Airtraq Avant
VIDEO LARYNGOSCOPE

US Patent No 6,843,769

OPTICS
INSTRUCTIONS FOR USE

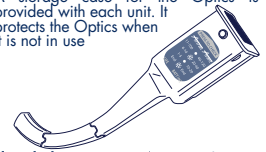
ENGLISH

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 hyper extension of the neck and permits intubating patients in virtually any position. Visualization can be performed directly through the eyecup or connecting it to any Endo Cam or to the accessories offered by the manufacturer.

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.

A storage case for the Optics is provided with each unit. It protects the Optics when it is not in use



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 provides direct connection to most Endo Cams.

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 100 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 between 11 and 100 uses remaining,
- A blinking green light means that there are between 6 and 10 uses remaining,
- A steady orange light means that there are between 1 and 5 uses remaining,
- A blinking orange 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 -5°C/23°F or over 55°C/131°F. The relative humidity must not exceed 95 %. The air pressure must not exceed 500 to 1060 hPa.

In order to protect the Optics, when not in use, insert it into its storage case.

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 Optics are packed with the battery already assembled. Remove the plastic tab off the battery box before first use.

The OPTICS DOES NOT WORK WHEN IT IS BEING CHARGED. IT SHOULD BE CHARGED AT LEAST 1.8 M AWAY FROM THE PATIENT.

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 20 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 the remaining time of use is between 40 and 120 minutes,
- A blinking green light means that the remaining time of use is between 20 and 40 minutes,
- A steady orange light means that the remaining time of use is between 10 and 20 minutes,
- A blinking orange light means that the remaining time of use is below 10 minutes. In this case, the Optics will not turn on.

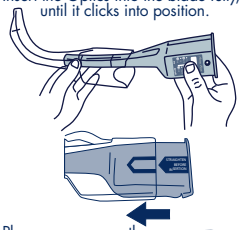
In order to avoid undesired discharge of the battery, Optics is automatically turned off when it is inside a blade, for more than 30 minutes. Three minutes before turning off, the light will flash every 10 seconds.

BATTERY AND SERVICE LIFE CHECK
The user can check battery and service life by pressing the CHECK button in the battery cover or placing the optics into its docking station.
(Please see docking station´s IFU).

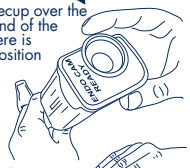
BLADE SIZES
Regular: A-511. Size 3
For use with ETT 7.0 – 8.5. Minimum patient mouth opening: 17 mm
Small: A-521. Size 2
For use with ETT 6.0 – 7.5. Minimum patient mouth opening: 17 mm

INTUBATION TECHNIQUE WITH AIRTRAQ AVANT

I. OPTICS, BLADE AND EYECUP ASSEMBLY
- Check Optics battery status and service life available in the Docking Station or by pressing the Check Button.
- Select the appropriate blade size based on the size ETT to be used.
- Straighten the curved portion of the Optics and align the orange indicators on the Optics and on the Blade .
- Insert the Optics into the blade fully, until it clicks into position.



- Place eyecup over the proximal end of the Optics. There is only one position in which it fits.



- Or place the camera over the proximal end of the Optics.

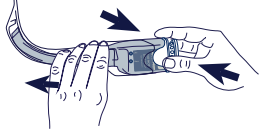
- Upon inserting the blade, the light will automatically start blinking for approximately 35 seconds until the anti-fog warms the lens of the blade. Once the device is ready for intubation the light will become steady.

II. PREPARATION
- Lubricate the ETT and place it into the lateral channel of the blade without contacting blade´s lens.
- Align the tip of the ETT with the end of the lateral channel.

III. AIRTRAQ AVANT PLACEMENT INTO THE AIRWAY (Fig. 1)
- Insert the Airtraq Avant into the midline of the patient's mouth. Take special care to avoid pushing the tongue inside the oropharynx.
- Before it reaches the vertical plane, begin looking to identify airway structures.
- 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.

IV. ETT INSERTION AND AIRTRAQ AVANT REMOVAL FROM PATIENT'S AIRWAY (Fig. 2&3)
- **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. If needed rotate ETT inside the channel. Check insertion depth.
- Inflate the ETT cuff as normal and check for proper positioning.
- Separate the ETT from the Airtraq Avant by pulling it laterally from the ETT, while holding the ETT in position.
- 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 before the Airtraq Avant gets to the vertical plane.
5. Do not insert too deep. 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, If needed rotate ETT inside the channel.

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 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.
- Do not touch the Optics LED.

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. Peracetic Acid Solution (0.08%).
   b. Isopropyl Alcohol (70%).
   c. Solution containing 70% isopropyl alcohol and 2% chlorhexidine (e.g. Clinell Wipe).
   d. Solution containing chlorine dioxide (e.g. Tristel Wipe)
   e. PDI Sani-Cloth® Germicidal Wipes (AF3, Bleach, Plus or Super Sani-Cloth®).
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.

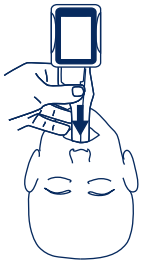
MD Rx Only MR

PRODOL MEDITEC LIMITED
1/F, 4/F, Block C
No. 18, 7th Science Ave.
Zhuhai, Guangdong 519085
China

EC REP & EUROPE
PRODOL MEDITEC S.A.
Muelle Tomás Olavarri 5, 3°
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
AIRTRAQ is a registered trademark.

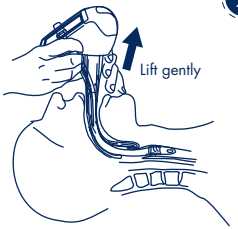
1



Slide midline

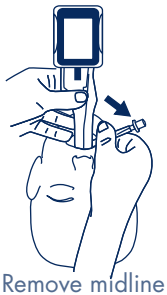
- Do not insert too deep
- Lift gently
- Twist Airtraq to center vocal cords
- Corkscrew ETT

2



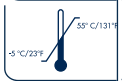
Center glottis
Advance ETT

3



Remove midline

SYMBOL GLOSSARY DEFINITIONS (MULTI LANGUAGE)

SYMBOL	EN DEFINITION	ES DEFINICIÓN	DE DEFINITION	FR DÉFINITION	IT DEFINIZIONE	PT DEFINIÇÃO	NL DEFINITIE	CS DEFINICE	JP 意味	RU ОПРЕДЕЛЕНИЕ
	Legal Manufacturer	Fabricante	Hersteller	Fabricant	Produttore legale	Fabricante Legal	Wettelijke fabrikant	Výrobce	法的メーカー	Официальный производитель
	Authorized representative in the European Community	Representante autorizado en la Comunidad Europea	Bevollmäch tigter in der Europäischen Gemeinschaft	Mandataire dans la Communauté européenne	Rappresentante autorizzato nella Comunità Europea	Representante Autorizado na Comunidade Europeia	Gemachtigde vertegenwoordiger in de Europese Gemeenschap	Zplnomocněný zástupce pro Evropské společenství	欧州共同体認定代表事務所	Уполномоченный представитель в Европейском сообществе
	Date of Manufacturer	Fecha de fabricación	Herstellungs datum	Date de fabrication	Data di produzione	Data de fabrico	Productiedatum	Datum výroby	メーカーの日付	Дата производства
	Do not re-use	No reutilizar	Nur zum einmaligen Gebrauch	Ne pas réutiliser	Non riutilizzare	Não reutilize	Niet nogmaals gebruiken	Nepoužívejte opakovaně	再使用しないでください	Не использовать повторно
	Medical device	Producto sanitario	Medizinprodukt	Dispositif médical	Dispositivo medico	Aparelho médico	Medisch apparaat	Zdravotnický prostředek	医療機器	Медицинское изделие
	Batch code	Número de lote	Losnummer	Code de lot / Numéro de lot	Numero Lotto	Número do lote	Lot nummber	číslo šarže	ロット番号	Номер партии
	Reference Number	Número de catálogo	Bestellnummer	Numéro de catalogue	Numero di catalogo	Número de catálogo	Catalogusnummer	Katalogové číslo	リファレンス/ カタログ番号	Справочный номер / Номер по каталогу
	Type BF applied part	Pieza aplicada tipo BF	Anwendungsteil vom Typ BF	Partie appliquée de type BF	Parte applicata di tipo BF	Peça aplicada tipo BF	Type BF toegepast onderdeel	Příložná část typu BF	タイプBF装着部	Рабочая часть типа BF
	Box/packaging recyclable	Embalaje reciclable	Verpackung recycelbar	Emballage recyclable	Imballaggio riciclabile	Embalagens recicláveis	Verpakking recyclebaar	Obal je recyklovatelný	リサイクル可能な包装	Упаковка пригодна для вторичной переработки
	Fragile, handle with care	Frágil, manipular con cuidado	Zerbrechlich - Vorsichtig behandeln	Fragile manipuler avec soin	Fragile, maneggiare con cura	Frágil, manuseie com cuidado	Breekbaar - voorzichtig behandelen	Křehké, zacházejte opatrně	壊れやすい、慎重に扱う	Хрупкий, обращайтесь с заботой
	Keep Dry/Protect from moisture	Mantener seco / Protéjalo de la humedad	Trocken lagern / Vor Feuchtigkeit schützen	Garder sec / Protection contre la moisissure	Mantenere asciutto / Proteggere dall'umidità	Manter seco / Proteger da humidade	Droog houden / Beschermen tegen vocht	Uchovávejte v suchu. / Chraňte před vlhkem	乾燥した状態に保ってください / 湿気から保護してください。	Хранить в сухом месте / Беречь от влаги
	Importer	Importador	Importeur	Importateur	Importatore	Importador	Importeur	Dovozce	輸入業者	импортер
	Temperature limit.	Límites de temperatura	Temperatur grenze	Limite de température	Limiti temperatura	Limitação de temperatura	Beperking temperatuur	Teplotní omezení	保管温度制限	Допустимая температура хранения
	Humidity limitation	Límites de humedad	Feuchtigkeits limiti erung	Limite d'humidité	Limiti umidità	Limitação de humidade	Beperking luchtvochtigheid	Limity vlhkosti vzduchu	湿度制限	Ограничение по влажности
	Atmospheric Pressure Limitation	Límites de presión atmosférica	Luftdruck limitierung	Limite de pression atmosphérique	Limitazione della pressione atmosferica	Limitação da Pressão Atmosférica	Atmosferische drukbeperking	Omezení atmosférického tlaku	大気圧制限	Ограничение атмосферного давления

SYMBOL GLOSSARY DEFINITIONS (MULTI LANGUAGE)

SYMBOL	EN DEFINITION	ES DEFINICIÓN	DE DEFINITION	FR DÉFINITION	IT DEFINIZIONE	PT DEFINIÇÃO	NL DEFINITIE	CS DEFINICE	JP 意味	RU ОПРЕДЕЛЕНИЕ
	Not Made with Natural Rubber Latex	Fabricado sin látex de caucho natural	Nicht mit Naturlatex hergestellt	Non fabriqué à partir de latex de caoutchouc naturel	Non composto da lattice di gomma naturale	Não fabricado com Látex de Borracha Natural	Niet gemaakt met natuurlijk rubberlatex	Při výrobě nebyl použit přírodní kaučuk	天然ゴムラテックス不使用	Изготовлено без использования натурального каучукового латекса
	Consult instructions for use	Consultar las instrucciones de uso electrónicas	Elektronische Anleitung zum Gebrauch konsultieren	Consulter le mode d'emploi. Disponible sur le site Internet à l'adresse	Consultare le istruzioni elettroniche per l'uso	Consulte as instruções eletrônicas de uso	Raadpleeg de elektronische gebruiksaanwijzing	Prostudujte elektronický návod k použití	使用説明書を参照してください	См. инструкции по применению
Rx Only	Federal (USA) law restricts the use of this device to sale by or on the order of a physician	Las leyes federales estadounidenses restringen la venta de este dispositivo a médicos o por prescripción facultativa	Laut US-Gesetzgebung darf dieses Produkt nur von einem Arzt oder im Auftrag eines Arztes gekauft werden	Les lois fédérales (USA) limitent la vente de ce dispositif aux seuls médecins ou sur prescription médicale	La legge federale (USA) limita la vendita di questo dispositivo a opera o per conto di un medico	A lei federal (dos Estados Unidos da América) restringe a utilização deste dispositivo a médicos ou mediante prescrição médica	De Amerikaanse federale wet beperkt de verkoop van dit apparaat aan of in opdracht van een arts	Podle federálních zákon ů USA je prodej tohoto za řízení povolen pouze léka řům nebo na léka řský předpis	米国連邦法は、本装置の販売を医師または 医師の指示によるものに限定しています。	Согласно федеральному законодательству США продажа этого устройства разрешена только врачам или по их заказу
	CE Mark, European Conformity	Marcado CE, conformidad técnica europea	CE-Kennzeich nung, kennzeichnet technische Konformität mit europäischen Richtlinien	Marquage CE, conformité européenne	Marchio CE, Conformità Europea	Marca CE, Conformidade Europeia	CE-markering, Europese conformiteit	Označení CE, Označuje shodu s evropskými technickými požadavky	CE マーク、欧州適合性	Знак CE, Европейское соответствие
	EAC Mark, Eurasian Conformity	Marca EAC, conformidad euroasiática	EAC-Zeichen, eurasische Konformität	Marque EAC, conformité eurasienne	Marchio EAC, Conformità eurasiatica	Marca EAC, Conformidade Eurasiana	EAC-keurmerk, Euraziatische conformiteit	Značka EAC, Euroasijská shoda	EAC マーク、ユーラシア適合性	Евразийское соответствие
	UKCA Mark, UK Conformity Assessment	Marcado UKCA, conformidad técnica de Gran Bretaña	UKCA Kennzeichnung, Kennzeichnet die technische Konformität gemäß der britischen Verordnung	Marque UKCA, évaluation de la conformité au Royaume-Uni	Marchio UKCA, Valutazione di conformità del Regno Unito	Marca UKCA, Avaliação de Conformidade do Reino Unido	UKCA Mark, UK Conformiteitsbeoordeling	Ozna čení UKCA, znamená technickou shodu ve Velké Británii	UKCA マーク、英国適合性評価	UkCA Mark, Великобритания Оценка соответствия
	This side up	Este lado hacia arriba	Diese Seite nach oben	Ce côté vers le haut	Questo lato in su	Este lado para cima	Deze kant naar boven	Touto stranou nahoru	こちら側を上に	Не кантовать
	Do not use if package is damaged	No utilice el producto si el envoltorio está dañado	Nicht verwenden, wenn die Verpackung beschädigt ist	Ne pas utiliser si l'emballage est endommagé	Non utilizzare se la confezione è danneggiata	Não utilize se a embalagem estiver danificad	Niet gebruiken indien de verpakking is beschadigd	Nepoužívejte, pokud je obal poškozený, a prostudujte si návod k použití	パッケージが開封または破損している場合は使用しな	Не использовать, если упаковка вскрыта или повреждена
	Distributor	Distribuidor	Verteiler	Distributeur	Distributore	Distribuidor	Distributeur	Distributor	ディストリビューター	распределитель
	Separate collection for waste of electrical and electronic equipment	Reciclaje: Equipos electrónicos	Recycling: Elektronische Geräte	Équipement électronique: Éliminer de manière appropriée	Raccolta separata per rifiuti di apparecchiature ettriche ed elettroniche	Separe para a recolha de resíduos de equipamento elétrico e eletrónico	Aparte inzameling van afval van elektrische en elektronische apparatuur	Recyklace: elektronická za řízení	電子機器廃棄物分別回収	Утилизация электроотходов
	Use-By date	Fecha de caducidad	Verfallsdatum	Utiliser avant	Usare entro / Data di scadenza	Use por Data / Expiração	Gebruik door / Vervaldatum	Datum použitelnosti	有効期限まで使用	Использовать до / Дата истечения срока годности
	Australian sponsor	Patrocinador Australiano	Australischer Sponsor	Sponsor Australien	Sponsor Australiano	Patrocinador Australiano	Australische sponsor	Australský zadavatel	オーストラリアのスポンサー	Австралийский спонсор
	Magnetic resonance conditional	Compatible con resonancia magnética bajo ciertas condiciones	Bedingt MR-sicher	Compatibilité RM conditionnelle	A compatibilità condizionata con risonanza magnetica	Condicional para ressonância magnética	MR-conditioneel	MR podmíněné	MR に条件付きで対応	Условно совместимо с МРТ
	Number of Units	Número de unidades	Nombre d'unités	Nombre d'unités	Numero di unità	Número de unidades	Aantal eenheden	Počet jednotek	ユニット数	Количество единиц