Airtraq Avant
VIDEO LARYNGOSCOPE

US Patent No 6,843,769

OPTICS
INSTRUCTIONS FOR USE

ENGLISH

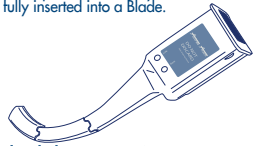
DESCRIPTION

The Airtraq Avant is a video laryngoscope designed to facilitate intubation. It allows full visualization of the airway, during 100% of the intubation. It does not require hyperextension of the neck and permits intubating patients in virtually any position.

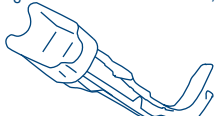
COMPONENTS

Airtraq Avant comprises 3 elements that have to be assembled by the user every time an intubation is to be performed:

The Optics: A **REUSABLE** piece that contains the optical, the anti-fog and the electronic systems and that is articulated to facilitate its insertion into the blade; The Optics element only works when it is fully inserted into a Blade.

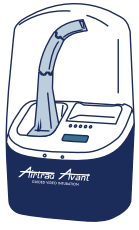


The Blade: A **DISPOSABLE** rigid piece of plastic, anatomically shaped, that consists of two side by side channels. One channel, which terminates in a distal lens, for insertion of the optics, and the other channel, open at its distal end, acts as a guide for the endotracheal tube,



The Eyecup: A **DISPOSABLE** piece that is assembled on top of the blade and which also has a proximal lens.

Additionally the Airtraq Avant system includes a Docking station that recharges the battery of the optics and displays its remaining service life. In case the Optics become damaged the LCD will show an error code. Detailed Instructions for Use of the Docking station are provided in its corresponding package. No service of the Docking station is required.



OPTICS SERVICE LIFE

Airtraq Avant Optics Service Life is defined by the manufacturer as the Number of Times that the Optics are functional. It is equal to 50 uses. Once the Service life is finished the Optics should be discarded by the user.

Service Life starts the first time the user turns on the Optics. Each time the Optics is turned on and the lens warming period has finished counts as one use.

The number of uses remaining, is displayed in the Docking Station when the Optics is inserted into it. The Optics also includes a light indicator that provides information about Service Life available:

- A steady green light means that there are 10 or more uses remaining,
- A blinking orange light means that there are less than 10 uses remaining,
- A steady red light means that the service life is finished.

Blades and Eyecup shelf life is limited to the expiration date.

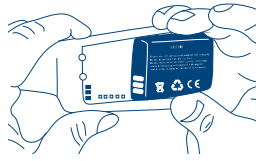
OPERATING, STORAGE AND TRANSPORT

The Optics should not be used, stored or transported at temperatures below 0 ºC/32ºF or over 40º C/104ºF. The relative humidity must not exceed 95 %. The air pressure must not exceed 500 to 1060 hPa.

BATTERY CHARACTERISTICS

Each Optics is equipped with a rechargeable battery that provides a voltage of 3.7 volts and powers the LED light and the anti-fog system.

The battery should be inserted before used. To insert the battery, remove the Optics battery cover, hold the battery like in the drawing below and place it in the battery case in this position.



The battery is supplied discharge. It is recommended to perform a full charge/discharge cycle of the battery before starting to use the Optics for Clinical purposes.

When the battery is fully charged the Optics can be used for approximately 15 intubations. The manufacturer recommends recharging the Optics battery using the Docking station after each intubation. A full recharge cycle of the battery will take 2 hours. The period of time to discharge, without use, a fully charged battery is over 30 days.

When the Optics is inserted into the Docking station it displays the battery charge status. The Optics also includes a light indicator that provides battery charge information.

- A steady green light means that there is more than 25 % battery charge remaining,
- A blinking orange light means that there is less than 25 % battery charge remaining, (approximately 4 intubations).
- A steady red light means that the battery charge is below 15 %.
- If the user tries to turn on the Airtraq Avant and battery is below 15 %, then the Optics will automatically turn off after 5 seconds, so a new intubation cannot be started.

In order to avoid undesired discharge of the battery, Optics is automatically turned off if it is left on inside a blade, for more than 30 minutes. Three minutes before turning off, the light will flash every 10 seconds.

BLADE SIZES

Regular: A-511. Size 3

For use with ETT 7.0 – 8.5. Minimum patient mouth opening: 17 mm

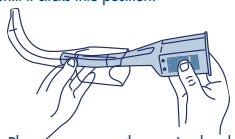
Small: A-521. Size 2

For use with ETT 6.0 – 7.5. Minimum patient mouth opening: 17 mm

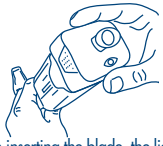
INTUBATION TECHNIQUE WITH AIRTRAQ AVANT

I. OPTICS, BLADE AND EYECUP ASSEMBLY

- Check Optics battery status and service life available in the Docking Station.
- Select the appropriate blade size based on the size ETT to be used.
- Insert the Optics into the blade fully, until it clicks into position.



- Place eyecup over the proximal end of the Optics with eye symbol facing the user.



- Upon inserting the blade, the light will automatically start blinking for approximately 90 seconds until the anti-fog warms the lens of the blade. Once the device is ready for intubation the light will become steady.

II. PREPARATION

- Fully deflate the ETT cuff.
- Lubricate the ETT and place it into the lateral channel of the blade.
- Align the tip of the ETT with the end of the lateral channel.
- Appropriately lubricate the blade without contacting blade´s lens.

III. AIRTRAQ AVANT PLACEMENT INTO THE AIRWAY

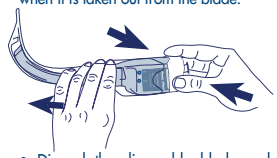
- Insert the Airtraq Avant into the midline of the patient's mouth. Take special care to avoid pushing the tongue inside the oropharynx. In some circumstances it may help to introduce it using the same technique as with a Guedel airway (Fig 1).
- Slide the Airtraq Avant through the oropharynx keeping it in the midline.
- Before it reaches the vertical plane, begin looking through the eyecup to identify airway structures (Fig 2).
- Continue insertion until the epiglottis is identified. Place the tip of the blade in the vallecula. Alternatively, the blade can be placed under the epiglottis, lifting it out of the way.
- Gently lift up the Airtraq Avant to expose the vocal cords (Fig 3).

IV. ETT INSERTION AND AIRTRAQ AVANT REMOVAL FROM PATIENT'S AIRWAY

- **Align the vocal cords in the center of the visual field** by gently moving the tip of the blade as needed.
- Gently advance the ETT in the lateral channel until it is visualized passing through the vocal cords. Check insertion depth (Fig 4).
- Inflate the ETT cuff as normal and check for proper positioning. Reposition, if needed.
- Separate the ETT from the Airtraq Avant by pulling it laterally from the ETT, while holding the ETT in position (Fig.5).
- Remove the Airtraq Avant from the patient´s airway following the midline.

V. DISASSEMBLY OF AIRTRAQ AVANT

- Separate the Airtraq Avant Optics from the Blade by firmly gripping both lateral sides of the eyecup and pulling apart. Make sure the Optics do not become in contact with any potentially contaminated surface.
- The Optics automatically turns off when it is taken out from the blade.



- Discard the disposable blade and eyecup as any other potentially contaminated waste following local governing ordinances and recycling plans regarding disposal or recycling.
- If needed, place the Optics back onto the Docking Station to recharge the battery.

USAGE TIPS

1. Initial experience should be gained in non-difficult airways.
2. Insert the Airtraq Avant, avoiding the tongue, and slide it softly and slowly.
3. Keep the Airtraq Avant in the mouth's midline.
4. Look through the eyecup before the Airtraq Avant gets to the vertical plane.
5. If structures (arytenoids, epiglottis, etc,) are not clearly recognized, withdraw the Airtraq Avant slightly.
6. Once the tip is located at the epiglottis, either at the vallecula (Macintosh style), or under the epiglottis (Miller style), gently lift up the Airtraq Avant (do not tilt or use a lever action).
7. Advance the ETT slowly.

MR CONDITIONAL

Non-clinical testing demonstrated that Airtraq Avant is MR Conditional and can be used in the MRI environment according to the following conditions:

- Static magnetic field of 3-Telsa or less
- Spatial gradient magnetic field of 720-Gauss/cm or less

IMPORTANT NOTE: The Airtraq Avant may be inside of the MRI environment (e.g., in the MR system room). It should not be utilized directly inside of the MR system (e.g., inside of the bore of the scanner), during its operation (i.e., scanning). As such, the assessment of magnetic field interactions of the product specifically involved evaluations of transitional attraction in relation to exposure to a 3-Tesla MR system, **only**.

WARNINGS AND PRECAUTIONS

- This product should only be used by personnel trained in insertion of endotracheal tubes.
- Do not put pressure on the teeth with this device.
- Do not touch the Optics LED.
- Do not force the Airtraq Avant into the upper airway.
- Do not incinerate unless battery has been removed.
- Do not submerge in liquids.
- Use only with non-flammable anesthetics.

OPTICS CLEANING AND DISINFECTION

Optics can be inserted and disengaged from the blade without contacting it.

Optics should never be in contact with the patient. Therefore, it is classified as a non-critical device.

In case that the Optics accidentally become dirty, recommended cleaning is low-level disinfection. Be sure to follow your institution's specific cleaning procedures in consultation with this manual.

1. Remove the Optics from the blade.
2. Cleaning: Use clean cotton gauze pads that are saturated with the cleaning solution to wipe down the exterior surfaces of the Optics. Use soft brushes with the cleaning solution to access areas that cannot be reached with the gauze pads. Be careful to keep running liquid off the surfaces. The following cleaning solutions may be used:
   a. Enzymatic Cleaning Solutions (e.g.: ENZOL™ Enzymatic Detergent).
   b. Neutral pH soap and water.
   c. Sodium bicarbonate solution (8-10 %).
3. The following Disinfection Agents may be used:
   a. Cidex™ OPA
   b. Peracetic Acid Solution (0.08%).
   c. Isopropyl Alcohol (70%).
   d. Solution containing 70% isopropyl alcohol and 2% chlorhexidine (e.g. Clinell Wipe).
   e. Solution containing chlorine dioxide (e.g. Tristel Wipe)
4. Blot dry the Optics using an individual sterile surgical towel.
5. Caution:
   - Do not autoclave.
   - Do not rinse under running water.
   - Do not soak in liquids.
   - Avoid liquid or moisture from going inside the Optics.
   - Avoid touching the lens of the Optics.

OPTICS DISPOSAL INSTRUCTIONS

Once the Service Life of the Optics is finished it should be disposed of as follows:

- Remove the battery cover by pulling it away from the main body (pull away from the small notches).
- Remove the battery from the Airtraq Avant and place it in an appropriate battery recycling container. The batteries are classified as non hazardous waste material and comply with European Directive WEEE.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

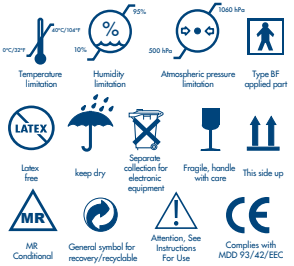
MANUFACTURER´S WARRANTY

The manufacturer warrants the Airtraq Avant Optics against faulty materials or manufacturing defects during the full Service Life of the device and and for a period of two years from the date of purchase, whichever comes first, provided that it is used in accordance with the procedures set forth in these instructions. This Warranty is applicable only if the device is purchased from an authorized distributor.

The AIRTRAQ AVANT BLADE and EYECUP are designed for SINGLE PATIENT USE.

Warning! Cleaning and reuse of the AIRTRAQ AVANT BLADE may compromise patient safety

Use of Airtraq Avant Blades that have been cleaned or sterilized after previous use may generate serious consequences in the product's performance and will void the Airtraq Avant warranty. The manufacturer disclaims all other warranties, whether expressed or implied, including, without limitation, the warranties of merchantability or fitness for a particular use.



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EU Representative:
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Muelle Tomás Olavarri 5, 3º
48930 Las Arenas SPAIN

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

For further advice on using the Airtraq Avant please visit:
www.airtraq.com or contact:
info@airtraq.com or
info.usa@airtraq.com

Fig 1

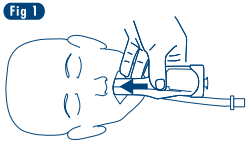

Fig 2

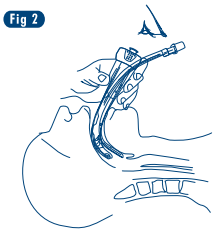

Fig 3

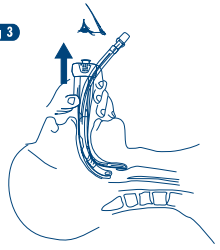

Fig 4

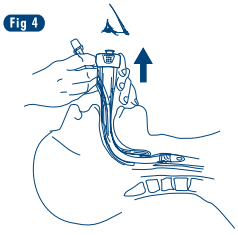

Fig 5