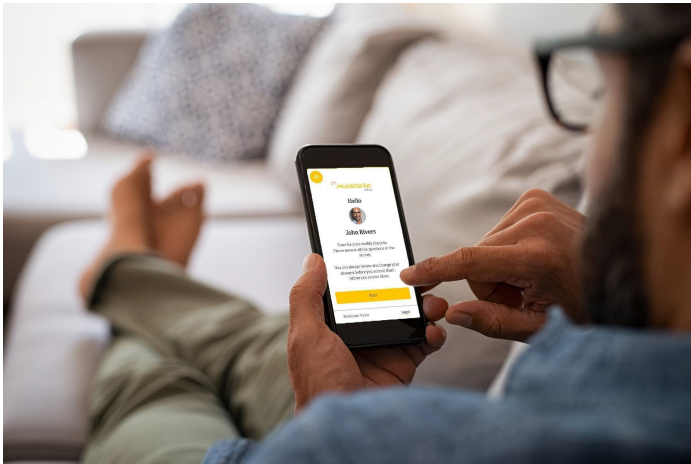


Welcome to

**moovcare**®

## INSTRUCTIONS FOR USE FOR PATIENTS AND CAREGIVERS



Moovcare® Lung web application is a supporting tool, it cannot replace physician consultation.  
In case of emergency please contact your healthcare professional or an emergency medical service.  
Moovcare® Lung is a class I medical device. Version V3.8.5 (API version 3.8.5)  
Obtention of the CE Marking: July 2017  
Notice publication: November 2023



**Sivan Innovation**

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**CEISO**

*69, rue de Paris, 91400 Orsay. France*



2797

**First CE marking**

*July 2017*



***Please read the instruction for use carefully before using MOOV CARE® Lung.***

- We advise you to keep this notice in case you need to review the process of using the web application. If you would like to access the previous instructions for use or if you want to receive it in paper form, please send your request to: **[contact@moovcare.com](mailto:contact@moovcare.com)**.
- For any questions, advice or information, please contact your physician.
- This medical device has been prescribed to you personally. Do not share your access codes with other people, even if their symptoms resemble yours, as this could compromise the proper functioning of this device for your medical follow-up.
- Technical support contact details:  
**[support@moovcare.com](mailto:support@moovcare.com)**: response within 24 hours.

**Assistance service - patients: 09 72 66 22 11** (free call)

Assistance hours: Monday to Friday 9:00 a.m. to 12:00 p.m. and 2:00 p.m. to 5:00 p.m. (Except public holidays)



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# 1. Concept

Moovcare® Lung is a web application that allows you to report your symptoms to your care team every week to allow them to intervene quickly in the event of a problem. Moovcare® lung uses the highest level of security to guarantee the confidentiality of your health data.

## 1.1. *In practice*

Your treating physician will ask you few questions before including you to Moovcare® application.

Once a week, you will receive an email link to a short questionnaire, you will need to report your symptoms on your phone, tablet or computer. If Moovcare® detects something suspicious, your care team will be alerted immediately

### ***A new paradigm in lung cancer follow-up***



## 1.2 *Professional healthcare users of Moovcare® Lung*

### **Treating physician**

The treating physician prescribes patients to Moovcare® follow-up application. All your answers are collected into Moovcare® physician dashboard, to constantly follow your health condition. If an anomaly is detected an alert will be sent immediately.

### **Other physicians in the health center**

Treating physician may designate a secondary physician to follow your symptoms in case of absence.

### **Medical and para-medical collaborators of physicians**

Employees designated by physicians may have access to your data to facilitate your follow-up.

## **2. Therapeutic indications, destination and benefits**

Moovcare® lung application is designed to remotely monitor lung cancer patients in order to early detect any relapse or complications.

Eligible patients:

- Lung cancer patients aged over 16 years.
- Non-progressive cancer after evaluation of the last treatment.
- Having access to the internet and benefiting from an active mobile number or who can be helped by relatives to complete the weekly questionnaire.

Moovcare® lung can be used by patients undergoing treatment.

Moovcare® lung was clinically validated in a PHASE III study (1), comparing Moovcare® lung to the standard follow-up.

<sup>1</sup> F. Denis, Lethrosne C, Pourel N, Molinier O, Pointreau Y, Domont J, et al. Randomized trial comparing a Web-mediated follow-up with routine surveillance in lung cancer patients. *J Natl Cancer Inst.* 2017 Sep 1;109(9). doi: 10.1093/jnci/djx029.

The study showed the following benefits:

- Early detection of relapses or complications.
- Increases overall survival.
- Improves patient's quality of life.
- Improves the general health condition of patients

## **3. Instruction for Use**

### **3.1 Prior instructions for use**

Moovcare® Lung is a medical device monitoring tool, prescribed by medical professionals only. The application does not replace the physician diagnosis but operates as a digital supporting tool to follow lung cancer patient's medical symptoms. Moovcare® will help you to declare specific symptoms linked to lung cancer on a weekly basis.

If you experience other symptoms during your Moovcare® follow-up, or if you will not be able to complete your questionnaire every week (because of a hospitalization, vacation, loss of web access, etc.). You should inform your treating physician.

Note : you have a free text window at the end of your questionnaire. This allows you to update the doctor in cases of additional medical information or new symptoms.

*This free text field is reserved solely for the communication of medical information (new symptoms) or to alert the practitioner in the event of an error in a previous questionnaire.*

***Personalized follow-up***

Moovcare® lung allows you to have a personalized follow-up, with constant communication with your treating physician by answering a questionnaire once a week.

***No installation required***

Moovcare® lung is a web-application, no installation or downloads are required. Internet connection and an email box are mandatory. We advise you to use a Gmail mailbox to receive emails and notifications from Moovcare®.

Moovcare® lung V.3.8.5 is compatible with the following versions of search engines:

- Chrome 119
- Firefox 120
- Internet Explorer 11
- Safari 14
- Edge 119

And also with the system operators:

- Android 12
- iOS 16
- Windows 7
- OSX 13.4.1

### ***Data security***

Moovcare® lung uses the highest level of security to guarantee the confidentiality of your health data.

All databases attached to the system comply with national data protection regulations. The data centers are located in France within a company certified ISO 27001:2013 for the hosting of health data and accredited by the French ministry for the storage of health data.

### ***Weekly questionnaire***

Once a week, you will receive by email a link to a simple questionnaire to allow you to report your symptoms on your phone, tablet or computer.

You can also use Moovcare® lung to report symptoms that appear at any time between two questionnaires.

### ***What kind of questions will I be asked?***

Moovcare® lung will ask you to report the typical symptoms that you may present and to indicate their severity if applicable. This can be a yes/no question, a symptom assessment from minor to major, with a request to enter your weight and temperature. Your referring doctor will be notified if an anomaly is detected by the algorithm. If you experience acute chest pain, whether or not associated with shortness of breath (dyspnea), contact a doctor or emergency department immediately.

### ***Note :***

- *Your temperature must be taken with the same thermometer. The weight you indicate in each questionnaire must be measured with the same scale/scale, without clothing and in the morning on an empty stomach.*
- *On the last screen of the questionnaire, you will need to validate your answers and click on "send" to transmit them to the Moovcard® lung system.*

## 3.2 Description of patient features

### 3.2.1 Registration for using the medical device Moovcare® lung

#### 3.2.1.1 Step 1: Follow-up with Moovcare® app.

Moovcare® lung is a medical device that can be prescribed only by a medical professional. Ask your physician if Moovcare® lung is available in the health center and if you fit the required criteria.

#### 3.2.1.2 Step 2: Required criteria

To determine your eligibility for Moovcare® lung monitoring, your doctor must ensure that you meet the following conditions:

- Are you older than 18.
- You are not symptomatic. Your doctor will ask you 5 questions to determine if you are.

**Note :** *When your doctor enrolls you in Moovcare® lung system, it records the medical information about your current condition.*

*You can choose a family member or reliable person (such as a caregiver) to help you complete the Moovcare® Lung Questionnaire at any time. This loved one may also receive a reminder if you miss a questionnaire.*

*If you consider it necessary, please inform your referring doctor.*

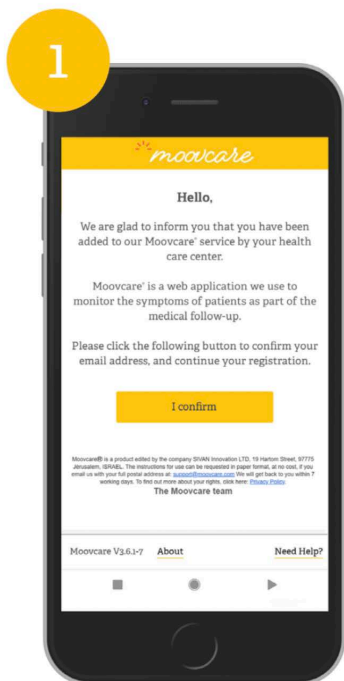
#### 3.2.1.3 Step 3: activate your account

Once registered on Moovcare® lung by your referring doctor (or a member of the accredited medical team), **you will receive an email to activate your account.**

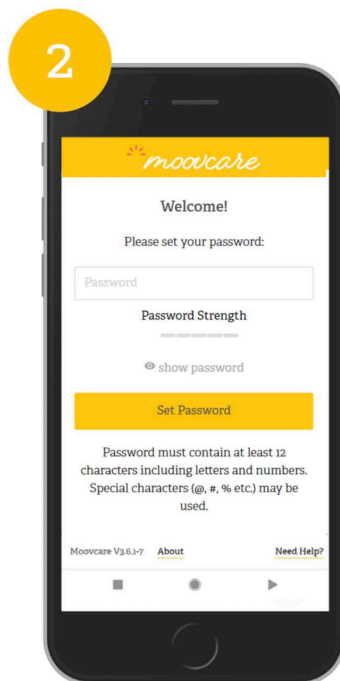
- If you don't see an email in your inbox, check your junk or spam box. Once the email is found, check it as "legit" so that subsequent emails arrive in your inbox.
- If you cannot find the activation email in your spam box, it is likely that the email address you entered when registering is incorrect. Please contact your healthcare center for assistance.



## After that ?



You will receive an email from Moovcare® asking you to confirm your email address. This email will give you access to the Moovcare® system documentation and will let you start with your first questionnaire.



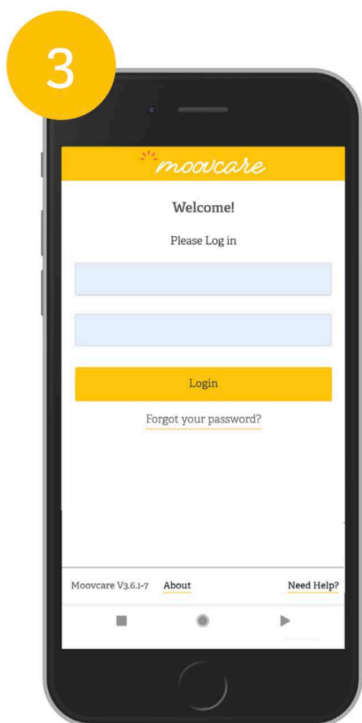
You will be asked to confirm your email address. Click on Confirm to open the Moovcare® lung application; you will then be asked to create a password with at least 12 characters, numbers and letters. Special characters (@, #, % etc.) can be used. First or last names cannot be used. The last 3 passwords cannot be reused.

Once the password has been created, click Set Password.

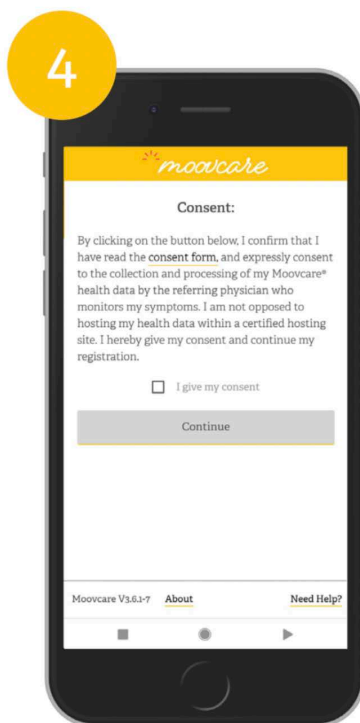
When creating your password, you will be informed of the strength of the password you choose.

**Note:** You will be asked for your password each time you want to log in to the application. You can save it to your device so that your browser recognizes it

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



The login screen will appear.  
Enter your password and click  
**Login** .



The consent screen will open. Read it carefully, it concerns your agreement on the collection and use of your health data in Moovcare® lung.  
**I give my consent** box and click  
**Continue** .

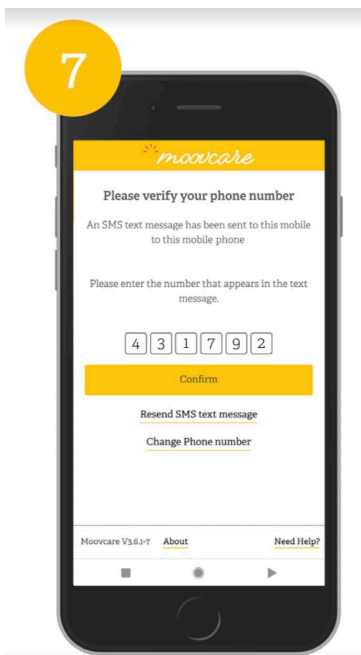
5

Then the Terms of Service will appear.  
Read the **Terms**, check the **I accept box** , then click **Continue** .

6

Fill in your personal information, then click **Confirm** .

**Note:** in the event of an error in your telephone number (you can check the one used to send the SMS on this same screen), click on **Change telephone number** to correct it and receive a new code.

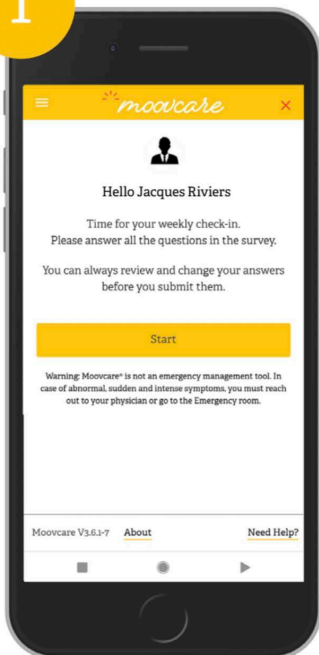


You will then receive a message on your phone with a code to identify yourself.

Return to Moovcare® lung app and enter the authentication code, then click **Confirm**.

### 3.2.2 Your weekly questionnaire

1

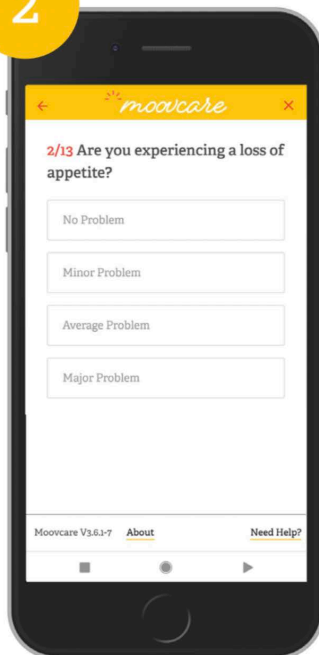


#### ***Your first weekly questionnaire***

Once you've activated your account, you'll be able to click Start to complete your first questionnaire.

Each week, you will then receive a link to your Moovcare® space, to complete your weekly questionnaire by clicking Start and send it to your doctor.

2



#### ***Answer your questionnaire***

Clicking on **To start**, you will be directed to the first question. You will be asked to report any characteristic symptoms you may have and to indicate the severity if applicable.

3

### Note :

- Your weight should be measured with the same scale/scale, in the morning on an empty stomach and without clothes.
- Your temperature should be taken every week with the same thermometer. If your temperature exceeds 38.2°C, click **Yes** and a window will open to allow you to enter your temperature.

- At the end of the questionnaire, you will find a free entry field. This is reserved strictly for transmitting medical information such as a change in your state of health or new symptoms not specified in the questionnaire.

Check your answers, then click **Send**. You will no longer be able to modify your answers. After this screen, you can close the page and you will receive a confirmation email shortly after.

- You can also use Moovcare® lung to report symptoms that appear at any time between two questionnaires using this address: <https://patient.moovcare.com>

Did you forget or delay answering the questionnaire?

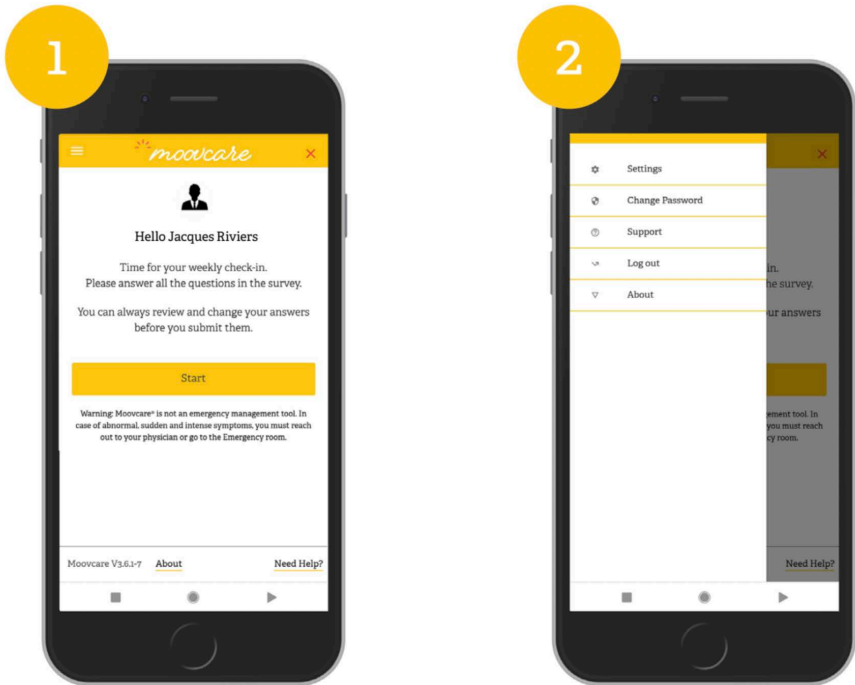
If you do not respond to the questionnaire within 24 hours after receiving the link, you and your designated relative, if applicable, will receive a reminder after 3 days. After 10 days, your doctor will also receive a notification, as will you and your loved ones.

Once your questionnaire has been sent, we invite you to check that you have received the sending confirmation by email. Otherwise, we recommend that you submit a new questionnaire.

### How to Request a new questionnaire?

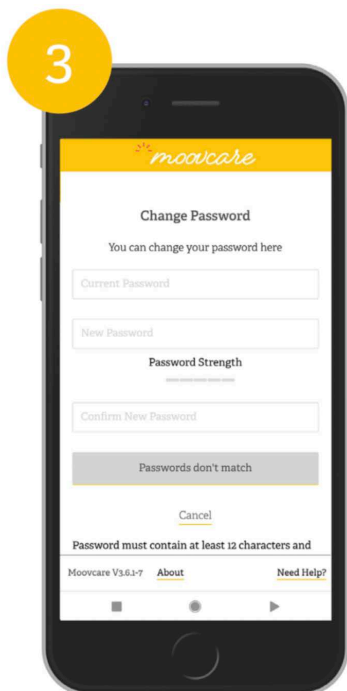
If you wish to submit a new questionnaire, you can do so by connecting to the site: <https://patient.moovcare.com>

### 3.2.3 Modifying your administrative data

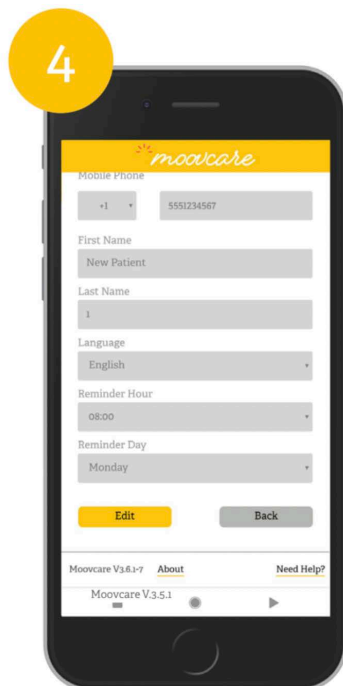


You can directly manage and modify your administrative data.  
On the home page, click on the menu **at the top left**.

Select **Change my password**.



Please enter your new password with at least 12 characters, numbers and letters. Special characters can be used. To reset a password, we need a double verification by means of a code sent by SMS to the mobile, to be provided in the application. Please note that your new password must be different from the previous 3.



In ***My settings***, you can change the ***language of the questionnaire*** as well as ***the time and day of sending your questionnaire*** .



Please note: when you wish to make a change in your settings, an authentication code via your phone will be sent to you.

3.2.4 View data history

You have the right to access your medical data. Your referring doctor will be able to export the history of your questionnaires if necessary.

3.2.5 Do you want to stop Moovcare® lung monitoring?

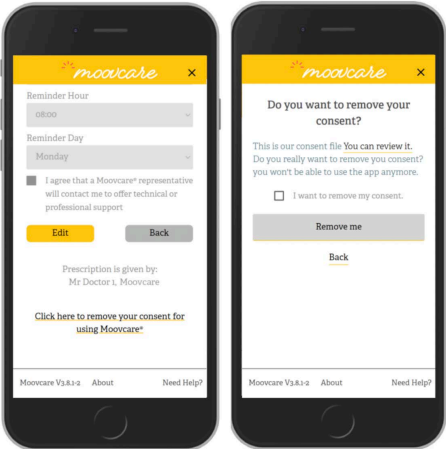
If you no longer wish to be followed by Moovcare® lung, you can withdraw your consent.

On the Welcome page, select **My settings** in the menu at the top left.

At the bottom of the list you will see **Withdraw my consent for Moovcare®**.

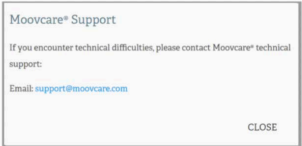
By clicking on this option, a screen will appear to confirm that you really want to stop Moovcare® lung monitoring.

If you wish to be followed by Moovcare® lung again, contact your referring physician. This will send you an email to allow you to reconnect using your email address and the same password used previously. You will then have to give your consent again.



3.2.6 Documentation/help

In the footer of the questionnaires, you will find information that you may need as part of your follow-up with Moovcare® lung.



3.2.7 Ask for help from a loved one or caregiver

You can ask a loved one or caregiver to complete the questionnaire for you if necessary. Please give this contact information to your doctor when registering.

The relative will not have access to the questionnaire separately.

If you do not complete the questionnaire every week, your loved one will receive a reminder.

Consent to a Moovcare representative contacting you for technical and professional assistance can be managed in the “Settings” section. By default, this consent is not checked and the technical team does not have access to your contact details. You can validate this option or not at any time.

Please note: we advise you not to send your link to a caregiver, but you can complete the questionnaire with them.

## 4. Satisfaction survey

At Sivan Innovation, we work to continually improve Moovcare® for your well-being and convenience. In order to constantly improve Moovcare®, SIVAN conducts a satisfaction survey among its users. This optional survey is managed independently of the application. SIVAN Innovation and SIVAN France are the sole recipients of this information, which will be anonymized and used for statistical purposes, in the form of internal reports. Every 2 months, you will be asked to complete this optional survey.

## 5. Who can benefit from Moovcare®?

- Lung cancer patients aged over 18.
- Moovcare® lung is not suitable for patients with significant cognitive problems; however, they can get help from a loved one during follow-up. This relative must be registered in the application and will receive information by email. A patient with a cognitive problem is a patient who does not have the ability to complete the questionnaire correctly.
- Eligibility: your referring doctor will ask you 5 questions to check if you are eligible for follow-up by Moovcare® lung.

## 6. Warnings and contraindications

The effectiveness of Moovcare® lung depends on your regular responses to the weekly questionnaire. If an anomaly is detected, an alert will be sent to your referring physician.

If you have not completed the questionnaire, you will receive reminders until you complete the questionnaire

If you are unable to answer the questionnaire on your own, a loved one or caregiver can help you and submit your questionnaire indicating the symptoms you are reporting.

We recommend that the relative who will assist you in answering the questionnaire be by your side to ensure that the answers are accurate.

If you or your loved one cannot answer the questionnaire, please contact your referring doctor.

Moovcare® lung does not replace a diagnosis carried out by a health professional.

If you use other medical devices as part of your medical follow-up or if you take medication, please inform your referring doctor before using Moovcare® lung.

The effectiveness of Moovcare® lung has been demonstrated provided that the questionnaire is answered every week. If new symptoms appear between two questionnaires, please contact your referring doctor.

If you no longer wish to use Moovcare® lung, please inform your doctor.

If you do not receive your questionnaires by email, please check your junk mail or Spam box.

If you encounter other difficulties which are not listed in this notice, please contact the support service by email at [support@moovcare.com](mailto:support@moovcare.com) to inform us. or by phone at 09 72 66 22 11.

Users are expressly informed that the use of Moovcare® lung 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). Access codes (passwords) are personal and should not be shared.

Do not use any automatic translator from your browser, this could disrupt the wording. Moovcare supports 4 languages: French, English, German and Spanish. If you would like to change your language, please do so through your account settings

There are no warnings associated with using the app

### Residual risk

The expected risks for this application are minimal but may still involve psychological harm such as emotional distress or embarrassment related to questionnaire questions and breach of confidentiality.

The questions from the questionnaire will be used in the clinical trial and any signals of harm will be assessed. In general, the application is unlikely to cause harm. However, if a patient experiences emotional distress arising from these issues, a psychological consultation should be carried out.

The risk of privacy breach will be minimized in several ways, as outlined below:

Moovcare® is a web-based algorithm in which patients enter symptom data via a password-secured digital platform. Registered patients receive a unique password to log into the site so that only they, a caregiver with whom they share the password, and their medical team can access their PRO data. For the study, data, including outcome questionnaires and graph abstraction forms, will be collected via a web-based platform by secure survey administration.

For the study - Strict confidentiality will be maintained. Paper-based research data will be minimal and stored in locked, secure areas accessible only by the study team. Research data will be kept in separate tables and identified by an identification number only where possible. A master list linking names and ID numbers will be kept in a separate, secure location. Only approved research team members will have access to secure files and will be informed about the protection of patients' rights to confidentiality. At the end of the study, when the database has been declared complete and accurate, the database will be locked.

Data transmitted between the server and end users is encrypted using SSL, and all databases are encrypted. Members of the research team will be responsible for keeping all participant data and patient participation confidential.

### Contraindications

- MOOV CARE® Lung is not suitable for people under the age of 18.
- MOOV CARE® Lung is not suitable for people with significant cognitive problems. However, these people can be helped by a relative for follow-up. This relative must be reported by the patient at registration to be registered and receive information by email. The patient has the option of adding a loved one or a trusted person at any time during their follow-up.
- MOOV CARE® Lung is not suitable for very symptomatic patients at the start of their surveillance for their lung cancer. A series of 5 questions to ask patients and to complete when registering a patient will verify this condition .

In the event of a serious incident, immediately contact the support team by email at [support@moovcare.com](mailto:support@moovcare.com) as well as the competent authority of the country in which you are located. It is also recommended to inform the agent by email at the following address: [sivan@ceiso.fr](mailto:sivan@ceiso.fr)

A serious incident is defined as follows: any incident which has led directly or indirectly to, likely to have led to or likely to lead to: death of a patient, user or other person; a serious degradation, temporary or permanent, of the state of health of a patient, a user or any other person; a serious threat to public health.

## 7. Personal data

The use of Moovcare® lung application requires entering personal data. Your physician or the healthcare professional who took care of your initial registration in the system will be responsible for collecting your data. You will need to provide personal information including your address, landline number, cell phone number and social security number. Your healthcare center has access to this administrative data in order to facilitate your exchanges. The use of Moovcare® lung application also requires that you consent to the processing of your health data. During your initial registration, your doctor will ask you a few questions about your state of health to validate your eligibility. You will also provide health data each time you answer the questionnaire.

SIVAN France will access the surname, first names, status in Moovcare®, social security number, date of birth, and personal data present on the Moovcare® lung prescription of the insured benefiting from reimbursement.

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 the same hardware. A cookie is a text file that the server stores on your device.

These data are then communicated to the health insurance and to any intermediary service providers in order to organize the financial transactions.

Your personal data is stored and secured with a certified health data host in France. You can find more information below. Moovcare® Lung app is a regulated medical device and as such all recorded data must be secured and archived for ten years.

SIVAN Innovation may need to use the data for study, research and development or statistical purposes, for its own needs or those of its partners, or at the request of national or international health authorities. All data will be anonymized before use.

Technical Support will ask for your consent before answering your questions. You will also need to give your consent for the phone call to be recorded. This data is recorded on our supplier's secure servers, which may be in the USA. Our supplier is committed to ensuring a level of security comparable to that required in Europe, through the use of binding contract rules.

To facilitate your registration and your Moovcare® follow-up, you also have the option of using the professional assistance of Moovcare®. You may have consented to this when you registered with the doctor or you may consent to this from your interface. You then authorize nursing staff at Sivan to access your personal data (surname, first name, email, telephone number, status in Moovcare®). You can withdraw your consent to this service whenever you want from the application.

In accordance with EU Regulation 2016/679 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (GDPR), you have the following rights concerning your personal data: right to access, right of rectification, right to erasure, right to limit processing, right to object to processing, right to data portability.

If you wish to exercise any of these rights, please contact your referring physician. You can also contact the Data Protection Officer (DPD) at Sivan at the following e-mail address: [dpo@sivan-innovation.com](mailto:dpo@sivan-innovation.com) specifying your surname, first name, e-mail address, the name of your care center and the nature of your request.

For portability purposes, you have the possibility to request access to your data directly, in

JSON file format. The file content has no specific required data format. You can receive: history of questionnaire responses, administrative and medical data, history of e-mails received, alerts (symptoms triggered, date, time, doctor who closed the alert).

We strive to comply with the GDPR in order to guarantee the security and your rights with regard to your personal data. However, in the event that you notice a violation of these regulations, you have the right to lodge a complaint with the National Commission for Computing and Liberties ( [www.CNIL.fr](http://www.CNIL.fr) ) or to the data protection officer (DPO) of the data processing manager (the DPO of the care center or the manufacturer of the application [dpo@sivan-innovation.com](mailto:dpo@sivan-innovation.com) ).













If you had consented to participate in a survey conducted by SIVAN INNOVATION and SIVAN France and you no longer wish your data to be used, you can then contact our DPO to exercise your rights over this data (address above).

A survey will be sent every two months to collect your comments on improvements following the use of Moovcare® lung and additional information regarding the use of the application. We do not collect any personal data that could lead to your identification. Your consent is required for this survey. Please note that if you do not respond to this survey, you will continue to receive it.

Some of your data (technical support, survey or billing) is transferred to Israel, to the manufacturer of the application. The European Union recognizes that Israel has an adequate level of security to protect personal data.

## 8. Symbols

Symbols used:

	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

## 9. Date of manufacture/CE marking

**CE marking holder:** SIVAN INNOVATION LTD. Obtaining CE marking: 2017-07

**Date of manufacture:** see the "About" section at the bottom of the page.

**Revision date :** date of publication of the Moovcare® lung leaflet from Version 3.8.5 (API 3.8.5) November 2023

## 10. *Legal Notice*

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Moovcare® is a medical device published by SIVAN INNOVATION Ltd, with capital of 100,000 shekels, whose head office is located at Hatidhar 15, 4366519, Raanana, Israel, 515096956.

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The 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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**MD** Moovcare® lung, class I medical device

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