REF SKIVR

CE Class I Medical Device

User manual

Distribution mode

Available for direct download at

http://virtualisvr.com/espace-client/

Use under licence

VIRTUALIS

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DESCRIPTION

SKIVR software is an immersive 3D simulation based on virtual reality technology, i.e. it allows a person to be immersed in an artificial digitally created world. **SKIVR** is software used for lower limb re-education and posturology.

INDICATIONS

Orthopedic, neurological, rheumatic functional re-education of the lower limb. Center of gravity displacement work.

CONTRAINDICATIONS

Epileptic patients, children under 15 years of age, pregnant women

FOR USE BY

Healthcare professionals: Physiotherapists; Neurologists; PRM doctors (Physical and Rehabilitation Medicine), etc.

Research Centers: CNRS, CHU, INSERM, etc.

WARNINGS AND CAUTIONS

During sessions, stay close to the patient in order to anticipate any loss of balance or discomfort caused by the use of virtual reality.

Define a working area of about 3m² to allow for risk-free movements.

Take a 10 to 15 minute break every 30 minutes of use.

Potential adverse effects are those due to the use of Virtual Reality, namely vomiting, malaise, dizziness, syncope.

The accessories required to use the software may emit radio waves that can interfere with the operation of nearby electronic devices. If you have a pacemaker or other implanted medical device, do not use the product until you have taken advice from your doctor or the manufacturer of your medical device.

⚠️   *Any serious incident should be notified in writing to* qualite@virtualisvr.com

Table of Contents

1. GENERAL

1.1. Advice for use

This type of re-education must be undertaken progressively, especially in Virtual Reality where the stimulation is much more "powerful" than the traditional optokinetic stimulators.

These stimulations have the potential to cause certain disorders: Vasovagal syncope, epileptic seizures, migraines, etc. (Despite a test phase on more than 2000 patients. Similarly to previous generation optokinetics, caution is required)

The contraindications are identical: Mainly epilepsy and migraines.

As postural reactions can be spectacular, it is VERY STRONGLY advised to place patients in a safe environment and to stay close to them throughout the session.

It is also recommended to increase the duration and intensity of the stimulation very gradually, after an initial short session to make sure of patients' tolerance to this type of stimulation.

Virtualis declines any liability for any disorders suffered by patients during or after use of its software.

1.2. Hardware and minimum configuration requirements

Hardware required to use the system:

- VR Ready PC
- VR System: HTC VIVE, HTC VIVE Pro or compatible system
- Lighthouse bases (HTC VIVE tracking)
- HTC VIVE Controller
- XBOX 360 Controllers
- Dynamic posturography platform (Motion VR)
- USB HUB

In order to install and use our virtual reality applications, we recommend a configuration equal to or higher than the system requirements:

Technical Minimum Requirements

GPU
NVIDIA: Gen9 GTX 970 / Gen10 GTX 1060
AMD Radeon: R9 290 / RW 480 / Vega 56

CPU
Intel: I5 4590
AMD: FX 8350 / Ryzen 1400

Operating System
Windows 7 SP1

RAM
8 Go

2. USE OF PATIENT MANAGEMENT

Once connected to the Patient Management software, you arrive on the home page. It is from this home page that you will be able to start your VR software as well as the other Patient Management functions.

The software can be grouped according to criteria such as "Assessment" or "Re-education" and then by pathology type: Neurology, Balance, Functional or Travel sickness.

You can start or switch from one software to another from the home page by clicking the corresponding "Start" or "Protocols" button.
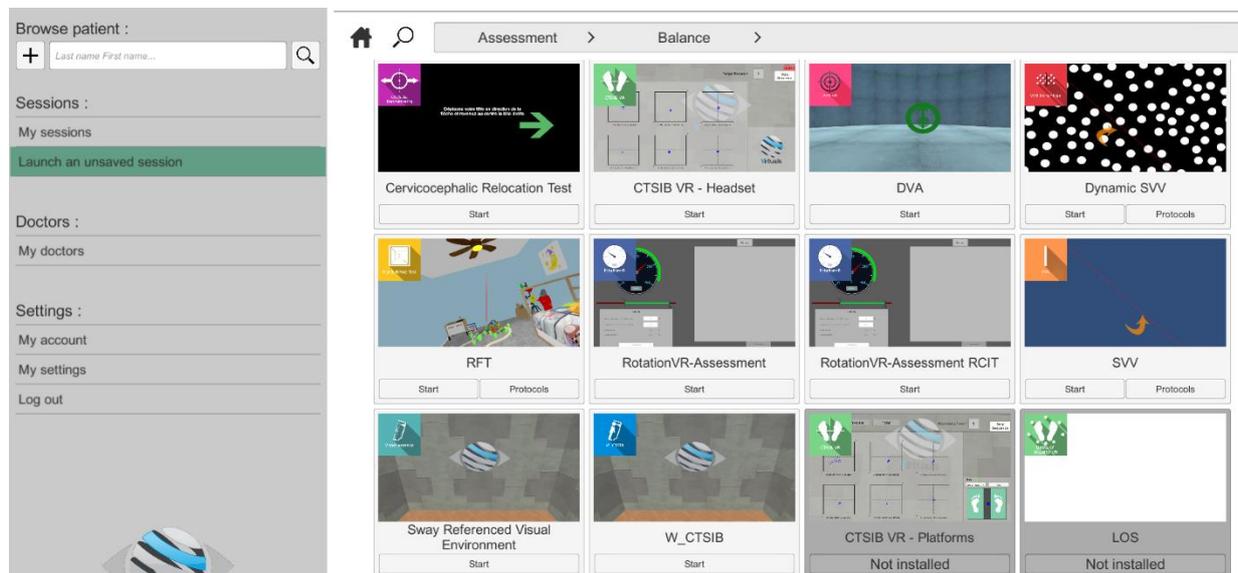
Some software can be started either in *manual mode*, by directly clicking the "Start" button, or in *protocol mode* by clicking the "Protocols" button.

Manual mode allows users to choose the settings for each environment. *Protocol mode* offers several sessions with different difficulty levels to test and gradually accustom patients to the VR environment.
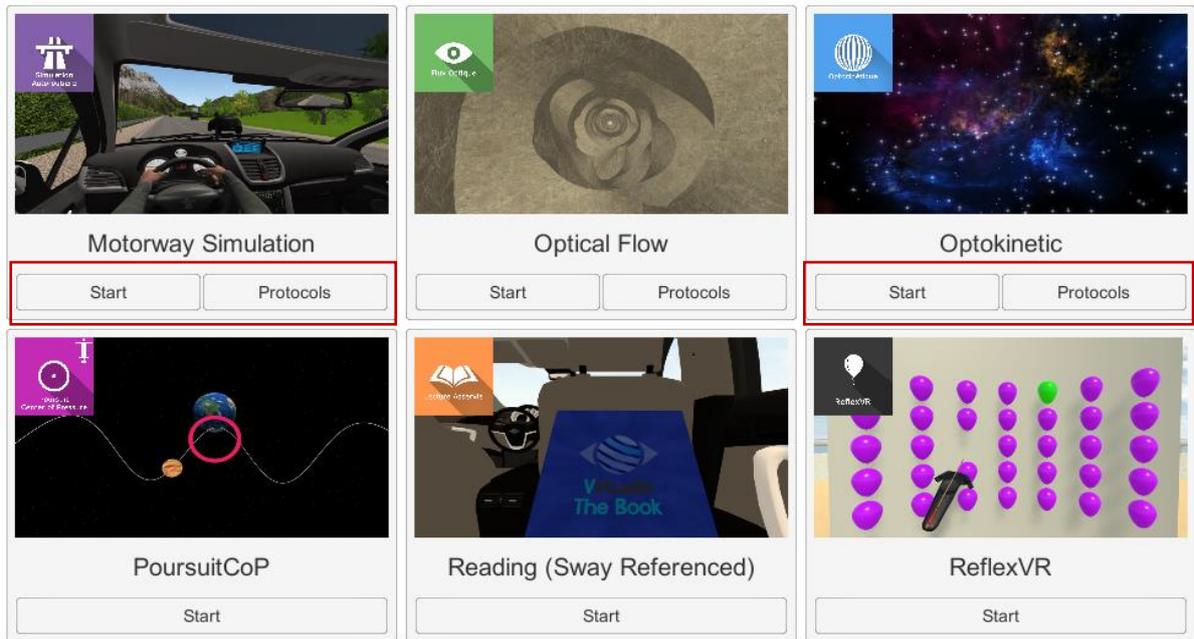
Software that is not part of your subscription package is greyed out. If you want to use it, please contact our sales department.
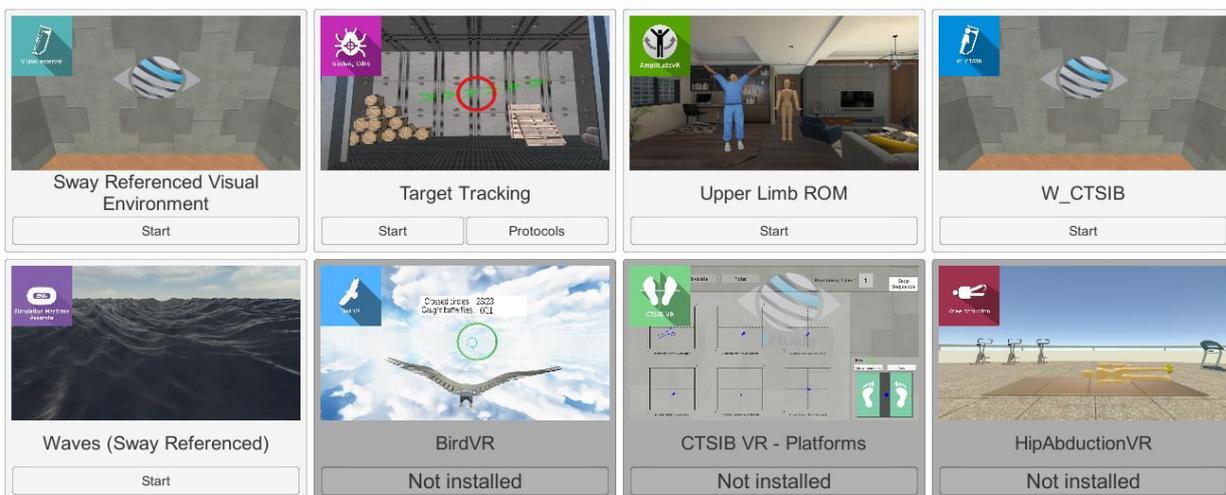
3. SKIVR

3.1. Start interface
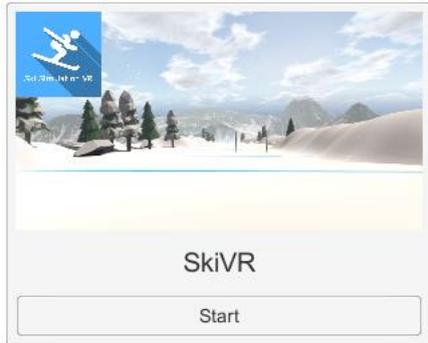
When the software is started in *manual mode* ("Start" button), the opening is performed in a launch interface, consisting of a module selection menu on the left, a set up area on the right, and an action area at the bottom right.

Depending on the module selected in the left menu, the set up area shows the various possible settings/information.

It is possible to access the general Patient Management menu from the start interface by simply clicking the "Quit" button located in the action area, or by pressing the "escape" key on the keyboard.

The module is launched by simply clicking the "Start" button in the action area.
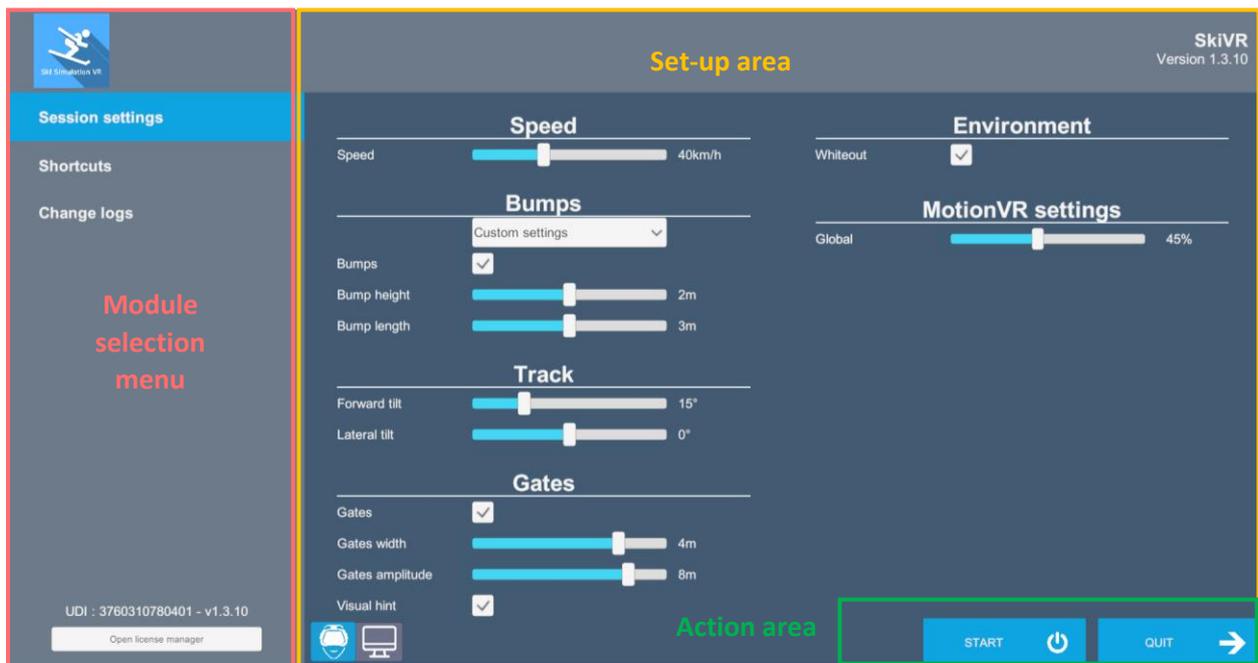
Once this button is pressed, the module starts by taking into account the specified settings. You also have the possibility to modify some settings when the module has been launched, using the mouse.

The Start/Quit buttons allow the environment to be played back or stopped entirely to adapt the experience to the patient's sensations.

Once an environment has been selected, it launches in the headset, and you can see and track what is happening in your patients' headset from the software window.

3.2.   Module field of application

This module allows work on global balance, the exploration of the support polygon, the proprioception of and the re-application of weight on the lower limbs.

3.3.   Installing the patient

Standing position on static or dynamic platform. Feet can be positioned at will: together, apart, front slot, etc.

3.4.   Session settings
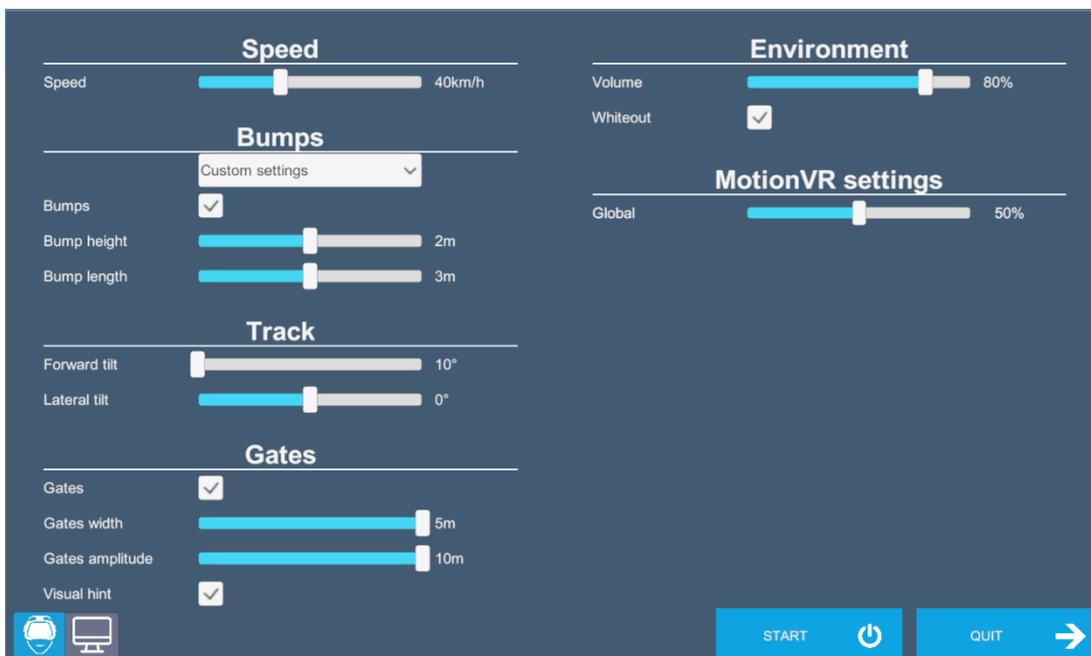
The variable settings for this module are as follows:

Piste settings

Speed:

Speed can be set using the cursor

Bumps

Pre-settings are possible: no bumps; soft bumps; medium or hard bumps

In the custom settings, the height and length of the bumps can be selected using the cursor

Track

Front and side tilt: the tilt degree can be customized using the cursor

Gates

Gate width and amplitude can be customized using the cursor

Visual hint

Gate visual aids can be enabled by checking the appropriate box

Environment

The environment can be customized by acting on settings such as: sound volume, body presence, snow or whiteout.

MotionVR settings

Platform amplitude values can be defined by using the cursor

Display mode

Two possibilities: Headset or Screen mode

You can choose between "headset" or "screen" mode by simply clicking on the corresponding icon; the selected icon turns blue.

Headset mode : The environment launches into the patient's headset

Screen mode : This mode requires having a second screen connected to the computer

Warning: in this mode the headset must not be used, and the patient must be placed in front of the second screen

By clicking on the arrow located on the right top of the screen, the StaticVR and MotionVR settings and additional options can be accessed by clicking on the buttons on the right side of the launch interface.

StaticVR settings

Raw data sent by the platforms

Yellow dots: Center of Pressure (COP) of each foot

Blue dot: Global Center of Pressure (COP)

The weight distribution for each foot is displayed
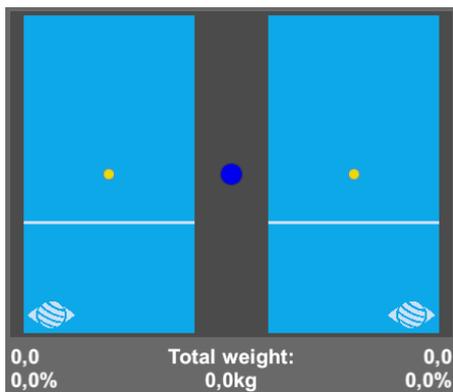
Smoothed data & settings:

Tare

Platform reset (must be carried out when empty)

Smoothing

Smoothing force applied to the data

Sensitivity

Multiplier applied to received data

Decrease to reduce motion sensitivity

MotionVR settings

Movement settings

Platform amplitude values can be defined either by using the cursor or by choosing one of the proposed values by simply clicking on the button corresponding to the value.

There is the possibility to choose an overall or per-axis movement amplitude, the presets provide a smooth transition.

For example:

- To work in anteroposterior mode, reduce the left and right amplitude
- To work in the mid-lateral position, reduce the forward and backward amplitude
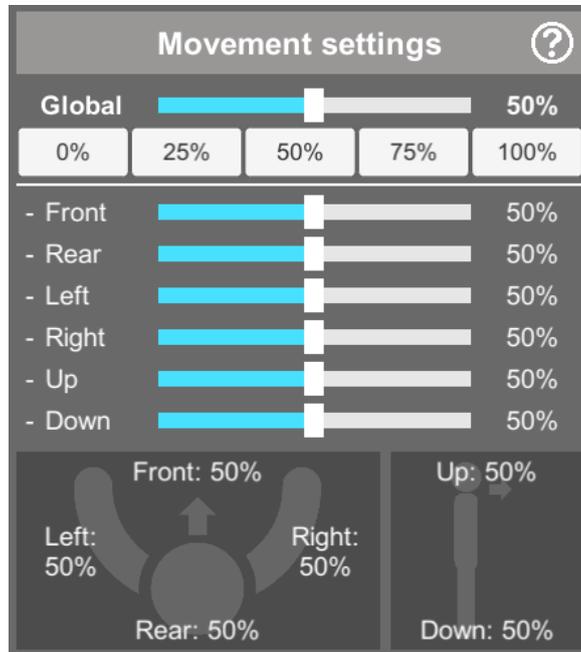
Movement preview

Used to view the platform tilt, height and amplitude settings (the action area is delimited by a black circle).
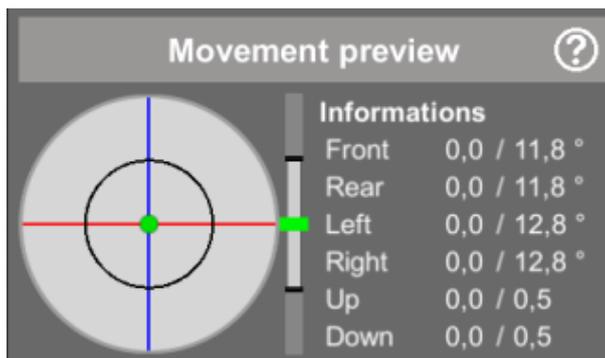
Options
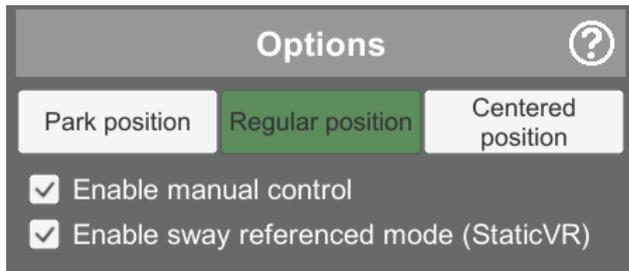
Platform positions

Park position: forces the platform to ground level

Regular position: allows the platform to move normally, as provided for in the software

Centered position: forces the platform into a horizontal position at its operating height

Activate manual control

Use the arrow keys on the keyboard and the "+" and "-" keys on the numeric keypad (up and down) to move around.

Enable sway referenced mode (for StaticVR platforms)

The platform movement is controlled by the patient's center of gravity

The [?] button on the launch interface at the bottom right provides access to other advanced options:

Check the corresponding box to **"Enable development options"**

Two types of display are possible:

- ☐ [StaticVR] Display graphics
- ☐ [StaticVR] Display port status

These boxes are development options used to control devices connected to the computer. It is not advisable to use them (slows down the software).

Recording Options:

You have the possibility of choosing the type of data to be recorded by ticking the corresponding box:

StaticVR:

- ☐ Raw data
- ☐ Smoothed data

MotionVR

□ Gross position (pitch & height)

Select the location on the computer to save the data and press the "Start Recording" button

If you press the emergency stop button, the platform will freeze in its current position.

A window opens and the following message appears

Emergency Stop

You have pressed an emergency stop button.
The platform will be stopped until the software is closed.

Warning:
Stopping the software or changing the selected window may trigger the reset of the platform to the default position.

Warning:

Stopping the software or changing the window may cause the platform to reset to the default position and cause movement that could be dangerous for the patient. It is therefore advisable not to touch the computer again until you have secured the patient when the emergency stop is triggered.

Score

Users get a score in real time, representing their success: number of doors passed through, and total number of doors.

3.5.   Shortcuts

Keyboard or joystick shortcuts are accessible:

- on the "Shortcuts" tab available at the start interface level
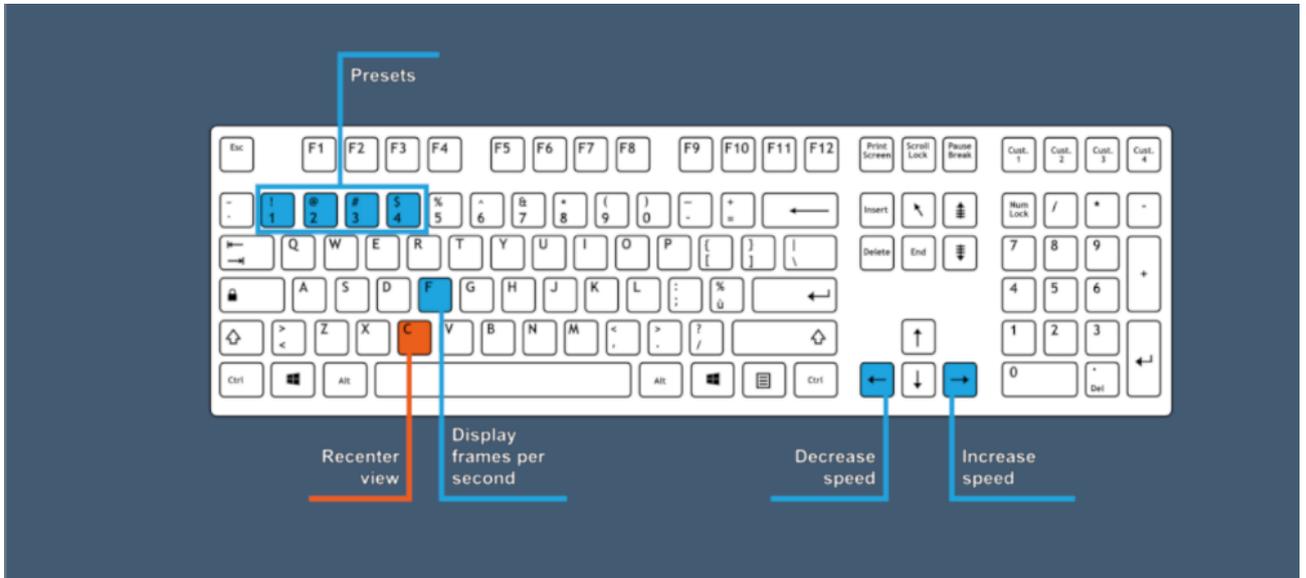
3.6. Data processing

Data retrieval and analysis uses the Patient Management software.