

tru corp



AirSim User's Guide

Version 2.1

True anatomy
True training
True to life

Handelspartner
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Contents

Contents	2
Orientation	3
Introducing AirSim	3
System	4
Materials and safety	4
Features	5
Supraglottic airway devices	7
<ul style="list-style-type: none">• Laryngeal Mask Airway• Laryngeal Tube• CobraPLA• PExpress• CombiTube	
Tracheal Tubes	13
Fibreoptic endoscopy	13
Care and maintenance	14
Warranty	15
Contact details	15

Orientation

Introduction

The AirSim is a faithful reproduction of the human airway anatomy and as such is invaluable as a training aid to facilitate the learning and development of airway management skills for all health professionals.

The major developmental approach which makes the product special is that:

- The airway is moulded from a master which was created from data collected from a CT scan of a person.
- The one piece mould together with the sophisticated dipping procedure during manufacture makes possible much of the realism offered.
- Integrated one piece and seamless construction for real life functionality.

Construction and material used will produce a human like tactile feedback during use. The airway will behave like it would in real life when being manipulated. These features of the airway trainer combine to give positive feedback during and after correct placement of an airway device.

System

The AirSim trainer is essentially comprised of two distinct components. These are:

1. The 'anatomical' component. This includes a one-piece, CT data derived, complete adult airway to include; upper and lower dentures (with/without breakaway incisors), hard palate, uvula, inflatable tongue, pharynx, epiglottis, larynx, vocal cords, trachea, carina and right and left main stem bronchi and left main stem extension.
2. The 'mechanical' component. This includes a robust mounting plinth, an adjustable spring-loaded mandible, an adjustable and lockable 'cervical' ball-and-socket joint and a futuristic head to complement the true anatomical realism and function of the airway. Finally, a compact and rugged carry case completes the specification allowing for easy portability and demonstration.
3. The 'airflow indicator component'. This is essentially an artificial 'lung'. This simple, yet effective device confirms correct placement of a tracheal tube or a supraglottic airway.

Materials

The materials used in the construction of AirSim have been selected because of their conformity to anatomical shape and their durability. The low coefficient of friction (COF) of our airway material gives unique tactile feedback producing true realism. The inherent tensile strength of the supporting structures provides a lightweight and sturdy product.

1. The ‘anatomical’ components of the AirSim are hand manufactured from a master tool derived from real human anatomy. The production relies on several innovative processes in polymer technology. These processes confer correct shape and function to the airway component.

2. The remaining structural materials are manufactured either by vacuum casting/moulding or injection moulding. They are sturdy, designed to withstand regular and constant use and are lightweight. These materials are constructed from Acrylonitrile Butadiene Styrene (ABS) sheet.

Technical Details are given in Appendix I.

Features

1. The tongue has a real life shape and texture which responds as it would in real life. It can be inflated to variable sizes to create different swollen tongue scenarios allowing varying degrees of difficulty for tracheal intubation. We recommend an initial inflation volume of no more than 20ml of air to create normal lingual tension.
2. The teeth are constructed from denture moulds to truly represent this part of the human anatomy giving further realism. A “breakaway teeth” option is available demonstrate the effects of bad practice.
3. The jaw has a unique spring loaded mandible allowing jaw thrust, realistic mouth opening together with the full range of jaw and mouth movements. This spring loaded mandible can be adjusted to re-create limited jaw/mouth opening. In addition the face is moulded around the lower jaw allowing bag and mask ventilation to be carried out.
4. The neck has a novel joint construction allowing a full range of extension and flexion movements. The neck may be fixed in any position using the ‘wing nut’ tensioner. In addition the neck joint may also locked in one of three fixed positions to create easy or difficult airway management scenarios. Using our unique neck joint system, the head can be accurately placed in the ‘sniffing the morning air’ position. This is achieved when the head is moved forward so that the marks on the fixed joint are in alignment with most forward mark on the swivel joint. The locking mechanisms have been improved to provide a more robust hold without the need for locking pins. Locking pins have however been retained as an additional feature. We have also fitted backs to the heads to enable the units to be gripped in a more realistic manner during procedures.
5. The plinth holding the unit is integrated and sturdy for stability during use. It is easily transported and can be safely stored in its carry cover. It can be fixed in place by means of two sturdy black suction cups. These may need to be moistened slightly for full adhesion depending on the surface the Airsim is placed.
6. The product provides a true anatomical fit and seal which makes it indispensable for the training of the insertion all currently available supraglottic devices which includes: Laryngeal Mask (Classic, Fastrach, Proseal and other single use varieties); Laryngeal Tube; Cobra PLA; PAXpress; Combitube (latest version only).
7. Faithful visualisation of internal features for bronchoscopic examination.
8. Unique capability for training in bag and mask ventilation and the insertion of oral, nasal, double lumen tracheal tubes and bronchial blockers (the latter two due to the anatomically accurate left main bronchus extension).
9. Facility for percutaneous cricothyroidotomy

Bag and mask ventilation



Supraglottic airway devices

Laryngeal Mask Airway

(Classic, Fastrach, Proseal Flexible, Unique, Portex disposable)



The AirSim accepts adult sizes 3, and 4 of all varieties of LMA

Pre-insertion Preparation

Prior to insertion, the cuff should be tightly deflated so that it forms a smooth "spoon-shape" without any wrinkles on the distal edge. This can be accomplished by pressing the device with its aperture side down on a flat surface with the fingers being used to guide the cuff into the desired shape.

- A completely deflated, smooth leading edge facilitates insertion, avoids contact with the epiglottis, and facilitates success in achieving the correct final position of the device at the upper oesophageal sphincter
- In order to ensure that the device is completely deflated, the "flip test" should be performed; when the tip of the deflated cuff is inverted, it should flip back to its original position - if it does not, there may be air inside the cuff or the mask may be incorrectly deflated
- Lubrication of the posterior surface of the cuff should be performed just before insertion to prevent drying of the lubricant; lubricate only the posterior surface of the cuff to avoid blockage of the aperture or aspiration of the lubricant; it is recommended that a bolus of lubricant be applied to the posterior tip of the deflated cuff
- A water-soluble lubricant, such as K-Y Jelly®, should be used; do not use silicone-based lubricants as they degrade the components.

The Laryngeal Tube (LT; VBM MedizinTechnik)

The AirSim accepts adult sizes 4 and 5 of the LT



The VBM is an alternative to ventilation with a face mask, Laryngeal Mask or for procedures where tracheal intubation is not necessary.

Due to the short tube and S-shape

- a blind insertion is possible without any instruments
- no irritation of vocal cords and trachea
- LT is positioned at the oesophageal inlet

Teeth marks

- thick middle line for orientation
- if necessary LT can be repositioned between the thinner lines to allow sufficient ventilation

Both cuffs

- are high volume cuffs which adjust to the anatomical situation

Ventilation hole

- lies in front of the larynx for efficient ventilation
- allows suctioning and bronchoscopy with a fibrescope

Material: Silicone

- latex free
- reusable
- autoclavable up to 134 C

Pharyngeal Cuff

- stabilizes tube
- blocks naso-and oropharynx

Oesophageal Cuff

- blocks entry of oesophagus
- reduces possibility of gastric ventilation

Instructions for use

1. Evacuate the cuffs completely with the syringe so that they lie smoothly on the tube.

Before insertion lubricate the cuffs and hold the tube like a pen above the Pharyngeal Cuff.

2. While holding the mouth open insert the tube down in a central position until the middle line of the teeth marks is level with the teeth.

When sliding down the palate make sure that the tongue is not pushed back.

3. Inflate the pharyngeal- and oesophageal cuff by fully pumping a few times to 80 cmH₂O. Due to the specially designed inflation line the pharyngeal cuff is filled first which stabilises the tube. Once the pharyngeal cuff has adjusted to the anatomy of the patient the oesophageal cuff will be automatically inflated.

Now press the red deflate valve to adjust to the desired pressure between 60-70 cmH₂O.

If in an emergency situation no cuff pressure gauge should be available the cuffs can also be inflated by means of the included syringe (follow the inflation volumes in the instructions of use).

4. The VBM Laryngeal Tube is now in place and the patient can be ventilated. Check Lung ventilation by auscultation.

If ventilation is not sufficient reposition the tube to distal or proximal between the thin teeth marks.

With the VBM Bite-block the LT can be protected and fixed safely.

For removal of the LT evacuate the cuffs completely with the included syringe to protect the cuffs against damage.

CobraPLA (Engineered Medical Systems Inc.)

The AirSim accepts adult sizes 3 and 4 of the CobraPLA



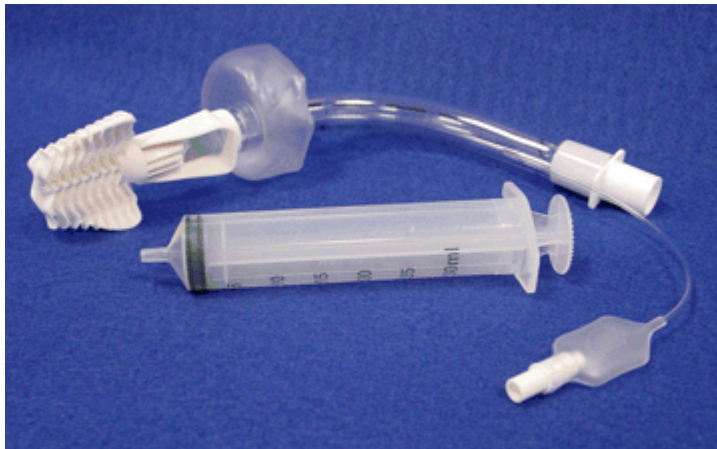
CobraPLA™ is an advance in supraglottic airway management. The PLA (Perilaryngeal Airway) is designed to be positioned in the hypopharynx where it abuts the structure of the laryngeal inlet.

The patented *Cobra head* design of the distal end of the CobraPLA holds both the soft tissue and the epiglottis out of the way, facilitating ventilation through the slotted openings.

The softened distal tip of the *Cobra head* provides easy passage of the device into the hypopharynx by bending in the direction of the glottis as the CobraPLA is inserted.

The large inner diameter of the CobraPLA's breathing tube increases air flow. This increased diameter, along with the gently curved ramp near the distal end, facilitates easy insertion of a bronchoscope for verification of correct placement. The cuff, when inflated, gently seals off the upper airway, allowing improved positive pressure ventilation.

The PAxpress (Vital Signs Inc)
One size for the adult AirSim



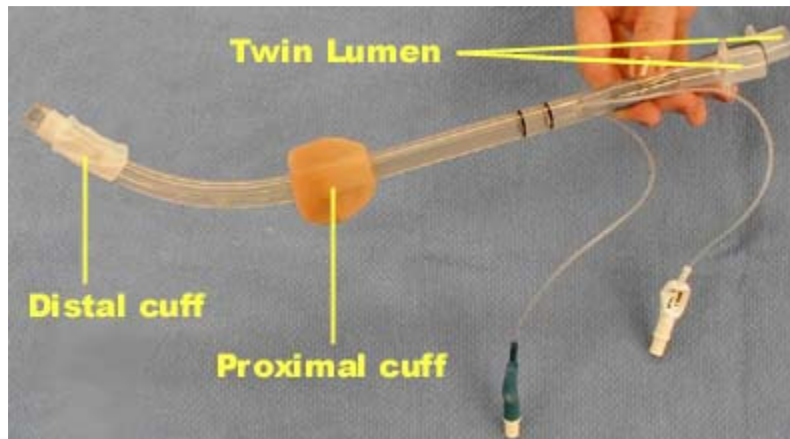
Intended as an alternative to a face mask, laryngeal mask airway (LMA) or cuffed oropharyngeal airway in those patients undergoing routine anaesthetic procedures.

Peak Inspiratory Pressure Limit 20 cmH₂O
Recommended oropharyngeal Cuff Vol. 30 to 60 ml
Tube ID 12.3 mm

For routine anaesthetic procedures, the PA_x is simple – One size fits our adult manikin – and secure. A flexible, gilled tip nestles in the hypopharynx; a high-volume, low-pressure cuff secures the PA_x in the oropharynx to provide a secure, hands-free airway.

The Combitube

The available sizes are 41 Fr and 37 Fr. and both fit the AirSim



The Combitube is a twin lumen device designed for use in emergency situations and difficult airways. It can be inserted blindly into the oropharynx and usually enters the oesophagus. It has a low volume inflatable distal cuff and a much larger proximal cuff designed to occlude the oro- and nasopharynx .

The Combitube has been used effectively in cardiopulmonary resuscitation. It has been used successfully in patients with difficult airways secondary to severe facial burns, trauma, upper airway bleeding and vomiting where there was an inability to visualize the vocal cords. The Combitube can only be used in the adult population as no paediatric sizes are available. The available sizes are 41 Fr and 37 Fr.

Oral Intubation (step by step guide)

The combitube can be inserted blindly without the aid of a laryngoscope. However, use of a laryngoscope has been reported to facilitate placement of the Combitube, it appears that the laryngoscope aids insertion by forcefully creating a greater space in the hypopharynx.

- Manikin head position can be neutral.
- When direct laryngoscopy is attempted and the vocal cords can be visualized, the Combitube should be placed in the trachea and used as a regular endotracheal tube.
 - Inflate the distal cuff with just enough air until no leak is present.
 - Check for and confirm tracheal placement by using the airflow indicator.
 - Connect the breathing circuit to the white connector number 2.
 - **Be aware that TruCorp only recommends the use of the latest version of the Combitube.**

Tracheal tubes (including double lumen varieties and bronchial blockers)



AirSim will accept any make or model of tracheal tube. It is not recommended that tracheal tubes of internal diameter less than 6.5 mm or greater than 10.0 mm are used in this manikin. Damage or inadequate tracheal seal may result.

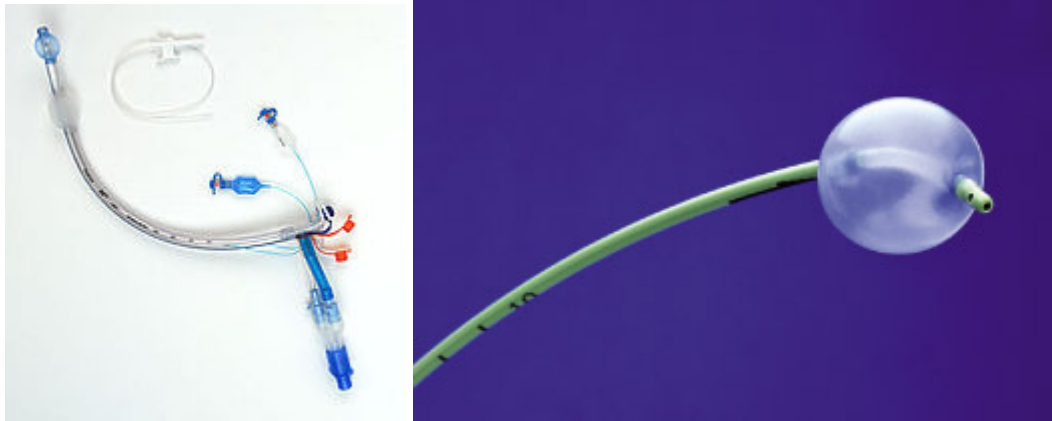
During tracheal intubation we recommend the standard procedure adopted for training in the 'live' procedure i.e. in humans.

It is important to ensure that the trainer is fixed or held firmly to a level surface which is at the correct height for the operator in question.

Nasotracheal intubation is easily achieved using the AirSim unit. **We strongly recommend that no greater than a size 7.0mm ID silicone-based wire-reinforced tracheal tube with a hemispherical bevel is used** (Fig). The use of larger tubes or tubes made of standard PVC is NOT recommended as these may damage the nasal passage.

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

For endobronchial use, the AirSim will come with an optional main bronchus extension adaptor (right/left) to facilitate placement of these specialised tracheal devices. Again, the standard and recognised teaching protocols for placement in humans apply for the AirSim. The manikin will accept 35-41 Fr tubes. In addition, AirSIM is particularly useful in the training of endobronchial tube blockers. These are specialised devices which are passed down the lumen of a regular tracheal tube and then guided into the left /right main stem bronchus.



Endoscopic airway management

The AirSim is ideal for training in the use of fibreoptic endoscopy **both by the nasal and oral routes**. The manikin faithfully reproduces a realistic view and feel of the internal anatomy of the upper and lower airway to the level of tracheal division. Additionally, fibreoptic examination through an already placed supraglottic device is readily available.

Cricothyroidotomy

The AirSim can be readily used for training in cricothyroidotomy. For needle cricothyroidotomy we supply the airway with a pinhole that has been pre-cut in the correct anatomical area. The material that the airway is constructed from has unique properties in that when dilated from pinhole size it accommodates the size of the dilation tool and thus gives an airtight seal around the said instrument whether this is a needle or a dilator. The pin hole is positioned in the correct anatomical area and is covered with a specialized and replaceable tape. The trainee has to identify the pinhole by palpation and then insert the needle and/or the dilators. When the needle or dilators are removed the material reverts to its original size. We also supply lots of spare sealing tape for further use.

Please note that the use of a scalpel or any sharp blade prior to performing cricothyroidotomy is NOT required. Doing so may damage the airway material in the area of the preformed pinhole and will invalidate the warranty.

Care and Maintenance

Cleaning and Storage

Store in clean, dry conditions away from heat and light; avoid contact with metals, solvents, oils or greases and strong detergents.

Thoroughly wash the AirSim in warm water, using a dilute (8-10% w/w) sodium bicarbonate solution until all visible foreign matter is removed.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants.

Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaners or iodine-containing cleaners for cleaning. Such substances are absorbed by the AirSim materials, resulting in exposure of the user to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances.

Clean the device using a small soft bristle brush (approximately ½ inch or 12.5mm in diameter). Gently insert the brush through the device, taking care not to damage the AirSim.

Thoroughly rinse the airway tube in warm flowing tap water to remove cleaning residues. Carefully inspect the device to ensure that all visible foreign matter has been removed.

Repeat the above as necessary.

Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues.

NB. It is important that generous amounts of a water soluble lubricant are used during airway and device interventions.

Getting the best out of AirSim. Hints and tips during use

- a) **It is important that generous amounts of a water soluble lubricant are used during airway and device interventions.**
- b) **Ensure that a generous amount of lubricant is applied to both surfaces of all supraglottic devices as the AirSim has no 'internal secretions'. This is particularly relevant to laryngeal mask airways.**
- c) **We also recommend that a lubricant be applied to the hard palate and tongue when the airway is being used for the first time in a teaching session or after cleaning.**
- d) **As a result of the true anatomical precision of AirSim, all current airway devices will perform well. Inadequate performance such as difficulty with insertion, airway leaks etc. are not due to the manikin. These are most likely down to operator error. Remove the device, prepare it to the manufacturer's data sheet (enc. in this manual) and start again.**
- e) **We recommend that when Airsim is not in use it should be replaced in its carry case. Exposure to direct sunlight may cause some discoloration in the red airway material**
- f) **Occasionally the pilot tubes of airway devices can get trapped in a gap between the plastic mandible and the head. Please be aware of this but be assured they are easily removed.**
- g) **The lightweight plinth is fixed to the working surface by means of two suction pads. The pads may need to be moistened slightly for full adherence to some working surfaces.**

Warranty

TruCorp warrants this unit to be free of defects in materials and workmanship and to give satisfactory service for a period of 90 days from the date of purchase. The TruCorp warranty adds an additional one (1) grace period to the normal product warranty to cover handling and shipping time. This ensures that our customers receive maximum coverage on each product. If the unit should malfunction it must be returned to the factory for evaluation. Our customer service department will issue an Authorised Return (AR) number immediately upon phone or written request. Upon examination by TruCorp, if the unit is found to be defective it will be repaired or replaced at no charge. However this warranty is VOID, if the unit shows evidence of having been tampered with or shows evidence of having been damaged by excessive heat, the use of sharp instruments, misapplication, misuse or other operating conditions outside of TruCorp's control. Components which wear or are damaged by misuse are not warranted.

Every precaution for accuracy has been taken in the preparation of this manual, however, TruCorp neither assumes responsibility for any omissions or errors that may appear nor assumes liability for any damages that result from the use of the product in accordance with the information contained in the manual.

Direct all warranty and repair requests/inquires to TruCorp Customer Service Department (Tel +44 (0) 2890335785). Before returning any devices please contact the TruCorp Service Department to obtain an Authorised Return (AR) Number. The designated AR number should then be marked on the outside of the return package. To avoid processing delays, also please be sure to include:

1. Returnee's name, address and phone number.
2. Model and serial numbers
3. Repair instructions



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Appendix I

Material Information for Airway component polymer

- Polymer samples were tested for **coefficient of friction (COF)** using a RDM CF-800 Tester. The dynamic coefficient of friction was measured by sliding a PVC medical tube of 9mm OD and mass of 12g over each of the surfaces of the polymer compound. The COF is a measure of the relative difficulty with which the surface of one material will slide over the adjoining surface. For these tests the force in grammes required to slide the weighted PVC tube over the polymer surface was recorded.
- Polymer samples were subjected to **tensile tests** using an Instron 4411 Universal Tensile Tester according to ASTM D638, using a crosshead speed of 500mm/min and an initial gauge length of 25mm. A minimum of 6 samples from each airway were tested. Tensile strength at break, modulus at 300% strain and percentage elongation at break were recorded
- **Results**

	Standard	Polymer
Coefficient of Friction	g Force	5.4
Tensile Strength at Break	ASTM D683	12.1
300% Modulus	ASTM D683	1.45
% Elongation at Break	ASTM D683	1620

Material safety data for ABS sheet:

- **Physical properties**
 - Solid flat sheet with smooth or embossed surface
 - Melting point 90°C
 - Solubility in water Insoluble
 - Specific gravity 1.05 g/cm³
 - Bulk Density 650 kg/m³
- **Fire and explosion data**
 - Auto-ignition Temperature >300°C
 - Flash point >300°C
 - Fire & Explosion Hazards Formation of toxic fumes and styrene
 - Extinguishing Media Water fog, Foam, CO₂, Dry Chemical
- **Health effects**
 - Effects of Inhalation Fumes from thermal decomposition and dust generated from machining may cause temporary breathing difficulties.
 - Effects of ingestion Non-toxic

Skin contact	None
• Waste disposal	
Controlled waste	No
Preferred Disposal method	Incineration or sanitary landfill
• Ecological hazards	
Water hazard	No ecological hazard
Land hazard	No hazard
• Transport	
Special requirements	None
Labelling	Not dangerous