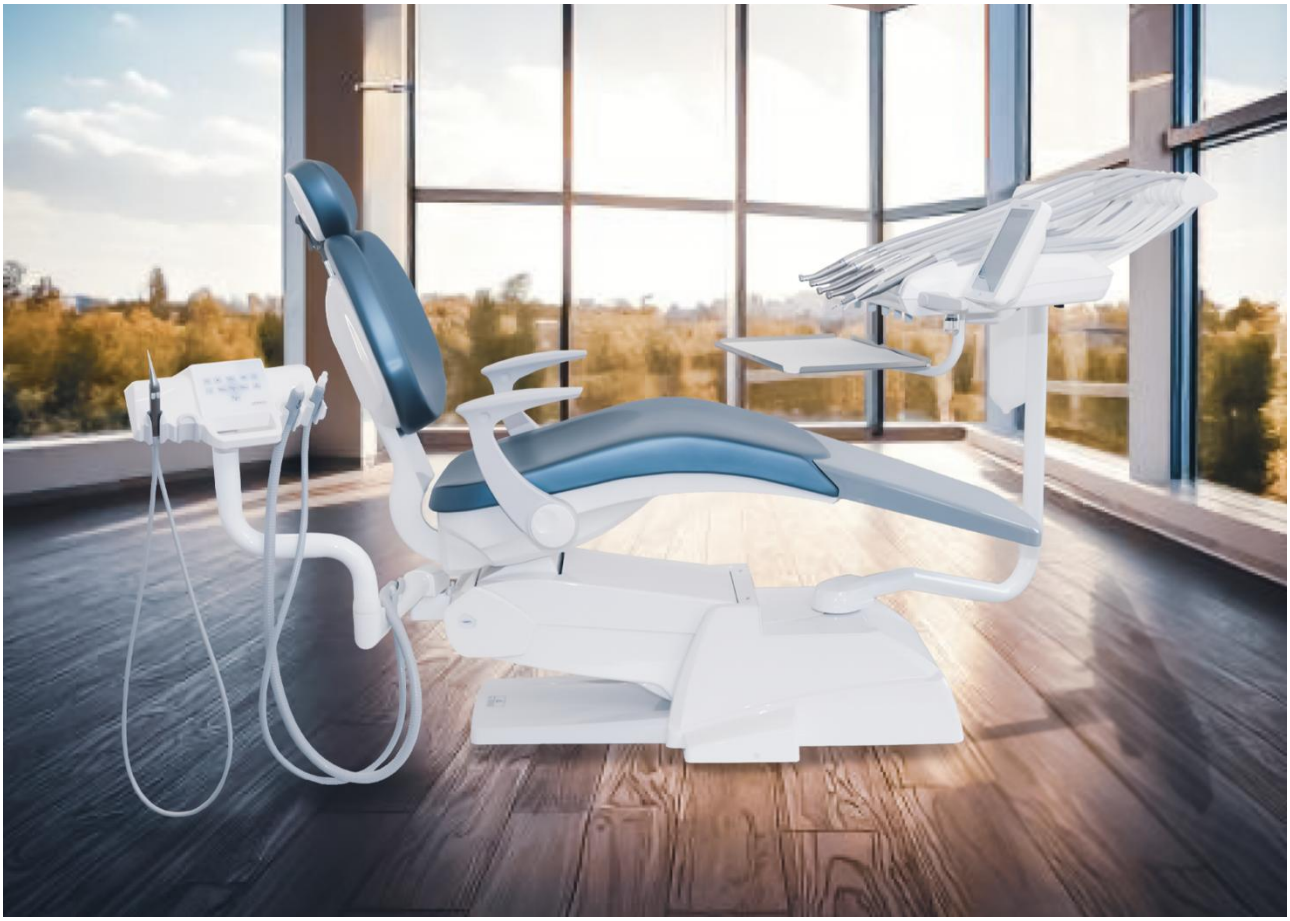
miglionico
DENTAL EQUIPMENT



USER AND MAINTENANCE MANUAL

NGF

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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 / *Serial Number*	UDI-DI di base / *Basic UDI-DI*
Poltrona ***Chair*** **(classe di rischio I)** ***(Risk class I)***	**SYNCRO**	**S.N. XXXXX**	80553499Z12110180D3

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 e ss.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' UE

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

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 treating 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. SYMBOLS

	ALTERNATING CURRENT	Hz	MAINS FREQUENCY IN HERTZ
	GROUND PROTECTION	VA	MAXIMUM POWER ABSORBED BY THE UNIT (IN VA)
	B TYPE DEVICE		INDICATION
	ON/OFF	MDS	MIXER
	WARNING	AF	ANTI RETRACTION SYSTEM TO HANDPIECES
V	NOMINAL VALUE OF VOLTAGE (IN VOLTS)		DON'T LEAN OR PUSH

DISPLAY SYMBOLS

	SPRAY OFF SPRAY ON		X-RAY VIEWER
	SPRAY ON/OFF		MICROMOTOR REVERSE ROTATION
	ASSISTANT CALL / DOOR OPENER		PERISTALTIC PUMP
	COLD WATER CUP FILLER AND CUSPIDOR		UPWARD CHAIR MOVEMENT
	WARM WATER CUP FILLER AND CUSPIDOR		DOWNWARD CHAIR MOVEMENT
	WATER TO CUSPIDOR		UPWARD BACKREST MOVEMENT
	ON/OFF OPTICAL FIBRE ON INSTRUMENTS		DOWNWARD BACKREST MOVEMENT
	MEMORIZE POSITION		ZERO POSITION
	OPERATING LIGHT		EMERGENCY POSITION
RM	RECALL MEMORY	PR	RINSING POSITION

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 info@miglionico.net
www.miglionico.net

DICHIARA CHE I PRODOTTI

RIUNITO MODELLO
❑ **"NICE GLASS"**
MATRICOLA_____DATA COLLAUDO_____

POLTRONA MOD. **"SYNCRO"**

MATRICOLA_____DATA COLLAUDO_____

Sono stati installati seguendo le procedure standard della Miglionico srl

IL TECNICO timbro e firma

_____

DATA INSTALLO

_____

DATI DEL CLIENTE

Rag. Sociale _____
Via _____
Città _____
Tel/fax _____
e-mail _____

CONCESSIONARIO timbro e firma

_____

Per ricevuta del manuale d'uso e manutenzione riunito	☐ SI ☐ NO
Per ricevuta del manuale d'uso e manutenzione telecamera	☐ SI ☐ NO
Per ricevuta del manuale d'uso e manutenzione lampada per compositi	☐ SI ☐ NO
Per ricevuta del manuale d'uso e manutenzione ablatore	☐ SI ☐ NO
Per ricevuta del manuale d'uso e manutenzione aspirazione chirurgica	☐ SI ☐ NO

☐ 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.

3.1 WARRANTY CONDITIONS

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 unit or the supply of a replacement unit is contemplated.

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

- **the “Installation, testing and warranty certificate” is not included in the registration procedure;**
- 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 a purchasing 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 3-year 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! ★★★★★

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 k.cea@miglionico.net or by phone (+39 3349910634) or our Customer Care Dept. customercare@miglionico.net

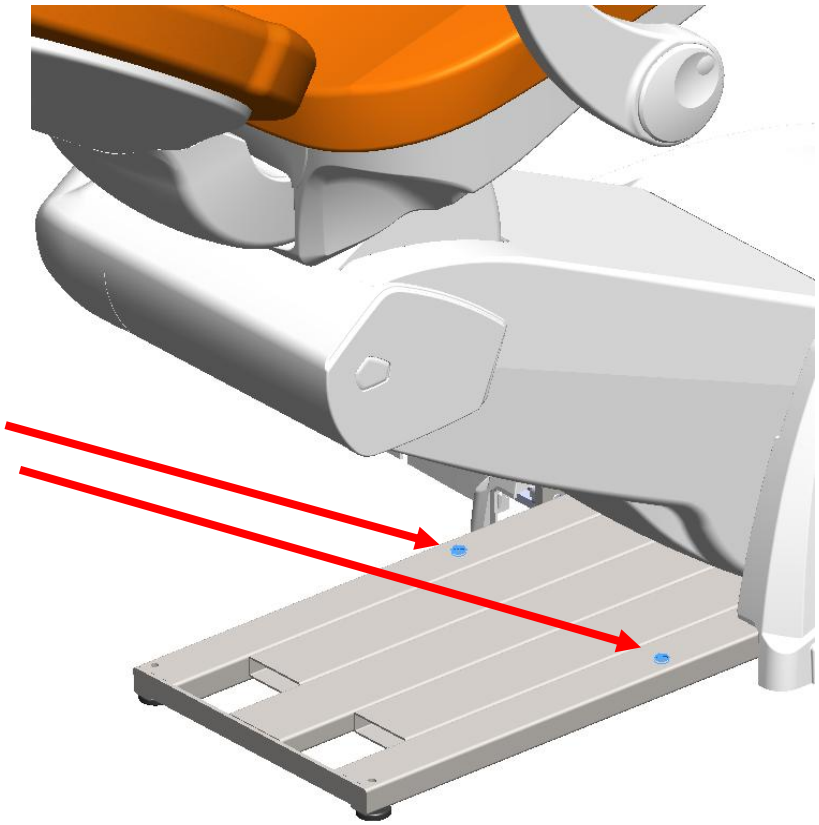
4. OPERATIONAL SETTING – ADVICES

4.1 OPERATIONAL SETTING

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 	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: • Hardness between 15 ÷ 20 F° (French degree) • Pressure between 150 ÷ 400 kPa (1.5 ÷ 4 bar) • Capability > 3l/min to 400 kPa (4 bar) In case of pressures higher than 400 kPa (4 bar) they have to insert an adequate pressure reducer before the unit installation. The supply tube has to be equipped with an arrest tap. 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.
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 ± 10% supply voltage. Absorbed power full-load 1400 VA The dental unit is equipped with a proper supply terminal board for a permanent connection to the power network, which has to have a 10 A - 250 V bipolar switch with differential intervention current IΔN=0.03 A, made in accordance with the European 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. The piping system 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.
Weights and dimensions	Chair weight Kg. 126 Chair + dental unit weight Kg. 197 Total weight (Chair, unit, operating light) Kg. 204

6. TECHNICAL DATA

6.1 UNIT

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

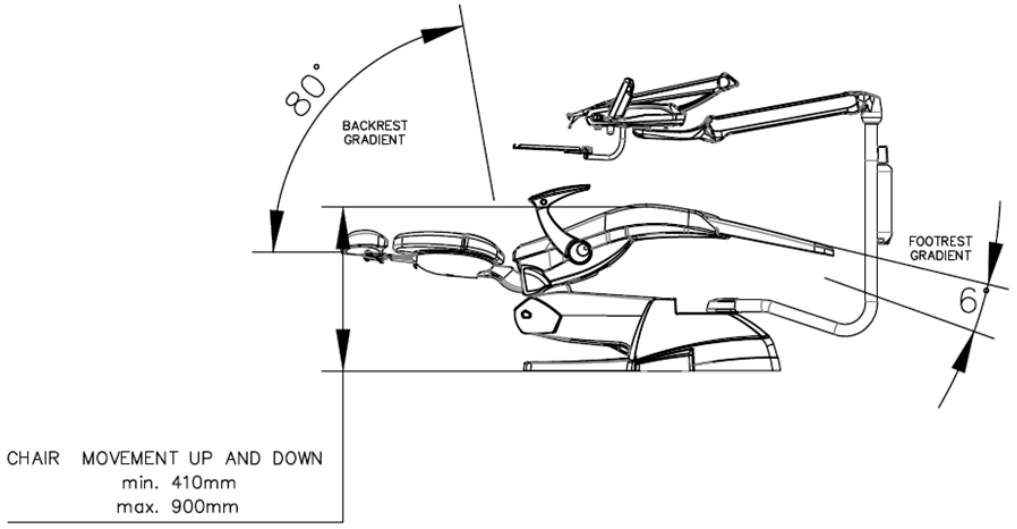
MODEL	NICE GLASS (NGF) – NICE TOUCH (NTF)
CLASSIFICATION (EN 60601-1)	Class I Type B
CLASSIFICATION (93/42 CEE)	Class II a
SUPPLY VOLTAGE	230 V
SINGLE PHASE ALTERNATIVE CURRENT	50/60 Hz
INTERMITTENT FUNCTIONING	1400 VA
ADDITIONAL WEIGHT SUPPORTED BY THE TRAY	KG 1,5

6.2 CHAIR

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

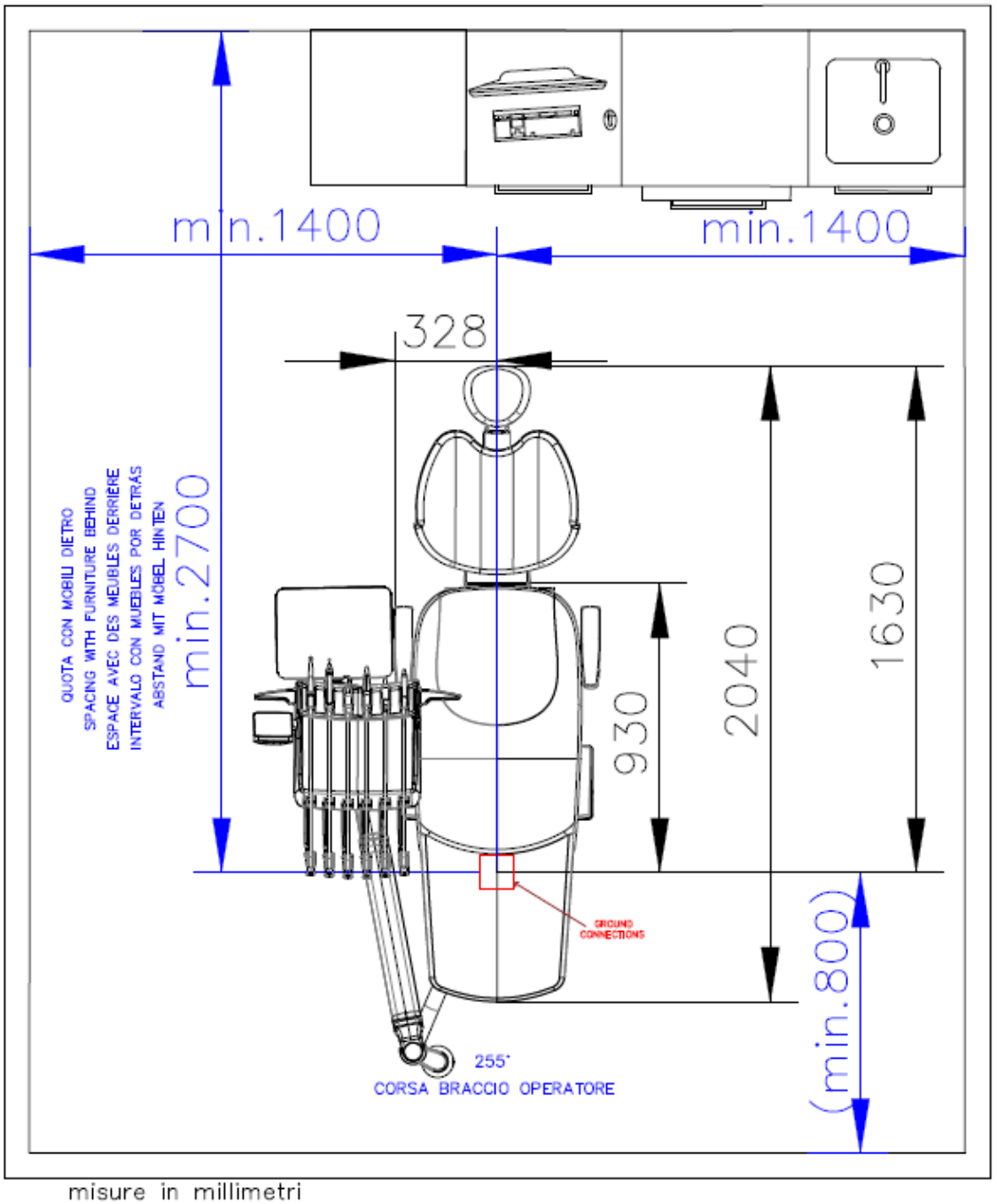
MODEL	SYNCRO (NSY)
CLASSIFICATION (EN 60601-1)	Class I Type B
CLASSIFICATION (93/42 CEE)	Class I
SUPPLY VOLTAGE	230 V
SINGLE PHASE ALTERNATIVE CURRENT	50 Hz
INTERMITTENT FUNCTIONING	18 min. of rest every 3 min. working
CHAIR MINIMUM HEIGHT	410 mm
CHAIR MAXIMUM HEIGHT	900 mm
BACKREST RISING MOTOR	ELECTRIC MOTOR 32 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

7. CHAIR MOVEMENT LIMITS



8. DIMENSIONS

IT - DIMENSIONI D'INGOMBRO
ENG - OVERALL DIMENSIONS
FRA - DIMENSIONS D'ENCOMBREMENT
ESP - DIMENSIONES GLOBALES
DE - GESAMTGRÖßE



misure in millimetri
measurements in millimeters
mesures en millimètres
medidas en milímetros
maße in millimeter

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 date set by technicians.
- the water network remains active when the clinic personnel is not the building.

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.

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.

11. PACKAGING DISPOSAL

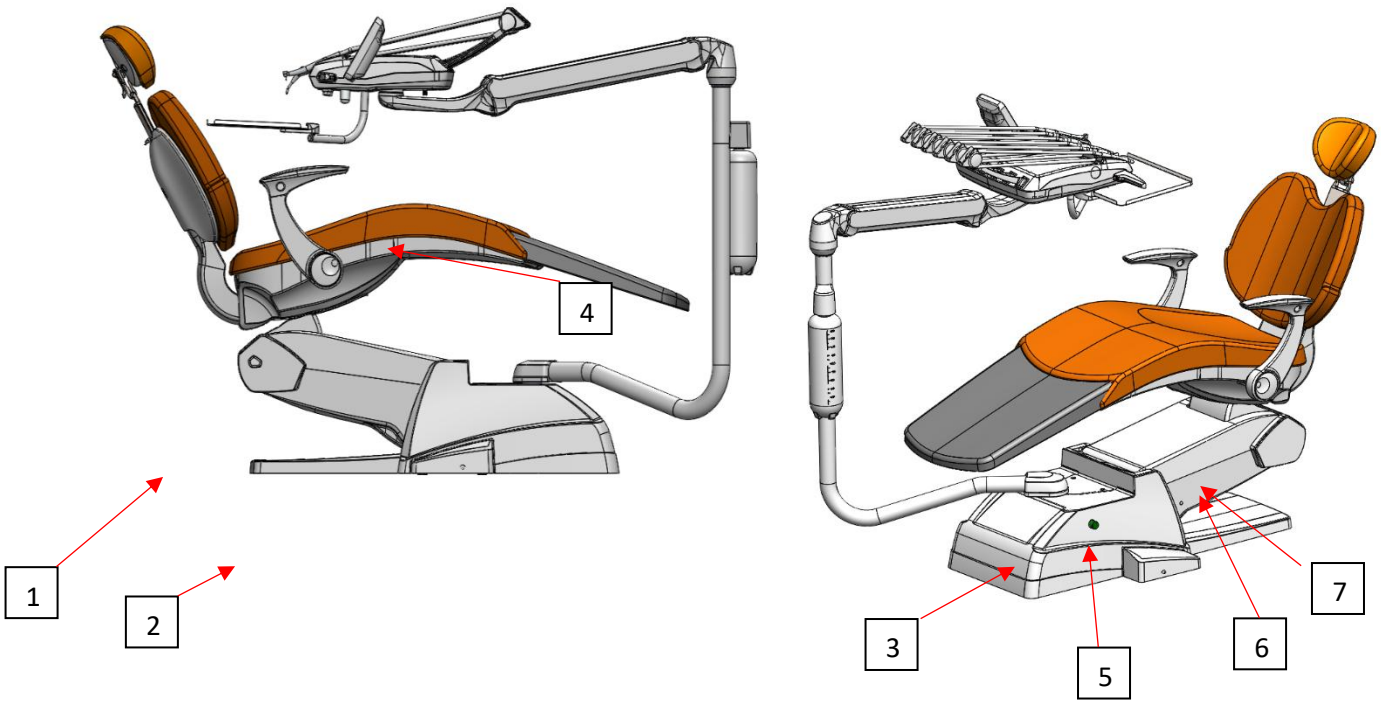
The materials used for the package are 100% recyclable and they have to be brought to an authorized garbage dump which will provide for the recycle or the disposal.

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. LABELS POSITION

13.1 EXTERNAL LABELS



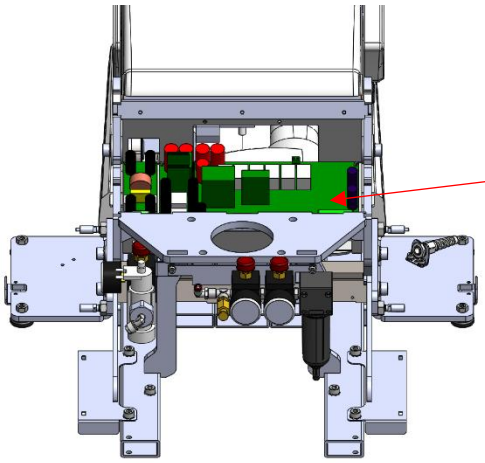
1	MIGLIONICO LOGOTYPE	
2	SAFETY DEVICE	ATTENZIONE: DISPOSITIVO DI SICUREZZA ANTI SCHIACCIAMENTO. WARNING: ANTI-CRUSH SAFETY DEVICE.
3	CE MARK	CE 0425
4	NG MODEL LOGO	
5	ON/OFF	
6	IDENTIFICATION LABEL	FAC SIMILE

7	USER MANUAL QR CODE	

13.2 FOOT CONTROL LABELS

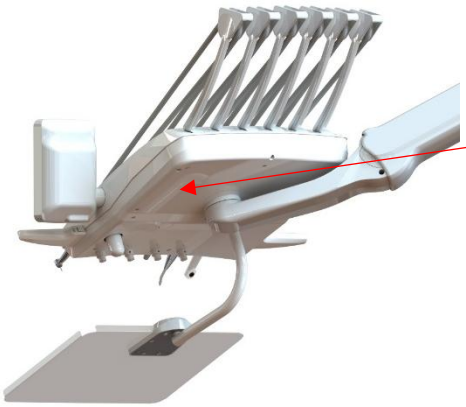
1	- RECALL MEMORY: PATIENT DESCENT - WATER TO HANDPIECES ON/OFF (WHEN THE INSTRUMENT IS SELECTED)	
2	RINSING POSITION	
3	JOYSTICK FOR CHAIR MOVEMENTS	

13.3 CHAIR BASE LABELS



1	GENERAL SUPPLY INPUT	

13.4 HYDRO CASE LABELS



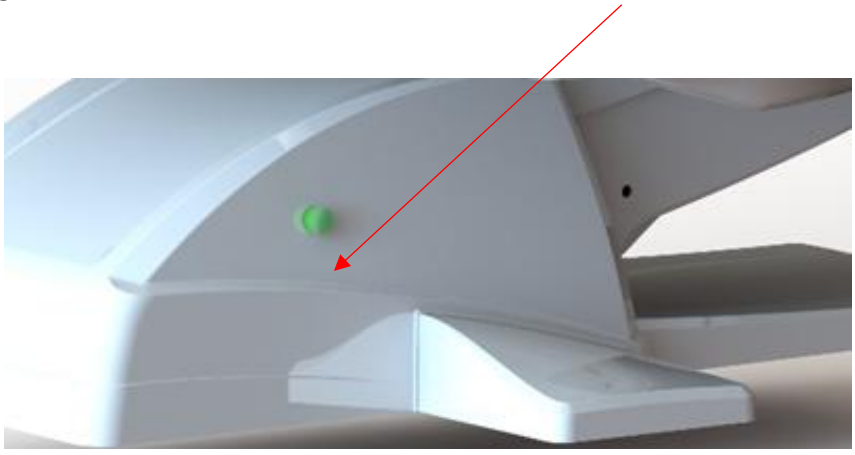
1	IDENTIFICATION TAG OF THE UNIT	

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).

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.



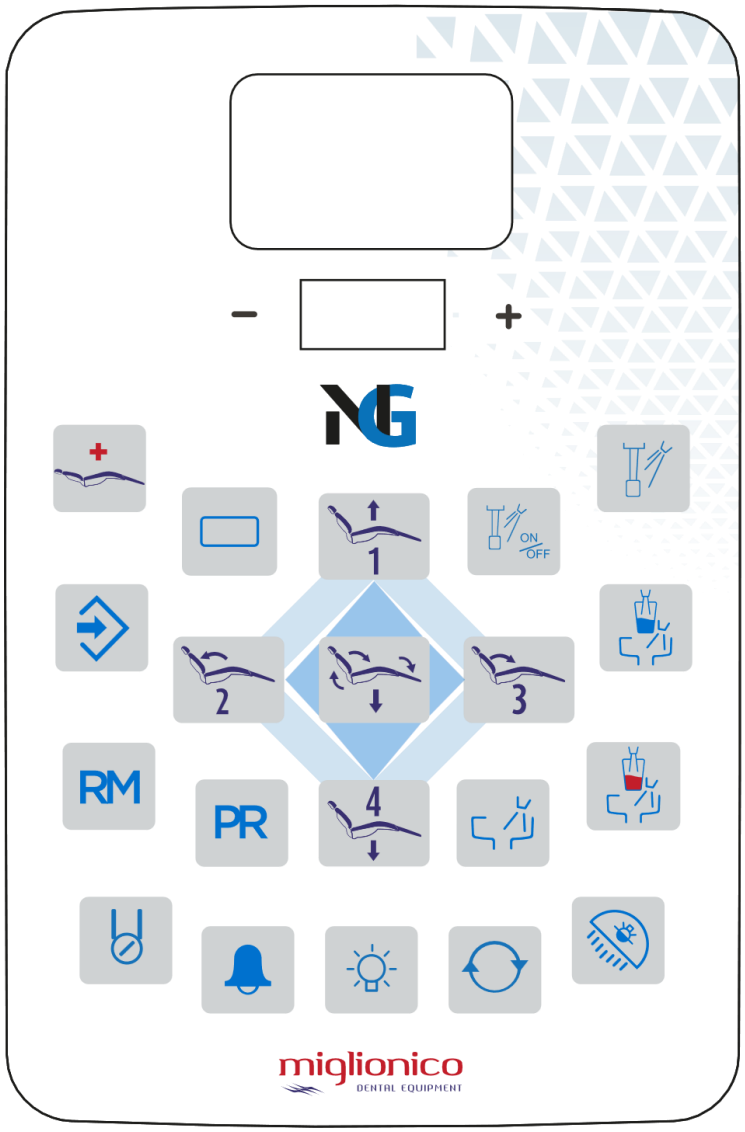
WARNING: The front carter at the base of the chair can be removed by authorized technician only because, even if the dental unit is switch off, there are some elements under voltage and there is an electric shock danger.

16. INSTRUCTIONS FOR USE

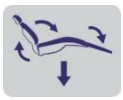
Operational instruments need to be withdrawn from their initial position and activated the foot control (see foot-control functions). The air-water syringe is not activated by the pedal but directly by using the buttons on it.
The dental unit is equipped with a functioning instruments priority system. 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.

ATTENTION: 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.

17. NG CONTROL PANEL



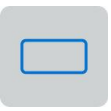
17.1 CHAIR FUNCTIONS

	Upward chair movement. If memorised, it recalls the working position n.1 along with the RM button. (On dentist's console only)
	Downward chair movement. If memorised, it recalls the working position n.4 along with the RM button. (On dentist's console only)
	Upward backrest movement. If memorised, it recalls the working position n.3 along with the RM button. (On dentist's console only)
	Downward backrest movement. If memorised, it recalls the working position n.2 along with the RM button. (On dentist's console only)
	Reset/zero position: It brings the chair to the zero position, to help the patient sit or get up from it.
	Thanks to this icon, it is possible to memorize the 4 positions of the chair (the 4 different positions are identified by the  icons), the emergency icon  (Trendelenburg position), the zero-position icon  (seat and backrest position adequate to allow the patient sitting/getting off the chair easily). To memorize the abovementioned positions, please proceed as follows: • Place seat and backrest in the desired position; • Press the MEMORIZE button;  • Press the button where you want to memorize the position within 3 sec. 

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.

	Rinsing/rest position: when you press this button, the backrest reaches the memorized position; if you press this button again, the backrest will go back to the initial position. To memorize this position, please proceed as follows: move the backrest in the most comfortable position for the patient when he needs to rest or rinse, press the memorize button  and then the PR button  within 3 seconds. In this way, the final position of the backrest is memorized and it will be recalled every time the  button is pressed.
	This button recalls the 4 memorized position. Press the button  and then press one of these buttons  within 3 seconds.
	Emergency position: it moves the chair to the previously memorized Trendelenburg position.

17.2 DENTIST'S CONSOLE FUNCTIONS

	Spray activation on turbine, micromotor and scaler when the instrument is withdrawn and the pedal lever is moved to the right (see foot control functions).
	Spray activation on turbine, micromotor and scaler when the instrument is withdrawn and the pedal lever is moved to the right and down at the same time (see foot control functions).
	Peristaltic pump on/off (if present).
	Micromotor rotation inversion.
	Led light on instruments on/off.
	X-ray viewer on/off (if the x-ray viewer optional is present).

17.3 HYDRO CASE FUNCTIONS

	NOT USED
	Operating light on/off. Press for 1 sec. IF PRESENT
	NOT USED
	NOT USED

17.4 OTHER FUNCTIONS

–	Button to reduce the value shown on the display.
+	Button to increase the value shown on the display.
	Display: it shows the maximum power of the scaler, the maximum speed of the micromotor, the turbine speed variation (if the proportional module is installed), the values of the "settings menu".
	Call assistant/door opener.

18. SETTINGS MENU

To adjust the cuspidor and cup filler time, the delay time of the switch-off of the fibre optic light on instruments and the peristaltic pump speed, please proceed as follows:

- Press the buttons + and − at the same time. When you hear a beep sound, release the buttons and you will see the following writing on the display: BA 06
  NOT AVAILABLE FOR THIS MODEL
- By pressing the doorbell icon you can adjust the cold water to cup filler function AF 06 .
  NOT AVAILABLE FOR THIS MODEL
- By pressing the doorbell icon you can adjust the warm water to cup filler function AC 06
  NOT AVAILABLE FOR THIS MODEL
- By pressing the doorbell icon you can adjust the optical fibre delay FO 06 .
  The number shown corresponds to the delay time of the switch-off of the fibre optic light on instruments after releasing the pedal lever, which can be adjusted by using the buttons + or − .
- By pressing the doorbell icon you can adjust the peristaltic pump. PP 99
  The number shown corresponds to the peristaltic pump speed, which can be adjusted by using the buttons + or −
- By pressing the doorbell icon once more you will exit the settings menu and the Miglionico logo will appear on your display.
  To save your changes, restart the unit from the main switch.

If the intensive disinfection system or the adaptive backrest system is present, the first option that will appear on the display after releasing the buttons + − will not be the activation time of the cuspidor flushing BA 06, but rather the activation menu for the backrest height adjustment.
To configure other settings, press the doorbell button

Keyboard lock: to disinfect the keyboards, read the "DISINFECTION" paragraph.

WARNING: if you want to stop the chair during automatic movement,

press one of these 4 icons 

19. INSTRUMENTS FUNCTIONS

19.1 TURBINE MODULE/HANDPIECE

After withdrawing it from its instrument housing, it is activated and regulated by the foot pedal lever.

The speed of the turbine is regulated by the pedal lever: when this is in its housing, the turbine is stopped; by moving the foot control lever all the way to the right, you can adjust its speed from 

up to the maximum value of 

.
This function (PROPORTIONAL) is optional. If not present, the turbine will start working at maximum speed as soon as the foot control lever moves from the rest position to the right (see foot control functions).

FUNCTIONS:

- By pressing this icon,  the air/water spray will be activated every time you move the foot control lever from the zero position to the right (see foot control functions).

- By pressing this icon,  the air/water spray will be activated every time you move the foot control lever from the zero position to the right and the steel lever at the base of the foot control down at the same time (see foot control functions).

The water flow is adjusted using the knob positioned under the dentist's console in correspondence of the instrument.

- By pressing this icon  the fibre optic on the instrument will light up.

- When the instrument is selected and the foot control lever is moved to the left, you will obtain the air-water spray function to wash the operating field without the turbine turning (see foot control functions).

- When the instrument is selected and the foot control lever is down, you will obtain the chip-air effect, that is a jet of air to dry the operating field without the turbine turning (see foot control functions).

- By pressing this icon  the peristaltic pump will be activated (if present). Different liquids can be used as an alternative to dental unit water (see peristaltic pump).

When selecting a turbine, some indication numbers will appear 

if the dentist's console is equipped with more than one turbine.
Each turbine will have different memorized parameters.

Make sure that the maximum operating pressure of the turbine has been checked at the time of installation, as indicated in the manual contained in the package.
For use, maintenance and cleaning of the handpieces, see the instructions contained in the packaging.

19.2 MICROMOTOR MODULE/HANDPIECE

After withdrawing it from its instrument housing, it is activated and regulated by the foot pedal lever.

The speed of the micromotor can be adjusted by the foot control lever: when the lever is in the zero position, the micromotor is off. On the other hand, if you move the lever to the right, the micromotor begins turning at the lowest speed but constantly increasing up to the maximum speed (40.000 g/min) if the display shows this value 

and the lever is pushed all the way to the right (see foot control functions).

The keys + and − set the value that goes from 

which corresponds to almost 1000 rpm up to 

which corresponds to almost 40.000 rpm.

The micromotor always starts from the lowest value, that is 1000 rpm. The maximum speed reached is the speed set on the display (value in percentage), moving the foot control lever all the way to the right.

FUNCTIONS:

- By pressing this icon,  the air/water spray will be activated every time you move the foot control lever from the zero position to the right (see foot control functions).

- By pressing this icon,  the air/water spray will be activated every time you move the foot control lever from the zero position to the right and the steel lever at the base of the foot control down at the same time (see foot control functions).

The water flow is adjusted using the knob positioned under the dentist's console in correspondence of the instrument.

- By pressing this icon  the fibre optic on the instrument will light up.

- When the instrument is selected and the foot control lever is moved to the left, you will obtain the air-water spray function to wash the operating field without the micromotor turning (see foot control functions).

- When the instrument is selected and the foot control lever is down, you will obtain the chip-air effect, that is a jet of air to dry the operating field without the micromotor turning (see foot control functions).

- By pressing this icon  the peristaltic pump will be activated (if present). Different liquids can be used as an alternative to dental unit water (see peristaltic pump).

When selecting a micromotor, some indication numbers will appear 

if the dentist's console is equipped with more than one micromotor.
Each micromotor will have different memorized parameters.

For use, maintenance and cleaning of the handpieces, see the instructions contained in the packaging.

19.3 SCALER MODULE/HANDPIECE

After withdrawing it from its instrument housing, it is activated and regulated by the foot pedal lever.

The vibration power is adjusted by the keys + and –
The adjustment range goes from A1 00 to A1 99.
it is activated by the foot pedal when you move the lever from the zero position to the right (see foot control functions).
If the scaler is produced by SATELEC, the following functions can be activated:

- From A1 00 to A1 30 , endodontic tips must be used;
- From A1 31 to A1 55, parodontid tips must be used;
- From A1 56 to A1 99, prophylaxis and conservative tips must be used.

FUNCTIONS:

- By pressing this icon,  the air/water spray will be activated every time you move the foot control lever from the zero position to the right (see foot control functions).

- By pressing this icon,  the air/water spray will be activated every time you move the foot control lever from the zero position to the right and the steel lever at the base of the foot control down at the same time (see foot control functions).

The water flow is adjusted using the knob positioned under the dentist's console in correspondence of the instrument.

- By pressing this icon,  the fibre optic on the instrument will light up (not available for all models).

- When the instrument is selected and the foot control lever is moved to the left, you will obtain the air-water spray function to wash the operating field without the scaler being active (see foot control functions).

- By pressing this icon  the peristaltic pump will be activated (if present). Different liquids can be used as an alternative to dental unit water (see peristaltic pump).

When selecting a scaler, some indication numbers will appear  if the dentist's console is equipped with more than one scaler.
Each scaler will have different memorized parameters.

For use, maintenance and cleaning of the handpieces, see the instructions contained in the packaging.

19.4 CURING LIGHT HANDPIECE/MODULE

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

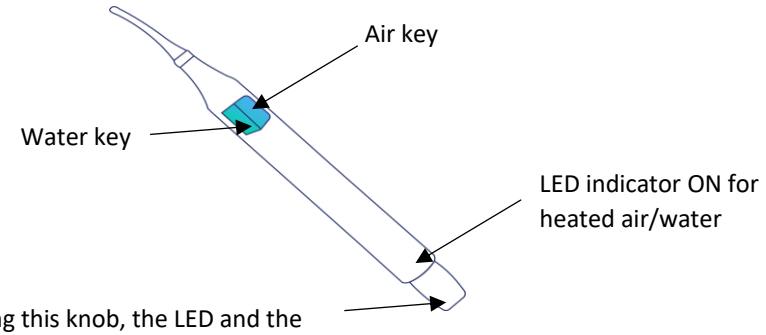
WARNING: Avoid directing the light towards the eyes and use protective glasses or screen.

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.

19.5 SYRINGE MODULE

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.



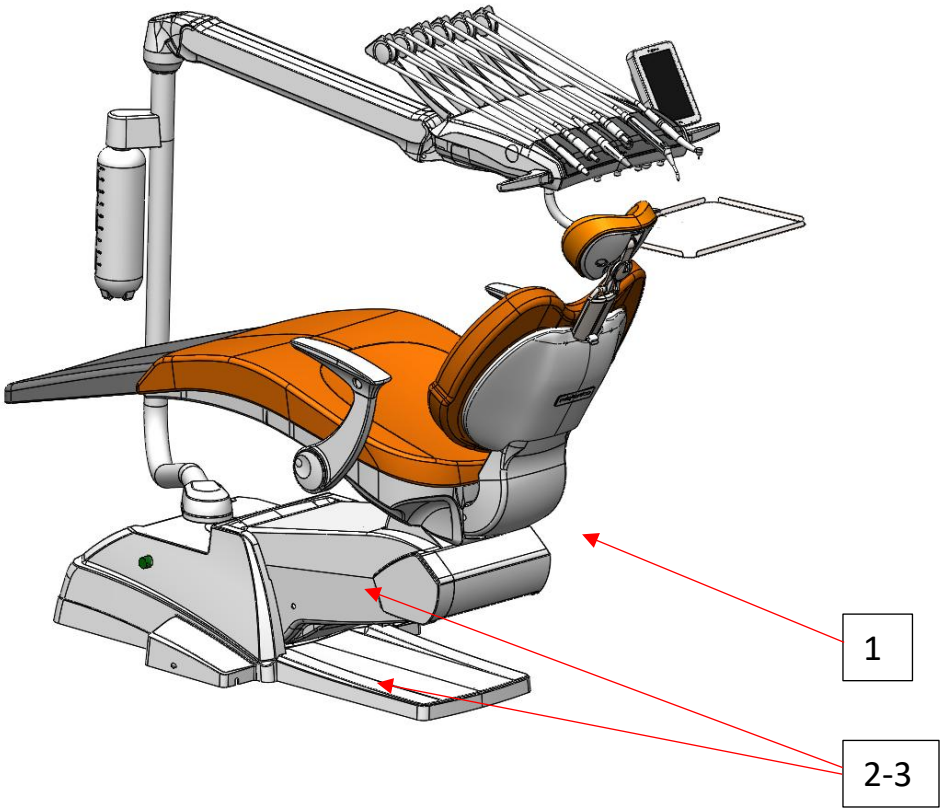
19.6 HANDPIECES

INTERFACE REQUIREMENTS OF THE USABLE HANDPIECES, DIFFERENT MODELS/MANUFACTURERS										
	Motive air/ Cooling air		Air spray		Water spray		Electric supply		Electric supply for 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	xxxxxxx	xxxxxxx	3,5	1
MICROMOTOR	36 / 50	2,2 / 5	15	3	0,15	2,5	0 ÷ 24Vdc	65	3,5	1
SCALER	xxxxx	xxxxx	xxxxx	xxxxx	0,15	2,5	24 Vac	100	3,5	1

WARNING: For use, maintenance, sterilization and cleaning of the handpieces, please refer to the instructions for use contained in the package of the handpieces. 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 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.

20. SAFETY/EMERGENCY SYSTEMS



1. Backrest safety system.

2/3. Upper and lower pantograph safety system.

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

When a security system is activated, an intermittent buzzer sound will go off.

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.

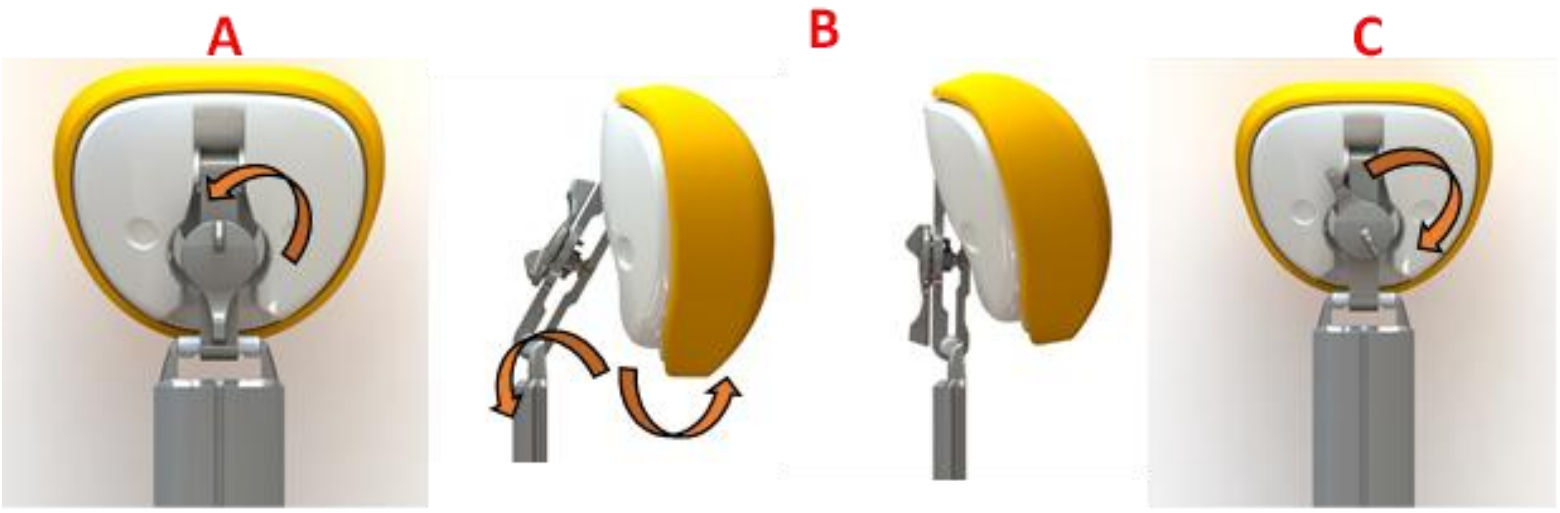
HANDPIECES SAFETY SYSTEM

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.

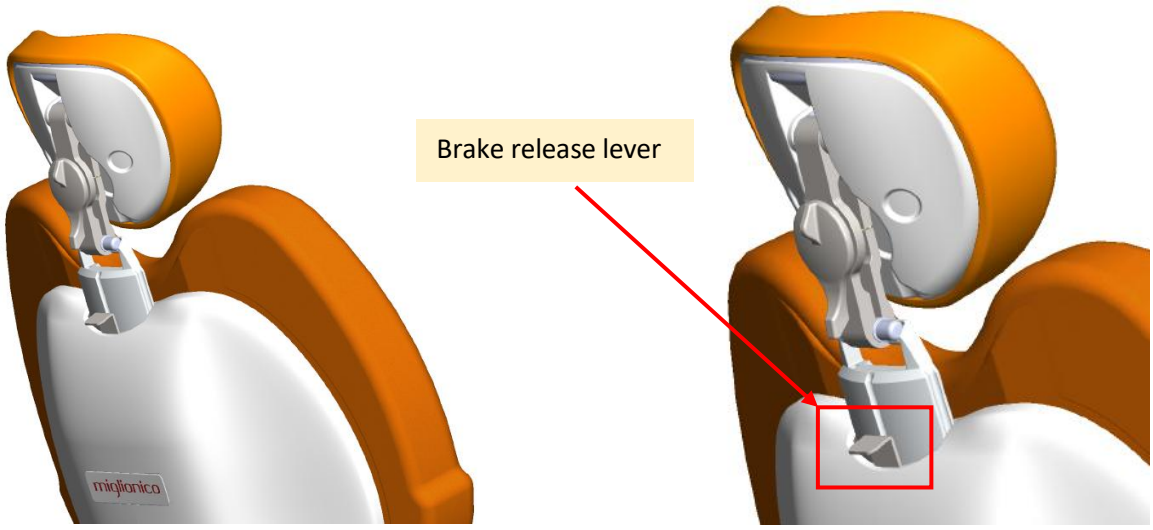
21. HEADREST

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.



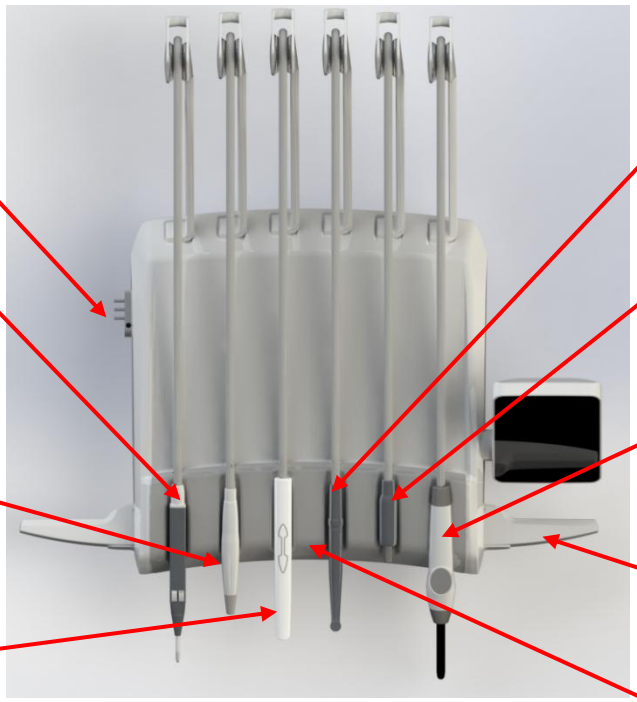
Simply pull the headrest to move it upwards and press the button to move it downwards to move the headrest vertically.

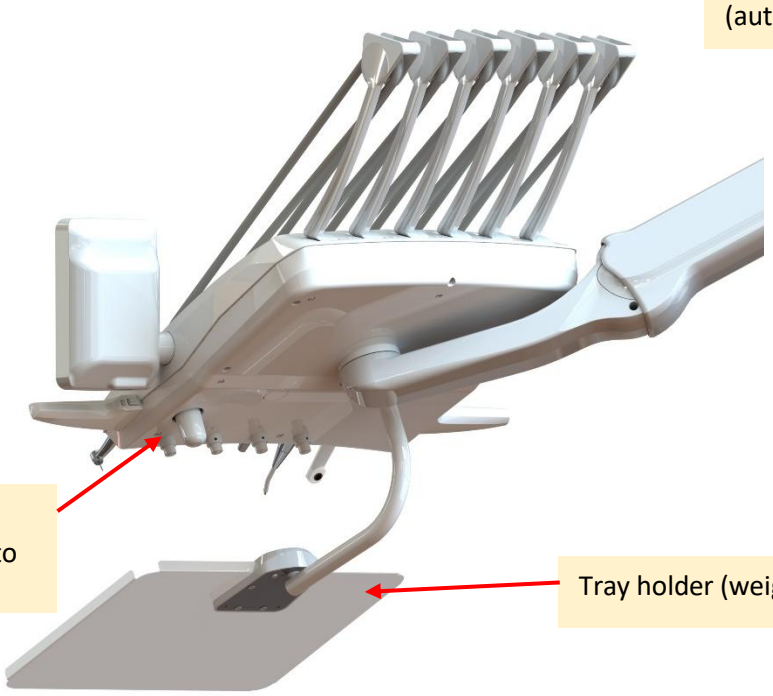


WARNING: When adjusting the headrest position, the patient must not place their head on it.

22. DENTIST'S CONSOLE CONFIGURATION

22.1 TOP DELIVERY VERSION

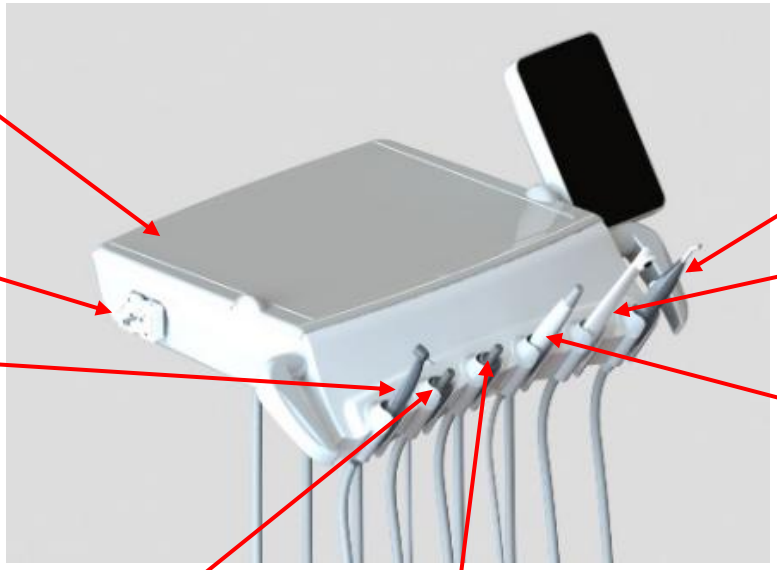




The dentist's console configuration may vary based on the options purchased.

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.

22.2 HANGING HOSES VERSION

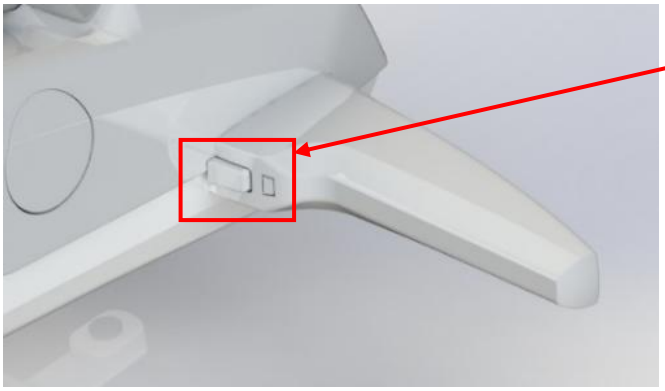


The dentist's console configuration may vary based on the options purchased.

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.

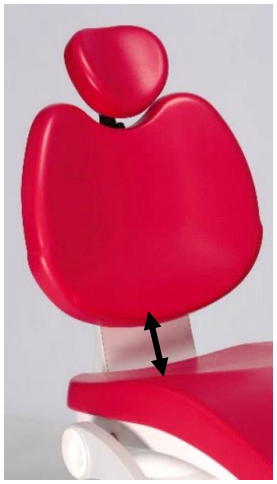
22.3 DENTIST'S CONSOLE HANDLE REMOVAL

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.



22.4 ADAPTIVE BACKREST MOVEMENT

1. Enter the TIME SETTINGS menu by pressing both + and – at the same time
   After releasing the buttons, one of the following setting will be displayed: SHORT MED TALL
2. Press the button **+** or **–** to set the backrest position.

SHORT	MED	TALL
Pediatric or short patient	Average height patient	Tall patient
		

3. After setting the backrest position, press 

WARNING: the height of the backrest must be adjusted before the patient lays his back on the backrest.

23 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.

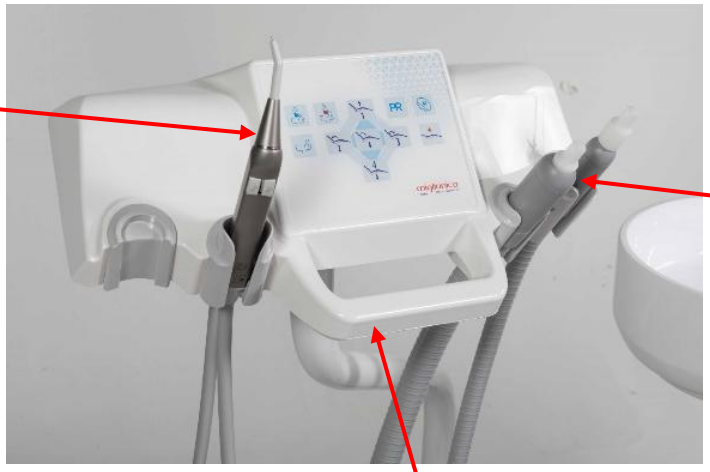
Fig. A

Fig. B

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

24 ASSISTANT'S CONSOLE CONFIGURATION

Angled syringe with adjustable spout (the handle is removable and autoclavable at 135°).



Hoses for surgical suction

Ergonomic handle to move the console

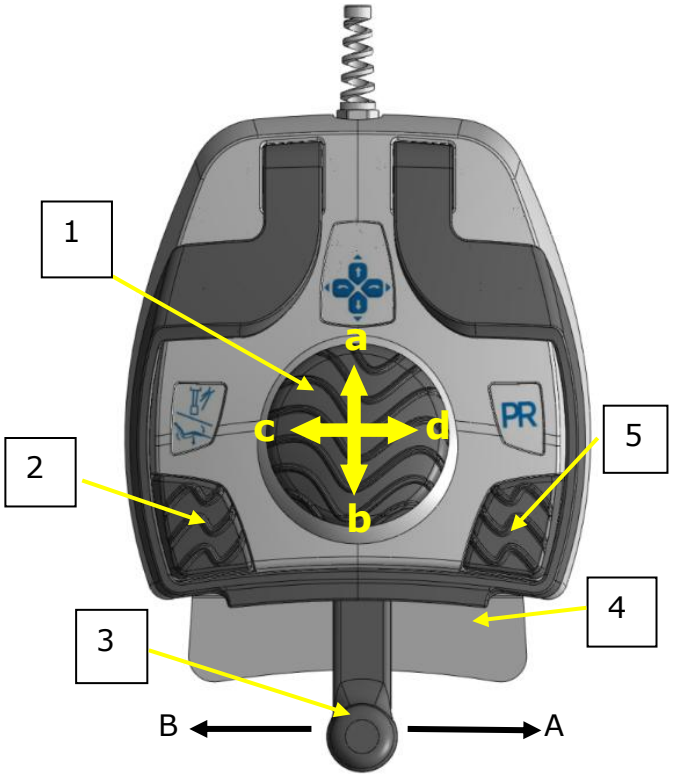
Assistant's control panel.

For more information about functions, please read par. 17.1 and 17.3

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

25 FOOT CONTROL FUNCTIONS

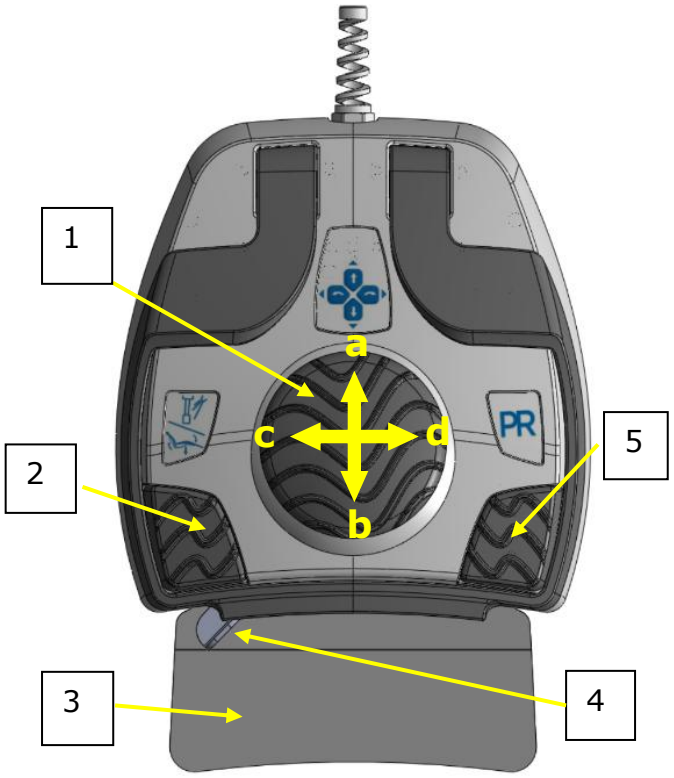
26.1 STANDARD FOOT CONTROL/ STANDARD WIRELESS FOOT CONTROL



	FUNCTION WHEN NO INSTRUMENT IS SELECTED	FUNCTION WHEN AN INSTRUMENT IS SELECTED
1. JOYSTICK	**a** – chair up **b** – chair down **c** – backrest down **d** – backrest up	**a** – chair up **b** – chair down **c** – backrest down **d** – 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. 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.

26.2 PUSH FOOT CONTROL/ WIRELESS PUSH FOOT CONTROL



	FUNCTION WHEN NO INSTRUMENT IS SELECTED	FUNCTION WHEN AN INSTRUMENT IS SELECTED
1. JOYSTICK	**a** – chair up **b** – chair down **c** – backrest down **d** – backrest up	**a** – chair up **b** – chair down **c** – backrest down **d** – 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.

26.3 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.

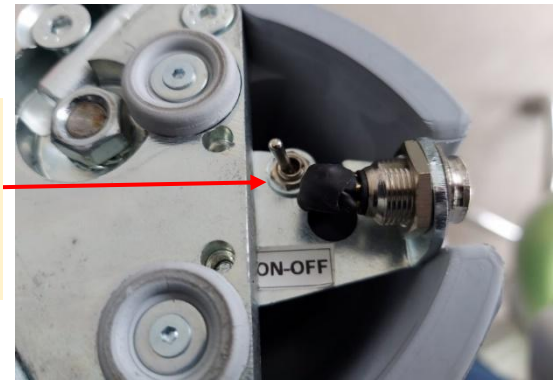
LED MEANING WHEN THE FOOT CONTROL IS CONNECTED TO THE UNIT OR TO THE POWER SUPPLY	RED LED	GREEN LED	BUZZER
BATTERY CHARGING Foot control in standby	SLOW BLINKING	OFF	OFF
BATTERY CHARGING Foot control in use	SLOW BLINKING	1 BLINK PER SECOND	OFF
BATTERY CHARGED Foot control in standby	FIXED*	OFF	OFF
BATTERY CHARGED Foot control in use	FIXED *	1 BLINK PER SECOND	OFF

* 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.

27. HOW TO SELECT INSTRUMENTS WATER SUPPLY SYSTEM

If you want to choose the water supply system for the instruments, rotate the ball valve under the dentist's console to the desired position.

Version with independent water supply system with bottle.

$H_2O_+ \Leftrightarrow H_2O$
BOTTLE

29 MAINTENANCE

29.1 CLEANING AND DISINFECTION

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 (UPHOLSTERY EXCLUDED, see par. 30.2), 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.
NG DENTIST CONTROL PANEL key locking procedure**:**

- Press both + and − for 3 seconds.
- After releasing these keys, press  .
- The display will show the word:  . All the led lights will be flashing and the control panel 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.

29.2 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

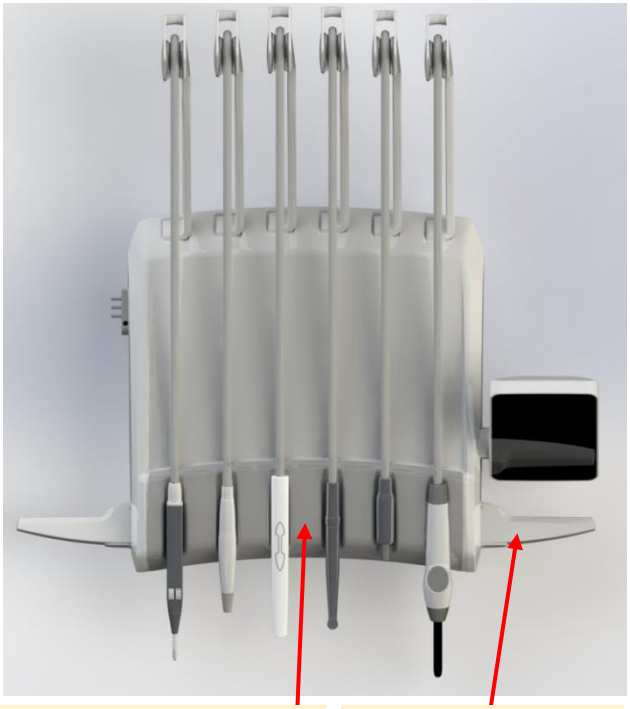
Aspect: milky white liquid

Density: D = 0,99 ± 0,05 g/cm³ (20 °C) pH: 3,6 ± 0,5

29.3 STERILIZATION

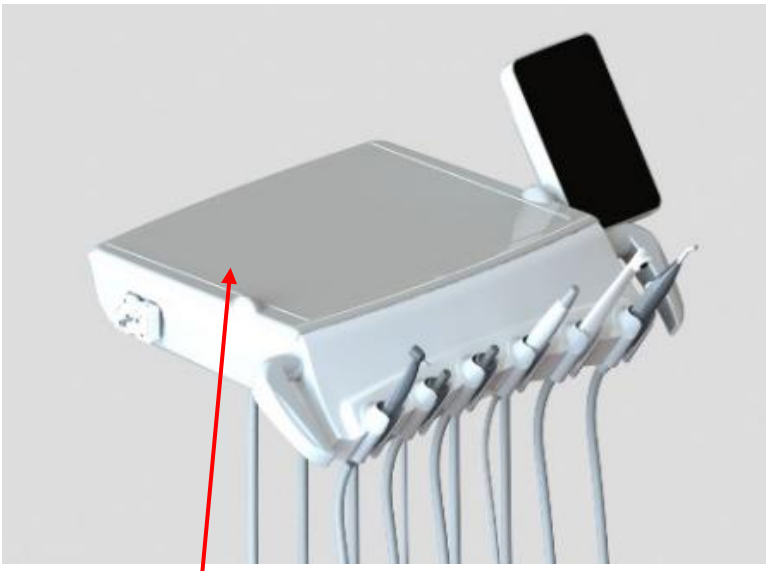
The autoclavable parts on the unit are:

DENTIST'S CONSOLE



Removable instrument protection (autoclavable at 135°)

Removable handle (autoclavable at 135°)



Tray-holder mat (weight load kg 1,5 - autoclavable at 135°)

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

29.4 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	TECHNICAL MANTAINANCE DESCRIPTION	TECHNICIAN'S SIGNATURE

30 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 GLASS” dental unit you purchased.

31 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	80MHz2700MHz	1kHz AM 80%
27	380MHz390MHz	18Hz PM 50%
28	430MHz470MHz	18Hz PM 50%
9	704MHz787MHz	217Hz PM 50%
28	800MHz960MHz	18Hz PM 50%
28	1700MHz1990MHz	217Hz PM 50%
28	2400MHz2570MHz	217Hz PM 50%
9	5100MHz5800MHz	217Hz PM 50%

32 TEST REPORTS AND WARNINGS

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

Emission RATES		
Emission test	**Compliance**	**Electromagnetic 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 the public low-voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/ flicker emissions IEC 61000-3-3	In compliance	

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 environment - guide**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	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 power supply lines	±2kV power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode	±1kV 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 aspects at r.f			
Miglionico Dental Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the navigator should 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 distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 √P from 150kHz to 80MHz d = 1,2 √P from 80 MHz to 800 MHz d = 2,3 √P from 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
RF radiated EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.			

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 power of transmitter (W)	**Separation distance according to frequency of the transmitter (m)**		
	From 150kHz to 80MHz d = 1,2 √P	From 80MHz to 800MHz d = 1,2 √P	**From 150kHz to 80MHz d = 1,2 √P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Notes: (1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. (1) (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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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