



FKS Life and Health Medical Care Inc.

FKS-01-001 Laryngoscope

Instructions for use





FKS Life and Health Medical Care Inc.

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1. Important Information – read before use

NOTE

Read these safety instructions carefully before using FKScope series production. The Instructions for use may be updated without further notice. Copies of the current version are available upon request.

WARNING

- ◆ FKS-01-001 Laryngoscope(FKS-01-001) is a single-use device and must be handled in a manner consistent with accepted medical practice for such devices in order to avoid contamination of the FKS-01-001 prior to insertion.
- ◆ FKS-01-001 images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics.

1.1. Instructions

Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operation and precautions related to the operation of the FKS-01-001 system. Before initial use of the FKS-01-001 system, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings, cautions, notes, indications and contraindications mentioned in these instructions.

1.2. Intended use

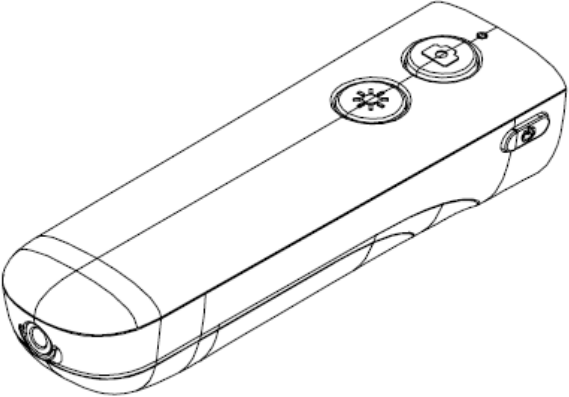
The FKS-01-001 Laryngoscope have been designed to be used with the TV monitor, accessories and other ancillary equipment within the airways.

2. System Parts

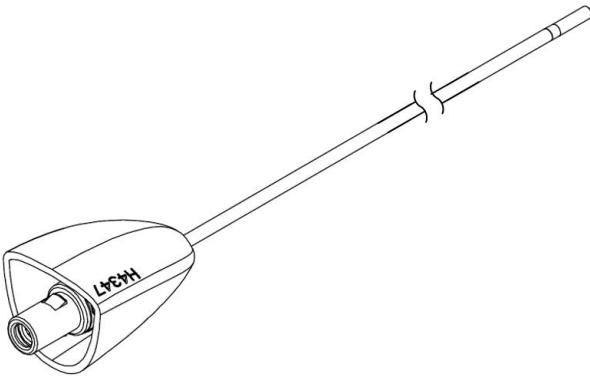
2.1. System Parts

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

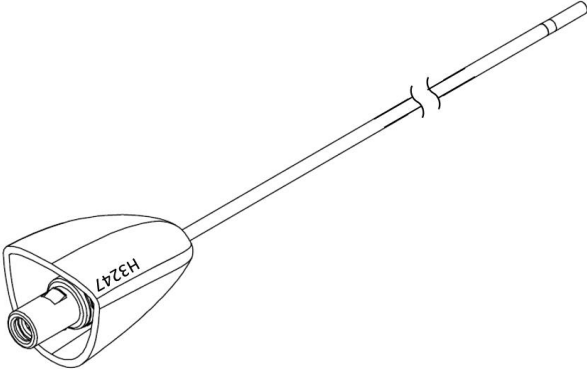
Main device

Handle	Part Number
	<p>4-1-HAD15533-01</p>

Part device (Disposable)

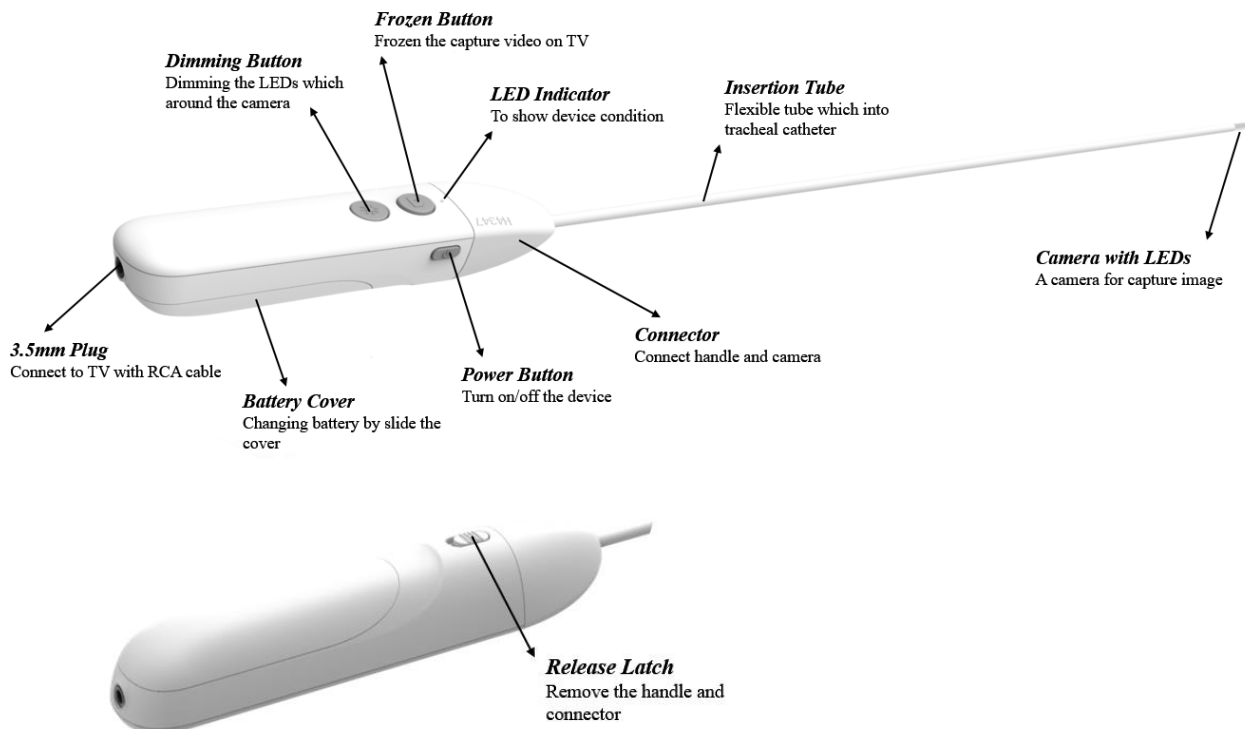
CCD D43(Charge Coupled Device)	Part Number
	<p>4-1-CCD43XXX-01</p> <p>Specifications</p> <p>Outer Diameter(OD): 4.30 mm</p> <p>Length: 470 mm</p> <p>Resolution: 640x480</p> <p>Field of View(FOV): 62</p>






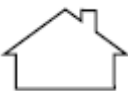


CCD D32(Charge Coupled Device)	Part Number
	4-1-CCD32XXX-01
	Specifications
	<p>Outer Diameter(OD): 3.20 mm</p> <p>Length: 470 mm</p> <p>Resolution: 320x240</p> <p>Field of View(FOV): 90</p>

2.2. Description of the FKS-01-001 system

There are two parts of the FKS-01-001: Handle and Tube. And there are two different type of tube.



2.3. Explanation of symbols used

Symbols for the FKScope device	Indication
	Do not use if the product sterilisation barrier or its packaging is damaged
	Single use product, do not reuse
	Company Address
	Only for indoor use
	Use By, followed by YYYY-MM
	Consult Instruction for use



3. FKScope System Usage

3.1. Preparation and Inspection

1. Check that the pouch seal is intact.
 - ◆ Do not use product if the product sterilisation barrier or its packaging is damaged.
 - ◆ Do not use a knife or other sharp instrument to open the pouch or cardboard box.
2. Make sure to remove the protective elements from the handle and from the insertion tube.
3. Check that there are no impurities on the product.
4. Check that there is no evidence of shipping damage or other damage such as rough surfaces, sharp edges or protrusions which may harm the patient.

3.2. Operating the FKScope



Turn on the FKS-01-001

Press the power button for 3 seconds which aside the handle.



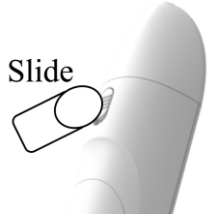
Dimming LEDs

Press the dimming button once to change brightness. There are four level of brightness which are 100% 、80% 、60% 、off.



Frozen Video

Press the frozen button once can freeze the image from monitor.



Release Latch

Press the latch to release handle and connector.



LED Indicator

To show the condition of device. Please follow the information in Table 1.

Table 1 LED Indicator Information

Button	Action	LED Light	Buzzer	Condition
Power on/off	Press 3 seconds	Green	Beep once	Power/CCD(with LED)/LED indicator ON
	Press 3 seconds	None	Beep once	Power/CCD(with LED)/LED indicator OFF
Video Freeze	Press once	Green	Beep once	Video Pause
	Press once	Green	Beep once	Video Resume
LED Dimming	Press once	Green	Beep once	LED in CCD Dimming Brightness (Cycle, 100%(Default), 80%, 60%, off).
LED Indicator	Battery lower 25%	Orange	Beep once per 3 seconds	Monitor still with image
	Battery lower 5%	Orange Blink	Beep thrice per 5 seconds	Monitor without image



	NG(Operation Error)	None	Always Beep	Monitor without image(Reconnect Charge Coupled Device)
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3.3. After Use

◆ **Do not attempt to clean and reuse the FKS-01-001(CCD) on another patient as it is a single use device.**

1. Switch off handle by pressing the power button for at least 3 seconds.
2. Disconnect the connector from the handle and dispose of the connector in accordance with local guidelines for collection of infected medical devices with electronic components.

The FKS-01-001 is a single use device. FKS-01-001 is considered infected after use and must be disposed of in accordance with local guidelines for collection of infected medical devices with electronic components. Do not soak rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. The design and material used are not compatible with conventional cleaning and sterilization procedures.

At the end of battery life open up the FKS-01-001 and remove the batteries to charge. Dispose of the batteries and FKS-01-001 separately in accordance with local guidelines.



4. Cleaning and Disinfection of FKS-01-001(Handle)

Disconnect FKS-01-001 from any mains power supply, remove any accessories and make sure the FKS-01-001 is completely turned off before cleaning and disinfection.

4.1. Cleaning

1. Clean the FKS-01-001 according to good medical practice using the below procedure:
2. Prepare a cleaning solution using a standard enzymatic detergent prepared per manufacturers recommendations. Recommended detergent: enzymatic, mild pH: 7-9, low foaming (Enzol or equivalent).
3. Soak a sterile gauze in the enzymatic solution and make sure that the gauze is moist and not dripping.
4. Thoroughly clean the button, rubber covers, screen, external casing of the monitor and stand with the moist gauze. Avoid getting the device wet to prevent damaging internal electronic components.
5. Using a sterile soft bristled brush that has been dipped in the enzymatic solution, brush the button until all evidence of soil is removed.
6. Wait for 10 minutes (or the time recommended by the manufacturer of the detergent) to allow the enzymes to activate.
7. Wipe the FKS-01-001 clean using sterile gauze that has been moistened with RO/DI water. Ensure all traces of the detergent are removed.
8. Repeat steps 1 to 6.

4.2. Disinfection

Wipe the surfaces of FKS-01-001 for approximately 15 minutes using a piece of sterile gauze moistened with the alcohol mixture indicated below (approximately once every 2 minutes). Follow safety procedures for the handling of isopropyl. The gauze should be moist and not dripping since



liquid can affect the electronics inside the FKS-01-001. Pay close attention to the button, rubber covers, screen, external casing and stand, slots and gaps on the FKS-01-001. Use a sterile cotton swab for these areas.

Solution	Concentration	Preparation
Isopropyl(alcohol) 95%	70-80%	80cc of 95% Isopropyl(alcohol) added to 20cc of purified water (PURW)*

*Alternatively, use EPA-registered hospital disinfection wipes containing at least 70% isopropyl.

Safety precautions and directions of use of the manufacturer must be followed.



5. Technical Product Specifications

5.1. FKS-01-001 Specifications

	FKS-01-001(D32)	FKS-01-001(D43)
<i>Optical System</i>		
Pixels	320x240	640x480
Light Source	1 pc x White LED	6 pcs x White LED
Depth of Field (DoF)	10mm - 40mm	5mm-50mm / 10mm-80mm
<i>Operating environment</i>		
Water Resistance	IP67 (for distal tip only)	IP67 (for distal tip only)
Operating Temperature	0°C ~ 50°C (±10%)	0°C ~ 50°C (±10%)
Operating Humidity	30%~90%Rh	30%~90%Rh
<i>Lens</i>		
Focal Length	0.68mm±5%	1.08mm±5%
F.O.V. (D/H/V)	90° /68° /50°	100° /74° /54°



6. Trouble Shooting

- ◆ If problems occur with the system, please use this trouble-shooting guide to identify the cause and correct the error.
- ◆ Do not use the FKS-01-001 system if it is damaged in any way.

No live image on the TV of the screen

<i>Cause</i>	<i>Action</i>
Continuing Beep	Reconnect handle and connector
Low Battery with orange light	Change the new battery
Monitor blurry	Reconnect 3.5mm to RCA cable
FKS-01-001 is damaged	Replace the FKS-01-001 with a new one

Flexible tube was broken

<i>Cause</i>	<i>Action</i>
Flexible tube failure	Stop using immediately
PVC cover damaged	Stop using immediately
FKS-01-001 is damaged	Replace the FKS-01-001 with a new one