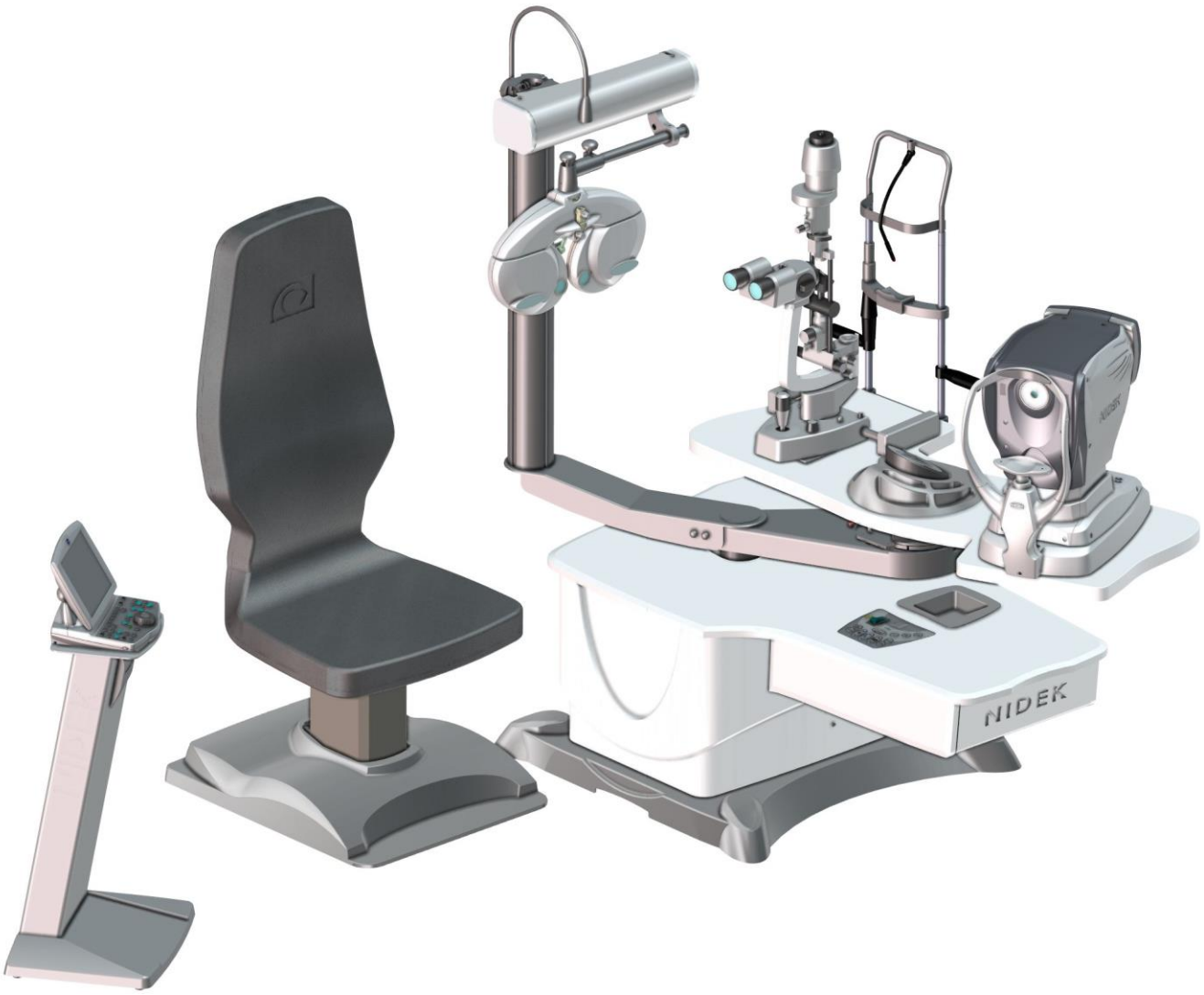
NIDEK

# REFRACTION STAND

# OT-4200




## OPERATOR'S MANUAL

CE

THE ART OF EYE CARE

Before use or maintenance, read this manual.

This Operator's Manual contains information necessary for correct and effective operation of NIDEK refraction stand OT-4200, and provides procedures for operation, cautions, specification, and procedures for maintenance.

This manual is necessary for proper use. Especially, the safety precautions and operating procedures must be thoroughly understood prior to operation of the unit. Keep this manual handy for reference.

There are no user-serviceable parts.

Therefore, if you encounter any problems or have questions about the unit during the operation, please contact NIDEK or your authorized distributor.

This unit complies with EU Regulation 2017/745 of the European Parliament and Council of 5 April 2017 covering medical devices.

CE

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# 1 OT-4200 RANGE

## 1.1 PRESENTATION OF THE OPHTHALMIC STAND

The refraction units OT-4200 is used to perform ophthalmic. This device avoids movement of the ophthalmologist and the patient thanks to the manual or electrical adaptation of the position of ophthalmic instruments to their position.

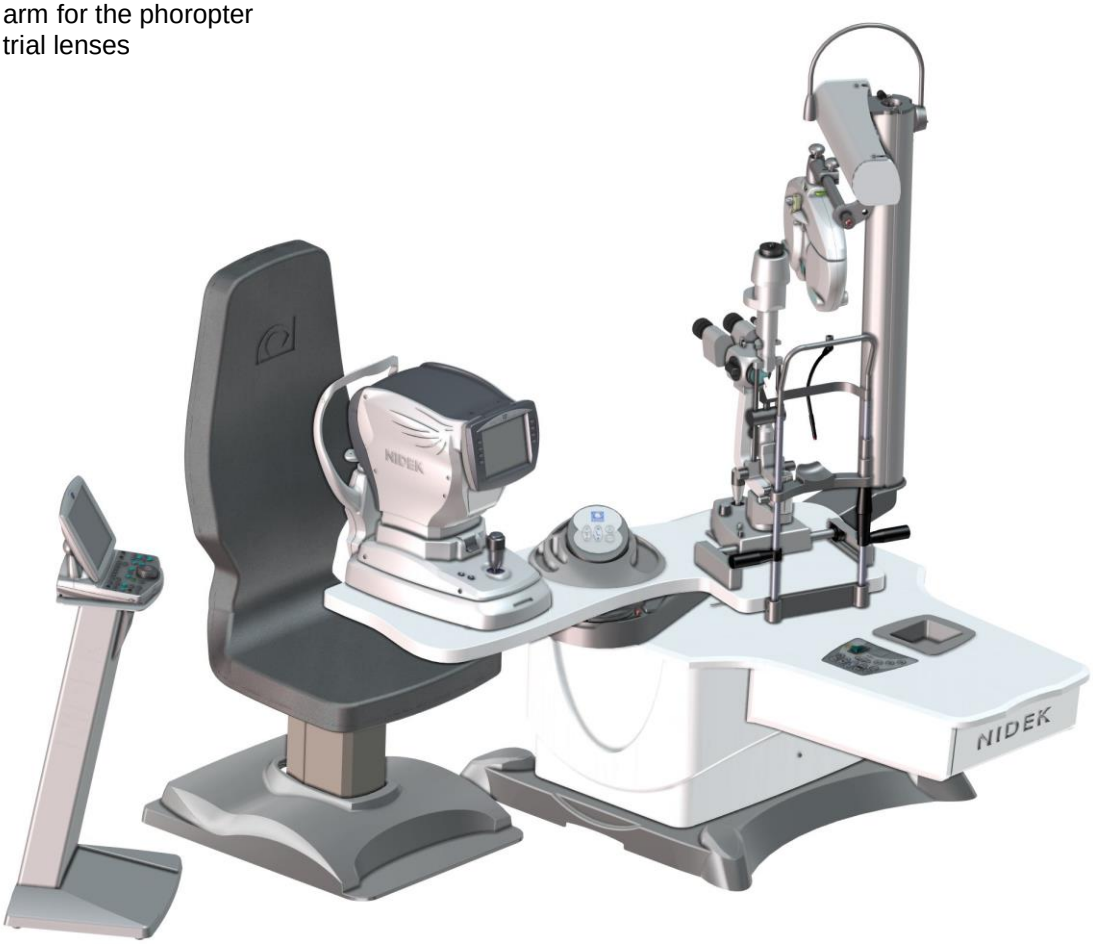
The deflections of the seat and table top have been carefully calculated to accommodate either children of 1.20 m as adults of 2 m but also persons with reduced mobility and disabilities that move with a wheelchair.

The refractor is mounted on a bracket whose height is adjusted along the table top: this guarantees a constant eye level between different devices, and spares you from annoying settings under consideration.

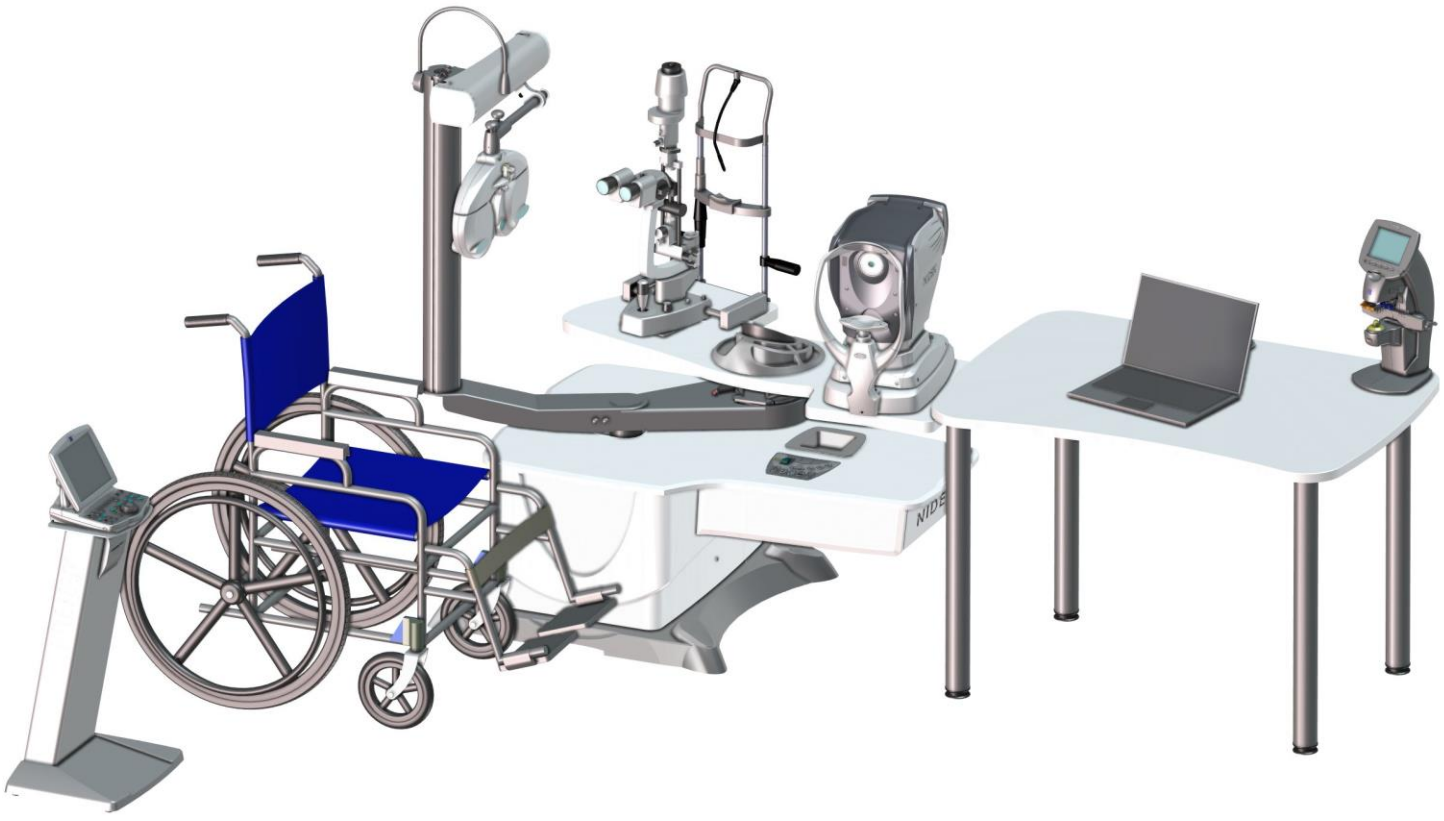
Finally, optional accessories allow you to fully customize the unit according to your wishes.

## 1.2 THE VARIOUS VERSIONS

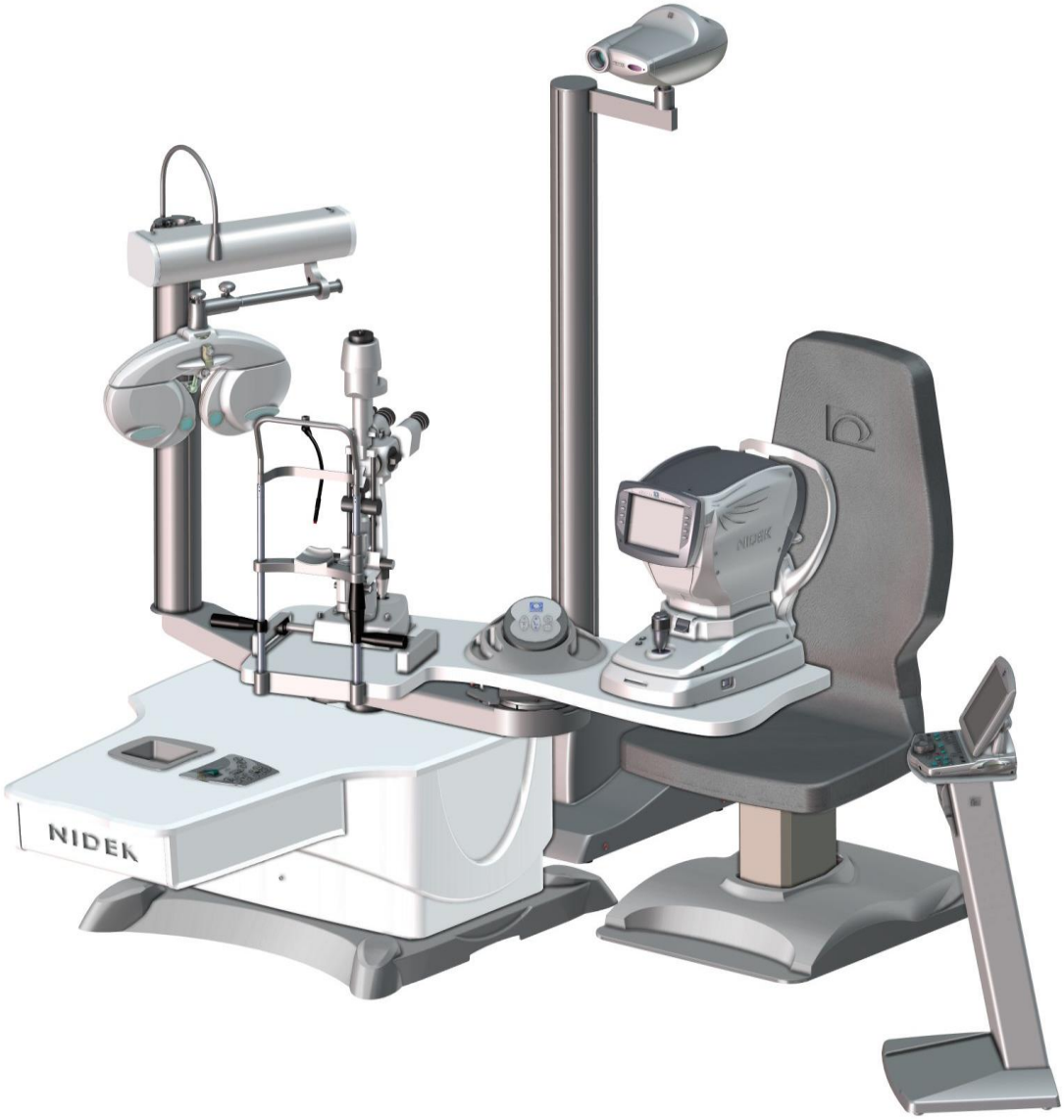
OT-4200
Right handed stand
Patient chair FE-2010
Table top for 2 instruments
A motorized arm for the phoropter
1 drawer for trial lenses



**OT-4200** with desk
Right handed stand
Table top for 2 instruments
A motorized arm for the phoropter
1 drawer for trial lenses



OT-4200
Left handed stand
Patient chair FE-2010
Table top for 2 instruments
A motorized arm for the phoropter
A column for chart projector
1 drawer for trial lenses



# 2 SAFETY

The following safety precautions should always be followed. The safety word **PRECAUTION** indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or property damage accident. Even situation indicated by **PRECAUTION** may result in serious injury under certain conditions. Safety precautions must be strictly followed at all times.

## 2.1 CAUTIONS IN INSTALLATION

PRECAUTION

Only NIDEK or an authorized distributor can install your refraction stand. NIDEK can't be responsible for any accidents resulted from improper servicing.

Install the ophthalmic unit in a place that will never be exposed to water. If water gets into the internal structure of the unit, electric shock or unit malfunction may result.

The installation location must satisfy the following environmental conditions:

- Place with low dust
- Flat floor, without waves of more than 5 mm,
- Stable, level place that is free from vibration or shock
- Floor supporting the weight of the unit,
- The back of the unit must be at the distance of at least 16 cm from the wall with the power source plug

If these environmental conditions are not satisfied, the unit could fall over, the floor could get damaged and it may result in some serious injuries.

Do not carry alone the ophthalmic unit. Injury, unit damage, damage of medical devices placed on the table top may result if the unit is carried by one person.

This unit has been declared conform to Directives 93/42/EEC for medical devices and 2004/108/EEC for electromagnetic compatibility because, among other requirements, the unit complies to norms EN 60601-1 and 60601-1-2 to assure a general safety and to provide reasonable protection against harmful interference in a typical medical installation.

It is up to the user to operate the unit in compliance with safety standards.

## 2.2 ELECTRICAL CONNECTION

PRECAUTION

Be sure to use an outlet equipped with a grounding terminal which meets the specified power requirements. If not, the unit may not deliver full performance, or malfunction or fire may result. In addition, if the outlet is not equipped with a grounding terminal, there is a fear of electrical shock or fire in the event of a power leak.

Securely connect the mains plug into an outlet. Insecure connection may result in fire

To disconnect the mains plug, hold it. If the power cord is pulled out, short circuit or electric shock may result in a case of break in the wires inside the power cord.

The access to the mains plug when it is plugged should be possible and easy.

Never put heavy objects on the power cord nor catch the cord between any objects. The cover of the power cord may become worn and fire or electric shock may result.

If the metal core of the power cord is exposed, if the power turns on and off by shaking the power cord, if cord or plug gets so heated that one cannot hold it, it means that the power cord is damaged. Contact NIDEK or your authorized distributor to replace it immediately. Electric shock or fire may result.

Wipe between the prongs of the mains plug with a dry cloth occasionally. If dust settles between the prongs, the dust easily takes up moisture, and short circuit or fire may result.

If the ophthalmic unit will not be used for a long time, disconnect the power cord from the wall outlet. Fire may result.

Note : By plugging electrical equipment to the multiple adapter located inside the unit, an electrical medical system may be created.

## 2.3 RECOMMENDATIONS FOR USE

PRECAUTION

Do not use the unit for other than the intended purpose. NIDEK is not responsible for accidents or malfunction caused by misuse.

Never disassemble nor touch the inside of the unit. Electric shock or unit malfunction may result.

If a failure in the unit cannot be solved by fuse replacement or power switch turning on, do not touch the inside of the unit. Disconnect the power cord from the outlet and contact NIDEK or your authorized distributor.

## 2.4 CLEANING

When parts become dirty, wipe with a dry and soft cloth. For stubborn dirt, immerse the cloth in a neutral detergent, wring well, and wipe. Finally wipe with a dry and soft cloth. Never use an organic solvent such as paint thinner to wipe off the exterior. This may ruin the surface.

The room lamp on the top of the aluminium lightning column can be dismounted for easy cleaning operation. Before cleaning, glasses of room light must be totally cold, or injury such as burns or breakages may result.

Service work should be performed only by service persons authorized by NIDEK. NIDEK is not responsible for any accidents resulted from improper servicing.

## 2.5 LABELLING

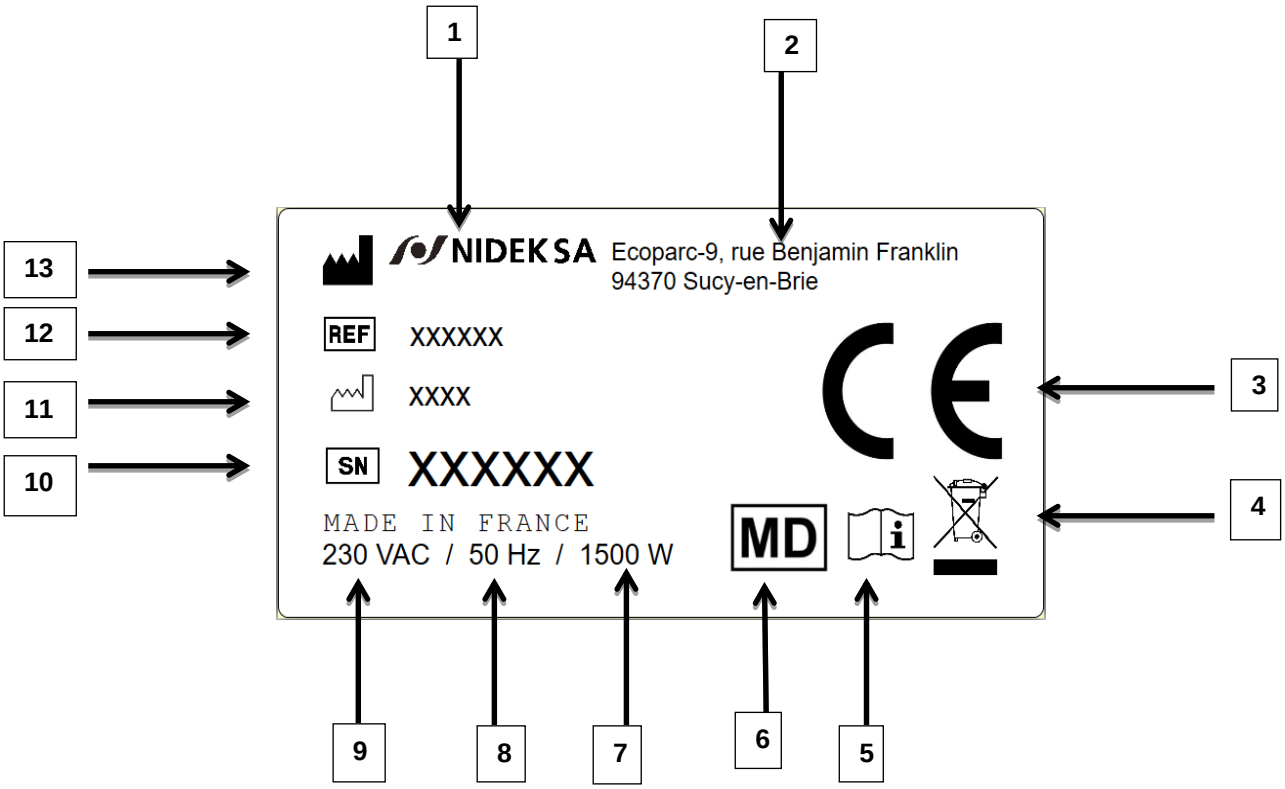
### 2.6.1 Indication plates

There are indications on the protective housings of the unit indicating that dangerous electrical voltages are accessible under them:

[1] Ecosystem: An Eco-organization approved by the French public authorities. For all collection solutions, refer to www.ecosystem.eco or contact NIDEK or its authorized distributor.

### 2.6.2 Label

The following label and indications are affixed to the unit to draw the operator's attention.




1 Manufacturer's logo

2 Address of the head office

3 In accordance with EU Regulation No. 2017/745 concerning medical device

4 The EEE[3] are subject to separate collection

5 Refer to the precautions for use and instructions for use

6 Medical Device

7 Maximum power

8 Frequency

9 Supply voltage

10 Serial number

11 Year of manufacture

12 product reference

13 Manufacturer

[3] EEE: Electrical and Electronic Equipment

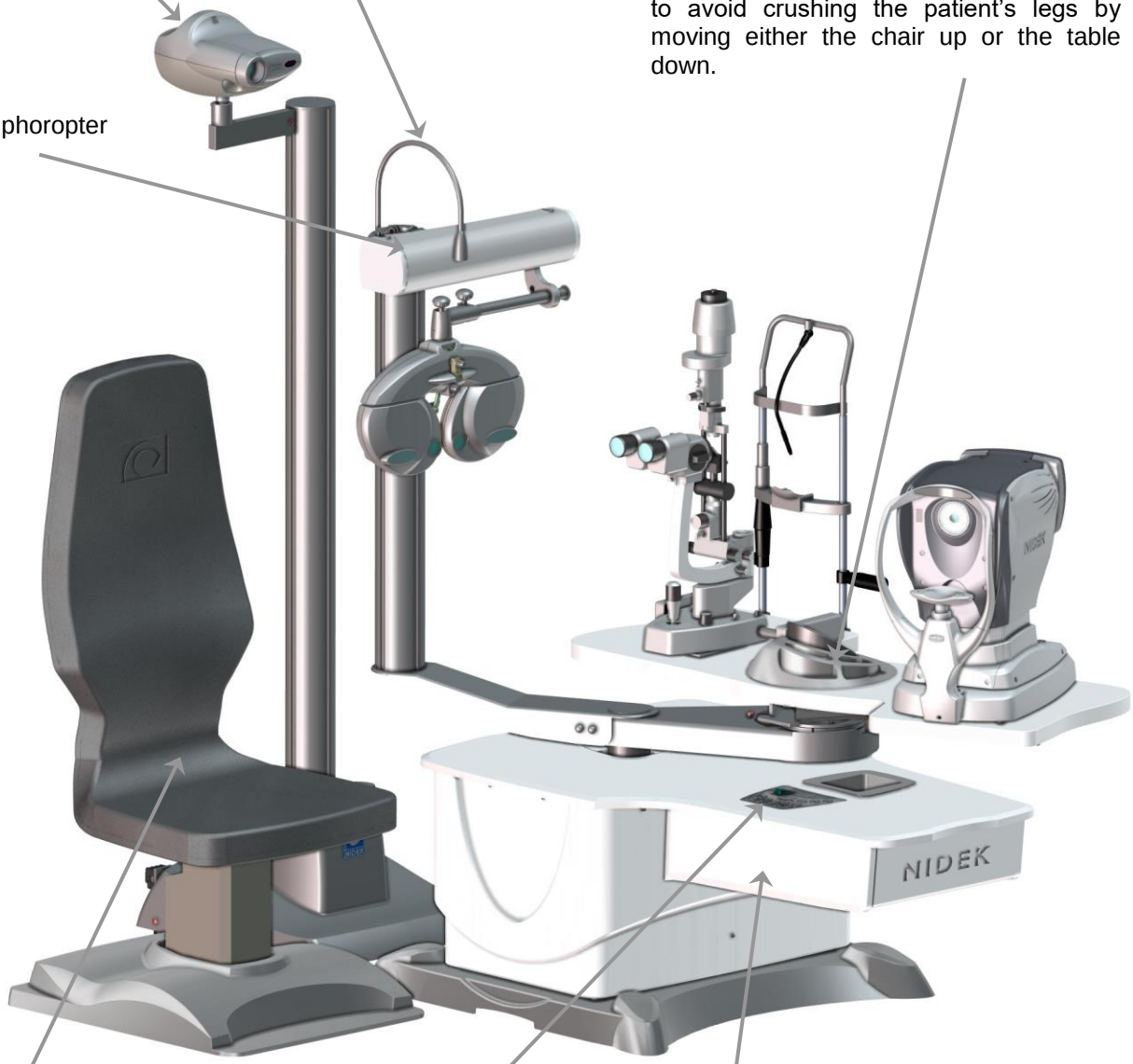
# 3 STAND'S DESCRIPTION

**Table top**
Electrical adjustment from 61 to 94 cm.
Combined with the patient chair, the unit is designed for comfortable examination either of adults or children.
It can hold 2 instruments and the phoropter.
Safety levers integrated under the tables to avoid crushing the patient's legs by moving either the chair up or the table down.

Light for near vision

Column for chart projector

Motorized arm for phoropter




**Patient chair**
Electrical height adjustment (20 cm of adjustment), 200kg loading capacity
Different models and options available

Control panel with general circuit breaker

Drawer for trial lenses and frames

# 4 USE

## 4.1 POWER ON

The ophthalmic unit must be properly connected to a wall outlet (seer § 2.2 « Electrical connection »): the green lamp of the circuit breaker is off. Then, press the circuit breaker button to position « I »: the green lamp of the circuit breaker is on, and the blue LED on the control panel gets illuminated.
There is an automatic initialization of the table top and the patient chair brings it to the lower position.

## 4.2 POWER OFF

Your ophthalmic unit shall be powered off daily. Press the circuit breaker button to the position « O » (circuit breaker and LED light off).

## 4.3 USED OF THE CONTROL PANEL


ON / OFF
Circuit breaker

READY
Blue LED

SHUNT Security

No functional button

Optional controls

Patient chair
Automatic up

Brake

Reset
Automatic return to 0 (table top and patient chair)

Lamp
Spot

Table top
Up / Down
Then press simultaneously more than 10 s on the buttons “Seat Down” and "Option C ":
you have memorized the height of the table top.

Patient chair
Up / Down

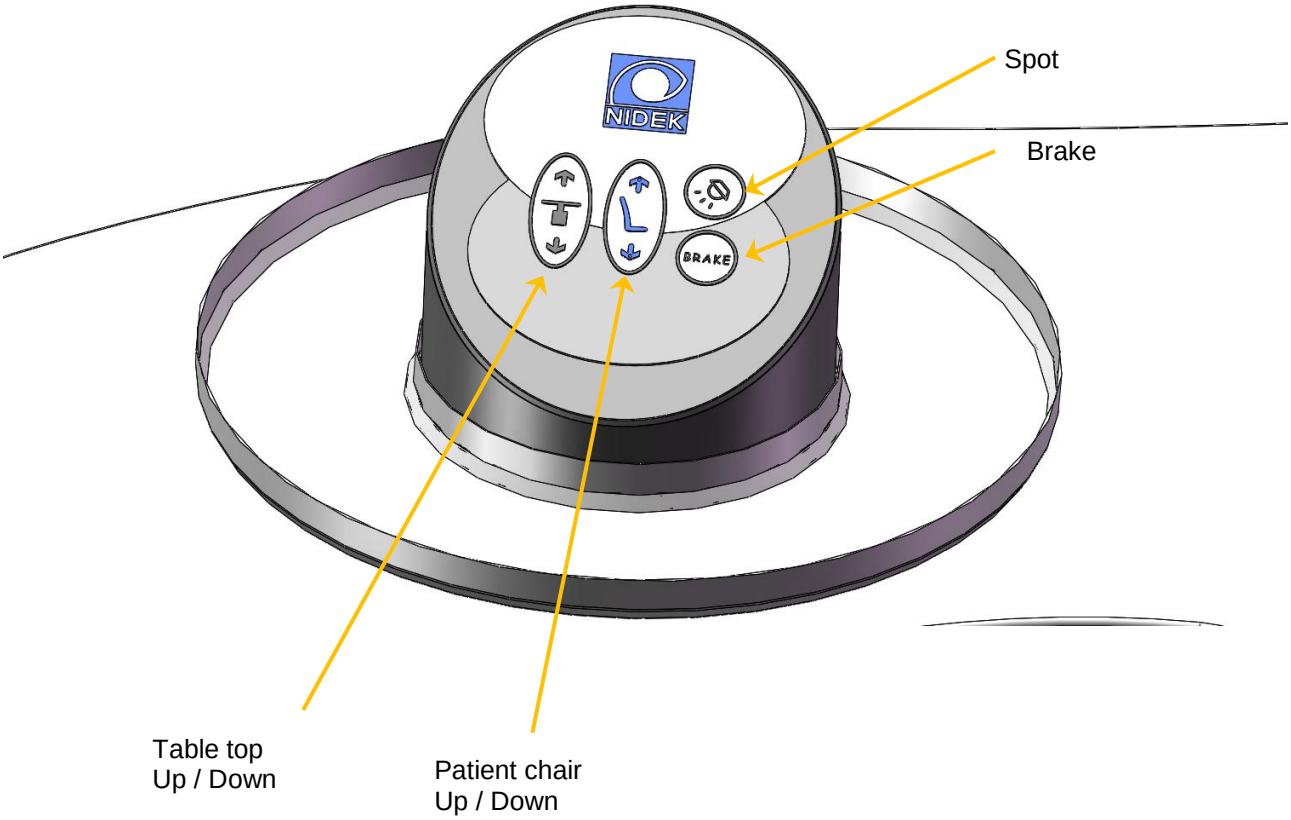
Phoropter
Exit / Back of the arm

## 4.4 RETRACTION OF THE PATIENT CHAIR

If the patient is in a wheelchair, the patient chair can be retracted. Press the button «  » to move up automatically the patient chair. In the upper position, the casters of the patient chair emerges to allow its movement.

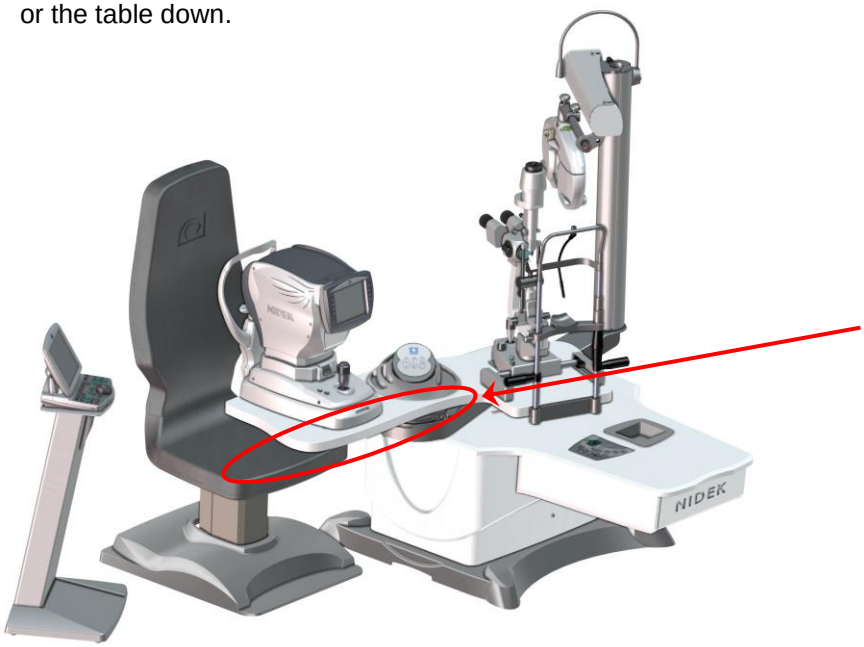
## 4.5 OT-4200'S SUPERIOR CONTROL PANEL

In the middle of the OT-4200's table-top is a 2nd control panel.



## 4.6 SAFETY LEVER

Safety lever is integrated under the tables to avoid crushing the patient's legs by moving either the chair up or the table down.




Up/Down security lever
If there is a contact between the legs of the patient, this part stop automatically the patient chair (up) and the table top (down).

The blue LED blinks slowly when security is enabled.

# 5 TROUBLESHOOTING GUIDE

In the event that the unit does not work properly, check the following table before contacting NIDEK or your authorized distributor.

## 5.1 DIAGNOSIS OF FAILURE

| Power ON | Suggestion |
|---|---|
| Nothing works any more | Put on the button « ON / OFF » |
| The unit does not turn on | The power cord may not be correctly connected. Reconnect it securely. |
| The green lamp of the circuit breaker is off | On your own electrical cabinet, check the fuse of the outlet the unit is connected to: it may be blown. If so, replace it by a new one. |

| Safety lever | Suggestion |
|---|---|
| The table top moves up, but not down. | Check that nothing is operating with the descent safety lever under the table top. |
| Patient chair moves down, but not up. | Check that nothing is operating with the descent safety lever under the table top. |

| Chair | Suggestion |
|---|---|
| The patient chair doesn't move up and not down. | Contact your authorized distributor. |

| Slit lamp | Suggestion |
|---|---|
| The slit lamp (or the ophthalmometer) does not light on, but everything else is OK. | Check the bulb of the device.<br>Check the plug of the SL |

| Devices on the Table Top | Suggestion |
|---|---|
| Only 1 of the 230V devices on the table top does not work. | Check the On/Off button of the device<br>Read the handbook of this device. |

If the problem cannot be solved by the suggestions below, contact your authorized distributor.

## 5.2 FAILURE TO RESOLVE : UP & DOWN

A failure of security up and down is when:
• The seat doesn't work up (but still down)
And
• The table doesn't work down (but still rises)

While you are waiting for the intervention of your authorized distributor, you can temporarily disable this security: press 5 seconds the button "SHUNT Security": the blue LED "READY" will flash quickly.
Then, the seat and table-top can work up and down again.

# 6 MAINTENANCE

## 6.1 CLEANING

When parts become dirty, wipe with a dry and soft cloth. For stubborn dirt, immerse the cloth in a neutral detergent, wring well, and wipe. Finally wipe with a dry and soft cloth.
For cleaning of devices, refer to their handbooks.

PRECAUTION
Never use an organic solvent such as paint thinner to wipe off the exterior. This may ruin the surface.

## 6.2 LIST OF SPARE PARTS

The refraction stand OT-4200 is equipped with automatic reset fuses: there is therefore no fuse to change. Outside the bulbs that are bulbs of commerce, the stands have no wear part change periodically. There is no spare part to predict.

# 7 TECHNICAL FEATURES

## 7.1 CE CLASSIFICATION

Classification under the provision of 93/42/EEC (MDD)
The ophthalmic unit OT-4200 is classified as Class I medical devices.

Protection against electric shock Class I
A Class I is a unit in which the protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of the unit to the protective (ground) conductor in the fixed wiring of the installation in a way that accessible metal parts cannot become live in the event of a failure in the basic insulation.
Use a power outlet which is equipped with a grounding terminal.
The ophthalmic unit OT-4200 is classified as a device without applied part.

Mode of operation
Classification of the ophthalmic units OT-4200 : continuous operation.

## 7.2 ELECTROMAGNETIC COMPATIBILITY

<table>
<tr><th colspan="3">Declaration of the MANUFACTURER – ELECTROMAGNETIC EMISSIONS</th></tr>
<tr><td colspan="3">This device is intended for use in the electromagnetic environment specified below. The customer or the user must be sure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Conformity</th><th>Electromagnetic environment – instructions</th></tr>
<tr><td>Emissions RF CISPR 11</td><td>Group 1</td><td>This device uses RF energy only for its internal function. Its RF emissions are very low and there are not likely to cause any interference in a nearby electronic device.</td></tr>
<tr><td>Emissions RF CISPR 11</td><td>Class B</td><td rowspan="3">This device is suitable for use in all non-domestic environments and can be used in domestic establishments and those directly connected to the public low voltage power supply, supplying domestic premises subject to consider the following warning: <u>Warning:</u> This device / system is intended to be used only by health professionals. This device / system may cause radio interference or may disrupt the operation of a device in range. It may be necessary to take mitigation measures, such as reorient or install this device to another place or shielding the location.</td></tr>
<tr><td>Harmonic emissions CEI 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations / Flicker<br>CEI 61000-3-3</td><td>Compliant</td></tr>
</table>

| Declaration of the MANUFACTURER – ELECTROMAGNETIC EMISSIONS | | | |
|---|---|---|---|
| This device is intended for use in the electromagnetic environment specified below. The customer or the user must be sure that it is used in such an environment. | | | |
| **Tests** | **Test level CEI 60601** | **Conformity** | **Electromagnetic environment – instructions** |
| Electrostatic discharges (ESD)<br>CEI 61000-4-2 | ±6 kV contact | Compliant | It is appropriate that the floors are wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.<br>During testing, it was found that discharge 8 kV can damage the unit consultation with functional impact but no impact on safety. |
| | ±2, 4 kV in the air | Compliant | |
| | ±8 kV in the air | Non Compliant | |
| Radiated RF disturbances<br>CEI 61000-4-3 | 3 V/m from 80 MHz to 2,5 GHz | Compliant | Portable and mobile RF communications equipment should not be used near any part of the device, including cables. The recommended separation distance, is a function of power and frequency of the transmitter. Increase the separation between the device and transmitter cable in case of problems. |
| Fast transient<br>CEI 61000-4-4 | ±2 kV for power supply lines | Compliant | The quality of the power supply network must be that of a typical commercial or hospital environment. |
| | ±1 kV for input / output | Compliant | |
| Surge voltage<br>CEI 61000-4-5 | ±1 kV line<br>±2 kV between line and earth | Compliant | The quality of the power supply network must be that of a typical commercial or hospital environment. |
| Conducted RF interference<br>CEI 61000-4-6 | 3 Veff from 150 kHz to 80 MHz | Compliant | |
| Voltage dips, short interruptions and voltage variations on power lines input<br>CEI 61000-4-11 | <5 % UT<br>(>95 % dip in UT)<br>for 0,5 cycle<br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><5 % UT<br>(>95 % dip in UT)<br>for 5 s | Compliant | The quality of the power supply network must be that of a typical commercial or hospital environment. If the user of this device requires continued operation during network outages of power, it is recommended to power the device from an uninterruptible power supply or a battery. |
| Magnetic field at the grid frequency (50/60 Hz)<br>CEI 61000-4-8 | 3 A/m | Compliant | The magnetic fields at mains frequency must have the characteristics of a typical location in a typical commercial or hospital environment levels. |

## 7.3 MAIN FEATURES

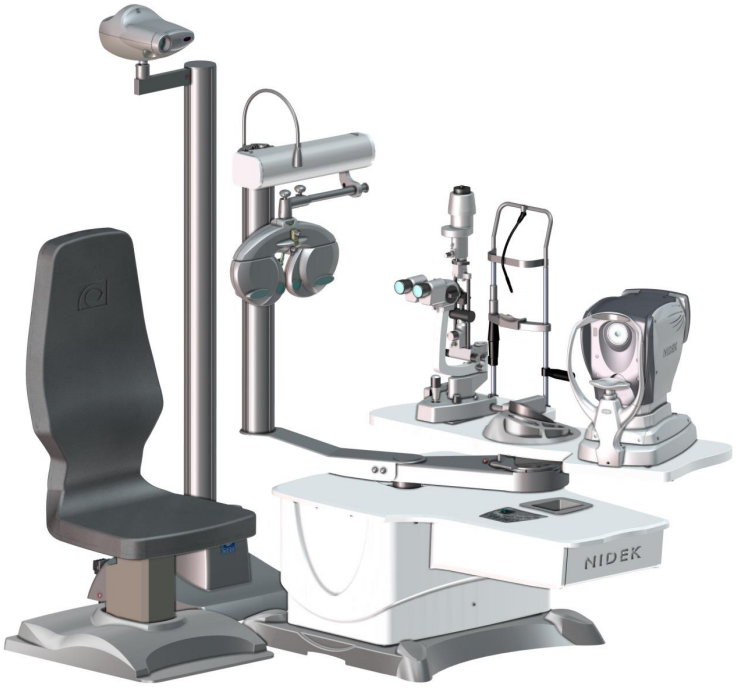
| | |
|---|---|
| Approximate net weight | 200 kg (without desk and devices) |
| Power source | 230 VAC / 50 Hz / 1000 VA |
| Table top | Electrically adjustable height (from 61 to 96 cm) with memory of the prefered table top height<br>Maximum load of the table top OT4200 35kg by position |
| Refractor | Refractor on a motorized arm.<br>The eye level of the refractor is identical to that of devices placed on the table top. |
| Furniture | In option, several models of furniture with:<br>1 drawer (for trial lenses and 2 frames)<br>Or a furniture with 3 drawers<br>In option 1 desk |
| Patient chairs | Electrically adjustable height (45 – 65 cm)<br>Maximum load 200kg<br>Several models available<br>Options: reclining backrest, 360° rotation, armrests, footrest, forth and back movement. |

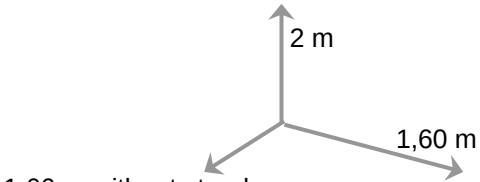
## 7.4 ELECTRIC DIAGRAM

The electric diagram is included in the unit.

## 7.5 DIMENSIONS

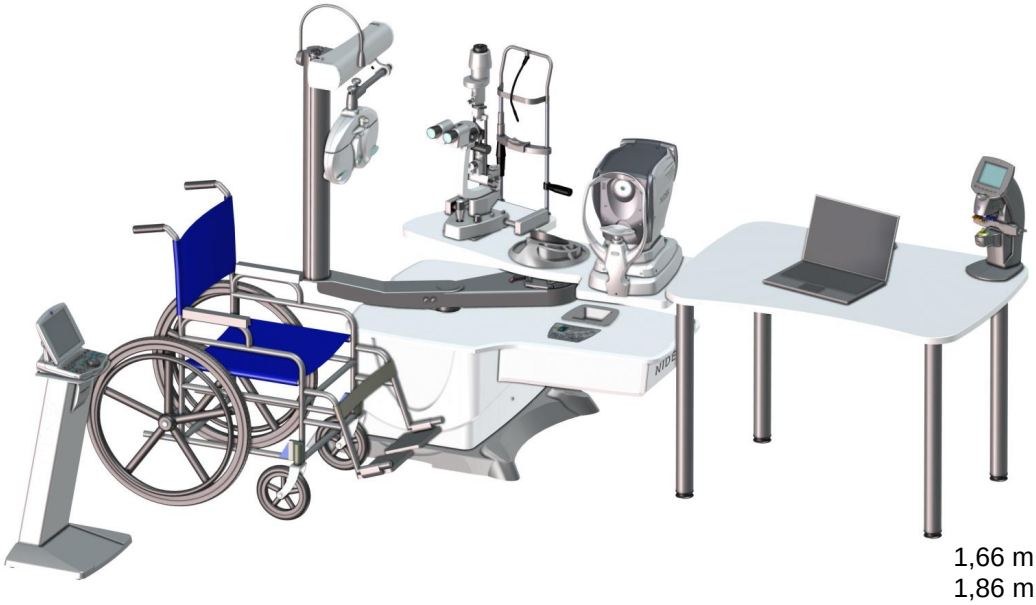
OT-4200

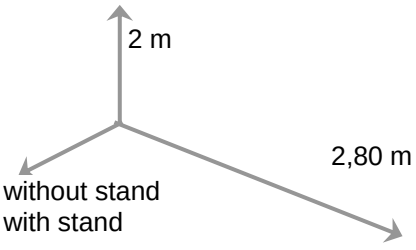



1,66 m without stand
1,86 m with stand

OT-4200 with desk






1,66 m without stand
1,86 m with stand

Head office PARIS
✉ 9, rue Benjamin Franklin
94042 CRETEIL - FRANCE
☎ +33 1 49 80 97 97
💻 +33 1 49 80 32 08

LYON Manufacturing facility
✉ 50, rue Jean Zay
69800 SAINT-PRIEST – FRANCE
☎ +33 4 37 28 18 18
💻 +33 4 37 28 18 19