Airtraq +Plus

VIDEO LARYNGOSCOPE

REF: A600

INSTRUCTIONS FOR USE
English

www.airtraq.com/ifu

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1. 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.

2. INTENDED USE AND BASIC INFORMATION

Reference: A600.

Description: Airtraq Plus Video Laryngoscope.

A600 Intended Use: The A600 Video Laryngoscope must be assembled into one of the Airtraq Plus Blades to serve its intended purpose. It displays colour, real-time images of the patient´s larynx during tracheal intubation.

Patient Population: The A600 is intended for any patient who needs to be intubated. The user is responsible for selecting the appropriate Blade type and size for the patient.

Intended User Profile: Healthcare professionals experienced in inserting endotracheal tubes.

Statement of Prescription: Federal (United States) law restricts this device to sale by, or on the order of, a physician.

The A600 is powered by an internal rechargeable Li-Ion battery which does not work while connected to the mains supply. The battery must be charged at least 2 m from the patient.

Compulsory Accessories: To perform its intended purpose, the A600 must be assembled into one of the Airtraq Plus Blades (Macintosh, Hyper Angulated, or Channeled). Blades are offered in different shapes and sizes and sold separately. Each Blade has its Product Reference. The Blades are considered accessories of the A600 Airtraq Plus Video Laryngoscope and have their specific "Instructions for Use."

Other Accessories / Spare Parts:

- **Charging Dock (Part #: A690):** Cradle and stand to charge and store the Video Laryngoscope.
- **AC/DC charger (Part #: A691):** Battery Charger. Output = 5.0, Volts 2.0 Amp.
- **Charging cable (Part #: A692):** USB-A to USB-C 90°.

- **Video cable (Part #: A680):** USB-C to HDMI (custom made cable).
- **Data cable (Part #: A681):** USB-C to USB-C.
- **Silicon Protective Cover (Part #: A620):** Protects A600 LCD from accidental drops.
- **Nylon storage case (Part #: A630):** Holds A600 and all its accessories, except A690.

Auxiliary Functions not included in IEC 60601 Essential Performance: The A600 provides the following additional auxiliary functions: sending real-time images via Wi-Fi to an external secondary display or mobile device; sending real-time images through a cable to an external display; video playback on A600´s screen; connection through a USB cable to a PC for video downloading or software update. A failure of these auxiliary functions, due to an abnormal circumstance, will mean reduced functionality but no hazardous situation can be expected. A failure of these auxiliary functions will not increase the patient's risk or compromise the A600´s intended use. Therefore, it would be acceptable.

3. UNPACKING AND INITIAL INSPECTION

3.1. Elements Inside the Nylon Storage Case

3.1.1 A600 Video Laryngoscope (Video Unit): CMOS video camera with integrated touch screen and rechargeable Li-Ion Battery. It is packed with its silicone protective case.

3.1.2. The AC/DC Charger (Part #: A691): to be connected to the mains supply to charge the Battery. It includes different types of plugs. Select the proper plug for your country and assemble it to the charger.

3.1.3 USB-A to USB-C 90º charging & data cable (Part #: A692): This cable connects the AC/DC charger to the Charging Dock or directly to the A600 Video Laryngoscope. Its length is 2 m.

3.1.4. USB-C to HDMI video cable (Part #: A680): This cable connects the A600 Video Laryngoscope to the A300 Max View Display or most generic displays with HDMI input. Its length is 3 m.

Caution: This is a custom made cable; a standard HDMI cable will not connect A600 to A300 or other displays.

3.1.5. USB-C to USB-C Data cable (Part #: A681): This cable connects the A600 Video Laryngoscope to a PC for video downloading or camera settings administration. Its length is 1.8 m.

Caution: A standard charging USB cable will not enable connection to the PC.

When transporting, it is recommended to store the A600 in the nylon case. When inside the nylon storage case, the A600 can be charged by connecting the USB-C cable directly to the Video Laryngoscope and passing it through the opening provided in the nylon case.

3.2. Charging Dock

Accessory to facilitate charge of A600. It shall be connected to the AC/DC charger through its USB-C port.

Unfold the Charging dock, so that its base and its shaft are at 90° (see picture beside).

3.3 Unpacking and Inspection

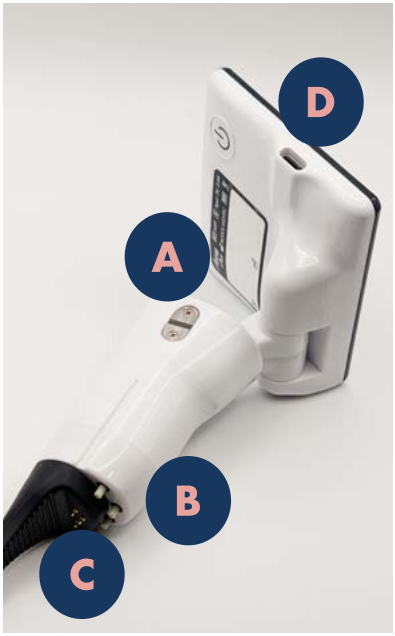
Before unboxing, please carefully inspect the shipping container to check for any visible damage that may have occurred during transport. If there are any signs of external packaging damage, please do not use the product and contact your Airtraq distributor for replacement.

The A600 Video Laryngoscope and the A690 Charging Station are supplied in a single package and boxed individually inside.

Airtraq Plus disposable Blades are not supplied with the A600 Video Laryngoscope. Single Use Blades are packed and purchased separately.

Remove the protective plastic film from the screen of the A600 Video Laryngoscope.

4. A600 SWITCHES AND CONNECTORS



4.1 Video Laryngoscope

A. **Power On switch:** Press the switch for 2 seconds to Turn On the device. The switch never turns off the device. To turn off the A600, press the corresponding icon on the screen.

B. **Automatic Blade detection switches** are automatically pushed when the A600 is inserted into any Airtraq Plus Blade. Each of them can also be switched manually to turn on the A600.

C. **Battery charge connectors:** Brass surface connectors that connect to Charging Dock.

D. **USB-C female port:** This port enables connection to a PC, battery charger, or A300 Max View Display via a specialized USB-C to HDMI cable.

4.2. Charging Dock

E. **USB-C female port:** To connect to AC/DC charger.

F. **Battery charge pins:** Brass surface connectors that connect to the Video Laryngoscope.

G. **Charge light indicator.**

5. A600 BATTERY CHARGE

⚠ WARNING: Battery charging should always be performed using the manufacturer's charger at least 2 meters away from the patient.

⚠ WARNING: Battery may be empty when the device is unpackaged. Please complete a full battery charging cycle before using the device.

5.1 Battery Capacity

A fully charged battery will provide at least 150 minutes of operating time as long as Wi-Fi is not activated. Wi-Fi activation reduces the operating time by around 20%.

It will take approximately 240 minutes to charge an empty battery to 100% capacity.

The A600 will only turn on for safety purposes if the remaining battery operating time is over 5 minutes.

The A600 Li-Ion battery capacity will decrease depending on how the device is used and recharged.

If the battery capacity falls below an acceptable level, the manufacturer can replace the A600 Li-Ion battery. Please contact your Airtraq agent for details.

5.2 Charging Methods

1. Direct connection to USB-C port: connect the AC/DC charger directly to the A600 Video Laryngoscope through the USB-C Female connector. Connect the USB-A connector to the Battery Charger and the USB-C 90° connector to the A600 Video Laryngoscope.
2. Using Charging Dock: mount the A600 Video Laryngoscope into the Charging Dock.

5.3 Preparing the Charging Dock

Unfold the Charging Dock, so that its base and its shaft are at 90°.

Connect the Battery charger provided to the Charging Dock using the USB-A to USB-C 90° cable. Connect the USB-A connector to the Battery Charger and the USB-C 90° connector to the Charging Dock.

Connect the Battery Charger to the mains supply.

While the A600 battery charges, the Charging Dock provides a blue blinking light signal. When the battery is fully charged, the light signal becomes steady.

5.4 Battery Charge Indicators

While in use, the A600 screen displays a battery indicator in the upper left corner. The indicator shows the approximate operating time in minutes and an icon to identify how much battery remains visually.

The time displayed is only approximate and relates to the operating mode. For example, the remaining time depends on whether the Wi-Fi transmission is activated.

While charging, the A600's displays battery indicators in the upper left and lower right corners. A more prominent battery indicator will appear in the centre if the user touches the screen. Once the battery reaches 100% of its charge, the A600 is turned off; thus, indicators are not displayed.

5.5 Battery Charge Messages

When the battery charge drops below specific levels, the A600 screen displays warning messages. Messages are shown during the bootup process and when the A600 is in use.

Messages appear at the following points: "med-low battery level "(45 minutes); "low battery level" (20 minutes) and "very low battery level" (10 minutes).

6. APP AIRTRAQ CAM FOR PC

"Airtraq Cam" app is an independent app that runs on PC and performs the following functions:

- Initial A600 setup (A600 must be connected to the PC via data cable (Part #: A681) USB-C to USB-C).
- Download videos recorded in A600 (A600 connected to PC through data cable).
- Live Video on PC connecting via Wi-Fi to A600 (with the possibility of recording on PC).

The App is available for Windows and MacOS.

You can download the "Airtraq Cam" app from the downloads section on the Airtraq website (www.airtraq.com) and install it on your PC.

Caution: It is recommended that you connect the A600 directly to the PC´s USB-C port without using an external hub.

7. INITIAL SET UP

Initial setup must be performed using the "Airtraq Cam" App installed on a PC connected to the A600 through the data cable provided (Part #: A681). Only one A600 can be connected to the PC at a time. The PC must be connected to the Internet to register the warranty and update the A600 SW.

If SW is not current, the App will prompt the user to update it.

The app will also prompt the user to register the warranty. The manufacturer recommends registering the warranty before using A600 (see warranty chapter).

- **Date and Time:** Date and time are used to name video files recorded. They are automatically synchronized when connecting A600 to a PC and opening the Airtraq Cam App.
- **Warranty Registration:** For the warranty to become effective, A600 must be registered. Fill in the required information on the corresponding screen of the Airtraq Cam App.
- **Select Language:** Scroll and select the desired language.
- **Set Cam ID:** The Cam ID is the device name that appears when A600 is connected to another device. It is also used to name the Wi-Fi Network generated by the A600. The user can define it as any combination of 1 to 10 letters/numbers.
- **Set optional Wi-Fi Password:** To protect the patient's information better, activate the Wi-Fi password. The password is used to block unauthorized devices from connecting to A600. The 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 option can also be set in the A600 Settings screen. When the 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 to comply with Canadian regulations.
- **Set Auto Recording Mode:** The auto-recording function automatically starts a new video recording every time the A600 enters Live Video. You can set it on or off as desired. This option can also be set in the A600 Settings screen.
- **Set Auto-recorded Video Maximum Size:** Select the maximum video file size (5 min [15 mb], 6 min [18 mb], 10 min [30 mb], 15 min [45 mb], 20 min [60 mb], 30 min [90 mb]). This selection can also be made in the A600 Settings screen. When the maximum size is reached, video recording is automatically stopped. Videos can be downloaded using "Airtraq Cam" to compress and reduce size.

8. UPDATING A600 INTERNAL SOFTWARE

A600 internal software can be upgraded using the "Airtraq Cam" app for PC.

The PC should have an Internet connection to automatically retrieve the latest version of A600 internal software from the Airtraq website (www.airtraq.com).

Connect the A600 to a PC (Windows or Mac) through the USB-C to USB-C data (Ref #681) cable provided. When the "Airtraq Cam" app is launched, a screen will appear indicating the device ID of the connected A600. A message will prompt the user to update the Software if a newer version is available.

Caution: It is strongly recommended to check periodically if a new software version for A600 is available.

9. ASSEMBLY OF AIRTRAQ PLUS BLADES ONTO THE A600

The A600 Video Laryngoscope and all Airtraq Blades feature a lock mechanism that simplifies assembly and disassembly, ensuring the Blade remains in place during intubation. It comprises a metallic piece with a slot on the Video Laryngoscope and a clip in the flexible tab of every Blade that hooks into the slot.

To mount the Blade onto the A600, users shall grip the Blade in the intubation position (the tip of the Blade pointing away), hold the A600 Video Laryngoscope so that the arrow on its body faces towards them, insert the Video Laryngoscope into the Blade, and slide it down until a click is heard.

The Video Laryngoscope will automatically turn on in Live Video mode after assembling the Blade.

To remove the Blade, pull out the flexible tab on the left side of the Blade laterally and slide the A600 out.

If the Blade accidentally becomes partially dislodged from the A600 during intubation, a warning message "Please Insert Blade" will appear.

10. TURN ON/OFF

Boot up to get into Live Video will take approximately 3 seconds. A600 can be started by:

A. Pressing the Power On switch for **2 seconds**. If a Blade is already assembled, the A600 will start in Live Video Mode (or in VL+FOB mode if that was the last option selected by the user). If a Blade is not assembled, the A600 will start in the Menu screen.

B. Inserting the A600 into any Airtraq Plus Blade. In this case it will start automatically, in Live Video Mode or VL+FOB mode.

C. Pressing any of the automatic Blade detection switches manually. This is not the recommended method for turning on the device. In this case, the A600 will start in Live Video Mode and it will display the message "Please Insert Blade".

11. SCREEN FLIP & SWIVEL. IMAGE ROTATION

The A600 Touch Screen can flip (1) and swivel (2). It allows the user to select the screen orientation.

The rotate icon allows the user to rotate the image 180 degrees. It will enable the image to be correctly orientated when the screen has been flipped and swiveled or when intubating face-to-face.

12. TOUCH PANEL & MENUS

The Touch Screen includes three icons underneath the image area:

Menu , Rotate , and Recording .

They are only active when A600 is Turned On.

Press any icon on the touch screen to select an action (the touch screen also works when icons are pressed using gloves).

Icons are self-explanatory.

13. RECORD, AUTO-RECORD & SNAPSHOT

WARNING: Videos and Snapshots could be considered confidential patient information. The user shall adhere to legal enforcement and the institution´s policies regarding patient data treatment.

Video and snapshot files are recorded in .avi and .jpg format and stored in the A600 internal memory, which has a capacity of 16 GB. It can store 200 videos or more than 10 hours of video.

Recording and snapshots are only activated when the A600 Video Laryngoscope is inserted into a Blade and in Live Video mode. Video recording is stopped when the Blade is removed from the Video Laryngoscope.

To start recording, press the icon below the image area or the icon in the lower right corner of the image area. While recording, an indicator , and a timer will appear in the lower right corner of the screen.

To stop recording, press the icon or icon . When the recording is stopped, the "File Saved" icon will appear in the upper right corner of the screen.

When the Auto-Recording function is activated, a new video recording will automatically start every time the A600 enters Live Video. Auto-Recording is selected in the Settings screen.

To take a snapshot, press icon . When the snapshot is taken, the "File Saved" icon is displayed in the upper right corner of the screen. A600 can store up to 200 snapshots. The Snapshot feature also works while recording video.

The free memory available is displayed in the Settings Screen. To free up memory space, the user should delete videos/snapshots using the Airtraq Cam App for PC.

Suppose memory is full or there are more than 199 videos or snapshots. In that case, A600 automatically deletes the oldest videos/snapshots until there is enough free storage to record a 30-minute video or 10 snapshots.

14. PLAY RECORDED VIDEOS AND VIEW SNAPSHOTS ON A600

Select "Gallery" from the Main Menu.

The screen will display a list of recorded videos and snapshots, showing the start date and time (hour, minute, second), as well as the duration. The last recorded video will be listed first.

You can navigate different pages using the up and down navigation icons and select the desired video by pressing anywhere on the corresponding line.

When playing back videos/snapshots, some action icons can be displayed or hidden by touching the center of the screen.

These icons provide the following functions: play /pause , fast forward /fast rewind , following video/snapshot on the gallery list ,previous video/snapshot on the gallery list, and back to the Gallery list .

When entering the Gallery list, videos and snapshots are listed in white. Once viewed, they become listed in grey.

15. DOWNLOAD TO A PC /MAC OR DELETE VIDEOS AND SNAPSHOTS

Videos are recorded into the A600 in .avi format and named automatically with the device ID and date and time at which they were recorded "airtraq_deviceid_yy_mm_dd_xxh_xxm_xxs.avi."

Snapshots are stored in .jpeg format and named automatically with the device ID, date, and time taken: "airtraq_deviceid_yy_mm_dd_xxh_xxm_xxs.jpeg."

Videos and snapshots can be downloaded by connecting the A600 to a PC

(Windows or Mac) through the USB cable provided and using the "Airtraq Cam" App for Windows or Mac.

The user can download videos in their original resolution or a compressed video file to reduce size.

Click on the selected download icon, and the App will display the videos and snapshots stored in the A600. Select the videos and snapshots to be downloaded. Alternatively, click on the "Download All" icon.

Select videos or snapshots to be deleted and press the delete icon. Alternatively, click "Delete All" to remove all stored videos and snapshots for the connected A600.

The A600 appears on the PC as a mass storage device. The user can manage files directly from their PC using its operating system.

16. AIRTRAQ CAM APP FOR MOBILE DEVICES

"Airtraq Cam" app is an independent app that runs on iOS and Android mobile devices (Tablets and Phones) and performs the following functions:

Live Video on a Mobile Device connected via Wi-Fi to A600.

Recording in a Mobile Device when A600 is connected via Wi-Fi.

Environments & versions: Android & iOS (iPhone & iPad).

Downloading app: Before starting to use a tablet/smartphone with A600, download and install the "Airtraq Cam" app from "App Store" or "Google Play." Ensure you have installed the latest version of your device's app before connecting it to A600.

17. CONNECTING WI-FI TO A300 AIRTRAQ MAX VIEW DISPLAY / TABLETS / PHONES / PC

When Wi-Fi is activated, the A600 creates its own Wi-Fi network whose name includes a 3-letter prefix and then the A600´s DeviceID. Its range is approximately 5m. It allows the user to connect to different types of devices (only one at a time).

To activate Wi-Fi go to the main menu and press the Wi-Fi icon . The A600 will automatically go to Live Video Mode, and a green Wi-Fi icon will appear in the upper right corner of the Live Video screen.

When the A600 connects to an A300 Max View Display or any mobile device, the icon turns white, and a "Linked" icon is displayed beside it.

To deactivate Wi-Fi, go to main menu and press the Wi-Fi icon .

When booting up, the Wi-Fi activation status is the same as the last time that the A600 was powered off in normal conditions.

A600 can only be connected to one device at a time by Wi-Fi. Before connecting to another device, users should exit the "Live Video" screen on the "Airtraq Cam" App or the A300 Airtraq MaxView Display.

A600 offers the option of activating a Wi-Fi Password that the receiver must enter to connect to it. This helps to avoid undesired connections to A600. Password´s activation/deactivation can be performed in the settings screen. A password change can only be performed using the "Airtraq Cam for PC "App.

When the Wi-Fi Password is activated, the Wi-Fi icons include a padlock .

⚠WARNING: Videos and Snapshots could be considered confidential patient information. The user shall adhere to legal enforcement and the institution´s policies regarding the treatment of patient data.

To connect via Wi-Fi to an A300 Airtraq MaxView Display, activate Wi-Fi on A600. The A300 will automatically detect and connect to the closest A600 Video Laryngoscope emitting Wi-Fi signal.

To connect a tablet or smartphone to the A600, launch the "Airtraq Cam" App on the tablet or smartphone and add the A600 by entering its Cam ID, either manually or by scanning its QR. The QR can be found on the A600's Settings screen. After adding the A600 to the Tablet or smartphone, select the A600 from the list and click "Connect."

For the best image, increase the screen brightness on your mobile device. To avoid incoming calls, turn airplane mode on and then turn Wi-Fi on.

The "Airtraq Cam" App for mobile devices allows users to record videos and take snapshots directly on the device.

To connect to a PC, download and install the Airtraq Cam App for PC. Upon launching the App, it will search automatically for A600 emitting Wi-Fi signals near the PC. Select the A600 that you want to connect to. If the Wi-Fi password has been set to "on," enter it when prompted. Click on Live Video, and the PC will display real-time video captured by A600. The app will allow users to record videos directly on the PC.

18. WIRED CONNECTION TO A300 MAX VIEW DISPLAY

The A600 can be connected to the A300 Airtraq MaxView Display wirelessly or using a wire. A wire connection can be a helpful alternative in case of heavy radio interference.

The A600 includes a special custom-made HDMI cable that connects it to the A300 MaxView Display. Its USB-C connector shall be connected to the A600 USB-C port, and the HDMI connector shall be connected to the A300 on its HDMI port.

Caution: a standard USB-C to HDMI cable will not connect A600 to A300.

19. WIRED CONNECTION TO A GENERIC HDMI MONITOR

The A600 can be connected by cable to generic monitors that accept 640 x 480 HDMI image input.

Caution: some larger TV's do not receive 640 x 480 input.

Connect using the same HDMI cable and plug the connectors as you would when connecting to the A300 MaxView Display.

20. VIDEO LARYNGOSCOPY TOGETHER WITH FIBERSCOPE MODE (VL+FOB)

This mode works similarly to Live Video, but allows the user to manually reduce the light provided by the A600 to 20% of its nominal intensity. This avoids excessive brightness when the FOB light starts to illuminate the larynx.

To start this function press icon VL+FOB on the main menu.

To reduce the light press icon . To restore to standard light, press icon .

21. VIEW SYSTEM INFORMATION AND SETTINGS

Select "Settings" in the main menu to see system information on the A600 Screen.

The A600 Settings Screen allows for the following modifications: Activating the Wi-Fi Password, Activating the Auto Recording Mode, and selecting the maximum size of the Auto-recorded video.

22. CLEANING AND LOW-LEVEL DISINFECTION INSTRUCTIONS

⚠ WARNING: To minimize the risk of contamination, ensure that the A600 Video Laryngoscope is cleaned and disinfected before each use, and always wear gloves when handling it.

The A600 is a non-critical device. Low-level disinfection is recommended between each patient's use. Follow your institution's specific cleaning procedures as outlined in this manual, in consultation with the relevant guidelines.

1. Remove A600 from the Blade and turn it off.
2. Cleaning: Use clean cotton gauze pads that are saturated with the cleaning solution to wipe down the exterior surfaces of the A600. Use soft brushes with the cleaning solution to remove residues from areas that cannot be reached with the gauze pads. Be sure to remove all visible contaminants or foreign matter. Be careful to keep running liquid off the surfaces. The following cleaning solutions may be used:
    - Enzymatic Cleaning Solutions (e.g.: ENZOLTM).
    - Neutral pH soap and water.
    - Sodium bicarbonate solution (8-10 %).
3. The following disinfection agents may be used:
    - Peracetic Acid Solution (0.08%).
    - Isopropyl Alcohol (70%).
    - Solution containing 70% Isopropyl Alcohol and 2% chlorhexidine (e.g. Clinell Wipe).
    - Solution containing chlorine dioxide (e.g. Tristel Wipe).
    - PDI Sani-Cloth® Germicidal Wipes (AF3, Bleach, Plus or Super Sani-Cloth®).

4. Blot dry the A600 using an individual sterile surgical towel.
5. Silicone case can be cleaned using the following disinfection agents:
    - Isopropyl Alcohol (70%).
    - Solution containing 70% Isopropyl Alcohol and 2% chlorhexidine (e.g. Clinell Wipe).

Isopropyl alcohol can cause slight swelling of the silicone, but as long as it evaporates completely, it will not deteriorate the silicone case.

Video Camera Lens Cleaning

The image may become blurry if any particle sticks to the video camera's lens.

Clean the camera lens using a micro swab with a microfiber tip/wand, humidified with any of the above cleaning solutions.

Caution:

- Do not autoclave.
- Do not rinse under running water.
- Do not soak in liquids.
- Avoid liquid or moisture from going into the A600.
- Avoid touching the lens of the A600.

23. OPERATING, STORAGE AND TRANSPORT CONDITIONS

- Operating Conditions: Temperature: between -10°C/14°F and 45°C/113°F; Humidity: between 10% and 95%; Pressure: between 500 hPa to 1060 hPa.
- Battery Charging conditions: Temperature: between 10°C/50°F and 40°C/104°F; Humidity: between 10% and 75%; Pressure: between 500 hPa to 1060 hPa.
- Storage and Transport Conditions: Temperature: between -10°C/14°F and 55°C/131°F; Humidity: between 10% and 95%; Pressure: between 500 hPa to 1060 hPa.

24. USE INSIDE OF THE MRI ENVIRONMENT

⚠WARNING: This device is now under testing regarding its use inside of the MRI environment. Tests will be according to the ASTM Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Therefore, it should not be used inside of the MRI environment.

25. TECHNICAL DATA

25.1 A600 Video Laryngoscope

Screen: 3.5″ IPS. Resolution 640 x 480. Viewing angle = 85°.
Touch Panel: OGS type 3.5″ Projected Contact Touch Panel.
Video Sensor: Digital CMOS. Resolution: 800 x 800.
Battery: Rechargeable Li-Ion 3.6 V, 1900mAh.
Electrical supply input ratings: 5.0 V, DC, 2.0 A.
Baseband Modulation – Wi-Fi – 802.11g.
Output RF Power: + 10 mW; Transmission range: 5 m (approx).
Internal Memory: 16 GB. (14 GB available for video recording, 10 hours).
Degree of Protection against water ingress: IP55 (IEC 60529).
Dimensions: 260 x 75 x 85 mm.
Weight: 195 grams.

25.2 A600 Video Laryngoscope Optical Characteristics (ISO 8600)

The characteristics detailed below are specific for each Blade.

FoV = Field of View in degrees.

DoV= Direction of View in degrees.

Blade	**Ref**	**FoV** Vertical	**FoV** Horizontal	**DoV** Vertical	**DoV** Horizontal
Channeled #0	A6C0	61°	70°	98°	10°
Channeled #1	A6C1	59°	70°	88°	10°
Channeled #2	A6C2	59°	70°	82°	10°
Channeled #3	A6C3	61°	70°	71°	10°
Hyper Angulated "H"	A6HA	56°	70°	55°	10°
MacIntosh #1	A6M1	58°	70°	98°	10°
MacIntosh #2	A6M2	57°	70°	103°	10°
MacIntosh #3	A6M3	62°	70°	116°	10°
MacIntosh #4	A6M4	63°	70°	116°	10°

25.3 A600 Video Laryngoscope Blades other Characteristics (ISO 8600)

The characteristics detailed below are specific for each Blade.

Max. IPW= Maximum insertion portion width in mm.

Min. MO= Minimum Mouth Opening in mm.

WL= Working Length in mm.

Blade	Ref	For use with ETT sizes	Min MO	Max IPW	WL
Channeled #0	A6C0	2.5 to 3.5	10.2	19.7	59.4
Channeled #1	A6C1	4.0 to 5.5	12.5	21.5	69.6
Channeled #2	A6C2	6.0 to 7.5	16.5	26.6	93.1
Channeled #3	A6C3	7.0 to 8.5	17.5	27.1	97.4
Hyper Angulated "H"	A6HA	N/A	13.4	23.5	104
MacIntosh #1	A6M1	N/A	11.1	17.8	59.5
MacIntosh #2	A6M2	N/A	11.6	18.3	62
MacIntosh #3	A6M3	N/A	13.4	25.4	92.2
MacIntosh #4	A6M4	N/A	13.4	25.7	97.9

25.4 AC/DC Charger (Part #: A690)

USB-A 2.0 Female connector for charging cable.

Interchangeable plugs included: USA, EU, UK, Australia, China, etc.

Type I (Australia, etc.); Type not classified (China, etc.).

Electrical supply input ratings: 100-240 V ~, 50-60 Hz, 0.5 A.

Electrical supply Output ratings: 5.0 V, 2.0 A, 10.0 W.

The power supply is designed for indoor use to meet IEC 60601-1/UL60601-1 and EN 60601-1-2 standards.

AC/DC Charger Dimensions (EU plug): 60 x 40 x 75 mm.

AC/DC Charger Weight (EU plug): 66 grams.

Charging Station Dimensions: 185 x 95 x 92 mm.

Charging Station Weight: 320 grams.

25.5 Charging Cable (Part #: A690)

Male USB-A 2.0 to male elbow 90° USB-C 2.0.

Cable Length = 2 m. O.D.= 4.0 mm.

25.6 Video Cable (Part #: A680)

Male USB-C 2.0 to male HDMI 20 pin.

This cable has a different pin assignment than the standard HDMI connector.

32 AWG. Cable length: 3 m. O.D. = 4.0 mm.

Caution: This is a custom made cable; a standard HDMI cable will not connect A600 to A300 or other displays.

25.7 Data Cable (Part #: A681)

Data transmission cable:

Male USB-C 2.0 to Male USB-C 2.0. Length = 1.8 m. O.D.= 3.4 mm.

26. REGULATORY

This device complies with the following standards and regulations:

- IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-18 International Standards for Medical Electrical Equipment.
- European Medical Devices Regulation (MDR) EU 2017/745.
- European Directives 2014/35/EU (Low Voltage Directive), 2014/30/EU (EMC Directive), 2014/53/EU (Radio Equipment Directive), and RoHS Directive.
- ISO 8601, ISO 14971, ISO 62304, ISO 62366-1, and ISO 10993 standards. UK Medical Devices Regulations 2002 (UK MDR 2002).

The Declaration of Conformity (DoC) is available upon request from the manufacturer.

This section does not provide an exhaustive list of all applicable regulations and standards. For further information, please contact the manufacturer.

26.1 IEC 60601-1 and IEC 60601-1-2 Notices and Warnings

According to IEC 60601 Standard A600, Airtraq Plus Video Laryngoscope is Medical Electrical Equipment.

According to IEC 60601-1(Clause 6), this device is classified as follows:

1. For protection against electric shock:
    - Power Source: Internally powered equipment.
    - Applied parts (considering the full ME System when it is assembled into a Blade): type BF Applied Part.
2. For the protection against harmful of water ingress: IP6x.
3. Method of sterilization: It does not have sterile parts.
4. Suitability for use in an oxygen-rich environment: not intended for use with flammable agents.
5. Mode of Operation: continuous operation.

AC/DC Charger is a Class II accessory for this device.

This device does not emit ionizing radiation.

It complies with requirements regarding Electromagnetic Compatibility. The manufacturer can provide detailed results of Emissions and Immunity Tests.

⚠WARNING: The area surrounding the camera in the Video Laryngoscope can contact the patient and may exceed 41°C (106°F) during normal operation. Patient contact with this area of the Blade during intubation is unlikely, as it would obstruct the camera view. Do not maintain continuous contact with this area of the Blade for longer than 1 minute; it is possible to cause thermal damage, such as a burn to the mucosal tissue.

⚠WARNING: Please stop using this Equipment immediately if it loses its primary functions.

⚠WARNING: Before each use, check the outer surface of the portions intended to be inserted into a patient to ensure there are no unintended rough surfaces, sharp edges or protrusions that may cause harm.

26.2 Electromagnetic Compatibility (EMC)

⚠WARNING: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). Observe the EMC instructions in this chapter during installation and operation.

⚠WARNING: The use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the A600 Airtraq Plus Video Laryngoscope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠WARNING: The use of accessories, transducers, and cables other than those specified in this manual or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The system is designed to comply with IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical medical installation.

The system complies with the applicable essential performance requirements specified in IEC 60601-1 and IEC 60601-2-18. Immunity testing results show that the system's essential performance is not affected under the test conditions described in the following tables.

26.2.1 Electromagnetic Emissions

The system 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.

EMC Table 26.2.1 Guidance and Manufacturer's Declaration of Electromagnetic Emissions

EMISSIONS 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	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flicker IEC61000-3-3:2008	Compliant	

26.2.2 Electromagnetic Immunity

The system 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.

EMC Table 26.2.2. 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	± 2 kV for power supply lines ± 1 kV for input/output lines	COMPLIANT	Mains power quality should be that of a home healthcare or hospital environment.
Surge Immunity IEC 61000-4-5:2014	± 0.5kV, ± 1 kV line-to-line ± 0.5kV, ± 1 kV, ± 2 kV line-to-ground	COMPLIANT	Mains power quality should be that of a home healthcare or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6:2003 + A1:2004 +A2:2006	3 Vrms at 0.15 MHz–80MHz 6 Vrms at ISM bands between 0.15 MHz–80MHz 80% AM at 1KHz	COMPLIANT	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d (m) d=1.2 √P

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	Dips: 0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles, Single phase: at 0° Interruptions: 0 % UT; 250/300 cycles	COMPLIANT	Mains power quality should be that of a home healthcare or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.

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.

26.2.3 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.

EMC Table 26.2.3. 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.

26.2.4 Accessory Conformance to Standards

To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by the manufacturer. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the system.

EMC Table 26.2.4. Standards for Accessories

ACCESSORY	MAX LENGTH
Charging Dock (Part #: A690)	-
AC/DC charger (Part #: A691)	-
Charging cable (Part #: A692)	2 m (6.56 ft)
Video cable AC/DC charger (Part #: A680)	3 m (9.84 ft)
Data cable AC/DC charger (Part #: A681)	1.8 m (5.90 ft)

26.3 FCC and Industry Canada Notices and Warnings

26.3.1 Statement according to FCC part 15.19.

This device complies with Part 15 of the FCC Rules and Industry Canada license-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.

26.3.2 Statement according to FCC part 15.21.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

26.3.3 Statement for Class B digital device according to FCC part 15.105.

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 by the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

Suppose this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. In that case, 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 to 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.

26.3.4 Statement according to RSS Gen Issue 3, Sect.7.1.3.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not

cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

26.3.5 Statement according to ICES.

This ISM device complies with Canadian ICES-001.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

26.4 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 at a minimum distance of 20 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

27. MAINTENANCE

The A600 should be periodically connected to the Internet and a PC running the Airtraq Cam App to synchronize the date and time and check for software updates.

A600 does not require routine maintenance or calibrations.

The user cannot replace the A600 battery, but the manufacturer can replace it for an economical cost. Please ask your Local Airtraq Distributor from which you bought the A600.

28. DISPOSAL INSTRUCTIONS

When A600 and A690 reach the end of their service life, they must be disposed of following WEEE or other national and local regulations on the disposal of electronic and electrical equipment.

The A600 contains a battery that can be removed for separate disposal. Remove the battery box using a screwdriver, "Torx 6," to extract it. Then disconnect the battery and dispose of it according to your organization's procedures.

29. WARRANTY & SERVICE LIFE

Warranty & Service Life

The manufacturer warrants this device against faulty materials or manufacturing defects for three (3) years from the date of purchase if it is used per the procedures set up in the instructions.

Caution: This warranty is only applicable if the device has been bought from an authorized distributor and its **warranty has been registered using the "Airtraq 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.

The Service Life of this device is limited to five (5) years. After the service life is finished, the manufacturer does not assume any responsibility regarding the device's proper functioning.

Handling Instructions for Defective Devices

1. Return units must be packed in the original and secured packaging. The device's accessories must also be sent back.
2. Customers must register the device warranty before the failure date and provide the A600's serial number, description of the problem, and proof of purchase.
3. When the device shows defects 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.
2. Damage, deterioration, or malfunction resulting from:
    - Accidental drop of the device.
    - Misuse, neglect, fire, water, lightning or other acts of nature.
    - Attempted repair or modification by anyone not authorized by the Supplier.

- Any damage to the product due to shipment. Causes external to the product include overpowering the unit, electric power fluctuations or failure, pouring liquids over the device, etc.
- Normal wear and tear.

30. TROUBLESHOOTING AND RESET

1. Make sure that the A600 battery is appropriately charged.
2. Connect A600 to a PC, open "Airtraq Cam" and ensure the latest SW version is installed.
3. Reset A600. Connect A600 to a PC, open the "Airtraq Cam" App, click "RESET A600" in the app toolbar, and carefully follow the prompts. The reset process shall be attempted even if the PC does not recognize the A600 as a mass storage device and its screen is black. The reset process comprises two steps. Performing only the first step allows the user to keep all the videos and snapshots in internal memory. Performing step 2 deletes all files stored in internal memory.

31. OTHER WARNINGS, CAUTIONS AND SAFETY INSTRUCTIONS

⚠ WARNING: Keep, read, and follow all these instructions.

1. Heed all warnings and cautions in these instructions.
2. To minimize the risk of contamination, ensure that A600 is cleaned and disinfected at a low level before each use, following the above instructions.
3. The A600 does not work when charged. It should be charged at least 2 m away from the patient.
4. Use only the A600´s battery charger supplied by the manufacturer. Do not charge near any heat source or during lightning storms. Protect the charging cord from being damaged.
5. To reduce the risk of fire or shock hazards, do not expose this equipment to rain or moisture. Do not place vessels containing liquids on top of the device and do not splash liquids on top of the device.
6. Do not use this equipment in the presence of flammable anaesthetics.

7. Do not attempt to service this device yourself, as opening or removing covers may expose you to hazards. Do not open the battery box unless you dispose of the entire device. Refer all servicing to qualified service personnel from your Airtraq Agent.
8. A600 shall never be serviced or maintained while in use with the patient.
9. Before each use or after a change of viewing modes/settings, the operator should ensure that the view observed through the device provides a live image (rather than a stored one) and that image orientation is correct.

32. USER ASSISTANCE INFORMATION

Instructions for use are available online at **https://www.airtraq.com/IFU**

Visit **www.airtraq.com** for further advice and examples of A600 in actual use.

Any serious incident concerning 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 the manufacturer please proceed following any of the below methods:

1. Contact directly with Manufacturer at its email: user.assistance@airtraq.com
2. Contact directly with Manufacturer at its address or by phone calling the numbers below:

   USA & Canada: +1877-624-7929

   EU & Other: +34 944-804690
3. Contact the Manufacturer's Representative for your area (details can be found at https://www.airtraq.com/where-to-buy-in/all-countries/)
4. Contact your Local Airtraq Distributor.

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33. GLOSSARY

SYMBOL	MEANING	SYMBOL	MEANING
	Manufacturer		Date of Manufacture
	Authorized representative in the European Community		Importer
	Catalogue Number		Serial Number
	Follow instructions for use		General Warning sign
	Type BF applied part		CLASS II equipment
	Separate collection for waste of electrical and electronic equipment		Fragile, handle with care
	Medical Device		Non-Ionizing radiation
	Federal (USA) law restricts the use of this device tosale by or on the order of a physician		Keep Dry/ Protect from moisture
	Temperature limitation		Humidity limitation
	Atmospheric pressure limitation		European Union CE Conformity mark
	Eurasian Conformity mark		UKCA—UK Conformity mark
	Japan Giteki Certification mark		Federal Communications Commission mark

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Year of first CE marking: 2025

Storage and Transport Conditions:

Operating Conditions:

Battery Charging Conditions: