



CHIRANA
Medical STARÁ
TURÁ

**Dental unit
Smile Mini 04**

Instructions for use





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1. Operating warnings

1.1. Symbols



ATTENTION

By this symbol are marked the attentions in the instructions for use, which require special attention. Before the first using of the product, please be familiar with all of the attentions written in this instructions for use.



By this symbol are marked other important attentions written in this instructions.

1.2. Target group

This Instructions for use is intended for the dentists and personnel of the dentistry.



The parts of the dental unit, which are in the contact with the patient, dentist and working personnel are not carcinogenic, mutagen, toxic and they do not content phthalates.

1.3. Service

The name and the address of the organization, which accomplishes the repair of the device require from the supplier of the device.



If the device is sold from the original user to the other user is necessary to notify the change of the user to the supplier of the device resp. to the producer.

1.4. Operating book

This book is intended for the records about the installation, repairs and regular revisions.



Each step should be recorded into this book and it is important to do the step only by the service technician.

1.5. Warranty conditions

You can download the guarantee conditions at the following address:

www.chirana.eu/preview-file/guarantee-conditions-units-2944.pdf

2. Purpose and use

The dental unit Smile Mini 04 is intended only for the use in the field of dentistry. The handling of the device can be done only by the qualified medical personnel.



ATTENTION

The unit is intended for the explosion-proof surrounding.

3. Assembly and installation

Assembly and installation of the dental unit Smile Mini 04 can perform a service technician of CHIRANA Medical inc. Stara Tura and service staff from companies that are authorized to perform that activity. Assembly and installation shall be carried out according to the instructions for assembly and installation of Smile Mini 04 and according to the installation plan Smile Mini 04

Smile dental unit Mini 04 is classified according to the type of protection against electric current as a Class of I. and can be installed only in rooms where the wiring complies the requirements of the national standards.

The device may be operated only by staff familiar with these instructions for use.



ATTENTION

- To eliminate the risk of electric shock, this device must be connected to the mains supply with protective earthing.



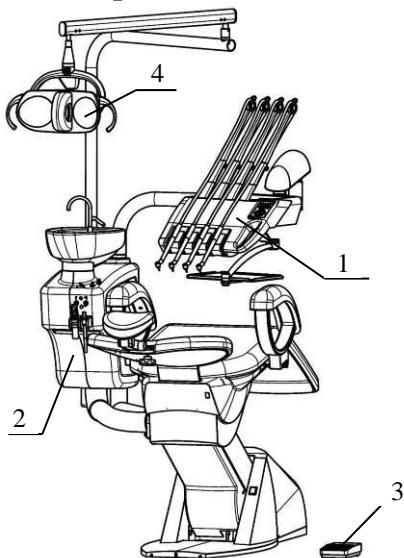
ATTENTION

- If national regulations require separation of amalgam, then the dental unit must be connected to an external amalgam separator.

4. The description of the device

The dental unit Smile Mini O4 consists of each other functionally connected parts. The version and the equipment of the parts can differ according to the version and equipment of the dental unit.

4.1. Main parts of the dental unit



- 1. Dentist table
- 2. Spittoon block
- 3. Foot actuator
- 4. Head of the light

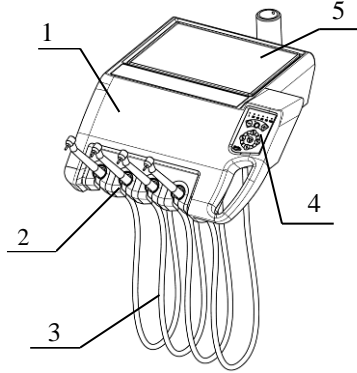


Some parts of the dental unit can have different variants, which differ from the basic pictures.

4.1.1. Dentist table

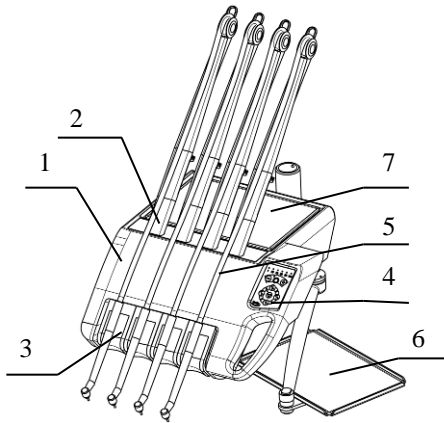
The dentist table is carried on the pantographic arm and it should be in the version with the lower guidance of the tool hoses or with the upper guidance of the tool hoses.

4.1.1.1. Dentist table – lower guidance



1. Dentist table
2. Holders of the tools
3. Hoses of the tools
4. Keyboard
5. Rubber tray

4.1.1.2. Dentist table – upper guidance



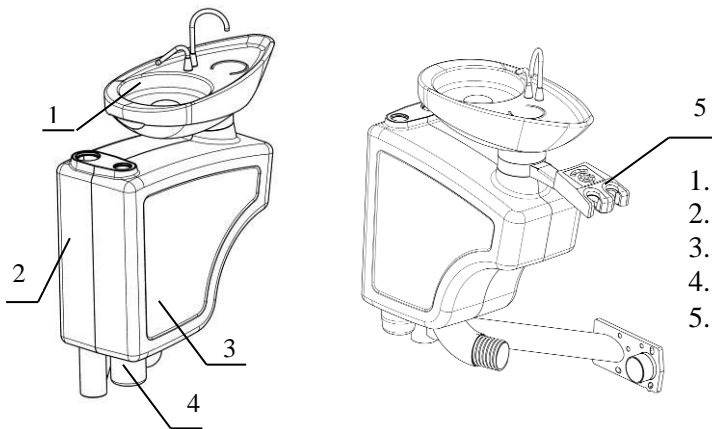
1. Dentist table
2. Upper guidance (whip)
3. Seating
4. Keyboard
5. Tools of hoses
6. Tray table with the arm and the rubber tray
7. Rubber tray

The dentist table can include from one to four tools from the given offer:

- 1x multifunctional syringe
- 3x turbine nozzle
- 2x commutator micromotor
- 2x brushless micromotor , but together at maximum three micromotors
- 1x ultrasonic scaler
- 1x polymerization lamp

The sequence of the tools on the dentist table can be optional – it depends on the order.

4.1.2. Spittoon block



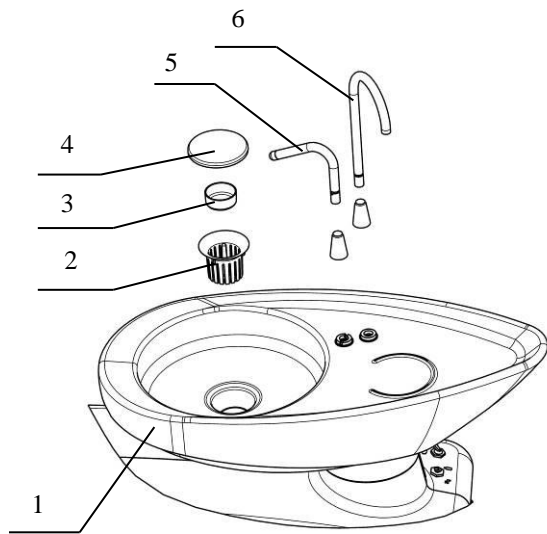
1. Spittoon bowl
2. Left cover
3. Right removable cover
4. Bottle with the water for cooling tools
5. Assistant table (optional equipment)

The spittoon block can content one or two tools from the given offer:

- 1x saliva ejector
- 1x suction bottle

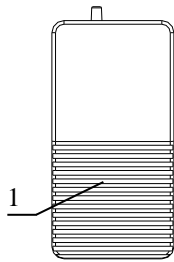
4.1.2.1. Spittoon bowl

The spittoon bowl is rotary. The pipes of the glass and bowl rinsing are detachable.

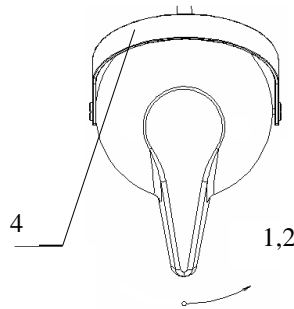


1. Spittoon bowl
2. Catcher
3. Bowl to the catcher
4. Cover of the sieve
5. Pipe of the bowl rinsing
6. Pipe of the glass filing

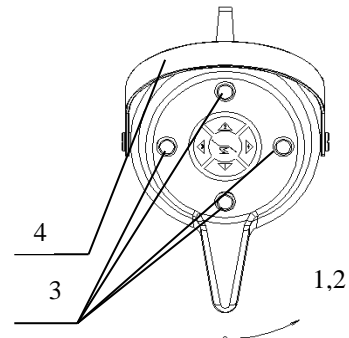
4.1.3. Foot actuator



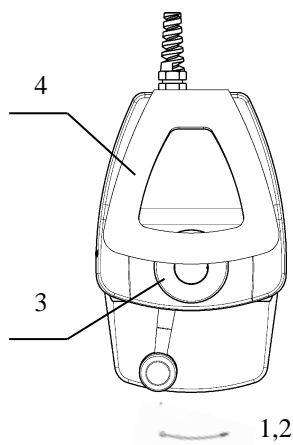
Foot switch



Rotary foot actuator



Multifunctional rotary foot actuator



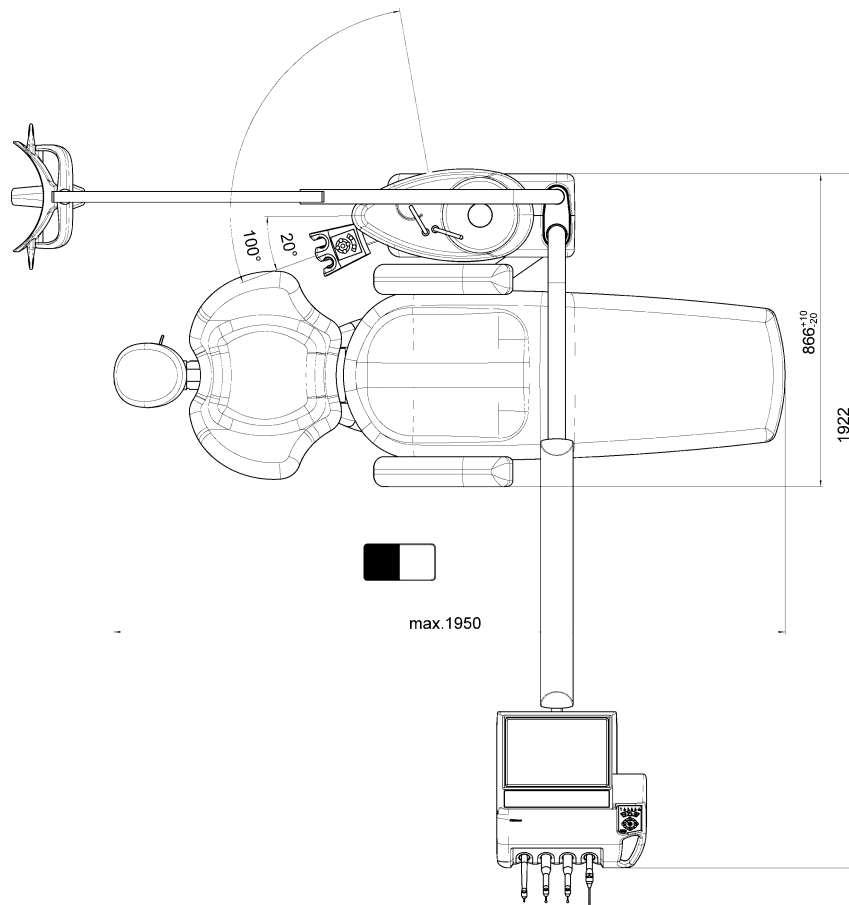
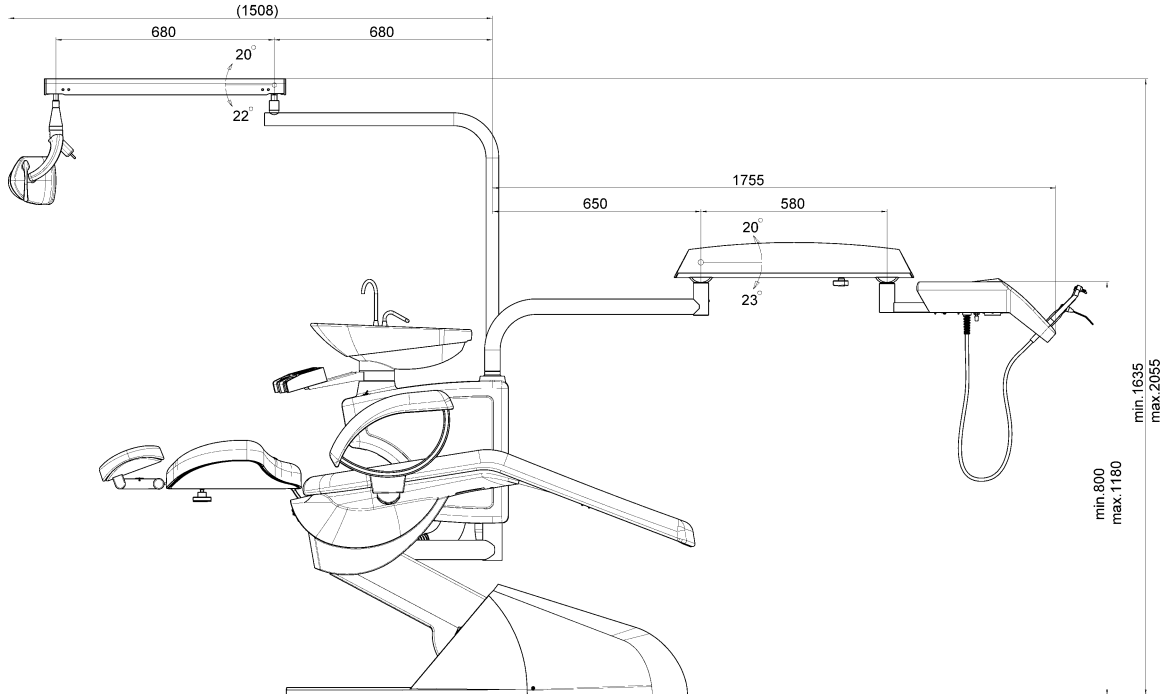
Foot controller FCR1-6

1. Launch of the tool
2. Speed/power control
3. Chair control
4. Carrier

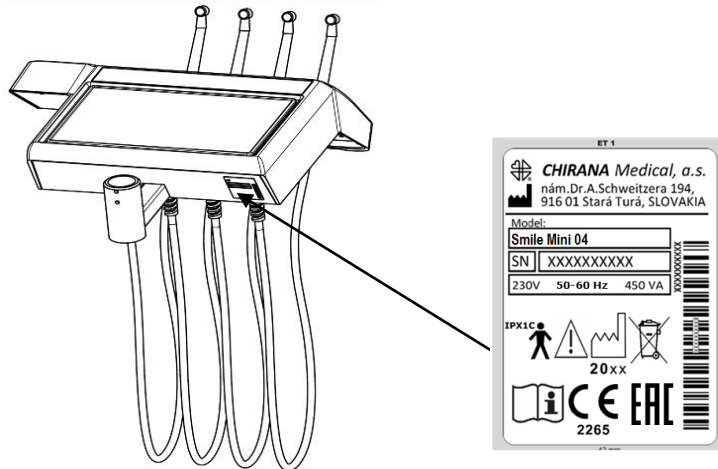
4.1.4. The head of the light









The headlights are available in four versions: a Halogen light FARO EDI, or LED lights FARO ALYA and FARO MAYA, FARO MAYA and LED A.

4.2. The dimensions of the dental unit




4.3. The production label



	Producer		Year of production
SN	Serial Number		The device must not be disposed with the household waste
IPX1C	Protection degree		CE mark according to Directive 93/42 / EEC on medical devices with a number of the notified body
	Classification of type B		Follow the instructions for use
	Familiarize yourself with the instructions in the instructions for use		Eurasian conformity mark

4.4. Technical data

Rated supply voltage	230V~, 220V~ (110V~) ± 10 %
Rated frequency	50 - 60 Hz ± 2 %
Max. input at 50 Hz (without chair)	450 VA
Type of attachment part	B 
Type of protection against the el. shock (fixed installation)	I
Degree of protection	IPX1C
Input pressure of air	0,5 MPa (+0,2 ; -0,03) MPa
Input pressure of water	0,6 MPa (-0,3) MPa
Range of water hardness	from 8,4 dH to 12 dH
Water temperature at the input	< 25°C
Water temperature at the output for cup (at heating the water)	40°C (-10)°C
Range of temperature of the surrounding	from +10°C to +40°C
Range of relative air humidity	from 30 % to 75 %
Range of atmospheric pressure	from 70,0 kPa to 106,0 kPa
Weight without chair	< 60 kg
Max. additional loading of the dentist's tray	2 kg

5. Basic equipment

The basic equipment and spare parts are delivered with the device and they are listed in the Packing list.



ATTENTION

- Do not modify this unit without the authorization of the producer
- In case of modifications, after the decision of the producer, must be carried out appropriate inspections and tests to ensure the continued safety of the use of the dental unit
- Use only spare parts from CHIRANA Medical inc.

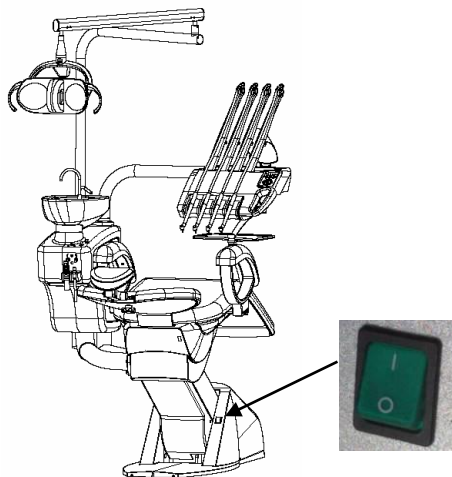
6. Additional equipment

Additional equipment delivered with the device is included in the part of the Packing list as an equipment delivered with the device for the special order.

7. Putting into operation

7.1. Switching of the device

The dental unit is switched by pressing the main switch in the position I.



After switching of the dental unit is the LED diode lighted up in the position I on the indicating scale of keyboard.



Before you switch off the main power switch turn off the by the switch of cooling the cooling of tools, otherwise there may be a short-term water leakage through the tools

After work, switch off the dental unit, press the power switch to the position O By switching of the unit is closed air intake, water and electricity in the unit.

It is recommended to always close the main water supply to the dental unit.

7.2. Switching of the light

The light is switched and is controlled by the switch (in the sensor version by the sensor) on the lower part of the body of the light. The light has its own instructions for use.



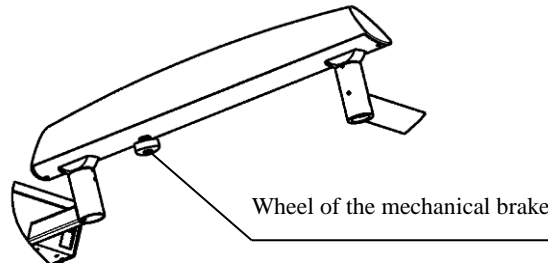
ATTENTION

The light footprint of the light is necessary to set in the place of the mouth; thereby it eliminated the risk of the damage of patient's sight.

8. Operation of the product

8.1. Manipulation with the dentist table

The vertical position of the dentist table placed on the pantographic arm is fixed by the brake. By mechanical loading of tray tables it is not given out to the mechanical falling of the table. Before changing of the vertical position of the dentist table is necessary to release the brake. The brake is released by turning of the wheel placed in the lower part of the dentist arm.

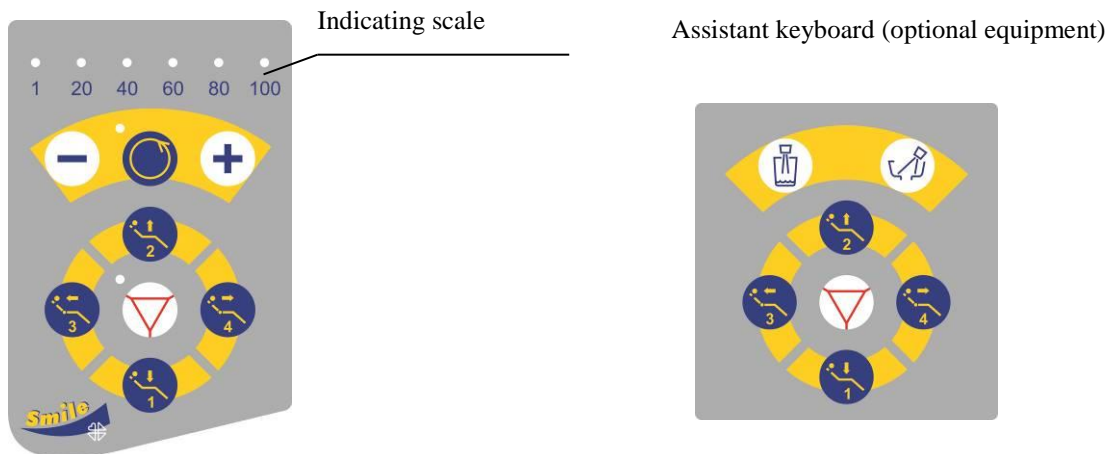


Grab the handle placed in the right lower side of the table on the dentist 's table with released brake and set the table in the required position. Lock again the arm by the usage of the brake wheel after releasing of the table into the required position.






Pay attention by the manipulation with the table in order not to allow getting something between the rear part of the table and the arm. It could come to the injury of shutting.

8.2. Description of functions controlled by the keyboard buttons



8.2.1. Buttons for the tools

-  Reversing revolutions of the micromotor (ENDO function of the ultrasonic scaler)
If the alarm light are set the left - handed revolutions of the micromotor. For some types of ultrasonic scalers is this button used for activating the function of ENDO
-  Reduction of the revolutions of the micromotor/performance of the scaler by step 5%
-  Raising of the revolutions of the micromotor/performance of the scaler by step 5%

8.2.2 Button for the chair

The controlling of the chair is the same from the dentist keyboard as well from the multifunctional foot actuator. The chair has its own instructions for use.



Safety button STOP

By pressing the button is stopped the movement of the chair. During the dentist work with the tools is the chair automatically blocked



Movement of the chair down

By holding of the button is controlled the movement of the chair down. By short pressing of the button is brought up the programme No.1.



Movement of the chair up

By holding of the button is controlled the movement of the chair up. By short pressing of the button is brought up the programme No. 2.



Movement of the rest down

By holding of the button is controlled the movement of the rest down. By short pressing of the button is brought up the programme No.3.



Movement of the rest up

By holding of the button is controlled the movement of the rest up. By short pressing of the button is brought up the programme No. 4, By repeating short pressing is the chair returned back to the last working position.

Setting of the programmed positions of the chair

Set the chair into the desired position. Push the programming button placed on the chair and while holding of this button press one of four controlling buttons of the chair. It sounds acoustic signal informing that the programming position was programmed.



When you move the chair make sure that nothing stands in the path of movement of the chair, back rest, arm with the dentist table and the spittoon block!

8.2.3 Buttons for spittoon block



Switch ON/OFF of the glass filing

Function is timed – it automatically gets to the switching OFF.

If you want to set the timer press the button for the required time. The acoustic signal occurs after releasing of the button and new time is written into the memory. The minimum time for setting is 3secs.



Switch ON/OFF of the bowl rinsing

Function is timed – it automatically gets to the switching OFF.

If you want to set the timer press the button for the required time. The acoustic signal occurs after releasing of the button and new time is written into the memory. The minimum time for setting is 3secs.

8.3. Setting of the tools on the dentist table



Tools have their own individual manual which is attached to the package of the each tool.

The tools placed on the dentist table (excepting the multifunctional syringe) are programmable blocked against simultaneous using.

Only the first pulled tool is prepared for the operation. All tools pulled after it are blocked.

8.3.1. Multifunctional syringe

Pull the syringe from the holder resp. take it up from the seating.

For starting the air press the blue button.

For starting the water press the green button.

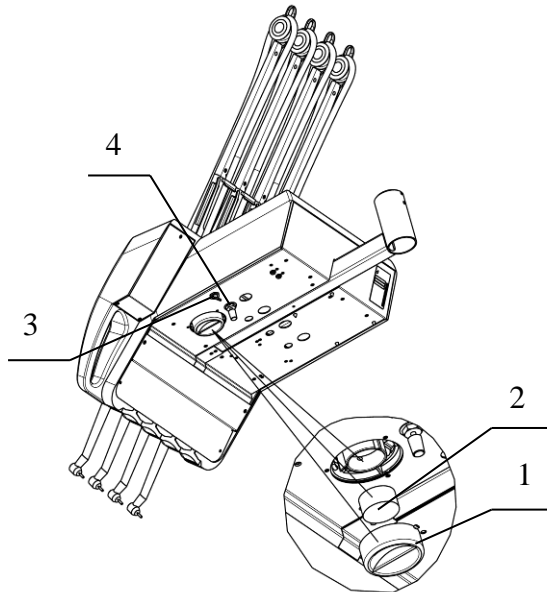
For starting of the water nebula press simultaneously blue and green button.

8.3.2. Turbine nozzle

The turbine nozzle is activated by the pulling of the holder resp. taking it up from the seating. If the nozzle is lighting, the light is switched for the whole time of its activation. For starting the activity of the turbine nozzle press the foot switch resp. deflects the lever of the foot actuator turned into right. By releasing of the foot actuator is the activity ended. The size and the direction of the revolutions of the turbine nozzle are possible to set.

Cooling of the tool (drill) with water spray:

Switching ON/OFF of the cooling of the tool with the water spray is realised with the switch of cooling placed on the bottom side of the dentist table. The switch is for all tools. If the cooling is switched ON, it is switched ON for the each toll, if it is switched OFF, it is switched OFF for all the tools. If the cooling is switched ON is possible to regulate the amount of the cooling water by the button placed on the bottom side of the dentist table.



1. Oil catcher
2. Insert to the oil catcher
3. Cooling switch
4. Regulating button of the amount of cooling water



In the basic equipment is one common regulator (button) for setting the amount of water for all tools(excepting multifunctional syringe). In dependence of the equipment can the unit content independent regulators of the amount of water for each tool separately.

8.3.3. Micromotor

The micromotor is activated by pulling from the holder, resp. taking it up from the seating. If the micromotor is lighted, then the lighting is switched ON during the whole time of its activation. For starting the activity of the micromotor press the foot switch resp. swing the lever pivot of foot actuator to the right. The release of foot actuator is operation ended. The size and direction of rotation of the micromotor can be set by clicking on the keyboard of dentist. Foot switch can be continuously adjusted by micromotor revolutions in advance by buttons in the set range

Cooling of tool (drill) is by water spray and is controlled as in the turbine nozzle.



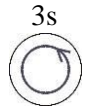
Revolutions of the micromotor can be adjusted continuously by foot just a foot actuator. Foot switch can only turn on the micromotor revolutions, respectively. switch off. Speed setting can be done using keyboard buttons of the dentist.





Actual number of revolutions depends on the drill used in the micromotor and micromotor nozzle.

Giromatic

Function in which the micromotor is cyclically changing the direction of rotation. This function is for the expansion of dental tubules.



Micromotor is activated by pulling out of the holder, respectively. by picking up from the seating. Press and for 3 seconds hold reversing of micromotor. Starting the function indicated by the reciprocating indications on the indicator scale. Frequency (range) of oscillation can be set by buttons  and .

To disable the function, briefly press the button of micromotor reversal.



This function is active only for commutator micromotor.



Revolutions of the micromotor are at capacity giromatic constant. The speed can not be changed even by buttons or foot control. By buttons may be changed only frequency (range) of oscillation of tool .

8.3.4. Ultrasonic scaler



ATTENTION

Use only terminals which are determined for it and do not work without cooling of the terminals with the water.

In other case the damage of the tooth or the damage of the scaler by the heat can be caused.

Recommend water flow is 20ml/min.

Scaler is activated by pulling out of the holder, respectively. by picking up from the seating. To start activities scaler press the foot switch, resp. Swing the lever pivot of the foot controller to the right. The release of the foot controller, the operation ends. Performance of scaler can be set by clicking on the keyboard of dentist or foot control. Foot switch can only turn scaler, respectively. switch off. Foot controller can be continuously adjust performance of suction scaler in advance by buttons is set the range.

If scaler lights, then the light is on for its whole action.

Cooling of the terminal by the water spray is likewise controlled as in the turbine nozzle.

For some types of scalers is this button  used for activating the function of ENDO

8.3.5. Polymerization lamp

To begin the operations of the polymerization lamp press the button on the lamp body. To stop of the activity press the button a second time. Different types supplied by polymerization lamp have different light regimes.



ATTENTION

The intensity of the polymerization lamp is very high hence it is necessary to protect your sight against direct view to the light source.

8.4. Controlling tools for the spittoon block

8.4.1. The saliva ejector

It is activated by switching the mechanical switch located in the saliva ejector mounted to the position ☉ (upwards). To stop the activity switch to position ☉ (down).

8.4.2. Suction

It is activated by switching the mechanical switch located in the suction mounted to the position ☉ (upwards). To stop the activity switch to position ☉ (down).

The suction performance of suction can be regulated by control valve placed on the hose ending.

8.4.3. Bowl rinsing

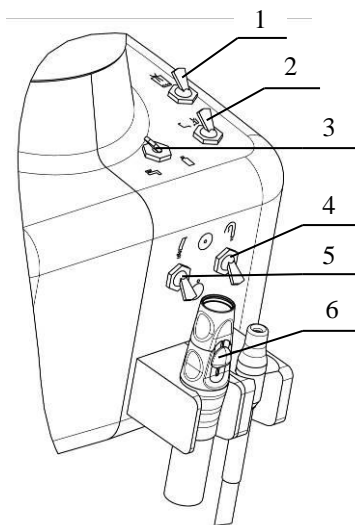
It is activated by switching the mechanical switch located under the spittoon bowl towards symbol of bowl. To stop activity switch the switch to its original position.

8.4.4. Cup filling

It is activated by switching the mechanical switch located under the spittoon bowl towards symbol of Cup. To stop activity switch the switch to its original position.

8.4.5. Switching of source of water for cooling instruments (Optional)

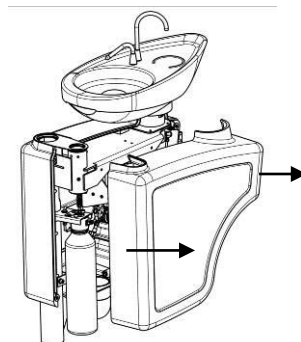
Slide the switch to select the source of water for supply water for cooling instruments. In the position ☐ is selected central (city) water supply in position ■ is selected pure water from the bottle.




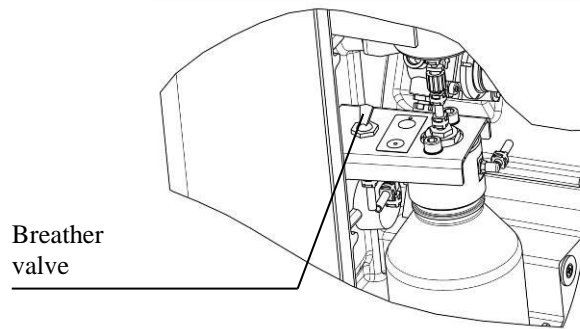
1. Switch of cup filling
2. Switch of bowl rinsing
3. Switch of source of water for cooling tools
4. Switch of the saliva ejector
5. Switch of suction
6. The damper of suction

8.5. Fulfillment of the bottle with clean water

Bottle with pure water is bolted to the spittoon block. Before handling a bottle pull it toward you remove the right side cover of the spittoon block.



Release pressure in the bottle by putting the vent valve to position .



Bottle unscrew by turning of the bottle to the left.



ATTENTION


When filling bottles make sure that in the bottle are no foreign substances that could affect the composition and quality of clean water. Fill up the bottle. volume of 0.9 litres (volume of the bottle is 1 liter).



ATTENTION

Never use demineralized water for industrial purposes.

Hold the bottle filled from the bottom, insert and turn right bottle screw.

Vent valve switch back to position  and attach the cover of the spittoon block



Bottle can be unscrewed and performed well without withdrawing the right door of the spittoon block. Before handling a bottle in this case is necessary to turn off the main switch of the dental unit that has been depressurized bottle.

8.6 Controlling of the assistant table (optional equipment)

8.6.1. Saliva ejector

It is activated into operation by pulling of the terminal from the holder. The function of the saliva ejector is stopped after inserting of the terminal to the holder.

The suction performance of the saliva ejector is possible to regulate by the regulation valve placed in the terminal of the hose. It is possible to completely stop its function.

8.6.2. Exhauster

It is activated into operation after pulling of the terminal from the holder. The function ends after inserting of the terminal from the holder. The suction function of the exhauster is possible to regulate by the regulation valve placed in the terminal of the hose. It is possible to completely stop its function.



If the unit contents the CATTANI system it is possible to turn off for a while exhaustion during long-time exhaustion. This is normal stage. Exhaustion is automatically resumed if the terminal of the exhauster or saliva ejector is pulled from the holder.

He exhaustion is finished with delay after insert in of the terminal from the saliva ejector or exhauster back to the holder. The delay can take a few seconds.



By blood, sputum exhaustion and by different sanitation resource comes foam, which can cause flooding of the separating CATTANI system and long – time breaking of exhaustion. If you want to avoid the existence of foam insert to the filter of the exhausting hoses (see picture in the Chapter 9.1.) one cleaning and antifoam pill CATTANI and exhaust small amount of water before using of the saliva ejector or exhauster. The pill is dissolved for a few hours. Cleaning and antifoam pills CATTANI have not only antifoam action but antibacterial function too.

8.7 The system of exhausting and waste separation

In the dependence of the version the dental unit can contain different systems of exhaustion and waste separation.

Ejector exhaustion , dry exhaustion (CATTANY system) or wet exhaustion. The spittoon valve Dürr MSBV ensures waste exhaustion from the spittoon bowl in the units connected to the central wet exhaustion. All information you can find in own instructions for use.

9. Maintenance of the product

9.1. Maintenance by service personnel



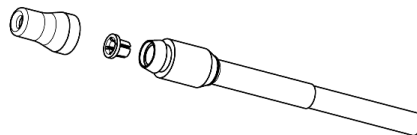
ATTENTION

Use gloves for this work!

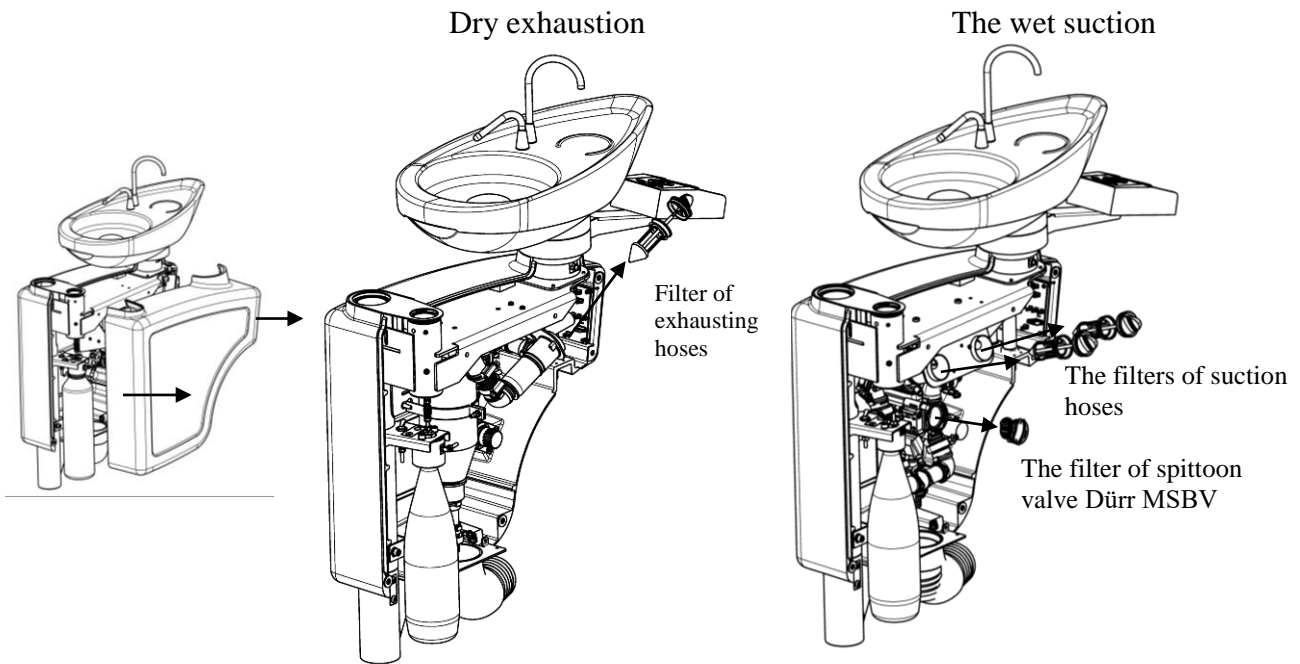
- Operating personnel must:
- Before starting work, rinse and blow through the hose tools (without tools) by running the tool with enabled cooling and rinse cup filling tube running the cup filling.
- Before and after longer break of the work (weekend, holiday) flush and nip hoses of tools (without tools) by starting of the device with switched cooling and flush the pipe of the glass filling by activation of the glass filling.

If the unit contents bottle for clean water it is recommended before longer break of the work fill hoses of the tools with disinfection agent for decontamination and prevention of the creating of biofilm see Chapter 10.

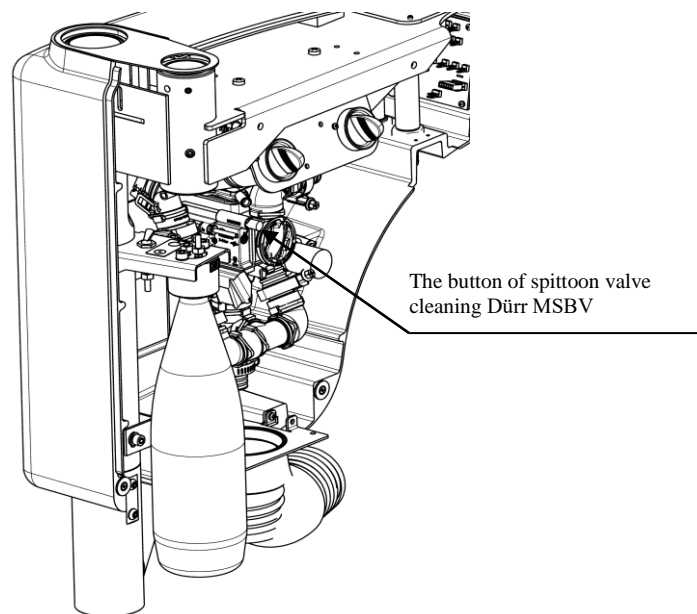
- 2 - 3 times a day to check condition and cleanliness of the catcher in the spittoon bowl and necessary, cleaned or replaced - see Fig. in Chap. 4.1.3.1.
- 2 - 3 times a day, clean the hose and ejector pump flushing with clean water min. 0.5 litres.
- Twice or three times per day the sieve in the terminal of the saliva ejector (ejector exhausting)



- Once per day clean filter of exhausting hoses (dry or wet exhausting) see picture bellow
- Once per day after work clean filter of the spittoon valve Dürr MSBV (wet exhausting) see picture below.



- Start the cleaning of spittoon valve Dürr MSBV twice a day by pressing the button on the spittoon valve Dürr MSBV (wet suction).



- 1x a month clean the conventional detergent, insert the looped oil - see Fig. in Chap. 8.3.2.
- - once per six months to replace a bottle of clean water and a bottle of disinfectant. However, if you notice wear and tear, scratches, discoloration, loss of transparency, deformation, or other damage, replace with a new bottle immediately.

Another maintenance of the device BY service personnel is limited to cleaning and sterilization of the device of sterilizable parts.

Maintenance, cleaning and sterilizing instruments (micromotor, turbine handpiece, micromotor nozzles) perform according to manufacturer's instructions of instruments.

Chemicals must be collected only on a tray with rubber. When accidental spillage of a substance such. Trikresol, Chlumského solution and other aggressive substances painted parts of the device, the surface must be immediately wiped with swab soaked in water.

9.2. Maintenance by service technician

- During the warranty period, the user must at regular six-month intervals invite authorized service technician who must:
 - - Check condition of filters for water and air inlet housing
 - - Check and, if necessary, readjust the working pressures of water and air in the inlet housing and dentist for different instruments according to the Instructions for Assembly and Installation
 - - Check the various regulatory and controls
 - - Check freedom of movement of arms and possibly readjust their braking.

10. Cleaning, disinfection and sterilization

Cleaning of the device (spittoon block, table, foot switch) is done with a damp cloth, non-flammable cleaning agents, taking care not to get water on the device. All parts of the appliance are thoroughly clothed and polished with a dry flannel cloth.

The spittoon bowl and exhausting components (saliva ejector, exhauster) are recommended to clean and disinfect twice per day for example with the agent Dürr Dental Orotol or Metasys Green and Clean MB and M2. The Dürr Dental MD 550 is specially designed to clean the spittoon bowl. To clean suction parts of the residual powders we recommend to use Dürr Dental MD 555 once a week. When cleaning, follow the instructions on the detergent label.



Do not use abrasive or highly foaming agents, as these can lead to malfunctions suction. Unauthorized are the solvents / example. acetone and the like. / and agents based on phenols ,chlorine and aldehydes.

Water ways of tool hoses are recommended to continually disinfect with disinfection agent for continual disinfection (decontamination) of water ways determined for dental devices (e.g. Alpron made by company Alpro). The bottle for clean water (optional equipment) – Chapter 8.5 fill with solution of disinfection agent for continual disinfection (decontamination) of water ways for dental devices diluted according to the manufacturer 's instructions.

During long – time break of dental unit is recommended to make disinfection (decontamination) as follows:

- Bottle for clean water (optional equipment) Chapter 8.5 fill with the disinfection agent for decontamination and prevention for the creation of biofilm in the water ways of dental units (e.g. Bilpron made by company Alpro).
- Switch the water source switch for cooling devices (optional equipment) to the position ■ - see Chapter 8.4.5.
- Switch ON cooling tools with water spray and by regulator set the maximum amount of cooling water – se Chapter 8.3.2.
- Hose of each tool (without tool) hold above the spittoon bowl and by activation of foot control (eventually with the button on the syringe) soak disinfection agent to the hose (syringe). Firstly the water leaks out. Let the water to leak till the disinfection agent cannot start to leak.
- Hoses filled with disinfection agent place on their place and switch OFF the dental unit. Disinfection agent will stay impregnated in the tool hoses and it will work during the whole time of inaction of the dental unit.
- Before starting of other action it is necessary to fill the bottle for clean water with clean water.

- Switch ON the dental unit and by the activation of foot control (eventually with the button on the syringe) leak continuously the disinfection agent from each tool hose to the spittoon bowl.



WARNING

Use only disinfection agents for the water ways for dental devices. Follow the instructions and date of consumption listed on the label of the bottle with the disinfection agent.

Autoclavable can:

- syringes
- Turbine nozzles
- Micromotors nozzles



ATTENTION

Tools have their own instructions for the sterilization with conditions that must be respected. Other parts can be disinfected with common disinfectants with virucidal action which do not cause corrosion of the material and do not disturb the surface.

11. Safety technical controls

Technical safety controls must be carried out in accordance with IEC 62353 every two years.

12. Transport

Symbols printed in the outer side of the package refer for the transport and storage and they have following meaning:



Fragile, carefully manipulate



this side up (vertical position of the shipment)



protect against humid



recycled material



temperature for the transport, storage



humidity for the storage



Restricted stacking

The device is necessary to transport in covered transportation without major upheaval at the -20°C to $+50^{\circ}\text{C}$, relative humidity of 100%, and shall not be exposed to the acting of aggressive pair.

The device must be packaged transported in packaging / packing case /, which is exclusively designed for this purpose.

13. Storage

The device must be stored in a dry room with a maximum relative humidity of 80% at temperatures from -5 ° C to + 50 ° C, and shall not be subject to the action of aggressive pair.
For longer storage of 18 months is necessary to test the dental unit by service organization.

14. Disposal of the device

The device must not be disposed with ordinary waste.

Dispose the device by separate collection.

Transfer the device to the distributor or directly to the waste processor.

Disinfect the device before handover.

Disassembly and disposal of the device should be carried out by a professional firm.

15. Guidance and declaration of the producer to the electromagnetic compatibility



Using other devices in the immediate vicinity of the dental unit SMILE MINI 04 may cause an incorrect function. If the usage of other devices in the immediate vicinity is necessary, then the dental unit SMILE MINI 04 and the devices should be observed to verify that they work normally.



Using other than the original accessories and cables provided by the manufacturer CHIRANA Medical, a.s. may cause increased electromagnetic emissions or decrease the electromagnetic resistance of the dental unit and cause its incorrect function.



Portable RF communication devices (including the endpiece equipment such as the antenna cables and the antennas) should not be used closer than 30 cm (12 inches) from any part of the dental unit SMILE MINI 04 including the cable to the foot controller. Otherwise, the function of dental unit may be impaired.

15.1. Electromagnetic radiation


The dental unit SMILE MINI 04 is designed for using in the electromagnetic environment described in the following table. The customer or user should ensure that the dental unit SMILE MINI 04 will be operated in the appropriate environment.

Measuring the interference radiation	Compliance	Electromagnetic environment
High frequency radiation according to CISPR 11	Group 1	The dental unit SMILE MINI 04 uses the high frequency energy only for its internal function. Therefore its high frequency radiation is very low and it is not probable that it would cause any interference to the close electronic devices
High frequency radiation according to CISPR 11	Class B	The dental unit SMILE MINI 04 is designed for using in all kinds of environment including the environments located in the housing zones and environments which are directly connected to the electric mains which supply also the housing buildings
Radiation of higher harmonic according to EN 61000-3-2	Class A	
Radiation of voltage / deviation spikes according to EN 61000-3-3	In accord	

15.2. Resistance against the electromagnetic interference

The dental unit SMILE MINI 04 is designed for using in the electromagnetic environment described in the following two tables. The customer or user should ensure that the dental unit SMILE MINI 04 will be operated in the appropriate environment.

Test of resistance	Testing level of the resistance according to EN 60601	Complying level	Electromagnetic environment
Electrostatic discharge (ESD) according to EN 61000-4-2	Contact discharge ±8kV Air discharge ±2kV, ±4kV, ±8kV, ±15kV	Contact discharge ±8kV Air discharge ±2kV, ±4kV, ±8kV, ±15kV	Floors should be made from wood, concrete or covered by ceramic tiles. If the floors are covered with the synthetic material then the air moisture is minimum 30 %.
Fast electric transition effect/group of the impulses EN 6100-4-4	±2kV for the feeding line ±1kV for the input /output line	±2kV for the feeding line ±1kV for the input/output line – not applied	Quality of the power supply network should correspond to a typical commercial or hospital environment
Impact impulse EN 61000-4-5	±1kV symmetrical voltage ±2kV common-mode voltage	±1kV symmetrical voltage ±2kV common-mode voltage	Quality of the power supply network should correspond to a typical commercial or hospital environment
Short-time voltage drop, short interruption and slow changes of voltage on the supply input line EN 61000-4-11	< 5% U_T 0,45°,90°,135°,180°, 225°,270°,315° < 5% U_T 0° 70% U_T < 5% U_T 5 seconds	0,5 periods 1 period 25/30 periods (50/60 Hz) 250/300 periods (550/60Hz)	Quality of the power supply network should correspond to a typical commercial or hospital environment If the user of the dental unit SMILE MINI 04 requires the permanent operation during the power supply failure, it is recommended to connect the dental unit SMILE MINI 04 to the backup source or the battery
Magnetic field of the network frequency (50/60Hz) EN 61000-4-8	30A/m	The test not applied - the dental unit SMILE MINI 04 does not contain magnetically sensitive components and it is designed for the permanent installation	Magnetic fields of the network frequency should correspond to a typical commercial or hospital environment
Comment – U_T is the AC voltage before applying the testing level			

Test of resistance	Testing level of the resistance according to EN 60601	Complying level	Electromagnetic environment
Interference spread by line induced by the RF field EN 61000-4-6	3 V _{eff} 150kHz to 80MHz 6 V _{eff} in ISM and the amateur radio bands	3 V _{eff} 6 V _{eff}	Distance of the used portable and mobile high frequency notification devices from any part of the dental unit SMILE MINI 04 including the cables, should not be less than the recommended protective distance calculated according the appropriate equation for the transmitting frequency Recommended protective distance: d = 1,2 √P 150 kHz to 80 MHz d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2,7 GHz
The RF field from the RF transmitter spread by radiation EN 61000-4-3	3 V/m 80MHz to 2,7GHz 385MHz–5785MHz Specific tests of resistance against the input/output by the device cover from the RF wireless communication devices according to the table 9 of the standard EN 60601-1-2:2015	3V/m according to the table 9 of the standard EN 60601-1-2:2015	where P is the rated maximum output power of the transmitter in Watts (W) in accordance with the data provided by the transmitter manufacturer and d is the recommended protective distance in meters (m) The field intensity from the stationary RF transmitters should be according the examination on-site ^{a)} for all frequencies lower than the complying level ^{b)} . In the surrounding of the device marked with the following symbol, the interference may occur. 

Comment 1: At 80MHz and 800MHz is valid higher frequency range.

Comment 2: These guidelines do not need to apply in all cases. The electromagnetic propagation is influenced by the absorption and reflections from the buildings, objects and people.

^{a)} The field intensity of the stationary transmitters (base stations of the wireless telephones, mobile radio-communication devices, amateur radio stations, radio and TV transmitters AM and FM) is not possible to determine theoretically in advance. In order to assess the electromagnetic environment in terms of the stationary transmitters should take into account the survey of electromagnetic characteristics of the specific site. If the measured field intensity in the site where the dental unit SMILE MINI 04 will be used exceeds the above mentioned complying level, then the dental unit SMILE MINI 04 should be observed to confirm its operation in accordance with the intended purpose. In case of observing abnormal characteristics, it may be necessary to perform other measures, for example other direction or installation of the dental unit SMILE MINI 04 at other site.

^{b)} In all frequency ranges from 150kHz to 80MHz should be the field intensity lower than 3V_{eff}-V/m.

15.3. Recommended protective distances between the portable and mobile high frequency communication devices and the dental unit SMILE MINI 04

The dental unit SMILE MINI 04 is designed for operation in the electromagnetic environment where is controlled the radiated high frequency interference. The customer or user of the dental unit SMILE MINI 04 may prevent the electromagnetic interference by keeping the lower mentioned minimum distances between the portable and mobile high frequency communication devices (transmitters) and the dental unit SMILE MINI 04 depending on the output power of the communication devices.

Specified maximum output power of the transmitter (W)	Protective distance according to the transmitter frequency (m)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For the transmitters which maximum output power is not described in the table, may be recommended the protective distance d in meters (m) specified by using the equation suitable for the transmitter frequency, where P is the rated maximum output power of the transmitter in Watts (W) according to the data of the transmitter manufacturer.

Comment 1: At 80MHz and 800MHz is valid the protective distance for the high frequency range.

Comment 2: These instructions do not have to apply in all cases. The electromagnetic propagation is influenced by absorption and reflections from the buildings, objects and people.