ULTRAEZAIR®

Instructions for Use

Revised: 2023-06-15

℞ Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Note: Please retain these Instructions as they are applicable to the following UltraEzAir® catalog numbers:

Item	Catalog Number
Base & Power Supply Adapter	PRP-102115
Mist Assembly	PRP-202004
Delivery Line for Olympus® Endoscopes	PRP-102073
Delivery Line for Pentax® Endoscopes	PRP-102099

AirKor®

7139 Azalea Ln.
Dallas, Texas 75230

Phone: +1 (972) 327-3346
E-mail: support@airkor.com
www.AirKor.com

See Symbols Glossary in Section 4.0 of the Instructions for Use

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1.0 Introduction

Indications for Use: *The UltraEzAir® is a topical anesthesia applicator used to apply topical anesthetic to a patient's oropharynx and upper airway region through the working channel of a flexible nasal laryngoscope using air flow. The device is designed for and intended to be used in office-based procedures by physicians trained and experienced in flexible endoscopic techniques for elective outpatient procedures such as:*

- *Transnasal esophagoscopy*
- *Fiberoptic endoscopic evaluation of swallowing with sensory testing (FEES/ST)*
- *Vocal fold injections*
- *Laryngeal biopsies*
- *Laryngeal mass excisions*
- *Laser excisions*
- *Stroboscopy Dynamic voice assessment*
- *Dynamic voice assessment*
- *Peritonsillar abscess drainage*

The safety and effectiveness of this device for use in the performance of topical anesthesia of the lower airways (below the level of the trachea) have not been established.

Device Description: The UltraEzAir® system delivers aerosolized topical anesthetic solution (mist) to a connected laryngoscope working channel where the User can then apply the mist to the adult patient oropharynx and upper airway region prior to endoscopic examination in a professional healthcare setting. The UltraEzAir® is an accessory to the laryngoscope used by a healthcare professional who has been trained in its use by AirKor®. See section 2.1 for a complete list of contraindications.

UltraEzAir is only intended to be used in adult patients weighing at least 80 pounds.

2.0 Safety Notices

The following information is provided to allow the healthcare professional to make an informed decision as to whether the UltraEzAir® system is suitable for use on a particular patient and to minimize the risk of harm to the patient, user, or bystanders.

2.1 Contraindications

The UltraEzAir® system should not be used in patients who are allergic to the anesthetic solution or to any of the materials used in the system, which include silicone and polycarbonate.

2.2 Residual Risks

Although care has been taken to make the UltraEzAir® system as safe to use as possible, residual risk will continue to remain even if all warnings and instructions are followed. The healthcare professional should weigh these risks against the anticipated

benefits of using the UltraEzAir® system to determine whether to accept these risks or not.

2.3 Adverse Effects

2.3.1 Respiratory Infection

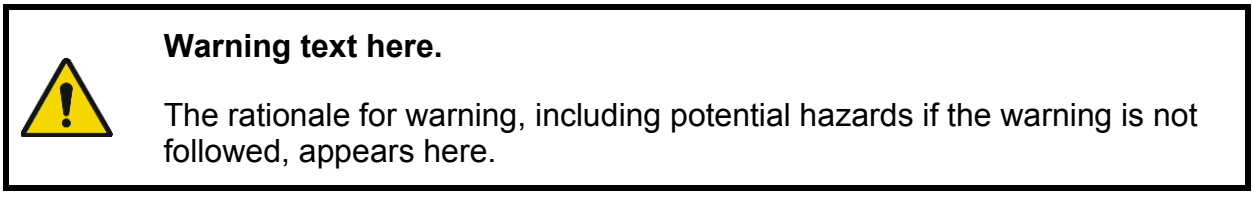
The UltraEzAir® system incorporates a 0.22-micron filter to reduce airborne particulate from entering the Mist Assembly, delivery line, laryngoscope, and ultimately the patient's airway. The Disposable Delivery Line and Mist Assembly is intended for single patient use. Disposal of the Delivery Line and Mist Assembly between the UltraEzAir® system and the flexible nasal laryngoscope after each patient exam reduces the risk of cross-patient infection. To minimize the risk of infection, clean and disinfect the Base per the instructions provided in section 5.4, never operate the system without its filter installed, and never reuse the disposable Delivery Line Set or Mist Assembly on more than one patient.

2.3.2 Physical Injury

Dropping the UltraEzAir® system can injure the user, patient, or a bystander, or can cause spillage that could cause someone to slip. To reduce this risk, never hand-carry the Base with a filled Mist Assembly. Instead, transport it on a rolling cart or remove the Mist Assembly prior to transporting the Base, and always handle the UltraEzAir® system with care during transport.

2.4 Warnings

Pay careful attention to all warnings in this document. Warnings are enclosed in a black box and bear a warning symbol, like this:



The upper, bold part of the warning identifies a mandatory action that must be followed or a restricted action that must not be performed. The lower, un-bolded part of the warning explains the importance of the warning.

The following warnings apply generally to the use of the UltraEzAir® system. Additional warnings are included throughout this document where applicable to advise the user how to avoid most risks associated with the UltraEzAir® system.

WARNING: No modification of this equipment is allowed.

Modification of the UltraEzAir® system could lead to malfunction of the device and/or injury to users and patients.

WARNING: Do not use the device in proximity to flammable agents.

UltraEzAir® is not designed for safe use in proximity to flammable agents. Remove any flammable agents from the area before operating UltraEzAir® to avoid injury to patients or users.

WARNING: Do not use the device in proximity to heat sources.

UltraEzAir® is not designed for safe use in proximity to heat sources. Remove any heat sources from the area before operating UltraEzAir® to avoid injury to patients or users.

WARNING: Do not use the device when it is wet.

UltraEzAir® is not designed for safe use when the device is wet. Dry the device before operation to avoid injury to patients or users.

3.0 Product Description

3.1 System Components

The UltraEzAir® system is shown in the following figure. It is connected to a third-party flexible nasal laryngoscope via the Delivery Line's Male Luer or custom biopsy valve. The flexible nasal laryngoscope is not part of the UltraEzAir® system but is required to use the system.

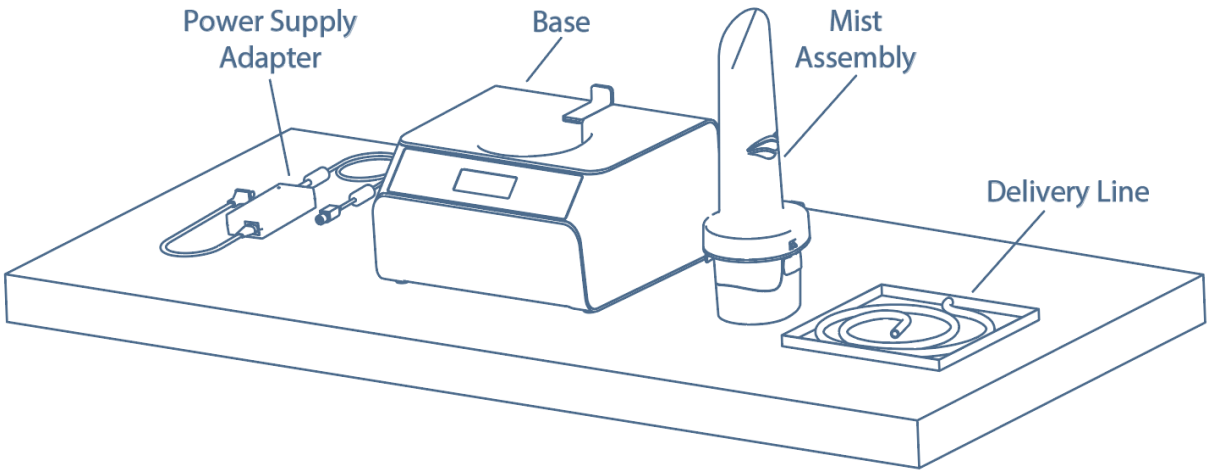


Figure 1 – UltraEzAir® System Components

The UltraEzAir® system (Figure 1 – UltraEzAir® System Components) is comprised of **durable** components that are reused between patients and **disposables** that are single-use and replaced between patients.

The **durables** include the **Base** and **Power Supply Adapter**. The **Base** contains the electronics that power and control the system, and the user controls required to operate the system. The **Base** also contains the indicators of system status that inform the user during operation of the system.

In addition, the **durable** includes the **Power Supply Adapter** (TDK-Lambda, Model: DTM110PW360C8).

The **disposable** components include the **Mist Assembly** and the **Delivery Line** which connects to either a Pentax or Olympus flexible nasal laryngoscope. The **Mist Assembly** consists of two components: the **Mist Cup** that will be filled with topical anesthetic solution, and the **Mist Stack**, which is where the aerosolized anesthetic is held before delivery to patient. Both disposable components are non-sterile.

The **Delivery Line** consists of a **Simpson adapter** (Y-adapter) that allows anesthetic solution to be dripped through the working channel of the flexible nasal laryngoscope. The Olympus Delivery Line also includes an Olympus adapter that allows the system to be connected to an Olympus® flexible nasal laryngoscope's working channel. The **Delivery Line** is provided non-sterile and for single-use only. See section 5.1.3 for more information on choosing the correct disposable for your application.

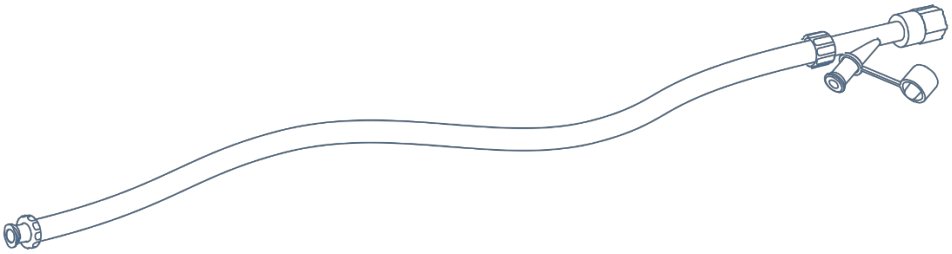


Figure 2 –Disposable Delivery Line for Pentax® Flexible nasal laryngoscopes.

Note that the Pentax Delivery Line connects directly to the Pentax Flexible nasal laryngoscope via the Luer connector and does not require an adapter.

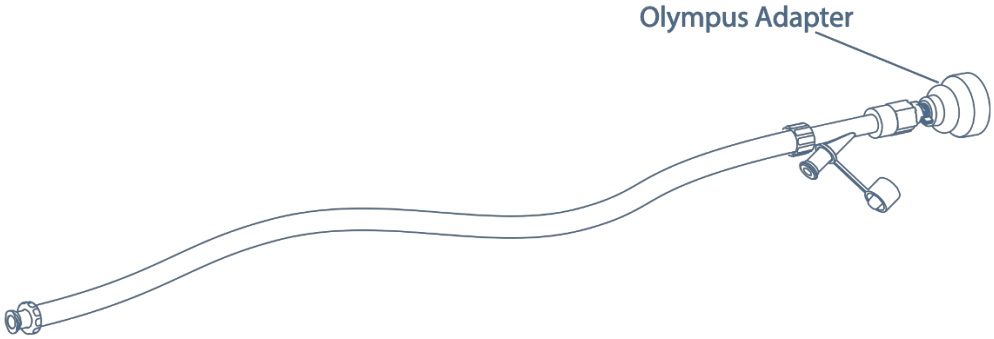


Figure 3 –Disposable Delivery Line for Olympus® Flexible nasal laryngoscopes

The air input **filter** is located on the bottom of the **Base**. This filter prevents airborne particulates and pathogens from being drawn into the **Mist Assembly** (Figure 4). The **filter** is not user-replaceable. See section 6.0 for more information.

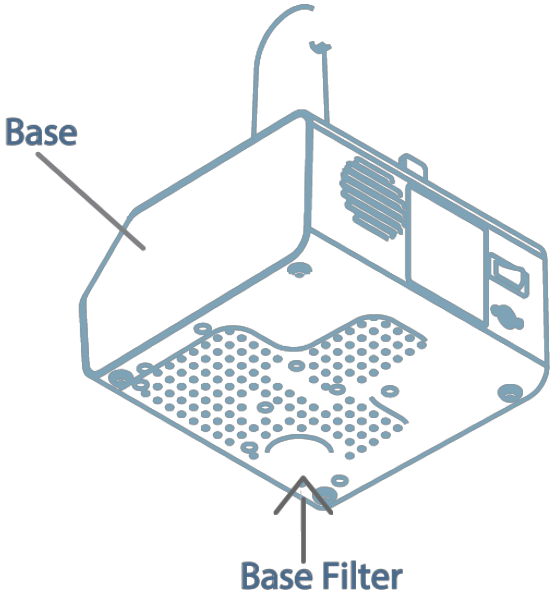


Figure 4 – Base Filter Location

3.2 Controls and Indicators

The UltraEzAir® system controls and indicators are shown in Figure 5.

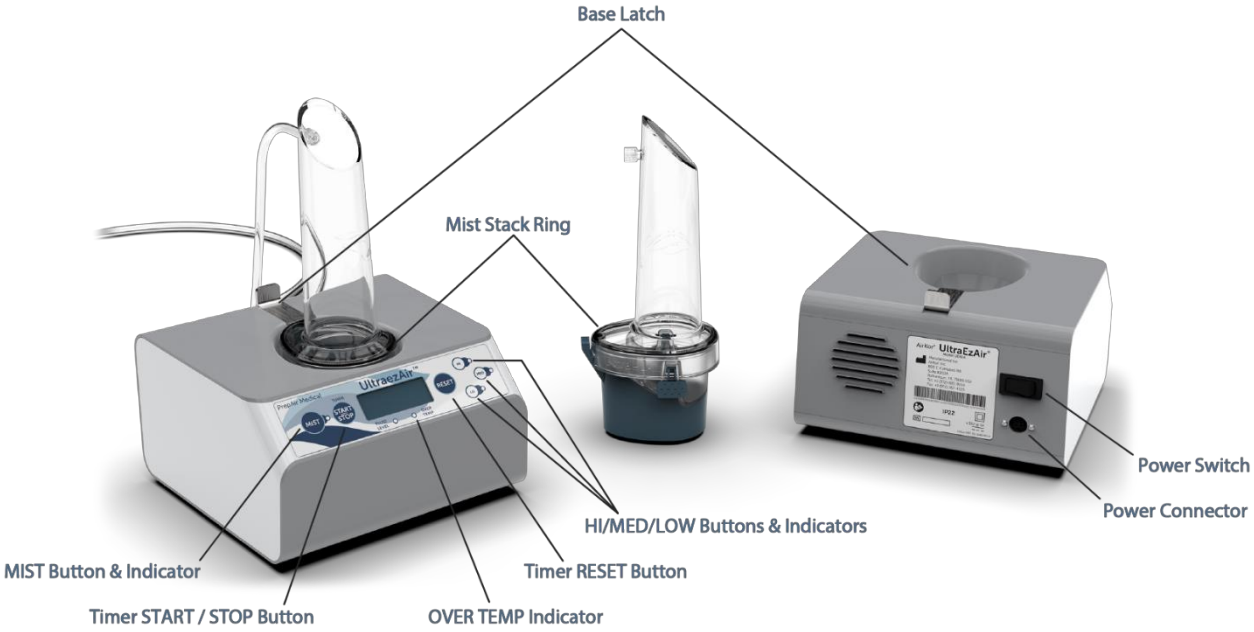


Figure 5 – System Controls and Indicators

The **Base Latch** is used to release the **Mist Assembly** for filling or disposal.

The **Power Switch** turns on power to the system but does not begin nebulizing.

The **MIST button** starts and stops nebulization. When nebulization is enabled, the **MIST indicator** and **Mist Stack ring** illuminate.

The **TIMER START/STOP button** starts and pauses the convenience timer, and the **Timer RESET** button resets it to 00:00.

The **HI/MED/LO buttons** select the mist delivery rate of the anesthetic solution per the following table. Each button has a corresponding LED to indicate which delivery rate is selected.

Delivery Rate Table		
Delivery Rate Setting	**Delivery Rate for Pentax VNL-1570STK (mg of lidocaine / min)**	**Delivery Rate for Olympus ENF-V2 (mg of lidocaine / min)**
LO	1.43	1.17
MED	1.69	1.19
HI	2.10	1.28

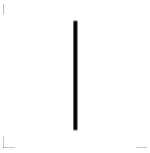
The **Over TEMP indicator** illuminates when the device is too hot. See section 7.0 Troubleshooting for more details.

3.3 Supported Laryngoscope Models

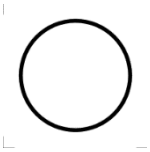
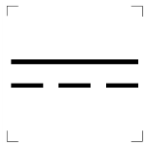
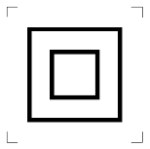
Note that the system has only been tested for compatibility with certain laryngoscope models. Therefore, only the following laryngoscope models are supported:

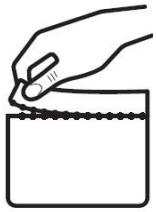
- Olympus® Rhino-Laryngo Digital Videoscope (ENF-V2) with following characteristics:
    - Instrument Channel Width: 2.0mm
    - Working Length: 365mm
    - Outer Diameter: 4.8mm
    - Outer Diameter Insertion Tube: 4.9mm
    - Deflection Up/Down: 130°
- Pentax® Therapeutic Naso-Pharyngo-Laryngoscope (VNL-1570STK) with the following characteristics:
    - Instrument Channel Width: 2.0mm
    - Working Length: 300mm
    - Outer Diameter: 4.9mm
    - Outer Diameter Insertion Tube: 4.9mm
    - Deflection Up/Down: 130°

4.0 Symbols Glossary[1]

Symbol	Source	Description
	47 CFR 19.209(b)	FCC Logo
	IEC 60417-5007	“ON” (Power)

[1] ISO 15223-1 "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements"

Symbol	Source	Description
	IEC 60417-5008	“OFF” (Power)
	IEC 60417-5031	Direct Current
	IEC 60417-5172	Class II Equipment
	ISO 7000-0624	Keep Away From Sunlight
	ISO 7000-0626	Keep Away From Rain
	ISO 7000-0632	Temperature Limit
	ISO 7000-1051	Do Not Re-Use
	ISO 7000-1641	Operator's manual; operating instructions (this document)
	ISO 7000-2492	Lot Number

Symbol	Source	Description
	ISO 7000-2493	Catalogue number
	ISO 7000-2498	Serial Number
	ISO 7000-2606	Do Not Use If Package Is Damaged
	ISO 7000-2607	Use by Date
	ISO 7000-2620	Humidity Limitation
	N/A	Perforated Package Opening Aid
	ISO 7000-2794	Packaging unit
	ISO 7000-3082	Manufacturer
	ISO 7010-M002	Refer to Instruction Manual

Symbol	Source	Description
	ISO 7010-W012	Warning: Electricity
	ISO 7000-0434	Caution- Consult instructions for use for important cautionary information
	21 CFR Part 801.109	Prescription Use Only
	ASTM F2503−13	MR Unsafe

5.0 Using the UltraEzAir® System

This section describes the setup, use, shutdown, cleaning, and disposal of the UltraEzAir® system.

5.1 Setup

This section describes how to set up the Base, fill the Mist Assembly, and connect the UltraEzAir® system to the flexible nasal laryngoscope using the disposable Delivery Line.

Clean and Disinfect the Base prior to initial use.

The Base must be cleaned and disinfected prior to initial use and at the beginning of each treatment day.

Put on appropriate Personal Protective Equipment (PPE) before handling the device.

Follow the facility safe handling policies and guidance where the system is deployed. At a minimum, the user must wear gloves when handling the device to avoid cross-contamination.

5.1.1 Set Up the Base

1. Ensure the UltraEzAir® Mist Assembly is either empty or removed from the Base before positioning the Base.

Do not hand-carry a filled Base.

While carrying a filled Mist Assembly is acceptable, the Base is not designed to prevent the Mist Assembly from falling out if the Base is tipped. This can result in spillage or physical injury. If the UltraEzAir® system needs to be moved after filling, either remove the Mist Assembly from the Base and transport them separately or transport the assembled unit on a rolling cart.

2. The Base should be set up on a stable surface within 3 feet of the patient. If desired, the Base can be set up on a rolling cart for easy transport (Figure 6).

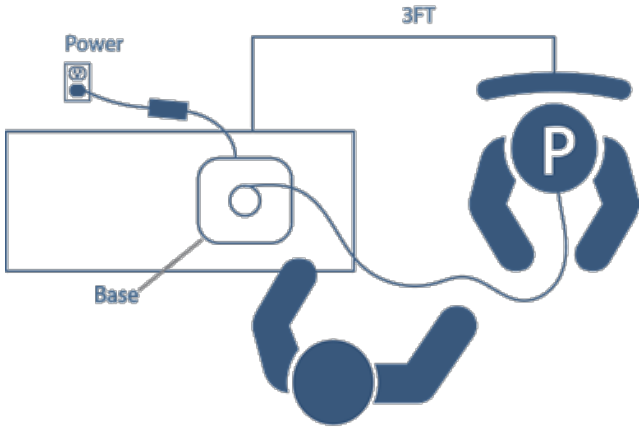


Figure 6 – Treatment Location Example (Top View)

Only operate the UltraEzAir® system on a stable surface.

Operation on an unstable surface could cause the UltraEzAir® system to tip over, potentially injuring or spilling anesthetic solution on the user(s) or patient. If used on a rolling cart, ensure the cart's wheels are locked during use.

Do not position the UltraEzAir® system too far away from or too close to the patient.

Positioning the UltraEzAir® system too far away (>3 feet) from the patient increases the likelihood of pulling on the flexible nasal laryngoscope and injuring the patient or tipping the UltraEzAir® system over, causing spillage. Likewise, placing the UltraEzAir® system too close to the patient increases the likelihood of user entanglement in the disposable Delivery Line, with the same results.

3. With the Base in position, plug the Power Supply Adapter into the power plug on the back of the Base, then plug the power cord into the wall. Ensure that the Power Supply Adapter and the power cord are positioned such that they will not become a tripping hazard (Figure 7).

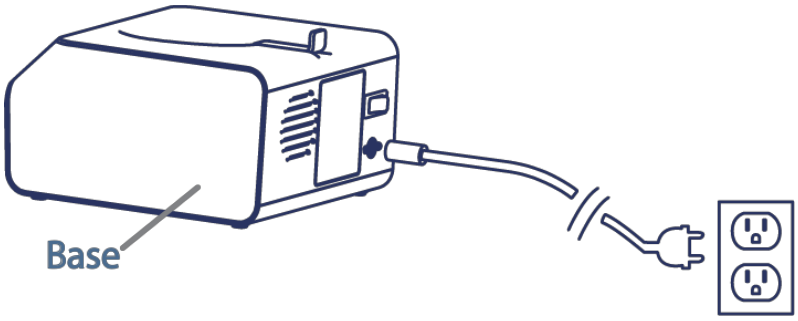


Figure 7 – Power Connection

Ensure that the Power Supply Adapter is easily accessible for unplugging.

The Power Supply Adapter is the means by which power can be completely removed from the UltraEzAir® system. In an emergency, it is necessary to be able to do this quickly to minimize harm.

5.1.2 Fill the Mist Assembly

1. Put on gloves before handling or filling the Mist Assembly.

Wear gloves and handle anesthetic solution carefully to avoid splashing or spillage.

Topical anesthetic solution causes localized numbness and tingling when absorbed through the skin. Careful handling will prevent anesthetic solution from spilling, and gloves protect the anesthetic solution from contacting unprotected skin.

2. Squeeze the sides of the Mist Cup to release it from the Mist Stack. Set the Mist Stack aside in a clean, dry location (Figure 8).

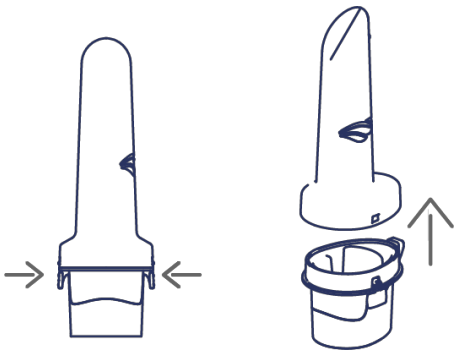


Figure 8 – Separation of Mist Stack from Mist Cup

Practice aseptic technique during filling and assembly.

Pathogens and irritants introduced into the Mist Assembly during filling and assembly can be inhaled into the patient's lungs, causing respiratory irritation or infection. Avoid touching or breathing on the interior surfaces of the Mist Assembly and handle the Mist Assembly components carefully to help reduce this risk.

3. Place the Mist Cup on a level surface and carefully fill the Mist Cup with anesthetic solution meeting the specification below. The Mist Cup must be filled

to between the MIN and MAX fill lines, or it will not operate as designed (Figure 9).

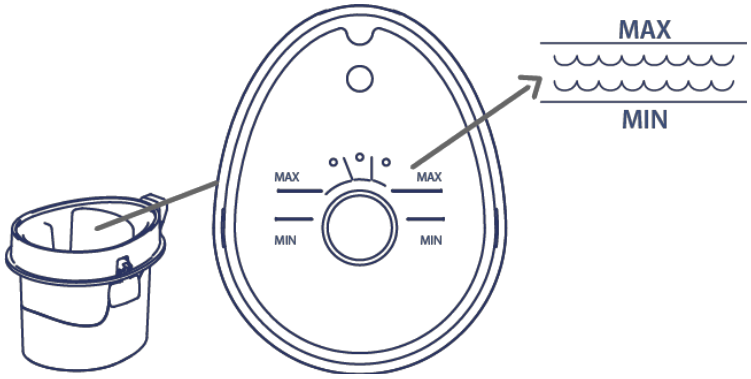


Figure 9 – Mist Cup MIN and MAX Fill Lines

The following topical anesthetic solution is specified for use with the UltraEzAir® system:

Topical Anesthetic Solution Specification	
Description	Lidocaine HCl Topical Solution USP 4%

Only use topical anesthetic solution in the UltraEzAir® system.

Use of other drugs, chemicals, or forms of anesthetic in the UltraEzAir® system could result in damage to the UltraEzAir® system and may lead to device malfunction and/or injury to Patient.

Ensure anesthetic meets the listed specifications.

The UltraEzAir® system was validated using Lidocaine HCl Topical Solution USP 4%. Gels or other formulations of anesthetic may not nebulize properly, resulting in extended numbing time. Delivery rate is calculated based on 4% topical lidocaine solution.

Ensure anesthetic is not expired.

Using expired anesthetic solution could result in damage to the UltraEzAir® system and may lead to device malfunction and/or injury to Patient. Only use unexpired Lidocaine HCl Topical Solution USP 4% with the UltraEzAir® system.

Only use supported UltraEzAir® system accessories.

The UltraEzAir® system is designed to be used with its specified accessories (see section 9.0). Unsupported accessories may not fit properly into the UltraEzAir® system or may lead to device malfunction and/or injury to user or patient.

Do not overfill the UltraEzAir® system.

Overfilling increases the risk of spillage and reduces the performance of the nebulization mechanism of the UltraEzAir® system. If the Mist Cup is overfilled, remove the excess before operating the UltraEzAir® system.

Do not operate the UltraEzAir® system when it is underfilled.

Insufficient anesthetic solution may lead to device malfunction and/or injury to user or patient. Damage caused by use of the UltraEzAir® system while it is underfilled is not covered by the warranty.

4. Carefully snap the Mist Stack onto the Mist Cup (Figure 10).

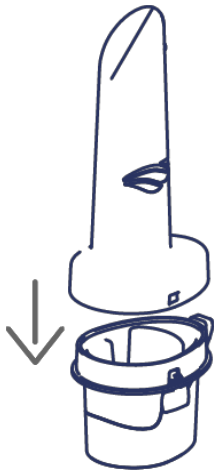


Figure 10 – Mist Stack to Mist Cup Assembly

5. Ensure the latches engage on both sides (Figure 11).

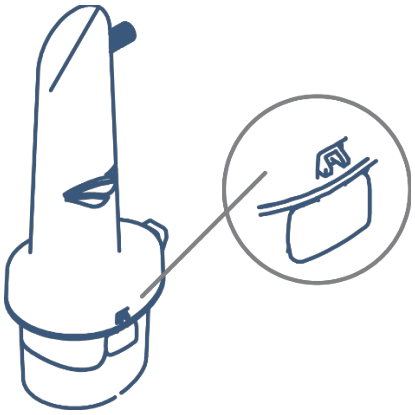


Figure 11 – Mist Stack Latches

6. Being careful not to drop or spill the Mist Assembly, orient it so that it fits into the recess in the Base, slide the Base Latch out, install the Mist Assembly into Base, release the Base Latch, and press down until the Base latch snaps closed. Make sure the Mist Assembly is fully seated and the Base Latch is fully latched (Figure 12).

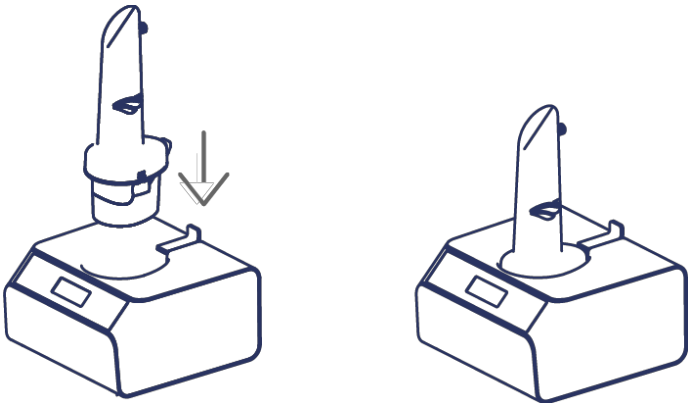


Figure 12 – Installing Mist Assembly into Base

5.1.3 Connect the Disposable Delivery Line

1. Obtain the appropriate disposable Delivery Line for your laryngoscope.
    - Olympus® style laryngoscopes with similar working channel ports should use the Delivery Line for Olympus® Endoscopes (REF PRP-102073). See 3.3 for supported laryngoscope models.
    - Pentax® style laryngoscopes with a Female Luer working channel port connection should use the Delivery Line for Pentax® Endoscopes (REF PRP-102099). See 3.3 for supported laryngoscope models.
2. Open the Delivery Line, being careful not to drop the contents.

3. Thread the Delivery Line's Female Luer onto the Mist Stack's Male Luer by turning the luer clockwise (Figure 13).

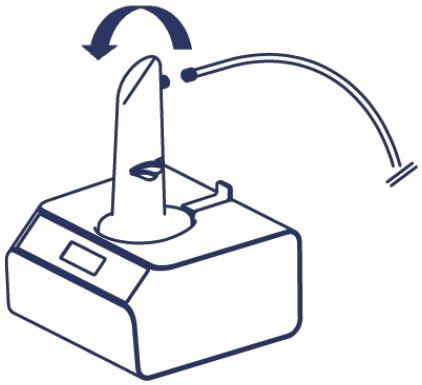


Figure 13 – Attach Delivery Line to Mist Stack

4. Connect the Simpson adapter (Y-adapter) side of the Delivery Line to the flexible nasal laryngoscope's working channel via the Male Luer of the Pentax Delivery Line (for connecting to a Pentax flexible nasal laryngoscope) or the Olympus Adapter of the Olympus Delivery Line (for connecting to an Olympus flexible nasal laryngoscope).
5. Verify that the Simpson adapter (Y-adapter) is capped.

Only use the UltraEzAir® system with supported flexible nasal laryngoscopes.

Use of unsupported flexible nasal laryngoscopes could result in leakage of anesthetic solution around the disposable connector or introduction of pathogens or irritants into the patient's airway. This could result in numbness or tingling with any unprotected skin that contacts the leaked anesthetic solution as well as respiratory irritation or infection. See 3.3 for supported laryngoscope models.

5.2 Use

This section describes how to turn on the UltraEzAir® system and determine the appropriate delivery rate and time.

5.2.1 Turn on the UltraEzAir® System

1. Flip the power switch of the Base to the ON (I) position (Figure 14).

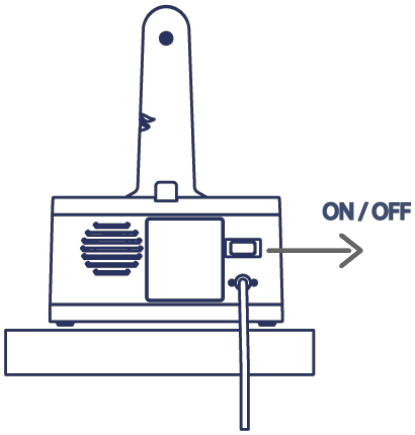


Figure 14 – UltraEzAir® Power Switch

2. The convenience timer display on the Base will turn on and initialize to 00:00.

3. Ensure the OVER TEMP indicator is off. If not, see section 7.0 Troubleshooting for further information.

5.2.2 Delivery Rate and Time

1. Use Table 1 for Pentax VNL-1570STK and Table 2 for Olympus ENF-V2 below as a guide to set the initial delivery rate for the patient. For dosage of the anesthetic, follow the drug manufacturer's labeling.

Mist Delivery Rate and Time for Pentax VNL-1570STK				
Delivery Volume (mL of 4% Lidocaine)	Delivered Lidocaine (mg of lidocaine)	Time (min:sec) Required for the Delivery Volume		
		HI (2.10 mg/min)	MED (1.69 mg/min)	LO (1.43 mg/min)
0.1	4	1:54	2:22	2:48
0.2	8	3:49	4:44	5:36
0.4	16	7:37	*	*

Table 1

Entries in the table marked with an asterisk (*) exceed the delivery volume possible at the indicated delivery rate (HI, MED, LO) before the safety timer expires.

Mist Delivery Rate and Time for Olympus ENF-V2				
Delivery Volume (mL of 4% Lidocaine)	Delivered Lidocaine (mg of lidocaine)	Time (min:sec) Required for the Delivery Volume		
		HI (1.28 mg/min)	MED (1.19 mg/min)	LO (1.17 mg/min)
0.1	4	3:08	3:22	3:25
0.2	8	6:15	6:43	6:50
0.4	16	*	*	*

Table 2

Entries in the table marked with an asterisk (*) exceed the delivery volume possible at the indicated delivery rate (HI, MED, LO) before the safety timer expires, for the flexible nasal laryngoscope being used.

2. After determining the delivery volume per drug manufacturer's recommendation, determine which delivery rate to use. Refer to Tables 1 and 2 above, for example dosage calculations. Select the delivery rate using the LO, MED, and HI buttons

on the Base. Confirm that the indicator next to the desired button illuminates to indicate the correct delivery rate (Figure 15).

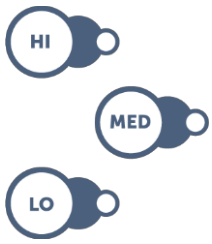


Figure 15 – HI, MED, LO Delivery Rate Selectors

5.2.3 Prime the Flexible Nasal Laryngoscope

1. Ensure that the Mist Cup is properly filled, and the Delivery Line and flexible nasal laryngoscope are connected.

Ensure the Delivery Line and flexible nasal laryngoscope are connected before nebulization.

Without the Delivery Line and flexible nasal laryngoscope connected, the UltraEzAir® system will nebulize anesthetic solution into the air, exposing the user, patient, and bystanders and potentially causing numbness or tingling on exposed skin.

Do not operate the UltraEzAir® system when it is underfilled.

2. The UltraEzAir® system does not automatically start nebulizing when the device is turned on. The user must press the MIST button to begin nebulizing/delivery. The MIST indicator illuminates (Figure 16) to show that the UltraEzAir® system is nebulizing/delivering anesthetic.

Figure 16 – Starting Delivery via MIST Button

Wait for a cone of aerosolized anesthetic to appear in the Mist Stack, travel through the Delivery Line, and exit the distal end of the flexible nasal laryngoscope (Figure 17).

Note: If the UltraEzAir® system is connected to the flexible nasal laryngoscope, a suction pump cannot be used simultaneously.

3. Do not insert the flexible nasal laryngoscope into the patient until nebulized anesthetic solution exits the flexible nasal laryngoscope. Users might find it useful to temporarily select the HI delivery rate to speed up this process.

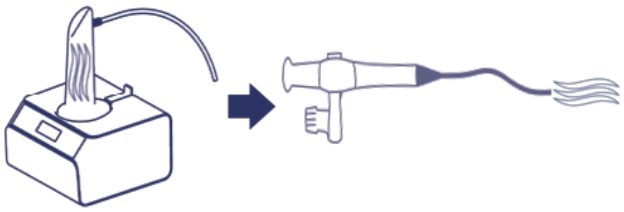


Figure 17 – Attach Delivery Line to Flexible nasal laryngoscope

5.2.4 Deliver Anesthetic

1. Insert the flexible nasal laryngoscope into the patient and direct the distal tip at the desired target sites for local anesthetic delivery. Be careful not to kink the Delivery Line.

Avoid anesthetic contact with sensitive areas.

While positioning the flexible nasal laryngoscope, be careful to avoid directing the flow of anesthetic into the patient's eyes or other sensitive areas that could become irritated by contact with the anesthetic.

2. As soon as the flexible nasal laryngoscope is in place, press the convenience TIMER START/STOP button to initiate timing. The timer will begin to count up. Remember to change the delivery rate back to the desired setting if it was changed to HI during priming.

Changing the delivery rate changes the delivery time.

The Mist Delivery Rate and Time Chart entries assume that all mist is delivered at the same delivery rate. If it is necessary to change the delivery rate once dosage has begun, the healthcare provider must determine how much lidocaine has been delivered and calculate the maximum remaining dosage time. For this reason, it is recommended to use a constant delivery rate throughout the entire procedure.

3. Monitor the patient for signs of anesthetic toxicity or allergy as directed in the drug manufacturer's labeling.

Watch for signs of lidocaine toxicity and do not deliver more than the recommended maximum dosage.

Pay attention to the TIMER and avoid distractions while delivering the anesthetic.

4. Apply lidocaine mist to the targeted areas of the anatomy and interactively palpitate the tissue to check level of numbness. Continue to apply mist to achieve a sufficient level of numbness.

Only apply mist to the upper airway.

UltraEzAir is only intended for use in the upper airway (oropharyngeal area). Do not apply mist to anatomy below the vocal folds.

5. Once a sufficient level of numbness has been achieved, press the MIST button to stop anesthetic delivery. The MIST indicator will no longer be illuminated to indicate that nebulization has stopped.
6. If used, press the TIMER START/STOP button to stop the convenience timer.

5.2.5 Check for Numbness

Follow the drug manufacturer's published guidance and accepted clinical practice to verify that the targeted tissue is sufficiently numb. Do not continue with the interventional procedure if numbness has not been achieved.

5.2.6 Perform Endoscopic Procedure

Once the targeted tissue has been sufficiently numbed, disconnect the Delivery Line from the flexible nasal laryngoscope and perform the desired interventional treatment.

Never perform the interventional procedure with the flexible nasal laryngoscope until the patient is sufficiently numb.

The interventional procedure should not be performed until the treatment area is sufficiently numb. Doing so may cause the patient to vomit, which could lead to serious complications such as asphyxiation, infection, or death. If numbing cannot be achieved using UltraEzAir, use an alternative numbing method or reschedule the patient to undergo the procedure under general anesthesia.

5.2.7 Disconnect and Discard Delivery Line and Mist Assembly

1. Ensure that the MIST and convenience TIMER are turned off.
2. Power off the Base unit.
3. Disconnect the Delivery Line from the Mist Assembly, elevating both ends to prevent any condensed anesthetic solution from escaping the Delivery Line.
4. Discard the Delivery Line containing any residual anesthetic solution as medical waste.
5. Slide Base Latch and remove Mist Assembly from Base.
6. Discard the Mist Assembly containing any remaining anesthetic solution as medical waste.

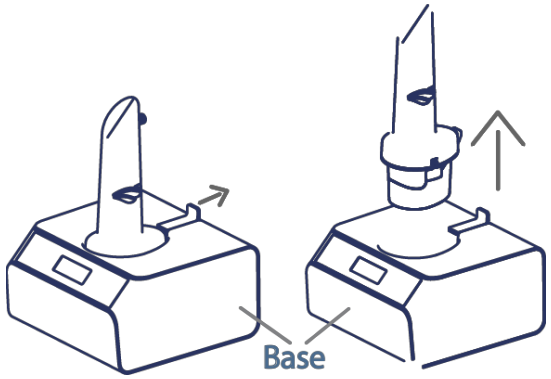


Figure 18 – Mist Assembly Removal from Base

5.2.8 Reset Convenience Timer

1. Press the timer RESET button to clear the convenience TIMER.

5.3 Between Patient Use

If the UltraEzAir® Base will be used on another patient the same day, a new Mist Assembly and Delivery Line Set must be used. If the UltraEzAir® system is not used on another patient within the same day, go to section 5.4 instead.

Never reuse a disposable Delivery Line or Mist Assembly on different patients.

Using the same disposable on multiple patients significantly increases the risk of cross-infection.

1. Press the convenience timer RESET button if the timer has not already been reset.
2. Repeat the previous sections beginning with section 5.1.2 to prepare and use the UltraEzAir® system with the next patient.

5.4 Cleaning and Disinfection

At a minimum, the Base shall be disinfected when visibly soiled and at the end of each day it is used[1]. Clean and disinfect the UltraEzAir® system components per the steps in the following sections.

5.4.1 Disinfection – Base

Per the CDC Guideline for Disinfection and Sterilization[2], the UltraEzAir® Base is considered a non-critical patient-care device that requires occasional low-level disinfection[3] with an EPA-registered hospital disinfectant using the label's safety precautions and use directions[4].

The Base will be cleaned and disinfected per the following:

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[1] https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html#rec5g, Category II, Recommendation 4.c.

[2] CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2019 (https://www.cdc.gov/infectioncontrol/guidelines/disinfection/)

[3] https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html#rec5g, Category II, Recommendation 4.c.

[4] https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/table1.html, Table 1A., Ethyl or isopropyl alcohol (70-90%), Exposure Time ≥ 1 minute

1. Wear protective gloves and other PPE appropriate for this task.
2. Use the power switch on the back of the Base to turn off the power and then disconnect the Power Supply Adapter from the Base unit.
3. If not removed, remove the Mist Assembly from the Base and discard.
4. Disinfection: Following the label directions for disinfection procedure and contact time, wipe down the external Base surfaces with Ethyl or isopropyl alcohol (70-90%). Use a cotton swab moistened with alcohol to gently clean the interior of the Mist Assembly receptacle. Ensure the surfaces remain wet with alcohol solution for a minimum of 1 minute.
5. After disinfection, allow the Base to dry, then store it until next use. See 5.5 for Storage information.

Turn off and unplug the UltraEzAir® system before cleaning and disinfection.

While the system is designed for safe operation during normal use, inadvertent short-circuiting during cleaning and disinfection could lead to device malfunction and/or injury to user or patient.

Do not submerge the Base in liquid.

The Base contains electrical components that can be damaged if submerged in liquid, potentially resulting in equipment failure, overheating, fire, or electric shock.

5.5 Storage

When storing the UltraEzAir® system either overnight or long-term, be sure to keep all components together, ideally in the original packaging, to avoid loss of components whose absence could render the system unusable. Only store the UltraEzAir® system in an environment that meets the storage conditions indicated in section 8.0.

Do not stack anything on top of the UltraEzAir® system.

The UltraEzAir® system is not intended to bear weight and stacking other items on top of it could damage it, rendering it unsuitable for use.

5.6 Disposal

Do not use any UltraEzAir® system component past its stated lifetime.

The UltraEzAir® system is designed to operate within specifications over its stated lifetime per 5.6.2. Beyond that, the performance can degrade without warning, resulting in device malfunction and/or injury to user or patient. Always properly dispose of UltraEzAir® system components whose stated lifetime has elapsed.

5.6.1 Delivery Line and Mist Assembly

The Delivery Line and Mist Assembly should be discarded after a single use as medical waste and replaced between each patient.

5.6.2 Base and Power Supply Adapter

The Base and Power Supply Adapter contain electronic components that must be properly recycled at the end of their useful lifetime, which is 3 years after purchase or quantity 2,500 5-minute uses, whichever comes first.

When the Base has exceeded its useful lifetime, re-package the Base and its Power Supply adapter in the original packaging and ship them to AirKor® for recycling/disposal. If the packaging was damaged or discarded, contact AirKor® for replacement packaging.

6.0 Preventative Maintenance

All preventative maintenance should be performed by trained AirKor® personnel.

Do not open the UltraEzAir® Base or Mist Cup.

These components contain electrical parts that could lead to electric shock if opened. Maintenance to the UltraEzAir® system should only be performed by trained AirKor® personnel.

Do not perform maintenance on the UltraEzAir® system while it is being used on a patient.

Attempting to perform maintenance on the UltraEzAir® system while it is being used on a patient could result in electric shock or respiratory irritation or infection.

Do not attempt to replace the air filter of the UltraEzAir system.

Use of the wrong filter, failure to install the filter, or incorrect installation could result in patient injury.

Preventative maintenance should be scheduled once per year. The trained AirKor® technician will replace the filter and verify operation of the pump as well as seals, valves, and gaskets.

Only trained AirKor® personnel should perform professional maintenance service.

Failure to adhere to safety guidelines and properly reassemble the UltraEzAir® could result in device malfunction and/or injury to user or patient.

7.0 Troubleshooting

Symptom	Potential Cause	Possible Solutions
Convenience Timer is not visible.	Device is not plugged in.	Plug in device.
	Device is not turned on.	Switch the device power switch to the ON (I) position.
Mist indicator and Mist Assembly ring do not turn on when MIST button is pressed.	The Mist Assembly is not fully latched into the Base.	Press the Mist Assembly into the Base until it latches.
	The device has overheated.	Allow the device to cool for 10 minutes.
Anesthetic delivery is too slow.	The delivery rate is too low.	Choose a higher delivery rate.
	The filter is plugged.	Schedule service to replace the filter.
	The Delivery Line is kinked.	Ensure the Delivery Line is not kinked.
	The Delivery Line is leaking.	Verify the tubing connections to the Mist Assembly and flexible nasal laryngoscope are all securely connected. Ensure the cap of the Y-adapter (Simpson adapter) is securely connected. If there is a leak in the Delivery Line, replace it.
Anesthetic delivery is too fast.	The delivery rate is too high.	Choose a lower delivery rate.

Symptom	Potential Cause	Possible Solutions
Little or no airflow.	The filter is plugged.	Schedule service to replace the filter.
	The Delivery Line is kinked.	Ensure the Delivery Line is not kinked.
	The Delivery Line is leaking.	Verify the Delivery Line connections to the Mist Assembly and flexible nasal laryngoscope are securely connected. If there is a leak in the Delivery Line, replace it.

8.0 Specifications

Device Specifications Table			
Specification		**Value**	
Mist Delivery Rate	Delivery Rate Setting	Pentax VNL-1570STK (mg of lidocaine / min)	Olympus ENF-V2 (mg of lidocaine / min)
	LO	1.43 (+/- 1 mg)	1.17 (+/- 1 mg)
	MED	1.69 (+/- 1 mg)	1.19 (+/- 1 mg)
	HI	2.10 (+/- 1 mg)	1.28 (+/- 1 mg)
Timer Tolerance		±1%	
Airflow Rate (at input to Mist Assembly)		1.5 LPM ± 20%	
Base	Weight	2 lbs	
	Dimensions	7.75in x 7.5in x 4.25in	
Mist Assembly	Weight	0.35 lbs	
	Dimensions	4in x 3in x 9.5in	
Olympus Delivery Line	Length	39.4 in	
Pentax Delivery Line	Length	38.5 in	
Classifications	Device Transportability	Portable	
	Protection Against Electrical Shock	External Class II, per ANSI/AAMI/IEC 60601-1, §6.2	
	Applied Parts	None; the UltraEzAir® system connects to a flexible nasal laryngoscope that acts as the applied part.	
	Sterilization	The UltraEzAir® durables and disposables are provided non-sterile.	
	Oxygen-Rich Environment	The UltraEzAir® system is not intended for use in an oxygen-rich environment.	
	Defibrillation	The UltraEzAir® system is not intended for use in conjunction with a defibrillator.	
	Operating Mode / Duty Cycle	The UltraEzAir® system is suitable for continuous operation.	
Power Supply Adapter	Input	90–264 VAC @ 47–63 Hz, 2A max	
	Output	36 VDC @ 3.06A	
	Weight	1.25 lbs	
	Length	115.5 in	
Fuse	Internal, non-accessible – non-serviceable, Ratings	Voltage: 250 V Current: 3 A Operating Speed: SLO-BLO Size: 10x3mm (Littelfuse 443) Breaking Capacity: 50 A @ 250 VAC	
Environmental Range	Storage & Transport	-25 ~ 70 °C (-13 ~ 158 °F) 5 ~ 95 %RH, non-condensing	

Device Specifications Table		
Specification		**Value**
Environmental Range	Operation	15 ~ 30 °C (59 ~ 86 °F) 30 ~ 75 %RH, non-condensing 700 ~ 1060 hPa (20.67 ~ 31.30 inchHg)
Safety Testing		ANSI/AAMI 60601-1 IEC 60601-1-2
Base Lifetime		3 years or 2,500 5-minute uses, whichever comes first
Mist Assembly Lifetime		Single patient use, discard at the end of each patient exam / procedure
Power Supply Adapter Lifetime		3 years or 2,500 5-minute uses, whichever comes first
Delivery Line Lifetime		Single patient use, discard at the end of each patient exam / procedure

Adherence to the preventative maintenance schedule provided in section 6.0 ensures that these parameters will continue to be met.

9.0 Supported Accessories and User-Replaceable Components

The following accessories and replaceable components are intended for use with the UltraEzAir® system.

Only use supported UltraEzAir® system accessories.

The UltraEzAir® system is designed to be used with its specified accessories (see table below). Use of unsupported accessories may lead to device malfunction and/or injury to user or patient.

Supported Accessories and User-Replaceable Components	
Item	**Catalog Number**
Base & Power Supply Adapter	PRP-102115
Mist Assembly	PRP-202004
Delivery Line for Olympus® Endoscopes	PRP-102073
Delivery Line for Pentax® Endoscopes	PRP-102099
Power Supply Adapter (TDK-Lambda)	Model: DTM110PW360C8

10.0 Electromagnetic Compliance

Electronic devices generate electromagnetic radiation during operation. This radiation can adversely affect other nearby electronic devices. To reduce this risk, the UltraEzAir® system has been tested per IEC 60601-1-2:2014 to ensure that the radiation it produces is acceptably low and that it continues to operate safely while exposed to electromagnetic interference (EMI) it is likely to encounter. However, the testing performed does not guarantee that the UltraEzAir® system will not affect nearby particularly sensitive devices, nor does it guarantee that the UltraEzAir® system will not be affected by nearby devices that generate excessive radiation. Follow these guidelines to minimize the likelihood of this happening.

The emissions characteristics of the UltraEzAir® system make it suitable for use in medical offices (CISPR 11 class A). UltraEzAir® is not intended for home-use environments.

Do not use the UltraEzAir® system adjacent to or stacked with other equipment. Maintain at least 12 inches from other electrical equipment, including portable RF communications equipment such as cell phones, walkie-talkies, or antennas. It is particularly important to keep life-supporting equipment separated from the UltraEzAir® system. Extra distance might be required between the UltraEzAir® system and devices that produce excessive EMI, such as high-frequency surgical equipment, magnetic resonance imaging (MRI) equipment, contactors, relays, and large motors.

If it is not possible to maintain this distance between the UltraEzAir® system and other equipment, closely monitor both the UltraEzAir® system and the other equipment to ensure they are operating normally. Signs that the UltraEzAir® system might be experiencing EMI-related degradation include:

- Flickering convenience timer display or indicators
- Increase or decrease in mist density
- Increase or decrease in airflow
- Increase or decrease in the speed of the convenience timer
- Unexpectedly starting or stopping mist delivery

Use only the power supply provided with the UltraEzAir® system. Use of other power supplies could increase the electromagnetic radiation the UltraEzAir® system produces or reduce the immunity of the UltraEzAir® system to EMI produced by other devices.

If interference does occur, try turning off the UltraEzAir® system and moving it away from other electronic equipment.

Do not use the UltraEzAir® system in close proximity to life-supporting equipment.

Although the UltraEzAir® system has passed electromagnetic emissions testing, it could still interfere with particularly sensitive nearby equipment.

Reciprocal interference between the UltraEzAir® system and devices used in conjunction can degrade performance.

The UltraEzAir® system is not intended to be used in conjunction with other devices.

The following tables include the UltraEzAir® system electromagnetic emissions and immunity compliance levels. No deviations were made to the standards; however, the following exemptions were claimed:

- Line-to-ground surges per IEC 61000-4-5 do not apply since the UltraEzAir® system uses a Class II power supply.
- The DC power port testing does not apply to the UltraEzAir® system since it is not intended to be permanently connected to a DC source. The AC power port testing was conducted instead.
- The UltraEzAir® system does not have a patient coupling port; therefore, no patient coupling port testing was done.
- The only signal input / output port on the UltraEzAir® system (between the Base and the Mist Assembly) has connections shorter than 3 meters; therefore, the UltraEzAir® system was not tested for electrical fast transients / bursts, surges line-to-ground, or conducted disturbances on that port.

UltraEzAir® System Emissions Compliance			
Phenomenon	**Standard**	**Classification**	**Explanation**
Conducted and Radiated Emissions	CISPR 11	Group 1	The UltraEzAir® 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.
		Class A	The UltraEzAir® system is suitable for use in professional healthcare settings. It is not intended for use in a domestic or residential setting.
Harmonic Distortion	IEC 61000-3-2	Class A	The UltraEzAir® system is classified as equipment that is not a portable tool, arc welding equipment, lighting equipment, PC, PC monitor or radio or TV receiver. It therefore falls into the general equipment classification.
Voltage Fluctuations and Flicker	IEC 61000-3-3	N/A	All devices subject to this standard use the same test criteria.

UltraEzAir® System Immunity Compliance: Enclosure		
The UltraEzAir® system has passed testing according to the standards and compliance levels indicated below. The electrostatic discharge compliance level is typical of environments having concrete, wood, or ceramic-tiled flooring. Synthetic materials can increase the likelihood of and voltage contained in electrostatic discharges. Therefore, if synthetic materials are used, the relative humidity must be maintained above 30%. The electric and magnetic field compliance levels are representative of the conditions present in a clinical or hospital environment.		
Phenomenon	**Standard**	**Compliance Level**
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2/4/8/15 kV air
Radiated RF Electric Fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

UltraEzAir® System Immunity Compliance: Input AC Power		
The UltraEzAir® system has passed testing according to the standards and compliance levels indicated below. These compliance levels are representative of the quality of mains power typical in a clinical or hospital environment. Poor power quality can introduce voltage transients exceeding these limits that could damage the UltraEzAir® system or cause it to operate incorrectly. If the UltraEzAir® system needs to be used with uninterrupted operation during power mains interruptions, it is recommended that the UltraEzAir® system be powered from an uninterruptible power supply.		
Phenomenon	**Standard**	**Compliance Level**
Electrical Fast Transient / Burst	IEC 61000-4-4	±2 kV 100 kHz
Surges Line-to-Line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Conducted Disturbances	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands 0.15 MHz–80 MHz 80% AM at 1 kHz
Voltage Dips	IEC 61000-4-11	0% U_T, 0.5 cycles at 0/45/90/135/180/225/270/315° 0% U_T, 1 cycle at 0° 70% U_T, 25/30 cycles at 0°
Voltage Interruptions	IEC 61000-4-11	0% U_T, 250/300 cycles

UltraEzAir® System Immunity Compliance: Signal Input / Output Port		
The UltraEzAir® system has passed testing according to the standards and compliance levels indicated below. The electrostatic discharge compliance level is typical of environments having concrete, wood, or ceramic-tiled flooring. Synthetic materials can increase the likelihood of and voltage contained in electrostatic discharges. Therefore, if synthetic materials are used, the relative humidity must be maintained above 30%.		
Phenomenon	**Standard**	**Compliance Level**
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2/4/8/15 kV air

UltraEzAir® Separation from RF Wireless Communication Equipment					
All wireless communication testing assumes that the UltraEzAir® system is operated with a separation distance of 12 inches (30 cm) to the transmitter. The tests performed are given below. To calculate the minimum separation distance to a transmitter with a different power than the one specified below, use the following equation: $$d = \frac{6}{E} \bullet \sqrt{P}$$ Where d is the separation distance in meters, E is the immunity test level for the frequency of the transmitter per the rightmost column in table below, and P is the power of the transmitter.					
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Immunity Test Level (V/m)**
385	380–390	TETRA 400	Pulse Modulation 18 Hz	1.8	27
450	430–470	GMRS 460, FRS 460	Frequency Modulation ± 5 kHz deviation 1 kHz sine	2	28
710	704–787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	9
745					
780					
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	28
870					
930					
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	28
1845					
1970					
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	28
5240	5100–5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	9
5500					
5785					

This device complies with Part 18 of the FCC rules.

UltraEzAir® System Immunity to RFID and Other Disturbances		
The UltraEzAir® system has passed testing set by the AIM 7351731 standard and FDA Guidance: "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices" at the compliance levels indicated below.		
Phenomenon	**Standard**	**Compliance Level**
RFID of animals - Advanced transponders	ISO 14223, Type A	65 A/m
Proximity Card Readers	ISO 14443-3, Type A	7.5 A/m
	ISO 14443-4, Type B	7.5 A/m
	ISO 15693-3	5 A/m
RFID for item management	ISO 18000-3	12 A/m
	ISO 18000-7	3 V/m
	ISO 18000-63 (Pulse Width: 1.656 µS)	54 V/m
	ISO 18000-63 (Pulse Width: 3.281 µS)	54 V/m
	ISO 18000-4	54 V/m
X-ray (30kHz)	N/A, FDA Guidance	10 V/m
NFC (13.56 MHz)	N/A, FDA Guidance	81.5 dBuA/m
Wireless Power Transfers (113 kHz and 126 kHz)	N/A, FDA Guidance	20 dBm
5G Cellular (742 MHz, 842 MHz, 1909.9 MHz, 1923.264 MHz)	N/A, FDA Guidance	30 dBm and 40 dBm

11.0 Limited Three-Year Warranty

AirKor® warrants this product to be free from defects in workmanship and materials, under normal clinical use and conditions, for a period of three (3) years from the date of purchase. AirKor® agrees, at its option during the warranty period, to repair any defect in material or workmanship, to furnish a repaired or refurbished product of equal value in exchange, or to provide credit towards an upgraded model of the product. The customer is responsible for paying return postage.

This warranty shall not apply to any defect, failure, or damage caused by improper use or improper or inadequate maintenance and care. AirKor® shall not be obligated under this warranty to:

a) Repair damage resulting from attempts by personnel other than AirKor® representatives to modify, repair, or service the product unless directed by a AirKor® representative;
b) Repair damage, malfunction, or degradation of performance resulting from improper use or use with incompatible chemicals;
c) Repair damage, malfunction, or degradation of performance resulting from operation with insufficient fluid level in Mist Assembly;
d) Repair damage, malfunction, or degradation of performance cause by the use of non- AirKor® supplies or consumables or the use of AirKor® supplies not specified for use with this product;
e) Perform user maintenance and cleaning or to repair damage, malfunction, or degradation of performance resulting from failure to perform user maintenance and cleaning as prescribed in the instructions for use;
f) Repair damage, malfunction, or degradation of performance resulting from use, storage, or transport of the product in an environment not meeting the specifications set forth in the instructions for use; or
g) Repair damage, malfunction, or degradation of performance resulting from failure to properly prepare and transport the product as prescribed in the instructions for use.

The above warranties are given by AirKor® with respect to this product and its related items in lieu of any other warranties, express or implied. AirKor® and its vendors disclaim any implied warranties of merchantability or fitness for a particular purpose, or any similar standard imposed by applicable legislation. AirKor®'s responsibility to repair, replace, or offer a refund for defective products and related items is the sole and exclusive remedy provided to the customer for breach of these warranties.

Some states, provinces, and countries do not allow the exclusion or limitation of incidental or consequential damages or exclusions or limitations on the duration of implied warranties or conditions, so the above limitations or exclusions may not apply to you. This warranty gives you specific legal rights, and you may also have other rights that vary by state, province, or country.

To the extent allowed by local law, except for the obligations specifically set forth in this warranty statement, in no event shall AirKor® and its vendors be liable for any indirect, special, incidental or consequential damages (including loss of profits) whether based on contract, tort, or any other legal theory and irrespective of whether AirKor® or the vendor has advance notice of the possibility of such damages.

12.0 MR Safety

UltraEzAir® is unsafe for use in a Magnetic Resonant environment.

Do not use UltraEzAir® in a MR environment.

Attempting to use the UltraEzAir® system in a MR environment could lead to the harm of users or patients.

13.0 Training

To ensure safe use of the system, users should contact support@airkor.com to request training on the UltraEzAir® system.

REVISION HISTORY

Rev.	Description of Change	Author
1	Initial Release	Realtime
2	PREP-35: Correct Sec. 2.3.1 from 10-micron to 0.22-micron inlet filter for particulate reduction.	Realtime
3	PREP-39: Corrected Timer Tolerance to +/-1% per the actual timer accuracy of the Texas Instruments TPL5111 timer device and the set resistor used in the circuit, across the use temperature range of 15C-30C in the table in Section 8.0. PREP-41: Added Fuse ratings to table in Section 8.0.	Realtime
4	PREP-51: Clarify graphic in Figure 5. Add pouch opening symbol to 4.0 Symbols Glossary. Update Sec. 7.0 Troubleshooting to remove implied fluid level sensor capability.	Realtime
5	PREP-52: Update to Indications for Use statement due to primary predicate change.	Realtime
6	PREP-58: Unify Wording: Mist PREP-61: Unify Wording: Laryngoscope PREP-63: Risk Analysis and Labeling: Magnetic Resonance considerations PREP-64: Rev 6 IFU Updates: including update to clarify Essential Performance determination and other additions and changes. PREP-65: Remove references to Fujinon Endoscopes PREP-68: Suction port connection no longer supported PREP-70: Updating tolerance for Air Flow Rate PREP-71: AirKor Company Address Change	Realtime
7	PREP-72: Updates for Instructions for Use Rev. 7 / Training Animation Video Rev. 2	Realtime
8	PREP-80: IFU Rev 8 and Quickstart Guide Updates PREP-81: Add requirements based on FDA requests and ARE results	Realtime

APPROVALS

Role	Signature	Date
Don Hurd (Quality & Regulatory)		06 / 15 / 2023
Morgan Beeson (ID Lead)		06 / 15 / 2023
Garyld Miles (Executive Management)		06 / 15 / 2023

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