



# USER AND MAINTENANCE MANUAL

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# P19T

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## **1. DECLARATIONS OF CONFORMITY**

#### DICHIARAZIONE DI CONFORMITA' UE

#### **EU DECLARATION OF CONFORMITY**

La Società MIGLIONICO S.R.L. (N. REG. Unico (SRN): in attesa di assegnazione), con sede legale e operativa Via Molise, Lotti 67/68 Z.I - 70021 Acquaviva delle Fonti (BA), dichiara, sotto la propria totale responsabilità, che il **dispositivo medico** denominato:

We undersigned MIGLIONICO S.R.L. (Single Registration Number (SRN): pending request), 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 / <i>Serial</i> <i>Number</i>	UDI-DI di base / Basic UDI-DI
Poltrona Chair (classe di rischio I) (Risk class I)	SYNCRO	S.N. XXXXX	805534993Z12110180D3

in accordo alla regola 13 dell'Allegato VIII, del Regolamento (UE) 2017/745 (MDR),

according to rule 13 of the Annex VIII of Regulation (EU) 2017/745 (MDR):

- è conforme ai requisiti essenziali ed alle disposizioni del Regolamento (UE) 2017/745 ess.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda; comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR) as per Technical File filed in company
- è fabbricato in accordo ai contenuti del Fascicolo Tecnico, che soddisfa i requisiti di cui all'Allegato II + III del sopra citato Regolamento.
   is manufactured in compliance with the content of the Technical File, which satisfies the requirements of Annex II + III of the aforementioned Regulation.
- non sono state utilizzate Specifiche Comuni per la conformità dei suddetti dispositivi; Common Specifications have not been used for the compliance of the aforementioned devices
- è conforme 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 /



#### **DICHIARAZIONE DI CONFORMITA'**

**DECLARATION OF CONFORMITY** 

La Società Miglionico S.r.l. (codice SRN IT-MF-000019774), con sede legale ed operativa in Via Molise, Lotti 67/68 Z.I – 70021 Acquaviva delle Fonti (BA) in qualità di fabbricante dei **dispositivi Medici**:

We undersigned MIGLIONICO S.R.L., with head office addressed in Via Molise, Lotti 67/68 Z.I - 70021 Acquaviva delle Fonti (BA), as the manufacturer of the following medical devices named:

Descrizione generale	Nomi commerciali	Nomi commerciali	UDI-DI di Base/Basic UDI-DI
	Commercial Name	Commercial Name	
Riuniti odontoiatrici"NICE"	NICE TOUCH NTX	NICE ONE	805534993riunitinice9W
	NICA TOUCH P19TP	NICE ONE P	
	NICE TOUCH NTPX	NICE ONE L	
	NICE TOUCH P19TPC	NICE TOUCH	
	NICE GLASS NGX	NICE GLASS	
	NICE GLASS NGPX	NICE TOUCH P	
	NICE GLASS P19G	NICE GLASS P	
	NICE GLASS P19GP	NICE TOUCH P CART	
	NICE GLASS P19GPC	NICE GLASS P CART	
	NICE GLASSE F	NICE TOUCH W	
	NICE TOUCH F	NICE GLASS W	
	NICE GLASS FP	NICE TOUCH P19T	
	NICE TOUCH FP		

Destinati ad di agevolare l'operatore per effettuare trattamenti nel cavo orale, di classe di rischio IIA, in accordo alla regola 12 dell'Allegato IX del Regolamento UE 2017/745, dichiara sotto la propria totale esclusiva responsabilità, che tali dispositivi:

Designed to facilitate the operator in trating the oral cavity, risk class IIA, according to rule 12 of annex IX To the EU Regulation 2017/745, declare under its own responsibility that the above-mentioned devices:

- sono conformi ai requisiti generali di sicurezza e prestazione ed alle disposizioni del Regolamento (UE) 2017/745 come da Documentazione Tecnica depositata presso l'ente e conservato presso la sede operativa del fabbricante; comply with general requirements of safety and performance and other provisions of the EU Regulation 2017/745, as specified in the Technical File retained by the Notified body and held by the Company;
- non sono state utilizzate Specifiche Comuni per la conformità dei dispositivi; no Common Specifications have been used for the conformity of the devices;
- sono fabbricati in accordo alla Documentazione Tecnica n. FT 001 MI, che soddisfa i requisiti di cui all'Allegato XI Parte A del sopra citato Regolamento, come da Certificato n. \_\_\_\_\_\_ rilasciato da ICIM S.p.a. con sede in Italia a Piazza Don Enrico Mapelli, 75 Sesto San Giovanni (MI) organismo Notificato 0425 il \_\_\_\_\_\_.
   are manufactured according to the Technical File n. FT 001 MI, that complies with the provisions Mentioned in Annex XI Part A of the above-mentioned Regulation, as per Certificate No. \_\_\_\_\_\_, issued on \_\_\_\_\_\_ by the Notified Body No. 0425, ICIM SPA, with legal address: Piazza Don Enrico Mapelli, 75 Sesto San Giovanni, Italy.

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

Il legale rappresentante /

Legal Representative /

# 2. <u>SYMBOLS</u>

$\sim$	ALTERNATING CURRENT	Hz	MAINS FREQUENCY IN HERTZ
	GROUND PROTECTION	VA	MAXIMUM POWER ABSORBED BY THE UNIT (IN VA)
★	B TYPE DEVICE	$\rightarrow$	INDICATION
0	ON/OFF	MDS	MIXER
$\underline{\mathbb{A}}$	WARNING	AF	ANTI RETRACTION SYSTEM TO HANDPIECES
V	NOMINAL VALUE OF VOLTAGE (IN VOLTS)	$\otimes$	DON'T LEAN OR PUSH

#### **DISPLAY SYMBOLS**

IT	SPRAY ON		X-RAY VIEWER		LOCK SCREEN / CLEAN
T	SPRAY OFF	$\diamond$	MICROMOTOR REVERSE ROTATION	J)	INSTRUMENTS
	SPRAY ON/OFF	$\odot$	PERISTALTIC PUMP	Ņ	ON/OFF OPTICAL FIBRE ON INSTRUMENTS
	COLD WATER CUP FILLER AND CUSPIDOR	ź	UPWARD CHAIR MOVEMENT	×	PROPORTIONAL SPEED
	WARM WATER CUP FILLER AND CUSPIDOR	Ś	DOWNWARD CHAIR MOVEMENT	L	FIXED SPEED
「山	WATER TO CUSPIDOR	5	UPWARD BACKREST MOVEMENT	$\Leftrightarrow$	MEMORIZE POSITION
оų	WARM WATER CUP FILLER TIMER	j	DOWNWARD BACKREST MOVEMENT	A A A A A A A A A A A A A A A A A A A	OPERATING LIGHT
оų	COLD WATER CUP FILLER TIMER	Jag.	ZERO POSITION	Ţ	ASSISTANT CALL / DOOR OPENER
о ці	WATER TO CUSPIDOR TIMER	+{	EMERGENCY POSITION		COUNTDOWN TIMER
	TIMER DELAY CUSPIDOR AFTER CUP FILLER	PR	RINSING POSITION	ŝ	SETTINGS
°-̈́Q́-	OPTICAL FIBRE TIMER DELAY	RM	RECALL MEMORY	公	НОМЕ



## 3. INSTALLATION, TEST AND WARRANTY 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 <u>info@miglionico.net</u> <u>www.miglionico.net</u>

# **DICHIARA CHE I PRODOTTI**

RIUNITO MODELLO	POLTRONA MOI	D. "SYNCRO"
MATRICOLADATA COLLAUDO		DATA COLLAUDO
Sono stati installati seguendo le procedure standa	ard della Miglion	
IL TECNICO timbro e firma		DATA INSTALLO
DATI DEL CLIENTE Rag. Sociale Via Città Tel/fax e-mail	CONCESS	IONARIO timbro e firma
Per ricevuta del manuale que e monutenzione riunito Per ricevuta del manuele d'une manutenzione telecamen Per ricevuta del manualenso e manutenzione lampada po Per ricevuta del manuele d'uso e manutenzione ablatore Per ricevuta del manuele d'uso e manutenzione aspirazion	ra er compositi e chirurgica	□ SI □ 0 □ SI □ 0

□ Sottoscrivo e autorizzo Miglionico srl al trattamento dei miei dati personali nel rispetto della legge 675/96 e successive modificazioni del D.LGS 196/2003.

Per accettazione delle condizioni di garanzia di seguito riportate.

CLIENTE Timbro e firma	L'AMMINISTRATORE UNICO MIGLIONICO SRL - timbro e firma

This document must be duly completed, signed and attached to the registration procedure accessible via QR code within 30 days from the installation date.

FAILURE TO INCLUDE THIS DECLARATION ON THE PLATFORM IMPLIES THE IMMEDIATE FORFEITURE OF THE THREE-YEAR WARRANTY EXTENDING.

The Dental unit comes with the "User and maintenance manual", "CE certification of compliance" and "installation, test and warranty certificate".

#### Warranty is valid for 12 months after installation date.

**Customers who desire to extend their warranty must include the "installation, testing and warranty certificate",** which must be duly completed, signed and attached to the registration procedure accessible via QR code within 30 days from the installation date. Failure to include the "installation, test and warranty certificate" in the registration form implies the immediate forfeiture of the right to the three-year extension of the warranty, as well as making it impossible for Miglionico s.r.l to comply with the legal obligations regarding the traceability of the medical device. It remains confirmed that the warranty covers all spare parts during the first year, including travel expenses and technical interventions, with the exception of material subject to wear and tear, such as:

- hoses, aspiration cannulas and nozzles
- syringe tips
- scaler tips
- light bulbs, filters
- upholstery cuts
- painted parts damaged by bumps.

For the second, third and fourth year, the warranty is limited to spare parts produced by Miglionico, excluding handpieces and PCs, but the cost of the technical intervention including travel is borne by the customer.

The warranty is not restored with each replacement of spare parts.

Under no circumstances the replacement of the equipment or the supply of a replacement equipment is contemplated.

The 3-years warranty extension is invalid in case of:

- "Installation, testing and warranty certificate" completed in its entirety not returned;
- Repair or maintenance procedure carried out by unauthorized personnel;
- Accessories/spare parts not provided by the manufacturer have been implemented onto the unit;
- 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
  sources.

All relevant documentation related to handpieces, operating light, compressor, suction system etc. is considered as an integral part of this manual.

#### 3.2 INTENDED USE

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 of saliva, water, blood or other liquids used for the local treatment of the operated parts, scaling, cleaning, lighting coverage of the oral cavity.

#### 3.3 STANDARD AND OPTIONAL ACCESSORIES

When placing the purchase order, each dental unit is configured according to the customer's request and is equipped with the required accessories, divided into the following categories:

- DENTIST CONSOLE CONFIGURATION
- ASSISTANT CONSOLE CONFIGURAITON
- HYDRO CASE CONFIGURATION



#### 3.4 PRODUCT REGISTRATION AND CUSTOMER CARE

To better manage the feedback and requests of end customers and to guarantee the traceability of products thanks to the acquisition of data relating to installations, Miglionico has finally established its Customer Care Department. The contact details of the new office are as follows.



Furthermore, to facilitate the product registration operation which allows the customer to access the free 3year warranty extension in addition to the standard 1-year warranty period, starting from unit s.n.: 24SY-04692 (production week n.17-2024), you will find the following card on the dentist's console of the unit instead of the extension request form:



To register the product, the customer must follow the following steps:

- Scan the first QR code with the serial number with your smartphone camera;
- Fill in all the fields with your clinic's information;
- Enter the date of installation and attach a photo of the INSTALLATION, VERIFICATION AND WARRANTY FORM filled out by the technician who installed the unit;
- Accept the privacy conditions and click on "send".

# The warranty extension certificate will be sent to the email indicated during registration. It will no longer be necessary to send the installation form via email to obtain the extension.

NOTE: don't forget the other QR codes on the card! Remind your customers to download the user manual via the central QR code and to leave us a review if they are satisfied with their purchase!  $\bigstar \bigstar \bigstar \bigstar \bigstar$ 

Furthermore, the following QR code will be present inside the hydro case to allow the customer to consult the user manual at any time.



Finally, in order to detect customer satisfaction with the new production line, the Customer Care will take care of calling your customers for a customer satisfaction survey regarding the products they purchased.

For further information or particular needs, you can contact the Sales Director Katia Cea at <u>k.cea@miglionico.net</u> or by phone (+39 3349910634) or our Customer Care Dept. <u>customercare@miglionico.net</u>



## 4. <u>OPERATIONAL SETTING – ADVICES</u> 4.1 <u>OPERATIONAL SETTING</u>

The operating spaces must respect the regulations about the application of the product: minimal dimension of the rooms mq 7,5; long side Mt 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 regulations in force.

#### 4.2 FIXING THE UNIT ONTO THE FLOOR

Warning: it is recommended to fix the unit onto the floor by using 2pcs 10 mm fisher screws





# 5. SUPPLY REQUIREMENTS AND INSTALLATION

OBJECT	SPECIFIC DESCRIPTIONS
Location	Relative humidity between 45% and 75% Temperature between 15 °C and 35 °C Air pressure between 860mbar÷ 1060 mbar (645 mmHg to 795 mmHg)
Water supply	<ul> <li>Water has to be adequate to the national rules for the drinking water. The water supply shall use drinking water, filtered and decalcified, for domestic use. The water shall have the following features:</li> <li>Hardness between 15 ÷ 20 F° (French degree)</li> <li>Pressure between 150 ÷ 400 kPa (1.5 ÷ 4 bar)</li> <li>Capability &gt; 3l/min to 400 kPa (4 bar)</li> <li>In case of pressures higher than 400 kPa (4 bar) they have to insert an adequate pressure reducer before the unit installation.</li> <li>The supply tube has to be equipped with an arrest tap.</li> <li>Before installation technicians must clean the tubes with care in order to avoid the possible penetration of impurities into the hydro case of the unit by purging it until the elimination of the impurities.</li> </ul>
Electric system	Complies with current regulations (regulations for electrical systems in rooms used for medical purposes for type 'A' medical clinics) on the date of installation. The single-phase mains voltage 230V ± 10% frequency 50Hz.
Electric supply	As indicated in the device data tag. Allowed tolerance on $\pm$ 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 I $\Delta$ N=0.03 A, made in accordance with the European regulations 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.
Air supply	The compressor must be placed in an open room, hygienically and protected from heat sources 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 must have an arrest tap.
Drain pipes	Piping has to be realized with a PVC (or higher quality) tube. Piping must 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.
Weight	Total weight Kg. 245

# 6. TECHNICAL DATA

#### 6.1 <u>UNIT</u>

The equipment is not proper to be used in presence of anaesthetic inflammable mixture with oxygen air or nitrous oxide.

MODEL	NICE TOUCH (P19T) – (P19TP) – (P19TPC)
CLASSIFICATION (EN 60601-1)	Class I Type B Ҟ
CLASSIFICATION (93/42 CEE)	Class II a
SUPPLY VOLTAGE	230 V
SINGLE PHASE ALTERNATIVE CURRENT	50/60 Hz
INTERMITTENT FUNCTIONING	1400 VA
ADDITIONAL WEIGHT SUPPORTED BY THE TRAY	KG 1,5

# 6.2 <u>CHAIR</u>

The equipment is not proper to be used in presence of anaesthetic inflammable mixture with oxygen air or nitrous oxide.

MODEL	SYNCRO (NSY)
CLASSIFICATION (EN 60601-1)	Class I Type B Ҟ
CLASSIFICATION (93/42 CEE)	Class I
SUPPLY VOLTAGE	230 V
SINGLE PHASE ALTERNATIVE CURRENT	50 Hz
INTERMITTENT FUNCTIONING	18 min. of rest every 3 min. working
CHAIR MINIMUM HEIGHT	410 mm
CHAIR MAXIMUM HEIGHT	900 mm
BACKREST RISING MOTOR	ELECTRIC MOTOR 42 Vdc MAX 10,5 A
BACKREST MOTOR	ELECTRIC MOTOR 32 Vdc MAX 5,2 A
MAXIMUM LOAD CAPACITY	KG 180
PROTECTION LEVEL AGAINST LIQUIDS PENETRATION	IPX0 – NO PROTECTION

#### 6.3 OPERATING LIGHT

If MIGLIONICO is not the supplier of the operating light, it must be in compliance with the CEE Directive 93/42 and 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
- Application diameter Ø 35 mm height 60 mm

Lightening modalities, brightness control and power on /off are specified in the section "CONTROL PANELS".

#### 6.4 <u>X-RAY UNIT</u>

If MIGLIONICO is not the supplier of the x-ray, it must be in compliance with current Regulations, equipped with CE Statement of compliance and user manual <u>subject to prior acceptance by Miglionico</u>.

Connection specifications:

- Electric supply needs to be independent from the unit and connected to a safety swich whose dimensions depend on the x-ray technical specifications.
- Application diameter to be defined depending on the model.

## 7. CHAIR MOVEMENT LIMITS







## 8. DIMENSIONS

#### P19T, P19TP VERSIONS



## Standard ground connection

Miglionico units' mod NG - NT - Nice Glass/Touch ground connection

Other brands' ground connection

## **P19TPC VERSION**



**Standard ground connection** 

 $\label{eq:model} \mbox{Miglionico units' mod NG - NT - Nice Glass/Touch ground connection}$ 

Other brands' ground connection

## 9. ESSENTIAL RECOMMENDATIONS 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 Directive 93/42, this equipment is exclusively destined to the dentist use, potentially assisted by auxiliary personnel, prepared for dental assistance.

It is necessary to study the user manual and to read carefully all the instructions concerning the instruments. After the unit is installed but before using it, it's necessary to follow the instructions down below:

- Sterilize operational instruments, which are not in sterile 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.

The patient should not wear short clothes to preserve the hygienic conditions.

WARNING: 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 s.r.l is not to be held liable for safety, reliability and performances if:

- the installation operations have not been carried out by qualified personnel authorized by MIGLIONICO and equipped with license.
- the electric, water, air supply systems, the water discharge system, the possible suction system and the rooms where the device is installed do not comply with the law.
- non-authorized modifications have been carried out (including connecting other medical devices or accessories) and/or non-original spare parts have been used.
- the device is not used as it is recommended in the user and maintenance manual.
- the annual technical maintenance is not carried out respecting the set date by technicians.

the water supply system is left open without any personnel being present.

Before activating the chair, please make sure that there are no any other equipment or accessories which can obstruct the chair movement.

WARNING: do not remove any carter before switching off the dental unit.





## **USER MANUAL**

WARNING: the front carter of the base can be removed ONLY by authorized technicians 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, please read the instructions in their packaging. Miglionico s.r.l is not to be held responsible for possible damages that caused by the inobservance and by the omission of the above-mentioned rules.



#### **10.1 ELECTRICAL CONNECTIONS COVER OPENING**

After removing the side covers of the hydro case (see par. 34), unscrew the 3 bolts on the external side and the 3 bolts on the internal side. Then, remove the frontal carter.



## 11. PACKAGING DISPOSAL

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

## 12. DENTAL UNIT DISPOSAL

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



# 13. <u>LABELS POSITION</u> 13.1 <u>EXTERNAL LABELS</u>



1	HYDRO CASE OPENING BUTTON	<b>(</b>
2	SAFETY DEVICE	ATTENZIONE: DISPOSITIVO DI SICUREZZA ANTI SCHIACCIAMENTO. WARNING: ANTI-CRUSH SAFETY DEVICE.
3	CE MARK	0425
4	P19T LOGO	
5	ON / OFF	O
6	CHAIR SERIAL NUMBER TAG	Construction of the second of the secon
7	HYDRO CASE SERIAL NUMBER TAG	Image: Construction of the state of the



#### 13.2 FOOT CONTROL LABELS



1	- RECALL MEMORY: PATIENT DESCENT - WATER TO HANDPIECES ON/OFF (WHEN THE INSTRUMENT IS SELECTED)	the second
2	RINSING POSITION	PR
3	JOYSTICK FOR CHAIR MOVEMENTS	

#### 13.3 CHAIR BASE LABELS



## 13.4 HYDRO CASE LABELS





# **14. IDENTIFICATION LABEL**

The dental unit is traceable by a serial number printed on the label. Please include your serial number when requesting information or spare parts.

Read par. 13.4 and 13.1 (5).



	MIGLIONICO S.r.i Via Molise 67/68 Z.I. <u>Ind</u> . – 70021 Acquaviva delle Fonti (BA) ITALY Tel +39 080 769652 www.miglionico.net
	Funzionamento continuo con carichi intermittenti Continuous work with temporary charges
	M 800 VA □ 600 VA <u>REF</u> SYNCRO
(01)0 000000000000000 (11)YYMMDD (21)XXXXXXX	SN 24SY-XXXXX YY-MM-DD

# 15. UNIT ON/OFF

The unit is equipped with a main switch located in the lower part of the chair. When you push and release the button, the button will turn green and two segments on the control panel display will light up, indicating the electricity supply activation. By pushing and releasing the general switch again, the unit will be turned off.

It is recommended to turn the main switch off every time you stop working or in any case, before every technical or maintenance operations that imply the intervention on the parts protected by carters.

For what concerns the NT models, you must turn off the unit by the dedicated function displayed on the control panel before turning of the main switch.



WARNING: The front carter at the base of the chair can be removed by authorized technician only 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 – LED BAR FUNCTIONS 16.1 INSTRUCTIONS FOR USE

Operational instruments need to be withdrawn from their initial position and activated the foot control (see footcontrol functions). The air-water syringe is not activated by the pedal but directly by using the buttons on it.

The dental unit is equipped with a functioning instruments priority system. Only the first selected instrument is active, and the rest of the instruments are blocked.

The **anti-retraction system** (AF) reduces to the minimum the concentration of liquids or debris coming from the operating area to the spray holes. This consists in the release of a jet of air every time the pedal lever is released, with the function "instrument spray on" or "instrument spray on/off" is active.

WARNING: When an instrument is removed from its position and is activated by the pedal, the chair movement controls are deactivated. This is to avoid accidental movements of the chair while operating on the patient.



#### 16.2 LED BAR FUNCTIONS 16.2.1 <u>REMOTE CONTROL</u>

The P19 dental unit is equipped with an integrated **LED** system to enhance the design and visually communicate to the operator the activation and status of the instruments and integrated functions.

The LED bar can vary light intensity and colour through the use of the remote control.





## 16.2.2 COLOUR VARIATION AND LIGHT EFFECTS

After pressing the Colour Change buttons, the visual effects change as shown:



#### 16.2.3 LIGHT EFFECTS CONNECTED TO FUNCTIONS



## 17. <u>NT CONTROL PANEL</u>





#### 17.1 TOUCHSCREEN DISPLAY TURNING OFF

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By pressing the icon for 5 seconds, the touch panel turns off. After that, it is possible to turn off the dental unit from the main switch.

#### 17.2 LOCK SCREEN / CLEAN

P

By pressing the icon for 3 seconds, a 20-second screen lock is activated, which allows cleaning the display easily.

#### 17.3 WI-FI FOOTPEDAL BATTERY LEVEL

WIRELESS foot pedal battery charge level indicator. It is green if the battery is charged and turns red when it is time to recharge the pedal. Present exclusively with WIRELESS pedal.

#### 17.4 DATE AND TIME SETTINGS

On the display, in any selected screen, the top bar with DATE and TIME will always be visible. To set the date and time, click on the bar, and a screen with a calendar and time setting will appear. Select the desired date and time and click on the icon at the bottom right corner to save. If you accidentally press on the date and time bar, just click on the save icon without making any changes or press on the bar again.



#### 17.5 COUNTDOWN TIMER

Thanks to the COUNTDOWN section, it is possible to set a timer that starts a countdown. When tools are removed (for example the curing light), the countdown timer will continue going down and will be visible on the upper bar in place of the timer icon. At the end of the countdown, an alarm sound will go off.

16/01/2019 12:1000 userNa me0 ② ③ ③ ④ ① PR シー、シー、シー、シー、 TIMER COUNTDOWN	16/01/2019 10:000 userName0 ② 00:25:30 ふ 企 PR シー シー シー シー CURING LIGHT
$ \begin{array}{c c} & & & & \land \\ \hline 00:25:30 \\ \hline & & & & \checkmark \\ h & m & s \\ \hline & & & & \\ \hline & & & & \\ \end{array} $	
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Thanks to the SETTINGS folder, it is possible to set the timers relating to the water to cup filler, cuspidor water and LED light for the instruments, and it is also possible to manage the users.

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## 17.6.1 <u>TIMERS</u>



#### 17.6.2 USERS

The unit can manage up to 4 users. Personalized parameters will be stored for each user, such as chair positions (1, 2, 3, 4) or micromotor programs.

Furthermore, you have the possibility to rename users by long-pressing on the selected user.







#### 17.7 CHAIR MOVEMENT AND MEMORIZING POSITIONS

In every instrument section, it is possible to manage chair movements and activate the basic functions of the unit by using the icons above and below the home and instrument sections.

In the HOME screen, it is possible to move the chair using the arrows corresponding to the chair parts and recall the memorized positions by the icons in the top bar. In the instrument sections, it is possible to activate the same functions thanks to the scroll bar. If the instrument is active, chair movements are blocked. If the instrument is picked up but is not active, movements can be activated.



^	Ŷ	<b>UPWARD CHAIR MOVEMENT</b> It rises the height of the seat. When a memory that includes this movement is recalled, this icon is activated.
$\checkmark$	) Ĵ	<b>DOWNWARD CHAIR MOVEMENT</b> It lowers the height of the seat. When a memory that includes this movement is recalled, this icon is activated.
L	is_	<b>DOWNWARD BACKREST MOVEMENT</b> It reclines the backrest. When a memory that includes this movement is recalled, this icon is activated.
7	12	<b>UPWARD BACKREST MOVEMENT</b> It rises the backrest towards the seat. When a memory that includes this movement is recalled, this icon is activated.





⇒	<b>MEMORIZATION</b> Thanks to this icon, it is possible to memorize the 4 positions of the chair and customize the positions already memorized by the system: EMERGENCY position, RESET position and RINSE position. Move the chair to the desired position, press the MEMORIZE POSITION icon, and press the icon in which you want to store the
	position within 3 seconds (1, 2, 3, 4 or position icons).
	WARNING: when memorizing a position, never bring the seat and backrest to their maximum limit; adjust to a few millimetres from the maximum limit and then memorize.
	RECALL MEMORY
RM	It recalls the 4 previously saved working positions. Press the RM icon and then the position you want to recall within 3 seconds. If you do not press one of the positions after 3 seconds, the icons will automatically disappear.
	RINSING POSITION
DD	It moves the backrest to the rinsing or patient rest position. A subsequent press on the icon brings the backrest back to the zero position. If after activating the position you do not want to return to the previous one, you must press one of the 4 chair movement buttons to reset the function
FIX	You can customize this position thanks to the MEMORIZE POSITION icon. Move the backrest to the most comfortable position for the patient when he needs to rinse and press PR within 3 seconds. In this way, the position will be memorized and activated every time this icon is pressed.
	RESET/ZERO POSITION
ž	It brings the chair to the zero position, to help the patient sit or get up from it. You can customize this position thanks to the MEMORIZE POSITION icon. Move the
~ `	chair to the most comfortable position for the patient to sit/get up and press RESET/ZERO POSITION within 3 seconds. In this way, the position will be memorized
	and activated every time this icon is pressed.
	EMERGENCY POSITION
1.0	It brings the chair to the Trendelenburg position.
	You can customize this position thanks to the MEMORIZE POSITION icon. Move the
	backrest to the desired position and press EMERGENCY within 3 seconds. In this
	way, the position will be memorized and activated every time this icon is pressed.

## **USER MANUAL**

#### **17.8 ADAPTIVE BACKREST POSITIONING**

To use the adaptive backrest movement function in one of the three available positions, the chair must be empty and the patient must not be sitting in it. Then, click on the backrest icon at the bottom left of the display (Fig. A) and select the desired height among:

- Short (suitable for children and people with below average height);
- Medium (suitable for people with an average height);
- Tall (suitable for particularly tall people).

Once the desired height has been chosen, the backrest automatically positions itself in the ideal position and the chosen backrest option will be shown on the display. (Fig. B)





## 17.9 BASIC FUNCTIONS



Û	ASSISTANT CALL / DOOR OPENER It is possible to associate this command to an external low voltage device, which can be, for example, a sound device placed in another room or an automatic door opening device.
	X-RAY VIEWER It activates/disactivates the X-ray film viewer screen.
V	WATER TO CUSPIDOR
「山	Activate the water flush to the cuspidor for a set time (to set the cuspidor timer, see
	par. 17.6.1 TIMER).
	WARM WATER CUP FILLER AND CUSPIDOR
ж	It fills the cup with warm water and then activates the cuspidor flushing for a set
- y	time and after a set time. (for glass and cuspidor timer settings, see par. 17.6.1
いし	TIMER).
	Pressing the icon again will stop the flushing.
	COLD WATER CUP FILLER AND CUSPIDOR
dh	It fills the cup with cold water and then activates the cuspidor flushing for a set time
	and after a set time. (for glass and cuspidor timer settings, see par. 17.6.1 TIMER).
5	Pressing the icon again will stop the flushing.
	OPERATING LIGHT
(A)	It turns the operating light on/off. If it's off, when the memorized positions (1, 2, 3,
"IIII	4) are recalled, it will turn on automatically. If it's on and you activate the RINSING
	or RESET positions, it will turn off at the end of the movement
	or Receir positione, it will turn on ut the end of the movement.



# 18. INSTRUMENTS

All the functions and parameters relating to the instruments can be set and managed by the screen which automatically appears when withdrawing the instrument or by the INSTRUMENTS section when the instrument is in its housing on the dentist console. This section allows you to access the screens of all instruments of the dentist console and change their settings without having to withdraw the instrument. The parameters saved in the instruments section activate automatically when the instrument is used. The instrument screens are in the same order as the instruments are positioned on the console. To switch from one instrument to another, swipe right or left.



## **19. MCX BIEN AIR MICROMOTOR**

When you withdraw it from its instrument housing, it is activated and regulated by the foot pedal lever. It can be used in two different modes: Restorative and Endodontics, which can be selected from the drop-down menu at the top right.





#### **19.1 RESTORATIVE MODE**

The Restorative mode allows you to adjust the speed of the micromotor, the type of handpiece used, manage the peristaltic pump, the spray, the optical fibre and the inversion of the rotating direction of the micromotor. By activating the pedal lever, the micromotor turns progressively from minimum rpm to the set value.



#### **FUNCTIONS**

MCX - 1	<b>INSTRUMENT</b> . It identifies which instrument you are using. If there are several identical instruments, the indicator will mark 1 / 2 / 3 according to their position on the console.
1:1 ~	<b>TYPE OF HANDPIECE</b> . By pressing this icon, it is possible to select which type of reducing or multiplying handpiece is being used on the micromotor. As the ratio changes, the number of rpms will vary. (For the list of handpieces and the related rpms of the micromotor, see par. 46)
100 rpm 25% 50% 75% MAX	<b>REAL MICROMOTOR RPM.</b> By activating the pedal lever, the micromotor rotates progressively from the minimum speed to the set value. The rpms can be adjusted by the cursor, the + and - keys and the shortcut keys. The micromotor speed limit depends on the ratio of the handpiece used (for the rpm values associated with the handpiece ratio, see par. 46).
ß	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.
	<ul> <li>INSTRUMENT SPRAY. SPRAY ON: Air-water spray active when the pedal lever moves to the right. By pressing it again, you will activate the SPRAY ON/OFF function: the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: SPRAY OFF.</li> </ul>
-×,-	<b>OPTICAL FIBRE.</b> It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments. To adjust the LED light delay, see par. 17.6.1 TIMER.
$\bigcirc$	<b>MICROMOTOR ROTATION INVERSION</b> . This function inverts the rmps rotating direction of the micromotor.

#### **19.2 ENDODONTICS MODE**

The Endodontics mode allows you to adjust the speed of the micromotor, the Torque value, the type of handpiece used, activate the auto reverse, auto stop and auto forward functions with related reverse time and cruise control, manage the peristaltic pump, spray, the optical fibre and inverse the micromotor rotating direction.

All these parameters can be memorized in 10 customizable and recallable programs.

By activating the pedal lever, regardless of its position, the micromotor turns at the set speed.



#### **FUNCTIONS**

MCX - 1	<b>INSTRUMENT</b> . It identifies which instrument you are using. If there are several identical instruments, the indicator will mark 1 / 2 / 3 according to their position on the console.
<u> </u>	<b>TYPE OF HANDPIECE.</b> By pressing this icon, it is possible to choose which type of reducing or multiplying handpiece is being used on the micromotor. As the ratio changes, the number of rpms and the micromotor torque limits will vary. (For specific speed and torque values of handpieces, see par. 46)
PROGRAM 01 V	<b>PROGRAM MENU</b> . It indicates the selected program. (see par. 20.4)
AUTO FORWARD >> 5s	<b>AUTO FORWARD.</b> When you move the foot pedal lever to the right, the micromotor turns clockwise, whereas it inverts the rotating direction when it reaches the selected torque at the set time via the slide bar and then turns clockwise again. Only this function can activate the CRUISE CONTROL function.
AUTO REVERSE 🗸	<b>AUTO REVERSE</b> . When you move the foot pedal lever to the right, the micromotor turns clockwise, whereas it inverts the rotating direction when it reaches the set torque until you release the foot pedal.
AUTO STOP V	<b>AUTO STOP.</b> When you move the foot pedal lever to the right, the micromotor turns clockwise and stops when it reaches the set torque. To restart the rotation, you must set the pedal lever to zero and bring it back to the right.

100 rpm +	<b>MICROMOTOR RPM.</b> By activating the foot pedal lever, regardless of its position, the micromotor turns at the set speed. The speed can be adjusted by the cursor, the + and – keys and the hotkeys. The speed limit of the micromotor depends on the ratio of the handpiece used. (for the speed values associated with the handpiece ratio, see par. 46)
0.25 Ncm	<b>TORQUE VALUE.</b> It's a settable value ranging from 0.25Ncm to 53Ncm, depending on the handpiece used (for the torque values associated with the handpiece ratio, see par. 46). When the set resistance is reached, the micromotor will react according to the type of function activated (AUTO FORWARD, AUTO STOP or AUTO REVERSE).
	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.
	<ul> <li>CRUISE CONTROL. It can be exclusively activated in ENDODONTICS mode and with AUTO FORWARD function active. This function allows the micromotor to continue turning even if you release the foot pedal lever after activating it by pushing the foot pedal lever to the right.</li> <li>Activate the cruise control function by pressing the icon;</li> <li>Once the icon is pressed, an alert will pop up. To make sure that the activation of this function is desired, press YES;</li> <li>The activated icon will flash red;</li> <li>Move the lever to the right to activate the micromotor;</li> <li>The micromotor will continue to turn even if you release the foot pedal;</li> <li>To stop the micromotor while this function is activated, move the pedal lever to the right;</li> <li>To deactivate this setting, press the icon again.</li> </ul>
	WARNING: pay particular attention to the micromotor when using it with this function active, remember that the micromotor will continue to turn if this function is not deactivated. It could be dangerous for the operator and the patient if not used with care.
	INSTRUMENT SPRAY. SPRAY ON: Air-water spray active when the pedal lever





moves to the right. By pressing it again, you will activate the **SPRAY ON/OFF function**: the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: **SPRAY OFF**.

**OPTICAL FIBRE.** It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments.

To adjust the LED light delay, see par. 17.6.1 TIMER.

**MICROMOTOR ROTATION INVERSION**. This function inverts the rmps rotating direction of the micromotor.





# 20. MX2 BIEN AIR MICROMOTOR

When you withdraw it from its instrument housing, it is activated and regulated by the pedal lever. It can be used in three different modes: Restorative, Endodontics and Surgery. These functions can be selected from the drop-down menu at the top right corner.


### 20.1 RESTORATIVE MODE

The Restorative mode allows you to adjust the speed of the micromotor, the type of handpiece used, manage the peristaltic pump, the spray, the optical fibre and the inversion of the rotating direction of the micromotor. By activating the pedal lever, the micromotor rotates progressively from minimum rpm to the set value.



MX2 - 1	<b>INSTRUMENT</b> . It identifies which instrument you are using. If there are several identical instruments, the indicator will mark 1 / 2 / 3 according to their position on the console.
1:1 ~	<b>TYPE OF HANDPIECE.</b> By pressing this icon, it is possible to choose which type of reducing or multiplying handpiece is being used on the micromotor. As the ratio changes, the number of rpms and the micromotor torque limits will vary. (For specific speed and torque values of handpieces, see par. 46)
100 rpm 25% 50% 75% MAX	<b>MICROMOTOR RPM.</b> By activating the foot pedal lever, regardless of its position, the micromotor turns at the set speed. The speed can be adjusted by the cursor, the + and – keys and the hotkeys. The speed limit of the micromotor depends on the ratio of the handpiece used. (for the speed values associated with the handpiece ratio, see par. 46).
	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.
	INSTRUMENT SPRAY. <b>SPRAY ON</b> : Air-water spray active when the pedal lever moves to the right. By pressing it again, you will activate the <b>SPRAY ON/OFF function</b> : the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: <b>SPRAY OFF</b> .
	<b>OPTICAL FIBRE.</b> It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments. To adjust the LED light delay, see par. 17.6.1 TIMER.
	<b>MICROMOTOR ROTATION INVERSION</b> . This function inverts the rmps rotating direction of the micromotor.

### 20.2 ENDODONTICS MODE

The Endodontics mode allows you to adjust the speed of the micromotor, the Torque value, the type of handpiece used, activate the auto reverse, auto stop and auto forward functions with related reverse time and cruise control, manage the peristaltic pump, spray, the optical fibre and inverse the micromotor rotating direction.

All these parameters can be memorized in 10 customizable and recallable programs.

By activating the pedal lever, regardless of its position, the micromotor rotates at the set speed.



MX2 - 1	<b>INSTRUMENT</b> . It identifies which instrument you are using. If there are several identical instruments, the indicator will mark 1 / 2 / 3 according to their position on the console.
<u> </u>	<b>TYPE OF HANDPIECE.</b> By pressing this icon, it is possible to choose which type of reducing or multiplying handpiece is being used on the micromotor. As the ratio changes, the number of rpms and the micromotor torque limits will vary. (For specific speed and torque values of handpieces, see par. 46)
PROGRAM 01 V	PROGRAM MENU. It indicates the selected program. (see par. 20.4)
AUTO FORWARD >	<b>AUTO FORWARD.</b> When you move the foot pedal lever to the right, the micromotor turns clockwise, whereas it inverts the rotating direction when it reaches the selected torque at the set time via the slide bar and then turns clockwise again. Only this function can activate the CRUISE CONTROL function.
AUTO REVERSE 🗸	<b>AUTO REVERSE</b> . When you move the foot pedal lever to the right, the micromotor turns clockwise, whereas it inverts the rotating direction when it reaches the set torque until you release the foot pedal.
AUTO STOP V	<b>AUTO STOP.</b> When you move the foot pedal lever to the right, the micromotor turns clockwise and stops when it reaches the set torque. To restart the rotation, you must set the pedal lever to zero and bring it back to the right.
RECIPROCAL	<b>RECIPROCAL.</b> This function will make the motor rotate with alternating rotation movements, with speed and torque pre-set automatically. When this mode is active, it is not possible to make changes to the other parameters.

100 rpm 25% 50% 75% MAX	<b>MICROMOTOR RPM.</b> By activating the foot pedal lever, regardless of its position, the micromotor turns at the set speed. The speed can be adjusted by the cursor, the + and – keys and the hotkeys. The speed limit of the micromotor depends on the ratio of the handpiece used. (for the speed values associated with the handpiece ratio, see par. 46)
0.35 Ncm +	<b>TORQUE VALUE.</b> It's a settable value ranging from 0.25Ncm to 53Ncm, depending on the handpiece used (for the torque values associated with the handpiece ratio, see par. 46). When the set resistance is reached, the micromotor will react according to the type of function activated (AUTO FORWARD, AUTO STOP or AUTO REVERSE).
Y	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.
	<ul> <li>CRUISE CONTROL. It can be exclusively activated in ENDODONTICS mode and with AUTO FORWARD function active. This function allows the micromotor to continue turning even if you release the foot pedal lever after activating it by pushing the foot pedal lever to the right.</li> <li>Activate the cruise control function by pressing the icon;</li> <li>Once the icon is pressed, an alert will pop up. To make sure that the activation of this function is desired, press YES;</li> <li>The activated icon will flash red;</li> <li>Move the lever to the right to activate the micromotor;</li> <li>The micromotor will continue to turn even if you release the foot pedal;</li> <li>To stop the micromotor while this function is activated, move the pedal lever to the right;</li> <li>To deactivate this setting, press the icon again.</li> </ul>
	WARNING: pay particular attention to the micromotor when using it with this function active, remember that the micromotor will continue to turn if this function is not deactivated. It could be dangerous for the operator and the patient if not used with care.
	INSTRUMENT SPRAY. <b>SPRAY ON</b> : Air-water spray active when the pedal lever moves to the right. By pressing it again, you will activate the <b>SPRAY ON/OFF function</b> : the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: <b>SPRAY OFF</b> .
	<b>OPTICAL FIBRE.</b> It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments. To adjust the LED light delay, see par. 17.6.1 TIMER.
$\bigcirc$	<b>MICROMOTOR ROTATION INVERSION</b> . This function inverts the rmps rotating direction of the micromotor.

## 20.3 SURGERY MODE

The surgery mode allows you to adjust the speed of the micromotor, the Torque value, the type of handpiece used, activate the auto reverse, auto stop and auto forward functions with related reverse time and cruise control, manage the peristaltic pump, spray, the optical fibre and inverse the micromotor rotating direction.

All these parameters can be memorized in 10 customizable and recallable programs.

By activating the pedal lever, regardless of its position, the micromotor rotates progressively from the minimum speed to the set value.



MX2 - 1	<b>INSTRUMENT</b> . It identifies which instrument you are using. If there are several identical instruments, the indicator will mark 1 / 2 / 3 according to their position on the console.		
<u>1:1 v</u>	<b>TYPE OF HANDPIECE.</b> By pressing this icon, it is possible to choose which type of reducing or multiplying handpiece is being used on the micromotor. As the ratio changes, the number of rpms and the micromotor torque limits will vary. (For specific speed and torque values of handpieces, see par. 46)		
PROGRAM 01 V	<b>PROGRAM MENU</b> . It indicates the selected program. (see par. 20.4)		
AUTO FORWARD >	<b>AUTO FORWARD.</b> When you move the foot pedal lever to the right, the micromotor turns clockwise, whereas it inverts the rotating direction when it reaches the selected torque at the set time via the slide bar and then turns clockwise again. Only this function can activate the CRUISE CONTROL function.		
AUTO REVERSE 🗸	<b>AUTO REVERSE</b> . When you move the foot pedal lever to the right, the micromotor turns clockwise, whereas it inverts the rotating direction when it reaches the set torque until you release the foot pedal.		
AUTO STOP V	<b>AUTO STOP.</b> When you move the foot pedal lever to the right, the micromotor turns clockwise and stops when it reaches the set torque. To restart the rotation, you must set the pedal lever to zero and bring it back to the right.		
100 rpm 	<b>MICROMOTOR RPM.</b> By activating the foot pedal lever, regardless of its position, the micromotor turns at the set speed. The speed can be adjusted by the cursor, the + and – keys and the hotkeys. The speed limit of the micromotor depends on the ratio of the handpiece used. (for the speed values associated with the handpiece ratio, see par. 46)		



0.35 Ncm +	<b>TORQUE VALUE.</b> It's a settable value ranging from 0.25Ncm to 53Ncm, depending on the handpiece used (for the torque values associated with the handpiece ratio, see par. 46). When the set resistance is reached, the micromotor will react according to the type of function activated (AUTO FORWARD, AUTO STOP or AUTO REVERSE).
Ø	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.
	INSTRUMENT SPRAY. <b>SPRAY ON</b> : Air-water spray active when the pedal lever moves to the right. By pressing it again, you will activate the <b>SPRAY ON/OFF</b> <b>function</b> : the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: <b>SPRAY OFF</b> .
-ÒĆ-	<b>OPTICAL FIBRE.</b> It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments. To adjust the LED light delay, see par. 17.6.1 TIMER.
$\bigcirc$	<b>MICROMOTOR ROTATION INVERSION</b> . This function inverts the rmps rotating direction of the micromotor.

## **20.4 PROGRAM MEMORIZATION**

It is possible to save up to 10 different programs to recall specific combinations of functions and set parameters:

- Set the desired values and parameters on the screen; ٠
- Press SAVE AS and immediately after the name of the program to which you want to associate the screen;
- By long-pressing on the name of the set program, you can change its name using the dedicated keyboard;
- With any parameter change on the screen, the program name will no longer be visible because it is no longer associated with that type of settings.



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# 21. <u>SCALER</u>

When you withdraw it from its instrument housing, it is activated and regulated by the foot pedal lever.

Prophylaxis and conservative tips are used.

All variants allow you to choose between direct or proportional mode.



<b>SCALER</b> <b>INSTRUMENT</b> . It identifies which instrument you are using. The indicates the two different types of scalers. SCALER 2: when the being used without ENDO mode. SCALER 1: when you are usin scaler with ENDO or PARO mode.			
100% 25% 50% 75% MAX	<b>SCALER POWER CONTROLLER</b> . The adjustment range goes from 0 to 100 in percentage. It can be adjusted by the cursor, the + and - keys and the shortcut keys. It can be managed in direct or proportional mode.		
	<b>DIRECT MODE</b> . In direct mode, the set power of the scaler will be reached automatically when activating the foot pedal lever. If you press it again, it activates the proportional function:		
	<b>PROPORTIONAL MODE</b> . In proportional mode, the power of the scaler is adjusted by the foot pedal lever: when the lever is in the zero position, the scaler is not active, whereas when you move the lever all the way to the right, the power will be progressively adjusted from a minimum to a maximum.		
	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.		
	INSTRUMENT SPRAY. <b>SPRAY ON</b> : Air-water spray active when the pedal lever moves to the right. By pressing it again, you will activate the <b>SPRAY ON/OFF function</b> : the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: <b>SPRAY OFF</b> .		
-` <b>`</b> _`-	<b>OPTICAL FIBRE.</b> It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments. To adjust the LED light delay, see par. 17.6.1 TIMER.		



# 22. ENDO SCALER (SATELEC)

It can be used in 3 different modes, which can be selected from the drop-down menu at the top right:

- with the "ENDODONTICS" function, endodontic tips are used.
- with the "PERIODONTOLOGY" function, periodontal tips are used.
- with the "SCALING" function, tips for prophylaxis and conservative are used (for all scaler models).



SCALER	<b>INSTRUMENT</b> . It identifies which instrument you are using. The number indicates the two different types of scalers. SCALER 2: when the scaler is being used without ENDO mode. SCALER 1: when you are using a Satelec scaler with ENDO or PARO mode.
100% 25% 50% 75% MAX	<b>SCALER POWER CONTROLLER</b> . The adjustment range goes from 0 to 100 in percentage. It can be adjusted by the cursor, the + and - keys and the shortcut keys. It can be managed in direct or proportional mode.
	<b>DIRECT MODE</b> . In direct mode, the set power of the scaler will be reached automatically when activating the foot pedal lever. If you press it again, it activates the proportional function:
	<b>PROPORTIONAL MODE</b> . In proportional mode, the power of the scaler is adjusted by the foot pedal lever: when the lever is in the zero position, the scaler is not active, whereas when you move the lever all the way to the right, the power will be progressively adjusted from a minimum to a maximum.
Ø	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.
	INSTRUMENT SPRAY. <b>SPRAY ON</b> : Air-water spray active when the pedal lever moves to the right. By pressing it again, you will activate the <b>SPRAY ON/OFF</b> <b>function</b> : the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: <b>SPRAY OFF</b> .
	<b>OPTICAL FIBRE.</b> It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments. To adjust the LED light delay, see par. 17.6.1 TIMER.

# 23. TURBINE

When you withdraw it from its instrument housing, it is activated and regulated by the foot pedal lever. The standard base turbine works in direct mode (the set speed will be reached automatically with the activation of the pedal lever), whereas it will work in proportional mode with the proportional valve (the speed is regulated by the pedal lever).



TURBINE 1	<b>INSTRUMENT</b> . It identifies which instrument you are using. If there are several identical instruments, the indicator will mark 1 / 2 / 3 according to their position on the console.
100%	<b>TURBINE SPEED REGULATOR</b> . The adjustment range goes from 0 to 100 in percentage. It can be adjusted by the cursor and the + and - keys.
	<b>DIRECT MODE</b> . This icon cannot be activated. It indicates the type of turbine regulation mode. In direct mode the set turbine speed will be reached automatically when the pedal lever is activated.
	<b>PROPORTIONAL MODE</b> . This icon cannot be activated, it indicates the type of turbine regulation mode. In proportional mode, the speed of the turbine is regulated by the pedal lever: when the lever is in the zero position, the turbine is stopped; by moving it to the right up to its maximum limit, there will be progressive regulation of the speed from a minimum to a maximum.
	<b>PERISTALTIC PUMP.</b> If it's not included on the unit, the icon will be deactivated. If it's present, the icon will turn the peristaltic pump on/off. When you activate it, a bar will appear to let you adjust the percentage of distilled water flow. The instrument spray must also be active for correct irrigation.
	INSTRUMENT SPRAY. <b>SPRAY ON</b> : Air-water spray active when the pedal lever moves to the right. By pressing it again, you will activate the <b>SPRAY ON/OFF function</b> : the air-water spray will activate when you move the pedal lever to the right and press the steel lever down at the same time. By pressing it again, you will deactivate the function: <b>SPRAY OFF</b> .
	<b>OPTICAL FIBRE.</b> It turns on / off the LED light on the handpiece if the OPTICAL FIBRE is present on the instruments. To adjust the LED light delay, see par. 17.6.1 TIMER.

# 24. <u>SYRINGE</u>

It is made up of a body, its hose and a metal handle complete with a removable and autoclavable spout.

It can be supplied as an option with heated water and air. The air/water supply is managed by the syringe itself.





# 25. CURING LIGHT

It activates automatically upon withdrawal. Read the manufacturer's instruction for use for functions.



WARNING: Avoid directing the light towards the eyes and use protective glasses or screen.

WARNING: It is recommended to have an authorized technician check the brightness of the curing light every six months, in order to be sure that correct polymerization has been carried out.

For use, maintenance, sterilization and cleaning of the handpieces, please refer to the instructions for use contained in the packages. Miglionico S.r.l. is not held responsible for any damage to things and/or people caused by failure to comply with or omission of the aforementioned provisions.



# 26. ORAL CAMERA ON DENTIST CONSOLE

For specifications on the MI-CAM oral camera functions, please read the separate manual supplied with the camera.

WARNING: the camera handpiece cannot be sterilized and it is not possible to use disinfectants. The use of disposable covers is mandatory.

## 27. HANDPIECES

INTERFACE REQUIREMENTS OF THE APPLICABLE HANDPIECES, BY DIFFERENT MANUFACTURERS										
	Motive water/ cooling		Air spray		Water spray		Electric supply		Electric supply optical fibre	
HANDPIECE TYPE	l/min	atm	l/min	atm	l/min	atm		power/W	Vdc	Amp.
TURBINE	35 / 50	2,2 / 4	15	3	0,15	2,5	xxxxxx	xxxxxx	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

WARNING: For use, maintenance, sterilization and cleaning of the handpieces, please refer to the instructions for use contained in the packages. Miglionico S.r.l. is not held responsible for any damage to things and/or people caused by failure to comply with or omission of the aforementioned provisions.

The applied handpieces must comply with the 93/42 EEC directive and the CEI-EN 60601-1 and CEI EN 60601-1-2 standards, accompanied by the CE declaration of conformity, conditions and warranty certificate and use and maintenance manual.





4

# 28. SAFETY/EMERGENCY SYSTEMS



1. Backrest safety system.

**2.** Cuspidor safety system (when it activates, it only stops the chair from moving upwards, all other movements are possible).

**3.** Chair arm safety system.

4. Chair lifting arm safety system.

The safety systems listed in the image above activate when an obstacle comes between the moving parts of the unit (except for safety system n.2). If activated, the entire chair lifts up to release the obstacle which hinders the movement (except for safety system n.2).

When a security system is activated, an intermittent buzzer sound will go off (except for safety system n.2).

WARNING: do not place hands or tools of any kind during the movement in the area indicated with the letter "B" in the image above.



### HANDPIECES SAFETY SYSTEM

When the turbine, micromotor or scaler handpieces are active, the chair's movements are blocked. The use of one instrument inhibits the action of the others, except the air-water syringe which is always active.



# 29. HEADREST

The headrest is adjustable. To adjust its position, you must:

- Rotate the lever all the way clockwise as shown in fig. "A";
- Position the headrest as shown in fig. "B";
- Close the knob as shown in fig. "C" and make sure the headrest is blocked.



Simply pull the headrest to move it upwards and press the button to move it downwards to move the headrest vertically.



WARNING: When adjusting the headrest position, the patient must not place their head on it.



## 30. <u>DENTIST'S CONSOLE CONFIGURATION</u> 30.1 <u>TOP DELIVERY VERSION</u>



The dentist's console configuration may vary based on the options purchased.

WARNING: When using dynamic instruments, the movements of the chair are blocked; this is to avoid accidental movements of the chair while operating on the patient.





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### **30.2 HANGING HOSES VERSION**



The dentist's console configuration may vary based on the options purchased.

WARNING: When using dynamic instruments, the movements of the chair are blocked; this is to avoid accidental movements of the chair while operating on the patient.

### 30.3 DENTIST'S CONSOLE HANDLE REMOVAL

To remove the handle, you must push the button and simultaneously pull the handle. To place it back, you need to insert the handle into its housing and push it until the button clicks.





# **31. PERISTALTIC PUMP**

This device is used to cool or irrigate the operating area with the desired sterile or non-sterile liquid. It can be used on the micromotor handpiece, when using handpieces with an external spray, and on the SATELEC scaler using the "steriljoint". The latter is placed between the scaling handpiece and the scaling hose and has a fitting for connecting the peristaltic pump hose.

To set up the system, proceed as follows:

- Connect the capsule complete with sterile silicone tubes to the housing (fig. A e B).
- Connect the tube with the needle to the bottle containing the liquid to be withdrawn, then connect the tube without terminal to the handpiece concerned.
- Tie the tube to the handpiece hose with the supplied ties.
- Withdraw the desired instrument from its housing.
- Press the 😓 button.
- Press one of the 2 following spray options:
- Move the pedal lever to the right (the peristaltic pump will be activated automatically when the instrument is withdrawn from its housing), or to the left (only the peristaltic pump will be activated with the consequent leakage of the liquid).

#### To adjust the speed of the peristaltic pump and consequent variation of the flow rate, go to the settings menu.







The pump body complete with silicone tube and accessories will be supplied separately to the dental unit, in a sterile independent packaging.



## 32. ASSISTANT'S CONSOLE CONFIGURATION



Hoses for surgical suction

Ergonomic handle to move the console

## 32.1 ASSISTANT'S CONSOLE FUNCTIONS





#### FUNCTIONS

¥*	Upward chair movement.
	Downward chair movement.
K	Upward backrest movement.
K	Downward backrest movement.
R.	Reset/zero position: It brings the chair to the zero position, to help the patient sit or get up from it.

	Rinsing position: It moves the backrest to the rinsing or patient rest position. A subsequent press on
PR	the icon brings the backrest back to the zero position.
+	Emergency position: It brings the chair to the previously memorized Trendelenburg position.
	It pours warm water into the cup and then activates the cuspidor flushing for a set time.
	Turns the operating light on/off. Press for 1 second.
	It pours cold water into the cup and then activates the cuspidor flushing for a set time.
ц ц	It activates the cuspidor flushing for a set time.

The assistant's console configuration may vary based on the options purchased.



# 33. FOOT CONTROL FUNCTIONS

## 33.1 STANDARD FOOT CONTROL/ STANDARD WIRELESS FOOT CONTROL



	FUNCTION WHEN NO INSTRUMENT IS SELECTED	FUNCTION WHEN AN INSTRUMENT IS SELECTED
1. JOYSTICK	<b>a</b> – chair up <b>b</b> – chair down <b>c</b> – backrest down <b>d</b> – backrest up	<ul> <li>a – chair up</li> <li>b – chair down</li> <li>c – backrest down</li> <li>d – backrest up</li> </ul>
2. RESET BUTTON	It activates the RESET/ZERO POSITION. See par. 17.1	Enable / disable constant water to the instruments. See par. 17.1 Deactivates water on/off function and activates constant water to the instruments. See par. 17.1
3. SIDE LEVER (towards A)	No function.	It activates the micromotor, turbine or scaler.
3. SIDE LEVER (towards B)	Operating light ON/OFF.	Air/water spray activation from the selected instrument (if available). It stores photos when the camera is withdrawn from its housing.
4. STEEL LEVER	Water to cup activation.	Air spray activation from the selected instrument (if available). It captures photos when the camera is withdrawn from its housing.
5. PR BUTTON	It activates the PR function. See 17.1.	It activates the PR function. See 17.1.

For all specifications on the oral camera functions, please read the separate manual supplied with the camera.

## 33.2 PUSH FOOT CONTROL/ WIRELESS PUSH FOOT CONTROL



	FUNCTION WHEN NO INSTRUMENT IS SELECTED	FUNCTION WHEN AN INSTRUMENT IS SELECTED
1. JOYSTICK	<b>a</b> – chair up <b>b</b> – chair down <b>c</b> – backrest down <b>d</b> – backrest up	<b>a</b> – chair up <b>b</b> – chair down <b>c</b> – backrest down <b>d</b> – backrest up
2. RESET BUTTON	It activates the RESET/ZERO POSITION. See par. 17.1	Enable / disable constant water to the instruments. See par. 17.1 Deactivates water on/off function and activates constant water to the instruments. See par. 17.1
3. CENTRAL STEEL LEVER	No function.	It activates the micromotor, turbine or scaler.
4. SMALL STEEL LEVER	Water to cup activation.	Air spray activation from the selected instrument (if available).
5. PR BUTTON	It activates the PR function. See 17.1.	It activates the PR function. See 17.1.

For all specifications on the oral camera functions, please read the separate manual supplied with the camera.

## 33.3 WIRELESS FOOT CONTROL INDICATIONS

If you use the foot control approximately for 3/4 hours a day, the foot control recharge can last up to 50/60 days. You can recharge the foot control by using the power cable supplied, or via the cable to be connected to the unit. However, it is recommended to recharge the foot control once a month to prolong the life of the battery.

The charging condition can be monitored by the LED on the foot control and by the acoustic buzzer: here is a summary table of the various signalling methods and their meaning.

LED MEANING WHEN THE FOOT CONTROL IS CONNECTED TO THE UNIT OR TO THE POWER SUPPLY	RED LED 🛑	GREEN LED	BUZZER ◀Ŵ
BATTERY CHARGING	SLOW BLINKING	OFF	OFF
Foot control in standby			
BATTERY CHARGING	SLOW BLINKING	1 BLINK PER	OFF
Foot control in use		SECOND	011
BATTERY CHARGED		055	OFF
Foot control in standby	TIALD	UT	011
BATTERY CHARGED		1 BLINK PER	OFF
Foot control in use	TIALD	SECOND	UFF

\* Even if the LED does not reach the FIXED state, the battery is charged after 6 hours of charging.

LED MEANING WHEN THE FOOT CONTROL IS NOT CONNECTED TO ANY CABLE	RED LED 🛑	GREEN LED	BUZZER 🗬 🔌
FOOT CONTROL IN USE	OFF	1 BLINK PER SECOND	OFF
BATTERY POWER > 20%	OFF	OFF	OFF
BATTERY POWER < 20%	1 BLINK EVERY 10 SECONDS	OFF	OFF
BATTERY POWER <= 10%	OFF	OFF	1 BEEPING EVERY 10 SECONDS

### **OPERATING SWITCH**

WARNING: the switch must always be placed in the ON position.



WARNING: The battery is a lithium battery and has a 6-month warranty.



# 34. HYDRO CASE CONFIGURATION

To access the internal part, it is necessary to remove the side panels, the external one first and then the internal one. To remove them, press the button on the upper part of the hydro case.

Once the cover is open, you can remove it.



To access the bottle/disinfectant compartment, open the front panel by pulling it outwards.



WARNING: do not remove any cover without first turning off the main switch of the unit.





### 34.1 HYDRO CASE WITH METASYS MST 1 ECO LIGHT SUCTION SYSTEM



It is recommended to follow the maintenance plans provided in the Metasys manual



### 34.2 HYDRO CASE WITH IN-BUILT AMALGAM SEPARATOR



It is recommended to follow the maintenance plans provided in the Durr manual.



## 34.3 HYDRO CASE WITH KDBD SYSTEM



It is recommended to follow the maintenance plans provided in the Durr manual.



# 35. HOW TO CHOOSE THE INSTRUMENTS WATER SUPPLY SYSTEM

If you want to choose the water supply system for the instruments, it is necessary to open the external cover of the unit (par. 34) and rotate the ball valve to the desired position.



Version with automatic disinfection system MDS, or MDS+ For details, see par. 30. (optional)



Version with independent water supply system with bottle. (optional)



Version with automatic disinfection system **MDS**, o **MDS+** <u>and</u> independent water supply system with bottle. (optional)

# 36. DISINFECTION SYSTEMS 36.1 MDS

The MDS automatic disinfection system mixes mains water with 1% of WK METASYS disinfectant liquid; this mixture reaches the instruments on the dentist's console.

The benefits of this mixture are listed in paragraph 36.4.



WARNING: The concentrated liquid level must be checked and topped up every week and the system must be serviced once a year. The maintenance is not covered by the warranty extension but is always to be borne by the customer.



WARNING: it is recommended to use only liquids supplied or recommended by MIGLIONICO for the purposes of correct functioning of the unit and the safety of both patients and operator.





### 36.2 <u>MMDS+</u>

The **MMDS+** automatic disinfection system has the same functions as the MMDS system with the possibility of starting an intensive disinfection cycle.

During the first phase, the device will carry out 2 washing cycles with the WK disinfectant liquid mixed at 3%, while during the second phase it will carry out 2 washing cycles with the WK disinfectant liquid mixed at 1%.

At the end of the 2 cycles, the unit is ready for operation.

During the cycle phases, the premixed liquid will pass through all the sections of the distribution block and the water ducts up to the ends of the handpieces if present.

#### 36.3 INTENSIVE DISINFECTION CYCLE MMDS+ ACTIVATION



1. Enter the "setting" menu and select INTENSIVE DISINFECTION

2. Press START

**3.** Put the instruments inside the housings of the system, as shown in the photo.



**4.** Press **START**. Once activated, the process cannot be stopped unless you restart the unit.

5. During the cycle, the unit will make a beeping noise every 5 seconds. The process is composed of 2 phases and it lasts 10 minutes totally. The first phase is composed by 2 washing cycles with the WK Metasys liquid at 3%, while the second one is composed by 2 washing cycles at 1%. It will not be possible to use the unit during the entire intensive disinfection cycle.

**6.** At the end of the process, the unit will make 3 beeping noises. Press OK to end the cycle.

WARNING: The concentrated liquid level must be checked and topped up every week and the system must be serviced once a year. The maintenance is not covered by the warranty extension but is always to be borne by the customer.

WARNING: If the "Disinfection cycle over" pop-up does not show, please start another disinfection cycle and contact the technical assistance.





### 36.4 INFORMATION ABOUT THE WK DISINFECTANT LIQUID

For years, several studies have shown how a dentist's clinic is a potential vehicle for the transmission of infections, which in some cases can also be very severe, both for patients and operators.

The risk can be caused by:

- Not properly sterilized handpieces;
- Contaminated water inside the spray hydro circuits of the unit.

The problem relating to the sterilization of contaminated instruments has now been solved thanks to the use of modern autoclaves; however, this is not enough to protect operators and patients from the risk of possible cross-infections.

One of the most critical and underrated aspects deals with the potential risk of cross-infections caused by the water supplied by the unit throughout the sprays.

Different studies, starting from the '60s, further investigated the topic of the contamination of the hydro circuits of dental units, which is caused by the presence of dangerous microorganisms in the water.

The mechanism that leads to the contamination of the water inside the dental unit can be summarized as follows:

Mains water which flows into the hydro circuits of the unit always contains microorganisms that, over time, adhere to the tube walls, thus generating a biofilm.

The biofilm is a concentrate of organic molecules and microorganisms on the surface of a material which creates a layer where they can grow and proliferate without restrictions.

Inside the dental unit, the biofilm can also contain other microorganisms coming from patients undergoing surgical treatment.

During surgical treatments, the bacteria of the patient's oral cavity can enter the hydric circuit of the unit through capillarity via the instruments, thus creating new biofilms or sticking to the already existing biofilms. So, the water microbic population increases sharply and it is constantly enhanced by potentially dangerous bacteria and viruses.

The activation of the instruments causes a continuous release of microorganisms of the biofilm, thus creating a great risk of cross infections.

The principal microorganisms inside the hydro circuits of the unit are: PSEUDOMONAS AERUGINOSA, LEGIONELLA, LACTOBACILLUS, SALMONELLA, STAPHYLOCOCCUS AUREUS, STREPTOCOCCUS, HIV, HBV, HCV, YEAST INFECTIONS, CHICKENPOX, MONONUCLEOSIS

#### WK LIQUID BY METASYS

It is a concentrate for sanitary water disinfection and the disinfection of dental unit piping systems. **CHEMICAL COMPOSITION** 

Water, hydrogen peroxide, stabilizers, and silver.

#### **CHARACTERISTICS OF THE PRODUCT**

Continuous disinfection of the dental unit piping systems based on hydrogen peroxide (diluted to 0,0235%). Continuous and dosed alimentation of hydrogen peroxide from a non-toxic concentrate. Biodegradable in compliance with the CEE Directive 84/449 CE Mark.

## 36.5 SUCTION HOSES WASHING SYSTEM

The suction hoses washing system washes the suction pipes and its circuits up to the suction motor (if it is a wet suction system).

#### **PROCEDURE:**



After that, the system begins to suck the liquid premixed with **Orotol plus** solution by **Dürr** diluted at 1.8%. The system will carry out a cycle sucking in 900ml of liquid.

#### ACOUSTIC SIGNALS:

SIGNAL	MEANING
Intermittent every 2 seconds	Cycle active and functioning
Extended for 5 seconds, stop suction	Washing cycle over
5 series of intermittent signals every 2 minutes	Absence of disinfectant liquid (pag 45)
Continuous and non intermittent	DANGER OF FLOODING. TURN OFF THE UNIT. CLOSE THE GENERAL WATER MAINS AND CONTACT TECHNICAL SERVICE IMMEDIATELY.



## 36.6 INFORMATION ON OROTOL PLUS DISINFECTANT LIQUID

#### Properties

Orotol<sup>®</sup> plus from the Dürr System-Hygiene line is a highly effective concentrate for the simultaneous disinfection, deodorization, cleaning and care of all dental suction systems, amalgam separators and cuspidors. The selected cleaning and disinfectant components ensure intensive, foam-free, material-friendly and environmentally friendly care. The daily use of Orotol<sup>®</sup> plus guarantees, even in cases of heavy contamination by germs or dirt (e.g. saliva, amalgam and dentin dust, blood, etc.), technically and hygienically flawless functioning of the suction systems.

#### **Product composition**

Orotol<sup>®</sup> plus is based on a combination of quaternary ammonium compounds, alkaline detergent components, complexing agents, special anti-foaming agents and additives in aqueous solution. 100 g of Orotol plus contain 4.4 g of dimethyl-dioctyl-ammonium chloride, 0.6 g of benzyl-dimethyl-dodecyl-ammonium chloride.

#### **Microbiological efficacy**

Orotol<sup>®</sup> plus has bactericidal, levuricidal, limited virucidal efficacy (enveloped viruses, incl. HBV, HCV, HIV and coronavirus), non-enveloped adenoviruses and noroviruses. Orotol<sup>®</sup> plus is included in the VAH list and IHO disinfectant list. Tested with organic filler in accordance with EN 13727, EN 14561, EN 13624, EN 14562, EN 14476, EN 17111 and DVV/RKI guidelines.





WARNING: during maintenance, cleaning and disinfection operations, protect your eyes, respiratory tract, mouth and skin by wearing glasses with a full-face shield, masks and disposable gloves.

For the disinfection and cleansing of all surfaces, MIGLIONICO has tested and selected Green & Clean SK produced by METASYS, therefore we recommend its exclusive use. If the customer uses any other product on the market, MIGLIONICO is not liable for warranty validity purposes.

You should not spray directly on the product's surfaces, but rather on a soft cloth to clean all parts of the dental unit and chair.

Before disinfecting the control panels, since they are soft touch systems, it is necessary to lock the keys. **NT DENTIST CONTROL PANEL** key locking procedure:

- Press this button for 3 seconds
- The display will be inactive for 20 seconds.



#### ASSISTANT CONTROL PANEL key locking procedure:

- Press these 2 icons at the same time:
- All the LEDs flash and the control panels remains inactive for 20 seconds.

To clean the cuspidor, here is a list of useful cleaning tips:

- **General maintenance:** clean the surface with warm water and delicate cleaner (we recommend the use of Green & Clean MB by METASYS) for the disinfection;
- Limestone, soap or mineral products stains: clean with an anti-scale cleaner. Complete the cleaning procedure by rinsing with warm water;
- Other kinds of stains: clean with an ammonia cleaner. Complete the cleaning procedure by rinsing with warm water;
- **Persistent stains:** if the covering film has not been damaged in all of its thickness, it is sufficient to use abrasive paste. To restore the initial brightness, use a polishing paste.

### 37.2 CLEANING AND CARE OF THE UPHOLSTERY

For cleaning the upholstery, Miglionico recommends using the FD 360 product from the Dürr System-Hygiene line.

#### Properties

FD 360 from the Dürr System-Hygiene line cleans and cares for the upholstery of the dental chair.

By using FD 360 it is possible to quickly and deeply eliminate even traces of dirt, stains or chromatic alterations that are difficult to remove because they are caused, for example, by unfixed fabric dyes. FD 360 cares and cleans thoroughly and without leaving residues; ensures a silky shiny appearance.

#### **Product composition**

FD 360 owes its action to a mixture of special surfactants, silicone compounds and protective components based on avocado oil.

#### Use

Use undiluted FD 360 cleaning liquid. Spray FD 360 on the surface to be cleaned and

immediately wipe with a soft cloth; for deeper cleaning, apply and rub FD 360 with the special sponge. In this way, a more efficient and deeper cleaning is achieved. With the combined use of FD 360 and the special sponge included in the set, it is possible to eliminate even stubborn stains or color alterations. Subsequently, remove the excess quantity of FD 360 with a dry cloth. If necessary, use FD 360 every day.

#### **Environmental impact**

The polyethylene and polypropylene packaging can be used for both material recovery and waste-to-energy processing. For recycling purposes, rinse the bottle with water. For further information, consult the safety data sheet.

#### **Physical data**

Aspect: milky white liquid

Density: D = 0,99 ± 0,05 g/cm<sup>3</sup> (20 °C) pH: 3,6 ± 0,5





## 37.3 STERILIZATION

The autoclavable parts on the unit are:

#### **DENTIST'S CONSOLE**



WARNING: for cleaning and sterilization of the handpieces, please read the instructions on the packaging.





## 38. <u>REGULAR CHECKS BY THE OPERATOR</u> 38.1 <u>DAILY</u>

• Cuspidor main filter cleaning.



- Suction filter cleaning (KDB or CAS1), if present.
- Surgical suction filters cleaning.



- Cuspidor cleaning using Green & Clean MB by METASYS.
- Surfaces cleaning using Green & Clean SK by METASYS as specified in the par. CLEANING AND DISINFECTION.
- Have the disinfectant liquids for surgical aspiration aspirated at the end of the day, before and after surgery. The use of the Orotol plus product from the Dürr System-Hygiene line is recommended. To be used as prescribed on the package.

## 38.2 WEEKLY

• Drain condensation from the air filter.



Refill the WK disinfectant tank. •



#### With DURR accessories

• If the amalgam separator or another DURR accessory is installed in the hydro case, please read the specific manual supplied with the dental unit.

#### With METASYS accessories

• If the amalgam separator or the MST1 ECO Metasys is installed, please read the specific manual supplied with the dental unit.

WARNING: the content of the tank has to be disposed of as specified in the respective manuals.





#### 38.3 COMPULSORY TESTS

TO BE CARRIED OUT ANNUALLY BY AN AUTHORIZED TECHNICIAN UPON REQUEST OF THE USER

- "AF" system check
- □ Water and air filtering system check
- □ "MDS" disinfection system check
- □ Replace the O'-rings on the micromotor connection
- □ Chair safety system check
- Cuspidor safety system check
- □ Assistant's arm safety system check
- □ Chair movements and memorizing functions check
- Internal electrical, hydric and air connections check
- □ Arm balancing check
- Headrest brake check
- □ Instrument functions check
- □ Instruments' water and air pressure check
- Curing light functions check
- Amalgam separator check
- □ Surgical suction check
- □ Instruct medical and auxiliary personnel in the use and maintenance of the dental unit

DATE	DESCRIPTION	TECHNICIAN SIGNATURE

# **39.** SAFETY TEST REPORT

Along with the dental unit, attached to this manual, you will find in paper format the result of the "TEST REPORT" carried out at our factory in Acquaviva delle Fonti (BA), relating to the "Safety Tests" carried out according to the CEI EN 60601 Standards -1 on the "NICE TOUCH" dental unit you purchased.

# 40. COMPATIBILITY RATES

The DM compatibility rates according to 60601-1-2 standard 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	80MHz22700MHz	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	2400MHz2570MHz	217Hz PM 50%	
9	5100MHz25800MHz	217Hz PM 50%	
Aspetti di emissione			
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Emission test	Compliance	Electomagnetic setting - guide	
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	Class B	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	Class A In compliance	It is possible to use the device in all establishments, including domestic establishments and those directly connected to	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	In compliance	the public low-voltage power supply network that supplies buildings used for domestic purposes	

### Immunity aspects

The Dental Unit produced by Miglionico 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	<ul> <li>6kV contact</li> <li>8kV air</li> </ul>	<ul> <li>6kV contact</li> <li>8kV air</li> </ul>	Floors should be made of 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 linee power supply lines		Main power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	IkV differential mode	IkV differential mode	Main 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% UT (>95% dip in UT) fo 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 seconds	< 5% UT (>95% dip in UT) fo 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 seconds	Main 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 ascpects 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 ensure 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
RF radiated EN 61000- 4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 IP from 150kHz to 80MHz d = 1,2 IP from 80 MHz to 800 MHz d = 2,3 IP 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).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the			

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.

#### Recommended separation distances between portable and mobile RF communications equipment and the device MIGLIONICO DENTAL UNIT

Dental units by Miglionico are 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	Separation distance according to frequency of the transmitter (m)			
power of transmitter (W)	From 150kHz to 80MHz d = 1,2 22P	Da 80MHz a 800MHz d = 1,2 22P	From 150kHz to 80MHz d = 1,2	
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.

(1) (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# 42. MICROMOTOR RATIO VALUES

## 42.1 MCX MICROMOTOR

RESTORATIVE

RATIO	MAX SPEED	MIN SPEED		MAX TORQUE	LIMIT TORQUE	MIN TORQUE
20:1	2'000 RPM	5 RPM		38.0 Ncm	38.0 Ncm (100%)	3.8 Ncm (10%)
16:1	2500 RPM	6 RPM		16,4 Ncm	16,4 (100%)	1,6 (10%)
10:1	4'000 RPM	10 RPM		12.3 Ncm	12.3 Ncm (100%)	1.2 Ncm (10%)
7:1	5714 RPM	14 RPM		14 Ncm	14 Ncm (100%)	1.4 Ncm (10%)
6:1	6'666 RPM	16 RPM		12.8 Ncm	12.8 Ncm (100%)	1.3 Ncm (10%)
						0.33 Ncm
4:1	10'000 RPM	25 RPM		3.3 Ncm	3.3 Ncm (100%)	(10%)
						0.42 Ncm
2:1	20'000 RPM	50 RPM		4.2 Ncm	4.2 Ncm (100%)	(10%)
						0.25 Ncm
1:1	40'000 RPM	100 RPM		2.5 Ncm	2.5 Ncm (100%)	(10%)
						0.11 Ncm
1:2	80'000 RPM	200 RPM		1.1 Ncm	1.1 Ncm (100%)	(10%)
			]			0.04 Ncm
1:5	200'000 RPM	500 RPM		0.4 Ncm	0.4 Ncm (100%)	(10%)

### ENDODONTICS

RATIO	MAX SPEED	MIN SPEED
128	312	100
70	571	100
64	625	100
32	1250	100
20	2000	100
16	2000	100
10:1	2000	100
8:1	2'000	100
4:1	2'000	100
2:1	2'000	100
1:1	2'000	100

MAX TORQUE	LIMIT TORQUE	MIN TORQUE
6,4	6,4	0,6
14	8	1,4
9,6	8	1
12,8	8	1,3
38	8	3,8
16,4	8	1,6
12,2	8	1,2
4.4	4.4	0.4
3,3	3,3	0.3
4.2	4.2	0.4
2.5	2.5	0.25



### 42.2 MX2 MICROMOTOR

### RESTORATIVE

		MIN
RATIO	MAX SPEED	SPEED
20:1	2'000 RPM	5 RPM
16:1	2500 RPM	6 RPM
10:1	4'000 RPM	10 RPM
7:1	5714 RPM	14 RPM
6:1	6'666 RPM	16 RPM
4:1	10'000 RPM	25 RPM
2:1	20'000 RPM	50 RPM
1:1	40'000 RPM	100 RPM
1:2	80'000 RPM	200 RPM
1:5	200'000 RPM	500 RPM

ENDODONTICS

RATIO	MAX SPEED	MIN
		SPEED
128	312	100
70	571	100
64	625	100
32	1250	100
20	2000	100
16	2000	100
10	2000	100
8:1	2'000	100
4:1	2'000	100
2:1	2'000	100
1:1	2'000	100

### SURGERY

		MIN
RATIO	MAX SPEED	SPEED
32:1	1250	3,1
20:1	2000	5
16:1	2500	6,2
1:1	40000	100
1:2	80000	200
1:5	200000	500

MAX TORQUE	MIN TORQUE
53.2 Ncm (100%)	5.3 Ncm (10%)
23,0 Ncm (100%)	2,3 Ncm (10%)
17.2 Ncm (100%)	1.7 Ncm (10%)
19,6 Ncm (100%)	2,0 Ncm (10%)
17.9 Ncm (100%)	1.8 Ncm (10%)
4.6 Ncm (100%)	0.46 Ncm (10%)
5.9 Ncm (100%)	0.6 Ncm (10%)
3.5 Ncm (100%)	0.35 Ncm (10%)
1.5 Ncm (100%)	0.15 Ncm (10%)
0.6 Ncm (100%)	0.06 Ncm (10%)

MAX TORQUE	MIN TORQUE
8	0,9
8	1,9
8	1,3
8	1,8
8	5,3
8	2,3
8	1,7
6,2	0.6
4,6	0.5
6	0.6
3,5	0,35

MAX TORQUE	MIN TORQUE
18	1,8
53,2	5,3
23	2,3
3,5	0,35
1,5	0,15
0,6	0,06

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Any serious incident occurred in connection with the medical device supplied by us must be reported to the Manufacturer, the Notified Body and the Competent Authority of the Member State in which it is based.



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