

- IVS4 -

**DESSINTEY**  
**Instructions for use**



**Please read carefully before using your device.  
Instructions for user to be kept.**

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## 1. Introduction

Dessintey develops intensive rehabilitation technologies to promote recovery and ensure better patient autonomy. Our mission is to assist patients throughout their healing and rehabilitation journey. Our technological solutions are aimed at increasing, diversifying and personalising their daily practice schedule from the moment they join the rehabilitation centre until they return home.

The IVS4 device provides assistance and facilitates mirror therapy, making it ergonomic, personalised, captivating and therefore more efficient and accessible, both for patients and their clinicians (doctors, physiotherapists, psycho-motor therapist and occupational therapists).

The device can be used by the clinicians mentioned before and by patients from 6 years of age and without any particular contraindications except discomfort as explained in §2.5.

## 2. Precautions for use

### 2.1. Safety information

The device must be installed in a dedicated room or technical rehabilitation platform. It is equipped with wheels to make it easier to handle, however they must be locked before using the device. Healthcare professionals are allowed to move the device within the same department, building and floor. Otherwise, they must call the Dessintey customer service.

If it is not possible to place the device in a dedicated room, we can offer you acoustic partitions to isolate patients and ensure they can concentrate.

The manufacturer is responsible for the safety and performance of this equipment provided the following conditions are met:

- Installation and repairs are carried out by qualified personnel or personnel duly authorised by Dessintey.
- The device may only be connected to a mains power supply equipped with a protective ground terminal
- The equipment is used in accordance with the instructions for use.

It is strictly forbidden to alter the equipment, touch or modify the camera settings or access the technical maintenance hatch at the rear of the device.

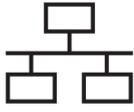
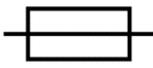
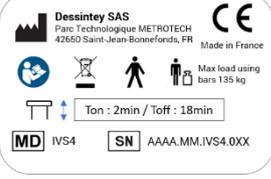
**Any modification to the device by unqualified professionals shall result in immediate termination of the warranty.**



**No modification of this equipment is allowed.**

## 2.2. Information, Identification et advertising Labelling & Symbols

The device includes information, identification and advertising labels, the details are presented below:

Symbol / Sticker / Label	Description	Sticker
	This label represents the logo of the Dessintey company, manufacturer of the IVS4 device. It is affixed on each of the clinician screen	Specific sticker
 <p>CONTACT qualite@dessintey.com +33 (0)9 72 64 93 07</p> <p>Dessintey SAS Parc technologique Metrotech 42650 Saint-Jean-Bonnefonds FRANCE www.dessintey.com</p>	This label shows the contact details of the Dessintey company. It is affixed on each side of the device under the table.	Specific sticker
	This symbol indicates protection by earthing. It is affixed near the earthing sockets.	Specific sticker
	This symbol indicates a risk of crushing (due to handling of the table or screen).	Specific sticker
	This symbol indicates the presence of a USB port	Specific sticker
	This symbol indicates the presence of an Ethernet port	Specific sticker
	<b>Sticker N° 1:</b> This Label contains the electrical information of the device as well as the symbols explained below.	Sticker N° 1
	This symbol indicates the presence of a fuse	On sticker N°1
	This symbol indicates alternative current must be applied.	On sticker N°1
	<b>Sticker N° 2:</b> This label contains the identification and warning information on the device as well as the symbols explained below.	Sticker N° 2
	This symbol identifies the manufacturer. It is followed by the name and address of the manufacturer of the device	On sticker N°2

Symbol / Sticker / Label	Description	Sticker
	This symbol indicates the conformity of the device at Regulation (UE) N° 2017/745	On sticker N°2
	This symbol requires all users to strictly comply with the present instructions for use.	On sticker N°2
	In accordance with 2002/96/CE Directive, this product cannot be thrown in the garbage and must be disposed of in an appropriate recovery and recycling facility.	On sticker N°2
	Type B part applied This symbol means that the device has parts that come into contact with the patient.	On sticker N°2
	This symbol indicates the safe operating load: 135 kg person in the highest position of the device with use of the bars.	On sticker N°2
	This symbol indicates the functioning cycle of the actuators (screen and table) to respect	On sticker N°2
	This symbol indicates that the product is a medical device. It is followed by the name of product.	On sticker N°2
	This symbol indicates the Serial Number of the device.	On sticker N°2

The Dessintey device boasts a high level of performance, safety and reliability provided all the installation and maintenance rules described in this manual are scrupulously respected.

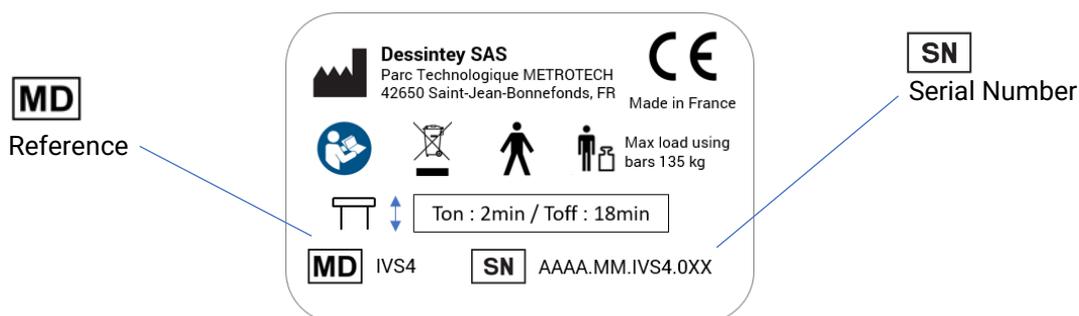
In particular, the indications marked with:



Indication that the non-compliance could result in risks to the safety of persons.

### 2.3. Registration number and explanation of symbols

The serial number of your IVS4 device is affixed to the back of your device, on the metal housing as well as on the setup screen of your software.



## 2.4. General precautions

As with any rehabilitation therapy, a medical examination must be performed before using the equipment.

- Only healthcare professionals who are qualified according to the condition of the person with a pathology and who have also been trained by an instructor approved by DESSINTEY, are authorised to use this device with their patients.
- The clinician must ensure that the adjustments (position of table and screen) are correct for the patient's morphology, comfort and physical condition.
- The clinician must take care of their patient during the adjustment phase of the device.
- The patient must immediately inform the clinician if they experience any discomfort during the session.
- The touch screen should only be used by a qualified and trained clinician.

To minimise the risk of burns, thermal shock or injury:

- Unplug the device when it is not used for long periods of time or before installing or replacing parts.
- Never use this device if the power cord or plug is damaged or if it does not work properly.
- Do not move the device by pulling on its power cord.
- Do not leave and do not insert objects into the openings as this could damage the machine.
- Do not use the device on a dirty or uneven floor or in a wet or salty environment and do not expose to bad weather.
- Do not use the device around sprays or oxygen.
- Do not adjust the table or the screen if the patient touches the devices
- Do not use any flammable agent near the device
- Do not put on the table or device any objects not provided with the IVS4.

Please contact the Dessintey customer service if you have any queries or defects on your device.



Do not approach one or more body parts close to the adjustment systems.

No care or maintenance operations should be performed when the device is being used by the patient.

To prevent any risk of interference, ensure that devices in the environment do not disturb the machine and comply with the standards thereof.

Limit the use of the table raising and lowering to the operating cycle indicated on the cylinders (2min ON, 18min OFF).

Do not sit on the device, whether it is running or not.

Change of fuse must be done by personnel of Dessintey.

The patient must not be in contact with the screen or his metallic enclosure during a time exceeding 1 second.

## 2.5. Indications

The main medical indications are the treatment of lower limb deficits and neurological pain by means of modified visual feedback.

The patient can use the IVS4 system once or three times a day depending on the clinician's recommendations.

## 2.6. Contraindications

Normal use of the device involves positioning the patient in front of one or more screens, a short distance away. A risk of discomfort may be felt by the patient during the first few minutes of use and then disappears normally. If discomfort persists and the patient feels uncomfortable, stop the session.

There are no other contraindications specified for this device.

## 3. Transport & Installation

### 3.1. Adjustment

#### 3.1.1. Wheels and brakes

Four wheels allow the device to move.

The two right wheels can be controlled by a right brake and the two left wheels can be controlled by a left brake.

There are three positions of the brake. The first two positions allows the movement of the wheels



The third position completely locks the wheels. The wheel is completely down.



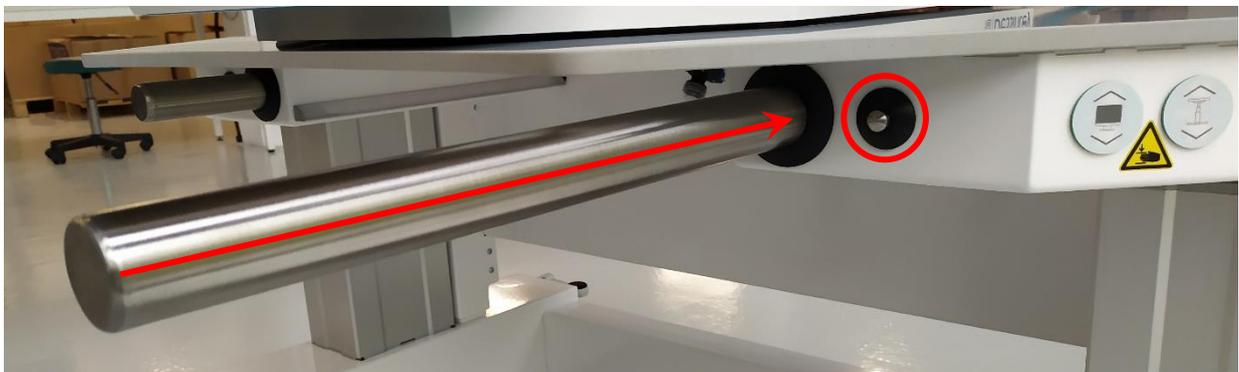
3.1.2. Grab bars

The grab bars can be used when the device is used for a standing position of the patient.

1 - To pull the bars you just have to pull them.



2 - To push the bars, you have to press the metallic button next to the bars while pushing them.



3.1.3. Screens

The device has 4 screens.

3.1.3.1. Therapist's screen

The therapist screen is tactile and can be manipulated in all directions thanks to the articulated arm.



**3.1.3.2. The patient's central screen**

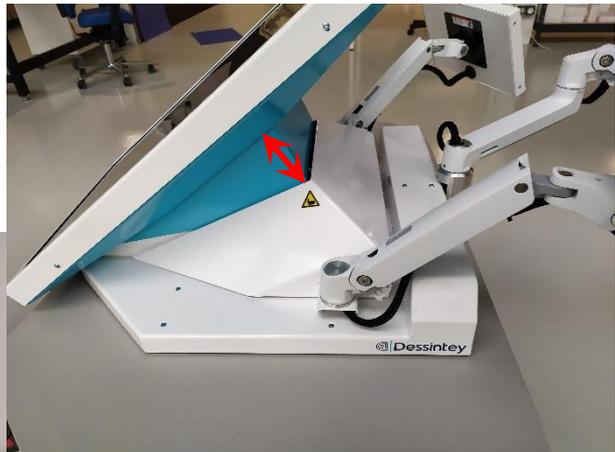
The patient central screen is located in front of the patient.

The central patient screen can also be adjusted in raised/lowered position using the up and down button:

Lower position with down button



Higher position with up button



**3.1.3.3. The lateral screens**

The two lateral screens follow the Left/right and Front-to-back movement of the patient's screen. The rotation of these screens is also possible thanks to the articulated arm.

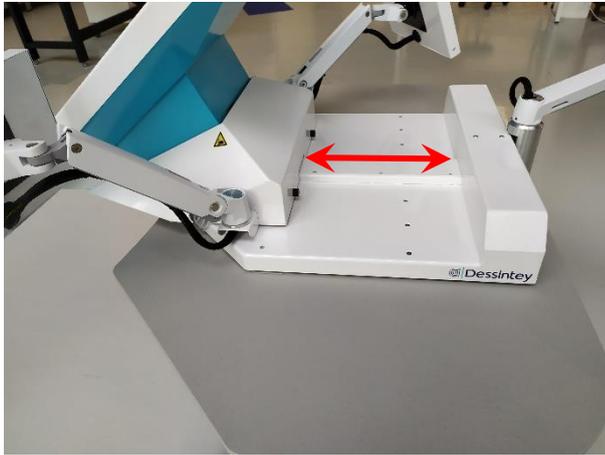


**3.1.3.4. Front to back and left to right movements**

The patient screen and the two lateral screens can follow a front-to-back and a left to right movement, by pushing/pulling manually the concerned part of the white structure on the table. This adjustment is made to position the screen above the patient's legs.

Front to back movement :

To move the screens manually, you must pull/push the upper part of the white structure:



Screens pulled to the front



Screens pushed to the back

Right to Left movement :

To move the screens manually, you must pull/push the lower part of the white structure:



The screens in the left position



The screens in the right position

Centered position :

A marker is visible on the table to align the screen in the centre of the table.



3.14. Lighting

To allow better visibility of the patient's legs, LED lights are available under the table. To activate and deactivate them, press the light button :



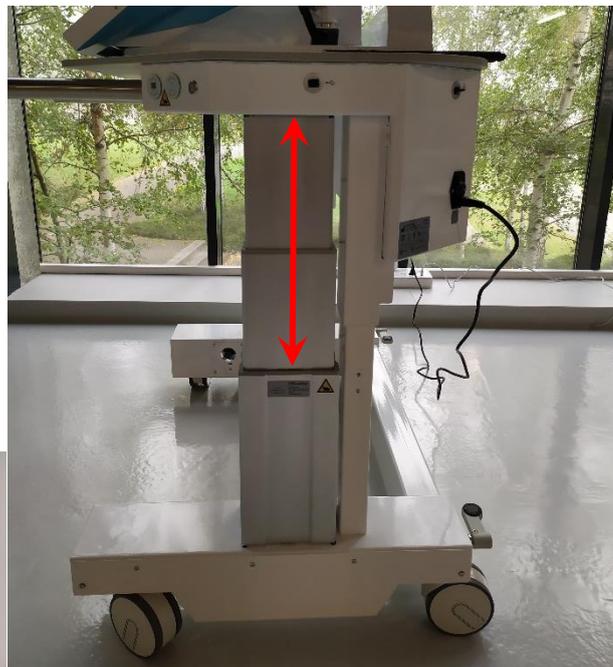
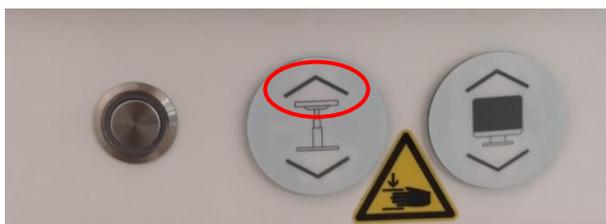
3.15. Table

The height of the table can be adjusted by using the up and down Table button:

Lower position with down button



Higher position with up button

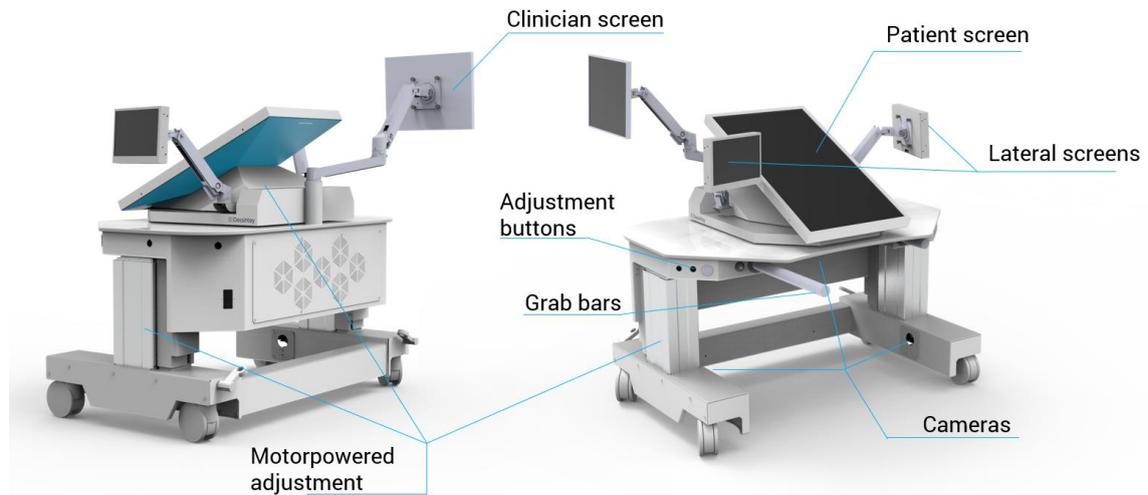


### 3.2. Delivery & Transport

Transport and delivery on site are provided by DESSINTEY or approved personal by DESSINTEY.

On delivery, you will receive the complete device including:

- height adjustable table on wheels
- Patient's central screen – up/down, left/right, and front/back adjustable
- Patient's Two lateral screens
- Clinician's touch screen on an ergonomic arm
- Three Cameras
- Keyboard
- Grab bars
- Instructions for use



The transport of the device must be done with the best practices to avoid switchover, damages, humidity, lateral movements, etc... Transport is done with specific cover and protection:





Information about transport and environmental conditions are stipulated on §7 of this instruction.

### 3.3. Installation

IVS4 is a medical device for indoor use only. It must be placed on a clean floor, free from humidity. This device is intended for use in a medical practice or on professional premises which must be ventilated, cool and lit.

Once the device is positioned as required, the wheels must be locked. The patient can be placed in front of the screen by following the steps described in §4.5.2. The aim is for the patient to be as comfortable as possible while maintaining a good illusion of movement.

Don't generate unintentional movements or jerks on the device.

Places of use of the device:

- Hospitals and Aftercare and Rehabilitation centres
  - Rehabilitation platform, gymnasium
  - In a dedicated space, e.g. booth, closed room
  - Patient's room
- Private rehabilitation platforms
- Specialised establishments under the supervision of medical and/or paramedical personnel (medico-social establishments, EHPAD (residential facilities for dependent elderly people), thermal baths, etc.)

It is not intended for use at home.

### 3.4. Manipulation.

Once installed, the device can be move from a piece to another as followed:

- Lower the table and the screen to the minimum position
- Store the central screen in the middle of the table (for right and left movement) and to the back of the table
- Store the 3 screens (lateral screens and therapist's screen)
- Pull the grab bars
- Unlock the wheels
- Use de grab bars to manipulate the device



If you need to pass doors:

- Do not pull the grab bars
- Use the table width to manipulate the device



### 3.5. Electric connection



1. Connect the device to the mains according to the country's standards (Example for France: NF C 15-100).
2. The mains power connection must only be used for the device and the device must be connected only with the power cord supplied by the manufacturer.
3. To avoid any risk of electric shock, this device must only be connected to a mains power supply fitted with a protective earth terminal.
4. Check that the earth resistance is less than 50Ω. If in doubt, have it checked by a qualified electrician.
5. When switching "ON" make sure that the device is protected from humidity.
6. The device must remain accessible for inspection and maintenance.

Please refer to §6.1 for electrical characteristics

Use the cable provided to connect the device to your plug. This acts as a disconnecting device. Do not position the device making it difficult to be disconnected from the power supply.

Please prefer connexion with inverter with a power of 500 VA minimum to connect IVS4 device.

### 3.6. Other connections

The IVS4 is fitted with 2 external ports as USB and Ethernet and Wi-fi connection.

#### 3.6.1. USB port

It can receive a mouse, a USB stick or drive (non-powered).

It is not allowed to connect device to get a phone or other device charge.

It should only be used for exporting PDF report (See §4.7.10 & §4.10).

A mouse can be connected for maintenance use only.

USB characteristics:



- U (voltage): 5V
- I (Intensity): Max 500 mA
- USB 2.0, high speed, 480 Mb/s

#### 3.6.2. Ethernet Port and Wi-fi connection

It should only be used for care and maintenance by DESSINTEY personnel (See §6.1).

Radio Frequencies Features and Specification are the followings:

- Operate at ISM frequency bands
  - 2.4GHz (bandwidth 20MHz / 40MHz),
  - 5GHz and 6GHz (bandwidth 20MHz / 40MHz / 80MHz / 160MHz),
- IEEE standards compatible: IEEE 802.11ax/ac/a/b/g/n (2T2R).
- Functional specifications & EIRP

<i>Standard</i>	<i>Frequency band if specific (GHz)</i>	<i>Mode</i>	<i>Theoretical data rates</i>	<i>Modulation techniques</i>	<i>EIRP (dBm)</i>	<i>EIRP 1TX (dBm)</i>	<i>EIRP 2TX (dBm)</i>
802.11ax	2.4	HE40	HE0-11	OFDMA	/	14	17
	5	HE20				12.5	15.5
		HE40				12	15
	5 & 6	HE80				9.5	12.5
		HE160				9	12
	6	HE20				10.5	13.5
		HE40				10	13
802.11ac		VHT80 & 160	MCS0-9	OFDM		15	18
802.11a			54 Mbps	OFDM	17.5	/	/
802.11b			11 Mbps	DSSS	18	/	/
802.11g			54 Mbps	OFDM	17.5	/	/
802.11n	2.4	HT20 & 40	MCS0-15	OFDM	/	16.5	19.5
	5					17	20

## 4. Use

### 4.1. Switching ON and Shutting Down

To switch on the device, press the ON/OFF button (0 = OFF and 1 = ON) at the base and back of the device. This will automatically power up the CPU and the application.

Enter the PIN code of your application to access the data table.

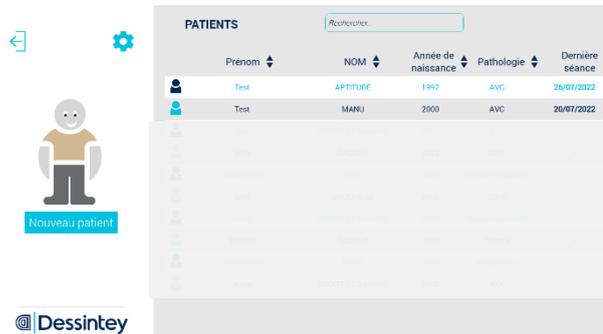
To shut down the application, go back to the PIN locking screen and click on the **SHUT DOWN** symbol at the bottom left corner of the screen.

In case of absence, we recommend returning to the PIN locking screen.

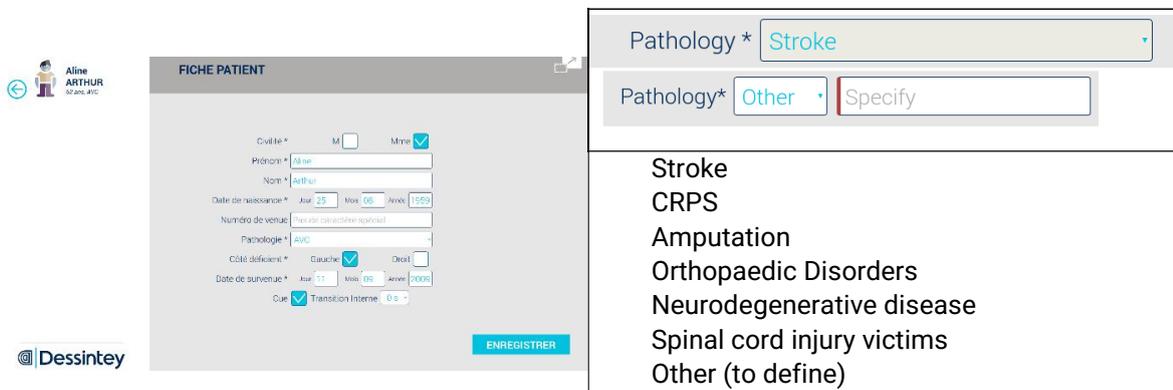


## 4.2. Creating a new patient

In order to ensure the most efficient possible care and customised monitoring, it is important to create a patient profile for each user. To do this, please click on the **NEW PATIENT** button on the welcome page of your device.



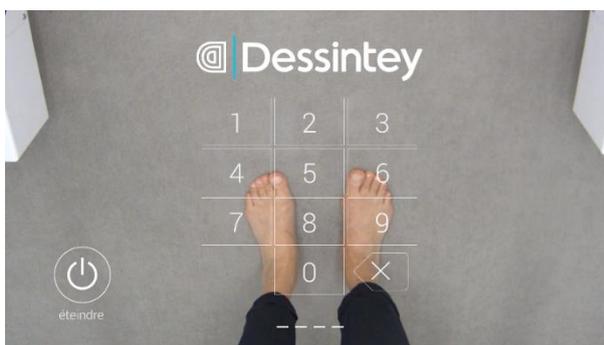
The items with a \* are mandatory. Using the drop-down menus select the pathology of your patient and the rehabilitation objective.



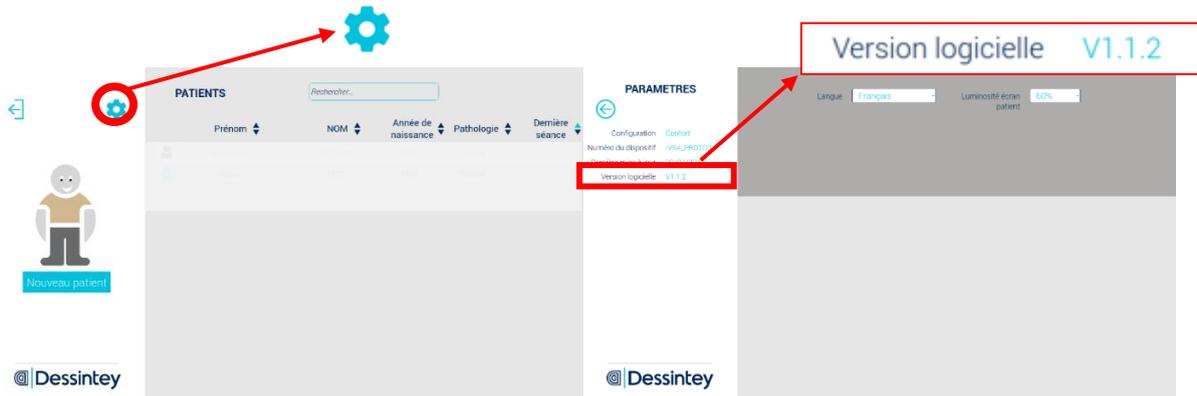
## 4.3. Software reference

To identify the software version:

- Enter PIN code :



Click on the setting icon and See the software version on the left:



## 4.4. Deleting a patient

For deleting an existing patient's profile, click on the patient profile you want to delete. Once you're in the patient's file you can click the BIN icon at the bottom right corner of the screen. Confirmation of the withdrawal is then requested. After the confirmation the patient's file no longer appears in the patients list and all data related with the patient will be permanently deleted from the machine (sessions, evaluations, observations and videos).



## 4.5. Installation advice

### 4.5.1. Beware of trapping zone

Some trapping zones are accessible to the patient and therapist. Because of manual movements and/or therapist attention, the risk for patients is minimised.

<p>Fingers can be trapped with a slot on the table</p>	<p>Fingers can be trapped with Stopper on the back of the mobile zone (front to back) of the patient screen</p>	<p>Foot can be trapped under the metallic structure, near the wheels</p>

Some trapping zones are accessible to the patient and therapist. Because of electrical movements which should be continuously maintained, therapist attention and labelling of the parts, the risk for patients is minimised.

The following label / sticker is affixed:

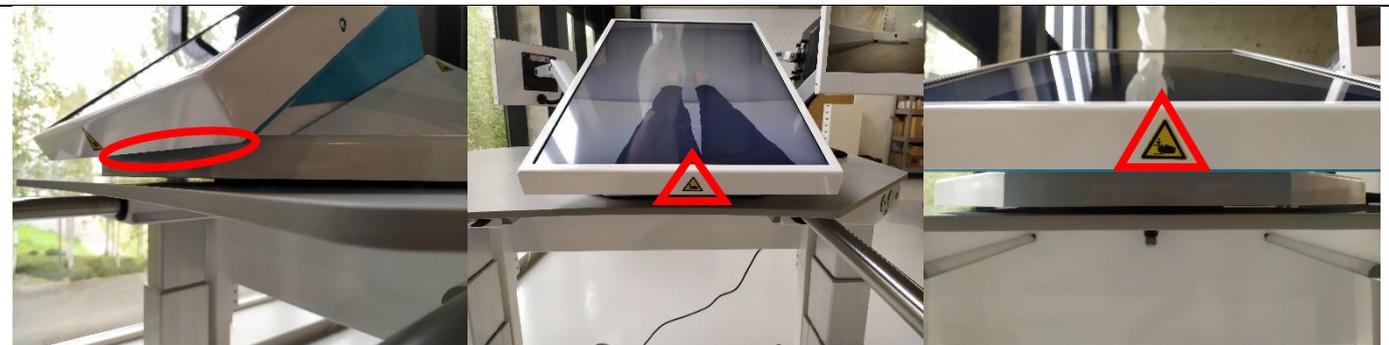


- Near the buttons for activating the movement



- Near the following zones with trapping risks.

Fingers can be trapped with the slot between Pivot area of the central patient screen and the support part attached to the table



Fingers can be trapped with the slot between the screen support and the base of the screen.



Finger can be trapped with the slot between the column and the table's support



#### 4.5.2. Clinician

Before taking charge of your patient, it is advised to place the clinician's screen the side of the disabled leg.

By default, the arm supporting the clinician's screen is fixed on a side decided when installing the device in your center. Clinician can change the side by rotating the arm at the back of the device.

#### 4.5.3. Patient

Patient must always be installed by a clinician.

At the beginning of the management, an "Installation advice" screen is provided for you to check the installation and comfort of your patient.

- 1 – Installation of the patient in front of the screen. In the sitting position, the patient can be placed in a suitable chair or work directly from their wheelchair. In the standing position, the patient can lean on the grab bars.

- 2 – Adjusting the height of the table using the side buttons  , paying attention to the patient's legs when lowering.

- 3 – Adjusting the angle of the screen position using the side buttons  , paying attention to the patient's finger when lowering.

- 4 – Adjusting the left/right and forward/backward positions of the patient screen manually

- 5 – Recording a video

- 6 – Viewing of the video for reproduction of the movements by the patient

Do not use the buttons at the same time, this will stop the movements.

### 4.6. Management phases

The patient can use the device several times a day, in accordance with the rehabilitation program established by their clinician. Following the creation of the patient, the clinician can access different options:

#### 1-Evaluation

Evaluate the pain your patient perceives and their speed and range of movement when performing a movement. You can also record a video of your patient and compare progress over time.



#### 2-Creating session

You have the choice between creating a free or guided session.

##### Free session:

Record movements freely and build sessions.



##### Guided session:

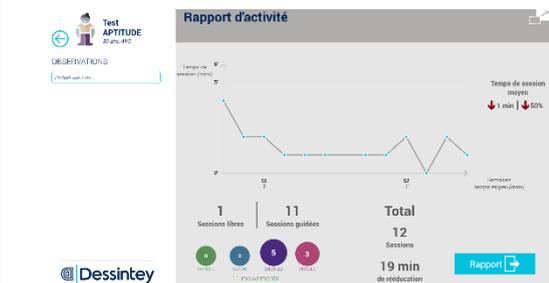
A varied selection of exercises adapted to the patient's assessed impairments is proposed to the clinician who can modify the exercises as well as all other session parameters as desired.



#### 3-Progress and Report

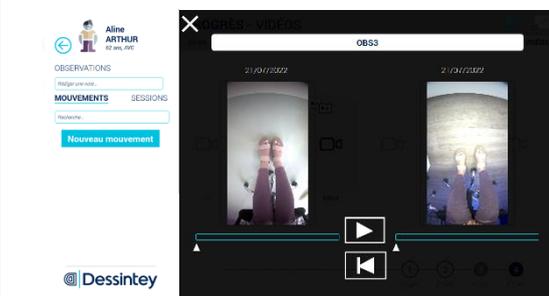
##### Activity:

Trace your patient's activity. Count the number of sessions performed by your patient and the level of participation of the different joints during the sessions.



##### Progress:

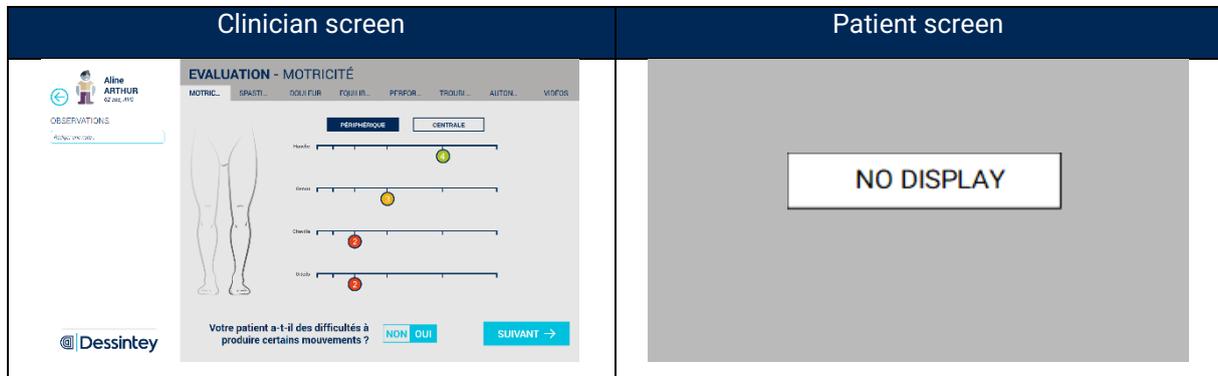
Compare recordings of movements made by your patient during their therapy to motivate your patient and analyse their progress.



## 4.7. Evaluation

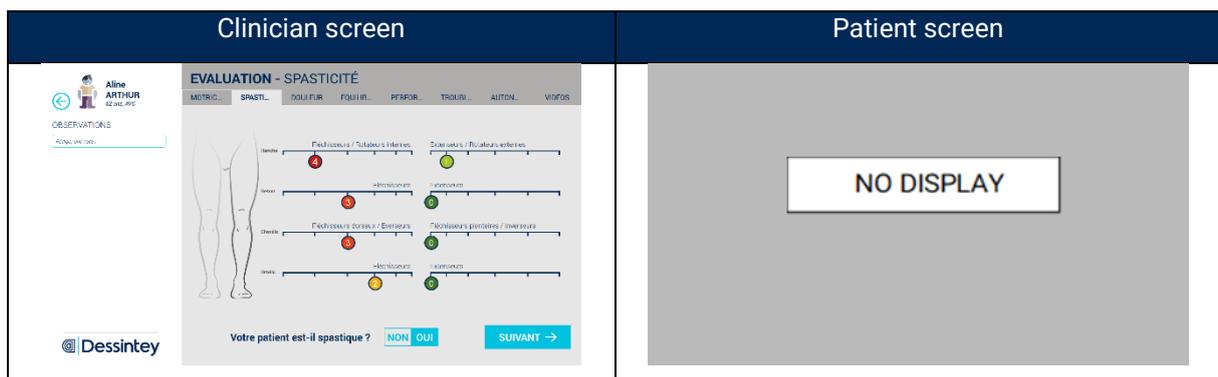
### 4.7.1. Motor function notation

At the beginning of the evaluation, the patient is asked whether he has difficulties to perform some movements. If yes, the clinician is asked to enter the MRC score, global or peripheric (according to the pathology) for different joints of the patient. If no, the motor function is rated to its maximum.



### 4.7.2. Spasticity notation

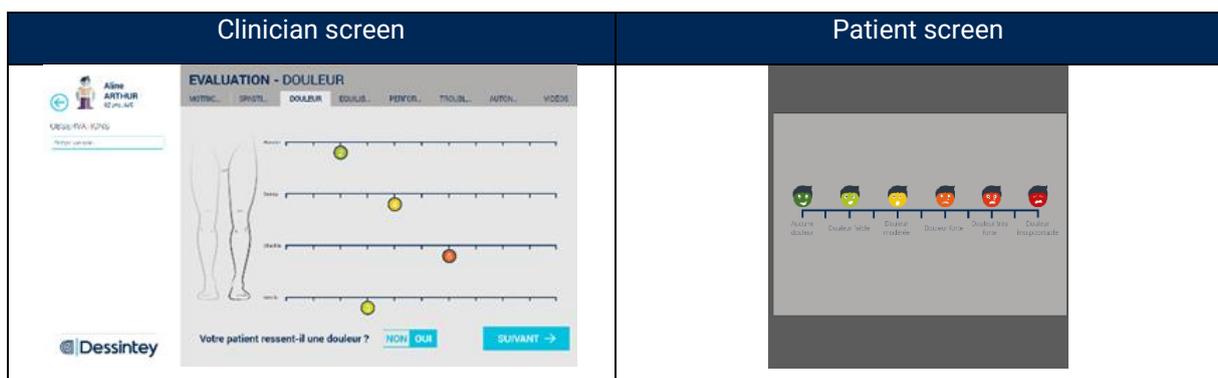
For Stroke patients, with cerebral palsy or suffering from another pathology, the patient is asked whether he suffers from spasticity. If yes, the clinician is asked to enter the Ashworth for different joints of the patient. If no, the spasticity is rated at its minimum.



### 4.7.3. Pain notation

The patient is asked if he feels any pain. If yes, the pain level given by patient will have to be set. To do so, the patient use the visual analogical scale which is displayed on his screen. To transfer the value to be quoted, the visual indicators on the patient screen can be seen on the clinician screen.

If no, the pain level is automatically rated to its minimum.



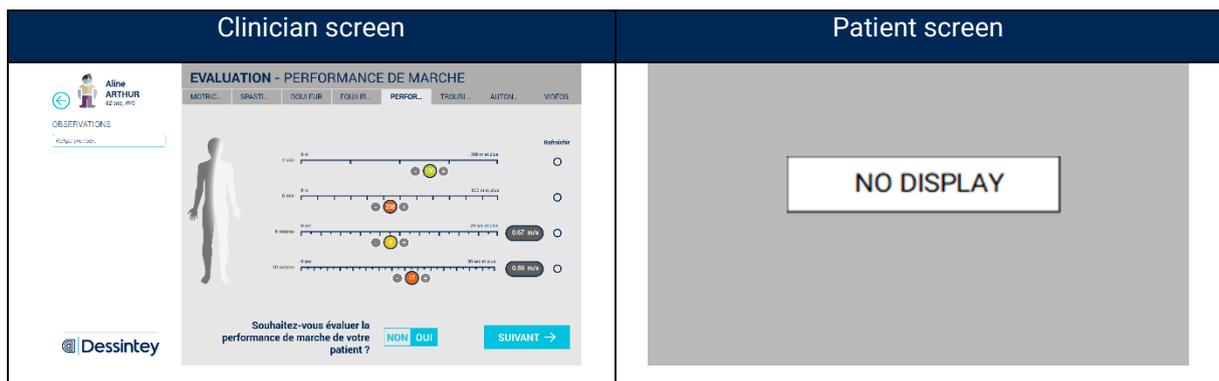
4.7.4. Balance notation

For each evaluation, the therapist is asked if he would like to rate the balance of the patient. If yes, the therapist can enter the information after testing the patient. 4 tests can be used : Tinetti, SPPB, TUG and BERG. If no, the balance is not taken into account.



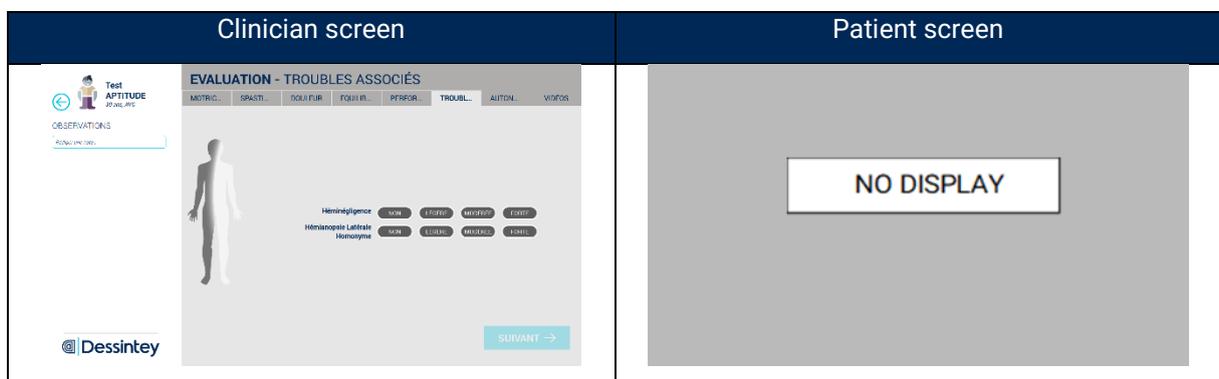
4.7.5. Walking performance

For each evaluation, the therapist is asked if he would like to rate the walking performance of the patient. If yes, the therapist can enter the information after testing the patient. 4 tests can be done : 2min, 6 min, 6 meters and 10 meters. If no, the walking performance is not taken into account.



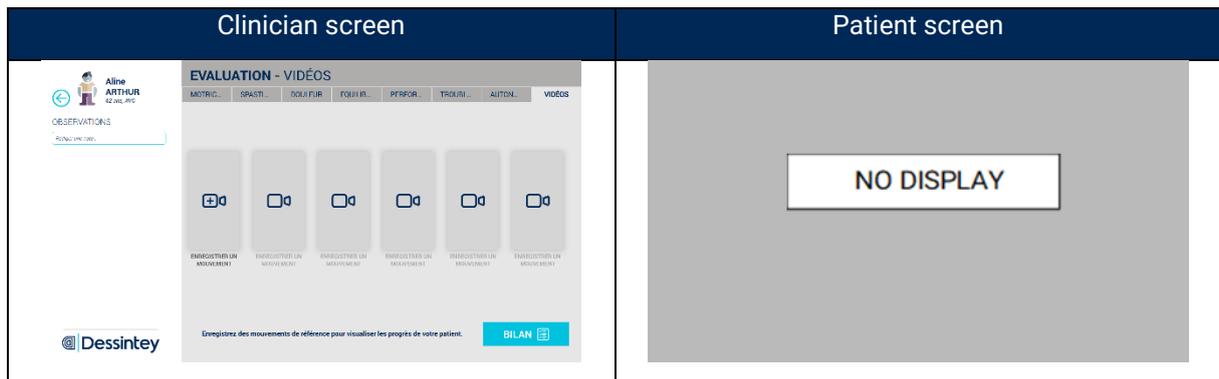
4.7.6. Associated troubles

For each new evaluation, the presence of listed associated troubles has to be indicated.



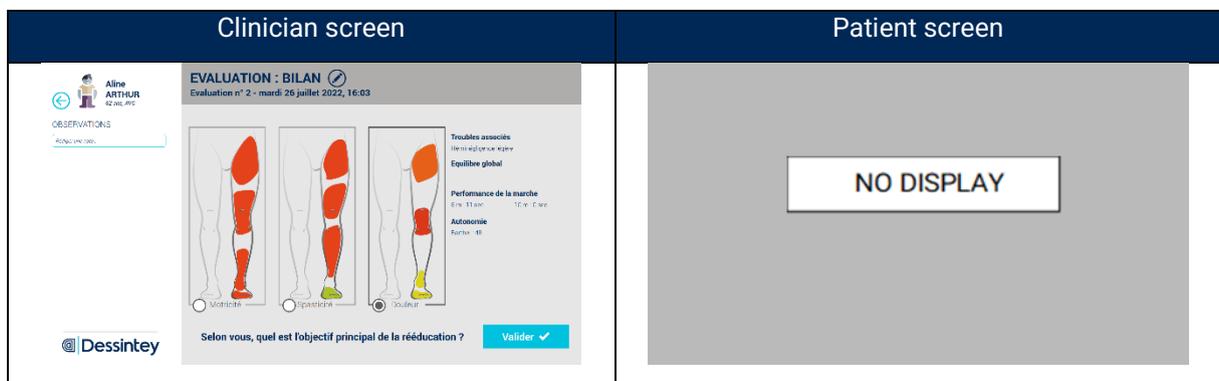
4.7.7. Videos

The last step of the evaluation is to record a reference video to see the progress of the patient.

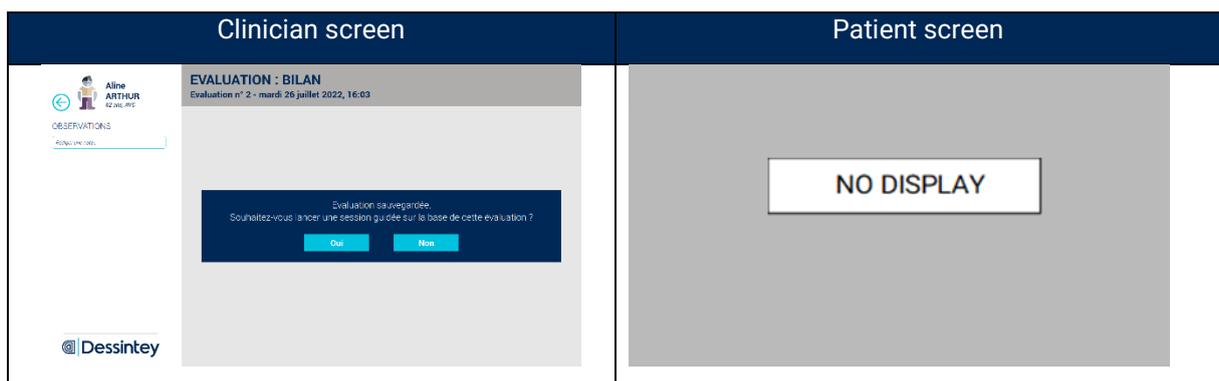


4.7.8. End of evaluation

At the end of the evaluation, a summary of the noted deficiencies of the patient is displayed and a specific rehabilitation objective related to his pathology is suggested. It is possible to change it.



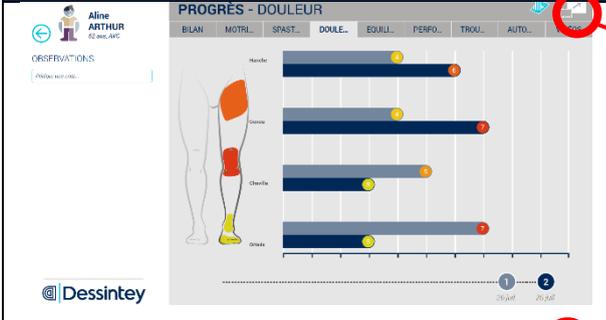
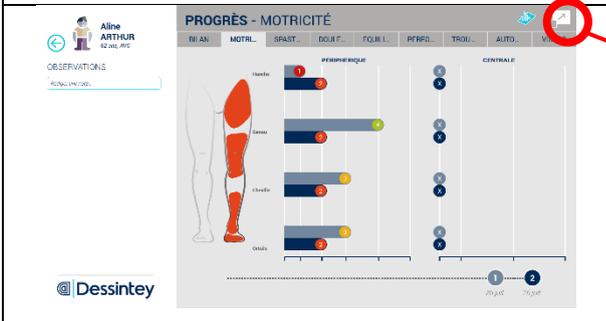
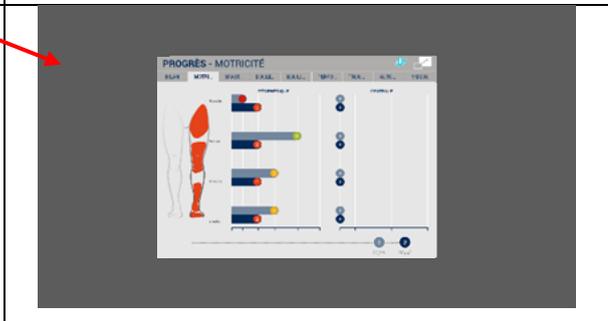
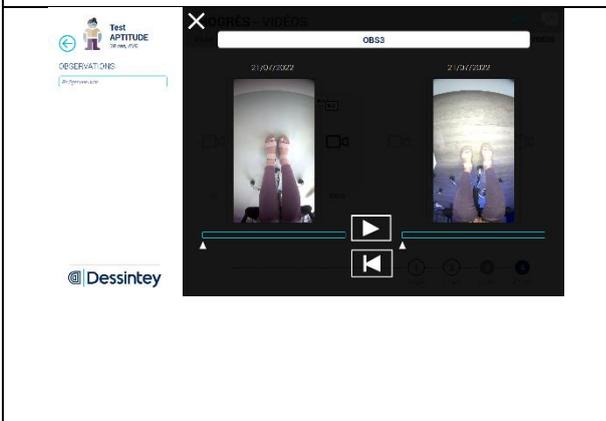
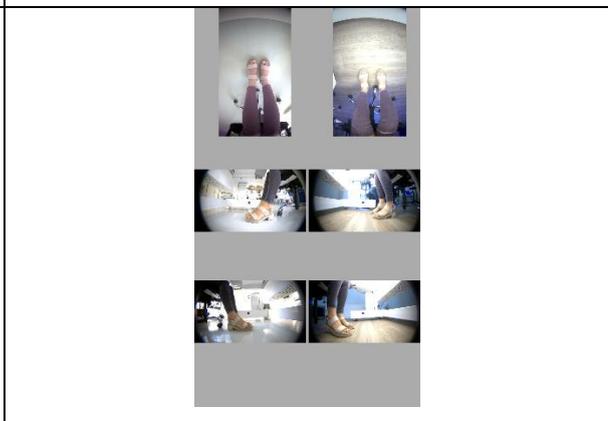
After each evaluation, a guided session start is suggested (see §4.9).



4.7.9. Progress

On the patient form, a progress tab makes possible to compare evaluations 2 by 2 for each noted deficiency. It is possible to compare videos to visualize the evolution of the patient to perform a specific movement.

To compare, select the desired dates in the evaluation list.

Clinician screen	Patient screen
	
	
	

## 4.7.10. Progress report and videos Export

To extract the Progress report in PDF version, the videos of evaluation, follow these instructions:

Progress PDF report		
1	Click on the circled icon "progress".	
2	Then click on the photo in blue at the top right.	
3	Type the patient's number and click on enter. This will be not applicable if you already enter this number during the patient file creation or if you already extract datas before.	
4	At this stage, insert the USB stick inside the IVS4. Click on the circled rectangle.	
5	A white rectangle appears around the key. Click on the image of the USB stick.	
6	Choose if you want to export observations.	
7	Choose if you want to export videos.	
8	Wait until the task is completed. This can be long if you have a lot of videos to export.	
9	Click on the blue rectangle and remove the USB stick.	
10	You can now find on the USB Stick a folder named by the patient number you enter on step 3. In this folder, you will find the PDF report and another folder with the videos (if you choose to export the videos).	

**4.8. Free session**

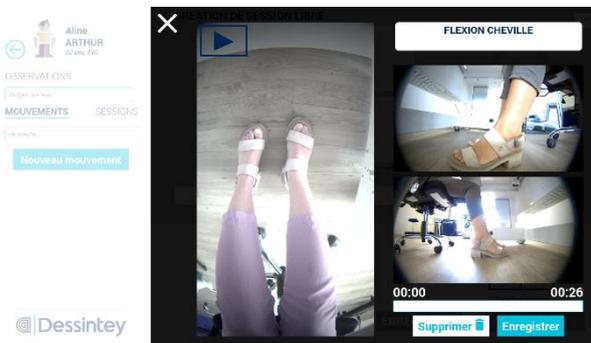
To record a new movement, click on « New movement ». Movements already saved are listed in the drop-down menu on the left.



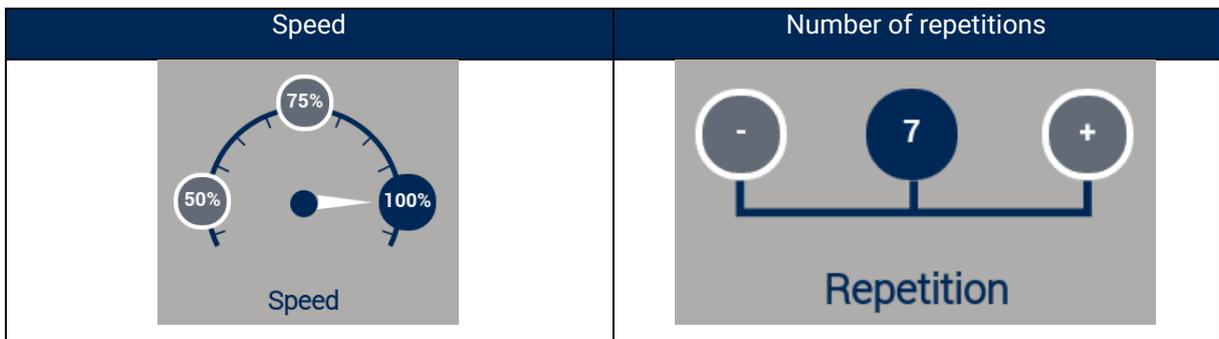
Click on the « record » icon, then on the « stop » icon at the end of the movement.



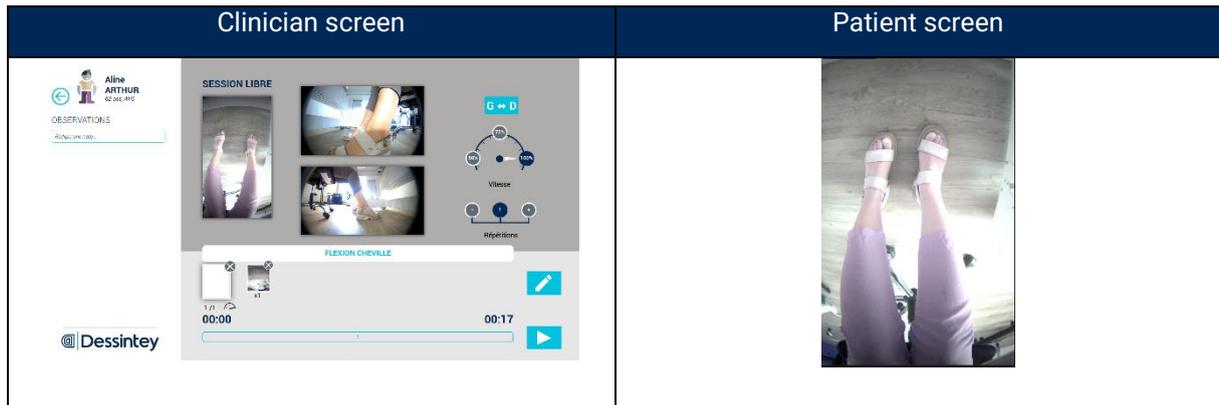
Give a name to the video and save it.



To build a session, make the videos of the list slide or double click on them. For each of them, configure the speed and the amount of repetitions.

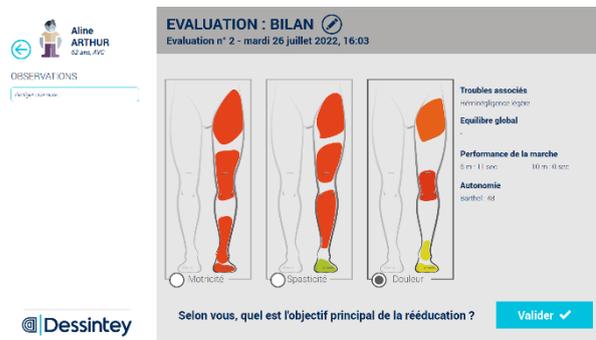


These parameters can be modified during the session.



### 4.9. Guided Session

After the confirmation of the evaluation, you'll have access to a Guided session. Function of the evaluation, you cannot change the rehabilitation goal proposed by the software because you already validate it after the evaluation.



It is possible to delete exercises, set the speed of the videos and the number of repetitions, as in a free session.

### 4.10. Activity Report

It is possible to access the patient's progress during the sessions. This report allows to consult the evolution of the time spent in session, the total rehabilitation time, the total number of sessions as well as the distribution of the work on each of the joints solicited during rehabilitation on the IVS4.



To extract the Activity report in PDF version, follow these instructions:

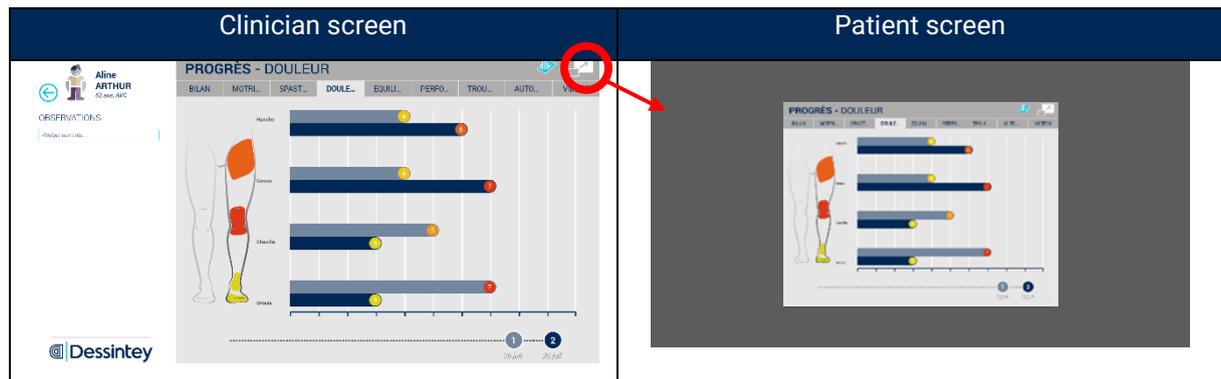
Activity PDF report		
1	Click on the circled icon "Activity".	
2	Then click on the photo in blue at the bottom right.	
3	Type the patient's number and click on enter.	
4	At this stage, insert the USB stick inside the IVS4. Click on the circled rectangle.	
5	A white rectangle appears around the key. Click on the image of the USB stick.	
6	Choose if you want to export observations.	
7	Wait until the task is completed. This can be long if you have a lot of videos to export.	
8	Click on the blue rectangle and remove the USB stick.	
9	You can now find on the USB Stick a folder named by the patient number you enter on step 3. In this folder, you will find the PDF report and another folder with the videos (if you choose to export the videos).	

### 4.11. Screen Share Function

By default, the display of the clinician's screen is different from the patient's screen as they do not require the same information.

However, there is a function available to show the screen seen by the clinician on the patient's screen, for a specific amount of time.

When you click on the symbol, the arrow turns around and the content of the clinician's screen appears on the patient's screen. Simply click on the symbol again to return to the initial display.



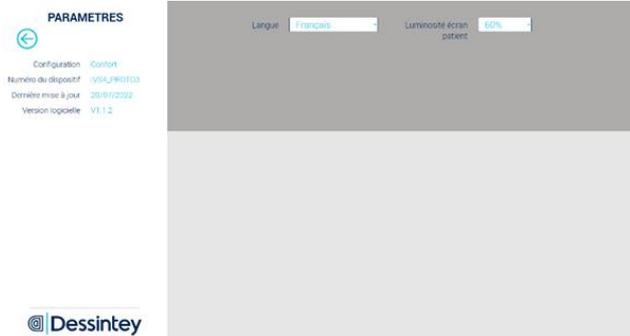
### 4.12. Preferences

2 levels of access, accessible from the home page, are provided on the IVS4 device to ensure proper use:

- **CLINICIAN level**

This level is intended for all the clinicians using the device.

It provides access to general information and the choice of the language of the software.



- **ADMINISTRATOR level**

A person must be defined as administrator. This person will have access to settings such as updates, hard disk cleaning, PIN code changes for ADMINISTRATOR and CLINICIAN sessions and sequence transition settings.



The sleep mode delay time (20 minutes by default) is adjustable from the scroll-down menu, allowing the administrator user chose the inactive time before the screen turns off. The device won't go on sleep mode during a session.

To change the CLINICIAN or the ADMINISTRATOR PIN input the 4 digits of the new password in the corresponding box. The box will be automatically erased. Then proceed to confirm the new PIN by typing it again. After the confirmation, the box will become green, verifying that the password was successfully changed.

In order to guarantee good security, it is recommended to personalize the ADMINISTRATOR and CLINICIAN PIN codes from the first use. These two PINs must be different from each other.

In the event of login problems, please contact the Dessintey customer service.

#### 4.13. End of session / Absence / Switch OFF

We recommend coming back to the PIN locking screen after each session with patients or during absence near the device.

We recommend shutting down the device at the end of each day by using the "Shut down" symbol on the PIN locking screen, waiting 5 seconds and switch off the device by the power switch on the rear of the device (switch on "0" position).

## 5. Cleaning

### 5.1. Pre-Cleaning / Cleaning / Recommendations

#### 5.1.1. General

Make sure the IVS4 is turned off.

Visible dirt and particles should be wiped off the device by using a wet cloth before starting the cleaning procedure.

Between patients/therapists these surfaces must however also be cleaned using either wipes or spray.

Please make sure no disinfectant or water is getting to electronic interfaces, like the USB connector, or the main power socket.

When using an impregnated wipe, some marks of cleaning products can persist on screens, for your comfort, we advise to dry with a soft cloth before products has dried.

All surfaces must be dry before reusing the device.

DESSINTEY cannot be held responsible for infectious diseases caught while using their products.

Specific for Screens, keyboard and sensitive parts

Please make sure no disinfectant or water is getting to electronic interfaces, like screens or keyboard.

Do not wipe the screens with a cloth or sponge that could scratch the surface.

To clean the therapist screen, patient screen, lateral screens, keyboard, never apply the cleaner directly to the products, please prefer spray on a very smooth wipe then clean the part.

Wipe off water drop immediately. Long contact with water may cause discoloration or spots.

Since the screens are made of glass, it may break or crack if dropped or bumped on hard surface.

Do not use abrasive cleaners and have a look and recommendations of §5.2.1 & §5.2.2.

## 5.2. Cleaning products

### 5.2.1. Components Products to NOT use

Products containing the following component are NOT recommended:

- sodium hydroxide (NaOH)
- Bleach & hydrogen peroxide
- Strong solvent
- Benzene & Thinner
- Ammonia
- Soap & multi-surface detergent

### 5.2.2. Products which can be used

Depend of the surface to clean we can recommend the followings:

#### 5.2.2.1. For disinfection of table and grab bars (patient contact)

Product like spray type product called "Disinfection and cleaning of non-invasive medical devices":

- Containing less than 5% non-ionic surface agent
- Containing as disinfectants the following components:
  - o Ethanol from 2.5 to 5%
  - o Propan-2-ol from 0.1 to 1%
- Having the following microbiological properties:
  - o Bactericide EN1276, EN13727, EN13697, EN14561 in 5 min.
  - o Tuberculocide on Mycobacterium Terrae EN14348 and EN14563 in 15 min.
  - o Fungicide EN14562 (on Aspergillus Fugimatus) in 5 min.
  - o Levuricide EN1650, EN13697, EN13624, EN14562 on Candida albicans in 5 min.
  - o Virucidal EN14476 on HBV, HCV, Adenovirus, Coronavirus, Norovirus, RSV, H1N1, HSV-1, Polyomavirus in 1 min, Rotavirus in 15 min.

#### 5.2.2.2. For Cleaning Screens and other parts:

- Products containing a high percentage of alcohol as rapid evaporation can occur,
- Water on a wipe,
- Dry Wipe.

## 5.3. Cleaning recommendation

Components	Procedure
After every patient	
Table	Spray on Wipe
Grab bars	Spray on Wipe
Between each therapist use	
Therapist screen	Spray on Wipe (without direct projection)
Keyboard	Spray on Wipe (without direct projection)
At the beginning or at end of the working day	
All steps cited above	
Patient screens (Lateral & Central)	Spray on Wipe (without direct projection)

## 6. Maintenance, Disposal and FAQ

### 6.1. Maintenance

This device requires annual maintenance. It is the customer's responsibility to contact the Dessintey team to plan regular maintenance work. For any request, please contact the Dessintey Customer Service.

For any malfunctions or anomalies, please contact the Dessintey customer service with the serial number of your device (see §2.3).

Intervention of DESSINTEY can be made on physical intervention or remote assistance can be provided when the device is connected to network by Wi-fi or Ethernet.

Information about fuse characteristics accessible by operators are described on sticker N°1 in §2.2. This sticker is fixed near the filter fuse.

There are three other internal fuses. Here are their characteristics:

Fuse F2, for the therapist's screen: T 2A L 250V

Fuse F3, for the computer: T 6.3A L 250V

Fuse F4, for the patient's screen: T 6.3A L 250V

Fuse F5, for the Light: T 2A L 250V

### 6.2. Disposal

In accordance with Directive 2002/96/EC, the device may not be disposed of with household waste but must be disposed of in an appropriate sorting area. When your device reaches the end of its service life, it must be taken to an appropriate recycling centre or returned to your dealer. In doing so, you help the environment by contributing to the conservation of natural resources and the protection of human health.

### 6.3. FAQ

In case of problems, please refer to the table below:

Malfunction found	Action(s) to be carried out
The device does not switch on.	<p>Is it properly connected to a power supply plug?</p> <p>If not, plug it into a power supply plug and turn the switch to "1".</p> <p>If so, check that the switch on the back of the device is in the "1" position.</p>
The table is not straight, or the columns are out of sync.	<p>Ask your patient to come away from the device, move chairs and other objects that may interfere with the table adjustments, out of the way. Press and hold the two lower buttons of the "TABLE" and "SCREEN" adjustments for a few seconds to do a reset. Please press for a long time to let the columns get as down as possible and finish the process of reset.</p>
The camera does not work or has a malfunction.	<p>Follow the process to shut down the application then start back up. If the problem persists, shut down the system using the "0" / "1" switch and then switch it back on. Attention, this operation may cause you to lose the data in progress.</p>
The application is frozen or no longer responds.	<p>Shut down the system using the "0" / "1" switch, then switch back on. Attention, this operation may cause you to lose the data in progress.</p>
The click on the screen is out of sync, the touch screen no longer responds.	<p>Shut down the application in the normal way if you can, otherwise use the "0" / "1" switch, then switch back on. Attention, this operation may cause you to lose the data in progress.</p>
The patient's screen is all black.	<p>Follow the process to shut down the application then start again.</p>
The clinician's screen is all black.	<p>Check that the screen is on (does the green LED on the back of the screen blink?). If so, shut down the system using the "0" / "1" switch and then switch it back ON. Attention, this operation may cause you to lose the data in progress.</p>
I programmed and recorded a free session that erased my previous session.	<p>Check that your previous session is not present in the Sessions tab (On the free session page, next to the Movements tab). You can find the history of all recorded sessions in the Sessions tab.</p>
Legs of patient are blocked by the table of the device (legs compressed).	<p>Switch OFF the device by turning OFF, pull out the power cord. Then Lift or Toggle the device to release the patient.</p>
Columns are going up & down without activation of buttons. Patient has a risk of being blocked for his legs, arms or fingers.	<p>Switch OFF the device by turning OFF, pull out the power cord.</p>

If a problem persists, please contact the Dessintey customer service which will guide you through overcoming the problem or schedule an intervention. You will be asked for the serial number of your device (see §2.3).

## 7. Features

### 7.1. Conditions of use

Operating temperature: +15°C to +35°C.

Storage temperature: -15°C to +45°C.

Transport temperature: -15°C to +45°C.

Altitude < 2000 m (contact the customer service if this is not the case).

Atmospheric pressure: 750 to 1060 hPa

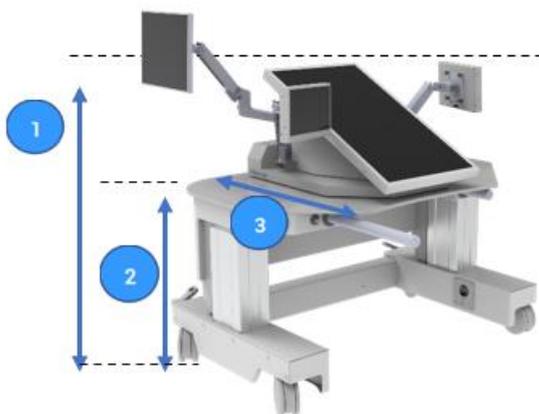
Humidity: from 20 to 90% with no condensation.

Electrical Characteristics: U = 100 – 240V / f = 50/60Hz / I<sub>max</sub> = 4A / P<sub>Max</sub> = 500W

The room must be sufficiently ventilated.

In case or transport in conditions out of range +10°C to +35°C, please unpack the device and wait 8 hours at room temperature before switching ON.

### 7.2. Dimensions



Dimensions of device: 1180 x 748 mm (L x l)

1 Device height (min – max): 1160 – 1560 mm

2 Table height (min - max): 630 – 1030 mm

3 Device depth (min – max): 725 – 1260 mm

Weight of IVS4 device: approximately 185kg

Safe operating load in highest position: 135 kg

### 7.3. Specifications

- Table adjustment columns:
  - Raising and lowering speed with no load: 22mm/s
  - Maximum allowable load: 2000N
  - Extension: 400mm
  -
- Actuator to adjust the patient's screen:
  - Raising and lowering speed with load: 6.2mm/s
  - Maximum allowable load: 2000N
  - Extension: 50mm
- The screen is at a minimum angle of 26°, and a maximum angle of 38°

Safe operating load: 135 kg person in the highest position of the device with use of the bars.

Information on the columns: the columns to adjust the height of the table are synchronised. For safety reasons, the height of the table cannot be adjusted at the same time as the patient's screen.



Be careful when handling, it is essential to look at the patient carefully when the moving parts of the device are in motion to make the right adjustments safely (arms, legs, etc.).

## 7.4. Essential performance

There is no essential performance associated to the device.

However, the device must not generate unintentional movements of the columns, in the event of electromagnetic and electrical disturbances when installing the patient at the workstation.

## 7.5. Applied & Accessible Parts

The applied parts to the patient are bars they lean on when device is used with standing position of the patient – *Contact time is defined as more than 10 minutes.*

The accessible part considered as applied part is the table – *Contact time is defined as more than 10 minutes.*

The accessible parts are the following:

- Buttons related to bar manipulation (in and out) – *Contact time is defined as 1 to 10 seconds.*
- Buttons for lighting (on/off) – *Contact time is defined as 1 to 10 seconds.*
- Buttons for table and screen movements (up/down) – *Contact time is defined as 1 to 10 seconds.*
- The metal part framing the central patient screen as well as the screen itself (protected by an anti-reflection glass) – *Contact time is defined as less than 1 second.*
- The foot of the device, horizontal part of the sheet metal where the wheels are located – *Contact time is defined as more than 1 minute.*

## 7.6. Field immunity levels of the equipment

Places of use of the device: See §3.2.

Due to electromagnetic disturbances, it is possible that the essential performance of the device ("must not generate unintentional movements of the columns, in the event of electromagnetic and electrical disturbances when installing the patient at the workstation") may be altered or lost. In this case, or if any anomaly appears, the clinician must move the patient away from the device to avoid any injury.

**WARNING:** this device should not be used next to or stacked with other products because it may cause a malfunction. If such use is necessary, this and the other devices should be observed to check they are operating correctly.

**WARNING:** The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device may cause an increase in electromagnetic emissions or a decrease in the immunity of this device and result in improper operation.

**WARNING:** RF portable communications devices (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the IVS4 device including cables specified by the manufacturer. Otherwise, the performance of these devices may be affected.

**Note:** the emission specifications of this device allow it to be used in industrial areas and in hospitals (class A defined in CISPR 11). When used in a residential environment (for which Class B as defined in CISPR 11 is normally required), this device may not provide adequate protection of radio frequency communications services. The user may need to take corrective measures, such as relocation or reorientation of the device.

<b>MANUFACTURER's Guidance and Declaration – Electromagnetic Emissions</b>			
IVS4 is intended for use in the electromagnetic environment specified below. The customer or user of the IVS4 should ensure that it is used in such an environment.			
<b>Emission test</b>	<b>Test level</b>	<b>Compl. level</b>	<b>Electromagnetic environment – guidance</b>
Conducted Emissions Terminal disturbance voltage CISPR 11 – EN 55011	150kHz to 30MHz	Class A Artificial hand connected	<p>The IVS4 device: uses RF energy only for its internal functions. As a result, its RF emissions are very low and not likely to cause interference in a nearby electronic device. is suitable for use in all premises other than domestic premises and those directly connected to the public low-voltage power supply grid supplying buildings for domestic purposes.</p>
Radiation disturbance CISPR 11 – EN 55011	30MHz to 1GHz	Group 1 Class A	
Harmonics IEC 61000-3-2	Class A		
Flickers IEC 61000-3-3	Equipment with rated current inferior or equal 16A per phase		

<b>MANUFACTURER's Guidance and Declaration – Electromagnetic Immunity</b>			
IVS4 is intended for use in the electromagnetic environment specified below. The customer or user of the IVS4 should ensure that it is used in such an environment.			
<b>Emission test</b>	<b>Test level</b>	<b>Compl. level</b>	<b>Electromagnetic environment – guidance</b>
Proximity Fields from RF wireless comm. Equip. IEC 61000-4-3	385MHz	27V/m - 18Hz	RF portable communications devices (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the IVS4 device including cables specified by the manufacturer.
	450MHz	28V/m - 18Hz	
	710 to 780MHz	9V/m - 217Hz	
	810 to 930MHz	28V/m - 18Hz	
	1720 to 1970MHz	28V/m - 217Hz	
	2450MHz	28V/m - 217Hz	
	5240 to 5785MHz	9V/m - 217Hz	
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, 4, 8 & 15kV air	± 8 kV contact ±2, 4, 8 & 15kV air	Device should be installed indoor in a hospital / commercial type building.
Radiated Frequency IEC 61000-4-3	80MHz to 6GHz	3V/m	/
Electrical fast transient / burst IEC 61000-4-4	AC/DC power ±2Kv f= 100kHz	Main Port Ethernet Port ± 2Kv	The power quality & power frequency magnetic fields should be that of a typical commercial or hospital environment. /
Surge IEC 61000-4-5	AC/DC power Line / Line Line / Ground	±1kV ±2kV	
Conducted Disturbance IEC 61000-4-6	3V (0.15 to 80MHz) 6V (ISM band) 80 % AM with 1 kHz	Main Port Ethernet Port 3V + 6V	
Power frequency magnetic field IEC 61000-4-8	30A/m 50 & 60Hz	30A/m	

Emission test	Test level	Compl. level	Electromagnetic environment – guidance
Voltage dips IEC 61000-4-11	100, 220 & 240V 0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25/30 cycles 40% UT for 5/6 cycles	100, 220 & 240V 0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25/30 cycles 40% UT for 5/6 cycles	The mains power quality should be that of a typical commercial or hospital environment. If the user of the IVS4 requires continued operation during a power cut, it is recommended that the IVS4 be powered from an uninterruptible power supply
Voltage interruptions IEC 61000-4-11	100, 220 & 240V 0% UT for 250/300 cycles	100, 220 & 240V 0% UT for 250/300 cycles	
Proximity Magnetic Fields IEC 61000-4-39	134,2 kHz / Pulse modulation 2,1 kHz / 65A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5A/m	134,2 kHz / Pulse modulation 2,1 kHz / 65A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5A/m	

## 7.7. Applicable standards

IVS4 meets the applicable requirements of Regulation (UE) 2017/745 on Class I electro-medical devices.

IVS4 complies with the essential requirements of the following standards:

- IEC 60601-1 Ed.3.2 + A1: 2012 + A2: 2020– Class 1 Type B
- IEC 60601-1-2 Ed.4.1 + A1: 2020 – Class A device
- IEC 62304 Ed.1.1 + A1: 2020 - class A
- EN 62366-1:2015 + A1: 2020
- EN ISO 20417: 2021
- EN ISO 15223-1: 2021
- EN ISO 15223-2: 2010
- EN ISO 7001 + A1: 2013 + A2: 2015 + A3: 2016 +A4: 2017
- EN ISO 13485: 2016
- EN ISO 14971: 2019 + A1: 2021