NIDEK

Consultation unit

ONE-I

If you would like to order parts, please feel free to contact us at our online store

For advice and inquiries
please do not hesitate to contact
our after-sales service on 01 49 80 97 97

manual

THE ART OF EYE CARE

Before use or maintenance

read this user's manual

This manual contains all the information need to use the NIDEK ONE-i consultation unit, such as operating procedures, precautions, features and maintenance instructions.

This manual is essential to ensure correct operation of the unit.

This device is intended for use by healthcare professionals, and all and methods of use must be fully understood before using the unit. Please keep it handy for reference.

This units does not contain any user-serviceable parts. Therefore, if you encounter any difficulties or have any questions, please contact NIDEK or your authorized distributor.

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

CE

MANUFACTURER :

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Contents

1 The ONE-i range

1.1 Consultation unit indications

The ONE-i is a consultation unit for refractive examinations. This device eliminates the need for the practitioner and patient to move around, by adapting the position of the ophthalmic instruments to them either manually or electrically. It is intended for use by vision care professionals, including ophthalmologists, optometrists, orthoptists, opticians and nurses.

2 Safety instructions

The safety precautions described below must always be followed. The logo PRÉCAUTION is intended to alert the user to a potentially hazardous situation which, if not avoided, may result in minor or serious injury, or property damage. **Strictly follow the instructions relating to .** PRÉCAUTION

2.1 Installation precautions

PRÉCAUTION

Only NIDEK or your authorized distributor is authorized to install the consultation unit. Otherwise, NIDEK cannot be held responsible for any accident caused by incorrect installation.

Install the consultation unit in a location that is never exposed to water. Water entering unit's internal structure may cause electric shock or malfunction.

The consultation unit must be installed under the following conditions:

- Little dust,
- Flat floor, with no undulations greater than 5 mm,
- Stable floor, not subject to vibration or shock,
- Ground resistant to the load exerted by the mass of the unit,
- Refer to installation manual

Failure to comply with these instructions may result in the unit tipping over, damage to the floor and serious injury.

Do not attempt to move the consultation unit, as this may cause injury, damage to the unit and to the medical equipment installed on the examination table. Please contact NIDEK or your authorized distributor to have the unit serviced by a NIDEK technician.

The ONE-i consultation unit is declared compliant with Regulation (EU) 2017/745 on medical devices because it has been tested and declared compliant 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 compliance with current safety standards.

2.2 Electrical connections

Be sure to use a wall outlet that complies with the specific requirements for the power supply. If this is not the case, the unit may not operate to its full potential . The wall socket must be fitted with a earth terminal, otherwise there is a risk of electric shock in the event of a current leak.

Plug the power supply fully into the wall socket. An unstable plug may cause a fire. Once plugged in, the power plug must be easily accessible.

Before changing any wearing parts, or if the consultation unit is not to be used for an extended period, unplug the power cord from the wall socket to avoid the risk fire. To do this, grasp the plug to unplug the cord. Do not unplug by pulling on the cord, otherwise the metal core of the cord may break, causing a short-circuit or electric shock.

Do not place heavy objects on the power cord pinch it. The power cord sheath may become worn, leading to fire or electric shock.

If the metal core of the power cord is stripped, if the consultation unit switches on and off when the power cord is moved (present a false contact), or if the cord or plug so hot that it cannot be held, then the power cord is damaged. Contact NIDEK or your authorized distributor for immediate replacement of the power cord to avoid risk of electric shock or fire.

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

***Note**: Connecting electrical appliances to the multi-outlet socket in the unit may lead to the creation of an electro-medical system.*

2.3 Precautions for use

Never use the consultation unit for purposes other than those for which it is intended. NIDEK cannot be held responsible for any accidents or malfunctions caused by improper use.

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 intervene on the unit's electrical circuits. Unplug the power cord from the wall socket and contact NIDEK or your authorized distributor.

Please note that the start-up initialization phase must be carried out with no-one around the table or on the chair. Unlike normal operation, where movements these are controlled by continuous pressure and under the practitioner's supervision, during initialization movements are automatic movements and you must ensure that no obstacles can cause collisions that could damage equipment or cause injury.

Please note that during examinations, movements are controlled under the constant supervision of the

practitioner. You must ensure at all times that there are no obstacles in the way of movement that could cause collisions, resulting in damage to equipment or injury.

The means to stop the movements are :

- In normal conditions, in the event of movement by continuous pressure, do not activate the movement control.
- In an abnormal situation, i.e. if a part of consultation unit comes into contact with a person or an object, the various anti-collision systems stop the movement, even if support is maintained.
- In an emergency, you can also switch off motors at any time by pressing the "Start/Stop" button on the control panel.

Please note that the USB port on the rear of the unit is intended for updating the unit's electronic board in agreement with NIDEK, and cannot be used for charging devices (smartphones, tablets, etc.). If this is the case, there is a risk of dangerous situations arising, which could endanger people's health or damage equipment or property.

Caution: do not pull on the bracket supporting the refractor head mechanism. There is a risk of the unit tipping over.

Appliances connected to the table must be either Class I or Class II. If they are Class I, they must be earthed.

2.4 Serious Incident reporting

If you consider a serious incident has occurred in connection with the unit, this incident must be notified to NIDEK SA and to the competent authority of the Member State in which you are established. In France, for example, this notification can be made via the national reporting system to the Agence Nationale de Sécurité du Médicament et des Produits de Santé[1].

Note: *By reporting incidents, you help to provide more information about the safety this unit.*

2.5 End-of-life disposal

Electrical and electronic equipment contains polluting materials (electronic boards, capacitors, etc.). Cleaning them up and recycling them helps preserve natural resources, particularly strategic raw materials.

ATTENTION: At the end of the useful life of your consultation unit, do not dispose of it with household waste. unit required to be collected and disposed of selectively.

In order to meet its obligations under European Directive 2012/19/EU on waste electrical and electronic equipment, NIDEK has joined Ecosystem[2] and finances the approved collection and recycling channel for professional electrical waste (WEEE Pro). This means you can dispose of your consultation unit free of charge.

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

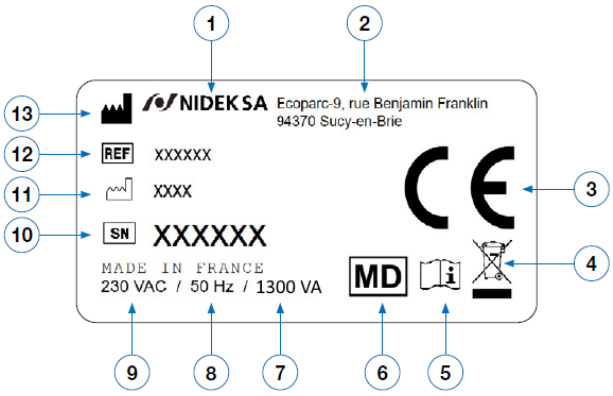
2.6 Labeling

2.6.1 Label

The unit's protective casings are marked whit indications that identity that there are dangerous electrical voltages under the casings to draw the operator’s attention:

2.6.2 Nameplates

The following label and indications are affixed to identify the consultation unit



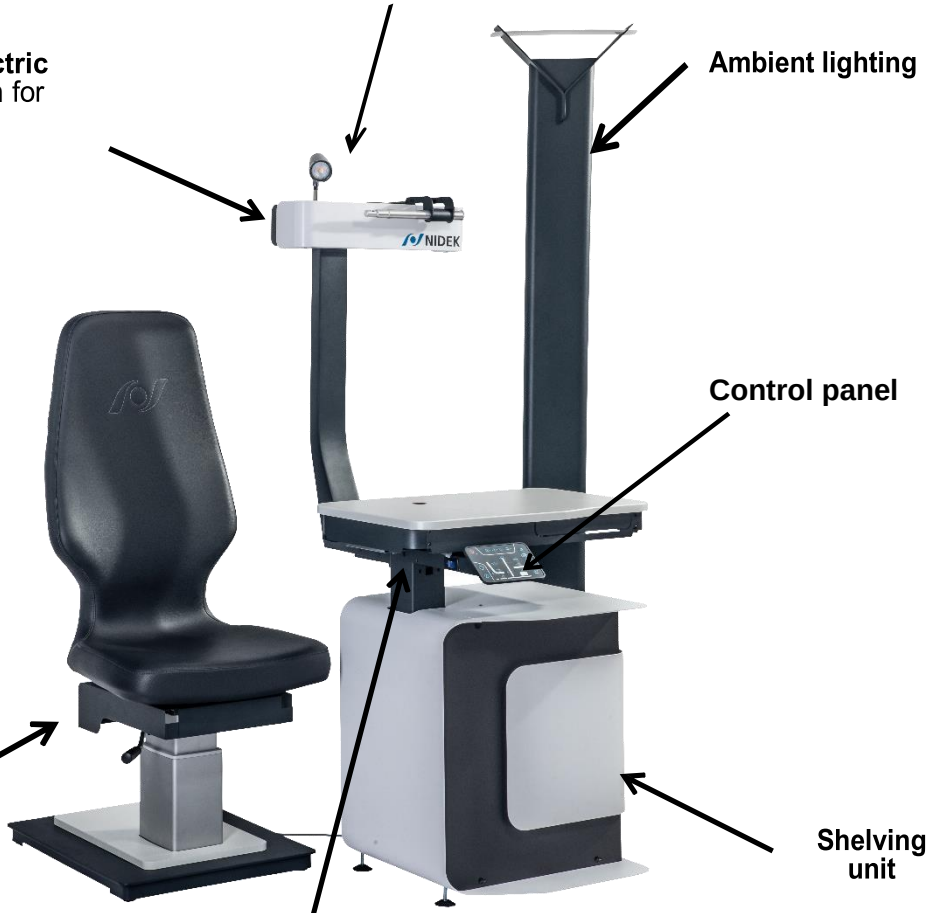
1. Manufacturer's logo
2. Manufacturer's address
3. In accordance with Regulation (EU) 2017/745 on medical devices
4. EEE[3] is collected separately
5. Please refer to precautions and instructions for use
6. Medical Devices
7. Maximum power
8. Frequency
9. Supply voltage
10. Serial number
11. Year of manufacture
12. Product reference
13. Manufacturer

[1] ANSM - See website www.ansm.fr

[2] Ecosystem: eco-organization approved by the French public authorities. To find out about all collection solutions, visit www.ecosystem.eco or contact NIDEK or its authorized distributor.

[3] EEE: Electrical and Electronic Equipment

3 Unit description



4 Use

4.1 Switching on 'unit

First of all, the unit must be correctly connected to a power supply (see §2.2 "Connecting unit to a wall socket"). The thermal cut-out (located on the left-hand side of the control panel) must be switched to position "I": its green LED lights up and the "ALERT" and "READYLEDs flash alternately. the 2 LEDs go out, press the desk's power button: the blue "READY" LED flashes initialization, then lights up. The table is now ready for use.

Note: tray initializes and returns to the preferred height (programmable by the user) and the seat automatically returns to the lowered position.

Remember*: the start-up initialization phase must be carried out with no-one around the table or in the chair.*

4.2 Switching off 'unit

Every day, remember to turn off your unit by switching the thermal circuit breaker (located at the rear of the frame) to the "Oposition. The blue (READY) and green (circuit-breaker) LEDs will go out.

4.3 Economy mode energy

After two hours of inactivity, the unit goes into standby mode (the blue LED goes out) to ensure component life. To restart the unit, simply press the panel's on/off button once.

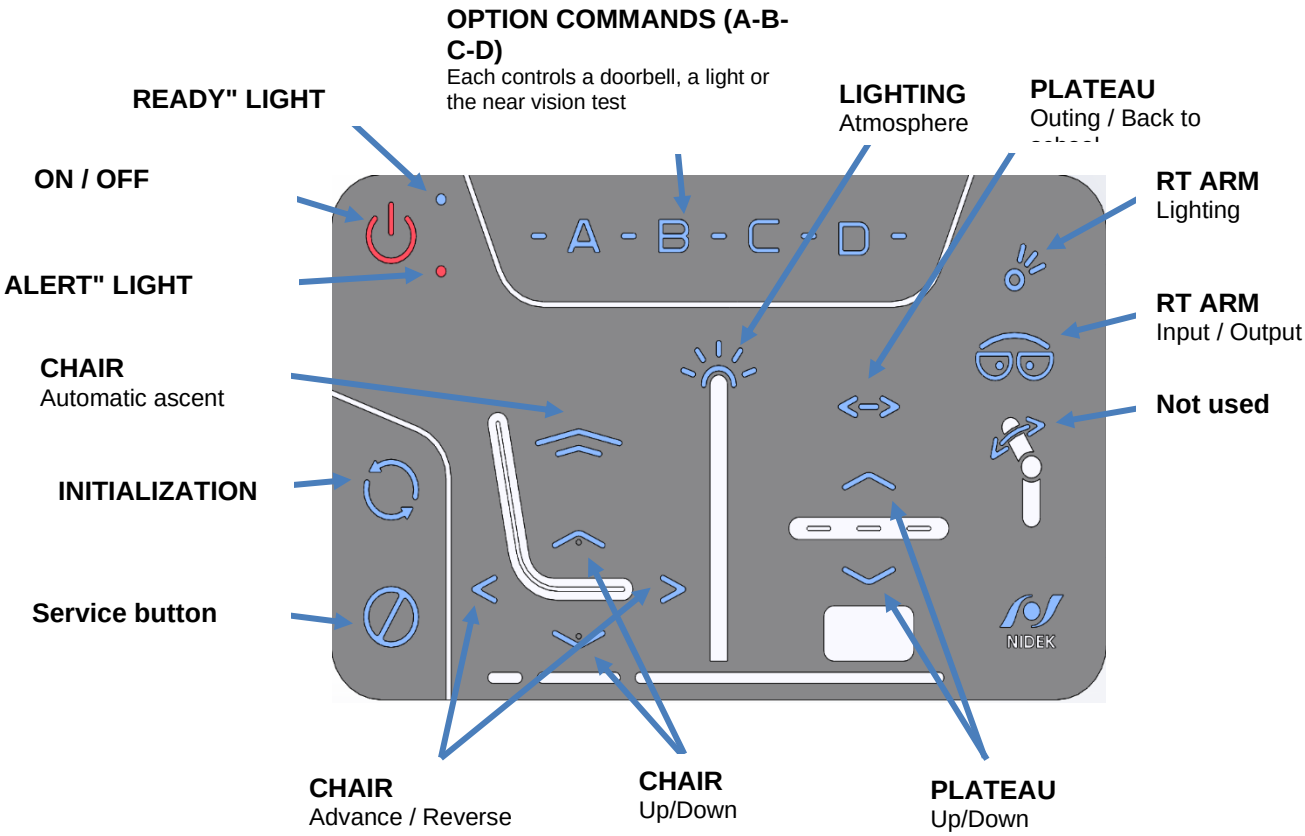
4.4 Using the control panel (tray up/down option)

READY:

- **The blue LED lights up continuously**: the unit is ready for operation.
- **Blue LED flashes**: unit is in initialization state

ALERT:

- **Red LED flashes slowly**: safety devices activated
- **Red LED flashes rapidly**: safety devices are bypassed (see *§ 5.1 "Troubleshooting*").



4.4.1 Motorized table top translation (Option)

As an option, the ONE-i consultation unit is equiped an electrically-driven tabletop.

4.4.2 Memorization of preferred height (optional) and mood lighting 'ambiance

To save the tray at a preferred height and adjust the ambient lighting intensity, follow these steps:

- Position the tray at your preferred working height. Ambient lighting intensity can be adjusted in 3 situations:

- When the tray is in the rest position, to adjust the intensity or lighting, a short press turns the lighting on or off, and a long press dims the lighting,
- When the refractor arm is extended after pressing the "Refractor arm" button, a short press turns the light on or off, and a long press dims the light,
- When the tray is in the examination position (in front of the patient), to adjust the intensity or lighting, a short press turns the lighting on or off, and a long press dims the lighting.

Once you've made your settings, press the "Lower seat" and "Option C" buttons simultaneously until the blue LED flashes: this saves the ambient lighting and the preferred height.

- When you switch on the unit by pressing the "Start/Stop" button (see red-circled button) or the initialization button, the tray will automatically return to this height

4.5 Operating the control panel (option without tray raising/lowering)

CHAIR
Up/Down

Phoropter ARM
Lighting

4.6 Using the motorized near vision test (option)

The near vision test is a device for remotely presenting the Parinaud[4] test in front of the patient during a refraction. This device allows 2 test height settings (to be adjusted with the NIDEK technician or authorized distributor) and rotation.

Control are made by buttons A & B or C & D buttons, B or C for lowering and raising the test, A or D for rotation (to be set by your NIDEK technician or authorized distributor).

The cycle of use of the Up/Down button is as follows:

- 1st press: descent to position 1,
- 2nd press: descent to position 2 (if configured or return to initial position),
- 3rd press: if position 2 is set, test returns to initial position.
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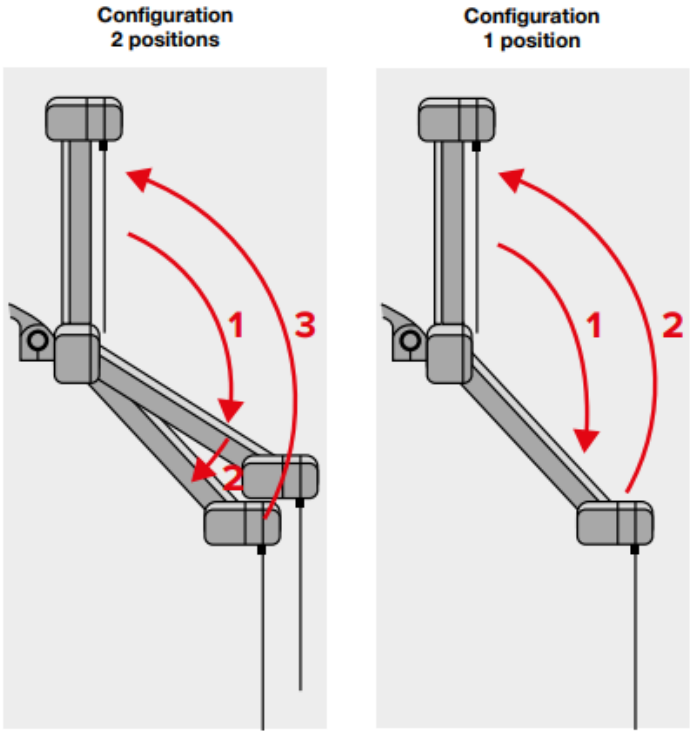


There are two possibilities for returning to the initial (vertical) position:

- When the refraction test is complete, press the refractor (RT) button: the test is straightened as the arm is retracted,
- The test continues: straighten the device with the button used to lower the test.

Note: The device can be used with the refractor extended.

[4] Parinaud test: the Parinaud scale reading test is a test with a text whose lines written in characters of decreasing size.

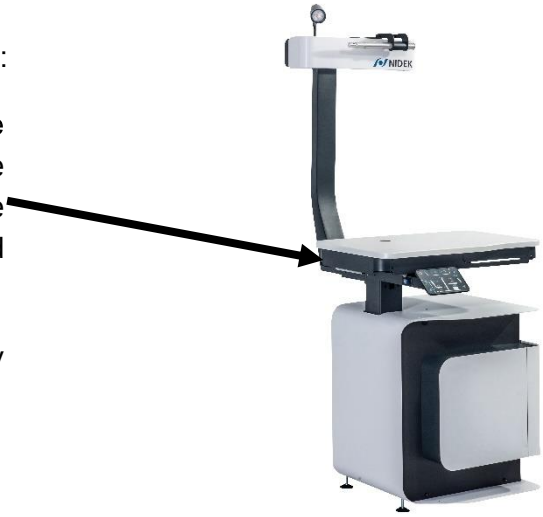
4.7 safety device

A safety device, integrated under the instrument tray, prevents crushing in the event of contact with the patient's legs.

Up/Down and Electric Shift safety:

In the event of contact with the patient's legs, this part stops the upward movement of the seat, the downward movement of the tray and the translation of the tray.

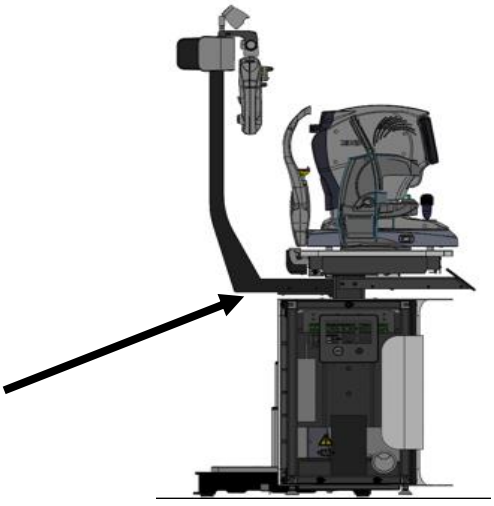
The red "ALERT" LED flashes slowly when safety is activated.



RT up/down safety device:

In the event of contact with patient's hand, this part stops the seat rising and the tray lowering.

The red "ALERT" LED flashes slowly when safety is activated.



5 Maintenance

PRÉCAUTION

Before carrying out any maintenance work or replacing worn parts, unplug the power cord (unless otherwise specified).

5.1 troubleshooting guide

If the consultation unit does not operate normally, please check the following before contacting NIDEK or your authorized distributor.

Ignition	Checks / Corrective actions
Nothing works	Press the "ON / OFF" button
Unit does not switch on	Power cord not plugged in correctly. Check its connection
Green light on main circuit breaker is off	On your electrical panel, check the fuse of the socket you are plugging into. the unit

Ascending / Descending safety	Checks / Corrective actions
The examination table rises, but does not descend not	Check nothing activates the Up / Down safety device. Descent below the plateau
The examination descends, but does not ascend not	Check nothing activates the Up / Down safety device. Descent below the plateau

Seat column	Checks / Corrective actions
The examination does not go up and down not	Contact your authorized distributor

Slit lamp	Checks / Corrective actions
Slit lamp doesn't light up while everything else works	Check the bulb Check slit lamp power connector

Set devices	Checks / Corrective actions
The 230V device on the tray does not work	Check that it is in the "ON" position Contact your authorized distributor

Near vision test	Checks / Corrective actions
VP test does not work	Check that the refractor arm is fully extended If so, please contact your authorized distributor

If the actions listed in the table above have not solved the problem(s), please contact NIDEK or your authorized distributor.

5.2 Maintenance and checks

Check daily that consultation unit is in good condition. Perform the following checks:

- control panel (to the naked eye),
- correct operation of the various movements. In the event of a malfunction, contact NIDEK or your authorized distributor.

Periodically, the chair is raised or the tray lowered, check the operation of the anti-crushing devices by manipulating them (by lifting the safety device under the tray and under the arm). The red "ALERT" LED should light up, and the chair "up" or tray "down" movements should stop.

In the event of a fault, please refer to *§ 5.1 "Troubleshooting guide"* and § 5.4 "Spare parts list".

Note: Apart from these recommendations, only NIDEK or your authorized distributor is authorized to repair or dismantle the consultation unit. NIDEK cannot be held responsible for accidents caused improper service.

5.3 Cleaning

Clean your unit daily with a soft, dry cloth. For stubborn stains, use cloth soaked in neutral detergent[5], wringing it out . Rinse surfaces with a cloth dampened with clear water to prevent premature hardening and cracking. Finally, wipe dry with a soft, dry cloth.

Please refer to your unit's manual for cleaning instructions.

CAUTION: Do not use products components such as Quaternary Ammonium to prevent damage to plastics. Never use organic solvents such as paint thinner or abrasive detergents to clean external parts. The finish of the consultation unit could be irreparably damaged.

5.4 List of spare parts

The ONE-i consulting unit is equipped with automatic reset fuses, so theres no need to change any fuses.

This unit has no wear parts to be replaced periodically. No spare parts are required.

[5] Neutral detergent: detergent with a neutral pH (between 6 and 8). This will avoid damaging the surfaces of the consultation unit. Follow the dosages recommended by detergent or disinfectant manufacturers.

6 Features and information

6.1 Classification CE

Rules 1 and 13 of the classification described in Annex VIII of Regulation (EU) N°2017/745 on medical devices define the ONE-i as a Class I medical device.

Protection against electric shock: As a Class I device, the ONE-i consulting unit provides protection against electric shock. addition to basic insulation, it features additional safety devices for grounding the conductive parts of accessible fixed wiring.

Operating mode: This ONE-i consultation unit is rated for continuous operation.

6.2 Electromagnetic compatibility

The consultation unit can be used in stores or hospitals, but never in the vicinity of active HF surgical equipment and RF-protected rooms with an ME system for magnetic resonance imaging where the intensity of electromagnetic interference is high.

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

The use of accessories or cables other than those supplied (there are no cables specified for use with this unit) by the manufacturer of this unit may result in increased electromagnetic emissions or reduced electromagnetic immunity of this unit, and cause .

Portable RF communication equipment (including peripherals such antenna and external antennas) must not be used within 30 cm of any part of the unit. This could lead to degradation of the 's performance.

Manufacturer's declaration - Electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The customer or user must ensure that it is used in such an environment.

Operating mode(s) :
Mode #1: waiting for movement
Mode #2: continuous movement

N.A : not applicable
N.R : not realized
N.D : not requested

Type of test	Standard	Specifications	Meeting requirements
Radiated emissions	CISPR 11 class B	**Envelope access**: Group 1 Class B at 10m -30 MHz - 230 MHz = 30 dBµV/m -230 MHz - 1 GHz = 37 dBµV/m	YES(1)
Driving emissions	CISPR 11 class B	**a.c. power input**: 240 Vac / 50 Hz Limits: Group 1 class B **0.15 MHz to 0.5 MHz :** 66 to 56 dBµV QP / 56 to 46 dBµV AV **0.5 MHz to 5 MHz :** 56 dBµV QP / 46 dBµV AV **5 MHz to 30 MHz :** 60 dBµV QP / 50 dBµV	YES(2)
	CEI 60601-1-2: 2014	**Patient-coupled cable:** Appendix H (informative) **1-30 MHz:** 24 dBµA	N.A
50 Hz harmonics	IEC 61000-3-2	Access 230 Vac 50 Hz : Limit Class A	YES
Voltage fluctuations (flickers)	IEC 61000-3-3	Access 230 Vac 50 Hz : PST<0.65	YES

In conformity, no account has been taken of the uncertainty associated with the result.

(1) Compliant, with modifications - see chapter 2.1
(2) Compliant, with modifications - see chapter 2.2

Manufacturer's declaration - Electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The customer or user must ensure that it is used in such an environment.

N.A : not applicable
N.R : not realized
N.D : not requested

Type of test	Specifications	Meeting requirements
Electrostatic discharges IEC 61000-4-2	**Envelope access and coupled patient access:** ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	**YES** **YES** Criterion **A**
Radiated electromagnetic fields at radio frequencies IEC 61000-4-3	**Envelope access :** 80 MHz to 2.7 GHz : 10 V/m 80% AM at 1 kHz, 1%.	**YES**
Proximity fields from RF Wireless communications equipment IEC 61000-4-3	**Envelope access :** Frequency spotlights: table 9 of the standard and § 3.2 Pulse modulation or MF as band	**YES**
Rapid electrical transients in bursts IEC 61000-4-4	**AC power supply:** ± 2 kV (100kHz) / 240Vac @50Hz DC power supply: ± 2kV (100kHz) **Signal access:** ± 1kV (100kHz)	**YES** **N.A.** **N.A** **.** Criterion **A**
Shock waves IEC 61000-4-5	**AC power supply: 240Vac @50Hz** ± 0.5 kV, ± 1 kV, ± 2 kV phase and ground ± 0.5 kV, ± 1 kV phase-to-phase **DC power supply :** ± 0.5 kV, ± 1 kV, ± 2 kV phase and ground ± 0.5 kV, ± 1 kV phase-to-phase **Signal access :** ± 2kV	**YES** **YES** **N.A.** **N.A.** **N.A.** Criterion **A**
RF disturbances Conduits IEC 61000-4-6	150kHz - 80MHz: 3V - AM 80%, at 1kHz, 1%. ISM band Amateur radio band **AC power supply:** 240Vac @50Hz **DC power supply** **Coupled patient access** **Signal access**	**YES** **YES** **YES** Criterion **A** **YES** **N.A.** **N.A.** **N.A.**
Magnetic field 50Hz IEC 61000-4-8	**Envelope access :** Level: 30 A/m (50Hz)	**YES** Criterion **A**
Supply voltage interruptions and dips IEC 61000-4-11	**AC power supply: 240Vac @50Hz** . 0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315 . 0 % UT ; 1 cycle - Single phase: at 0°. . 70% UT; 25 cycles - Single phase: at 0°. . % UT; 250 cycles	**YES (Crit A)** **YES (Crit A)** **YES (Crit A)** **YES (Crit C)**

In declaring conformity, no account has been taken of the uncertainty associated with the result.

Criterion A: no untimely movements
Criterion B: to be defined by the manufacturer
Criterion C - permissible loss of capability: reset accepted (IEC 61000-4-11)

6.3 Features t echniques

General features :

Approximate net weight	150 kg *(without equipment)*
Power supply	230 VAC / 50 Hz / 1300 VA
Tray	Electrically adjustable height from 78 to 96 cm with memory for preferred height **Maximum load**[6] on tray: 40
Refractor	Arm-mounted refractor with electric or manual translation The eye height the refractor is identical to that of the fixtures on the tabletop.
Storage unit	Optional storage cupboard
Examination chairs	Electrically height-adjustable via control panel (40 - 65 cm) Maximum load: 200 kg / Patient height between 120 and 200 cm Available models : • FE-2010 • FE-3001 • FE-1001 Options : • Rotation • Footrests • Antero-posterior adjustment

Environmental conditions for transport and storage :

Temperature	From 5 to 50°C
Humidity	10% to 90% *(non-condensing)*
Atmospheric pressure	700 to 1060 hPa[7]
Maximum storage time	3 months if stored outside a warehouse certified by Nidek SA

Environmental conditions during use :

Temperature	From 10 to 30°C
Humidity	From 30% to 75% *(non-condensing)*
Atmospheric pressure	800 to 1060 hPa

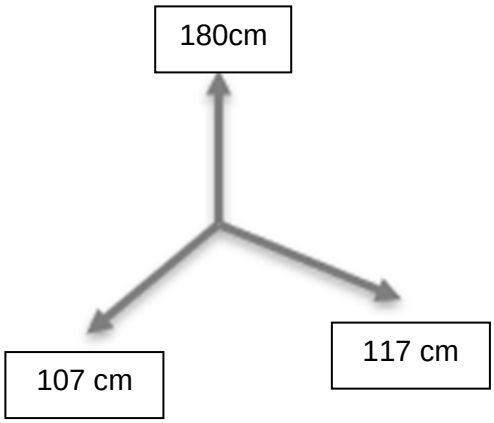
Under these good conditions, and with appropriate checks and maintenance, the consultation unit is expected to have a service life of 10 years from installation.

[6] **CAUTION**: If the maximum acceptable weight on the tray is exceeded, there is a risk of damage to the device and to the patient. It is important not to exceed this maximum load.

[7] hPa: Hectopascal

6.4 Dimensions

- **Single unit**



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