

User Guide

COVID-19 Airway Contamination Instruction Manual

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7-SIGMA Simulation Systems

Modular Airway Trainer



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1 Introduction

1.1 Realistic Intubation

7-SIGMA, Inc. is pleased to present the 7S3 Modular Airway Trainer. Our airway management training system is unparalleled in its attention to the details crucial to realistically simulating intubation, ensuring that medical practitioners receive training that translates into superior patient care. The 7S3 Modular Airway Trainer pairs faithful replication of appearance, weight distribution and biomechanics with a modular construction supporting an expandable portfolio of configurations, making the 7S3 Modular Airway Trainer a vital tool for instilling the skillsets, knowledge, and confidence necessary for successful intubation. The 7S3 Modular Airway Trainer is the superior choice for developing best practices to safely intubate.

1.2 Quality

Our name, 7-SIGMA, says it all. Our strategy is to strive for an error free process. We pursue this goal through feedback from the market, attention to product performance, and continuous process improvement. Our Quality Management System includes:

- Follow ISO 9001:2008 Certified Quality Management System
- ISO 14001:2004 standards implemented



2 Manikin Modular Construction

The airway manikin is modular. Removable and interchangeable parts allow for numerous training configurations as well as easy replacement and cleaning without the use of tools.

2.1 Torso Components

The torso is comprised of: the body; the chest rise and lung shelving; the base plate; the face skin; and the front skull. (Figure 1)



Figure 1

2.2 Airway Components

The airway assembly is comprised of: the airway; the airway cradle; the upper teeth; the jaw and lower teeth; the muzzle; the lung balloons; and the acoustic gurgler. (Figure 2,3)

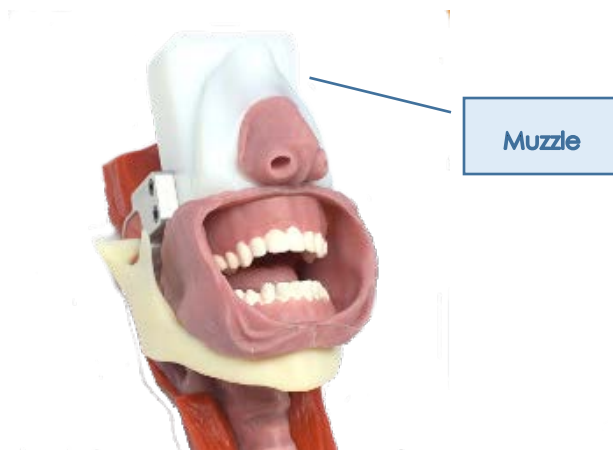


Figure 2

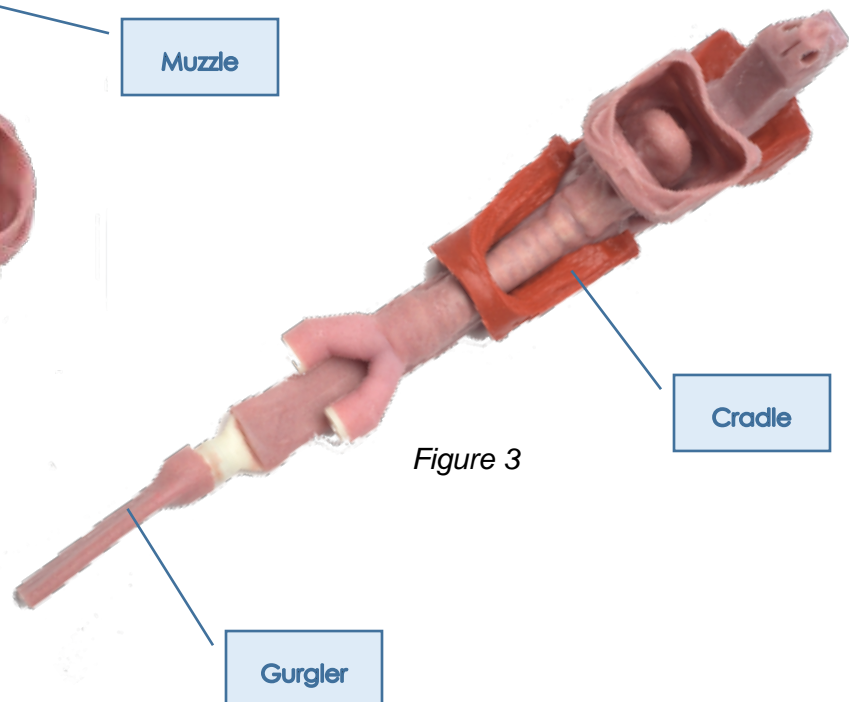


Figure 3

3 COVID Module Assembly

3.1 Assemble COVID Module

Remove the aerosolization adapter from the plastic bag and connect blue tube to lung of manikin. Connect clear plastic tubing end to lung bag, or BVM. Shake Airway Contaminant well for over 1 minute, as color should be a light milky white. Fill albuterol cup (twist to remove), with airway contaminant / saliva mixture to line. You can add water, Tonic water (with quinine), or isopropyl alcohol (70% or more) if you would like to thin out mixture or if it becomes "clumpy". Connect air tubing to pump or to wall air (40-60 LPM) (Figure 4,5). Spray additional saliva airway contaminant onto surface of model and inside mouth to represent droplets of particles.



Figure 4 - COVID Kit, with Nebulizer adapter, pump, contaminant saliva, and UV flashlight.

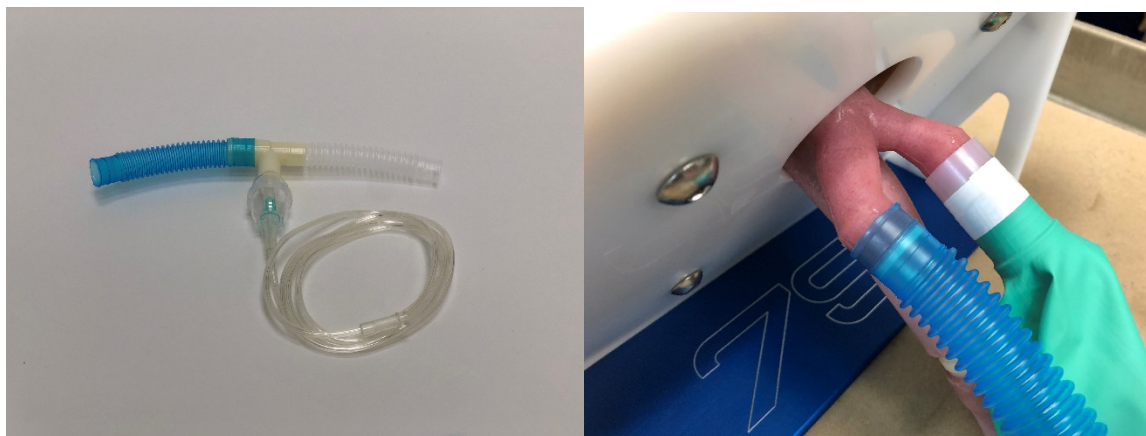


Figure 5, 3 - Aerosolization Adapter (blue end goes to lung of 7S3 manikin, tubing goes to wall air (@40-60psi), or to 7S3 pump).

4 Airway Disassembly

4.1 Remove Base Plate (in Full Torso model only)

Remove the base plate by depressing the two black buttons located at the bottom of each arm. They will pop out as shown. Turn them counter-clockwise to detach the base plate from the torso. Lift the hook and loop tab holding chest skin to the base plate. Remove the base plate, exposing the chest rise and lung shelving module. (Figure 6,7)

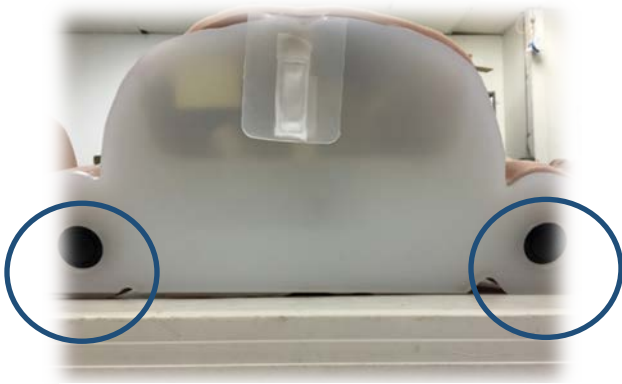


Figure 6



Figure 7

4.2 Disconnect Lung Balloons

Disconnect the right and left lung balloons by reaching into the chest cavity and gently pulling the plastic tubes from the rubber bifurcation. A slight twisting motion may help.

4.3 Remove Chest Rise (in Full Torso model only)

Remove the chest rise module from the chest cavity. (Figure 8)



Figure 8

4.4 Remove Face Skin

Remove the face skin by releasing the hook and loop neck strap and then peeling back the face skin, beginning from the crown of the head and moving toward the torso body. NOTE: The face skin is attached at the base of the neck by a series of four silicone "buttons" which are inserted into corresponding holes in the torso body. Gently remove each button from its corresponding hole by pulling upwards. (Figure 9)



4.5 Unlock Skull

Unlock the front skull from the back skull by simultaneously depressing the identical metal buttons on either side of the skull and lifting the front skull straight up while retaining pressure on the tabs. (Figure 10)



4.6 Airway module

Unlock the airway module from the front skull by pressing the metal button located on the right temple of the skull. Slide the white plastic muzzle toward the jaw until it is out of the front skull. This may require firm, steady force.

Lift the airway module out of the neck cavity and pull the airway module from the chest cavity.

Figure 9,10

Disassembly is Complete

5 Airway Reassembly

5.1 Airway

Insert the distal end of the airway with the bifurcation into the neck cavity and through the hole into the chest cavity. Pull gently from inside the chest cavity if necessary, to position the airway module. (Figure 11)

Figure 11



5.2 Muzzle

Insert the white plastic muzzle into the front skull by pushing it into the tracked support portion of the front skull until the locking mechanism clicks.

Figure 12

5.3 Skull

Place the front skull onto the metal posts of the back skull, press down until the locking mechanism clicks.

5.4 Cradle

Adjust the cradle portion of the airway module into the back skull so that it sits in place. (Figure 12)



5.5 Lung Balloons

Place lung balloons on the chest platform, making sure both lung air bags are lying evenly on the platform. (Figure 13)

Figure 13

5.6 Lung Bag Tube

Connect the lung bag plastic tube to the bifurcation of the airway module by pressing the plastic tubes into the bifurcation.



5.7 Chest Platform

(in Full Torso model only)

Slide the chest platform into the cavity until it is flush with the base of the torso. (Figure 13)

5.8 Base Plate Positioning

Place the base plate into position, inserting the posts of the black buttons into the corresponding holes and depressing the buttons so they are flush with the base plate. Secure the chest skin to the chest rise module by re-affixing the hook and loop tab.

5.9 Face Skin Adjustment

Beginning at the crown of the skull, place the face onto the front skull by adjusting the upper skull portion of the face skin around the indented area adjoining the front and back skull. Adjust the face around the jaw and mouth until properly seated. Secure the face skin to the torso by pressing the silicone buttons on the face skin into the holes in the collar portion of the torso. Adjust face skin and neck so that the face skin is sitting securely and pull the hook and loop tabs around the back of the neck and secure together.

Airway Assembly is Complete

6 Care and Maintenance

Care, Clean and Disinfecting Instructions for the 7S³ Trainer and Airway.

7-SIGMA Simulation Systems is not responsible for routine care and maintenance of your product.

6.1 Care

- a) Conduct training sessions on a clean, hard, and stable surface.
- b) Keep ink pens, markers, any other staining devices, and liquids away from the Trainer.
- c) Store in a clean, room temperature area. Cover with clean, white sheet or place in storage case (optional).
- d) Store Trainer in upright or supine position.

6.2 Cleaning

- a) After each use, clean external surfaces with a mild soap and tap water solution. Rinse by wiping with soft cloth, moistened with clean tap water. Gently dry the Trainer with a clean, lint free cloth.
- b) To clean the Complete Airway Assembly, you will need to remove it from the torso (see Airway Disassembly section steps).
- c) Hold the airway over a sink or basin, plug the tubes, and fill completely with a mild soap and warm tap water solution. Using a swab stick, gently scrub the inside of the mouth and nostrils. When done cleaning, drain completely and rinse with clean, warm tap water to completely remove the soapy solution.
- d) Dry the Airway Assembly completely with warm air before assembly into the torso.

* All silicone and plastic parts are dishwasher safe. Note, some discoloration may occur if you use a high temperature setting. This is normal, and will return to original color in a few hours.

6.3 Disinfecting the Airway

After prolonged use, disinfect the airway with a bleach and water solution (1 cup of 5-6% household bleach to 5 gallons of water) after performing the above soap and water cleaning process, and allow to air dry (must stay wet for at least 2 minutes).

Note: The bleach and water solution, rinsing, and drying process is specified by the Center for Disease Control at <https://www.cdc.gov/disasters/bleach.html>.

7 Airway Lubricant - Usage Instructions

Welcome to your new **7-SIGMA Simulation Systems (7S³) Torso Airway Trainer**. To achieve the best experience with our Torso Airway Trainer, we recommend the followings:

7.1 Preparing the Airway

To prepare the Torso Airway Trainer for a class, please take a few moments to lubricate it properly.

1. Put 2–3 squirts of 7S³ Lubricating Spray down the tongue.
2. Put the lubricant on your finger and wipe it over the posterior oral pharynx.
3. Take an endotracheal tube and spray it with the airway lubricant, covering the balloon. Then pass the tube forward and backwards thru the vocal cords. This will lubricate the opening of the trachea.

7.2 Training

Follow these steps while training:

1. Lubricate the nasal airway as you would for a patient.
2. The oral airway may need to be lubricated on occasion.
3. Lubricate an iLMA, Supreme LMA, Classic LMA, or an iGEL as you would if inserting into a patient.
4. To insert a King Tube, inflate the balloons and use 7S³ Lubricating Spray, to lubricate both balloons.
5. Use the same method to lubricate an endotracheal tube before insertion.

If you have any questions regarding the use of the **7S³ Torso Airway Trainer/Airway**, please do not hesitate to contact us.

Technical Support

Email: technicalsupport@7-sigma.com

Phone: 1.888.722.7224

8 Limited Warranty

8.1 Covered by This Limited Warranty

- Under this Limited Warranty, 7-SIGMA warrants the product to be free from defects in materials and workmanship arising under proper and normal use, for a period of one (1) year from the date of purchase.
- If the product proves defective due to improper materials or workmanship, 7-SIGMA will, at 7-SIGMA's discretion and without charge for labor or parts, repair or replace the product or its defective parts upon the terms and conditions set out below. 7-SIGMA shall have sole discretion as to which of these remedies it shall provide.

8.2 Not Covered by This Limited Warranty

- This Limited Warranty does not cover any damage, deterioration, or malfunction resulting from any alteration, modification, improper or unauthorized repair or maintenance, misuse, abuse, accident, neglect, improper storage, or any other cause which does not relate directly to a defect in materials and/or workmanship of this product.
- This Limited Warranty does not cover normal wear and tear, staining, discoloration or cosmetic irregularities which do not impede or degrade product performance.
- This Limited Warranty does not cover consumables provided with the product.
- The Limited Warranty does not cover, and 7-SIGMA shall not be responsible for, shipping damage or damage caused by mishandling by the freight carrier and any such damage is the responsibility of the freight carrier.

8.3 Conditions

- Only the original purchaser of this product is covered under this Limited Warranty. This Limited Warranty is not transferable to subsequent purchasers or owners of this product. The original invoice or sales receipt must be presented together with the defective product to invoke this Limited Warranty. 7-SIGMA reserves the right to refuse service under this Limited Warranty if the above documentation/information cannot be presented or if the information contained in it is incomplete or illegible.
- If 7-SIGMA elects to replace or repair the defective product, the replaced or repaired product will be warranted for the remainder of the Limited Warranty period applicable to the originally shipped product, but the Limited Warranty shall not be extended beyond the original Limited Warranty period.

- This Limited Warranty will not reimburse nor cover the damage resulting from adaptations or adjustments which may be made to the product, without the prior written consent of 7-SIGMA, in order to conform to the national or local technical or safety standards in force in any country other than the ones for which the product was originally designed and manufactured.
- This Limited Warranty will not apply if the serial number on the product has been altered, deleted, removed or made illegible.
- 7-SIGMA's sole and exclusive obligation and the original purchaser's exclusive remedy under this Limited Warranty is 7-SIGMA's repair or replacement of the defective product or a credit for the purchase price of the defective product.

TO THE MAXIMUM EXTENT PERMITTED BY LAW, THIS LIMITED WARRANTY AND THE REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES AND CONDITIONS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. TO THE MAXIMUM EXTENT PERMITTED BY LAW, 7-SIGMA SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, AND ANY REPRESENTATION OR WARRANTY ARISING BY USAGE OF TRADE, COURSE OF DEALING OR COURSE OF PERFORMANCE. 7-SIGMA'S TOTAL LIABILITY FOR ANY CLAIM OR DAMAGE ARISING OUT OF OR IN CONNECTION WITH THE MANUFACTURE, SALE, DELIVERY OR USE OF THE PRODUCTS WILL BE LIMITED TO PROVEN DIRECT DAMAGES, NOT TO EXCEED THE PURCHASE PRICE OF SUCH PRODUCTS. IN NO EVENT WILL 7-SIGMA BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING, WITHOUT LIMITATION, ANY CLAIM FOR LOSS OF ACTUAL OR ANTICIPATED REVENUES OR PROFITS.

8.4 How to get Warranty Service

All defective products must be returned with a Return Merchandise Authorization Number (RMA) which customer must request from 7-SIGMA. Customer must include the following information:

- Proof-of-purchase in the form of the dated purchase receipt
- Model number of the Defective Product
- Serial number of the Defective Product
- Detailed description of the defect
- Shipping address for return of the repaired or replacement product

Requests for RMAs should be directed to: ***customerservice@7-sigma.com*** or ***1-888-722-7224 (TF)***

9 Contact Information

9.1 Phone & Fax

Toll Free:

Phone: 1.888.722.7224

Customer Service – Option 1

Technical Support - Option 2

Fax: 1.844.898.4755



9.2 Email

Technical Support

technicalsupport@7-sigma.com

Customer Service

customerservice@7-sigma.com

9.3 Address

7-SIGMA, Inc.

2843 26th Avenue South / Minneapolis, MN 55406

<http://www.7-sigma.com/7-s3>

9.4 Facebook



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9.5 Twitter



Follow us: @7S3Medical

10 Appendix A

10.1 Product Listing

Part Number	Name/Description	
Full Torso Trainer		
770001	CA Adv Skills Torso Airway Trainer.	
770003	AA Adv Skills Torso Airway Trainer.	
770007	CA Burn Victim Skills Torso Airway Trainer	
770009	AA Burn Victim Skills Torso Airway Trainer	
Partial Airway Trainers		
770011	CA Adv Skills Partial Airway Trainer	
770012	AA Adv Skills Partial Airway Trainer.	
770017	CA Burn Victim Skills Partial Airway Trainer	
770018	AA Burn Victim Skills Partial Airway Trainer	
770200	Child Airway Skills Trainer (5 yr old female)	 
Complete Airways		
570.770.1001	CA Adv Skills Complete Airway Assy.	
570.770.3001	AA Adv Skills Complete Airway Assy.	
570.770.1017	CA Burn Victim Skills Complete Airway Assy.	
570.770.3017	AA Burn Victim Skills Complete Airway Assy.	

Base Airways		
570.770.1013	CA Base Airway Adv.	
570.770.3013	AA Base Airway Adv.	
Burn Victim Kit		  
Kit Includes: Burn Victim Complete Airway and Burn Victim Face Skin		
580.770.7000	CA Burn Victim Skills Kit	
580.770.9000	AA Burn Victim Skills Kit	
Accessories		
365.770.1001	Airway Lubricant	
560.770.1072	Upper Teeth	
560.770.1073	Lower Teeth	
560.770.1081	Burn Victim Upper Teeth	
560.770.1082	Burn Victim Lower Teeth	
570.770.1005	CA Face Skin	
570.770.3005	AA Face Skin	
570.770.1055	CA Burn Victim Face Skin	
570.770.3055	AA Burn Victim Face Skin	
7S ³ Skills Trainer		
770100	With Cricoid and Suturing Kits	
580.770.6042	CA Cricoid Skin Strips (Pack of 10)	
580.770.6052	AA Cricoid Skin Strips (Pack of 10)	
Coming Soon		
	Bronchoscopy Trainer	
	Sensor Based Bronchoscopy Trainer	