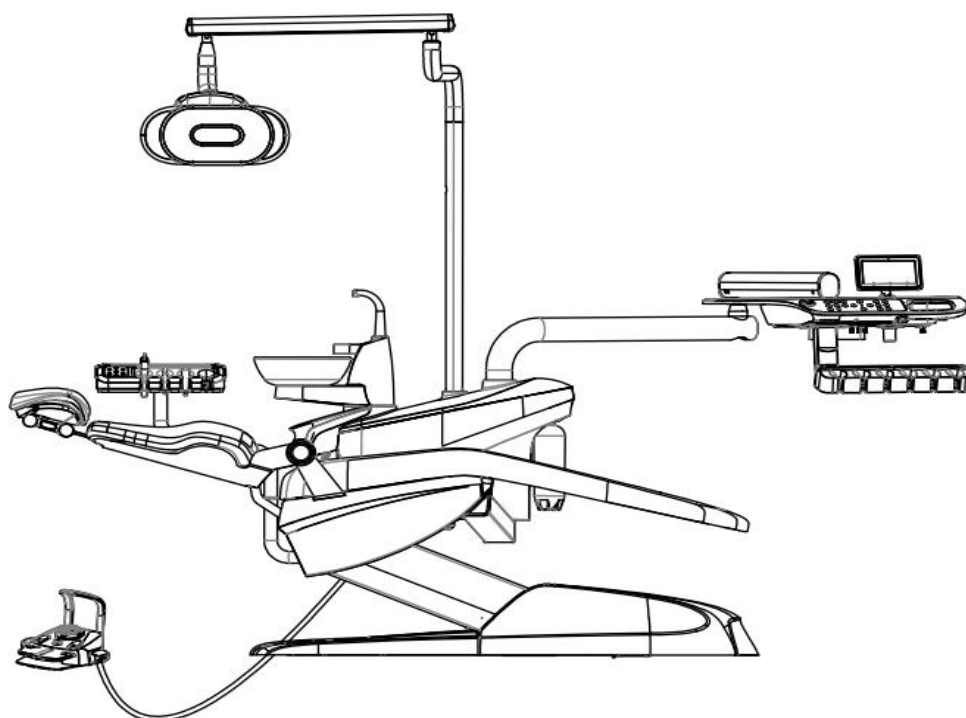

Integral Dental Unit



Version: A1

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Note: Please read the instructions carefully before operating this machine



Read this manual carefully before operating the device.

1.Product introduction

1.1 Device Description

The Integral dental unit is a dental treatment unit tested in accordance with IEC 80601-2-60. This product is used in dentistry only and may only be used by trained medical personnel and trained professional in the field of general dentistry.

The Integral dental unit consists of a dental chair, side box, dental light, instrument tray, 3-way syringe (JIBPT-CX-02) , strong suction, weak suction, Spittoon, X-ray Viewerer, and Foot control pedal. Optional accessories include ultrasonic scalers, curing lights, dental handpieces and dental electrical motor.

1.2 Intended Use

The Dental Unit is intended for use in dental care medical operation. The Dental unit is to be used by authorized professionals with the scope of his/her education, training and experience.

The dental unit is intended to provide a motorized patient chair and serve as a base for ancillary dental devices and accessories by providing air, water, vacuum, and low voltage electrical power to hand-held dental instruments.

1.2.1 Indications for use

Dental care medical operations include evaluation, diagnosis, prevention and/or treatment of diseases, disorders and/or conditions of the oral cavity, maxillofacial area and/or the adjacent and associated structures and their impact on the human body.

1.2.2Contraindicaitons

There are no known contraindications other than the weight limit.

1.2.3 Intended patient population

Age: Toddler to geriatric

Weight: Less than or equal to 150kg+15kg accessories

1.2.4 Intended users

Intended healthcare user

Education: Dental care professionals

Intended service user

Education: Dental unit service and maintenance professionals. ①

1.2.5 Expected Lifetime of Equipment

The expected lifetime is 8 years.

1.2.6 Clinical benefits

According to MDR (EU) 2017/745 Article 2(53), a clinical benefit is defined as a positive impact of a device on the health of an individual, which can include a positive impact on patient management.

The dental unit is an active non-invasive medical device intended to position patients appropriately, supply power, water and compressed air to connected dental handpieces, deliver water spray, dry air and air-water mist, and provide suction functionality.

The Dental Unit itself does not directly interact with the patient's oral tissues to cure or treat dental diseases (such as caries or periodontal disease); therefore, its clinical benefits are indirect.

2. Overall machine structure

2.1 Integral dental unit (figure 1)



Code	Name	Code	Name
1	Dental Chair	7	Light Arm
2	Back Rest	8	Dental Light
3	Head Rest	9	Side box
4	Assistant tray	10	X-ray Viewer
5	Spittoon	11	Instrument Tray
6	Light Stand		

2.2 Configuration tables for each model

--	--	--	--	--	--	--	--	--	--

3. Technical Parameters

3.1 The main technical specifications

Mains Voltage and frequency	
Power supply	AC230V
Frequency	50/60Hz
Input power	600VA
Fuse rating and type	
Marking for fuses in Mains par	T3.15AL,250V
Marking for fuses in output of transformers	T10AL,250V
Classification	
Protection against electric shock	Class I
Degree of protection against electric shock	Type B
Classification according to the degree of protection against ingress of water	IPX4 for foot switch, IPX0 for main unit.
Equipment not suitable for use in the presence of flammable mixtures	Not Category AP /APG equipment
Mode of operation:	Non-continuous operation for patient chair motor: On: 2 min. / OFF: 20 min.
Maximum allowed load on patient seat	
Maximum allowed load patient weight 150kg	Accessories load of 15kg
Water supply	
Pressure range	0.2Mpa-0.6Mpa
Input rated water flow	≥10L/min
Heating water temperature	AC24V 80W; 40±5°C
Quality	Hardness; ≤80dH
pH	6.5-8.5
Connection	1/4"
Backflow Prevention	The water supply line must be equipped with a backflow prevention valve
Air supply	
Pressure range	0.55Mpa-0.6Mpa
Flow rate	≥50L/min
Humidity	Dew point not greater than -20°C at atmospheric pressure
Quality	Medical grade, dry and oil-free
Oil contamination	oil contamination limit (Max. 0.5mg/m³).
Particulate contamination	Particulate pollution limit (1µm ~ 5µm size of particles not more than 100 /m³)
Air filter aperture	Air filter aperture does not exceed 25µm, the input gas should not contain oil, water, bacteria, etc.
Connection	1/4"

Water and air filters	Water filter:25um(internal),5um (external suggested) Air filter: 25um (internal)
Suction	
Strong suction pressure	at 400kPa air input:25kPa—28kPa suction flow rate> 1000mL/min
Weak suction pressure	at 200kPa water input:10kPa—14kPa suction flow rate> 400mL/min
Drain connection	
Capacity	4L/min
Connection	φ 50/46mm
Transportation conditions	
Temperature	-40-70°C
Relative Humidity	10%~100%
Atmospheric Pressure	50kPa ~106kPa
Storage conditions	
Temperature	-40-70°C
Relative Humidity	10%~100%
Atmospheric Pressure	50kPa ~106kPa
Operation conditions	
Temperature	5-40°C
Relative Humidity	≤ 80%
Atmospheric Pressure	80kPa ~106kPa
Dental Operating Light	
Model	D600
Ratings	AC 12-24V;50/60Hz;36 VA Max.

4.Function Symbols

4.1.Description of identification symbols

	Type B equipment		Protective grounding		Alternating current
	Consult electronic instruction for use		Beware of pinched hands		No push
	No sitting or lying down		Watch your head		Pay attention to the electricity
	Warning/ Caution/ Note		Professional recycling		Avoid sun exposure
	Place upward		Fragile, handle with care		Keep out of the rain
	Avoid stress		Serial number		Unique Device Identifier
	Manufacturer		Manufacture date		Fulfills the requirement of Medical Device Regulation (EU)2017/745
	Medical device		Refer to instruction manual/booklet		European Authorized Representative

4.2.Description of function symbols

You can manually operate the dental chair functions using the dental chair direction buttons on the main and Assistant control panels. The icons and corresponding operations for each icon are listed below.

Serial number	Symbol	Function	Serial number	Symbol	Function
A		Backrest upward movement	J		Dental light button
B		Backrest downward movement	K		X-ray Viewer button

Serial number	Symbol	Function	Serial number	Symbol	Function
C		Seat moves upward	L		Cuspidor flushing button
D		Seat moves down	M		Mouthwash water
E		Preset button	N		Doctor key
F		Spitting position	O		Memory position I
G		Treatment position	P		Memory position II
H		Water heating	Q		Memory position III
I	SET	Setting key			

A Dental chair backrest upward movement button

If this button is pressed, the dental chair backrest will move upward. When you reach the position you need, stop pressing the button and the dental chair backrest will stop moving immediately.

B Dental chair backrest downward movement button

Keep pressing this button to cause the dental chair backrest to move downward. When you reach the position you need, stop pressing the button and the dental chair backrest will stop moving immediately.

C Dental chair upward movement button

Keep pressing this button and the dental chair will move upward. When you reach the position you need, stop pressing the button and the dental chair will stop moving immediately.

D Dental chair downward movement button

Keep pressing this button and the dental chair will move downward. When you reach the position you need, stop pressing the button and the dental chair will stop moving immediately.

E Dental chair preset button

Press this button and the seat and backrest will automatically reach the preset seat position. (Default chair position: the backrest is at the highest limit position and the seat is at the lowest limit position.

F Dental chair spitting button

Press this button once, the backrest will automatically reach the highest limit position, the chair seat will not move, the dental light will be turned off, and the cuspidor flushing will be turned on to facilitate the patient's spitting. In this position, press this button again, the backrest will return to the original treatment position, the dental light will return to the state before pressing this button for the first time, and the cuspidor flushing will automatically turn off.

G Treatment position button

Press this button once, the seat will rise to the highest position, and the backrest will recline to the extreme position.

H Side box water heater

Press the heating button and the indicator light on the control panel flashes, indicating that the water heater is in the heating state. When the water temperature reaches the set value, the indicator light will stay on. When the water temperature is lower than the set temperature, it will automatically reheat. Press the button again to activate the heating function turn off.

I Setting key

Press and hold the setting button for 3 seconds to enter the setting interface and select the function key to be set to make the corresponding settings. For the settings of related function keys, please refer to the cuspidor flushing/water supply settings and dental chair memory position settings.

J Dental light button

Click once to turn on the dental light and click again to turn off the dental light.

K X-ray Viewer key

Press once to turn on the X-ray Viewer and click again to turn off the X-ray Viewer.

L Cuspidor button

Press this button once, and the system will automatically start flushing according to the set time. Press this button during the flushing process to stop flushing.

If you need to set the flushing time, the method is as follows:

Press the "SET" button on the main control panel of the instrument tray. After the indicator light turns on, press the cuspidor flushing button to set.

Press the first time, the buzzer will sound, and the cuspidor flushing time is 30 seconds.

Press the second time, the buzzer will sound twice, and the cuspidor flushing time is 60 seconds.

Press the third time, the buzzer will sound three times, and the cuspidor flushing time will be 3 minutes.

Press the fourth time, the buzzer will sound four times, and the cuspidor flushing time is always on. After the setting is completed, press the setting button again, the indicator light goes out, and the setting is completed. The computer automatically records the new setting data. When used later, only Just press the cuspidor flushing button, and the water will automatically flush until the set time.

M Mouthwash button

Press this button and the system will automatically start supplying water according to the set water output. Pressing this button during the water supply process will stop the water supply.

The specific settings are as follows:

Long press "SET" key for 3 seconds to enter the setting  interface and press it again, and

the indicator light will turn on.

Place an empty cup at the mouthwash spout, press and hold the "mouthwash" button on the main control panel, and the water will flow out. Release it when the amount of water you need is met, and the water flow will stop. Press the main control panel again. Press the "SET" button on the computer, the indicator light goes out, and the above process is automatically recorded by the computer as new setting data, and the setting is completed.

N Doctor key O I Memory position P II Memory position Q III Memory position

This treatment machine provides "A" "B" "C" Three doctor positions, each doctor position can be preset " I " " II " "III" 3 memory positions.

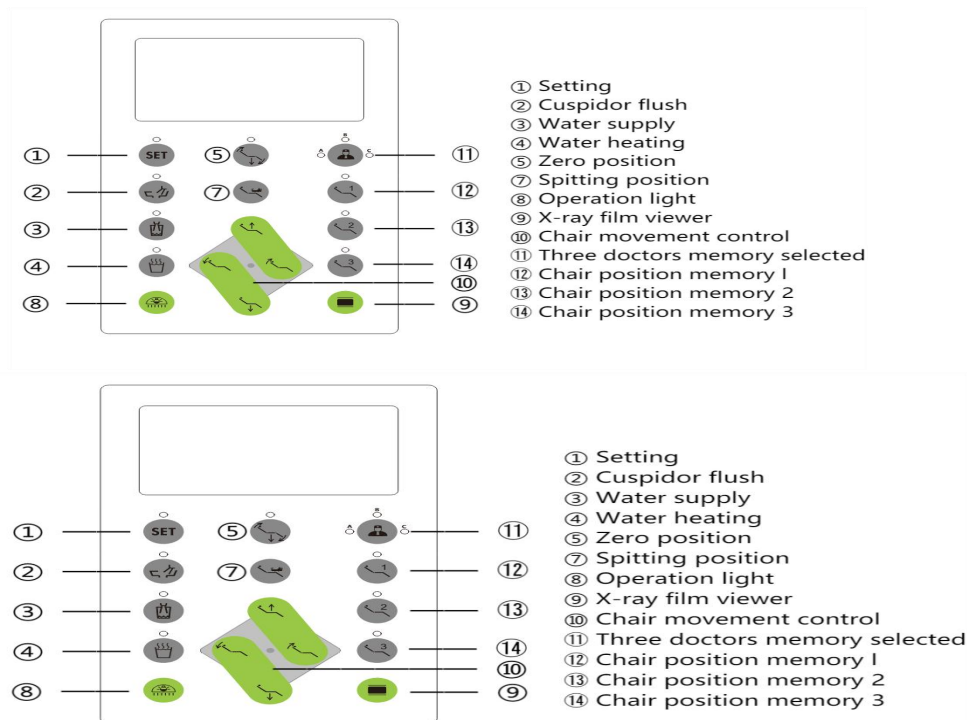
The specific setting method is as follows:

Press and hold the "SET" button on the main control panel of the instrument panel for 3 seconds to enter the setting interface and press again  Select a doctor's position and pass  four movements

Move the button to the required position, select the corresponding memory position, and press the "SET" button on the main control panel. The indicator light will go out. The above process will be automatically recorded by the computer as the new setting data, and the setting is completed.

4.3. Main control panel and Assistant control panel

The Assistant control panel of the QL2028 model can control the dental chair, cuspidor, water heater and dental light functions. Which indicator light on the control panel is on means that the indicator light is in normal working condition and you can perform normal operations.



5. Equipment installation

5.1 Installation preparation (to be carried out by professional personnel designated by the manufacturer or dealer)

Unpacking inspection: Check the integrity of the package and verify that all item listed in the package, including the detailed list is shown in the table below, are present. Ensure there are no impurities or damage on the package and product. If any component is missing or damaged, refrain from using the device and promptly, please contact the sales unit or our company immediately.

Packing accessories:

Serial number	Name/Model	Quantity	Serial number	Name/Model	Quantity
1	Integral dental unit	1 set	5	Lamp arm box	1
2	Manual	1 copy	6	Kits	1 package
3	Certificate	1 piece	7	Dental light	1
4	Warranty Card	1 piece	8	Doctor's chair(optional)	1 piece

Before each operation, carefully prepare and inspect according to the following instructions. If any irregularities are suspected, following the Trouble Shooting procedures outlined in Section 8.19



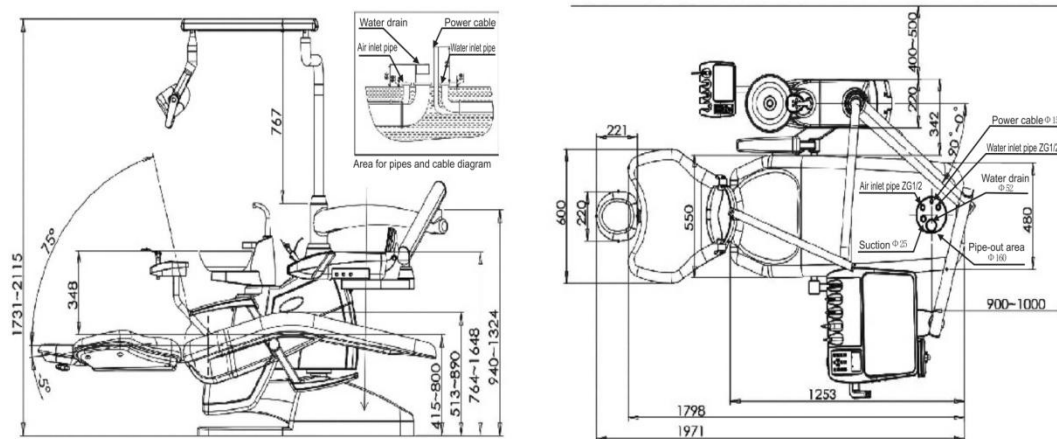
Using a malfunctioning device may compromise patient or operator safety and may lead to more severe equipment damage.

5.1.1 The diagnosis and treatment room should be clean, dry, ventilated, and maintained in a good working environment. And ensure that the bottom plate of the dental chair must be in contact with a level, solid ground.

5.1.2 The size of the treatment machine (length × width × height) is 1500mm×1450mm×2020mm, and its movement range is 2050mm×1800mm×2320mm. The space for doctors to diagnose and treat should not be less than 3000mm×2000mm×2500mm. See Construction Reference Figure 16 for specific dimensions.

5.1.3 Under the ground at the location of the floor box, there must be water, air, and electricity input and output ports for the machine, distributed within the range of 160×120mm. The water inlet pipe (blue) and air inlet pipe (transparent) are Φ8×5 PU pipes, and the drainage pipe is a Φ16mm steel wire hose. See Construction Reference Figure 16 for specific dimensions.

5.1.4 The capture area is shown in Figure 16.



5.2 Host installation

5.2.1 First place the dental chair in the predetermined position. The design of this machine has taken into account the stability of the entire machine, so there is no need to install anchor fixing screws. However, the ground in contact with the bottom of the dental chair must be level and solid to prevent accidents caused by uneven ground.

5.2.2 If the entire machine rotates or tilts due to uneven ground, you can screw the six M10 hexagonal flat-end set screws in the accessory into the six M10 threaded holes on the bottom plate of the dental chair, and make it fully contact with the ground. When adjusting, the level of the entire machine should be maintained and as many contact points as possible should be maintained to ensure the stability of the entire machine.

5.3 Dental light installation (read the dental light manual in detail before installation)

Put the wire from the lamp arm through the lamp stand, and then connect the two well. After that, connect the wire connector on the lamp arm to that in the dental cabinet, and put them into the column. Then put the lamp stand onto the column, and put the lamp arm in the right place. (Note: don't damage the wire.)

Connect the lamp base wire insert through the decorative jacket to the lamp arm wire insert, insert the lamp base handle into the lamp arm hole, and fasten it with screws, and then cover the screw and seam with the decorative jacket. (Figure 17).

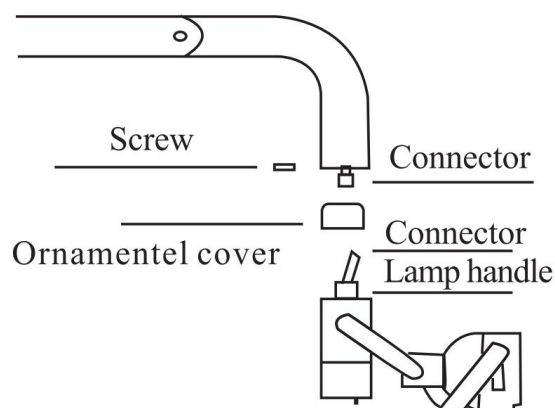


Figure 17

5.4 Floor box installation

Screw the two G1/2×φ8 pipe joints in the accessories of this machine into the water inlet pipe (blue) and air inlet pipe (transparent) respectively for later use. Pay attention to sealing when connecting to ensure there is no air or water leakage. Open the floor box cover, install the floor box to a position level with the ground (for the smooth drainage system of the whole machine) and not higher than the ground. This position must ensure that the dental chair is connected between the treatment machine Side box and the floor box during the up and down movement. The bellows does not bend.

5.5 Pipe installation

Before connecting the pipeline to the treatment machine, dirt and impurities in the pipeline must be removed to extend the service life of the machine. Connect the Φ8×1.5 PU pipe in the machine to the water source and air source, and pay attention to sealing. In addition, insert the steel wire hose into the drain pipe opening, connect the drain pipe, and pay attention to firmness and sealing.

5.6 Power connection

This machine is equipped with a single-phase three-pin socket before leaving the factory. If the user does not have a grounding device, he must ground the power socket before powering on.

5.7 Handpieces installation

Connect the handpieces according to the requirements in the operating instructions of each handpiece, and be careful not to idle the handpieces without load for a long time or start it with overvoltage. (It is up to the purchaser or user to choose the dental handpiece suitable for this connector)

5.8 X-ray Viewer installation

The X-ray Viewer is already installed when the Integral dental unit leaves the factory and does not need to be installed before use.

5.9 Installation of configurable ultrasonic scalers, curing lights, dental handpieces and low voltage electric motors

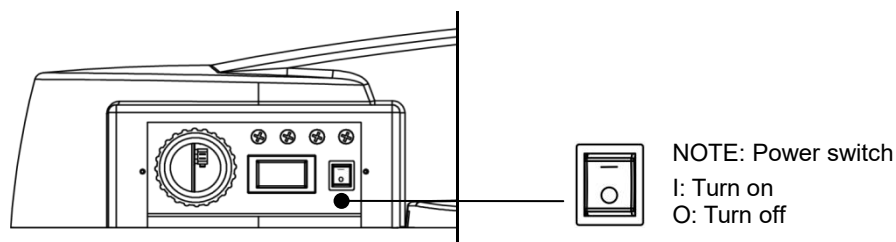
Install according to the manufacturer's instructions of the ultrasonic scaler, light curing machine, dental handpiece and low-voltage electric motor, and connect the input power to the reserved 24v power cord input port of the machine.

6.Start debugging

After all connections and components are installed, enter the debugging stage of the machine, connect the power supply, air source, and water source to put the equipment on standby.

6.1 Power switch

6.1.1 The location of the power supply is next to the fuse holder of the floor box, see Figure 5.



6.1.2 Floor box fuse, See Figure 6.

F1, F2: 24V output power fuse (F10AL 250V)

F3, F4: Machine power input fuse (T6.3AL 250V)

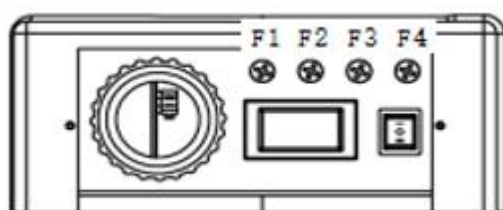


Figure 6. QL2028 floor box

6.2 Dental chair backrest

Dental chair backrest movement. See Figure 7.

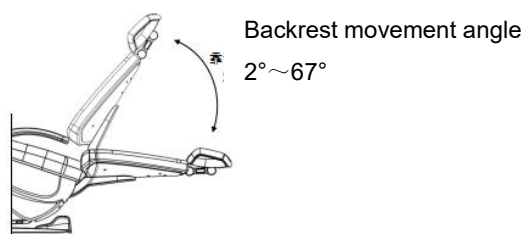


Figure 7.

6.3 Dental chair Headrest

To adjust the height and angle of the Headrest, you need to press down the locking buckle first, adjust the Headrest to the angle and height suitable for the patient, and then loosen the locking buckle to lock the headrest. See Figure 8.



Figure 8.

6.4 Side box

The Side box water supply system can provide purified water or tap water for the dental handpiece device. The system includes 1000ml water bottles installed outside the Side box. See Figure 9

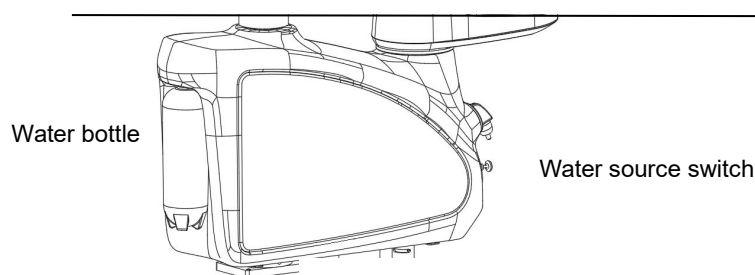


Figure 9. QL2028 Side box.

Under normal circumstances, the water supply for the dental handpiece device is tap water. If you need to use water from a water purification bottle, you can turn on the water source switch in Figure 9. There is a suction filter in the Side box. The suction filter is connected to the Strong suction and the weak suction to filter and remove the separated solids in the material.

This model has a rotatable Side box, which can be rotated 90 degrees outward, making it convenient for four-hand operation and after-sales maintenance.

6.5 Dental treatment Instrument tray

6.5.1 Startup of the dental handpiece device

The handpiece pre-activates when you lift it from its holder. Please press the foot control to operate the activated dental handpiece.

6.5.2 Balance arm air lock switch

You can use the balance arm air lock switch to place objects of various sizes on the Instrument tray on the control end and maintain the operating position. The thumb-activated airlock switch limits vertical movement but allows the control head to move side to side for horizontal positioning, see Figure 11.

6.5.3 Foot control (Fig. 10)



A Chair position setting: this control is used for up and down of the chair and backward and forward of cushion.

B Cup filling: push this button, automatic water supply to the cup

C Cuspidor flush: push this button: automatic cuspidor cleaning

D Blowing control: push this button, the handpiece is blowing to clean the crumbs.

E Water control: push this button, the handpiece is worked by the water.

F Air control: push this button, the handpiece is worked by the air

G Pressing both pedal for air and water control, handpieces will work and with water fog.

6.6 Dental Assistant control

The standard components of the dental Assistant control include a Strong suction, a weak suction, a 3-way syringe and an auxiliary control panel.

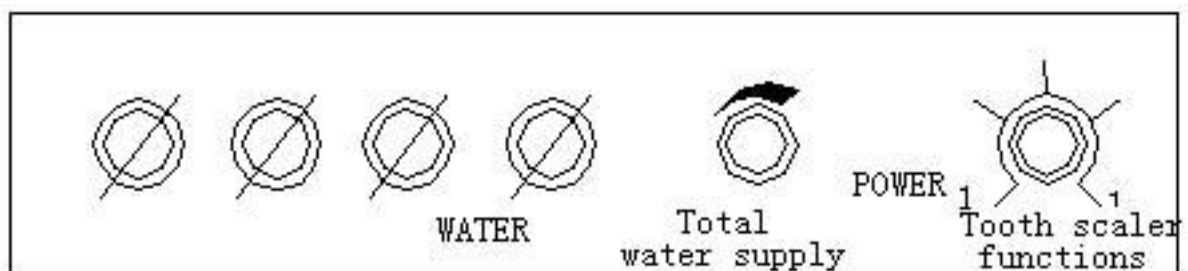
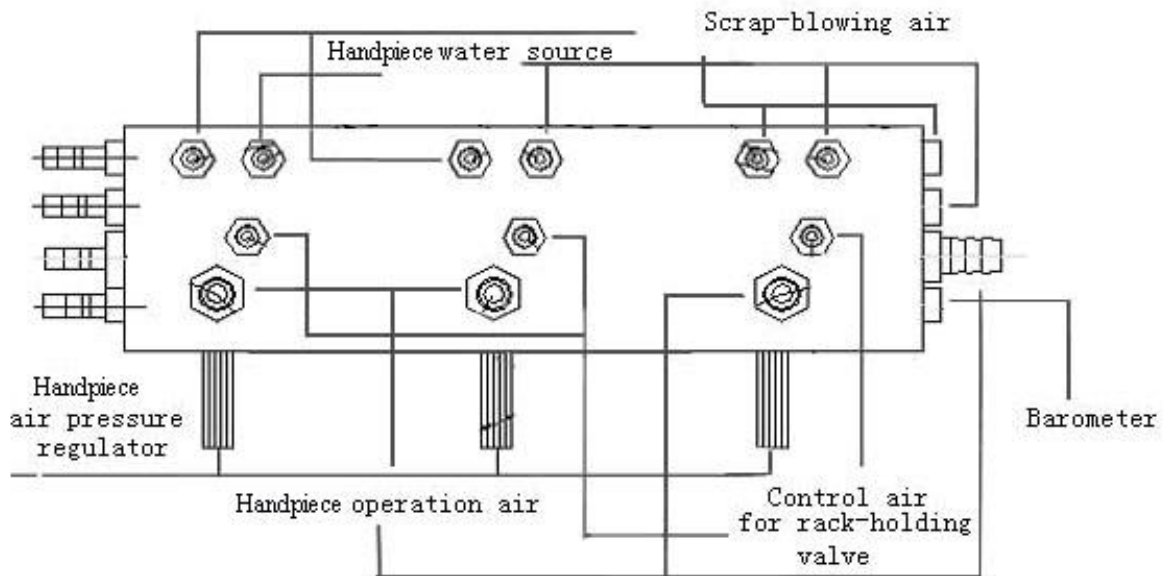
6.7 Cuspidor

You can press the flush  or water supply button  on the main control button panel or the Assistant-control button panel to realize the flushing or water supply function of the cuspidor. The factory default setting for cuspidor flushing is automatic flushing for 30 seconds, and the factory default setting for water supply is automatic water supply of 100ml. Both the cuspidor flush and water supply functions can be reset.

6.8 Adjusting the dental treatment Instrument tray

6.8.1 Dental handpiece adjustment

The QL2028 model provides and regulates air and water for the operation of dental handpiece auxiliary equipment. You can adjust the cooling water, blowing air and operating air pressure of the dental treatment Instrument tray. See Figure 11.



6.8.2 Blowing air adjustment

The cooling air controller adjusts the cooling air to all dental handpieces by manually turning a knob.

To regulate cooling air:

The step 1 is to remove the dental handpiece from the holder. The step 2 is to find the blowing air controller. Step 3: Depress the foot control to activate the dental handpiece. The step 4 is to adjust the blowing air to achieve the ideal atomization effect (Figure 11). Step 5: Adjust the blowing air:

Turn the controller clockwise to reduce the flow. Turn the controller counterclockwise to increase flow.

6.8.3 Cooling water adjustment

The system includes cooling flow control for each dental handpiece, with manual adjustment by turning a knob.

The step 1 is to remove the dental handpiece from the holder, and the step 2 is to find the cooling water flow adjustment. The step 3 is to turn on the cooling water (on the foot control panel, open the water/no water status valve). Step 4: Depress the foot control to activate the dental handpiece. Step 5: Adjust the cooling water flow: Turn the controller clockwise to reduce the flow. Turn the controller counterclockwise to increase flow.

6.8.4 Configurable adjustment of ultrasonic scalers, curing light, dental handpieces and dental electric motor



Tip: Please adjust the working air pressure of the corresponding configuration to meet the working specifications of the manufacturer of the corresponding configuration. Please consult the product instruction manual for your corresponding configuration to understand the specifications for the operation of the corresponding configuration.

7.Maintenance

Modification of this equipment is not allowed

7.1 The outer surface of the equipment cleaning and disinfection methods:

7.1.1 Cleaning

It is recommended to use Metrex CaviCide as a cleaning agent for the outer surface of the equipment (plastic shell and metal outer surface、Cuspidor). It is recommended to use Metrex CaviWipes to clean areas frequently touched by patients (leather mats, handrails, etc.). (Post-operative care should be initiated immediately, ideally within 30 minutes following the completion of the operation. The cleaning process should be initiated no later than 24 hours after the operation).

Metrex CaviCide EPA registration number: 46781-6

Metrex CaviWipes EPA registration number: 46781-8

7.1.2 Disinfection

It is recommended to use medical alcohol solution to disinfect areas frequently touched by patients.

parts	Clean	Disinfection	Sterilization
3-way Syringe (JIBPT-CX-02)	Automatic cleaning verification	N/A	3- way syringe Tip Sterilization parameter. Setting sterilization pressure: 134°C,4 min
Oral Lamp	use Metrex CaviCide as a cleaning agent for the outer surface of the equipment	to use medical alcohol solution to disinfect areas frequently touched by patients	N/A
Instrument tray	use Metrex CaviCide as a cleaning agent for the outer surface of the equipment	to use medical alcohol solution to disinfect areas frequently touched by patients	N/A
Leather	use Metrex CaviWipes to clean areas frequently touched by patients	to use medical alcohol solution to disinfect areas frequently touched by patients	N/A

Use soft and disposable paper or sterilized gauze when cleaning and disinfecting.

It is recommended to use rags, sponges, or other reusable materials for general cleaning tasks, provided they are properly disinfected between uses.

Cautions: Prevent contact with internal device components, Control system, during the surface cleaning.

7.2 Water tubing disinfection:

7.2.1 Dental unit waterlines need disinfection to prevent biofilm and ensure patient safety.

7.2.2 Disinfectant selection

It is recommended to use a slightly acidic hypochlorous acid solution with a concentration of 85-100mg/L as the disinfectant. Before disinfection, please carefully read the label of the disinfectant you purchased. If the hypochlorous acid concentration is higher than the recommended concentration, it needs to be diluted before use. For example, if your disinfectant has a concentration of 200mg/L, you need to dilute it with pure water in a ratio of 1:1 (For example, by adding 250 mL of the disinfectant concentrate to 250 mL of pure water and stirring them evenly, a 500 mL disinfectant solution with a chlorine content of 100 mg/L can be obtained. and then it can be used).

7.2.3 Disinfection method

— Use a water bottle to hold 500ml of disinfectant solution, turn on the water source switch on side box.

— turn on the cuspidor flushing button and the mouth wash water button, and allow them to run for approximately 30 seconds.

—Remove all the handpiece tubes from the stand. Rotate the water adjustment knob of the handpiece tube counterclockwise to maximize the water output. Then press the water control button on the foot pedal to make the handpiece tube dispense water for 30 seconds.

—Remove the two Three-way Syringes from the rack, press the water outlet button of the Three-way Syringe to make it dispense water until all the disinfectant in the water bottle is used up.

—After completing these actions, the disinfectant solution will fill every water pipe in the dental unit.

—Stay still overnight.

Attention: When in a stationary state, the input air source of the dental unit cannot be turned off; only the power supply of the dental unit can be shut off.

—Before the next day's use, turn off the water source switch on side box, Then replace the water reservoir bottle with a clean bottle filled with purified water. Turn on the water source switch on the side box.

Remove the two three-way syringes from the hangers, press their water discharge buttons, and let water flow for about 90 seconds.

Remove all handpiece tubes from the hangers. Step on the water control pedal to let water flow through the handpiece tubes for about 90 seconds.

Turn on the cuspidor flushing button and the mouth wash water button, and let them operate for about 90 seconds.

This will completely remove any disinfectant residue from the waterlines.

Attention: After disinfection is completed, when using it for the first time, please adjust the water volume of the mobile tube according to your needs.

7.2.4 Disinfection frequency: The first disinfection shall be performed following the steps above. After the initial treatment, subsequent use shall be operated following the steps above once a

month.

Attention: If your dental unit has not been used for more than one month, it must be disinfected according to the above-mentioned methods before it can be used again.

7.3 3-way syringe cleaning and sterilization methods:

7.3.1 Cleaning

7.3.1.1 Automatic cleaning

Cleaning solution: Belimed Protect CLEAN NE

Follow the procedure set below. Make sure the washer-disinfector door is closed and start the washer-disinfector.

Prewash: 180 seconds

Cleaning: 420 seconds, 50°C

Cleaning solution: 5mL/L (2.8mL /s)

Rinse: 60 seconds, 45 °C

Cold air: 120 seconds

Drying: 180 seconds, 55 °C

7.3.1.2 Manual cleaning

Perform pre-treatment: Remove triple gun, strong and weak suction handles, rinse with purified water

Dry the surface and place it in the refreshing frame, add Myris Surface Disinfectant.

Soak for 2-3 minutes and wipe over the surface with disinfectant wipes.

Dry naturally

Transfer to sterilizer for sterilization

7.3.2 Sterilization

Three-way syringe Tip Sterilization parameter. Setting sterilization pressure: 201.7~229.3 kPa, temperature: 134°C, Sterilization time setting range: 4 min, drying time setting range: 15 min.

Three-way syringe can be sterilized up to 250 times; the product is not destroyed.

7.4 Water system

7.4.1 To ensure the normal use of this equipment, a filter is installed at the water inlet end of the equipment to block impurities in the water from entering the equipment. However, over time, sewage will block the filter element and affect the flow of water. At this time It is necessary to clean

or replace the filter element to restore function.

7.4.2 Under normal circumstances, if one of the following conditions occurs, the filter element must be cleaned or replaced.

7.4.2.1. Used for more than one year;

7.4.2.2. The pressure loss of the filter element is above 0.1MPa;

7.4.2.3. The filter element is contaminated;

7.4.2.4. The outlet water becomes turbid;

7.4.3 The specific method for cleaning and replacing the filter element is: open the floor box cover, remove the water filter, unscrew the water filter shell counterclockwise, take out the lower sealing ring and filter element in turn, after cleaning or replacement, remove the water filter in reverse order Install the filter and pay attention to sealing. (For user-configured filters, please refer to the above paragraph.)

7.4.4 This equipment is equipped with a sampling point for input water. See the sampling port for below picture

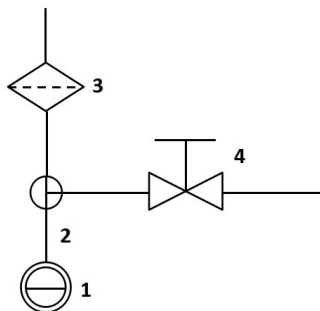


Figure 9. Sampling point for input water

Illustrate:

1---Input water supplied by domestic drinking water

2-Input water connection port

3-Water particulate filter

4-Input water sampling connection port

7.5 Air system

7.5.1 In order to ensure that the air input to the machine is clean, dry and the air pressure is stable, an air filter pressure reducing valve is installed at the air inlet of the floor box of the machine to stabilize the air pressure so that it does not exceed the set value and plays a role. It has the

function of filtering impurities and moisture in the air to a certain extent. The filtered water will accumulate in the filter cup. Over time, if too much water accumulates, the water must be drained to avoid affecting the filtration effect.

7.5.2 Under normal circumstances, the filter pressure reducing valve must be drained under one of the following circumstances.

7.5.2.1 The use time is more than one week;

7.5.2.2 The water in the filter cup occupies three-quarters of the volume;

7.5.2.3 The water in the filter cup changes color (not colorless and transparent water).

7.5.3 The specific method to drain the filter pressure reducing valve is: open the floor box cover and turn the nut at the bottom of the filter clockwise by hand to drain the water. After the water is drained, tighten the nut counterclockwise, in order to keep the environment clean, absorbent materials, such as cotton cloth, paper towels, sponges, etc., can be placed on the outlet pad to absorb the discharged water.

7.6 Inspection

7.6.1. visual inspection should be conducted following each cleaning process. No visual contamination should be found; otherwise, the entire cleaning/disinfection process must be repeated.

7.6.2. Check the device and accessories. If there is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used. Any new replacement must be cleaned, disinfected and dried.

7.6.3. If the service time of the product reaches the specified service life, please replace it in time.

7.7 Maintenance

It is recommended that professional maintenance personnel from the hospital conduct electrical safety inspection and maintenance once every six months to specifically check whether the leakage current and protective grounding connection meet the requirements.

7.8 Storage/transportation environment

Temperature: -40 to 70 °C

Relative Humidity: 10 to 100 %

During transportation, excessive impact and shaking shall be prevented. Lay the device carefully and securely, avoiding inversion. Ensure it is not mixed with dangerous goods and it is protected from exposure to sun, rain, or snow

8.Precautions

1. Read carefully and understand all the contents in the instruction manual before operating.
2. The power socket cord should be configured as standard, the ground wire must be firm, and maintenance personnel should replace the soft power cord. Do not place it in a place where it is difficult to disconnect power supply, this product must not be connected to other mobile devices.
3. The main water, air and power switches should be turned off when leaving get off work.
4. The influence of electromagnetic interference has been taken into consideration in the design of this product. In order to ensure normal application, it should be kept away from high-frequency electrical signaling equipment during operation to avoid interference.
5. The compressed air provided for this machine should be oil-free, and other hygienic indicators should meet relevant requirements.
6. During the operation of this machine, make sure that there are no accessible objects within the range of motion. To disconnect the network power supply, press the one-button water and air switch.
7. If used together with external equipment for Implant work, the power supply of the machine must be disconnected every time. To avoid personal injury due to malfunction and accidentally touching the control buttons.
8. Users must configure the amalgamator at the end of the wastewater discharge system of this machine.
9. Perform routine maintenance once a quarter. When replacing electrical components or performing maintenance and cleaning, the power supply must be cut off and maintenance personnel must replace the components.
10. This machine cannot be used in the presence of flammable anesthetic air mixed with air or flammable anesthetic air mixed with oxygen or nitrous oxide.
11. The placement of wastewater and waste must comply with local environmental protection requirements.
12. After parts and components are scrapped, they must be disposed of in accordance with local regulations.
13. Maintenance of this machine must be carried out by professional maintenance personnel authorized by the company. Unauthorized disassembly and repair may cause fatal harm to the machine, and you will no longer have the right to the warranty service provided by the company.

14. Do not touch the dental light bulb directly with your hands. Wait for the bulb to cool down before replacing it with protective gloves to avoid burns. It is strictly forbidden to touch the PCB board and the manufacturer's electronic components with your hands or metal instruments.

15. This machine needs to be operated by professional medical personnel. Please receive technical training and technical guidance before use.

16. Warning: To avoid the risk of electric shock, this equipment must be connected to a power supply network with protective grounding.

17. When using the X-ray Viewer, do not touch the X-ray Viewer with sharp and hard objects, and keep the surface of the X-ray Viewer dry to avoid damage to the X-ray Viewer and moisture.

18. Contraindications: None

19. Common faults and troubleshooting

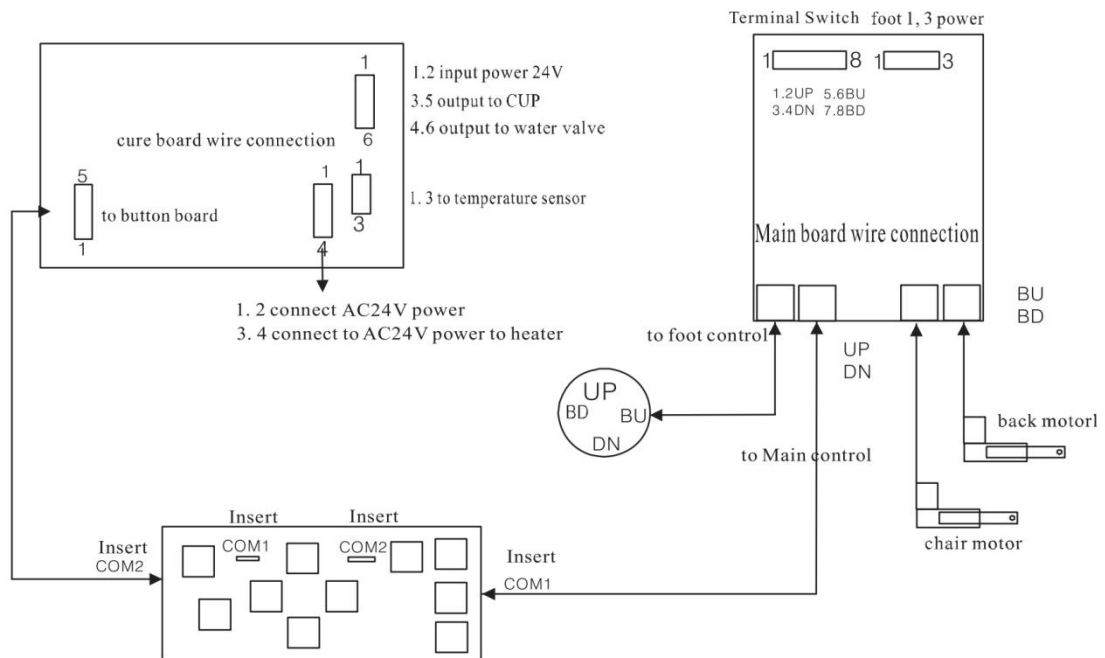
Failure causes and solutions		
Fault	reason	Approach
Continuous water control with handpieces	Defective water outlet valve	Refer to the handpiece's user manual
Water coming out of handpieces contains bubbles	1. Defective high-speed handpieces gasket 2 broken pipes	A Refer to the handpiece's user manual B Check and replace
Poor water atomization from handpieces	1 The nozzle of the high-speed handpieces head is blocked 2 Improper atomization adjustment	A Contact your handpieces provider B Re-adjust the atomizer
No water sprays out from handpieces	1 Water pressure is too low 2 The water regulating valve is not opened The water switch on the 3-pin switch is not turned on 4 The water source switch is not turned on 5. Replacement of tap water and purified water switch 6 There is no pressure in the pure water cup	A Adjust water pressure B Open the water regulating valve C Turn on the foot pedal water switch D Turn on the water source switch E Adjustment switch F Adjust the simple pressure reducing valve switch
Handpieces head is weak	1. Defective needle and bearing. 2. Not enough work pressure	A Contact your handpieces provider B Check air pressure
Air leaks when the handpieces is not working	Hanger valve loose	Adjust the corresponding position of the hanger valve
Unstable work pressure	1 filter blocked 2 The air intake pipe is twisted and held back	A Cleaning B Check the pipeline
The flushing water is not flowing smoothly	The solenoid valve is blocked by foreign matter	Clean the solenoid valve core
Weakness in sucking saliva	1 filter clogged 2. Insufficient water pressure or air pressure	A Clean the filter B Adjust water or air pressure
3-way syringe does not produce water	1 water pipe blocked 2. The water outlet adjustment button is improperly adjusted.	A Plug the nozzle and press the water and air buttons at the same time B Readjust
3-way syringe spray containing moisture	1 There is too much water in the air filter 2 Valve core failure 3. The nozzle installation is not suitable	A timely drainage B Check and replace C Reinstall

If the equipment still cannot work normally after the above inspections and treatments, please contact the dealer or our company's after-sales service staff and inform the product model, factory number and fault details.

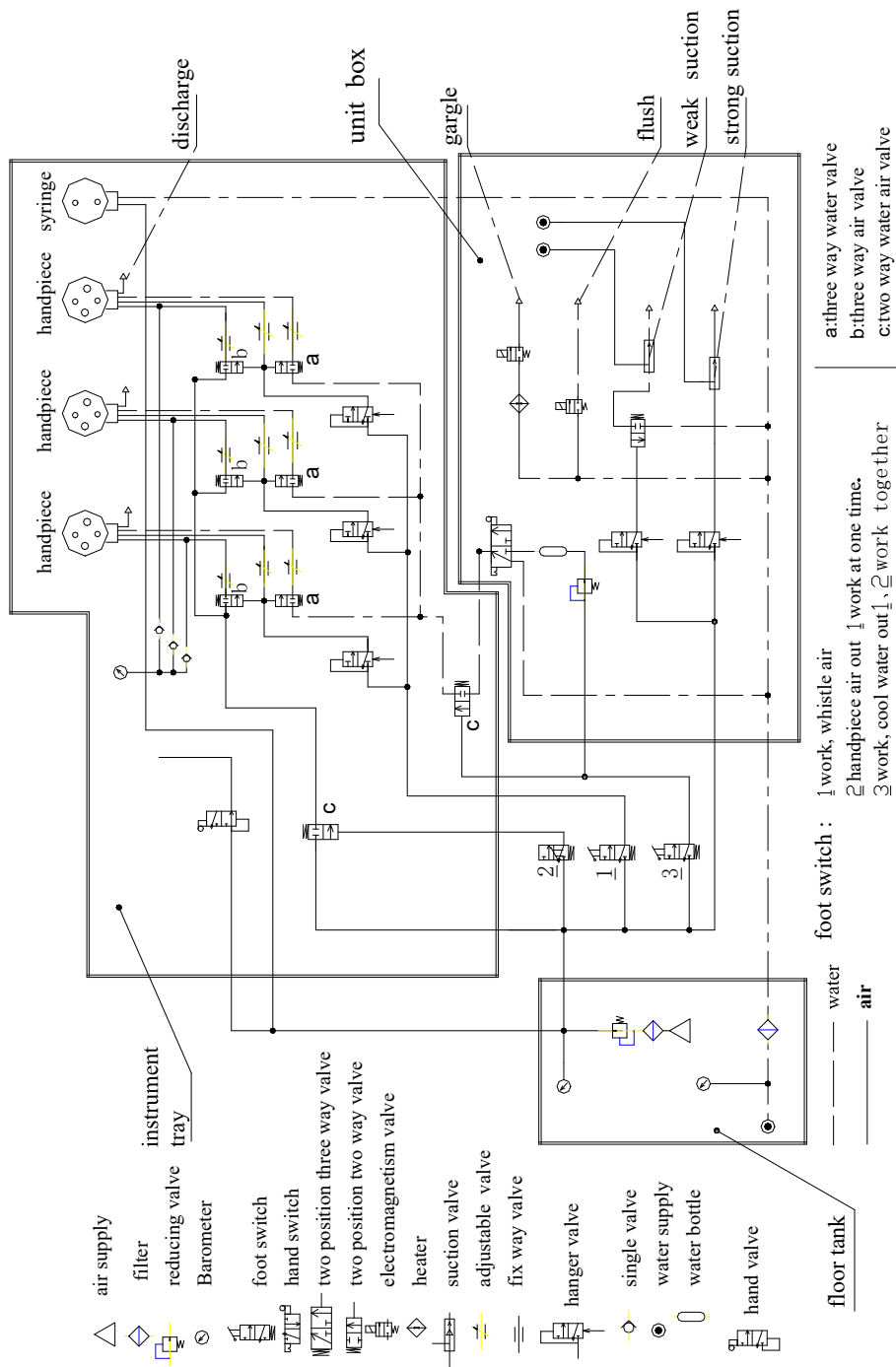


Note: This manual is for use with standard products. If it is a special-order product, please refer to the relevant attachment page of this manual.

9.Circuit Schematic Diagram



10. Water air schematic diagram



Note: Non-professionals are not allowed to disassemble this machine. Our company only provides accessories to customers with maintenance agreements.

11. Electromagnetic compatibility



Notice:

- *Integral dental unit Comply with the relevant requirements of electromagnetic compatibility of IEC 60601-1-2 standard.*
- *Users should install and use it according to the electromagnetic compatibility information provided in the accompanying documents.*
- *Portable and mobile RF communications equipment may affect Integral dental unit performance, avoid strong electromagnetic interference when use it, such as being close to handpieces, microwave ovens, etc.;*
- *The following RF emitters may be source of electromagnetic disturbance: Diathermy, electrocautery, MRI, EAS and RFID. Please avoid to be exposed to these potential electromagnetic disturbance sources.*
- *Device's functions/performance and a description of what the operator can expect if the functions/performance are lost or degraded due to EM disturbances. For IEC 60601-4-2, these are functions/performance needed to demonstrate the device performs as intended, and for all other IEC 60601 standards this is Basic Safety and Essential Performance.*
- *Guidance and manufacturer's declaration are detailed in appendix.*



Warning:

- *Integral dental unit should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed and verified that it can operate normally under the configuration it is used in.*
- *Remove Integral dental unit except for cables sold by manufacturers as spare parts for internal components, use of accessories and cables other than those specified may result in Integral dental unit increased emissions or decreased immunity.*
- *Appendix:*

Serial number	Name	Cable length (m)	Whether to block	Remark
1	POWER CABLE	2	NO	/
2	PEDAL CABLE	1.8	YES	/

Guidance and Manufacturer's Statement–electromagnetic emission			
The Integral dental unit is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment:			
Launch test	Conformity	electromagnetic environment–guide	
RF emissions CISPR 11	Group 1	Dental units use radiofrequency energy only for their internal functions. Therefore, its RF emissions are very low and are less likely to cause interference in nearby electronic equipment	
RF emission CISPR 11	Class B	Integral dental unit Suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network for domestic use	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		
Guidance and Manufacturer's Statement–Electromagnetic immunity			
The Integral dental unit is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment–guide
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tiles, and if floors are covered with synthetic materials, the relative humidity should be at least30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power should be of a quality typical for use in a commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power should be of a quality typically used in a commercial or hospital environment
Voltage dips, short interruptions and voltage variations	<5% U _T (>95% dip in U _T) for 0.5 cycle	<5% U _T (>95% dip in U _T) for 0.5 cycle	Mains power should be of a quality typically used in a commercial or

on power supply input lines IEC 61000-4-11	40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	hospital environment. If the user of the dental unit requires continuous operation during a power outage, an uninterruptible power supply or battery power supply is recommended
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should have power frequency magnetic field level characteristics typical of a typical location in a typical commercial or hospital environment.
Note: U_T Refers to the AC network voltage before applying the test voltage.			

Guidance and Manufacturer's Statement–Electromagnetic immunity

The Integral dental unit is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment–guide
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms}	Portable and mobile radio frequency Communications equipment should not be used closer to any part of the dental unit, including cables, than the recommended isolation distance. This distance is calculated by the formula corresponding to the frequency of the transmitter. Recommended isolation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz~800MHz $d = 2.3\sqrt{P}$ 800MHz~2.5GHz In the formula: P —According to the transmitter manufacturer's maximum Rated output power in watts (W); d—Recommended isolation distance, in meters (m) b. The field strength of fixed radio frequency transmitters is determined by a survey of the electromagnetic field c and should be lower than the compliance level in each frequency range d. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: On 80MHz and 800MHz frequency, the formula for the higher frequency band is used.

Note2: These guidelines may not be suitable in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and human bodies.

^aThe field strengths of fixed transmitters such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and television broadcasts cannot be predicted with theoretical accuracy. To assess the electromagnetic environment of fixed RF transmitters, a survey of the electromagnetic field should be considered. If the measured field strength in the location where the dental unit is located is higher than the applicable RF compliance levels above, the dental unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the dental unit.

^bIn the entire frequency range of 150kHz to 80MHz, the field strength should be less than 3V/m.

Portable and mobile radio frequency Recommended isolation distance between communications equipment and dental unit			
Integral dental unit is expected to be radio frequency Used in electromagnetic environments with controlled radiation disturbance. Based on the maximum rated output power of the communication equipment, the purchaser or user can maintain portable and mobile radio frequency Minimum distance between communication equipment (transmitter) and dental unit to prevent electromagnetic interference.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333
For transmitters with maximum rated output power not listed above, recommended isolation distances d, in meters(m) as a unit, which can be determined by the formula in the corresponding transmitter frequency column, here P is the maximum rated output power of a transmitter as provided by the transmitter manufacturer, in watts (W) as the unit. Note 1: At the 80MHz and 800MHz frequency points, the formula for the higher frequency band is used. Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human bodies.			
