

Fiber optic laryngoscope handles Directions for use

Intended use

The fiber optic laryngoscope handle is an accessory used with compatible rigid fiber optic laryngoscope blades which are used to examine and visualize a patient's airway and aid placement of a tracheal tube.

About this document

This directions for use apply to Welch Allyn reusable fiber optic laryngoscope handles: 60813, 60814, 60815. Welch Allyn reusable fiber optic laryngoscope handles may be used with Welch Allyn fiber optic laryngoscope blades MacIntosh REF: 6906X, English MacIntosh REF: 6921X, and Miller REF: 6806X.

Warnings and cautions



WARNING: Reusable fiber optic laryngoscope handles must be reprocessed after each use.



WARNING: The reprocessing procedure and the equipment and materials described must be followed and conducted by persons trained and familiar with medical device reprocessing.



WARNING: Consult cleaning and disinfecting agent manufacturer instructions for their proper preparation and use.



WARNING: Repeated reprocessing may degrade elements of the handle. Follow inspection procedures to assure damage has not occurred to the handle.



WARNING: High level disinfection and/or sterilization are not achieved by these methods.



WARNING: Lamps, if left illuminated, could generate sufficient heat to cause burns



WARNING: Discard any component that shows evidence of damage or deterioration.



WARNING: Do not modify this equipment. Any modification of this equipment may lead to patient injury. Any modification of this equipment voids the product warranty.



WARNING: Personnel shall follow their facility policies and procedures and wear appropriate personal protective equipment when handling potentially contaminated equipment.



WARNING: Laryngoscope equipment is not suitable for use in intense magnetic fields



CAUTION: Only use lamp specified. Failure to follow these instructions may cause damage or poor performance of the handle.



CAUTION: If the device will be unused for several months or longer, remove the batteries prior to storing the device.

Reprocessing instructions

These *reprocessing* instructions refer to procedures for cleaning and intermediate level disinfection. Fiber optic laryngoscope handles must be reprocessed prior to first use and between each use using the following method as outlined in this document:

- Cleaning and intermediate level disinfection

Welch Allyn has validated the above instruction as being capable of preparing these laryngoscope handles for re-use. The user must ensure that the reprocessing as actually performed by the user's personnel, with the user's equipment and materials, achieves the desired result. This may require validation and routine monitoring of the user's actual process

NOTE: The main handle and bottom cap components are compatible with the disinfection solution and autoclave methods identified which are provided for facilities who wish to perform either method after cleaning and intermediate level disinfection.

Cleaning and intermediate level disinfection instructions

Point of use:	<ol style="list-style-type: none"> 1. Separate blade assembly from handle and place handle into suitable containment for subsequent reprocessing (per figure 1). Do not place handle with sharp devices. 2. Prevent the handle from drying (i.e. wrap/cover in moist germicidal wipe).
Preparation for decontamination:	<ol style="list-style-type: none"> 1. Select an appropriate quaternary ammonium isopropanol based germicidal cleaner labeled suitable for use on healthcare equipment and capable intermediate level disinfection. Reference EPA-registered disinfectants: http://www.epa.gov/oppad001/chemregindex.htm Outside of the U.S., please consult applicable regulatory body for equivalent quaternary ammonium isopropanol germicidal cleaner. 2. Remove batteries and lamp cartridge (per figure 2).



Figure 1

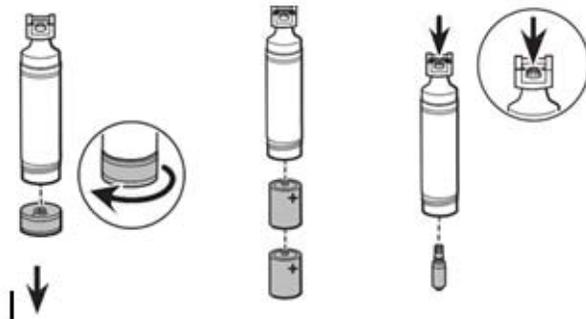


Figure 2

<p>Cleaning and intermediate level disinfection:</p>	<ol style="list-style-type: none"> 1. Follow the germicidal wipe manufacturer's instructions to clean all exposed surfaces of the main handle, end cap, and lamp cartridge. 2. If necessary, brush with a dry, soft-bristled brush and re-wipe to loosen/remove excessive visible soil. 3. After all visible soil is removed, re-wipe to wet all surfaces and allow adequate contact time for disinfection as directed by the germicidal wipe manufacturer. <p> CAUTION: Only use quaternary ammonium isopropanol based germicidal wipes.</p>
<p>Drying:</p>	<p>Allow components to air dry.</p>
<p>Maintenance, Inspection and Testing</p>	<ol style="list-style-type: none"> 1. Inspect each component area (per figure 3) for damage or deterioration. <p> WARNING: Discard any component that shows evidence of damage or deterioration.</p> <p>Contact Welch Allyn for component replacement.</p> <ol style="list-style-type: none"> 2. Reassemble handle (per figure 4) with new or batteries in known good condition. 3. Attach handle to a clean and disinfected test blade assembly in known working condition. Verify that: <ul style="list-style-type: none"> • Blade assembly engages and locks onto handle. • Blade assembly deploys into its locked position on handle AND lamp illuminates. • Light output is satisfactory. <p>If the lamp fails to light or output is low, check or replace the lamp and/or batteries.</p>
<p>Storage</p>	<p>Store handle per facility practice to allow device to remain clean, dry, and ready for service.</p>

End of reprocessing instructions for intermediate level disinfection.

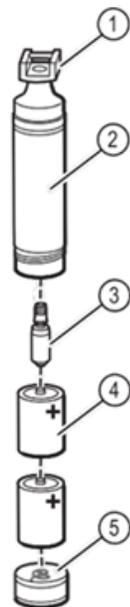


Figure 3

- 1. Handle REF. number
- 2. Main handle
- 3. Lamp cartridge assembly
- 4. Batteries
- 5. Bottom cap

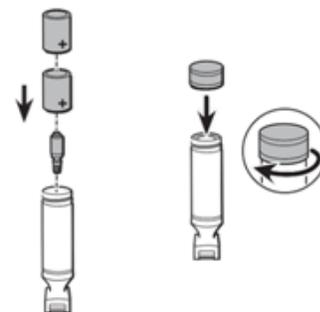


Figure 4

Cold solution disinfection instructions

NOTE: The main handle and bottom cap are compatible with this cold solution disinfection method which is provided for facilities who wish to solution disinfect **after cleaning and intermediate level disinfection.**

Disassembly:	<ol style="list-style-type: none"> 1. Disassemble the handle and remove batteries and lamp cartridge per figures 3. 2. Set batteries and lamp cartridge aside.
Preparation for decontamination:	<ol style="list-style-type: none"> 1. Select a 14 day (2.4 – 2.6%) glutaraldehyde disinfectant. 2. Prepare disinfection solution per manufacturer instructions.
Cold solution disinfection:	<ol style="list-style-type: none"> 1. Immerse main handle and bottom cap (only) in disinfection solution, for a time duration identified by the disinfection solution manufacturer. 2. Thoroughly rinse all components in potable water, softened water or per disinfection solution manufacturer instructions to remove disinfecting solution.
Drying:	Dry all components with a clean cloth or allow to air dry.
Maintenance, Inspection and Testing	<ol style="list-style-type: none"> 1. Inspect each component area (per figure 2) for damage or deterioration. <p> WARNING: Discard any component that shows evidence of damage or deterioration.</p> <p>Contact Welch Allyn for component replacement.</p> 2. Reassemble handle (per figure 4) with new or batteries in known good condition. 3. Attach handle to a clean and disinfected test blade assembly in known working condition. Verify that: <ul style="list-style-type: none"> • Blade assembly engages and locks onto handle. • Blade assembly deploys into its locked position on handle AND lamp illuminates. • Light output is satisfactory <p>If the lamp fails to light or output is low, check or replace the lamp or batteries.</p>
Storage	Store handle per facility practice to allow device to remain clean, dry, and ready for service.

Autoclave instructions

NOTE: The main handle and bottom cap are compatible with these autoclave methods which are provided for facilities who wish to autoclave **after cleaning and intermediate level disinfection.**

Disassembly:	<ol style="list-style-type: none"> 1. Disassemble the handle and remove batteries and lamp cartridge per figures 3. 2. Set batteries and lamp cartridge aside.
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After battery and lamp cartridge removal, select **ONE** of the following autoclave methods below for the main handle and bottom cap:

Gravity autoclave: Follow equipment manufacturer and facility procedures in the set-up and operation of autoclave equipment. Gravity autoclave settings are as follows:

- Temperature: 132 C (270 F)
- Exposure time: 3 minutes (unwrapped)
- Minimum dry time: 1 minute

Pre-vacuum autoclave: Follow equipment manufacturer and facility procedures in the set-up and operation of autoclave equipment. Pre-vacuum autoclave settings are as follows:

- Temperature: 132 C (270 F)
- Exposure time: 3 minutes (unwrapped)
- Minimum dry time: 1 minute

Maintenance, Inspection and Testing	<ol style="list-style-type: none"> 1. Inspect each component area (per figure 2) for damage or deterioration. <div style="margin-left: 20px;">  WARNING: Discard any component that shows evidence of damage or deterioration. Contact Welch Allyn for component replacement. </div> 2. Reassemble (per figure 4) with new or batteries in known good condition. 3. Attach handle to a clean and disinfected test blade assembly in known working condition. Verify that: <ul style="list-style-type: none"> • Blade assembly engages and locks onto handle. • Blade assembly deploys into its locked position on handle AND lamp illuminates. • Light output is satisfactory. If the lamp fails to light or output is low, check or replace the lamp and/or batteries
Storage:	Store handle per facility practice to allow device to remain clean, dry, and ready for service.

Maintenance instructions

Replace the lamp



WARNING: Lamps, if left illuminated, could generate sufficient heat to cause burns.



CAUTION: Use only Welch Allyn replacement lamps REF: 06000 to ensure proper illumination alignment.

1. Unscrew bottom cap of handle counterclockwise and remove batteries per figure 3.
2. Remove lamp cartridge assembly from main handle by applying finger pressure in the direction shown by the arrow per figure 4.
3. Remove shroud cap from shroud by rotating shroud cap counterclockwise per figures 5 and 6.
4. Rotate lamp counterclockwise to remove per figure 6.
5. Replace lamp and rotate shroud cap clockwise to tighten per figure 7.
6. To replace lamp cartridge assembly in the main handle, invert handle, then gently slide the cartridge down the inside of handle, tipping it side to side until the shroud cap exits opening on top.
7. Re-insert batteries and apply slight pressure to set the cartridge in place.
8. Replace and tighten bottom cap.
9. Reprocess repaired assembly as appropriate per these instructions.

Figure 3

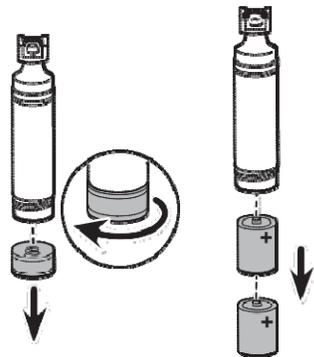


Figure 4

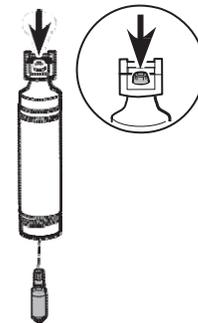


Figure 5

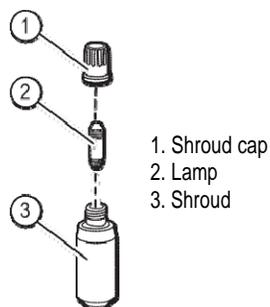


Figure 6

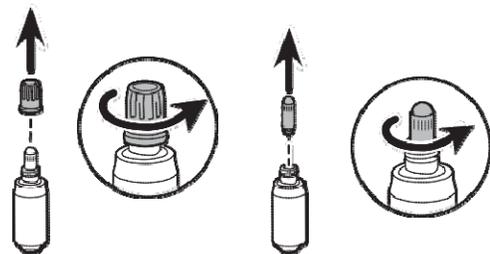
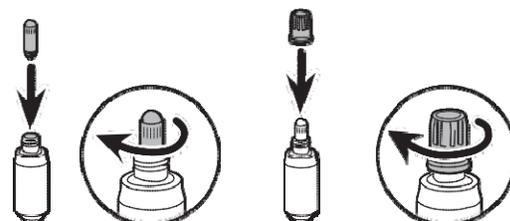


Figure 7



Replace the batteries

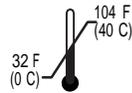
1. Unscrew bottom cap of handle per figure 3 and remove batteries.
2. Alkaline batteries are supplied with your handle for maximum performance and are recommended as replacements; however carbon-zinc batteries may also be used.
 - Medium handle, REF 60813 uses two “C” size
 - Penlight handle, REF 60814 uses two “AA” size
 - Stubby handle, REF 60815 uses two “AA” size
3. Insert batteries and reinstall bottom cap per figure 3.
4. Verify lamp and blade engagement/operation using a known working test blade.
5. Reprocess repaired assembly as appropriate per these instructions.

Specifications

Electrical:

For information about electromagnetic compatibility (EMC) see Welch Allyn website: <http://www.welchallyn.com>

Operating:



Storage/Transport:



Approvals:

Conforms to ASTM F 965 and ISO-7376-1, IEC/EN 60601-1, IEC/EN 60601-1-2



The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive.



Complies with EMC Framework of Australia

Warranty:

One year

Service Information:

For Technical Support or to obtain information about any Welch Allyn product, contact Welch Allyn Technical Support: www.welchallyn.com/support.



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