MW11 **Difficult Airway Management Simulator Assessment System**

User's Manual

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Introduction

Manufacturer's note

The Difficult Airway Management Simulator Assessment System is the world exclusive system that offers objective feedback on intubation skills carried out by "hands-on" with the true-to-life airway manikin and real instruments. Real time visualization of performance on each evaluation point helps to assess trainees' skill as well as to identify the area where trainees need further improvement.

Features

Objective feed-back is given at two levels:

- -Intubation Result: higher possibility of saving patient's lives
- -Skills Assessment: lower negative impact on patients

Feedback on assessment criteria is quantitatively monitored and displayed.

-Sniffing position, Force on incisor, Blade position, Force on tongue, Lift epiglottis, Tube positioning and Cuff pressure

Each session can be saved and stored for review and debriefing.

A variety of difficult airway can be set by touch panel control.

All-in-one unit is convenient for training.

Training Skills

Tracheal intubation Intubation and ventilation on difficult airways

This Difficult Airway Management Simulator Assessment Model has been developed for the training of medical and paramedical professionals only. Any other use, or any use not in accordance with the enclosed instructions, is strongly discouraged. The manufacturer cannot be held responsible for any accident or damage resulting from such use. Please use this model carefully and refrain from subjecting to any unnecessary stress or wear. Should you have any questions on this simulator, please feel free to contact our distributor in your area or KYOTO KAGAKU at any time. (Our contact address is on the back cover of this manual)

Safety guidelines

● The signs below represent uses that may be dangerous or harmful.

⚠Warning	This sign represents dangerous use that may lead to fire hazards or electrocution.
<u></u> ∴ Caution	This sign represents harmful use toward the product or its parts that may lead to permanent damage or disfiguration.

The signs below represent strongly recommended uses.

	A circle with a cross represents actions that are strongly discouraged. *This sign asks users not to take the product apart.	
0	This sign represents rules that we are strongly encouraged.	

⚠ Warning			
When the simulator becomes hot or begins to smoke, unplug the power cord immediately.	Unplug the power cord when the simulator is not in use.		
This is a major fire hazard.	This will prevent electrocution or fire hazards that may cause burns and damages.		
Remove any dust that has accumulated on the power plug and insert the plug completely into the power socket.	Keep the simulator, its machinery and power cord away from water or detergent.		
Dust or a loose connection can lead to a major fire hazard.	Contact with such liquid can lead to fire hazards and/or electrocution.		
Do not handle the power cord with wet hands.	Keep flammable materials away from the simulator.		
This may lead to electrocution.	Such materials can lead to fire hazards and damages to the simulator.		
Use an AC power supply of designated voltage.	When unplugging the power cord, hold the plug and pull.		
Use of wrong voltage can lead to a major fire hazard.	Unplugging by holding the cord may lead to damages to the cord itself, fire hazards or electrocution.		
Do not attempt to take apart or alter the product.	Please do not bend, twist or damage the power cord.		
This could lead to fire hazards, electrocution and injuries.	This may lead to fire hazards and electrocution.		

Safety Guidelines

▲ Caution			
 Do not apply excessive force or pressure onto the simulator. Do not use the manikin for tracheotomy. This simulator is not designed for tracheotomy training. 	 Hold the handle when moving the simulator. It is dangerous to move the simulator by holding manikin the monitor, its pole or the manikin. Be sure to lift the unit at least 2 people if transfering from one level to another. 		
 Do not mark the manikin with a pen or leave printed materials in direct contact with its surface. The inks marks on the manikin are not removable. 	 Discoloration of the surface may occur after used after a long period of time. Discoloration does not affect the function of the simulator. 		
 Clean the manikin with water or mild detergent and coat with baby powder. Be careful not to apply water or detergent on the internal machinery. 	Do not install other software onto the computer; it may lead to system malfunctions.		
 Store the simulator in room temperature, away from heat, direct sunlight and moisuture to prevent discoloration or other damages. 	 Follow the instructed shutting down procedures. Shut down your computer first. Do not turn off the power or unplug the power cord without shutting down the program. Misuse may lead to damages. 		

- Supply voltage: AC100-240V 50/60Hz 120VA
- All external equipment connected to the simulator for signal input/output (ie. USB, HDMI, LAN cable) should be applicable to the IEC standards.
- Altitude: Up to 2.000 meters from sea-level
- Environmental conditions: From 5 degreesC. to 40 degreesC.
- Relative humidity: Less than 80 per cent (no condensation)
- Overvoltage category: II
- Pollution degree: 2
- Maximum load of the side tables: 2.5kg each
- Power cord supply: Do not use power supply cords other than the one attached to this product.
- Do not apply lateral force to the pole to prevent the simulation unit from getting unstable.

Before use

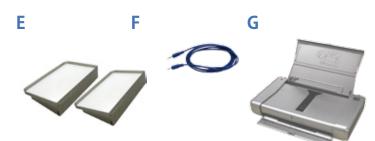
Unit contents Recommended devices

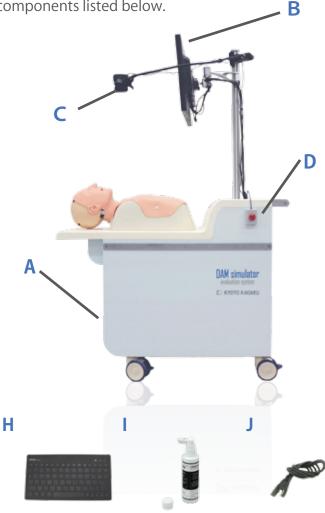
Unit contents

Before using the simulator, ensure that you have all components listed below.

- **A** 1 unit base
- **B** 1 monitor
- C 1 video camera
- **D** 1 emergency button
- **F** 2 side tables
- 1 cable for video laryngoscope
- **G** 1 printer
- H 1 keyboard
- 1 lubricant for manikin
- J 1 power supply cable

1 user's manual





Recommended devices

- Tracheal tubeInner diameter 7.5mm
- Laryngoscope
 Macintosh (bending type)
 blade size No. 4
- Video laryngoscope Airway scope AWS-S100L

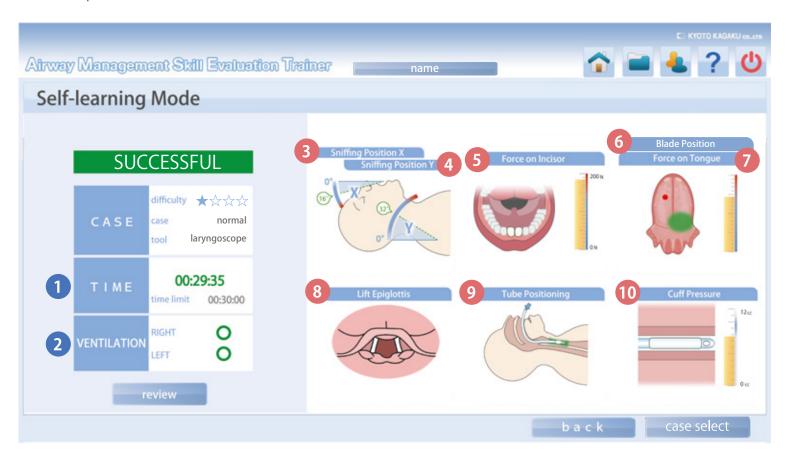
Replacement parts



Before use

Assessment criteria

MW11 Difficult Airway Management Simulator Assessment System provide objective assessment and analysis of the user's performance.



Intubation result on the left of the screen is the Successful/Failure assessment with criteria 1 and 2, and on the right of the screen is the skills assessment with criteria 3 to 10.

The skills assessment focuses on the negative impact given to the patient during the procedure.

Assessment criteria

Intubation result

1 Time limit A procedures completed under 30 seconds is defined to be successful. Setting of time limits can be changed.

2 Lung ventilation
Dural lung ventilation is defined to be successful.
Unilateral ventilation and ventilation to the stomach are also assessed.

Skills assessment

Force on tongue

Lift epiglottis

Tube positioning

10 Cuff pressure

Sniffing position

X is the angle of head extension at the occipital joint and Y is the angle of the cervical or neck flexure. Recommended angles are 15 degrees and 30 - 35 degrees respectively, and the dotted green lines indicate the ideal positioning. Maximum respective degrees during the session are shown on the assessment results page.

The bar on the right indicates the amount of force applied to the front teeth (units are in Newtons (N)). On average, front teeth break with approximately 200 N of force applied*. Maximum applied force during the session is shown on the assessment results page.

The central point applied force on the tongue with the blade is indicated by the red dot. The green region is the recommended area of force application. The position of blade at the time when the tube has passed the vocal cords is shown on the result page.

The bar indicates the force applied to the tongue. If the force exceeds the level indicated in blue, the force cannot be measured. The force on tongue at the time when the tube has passed the vocal cords is shown on the result page.

The lift of the epiglottis is measured by the Cormack standard and is classified into Grades 1-4. The degree of lifting at the time when the tube has passed the vocal cords is shown on the result page.

The insertion depth of the tube is assessed into 5 levels (18cm or less, 18cm to 22cm, 22cm to 23cm, 23cm to 25cm, and 25cm or more). The green highlighted area indicates the recommended positioning of the tube end. The final position of the tube is shown on the result page.

This measures the amount of air pumped into the cuff. Units are in cc, and recommended amount ranges from 5cc to 11cc. (The assessment results and recommendations may vary with tubes that are not 7.5mm in diameter). The final result is displayed on the assessment results page.

^{*} Janet B. Quinn, "A tooth broken after laryngoscopy: unlikely to be caused by the force applied by the anesthesiologist.", Anesthesia & Analgesia, pp.594-596, 2005.

Before use

Difficulty levels

Definitions of each difficulty level

Normal (Difficulty level ★)

Simulation of patient with no airway difficulties.

Opening the mouth and retroflexion of the neck is most easy out of all four levels.

Lock Jaw (Difficulty level ★★)

Simulation of patient with locked jaw. Opening the mouth is more difficult.

■ Rigid Neck(Difficulty level ★★★)

Simulation of patient with limitations in neck retroflexion. Users face difficulty when trying to raise the chin.

Micrognathia (Difficulty level ★★★★)

Simulation of patient with micrognathism (recess of lower jaw). Opening the mouth as well as retroflexion of neck are more difficult.

Before use

Two learning modes

Self-learning Mode

Login with a user account to save training data.

When creating an individual user account, following information is required:

OUser ID Name Password Name of Department/Organization

● Grade in School ● Years of Experience

Guest-learning Mode

Login as a guest user to take the assessment and see the results. Results cannot be saved in the Guest-learning mode. This mode is useful for seminars.

Software icons

Following icons are on the top right corner of your screen.



Home

Return to the main scenario selection menu



Data

Display all assessment results data from the past



Accounts

Manage your accounts



Print

Print your assessment results page



Help

Open the help menu



Power

Log out of an account or shut down the system

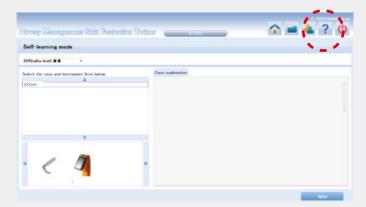


Help icon guides you through the help menu during your simulation procedure.

Tap on the "Help" icon

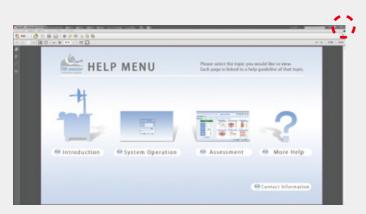


Tap on the "Help" icon on the top right corner.



2 Help menu display

Once the help menu is displayed, tap on the topic of interest. To close the help menu, tap on the X button on the top right corner.



Preparation



Locking the wheels

Lock the wheels before using the simulation unit to prevent the unit from moving.

Move the simulation unit to the designated location and push down on the black tab on each wheel. Do this to all four wheels to secure the unit in place.





Attaching the side tables

Attach side tables on the simulation unit for additional equipment space.

Lift and handle the side tables with both hands to prevent injuries or damages.



Insert the side tables onto the bar along the simulation unit. Refer to the images on the right for more details.



If the side tables are not in use, store the side tables in the drawer of the simulation unit.

Preparation

Setting up accessories for the simulation unit

Setting up the keyboard

The keyboard is used to set up account information.

Turn on the power switch on the back of the keyboard. The keyboard is wirelessly connected to the PC.



Setting up the printer

The printer is used to print out the result screen. Turn on the printer with the power switch on the top.



Setting up the emergency button

The simulation unit does not work properly if the emergency button is pushed down. Verify that the emergency button is set up correctly.

- 1 Verify that the emergency button is not pressed down.
 - Released
 Emergency button not activated



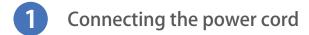


If the button is pressed down, turn the button clockwise to release the lock.



Preparation

Setting up the simulation unit



Connect the power cord to the socket on the rear side of the simulation unit.



2 Turning on the power

Push the power switch next to the power socket to the [-] sign. The light of the simulation unit poser button on the top edge of the table will blink dimly.



3 Turning on the simulation unit

Push the simulation unit power button on the top edge of the table. The button will blink light up green when it is turned on. The software will automatically turn on with the simulation unit. Wait for the login screen to appear on the monitor.



Do not press the power button of the touch-screen monitor.

The touch-screen monitor will automatically power on when the simulator power switch is turned on. If the monitor does not turn on after the simulator power switch has been turned on, please check the monitor power button.





Self-learning mode

Please use the pen attached to the right bottom corner of the monitor to operate the touch-screen feature. Touch-screen monitors can also be operated with the fingers.



When the login screen is displayed, enter the user ID and password, and tap on the Login button.

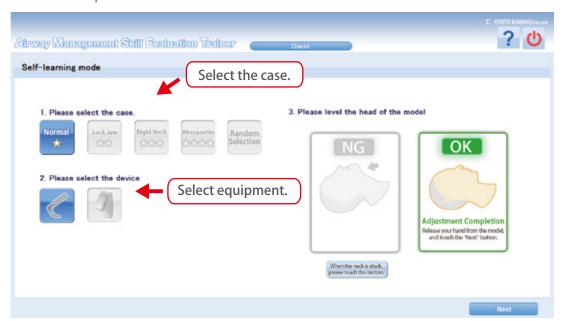


To login as a guest ▶▶ P. 16
To create a new account ▶▶ P. 24

2 Select the case and equipment you are using

Select a case scenario and an equipment from the buttons on the left half of the window. Then adjust the head of the manikin so that it lies parallel to the simulator table. When the head is positioned correctly, the indicator on the right side shows "OK" (see below). In case the manikin neck is rigid, press the button under the "NG" indicator to release. Then retry positioning till the indicator confirms "OK".

Press "Next" to proceed.



To use video laryngoscope P. 17

Self-learning mode

3 Initial positioning of manikin head

Initial position and scenario are set automatically. Do not touch the manikin until the indicator gauge reaches 100% and the display transits to a new screen.





4 Manual setting of manikin head

Initial position of manikin head can be set manually when the automatic initialization is failed.



Adjust the head of manikin until all 3 indicators show "OK". Once the manikin has been positioned correctly, "Next" button appears. Press "Next" to proceed.



Abnormal operation of the chin ▶▶ P. 34

Self-learning mode



Beginning the assessment

When the positioning is completed, the below image appears on the screen.



Details on assessment criteria P. 5-6

Adjust the camera to capture your hand motions for video recording so that image of the trainee and the manikin head is displayed on the left side of the screen.



In order to measure the cuff pressure correctly, release all air from the cuff before procedure implementation.

Spray lubricant to intraoral, tube and blade before procedure implementation.

Tap on the "Start" button to begin the session. The video recording and sensor data recording will also begin.

When intubation is completed and air inflow is verified at lungs, the assessment will automatically stop and the assessment results page will appear. The session can also be finished manually by tapping on the "Stop" button.

Trouble shooting P. 34

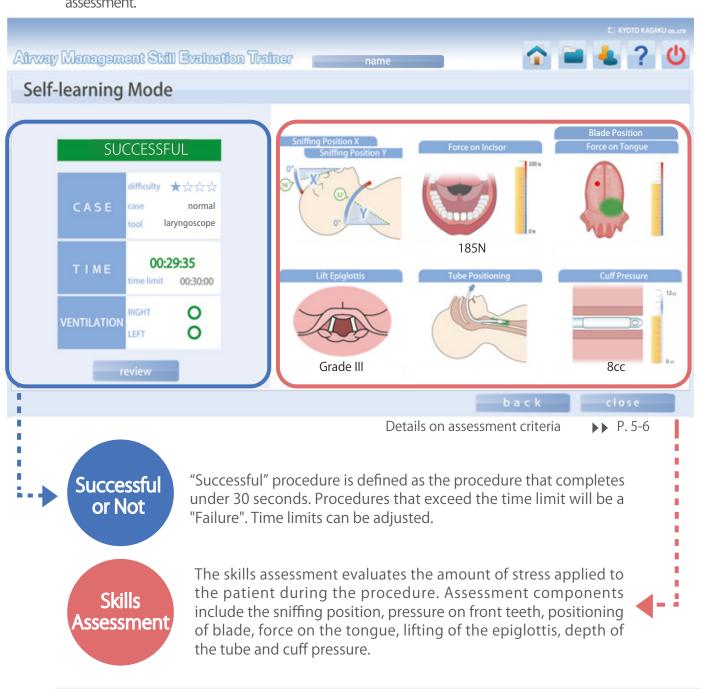
Self-learning mode

5

Assessment results

The results page will appear once the assessment is completed.

The results page displays intubation result of successful or failure, as well as the multidimensional skills assessment.





Before moving onto next session, release all air from the cuff and spray lubricant to intraoral, tube and blade.

Session finishes automatically when the procedure lasts certain length of time. ▶▶ P. 34

Guest-learning mode



Train as a guest

Go to the Login page and check the "Login as Guest" option. The ID and Password can remain blank. Tap on the Login button.



After logging in, the guest user can select a difficulty level, a case scenario and an equipment and start the session in the same way as an individual account user.

Self-learning mode ▶▶P. 12



Assessment record of guest users cannot be saved.

Guest users cannot save their assessment results. To save assessment records, create an individual user account before starting the session.

Create a new account P.24

Using the video laryngoscope

To use the video laryngoscope for assessment, the equipment must be connected to the simulator before beginning the session.

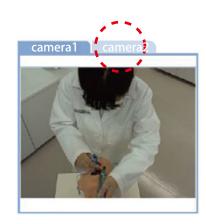




Insert one end of the cord into the port near the simulator power switch, and connect to the video laryngoscope.



Then select the video laryngoscope on the screen. When you proceed to the assessment page, tap on the camera 2 tab to see the image captured by the video laryngoscope.





Use a video laryngoscope with a mini plug compatibility.

The simulator uses mini-plug to connect with a video laryngoscope. Be sure to use a device that is compatible with the mini-plug.

■ Recommended device
Pentax Airway Scope - AWS S100L

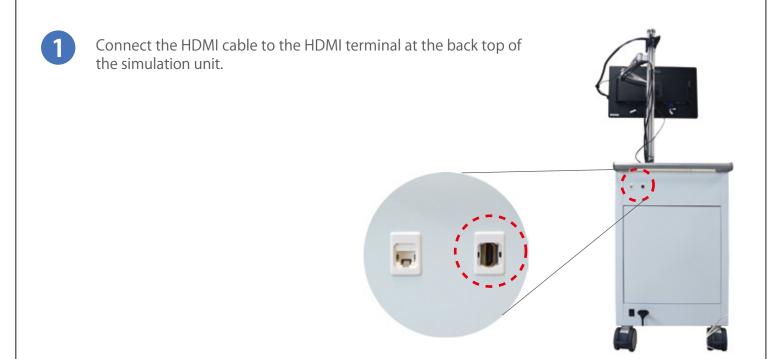


Connecting the external monitor

To use the external monitor, connect the monitor by the following steps.



Before connecting the external monitor, Be sure to turn off the power of the simulator unit.



Put the power of the simulator, verify that the monitor display the image same as the main monitor.

Changing the assessment time limit

How to change the time limit (default is 30 seconds.)

1 Open the Login page

Tap on the Power Icon on the top right corner and log out.

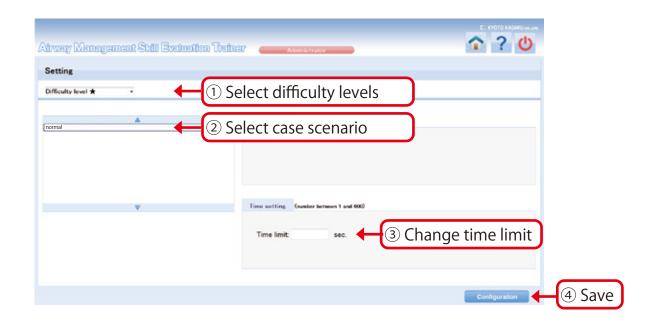
2 Open the Settings page

Check the Setting option. Then ID will automatically fill in. Enter in " **admini** " as the password. Tap on the Login button.



3 Change the time limit

In the settings page, select the difficulty level on the top left corner, as well as the case scenario. The time limit for the chosen scenario can be changed on the lower right section of the screen. Tap on the "Configuration" button to save the change.

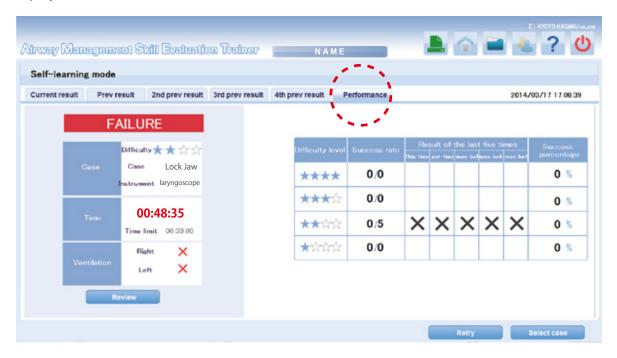


Overview of assessment result



Displaying the 5 most recent assessment results

Tap on the "Performance" tab on the assessment results page. For each respective case scenario, the total number of assessments completed, the number of passing assessments completed, results of the 5 most recent assessments and the success rate of last 5 trials will display.



Details of each of last 5 assessment can display by clicking the tabs.

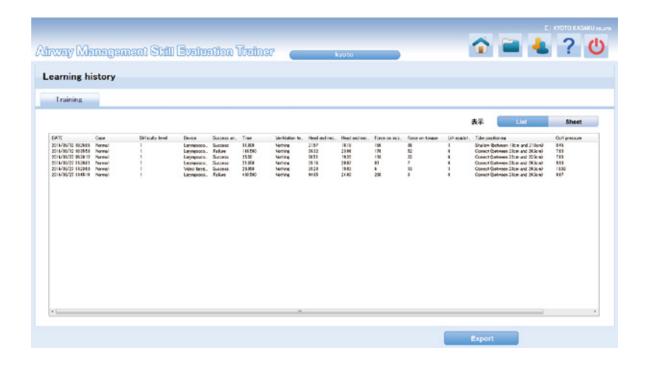
On each assessment result display, recorded video of the training session can be replayed by tapping on the review button.

Overview of long term assessment results

To see an overview of past assessment results of longer period, tap on the Data Icon on the top right corner.



List of the past assessment result is shown.
Each assessment result can be opened in sheet format by selecting the line and tapping on the "Sheet" button.



Exporting past assessment results

Assessment data can be exported onto USB drives.

Connect the USB drive

Insert a USB drive to the USB port beneath the simulation unit power button.

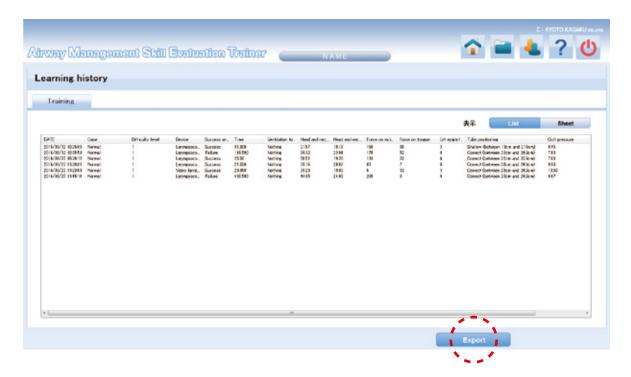


Display the assessment data

Tap on the Data Icon ito display the assessment data.

3 Select the data to export

Select the data to export and tap on the Export button.



4 Export

Select your USB drive on the computer and save the data. The assessment video file, sensor file and an image of the assessment results page are saved.

Print the assessment results

Use the included printer to print your assessment results.

Open the assessment results data to print and tap on the Print icon on the top right corner.



Press OK to print.



Create the new account

An individual user account needs to be created to save assessment data.

1 Open the "Creating an account" page

Tap on the Create an account link on the Login screen.



2 Account information

Input the following information for the new account.

- ●User ID ●Name ●Password
- Name of Department/Organization
- Grade in School Years of Experience



- *Enter your password twice for confirmation.
- *Enter N/A for inapplicable fields

When all information is completed, tap on the Confirm button on the bottom right corner.

3 Verification of account information

Verify your account information and tap on the "Save" button to submit. Tap on the "Change" button to edit your account information.

Editing an existing account

How to edit your account information

1 Open the account information page

Tap on the "Accounts" icon on the top right corner to open the account information page.

2 Open the account editing page

Tap on the "Change" button on the bottom right corner to open the editing window.



3 Editing the account information

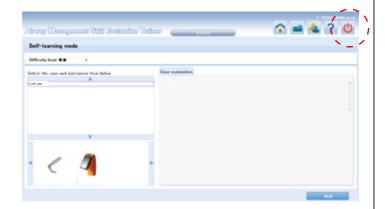
Edit the account information and tap on the Update button on the bottom right corner to save the change.



Changing accounts/ Turn off the power

1 Tap on the "Power" icon ტ

Tap on the "Power" icon on the top right corner of the screen.



2 Logout / Exit the system

A pop up will appear.

- To switch accounts
 - → Tap on the "Logout" button to return to the Login page.
- To shut down
 - → Tap on the "Exit this software" button.



3 Exit the system / Power off

When you tap on the "Exit this software" button, the simulator power will automatically turn off. The simulation unit power button blinks dimly indicating "stand-by".



4 Turn off the electrical power

Once the light for the simulation power button changes to dim blinking, turn off the electricity power switch to the "O" mark, and plug out the power cable.



Replacing parts

Replacing the face mask and the chest skin





Replacing the face mask

- 1. Reach behind the neck to disengage the face mask from the transparent band.
- 2. Unhook the mask from the ears and remove it.







- 3. Place the new mask on the manikin head.
- 4. Hook the mask onto the ears and connect the back of the neck with the transparent band.











Exchanging the chest skin

1. Unhook the chest skin layer from the torso and remove the skin.





2. Place the new chest skin layer on top of the torso and hook to secure it in place.



Replacing the lungs

! Turn off the power before start replacing any parts.



Replacing the lungs

1.Remove the chest skin from the torso.





2. Remove the plastic lung pouch from the torso.



3 .Take the new plastic lung pouch and peel off the cover of the double-sided tape. Align the hole of the model with the pouch and seal it tightly to prevent air from leaking. Place the chest skin layer back onto the torso.







Replacing the stomach

! Turn off the power before start replacing any parts.



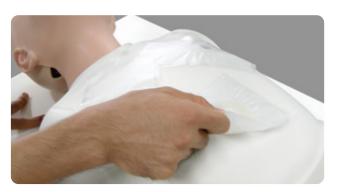
Replacing the stomach

1 .Remove the chest skin layer from the torso.





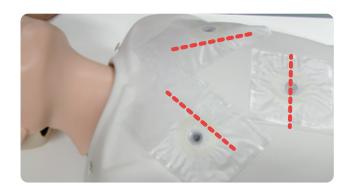
2. Remove the plastic stomach pouch from the torso. Remove any remaining double-sided tape from the surface of the torso.



3. Take the new plastic stomach pouch and peel off the cover of the double-sided tape. Align the hole of the model with the pouch and seal it tightly to prevent air from leaking. Place the chest skin layer back onto the model.









Refer to the image above to align the plastic lungs and stomach pouches correctly on the torso.

Replacing the tongue



! Turn off the power before start replacing any parts.

Removing the tongue

1. Remove the facial mask, and remove the body cover from the simulation unit.





- * When removing the body cover, slowly pull it away from the simulation unit to prevent any damages to the internal machinery.
- 2. Remove the tongue unit. Pull out the cable of the tongue from the terminal.





terminal

3. Unscrew the screw with white knob on the side of the white band to remove. Next, unlock the metal locks on sides of the tracheal section to disengage and remove the trachea from the tongue. Then pull off the white ring around the throat portion.



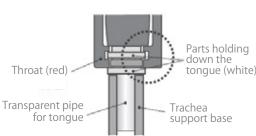




4. Open the mouth and remove the pin under the tongue from the lower jaw.



5. Spread the red throat portion outward and pull away the internal parts.







Replacing the parts

Replacing the tongue

Turn off the power before start replacing any parts.



Attaching the tongue

1. Spray lubricant on the lower part of the tongue, and insert it into the throat. Pull open the red throat portion around the white base of the tongue.

Be sure to place the blue cord above the base of the tongue.









Be sure to cover the entire internal machinery with the throat portion

2. Spray lubricant on top of the throat and place the white ring to secure the tongue in place.





3. Open the mouth and insert the pin under the tongue to the lower jaw. Pull the blue cord until the arrow comes into view.





4. Align the tracheal part with the tongue and then connect them together with the metal parts. Attach the white band onto the throat part to secure it in place.





5. Insert the cable from the new tongue part to the terminal.

Place the body cover back onto the torso and cover the manikin head with the face mask.





joining terminal

Replacing the parts

Replacing the force on tongue sensors

I Turn off the power before start replacing any parts.



Removing the sensors

1. Remove sensors that are used to measure the force on the tongue and blade placement.

The sensors are located in the portion circled in the image below.

First, remove the tongue part, following the instruction on page 30.

Then, remove the cable from its terminal by pushing down on the white tab of the cable and pulling the cable head outward.







Removing the tongue ▶▶ P.30



2. Unscrew the white screw on the bottom of the chin.
Hold down on the lower jaw and push the sensors from outside of the red part to disengage the sensor unit and push it into the oral cavity. Once the sensor unit has released from the housing, pull it out from the tracheal opening.





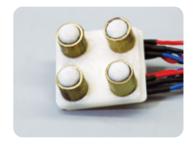


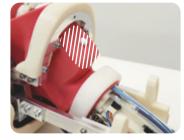


Installing the sensors

1. Insert the new sensor unit from the tracheal opening. Adjust its position with fingers put through the oral cavity. Be sure to place the blue cord above the tongue parts and place the flat side of the sensor unit (with the four knobs) against the white dashed area in the right bottom image. Fasten the white screw on the bottom of the chin to fix the sensor unit. Look in through the oral cavity to verify the positioning of the sensor unit and then attach the tongue back in place.







2. Connect the cable from the new sensor unit into the terminal.

Attaching the tongue ▶▶ P.31

Trouble shooting



Power falls on its own immediately after turning on the simulation unit power button.



Check the emergency button.

If the emergency button is turned on when the simulator starts, the simulator will be force terminated for safety.

After having verified that power button indicates stand-by (dim blinking), turn off the main power switch on the back bottom of the simulator and wait for about five minutes. Then, release the emergency button and turn on the main switch.





Check the switch of the monitor.

Initial setting of the monitor is "on".

But if it might have been turned off, check whether the monitor switch on the bottom of the monitor is turned on.

At the same time, check connection between the simulator and the monitor.

* Always keep the monitor's power turned on.

Trouble shooting during assessment



There is a big difference between the actual amount of air injected into the cuff and the amount of air measured.



Replace the tube.

The cuff of the trachea tube can be stretched and expanded by repeated use. This may result in variation between measured volume and real volume of the injected air.

If there is a big difference between the actual amount of air injected into the cuff and the amount of air measured, replace the trachea tube with a new one.



Abnormal operation of the chin. (The chin is wobbled or the mouth is shut tight)



Press the emergency button to stop the motor.

Cause of abnormal operation may be the motor is getting to be unstable. Press the emergency button. Then the chin becomes free.

The simulator is turned off automatically for safety when the emergency switch is pressed. Once the simulation unit power switch indicates stand-by (dim blinking), turn off the main power switch on the back bottom of the simulator and wait for about five minutes. Then, release the emergency button and turn on the main power switch.

Setting up emergency button ▶▶ P.10



- 1 The screen returns to the initial positioning display automatically when start button on measurement screen is not tapped for a while.
- ② Measurement finishes automatically if the procedure lasts longer than usual.



The measurement screen is designed to be switched over after five minutes.

To prevent an abnormal heating of the monitor, the measurement screen returns to the initial positioning display automatically if the session has not started for over five minutes.

Also, to save the memory for recording data, measurement finishes automatically if the procedure takes up more than 5 minutes.

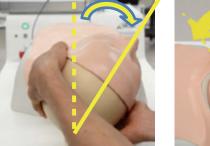
Trouble shooting during assessment



Reset the neck with following procedures.

Move the head back and forth and turn the head to the right. Place the head back in place with the face upright and re-adjust it to meet settings requirements on the initial

positioning screen.





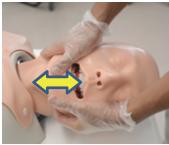
In spite of being set to the normal mode, the movement of the jaw is rigid.

Reset the jaw with following procedures.

Move the chin back and forth and turn the face to the left. Place the head back in place with the face upright and re-adjust it to meet settings requirements on the initial

positioning screen.





While training, the sensors do not react.

Tap on the "Back" button circled in yellow and restart the initialization procedure on the installation screen.

When problems still persist, shut down and restart the simulator.

Turn off the simulator power ▶▶ P.26



♠ Caution

Difficult Airway Management Simulator Assessment System Do not mark on the model and its components with a pen or leave printed materials in contact with the model surface. Ink marks on the model are not removable.

The contents of the instruction manual are subject to change without prior notice.

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