

McGRATH®

Video Laryngoscope | Series 5

Operator's Manual

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Revision 4.2
21st September 2007

AIRCRAFT
MEDICAL





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1 Introduction

1.1 Description

The **McGRATH®** Series 5 Video Laryngoscope (“the **McGRATH®**”) is a device to aid the intubation of the trachea. A rigid laryngoscope blade restrains the tongue, allowing a clear view of the larynx and entrance to the trachea. The need to provide a guaranteed airway is fundamental to an anaesthetist’s task prior to an operation. Paramedics, A & E Consultants and General Practitioners may also be required to insert a tracheal tube in an emergency to keep the airway open where an unconscious patient is undergoing cardio-pulmonary resuscitation.

The **McGRATH®** incorporates a light source and miniature camera within the CameraStick™ assembly to view the larynx during the procedure of intubation. The image is displayed on an LCD screen mounted to the handle of the device.

A single AA 1.5V battery mounted within the handle powers the camera, display and light.

The disposable sterile blade covers the camera/light assembly.

1.2 Accessories and Part Numbers



UNDER NO CIRCUMSTANCES SHOULD ANY OTHER TYPE OF LARYNGOSCOPE BLADE BE USED WITH THIS MEDICAL DEVICE



DO NOT OPEN ANY SEALED PART OF THE DEVICE UNDER ANY CIRCUMSTANCES. TO DO SO WILL IMPAIR THE PERFORMANCE OF THE DEVICE AND PATIENT SAFETY

The **McGRATH®** is not supplied with batteries or with disposable intubation blades – blades should be purchased separately from your distributor.

McGRATH® Intubation Blades (Box of 10) 550-004-000

McGRATH® Intubation Blades (Carton of 30) 550-006-000

McGRATH® Series 5 Video Laryngoscope 500-000-000

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1.3

Specifications

Laryngoscope Assembly

Size	200mm x 50mm x 150mm
Weight	0.27kg
Power	AA 1.5V Battery Giving typically 1 hour of non-continuous use.
Light source	High intensity LED fibre
Display	Colour LCD (1.7" diagonal)
Camera	VGA
Protection	IP65
Materials	Durable medical grade rubber, thermoplastics and stainless steel. This device and packaging are latex free.

Disposable Intubation Blade

Size	110mm x 12mm x 15mm
Material	Medical grade optical polymer. This device and packaging are latex free.
Packaging	Packaged sterile for single use only

1.4

Regulatory

This product complies with EN 60601-1 and EN 60601-1-2 safety standards. The CE mark indicates that it meets the requirements of European Council Directive 93/42/EEC concerning medical devices.



Aircraft Medical Limited operates an approved Quality Management System in accordance with BS EN ISO 13485.

“McGrath” is a registered trademark of Aircraft Medical Limited.

“Aircraft” is a registered trademark of Aircraft Medical Limited.

“CameraStick” is a trademark of Aircraft Medical Limited.

Only personnel trained in and licensed to perform intubation with a laryngoscope may use this device.

The user must contact the distributor to arrange responsible disposal and compliance with Waste Electrical and Electronic Equipment regulations applicable, and any similar future environmental regulation applicable (including but not limited to Directives 2002/95/EC and 2002/96/EC as implemented in the Territory).

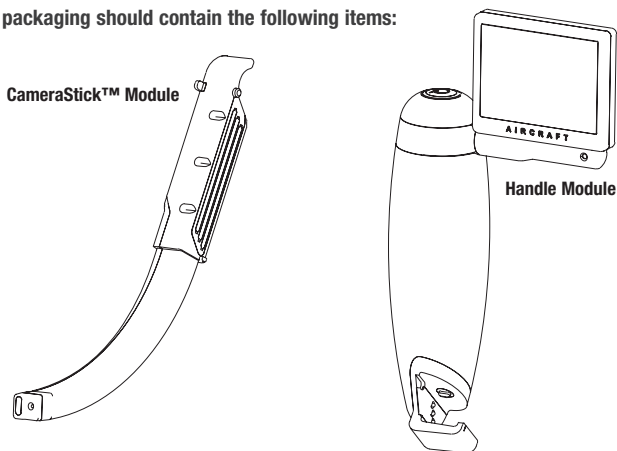
CAUTION : FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

2 Functional

2.1 Unpacking and Inspection

Unpack the **McGRATH®** and check for any visible signs of damage that may have occurred during shipment. In the event of signs of damage do not use the laryngoscope, and inform the local agent or distributor.

The packaging should contain the following items:



The **McGRATH®** is supplied in a non-sterile state. It will be necessary to disinfect the laryngoscope before use on a patient. (See section 3.1)

The laryngoscope blade is supplied in a sterile state. Ensure that handling precautions are taken in accordance with local, national and harmonised standards.

2.2 Batteries

For safety reasons, the batteries are not supplied with the unit. The **McGRATH®** will accept any AA battery. The McGrath will give longer use with Ni-Hi or rechargeable batteries.

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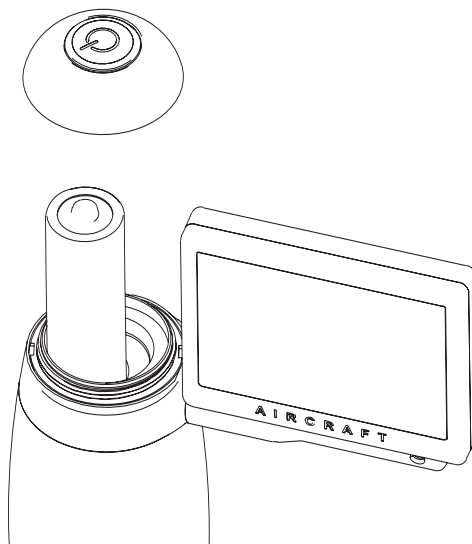
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2.3 Fitting the battery

Locate the **handle module** and a AA battery. Unscrew (by turning anti-clockwise) and remove the **top cap** and install the battery taking care to orientate the battery as indicated on the device.

Fit the **top cap** back onto the **handle module**, making sure that it is fully tightened.

Check that the device powers up, by pushing the **STANDBY** button. When satisfied that the equipment is working correctly, re-push **STANDBY** button to switch the device to standby mode.

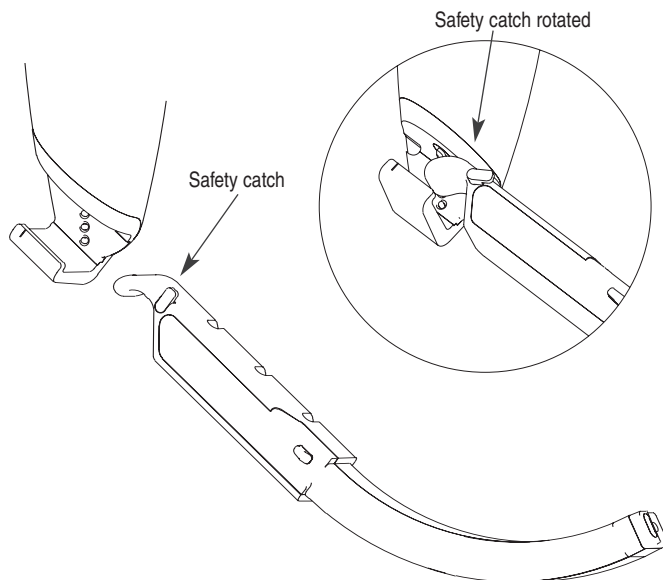


2.4 Fitting the CameraStick™

Locate the CameraStick™ module, release the **safety catch** by pulling out and rotating, then slide the CameraStick™ into the clamp at the bottom of the **handle module**. Return the safety catch to the upright position. It should be possible to hear the ratchet tooth 'clicking' as the CameraStick™ passes through the clamp. Ensure that CameraStick™ slides smoothly through the clamp whilst still requiring a reasonable amount of force to deflect the ratchet tooth.



FAILURE TO RELEASE THE SAFETY CATCH WHEN FITTING THE CAMERASTICK WILL LEAD TO DAMAGE TO THE HANDLE



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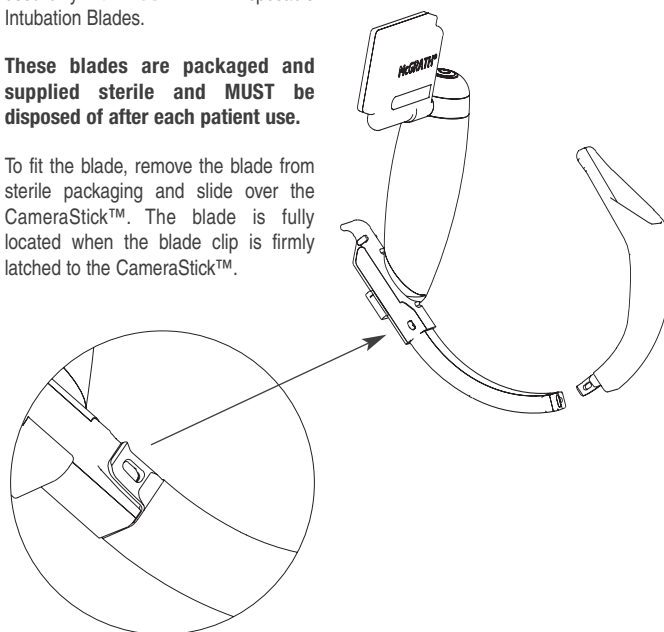
2.5

Blade Fitting

The **McGRATH®** is designed to be used only with **McGRATH® Disposable Intubation Blades**.

These blades are packaged and supplied sterile and MUST be disposed of after each patient use.

To fit the blade, remove the blade from sterile packaging and slide over the CameraStick™. The blade is fully located when the blade clip is firmly latched to the CameraStick™.



ENSURE THAT LOCAL HANDLING PROCEDURES ARE FOLLOWED AT ALL TIMES WHILST HANDLING STERILE DEVICES



CHECK THAT THE BLADE IS CORRECTLY FITTED TO THE CAMERASTICK BEFORE USING ON A PATIENT



McGRATH® BLADES MUST ONLY TO BE USED WITH A McGRATH® SERIES 5 VIDEO LARYNGOSCOPE. DO NOT ATTEMPT TO USE ANY OTHER LARYNGOSCOPE BLADE WITH THIS EQUIPMENT



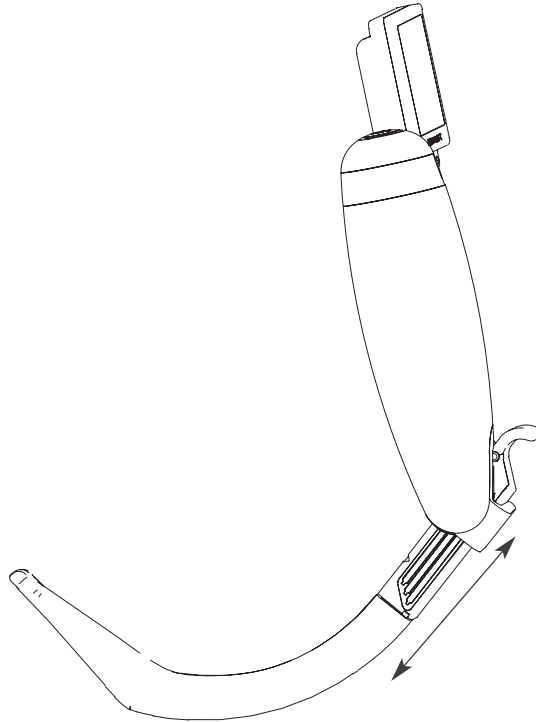
IF THERE IS ANY EVIDENCE THAT THE STERILE BARRIER ON THE BLADE PACKAGING HAS BEEN BREACHED, DO NOT USE THE BLADE



DO NOT PUT DEFOGGING LIQUID ON THE CAMERASTICK OR ON INTERNAL SURFACES OF THE BLADE

2.6 Blade Adjustment

The length of the blade may be adjusted for operation by sliding laterally through the clamp. The ratchet tooth grips the blade at 3 different length settings.



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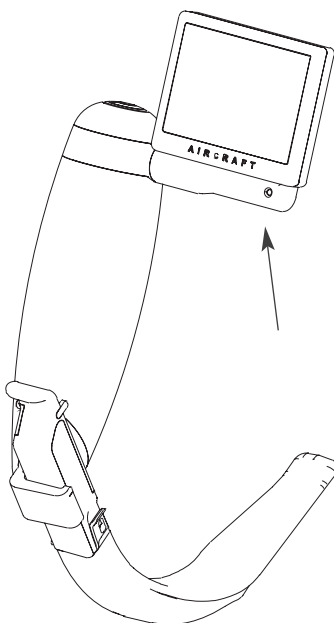
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2.7 STANDBY - Switching on / off

The Laryngoscope is switched on by pushing the STANDBY button. The LED on the display will light up to show that power is applied to the system. Switch the equipment to standby by pushing the STANDBY button. Ensure that the equipment is always switched to standby after use to preserve the charge in the battery.

When the unit is turned on the device automatically checks the charge state of the battery. If the battery has sufficient charge to operate, the LED on the display illuminates continuously.

When the device battery requires to be changed, the LED will begin to flash to indicate that the battery charge is low. When this occurs, it is recommended that the battery is changed IMMEDIATELY as the device will only remain operational for a very short period in this condition.



2.8 Using the Laryngoscope

The laryngoscope should be turned on as detailed in section 2.7. A bright light should appear at the tip of the CameraStick™, and an image on the screen at the top of the handle

Anaesthesia should be induced according to the anaesthetist's preference.

The tip of the laryngoscope blade should be inserted into the mouth in the midline, superior to the tongue, and rotated towards the larynx in a sagittal plane until the epiglottis is visible. Either direct vision, along the superior surface of the blade, or indirect vision via the camera, can be used to guide the laryngoscope tip toward the larynx. Care should be taken, as with conventional laryngoscopy, that the blade does not make contact with the teeth.

The tip of the blade should be guided into the vallecula. Further rotation, and/or minimal force applied along the long axis of the handle, should lift the epiglottis and allow the a view of the glottis. Again, either direct or indirect vision can be used to view the glottis.

Once the glottic opening has been correctly identified, a correctly sized tracheal tube can be passed between the vocal cords. A bougie or a malleable introducer may be used to assist the passage of the tracheal tube. If a malleable introducer is used, we recommend that a "hockey stick" curve be made at a point about 5cm from the tip of the tracheal tube.

The laryngoscope can then be carefully withdrawn by reversing the process described above. Confirmation of the correct placement of the tracheal tube should be both visual, and by the use of capnography.

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3 Maintenance and Cleaning



ALWAYS ENSURE THAT THE BATTERY IS REMOVED BEFORE CLEANING. THE HANDLE AND CAMERASTICK™ MUST NOT BE IMMERSERD.

3.1 Cleaning Method

3.1.1 The device should be cleaned after each patient usage. Always ensure that battery is removed when being cleaned. The unit is waterproof to a rating of IP65 and therefore NOT suitable for immersion. The device should be cleaned in accordance with local cleaning regimes for non-immersable sterile devices.

3.1.2 Dispose of all chemical disinfectants in accordance with manufacturer's guideline.



ENSURE THE DEVICE IS COMPLETELY DRY BEFORE USING



DO NOT AUTOCLAVE THIS DEVICE



DO NOT IMMERSE THE DEVICE

3.1.3 Aircraft Medical recommend that the device be cleaned and disinfected using the following guidelines:

Cleaning

- Prepare or dilute an enzymatic cleaner solution such as ENZOL (CIDEZINE) in accordance with manufacturer's instruction. Disarticulate the Handle and CameraStick, wet a sterile pad with the prepared solution and wipe all exposed surfaces of the device. The Handle and CameraStick should each be wiped for not less than 2 minutes.
- Allow the unit to dry, wet a sterile pad with sterile water and wipe all exposed surfaces of the device until any residue is removed.

Disinfection

- Wipe the device with a disinfectant solution such as Cidex OPA and allow to dry for 20 minutes.
- Wet a sterile pad with sterile water and wipe all exposed surfaces of the device.
- Intermediate disinfection may be carried out by wiping the Handle and CameraStick each 2 minutes with 70% IPA wipes.

The device may be sterilised using EtO.

3.2 Disposal of Intubation Blades

The intubation blade must be disposed of after each procedure. The blade must be disposed of in accordance with standard departmental practices.

3.3 Handling and Product Preservation

Ensure that care is taken at all times whilst handling the device. If the device is dropped, it is recommended that you check for any visible signs of damage. If the device is showing no signs of damage but is not functioning refer to the Troubleshooting Section.

It is also recommended that the battery is removed from the device and the device returned to its original packaging when not required for use.

Avoid leaving unattended in situations where it may be misused or damaged.

3.4 Environmental

Operating Conditions:

- 10°C to 40°C ambient
- Relative Humidity 10% to 50%
- Atmospheric Pressure 700h Pa to 1060 hPa
- Category 2 Pollution Degree 2

Storage & Transport Conditions:

- -10°C to +70°C ambient
- Relative Humidity 10% to 90%

3.5 Maintenance

3.5.1 Inspection

The device should be inspected at regular intervals for:

- visible signs of external damage
- scratches or defects on the lens of the CameraStick™
- signs of deterioration of the LCD display
- build-up of material on contact strips on CameraStick™ and contact pin area of Handle

3.5.2 Product Checks

Additionally, at six month intervals the following should be checked by a qualified technician:

- check for signs of oxidization on electrical contacts
- perform the functional checks

In the event of problems the device must be returned to the distributor for repair or exchange.

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3.6 Troubleshooting, Replacement Parts and Repair

Any other faults will require to be diagnosed by an authorised repair centre. The device must only be diagnosed, repaired and serviced by an official Aircraft Medical Limited distributor or agent.

Distributor Contact Details:

When switched on, there is no display on the screen.

Is the battery charge LED illuminated?

The LED is not illuminated

- Check that the battery is inserted in the correct orientation. (refer to section 2.3)
- Replace battery
- [For Service Technicians Only] Check for oxidation on the battery contacts and, if required, clean the contacts using a fibre-pencil or similar. The unit must be cleaned after any friction type device is used on it.

LED Flashing

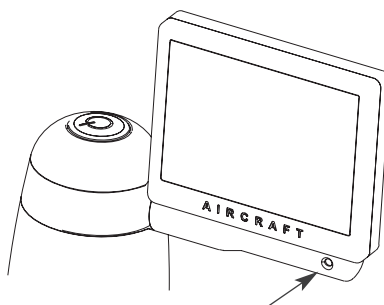
The LED flashing indicates that the battery requires changing.

- Change the battery

The LED is illuminated

- [For Service Technicians Only] Check the LEDs situated at the end of the CameraStick™ module. If these are not lit there may be oxidation of the CameraStick™ or CameraStick™ clamp contact trips / pins. Clean contacts using a fibre-pencil or similar. The unit must be cleaned after any friction type device is used on it.
- [For Service Technicians Only] The unit may be receiving no signal from the camera. This also may be caused by oxidation of the CameraStick™ or CameraStick™ clamp. Clean contacts using a fibre-pencil or similar. The unit must be cleaned after any friction type device is used on it.

If none of the above achieves positive results, return the unit to your local dealer for repair.



Poor picture quality

The image displayed on the screen is blurred or fuzzy

- Check for fogging on the intubation blade. Remove the blade and check that the image is clear and bright. If necessary wipe the camera at the end of the CameraStick™ with a clean, soft wipe.
- Check that the CameraStick™ is fully inserted in the blade and that the blade has latched to the CameraStick™ .
- [For Service Technicians Only] Clean the contact strips on the CameraStick™ and the contact pins on the handle clamp with a fibre-pencil. The unit must be cleaned after any friction type device is on it.

The image on the screen flickers or has lines across it

- Check that the battery is fully charged
- Remove battery and check battery for oxidation
- [For Service Technicians Only] Clean the contact strips on the CameraStick™ and the contact disc of the Top with a fibre-pencil. The unit must be cleaned after any friction type device is on it.

If none of the above achieves positive results, return the unit to your local dealer for repair.

Loose or poorly fitting components

If any components become loose, physically damaged or fit poorly, under no circumstances use the equipment and return the unit to your local dealer for repair or replacement.

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4 Warranty

Aircraft Medical Limited warrants that the device supplied is, on leaving the factory, free from defects in materials or workmanship. This warranty is valid only if the product is supplied to the end user by an Aircraft approved agent or distributor and has been maintained in accordance with procedures documented in the Operator's Manual. If failure occurs from manufacturing defects within 12 months of purchase, Aircraft Medical will repair or replace the defective item.



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