

# Instructions for Use

## Operating Manual

### Rigid Laryngostroboscope, Models 9106 and 9108

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# Table of Contents

- 1 Introduction ..... 4**
  - 1-1 Intended Use..... 4
  - 1-2 Warnings and Precautions ..... 4
  - 1-3 Using this Manual ..... 5
- 2 Specifications ..... 5**
  - 2-1 Components..... 5
  - 2-2 Appearance..... 6
  - 2-3 Specifications..... 6
  - 2-4 Environmental and Storage Conditions ..... 7
  - 2-5 Prolonging the Life of the Rigid Laryngostroboscope ..... 7
- 3 Preparation and Use..... 8**
  - 3-1 Assembly ..... 8
  - 3-2 Cleaning, High Level Disinfection, and Sterilization..... 9
    - 3-2-1 Cleaning ..... 9
    - 3-2-2 High Level Disinfection ..... 10
    - 3-2-3 Sterilization..... 10
  - 3-3 Use..... 10
- 4 Disposal..... 12**
- 5 Warranty..... 12**

# 1 Introduction

The PENTAX Medical Rigid Laryngoscopes, Model 9106 (9106) and Model 9108 (9108), provide optimal viewing of the vocal folds with a maximum transmission of light. The fiberoptic cable of the rigid Laryngoscope is continuous from the distal end of the cable to the tip of the rigid Laryngoscope (i.e., there is no detachment where the cable inserts into the rigid Laryngoscope). This provides the user with bright, clear, high-quality imaging capabilities. This instrument is intended to observe glottic action with the use of a stroboscopic light source.

## 1-1 Intended Use

The Rigid Laryngoscopes, Models 9106 and 9108, are intended to observe glottic action with the use of a stroboscopic light source. The instrument is inserted perorally when indications consistent with the need for observation are observed. Never use these Laryngoscopes for any purpose other than that for which they have been designed.

## 1-2 Warnings and Precautions



### **Warning**


You should read and understand the instructions in this manual before you perform any procedures using the 9106 or 9108. Failure to do so may result in injury to the patient or damage to the instrument.




### **Caution**

Failure to follow the enclosed maintenance instructions could render the 9106 or 9108 non-usable and void any effective warranty.


Warning and Caution messages appear throughout this manual in the following formats:

	<p><b>Warning</b></p> <p>Warning messages tell you about conditions that could result in death or serious injury.</p>
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	<p><b>Caution</b></p> <p>Caution messages tell you about problems that might result in minor or moderate injury, or property damage.</p>
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## 1-3 Using this Manual

This manual uses the following conventions:

Convention	Definition
 <b>Note</b>	Important information about a subject or the use of the device. Failure to follow a note can result in configuration or installation issues.
<i>Italics</i>	Reference to other sections in this manual or to other documents.

## 2 Specifications

### 2-1 Components

The 9106 and 9108 include the following components:

- Rigid Laryngostroboscope
- PENTAX Medical Laryngeal Stroboscope Adaptor, Model 7175-4200

2-2 **Appearance**

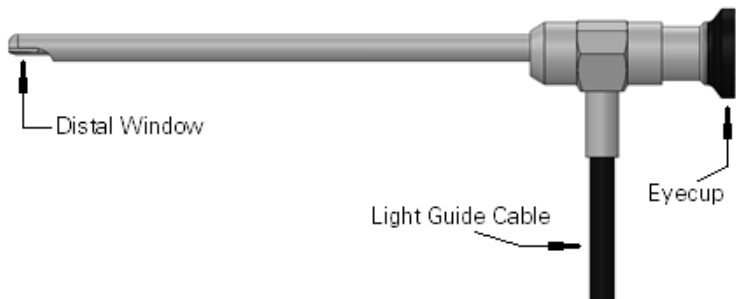


Figure 1. Rigid Laryngostroboscope

2-3 **Specifications**

<b>9106 Specifications</b>	Total Length	252 mm
	Working Length	189 mm
	Outer Diameter	9.5 mm
	Actual Visual Field Angle	35 degree
	Angled View	70 degree
	Depth of Field	2 mm-40 mm
	Integral Light Cable	Yes
<b>9108 Specifications</b>	Light Guide Length	1727 mm
	Total Length	226 mm
	Working Length	186 mm
	Outer Diameter	6 mm
	Actual Visual Field Angle	35 degree
	Angled View	70 degree
	Depth of Field	2 mm-40 mm
	Integral Light Cable	Yes
	Light Guide Length	1750 mm

## 2-4 Environmental and Storage Conditions

The 9106 and 9108 require the following conditions:

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Operating Conditions:	<ul style="list-style-type: none"><li>• Temperature: 10°C to 40°C (50°F to 104°F)</li><li>• Relative humidity: 20% to 80% (non-condensing)</li><li>• Atmospheric pressure: 700mb to 1060mb (0.69atm to 1.05atm)</li></ul>
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Storage/Transportation Conditions	<ul style="list-style-type: none"><li>• Temperature: -10°C to 60°C (14°F to 104°F)</li><li>• Relative humidity: 20% to 80% (non-condensing)</li><li>• Atmosphere pressure: 700mb to 1060mb (0.69atm to 1.05atm)</li></ul>
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## 2-5 Prolonging the Life of the Rigid Laryngostroboscope

The 9106 and 9108 provide high-quality performance over many examinations. The following precautions are essential to guarantee their longevity:

- Bend the fiberoptic cable as little as possible. Never kink the cable. Excessive bending causes fiberoptic bundles to break and results in diminished transmission of light.
- If the quality of the rigid Laryngostroboscope becomes significantly degraded as a result of broken fibers, the entire rigid Laryngostroboscope must be replaced. You cannot replace the cable.
- Do not scratch the lenses of the rigid Laryngostroboscope.

## 3 Preparation and Use

### 3-1 Assembly

You can connect the 9106 and 9108 with several light sources.

To use without a camera:

1. Insert the cable into a light source and look through the eyepiece (an adaptor may be required). When using the PENTAX Medical Laryngeal Stroboscope, Model 9400, the 7175-4200 adaptor provided with the rigid Laryngostroboscope should be used.
2. Use the brightness adjustment on the front panel of the PENTAX Medical Laryngeal Stroboscope, Model 9400, to control the amount of light to the rigid Laryngostroboscope.

To use with a C-mount camera and attachment lens (e.g., with PENTAX Medical's 3-CCD HD Camera, Model 9214HD, and Lens Coupler, such as Model 9118B):



Figure 2. Rigid Laryngostroboscope

1. Screw the attachment lens into the C-mount of the camera.
2. Insert the rigid Laryngostroboscope eyecup into the lens coupler.
3. Align the eyecup and adaptor, and lock them into place using the screw.



**Caution**

You must loosen the screw prior to removing the adaptor from the eyecup in order to avoid damage to the rigid Laryngostroboscope.



**Note** To use the 9106 or 9108 with other light sources, adaptors may be required. Please contact your local representative for information.

## 3-2 Cleaning, High Level Disinfection, and Sterilization



### **Warning**

The 9106 and 9108 are provided in a non-sterilized condition. Do not use until you clean, disinfect and sterilize the rigid Laryngostroboscope, as this could result in bodily harm to the patient.

### 3-2-1 Cleaning



### **Caution**

Meticulous and thorough cleaning of the device is required in order to achieve high level disinfection or sterilization. Failure to properly clean the device will result in ineffective or incomplete high level disinfection or sterilization.



### **Caution**

Do not immerse the rigid Laryngostroboscope longer than necessary in a germicidal solution. This can cause damage, including clouding of the lenses and loosening of gluing agents.



**Note** Avoid any harsh materials that can scratch or mar optical and outer surfaces of the device.



**Note** Remove any detachable items or components and process these in a similar manner.

After every use, wash and clean each device, removing all tissue, materials, and debris.

1. Soak the device in an enzymatic pre-soak/cleaner prepared as recommended by the manufacturer.
2. Remove the device and place it in a non-abrasive liquid detergent, prepared as recommended by the manufacturer.
3. Using a soft brush and cloth, clean the device manually, concentrating on any crevices, seams, or other surface discontinuities.
4. Rinse the device thoroughly in running tap water at a moderate temperature.

5. Using a gauze pad, wipe moisture from the device.

### 3-2-2 High Level Disinfection

There are two options for high level disinfection:

- Totally immerse the device in a 2.4% Glutaraldehyde soak for 45 minutes at 25°C.
- Totally immerse the device in a CIDEX® OPA soak for 12 minutes at 20°C.

### 3-2-3 Sterilization



#### **Caution**

Do not autoclave. Exposure to temperatures greater than 60°C (140°F) can damage the device and render it unusable.

There are three options for sterilization:

- Totally immerse the device in a 2.4% Glutaraldehyde solution for the time and at the temperature recommended by the manufacturer to achieve liquid chemical sterilization.
- Use Ethylene Oxide (EtO) according to the following parameters:
  - EtO concentration: 600 ± 30 mg/L
  - Humidity: 70% ± 5%
  - Exposure: 240 minutes
  - Degas at standard cycle: 12 hours at 55°C ± 2°C
- This device is compatible with STERRAD® 100S when following the sterilant manufacturer's procedures and guidelines.

### 3-3 Use



#### **Caution**

Thoroughly inspect the device before each use. Check the function of the device and visually inspect optics for moisture or contamination. Do not drop the device or subject it to sudden impact. Refer to section 5, *Warranty* for information about damage to the device.



**Caution**

Never insert the rigid Laryngostroboscope in water or any other substance or agent with a temperature greater than 150 °F (65 °C). Hot beads can damage the rigid Laryngostroboscope and should not be used for anti-fogging.



**Note** The optimal working distance from the distal window for visual use of this rigid Laryngostroboscope is 5 to 50 mm.



**Note** The angle of entry with the 70-degree rigid Laryngostroboscope is markedly different from the 90-degree rigid Laryngostroboscope to which you may be accustomed. Instead of the rigid Laryngostroboscope pointing upward in the patient's mouth, the 70-degree rigid Laryngostroboscope angles downward to allow a closer view of the vocal fold.



**Warning**

Although complications resulting from use of a rigid Laryngostroboscope for viewing the larynx are extremely rare, the following risks are possible:

- Laryngospasm.
- Blood pressure elevation during procedure.
- Bleeding as a result of injury caused by improper scoping procedure.
- Adverse reaction to anesthetic (if used to prevent gagging).

To use the 9106 or 9108:

1. Follow cleaning and high level disinfection or sterilization procedures in section 3-2, *Cleaning, High Level Disinfection, and Sterilization*.
2. To avoid fogging:



**Note** You can apply various anti-fogging solutions to the lens of the rigid Laryngostroboscope to help prevent fogging; inquire at medical or dental supply houses.

- a. Dip the working end of the rigid Laryngostroboscope into a container with hot tap water for 10-20 seconds.
- b. Blot with a soft tissue prior to insertion into patient's mouth.

You may have to repeat this during the scoping procedure.

## 4 Disposal



This product is a medical device. In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted waste, but should be collected separately. Contact your local PENTAX distributor for correct disposal and recycling. By disposing of this product correctly you will help ensure that the waste undergoes the necessary treatment, recovery and recycling and thus prevent potential negative effects on the environment and human health which could otherwise arise due to inappropriate waste handling.



**Note** Follow local, state, and federal guidelines for the proper disposal of waste products.

## 5 Warranty

All devices are guaranteed against defective materials and workmanship for one (1) year. This is a sealed unit and all repairs must be made by factory-trained personnel only. Improperly treated, misused, mishandled or out-of-warranty products will be repaired or replaced for a fee.