NIDEK

CONSULTATION UNIT

AFFINITY

CE

USER'S MANUAL

THE ART OF EYE CARE

Please read this user's manual before operation or maintenance.

This manual contains the information necessary to use the NIDEK AFFINITY consultation unit, such as the methods and precautions of use, and the characteristics and instructions relating to the maintenance.

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

This device is intended for use by health professionals, and the precautions and methods of use must be perfectly understood before using the unit. Please keep these instructions at hand for reference if necessary.

This consultation unit does not have any parts that are replaceable by the user. Therefore, if you have any difficulties, or if you have any questions, please contact NIDEK or your authorised distributor (no bulbs, no fuses …).

This unit complies with the European Directive 93/42/EEC as amended by the Directive 2007/47/EEC relating to medical devices.

CE

THE ART OF EYE CARE

CONTENTS

1 THE *AFFINITY* LINE

1.1 PRESENTATION OF THE CONSULTATION UNIT

The *AFFINITY* unit is a consultation unit that permits an ophthalmological examination. This device avoids movements of the ophthalmologist and the patient by adapting the position of the ophthalmological instruments either electrically or manually.

The arm has motorised movement and inclination of the refractor and is fixed on a bracket whose height is adjusted at the same time as that of the plate which guarantees a constant height of the eye between the different apparatus.

Many alternatives allow you to configure your consultation unit as your projects require: *AFFINITY* is available in a version with electrical movement of the plate, with forward-backwards adjustment of the seat, and with a lighting column of adjustable intensity…

Accessories are also optionally available which allow customisation of the complete unit as required by the user.

1.2 THE DIFFERENT CONFIGURATIONS AND OPTIONS

AFFINITY “Anthracite”
Right hand operation
Plate with two instruments
Refractor on a motorised inclinable arm
Black examination chair FE-3001 with reclining back and armrests
Furniture with one drawer for test glasses and a two-drawer unit

AFFINITY “Red”
Left hand operation
Plate with two instruments
Refractor on a motorised arm
Folding examination chair FE-2002
Furniture with one drawer for test glasses

AFFINITY “Blue”
Right hand operation
Plate with two instruments
Refractor on a motorised inclinable arm
Examination chair FE-3001 with reclining back
Furniture with one drawer for test glasses and a two-drawer unit

2 SAFETY

The safety precautions described below must always be respected. The logo **PRECAUTION** serves to bring attention to a potentially dangerous situation which, if not avoided, could result in minor to serious injuries, or to material damage. Please follow strictly the instructions corresponding to **PRECAUTION**

2.1 PRECAUTIONS REGARDING THE INSTALLATION

PRECAUTION
Only NIDEK or your authorised distributor is permitted to install the consultation unit. To the contrary, NIDEK will not be responsible for any accident resulting from incorrect installation.
Install the consultation unit in a place that is never exposed to water. Water that enters the internal structure of the unit may cause electrical discharges or a malfunction.
The installation of the consultation unit must be carried out in the following conditions:
Little dust,
Flat ground, without any variations greater than 5 mm,
Stable ground, not subject to vibrations or shocks,
Ground that is resistant to the load exerted by the mass of the unit,
Place the rear panel of the unit at least 16 cm from the wall where the current outlet is located.
The lack of observation of these instructions could lead to the reversal of the unit, deterioration of the ground, and cause serious injuries.
Do not try to move the consultation unit by yourself, as you could injure yourself, damage the unit, and harm the medical instruments installed on the examination plate.
This unit complies with the European Directive 93/42/EEC as amended by the Directive 2007/47/EEC relating to medical devices. It is declared compliant with the Standards EN60601-1 and 60601-1-2 to ensure basic security and reasonable protection against harmful interference occurring in a typical medical installation.
It corresponds to the user to utilise this unit according to the safety standards in force.

2.2 ELECTRICAL CONNECTION

PRECAUTION
Please use a wall outlet according to the specific requirements required for the power supply. The use of a non-compliant wall outlet could cause malfunction of the device or partial operation of the unit. Furthermore, if the wall outlet is not equipped with a grounding terminal, there is a risk of electrical discharges in the case of current leakage.
Connect the power supply plug completely into the wall outlet. A loose connection could cause a fire.

Access to the power plug, once connected, must be possible and easy.

When the consultation unit is not used for a long period, or when wear parts must be changed, disconnect the power cord from the wall outlet. Otherwise, there is a risk of fire.
Grasp the plug to disconnect the power cord. If you pull on the power cord, the metallic core of the cord could break and cause a short circuit or electrical discharges.
Do not place heavy objects on the power cord and do not squeeze it. The power cord sheath may wear out, with a risk of causing a fire or electrical discharges.

If the metallic core of the power cord is bared, if the consultation unit turns on and off when the power cord is moved, or if the cord or the plug is too hot to hold, the power is cord is damaged Contact NIDEK or your authorised distributor to carry out the immediate replacement of the power cord. Otherwise, there is a risk of electrical discharges or fire.
From time to time, you should clean between the pins of the power supply plug using a dry cloth. If dust settles in there, it could absorb humidity and cause a short-circuit or a fire.
Note: Do not connect anything to the multiple outlet socket in the unit without the approval of NIDEK or your authorised distributor. Connecting any electrical apparatus to this socket could cause an electrical fire.

2.3 PRECAUTIONS FOR USE

PRECAUTION
Do not ever use the consultation unit for purposes other than those intended. NIDEK cannot be held responsible for any accident or malfunction due to a different use.
Do not ever dismantle or touch the internal structure of the consultation unit. There is a risk of electrical discharges or malfunctions.
If a failure of the consultation unit cannot be resolved by resetting the circuit breaker, do not intervene in the electrical circuits of the unit. Disconnect the power cord from the wall outlet and contact NIDEK or your authorised distributor.

Attention, the initialisation phase of the start-up must be performed without anybody around the table or in the chair. In effect, differing from the operating mode during examinations where the movements susceptible to presenting any danger are controlled by continuous support and under the supervision of the practitioner, there are automatic movements during initialisation (Table, RT Arm, Instrument Plate) and you should ensure that no obstacles can cause collisions likely to damage the equipment or cause injury.

Attention, during the examinations, the movements likely to present a danger (raise or lower the instrument plate or chair) are controlled by continuous support and under the constant supervision of the practitioner. While the plate has an anti-collision sensor, you should ensure at all times during movements that no obstacles can cause collisions likely to damage the equipment or cause any injury. In the event of failure of the anti-collision sensor, it is possible to disable it (see § 5.2) temporarily.

Reminder:
Periodically, during an order to “raise” the seat or “lower” the plate, verify the operation of the anti-collision sensor by handling it (by lifting the housing under the plate). The red LED “Alert” should light, and the movements of “raising” the seat or “lowering” the plate should stop.

The means of stopping the movements:
- In a normal situation; stop actuating any movement order (In addition, the anti-collision device cuts the movements even if pressure is maintained on the switch).
-In an “abnormal” situation: In addition to the anti-collision device, you can always disconnect the power supply of the motors by pressing the "On / Off" key located on the control console.

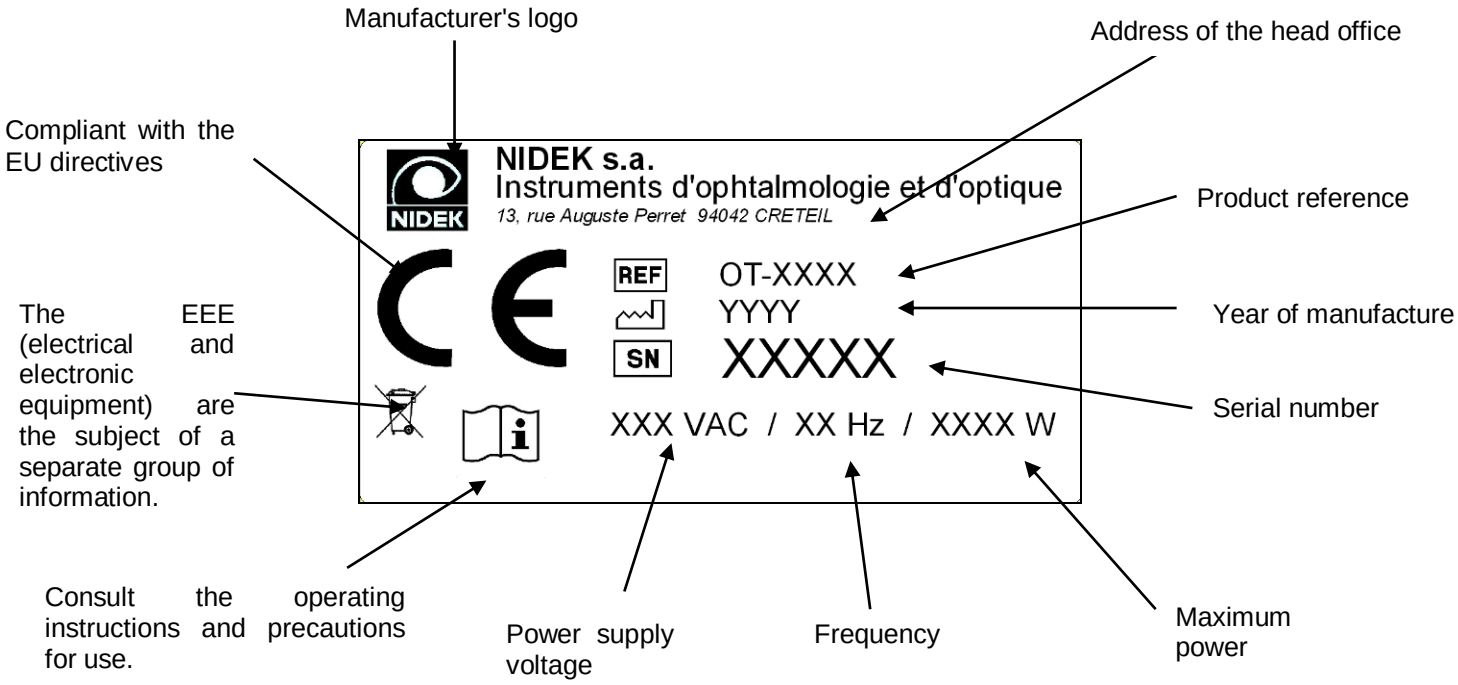
Attention, the USB port behind the unit is intended to update the electronic card in conjunction with NIDEK, and cannot be used for charging electronic devices (smartphone, tablet,…). Only equipment compliant with the applicable IEC standards may be connected to the USB port (60950-1 for a computer, for example). Otherwise, there is a risk of dangerous situations occurring that could cause a risk to personal health or damage to equipment or property.

2.4 MAINTENANCE

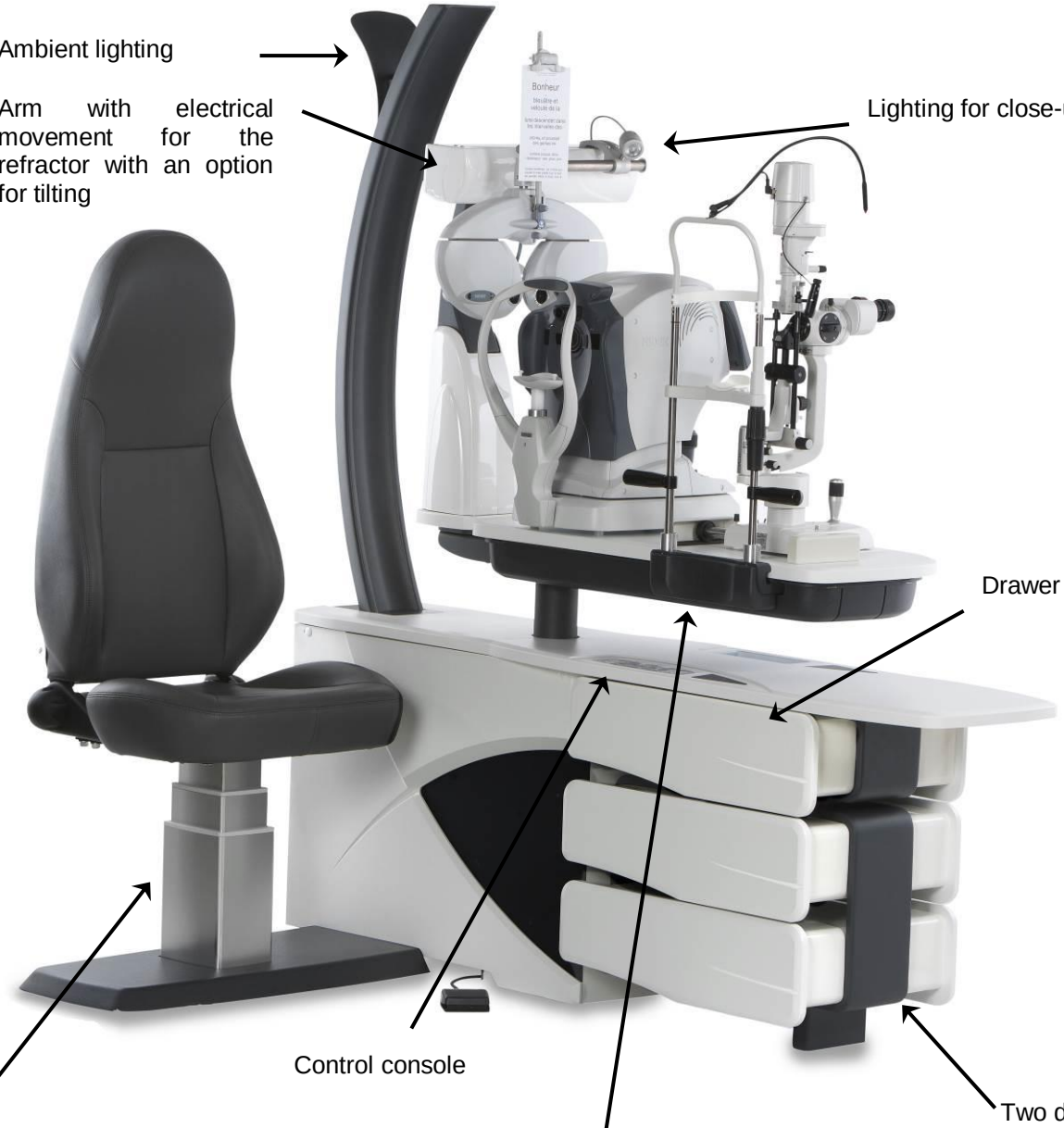
Verify the good condition of the consultation unit. Check the control panel with the naked eye and check for proper operation. In the event of an anomaly, there is a risk of malfunction. Contact NIDEK or your authorised distributor.
Don't ever use an organic solvent such as thinner or an abrasive detergent to clean the external parts. The finish of the consultation unit may be irreparably damaged.
Allow the lamp to cool before handling it. Otherwise, there is a risk of burns and breakage.
Only NIDEK or your authorised distributor is permitted to repair or dismantle the consultation unit. NIDEK cannot be held responsible for an accident due to incorrect after-sales service.

2.5 NAME PLATES

The nameplates and following indications are attached to the unit for the attention of the operator.



3 DESCRIPTION OF THE UNIT



4 UTILIZATION

4.1 ENERGISING

First, the unit must be properly connected to an electrical power supply (see § 2.2 “Connection of the unit to a wall outlet”)
The thermal interrupter (located behind the frame) must be engaged in the “I“ position with the green light turned on. The leds Alert and Ready flash alternately, when the 2 leds go out, press the power button on the console, the blue LED “READY” light flashes during start-up and then settles. The table is ready to use.

The plate initialises and returns by itself to the preferred height (programmable by the user) and the seat drops automatically to its lowest position.

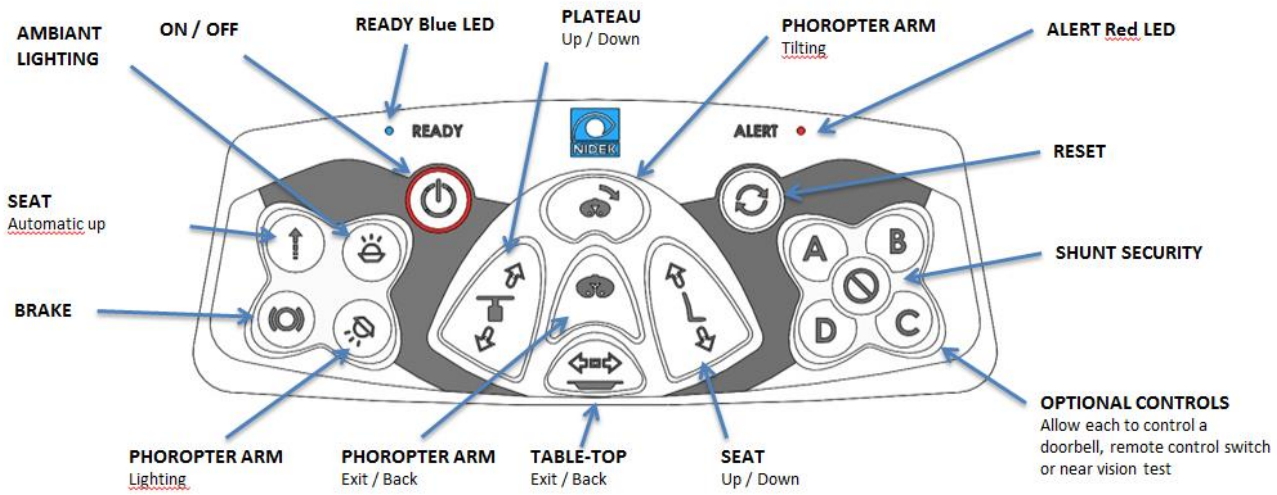
4.2 DISCONNECTING THE UNIT

Remember to turn off your unit every day by moving the thermal interrupter (located behind the frame) to the position “O”. The blue LED and green light of the disconnect switch turn off.

4.3 USE OF THE CONTROL CONSOLE

READY
The LED is continuously lit: the unit is ready to operate
Flashing LED: the unit is starting-up

ALERT
The LED flashing slowly: the safety features are activated or a network failure
The LED flashing rapidly: the safety features are shunted (see § 5.2)



4.4 ELECTRICAL MOVEMENT

As an option, the AFFINITY consultation unit can be equipped with a plate that is moved electrically. In this case, a 2nd control console is located on the plate, between the two instruments. This permits control of the principal functions of the unit: raising and lowering the seat and the table, and electric movement of the plate.

4.5 STORING THE PREFERENTIAL HEIGHT OF THE PLATE AND AMBIANT LIGHTING

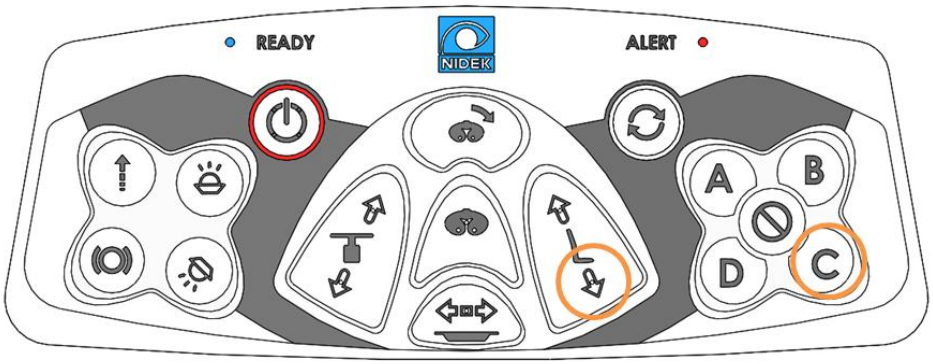
4.5.1 Storing the preferential height of the plate

Position the plate at your preferred work height.

Then simultaneously press the "Seat down" and "Option C" buttons until the blue led flashes: you memorize the height of the board.

WARNING: Simultaneous pressing of the "Seat down" and "Option C" buttons until the blue led flashes, record the preferred height and the ambiant lighting, make sure that the preferential height and lighting are correctly adjusted before this operation.

When you press the "Reset" key, the plate automatically returns to this height.



4.5.2. Ambient lighting

The intensity of the ambient lighting can be adjusted in 3 situations:

- Table in the rest position, adjust the intensity or ignition, a short press turns the lighting on or off, a long press varies the intensity of the lighting.

- Pressing the RT arm button, once the arm is out to adjust the intensity or ignition, a short press turns the lighting on or off, a long press varies the intensity of the lighting.

- Table in examination position, after turning the examination plate set the intensity or ignition, a short press turns the lighting on or off, a long press varies the intensity of the lighting.

Once you have made your settings press the buttons "Seat down" and "Option C" simultaneously until the blue led flashes: you memorize the ambient lighting.

WARNING: Simultaneous pressing of the "Seat down" and "Option C" buttons until the blue led flashes, record the preferred height and the ambiant lighting, make sure that the preferential height and lighting are correctly adjusted before this operation.

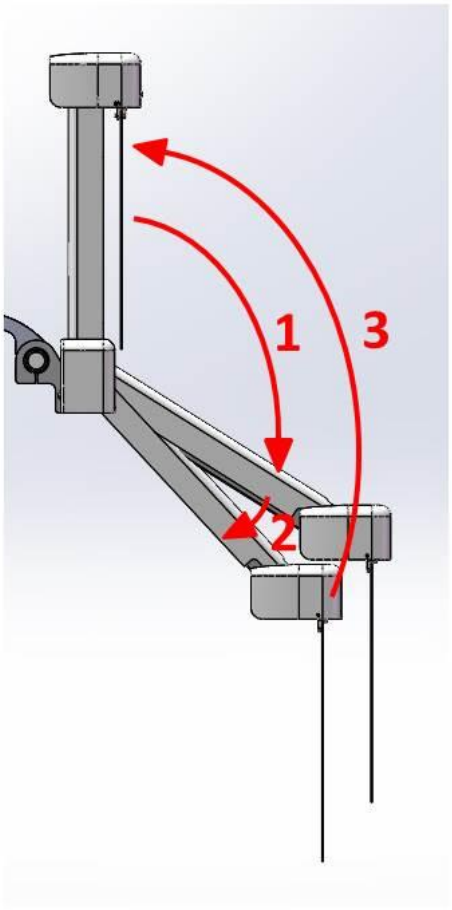
4.6 USE OF NEAR VISION TEST

The near-vision test is a device that makes it possible to remotely present the Parinaud test in front of the patient during a refraction, this device allows 2 height adjustments of the test (to be adjusted with the NIDEK technician or the authorized distributor) and rotation.

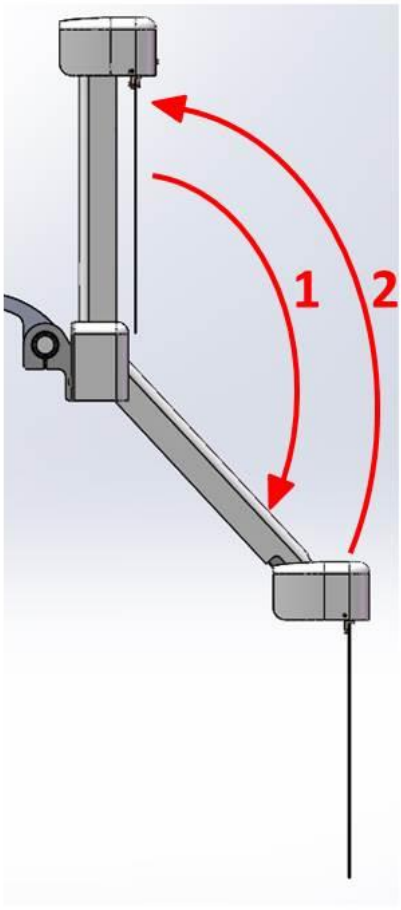
The commands are made by the buttons A & B or C & D, B or C for up and down, A or D for the rotation (to be setted with the technician NIDEK or the authorized distributor).

The cycle of use of the up / down button is as follows:
- 1st press: down to position 1
- 2nd press: down to position 2, if configured or raised to the initial position.
- 3rd press: if position 2 is configured, the test returns to the initial position.

Configuration 2 positions



Configuration 1 position



The device is usable when the RT is out, on a fixed arm or with inclination.

For the return to the initial position (vertical) two possibilities:
- The refraction examination is finished, press the RT key, the test is raised at the same time as the arm returns.
- The examination continues straightened the device with the key used for the descent of the test.

4.7 SAFETY DEVICE

A safety device installed under the instrument plate prevents any crash in the case of contact with the patient's legs.

Safety up and down
In case of contact with the patient's legs, this device stop the rise of the seat and the descent of the plate.

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

5 TROUBLESHOOTING GUIDE

If the consultation unit does not work normally, perform the following checks before calling NIDEK or your authorised distributor.

5.1 DIAGNOSIS OF A FAILURE

Lighting	Corrective actions
Nothing works	Press the “ON / OFF” button
The unit does not light-up	The power supply cord is not properly connected. Check its connection
The green light of the general disconnect is off.	On your electrical panel, check the fuse feeding the electrical outlet to which the unit is connected

Safety Raising/Lowering	Corrective actions
The examination plate rises but does not lower	Verify that nothing is activating the raise/lower safety device under the plate
The examination seat lowers but does not rise	Verify that nothing is activating the raise/lower safety device under the plate

Seat column	Corrective actions
The examination seat does not rise or lower	Contact your authorised distributor.

Slit Lamp	Corrective actions
The slit-lamp does not turn on, although everything else works.	Check the bulb of the lamp Check the power connection of the lamp

Apparatus of the plate	Corrective actions
Only one apparatus of 230 V on the plate does not work	Check that it is on the “ON” position Check the operating instructions of the apparatus

Near vision test	Corrective actions
The near vision test doesn’t work	Check that RT's arm is out If yes, contact your authorized distributor

If the previous actions do not resolve the problems, you should contact NIDEK or your authorised distributor.

5.2 RESOLVE A FAULT: RAISING / LOWERING

A safety failure of raising/lowering occurs when:

• The seat cannot be raised any more (but it can still go down)
And
• The plate does not go down any more (but can still go up)

While waiting for the attention of a NIDEK technician or from the local authorised distributor, you can **temporarily** deactivate the safety device. Press on the “Safety SHUNT” button for ten seconds on the control console; the red LED “ALERT” light flashes rapidly. The seat and the table can now be raised and lowered.

CAUTION: This operation is to be used as a last resort and for a limited period. It requires handling the table with much care. A NIDEK technician must be called to repair the product.

6 MAINTENANCE

6.1 CLEANING

Clean your unit with a soft dry cloth. For resistant tasks, use a cloth dampened with a mild neutral detergent and previously wrung out. Finally, wipe off the unit with a soft dry cloth.
For cleaning equipment placed on the unit, please refer to the apparatus manuals.

PRECAUTION

Don't ever use an organic solvent such as thinner or an abrasive detergent to clean the external parts. The finish of the consultation unit may be irreparably damaged.

6.2 LIST OF SPARE PARTS

The AFFINITY consultation unit is equipped with fuses for automatic reset, so there is no fuse to change.
This unit has no spare part to be periodically changed. Therefore, there are no spare parts to consider.

7 TECHNICAL CHARACTERISTICS

7.1 EC CLASSIFICATION

Rule 12 of the classification described in Annexe IX of the Directive 93/42/EEC as amended by Directive 2007/47/EEC and regarding medical devices indicates that the AFFINITY is a Class I medical device.

Protection against electrical shocks
As a Class I apparatus, the AFFINITY consultation unit ensures protection against electrical shocks, and that, in addition to its basic insulation, it provides additional safety devices for grounding the conductive parts of the accessible fixed wiring.

Mode of operation
This AFFINITY consultation unit is classified for continuous operation,

7.2 ELECTROMAGNETIC COMPATIBILITY

Methods of operation:
Method #1: Waiting for a movement
Method #2: Continuous movement

N.A. Not applicable **N.R.** Not realized **N.D.** Not required

Type of test	Standard	Specifications	Respect of Requirements
Radiated Emissions	CISPR 11 Class B	**Access by envelope**: Group 1, Clause B at 10 m → 30 Mz – 230 MHz = 30 dBµV/m → 230 Mz – 1 GHz = 37 dBµV/m	**YES (1)**
Conducted 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 – 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 dBµ dBµV QP / 50 dBµV AV	**YES (2)**
	CEI 60601-1-2 2014	Cable coupled to the patient: Annexe H (information) **1-30 MHz:** 24 dBµV	**N.A.**
50 Hz Harmonics	CEI 61000-3-2	Access 230 Vac 50 Hz Limit Class **A**	**YES**
Voltage Fluctuations (Flickers)	CEI 61000-3-3	Access 230 Vac 50 Hz PST < 1 PLT <0.65	**YES**

(1) Agreed, with modifications – See chapter 2.1
(2) Agreed, with modifications – See chapter 2.2

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

N.A Not applicable **N.R.** Not realized **N.D.** Not required

Test Standard	Specifications	Verdict
Electrostatic discharge CEI 61000-4-2	**Envelope access and access coupled to the patient:** ±8 kV contact ±2 kV, ±4 kv, ±8 kv, ±15 kv air	 **YES** **YES** Criteria **A**
Electromagnetic fields radiated at radio frequencies CEI 61000-4-3	**Envelope access:** 60 MHz to 2.7 GHz: 1D V/m 60% AM at 1 kHz, 1%	**YES**
Proximity fields from RF Wireless communications equipment CEI 61000-4-3	**Envelope access:** **Frequency spots:** Table 9 of the Standard and § 3.2 Pulse modulation or MF as band	**YES**
Fast electrical transients and bursts CEI 61000-4-4	**-AC Power Supply:** ±2 kV (100 kHz) / 240 Vac @50 Hz **-DC Power Supply:** ±2 kV (100 kHz) **-Signal access:** ±1 kV (100 kHz)	**YES** **N.A.** **N.A.** Criteria **A**
Shock Waves CEI 61000-4-5	**-AC Power supply:** 240 Vac @50 Hz ±0.5 kV, ±1 kV, ±2 kV phase to ground ±0.5 kV, ±1 kV between phases **-DC Power supply:** ±0.5 kV, ±1 kV, ±2 kV phase to ground ±0.5 kV, ±1 kV between phases **-Signal Access:** ±2 kV	 **YES** **YES** **N.A.** **N.A.** **N.A.** Criteria **A**
Conducted RF disturbances CEI 61000-4-6	150 kHz – 60 MHz: 3 V – AM 60%, to 1 kHz, 1% ISM Band Amateur Radio Band **-AC Power Supply:** 240 Vac @50 Hz **-DC Power Supply:** **-Access coupled to patient** **-Signal access:**	√ √ √ Criteria **A** **YES** **N.A.** **N.A.** **N.A.**
50 Hz Magnetic Field CEI 61000-4-6	**Envelope access:** Level: 30 A/m (50 Hz)	 **YES** Criteria **A**
Power supply cuts and dips CEI 61000-4-11	**AC Power Supply:** 240 Vac @ • 0% U_T; 0.5 cycle to 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° • 0% U_T; 1 cycle – single phase at 0° • 70% U_T, 25 cycles, single phase at 0° • % U_T, 250 cycles	 **YES (Crit. A)** **YES (Crit. A)** **YES (Crit. A)** **YES (Crit. C)**

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

Criteria A: Tolerance on movements: ±2mm
Tolerance on rotation: ±3°
Criteria B: To be defined by the manufacturer
Criteria C: Loss of admissible aptitude: Reset accepted (CEI 61000-4-11).

7.3 GENERAL CHARACTERISTICS

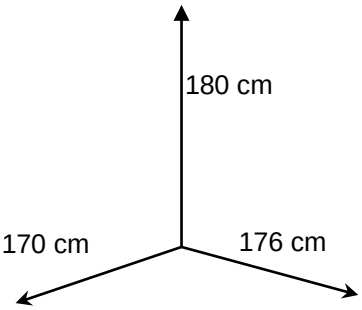
Approximate net weight	250 kg (without apparatus or desk)
Electrical power supply	230 VAC / 50 Hz / 1500 W
Plate	Electrically adjustable height from 75 to 93 cm, with a memory of the preferred height Maximum load of 80 kg (maximum 45 kg per instrument)
Furniture	Optional: two drawer block and desk
Refractor	On a moveable arm (motorised tilting is an option)
Examination seat	Electrically adjustable height over 18 cm (40 to 65 cm) Maximum load of 200 kg Optional: rotation, liftable armrests, footrests, and forward-backwards adjustment

7.4 ELECTRICAL DIAGRAM

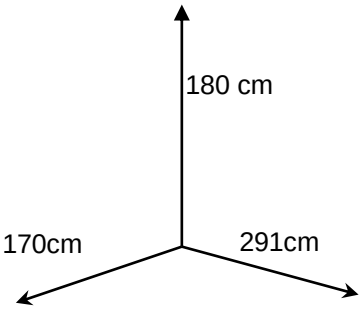
The electrical diagram of your unit is included in the product, on the back of the access panel to the electrical board.

7.5 DIMENSIONS

AFFINITY
One unit



AFFINITY
Unit with desk



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