# **EICKVIEW SD** ENDOSCOPY MONITOR

# **USER MANUAL**



Art. No. 307000



TELEPHONE +49 7461 96 580 0 www.eickemeyer.com

# Description

Thank you for purchasing the EickView SD Endoscopy Monitor Please read the Instructions for Use carefully before use for proper use of the product. Please keep this Instructions for Use for future reference.

Product name:	EickView SD Endoscopy Monitor
Date of manufacture:	See the product label
Preparation/revision date:	September 13, 2023
Version of the Instructions for Use:	1.0
Software release version:	V1
Product performance, structure and composition:	It consists of an image processor and accessories, which include a power cord and a signal cable.
Scope of application:	The product is used in conjunction with our electronic endoscopes to process the images collected by the endoscope and display them on the screen of the device.
Manufacturer:	Eickemeyer – Medizintechnik für Tierärzte KG
Legal Manufacturer Address:	Eltastraße 8 78532 Tuttlingen GERMANY
After-sales service company:	Eickemeyer – Medizintechnik für Tierärzte KG
Contact Details:	+49 7461 96 580 0 E-mail: info@eickemeyer.com
Website:	http://www.eickemeyer.com



# **Intellectual Property**

This Instruction for use and the intellectual properties corresponding to products belong to Eickemeyer – Medizintechnik für Tierärzte KG (hereafter referred as "EICKEMEYER®").

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# Statement

EICKEMEYER® reserves all the rights for the final interpretation of the IFU. EICKEMEYER® reserves the right to modify the IFU without prior notice. Modifications to the content of the IFU will be reflected in the latest version.

EICKEMEYER®shall not be held responsible for any software and equipment not provided by EICKEMEYER® or its distributors.

Only when all of the following requirements are met shall EICKEMEYER® be held responsible for the safety, reliability, and performance of the product:

- Assembling, expansion, adjustment, improvement, and repair shall be carried out by professionals recognized by EICKEMEYER®;
- All replaced parts involved in repair and supporting accessories and consumables are genuine (original) parts of EICKEMEYER® or approved by EICKEMEYER®.
- The related electrical equipment complies with national standards and the requirements specified in the IFU;
- This product shall be operated according to the IFU.

# Warranty and Repair Service

The standard warranty period for this product is one year.

If the warranty period in your sales contract with the seller is inconsistent with the above standard warranty period or unless otherwise agreed, please consult and confirm with EICKEMEYER® through the free service hotline at +49 7461 96 580 0. If it is not confirmed by EICKEMEYER®, please promptly negotiate and confirm with the seller.

The warranty period starts from the "Installation Date" filled in the Product Warranty Card attached to the product, which is the only proof for calculating the warranty period. To protect your rights and interests, please urge the installer to return the second page of the Product Warranty Card to EICKEMEYER® within 30 days from the date of installation. If the Product Warranty Card of the product you purchased is not returned to EICKEMEYER® in time, the warranty period will be extended for 45 days starting from the "Ex-warehouse Date" indicated on the product packaging box.

Within the warranty period, you may enjoy free after-sales services for the product. Please note that EICKEMEYER® will offer a fee-based repair service even within the warranty period if the product needs to be repaired due to the following reasons, and you need to pay for the repair and accessories:

- Artificial damage;
- Improper use;
- The grid voltage exceeds the voltage range specified for the product;
- Force majeure;
- Parts or accessories not approved by EICKEMEYER® are replaced or used, or repairs are conducted by personnel not authorized by EICKEMEYER®; and
- Other failure not arising from the product itself.

After the warranty period of the product expires, EICKEMEYER® may continue to provide feebased repair services. If you fail to pay for or delay the payment for the repair service, EICKEMEYER® will temporarily suspend the repair service until you make the payment.

# After-sales Service Unit

Customer: Eickemeyer – Medizintechnik für Tierärzte KG Postcode: 78532 After - sales service hotline: +49 7461 96 580 0 Sales hotline: +49 7461 96 580 0 Official website: www.eickemeyer.com



- This product shall be used by professional clinicians, medical electrical specialists or trained clinical medical personnel in a designated situation. Personnel using this product shall be adequately trained. No operation shall be performed by unauthorized or untrained personnel.
- Stay meticulous and attentive while working to avoid accidents!
- Daily care and maintenance are necessary.
- In case repairs are needed, it is advisable to use the original parts.

# Forward

# Description

This Instructions for Use (hereinafter referred to as "IFU") details the purpose, functions and operation of the product. Prior to using this product, please read carefully and understand the IFU to ensure its correct use as well as the safety of the patient and operator.

The IFU describes this product in its most complete configuration, and some of them may not apply to the product you have purchased. If you have any questions, please feel free to contact this Company.

These operation instructions contain precautions on how to operate the Medical Image Processor safely, correctly, and effectively. They help reduce failure, maintenance cost and downtime, and improve the reliability and service life of the instrument. It can be used not only as an IFU, but also as a reference manual. Therefore, this IFU must be kept next to the device and available at any time.

Read Chapter 1 "Safety" carefully before using it for the first time.

# **Applicable Objects**

The IFU is intended for use only by specially trained clinical medical staff.

# Illustrations

All illustrations provided in the IFU are for reference only. The settings or data in the illustrations may not be exactly the same as the actual display of the product.

# Key to Conventions Used

- **Italics** Bold italics are used in the IFU to represent the chapters quoted.
- Terms such as danger, warnings, and caution are used in the IFU to prompt any hazard information and its severity.

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# **Chapter 1 Safety**

## **1.1 Safety Information**

This chapter lists the basic safety information that users must pay attention to and observe when using the EickView SD Endoscopy Monitor (hereinafter referred to as image processor). Other safety information that is identical, similar, or relevant to specific operations will appear in respective chapters.



• Indicating an urgent danger that, if not avoided, may result in death, serious physical injury or property damage.

**M**warnings

• Indicating a potentially dangerous or unsafe operation that, if not avoided, may result in death, serious physical injury, or property damage.



• Indicating a potentially dangerous or unsafe operation that, if not avoided, may result in minor physical injury, product failure, damage, or property damage.

### Precautions

• Stressing important precautions, providing instructions or interpretations for better use of the product.

### 1.1.1 Danger

There is no such safety risk.

### 1.1.2 Warnings

# **A**Warnings

- The image processor shall be used in conjunction with our endoscope, and can only be used by professional clinicians, medical electrical specialists, or trained clinical medical staff in a designated situation.
- The responsible surgeon must take charge of the operating procedures and technical application of the equipment! The trained surgeon (responsible surgeon) is entitled to decide how to make full use of the equipment in light of the actual application conditions.
- Prior to first use, please read the IFU carefully.
- Before using the image processor, the user must check the image processor and its accessories to ensure their proper and safe operation.
- It shall not be used in an environment where flammable or explosive items are placed to prevent fire or explosion.
- The image processor and its supporting equipment shall be properly installed or carried to protect the image processor from falling, being collided, receiving intensive oscillation, or being damaged due to other external mechanical forces.
- The electromagnetic field may affect the performance of the image processor and its supporting equipment, so the equipment in use near the image processor and its supporting products must meet the corresponding EMC requirements, otherwise, electromagnetic interference may result in failure or collapse to the image processor. Mobile phones, X-ray or MRI equipment are all possible sources of interference, all of which may emit high intensity electromagnetic radiation.
- All other devices. For example, some similar digital interference devices must meet relevant requirements in the standards when they are connected to an image processor. The person responsible for connecting the equipment must ensure the operability of the system and be responsible for meeting the system requirements. If you have any other questions, please consult the local equipment supplier or the technical service center of EICKEMEYER®.
- Repairs or upgrades to the image processor must be made by trained maintenance personnel authorized by the Company.
- Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.
- EICKEMEYER® shall not be held accountable for any personal injury and property damage because:
  - Equipment parts are not original parts of EICKEMEYER®;
  - The IFU is lost;

- Installation, commissioning, revision, upgrading and repair are done by personnel not authorized by EICKEMEYER®.
- EICKEMEYER<sup>®</sup> will not be responsible for any damage or incident arising from using consumables or accessories that are not of the specifications required by EICKEMEYER<sup>®</sup>.
- The host is prohibited from use while charging. EICKEMEYER® will not be responsible for any damage or incident caused by unauthorized use.

### 1.1.3 Caution



• The use environment and power supply of the image processor must comply with the requirements in *Section 4.2 Image processor Technical Parameters*.

### 1.1.4 Precautions

### Precautions

- Please place the IFU near the image processor so that it is easily and promptly accessible when required.
- The IFU introduces the product in its most complete configurations and functions, and the image processor you have purchased may not have certain configurations or functions.

<u>^</u>	Attentions/Caution/Warning	g 🚱	Consult instructions for use or consult electronic instructions for use
X	Type BF applied parts	UDI	UDI code
MD	Medical device	$\mathbb{R}_{\text{Only}}$	Prescription medical device (FDA)
<b>CE</b> <sub>2797</sub>	CE Marking	ECREP	EC Authorized Representative
SN	Serial number	[m]	Date of manufacture
	Manufacturer	20%	Humidity limitation 20%– 90%
X	Waste electrical and electronic equipment directive	-20°C	Temperature limit -20°C– 50°C
	Atmospheric pressure limitation 70 kPa–106 kPa	Ţ	Keep dry
Ţ	Fragile; handle with care		Stacking limit by 5
<b>†</b> †	This way up		

# 1.2 Labels and Identification



cription medical device .)

uthorized esentative

# **Chapter 2 Overview**

# **2.1 Product Description**

# 2.1.1 Scope of Application

The product is used in conjunction with our electronic endoscopes to process the images collected by the endoscope and display them on the screen of the device.



- This product shall be used by professional clinicians, medical electrical specialists or trained clinical medical personnel in a designated situation. Personnel using this product shall be adequately trained. No operation shall be performed by unauthorized or untrained personnel.
- Before using the image processor, the user must inspect the image processor and its accessories to ensure their proper and safe operation.



• The use environment and power supply of the image processor must comply with the requirements in *4.2 Image processor Technical Parameters*.

# 2.1.2 Structural Composition

It consists of a host and accessories, which include a power cord and a signal cable.

### 2.1.3 Contraindications

Not observed

# 2.1.4 Product Structural Diagram



Left front view of Image Processor



Right front view of Image Processor



Real view of image i locesso	Rear v	view	of	Image	Processor
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No.	Port	Instructions
1	USB I	Data copy, USB flash drive upgrade, etc.
2	VL-Port	To connect the video laryngoscope
3	Endoscope Port	To connect the endoscope
4	DC	Power input port
5	USB II	Online upgrade and debugging port

6	HDMI	High-definition multimedia interface (HDMI)
		port
7	SDI	Serial digital interface (SDI) port
8	DVI	Digital visual interface (DVI) port

Instructions of ports

### 2.1.5 Battery

#### 2.1.5.1 Overview

The image processor has a built-in lithium-ion battery (hereinafter referred to as the "Battery") and operates on battery power. The Battery will be charged when the image processor is connected to the adapter. When charging in the power-on state, the image processor will enter the charging mode and fail to operate.

### Precautions

- Do not charge if the mains voltage fluctuates significantly.
- Warnings: S-8 cannot be used while charging.
- It takes 4–5 hours to charge the battery in full in case of running down of battery. Rechargeable batteries have a continuous operating time of approximately 3–5 hours with load.
- If this product will not be used for a long time, please charge and discharge the battery at a 3-month interval to avoid battery damage.
- The battery belongs to consumable part and, once exhausted and failed, must be replaced. If the battery supplies power for a too short time after it is fully charged, it may have been damaged or failed. The power supply time of the battery depends on the configuration and frequency of use of the image processor, e.g. long-time backlight of the display screen.
- If the battery suffers from obvious damage (bulging, deformation, weeping) or the battery cannot store energy, it shall be replaced and reasonably recycled.
- If the battery is to be replaced, contact the distributor selling this product to you or the manufacturer.
- Replacement of battery can only be done by the technical service engineer of the Company!

#### 2.1.5.2 Battery Level



Green = Battery level ≥ 40% Orange = Battery level ≥ 20% Red = Battery level < 20%



State of charge

#### 2.1.5.3 Battery Maintenance

To ensure safe operation and prolong the battery life as much as possible, please pay attention to the

following guidance for use:

- The battery performance must be checked once a year. Before the image processor is subject to repair or the battery is suspected to be the failure source, the battery performance shall also be checked;
- Every 3 months of use (or storage) or when the running time of the image processor becomes significantly short, the battery shall be fully charged and discharged (the image processor shall be discharged first, and then charged to 100%) to ensure that the battery is charged for storage.

### 2.1.5.4 Battery Recycling

If the battery suffers from obvious damage (bulging, deformation, weeping) or the battery level is exhausted, it shall be replaced and reasonably recycled. At the end of the product's service life, open the display unit and dispose of the battery and the display unit separately according to local regulations.

# Warnings

• Do not disassemble the battery, put it into fire or make it short-circuited. Battery burning, explosion and leakage may cause personal injury.

# **Chapter 3 Use and Maintenance**

# 3.1 Installation and Use

# **A**Warnings

- The software copyright of the image processor is owned by the Company, and no organization or individual is allowed to tamper, copy, or exchange it by any means or in any form without permission.
- the image processor host must be connected to the endoscope manufactured by EICKEMEYER®. EICKEMEYER® shall assume no responsibility for any damage or incident caused by connecting to endoscopes not manufactured by EICKEMEYER®.
- When the image processor host is connected to energized endoscopes or endoscope accessories not manufactured by EICKEMEYER®, leakage currents of patients may be increased.
- When the endoscope connected to the image processor host loses its function, it shall be removed from the patient immediately and disconnected from the image processor host.
- Do not use this product in the presence of high-frequency electrosurgical equipment, as it may cause injuries to patients or damage to equipment.

# 3.1.1 Unpacking and Inspection

Before unpacking, please carefully check the packing box to determine whether the product is damaged during transportation. Notify the carrier or this Company immediately if any damage is found.

If the package is intact, please unpack the it correctly, carefully take out the image processor from the packing box, and count one by one according to the packing list. Check whether the product has suffered from any mechanical damage and whether the items are complete. If you have any questions, please feel free to contact the After-Sales Service Department of this Company.

# Warnings

• The user shall keep the packaging materials away from children. Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.

### Precautions

- Please keep the packing box and packaging materials for future shipping or storage.
- If you open the package and find that some fittings are missing, please contact the distributor selling this product to you or the manufacturer as soon as possible.

## 3.1.2 Charging Requirements

The image processor shall be charged with an adapter of the *following specification* that complies with the requirements of IEC 60601-1:2005 + A1:2012 + A2:2020.

Adapter						
Specification	Parameter					
Output voltage	DC 12V					
Output current	6 A					



- The appropriate power supply must be selected according to the recommended adapter specification. Otherwise, it may cause serious harm to the device.
- Operation is prohibited while charging.
- When disconnecting the image processor from the adapter, pull the plug out of the socket.

### 3.1.3 Environment Requirements

The use environment of the image processor shall comply with the requirements in *Section 4.2 Image processor Technical Parameters.* 

The use environment of the image processor shall also be free of noise, vibration, dust, and corrosive or flammable and explosive substances.



- To avoid electric shock risks, the device shall only be connected to the earthed power supply.
- When disconnecting the device from the power supply, the plug must be pulled out of the wall socket.

### 3.1.4 Power Supply Requirements

The product shall operate in compliance with the requirements in *Section 4.2 Image processor Technical Parameters*.



• Please make sure that the image processor operates under the specified environmental and power conditions, otherwise, it will not meet the technical specifications stated in *A Product Specification* and may lead to unexpected consequences such as image processor failure.

### 3.1.5 Endoscopic Connection

#### Precautions

- The image processor host must be connected to the endoscope manufactured by EICKEMEYER®. EICKEMEYER® shall not assume any responsibility for any damage or incident caused by connecting to endoscopes not manufactured by EICKEMEYER®.
  - (1) Check whether the endoscope is intact in appearance;
  - (2) Check the IFU attached to the host and prepare to connect the endoscope.
  - (3) Connect the image processor host to the endoscope.
  - (4) Press the Power button to start the host.

#### Precautions

• The plugs for the wiring of the image processor host and the endoscope have alignment marks. When inserting, pay attention to the direction of the connector and do not forcefully insert for connection. Applying force when not aligned may damage the plug.



[Figure 3-1] Diagram of Endoscope Connection

### 3.1.6 Monitor (Display Device) connection



[Figure 3-2] Diagram of Host Interface

Connect the video output interface of the image processor to the monitor with a signal connecting

line.

# 3.2 Care and Maintenance



Disconnect the image processor from any main power supply, remove all connectors, and ensure that the image processor is totally switched off before care and maintenance.

After use, the host shell shall not come into contact with the human body. Use a neutral cleaning agent to disinfect its external surface.

### Precautions

• The rag shall be moist but not dripping so as not to harm the electronics inside the display unit.

# Chapter 4 Operation Guide for Image Processor

# 4.1 Host System Operation

### 4.1.1 Interface Switching

Page	Real-time Display	File	User	Setting
Marks			-+	0
Functions	Display of real- time video stream	File management	User management	System conventional settings and function settings

Click different interface icons on the touch screen to switch to the corresponding interface.

# 4.1.2 Login Interface

Tap the power button of the host machine, and the power indicator lamp and the screen will be lit. The login interface will be automatically entered after the system startup, as shown in Fig. 4-1.

09:18		
	Username	•
	Password	*
	Login Anonymous Login	

[Figure 4-1] Login page

(1) Regular login: Click , and a drop-down box for the user name will appear. Select the user or call out the keyboard to enter the user name, then enter the password, and click the "Login" button. If the user name and the password are correct, the real-time display interface will be entered, and

the login user is Admin or a regular user at this time. (Click the show/hide icon **\*\*** to show/hide the password entered).

Note: The default user name of Admin is admin, and the default password is 00000000; (2) Anonymous login: Click the "Anonymous Login" button to directly enter the real-time display interface. The login user is an anonymous user at this time, and the anonymous user cannot set advanced options.

# 4.1.3 Real-time Display

(1) After the endoscope is connected, the Real-time Display page will display the real-time video stream of the endoscope, the use time of the endoscope will start to be counted, and the inner and outer diameters of the endoscope will be displayed in the lower right corner, as shown in Fig. 4-2.



[Figure 4-2] Real-time Display page

(2) Image adjustment: Click the Image Settings button, then drag the slider

to adjust the hue, clarity, contrast, and LED brightness, and

adjust the white balance of the real-time image for the current scene by the white balance button



in the upper right corner, and then select the icon to (3) Press the Custom button complete the corresponding function.

# 4.1.4 File management

Click On the touch screen to enter the File page, as shown in Fig. 4-3.



[Fig. 4-3] File page

Then click the "Picture and Video" folder in the corresponding folder of date to enter the File View page, as shown in Fig. 4-4.



[Fig. 4-4] File page

Click the file thumbnail to view the file content (picture, video, graphic report), and click  $\mathbf{k}$  and





[Figure 4-5] File Export Pop-up Window

(5) Creation of video or graphic report: Select a picture or a video, and click Create Graphic Report or Create Video Report to enter the Input Information interface. Input the information, and click Create Graphic Report or Create Video Report again to generate a graphic or video report.

### 4.1.5 User management

Click a on the touch screen to enter the User page, as shown in Fig. 4-6.

		Administrator	admin		0
	2	Userì	User one		0
•					
2					
0					
100%		_		-	
12:00	-	<b>2</b> 4	1-2		

#### [Fig. 4-6] User page

(1) New user: Log in as Admin, then click to enter the New User page, enter the legal user name and password, verify the password, and click . If you can see the new user name on the User page, the new user is successfully added;

(2) Edit user: You can edit all users when logging in as Admin; You can only edit the current user when logging in as a regular user; You cannot edit any user when logging in as an anonymous user.

Select the user, click to enter the Edit User page, enter the legal user name and password,

verify the password, and click . If you can see the edited user name on the User page, the user is successfully edited;

(3) Switch user: Enter the User page, select the user, click to enter the Switch User page,

enter the correct password, and click . Then the user will be switched to the currently selected one.

(4) Delete user: Log in as Admin, select the user, and click

window Confirm Delete to delete the selected user.

(5) Log out user: Click this button to log out the user and enter an anonymous status

### 4.1.6 Setting

Click <sup>(i)</sup> on the touch screen to enter the Settings page, as shown in Fig. 4-7.

		Language	
		Device language	中文 ~
٢	Language 📏	中文	
	Time and date	English	
2	General		
۵	settings		
	Device information		
100%			
12:00			

#### [Fig. 4-7] Settings page

(1) Language settings: Click the Device Language bar to show the drop-down options

Device Language English Y

Select a language, and the system language will be switched to the selected one;

(2) Data and date settings:

1) Time zone settings: Click the Time Zone Configuration bar to show the drop-down options

Time Zone Configuration  $East 8 \vee$ 

Select a time zone, and the system time zone will be switched to the selected one;

2) Time system settings: Select 24H or 12H, and the time system will be switched to the selected one;

3) Date format: Select "YYYY/MM/DD" or "DD/MM/YYYY", and the system date format will be switched to the selected one;

4) Date and time settings: Select the date and time by sliding up and down, and click to confirm;

(3) General settings:

1) Startup password: Click the startup password switch **(C)** to control the login verification

(turn on the switch, and login verification is required for startup);

2) Restore factory settings: Click the button to restore the factory settings

3) System upgrade: Click the button to check whether there is an upgrade file in the USB flash drive, and click the file to upgrade the system after the administrator certification

(4) Device information: Enter the Device Information page to view the information on the host machine and lens body;

Storage method	Internal storage 64 GB
Power Supply Requirements	Nominal voltage: DC 7. 2 V; battery capacity $\geq$ 9500 mAh
Protection against Electric Shock	Class II, Type BF applied part
Operating environment	
Temperature	5–40°C
Relative humidity	30%-80%RH, non-condensing
Atmospheric pressure	70-106kPa
Altitude	≤ 2000 m
Storage	
Temperature	0~45°C
Relative humidity	$30 \sim 80\%$ RH, non-condensing
Transportation	
Temperature	-20~50°C
Relative humidity	$20 \sim 90\%$ RH, non-condensing
HDMI port	HMDI 2.0
SDI port	3G-SDI
DVI port	DVI-D
USB port	USB 2.0

# 4.2 Image processor Technical Parameters



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