stomdevice

VRN®

OPERATION INSTRUCTION

K08D

ULTRASONIC SCALER

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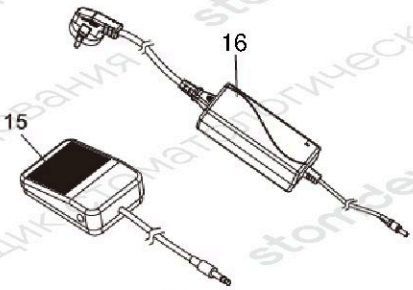
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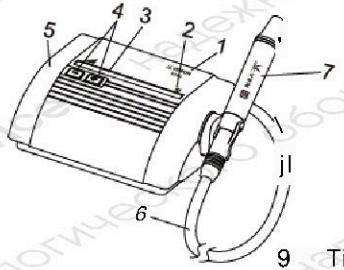
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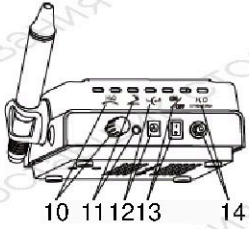
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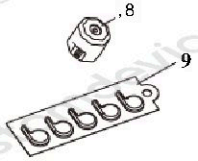
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COMPONENTS









1 Model and LOGO
2 Power On/Off LEDs
3 Power control LEDs
4 Power control buttons
5 Unit
6 Detachable cable
7 Detachable handpiece
8 Tip wrench
9 Tips
10 Water volume knob and icon
11 Foot switch connection and icon
12 External power supply connection and icon
13 Power switch and icon
14 Fluid circuit connection and icon
15 Foot switch
16 External power supply

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COPYRIGHT AND STATEMENT

Copyright © Guilin Veirun Medical Technology Co., Ltd.

Congratulations to become valued customers of Guilin Veirun Medical Technology Co., Ltd. Thanks for using K08D ultrasonic scaler. It will bring you the new experiences and conveniences.

This instruction manual is including the latest information when printing. Guilin Veirun Medical Technology Co., Ltd reserves the rights to change the design of the equipment, the technique, fittings the instruction manual and the content of original packing list at any time without notice. If there are some differences between blueprint and real product, take the real product as the norm.

This instruction manual is protected by copyright law. Without any official authorization, any form of duplication, copy or translated into another language is notallowed.

Read the instruction manual originally delivered with each of the components before using this product, and follow the instruction manual to operate. Otherwise, Guilin Veirun Medical Technology Co., Ltd does not take any responsibility for any errors and damage to the product because of violation operation.

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Note: Guilin Veirun Medical Technology Co., Ltd does not promise any implied guarantee to the product special use for merchantability and applicability.

If you need after-sale service support, please contact with authorization dealer or manufacturer.

Wainning

The device is not suitable for use in the presence of flammable anesthetic mixtures with airor with oxygen or nitrous oxide.

The device requires no calibration.

The device is not repairable and contains no user serviceable parts.

No modification of this equipment is allowed. (3rd Edition)

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

The manufacturer does not require such preventive inspections by other persons.

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The installation and components of equipment

Instruction

Guilin Veirun Medical Technology Co., Ltd. is a professional manufacturer in researching, developing and producing ultrasonic scalers. The product is mainly used for teeth cleaning and is also an indispensable equipmentfortooth disease prevention and treatment. The product K08D ultrasonic scaler has scaling, perio and endo functions. It contains the following features:

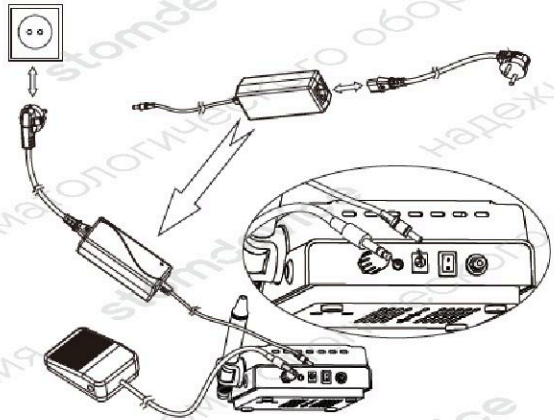
- Automatic frequency tracking ensuresthatthe machine always works on the best frequency and performs more steadily.
- The handpiece is detachable and can be autoclaved to the high temperature of 135"C and the pressure of 0.22MPa.
- Digitally controlled, easy operation and more efficient for scaling.

Components

- The components of machine are listed in the packing list.
- Product performance and structure Ultrasonic scaler is composed of electro circuit, water way and ultrasonic transducer.
- The device is used for the dental calculus elimination and root canal irrigation.

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INSTALLATION AND CONNECTION



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Always check that the unit is installed in a safe and stable position. An eventual fall maysuddenly pull on the cord and the handpiece, hurting the patient and the user, and damaging the unit.

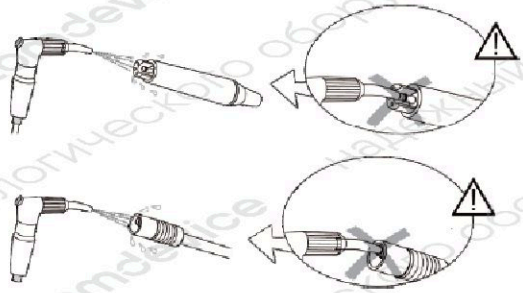
Check that the rated voltage of the power supply corresponds to the local line voltage to prevent damaging the unit.

Use the unit only in a FI protected mains supply (FI = Residual current protection).

For USA or Canada: connect only to an Hospital Grade outlet.

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PREPARING FOR TREATMENT



Clean, disinfect and sterilize the different pieces and accessories of this product before each use. Please refer to the information provided in the operating instructions. Non-sterile pieces and accessories may cause bacterial or viral infections.

Blow dry the connections to remove eventual presence of liquid to ensure a proper electrical contact. Never blow compressed air in the irrigation connections as this will irremediably damage internal parts

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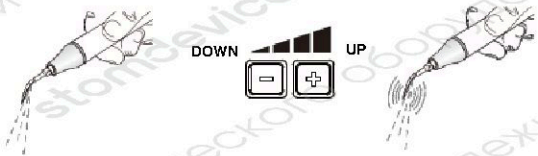
MA WRENCH



The device is used for the dental calculus elimination and root canal irrigation.With a special structure design,wrench makes sure that users can handling the tip effectively during
Using it,and protects user' s hand from hurting in the process of loading and unloading thetip.
Sterile environment: Temperature 135 degrees, Pressure 0.22Mpa,in the steam.
Steps:
(1) Align the legsofthewrench to thetip.
(2) Install the tip: grip the handle, rotate the tip in right-handwisetill thetip dose not turn round anymore.
(3) Unloading thetip: grip handle then rotate thetip in counter-clockwise by wrench to remove it.
(4) [illegible] after using, please putthe wrench into disinfection cabinet to disinfect.
(5) After disinfection, the surface temperature of the wrench is too high to be used again, so users must wait until it is cool down, avoiding hurt.
(6) When not use the wrench,put it at some place that is dry and ventilated,and keep it clean.

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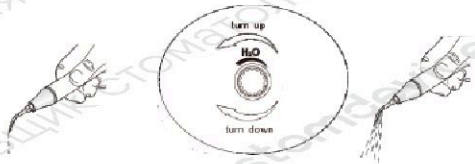
SETTING THE ULTRASOUND POWER



Using the vibration intensity knob increases or decreases the power of the ultrasound. Adjust vibration ntensity on-demand, generally, the medium is right, it also can be adjusted in the clinical course according to the sensitivity of patients and the hardness of the dental stone.

⚠ Adjust power to the lowest when just turn on the host.

SETTING THE LIQUID FLOW RATE



Depress the foot switch, and the tip starts vibrating, and then revolve the water volume knob and the water spraying puffs, itwill cool down the handle and clean the surface of teeth.
Never work dry to avoid heat damage on the tooth. The tip of the instrument immediately heats up when used dry.

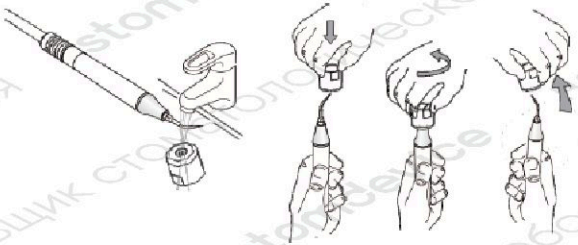
⚠ Adjust water volumn to larger when lust turn on the host.

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FOOT SWITCH FUNCTIONS



END OF TREATMENT



Clean the instrument with running water before disinfection.
Please conform to the recommendations of the "Reprocessing Instructions" manual delivered with your product regarding the procedures ofcleaning, disinfecting and sterilizing of the components.

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ADDITIONAL INFORMATION

K08D Ultrasonic scaler has a endo function with the use of the E1 or E2 endo chuck provided by Guilin Veirun medical technology Co., LTD., which can grip the ultrasound root canal file with a outer diameterof 0.8mm 15#-40#.

Use steps:

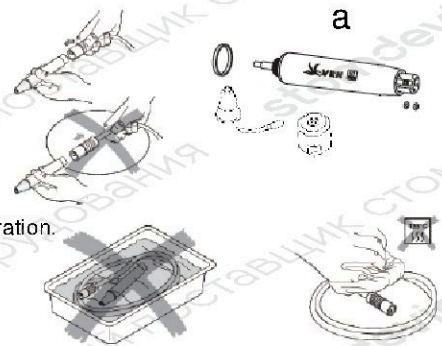
1) Fix the endo chuck on the top of handpiece by using the endo wrench.
2) Screw off the nut of the endo chuck.
3) Insert the ultrasound root canal file into the endo chuck.
4) Screw down the nut of endo chuck tightly by using the endo wrench.
5) Press the and "+" buttons at the same time, then the function indicator light would show E from G and the machine turns into the endo mode.
6) Put the ultrasound root canal file into patient's tooth root tube slowly, and then begin the root-canal therapy by stepping down the foot switch. You could adjust the power according to need.

Note:

1) Make sure the endo chuck must be tightened during its installation.
2) Make sure the nut must be tightened during its installation.
3) Ultrasound root canal file must be inserted into the bottom of endo chuck.
4) Do not press hard when the tooth root tube is processing root-canal therapy.
5) Do not step down the foot switch until the ultrasound root canal file is not put into root tube.
6) During the endo function, we advice to slowly increase the inchoate power control from 1 to 5 grade.

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Sterilization and maintenance



Sterilization of detachable handpiece

Autoclaved under high temperature/pressure:

1)121 XJ/Ibar(0.1MPa) 20 minutes

2)135t/2.2bar(0.22MPa) 15 minutes

3)Pull out the handpiece and unscrew the scaling tip andendochuck after each operation.

4)Pack the handpiece with sterile gauze or sterile bag before sterilizing.

5)Reuse handpiece after it cools naturally in case of scalding hand.

Notice:

1)Dry the cleaning liquid in the handpiece with compressed air before sterilization.

2)Be sure that the scaling tip has been unscrewed from the handpiece and it cannot be sterilized with others.

3)Please check whether the outer of the handpiece is damaged during the treatment or sterilization, and do not apply any protective oil on the surface of handpiece.

4)There are 2 waterproof O-ring at the end of handpiece. Since sterilization and repeated pulling and inserting will reduce its using life, please lubricate them with dental lube frequently. Change the new 0- ring if it is damag ed or worn excessively.

5)The sterilizable parts can be sterilized over 250 times.

6)The following sterilizing methods care forbidden:

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- **Put handpiece into any liquid for boiling;**
- **Dip handpiece in disinfectors such as iodine, alcohol and glutaraldehyde;**
- **Put handpiece into oven or microwave oven for baking.**

Sterilization of tips and endochuck

All the scaling tips and endochuck can be autoclaved under high temperature and pressure.

Sterilization of wrench and endo wrench

1)The wrench and endo wrench can be sterilized under high temperature and pressure.

2)The following sterilization methods for wrench are forbidden:

- Braise in liquor;
- Dip in iodine, alcohol or glutaraldehyde;
- Torrefy in oven or microwave oven

Notice:

We are not responsible for any damage of the torque wrench directly or indirectly made by any way in the above items.

Clean of tips, endochuck, wrench and endo wrench

The scaling tip, endochuck, wrench and endo wrench can be cleaned by ultrasonic cleaner.

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MAINTENANCE



⚠

Always use VRN original parts. Using non-original instruments may damage the unit, and practitioner or patient may be injured.

SAFETY PRECAUTIONS

VRN and the dealer of this product accept no liability for direct or consequential injury ordamage resulting from improper use, arising in particular through non-observance of the operating instructions, or improper preparation and maintenance.

⚠

Contraindication: ultrasonic oscillations may prevent cardiac pace makers and defibrillators from functioning properly. Therefore, we recommend that patients with a cardiac pace maker or a defibrillator should not be treated with this product.

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Use for the intended purpose only: before using the product, make sure that you have studied the operating instructions. This also applies to any equipment used with this product. Failure to observe the operating instructions may result in the patient or user suffering serious injury or the product.

Risk of explosion: do not use this product in the presence of inflammable anaesthetics orgases.

This product must be used only by trained and qualified personnel.

Clean, disinfect and sterilize the different pieces and accessories of this product before each use.

Please refer to the information provided in the operating instructions. Non-sterile pieces and accessories may cause bacterial or viral infections.

This product has been investigated with regard to safety from electrical shock and fire hazard.

ETL (Electrical Testing Laboratories) has not investigated the physiological effects.

Always examine the product for damage before commencing treatment. Damaged accessories or a damaged unit must not be used and must be replaced. Use original VRN spare parts and accessories only.



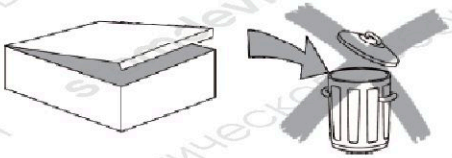
Have this product exclusively repaired by an approved VRN repair center.

Use exclusively the external power supply delivered with the VRN unit.

Certain types of mobile telecommunication equipment could potentially interfere with this oroduct. The separation distances recommended in the "Electromagnetic compatibility" manual must be taken into account.

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STORING THE PRODUCT



Keep the original packaging until the product is to be disposed of permanently.
It can be used for shipping or storing at any time.
Should you wish to put your product out of use for an extended period of time:

- Proceed as described in the "Cleaning, disinfecting and sterilizing" chapter,
- Pack the product and all accessories in the original packaging.

Please refer to the storage and transport conditions in the "Technical data" chapter.

DISPOSAL

The product must not be discarded in domestic household waste.
Should you wish to definitively dispose of the product, please comply with the regulations which apply in your country.
Waste Electrical and Electronic Equipment belonging to customers located in the European Union may be shipped to VRN for recycling in accordance to the WEEE regulations. The costs of recycling, exclusive of shipping fees, are covered by VRN.

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WARRANTY

Damages due to non-adherence to the operating instructions or wear out of parts are excluded from warranty.



The warranty of your product will be cancelled if you try to open it.

ACCESSORIES

Accessories are available from VRN or any authorized dealers. Please contact your customer service directly.

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VRN SERVICE

Should your product need additional servicing or repairs, please send it to yourdealerorto an authorized VRN Repair Center.

In the case of non-authorized repairs ordamages due to non-adherence to the operating instructions, VRN accepts no liability whatsoever. This will also void the warranty.

It is best to ship your product in the original packaging. It protects your product against damage during shipment.

△

Risk of transmitting micro-organisms! To protect the personnel of the repair center and for safety reasons during transport and shipment, the product and the accessories returned to the factory for repair or revision must be cleaned, disinfected and sterilized in accordance with the operating manual. Repair can be refused for

When sending your product directly to the approved VRN repair center, please include the name of your dealer. This simplifies processing.

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SYMBOLS

VRN	* Manufacturer' s logo		Caution! Read the operation instruction		Class H equipment	1	Applied part, type BF
	Disposal		Manufacturer		Used indoor only	SN	Serial number
135C	Autoclavable	90% 0%	Storage Humidity	-20℃ 55℃	Storage Temp		Keep dry
	Fragile		Refer to instruction manual/ booklet	EC REP	Authorised representative in the European community	C € 0123	CE marking :refers to directive 93/42 EEC including EN60601-1 and EN60601-1-2
- +	Electrical Outlet		Foot switch connection	HQ 0.01Mpa-0.5Mpa	Water supply	ON/ /OFF	Power Switch
	Production date	IPX1	Prevent water droplets intrusion				

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TECHNICAL DATA

Description	Manufacturer Guilin Veirun Medical Technology Co., Ltd.
Models	K08D
Classification EN 60601-1	- Class II -Applied part, Type BF -IP20, unit - IPX1, foot pedal Not category AP/APG equipment
Classification 93/42 EEC	Class IIa
Operating m ode	Continuous operation
Power Supply	
Adaptor Input	100-240 VAC / 50-60 Hz, 1.2A
Adaptor Output	30VDC
Power consumption	30VA-48 VA
External power supply	45W30V 2m R5.5-2.5+
Ultrasonic specifications:	
Maximum output	8 Watts
Frequency range	25-31kHz
Weight	Approx. 3kg
Dimensions in mm (HxWxD)	55 x 160 x 160
Operating conditions	+10 •○to +40 P 30% to 75% relative humidity
Storage and transport conditions	-10 r to +40 ”C 10% to 95% relative humidity 500 hPa to 1 060 hPa air pressure

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TROUBLESHOOTING

Fault	Possible cause	Solutions
The scaling tip doesn' t vibrate and there is no water flowing out when stepping on the foot Switch	The power plug is in loose contact	Make the plug insert to the socket well
	The foot pedal is in loose contact (wire foot Switch)	Insert the foot switch to its socket tightly
	The fuse in the main unit is broken	Contact the dealers or us
	The battery for wireless control foot Switch died	Change the new batteries
The scaling tip does not vibrate but there is water flowing out when stepping on the foot Switch	The tip is in loose contact	Screw the tip on the handpiece tightly
	The connect plug between the handpiece and the circuit board is in loose contact	Contact the dealer or us
	Handpiece problem	Send the handpiece to dealer or us to repair
	Cable problem	Contact the dealer or us
The scaling tip vibrates but there is no spray when stepping on the foot Switch	The water control knob is not on	Turn on the water control knob [note 1]
	There is impurity in the electric-magnetic valve	Take the electric-magnetic valve apart or contact the dealer or us
	The water system is blocked	Clean the water pipe by multi-function syringe [note 2]
There is still water flowing out after the power is off	The electric-magnetic valve problem	Contact the dealer or us
The handpiece generates heat	The water control knob is in a low setting	Turn the water control knob to a higher grade [note 1]

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Fault	Possible cause	Solutions
The amount of spouting water is too little	The water control knob is in a low setting	Turn the water control knob to a higher grade [note 1]
	The water pressure is not high enough	Make the water pressure higher
	The water system is blocked	Clean the water pipe by multi-function syringe [note 2]
The vibration of the tip becomes weak	The tip has not been screwed on to the handpiece tightly	Screw the tip tightly
	The coupling between the handpiece and the cable is not dry	Dry it by the hot air
	The tip is damaged [note 3]	Change the new scaling tip
There is water leaking from the coupling between the handpiece and the cable	The waterproof O-ring is damaged	Change the new waterproof O-ring
The U-file does not vibrate	The screw is loose	Tighten it
	Endochuck is damaged	Change the new endochuck
There is noise coming from the endochuck	The screw is loose	Tighten it

Notice:

If the problem still cannot be solved, please contact with local dealer or manufacturer.

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Notes

【note 1]

Turn the water control knob as symbol showed. It comes to the min, on the contrary direction, it comes to the max.

[note 2 】

1)Clean the water pipe with the multi-function syringe of the dental unit ;

2)Disconnect the water pipe from main unit;

3)Get through to the power and turn on the power switch;

4)Connect the multi-function syringe of dental unit to the water pipe;

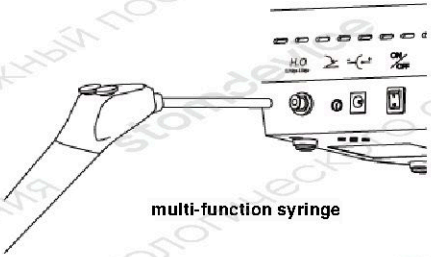
5)Disassemble the tip or handpiece;

6)Step on the foot switch;

7)Turn on the switch of the multi-function syringe, press the water into the machine and the impurity blocked in the water pipe can be eliminated.

【note 3 】If the scaling tip has been screwed on tightly and there is fine spray too, the following phenomena show that the scaling tip is damaged:

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multi-function syringe

TROUBLESHOOTING FOR THE ELECTRIC-MAGNETIC VALVE

If the water is not clean or the electric-magnetic valve works too long, there will be the scale and impurity generated on the insidewall and valve plug. It will cause the water way to be blocked, and could repair as following steps:

1) Follow the [note 2]

2) Uninstall the electric-magnetic valve by following steps:

a)Tum off the power, and unplug the power cable;

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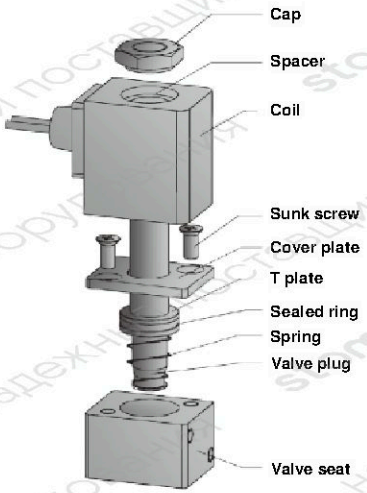
bJUnscrew the cap, and move out the hood of main unit;

c)Unscrew the cap on the electric-magnetic valve, and Uninstall the electric-magnetic valve as shown on Figure ;

d)Take out the valve plug, and clean out the impurity on the insidewall;

e)Install the parts as shown on the figure .

f)Ensure the water way is working by repeat [note 2]



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EMC DECLARATION

Table 1

Guidance and manufacturer's dedaration - electromagnetic emissions		
The [K08] is intended for use in the electromagnetic environment specified below. The customer or the user of the [K08] should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The [K08] uses 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]	The [K08] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [K08] or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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Table 2

Guidance and manufacturer's declaration - electromagnetic emissions			
The [KOS] is intended for use in the electromagnetic environment specified below. The customer or the user of the [K08] should assure that it is used in such an environment			
Immunity Test	**IEC60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC61000-4-2	±6 kV contact +8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

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Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in Ur) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in IH for 5s	<5%○T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in Uy) for 5 cycle 70% U_T (30% dip in Ur) for 25 cycle <5%Lh- (>95% dip in U_T) for 5S	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [K08] requires continued operation during power mains interruptions, it is recommended the [K08] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_T is the a.c. mians voltage prior to application of the test level.			

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Table3

Guidance and manufacturer's declaration - electromagnetic emissions			
The [KOS] Is intended for use in the electromagnetic environment specified below. The customer or the user of the (K08] should assure that it is used in such an environment			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the [K08], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC61000-4-6	3Vrms 150KHz to 80MHz	3V	\d = UV?
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	$d = 1.2\sqrt{P}$ **80 MHz to 800 MHz** **d = 2.3-/P s00MHz to2,S GHz** where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by

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			an electromagnetic site survey," should be less than the compliance level in each frequency range? Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location In which the [K08] is used exceeds the applicable RF compliance level above, the [K08] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [K08].

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Table 4

Recommended separation distances between portable and mobile RF communications equipment and the [K08]			
The [K08] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [K08] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the (K08] 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 transmitter m**		
	150 kHz to 80 MHz d = 127F	**80MHz to 800MHz** *d* **= UV F**	**800MHz to 2.5GHz** *d = 2,yJp*
0,01	**0.12**	0.12	0.23
◯,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 estimated 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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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