

McGRATH® MAC

Video Laryngoscope

Designed & manufactured
by Aircraft Medical



Operator's Manual (Instructions for use)



Doc no: 100-105-000

Revision B

April 2017

From Serial Number 300706 onwards

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Manufacturer's Declaration

The McGRATH® MAC Video Laryngoscope (the device) has been tested to product specific standard IEC 60601-1-2:2007 [Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests].

In addition, specific requirements of standard IEC 60601-2-18:2009 [Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment] have been applied that relate to IEC 60601-1-2:2007.

The following tables contain the corresponding manufacturer's declaration for the electromagnetic emissions and electromagnetic immunity of the device.

Table 1 - Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. The operator of the device should assure that it is used in such an environment.		
Emissions Test	Compliance Level	Notes
Conducted RF emissions CISPR 11:2009 +A1:2010	Not Applicable	Test not applicable as the device is battery powered
Radiated RF emissions CISPR 11:2009 +A1:2010	Group 1 Class B	Compliant
Harmonic emissions IEC 61000-3-2:2005 +A1:2008+A2:2009	Not Applicable	Test not applicable as the device is battery powered
Voltage fluctuations/flicker IEC 61000-3-3:2008	Not Applicable	Test not applicable as the device is battery powered

Table 2 - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The operator of the device should assure that it is used in such an environment.		
Immunity test	Compliance level	Notes
Electrostatic Discharge (ESD) IEC 61000-4-2:2008	±2 kV, ±4 kV and ±6 kV contact ±2 kV, ±4 kV and ± 8 kV air	Compliant
Radiated RF Immunity IEC 61000-4-3:2006 +A1:2007+A2:2010	3 V/m Modulation of 80% AM @ 1 kHz. Frequency 80 MHz - 2.5 GHz	Compliant
Electrical Fast Transient Bursts IEC 61000-4-4:2012	Not Applicable	Test not applicable as the device is battery powered
Surge Immunity IEC 61000-4-5:2014	Not Applicable	Test not applicable as the device is battery powered
Conducted RF Immunity IEC 61000-4-6:2003+A1:2004+A2:2006	Not Applicable	Test not applicable as the device is battery powered
Magnetic Immunity IEC 61000-4-8:2009	3 A/m	Compliant
Voltage Dips IEC 61000-4-11:2004	Not Applicable	Test not applicable as the device is battery powered



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1 Introduction

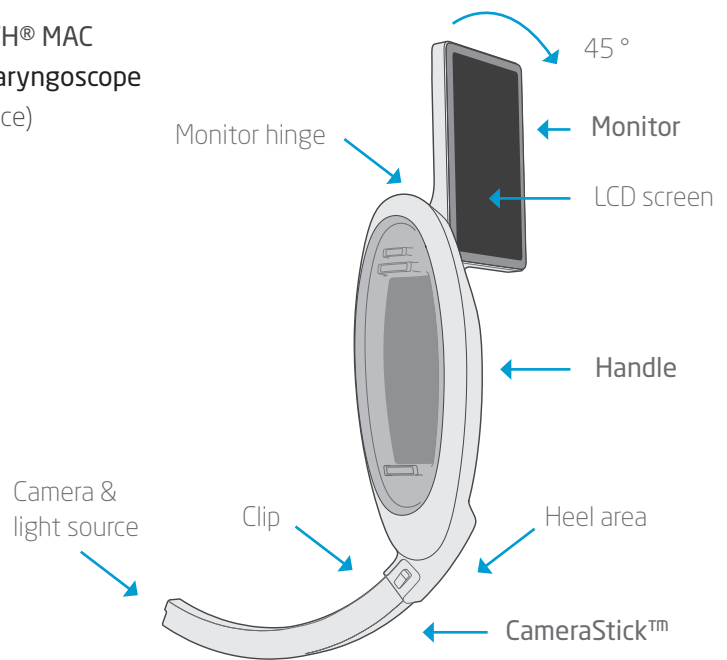
1.1 Description

The McGRATH® MAC Video Laryngoscope (McGRATH® MAC or the device) is a tool used to aid the intubation of the trachea. As a rigid laryngoscope it holds and shapes the anatomy allowing a clear view of the larynx and entrance to the trachea. The need to provide a secure airway is fundamental to an anesthesiologist's role prior to a surgical procedure. Paramedics, emergency physicians 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.

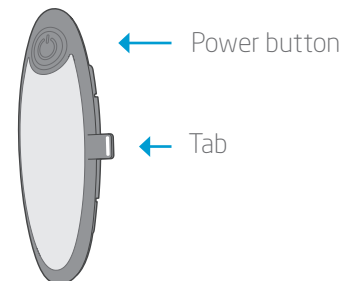
The device incorporates a light source (LED) and miniature camera (camera) to view the larynx during the procedure of laryngoscopy. The image is displayed on an LCD screen (screen) contained within a monitor mounted to the handle of the device.

A McGRATH® MAC 3.6V battery (battery unit) mounted within the handle powers the screen, camera, and LED. The McGRATH® disposable laryngoscope blade (blade) covers the camera and LED assembly (CameraStick™) to prevent direct patient contact. McGRATH® blades are supplied sterile and are single use.

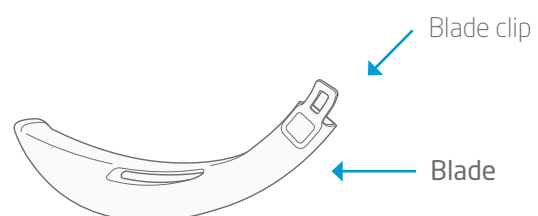
**McGRATH® MAC
Video Laryngoscope**
(the device)



**McGRATH® MAC
3.6V Battery**
(battery)



**McGRATH®
disposable
laryngoscope
blade (blade)**
SUPPLIED SEPARATELY





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, PATIENT SAFETY AND VOID THE WARRANTY



NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE MIXTURES

The device is supplied with a battery. Blades and additional batteries can be purchased separately from your Aircraft Medical agent or distributor.

McGRATH® MAC Video Laryngoscope	300-000-000
McGRATH® 3.6V Battery	340-000-000
McGRATH® MAC 1 Disposable Laryngoscope Blades (Carton of 50)	350-072-000
McGRATH® MAC 2 Disposable Laryngoscope Blades (Carton of 50)	350-017-000
McGRATH® MAC 3 Disposable Laryngoscope Blades (Carton of 50)	350-005-000
McGRATH® MAC 4 Disposable Laryngoscope Blades (Carton of 50)	350-013-000
McGRATH® X blade™ X3 Disposable Laryngoscope Blades (Carton of 10)	X3-003-000
McGRATH® MAC Quick Start Guide	300-048-000
McGRATH® MAC Product Box	300-040-000

1.3 Specifications

Laryngoscope Assembly

Size	180mm x 68mm x 110mm
Weight	0.200kg
Power	Proprietary 3.6V Lithium Battery *Giving 250 minutes of use typically
Protection	IPx7
Light source	High intensity LED
Display	2.5" LCD colour display
Camera	CMOS
Materials	Durable medical grade thermoplastics with reinforced structural alloy core. The device and packaging are latex free

* WHERE THE AMBIENT TEMPERATURE IS 20°C. BATTERY LIFE MAY VARY WHERE THE AMBIENT TEMPERATURE IS HIGHER OR LOWER





Disposable Laryngoscope Blade


The device must be used only with McGRATH[®] disposable laryngoscope blades

Material	Medical grade optical polymer
Packaging	Packaged sterile for single use only
	This device and packaging are latex free

1.4 Regulatory

 This product complies with ISO 7376, EN 60601-1 and EN 60601-1-2 safety standards. The CE mark indicates that it meets the requirements of European Council Directives 93/42/EEC and 2007/47/EC concerning medical devices.

 In addition to the above compliance, sterility aspects of the McGRATH[®] Disposable Laryngoscope Blade have been certified by Aircraft Medical's notified body.

 The McGRATH[®] Disposable Laryngoscope Blade is classified as a type BF applied part in accordance with section 8.3 of EN60601-1.

The device is regulated in the USA under FDA Regulation Number 868.5540 and device listed under the name McGRATH[®] MAC.

"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.

"X blade" and "X3" are trademarks of Aircraft Medical Limited.

"E.T. CONTACT ZONE" is a trademark of Aircraft Medical Limited.

"DepthGuide" 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 their Aircraft Medical agent or 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 country of use).

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

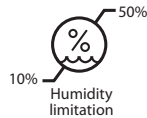


1.5 Environmental

McGRATH® MAC Device and Battery

Operating Conditions:

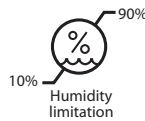
- 10°C to 40°C ambient
- Relative Humidity 10% to 50%
- Atmospheric Pressure 700hPa to 1060hPa
- Category 2 Pollution Degree 2



McGRATH® MAC Device and Battery

Storage & Transport Conditions:

- -10°C to 40°C ambient
- Relative Humidity 10% to 90%



McGRATH® MAC Blade

Storage & Transport Conditions:

- -10°C to 70°C

The McGRATH® MAC Video Laryngoscope and replacement batteries when purchased are supplied non sterile prior to use. They should be cleaned and disinfected before use.



2 Functional

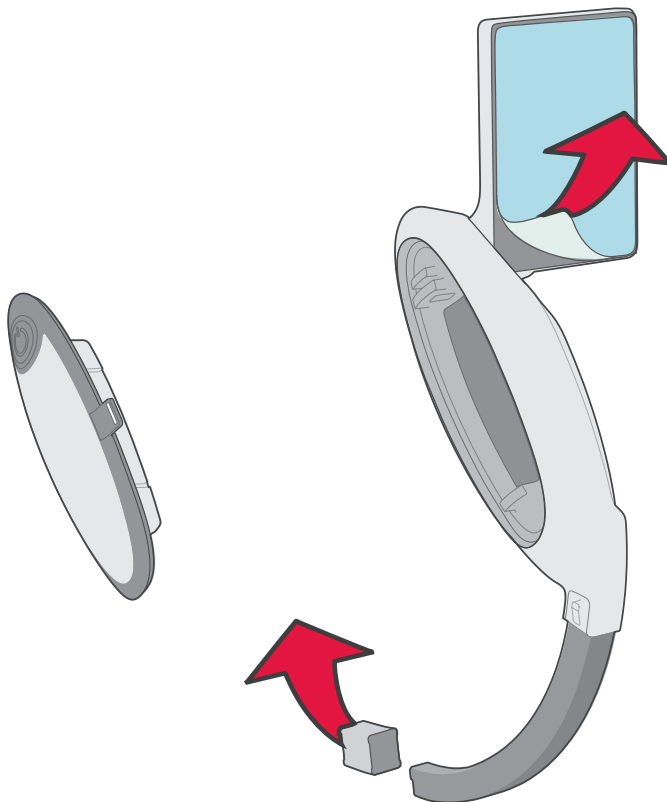
2.1 Unpacking and Inspection

Unpack the device 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 device and inform your Aircraft Medical agent or distributor.

Remove the protective sheet from the monitor screen.

The device and battery unit are supplied separately in a non-sterile state. It will be necessary to clean and disinfect the device and battery before first patient use, as instructed in Section 3 of this manual.

The laryngoscope blade is supplied in a sterile state. Ensure that handling precautions are taken in accordance with local, national and harmonised standards. (Please note that the McGRATH[®] disposable laryngoscope blades are not supplied with the device. These are packed and purchased separately).





2.2 Battery

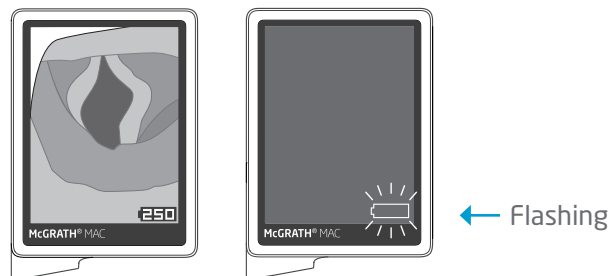
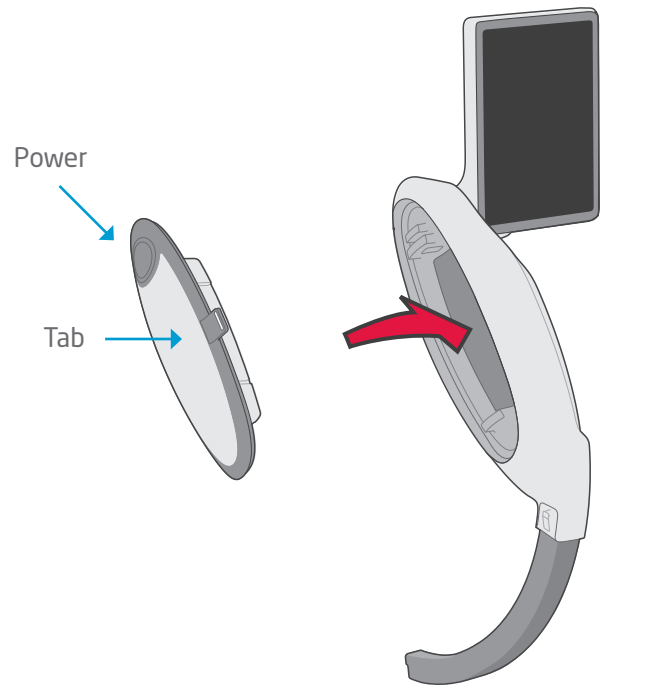
The device must only be used with the McGRATH[®] 3.6V battery. Push the battery unit into the cavity of the handle as illustrated.

The device turns on and off by a single push of the Power button.

The life of the battery unit is displayed on the bottom right hand corner of the screen. This counts down from 250 as each unit of power is consumed. When the counter reaches 4, the battery icon will flash. Replace the battery unit when this happens.

Remove the battery unit by pulling the tab and dispose of under local regulations for disposal of batteries.

If the device is not to be used for an extended period of time (more than 1 month) remove the battery unit before storage.





2.3 Disposable Laryngoscope Blade Fitting

To fit the blade, open the peel pouch and slide the blade over the CameraStick™ portion of the device. The blade is fully located when the blade clip is firmly latched to the CameraStick™. To remove the blade lift the clip and pull the blade off.



McGRATH® DISPOSABLE LARYNGOSCOPE BLADES ARE SINGLE USE AND MUST BE DISPOSED OF AFTER EACH PATIENT USE



ENSURE THAT LOCAL HANDLING PROCEDURES ARE FOLLOWED AT ALL TIMES WHILE HANDLING DISINFECTED DEVICES



McGRATH® DISPOSABLE LARYNGOSCOPE BLADES MUST ONLY BE USED WITH A McGRATH® MAC VIDEO LARYNGOSCOPE. CHECK THAT THE BLADE IS CORRECTLY FITTED TO THE CAMERASTICK™ BEFORE USE



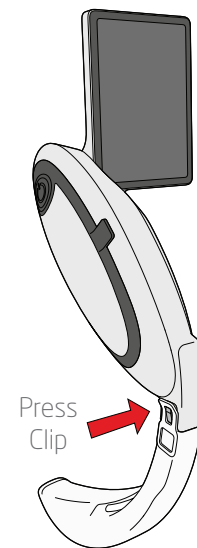
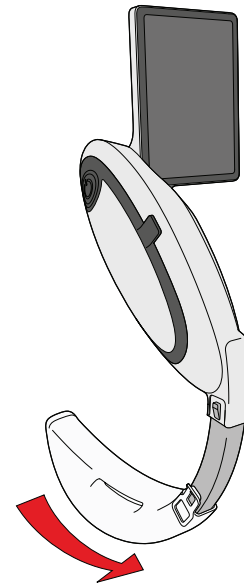
PRESS THE BLADE CLIP TO ENSURE THAT THE BLADE IS SECURELY ENGAGED. IF THE BLADE CLIP DOES NOT SECURELY ENGAGE ONTO THE CAMERASTICK™ DO NOT ATTEMPT TO USE THE BLADE



DO NOT ATTEMPT TO USE ANY OTHER LARYNGOSCOPE BLADES WITH THE DEVICE



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





2.4 Using the Laryngoscope

Multiple disposable blade types are available for use with the McGRATH® MAC Video Laryngoscopes.

The McGRATH® MAC range of disposable blades are for use with routine and difficult airways. The McGRATH® X blade™ range are for use with difficult and extreme airways. These blades require different techniques which are explained in the Addendum section of this manual.

The Addendum comprises the following sections:




- Using the Laryngoscope - McGRATH® MAC blade range
- Using the Laryngoscope - McGRATH® X blade™

3 Cleaning and Low Level Disinfection

The device and battery should be cleaned and low level disinfected separately after each patient use. Cleaning and low level disinfection should be carried out as per section 3.1, 3.2, 3.3, and 3.4 of the manual in accordance with local regulations. Follow hospital policy and protocol when handling and cleaning soiled items.

The instructions provided have been validated by Aircraft Medical as being capable of preparing the device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. This normally requires validation and routine monitoring of the process.

The following methods have been approved by Aircraft Medical:

PRODUCT	CLEANING	LOW LEVEL DISINFECTION*
 McGRATH® Disposable Laryngoscope Blade	Supplied Sterile Do Not Reprocess	Supplied Sterile Do Not Reprocess
 McGRATH® MAC with McGRATH® 3.6V Battery removed	70% IPA Wipe	70% IPA
 McGRATH® 3.6V Battery	70% IPA Wipe	70% IPA



ENSURE THE DEVICE IS COMPLETELY DRY BEFORE USING



DO NOT AUTOCLAVE THE DEVICE



DO NOT REPROCESS THIS DEVICE IN AN ULTRASONIC CLEANER

When cleaning and low level disinfecting the McGRATH[®] MAC with the battery unit removed, low level disinfection claims will only apply to exposed surfaces of the McGRATH[®] MAC and McGRATH[®] 3.6V Battery.

Dispose of 70% IPA wipes in accordance with local regulations and hospital policy.

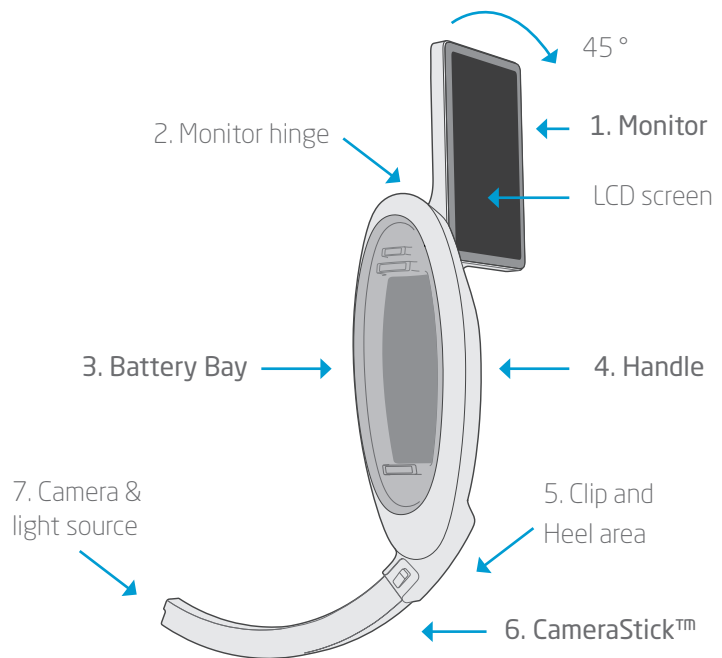


3.1 Device Cleaning

Clean with 70% IPA Wipe, With McGRATH® 3.6V Battery Removed

The following process steps should be followed to clean the device: Using a 70% IPA wipe, clean the device systematically working from Steps 1 through 7 (from top to bottom of the device). Ensure that the 70% IPA wipe comes in contact with all surfaces of the device even if no visible soiling is present. Ensure a minimum contact time of 1 minute on all surfaces when using 70% IPA wipes.

1. **Monitor:** Ensure the 70% IPA wipe gets into the various grooves around the screen.
2. **Monitor Hinge:** Rotate the monitor to the upright position. Feed the 70% IPA wipe into the space between the monitor and handle to ensure effective penetration. Rotate the monitor to its opposite position and repeat.
3. **Battery Bay:** Ensure all surfaces of the Battery Bay (with battery removed) are thoroughly treated with the 70% IPA wipe. Ensure that the join between the battery module and the handle is thoroughly treated with the 70% IPA wipe.
4. **Handle:** Ensure all surfaces of the handle are thoroughly treated with the 70% IPA wipe.
5. **Clip and Heel Area:** Take particular care in ensuring that the small metal clip feature is clean, in particular the internal corner between the clip and the surrounding plastic body.
6. **Camera Stick:** Ensure all surfaces of the camera stick are thoroughly treated with the 70% IPA wipe.
7. **Camera Lens:** Clean the camera lens with the 70% IPA wipe, ensure that the interface between the metal Camera Stick and camera lens is clean.



Subsequent cleaning should be repeated where visible soiling is still present using a new 70% IPA wipe.

3.2 Device Low Level Disinfection

Disinfect with 70% IPA Wipe, With McGRATH[®] 3.6V Battery Removed

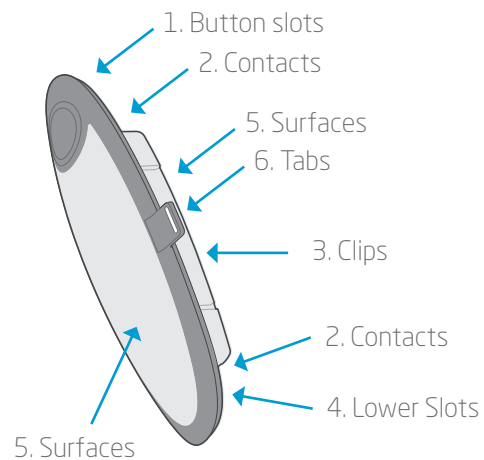
Follow the same process steps as per cleaning, to low level disinfect the device. Using a new 70% IPA wipe, disinfect the device systematically working from Steps 1 through 7 as per cleaning instruction (from top to bottom of the device). Ensure that the 70% IPA wipe comes in contact with all surfaces of the device. Ensure a minimum contact time of 1 minute on all surfaces when using 70% IPA wipes.

3.3 Battery Cleaning

Clean with 70% IPA Wipe - McGRATH[®] 3.6V Battery

The following process steps should be followed to clean the battery. Using a 70% IPA wipe, clean the device systematically working from Steps 1 through 6 (from top to bottom of the battery cover). Ensure that the 70% IPA wipe comes in contact with all surfaces of the device even if no visible soiling is present. Ensure a minimum contact time of 1 minute on all surfaces when using 70% IPA wipes.

1. **Battery Slot:** Ensure the 70% IPA wipe gets into the two button slots at the back of the battery push button.
2. **Contacts:** Ensure the 70% IPA wipe gets into the space around and under the two metal battery contacts.
3. **Clips:** Run the 70% IPA wipe along and into the gaps around the battery retaining clips
4. **Lower Slot:** Ensure the 70% IPA wipe gets into the lower slot at the base of the battery.
5. **Surfaces:** Wipe all surfaces of the battery cover with the 70% IPA wipe
6. **Tab:** Run the 70% IPA wipe along all surfaces of the Tab.



Subsequent cleaning should be repeated where visible soiling is still present using a new 70% IPA wipe.



3.4 Battery Low Level Disinfection

Disinfect with 70% IPA Wipe - McGRATH® 3.6V Battery

Follow the same process steps as per cleaning, to low level disinfect the battery.

Using a new 70% IPA wipe, disinfect the device systematically working from Steps 1 through 6 as per cleaning instruction (from top to bottom of the device).



4 Storage

Post cleaning and decontamination, the device and battery should be air dried or wiped dry with a lint free cloth.

Decontaminated devices should be packaged immediately upon completion of the 2 minute drying phase and should be stored in accordance with local guidelines.

The McGRATH® MAC Video Laryngoscope and replacement batteries when purchased are supplied non sterile prior to use. They should be cleaned and disinfected before use.



5 Troubleshooting



IF ANY COMPONENTS BECOME LOOSE, PHYSICALLY DAMAGED OR FIT POORLY, UNDER NO CIRCUMSTANCES USE THE EQUIPMENT. INSTEAD RETURN IT TO YOUR AIRCRAFT MEDICAL AGENT OR DISTRIBUTOR FOR REPAIR OR REPLACEMENT.

No image shown on screen

If, when switched on, there is no display on the screen

- Replace battery unit.

Poor picture quality

If the image displayed on the screen is blurred or fuzzy

- Replace the blade
- Remove the blade and check that the image is clear. If necessary wipe the camera at the end of the CameraStick™ with a lint free wipe.

If none of the above achieves positive results, return the unit to your Aircraft Medical agent or distributor for diagnostics and repair.

No parts of the device are to be serviced or maintained while in use with the patient.

Ensure that before each use, the outer surface of the blade should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.

During use with MAC blade, if the camera system loses function and the LED remains functioning, the device can still be used as a direct view Laryngoscope. During use with the MAC blade, a failure of the LED requires the removal of the Video Laryngoscope and an alternative device to be used. During use with the X-Blade, any failure of the camera system or LED requires the removal of the Video Laryngoscope and an alternative device to be used.



6 Warranty

The McGRATH® MAC is supplied with a manufacturer's warranty.

- Only products supplied by an approved Aircraft Medical agent or distributor are covered by the manufacturer's warranty.
- To be covered by the warranty the product must be maintained in accordance with the procedures documented in the Operator's Manual.
- Devices returned under the warranty claim should be decontaminated per the Cleaning and Low Level Disinfection method defined in section 3 before transportation.

For full terms of warranty, please contact your Aircraft Medical agent or distributor.

McGRATH® MAC

Video Laryngoscope

Designed & manufactured
by Aircraft Medical



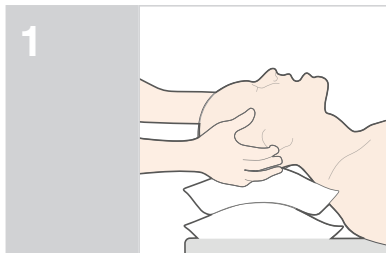
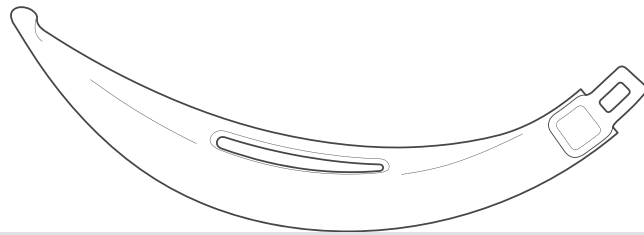
Addendum

Using the Laryngoscope - McGRATH® blade range

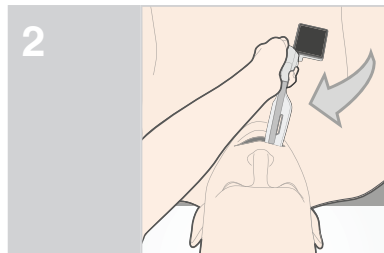
- Using the Laryngoscope - McGRATH® MAC blade range
- Using the Laryngoscope - McGRATH® X blade™



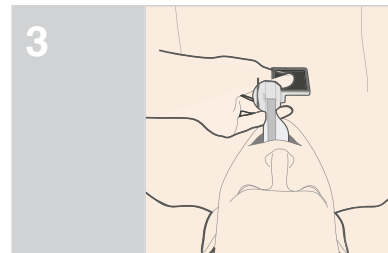
USING THE LARYNGOSCOPE - McGRATH[®] MAC blade range



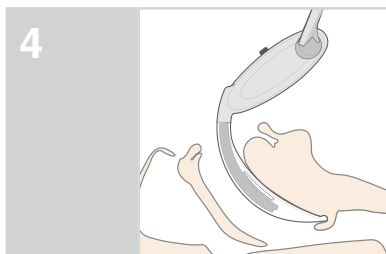
1 If possible, position the patient in the optimal position for direct laryngoscopy.



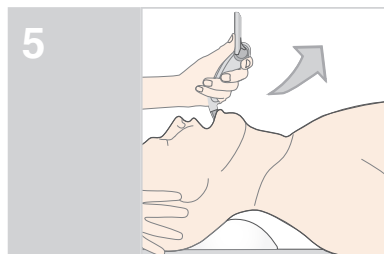
2 Look into the mouth; insert the blade into the right side of the mouth.



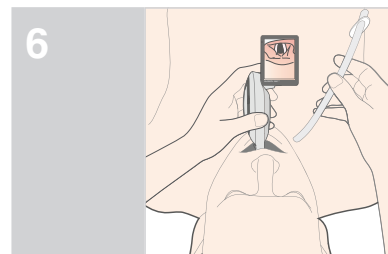
3 Move the device to a central position while sweeping the tongue to the left.



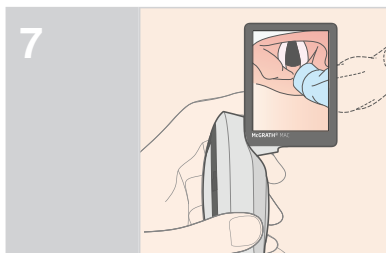
4 Advance the tip of the McGRATH[®] MAC blade into the vallecula.



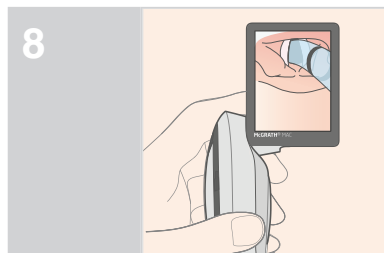
5 Visualise the epiglottis on the screen. Lift the anatomy forwards and upwards to expose a direct and indirect view of the glottis. When the device is in the optimal position the glottis should be viewed in the central upper section of the screen.



6 Advance the tube gently and atraumatically through the vocal cords. Tube placement can be performed either by looking directly in the mouth, indirectly on the screen or a combination of both(1).



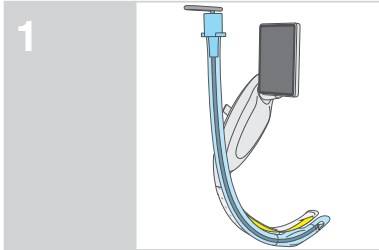
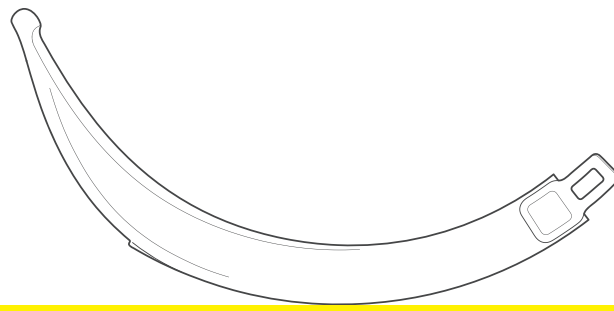
7 Indirectly visualise the tube placement through the vocal cords. In optimal tube placement technique, the E.T. tube will enter from the right hand side of the display.



8 The screen view can be used to confirm the correct insertion depth of the endotracheal tube.

(1) If a direct pathway for the tube was not created by sweeping the tongue or aligning the airway axes a stylet or a bougie may need to be used.

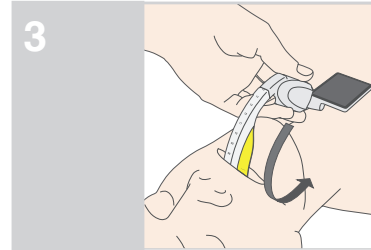
USING THE LARYNGOSCOPE - McGRATH® X blade™



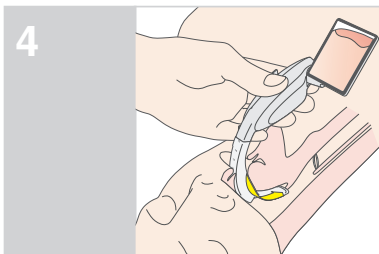
1 Load the E.T. tube onto a stylet(1) and form to the curvature of the X blade™.



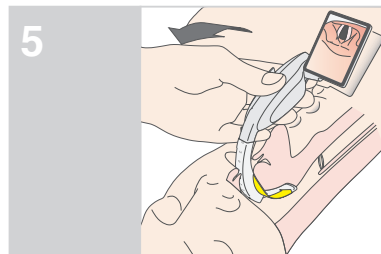
2 Where possible, elevate the patient's head into the "sniffing" position for optimal access.



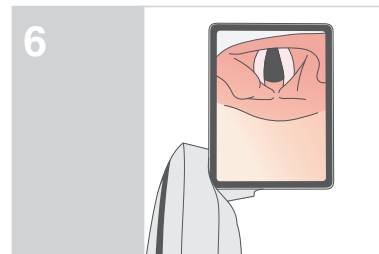
3 Using a mid-line approach roll the blade into the mouth. Ensuring the anterior side of the blade maintains contact with the tongue, advance the blade until the epiglottis is seen on the top of the screen.



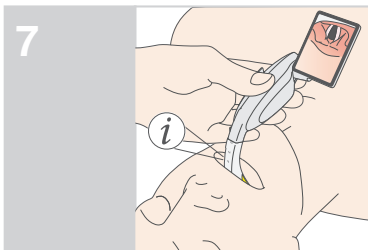
4 Place the tip of the X blade™ into the vallecula.



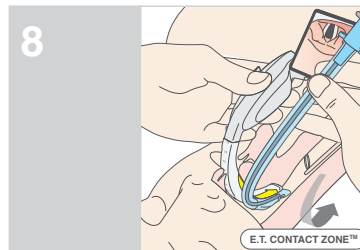
5 Using minimal force, rock the device back towards the user to lift the epiglottis and obtain an indirect view of the glottis.



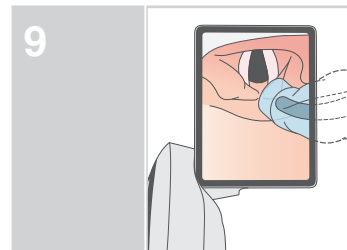
6 When the device is in the optimal position the glottis will be viewed in the central upper section of the screen(2).



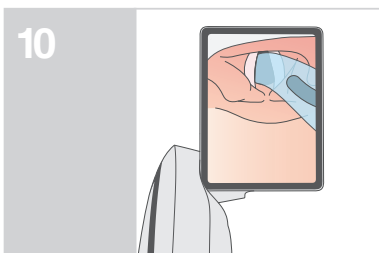
7 The DepthGuide™ numeric markings on the posterior side of the blade may be used as an indication of the depth of blade insertion(3).



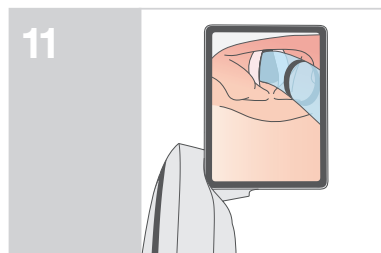
8 Insert the E.T. tube at the right side corner of the mouth. Advance in a rolling movement following the curvature of the blade, ensuring it maintains contact with the section of the blade labelled E.T. CONTACT ZONE™.



9 When using optimal technique, the E.T. tube should enter the screen on the right hand side; advance the tube until the tip is in front of the vocal cords.



10 Holding the stylet secure, slide the tube off the stylet and through the cords, ensuring the stylet does not pass through the cords. Once the tube has passed through the cords remove the stylet completely.



11 The screen view can be used to confirm the correct insertion depth of the endotracheal tube.

(1) Clinical experience has shown that intubation without any introducer, or with a bougie, will not facilitate optimal tube placement.

(2) It is important not to advance the blade too deep in order to maintain maximum space to facilitate the E.T. tube placement.

(3) Reference to these numbers can be useful during training to avoid inserting the blade too far.



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