General terms and conditions of use and sale of the MOOVCARE application® In France

Any use of the Application is subject to prior knowledge and express acceptance of these General Terms of Use (part 2), these General Terms of Sale (part 3) and their common general provisions (part 1).

1 PART 1 - PROVISIONSGENERALCOMMUNES

1.1 Legal

noticeApplication

Publisher

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

European representative of the Application Publisher
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

Application Importer
SIVAN France (824 329 106 R.C.S. PARIS)
163 Quai Aulagnier, 92600 Asnières-sur-Seine, FRANCE
Telephone: +33 1 88 24 40 57

Certified health data host
AVENIR TELEMATIQUE SA (ATE), with a capital of €60,000
whose registered office is located at 21 avenue de la Créativité, F-59650 VILLENEUVE D'ASCQ, and registered with the Trade and Companies Register of Lille Metropole B 347 607 764 under number 347 607 764.
Telephone: (+33) 09 78 07 20 78
Mail : contact@ate.info

1.2 Definitions

The terms defined below have the meaning and scope given in their definitions within the framework of the conclusion and execution of the general terms of use and general terms of sale of the MOOVCARE medical device.®, of class I, whose technical instructions for use can be accessed by clicking on:https://patient.moovcare.com/legal orhttps://dashboard.moovcare.com/legal

« Application » refers to a medical software device consisting of a web application, specific software with a SaaS web platform and accessible at the addresshttps://patient.moovcare.comfor Patient Users or downloadable from an app store for Patient Users;
and dashboard.moovcare.com for Professional Users of a Care Center
; the Practitioner decides under his sole responsibility to prescribe the use of the Application to the Patient;

"Care Center"refers to the healthcare facility subscribing to the Application, its services and content, and comprising administrative staff to support the activity of Practitioners;

"CGU"refers to these general terms and conditions of use of the Application provided for in part 2 of this document;

« **CGV**» refers to these general terms and conditions of sale of the Application concluded between the Patient User and the company SIVAN France which markets the Application and provided for in part 3 of this document;

« Compte MOOVCARE® » refers to the secure account allowing the User to access their personal space, for the purpose of using the Application's Services and Content, and in specific cases:

- **"Patient Account"**refers to the secure account of a Patient meeting the eligibility criteria of the Application, strictly assessed by the Practitioner, under his own and exclusive responsibility;

- **“Practitioner Account”**refers to the secure account created by the Practitioner's Care Center Administrator and intended for the Practitioner;
- **“Practitioner Assistant Account”**refers to the secure account created by the Care Center Administrator and intended for the Practitioner's Assistant;
- **“Personal Medical Account”**refers to the secure account created by the Care Center Administrator and intended for Medical Staff;
- **"Specialized Nurse Account"**refers to the secure account created by the Care Center Administrator for a specialized Nurse;
- **"Administrator role at the Care Center"**refers to the secure function assigned by SIVAN INNOVATION Ltd to an account previously determined by the Care Center (whether it is a Practitioner account, Assistant to the Practitioner, Medical Staff or Specialized Nurse), at the time of the care center's subscription to the Application;

"Contents"refers to all texts, images, functionalities and more broadly any element existing within the Application;

« **Order** » refers to the purchase by the Patient User of the Application on the basis of a medical prescription issued by the Prescriber to the Patient User;

“Personal data”refers to any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;

"Publisher"or the**" Company "** refers to the company SIVAN INNOVATION Ltd which publishes the Application within the meaning of Law No. 2004-575 of 21 June 2004 for confidence in the digital economy (known as the "LCEN law");

“Personal space”refers to the private and secure space to which the User has access via a MOOVCARE Account®, for the use of the Application's Services and Content;

- **"Patient Area"**: refers to the Patient User's personal space giving them access to the Application, its Services and Content as it relates to them;
- **"Practitioner Area"**refers to the Practitioner User's personal space giving them access to the Application, its Services and Content with regard to their Patients and their personal information;
- **"Practitioner's Assistant Area"**refers to the personal space of the Practitioner's Assistant User giving him/her access to the Application, its Services and Content, within the strict limits of his/her duties;
- **“Personal Medical Space”**refers to the Personal Space of the Medical Personnel User giving them access to the Application, its Services and Content, strictly within the limits of their duties;
- **"Specialized Nursing Area"**refers to the personal space of the specialized Nurse User giving him/her access to the Application, its Services and Content, within the strict limits of his/her duties;

« **Force majeure**" refers, according to the terms of Article 1218 of the Civil Code, to an event beyond the control of the debtor and preventing the performance of his

obligation, which could not reasonably have been foreseen at the time of the conclusion of the contract and whose effects cannot be avoided by appropriate measures.

« **Prescriber**» refers to the healthcare professional who prescribes the Application to the Patient User by means of a prescription; « **Technical user manuals**" refers to the notices made available to Users by the Publisher describing the functionalities of the Application and accessible here (https://patient.moovcare.com/legal orhttps://dashboard.moovcare.com/legal);

« **Funding body**» refers to any company, or private or public body or body responsible for a public service mission, and in general any legal entity providing all or part of the financing of the Application for the benefit of Patient Users under certain conditions defined by regulations and where applicable by contractual commitments;

" Patient " refers to any Patient accessing the Application under the responsibility of their Practitioner and subject to meeting the eligibility criteria;

« **Close** » refers to any person in the Patient's family, any trusted person or caregiver visiting the Patient's home who can assist them in filling out their questionnaire, managing their profile or reminding them of the questionnaire;

"Professionals"refers to the following healthcare professionals and administrative staff:

- **"Practitioner"**refers to any specialist physician in charge of monitoring cancer patients, accessing the Application; any monitoring, medical decision or medical act being provided or delivered to the Patient outside the framework of the Application, under his own and exclusive responsibility;
- **"Practitioner's Assistant"**refers to any health or administrative professional attached to the Practitioner to facilitate their administrative or medical activity as appropriate, accessing the Application within the strict limits of their duties, under the Practitioner's own and exclusive responsibility;
- **"Medical Personnel"**refers to any healthcare professional attached to the Practitioner in order to facilitate their administrative or medical activity, accessing the Application, where applicable under a delegation of tasks, within the strict limits of their duties, under the Practitioner's own and exclusive responsibility;
- **"Specialized nurse"**refers to any nursing healthcare professional attached to the Practitioner in order to facilitate their administrative activity, accessing the Application, where applicable under a delegation of tasks, within the strict limits of their missions, under the Practitioner's own and exclusive responsibility;

"Healthcare professional"refers to any Practitioner, Medical Staff or Nurse accessing the Application;

« **Data protection regulations**» refers to the applicable data protection regulations consisting of, on the one hand, Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data of 27 April 2016 (known as the “GDPR”), and on the other hand, Law No. 78-17 of 6 January 1978, as amended, relating to information technology, files and

freedoms (known as the “Data Protection Act”).

“Data controller”within the meaning of the Data Protection Regulations means:

• Regarding health/medical data relating to Patient Users
: the Practitioner User of the Application or the Care Centre of which he/she is employed where applicable, is Responsible for the processing, as far as he/she is concerned, of the personal data of his/her patients with regard to the Application, within the meaning of the Regulations relating to data protection;

• Regarding administrative data relating to Professional Users: SIVAN INNOVATION Ltd is responsible for the collection and processing of personal data relating to Professionals, for the management of Professional Users of the Services and functionalities of the Application;

« Services » refers to all the services offered to Users from the Application, to allow Patient Users to benefit from the functionalities of the Application described in the Technical Instructions for Use, the latter benefiting from medical monitoring, where appropriate, outside and independently of the Application;

" Subcontractor " As defined by the Data Protection Regulations, this refers to the person, company, or other organization that processes personal data on behalf of the data controller. SIVAN INNOVATION Ltd is a Data Processor for the Practitioner User;

« **subsequent subcontractor**"As defined by the Data Protection Regulations, this refers to the person, company or other body that processes personal data on behalf of the data controller, chosen by the Data Processor. The Approved Health Data Hosting Provider is a Data Processor of the Publisher;

« Support technique » refers to the technical support service offered by the Publisher to Users of the Application;

"Users"refers to any Patient User, or Healthcare Professional or Professional (Practitioner, Medical Staff, Specialized Nurse), referred to interchangeably, accessing the Application, its Services and Content, after creating a MOOVCARE Account®;

1.3 Contractual documents

The contractual documents consist of:

- These Terms and Conditions
- These Terms and Conditions
- Technical user manuals

These General Terms and Conditions of Use, these General Terms and Conditions of Sale, the Technical User Manuals, and any agreement entered into with Practitioners and Treatment Centers, constitute the entirety of the contractual relationship between the User, each in their own capacity, and the Company.

If any provision of these Terms of Use or Terms of Sale is held to be invalid by a court of competent jurisdiction, the invalidity of that provision shall not affect the validity of the remaining provisions. No waiver of any provision of these Terms of Use or Terms of Sale shall be deemed a waiver of that provision or any other provision of these Terms of Use or Terms of Sale.

1.4 Entry into force and duration

1.4.1 With regard to Patient Users

These Terms and Conditions of Use become fully applicable to Patient Users on the day they are accepted by checking a box during the MOOVCARE service registration process.® :

- of these Terms and Conditions;
- of the information and consent notice regarding the collection and processing of their personal health data;

These Terms and Conditions come into effect on the day the Patient User orders the Application.

The General Terms and Conditions of Use and the General Terms and Conditions of Sale remain in force with respect to the Patient User for the entire duration necessary for the use of the Application by the Patient User, as assessed by the Practitioner User, under his own and exclusive responsibility.

In general, the Patient User acknowledges that the expression of their consent to the Terms of Use and Terms and Conditions of Sale is materialized by the activation of a checkbox associated with a proof convention defined in these Terms of Use and Terms and Conditions of Sale.

1.4.2 With regard to Professional Users and Healthcare Centers

These Terms and Conditions come into effect without reservation with regard to Professional Healthcare Users and their Care Center on the day of acceptance by activating a click during the registration steps for the MOOVCARE® service, under these Terms and Conditions.

The professional User declares and warrants that his acceptance of these Terms and Conditions is within the scope of his duties within the Care Centre, and that his acceptance of these Terms and Conditions binds the Care Centre in which he works without reservation.

These terms and conditions remain in effect with respect to the Professional User and the Care Centers for the entire duration of the Practitioner User's/Care Center's contractual relationship with the Company: termination of registration takes effect either on the date of the User Practitioner's request to unsubscribe, either on the day of termination of their registration by the Care Center/by the Publisher, under the conditions described in these Terms and Conditions.

1.5 Application Overview

The Application is a digital space constituting a Class I medical device bearing a CE marking, whose functionalities are described in the Technical Instructions for Use, which allows Users to access freely from their MOOVCARE Account®, to different Services and Content.

GENERAL WARNINGS

Users are advised that the Application only transmits data generated within the Application, as described in the User Manual, to healthcare professionals. It does not, under any circumstances, allow for diagnosis, medical treatment, or the monitoring of emergency situations.

The Professional User uses the application in compliance with his legal, regulatory and ethical obligations, governing the continuation of his professional practice, it being specified that any medical follow-up of the patient that he provides, any medical decision that he may have to make, or any medical act that he may have to deliver, where applicable on delegation of tasks, is done outside the Application and under his own and exclusive responsibility, or that of the care center to which he is attached, where applicable.

He acknowledges that his use of the Application's features and services does not replace or dilute his obligations and responsibilities in this regard. He uses the application under his sole control, direction, and responsibility.

Furthermore, the Patient User is alerted that the Application is not intended to provide access to services that replace their own actions and diligence in taking their treatment or respecting their care pathway.

Finally, the User is alerted that the Personal Space may contain personal data relating to the health of Patient Users. Given the sensitivity of this data, the User is warned of the need to monitor third-party access to their MOOVCARE account.®The User is responsible for implementing all necessary and appropriate security measures to protect access to their MOOVCARE account.®.

Where applicable, the Practitioner User provides access to the Application to the Practitioner's Assistant Users, Medical Staff or Specialized Nurses, within the framework of a delegation of tasks, under his own and exclusive responsibility.

2 PART 2 - General Terms and Conditions of Use of the Application

Any use of the Application is subject to prior reading and express acceptance of these General Terms of Use (hereinafter
"CGU").

2.1 Object

The Terms and Conditions of Use are intended to govern the use of the MOOVCARE medical device.®, of class I, whose technical instructions for use can be accessed by clicking on:https://patient.moovcare.com/legal orhttps://dashboard.moovcare.com/legal.

Their purpose is to define the rules for using the Application as well as the respective rights and obligations of the Users of the Application and the Publisher.

2.2 Terms of access and use

Users may not use the Services and Content provided within the Application for any purpose other than that defined in these Terms of Use and in the Technical Instructions for Use, and in particular are prohibited from using the Application, including the Services and Content, to promote a product, a service, a health establishment or generally for any advertising or promotional purpose.

The Application's Services and Content are for the personal use of Users and may not be used for the benefit of a company or any other organization. Commercial companies, and generally any organization or entity, may not become Users. Any other use that infringes upon the Publisher's rights may expose the User to legal action.

The User acknowledges that they are accessing a secure personal space, in their capacity as a Professional or Patient. They agree not to share their login credentials with third parties.

The User acknowledges and accepts that all costs of connecting to the internet network remain his sole responsibility, and in no case the responsibility of the Company.

Furthermore, the User is informed that at all times, they must use the current validated version of the Application. Under no circumstances may an older version of the Application be used. Upon release of a new version, the Publisher undertakes to maintain its accessibility, performance, and security for 3 years. The User is prohibited from obstructing the Application update by any technical means.

2.2.1 Mandatory configuration

The User is informed that using the Application requires certain configurations as defined below. MOOVCARE® can be used on internet browsers from the following

versions, ensuring SSL compatibility:

- Firefox 134 ;
- Chrome 132 ;
- Safari 17 ;
- Edge 132 ;
- Internet Explorer 11;

And provided that the browsers are used on the following operating systems from the following versions:

- Android 15
- iOS 18
- Windows 10 and 11
- OSX 14

2.2.2 Patient User Eligibility Requirements

Only Patients meeting minimum eligibility criteria, strictly assessed by the Practitioner User under their own and exclusive responsibility, taking into account the Patient's needs, particularly with regard to their state of health, their medical file, as well as their ability to use the Application, may benefit from the Application.

The minimum eligibility requirements for using the Application correspond to the clinical recommendations and characteristics of the MOOVCARE® medical device defined by the CE marking and recalled below:

- Patient over 16 years of age being monitored for lung cancer after initial primary treatment with or without maintenance treatment;
- Patient with few symptoms at the time of registration; their score being assessed by the healthcare professional, by completing an eligibility questionnaire for registration.
- Patient not presenting with significant cognitive problems or who should be able to get help from a relative for follow-up;
- Patient must be literate (know how to read and write) or have a literate relative.

2.2.3 Creating a MOOVCARE® Account

Access to the Services and Content offered through the Application requires the prior creation of a MOOVCARE Account.®at which time the User, whoever he or she may be, will be asked to accept these Terms and Conditions, by means of a checkbox.

The Patient User must also accept the information-consent notice regarding the collection and processing of personal health data concerning him/her within the framework of the Application.

When creating the MOOVCARE Account®Each User agrees to provide complete, accurate, and up-to-date information. The Professional User enters the data that allows for their identification, and where applicable, the data of the User on whose behalf they are responsible for creating a MOOVCARE Account.®, under his full responsibility, control and direction.

The Patient Account created by the Practitioner User is only activated upon authentication of the associated email and mobile phone number and acceptance by the Patient User of the Terms and Conditions and the information notice consenting to the collection and processing of their health data within the framework of the Application.

2.2.4 Login to your MOOVCARE® account

Connecting to your MOOVCARE account®relies on a reliable and secure User authentication system. Each time the Application is accessed, the User authenticates themselves via:

- **A login** corresponding to the email address used in the application,
- **A password** chosen by the User and strictly confidential.

Upon their first login, all Users are asked to:

- Authenticate their email address by clicking a button from the activation email received in their personal email inbox;
- Authenticate their mobile phone number via a code**OTP access**(One Time Password; "one-time password" in French), a one-time password sent to the User by SMS.

The User's authentication using their credentials, as part of their access to the Application, irrefutably establishes the User's responsibility for all operations performed using those credentials, under the conditions defined in the "Evidence Agreement" section of these Terms of Service. In other words, any action performed by the User via their MOOVCARE Account is considered valid and binding.®, based on its authentication elements, will be deemed to have been carried out by the User and under their sole responsibility.

In this respect, the User undertakes to keep his authentication details secret, it being understood that the Publisher cannot be held responsible for any loss or damage arising from a failure to comply with this obligation, any use of the aforementioned details being made under the sole responsibility of the User.

In the event of loss or theft of the login and/or password, the User agrees to inform the Publisher immediately at the following email address:courrier@sivan-innovation.com

In addition, the User may, at any time, modify their authentication details through the Application, particularly if they suspect unauthorized use of their access codes by a third party.

Any change to the authentication methods (email address or mobile phone number) will trigger a new verification of these elements. The User Account is then*in fact*suspended.

The user can also connect with**Pro Santé Connect.**

Pro Santé Connect is an online service implemented by the French Digital Health Agency (ANS) that simplifies the electronic identification of healthcare professionals. Users can log in using their e-CPS mobile application or their CPS card, along with a card reader and the necessary components.

2.3 Application services and features, and associated warnings

This article aims to describe and provide warnings regarding the various sections and features associated with the Application's Services and Content, where applicable:

- Within the framework of the Personal Space for Healthcare Professional Users
- Within the Patient Area.
- As part of the use of the Technical Support Service, for all Users.

2.3.1 Services and features of the Healthcare Professionals' Personal Space

2.3.1.1 Creating a Patient Account and tracking Patient Accounts during the Validation process

The Application allows the Professional User to manage the opening of Patient Accounts.

WarningUser attention is drawn to the fact that the creation of a Patient Account implies that the Patient meets the eligibility conditions for the use of the Application, assessed from the answers to a pre-eligibility questionnaire, under the Practitioner's own and exclusive responsibility, in accordance with the Patient's needs and capabilities.

After a Patient Account is created, it remains on the patient list with a "pending" status. The Patient User is invited by email, to the email address they provided to the Professional User when creating the MOOVCARE Account.®, to verify their email address, then to log in to the Application and accept, via checkboxes:

- These Terms and Conditions;
- The information and consent notice for the collection and processing of health data within the framework of the Application.

Warning User attention is drawn to the fact that in the absence of consent to the Terms and Conditions and the information-consent notice, the Patient Account cannot be activated and remains on a waiting list.

The healthcare professional user has access to a dashboard providing an overview of their list of active and pending validation patient users.

Note: To facilitate the opening of a Patient Account, the Professional can use a health insurance card reader. To use it, it is necessary to install the iconnect driver from Sephira, at no additional cost.

2.3.1.2 Alert management

A feature of the Application, combined with a monitoring system for the Application and the data produced within it, allows alerts to be generated when one or more data points collected within the Application are abnormal.

Only Practitioner Users can receive alerts, and within a Healthcare Center, Healthcare Professional Users are responsible for organizing and designating alert

recipients through the Healthcare Center administrator function. It is the Healthcare Center's responsibility to assign this responsibility to one or more MOOVCARE® accounts.

- **Receiving alerts in the Practitioner User's email inbox**

An alert can be sent to the Practitioner User, to the email address he indicated for the creation of his MOOVCARE® Account, by SMS or via the download of the progressive application, and where applicable, within a Care Center, the Professional Health Users undertake, under their responsibility, to organize and designate the professional health recipients of the alerts (via a Medical or Specialized Nursing Staff profile).

The Practitioner User is informed by email, SMS or notification on the progressive application of the presence of alerts within the Application and is invited to log in to their secure personal space to view the data relating to the Patient User.

Warning User attention is drawn to the fact that alert emails, SMS or notifications received by the Practitioner User do not contain any personal health data.

- **Access to a list of alerts to be addressed within the Application**

Within the Application, the Practitioner User has access to an updated list of alerts to be dealt with.

Warnings User attention is drawn to the fact that under no circumstances does the Application allow for medical monitoring or medical care of the patient, nor the treatment of emergency situations.

The Practitioner user is informed and acknowledges that it is their own and exclusive responsibility to react to the alert triggered within the Application, and to carry out the necessary medical follow-up, if necessary, outside of the Application.

These actions may be entered in the Application by qualifying the alert when it is being dealt with.

In the event of abnormal data collected within the framework of the Application, it is the Patient User's responsibility to consult the healthcare professional providing their medical follow-up outside of the Application or to go to the emergency services.

It is also the responsibility of the Professional Healthcare Users to alert the Patient User to the abnormal nature of any data collected within the framework of the Application, where appropriate, and to arrange a consultation or refer them to the competent emergency services, in accordance with the legal, regulatory, and ethical obligations that govern the continuation of their professional activity, their use of the Application neither replacing nor diluting their obligations and responsibilities in this respect.

2.3.2 Access to questionnaires

● Access within a patient record

A patient file is made available to the Healthcare Professional User within the Application to give them access to all information relating to each Patient User following the completion of questionnaires by the Patient via the Application.

Warnings : The Patient User's attention is drawn to the fact that under no circumstances does the teletransmission of data produced within the framework of the Application to Professional Healthcare Users via the application constitute medical care, nor does it constitute the management of emergency situations.

Furthermore, the functionality of visualizing Patient User data in the form of a chronological table of questionnaire responses does not in any way include an analysis or transformation of the data entered.

● Notifications for overdue questionnaires and questionnaire reminder function

The Service will generate reminder emails for the Patient User, sent to the email address they provided when creating their MOOVCARE® Account. The Healthcare Professional User is also notified if one of their Patients has not completed their questionnaire. They also have the option to send reminders to the Patient to encourage them to complete the questionnaires within the Application by activating a specific feature.

● Clinical data update

Following the generated alert, the Practitioner may decide on further examinations to determine a recurrence, complications, or supportive care follow-up. They can then update the clinical data, indicating whether or not the patient is still being monitored by the Application.
Warnings The Patient User's attention is drawn to the fact that the Application does not in any way provide medical monitoring or medical care, nor does it allow the treatment of emergency situations.

2.3.3 Patient Area Services and Features

2.3.3.1 Access to a Patient Account

Given the eligibility conditions for opening a Patient Account on the Application, compliance with which is subject to the assessment of the Practitioner User, based on a pre-eligibility questionnaire, according to the needs and capabilities of the Patient User, under his own and exclusive responsibility, the Practitioner User creates a Patient Account.

The Patient Account becomes active upon verification of their contact details (email address and mobile phone number) and any personal data not initially completed by the Professional, the indication of the prescription date in the application and the optional upload of the prescription, the creation of a password and acceptance by the Patient User:

- These Terms and Conditions;
- From the information-consent notice to the collection and processing of one's health data within the framework of the Application.

Warning The Patient User's attention is drawn to the fact that their Patient Account cannot be activated if they do not first consent to the Terms and Conditions and the information-consent notice.

Furthermore, the Patient User is warned that if, in the course of using the Application, they withdraw their consent, they will no longer be able to benefit from the Application's Services and Content.

2.3.3.2 Completing questionnaires related to the Patient User's symptoms

As part of the Application, weekly questionnaires relating to symptoms are submitted to the Patient User.

Warnings The Patient User is expressly informed that the questionnaires submitted to him within the framework of the Application do not in any way allow the Healthcare Professional User to provide medical follow-up to the Patient User, which can only take place outside the Application, under the sole and exclusive responsibility of the Practitioner User.

This Service also allows the Patient User to indicate the presence of certain symptoms (yes/no answer), to indicate their weight and temperature, to assign a score to some of their symptoms, on a scale of 0 to 3 (No problem, slight problem, medium problem, major problem) and to write, if they wish, a comment in a free comment space.

Before submitting, the Patient User can modify their answers if they wish. Once submitted, the Patient User no longer has access to their answers. An acknowledgement of receipt of the answers is sent to the Patient User.
Warning The information provided by the Patient User remains entirely under their control, direction, and responsibility. Under no circumstances does the Publisher verify the consistency or scientific, medical, or health-related relevance of the information entered by the Patient User. Under no circumstances does the service provided to Patient Users via the application replace, in whole or in part, the care and support provided by healthcare professionals, in accordance with their professional, legal, or ethical obligations.

Furthermore, the Services and Content that Professional Healthcare Users benefit from within the application do not in any way dilute their legal, regulatory and ethical obligations and their professional responsibilities in this regard.

2.3.3.3 Notifications of receipt of a new questionnaire and reminders

Within the framework of the Application, the Patient User benefits from:

- Automatic sending of an email notification to the email address he provided when creating his MOOVCARE account®, upon receipt of a new questionnaire within the Application, and inviting him to follow the link to his personal space to complete it; and/or by SMS to the mobile phone number provided in the application, and by notification on the Application if he has installed it on his

device where applicable.
- The automatic sending of a notification by email and on the installed Application, if applicable, of a reminder to complete a questionnaire;
- A reminder, within the Application, by the Healthcare Professional User who wishes to do so, to complete a questionnaire.

Warnings The Patient User's attention is drawn to the fact that under no circumstances does the application allow for medical monitoring or medical care of the Patient User, nor the treatment of emergency situations.

Where appropriate, it is the Patient User's responsibility to consult the healthcare professional in charge of their care, and it is the responsibility of Healthcare Professional Users to refer Patients, where appropriate, to the appropriate emergency services, in accordance with the legal, regulatory, and ethical obligations that govern the conduct of their professional activity, their use of the application neither replacing nor diluting their obligations and responsibilities in this regard.

2.3.3.4 Free comment space

A chat box providing a space for free comments is available to Patient Users within the Application, allowing them to communicate any additional medical information or new symptoms. When posting comments in the Application's chat box, the Patient User agrees to disseminate content that complies with applicable laws and regulations.

In particular, the Patient User is prohibited from:

- Disseminating information that is contrary to public order or morality;
- Spreading defamatory, abusive, harassing, or threatening statements to anyone, or in violation of the rights of others;
- To glorify crimes against humanity, to incite racial hatred or pedophilia;
- Creating a false identity or impersonating someone else;
- Misusing the Application for propaganda or proselytizing, prospecting or soliciting;
- Publishing information of a commercial, advertising or propaganda nature in favor of tobacco, alcohol, or any other regulated substance, product or service, including medicines, medical devices or healthcare professionals or healthcare facilities;
- Disseminating content that infringes on the personality rights of third parties;
- Publishing information that violates personal data protection legislation allowing the identification of natural persons without their consent, including their surname, postal and/or electronic address, telephone number, photograph, sound or audiovisual recording, or collecting and storing personal data relating to other Users;
- To transmit any message containing computer viruses or any other code, file or program designed in particular to interrupt, destroy or limit the functionality of any software, computer, or telecommunications tool.

The Patient User is informed that he/she posts comments in the Application's dialog box, where applicable, under his/her sole and entire responsibility, whatever their nature, purpose and objective.

As such, Patient Users acknowledge that the free comment space is not accessible to any third party and is not subject to any moderation.

However, the Publisher may take action on any report from a Patient User, notified in accordance with applicable legal procedures, relating to a comment that does not comply with the provisions listed above or whose content infringes the rights of third parties.

2.4 Services and features for all users

The Publisher provides Users of the Application with a technical support service to assist them in the event of a persistent technical problem, unresolved with healthcare staff, or in the event of a complaint.

The contact details for the Technical Support Service are available in all User Areas, with a response generally in less than 24 working hours.

When communicating by email, the User agrees to disseminate content that complies with applicable laws and regulations. The User is informed that any information they provide is their sole and entire responsibility, regardless of its nature, purpose, or objective.

Notably :

- The healthcare professional user is informed that this is a technical assistance service and that they are prohibited from publishing information that contravenes the regulations on the protection of personal data allowing the identification of natural persons without their consent, in particular their surname, postal and/or electronic address, telephone number, photograph, sound or audiovisual recording, or from collecting and storing personal data relating to other users.
- The Patient User is informed that this is a Technical Assistance Service and that they should not transmit sensitive personal data such as their health data.

The Patient User is informed that when contacting Support by telephone, their prior consent to the processing of their data for technical support purposes is required. If the Patient User refuses to give their consent, they understand that contact with the technical service cannot be established.

Users of the Support Service are informed that their telephone communication may be recorded for regulatory purposes.

To facilitate patient registration within the Application, the Company may also offer Patient Users technical support by calling them directly. Consent to this option is recorded in the Application when the Professional User registers the Patient User using a checkbox. An information notice regarding this consent to SIVAN services is available within the Application. The SIVAN representative providing technical support will then be authorized to view the Patient User's phone number, first name, and last name in their administrator interface until the patient account is activated. The Patient User is free to accept or refuse the terms of this call, specifically informing the representative that they refuse to be recorded at the time of the call. They are also informed in their initial email of the conditions for withdrawing this

specific consent. It is important to note that this consent is independent of the consent provided for the use of the Application and its clinical purpose.

Warning: The Patient User is informed that this service is strictly limited to technical assistance and in particular that no health data should be exchanged.

2.5 Code of Ethics for Healthcare Professionals

The use of the Application for the electronic transmission of results produced within the framework of the Application does not in any way relieve the Healthcare Professional User of their ethical obligations.

The Healthcare Professional User undertakes, within the framework of their use of the Application, to unconditionally respect all the ethical rules governing the exercise of their profession as defined in the Code of Ethics and interpreted by the National Council of their professional order.

In this respect, the Healthcare Professional User acknowledges that their use of the Application, its Services and Content does not infringe any of the ethical obligations, particularly with regard to the principle of independence, the prohibition of any form of collusion or the prohibition of any direct or indirect advertising, including in favor of a drug or product.

In particular, the Healthcare Professional User undertakes to comply with the regulations applicable to the implementation, if necessary, of task/care delegation protocol(s).

Acceptance of these Terms and Conditions does not replace, nor in any way prejudge, the implementation of a task delegation protocol, which is the sole responsibility of the Professional Healthcare Users.

The Healthcare Professional User also undertakes to respect the strictest confidentiality regarding health and privacy information of Patient Users, which has come to their attention by any means whatsoever, in accordance with their legal, regulatory and ethical obligations as set out in Articles L. 1110-4, L.1110-12, R.1110-1 et seq. of the Public Health Code, 226-13 of the Penal Code and the Code of Ethics governing the exercise of their profession where applicable.

The Healthcare Professional User is therefore prohibited from communicating, directly or indirectly, any information concerning Patient Users and subject to the protection of medical confidentiality, to any unauthorized third party.

As such, the healthcare professional User is personally responsible for any disciplinary action that may be brought against him based on an act, behavior or attitude contrary to any of the ethical obligations governing the exercise of his profession, including in the context of his use of the Application.

The Healthcare Professional User undertakes to comply with the procedure for communicating the contract concluded with the Company to the relevant national Order of healthcare professionals and described in the Public Health Code and to take it upon himself to comply with the obligations defined therein.

2.6 Information and consent

The Application, as a medical software device, does not allow for any medical monitoring in itself.

Practitioner Users offering the use of the Application to their patients provide them with all the information due to them in accordance with the provisions of the Public Health Code and the Code of Medical Ethics.

The information notice regarding the collection and processing of personal data implemented within the framework of the Application is given to the Patient, before the issue of their consent by means of a checkbox associated with a proof agreement.

Furthermore, each User acknowledges that they have received, read and understood all the terms of the Technical Instructions for Use of the Application describing the terms of use of the medical software device according to their status (Healthcare Professional, Assistant or Patient).

2.7 Obligations and responsibilities

The Publisher is responsible for placing the Application on the market, as a medical device benefiting from CE marking, under the conditions of common law.

The Publisher provides Users with up-to-date Technical User Manuals directly within the application. If Users wish to access a printed copy of the Technical User Manual, they can request it from the manufacturer by mail or by sending an email tocontact@sivan-innovation.com.

However, if the Healthcare Professional User wishes to access previous technical user manuals, they can do so upon request at the addresscontact@sivan-innovation.com by requesting the desired Application version number.

The healthcare professional user is responsible for their use of the Application.

The Practitioner User agrees to validate the suitability of the Application, its Services and its Content to the needs of the Patient User.

The Practitioner User remains personally and exclusively responsible for the medical acts that he or she may be required to deliver as part of the follow-up of his or her Patient.

The Application's Services do not provide medical care and are in no way intended for emergency situations. In such cases, the healthcare professional User is obligated to refer their patient to the appropriate emergency services, in accordance with their legal, regulatory, and ethical obligations.

In particular, the healthcare professional user must take into account:

- Rules relating to respect for medical confidentiality, in accordance with the provisions of Article L.1110-4 of the Public Health Code, the violation of which is punishable under Article 226-13 of the Penal Code;
- The legal framework that governs his profession.

The Patient User is responsible for their use of the Application. In general,

Users agree to use the Application:

- In compliance with laws, regulations and the rights of third parties, including intellectual and industrial property rights;
- In a fair and appropriate manner. It is their responsibility, in particular:
- To fulfill their security obligations, in accordance with Article "Security" of these Terms and Conditions;
- To use the Application, its Services and Content in compliance with the Terms of Service and applicable legal and regulatory provisions;
- Not to market all or part of the Services or Content accessible via the Application.

In the event of non-compliance with one or more provisions of these Terms of Service, access to the Application or the MOOVCARE Account will be revoked.®The User's access may be unilaterally, automatically and without notice, temporarily suspended or permanently blocked.

2.8 Assurance

The Practitioner User declares that they have taken out an insurance policy with a reputable and solvent insurance company to cover damages caused to Patient Users and third parties in connection with their activity and to verify that this insurance policy also covers the risks of damage related to the use of the Application.

2.9 Materiovigilance

Any User who becomes aware of an incident or risk of an incident involving a medical device or the Application that has resulted or is likely to result in the death or serious deterioration of the health of a patient, a User or a third party must report it without delay.

An adverse event or risk of incident can be reported concerning a medical device:

- With the local medical device vigilance correspondent according to the procedure of the care center that appointed him/her;
- To the Publisher's medical device vigilance officer at the address amandine.caillon@sivan-innovation.com;
- On the ANSM website: on the ANSM website page dedicated to reporting medical device vigilance

incidents:https://solidarites-sante.gouv.fr/soins-et-diseases/health-signaling-gouv-fr/

2.10 Transparency

In accordance with Law No. 2011-2012 of 29 December 2011 on transparency and conflicts of interest and its implementing decrees, the Company may be required to process and make public:

- The existence of contracts concluded with Professional Users granting them the right to use the Application;
- As well as certain information concerning them in their capacity as healthcare professionals;
- Information relating to these agreements, as defined by the implementing decrees,
- Just like the remuneration they receive in accordance with contractual commitments.

The information mentioned in Article R. 1453-3 of the Public Health Code will be transmitted to the authority responsible for the single public website and to the Company no later than:

- the 1isSeptember for agreements concluded or remuneration paid during the first half of the current year
- The 1isMarch of the following year for agreements concluded or remuneration paid during the second half of the previous year.

2.11 Intellectual property

The Publisher holds the intellectual and industrial property rights to the Application. Use of the Application does not, under any circumstances, grant Users any ownership rights to the Application, its Services, and Content.

2.11.1 Content and Services

Any use, reproduction, copying, or distribution of one or more elements of the Application for any purpose other than private use is prohibited. The User acknowledges that all Application Content, including but not limited to the domain name, texts, graphics, photographs, drawings, sounds, data, images, audio and video, as well as the Application's structure, navigation plan, logos, the design and organization of its sections, their titles, databases, their structure and content, whether existing or future, belong exclusively to the Publisher, with the authorization of the rights holders where applicable.

This Content is intended exclusively for the User's personal use, who benefits from a private, non-collective, and non-exclusive right of use. Unless expressly authorized in advance by the Publisher, all reproduction, representation, and use by the User other than those specified above, and in particular:

- Any adaptation, making available to the public on demand or otherwise,

distribution, rebroadcasting in any form whatsoever, networking, public communication, whether free of charge or for a fee, of all or part of the works, services, and all elements protected or likely to be protected by intellectual property law reproduced within the Application;

- Any link, access, modification, addition, deletion that relates to the automated processing system of the online edition and that modifies the conditions of publication or the editorial policy.

Any failure by the User to comply with these obligations would constitute an infringement punishable under Articles L. 335-2 et seq. of the Intellectual Property Code.

2.11.2 Databases

In accordance with the provisions of Law No. 98-536 of 1 July 1998 transposing into the Intellectual Property Code Directive 96/9 EC of 11 March 1996 concerning the protection of databases, the Publisher is producer and owner of all or part of the databases, their structure and their contents, comprising the Application.

By accessing the Application, the User acknowledges that the data comprising it is legally protected, and, in accordance with the provisions of the aforementioned law of July 1, 1998, it is prohibited in particular from extracting, reusing, storing, reproducing, representing or retaining, directly or indirectly, on any medium, by any means and in any form whatsoever, all or qualitatively or quantitatively substantial part of the content of the databases appearing within the Application which he accesses, as well as from making repeated and systematic extractions or reuses of qualitatively and quantitatively non-substantial parts, when these operations manifestly exceed the conditions of normal use.

2.11.3 Trademarks, distinctive signs and logos

All trademarks used within the Application are the property of the Publisher. Unless expressly authorized in advance by the Publisher, any reproduction (in whole or in part) and use of these trademarks, whether figurative or not, belonging to the Publisher, may subject the User to legal action.

2.12 Limitations of liability

The Publisher is bound by an obligation of means in making the Application available and providing its Services and Content. Consequently, the User acknowledges that the Publisher cannot be held liable for any material or immaterial, direct or indirect damage, regardless of its cause (including but not limited to: including damages that may be caused by the potential spread of viruses, computer fraud, or due to the constraints and limitations of the internet network) nor any resulting consequences:

- Regarding its use of the Application, its Services and Content;
- The inability to access the Application, Services and Content, except of the damages directs consecutive of a mistake heavy or intentional;

Furthermore, the Publisher will not be held liable in the event of inaccessibility of the

Application and its Content and Services caused by events beyond its control (“Force Majeure event”).

A Force Majeure event includes any act, event, non-occurrence, omission, or accident beyond the Publisher's control. The performance of these Terms of Use will be suspended for the duration of the Force Majeure event, and the Publisher will make every effort to end the Force Majeure event or find a solution enabling it to fulfill its contractual obligations despite the Force Majeure event. In all circumstances, each Healthcare Professional User remains fully and exclusively responsible for the acts and decisions related to their professional activity, in accordance with the legal, regulatory, and ethical obligations governing their professional practice.

2.13 Security

In general, the security of a MOOVCARE® Account requires Users to:

- To comply with security instructions and in particular the rules relating to the definition and change of one's identifiers;
- To respect access management, in particular, not to use the identifiers or authentication elements of another User, nor to seek to know this information;
- To keep their login details strictly confidential and not to disclose them to third parties, and, in general, to any third party whatsoever, regardless of their qualities and professional activities;
- To notify the Publisher of any technical malfunctions observed and any anomalies discovered, such as intrusions;

In particular, it is the User's responsibility to take all appropriate measures to protect their own data and equipment from contamination by viruses or other forms of attacks that may circulate via the Application.

Users are informed that technical interventions within the Application are carried out in compliance with the provisions of the Regulations relating to data protection, as well as all the provisions of the Public Health Code.

Users acknowledge the inherent risks associated with the use of telecommunications, even with secure access such as that implemented within the Application, and particularly in terms of:

- Internet network reliability issues.
- Continuity of access to the Application and its Content and Services is not guaranteed;
- Performance not guaranteed, particularly due to the spread of viruses;
- Any other technical constraints that are not under the control and responsibility of the Publisher.

Under no circumstances shall the Publisher be held responsible for these risks and their harmful consequences, regardless of their extent, for the User.

2.14 Protection of personal data

The Company is the Data Controller for personal data implemented for the management of Professional Users of the Services, Content and functionalities of the Application.

As part of the processing of this data, a transfer to a third country is carried out since the Company is based in Israel. Israel is recognized by the European Union as a country offering an adequate level of protection.

The Practitioner Users or, as the case may be, the Care Centre, each in their own capacity, are responsible for the processing of personal data relating to their own Patient Users, collected and processed within the framework of the Application, within the meaning of the Data Protection Regulations.

This processing of personal data is implemented in order to allow Patient Users to benefit from a teletransmission to Healthcare Professional Users of their health data produced via the Application and for the purposes of telemonitoring (purpose).

The legal basis for this processing is Article 6(c) of the GDPR and is based on the legal exception of Article 9(2)(h) of the GDPR.
All data collected through the Application is stored in accordance with Article L-11118 of the French Public Health Code, with a certified health data hosting provider. This health data hosting provider is located in France.

The Company, as the application publisher, acts as a data processor for this processing. The appendix to these terms and conditions sets out the relevant elements governing the relationship between the data controller and the data processor.
As part of this data subcontracting, a transfer to a third country is carried out since the Company is based in Israel. Israel is recognized by the European Union as a country offering an adequate level of protection. Other transfers are described in this same appendix. Each Practitioner or Healthcare Center User is personally responsible for complying with the Regulations in their capacity as Data Controller and in particular (i) registering the processing thus implemented under their responsibility in their register of activities, (ii) conducting a data protection impact assessment for Patients, (iii) the application of adequate security measures in order to characterize adequate technical and organizational guarantees for the protection of personal data, for the implementation of the processing of personal health data relating to Patient Users whose data produced within the framework of the Application is transmitted to it electronically.

Patient Users have been informed of the collection and processing of personal health data, including medically sensitive data, and of their rights in this regard.
Patient users were also informed that SIVAN France is the data controller for billing purposes related to the application. Therefore, when the patient is insured, their contact information, social security number, order date, and order details are used to arrange coverage with the funding organization.

At the stage of activating his MOOVCARE Account®The Patient User must expressly consent, by means of a checkbox, to the collection and processing of personal health data / medical data, as well as to the handling of billing by SIVAN France.

The Patient User is informed that they can withdraw their consent to monitoring by the Application at any time without consequence to their care by their Practitioner.

His attention was specifically drawn to the sensitivity of the health data he enters via the Personal Space, which is also covered by medical professional secrecy.

Personal health data, collected during prevention, diagnosis, care or social and medico-social monitoring activities (referred to as "medically sensitive data") within the meaning of the provisions of Article L.1111-8 CSP, may be collected and processed within the framework of the Application, and as such are hosted with a certified health data host.

In accordance with the Data Protection Regulations, the Patient User has a right to object to the hosting of personal data concerning him/her by a third-party host, which he/she can exercise with the Data Controller.

The personal data of Patient Users is strictly intended for:

• To the Practitioner User, in his capacity as Data Controller;
• To the Practitioner's Assistant Users, Medical Staff, Specialised Nurse specifically authorized and in strict compliance with their missions;
• To the Company's Staff members, specifically authorized, in strict compliance with their duties;
• To the staff members of the technical service providers and subsequent subcontractors, specifically authorized, in strict compliance with their missions;
• To the strictly authorized administrators of the certified health data hosting provider, as defined in Article L.1111-8 of the Public Health Code, and subsequent subcontractors, in strict compliance with their duties
• To the staff members of SIVAN France and SIVAN Innovation for technical aspects, authorized to manage the billing and reimbursement of the Application.

The Data Controller guarantees that the personal data of Users and Patients will not be transmitted to any unauthorized third party without their consent.

Furthermore, data relating to the Patient User's relatives may be collected by the Healthcare Professional within the framework of the Application. The Patient User's relative will receive an email at the email address provided by the Patient User when creating their MOOVCARE Account.®This aims to inform the user that personal data concerning them is collected and processed within the framework of the Application and of their rights in this regard, in particular their right to object. Furthermore, the Patient User undertakes to inform their relative that their identification data has been entered within MOOVCARE.®and to inform him of the rights defined in this clause.

The Patient User is informed that, after anonymization of the data produced in the context of the implementation of the Application by a process in accordance with the Regulations relating to data protection or pseudonymization in compliance with the reference methodologies or applicable standards of the CNIL to which the Company has committed itself, the Company may be required to use the data for the purposes of studies, evaluation, research and development, for its own needs or those of partners, or at the request of national or international health authorities.

The Patient User can learn about these different uses of their data by logging into the

website: www.sivan-innovation.com

The Patient User is finally informed that, subject to having obtained his consent as a legal basis within the meaning of Article 6.1.a of the GDPR and 9.2.a of the GDPR, he may be contacted by the Company in order to measure his satisfaction in the context of the use of the Application.
Through consent to Moovcare®, to ensure the billing of the device, particularly to the funding bodies.

The Patient User is hereby informed that they may be contacted by the Company for the following reasons, on the legal basis as defined in Articles 6.1.c and 6.1.f of the GDPR:

- Within the framework of medical device vigilance and quality assurance;
- With the aim of continuously improving the system;
- In order to measure the user's satisfaction with the Application. The lawfulness of this processing will be based on the Patient User's consent in the case of automated processing (example: satisfaction questionnaire).
- To process the exercise of rights where applicable

The Patient User consents to this by accepting these Terms and Conditions.

The Healthcare Professional User consents to such uses by accepting these Terms and Conditions, and the Patient User consents to them by accepting these Terms and Conditions and the information and consent notice.

As part of the Technical Support Service, the collected data is stored on servers located in Europe. This data may be shared with authorized personnel at the Publisher or with strictly limited personnel at SIVAN France, the Publisher's subcontractor based in France, for the processing of technical support requests or complaints, depending on the nature of the request. Users are informed that this data may be transferred to the Publisher, based in Israel. Israel is recognized by the European Union as providing an adequate level of security for the protection of personal data.

The Patient User's use of the Technical Support Service is based on their prior consent. This type of consent is separate from that provided for the clinical use of the Application.
When consent is given solely to assist the Patient User with registration in the Application, the Patient User is informed that the Technical Support employee may have access to their first and last name and phone number. Access to this data is subject to the Patient User's consent, which they may revoke at any time from their Personal Account.

In the context of billing the Application by SIVAN France and its handling where applicable, the data necessary for this processing (name, surname, email address, mobile phone number, bank details or prescription/prescription date/associated treatment sheet/social security number) are used to organize the related processing.

Cookies :
In accordance with data protection regulations, Users have the right to access, object

to, rectify, port, restrict and erase their personal data, it being understood that in the event of exercising these rights of restriction and erasure:

• The Patient User will no longer be able to access and use the Application;
• The Professional User will no longer be able to use the Application's Services and Content once the Patient User has exercised one of their rights of limitation or erasure.

The User also has the right to define general guidelines regarding the retention, erasure, and communication of their data after their death, which may be registered with a digital trusted third party certified by the CNIL, and specific guidelines concerning the processing of personal data mentioned in these guidelines, which may be registered with the Company at the address below and which are subject to its specific consent in this respect.

The User also has the right to lodge a complaint with the CNIL:www.cnil.fr

Requests to exercise the rights of access, objection, restriction, portability, erasure and rectification can be addressed to:

• By the Professional User: to the Company's Data Protection Officer (DPO), specifically authorized to respond to User requests to exercise their rights, with a copy (front and back) of an identity document, to the email addressdpo@sivan-innovation.com ;

• By the Patient User and their relative, if applicable, by attaching to their request a copy of both sides of their identity document:
  o With the specifically designated service of the Data Controller (with their Practitioner or the Care Centre),
  o Or directly to the certified health data host at the following address: AVENIR TELEMATIQUE SA (ATE), 21 rue de la Créativité, 59650 VILLENEUVE D'ASCQ.

The Patient User is informed that he/she can exercise his/her right to withdraw his/her consent following the same procedures described above.

Users are informed that they can lodge a complaint with the CNIL.

Data retention period

Regarding Healthcare Professionals: personal data is kept for the duration of the Application's use, for a given healthcare center.

As the Application is a regulated Medical Device, this information is then archived for regulatory traceability purposes for 10 years.

Regarding the Patient User: personal data is kept for the duration of the Application's use.

As the Application is a regulated medical device, the data is then securely archived for 10 years before being anonymized. After anonymization of the health data generated within the Application using a process compliant with data protection regulations, the Company may use the data for studies, research and development,

or statistical purposes, for its own needs or those of partners, or at the request of national or international health authorities.

Users of the Technical Support Service are informed that their personal data collected in this context is kept for a maximum of 5 years after the last contact.

When data is transmitted electronically to a funding body, information is stored in encrypted form for 8 days in the active database and then archived for 3 months. Social security reimbursement statements are kept for 2 years after the reimbursement period ends.

The User also has the right to define general guidelines relating to the storage, erasure and communication of his personal data after his death which can be registered with a digital trusted third party certified by the CNIL, and specific guidelines, concerning the processing of personal data mentioned by these guidelines, which can be registered with the Data Controller at the aforementioned address and which are subject to his specific consent in this respect.

The Data Controller implements all security measures to ensure the protection and security of User data, in particular with regard to unauthorized access by a third party.

If the User noticed a lack of protection of their data or felt they needed to make a complaint about its processing, they could then inform, at their discretion:

- The Publisher's Data Protection Officer, based in the European Union, can be contacted by sending an email to the following address:dpo@sivan-innovation.com,
- The data protection officer of the Care Centre,
- or contact the supervisory authority, the CNIL.

Notification of a Personal Data Breach

In the event of a personal data breach and upon becoming aware of this incident, the User concerned and/or the Data Controller concerned will be informed by an email from the Company.

The Company will clearly and precisely indicate the incident in order to allow the Data Controller to notify the CNIL of this breach within 72 hours if this incident requires a declaration to this supervisory authority.

The Data Controller will personally handle its obligation towards the data subjects in accordance with the Regulations.

The Company's personal data security and confidentiality policy can be consulted on the Company's website.www.sivan-innovation/privacy/ or directly within the application.

2.15 Evidence agreement – Electronic signature

The computerized records stored in the Publisher's computer systems under an encryption system will be considered as evidence of communications and various

transmissions of written and electronic documents between Users and the Application, and the Publisher.

The User acknowledges and accepts that, after authentication, any expression of will through the use of the features offered within the Application, and in particular (1) the giving of his express consent for the collection and processing of his personal health data in the case of the Patient User (2) the acceptance of the Terms and Conditions, constitutes an electronic signature within the meaning of the provisions of Articles 1366 et seq. of the Civil Code, and manifests his consent by characterizing its proof.

In accordance with the provisions of Articles 1366 et seq. of the Civil Code, the implementation of an electronic signature, based on a reliable identification process guaranteeing its link with the act to which it is attached, is considered a valid signature and proof within the meaning of the aforementioned provisions.

The User may not contest the admissibility, validity, or probative value of the aforementioned electronic or physical documents on the basis of any legal provision that specifies that certain documents must be written or signed to constitute proof. Thus, the aforementioned documents constitute evidence and, if produced as evidence by the Publisher in any legal or other proceedings, will be admissible, valid, and enforceable in the same manner, under the same conditions, and with the same probative value as any document that would be created, received, or stored in writing.

2.16 Changes to the Terms of Service and Application Updates

The Publisher reserves the right to modify these Terms of Use or the rules concerning the use of the Application at any time. Each new version of these Terms of Use will be posted within the Application. Each User is required to consult these Terms of Use regularly.

Continuing to use the Application after any changes to the Terms of Service constitutes acceptance of the changes to the Terms of Service.

The Publisher also reserves the right to modify the Application, Services, and Content. Technical changes may occur without prior notice from the Publisher. Furthermore, the Publisher reserves the right to temporarily or permanently suspend access to the Application without notice or compensation of any kind.

Furthermore, the improvement or addition of an important Service and/or feature will systematically be the subject of specific information, and the User will again be asked to give their express consent to the acceptance of the Terms and Conditions where applicable.

The Publisher may at any time transfer to a subsidiary or successor, regardless of the transaction, all or part of the rights and obligations defined in these Terms of Use, and the Application.

The User is not authorized to assign their agreement with the Publisher under these Terms of Use.

2.17 Termination

2.17.1 Termination initiated by the Publisher

Each User agrees that the Publisher may immediately terminate their access to the Application without prior notice, formal demand, or compensation of any kind, in the event of a breach of any of the obligations described in these Terms of Service, or of applicable law. Without limiting the foregoing, the following may, in particular, constitute grounds for termination of the User's registration:

- Infringements or violations of these Terms and Conditions;
- Failure to comply with a legal or regulatory provision in force;
- An attempt at unauthorized connection, through fraudulent use of the system or through the usurpation of access codes;
- A technical malfunction led to the erroneous deactivation of the User's registration.

2.17.2 Termination initiated by the User

At any time, the Practitioner User has the option to close their MOOVCARE Account®by contacting the Publisher at the following email address:courrier@sivan-innovation.com

The accounts of other Professional Users may be terminated at the initiative of the Care Center.

The Patient User has the option to close their MOOVCARE Account®by contacting the Practitioner User or the Administrator of the Care Center benefiting from the electronic transmission of data produced within the framework of the Application concerning him/her. He/She is informed that the closure of his/her MOOVCARE Account®This will not result in the automatic deletion of the personal data concerning him/her. It will be kept in compliance with the requirements of the Data Protection Regulations, as well as the legal and regulatory obligations of Healthcare Professional Users, which the Patient User expressly accepts.

The User is informed that following this action they will no longer be able to access the Application, Services and Content.

2.18 Applicable law

The Application was designed for French Users. These Terms of Use are governed by French law.

Consequently, Users acknowledge that, in general, any information disseminated and/or exchanged there may not be consistent or appropriate outside of France.

In the absence of an amicable settlement, any dispute relating to the Application or its use will be submitted to the French courts.

3 PART 3 - General Terms and Conditions of Sale of the Application

Any use of the Application is subject to prior knowledge and express acceptance of these General Terms and Conditions of Sale ("GTC") by the Patient User.

3.1 Object

These Terms and Conditions govern the commercial relationship between the Patient User and the Company. They detail the rights and obligations of both the Patient User and the Company with respect to the Order. The Patient User acknowledges having read and accepted these Terms and Conditions without reservation.

Any order placed by the Patient User is exclusively subject to the provisions of these Terms and Conditions.

3.2 Responsibility

The Patient User is responsible for their use of the Application, Services and Content. They agree to verify that the Application meets their needs.

In general, the Patient User agrees to use the Application, Services and Content:

- in compliance with laws, regulations and the rights of third parties, including intellectual and industrial property rights,
- in a fair manner and in accordance with its intended purpose.

The Patient User agrees not to market all or part of the Application, Services and Content.

In the event of non-compliance with one or more provisions of the Terms of Use and/or Terms of Sale by the Patient User, access to the Application, Services and Content may be, unilaterally, automatically and without notice, temporarily suspended or permanently blocked.

The Company is bound by an obligation of means in the context of making the Application, Services and Content available.

The Patient User is hereby informed that the Application is not intended to provide access to services that replace their own actions and diligence in taking their medication or adhering to their care plan. The Application is solely a function for the electronic transmission of data generated within the Application to Professional Users, the Company assumes no responsibility for the care and/or advice that may be provided by Professional Healthcare Users.

The medical monitoring of the Patient User, any medical decision taken by Professional Users or any action they may be required to perform on the Patient User is done outside the Application and under the sole and exclusive responsibility of the Professional Health Users.

The Patient User acknowledges that the Company cannot be held liable for any material or immaterial, direct or indirect damage, whatever its cause (including

damage that may be caused by the possible spread of the virus, by computer fraud, due to the constraints and limitations of the internet network, or by the loss, deterioration or alteration of files) nor for the resulting consequences:

- Regarding the use of the Application, Services and Content;
- The impossibility of accessing the Application, Services and Content, except for direct damages resulting from gross negligence or intentional misconduct.

3.3 Price

The selling price of the Application is accessible to Patient Users before the Order.

This price is broken down as follows:
Quarterly remote monitoring package = €500 including VAT (20%)

The sale price of the Application is subject to value added tax (VAT).

As the Application is registered on the list of reimbursable products and services (LPPR), the portion of the price remaining to be borne by the Patient User depends, where applicable, on reimbursement rights and on their affiliation to compulsory and supplementary health insurance organizations (Financing Organization).

Under no circumstances does the Application include functionalities for managing reimbursement requests from mandatory and/or supplementary health insurance organizations or for generating treatment forms. These operations are the sole responsibility of the Prescriber, as applicable, using their own information system.

The sale price does not include the costs, which remain the responsibility of the Patient User and the Care Centre, relating to telephone or electronic communications necessary for the subscription, use and access of the Application.

3.4 Ordering Process

Ordering operations are carried out as follows:
The Prescriber prescribes the Application to their Patient. By then registering the Patient on the Application, it is necessary that the Patient has previously agreed to this type of monitoring.

By accepting these Terms and Conditions and giving their consent, the Patient agrees to the Order being placed. They then agree that SIVAN France may receive the prescription in lieu of the Order. The Prescription can be downloaded to the Application by the patient or a Professional, using the secure MOOVCARE® Lung platform.
The prescription can also be sent by email by a Professional with a compatible secure email address, to the following secure email address:

sivan.france@medical75.apicrypt.org

Or by sending it to SIVAN France, by post to the following address: SIVAN France – Accounting - 163 Quai Aulagnier, 92600 Asnières-sur-Seine.

SIVAN France has joined the national agreement enabling direct billing. Therefore, SIVAN will handle all necessary procedures with mandatory and supplementary

health insurance providers directly for insured patients receiving care under the Long-Term Illness scheme.

The initial order is for a period of 6 months following an assessment of the patient's eligibility. Renewal is handled by the healthcare professional during the follow-up visit, after discussion with the patient, a further assessment of eligibility, and an evaluation of their agreement to this additional monitoring modality.
The prescription date is recorded in the Application. The Patient User will then be notified of the expiry date of this prescription and can request a renewal from their Prescriber during the follow-up visit. Professional Users also have access to this information.

3.5 Payment methods

Except in the case where the payment for the Application is directly covered 100% by a financing organization to SIVAN France, payment for the Order is made by credit card (Carte Bleue, Visa, Mastercard, American Express) via a secure payment system.

The Patient User must enter their card number, its expiry date and the three digits of the cryptogram on the back of it, directly in the area provided for this purpose.

The Patient User's attention is drawn to the fact that payment is made through a solution which features highly secure pages for entering payment data.

Bank card details are used only for the purpose of the transaction.

Only full payment allows the Patient User to benefit from the Application, Services and Content selected.

Warning: The Patient User is informed that he/she must be the holder of the bank card used for the payment of his/her Order or failing that be duly authorized to use it to proceed with the payment of his/her Order.

He guarantees SIVAN France that he fulfills all the conditions of access, use and sale and that the bank account associated with the means of payment used to settle his Order is sufficiently funded to satisfy his payment obligation.

3.6 Billing and coverage by a funding body

The Patient User is informed that the coverage by a Funding Organization of the sale price of the Application is conditional upon the latter being affiliated with a health insurance organization and/or a supplementary one.

An agreement has been established between the Funding Body and the Company, in order to allow the Patient User to benefit from third-party payment, provided that he is affiliated with a health insurance organization.
SIVAN France then sends the electronic treatment sheets and prescriptions directly to the Funding Organization to be reimbursed in return.
In this context, SIVAN may authorize itself to contact the Patient for additional information in order to complete the care provided.

The Patient User is informed that SIVAN France is not responsible for forwarding the invoice to a funding body. SIVAN France cannot be held liable in any way for the lack of full or partial coverage of the Application's sale price by a funding body.

The Patient User agrees to receive their invoice electronically, at the email address provided in the application.

3.7 Right of withdrawal

In accordance with Article L. 221-18 of the Consumer Code,*« the*The consumer has 14 days to exercise their right of withdrawal."Ion of a contract concluded remotely."

This period begins to run from the day of the Order.

The Patient User may exercise their right of withdrawal before the end of the 14-day period without having to justify their decision or incur any costs, at their discretion:

By any unambiguous statement indicating his/her intention to cancel his/her Order, such as for example

- by sending an email to SIVAN France at the address support@moovcare.com
- or by mail to the following address: SIVAN France, 163 Quai Aulagnier, 92600 Asnières-sur-Seine, clearly stating your identity, contact details and order number
- Or by using the form template below, to be sent by post to the address of SIVAN France or by email to the address support@moovcare.com

MODÈLE DE FORMULAIRE DE RÉTRACTATION

(Veuillez compléter et renvoyer le présent formulaire uniquement si vous souhaitez vous rétracter.)

A l'attention de la société SIVAN France par courrier – 163 Quai Aulagnier, 92600 Asnières-sur-Seine– email : support@moovcare.com.

Je, soussigné(e) _____ (nom, prénom), domicilié Code postal Ville

vous notifie par la présente ma rétractation du contrat portant sur la vente de l'Application Moovcare édité par la société SIVAN INNOVATION Ltd.

Prescription du Docteur effectuée le : __/ /

Signature de l'Utilisateur Patient (uniquement en cas de notification du présent formulaire sur papier) :

Date :

The Patient User is informed that:

- The use of the withdrawal form template is not mandatory;
- In order for the withdrawal period to be respected, it is sufficient for him to send SIVAN Francesa communication relating to the exercise of the right of withdrawal before the expiry of the 14-day withdrawal period.

If the Patient User exercises their right of withdrawal within 14 days of the Order, the Patient User will be reimbursed for all sums paid, free of charge, via the same payment method used for the initial transaction.

In such a case, SIVAN France will proceed to reimburse all sums paid for the Order without undue delay and, in any event, at the latest within 14 days from the date on which it was informed of the Patient User's decision to withdraw.

SIVAN France will process the refund using the same payment method used by the Patient User when placing the Order, unless otherwise expressly agreed by the Patient User for the use of another means of payment and provided that this method of reimbursement does not incur any costs for the Patient User.

The Patient User will be responsible for informing the funding body of their decision to withdraw.

The Patient User is informed that exercising their right of withdrawal will result in the termination of the Terms and Conditions of Use and the Terms and Conditions of Sale, and that they will consequently no longer have access to the Application, its Content and Services.

3.8 Guarantees

The Application benefits from the warranty against hidden defects provided for in Articles 1641 et seq. of the Civil Code.

When the Patient User decides to invoke the warranty against hidden defects in the Application:

- He has a period of two (2) years from the discovery of the defect to take action;
- He can choose between terminating the Terms and Conditions and ceasing use of the Application or continuing to use the Application and obtaining a reduction in the sale price in accordance with Article 1644 of the Civil Code.

3.9 Evidence agreement – electronic signature

The computerized records kept in the computer systems of SIVAN France will be considered as proof of communications and various transmissions of written and electronic documents between Patient Users and the Company.

The Patient User acknowledges and accepts that, after identification, any expression of will through the use of the features offered within the Application and in particular the acceptance of the Terms and Conditions and the selection of Services, constitutes an electronic signature within the meaning of the provisions of Articles

1366 et seq. of the Civil Code, and manifests his consent by characterizing its proof.

In accordance with the provisions of Articles 1366 et seq. of the Civil Code, the implementation of an electronic signature, based on a reliable identification process guaranteeing its link with the act to which it is attached, is considered a valid signature and proof within the meaning of the aforementioned provisions.

The Patient User may not contest the admissibility, validity, or probative value of the aforementioned electronic or physical documents on the basis of any legal provision that specifies that certain documents must be written or signed to constitute proof. Thus, the aforementioned documents constitute evidence and, if produced as evidence by SIVAN France in any legal or other proceedings, will be admissible, valid, and enforceable in the same manner, under the same conditions, and with the same probative value as any document that would be created, received, or stored in writing.

3.10 Proof of Order

The online provision of the bank card number and the final validation of the Order constitute proof of the entirety of said Order in accordance with Articles 1366 et seq. of the Civil Code and shall constitute the obligation to pay the sums committed for the provision of the Application.

This validation constitutes a signature and express acceptance of the banking transactions carried out within the framework of the Application. However, in the event of fraudulent use of their bank card, the Patient User is advised to contact SIVAN France customer service as soon as they become aware of such use.(contact@sivan-innovation.com)or by calling technical support.

Computerized records, stored in SIVAN France's computer systems under reasonable security conditions, will be considered as proof of communications, orders and payments made between the Patient User and the Company.

Order forms and invoices are archived on a reliable and durable medium so as to correspond to a faithful and durable copy in accordance with Article 1379 of the Civil Code.

3.11 Complaints handling – customer service

Any complaint related to the Application, its Content and Services should be addressed to SIVAN customer service:*contact@sivan-innovation.com*.

On this occasion, the Patient User is informed that he/she must not transmit any data relating to his/her health.

3.12 Changes to the Terms and Conditions

These Terms and Conditions may be modified by the Company at any time. Any Order placed after such modification will constitute acceptance of the modified Terms and Conditions.

3.13 Applicable law

These Terms and Conditions are governed by French law and will be executed and interpreted in accordance with French law.

In the absence of an amicable settlement, any dispute relating to the services or in connection with an Order will be submitted to the French courts, regardless of the place of residence of the Patient User and/or the place from which the Order was placed.

4 Appendix: Processing of personal data – relationship between data controller and data processor

With regard to the processing of Patient data, the Practitioner Using the Application or the Care Centre for which he/she is employed, if applicable, has the status of "data controller".

SIVAN INNOVATION and SIVAN France, as subcontractors for Patient User data, commit to:

- Personal data will be processed solely for the purposes outlined in these Terms and Conditions and accepted by the Practitioner/Treatment Center.

- Process the data in accordance with the documented instructions of the Practitioner User / the Care Center,

- Inform the Practitioner/Treatment Center within 48 hours if they believe an instruction constitutes a violation of the regulations concerning the protection of personal data.

- To guarantee the confidentiality of personal data processed within the framework of the Application,

- Subjecting SIVAN INNOVATION and SIVAN France employees involved in the processing of personal data to an obligation of confidentiality and to training sessions on the protection of personal data.

In the event of termination of the contractual relationship for any reason whatsoever, SIVAN INNOVATION and SIVAN France undertake to choose the Practitioner User /from the Care Center to:

- Delete the personal data in their possession,

- Return said personal data to the Data Controller following the reversibility procedure implemented by the approved/certified health data hosting provider.

SIVAN INNOVATION and SIVAN France also commit, to the fullest extent possible, to assisting the Practitioner User / the Care Center:

- In conducting any impact analysis of processing related to the Application,
- In the event of prior consultation with the CNIL.

- **Procedures for exercising the rights of individuals**

SIVAN INNOVATION and SIVAN France are committed, to the fullest extent possible, to assisting the Practitioner/Care Center in processing any request of a person exercising their rights of access, rectification, erasure, portability or objection.

Any request from the Practitioner User / Care Center arising from a complaint by a person whose personal data has been collected must be notified to SIVAN FRANCE via the following email address:dpo@sivan-innovation.com

When a person exercises their rights directly with SIVAN INNOVATION or SIVAN France, the latter undertake, upon receipt of this request, to forward it to the data controller.

SIVAN FRANCE draws the attention of the Practitioner User or the Care Centre as appropriate, to the fact that it is their responsibility to keep up to date a register of access, rectification and objection requests in electronic format, containing the different dates and the description of the exchanges that took place with the persons concerned.

- **Notification of personal data breaches**

In the event of a personal data breach, SIVAN INNOVATION or SIVAN France will notify the Practitioner User / Care Centre or its Data Protection Officer by email of such a breach as soon as possible or within 48 hours of becoming aware of it.

This notification is accompanied by all useful information to enable the Data Controller, if necessary, to notify the competent authority of this breach.

- **Security measures and guarantees**

The security measures and guarantees provided by SIVAN INNOVATION and SIVAN France regarding the implementation of appropriate technical and organizational measures for the protection of personal data are described at the end of this appendix. SIVAN INNOVATION and SIVAN France are ISO 27001 certified for the development, distribution, management, and services related to medical information applications and telemedicine. The certificate can be provided upon written request.

- **Processing Activities Register**

SIVAN INNOVATION and SIVAN France inform the Practitioner User / the Care Center that it has an electronic register containing all the following information:

The name and contact details of the data controller, as well as the names and

contact details of the data controller's representative and the contact details of its data protection officer, and his name where applicable.

- The categories of processing carried out on behalf of the data controller

- Where necessary, transfers of personal data to a third country or international organization, including the identification of that third country or international organization and, where appropriate, documentation demonstrating the existence of appropriate safeguards,

- A general description of the technical and organizational security measures, including the terms of this document.

SIVAN INNOVATION and SIVAN France inform the Practitioner/Care Center that this register may be made available to the CNIL upon request and that it does not exempt the Practitioner/Care Center from maintaining its own register, which must include, in addition to the aforementioned information:

- The purposes of the processing,

- A description of the categories of persons concerned and the categories of personal data,

- The categories of recipients to whom personal data have been or will be disclosed, including recipients in third countries or international organizations,

- The timeframes planned for the deletion of the different categories of data.

- **Security level assessment procedure**

SIVAN INNOVATION and SIVAN France have put in place a procedure for evaluating the level of security applied to the protection of personal data processed within the framework of the Application.

The purpose of this procedure is to verify, once a year, whether the measures referred to in this Annex and in the Personal Data Protection Policy of SIVAN INNOVATION and SIVAN France to ensure data protection are still relevant and appropriate with regard to the Regulations on the protection of personal data.

- **Obligations of the data controller**

SIVAN INNOVATION and SIVAN France can only act on the instructions of the data controller (Practitioner User / the Care Center) with regard to the purpose which falls under its responsibility (use of the Application by Patient Users), the data controller, in this capacity, undertakes to document and provide SIVAN in writing all instructions concerning the processing of personal data.

The Practitioner User / the Care Centre responsible for processing agrees that only the data necessary for the use of the Application is processed in terms of the quantity of data, the scope of its processing and the duration of its retention.

The data controller is informed that it is his responsibility to:

- Provide information to the individuals concerned by the processing operations at the time of data collection,

- Ensure, both beforehand and throughout the processing, compliance with the obligations stipulated by the Data Protection Regulations.

- Supervise the processing and conduct audits and inspections if deemed necessary.

- **Information and advice**

The Practitioner User / the Care Centre as data controller declares that, by virtue of the terms of this Annex and the Personal Data Protection Policy of SIVAN INNOVATION and SIVAN France, it has obtained the information, advice and assistance necessary to ensure that SIVAN INNOVATION and SIVAN France comply with their obligations under the Regulation on the protection of personal data and that it has been able to verify that it is itself in compliance with the obligations incumbent upon it under this same Regulation.

- **Data Protection Officer**

The data protection officer appointed by SIVAN INNOVATION and SIVAN France can be contacted at the following email address:dpo@sivan-innovation.com

- **Subcontracting**

Within the scope of these Terms and Conditions, the data controller is informed of and consents to the involvement of the Sub-processors listed below. The data controller is also informed that SIVAN INNOVATION may engage another sub-processor to carry out specific processing activities. In this case, SIVAN INNOVATION and SIVAN France will inform the data controller in advance and in writing of any planned changes regarding the addition or replacement of sub-processors.

This information will specify the outsourced processing activities and the identity and contact details of the subcontractor. The data controller will then have a minimum of 8 days from the date of receipt of this information to raise any objections.

In the absence of reservations within the aforementioned period, the subcontractor concerned will be deemed approved by the data controller.

In the event of reservations, the data controller must provide objective reasons justifying their refusal. If these reasons are valid, SIVAN INNOVATION will ask its subsequent subcontractor to take into account the reservations expressed by the data controller or will propose an alternative subcontractor.

SIVAN INNOVATION undertakes to ensure that its Subcontractors Subsequent

provide sufficient guarantees regarding the implementation of appropriate technical and organizational measures defined below, so that each processing meets the requirements of the European General Data Protection Regulation.

Each subcontractor of SIVAN INNOVATION and SIVAN France is required to comply with the obligations of this Annex.

SIVAN INNOVATION remains fully responsible for its subsequent subcontractors.

With regard to the processing of data for which SIVAN INNOVATION internationally, or SIVAN FRANCE (in Europe) has the status of "data controller" (sale of the device, technical assistance, improvement of the quality of the Application, satisfaction or medico-economic studies, and more generally in order to respond to all requests issued or required by the health authorities), SIVAN INNOVATION and SIVAN France undertake to comply with the Regulations on the protection of personal data.

Organizational and technical measures implemented for the design and distribution of the device

The Moovcare® Lung device is only available in the cloud (web application) or as a downloadable application for patient users.
No application servers are hosted by SIVAN INNOVATION: all application servers are hosted by ATE (Health Data Hosting certified HDS:2018).

SIVAN INNOVATION guarantees that it has implemented the following technical and organizational measures in relation to the processing of personal data:

Measures to ensure confidentiality

- **Physical access control**

Measures designed to prevent unauthorized persons from physically accessing computer and data processing systems for processing personal data, and confidential storage media and files:

At SIVAN INNOVATION premises, security features include door entry codes, fire alarms, and fire extinguishers.

At SIVAN France premises, security measures include door access (electronic badge system at the building's main entrance, then controlled key allocation + keypad at the entrance to the premises), fire alarm and fire extinguishers.

Stringent access control measures are also in place at our HDS-certified health data host and our subcontractors certified to ISO 27001:2013 or equivalent.

- **Logical data access control**

Measures designed to prevent protected data from being processed or used by unauthorized persons, ensuring that the data cannot be read, copied, modified, recorded, or erased during processing without authorization. These security measures exist, in particular, for design traceability and software development:

- Password / login,
- Password must be changed every 3 months.
- Disconnect, automatic locking.

- Authorization concepts (limiting access to authorized employees based on their role).
- Connection tracking.
- Firewall and antivirus software are regularly updated.
- Record traceability policy (design and development software)

In addition, software containing customer data (access to the back office of the MOOVCARE® Poumon application, for customer relationship management) has enhanced security measures: Two-factor authentication process One Time Password (respecting a minimum length, regular change and strict confidentiality regarding the passwords used).

Measures intended to prevent protected data from being processed or used by unauthorized persons, so that the data cannot be read, copied, modified, recorded or deleted during processing without authorization in the MOOVCARE® Lung web application:

- The data recorded or calculated in MOOVCARE® Lung is all stored with a certified health data host (HDS), as defined in Article 1111-8 of the Public Health Code.
- Users are authenticated via their mobile phone number and email address (authentication of the email address following receipt of the initial email then verification of the mobile phone number via the entry of a one-time code).
- A password is required for each user with constraints following the recommendations of the OWASP Application Security Verification Standard 4.0 guide: (minimum 12 characters, not 100% numeric, regular check if the email used for login is blacklisted, otherwise the user is asked to create a new password).
- Limited number of access attempts for all users
- Limited usage time
- The user is alerted to the need for confidentiality regarding their login credentials.

- **Separation instruction**

Measures ensuring that data collected for different reasons are processed separately, and are therefore isolated from other data and systems in order to prevent any unforeseen processing of this data for other reasons:

- Authorization concepts for accessing internal projects based on each person's role.
- Separation complete of the elements of each software And applications developed by the manufacturer.
- Separation of databases according to countries
- Database instance for each indication.
- Data independence for a given care center in MOOVCARE® Lung.
- Separation of development and production systems.

- **Pseudonymisation**

Measures to reduce personal references during data processing, to such an extent that personal correlation with the data subject is impossible without additional information. Therefore, any additional information must be kept separate from the pseudonym: Hash value process

This pseudonymization measure is implemented on the backoffice platform so that authorized personnel cannot access the patient user's personal data without the patient's initial consent. Measures to guarantee integrity

- **Data transfer control**

Measures ensuring that personal data cannot be read, copied, modified, recorded or erased without authorization during their electronic transmission, transport or storage on data carriers, as well as measures ensuring the verification and determination of the locations to which the transmission of personal data is destined:

- Data transmission via secure data networks (HTTPS).
- Data confidentiality and integrity (encryption of data streams and strong authentication during connections).
- From a legal standpoint, the law requires the hosting provider to guarantee the integrity and confidentiality of data, as well as traceability of data handling; these obligations necessitate:
- to secure external access points;
- to ensure that only authorized persons can access personal data;
- to ensure an audit and traceability of attempts to connect to the data as well as the manipulations carried out;
- to ensure that data is not retained at the end of the service.

Measures to ensure availability and capacity:

- **Availability check**

Measures designed to ensure that personal data is protected against accidental loss or destruction. These measures are implemented both at the certified healthcare hosting provider and at our main suppliers:

- Data backup process by our certified health data hosting provider.
- Duplicate databases across multiple systems.
- Geographic distribution: resources are distributed across multiple data centers.
- Powered by different networks. Redundancy is intrinsically integrated into the infrastructure.
- Uninterruptible power supply.
- Fire alarm system.
- Air conditioning system.
- Alarm system.
- Environment monitoring by the hosting provider.

- **Rapid recovery**

Measures ensuring rapid recovery of data availability and accessibility in the event of a physical or technical incident.

At SIVAN INNOVATION and SIVAN France:

- Incident management process.
- Data backup process.

Such measures are notably taken at our subcontractors certified to ISO 27001 or

equivalent standards:

- Incident management process.
- Business Continuity Plan.
- Switching process for database servers.
- Data backup process.

Measures concerning the regular assessment of data processing security

Measures guaranteeing the security of data processing, in accordance with the law:

- Data protection management procedure.
- Procedure for setting up technical support
- Procedure in case of data breach.
- Conducting risk analyses to evaluate the performance and safety of the medical device (according to ISO 14971:2012 and 2019).
- Conducting impact analyses on data protection and security (CNIL PIA v2.0 tool).

List of subcontractors:

Name	Activity	Treatment location	Legal basis/certificate
Future Telematics (ATE)	Health data hosting provider France	France	certified HDS For accommodation of the health data
Mailjet / Sinch	API communication par email	Data centers: Germany, Belgium	ISO 27001, SOC 2 Transfert https
Vonage Business Limited	communication via messaging (SMS)	Europe, United Kingdom	IBM SoftLayer platforms with certified servers (ISO 27001, SOC 2, SOC 3). transfert https Standard Contractual Clauses
Aircall	telephony, telephone recording technical support	France, Belgium, United Kingdom	Consent, standard contractual clauses