

For Software version 2.00 and posteriors For Serial Numbers higher than M-20000

Instructions For Use ENGLISH

The Instructions for Use may be updated without further notice. The latest version is available on www.airtraq.com.

To check for latest software versions available connect A-390 to 'Airtraq Cam' application on PC or visit www.airtraq.com

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1. A-390 INTENDED USE AND BASIC INFORMATION

Code: A-390

Description: Airtraq Wi-Fi Camera

The A-390 is an accessory for the Airtraq Video Laryngoscope. It is

compatible with all Airtraq Video laryngoscopes models. Intended Use: The A-390 shall be attached to an Airtraq Video Laryngo-scope and its intended purpose is to provide full colour, real-time images on its 2.8 inch integrated touch screen.

A-390 is powered by an internal rechargeable 3.7 V Li-Po battery. A-390 does not work while connected to a battery charger. A-390 battery shall be charged at least 1.8 m. away from the patient. In case A-390 is not operative by any cause (battery not charged, etc) the user can still intubate looking directly through the eyecup of the

Airtraq Video Laryngoscope. Auxiliary Functions: The A-390 provides the following additional functions that are not included in its intended purpose: sending real time images via Wi-Fi to a mobile device; video playback on A-390's screen;

wire connection to a PC for video downloading or software update. A temporary failure of any of these functions, due to an abnormal circumstance, will not increase the patient's risk and will not compromise A-390's intended use, therefore it would be acceptable.

2. A-390 COMPONENTS

2.1. A-390 Camera

CMOS video camera with integrated touch screen and rechargeable

Li-Po Battery. 2.2. USB-C cable

To be used to connect the A-390 to a PC for video downloading or for camera's settings administration.

May also be used to charge the A-390 directly from a USB power source. **2.3. Silicon protective case** Provides additional protection against shocks.

It can be easily installed onto or removed from the camera.

2.4. Battery charger Must be connected to mains supply to charge the 3.7 volts, Li-Po Battery.

2.5. Docking station

Accessory to facilitate charge of A-390. Docking Station can also be used to charge the A-360 Airtrag Wi-Fi Camera. The mains power supply is connected to the Docking Station through its micro USB-C connector.

2.6. Neoprene pouch

Can be used to store some of the A-390 accessories.

2.7. Storage case (two sizes)

Can be used to store all or some of the above items. It is recommended that the A-390 be stored and transported inside the storage case to protect the camera while not in use.

A-390 can be charged when it is inside the storage case by connecting the USB-C cable directly to the camera and zipping the case partially closed allowing room for the cable to exit the case and plugged into power.

A-390 SWITCHES, INDICATORS AND CONNECTORS



A. Automatic power button: This button is automatically pushed when the A-390 is inserted onto any Airtraq. It can also be pushed manually to turn on the A-390. To turn off the A-390 press the corresponding icon on the menu. B. Battery charge connector: Brass surface connectors that connect to docking station for battery charge. C. USB-C female connector: to connect to PC or to battery charger.

D. Battery charge connector: Brass surface connectors that connect to Camera for battery charge.

E. USB-C female connector: to connect to mains power supply.

4. A-390 BATTERY CHARGE AND CHARGE STATUS CHECKING

The A-390 DOES NOT WORK WHEN IT IS BEING CHARGED IT SHOULD BE CHARGED AT LEAST 1.8 M AWAY FROM THE PATIENT It is recommended to perform a full charge/discharge cycle of the battery

before starting to use the A-390 for clinical purposes. After a full charge, the A-390 can operate for around 120 minutes when Wi-Fi is deactivated and for around 90 minutes when Wi-Fi is activated. Recharging takes approximately 110 minutes.

Without use, the battery will discharge at a rate of around 1% per day. If the A-390 can be turned on, then a minimum of 10 minutes of

operating time is guaranteed. When the A-390 is turned on, a battery charge status icon and available minutes of operating time appear on the screen.

To charge battery: 1. Connect the battery charger to Docking station and to mains electrical supply. 2. Place A-390 onto docking station.

3. A-390 can also be charged connecting directly the battery charger provided to the USB-C connector of the A-390. Upon starting to charge battery the A-390 will automatically turn Off.

Also, touching the screen while charging or when fully charged will show available minutes of operating time and a battery icon.

When in use, the battery charge indicator on the header of the screen will show available minutes of operating time and a battery icon in different colours. Service life for the rechargeable battery depends upon the number of charge-discharge cycles performed. Battery can be expected to lose around 25% of its capacity after 500 charge cycles. At around 75%, (after 500 cycles) the camera should continue working well; it just won't

provide as many minutes of service per charge. The A-390's battery can only be replaced by the manufacturer. The A-390 should never be opened by unauthorized personnel. It could result in a HAZARDOUS SITUATION and will void the warranty.

MOUNTING THE A-390 ONTO THE AIRTRAG To mount the A-390 onto the Airtrag:

- Remove eyecup from Airtraq.
- Place A-390 onto Airtraq's proximal end. Make sure the A-390 is fully

inserted.

- A-390 will automatically turn on and start in Live Video mode.
 If during intubation, A-390 accidentally becomes partially dislodged from the Airtraq blade, a warning message will appear on the screen indicating "Blade detached". This is to notify the user that the camera is not fully seated on the Airtraq blade. If A-390 accidentally becomes partially dislodged and A-390 is recording video, and within five seconds the user re-attaches the A-390 securely to the blade, then recording will restart automatically maintaining the same video file. If the user does not correct the "Blade detached" condition within 5 seconds then the recording will be stopped.

To remove A-390 from the Airtrag once intubation is finished lift up and pull A-390 away from Airtraq.

6. TURN ON/OFF

A-390 can be started in two different ways, in both methods it will start in "Live Video" mode: • Automatically by sliding A-390 onto an Airtraq blade.

Pressing the automatic power button.
Boot up will take 7 seconds.
To turn off the A-390 press the "Power off" icon on the main menu. The unit will show a message to the user and a "cancel" icon will appear and it will A-390 automatically shuts off when there is no action from the user for 30 minutes when inserted onto an Airtraq blade or 5 minutes if not. The A-390 will show a shutdown message and the user has 5 seconds to cancel the process if wished.

7. TOUCH PANEL AND MENUS

Press the action icons on the screen to select an action (touch panel also works when icons are pressed using gloves). When in Live Video, pressing the "Back" (1/2) Icon 🖆 will make

A-390 to return to the main menu. Main Menu is shown below:



8. AIRTRAQ CAM APP FOR PC & MOBILE DEVICES

8.1 AIRTRAQ CAM APP FOR PC

Functions:

- Initial set up (A-390 connected to PC through USB).
 Download videos recorded in A-390 (A-390 connected to PC through USB).
 Live Video on PC connecting via Wi-Fi to A-390.
- Recording Video in PC while A-390 and PC are connected via Wi-Fi. **Environments & versions:**

Windows and MacOS

Downloading app: Download to PC The "Airtraq Cam" app from the downloads section on the Airtraq website (www.airtraq .com) and install it on the PC. <u>8.2 AIRTRAQ CAM APP FOR MOBILE DEVICES</u>

Functions:

- Live Video on Mobile Device connecting via Wi-Fi to A-390.
- Recording Video in Mobile Device when A-390 is connected via Wi-Fi. **Environments & versions:**
- Android •iOS(iPhone & iPad)
- Downloading app:

Before starting to use a tablet/ smartphone with A-390, download from "App Store" SM or "Google Play" TM the "Airtrag Cam" app and install it. Make sure that you have the latest available version installed on your device before attempting to connect to it.

9. INITIAL SET UP. CAMERA SETTINGS

Initial set up must be performed connecting the A-390 to a PC through the USB cable provided and using the "Airtraq Cam" App. Only one A-390 at a time can be connected to the PC.

Some options can also be selected directly on the Settings screen of the A-390. When the App is launched a screen will show up with the A-390 connected to the PC. App will prompt the user to register the warranty. Manufacturer recommends registering the warranty before starting to <u>use A-390</u>

Select Language: Scroll and select the desired language.

 Set Date and Time: Date and time are used to name video files recorded. They are automatically updated when connecting A-390 to a PC and opening the Airtraq Cam App. • Set Cam ID: Cam ID is used to name the Wi-Fi Network generated by

the A-390. Any combination of a maximum of 10 letters/numbers.

• Set optional Wi-Fi Password: Optionally, to better protect patient's information activate Wi-Fi password. Wi-Fi password is used to block non-authorized devices from connecting to A-390. User can set it to any combination of five letters/numbers. Password protection can be set on or off. It is off by default. This Zcan also be set in the A-390 Settings screen. When Password is activated the Wi-Fi icon includes a padlock. • Set limitation to Wi-Fi Power (Canada only): Users can limit the maximum RF power in order to comply with Canadian regulations Auto-re-cording options can be set in the A-390 camera. Press "Settings" icon. Set Auto Recording Mode: The auto-recording function will automatically start a new video recording every time the A-390 goes into Live Video. Set it on or off as desired. This option can also be set in the A-390 Settings screen.

• Set Auto-recorded video maximum size: select the maximum video file size: (5 min [15 mb], 6min [18 mb], 10 min [30 mb], 15 min [45 mb], 20 min [60 mb], 30 min [90 mb]). This selection can also be set in the A-390 Settings screen. When the maximum size is reached, video recording is automatically stopped. Videos can be downloaded using "Airtraq Cam" in order to compress them and reduce its size.

10. PAEDIATRIC MODE

When using a pediatric Airtraq Blade the A-390 must be manually set to Pediatric mode, otherwise the image will be too bright. Upon pressing the "Start Pediatric" icon, a message saying "Pediatrics Mode On" will appear on the screen and the icon will change to "Stop Pediatric"

The message will blink for the first 3 seconds. If the A-390 is set to pediatric mode when using an adult Airtraq blade the image will become too dark.

11. IMAGE ROTATION

Depending on intubation position, the user can rotate the image 180 degrees to correct the glottis orientation by pressing the rotate icon

12. RECORD, AUTO-RECORD & SNAPSHOT

RECORDING AND SNAPSHOT ARE DEACTIVATED WHEN A-390 CAMERA IS NOT INSERTED ONTO AN AIRTRAQ BLADE. RECORDING AND SNAPSHOT ARE DEACTIVATED WHEN WIFI IS ACTIVATED. The user has the option to record or take snapshots in the mobile device or PC that is Wi-Fi connected to the A-390 through the corresponding recording or snapshot button of the "Airtraq Cam" App. To start recording when in Live Video press icon and While recording, the icon will change to and a timer will appear on the header of the screen.

To stop recording press the "Stop Recording" icon . The screen will show a message informing that recording will stop in 5 seconds unless user presses "Cancel".

When Auto-Recording function is activated, it will automatically start a new video recording every time the A-390 enters into Live Video. Video files are recorded in avi format and stored in A-390's internal memory. A-390 is able to store 200 videos or around 6 hours of video. A Snapshot can be taken by pressing in the centre of the image of the live video screen. The Snapshot feature also works while recording video. Multiple Snapshots can be taken at a maximum speed of 1 picture every 2 seconds. Snapshots are stored on the A-390's internal memory as a ipeg file and can be viewed in the snapshot gallery. Free memory available is displayed in the Setting/ info Screen. If when the A-390 is turned on memory is full or there are more than 199 videos or snapshots, then A-390 automatically deletes the oldest videos/snap-

shots stored until there is enough free storage to record a 30 minutes video or to record 10 snapshotsTo free up memory space the user should delete videos/snapshots using "Airtraq Cam" App for PC/MAC. A-390 can store up to 200 snapshots.

PLAY RECORDED VIDEOS AND VIEW SNAPSHOTS ON A-390

- Select "Videos" 🗃 from Main Menu. The screen will display a list of the recorded videos showing starting date/time and duration. Last recorded video will be first on the list.
- Navigate through different pages using Up and Down navigation icons and select the desired video
- Action icons provide the following functions: play/pause and fast forward/rewind.
- Select "Snapshots" i at the bottom of the Videos Menu. The screen will display a list of Snapshots taken showing date/time with
- the most recent Snapshots on top of the list.
- Navigate through different pages using Up and Down navigation icons and select the desired Snapshot.

DOWNLOAD VIDEOS AND SNAPSHOTS TO A PC /MAC

Videos are recorded into the A-390 in avi format and named automati-cally with the device ID and date and time at which they were recorded

"device id_yy_mm_dd_xxh_xxm_xxs.avi". Snapshots are stored in jpeg format and named automatically with the device ID, date and time at which they were taken "deviceid_yy_mm_d-

d_xxh_xxm_xxs.jpeg". Videos and snapshots are downloaded connecting the A-390 to a PC (Windows or Mac) through the USB cable provided and using the "Airtraq Cam" App for Windows or Mac. The user can select to download videos in its original resolution or to download compressing the video file to reduce its size.

When the App is launched, a screen will show up with the A-390 connected to the PC. Only one A-390 at a time can be connected to the PC. Click on the download icon selected and the App will display the list of videos and snapshots stored into the A-390. Select the videos and snapshots to be downloaded. Alternatively, click on "Download All" icon. Select video or snapshots to be deleted and press the delete icon. Alternatively, click on "Delete All" if you want to remove all stored videos and snapshots for the connected A-390.

CONNECTING WI-FI LIVE VIDEO & RECORDING ON TABLET/PHONE /PC

To enable Wi-Fi go to Main Menu and press Wi-Fi icon . Wi-Fi icon will turn to and an icon will appear on the header of the screen. In case Wi-Fi was activated the last time that A-390 was turned off, then during booting process A-390 will automatically activate WiFi. A-390 CAN ONLY BE WI-FI CONNECTED TO ONE DEVICE AT A TIME. A-390 CAN ONET BE WITH CONNECTED TO ONE DEVICE AT A TIME Before connecting to another device, the user should exit the "live Video" screen on "Airtraq Cam" App be. When the A-390 is connected to an external device, and thus it is not possible to connect another external device, the A-390's header displays a "connected" icon Each A-390 creates an ad-hoc Wi-Fi network named AIQ+DeviceID+5

numbers automatically generated. To connect a Tablet /smartphone to an A-390, launch "Airtraq Cam"App, add on the external device the A-390 that you want to connect with by entering its Cam Id, either manually or by scanning its QR. QR can be found on the Settings screen of A-390. After adding the A-390 to the Tablet/Smartphone, select the A-390 from the list and click on "Connect". Repeat this procedure for every new camera that needs to be connected to the external device.

For the best image, increase screen brightness in your mobile device.

For the best image, increase screen brightness in your mobile device. To avoid incoming calls, turn airplane mode on and then turn Wi-Fi on. "Airtraq Cam" App for mobile devices allows the user to record videos and take snapshots directly on the mobile device. To connect a PC download and install "Airtraq Cam" App for PC. Upon launching the App, it will search automatically for A-390 that are emitting Wi-Fi signal near the PC. Select the camera that you want to connect to. If Wi-Fi password required has been set to "on", enter it now. Click on Live Video and the PC will display real time video captured by A-390. The app will allow user to record Video directly on the PC.

16. VIEW SYSTEM INFORMATION

Select "Settings" [] in main menu to see system information on the A-390 Screen.

A-390 settings Screen allows to modify: Activation of Wi-Fi Password, Activation of Auto Recording Mode and Selection of Auto-recorded video maximum size

17. UPDATING A-390 INTERNAL SOFTWARE

A-390 internal software can be upgraded using the "Airtraq Cam" app

The PC should have Internet connection in order to automatically retrieve to the PC should have internet content of the provide the providet the the latest version of A-390 internal software from Airtrag website

(www.airtrag.com). Connect A-390 to a PC (Windows or Mac) through the USB cable provided. When "Airtrag Cam" app is launched a screen will appear with the A-390 connected to the PC. If there is a newer version available a message will prompt the user to update.

It is strongly recommended to check periodically if a new software version for A-390 is available.

18. TROUBLESHOOTING

Make sure that A-390 battery is properly charged. Connect A-390 to a PC, open "Airtraq Cam" and make sure that the latest version is installed. To reset A-390 connect A-390 to a PC, open the "Airtraq Cam" app and click on "RESET A-390" in the app toolbar and carefully follow the prompts. The reset process can be performed even if the A-390 is not recognized by the PC as a mass storage device and its screen is totally black.

Reset process allows the user to perform only step 1 to keep all the videos and snapshots in internal memory or to perform also step 2 which deletes all files stored in internal memory.

19. CLEANING INSTRUCTIONS

The A-390 is a non-critical device. Recommended cleaning is low-level disinfection between each patient use. Be sure to follow your institution's specific cleaning procedures in consultation with this manual. 1. Remove A-390 from the Airtraq and turn it off.

- Cleaning: Use clean cotton gauze pads that are saturated with the cleaning solution to wipe down the exterior surfaces of the A-390. Use soft brushes with the cleaning solution to remove any residues from areas that cannot be reached with the gauze pads. Be sure to remove all visible contaminant or foreign matter. Be careful to keep running liquid off the surfaces. The following cleaning solutions may be used: a. Enzymatic Cleaning Solutions (e.g.: ENZOLTM).
 - 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 A-390 using an individual sterile surgical towel.5. Silicone case can be cleaned using the following disinfection agents:

- a. Isopropyl Alcohol (70%).
- b. Solution containing 70% Isopropyl Alcohol and 2% chlorhexidine

(e.g. Clinell Wipe). Isopropyl alcohol can cause slight temporary swelling of the silicone, but as long as it is allowed to evaporate completely it will not deteriorate silicone case.

Caution:

- Do not autoclave. Do not rinse under running water.
- Do not soak in liquids.
- Avoid liquid or moisture from going into the A-390.
- Avoid touching the lens of the A-390.Be careful with A-390 touch screen.
- 20. OPERATING, STORAGE AND TRANSPORT CONDITIONS
- Storage and Transport Conditions: Temperature: between -5°C/23°F and 55°C/131°F; Humidity: between 10% and 95%; Pressure: between 500 to 1060 hPa
- 2. Operating Conditions: Temperature: between -5°C/23°F and 40°C/104°F; Humidity: between 10% and 95%; Pressure: between 500 to 1060 hPa
- **3. Battery Charging conditions:** Temperature: between -5°C/23°F and 40°C/104°F; Humidity: between 10% and 65%; Pressure: between 500 to 1060 hPa

21. TECHNICAL DATA

21.1. A-390 Camera

Electrical supply input ratings: 5 V DC, 2.0 A Supply Voltage: Rechargeable Li-Po 3.7 V, 1400mAh. Baseband Modulation – Wi-Fi - 802.11b: DSSS Pasebana Modulation – WI-FL - 802.11b: DSSS Frequency range: Transceiver: 2412MHz to 2472MHz Output RF Power: + 9.76 dBm EIRP Typ Transmission range: 5 m (approx.). Screen: 2.8" TFT-LCD, 640 x 480 RGB. Touch Panel: OGS type 2.8" Projected Capacitive Touch Panel. Video Sensor: Digital CMOS video sensor, VGA 640 x 480. Video resolution: 480 x 480 Video resolution: 480 x 480. Dimensions: 61 x 91 x 64 mm. Weight: 110 grams. **21.2. Stand-alone Battery Charger** Electrical supply input ratings: $100-240 \text{ V} \sim$, 50-60 Hz, 0.7 A. Electrical supply Output ratings: 5.0 V =, 2.0 A, 10.0 WEMC: EN55024, EN55022/B, EN 60601-1-2. UL recognized component. Valid for USA and Canada. Micro USB-C male connector. Cable length: 1.9 m.

22. REGULATORY

This device, when working as an accessory for Airtraq Video Laryngoscopes, meet the requirements of ISO 8600, ISO 14971, ISO 62304, ISO 62366, ISO 10993, European Medical Devices Regulation MDR (EU) 2017/745 of 5 April 2017. The Declaration of Conformity (DoC) is available from the manufacturer. This device complies with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-18 International Standards for Medical Electrical Equipment

60601-2-18 International Standards for Medical Electrical Equipment. This device is in compliance with the RoHS European Directive.

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

This device is specified as Internally Powered equipment, accessory, type BF Applied Part, IPXO, ordinary equipment, not intended for use with

Fr Applied Parr, IFAO, orainary equipment, not intended for use with flammable agents, continuous operation. According to IEC 60601 Standard A-390 together with Airtraq Laryngoscope comprise a Medical Electrical System. It complies with requirements regarding Electromagnetic Compatibility. Detailed results of Emissions and Immunity Tests are available from the manufacturer. A-390 is a portable RF communications equipment and can affect Medical Electrical Equipment. This equipment is intended for use by healthcare professionals only. This

This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of

nearby equipment indy cause radio interference of indy distopine operation of nearby equipment. It may be necessary to take mitigation measures, such as, reorienting or relocating the A-390. This device shall only be used with cables and accessories provided by the manufacturer. Using other cables or accessories may result in increased emissions or decreased immunity of the ME System. This device is classified as Internally Powered equipment powered by 3.7 V redergraphic better, the protection provided by device is classified as internally powered equipment powered by 3.7

V rechargeable battery for protection against electric shock. The A-390 is classified as BF Applied Part. This device is classified as BF Applied Part. This device is classified as IPX0, ordinary equipment, for degree of protection against ingress of water, as per IEC 60529 International Standard (Degrees of Protection provided by enclosures). No sterile parts. Mode of operation continuous. This device has non-ionizing radiation. FCC AND INDUSTRY CANADA NOTICES AND WARNINGS

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's

authority to operate the equipment. This device complies with Part 15 of the FCC Rules and Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference

that may cause undesired operation. Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

 (1) l'appareil ne doit pas produire de brouillage, et
 (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement. NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of

the following measures: -- Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help. FCC& IC Radiation Exposure Statement:

This equipment complies with FCC and Canada radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20cm between the

radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Déclaration d'IC sur l'exposition aux radiations: Cet équipement est conforme aux limites d'exposition aux radiations définies par le Canada pour des environnements non contrôlés. Cet équipement doit être installé et utilisé à une distance minimum de 20 cm entre l'antenne et votre corps.

Cet émetteur ne doit pas être installé au même endroit ni utilisé avec une autre antenne ou un autre émetteur.

DISPOSAL INSTRUCTIONS 23.

The A-390 and related accessories contain batteries, that cannot be removed, and other environmentally hazardous materials. When A-390 has reached the end of its useful service life, it must be disposed of in accordance with WEEE or other national and local regulations on disposal of electronic and electrical equipment.

24. MANUFACTURER'S WARRANTY

Warranty & Service

The manufacturer warrants this device against faulty materials or manufacturing defects for a period of one (1) year from the date of purchase, provided that it is used in accordance with the procedures set purchase, provided that it is used in accordance with the procedures set up in the instructions for use. This warranty is only applicable if the device has been bought from an authorized distributor and its **warranty has been registered using the "Airtrag Cam" App for PC.** The manufacturer disclaims all other warranties, whether expressed or implied, including, without limitation the warranties of merchantability or fitness for a particular purpose. **Handling Instructions for Defective Devices** 1. Return units must be packed in original and secured packaging materials. All accessories of the device have to be sent back

- materials. All accessories of the device have to be sent back.
- Customer must have registered the device warranty prior to the date of failure and provide serial number of the A-390, description of the
- problem and proof of purchase.3. In all cases when the device shows defects which are not covered by the warranty, the customer will remain responsible for all handling costs and transportation fees. Exclusions from Warranty

- 1. Product, where the serial number has been defaced, modified or removed.
- Damage, deterioration or malfunction resulting from:
 A. Accidental drop of the device.
 B. Misuse, neglect, fire, water, lightning or other acts of nature.
 C. Attempted repair or modification by anyone not authorized by Supplier.

 - Any damage of the product due to shipment. Causes external to the product, such as: over powering the unit, electric power fluctuations or failure, pouring liquids over the device, etc. F. Normal wear and tear.

INSTRUCTIONS IMPORTANT SAFETY

- Keep, read and follow all of these instructions.
- 2. To minimize risk of contamination, ensure that A-390 is cleaned and low-level disinfected before and after each use in accordance with chapter 19. Heed all warnings in these instructions.
- 4. The A-390 does not work when it is being charged. It should be charged at least 1.8 m away from the patient.
- 5. Use only the A-390's battery charger supplied by the manufacturer.
- 6. A-390 is portable RF communications equipment. It may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as, reorienting or relocating the A-390.
- 7. To reduce the risk of fire or shock hazard, do not expose this equipment to rain or moisture.
- 8. Do not charge near any heat source.

- 9. Protect the charging cord from being damaged.
- Do not use this equipment in presence of flammable anaesthetics.
- 11. ESD (Electrostatic discharge) may cause malfunction of these devices.
- 12. Unplug this apparatus during lightning storms or when unused for long periods of time.
- 13. Do not place vessels containing liquids on top of the apparatus. Do not splash liquids on top of the device.
- 14. Do not attempt to service these devices yourself as opening or removing covers may expose you to hazards. Refer all servicing to qualified service personnel from your Airtraq distributor. 15. A-390 shall never be serviced or maintained while in use with the patient.
- A-390 shall only be connected to Airtraq video laryngoscopes. Connection to other ME Equipment or ME System may cause unexpected harm.
- 17. That before each use or after a change of viewing modes / settings, the operator should check to ensure the view observed through the device provides a live image (rather than a stored one) and has the correct image orientation.

26. USER ASSISTANCE INFORMATION

Instructions for use are available online at https://www.airtraq.com/IFU Visit www.airtraq.com for further advice on using the A-390 Any serious incident that occurs in relation to this device should be repor-ted 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

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

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27. GLOSSARY OF SYMBOLS

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SYMBOL	SYMBOL MEANING		SYMBOL	SYMBOL MEANING	s	YMBOL	SYMBOL MEANING	SYME	BOL	SYMBOL MEANING
	Legal Manufacturer		~~	Date of Manufacturer		SN	Serial Number	M	D	Medical device
Rx Only	Federal (USA) law restricts the use of this device to sale by or on the order of a physician		(i) ww.airtraq.com/ifu	Consult instructions for use	((Non-ionizing radiation			Fragile, handle with care
Ť	Keep Dry / Protect from moisture	3703	277	Temperature limit.	10 %		Humidity limitation			Atmospheric Pressure Limitation
<u><u>tt</u></u>	This side up		Œ	CE Mark, European Conformity	F	Ö	FCC Compliance Mark	EA]	EAC Mark, Eurasian Conformity
UK CA	UKCA Mark, UK Conformity Assessment.	1	EC REP	EC Rep- Authorized representative in the European Community.	ţ		Importer			Distributor
X	Separate collection for waste of electrical and electronic equipment		O	Box/packaging recyclable	ŧ	E 117-303003	Giteki mark			