



moovcare

By Sivan

MOOV CARE® Toxicity

**Medical monitoring of toxicities related to
cancer treatments**

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 **Sivan**

**User Guide for Healthcare
Professionals**



2797

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MOOVCARE® Toxicity is a registered trademark of Sivan Innovation. All trademarks are the property of their respective owners.

Please read this entire guide carefully before using MOOVCARE® Toxicity, Medical Device as it contains important information.

Please carefully follow the information provided in this guide when using MOOVCARE® Toxicity. Keep this guide in a safe place. You may need to refer to it later.

A technical support team is available to help you use MOOVCARE® Toxicity.

Contact us directly by email at support@moovcare.com or by phone at 09.72.57.22.10 and we will get back to you with an answer within 24 hours.

The user manual can be requested in printed form, free of charge, by simply sending an email to support@moovcare.com with your full address (response within 7 working days).

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1. Introduction

This manual is intended to guide healthcare professionals in using the MOOV CARE® Toxicity application. This manual is available to users at any time via a dedicated menu.



À Propos	Informazioni	About
France	Italia	USA
Moovcare® Poumon : dispositif médical de classe IIa Web-application de télésurveillance personnalisée des patients atteints d'un cancer du poumon	Moovcare® Polmone: Dispositivo medico di classe IIa Applicazione web per la telerabilitazione personalizzata dei pazienti affetti da tumore al polmone	Moovcare® Lung: Decision support tool compliant with the FDA classification for Mobile Medical Devices, Section VB Personalized web-based telemonitoring application for patients with lung cancer
Moovcare® Toxicité : dispositif médical de classe IIa Web-application de télésurveillance pour la détection précoce des toxicités liées aux traitements anticancéreux	Moovcare® Tossicità: Dispositivo medico di classe IIa Applicazione web di telemonitoraggio per la rilevazione precoce delle tossicità legate ai trattamenti oncologici	Moovcare® Toxicity: Decision support tool compliant with the FDA classification for Mobile Medical Devices, Section VB Web-based telemonitoring application for the early detection of treatment-related toxicities in cancer patients
Guide d'utilisation des patients Poumon Guide d'utilisation des patients Toxicité Conditions Générales d'Utilisation	Manuale d'uso per pazienti Polmone Termini di servizio	Lung Patients user guide Toxicity Patients user guide Terms of service
Mentions légales	Menzioni legali	Legal Mentions
Politique de confidentialité	Politica sulla privacy	Privacy policy
Consentement du patient Consentement à l'assistance technique	Consenso del paziente	Patient Consent Excluding patients under clinical research
Sivan Innovation Ha-Tidhar Street 5, Ra'anana - Israel 4366507	Sivan Innovation Ha-Tidhar Street 5, Ra'anana - Israel 4366507	Sivan Innovation Ha-Tidhar Street 5, Ra'anana - Israel 4366507
Sivan France 163 Quai Aulagnier F-92600 Asnières-sur-Seine, France	Sivan France 163 Quai Aulagnier F-92600 Asnières-sur-Seine, France	Sivan France 163 Quai Aulagnier F-92600 Asnières-sur-Seine, France
KAPSIKUM 4 rue René Razel 91400, Saclay, France	KAPSIKUM 4 rue René Razel 91400, Saclay, France	KAPSIKUM 4 rue René Razel 91400, Saclay, France
CE 2797	CE 2797	CE 2797

A printed version can be requested, at no extra charge, simply by sending an email tosupport@moovcare.com with your full address (response within 7 business days). This manual must be read before using MOOV CARE® Toxicity. This application is a medical device intended for healthcare professionals.

1.1. Symbols used

	Symbol indicating the medical device manufacturer		Warning symbol
	Symbol indicating the serial number with the 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 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's symbol
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2. Moovcare Toxicity - Product Description

2.1. Product presentation

MOOV CARE® Toxicity is a medical device designed to monitor adult patients with metastatic cancer undergoing chemotherapy, targeted therapies, and/or immunotherapy in order to detect any toxicity related to cancer treatments. It is a software program based on an algorithm that analyzes clinical symptoms. These symptoms, which can be precursors to complications, are collected using questionnaires completed by the patients.

It allows for active, individual and remote monitoring of patients by their doctor.

Once registration is complete, the system sends the patient a link via email allowing them to fill out a questionnaire each week. Patients can also log in to their interface whenever they wish and complete a questionnaire if they deem it necessary. Questionnaires can be completed by the patient using a computer, tablet, or smartphone. Patients do not have access to any historical data they have entered.

The MOOV CARE® Toxicity algorithm then analyzes the patient's responses and in case of potential toxicity, an alert is generated to the care team, via their interface, as well as by email or SMS (optional).

All alerts and responses from the patient can be viewed by the medical staff of the center to which they are attached.

MOOV CARE® Toxicity is a digital application accessible through a secure personal space. It requires no download or installation. It can be used on any compatible computer, tablet, or smartphone.

MOOV CARE® Toxicity is a class IIa medical device.

2.2. Warnings

MOOV CARE® Toxicity is not a substitute for a diagnosis established by a healthcare professional.

Please ensure you consider any new comorbidities, the introduction of new medications, the use of other devices, or anything else that might affect the recorded symptoms. Very little information from the patient's clinical record is entered into MOOV CARE® Toxicity; therefore, it is best to refer to the patient's medical record to establish a diagnosis. This is essential to ensure the alert notification is interpreted correctly.

Users are expressly informed that using MOOV CARE® Toxicity in a potentially hazardous environment is associated with security risks that cannot be fully mitigated by the manufacturer of the digital health application. (Example: saving login/password on a public computer)

Do not use browser-based automatic translators as this may interfere with the correct wording.

Your MOOV CARE® Toxicity access code (password) is personal and confidential. It must not be shared with anyone. The performance of this medical device depends on the proper management of alerts issued by MOOV CARE® Toxicity. Improper management of an alert or an unmanaged alert would not be in the patient's best interest.

If an alert is triggered by the device, you must confirm the alert and check with your patient that no errors were entered when completing the questionnaire.

If you are unable to address the alert within the allotted time, you have the option of designating other physicians at your center during the system's implementation to take over. Alerts are then forwarded to these physicians through a follow-up system until the alert is resolved. Furthermore, some alerts are related to complications that may require immediate treatment. You also have the option of designating a nurse to manage alerts by setting up specific authorizations.

We also ask you to qualify the alert received when your investigation is complete and a diagnosis is made.

If your patient forgets to answer their questionnaire, you will receive more frequent notifications indicating that your patient is late.

2.3. Indications

Monitoring of adult patients with metastatic cancer undergoing treatment with chemotherapy, immunotherapy or targeted therapies.

2.4. Contraindications

No adverse effects have been identified to date.

The contraindications for MOOV CARE® Toxicity are as follows:

- The application is not suitable for people under 18 years of age.
- If a patient requires assistance using MOOV CARE® Toxicity (for example, due to significant cognitive problems), a family member or friend can assist with monitoring. This family member or friend must be designated by the patient during registration to be enrolled and receive information by email. The patient can add a family member or trusted person at any time during their follow-up.

2.5. Target users

The application is designed for use by healthcare professionals and their patients. The application includes five user interfaces:

- one for patients,
- one for doctors,
- one for the assistant's profile,
- One for the nursing profile, at least one of the healthcare professional accounts will be configured as the health center administrator.
- one for Sivan support (Back Office) which creates health center accounts and professional user accounts

2.6. Target patients

Metastatic patients undergoing chemotherapy, targeted therapy or immunotherapy.

2.7. Performance characteristics

The use of MOOV CARE® Toxicity improves the quality of life for patients using this medical device. A clinical study conducted on 1191 patients demonstrated a statistically significant improvement in physical function, symptom control, and quality of life at 3 months, with average improvements of approximately 2.5 points on a quality of life scale of 0 to 100 points.

2.8. Prerequisites for using the DM

No installation required – MOOV CARE® Toxicity is a web application that requires no installation or configuration before use. However, it is sometimes necessary to check accessibility by configuring the firewalls of the device being used (computer). Healthcare professionals do not need to download the application from download platforms. However, all users (healthcare professionals and patients) must have an internet connection and an email address to use it. As MOOV CARE® Toxicity is a web application, users are always browsing the latest validated version without needing to update.

MOOV CARE® Toxicity can be used on internet browsers from the following versions (ensuring SSL compatibility): Firefox 109, Chrome 109, Internet Explorer 11, Safari 16, Edge 110 and provided that the browsers are used on the following operating systems from the following versions: Android 12; Windows 7; iOS 18; OS X 13.4.

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

2.9. Software lifespan

The software has a lifespan of 3 years.

2.10. Report a serious incident

Report a serious incident

In case of a serious incident, contact the support team immediately by email at support@moovcare.com as well as the competent authority in the country where you are located. It is also recommended to inform the agent by email at the following address: contact@kapsikum.com

A serious incident is defined as follows: any incident that has directly or indirectly resulted in, is likely to have resulted in, or is likely to result in:

- the death of a patient, user or any other person;
- a serious deterioration, temporary or permanent, in the health of a patient, of a

- user or any other person;
- a serious threat to public health
-

3. User guide

3.1. User profiles

The MOOV CARE® Toxicity application includes the following profiles:

- Administrator
- Doctor
- Nurse
- Medical Assistant
- Patient or relative

This guide will cover all profiles except for the patient and the relative.

Functionality	Administrator	Doctor	Nurse	Medical Assistant
User account creation	FD	FND	FND	FND
User account editing	FD	FND	FND	FND
Account deactivation	FD	FND	FND	FND
Patient creation	FND	FD	FD	FD
Viewing patient alerts	FND	FD	FaD	FaD
Visualizing staff data	FD	FD	FD	FD
Staff Member Management	FD	FND	FND	FND
Receiving alert notifications	FND	FD	FD	FND
Consulting the patient list	FND	FD	FD	FD

- Feature available (FD)
- On-demand functionality (FaD)
- Feature not available (FND)

Note The features presented here will be detailed later in this guide.

This screen provides an overview of the patients in your account and allows easy access to key actions. Here you can see:

This screen displays new alerts and alerts currently under investigation.

In the top right corner, the user has access to different interfaces. The menu in the top left corner allows them to access their personal settings and log out.



Figure 5: Patient record - List of alerts

Each patient has a personal file in which designated healthcare staff have access to the clinical and personal data of the patient concerned, as well as the actions available to manage the follow-up of that patient, provided that the rights have been assigned to them.



Figure 6: Patient questionnaire history

It is possible to display the patient's questionnaire history. The color code represents the symptoms that triggered an alert.

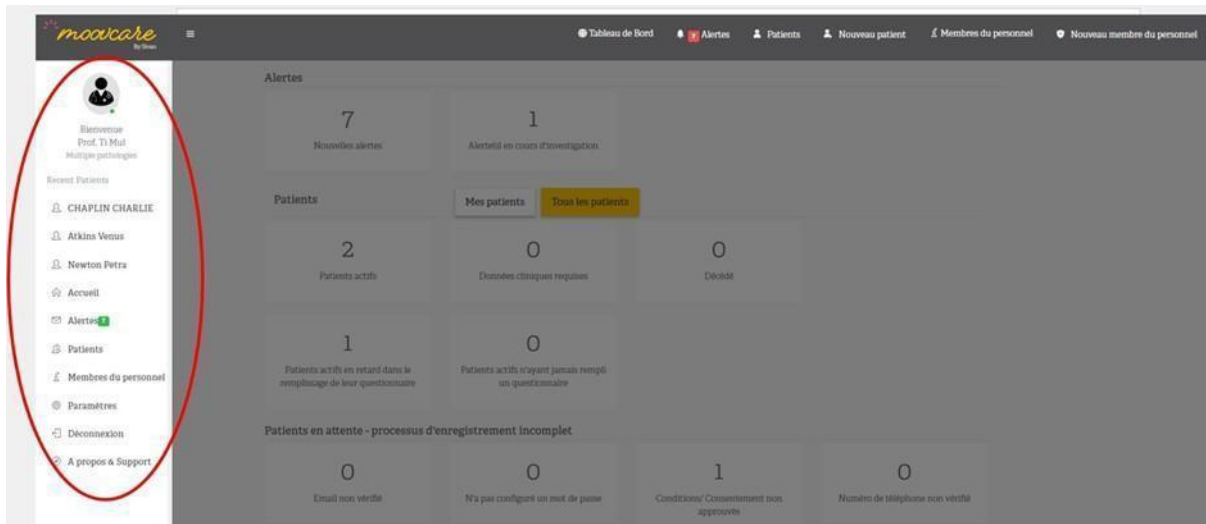


Figure 7: Application Menu

This space, present on all pages of your personal space, allows access to technical support/documentation.

3.2.2. Create an account

Access to the MOOV CARE® Toxicity personal space requires the creation of an account.

Only individuals designated by the medical team within a healthcare center can create an account for another healthcare professional. The opening of a center is managed by the SIVAN team.

Once the account is created, an email is sent to confirm the user's registration. The subject of the email is "Moovcare email verification" and the email contains the user's first and last name. To activate your account, simply follow these steps:

- Click on the link received by email
- Choose a password (at least 12 characters, combining letters, numbers and special characters)
- Enter a mobile phone number (allows account validation and receipt of SMS alerts)
- Log in by entering your password and email address
- Read and accept the General Terms and Conditions of Use (GTC)
- Enter the security code received by SMS

3.2.3. Account access

Access to the account is via the website <https://dashboard.moovcare.com/>

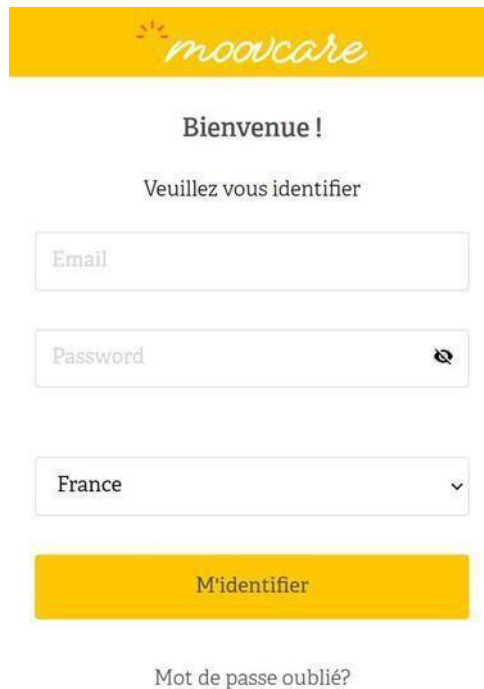
The image shows the Moovcare login interface. At the top is a yellow banner with the 'moovcare' logo. Below it, the text 'Bienvenue !' is centered. Underneath is the instruction 'Veuillez vous identifier'. There are three input fields: 'Email', 'Password' (with a toggle icon for visibility), and a dropdown menu currently set to 'France'. A yellow 'M'identifier' button is below the fields. At the bottom, there is a link for 'Mot de passe oublié?'.

Figure 1: Connection interface

Enter your email address and password, then click "Log in" to access your personal account. If you enter the wrong password, you can enter it again.

Attention : **The number of login attempts is limited to 10 attempts per hour.** If this quota is exceeded, a pop-up will appear indicating the need to contact support to reset the password.

Forgot your password?

If you have forgotten your password, the process to follow is as follows:

- Click on "Forgot your password?" on the login page (see Figure 1)
- Upon receiving a verification SMS, enter the code received into the application.
- Once the phone number is verified, open the email you received and click on the password recovery link.
- Enter a new password
- Access the login interface and log in with your username and new password.

Attention : If the email address is invalid, the email allowing you to change your password cannot be sent. This information is indicated by the following red message: **"Sorry, we can't find that email address."**

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

3.2.4. Configure your personal space

The default settings of your MOOV CARE® Toxicity personal space (language, calendar, units of measurement) are automatically determined by the country entered by the administrator of your care center.

In your personal space, within the menu you have the option to change the settings

following:

- Personal data: Title, First name, Last name, Gender, Date of birth
- Contact details: Email address, Mobile number, Landline number, how would you like to receive alerts (communication channel: SMS or email)
- Assistant: Named assistant (only for the doctor profile)
- Tracking parameters: Language, Temperature unit, Weight unit
- Password

Note: The format of telephone numbers to be used corresponds to the international format and must include the country code.

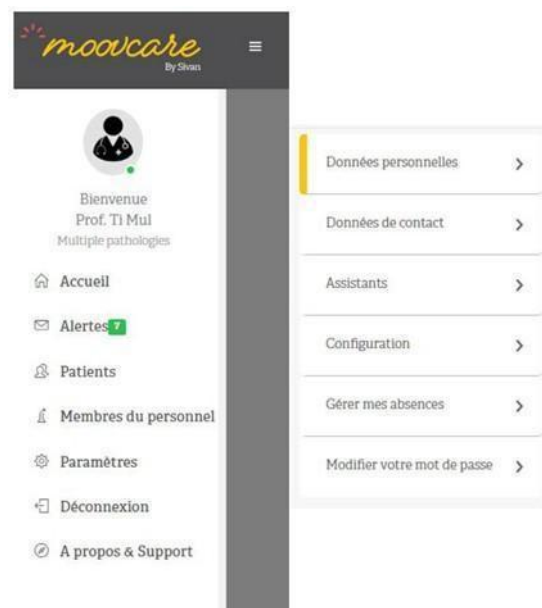


Figure 2: Personal Space Interface

3.2.5. Connection session expired

A login session is scheduled to expire after 30 minutes of inactivity. Two minutes before the automatic logout, a window will appear asking if you wish to continue this session.

To reply, click the designated button. If you do not reply, you will be automatically logged out.

3.3. Patient administrative management

3.3.1. Registration of a new patient

Before creating an account, the patient must be informed of the following points:

- The patient must inform the practitioner of any new symptoms not listed in the questionnaires provided. This information can be provided in the free text field at the end of the questionnaire.
- If the patient is unable to complete a questionnaire (no internet access, hospitalization, etc.), they must inform the practitioner.

From the main menu, you can add a patient by clicking on **New patient**.

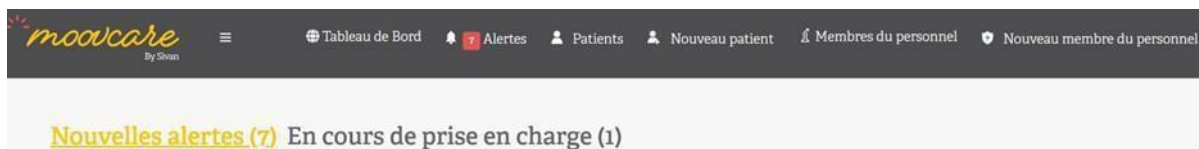


Figure 3: MOOV CARE® Toxicity Menu

The following administrative information is required to register the patient in the MOOV CARE® Toxicity system:

- First name
- Surname
- Email address – This link will allow the patient to activate their profile and receive links to complete questionnaires.
- Date of birth
- Mobile phone number – Will allow the patient to receive the authentication code needed to activate the account
- Referring physician – The referring physician is the one who will receive alerts if an

anomaly is detected. The other fields are optional:

- Home phone number
- Patient number stored internally at the care center
- Secondary referring physician - Secondary referring physicians will receive alerts if the primary referring physician has not responded to the alert within 24 hours. All secondary physicians on the list will be alerted.

-

Once the required information has been entered, click on "Create a patient" to finalize the registration.

The account status will be " **On hold** ".

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

profile. Recommendations :

- Register the patient in MOOV CARE® Toxicity as soon as a date for intervention is available so that he/she has time to activate his/her account before the intervention.
- Check with the patient that they have received the email containing the activation link. Remember to check your spam folder.
- Inform the patient correctly about how MOOV CARE® Toxicity works and remind them of the importance of completing the questionnaires.
- If the patient has difficulty activating their account, it is best to assist them.

Once the patient's account is activated, its status will be "Active". The patient will then be able to receive questionnaires to complete.

3.3.2. Modification of a patient's administrative information

In the patient list, click on the patient's name or surname to access their file. Their personal data can be modified by clicking on the corresponding tab.

All information can be modified. It is important to click the "Save" button after making the change for it to take effect.

Important : it is only possible to change the patient's email address while the account is in "Pending" status.The modification is not possible otherwise.

3.3.3. Stop monitoring with MOOV CARE® Toxicity for a patient

To stop monitoring a patient, click on the patient's record. Click on the "Personal Data" tab, then the "Actions" sub-tab. To stop monitoring, select one of the reasons provided:

- Patient deceased
- The patient's account must be closed.

The patient's account will change to "Deactivated" status.

Note: The patient also has the option to withdraw their consent to no longer be monitored by MOOV CARE® Toxicity. Their status will then appear as "Deactivated." The patient's data must be archived (detailed below) so that they are no longer visible on the dashboards.

3.3.4. Archiving a patient's data

To archive a patient's data, click on the patient's record. Click on the "Personal Data" tab, then the "Actions" sub-tab. There are then two possible scenarios:

- The patient has not withdrawn their consent: monitoring must therefore be stopped (see 3.2.4). The "Archive" button will allow the patient's data to be archived.
- The patient has withdrawn their consent: the "Archive" button will allow the patient's data to be archived.

To exercise the patient's right to erasure, you should contact your data processors (SIVAN Innovation, ATE), as the erasure of patient data is carried out with the healthcare hosting provider.

3.3.5. Reactivate MOOV CARE® Toxicity monitoring for a patient

A patient's deactivated account can be reactivated.

Click on the patient's record. Click on the "Personal Data" tab, then the "Actions" sub-tab.

The "Activate Account" button allows you to track the patient again. The patient will need to complete the account validation steps again to receive the questionnaires.

3.3.6. Patient account status

The patient account can have the following statuses:

- Active: the patient can receive and answer questionnaires
- Pending: The patient has not validated their account and therefore cannot receive questionnaires.
- Deactivated: the patient's account is deactivated, they can no longer receive

questionnaires. For patients "pending", the application is waiting for action from them:

- Acceptance of the General Terms and Conditions of Use (GTC)
- Confirmation of consent
- Confirmation of mobile phone number

- Email address confirmation

It is possible to send an activation email to the client so that they can carry out these operations.

3.3.7. Register a loved one, a trusted person, or a caregiver at home to help the patient

The patient may require assistance from a third party to use the application. This person must be registered in the MOOV CARE® Toxicity system in order to receive email alerts.

In the patient's file, on the "Profile" tab, click on the "Nearby" sub-tab. Enter the required information. The third party will need to activate their profile via email and will also need to accept the Terms and Conditions of Use.

3.3.8. Register a general practitioner

You have the option to save the contact information of a general practitioner for a given patient, so you can contact them if needed. Please note that the general practitioner is only registered for informational purposes; they will under no circumstances be contacted by the MOOV CARE® Toxicity system or informed of the patient's condition.

3.4. Patient follow-up

3.4.1. Questionnaire management

General Information

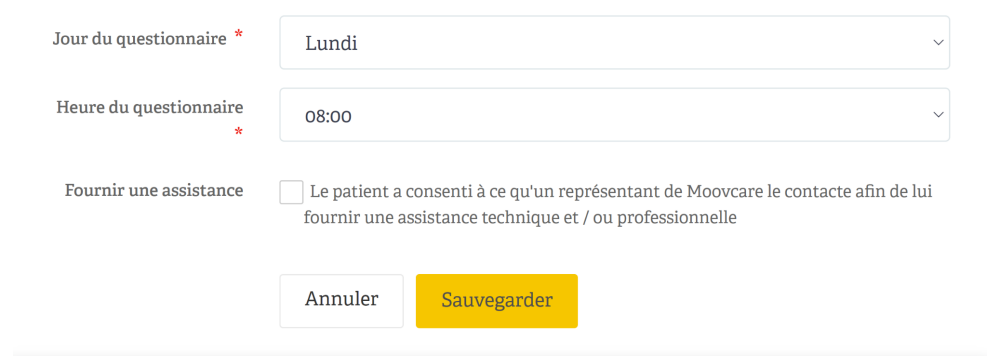
Patients will receive the questionnaire by email on a weekly basis.

Note: these links are not for single use, so the patient can answer the questionnaire several times.

These questionnaires consist of questions about specific side effects in order to assess their severity. It is important that patients are informed about these symptoms and their severity scale when they register on the platform.

A comment field is also available at the end of the questionnaire. Please note that it is important that patients only fill it out with medical information such as changes in their condition or a new phenomenon.

To better tailor your patient's follow-up, the day the questionnaire is sent can be configured from the patient's record. It can be adapted to the day of treatment (e.g., if chemotherapy is administered on Monday, you can configure the questionnaire to be sent on Tuesday or Wednesday depending on the toxicities you wish to detect).



The screenshot shows a web form for configuring questionnaire delivery. It includes two dropdown menus for selecting the day and time, a checkbox for assistance, and two action buttons.

Jour du questionnaire *	Lundi
Heure du questionnaire *	08:00
Fournir une assistance	☐ Le patient a consenti à ce qu'un représentant de Moovcare le contacte afin de lui fournir une assistance technique et / ou professionnelle
Annuler Sauvegarder	

Return of a questionnaire

To send a questionnaire back to a patient, go to the "Profile" tab of the patient's record, then to the sub-tab

"Actions" click on "Resubmit the questionnaire".

Patient late in completing their questionnaire

If a patient does not respond to their questionnaire within 4 days, the referring physician will receive automatic reminders.

In the patient tab of the dashboard, these patients who are late can have 2 statuses:

- Active, with the indication "delayed": No response to the questionnaire for 4 days or more
 - Active, with the indication "non-compliant": No response to the questionnaire for 24 days or more.
- These patients are no longer receiving emails from MOOV CARE® Toxicity

3.4.2. View a patient's information

List of patients

Patients from the same care center are listed in the "Patients" tab. A filter allows you to sort them. :

- Patients followed by the same referring physician
- Depending on the status ("Activated", "Pending",

"Disabled"), the following information is available for each patient:

- Last active date: last date on which a patient performed an action on MOOV CARE® Toxicity (registration, completion of a questionnaire).
- Actions: lists the different actions

that can be taken. Clicking on a patient

allows access to their file.

Patient profile

Arrêt de suivi	
Actif	
Données d'activation	
Email vérifié	✓
A accepté les Conditions Générales d'Utilisation	✓
A donné son consentement	✓
Moovcare Toxicité - A donné son consentement	✓
Téléphone mobile vérifié	✓
Suivi clinique	
Prescription de(s) questionnaire(s)	✓
Attaché à un médecin - M. KNOWLES BEYONCE	✓
Actions	

A patient's file contains all of their personal data.

A "Clinical Data" tab allows the recording of the patient's treatments. This information is not taken into account in the MOOV CARE® Toxicity monitoring and will only have informational value.

For patients with 17 or more questionnaires, some data may not display correctly. In this case, please contact the support team to receive a complete report if needed.

You can leave a comment by clicking on the comment icon.

3.4.3. Transmitting one's medical data to a patient

The patient can request to retrieve their medical data.

Click the "Export" button to download the questionnaire history in PDF format.

***Notel** if a patient has completed 12 or more questionnaires, some data may not display correctly. Contact the support team to receive a complete report if needed.*

If your patient requests to retrieve their medical data (by exercising their access rights or data portability), please contact our Technical Support who will provide it to you in the form of a .JSON file.



Figure 13: Data Export

3.5. Alert management

3.5.1. Receive alerts

Alert content

It is possible to configure the application to receive alerts in the dashboard menu. These alerts can be sent in two ways:

- By email
- Via SMS

Alerts are sent if a symptom is detected by the algorithm following the completion of a questionnaire:

- The algorithm identified a potential symptom dynamic or synergy.
- The patient filled in the free text comment field
-

The email notification allows the following actions:

- Access to the application
- Transfer of the alert to a colleague
- Access to the patient's questionnaire history

Alert configuration

By default, alerts are received in real time, but it is possible to group them into a daily notification summarizing the alerts of the last 24 hours: Menu > Settings > Contact data > Notification frequency.

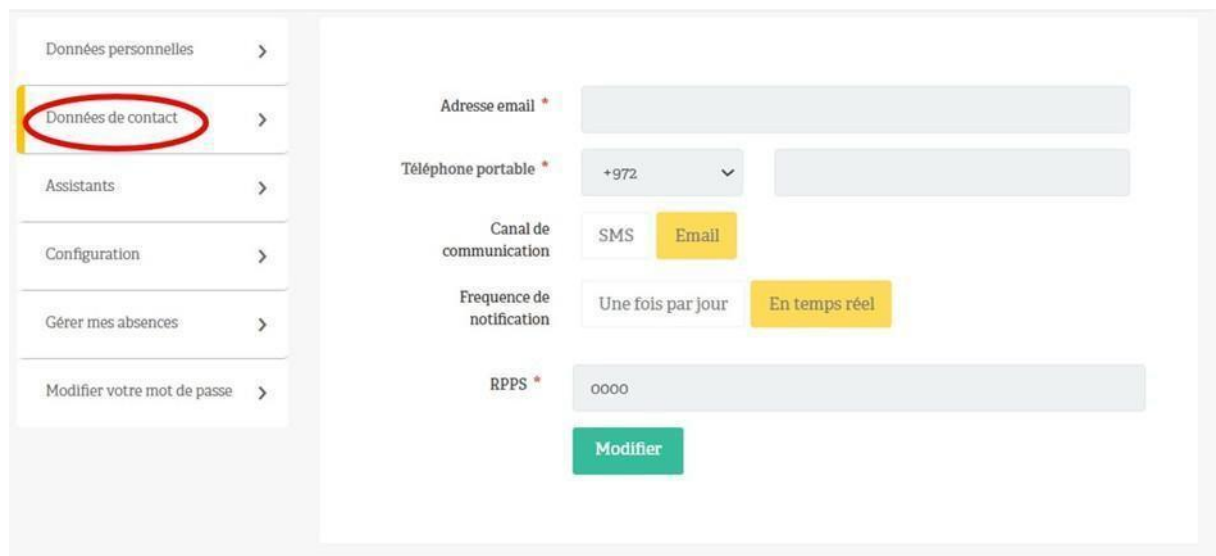


Figure 11: Alert Management

The notification sending time is also configurable when the notification frequency is set to "Once a day".

Attention This change may cause a delay in sending the daily email. It is recommended to proactively check alerts for 48 hours after this change.

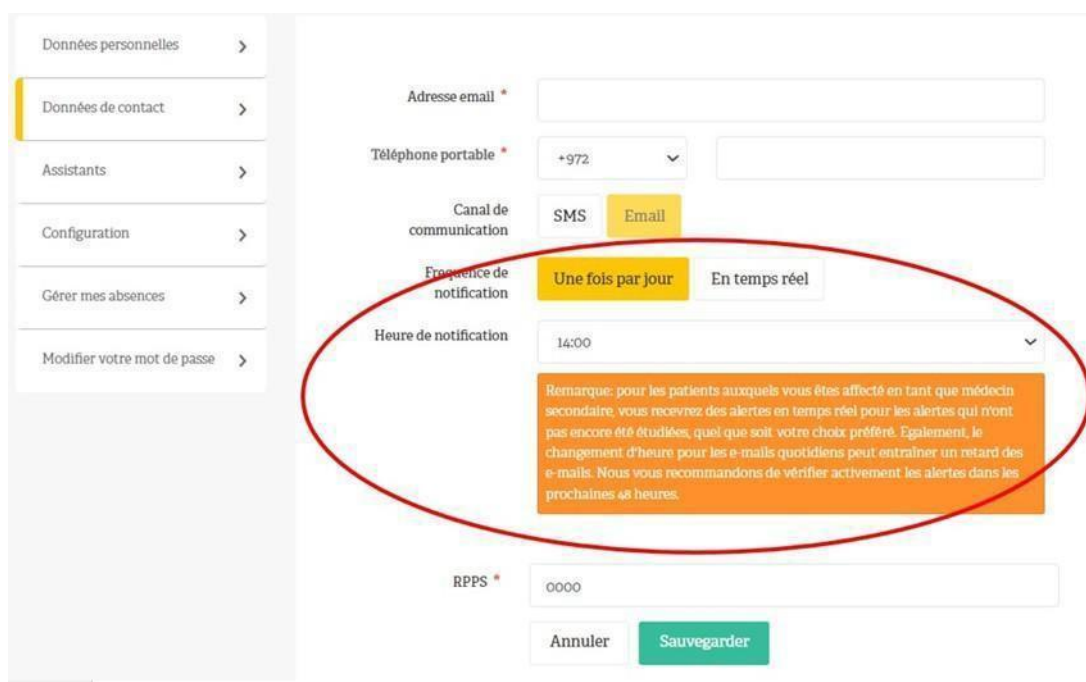


Figure 12: Selecting the alert frequency

Note: For secondary physicians, alerts are not received in real time, regardless of the configuration chosen.

3.5.2. View the triggered alerts

The addresses are accessible in the "Alerts" tab of the dashboard. There are two types of sections:

- New alerts: alerts not being handled.
 - o You will receive notifications (one notification followed by a reminder) until the alert is addressed.
 - o After 24 hours without treatment, this patient's secondary physicians also receive a notification.
 - o After 48 hours without treatment, the patient is notified
- Alerts currently being processed: These alerts can have different statuses.
 - o Under investigation
 - o Transferred
 - o Closed

Patient-specific alerts are available in their patient record.

3.5.3. Manage an alert

An alert provides the following information:

- The patient in question, along with their contact information.
- The time and date the alert was triggered
- The so-called "warning signs" symptoms
- Action buttons to manage the alert
 - o "Manage": Alert considered "being processed"
 - o "Transfer": Passing the alert on to one or more colleagues (see below)
 - o "Close": Alert closed. Will require specific actions
- Access to the patient's questionnaire history
- A transfer notice will be issued if the alert is received by a secondary/relay physician.

NoteThe action buttons redirect the user to the application. No health information is displayed in the emails in order to comply with our privacy policy.

Transfer of an alert

Clicking the "Forward" button displays the alert mailing list. All healthcare professionals listed will receive an alert.

Note: The doctors presented in this list have all been previously registered in the patient's file as Secondary Doctors.

Attention : If no doctor (secondary or not) has dealt with the alert within 48 hours, the patient will receive a notification by email/SMS asking them to contact their healthcare facility or referring physician.

Alert closed

- Indicate whether any action has been taken
 - o If "no", the alert is closed without any specific action.
 - o If "yes", select the actions taken from the displayed list. (An "Other" line allows you to manually enter the action taken if it is not suggested.)

3.5.4. Automatic alert forwarding

In the event of a prolonged absence, it is possible to set up an automatic transfer of alerts to healthcare professionals previously defined as substitutes.

- Select period of absence – if you are absent for a day, double-click on the desired date
- Select the name of the alternate from the list

Warning: MOOV CARE® Toxicity does not verify the availability of the substitute and will not be held responsible for an alert not dealt with within 48 hours.

3.6. Administrator Account: Roles and Skills

3.6.1. Administrator profile and features

Profile with administrative management rights for a care center using MOOV CARE® Toxicity. The medical team member with this role will be able to perform the following actions:

- Creating user accounts for the following profiles:
 - o Practitioners at the center
 - o Assistant(s)
 - o Nurse(s)
- Account editing
- Account deactivation

A doctor can designate a secondary doctor. Both doctors will receive alerts for this patient.

3.6.2. Management of healthcare professional profiles

Create user accounts

To create a healthcare professional within the MOOV CARE® Toxicity application, click on the "New staff member" tab located on the fixed toolbar at the top of the page.

For each profile, the administrator must fill in the person's "Personal Data" and "Contact Data". All fields are mandatory.

The email address entered will be the address to which the profile activation link will be sent.

The phone number entered will receive the verification code.

Suivez les étapes pour ajouter un nouveau Membre du personnel

Données du membre du personnel

Données personnelles >

Données de contact >

Profil *

Médecin

Assistant(e)

Infirmier(e)

Titre *

M.

Mme.

Dr.

Prof.

Prénom *

Nom *

Genre *

Homme

Femme

Langue *

Français

Suivant

Figure 14: Creating a new user

The MOOV CARE® Toxicity system includes a default setting for the Assistant and Nurse profiles. The default setting includes only basic administrative functions. By default, The assistant and the nurse can:

- Add a patient: enter personal information, contact details, select the referring physician and the referring physician only.
- View the staff of the health center to which he is attached
- View the list of patients at the health center: administrative information only

Define the access rights and functionalities of an assistant and nurse profile

The Assistant and Nurse profiles are defined by default with minimal access to patients' personal data.

It is possible to grant these profiles access to the following features:

- Managing medical staff
- Manage alerts
- Receiving alerts by email

To do this, select a nurse from the "Personnel" list.

4 Médecins

b

Statut: Tout

Nom	Email	Téléphone	Assistants	Statut	RPPS	Autorisations
Dr. B A	martin.dalmas+020@sivan-innovation.com	+(33) 6 33 38 98 30		En attente	2	Défaut
Dr. B A	martin.dalmas+030@sivan-innovation.com	+(33) 6 33 38 98 30		En attente	2	Défaut
Dr. B A	martin.dalmas+0002@sivan-innovation.com	+(33) 6 33 38 98 30		En attente	2	Défaut
M. KNOWLES BEYONCE	caroline.borges+doctmultisurvey@sivan-innovation.com	+(33) 7 66 65 28 77		Actif	10106186967	Défaut

0 Assistants

rechercher

Statut: Tout

Nom	Email	Téléphone	Médecin	Statut
Pas de résultat				

1 Infirmier(e)s

rechercher

Statut: Tout

Nom	Email	Téléphone	Médecin	Statut	RPPS	Autorisations
Mme. Connor Sarah	dnwliqrjg@gmail.com	+(33) 6 12 34 56 78	M. KNOWLES BEYONCE	En attente		Défaut

Figure 15: Selection of a Nursing Profile

Access the permissions tab

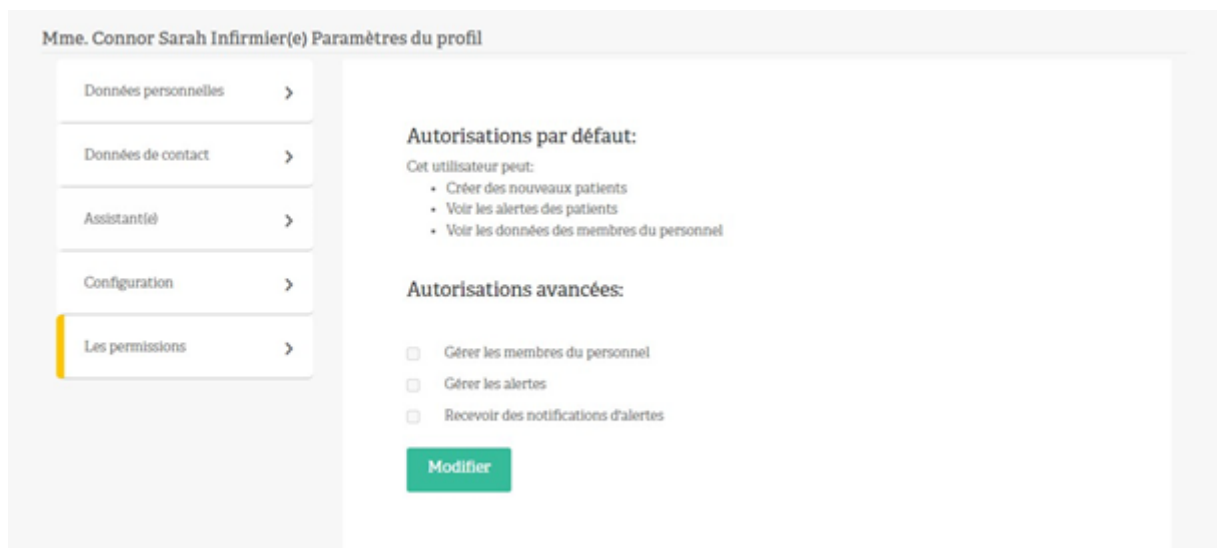


Figure 16: Permissions of a profile

Click on "Edit" and select the desired functions from the following list:

- Managing medical staff: the nurse will be able to add new staff members and modify the details of existing staff.
- Manage alerts:
 - o The nurse will be able to close, investigate and forward alerts to other doctors.
 - o The assistant will only be able to forward the alerts, not manage them.
- Receiving alert notifications: The nurse/assistant can receive alert notifications and forward the alert if necessary.

The nurse/assistant must be informed of these new authorizations.

***Note** A doctor must always be responsible for managing an alert, even if a nurse has been designated, the doctor will always be informed and will have the responsibility to manage the alert.*

Edit accounts

Editing healthcare professional accounts is not permitted, even for the administrator. Only users can modify their own information.

Archive accounts

It is possible to archive a staff member's account.

This option is only available if the doctor is no longer following the patients (this applies to the primary or secondary doctor) and their account has been deactivated.

A request to archive this staff member's information can be made directly to us by email sent to tosupport@moovcare.com.

If an account has been archived in error, the user will no longer have access to it. A new verification link will be sent to the user, who will then have to complete the validation steps again, including accepting the Terms and Conditions.

4. Contact et Support

A technical support team is available to help you use MOOV CARE® Toxicity.

Contact us directly by email at atsupport@moovcare.com and we will get back to you with an answer within 24 hours.

For any technical assistance, you can contact us at any time via email at atsupport@moovcare.com and we will make sure to respond to you within 24 hours.

Contact us by phone at 09 72 57 22 10 (free call) from Monday to Friday from 09:00 to 12:00 and from 14:00 to 17:00 (French time)

5. Update and Maintenance

No user maintenance is required. Updates performed by Sivan Innovation fix bugs and implement new features.

MOOVCARE® Toxicity, being a SaaS (Software as a Service) solution, does not require any disposal precautions.

6. Manufacturer Information

Moovcare® is a medical device published by SIVAN INNOVATION Ltd, with a capital of 100,000 shekels, whose registered office is located at Hatidhar 5, Raanana, Israel, 51-509695-6.

Tel. : +972 2-567-7808 - Email : courrier@sivan-innovation.com

Publishing Director & Editorial Manager: Mr. Daniel Israel, President

SIVAN Innovation is represented by its agent Kapsikum, whose registered office is located at 4 rue René Razel 91400, Saclay, France

Email : contact@kapsikum.com

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

Tel.: (+33) 9 78 07 20 78 - Email: contact@ate.info

Legal representative: Mr. Maxence ROUSSEAU, President

Moovcare® lung, class IIa medical device <https://www.moovcare.com/>

7. Operating Principle

MOOVCARE® Toxicity is a medical device designed to monitor adult patients with metastatic cancer undergoing chemotherapy, targeted therapies, and/or immunotherapy, in order to detect any toxicity related to cancer treatments. It is a software program based on a clinical symptom analysis algorithm. It allows for active, individualized, and remote patient monitoring by their physician.

In practice:

MOOVCARE® Toxicity includes a questionnaire based on classic symptoms that patients may experience, which can be precursors to toxicities.

Once registration is complete, the system sends the patient a link via email allowing them to fill out a questionnaire each week. Patients can also log in to their interface whenever they wish and complete a questionnaire if they deem it necessary. Questionnaires can be completed by the patient using a computer, tablet, or smartphone. Patients do not have access to any historical data they have entered.

The MOOVCARE® Toxicity algorithm then analyzes the patient's responses and in case of potential complications, an alert is generated to the medical care team, via their interface, as well as by email or SMS (optional).

All alerts and responses from the patient can be viewed and analyzed by the medical staff of the specific center.

MOOVCARE® Toxicity is a digital application accessible through a secure personal space. It requires no download or installation. It can be used on any compatible computer, tablet, or smartphone.

8. Regarding your personal data

Using the MOOV CARE® Toxicity platform requires the entry of certain personal data for it to function. As part of your professional activity, you will be required to provide your surname, first name(s), date of birth (optional), your healthcare provider ID, gender, title, language, email address, work phone number, mobile phone number, and the phone number of the healthcare facility to which you are affiliated or for which you are employed.

The data controller is the study sponsor. None of your direct personal data will be used in the research database. The data entered into the electronic file will be limited and separate from the data collected for the operation of the MOOV CARE® Toxicity platform.

Providing this personal data allows us to establish regular communication with a given patient, while ensuring the secure transfer of that patient's personal information. For example, we validate your identification information using your email address and mobile phone number.

The collection of your personal data also allows us to communicate with you information on the use of the application itself, in the event of security information related to the application, and which may be used for commercial purposes (manufacturer - healthcare establishment relationship).

Cookies: The device is available in different versions 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 using 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 that we will collect the data provided. The aim is to improve the technical support we provide. This information is shared with the technical team, the regulatory department, the quality assurance department, and the sales teams.

Your personal data is stored for the duration of your use of the application by a specific healthcare center. As the MOOV CARE® Toxicity application is a controlled device, this information is then archived for regulatory traceability purposes for 10 years.

Regarding the transmission of your personal data: The application interface data is hosted by the hosting provider whose contact details are provided below. To provide technical support following the implementation of the health center, management is transferred to Israel, where SIVAN INNOVATION's headquarters are located. Israel is a country recognized by the EU as having an adequate level of personal data protection. As part of our business relationship, data may be hosted outside Europe by one of our subcontractors. In this case, we ensure that this data is properly protected and that security measures stipulated in the standard contractual clauses (SCC) are implemented.

In accordance with the new French Data Protection Act and Regulation (EU) 2016/679 (GDPR), your personal data is covered by the following rights:

- Right of access
- Right to rectification Right to erasure
- Right to restrict processing Right to object
- Right to data portability

To request the exercise of your rights, you can contact our Data Protection Officer at the addressdpo@sivan-innovation.com.

In this request, please specify your surname, first name, email address, institution as well as the nature of the right(s) you wish to exercise, accompanied by a copy of your identity card in order to authenticate you.

We make every effort to comply with Data Protection Regulations to guarantee the security of your data and your rights. However, should you notice a breach of these regulations, you have the right to lodge a complaint with the supervisory authority (the CNIL, www.cnil.fr, or the data protection officer (DPP or DPO in English) of the data controller of your data (DPO of the healthcare facility or DPO of the application manufacturer, dpo@sivan-innovation.com).



MOOV-TOX_PHYSICIAN_IFU_ENGLISH_05_26