

Ancar

DENTAL
INTELLIGENCE
with heart



Sd-60

USER MANUAL

July 2014, QS4 626 v.2



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

Manufacturer's Name

ANTONI CARLES, S.A.

With medical device manufacturing and assembly license number 2509-PS granted by the Health Authorities of Spain

Name of device

Type or Model:

Dental Unit

Code GMDNS: **34991**

Sd-60

Device Class According to the intended use and the criteria of Annex IX of the Directive:

Class IIa (rule 11).

Scope of Application:

All (including pieces and accessories)

Power Supply:

220-240 V ~ / 50-60 Hz

Electrical Classification

Type B

This Declaration is based on Certificates issued by DNV:

78388-2010-CE-IBE-NA according to **annex V, DIR 93/42/EEC,**

No. 109037-2012-AQ-IBE-ENAC, according to **ISO 9001:2008,** and

No. 112630-2012-AQ-IBE-NA, according to **ISO 13485:2003.**

Notified Body:

0434 DNV (Det Norske Veritas) – Region Norge As.

We, the undersigned, under our sole responsibility, hereby certify and declare that the medical devices specified above are in conformity with the essential requirements applicable to them, of **RD 1591/09**, transposition to the Spanish law of the directive **93/42/CEE** 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 products for dentistry. Equipment
- EN ISO 7494-1:2011** Dental units. Part 1. General requirements and testing methods
- EN ISO 7494-2:2003** Dental units. Part 2. Air and water supply
- EN 60601-1:2006 + AC:2010** Medical electrical equipment. General requirements for safety.
- EN 60601-1-2:2007 + AC:2010** Medical electrical equipment. General requirements for safety. Electromagnetic Compatibility - Requirements and tests.
- EN ISO 14971:2012** Medical Devices. Application of Risk Management to Medical Devices.

Authorized Signatory

Stamp, Date

Josep Álvarez
Regulatory & Safety Officer

Antoni Carles Bosch
General Manager

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31 July 2014

TABLE OF CONTENTS	PAGE
1.- GENERALITIES	2
2.- GUARANTEE	2
3.- IDENTIFICATION	3
4.- PRECAUTIONS	3
5.- CLAUSES	4
6.- TECHNICAL FEATURES	5
6.1.- Chair	5
6.2.- Dental Unit	5
7.- DIMENSIONS AND TRANSPORTATION	6
8.- DENTAL UNIT DESCRIPTION	7
8.1.- Circuit box	8
8.2.- Pneumatic pedal	9
8.3.- Water Cabinet	10
8.4.- Cannula support	12
8.5.- Keypad	13
8.6.- Headrest	14
8.7.- Optional armrest	14
9.- SAFETY MOVEMENTS	15
10.- CLEANING AND STERILISING	15
11.- TECHNICAL DATA	16
ANNEX 1. CLEANING & DISINFECTING OF CATTANI GLASS, CANNULAS AND BASIN	17
ANNEX 2. SPITTOON BASIN CUT-OFF VALVE AND ASPIRATION UNIT (CATTANI)	18
ANNEX 3. VSA300: SUCTION SYSTEM (DÜRR DENTAL)	19
ANNEX 4. ASPIRATION SYSTEM TYP1 (METASYS)	20
ANNEX 5. ECO ASPIRATION SYSTEM (METASYS)	21
ANNEX 6. SELF WATER SYSTEM KIT	22
ANNEX 7. COMBI-SEPARATOR CAS 1 (DÜRR DENTAL)	23
ANNEX 8. COMBI-SEPAMATIC CS 1 (DÜRR DENTAL)	23
ANNEX 9. HYGIENE SYSTEM H1 (METASYS)	24
ANNEX 10. SELECTIVE CANNULA SYSTEM S1 (METASYS)	25
ANNEX 11. MINILIGHT SYRINGE (LUZZANI)	26
ANNEX 12. OPTIONAL ITEMS	28
ANNEX 13. CLEANING AND DISINFECTING OTHER PARTS OF THE UNIT	29
ANNEX 14. SAFETY NOTES	30

1.- GENERALITIES

Thank you for purchasing the **Sd-60** dental unit.

This instruction manual contains information on the dental unit, including its configuration and maintenance.



This symbol means the unit is certified under Directive 93/42/EEC by the DNV



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.

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 installed and serviced by authorised technicians.

The unit 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 unit without prior warning.

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

Under Directive 93/42/EEC, the dental unit and dental chair manufactured by **Antoni Carles, S.A.** are class IIa equipment. It is absolutely prohibited to install any class IIb or III dental instrument, e.g. surgical lasers, electronic scalpels, X-rays or electric cauterizers. Only class I or IIa equipment may be installed, in compliance with the provisions in the aforementioned Directive and standardised regulations EN60601-1, EN60601-1-2.

2.- GUARANTEE

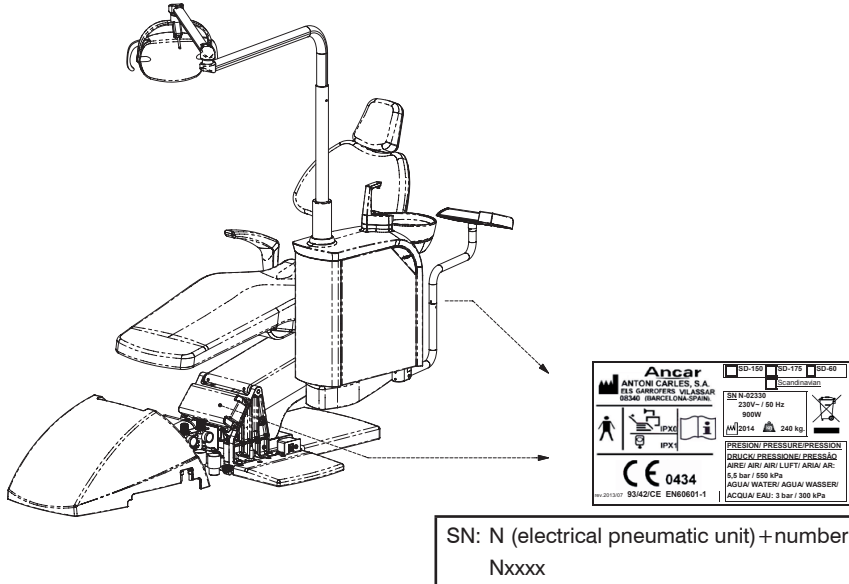
The device comes with a Certificate of Guarantee. If you do not receive this, ask your dealer directly. The Certificate of Guarantee must be completed and returned to the manufacturer (**Antoni Carles, S.A.**) **within 8 days** of delivery of the device.

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/EEC, you must also return the installation form.

3.- IDENTIFICATION

The identification tag, containing technical information required for connection, is duplicated. You'll see from the back of the seat, and it also can be found close to the base on the side of the chair. It 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 (Doctor, user) must ensure there is no-one (patient, guests, children) in the vicinity. Be aware of people around the backrest area and around the instrument 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.

If the unit is to be out of use for a long period of time, disconnect it from the mains supply and close the main air and water inlet taps.

Make sure the general power switch (fig. 4, "J") is turned off if the equipment is to be left without staff supervision. This prevents the water pipes from having to sustain a constant pressure. The air and water inlets must not exceed a pressure of 10.3 Bar, nor should the pipes be exposed to temperatures exceeding 46°C, to avoid system faults and damage to property.

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 equipment is not designed to work in operating theatres.

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 for the environment or 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 **SD-60** dental unit conforms to the basic requirements of Directive 93/42/EEC 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.

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 -20°C to $+50^{\circ}\text{C}$.
- 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 $+10^{\circ}\text{C}$ to $+40^{\circ}\text{C}$.
- 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.- TECHNICAL FEATURES

6.1.- Chair

Ergonomic design for the patient.

Dental chair with silent, automatic and highly reliable movement.

Microprocessor-controlled movements:

- automatic chair return-to-zero movement (configurable height).
- automatic chair-to-spittoon movement.
- 3 programmable chair settings (configurable seat height and backrest).

High quality, hygienic anatomic upholstery

Safe movement of the seat and backrest of the chair, which are raised upwards until unlocked.

Height-adjustable, folding headrest.

Includes Trendelenburg position.

6.2.- Dental Unit

Easy-maintenance finish.

Instrument tray at water unit with space to hold 2 instruments and a 7-function control panel. Includes syringe and a pneumatic hose (usually turbine).

Available connection for turbine with light fitting.

70° rotational water unit, spittoon with automatic cup filler and basin washer system. Optional fitting of different suction systems and amalgam systems.

Cannula and circuit boxes located in the front of the chair.

Control panel on cannula support by the water unit.

The unit is designed to hide all tubes or cables out of sight, except for those on the instrument tray.

The unit conforms to the basic requirements applied by Directive 93/42/EEC on medical devices, to 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 to ISO standard 14971, a Risk Management analysis.

7.- DIMENSIONS AND TRANSPORTATION

The dental unit is suitably packaged and protected.

The package includes the dental unit secured to a pallet, with a further case containing the water unit (Fig. 2).

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.

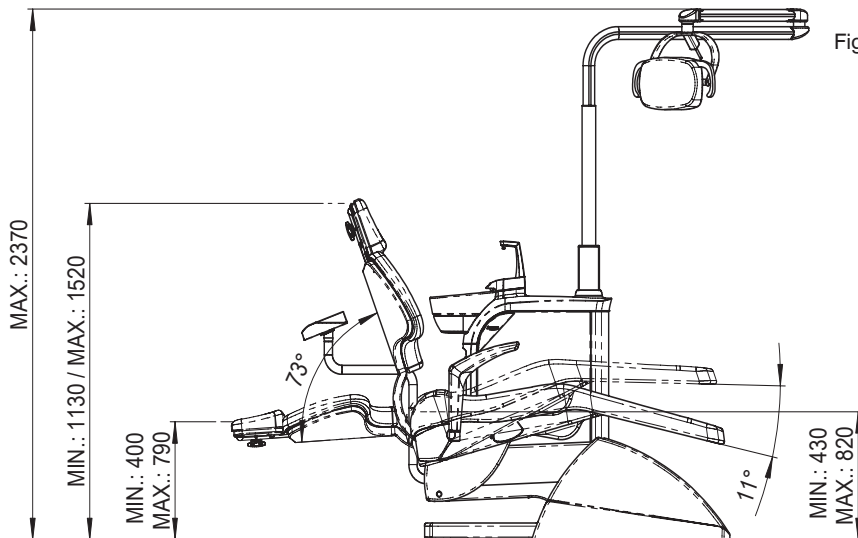
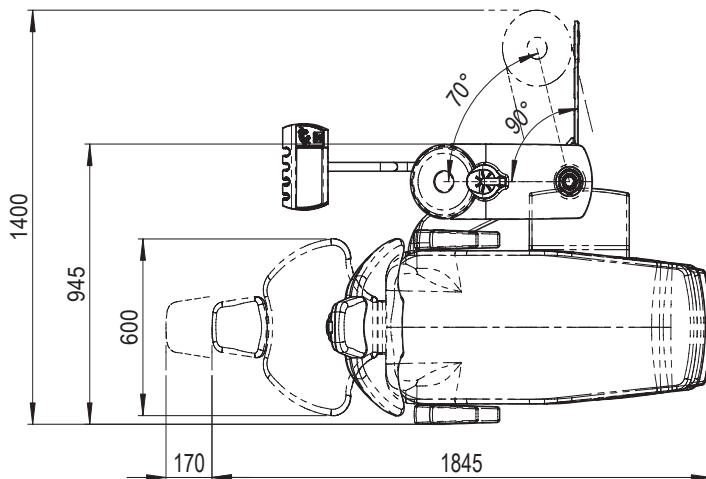


Fig. 2



8.- DENTAL UNIT DESCRIPTION

(A) Fig. 4	Circuit box	Page 8
(B) Fig. 5	Pneumatic pedal	Page 9
(E) Fig. 6-11	Water unit	Pages 10, 11
(D) Fig. 12-15	Cannula support + Control panel	Page 12, 13
(C) Fig. 16-17	Chair	Page 14

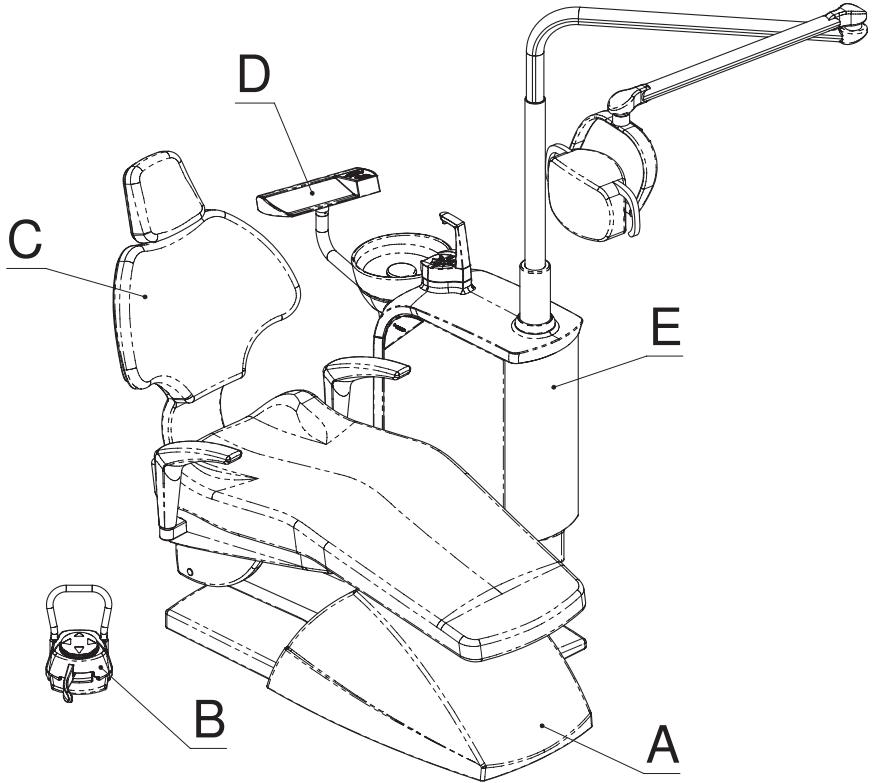


Fig. 3



Should you have to move a pre-assembled unit, fit the chair first with the seat at its lowest position and the back raised, making sure the water unit is fully retracted over the chair at all times, keeping the unit as solid as possible.

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

8.1.- Circuit box

The circuit box contains all points for connecting the dental unit to the clinic's power supply, as well as controls for adjusting the air and water supply. Regulator directional movement conforms to Standard UNE 20128.

As indicated in the diagram, the front part of the chair base contains: (Fig. 4)

- A. Movement panel connection cover.
- B. Connection panel and transformer cover.
- C. Water inlet pressure control. Fitted with a solid particle filter. Check around once per month. Clean using pressurized water. To modify water regulation pull ("1") and turn ("2").
- D. Air inlet pressure control. Fitted with a solid particle filter. Check around once per month. Clean using pressurized water. To modify air regulation pull ("1") and turn ("2").

Inlet water must be solid particle free and well purified.

The compressor should be correctly installed to avoid the build-up of humidity in the air circuit.



Note: when activating the general power switch, 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.

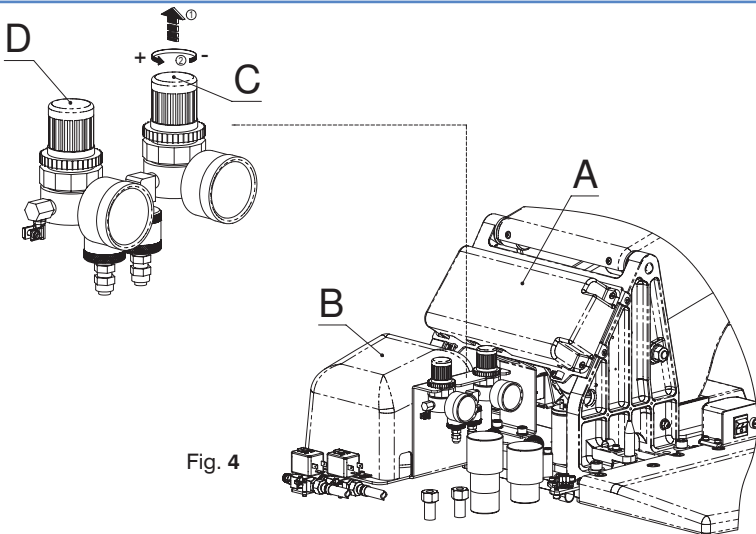


Fig. 4

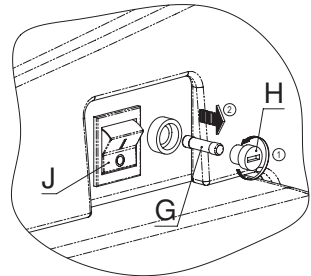
By the circuit box, at its right side you will find:

- General power switch (J). Up, on; down, off. Pilot light.
- General mains fuse (H), rating T6.3A/L/250V, type 5x20mm.

Fuses should be replaced (G) by an authorised technician.



General power switch must be turned off if the unit is left unsupervised. Deactivating this switch prevents water pipes from being subjected to constant pressure through the intake.



8.2.- Pneumatic pedal:

INSTALLATION AND USE

Pedal for adjusting the optional instruments on the cannula support tray: Micromotor, turbine. (fig 5).

Regulates turbine and pneumatic micromotor power by activating the trigger (**B**); select air only or air and water, using lever-operated spray function (**A**).

Lever-operated chip blower function (**A**) when the lever (**B**) is in the rest position.



Optional instrument cleaning turbines and micromotors, removing every last drop of water with an automatic air blower.

Safe movement of all optional instrument tray items: by adjusting the control lever the chair is locked in place, or it can be secured in any position.

PEDAL FUNCTIONS

- A. Chip blower control button/lever. Short-burst air blower.
- B. Control trigger to activate and adjust the selected instrument while still on the tray.
Pressing the trigger (B): air only, no water.
Pressing the trigger (B) and lever (A): water and air, spray function.
- C. Backrest return movement.
- D. Lower chair manually movement.
- E. Backrest recline movement.
- F. Raise chair manually movement.



Safety:

To block any button-activated memory, press the control pedal.

When activating the control pedal, all chair movements are blocked.

This pedal can accept as an option the setting to zero automatically. By default, it is not incorporated.

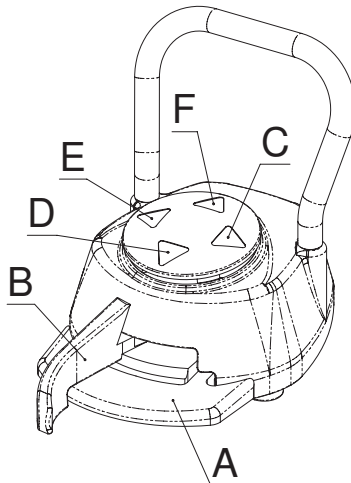
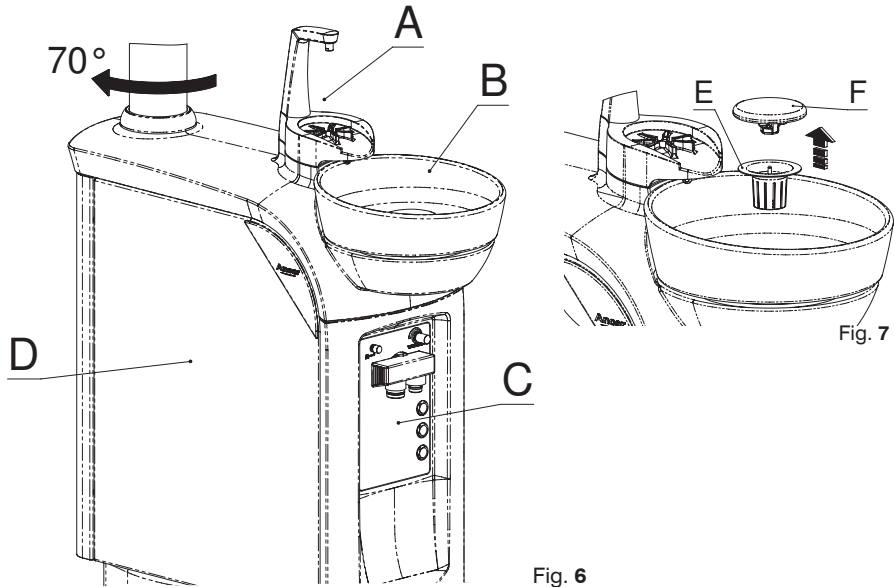


Fig. 5

8.3.- Water Cabinet

The water unit has a rotation of 70° approx. towards the arm support, facilitating the ergonomics of daily use. The upper part holds the cup holder (A) and spittoon (B), made of porcelain to offer high standards of hygiene (fig. 6).

To avoid splashes and the passing of solids, spittoon is fitted with filter (E) and cover piece (F) located in the drain of the spittoon (fig. 7).



Front panel (C) supports cannula filter, (D) is a lateral door towards Water Unit (fig. 8).

To get access to interior you must push gently inwards ("1") at upper corner (K), it will open by itself ("2"). Take in consideration opening is only up to 90° .

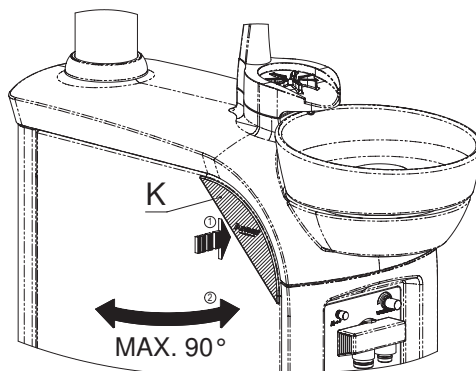


Fig. 8

You can easily dismount porcelain pieces of spittoon following steps depicted in fig. 9 and those of tap in fig. 10.

Turn 180° ("1") the spittoon (B), and upwards ("2") it.

For tap, first hold upwards ("1") glass faucet (G), then remove ("2") glass support (H), so you can get access to spittoon faucet (J), detach it ("3").

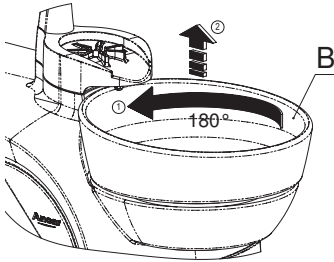


Fig. 9

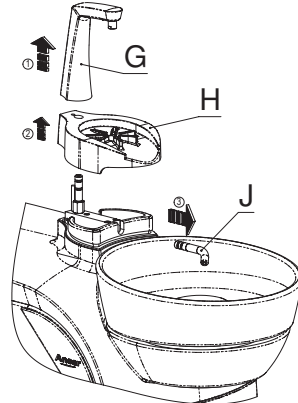


Fig. 10

Inside it comes with two stopcocks to regulate the cup water (L) and spittoon water (M).

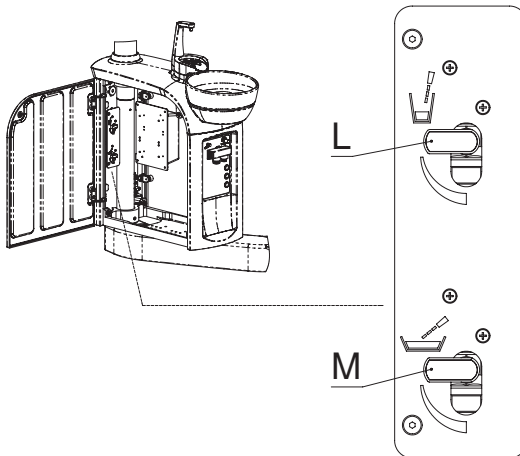
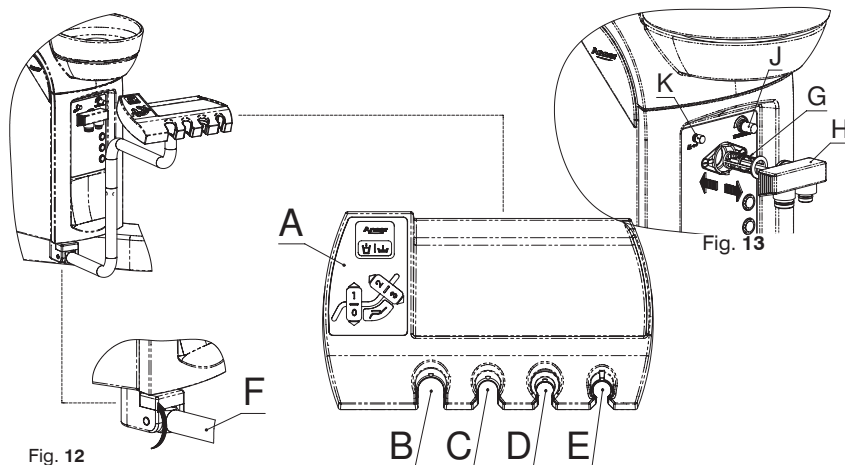


Fig. 11

8.4.- Cannula support (surgical suction, instruments, keypad)

The surgical suction motor is activated by lifting any of the cannulas. The tube support is mounted on an arm with a large capacity of movement to find the desired position. The cannula support has an auxiliary keypad (A), medium and large capacity surgical suction (B and C) and, as optional instruments, a 3F syringe (always placed at E), and Turbine (position D).

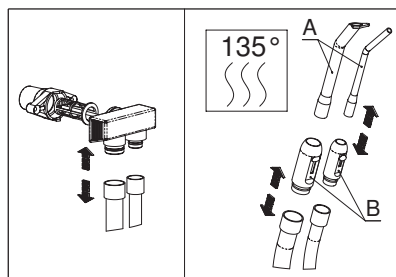


The cannula support safety connected in sequence with the pedal, blocks any automatic or manual movement following any slight tilt (F) of the support arm. This safety is particularly useful following any inadvertent collisions with furniture, stools, etc.

The surgical air suction tubes manifold (H) contains a changeable (G) filter, which allows the use of foamless tablets. The suction of a glass of clean water is recommended after each use, cleaning the filter at the end of each day. Always clean using manufacturer-recommended products

J Water controller for turbine.

K Chair movement positional memory storage button ("enter"). Detail about how to set a new memory position in next clause (8.5 Keypad).



Cannulas (A) and cannula-holders (B) can be sterilised and are autoclave-safe. If not fitted with a continuous suction system, the separator system should be left for a short emptying period.

Fig. 14

SURGICAL SUCTION

Depending on the type of amalgam separator installed (Cattani, Metasys, Dürr), all manufacturers recommend their own products and methods for disinfecting cannulas, attached to this manual. The cannula and cannula-holder sterilisation process is the same for all systems.

Both cannula holders and tubes are safe for autoclave sterilisation. It is recommended to use foamless disinfecting tablets, which can be left to work overnight. Furthermore, the outer tubes and tongues should be lubricated every 15 days with Lubri-Jet products, drying off any excess water.

3F SYRINGE (Optional)

The second instrument on the cannula support is the 3F syringe, with 3 functions: air, water and spray. This instrument works independently from the control pedal. See appendix.

8.5.- Keypad.

The assistant's keypad is located on the cannula support (Fig. 15).

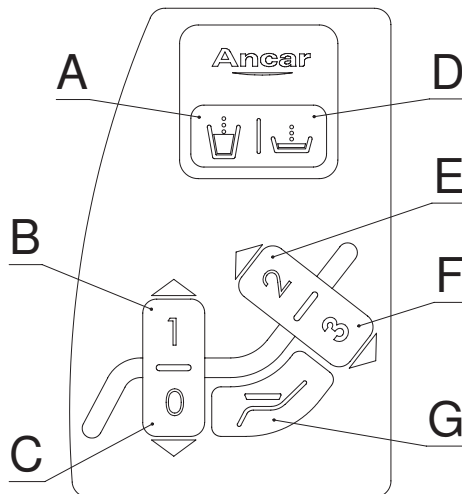


Fig. 15

A. Cup tap and spittoon tap. Timed, **2s-12s**.

Spittoon and cup taps can be set-up to work simultaneously or independently.

B. Pressed continuously: Raise chair manually.

Pressed once: Automatic movement -> Free memory position 1

C. Pressed continuously: Lower chair manually.

Pressed once: Automatic movement: -> Reset.

D. Spittoon tap. Timed, **10s-180s**. Can be turned off using the same button.

E. Pressed continuously: Manually raise backrest.

Pressed once: Automatic movement -> Free memory position 2

F. Pressed continuously: Manually lower backrest.

Pressed once: Automatic movement -> Free memory position 3.

G. Spittoon return position. Pressing this once returns the backrest to the spittoon position.

Pressing it twice will return the backrest to the original position.

Chair movement positional memory storage button ("enter") is by the water unit at the cannula support (fig. 13, **K**). Set the chair to the desired position using the manual function keys. Hold "Enter" key ("**K**") and press any of the three positions (1, 2 or 3); wait for the "beep" to confirm setting. Release "Enter" key ("**K**")

8.6.- 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 Fig. 16.

OPERATION

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

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

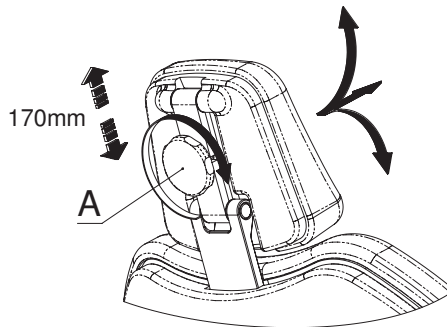


Fig. 16

8.7.- Optional armrest

To rotate the optional armrest (B), it must be pulled upwards (kept in its housing) until the rotation mechanism is released, allowing it to be turned until reaching the track limit where it stops. To return the armrest to its initial position, simply lift it and turn it inside until it locks automatically (Fig. 17).

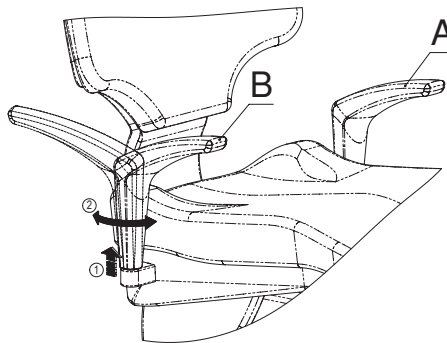


Fig. 17

Standard armrest (A), is fixed.

9.- SAFETY MOVEMENTS

- The dental chair includes mechanical safety stops for the chair and backrest, ensuring correct manoeuvring 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, suspends all chair movement (seat and backrest) before lifting it a few centimeters.
- The base safety feature, in the event of pressure or knocks against other objects during manual or automatic lowering, suspends all chair movement (seat and backrest) before lifting it a few centimeters.
- The cannula safety feature, in the event of any pressure against the arm, or knocking against other objects during manual or automatic lowering, suspends all chair movement (seat and backrest).
- The control pedal safety blocks all movements of the chair (seat and backrest) once the control lever is activated, allowing the user to work in the patient's oral cavity in complete safety. If the chair is moving, it can also be stopped by activating the pedal trigger ("B", fig. 5).
- The control pedal safety disables all automatic movements, preventing any inadvertent action due to the sensitivity of the three-way directional button.
- If the chair moves to a memorised location, pressing any key on the directional keypad or the pedal will stop the unit.

10.- CLEANING AND STERILISING

When cleaning your dental unit, it is essential to 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.

Before being shipped, all ANCAR equipment is thoroughly cleaned using ECO-JET1 Cattani Magolia disinfectant spray.

For cleaning and disinfecting the different parts of the system, please check:

- Section 8.4 "Cannula Support".
- Annex 1, "Cattani System and Suction".
- Annex 2, "VSA300 Suction System (Dürr Dental)".
- Annex 3, "Aspiration System TYP1 (Metasys)".
- Annex 4, "ECO Aspiration System (Metasys)".
- Annex 7, "Combi-Separator CAS1 (Dürr Dental)".
- Annex 10, "Hygiene System H1 (Metasys)".
- Annex 11, "Selective Cannula System S1 (Metasys)".
- Annex 12, "Minilight Syringe (Luzzani)".
- Annex 14, "Cleaning other parts of the unit"

STERILISING AND AUTOCLAVE.



Hand instruments should be sterilised in an autoclave at a temperature of 135°C; it is however recommendable to follow the instructions of the instrument manufacturer.

Cannulas, the cannula-holder and tubes can also be sterilised. Check the section entitled "Cannula support".

We remind you that regular maintenance and proper use of the unit will prolong its working life.

11.- TECHNICAL DATA

Voltage	220-240 V~
Frequency	50 Hz
Air pressure	5.5 Bar
Water pressure	3 Bar
Power	900 W
Electrical protection type	I
Operation type	Intermittent
Maximum load (patient)	160 Kg.
Maximum load (instrument tray)	2 Kg.
Electric micromotor instrument	24V dc /65 W
Instrument light	Bulbs-LEDs 3-3.5v / 2.5 W
Ultrasound	24Vac / 35 W.
Polymer LED	24V ac / 150 W.
Syringe 3F	--
Syringe 6F (optional)	24Vac / 150 W.
Operator light (depending on model)	17Vac / range from 9 to 95 VA.
Operator light (light intensity)	Range from 3.000 to 50,000 lux
Operator light (cool beam)	140 x 70 to 180 x 90 cm
Unit standard 93/42/EEC	Class IIa
Insulation type	Type B
Unit net/gross weight	240 Kg. / 290 Kg.
Dental unit type	Electro-pneumatic
Installation type	Permanent
Main fuse	T 6.3A / L /250V
Movement Panel Fuse, 24V line	T 32 mA / L / 250V
Primary transformer fuse, 9015093 PCB	TT 2.5A / L / 250V
Line protection 24V ac (ye/ye)	Polyswitch RUE600
17V ac line protection (re/re)	Polyswitch RUE600 + RUE185
Auxiliary outputs 24V ac	4 x water unit
Auxiliary output 24V ac	1 x circuit box
Suction connection	500W / 230V. Relay 20A/250V
Auxiliary connection	Free contact pot. 250V/5A
Main electro-valves	24 V dc

Upon request, the water unit can be supplied with gravity-drained or continuous suction systems, and with an amalgam separator option for wet- or dry-ring systems. See appendices to this manual for specific instructions for each manufacturer.

As the diagram 8 shows, when you open the door pressing the upper corner there is access to all elements placed inside the water box.

ANNEX 1. CLEANING AND DISINFECTING OF CATTANI GLASS, CANNULAS AND BASIN



Before opening the water cabinet door or removing the container, disconnect the unit from the electrical mains using the main switch. Use suitable protective gloves.

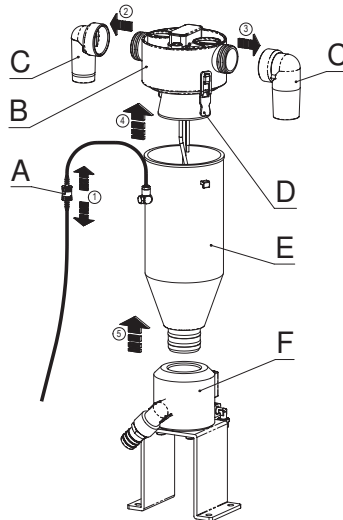


Fig. 18

Vessel, once at the end of each day.

To remove (E), switch off (A) and pull out the two raccords (C) from suction tubes. To remove the cover (B), lift it slightly fixations (D) and pull up vessel (E) from the support (F). You may also clean it. Place again the vessel following the instructions in reverse. Use the Puli-Jet (Cattani) and water.

Cannula circuit, at lunch time and at night.

Cleaning and disinfecting: Use Cattani Pulijet.

Concentration: 50cl per litre of water. Take in water through each cannula.

External cannula surfaces, after each treatment

Disinfectant: Eco-Jet Cattani.

Rinse basin with water after each treatment.

Cannula filter: foamless disinfectant

Use anti-odour tablets for the cannula filter.



Caution

Do not clean with foam. Do not use sodium hypochlorite.

ANNEX 2. SPITTOON BASIN CUT-OFF VALVE AND ASPIRATION UNIT (CATTANI)



Before opening the water cabinet door or removing the container, disconnect the unit from the electrical mains using the main switch.

The spittoon suction unit (B) requires a maintenance operation on the filter (C). You need to turn the part ("1") and then remove it ("2") to extract the solid particles.

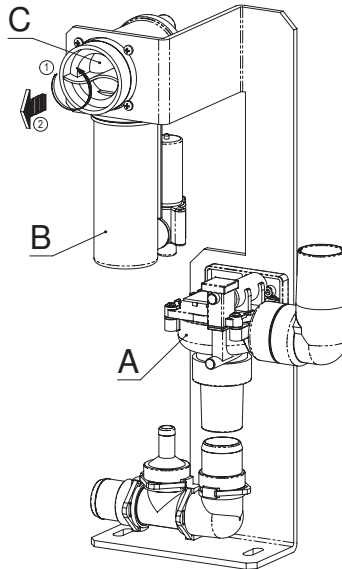


Fig. 19

To ensure the proper operation of the spittoon suction unit and the amalgam separator, the bowl rinse must be timed at around 20 seconds (as minimum).

The cut-off valve (A) works in the presence of air.



Caution

Be aware of the biological danger of infection with epidemic diseases.

Before doing anything with used utensils and equipment, deep-clean them using disinfectant.

To carry out any maintenance operation, use gloves, goggles and a disposable mask.

Aspirated liquid is likely to be contaminated and represents a contamination risk in terms of infectious diseases. In addition, the equipment used for work could be under pressure, which increases the risk of contaminated splashing.

ANNEX 3. VSA300 SUCTION SYSTEM (DÜRR DENTAL). MAINTENANCE OF THE SUCTION SYSTEM TOGETHER WITH THE SPITTOON VALVE



Before opening the water cabinet door or removing the container, disconnect the unit from the electrical mains using the main switch. Use suitable protective gloves.

The drainage/suction unit (B) has a filter (C) that requires maintenance. As the figure shows, turn the part ("1") and then pull it ("2") gently towards you before lifting.

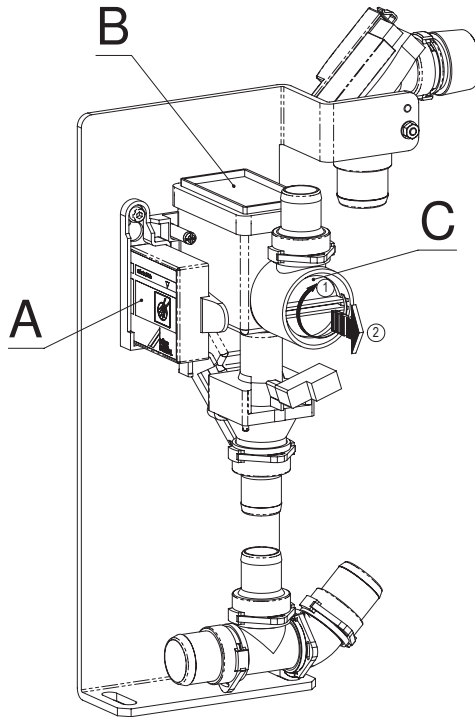


Fig. 20

Inside, it has a control box with a reset button (A).

Check the manufacturer's original instruction manual accompanying the documents supplied with the dental unit to find out how it works or if in any doubt before carrying out maintenance, cleaning or disinfection. Always use cleaning and disinfecting products recommended by the manufacturer.

ANNEX 4. ASPIRATION SYSTEM TYP1 (METASYS)



Before opening the water cabinet door or removing the container, disconnect the unit from the electrical mains using the main switch.

The filter (A) requires maintenance: turn the part ("2.1") and then remove it ("2.2").

To access the separation and sedimentation element (C) you need to turn the ("1.1") sealing flange (B) upwards and remove it, pulling it forwards ("1.2").

The control keyboard is accessible to the outside opening the side door of the water cabinet.

Monitoring LED (D): ready for use. Green light on: there is a network connection.

Monitoring LED (F): centrifuge fault. Flashing red light: fault! Turn off the main switch and turn it on again after a brief pause.

Monitoring LED (E): indicating the container filling level (C). Yellow light shining with buzzer sounding which can be stopped using the reset key (G). Warning that the container is 95% full. You are advised to change the container.

When the light (E) stays yellow and the buzzer cannot be turned off, this indicates that the collection container is 100% full and the container needs to be changed. You cannot carry on working. The aspiration valve is locked.

Alarm reset key (G).

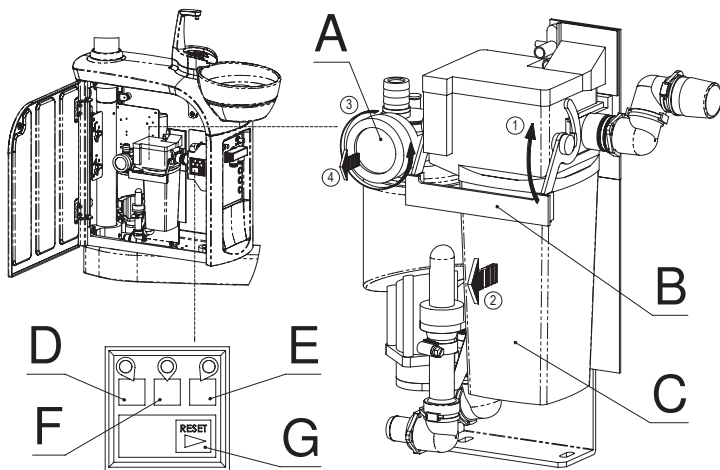


Fig. 21

Check the manufacturer's original instruction manual accompanying the documents supplied with the dental unit to find out how it works or if in any doubt before carrying out maintenance, cleaning or disinfection. Always use cleaning and disinfecting products recommended by the manufacturer.



Removing the full container:

Wear protective gloves. Avoid contact with the content of the container. For technical and hygiene reasons, the collection container is designed to be disposable.

ANNEX 5. ECO ASPIRATION SYSTEM (METASYS)



Before opening the water cabinet door or removing the container, disconnect the unit from the electrical mains using the main switch.

This is a single-chamber automatic air/water separator with integrated heavy particle collector. To access the separation and sedimentation element (B) you need to turn ("1") the sealing flange (A) up and pull it forwards and out ("2").

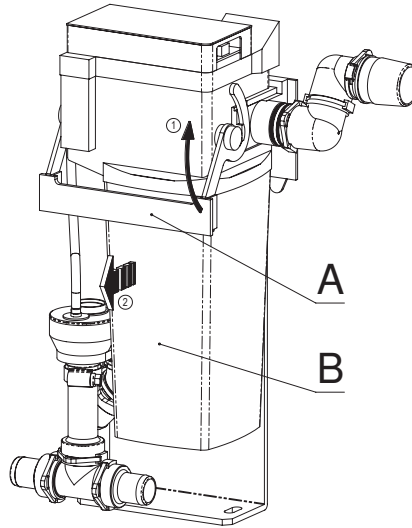


Fig. 22

Check the manufacturer's original instruction manual accompanying the documents supplied with the dental unit to find out how it works or if in any doubt before carrying out maintenance, cleaning or disinfection. Always use cleaning and disinfecting products recommended by the manufacturer.



Removing the full container:

Wear protective gloves. Avoid contact with the content of the container. For technical and hygiene reasons, the collection container is designed to be disposable.

ANNEX 6 SELF WATER SYSTEM KIT

Access to the bottle (with capacity for 1 liter) is via the outside of the water unit removing cover (A) following outwards movement ("1").

It is an independent running water system; the air regulator is normally found sealed.

To refill with water, you need to unscrew ("2") the bottle (C) and take it out through the bottom ("3"). Internally there is a safety pressure switch so it activates automatically.

Please remove bottle (C) gently and take care about internal tube (B).



Important recommendations.

If you are not going to use the Self Water System for a long time – weekends, holidays, etc. – for ventilation you are recommended to purge the instrument liquid lines and the syringe. This will help to prevent any stagnation of liquids in the water lines.

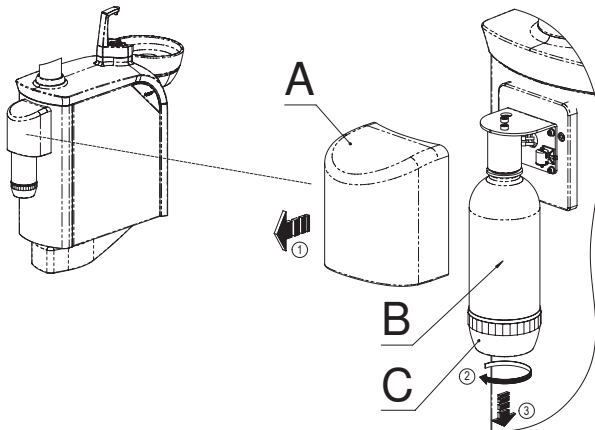


Fig. 23

ANNEX 7. COMBI-SEPARATOR CAS 1 (DÜRR DENTAL)

The control panel is placed internally (A).

You are recommended to clean the tank (B). To remove it, unscrew ("1"), but before taking it out ("2") be careful with the part that measures the level of the amalgam element content and sticks out at the bottom.

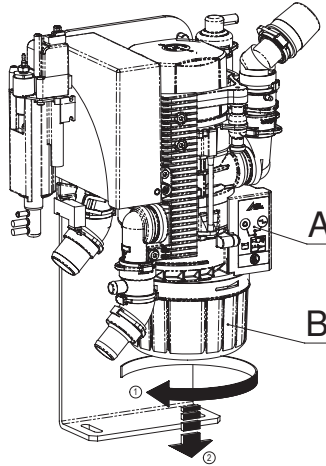


Fig. 24

ANNEX 8. COMBI-SEPAMATIC CS 1 (DÜRR DENTAL)

System designed to be used in dry aspiration systems. It does not hold any elements. All aspirated liquid passes through an integrated pump that delivers it to the drain.

The pump unit (A) is powered by the aspiration effect of the compressor which is activated when the cannula is pulled. This opens the cut-off valve (B). The rinsing unit (C) provides the suction unit with a permanent supply of fresh water during suction, assuring device will not operate in dry conditions.

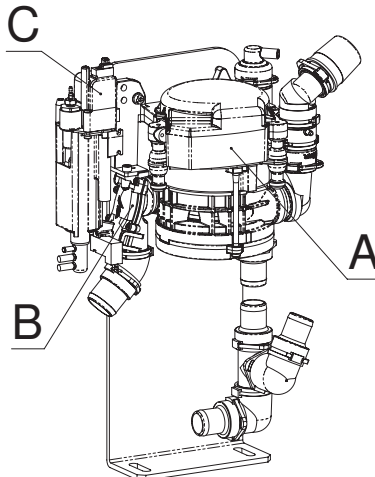


Fig. 25

ANNEX 9. HYGIENE SYSTEM H1 (METASYS)



Do not use additional cleaning or disinfection products for the aspiration installation in treatment areas where an H1 hygiene system has been set up as there is a risk of negative chemical interactions resulting from the combination of different chemical products.

CONTROL KEYBOARD

The control keyboard is accessible opening the side door of the water cabinet.

Pilot light (D): malfunction. Red flashing light and repeated bleep up to five times for each time the aspiration tubes go up. Hygiene system out of service but aspiration available: contact a technician.

Pilot light (E): empty tank message. Yellow light and single bleep every time the aspiration tubes go up: replace the cartridge A.

Pilot light (D): program functioning. When it is green: ready for working. Green light flashing slowly: first wash program operating. Green light flashing quickly: special wash program operating.

Key for turning on the special washing program (G): Activated by pressing the "Push" key.

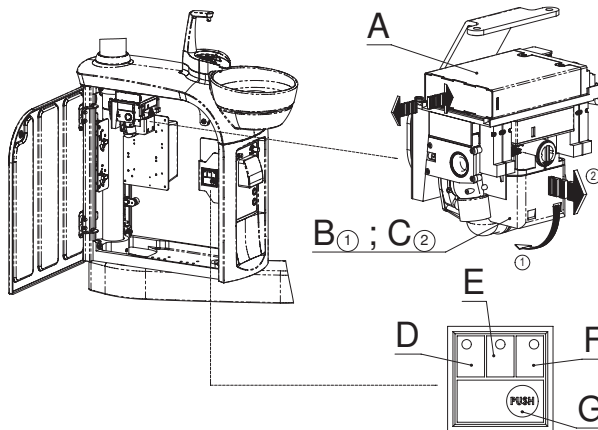


Fig. 26

MAINTENANCE

Daily washing of the filter grid: Pull the container clip (B) down ("1"). Remove ("2") the filter container (C) horizontally. Move the filter grid upwards (the filter must be replaced acting in reverse order).

Tip the amalgam residue into the container provided for the purpose.

We advise replacing the filter grid every 2 to 3 months.

If aspiration power is reduced, check whether the filter grid has been perforated.

After sterilising, do not forget to grease the joints with Vaseline!

Replacing the cartridge (A): Replace when the yellow pilot light (E) is flashing on the control panel and you hear the beep, because that means the tank is empty.

Turn off the unit's main switch. All you need to do is press on the back of the cartridge to open the catch and put the cartridge in position for changing. You can then remove the cartridge from the unit.

AUTOMATIC CLEANING PROGRAM

First Wash

Duration: approximately 2 minutes. The pilot light **F** flashes slowly.

Switching on: every time you press the treatment unit's main switch.

Function: Preparation for subsequent treatments based on higher disinfectant dosage.

Permanent Wash Cycle

The pilot light **F** is permanently on.

Duration: from when the aspiration tube(s) go up to when they go back into position.

Switching on: At least one aspiration tube is up.

Function: Prevent the formation of deposits by washing, disinfecting and foaming the aspiration system, periodically dosing it with chemical products.

Special Washing Program

The pilot light **F** flashes quickly. Duration: approximately 5 minutes.

Switching on: pressing the "Special washing program" key.

Function: if necessary, painstakingly clean and disinfect the aspiration system after prolonged aspiration use. We recommend using the program at least once a day and after prolonged use of aspiration.

ANNEX 10. SELECTIVE CANNULA SYSTEM S1 (METASYS)



Please always wear protective gloves while working.

MAINTENANCE: Daily washing of the filter grid

Turn the container clip **A** down ("1"). Remove ("2") the filter container (**B**) horizontally.

Pull the filter grid up (the filter must be replaced acting in reverse order). Place the amalgam residue in the container provided for the purpose. We advise you to replace the filter grid with a frequency of between 2 and 3 months.

If aspiration power is reduced, check whether the filter grid is broken.

After sterilising, do not forget to grease the joints with Vaseline!

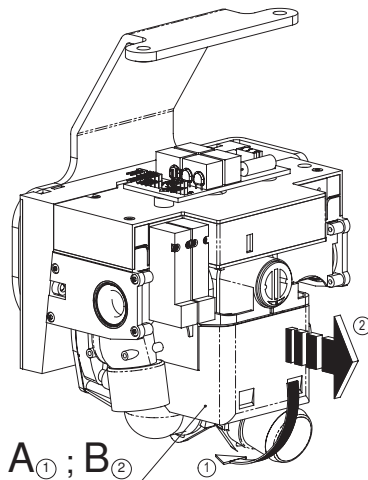


Fig. 27

ANNEX 11. MINILIGHT SYRINGE (LUZZANI)

GENERAL

The Minilight syringe is an instrument designed exclusively for dental use, its function being to introduce air and water (individually or simultaneously, at either room or body temperature) into the area of operation to keep it continuously clean and dry.

GENERAL CHARACTERISTICS

The Minilight syringe has been designed using state of the art ergonomics to facilitate use and to allow rapid cleaning and sterilisation. Both the tip and the outer grip are easily removable, allowing the instrument to be completely disinfected and sterilised in the autoclave at 135°C. Grips are available in different shapes and colours according to the dentist's preferences: straight or L-shaped. Furthermore, the air and water may be heated to body temperature to avoid patient irritation from using colder room temperature air or water.

MODELS

The models differ according to the number of features available:

- 3F cold water/air spray
- 5F cold water/hot and cold air/hot and cold spray
- 6F hot and cold water/air/spray
- Air or water only
- L with Light

The Minilight syringe version is shown above. The handles can be interchanged on all versions: technopolymer curve or straight stainless steel.

CE MARKING

All products carry CE marking.

PRODUCT BATCH

Each product can be traced by a serial number located on the bottom, which identifies the exact batch of production. This number can be used to find out the date of manufacture, in relation to the control panel.

GUARANTEE

The product is guaranteed by our company for 12 months after delivery. Any unauthorised modification or handling will automatically void the guarantee. The company therefore accepts no responsibility for damages to people, animals or other objects due to misuse of the equipment. For any disputes, the competent authority is the Milan tribunal in Italy.

TECHNICAL FEATURES

Type B, insulation class II, intermittent function: 10 seconds ON, 20 seconds OFF.

ITEM		6F	5F	3F
SUPPLY VOLTAGE	VCA	24	24	***
CURRENT CONSUMPTION	A	4.3	0.7	***
MAX. ELECTRIC. POWER	W	103	0.7	***
MAX. WATER PRESSURE	BAR	2.5	2.5	2.5
MAX. AIR PRESSURE	BAR	4.5	4.5	4.5
MAX. AIR CAPACITY	l/min	10	10	10
MAX. WATER CAPACITY	Cc/min	110	110	110

INSTALLATION

The unit may only be connected by an Antoni Carles-authorized technician.

NORMAL USE

- To introduce cold water into the area of operation, press the left button on the handle.
- To introduce cold air into the area of operation, press the right button on the handle.
- To introduce a cold air and water spray, press both buttons on the handle simultaneously.
- To introduce warm water into the area of operation, turn the switch on the base of the handle to the right (the green indicator will light up) and press the left button on the handle (only on models 6F and L).
- To introduce warm air into the area of operation, turn the switch on the base of the handle to the right and press the right button on the handle (only on models 6F and L).
- To introduce warm a water and air spray into the area of operation, turn the switch on the base of the handle to the right and press the two buttons on the handle simultaneously (only on models 5F, 6F and L).

Note: The switch is used to select between warm and cold functions. The water or air is heated instantaneously upon use. For this reason, the handle can be left constantly in the “on” position without causing any problems or danger.

CLEANING OR DISINFECTING



After each intervention and to maximise hygiene standards, the syringe can be cleaned and sterilised. This is done through the following phases:

- Remove the tip (unscrewing it at the mouth) and/or the complete handle (pressing the button on the handle bottom upwards).
- Clean with a cloth, removing any stains or dirt.
- Place in the autoclave with the steam set at 135°C for 20 minutes.

MAINTENANCE

The unit requires no specific maintenance, except for the regular cleaning and sterilisation described above. Avoid all kinds of lubrication, since this can cause irreparable damage to the syringe.

SURFACES AND COMPONENTS

The product contains no dangerous, toxic or harmful components, nor does it come into contact with any such products during manufacture.

ANNEX 12. OPTIONAL ITEMS

AUXILIARY AIR & WATER OUTLETS / USB CONNECTOR

It is defined as optional in water unit to have available quick water (D) and air (E) outlet connectors, as well as a direct point-to-point USB connector (A), the other end will be passed through interior of dental unit. (B) is the manifold of suction cannula tubes, already referred in clause 8.4 (page 12).

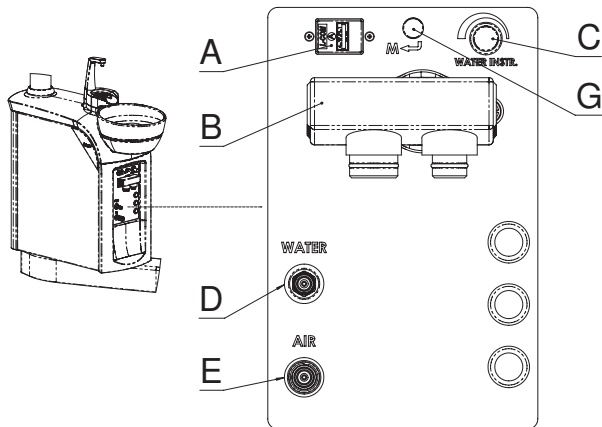


Fig. 28

Usual items have been replaced, but maintain same functionalities: (C) water controller for turbine; (G) chair movement positional memory storage button ("enter").

AUXILIARY POWER OUTLET

By the general ON/OFF switch you may ask for an auxiliary 230V ac / 50W outlet (A).

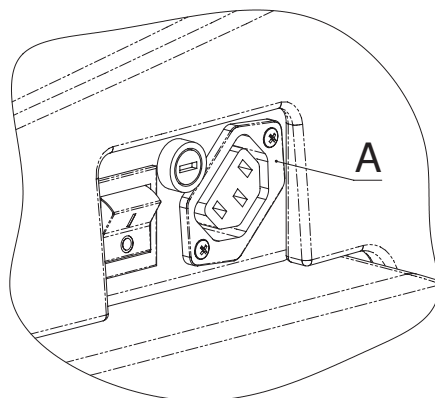


Fig. 29

ANNEX 13. CLEANING AND DISINFECTING OTHER PARTS OF THE UNIT. OTHER SAFETY NOTES: UNIT, LAMP, ELECTRICAL SYSTEM

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.

Cleaning and Disinfecting the Column Arm and Light

Spray disinfectant. Do not spray on hot surfaces.



To disinfect the dental light, wait for the head to cool.

Regularly disinfect these parts using a disinfectant with at least an antimicrobial and fungicidal action.

To clean the light, head and handles, use a damp cloth. Clean reflective surfaces using a dry cloth.



Check manufacturer instructions.

Cleaning and disinfecting the Basin/Spittoon.

Use disinfectants recommended by Cattani or Metasys. See appendices I and II.

Cleaning and disinfecting the water unit

Regular cleaning and disinfecting: use antimicrobial, fungicidal, virucidal and sporicidal disinfectant.

Cleaning and disinfecting the instrument tray, auxiliary 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.

ANNEX 14. SAFETY NOTES

GENERAL PRECAUTIONS

Read 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 unit, read all appendices in this manual.

Upon first start-up: carry out a thorough clean of the water channels by passing a solution of water and disinfectant through all water pipes connected to the instruments and water unit.

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, close the main water and air taps and disconnect the unit from the electrical supply.

If the unit is assembled with an amalgam separator system, please do not dispose of the contents of the collection tank once it is full, nor empty the tank into the drain to reuse it. Contact the separation system manufacturer's office or consult our Sales Dept. See appendix II.

Do not replace fuses yourself. Contact Antoni Carles, S.A. authorised technicians via our Sales Dept.

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

Regularly check for water or air leaks in the dental unit circuit box, and make sure the area is kept clean and free from humidity, rust or electrolysis.

Do not use the unit to support or hold furniture or other materials. Do not stand on the water unit. Do not sit on the water unit support. Do not hang on the light. The unit should only be used by qualified personnel.

DENTAL LAMP SAFETY MEASURES

Move the light using the handles only. Do not move it by the lamp head.

Do not mark the protective screen.

Check regularly that the built-in fan is working correctly. If damaged, it may harm the bulb due to a temperature increase.

Do not force the regulator rotation past its minimum and maximum power levels.

REPLACING THE BULB

Disconnect the unit from the power supply using the general power switch.

Wait 30 minutes for the bulb to cool.

Remove the bulb following the manufacturer instructions. Do not touch the new bulb with your hands. Use a cotton cloth.

Use special containers to dispose of the old bulb. Consult your local authorities for means of disposal.

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 a light overload, the built-in thermal protection in the 17VCA line may have suspended operation of the unit. Wait 15 minutes for it to reset. Should the problem persist, call the authorised technical service line.

In the event of an overload in the instrument line and water unit, the built-in thermal protection in the 24VCA line may have suspended operation of the unit. Wait 15 minutes for it to reset. Should the problem persist, call the authorised technical service line.

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.

NOTES ON ELECTROMAGNETIC INTERFERENCE

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.

This device meets EMC standard (EN 60601-1-2:2007 + AC:2010)

- a) this medical electrical device requires special precautions regarding EMC standard and should have to be installed and set up accordingly EMC info included in enclosed documents.
- b) Portable and mobile RF communication equipment (e.g., cell phones) could affect medical devices.
- c) Accessories usage, transducers, wires others than specified or supplied by manufacturer as replacement parts may result in increased emissions or decreased immunity of this device.
- d) This device should not have to be used close to other equipment. If necessary this proximity, then it must have to be checked that system to verify final configuration operates correctly.

Electromagnetic emissions

Essay	Level	Remarks
Radio frequency radiated (30-1000 MHz) Continuous conducted (0.15-30 MHz)	Class B	Matches with domestic locations requirements with respect close equipment.
Discontinuous conducted	Conforms	Low emissions, so it is suitable for use in all establishments, including domestic ones. It is not probable could provoke any disturbance with close electronic devices.
Voltage fluctuations		
Harmonic current		

Separation of distance recommended in between portable radiofrequency communications devices and cell phones and dental unit.

Dental unit is designed to be used in an electromagnetic environment whereas radiofrequency disturbances are controlled. User of dental unit could avoid EMC interferences keeping a minimum distance with transmitter devices as recommended, depending on maximum output.

Maximum output nominal value of transmitter in watts	Separation distance depending on transmitter frequency in meters		
	150kHz – 80 MHz	80 MHz – 800 MHz	800 MHz – 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

These indications could not be of application as electromagnetic propagation could be affected by absorption and reflection from structures, objects and people.

Electromagnetic immunity

Essay	Levels	Remarks
Electrostatic discharge	Air discharge: 2, 4, 8 kV Contact discharge: 2, 4, 6 kV	Better behavior with wood or ceramic tiles. If synthetic material, humidity > 30%
Fast transients in burst immunity	2 kV I/O ports	Mains power quality should be that of a typical commercial or hospital conditions.
Surge transients	Common mode 0.5, 1, 2 kV Differential mode 0.5, 1 kV	
Low frequency magnetic field immunity	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location.
Current injections	3V rms (150 kHz – 80 MHz) 3 V/m (80MHz – 2.5 GHz) Signal and control ports & AC / DC supply, access by ground terminal	Separation recommended 1.2 √P (up to 800MHz) 2.3 √P (from 800MHz) P is the maximum output power rating of the transmitter
Voltage variations	Short interruptions and voltage dips	If user requires continuous operation while interruptions in mains power supply, it is recommended to get a non-interruption electrical alimентация.

NOTES ON INFLAMMABLE ANAESTHETIC MIXTURES

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

Ancar

DENTAL
INTELLIGENCE
with heart



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July 2014

0434

Subject to design and/or specification changes
without prior warning. Made in Europe.

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