Hydra Conventional Laryngoscope Handles

Instructions for Use

INTENDED USE

- The Hydra laryngoscope handle, when connected to a compatible blade, is used to illuminate the oropharynx and trachea to assist with endotracheal intubation or allow examination of the oral cavity.
- Three sizes of Hydra handle are available: Adult, Paediatric and Stubby. The handles may be used with any ISO 7376 compliant directly illuminating (conventional) laryngoscope blade.
- The non-contact variant of the device is designed to stop the laryngoscope blade from folding all the way closed, thereby preventing contact between the handle and tip of the laryngoscope blade. We cannot guarantee compatibility of non-contact handles with blades other than those manufactured by PROACT Medical Ltd.

WARNINGS

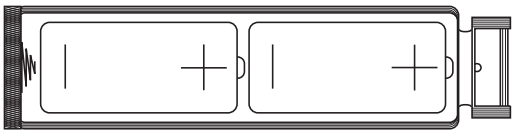
Tracheal intubation requires specialist training. Only competent trained personnel should use this device.

- PROACT Medical advocate that intubation is only attempted with a full alternate plan in place in the event of difficult intubation due to equipment failure or physiological complications. This should include the availability of back-up devices and alternative means of ensuring ventilation.
- Power output from rechargeable cells can fall rapidly during use, resulting in sudden failure of illumination. We recommend that rechargeable batteries are not used.
- Use of damaged batteries or the presence of conductive material inside the battery chamber may result in an internal short-circuit, causing the batteries and handle to overheat. In this event, care should be taken when removing the battery cap, as internal components may become hot enough to burn the skin.
- Non-LED lamps, if left illuminated in an exposed position, could generate sufficient heat to burn human tissue.
- Remove batteries from handles when not in use. Ensure that used batteries are disposed of in accordance with appropriate national and local laws, regulations and procedures.
- In the event that this device is involved in a serious clinical incident, please report it to your local competent authority and PROACT Medical Ltd.

PRE-USE CHECKS

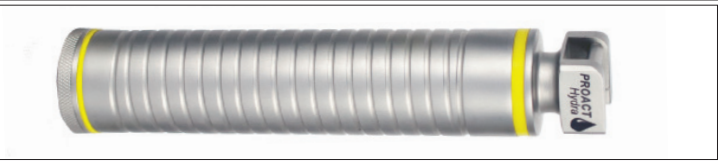
Do not use this device unless the following checks have been performed prior to each use:

- Check device and batteries for completeness, sharp edges, damage, flaws or loose parts.
- Unscrew cap at base of handle to insert fresh batteries, observing correct polarity.
- Engage and disengage laryngoscope twice prior to use to confirm operation, ensure consistent light when force is exerted on blade tip in all directions.
- Insufficient, flickering or absence of light may indicate that batteries require replacing or a problem with the laryngoscope blade or handle contact.



INSTRUCTIONS FOR USE

- These directions are general guidelines intended for use by a qualified medical personnel. Any instructions and contraindications are not exhaustive and it is the responsibility of the clinician to ensure the safe and correct use of this device..
- Select the appropriately sized device for the patient.
- Attach compatible laryngoscope blade to handle.
- Ensure blade is fitted firmly onto handle and clicked into place.
- To switch on, pull blade up and lock into position. Light will activate automatically.
- Examine / intubate trachea following current accepted medical guidelines.
- To switch off, move blade down. Light will automatically switch off.



HYDRA LARYNGOSCOPE HANDLES, CONVENTIONAL (ISO 7376) FITTING

Part Number	Part Number Non-Contact	Size	Batteries Required	Dimensions (Length x Dia.)	UDI-DI
HYCVH001	Standard	Adult	2 x C	144 x 29mm	25056094500277
HYCVH002	Standard	Paediatric	2 x AA	144 x 21mm	25056094500284
HYCVH003	Standard	Stubby	2 x AA	113 x 33mm	25056094500291

HYDRA LARYNGOSCOPE HANDLES, CONVENTIONAL (NON-CONTACT) FITTING)

HYCVHNC1	Non-Contact	Adult	2 x C	144 x 29mm	25056094501106
HYCVHNC3	Non-Contact	Paediatric	2 x AA	144 x 21mm	25056094501113
HYCVHNC3	Non-Contact	Stubby	2 x AA	113 x 33mm	25056094501120

REPROCESSING

- Infection from patient to patient can potentially be transmitted by any piece of medical equipment. To prevent this, appropriate action must be taken to reprocess this device between uses.
- Selection of the appropriate method for reprocessing should be determined by the user, with due consideration of applicable local regulations, policies and guidance. Three methods of reprocessing have been validated by the manufacturer, low-level disinfection, high-level disinfection and sterilisation via steam autoclave.
- The Hydra handle may continue to be used indefinitely provided the device is in a safe and functional condition, and the requirements of pre-use checks are met.
- The instructions below have been validated by the manufacturer (PROACT Medical Ltd.) as being capable of preparing medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Initial treatment at the point of use

- Remove gross contamination as soon as possible after use, using a clean cloth or disposable wipe and running water.
- Pay particular attention to the knurled bottom cap and around the hook on area. Use a soft brush if necessary.

Low Level Disinfection

- Manual cleaning and disinfection
  - Using a 70% alcohol or chlorine based disinfectant wipe, wipe down the top of the handle to the bottom whilst twisting the handle. Repeat the process 3 times, with a new wipe each time. Ensure all surfaces are completely moistened for the contact time specified by the wipe manufacturer.
  - Pay particular attention to any recesses and difficult to access areas around the top block where the blade attaches to the handle.
  - Follow the disinfectant wipe manufacturer's instructions regarding drying.
- Inspection and storage
  - Recheck the handle for any contaminants or abrasions. Repeat the process again if necessary and move to high level disinfection if the contaminants cannot be removed.
  - Ensure disinfected handles are stored in a way to prevent recontamination or moisture.

High Level Disinfection

- Preparation before Cleaning
  - Remove batteries prior to reprocessing.
  - Hydra Handles should be cleaned and disiinfected with the bottom cap removed.
- Automated cleaning and disinfection
  - Process in an automatic washer/disinfector. The machine and selected cleaning cycle must conform to the requirements of ISO 15883.
  - The washer disinfector should achieve a temperature of 90°C for a minimum of 1 minute.
  - Use a pH neutral enzymatic detergent in accordance with the manufacturer's directions for use.
  - The selected washer disinfector cycle should include a suitable drying cycle to ensure the handle is fully dry before removal.
- Inspection and storage
  - Check handles for visible contaminants or abrasions.
  - Ensure disinfected handles are stored in a way to prevent recontamination or moisture.

Sterilisation via Steam Autoclave

- Packaging for Sterilization
  - To maintain sterility at the point of use, pack the handles in a sealable pouch compliant with BS EN 868-5, with the bottom cap removed.
- Steam Autoclave
  - Process in a steam autoclave. The machine and selected sterilisation cycle must conform to the ISO 17665 series of international standards.
  - Selected cycle should ensure a temperature of 134-137°C for 3-3½ minutes.
- Storage
  - Ensure sterilised handles are stored in a way to prevent recontamination, moisture, or damage to sterile packaging.

WARRANTY

- Hydra laryngoscope handles are individually serial numbered to enable recording of devices through reprocessing cycles, the maintenance of such a record is required for any warranty claim.
- PROACT Medical Ltd. offer a warranty period of 4,000 cycles or 5-years (whichever is sooner) for Hydra handles to be free from manufacturing or materials fault under routine and proper careful use. in accordance with local guidelines.
- The warranty does not cover failure due to normal wear and tear, misuse, external impact or damage caused by failure to correctly follow the instructions for use or through unauthorised repairs or modifications of any kind.
- At the end of their usable life, handles should be disposed of as clinical waste in accordance with local guidelines.

MD MEDICAL DEVICE

DO NOT USE IN AN MRI ENVIRONMENT

CE

UKCA

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