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Vision System

Instructions for Use

Please read all information carefully! If not following the instructions correctly may lead to serious surgical consequences!

Product name: Vision System

Type(s)/model(s): VS-10-S, VS-20-S, VS-40-S

Type(s)/model(s) of Visual Stylet: VS-10, VS-20, VS-40

Type(s)/model(s) of UE Display: UE-M8-S

Thank you for purchasing our products.

 Please read this manual carefully before using this device and keep it well for future use.

 When using the device, please carefully read the operating instructions and carry out proper maintenance, which will greatly reduce the occurrence of malfunctions and extend the service life of the device.

 The paragraph marked "  " should be read and executed carefully to avoid injury or damage to the device, operators, or patients.

 If there is a problem with the device during use, please contact your local dealer or the company for help.

Commitment: When dealing with failures, we promise to provide users with the necessary and more detailed technical information if needed.

 Due to the continuous improvement of the products, the appearance or specifications of the products provided by the company may be different from this manual without prior notice.

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Warning

This product cannot be used in places where there is a risk of fire.

This product cannot be used in the presence of a mixture of flammable anesthetic gas and air or a mixture of nitrous oxide.

There are special parts inside this device, users are not allowed to disassemble or modify this device by themselves.

The light at the front of the device cannot be shine into patients' or other persons' eyes.

The battery is located inside the device. Keep away from fire, sunlight, or excessive heat, as this may result in equipment damage or reduced service life.

This device can only be used with Disposable Medical Laryngeal Masks produced by our company.

A spare product that is ready to be called at any time can ensure that it can be replaced in time and continue to be used in the event of product failure.

The waterproof level of the insertion part of the visual stylet is IPX6, the rest parts of the Vision System are IPX0 and not waterproof. Please prevent water or other liquids from entering the device to avoid damage to the device.

Safety Advice:

This device must be protected from any external adverse effects such as strong electromagnetic radiation or high temperatures.

This product should be handled with care during transportation and use to prevent shock, severe vibration and moisture.

This device can only be charged with the charger provided by our company.

This product should only be repaired by the personnel authorized by our company. In case of any breakdowns or malfunctions, please contact our service department in time.

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Cautions

Check the product before use to ensure that it is free of rust, no indentation, no scratches, no sharp edges or protrusions, and the UE Display can be turned on and display the screen normally.

Please follow the disinfection method in the manual before use. When wiping the insertion tube of the visual stylet, avoid excessive force.

Hold the Visual stylet with the round handle part. Do not hold the insertion tube of the Visual stylet directly during operation.

Avoid using petroleum-based lubricants.

Please check if the products in good condition before use, and if there's any damage or performance defects, do not use it before troubleshooting.

Before use, please check if the battery power is sufficient or the power cable is connected. Otherwise, it may cause inconvenience or accident due to battery exhausted.

Before use, connect to the UE Display to confirm that the camera can work normally and the image is clear. Use a cotton swab to clean the camera when the image is blurred.

Battery life will be reduced if the battery is out of power for a long time. When the product power is below 20%, it is recommended to charge in time. Do not charge for more than 5 hours every time. When the product is not used for a long time, it is recommended to charge once every two months to supplement the battery capacity. It is recommended that the temperature during charging range from 0 ° C to 45 ° C to avoid being exposed to overheated environment, which may cause accidents.

Check whether there are scratches, glue off and other phenomena on the surface of visual stylet, don not use if it is damaged.

The type-C interface on the UE Display of this product is used for data transmission, and the visual stylet cannot be directly inserted into the type-C interface of the UE display.

This device has a certain period of service life and there is a risk of use outside of this period. After the service life is exceeded, please disassemble and scrap it according to the requirements of environmental regulations, or return to your local dealer or the factory to check whether it can still be used. The company is not responsible for the adverse consequences caused by continued use without identification.

Zhejiang UE Medical Corp. reserves the right of final interpretation.

Contraindications: None

1.1 Intended purpose

The Vision System is used to process the images acquired by the visual stylet and then send them to the display for imaging.

1.2 Performance

Discharge type that the device belongs to: internal power supply.

Type of the device: Type BF.

Application part of the device: Visual Stylet.

The device is not waterproof.

The device is portable handheld device.

Item	Technical name	Technical indicators
Vision System Parameters	Resolution ^{ra(d)}	≥0.9C/(°)(-10%)
	Field of view	90°±15%
	Depth of field	3~100mm
	Waterproof level	Visual Stylet: IPX6 UE Display: IPX0
	Illuminance	≥500Lux
UE Display	Model	UE-M8-S
	Monitor size	8 inch, ratio 4:3
	Screen type	TFT LCD
	Resolution	1024*768 pixels
	Storage capacity	32G
	Signal interface	10 Pin aviation plug
	Data interface	USB / TYPE-C
	Charging interface	DC Connector
	Battery Life	≥3h
	Batter capacity	3.7V/7000mAh

Item	Technical name	Technical indicators
Power Adapter	Model	UVS
	Input	AC 100-240V, 50-60 Hz
	Output	DC 5V, 3A, 15W
Operating Environment	Temperature	5~40°C
	Relative Humidity	≤83%
	Atmospheric pressure	860hpa~1060hpa
Transportation and storage environment	Temperature	-40°C~+55°C
	Relative Humidity	≤93%
	Atmospheric pressure	500hpa~1060hpa

2 Part 2

2.1 Work Principle

The images are captured through the Visual Stylet, output in real time on the UE Display, which can make medical institutions to implement laryngeal mask and intubation, placement, alignment and intraoperative airway management.

Used with UE visualization products, except for visual products in clinical image processing, can also provide electrical source for visual products, electronic signal processing unit as the core, usually received visual products, electronic signal processing and transmission to the monitor imaging

The Visual Stylet is placed into the independent sealed channel of laryngeal masks and intubation. The Visual Stylet collects images and connects the display terminal through the Adapter Cable to realize the visual positioning of laryngeal masks and intubation.

Adapter Cable of different port, cooperate to UE display is connected to the port of our different endoscopic, laryngeal mask, intubation, implemented as imaging.

2.2 Structure

The Vision System consists of UE Display (including data cable, display and power adapter), Visual Stylet and Adapter Cable.

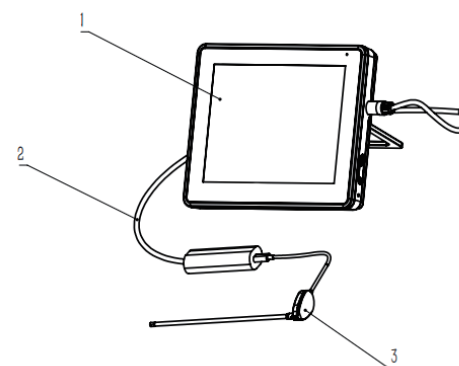
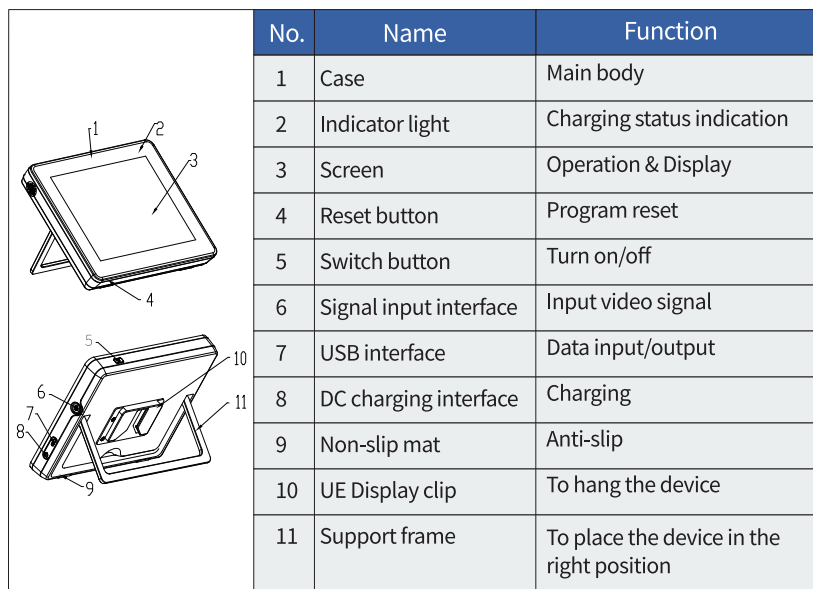


Figure 1 Vision System

1-UE Display, 2-Adapter Cable, 3-Visual Stylet



2.2.1 Visual Stylet and specifications correspond to laryngeal mask model parameters

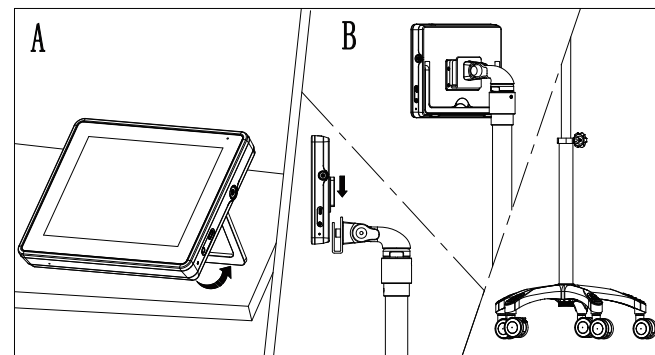
40: indicates the Visual Stylet VS-40, which can be used with 3#, 4#, 5#, 6# Disposable Medical Laryngeal Masks.

20: indicates the Visual Stylet VS-20, which can be used with 2#, 2.5# Disposable Medical Laryngeal Masks.

10: indicates the Visual Stylet VS-10, which can be used with 1#, 1.5# Disposable Medical Laryngeal Masks.

2.3 Product Placement and Installation

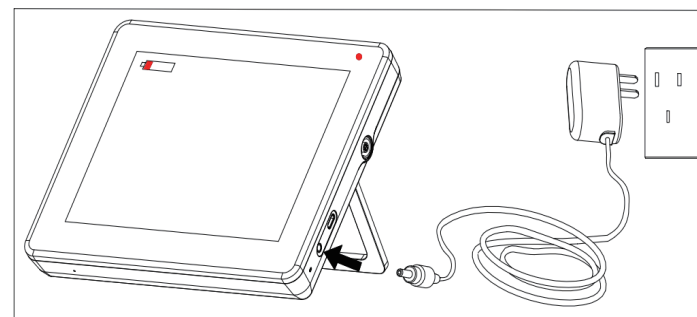
The product can be placed in two ways. As shown in Figure A below, the product can be supported on the platform by turning the support frame on the back at an angle. As shown in Figure B below, the clip on the back of the product can be fixed on the supporting mobile trolley, which is convenient and fast to operate.



2.4 Instructions for use:

Switch button: Press and hold the switch button for 1-2 seconds to start the UE Display, and then release it. When shutting down, press the switch button for 1-2 seconds to shut down.

Working status: The power indicator on the screen is green when UE Display is working normally, the battery power is displayed in the battery icon on the screen. When the battery is low (the indicator is red), please charge it in time.



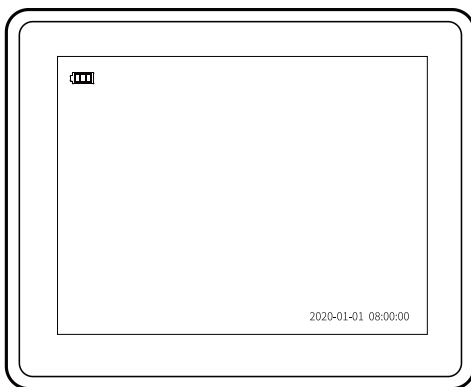
Charge: When the device needs to be charged, insert one end of the power adapter into a properly grounded power socket, and insert the DC plug located at the other end into the power socket of the EU display. When charging, the power indicator light is orange-yellow. Once the charging is complete, the light turns green, and the battery indicator icon shows full marks.

Photo: Turn on the UE Display, click the photo button on the handle of the Adapter Cable, indicating that the photo is taken successfully. After connecting the UE display to the computer with the configured data cable, the photos in the product can be viewed.

Recording: Turn on the UE Display, press and hold the video button on the handle of Adapter Cable for 1~2s, and a blinking red dot appears on the top of the display, indicating that recording is taking place. Press and hold the video button for 1-2s again, and if recording is complete below the display terminal, the recording function is exiting. After connecting the display terminal to the computer with the configured data cable, you can view the video in the device.

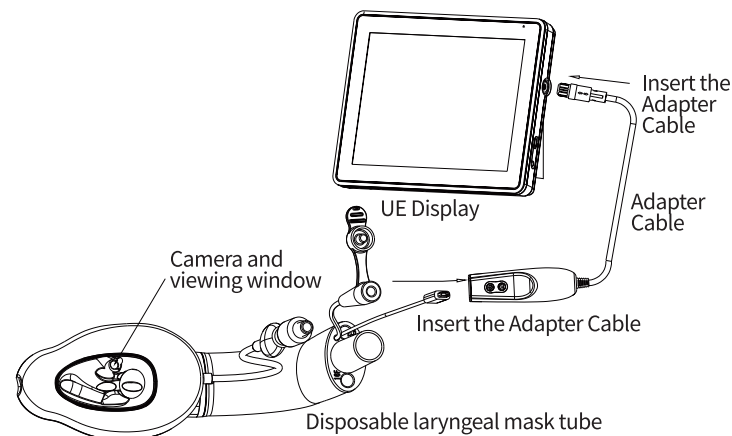
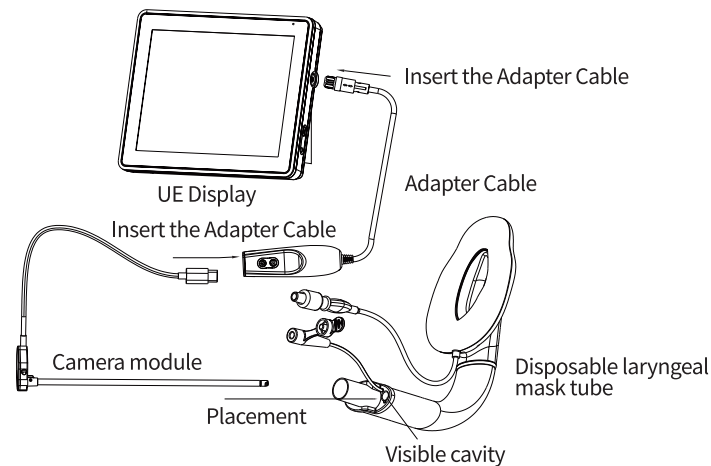
Data reading: By connecting the device to the computer, the device will store pictures, videos and other data out. When the device is on, use the USB data cable to connect the device to the computer. After being recognized, the icon of the USB flash drive of the device will appear in "My Computer". Double-click to enter and perform related operations

Display main screen: After starting up, directly enter the display screen. There is a battery indicator icon in the upper left corner of the display area, and the real-time time is displayed in the lower right corner



2.5 Instructions for Operation

2.5.1 Laryngeal Masks Operation



1. Place the UE Display in a position suitable for viewing, insert the aviation connector male seat of the Adapter Cable into the signal input interface of the UE display, and then insert the type C male head of the rear end of the Visual Stylet into the type C female seat of the Adapter Cable to ensure that there is no large gap between the connectors and the connection is stable.
2. Press and hold the switch button the screen will appear startup screen and waiting screen, about 1-2s, then the UE Display will show the scene captured by the high-definition camera.

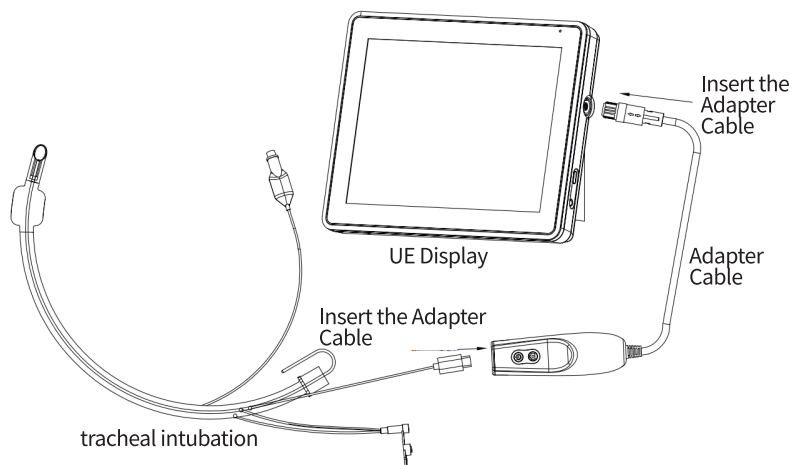
3.The operator holds the disposable laryngeal mask in the left hand and the round handle part of the Visual Stylet in the right hand. Then insert the Visual Stylet straight into the observation channel of the disposable laryngeal mask (Mark with ● is the observation channel) until the round handle part is aligned and locked in the positioning groove of the connector, and the lower surface of the round handle part is almost flat against the plane of the laryngeal mask. Then please make sure the camera of the Visual stylet is close to the observation window of the laryngeal mask, and the front contour of the laryngeal mask can be clearly displayed on the UE Display. During the process, please keep the insertion part of the Visual stylet from touching the right-angled sharp part of the connector.

4. During the operation, if the patient's cough or spontaneous breathing causes the mist or saliva on the observation window of the disposable laryngeal mask airway, or the observation window is contaminated by a large amount of blood or secretions in the oral cavity, please use a syringe without a needle to inject gas or saline solution through the cleaning channel of the laryngeal mask.

5.When pulling out the Visual Stylet, hold the round handle part and turn it to the left until it cannot be turned, then release the handle part to make it pop out naturally, and then pull it upwards.

6.Press and hold the UE display switch button for about 3 seconds and close the UE display as prompted.

2.5.2 Intubation operation



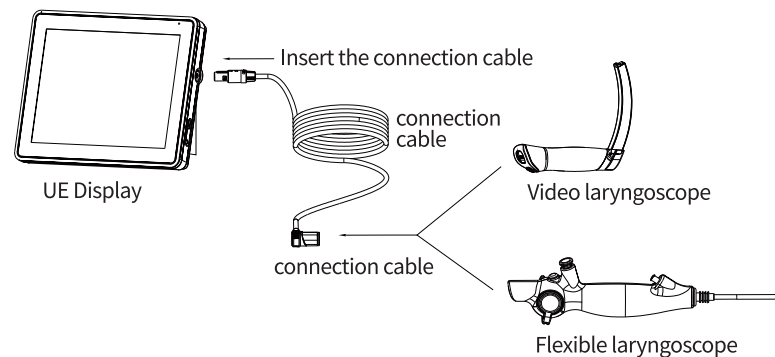
1.Place the UE Display in a position suitable for viewing, insert the aviation connector male seat of the adapter cable into the signal input interface of the UE display, and then insert the type C male head of the rear end of the visual stylet into the type C female seat of the adapter cable to ensure that there is no large gap between the connectors and the connection is stable.

2. Press and hold the switch button, the screen will appear startup screen and waiting screen, about 1-2s, then the UE Display will show the scene captured by the high-definition camera.

3. Tracheal intubation was performed by conventional tracheal intubation under video.

4.Press and hold the UE display switch button for about 3 seconds and close the UE display as prompted.

2.5.3 Endoscopic operation



1.Place the UE display in a suitable viewing position, insert the aviation connector of the HD cable into the signal input interface of the UE display, and then insert the plug of the HD cable into the socket of the endoscope, ensuring that there is no large gap between the plugs and the connection is stable.

2. Press and hold the power button, the screen will display the boot screen and waiting screen, about 1-2 seconds, and the UE display will show the scene captured by the camera clearly.

3. Perform conventional endoscopy under video surveillance.

4. Press and hold the UE display power button for about 3 seconds and follow the prompts to turn off the UE display.

3.1 Precautions for clinical application

The operation technology of the Vision System requires your special attention:

Strong sunlight will reduce the display of the throat structure on the UE Display, and it is not recommended to be used in an outdoor environment with strong sunlight.

When using the Visual Stylet, if necessary, please use water-soluble medical grade lubricants such as medical silicone oil. Do not use petroleum-based lubricants such as olive oil, lidocaine ointment or other lubricants containing petroleum or vaseline.

3.2 Maintenance, Cleaning, and Disinfection

3.2.1 Cleaning Visual stylet and Disinfection

The product does not contact the human body directly, using a medical non-woven cloth to wipe the product with a small amount of medical alcohol.

3.2.2 Maintenance

 The UE Display can only be wiped and disinfected with medical alcohol.

 It is not recommended to use strong acid and strong oxidizing disinfectant, and it is not recommended to use other disinfection methods that exceed the requirements of the working environment of the product.

 The Visual Stylet cannot be disinfected by ultrasonic, high temperature nor high pressure sterilization.

3.3 System and software updates

When the product is damaged, system breakdown and other faults, do not disassemble and repair, please contact the customer service department of the company to request after-sales repair or upgrade services.

4.1 Troubleshooting

Trouble	Cause	Solution
The image is not clear	The camera is fogging	Preheat or remove mist
	The camera is blurred	Remove dirt on the camera with medical alcohol
	There are water droplets or color bars in the field of view	Stop using it and send it to the distributor or factory for repair
Unable to start up	Battery off	Charging
	Crash or battery failure	Stop using it and send it to the distributor or the factory for repair
	Switch button damaged	Stop using it and send it to the distributor or the factory for repair
No image on the UE Display	Poor connection between the insertion section of Visual Stylet and Adapter Cable, or poor connection between the Adapter Cable and the UE Display	Unplug the insertion section of Visual Stylet and Adapter Cable and reconnect
	The system is crashed	Stop using it and send it to the distributor or the factory for repair
	The Insertion section of Visual Stylet or Adapter Cable or the UE Display may be damaged	

4.2 Product recycling

When scrapping: non-degradable objects that shall be handed over to the special environmental protection department for recycling.

4.3 Warranty Period

This product is guaranteed for 1 year from the date of sale.

 Note: In order to prevent infection and to ensure the safety of all maintenance personnel, the equipment should be completely cleaned and disinfected before being returned to our company for maintenance. If the equipment has been used by HA positive patients or other infectious patients, please inform us in advance.

 Note: The Vision System has a certain period of service life, there is a risk of use outside of this period.

4.4 Storage and Transportation

During transportation, it shall be kept clean and free from pollution, and it is strictly prohibited heavy pressure and to immerse in rain and snow.

Handle with care during transportation to avoid fierce collision.

It should be stored in a well-ventilated room without corrosive gas, and please away from fire.

4.5 Mark Index

Icon	Meaning	Icon	Meaning
	Caution		Direct current
	Keep away from sunlight		Manufacturer
	Keep dry		Medical Devices
	Refer to instructions for use		Series number
	Type BF APPLIED PART		Date of manufacture
	Switch button		European Representative in European Community/European Union
	CE Mark		Low battery
	Stack limit		Waste electrical and electronic equipment shall be treated separately (please observe local laws and regulations)
	Fragile, handle with care		
	Use-by Date		
	Battery indicator		

4.6 Accessories List

Packing list *1, Warranty card *1, Certificate of compliance*1, Instruction manual *1, UE Display *1, Power adapter *1, Data cable *1.

Optional accessories list:

Accessory Name	Model	Replacement cycle	Remarks
Adapter Cable	FS-B3-11	5 years	/
Adapter Cable	FS-B3-12	5 years	/
Adapter Cable	FS-B3-17	5 years	/
Visual Stylet	VS-10	2 years or 5000 times	/
Visual Stylet	VS-20	2 years or 5000 times	/
Visual Stylet	VS-40	2 years or 5000 times	/
Clip	FS-T3-01	5 years	UE Display hanging rod
HD Cable	FS-B3-14	5 years	For connection with endoscope

4.7 Production date and Service life

Production date: See product label for details

Service life:

UE Display: 5 years

Visual Stylet: 2 years or 5000 times

4.8 Customer Service

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Appendix: EMC Performance Index

Basic Performance of the Product

Mode	Description
Operating Mode	Ensure there is no unacceptable risk if the operator is viewing an image with an unexpected image orientation.
Charging Mode	During endoscopic surgery, operators observe real-time images instead of video recordings to ensure there are no unacceptable risks.

For the device, special precautions regarding electromagnetic compatibility (EMC) are required, and it must be installed and used in accordance with the EMC information specified in this manual. Portable and mobile radio frequency communication equipment may affect this device.

The following cables must be used to meet electromagnetic emission and anti-interference requirements:

Except for cables (transducers) sold as spare parts for internal components, using accessories and cables (transducers) that are not specified may increase the emission of the device or system or reduce the immunity.

The device or system should not be used close to or stacked with other equipment. If it must be used close or stacked, it should be observed to verify that it can operate normally under the configuration used.

Guidelines and Statement of the Manufacturer-Electromagnetic Emission

Guidelines and Statement of the Manufacturer-Electromagnetic Emission		
The display shall be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment		
Emission Experiment	Conformance	Electromagnetic Environment – Guideline
RF Emission CISPR11:2016	Group 1	The display only uses radio-frequency energy for its internal function. Therefore, its radio frequency emission is very low and has a low possibility for causing interference to nearby electronic equipment.
RF Emission CISPR11:2016	Class A	The display is suitable for use in non-domestic and all facilities that are not directly connected to the public low-voltage power supply network of domestic residences.
Harmonic Emission IEC61000-3-2(ed 5.0):2018	N/A	
Voltage Fluctuation/-Flicker Emission IEC61000-3-3(ed 3.1):2017	N/A	

Guidelines and Statement of the Manufacturer-Electromagnetic Immunity

Guidelines and Statement of the Manufacturer-Electromagnetic Immunity			
The display shall be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment			
Immunity Test	IEC 6060 Test Level	Conformity Level	Electromagnetic Environment– Guideline
Electrostatic Discharge IEC61000-4-2:2008	± 8 kV Contact Discharge ± 15 kV Air Discharge	± 6 kV Contact Discharge ± 8 kV Air Discharge	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient Burst IEC61000-4-4:2012	± 2kV for Power Supply line ± 1kV for Input/Output line	± 2kV for Power Supply line ± 1kV for Input/Output line	The network power supply should be of the quality used in a typical commercial or hospital environment
Surge IEC61000-4-5:2017	± 1kV line to line ± 2kV line to ground	± 1kV line to line	The network power supply should be of the quality used in a typical commercial or hospital environment

Voltage dips, short interruptions, and voltage variations on the power input line IEC61000-4-11:2017	<5% U_T, lasting for 0.5 cycle (In U_T, >95% Temporary Reduction) 40% U_T, lasting for 5 cycles (In U_T, 60% Temporary Reduction) 70% U_T, lasting for 25 cycles (In U_T, 30% Temporary Reduction) <5% U_T, lasting for 5 seconds (In U_T, >95% Temporary Reduction)	<5% U_T, lasting for 0.5 cycle (In U_T, >95% Temporary Reduction) 40% U_T, lasting for 5 cycles (In U_T, 60% Temporary Reduction) 70% U_T, lasting for 25 cycles (In U_T, 30% Temporary Reduction) <5% U_T, lasting for 5 seconds (In U_T, >95% Temporary Reduction)	The network power supply should be of the quality used in a typical commercial or hospital environment. If the user needs continuous operation during the power interruption, it is recommended that the display needs to be powered by an uninterruptible power supply or battery
Power Frequency Magnetic Field (50Hz/60Hz) IEC61000-4-8:2009	3A/m	3A/m	The power frequency magnetic field should have the power frequency magnetic field level characteristics of a typical place in a typical commercial or hospital environment
Note: U _T refers to the voltage of the AC network before the implementation and test of voltage.			

Guideline and Statement of the Manufacturer-Electromagnetic Immunity

Guideline and Statement of the Manufacturer-Electromagnetic Immunity			
The display shall be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment			
RF conduction IEC61000-4-6:2013 RF radiation IEC61000-4-3:2010	3V (Valid Value) 150 kHz-80kHz 3V/m 80MHz-2.5GHz 80MHz-2.7GHz	3V (Valid Value) 3V/m 3V/m 80MHz-2.7GHz 80% AM at 1kHz	Portable and mobile radio frequency communication equipment should not be used closer to any part of the display than the recommended isolation distance, includes the cable. The distance should be calculated by the formula corresponding to the transmitter frequency. 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 maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); d----Recommended isolation distance, in meters (m) The field strength of the fixed transmitter is determined by surveying the electromagnetic field a, and in each frequency range b should be lower than the coincidence level. Interference may occur in the vicinity of equipment marked with the following symbols. 
Note 1: If the frequency point is 80MHz and 800MHz, the higher frequency band formula should be used. Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and emission from buildings, objects and humans.			

- a. Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and ground mobile radios, amateur radio, AM and FM radio broadcasting, and television broadcasting, etc., whose field strength cannot be accurately predicted in theory. In order to assess the electromagnetic environment of fixed radio frequency transmitters, the survey of electromagnetic fields should be considered. If the measured field strength of the place where the display is located is higher than the above applicable RF compliance level, the display should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary if the direction or position of the display is readjusted.
- b. If the entire frequency range is 150kHz-80MHz, the field strength should be less than 3V/m.

Recommended isolation distance between portable and mobile RF communication equipment and the display

Recommended isolation distance between portable and mobile RF communication equipment and the display

The display should be used in an electromagnetic environment where radio frequency radiation disturbances are controlled. According to the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication device (transmitter) and the display as recommended below.

Maximum Rated Output Power of the Transmitter W	Isolation Distance Corresponding to Different Frequencies of the Transmitter/m		
	150kHz-80MHz $d = 1.2 \sqrt{P}$	80MHz-800MHz $d = 1.2 \sqrt{P}$	800MHz-2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d , in meters (m), can be determined by the formula in the corresponding transmitter frequency column, P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W).

Note 1: If the frequency point is 80MHz and 800MHz, the higher frequency band formula should be used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and emission from buildings, objects and humans.

Date of Revision of Instruction Manual: May 2026.