Hydra II Green System Laryngoscope Handles

Instructions for Use

INTENDED USE

- The Hydra II 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 II handle are available: Adult, Paediatric, and Stubby. The handles may be used with any ISO 7376 compliant light-guide illuminated (Green System) laryngoscope blade.
- The no 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

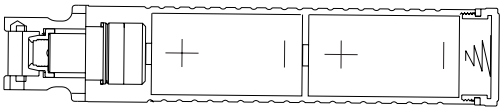
Tracheal intubation requires specialist training. Only competent trained personnel should use this device.

- PROACT Medical advocate that intubation is only attempted with a full alternate plan in place for 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.
- It is recommended that any handle that is suspected of being exposed to Creutzfeldt-Jakob Disease (CJD) or similar dangerous contamination should not be reprocessed.
- 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 ④, as internal components may become hot enough to burn the skin.
- 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 the device is involved in a serious clinical incident, please report it to your local competent authority and PROACT Medical Ltd. Retain any device related to an incident.

PRE-USE CHECKS

Do not use this device unless the following checks have been performed before each use.

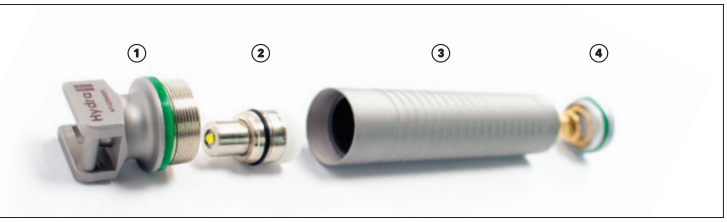
- Check device and batteries for completeness, sharp edges, damage, flaws or loose parts.
- Ensure that LED module ② is fully tightened within top block ①
- Unscrew cap at base of handle ④ to insert fresh batteries, observing correct polarity.
- Engage and disengage laryngoscope twice prior to use to confirm operation, ensure sufficient and 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 LED or handle contact. Discard for further investigation and correction and/or repair.



INSTRUCTIONS FOR USE

These directions are general guidelines intended for use by 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 handle 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, FIBRE OPTIC TYPE (ISO 7376) FITTING					
Part Number	**Part Number Non-Contact**	**Size**	**Batteries Required**	**Dimensions (Length x Dia.)**	**UDI-DI**
HYGSH201	Standard	Adult	2 x C	157 x 29mm	25056094502196
HYGSH202	Standard	Paediatric	2 x AA	157 x 22mm	25056094502202
HYGSH203	Standard	Stubby	2 x AA	130 x 33mm	25056094502219
HYDRA LARYNGOSCOPE HANDLES, FIBRE OPTIC TYPE (NON-CONTACT) FITTING					
HYGSH291	Non-Contact	Adult	2 x C	157 x 29mm	25056094502257
HYGSH292	Non-Contact	Paediatric	2 x AA	157 x 22mm	25056094502264
HYGSH293	Non-Contact	Stubby	2 x AA	130 x 33mm	25056094502271
HYSP201	Replacement LED module for all handles				
Please see www.proactmedical.co.uk/spares for a full list of spare parts/kits.					

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 II 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 this 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, around the lens and 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 lens and 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
  - Hydra II handles should be cleaned and disinfected with the bottom cap ④ REMOVED.
  - LED Module ② and batteries are NOT suitable for processing via washer disinfector. Ensure they are removed before starting this process.
- 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.
  - Ensure that procedures include sufficient rinsing using demineralised water to remove any deposits from the device, especially both ends of the fibre optic bundle.
  - The selected washer disinfector cycle should include a suitable drying cycle to ensure the handle is fully dry before removal.
- Inspection and storage
  - Check handle for visible contaminants or abrasions, repeat the process again if required.
  - If the handle is only subjected to high level disinfection, and not steam sterilisation. then the LED module ② should be reinserted and tested at this point.
  - Ensure disinfected handles are stored in a way to prevent recontamination or moisture.

Sterilisation via Steam Autoclave

- Preparation for Sterilisation
  - Hydra II handles should be cleaned and disinfected with the bottom cap ④ REMOVED.
  - LED module ② and batteries are NOT suitable for Steam sterilisation. Ensure they are removed.
- Steam Autoclave
  - Process in a steam autoclave. The machine and selected sterilisation cycle must conform to the ISO 17665 series of international standards.
  - Routine cycles ensuring a temperature of 134-137°C for 3-5 minutes have been validated.
  - Cycles of up to 18-60 minutes at 134-137°C are not thought to adversely affect the products performance, but may shorten the life, and affect the warranty, of the seals and O-Rings.
- Inspection and Storage
  - Reinsert and test the LED module ②
  - Store 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 to accompany any warranty claim.
- PROACT Medical Ltd offer a warranty period of 4,000 cycles or 5-years (whichever is sooner) for Hydra handles and twelve-months for LED units, battery holders and silicone base and cap seals to be free from manufacturing or materials fault under routine and proper careful use. See **www.proactmedical.co.uk/spares** for a full list of spare parts and fitting instructions.
- 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

MR DO NOT USE IN AN MRI ENVIRONMENT

UK CA

CE

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