

Consultation unit





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Instruction Manual





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Read this instruction manual **before** use or carrying out any maintenance

This manual contains the information required to use NIDEK'S Affinity consultation unit, such as how to use it, precautions for use, specifications and maintenance instructions.

This instruction manual is essential for ensuring the correct use of the unit.

This device is intended for healthcare professionals, the precautions for use and different uses must be perfectly understood before using the unit. Please keep it to hand for future reference, if required.

This consultation unit has no user-replaceable parts. As a result, if you have any issues or questions, please contact NIDEK or your authorised distributor.

This unit complies with regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 relating to medical devices.



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1. The Affinity Range

1.1. Description of the consultation unit

Affinity is a consultation unit for performing refraction tests. This device eliminates the need for the practitioner and patient to move, by adjusting the position of ophthalmic instruments for them, either manually or electronically. It is intended to be used by eye care professionals, including ophthalmologists, optometrists, orthoptists, opticians and nurses.

1.2. Introduction to the different versions



Affinity anthracite

- Right-handed
- Table top for 2 instruments
- Electrically tilting refractor arm
- Black FE-3001 exam chair with reclining back (armrests optional)
- 1-drawer cabinet for trial lenses and one two-drawer unit
- Stand-alone RT console

Affinity red

- Left-handed
- Table top for 2 instruments
- Electrical refractor arm
- FE-2010 retractable exam chair
- 1 cabinet for trial lenses





Affinity blue

- Left-handed
- Table top for 2 instruments
- Electrically tilting refractor arm
- FE-3001 exam chair with reclining back
- 1 cabinet for trial lenses and one twodrawer unit
- Exam chair with back-and-forth adjustment (motorised option available)

Affinity 3 anthracite

- Right-handed
- Table top for 3 instruments
- Electrical refractor arm
- Grey FE-2010 exam chair
- 1 cabinet for trial lenses





Affinity RT anthracite

- Right-handed
- Electrically tilting refractor arm
- Electronically-powered near vision test (optional)
- FE-3001 exam chair
- RT console tray (optional)



2. Safety Instructions

The safety precautions detailed below must be always be observed.

This logo **CAUTION** is used to draw attention to a potentially dangerous situation which, if not avoided, may result in minor or serious injuries or damage to property. Carefully follow the instructions regarding **CAUTION**.

2.1. Installation precautions

Only NIDEK or your approved distributor is authorised to install a consultation unit. Otherwise, NIDEK will not be liable for any accidents due to incorrect installation.

Install the consultation unit in a location where it is unlikely to suffer any water damage. If water enters the unit's internal structure, you may experience an electric shock or system malfunction.

Installation of the consultation unit must be carried out under the following conditions:

- minimal dust,
- level ground, with no undulations greater than 5 mm,
- stable ground not subject to vibrations or shocks,
- ground that can withstand the weight exerted on it by the unit,
- position the back panel of the unit at a minimum of 16 cm from the wall where the power socket is located.

Failure to comply with these instructions may cause the unit to tip over, damage to the floor, and may cause serious injuries.

Do not attempt to move the consultation unit, due to the risk of injury, damage to the unit and damage to the medical devices installed on the equipment table. Please contact NIDEK or your approved distributor so that a call-out from a NIDEK technician may be arranged.

The Affinity consultation unit has been declared compliant with regulation (EU) 2017/745 on medical devices as it has been tested and declared compliant with standards EN 60601-1 and 60601-1-2 which ensure basic safety and reasonable protection against harmful interference seen in typical medical installations.

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

2.2. Electrical connection

Please ensure that you use a wall socket that meets the specific requirements for the power supply. If not, the device may not work to its full capability. The wall socket must be equipped with an earth terminal, otherwise there is a risk of electric shock in the event of a current leakage.

Insert the plug fully into the wall socket. An unstable electrical connection may cause a fire. You must be able to access the plug easily once it has been inserted.

Before changing any worn parts or if the consultation unit has not been used for a long time, unplug the power cable from the wall socket to avoid the risk of fire. To do this, grasp the plug in order to disconnect the power cable. Do not pull on the power cable to disconnect, or 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 and do not pinch it. The cable cover may become worn, which may result in a fire or an electric shock.

If the metal core of the power cable is exposed, if the display unit turns on and off when the power cable is moved (there is a loose connection), or if the cable or plug becomes so hot that it cannot be held, then the power cable is damaged. Please contact NIDEK or your approved distributor to arrange immediate replacement of the cable in order to avoid the risk of electric shock or fire.

Clean in between the pins of the plug from time to time with a dry cloth. If there is any dust, this may absorb humidity and cause a short-circuit or fire.

Please note: connecting electrical devices to the unit's multi-socket device can lead to the creation of a medical electrical system.

2.3. Precautions for use

CAUTION

Never use the consultation unit for anything other than its intended purpose. NIDEK will not be liable for any accident or malfunction due to 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 tamper with the unit's electrical circuits. Disconnect the power cable from the wall socket and contact NIDEK or your approved distributor.

Please note, the initialisation phase at start-up must be carried out without anyone near the table or in the chair. Unlike during normal operation where movements are controlled with constant pressure and under the supervision of the practitioner, during initialisation, movements are automatic and you must ensure that there are no obstacles that may cause collisions and that could damage the equipment or cause injury.

Please note, during exams, movements are carried out under the constant supervision of the practitioner. When moving, you must ensure that there are no obstacles that could cause collisions and that could damage the equipment or cause injury.

The ways to stop movement include:

- under normal circumstances, for movements involving constant pressure, stop using the movement control,
- in abnormal circumstances, i.e. if part of the consultation unit comes into contact with a person or object, the various anti-collision systems will stop the movement, even if pressure is maintained.
- in the event of an emergency, you can also switch the power off at any time by pressing the 'Start/Stop' button on the control panel.

Please note, the USB port found at the back of the unit is intended for updates to the printed circuit board, as agreed with NIDEK and should not be used to charge other devices (smartphones, tablets, etc.). If not, there is a risk of dangerous situations arising which may cause a risk to people's health or damage to the equipment or property.

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 reporting

If you think that a serious incident has occurred in relation to the unit, this incident must be reported to NIDEK SA and the competent authority in the Member State in which you reside. For example, in France this information can be reported via the *Agence Nationale de Sécurité du Médicament et des produits de santé*⁽¹⁾ (ANSM, French National Agency for the Safety of Medicines and Health Products) national reporting system.

Please note: by reporting incidents, you are helping to provide more information on the safety of this unit.

2.5. End-of-life disposal

Electrical and electronic equipment contain polluting substances (circuit boards, capacitors, etc.). Their decontamination and subsequent recycling allows us to preserve natural resources, in particular their strategic raw materials.

Please note: when your consultation unit comes to the end of its useful life, do not dispose of it with household waste. This unit must be collected and disposed of in a selective way..

In order to meet the requirements stipulated in EU Directive 2012/19/EU on waste electrical and electronic equipment, NIDEK, to allow for appropriate reuse and recycling of parts, is a member of Ecosystem⁽²⁾ and helps fund an approved collection and recycling scheme for professional electrical waste (DEEE Pro). You can dispose of your consultation unit free of charge at the end of its life.

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

2.6. Labelling

2.6.1 Name plates

The unit's protective casing is labelled to indicate that dangerous electrical voltages are present under the casing:



- (1) ANSM: see website www.ansm.fr
- (2) Ecosystem: eco-organisation approved by the French public authorities. To find out more about all collection options, please visit www.ecosystem.eco or contact NIDEK or its approved distribut.

2.6.2 Label

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



- 1. Manufacturer's logo
- 2. Head office address
- 3. In accordance with Regulation (EU) 2017/745 on medical devices
- 4. EEE waste(3) is subject to selective waste collection
- 5. Review 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 number
- 13. Manufacturer



3. Unit Description

3.1. Affinity 2 instruments



3.2. Affinity 3 instruments





3.3. AFFINITY RT



4. Use

4.1. Turning the unit on

The unit must first be properly connected to a power source (see § 2.2 'Electrical connection'). The thermal circuit breaker (located at the back of the unit) must be switched to position 'I': its blue light will turn on and the 'ALERT' and 'READY' lights will flash alternately. When the two lights go out, press the start button on the console: the blue 'READY' light will flash during initialisation and will then become solid. When this happens, the table is ready for use.

Please note: the table will initialise and return to the preferred height (which can be programmed by the user), the chair will automatically return to the lowest position.

Remember: the initialisation phase at start-up must be carried out without anyone near the table or in the chair.

4.2. Turning the unit off

Remember to turn your unit off every day, by switching the thermal breaker (at the back of the unit) to the 'O' position. The blue light (READY) and the circuit breaker will turn off.

4.3. Energy saving mode

After two hours of inactivity and in order to guarantee the life of the components, the unit goes to sleep (the blue led turns off).

To restart the unit, simply press the on/off button on the panel once.



4.4. Using the control panel

READY :

- Solid light: unit is now working
- Flashing light: the unit is initialising

ALERT :

• Light flashing slowly: safety features have been activated



4.5. Using the remote console (Affinity 3 only)

The Affinity consultation unit has the option of including a manual 3-instrument table. If you choose this option, a second control panel is positioned in the centre of the table. It controls the unit's main functions: raising/lowering the chair and table, brakes and changing the ambient lighting.



4.6. Using the table top console (option for Affinity 2)

The Affinity consultation unit has the option to be equipped with a electrically operated table top. If you choose this option, a second control panel is positioned on the table top between the 2 instruments. It controls the unit's main functions: raising/lowering the chair and table and the electrically operated table top.





4.7. Personalising the preferred height and ambient lighting

To position the table top at your preferred height and adjust the intensity of the ambient lighting, take the following steps:

- Position the table at your preferred working height. When you turn the unit on by pressing the 'ON/OFF' button (see button circled in red) or using the initialisation button, the table top will automatically reposition itself to this height. The intensity of the ambient lighting can be adjusted in 3 ways:
 - ► when the table is in the rest position, to adjust the intensity or lighting, a short tap turns the lighting on or off and a prolonged press varies the intensity of the lighting
 - ▶ when the refractor arm is extended after pressing the 'Refractor arm' button, to adjust the intensity or lighting, a short press turns the lighting on or off and a prolonged press varies the intensity of the lighting
 - ► when the table is in the exam position, after having turned the equipment table, to adjust the intensity or lighting, a short press turns the lighting on or off and a prolonged press varies the intensity of the lighting
- Once you have made your adjustments, simultaneously press the 'Lower seat' and 'Option C' buttons (see buttons circled in orange) until the blue light flashes: you have saved the preferred ambient lighting and height settings.



4.8. Using the electronically-powered NV test (optional)

The near vision test is a device for remotely performing a Parinaud(4) test on a patient during a refraction exam. This device allows 2 height settings for the test (to be set by the NIDEK technician or the approved distributor) and rotation.

The controls are done via buttons A & B or C & D or C for lowering and raising the test, A or D for rotation (to be set by the NIDEK technician or the approved distributor).

The cycle for using the Raise/Lower button is as follows:

- 1st press: lower to position 1,
- 2nd press: lower to position 2, (if configured or reset to initial position),
- 3rd press: if position 2 is configured, the test will return to its initial position.



To return to the initial position (upright), there are two options:

- If the refraction test has ended, press the refractor (RT) button: the initial test position is restored while the arm retracts.
- If the test is continuing: retract the device with the button used to lower the test.

Please note: the device can be used while the refractor is extended, on a fixed or tilting arm.



4.9. Safety device

4.9.1. Affinity 2 instruments

A safety device, integrated into the instrument table, prevents the patient's legs from being crushed.

In order to prevent crushing on retraction/extension of the table and the electronically-powered RT arm (optional), a force limit is applied to the motors.



Sécurité Montée / Descente

En cas de contact avec les jambes du patient, cette pièce arrête la montée du siège et la descente du plateau.

Le voyant rouge «ALERT» clignote lentement lorsque la sécurité est activée.

4.9.2. Affinity 3 instruments

A safety device, integrated into each table leg, prevents the patient's legs from being crushed.

In order to prevent crushing when the electronicallypowered RT arm is retracted/extended (optional) a force limit is applied to the motor.

Raising/Lowering safety feature

In the event of contact with the patient's legs, safety devices are placed under the legs and under the centre of the table and stop the seat from being raised and the table from being lowered.

The red 'ALERT' light flashes slowly when the safety feature is activated.



5. Maintenance

Before any maintenance activities are carried out or wearing parts are changed, unplug the electrical power cable (unless otherwise indicated).

5.1. Troubleshooting guide

In the event the consultation unit is not working properly, carry out the following checks before calling NIDEK or your approved distributor.

Lighting	Checks/Corrective actions	
Nothing works	Check that the unit's circuit breaker is turned on, then press the 'ON/OFF' button.	
The unit does not turn on	The power cable is not connected properly. Check its connection.	
The main circuit breaker's blue light is off	On your distribution panel, check the fuse for the socket to which the unit is connected.	
Raising/Lowering safety	Checks/Corrective actions	
The equipment table can be raised, but not lowered	Check that nothing is activating the Raise/Lower safety device under the table	
The exam chair can be lowered, but not raised	Check that nothing is activating the Raise/Lower safety device under the table	
Chair column	Checks/Corrective actions	
The exam chair cannot be lowered or raised	Contact your approved distributor	
Slit lamp	Checks/Corrective actions	
The slit lamp does not turn on but everything else is working	Check the bulb in the device Check the slit lamp's power cable. Contact your approved distributor	
Table top devices	Checks/Corrective actions	
Only one 230V device on the table is not working		
Only one 2000 device on the table is not working	Check that it is in the 'ON' position Contact your approved distributor	
Near vision test	Check that it is in the 'ON' position Contact your approved distributor Checks/Corrective actions	

If the actions in the table below do not resolve the problem(s), you should contact NIDEK or your approved distributor.



5.2. Maintenance and checks

Check the condition of the consultation unit daily Carry out the following checks:

- Control panel (with the naked eye),
- Proper functioning of various movements. In the event of any abnormalities, contact NIDEK or your approved distributor.

Regularly check that the anti-crush device is functioning by handling it (by lifting the housing under the table or the bars under the Affinity 3 arms) when 'raising' the chair or 'lowering' the table. The red 'ALERT' light should turn on and the chair's 'Raising' movement or the table's 'Lowering' movement should stop.

In the event of a fault, you can refer to paragraphs § 5.1 'Troubleshooting guide' and § 5.4 'Spare parts list'.

Please note: apart from these recommendations, only NIDEK or your approved distributor can repair or disassemble the consultation unit. NIDEK will not be liable for any accident due to incorrect after-sales-service.

5.3. Cleaning

Clean your unit daily with a soft, dry cloth. For stubborn marks, use a cloth soaked in a neutral detergent⁽⁵⁾, ensuring that you wring it out first. Rinse the surfaces with a cloth soaked in clean water in order to prevent premature hardening or cracking. To finish, wipe with a soft, dry cloth.

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

Please note: products containing Quaternary Ammonium compounds should be avoided to prevent any damage to plastics. Never use organic solvents such as paint thinner or abrasive cleaners to clean external parts. The finish on the consultation unit may be irreparably damaged.

5.4. Spare parts list

The Affinity range is equipped with self-resetting fuses and therefore there are no fuses to change.

This unit does not have any consumable parts that require changing regularly. No spare parts are required.

⁽⁵⁾ Neutral detergent: detergent with a neutral pH (between 6 and 8). This will ensure that the surfaces of the consultation unit are not damaged. Please follow the dilution instructions recommended by the detergent or disinfectant manufacturers..

6. Specifications and Technical Information

6.1. CE Classification

Rules 1 and 13 of the classification described in Annex VIII of Regulation (EU) 2017/745 on medical devices identify Affinity as a Class I medical device.

Protection against electric shocks: as a Class I device, the Affinity consultation unit provides protection against electric shocks. In addition to its basic insulation, it includes additional safety devices for earthing the conductive parts of the exposed fixed wiring.

Operation mode: this Affinity consultation unit is classed as continuously operating.

6.2. Electromagnetic compatibility

The consultation unit can be used in shops or hospitals, except for near active HF surgical equipment and rooms protected against RF with a ME magnetic resonance imaging system where the intensity of electromagnetic interference is high.

CAUTION

Do not use in proximity to, on top of or underneath, another electronic device beyond its intended use. There is the risk of malfunction. If such use is required, the device and other pieces of equipment must be checked to ensure normal functioning under the intended conditions.

The use of accessories or cables other than those provided (there are no specific cables for use with the unit) by this unit's manufacturer may result in increased electromagnetic radiation or decreased electromagnetic immunity of this unit and cause malfunction.

Portable RF communication equipment (including peripheral devices such as antenna cables and external antennas) should not be used within 30 cm of any part of the unit. This could negatively impact the unit's performance.



Manufacturer's declaration - electromagnetic radiation

This device is intended to be used in the electromagnetic environment specified below. It is the customer's or user's responsibility to ensure that it is used in such an environment.

Operation mode(s):

Mode N°1: waiting for movementt Mode N°2: continuous movements

N.A: not applicable N.I: not implemented N.R: not requested

Type of test	Standard	Specifications	Meets requirements
Radiated emissions	CISPR 11 Class B	Enclosure port: Group 1 Class B at 10 m ▶ 30 MHz - 230 MHz = 30 dBµV/m ▶ 230 MHz - 1 GHz = 37 dBµV/m	YES ⁽¹⁾
Conducted emissions	CISPR 11 Class B	AC mains port: 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⁾
	IEC 60601-1-2: 2014	Patient-coupled cable: annex H (information only) 1-30 MHz: 24 dBµA	N.A.
Harmonics 50 Hz	IEC 61000-3-2	Access 230 Vac 50 Hz: Class A limit	YES
Voltage fluctuations (flickers)	IEC 61000-3-3	Access 230 Vac 50 Hz: PST<1 PLT<0.65	YES

In order to declare compliance, the uncertainty associated with the result has not been taken into account.

(1) Complies, with changes - see chapter 2.1(2) Complies, with changes - see chapter 2.2

Manufacturer's declaration - electromagnetic immunity

This device is intended to be used in the electromagnetic environment specified below. It is the customer's or user's responsibility to ensure that it is used in such an environment.

N.A: not applicable N.I: not implemented N.R: not requested

Type of test	Specifications	Meets requirements
Electrostatic discharges IEC 61000-4-2	Enclosure port and patient-coupled port: ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	YES YES Criteria A
Radiated radio-frequency electromagnetic fields 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	Enclosure port: Frequency points: table 9 of standard and § 3.2 Pulse modulation or MF as band	YES
Electrical transients fast in bursts IEC 61000-4-4	. AC mains port: ± 2 kV (100kHz) / 240Vac @50Hz . DC mains port: ± 2kV (100kHz) . Signal port: ± 1kV (100kHz)	YES N.A. N.A. Criteria A
Shock waves IEC 61000-4-5	. AC mains port: 240V AC @50 Hz \pm 0.5 kV, \pm 1 kV, \pm 2 kV phase and earth \pm 0.5 kV, \pm 1 kV between phases . DC mains port: \pm 0.5 kV, \pm 1 kV, \pm 2 kV phase and earth \pm 0.5 kV, \pm 1 kV between phases . Signal port: \pm 2kV	YES YES N.A. N.A. N.A. Criteria A
Conducted RF interference IEC 61000-4-6	150 kHz - 80 MHz: 3V - AM 80%, to 1 kHz, 1% ISM band Amateur radio band • AC mains port: 240V AC @50 Hz	✓ ✓ Criteria A YES N.A.
50 Hz magnetic field	Patient-coupled port Signal port Enclosure port:	N.A. N.A. YES
IEC 61000-4-8	Level: 30 A/m (50 Hz)	Criteria A
Power cuts and voltage dips mains port IEC 61000-4-11	AC mains port: 240V AC @50 Hz . 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° . % YT; 250 cycles	YES (Crit A) YES (Crit A) YES (Crit A) YES (Crit C)

In order to declare compliance, the uncertainty associated with the result has not been taken into account.



6.3. Technical specifications

General specifications

Approximate net weight	200 kg (without devices or desk)
Electrical supply	230V AC/50 Hz/1500W
Table top	Electrically adjustable height from 75 to 93 cm with saved preferred height Table maximum load(6): 40 kg per position (2 x 40 = 80 kg for 2 instruments and 3 x 40 = 120 kg for 3 instruments)
Refractor	Refractor on electrically operated and tilting (optional) arm (for 2 instruments only) The height of the refractor's eyepiece is the same as that on the devices positioned on the table top
Storage unit	Several unit models are available as optional additions (for Affinity 2 and RT 3) • Two-drawer unit • Desk
Exam chairs	Electronically adjustable height via the control panel (40-65 cm) Maximum load: 200 kg/Patient height between 120 and 200 cm Available models: • FE-1001 • FE-2010 • FE-3001 Options: • Rotation • Adjustable armrests (FE-3001 only) • Foot rests • Back-and-forth adjustment (manual or electrical options)

Environmental conditions for transport and storage

Temperature	From 5 to 50°C
Humidity	From 10% to 90% (without condensation)
Atmospheric pressure	From 700 to 1060 hPa ⁽⁷⁾
Maximum shelf life	3 months if stored outside of a warehouse certified by NIDEK SA

Environmental conditions during use

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

Under these correct conditions of use and with appropriate checks and maintenance, the life expectancy for a consultation unit is 10 years from the date of installation.

(6) PLEASE NOTE: if the table's maximum acceptable weight is exceeded, there is a risk of damage to the device as well as a risk to the patient. It is essential that this maximum load is not exceeded.
 (7) hPa: hectopascal

6.4. Dimensions



189 cm

280 cm



280 cm

NIDEK SA

170 cm

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