Instructions for use

Medical Video Endoscope Image Processor

UTV100

Zhuhai Pusen Medical Technology Co., Ltd.

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- Parts are dismantled, stretched and readjusted;
- The product is not properly used in accordance with the operation guide.

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Contents

1. Important Information – Please Read Before Use

NOTE

Read these safety instructions carefully before using the equipment. These safety instructions may be updated without further notice. Copies of the current version are available upon request.

1.1. Instructions

Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operations and precautions related to the operation of the device. Before initial use of the device, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with its intended use, warnings, cautions, notes, and contraindications mentioned in these instructions.

1.2. Intended Use

This instrument has been designed to be used to process signals from a video endoscope and convert it to a signal that can be displayed on a monitor.

This equipment can be used as a monitor itself.

1.3. Use Environment

The equipment is for use in a hospital or qualified medical institution.

1.4. Warnings, Cautions, Notes

The warnings, cautions, and notes shown below describe potential safety hazards associated with the use of the system. The information given in these warnings, cautions, and notes serves only to instruct in the correct handling of the system.

Throughout the following warnings, cautions, and notes, the following definitions are used:

WARNING ⚠

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the system.

CAUTION

Alerts the user to the possibility of problems with the system associated with its use or misuse. Such problems include system malfunction, system failure, damage to the system, or damage to other property.

NOTE

Advise owner/operator regarding important information on the use of the system.

GENERAL WARNINGS ⚠

- Do not use the system if it is damaged in any way.
- Perform a visual and functional inspection before using the system (see chapter 3). Do not use the system if any part of the check fails.

- The system is neither MRI (magnetic resonance imaging) safe nor MRI compatible.
- Do not use the system during defibrillation.
- When in contact with the patient, do not simultaneously touch the power socket or docking connector.
- Patients should be adequately monitored at all times during use.
- The equipment may interfere with other medical equipment used in combination with it. Before use, refer to the "Appendix 1"to confirm the compatibility of the equipment with all equipment to be used.
- Do not use the equipment in locations exposed to strong electromagnetic radiation (for example, in the vicinity of a microwave therapeutic equipment, MRI, wireless set, short-wave therapeutic equipment, cellular/portable phone, etc.). This may impair the performance of the equipment.
- Strictly observe the following precautions. Failure to do so may place the patient and medical personnel in danger of electric shock.
  - If other devices are used in combination with the equipment, the devices need to meet the requirement of leakage current, or it might result in high leakage current to the patient.
  - Keep fluids away from all electrical equipment. If fluids are spilled on or into the Eview, stop operation of the Eview immediately and contact PUSEN company.
  - Do not prepare, inspect or use the equipment with wet hands.
- Never install and operate the equipment in the following locations. A explosion or fire may result because the equipment is not explosion-proof.
  - The concentration of oxygen is high.
  - Oxidizing agents (Such as nitrous oxide(N_2O)) are present in the atmosphere.
  - Flammable anesthetics are present in the atmosphere.
  - Flammable fluids are near.

GENERAL CAUTION

- Federal law restricts this device to sale by or on the order of a physician.
- Keep the equipment dry during preparation, use, and storage.
- The battery in the equipment can only be changed by a specialist authorized by the manufacturer.

GENERAL NOTES

- Have a suitable backup equipment readily available for immediate use so the procedure can be continued if a malfunction occurs.
- PUSEN is not responsible for any damages to the equipment or patient resulting from incorrect use.

2. Components

WARNING ⚠

•The equipment consists of the parts described in chapter 2. They may only be replaced by PUSEN authorized parts. Failure to comply with this may reduce safety and efficiency of the product.

• The user should be full responsible for use the devices which are not compatible with the equipment. It might be able to be used in combination with the future products of PUSEN, please contact PUSEN for more information.

Repair and Modification

The equipment doesn't contain any part that can be repaired by users. Do not attempt to disassemble, modify or repair the equipment; Otherwise, it may result in patient or operator injuries and equipment damages, or intended functions cannot be assured. Some non-functional failures can be eliminated in accordance with chapter 8 "Troubleshooting". If problems persist after operations have been performed in accordance with chapter 8, please contact PUSEN. The equipment can only be repaired by a specialist authorized by PUSEN.

2.1. Basic components

Before you install and use the equipment please ensure that the following items are available:

Eview UTV100	Part numbers:
	3.01.00

Instructions for use	Part numbers:
	1.12.00002

Equipotential line	Part numbers:
	1.20.00012

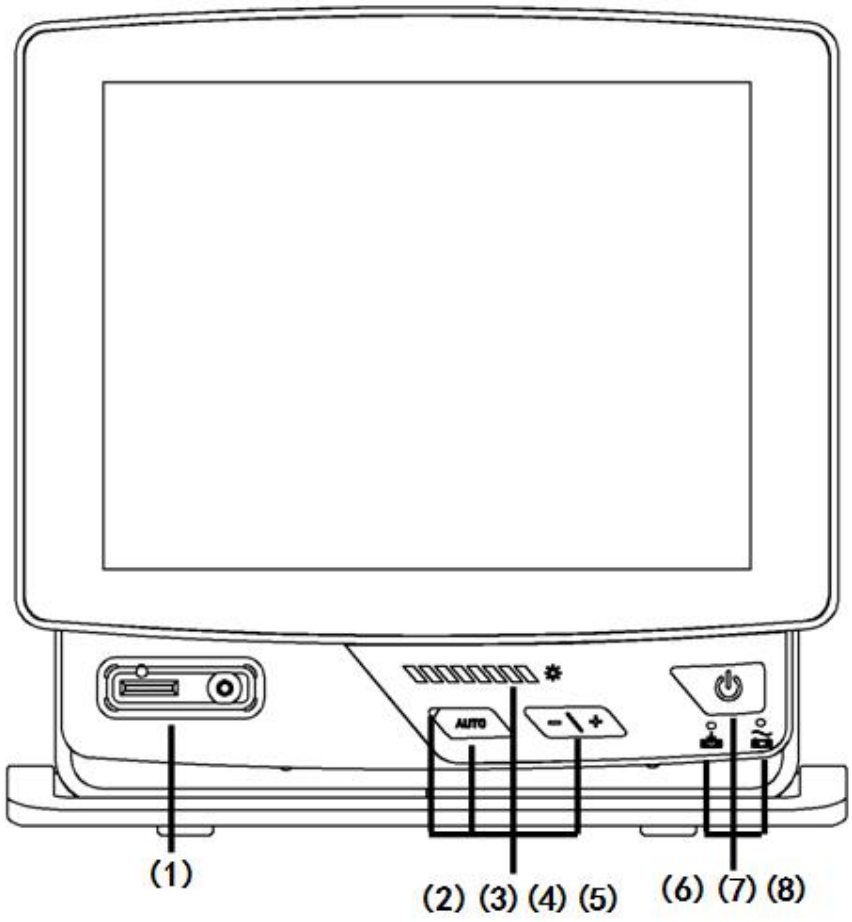
Power cord	Part numbers:
	Europe configuration: 1.20.00005
	China configuration: 1.20.00004
	USA configuration:1.20.00006

NOTE

The power plug supplied with the device may differ from these in this figure as the cables sold in every country should be in compliance with local applicable standards.

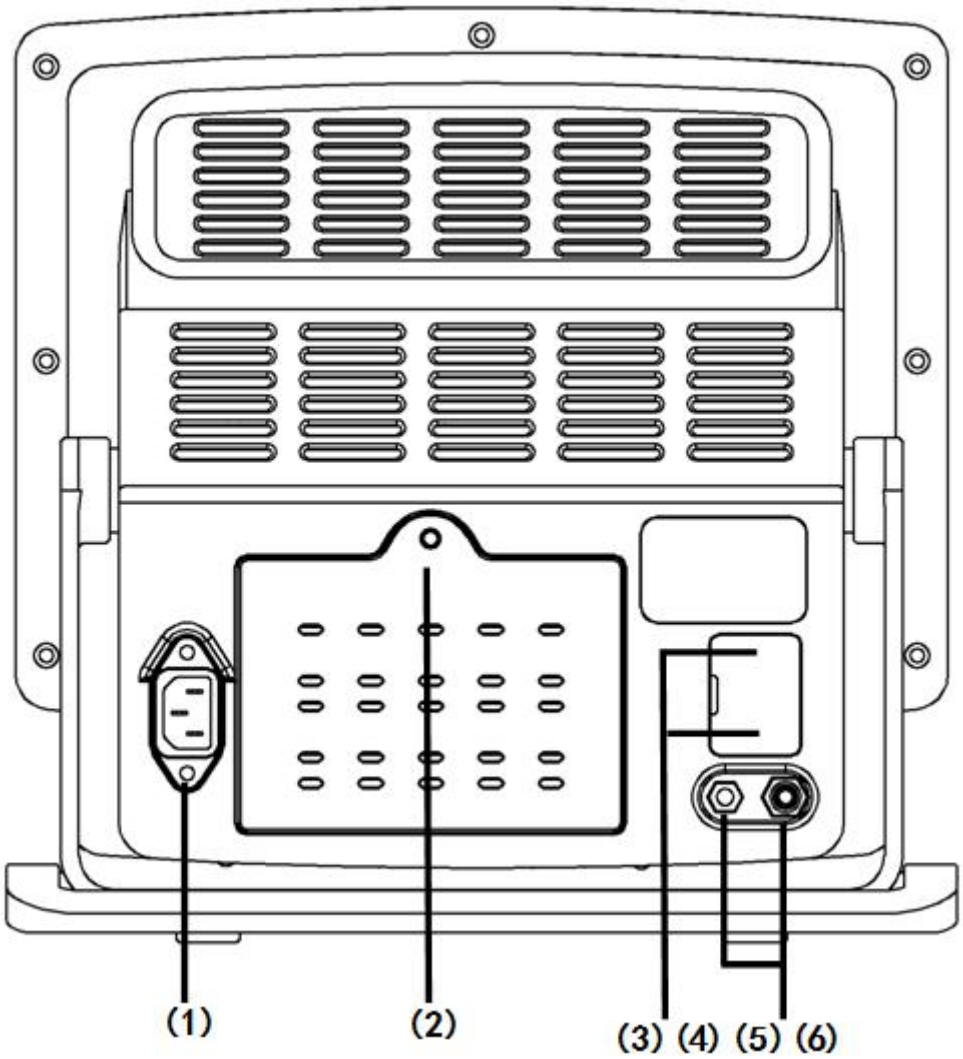
2.2. Description of the Equipment

Front:



(1) Handle socket.
(2) Automatic/manual light source indicator: The indicator turns off in manual mode and turns on in automatic mode.
(3) Automatic/manual light source switch: Used to switch the light intensity between manual adjustment mode and automatic adjustment mode.
(4) Light source intensity indicator: Indicates light intensity levels.
(5) Light source intensity manual adjustment buttons: Used to adjust the light intensity in manual adjustment mode.
(6) Battery indicator: Turns on when the battery is charging and turns off when the battery is not charging.
(7) ON/OFF button: Used to switch the Eview on and off. Press to turn on, press and hold for at least 1 second to turn off.
(8) AC/DC indicator: Green in AC power supply mode and orange in DC power supply mode.

Back:



(1) Main power socket.
(2) Battery compartment cover and screw.
(3) USB data interface.
(4) HDMI output.
(5) Equipotential connection port.
(6) AV output.

2.3. Explanation of Symbols Used

<table>
<tr><th colspan="6">Symbols</th><th>Explanation</th></tr>
<tr><td>  </td><td>Max. battery status of the Eview</td><td>  </td><td>Min. battery status of the Eview</td><td>  </td><td>Fully charged battery still connected to charger</td><td rowspan="2">The icon remains green until one block is left, after which it turns to red.
When remaining battery capacity is 10%, the red battery icon starts flashing.
Charging is shown with blocks flashing
Current capacity is shown with non-flashing blocks.</td></tr>
<tr><td>  </td><td>Battery is charging</td><td>  </td><td>Current battery capacity</td><td>  </td><td>Out of battery</td></tr>
<tr><td colspan="6">  </td><td>ON/OFF button.</td></tr>
<tr><td colspan="6">  </td><td>Equipotential port</td></tr>
<tr><td colspan="6">  </td><td>Waste bin symbol, indicating that waste must be collected according to local regulations and collection schemes for disposal of batteries. Only applies to batteries in the Eview.</td></tr>
<tr><td colspan="6">  </td><td>Waste bin symbol, indicating that waste must be collected according to local regulations and collection schemes for disposal of waste electrical and electronic equipment (WEEE). Only applies to the Eview.</td></tr>
<tr><td colspan="6">Li-ion</td><td>Li-ion battery. Only applicable for the batteries in the Eview.</td></tr>
<tr><td colspan="6">  </td><td>Re-chargeable battery. Only applicable for the batteries in the Eview.</td></tr>
<tr><td colspan="6">  </td><td>Manufacturing Date</td></tr>
<tr><td colspan="6"> 
</td><td>Temperature limitation: Temperature should fall between 0- 45°C (32-113°F) during storage and transportation.</td></tr>
</table>

	Humidity limitations: Relative humidity should fall between 30 - 95% during storage and transportation.
	Manufacturer
	EU authorized representative
	CE mark. The product complies with the EU Council Directive 93/42/EEC concerning medical devices.
	Serial number
	WARNING
	Consult Instruction for use
	Caution: Federal law restricts this device to sale by or on the order of a physician.

3. Use of the Equipment

3.1. Preparation and Inspection

WARNING ⚠

- Do not use the equipment if it is damaged in any way or if any part of the functional check described below should fail.
- The Eview's life time is 5 years, in order to guarantee the safety and efficiency, do not use if the product has already expired.
- The equipment consists of the parts described in chapter 2. They may only be replaced by PUSEN authorized parts. Failure to comply with this may reduce safety and efficiency of the product.
- Be sure to connect the power plug of the power cord directly to grounded wall main outlet. If the Eview is not grounded properly, it can cause an electric shock.
- Do not connect the power plug to the 2-pole power circuit with 3-pole to 2-pole adapter. It can prevent proper grounding and cause an electric shock.
- Do not connect the power plug using an extension cord. It can prevent proper grounding and cause an electric shock.
- Always keep the power plug dry, a wet power plug may cause en electric shock.
- Be sure that before each use or after a change of mode, the view observed through the endoscope provides a live image (rather than a stored one) and has the correct image orientation.

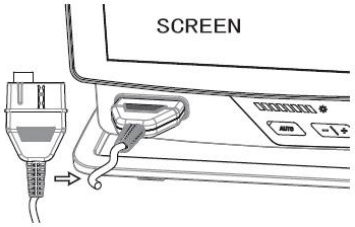
CAUTION

- Pay attention to the battery symbol indicator on the Eview when using battery power. Promptly recharge the Eview when the battery level is low (see section 6.1).
- Place the Eview on a stable flat surface while in use. Dropping the Eview could damage it.
- Position the power cord where it is unlikely to be stepped on. Do not place any objects on the power cord.
- If the equipment is used adjacent to or stacked with other equipment, observe and verify normal operations of the equipment prior to using it. Consult the tables in Appendix 1 for guidance in positioning the equipment.

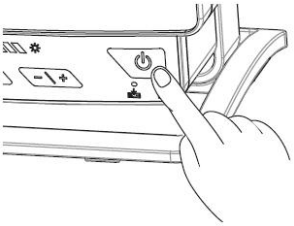
NOTE

Have a suitable backup equipment readily available for immediate use so the procedure can be continued if a malfunction occurs.

1. Closely examine the Eview for any damages.
2. Check for any damages to the Eview cable and power cord (free from wear and tear)
3. Insert the device plug of the power cord into the power supply cord receptacle of the equipment, then insert the power cord into the power sockets..
4. Connect the video endoscope to the Eview by inserting the connector on the endoscope into the corresponding socket on the Eview.



5. Press the ON/OFF button to turn on the Eview.



6. Examine to see if light is emitting from the optical fibers at the distal tip.
7. Point the distal tip of the insertion cord towards an object and check that live video images appear on the screen.
8. Adjust the image preferences on the Eview if necessary. Refer to section 7 for details.
9. If the object cannot be seen clearly, wipe the lens at the distal tip using a piece of clean gauze.

3.2. After Use

Disconnect the video endoscope from the Eview.
Turn off the Eview by holding down the ON/OFF button for at least 1 second.

At the end of product life, open up the Eview and remove the battery. Dispose of the battery and the Eview separately in accordance with local guidelines.

WARNING ⚠

Clean and disinfect the Eview after each use according to the instructions in chapter 4.

4. Cleaning and Disinfection of the Eview

Before initial use, the Eview must be cleaned and disinfected according to the cleaning instructions. Clean and disinfect the Eview immediately after each use.

WARNING ⚠

- Disconnect the Eview from any main power supply, remove any accessories, and make sure the Eview is completely turned off before cleaning and disinfection.
- When disconnecting the Eview from a power supply, pull the plug out of the wall socket.

CAUTION

- Do not allow water or any liquid to drip inside the unit(s).
- When using cleaning or disinfecting solutions, follow the manufacturer's specifications for exposure time and service life.

4.1. Cleaning

NOTE

Recommended Cleaning Agents:

Cleaning agent	Manufacture
Metrex Empower	Metrex Research, LLC

Manual Cleaning at room temperature

1) Shut off the Eview, disconnect the power supply.
2) Prepare a cleaning solution using the recommended enzymatic detergent.
3) Soak a piece of medical gauge in the enzymatic solution, and make sure that the gauze is moist and not dripping.
4) Thoroughly clean the buttons, screen, external casing the Eview with the moist gauze. Avoid getting the device wet to prevent damaging internal electronic components.
5) Wait for 10 minutes (or the time recommended by the manufacture of the detergent) to allow the enzymes to activate.
6) Wipe the Eview clean using medical gauze which has been moistened with RO/DI water. Endure all traces of the detergent are removed.
7) Repeat step 1 to 6, until the surface of the Eview is clean, no stains and water marks by visual check.

4.2. Disinfection

NOTE

Disinfection prior to manual cleaning is ineffective, and results in proteins and organic residues becoming fixed on the instrument, thus preventing correct disinfection.

Manual disinfection at room temperature

1) Prepare a piece of gauze moistened with the disinfectant (isopropyl (alcohol)), make sure the gauze is moist and not dripping to avoid any liquid to drip inside the unit.
2) Wipe the buttons, screen, external casing, grooves and gaps of the Eview.
3) Place the Eview for 10 minutes at room temperature after disinfection.
4) Wipe the surface of the Eview with a dry gauze.

Solution	Concentration
isopropyl (alcohol)	70-80%*

*Alternatively, use EPA-registered hospital disinfection wipes containing at least 70% isopropyl. The manufacturer's safety precautions and directions for use must be followed.

After cleaning and disinfection, the Eview must undergo the inspection described in section 3.1. After use, the Eview must be stored in accordance with local guidelines until it is used again.

5. Technical Product Specifications

Display Max. resolution	 1,024 * 768
Orientation	Landscape
Display type	12.1”color TFT LCD
Startup time	Approximately 20 seconds
Storage capacity	8 GB
Power Power requirement	 100-240V~50/60Hz1.0-0.5A
Battery type	PS18650A,10.8V4400mAh
Electric shock protection	External power supply devices for class I equipment with an internal battery.
Operating environment Temperature	 10-40°C (50-104°F)
Relative humidity	30-85%
Atmospheric pressure	800-1060hPa
Altitude	≤2000m
Storage and transportation Temperature	 0-45°C (32-113°F)
Relative humidity	30-95%
Dimensions Width	 315mm
Height	308mm
Thickness	187mm
Weight	4.3 kg
Connections USB connection	 Type A
AV connection	RCA connector
HDMI connection	Optional

WARNING ⚠

- To avoid the risk of electric shock, the equipment can only be connected to a power source with ground protection.
- When disconnecting the equipment from a power supply, the plug must be pulled out of the wall socket.

6.Use of the Eview and Its Connection Accessories

WARNING⚠

The equipment consists of the parts described in chapter 2. They may only be replaced by PUSEN authorized parts. Failure to comply with this may reduce safety and efficiency of the product.

CAUTION

- The Eview can only be repaired by a specialist authorized by PUSEN.
- You are not permitted to modify the equipment.

6.1. Charge the Eview

Insert the power connector into the power inlet of the Eview and then connect the power supply to the wall socket.

The battery indicator on the console will flash when charging and will turn green when the battery is fully charged. The battery icon will change as shown here:

Max. battery status of the Eview

Min. battery status of the Eview

The icon remains green until one block is left, after which it turns to red.

When remaining battery capacity is 10%, the red battery icon starts flashing.

Battery is charging

Current battery capacity

Charging is shown with blocks flashing

Current capacity is shown with non-flashing blocks.

If the battery is fully charged and is still connected to a charger, the battery icon changes to:

6.2. Battery Maintenance

To prolong battery life, it is recommended to fully charge the Eview at least every third month and store it in a cool place if the Eview is not used for a long time. The battery charging procedure takes approximately 3-4 hours. The battery should be charged at temperatures between 10-40°C.

7. How to Operate the Eview

WARNING ⚠

Anytime you observe an irregularity in the Eview function, stop the examination immediately and take action according to following instructions. Using a defective device may cause the patient and/or operator injury.

- If the live image disappears or if the image freezes and cannot be restored, temporarily turn the Eview off and wait for about 10 seconds. Then turn it back on again. For ancillary equipment used in conjunction with the equipment, also turn the power off and then on again as directed in their respective instruction manuals. If this fails to correct the problem, immediately stop using the equipment and turn the Eview off. Then gently withdraw the endoscope from the patient.
- If any other abnormality occurs or is suspected, immediately stop using the equipment, turn off all equipments, and gently withdraw the endoscope from the patient.

After withdrawing the endoscope, take action according to the instructions in chapter 8,"Troubleshooting". If the problems cannot be resolved by the remedial action, please contact PUSEN.

7.1. How to Operate the Eview

The Eview has a ⏻ button in the lower right corner to turn the Eview on and off.

How to Turn On the Eview

(Assumption: Eview is turned off)

⏻

Press the ⏻ button located in the lower right corner of the Eview.

- The button will light up;
- The Eview is now in STARTUP IMAGE MODE;
- If the Eview is connected to the Uscope, the Eview will be ready in WORKING MODE after about 1 minute.

NOTE: During startup, the screen may flicker for about 2 seconds.

How to Turn Off the Eview

(Assumption: Eview is turned on)

⏻

Press the ⏻ button located in the lower right corner of the Eview for at least 1 second.

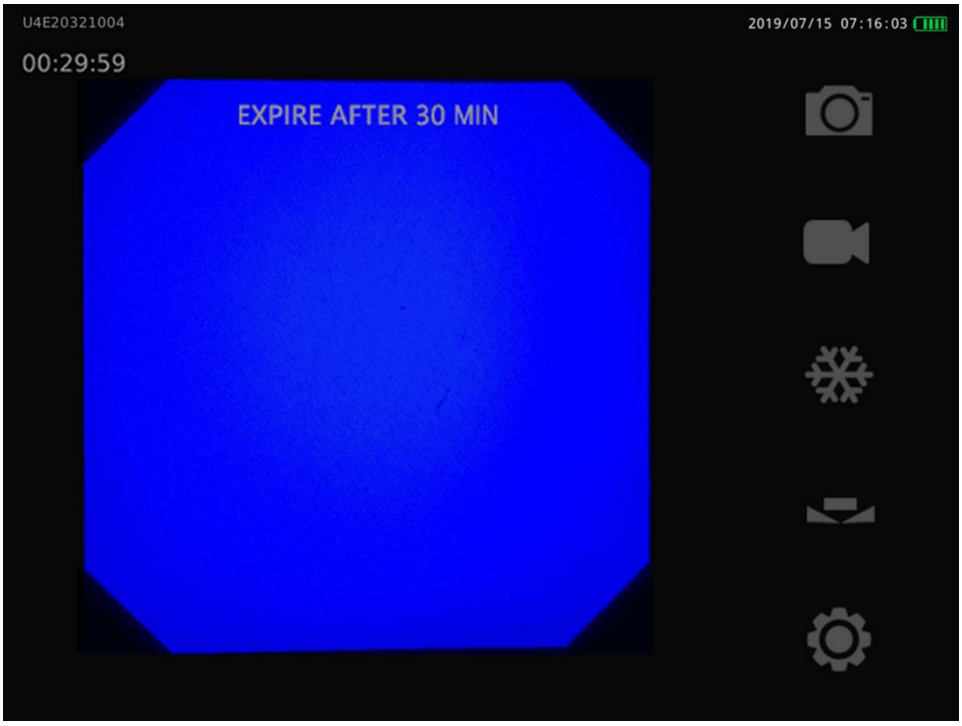
- A shutdown indicator showing that the Eview is turning off will appear on the screen.

NOTE: If you press the button located in the lower right corner of the Eview for at least 3 seconds, the Eview will turn off regardless of whether the shutdown indicator is shown on the screen or not.

7.2. Modes in the Eview

The Eview has two modes of operation: LIVE VIDEO MODE and MANAGEMENT MODE.

LIVE VIDEO MODE:



The live image is displayed on the left side of the screen. The current time and battery icon are displayed in the upper right corner of the screen. The available working time and SN of Uscope is displayed on the upper left corner of the screen. The hints are displayed on the upper of the screen. Operation buttons are displayed on the right of the screen. When the available working time of Uscope is less than 30 minutes, the hints will be displayed on the screen, and the Uscope will expire in 30 minutes.

SNAPSHOT

Tap the  button to take a snapshot.

VIDEO

Tap the  button to make a video, the button will change to  "REC" is showing at regular intervals indicating that a video is making. The record of the video starts as soon as the button is tapped. The snapshot button is not available in the process of video.

Tap again  to stop video, the button will change to  and the snapshot button back to a usable state.

FREEZE

Tap the  button to freeze the image, the button will change to  and indicate at the upper that the image is in frozen state, the video button and white balance button are not available in the process of freeze.

Tap again  to unfreeze the image, the button will change to  and the video button and white balance button back to a usable state.

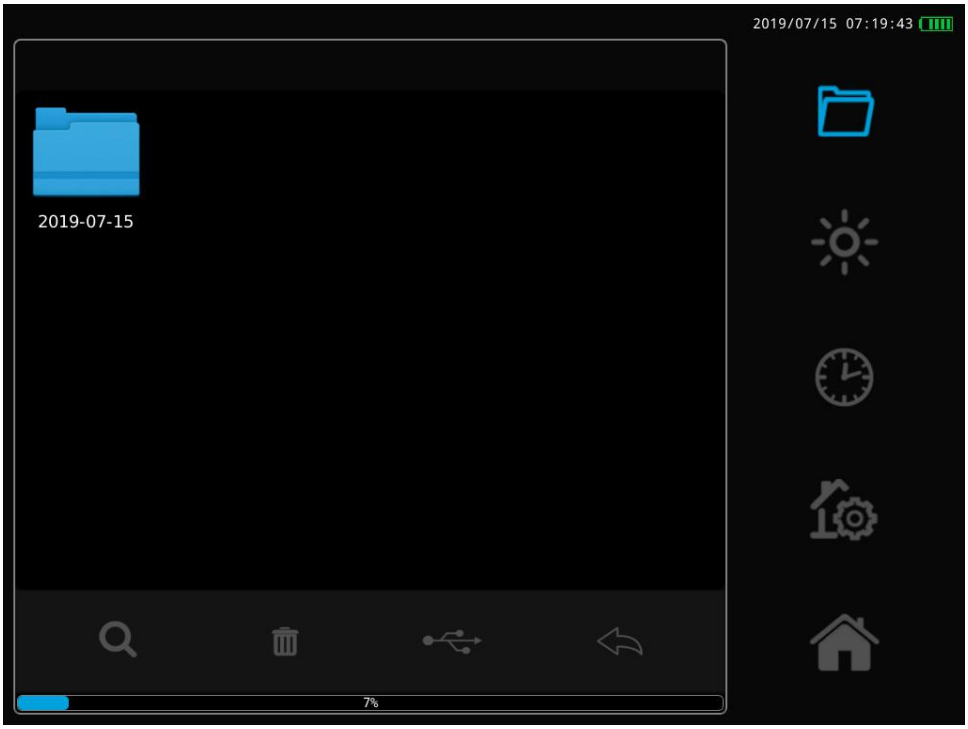
WHITE BALANCE 	Press and hold the  button for 3 seconds, white balance calibration will start and the button will change to  , the snapshot, video, freeze and white balance buttons are not available in the process of white balance calibration. These buttons will back to usable state after white balance calibration has completed.
SETTING 	Tap the  button to enter the management mode. Management mode includes document management, brightness setting, image enhance, date and time setting, and factory maintenance.

MANAGEMENT MODE:

The management mode mainly includes document management, brightness setting, date and time setting, factory maintenance and HOME key functions.

In any interface of management mode, tap the  HOME key to return to live video mode immediately.

Tap the  to enter the file management interface in the management mode.



Tap a folder  once to select it.

Tap  or double click the folder to view the contents of the folder.

- Tap  to go back to the previous level.

Repeat the above steps until the desired file or folder is located.

Tap  or tap  to go back to live video mode.

View Snapshots or videos

Tap a file to select it, the file is highlighted when selected.
When a snapshot file is selected:

Tap  or double click the snapshot file to enter snapshot browsing interface to view the snapshot.

-Tap  or  to toggle between snapshots in the folder.

-Tap  to zoom in the snapshot, tap  to zoom out the snapshot.

-Tap  to copy the snapshot to the USB stick.

-Tap  to delete the snapshot.

When a video file is selected:

-Tap  or double click the video file to enter the video playing interface.

- Tap  to pause playing the current video.

- Tap  to stop play the current video and return to the interface of browsing mode.

Delete Files

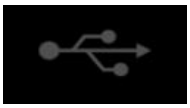
Tap a file or folder to select it.
- The file is highlighted when selected.

Tap  to delete a file or folder.

- Tap  to confirm deletion.

- Tap  to cancel deletion.

Export Files



Tap a file or folder to select it.
- The file is highlighted when selected.

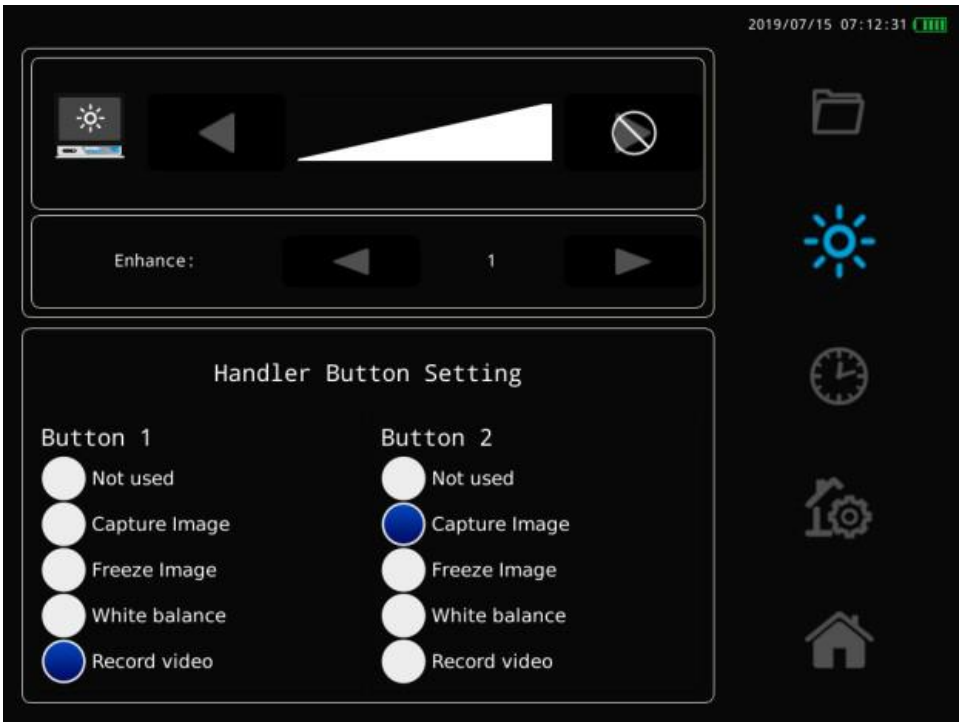
Tap  to copy the file or folder to the USB stick.

-The Sign will pop up when the copying is going on.

- The button will turn back to  when the copying process is complete.

NOTE: Do not unplug the USB stick or delete files from the Eview when copying.

Tap  to enter the brightness setting interface:

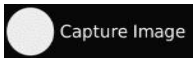


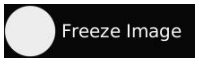
-Tap  to decrease the screen brightness, tap  to increase the screen brightness.

In the Row  , Tap  and  to increase or decrease the image texture. The increase level can be set to 1,2,3, and the default setting is 0.

Handler Button Setting is used for setting function to handle with custom defined buttons.

-Tap  to set button 1 or button 2 as no function.

-Tap  to set button 1 or button 2 in snapshot function.

-Tap  to set button 1 or button 2 in freeze function.

-Tap  to set button 1 or button 2 in white balance calibration function.

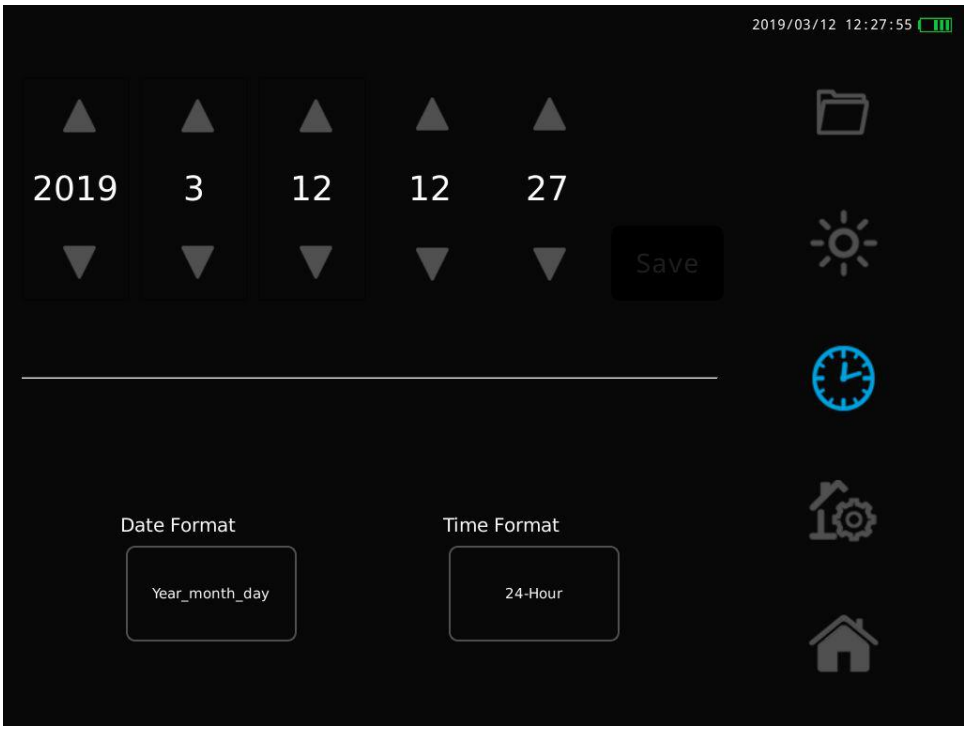
-Tap  to set button 1 or button 2 in video function.

-Changes are saved automatically.

Note

- When there is only one custom defined button on the handle, the button is default allocated as Button 1, the Button 2 setting will not function.

Tap  to enter the date and time setting interface:



- Tap  to toggle between 12 and 24 hour clock.

- Tap  to toggle between several date formats.

- Tap  to increase value and  to decrease value. Year, month, day, hour, and minute can be set.

- Tap  to save.

Tap  to enter the factory maintenance interface:

- The factory maintenance can only be accessed by entering password on the upper screen.
- The software version and SN of the equipment is showed on the bottom.

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8. Disposal

WARNING ⚠

- The device features a built-in lithium battery, which is not user replaceable. Tampering with your device, or attempting to open it, will void the warranty and can result in a safety hazard.
- Use only the power cord that shipped with your device to charge the battery.

Disposal of Old Electrical & Electronic Equipment (Applicable in the European Union and other European countries with separate collection systems)

This symbol on the product or on its packaging indicates that this product shall not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. Please inform yourself about the local rules on the separate collection of electrical and electronic products. The correct disposal of your old product helps prevent potentially negative consequences on the environment and human health.

Disposal of waste batteries (applicable in the European Union and other European countries with separate collection systems)

This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste. Please inform yourself about the local rules on separate collection of batteries. The correct disposal of batteries helps prevent potentially negative consequences on the environment and human health.

9. Troubleshooting

If problems occur with the equipment, please use this troubleshooting guide to identify the cause and correct the error.

When troubles or failures other than those listed in the following table are observed, turn off the Eview and turn it on again. If the problem still cannot be resolved, please contact PUSEN for repair.

The device does not turn on.	
Cause	Action
The power supply is not connected or the battery is flat.	Connect the device to the mains power.
The equipment is damaged.	Use a backup equipment and contact the manufacturer.
During startup, tooltip pop up and display the failure configuration of FPGA	Turn off the Eview by pressing and holding the ON/OFF button for at least 1 second. When the Eview is off, restart it by pressing and holding the ON/OFF button again. If this does not solve the problem, please use a backup equipment and contact the manufacturer.
There is no live image on the left side of the screen but the user interface shows up on the display.	
Cause	Action
The Uscope is not connected with the Eview. or the Uscope is poor connected with the Eview.	Turn off the device and insert the connector of the Uscope into the corresponding socket on the Eview.
There are communication problems between the Eview and the Uscope	Turn off the Eview by pressing and holding the ON/OFF button for at least 1 second. When the Eview is off, restart it by pressing and holding the ON/OFF button again.
The Uscope is damaged or expired.	Replace the Uscope with a new one.
The image display is dark.	
Cause	Action
The optical path of the Uscope and the Eview is not connected.	Turn off the device and insert the connector of the Uscope into the corresponding socket on the Eview.
The Eview light source is not turned on.	Turn the light source switch of the Eview on and adjust the brightness of the light source to a suitable level.
The brightness level of the light source is too low.	Adjust the brightness of the light source to a suitable level.
The light source is damaged.	Use a backup equipment and contact the manufacturer.
The image shown on the left side is frozen.	
Cause	Action
A communication error has occurred between the Uscope and the Eview.	Turn off the Eview by pressing and holding the ON/OFF button for at least 1 second. When the Eview is off, restart it by pressing and holding the ON/OFF button again.
The current image has been frozen.	Unfreeze the image.

The Uscope is damaged.	Replace the Uscope with a new one.
Low picture quality.	
Cause	Action
Light is reflecting on the Eview screen.	Move the Eview to a position where no direct light is shinning on the screen.
Ambient light is too strong.	Decrease the brightness of the ambient light.
Dirty/damp screen.	Wipe the screen with a clean cloth.
Blood on the lens (distal tip).	Inject more lavage fluid. If the lens cannot be cleaned in this manner, withdrawing the Uscope and wipe the lens with sterile gauze.

Appendix 1: Electromagnetic Compatibility

Like other electrical medical equipment, the equipment requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC) the equipment must be installed and operated according to the EMC information provided in this manual.

The equipment has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

NOTE

Electromagnetic interference may occur to the equipment when it is placed near equipment marked with the following symbol or other portable and mobile RF communications equipment such as cellular phones, if radio interference occurs, mitigation measures may be necessary, such as reorienting or relocation the equipment or shielding the location.

WARNING ⚠

The equipment consists of the parts described in chapter 2. They may only be replaced by PUSEN authorized parts. Failure to comply with this may reduce safety and efficiency of the product.

WARNING ⚠

If the equipment is used adjacent to or stacked with other equipment, observe and verify normal operation of the equipment prior to using it. Consult the tables below for guidance in positioning the equipment.

Electrical Connection

Pins of connectors identified with the ESD warning symbol should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used.

ESD Precautionary Procedures:

- Connect all equipments that needs to be connected with the equipment to Equipotential port (by protective earthing)
- Only equipments and accessories permitted in the user's instruction can be used.

All staff involved should receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.

Guidance and manufacturer's declaration – electromagnetic emission		
The Medical Video Endoscope Image Processor(Eview: UTV100) is intended for use in the electromagnetic environment specified below. The customer of the user of the equipment)should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The **equipment** 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 emission CISPR 11	Class A	The **equipment** is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2 (UTV100, UE3011)	±6 kV contact ±8 kV air	±2 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic discharge (ESD) IEC 61000-4-2 (UTV100, PU3021, PU3021A, PU3022, PU3022A)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4 (UTV100, UE3011)	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4 (UTV100, PU3021, PU3021A, PU3022, PU3022A)	±2 kV for power supply lines ±1 kV for signal cable	±2 kV for power supply lines ±1 kV for signal cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 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	<5% U_T (>95% dip in U_T) for 0.5 cycle 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains dip &interruptions, it is recommended that the equipmentbe powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 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 an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] 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 equipment is used exceeds the applicable RF compliance level above,the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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

Recommended separation distances between
portable and mobile RF communications equipment and The Medical Video Endoscope(UTV100)

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment 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 $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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.

Appendix 2: Warranty and Replacement

The warranty period for the Eview is one year from delivery to the customer. We agree to replace the Eview free of charge if proof can be provided of faulty materials or faulty workmanship.
In doing so, we cannot accept the cost of transportation or risk of shipment.
A defective Eview must be handled exclusively by persons authorized by PUSEN. During our inspection of the Eview, we will provide a suitable replacement for the Eview. To prevent infection, it is strictly forbidden to ship contaminated medical devices. The medical device (Eview) must be disinfected before shipped to PUSEN. The cleaning and disinfection procedures explained in 4.1 and 4.2 must be followed. PUSEN reserves the right to return contaminated medical devices to the sender.

If you have any problems while using the equipment, please contact the manufacturer or the authorized European representative.

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