

Dental Unit DUKE EASY







DUKE EASY S.T.01/3AW Rev.0 01/2017

ENGLISH (Translation of the original instructions)

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WARNING

Before using the equipment, read the O.M.S. instruction manual completely and any instructions supplied with the accessories.

1. GENERAL INFORMATION

The instruments table of Duke Easy can accommodate two tools, a syringe and a suction cannula. The tools are hanging tubes.

Attaching the arm at the base of the dental chair allows a rotation of the table around the patient allowing use at right and left-handed operators at the same time with a single device.

Ability to install a table tray on a double pantografic arm.

High-speed suction tubes and their connections are easily removable for disinfection treatment. The filter easily and hygienically clean.

Duke Easy is combinable with the Directive 93/42 Moon dental chair/CE and O.M.S. s manufactured by. CE 0051 refers only to Duke Easy.



1.1. SAFETY 1.1.1. Warning symbol



WARNING: Indicates a hazardous situation that can lead to property damage or mild to moderate injury.

DANGER: Indicates a hazardous situation that may result in serious injury or death

1.1.2. Rules

- DANGER: to prevent the risk of electrical shocks, the equipment must be connected exclusively to power lines provided with a grounding system according to the law in force in your country.
- DANGER: Before powering the equipment after installation, a repair or technical service, check and, if necessary, hook up the connection of the grounding cables to the screw identified by the grounding system symbol.
- DANGER: The device must be installed in rooms featuring electrical systems that are up to local code.
- DANGER: The installation of the dental unit has to be done by an OMS authorized technician; the choice of the pipelines is up to the designer of the electrical system and they have to be placed by a qualified technician according to the law in force in the country.
- DANGER: Never allow the device to be used by non-professional operators or anybody who has not read the instruction manual.
- Always check that the device is in good condition.
- WARNING: Do not use the device if any part of it is defective or worn. If this is the case, call in authorized O.M.S. technical personnel.
- WARNING: Have defective or worn parts replaced with original, warranted O.M.S. spare parts only.
- DANGER: Do not operate the equipment on patients with pacemakers.
- DANGER: Device not suitable for use in rooms where use is made of a flammable anaesthetic mixture with air or with oxygen or with nitrous oxide.
- WARNING: Do not use the device when there is liquid on the floor.
- WARNING: Tips and dental drills for micromotors, tooth scalers and turbines are not included in O.M.S. supply. We recommend using parts conforming to the standard ISO 10993 that have to be cleaned and sterilised according to the methods defined by their manufacturers.
- DANGER: Do not make changes to this device without the manufacturer's permission. The use of unapproved accessories and/or unauthorised changes can cause imminent personal injury hazards as well ad material damages.
- WARNING: All maintenance work must be carried out with the device switched off and with no patient in the chair.
- DANGER: some parts, identified by the symbol "WARNING LIVE PARTS"



, are energised with mains voltage even after switching off the power switch. If these parts require service, cut out voltage to the system supplying power to the equipment, before making any operations.

- DANGER: the power switch isolates the equipment from the mains electricity. So, before performing any operations in the equipment, make sure that the power switch is off.

- WARNING: For special operations that require chair movements to be locked, make sure to enable the specific function (see par. LOCKING CHAIR MOVEMENTS).
- WARNING: The instructions found in this manual and in the wiring diagram must be followed to connect a suction unit; the suction unit must have EC markings as per directive 93/42/EEC as amended "Medical Equipment" and meet international safety regulations IEC EN 60601-1 (Medical electrical equipment General safety regulations), IEC EN 60601-1-2 (Medical electrical equipment Collateral standard: Electromagnetic compatibility).
- DANGER: when moving the chair, both in manual and especially in automatic mode, do not place hands and feet near the bottom of the chair to avoid crushing hazards



- WARNING: during automatic chair movement, the operator must stand near the dental unit.
- WARNING: When moving the instrument table, assistant table and operating lamp, be careful of the patient and personnel in the surgery to avoid injuring or crushing the patient or personnel in the surgery.
- WARNING: Never sit on the tip or foot of the chair.
- WARNING: During instrument table movement, patients and personnel in the surgery could be injured by sharp instrument tips.
- WARNING: before putting equipment into operation after periods of disuse, accurately disinfect the air and water supply lines, clean and drain the lines and then proceed with disinfection.
- WARNING: In the event of prolonged dental work on senior citizens, be careful of the formation of bedsores.
- WARNING: When moving the chair and, especially, the head rest, the patient's hair could become entangled.
- WARNING: The equipment is equipped with a general water tap. During use, the tap should be open. At the end of the work day, the tap should be closed or, alternatively, close the unit's general supply tap in the surgery.

1.1.3. DEFINITION OF INTENDED USE

Dental unit intended to treat dental pathologies, intended for professional operator use (dentists).

1.2. ADMITTED ENVIRONMENTAL CONDITIONS

1.2.1. ADMITTED ENVIRONMENTAL CONDITIONS FOR TRANSPORTATION AND STORAGE

The packaged device can be exposed for a period of no more than 15 weeks to the following environmental conditions:

Temperature range -40 to +70°C

Relative humidity range: 10 to 100% non condensing

Atmospheric pressure from 500 to 1060 hPa

1.2.2. ADMITTED ENVIRONMENTAL CONDITIONS FOR OPERATION

Temperature range +10 to +40°C Relative humidity from 30 to 75% Atmospheric pressure from 800 to 1060 hPa Nominal operating altitude ≤ 3000m Pollution degree 2 Overvoltage category II

1.3. WARRANTY

The product is covered by a warranty period of 36 (thirty six) months from the date of installation from the purchaser. The warranty conditions are shown inside the warranty booklet supplied with the device. The guarantee applies to the purchaser and to the product specified in the installation and testing report and covers all mechanical and electrical interventions relating to the product concerned.

The guarantee will be valid after the ordering party will be compiled and sent to O.M.S. spa of installation and testing. Essential condition to access the warranty is return to O.M.S. spa of installation and testing, in the original by fax or by certified mail within ten days of installation, under penalty of forfeiture of the guarantee.

O.M.S. SPA Officine Meccaniche Specializzate Via Dante 20/A 35030 Caselle di Selvazzano (PD) Italia fax: +39 0498975566 - e-mail: - PEC: omsstaff@legalmail.it

2. TECHNICAL SPECIFICATIONS

| Model | DUKE EASY |
|-------------------------------|---|
| Manufactured by | O.M.S. S.p.A. Officine Meccaniche Specializzate Via Dante 20/A - 35030 Selvazzano Dentro Padova Italia |
| Class Applied parts Type | і в Т |
| Equipment protection level | IPXO |
| Foot control protection level | IPX1 |

ELECTRICITY SUPPLY

Rated voltage 230 Vac +/-10% Rated frequency 50/60 Hz Connection to the mains with cables that comply with current code in the given area of use. Rated current 4A Rated power 900 W

HYDRO-PNEUMATIC SUPPLIES

Pneumatic supply from 450 kPa to 650 kPa (from 4.5 to 6.5 bar) (consumption of aspirated air equalling approx. 40 litres/minute) Water supply from 200 kPa to 400 kPa (from 2 to 4 bar) (consumption of water equalling approx. 2 litres/minute) Max. temperature 30 °C

OPERATING PERIODS

| Chair | intermittent | 1' on / 10' off |
|---------------------------|--------------|-----------------|
| Syringe 6F (hot water) | intermittent | 5' on / 10' off |
| Polymerization lamp | intermittent | 20' on / 3' off |
| Tooth scaler (with water) | intermittent | 3' on / 5' off |
| Micromotor | intermittent | 3' on / 3' off |
| Operating lamp | continuous | |
| Syringe 3F (cold water) | continuous | |

EDI OPERATING LAMP (with cooling fan) Halogen lamp: 17 Vac, 95 W Colour temperature: 5,000 °K Focal distance: 700 mm Operating field (at 700 mm): 60x180 mm Max. luminous intensity (at 700 mm): 25000 Lux.

ALYA SPOT LIGHT (led) Colour temperature: 5,000 °K Focal distance: 700 mm Operating field (at 700 mm): 170x85 mm Max. luminous intensity (at 700 mm): 8000-50000 Lux. Cri (colour rendering index) >85

MAIA SPOT LIGHT (led) Colour temperature: 5,000 °K Focal distance: 700 mm Operating field (at 700 mm): 170x85 mm Max. luminous intensity (at 700 mm): 3000-35000 Lux.

GCOMM POLARIS OPERATING LAMP (led) Colour temperature: 4200-6000 °K Focal distance: 700 mm Operating field (at 700 mm): 70x140 mm Luminous intensity: 15000-30000 Lux.

MISCELLANEOUSWeightcirca 165 KgMaximum load allowed on chair135 KgLength of foot control cable2.5 mMinimum space recommended for device installation approximately 3.20x3.00x3.00 m (LxHxD)

IMPORTANT NOTE

The devices, in the models foreseen and indicated in this document, are designed and built in compliance with directive 93/42/EEC "Medical Devices" (as amended) and international safety standards IEC EN 60601-1 (Medical Electrical Equipment - General Requirements for Safety), IEC EN 60601-1-2 (Medical Electrical Equipment - Collateral standard: Electromagnetic Compatibility), IEC 80601-2-60 (Medical electrical equipment: Particular requirements for basic safety and essential performance of dental equipment), ISO 6875:2011 (dental chairs), ISO 7494-1:2011 (dental units)

, UNI CEI EN ISO 14971:2009 (risk analysis), CEI EN 62304:2006 (ing. Software), CEI EN 62366:2008 (ing. Usability), CEI EN 60601-1-6:2011 (usability).

O.M.S. declines any and all responsibility for equipment safety and reliability in the following cases: if installation, additions, re-calibration, modifications or changes are not performed by O.M.S. authorised technicians following the instructions and using the components supplied by O.M.S. exclusively; if the electric system installed in the workplace does not comply with IEC standards; and/or if the equipment is not used according to the operating instructions.

NAMEPLATE DATA

An identification plate is affixed to the equipment indicating general device data.



- A. Device model
- B. Rated voltage and nature of current (alternating ~)
- C. Rated frequency
- D. Rated current
- E. Rated power
- F. Device serial n°
- G. Manufacturer
- H. Cooling fluid temperature
- I. WEEE symbol
- J. Applied part Type B
- K. Certification markings: Medical device directive 93/42/EEC and subsequent amendments
- L. Mandatory, see enclosed documentation
- M. Follow operating instructions

3. TECHNICAL INSTRUCTIONS FOR INSTALLATION

3.1. PACKAGING

The unit is shipped in a box containing instructions accessory box, S.T. 01/3, lamp *, arm lamp *, * suction, fixing screws. (*)Present only in case of a specific request at the order.

Outside each box there is a flag that indicates the order confirmation numbera and the model. Note: the packaging of an eventual seat O.M.S. is separated.

3.2.ASSEMBLY

- 1. Remove the equipment from its packaging;
- 2. Place the chair on the previously made settings using the installation plan and adjust any "play" by tightening or unscrewing the adjustment feet as necessary, secure the chair to the floor using the two supplied dowels;
- 3. If an operating mounting lamp and electrical connection;
- 4. verify (and possibly perform) ground cables to the screw marked with the ground symbol;

5. to connect the vacuum pump (see the wiring diagram) in the same manner as described in the next bullet for power cables (securing leads and traction).

6. remove the cover at the base of the dental chair, unscrewing the screws D





to maintain water and air connections (see section

developed), aspiration, exhaust and finally the power grid (Terminal); the power cables on the terminal board must be general, with nylon ties, insulating specially drilled and placed under the Terminal, in particular it must be ensured that, in the event of failure of the fasteners (clamps), the protective conductor is not subject to traction as long as network cables are still connected to terminal 3. Fit the accessories (instruments), if any, on the instrument and dental assistant tables.

N.B.: Refer to the wiring and installation diagrams provided for all electrical connections.

3.3.CONNECTIONS

First, make sure that the flow of air and water from the water and pneumatic mains is regular. O.M.S. declines any and all responsibility for faults or damage originating from non-compliance with the warning below:

Water supply:

Water with medium/low salt content (fit a water softening device if necessary), to be connected to the 6x8 diameter tube (see paragraph TECHNICAL SPECIFICATIONS for admitted pressure). Pneumatic supply:

Compressed air, preferably dehumidified and oil-suspension free, to be connected to the 4x6 diameter tube (see paragraph TECHNICAL SPECIFICATIONS for admitted pressure).

We recommend making a temporary direct connection between the water delivery pipe and the drain pipe, and letting the water circulate for a few seconds before installing the equipment. This enables elimination of any impurities from the tubes.

3.4. TESTING AND PUTTING INTO OPERATION

IMPORTANT WARNING

During testing, check the mechanical stability of the equipment after placing all the mobile elements and accessories (table, lamp, etc.) in the most unsuitable position possible.

1. Ensure that the instrument table is perfectly level: if an unusual tilting is identified, adjust the table using the screw (detail A in Figure) located inside the front part of the arm.



- 2. Check the manual pantograph base and backrest up and down controls, and the automatic return to exit, rinse position and return to last position control to ensure they are working properly. Check and store correct positioning of the programs (see sections MANUAL CONTROLS and AUTOMATIC CONTROLS).
- 3. Check that limit switches and safety systems are working properly (see section SAFETY SYSTEMS).
- 4. Check correct calibration of the pressure regulators and general flow regulators and that of each instrument. These devices have already been calibrated by O.M.S. in the workshop, but they may require an inspection or re-calibration.

Note: The equipment is equipped with a general water tap. During use, the tap should be open. At the end of the work day, the tap should be closed or, alternatively, close the unit's general supply tap in the surgery.

DANGER: Before performing any operations in the equipment, always make sure that the power switch is off..

4. CONTROLS - ADJUSTMENTS - INDICATORS

4.1. SAFETY SYSTEMS

The dental chair is supplied with safety devices which minimise the risk of crushing or collision with underlying objects during chair descent. Safety devices include a special sensor on the dental chair back and an electromechanical safety device installed at the base of the dental chair back.



Whenever the sensor installed on the dental chair back is engaged during a descent movement (either of the pantographic arm or chair back), the part moving down stops. A warning LED at the bottom of the seat (detail B) goes ON and stays ON until the obstacle causing safety device engagement is cleared. To perform the required movement, remove the obstacle and repeat the control.

The sensor installed on the back of the dental chair is calibrated as instructed below.

- Place the chair in the permanent position;
- Put a screwdriver in the hole for the calibration of the sensor located at the bottom of the chair seat (detail B). Turn the screwdriver clockwise to reduce the sensor sensitivity and anticlockwise to increase it.
- Control the pantographic arm or chair back to move downwards and touch the back of the dental chair to engage the safety sensor (detail A) in order to check its sensitivity. Repeat the operations from the previous item until the ideal sensor sensitivity is found.

When the back safety sensor is engaged, all downward movements of both the back and pantographic arm are disabled.

The back of the dental chair is also provided with an electric and mechanical safety device which stops the descent movements of both the pantographic arm and back whenever obstacles are present in the outreach of the keyboard. Whenever this safety device is engaged, all downward movements of both the pantographic arm and back are disabled.

During automatic movements of the dental chair (position reset, memorised positions or rinsing positions), press any control of the dental chair (on the pushbutton panels of the dental unit or foot control) to immediately stop the dental chair.

Dental chair movement may be disabled both at equipment switch on and during normal operation, if one or more than one safety system is active.

4.2.INSTRUMENT TABLE



The instrument table offers two tools, a syringe and a suction cannula.

Comprises the Group of solenoid instruments with clearly visible, all its adjusters. The functions of each device are described in the chapters to the forms tool. Regulations that are not equipped with knob must be takend off by authorised technicians O.M. S

4.2.1. PULSANTIERA

The controls are entirely under sealed membrane, this enables greater reliability, eliminating crevices and the disinfection of the surface.

The key functions are:



Reversing command of the micromotor with warning led (with led off the direction of rotation is normal)



command of spray preselection and fiber optics (press button for 3 seconds), with preselected led fibre optic lighting and with preselected spray active led. The other buttons are inactive.



4.2.2. TURBINE MODULE

Turbine operation is achieved by lifting the instrument from its position, moving it to the surgical field, and then press the foot pedal (see operation section).

Lifting the instrument by the table are inhibited all other dynamic tools and all the movements of the dental chair.

The spray is always preselected. To adjust the water to spray one acts on the faucet in place behind the Chair. By turning the tap clockwise you get a gradual decrease of water flow to the spray until its complete exclusion, the opposite rotating in the opposite direction. It is recommended not to intervene in other regulations placed at the side of the spray faucet.



If the instrument is equipped with optical fibres lighting system, these are switched on by pressing the

control command pad spot Tablet (when the function is on, it affects all instruments). The activation of the function is displayed by the lit led (D).

Air pressure Recommended (measured during operation of the turbine) is set at the time of testing in the O.M.S.. Calibration must be re-evaluated at the time of installation of the appliance using a manometer, respecting the pressure values indicated by the manufacturer of the turbine. This must be done by an authorised O.M.S..

For more details see the attached manufacturer's instructions.

4.2.3. ELECTRIC MICROMOTOR MODULE

The function of the micromotor is achieved by lifting the instrument from its place, moving it to the surgical field and then pressing the foot pedal (see operation section MICROMOTOR).

Lifting the instrument from the table are inhibited all other dynamic tools and all the movements of the dental chair.

The micromotor allows you to work with a variable speed from a minimum of about 900 RPM to a maximum of 40,000 rpm

Normally the micromotor will have a clockwise direction rotation. For reversal of direction of rotation,

after lifting the tool, activate the reverse command 🧼 in t

in the instruments table.

It is recommended that the change of direction of rotation is made only when the motor is stopped, to prevent damage.



The spray is preset by typing the command _____; the activation of the function by the lit led is displayed. See also section OPERATION micromotor.

To adjust the water to spray one acts on the faucet in place behind the Chair. By turning the tap clockwise you get a gradual decrease of water flow to the spray until its complete exclusion, the opposite rotating in the opposite direction. It is recommended not to intervene in other regulations placed at the side of the spray faucet.



If the instrument is equipped with optical fibres lighting system, these are switched on by pressing

, place on command pad table (when the function is on, it affects all instruments). The command The activation of the function is displayed by the lit led (D).

SCALER MODULE

Generator operation is achieved by lifting the instrument from its place, moving it to the surgical field and then pressing the foot controller lever (see operation section GENERATOR).

Lifting the instrument by the table are inhibited all other dynamic tools and all the movements of the dental chair.

To adjust the water to spray one acts on the faucet in place behind the dental chair. By turning the tap clockwise you get a gradual decrease of water flow to the spray until its complete exclusion, the opposite rotating in the opposite direction. It is recommended not to intervene in other regulations placed at the side of the spray faucet.



If the instrument is equipped with optical fibres lighting system, these are switched on by pressing

the command

, placed on the command pad of the table (when the function is on, it affects all instruments). The activation of the function is displayed by the lit led (D).

For more details see the attached manufacturer's instructions.

For the scaler SATELEC NEWTRON SP power regulation must be done according to the tip on the handpiece.

4.2.4 SYRINGE MODULE

The syringe operates at any time by simply pressing one of the two levers enabling either water or air supply (left-hand lever for water and right-hand lever for air). When these two supply buttons are pressed simultaneously, spray water is delivered.

For further details refer to the manufacturer's operating instructions enclosed.

4.3.FOOT CONTROL

The equipment foot control was designed to control all the possible functions of the instruments with a simple movement of the lever (A).



N.B.: when the instrument is extracted, it is automatically connected to the foot control, thus disabling all the other instruments even at a subsequent extraction (by the dental assistant, for instance).

4.3.1. TURBINE OPERATIONS

Extract the instrument from its housing (this operation is shown on the display). Then:

- pressing the lever (A) of the foot control in the rest position will enable the chip-blower;

- move the lever A to the right to operate the instrument. If lever A is pressed simultaneously, the turbine is sprayed (standard configuration). Upon request, at the time of installation, the technician can change the connections so that the spray function can be operated without having to press the lever.

4.3.2. MICROMOTOR OPERATIONS

Extract the instrument from its housing (this operation is shown on the display). Then:

- pressing the lever (A) of the foot control in the rest position will enable the chip-blower;
- move the lever A to the right to operate the instrument. The spray is pre-selected in the instrument



table by engaging the control is then, spray delivery is possible when the foot control lever (A) is slightly pressed with the instrument in operation (standard configuration). Upon request, at the time of installation, the technician can change the connections so that the spray function can be operated without having to press the lever.

To invert the micromotor rotation, move the foot control lever A to the left and press it downwards. This operation is viewed on the display, and an on-off beep accompanies this function, which is disengaged by moving the lever (A) to the left again and pressing it downwards.

4.3.3. SCALER OPERATIONS

After removing the instrument from its place by moving the lever (A) to the right to activate the tool.



The spray you pre-select in instruments table by typing the command "; then you can have the spray dispensing by pressing the lever rheostat (A) if the instrument is in function (standard configuration). Upon request, at the time of installation, the technician can change the connections so that the spray designed to be dispensed without the need to depress the lever.

4.3.4. CHAIR CONTROLS FROM THE FOOT CONTROL

The foot control is equipped with two side levers (see det. B and C) that are operated to position the dental chair using foot controls:

- moving the lever (B) up will raise the seat;
- moving the lever (B) down will lower the seat;
- moving the lever (C) up will lower the backrest;
- moving the lever (C) down will raise the backrest.



4.3.5. OTHER ACCESSORIES

For accessories not previously described buy indicated in the product description, see the specific user manuals supplied with the equipment.

4.4.GROUND BOX

In the box to the floor are housed all electrical control systems, pneumatic and water together. Inside, it is possible to carry out the connection of the appliance to the mains, the mains water supply, drainage, compressed air and the flue pipe from the engine of the surgical suction, if any. Access is by unscrewing the screws D and remove plastic cover C with the caveat of disconnect power before opening (as described in the section on SAFETY).



4.4.1. AIR PRESSURE REGULATOR

The air pressure regulator is used to maintain the air pressure in the instruments on board.

The setting of the regulator is made at the time of testing in the O.M.S. and can be modified only for technical reasons; This must be done by an authorized technician.

The regulator collects the condensate present in compressed air; condensate discharge CONDENSATE DRAIN section.

4.4.2. WATER PRESSURE REGULATOR

The water pressure regulator maintains a constant pressure in the instruments table. The adjustment made at the time of testing in the O.M.S. may be changed only for technical reasons; This must be done by an authorized technician.

The regulator is equipped with a filter that must be periodically checked and possibly replaced, as described in the section on WATER FILTERS.

4.5. OPERATING LAMP

The lamp usage is limited to only two things: -power on/off; -brightness adjustment.

For more details see the attached manufacturer's instructions.

5. HIGH SPEED ASPIRATION

The equipment can be connected to a high speed air ring, liquid ring or ecological liquid ring type aspiration system. The main unit is supplied with a cannula arm (see section 4.5 CANNULA HOLDER). Some aspiration elements (e.g. the separator tank) can be fitted in the main unit.

The aspiration system consists of the following parts (see Figure 16CT):

- A. a drain (located on the column);
- B. a filter;
- C. a drain plug;
- D. 2 aspiration tubes, approx. 1.5 m in length and 11 and 16 mm in diameter;
- E. aspiration end pieces, 11 and 16 mm in diameter.

If the dental unit is connected to a centralized aspiration system, the main unit shall feature a shutter solenoid value to select the work station.

The aspiration system of the dental unit can also be connected to amalgam separation systems that are fitted inside the main unit.



6. CHAIR

7.1. HEADREST to DOUBLE ARTICULATION

The articulating headrest is height adjustable with a range of about 23 cm and has two joints that can be controlled simultaneously using the lever at the rear; It allows you to move easely the headboard on two axes of rotation.

Bringing the headboard cushion to an angle of approximately 90° to the joint mechanism, it can be rotated 180° on himself. It can also lower the swivel mechanism in a position that gives the most comfort for patients of modest stature headboard.

Caution: once you have placed the headboard in the working position replace the latch in position to block the movement.











6.1. DOUBLE JOINT HEADREST

The double-articulating headrest is height adjustable with a range of about 23 cm and has two joints that can be controlled simultaneously using the lever at the rear; It allows you to easily move the headboard on two axes of rotation.

Bringing the headboard cushion to an angle of approximately 90° to the joint mechanism, it can be rotated 180° on himself. It can also lower the swivel mechanism in a position that gives the most comfort for patients of modest stature headboard.

Caution: once you have placed the headboard in the working position replace the latch in position to block movement.





6.2. HEADREST WITH 3D MOVEMENT

The 3D movement headrest is height adjustable with a range of about 23 cm and has articulation on rear joint, which allows the lateral movement, using the lever at the rear; It allows you to easily move the hearest on three axes of rotation.

Caution: once you have placed the headrest in the working position replace the latch in position to block the movement.



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6.3.ARMRESTS

The dental chair is supplied with one armrest on the left-hand side. The movement of the armrest is synchronised with the movement of the chair back. Upon request, the dental chair can be supplied with both armrests (whose movement is synchronised with that of the chair back). The right-hand side armrest features a button (at its base) which, when pressed, enables to lower the armrest frontally or backwardly for easier patient's passage.

Once the armrest has been swung back, it can also be removed by simply pulling it in the direction of its axis of rotation, turning it slightly to the left and right to help it release. Repeat the procedure in reverse to refit the armrest, making sure it is inserted all the way in before turning the armrest.

Perform armrest removal and insertion operations gently and under no circumstances use force if you encounter resistance.

7. SERVICE AND MAINTENANCE

A number of operations are described below. We strongly recommend you perform this work following the procedures given at the stated intervals in order to keep your equipment at peak efficiency. The following paragraphs list the various maintenance activities, with the relevant frequency, required worker and reference details.

Activities are classified in:

- Cleaning/disinfection,
- Adjustments,
- Scheduled maintenance
- Extraordinary maintenance

They take into account all configurations using the various accessories in stock and thus can be applied based on the options you selected in the order.

7.1. CLEANING AND DISINFECTION

For the sake of hygiene (and to avoid surfaces being exposed at length to spots of corrosive substances), clean the equipment frequently.

Furthermore, for the sake of hygiene and cleaning, and to avoid the risk of damage, O.M.S. recommend you use products that contain:

- Quaternary ammonium
- Phenolic compounds
- Iodophors

that do **not** contain:

- Alcohol
- Hypochlorite
- Soda
- Organic solvents

O.M.S. recommends these factory tested products. Always refer to the manufacturer's instruction and safety sheets:

- 1. Detergent
 - ZETA 4.
- 2. Disinfectant
 - OROCID MULTISEPT

Chair upholstery

To thoroughly clean chair upholstery, a product suitable for sky can be used such as:

- EMULSIO.

For daily cleaning and disinfection, use a gentle product such as:

- GREEN & CLEAN SK.

O.M.S. provides factory tested and inspected products upon request.

O.M.S. decline all responsibility for problems resulting from the use of substances other than those recommended.

| CLEANING AND DISINFECTION | | | | |
|---------------------------|-----------|----------|-----------------|--|
| Activity | Frequency | By whom? | Note/references | |

| Instrument table, instrument tube exterior | After each patient | Trained operator | Only use products indicated by OMS. |
|---|-----------------------|---------------------|---|
| Instrument table: instrument holder, handles, tray mat Assistant table mat | After each patient | Trained operator | Autoclave (if applicable) Only use products indicated by OMS. |
| Instruments and syringe | After each patient | Trained operator | Clean, disinfect and sterilise when indicated by the instrument manufacturer's instructions. |
| Chair: Upholstery, headrest and armrests | After each patient | Trained operator | Only use products indicated by OMS. |
| Operating lamp components | After each patient | Trained operator | Clean, disinfect and sterilise when indicated by the manufacturer's instructions. |
| Foot control cleaning | Daily | Trained operator | Only use products indicated by OMS. |
| Spittoon, cannula and spittoon filter | Daily | Trained operator | Only use products indicated by OMS. |
| High speed aspirator, system and terminals | After each patient | Trained operator | Suction clean water for several seconds. Clean and sterilise (130°C) terminals (nozzles). |
| High speed aspirator, system and terminals | Daily | Trained operator | Clean with specific product for several minutes. Lubricate drain mouth. |
| Painted cases | Daily | Trained operator | You are strongly advised not to use denatured alcohol or cleaners containing soda or organic solvents as they could damage the paintwork and upholstery. |

7.1.1. INSTRUMENTS

For instrument cleaning, sterilization and lubrication, we recommend consulting the instructions supplied by the manufacturer(s) for each model that are attached to this manual and added to the equipment packaging.

7.1.2. **CHAIR**

Gentle sky upholstery products must be used for daily cleaning and disinfection.

Products suited for sky must be used for periodic in-depth upholstery, armrest and headrest cleaning following the procedure below:

- 1. Shake well before use
- 2. Pour the product on a dry cloth, do not pour directly on the surface to be cleaned
- 3. Start with a small surface, making sure the sky remains unaltered, extending onto the rest of the upholstery until fully evaporated
- 4. Remove residue from the cleaned surface with a dry cloth
- 5. Do not overly use and wait at least 60 days before the next cleaning

7.1.3. HIGH SPEED ASPIRATION

The best performance is obtained from your high speed aspiration system if the simple operating and maintenance instructions below are strictly adhered to. Failure to comply with these instructions would jeopardise the performance of the aspirator performance, sometimes with serious consequences.

<u>After each intervention</u>, we recommend aspirating clean water for a few seconds in order to rinse the tubing. Dental tips must be thoroughly cleaned and sterilised: We recommend brushing the cannulas both inside and outside using the supplied pigs (to be found in the "aspiration system accessory kit") and a suitable detergent.

Aspiration end pieces supplied by O.M.S. can be autoclaved at a temperature of 130°C.

In order for the aspirated deposits not to clog the filter and corresponding aspiration tubing the following washing cycle must be carried out <u>at the end of each working day</u>.

For this operation use the products recommended by the aspiration system manufacturers.

- 1. Use one of the two aspiration cannulas to aspirate the amount of solution indicated in the bottle making sure that only the cannula end is introduced into the bottle.
- 2. Let the aspirator run for 3 to 4 minutes, then stop it. Drain the liquid and repeat the previous operation with the other cannula. Aspirate using one cannula at a time so that the other cannula can be used for air suction, thus preventing the aspiration system from getting blocked due to an excessive aspiration of liquid.
- 3. Unscrew the drain plug and clean the filter inside the drain (in the column). Replace it, if necessary. Periodically grease the drain and plug mouthpiece with vaseline, because disinfectants may stiffen these parts, thus making plug extraction difficult.

Do not mix detergents having different features.

Never immerse aspiration tubes if they do not fit the required cannula.

| ADJUSTMENTS | | | | | |
|------------------------------------|-----------------|------------|--------------------------------|--|--|
| Activity | Frequency | By whom? | Note/references | | |
| General surgery water tap | End of the work | Trained | Close the dental unit water | | |
| | day | operator | supply tap | | |
| Instrument spray water pressure | When necessary | Trained | Tap under the instrument table | | |
| adjustment | | operator | (adjustment without tool) | | |
| Instrument air pressure | When necessary | Authorised | Tap under the instrument table | | |
| adjustment | | technician | (adjustment with tool, | | |
| | | | authorised technician only) | | |
| Clutch adjustment (accessible from | When necessary | Trained | | | |
| the exterior) | | operator | | | |
| Cup/spittoon water flow | When necessary | Trained | | | |
| adjustment | | operator | | | |
| Oscillating arm spring adjustment | When necessary | Authorised | | | |
| (interior) | | technician | | | |
| Main unit water pressure | When necessary | Authorised | Pressure regulator calibration | | |
| adjustment | | technician | | | |
| Main unit air pressure adjustment | When necessary | Authorised | Pressure regulator calibration | | |
| | | technician | | | |

7.2. ADJUSTMENTS

7.2.1. INSTRUMENT SPRAY PRESSURE

The water delivered to the spray is regulated by rotating the tap located under the relevant instrument module: when turned anticlockwise, the flow of water to the spray is gradually reduced; when turned clockwise, the opposite applies.

7.2.2. MAIN UNIT AIR PRESSURE

An air pressure regulator is installed in the spittoon unit that keeps air pressure constant in table instruments.

The regulator is calibrated during the testing phase at O.M.S. and calibration can be changed exclusively for technical reasons. This operation must be performed by an authorised technician.

The regulator collects any condensate present in the compressed air. For condensate draining refer to paragraph CONDENSATE DRAINAGE.

7.2.3. CLUTCH ADJUSTMENT

- the arm movement have regulations that allow to obtain the desired friction level for each of them:
- arm movement (tilting toolbar tray);



7.2.4. SWIVEL ARM SPRING

The strength of the table-holding arm can be regulated by means of an adjustable spring (det. B in Figure). This device perfectly offsets the weight of the table, which changes according to the new instruments that are added to it or the actual use being made of it (light or heavy loads). This adjustment must be performed by an authorised O.M.S. technician.



7.2.5. MAIN UNIT WATER PRESSURE

The water pressure regulator is used to keep the water pressure of the instrument in the table constant. The regulator is calibrated during the testing phase at O.M.S. and calibration can be changed exclusively for technical reasons. This operation must be performed by an authorised technician.

The regulator has a filter that must be checked periodically and replaced, if necessary, as described in paragraph MAIN UNIT WATER FILTERS.

7.3.SCHEDULED MAINTENANCE

| SCHEDULED MAINTENANCE | | | | | |
|------------------------------------|------------------|------------|-----------------------------|--|--|
| Activity | Frequency | By whom? | Note/references | | |
| Condensation drain | Weekly | Trained | | | |
| | | operator | | | |
| Instrument lubrication | According to the | Trained | | | |
| | instrument | operator | | | |
| | manufacturer's | | | | |
| | instructions | | | | |
| Aspiration system check and | Monthly | Authorised | Recommended | | |
| cleaning | | technician | | | |
| Aspiration anti-foam agent tablet | Every 2 - 3 days | Trained | Place in drain filter | | |
| change | (when necessary) | operator | | | |
| Aspiration cannula tab lubrication | 15 days | Trained | Silicone spray | | |
| | | operator | | | |
| Aspiration tube replacement | Annually | Authorised | | | |
| | | technician | | | |
| Disinfect separate distilled water | Monthly | Trained | | | |
| container for instrument supply | | operator | | | |
| Replace the main unit water filter | Annually | Authorised | | | |
| | | technician | | | |
| Check the instrument water filter | Every 2 years | Authorised | | | |
| | | technician | | | |
| Replace amalgam tank | When indicated | Trained | According to the instrument | | |
| | by separator | operator | manufacturer's instructions | | |
| Replace disinfection system | When indicated | Trained | According to the instrument | | |
| disinfectant cartridge | by the | operator | manufacturer's instructions | | |
| | disinfection | | | | |
| | system | | | | |
| General functional checks | Yearly or after | Authorised | | | |
| | 8000 operating | technician | | | |
| | hours | | | | |
| Periodic safety/performance | Two years | Authorised | Mandatory by law | | |
| checks - IEC 62353 | | technician | | | |

7.3.1. CONDENSATION DRAIN

The equipment is supplied with an air filtering device and a condensate drain valve.

Any condensate accumulating in the transparent cup is expelled by pushing upwards the needle valve located on the cup bottom, as shown in figure 17C and 17T.

N.B.: check for condensate on a weekly basis.



N.B.: check for condensate on a weekly basis.

7.3.2. ASPIRATION SYSTEM

Every 30 days of operation (and especially in the event of system inactivity for several days) check the entire aspiration system and make sure that it works correctly. This check must be performed by an authorised technician.

If foam-generating substances are used (e.g. hydrogen peroxide, etc.), the system may temporarily stop. If this malfunctioning occurs, use "antifoam agent" tablets. These tablets (a sample of which is included in the aspiration accessory kit) must be placed in the drain filter and usually last a few days of operation.

All the parts of the aspiration cannulas are easy to disassemble (see Figure) for disinfection and cold



sterilization..

Every 15 days spray the closing tabs of each cannula with silicon spray. Spray the end piece inside when the tab is closed, and the outside when the tab is open. Then, open and close each end piece repeatedly. For functional and hygienic reasons we recommend replacing the external aspiration tubes and end pieces at least once a year.

7.3.3. INSTRUMENT WATER FILTER

To prevent impurities that are always present in the water mains from jeopardising instrument operation, the water flows through a filtering pad located near the water pressure regulator (see Figure.



Every 12 to 24 months ask a technician to check the filter for possible clogging during the periodic overhaul. Replace the bronze sintered pad, if necessary.

7.3.4. FUNCTIONAL SAFETY CHECKS

To guarantee dental unit operating and functional safety, have an authorised OMS technician perform routine maintenance once a year.

Medical electrical devices are built to guarantee patient, operator or third party safety in the event of fault. Consequently, the actual level of safety must be periodically checked.

Run periodic safety checks and tests at least once every two years to find any electrical faults (i.e. damaged insulation) that could reduce the initial level of safety.

These checks should be performed by an authorised OMS technician with suitable tools and equipment according to specific standards; regulation IEC 62353 is the reference standard for medical electrical device controls manufactured in accordance with IEC 60601-1.

Periodic checks and tests include visual inspection, grounding connection measures and dispersed currents; the results and values measured must be recorded in a specific form and kept to demonstrate device compliance in time (complete with accessories) and to monitor device safety levels.

Technical safety checks must be performed and documented:

- after first start up (installation),
- after repairs or maintenance work,
- during periodic tests.

N.B. Dental unit use is only permitted if all safety checks were passed.

7.4.EXTRAORDINARY MAINTENANCE

Some extraordinary maintenance activities are described below and, except for paint touch-ups, we recommend they all be performed by authorised O.M.S. technicians.

Upon request, O.M.S. will provide all wiring diagrams, component lists, descriptions, calibration instructions or other information to assist authorised O.M.S. technicians in device repairs.

| EXTRAORDINARY MAINTENANCE | | | | | |
|---|----------------|--------------------------|-----------------|---------------|-----------|
| Activity | Frequency | By whom? | | Note/refer | ences |
| Paint touch-ups | When necessary | Trained operator | | | |
| Fuse replacement | When necessary | Authorised technician | Refer docume | to ntation | technical |
| Work due to malfunctions, faults or downtime | When necessary | Authorised technician | Refer docume | to ntation | technical |

7.4.1. **TOUCH-UPS**

Any minor scratches on the enamel can be touched up with the bottle of paint provided in the accessories box for this very purpose. Shake the bottle before use and mix the paint well, plunging the brush up and down several times inside the bottle containing the enamel. Touch up by "dabbing" the damaged area with small drops of paint.

7.4.2. FUSE REPLACEMENT

WARNING: Before replacing a fuse, you must first determine the reason why it has blown and carry out the replacement only once the causes have been eliminated. The new safety fuse must have the same features as the replaced fuse. These specifications are shown in the electrical diagram of the equipment.

On the basis of the dental chair is easy to spot the General protection fuse (B) external-replaceable with a screwdriver; before the replacement make sure that the main switch (A) is switched off. Fuse replacement should occur only after you remove the cause that caused the intervention; If the problem persists after replacing the fuse you must request the assistance of a OMS qualified technician.



The fuses are also present on the electronic cards;

The replacement of fuses placed on electronic boards (placed inside the casing at the base of the dental chair) shall be carried out only by an authorised O.M.S..

Are stated below, for illustrative purposes only, the values of the main fuses:

B. General fuse 8AT, 230 Vac



- E. not used
- F. not used
- G. spittoon 4AT, 24 Vac
- H. General tab 6, 3AT, 24Vac

Spare fuses supplied by O.M.S. are packed in the accessory box. Fuses should only be replaced by an authorised O.M.S. technician.

7.4.3. ELECTROMAGNETIC POTENTIAL

The device is designed and built to the IEC standard EN 60601-1-2 (Medical electrical equipment; Collateral standard: Electromagnetic compatibility) and hence its level of immunity and emissions is such as not to create dangerous interference with equipment built in compliance with the same standard. WARNING: Interference can instead occur with electrical equipment with a level of emissions or immunity that do not meet IEC standard EN 60601-1-2. In such cases, this equipment must not be used at the same time as O.M.S. equipment. Should the device freeze due to said interference, switching it off and back on again may be sufficient to resume normal operation.

In the event of brownouts, the micromotor may temporarily lose speed that does not jeopardise its safety and performance. The duration of the event is limited to the duration of the brownout.

| Manufacturer's guide and statement - electromagnetic emissions | | | | |
|--|--------------------------|--|--|--|
| The device is intended to oper | ating in the electromagn | etic environment indicated below. The device customer or user must | | |
| | guarantee that | it is used in this environment. | | |
| Emission test | Conformity | Electromagnetic environment – guide | | |
| RF emissions | Group 1 | The device only uses RF energy for its internal operations. | | |
| CISPR 11 | | Consequently, its RF emissions are very low and most likely do not cause | | |
| | | any interferences with nearby electronic equipment. | | |
| RF emissions | Class B | The device is suited for use in all environments, including home ones | | |
| CISPR 11 | | and those directly connected to a low voltage public mains that powers | | |
| Harmonic emissions | Class A | buildings used for residential purposes. | | |
| IEC 61000-3-2 | | | | |
| Voltage fluctuation | Compliant | | | |
| emissions/flicker | | | | |
| IEC 61000-3-3 | | | | |

| | Manufacturer's guide and statement - electromagnetic immunity | | | | | |
|--|--|----------------------|---|--|--|--|
| The device is intended | The device is intended to operating in the electromagnetic environment indicated below. The device customer or user must | | | | | |
| | guarantee that it i | s used in this envir | onment. | | | |
| Immunity test | IEC 60601 test level | Level of | Electromagnetic environment - guide | | | |
| | | conformity | | | | |
| Electrostatic discharge | on contact ± 6 kV | ± 6 kV | Floors must be made of wood, cement or ceramic | | | |
| (ESD) | in air ± 8 kV | ± 8 kV | tile. If floors are lined with synthetic material, | | | |
| IEC 61000-4-2 | | | relative humidity must be at least 30%. | | | |
| Transistors/Burst | ± 2 kV for power lines | ± 2 kV | The mains voltage quality must be that typical of | | | |
| IEC 61000-4-4 | ±1 kV for input/output lines | ± 1 kV | a retail or hospital environment. | | | |
| Surge | ±1 kV between phases | ± 1 kV | The mains voltage quality must be that typical of | | | |
| IEC 61000-4-5 | ± 2 kV between phase and | ± 2 kV | a retail or hospital environment. | | | |
| | grounding | | | | | |
| Brownouts, short | <5 % U⊤ | <5 % U⊤ | The mains voltage quality must be that typical of | | | |
| blackouts and voltage | (>95 % brownout in U_T for 0.5 | 0.5 cycles | a retail or hospital environment. If the device | | | |
| variations on input power | cycles) | (10mS) | user requires continuous operations during a | | | |
| lines | | | blackout, the device should be powered by a UPS | | | |
| IEC 61000-4-11 | 40 % U _T | 40 % U _T | or batteries. | | | |
| | (60 % brownout in U_T for 5 | 5 cycles (100mS) | | | | |
| | cycles) | | | | | |
| | | | | | | |
| | 70 % U _T | 70 % U⊤ | | | | |
| | (30 % brownout in U_T for 20 | 20 cycles | | | | |
| | cycles) | (500mS) | | | | |
| | = % 11 | = 9/11 | | | | |
| | $< 5 \% U_{T}$ | <5 % UT | | | | |
| | $(395 \%$ brownout in O_T for 5 5) | 55 | | | | |
| Magnetic field at mains | 3 A/M | 3 A/M | Magnetic fields at mains frequency should have | | | |
| trequency (50/60 Hz) | | | ieveis typical of a retail or hospital environment. | | | |
| 1EC 01000-4-8 | | | | | | |
| N.B.: U_T is the AC mains voltage before the application of the test level | | | | | | |

| Manufacturen's quide and statement $-$ electromagnetic immunity | | | | |
|--|------------------------|------------------------|--|--|
| The device is intended to operating in the electromagnetic environment indicated below. The device customer or user must ouarantee that it is used in this environment. | | | | |
| Immunity test | IEC 60601 test level | Level of conformity | Electromagnetic environment - guide | |
| | | | Portable and mobile RF communication devices should not be used near any part of the device including wires, from the recommended separation distance calculated with the equation applicable to the transmitter frequency. Recommended separation distance: $d = 1,17 \sqrt{P}$ | |
| Conducted RF | 3 Veff | 3 V | | |
| IEC 61000-4-6 | from 150 kHz to 80 MHz | | d = 1,17 JP from 80 MHz to 800 MHz | |

| Radiated RF | 3 V/m | 3 V/m | <i>d = 2,34 JP</i> from 800 MHz to 2,5 GHz | |
|---|--|-----------------------|--|--|
| 120 01000-4-3 | Trom OU MHZ TO 2,5 GHZ | | where P is the maximum rated transmitter output power in Watt (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). | |
| | | | The fixed RF transmitter field intensity, as determined by an on-site ^a electromagnetic survey, should be under the level of conformity for each frequency interval ^b . | |
| | | | Interferences may occur near devices marked by the following symbol: | |
| | | | (((•))) ▲ | |
| NOTE 1: At 80 MHz and 8 | 00 MHz, the separation dist | ance is applied for t | he highest frequency interval. | |
| NOTE 2: These guideline individual absorption and r | s may not apply to all situat reflection. | tions. Electromagne | tic propagation is influenced by building, object and | |
| a Fixed transmitter field intensities, like base stations for radio telephones (mobile and cordless phones) and land line radio | | | | |

- communication devices, radio stations, AM and FM radio transmitters and TV transmitters cannot be theoretically foreseen with precision. To evaluate an electromagnetic environment caused by fixed RF transmitters, an on-site survey should be considered. If field intensity measured at the device installation site exceeds the applicable level of conformity indicated above, device operations should be monitored. If abnormal performance is noted, additional measures such as a different device orientation or position may be necessary.
- b Field intensity in the frequency interval from 150 kHz to 80 MHz should be under 3V/m.

Recommended separation distance between portable and mobile radio communication devices and the device

The device is intended to work in the electromagnetic environment in which radiated RF disturbances are under control. The device customer or user can contribute in preventing electromagnetic interferences by ensuring a minimum distance between RF mobile and portable communication devices (transmitters) and the device and recommended below, according to the maximum radio communication device output power.

| Specific transmitter maximum output power W | Separation distance from transmitter frequency m | | |
|---|---|------------------------|-------------------------|
| | from 150 kHz to 80 MHz | from 80 MHz to 800 MHz | from 800 MHz to 2,5 GHz |
| | d = 1,17 √P | d = 1,17 √P | d = 2.34 √P |
| 0,01 | 0,12 | 0,12 | 0,24 |
| 0,1 | 0,37 | 0,37 | 0,74 |
| 1 | 1,17 | 1,17 | 2,34 |
| 10 | 3,70 | 3,70 | 7,40 |
| 100 | 11,70 | 11,70 | 23,40 |

For specified transmitters for a maximum output power not indicated above, the d recommended separation distance in metres (m) can be calculated using the equation applicable to the transmitter frequency where P is the maximum transmitter rated output power in Watt (W) according to the transmitter manufacturer

NOTE 1: At 80 MHz and 800 MHz, the separation distance is applied for the highest frequency interval.

NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is influenced by building, object and individual absorption and reflection.

7.4.4. DISPOSAL OF THE DEVICE AT THE END OF ITS SERVICE LIFE

European Directives 2002/96/EC and 2003/108/EC on Waste Electrical and Electronic Equipment (WEEE).

The symbol showing the crossed out bin (see Figure 3) affixed on the equipment or packaging means that the product must be disposed of separately from other waste at the end of its operating life. Consequently, at the end of the equipment's life, the user is required to take it to a suitable separate collection facility handling electronic and electrical waste or return it to the dealer on purchasing a new piece of equivalent equipment, on a one-for-one basis.

Suitable separate collection with a view to the subsequent recycling, treatment and environmentally friendly disposal of the discarded equipment helps avoid negative effects on the environment and on health and encourages the re-use and/or recycling of the equipment's component materials.

8. FORM TO REPORT ACCIDENTS TO PERSONS

Dir. 93/42/EEC Annex II (G.D. 2/1 Rev. 0)

CUSTOMER NAME:

ADDRESS

DAMAGE CAUSED TO THE PATIENT'S OR USER'S HEALTH _____

.....

Date _____

Signature_____

AREA RESERVED TO THE COMPANY (QUALITY ASSURANCE) POSSIBLE CAUSES OF THE ACCIDENT:

- 1. Equipment malfunctioning
- 2. Deterioration of equipment features and/or performance
- 3. Poor instructions for use

Other causes ____

SERIOUSNESS OF THE DAMAGE_____

OPERATIVE DECISIONS PROPOSED _____

Date _____ Signature_____

AREA RESERVED TO THE COMPANY (GENERAL MANAGEMENT)
OPERATIVE DECISIONS

CORRECTIVE ACTIONS

Date _____ Signature_____

In the event of an accident this form must be sent to O.M.S. S.p.A. with maximum urgency.