# **High Frequency Unit**

**Instruction Manual** 



## Introduction

High frequency unit is a electrosurgical device that designed for effective and safe soft tissue handling to replace the mechanical scalpel. It heat the tissue with the high frequency and high voltage current produced by effective electrode tip when touching with organism, to achieve cutting and coagulation. It has the advantages of fast cutting, effective haemostasis, easy to operate, safe and convenient, and could shorten the surgery time, reduce the patient blood loss and transfusion volume, and minimize patient discomfort and apprehension, thus reduce the possibility of complication and surgery cost.

Safe and effective high frequency soft tissue handling is not only dependent on the instrument safety assurance, but also, to a large extent, on factors under the control of the operator. Operator must be properly trained and alert medical personnel.

In order to assure safe handling, operator must read, understand and follow the important notes and warnings that summarized in this chapter, as well as the instruction manual.

In particular for those with little or no experience with high frequency soft tissue handling, or for those only familiar with conventional low frequency units, in order to familiarize yourself with the device, we kindly ask you to study this manual carefully prior to first usage of the device.

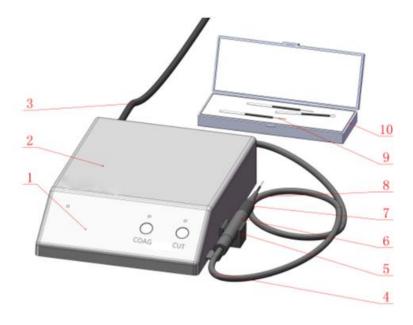
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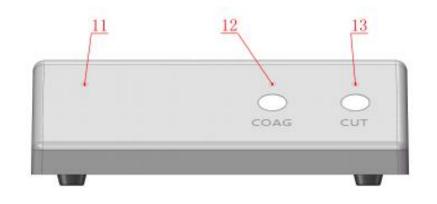
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## A. General Description

High frequency unit is comprised of control box, surgical electrode(needle-, loop- and ball-typed), handpiece, handpiece cord, mains power cord, etc., as depicted in the following figure.







- 11. Green lamp 12. Blue lamp(COAG)
- 13. Orange lamp(CUT)



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  14. Handpiece cord connector
  15. Warning symbol(see chapter N)
  16. Mains

  power inlet
  17. Main ON/OFF switch
  18. Fuse
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#### Intended use/Indications

High Frequency Unit is an electrosurgical device intended to cut or remove soft tissue or to control bleeding in the oral cavity during surgical procedures in all phases of dentistry, including prosthodontics, periodontics, endodontics, pedodontics, orthodontics, oral surgery, and routine restorative dentistry. The device is used for patients who are not less than 10 years old.

#### Intended user

The intended user of High Frequency Unit is professionally trained physicians/healthcare personnel.

#### Intended medical condition

High Frequency Unit is intended to be used in hospitals or clinics for patients who require soft tissue cutting or coagulation during oral surgery.

#### B. Features

#### **B1. High Frequency**

operates at a frequency of 27.126MHz, which is about ten times higher than conventional soft tissue surgery units. Comparing with the conventional working frequency, it has multiple advantages-operationally as well as functionally.

1. At the high frequency, the entire surface of the patients body is acting as a large passive or neutral electrode, which returns the high frequency signal via the air. Conventional soft tissue surgery units use cumbersome neutral electrode, which will increase patient discomfort and apprehension, since does not need neutral electrode, this problem is rendered obsolete.

2. The working frequency(27.126MHz) does not stimulate nerve tissues, so the deep anaesthesia used in conventional soft tissue surgery units is not required. However, in most cases some level of anaesthesia could be used to improve patient comfort.

3. The high frequency of plays a central role for the completely automatic and instantly responding power tuning system. The unique power tuning system is continuously controlling and precisely adapting the power output from a cutting instrument. The instrument delivers the exact amount of energy to make a perfect incision, irrespective of varying clinical conditions. When a cutting instrument is near to bone or tooth structures, the tuning system immediately reduces the power to avoid thermal bone tissue necrosis.

#### **B2. Ergonomics**

s unique use of high frequency and automatic power tuning, replaces the current

waveform selection switches and power adjustment switches on conventional units, and handpiece control replaces the conventional foot switch, all of which make it more convenient to operate.

Conventional units cause different levels of discomfort and apprehension to the patients. The sleek and clutter-free design of could reduce the patient discomfort and apprehension.

#### C. Set-up

high frequency unit is comprised of control box, handpiece, handpiece cord, holder casing with seven different types of surgical electrode(needle-, loop- and ball-typed), and mains power cord.

#### C1. Handpiece and Cord

1. Connect the handpiece with the matching connector at the end of the handpiece cord.

2. Connect the opposite end of the handpiece cord with the matching connector at the rear of the control box.

3. Clip the handpiece in place by pressing it laterally into the handpiece holder.

#### C2. Handpiece Holder

Attach the handpiece holder by inserting its tongue into the slot in the side of the control box (left or right side at option).

#### C3. Control Box

1. Check that your unit is correctly rated for your local power line supply voltage (see the power supply socket label on the rear of the control box).

2. Connect the power cord with the matching power inlet on the rear of the control box, and plug into a wall socket with appropriate protective ground connection.

ANOTE! Should your unit not be equiooed with the appropriate power cord (i.e. pins different from your local standard), please contact customer service or authorized distributor.

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### **D. Operation Controls**

#### D1. Mode Switch Panel

Press the power button to - side at the rear of the control box, and the green lamp is on.

Finger touch-switches:

1. Coagulation Mode: Blue lamp is on or off

-When blue lamp is ON it represents that the device is under the coagulation mode with handpiece ready to operate.

-When blue lamp is OFF it represents that the device is under the standby mode with handpiece inoperative.

2. CUTTING Mode: Yellow lamp is on or off

- When yellow lamp is ON it represents that the device is under the cutting mode with handpiece ready to operate.

-When yellow lamp is OFF it represents that the device is under the standby mode with handpiece inoperative.

#### **D2. Control Box ON/OFF**

ON: Press the handpiece finger switch button (press and hold the rubber ring between fingers).

OFF: Release the handpiece finger switch button.

 $\square$  NOTE! The finger switch button is only operative in the active modes, such as the coagulation mode or cutting mode.

#### E. How to Operate

Press the power button to - side at the rear of the control box, the device will go to the standby mode, and the green lamp on the top left corner is on.

Working environment: Ambient temperature: 1040; Relative humidity: 30%75%; Atmospheric Pressure: 70KPa106KPa.

Cutting (dissection):

1. Firstly, make sure that the device is in the standby mode (only the green lamp is on). If blue lamp or yellow lamp is on, touch the cutting and coagulation mode buttons on the mode switch panel to turn them off, respectively.

2. Insert the desired surgical electrode(needle-, loop-typed) into the handpiece fully and firmly.

3. Touch the cutting mode button on the mode switch panel to turn on the yellow lamp and start the cutting mode.

4. The surgical electrode is now ready for operation. Press the finger switch button on the handpiece to activate the device. Note the acoustic signal for cutting.

Coagulation (stopping bleeding):

1. Firstly, make sure that the device is in the standby mode (only the green lamp is on). If blue lamp or yellow lamp is on, touch the cutting and coagulation mode buttons on the mode switch panel to turn them off, respectively.

2. Insert the desired surgical electrode(ball-typed) into the handpiece fully and firmly.

3. Touch the coagulation mode button on the mode switch panel to turn on the blue lamp and start the coagulation mode.

4. The surgical electrode is now ready for operation. Press the finger switch button on the handpiece to activate the device. Note the acoustic signal for coagulation.

NOTE: Do not start clinical work until having carefully studied Chapter F Preparation

and Familiarization.

Caution: Any treatment must be initiated by checking that the ON/OFF finger switch button responds with an acoustic signal. Do not touch the handpiece tip, when the acoustic signal is sounding.

Caution: As soon as the treatment has been completed and also during any pause in an on-going treatment, please switch to the standby mode (only green lamp is on).

Caution: When inserting and removing the surgical electrode, please switch to the standby mode (only green lamp is on).

#### F. Preparation and Familiarization

When using high frequency unit first time, the operator must get familiar with through practicing prior to starting clinical work. This could be done by practicing with a piece of fresh and lean meat which, when held in the operators hand, constitutes an acceptable clinical practicing model.

#### F1. Dissection Exercise

1. Select the standby mode by touching the switch button to turn off the blue lamp and yellow lamp.

2. Insert needle-, loop-typed electrodes.

3. Touch the cutting mode button to turn yellow lamp on, and check that the ON/OFF finger switch button responds with an acoustic signal.

4. Place the meat in the palm of hand on a piece of paper towel. The meat should not be too dry. If so, moisten with water first.

5. Hold the handpiece in a pencil-typed grip and hold the electrode tip slightly above the tissue surface. Press the ON/OFF finger switch button, you will hear the acoustic signal for the cutting mode.

6. Slightly press the electrode tip on the meat surface and advance the tip with a single

continuous stroke to make an incision which is a few millimeters deep in the meat, while using the high speed suction for odor evacuation.

7. Practice making deep and shallow incisions, and also incisions of varying depth. The electrode tip should always be in motion and be moved as fast as the tissue resistance permits.

#### F2. Coagulation Exercise

Coagulation mode is using the ball-typed electrode to control isolated areas of bleeding.

1. Select the standby mode by touching the switch button to turn off the blue lamp and yellow lamp.

2. Insert ball-typed electrode fully into the handpiece. Touch the coagulation mode button to turn blue lamp on, and check that the ON/OFF finger switch button responds with an acoustic signal.

3. Hold the handpiece in position slightly above the meat tissue surface and press the ON/OFF finger switch button, you will hear the acoustic signal for the coagulation mode.

4. Make repeated taps with the electrode on meat tissue. This will result in small target areas of coagulation which will effectively stop spot bleeding in a clinical situation.

#### F3. General Advice

1. Turn on the electrode (with acoustic signal) prior to contacting with the tissue.

2. Keep the surgical electrode clean and free of tissue remnants.

3. Keep the cutting electrode in motion in a steady and continuous stroke.

4. Keep the coagulating ball-typed electrode in motion in a tapping movement.

#### G. Clinical Applications

high frequency unit is used for cutting soft tissue and coagulation in oral operation.

#### G1. Contraindications to High Frequency Soft Tissue Handling Unit

1. Operators with cardiac pacemakers or other implanted electronic devices are forbidden to use this unit, and restriction also applies to the patients with cardiac pacemakers or other implanted electronic devices.

2. Do not use this device in proximity to flammable anaesthetic gases and oxygen.

3. Medical consultation should always be considered prior to using this device in those patients who may be systemically and medically compromised, especially those with abnormal healing processes such as diabetes, blood dyscrasias, collagen disturbances and patients undergoing irradiation treatment.

#### H. Cleaning and Sterilization

#### H1. Cleaning

It is crucial to use clean electrode in surgery to form clean and well-defined incisions.

Apply the dilution rate of the neutral detergent (Metrex) according to the detergent Instruction (1:64-1:512), 10s wash time and 10s rinse time. Dilute the neutral detergent with the dilution rate of 1:512 by distilled water. Wipe the soft tissue remnants and wash sample with the diluted neutral detergent individually for at least 10s, then rinse the samples with distilled water individually for at least 10s. Use sterile gauze to remove water from each sample individually.

#### H2. Sterilization

The Electrodes, handpiece and cord are provided non-sterile. The Electrode always should be cleaned before sterilization.

Sterilization equipment should have validated certification and performance qualification tests of their process cycles for efficient processing.

Note: The product must be sterilized by Pulse vacuum pressure steam sterilizer.

For (Porous Load) fractionated and pulse cycles, sterilization temperature should be pre-vacuum 135°C for a minimum of 3 minutes.

The maximum re-sterilization times for the electrode are 500 times.

**V**NOTE! Hold the handpiece with surgical electrode very carefully in order to avoid breakage and deformation.

#### H2. Control Box

Please wipe with an alcohol sponge or non-aggressive surface disinfectants to clean and disinfect the control box. Control box can not be autoclaved.

## I. Accessories

Serial Number	Description	Specification
K-T001 Handpiece		1
K-T002	Handpiece cord with connectors	1
K-T003 Holder casing(Seven electrodes)		1

Serial Number	Figure	Туре	Shank	Tip part
K-A001		Needle	Straight	Straight wire, thin
K-A002	C	Loop	Straight	Circular wire,diam.5mm
K-A003	6	Ball	Straight	Ball,diam.3mm
K-A004		Needle	Straight	Straight wire, heavy
K-A005		Needle	Angled	Angled wire, heavy
K-A006		Needle	Angled	Angled wire, thin
K-A007		Loop	Straight	Circular wire,diam.10mm

J. Maintenance and Safety

Please comply with the following instructions:

1. high frequency unit must be installed and operated in accordance with this instruction manual.

2. If any signs of operational, electrical or mechanical defects are found, the high frequency unit and its accessories must not be taken into use.

3. If heavy sparking between electrode and tissue is observed, the high frequency unit and its accessories must not be taken into use.

4. The control box must not be exposed to excessively high or low temperatures, and environment with extreme moisture.

5. Technical changes, including repairs, adjustments and calibrations must only be made by customer service or specialists authorized by .

6. Do not open the control box or disassemble the handpiece.

7. Submit your to your distributor or customer service for general service check-up at least every two years.

## K. Symbols Symbol Description Bangvo® Registered trademark ★ Type B application Device model Ŷ Warning Í P Handpiece cord connector AC220V,50Hz Voltage and frequency of input power T1AL 250V Specification of fuse

## L. Technical Specifications

Product name/model:	High frequency unit/
Mains connection:	1-phase with protective earth
Mains voltage:	AC 220V/50 Hz
Classification	Class 1, type Bᢜ
Primary fuses	T1A,AC 250V
Operating frequency	27.126 MHz
Rated maximum output power	Coagulation mode: < 50W at non-inductive load impedance of 500 ohms Cutting mode: < 25W at non-inductive load impedance of 500 ohms
Maximum power consumption	150 VA
Control box dimension	27219062.5mm

Weight	4.5 kg
Service life	5 years

Product license information

Production license number:	To be announced
Registration number:	To be announced
Technical specification number:	To be announced

### M. Warranty

For the , customer service grants a warranty of 12 months as from the date of the Contract of Sale and in accordance with terms and conditions defined on the Guarantee Card with each unit.

Defects proven to be caused by failure of materials, construction or manufacturing will be repaired free of charge. Any further liability is explicitly declined.

The warranty does not apply to normal wear or damage resulting from accident, abnormal use, misuse, abuse or neglect.

Guarantee repairs or replacements will only be carried out upon receipt of the detect unit together with its Guarantee Card.

Responsibility as to the safety, reliability and performance of the will not be accepted by customer service:

1. If the equipment has not been used under nomal conditions for its intended purposes and in strict accordance with this manual and /or

2. If any technical changes including repairs, adjustments, calibrations and reconstructions have been made by anyone other than customer service or specialists authorized by .

The purchaser assumes all the risks and liabilities resulting from the use of high

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frequency unit, whether used separately or in combination with other products that not manufactured by .

continually strives to improve its products and therefore reserves the right to improve, modify or discontinue products at any time, and to change the specifications without notice and without incurring obligations.

### N. Important Notes and Warnings

1. The use of high frequency electrosurgical unit will result in electromagnetic interference to other instruments.

Warning: Do not use for the patients with implanted cardiac pacemakers. Warning: The use of will cause electromagnetic interference to other unshielded medical electronic instruments.

2. The risk for igniting flammable gases or other materials is inherent in soft tissue surgery and can not be eliminated by device design.

Warning: Precautions must be taken to avoid contact of flammable materials and substances with high frequency electrosurgical unit, whether they are in the form of an anesthetic or skin preparation agent, are produced by natural processes within body cavities, or originate in surgical drapes, tracheal tubes or other materials.

3. The warning symbol on the handpiece cord connector on the control box denotes as follows:

Rated maximum power output: 50 W at non-inductive load impedance of 500 ohms Operating frequency 27.126 MHz

 $\swarrow$  Warning: For the safety of the operator, surgical electrode should only be inserted or removed from the handpiece in the standby mode (only green lamp is on).

Warning: The surgical electrode in the handpiece must not be touched when the acoustic signal is sounding.

**I**Note: Any operation should be initiated by checking that the ON/OFF finger switch button on the handpiece responds by an acoustic signal.

4. The Medical Device Vigilance System imposes on manufacturers the duty to promptly report to Competent Authorities in case a medical device made by the manufacturer has caused an incident that led to a serious deterioration of the state of health of a patient or user.

In the improbable event that your high frequency unit should be involved in such an incident, it is therefore very important that you:

a. Promptly inform customer service;

b. stop using the unit immediately, and

c. immediately store the unit separately and exactly in the condition which it was, i.e. without any kind of cleaning or disassembling.

5. **INVICE:** The use of must comply with corresponding medical operation rules, laws and regulations, which should be done by the trained doctors and technicians only.

## O. Electromagnetic Compatibility

## <u>/</u>Note

1. high frequency unit is compliant with YY0505 standard for EMC related requirements.

2. User should install and use the produce according to EMC information provided by manufacturer.

Portable and movable RF communication equipment can influence the performance
of , avoid strong electromagnetic interference, such as near to movable phone, microwave
oven.

4. For details see attached Guide and Declaration of manufacturer.



1. high frequency unit should not be close to or stacked with the other devices. If being used with other devices, please observe and verify that it can work normally with chosen configuration.

2. Class A device is intended to use in industrial environment, due to conducted disturbance and radiation disturbance of ,, make sure EMC may have potential difficulties in the other environment.

3. Except original cable produced by manufacturer of high frequency unit, use of other accessory and cable may cause emission increase or immunity reduce.

### O1. Appendix-Guide and Declaration of the Manufacturer

Guide and Declaration of Manufacturer-EME				
high frequency unit is intended to use in below electromagnetic environment, buyer or user should make sure it is used in such electromagneticenvironment.				
Emission Test	Conformity	Electromagnetic environment-Guide		
radio-frequency emission GB 4824	Group 1	high frequency unit only use radio frequency energy for its internal function. So, it has low RF frequency, and low possibility of generating interference with electronic devices nearby.		
radio-frequency emission GB 4824	Class A			
harmonic emission GB 17625.1	NA	high frequency unit is suitable for non-domestic and all facilities that connect residential public low voltage supply network indirectly.		
voltage fluctuation scintillation emission GB 17625.2	NA			

#### Guide and Declaration of Manufacturer-EMI

high frequency unit is intended to use in below electromagnetic environment, buyer or user should make sure it is used in such electromagnetic environment.

Immunity Test	IEC 60601Test Level	Coincidentdet Level	Electromagnetic-guid e environment.	
Electro-Static discharge (ESD) GB/T 17626.2	6 kV contact discharge 8 kV air discharge	6 kV contact discharge 8 kV air discharge	Ground should be woody, concrete, ceramic, if ground was covered by synthetic material, the relative humidity should be at least 30%.	
Electrical fast transient(EFT) GB/T 17626.4	2kV to power line	2kV to power line	Mains should have quality for typical commercial or hospital environment.	
Surge GB/T 17626.5	1 kV line-to-line 2 kV line-to ground	1 kV line-to-line 2 kV line-to ground	Mains should have quality for typical commercial or hospital environment	
Power supply input wire voltage sag, short interruption, and voltage change GB/T 17626.11	<5 % $U_{T}$ ,0.5 $U_{T}$ ,>95% 40 % $U_{T}$ ,5 $U_{T}$ ,60% 70 % $U_{T}$ 25 $U_{T}$ ,30% <5 % $U_{T}$ ,5s $U_{T}$ ,>95% <5 % $U_{T}$ , last 0.5 cycle at $U_{T}$ ,>95% sag 40 % $U_{T}$ , last 5 cycle at $U_{T}$ , 60% sag 70 % $U_{T}$ last 25 cycle at $U_{T}$ ,30% sag <5 % $U_{T}$ , last 5s at $U_{T}$ ,>95% sag	<5 % $U_{T}$ ,0.5 $U_{T}$ ,>95% 40 % $U_{T}$ ,5 $U_{T}$ ,60% 70 % $U_{T}$ 25 $U_{T}$ ,30% <5 % $U_{T}$ ,5s $U_{T}$ ,>95% <5 % $U_{T}$ , last 0.5 cycle at $U_{T}$ ,>95% sag 40 % $U_{T}$ , last 5 cycle at $U_{T}$ , 60% sag 70 % $U_{T}$ last 25 cycle at $U_{T}$ ,30% sag <5 % $U_{T}$ , last 5s at $U_{T}$ ,>95% sag	Mains should have quality for typical commercial or hospital environment. If user of high frequency unit requires continuous working during power interruption, Uninterruptible power supply or battery powered is recommended for the product.	
Power frequency magnetic field50/60Hz GB/T 17626.8	3A/m	3A/m,50/60Hz	Power frequency magnetic field should have typical place characteristics in typical industrial or medical environment.	
$U_T$ Remark: $U_T$ means AC voltage before applied test voltage.				

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high frequency unit is intended to use in below electromagnetic environment, buyer or user should make sure it is used in such electromagnetic environment.				
Immunity Test	IEC 60601Test Level	Coincident Level	Electromagnetic-guide environment.	
Radio-frequency	3 V effective value	3 V effective	Portable and movable RI communication device should not be closer to any part of high frequency unit that recommended distance, including cable when they are working. The distance should be calculated by relevant transmittee frequency formula.	
conduction GB/T 17626.6	150 kHz80 MHz	value	<b>Recommended isolation distance</b> $d = 1.2\sqrt{P}$	
Radio-frequency radiation GB/T 17626.3	3 V/m 80 MHz2.5 GHz	3 V/m	$d = 1.2\sqrt{P}  80 \text{ MHz}800 \text{ MHz}$ $d = 2.3\sqrt{P}  800 \text{ MHz}2.5 \text{ GHz}$ P According to the maximum rated output of transmitter provided by transmitter manufacturer, the unit is watt. dRecommended isolation distance, the units m. Field intensity of stationary RF transmitter is	
			determined by survey <sup>c</sup> of electromagnetic field in each frequency range, <sup>d</sup> should be lower tha coincidentdet level. Interfere may appear when near to th devices with below symbol.	

2The guide may not be suitable for all conditions, electromagnetic propagation is affected by buildings, objects, absorption and reflection of human body.

a Stationary transmitter, such as wireless cellular system, cordlesstelephone, movable ground radio base station, amateur radio, amplitude and FM radio, videocast, their field intensity cant be foreseen accurately. In order to evaluate electromagnetic environment of stationary RF transmitter, survey of electromagnetic field should be considered. If filed intensity of high frequency unit is higher than above applicable RF coincident level, observe and verify if it can work normally. If there has abnormal performance, supplement measure is necessary, such as re-adjust direction or position of the product.

b In frequency range 150KHz80MHz, field intensity should be lower than 3 V/m.

## Recommended isolation distance between portable and movable RF communication device and high frequency unit

high frequency unit is intended to use in RF radiation disturbance controlled electromagnetic environment. According to the maximum rated output, as recommended in below, buyer or user can prevent electromagnetic interference by maintain the minimum distance between portable and movable RF communication device (transmitter) and device or system.

Max. Rated output	Isolation distance for different frequency/m			
of transmitter W	<b>150 kHz 80 MHz</b> d = $1.2\sqrt{P}$	80 MHz 800 MHz d = $1.2\sqrt{P}$	800 MHz 2.5 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 unlisted the maximum rated output above, recommended isolation distance is d, the unit is m, formula in relevant transmitter frequency column can be used to confirm, here P is the maximum rated output provided by transmitter manufacturer, the unit is W.

1In frequency 80 MHz and 800 MHz, use higher frequency range formula.

2 The guide may not be suitable for all conditions, electromagnetic propagation is affected by buildings, objects, absorption and reflection of human body.

## P. Storage, Maintenance, Transportation

Before scrapping, all the original packages need to be remained, in case of using them for

transportation and storage.

#### P1. Storage, Maintenance

1. For the storage of this product, keep it away from toxic, corrosive, inflammable and explosive substances.

2. Handle the product with care, keep it away from vibration, and install or store it in a shade, dry and ventilated place.

3. The product should be stored in an environment with the relative humidity less than 80%, atmospheric pressure between 50kPa to 106kPa, temperature between -10 to 50.

4. Power switch should be turned off, disconnect the power plug when the product is not in use.

## P2. Transportation

- 1) The product should be kept in original package for transportation to avoid damage.
- 2) Handle with care, and prevent excessive shock and vibration during transportation.
- 3) Do not mix with dangerous substances during transportation.
- 4) Avoid to be exposed to the sun, rain and snow during transportation.

## **Q. Environmental Protection**

Disposal of the waste produced by this product should be done in line with local laws and regulations.