DYNEELAX®

Instruction for use of the DYNEELAX®

MEDICAL DEVICE FOR THE LAXIMETRIC ANALYSIS OF KNEE LIGAMENTS IN MOTORIZED TIBIAL TRANSLATION AND ROTATION

Genourob®
INNOVATIVE LAXIMETRY

Summary

I. Introduction

Thank you for purchasing the Dyneelax: Knee ligament injury analysis aid. It combines the performance of GNRB (motorized tibial translations) and ROTAM (motorized tibial rotations) in a single device (2 in 1).

It is currently the most accurate arthrometer of its generation.

The result of some fifteen years of R&D in this field, Dyneelax is an automated dynamic laximetry device that can help diagnose or monitor partial or total lesions of knee cruciate ligaments and peripheral collagen structures. The principle of the device is to induce a translational or rotational force on the tibia in relation to the femur and to measure the resistance of the knee ligaments to these imposed translations or rotations.

At GENOUROB, the constant search for innovative instruments, for medical and paramedical professionals, is at the very heart of our profession thanks to the scientific coordination of engineers and health professionals specialized in the treatment and care of patients with this type of lesion.

We hope that it will bring you the satisfaction you are looking for whether it is used in current practice, the development of your knowledge or scientific research in this field.

Best regards,

Stéphane NOUVEAU
Chief Executive Officer of the company Genourob

II. List of making symbols

	Selective sorting components		Handle with care
	General safety		Admissibe temperature range
	Warning		Admissible humidity range
	Must be kept dry		Admissible air pressure range
	Type B electromagnetic device		Direct current
	Marking CE of Dyneelax		Alternating current
	Read instructions for use		Indicates the direction of the positioning foot cup
	Show where put hands for the transport of Dyneelax		Grounding symbol
	Warning do not push		

III. What is the Dyneelax ?

The DYNEELAX (for DYNamic (K)NEE LAXimeter) is a device to help diagnose partial or total lesions of the knee's cruciate ligaments and peripheral collagenous structures, which must be used by a orthopaedic surgeon, sport medicine practitioner or physiotherapists.

The principle of the device is double as it allows:
- to either apply a thrust force on the calf thanks to an articulated mechanical system and to record the displacement of the tibia in relation to the femur for each force thanks to a sensor placed on the Anterior Tibial Tuberosity (ATT).
- or to induce a force of internal or external rotation of the tibia in relation to the femur and to measure the resistance of the peripheral collagenous structures of the knee to this imposed rotation.

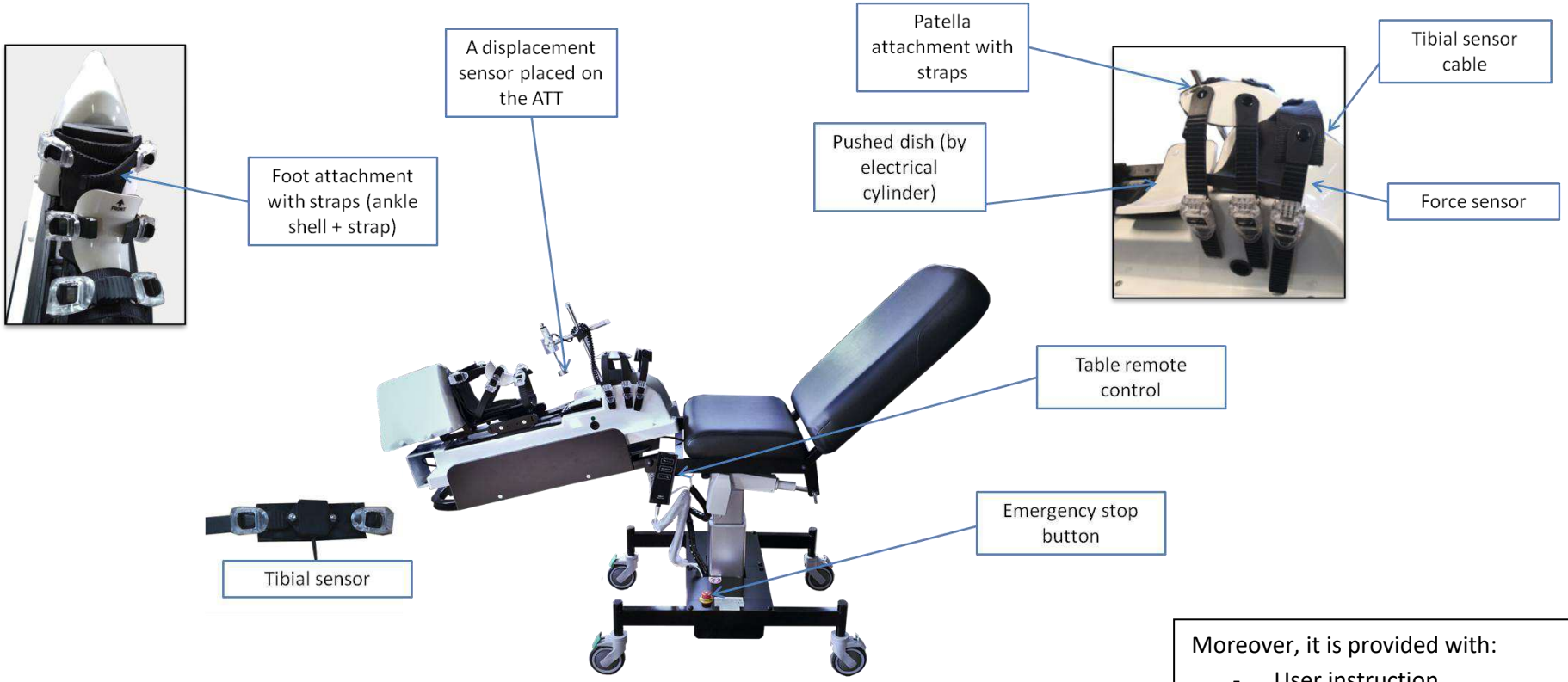
Measurements are taken on both lower limbs and the analysis of the lesions can be done by observing the difference between these two values and especially by comparing the slope of the curves obtained.

The device can be used to help with diagnosis, to follow the evolution of a pathology or a ligamentoplasty (cruciate ligament operation).

This device makes it possible to objectify laximetric evaluations made at knee level by ensuring better reproducibility of the tests carried out thanks to the numerous parameters (clamping and positioning) recorded for each patient. It is thus possible to put the patient back in the same examination conditions each time a new test is performed.
A software (new graphic interfaces in comparison with GNRB) ensures optimal use of the product to avoid handling errors. Very intuitive and easy to use, the operator is guided on the different parameters to be validated before launching the tests.

More powerful than the motorized devices that preceded it, the Dyneelax becomes the most technologically advanced laximetry device at the international level in this field

DESCRIPTION OF THE DEVICE



Cable	Maximum lenght
USB cable	1.8 m
Device power cable	1.8 m
Displacement sensor cable	0.3 m
Tibial sensor cable	0.3 m

Moreover, it is provided with:

- User instruction
- A computer/tablet Dell
- A USB key with the notice in PDF format as well as an executable to install the software

IV. General safety instructions

SAFETY PRECAUTIONS

- This device must be used only by formed medical staff.
- **Dyneelax has been conceived for a consecutive performance time of 10 minutes and followed by a rest time for 15 minutes.**
- **The examination table has been conceived for a consecutive performance time of maximum 2 minutes followed by a rest time of 20 minutes.**
- Once installed, the device must not be displaced.
- The data should only be interpreted by medical staff and/or by an instructor of GENOUROB®.
- **If by any chance a power cut happens during the test; undo the straps as fast as possible off the patient.**
- Patients should not exceed a weight of 150 kg or a leg with a weight greater than 37 kg.
- **For the patients who had an anterior cross ligament surgery, follow the protocols in force (134 at 3 months, 150 at 4 months, 200 at 5 months and more for translation).**
- Do not use this device with patients who are unable to understand or follow instructions given by medical staff using the control.
- To avoid any errors or confusion with other patients, check the patient information before saving it.
- Dyneelax should not be used adjacent to or stacked with other electromedical equipment. If such use is necessary, a verification of the essential performance (decrease in test accuracy, unwanted device movement) of the device should be performed in this configuration to validate that there is no loss or alteration of essential performance due to EM disturbances.

HYGIENE PRECAUTIONS

- Do not use this device with patients affected from contagious skin conditions **(apply good medical practices):** the device may be covered with a disposable sheet without affecting its performance.
- It is recommended to sanitize the device with an alcohol-based product (see description below) or wipe before using it for the first time and between patients.
- The precautions regarding hygiene for equipment in contact with patients' skin must be followed: the device must be disinfected using bactericidal products (EN 1040, EN 1276, NF T72-190, active against Mycobacterium tuberculosis) and fungicidal products (EN1275, EN1650, active against HIV-1, active against BVDV, rotavirus and herpesvirus).
- Do not use water or other liquids next to the device. It is forbidden to use the device in an operating room.
- Do not wash the device with water or other liquids.

ELECTRICAL, MECHANICAL AND THERMAL RISKS

- **WARNING:** To avoid electrical shock, this appliance may only be connected to a power supply network with a protective ground.
- **WARNING:** An additional base multiple sockets or extension cord must not be connected to electro-medical Dyneelax system.
- Power must be connected to the 230 Volt-50 Hz (100-240 V 50-60 Hz 2A).
- Leave the plug accessible area in order to proceed safely stop **Dyneelax**.
- The parties applied to the patient (shell boot straps) can reach 45° C when using the Dyneelax within the maximum permitted environmental conditions (ambient temperature 40° C).
- Do not dissemble the machine: maintenance and calibration are carried out by personnel trained for this purpose within Genourob society.
- **It is strictly forbidden to use the displacement sensor without the safety block or turn .** In the event of breakage, contact GENOUROB immediately for maintenance.

MAINTENANCE

- **WARNING:** It is prohibited to change part of the **Dyneelax** without GENOUROB's authorization: spare parts can only be replaced by personnel trained for this purpose within the GENOUROB society.
- Any damage to the device should trigger maintenance (the jack, motors sensor, computer or remote control). In such events, phone GENOUROB society on (+33 (0) 2 43 90 43 01).
- The use of sensors and cables other than those specified, with the exception of the sensors and cables by the company GENOUROB equipment as replacement of internal components can result in increased levels of emissions or decrease in the equipment immunity levels.
- The Dyneelax should not be used adjacent to or stacked with other equipment. If this use is required, a check of proper operation of the device in this configuration is to be performed.
- It is prohibited to use the device with a damaged power strip or connecting cables exposed.
- **In the event of unwanted movements, trigger the emergency stop button and warn Genourob to set up an intervention (+33 (0) 2 43 90 43 01).**
- Portable and mobile FR communication devices can affect MEDICAL ELECTRICAL EQUIPMENT.
- It is strictly forbidden to delete BDDs (databases) from the Dyneelax software.
- It is strongly recommended to save BDDs regularly to an external hard disk.
- In the event of an important accident related to the device, Genourob must be informed and the competent authority of the country.

V. Installation

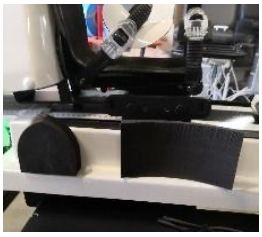
1) Deconditioning

- Remove the device from the palette (if applicable, in accordance with the procedure on the shipping package).

⚠The installation of the device should not be realized by a person with reduced mobility and it is ESSENTIAL to have completed all the steps before proceeding.

2) Installation and connection of the device

- Remove the foams from the carton and place them on the device in the positions provided.



- Connect the displacement sensor at the device (red pastille)

- Take out the tibial sensor and connect it (blue pastille)

- Connect the power supply unit to the mains

- Connect the USB cable to the device (if required) then switch on the PC

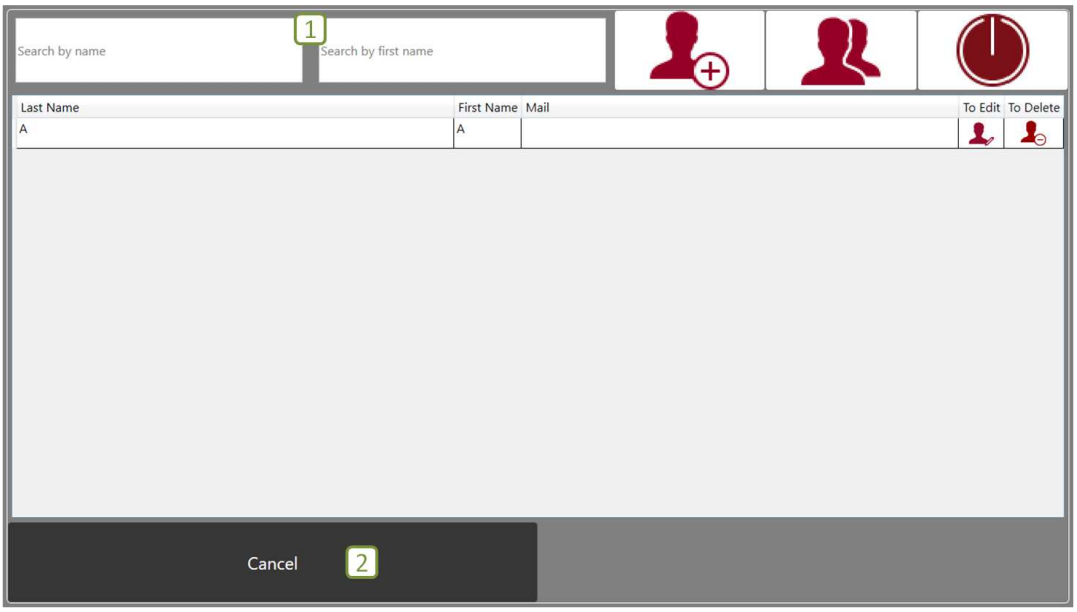
Verification of the installation

To verify the correct installation of the device, please:

- Turn on the PC, the software will open automatically
- Try to displace the device from the table, if it moves, that means that the indexing finger is misplaced
- Create a patient and launch a test, if an error message appears, that means that the device did not work

3) User management

To create a user, click on  . The window « User list» appears. From this, it is possible to:



1) Search a user by his last name/ first name

2) “Cancel” allows you to close the window and come back to the patient management

 Add a new user

 Edit the information of a user

 Delete a user

N.B.: The first time the software is used, the application automatically launches the account creation page. It is impossible to access another window without having created an account.

To create a user account it is necessary:

1) Fulfill the obligatory information marked by a *
2) Fulfill, if you wish, the non obligatory information
3) "Exit" allows to quit without register OR
4) "Valid" allows to register the user

Allows to comes back to the list of user

VI. Medical protocol of use

1) Terms of use

The device must be used by medical staff, in a dry environmental or in a temperature between 0° C and 40° C and a hygrometry rate between 30 and 70%.
The device must not be used on patients who had a ligamentoplasty less than 1 month ago (see IV) General safety instructions for more information). This device is usable exclusively for laxity measurements of inferior members with patients whose weight is a maximum of 150 kg (or with a leg < 37 kg). The device must **only** be use with PC/tablet.

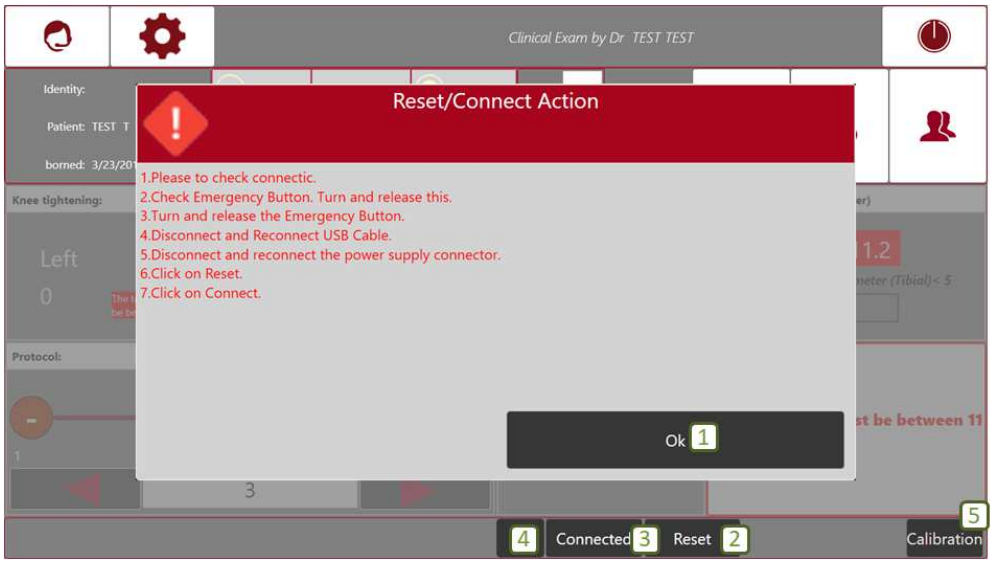
Moreover, it is recommended to sanitize the device with an alcohol-based product or wipe **before using it the first time and between each patients** (see IV) General safety instructions for more information).

The device must not be use if an element does not work or is broken (see IV) General safety instructions for more information).

For more information with the maintenance, please refer to IX) Maintenance & recycling.

2) Reset in case of disconnection

In case of disconnection of the power supply, the USB cable or the release of the emergency stop button, the message below will appear on the measurements and management of the test data screen.



1) Click on “Ok” after taking into account all the information, that means, check the emergency stop button, the USB cable **(must be disconnected on the PC side)** and the power supply.
2) Click on “Reset”
3) Click on “Connected”
4) If the device is correctly reconnected, the green light will be on.
5) If a disconnection interferes with the rotation, it will be necessary to carry out a calibration if the boot is not centred.
   For that it is **essential** that no patient be on the device then clicks on the “Calibration” button.

3) Safety case

In the case that the jack is locked (materialized by a beep when you want to use the table), it is necessary to reset the control. To do this, press the two buttons on the first line simultaneously (see picture) for a few seconds.

4) Protocol

The test allows to compare measure made by each knee (right and left) and it's separated in 3 parts:

a) Management of patients information
b) Patient installation and management of the test data
c) Measurement preparation

⚠ **Before each test on a new patient, it is necessary to explain the device operation to avoid the surprise effect during the test, when the tibia his pushed or when he is in rotation. It will have for consequence a better condition to a muscle relaxation and have a better result at the test.**

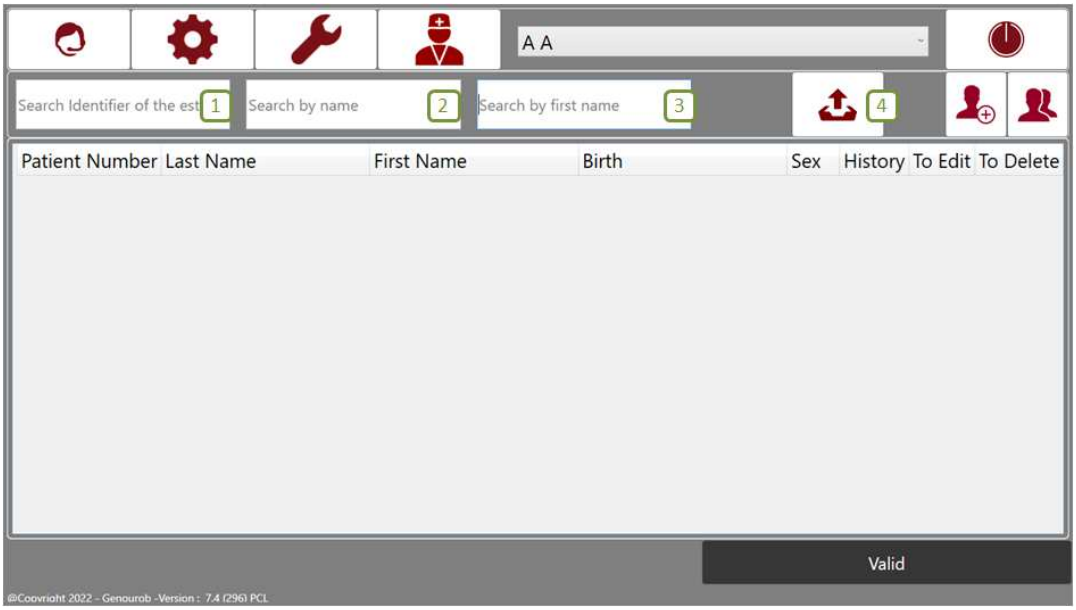
A full DYNEELAX test lasts between 15 and 20 minutes.

If a power cut happens during the test, unstrap the patient as quickly as possible.

a) Patient information management

This step allows to seize, to edit, to consult or to delete a patient's personal information in the database therefore the tests results.

Patient file tab



1) Research of the patient by Patient Number
2) Research of the patient by his last name
3) Research of the patient by his first name
4) Export of the "partial" database: after configuring the save path, selecting the required fields and the start date of the export, click on "Export".

Assistance by Iperius

Access to application settings

Access to the users list

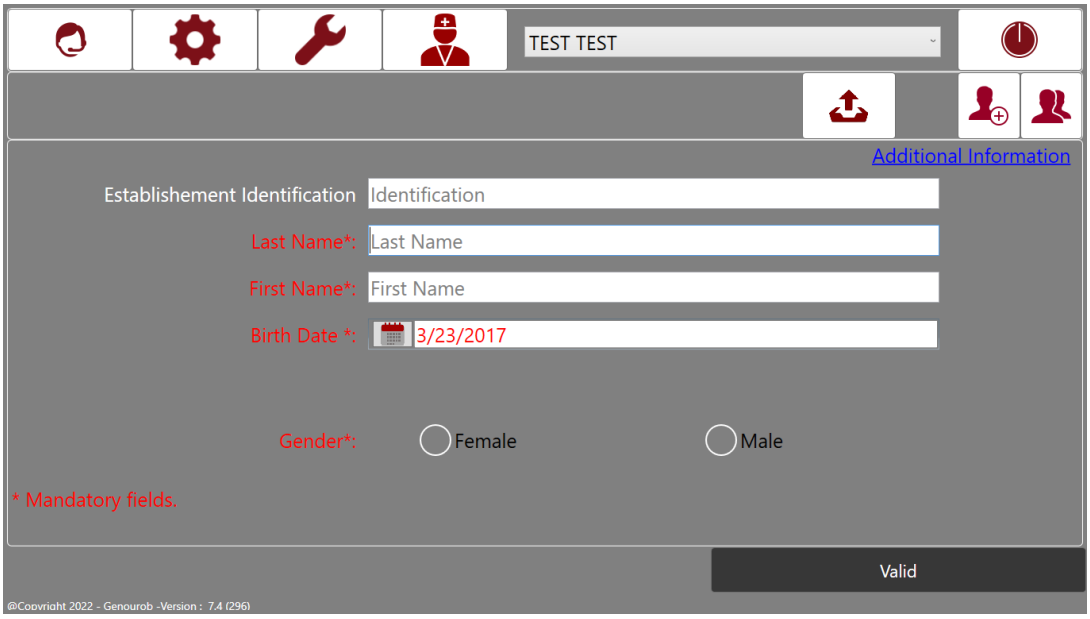
Allows to close the application

Add a patient

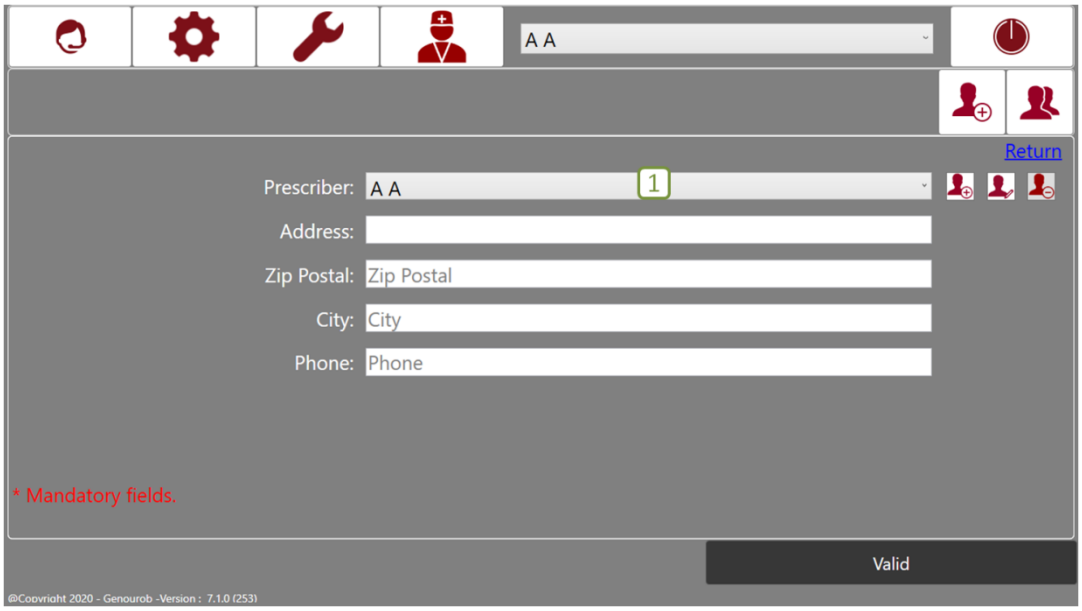
Access to the patients list

Add a patient

After clicking on the button  “Add a patient”, the file tab “patient file” appears.



Fill in the obligatory information marked by a *.
You are free to seize other information. By clicking on “Additional information” it is possible to fulfill other information.



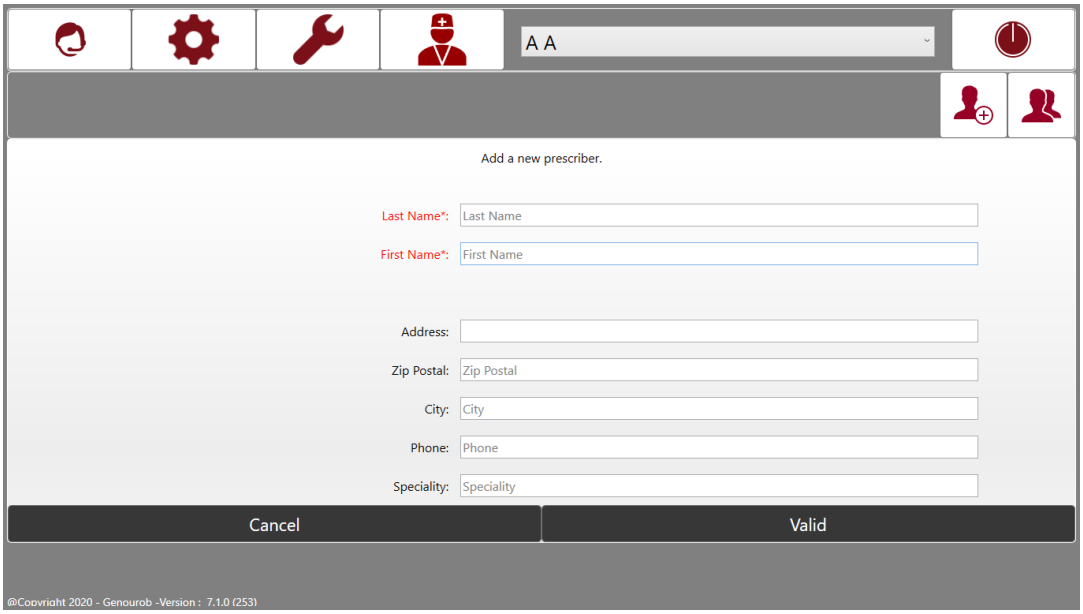
If you wish, you can fill in the prescriber’s information. For this you need:

1) In the list, select existing prescribers

 Edit an existing prescriber in the list

 Delete an existing prescriber in the list

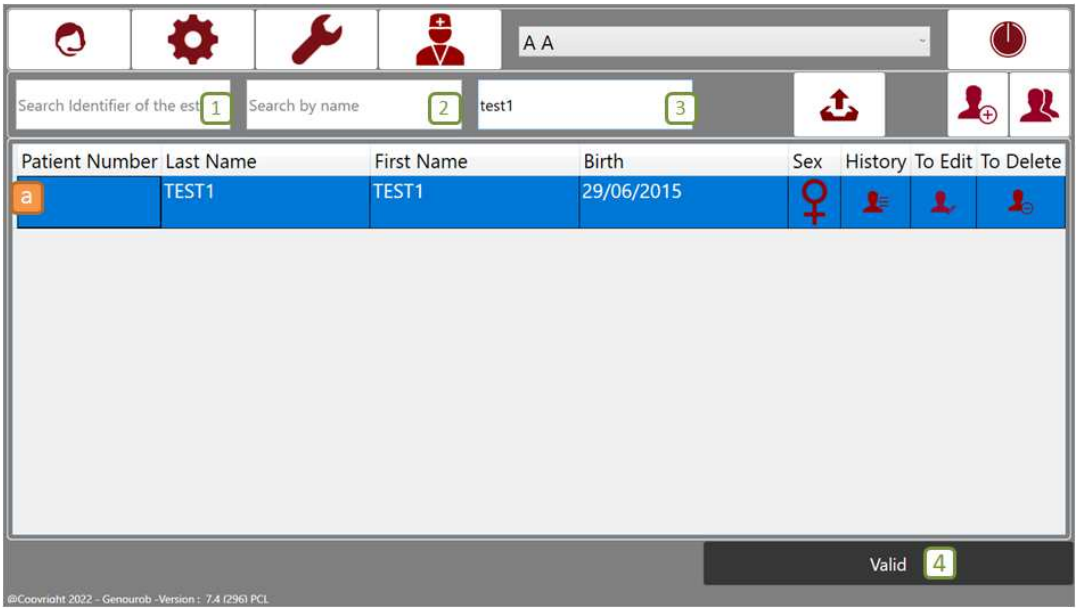
Create the prescriber, if this is the case, the bellow window will appear.



Fill in the obligatory information marked by a * and click on « Valid».

To finish the creation of the patient file, click on “Valid” then on “Add a patient” to create the profil, the management of the test data page appears.

Select, modify or delete a patient



To research a patient, many possibilities:

1) By the User Name
2) By the Last Name
3) By the First Name

To “Edit” the patient information, it is necessary to click on

To “Delete” the patient information, it is necessary to click on

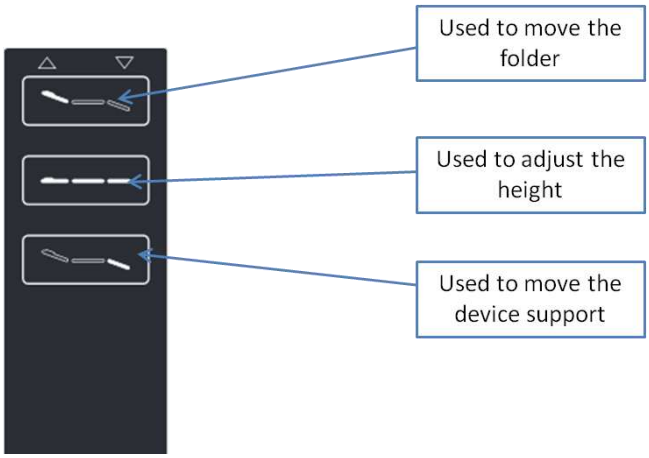
To select a patient, it is necessary to click on the line to highlight it (a) and whether to click on “Valid” **(4)** or double click.

b) Installation of the patient and patient file tab

To displace the device on the table, it is necessary to unlock the indexing finger by pulling the button. Then when the device is placed on the opposite side, a click validates its correct set up.

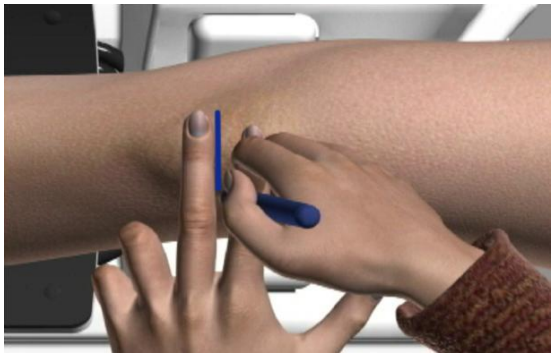
Installation of the patient

After having the clothes removed from the lower limbs, the patient is on the table lying down. Adjusted if it’s the first exam or adjusted according to the incline values of the previous exam; the inclination of the leg must be less than 30°. The body is relaxed, head on the couch, arms by their side.

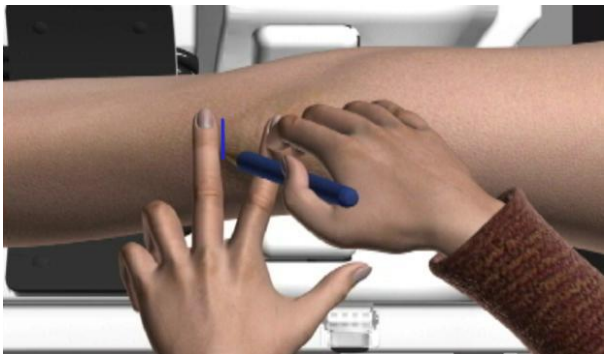


The knee must be in the centre of the support on which the patella is secured. Place the foot on the adjustable foot-rest. Do not forget to place the support on the cup for the translation test.

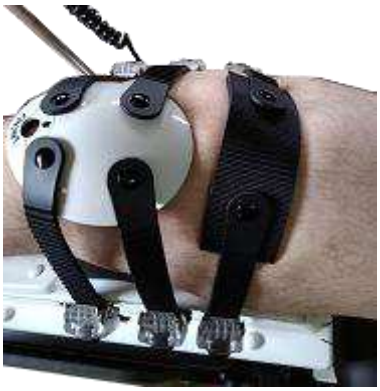
Locate the positions of the patella and the ATT (Anterior Tibial Tuberosity). Place a finger on the apex of the patella and mark its position.



Mark the position of the ATT.



Place the knee-cup so that the mark on the skin lines up with the lines of the “FRONT” hole. Fix the third strap around the thigh to tighten it; do not tighten the knee-cup yet.



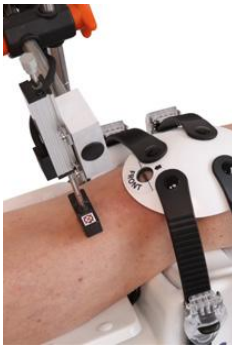
⚠ **The knee-cup must be horizontal and centered on the patella.**

⚠ **It is possible to use the "Mini" knee-cup for small knees to improve comfort (as well as placing extra foam under the calf).**

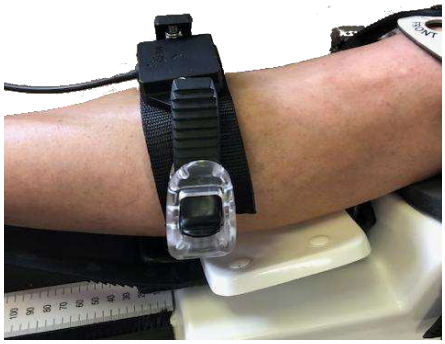
Fasten the foot in the support. Adjust the position of the support until the heel fits snugly. Fix the foot in position by tightening both buckles.

Use the second buckle situated at the malleolus, tigh the ankle and adjusts the third buckle.

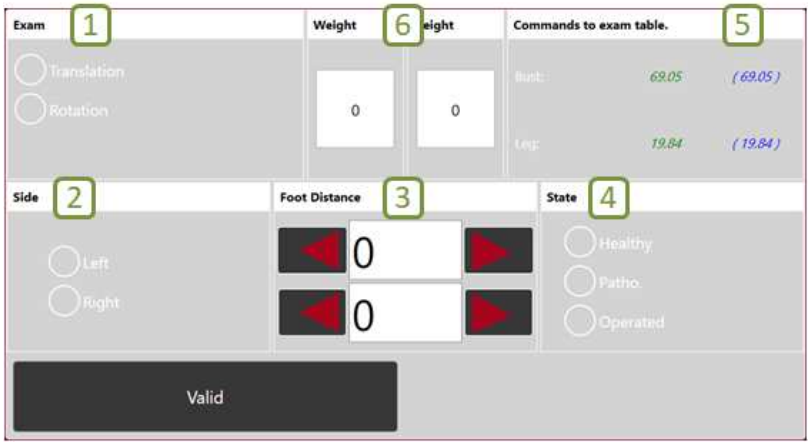
Pose the displacement sensor. For this, loosen the two screws and place the sensor block on the ATT mark.



Position the tibial sensor around the calf using the straps and buckles, as close as possible to the knee cup



Management of the test data



1) Choose the exam type (Translation or rotation)
2) Choose the side that will be tested (right or left)
3) Take the “Foot distance” measurements as it appears in the aperture.

   ⚠ Each time a particular patient is tested this value must be the same. **(A test will not be made if the measurements are not taken)**
4) Choose the condition of the knee (healthy, pathological or operated)
5) Based on the blue statistics, adjust the table to be at the same place as the previous exam. (if existing).

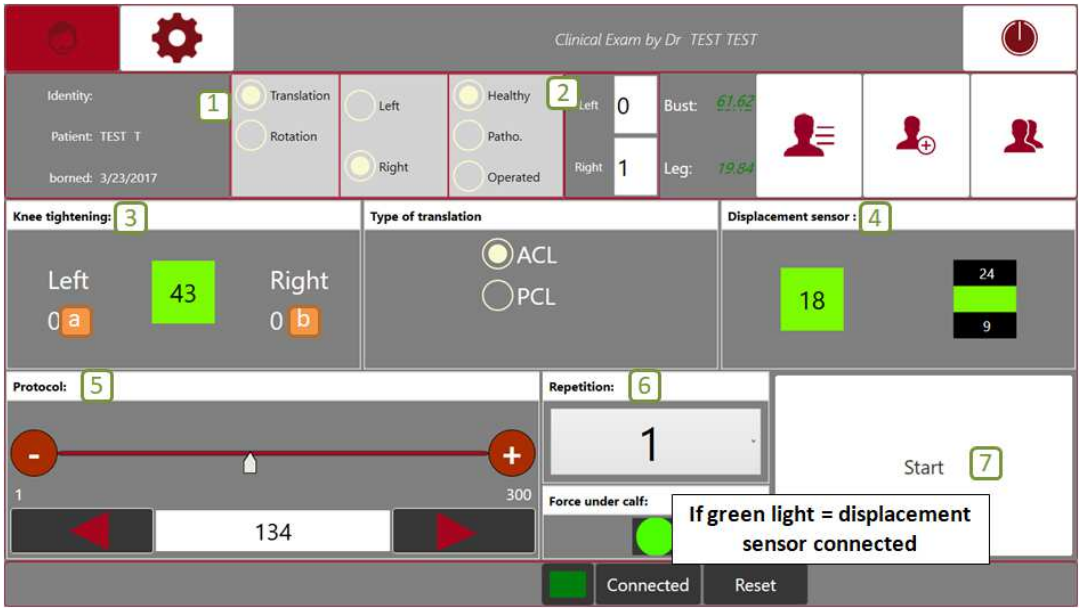
Moreover, it is possible if you wish to be informed of the patient weight (kg/lbs) and height (cm/inch) **(6)**.

For the rest, we will follow a complete protocol of the test starting by translation then rotation (on each leg). For this the information on the pre measurement screen will be informed, click on « Next »

Going through the pre measurement tab is necessary only for the first test (or informed the foot distance). Then, the test management can be done on the measurement management page.

c) Measurement preparation screen

Translation



1) Patient information
2) Test setting tab, this tab allows between each test to modify them with the buttons.
3) This tab shows tightening. It must be between 50 and 140 (±10) and must be painless. Adjust the tightening using the buckles. The value of the previous tightening for the leg is informed in (a) or (b)
4) Put the sensor at 90° to the tibia and the value showing must be between 9 and 24. If this case, it will appear in green light and if not in red light
5) This tab allows to adjust the test value. **Always start the test at a maximum of 134.** The selection can be made using arrows or + and -
6) Allows to select the numbers of the test repetition (from 1 to 5)
7) The “start” button allows to show a message before launching the test

⚠ **The button is only clickable if all the conditions (filled foot distance, tightening, sensor placement) are correct**

Allows access to the patient history

Allows to come back to the patients list

The translation test must be made three times for each leg to be assured of the good of the measurement reproducibility.

The recommended protocol is a test at 134, at 150 and 3 tests at 200 (for a pathological knee, comes first one 200 test).

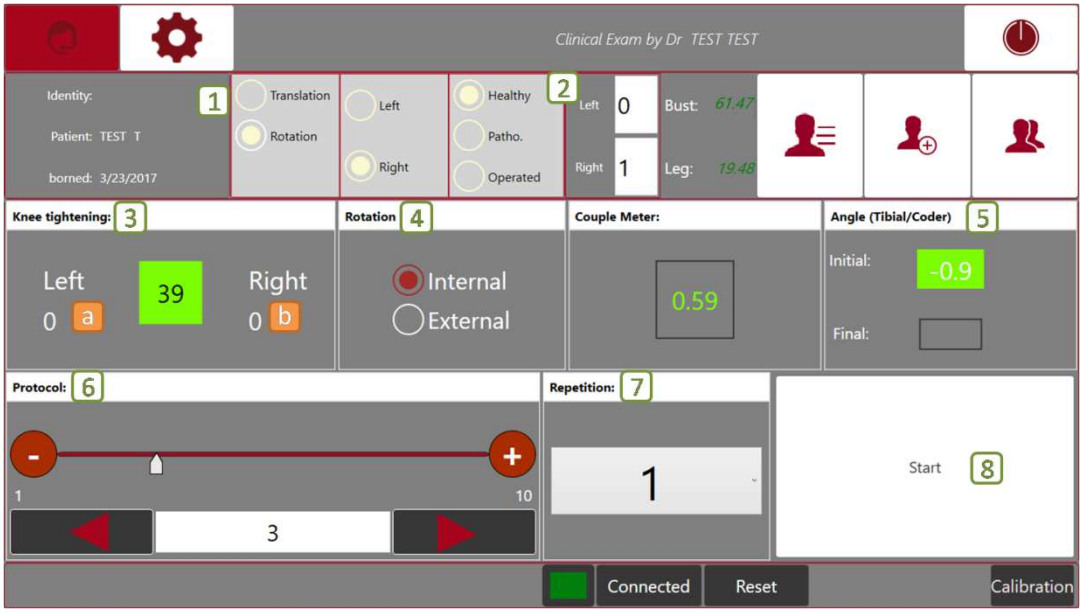
To validate the translation Dyneelax tests, we apply the following principles:

- The tightening should be the same (to +/-10%) of the healthy side/ pathological side (or on one side compared to the other).

- The final tightening (after the last test to 200) must be to +/-10%.

- The slope calculation P2 (heathly side so really healthy) must be less than 30 (35 if the patient is hyperlaxe) at the end of the last test to 200.

Rotation



1) Patient information
2) Test setting tab, this tab allows between each test to modify them with the buttons.
3) This tab shows tightening. It must be between 50 and 140 (±10) and must be painless. Adjust the tightening using the buckles. The value of the previous tightening for the leg is informed in (a) or (b)
4) This tab allows to choose the rotation that will be made: either internal or external. It is necessary to do both on each leg to analyze the test
5) This tab shows the tibial sensor. To do this, remove the foam used in translation, remove the displacement sensor. The value must be between -5 and +5. If this is case, it will appear in green light otherwise in red light.
6) This tab allows to adjust the test value. **Always start the test at a maximum of 3.** The selection can be made using arrows or + and -
7) Allows to select the numbers of the test repetition (from 1 to 5)
8) The “start” button allows to show a message before launching the test

⚠ **The button is only clickable if all the conditions (tightening, sensor placement) are correct. Moreover, it is necessary to take the foam off the cup.**

Allows access to the patients historical medical file

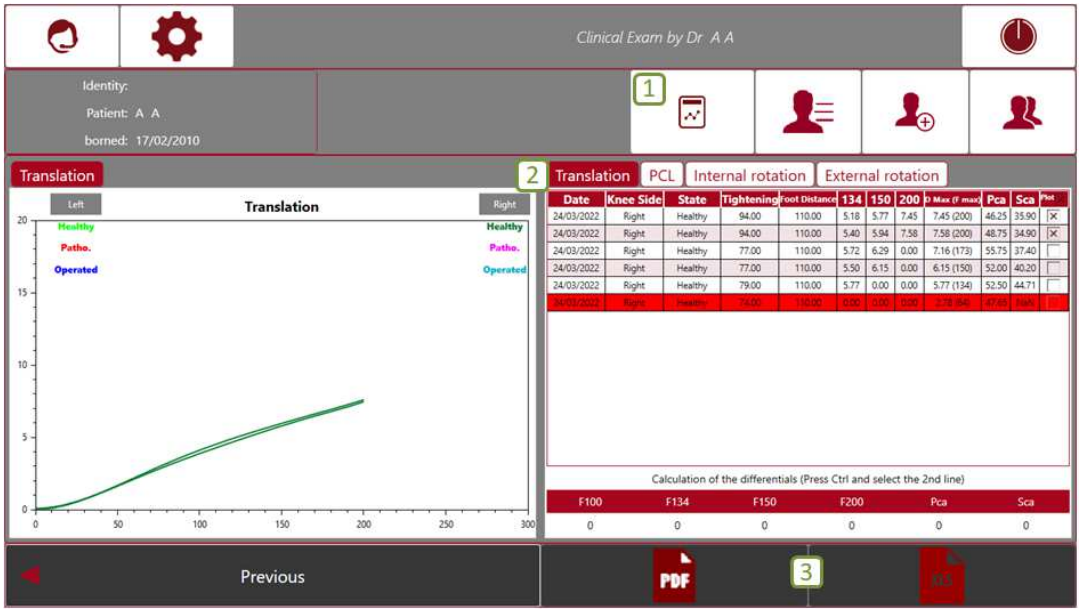
Allows to come back to the patient list

The rotation test must be made three times in internal and three times in external for each leg to be assured of the good measurement reproducibility.
The recommended protocol is one test at 3, and three tests at 5. Three tests at 8 can be performed if DMax < 10 (and at the judgement of the practitioner).

To validate the rotation Dyneelax tests, we apply the following principles:
- The tightening should be the same (to +/-10%) of the healthy side/ pathological side (or on one side compared to the other).
- The final tightening (after the last test to 5) must be to +/-10%.

d) Results interpretation

The tab "Results" appears between each realized test, in which case only appears the exam results in progress.



1) Allows to choose the display mode (Graph in progress or multi graphs).
2) Allows to choose a test to interpret (translation, rotation internal or external, PCL).
3) The PDF or XLS button allows to export the results. For this, select the tests you wish you visualize on PDF with helps of the case "Trait" then click on PDF.

Translation

Select the tests you want to compare. To have an optimized interpretation, the compared tests must be:

- Be carried out at the same tightening (± 5)
- Be carried out at the same day (in the event of an operated pathological knee, we will take the last value of the healthy operated knee)

Color codes of the curves:

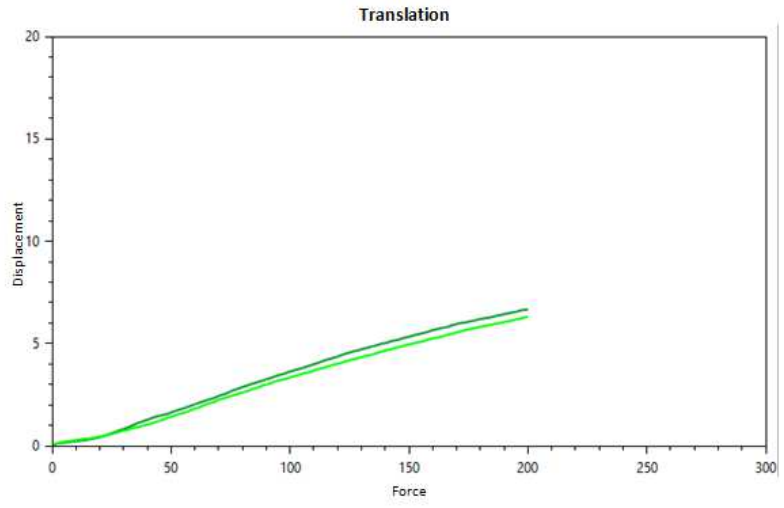
- Green = left healthy knee
- Dark knee = right healthy knee
- Red= left pathological knee (with suspected lesion of ACL)
- Purple = right pathological knee (with suspected lesion of ACL)
- Blue = operated left knee (ligamentoplasty)
  Dark blue = operated right knee (ligamentoplasty)

Preoperative analysis

The results appear under the shape of ligament elongation curves or flexibility (= inverse of stiffness) under the effect of a force of 0 to 300.
The ACL loading occurs in a linear way.
Each knee has its own characteristic (variable P2 slope; P2 = slope between 100 and 200) and it is the difference of performance (P2) between each knee which will be studied.
The results are interpreted according to the slope P2 of each knee and of displacement differential at 134 (noted Δ at 134: international reference).

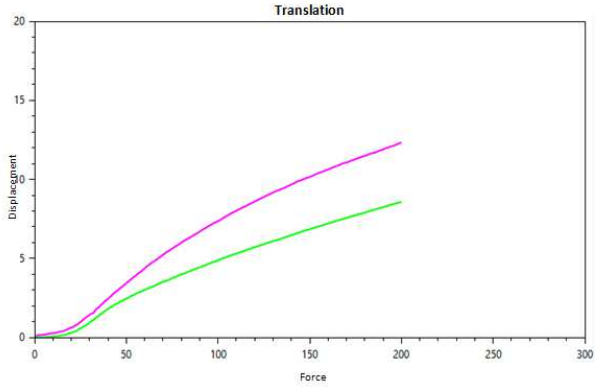
Healthy knee

The curves are stackable (parallel curves) and the pathological knee / healthy knee elongation differential is less than (Δ < 1 at 134).



Pathological knee

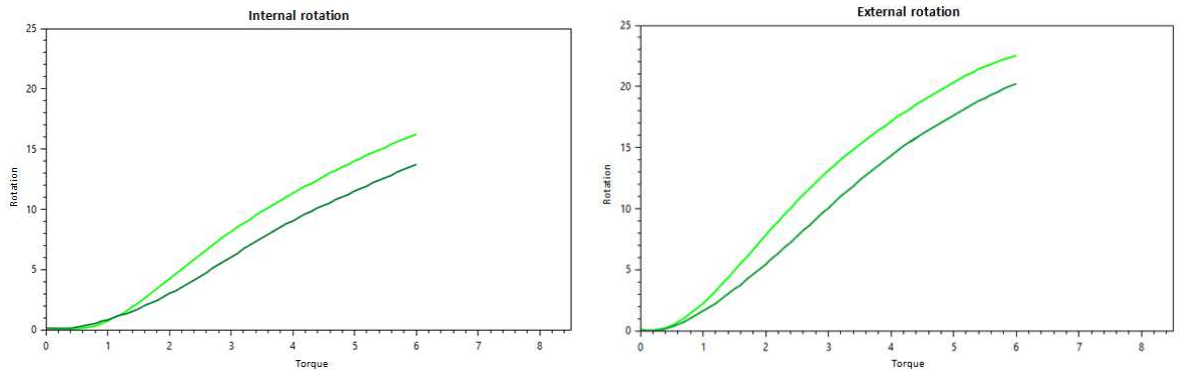
The curve can keep a double slope if the remaining ligament tissue quality is mechanically efficient.
If this tissue is of a low tensile strength, the P2 slope of the pathological knee is superior to the one of the healthy knee.
The threshold for complete lesions is Δ > 3 (Δ(P2) > 10) and for partial lesions 1.5 < Δ < 3.



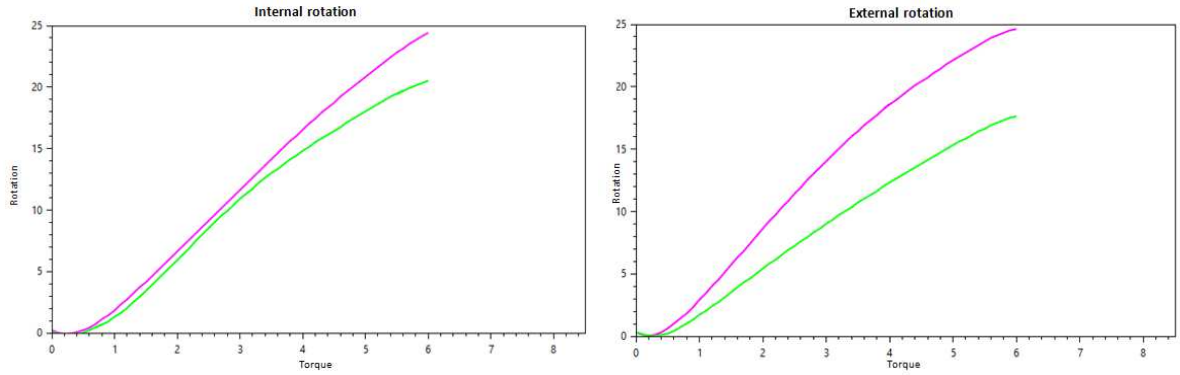
Rotation

In rotation, the results interpretation occurs according to the stackable curves (parallel curves).

Healthy knee

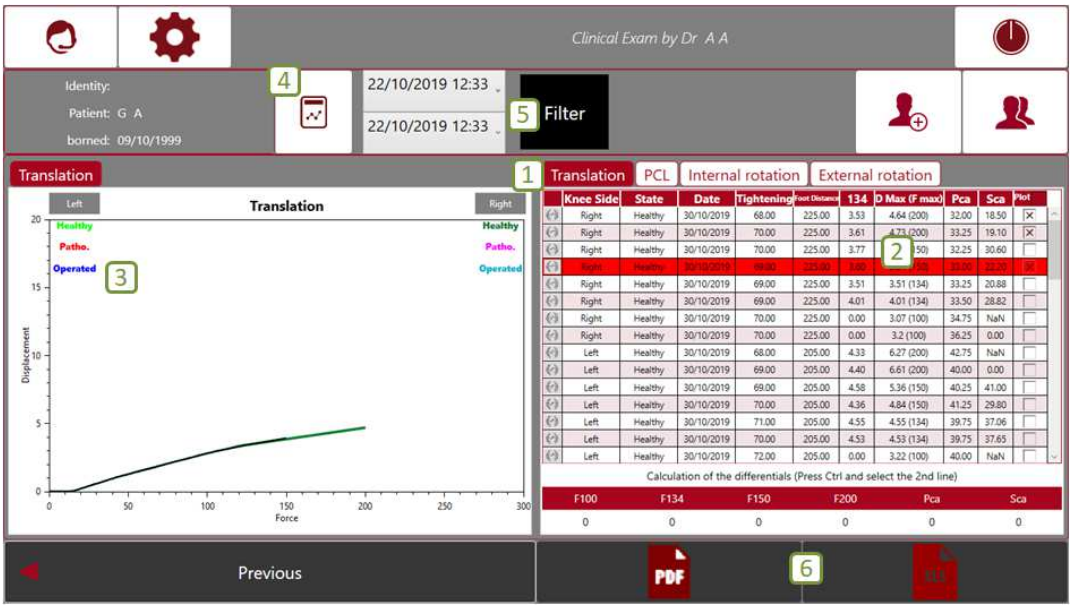


Pathological knee



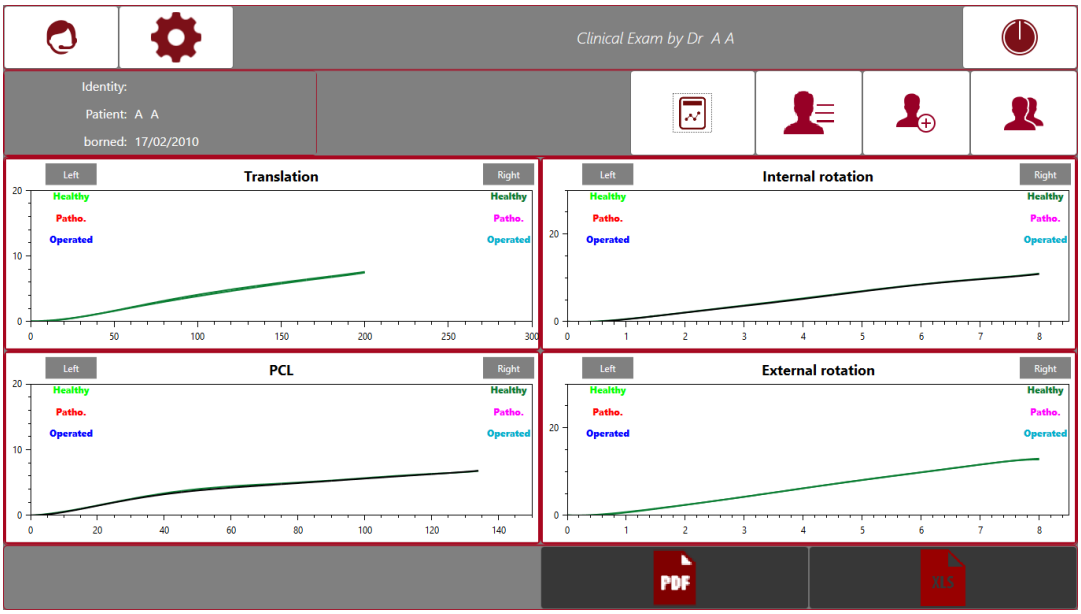
If the delta between healthy and pathological knee is highter than 3 (at 5), it's a sign of damage of ligamentary structures.

e) Patients historical medical file



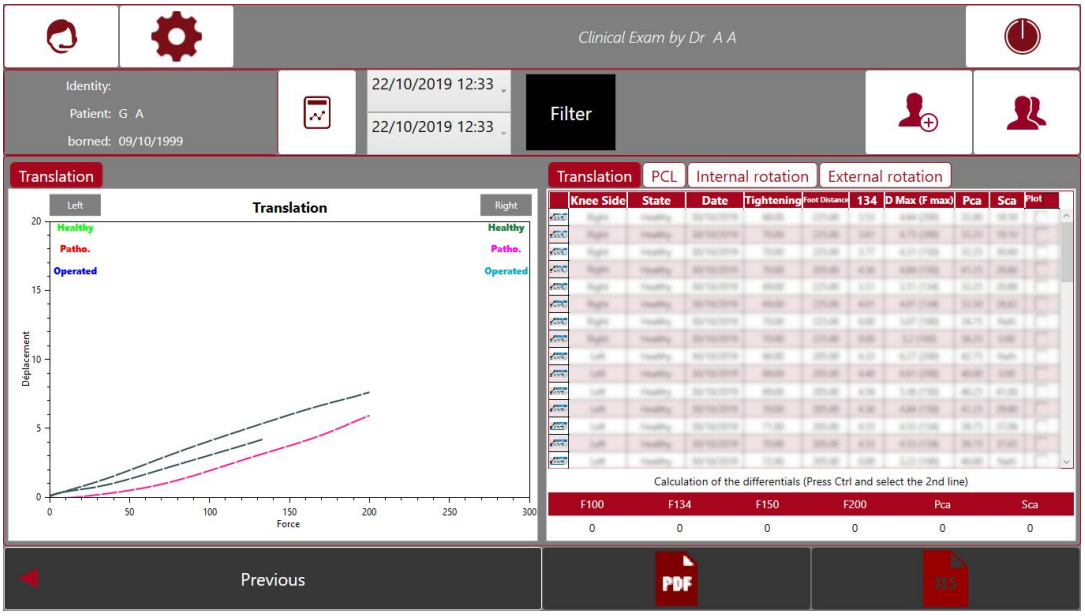
1) Tab allowing to choose the type of test to show (translation tests load first, a delay to load data and access the rotation or PCL tab is occasionally required)
2) Historical tab of tests, from this tab, we chose the values that we wish to visualize on the graph. **(3)**
3) Represented curves graph selected by checked choices.
4) Allows to access the function of multi graphs (see below).
5) Filter: Choose the first date of the Exam 1 then Exam 2 and click on Filter.
6) The PDF or XLS button allows to export the results. For this, select the tests you wish you visualize on PDF, then click on PDF.

Fonction of multi graphs



This tab allows to visualize at the same time the translation tests, internal and external rotation, PCL (if applicable). The curves choices occur according to the previous one. **(3)**

Import data of GNRB



Data imported from GNRB are presented with the logo gnrb at beginning of line.
On the graph, the curves are displayed as dotted lines.

Summary protocol:

- In the first place, it is a new patient, create a patient file. The opposite case, search it and select it.

- After having the clothes removed from the lower limbs, the patient is laying down (following the previous setting test for the exam table and the foot distance).

- Locate and mark the patella and the Anterior Tibial Tuberosity (ATT). Place and tighten (approximately) the knee cup by making the patella mark appear in the centre cercle « FRONT ». Fasten the third strap, the heel cup as well as the strap located close to the malleolus. Place the sensor displacement.

- On the pre measurement screen, select the translation exam then the side of the exam (left or healthy) and the knee condition. If its the first exam, enter the foot distance.

- Adjust the tightening so that it is between 50 and 140 (equivalent to the previous test) and place the displacement sensor so that the value is around 15. Start by a translation test at 134 then 150. Then launch 3 tests at 200 (launch a test alone at 200 in the first place on the pathological).

- Change test mode and move to rotation test. Select internal, launch a test at 3 then three at 5 (launch alone a test at 5 in the first place on the pathological). Three tests at 8 can be performed if DMax < 10 (and at the judgement of the practitioner). Make the same for the external rotation.

- Once the tests are over on the first knee, do the same for the second by modifying the information in the dedicated frame.

VII. PCL Modul

What is the PCL modul ?

PCL modul is an option developed for the DYNEELAX which can be used with the DYNEELAX device. It diagnoses total or partial ruptures of the Posterior Cruciate Ligament (PCL) of the knee.

The principle of the device is based on the posterior drawer test. This involves applying posterior pressure to the anterior and proximal tibia face using an articulated mechanical system and to record the displacement of the tibia for each force (from 0 to 134) via a sensor placed on the tibia.

Measurements are performed on both legs and the diagnosis is obtained from comparing the two sets of values and the gradients of the curves obtained.

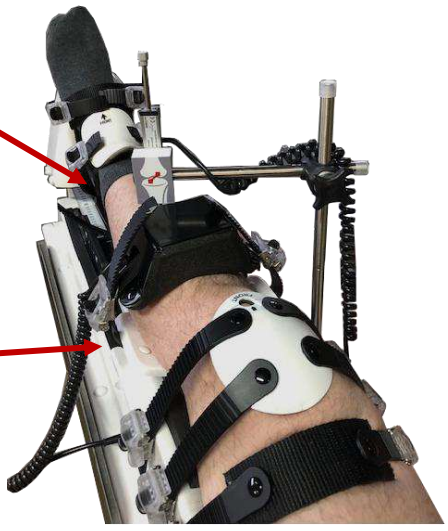
TEST EXECUTION

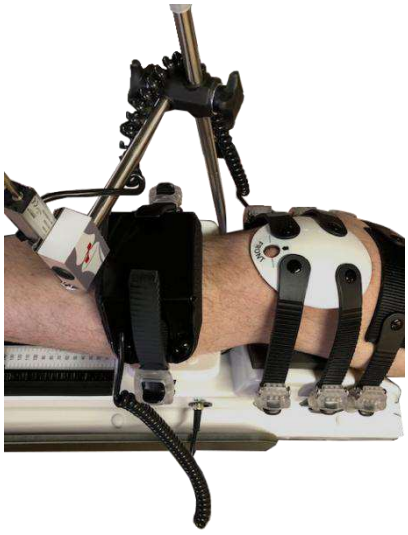
⚠ **The cup only moves to the upper position if you connect the PCL modul (automatic rise).**

To position the patient, it is essential to position the table at a maximum of 25° so that the patient's leg is in extension. It is essential to add one or two of the foot foams provided under the patient's heel and remove (if it this is not already done) the foam on the cup.

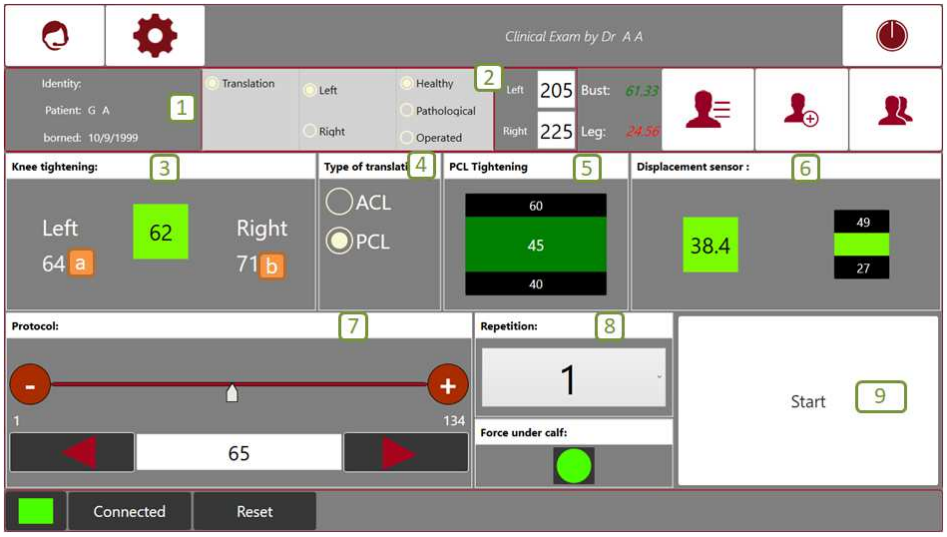
Add one or two of the foot foams under the patient's heel

Fix the PCL module with the straps on the knee cup





Do not strap or unstrap the patient before connecting PCL Modul



1) Patient information
2) Test setting tab, this tab allows between each test to modify them with the buttons.
3) This tab shows tightening. It must be between 50 and 140 (±10) and must be painless. Adjust the tightening using the buckles. The value of the previous tightening for the leg is displayed in (a) or (b)
4) This tab shows the translation that will be performed: ACL or PCL.
5) This tab shows the PCL Tightening. To do this, place the PCL modul using the two straps (the straps must be in the middle of the side edge of the calf shell). The PCL tightening should be between 40 and 60. Adjust the tightness with the buckles.

⚠ The straps must not fit into the PCL modul on the sides.

6) Place the displacement sensor. To do this, loosen the two screws and place the sensor block on the anterior rim (anterior tibial bone). Put the sensor at 90° to the tibia and the value showing must be between 27 and 49.
7) This tab allows to adjust the test value. **Always start the test at a maximum of 65.** The selection can be made using arrows or + and -
8) This allows to select the numbers of the test repetition (from 1 to 5)
9) The “start” button allows to show a message before launching the test

⚠ **The button is only clickable if all the conditions (filled foot distance, position table, tightening, sensor placement, cup in up position) are correct**

The recommended protocol is a test at 65, at 100 and 3 tests at 134 (for a pathological knee, comes first one 134 test).

⚠ UNSTRAP THE PATIENT BEFORE DISCONNECTING THE PCL MODUL AND MOVING ON TO ANOTHER MEASUREMENT

To validate Dyneelax tests with PCL modul, we apply the following principles:
- The tightening should be the same (to +/-10%) of the healthy side/ pathological side (or on one side compared to the other).
- The final tightening (after the last test to 134) must be to +/-10%.

RESULTS INTERPRETATION

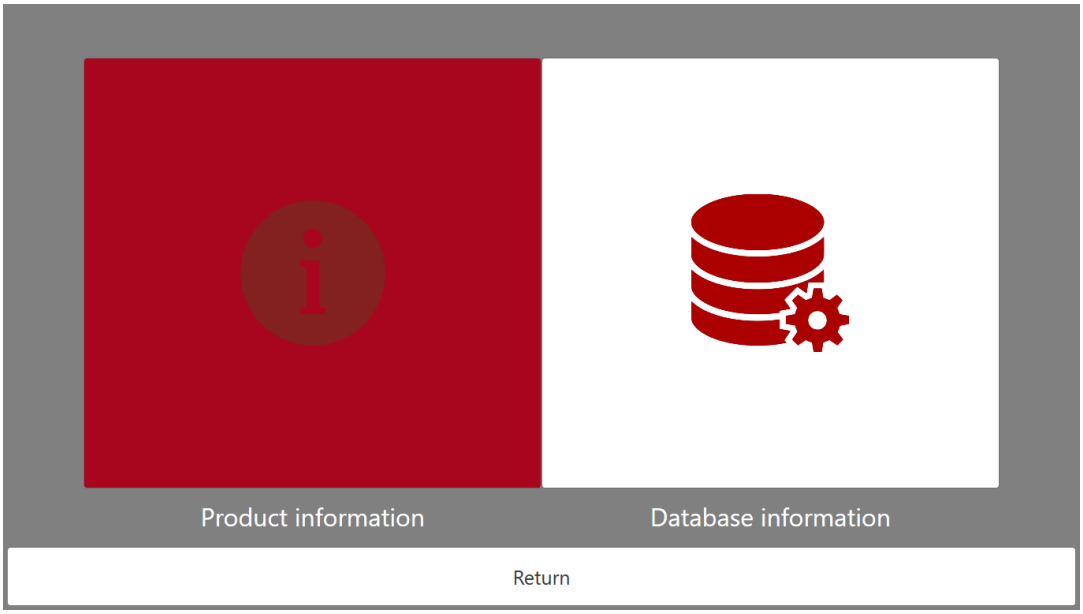
The tab “Results” appears between each realized test, in which case only the exam results in progress appear.

Select the tests you want to compare. To have an optimized interpretation, the compared tests must be:

- carried out at the same tightening (± 5)
- carried out on the same day (in the event of an operated pathological knee, we will take the last value of the healthy operated knee)

The injury threshold (for a 134 test) is a difference of 3 between the two knees.

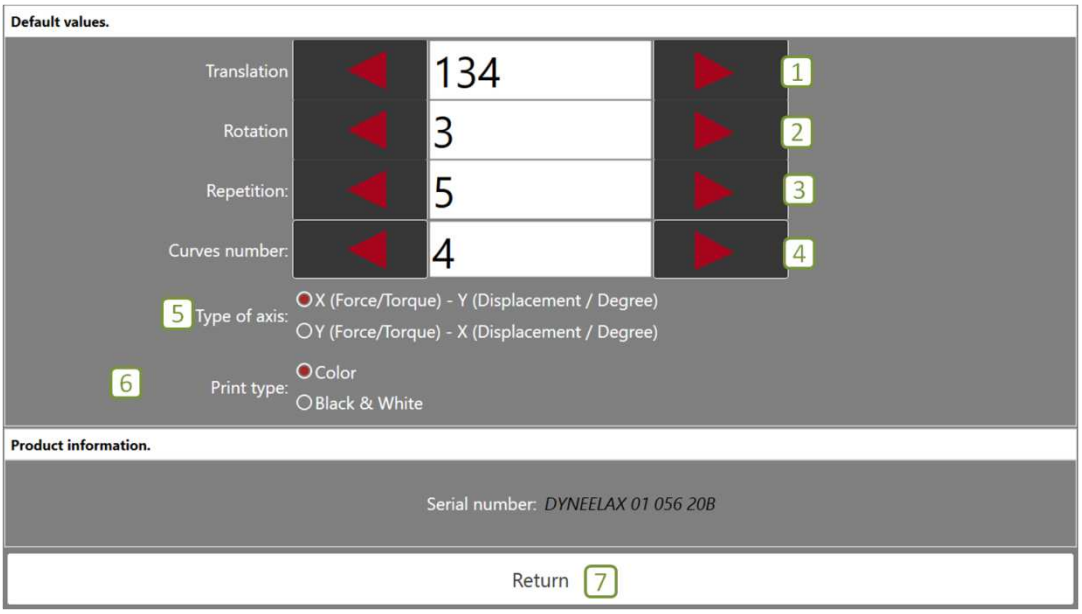
VIII. Settings



The tab allows access to 2 submenus:

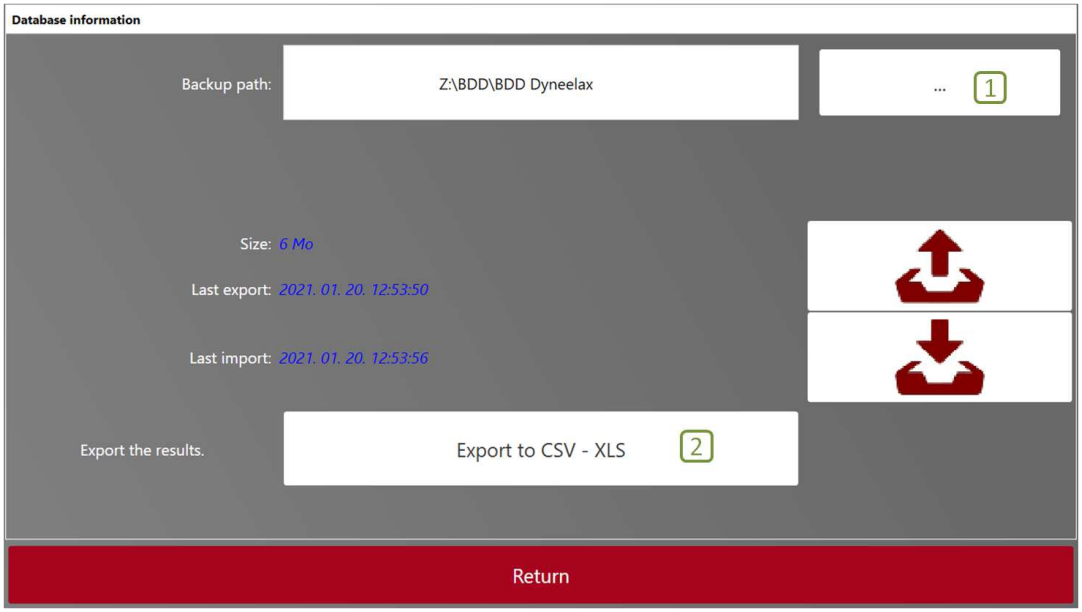
- Product information
- Databases information

Product Information



1) Allows to adjust the value of the translation by defect.
2) Allows to adjust the value of the rotation by defect.
3) Allows to adjust the number of repetitions by defect.
4) Allows to adjust the number of curves showing by defect.
5) Allows to adjust the axes orientation.
6) Allows to adjust the type of impression to export to PDF.
7) Allows to come back to the main menu in the settings.

Databases information



1) Allows to modify the backup path.
2) Allows to export the database in CSV-XML format to open it via Excel.

Allows to export the database, with the last export date indicated.

Allows to import database, with the last import base indicated.

IX. Maintenance & recycling

- Any damage to the device should trigger maintenance Such as: (a broken pad, a broken sensor, safety block, a damaged cable…)

- In such events, phone GENOUROB®, **Bâtiment 60, rue Henri Geret, 53000 Laval, France** on +33 (0)2 43 90 43 01 from 9am to 6pm, Monday to Friday, or send an email to the following address: contact@genourob.com.

- The device must be disposed of with care and must not be thrown away with consumer waste. Electrical Waste and electronic equipment (DEEE) can pollute the environment and must be disposed of in accordance with a specific circuit suitable for DEEE.

We recommend that you contact your local waste administration for information on the selective sorting of electrical and electronic equipment.

X. Terms of use, of stock and of transport

No transport must be made without the technical assurance from GENOUROB® technician.

The Dyneelax :

✓ Must be handled with care	
✓ Must be kept dry	
✓ Must be stored in a room where the temperature is between 0° C and 40° C.	 5°C 40°C
✓ Must be stored in a room where the humidity is between 30% and 70%.	 30% 70%
✓ Must be stored under atmospheric pressure between 860 and 1060 HPa	 860 HPa 1060 HPa

XI. Certifications

The device has been certified by CE 0459

First marketing's date: 19/05/2020

The manufacturing's date is legible in the serial number:

xxyyyzz L

xx: Medical device's number

yyy: Date of the manufacturing's date:

zz : last two digits of the manufacturing's year

L : letter corresponding to the manufacturing's month.

The Dyneelax device complies with the EMC and safety standard IEC 60601-1-1-2 and IEC 60601-1: certification awarded by the LCIE (33 avenue general Leclerc, 92260 Fontenay aux Roses).

GENOUROB complies with iso 13485:2016 – NF EN ISO 13485: 2016: certification awarded by the LNE-GMED (1, rue Gaston Boissier, 75724 Paris Cedex 15).

XII. Manufacturer's declaration

Electromagnetic emissions		
The Dyneelax is intended for use in the electromagnetic environment specified below. Users should ensure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment- guidance**
Electromagnetic radiation disturbance(Radiated emissions) CISPR 11	Group 1	The Dyneelax uses RF energy for internal operation. These RF emissions are very low and are not likely to cause interference with nearby electronic equipments.
Interference voltage at power terminals CISPR 11	Class B	The emissions characteristics of the Dyneelax allows it to be used in industrial areas and in hospitals. (Class A defined in CISPR 11).
Harmonic emissions EN 61000-3-2	Class A Complies with requirements	
Voltage fluctuations and flicker EN 61000-3-3	Applicable	

Electromagnetic immunity			
The Dyneelax is intended for use in the electromagnetic environment specified below. Users ensure that it is used in such an environment.			
Immunity test	**CEI 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge EN 61000-4-2	8 kV Contact 15 kV air	8 kV Contact 15 kV air	The floor must be in wood, concrete or tile. If the floor is covered by a synthetic material, the humidity must be at least 30%.
Electrical fast transient/ burst EN 61000-4-4	2 kV for power supply lines 1 kV for input/ output lines	2 kV for power supply lines 1 kV for input/ output lines	Home health care environment and an environment of a professional health care facility.
Surge EN 61000-4-5	Differential mode 1 kV 2 kV Common mode	Differential mode 1 kV 2 kV Common mode	Home health care environment and an environment of a professional health care facility.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	<5% UT - during 10 ms 40% UT - during 100 ms 70% UT - during 500 ms <5% UT - during 5 s	<5% UT - during 10 ms 40% UT - during 100 ms 70% UT - during 500 ms <5% UT - during 5 s	Home health care environment and an environment of a professional health care facility. If the user of the Dyneelax requires continued operating during interruptions of the main power supply, it is recommended that the Dyneelax be powered by an inventer or a battery.
Magnetic field at assigned industrial frequency (50/60 Hz)	30 A/m	30 A/m	The magnetic field at assigned frequency must be at a level of a home health care environment and an environment of a professional health facility.
Note: UT *is the AC mains voltage for the test.*			

XIII. Publications

1. Jenny J-Y, Puliero B, Schockmel G, Harnoist S, Clavert P. Experimental validation of the GNRB® for measuring anterior tibial translation. Orthop Traumatol Surg Res. 1 mai 2017;103(3):363-6.

2. Jenny J-Y, Arndt J. Anterior knee laxity measurement using stress radiographs and the GNRB® system versus intraoperative navigation. Orthop Traumatol Surg Res. 1 oct 2013;99(6, Supplement):S297-300.

3. Klouche S, Lefevre N, Cascua S, Herman S, Gerometta A, Bohu Y. Diagnostic value of the GNRB ® in relation to pressure load for complete ACL tears: A prospective case-control study of 118 subjects. Orthop Traumatol Surg Res OTSR. mai 2015;101(3):297-300.

4. Lefevre N, Bohu Y, Naouri JF, Klouche S, Herman S. Validity of GNRB® arthrometer compared to Telos™ in the assessment of partial anterior cruciate ligament tears. Knee Surg Sports Traumatol Arthrosc Off J ESSKA. févr 2014;22(2):285-90.

5. Mouton C, Theisen D, Meyer T, Agostinis H, Nührenbörger C, Pape D, et al. Combined anterior and rotational knee laxity measurements improve the diagnosis of anterior cruciate ligament injuries. Knee Surg Sports Traumatol Arthrosc Off J ESSKA. oct 2015;23(10):2859-67.

6. Pouderoux T, Muller B, Robert H. Joint laxity and graft compliance increase during the first year following ACL reconstruction with short hamstring tendon grafts. Knee Surg Sports Traumatol Arthrosc [Internet]. 28 sept 2019 [cité 8 oct 2019]; Disponible sur: https://doi.org/10.1007/s00167-019-05711-z

7. Robert H, Nouveau S, Gageot S, Gagnière B. A new knee arthrometer, the GNRB®: Experience in ACL complete and partial tears. Orthop Traumatol Surg Res. 1 mai 2009;95(3):171-6.

8. Ryu SM, Na HD, Shon OJ. Diagnostic Tools for Acute Anterior Cruciate Ligament Injury: GNRB, Lachman Test, and Telos. Knee Surg Relat Res. 1 juin 2018;30(2):121-7.

9. Senioris A, Rousseau T, L'Hermette M, Gouzy S, Duparc F, Dujardin F. Validity of rotational laxity coupled with anterior translation of the knee: A cadaveric study comparing radiostereometry and the Rotab®. The Knee. mars 2017;24(2):289-94.

XIV. Version of the notice

The notice is currently in version H dated 17/03/2022.