



made in Italy

User and maintenance manual
“NICE GLASS P” model
and
“NICE GLASS P CART”

PNICEGLASS

PCNICEGLASS

INDEX

Nice GLASS USER MANUAL

Sec. 1 – STATEMENT OF COMPLIANCE	4
Sec. 2 – SYMBOLS	5
Sec. 3 – INSTALLATION, TEST AND WARRANTY CERTIFICATE	6
Sec. 3.1 – WARRANTY CONDITIONS	7
Sec. 4 – OPERATIONAL SETTING AND ADVICES	8
Sec. 5 – SUPPLY REQUIREMENTS AND INSTALLATION	8
Sec. 6 – TECHNICAL DATA	9
Sec. – 6.1 operator lamp	9
Sec. 7 – CHAIR MOVEMENT	10
Sec. 8 – ENCUMBRANCE DIMENSION	10
Sec. 9 – ESSENTIAL ADVICES FOR USE	11
Sec. 10 – IMPORTANT WARNINGS	11
Sec. 11 – PACKAGE DISPOSAL	12
Sec. 12 – DENTAL UNIT DISPOSAL	12
Sec. 13 – LABELS LOCALIZATION	12-13
Sec. 14 – IDENTIFICATION TAG	14
Sec. 15 – HANDPIECES	14
Sec. 16 – START	15
Sec. 17 – INSTRUCTIONS FOR USE	15
Sec. 18 – INSTRUMENTS FUNCTIONS	16
Sec. 18.1 – Turbine Module/Handpiece	16
Sec. 18.2 – Micromotor Module/Handpiece	16
Sec. 18.3 – Scaler Module/Handpiece	17
Sec. 18.4 – Curing light module /Module	17
Sec. 18.5 – Camera Module	18
Sec. 18.6 – Syringe Module	18
Sec. 19 – CONTROL KEYBOARDS	19
Sec. 20 – CONTROL MENU	20
Sec. 21 – SAFETY SYSTEM	21
Sec. 22 – HEADREST	21
Sec. 23 – OPERATOR TABLET ASSEMBLAGE	22
Sec. 23.1 – Disassembly of the operator tablet handle	22
Sec. 24 – PERISTALTIC PUMP	23
Sec. 25 – ASSISTANT TABLET ASSEMBLAGE	24
Sec. 25.1 – Disassembly of the assistant tablet handle	24
Sec. 26 – FOOT-CONTROL FUNCTIONS (PEDAL)	25-27
Sec. 27 – HYDRO UNIT ASSEMBLAGE	28

INDEX

Sec 27.1 – Hydro unit with “MST1” Metasys suction system	28
Sec. 27.2 - Hydro unit with Metasys suction system amalgam separator	28
Sec. 28 – SOLENOID VALVES , CUSPIDOR, PRESSURE REDUCERS	29
Sec. 29 – BOILER (WARM WATER TO THE GLASS)	29
Sec. 30 – “MDS” AUTOMATIC DESINFECTION SYSTEM	30
Sec. 30.1 INFORMATION ABOUT “GREEN & CLEAN WK” METASYS DISINFECTION LIQUID	31-33
<u>MAINTENANCE</u>	
Sec. 31 – MAINTENANCE	34
Sec. 31.1 – Cleaning and disinfection	34
Sec. 31.2 – Sterilization	34
Sec. 32 – OPERATOR’S VERIFICATIONS	35
Sec. 32.1 – Daily	35
Sec. 32.2 – Weekly	35
Sec. 32.3 – Annual verifications are obligatory to done by an authorized technician after the installation	36
Sec. 33 – HYDRAULIC AND PNEUMATIC SCHEME WITH “MDS” 111-02-00I	37
Sec. 34 – HYDRAULIC AND PNEUMATIC SCHEME WITH “MDS” 111-02-00I	38
Sec. 34.1 – With “MDS” to the operator tablet and to the glass	38
Sec. 35 – SAFETY TEST REPORT	39
Sec. 36 – EMS TEST RESULTS	40
Sec. 37 RADIOFREQUENCY AND ESD TEST REPORT	41-44



STATEMENT OF COMPLIANCE

The manufacturer: **MIGLIONICO S.r.l.**

Headoffice and plant: via Molise lotto 67/68 Z.I. 70021 Acquaviva delle Fonti (BA)

Tel/fax 0039 080759552

e-mail info@miglionico.net

Web: www.miglionico.net

DECLARES that:

Medical device named **"DENTAL UNIT", brandname MIGLIONICO**

Classification (EN 60601-1) : Class I Type B

Classification (93/42 CEE) : Class II a

made in the following models:

"NICE TOUCH", registered as **DM 299641/R**

"NICE GLASS", registered as **DM 299980/R**

"NICE TOUCH P", registered as **DM 611157/R**

"NICE GLASS P", registered as **DM 611120/R**

"NICE TOUCH P CART", registered as **DM 1062828/R**

"NICE GLASS P CART", registered as **DM 1062826/R**

"NICE TOUCH W", registered as **DM 1062898/R**

"NICE GLASS W", registered as **DM 1062897/R**

and

Medical Device named **"DENTAL CHAIR" mod. "SYNCRO"**

Classification (EN 60601-1) : Class I Type B

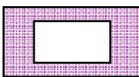
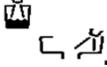
Classification (93/42 CEE) : Class I

are in compliance with applicable requirements of 93/42/EEC Directive, Annex II , modified by the European Directive 2007/47 EC, transposed in Italy by Dlgs. 46 of 1997/02/24 as MED n. 24036 Certificate issued by European Notified Body n° 0476.

Effective date 17/01/2014

Miglionico srl Director
Giuseppe Miglionico

Sec. 2 SYMBOLS

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	
CALBENIUM MIXER	MDS	ANTI RETRACTION FLUID ON HANDPIECES	AF

INSTALLATION, TEST AND GUARANTEE CERTIFICATE

MIGLIONICO S.r.l.
 sede legale e stabilimento
 via Molise, Lotti 67/68 Z.I. - 70021 Acquaviva delle Fonti (BA)
 Tel/fax 080759552 e-mail info@miglionico.net
 www.miglionico.net



DICLARES THAT THE PRODUCT

DENTAL UNIT mod. Serial n. Installation date / / 2014	CHAIR mod. "SYNCR0" Serial n. Installation date / / 2014
--	--

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.

Sec. 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 , stamped , 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.

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.

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

Sec. 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.

Sec. 5 SUPPLY REQUIREMENTS AND INSTALLATION

Object	SPECIFIC DESCRIPTIONS						
Setting	<ul style="list-style-type: none"> • Relative humidity between 45% and 75% • Temperature between 15 °C and 35 °C • Air pressure between 860mbar÷ 1060mbar (645 mmHg to 795 mmHg) 						
<p>Water supply</p> 	<p>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:</p> <ul style="list-style-type: none"> •Hardness between 15 ÷ 20 F° (French degree) •Pressure between 150 ÷ 400 kPa (1.5 ÷ 4 bar) •Capability > 3l/min to 400 kPa (4 bar) <p>In case of pressures higher than 400 kPa (4 bar) they have to insert an adequate pressure reducer before the unit installation.</p> <p>The supply tube have to be equipped with an arrest tap.</p> <p>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</p>						
 <p>Electrical system</p>	<p>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.</p> <p>The net single phase 230V ± 10% frequency 50/60Hz voltage.</p>						
 <p>Electrical supply</p>	<p>As indicated in the device data tag.</p> <p>Allowed tolerance on ± 10% supply voltage</p> <p>Absorbed power full-load 1400 VA</p> <p>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.</p>						
Suction system	<p>Ejection air tube of the suction system should discharge air outside the housing rooms, for hygiene and environmental reasons.</p> <p>Nether or external tube ought to have a 350 l/min air capacity and a 20kPa (0.2 bar) low pressure value.</p>						
Pneumatic supply	<p>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</p> <p>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.</p>						
Discharge pipes	<p>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.</p>						
Weights and encumbrance	<table> <tr> <td>Chair weight</td> <td>kg. 86</td> </tr> <tr> <td>Chair and unit weight</td> <td>kg. 185</td> </tr> <tr> <td>Total weight (chair, unit, lamp, aspirator)</td> <td>kg. 189.5</td> </tr> </table>	Chair weight	kg. 86	Chair and unit weight	kg. 185	Total weight (chair, unit, lamp, aspirator)	kg. 189.5
Chair weight	kg. 86						
Chair and unit weight	kg. 185						
Total weight (chair, unit, lamp, aspirator)	kg. 189.5						

Sec. 6 TECHNICAL DATA

DENTAL UNIT

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

MODEL	NICE GLASS	
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	KG1,5	

CHAIR

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

MODEL	SYNCRO	
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 MOTOR 24 Vdc MAX 10,5 AMP	BACK MOTOR
ELECTRIC MOTOR	24 Vdc MAX 5,2 AMP	

PROTECTION LEVEL AGAINST WATER PENETRATION	IPX0 Device with wrapping not protected from water penetration
--	---

OPERATOR LAMP

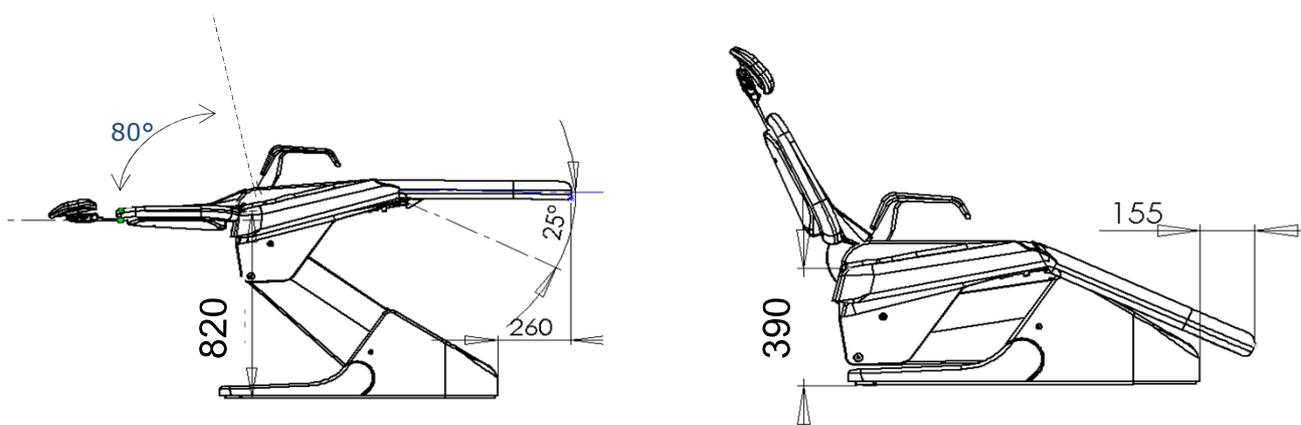
If MIGLIONICO doesn't provide, **it has to be corresponded to CEE Directive 93/42 and to CEI-EN 60601-1 , equipped with CE Statement of compliance and user manual.**

Connection specifications:

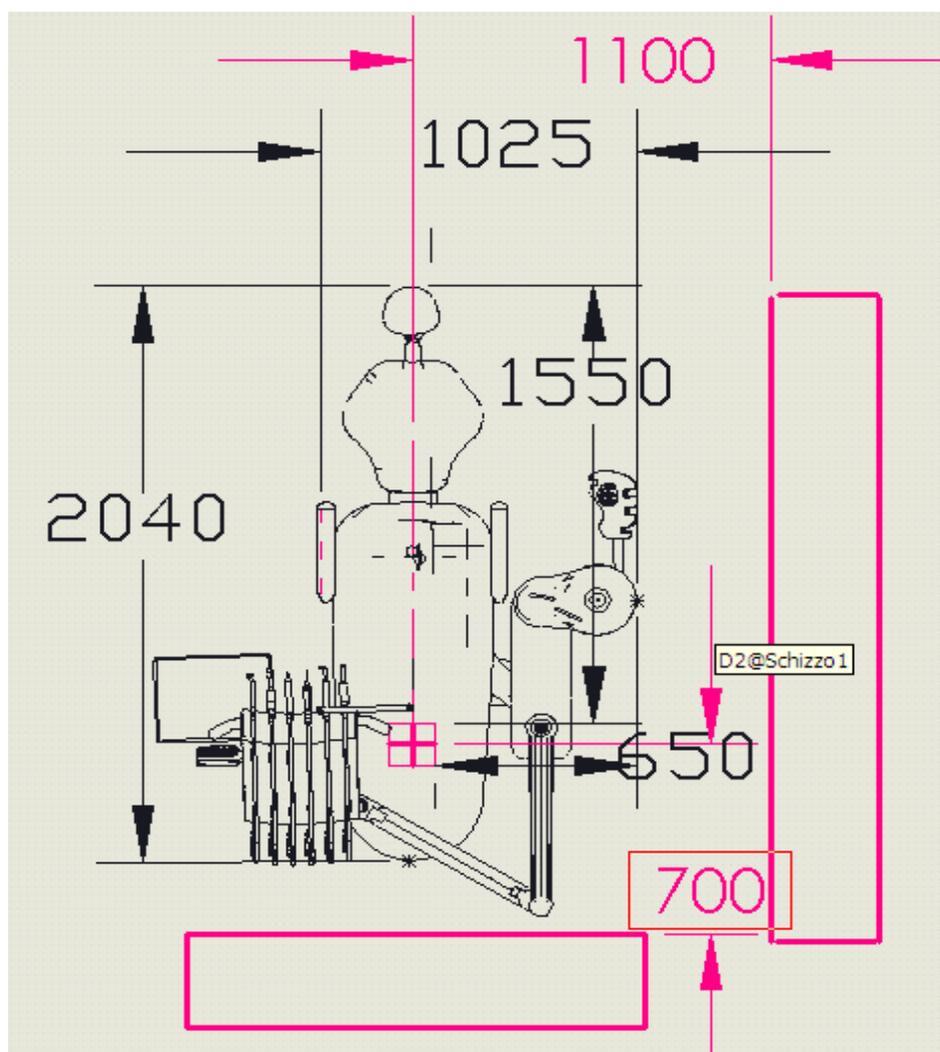
- Electric supply for halogen lamp 17V ac +/- 10% , max power 100W
- Electric supply for led lamp 24Vac +/- 10 % max power 30W
- Maximum weight 10 kg
- Pivot of attack diameter Ø 35 mm height 90/100 mm

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

Sec. 7 CHAIR MOVEMENT



Sec. 8 ENCUMBRANCE DIMENSION



Sec. 9 ESSENTIAL ADVICES FOR USE



This equipment is corresponded to the quality standart CEI EN 60601-1 (general standarts for electro - medical devices safety) and CEI EN 60601-1-2 the standarts 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 poliled 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.

Sec. 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 technican 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 personnel caused by the inobservance and by the omission of the above-mentioned rules.

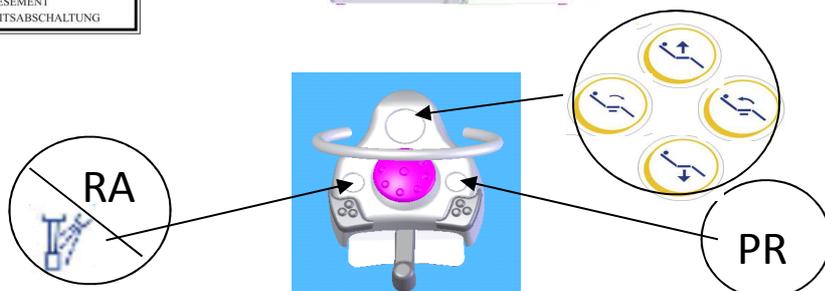
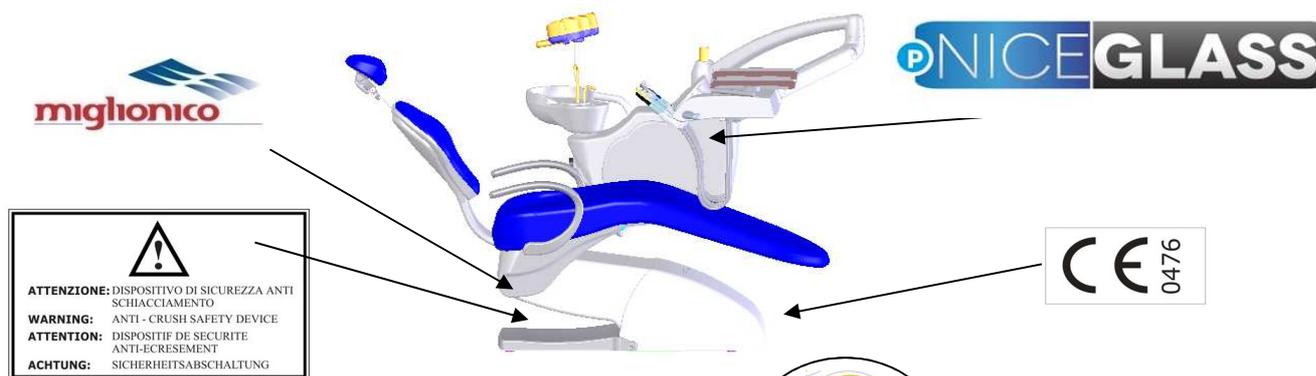
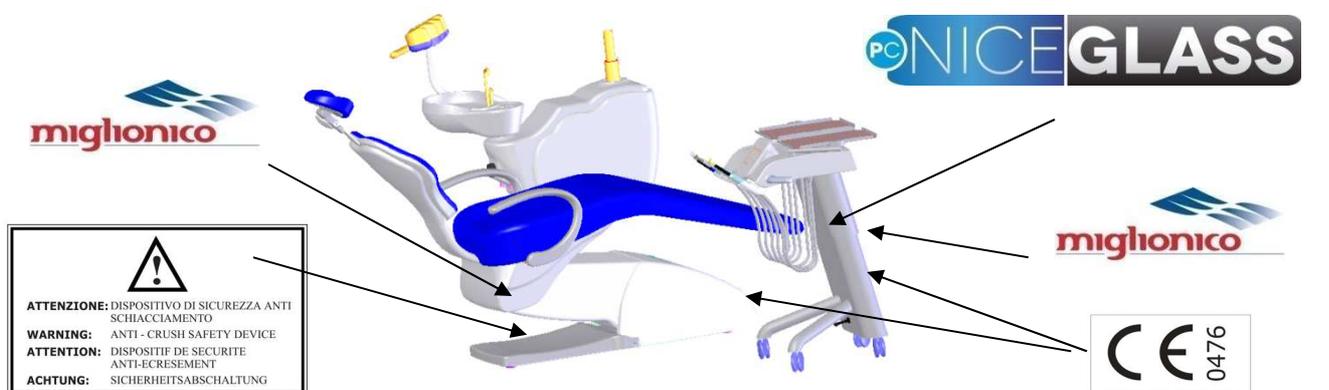
Sez. 11 PACKAGE DISPOSAL

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.

Sec. 12 DENTAL UNIT DISPOSAL

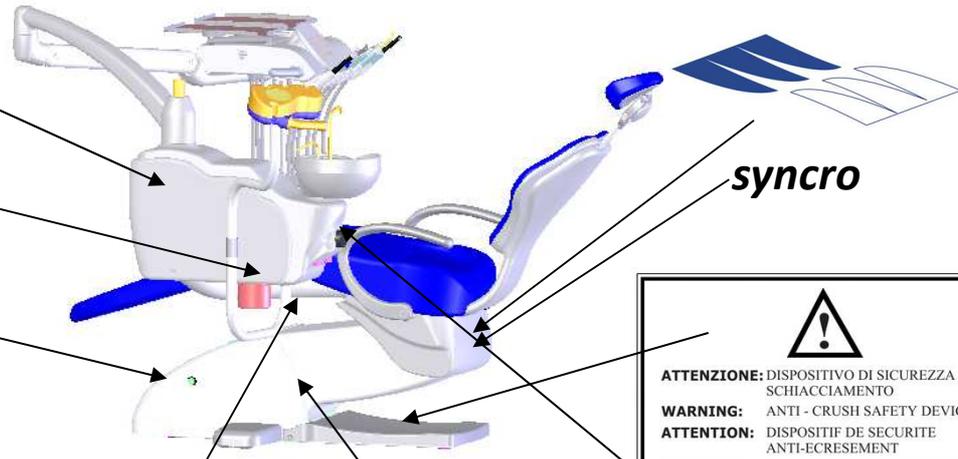
When the dental unit will be permanently off duty, before delivering it to a garbage dump authorized for the recycle of materials, it is necessary to remove the supply cables and the fuses and break the electric parts in a irreparable way.

Sec. 13 LABELS LOCALIZATION



NICE GLASS P e NICE GLASS PC
user manual

CE 0476



syncro

ATTENZIONE: DISPOSITIVO DI SICUREZZA ANTI SCHIACCIAMENTO
WARNING: ANTI - CRUSH SAFETY DEVICE
ATTENTION: DISPOSITIF DE SECURITE ANTI-ECRESEMENT
ACHTUNG: SICHERHEITSABSCHALTUNG

ATTENZIONE: NON STAZIONARE NELLA ZONA SOTTOSTANTE IL RIUNITO DURANTE L'USO DELLA POLTRONA.
WARNING: DO NOT STAY IN THE AREA UNDER THE UNIT DURING THE USE OF THE CHAIR.
ATTENTION: NE PAS STATIONNER DANS LE ZONE AU DESSOUS L'UNIT PENDANT L'USAGE DU FAUTEUIL.
ACHTUNG: NICHT IM UNTEREN BEREICH DERANLAGE AUFHALTEN WÄHREND DAS GERÄT IN BETRIEB IST.

Via Molise 5768 Z.I. 79021 Acquaviva delle Fonti (BA) Italia Tel +39 (0)80 798592 www.miglionico.net	
Funzionamento continuo con carichi intermittenti Continuous work with temporary charges	
<input type="checkbox"/> DENTAL CHAIR	TYPE
<input type="checkbox"/> DENTAL UNIT	SERIAL N° 0671
CE 0476	V230 ~ 50/60 Hz IPX0
	<input type="checkbox"/> 800 VA
	<input type="checkbox"/> 600 VA

IMPORTANT

IT Per la decontaminazione e la disinfezione dei prodotti MIGLIONICO si consiglia l'utilizzo esclusivo di METASYS - GREEN & CLEAR RD N, non rispondendo ai fini della garanzia, degli effetti di altri prodotti presenti in commercio.

DE MIGLIONICO empfiehlt zum Reinigen und Desinfizieren ausschließlich METASYS - GREEN & CLEAR RD N zu verwenden, da für andere im Handel erhältliche Produkte nicht garantiert werden kann.

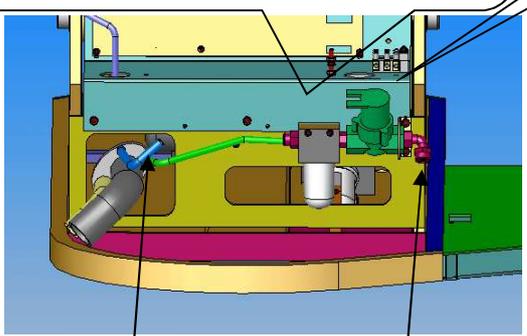
EN For cleaning and disinfecting dental units, MIGLIONICO recommends only METASYS - GREEN & CLEAR RD N. For any problem caused by the use of different products, MIGLIONICO will not be responsible also during the guarantee period.

FR Pour le nettoyage et la désinfection des unités MIGLIONICO recommande exclusivement METASYS - GREEN & CLEAR RD N. MIGLIONICO ne sera pas responsable des effets causés par l'emploi d'autres produits, même pendant la période de garantie.

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 OPERATING DISCONNECT THE UNIT FROM THE ELECTRICAL MAIN.
ATTENTION: PARTIES SOUS TENSION MEME AVEC L'INTERRUPTEUR PRINCIPAL DEBRANCHER. AVANT TOUTES INTERVENTIONS DISJOINDRE L'UNIT DU RESEAU ELECTRIQUE.
ACHTUNG: TEILE UNTER SPANNUNG AUCH BEI ABGESCHALTETEM NETZSCHALTER. VOR DEM OFFNEN DES GERÄTES MIT DEM AUSSERHALB DER EINHEIT INSTALLIERTEN SCHALTER DIE EINHEIT SPANNUNGSLOS MACHEN UND SICHERN.

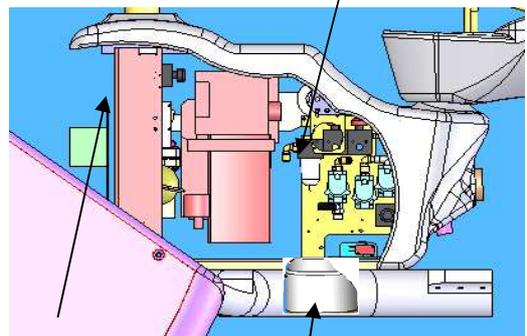
N L
 MAINS 230 V~50 Hz

H₂O + calbenium ↔ H₂O



ARIA
 AIR
 AIRE
 LUFT

H₂O



Via Molise 5768 Z.I. 79021 Acquaviva delle Fonti (BA) Italia Tel +39 (0)80 798592	
Funzionamento continuo con carichi intermittenti Continuous work with temporary charges	
<input type="checkbox"/> DENTAL CHAIR	TYPE
<input type="checkbox"/> DENTAL UNIT	SERIAL N°
CE 0476	V230 ~ 50/60 Hz IPX0
	<input type="checkbox"/> 800 VA
	<input type="checkbox"/> 600 VA

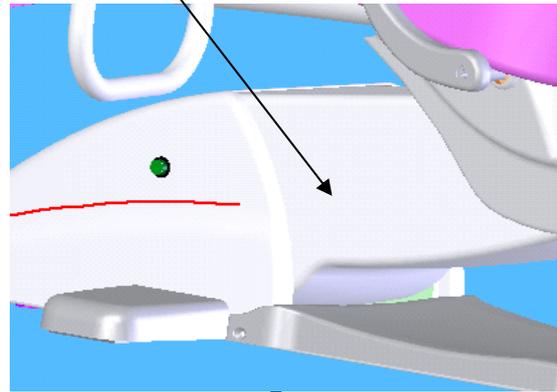
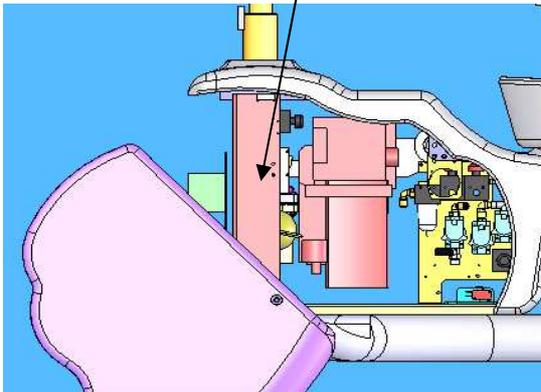
CALBENIUM

WK

Sec. 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.

 Via Sammichele Z.I. 70021 Acquaviva delle Fonti (BA) Italia Tel +39 (0) 80 759552	
  Funzionamento continuo con carichi intermittenti Continuous work with temporary charges	
<input type="checkbox"/> DENTAL CHAIR <input type="checkbox"/> DENTAL UNIT	TYPE SERIAL N° V230~50/60 Hz IPX0 <input type="checkbox"/> 800 VA <input type="checkbox"/> 600 VA
	



Sec. 15 HANDPIECES

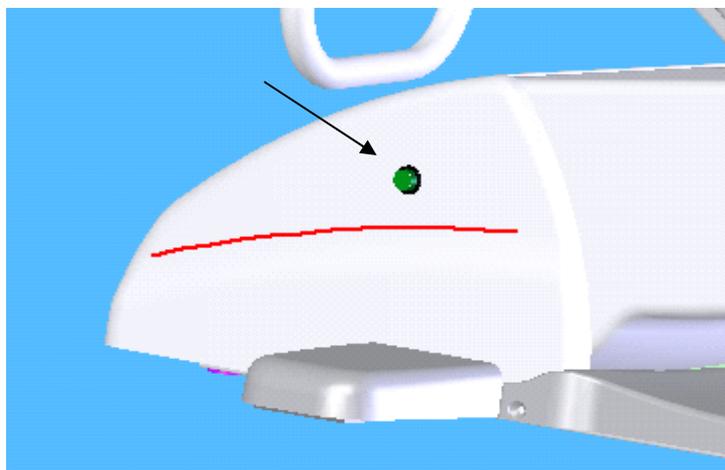
INTERFACE FEATURES OF THE APPLICABLE HANDPIECES, BY DIFFERENT MANUFACTURERS										
HANDPIECE TYPE	Motive water/cooling		Air spray		Water spray		Electric supply		Electric supply optic fiber	
	l/mi n	atm	l/mi n	atm	l/m in	at m		Power a/W	Vdc	Amp
TURBINE	35/5 0	2,2/4	15	3	0,1 5	2,5	xxxxxxx	xxxxxxx	3,5	1
MICROMOTOR	36/5 0	2,2/5	15	3	0,1 5	2,5	0±24Vdc	65	3,5	1
SCALER	xxxx x	xxxxx	xxxx x	xxxx x	0,1 5	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 ought to be corresponded 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 warranty certificate and user and maintenance manual.

Sec. 16 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 technician because, even if the dental unit is switch off, there are some elements under voltage and there is an electric shock danger.

Sec. 17 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.

Sec. 18 INSTRUMENTS FUNCTIONS

Sec. 18.1 TURBINE MODULE/HANDPIECE:

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

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.

Sec. 18.2 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)
- when the key "18" operator keyboard is active, the air/water spray is active every time the pedal lever moves 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 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.

Sec. 18.3 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":

from "00" to "30" use endodontic tips (SATELEC)

from "31" to "55" use periodontal tips (SATELEC)

from "56" to "99" use for prophylaxis and conservative treatment (EMS , SATELEC , MIGLIONICO)

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

If there is the peristaltic pump, use different liquids as an alternative to the dental unit water (see peristaltic pump)

The water supply is controlled by the keys "18" and "20" from the operator keyboard or by the left button on the pedal. When the peristaltic pump is activated (key "1" operator keyboard) water supply is deactivated automatically . The liquid that arrives to the scaler is going from the sack or from the bottle with the sterile liquid situated on the peristaltic pump (see peristaltic pump section). 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.

Sec. 18.4 CURING LIGHT MODULE:

Take curing light from its position to start working . The following keys mean:



Start / stop polymerization cycle



Selection of the programs of polymerization



Prog. "1" pulsating polymerization for 10 sec.



Prog. "2" polymerization with increasing intensity, 5 sec. to reach the maximum power for 10 sec.



Prog. "3" polymerization at the maximum power, 10 sec. at the maximum power

NICE GLASS P e NICE GLASS PC

user manual



ATTENTION: if there is curing light mounted on the operator tablet without the brand "MIGLIONICO" 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.

Sec. 18.5 INTRA CAMERA MODULE:

1. TO FIX THE IMAGE from camera , push the the STEEL PEDAL down.

2. TO SAVE IMAGE IN MEMORY :move LEVER of the pedal to the left. The foto is saved in the folder and camera returns in "live". The number of saved images during the day You can see in the small window above the screen of the monitor.

3. VISUALIZATION IN FULL SCREEN the images done, move LEVER to the left again and keep until You can see full screen image. In the upper side of the screen you can see 2 windows with numbers. In the right window there are the numbers of the all images done including previous days ;in the left window there are the fotos in the memory.

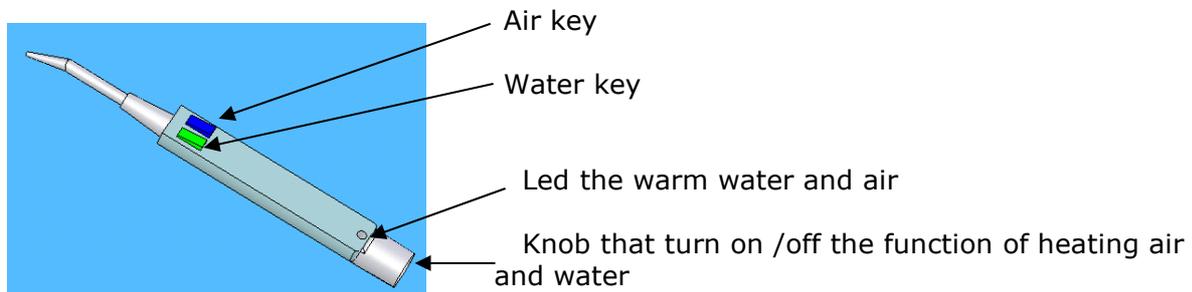
4. VISUALIZATION IN 4 IMAGES: in the "live" mode move the pedal to the left until you see full screen image , keep the pedal for a few sec.until you see the screen divided into 4 fotos.

5. TO DELETE ALL FOTOS: keep the lever of the pedal in the left until you see a message on the screen "delete all fotos ?" . Choosing "yes" push shortly the pedal down , choosing "no"move the pedal to the left

ATTENTION: the camera handpiece is not autoclavable and it is not possible to use disinfectants. It is obligatory to use disposable covers.

Sec. 18.6 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.



Sec. 19 CONTROL KEYBOARDS

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 "13-16-17-19". **To memorize comfortable position of the chair (for example , PR position):** find the most comfortable position of the backrest and the chair , push the "5" 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. on/off the peristaltic pump
3. Call assistant /open the door
4. on/off fiber optic of the instruments
5. memorization of the 4 chair positions (the 4 different positions are indicated in the keys 13-16-17-19), emergency key "6" (trendelemburg position), reset key "9" (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 "5"(to activate memorizing)
 - Push in 3 seconds the key "13-16-17-19-6-9" 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.

6. Emergency position : the chair moves in Trendelemburg memorized position
7. on/off panorama film viewer
8. micromotor reverse button
9. reset key: the chair goes to the "zero"position
10. RM: recalls the 4 positions memorized. Push the "RM" button and in 3 seconds the key "13-16-17" or "19" in correspondence 1-2-3-4 chair memorized positions
11. hot water supply to the glass with following cuspidor irrigation in memorized period of time.
12. Operator lamp button; push and hold it till the the operator lamp switch on;with th lamp switched on , push and hold until the lamp switch off. With the lamp switched off, pushing and holding for a long time leds the lamp to its maximum intensity. After 3 seconds push it will start the regulation of the intensity, releasing the key the reached intensity is memorized. After following switching off and switching on the lamp, the light intensity is at their maximum.
13. chair upward movement button and recall the position 1, if it has been memorized
14. "the cold water to the glass" button with following cuspidor irrigation in the memorized period of time
15. cuspidor irrigation button in settled period of time.
16. backrest downward movement button and recall the position 2, if it has been memorized

17. backrest upward movement button and recall the position 3, if it has been memorized
18. Turbine, micromotor and scaler spray button , controlled from the pedal . For activate this function , take the instrument and move the lever of the pedal to the right and push down at the same time (see foot control functions)
19. chair downward movement button and recall the position 4, if it has been memorized.
20. Turbine , micromotor and scaler automatic spray button . To activate function , take instrument and move the pedal lever to the right (see foot control functions).
21. button to reduce the parameter value of instrument taken indicated on the display.
22. button to increase the parameter value of the instrument taken indicated on the display.
23. display: visualizing the power of the scaler, the turns of the micromotor, the values of "CONTROL MENU"

Sec. 20 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, peristaltic pumps speed : **TAKE THE TURBINE FROM ITS PLACE** , 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 "3", 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 "3" control hot water to the glass (same regulation as for the cold water). Pushing the key "3" control the fiber optic: the led of the buttons "4" indicates that the fiber optic is on and the value indicated on the display shows the time of switching off of the fiber optic after you have finished work with the foot-control and it can be regulated with the buttons "+" and "-".

Push the "3" button to regulate the speed of the peristaltic pump, the LED of the "2" button is on , the displayed value indicates the speed of the peristaltic pump, it can be changed pressing the "+" and "-" buttons. Press the "3" button to exit from the menu settings .

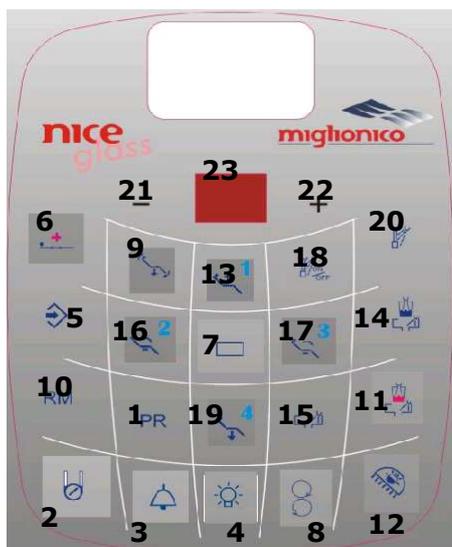
To memorize all the parameters done you need to turn off and turn on the unit - the values are memorised , and finally you can **TURN THE TURBINE ON ITS POSITION.**

ATTENTION: if you want to stop the chair during its automatic movement push one of the 4 buttons (13-16-17-19) or the activate the safety system , pushing the basement of the chair.(see sec. "safety")

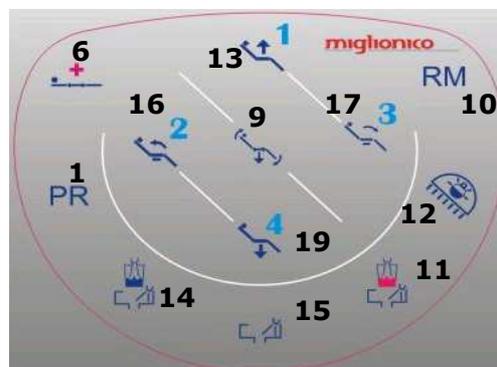
ATTENTION: When the peristaltic pump button(«2») is active ,there is no water supply to the instruments

Assistent keyboard block : read sec. «disinfection» to disinfect the assistent keyboard .

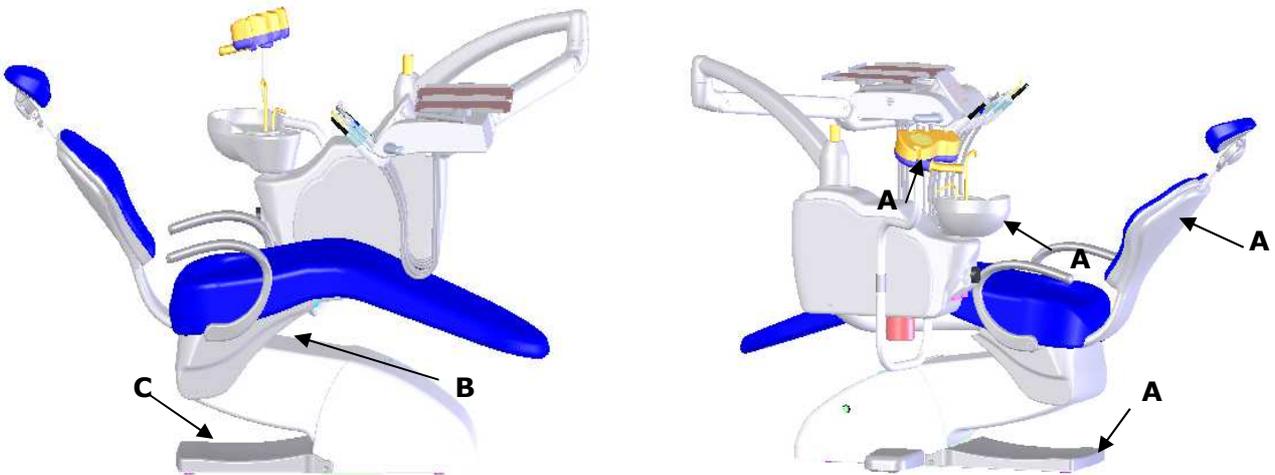
OPERATOR KEYBOARD GLASS



ASSISTANT KEYBOARD



Sec. 21 SAFETY SYSTEM



CHAIR SAFETY SYSTEM

Elements of safety system, indicated with letter "A", must be activated 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.

Pushing element indicated with the letter "C" activate the basement safety system.

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.

Sec. 22 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"

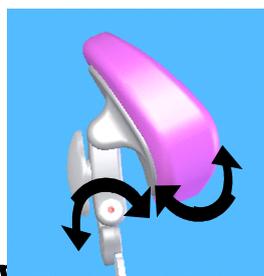
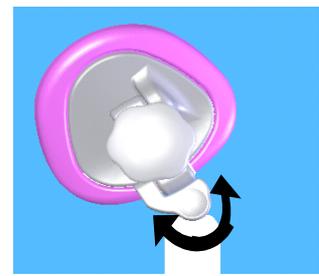


fig."C"



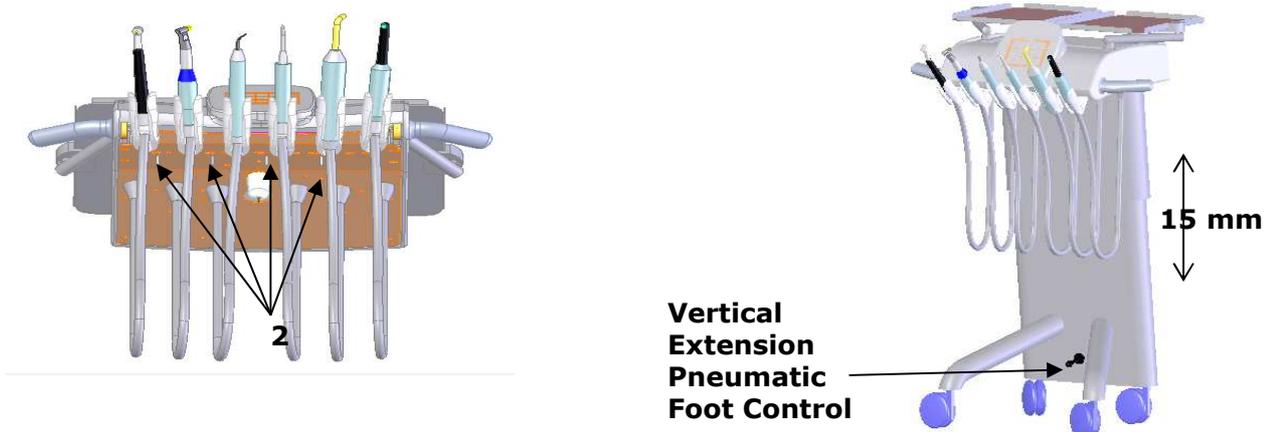
fig."D"



Sec. 23 OPERATOR TABLET ASSEMBLAGE

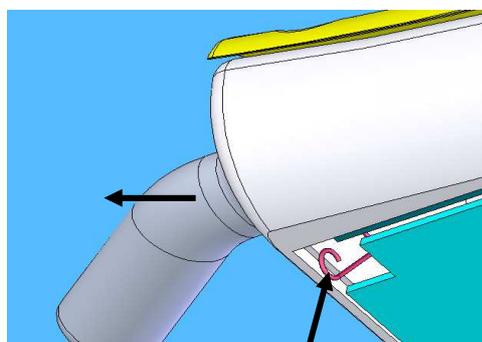
1. Tray holder (capacity Kg 1,5)
2. Regulation of the water spray to the instruments (in correspondence)
3. Syringe with an adjustable spout (removable handle, autoclavable in the sterilizer at 135°) with heated and non-heated water and air
4. Ultrasound tartar scaler (with/ without fiber optic)
5. Micromotor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

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



Sec. 23.1 Disassembly of the operator tablet handle

To extract the handle push the hook in the indicated direction and at the same time pull the handle. To assembly insert the handle in its place, move it lightly until the pivot is in its place and push it right to the end, then check the handle firmness doing little traction movements.



Sec. 24 PERISTALTIC PUMP

This device is useful to make cold or irrigate the operating zone with the desired liquid or other type of solutions.

To prepare the system:

Put the capsule, equipped with the silicon sterile tubes, on its settlement (fig. "A" "B"); connect the tube with the needle to the bottle containing the liquid and the other tube connect to the handpiece; connect tube to the cable of the module using the special connecting device

The peristaltic pump activates pushing the key "2" on the operator keyboard if:

- The instrument (micromotor or scaler)has been activated
- The instrument should be adapted to perform the function at the time of purchase, or debugged by a qualified technician;
- One of the two buttons ("spray to the instruments") is activated
- The pedal lever moves to the right (activation the peristaltic pump together with the instrument taken), or to the left (activation only the peristaltic pump with the successive liquid supply to the instruments).

ATTENTION: when the key "2" peristaltic pump is activated the water to the others instruments is de-activated

fig."A"

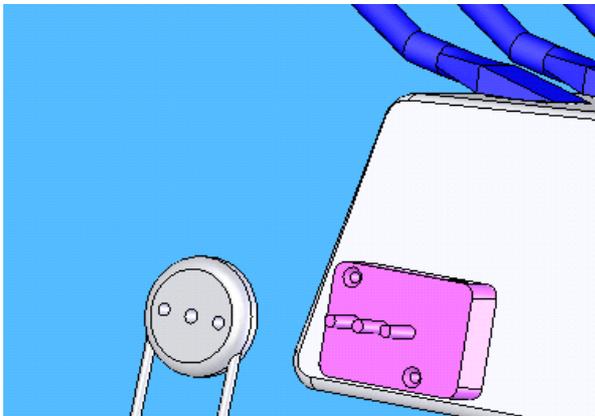
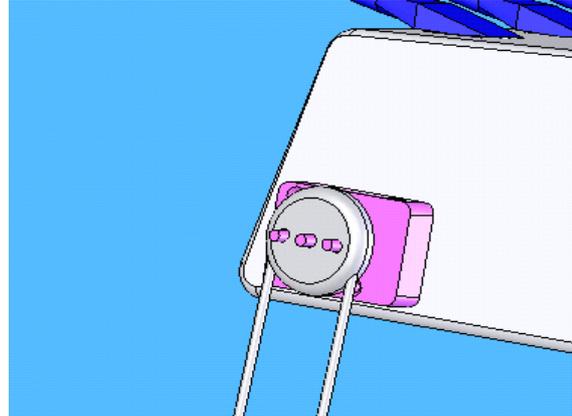


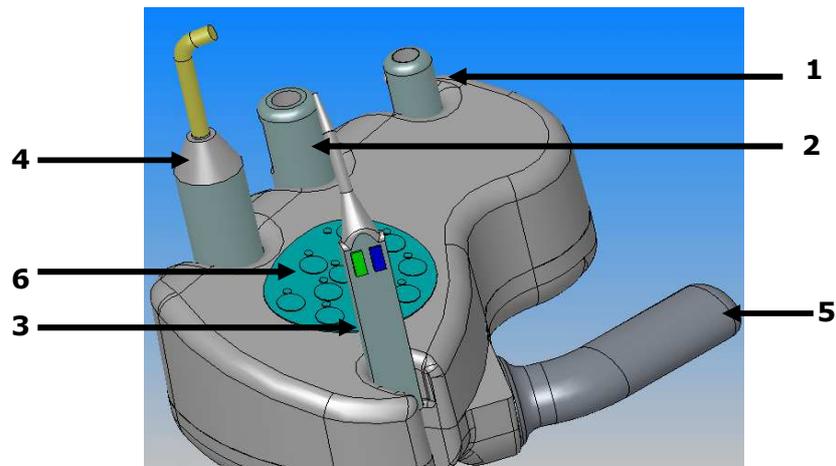
fig."B"



On the operator tablet is installed the "SATELEC" peristaltic pump. The pump, equipped with the silicon tube and accessories, will be furnished apart from the dental unit, inside sterile , separate packaging.

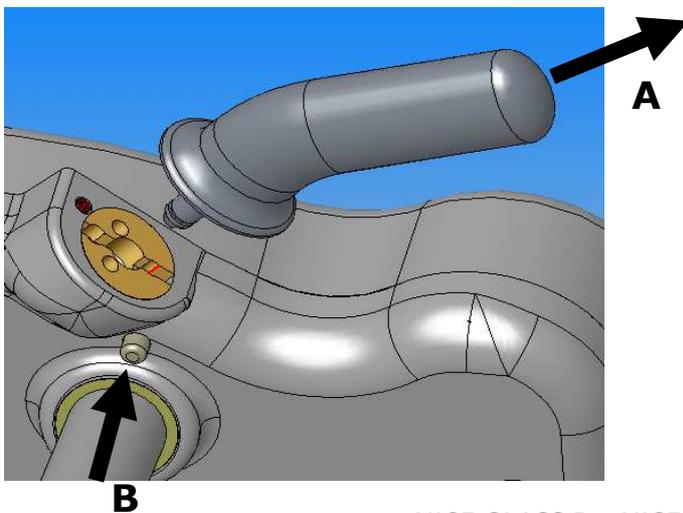
Sec. 25 ASSISTANT TABLET ASSEMBLAGE

1. Saliva suction
2. Water suction
3. Non-heated air/water syringe
4. Curing light
5. Removable handle, autoclavable at 135°
6. Control keyboard



Sec. 25.1 Disassembly of the assistant tablet handle

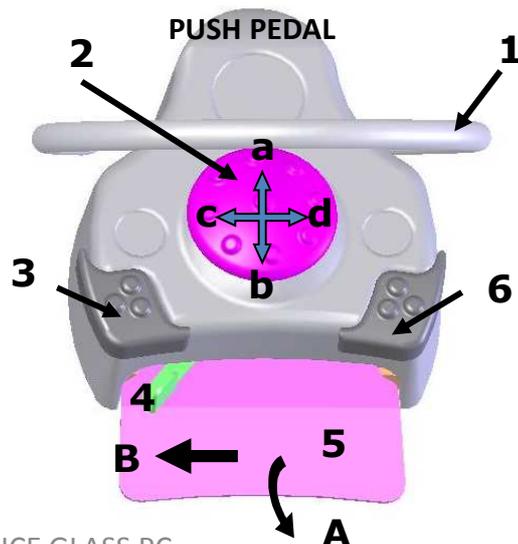
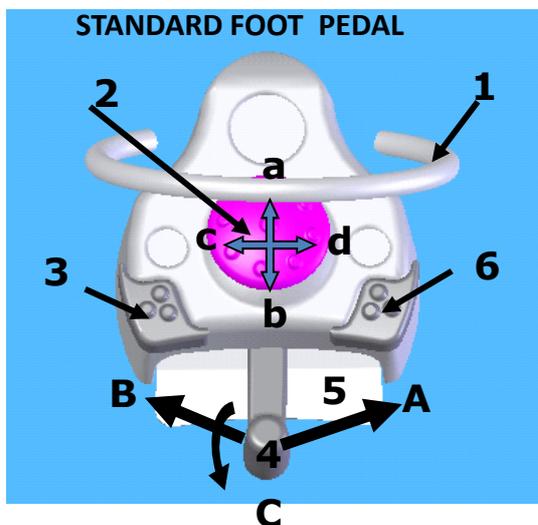
To extract the handle push the button "B" in the indicated direction and at the same time pull the handle in the direction indicated by the arrow "A". To assembly the handle insert the handle it into the slot, move it lightly until the holding axle is in its place, press the lever until it stops, and then make sure the strength of its binding, slightly pulling for it.



Sec. 26 FOOT – CONTROLS FUNCTIONS (PEDALS)

In the present table there are descriptions the main features of the both foot –controls, there the numbers are the parts of the pedals, the letters are the movement directions.

DESCRIPTION	STANDARD FOOT PEDAL	PUSH PEDAL
1. PEDAL HANDLE (1)	YES	YES
2. JOYSTICK (2) to control the chair movements: a – seat up, b- seat down, c – backrest down, d-backrest up	YES	YES
3 RESET BUTTON (3) . Use in 2 modes: <ul style="list-style-type: none"> • With the instrument taken it choose the programm for water supply a) it activates /deactivates constant «water supply to the instruments» (LED«20»button) b) it activates function «on/off water supply» (LED«18»button) – regulated water supply <ul style="list-style-type: none"> • With the instruments in the rest mode it activates RESET OR LAST POSITION of the chair (LED «9»button). 	<ul style="list-style-type: none"> • With the instrument taken : a) YES,for activate function «constant water supply to the instrument» push the RESET BUTTON (3) , for deactivate this function , push the RESET BUTTON (3) again. b) YES, after activation function «on/off water supply» doctors control water supply , pushing the STEEL PEDAL (5) every time when they need water to the instruments . <ul style="list-style-type: none"> • With the instruments in the rest mode – YES 	<ul style="list-style-type: none"> • With the instruments taken: a) YES, push the RESET BUTTON (3) for activate water supply, push again for deactivate . b) YES, doctors control water supply, moving SMALL STEEL LEVER(4) of the pedal in B – direction. <ul style="list-style-type: none"> • With the instruments in the rest mode – YES

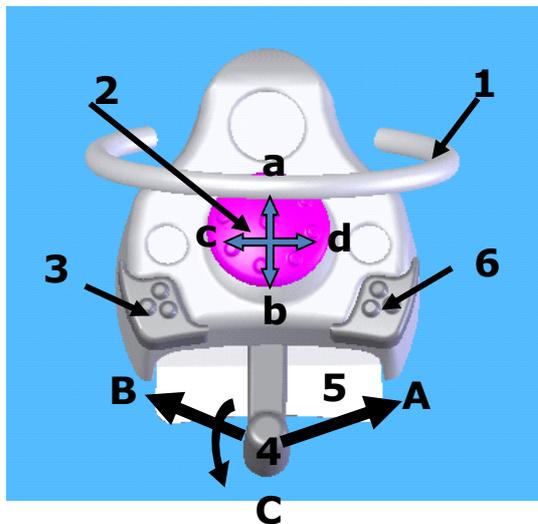


Sec. 26 FOOT – CONTROLS FUNCTIONS (PEDAL)

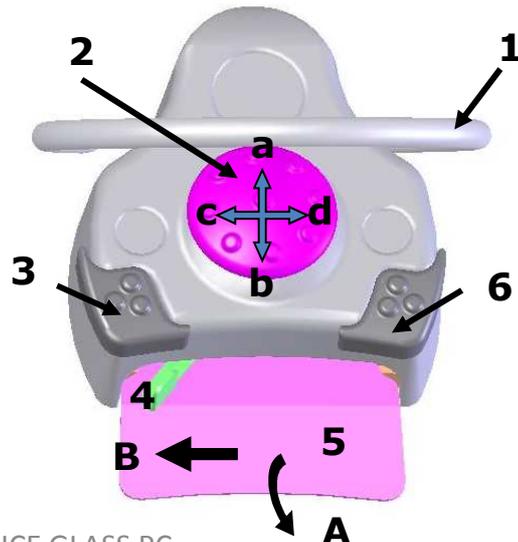
(continuation of the table)

DESCRIPTION	STANDARD FOOT PEDAL	PUSH PEDAL
<p>5. STEEL PEDAL(5) . Use in 2 modes:</p> <ul style="list-style-type: none"> • With the instrument taken • With the instruments in the “rest” mode 	<p>YES</p> <ul style="list-style-type: none"> • With the instrument taken it controls water supply to the instruments with the LED «18»button (regulated water supply) is swithed on. • With the instruments in the «rest mode» it activates water supply to glass of the patient. 	<p>YES</p> <ul style="list-style-type: none"> • With the instruments taken it controls micromotor, turbine(with the valve presented) , scaler power, fixes images from the camera). • With the instruments in the «rest mode» there is NO ANY FUNCTION.
<p>6. PR BUTTON (6). Use in 2 modes:</p> <ul style="list-style-type: none"> • With the instrument taken • With the instruments in the “rest” mode 	<p>YES</p> <ul style="list-style-type: none"> • With the instrument taken Push the PR BUTTON (6). This function automatically memorizes the last working position, activates Rinse Position(backrest is moving up and operator light is automatically switched off , if it was on). Pushing the PR BUTTON (6) again the chair returns automatically in the last working position. • With the instruments in the “rest” mode The same function like with instrument taken 	<p>YES Use in 2 modes:</p> <ul style="list-style-type: none"> • With the camera taken (look point 4/ b of the present table) Push PR BUTTON (6) for save image in the memory, for look through the images done in full screen mode or with the screen divided into 4 pictures, for delete all imaged done. • With the instruments in the “rest” mode Switch on/off the operating light <p>NOTE: PR FUNCTION IS ABSENT , ONLY FROM THE OPERATOR OR ASSISTANT KEYBOARD</p>

STANDARD FOOT PEDAL



PUSH PEDAL



Sec. 27 HYDRO UNIT ASSEMBLAGE

Switch off the unit to enter in the hydro unit .
To access the electronic part of the hydro unit, remove the right and left carter **removing** inside tension springs (Figure "B").

ATTENTION: do not remove any carter if the unit is not switch off.

fig. A

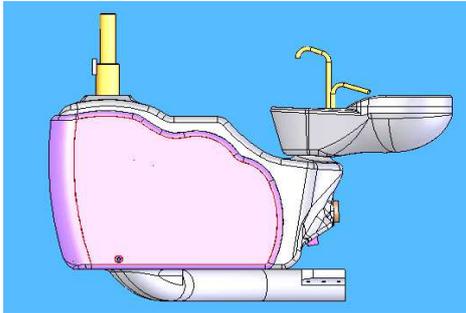
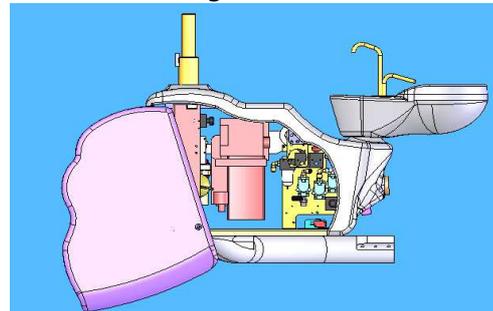
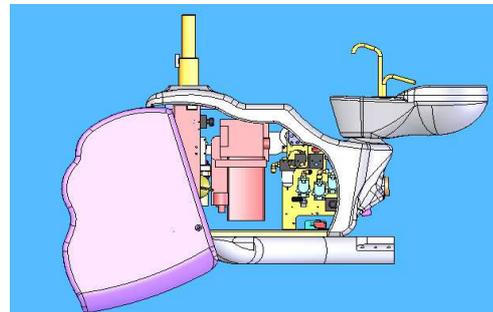


fig. B



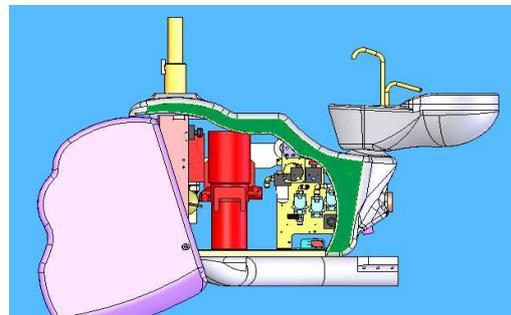
Sec. 27.1 Hydro unit with Metasys "MST1" suction system integrated

The details for the maintenance are indicated in the manual Metasys included with this one.



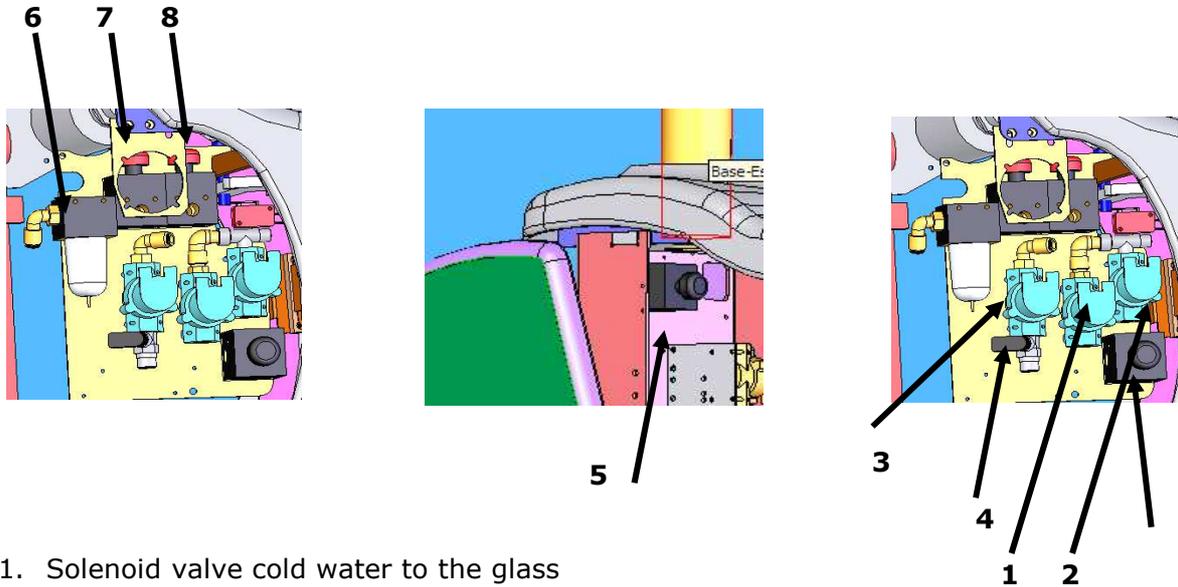
Sec. 27.2 Hydro unit with Metasys amalgam separator integrated into the suction system

The details for the maintenance are indicated in the Metasys manual included with this one.



If the suction system of the liquids or amalgama is not integrated in the hydro unit , there is no any device provided.

Sec. 28 SOLENOID VALVES, CUSPIDOR, PRESSURE REDUCERS



1. Solenoid valve cold water to the glass
2. Solenoid valve warm water to the glass
3. Solenoid valve water to the cuspidor
4. Tap for the regulation of the water to the cuspidor
5. Pressure reducer of the water to the handpieces
6. Air filter
7. Pressure reducer of the air to the handpieces
8. Pressure reducer of the air spray to the handpieces and mixer disinfectant tank
9. Pressure reducer of the water to the glass

Sec. 29 BOILER (WARM WATER TO THE GLASS)

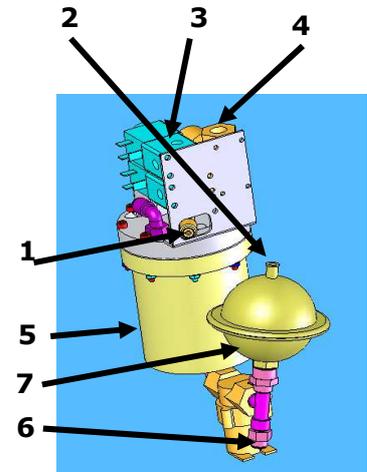
Press power button of the additional thermostat boiler

ATTENTION: the activation of this thermostat will be necessary only if the device is working without water or in case of malfunction of the standard thermostat. If the problem is persistent call the customer service.



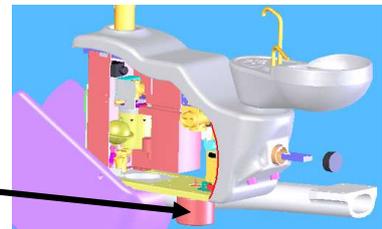
Sec. 30 "MDS" AUTOMATIC DESINFECTION SYSTEM

1. Connector for air supply from the pressure reducer to the handpieces
2. Air pressure 0,5 bar
3. Connector for air supply to the mixer with 2 bar pressure
4. Mains water supply connector
5. Mix tank
6. Connector for water and "GREEN & CLEAN WK" METASYS solution supply
7. Little tank for the water supply to the handpieces during replenishment of the main tank

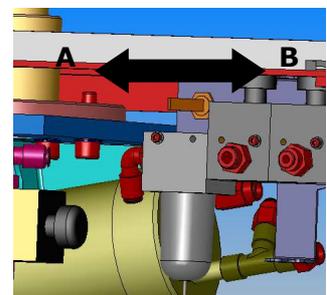


ATTENTION: the "GREEN & CLEAN WK" METASYS liquid level must be controlled and filled every week

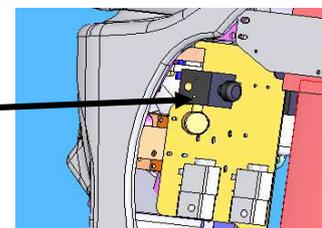
Desinfection liquid tank



- With the lever in the "A" position there is water with "GREEN & CLEAN WK" METASYS 1% solution supply to the handpieces.
- With the lever in the "B" position there is mains water supply to every valve



Pressure reducer that pressurizes the little tank that distributes the water to the handpieces during the replenishment of the mixer tank regulated at 2 bar pressure



ATTENTION: it is indicated to use only or GREEN & CLEAN WK METASYS liquid, furnished by MIGLIONICO, for providing correct functioning of the unit and for the patient and operator safety

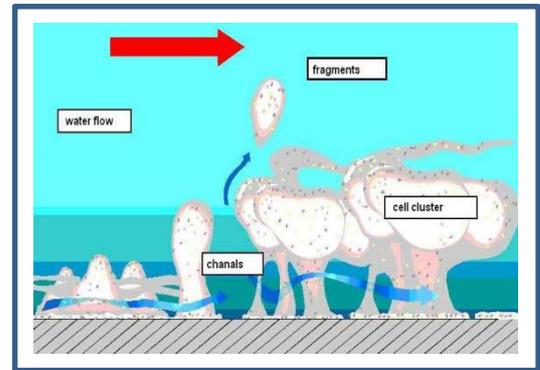
Sec. 30.1 INFORMATION ABOUT "GREEN & CLEAN WK" METASYS DISINFECTION LIQUID

Microbial contamination of medical process water is a common problem in dental practices. During the treatment of patients, the process water can be polluted with blood and saliva. In this nutrient enriched environment microorganisms find optimal growth conditions. It is a long known fact that **dental unit waterlines (DUWL)** are densely populated with a broad diversity of microorganisms. Bacteria in this aquatic environment show a tendency to interact with the inner surfaces of the tubes of the DUWL. Without adequate measures, this will result in a massive bacterial growth and biofilm formation in the water-bearing pipes in the dental unit (Whitehouse et.al. 1991). The source of bacteria for biofilm in the DUWL may be the supplied municipal water and/or the suck-back of patient saliva (Szymanska 2003).

The formation of biofilm in DUWL has been documented in the literature (Szymanska et.al. 2008). In general, organisms colonizing the water supplies are non-pathogenic environmental bacteria. However, microorganisms isolated from DUWL such as *PSEUDOMONAS AERUGINOSA* (Douglas and van Noort. 1993; Fayle and Pollard 1996) and *LEGIONELLA PNEUMOPHILA* (Reinthal et.al 1988; Williams et.al. 1996) could pose a risk to patients and dental staff. Practical field tests in different dental clinics in the European Union revealed a microbial load ranging from 500 to 105 CFU/ml in almost all taken DUWL water samples (Walker et. al. 2000). These results clearly showed that without adequate water decontamination measures, the water supplied in dental units fails current Eudrinking water guidelines (Council Directive 98/83/EC) on bacterial load (Threshold value <100 CFU/ml).

How exactly biofilm is formed ?

'Biofilm' is a multilayered coating consisting of micro organisms, originating in the settlement of micro organisms on surfaces. Biofilms are commonly perceived as a "slimy layer" or "coating." Extracellular Polymer Substances (EPS) form hydro gels in combination with water. Subsequently, a slimy coating develops in which nutrients and others substances are dissolved. In addition, these EPS provide a stable shape (hydrate sphere) for the system. Within biofilms dissolved substances are mainly transported by means of an equalisation of concentrations. The transport of nutrients occurs by means of water flowing within the "slimy layer." The biofilm contains both areas that are supplied with oxygen - (the water facing side) as well as areas not supplied with oxygen (the inner walls of the dental unit). This gives way to a versatile population of micro organisms. This complex structure can hardly be destroyed by means of ordinary disinfectants because they commonly only temporarily damage the biofilm's top boundary layers (shearing forces rip off pieces which subsequently block instruments). Such unsuitable disinfectants have to be used in high concentrations in order to prevent a returning settlement and remove persisting biofilms (e.g. with agents such as biguanidines). Effects of these high concentrations are malfunctions and material damages of the dental units. To find an effective method for reduction, removal and prevention of biofilm in the DUWL was the clear purpose for designing the water disinfection system.



Considering these aspects the use of a hydrogen peroxide-based water disinfectant and its continually addition to the medical process water promised to be an efficient method for achieving the intended clinical purpose.

For reducing the risk of biofilm formation and for preventing its expansion into the water-bearing pipes - by minimizing the numbers of bacteria in the process water delivered by DUWL - several water decontamination and disinfection methods have been explained and described in the literature. Liaqat I. and Sabri A. N. (*Effect of biocides on biofilm bacteria from dental unit water lines. Curr. Microbiol. 56:619-624 (2008)*) have demonstrated the antimicrobial effects of various chemical compounds, including hydrogen peroxide (H₂O₂). The use of hydrogen peroxide-based disinfectants is a suitable method for reducing bacterial count in DUWL (Linger J. B., Molinari J. A., Forbes W. C., Farthing C. F., Winget W. J., *Evaluation of a hydrogen peroxide disinfectant for dental unit waterlines. J. Am. Dent. Assoc. 132:1287-1291 (2001)*).

The antimicrobial effect of hydrogen peroxide was also demonstrated in field studies using different commercially available disinfectants (Holman R., Walker J. T., *Comparison of the efficacies of disinfectants to control microbial contamination in dental unit water systems in general dental practices across the European Union. Appl. Environ. Microbiol. 72:pp. 1380-1387 (2005)*).

Hydrogen peroxide is considered as a strong oxidizer that induces oxidative stress in living cells. Much of the damage on the molecular level is caused by superoxide anion (O₂⁻) and hydroxide radicals (•OH) generated from H₂O₂. The biological targets for these highly reactive oxygen species are DNA, RNA, proteins and lipids .

GREEN&CLEAN WK METASYS EFFICIENCY

REDUCES BACTERIA AND PROTECTS AGAINST INFECTIONS

The formation of biofilm in water pipes poses a significant health risk. Contaminated and polluted water increases the risk of infection for patients and staff. Continuous decontamination reduces bacteria and protects against infections caused by microorganisms, such as legionella. The use of a disinfection system is therefore recommended (Source: RKI guidelines). Water Desinfection systems and in combination with GREEN&CLEAN WK, provide continuous cleaning and decontamination of all water pipes in the dental unit. This way, biofilm is reliably and completely removed. The patient is protected against infections and is not exposed to harmful chemicals.

Through the addition of limescale inhibitors, calcification in the pipe systems is prevented even at very high levels of water hardness.

GREEN&CLEAN WK METASYS is 2 % ready-to-use solution on hydrogen peroxide basis for the decontamination of process water and the prevention of limescale deposits in the pipe systems of dental units

BROAD SPECTRUM OF EFFICACY:

- prevention of biofilm
- no formation of resistance is possible
- limescale inhibitor: prevents calcification
- protects hand and angle - pieces
- CE 0408

Active agent

Hydrogen peroxide

Composition/ Information on ingredients

hydrogen peroxide solution ...% - ca.2 %

silver-nitrate <0,1 %



The dosing of the GREEN&CLEAN WK METASYS and the process water mixture completely eliminates **PSEUDOMONAS AERUGINOSA** after the duration of 15 min and reduces the germs of **STAPHYLOCOCCUS AUREUS** and **ESCHERICHIA**. This concludes that the patient is protected against an infection when the water desinfection system is in operation.

During an examination of a water sample taken from one dental unit a count of more than $2 \cdot 10^4$ **LEGIONELLA PNEUMOPHILA** CFU per 100ml were registered. Two months after using disinfection system with "GREEN & CLEAN WK" a renewed water sample was taken for microbial analysis. It was found that Legionella pneumophila was completely eliminated.

This test was conducted at a dental unit that had been in operation for 10 years. A water desinfection system was installed and the tubes were flushed through with GREEN&CLEAN WK for one hour.

The following photos show the abstracted tube before and after the test:



Global Harmonisation Task Force:

The preparation is not dangerous in the sense of Directive 1999/45/EC. This mixture is classified as not hazardous according to Regulation (EC) 1272/2008 [GHS].

EN ISO 13485:2003/AC:2009;

EN ISO 14971:2009;

EN ISO 10993-1:2009/AC:2010;

EN 14885:2006;

EN 980:2008;

EN 1041:2008.

Does not accumulate in organisms.

Personal protection equipment :

- **Suitable eye protection** - framed glasses. If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

- **Suitable gloves type** - single-use gloves. Subsequently wash again with water.

- **Respiratory protection** - with correct and proper use, and under normal conditions, breathing protection is not required.

- **General protection and hygiene measures**

Avoid contact with skin, eye and clothing.

- **After ingestion** - do not induce vomiting. If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

www.metasys.com

Sec. 31 MAINTENANCE

Sec. 31.1 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 this product (for disinfecting the surfaces of medical devices (e.g. alcohol-sensitive surfaces of dental units such as unit handles, imitation leather and plastic covers) particularly well suited for use on alcohol-sensitive surfaces of medical devices.



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.

It is possible to clean and to desinfect the surfaces using also the neutral liquid soap (alcohol free).



Before to disinfect the touch screen, you must activate the key lock (Glass model only): on operator keyboard simultaneously press the "+" and "-", after 3 seconds buzzer will be activated, after press the button "12" - the operator lamp activation, on the display will appear "CL" and operator keyboard will be inactive for 20 seconds, during this period it is possible to make the desinfection. Assistant's keyboard is blocked for 20 sec. by simultaneously pressing 11 (warm water to the glass) and 14 (cold water to the glass). In this period, LED indicators are flashing.

Sec. 31.2 STERILIZATION

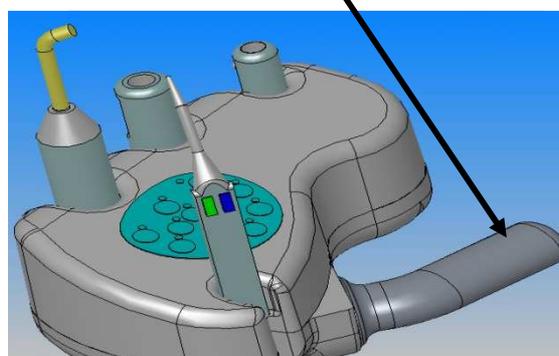
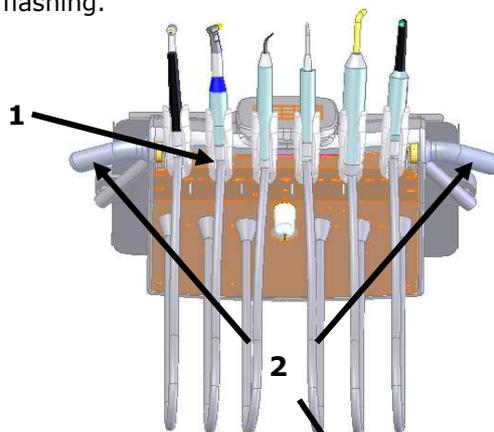
The parts that can be sterilized in the autoclave are:

1. The instruments holders
2. The lateral handles of the operator tablet and the assistant tablet

The above mentioned parts are easily removable in order to replace them between one patient and the next. Other parts can be demanded to the dealer or directly to MIGLIONICO

3. The air-water syringe cover.
4. Stainless steel tray holder(-s).

ATTENTION: for the handpieces disinfection and sterilization consult the instructions in their packages.



Sec. 32 OPERATOR' S VERIFICATIONS

Sec. 32.1 Daily :

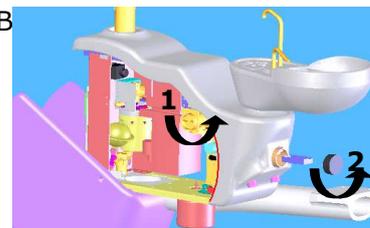
- **The cuspidor main filter cleaning** fig."A"

fig."A"



- **The cuspidor secondary filter cleaning** , if present, "1" fig."B"
- **The surgical suction filter cleaning** "2" fig."B". If the unit is equipped with a mini canister to avoid the suction stops, in this filter always need to be present a capsule antifoaming-disinfectant by CATTANI.

fig."B"



- **The suction system cleaning** with the disinfectant liquids for the surgical suction every day, after surgical procedures. It is advised to use :

Green & Clean WK by METASYS for disinfection and deodorising of suction systems - dual, actively defoaming concentrate for the disinfection and deodorising of suction systems and amalgam separators

- dual system (red/green) active against microbiological resistance
- excellent active defoaming
- easy handling through well-designed dispenser
- high environmental compatibility
- high material compatibility
- enzymatic product with excellent protein dissolving power
- ideal for all amalgam separators and air-water separators
- DGHM/VAH listed
- CE 0408



Use as prescribed in the package :

1. Dispense, 6 ml
2. Dilute with water, 600 ml
3. Suck off with the aspiration tubes , 200 ml each
4. Pour remaining liquid into cuspidor, 200 ml

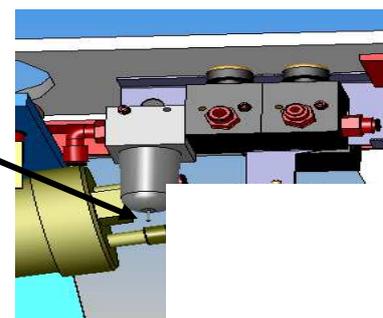


In the absence of the Green & Clean WK disinfection liquid use DURR aspiration system disinfection liquid . Use as prescribed in its package.

Sec. 32.2 Weekly:

Pull out the condensation from the air filter "1" fig."C".

fig."C"

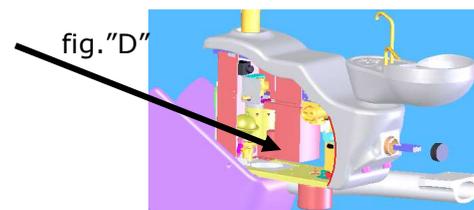


Hydro unit accessories :

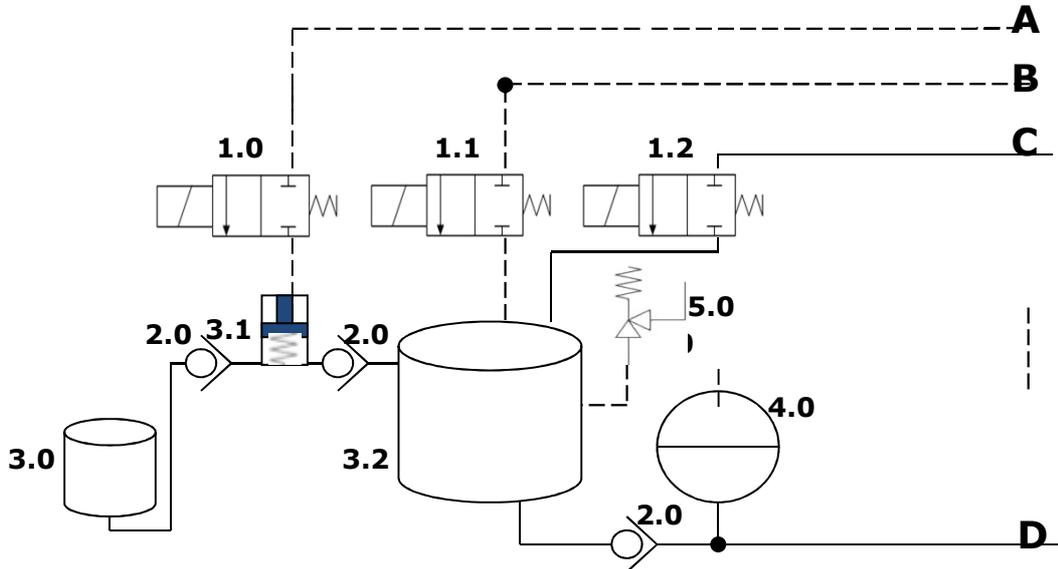
- MST1 ECO Metasys amalgam separator " fig."D"
- DURR Cuspidor drain system (with the selection valve)

ATTENTION: the content of the "MST1 ECO Metasys" amalgam separator or DURR cuspidor drain system , ought to be dispose as specified in their manuals.

fig."D"



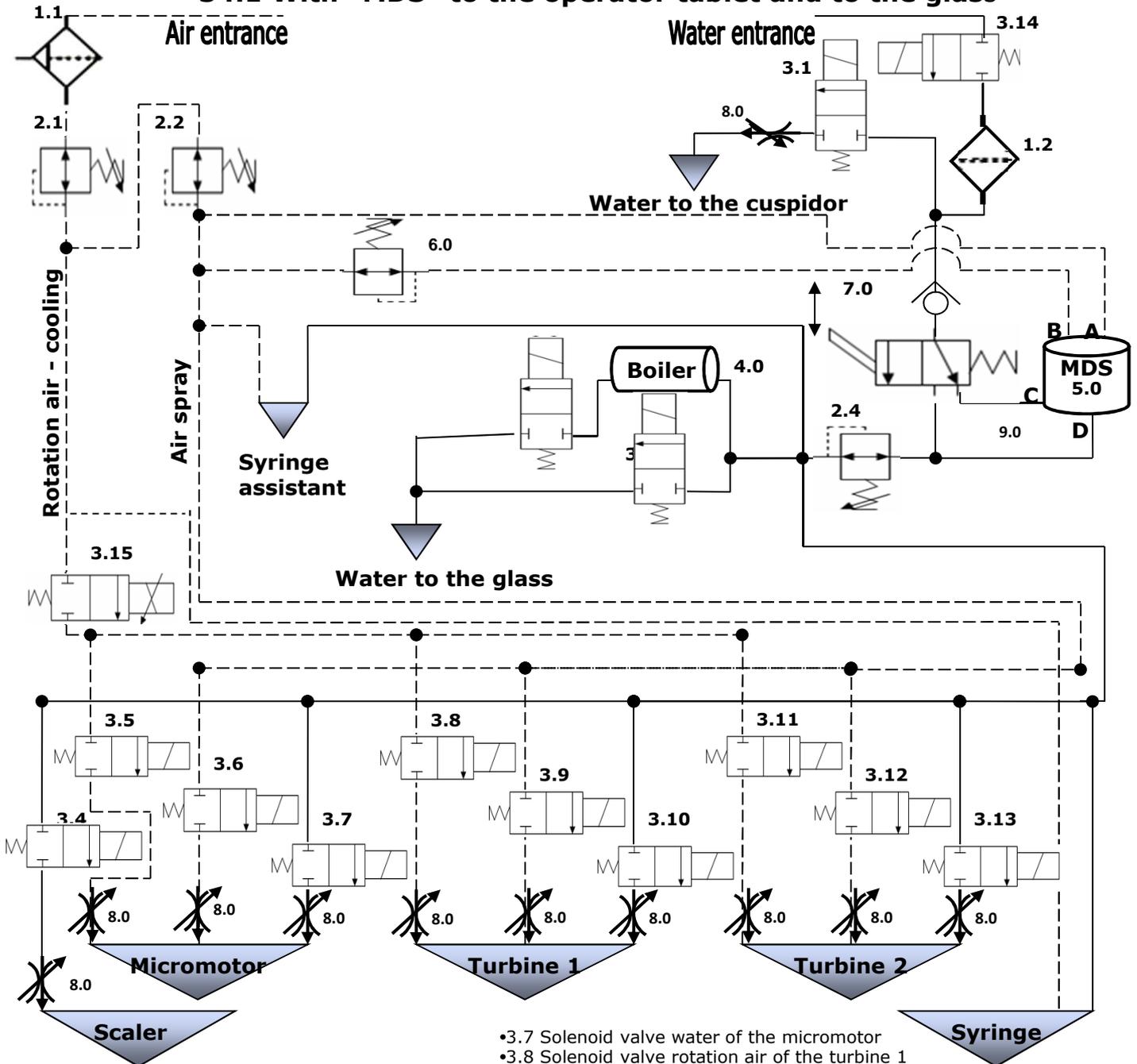
Sec. 33 HYDRAULIC AND PNEUMATIC DIAGRAM WITH "MDS" 111-02-00I



- A. Air input to pressurize the dispenser
- B. Air input to pressurize the tank
- C. Net water input
- D. Water with disinfectant output

- 1.0 Solenoid valve for the disinfectant dispenser
- 1.1 Solenoid valve to pressurize the mix tank
- 1.2 Solenoid valve for the net water entrance
- 2.0 Valve of no return
- 3.0 Tank with concentrated disinfectant
- 3.1. Concentrated disinfectant dispenser
- 3.2. Tank for water and desinfectant mixture
- 4.0 Water supply tank for the instruments during mixing the disinfectant with the water

**Sec. 34 HYDRAULIC AND PNEUMATIC SCHEME WITH "MDS" 111-02-001
34.1 With "MDS" to the operator tablet and to the glass**



- 1.1 Air filter
- 1.2 Water filter
- 2.1 Pressure reducer of rotation air
- 2.2 Pressure reducer of air spray
- 2.3 Water pressure reducer
- 2.4 Pressure reducer
- 3.1 Spittoon solenoid valve
- 3.2 Warm water solenoid valve to the glass
- 3.3 Cold water solenoid valve to the glass
- 3.4 Solenoid valve water of the scaler
- 3.5 Solenoid valve rotation air of the micromotor
- 3.6 Solenoid valve air spray of the micromotor

- 3.7 Solenoid valve water of the micromotor
- 3.8 Solenoid valve rotation air of the turbine 1
- 3.9 Solenoid valve air spray of the turbine 1
- 3.10 Solenoid valve water of the turbine 1
- 3.11 Solenoid valve rotation air of the turbine2
- 3.12 Solenoid valve air spray of the turbine 2
- 3.13 Solenoid valve water of the turbine 2
- 3.14 General solenoid valve of the water
- 3.15 Proportional solenoid valve of air
- 4.0 Boiler
- 5.0 Disinfectant mixer
- 6.0 Pressure reducer for the supply tank
- 7.0 Selector of the net water or liquids tank
- 8.0 Tap for the water regulation
- 9.0 No return solenoid valve

Sec. 35 SAFETY TEST REPORT

Result of the "TEST REPORT" of the dental unit "NICE GLASS" , 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

Sec. 36 EMC TEST RESULTS

EMISSION TEST		CONFORMITY	
Radiated RF emission CISPR 11		Group1 Class B	
Conducted RF emission CISPR 11		Group 1 Class B	
Oscillations measure IEC 61000-3-2		Class A	
Voltage variations and flicker measure IEC 61000-3-3		Adequate	
IMMUNITY TEST	Test level IEC 60601-1-2	Conformity level	
Electrostatic discharges (ESD) IEC 61000-4-2	±6 kV in contact ±8 kV in air	±6 kV in contact ±8 kV in air	
Electric fast transistors IEC 61000-4-4	±2 kV for the power supply connections ±1 kv for the entrance/exit connections	±2 kV for the power supply connections	
Pulses IEC 61000-4-5	±1 kV in a differential way ±2 kV in a common way	±1 kV in a differential way ±2 kV in a common way	
Voltage deficits, short interruptions and voltage variations on the supply entrance connections IEC 61000-4-11	<5% Ut (>95% deficit Ut) for 0,5 cycles 40% Ut (60% deficit Ut) for 5 cycles 70% Ut (30% deficit Ut) for 25 cycles <5% Ut (>95% deficit Ut) for 5 s	<5% Ut (>95% deficit Ut) for 0,5 cycles 40% Ut (60% deficit Ut) for 5 cycles 70% Ut (30% deficit Ut) for 25 cycles <5% Ut (>95% deficit Ut) for 5 s	
Magnetic field to the net frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	
RF conducted IEC 61000-4-6	3 V from 150 kHz to 80 MHz	3 V from 150 kHz to 80 MHz	
RF irradiated 3 V/m from 80 MHz to 2,5 GHz		3 V/m from 80 MHz to 2,5 GHz	
Maximum nominal exit power of the transmitter W	Separation distance to the transmitter frequency m		
	From 150 kHz to 80 MHz $d=1,2 \sqrt{p}$	From 80 Mhz to 800MHz $d=1,2 \sqrt{p}$	From 800 MHz to 2,5 GHz $d=1,2 \sqrt{p}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	
10	3,8	3,8	7,3
100	12	12	23

Sec. 37 LABORATORY RADIOFREQUENCY AND ESD TEST REPORT

MANUFACTURER 'S USER GUIDE AND ADVICES ABOUT ELECTROMAGNETIC FIELD (EN ISO 60601-1-2 art.6)

Emissions		
Emission test	Conformità	Electromagnetic Environment - guidance
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 environment - 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..

Immunity aspects at r.f.			
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.			
Immunity test	Test level EN 60601-1-2	Compliance Level	Electromagnetic environment - guide
RF conducted EN 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff from 150kHz to 80MHz	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)
RF radiated EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	
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:			
			

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.