NIDEK

CONSULTATION UNIT

lyPOP

USER'S MANUAL

CE

THE ART OF EYE CARE

Before use or maintenance, read this user's manual

This manual contains the information necessary for using the Nidek LyPop consulting unit such as the methods and precautions for use, the characteristics and the maintenance instructions.

This user's manual is essential to ensure proper use of the unit.

This device is intended for health professionals, the precautions and the methods of use must be thoroughly mastered before using the unit.

Be sure to keep it to hand so that you can refer to it if necessary.

This consultation unit has no parts that are replaceable by the user. Therefore, if you encounter difficulties or if you have any questions, please contact NIDEK or your authorised distributor (no bulbs, no fuses, etc.).

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

CE

CONTENTS

1 THE LYPOP RANGE

1.1 PRESENTATION OF THE CONSULTATION UNIT

The LyPop-OT1400 Consulting Unit is intended for performing refraction examination. This feature prevents movement of the practitioner or the patient, by adapting the position of the ophthalmology instruments to them either manually or electrically.

1.2 THE DIFFERENT VERSIONS

“Grey” LyPop
Right side working
Black examination chair
Back&forth adjustment
Single column projector
Foot rest
Pivoting tabletop for 2 instruments
Phoropter on a manual translation arm
RT control stand
1 drawer for trial lenses

“Red” LyPop
Right side working
Red examination chair
Back&forth adjustment
Pivoting tabletop for 2 instruments
Phoropter on a manual translation
Single column projector
Single column projector
Foot rest
RT control stand
1 drawer for trial lenses

“Blue” LyPop
Left side working
Blue examination chair
Back&forth adjustment
Foot Rest
Pivoting ~~tray~~ tabletop for 2 instruments
Phoropter on a manual translation
Single column projector
1 drawer for ~~test~~ trial lenses

2 SAFETY

The safety precautions described below must always be respected. The logo
PRECAUTION is used to attract the attention to a potentially hazard situation which, if it is not avoided, may result in minor to severe injury, or damage to the equipment. Instructions pertaining to
PRECAUTION must be followed strictly

2.1 PRECAUTIONS RELATING TO INSTALLATION OF THE UNIT

PRECAUTION

Only NIDEK or your authorized distributor is authorised to install the consultation unit. Failing this, NIDEK cannot be held responsible for accidents due to incorrect installation.

Install the consultation unit in a location which is never exposed to water. Water entering the internal structure of the unit can cause electric shocks or malfunctioning.

- Conditions for installing the consultation unit:
- Little dust,
- Flat floor, without upper undulation of > 5 mm,
- Stable floor, not subject to vibration or shocks,
- Floor resistant to the load caused by the weight of the unit,
- Place the rear panel of the unit at least 16 cm from the wall where the mains supply socket is located
- Failure to observe these instructions may result in the unit falling over, or cause damage to the floor, or serious injury.

Do not try to move the consultation unit alone; there is a risk of injury, damage to the unit and to the medical equipment installed on the examination tray.

This unit complies with the European Directive 93/42/EEC amended by Directive 2007/47/EEC relating to medical devices. It is declared to be in conformity with the EN 60601-1 and 60601-1-2 standards to ensure basic safety and reasonable protection against harmful interference occurring in a typical medical installation. It the user's responsibility to use this unit in compliance with the safety standards in force.

2.2 ELECTRICAL CONNECTION

PRECAUTION

Be sure to use a wall socket complying with the specific requirements for the power supply. Use of a non-compliant wall socket may cause malfunctioning or partial operation of the unit. In addition, if the wall socket is not fitted with an earth terminal there is a risk of electric shock in the event of current leakage.

Insert the power supply plug fully into the wall socket. Unstable connection could cause a fire.
Access to the power plug must be possible and easy once it is connected.
Before changing wear parts, disconnect the power cable from the electricity supply.
If the consultation unit is not to be used for a prolonged period of time or when wear parts need to be replaced, disconnect the power cable from the wall socket. Otherwise, there is a risk of fire.

Grasp the plug to disconnect the power cable. If you pull on the power cord, the metal core of the cable may break and cause a short circuit or electric shocks.

Do not place heavy objects on the power cable or trap it. The power cable sheath may wear; this could cause a fire or electric shocks.

If the metal core of the power cable is stripped, if the consulting unit turns on and off when the power cord is moved, or if the cable or the plug are so hot that they cannot be touched, the power cable is damaged. Contact your authorized dealer immediately for the replacement of the cable. Otherwise, there is a risk of electric shocks or fire.

From time to time, clean between the pins of the power supply plug with a dry cloth. If dust collects there, it may absorb moisture and cause a short-circuit or a fire.

Note: Connecting electrical appliances to the multiple socket in the unit may result in the creation of an electro-medical system

2.3 PRECAUTIONS FOR USE

PRECAUTION

Never use the consultation unit for purposes other than those for which is intended. NIDEK cannot be held responsible for any accident or malfunction due to inappropriate use.

Do not dismantle and never touch the internal structure of the consultation unit. There is a risk of electric shocks or fire.

If a failure of the consultation unit cannot be resolved by the replacement of a fuse or resetting of the circuit breaker, do not intervene on the electrical circuits of the unit. Disconnect the power cable from the wall socket and contact your authorised distributor.

2.4 CRITICAL INCIDENT REPORT

If a critical incident occurs with your stand, you should report it to Nidek SA and to the competent authority of the Member State in which you are established.

Note: By reporting incidents, you contribute to providing more information about the safety of this unit

2.5 END-OF-LIFE DISPOSAL

Electrical and electronic equipment contains polluting materials (electronic cards, capacitors, etc.).
Their decontamination and recycling help to preserve natural resources.

ATTENTION: At the end of the useful life of your consultation unit, do not throw it away with household waste. This unit is required to be collected and disposed of in a selective manner.
In order to fulfil its obligations under the EU Directive 2012/19/EU on waste electrical and electronic equipment, NIDEK is a member of Ecosystem2 and finances the recycling channel for professional electrical waste (WEEE pro)

For specific information on disposal in other countries, please contact your distributor or consult local regulations for disposal of electronic products.

2.6 LABELLING

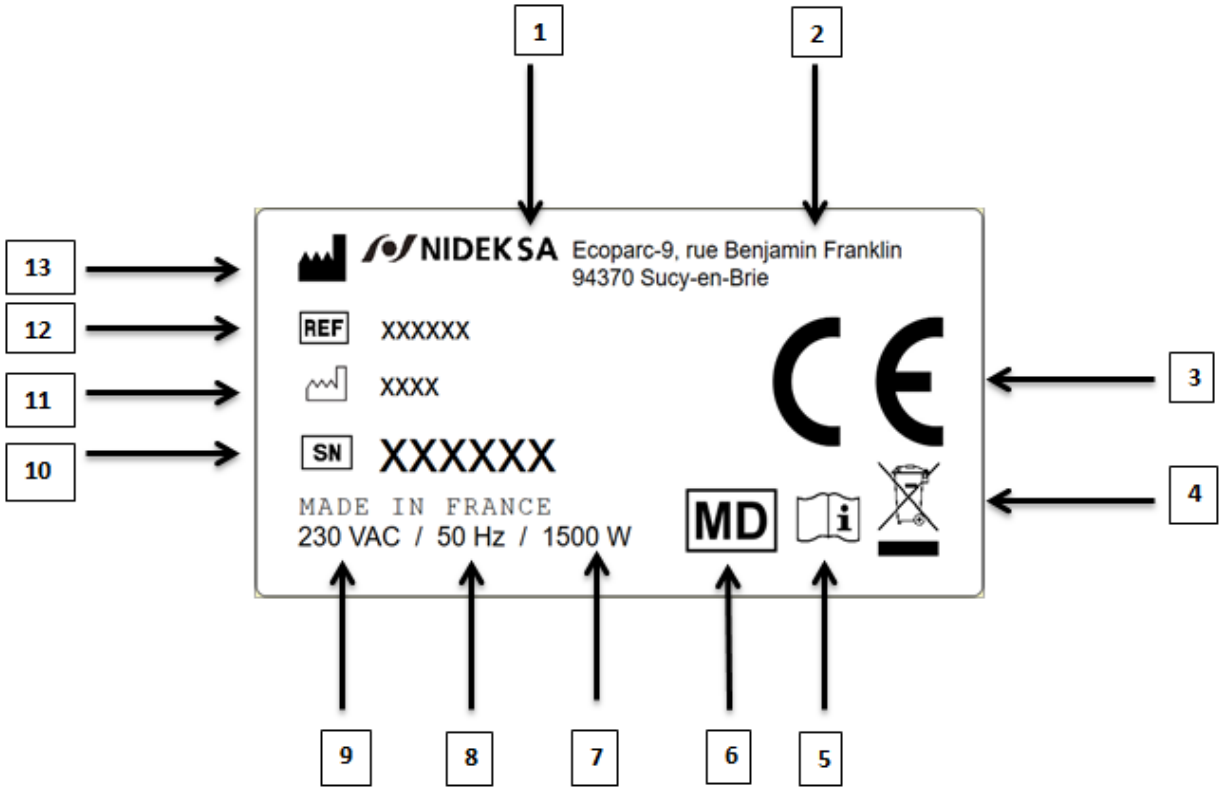
2.6.1 Indication plates

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

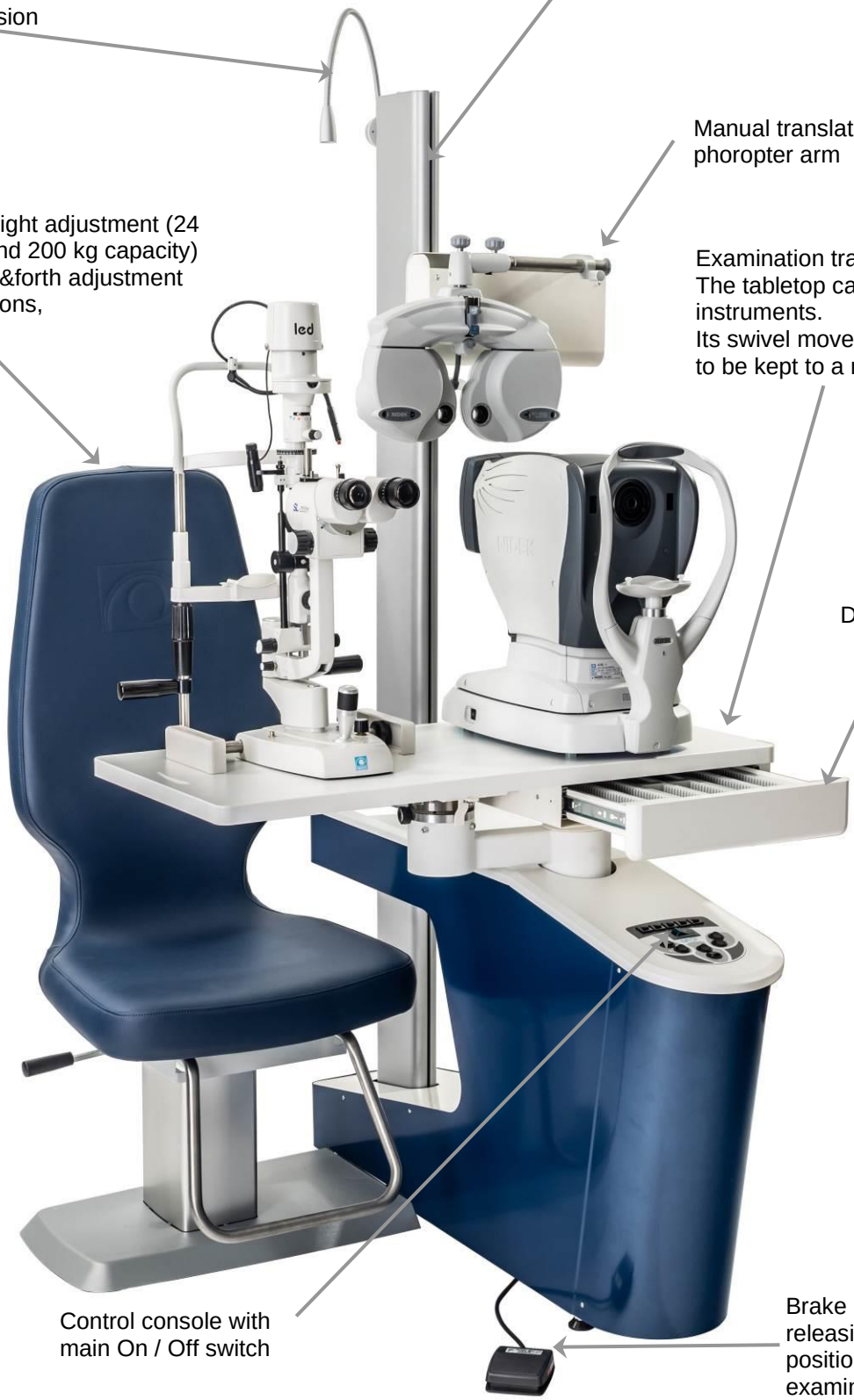
The following label and indications are affixed to the unit to draw the operator’s attention.



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[1] 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

[1] EEE: Electrical and Electronic Equipment

3 DESCRIPTION OF THE UNIT



4 USE

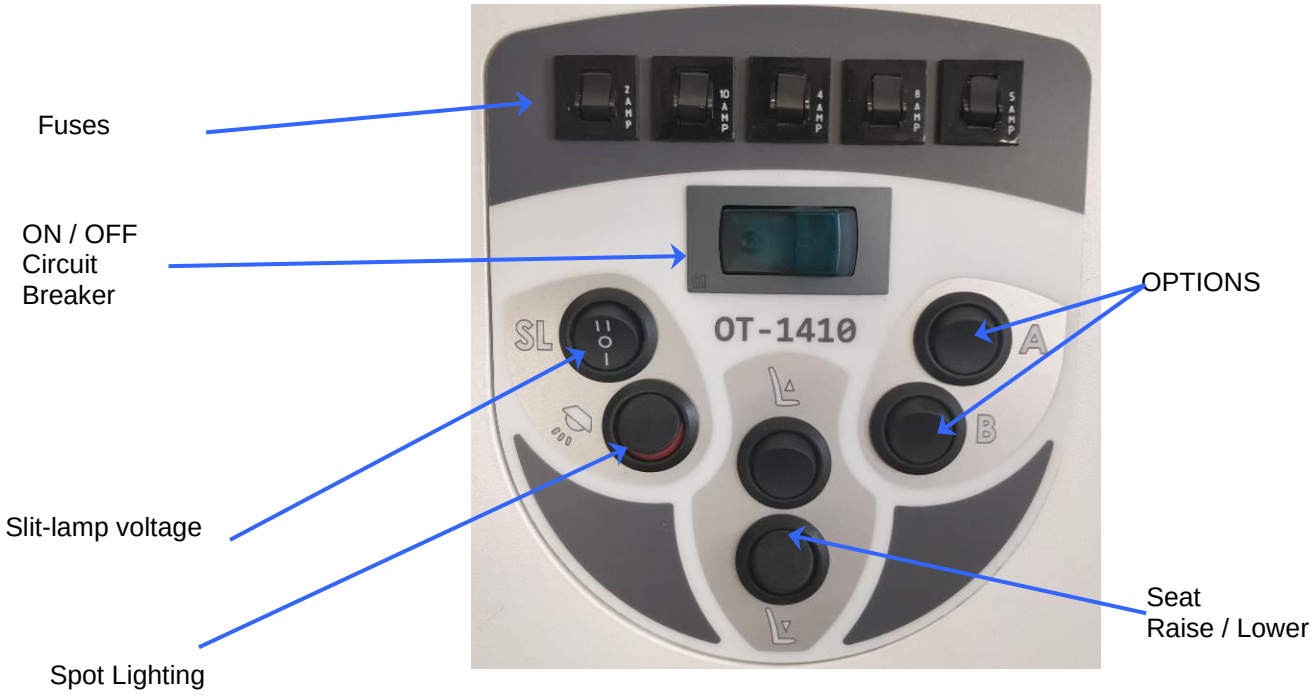
4.1 SWITCHING ON

First, the unit must be properly connected to a power source (see § 2.2 "Connection of the unit to a wall socket"). The thermal circuit breaker (located on the console) must be set to the "I" position: its green light goes on.

4.2 SWITCHING OFF THE UNIT

Remember to switch your unit off at the end of every day by positioning the thermal circuit breaker (located on the console) on the "O" position. The green circuit breaker light is off.

4.3 USE OF THE CONTROL CONSOLE



Attention, during examinations, movements likely to cause danger (raising / lowering the seat) are controlled by continuous pressure and under the constant supervision of the practitioner.

Means of stopping movement
- In a normal situation: release the movement control,
- In an "abnormal" situation: you can switch off the power supply to the motors at any time by pressing the main switch located nearby on the control console

4.4 USE OF THE BRAKE PEDAL

As soon as the voltage is switched on to your unit the examination tray will be locked.
During a consultation, press the pedal to release the tray and position your appliance in front of the patient, then release it once in position.
Repeat this operation for your 2nd appliance following the direction of the arrows on the tray.

5 MAINTENANCE

If the consultation unit does not operate normally, perform the checks below before requesting assistance from your authorised distributor.

If these corrective actions do not solve the problem, contact NIDEK or your authorised distributor.

5.1 TROUBLESHOOTING GUIDE

Illumination	Corrective actions
✦ Nothing works: ✦ The unit does not light ✦ The green main switch light is off.	✦ Press the "On / Off" button ✦ The power cable is not properly connected. Check its connection. ✦ On your electrical table, check the fuse of the electrical socket to which the unit is connected.

Seat column	Corrective actions
✦ The examination seat does not move up or down	✦ Contact your authorised distributor.

Slit-lamp	Corrective actions
✦ The slit-lamp does not light, but all the rest works	✦ Check the bulb of the appliance. ✦ Check the power connector of the SL

Tray appliances	Corrective actions
✦ A device powered by 230V on the tray does not work	✦ Check that it is in the "ON" position ✦ See the instruction manual for the appliance.

Brake pedal	Corrective actions
✦ The tray is free when the unit is switched on.	✦ Check if a fuse does not need to be reset, Otherwise contact your authorised distributor.
The pedal no longer releases the tray when you press it	Contact your authorised distributor.

If the above actions have not succeeded in solving the problems, contact your authorised distributor.

5.2 MAINTENANCE & CHECKS

Check the condition of the stand daily. Check the following :
- Control panel (visual check),
- Proper operation of the various movements.

In case of a problem, you can refer to paragraphs 5.1 "Troubleshooting guide". If problem continue, please contact Nidek or your authorised distributor

Note: Apart from these recommendations, only NIDEK or your authorised distributor is authorised to repair or dismantle the stand. NIDEK cannot be held responsible for any accident due to incorrect service

5.3 CLEANING

PRECAUTION

Clean your stand daily with a soft dry cloth. For stubborn stains,use a cloth soaked in a neutral detergent , wringing it out first. Rinse the surfaces with a cloth dampened with clean water to avoid premature hardening and cracking. Finally wipe with a soft, dry cloth.
For cleaning appliances placed on the unit, refer to their own instructions.

CAUTION: Products containing components such as Quaternary Ammonium should not be used to avoid any damage to the plastic materials. Never use organic solvents such as paint thinner or abrasive detergent to clean the external parts. The appearance of the stand may be irreparably damaged.

5.4 SPARE PARTS LIST

The LyPop consulting unit is fitted with manual resetting fuses: So there are no fuses to change.

6 TECHNICAL SPECIFICATIONS

6.1 EC CLASSIFICATION

Rule 12 of the classification described in Appendix IX of Directive 93/42/EEC modified by directive 2007/47/EEC defines that the LyPop is a Class I medical device.

Protection against electric shocks
As a Class 1 device, the LyPop consultation unit provides protection against electric shocks and, in addition to the basic insulation, includes additional safety earthing of accessible conductive parts of the fixed wiring.

Mode of Operation
This LyPop consultation unit is classified in continuous operation.

6.2 ELECTROMAGNETIC COMPATIBILITY

Manufacturer's Declaration - Electromagnetic Emissions
This device is intended to be used in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

N.A *: Non Applicable* ***N.R*** *: Non Réalisé* ***N.D*** *: Non Demandé*

Type d'essai	Norme	Spécifications	Respect des exigences
Emissions Rayonnées	CISPR 11 classe B	**Accès par l'enveloppe:** Groupe 1 Classe B à 10m → 30 MHz – 230 MHz = 30 dBµV/m → 230 MHz – 1 GHz = 37 dBµV/m	**OUI**
Emissions conduite	CISPR 11 classe B	**Entrée d'alimentation a.c :** 240Vac / 50Hz Limits : Group 1 Class B **0,15 MHz à 0,5 MHz :** → 66 à 56dBµV QP / 56 à 46dBµV AV **0,5 MHz à 5 MHz :** → 56dBµV QP / 46dBµV AV **5 MHz à 30 MHz :** → 60dBµV QP / 50dBµV AV	**OUI (1)**
	CEI 60601-1-2: 2014	**Câble couplé au patient:** Annexe H (informatif) **1-30MHz:** 24dBµA	**N.A**
Harmoniques 50Hz	CEI 61000-3-2	Accès 230Vac 50Hz: Limite Classe **A**	**OUI**
Fluctuations de tensions (Flickers)	CEI 61000-3-3	Accès 230Vac 50Hz: PST < 1 PLT < 0.65	**OUI**

(1) Conforme, avec modifications – Voir chapitre 2.1

Pour déclarer la conformité, il a été tenu compte de l'incertitude associée au résultat

Manufacturer's Declaration - Electromagnetic Immunity

This appliance is intended to be used in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

***N.A** : Non Applicable* ***N.R** : Non Réalisé* ***N.D** : Non Demandé*

Norme d'essai	Spécifications	Verdict
Décharges Electrostatiques CEI 61000-4-2	**Accès enveloppe et accès couplé au patient:** ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	**OUI** **OUI** Critère **A**
Champs électromagnétiques rayonnés aux fréquences radioélectriques CEI 61000-4-3	**Accès enveloppe :** 80 MHz to 2.7 GHz : 3 V/m 80 % AM at 1 kHz, 1%	**OUI (10V/m)**
Proximity fields from RF Wireless communications equipment CEI 61000-4-3	**Accès enveloppe:** **Spots de fréquence:** Tableau 9 de la norme et § 3.2 Pulse modulation or MF as band	**OUI**
Transitoires électriques rapides en salves CEI 61000-4-4	**. Alimentation AC :** ± 2 kV (100kHz) / 240Vac @50Hz **. Alimentation DC :** ± 2kV (100kHz) **. Accès Signaux**: ± 1kV (100kHz)	**OUI** **N.A** **N.A** Critère **A**
Ondes de choc CEI 61000-4-5	**. Alimentation AC:** 240Vac @50Hz ± 0.5 kV, ± 1 kV, ± 2 kV phase et Terre ± 0.5 kV, ± 1 kV entre phases **. Alimentation DC :** ± 0.5 kV, ± 1 kV, ± 2 kV phase et Terre ± 0.5 kV, ± 1 kV entre phases **. Accès Signaux**: ± 2kV	**OUI** **OUI** **N.A** **N.A** **N.A** Critère **A**
Perturbations RF Conduites CEI 61000-4-6	150kHz - 80MHz: 3V - AM 80%, à 1kHz, 1% Bande ISM Bande radioamateur **. Alimentation AC:** 240Vac @50Hz **. Alimentation DC** **. Accès couplés au patient** **. Accès Signaux**	☑ ☑ ☑ Critère **A** **OUI** **N.A** **N.A** **N.A**
Champ magnétique 50Hz CEI 61000-4-8	**Accès enveloppe:** Niveau : 30 A/m (50Hz)	**OUI** Critère **A**
Coupures et creux de tension d'alimentation CEI 61000-4-11	**Alimentation AC:** 240Vac @50Hz • 0 % U_T; 0,5 cycle à 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° • 0 % U_T; 1 cycle - Single phase: à 0° • 70 % U_T; 25 cycles - Single phase: à 0° • % *Ur*; 250 cycles	**OUI (Crit A)** **OUI (Crit A)** **OUI (Crit A)** **OUI (Crit C)**

Pour déclarer la conformité, il a été tenu compte de l'incertitude associée au résultat

Critère A : Pas de mouvements intempestifs
Critère B : A définir par le fabricant
Critère C - Perte d'aptitude admissible : Reset accepté (CEI 61000-4-11).

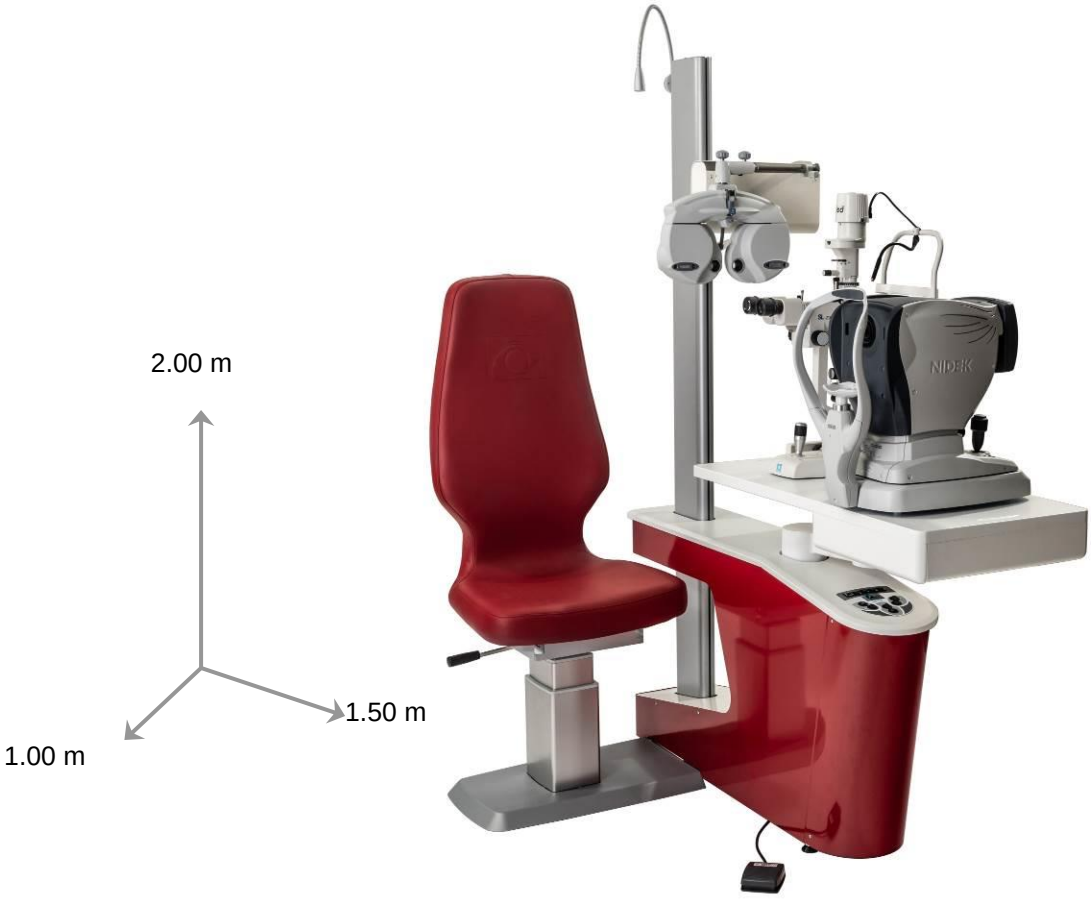
6.3 GENERAL CHARACTERISTICS

Approximate net weight	120 kg (without appliances)
Electricity supply	230 VAC / 50 Hz / 1000 W
Tabletop	Fixed height (85 cm from the floor) Maximum load on the tray 50kg (2x25kg)
Phoropter	Refractor on a manual translation arm The height of the refractor eye is the same as that of the appliances placed on the tray.
Trial lenses	Option: drawer with tray for 236 test lenses
Examination seats	Electric height adjustment (38 - 62cm) Maximum load 200 kg A foot rest and anterior posterior adjustment are available as options,

6.4 ELECTRICAL DIAGRAM

The electrical diagram for your unit is included with the product.

6.5 DIMENSIONS



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