

In the patient file, in the "Clinical data", you can record the patient's treatments. This information will allow you, for information purposes, to have some information on his medical follow-up.

Please note, this information is strictly optional and is not taken into account in patient monitoring by MOOV CARE<sup>®</sup>.

#### 3.3.4. Follow your patients

##### 3.3.4.1. Consult the list of patients followed by MOOV CARE<sup>®</sup> Lung

**The patients from the same care center monitored by MOOV CARE<sup>®</sup> Lung are listed in the "Patient" tab at the top of the dashboard.**

A filter is at your disposal to view all patients at the same time or to sort patients according to your wishes.

You can display: Your patients

Patients followed by a referring doctor

Specific patient status: Active, Pending, Rejected, Deactivated, Ineligible, Eligibility Required.

Other details can also be viewed for each patient:

1. Last activity date – last date a patient performed an action on Moovcare (registration, completion of a questionnaire).
2. Actions – you can perform different actions for each patient: send emails and change their status as needed.

#### **3.3.4.2. View a patient's personal data**

From your personal space, click anywhere on the patient's first or last name to access their file and click on the **"Profile"** in his patient file.

#### **3.3.4.3. View a patient's questionnaire history**

**In a patient's file** you can access the table **questionnaire history** filled out by your patients.

You then have the possibility of exporting this history in PDF format to give it to your patients who wish it, by clicking on **"Export"**. This function is particularly offered when exercising the patient's right of access. In the event that the patient has completed 12 or more questionnaires, some of the data may not display correctly. In this case, please contact us to receive the full report.

#### **Understanding the history of questionnaires:**

Each column corresponds to a questionnaire entered (the date is indicated). Each line corresponds to the symptoms completed in the questionnaire.

**Depending on the scores, a color code will allow you to quickly visualize the evolution of symptoms**

**over time.** The legend is indicated below the table. The most recent questionnaires filled by the patient will be on the right of the table and you can scroll to the right to see the oldest ones. You can access the patient's comment by clicking on the comment icon at the bottom.

**Survey history** [Export](#)

No Problem    Minor Problem    Average Problem    Major Problem

Follow-up: Lung cancer

	07/11/2019	22/12/2019	09/03/2020	12/03/2020
Alert				
Weight	70.0Kg	50.0Kg	50.0Kg	60.0Kg
Appetite Loss	-	1	1	1
Weakness	3	2	1	1
Cough	3	1	1	1
Pain	2	2	1	1
Breathlessness	2	1	1	1

### 3.3.4.4. Cases of non-active patients

If a patient is in status **“On hold”** activation you can see why by consulting its file.

In the tab **“Personal data”**, you will be able to understand at which stage of the account activation process the patient file is blocked. The patient's file may remain pending if the patient: has not accepted the General Conditions of Use, has not validated their consent, has not validated their mobile phone or email address during their process activation.

To do this, in the sub-tab **“Actions”**, you can resend the patient’s activation email, the system will ask them to validate the necessary steps in order to validate their activation.

Otherwise, if you encounter other technical problems we invite you to contact MOOV CARE<sup>®</sup> Lung technical support (mentioned at the beginning of the document). Our technical service is at your disposal to support you.

Patient status may also appear:

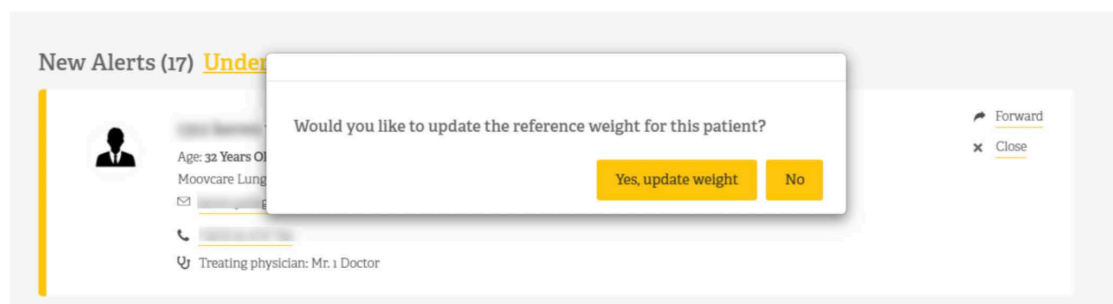
- ❖ **Active:** patient who has completed the registration process and regularly completes the questionnaires.
- ❖ **On hold:** patient who has not yet completed the registration process
- ❖ **Disabled:** You have deactivated the patient file. In this case, you can activate its tracking again by clicking on the button “**Enable**”. The patient can also be deactivated if they have withdrawn their consent. In this case, the patient must connect to his environment to reactivate his monitoring.
- ❖ **Not eligible:** The patient cannot be followed by the application because he does not meet the eligibility criteria. You must give the patient the questionnaire again by clicking on “**Verification of eligibility**”.
- ❖ **Eligibility required:** This patient's file was opened by a caregiver or assistant and is awaiting a Moovcare prescription® by a doctor (do the eligibility test)

### 3.3.4.5. Updating the patient's reference weight in the event of a recurring alert not related to cancer

In some cases, a patient may enter an incorrect weight or cause a recurring weight alert that is unrelated to cancer. We now allow authorized doctors or nurses to modify clinical data, add an updated weight value and therefore stop alerts of this type. This option may impact future weight-related alerts. Please use this option after validating the new weight with the patient.

To use this option, you must first close the weight alert.

After closing, you will be asked if you want to change the patient's reference weight. If so, click yes.



The previous data related to the patient's weight will be displayed and you will be asked to enter the new reference weight.

Note that the minimum value shown should be the minimum value entered by the patient in the last

3 months.

Click "continue".

12/2021	22/12/2021	22/12/2021	26/12/2021	26/12/2021	26/12/2021	26/12/2021	26/12/2021	27/12/2021
.0Lb	194.0Lb	194.0Lb	145.5Lb	194.0Lb	194.0Lb	145.5Lb	194.0Lb	194.0Lb

Update reference weight

New reference weight

Weight should be between 145Lb - 352Lb

Continue

You will be asked to review and validate the new reference weight.

Once approved, the new reference weight will be taken into account for new weight alerts.

You can always see the new reference weight added under the “clinical data” tab within the patient profile.

Please note that if the patient reports a weight change again, this may trigger a new alert.

Weight history - Patient entries

12/2021	22/12/2021	22/12/2021	26/12/2021	26/12/2021	26/12/2021	26/12/2021	26/12/2021	27/12/2021
.0Lb	194.0Lb	194.0Lb	145.5Lb	194.0Lb	194.0Lb	145.5Lb	194.0Lb	194.0Lb

Update reference weight

Reference weight for Riviers Jacques will be updated into 194Lb

I understand that updating the reference weight will reset patient previous weight entries and may impact future patient weight alerts. The reference weight was validated with the patient.

Cancel Confirm

### 3.3.5. Alert management/notifications

In this manual, we differentiate between the terms “alerts” and “notifications”.

The term “alert” is used to notify you of an answer to one of the Moovcare Lung questions that should attract your attention.

This information does not replace your vigilance regarding the latter. We invite you to consult all of the patient's responses.

### 3.3.5.1. Receive alerts/notifications

**In the event of an anomaly detected by MOOV CARE<sup>®</sup> Lung when patient enters a questionnaire and/or if the patient has completed the free comment field, you receive an alert** via email. These alerts correspond to the algorithm's analysis of symptom dynamics and possible synergy.

You can, from the email, either:

- Log in to the application to view the alert content and manage the alert
- Forward the alert to a colleague by clicking on the corresponding link
- Access the questionnaire history for this patient

You also have the possibility, from this email, to contact the patient directly by email by clicking on their email address.

You will also be alerted by SMS that a patient requires your attention by default. If you wish to be contacted only by e-mail, by SMS or both, you can modify your communication channel in your personal settings within the Dashboard Menu.

You can access your dashboard and manage your alerts optimally on your mobile phone via the following link: <https://dashboard.moovcare.com/login/>.

### 3.3.5.2. View triggered alerts

You will be able to view the alerts triggered for all patients from your dashboard in the **"Alerts"** section

You can see 2 sections:

- **New alerts:** corresponding to alerts triggered by patients you have not yet treated.
- **Alerts being supported:** corresponding to patient alerts of which you have become aware and which are currently under investigation.

**Please note, you will be contacted for "new alerts" as long as they are not: under investigation, transferred, or closed.**

**We encourage you to update pending alerts.**

It is also possible to view the content of alerts for a given patient from their patient file in the “ tabs Alerts” And “Questionnaire history”.

### **3.3.5.3. Manage an alert**

You will receive alerts by e-mail and/or SMS of an alert generated by one of your patients or of an alert transferred by one of your colleagues. A link found in this email titled “**MOOV CARE alert - a patient requires your attention**”, will allow you to access the links to manage this alert. In the email, you will find a direct link to your patient's profile, on their alerts page. Please note that in order to respect the confidentiality policy, you do not have access to the content of the alerts (details of symptoms) directly in the body of the email.

You will also have a button, allowing you to log in to your dashboard. From your dashboard, you can manage new alerts.

**The alert gives you the minimum information necessary to decide on the relevance of the alert:**

- the patient** corresponding to the alert with **his contact information** in order to be able to contact him quickly and confirm the symptoms with him
- Time and date** of triggering the alert
- The symptoms that triggered the alert (“**alert triggers**”)
- The functionalities to manage the alert (action buttons “**investigate**”, “**transfer**”, “**close**”)
- Quick access to your questionnaire response history “**questionnaire history**”

To manage an alert, you have the option:

- **To investigate the alert:** If you decide to investigate the alert, you therefore think that this alert is relevant and that it is necessary to take further action on the patient's state of health.

**The content of the alert gives you the patient's contact details so you can contact them by telephone or email, if you deem it necessary, and confirm the symptoms with them.**

When you clicked “Investigate”, MOOV CARE<sup>®</sup> system will consider you to have taken care of the alert. You will no longer receive any reminders regarding this alert.

The alert will then be placed in the alerts “**Currently being supported**”.

Secondly, when you have sufficient information regarding the relevance of this alert, you will need to **Close** and qualify it.

Once the alert is closed, you will be asked if any action was taken as a result of this alert.

If you answer “no” (for example if the alert was not relevant), the alert will close. If you answer “yes”, you will be asked to select all relevant actions performed from the following list:

- Inviting the patient for an early follow-up visit
- Early consultation for scanning
- Change in dose or treatment regimen (reduction or increase)
- Addition of a drug or treatment (of any type, including radiotherapy, adjuvant treatment, etc.)
- Reduction of a medication/treatment
- Phone contact
- Nursing monitoring
- Monitoring of the study coordinator (only concerns clinical studies)
- Invitations to consult a general practitioner
- Other – (you can enter the action performed)

**Attention:** it is important for the monitoring of the patient by the medical team, including secondary doctors, that you qualify the alerts being treated once you have the information. If a secondary doctor subsequently intervenes on this patient, he will then be able to quickly access this information from the patient file, to see the history of alert handling for this patient.

You will be able to find the Alerts “**Closed**” in the patient file corresponding to the alert (“alert” section, sub-tab, “closed”).

- **Forward the alert:** You have the option of transferring the alert to one or more healthcare center employees with access rights to handle alerts (see chapter 3.3.5.4)

Reminder: an ignored alert will trigger again to alert emails and will also activate an escalation process.

Please be sure to mark the alert “for review,” “closed,” or “qualify” after reading an alert.



#### 3.3.5.4. Automatic transfer of an alert

When you cannot manage an alert for one of your patients, **an automatic transfer system is put in place to ensure that all medical alerts are processed as quickly as possible.**

You will be able to view the mailing list of alerts that are automatically triggered if you do not respond to the alert within 24 hours of receipt or if you click **"To transfer"**. Doctors will all receive the alert by e-mail as well as a reminder in the event of non-response (after 48 hours after the initial alert).

*Please note: The doctors on this mailing list are the doctors who have been recorded in the patient's file as Secondary Doctors.*

Important: If there is no response from all doctors on the mailing list after 48 hours, a message is automatically sent by e-mail/SMS to the patient asking them to contact the healthcare establishment or their referring doctor. On the other hand, all doctors who are part of the distribution list will receive an information email as long as no doctor has managed the alert.

**Transfer of alert to the referring physician:** The nurse has the possibility of transferring an alert during treatment to the referring physician.

#### 3.3.5.5. Manage your absences: calendar for your leave

If you have to be absent for a given period, you can use this function to automatically transfer all the alerts you should receive, directly sent to a colleague, whom you have previously defined as your substitute.

You will only have to define your dates, and choose the name of your substitute from the list. If you wish to indicate only one day of absence, click twice on the desired date (departure day / end day). Note that Moovcare® does not check the availability of the substitute you have chosen. And Moovcare® will therefore not be held responsible if an alert is not seen within 48 hours. We therefore invite you to contact the substitute you have chosen, and to ensure that he/she is available for the given period.

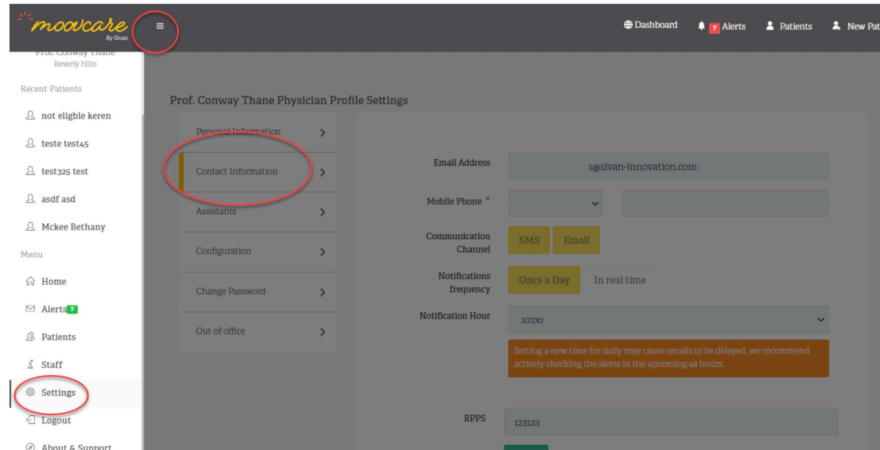
In this tab, you will always have the possibility to modify your departure and return dates, as well as your substitute.

As in previous point 3.3.5.4, the alert escalation process remains enabled so that alert support security remains in place.

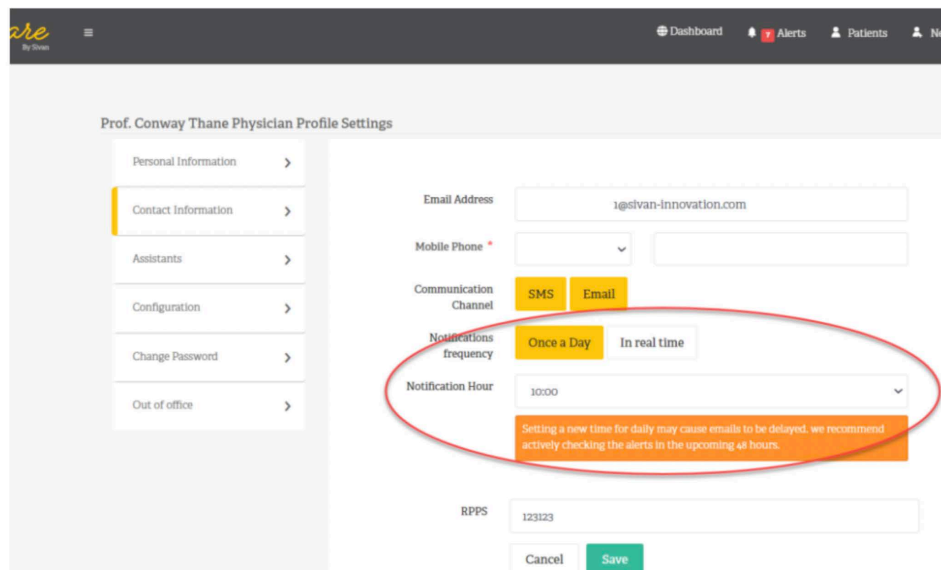
### 3.3.5.6 Customizing alerts

You can customize the receipt of alerts. By default, alerts are received in real time. You can choose to receive alerts in the form of a alone daily message which includes all alerts from the last 24 hours.

To do this, go to “Menu->Settings->Contact data->Edit”



If you choose the frequency “Once a day”, you must also choose the time of the alert. Click “Save” once the settings are complete.



By choosing this option, you will receive a message daily detailing the various alerts received over the last 24 hours. When viewing alerts, we recommend using the “Manage” option (alert switching to “Under investigation”) to sort the alerts you have already read. This will help you better manage your alerts.

Note: This customization of receiving emails will have no impact on the real time alerts in Moovcare®.

Note: For patients to whom you are assigned as a secondary physician, you will receive real-time alerts for alerts that have not yet been investigated, regardless of your preferred choice. Also, the time change for daily emails may cause a delay in e-mails. We recommend actively checking for alerts within the next 48 hours after you choose to receive emails once a day.

### 3.3.6. Transmit medical data to a patient

If your patient requests to recover their medical data (exercise of their rights of access or data portability), you can download a pdf from the tab “Questionnaire history” in his patient file.

	08/11/2020	10/11/2020	10/11/2020
Alert			
Weight	55.0Kg	55.0Kg	55.0Kg
Appetite Loss	-	3	2
Weakness	3	2	2
Pain	3	2	2
Cough	3	2	2
Breathlessness	2	2	2
Depression	-	2	2
Fever	-	-	-
Face swelling	Yes	No	Yes
Lump under skin	No	Yes	Yes
Voice changing	No	Yes	Yes
Blood in sputum	No	Yes	Yes
Comment	-		

For portability purposes, the patient also has the possibility of requesting direct access to their data, in JSON file format. The file contents do not have a specific required data format. He can then receive his profile data as well as the history of emails received.

### **3.4.Secondary practitioner / Relay doctor**

When a referring doctor cannot process an alert concerning his patient, an automatic transfer system to the list of secondary doctors (relays) is set up after 24 hours to ensure that there is the maximum chance that all the medical alerts are processed as quickly as possible.

A doctor can be a referring practitioner for a patient and a secondary/relay doctor for a patient.

When registering a patient for the MOOVCARE<sup>®</sup> service, it is obligatory to appoint a referring doctor.

Secondary/relay practitioners are doctors registered with the MOOVCARE service<sup>®</sup> Lung for the same care center, and who have been designated as a secondary/relay doctor for a given patient by the patient's referring doctor upon registration. In the alert emails received: you will find the mention of the transfer of the alert if applicable.

By entering a patient's file, you can find out if you are the referring practitioner or a secondary/relay practitioner for a patient. When you are a secondary/relay practitioner, you can process alerts in the same way as if you were the patient's referring practitioner.

**Transfer of alert to the referring physician:** The nurse has the possibility of transferring an alert during treatment to the referring physician.

### **3.5.Care center administrator**

#### **3.5.1. Administrator profile and features**

The Care Center Administrator is selected by the medical team wishing to use MOOVCARE<sup>®</sup> Lung. This person must be communicated to the SIVAN Innovation representative in order to be able to create their profile.

An administrator can be a person from the medical team. It will have the same functionalities of the profile defined with additional administrative functions.

These administrative features allow this profile to be able to create profiles in a healthcare center.

The profile which will have administrative functionalities will be able to create accounts in the same care center, for:

- The center's practitioners
- The assistant(s).

-The nurses

### 3.5.2. Management of health professional profiles

#### 3.5.2.1. Create user accounts

The screenshot shows the MOOVcare application interface for adding a new staff member. The header includes the MOOVcare logo and navigation links for Alerts, Patients, New Patient, Staff, and New Staff. The main content area is titled "Follow the steps for adding a new Staff Member" and features a "Member Information" section with two tabs: "Personal Information" (selected) and "Contact Information". The form fields include:

- Category: Physician, Assistant, Nurse
- Title: Mr., Ms., Dr., Prof.
- First Name: Text input field
- Last Name: Text input field
- Gender: Male, Female
- Date of Birth: Day, Month, Year dropdown menus

To create a healthcare professional within MOOV CARE<sup>®</sup> application, you just need to click on the tab "Staff member".

For each profile, the administrator must provide: the person's personal data and contact data.

Please note, all fields to be completed are mandatory.

The email entered in the healthcare professional's profile will correspond to the email on which they will receive their link to activate their profile. As for their mobile, the number communicated during registration will be the number on which they will receive the authentication code.

Also, during daily use of the application, the MOOV CARE<sup>®</sup> alerts will be communicated by SMS and e-mail by default (the 2 communication channels are selected by default).

Important: in France, the integration of the “Annuaire Sante” within the Moovcare interface allows the creation of a doctor directly from his RPPS number, and the finalization of the profile by adding only the email and mobile number.

If he wants to, the healthcare professional can modify his settings in his personal environment from the tab “**Settings**”.

Please note, when creating an account, it will be necessary to define the category of health professional created. That's to say, the administrator will have to choose between: A doctor, an assistant, a nurse.

When adding a new staff member, the unique identifier must be entered.

- For doctors -RPPS
- For nursing staff -ADELI

To find out the access and functionalities of the doctor profile, please direct to the corresponding chapters.

For Assistant and Nurse profiles, the MOOV CARE<sup>®</sup> system is set by default for both profiles.

The default setting includes only basic administrative functions. The assistant or nurse

will be able by default to:

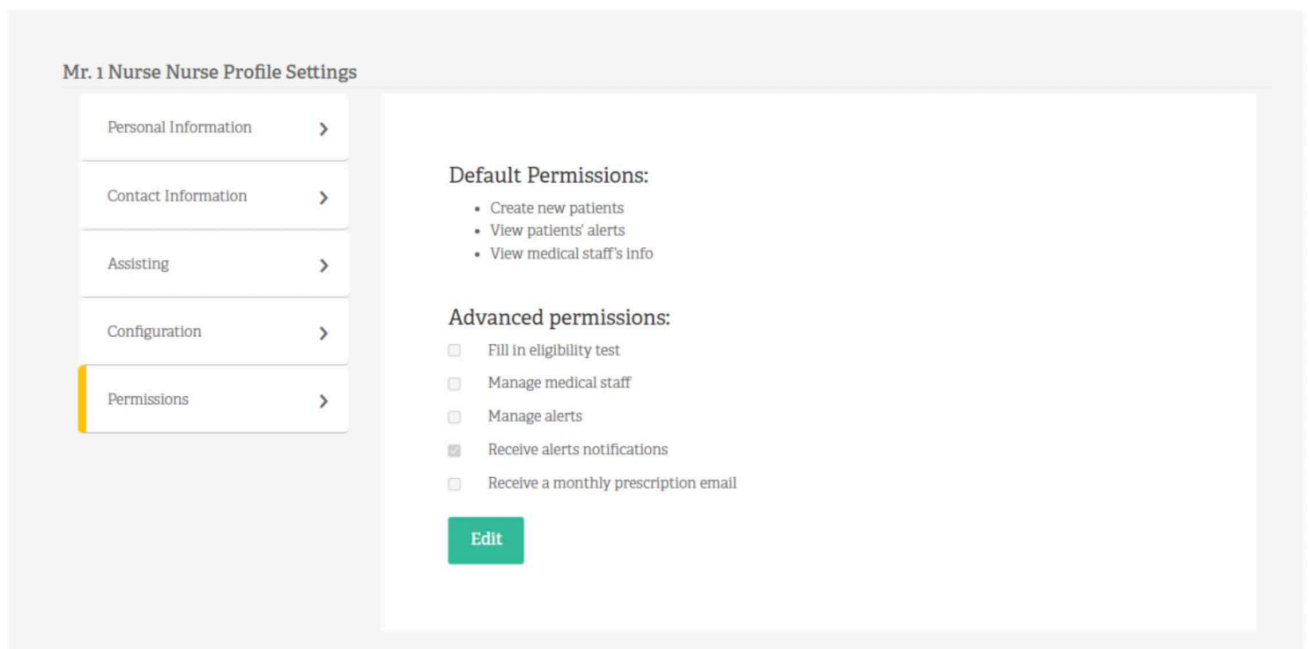
- Add a patient: Only enter personal data, contact data, select the referring doctor and the secondary doctor.
- Consult the staff members of the health center in which he is attached
- Consult the list of patients of the care center: Administrative information only

### 3.5.2.2. Define the access rights and functionalities of an Assistant and Nurse profile

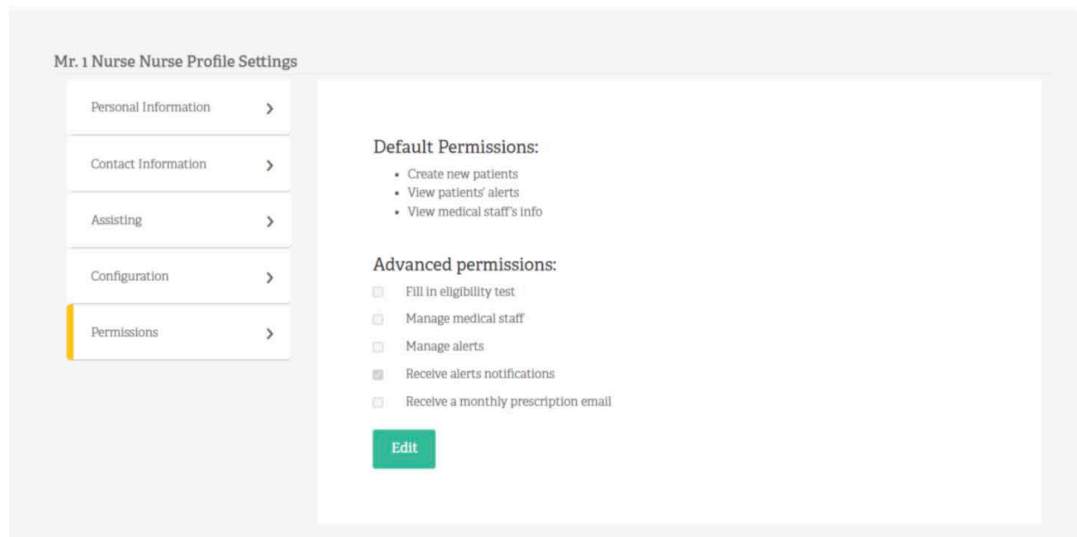
The doctor profile is the most complete profile in terms of access and functionality for using the MOOV CARE<sup>®</sup> device.

The Assistants and Nurses profiles are defined by default with minimum access to patient personal data. You have the option to select pre-authorization for each nurse, so that he/she can access one or more of the following functions: Complete eligibility test, Manage staff members, Manage alerts, receives alerts by email (1/day).

To do this, you must select a nurse from the “Staff members” list



Go to the “Permissions” tab



Click “Edit” and select one or more of the following functions:

- Complete the eligibility test: the nurse can complete the patient eligibility test.
- Manage staff members: The nurse can add new staff members and edit existing staff details.

- Manage alerts: the nurse can close, search and transfer alerts to other doctors.

- Receive alerts. The nurse/assistant may receive alerts and transmit the alert if necessary. If permission is granted, alerts will be received in real time by default, and the nurse/assistant can customize the receipt of alerts. alerts according to your needs (see [3.3.5.6](#) for personalization instructions)

Please inform the nurse after granting authorizations, and ensure that he/she understands his/her responsibility. Note: A doctor must always be responsible for managing an alert. Thus, even if a nurse has been designated, the doctor will always be informed and will assume responsibility for managing the alert.



Management of INS permissions (for France only): the account administrator can access INS data, as well as the teleservice to connect to INSi.

### **3.5.2.3. Edit accounts**

To edit personal data of patient users, click on the first or last name of the user to modify.

By accessing a patient file, you can modify the profile data in the corresponding sub-tabs (see corresponding chapter in the functionalities of the referring doctor).

Please note, if you wish to modify the email address or mobile phone number of a patient profile, please read the procedure in the referring doctor chapter which is similar.

Any healthcare professional has the possibility of modifying their personal information in their own environment. No other professional profile, nor even the Administrator, will be able to change this information.

### **3.5.2.4. Disable accounts**

You have the possibility of archiving a member of staff when this person leaves your establishment, for example.

This option can only be available if the doctor no longer follows patients (this is valid for the primary or secondary doctor) and his account has been disabled.

A request to archive this member of staff can be made to us directly by email sent to [support@moovcare.com](mailto:support@moovcare.com).

*In the event of an error, be careful, the user account may be blocked! You can then return a message penough for this user to reactivate their account. He will also have to again accept the*

*CGU if he logs into his account himself.*

### 3.6. Patient followed / Close

Below you will find the key points to know to guide your patient in the use of MOOV CARE<sup>®</sup> Lung.

- **Technical equipment:**the patient must have an email box and an internet connection to be monitored par MOOV CARE<sup>®</sup> Lung. There is no application to install and MOOV CARE<sup>®</sup> Lung can be used on computer, smartphone or tablet (same access conditions as for health professionals).

- **Inscription** : A patient cannot register for MOOV CARE<sup>®</sup> Lung alone. His referring doctor must prescribe it and register him after checking his eligibility conditions. On the other hand, the patient's complete registration requires that they have validated the general conditions of use and given their consent to the processing of their data (see below).

- **Activation of your account** : After registration by their doctor, the patient then receives an activation email to create a password, to give their consent and accept the General Conditions of Use.

- **Personal space** :Patients have a personal space accessible from <https://patient.moovcare.com>. They can then access certain personal data and enter a new questionnaire. However, they do not have access to their previous answers from their personal space, so as not to be influenced in their answers.

- **Questionnaire receipt** : Upon registration, the patient will receive their first link to their questionnaire and then every week, they will receive a link by email. If he does not respond within 24 hours of receiving the link, he and his loved one, if designated, will receive reminders by email.

He may make a new entry at any time before the scheduled receipt of the following week's questionnaire if he notices an entry error, if he notices a change or appearance of a symptom or for any other reason. . Simply re-click on one of the links received by e-mail and follow the process indicated or connect directly to the application.

- **Loss of questionnaire** : If he loses his questionnaire, he can go to the website <https://patient.moovcare.com>, click on the “start” button after logging in using your email and password.

- **Loved one/Trusted Person/Caregivers at home:** The patient has the possibility of designating a relative to help him in his follow-up (profile to be entered in his patient file by the doctor). This relative will not have access to the questionnaires but will be able to assist them in the data entry. He will also receive notifications in the event of a delay in completing the questionnaire by the patient.

- **Modification of data / withdrawal of consent:**The patient can modify their personal data alone or withdraw their consent. Changing the phone number or email address will automatically send a re-authentication SMS or email to the patient.

- **Documentation patient :** From the “About” section, the patient has access to their instructions, support contact details, general conditions of use, legal notices, confidentiality policy (similar to healthcare professional screens).

### **Instructions for answering the questionnaires**

The questionnaire is made up of twelve simple mandatory questions:

- 6 questions assess the severity of a symptom and require responding with “no problem”, “minor problem”, “moderate problem”, “major problem”. This symptom severity scale is a universal scale used by learned societies. This scale has also been validated in clinical studies. Its aim is to help the patient self-assess during the questionnaire. It is necessary to inform the patient about completing the questionnaire concerning the different symptoms as well as the severity scale when prescribing.
  - Loss of appetite
  - Feeling weak
  - Pain
  - Cough
  - Shortness of breath
  - Depressed
- 5 questions assess the presence of a symptom and require a yes or no answer.
  - Fever at least equal to 38.2C°
  - Sudden swelling of the face
  - Appearance of a lump under the skin
  - Voice change
  - Appearance or increase of blood in sputum
- The weight and temperature must be entered following the instructions below: the answers are numerical answers with decimal places.
  - The weight in kilograms entered in each questionnaire must be collected by the same

- scale, in the morning, on an empty stomach, without clothing.
- The temperature in degrees Celsius must be entered if it is above 38.2°C. It must be taken with the same thermometer at each seizure, either with a rectal thermometer or an infrared thermometer, noting the temperature equivalence of a rectal thermometer. If the fever is at least equal to 38.2°C, a window will appear allowing you to specify the temperature.
- And an optional free comment window. It is **strictly** reserved for providing medical information such as a change in state of health or a new phenomenon.

An indication at the bottom of the page of the questionnaire informs the patient that in the event of sudden pain associated or not with dyspnea (shortness of breath) they must immediately contact their doctor or go to the emergency room.

Important: The medical team must make the patient aware during visits of the importance of the data entered in the questionnaire.

#### 4. CONTRAINDICATIONS

Contraindications to the use of the MOOV CARE<sup>®</sup> Lung medical device are few in number, but must be respected:

- MOOV CARE<sup>®</sup> Lung is not suitable for people under 16 years of age.
- MOOV CARE<sup>®</sup> Lung can be used in pregnant women. However, it is necessary to take into account the changes in symptoms associated with this condition.
- MOOV CARE<sup>®</sup> Lung is not suitable for people with significant cognitive problems. However, these people can get help from a loved one for follow-up. This relative must be indicated by the patient during registration to be registered and receive information by e-mail. The patient has the possibility of adding a loved one or a trusted person at any time during their follow-up (*refer to the "patient/relative" section of the instructions for use for more information*).
- MOOV CARE<sup>®</sup> Lung is not suitable for patients who are very symptomatic at the start of their surveillance for their lung cancer. A series of 5 questions to ask patients and complete when registering a patient will verify this condition.

## 5. INTERACTIONS

MOOV CARE<sup>®</sup> Lung is not a drug, nor an invasive system. This is a medical device that records symptoms and analyzes them. There are therefore no expected interactions.

You should ask your patients to notify you of any new treatments who will be prescribed to him by a healthcare professional and which could interfere with his symptoms. Women will need to notify you of a pregnancy.

MOOV CARE<sup>®</sup> Lung has a patient clinical data tracking system. This medical information, entered when registering a patient and updated every 3 months following the triggering of the alert, are present for informational purposes only. No information is taken into account in the MOOV CARE tracking system<sup>®</sup>. This information is present to allow healthcare professionals to have the information necessary for the proper monitoring of patients. In case of doubts regarding the use of MOOV CARE<sup>®</sup> Lung and for any medical questions, contact the medical department of the SIVAN Innovation Company.

## 6. ADVERSE EFFECTS

MOOV CARE<sup>®</sup> Lung is not a drug, nor an invasive system. This is a medical device that records symptoms and analyzes them. During clinical studies carried out as part of the development of the device, no adverse effects linked to MOOV CARE<sup>®</sup> Lung were noted.

Access codes (passwords) to MOOV CARE<sup>®</sup> are personal and confidential. They must not be shared with any third party.

The performance of this medical device depends on the proper management of alerts issued by MOOV CARE<sup>®</sup> Lung. Poor management or an untreated alert would be unfavorable for the patient.

In the event of an alert triggered by the device, you must validate the alert and check with your patient that there were no errors when completing the questionnaire.

If you cannot process the alert within the expected time frame, you have the option of designating, when the system is set up in your center, doctors who can take over. The alerts are transferred to them with a reminder system until treatment of the alert. Please note that certain alerts are linked to

complications which may require immediate attention.

We also invite you to qualify the alerts in progress when your investigation is completed and a diagnosis is made.

If your patient forgets to complete their questionnaire, they will receive email/SMS reminders until the questionnaire is completed. You will receive yourself *at a greater frequency of alerts indicating that your patient is late in completing the questionnaire.*

The precision of MOOV CARE<sup>®</sup> Lung is conditioned by the patient completing the questionnaire each week.

Please note that you can authorize a relative designated by your patient to help them or complete the questionnaire in their place, if this is impossible due to their state of health.

If your patient wishes to no longer use MOOV CARE<sup>®</sup> Lung for its monitoring, it is very important that you offer another monitoring method.

## 7. WARNINGS

MOOV CARE<sup>®</sup> Lung does not replace a pre-established diagnosis by a healthcare professional.

Be sure to take into account a new associated pathology, the introduction of new medications, the use of other medical devices, or anything that could modify the recorded symptoms. Little information regarding the patient's clinical file is provided in MOOV CARE<sup>®</sup>: it is preferable to refer to the patient's medical file to make a diagnosis. This notion is essential for interpreting the message alert and see if the evolution of symptoms is not linked to the cancer pathology being treated.

Users are expressly informed that the use of Moovcare<sup>®</sup> in a potentially hazardous environment is associated with security risks that cannot be fully addressed by the manufacturer of the digital health application. (Example: recording the login/password on a public computer).

Do not use any automatic translator from your browser, this could disrupt the wording. Moovcare supports 5 languages: French, English, German Italian and Spanish. If you would like to change your language, please do so through your account settings.

### MATERIOVIGILANCE:

Any operating anomaly observed during the use of MOOV CARE<sup>®</sup> Lung medical device must be reported

to the manufacturer or to the authorized representative established in the European Community at the following address: [qualite@sivan-innovation.com](mailto:qualite@sivan-innovation.com).

You also have the possibility of reporting any event to the health authorities on the dedicated site: <https://solidarites-sante.gouv.fr/soins-et-diseases/health-reporting-gouv-fr/>.

If you encounter other difficulties not mentioned in this user manual, please contact the support service by email at [support@moovcare.com](mailto:support@moovcare.com) or by telephone at 09 72 57 22 10 Monday to Friday from 9:00 a.m. to 12:00 p.m. and from 2:00 p.m. to 5:00 p.m. (France).

## 8. REGARDING YOUR PERSONAL DATA

Using MOOV CARE<sup>®</sup> application requires you to enter certain personal data to make it work. As part of your professional activity, you are required to communicate to us your last name, first names, (optional date of birth depending on your profile), gender, RPPS or ADELI number when you are a health professional, title, language, e-mail address -email, professional telephone number, mobile telephone number, the care center to which you are attached or for which you are employed. This data collection and other associated data processing is in the legitimate interest of SIVAN INNOVATION and SIVAN France, for the proper execution of the contract established with your healthcare establishment.

The doctor's date of birth is not required. Additional unique identifiers will be added to your dashboard such as RPPS for the doctor and ADELI for the others.

Providing this personal data makes it possible to establish a regular means of communication with a given patient, while securing the transfer of this patient's personal data. You authenticate yourself, for example, using your email address and your mobile phone number.

Collecting your personal data also allows us to communicate with you for information purposes on the use of the application itself, in the event of security information linked to the application, and may be used for commercial purposes ( manufacturer-care center relationship).

This device is available in different variants, depending on the country in which it is used. A functional cookie allows you to be automatically redirected to the corresponding country after your first connection with the same browser and computer hardware. A cookie is a text file that the server stores on your device.

When you contact our technical support, you are also informed that the call may be recorded and we inform you that we also collect the data communicated. The objective is then to be able to manage technical assistance. Technical service, regulatory service, quality and sales teams are the recipients of this information.

Your personal data is kept for the time you use the application, for a given care center. MOOV CARE<sup>®</sup> application being a regulated medical device, this information is then archived for regulatory traceability purposes for 10 years.

Concerning the transfer of your personal data: The data specific to the application interfaces are hosted by the host whose contact details you will find below. In order to provide a technical assistance service and when the care center is created, a transfer is organized to Israel, where the headquarters of SIVAN INNOVATION is located. Israel is a country recognized by the EU as having an adequate level of protection for personal data. As part of our commercial relationship, it is possible that the data is hosted outside Europe by one of our subcontractors. We then ensure that this data is properly protected and that standard clause contracts are put in place.

For your information, patient data, and in particular their sensitive personal data, are secure and confidential: only the medical team, responsible for this specific treatment, has access to it. Persons authorized at SIVAN France access the social security number, date of birth and birth order and personal data present on the MOOV CARE<sup>®</sup> prescription of the insured person receiving reimbursement (for France only). This data is then communicated to health insurance and any intermediary providers in order to organize financial transactions. Professional support is now available for patients, authorized SIVAN France staff will access the name, first name, email address and telephone number of patients who have given their consent, for the time that this consent remains valid. The patient can withdraw their consent directly from the application.

In accordance with the Data Protection Act and European Regulation 2016/679 (GDPR), you benefit from the following rights relating to your personal data:

- Right of access
- Right of rectification
- Right of erasure
- Right to limitation of this processing
- Right to object to this processing
- Right to portability of your data















In order to request the exercise of your rights, you can contact our data protection officer at [atdpo@sivan-innovation.com](mailto:atdpo@sivan-innovation.com). In this request, please specify your name, first name, email address, establishment as well as the nature of the rights you wish to exercise, accompanied by a copy of your [identity card](#) in order to authenticate you.

We do everything we can to comply with the Data Protection Regulations, in order to guarantee the security of your data and your rights. However, in the event that you notice a breach of these regulations, you have the right to lodge a complaint with the supervisory authority (the CNIL, [www.cnil.fr](http://www.cnil.fr), or the data protection delegate).data (DPD or DPO in English)of the data controller of your data (DPD of the health establishment or DPD of the application manufacturer,[dpo@sivan-innovation.com](mailto:dpo@sivan-innovation.com) ).

You have the opportunity to give us your opinion on Moovcare® anonymously via a short satisfaction survey which will allow us to continually improve the application.

## 9. SYMBOLS

The following symbols may be visible in the app, in emails or on MOOV CARE® Lung documentation.

	Symbol indicating the manufacturer of the medical device		Symbol identifying a warning
	Symbol indicating serial number with software version		Medical Device Symbol
	Symbol indicating the unique identification number of the medical device		CE marking symbol, followed by the notified body number
	Symbol indicating consultation of the user manual		Symbol of the authorized representative in the European Union
	Website address		Indicates that an alert has been issued
	Indicates that a photo can be viewed (png or jpeg)		Importer symbol

## 10. DATE OF MANUFACTURING/CE MARKING

Date of manufacture: refer to the “about” section in the application menu, and in the “about” footer of the application.

CE marking holder: SIVAN INNOVATION LTD.

Date of affixing of the CE marking: July 2017

## 11. REVISION DATE

Date of publication of the notice: February 2025

## 12. LEGAL NOTICE

Moovcare® is a medical device published by SIVAN INNOVATION Ltd, with capital of 100,000 shekels, whose head office is located in Hatidhar 5,4366507, Raanana, Israel, 515096956.

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Moovcare® lung application is hosted by SAS AVENIR TELEMATIQUE - ATE, with share capital of €60,000, whose head office is located at 21 Avenue de la Créativité, 59650 Villeneuve d'Ascq, and registered with the RCS of Lille MÉTROPOLE under the number 347 607 764.

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Moovcare® lung, class I medical device

[www.sivan-innovation.com](http://www.sivan-innovation.com)

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