Instruction for use of the ROTAM

DIAGNOSTIC INSTRUMENT FOR
PERIPHERALS LIGAMENTS AND ANTERIOR
LIGAMENTS INJURIES

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1. INTRODUCTION

The ROTAM is a device which allows diagnosis of complete or partial failures of the anterior crossed ligament of the knee and associated ligaments.

The principle of the device is to lead a rotation effort of the tibia relative to the femur and to measure the resistance of knee ligaments at this opposite rotation.

We perform measurements on the 2 inferiors members and the diagnostic of failure can be done by observing the difference between these 2 values.

2. Glossary of marking symbols


Selecting sorting components


General safety


Warning


Keep dry


Type B electromagnetic device


Mark CE of the ROTAM


Read instruction 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

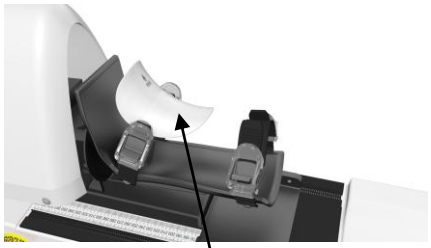

Direct current


Alternating current

3. DESCRIPTION OF THE DEVICE

It composed of:

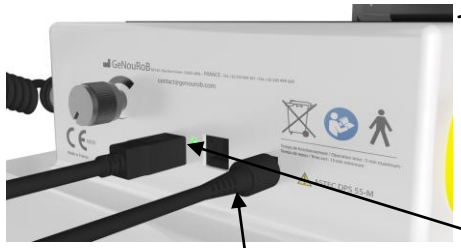
- An USB key for the ROTAM® software
- This instruction manual
- An interpretation guide for results
- A quick start manual



Foot attachment with straps

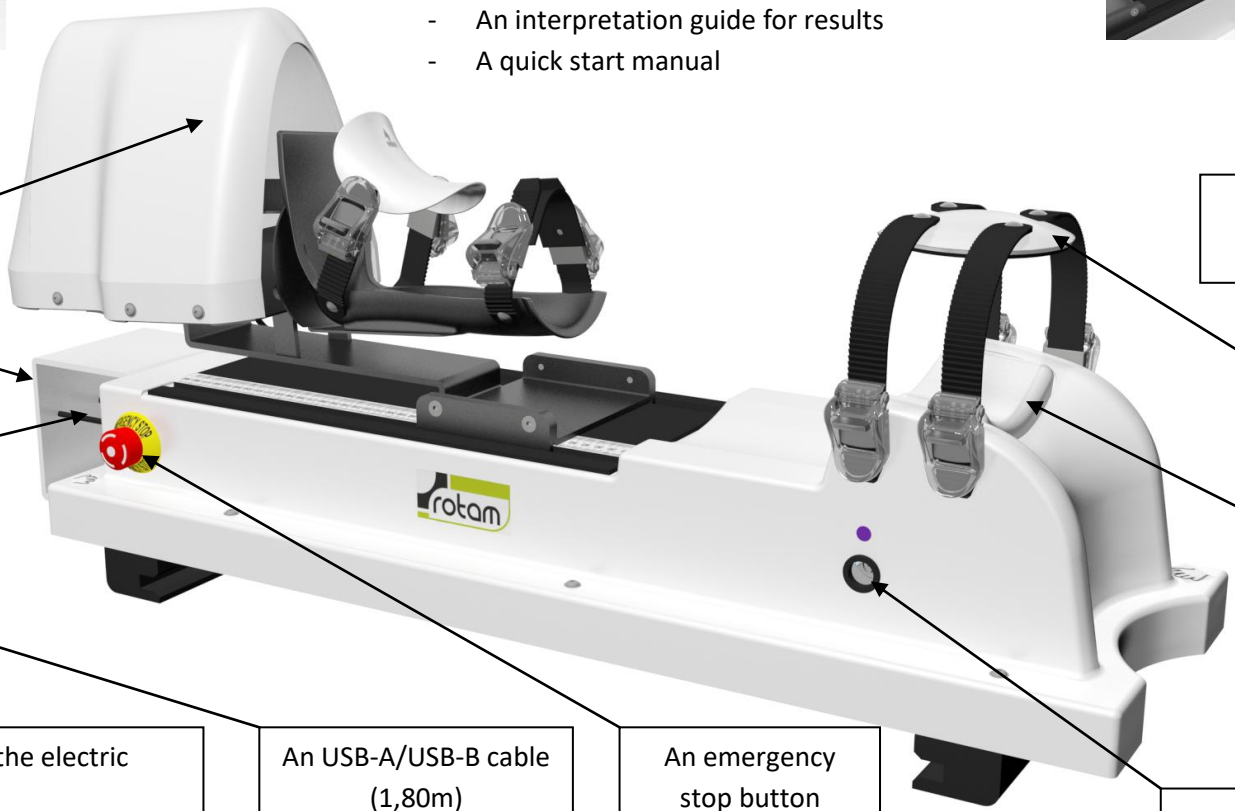
A motor and rotation sensors

A protect connections



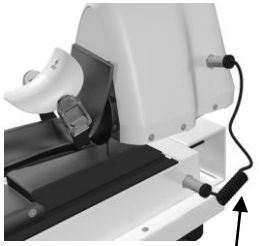
A 2m cable to connect the ROTAM to the electric power supply

A 1.7m mains power cable



An USB-A/USB-B cable (1,80m)

An emergency stop button



A 0,30m cable of the rotation module

Patella attachment with straps

Force sensor

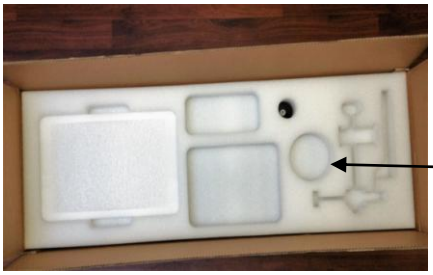
Electrodes cable

4. USER GUIDE

4.1. Installation of the device ROTAM

Warning, the ROTAM installation can't be done by someone with reduced mobility

4.1.1 Unpacking



(See first instructions for use)

4.1.2 Installation of the ROTAM

The ROTAM must be on an examination table in order to place easily the legs on this device. The patient must be lie down on the table and put his head on the headrest (optimal relaxation).

4.2. Connections

Connect the power supply cable to the ROTAM then connect the PC to the device using the USB cable.

Connect the power supply bloc to the sector (tension 100- 240 V ~ 2 A 50/60 Hz).
When thel ROTAM device is turn on, a green LED is on.
When all the connections are connect and that the ROTAM is on, start the PC.

4.3. Installation of protect connections

Install the protect connections in the next way : place the cover on the front and secure with butterflies for that.

5. ROTAM SOFTWARE

5.1. ROTAM software installation on a PC

You have the possibility, if you wish, to install ROTAM software on a PC.

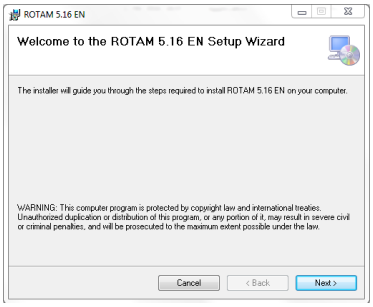
The computer and the USB cable associated to the ROTAM and on which will be installing the ROTAM software, must be accord to the norm EN 60950-1.

This software can be installed only on a computer with the explotation system WINDOWS.

A/ Insert the USB key in the computer drive.

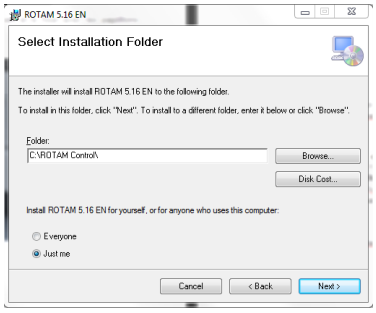
B/ Click on Setup

C/ The window « Welcome to ROTAM Wizard » opens automatically, click on Next

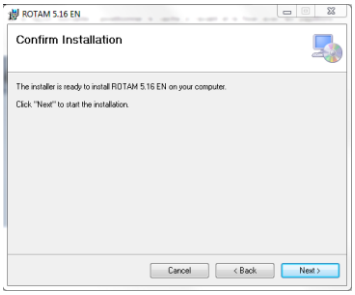


D/ The window « Select Installation Folder » opens, select « Everyone » and click on Next

If you don't wish to install the ROTAM software at the default slot, please edit the access path registered in the field « Folder » (You can use the exploratory by clicking « Browse »).

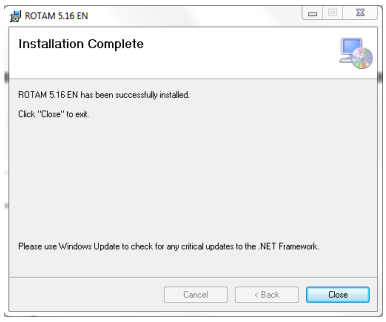


E/ The window « Confirm installation » opens, click on Next



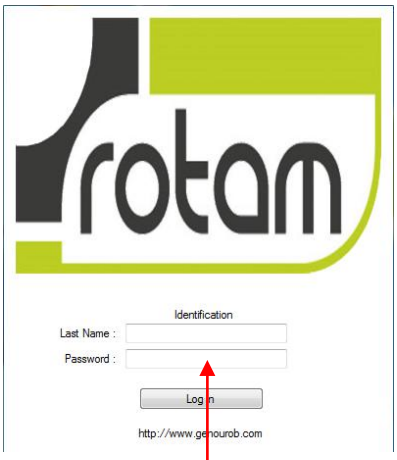
F/ Wait for the software installation

G/ The window « Installation complete » opens, click on Close



5.2. First used of the software

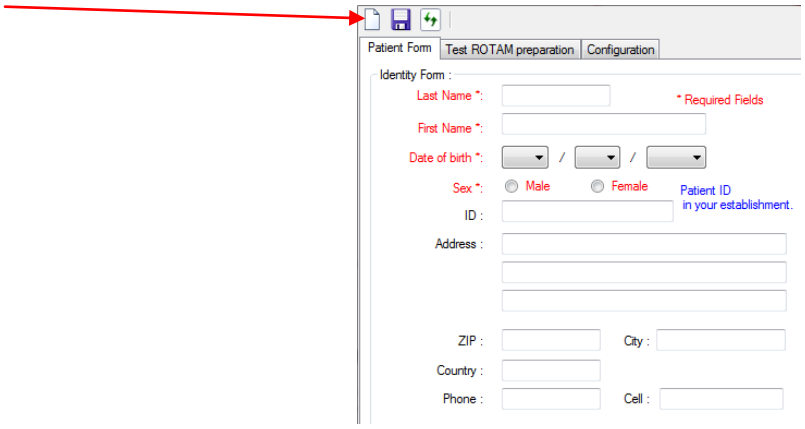
At the launch of the software the following window shows up :



By default, the « Name» and the « Password » are **admin** and **admin**.
It is then possible to create and delete accounts, by going into the software configuration section (cf chapter 5.5. Tab configuration).

5.3. Tab patient record

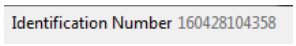
This rubric allows to enter the personnals informations of a patient and to stock them in a data base.
To create a new patient, you must click on the icon  placed in the toolbar at the left.



When entering a new patient, you must at least enter his « Last name », his « First name », his « Birthday » . All the other informations are optional.

After completing at least the last name, the first name, the birthday and the sexe, to save the new folder click on the icon representing a floppy in the toolbar: 

Automatically, a unique identifier is attributed to the patient (Interest in the context of statistical studies to achieve by example…).



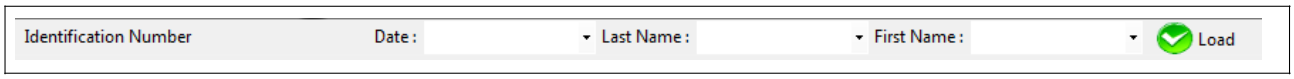
Show the identifier of the patient.

Allow to delete definitively a patient of the data base (Appears only after the creation of the first patient).

Allow to load the data of the patient stock in the data base.

To call a patient record already saved, we can use the research by date or by name:

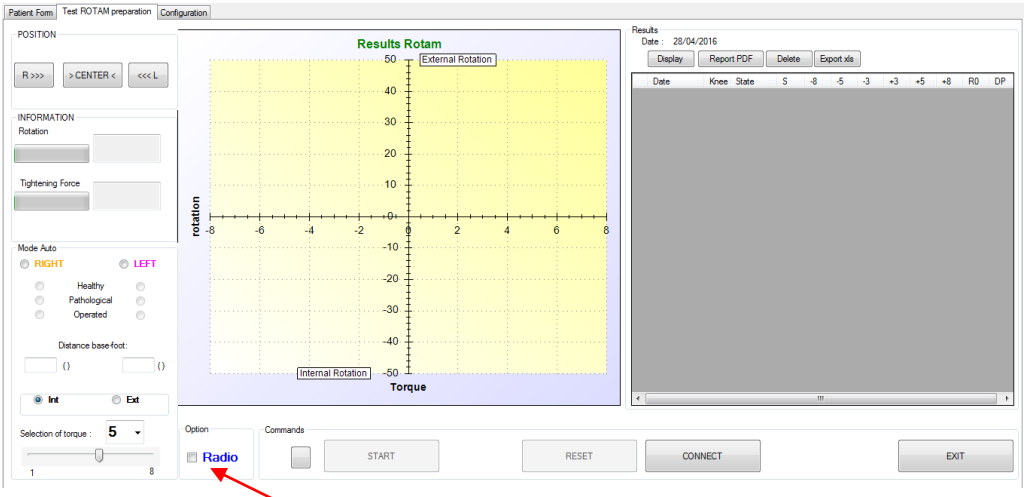
- **By date**: When a date is in, with the drop-down menu (to the right of « name »), you have the list of associated names to the date then a list of first name according to the name.
  Find the researched patient and validate it by clicking on « Load ».
- **By name**: type the name of the patient in the correspondent case placed to the right in the toolbar and search the first name associated with the drop-down menu.
  Find the researched patient and validate it by clicking on « Load ».



If more patients are homonyms (same last name and same first name), a drop-down menu will show up after the selction of the last name and first name and will allows you to load the right patient record with the help of the birthday.

5.4. Tab preparation test ROTAM

This tab will allows you to set and to start a test.

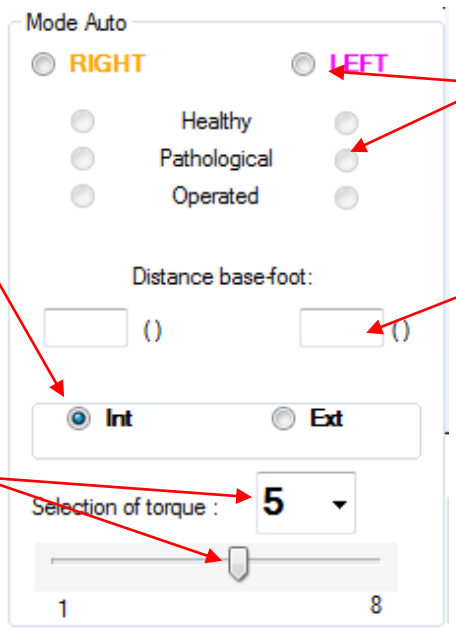


Option Radio: To activate the radio mode, please check the Radio case in Options section.

5.4.1 Automatic mode

Before each test, the user must select the following sets:

Choose the direction of the leg's rotation:
-intern
-extern



Complete the characteristics of the tested knee:
-Right knee or left
-pathologic knee, healthy or operated
- The distance base-foot

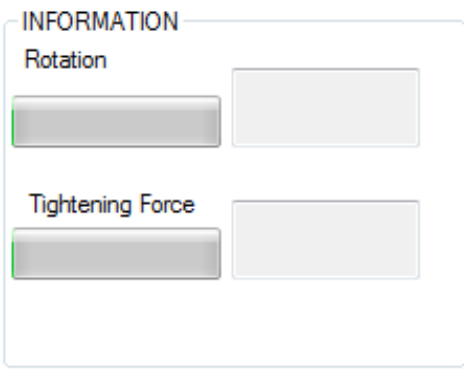
Complete the distance base-foot (data for positioning the patient always in the same conditions)

Select the rotation force torque from the drop-down menu or the bar.

5.4.2 Information

This display allows you to follow in real time the saved sets by the ROTAM during the test:

- Left torque: left ligament resistance
- Right torque: right ligament resistance
- Rotation: leg rotation angle
- Tighten: tightening force of the knee



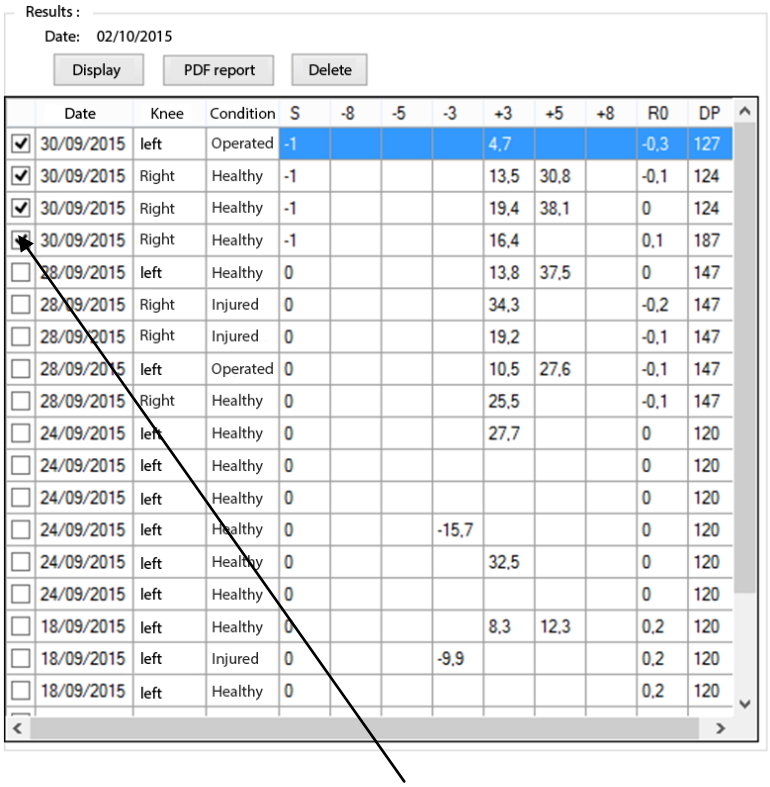
5.4.3 Controls

This module allows you to launch the ROTAM test and doing a reset of the programme after a loss of connection software.

5.4.4 Connections

This module allows you to connect the software to the ROTAM. When the connection is on, the light signal is **green**.

5.4.5 Results



The software show the test results in the Result board.

A test can be selected or unselected by checking his correspondent case.

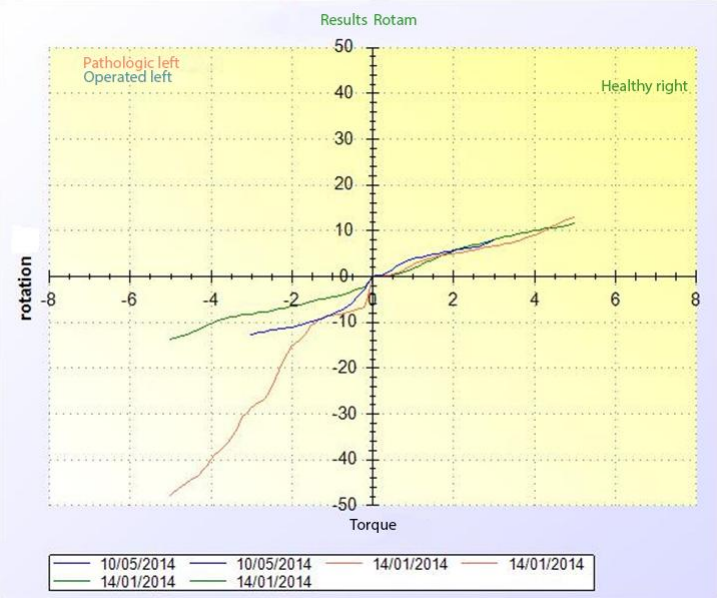
By default, the software selects and shows the last 4 saved tests. This number is editable in the configuration tab.

– The button « **Display** » allows you to generate the graph with the marked tests.
– The button « **Delete** » allows you to delete definitively all the marked test data. The deletion is irreversible.
– The button « **PDF Report** » allows you to generate a PDF file with the marked tests and the correspondent graph. Reports can be found in "My Documents\PDF Genourob"
– Export everything. All results are exported in an Excel file

5.4.6 The graph

The graph allows you to view test results selected in the board.

We'll find in abscissa the torque force exerted on le the patient leg and in ordinate the correspondent rotation.



- The red curves represent the pathological knee,
- The green curves represent the healthy knee,
- The blue curves represent the operated knee.
- More the curves are darks, older they are.

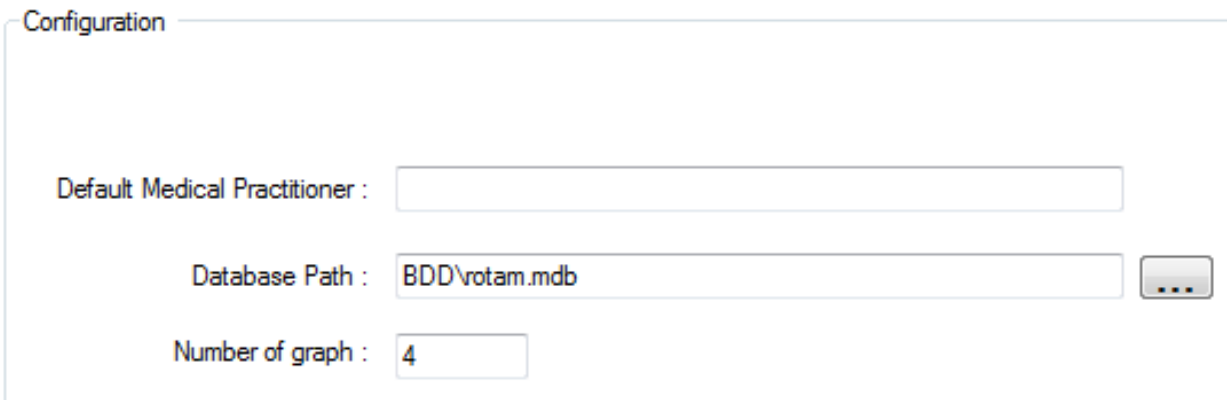
You can access a few options, by doing a right-click on the graph. In the menu who shows up:

- **Copy**, allows you to copy the graph in the clipboard.
- **Save as...**, allows you to save the graph picture.
- **Layout...**, allows you to configure the graph layout during an impression.
- **Print...**, allows you to print the graph.
- **Show points values**, allows you to show the value of a point by pointing the curve with the cursor. (x,y) appears , x represent the pressure and y le shifting.
- **Cancel zooms**, allows you to cancel one by one the previous zooms.
- **Cancel all zooms**, allows you to cancel all the previous zooms.
- **Reset scale**, allows you to return to the default scale.

5.5. Configuration tab

The configuration tab gives access to you to the account management, of the printer and saves.

5.5.1 Configuration

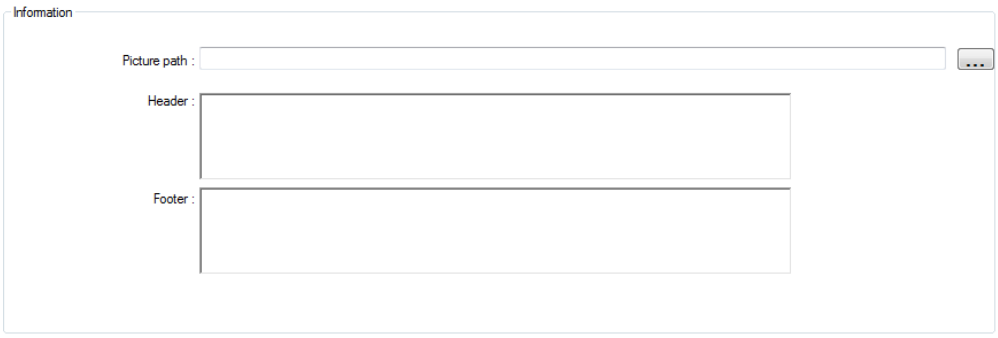


- **Default practitioner name**: enter here the name of the practitioner who primarily use the ROTAM. It's this name which is found in the tab « Patient record » when a new patient is saved in the data.
- **Path of the data base**: select a ROTAM data base.

  By default the data base is placed in C:\Program Files\ROTAM Control\BDD\rotam.mdb. However, here indicating another path, it's possible to work with another data base.
- **Default ROTAM test**: allows you to specify the default test used in the tab « Preparation ROTAM test » : 134, 150, 200, 250.
- **Curves number**: allows you to configure the test numbers (99 maximum) whose curves will automatically appear in the graph tab « Results ».

It's mandatory to click the « validate the configuration » button to save and apply the new settings.

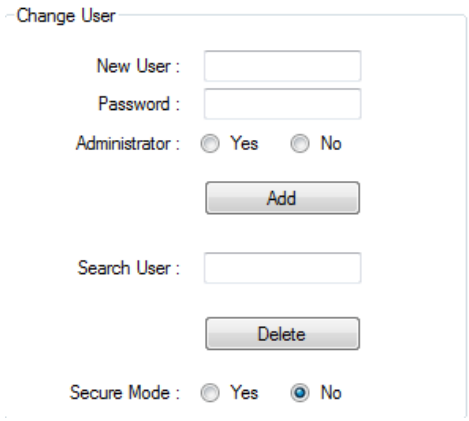
5.5.2 Information



All the information indicated here will appear on the impression.

- **Picture Path**: Enter in the "image path" field: the image to print. The image must have a size of 795 x 80 pixels in the case of portrait or 1135 x 80 pixels in the case of the landscape.
- **Header**: the information printed on the top of the document.
- **Footer**: information printed on top of the document.

5.5.3 Account management



Different fields of the account management part:

- **New user**: enter the name for the new user
- **Password**: enter the password for the new user
- **Administrator**: choose the rights for the new user
- **Add**: validating the new user
- **User research**: enter the name of the user to delete
- **Delete**: delete the researched user
- **Secure mode**: If activated, requires user name and password to the software launch

Administrators are the only to have access at this part.
An administrator can delete all users, including administrators, but can't delete the last administrator.

6. UTILISATION GUIDE

Imperatively follow the instructions of the following user guide and watch the explanatory movie use in the utilization software that you have previously installed on the PC.

This device is usable exclusively for measuring of laxity on legs for patients who's the weight is less than 135Kg.

For patients undergoing surgery of the anterior crossed ligament, it's strictly forbidden to make a ROTAM test on plasty less than three months.

The environmental conditions for optimal use of the ROTAM are temperature between 10°C and 40°C, hygrometry rate comprised between 30 and 70% and atmospheric pressure comprised between 800 and 1060 HPa.

It removed the patient's clothes legs.

Explain to the patient the operation of the ROTAM to avoid the patient surprise during the test, during the forced rotation of the tibia relative to the femur. This is so the test is done under the best relaxation conditions.

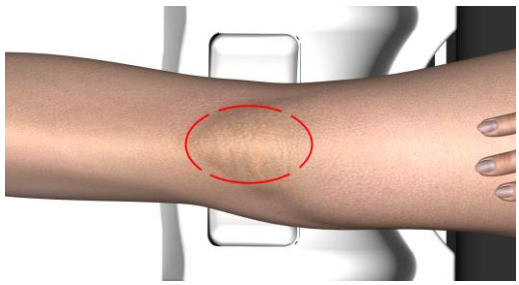
The test is based on the comparison of measurements on each knee (healthy or pathologic) and is divided into three distinct parts:

1. ***Attachment of the leg on the ROTAM (Three steps)***
2. ***Data saving of the patient and tests launching (two steps)***
3. ***Tests analysis for the diagnostic help***

1. *Attachment of the leg in five steps*

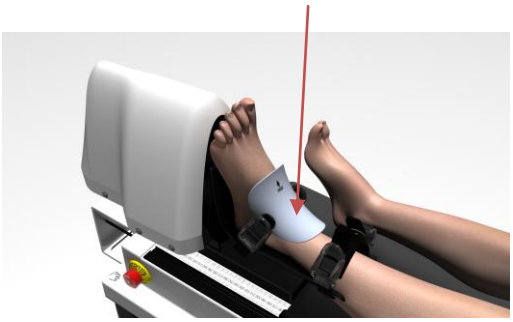
1.1 Position the patient on the device

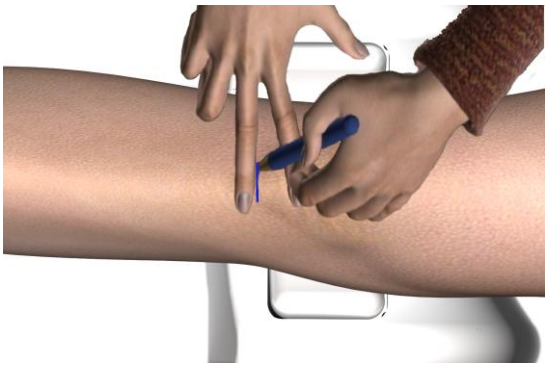
- ☐ The patient is lie down on the back (in dorsal decubitus), the backrest angle shouldn't exceed 30° and placed in the ROTAM axis
- ☐ The body is released, the head rests on the examination table and the arms are extended
- ☐ The hip must be in the leg axis



- ☐ The knee must rests to the support center where the patella tightening is done

☐ The foot rests on the adjustable boot





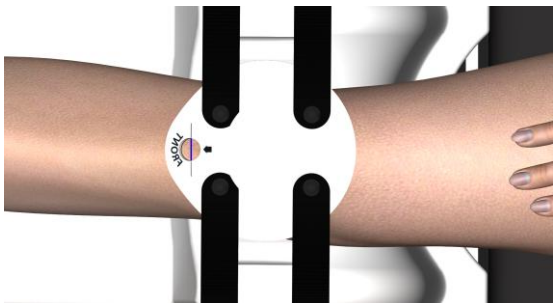
1.2 Fasten the knee-cup on the patella

☐ Locating the positions of the patella and the TTA and fix the patient's leg.

☐ Attach the knee-cup on the patella showing the trait of the patella in the center of the hole marked "front". The knee-cup must be horizontal and center on the patella

☐ Fix the third strap around the thigh to tighten it

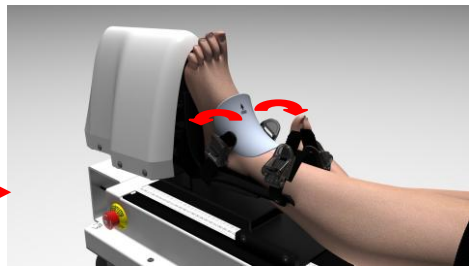
☐ Don't process to the final tighten of the strap



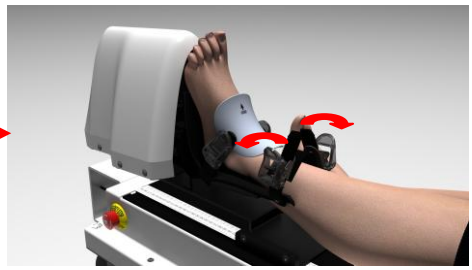
1.3 Fasten the foot in the support and take the measurement

☐ Adjust the position of the support (boot) until the heel fits snugly

☐ Fix the foot in position by tightening both buckles

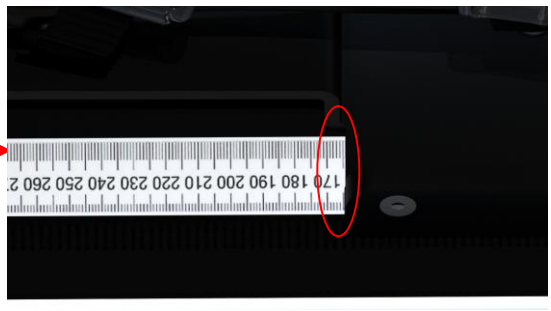


☐ Fix the tibia by tighten with the two straps



☐ Take the 'support-foot' measurement as it appears in the aperture

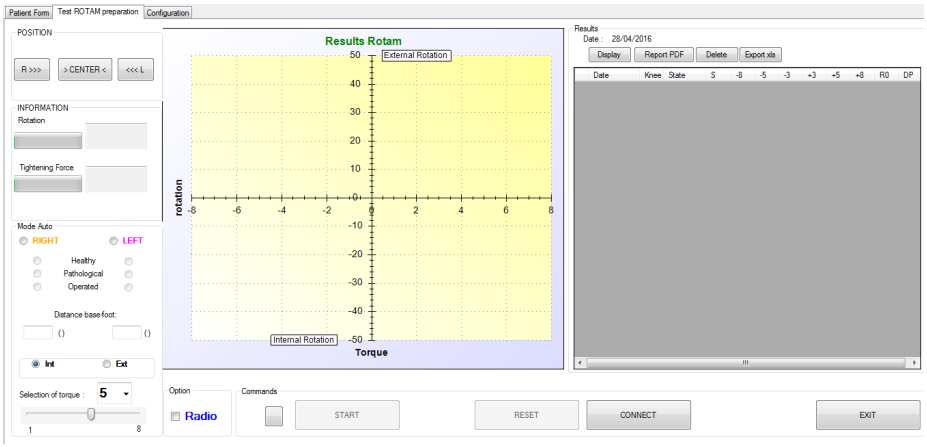
Note: each time a particular patient is tested this value must be the same



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

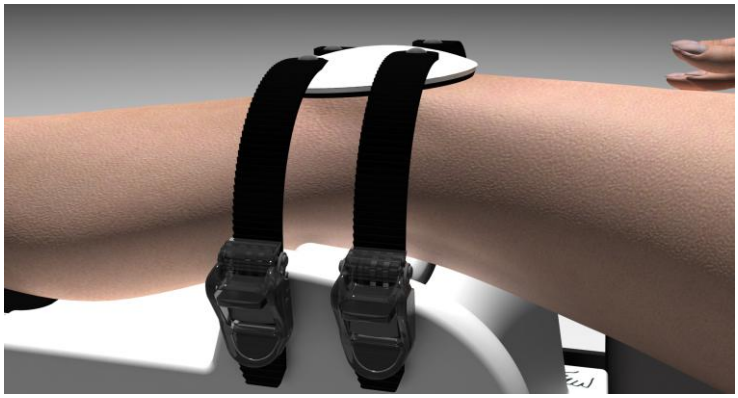
2.1 Enter patient's info in ROTAM software

- ☐ In the « Patient record » tab, enter the coordinates of the new patient, or open his previous created record
- ☐ In the « preparation ROTAM test », under 'settings' rubric select the tested knee and clarify his status
- ☐ enter the support-foot distance (see §1.4)



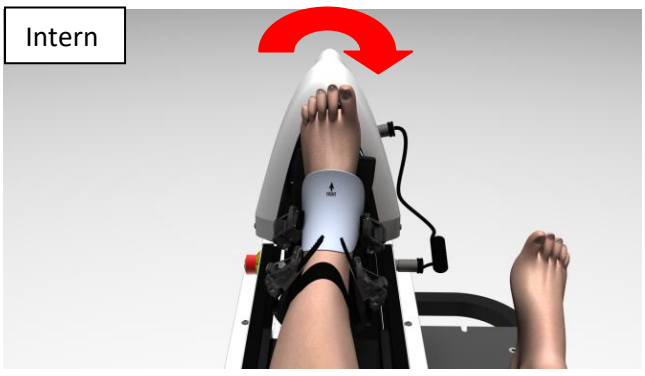
2.2 Tighten the knee-cup and the thigh strap and launch the tests

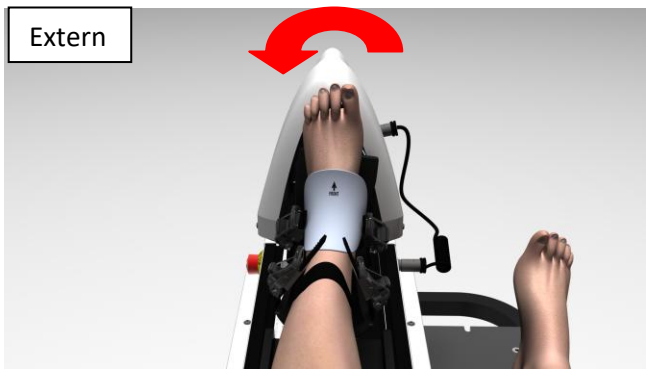
- ☐ Secure the knee-cup by tightening the 4 buckles to at least 60N (tighten in pairs, front/back).



The tightening must be infra-painful

- ☐ Choose the rotation direction (intern or extern)





- ☐ Launch the tests, at least twice, at 3, 5 and 8 Nm (if possible)

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

To validate the ROTAM 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%

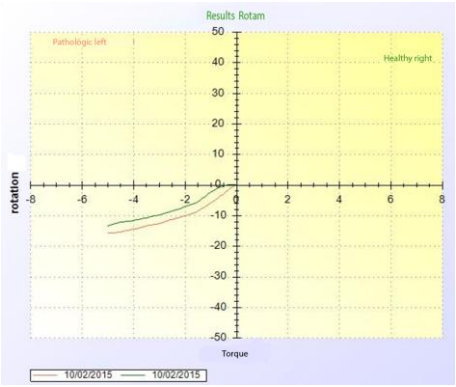
- The slope calculation P2 (healthy side so really healthy) must be less than 30µm / N (35µm / N if the patient is hyperlax) at the end of the last test to 200N

3. Tests analysis for diagnostic help

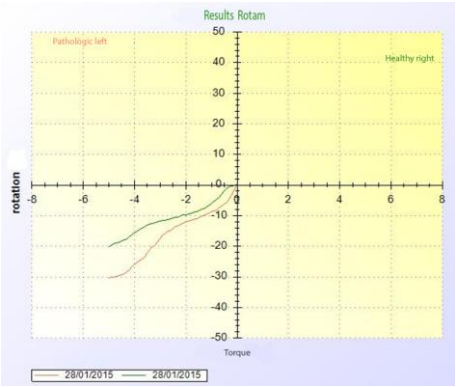
☐ having tested both legs, display the curves via the 'Results' tab
☐ In the number table, select the data you would like to see for the curve and click on the small corresponding box to the left, then click on 'Display'
☐ click on 'Print' or 'Export' (csv or xls formats) according to needs

Color codes of the curves:

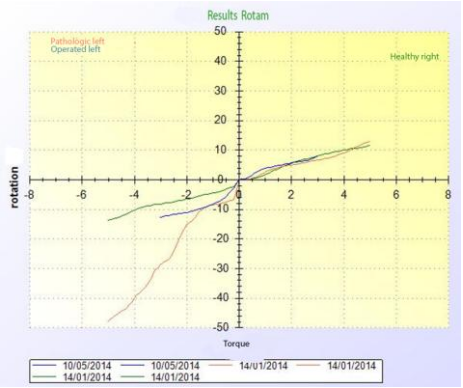
- green: healthy knee
- red: pathologic knee
- blue: knee having had ACL surgery



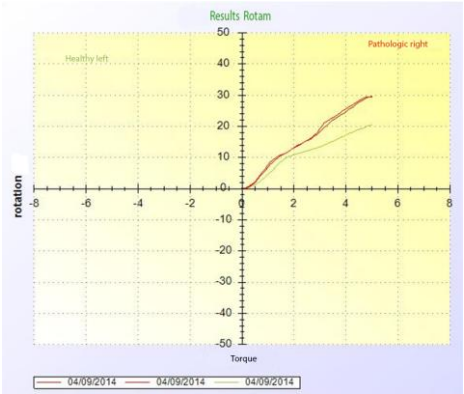
No lesion of ligament peripheral structures controlling the internal tibia rotation



Lesion of ligament peripheral structures controlling the internal tibia rotation



Control favorable postoperative (blue curve) in internal tibia rotation. No lesion of ligament peripheral structures controlling the external tibia rotation



Lesion of ligament peripheral structures controlling the external tibia rotation

4. Using the emergency stop button

The PC must be imperatively present in the patient's environment and the practitioner must always stay at proximity of the emergency stop button.

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 actuator will return to its initial position. Release the patient.

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.

Then, unplug the power supply from the power box of the ASTEC DPS 55M.

7. SAFETY INSTRUCTIONS AND PRECAUTIONS FOR USE

- This device is only for use by medical staff.

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

- For patients who underwent intervention of the anterior crossed ligament, it is strictly forbidden to make a ROTAM test on a plasty less than three months.

- 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.

- 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).

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

- In case of power supply interruption, the device can function again only after a launch of ROTAM software. At this moment, the boot takes again his neutral position, BE CAREFUL, do not place your fingers around the boot to avoid pinching.

- The ROTAM has been created for a functional time of 5 minutes maximum, follow by a rest time of 15 minutes minimum.

- Do not clean with water or other liquids.

- 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 food, ASTEC reference DPS55-M (Certified Medical: maximum temperature 43 ° C), provided by the company GENOUROB® should be used to electrically power the ROTAM.

- The parties applied to the patient (shell boot straps) can reach 45 ° C when using the ROTAB 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 ROTAM

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

- 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 ROTAM

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

- Prohibition to change the GNRB ROTAB undocumented GENOUROB: 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.

- Le ROTAM ne doit pas être utilisé adjacent ou empilé à d'autres équipements. Si cet usage est nécessaire, une vérification de bon fonctionnement du ROTAM dans cette configuration est à réaliser.
- 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

8. TRANSPORTING THE ROTAM

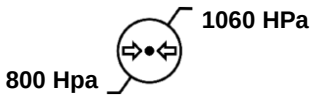
The ROTAM
- must be handle with care

- must be kept dry

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

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

- must be stored under atmospheric pressure between 800 and 1060 HPa



To transport the ROTAM, please put your hands where indicated by the labels.

9. MAINTENANCE AND RECYCLING

Any damage to the device should trigger maintenance such as a broken pad, a damaged cable…

In such events, phone GENOUROB® on +33 243 904 301 from 9am to 18pm, 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.

We advise you to approach your town hall for inforamtion on the recycling of measures put in place for electrical and electronic equipments.

10. CERTIFICATIONS - Manufacturing and marketing's dates

Manufacturer's address :

GENOUROB SAS
Bât. 60 rue Henri Géret
53000 LAVAL- France

First marketing's date: **29/01/2019**

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 ROTAM device complies with the EMC and safety standard IRC 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).

11. APPENDIX I : MANUFACTURER'S DECLARATIONS

Electromagnetic emissions		
The ROTAM 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	ROTAM 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 ROTAM 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 ROTAM requires continued operation during interruptions of the main power supply, it is recommended that the ROTAM 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 ROTAM requires continued operation during interruptions of the main power supply, it is recommended that the ROTAM 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 ROTAM 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