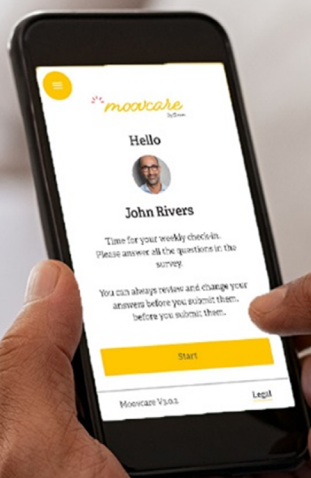





PATIENT USER GUIDE



Moovcare® web application is a supporting tool, it cannot replace the physician consultation
In case of emergency please contact your healthcare professional or an emergency medical service.

Moovcare® medical device class I, Version V3.8.0 (API version 3.8.0)

Date of CE marking  : July 2017

Manufacturer: SIVAN INNOVATION Ltd.,  19 Hartom Street, 97775 Jerusalem, Israel.

Mandataire européen : SIVAN France,  6 rue Paul Baudry, 75008 Paris, France.



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

- We highly recommend keeping this leaflet, you might need to read it again. If you would like to access to previous instructions of use or if you would like to receive it in a paper form, please send your request to contact@moovcare.com.
- Consult your doctor for any question, advice or information.
- This medical device has been personally prescribed to you. Do not share your personal access with other people, even if the signs of their illness are the same as yours.
- **Technical support:**
Email: support@moovcare.com -a response will be given within 24 hours.

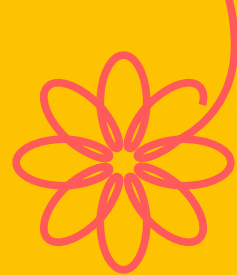


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1. Concept

Moovcare® is a web-based application that lets you report your symptoms to your care team every week so they can intervene quickly if there's a problem.

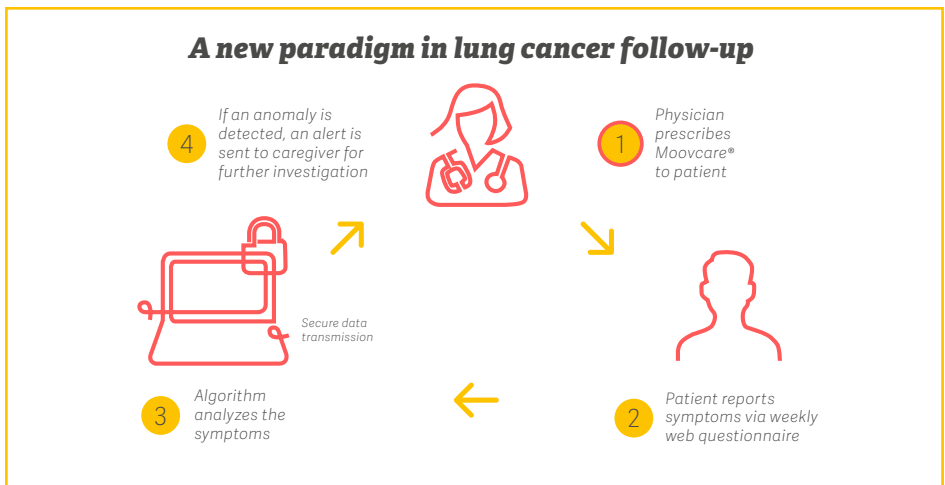
Moovcare® uses the highest level of security to ensure the privacy of your health information.

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



1.2. Moovcare® healthcare users

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 and benefits

Moovcare® application is intended to remotely monitor lung cancer patients for early detection of relapses or complications.

Moovcare® is a medical device therefore can be prescribed only by a physician.

Inclusion patient criteria's:

- Lung cancer patients > 16 years.
- Non-progressive post evaluation of last treatment, for asymptomatic or few symptoms patients.
- Has internet access or may be supported by relatives to complete the weekly questionnaire.

Moovcare® lung can be used with maintenance treatment. Moovcare® lung was clinically validated in a study¹ PHASE III, compared Moovcare® lung to the standard follow-up.

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

¹F. Denis, Iethrosne 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; 109 (9):d jx029.

3. Operating instructions

3.1. Prior instructions for use

Moovcare® 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 base.

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 symptom (ex: skin rash, diarrhea or other).

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®.

3. Operating instructions

Moovcare® lung V3.6.1 can be used on Internet browsers of the following versions :

- Chrome 89
- Firefox 87
- Internet Explorer 11
- Safari 14

And also with the operating systems:

- Android 10
- iOS 13
- Windows 7
- OSX 10.15

Data security

Moovcare® uses the highest level of security to ensure the privacy of your health information. All the databases attached to the device respect the national regulation regarding data protection. If you are located in Europe, datacenters are located in Europe, within a company ISO27001:2013 and HDS:2018 certified for health data storage. If you are located in USA, datacenters are located in USA, into HIPAA compliant datacenters.

Weekly questionnaire

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

You can also use Moovcare® to report symptoms that occur any time between scheduled questionnaires.

What kind of questions will I be asked?

Moovcare® will ask you to report typical symptoms you may be experiencing, and to indicate the severity of the symptom, where relevant.

It can be a yes/no question, a scaling a symptom from none to major or to type measurements of your weight or temperature. Each question is mandatory, even if the symptom is not experienced. Your doctor will receive a notification in case of abnormality detected by the algorithm. S/he will contact you to confirm your health condition and you will determine together the next steps.

In case of sudden chest pain (linked or not) to dyspnea (shortness of breath), please contact a doctor immediately or go to the emergency room.

Note: temperature entered must be taken with the same thermometer, a rectal thermometer or an infrared thermometer.

- The weight seized on each questionnaire must be collected on the same scale, in the morning, on an empty stomach, without clothing.
- In the last screen of the questionnaire you can validate your answers and click "submit" to send it to Moovcare® system.

3. Operating instructions

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

In order to determine your eligibility for the Moovcare® lung follow-up, the physician must verify that you have the following conditions:

- You are >16 years old.
- You're not symptomatic. Your doctor will ask you 5 questions to determine if you are.
- Other reasons might be considered.

Note: when registering within the Moovcare® lung system, the physician registers clinical information about the current state of your health condition

You can choose a relative (someone of your family or a reliable person such as a home caregiver) to help you to answer Moovcare® questionnaire at any time. If you deem it necessary, please advise your treating physician. Your relative will be able to help you to fill in your questionnaire and will receive reminder if you miss a questionnaire.

3.2.1.3. Step 3: activate your account

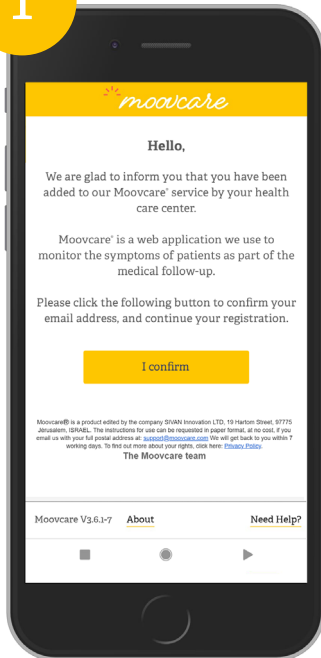
Once registered to Moovcare® lung by your treating physician (or an authorized member of the care team), **you will receive an email to activate your account**.

- If you do not receive it in your Inbox, first check your "spam" or "junk mail" box. Once found, mark the mail as "legit" so that the following mails reach your main Inbox.
- If you do not find the email to activate your account in your spam, it is likely that the email address entered during your registration is wrong. Please contact the coordination nurse at the health center for support.

3. Operating instructions

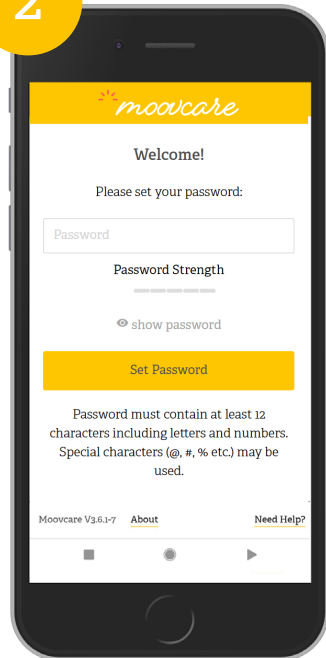
What happens next?

1



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.

2

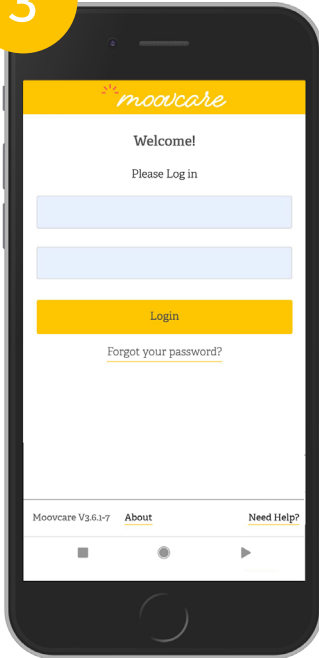


Click **Confirm** to open Moovcare® app, where you will be asked to choose a password with a minimum of 12 characters including letters & numbers. Special characters may be used. When you've done this, tap **Set Password**.

Note: Your password will be asked each time you would like to connect to the application. You can save it into your device in order that your browser recognizes it.

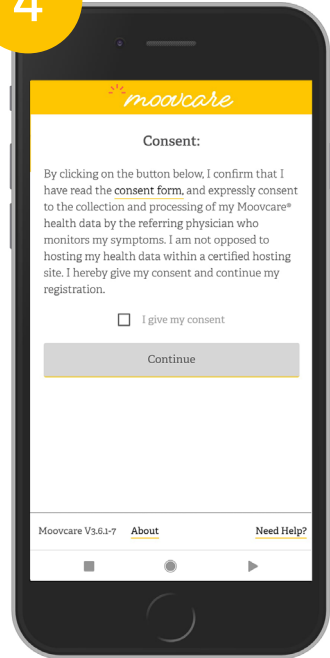
3. Operating instructions

3



The Login screen will appear. Re-enter your password and tap **Login**.

4



The consent screen will appear. It concerns the process of your personal data by your care team with Moovcare®. Read the **Consent**, mark the checkbox, then tap **Continue**.

3. Operating instructions

5

moovcare

Terms of Service

By checking the box below, I declare that I have read and agree to the **TERMS**.

☐ I have read and agree to the Terms

Continue

Moovcare V3.6.1-7 About Need Help?

Next **Terms of Service** will appear. Read the **Terms**, mark the checkbox and tap **Continue**.

6

moovcare

Please review and confirm your details

Mobile Phone

+1 5551234567

City

Id Number

Gender

All fields are required

Confirm

Moovcare V3.6.1-7 About Need Help?

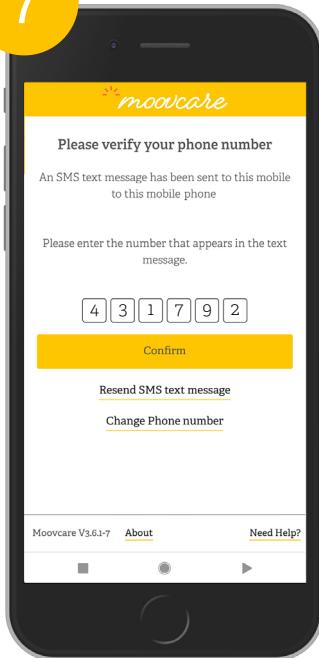
Enter your personal details, then tap **Confirm**.

Note : in cases of mistakes in your phone number (you can read the one used for the SMS into the same screen), you can click on "Change phone number" in order to correct it and receive the code.

3. Operating instructions

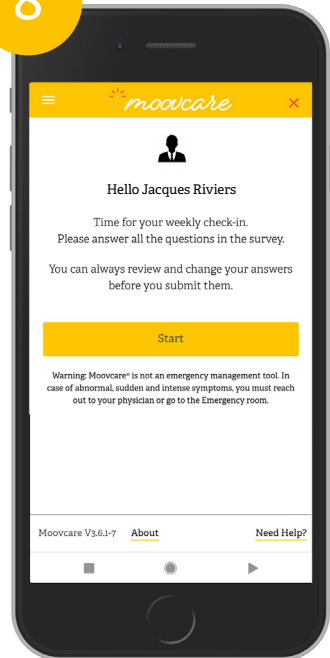
Here we are...

7



You will then receive an SMS on your phone with a code to identify yourself by verifying your phone number. Enter the verification code into the Moovcare® app. Then click **Confirm**.

8

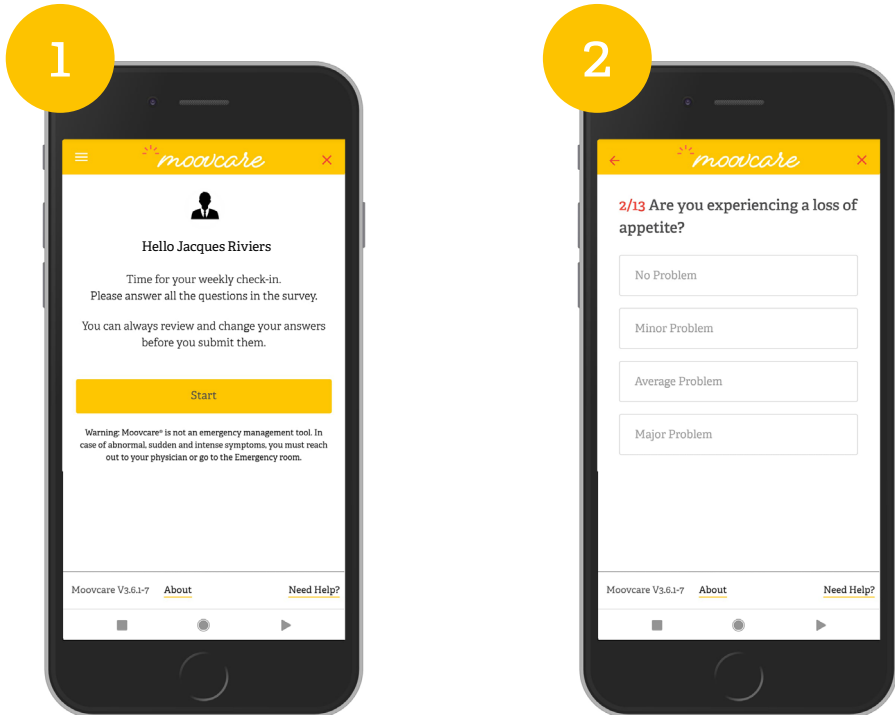


Done!

You are now ready to take the first survey that your physician has prescribed to you. To begin, click **Start**.

3. Operating instructions

3.2.2. Your weekly questionnaire



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.

Answer your questionnaire

By clicking **Start**, you are directed to your weekly questionnaire. You will be asked to report typical symptoms you may be experiencing and to indicate the severity of the symptom, where relevant. All identified symptoms are related to lung cancer. Every symptom needs to be quoted, even if not experienced.

3. Operating instructions

3

The screenshot shows the Moovcare mobile app interface for a 'New Patient 1'. The app has a yellow header with the Moovcare logo. Below the header, there is a text prompt: 'After reviewing your answers please scroll down and click Submit'. Below this, there is a yellow 'Submit' button. Under the button, there are three questions, each with a text input field and a checkmark icon on the right: 'What is your current weight?' (with '88 kg' entered), 'Are you experiencing a loss of appetite?' (with 'No Problem' entered), and 'Are you feeling weak?'. At the bottom of the screen, there is a footer with the text 'Moovcare V3.6.1-7' and two links: 'About' and 'Need Help?'.

Note :

- The weight must be collected by the same scale, in the morning, on an empty stomach, without clothing.
- The temperature must be taken with the same thermometer each time. Either with a rectal thermometer or an infrared thermometer. If your temperature is higher than 38.2 C° / 100.76 F, click *Yes* and a window will appear allowing you to enter your temperature.
- At the end of the questionnaire, you will have an optional free comment window, it is *strictly* reserved to inform medical information such as a change in your health or new symptoms.
- Verify your answers and then click on *Submit*, after that you will not be able to change your answers.
- Following this screen, you can safely close this page. You will shortly receive a confirmation email.
- You can use Moovcare® to report symptoms that occur any time between the scheduled questionnaire by using this address : <https://patient.moovcare.com>

Forgotten or delayed response to the questionnaire?

If you did not replay the questionnaire within 24 hours of receiving the link, you and your relative will receive a reminder after 3 days.

After 10 days your physician will also receive a notification.

Once your questionnaire is submitted, please check your inbox for a confirmation email from moovcare. If you did not receive such an email, we recommend filling in another questionnaire.

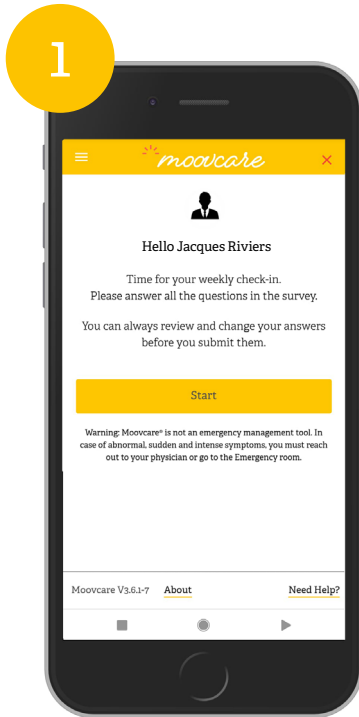
How do I request a new questionnaire?

If you want to submit a new questionnaire, you can do easily by entering the patient website address:

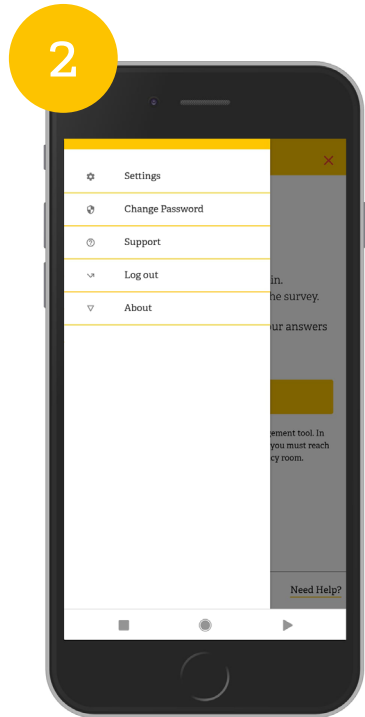
<https://patient.moovcare.com>

3. Operating instructions

3.2.3. Modifying your administrative data



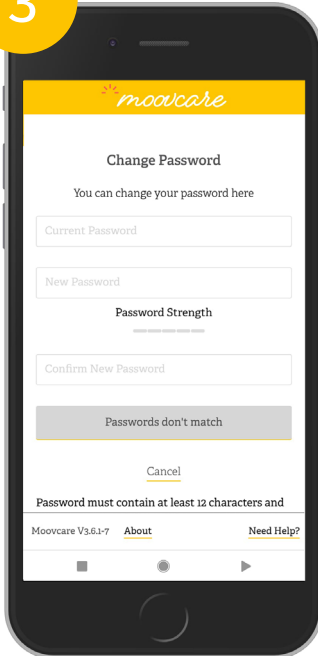
You can directly manage and update your administrative data.



At the Welcome page go to **left – top menu** and choose **Change password**.

3. Operating instructions

3

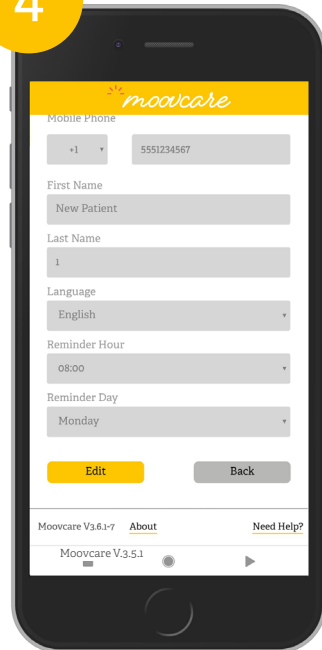


The screenshot shows the 'Change Password' screen in the Moovcare app. At the top is a yellow header with the 'moovcare' logo. Below the header, the title 'Change Password' is centered, followed by the instruction 'You can change your password here'. There are three input fields: 'Current Password', 'New Password', and 'Confirm New Password'. Below the 'New Password' field, a 'Password Strength' indicator shows a series of dots. A message 'Passwords don't match' is displayed below the 'Confirm New Password' field. At the bottom, there is a 'Cancel' link and a note: 'Password must contain at least 12 characters and'. The footer contains 'Moovcare V3.6.1-7', an 'About' link, and a 'Need Help?' link.

You will be asked to enter your new password with at least 12 characters, including numbers and letters.

To reset a password, we need a double check using a code sent by SMS on the mobile, to provide in the application to allow the change of password.

4



The screenshot shows the 'Mobile Phone' settings screen in the Moovcare app. It has a yellow header with the 'moovcare' logo. The title 'Mobile Phone' is at the top. Below it is a form with several fields: a country code dropdown (showing '+1') and a phone number field (showing '5551234567'); 'First Name' (showing 'New Patient'); 'Last Name' (showing '1'); 'Language' (a dropdown menu showing 'English'); 'Reminder Hour' (a dropdown menu showing '08:00'); and 'Reminder Day' (a dropdown menu showing 'Monday'). At the bottom of the form are two buttons: 'Edit' (yellow) and 'Back' (grey). The footer contains 'Moovcare V3.6.1-7', an 'About' link, and a 'Need Help?' link.

Settings option will enable you to change all your contact information, including the defined day and hour at which you would like to receive your weekly questionnaire.

3. Operating instructions

3.2.4. See 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. Want to stop Moovcare® follow-up?

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

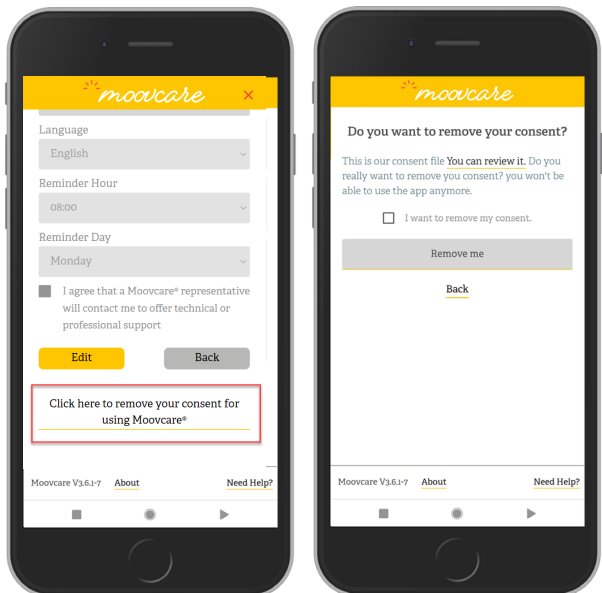
At the Welcome page, go to the left-top menu, choose **About**.

At the bottom of the list you will find **"Remove your consent"** option.

By clicking this option, an additional screen will appear to make sure you want to stop Moovcare® follow-up. This decision stops the questionnaire process: you will be no more follow with Moovcare®.

Your treating physician will be informed of your decision. It is important to contact him/her in order to define a rhythm of visit for your next follow-up.

If, however you wish to be followed again by Moovcare® lung, contact your treating physician. You will then have to give your consent again.



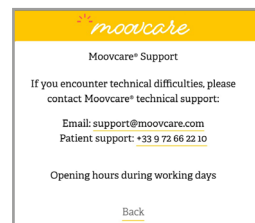
3.2.6. Documentation/help

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

3.2.7. Get support from relative or caregiver

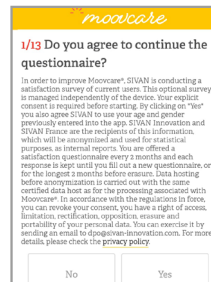
You can be assisted by a relative or caregiver to complete the questionnaire if needed, please provide the contact info to your treating physician at any time.

The relative will not have access to the questionnaire separately. If you do not fill out your questionnaire every week, your relative will receive a reminder.



4. Satisfaction questionnaire

We at Sivan Innovation always working for improving Moovcare® for your well-being. In order to constantly improve Moovcare®, SIVAN is conducting a satisfaction survey of current users. This optional survey is managed independently of the device. SIVAN Innovation and SIVAN France are the recipients of this information, which will be anonymized and used for statistical purposes, as internal reports. Every 2 months you will be promoted to fill in this optional survey.



The screenshot shows a mobile app interface for a satisfaction questionnaire. At the top, the 'moovcare' logo is in a yellow bar. Below it, the text reads '1/13 Do you agree to continue the questionnaire?'. A detailed privacy notice follows, explaining that SIVAN is conducting a satisfaction survey, that the survey is optional and managed independently of the device, and that SIVAN Innovation and SIVAN France are the recipients of the information. It states that the information will be anonymized and used for statistical purposes, and that the survey is conducted every 2 months. At the bottom, there are two buttons: 'No' and 'Yes'.

5. Who can benefit from Moovcare®?

- Lung cancer patients over the age of 16.
- Moovcare® lung is suitable for pregnant women, but it is necessary to report pregnancy to the referring physician as soon as possible.
- Moovcare® lung is not suitable for patients with significant cognitive problems; however, they can get help from a relative during their follow-up. This relative should be registered in the app and will receive information by email.
- A patient with a cognitive problem is a patient who does not have the capabilities to complete the questionnaire properly.
- Eligibility: Your referring physician will ask you 5 questions to see if you are eligible for follow-up by Moovcare® lung.

6. Warnings

Moovcare® performance depends on your regular response to the questionnaire each week.

In case of anomaly is detected, an alert will be sent to your treating physician.

If you did not fill out your questionnaire, you will receive reminders until you fill it out.

If you do not have the opportunity to complete your questionnaire alone, a relative or a caregiver can help you to submit your questionnaire based on the symptoms you report.

We recommend answering the questionnaire in your presence to make sure the answers are accurate.

Please do not transfer the link to your relative.

If you or your relative do not have the option to fill it out, please contact your treating physician.

- Moovcare® lung does not replace a diagnosis given by a health professional.
- Regarding inclusion in Moovcare® :
 - Moovcare® lung can be used by pregnant women, but it is necessary to report this condition as soon as possible to the treating physician.
 - Moovcare® lung is not suitable for patients with a significant cognitive problem however they can be supported by a relative during the follow-up. This relative need to be registered and receive information by mail.
 - A patient with a cognitive problem is a patient who is unable to complete the questionnaire accurately.
- If you are followed by another medical devices or taking medication, please consult your treating physician before using Moovcare® lung.

- Moovcare® has proven to be effective in filling the questionnaire once a week. If new symptoms appear between the scheduled questionnaire, contact your treating physician.
- If you no longer wish to use Moovcare® lung, please inform your treating physician.
- If you do not receive your questionnaires by email, check your SPAM.
- If you encounter any other difficulties not mentioned in this user manual, please contact the support by email at support@moovcare.com.
- Users are expressly informed that the use of Moovcare® lung in a potentially hazardous environment is associated with safety risks that do not may not be fully processed by the manufacturer of the digital health app (Example: registration of the login / password on a public computer).

7. *Personal data*

Using Moovcare® application requires you to enter your personal data. Your treating physician or other caregiver who perform the initial registration will be responsible for collecting your data. You will also need to enter some of your personal details, such as: address, telephone number, mobile phone number, social security number. The health center has access to these administrative data to facilitate your exchanges. The use of the Moovcare® application also requires your consent to monitor and store your health data. At the initial registration the physician will ask you few questions about your health condition to complete eligibility process. You will also report your health data each time you answer a questionnaire.

Your personal data are all stored into securized data centers, depending on your country, more details are provided end of the document. Moovcare® application is a regulated health medical device, all data is securely archived for 10 years.

SIVAN Innovation may be required to use the data for the purposes of studies, research and development, or statistics, for its own or partner needs, or at the request of national or international health authorities. All data will be pseudonomized before any usage.

Telephonic technical support will ask for your consent before providing the service. You will need to provide your consent again to record the phone conversation. This data is stored on a secured server in USA. Our provider commits to offer an adequate level of data protection compliant with GDPR, with the use of standard contractual clauses. Data might also be transferred to the manufacturer site based in Israel. Israel is recognized by the European Union as having an adequate level of security for personal data protection.

Some of your personal data (technical support / satisfaction survey) are transfered to the manufacturer, outside of Europe. European Union recognizes the country of the manufacturer with an adequate level of protection regarding personal data.

In accordance with the French privacy law and the European regulation 2016/679 you benefit from the following rights in respect of your personal data, in the limit of law definition: right access the data, right of rectification, right to erase, right to the limitation of this treatment, right to oppose this treatment, right to the portability of your data, right on data profiling.

For portability purposes, you have the option of requesting direct access to your data, in JSON file format. The content of the file does not have a specific required data format. You can receive: the history of responses to the questionnaire, administrative and medical data, history of e-mails received, alerts (symptoms that were triggered, date, time, doctor who closed the alert).









If you wish to apply one of your rights, please contact your treating physician or the medical physician responsible at the health data center.

You can also contact Sivan's data protection officer at DPO@sivan-innovation.com. In this application, please give us your name, surname, email address, institution and your request.

If you had consented to participate in a survey conducted by SIVAN INNOVATION and SIVAN France and you no longer want 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 feedback 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. Note that if you do not respond to this survey, you will continue to receive it.

We make every effort to respect the GDPR in order to guarantee the security and your rights regarding your personal data. However, in the event that you find a breach of this regulation, you are entitled to lodge a complaint with the supervisory authority, the CNIL (www.CNIL.fr) or the data protection officer (DPO) of the data processing Manager (DPO of the health facility or DPO of the application manufacturer, DPO@sivan-innovation.com).

8. Symbols

	Manufacturer		Software version		Edit
	Date of manufacture		number Read instruction		Return
	Authorized European representative		for use		Menu

9. Date of manufacture/CE marking

CE mark holder: SIVAN INNOVATION LTD. CE marking approval: July 2017

Date of manufacture: refer to the about section which is located at the bottom of the questionnaire pages.

Revision date: Date of publication of the notice Moovcare® lung v3.8.0 (API 3.8.0) : May 2021

10. Legal notice

Moovcare® lung is a medical device published and distributed by SIVAN INNOVATION Ltd, with a capital of 100 000 shekels whose registered office is located at 19 Ha rtom Street, 97775 Jerusalem, Israel, 51-509695-6.

Tel.:(+ 33) 02 43 78 33 31 - Fax: (+ 33) 02.43.78.49.93 - Mail: courrier@sivan-innovation.com

For France, the publication Director: Mr. Daniel Israel, President

For France, the editorial officer: Mr. Daniel Israel, President

10. Legal notice

The application Moovcare® lung is hosted by the company Avenir Telematique SA (ate), with capital of 60 000 € whose head office is located 21 Avenue de la creativité, 59650 Villeneuve d'Ascq, France, and registered in the register of Business and companies of Lille MÉTROPOLE under number 347 607 764

Tel.: (+ 33) (0) 3 28 80 03 00 - Mail: contact@ate.info

Legal representative: Mr. Maxence ROUSSEAU, President

Moovcare® lung, class I medical device

www.sivan-innovation.com

For European users, Moovcare Lung is hosted by the EURIS Health Cloud company, , (408 760 130 R.C.S. NANTERRE), 116 rue de Silly - 92100 Boulogne-Billancourt – France (Datacenters located in Germany). Data Protection Officer: dpo@euris.com.

In the United States of America (USA), the datacenter HIPAA compliant provider that is used to host all the personal data obtained through the use of software and applications (MOOV CARE®) is EURIS-HEALTH CLOUD company, (408 760 130 R.C.S. NANTERRE), 116 rue de Silly - 92100 Boulogne-Billancourt – France (Datacenters located in USA).



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