ENGLISH

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Airtraq sp

VIDEO LARYNGOSCOPE

US Patent No 6,843,769

INSTRUCTIONS FOR USE

REF: A011, A021

PRELIMINARY WARNING. ELECTRONIC IFU

⚠ Warning: Instructions for use (IFU) are available online at www.airtraq.com/ifu. Users can consult or download the latest and previous versions in different languages. Printed copies are available from the manufacturer upon request.

INTENDED USE AND DESCRIPTION

Airtraq SP is a video laryngoscope to facilitate intubation. It allows visualization of the airway during intubation. It minimizes hyper extension of the neck and permits intubating from virtually any position. ET Tube is loaded into the lateral channel of the device and when advanced it is guided towards the glottis of the patient.

It is a SINGLE USE medical device provided clean and ready to use.

To perform its purpose Airtraq SP must have attached to its proximal end, either

- its eyecup or
- the Wi-Fi Camera (Ref A-390) offered by the manufacturer, attached after removing its eyecup, or
- an Endoscopic camera attached to the eyecup.

⚠ Warning: the Wi-Fi Camera (Ref A-390) may not be available in some countries.

SIZES & OTHER DATA

Reference	A-011	A-021
Size	Regular	Small
Colour	Blue	Green
For use with ETT sizes	7.0 – 8.5	6.0 – 7.5
Min. mouth opening	16 mm	15 mm
Max. insertion portion width	27.4 mm	26.6 mm
Working Length	119.5 mm	115.1 mm
Field of View Vertical	27°	27°
Field of View Horizontal	32°	32°
Direction of View Vertical	112°	112°
Direction of View Horizontal	12°	12°

USE INSIDE OF THE MRI ENVIRONMENT

This medical device was determined to be MR conditional according to the terminology specified by ASTM Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

The device can be used in the MRI environment according to the following conditions:

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

IMPORTANT NOTE: The device is intended for use inside of the MRI environment (e.g., in the MR system room). It will 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 for the device specifically involved evaluations of translational attraction in relation to exposure to a 3-Tesla MR system, only.

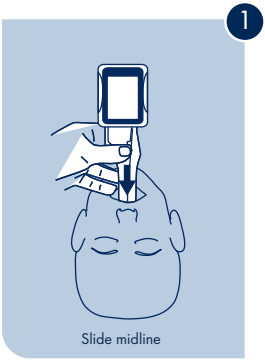
TECHNIQUE FOR USING THE AIRTRAQ SP

I. PREPARATION & TEST

- Select the appropriate size Airtraq SP based on the size ETT to be used.
- Press orange switch to Turn On the light. Airtraq SP automatically Turns On when attaching A390 Wi-Fi Camera.
- The anti-fog system is immediately activated upon switching the light.
- Lubricate the ETT and place it into the lateral channel of the Airtraq SP without contacting the lens.
- Align the tip of the ETT with the end of the lateral channel.

II. AIRTRAQ SP PLACEMENT (FIG. 1)

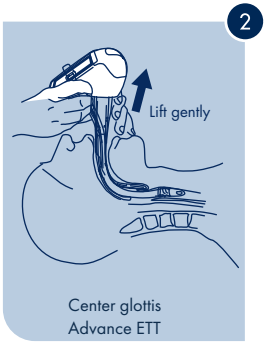
- Insert the Airtraq SP into the midline of the patient's mouth. Take special care to avoid pushing the tongue inside the oropharynx.
- Before it reaches the vertical plane, begin looking to identify airway structures.
- Continue insertion until the epiglottis is identified. Place the tip of the Airtraq SP in the vallecula. Alternatively, the tip can be placed under the epiglottis, lifting it out of the way.
- Gently lift up the Airtraq SP to expose the vocal cords.



✓ Do not insert too deep

III. ETT INSERTION (FIG. 2)

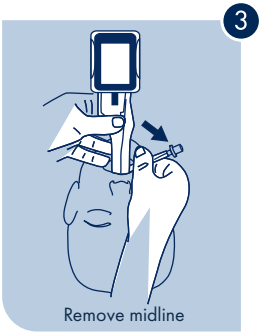
- Align the vocal cords in the center of the visual field by gently moving the tip of the Airtraq SP as needed.
- Gently advance the ETT in the lateral channel. If needed rotate counterclockwise ET tube inside the channel (corkscrew maneouver). Check insertion depth.
- Inflate the ETT cuff as normal and check for proper positioning.



✓ Lift gently
✓ Twist Airtraq to center vocal cords
✓ Corkscrew ETT

IV. AIRTRAQ SP REMOVAL (FIG. 3)

- Separate the ETT from the Airtraq SP by pulling it laterally from the ETT, while holding the ETT in position.
- Remove the Airtraq SP from the patient´s airway following the midline.



USAGE TIPS

1. Initial experience should be gained in non-difficult airways.
2. Insert the Airtraq SP, avoiding the tongue, and slide it softly and slowly.
3. Keep the Airtraq SP in the mouth's midline.
4. Look before the Airtraq SP gets to the vertical plane.
5. Do not insert too deep. If structures (arytenoids, epiglottis, etc.) are not clearly recognized, withdraw the Airtraq SP 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 SP (do not tilt or use a lever action).
7. Advance the ETT slowly. If needed rotate ETT inside the channel.

WARNINGS AND PRECAUTIONS

- This product should only be used by personnel trained in insertion of endotracheal tubes.
- Do not sterilize. Do not submerge in liquids.
- Do not incinerate unless batteries have been removed.
- Use only with non-flammable anesthetics.

IEC 60601-1 AND IEC 60601-1-2 NOTICES AND WARNINGS

1. The "Applied Part" of the device is its distal end.
2. Applied Part of this device is BF type. It is ordinary equipment, not intended for use with flammable agents, continuous operation.
3. According to IEC 60601 Standard, Airtraq laryngoscope with A-390 together comprise a Medical Electrical System. It complies with requirements regarding Electromagnetic Compatibility. Detailed results of Emissions and Immunity Tests are available from the manufacturer.
4. This equipment is intended for use by healthcare professionals only. Portable and mobile RF communication equipment may affect its performance. When using the device please avoid strong electromagnetic interferences.
5. This device is classified for protection against electric shock as Internally Powered Equipment. It is powered by one 1.5 V (AAA) Alkaline battery.
6. Temperature around the blade tip of the device may occasionally exceed 41°C due to heat generated by the LED. Risk of harm for the patient is minimal because the LED does not contact with the patient directly, and the device is in contact with the patient for a short time.
7. If unit does not light or its performance is deteriorated, substitute it by a new one or use other available airway management device.
8. Before using the device, check that the surface to be inserted into the patient does not have marks or sharp edges which may cause harm to a patient.

ELECTROMAGNETIC COMPATIBILITY (EMC)

ELECTROMAGNETIC EMISSIONS

This device is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

Table 1. Guidance and Manufacturer's Declaration of Electromagnetic Emissions

EMISIONS TESTS	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Conducted and radiated RF CISPR11:2015 + A1:2016 + A2:2019	Group 1, Class B	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic distortion IEC 61000-3-2:2005 +A1:2008 + A2:2009	Not Applicable	The device is powered exclusively from an internal non-rechargeable battery and has no mains connection; therefore, requirements per IEC 61000-3-2 and 61000-3-3 do not apply.
Voltage fluctuations and flicker IEC61000-3-3:2008	Not Applicable	

ELECTROMAGNETIC IMMUNITY

The device is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

Table 2. Guidance and Manufacturer's Declaration of Electromagnetic Immunity

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact ± 2kV, ±4kV, ± 8kV, ± 15kV air	COMPLIANT	The floors should be wood, concrete, or ceramic tile. If they are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields IEC 61000-4-3:2006 +A1:2007 + A2:2010	10 V/m 80MHz–2.7 GHz 80% AM at 1 kHz	COMPLIANT	d=1.2 √P 80 MHz to 800 MHz d=2.3 √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrical Fast Transient Bursts IEC 61000-4-4:2014		Not Applicable	No mains or long I/O cables through which bursts can couple.
Surge Immunity IEC 61000-4-5:2014		Not Applicable	The equipment operates exclusively from an internal battery and has no connection to the AC mains or any external cable through which surge transients could be coupled.
Conducted disturbances induced by RF fields IEC 61000-4-6:2003 + A1:2004 +A2:2006		Not Applicable	The device operates exclusively from an internal battery and has no external cables or ports capable of coupling conducted RF disturbances.
RATED power frequency magnetic fields IEC 61000-4-8:2009	30 A/m; 50/60 Hz	COMPLIANT	Power frequency magnetic fields should be at levels characteristic of a typical location in a home healthcare or hospital environment.
Voltage Dips and interruptions IEC 61000-4-11:2004		Not Applicable	The equipment operates exclusively from an internal battery and has no AC mains connection or dependency during normal operation

Note: UT is the AC mains voltage prior to the application of the test level. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

RECOMMENDED SEPARATION DISTANCES

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Table 3. Recommended Separation Distance

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO THE FREQUENCY OF TRANSMITTER (m)		
	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	80 MHz to 800 MHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the transmitter's frequency, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

BATTERY CHARACTERISTICS

Each Airtraq SP is equipped with one AAA Alkaline battery that provides 1.5 volts. Battery cover shall only be manipulated for device disposal.

In case the device is used ONLY ON MANIKINS for training, then its battery can be replaced.

STORAGE, TRANSPORT, SHELF LIFE AND SERVICE LIFE

The Airtraq SP should not be used, stored or transported at temperatures below -5°C/23°F or over 55°C/131°F. The relative humidity must be between 10% and 95%. The air pressure must not exceed 500 to 1060 hPa.

Airtraq SP shelf life is limited to the expiration date.

Airtraq SP service life is only limited by battery capacity, which is enough to guarantee at least two hours of service.

DISPOSAL

To dispose the Airtraq SP once it has been used:

- Remove the battery cover by pushing up its clip and pulling the cover away from the main body.
- Remove the batteries from the Airtraq SP and place them in an appropriate battery recycling container (dispose of them according to established recycling policies). The batteries are classified as non hazardous waste material and comply with European Directive WEEE. However, the manufacturer recommends separating them from standard trash.
- Discard the Airtraq SP as any other potentially contaminated waste.

MANUFACTURER´S WARRANTY

The manufacturer warrants the Airtraq SP against faulty materials or manufacturing defects for only one use or until the expiration date, whichever comes first, provided that the Airtraq SP 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.

This device has not been designed to be cleaned or sterilized. Use beyond this recommendation may generate serious consequences in the product's performance and will void the Airtraq SP's warranty. The manufacturer disclaims all other warranties, whether expressed or implied, including, without limitation, the warranties of merchantability or fitness for a particular use.

USER ASSISTANCE INFORMATION

Instructions for use are available online at:
www.airtraq.com/IFU
Visit **www.airtraq.com** for further advice on using this device.
Any serious incident that occurs in relation to this device should be reported to the manufacturer and the competent Health Authority in which the user and/or patient is established. For communication with manufacturer, please email: **user.assistance@airtraq.com**, or:

1. Contact directly with Manufacturer at its address or by phone:
   USA & Canada: +1877-624-7929
   EU & Other: +34944804690
2. Contact Manufacturer´s Representative for your area (details below) or
3. Contact your Local Distributor.

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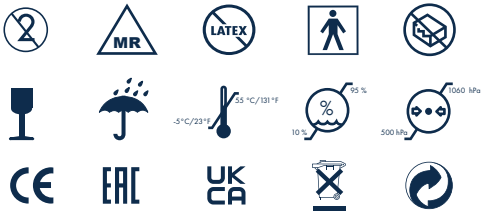
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Airtraq is a registered trademark.

MD Rx Only www.airtraq.com/ifu



GLOSSARY OF SYMBOLS

SYMBOL	MEANING	SYMBOL	MEANING	SYMBOL	MEANING
REF	Reference Number	QTY	Number of Units		Legal Manufacturer
LOT	Batch code		Manufacturing Date		Use-By date
EC REP	Authorized representative in the European Community		Importer	MD	Medical device
	Fragile, handle with care		Follow the instructions for use		Do not re-use
	Temperature limit		Humidity limitation		Atmospheric Pressure Limitation
LATEX	Not made with natural rubber latex		Keep Dry / Protect from moisture	Rx Only	Federal (USA) law restricts the use of this device to sale by or on the order of a physician
CE	CE Mark European Conformity	EAC	EAC Mark, Eurasian Conformity	UK CA	UKCA Mark, UK Conformity Assessment
	This side up		Do not use if package is damaged		Distributor
	Separate collection for waste of electrical and electronic equipment		Type BF applied part	Australian Sponsor	Australian sponsor
MR	Magnetic resonance conditional		Box/ packaging recyclable		