Ancar

DENTAL
INTELLIGENCE
with heart

ANCAR 3000
USER'S 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:
Chair, Dental Unit
GMDNS Code: **36780**

Type or Model:
Ancar 3000

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 **ANCAR-3000** dental chair.

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

CE This symbol means the unit is auto-certified under Directive 93/42/EEC (modified in accordance with 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 responsability to keep the unit clean, disinfected and in perfect working order.

1.- WARNINGS

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

This equipment may only be moved by authorized technicians.

The chair must be installed in an environment with 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 chair without prior warning.

The chair must be used in accordance with the use instructions.

Under Directive 93/42/EEC (modified in accordance with 2007/47/EC), the dental chair manufactured by **Antoni Carles, S.A.** is a class I equipment. It is suitable to be interconnected to other devices as in compliance with the provisions in the aforementioned Directive and standardized regulations of EN60601-1 and EN60601-1-2 norms.

2.- GUARANTEE

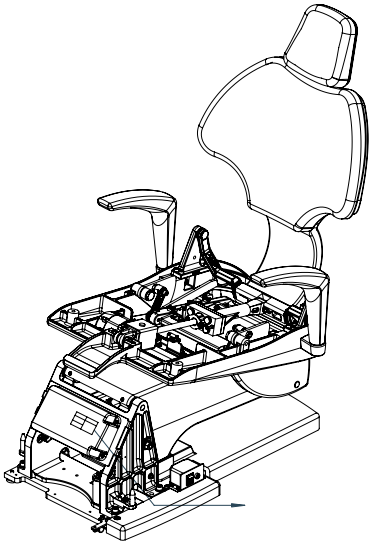
The device comes with a Certificate of Guarantee. If you do not receive this, ask your dealer directly. The certificate of Guarantee must be completed and returned to the manufacturer (**Antoni Carles, S.A.**) **within 8 days** of delivery of the device.

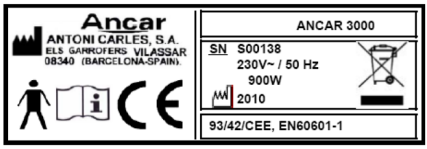
The guarantee is only valid if the device has been used correctly and installed by an authorised technician.

Moreover, to comply with Health Equipment traceability in accordance with Directive 93/42/EEC (modified in accordance with 2007/47/EEC), you must also return the instalation form.

3.- IDENTIFICATION

The identification tag, containing technical information required for connection, can be found close to the base on the front of the chair, and is visible when the outer cover is removed (Fig. 1).





SN: S (chair) + number
Sxxxx

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 (Doctor, user) must ensure that there is no-one (patient, guests, children) in the vicinity. Be aware of people around the backrest and footrest area.

After using the chair, switch it off, as well as at the end of each working day. The chair itself should remain switched off. If it is to be out of use for a long period of time, please also disconnect it from the mains supply.

Make sure the general power switch is turned off if the equipment is to be left without staff supervision. This prevents any distracted use of the pedal to provoke a non intended movement for the patient while being in treatment.

To prolong the working life of the lifting unit components, take care not to overload the chair.

It is advisable not to use mobile telephones in proximity of the working unit.

This chair is not designed to work in operating theatres.

ENVIRONMENTAL PROTECTION

TAll 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 2002/95/EC and 2002/96/EC..

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

In order to avoid potential negative consequences for the environment or even human health, this equipment should be disposed of (i) in EU member countries – in accordance with the WEEE (Waste Electrical and Electronic Equipment) Directive, and (ii) for all other countries, in accordance with local provisions and recycling laws.

EMC

The **ANCAR-3000** dental unit conforms to the basic requirements of Directive 93/42/EEC concerning medical devices, (modified in accordance with 2007/47/EC), 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.

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 margin from -20ºC to +50ºC.
b) a relative humidity margin of 10% to 100%, including condensation.
c) an atmospheric pressure margin of 500 hPa to 1060 hPa (from 500 mbar to 1060 mbar).

- Functioning conditions:

d) ambient temperature margin from +10ºC to +40ºC.
e) a relative humidity margin of 30% to 75%, including condensation.
f) an atmospheric pressure margin of 700 hPa to 1060 hPa (from 700 mbar to 1060 mbar).

5.- CLAUSES

Antoni Carles, S.A. will not assume responsibility for damages 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 damages 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.

6.- TRANSPORT AND DIMENSIONS

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

The package includes the dental chair secured to a pallet, including in the same box pedal, upholstery and front chassis, as well as articulated headrest.

It is essential that the box should not be knocked when in transit, and under no circumstances must it fall to the floor. Great care should be taken when moving the equipment; we recommend transportation by Antoni Carles, S.A. authorized technicians.

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

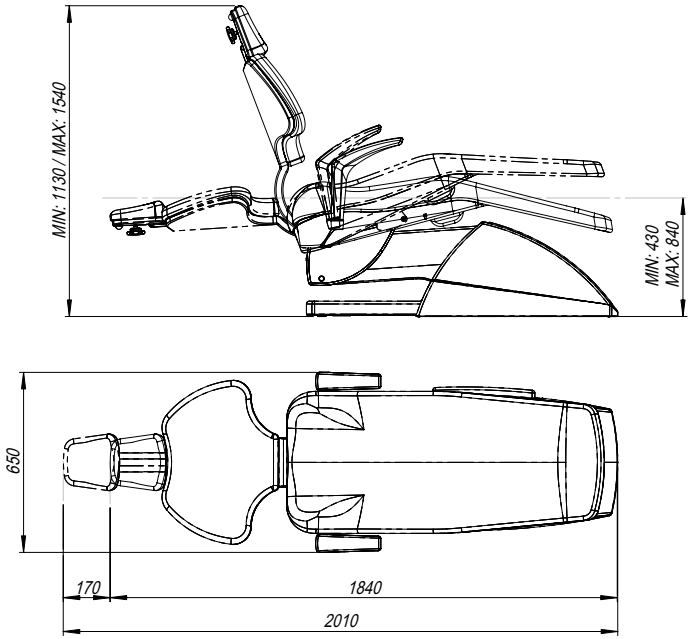


Fig. **2**

Should you have to move a pre-assembled unit, fit the chair first with the seat at its lowest position and the back raised.

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

7.- TECHNICAL FEATURES

Ergonomic design for the patient.

Dental chair with silent, automatic and highly reliable movement.

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

High quality, hygienic anatomic upholstery.

Safe movement of the base and backrest of the chair, which is raised upwards until block is released.

If the chair moves to a memorized location, pressing any directional key on the pedal will stop the unit.

Height-adjustable, folding headrest.

Includes Trendelenburg position.

The chair conforms to the basic requirements applied by Directive 93/42/EEC 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 standard ISO14971, a Risk Management analysis.

8.- ANCAR 3000 DENTAL CHAIR COMPOSITION

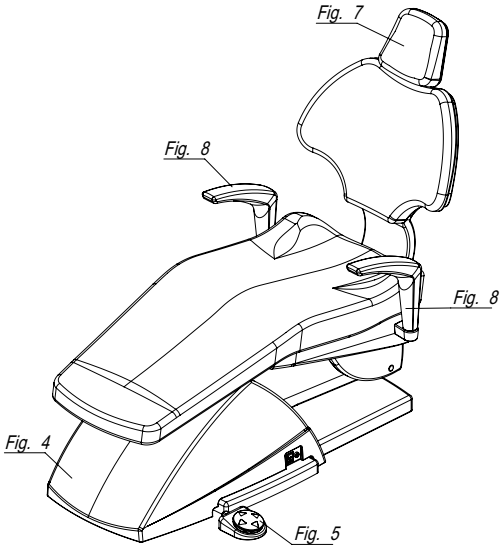


Fig. **3**

8.1.- Circuit box

The circuit box contains all points for connecting the dental chair to the clinic's power supply.

As indicated in the diagram, the front part of the chair base contains:

A. General power switch. Up ("**I**"), on; Down ("**O**"), off. Pilot light..

B. General mains fuse, rating **T4A** / 250 V, type 5x20 mm. It is recommended that fuses should be replaced by an authorized technician.

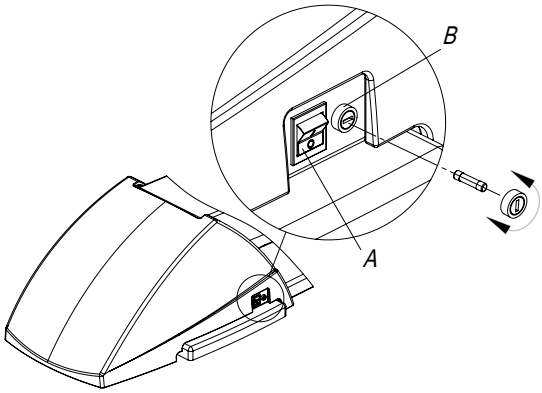


Fig. **4**

NNote: when activating the general power switch ("A"), the connection panel will perform a function test, producing an audible beeping sound. If you do not hear this sound, switch off the unit and contact your technical service provider.

8.2.- Pedal

MOVEMENT FUNCTIONS

A. Raise chair manual button.
Pressed once performs automatic movement towards memory positon #**1**.

B. Lower chair manual button.
Pressed once performs automatic movement towards reset position.

C. Lower backrest manual button.
Pressed once performs automatic movement towards memory position #**2**.

D. Raise backrest manual button.
Pressed once performs automatic movement towards memory position #**3**.

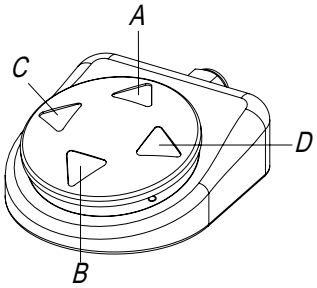
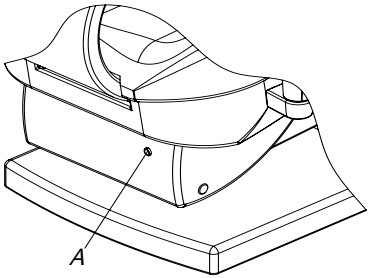


Fig. **5**

RECORDING POSITIONS

Push button to perform record of memory locations placed at the rear part of backrest close to its base.
- Place the chair seat height and backrest angle in the desired position.
- Press for two seconds the recording push button and one of the three available buttons of the pedal to associate the position. There are up to three: "**A**", "**C**", or "**D**".
- You will listen a validation "beep".



Safety: When activating the pedal, a press at any button, will abort a button-activated memory movement.

8.3.- Headrest

Thanks to its articulated movement, this head support allows the patient's head to be positioned easily and ideally, according to the treatment required. It can be easily adjusted lengthways, as shown in image.

OPERATION

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

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

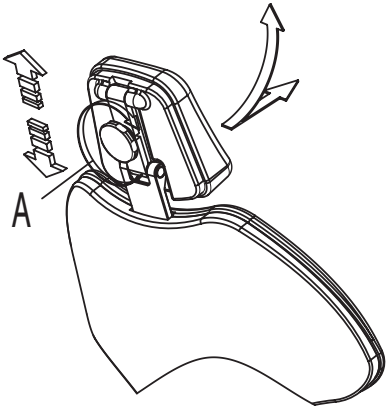


Fig. **7**

8.4.- Armrest

To turn the armrest, first release it by lifting it upwards. Then turn it and set it to the desired position where it is locked in place. Repeat this action to leave it in the closed position.

As an optional, chair can be fitted with both armrests, left and right.

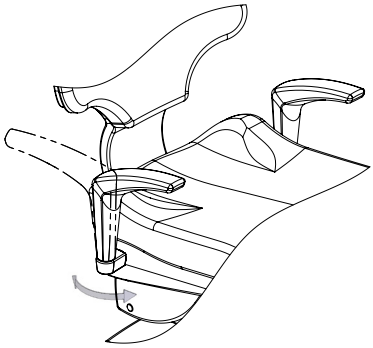


Fig. **8**

9.- SAFETIES

- The dental chair includes mechanical safety stops for the chair and backrest, ensuring correct maneuvering and positioning.
- Motor overload control through integrated heat sensors. Should the heat sensors go off, wait 15 minutes for them to cool.
- The backrest safety feature, in the event of pressure or knocks against other objects during manual or automatic lowering recline, raise it a few centimeters and suspends all chair movement (seat and backrest).
- The base safety feature, in the event of pressure or knocks against other objects during manual or automatic lowering recline, raise chair a few centimeters to unlock, and suspends all chair movement (seat and backrest).
- The control pedal safety blocks all automatic chair movements (seat and backrest) simply by pressing any position of the three-dimensional button movement.

10.- TECHNICAL DATA

Voltage	220-240 V~
Frequency	50 Hz
Power	900 W
Electrical protection type	I
Type of operation	Intermitent
Maximum load (patient)	160 Kg.
93/42/EEC type unit	Class I
Type of insulation	Type B
Net / gross weight of the unit	180 / 220 kg.
Type of installation	Permanent
Main fuse	T 4A / L / 250V
Movement Chart Fuse	T 32 mA / L / 250V

APPENDIX 1. CLEANING

It is of utmost importance to use for cleaning the dental chair neutral products. Cleaning products with high chemical content can damage the plastic or upholstery parts. When performing the cleaning operation, be careful not to wet it, as there are inside electronic components. There is a wide range of cleaning products to get an optimal outcome from different specialists in the field of dental hygiene.

ANCAR executes a sistematic cleaning of its equipments, previous to release them, by means of disinfectant ECO-JET1 Spray of Magnolia (Cattani Group).

Cleaning and disinfecting

Before performing these kind of operations disconnect the chair from the mains.
Do not wet or flood chair with water.
Never use domestic detergents or disinfecting foams.

Upholstery cleaning

Clean periodically with a soapy solution.

Polyurethane cleaning (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..

Disinfecting and Cleaning of external metalic parts

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

APPENDIX 2. SAFETY OBSERVATIONS

GENERAL PRECAUTIONS

Consult all necessary manuals. Keep all manuals – dental unit, chair, instruments, light and additional kits – in a safe place for future reference.

Before starting up the chair, read all appendices in this manual.

Disconnect the unit from the mains, turning off the general power switch at the end of each working day. If the unit is to be left unused for a long period of time, disconnect the unit from the electrical supply.

Do not replace fuses yourself. Contact an Antoni Carles-authorised technician through our Sales Department Department.

Hire an authorised maintenance service. This will give you greater safety and prolong the life of the unit. Check with our Sales Dept. Department

Do not use the unit to support or hold furniture or other materials. The unit should only be used by qualified personnel.

ELECTRICAL SAFETY MEASURES

It is advisable not to use mobile phones in proximity of the dental unit. Observe regular hospital standards.

In the event of an overload in the chair, the thermal protection built into one of the motors may have been triggered and suspended all operations. Wait 15 minutes for it to reset. Should the problem persist, call the authorised technical service line.

Do not add additional multiple intake bases or extensions to auxiliary intakes available on electronic charts.

PRECAUTIONS ON ELECTROMAGNETIC INTERFERENCES

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

The patient may be at risk from the approximate use of electronic scalpels or other electric/electronic equipment which may generate electromagnetic or other types of interference, causing the unit to malfunction. It is advisable to switch off the unit at the mains before using such equipment.

Risk of interference with other separate equipment (such as an implant motor) Disconnect the dental unit power supply to prevent any movements indirectly caused through faults and/or through accidental activation of the controls.

PRECAUTIONS ON FLAMMABLE ANAESTHETIC MIXTURES

Do not use the unit/chair in proximity of mixtures of flammable anaesthetic gas with oxygen or nitrogen protoxide.

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