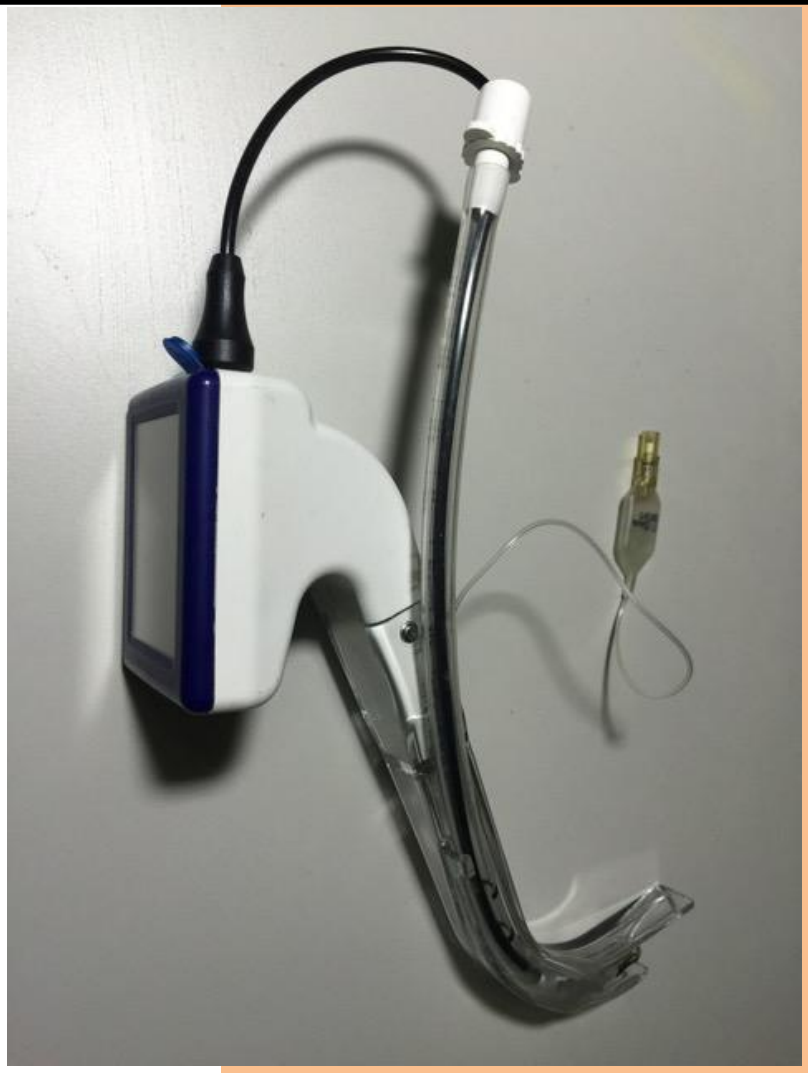
INSTRUCTION

JESCOPE

Video Intubation Laryngoscope



Jescope Ltd.

J1000

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Jescope Ltd.

CONTENTS

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Chapter 1: IMPORTANT INFORMATION

PRODUCT DESCRIPTION

The JESCOPE Video Intubation Laryngoscope provides a consistently clear view of a patient`s airway, enabling quick intubation.

The JESCOPE Video Intubation Laryngoscope includes a stylet camera with LED light source. The stylet camera connects to a color video monitor for real-time viewing. It features a comprehensive range of configurations and sizes, providing clinicians variable endotracheal tube sizes ranging from 5.0 mmID to 8.0 mmID (The age of the patient is over six years old and the body weight is over 30 kg).

The JESCOPE Video Intubation Laryngoscope is designed for physicians and other healthcare professionals who need to effectively manage standard to difficult airways. It is easy to use, learn, and teach. It is ideal for acute care settings and emergency environments. It also integrates easily into standard emergency department (ED), operating room (OR), and intensive care unit (ICU) applications.

STATEMENT OF INTENDED USE

JESCOPE Video Intubation Laryngoscope is intended for use by qualified medical professionals to obtain a clear, unobstructed view of the vocal cords for tracheal intubation.

ESSENTIAL PERFORMANCE

The essential performance of the JESCOPE Video Intubation Laryngoscope is to provide a clear view of the vocal cords, enabling quick tracheal intubation.

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STATEMENT OF PRESCRIPTION

Caution:
Federal (United States) law restricts this device to sale by or on the order of a physician.

This system should be used only by individuals who have been trained and authorized by a physician or used by healthcare providers who have been trained and authorized by the institution providing patient care.

NOTICE TO ALL USERS

Jescope Ltd. recommends that all users read this manual before using the system. Failure to do so may result in injury to the patient, compromise the performance of the system, and may void the system warranty.

Jescope Ltd. recommends that new users:
• Obtain instruction from a qualified individual
• Practice using the system on a mannequin before clinical use
• Acquire clinical experience on patients without airway abnormalities

PRECAUTIONS & WARNINGS

Warnings indicate that injury, death, or other serious adverse reactions may result from use or misuse of the device.
Cautions indicate that use or misuse of the device may cause a problem, such as a malfunction, failure, or damage to the product.
Throughout the manual, pay attention to sections labeled Important, as these contain reminders or summaries of the following cautions as they apply to a specific component or use situation.

To ensure safe and reliable operation for the user and patient, please heed (pay attention) the following warnings and cautions.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and operated according to the instructions in this manual.

To maintain electromagnetic interference (EMI) within certified limits, JESCOPE Video Intubation

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Laryngoscope must be used with the JBLADE, stylet camera cables, components, and accessories specified or supplied by Jescope Ltd.
For additional information, see the System Parts & Accessories and Product Specification sections.
The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the system.

The JESCOPE Video Intubation Laryngoscope should not be used adjacent to or stacked with other equipment.
If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

This device can radiate radio frequency energy and is very unlikely to cause harmful interference with other devices in the vicinity.
There is no guarantee that interference will not occur in a particular installation. Evidence of interference may include degradation of performance in this device or other devices when operated simultaneously.
If this occurs, try to correct the interference by using the following measures:
• Turn devices on and off in the vicinity to determine the source of interference
• Reorient or relocate this device or other devices
• Increase the separation between devices
• Eliminate or reduce EMI with technical solutions (such as shielding)
• Purchase medical devices that comply with IEC 60601-1-2 EMC Standards
Be aware that portable and mobile radio frequency communications equipment (cellular phones, etc.) may affect medical electrical equipment; take appropriate precautions during operation.

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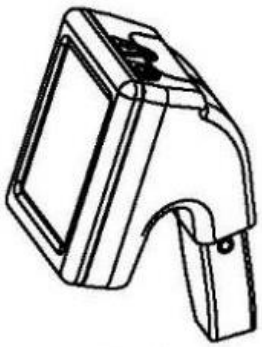
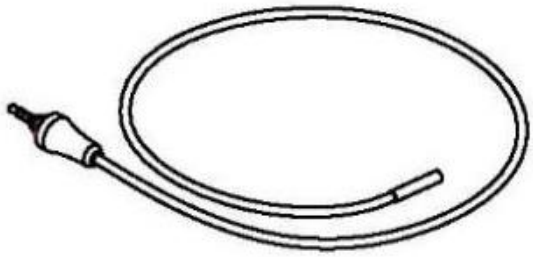
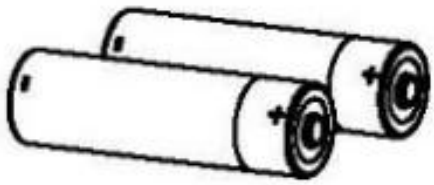
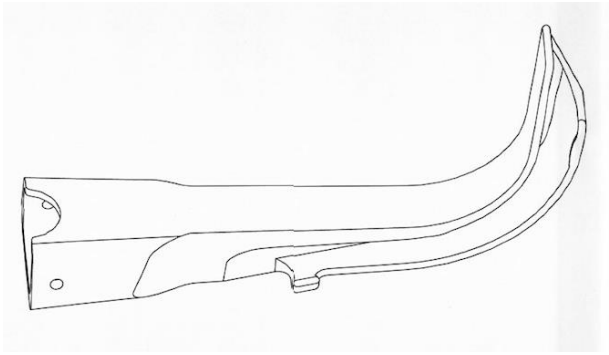
Chapter 2: INTRODUCTION

SYSTEM PARTS & ACCESSORIES

The JESCOPE Video Intubation Laryngoscopes consist of the following components.

Table 1.
System Components

PARTS & ACCESSORIES	
Required Components	
Video monitor	*Stylet camera*
	
Alkaline battery	JBLADE sizes L, M, and S (for single-use only)
	

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BUTTONS, ICONS, & CONNECTIONS

The main component of The JESCOPE Video Intubation Laryngoscope is the full-color monitor.

Figure 3.
Front Panel of Video Monitor

The top panel of the monitor includes the battery socket, power switch, connector for a stylet camera.

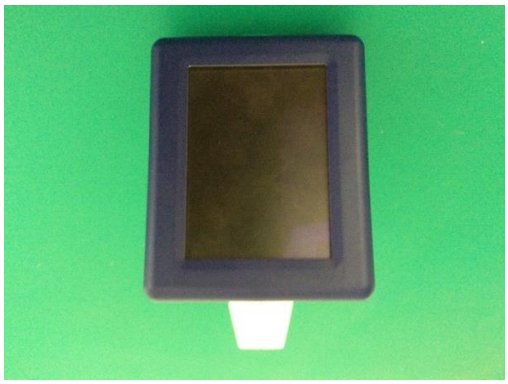

Figure 4.
Rear Panel of Video Monitor

Battery socket
Power switch
Stylet camera port

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JBLADE & STYLET CAMERA

The JESCOPE Video Intubation Laryngoscope features a reusable video monitor, a reusable stylet camera and single-use JBLADE that must be disposed of after one use.
The stylet camera contains the camera with LED light source and it sends a real-time video feed to the monitor.

The reusable stylet camera must be cleaned and high-level disinfected between uses.
The stylet camera is connected to the video monitor via a paired phone-jack connector.

The JBLADE slips over the connector portion of the video monitor and clicks into place, shielding the video monitor from contact with mucous membranes and skin.
Single-use JBLADE are available in a variety of sizes, enabling you to treat endotracheal ranging from 5.0mmID to 8.5mmID.

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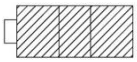
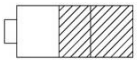
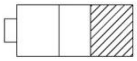
BATTERY INDICATOR

At the right upper corner of the video monitor, there is a battery indicator that indicate battery level.

Check battery indicator each time before and after operating the JESCORE.

Install new battery as soon as possible if battery low is shown.

Table 2.
Battery Indicator

STATUS	DESCRIPTION	FUNCTION
	New battery	It could be used for 45 minutes.
	Medium battery	It could be used for 30 minutes.
	Low battery	The battery level is low, it should be changed for new ones.

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Chapter 3: SETTING UP

Before you can use JESCOPE Video Intubation Laryngoscope for the first time, you must inspect the components, set up the system, and perform a functional test as recommended by Jescope Ltd.
Complete the following procedures:

1. Perform Initial Inspection
   —Inspect the system for any obvious physical damage that may have occurred during shipment.

2. Insert two AA alkaline batteries into the socket.

3. Lubricate stylet camera and insert it into a selected endotracheal tube.

4. Connect the Video Laryngoscope: Insert the connector of video monitor into the connector of JBLADE.

5. Lubricate the tube-guiding groove of JBLADE.

6. Insert the endotracheal tube, where stylet camera in it, into the JBLADE by sliding it along the endotracheal tube guiding groove.

7. Connect stylet camera plug to video monitor.

8. Press power switch for one second.

9. Perform a Functional Check
   —Before you use the device for the first time, perform a functional check to ensure that the system is working properly.

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PERFORM INITIAL INSPECTION

When you receive the JESCOPE Video Intubation Laryngoscope, Jescope Ltd. recommends that an operator familiar with the instrument perform a full visual inspection of the system for any obvious physical damage that may have occurred during shipment.

1. Verify that you have received the appropriate components for your system by referring to the packing list included with the system.

2. Inspect the components for damage.

3. If any of the components are missing or damaged, notify the carrier and Jescope Ltd. Customer Care or your local representative.

4. For additional contact information, see Contact Information.

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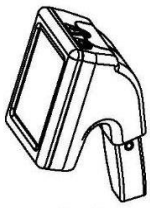

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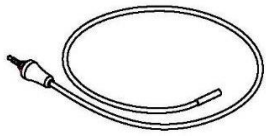

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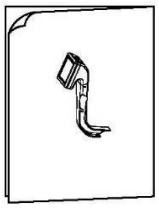

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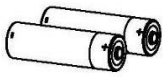

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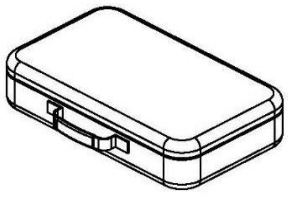

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CONNECT THE STYLET CAMERA

Before installation, be sure that the power of monitor is off.

1. Left the stylet camera connector socket cover gently.

2. Hold the plug of stylet camera and insert it into the socket.

3. Make sure that the black plug touches the white monitor.

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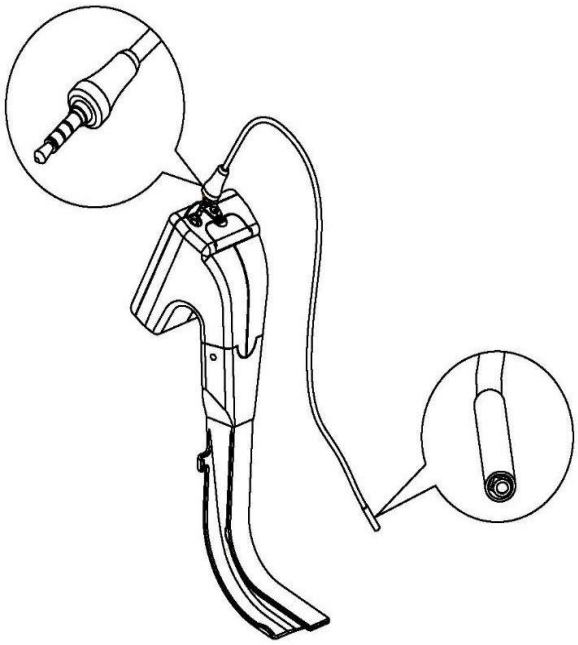

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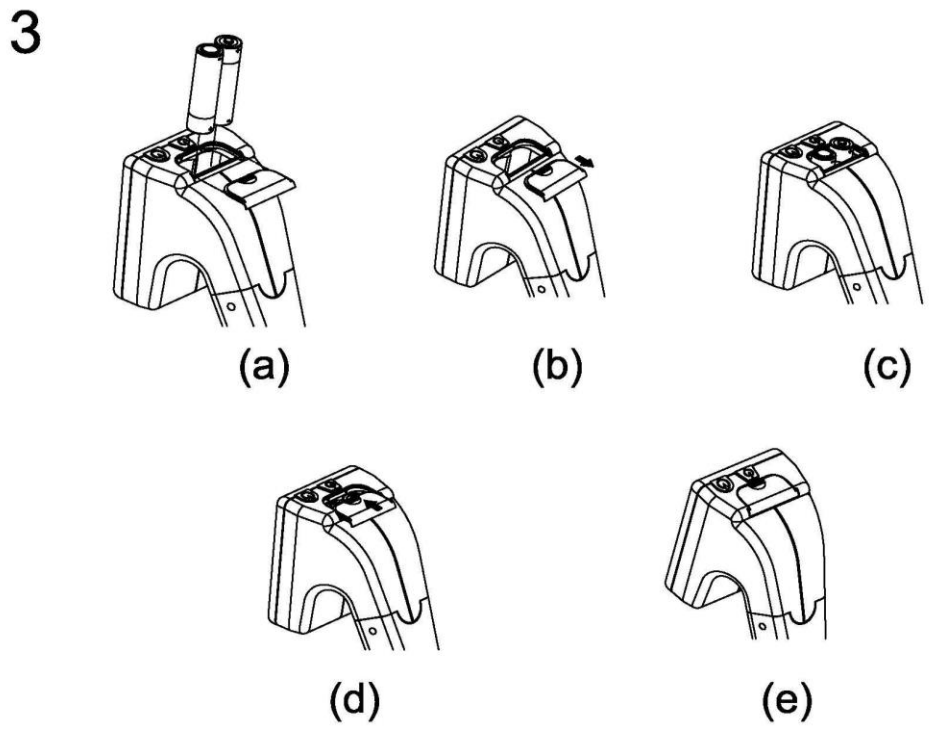
INSTALL BATTERY

The JESCOPE Video Intubation Laryngoscope is designed to use Two AA Alkaline Battery (LR6) battery.

1. Press and push the cover of the battery socket to open it.
2. Insert two AA alkaline batteries according to the +/- sign on battery and in socket.
3. Slide cover into the groove of battery socket until click sound heard.



WARNING

Care for handling Two AA Alkaline Battery (LR6) used in the video intubation laryngoscope

- This battery is NOT rechargeable. Never try to charge it.
- The average life span of AA(LR6) battery is about 40 minutes.
- Remove the batteries from the unit after use; otherwise, leakage of the battery may occur.
- Do not use batteries other than those designated; otherwise, overheating or bursting of the battery may occur.
- Never heat the battery nor throw it into the fire.
- Before discarding the battery , follow local or country regulation for disposal.

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TURN POWER ON

Press power switch for one second to turn it on.

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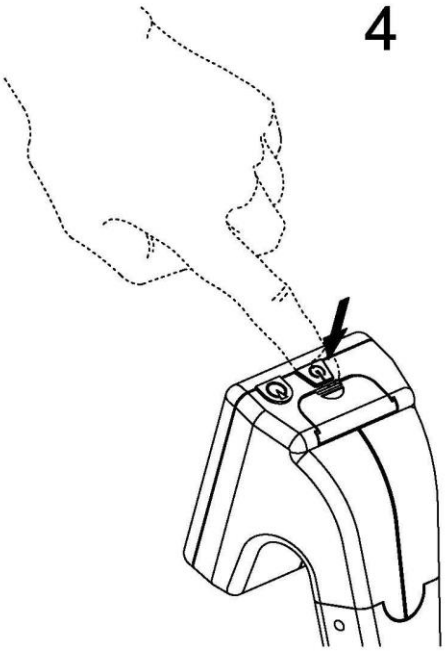

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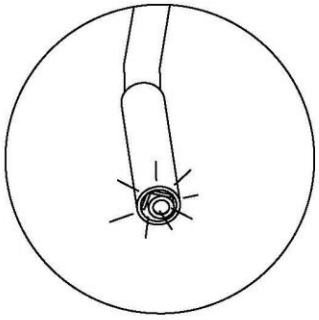

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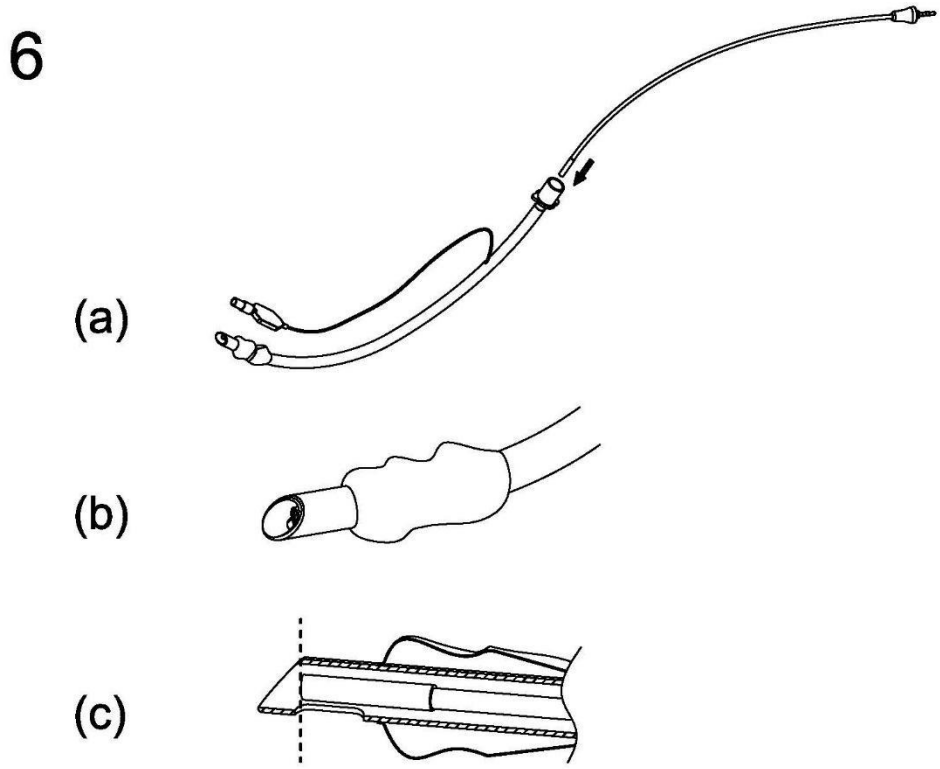
INSERT STYLET CAMERA INTO ENDOTRACHEAL TUBE

1. Lubricate stylet camera with sterile lubricant from camera lens end to the middle of the stylet camera.
2. Remove lubricant on stylet camera lens with sterile gauge if lens is contaminated by lubricant.
3. Insert lubricated stylet camera into the endotracheal tube.
4. Keep the stylet camera tip at the posterior edge at endotracheal tube opening.



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CHECK LIGHT SOURCE POSITION

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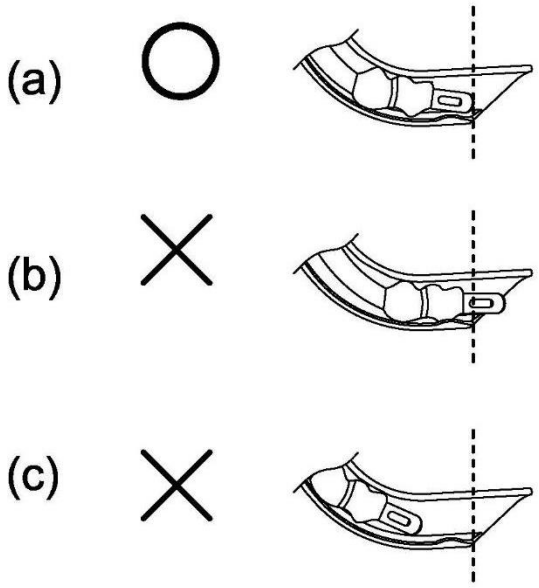

WARNING

Several areas of the video laryngoscope or Stat that contact the patient can exceed 41°C as part of normal operation:

- The first area is the light-emitting area surrounding the camera where the anti-fog feature is located. When used as indicated, continuous contact with this area is unlikely because, if tissue were to contact this area, the view would be lost and devices would need to be adjusted to regain the airway view.
- The second area is the area surrounding the camera, out of view of the camera. Continuous contact with this area is unlikely because the product is typically not held stationary for an extended period of time exceeding 1 minute.

If continuous contact is maintained for longer than 1 minute, it is possible to cause thermal damage such as a burn to the mucosal tissue.

Note:
Typical intubations are less than 1 minute in duration.

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PERFORM A FUNCTIONAL CHECK

Before you use the device, perform a function check to ensure the system is working properly.

Please contact your Jescope Ltd. Customer Care representative if your system does not function as described below.

1. Ensure that the battery has been properly installed according to the procedure Install the Battery on page 12.

2. Ensure that a JBLADE has been firmly attached to the video monitor according to the procedure on page 19.

3. Ensure that the endotracheal tube has been installed in the tube-guiding groove properly according to the procedure insert endotracheal tube into JBLADE on page 20.

4. Ensure that the stylet camera, inserted in the endotracheal tube, is connected to the monitor properly according to the procedure connect the stylet camera on page 20.

5. Press the ON/OFF button, on the top of the video monitor, the monitor turns on and is running on battery power.

6. Look at the monitor screen, and verify that the image displayed is being received from the stylet camera.

7. Check battery indicator to ensure that the battery power is more than one third.

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Chapter 4: USING THE SYSTEM

Prior to using the device, set up the system according to the instructions in the previous chapter.

To fully optimize the feature, you should warm up the JSCOPE about 1 minute prior to use.

Using the JESCOPE system consists of the following procedures:

1. Prepare the JESCOPE system
2. Intubate Using the JESCOPE Esophageal Leading Technique

PROCEDURE 1. PREPARE THE JESCOPE SYSTEM

Table 3.
Selection of endotracheal tube size

JBLADE size	Endotracheal tube size (mm I.D)
L	7.0 ~ 8.0
M	6.0 ~ 7.0
S	5.0 ~ 6.0

A medical professional must evaluate on a patient-by-patient basis to select an appropriate endotracheal tube.

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1. Ensure that each JESCOPE system component has been properly cleaned, disinfected, or sterilized according to the guidance provided in Table 5.
2. Using the information in Table 3, in combination with a clinical assessment of the patient and the experience and judgment of the clinician, select the JBLADE/endotracheal tube combination that is appropriate for the patient.
3. Lubricate stylet camera❶ and insert it into the endotracheal tube❷.
4. Lubricate tube-guiding groove of JBLADE❸.
5. Insert the video monitor male connector into a JBLADE female connector, as described in the procedure connect the JBLADE on page 19❹.

NOTE

It is recommended that you leave the JBLADE in its packaging until you are ready to begin the intubation.

6. Insert the endotracheal tube, which stylet camera in it, into tube-guiding groove, as described in page 20❺.
7. Ensure that the video monitor is turned off.
8. Attach the stylet camera to the monitor, according to the instructions in Connect the stylet camera on page 20❻.
9. Press the Power button. The video monitor turns on❼.

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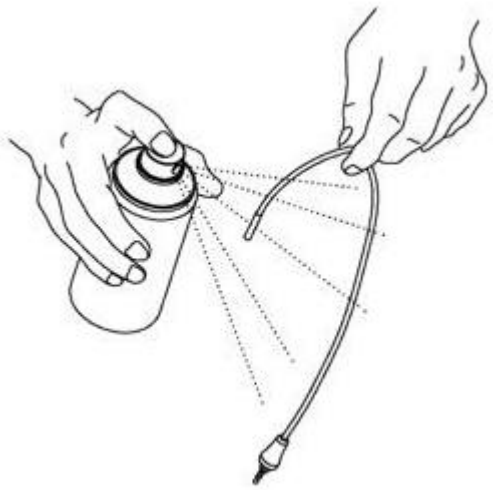

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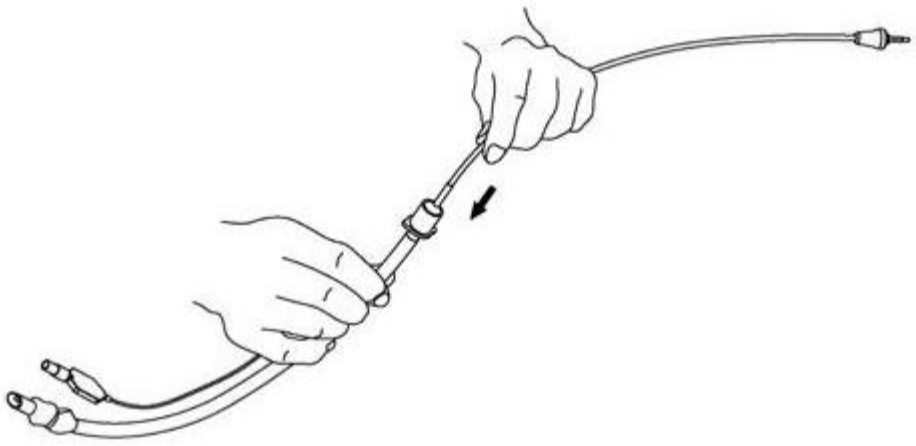

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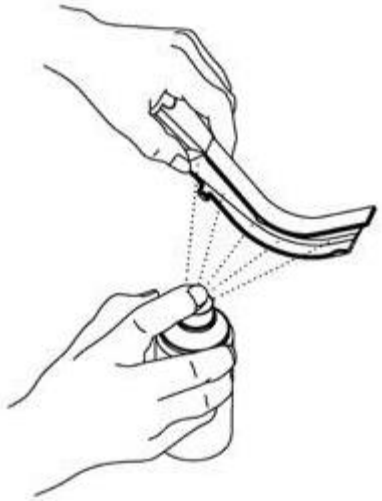

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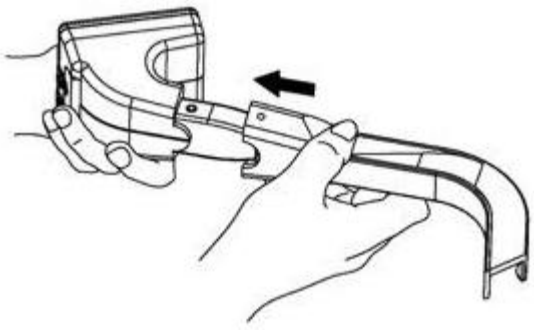

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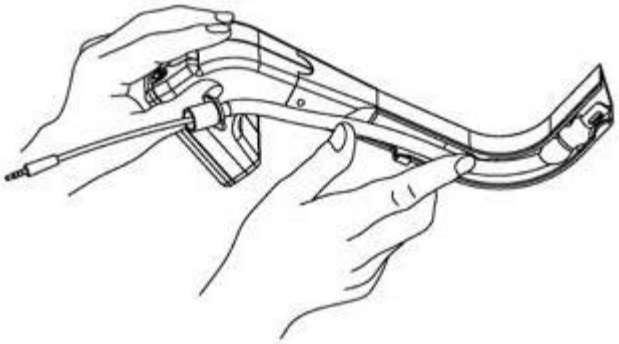

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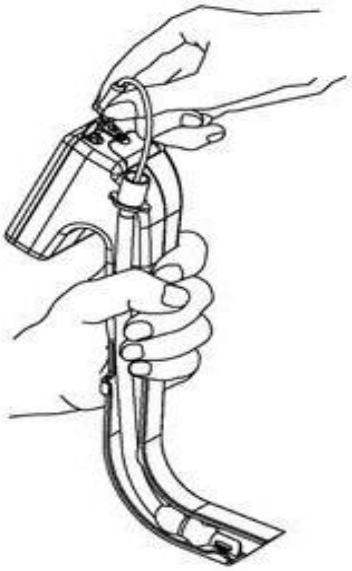

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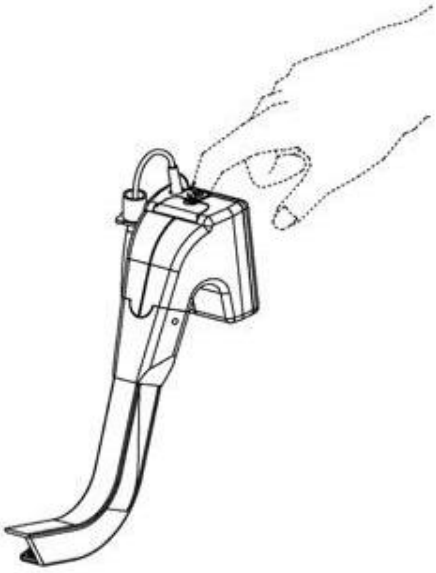

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PROCEDURE 2. INTUBATION USING THE ESOPHAGEAL LEADING TECHNIQUE

To perform an intubation, Jescope Ltd. recommends using the JESCOPE Esophageal Leading Technique.
Prior to beginning this procedure, verify that the monitor is receiving an accurate image from the stylet camera.

1. With the JESCOPE in the left hand, introduce the epiglottis lifting blade into the middle of the oropharynx❶.
2. Slide the blade tip on the posterior wall of the hypopharynx down into the esophagus❷.
3. On the screen, you can either see post cricoid mucosa, arytenoid, or piriform sinus in the hypopharynx.
4. Withdraw blade tip 1cm or 2cm to move it out of esophagus.
5. Now, the epiglottis lifting blade will be underneath the epiglottis.
6. If the epiglottis is seen, advance the blade tip into esophagus again and then do step 4. Failure to elevate epiglottis, use a larger size JBLADE.
7. Identify the vocal cord, and then manipulate the blade in order to obtain the best view of the vocal cord❸.
8. Carefully push the endotracheal tube into the trachea through the vocal cord❹.
9. Advance the endotracheal tube 6cm for S size JBLADE, or 7cm for M size JBLADE, or 8cm for L size JBLADE after the tip of stylet camera pass through the vocal cord❺.
10. Hold endotracheal tube firmly and withdraw JESCOPE from oral cavity.
11. Remove stylet camera from endotracheal tube❻.
12. Turn power off❼.

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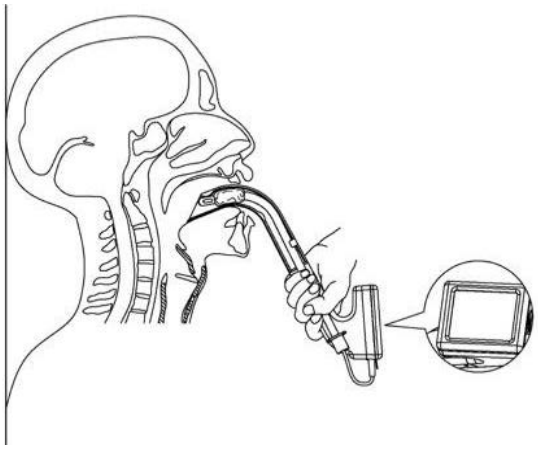

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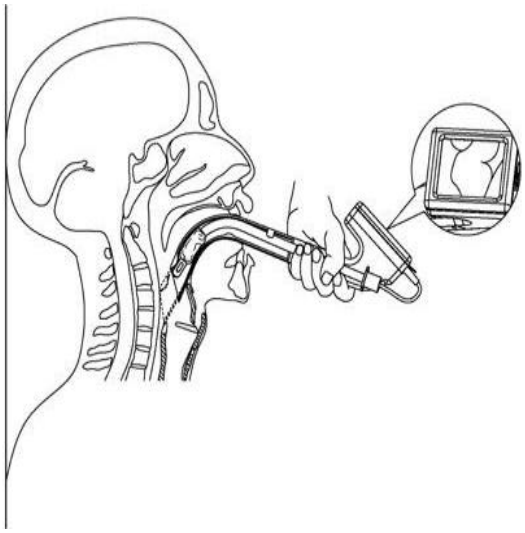

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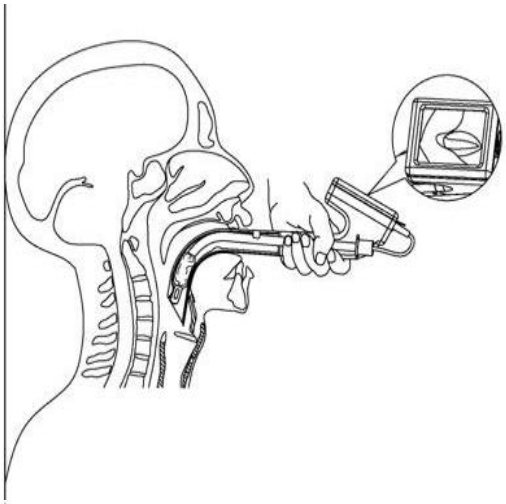

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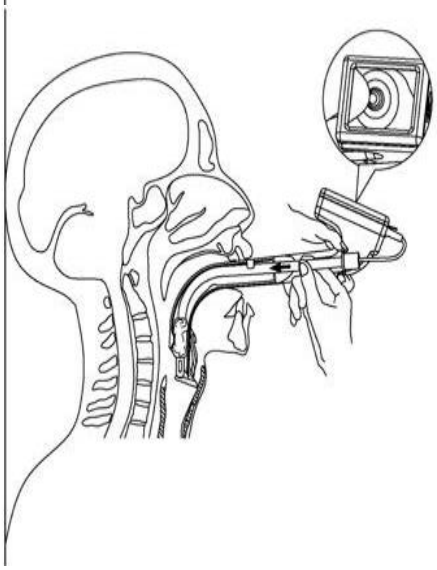

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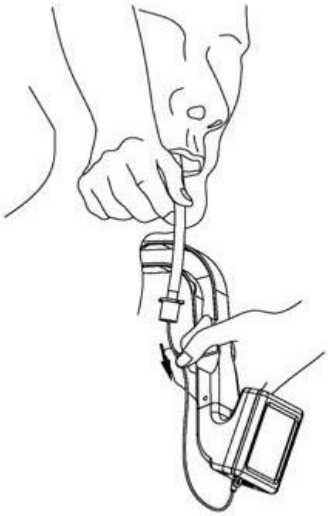

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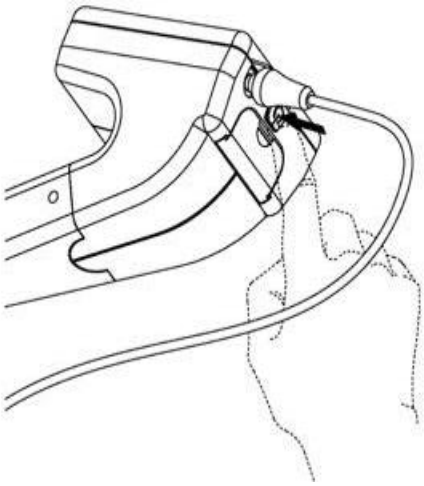

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Chapter 5: CLEANING & DISINFECTING

GENERAL INFORMATION

Table 4.
Risk Assessment for JESCOPE System Reprocessing

DEVICE	STERILE	USE	CDC CLASSIFICATION	DISINFECTION LEVEL			STERILIZATION
				Low	**Int.**	**High**	
Monitor	Nonsterile	Reusable	Noncritical	X			
Stylet Camera	Sterile	Reusable	Semi-critical			X	

CLEAN THE VIDEO MONITOR

Clean the video monitor when it is visibly soiled and on a regular basis, as per a schedule established by the medical care facility or provider.

1. Turn off the video monitor, and then remove batteries.

2. Using 70% isopropyl alcohol, bleach (100 ppm), or a mild detergent with water, wipe the exterior of the video monitor.

CLEAN & DISINFECT THE STYLET CAMERA

The JESCOPE stylet camera requires high-level disinfection prior to use.
For more information about the risk assessment of JESCOPE components, see Table 4.

The expected product life of the reusable stylet camera is one year or 1000 use cycles, validated

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through simulated use, using the following cleaning and disinfection agents:
Aniosyme synergy 5, Virusolve+

In this procedure, the term pure water refers to water that is suitable for high-level disinfection according to local regulations and your medical facility.

Table 5.

Cleaning & Disinfection Methods for the JESCOPE stylet camera

CHEMICAL	Purpose	CONDITIONS
Aniosyme synergy 5™	Clean	**Conditioning:** 20–29°C (68–84°F) **Exposure:** Prepare solution at 5ml/L Soak component for 3 minutes. Before removing from solution, brush all surfaces. **Rinse:** Rinse for 3 minutes under running water.
Virusolve+	High level Disinfection	**Conditioning:** 18–22°C (64–72°F) **Exposure:** Soak for 10 minutes, ensuring that all air bubbles are removed from the surface of the blade **Rinse:** Immersions with agitation in pure water for 1-minute

IMPORTANT

Do not use metal or abrasive brushes, scrub pads, or rigid tools to clean the stylet camera. The window that protects the camera and light can be scratched, permanently damaging the device.

This product is heat-sensitive, and exposing the components to temperatures more than 40°C (104°F) will cause damage to the electronics and void the device warranty.

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PROCEDURE FOR CLEAN AND DISINFECT THE STYLET CAMERA

1. Rinse the stylet camera in clean tap water and scrub with a soft-bristled brush until all visible contamination has been removed. To prevent damage, use a cotton swab in order to clean around the camera window.
2. To prepare Aniosyme synergy 5™ according to the user manual, dilute 5ml of the solution to 1 liter with tap water and adjust the temperature to 25°C ± 4°C. Then soak the stylet camera for 3 minutes and manually clean the stylet camera to remove any foreign material from the surface of the device.
3. Rinse the stylet camera in clean, running water.
4. Visually inspect the stylet camera for contamination. If there are any signs of contamination, restart procedure 1 to 3.
5. Using a clean, lint-free cloth, hospital-grade clean air, or a low-temperature dryer, dry the stylet camera. The component should now be clean. Handle the product carefully to avoid recontamination. Before each use, reusable stylet camera must be high-level disinfected. Continue with this procedure in order to high-level disinfect the reusable stylet camera.
6. Ensure the stylet camera has been properly cleaned, according to Step 1 through Step 5.
7. Prepare and adjust the disinfection solution Virusolve+ to 5% and 20 °C ± 2 °C according to the manufacturer's instructions and the conditions specified in Table 5.
8. Soak the stylet camera in the disinfection solution for 10 minutes, ensuring that all air bubbles are removed from the surface of the blade.
9. Immersions with agitation in pure water for 1-minute
10. Dry the stylet camera by using a sterile cloth, hospital-grade clean air, or a low-temperature dryer.
11. Inspect the reusable stylet camera and then store it in a clean environment.

WARNING

Cleaning is critical to ensuring the component is ready for disinfection. Failure to properly clean the device could result in a contaminated instrument after completing the disinfection procedure.

When cleaning, ensure all foreign matter is removed from the surface of the device. This allows the active ingredients of the chosen disinfection method to reach all the surfaces.

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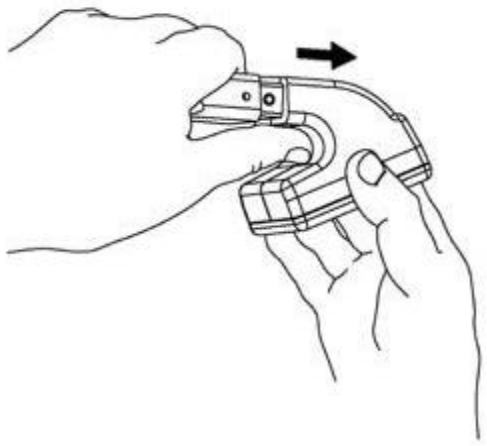
REMOVE THE JBLADE

The JBLADE is a single-use device. After each use, it is a biohazard, and it should be removed from the video monitor and disposed of in a manner consistent with local protocols.

1. Hold the JBLADE in left hand.
2. To reduce the force required to remove the JBLADE from the video monitor, use your left thumb firmly push the neck of video monitor.
3. With the right hand, grasp video monitor and pull gently.



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Chapter 6: MAINTENANCE & SAFETY

INSPECTIONS

In addition to the user performing routine inspections before and after every use, periodic inspections should be performed to ensure safe and effective operation.

It is recommended that an operator familiar with the instrument perform a full visual inspection of all components at least every three months.

The inspector should check the system for the following:

- External damage to the equipment
- Damage to the component of power socket
- Damage to the connectors or cable insulation of stylet camera

Report any suspected defects to Jescope Ltd. Customer Care at:

Local representative
Phone: 886-2-22984263 (Taiwan)
Email: info@jescopel.com

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DEVICE REPAIR

Do not use the JESCOPE video intubation laryngoscope if it is out of order or damaged.

Jescope Ltd. does not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories.

All service must be performed by a qualified technician.

If you have any questions, contact your local Jescope Ltd. representative or Jescope Ltd. Customer Care.

TRANSPORTATION

The JESCOPE system components may be safely transported or stored under the environmental conditions specified in Environmental Specifications on page 27.

Prior to shipping or storing the video monitor, ensure that no battery is installed in the battery socket.

DEVICE DISPOSAL

Disposal of this device in accordance with WEEE requirements can be coordinated through your Jescope Ltd. Service Center.

WARNING

Before every use, ensure the instrument is operating correctly and has no sign of damage. Do not use this product if the device appears damaged. To ensure patient safety, routinely inspect the stylet camera before and after every use to ensure the stylet camera is free of glass broken, rough surfaces, sharp edges, cracks, protrusions, shell separation, surface delamination, or any other indication of wear. If found, do not use the damaged or worn blade, otherwise blade breakage may occur and could cause patient injury or death.

Always ensure that alternative airway management methods and equipment are readily available.
Report any suspected JESCOPE component to Jescope at:

Phone: 886-2-22984263
Email: info@jescope.com

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Chapter 7: WARRANTY

Jescope Ltd. includes a one-year warranty when you buy a JESCOPE system.
You may also purchase a JESCOPE warranty that extends your warranty from the date of purchase.

ORIGINAL FIRST YEAR TOTAL CUSTOMER CARE WARRANTY

Jescope Ltd. warrants the JESCOPE Video Intubation Laryngoscope against defects in material and workmanship.

This warranty applies for one (1) year from the date of shipment from Jescope Ltd.

This warranty applies only to the original purchaser of the JESCOPE system.

If a customer`s system requires service or repair, Jescope Ltd. will, at its discretion, either repair or replace the customer`s unit and provide a loaner unit within 5 business day from the date of customer service notification.

The customer agrees to send the defective unit to Jescope Ltd. (cleaned and disinfected as appropriate) upon receipt of the loaner unit, and the customer agrees to return the loaner unit within 5 business days of receipt of the repaired unit.

• This warranty does not apply if the product has been damaged due to, or as the result of, service or modification by anyone other than an authorized Jescope Ltd. Service Center.
• This warranty does not apply if there is evidence of the equipment being exposed to temperatures in excess of 60°C (140°F).
• All exchanged parts become property of Jescope Ltd.

The product shall be used in accordance with the instructions contained in this manual.

Consumable items (e.g., JBLADE) shall be used in conformance with Jescope Ltd. product specifications.

Consumable items are not covered under this warranty.

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WHAT IS COVERED?

Warranty coverage is extended to the JESCOPE video Intubation Laryngoscope:
• Video Monitor
• Stylet camera

Additional JESCOPE video Intubation laryngoscopes, video monitors, or stylet purchased either singularly or as a part of a system are warranted separately.

PREMIUM CUSTOMER CARE WARRANTY
The JESCOPE video intubation laryngoscope warranty from Jescope Ltd. may be extended from the date of purchase.

DISCLAIMER OF ADDITIONAL WARRANTIES
There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in this chapter.

The contents of this manual do not constitute a warranty.

Some States disallow certain limitations on applied warranties.

The purchaser, user, and patient should consult State law if there is a question regarding this disclaimer.

The information, descriptions, recommendations, and safety notations in this manual are based upon Jescope Ltd. experience and judgment with The JESCOPE video intubation laryngoscope as of this manual's effective date.

The contents of this manual should not be all-inclusive, or to cover all contingencies.

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Chapter 8: PRODUCT SPECIFICATIONS

SYSTEM SPECIFICATIONS

Table 6.

GENERAL SPECIFICATIONS		
Classification	Electrical Class I, Type BF Applied Part	
Battery	Two AA Alkaline Battery (LR6)	
Illumination lamp	LED (100,000 lux)	
Ingress protection against water	IP33 Protected from solid object diameter greater than 2.5 mm and spraying water	
Expected product life	Laryngoscope	50,000 hours
	Stylet camera	LED work for 50,000 hours
	JBLADE	For 1 use only
ENVIRONMENTAL SPECIFICATIONS		
Operating Conditions		
Temperature:	10 to 40 ℃	
Relative humidity:	0 to 95 %rh	
Atmospheric pressure:	860 to 1060 hPa	
Shipping & Storage Conditions		
Temperature:	-20 to 60 ℃	
Relative humidity:	0 to 95 %rh	
Atmospheric pressure:	860 to 1060 hPa	

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COMPONENT SPECIFICATIONS

Table 7.

SPECIFICATION	COMPONENT
Video Monitor LCD Panel, 640 X 480 Pixel, 3 in Hight: 86mm Width: 70mm Depth: 96mm	
Stylet Camera Length: 55 ± 5cm Camera tube diameter: 4.5 ± 0.1mm	

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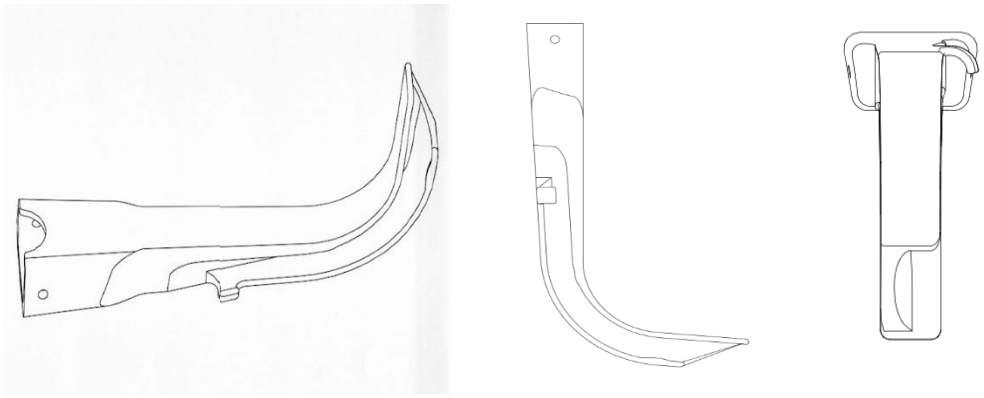
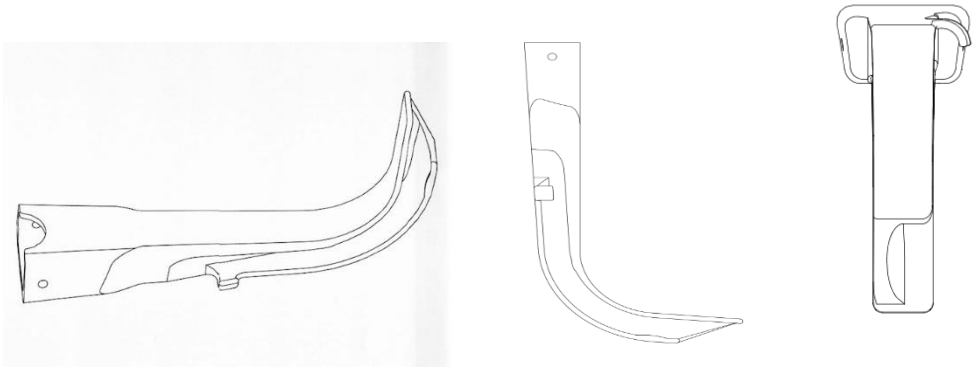
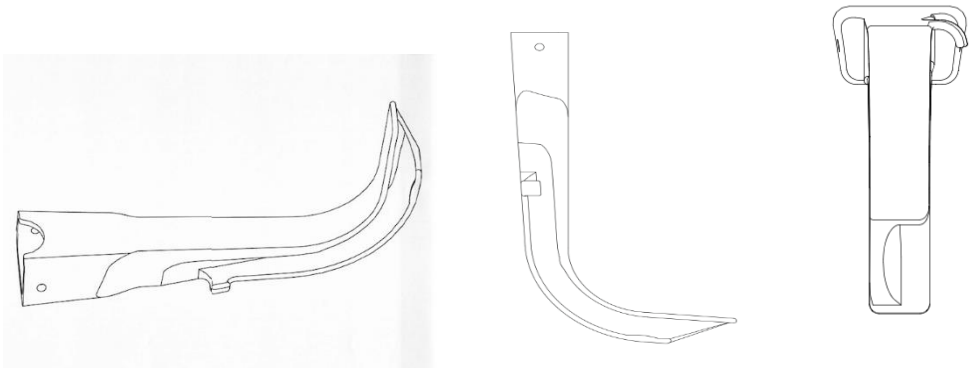
SPECIFICATION	COMPONENT
JBLADE size L	
JBLADE size M	
JBLADE size S	

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Table 8.
Title of symbol

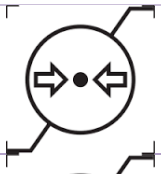
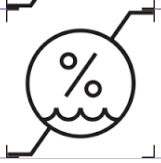
Symbol	Title Meaning	Symbol	Title Meaning
	Manufacturer		Warning or caution sign
	Authorized Representative in the European Community		Refer to instruction manual
	**Do not reuse**		Catalogue(part) number
	Serial number		Keep dry
	Type BF applied part		Batch code
	Temperature limitation		Atmospheric pressure limitation
	Do not use if package is damaged		Humidity limitation

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Table 9.
Rating of IP (Ingress Protection)

IEC (International Electrotechnical Commission) Standard (IEC60529: 2001)

IP-□□

Protection specification code (International Protection)

"First Digit" Protection against solid object

Code	Level of protection	
0		No protection
1	φ50 mm	Ingress of solid object diameter 50 mm is protected
2	φ12.5 mm	Ingress of solid object diameter 12.5 mm is protected
3	2.5 mm	Ingress of solid object diameter 2.5 mm is totally protected
4	1 mm	Ingress of solid object diameter 1.0 mm is totally protected
5		Protected against harmful dust
6		Totally protected against dust

Internal standard of oil endurance

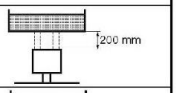
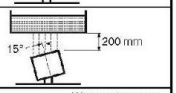
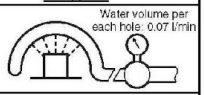
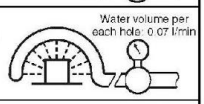
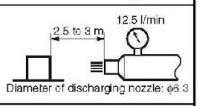
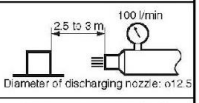
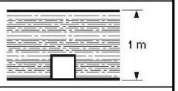
Level of protection	
Prevention	Protected against oil dripping and splashing from all direction
Endurance	Internal part is protected against oil dripping and splashing from all direction

Note: We use standardized oil for the above test.
(Equivalent to former JEM standard [Standards of the Japan Electrical Manufacturers' Association])

*1. Our company Test Method
IP67 for proximity sensor:
In addition to the following test, heat shock cycle test (0°C cold water for 1 hour, 70°C hot water for 1 hour) is conducted repeatedly for 5 times, confirming no CR and detection distance problem

*2. Note for our test outline
Proximity sensor E2F term of use: inside water in 10 m depth, in natural condition.
1) sink into 2 atm of water for 1 hour, no water ingress
2) repeat the heatshock cycle for 20 times, confirming no CR and detection distance problem

"Second Digit" Protection against liquid object

Code	Level of protection		Test method outline (test performed using pure water)
0	No protection	no protection against liquid object	No test
1	Protection against water drop	No harmful effect of vertical water drip	By using water drip tool vertically dropping water for 10 min 
2	Protection against water drop	No harmful effect of water drip from vertical direction when the enclosure is tilted at 15° from its normal position	By using water drip tool, move it in angle of 15°, dripping water for 10 min (2.5 min per direction) 
3	Protection against water spray	No harmful effect of water spray at any angle up to 60° from the vertical direction	By using tool as descripted in right picture, spraying water vertically in angle up to 60° for 10 min 
4	Protection from water splash	No harmful effect of water spray from all direction	By using tool as descripted in right picture, splashing water from all direction for 10 min 
5	Protection from water jets	No harmful effect of water splash from all direction	By using tool as descripted in right picture, Jet the water from all direction to the object surface for 1 m^2/min, at least for 3 min in total. 
6	Protection from strong water jets	No harmful effect of strong water jets from all direction	By using tool as described in right picture, Jet the water from all direction to the object surface for 1 m^2/min, at least for 3 min in total. 
7	Protection from water dip *1	No harmful effect of water dip in certain level of pressure and length of time	Dip into 1 m depth water for 30 min 
8	Protection from water sink *2	No harmful effect against water sink which the condition is decided between customer & manufacturer (in severer condition comparing to no.7)	Should be decided between customer and manufacturer

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ELECTROMAGNETIC COMPATIBILITY

The Video Intubation Laryngoscope/JESCOPE J1000 is designed to be following IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical medical installation.

The Video Intubation Laryngoscope/JESCOPE J1000 complies with the applicable essential performance requirements specified in IEC 60601-1 and IEC 60601-2-18. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables.

Table 10.
Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The Video Intubation Laryngoscope/JESCOPE J1000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Video Intubation Laryngoscope/JESCOPE J1000 should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The Video Intubation Laryngoscope/JESCOPE J1000 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 Video Intubation Laryngoscope/JESCOPE J1000 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

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Table 11.
Guidance and Manufacturer's Declaration — Electromagnetic Immunity

The Video Intubation Laryngoscope/JESCOPE J1000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Video Intubation Laryngoscope/JESCOPE J1000 should assure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT– GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	In compliance	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	In compliance	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	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Video Intubation Laryngoscope/JESCOPE J1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d (m) $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note:
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.

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 Video Intubation Laryngoscope/JESCOPE J1000 is used exceeds the applicable RF compliance level above, the Video Intubation Laryngoscope/JESCOPE J1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Video Intubation Laryngoscope/JESCOPE J1000.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Table 12.
Recommended Separation Distances
between Portable and Mobile RF Communications Equipment and the Video Intubation Laryngoscope/JESCOPE J1000

The Video Intubation Laryngoscope/JESCOPE J1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Video Intubation Laryngoscope/JESCOPE J1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Video Intubation Laryngoscope/JESCOPE J1000 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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:
At 80 MHz and 800 MHz, the separation distance for 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.

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CONTACT INFORMATION

To obtain additional information regarding your laryngoscope, please contact:

Corporate Headquarters Jescope Ltd.

No.60, Dehui St., Zhongshan Dist., Taipei City 104, Taiwan (R.O.C.)

Jescope Ltd.

2F, No.119, Wugong Rd., Wugu Dist., New Taipei City 248, Taiwan (R.O.C.)

EC REP: **MedNet EC-REP GmbH | www.mednet-ecrep.com**

Borkstrasse 10, 48163 Münster Germany

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