

⚠ Caution | 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.

MW16

Laparoscopic Suture Simulator - Assessment System

Instruction Manual



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Introduction

● Before use

Laparoscopic Suture Simulator assesses skills in laparoscopic intestinal suture, as well as simple skin suture. The simulator also facilitates basic training in laparoscopy.

For questions regarding this simulator, please contact our distributor in your area or Kyoto Kagaku Co., Ltd. Our contact information can be found on the back cover of this manual.

● Features

- A variety of training options

- 3 training modes

- All in one unit is convenient for training

- Three training modes that are automatically switched with touch panel operation

- Innovative assessment criteria and quantitative measurement that provide objective feedback to trainers

- Trainees' personal skills assessment data can be saved for reviewing and analysis.

- True-to-life simulated tissues that provides convincing hands-on experiences

- Integrating advantages of different training methods

- Quantitative feedback combined with realistic hands-on experience

- Real-time feedback, group sessions, reviewing and debriefing

- Real clinical instruments can be used.

- Supply voltage: AC100-240V 50/60Hz 180VA
- All external equipment connected to the main body for signal input/output (ie. USB, HDMI, LAN cable) should be applicable to the IEC standards.
- Altitude: 2.000meters above sea-level
- Environmental conditions: 5degreesC. to 40degreesC.
- Relative humidity: Less than 80 per cent(no condensation)
- Overvoltage category: II
- Pollution degree:2
- Power cord supply: Please do not use power supply cords other than the one attached to this product.
- To maintain stability, please do not apply lateral force to the pole.
- Do not exceed the maximum load of 2.5kg on the side trays.

⚠ DOs and DON'Ts

DOs

● Operate the system under the designated circumstances

Power input: AC100V~230V plus or minus 10%, 50Hz/60Hz
 Temperature range: between 0 degrees C and 40 degrees C (no congelation)
 Relative humidity; between 0%to 80% (no condensation)
 *Connecting to power source outside of the designated range may lead to fire.

● Safe disposition

To avoid short circuit, do not run the simulator set above a power receptacle.

● Handle the power plug and cord observing following precautions

1. Clean the head of the plug periodically.
 2. Plug in the plug to the outlet firmly to the end.
 3. Always hold the plug when unplugging. Do not pull the cable.
 4. Do not force to bend, twist the cable and avoid scratching or cutting on it.
 5. Unplug the power cord when the simulator is not in use.
 6. Remove any dust that has accumulated on the power plug and insert the plug completely into the power socket.
- Failing to follow the above precautions can result in damage in the plug and the cable, constituting risk of fire or shock.

● When the electric parts get warm or produce smoke, immediately turn off the power and unplug from the power source

Risk of fire. Contact your distributor or the manufacturer for repair.

● Handle with care

The materials for the models are special compositions of soft resin. Please handle them with utmost care at all times.

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.

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 transferring from one level to another.

● Storage

Store the simulator at room temperature, away from heat, moisture and direct sunlight.

Storage under the temperature above 50 degrees C may reduce the performance quality of the simulator.

Store the intestine sheets in the storage case provided to prevent the sheets from shrinking in size. Deformation of the sheets will cause errors in the evaluation. Over time plasticizer may appear on the surface; this does not affect performance of the system.

● Follow the instructed shutting down procedures

Shut down the computer first. Do not turn off the power or unplug the power cord without shutting down the program. Misuse may lead to damages.

DON'Ts

● Do not disassemble or open electric or precision components

Do not remove or alter cable connections in the inner machinery. Connection cables and their settings have been preset; changes to the set up may lead to malfunctions or damages to the simulator. Also, do not open up or disassemble the housing for electric parts or precision components.

Refrain from opening up any lids, caps or covers for such area, and never run the system while any of such covers are open.

*Never disassembling the electric components, power plug and cable as it may create a risk of fire, shock or injury. Contact your distributor or the manufacturer for repair.

● Never wipe the product and components with thinner or organic solvent

● Ink marks on the soft surface won't be removable

Don't mark on the product and components with pen or leave any printed materials in contact with their surface.

● Do not give shocks

The electric components are precision instruments. Strong shocks or continuous vibration may cause breakages of its internal structure.

● Do not run the system continuously over 2 hours

Take at least 30 minutes shutdown, turning off the power, every 2 hours.

● Do not wet the electric components

Do not pour or spill water or liquid detergent over the electric components, power cable and power plug. Running the system while the electric components are wet may create a shock hazard or a risk of fire.

● Do not handle the power plug with wet hands

Risk of shock.

● No fire

Do not put the product close to fire. It may lead to discoloration or deformation of the product as well as short circuit, creating a risk of fire.

● Do not install other software onto the computer It may lead to system malfunctions.

● Do not apply force or push skin sheets together.

Always keep the skin sheets in the provided storage box. Applied force can deform the sponge layer and will lead to errors in the evaluation.

Discoloration of the surface may occur after used after a long period of time. Discoloration does not affect the function of the simulator.

Before use

Set includes Part names

1 Set includes

Before your first use, ensure that you have all components listed below.



Wireless remote controller for large screen monitor



b



c



e

- a. Laparoscopic Evaluation Simulator
 - main unit 1 unit
 - Large screen monitor (with remote control), touch screen monitor, PC machine, suture evaluation camera, dermal suture evaluation camera (internal), 2 side tables and torso cover (for laparoscopic surgical training)
- b. Printer 1 unit
- c. Keyboard 1 unit
- d. Trocar 2 units
- e. Intestine sheet (muscle layer) 30 sheets
(Outside: muscle layer Inside: mucosal layer)
- *Intestinal sheets come with case
- f. Skin sheet for suturing 40 sheets
- g. Needle storage case 1 unit
- Instruction manual



f



g

2 Part names

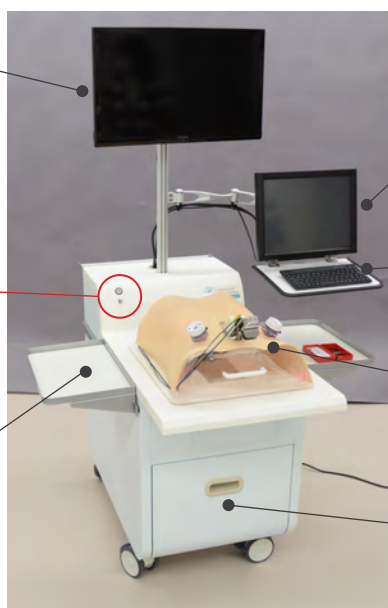
Large screen monitor (24 in)

*Angle and position are adjustable

PC power button

USB port

Side table (2 units)



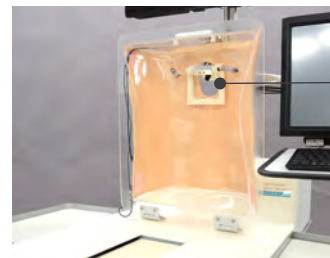
Touch screen monitor (14 in)

*Angle and position are adjustable

Keyboard

Torso cover (for laparoscopic surgical training)

Storage shelf (for side tables and other equipment)



Camera for training recording



Inspection door (stores electronic/mechanical components)

Main power button and socket

1 Setting the pole to support the monitor

Before your first use, ensure that you have all components listed below.



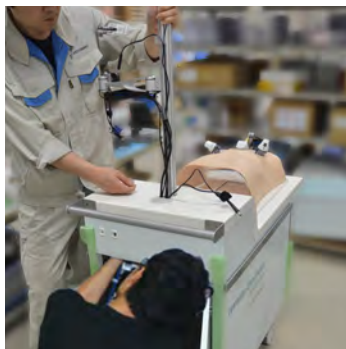
1. Tools and the instruction manual is in the drawer of the simulator unit.



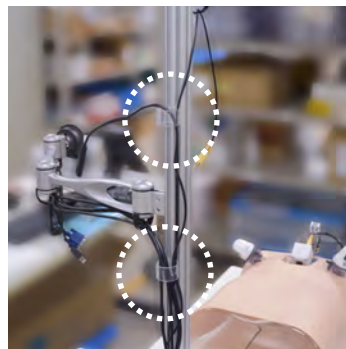
2. Find the hexagon wrench packed .



3. Open the back wall of the simulator unit. Loosen the four hexagon bolts with the wrench that fix the lower end of the pole.



4. Lift the pole and fix it by tightening four hexagon bolts.



5. Align the cables by adjusting cable guides on the pole.

2 Setting the monitor

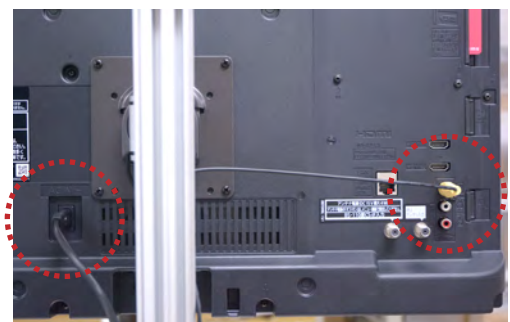
Large screen monitor



1. Put the metal fitting at the back of the monitor over the fitting at the head of the supporting arm.



2. Fix the fittings with two screws.



3. Connect power cable and monitor cable.

2 Setting the monitor

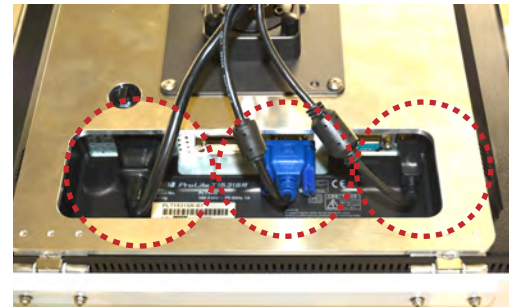
Touch screen monitor



1. Put the metal fitting at the back of the monitor over the fitting at the head of the supporting arm.



2. Fix the fittings with two screws.



3. Connect power cable and monitor cable and the USB cable.

3 Setting the keyboard

Before your first use, ensure that you have all components listed below.



1. Set the dry batteries to case on the back of the keyboard.
*At the time of delivery, sample batteries are enclosed.



2. Turn on the switch at the back of the keyboard.

4 Connecting the printer



1. Connect the USB cable and power cable at the bottom of the pole to the port at the back of the printer.



2. Peel off the tapes before using.
*Ensure to turn on the printer **AFTER** turning on the main power of the simulator.

1 On-screen operation

This simulator is operated with the PC, and controls such as selecting, evaluating, recording and registering are all operated by the touch screen. Users may directly touch the screen on the touch screen monitor and/or use the keyboard to operate the simulator.

■ Touch screen monitor (14 in)

■ Keyboard

This is a wireless keyboard with a trackball mouse feature. The trackball is located on the top right corner of the keyboard. The left and right click buttons are located on the top left corner of the keyboard. Users may use the keyboard to change the point settings for assessment, file names and passwords.

TK-FDP021BK



Wireless connection distance: Approx. 10m around non-magnetic material (ie. Wooden desks), approx. 3m around magnetic material (ie. Steel desks)

Power: Alkaline AAA batteries, manganese AAA batteries, nickel metal-hydride AAA batteries

Estimated battery life: Approximately 1 month *Test results of manufacturer



The low-battery lamp will flash 10 times when the battery is low. Please replace the batteries with new ones to avoid unstable operations of the keyboard.

● How to change the battery

1. Remove the battery cover on the backside of the keyboard.
2. Remove the batteries.
3. Insert new batteries.
4. Re-attach the battery cover.

2 Operation icons



Power icon:

Exits the simulator software and returns to the desktop screen.



Setting icon:

Edits system settings



Home icon:

Returns to the evaluation top page



Data icon:

Displays recorded data



Help icon:

Displays the help menu



Print icon:

Print the displayed screen

1 3 training modes

The Laparoscopic Suture Evaluation Simulator features 3 types of training modes.

■ Laparoscopic intestinal suture

The intestinal suture mode facilitates training in laparoscopic suturing skills. The suture must be completed with 3 simple interrupted stitches. The assessment will display either pass or fail according to the "full layer suture" and "leak pressure" results. The simulator will display assessments for 5 evaluation criteria.

Skills to be assessed

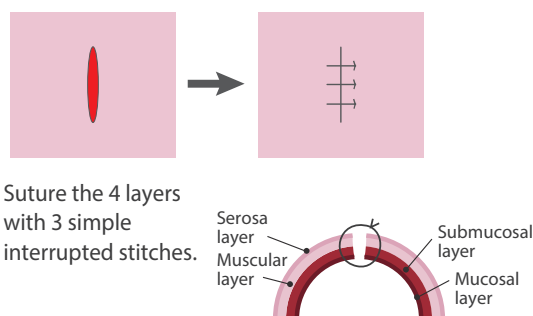
Laparoscopic suturing
- 3 simple interrupted
stitches

Instrument tying

*See pg. 15-16 for details on additional evaluation criteria

Assessment criteria

5 assessment criteria



Suture the 4 layers
with 3 simple
interrupted stitches.

■ Skin suture under direct vision

The skin suture mode facilitates training in skin suturing skills. Skills will be assessed on the 3 simple interrupted stitches and their knots tied with forceps.

Skills to be assessed

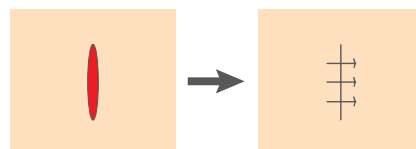
Suturing - 3 simple
interrupted stitches

Instrument tying

*See pg. 25-27 for details on additional evaluation criteria

Assessment criteria

6 assessment criteria



Suture and close the wound with 3 simple
interrupted stitches.

■ Laparoscopic forceps training

The forceps training mode facilitates training in the laparoscopic use of forceps. Skills will be assessed on the time spent on the training session.

Skills to be assessed

Basic use of laparoscopic
forceps

*Training kit is not included in the set

Measurement criteria

Completion time



Intestinal suture and skin suture training can only be assessed when completed with 3 simple interrupted stitches.

1 Starting up the simulator

Read the following instructions to start the simulator.

1. Connect the power cord

Insert the power cord to the outlet on the back side of the simulator and plug into a power source.



2. Turn on the power

a. Turn on the main switch next to the power outlet from "O" to "—".

b. Turn on the computer. Hold down the computer button for about 2 seconds until the button turns green. The computer and simulator software are turned on automatically.



3. Starting the software

The 3 training modes, the intestinal suture, skin suture, and forceps training, will be displayed on the desktop screen. Select a mode to begin.



.....
This computer is pre-installed with the simulator software. Please do not install other programs, as it may lead to malfunctions.

1 Perform suturing

1. Display the top page

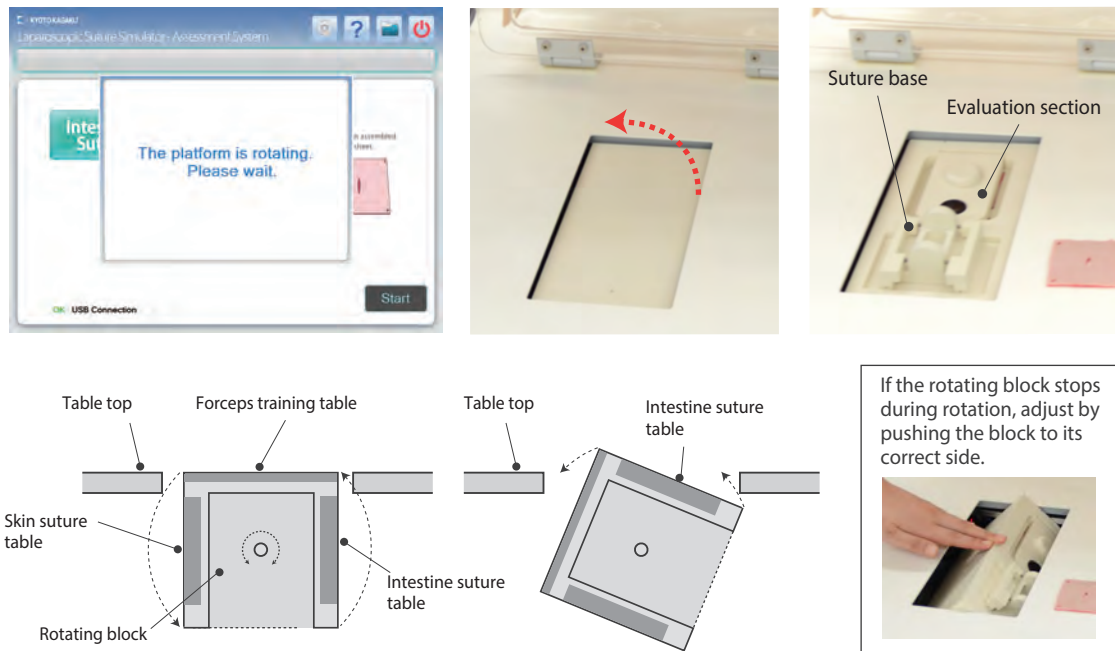
Select the "Intestinal suture" on the desktop screen to open the top page.



* On the top page verify that the USB connection indicator shows "OK" in green.
If it shows "NO", please contact your local distributor or Kyoto Kagaku Co., LTD.

2. Set up the intestine sheets

- As shown on the top page screen, lift the torso cover up. Prepare one set of intestine sheet (muscle and mucosal layer) and select "Start".
- Once "Start" is selected, the rotating block on the table top will automatically turn to the intestine suture table and the preparation page will display.

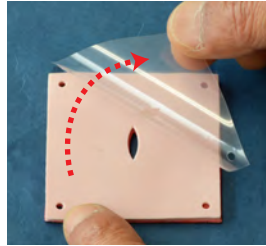


.....
If the rotating block stops during a rotation, an error message will appear. Adjust the block by pushing it to the correct side. The error message will disappear, and the instructions for the intestine sheets will be displayed.

1 Perform suturing

Preparation the intestine sheets

Peel off the transparent protective film from the muscle layer.

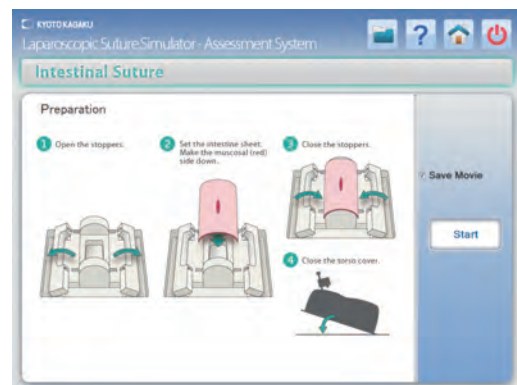


Remove the transparent protective film before using the intestine sheets. The intestine sheets cannot be reused once the protective film is removed. To avoid misuse, do not return "used" sheets to the storage box.

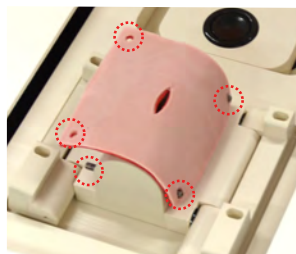
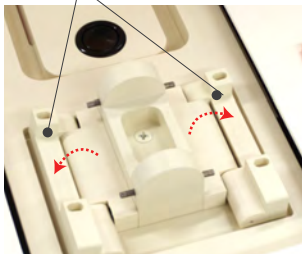
d. Set the intestine sheets according to the instructions shown on the screen.

1. Open the stoppers on both sides of the suture base.
2. Attach the assembled intestinal sheet by its four corners.
*Set the intestine sheets light colored side up.
3. Close the stoppers on both sides.

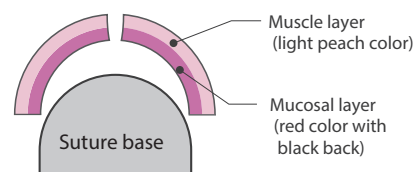
Once the intestine sheets are set in place, close and return the torso cover to its original position.



stoppers



Set the intestine sheets light colored side up.

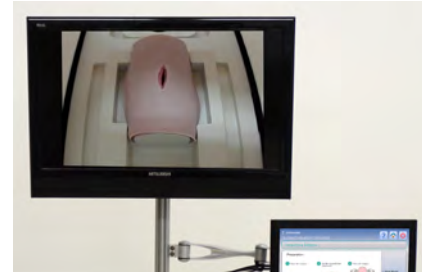


*Place the back side on the bottom.



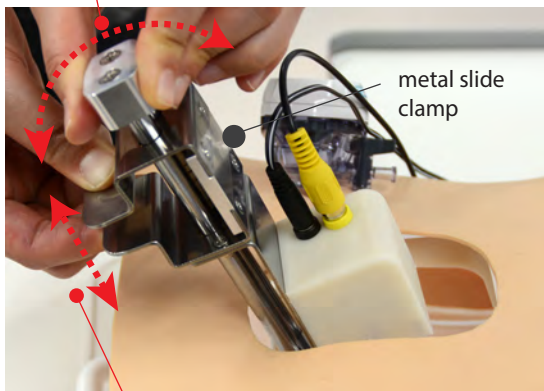
1 Perform suturing

3. Once the intestine sheets are set correctly, the large screen monitor will display an image of the intestine sheets through the camera set on the torso cover. If the image on the screen is blurred or needs adjustment, proceed to the following steps.



- ① Zoom in/out: Return the torso cover to its original position, and use the camera position adjuster to move the camera up or down.
- ② Adjust positioning: use the camera position adjuster to change the direction of the camera.
- ③ Focus: use the camera lens to adjust the focus.

Adjust positioning: use the camera adjuster to move the camera back and forth.



Zoom in/out: Pinch the metal slide clamp and slide the camera up and down.

Focusing: twist the lens.



4. Preparing the forceps, needle and thread

Be sure to use black thread. The simulator cannot detect lightly colored thread.



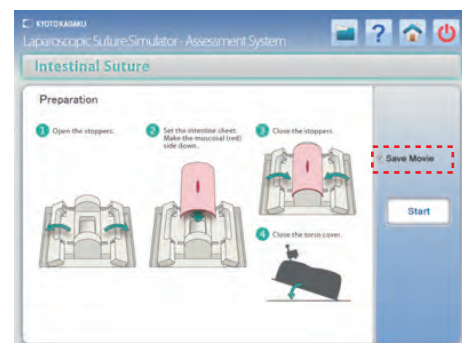
Use black suturing thread and a round suture needle for training.

5. Saving the movie

Users can save their training session by checking the "Save movie" check box on the screen. Movies of up to 20 minutes can be saved.



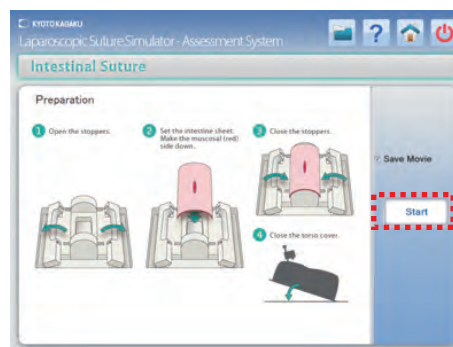
"Save movie" check box need to be checked before the session. Otherwise the session cannot be saved.



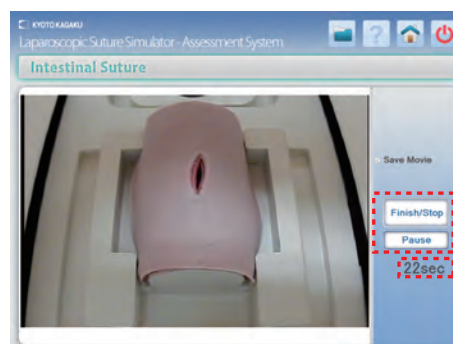
1 Perform suturing

6. Begin and end a training session

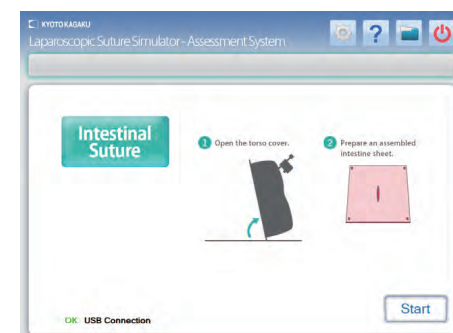
To begin a training session, select the "Start". This will activate timer. Perform the suture while watching the image on the large screen monitor. The session can be paused and restarted by selecting "Pause" "Finish/Stop" buttons. Select "Finish/Stop" once the suture is complete. The timer will stop and evaluation screen will display.



Note During the system is on "Pause", the "Finish/Stop" will change to "Start".



Caution Perform the suture with 3 simple interrupted stitches. Otherwise, session cannot be scored correctly. To stop or restart a training session, select the Home icon to return to the top page. No training data will be recorded.



top page

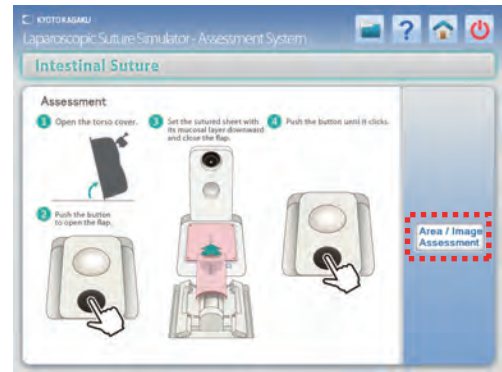
1 Skills assessment

1. Preparing the evaluation

Once you have selected the "Finish/Stop", the assessment page will display. Follow the instructions on the screen to move the intestine sheets to the evaluation section. Select the "Area/ Image evaluation" to display the full layer suture evaluation screen.

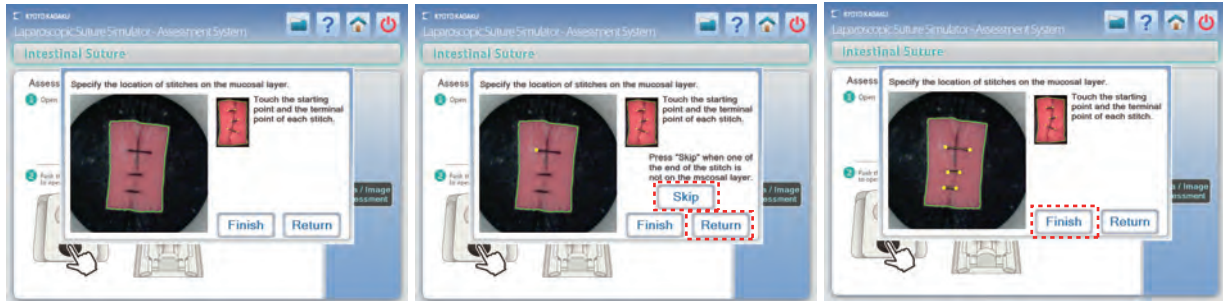


Place the intestine sheet so that the light color side faces up. Close the lid on the measurement section and press down on the black button until you hear a click. The air pressure measurement may be inaccurate with a loose lid.



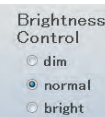
2. Image evaluation

The screen will display the rear side view of the sutured intestine sheets. Select the ends of the thread on each suture. If the suture is incomplete and the thread is not visible, move to the next suture. If a stitch seen on the mucosal layer does not cross the wound, this stitch is incomplete in full-layer suture. In that case, select the starting point and select "Skip". Select "Finish" when thread selection is complete. Select "Return" to undo thread selections. Once all three threads have been selected and the user has selected "Finish", the leak pressure screen will display.



3. Leak pressure evaluation

The leak pressure evaluation will automatically begin (the measurement will take approximately 5 seconds). Once the measurement is complete, buttons for the assessment screen and retesting option will appear. Select the assessment screen to display the assessment results. Select the retest option to redo the leak test. (i.e. when the lid is not shut completely.)

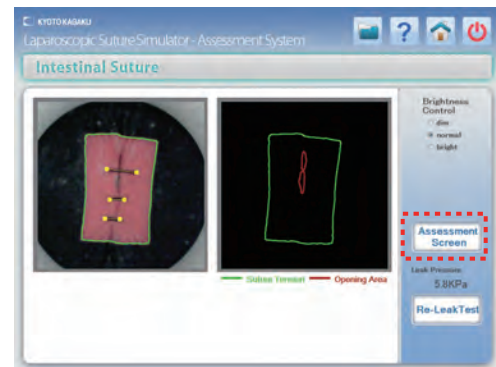


When the recognized opening area shown on the right image (area enclosed by a red line) is considerably different from the opening area shown on the left image, brightness may not be adequate. Adjust the brightness by the brightness control option and select "Re-Leak Test".

1 Review and save the result

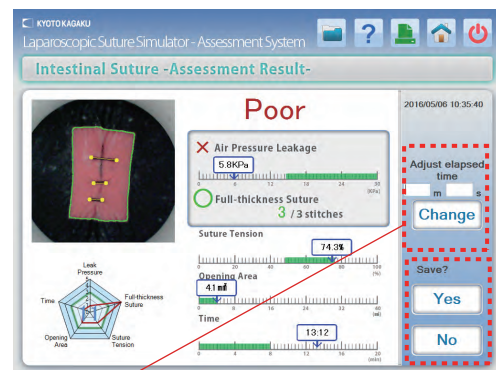
1. Assessment results

Once the full layer suture evaluation and leak test is complete, the assessment result will display. The suturing skills will be assessed against the data of professional surgeons with five other assessment points.
(*See pg.15-16 for assessment details)

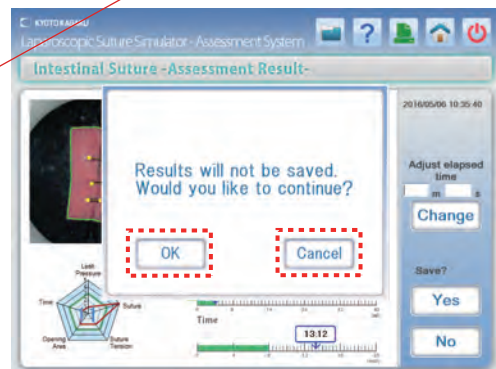


2. Saving the results - Part 1

Select "Yes" to save the assessment results. The file name input screen will appear.
Select "No" to discard the results and display the top screen. Reset a new intestine sheet to begin a new training session. (Select "Cancel" to see the previous page.)
See pg. 9-11 to continue using a new set of intestine sheets.



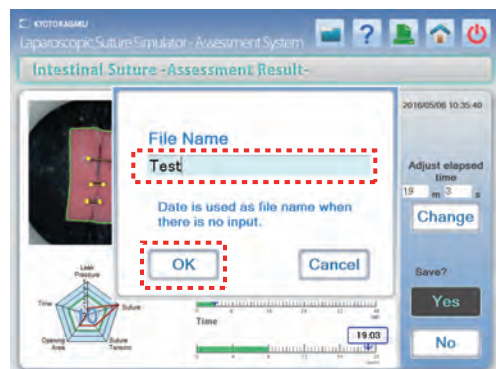
Caution Time required to the session can be input or adjusted for record, in case time is not measured correctly. Input the elapsed time to complete the session in the windows and select "change".



3. Save the results - Part 2

Select "Yes" to save the evaluation results. Enter the file name and select "OK" to save.

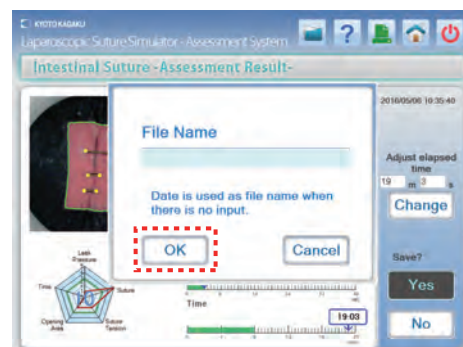
Caution Symbols such as ¥ / : * ? < > | cannot be used in the file name.




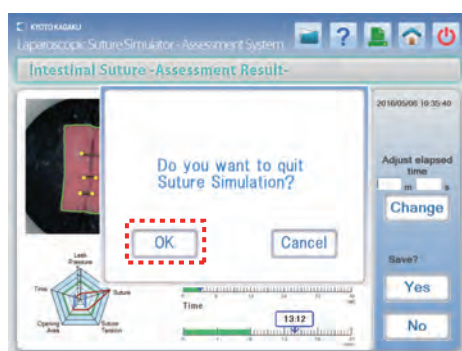
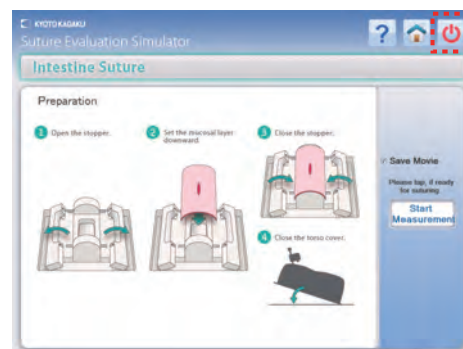
1 Review and save the result


3. Save the results- Part 2

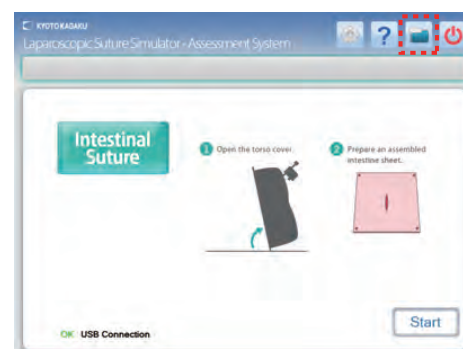
If there is no file name entered, the date and time will be used as the file name. Select "OK" and the intestine sheet manual will automatically display.



Select the Power icon  to end the training session or change to a different training method. Select "OK" and the desktop screen will display. (See pg. 43 to exit the program)



4. Saved data can be accessed from the top page.
Select the Data icon  to display.
(See p. 34-35 for more details)



.....
If "Save movie" box is checked before training, the movie will also be saved alongside with the assessment results under the same file name.

1 Skills to be assessed

The intestinal suture mode facilitates training in laparoscopic suturing skills. The suture must be completed with 3 simple interrupted stitches. The assessment will display either pass or fail according to the "full layer suture" and "leak pressure" results. The simulator will display assessments for 5 criteria.

Skills to be assessed

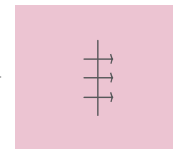
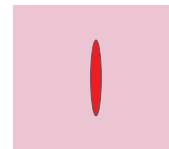
Laparoscopic suturing
- 3 simple interrupted
stitches

Instrument tying

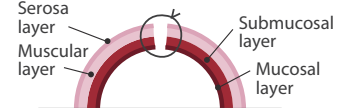
*See pg. 15-16 for details on additional evaluation criteria

Assessment criteria

5 assessment criteria



Suture the 4 layers
with 3 simple
interrupted stitches.



Intestinal suture can only be evaluated when completed with 3 simple interrupted stitches.

2 Assessment criteria

The suturing skills are assessed against the data of professional surgeons. The acceptable range of each assessment criterion is displayed in green. There are 5 assessment criteria, of which 2 are used to determine successful procedure.

● Good/ Poor grading

Good: The leak pressure is within the recommended range and three out of three stitches have successfully sutured the full layers together.

Poor: Either of two criteria is not met.

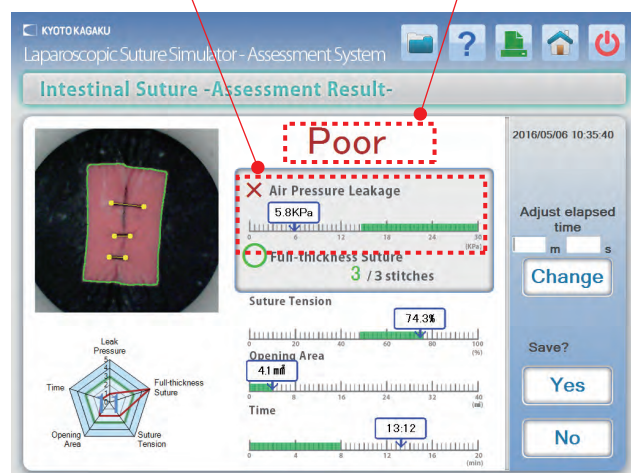
● Individual assessment criteria

① Leak pressure

This check point tests for leaks from the suture and measures the internal pressure when air is blown against the sutured wound. Units are Kpa, and the threshold leak pressure is above 14.5KPa.

Leak pressure

Good/ Poor grading



The letter "Poor" can be hidden by changing the display setting. See p.42 for details.

2 Assessment criteria

② Full layers suture

This check point verifies that all three simple interrupted stitches have successfully sutured through all layers.

The number of successful stitches will be displayed. 3 out of 3 stitches need to be successful to "pass".

③ Suture tension

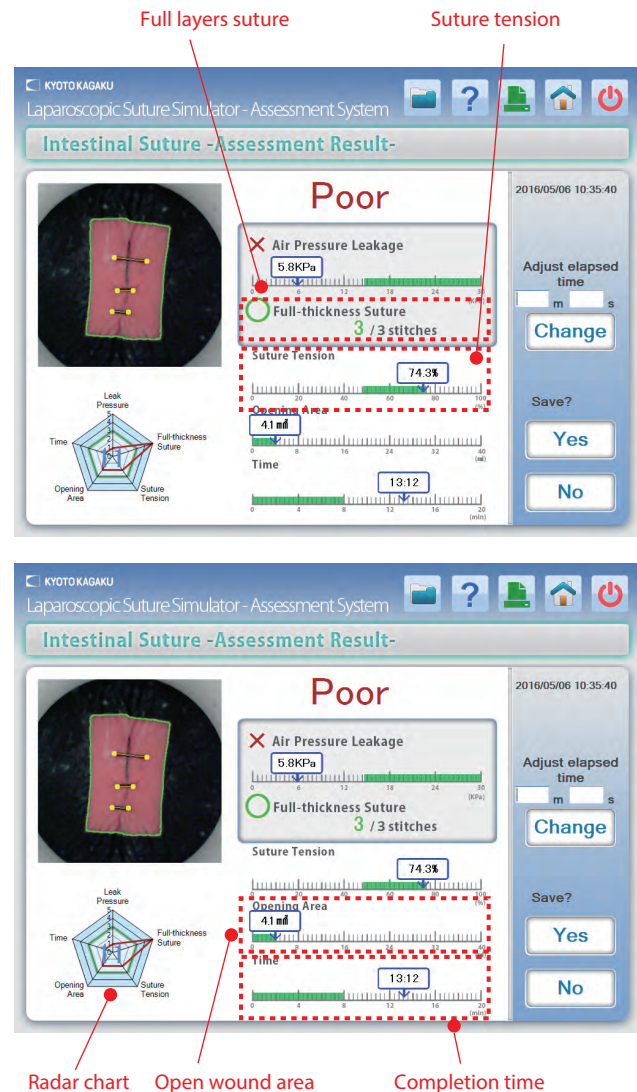
This check point measures the amount of force applied to the skin layers by the knots. The surface area of the sutured skin layers will be compared to that of before training. Passing range is 49-73%.

④ Open wound area

This check point measures the area of the open wound. The smaller the area, the better; passing range is 0-3.9mm².

⑤ Completion time

This check point measures the time spent to complete the suture. Passing range is 0:00 - 7:49 seconds.



● Radar chart

The recommended range shown in green is the data of professional surgeons, and the range shown in red is the trainee's results. The radar chart display helps users see all 5 assessment points in one simple layout.

*Regarding the score of "full layer (thickness) suture" shown on the radar chart, spacing and centering of the stitches are taken into account in addition to the number of successful stitches

1 Perform suturing

1. Display the top page

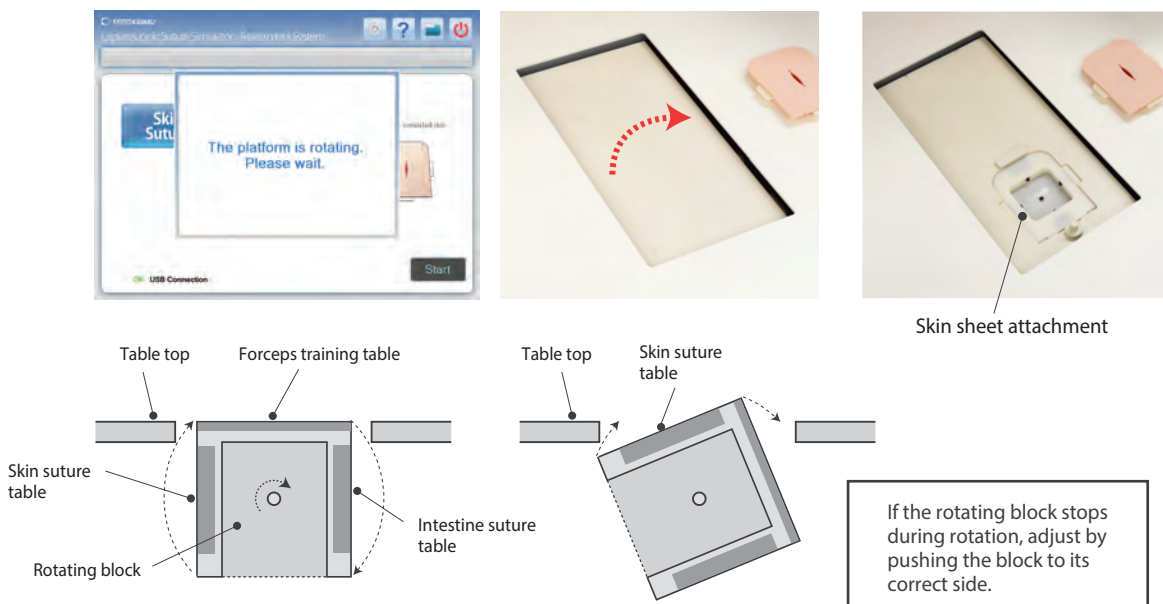
Select the skin suture button on the desktop screen to open the top page.



* On the top page verify that the USB connection indicator shows "OK" in green.
If it shows "NO", please contact your local distributor or Kyoto Kagaku Co., Ltd.

2. Set up the skin sheets

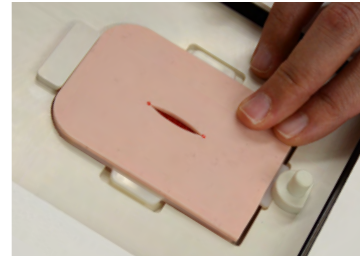
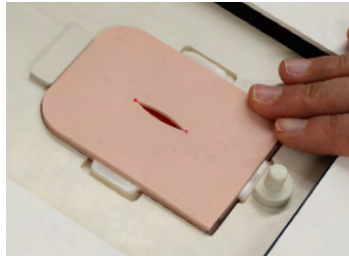
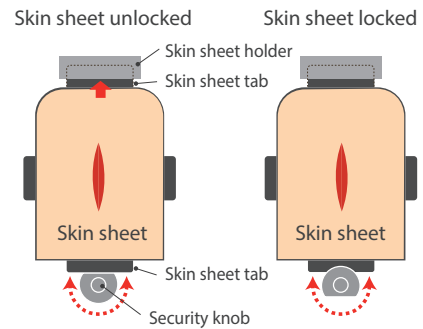
- As shown on the top page screen, lift the torso cover up. Prepare one piece of skin sheet and select "Start".
- Once "Start" is selected, the rotating block on the table top will automatically turn to the skin suture table and the instructions will display on the screen.



.....
If the rotating block stops during a rotation, an error message will appear. Adjust the block by pushing it to the correct side. The error message will disappear, and the instructions for the skin sheets will be displayed.

1 Perform suturing

c. Set up the skin sheet. Ensure that the flat side of the security knob faces inside. Insert the top edge with the rounded corners into the attachment section. Once the skin sheet is set, turn the security knob to lock the sheet in place. To remove the skin sheet, turn the security knob to unlock the skin sheet.



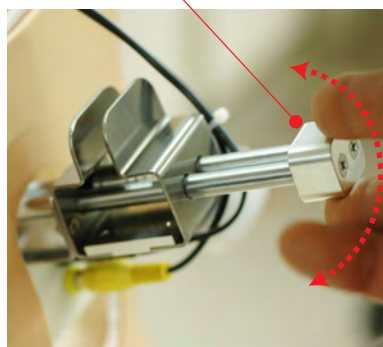
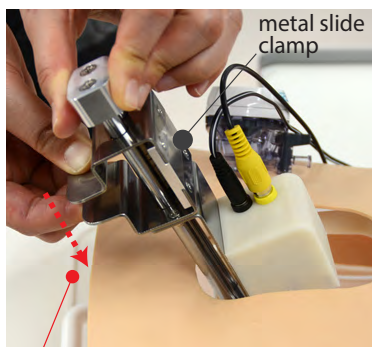
Please take precaution when inserting or removing the skin sheet. Forceful treatment of the skin sheet may lead to damages.

3. Once the skin sheet is set correctly, the large screen monitor will display an image of the skin sheet through the camera set on the torso cover. If the image on the screen is blurred or needs adjustment, proceed to the following steps.



- ① Zoom in/out: pinch the metal slide clamp while sliding the camera to the bottom, then lift the torso model.
- ② Adjust positioning: use the camera position adjuster to change the direction of the camera.
- ③ Focus: use the camera lens to adjust the focus.

Adjust positioning: use the camera adjuster to move the camera back and forth.



Zoom in/out: Pinch the metal slide clamp while sliding the camera to the bottom.

Focusing: twist the lens.

1 Perform suturing

4. Preparing the needle and thread

- Please use **black suturing thread**.

This simulator will evaluate the stitches based on images. Lightly colored thread is difficult to detect by the computer. Please prepare black suturing thread for training and use with the suturing needle.



Use black suturing thread. We recommend using the suturing equipment listed on the right.

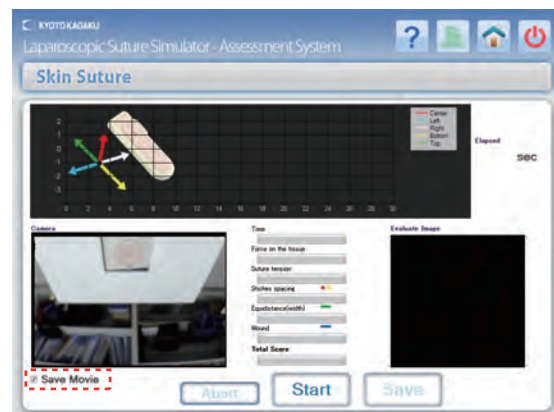
- Replacement parts
11230-020
NUROLON™ Nylon Suture
(With needle) x 1

5. Saving the movie

Users can save their training session by checking the "Save movie" check box on the screen.

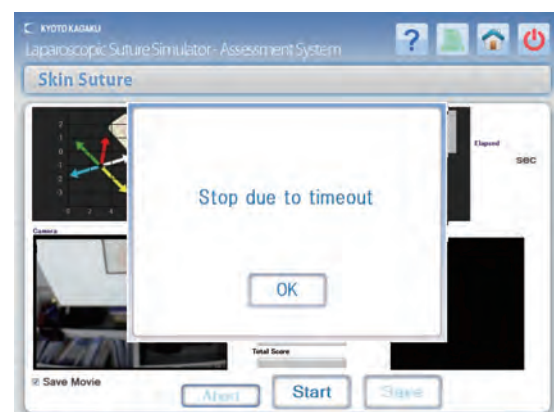


"Save movie" check box need to be checked before the session. Otherwise the session cannot be saved.



The movie can record up to 10 minutes. After 10 minutes, a pop-up message will appear, indicating that the time is up. Once "OK" is selected, the screen will return to the skin suture top page. (The session will not be evaluated or recorded.)

Please replace the skin sheet to begin a new session.



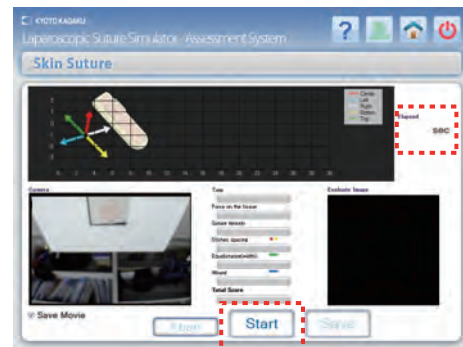
1 Perform suturing

6. Begin and end a training session

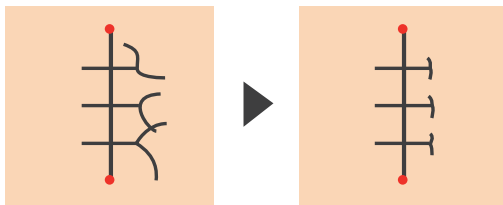
- Once preparation is ready and "Start" is selected, a 3 second count down will display, followed by a "Go" sign to indicate the beginning of the session. To quit the session, please select "Abort".



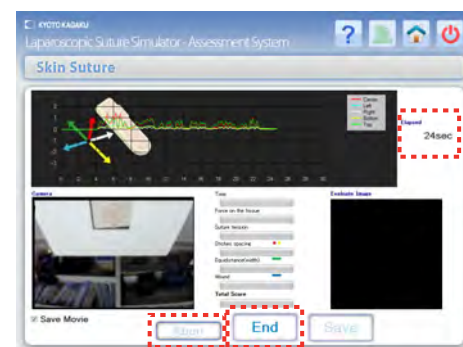
Perform the suture with 3 simple interrupted stitches. If the training is stopped, no training data will be recorded. The "Start" will automatically change to the "End" 20 seconds into the training session.



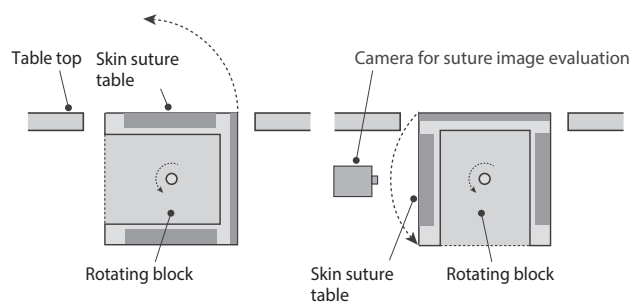
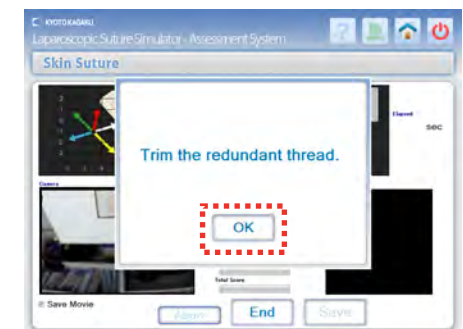
- Once the 3 stitches are complete, select the "End". A pop-up message will display, indicating to prepare the thread for evaluation. Please cut off any excess thread remaining on the stitches.



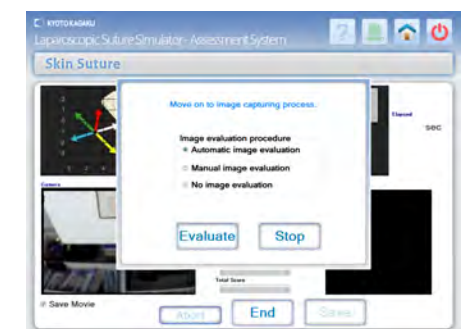
Cut off redundant thread from the knots.



- Once the thread is prepared for evaluation and "OK" is selected, the rotating block will turn, and the screen will display the evaluation option menu.



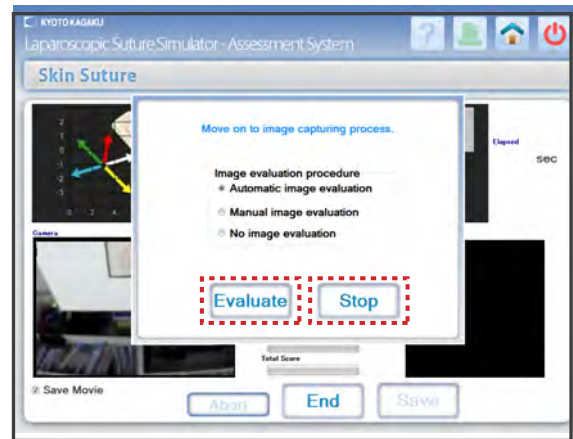
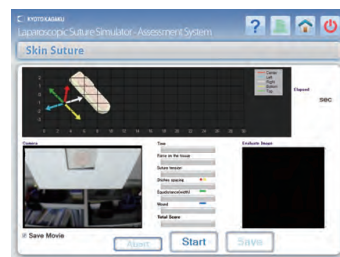
The rotating block with the skin sheet will turn to the image evaluation side.



1 Skills assessment

1. Use the left click button on the keyboard to select 1 out of 3 evaluation options and then select "Evaluate".

* Select "Stop" to return to the skin suture top page without saving data.



● To exclude image evaluation

Select the "No image evaluation" option and select "Evaluate" to see scores for completion time, force on the tissue, and tension.

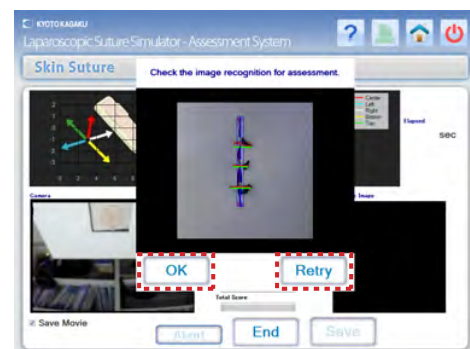
● To include image evaluation

Select either the "Automatic image evaluation" or "Manual image evaluation" option and select "Evaluate".

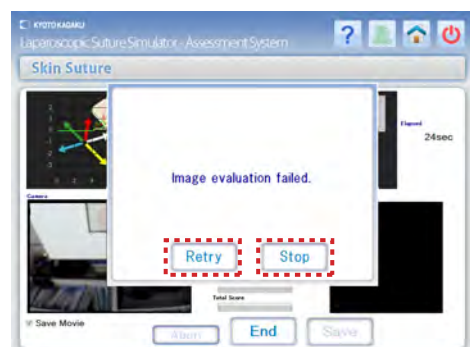
2. Automatic image evaluation

Once the "Automatic image evaluation" option and "Evaluate" are selected, the system will automatically detect the stitches on the image. If all the stitches have been detected correctly, select "OK".

If detection is not correct, select "Retry" to return to the evaluation option menu.



.....
An error message will display when the thread are not arranged appropriately and the stitches are not detected automatically. Select "Retry" to return to the evaluation option menu. Select "Stop" to return to the top menu, without saving data.



1 Skills assessment

3. Manual image evaluation

Once the "Manual image evaluation" option and "Evaluate" are selected, the stitches can be recognized manually.

Once "Evaluate" is selected, an image of the stitches will appear on the screen. Use the left click button on the keyboard to select the starting and ending point of each stitching.

Select "OK" to proceed to the next selection, and select "Return" to undo a selection. Select "OK" when all three stitches are selected for assessment.

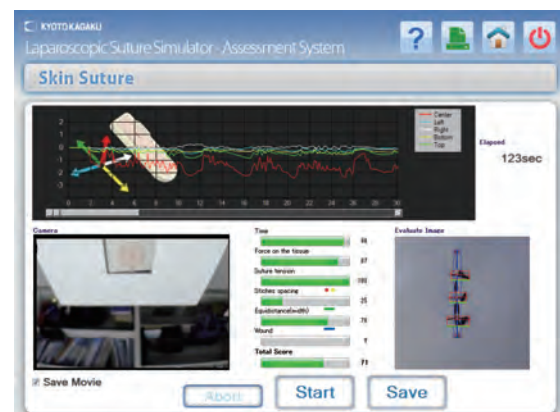
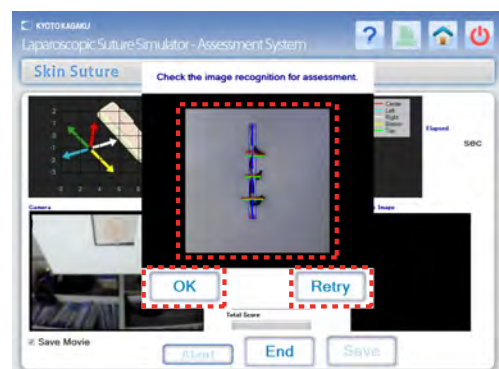
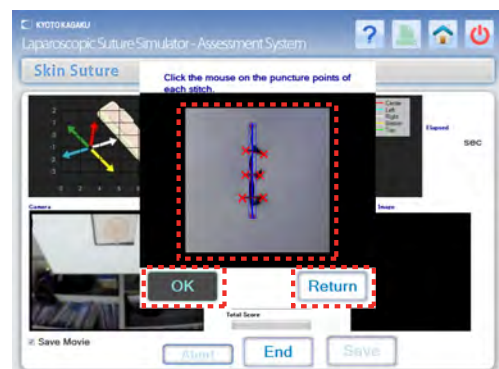
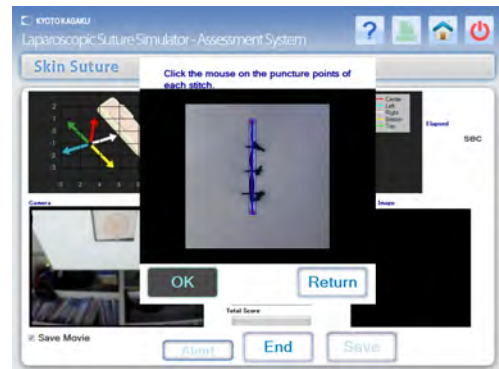


6 points need to be selected to proceed to assessment result.

Once "OK" is selected the assessment results will be displayed.



To adjust the recognition of stitches, select "Retry" to return to the evaluation option menu.

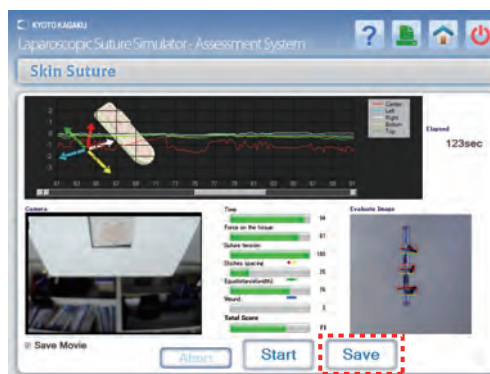


Assessment results page for the completed session

1 Review and save the result

1. Assessment results

Once the image has been analyzed, the assessment results page appears and the rotating block with turn to bring the skin sheets back to the table top. The suturing skills will be assessed against the data of professional surgeons with six other assessment points.

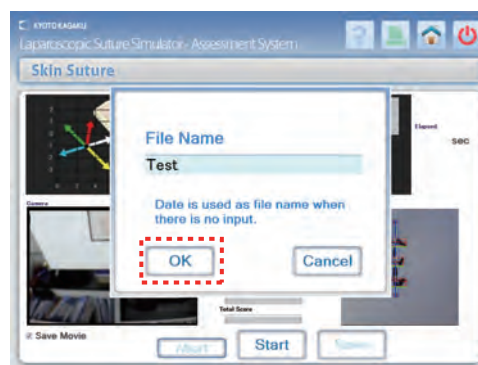
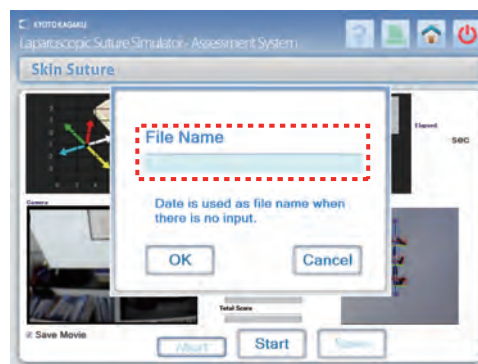


2. Saving the results - Part 1

Select "Save" to save the assessment results. Enter the file name and select "OK" to save.

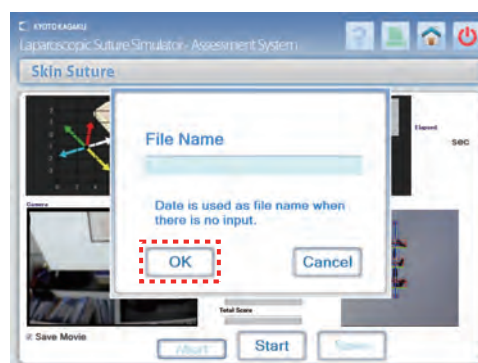


.....
Symbols such as ¥ / : * ? < > | cannot be used in the file name.



3. Saving the results - Part 2

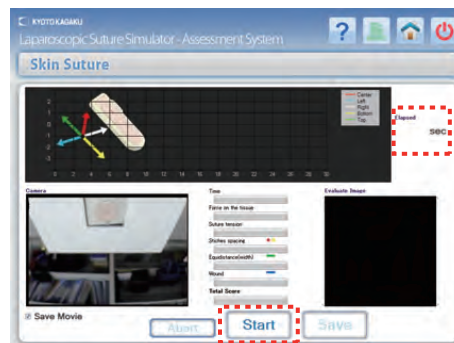
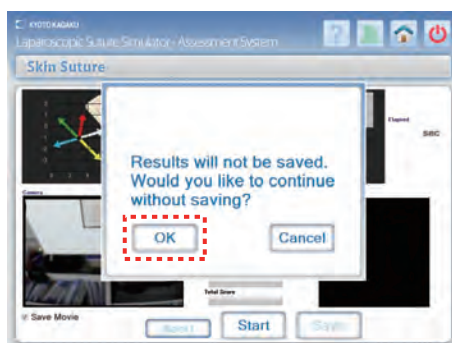
If there is no file name entered, the date and time will be used as the file name. Select "OK" and the skin suture top page will display.



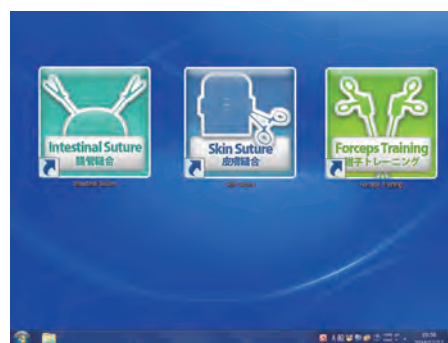
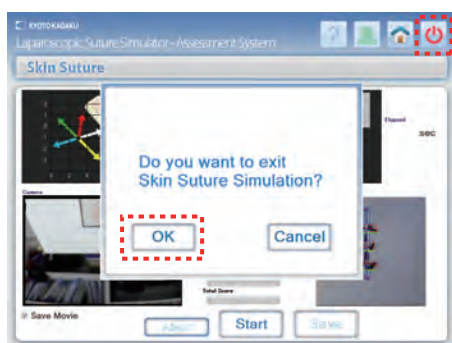
3 Review and save the result

4. To start another session without saving current data, remove the used skin sheet and replace with a new skin sheet. Once the "Start" is selected, a warning sign will appear.

Select "OK" to continue to the skin suture top page.
Select "Start" to start the 3 second countdown, and begin training when a "Go" sign is displayed.



5. To end the training session or try another training mode, select the power icon on the top page right corner. Select "OK" on the warning message to display the desktop screen.
(See pg. 43 for more details on ending training sessions)



6. Saved data can be accessed from the top page. Select the Data icon to display the top page.
(See pg. 32-33 for more details)



If "Save movie" box is checked before training, the movie will also be saved alongside with the assessment results under the same file name.



1 Assessment points

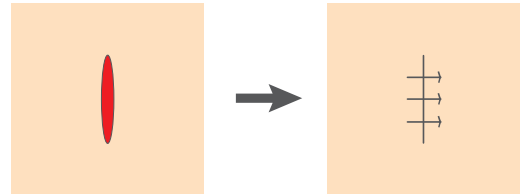
The skin suture mode facilitates training in skin suturing skills. Users will be assessed on the 3 simple interrupted stitches and their knots tied with forceps.

Skills to be assessed

Suturing - 3 simple interrupted stitches
Instrument tying

Assessment criteria

6 assessment criteria



Suture and close the wound with 3 simple interrupted stitches.



Proper evaluation cannot be obtained when suture is made with unintended methods, such as mattress suture or continuous suture.

2 Formula and coefficient

● Formula

This simulator assess the skin suturing skills by a unique evaluation function shown below.

$$E_{Suture} = \omega_T I_T + \omega_{FoT} I_{FoT} + \omega_{JuT} I_{JuT} + \omega_{DbS} I_{DbS} + \omega_{EqD} I_{EqD} + \omega_{WoD} I_{WoD}$$

(Total score)

● Criteria

- | | |
|------------------------------------|---|
| ① Completion time | I_T : Index of Completion Time |
| ② Force on tissue | I_{FoT} : Index of Force on the Tissue |
| ③ Suture tension | I_{JuT} : Index of Judging Tension |
| ④ Distance between stitches | I_{DbS} : Index of Distance between Sutures |
| ⑤ Equidistance from the wound edge | I_{EqD} : Index of Equidistance from the wound edge |
| ⑥ Wound Dehiscence | I_{WoD} : Index of Wound Dehiscence |

Weight coefficient $\omega_{T, FoT, JuT, DbS, EqD, WoD}$: Weighting Coefficients

(Reference)

Oshima, N. ; Solis, J. ; Ishii, H. ; Matsuoka, N. ; Hatake, K. ; Takanishi, A.

"Acquisition of quantitative data for the detailed analysis of the suture/ligature tasks with the WKS-2R"
Proceedings of 6th International Special Topic Conference on Information Technology Applications in Biomedicine, 2007. 8-11 Nov. 2007 Page(s) : 107-110

Oshima, N. ; Solis, J. ; Ogura, Yu. ; Hatake, K. ; Takanishi, A.

"Development of the suture/ligature training system WKS-2 designed to provide more detailed information of the task performance Proceedings of IEEE/RSJ International Conference on Intelligent Robots and Systems 2007. ct.9 2007-Nov. 2 2007 P 58 - 63

3 Normalization of points

Score points on each criteria are normalized by using the collected data of surgeons and those of unskilled trainees. The average of the surgeon group's data is set to "1", while the average of the unskilled group's data is set to "0", and then they were linearly-connected. Each evaluation parameter is normalized as follows.

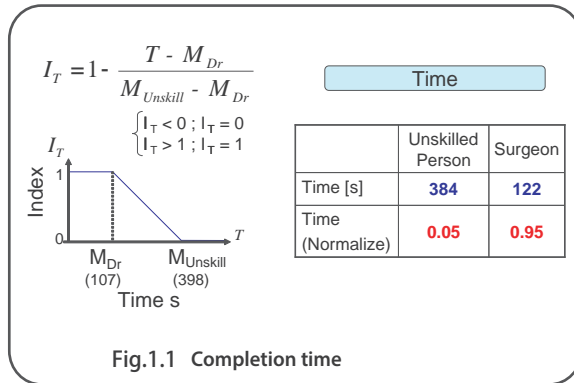


Fig 1.1 shows the calculation for completion time. Average completion time for a surgeon is 107 seconds, and 398 seconds for an average trainee. Completion times below 107 seconds will receive an IT value of 1, and those above 398 seconds will receive an IT value of 0. IT values for completion times between 107 and 398 seconds will be determined by the formula above.

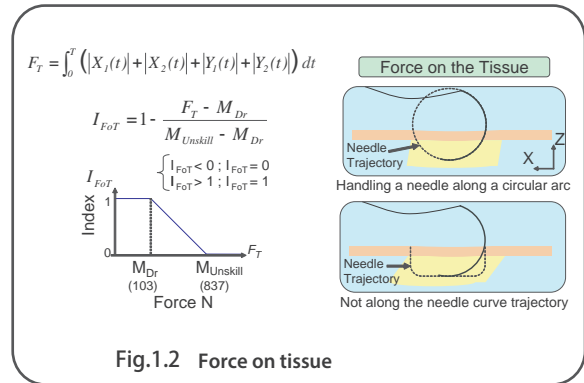


Fig. 1.2 Normalization of force on the tissue. The data of the force applied on the tissue during the suturing operation is normalized according to "the smaller, the better" principle.

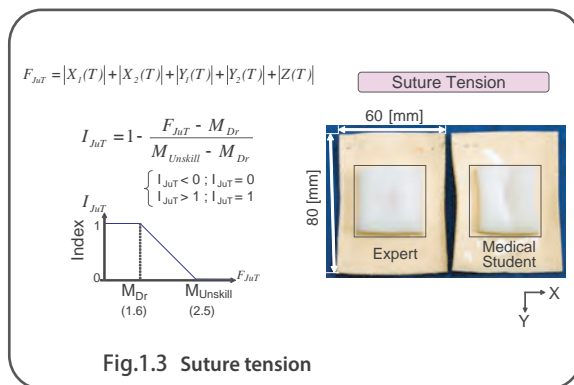


Fig 1.3 shows the calculation of suture tension. Less deformation of the skin sheet will lead to higher results.

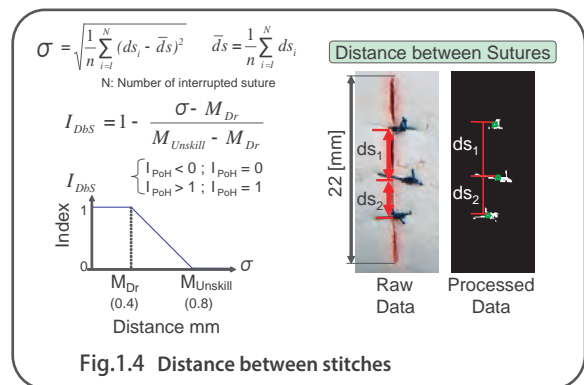


Fig 1.4 shows the calculation of distance between the stitches. The center point of the suture is determined, and distances are then calculated. The smaller the difference between d1 and d2 will yield higher score.

3 Normalization points

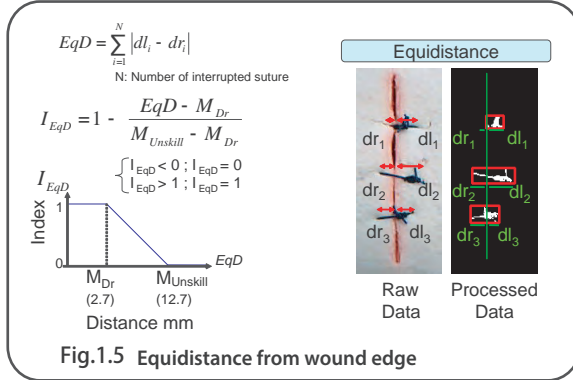


Fig 1.5 shows the calculation of equidistance from the wound edge. Difference in length of each side of the stitch from the wound is obtained from image processing.

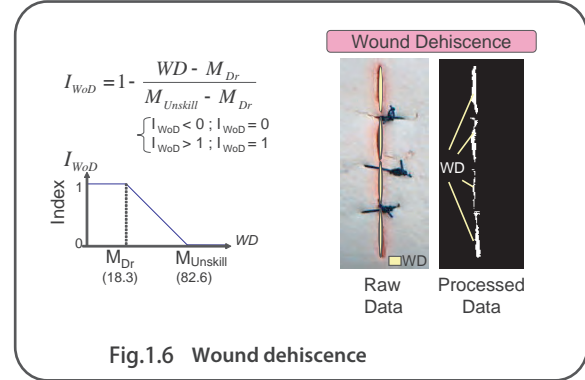
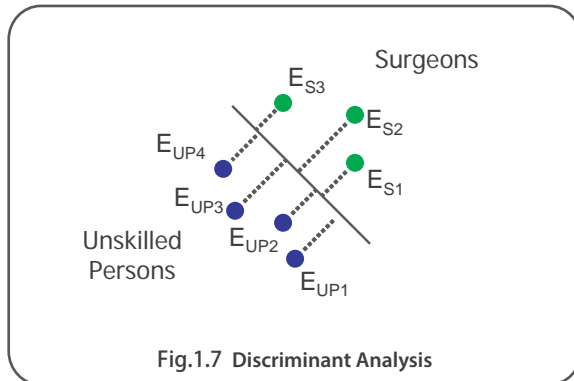


Fig 1.6 shows the calculation of wound dehiscence. The point will be given with the assumption that the wound should be completely closed.

4 Regarding the weight coefficient



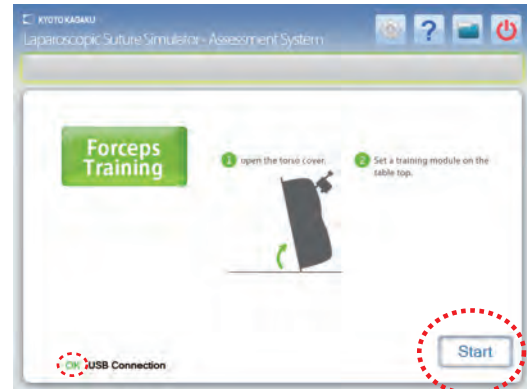
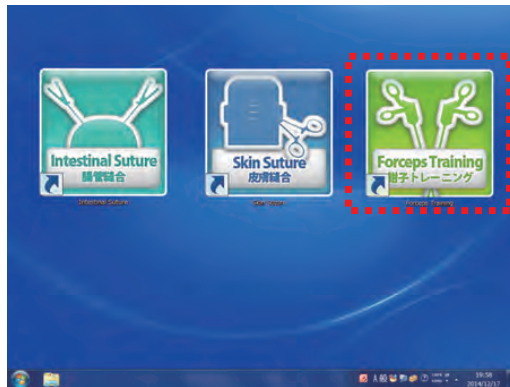
The weight coefficient is derived from a linear discriminant analysis seen in Fig 1.7. A line that best separates the data of the trainee and professional surgeon is drawn to determine the weight coefficient.

- | | |
|--------------------------------|-------------------|
| ① Completion time | $I_T = 0.843$ |
| ② Force on tissue | $I_{FoT} = 0.257$ |
| ③ Suture tension | $I_{JuT} = 1.367$ |
| ④ Distance between stitches | $I_{DbS} = 0.330$ |
| ⑤ Equidistance from wound edge | $I_{EqD} = 1.072$ |
| ⑥ Wound dehiscence | $I_{WoD} = 0.746$ |

1 Perform training

1. Display the top page

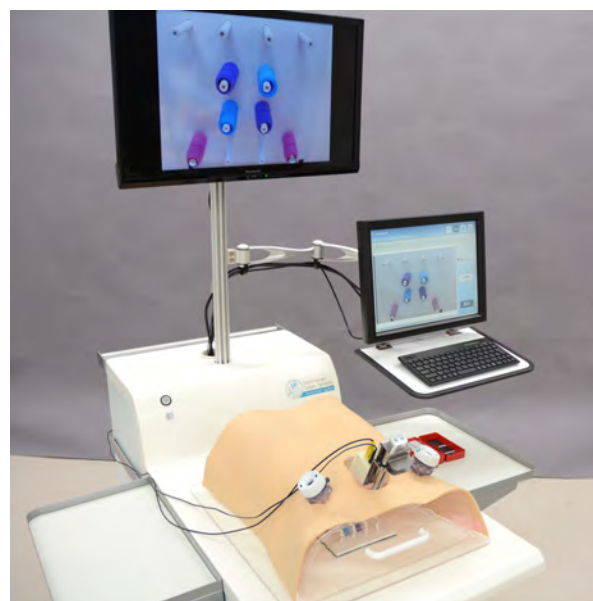
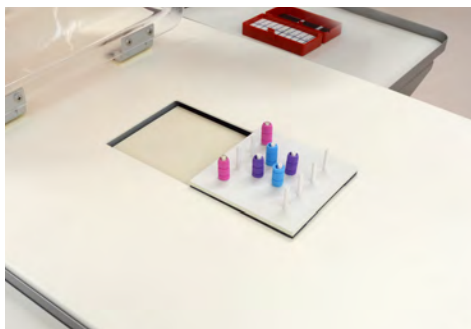
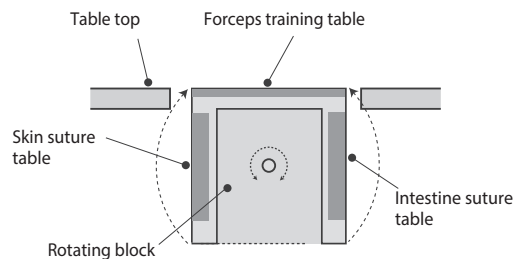
Select the forceps training button on the desktop screen to open the top page.



* On the top page verify that the USB connection indicator shows "OK" in green.
If it shows "NO", please contact your local distributor or Kyoto Kagaku Co., LTD.

2. Forceps training preparation

a. As shown on the top page screen, lift the torso cover up. Arrange the forceps training kit on the table top and select "Start" on the screen.

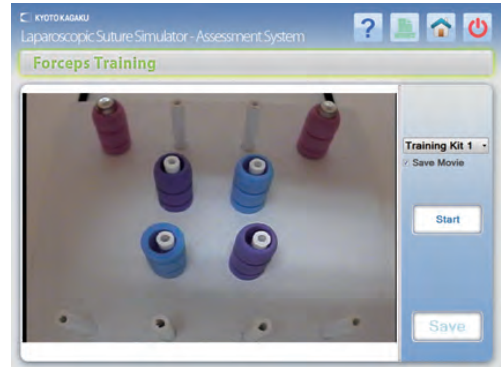


*Example of forceps training kit (not included in the set)

1 Perform training

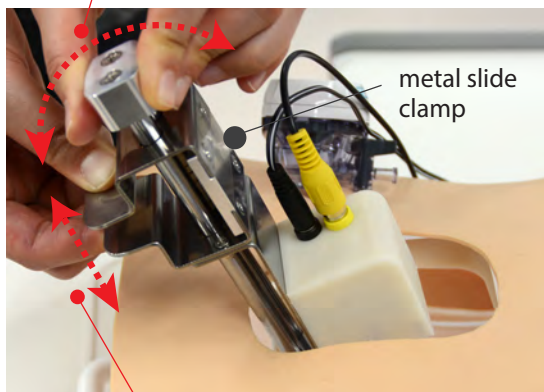
b. Once "OK" is selected, the screen on the right will appear.

The image of the forceps training kit on the table top will also appear on the large screen monitor. If the image on the screen is blurred or needs adjustment, proceed to the following steps.



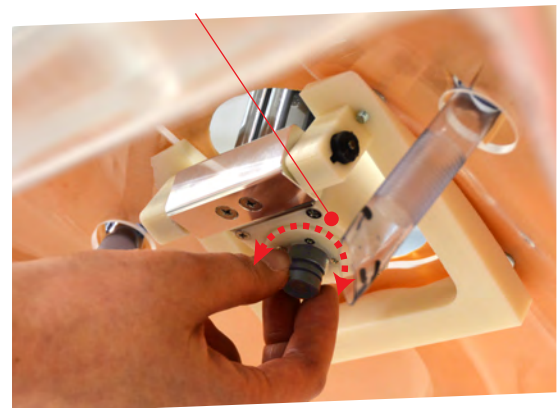
- ① Zoom in/out: Return the torso model to its original position, and use the camera position adjuster to move the camera up or down.
- ② Adjust positioning: use the camera position adjuster to change the direction of the camera.
- ③ Focus: use the camera lens to adjust the focus.

Adjust positioning: use the camera adjuster to move the camera back and forth.



Zoom in/out: Pinch the metal slide clamp while sliding the camera up and down.

Focusing: twist the lens.



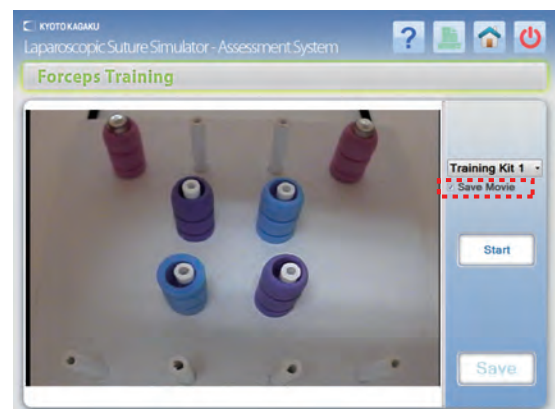
c. The forceps training mode requires users to register training guidelines. (See pg. 40 for more details on how to register)

3. Saving the movie

Users can save their training session by checking the "Save movie" check box on the screen. Movies of up to 20 minutes can be saved.



.....
"Save movie" check box need to be checked before the session. Otherwise the session cannot be saved.



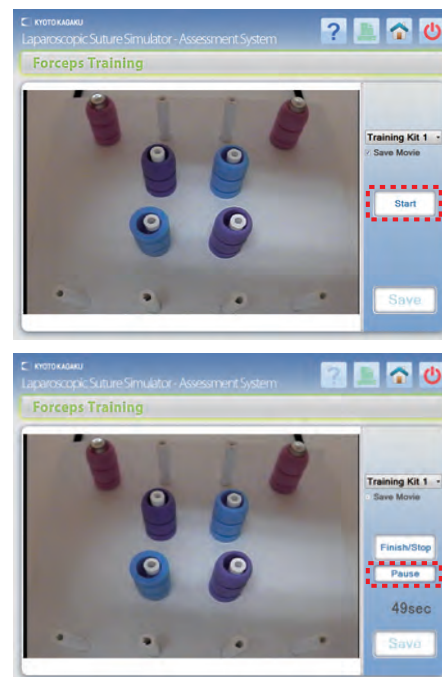
1 Perform training

4. Begin and end a training session

Prepare the forceps and select the "Start". Perform the forceps training while watching the image on the large screen monitor. The timer will stop when "Pause" is selected, and the timer will restart when "Start" is selected. Select the "Finish/Stop" once the training session is complete. The timer will stop and the completion time will be used as the evaluation result of this training mode. The forceps training mode evaluates users on their performance in a given time.



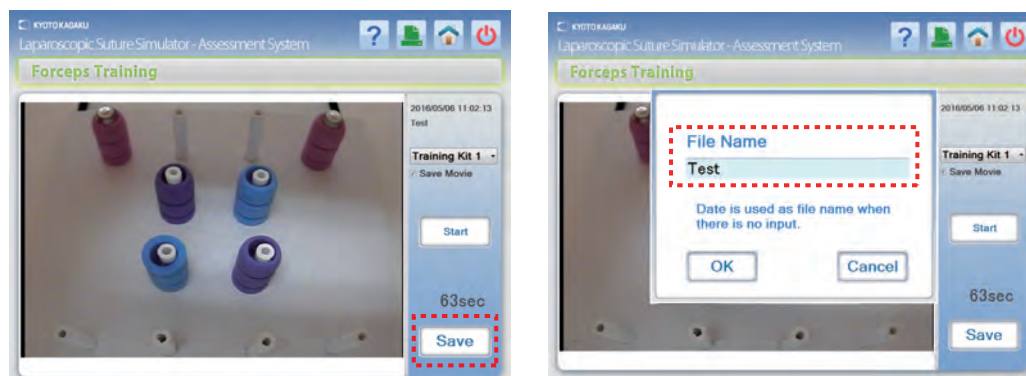
During the system is on "Pause", the "Finish/Stop" will change to "Start".



2 Review and save the result

1. Saving the results - Part 1

To record the evaluation results, select the "Save" to save the data with a file name. Enter the file name and select "OK" to save the evaluation data.

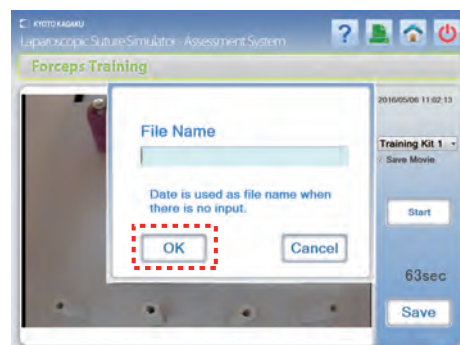


Symbols such as ¥ / : * ? < > | cannot be used in the file name.

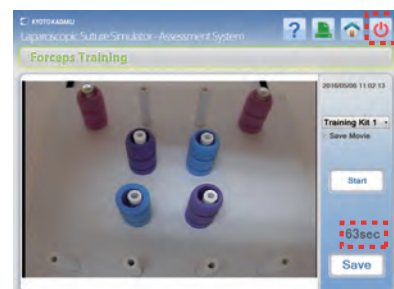
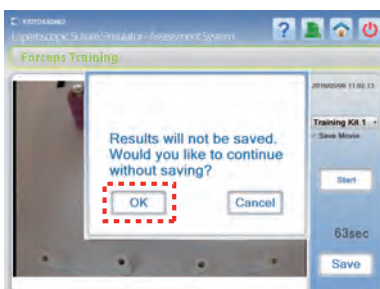
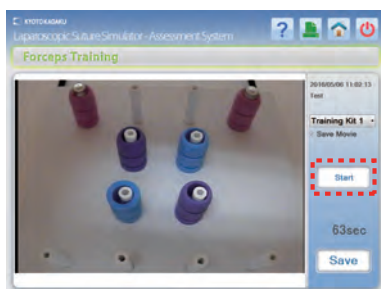
2 Review and save the result


2. Saving the results - Part 2

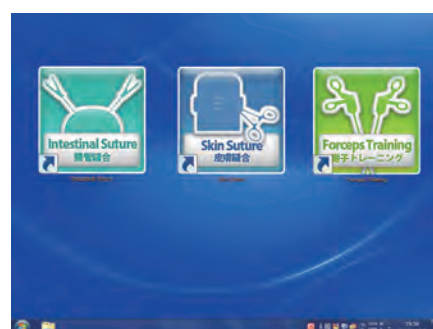
If there is no file name entered, the date and time will be used as the file name. Select "OK" and the forceps training screen will automatically display.




3. Select "Start" again to start another session without saving the current data. A warning message will display; select "OK" to begin the time count.



4. To end the training session or try another training mode, select the Power icon  on the top page right corner. Select "OK" on the warning message to display the desktop screen. (See pg. 43 for more details on ending training sessions)




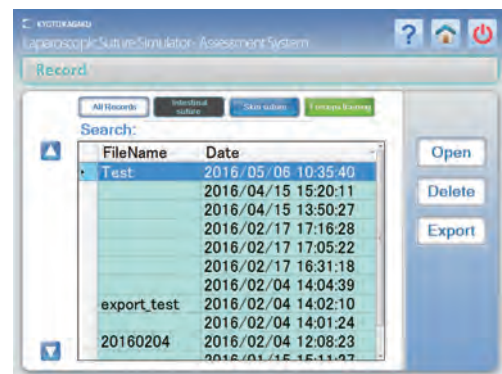
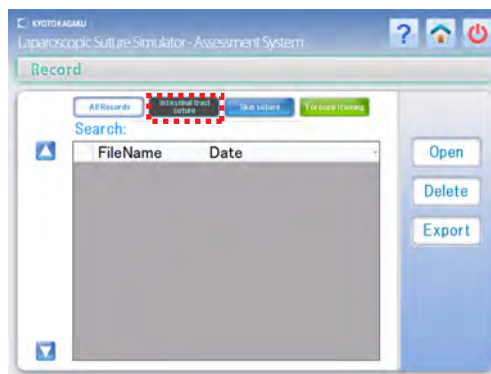
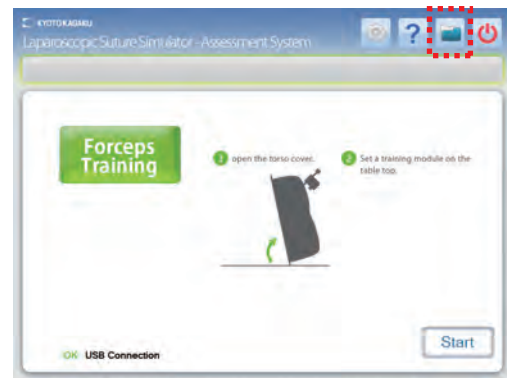
5. Saved data can be accessed from the top page. Select the Data icon  to display the top page. (See pg. 32-33 for more details)



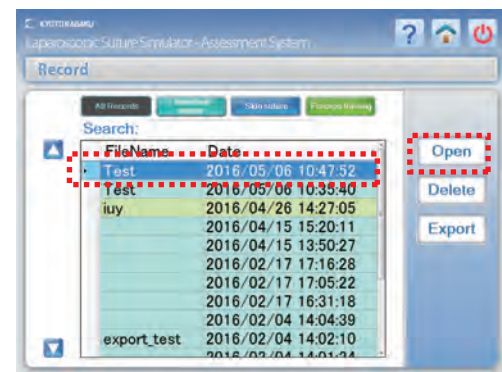
.....
If you selected "Save movie" before training, the movie will be saved alongside with the evaluation results under the same file name.

1 Reviewing saved data

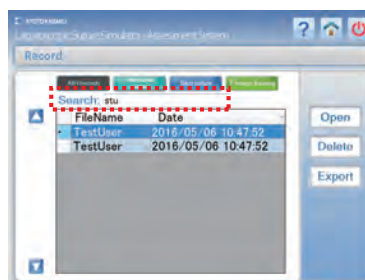
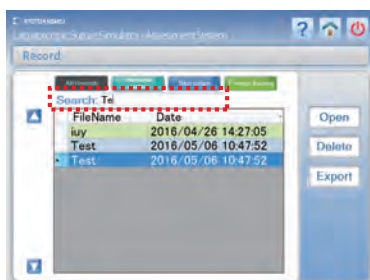
1. Select the "Data" icon  on the top right corner of the screen to see all saved data results. Data for laparoscopic suture is displayed in green, data for skin suture is displayed in blue, and data for forceps training is displayed in yellow-green. 4 list of data are prepared: all, intestinal tract suture, skin suture, or forceps training.



2. Select a saved data file and select "Open" to view the evaluation results page.



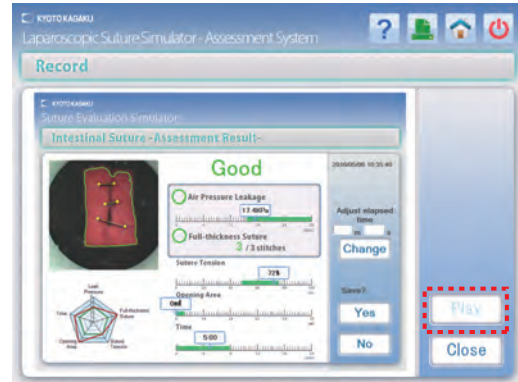
3. The search bar allows finding files by their file names.



Keyword for search can be partial.

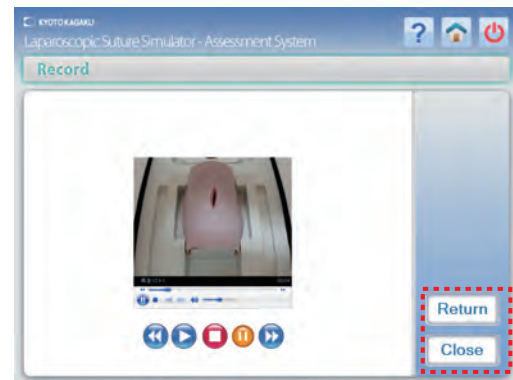
1 Reviewing saved data

4. The evaluation results will be displayed as seen below. Select the "Play" button to replay the saved movie.



If there is no movie saved for the file,
the "Play" cannot be selected.

5. The movie will display on the screen. The movie will also display on the large screen monitor. Use the remote control to operate the large screen monitor. Select the "Return" to return to the evaluation results page, and select "Close" to return to the file data page.



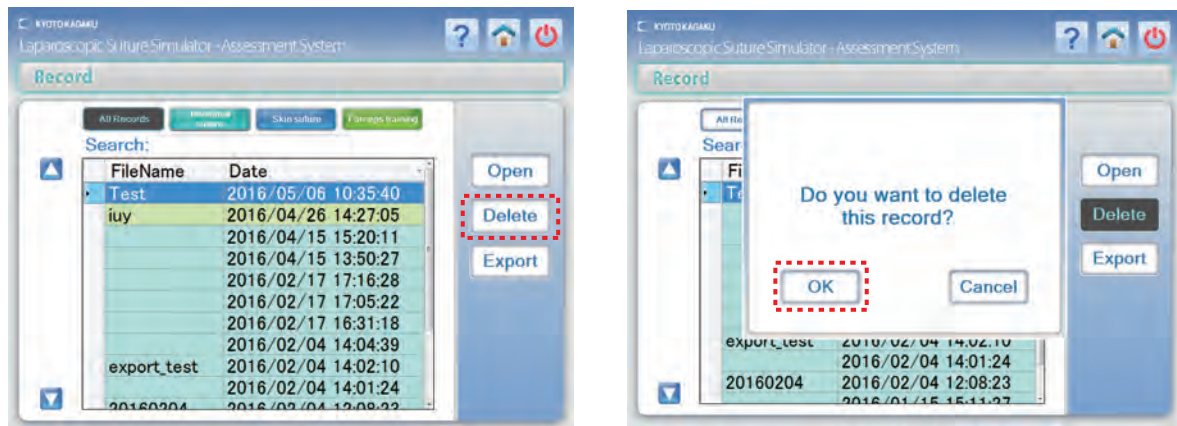
[Operating the remote control]

Press mode button on the top right of the remote control to change from the "Video output" to "HDMI output" option and confirm by pressing the button in the middle of the arrows.



2 Deleting saved data

Select a file to delete and select the "Delete". A warning message will display; select "OK" to confirm.

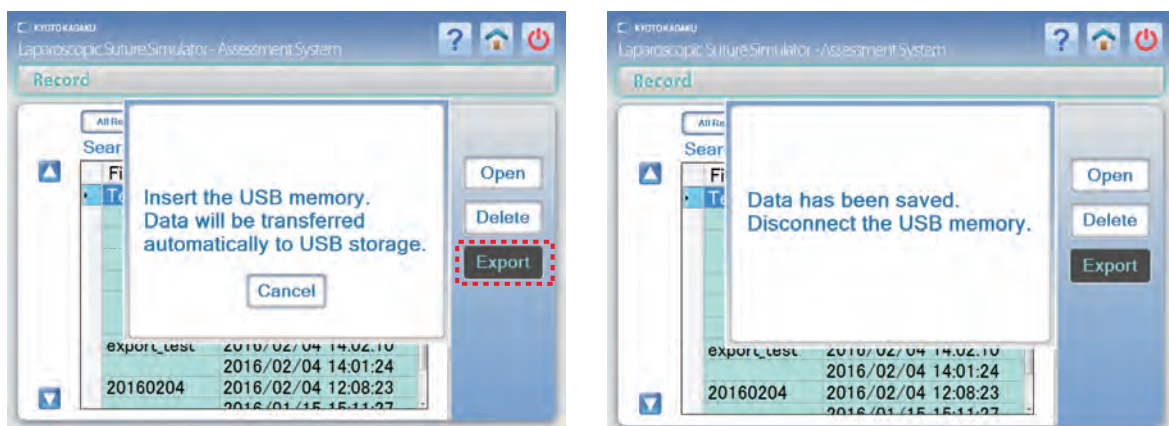


3 Exporting saved data


Select a file to export and select the "Export". Insert the USB memory following the message appears on the screen.

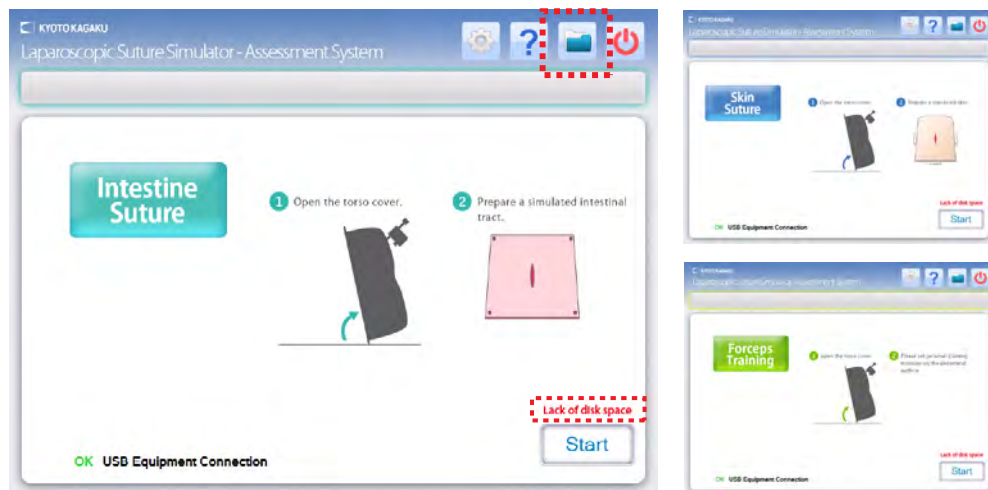
Once the exporting is complete, remove the USB memory following the message appears on the screen. This will complete the data export.

In case the export is failed, i.e. when the files of the same names are already on the USB memory, dialogue window also instruct to remove the USB memory. Follow it.



4 Memory shortage

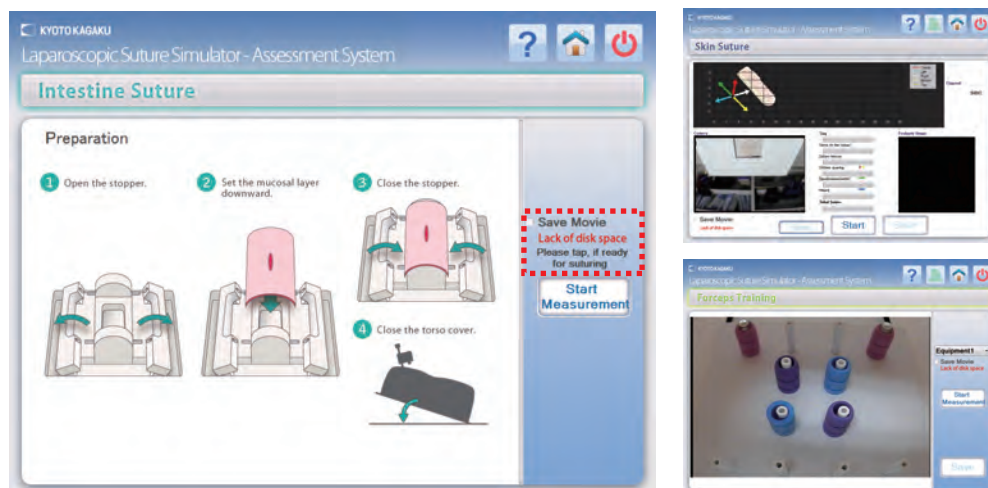
1. If there is not enough memory to store a movie, a warning message will appear on all 3 training mode top pages. To save the data, make space in the memory by deleting redundant data. Data can be deleted by selecting the Data icon  and selecting any data files that can be deleted or exported.



Note

The warning message will disappear once memory is recovered to store the data. Alternatively users can also proceed to another session without saving the data.

2. The memory-shortage warning message will also appear below the "Save Movie" check box. To save the data, make space in the memory by following step 1.

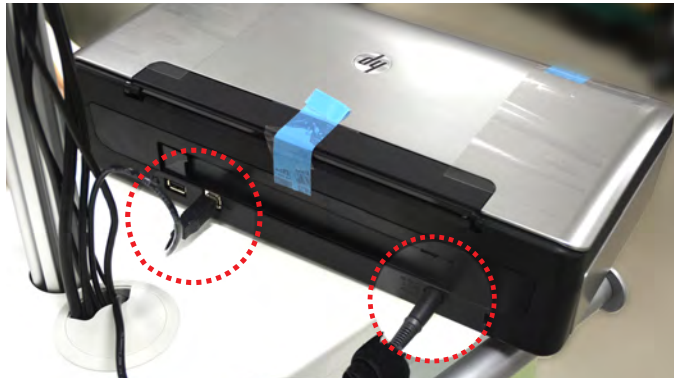


Print

1 Print

The evaluation result screen image can be print out using the provided printer.


1. Connect the USB cable and power cable at the bottom of the pole to the port at the back of the printer.
(Set the printer on the simulator unit.)



2. Open the lid on the printer and turn the power on. Insert paper.



* See the printer manual for more details

3. Select the Print icon  on the top right corner to print the displayed screen. A print dialog window will open; configure the print settings and select "OK" to print.



Only screens with the Print icon can be printed.

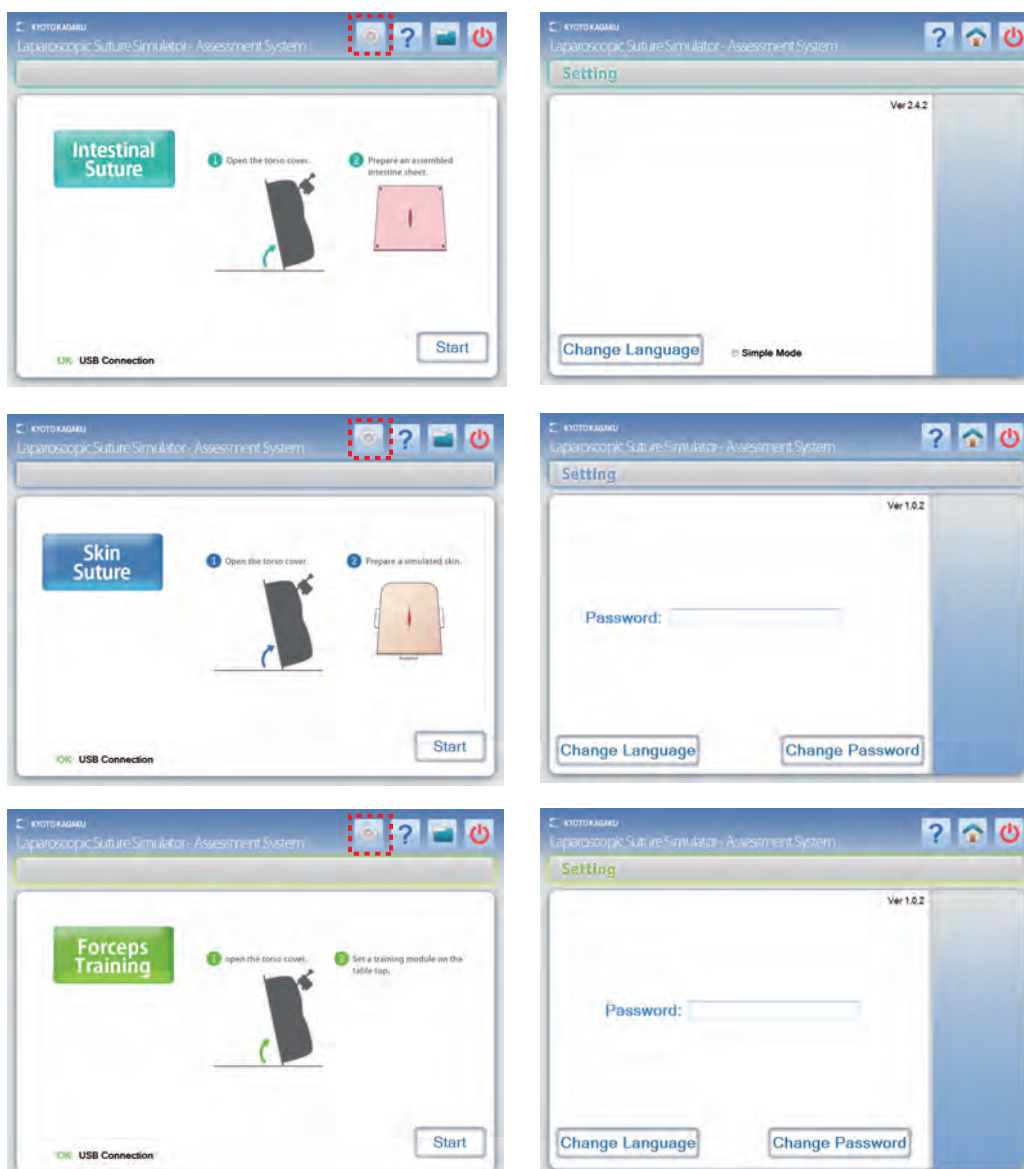
Settings

1 Settings

The following settings can be changed.

- ① passwords
- ② weight coefficient of the skin suture assessment
- ③ settings for the forceps training
- ④ language (Japanese/English)
- ⑤ display of assessment result (intestinal suture)

1. These settings can be changed from the top page of each training mode. Select the Setting icon on the top page right corner to display the screen shown on the right column below.



2. Before changing other settings, change your password. The password can be set or changed on the top page of the skin suture or forceps training page.

Settings

1 Settings


① Change passwords

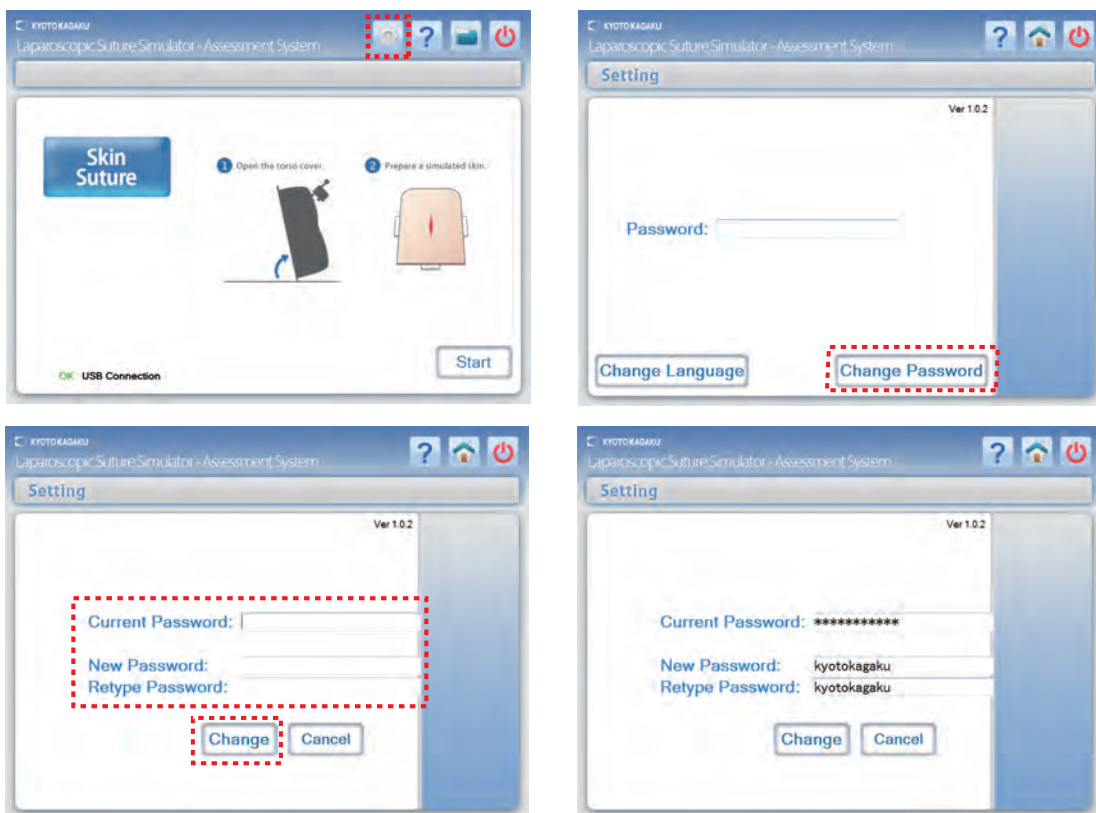
This simulator system has been programmed with a preset password for the skin suture and forceps training evaluation settings.

We strongly recommend changing your password for stronger security.

*The system settings can still be changed with the preset password.

Preset password: kyotokagaku

To change the password, select the Setting icon  on the skin suture or forceps training top page, and select the "Change password". Type a new password (capitalized and non-capitalized alphabets can be used) and select "Change".



1. Current password: Type your current password
2. New password: Type your new password
3. Password confirmation: Re-type your new password for confirmation


■ Password compatible characters

Capitalized and non-capitalized alphabets can be used. Symbols and double-byte characters cannot be used.

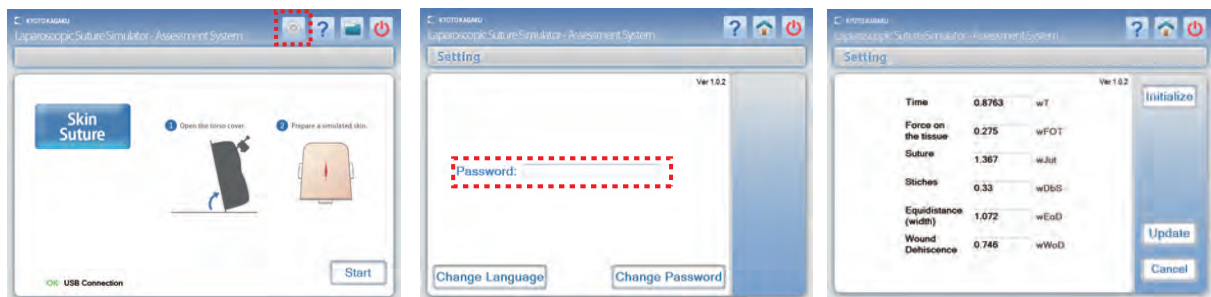
Settings

1 Settings


② Change weight coefficient of the skin suture assessment

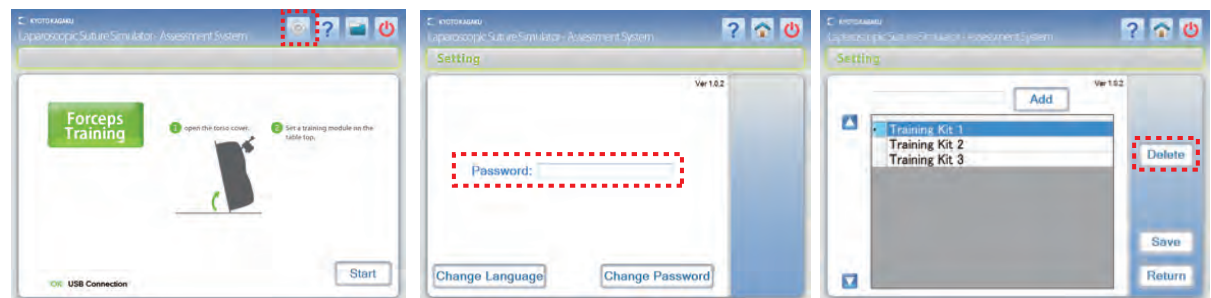
Select the Setting icon  on the top right of the skin suture top page, input the password and press enter on the keyboard. The weight coefficient page will be displayed. Each coefficient of the 6 criteria points can be changed.

1. Initialize: Resets all coefficients to the default value.
2. Update: Confirms changes to the coefficient values.
3. Cancel: Cancels any changes made and closes the page.



③ Change the settings for the forceps training

Select the Setting icon  on the top right of the forceps training top page, input the password and press enter on the keyboard. The settings for each training method will display.



The preset names of options are "Training kit 1", "Training kit 2", "Training kit 3".
Register name of training for each option.


Add or delete existing training options.

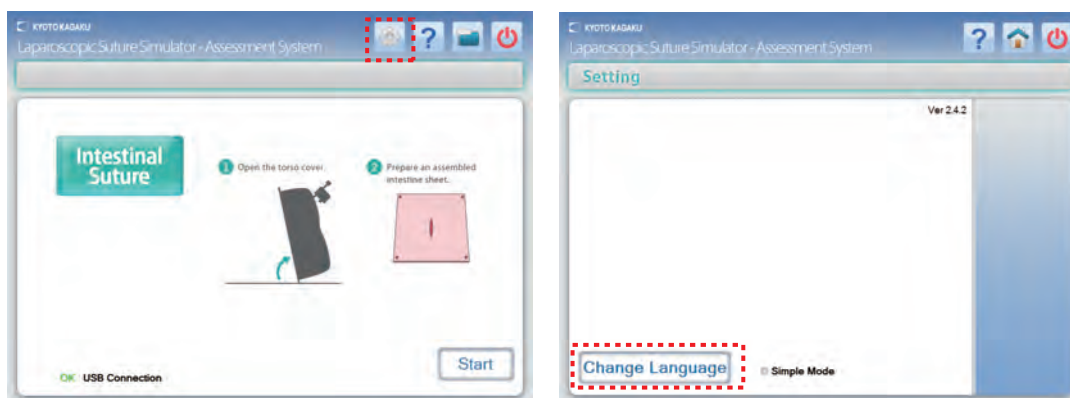
1. Add a training option by entering a name and selecting the "Add" button.
2. Delete a training option by selecting an option and selecting the "Delete" button.
3. Select the "Save" button to save changes.

Settings

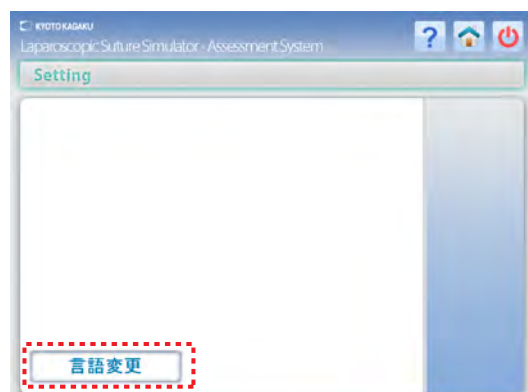
1 Settings

④ Change the language

Select the Setting icon  on the top right of top page of the any training mode, and select the "Change language". All screen settings will be changed from English to Japanese. The language change will be applied to the entire training system.



Select the button again to change the language setting from Japanese to English.

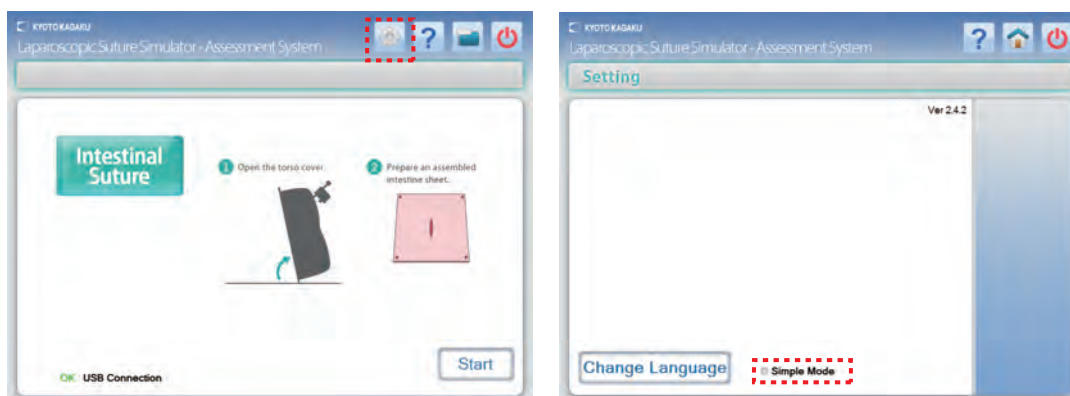


.....

The setting icon on the top page of the intestinal suture only displays language changes and simple mode setting.
The password is not required to change these settings.



⑤ Change the display setting for assessment result of intestinal suture (simple mode).

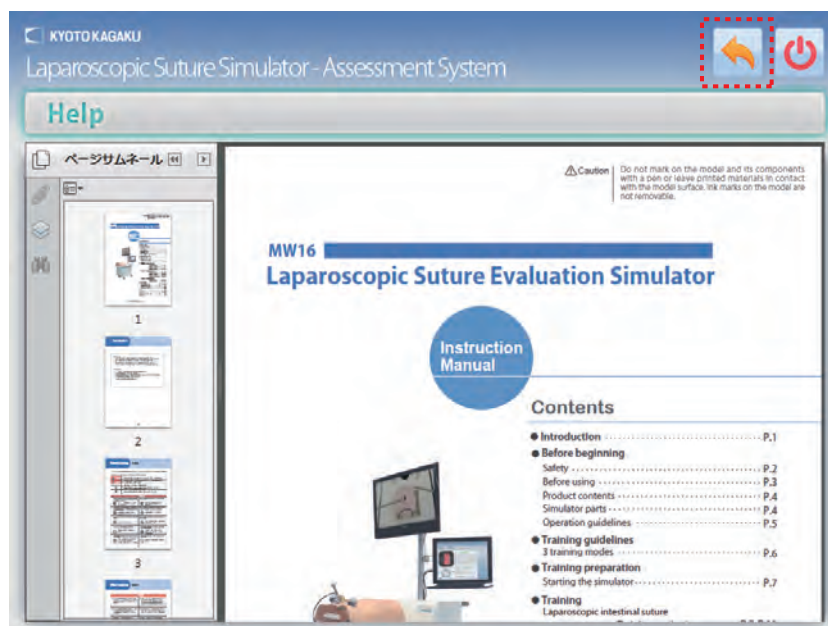
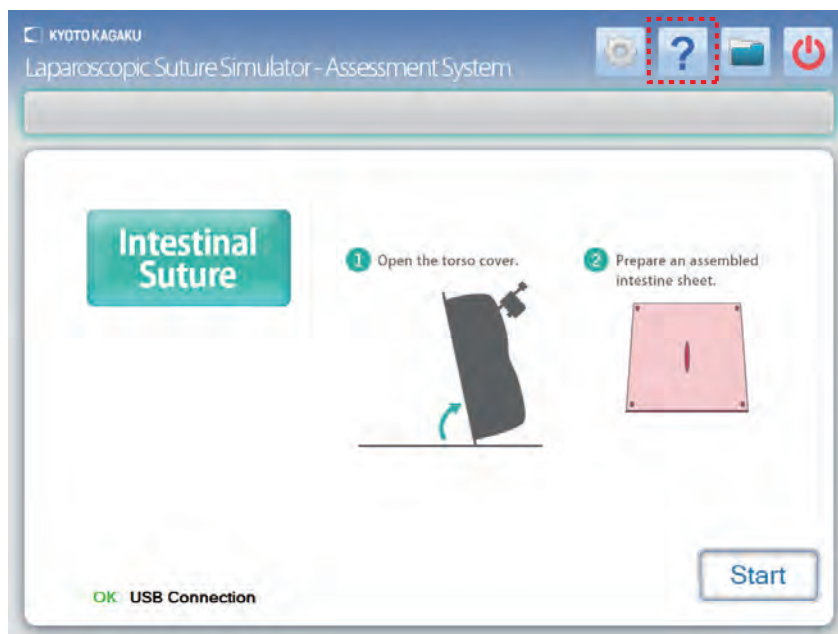
The letter "poor" can be hidden when necessary, by checking the check box for "simple mode".
The simple mode facilitate training of beginners.



1 Operation manual

Instruction manual can be shown on the monitor of the simulator.


1. Select the Help icon  on the top right of the screen to display this user manual on the screen.
To return to using the simulator, select the Return icon .

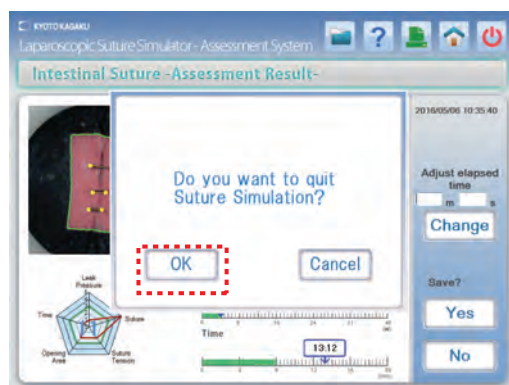
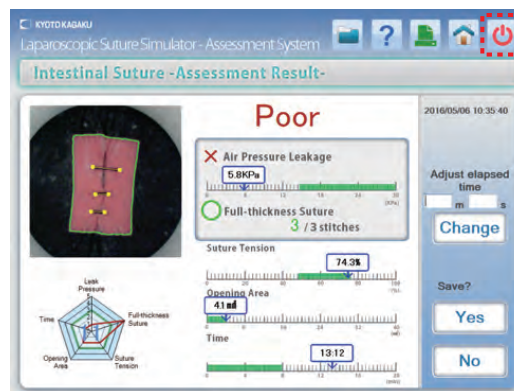


After use

1 After use

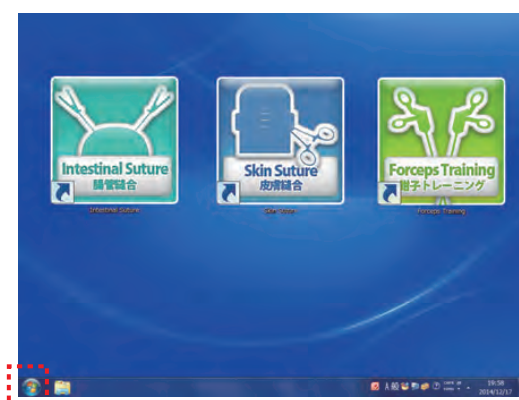
1. Exit the simulator software

Select the Power icon  on the top right of the screen to exit the page. A confirmation message will appear; select "OK" to display the desktop page.



2. Turn off the simulator

Select the Start icon on the bottom left of the screen and shut down the computer. Turn the main power switch off and unplug the power cord.



Be sure to turn off the computer before turning off the main power switch of the simulator.

3. Remove and discard all intestine and skin sheets used during the training sessions.
4. Place used needles and thread into the provided storage case and discard.
5. When necessary clean the simulator with water or mild detergent. Clean the torso cover with water or mild detergent and coat with baby powder. Please be aware not to apply water or detergent on the internal machinery.



Caution

Do not let ink from pens, newspapers, product manual or other sources contact the manikin. Ink marks on the manikin will be irremovable.

- For inquiries and service, please contact your distributor or KYOTO KAGAKU CO., LTD.

KYOTO KAGAKU co.,LTD

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3109 Lomita Boulevard, Torrance, CA 90505-5108, USA

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