miglionico
DENTAL EQUIPMENT

User and maintenance manual

NICE ONE

CE 0425

REV 2 25/05/2018

DICHIARAZIONE DI CONFORMITA'
DECLARATION OF CONFORMITY

La Società MIGLIONICO S.R.L., con sede legale e operativa Via Molise, Lotti 67/68 Z.I - 70021 Acquaviva delle Fonti (BA), dichiara, sotto la propria totale responsabilità, che i **riuniti odontoiatrici** denominati:
We undersigned MIGLIONICO S.R.L., with head office addressed in Via Molise, Lotti 67/68 Z.I - 70021 Acquaviva delle Fonti (BA), declare under its own responsibility that the medical devices named:

Nome commerciale / *Commercial Name*	Numero di serie / *Serial Number*
"NICE ONE" **"NICE ONE P"** **"NICE ONE P CART"** **"NICE ONE W"** **"NICE ONE L"** **"NICE ONE L P"**	
"NICE TOUCH" **"NICE GLASS"** **"NICE TOUCH P"** **"NICE GLASS P"** **"NICE TOUCH P CART"** **"NICE GLASS P CART"** **"NICE TOUCH W"** **"NICE GLASS W"**	

classe di rischio IIa, in accordo alla regola 11 dell'Allegato IX, della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.L.vo 24/02/97, n. 46, e ss.mm.ii.) emendata dalla Direttiva 2007/47/CE (recepita in Italia con Decreto Legislativo 25 gennaio 2010, n. 37),
risk class IIa, according to rule 11 to the Directive 93/42/EEC and further amendments, Annex IX (enforced in Italy by Legislative Decree No. 46/1997 and further amendments), as amended by the Directive 2007/47/EC (enforced in Italy by Legislative Decree No. 37/10):

- sono conformi ai requisiti essenziali ed alle disposizioni della direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico archiviato presso l'Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as the Technical File retained by the Company;

- sono fabbricati in accordo al Sistema Qualità, che soddisfa i requisiti di cui all'Allegato II escluso punto 4 del sopra citato decreto legislativo, come da Certificato n. 0425-MED-003255-00, rilasciato in data 17/01/2018 dal ICIM SPA, Organismo Notificato n. 0425.
  are manufactured according to the Quality System which satisfies requirements of Annex II excluding point 4 of the above mentioned Decree, as per CE Certificates No. 0425-MED-003255-00, issued on 17/01/2018 by the Notified Body No. 0425, ICIM SPA

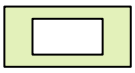
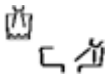
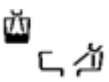
- sono conformi alla direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011, sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche.
  comply with Directive 2011/65 / EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Acquaviva delle Fonti (BA), gg/mm/aaaa

Il legale rappresentante/ *Legal Representative*

MIGLIONICO SRL
Via Molise Lotto 67-68 Z.I.
70021 ACQUAVIVA DELLE FONTI (BA)
C.F. & P.IVA 05306940726

2. SIMBOLOGIA

ALTERNATING CURRENT		PANORAMA FILM VIEWER LIGHTING	
EARTH PROTECTION		MICROMOTOR INVERSAL ROTATION	
B TYPE DEVICE		PERISTALTIC PUMP ACTIVATION	
ON/OFF		CHAIR CLIMB MEMORY POSITION “1”	
WARNING		CHAIR DESCENT MEMORY POSITION “2”	
NOMINAL VALUE OF VOLTAGE IN VOLTS	V	BACK CLIMB MEMORY POSITION “3”	
NET FREQUENCY IN HERTZ	Hz	BACK DESCENT MEMORY POSITION “4”	
MAXIMUM POWER IN VA ABSORBED BY THE UNIT	VA	AUTOMATIC RETURN	
TOOLS SWITCH WITH WATER SPRAY		EMERGENCY POSITION	
CHIP-BLOWER		RINSE POSITION	PR
FLASHING WATER SPRAY ON TOOL		MEMORY CALL	RM
COLD WATER TO GLASS AND SPITTON		ASSISTANT CALL/DOOR OPEN	
HOT WATER TO GLASS AND SPITTON		OPERATOR LAMP	
WATER TO SPITTOON		MEMORIZATION	
INDICATION		ON/OFF OPTICAL FIBER ON TOOLS	
MIXER	MDS	ANTI RETRACTION FLUID ON HANDPIECES	AF
DO NOT STAY – DO NOT PUSH			

3. INSTALLATION, TEST AND GUARANTEE CERTIFICATE

DICLARES THAT THE PRODUCT

DENTAL UNIT MOD.
❑ **"NICE ONE"**
SERIAL N°_____
INSTALLATION DATE_____

POLTRONA MOD.
❑ **"ACTIO"**
SERIAL N°_____
INSTALLATION DATE_____

Has been well installed following the standard certificate Miglionico's procedures

THE TECHNICIAN signature and stamp
_____

INSTALLATION DATE
_____

CUSTOMER DETAILS
Company _____
Address _____
City _____
Phone/fax _____
e-mail _____

DEALER signature and stamp
_____

Besides the customer declares :

To have received end user's manual of dental unit • YES • NO
To have received end user's manual of camera • YES • NO
To have received end user's manual of curing light • YES • NO
To have received end user's manual of scaler • YES • NO

I agree and authorize Miglionico srl to process my personal data in compliance with Law 675/96 and its subsequent amendments with Legislative Decree 196/2003.
For acceptance of declaration below.

THE CUSTOMER
Signature and stamp

MIGLIONICO SRL
CEO's signature and stamp

This Certificate must be completed in its each part , signed and returned to Miglionico srl within 30 days from the date of installation.
IN CASE OF THIS CERTIFICATE IS NOT RETURNED TO MIGLIONICO S.R.L., THE EXTENSION OF THE THREE YEARS WARRANTY WILL BE NOT GRANTED.

3.1 WARRANTY CONDITIONS

The Dental unit is equipped with the maintenance, statement of compliance CE, installation, test certificates, warranty certificate. Warranty is valid for 12 months after installation date. To prolong the warranty period, it must be completed by installation certificate within 30 days from installation date.
A certificate of "installation, test and warranty" must be completed in each page, stamp, signed and sent to the factory. In case of absence one of abovementioned documents, warranty is annulled, because of the impossibility for Miglionico to realize all the duties established by the law, the client will be responsible for this infraction.
All the handpieces (turbine, contrangles, scalers, curing light, operator lamp) are provided by user maintenance, sterilization maintenance and warranty certificate given directly by their manufacturer. In case of malfunction during the warranty period it is necessary to address request directly to the handpieces manufacturer.
Miglionico srl is not responsible for controversies between the client and the handpieces manufacturer.
Warranty does not cover transport/call expenses which are at the client's charge.
Warranty applies to all parts manufactured by MIGLIONICO with material or manufacturing defects, except the parts like:

- light bulb, filters
- suction tubes , aspiration cannula and aspiration nozzle(6 months warranty)
- syringe handpieces
- scaler handpiece
- upholstery cutting
- painting damaged by hits or cuts (within 10 days from installation).

In any case MIGLIONICO doesn't provided with any detail substituted or the doesn't supply any the equipment substituted during the repairing period.
Warranty is invalid in case of:

- Absence of the installation, test certificate, warranty certificate
- Interference of unauthorized personnel or without original spare parts
- Application of gadgets not provided from manufacturer
- Damages caused by natural disaster, equipment misuse, negligence, incorrect installations, tampering, modification of the product, or the serial number, or accidental damage because of negligence of the client or third parties. Warranty also does not apply in the case of failures due to the electric supply more than indicated or sudden changes in electric voltage supply of the device connected, as well as in the case of failures caused by infiltration of liquids, fire, static discharge inductive / or electrostatic discharges caused by lightning, power surges or other external occasions.

All important accompanying documentation related to handpieces, operator lamp, compressor, suction system etc. is considered as an integral part of this manual.

3.2 APPLICATION

The equipment is destined to be used for diagnosis, prevention, check, therapy or cure of human disease of the oral cavity and oropharynx.
The device is used for different dental procedures, retraction saliva, water, blood, liquids used for treatment the operated parts, scaling , cleaning , lighting coverage of the oral cavity.

3.3 STANDART ACCESSORIES AND OPTIONAL

There are no any standard accessories provided. The dental unit can be equipped with the accessories ordered by the client, specified in the paragraphs:

- OPERATOR TABLET ASSEMBLAGE
- ASSISTANT TABLET ASSEMBLAGE
- HYDRO UNIT ASSEMBLAGE

4. OPERATIONAL SETTING AND ADVICES

Operational settings ought to respect rules concerning the intended use:
minimum dimension of the rooms sq.m. 7,5; long side m 3
washable floor
advised illumination with fluorescent tubes 5500° k
the systems (electrical, water-sewer, compressed air and surgical suction) have to be realized according to the rules in force.

5. SUPPLY REQUIREMENTS AND INSTALLATION

OBJECT	SPECIFIC DESCRIPTIONS
Settings	• Relative humidity between 45% and 75% • Temperature between 15 °C and 35 °C • Air pressure between 860mbar÷ 1060mbar (645 mmHg to 795 mmHg)
Water supply 	Water have to be adequate to the national rules for the drinking water. For water supply they have to use drinking water, filtered and decalcified, for domestic use. The water ought to have the following features: • Hardness between 15 ÷ 20 F° (French degree) • Pressure between 150 ÷ 400 kPa (1.5 ÷ 4 bar) • Capability > 3l/min to 400 kPa (4 bar) In case of pressures higher than 400 kPa (4 bar) they have to insert an adequate pressure reducer before the unit installation. The supply tube have to be equipped with an arrest tap. Before installation they have to do an accurate cleanliness of the tubes in order to avoid the possible penetration of impurities into the unit water group, by purging it until the elimination of the impurities
Electrical system 	Adequate to the rules in force (rules for electrical systems in rooms used as medical purpose for doctor's office type "A") at installation data. The net single phase 230V ± 10% frequency 50/60Hz voltage.
Electrical supply 	As indicated in the device data tag. Allowed tolerance on ± 10% supply voltage Absorbed power full-load 1400 VA The dental unit is equipped with a proper supply terminal board for a permanent connection to the power network, which has to have a 10 A - 250 V bipolar switch with differential intervention current IΔN=0.03 A, made in accordance with the European rules concerning the device.
Suction system	Ejection air tube of the suction system should discharge air outside the housing rooms, for hygiene and environmental reasons. Nether or external tube ought to have a 350 l/min air capacity and a 20kPa (0.2 bar) low pressure value.

Pneumatic supply	The compressor has to be situated in an open room, hygienically and from heat sources protected to not pick up air discharge from the surgical aspirator Air pressure ought to be included between 500kPa and 700 kPa (5 ÷ 7 bar). Major or equal 60l/min a 500 kPa (5 bar) capacity. Compressor equipped with air dry system and antibacterial filter. Supply tube has to be have an arrest tap.
Discharge pipes	Pipes has to be realized with a PVC (or higher quality) tube. Pipes has to have a slope not less than 1.5 cm each meter and a siphon that allows the inspection every 4 metres if the distance to the upright column is higher than that.
Weights and encumbrance	Chair weight kg. 86 Chair and unit weight kg. 185 Total weight (chair, unit, lamp, aspirator) kg. 189.5

6. TECHNICAL DATA

6.1 DENTAL UNIT

The equipment is not proper to a usage in the presence of anesthetic inflammable mixture with oxygen air or nitrous oxide.

MODEL	NICE ONE
CLASSIFICATION (EN 60601-1)	Class I Type B
CLASSIFICATION (93/42 CEE)	Class II a
SUPPLY VOLTAGE	230 V
SINGLE PHASE ALTERNATIVE CURRENT	50/60 Hz
INTERMITTENT FUNCTIONING	(verify indications for use)
ADDITIONAL WEIGHT SUPPORTED BY THE TRAY	KG 1,5

6.2 CHAIR

The equipment is not proper to a usage in the presence of anesthetic inflammable mixture with oxygen air or nitrous oxide.

MODEL	ACTIO
CLASSIFICATION (EN 60601-1)	Class I Type B
CLASSIFICATION 93/42 CEE	Class I
VOLTAGE SUPPLY	230 V
SINGLE PHASE ALTERNATIVE CURRENT	50/60 Hz
INTERMITTENT FUNCTIONING	every working minute 18 minutes of rest
CHAIR MINIMUM HEIGHT	390 mm
CHAIR MAXIMUM HEIGHT	820 mm
CHAIR CLIMB MOTOR	ELECTRIC MOTOR24 Vdc MAX 10,5 AMP
BACK MOTOR	ELECTRIC MOTOR 24 Vdc MAX 5,2 AMP
MAXIMUM SUPPORTED WEIGHT	KG 180
PROTECTION LEVEL AGAINST WATER PENETRATION	IPX0 Device with wrapping not protected from water penetration

6.3 OPERATOR LAMP

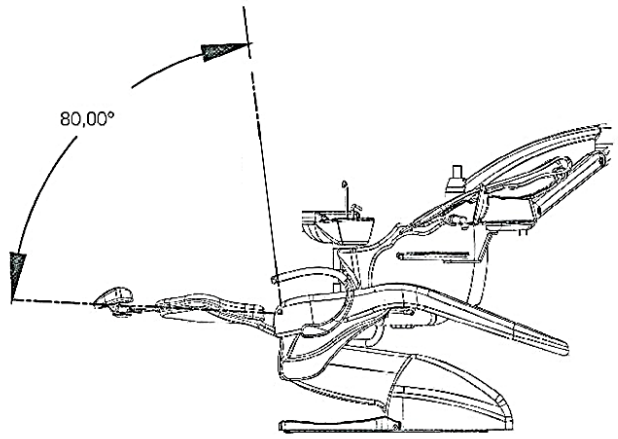
If MIGLIONICO doesn't provide, **it has to be corresponded to CEE Directive 93/42 and to CEI-EN 60601-1, equipped with CE Statement of compliance and user manual.**

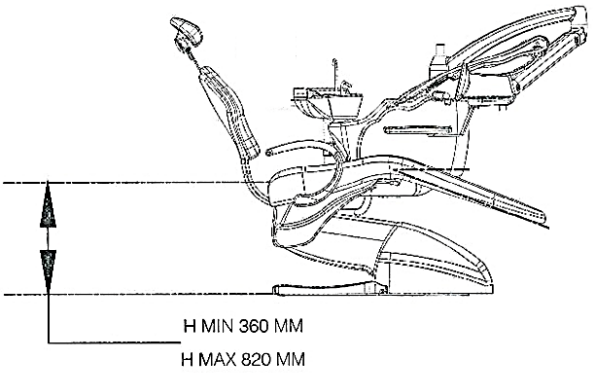
Connection specifications:

- Electric supply for halogen lamp 17V ac +/- 10% , max power 100W
- Electric supply for led lamp 24Vac +/- 10 % max power 30W
- Maximum weight 10 kg
- Pivot of attack diameter Ø 35 mm height 60 mm

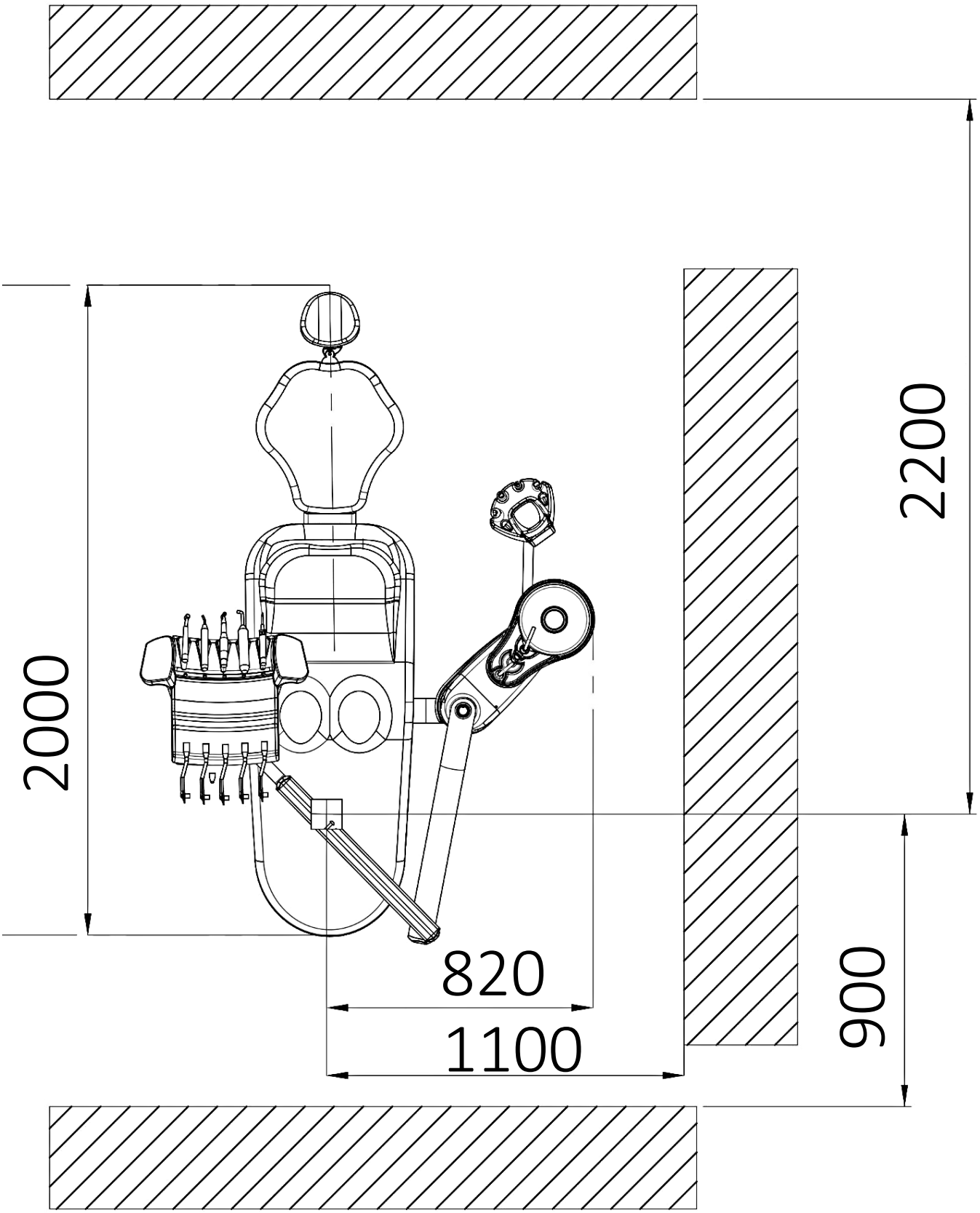
Lightening modalities, intensity control and power on /off are specified in the section "CONTROL KEYBOARDS"

7. CHAIR MOVEMENT





8. ENCUMBRANCE DIMENSION



9. ESSENTIAL ADVICES FOR USE

This equipment is corresponded to the quality standard CEI EN 60601-1 (general standards for electro - medical devices safety) and CEI EN 60601-1-2 the standards corresponded to the CE Directive93/42, this equipment is exclusively destined to the dentist use, potentially assisted by auxiliary personnel, prepared for the dental assistance.

It is necessary to study the user manual and to read carefully all the instructions concerning the instruments.

It is necessary to follow these instructions after the installation and before using the device:

- Sterilize operational instruments, which are not in steril packaging (ref. to the "operational tools" section)
- Sterilize at 135°C in the autoclave the removable parts in silicon (handles and carpet)
- Disinfect all the parts normally are not come into contact with the patient (ref. to the "cleaning and disinfection" section)
- Activate the water to the glass and to the handpieces with spray at least for 3 minutes, so the disinfection liquid starts to circulate.
- Remove all handpieces and dental cutter after every operation
- Protect eyes, respiratory tracts, mouth and skin by wearing glasses, special mask and disposable gloves to protect from fragments coming from the patient mouth. Moreover use the aspirator at high speed in order to suck the dust and the little particles released in the air during the handpieces use.

ATTENTION: remove handpieces (micromotor handpieces, turbine handpieces, scaler handpiece, optic terminal of the lamp, syringe covers, silicon handles and carpet under the instruments) from their lodging after every operation in order to realize their sterilization and avoid cross-contaminations.

10. IMPORTANT WARNINGS

Miglionico srl is not responsible for safety, reliability and performances if:

- the installation operations have not been done by qualified personnel authorized by the MIGLIONICO and equipped with license.
- the electric, water, pneumatic supply systems, the water discharge system, the possible suction system and the rooms where the device is installed are not corresponded to the laws.
- non-authorized modifications have been done (including the connection of other medical devices or accessories) and non-original spare parts have been used.
- the device is not used as is suggested in the user and maintenance instructions.
- the annual technical verification is not done according to the date set by technician

Before activate chair please be sure that there are no any other equipment or accessories encumbered chair movement.

ATTENTION: do not remove any carter before having switch off the dental unit.

ATTENTION: the front carter of the base can be removed ONLY by authorized technician because, even if the dental unit is switched off, there are some elements under voltage and there is an electric shock danger.

For the use, maintenance, sterilization and cleaning of the handpieces read the instructions in their packaging. Miglionico srl is not responsible for possible damages that personal caused by the inobservance and by the omission of the above-mentioned rules.

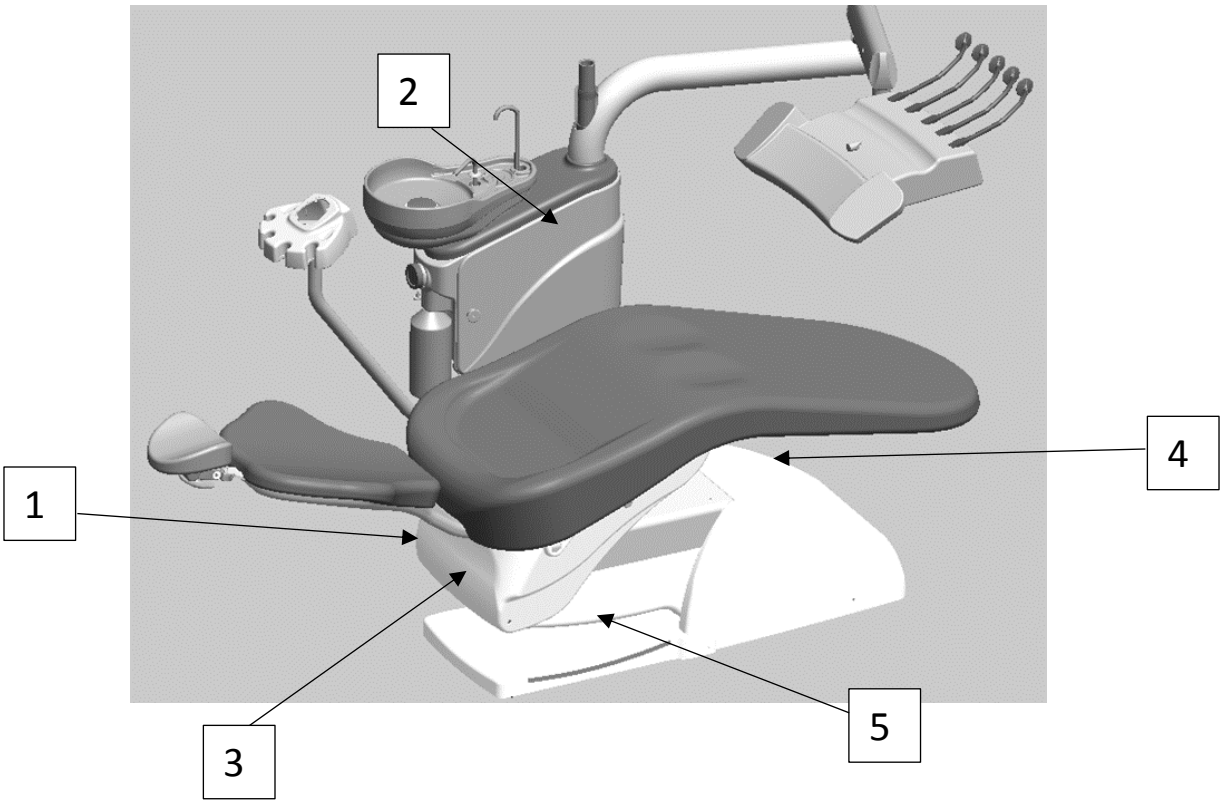
11. PACKAGE DISPOSAL

The materials used for the package are recyclable at 100% and they have to be delivered to an authorized garbage dump which will provide for the recycle or the disposal.

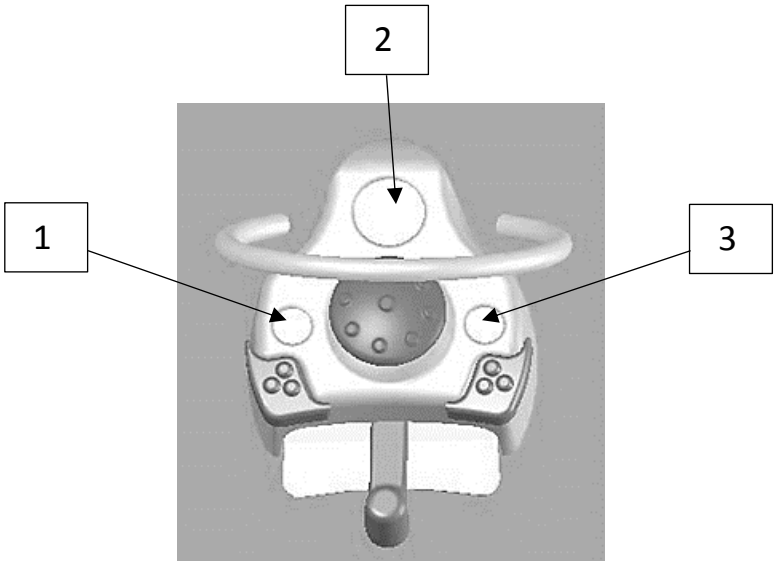
12. DENTAL UNIT DISPOSAL

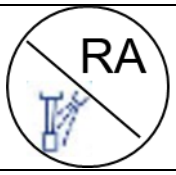
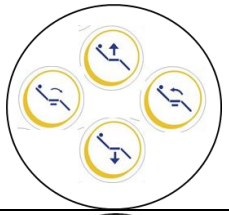
When the dental unit will be permanently off duty, before delivering it to a garbage dump authorized for the recycle of materials, it is necessary to remove the supply cables and the fuses and break the electric parts in a irreparable way.

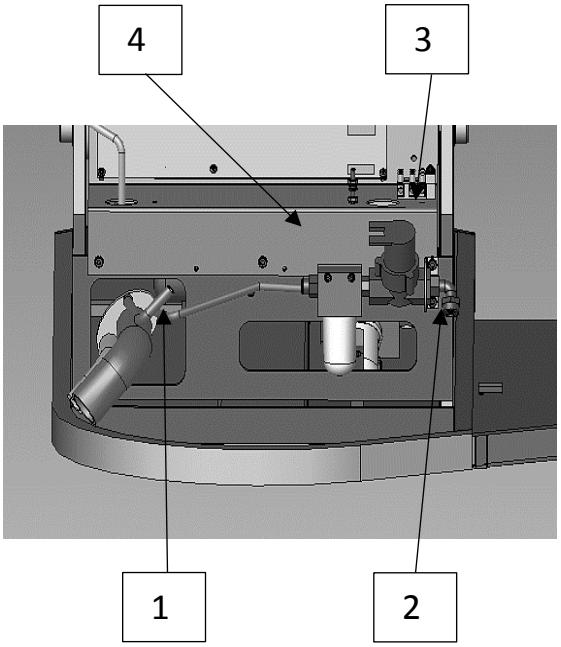
13. LABELS LOCALIZATION



1	
2	NICE ONE
3	*actio*
4	



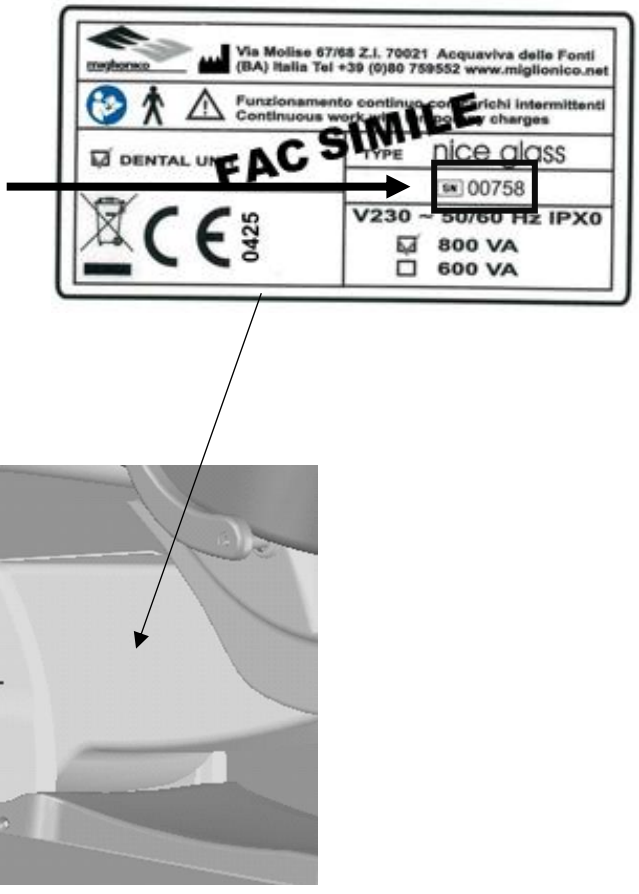
1	
2	
3	



1	ARIA AIR AIRE LUFT
2	H_2O
3	N L MAINS 230 V~50 Hz
4	ATTENZIONE: PARTI SOTTO TENSIONE ANCHE CON L'INTERRUTTORE DISINS PRIMA DI INTERVENIRE DISINSERIRE L'ALIMENTAZIONE ELETTRICA. WARNING: LIVE PARTS EVEN WITH LINE SWITCH OFF. BEFORE OPERAT ING DISCONNECT THE UNIT FROM THE ELECTICAL MAIN. ATTENTION: PARTIES SOUS TENSION MEME AVEC L'INTERRUPTEUR PRINC IPAL DEBRANCHE. AVANT TOUTES INTERVENTIONS DISJOINDRE L'UNIT DU RESEAU ELECTRIQUE. ACHTUNG: TEILE UNTER SPANNUNG AUCH BEI ABGESCHALTETEM NETZSCHALTER. VOR D EM OFFNEN DES GERETES MIT DEM AUSSERHALB DER EINHEIT INSTALUERTEN SHAELTER DIE EINHEIT SPANNUNGSLOS MACHEN UND SICHRN.

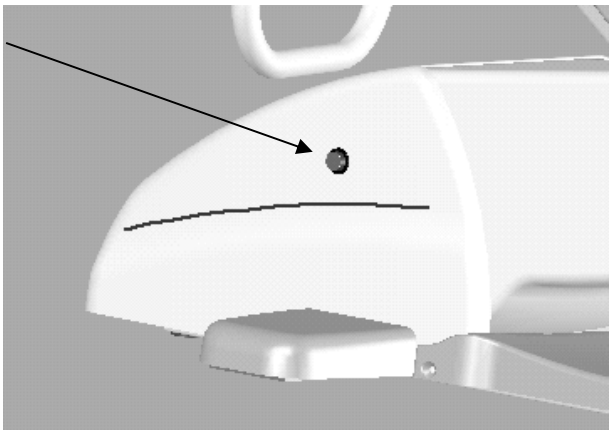
14. IDENTIFICATION TAG

The dental unit is retraceable by a matriculation number printed on the label. Communicate matriculation number in order to ask for information or spare parts.



15. START

The unit is equipped with a button situated in the lower part of the chair. Pushing deeply on the button it is starting to light and LED indicators on the operator tablet will switch on indicating the electricity supply activation. With a following push the unit will be disconnected from the net.



It is suggested to disconnect the master switch every time before the work stop or in any case, before every technical or maintenance operations that imply the intervention in the parts protected by carters.

ATTENTION: the front carter of the base can be removed only by authorized technican because, even if the dental unit is switch off, there are some elements under voltage and there is an electric shock danger.

16. INSTRUCTIONS FOR USE

Operational instruments need to be taken from their position (to activate the function) and after need to be activated by the pedal (see foot-control functions), except the air-water syringe which is not activated by the pedal but directly by the buttons on it.

The dental unit is equipped with a functioning instruments priority system. Only one instrument , taken first, is active, the other instruments are blocked.

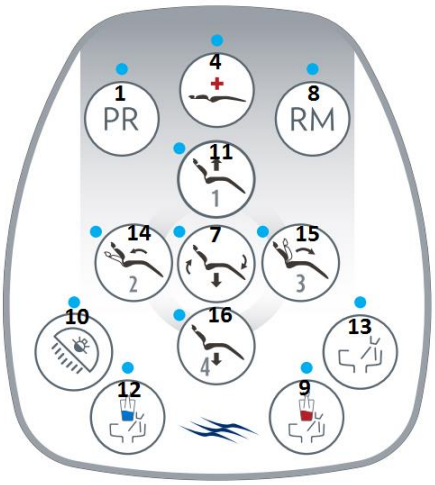
Anti-retraction system (AF) reduces to the minimum the concentration of liquids or elements coming from the operational zone to the spray holes. When the function "the water supply to the instrument " or" the water supply to the instrument ON / OFF"is activated, the system produces compressed air to the hole of the spray every time you leave pedal lever (18-20 buttons on the operator panel.)

ATTENTION: when any instrument is taken from its place, the chair control function is de-activated to avoid any movements of the chair during an operation on the patient.

17. CONTROL KEYBOARDS

OPERATOR KEYBOARD

ASSISTANT KEYBOARD



Description of the functions of the keys :

1. PR rinse position: Push PR button and the backrest starts to move to the comfortable position to rinse patient's mouth , a successive push PR button turns the backrest back into the last working position. If it is not necessary to return backrest into the last working position , for cancel this action , push one of the 4 buttons "11-14-15-16". To memorize comfortable position of the chair (for example , PR position): find the most comfortable position of the backrest and the chair , push the "3" button (to activate memorizing) and choose the button there you want these settings to be memorized (for , example, PR button("1")) and push this button within 3 seconds. So, the settings have been memorized on the "RP " button.
2. Call assistant /open the door
3. memorization of the 4 chair positions (the 4 different positions are indicated in the keys 11-14-15-16), emergency key "4" (trendelemburg position), reset key "7" (seat and back position that allowed the ascent and the descent of the patient).

   For memorize the positions just follow steps :

   - Choose comfortable position of the seat and the backrest
   - Push the key "3"(to activate memorizing)
   - Push in 3 seconds the key "11-14-15-16-7-4" where the position should be memorized

ATTENTION: do not memorize position when the seat and the backrest have reached up to the stop, memorize position in few millimetres before when the seat and backrest reach the maximum limit of movement.

4. Emergency position: the chair moves in Trendelemburg memorized position
5. on/off panorama film viewer
6. micromotor reverse button
7. reset key: the chair goes to the “zero”position
8. RM: recalls the 4 positions memorized. Push the “RM” button and in 3 seconds the key “11-14-15” or “16” in correspondence 1-2-3-4 chair memorized positions
9. hot water supply to the glass with following cuspidor irrigation in memorized period of time.
10. Operator lamp button
11. chair upward movement button and recall the position 1, if it has been memorized
12. “the cold water to the glass” button with following cuspidor irrigation in the memorized period of time
13. cuspidor irrigation button in settled memorized
14. backrest downward movement button and recall the position 2, if it has been memorized.
15. backrest upward movement button and recall the position 3, if it has been memorized
16. chair downward movement button and recall the position 4, if it has been memorized
17. Turbine , micromotor and scaler automatic spray button . To activate function , take instrument and move the lever of the pedal to the right (see foot control functions).
18. button to reduce the parameter value of instrument taken indicated on the display.
19. button to increase the parameter value of the instrument taken indicated on the display.
20. display: visualizing the power of the scaler, the turns of the micromotor, the values of “CONTROL MENU”

18. CONTROL MENU

To regulate the time of the water supply to the cuspidor and glass, the time of delay to switch off of the fiber optic: push contemporaneously the keys “+” and “-”; when you hear the buzzer , leave the buttons : the “cuspidor” led is on and the number appeared on the display indicates the activation time of cuspidor; to regulate use the buttons “+” and “-”. Pushing the key “2”, control the cold water supply to the glass: the time appeared indicates the time for water supply to the glass and can be regulated by the buttons “+” and “-”. Pushing the key “2” control hot water to the glass (same regulation as for the cold water). Press the "2" button to exit from the menu settinds .

19. HANDPIECES

INTERFACE FEATURES OF THE APPLICABLE HANDPIECES, BY DIFFERENT MANUFACTURERS										
	Motive water/ cooling		**Air spray**		**Water spray**		**Electric supply**		**Electric supply optic fiber**	
HANDPIECE TYPE	l/min	atm	l/min	atm	l/min	atm		Power a/W	Vdc	Amp
TURBINE	35/50	2,2/4	15	3	0,15	2,5	xxxxxxx	xxxxxxx	3,5	1
MICROMOTOR	36/50	2,2/5	15	3	0,15	2,5	0÷24Vdc	65	3,5	1
SCALER	xxxxx	xxxxx	xxxxx	xxxxx	0,15	2,5	24 Vac	100	3,5	1

ATTENTION: for the instructions of usage , maintenance and handpieces disinfection modality, please read the manual for every single handpiece. The applied handpieces ougth to be corrisponded to the CEE Directive 93/42 and to the quality standart CEI-EN 60601-1 and CEI EN 60601-1-2, must be equipped with CE statement of compliance, conditions and waranty certificate and user and maintenance manual.

20. INSTRUMENTS FUNCTIONS

20.1 TURBINE MODULE/HANDPIECE

Turbine speed is controlled by the pedal lever: when it is in the zero position the turbine is unactivated, moving it to the right till the end, you can control speed from a minimum to a maximum. This is an **optional function**, if there is no this function, turbine speed run up to maximum when pedal lever is moved from the zero position to the right (see foot – control functions)

For water supply:

- Push the button “20” on the operator keyboard to activate the air/water spray and move pedal lever from the zero position toward the right (see foot – control functions)
- Push the key “18” on the operator keyboard to activate air/water spray and move pedal lever from the zero position to the right and at the same time pushing down steel lamina of the pedal (see foot – control functions)

Water supply can be controlled by the steel controller under the operator tablet in correspondence to the instruments.

Push the key “4” operator keyboard to activate the fibres optic of the handpieces

Other pedal functions of the turbine control :

- when the instrument is taken and the pedal lever is to the left, function “air/water spray“ is active to wash the operational zone without turbine activation (see foot control functions)
- when the instrument is taken and the pedal lever is down, “air blow “function is to dry the operational zone without the activation of the turbine (see foot control functions).

During the installation check the pressure on maximum rotation of the turbine, as indicated in the manual contained in its packaging.

For other information about the maintenance and cleaning of the turbine read the instructions contained in their packaging.

20.2 MICROMOTOR MODULE/HANDPIECE

Take micromotor from its place and activate by the pedal lever:

The micromotor speed is regulated by the pedal lever: when it is in the zero position the micromotor is unactive, moving the lever to the right the micromotor starts to run with the minimum rotation and increases speed till the maximum (40.000 rpm), if on the display of the operator keyboard is indicated “99” and the lever is in the maximum right position (see foot- control functions).

By the keys “+” and “-“ on the display the value of the micromotor speed can be set from the “00”, that is the minimum speed , till “99” , that corresponded to 40.000 r/min, that is the maximum speed. The micromotor speed always starts from the minimum rpm - 400 rpm. The speed set on the display is always the maximum, when the pedal lever is in the maximum right position. The visualized value is always in percentage in respect to the value of the maximum rotations (40.000 rpm)
For water supply:

- when the key “20” operator keyboard is active, the air/water spray is active every time when the pedal lever moves from the zero position to the right (see foot-control functions)

Water supply can be regulated by the knob situated under the operator tablet in correspondence to the each instrument.

The key “4” operator keyboard is to activating the fibres optic.

If there is the peristaltic pump it is possible to use also different solutions instead from the unit water (see peristaltic pump)

Other pedal functions for the micromotor:

When the instrument is taken and the pedal lever is on the left, the” air/water spray” function to wash the operational zone is active without micromotor activation (see foot control functions)

When the instrument is taken and the pedal lever is down, “air blow” to dry the operational zone is active without the activation of micromotor (see foot control functions).

For other information about the maintenance and cleaning of the instruments read the instructions contained in their packaging.

20.3 SCALER MODULE/HANDPIECE

Take scaler from its place and activate by the pedal lever.

The power of the vibrations is controlled by the keys “+” and “-“placed from the right and from the left of the operator keyboard display, the regulation range is varied from “00” to “99”.

The activation starts when the pedal lever moves from the zero position to the right (see pedal functions).

The water supply is controlled by the key “17” from the operator keyboard or by the left button on the pedal.To regulate the water supply use The knob situated under the operator tablet in correspondence with the instrument.

Push the key “4” on the operator keyboard to activate the lighting of the fibres optic (when there is O. F.)

For other information about the maintenance and cleaning of the instruments read the instructions contained in their packaging.

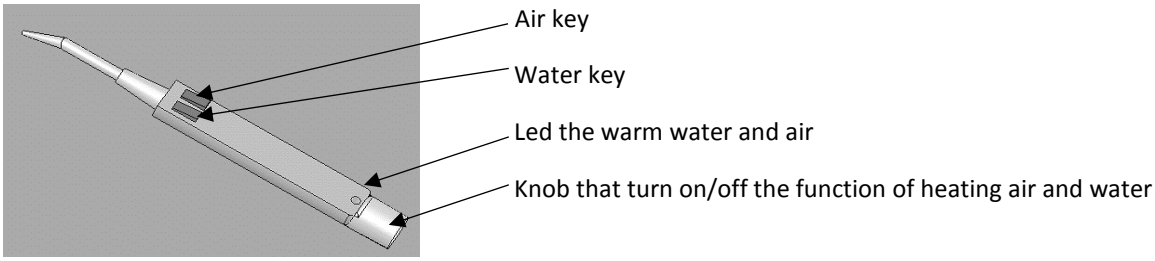
19.4 CURING LIGHT MODULE:

(Read the attached user manual)

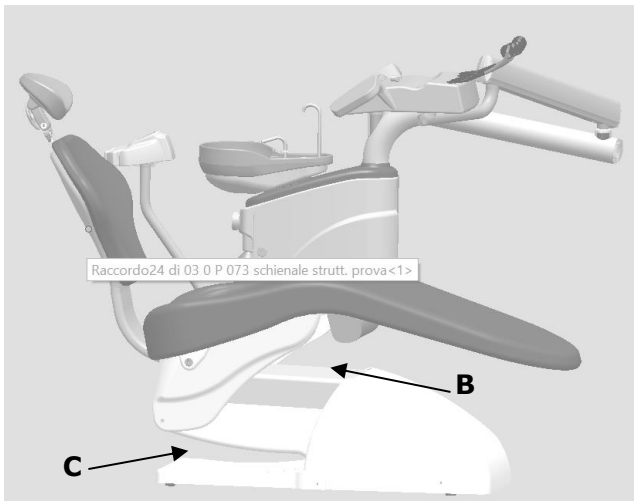
ATTENTION: Don’t direct the curing light to the eyes and use glasses or a protection screen. For other information about the maintenance and cleaning of the instruments read the instructions contained in their packaging. Miglionico srl is not responsible for possible damages caused by the in-observance and by the omission of the above-mentioned rules.
ATTENTION: it is necessary that an authorized technician controls the intensity of the brightness of the curing light to be sure that the polymerization is correct.

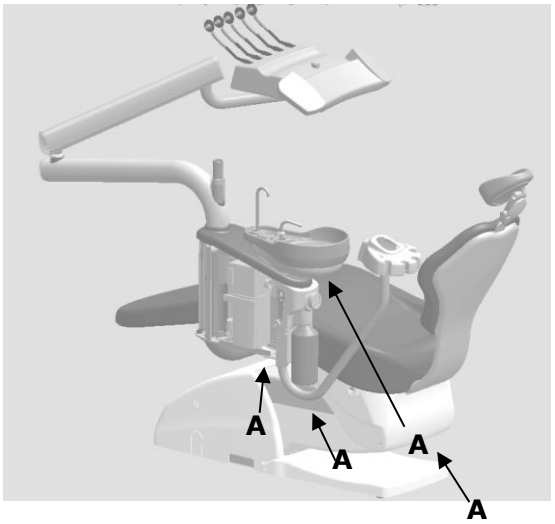
Sez. 19.5 SYRINGE MODULE:

The module consists of a base with a wire, with a metal handles and removable, autoclavable handpiece. It is possible to have a function of warm air and warm water supply as optional**.**



20. SAFETY SYSTEM





CHAIR SAFETY SYSTEM

Elements of safety system , indicated with letter "A“, must be activates when there is an obstacle between moving parts of the chair or furniture, after activation on if the elements of the safety system , chair is automatically moves up to release the object obstructing movement.

ATTENTION: do not put hands or any other thing during the movement in the zones indicated with the letter “B” in the image above.

INSTRUMENTS SAFETY SYSTEM

When any instrument is taken the movements of the chair are blocked. While using one instrument the other instruments are blocked, except the "air/water” syringe , which is always active.

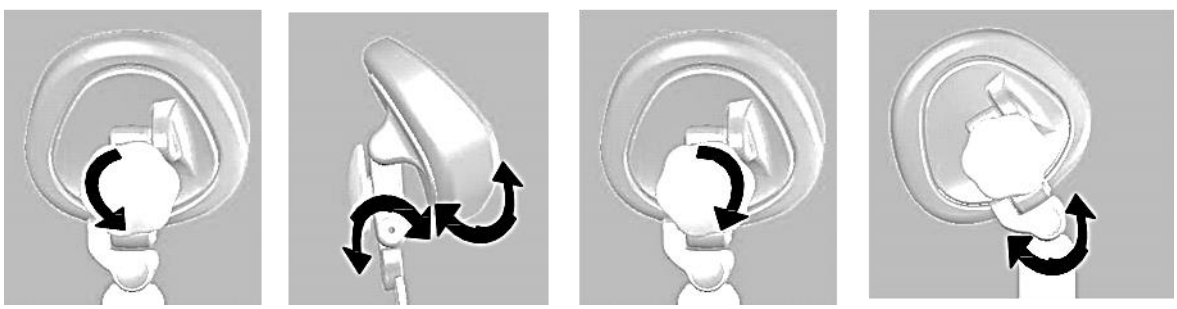
21. HEADREST

The headrest can be regulated. In order to obtain different positions turn the knob as indicated in fig. “A” in clockwise till the end of its movement, position the headrest as indicated in fig. “B”, close the knob fig. “C” and then check that the headrest is blocked.

Pull or push till the desired position to obtain the movement in the vertical direction.

ATTENTION: during the headrest positioning operations the head of the patient must be slightly raised.

fig.”A” fig.”B” fig.”C” fig.”D”

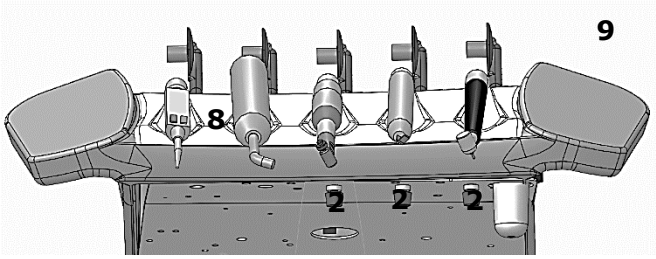


22. OPERATOR TABLET ASSEMBLAGE

1. Tray holder (capacity Kg 1,5)
2. Regulation of the water spray to the instruments (in correspondence)
3. Syringe with an adjustable spout (removable handle, autoclavable in the sterilizer at 135°) with heated and non-heated water and air
4. Ultrasound tartar scaler (with/ without fiber optic)
5. Micromotor (with/ without fiber optic)
6. Turbine (with/ without fiber optic)
7. Led curing light
8. Removable tools protection (autoclavable in the sterilizer at 135°
9. Control keyboard

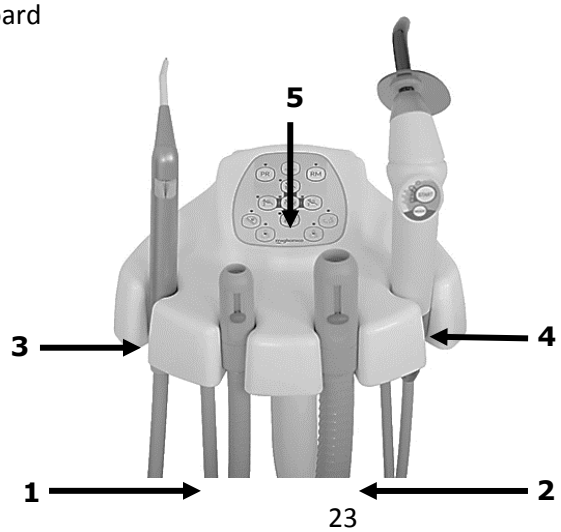
La disposizione degli strumenti può variare rispetto alle singole necessità.

ATTENTION: the chair movements are blocked when dynamic instruments are activated in order to avoid accidental movements of the chair while operating on the patient

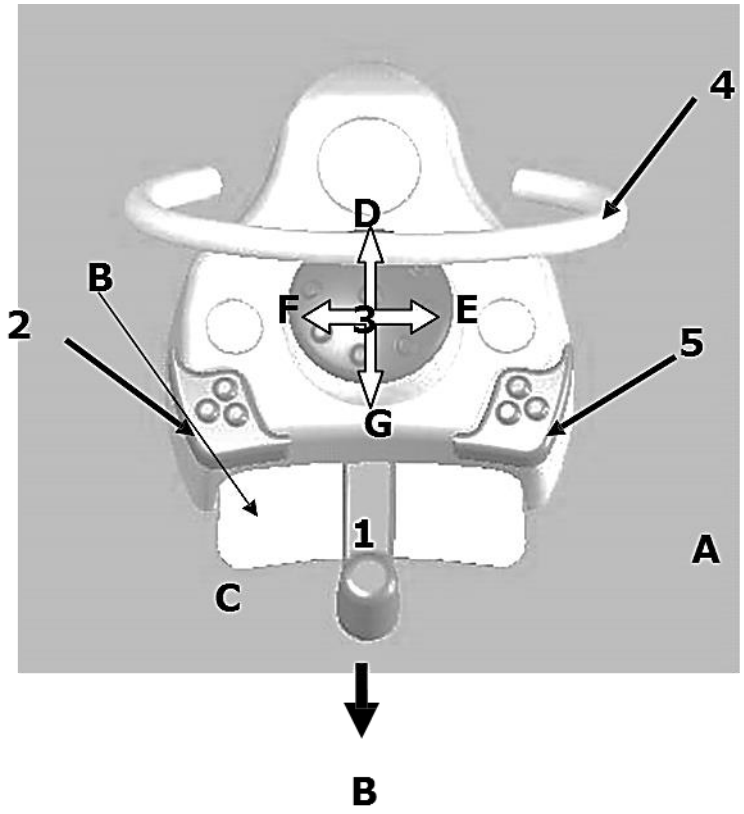


23. ASSISTANT TABLET

1. Saliva suction
2. Water suction
3. Non-heated air/water syringe
4. Curing light
5. Control keyboard

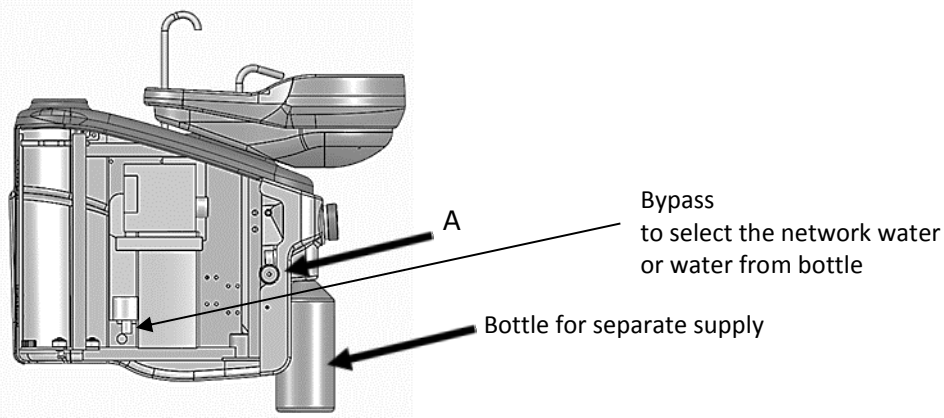


24. FOOT CONTROL



1. Command dynamic tools lever. To position "A" and for its entire stroke, there is the adjustment of the revolutions of the micromotor and turbine (if present the proportional solenoid valve) from a minimum to a maximum, with spray if the LED "17" of the operator keyboard is lighted. With instrument picked up if you press the lever "B", you will have a breath of air from the turbine and micromotor (cheep-air), if you bring the lever to the "C" you will have an air-water spray (CIP blower)
2. With the instrument taken, on and off the spray turbine, scaler and micromotor and status is displayed with the LED "17" on the operator keypad, when pressed with the rest instrumentation, activates the function of the chair "automatic return" key 7 " operator keypad.
3. 3 Joystick to control the movements of the chair, the position "D" drives up the chair in the position "G" makes off in the position "F" sends down the back and in position "E" makes him climb.
4. The joystick is disabled if the turbine, scaler and micromotor are removed from their housing with instrument work.
5. Pedal Handle
6. Button to activate the chair "PR" function as explained in the chapter "OPERATOR KEYBOARD"
7. In the pneumatic NICE ONE version, all functions of 2-3-5-C keys are disabled

25. SETTING HYDRIC GROUP



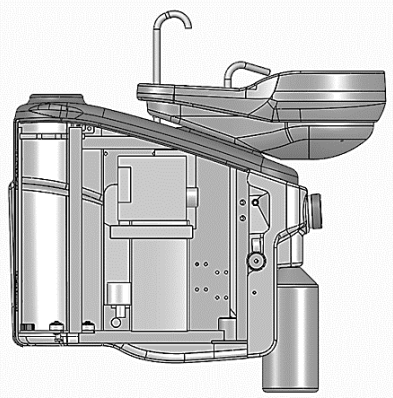
To access the inside of the Water Group you must turn off the main switch. To access the electronics area you must remove the right side panel and the left side panel, rotating counter clockwise the knob on the crankcase, first remove the outer casing of the unit body to the patient with the knob as shown at "A ".

CAUTION: Do not remove any cover without first turning off the main switch of the dental unit.

Bottle for separate supply to the handpieces, we recommend using a mixture of water and disinfectant recommended by MIGLIONICO. To fill, simply unscrew it and after filling it, screw it. The depressurization occurs during unscrewing, the pressurization takes place automatically after it is screwed

25.1 HYDRIC GROUP WITH MST 1 ECO “METASYS” SUCTION SYSTEM

Details for the maintenance are indicated in the Metasys manual attached to this.



When the liquid separation system or amalgam is external to the dental unit, the unit body is not provided for any device.

26. MAINTENANCE

26.1 CLEANING AND DISINFECTION

ATTENTION: during the maintenance, cleaning and disinfection operations protect eyes, respiratory tracts, mouth and skin by wearing special glasses, disposable masks and gloves.

To disinfect and the clean all the surfaces, MIGLIONICO has tested and selected GREEN&CLEAN SK ALCOHOL-FREE DISINFECTANT FOAM, it is advised to use only this product for disinfecting the surfaces of medical devices. The use of other product may invalidate warranty.Do not vaporize the product on the surfaces but on a soft cloth and then clean with it all the unit and the chair parts.

26.2 STERILIZATION

The parts that can be sterilized in the autoclave are:

1. The silicon carpet under the handpieces
2. The cuspidor

ATTENTION: for the handipieces desinfection and sterilization consult the instructions in their packages.

27. PERIODIC CHECKS BY OPERATOR

27.1 DAILY

- Cleaning the filter bowl,
- Cleaning of surgical suction filter,
- Clean all surfaces with Green & Clean SK of the company METASYS using the product as specified in section.
- CLEANING AND DISINFECTION
- Do aspire end of each day, before and after surgery liquids disinfectants for surgical aspiration. Prescribing the exclusive use of the product of the company Green & Clean M2 METASYS To be used as directed on the package

Da utilizzarsi come prescritto sulla confezione.

27.2 WEEKLY

Drain the air filter in the water group

With ” METASYS “ accessories

If the hydric unit is installed amalgam separator "Metasys dynamic compact" or "ECO MST1 Metasys", refer to the specific manual supplied together ATTENTION: the content of the "ECO MST1 Metasys" amalgam separator or compact dynamic Metasys system, ought to be arranged as specified in Their manuals.

27.3 ANNUAL VERIFICATIONS ARE OBLIGATORY TO DONE BY AN AUTHORIZED TECHNICIAN AFTER THE INSTALLATION

- ❑ "AS" system control
- ❑ Air and water filtering system control
- ❑ "MDS" disinfection system control
- ❑ The seal ring on the micromotor attachment change
- ❑ Safety system control of the chair
- ❑ Safety system control of the cupidor
- ❑ Safety system control of the assistant arm
- ❑ Functional control of the chair and the memory system
- ❑ The internal electric water and air connections control
- ❑ Arms balance control
- ❑ Headrest bar block system control
- ❑ Functional control of their instruments
- ❑ Instruments water and air pressure control
- ❑ Curing lamp functional control
- ❑ Amalgam separator control
- ❑ Surgical suction control
- ❑ Training for medical and auxiliary staff about maintenance and utilization of the dental unit

DATE	OPERATION DESCRIPTION	TECHNICIAN SIGN

28. SAFETY TEST REPORT

Result of the "TEST REPORT" of the dental unit "NICE ONE" , effected at our plant in Acquaviva delle Fonti (BA), concerning the "Safety test" realized according to the quality standart CEI EN 60601-1.

DATE_____

Responsible person

_____

29. COMPATIBILITY VALUES

The DM compatibility values according to 60601-1-2 are:

- ESD immunity 15kV air 8kV contact
- burst 2kV/100kHz
- magnetic field: 30A/m
- CISPR Emissions 11 class A o B
- Harmonic EN 61000-3-2 class A
- immunity to RF currents in the 150kHz-80MHz range 3V modulation 80% 1kHz
- immunity to surge 1kV differential mode and 2kV common mode
- immunity to RF field:

Field (V/m)	Frequency	Modulation
3	80MHz÷2700MHz	1kHz AM 80%
27	380MHz÷390MHz	18Hz PM 50%
28	430MHz÷470MHz	18Hz PM 50%
9	704MHz÷787MHz	217Hz PM 50%
28	800MHz÷960MHz	18Hz PM 50%
28	1700MHz÷1990MHz	217Hz PM 50%
28	2400MHz÷2570MHz	217Hz PM 50%
9	5100MHz÷5800MHz	217Hz PM 50%

30. RF AND ESD TEST REPORT

MANUFACTURER 'S USER GUIDE AND ADVICES ABOUT

ELECTROMAGNETIC FIELD

(EN ISO 60601-1-2 art.6)

RF Emissions Cispr 11	Group 1	Miglionico Dental Unit use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions Cispr 11	--	Miglionico Dental Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Classe B Conforms	It is possible to use the device in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Conforms	

Immunity aspects			
Miglionico Dental Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environement - guide**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Burst/Fast Transient EN 61000-4-4	±2kV power supply lines	±2kV power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5% U_T (>95% dip in U_T) fo 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) fo 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Magnetic power frequency fields should be that of a typical commercial or hospital environment..

<table>
<tr><th colspan="4">Immunity ascpects at r.f.</th></tr>
<tr><td colspan="4">Miglionico Dental Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the navigator should assure that it is used in such an electromagnetic environment.</td></tr>
<tr><td>Immunity test</td><td>Test level
EN 60601-1-2</td><td>Compliance
Level</td><td>Electromagnetic environement - guide</td></tr>
<tr><td>RF conducted
EN 61000-4-6</td><td>3 Veff from 150kHz to 80MHz</td><td>3 Veff from 150kHz to 80MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance
calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
d = 1,2 ·√P from 150kHz to 80MHz
d = 1,2 ·√P from 80 MHz to 800 MHz
d = 2,3 ·√P from 800 MHz to 2,5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m)</td></tr>
<tr><td>RF radiated
EN 61000-4-3</td><td>3 Veff from 80MHz to 2,5GHz</td><td>3 Veff from 80MHz to 2,5GHz</td></tr>
<tr><td colspan="4">Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the appliance

Miglionico Dental unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of the transmitter (m)**		
	From 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$	**From 80MHz to 800MHz $d = 1,2 \cdot \sqrt{P}$**	**From 800MHz to 2GHz $d = 2,3 \cdot \sqrt{P}$**
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:
(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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