Welch Allyn®

MM 721357 Ver. C

Standard laryngoscope handles Directions for use

Intended use

The standard laryngoscope handle is an accessory used with compatible rigid standard 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 standard laryngoscope handles REF: 60200, 60300, 60400, 60305. Welch Allyn reusable standard laryngoscope handles may be used with Welch Allyn standard laryngoscope blades MacIntosh REF: 6904X, English MacIntosh REF: 6924X, and Miller REF: 6804X and REF 68470.

Warnings and cautions

WARNING: Welch Allyn reusable standard 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: 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: Failure to follow these instructions may cause damage to this handle.

CAUTION: Do not immerse/soak handle, damage to handle may occur.

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. Standard 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

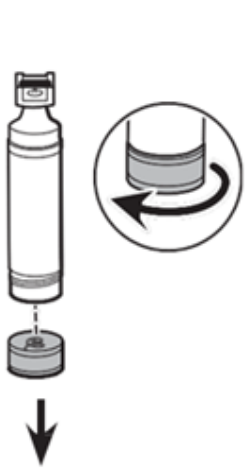
Welch Allyn has validated the above instruction as being capable of preparing these laryngoscope handles for re-use. The user must ensure that the reprocessing as actually performed by the user's personnel, with the user's equipment and materials, achieves the desired result. This may require validation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

NOTE: The main handle and bottom cap components of handles marked “AUTOCLAVE” are compatible with the autoclave methods identified which are provided for facilities who wish to autoclave after cleaning and intermediate level disinfection.

Cleaning and intermediate level disinfection instructions

Point of use:	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:	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 per figure 3.

Figure 1



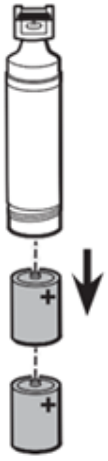


Figure 2

Cleaning and intermediate level disinfection:	1. Follow the germicidal wipe manufacturer's instructions to clean all exposed surfaces of the handle and end cap. 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. ⚠ CAUTION: Only use quaternary ammonium isopropanol based germicidal wipes.
Drying:	Allow components to air dry.
Maintenance, Inspection and Testing	1. Inspect each component area (per figure 3) for damage or deterioration. ⚠ WARNING: Discard any component that shows evidence of damage or deterioration. Contact Welch Allyn for component replacement. 2. Reassemble batteries into 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: • 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 batteries.
Storage:	Store handle per facility practice to allow device to remain clean, dry, and ready for service.

End of reprocessing instructions for intermediate level disinfection.

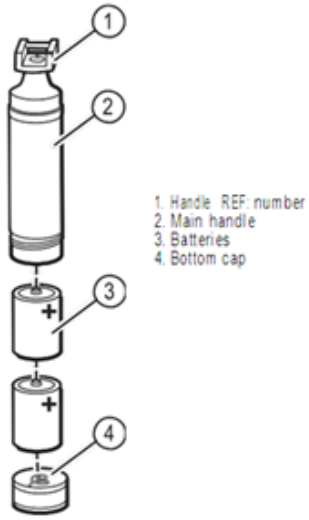


Figure 3

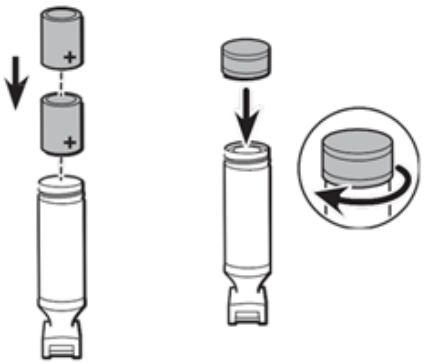


Figure 4

Autoclave instructions

NOTE: The main handle and bottom cap components of handles marked “AUTOCLAVE” are compatible with the autoclave methods identified which are provided for facilities who wish to autoclave **after cleaning and intermediate level disinfection.**

Disassembly:	Remove batteries per figure 2 and set aside.

After battery removal, select **ONE** of the following autoclave methods below for the main handle and bottom cap (only):

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	1. Inspect each component area per figure 3 for damage or deterioration. WARNING: Discard any component that shows evidence of damage or deterioration. Contact Welch Allyn for component replacement. 2. Reassemble batteries into handle per figure 4. 3. Attach handle to a clean and disinfected test blade assembly in known working condition. Verify that: • 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 batteries
Storage:	Store handle per facility practice to allow device to remain clean, dry, and ready for service.

Maintenance instructions

Replace the batteries

1. Unscrew bottom cap of handle per figure 5 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.
    - Large handle, REF 60200 uses two “D” size
    - Medium handle, REF 60300 uses two “C” size
    - Penlight handle, REF 60400 uses two “AA” size
    - Stubby handle, REF 60305 uses two “AA” size
3. Insert batteries and reinstall bottom cap per figure 5.
4. Reprocess repaired assembly as appropriate per these instructions

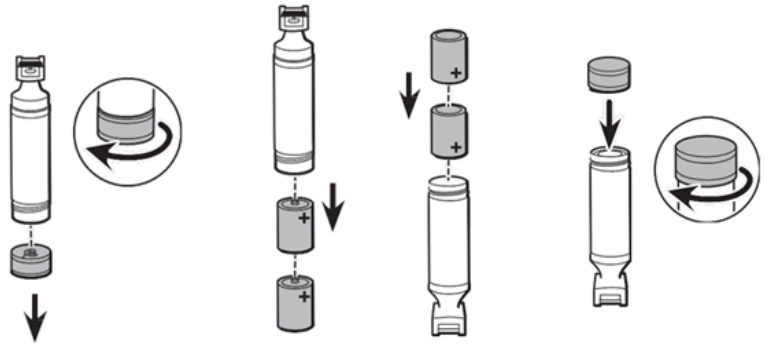


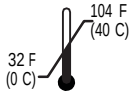
Figure 5

Specifications

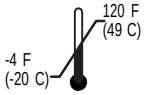
Electrical:

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

CE 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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