NIDEK

OT–6400

Refraction UNIT

USER'S MANUAL

CE

THE ART OF EYE CARE

NIDEK

Before use or maintenance, read this user's manual

This manual contains information necessary for the use of the NIDEK OT-6400 consultation unit: operating procedures, precautions for use, specifications and maintenance instructions.

This user manual is essential to ensure the unit is used properly.

The device is intended for health care professionals; the precautions for use and the methods of use must be fully understood before using the unit. Keep the manual handy for reference.

This consultation unit contains no user-replaceable parts. Therefore, if you have any problems or questions, please contact NIDEK or your authorized dealer.

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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CONTENTS

1. THE OT-6400 RANGE

1.1. INTENDED USE OF THE CONSULTATION UNIT

The OT-6400 is a rotating consultation unit that enables refractive examination to be performed. This device avoids the practitioner or the patient needing to move by adapting the position of the ophthalmology instruments (manually or electrically). It is intended for use by vision health professionals, including ophthalmologists, optometrists, orthoptists, opticians and nurses.

The motorized travel and tilting arm of the phoropter is attached to a stand of which the height is adjusted at the same time as that of the tabletop and which guarantees a constant eye height between the devices.

The OT-6400 is available as a 3 or 4-shelf instrument carrier, with a fixed or inclining seat and a light column supporting the test projector.

1.2. PRESENTATION OF THE VERSIONS

"Lacquered" OT-6400
A small desk
Examination chair with adjustable backrest
3 instruments plus the tilting pivot arm phoropter
1 refraction bin with storage for 232 test lenses
1 lighting column matching the colour of the unit

2. SAFETY INSTRUCTIONS

The following safety precautions must always be observed. The CAUTION logo is used to draw attention to a potentially hazardous situation that, if not avoided, may result in minor or severe injury or material damage. Follow CAUTION instructions strictly.

2.1. CAUTION INSTRUCTIONS CONCERNING THE INSTALLATION

CAUTION

Only NIDEK or your authorized dealer is authorized to install the consultation unit. Otherwise NIDEK cannot be held liable for accidents due to incorrect installation.

Install the consultation unit in a place that is never exposed to water. Water entering the internal structure of the unit can cause an electric shock or a malfunction.

The installation of the consultation unit must be performed under the following conditions:

- Low dust,
- Flat floor, with no ripple greater than 5 mm,
- Stable floor, not subject to vibrations or shocks,
- Floor capable of withstanding the load exerted by the weight of the unit,
- Position the rear panel of the unit at least 16 cm from the wall where the power socket is located.

Failure to follow these instructions may result in the unit falling over, damage to the floor, and cause serious injury.

Do not attempt to move the consultation unit, as there is a risk of injury, damage to the unit, and damage to the medical devices installed on the examination tabletop. Contact NIDEK or your authorized dealer for service by a NIDEK technician.

The OT-6400 consultation unit is declared to comply with EU Regulation 2017/745 concerning medical devices as it has been tested and declared to comply with EN 60601-1 and 60601-1-2 to ensure basic safety and reasonable protection against harmful interference occurring in a typical medical installation.

It is the user's responsibility to use this unit in accordance with the safety standards in force.

2.2. ELECTRICAL CONNECTIONS

CAUTION

Make sure you use a power socket that meets the specific requirements for the power supply. If this is not the case, the appliance may not work to the best of its capabilities. The mains socket must be earthed, otherwise there is a risk of an electric shock in the event of current leakage.

Insert the supply plug fully into the power socket. An unstable connection may cause a fire. Once the plug is connected, it should be easily accessible.

Before changing any wear parts or if the consultation unit is not used for an extended period of time, disconnect the power cable from the wall socket to avoid a fire hazard. To do this, grasp the plug to disconnect the power cable. Do not disconnect the plug by pulling on the power cable, otherwise the metal core of the power cable may break and cause a short circuit or electric shock.

Do not place heavy objects on the power cable or trap it. The power cable sheath may wear, causing a fire or electric shock.

If the metal core of the power cable is exposed, if the consultation unit turns on and off when the power cable is moved (there is a poor connection), or if the power cable or plug is so hot that it cannot be held, then the power cable is damaged. Contact NIDEK or your authorized dealer to replace the cable immediately to avoid the risk of an electric shock or fire.

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

Note: Connecting electrical devices to the multi-socket base in the unit can result in the creation of an electro-medical system.

2.3. PRECAUTIONS FOR USE

CAUTION

Never use the consultation unit for purposes other than those intended. NIDEK will not be liable for any accident or malfunction caused by misuse.

Never disassemble or touch the internal structure of the consultation unit. There is a risk of electric shock or malfunction.

If a fault in the consultation unit cannot be resolved by resetting the circuit breaker, do not try to work on the electrical circuits of the unit. Unplug the power cable from the wall socket and contact NIDEK or your authorized dealer.

Be careful, the initialization phase at start-up must be carried out without anyone around the table or on the chair. Unlike normal operation where movements are controlled by continuous pressure on the control and under the supervision of the practitioner, during initialization these movements are automatic, and you must ensure that no obstacles can cause collisions that could damage the equipment or cause injury.

Be careful during examinations, movements are controlled under the constant supervision of the practitioner. You must always make sure that no obstacle can cause collisions that could damage the equipment or cause injury.

The means to stop movement are:

- In a normal situation during a movement by controlled by continuous pressure on the control, release the control.
- In an abnormal situation, i.e. if part of the consultation unit comes into contact with a person or an object, the anti-collision systems stop the movement, even if the pressure on the control is maintained.
- In an emergency, you can also switch off the power supply to the motors at any time by pressing the "on/off" key on the control panel.

Please note that the USB port located on the side of the console is intended for updating the unit's electronic board in association with NIDEK, it cannot be used for charging devices (smartphone, tablet, etc.). Otherwise, there is a risk of hazardous situations that could cause a risk to human health or damage equipment or goods.

Devices connected to the table must be Class I or Class II. If they are Class I they must be earthed.

2.4. SERIOUS INCIDENT DECLARATION

If you consider that a serious incident has occurred in connection with the unit, that incident must be notified to NIDEK SA and the competent authority of the Member State in which you are established. In France, for example, this notification can be made via the national system of reporting to the National Agency for the Safety of Medicinal and Health Products[1].

Note: By reporting incidents, you help provide additional information about the safety of the unit.

2.5. END-OF-LIFE DISPOSAL

Electrical and electronic equipment contains polluting materials (electronic boards, capacitors, etc.). Their depollution and recycling helps to preserve natural resources, particularly strategic raw materials.

WARNING: At the end of the useful life of your consultation unit, do not dispose of it with household waste. This unit must be collected and eliminated selectively.

In order to fulfil its obligations under the European Directive 2012/19/EU on waste electrical and electronic equipment, and to enable the appropriate reuse and recycling of parts, NIDEK adheres to the

[1] ANSM – See the website www.ansm.fr

Ecosystem[2] and finances the approved collection and recycling system for professional electrical waste (WEEE Pro). This allows you to dispose of your consultation unit at the end of its life free of charge.

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

2.6. LABELLING

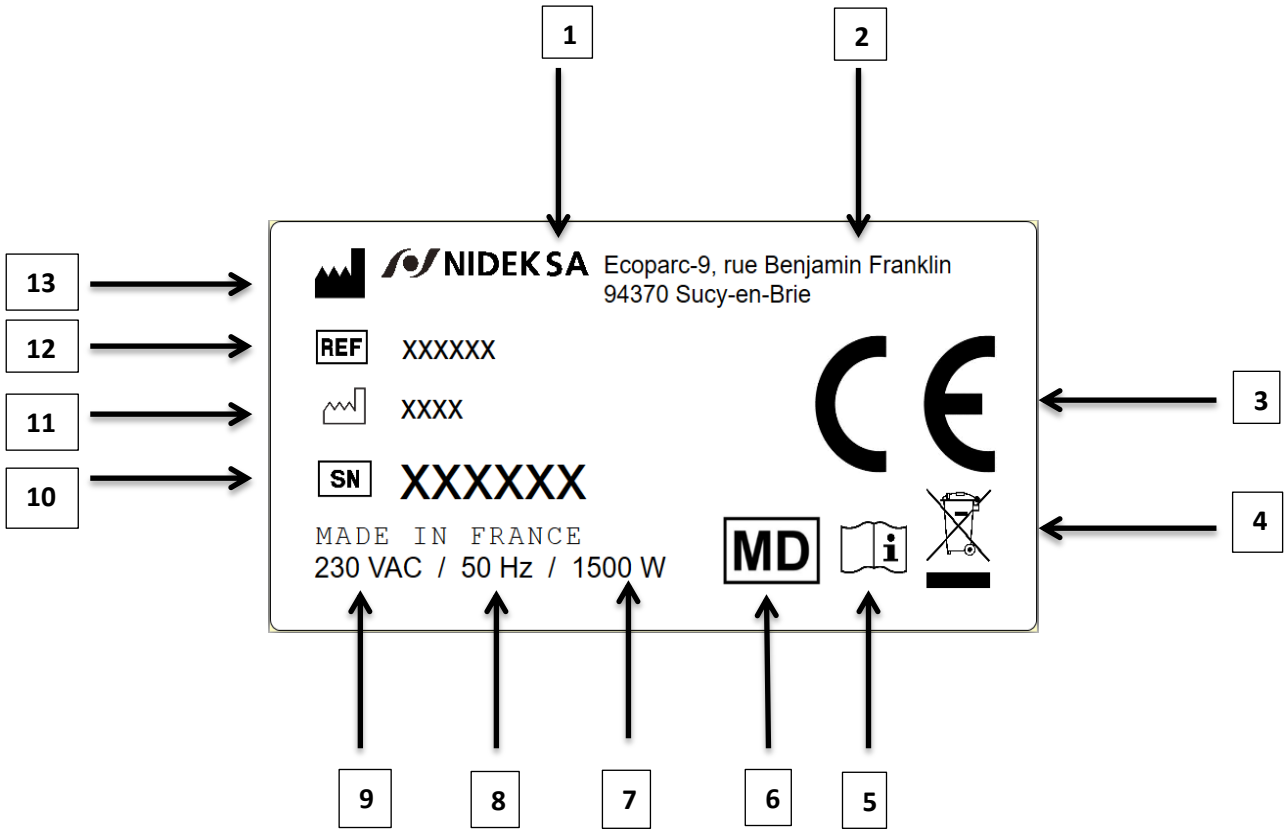
2.6.1 Indication plates

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

[2] 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

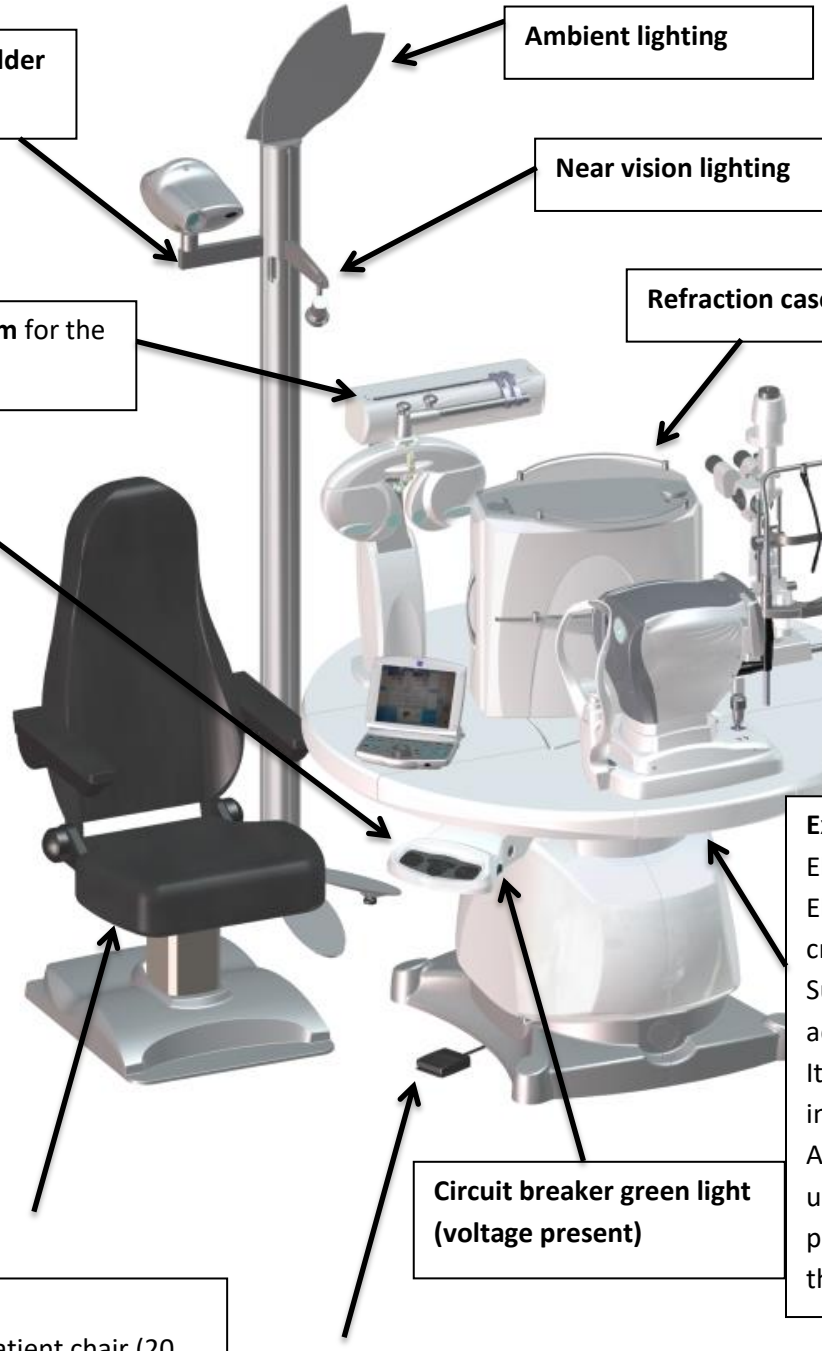
12 product reference

13 Manufacturer

[3] EEE: Electrical and Electronic Equipment

NIDEK

3. DESCRIPTION OF THE UNIT



Test projector holder

Ambient lighting

Near vision lighting

Refraction case

Electric travel arm for the phoropter

Instrument shelf

Control console

Examination tabletop
Electric rotation,
Electrically adjustable height over 18 cm (75 to 93 cm)
Suitable for testing children and adults
It can accommodate up to 4 instruments plus the phoropter
A safety device, built into the underside of the instrument shelves, prevents crushing if in contact with the patient's legs.

Circuit breaker green light (voltage present)

Examination chair
Electric -elevated patient chair (20 cm adjustment and 200 kg force)
One model available: FE-3001 with manual reclining (height adjustable from 45 to 65 cm)

Brake pedal
Blocking and antero-posterior adjustment of the

NIDEK

4. OPERATION

4.1. SWITCHING THE UNIT ON

First of all, the unit must be properly connected to a power source (see *§ 2.2 "Connecting the Unit to a power socket").* The thermal circuit breaker (located on the side of the control console) must be set to position "I": Its green LED and the blue "ready" LED on the console light.

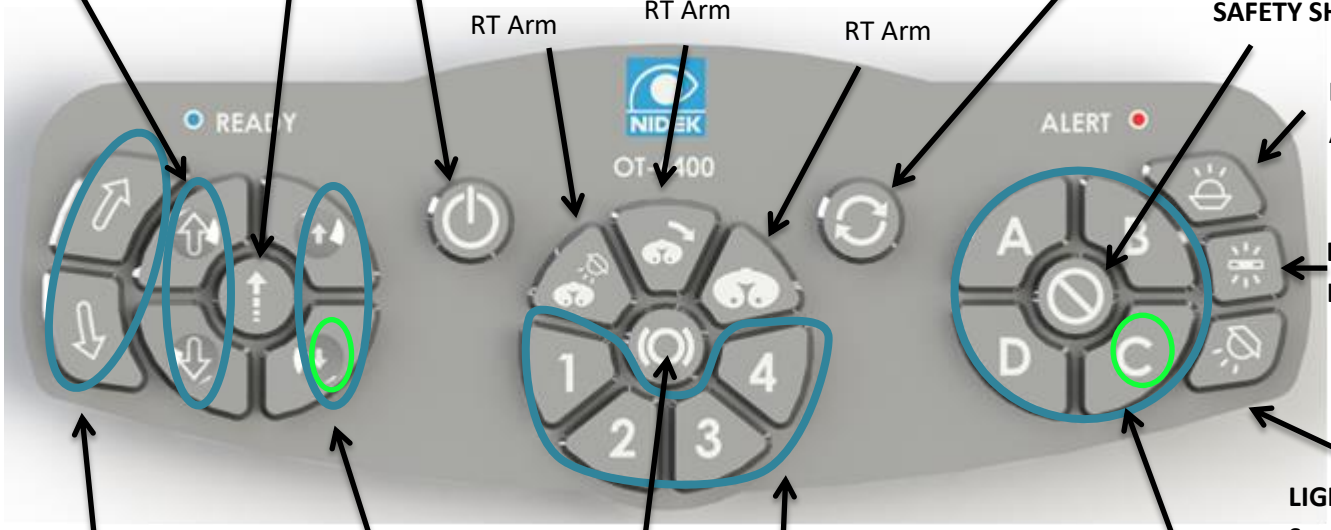
The tabletop initializes and returns to position 1 and/or to the high position and the seat automatically descends to the low position.

Note: That initialization is programmable using the smartphone downloadable application (see "*OT-6400 Application User Manual*").

4.2. SWITCHING THE UNIT OFF

Remember to switch off your unit daily by switching the thermal circuit breaker (located on the side of the desk) to the "O" position: The blue "ready" LED and the green LED on the circuit breaker go off.

4.3. USING THE CONTROL CONSOLE



SEAT
Automatic rise

TABLE
Raise/lower

ON / OFF

LIGHTING
RT Arm

TILT
RT Arm

EXIT*
RT Arm

INITIALIZATION

SAFETY SHUNT

LIGHTING
Ambient

LIGHTING
Locker

LIGHTING
Spot

ELECTRIC ANTERO-POSTERIOR ADJUSTMENT OF THE TABLETOP
This allows the tabletop to be electrically rotated slowly to perform antero-posterior adjustment

SEAT
Up/down

BRAKE

ELECTRIC ROTATION
Calling devices according to their position on the tabletop.

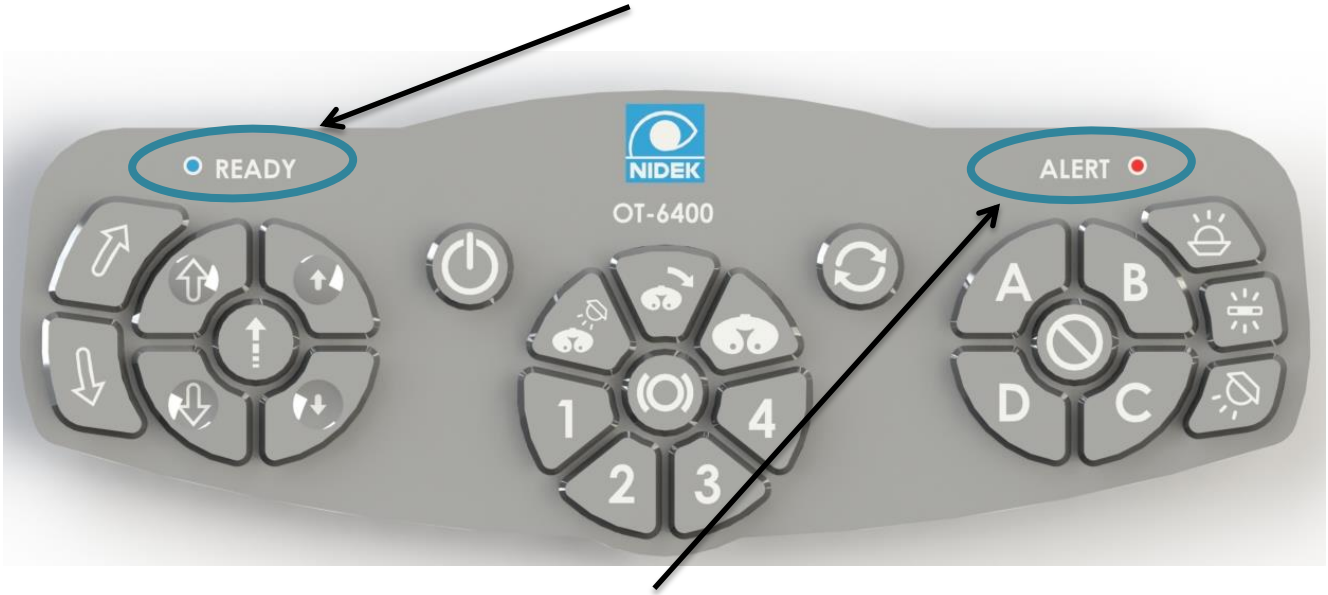
OPTION CONTROLS
Each one allows you to control a bell or a remote control switch

MEMORISATION OF THE PREFERRED TABLETOP HEIGHT :
Press "seat down" and "option C" simultaneously for 8 seconds: The "ready" LED flashes 3 times to confirm the save.

"READY"

The LED is on continuously: The unit is in operating condition

The LED flashes: The unit is in the initialization state



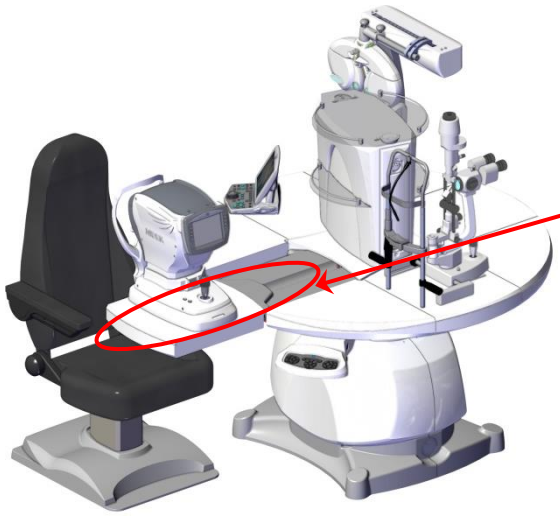
"ALERT"

The LED flashes slowly: The safety systems are activated

The LED flashes rapidly: They are shunted

4.4. SAFETY DEVICE

A safety device, built into the underside of the instrument shelves, prevents crushing in case of contact with the patient's legs.



Raise/lower safety device

In case of contact with the patient's legs, this device stops the upward movement of the seat and the downward movement of the tabletop.

5. MAINTENANCE

CAUTION: Before carrying out any maintenance or wear part changes, disconnect the power cable (unless indicated otherwise).

5.1. TROUBLESHOOTING GUIDE

If the consultation unit does not operate normally, perform the following checks before contacting NIDEK or your authorized dealer.

5.1.1. Fault diagnosis

Switching on	Checks / Corrective action
Nothing works	Press the "ON / OFF" button
The unit does not turn on	The power cable is not connected properly. Check its connection.
The green light on the main circuit breaker is off	On your electrical panel, check the fuse supplying the electrical socket to which the unit is connected.

Installation	Checks / Corrective action
The green light on the main circuit breaker is on The unit does not initialise The "ready" LED flashes and the "alert" LED is on	Check that the near vision rod is raised against the RT cell. Make sure the tabletop drawer is closed.

Raise/lower safety device	Checks / Corrective action
The examination tabletop moves up but not down	Check that nothing is activating the raise/lower safety devices under the tabletop.
The chair moves down but not up	Check that nothing is activating the raise/lower safety devices under the tabletop.

Seat column	Checks / Corrective action
The chair does not move down or up	Contact your authorized dealer.

Slit lamp	Checks / Corrective action
The slit lamp does not light although everything else works	Check the bulb. Refer to the instructions for the device.

Tabletop devices	Checks / Corrective action

Only one 230V powered device on the tabletop does not work.	Check that it is in the "ON" position. Refer to the instructions for the device.

If the actions in the table above do not solve the problem(s), contact NIDEK or your authorized dealer.

5.1.2. Fault resolution

Below are a number of failures that can occur with the associated remedies:

- Tabletop and seat up/down movement

• The seat does not move up (but can still move down)

And/or

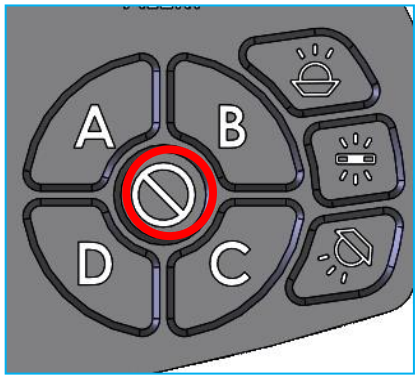
• the tabletop does not move down (but can still move up)

And/or

While waiting for repair by NIDEK or your authorized dealer, you can use your unit in degraded mode.

In the event of a failure, you can temporarily deactivate the safety devices and some motors: The seat and table can still be raised and lowered **by sustained, pressure on the control and under the constant supervision of the practitioner**.

To switch to degraded mode, the press the "SAFETY SHUNT" button on the control panel for 5 seconds (see the illustration below). The red "alert" LED will then flash rapidly. The seat and table can be raised and lowered again.



WARNING: This operation should only be used as a last resort and for a limited time. It requires very careful handling of the table. Call a NIDEK technician to repair the product.

5.2. MAINTENANCE AND CHECKS

Check the condition of the consultation unit daily. Perform the following checks:

- Control panel (with the naked eye),
- Operation of the various movements.

In the event of a fault, contact NIDEK or your authorized dealer.

In the event of a failure, you can refer to § *5.1 "Troubleshooting Guide"* and *§ 5.4 "Spare Parts List"*.

Note: With the exception of these recommendations only NIDEK or your authorized dealer is authorized to repair or dismantle the consultation unit. NIDEK cannot be held liable for an accident due to incorrect after-sales service.

5.3. CLEANING

CAUTION

Clean your unit daily with a soft dry cloth. For heavy-duty tasks, use a cloth soaked in a neutral detergent[4] and wrung out. Rinse surfaces with a damp cloth soaked in clean water to prevent premature hardening and cracking. Finally, wipe with a soft dry cloth.

To clean the devices placed on the unit, refer to their instructions.

WARNING: Products with components such as quaternary ammonium should not be used to avoid their negative effects on plastics. Never use organic solvents such as paint thinners or abrasive detergents to clean external parts. The finish on the consultation unit may be irreparably damaged.

5.4. SPARE PARTS LIST

The OT-6400 consultation unit is equipped with self-resetting fuses, so there are no fuses to change.

This unit has no wear parts requiring periodical replacement. Consequently no spare parts need to be stocked.

5.5. USB FLASH DRIVE

A USB flash drive containing the original program for your OT-6400 is located in the centre box of the unit against the front of the drawer. **It is essential** not to use this key for personal use or

[4] Neutral detergent: a detergent with a neutral pH (between 6 and 8). This will not damage the surfaces of the consultation unit. Follow the dosage recommended by the manufacturers of the detergents or disinfectants.

to connect it to another device. It can be used when working with a NIDEK technician or via the Hotline.

6. CHARACTERISTICS AND TECHNICAL INFORMATION

6.1. CE CLASSIFICATION

Rules 1 and 13 of the classification described in Appendix VIII to EU Regulation No. 2017/745 concerning medical devices define that OT-6400 is a Class I medical device.

Protection against electric shocks: As a Class I device, the OT-6400 consultation unit provides protection against electric shocks. In addition to the basic insulation, it includes additional safety devices for earthing the conducting parts of the accessible fixed wiring.

Operating mode: This OT-6400 consultation unit is classified for continuous operation.

6.2. ELECTROMAGNETIC COMPATIBILITY

The consultation unit can be used in shops or hospitals, except in the vicinity of active HF surgical equipment and RF protected rooms with ME systems for Magnetic Resonance Imaging where the intensity of electromagnetic interference is high.

CAUTION

Do not use the unit near, on, or under any other electronic device outside the intended operating conditions. There is a risk of abnormal operation. If such use is necessary, the device and other equipment must be checked to ensure normal operation under the conditions intended.

Use of accessories or cables other than those supplied by the manufacturer of the unit (there are no approved cables for using the unit) may result in increased electromagnetic emissions or decreased electromagnetic immunity of the unit and may result in malfunction.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) must not be used within 30 cm of any part of the unit. This could cause a reduction in the performance of the unit.

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

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 (1)
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 (2)
	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) Compliant, sport led light OFF and with modifications
(2) Compliant, with modifications

Manufacturer's Declaration – Electromagnetic Immunity
This device is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.

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 : 10 V/m 80 % AM at 1 kHz, 1%	 OUI Critère A
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 Critère A
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 B
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 OUI
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° • % U_T; 250 cycles	 OUI (Crit A) OUI (Crit A) OUI (Crit A) OUI (Crit C)

Criterion A: Movement tolerance: +/- 2 mm

Rotation tolerance: +/- 3°

Criterion B: The appliance may be disturbed during electromagnetic tests, but dangerous situations should not be encountered (cf. Risk Analysis)

Criterion C – Allowable loss of capacity: Reset accepted (IEC 61000-4-11)

6.3. TECHNICAL SPECIFICATION

- General specifications:

Approximate net weight	250 kg *(without appliances or desk)*
Power supply	230 VAC / 50 Hz / 1500 VA
Tabletop	Electrically adjustable height from 75 to 93 cm with memory of the preferred height 3 motor-driven instrument shelves and 1 drawer or motor-driven instrument tabletop **Maximum load**[5] on tabletop: 40 kg per instrument
Rotation	Declutchable electric (with soft start and stop)
Phoropter	Phoropter on a pivoting arm with motorized tilt and travel The eye height of the phoropter is the same as that of the devices on the tabletop
Storage cabinet	Several optional furniture models: • Desk with a 4-drawer cabinet
Examination chair	Height electrically adjustable from the control panel (45–65 cm) Maximum load: 200 kg / patient height between 120 and 200 cm Model available: • FE-3001 Options: • 360° rotation • Lift-up armrests • Footrest • Antero-posterior adjustment

[5] **WARNING:** If the maximum permissible weight on the tabletop is exceeded, there is a risk of damage to the device as well as a risk for the patient. It is important not to exceed this maximum load.

- Environmental conditions for transport and storage:

Temperature	5 to 50°C (32 to 122°F)
Humidity	10% to 90% *(without condensation)*
Atmospheric pressure	From 700 to 1060 hPa[6]
Maximum storage time	3 months

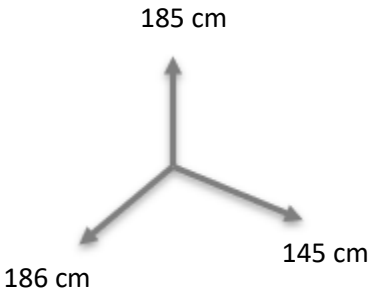
- Environmental conditions for use:

Temperature	10 to 30°C (32 to 122°F)
Humidity	30% to 75% *(without condensation)*
Atmospheric pressure	From 800 to 1060 hPa

Under these conditions of use and with appropriate checks and maintenance, the expected service life of the consultation unit is 10 years from installation.

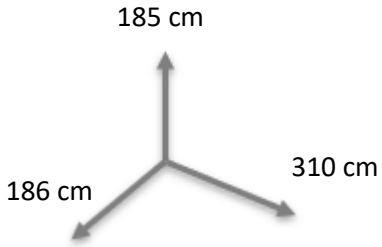
6.4. DIMENSIONS

- OT-6400 alon

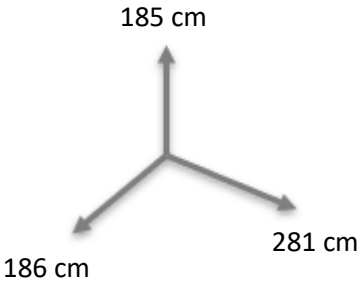


[6] hPa: Hectopascal

- OT-6400 with a large desk



- OT-6400 with a small desk



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