

Airtraq +Plus

VIDEO LARYNGOSCOPE

REF: A600 & A600B

INSTRUCTIONS FOR USE

English



www.airtraq.com/ifu



INDEX

- 1. PRELIMINARY WARNING. ELECTRONIC IFU..... 4**
- 2. INTENDED USE AND BASIC INFORMATION 4**
- 3. UNPACKING AND INITIAL INSPECTION 5**
- 4. A601 SWITCHES AND CONNECTORS..... 7**
- 5. A601 BATTERY CHARGE..... 8**
- 6. APP AIRTRAQ TOOLS FOR PC 10**
- 7. INITIAL SET UP..... 10**
- 8. UPDATING A601 INTERNAL SOFTWARE..... 12**
- 9. ASSEMBLY OF AIRTRAQ PLUS BLADES ONTO THE A601 12**
- 10. TURN ON/OFF..... 14**
- 11. SCREEN FLIP & SWIVEL. IMAGE ROTATION 14**
- 12. TOUCH PANEL & MENUS 15**
- 13. RECORD, AUTO-RECORD & SNAPSHOT..... 15**
- 14. PLAY RECORDED VIDEOS AND VIEW SNAPSHOTS ON A601 16**
- 15. DOWNLOAD TO A PC /MAC OR DELETE VIDEOS AND SNAPSHOTS..... 16**
- 16. AIRTRAQ CAST APP FOR MOBILE DEVICES 17**
- 17. CONNECTING WI-FI TO A300 AIRTRAQ MAXVIEW DISPLAY /
TABLETS / PHONES 17**



| | | |
|------------|---|-----------|
| 18. | WIRED CONNECTION TO A300 MAXVIEW DISPLAY | 18 |
| 19. | WIRED CONNECTION TO A GENERIC HDMI MONITOR | 18 |
| 20. | VL TOGETHER WITH FIBERSCOPE. "VL+FOB" MODE | 19 |
| 21. | VIEW SYSTEM INFORMATION AND SETTINGS | 19 |
| 22. | CLEANING AND LOW-LEVEL DISINFECTION INSTRUCTIONS | 19 |
| 23. | OPERATING, STORAGE AND TRANSPORT CONDITIONS | 21 |
| 24. | USE INSIDE OF THE MRI ENVIRONMENT | 21 |
| 25. | TECHNICAL DATA | 21 |
| 26. | REGULATORY | 24 |
| 27. | MAINTENANCE | 32 |
| 28. | DISPOSAL INSTRUCTIONS | 32 |
| 29. | WARRANTY & SERVICE LIFE | 32 |
| 30. | TROUBLESHOOTING AND RESET | 33 |
| 31. | OTHER WARNINGS, CAUTIONS AND SAFETY INSTRUCTIONS | 34 |
| 32. | USER ASSISTANCE INFORMATION | 35 |
| 33. | GLOSSARY | 36 |



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 & A600B. The difference between both references is that A600B does not include all the accessories provided with A600. Table 2.1 provides a list of accessories included with each product code.

Description: Airtraq Plus Video Laryngoscope Video Unit (A601) and accessories.

Intended Use: The Airtraq Plus Video Laryngoscope displays colour, real-time images of the patient's larynx during tracheal intubation.

The A601 is designed to be used exclusively in combination with an Airtraq Plus Blade. Use of the A601 without a Blade is not an intended mode of operation and is contraindicated for clinical use.

Patient Population: The A600 & A600B are 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 A601 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 A601 must be assembled into one of the Airtraq Plus Blades.

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 & A600B and have their specific "Instructions for Use."

In addition to its primary clinical use (with Blade mounted), the A601 may be connected via the A681 USB-C/USB-C cable to a personal computer running the Airtraq TOOLS application for service operations such as firmware update, diagnostic data download and configuration. This service mode is described in chapter 6.



Other Accessories / Spare Parts:

The table below lists the components and accessories associated with the A600 and A600B configurations, indicating which items are included in each reference.

Table 2.1. Accessories / Spare Parts included with the A600 and A600B

| CODE | DESCRIPTION | DETAILS | A600 | A600B |
|-------|--------------------------|---|------|-------|
| A601 | Video Laryngoscope | Video Unit | X | X |
| A690 | Charging Dock | Cradle and stand for charging and storage of the Video Laryngoscope | X | |
| A691 | AC/DC charger | Output: 5.0 V, 2 A | X | X |
| A692 | Charging cable | USB-A to USB-C (90° connector) | X | X |
| A680 | Video cable | USB-C to HDMI (dedicated cable) | X | |
| A681 | Data cable | USB-C to USB-C | X | X |
| A620 | Silicon Protective Cover | Protects A601 display from accidental drops | X | X |
| A630 | Nylon storage case | For storage of the A601 and selected accessories | X | |
| A630B | Nylon storage case | For storage of the A601 and selected accessories | | X |

3. UNPACKING AND INITIAL INSPECTION

3.1. A600 & A600B-Elements Inside the Storage Case



A600 Storage Case



A600B Storage Case



3.1.1. A601 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 90° charging & data cable (Part #: A692): This cable connects the AC/DC charger to the Charging Dock or directly to the A601. Its length is 2 m.

3.1.4. USB-C to HDMI video cable (Part #: A680): This cable connects the A601 to the A300 MaxView Display or most generic displays with HDMI input. Its length is 3 m. This accessory is not included in A600B.

Caution: This is a custom made cable; a standard HDMI cable will not connect A601 to A300 or other displays.

3.1.5. USB-C to USB-C Data cable (Part #: A681): This cable connects the A601 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 A601 in the nylon case. When inside the nylon storage case, the A601 can be charged by connecting the USB-C cable directly to the Video Laryngoscope Video Unit and passing it through the opening provided in the nylon case.



3.2. Charging Dock

This accessory is not included in A600B.

Accessory to facilitate charge of A601. 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.

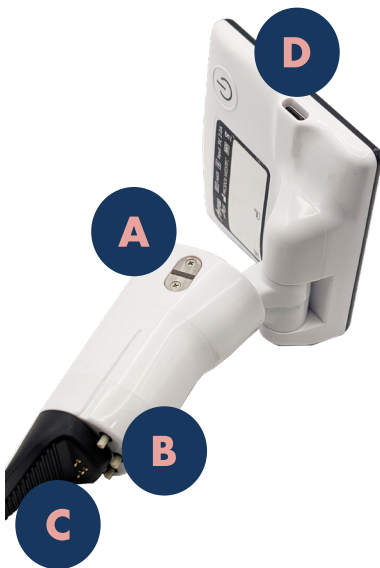
Each of the references A600 & A600 B is supplied in a single package.

Airtraq Plus disposable Blades are not supplied with the A600 & A600B. Single Use Blades are packed and purchased separately.

Remove the protective plastic film from the screen of the A601.

4. A601 SWITCHES AND CONNECTORS

4.1. Video Laryngoscope Video Unit



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 A601, press the corresponding icon on the Menu.

B. Automatic Blade detection switches are automatically pushed when the A601 is inserted into any Airtraq Plus Blade. Each of them can also be switched manually to turn on the A601.

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 MaxView 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 A601.
- G. Charge light indicator.**

5. A601 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 180 minutes to charge an empty battery to 100% capacity. The A601 will only turn on for safety purposes if the remaining battery operating time is over 5 minutes.


The A601 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 A601 Li-Ion battery. Please contact your Airtraq agent for details.



5.2. Charging Methods

1. Using Charging Dock (This accessory is not included in A600B): mount the A601 into the Charging Dock.
2. Connecting the Battery Charger directly to the A601 USB-C female connector. In this case, A601 must be kept inside its storage case to protect the optical and electronic elements of the A601. The charging cable (A692) must be passed through the circular opening located on the lateral side of the storage case, A630 or A630B.

 **WARNING:** do not leave the A601 for recharging the battery on open surfaces, where the distal end could come into contact with users, other equipment, or charged surfaces that may accidentally damage the A601.

5.3. Preparing the Charging Dock

This accessory is not included in A600B.

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 A601 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 A601 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 A601 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 A601 is turned off; thus, indicators are not displayed.



5.5. Battery Charge Messages

When the battery charge drops below specific levels, the A601 screen displays warning messages. Messages are shown during the bootup process and when the A601 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 TOOLS FOR PC


“Airtraq TOOLS” App is an independent App that runs on PC and performs the following functions:

- Initial A601 setup.
- Download videos recorded in A601.
- Software update and warranty activation.

The App is available for Windows and MacOS.

You can download the “Airtraq TOOLS” App from the downloads section on the Airtraq website (www.airtraq.com) and install it on your PC.

A601 must be connected to the PC via data cable (Part #: A681) USB-C to USB-C. When connected to the PC A601 must be kept inside its storage case to protect the optical and electronic elements of the A601. The data cable (A681) must be passed through the circular opening located on the lateral side of the storage case, A630 or A630B. The handling restrictions of chapters 9, 22, and 31 apply for manipulation when the A601 is connected to a PC: handle the A601 only by its handle and body; do not approach or contact the lower distal end of the A601.

 **WARNING:** do not leave the A601 while connected to a PC on open surfaces, where the distal end could come into contact with users, other equipment, or charged surfaces that may accidentally damage the A601.

Caution: The manufacturer recommends connecting the A601 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 TOOLS” App installed on a PC connected to the A601 through the data cable provided (Part #: A681).

Only one A601 can be connected to the PC at a time. The PC must be connected to the Internet to register the warranty and update the A601 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 A601 (see warranty chapter).

- **Date and Time:** Date and time are used to name video files recorded. They are automatically synchronized when connecting A601 to a PC and opening the “Airtraq TOOLS” App.
- **Warranty Registration:** For the warranty to become effective, A601 must be registered. Fill in the required information on the corresponding screen of the “Airtraq TOOLS” App.
- **Select Language:** Scroll and select the desired language.
- **Set Device ID:** It is the device name that appears when A601 is connected to another device. It is also used to name the Wi-Fi Network generated by the A601. 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 A601. 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 A601 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 A601 enters Live Video. You can set it on or off as desired. This option can also be set in the A601 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 A601 Settings screen. When the maximum size is reached, video recording is automatically stopped. Videos can be downloaded using “Airtraq TOOLS” to compress and reduce size.



8. UPDATING A601 INTERNAL SOFTWARE

A601 internal software can be upgraded using the “Airtraq TOOLS” App for PC. The PC should have an Internet connection to automatically retrieve the latest version of A601 internal software from the Airtraq website (www.airtraq.com).

Connect the A601 to a PC (Windows or Mac) through the USB-C to USB-C data (Ref #A681) cable provided. When the “Airtraq TOOLS” App is launched, a screen will appear indicating the device ID of the connected A601. A message will prompt the user to update the Software if a newer version is available.

Once the update is completed, a message will appear on the device’s screen, as well as on the PC running the “Airtraq TOOLS” App.

Caution: It is strongly recommended to connect the A601 to the “Airtraq TOOLS” App for PC, to periodically check for software updates.

9. ASSEMBLY OF AIRTRAQ PLUS BLADES ONTO THE A601

The A601 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 A601, users shall grip the Blade in the intubation position (the tip of the Blade pointing away), hold the A601 so that the arrow on its body faces towards them, insert the A601 into the Blade, and slide it down until a click is heard.

The A601 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 A601 out.

If the Blade accidentally becomes partially dislodged from the A601 during intubation, a warning message "Please Insert Blade" will appear.

⚠️ WARNING: Handling and pre-use verification:

The A601 must be handled by its body and handle. The distal end, which houses the camera, and the Battery charge connectors must not be touched. Before each clinical use, after mounting the Blade, verify on the A601 screen that a quality image, sufficient to identify the target anatomical structures, is displayed in the proper orientation. Do not use the device if this verification is not successful— contact your Airtraq distributor.



10. TURN ON/OFF

Boot up to get into Live Video will take approximately 3 seconds. A601 can be started by:

- A.** Pressing the Power On switch for **2 seconds**. If a Blade is already assembled, the A601 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 A601 will start in the Menu screen.
- B.** Inserting the A601 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 A601 will start in Live Video Mode and it will display the message "Please Insert Blade".

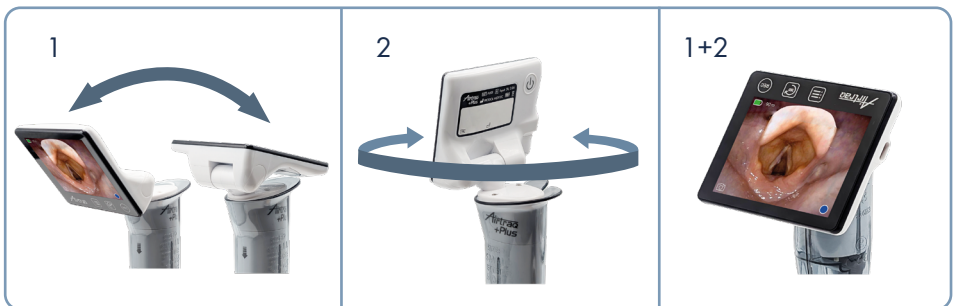
To turn off the device, the user shall go to the Menu and click the corresponding icon.


The A601 turns off automatically if there is no user action:

- after 5 minutes if it is not assembled into a blade.
- after 30 minutes when it is assembled into a blade.

11. SCREEN FLIP & SWIVEL. IMAGE ROTATION

The A601 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 A601 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 A601 internal memory, which has a capacity of 16 GB. It can store 200 videos or more than 10 hours of video. The maximum duration for each video is 30 minutes.

Recording and snapshots are only activated when the A601 is inserted into a Blade and in Live Video mode. Video recording is stopped when the Blade is removed from the A601.

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 A601 enters Live Video. Auto-Recording is selected in the Settings screen. Maximum Size of the auto-recorded videos is also set 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. A601 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 TOOLS" App for PC. Suppose memory is full or there are more than 199 videos or snapshots. In that case, A601 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 A601

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 A601 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 A601 to a PC (Windows or Mac) through the USB cable provided and using the "Airtraq TOOLS" 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 A601. 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 A601.

The A601 appears on the PC as a mass storage device. The user can manage files directly from their PC using its operating system.



16. AIRTRAQ CAST APP FOR MOBILE DEVICES

“Airtraq CAST” 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 A601.
- Recording in a Mobile Device when A601 is connected via Wi-Fi.



“Airtraq CAST” App is intended solely for optional secondary viewing of the video stream for convenience. The primary viewing display is always the one integrated in the A601. The App is not intended to diagnose, treat, mitigate, or prevent disease, nor to affect the structure or function of the body. Environments & versions: Android & iOS (iPhone & iPad).

Downloading App: Before starting to use a tablet/smartphone with A601, download and install the “Airtraq CAST” App from “App Store” or “Google Play.” Ensure you have installed the latest version of your device’s App before connecting it to A601.



17. CONNECTING WI-FI TO A300 AIRTRAQ MAXVIEW DISPLAY / TABLETS / PHONES

When Wi-Fi is activated, the A601 creates its own Wi-Fi network whose name includes a 3-letter prefix and then the A601’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 A601 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 A601 connects to an A300 MaxView 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 A601 was powered off in normal conditions.

A601 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 CAST” App or the A300 Airtraq MaxView Display.



A601 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 A601. Password's activation/deactivation can be performed in the settings screen. A password change can only be performed using the "Airraq TOOLS" 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 Airraq MaxView Display, activate Wi-Fi on A601. The A300 will automatically detect and connect to the closest A601 emitting Wi-Fi signal.

To connect a tablet or smartphone to the A601, launch the "Airraq CAST" App on the tablet or smartphone and add the A601 by entering its Device ID, by scanning its QR. The QR can be found on the A601's Settings screen. After adding the A601 to the Tablet or smartphone, select the A601 from the list to 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 "Airraq CAST" App for mobile devices allows users to record videos and take snapshots directly on the device.

18. WIRED CONNECTION TO A300 MAXVIEW DISPLAY

The A601 can be connected to the A300 Airraq 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 (reference A600B does not include this cable). Its USB-C connector shall be connected to the A601 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 A601 to A300.

19. WIRED CONNECTION TO A GENERIC HDMI MONITOR

The A601 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. VL TOGETHER WITH FIBERSCOPE. "VL+FOB" MODE

This mode works similarly to Live Video, but allows the user to manually reduce the light provided by the A601 to 20% of its nominal intensity. This avoids excessive brightness when the fiberoptic bronchoscope (FOB) light starts to illuminate the larynx.


To start this function, press the 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 A601 Screen. The A601 Settings Screen allows for the following modifications: activating the Wi-Fi Password, enabling the Auto Recording Mode, and selecting the maximum size of the Auto-recorded videos.

22. CLEANING AND LOW-LEVEL DISINFECTION INSTRUCTIONS

 **WARNING:** To minimize the risk of contamination, ensure that the A601 is cleaned and disinfected before each use, and always wear gloves when handling it.

The A601 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 A601 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 A601. 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 A601 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 A601.
- Do not touch the camera window or the distal end of the A601 with fingers, either during handling or during cleaning. Clean the camera window only with the micro swab as described above.
- Handle the A601 only by its body and handle, both during clinical use and between uses.



23. OPERATING, STORAGE AND TRANSPORT CONDITIONS

- **Operating Conditions: Temperature:** between -5°C/23°F and 40°C/104°F; Humidity: between 10% and 95%; Pressure: between 500 hPa and 1060 hPa.
- **Battery Charging Conditions: Temperature:** between 10°C/50°F and 35°C/95°F; Humidity: between 10% and 75%; Pressure: between 500 hPa and 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 and 1060 hPa.
- **Storage between uses:** Between clinical uses, store the A601 either (a) mounted on the Charging Dock (A690) when recharging, or (b) inside the nylon storage case provided (A630 / A630B), where the battery can also be recharged. Do not leave the A601 on open surfaces where the distal end could come into contact with users, other equipment, or charged surfaces. These storage practices help to protect the camera and the integrated electronics from accidental damage.

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. A601 Video Laryngoscope Video Unit

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 dust and water ingress: IP65 (IEC 60529).

Dimensions: 260 x 75 x 85 mm.

Weight: 195 grams.



25.2. A601 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.

Table 25.2. Optical Characteristics for each Blade

| BLADE | REF | FoV | FoV | DoV | DoV |
|---------------------|------|----------|------------|----------|------------|
| | | VERTICAL | HORIZONTAL | VERTICAL | 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° |
| Miller #0 | A6M0 | 56° | 70° | 95° | 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. A601 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.

Table 25.3. Blades other characteristics

| 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 |
| Miller #0 | A6M0 | N/A | 9.3 | 15.4 | 49.5 |
| 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 #: A691)

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. This accessory is not included in A600B.



25.5. Charging Cable (Part #: A692)

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.

This accessory is not included in A600B.

Caution: This is a custom made cable; a standard HDMI cable will not connect A601 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:

- International Standards for Medical Electrical Equipment: IEC 60601-1 and IEC 60601-1-2.
- European Medical Devices Regulation (MDR) EU 2017/745.
- European Directives applicable in parallel to MDR: 2014/53/EU (Radio Equipment Directive) for the Wi-Fi module, Directive 2011/65/EU (RoHS), and Directive 2012/19/EU (WEEE).
- ISO 8600-1, ISO 14971, IEC 62304, IEC 62366-1, and ISO 10993 series.
- UK Medical Devices Regulations 2002 (UK MDR 2002).

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

This chapter 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 & A600B, Airtraq Plus Video Laryngoscope is Medical Electrical Equipment.



Auxiliary Functions not included in IEC 60601 Essential Performance: The A600 & A600B provide 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 A601 '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 & A600B 's intended use. Therefore, it would be acceptable.

IEC60601 Essential Performance clarification: The essential performance of the A600 & A600B, as defined in the risk management file, applies when the device is in its intended clinical use configuration, i.e. with an Airtraq Plus Blade mounted and displaying a live image for tracheal intubation. In that configuration, under severe accidental electrostatic discharge per IEC 61000-4-2 (± 8 kV contact; ± 2 , ± 4 , ± 8 and ± 15 kV air), the A600 & A600B may experience a momentary image interruption of less than 3 seconds. During and after the ESD event, no hazardous situation occurs: the displayed image is not misleading (no frozen frame presented as live), and the device self-recovers to normal operation without user action. The residual risk from the momentary image interruption is acceptable. In the event of a temporary interruption of the charging process caused by a severe accidental electrostatic discharge, the residual risk is also acceptable.

When the A601 is idle between clinical uses, or when it is connected to a PC or its battery is charged via USB-C, it must be stored in the provided case (A630 or A630B). In all the above cases, as well as when it is being charged on its Charging Dock, the device must be handled by its body and handle and its distal end shall not be touched (see chapters 9, 22 and 31).

Under these handling conditions, direct electrostatic discharge to the bare camera window is not a reasonably foreseeable event. The risk control measures defined in the risk management file (handling instructions, storage instructions, mandatory Blade for clinical use, and pre-use image verification) ensure that any hypothetical damage to the camera in a non-clinical state is detected before patient exposure, so that the residual risk is acceptable.


Additionally, in the event of a temporary interruption of the charging process due to a severe accidental electrostatic discharge, the residual risk is acceptable.




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: IP65.
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 & A600B 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 CISPR 11:2015 + 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 IEC 61000-3-3:2008 | 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 | $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 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), $d=1.2 \sqrt{P}$ |



| | | | |
|--|---|-----------|---|
| 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 $d=1.2 \sqrt{P}$ | 80 MHz to 800 MHz $d=1.2 \sqrt{P}$ | 80 MHz to 2.5 GHz $d=2.3 \sqrt{P}$ |
| 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 (Part #: A680) | 3 m (9.84 ft) |
| Data cable (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 A601 should be periodically connected to the Internet and a PC running the “Airtraq TOOLS” App to synchronize the date and time and check for software updates. A601 does not require routine maintenance or calibrations.

The user cannot replace the A601 battery, but the manufacturer can replace it for an economical cost. Please ask your Local Airtraq Distributor from which you bought the A601.

28. DISPOSAL INSTRUCTIONS

When A601 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 A601 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 outlined in the instructions for use.

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 TOOLS” 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. Returned 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 A601'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 including: overpowering the unit, electric power fluctuations or failure, pouring liquids over the device, etc.
 - Normal wear and tear.

30. TROUBLESHOOTING AND RESET

1. Always connect to an AC/DC battery charger and make sure that the A601 battery is appropriately charged.
2. In case A601 cannot be charged nor turned on, then the user can force the "EMERGENCY RECOVERY" performing the following steps:
 - Connect A601 to a PC through the USB-C
 - Within 1 second of connecting the USB-C, press and release quickly, 3 times, the central switch for automatic blade detection (see chapter 4;4.1;B).
 - After the above action the A601 should start the Emergency Recovery.
 - Follow instructions detailed on the A601 screen.
3. Connect A601 to a PC, open "Airtraq TOOLS" and ensure the latest SW version is installed.
4. Reset A601. Connect A601 to a PC, open the "Airtraq TOOLS" App, click "RESET A601" in the app toolbar, and carefully follow the prompts. The reset process shall be attempted even if the PC does not recognize the A601 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 A601 is cleaned and disinfected at a low level before each use, following the above instructions.
3. The A601 does not work when charging. It should be charged at least 2 m away from the patient.
4. Use only the A601 '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. A601 shall never be serviced or maintained while in use with the patient.
9. Before each use clinical 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.
10. Handle the A601 only by its body and handle, both during clinical use and between uses. Do not touch the distal end or the camera window with fingers. Between clinical uses, keep the A601 on the Charging Dock or inside the nylon storage case provided. These practices protect the camera and the internal electronics from accidental damage.



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 & A600B 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.

























Airtraq is a registered trademark.

Apple and the Apple logo, iPad and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries. App StoreSM is a service mark of Apple Inc.

Wi-Fi and the Wi-Fi logo are registered trademarks of the Wi-Fi Alliance. All other trademarks and copyrights are the property of their respective owners.



33. GLOSSARY

| SYMBOL | MEANING | SYMBOL | MEANING |
|---|--|---|--|
|  | Manufacturer |  | Date of Manufacture |
|  | Authorized representative in the Europea 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 to sale 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 |



PRODOL MEDITEC LIMITED

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

EC REP & EC



PRODOL MEDITEC S.A.

Muelle Tomás Olavarrí 5, 3°
48930 Las Arenas,
SPAIN

CONTACT:

USA:
877-624-7929
info.usa@airraq.com
OTHER:
+34944804690
info@airraq.com

U.S. Agent: Danny Daniel

11300 49th Street North
33762-4807 Clearwater
Florida, USA

UK Responsible

Person:

Advena Ltd UK
Pure Offices, Plato Close,
Warwick, CV34 6WE
United Kingdom



www.airraq.com/ifu



Rx Only



YEAR OF FIRST CE MARKING: 2024

Storage and Transport Conditions:



Operating Conditions:

Battery Charging Conditions:

