

Directions for Use

Version 1.6 • 16 April 2020



7-SIGMA Simulation Systems

Modular Airway Trainer



MAE

5-Year-Old Female

7-SIGMA Simulation Systems - 2843 26th Ave. South – 888-722-7224 (TF)

customerservice@7-sigma.com - www.7-sigma.com/7-s3

Table of Contents

1	Introduction	3
2	Modular Construction	4
3	Airway Disassembly	5
4	Airway Reassembly.....	8
5	Care and Maintenance	9
6	Airway Lubricant - Usage Instructions	10
7	Limited Warranty	11
8	Contact Information	13
9	Appendix A.....	14

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.

TO GET THE MOST OUT OF YOUR MANIKIN, PLEASE HANDLE THE MODEL AS YOU WOULD A REAL PATIENT. This manikin is NOT like other manikins. It's realism contributes to it's effective training, which includes respect for delicate tissues, and human beings.

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 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; base plate; the face skin; and the front skull. (Figure 1)

Figure 1



2.2 Airway Components

The airway assembly is comprised of; the front skull; the airway; the upper teeth; the jaw and lower teeth; the torso, the lung balloons; and the stomach balloon. (Figure 2)

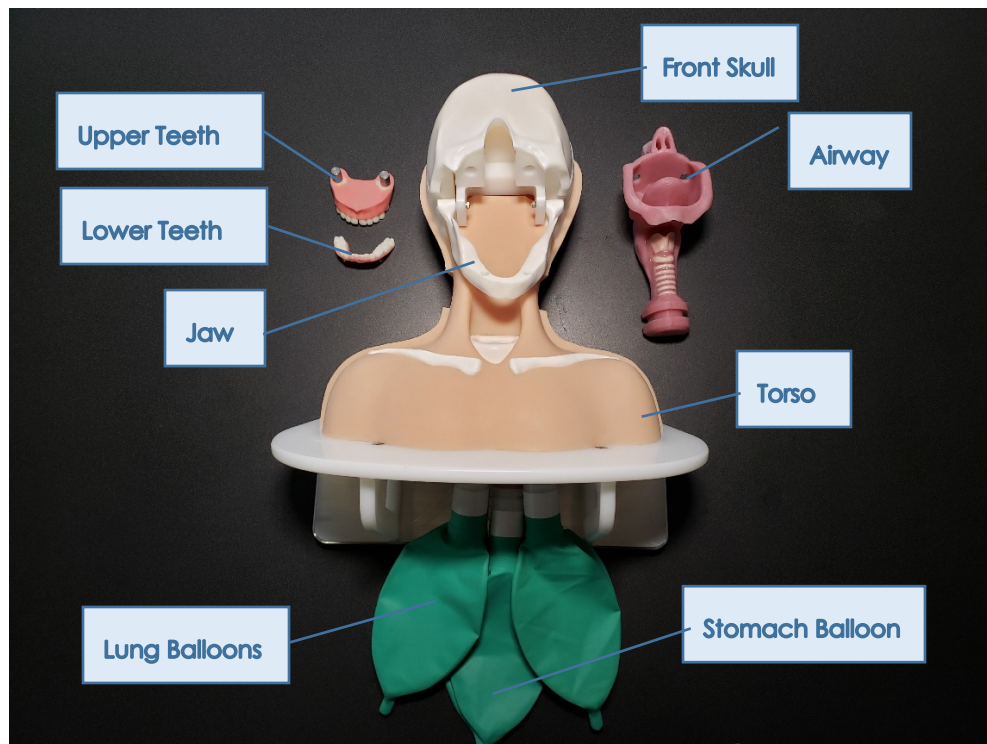


Figure 2

3 Airway Disassembly

3.1 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 not attached at the base of the neck, it simply rests atop the torso. (Figure 7)

Figure 7



3.2 Remove Teeth

Remove the lower teeth from the jaw, by disengaging the magnet with your fingers and lift straight up from jaw. Remove the upper teeth by disengaging the magnet with your fingers and pull straight down from the front skull.

(Figures 8, 9, 10)

Figure 8

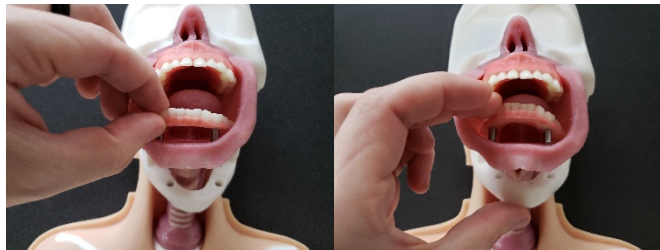


Figure 9



Figure 10

*** The top teeth have a higher force magnet, allowing them to sustain intubation forces, therefore you may have some difficulty removing the teeth. Please use care, and know that they are not permanently attached, and are made to remove.**

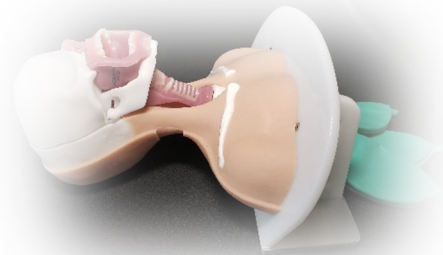
3.3 Airway module

Remove the airway module from the front skull by sliding the airway towards the front of the face, until it is out of the front skull. This may require firm, steady force (Figure 12).



Figure 12

Figure 11



Grasp the base of the trachea close to the chest, with your thumb, and using a slight pulling motion, remove the airway base from the plastic connector. (Figure 13). Lift the airway module out of the neck cavity and pull the airway module from the chest cavity.



Figure 13

***NOTE: The base of the trachea is fragile, and care must be used in removing this portion of the model so as not to TEAR the tissues.**

3.4 Lung module

Remove the lung module from the base of the chest by grasping the bronchus close to the neck, and using a slight twisting motion, remove the lung base from the plastic connector. Pull the bifurcation module out of the chest cavity. Remove lung balloons by simply twisting and pulling slightly to pull apart (Figure 15).

Figure 15



*** NOTE: The base of the bronchus is fragile, and care must be used in removing this portion of the model so as not to TEAR the tissues.**

Disassembly is Complete

4 Airway Reassembly

4.1 Skull

Place the front skull onto the metal posts of the back skull, press down until the front skull is flat to the back skull (Figure 16).

Figure 16



4.2 Airway

Insert the distal end of the airway with the flange into the neck connector in the chest cavity. Place nasal and oral cavities into the front skull and insert until the back of the airway meets the "spine" of the torso. (Figure 17)

Figure 17



4.3 Lung Bifurcation

Place bifurcation into the chest side of the plastic neck connector, with a twisting motion. A small amount of isopropyl alcohol or soapy water can help with the seating of this tissue inside the connector.

Figure 18



4.4 Lung Balloons

Connect the lung balloons to the plastic tube connectors in the bifurcation of the airway module by pressing the plastic tubes into the bifurcation. Make sure to seat them all the way to the top of the connector to minimize the chance of air leak (figure 18).

Figure 19

4.5 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. place the face skin atop 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. (figure 19)



Airway Assembly is Complete

5 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.

5.1 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.

5.2 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.

5.3 Disinfecting the Airway

After prolonged use, you may disinfect the airway with a bleach and water solution after performing the above soap and water cleaning process.

6 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:

6.1 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, trachea, and through the vocal cords.
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.

6.2 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

7 Limited Warranty

7.1 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.

7.2 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.

7.3 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.

7.4 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)**

8 Contact Information

8.1 Phone & Fax

Toll Free:

Phone: 1.888.722.7224

Customer Service – Option 1

Technical Support - Option 2

Fax: 1.844.898.4755



8.2 Email

Technical Support

technicalsupport@7-sigma.com

Customer Service

customerservice@7-sigma.com

8.3 Address

7-SIGMA, Inc.

2843 26th Avenue South / Minneapolis, MN 55406

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

8.4 Facebook



Like and Follow us: @7S3USA




8.5 Twitter



Follow us: @7S3Medical

9 Appendix A

9.1 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 Trainer (Mae)	
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



