Genourob®
INNOVATIVE LAXIMETRY

Certified Company ISO 13485 : 2016, NF EN ISO 13485 : 2016 by LNE GMED

INSTRUCTIONS FOR USE OF THE GNRB®

gnrb

MEDICAL DEVICE FOR KNEE LAXITY ANALYSIS

Last update, version P : 04/02/2021

ACKNOWLEDGEMENT

Thank you for having purchased this GNRB®.

The GNRB® is a revolution in instrumental methods for measuring laxity of the knee. It is more precise, reliable and consistent than other measuring instruments.

The device was designed in 2005, the result of an initiative by Dr Henri Robert and Stéphane Nouveau. They noted that ACL injury screening was neither consistent, nor quantifiable, using physical examinations and existing instrumental methods. Partial injuries were hard to detect.

With the support of the ESIEA (French Institute of Applied Electronics and Computing), they designed and developed the GNRB®, which provides solutions to each of the drawbacks of other existing measuring appliances. This device provides more precision and good measurement repeatability. See Publication « Orthopaedics & Traumatology : Surgery & Research (2009) 95, 171-176 ».

In the light of current repair innovations in ACL reconstruction, this device has the advantage of detecting partial injuries, enabling a single bundle to be repaired.

The device can be used in pediatrics for diagnosing knee sprains.

There have been several French (SOFCOT, SFA and SOO) and international publications (ESSKA Porto 2008, ISAKOS OSAKA 2009) on this subject.

Again, thank you for purchasing this device, we welcome the opportunity of working with you. Please feel free to send us the results of your tests, along with any comments and suggestion you may have concerning the use of the GNRB®. This is all part of an ongoing progression to ensure that our device meets as closely as possible the requirements of those who use it.

Stéphane NOUVEAU
Director

Henri ROBERT
Orthopaedic Surgeon

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1. INTRODUCTION

The GNRB® is a device that diagnoses total or partial ruptures of the anterior cruciate ligament of the knee.

For years, we believed that the analysis of laxity at 134 N or at 250 N was enough to explain the lesions or not, of the LCA. It seems very clear now that a dynamic analysis of the elasticity of the capsulo-ligamentary complex is more relevant and it is that which the GNRB® allows by the analysis of the slopes of resulting curves.

Some arthrometers had begun the analysis of the displacement curves but these devices had the problem of a very bad consistency (manual traction, no parameter setting of the tightening…).

The GNRB® is a device which allows the diagnosis of total or partial ruptures of the anterior cruciate ligament of the knee.

It has a number of advantages:

- the device is non-invasive
- it does not use X-rays or other dangerous techniques
- it adapts to the morphology of each patient
- it is easy to install and use
- it produces reliable and repeatable results
- its results are operator free
- it is easy to transport and clean
- the software is easy to use for beginners

The principle of the device is to apply pressure to the calf using an articulated mechanical system and to record the displacement of the tibia for each force (from 0 to 300 N) via a sensor placed on the ATT (Anterior Tibial Tuberosity).

A microprocessor controls the device and transfers the recorded data to a computer (the data is recorded and analyzed using specially-designed software).

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

The installation tutorial provided on the following pages will help you set up your device quickly and easily.

Detailed descriptions are included in the various chapters of the instruction manual.

Please read this instruction manual carefully. Follow safety instructions to ensure that your GNRB® operates correctly. GENOUROB® cannot in any way be held responsible in the event of your failure to comply with these instructions.

2. LIST OF MARKING SYMBOLS

Selective sorting components

General safety

Warning

Keep dry

Type B electromagnetic device

Read instructions for use

Show where put hands for the transport

Fragile - handle with care

Admissible temperature range

Admissible humidity range

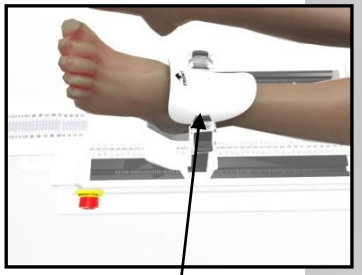
Admissible air pressure range

Indicates the direction of the position of the knee and foot cups

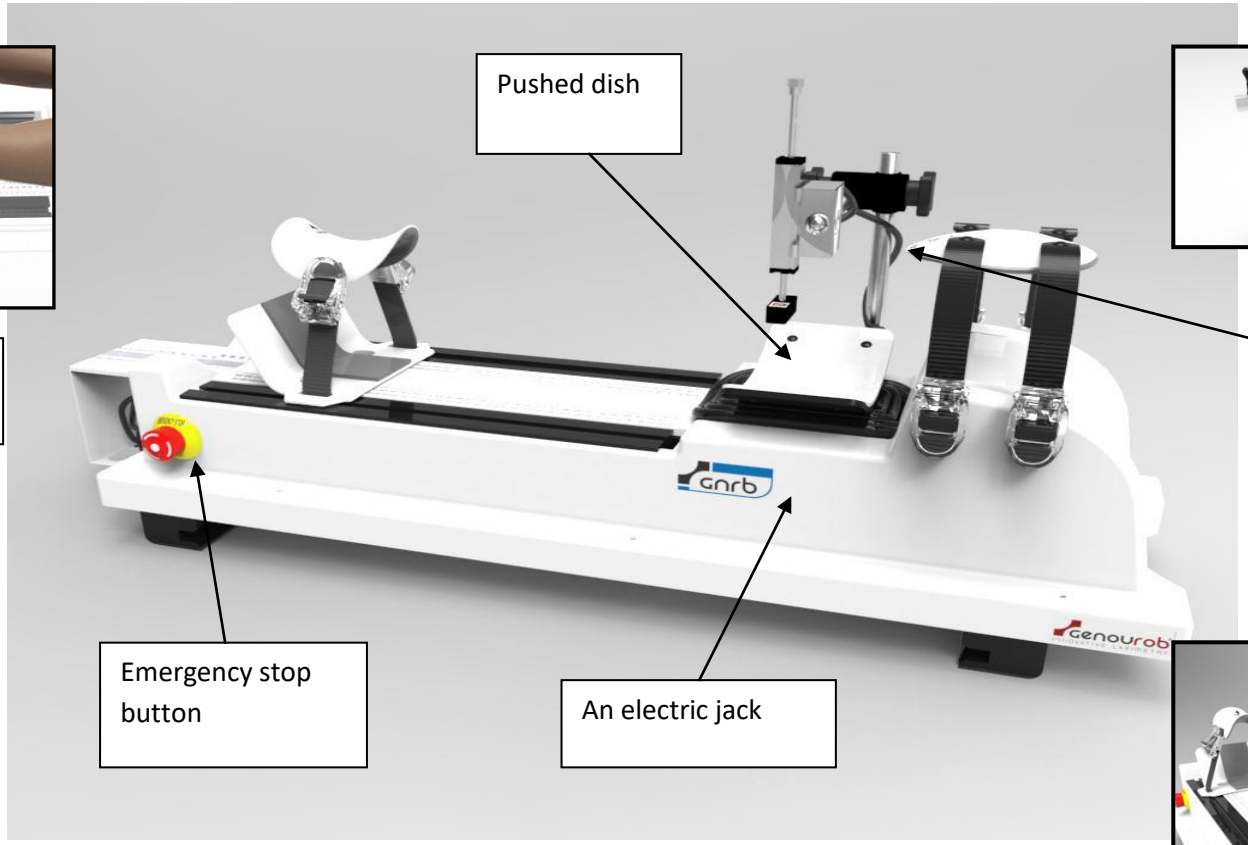
Direct current

Alternating current

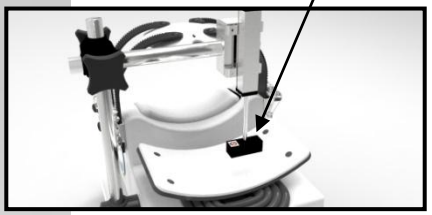
3. DESCRIPTION



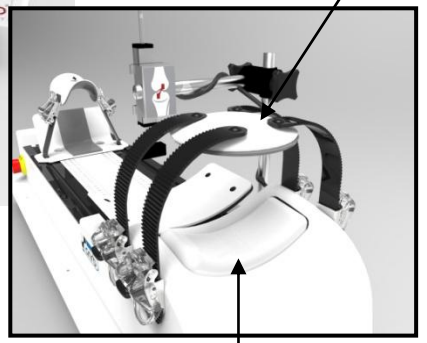
Adjustable straps for fixing the patient's foot



A displacement sensor placed on the ATT

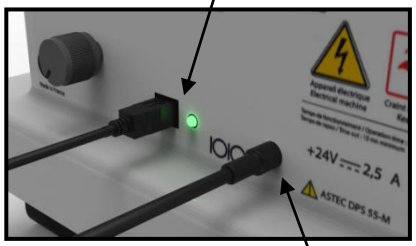


Adjustable straps for fixing the patient's patella



Force sensors

USB interface cable (1.80m)



Cable to connect the GNRB to the electric power supply (2m) + mains power (1.70m)

It is also composed by :

-An USB key for the GNRB software
-This instruction manual
-A PC together with its power supply cables and user manual
-A results interpretation guide

4. GENERAL SAFETY INSTRUCTIONS

You are working with a device that applies radio frequency energy and which is sensitive to devices that transmit radio frequency energy. Please refer to the declaration tables regarding electromagnetic emissions and electromagnetic immunity in Appendix 1 of this instruction manual.

You are working with an electrical device. Incorrect use may cause electric shocks. Only the Mascot power supply, Ref. CINCON TR70MA240-02E13-VI, supplied by GENOUROB® should be used for supplying electric power to the GNRB®

The level of protection against electric shocks of the parts applied to the patient (displacement sensor, the curved support under the calf, the leg support and stops) classifies the GNRB® as a type B device.

Use of accessories, sensors and cables other than those specified, with the exception of sensors and cables sold by GENOUROB for the equipment or as spare parts for internal components, can cause equipment emission levels to rise or fall.

The power cable must be connected to a 230 Volt-50 Hz mains supply.

To prevent risk of electric shock, this device must be connected to a supply network with fitted earthing plug

It is forbidden to use the device with a damaged power supply unit or with bare connection cables.

Do not dismantle the device: maintenance and calibration is to be performed by trained GENOUROB® staff.

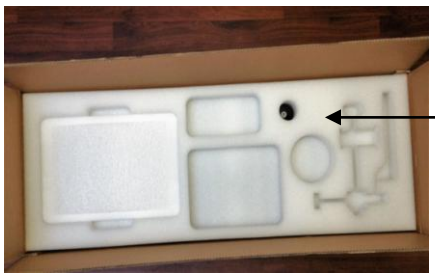
The GNRB® should not be used adjacent to or stacked with other equipment. If this is unavoidable, you should first check that the GNRB® functions correctly like this.

The instructions in the installation guide and instruction manual must be followed exactly.

5. INSTALLATION GUIDE

5.1. Installation of the GNRB® device

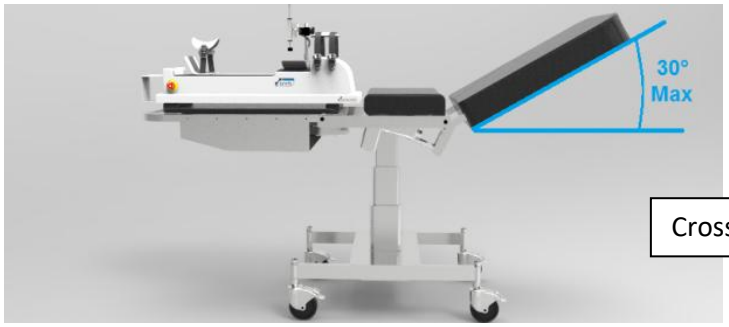
5.1.1. Unpacking

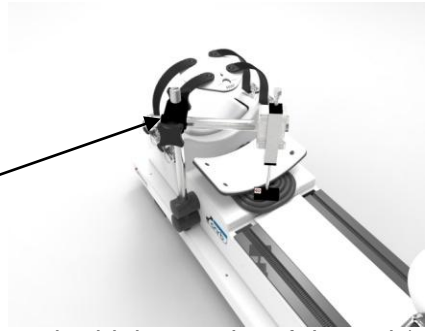


(See first instructions for use)

5.1.2. Installation of the GNRB®

The GNRB® should be placed on an examination table so that the patient's legs can be positioned comfortably on the device. The patient must be able to lie down on the table and rest their head on the support (optimal relaxation).
The GNRB® can also be placed on a floor mat as an alternative to a table.





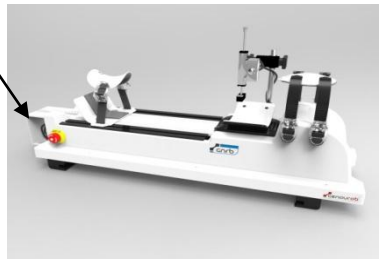
Using the cross block screws, raise the displacement sensor to the highest point of the rod (up to the cap) and pivot it vertically.

Do not knock or pivot the block located at the end of the sensor.

5.2. Connections

Connect the power supply cable to the GNRB®, and then connect the PC to the device using the USB cable.

The front



Connect the power supply unit to the mains (230 V – 50 Hz).

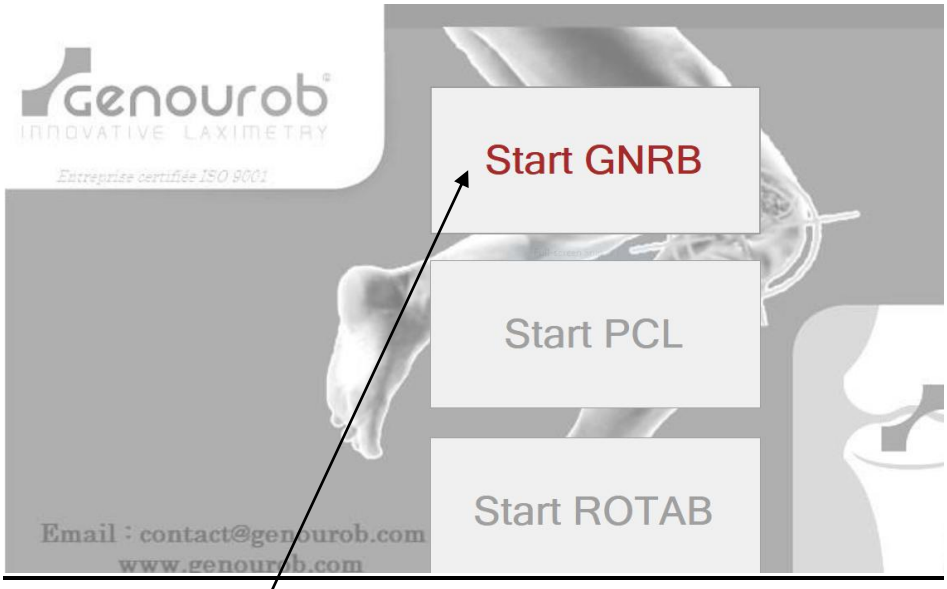
When the GNRB® is powered a green light shows.

When the connections are all made and the GNRB® is switched on, switch on the PC.

6. USING THE GNRB® FOR THE FIRST TIME

6.1. Login GNRB application

When the application is launched, the following window appears:



Only the button "Start GNRB" is activated and allows to login the application.
When you click on this button, the following window appears:

The default "Login" and "Password" are **admin** and **admin**. You may then create or remove accounts via the configuration page of the application (see « 7.5.4. Account management »)

6.2. First time use

When you switch on the GNRB for the first time, we recommend that you change the administrator login and password. To do so, go into the “Account management” tab, create a new user by entering their name and password, tick the administrator box and then confirm by clicking on the “Add” button. You can then remove the initial administrator account by typing “admin” into the “search for user” box and clicking on “delete”.

You can now close the application. The next time it is launched, the new administrator login must be used.

7. DESCRIPTION OF THE GNRB® SOFTWARE

7.1. Toolbar

Located at the top of the screen, the toolbar is used to launch the various commands listed below. It also displays the ID, date, last name and first name of the selected patient.

To add a new patient.

To register a new patient or make changes to the file of an existing patient.

To reload patient data stored in the database.

To **permanently** remove a patient from the database (this icon only appears once the first patient has been registered).

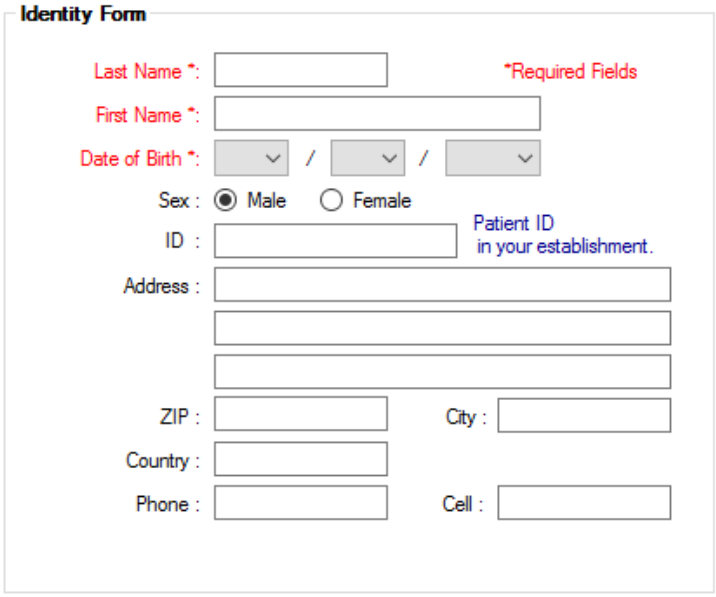
Patient's identifier.

To search for and upload a patient from the database use the green “Load” button.

If some patients have the same last name and first name, after choosing the last name and first name, the drop down menu gives you a list of the birth dates matching the name, then you can choose the right patient.

7.2. Patient file tab

7.2.1. Identity form



This section allows you to enter personal information about a patient and to store it in a database.

To record a new patient, you have to complete « Last Name », « First Name » and « Date of Birth ». The rest of the information is optional.

After creating a new patient file, having filled in at least the Last Name and First Name, register the patient by clicking on the “disk” icon on the toolbar:

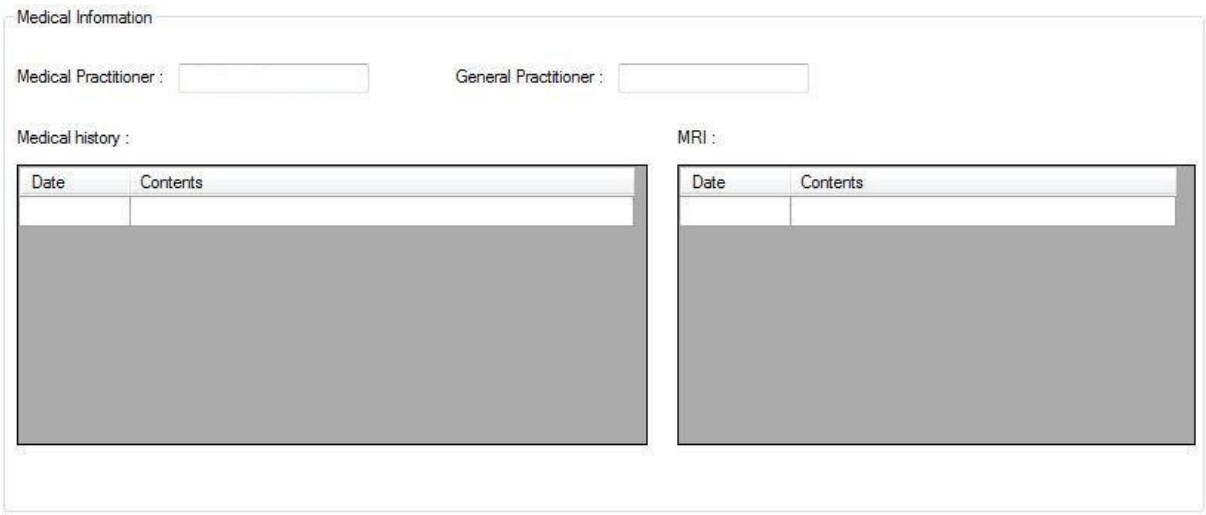
A unique ID is automatically attributed to the patient (this can be used for statistical studies, for example).

To enter a new patient, click on the icon located on the toolbar.

To call up the file of a registered patient, you simply need:

- to type their last name and first name in the relevant boxes located on the right-hand side of the toolbar. Confirm by clicking on “Load” or,
- to type the date of their last consultation (on the right of the name boxes) and to choose from the list given by the drop down menu. Confirm by clicking on “Load”.

7.2.2. Medical information



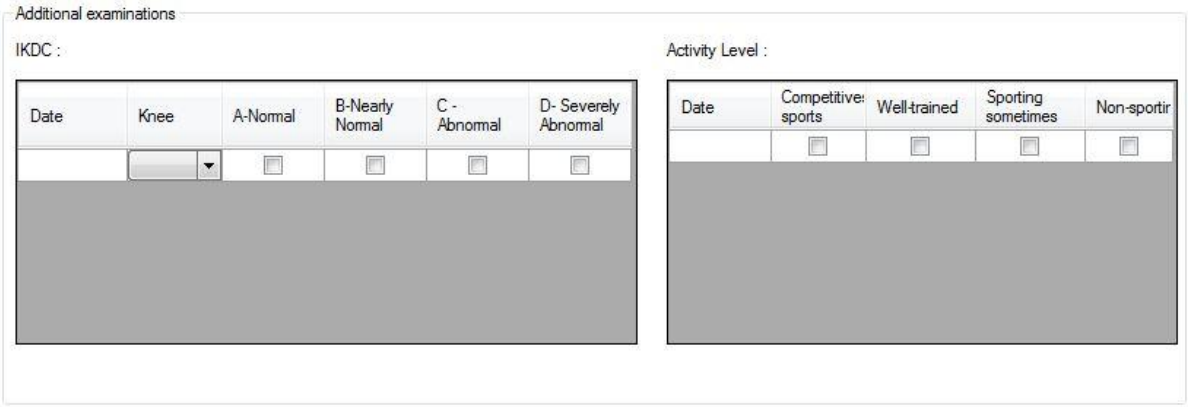
This section is for recording the medical history of a patient.

- The "Medical Practitioner" box is used for displaying the name of the practitioner who is to use the GNRB®. This box is automatically filled by the name supplied in the box “Default Specialist name” located in the configuration tab
- The “General practitioner” is for entering the name of the doctor who referred the patient.
- The “Medical History” chart is used to list the patient’s previous medical problems. For this :
  - click on the 1st box of an empty line to enter the date in a MM/DD/YYYY format (M: month / D: day / Y: year),
  - click on the 2nd box to add information about the Medical History.

– The MRI is for listing observations following an MRI. This chart is completed in the same way as for “Medical History”.

After having made changes to the “Medical History”or “MRI” charts of a patient, you must remember to save the information by clicking on .

7.2.3. Additional examinations



IKDC:

These charts allow you to manually enter the results of the knee examinations. To enter test results:

– click on the 1st box of an empty line to enter the date in a MM/DD/YYYY format
– click on the 2nd box to indicate if it is the left or the right knee
– click on the following boxes to give the test results

After having made changes to the “IKDC” chart of a patient, you must remember to save the information by clicking on

Activity level:

These charts are to indicate the activity level on the date of the examination. To enter test results:

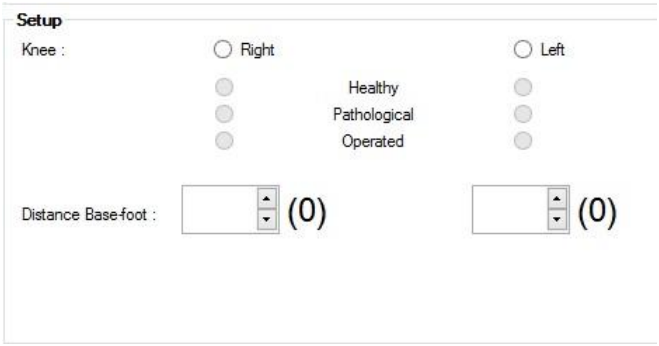
– click on the 1st box of an empty line to enter the date in a MM/DD/YYYY format
– click on the following boxes to give the activity level declared by the patient.

After having made changes to the “Additional examinations” chart of a patient, you must remember to save the information by clicking on

7.3. GNRB test preparation tab

This tab enables you to program and perform a test.

7.3.1. Settings



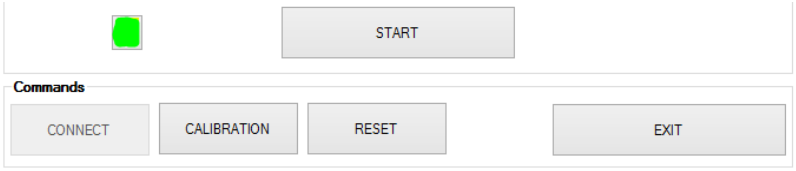
Compulsory information:

Click on the correct button :

- choose the right or left knee,
- enter information about the state of the knee: healthy, pathological or operated.

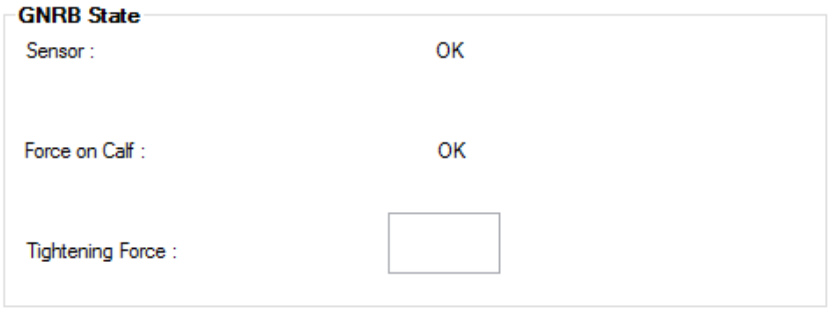
In the box "Distance base-foot", you must enter the distance between the patient's foot and the edge of the GNRB® (use the rule as a marker). This information is normally supplied during a first test and subsequently acts as a reminder. When preparing the following test, the value entered will appear in brackets next to the field.

7.3.2. Controls



- To connect the computer to the GNRB®, click on the "Connect" button. Once the connection is established, the name of the port or the USB convertor to which the GNRB® is connected appears on the right-hand side. The button is then grey and inoperative.
- If this is not the case, the connection has failed. Check that the USB cable between the computer and the GNRB® is correctly plugged in.
- Click again on the connection button.
- If the connection still fails, contact GENOUROB® by email on contact@genourob.com.
- Click on "Start" to perform a test. A window then appears, summarizing the test settings. Confirm by clicking on "Yes" or cancel by clicking on "No".
- Click on "Calibration" to calibration test. 3 tests are performed to define a covariance. To be displayed in the results table
- The "Exit" button allows you to close down the application.

7.3.3. GNRB status

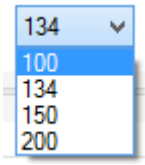


Once connected to the GNRB, this window provides information about the status of the sensors, as well as the previous and current patella pressure readings.

- When the distance sensor is in place and correctly positioned on the patient (the metal rod must extend 5mm minimum and 25mm maximum), an “OK” message appears on the relevant line.
- If this is not the case, an “OFF” message appears.
- Likewise, the device displays the force exerted by the calf on the plate.
- If the ERROR message appears, the sensor is faulty. You should then contact the GENOUROB® maintenance service.
- Otherwise, it is in the “OK” position.

The test can only be started if the two functions described above are working correctly, with the distance sensor OK and the calf sensor not displaying ERROR.

7.3.4. Push force



You can do the test for 4 different push force modes. TO change the force applied, click on the

arrow on the drop down menu:

- The “100” mode enables you to perform tests up to 100 Newtons, whilst recording displacements for the thresholds 100 N.
- The “134” mode enables you to perform tests up to 134 Newtons, whilst recording displacements for the thresholds 100 N and 134N.
- The “150” mode enables you to perform tests up to 150 Newtons, whilst recording displacements for the thresholds 100N, 134N, and 150N.
- The “200” mode enables you to perform tests up to 200 Newtons, whilst recording displacements for the thresholds 100N, 134N, 150N, and 200N.

7.3.5. Number of test measurements

When a test is performed, one recording is made by default. You can, however, change the position of the cursor shown above, to enable 1 or 3 measurements to be performed consecutively. The average of these results is then transmitted to the software. In this configuration after 3 pressure cycles, the displacement will only be recorded for the last 2 cycles.

7.3.6 Radiology Option

When this option is enabled, the GNRB launch one push and the tibia is blocked in high position during 5 s (time needed to take a radio).

7.3.7. Contraction Option

When this option is enabled, the muscular contraction is recorded during the test. Electrodes must be placed on the patient.In the data table, a « C » appears at the end of the record line, to inform the user that a muscular contraction has been recorded during the test and the result of the test can be wrong.

7.3.8. Data table

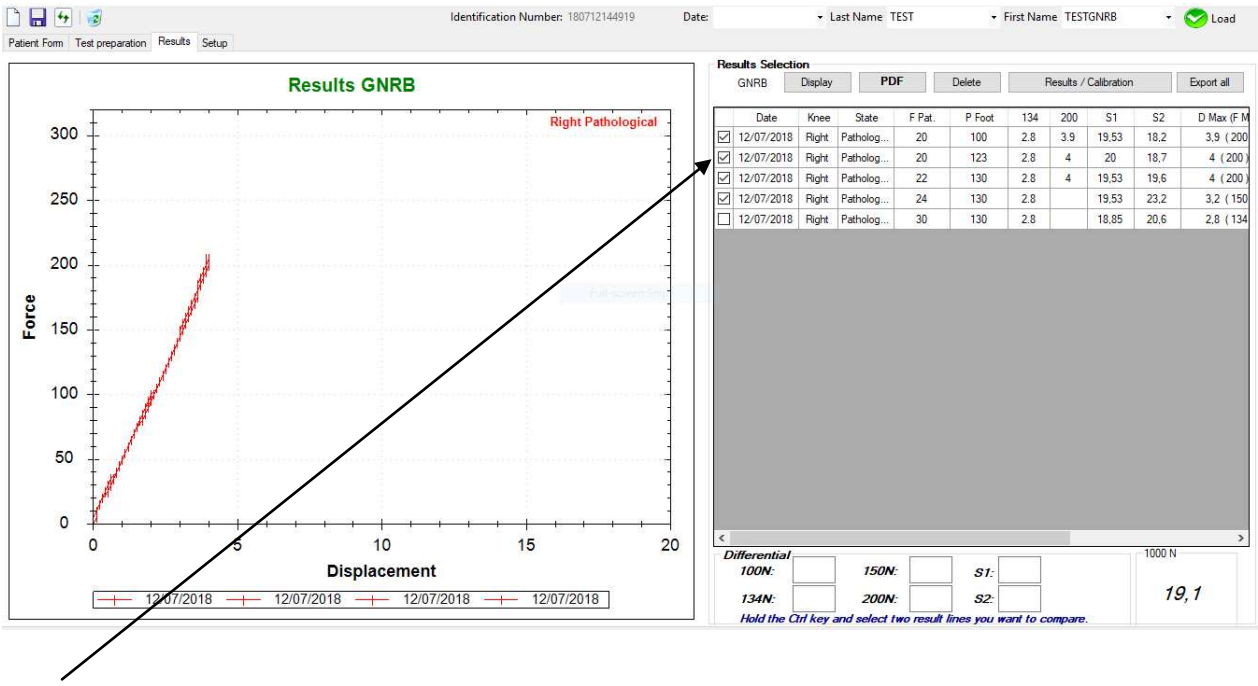
The « Data table » allows you to immediately view the results of a test that has just finished. Only measurements for the reference push forces at 134 N are visible.

In the column S2 is the slope of curve of the test between 100 and the maximum pressure. This slope is in µm per Newton. This is the gradient of the best-fit line.

7.4. The results tab

This Tab enables you to display, delete, print and export to Excel, the results of the tests recorded in the database.

7.4.1. Selecting results



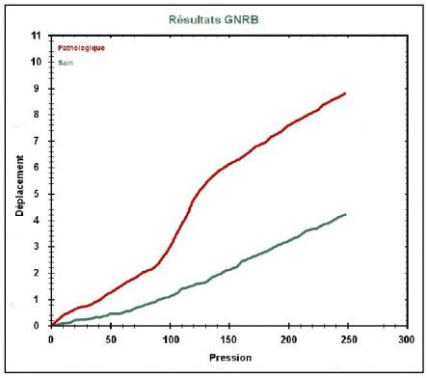
A test can be selected or deselected by ticking the corresponding box.

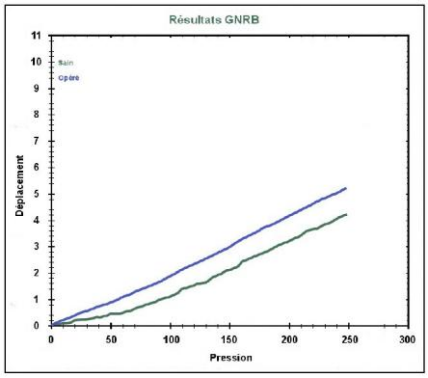
By default, the application selects and displays the last 4 saved tests. This number can be changed in the configuration tab.

- The “Display” button produces a graph with the ticked tests.
- The "Delete” button: warning – this button permanently deletes all the data of the ticked tests. The deletion takes place both in the database and in the results table. Deletion is irreversible.
- The "Report PDF” button allows you to print the ticked tests and their graphs or Calibration Table in the pdf file. This file is saved in the ‘C:\Documents\PDF Genourob’.
- When you click Report PDF, is it possible to write a comment : a new windows with field comment appears and it is including in the PDF bottom, if you click ‘OK’.
- Click on the button 'result / calibration' and then you can see the results of the tests or the calibrations of GNRB tests.
- “Export All.” : all results are exported in an Excel file

7.4.2. Graphs

- The graphs enable you to view the results of the test selected in the GNRB® table.
- By default, the x axis shows the force exerted under the calf, whilst the y axis shows the corresponding displacement.
- It is possible to reverse the axes through the setup tab (See Setup tab chapter).





  - the curves in red shows the test results of pathological knee,
  - the curves in green shows the test results of a healthy knee,
  - the curves in blue, shows the test results of an operated knee,
  - the darker the curves, the older they are.

Several options are available by **right-clicking** on the graph.

In the menu which appears:

– **Copy** allows you to copy the graph into the clipboard.

– **Save image under...** allows you to save the graph.

– **Lay out...** allows you to set the lay-out of the graph before printing.

– **Print...** allows you to print the graph.

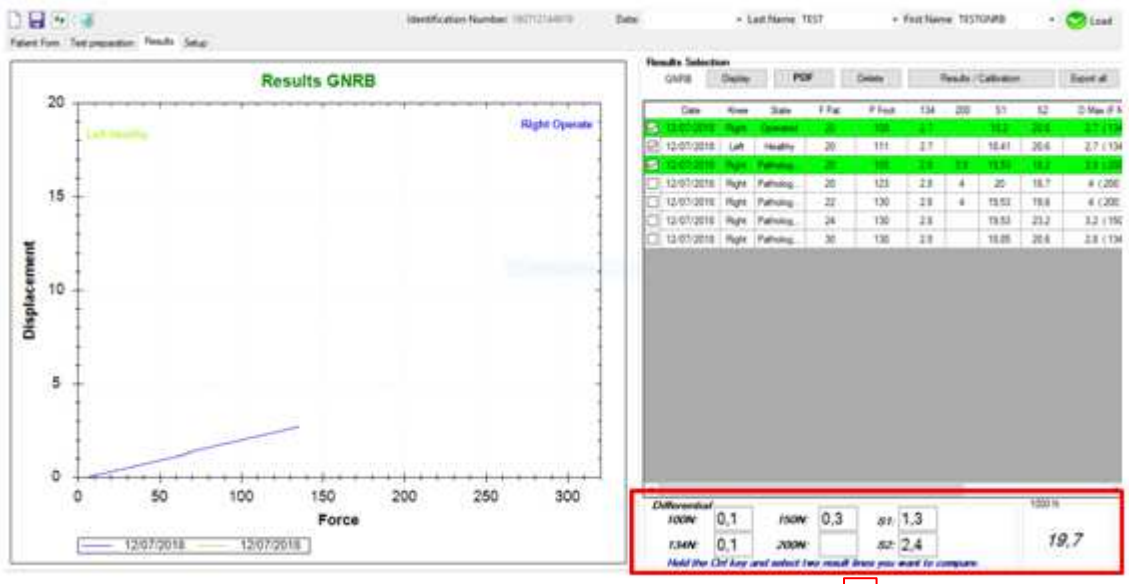
– **Display point values** allows you to display the value of a point by pointing the cursor at the curve. (x,y) appears, with x representing the force and y the displacement.

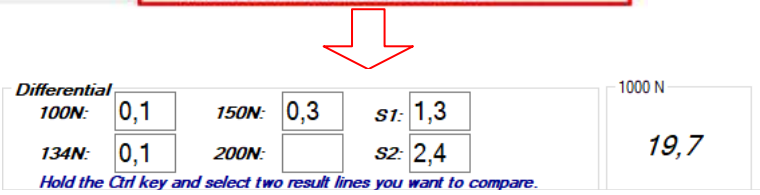
– **Cancel zooms** allows you to cancel previous zooms one by one.

– **Cancel all zooms** allows you to cancel all previous zooms.

– **Reset scale** allows you to return to the default scale.

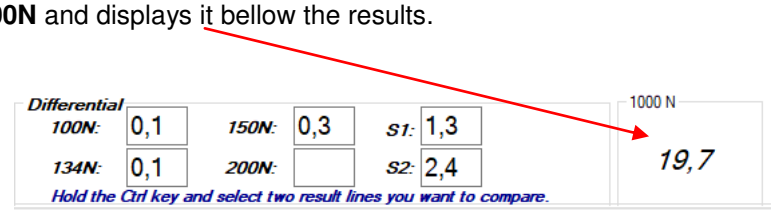
7.4.3. Differential Results





In order to compare results of two different tests, hold down the CTRL key whilest selectioning the two lines of results that you want to compare. The software will then display the side to side difference of the tibial displacement (at 100 N, 134 N, 150N and 200N) and the side to side difference of the slopes of the curves (S1 and S2).

The application estimates the displacement at **1000N** and displays it bellow the results.



7.5. Setup tab

The Setup tab gives you access to account management and printer management, among other things.

7.5.1. Setup

- **Medical Practitioner**: enter here the name of the doctor who will mainly be using the GNRB®. This is the name that will appear in the "Patient file" tab.
- **Database path**: select a GNRB® database. The default location of the database is C:\LDAcontrol\BDD\LDA.mdb. By entering a different path here, however, you can work with another database.
- **Default GNRB test**: allows you to specify the default test used in the "GNRB® test preparation" tab: 134 N, 250 N.
- **Number of graphs**: allows you to set the number of tests (99 maximum), the curves of which will automatically appear in the graph of the "Results" tab.
- **Path radiology file :** You can send the results reported on the internal computer system to the health facility
- **Define Axe:** this option allow you to reverse the axes by choosing
  - **Y (Force) – X (Displacement)**
  - Or **X (Force) – Y (Displacement)**

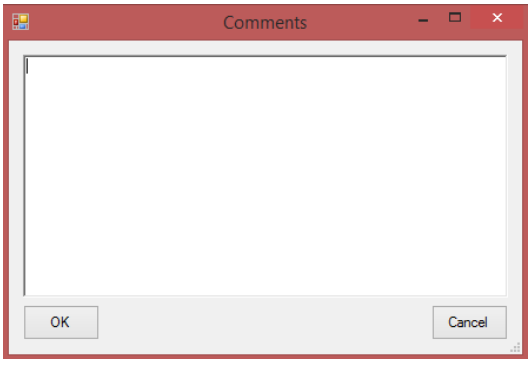
You must click on the "Confirm the configuration" button to save and apply the new settings.

7.5.2 Print document in the PDF format

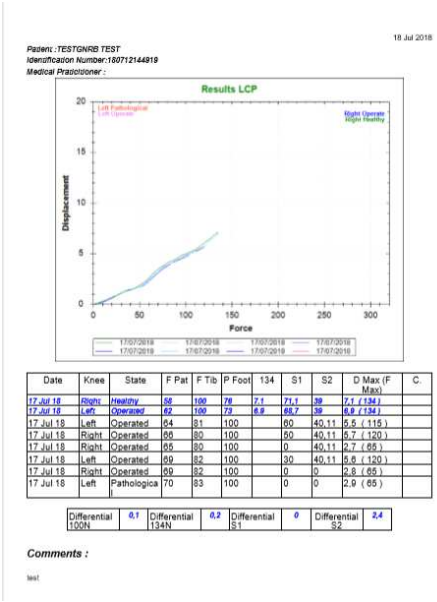
After printing your document , it is possible to configurate your print mode.

- To print a color document, select '**color**'
- To print a black and white document, select '**Black and white'**

- When you click Report PDF, it is possible to write a comment (a new windows with field comment appears and it is included in the PDF bottom, if you click 'OK').



In this window, it is possible to write a comment.
This text will be included at the bottom PDF Report, if you click 'OK'



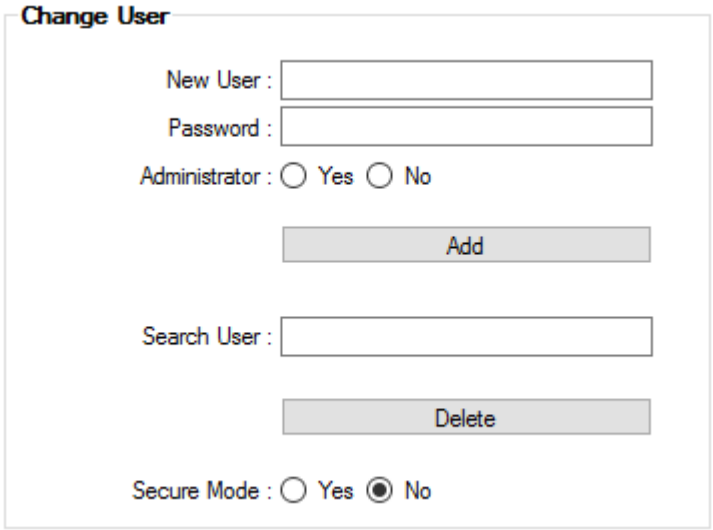
-The document is opened, and the file will be recorded in the "My documents" Directory and the sub Directory "PDF Genourob".
- The name written in this model *"GNRB_[last Name]_[First Name]_[ID]_[Test Date].pdf*

7.5.3. Information

- **Picture path**: indicates in the field “Picture path”: the picture to be printed. The picture has to have a size of 795 x 80 pixels in the case of a portrait or 1135 x 80 pixels in the case of landscape. This section allows the user to add a picture (logo) on the upon left corner of the PDF file created
- **Header** : information printed at the top of the document.
- **Footer** : information printed at the bottom of the document.

All the information entered here will appear on the printout

7.5.4. Change User



The account management fields are as follows :

- **New user** : enter the name of the new user
- **Password** : enter the password of the new user

- **Administrator** : chose the rights of the new user
- **Add** : confirm the new user
- **Look for user** : enter the name of the user to be deleted
- **Delete** : delete the user found
- **Secure mode** : if activated**,** requires user name and password every time the software is launched.

The user name and password must be lowercase.

Only administrators may access this part.
An administrator may delete all the users, in "Administrators", but cannot delete the last administrator.

8. INSTALLATION OF THE GNRB® SOFTWARE ONTO A PC

If you want, you can install the GNRB® software onto a PC.

The PC used with the GNRB®, and on which the GNRB® software is to be installed, must comply with the standard EN 60950.

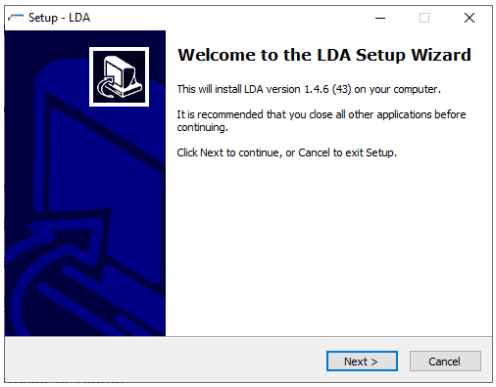
This software can only be installed on a computer running a WINDOWS operating system.

A/ Insert the USB key

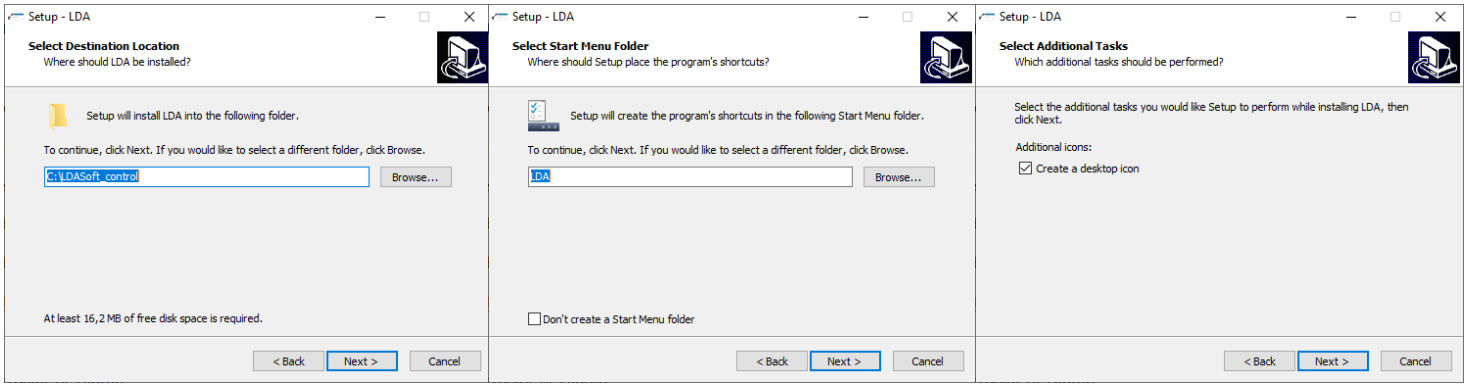
If the installation does not start automatically, please follow the instructions B/ and C/ below. If it does, go on to step D/.

B/ Click on setup

C/ The “Welcome to the LDA Setup Wizard” window opens automatically. Click on Next.

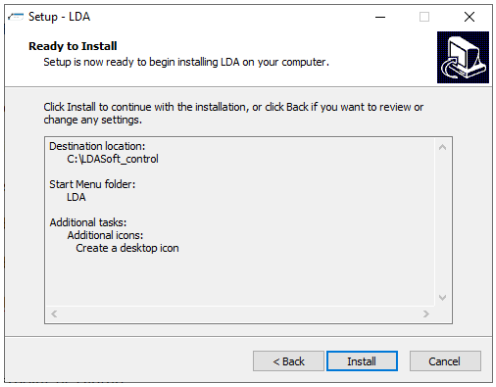


D/ The “Select..” windows open. Click on Next.

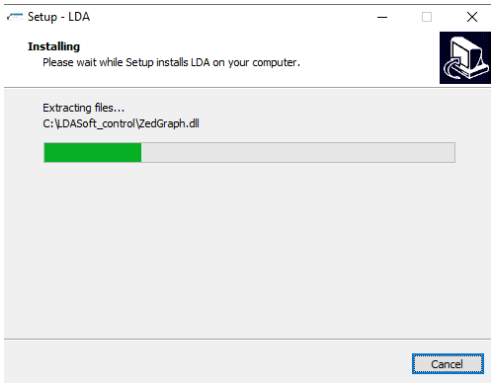


If you do not wish to install the GNRB® software in the default location, change the access path in the "Folder" field (click on "Browse").

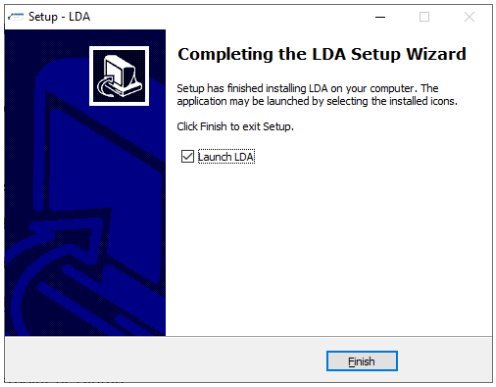
E/ The "Ready to install" window opens. Click on "Install".



F/ Wait until the application has been installed.



G/ The "Completing the LDA setup Wizard" window opens. Click on Finish.



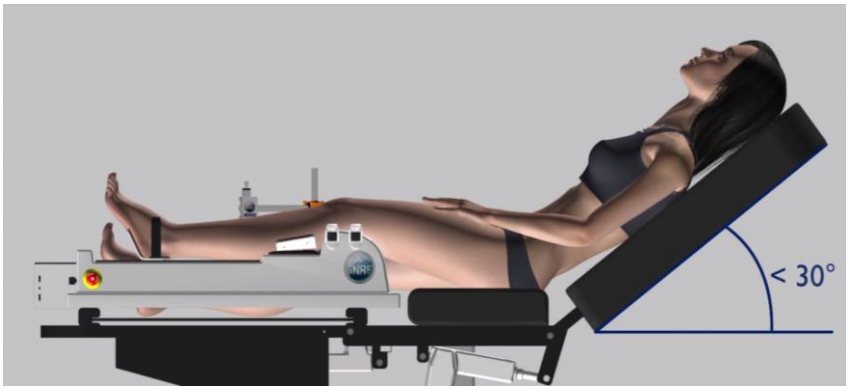
9. INSTRUCTIONS FOR USE

There are three distinct stages to using the GNRB (test each leg - healthy and injured) :

1. ***Securing the leg to the GNRB***
2. ***Recording patient info and starting the tests (two steps)***
3. ***Analysis of the GNRB data to support diagnosis***

1. *Securing the leg in five steps*

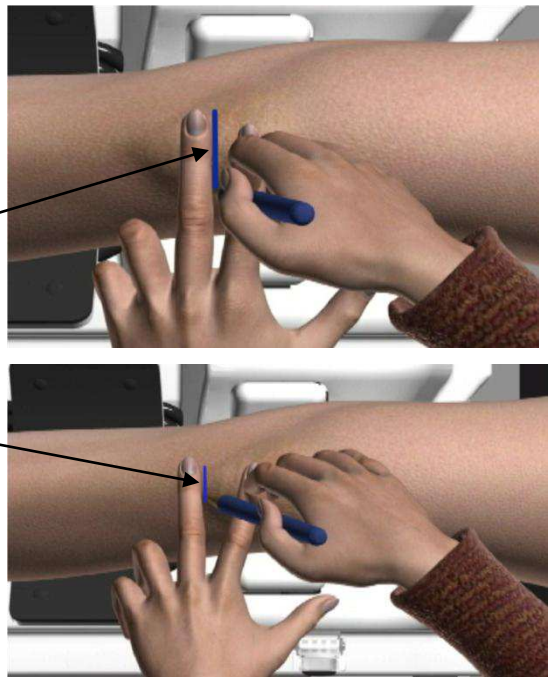
1.1. Position the patient on the apparatus



- ☐ the patient is lying down in the middle of the GNRB
- ☐ 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
- ☐ the foot is on the adjustable foot-rest

1.2. Locate the positions of the patella and the ATT

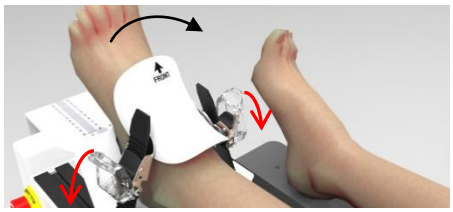
- ☐ Place a finger on the apex of the patella (underneath the rotula) and mark this position
- ☐ Mark the position of the ATT (anterior tibial tuberosity)

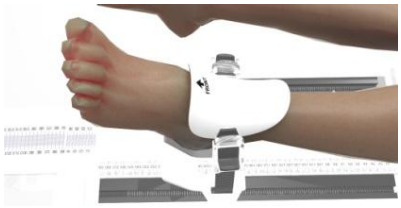


1.3. Fasten the knee-cup on the rotula (patella)

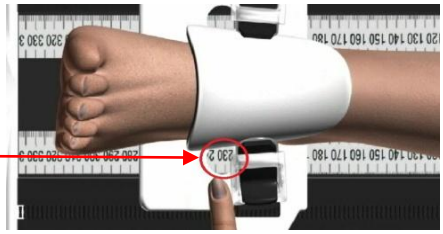
- ☐ Place the knee-cup so the mark on the skin lines up with the lines of the 'FRONT' hole
- ☐ The knee-cup must be horizontal and centered on the rotula
- ☐ Fix the third strap around the thigh to tighten it
- ☐ Do not tighten the knee-cup yet

1.4. Fasten the foot in the support and take the measurement





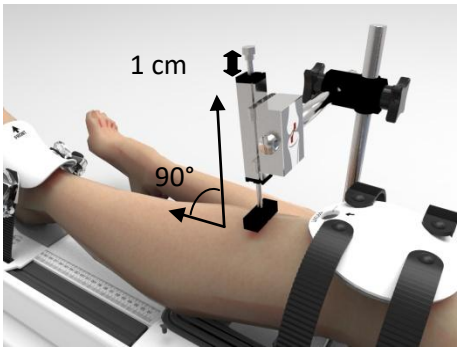
- ☐ Adjust the position of the support until the heel fits snugly
- ☐ Fix the foot in position by tightening both buckles
- ☐ Take the 'support-foot' measurement as it appears in the aperture



Note: each time a particular patient is tested this value must be the same

1.5. Position the displacement sensor

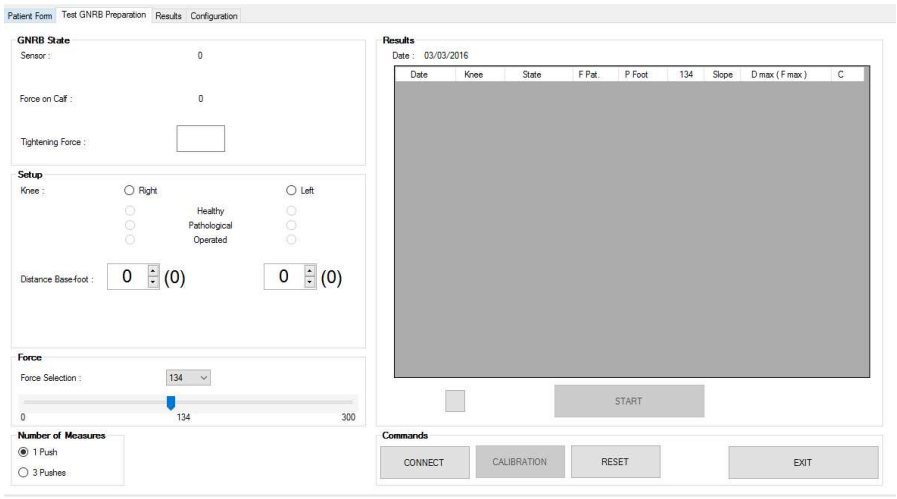
- ☐ Position the sensor block on the ATT mark (see §1.2)
- ☐ Put the sensor at 90° to the tibia
- ☐ Make sure there's at least one cm of rod showing
- ☐ Fix the sensor firmly by tightening the two knobs



2. Recording patient info and starting the tests, two steps

2.1 Enter patient info into the GNRB software

- ☐ Via the 'Patient File' tab, enter the details of the new patient or bring up the file of a continuing patient
- ☐ Via the 'GNRB Test Preparation' tab, under 'Measurements' select the knee to be tested and note its condition
- ☐ Enter the support-foot distance (see §1.4)

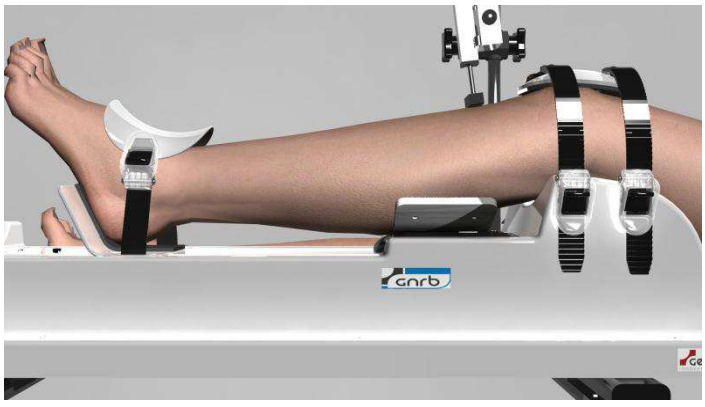


2.2 Tighten the knee-cup and the thigh strap and launch the tests

- ☐ secure the knee-cup by tightening the 4 buckles to at least 50N (tighten in pairs, front/back)
- ☐ start the tests, for: one at 134, one at 150 and three at 200N.

Note: the tightness is shown in real time under 'GNRB status' and must be identical for a particular patient for each test

⚠ The knee-cup must stay horizontal and not slip during the tests



To validate the GNRB test we apply the following principles:

- The initial 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 N) must be same to +/- 10%

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

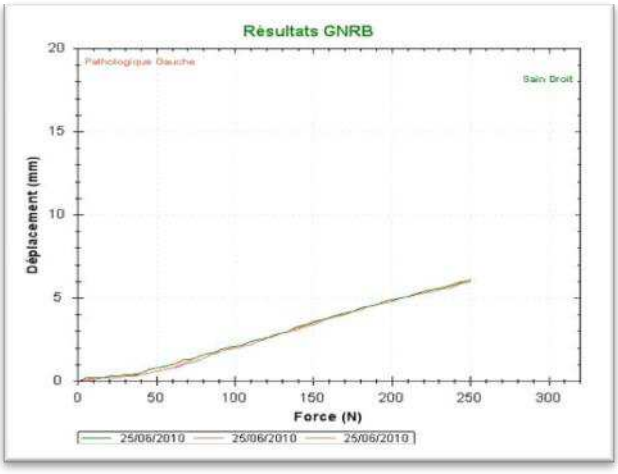
3. Analysis of the GNRB data to support diagnosis

- ☐ having tested both legs, display the curves via the 'Results' tab
- ☐ in the number table, select the data you would like to see for the curve and click on the small corresponding box to the left, then click on 'Display'
- ☐ click on 'Print' or 'Export' (csv or xls formats) according to needs

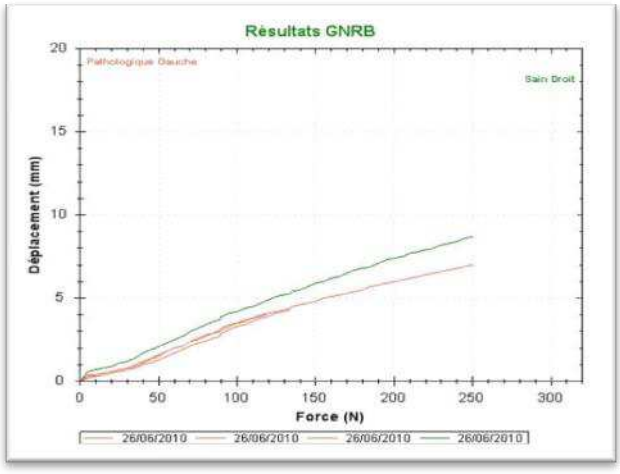
Colour codes of the curves:

- green: healthy knee
- red: injured knee
- blue: knee having had ACL surgery

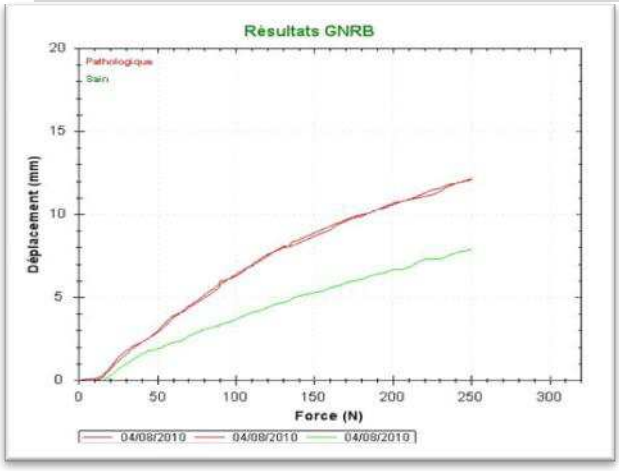
SSD : side to side difference



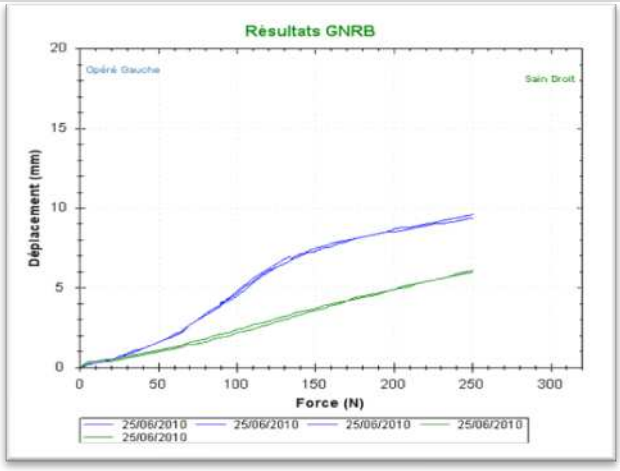
No ACL lesion (SSD < 1mm)



Partial lesion detected (SSD between 1 and 3mm)



Complete lesion detected (SSD > 3mm)



After ACL operation

You can also analyze the slope of the curves with S2 (µm/ N) on the table. It's the compliance (1/ stiffness). Stiffness is a biomechanical parameter of the knee. "It gives us functional information on the ACL deficient knee or of the graft. It has a high pronostic value after ACL surgery" (Bercovy, Evaluation…, RCO, 1995, 81; 114-127).

A "punch" emergency stop button is situated on the front right side of the device.

If you need to (if the patient experiences pain during the test for example), press firmly on the button. The test in progress will cease immediately and the jack will return to its initial position. Release the patient.

A monthly check of the emergency stop button is recommended using the following procedure:

- Do a GNRB® test, without patient by raising the movement sensor slightly
- As the dish is rising, press on the emergency stop button

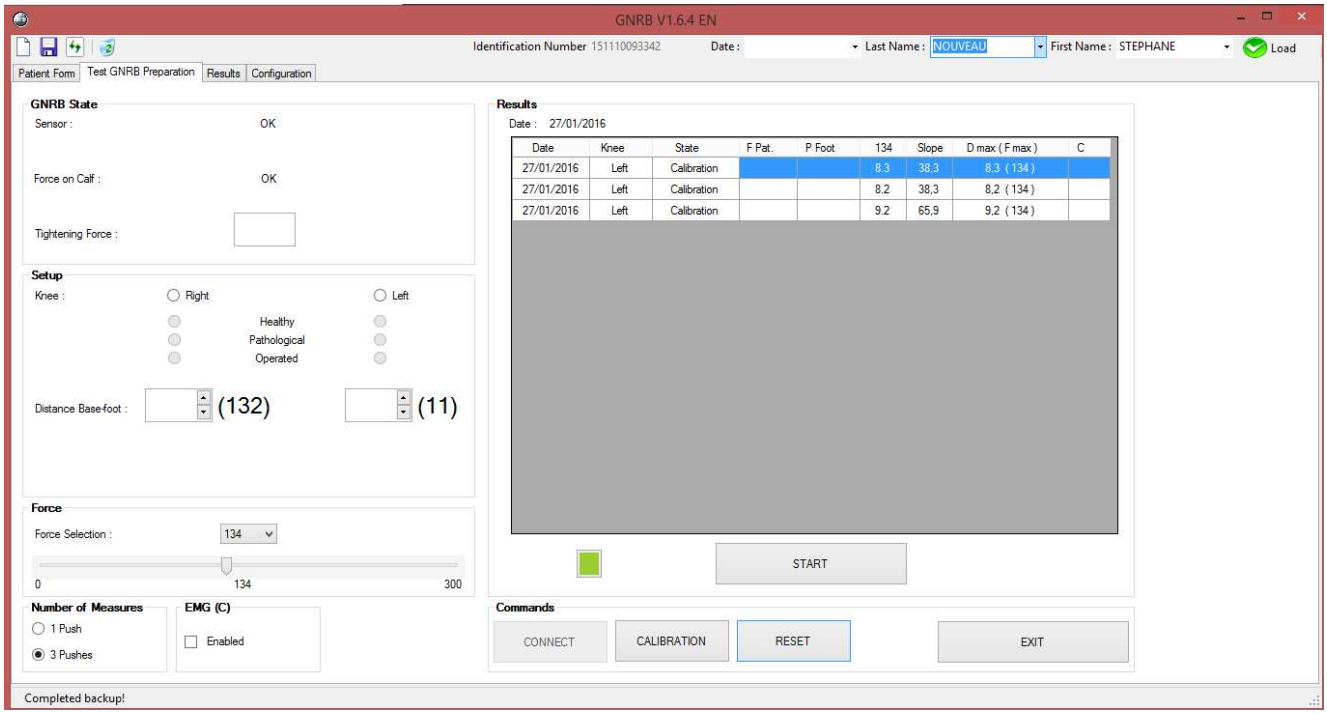
The dish should come back at once to its low position.

In case of malfunction, notify GENOUROB® at once so they can carry out the necessary maintenance.

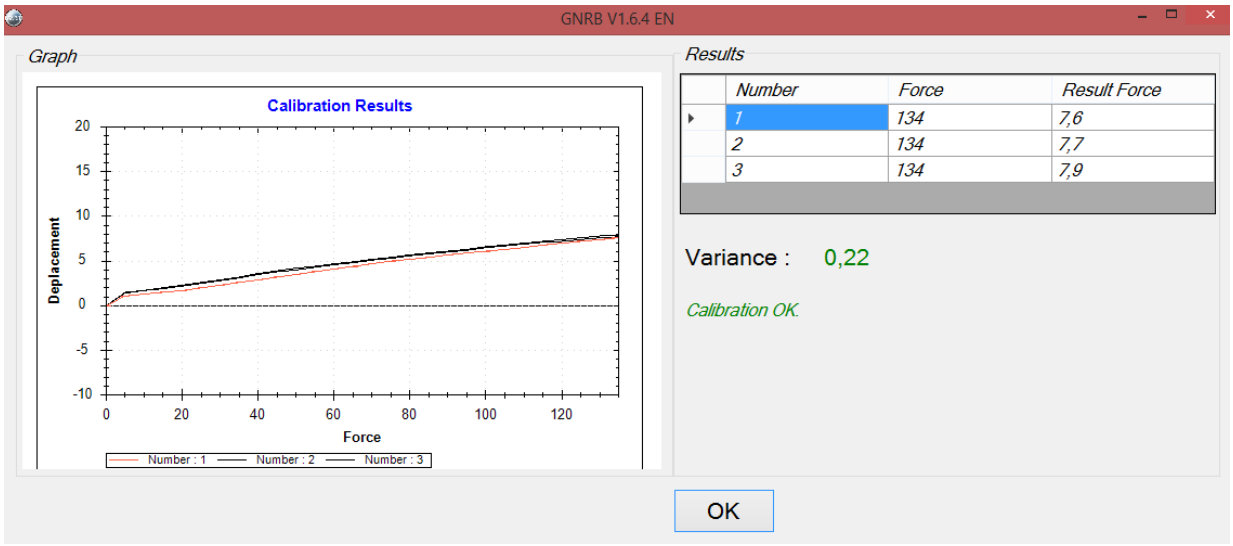
Do not forget to unbolt the emergency stop button to make the other tests.

10. Calibration of the device

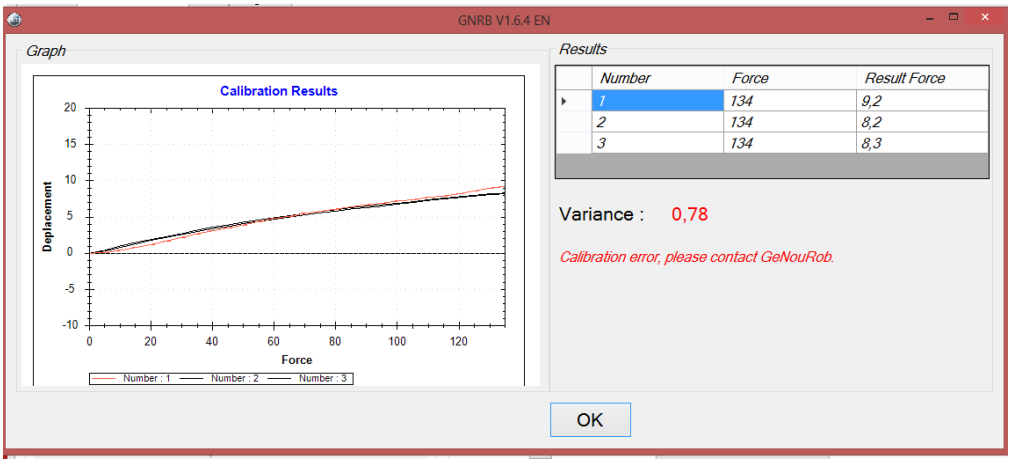
The calibration of the device is used to ensure that the device is working properly.
The tab "Calibration" is between "Connect" and "Reset", click on it.
It is only possible to carry out extensive 134 and 200N.
Start the test by clicking on the corresponding tab.
The value of the variance must be between 0 and 0.5 to validate the calibration test.



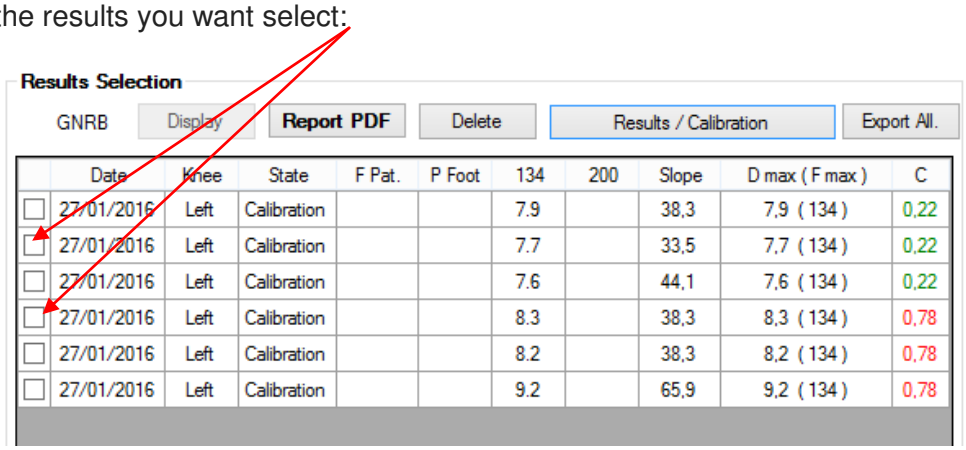
If the calibration results are good, this kind of window should pop up with the following message “Calibration OK” written in green :



If the calibration results are not good, contact GeNouRoB Maintenance:



Click on the results you want select:



Date	Knee	State	F Pat.	P Foot	134	200	Slope	D max (F max)	C
27/01/2016	Left	Calibration			7.9		38,3	7,9 (134)	0,22
27/01/2016	Left	Calibration			7.7		33,5	7,7 (134)	0,22
27/01/2016	Left	Calibration			7.6		44,1	7,6 (134)	0,22
27/01/2016	Left	Calibration			8.3		38,3	8,3 (134)	0,78
27/01/2016	Left	Calibration			8.2		38,3	8,2 (134)	0,78
27/01/2016	Left	Calibration			9.2		65,9	9,2 (134)	0,78

The calibration results in PDF format:

Genourob SA
Quartier Ferrié
Rue Chef de Bataillon Henri Géret
53 000 LAVAL

janv. 27, 2016

Patient : STEPHANE NOUVEAU
Identification Number :151110093342
Medical Practitioner :

Date	Knee	State	F Pat	P Foot	134	200	Slope	D max (F max)	C.
27 janv. 2016	Left	Calibration			7.9		38,3	7,9 (134)	0,22
27 janv. 2016	Left	Calibration			7.7		33,5	7,7 (134)	0,22
27 janv. 2016	Left	Calibration			7.6		44,1	7,6 (134)	0,22
27 janv. 2016	Left	Calibration			8.3		38,3	8,3 (134)	0,78
27 janv. 2016	Left	Calibration			8.2		38,3	8,2 (134)	0,78
27 janv. 2016	Left	Calibration			9.2		65,9	9,2 (134)	0,78

11. Safety instructions and precautions for use

This device is only for use by medical staff.

This device is only to be used for measuring the laxity of lower limbs.

The data is only to be interpreted by medical staff trained by an instructor from GENOUROB®.

Do not use this device on patients having undergone an anterior cruciate ligament operation on the knee less than 3 months previously.

Do not use this device with patients who are unable to understand or follow the instructions given by the medical staff at the controls.

Do not use this device with patients affected by contagious skin infections (follow good medical practice): the device may be covered with a disposable sheet without affecting its performance.

Do not turn the plastic block on the displacement sensor (this may damage the sensor).

It is strictly forbidden to use the displacement sensor without the safety block. In the event of breakage, contact GENOUROB® immediately for maintenance.

It is forbidden to use this device in an operating theatre in order to avoid any bodily or medical fluid.

We recommend you use this device in a room temperature of under 40 °C.

We recommend disinfecting the device with an alcohol-based product (see description below) or wipe before using for the first time and between patients.

The customary 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).

If in doubt over the use of a particular product, you are advised to contact GENOUROB® for confirmation.

Do not clean with water or other liquids

If there is a power cut, the device can work again only by relaunching the GNRB® software

At this time, the small dish goes back to its low position, WARNING - to avoid pinching, do not put your fingers around the small dish.

The GNRB® was designed to be used for 5 minutes maximum, followed by a rest time of 15 minutes minimum.

If a power failure should occur during the test, unstrap the knee cup as quickly as possible.

You are working with an electrical device. Misuse results in risk of electric shock. Only power supply, CINCON referenceTR70MA240-02E13-VI (Certified Medical: maximum temperature 43 ° C), provided by the company GENOUROB® should be used to electrically power the GNRB.

The parties applied to the patient (shell boot straps) can reach 45 ° C when using the GNRB within the maximum permitted environmental conditions (ambient temperature 40 ° C)

To avoid electrical shock, this appliance may only be connected to a power supply network with a protective ground.

An additional base multiple sockets or extension cord shall not be connected to electro-medical GNRB® system.

Power must be connected to the 230 Volt-50 Hz (100-240 V 50/60 Hz 2A).

It is prohibited to use the device with a damaged power strip or connecting cables exposed.

Leave the plug accessible area in order to proceed safely stop GNRB®.

Do not disassemble the machine: the maintenance and calibration are carried out by personnel trained for this purpose within the GENOUROB® society.

It is prohibited to change any part of the GNRB® without GENOUROB's authorization: spare parts can only be replaced by personnel trained for this purpose within the GENOUROB® society.

The use of sensors and cables other than those specified, with the exception of the sensors and cables sold 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 GNRB® 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.

Portable and mobile RF communication devices can affect MEDICAL ELECTRICAL EQUIPMENT

It is strictly forbidden to delete BDDs (databases) from the GNRB software.

It is strongly recommended to save BDDs regularly to an external hard disk.

12. TRANSPORTING THE GNRB®

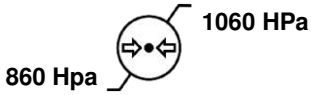
The GNRB® - must be handled with care

- must be kept dry

- must be stored in a room where the temperature is between 0°C and 40 °C

- must be stored in a room where the humidity is between 30% and 70 %

- must be stored under atmospheric pressure between 860 and 1060 HPa



- to transport GNRB®, please put your hands where indicated by the labels.

13. MAINTENANCE AND RECYCLING

Any damage to the device should trigger maintenance. Such as:

- a broken pad
- a broken displacement sensor safety block
- a damaged cable
- …

In such events, phone GENOUROB® on +33 243 904 301 from 9am to 6pm, Monday to Friday, or send an email to the following address :

contact@genourob.com

Then, a maintenance contract will be put in place between GENOUROB® and the client.

There is a telephone helpline to assist you with any inquiries regarding the use of the software: call +33 243 904 301 from 9am to 12 or from 2 to 5pm Monday to Friday, or send an email to the following address:

contact@genourob.com

Attention, this device and all its components, should be disposed of according to local laws and must not be thrown away with household refuse.

14. CERTIFICATIONS- Manufacturing and marketing's dates

Manufacturer's adress : **GENOUROB SAS**
Bât. 60 rue Henri Géret
53000 LAVAL- France

First marketing's date : **02/01/2009**

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

xxyyyzz L

xx : Medical device's number
yyy : date of the manufacturing's day
zz : last two digits of the manufacturing's year
L : letter corresponding to the manufacturing's month.

The device has been CE certified by LNE-GMED (1, rue Gaston Boissier, 75724 Paris Cedex 15) :

CE 0459

The GNRB® device complies with the EMC and safety standard IEC 60601-1-2 and IEC 60601-1 : certification awarded by the LCIE (33 avenue du Général 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).

15. APPENDIX I : MANUFACTURER'S DECLARATIONS

Electromagnetic emissions		
The GNRB 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	GNRB uses RF energy for internal operation
Interference voltage at power terminals (Emissions conducted) CISPR 11	Class B	
Harmonic emissions EN 61000-3-2	Class A Complies with requirements	
Voltage variation, voltage fluctuations and flicker (IEC61000-3-3)	Complies with requirements	

Electromagnetic immunity			
The GNRB is intended for use in the electromagnetic environment specified below. Users should 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 (ESD)	± 8 kV Contact ± 15 kV air	± 8 kV Contact ± 15 kV air	Home health care environment and an environment of a professional health care facility
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	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Home health care environment and an environment of a professional health care facility
Magnetic field at assigned industrial frequency (IEC61000-4-8)	30 A/m	30 A/m	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)	• 0% UT for 0.5 cycles A 0°, 45°, 90°,135°, 180°,225°,270° et 315° • 0% UT for 1 cycle • 70% UT for 25 cycles of 50Hz and for 30 cycles of 60HZ cycles . Single phase: at 0 °	• 0% UT for 0.5 cycles A 0°, 45°, 90°,135°, 180°,225°,270° et 315° • 0% UT for 1 cycle • 70% UT for 25 cycles of 50Hz and for 30 cycles of 60HZ cycles . Single phase: at 0 °	The quality of the main power supply should be that of Home health care environment or hospital environment. If the user of the GNRB requires continued operation during interruptions of the main power supply, it is recommended that the GNRB be powered by an inverter or a battery.
Voltage interruptions (IEC61000-4-11)	0 % UT ; For 250 cycles of 50 Hz For 300 cycles of 60 Hz	0 % UT ; For 250 cycles of 50 Hz For 300 cycles of 60 Hz	The quality of the main power supply should be that of Home health care environment or hospital environment. If the user of the GNRB requires continued operation during interruptions of the main power supply, it is recommended that the GNRB be powered by an inverter or a battery.
Note : U_T *is the AC mains voltage for of the test.*			

Electromagnetic immunity, radio frequency portable equipment			
WARNING: RF portable communication devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the GNRB device, including cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated Radiofrequency Electromagnetic Fields (IEC61000-4-3)	10 V/m 80 MHz - 2.7 GHz 80% MA à 1kHz	10 V/m 80 MHz - 2.7 GHz 80% MA à 1kHz	Home health care environment and an environment of a professional health care facility
Proximity fields issued by RF wireless communication devices (IEC 61000-4-3 interim method)	9 V/m 710 MHz, 745MHz,780MHz, 5240MHz, 5550MHz, 5785 MHz 27V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745MHz, 780MHz, 5240MHz, 5550MHz, 5785 MHz 27V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Home health care environment and an environment of a professional health care facility
Conducted disturbances, induced by RF fields (IEC61000 4-6)	3 V/m 150 kHz at 80 MHz 6V in ISM band and band between 0.15 MHz and 80 MHz including non-professional radio band 80% MA à 1kHz	3 V/m 150 kHz at 80 MHz 6V in ISM band and band between 0.15 MHz and 80 MHz including non-professional radio band 80% MA à 1kHz	Home health care environment Professional health care facility environment

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