Ancar

DENTAL
INTELLIGENCE
with heart

ANCAR 3100
USER MANUAL

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ISO 9001
109037-AQ-IBE

ISO 13485
112630-AQ-IBE

EC Declaration of Conformity (Directive 93/42/EEC)

Manufacturer's Name
ANTONI CARLES, S.A.

With manufacturing and putting together of medical devices license number **2509-PS** granted by the Health Authorities of Spain.

Name of device:
Dental Unit
GMDNS Code: **34991**

Type or Model:
Ancar 3100

Device Class according to the intended use and the criteria of Annex IX of the Directive:
Class I (rule 12)

Scope of Application: **All (including parts and accessories)**

Power Supply: **220-240 V ~ / 50-60 Hz**

This Declaration is based on **Certificates** issued by **DNV**:
#109037-2012-AQ-IBE-ENAC according to **ISO 9001:2008.**
#112630-2012-AQ-IBE-NA according to **ISO 13485:2003.**

We, the undersigned, under our sole responsibility, certify and declare that the medical devices specified above are in conformity with the essential requirements, which are applicable to them, of **RD 1591/09**, transposition to the Spanish law of the directive **93/42/EC** as amended by the directive **2007/47/EC**. We also declare that we comply with the design and construction requirements of the following standards:

EN 1640 :2009	Dentistry. Medical devices for dentistry. Equipment.
EN ISO 7494-1:2011	Dentistry. Dental Units. Part 1. General requirements and test methods.
EN 60601-1:2006 + AC :2010	Medical Electrical Equipment. General requirement for safety.
EN 60601-1-2:2007 + AC :2010	Medical Electrical Equipment. General requirement for safety. Electromagnetic Compatibility – Requirements and tests.
EN ISO 14971 :2012	Medical Devices. Application of Risk Management to Medical Devices.

Authorized Signatory *Stamp, Date*

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Josep Álvarez
Regulatory & Safety Officer

Antoni Carles Bosch
General Manager

November 27, 2013

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DESCRIPTION PAGE

Thank you for purchasing the orthodontics dentistry equipment **ANCAR-3100**.

This instruction manual contains information about the dental equipment, its configuration and maintenance.

CE This symbol means the unit is certified under directive 93/42/EEC (modified in accordance with standard 2007/47/EC).

Notes

This symbol means **CAUTION, PRECAUTION.**

Before starting-up the unit you must have read and fully understood the user manual.

Keep this manual in a safe place for future reference, for as long as you use the equipment.

Follow all safety standards.

It is the user's responsibility to keep the unit clean, disinfected and in perfect working order.

1.- WARNINGS

This dental equipment is for the exclusive use of a professional, who should have the appropriate training and be a member of a dental association to practise as a dentist.

This equipment may only be moved by authorised technicians.

The unit must be installed in an environment under controlled conditions, including temperature (+10˚C to +40˚C), humidity (30-75 %) and atmospheric pressure (700 a 1060 hPa), free from dust and condensation and protected from direct sunlight.

The electrical circuit at the premises where the unit is to be installed must satisfy the provisions in standard IEC 601.1 regarding protection against electric shock for class I equipment.

Antoni Carles, S.A. reserves the right to make any improvements or modifications to the dental unit without prior warning.

The unit must be used in accordance with the instructions of use.

Under Directive 93/42/EEC (modified in accordance with 2007/47/EC), the orthodontic chair with cannules support manufactured by Antoni Carles, S.A. are class I equipment. Only may be installed equipment in compliance with the provisions in the aforementioned Directive and standardised regulations EN60601-1, EN60601-1-2.

2.- GUARANTEE

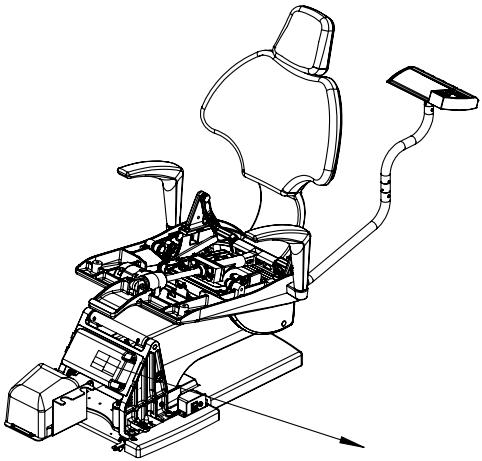
The device comes with a Certificate of Guarantee. If you do not receive this, ask your dealer directly. The Certificate of Guarantee must be completed and returned to the manufacturer (Antoni Carles, S.A.) **within 8 days** of delivery of the device.

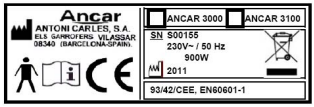
The guarantee is only valid if the device has been used correctly and installed by an authorised technician.

Moreover, to comply with Health equipment traceability in accordance with Directive 93/42/CEE you must also return the installation form.

3.- IDENTIFICATION

The identification tag, containing technical information required for connection, could be found on cover of movement electronic card, and is visible when the outer cover is removed (fig. 1).





4.- PRECAUTIONS

The unit should be installed in a bright place away from corridors or passageways, and should have adequate room to accommodate both the patient and the user.

The dental chair should be fixed to the floor to guarantee stability.

Before moving the chair, the operator (dentist, user) must ensure there is no-one (patient, guests, children) in the vicinity, movement's area of chair. Be aware of people around the backrest area and around the cannula tray.

After using the unit, switch off all instruments as well as the unit itself, which should remain switched off at the end of each working day by main switch. If the unit is to be out of use for a long period of time, or remain without direct personnel supervision, also disconnect it from the mains supply.

To prolong the working life of the lifting unit components, take care not to overload the chair. In the event of an overload in the chair, the built-in thermal protection of the motors may have triggered and suspended all movement. Wait 15 minutes for it to reset. Should the problem persist, call the authorised thecnical service line.

Do not replace fuses yourself. Contact an Antoni Carles-authorised technician through our Sales Department. This will give you greater safety and prolong the life of the unit.

To avoid adverse effects to dental chair and instruments, it is advisable not to use mobile telephones or other devices emitting radio waves in the proximity of the working unit. Please observe standards of application to hospitals.

This equipment is not designed to work in potentially flammable environment. Do not place in an operating theatre or in presence of anesthetic gas mixtures with oxygen or nitrogen protoxyde.

ENVIRONMENTAL PROTECTION

All packaging materials are produced in respect for the environment and are fully recyclable: wooden pallets, cardboard, plastic bags and, bubble-wrap. Collecting used materials helps collection and recycling, and reduces waste material.

Antoni Carles, S.A. is obliged to satisfy the objectives set by Community directives 2011/65/EC and 2012/19/EC.

This symbol is only applicable for member countries of the European Union.

In order to avoid potential negative consequences on the environment and possibly on human health, this instrument must be withdrawn (i) in member countries of the EU – in accordance with WEEE (Electric and Electronic Material Waste Directive), and (ii) for other countries in accordance with local provisions and recycling laws.

EMC

The **ANCAR-3100** dental unit conforms to the basic requirements of application of directive 93/42/CEE (modified in accordance with 2007/47/EC) concerning medical devices, and complies with the design and construction requirements contained in standard EN60601-1-2 regarding the safety of Electromagnetic Compatibility and Electrical Medical Equipment, causing no electromagnetic disturbances and complying with immunity standards.

REMARKS ON ELECTROMAGNETIC INTERFERENCES

Electronically-controlled instruments may harm patients fitted with pacemakers and/or hearing aids because of possible electromagnetic interferences.

Close use of electronic scalpels or other electric / electronic devices which may generate electromagnetic or other types of interferences, may caused undesired operation as a result of its association with dental chair and pose an hazard to the patient. It is advisable to disconnect the dental chair at the mains before using these kind of devices.

Risks of intervention with other separate equipment (such as for instance an implant motor). Disconnect the dental chair from mains to avoid any possible indirect movement caused through faults and/or accidental activation of motion command controls.

ENVIRONMENTAL CONDITIONS

While it is in its packaging for transport and storage, the equipment can withstand being exposed for no longer than 15 weeks to environmental conditions that do not exceed:

a) ambient temperature from -20 ˚C to +50 ˚C.
b) a relative humidity of 10 % to 100 %, including condensation
c) an atmospheric pressure of 500 hPa to 1 060 hPa (from 500 mbar to 1 060 mbar).

- Functioning conditions:

d) ambient temperature from +10 ˚C to +40 ˚C.
e) a relative humidity of 30 % to 75 %, including condensation
f) an atmospheric pressure of 700 hPa to 1 060 hPa (from 700 mbar to 1 060 mbar).

5.- TECHNICAL FEATURES

Ergonomic design for the patient.

Dental chair with silent, automatic and highly reliable movement.

Microprecessor-controlled movements:
- Automatic chair return movement.
- 3 programmable chair settings.

High quality, hygienic anatomic upholstery.

Pneumatic pedal to control movements. Botton to register positions into memory placed at the backrest part of the chair in the base of the chair.

Height-adjustable, folding headrest.

Includes Trendelenburg position.

Chair with cannule support tray at its rear area enabling access to the patient from both the right and the left for the doctor to work, including housing for small and big surgical aspirations.

Command panel in the suctions tray.

Connections box built into chair.

Safety system to block the chair movements, by going back, ascending or descending, until it is set free, when it detects one of the following activations:
- At instrument tray arm (rise and fall blocking).
- At lower contact articulation of instrument tray to chair.
- At chair base and backrest.
- Manual activation of the keyboard or pedal cancels automatic movement under way.

This unit conforms to the basic requirements applied by Directive 93/42/CEE on medical devices, complies with the design and construction requirements contained in Standards EN60601-1 and EN60601-1-2 regarding the safety of Electromagnetic Compatibility and Electrical Medical Equipment, and conforms to ISO 14971, Risk Management analysis standard.

6.- CLAUSES

Antoni Carles, S.A. will not assume responsibility for damage caused by fire, natural disasters, third party activities or other accidents caused by operator negligence or misuse, or from using the equipment under unusual conditions.

Antoni Carles, S.A. will not assume responsibility for damage deriving from the improper use of equipment, causing a loss of business or loss of earnings**.**

Antoni Carles, S.A. will not assume responsibility for results of diagnoses made by a doctor using this equipment.

7.- DIMENSIONS AND TRANSPORTATION

The dental unit is suitably packaged and protected (Fig. 2).

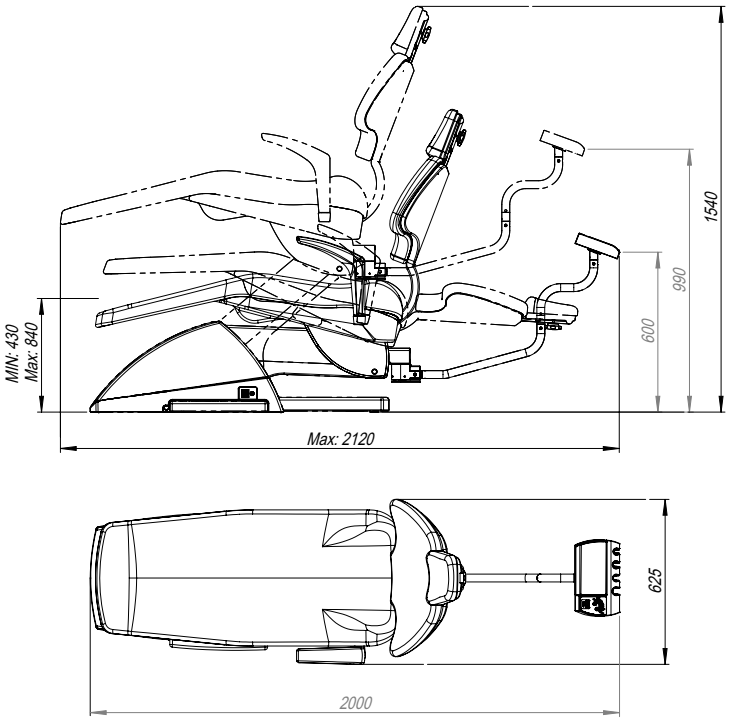
One box contains the palette-held dentistry chair, the pedal unit, upholstery and front cover. In a second box, the aspirations support arm.

It is essential that none of the boxes are knocked when in transit, and under no circumstances must they fall to the floor. Great care should be taken when moving the equipment; we recommend it be transported by technicians authorised by **Antoni Carles, S.A.**

Before assembling the unit, a technician, along with yourself and the authorised member of staff on-site should determine its best location with regard to comfort and ergonomics.

If any assembled unit has to be moved, set the chair with its seat as low as possible and the back raised, and make sure the cannula tray is retracted as far as possible on the chair and at all times.

Once in its new position, remember to secure the chair to the floor.



8.- ANCAR-3100 DENTAL UNIT COMPOSITION (Figure 3)

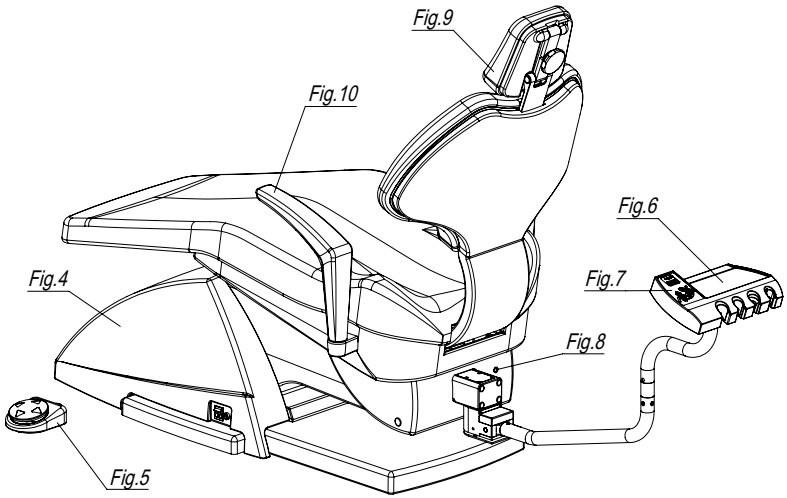


Figure 3

8.1.- Circuit Box

Inside circuit box you will find all points for connecting the dental unit to the clinic's power supply.

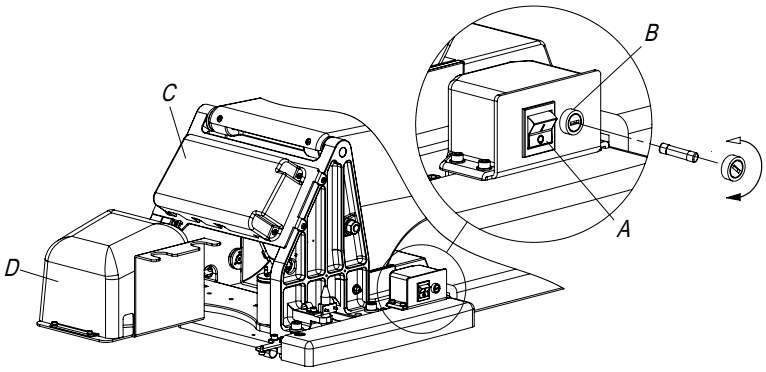


Figure 4

View of the chair base (front part):

- **A.** General power switch. Towards up (« I »), turn it on; towards down (« O »), turn it off. Pilot light.
- **B.** General mains fuse of protection, in phase, T6,3A / 250 V, slow blow, 5x20 mm. Fuse replacement should be supervised by an authorised technician.
- **C.** Movement electronic card cover.
- **D.** Connection electronic card and transformator cover.

Note: when activating the general power switch (« A »), the circuit box PCB will perform a function test, producing an audible beeping sound dl. If you do not hear this sound, switch off the unit and contact your technical service provider.

If instrument's lines (17Vac or 24Vac) have carried a hard workload, it may be that the integrated thermal protection at power lines is switching off the operation. Wait please about 15 minutes to its normal recover. In case the fault persists, call technical assistance.

Do not connect other bases or extensions to the available outputs.

8.2.- Pedal

Positioning of chair.

MOVEMENT FUNCTIONS (Fig. 5)

A. Manual seat raising button.
One simple pulsation actives automatic movement of memory position **1**.

B. Manual seat lowering button.
One simple pulsation actives automatic movement of memory position to reset, zero.

C. Manual backrest lowering button.
One simple pulsation actives automatic movement of memory position **2**.

D. Manual backrest raising button.
One simple pulsation actives automatic movement of memory position **3**.

Safety: To block any memory in progress, being activated by keyboard, it is enough to press pedal.
One press will deactivate memory in progress. Second push will enable a new automatic movement (it will activate a new memory position).

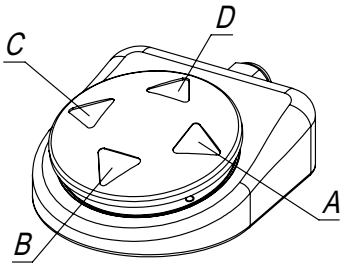


Figure 5

HOW TO REGISTER A POSITION

"**A**": Button to register memory positions is placed at rear part of backrest, in the seat area of chair. By default there are already associated positions to three memories.

- It is advised to perform first of all one return to zero (even one reset of chair).
- Place chair at desired seat height and backrest inclination.
- Press for over 2 seconds memory register push button ("**A**") and pedal at one of the three available buttons to associate chosen position. There are up to 3 available: "**A**", "**C**", "**D**".
- You will hear a "beep" as confirmation. Release button "**A**".

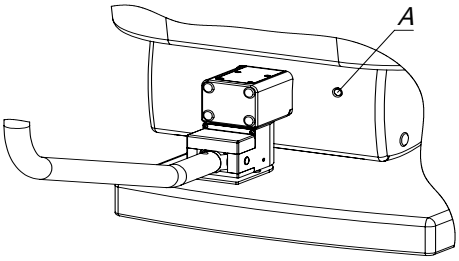


Figure 6

8.3.- Cannula support tray

Ergonomic conception to make easy professional work.

Functions:

- Movement command control.
- Cannula support for middle and big volume surgical suction.

With rounded and flat form shapes, tray could be easily cleaned and disinfected.

Cannula support is assembled into an arm provided with a broad range of available movements so you could obtain almost any working position. Surgical suction starts aspiration motor when cannula is removed from support.

Suction cannules connections should have to be made apart from chair installation.

Cannula could be esterilized, they could be submit to autoclave process, with the exception of the inner rubber. If there is not any continuous aspiration system, please allow some time to evacuate to the operation procedure.

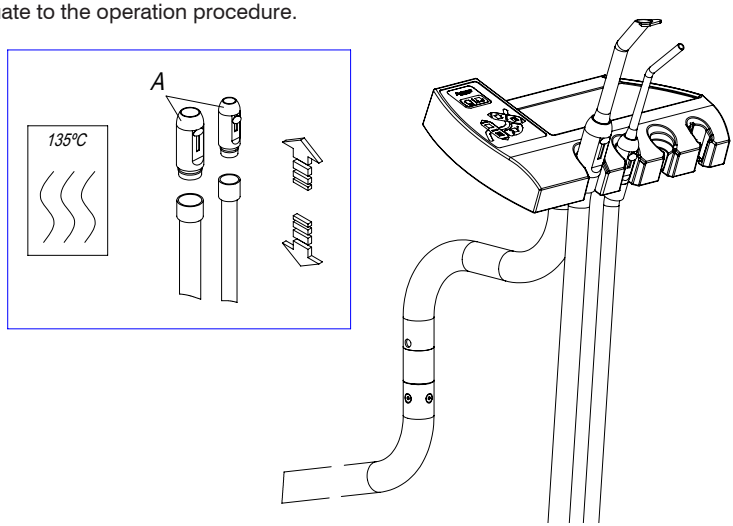


Figure 7

8.4.- Control Panel

CHAIR MOVEMENT FUNCTIONS

- Safety for movements integrated with activation of micro-switches and pedal.
- Movement activation functions in parallel with pedal.

A. Pressed continuously: Backrest return movement.
Pressed once: Automatic movement to memory position 2.
B. Pressed continuously: Backrest recline movement.
Pressed once: Automatic movement to memory position 3.
C. Pressed continuously: Manual chair raising.
Pressed once: Automatic movement to memory position 1.
D. Pressed continuously: Manual chair lowering.
Pressed once: Automatic reset movement.

There are three other buttons (spittoon return, spittoon tap and glass tap water) without any specific associated operation.

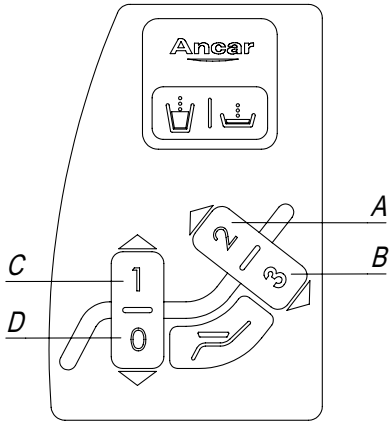
To registrer memory positions (1, 2, 3):

It is advised to previously perform a zero return (et même un reset du fauteuil).

Position chair with the help of manual movement buttons at the desired point (seat and backrest).

Maintain rear backrest button pressed, the one placed at the chair seat base ("**A**", figure 6) and press also at one of these three positions (1, 2, or 3), wait till receive a confirmation «beep». Release button "**A**".

Schéma 8



8.5.- Headrest

Thanks to its articulated movement, this head support allows the patient's head to be positioned easily and idelly, according to the treatment required.

The head support upholstery can be replaced simply by removing it from the base, allowing comfortable maintenance.

OPERATION

- the lengthways adjustment is easily connected. The piece is gripped firmly with the position held internally.
- By turning the piece «**A**» you can achieve the desired inclination. Once the headrest is set in the optimal position, lock the mechanism by turning lever «**A**» anticlockwise.

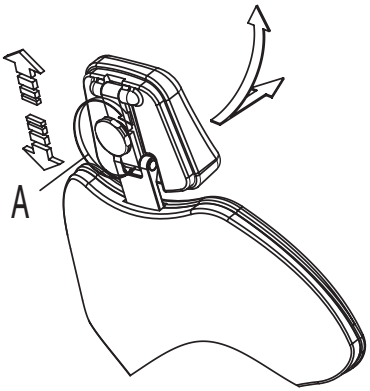


Figure 9

8.6.- Optional armrest

The unit can be fitted with left and right armrests.

To turn the armrest, first release it by lifting it upwards (while maintaining at its position) until turning mechanism is released and allows to turn until it reaches maximum limit (end of stroke), where it will block. To reset armrest to its oritinal position, it is enough to lift it again and push it inward, until it blocks by itself automatically (Fig. 10).

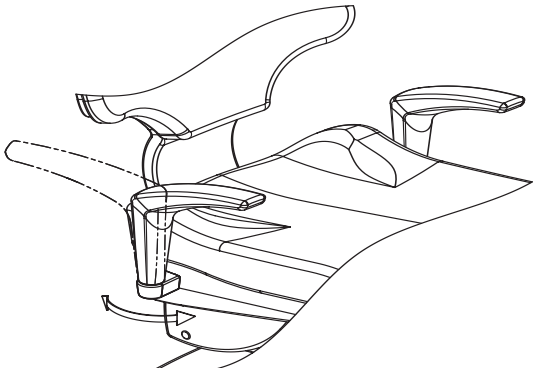


Figure 10

9.- TECHNICAL DATA

Voltage	220-240 V~
Frequency	50 Hz
Power	900 W
Electrical protection type	I
Type of operation	Intermittent
Maximum load (patient)	160 Kg.
93/42/CEE type of unit	Class I
Type of dental chair	Electronic.
Type of insulation	Type B
Net / Gross weight of the unit	186 / 226 kg.
Type of installation	Permanent
Main fuse	T 6.3A / L / 250V
Movements chart fuse, 24V line	T 32 mA / L / 250V
Primary trafo fuse, 9015093 PCB	TT 2.5A / L 7 250V
24 V ac line protection (ye/ye)	Polyswitch RUE600
17 V ac line protection (re/re)	Polyswitch RUE600+ RUE185
24 V ac outputs	2 x circuit box
Suction connection	500W / 230V. Relais 20A/250V
AUX contact free power circuit box PCB	Max 250V/5A

10.- SAFETY MOVEMENTS

- The dental chair includes mechanical safety stop switches at end positions for seat and backrest, ensuring correct manoeuvering and positioning.
- Motor overload control through integrated heat sensorss. Should the heat sensors go off, wait 15 min. for them to cool.
- The backrest safety feature, in the event of pressure or knocks against other objects when descending backrest (either manual or by means of a memory), any chair movement will be suspended (both seat and backrest) before raising backrest a few centimeters.
- The base safety feature, in the event of pressure on the base or knocks against other objects during manual or automatic reclining, suspends all chair movements (both seat and backrest) before lifting raising it a few centimeters.
- The cannula support safety feature suspends all chair movements (both seat and backrest) and return in the opposite direction to the suspenden movement a few centimeters when any kind of pressure is applied against the arm or an obstacle is encountered when descending or lifting it, either in automatic or in manual.
- Cannula arm base safety, after any pressure by contact against piece at the below part when descending encountering an obstacle stops all movements.
- Safety device in the adjustment pedal does not allow automatic movements, thus preventing unwanted activations due to the sensitivity of the three-dimensional movement button. Exception will be made if memories have been set up.
- Keyboard and keyboard safety feature enables to stop any chair movement in the event chair is carrying out a memory movement, and it is pressed any movement key.

When a safety movement device is activated, the chair moves in the opposite direction to the seat and backrest motor to release the trapped component.

11.- CLEANING AND STERILISING

When cleaning your dental unit, it is essential that you use neutral products. Cleaning products with high chemical content can damage plastic parts or upholstery. When cleaning, take care not to wet the equipment too much, as its interior is made up of electrical components. Various specialists in the dental hygiene industry offer a wide range of cleaning products for achieving optimum results.

ANCAR thoroughly and systematically cleans your equipment, prior to its dispatch, with Magnolia Spray ECO-JET1 (Cattani Group).

For cleaning and disinfecting the different parts of the device, please check:
- Appendix 1, “Cleaning other parts of the unit”.

STERILISING AND AUTOCLAVE.

Hand instruments should be sterilised in the autoclave, at an average temperature of 135˚C, though we recommend that you follow the instructions of the instrument manufacturer.
The cannulae and cannula holders can also be sterilised, except for the internal rubber. If not fitted with a continuous suction system, the separator system should be left for a short emptying period.
Proper use and maintenance of the equipment will prolong its working life.

APPENDIX 1. CLEANING AND DISINFECTING OTHER PARTS OF THE UNIT.

Cleaning and disinfecting

Always disconnect the unit from the mains before carrying out any procedures.

Do not wet or flood the unit with water.

Do not use domestic detergents or disinfecting foams.

Cleaning upholstered areas

Clean periodically with a soapy solution.

Cleaning polyurethane areas (unit base cover, upholstery support, lifting mechanism covers)

Polyurethane areas must be cleaned using a cloth soaked in soapy water.

It is recommended to avoid using concentrates, detergents and strong abrasives to remove difficult stains.

Clean regularly.

Cleaning and disinfecting exterior metal parts (excluding instruments)

Use any product with an antimicrobial, fungicidal, sporicidal or virucidal action that is compatible with the medical industry.

Check manufacturer instructions.

Cleaning and disinfecting the auxiliary instrument tray and hoses.

Cleaning and disinfecting: clean after each treatment using antimicrobial, fungicidal, virucidal and sporicidal disinfectant.

ANCAR recommends the use of the BODE X-WIPES reloadable wet wipe dispenser for professional washing and disinfection. Suitable for all BODE surface disinfectants at concentrations that take effect within 1 hour.

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