SCOPEYE®

SE-EDN

Rev. 2

ENG

MediThinQ Co., Ltd.

www.medithinq.com

Eyes Up Display

SCOPEYE®

Surgeon's fatigue due to monitor-oriented operation was a long debated topic among medical staffs.
With SCOPEYE, there is no need for surgeons to turn their heads to focus on monitor screens
which creates ergonomic challenges and discomfort during long operations.

Contents

Definition of Symbol

Symbol	Definition
	Direct Current
	Protective earth / ground
	Power
	General warning sign
	Warning for electrical hazard
	CE marking is signify that products sold in the European Economic Area (EEA) have been assessed to meet high safety, health, and environmental protection requirements
	Non-ionizing radiation including wireless connections
	Refer to instruction manual/booklet
Rx ONLY	USA Federal Law indicates that the product is a medical device and its use or sales are limited to physician's instruction
	General mandatory sign
	Introducing useful tips to help users to comfortably operate SCOPEYE.
	BS EN 50419, Directive 2002/96/EC (WEEE) Article 11(2) compliant electrical and electronic equipment marking, indicating that the product is not suitable for disposal in landfills
	Manufacturer
	Manufacturing date
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified
MD	Indicating that it is a medical device
UDI	Indicates a carrier that contains unique device identifier information
	Do not use if package is opened or damaged
EC REP	Indicates the authorized representative in the European Community/European Union
CH REP	Indicates the authorized representative in the Swiss Representative
UK REP	Indicates the authorized representative in the UK Responsible Person
UK CA	UKCA marking is an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold with in the Great Britain market
	Indicates the entity importing the medical device into the locale
RoHS Compliant	Indicates that a product complies with the RoHS directive, which restricts the use of certain hazardous substances

Safety Instruction

Please be noted that comments with below symbols have meanings to warn.

It is related to physical safety of medical staff and patient.
When ignored, there can be an injury of medical staff or patient.

Special procedures or precautions to prevent product damage. Please follow given steps.

Guidance for smooth maintenance or important information.

Warning for possible electrical hazards,
Contact an authorized technician for all repairs.

※ The warranty of the product will be void when ignoring warnings or precautions.

For safe use, please note below followings.

1. Read the manual carefully before use and follow the instructions for correct operation.
2. Make sure none of the components in the package is broken or missing.
3. When water damaged, unplug and ask inspection to an authorized engineer.
4. Unplug if the product is not in use for a long period of time.
5. Make sure product operation before connected to medical equipment.
6. Do not arbitrarily disassemble the product.
7. Failure to follow maintenance and cleaning guide mentioned in the manual can cause a product damage.
8. Do not place heavy objects on the power adaptor in order to prevent fire or electric shock.
9. In order to prevent electrical hazard, make sure to connect to electrical grounded cables.
10. Do not modify the product without manufacturer's approval.
11. Place the adaptor away from liquid, for it is not water-proof.
12. Do not operate product in place with direct sunlight, excessive dust, mechanical vibration or shock.
13. The product must be maintained in a stable usable state by the administrator.
14. It is recommended to use included cables for wired connection. Random foreign cables may cause product degradation.

Electromagnetic compatibility is guaranteed in accordance with EMC information in this manual.
Product setting and operation should be followed as guided in the manual.

Product Management Method

Cleaning

- External parts of SE-EDN: wipe off the dust with a dry cloth once a week.
- Lens: Microfiber cleaning cloth for glasses is recommended for SE-EDN. If foreign substance are found on lens, wipe the lens with a cloth using alcohol.

If sterilization is required, clean it with a cloth dampened with alcohol.
- Using 70~90% alcohol is recommended for sterilization

Use only a small amount of alcohol to clean the external plastic parts and lenses of SCOPEYE. If alcohol gets inside the lens and devices, it may cause malfunction or damage.

Headband is natural leather. Do not use alcohol.

Transportation and Storage

- Temperature: -10˚C ~ 60˚C (14˚F ~ 131˚F)
- Relative Humidity: 10% ~ 90%
- Air Pressure: 700 hPa. ~ 1060 hPa.

Operation Enviroment

- Temperature: 5˚C ~ 35˚C (41˚F ~ 95˚F)
- Humidity: 20% ~ 80%
- Air Pressure: 700 hPa. ~ 1060 hPa.

Product

EU Declaration of Conformity (DoC) for Medical Equipment

EU Declaration of Conformity for the product has been submitted.
If a softcopy of the document is required, please contact manufacturer.

Purpose of Use

This product is Head-mounted display that acquires real-time images from various medical devices wireless or wired them into 2D or 3D through without post-processing, making it easier for doctors performing surgery to obtain information needed for surgery. The device allows doctors to understand and perform surgery without time delay or omission of information and without having to move or turn their heads to check the image.

Determination as medical device for SCOPEYE

Facilitate of other medical device, Medical devices that support to achieve the purpose of medical devices.

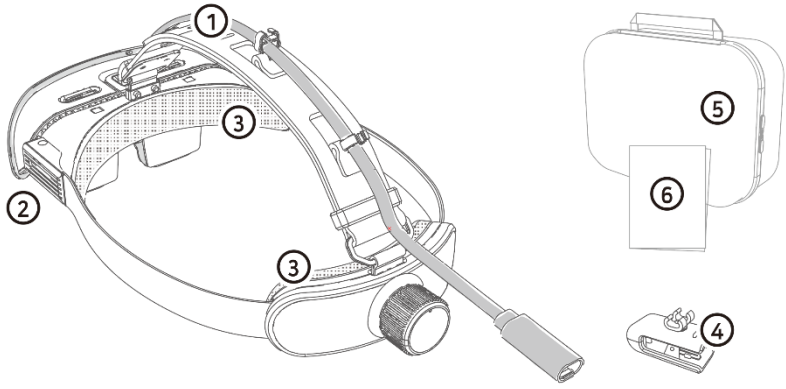
User

The product is to be used only by professional medical staffs fully familiar with its manual.
Patient population: not specified

Contra-indication

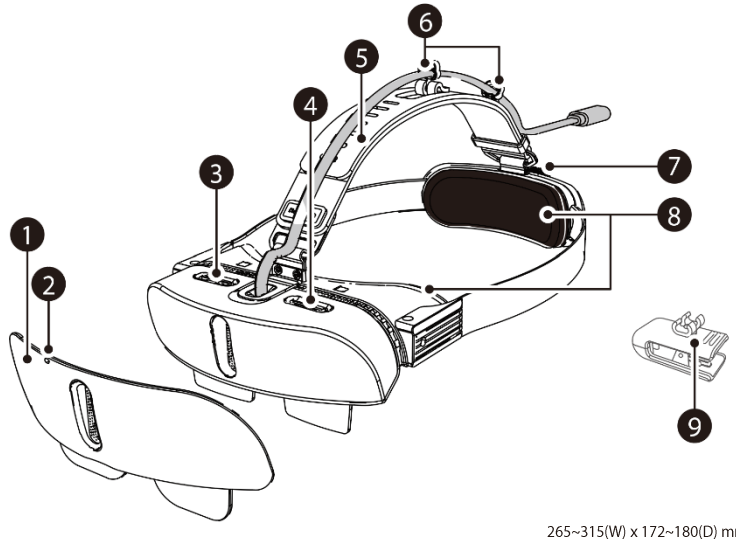
Do not use a converter to connect to equipment that does not support DVI / HDMI / SDI.
This device does not come into contact with the patient and is not a chemical, biological, or blood-related device. No side effects occur.

SE-EDN Package



① SE-EDN
② Shader: transparent 5% /15% / 35%
③ Head cushion (front, rear)
④ Pin
⑤ Carrying case
⑥ User manual

Names of SE-EDN



265~315(W) x 172~180(D) mm / 410 g

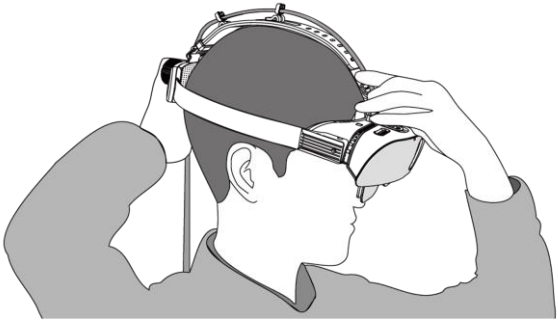
NAME		DESCRIPTION
①	Shader	Control display clearness and secure external view by adjusting the light level. Ex. Control the transmittance of the screen
②	Straphole	Use the grove to tie up with strap in order to avoid the shader falling off during operation
③	2D/3D button	Convert image from 2D to 3D
④	FLIP button	Change image direction
⑤	Headband	Use the pin-and-tuck locking device to fix it according to the shape of the head
⑥	Cable holder	This holder is used to fix the cable to the headband
⑦	Headband dial	Use the band by turning the dial to fit your head circumference
⑧	Head cushion	Replace them according to the frequency of use (front, rear)
⑨	Pin	Fix the pin on clothes in order to reduce the weight of SE-EDN on user's neck and shoulder

Change display option by pressing FLIP button in order to see inverted images due to different staff position.
Original image▷ (FLIP) ▷ Mirror image ▷ (FLIP) ▷ Flip image ▷ (FLIP) ▷ Original image

Original image	Mirror image	Flip image
SCOPEYE	SCOPEYE	SCOPEYE

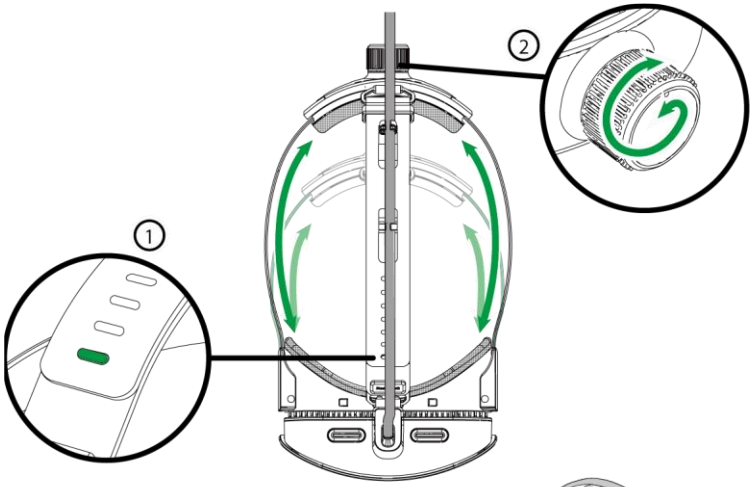
Wearing SE-EDN

1 Wear SE-EDN with both hands.

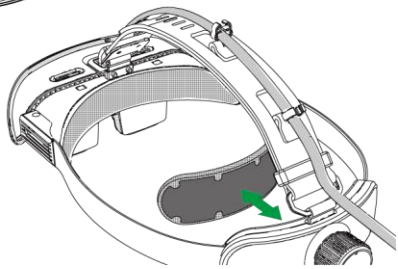


Please be careful not to touch the lens with skin.

Pull the band according to the size of your head (265~315 mm) and fix it to the pin-and-tuck lock ①, then turn the headband dial ② according to your head circumference (172~180mm) and put it on.



The head cushion (front, rear) can be replaced depending on the frequency of use.

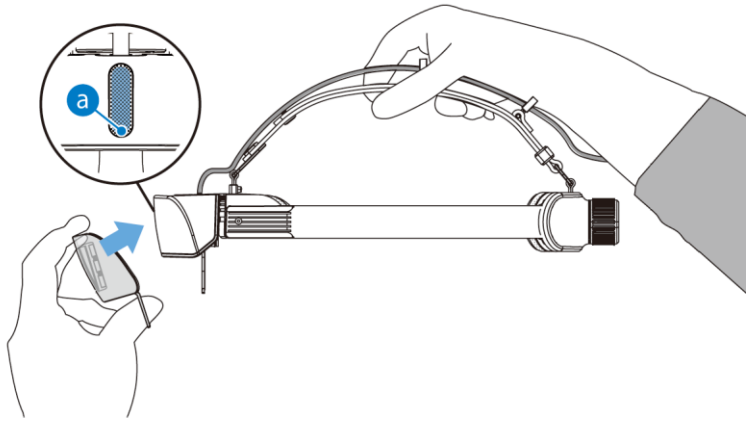


Attachment and removal of shader

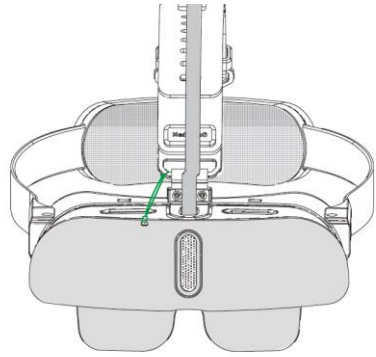
According to the light condition in the operation room, choose a proper semi-transparent shader for clear display images: 50%, 75%, or 85%

Attaching shader

Attach the shader from magnetic parts ⓐ by pushing it all the way to the end. There will be a clicking sound when the shader is perfectly attached.

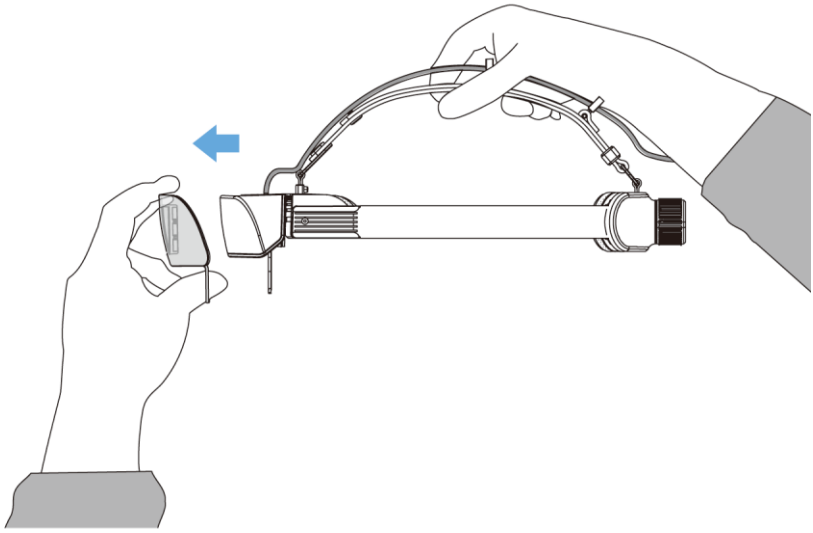


Strap can be used to tie up the shader in order to avoid the shader falling off during operation.



Removing shader

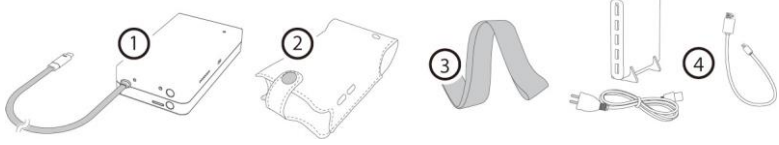
Remove the shader carefully so that fingers can be away from the lens.



If the shader is pushed or pulled with too much force, SE-EDN could be damaged. Do not use too much force on the shader.

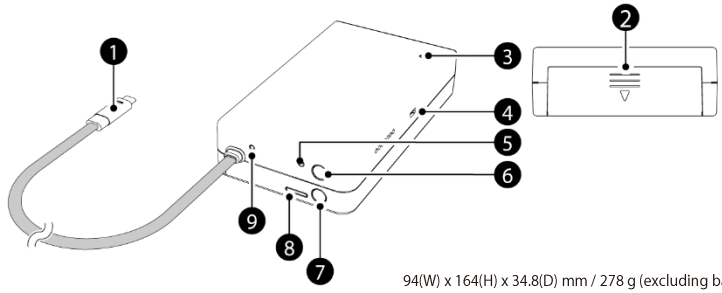
Wireless Receiver

Receiver Components



① Receiver
② Pouch
③ Receiver pouch holder
④ Battery charging station / cable

Names of Receiver



94(W) x 164(H) x 34.8(D) mm / 278 g (excluding battery)

NAME		DESCRIPTION
①	USB-C	Connection to the receptacle of SE-EDN
②	Battery cover	Protection cover to insert battery into the receiver
③	Power LED	Indication of power status (white color)
④	UPDATE port	Port for firmware update
⑤	MODE button	Change the option of the mode
⑥	Power button	Change the power status of receiver
⑦	RESET button	Change status of the receiver battery - Press when receiver is OFF: wake up from sleep mode - Press when receiver is ON: forced termination
⑧	Battery LED	Indication of remaining battery (●●●●(Full) > ●●●○ > ●●○○ > ●○○○ >○○○○(Low))
⑨	Display LED	Indication of streaming connection status (blue color)

Turning SE-EDN on and off

Turning wireless type Receiver On/Off

Turning on

Check the remaining battery level of the receiver before power on.

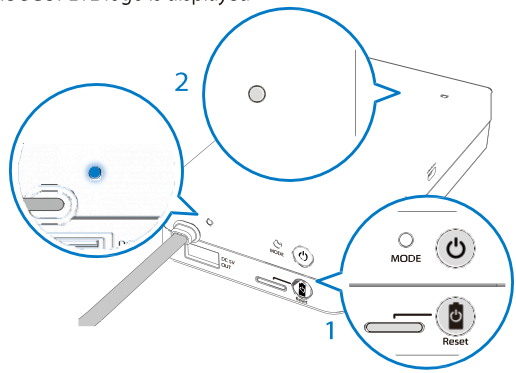
1 Prepare fully charged battery and insert it to the receiver.

2 Press the power button for 3 seconds for power on.

3 Check that the white led power light and blue led display light at the receiver is on.

4 Booting will be started as the power led and display led to blinks.
After the booting complete, the image will be displayed on the SE-EDN.

If the display LED (BLUE) turns off after booting complete, the connection with the transmitter (tx) is disconnected.
"Only the SCOPEYE logo is displayed"



- The time for incoming image may vary depend on its Wi-Fi environment.
- Do not press RESET button while in use. SE-EDN and receiver will forcibly shut down and it may cause product malfunction.

For using receiver, please refer to below.
▶ page 14, “Connection method with SE-EDN for Receiver”.

Turning off

Press the power button at the bottom of receiver until the white LED light of the power is perfectly off. Receiver will shut down when power LED is off.

- Even after power is off, the LED lights of battery can be flicking for 5~10 seconds. Power is to be automatically off.
- If you want to reuse the product right after power off, please press the power button after 5~10 seconds.

SE-EDN connection method

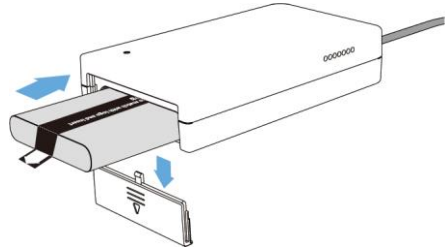
Connection method with SE-EDN for Receiver

1 Prepare receiver (SE-TXD) to connect with surgical equipment.

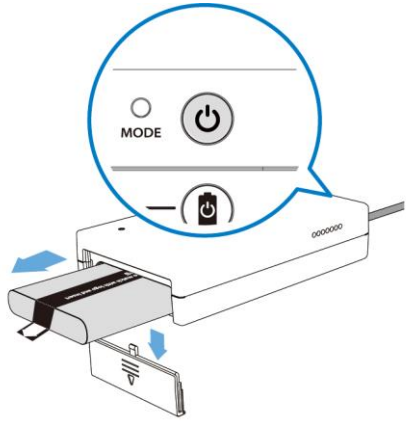
Please refer to below for using transmitter (SE-TXD)
▶Page 16~18, "Transmitter (SE-TXD)"

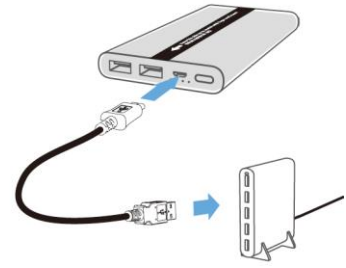
Battery is charged under 30% for safe shipping. Fully charge the battery before first use.

2 Remove the battery cover by pushing it downwards, then insert the battery by following the direction of the arrow.



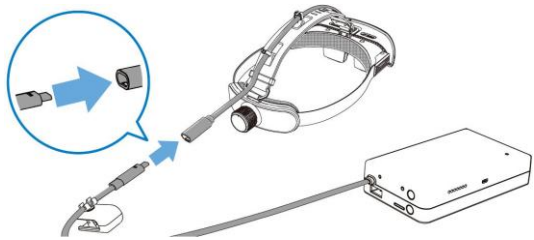
After powering off the receiver, open the battery cover case and pull the battery away from receiver.
(When the receiver is powered on, turn off the receiver using the "OFF" method on page 13, and then remove the battery.)





Make sure not to damage the lens of SE-EDN when trying to connect to receiver.

3 Connect the other side of USB C cable to the receptacle of SE-EDN.



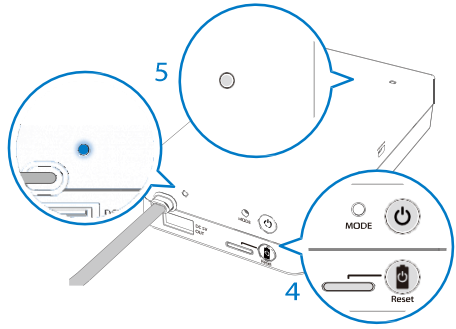
When connecting receiver's USB C cable and SE-EDN, connect them completely until you hear a "click" sound.

You can set the pin on clothes to fix cable location.

4 Press the power button for 3 seconds.

5 LED light on the receiver will be on.

6 Receiver will be on as led blinks and booting will be started.
There will be logo image on the wearable display of SE-EDN for 30 seconds.



- The time for incoming video may vary depending on the surrounding wireless environment.
- Move the receiver at least 50cm away from the transmitter for quick video reception.

If only the scopeye logo is displayed and the video does not start playing, check the Display LED.
If the Display LED(blue) is off, the connection with the transmitter (tx) is disconnected.

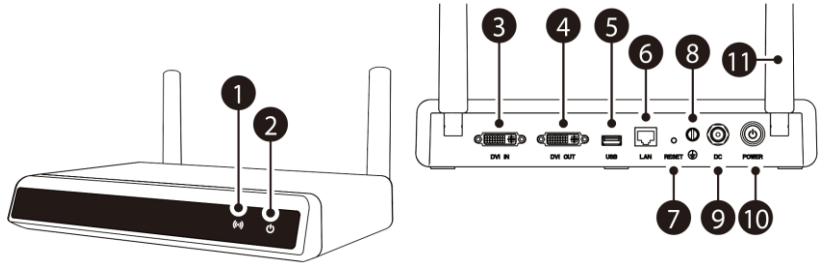
7 Wear SE-EDN and confirm that the video image from surgical equipment is well found on wearable display.

Transmitter (SE-TXD)

SE-TXD Components

① SE-TXD
② Antenna 2ea
③ Power adaptor
④ DVI-DVI / DVI-HDMI cable
⑤ Quickguide

Names of SE-TXD



200(W) x 300(H) x50(D) mm / 1650g

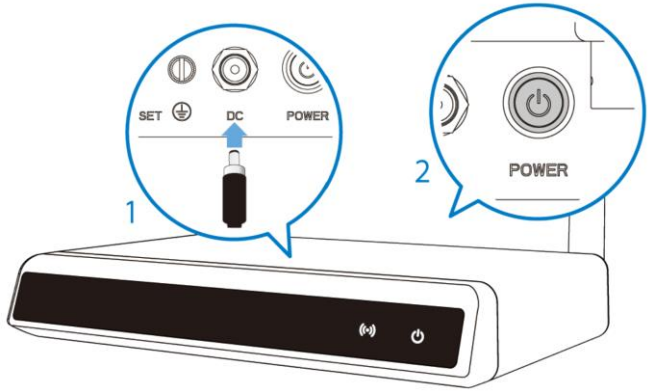
NAME	DESCRIPTION
① WiFi LED	Connection status of imaging device for wireless transmission
② POWER LED	Indication of SE-TXD power / WiFi channel status
③ DVI IN port	Input of image/video source
④ DVI OUT port	Pass-through output of DVI input port video source (original video)
⑤ USB port	Connection terminal of firmware update for SE-TXD
⑥ LAN port	Ethernet connection (Disabled this port for SE-TXD)
⑦ RESET button	Reset of SE-TXD
⑧ GROUND	Ground connection
⑨ DC port	Power supply to the SE-TXD
⑩ POWER button	Power On/Off
⑪ Antenna	Antenna used to receive radio waves

Turning SE-TXD ON/OFF

Turning On

1 Connect antennas to the SE-TXD and connect DC power adaptor.

2 Press the POWER button at the SE-TXD to turn on the power and check the LED lighting status of the SE-TXD.



	ON	OFF
POWER (White LED)	Lighted	-
WIFI (Blue LED)	Lighted	-

Check if the SE-TXD's WiFi LED is lighted blue.

Turning Off

1 Turn off the power by pressing the POWER button on the SE-TXD and check that the LED light off.

How to connect SE-TXD

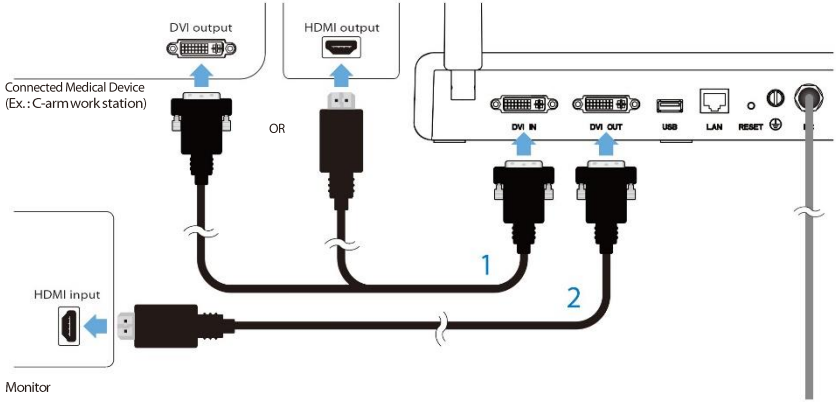
Check SE-TXD product components before use.

Check names of cable connectors.

1 Get SE-TXD ready.

2 Connect the DVI-DVI or DVI-HDMI cable between DVI or HDMI output on the medical device and DVI-IN on the SE-TXD.

3 Connect the DVI-HDMI cable between DVI OUT on the SE-TXD and HDMI port on the monitor.



Specification

SE-EDN

Optical type	Binocular
Optical technology	Light guide
Form factor	Detachable Visor / Top down optics
Resolution	1080p (per eye), 16:9
FOV (Field Of View)	>40°
Connector type	USB C

Wireless Receiver

Power input	DC 5V 2.4A
Battery	Lithium polymer batteries 10,000 mAh
Actuation time	Approx. 3 hours

Transmitter (SE-TXD)

Video input/output	DVI (1920x1080 Max) / DVI (pass-through)
Video encoder	H.264 (920 x 1080 Max)
Wireless standard	IEEE 802.11n 5GHz
Power input	DC 12V 3.34A
Power consumption	6W Max

Essential performance

SE-EDN

No.	Function reviewed	Description	Standards	Risk analysis results acceptable(Y/N)	Test criteria	method	Conclusion & remarks
1	Video Stream	Received images from medical imaging equipment and display a real time through Glasses to surgeon.	N/A	N	After entering the pattern generator image, review the image quality.	Visually	No delay, no frame skip, no mosaics is essential performance.
2	Color of video	The three primary colors (red, blue, green) should be displayed normally.	N/A	N	Input primary colors with the pattern generator.	Visually	The same color as the original in the pattern generator should appear on the glass.
3	Resolution input	It must support DP ALT mode of medical imaging equipment.	Display-Port Alternate Mode standard	N	When inputting DP ALT of standard, it should be played normally.	Visually	When inputting DP ALT of standard, it should be played normally.

Troubleshooting

SE-EDN Troubleshooting

If the problem occurs in use, please refer to the instruction below.

If the troubleshooting does not solve the problem, contact a service center.

If the image stops or does not play on the SE-EDN for more than 5 seconds.

1. Please check WiFi LED on the front of Transmitter (SE-TXD) is on.

   If the WiFi LED is on,
   Press the reset button 2 times at the Receiver to forcibly shut down. And then, press the power button for 3 seconds for rebooting.

   If the WiFi LED is off,
   Check the cable connection between the transmitter (SE-TXD) and the imaging(medical) equipment.

If the power does not turn on

1. Check the battery insertion status.
2. Check the battery power level.

After the installation, image/video is not displayed at the either on SE-EDN or monitor.

1. Turn off the power of transmitter (SE-TXD) and then, turn on the power of transmitter (SE-TXD) sequentially.

The speed of playing image/video is slow and broken with unstable reception.

1. Press the reset button 2 times at the Receiver to forcibly shut down. Press the power button for 3 seconds for rebooting to improve the speed of playing image/video.

Product Warranty

We provide the highest quality products and technology and guarantee that there are no manufacturing defects for normal use and care.

- The free warranty period of Transmitters (SE-TXD) is 2 years from the date of product purchase when the purchase invoice is provided.
- The warranty period of SE-EDN is 1 year from the date of product purchase when the purchase invoice is provided.
- The warranty period of battery is 1 year from the date of product purchase when the purchase invoice is provided.

During the product warranty period, the manufacturer supports repair or replacement of malfunctioning products due to defects. However, accessories are not covered under warranty.

The product warranty does not apply to users in the following cases.

- If the user modified the product in any ways
- If the user uses an attachment that causes damage to the product
- If the sales/serial number/logo is damaged, removed, or changed
- Product damage due to abuse, misuse, accident, water or theft
- In case of physical damage to the product
- Failure due to loss of accessories

For other inquiries related to the use of the product, please contact the service center.
T. 031 8041 1470 E. info@medithinq.com

EMC Guide

Guidance and Manufacturer's Declaration for EMC

This device has been tested for EMI/EMC compliance, but interference can still occur in an electromagnetically noisy location. Attempt to maintain a suitable distance between electrical devices to prevent malfunction.

Electromagnetic Emissions

The Equipment Under Test is intended for use in the electromagnetic environment specified below. The customer or user of the product should assure that it is used in such an environment.

Immunity test	Compliance	Electromagnetic Environment
RF Emissions (CISPR 11)	Group 1	The product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions (CISPR 11)	Class A	The product is suitable for use in all establishments other than domestic 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	

Electromagnetic Immunity

The product system is intended for using in the electromagnetic environment specified below. The user of this system should assure that it is used in the following environment.

Item	Description
Immunity test	· Electrostatic discharge (ESD) IEC 61000-4-2
IEC 60601 test condition	· Contact ±8V · Air ±15V
Compliance Level	· Contact ±8V · Air ±15V
Electromagnetic Environment - Guidance	· Floors should be wood, concrete or ceramic tile. · If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical Fast Transient/Burst IEC 61000-4-4

Item	Description
Immunity test	· Electrical fast transient/burst IEC 61000-4-4
IEC 60601 test condition	· Power supply lines ±2V · Input / output lines ±1V
Compliance Level	· Power supply lines ±2V · Input / output lines ±1V
Electromagnetic Environment - Guidance	· Main power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5

Item	Description
Immunity test	· Surge IEC 61000-4-5
IEC 60601 test condition	· Differential mode ±1kV / Common mode ±2kV
Compliance Level	· Differential mode ±1kV / Common mode ±2kV
Electromagnetic Environment - Guidance	· Main power quality should be that of a typical commercial or hospital environment.

Voltage Dips, Short Interruptions/Voltage Variations on Power Supply Input Lines IEC 61000-4-11

Item	Description
Immunity test	· Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11
IEC 60601 test condition	· <5% UT (>95% dip in UT) for 0.5 cycle. · 40% UT (60% dip in UT) for 5 cycles. · 70% UT (30% dip in UT) for 25 cycles. · <5% UT (<95% dip in UT) for 5 sec.
Compliance Level	· <5% UT (>95% dip in UT) for 0.5 cycle. · 40% UT (60% dip in UT) for 5 cycles. · 70% UT (30% dip in UT) for 25 cycles. · <5% UT (<95% dip in UT) for 5 sec.
Electromagnetic Environment - Guidance	· Main power quality should be that of a typical commercial or hospital environment. If the user of the product image intensifier requires continued operation during power mains interruptions, it is recommended that the product image intensifier be powered from an uninterruptible power supply or a battery.

UT is the AC power prior to approving the test level voltage.

Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8

Item	Description
Immunity test	· Power frequency (50/60 z) magnetic field IEC 61000-4-8
IEC 60601 test condition	· 3 A/m
Compliance Level	· 3 A/m
Electromagnetic Environment - Guidance	· Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6 / Radiated RF IEC 61000-4-3

Item	Description
Immunity test	· Conducted RF IEC 61000-4-6 · Radiated RF IEC 61000-4-3
IEC 60601 test condition	· 3 Vrms 150 kHz to 80 MHz · 3 V/m 80 MHz to 2.5 GHz
Compliance Level	· 3 Vrms 150 kHz to 80 MHz · 3 V/m 80 MHz to 2.5 GHz
Electromagnetic Environment - Guidance	· Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the below equations applicable to the frequency of the transmitter. $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{V_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz · 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 meters (m). · Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range b. · Interference may occur in the vicinity of equipment marked with ((•))

· At 80 MHz and 800 MHz, the higher frequency range applies.
· These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

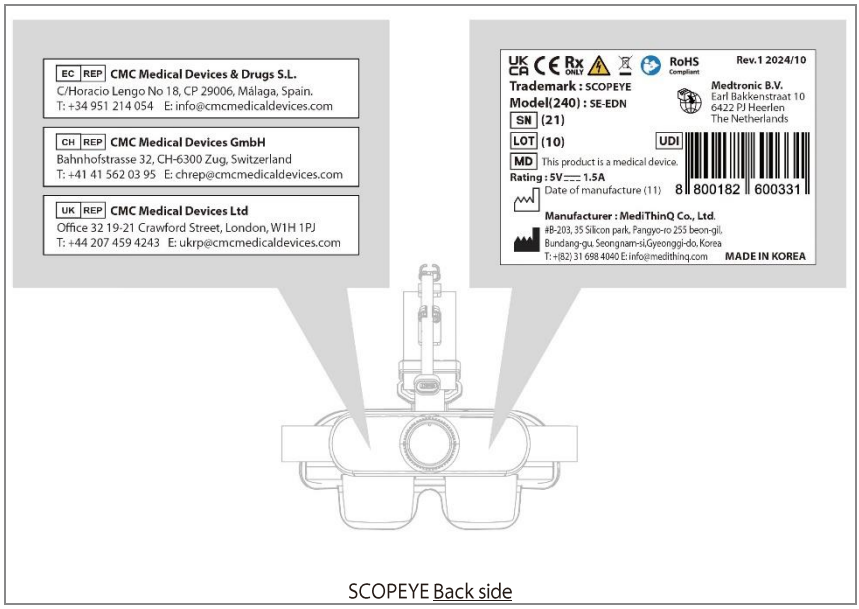
· Field strengths from fixed transmitters, such as base stations for radio (cellular/cord- less) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.
· Over the frequency range 150 KHz to 80 MHz, field strengths should be less than [V1] V/m.

Environmental Information

Product Disposal (Waste Electrical and Electronic Equipment)

This symbol on the product indicates that this product must not be disposed of with local wastes under European Directive 2001/19 / EC, which regulates waste electrical and electronic equipment.
Dispose of the equipment waste at the designated collection point for the recycling of electrical / electronic equipment waste.
Separate and recycle from other types of waste so that untreated waste disposal does not harm the environment or the human body, and encourage continuous reuse of raw materials. For more information about recycling this product, please contact your local government office or municipal waste disposal service.

Label attachment composition



SCOPEYE Back side

※ The warranty of the product is invalidated if ignored.

Revision history			
No.	**Date** (yyyy/mm)	**Version**	**Note**
1	2023/10	Rev. 1	
2	2024/07	Rev. 2	
3			
4			
5			
6			

EC REP

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MD This product is a medical device.

UK CA CE

SCOPEYE®