Laparoscopic Suture Simulator - Assessment System

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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.
Before use

Safety

The safety rules below focus on the safety of the user; please read carefully before using the product.

- 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.
  - **Caution**: This sign represents harmful use toward the simulator or its parts that may lead to permanent damage or disfiguration.

- These signs below represent strongly recommended uses for safety.

  - A circle with a cross represents actions that are strongly discouraged. This sign asks users not to attempt taking the simulator apart.
  - This sign represents rules that are strongly encouraged to follow.

### Warning

- When the manikin or the control box becomes hot or begins to smoke, immediately unplug the power cord.
  - This is a major fire hazard. Please contact your local distributor or Kyoto Kagaku Co., Ltd for repairs.

- Remove any dust that has accumulated on the power plug and insert the plug completely into the power socket.
  - Dust and incomplete connection can lead to a major fire hazard.

- Do not handle the power cord with wet hands.
  - This is to avoid electrocution.

- Use the designated power supply.
  - Misuse may lead to damages and fire hazards.

- Do not attempt to take apart or remodel the product.
  - This could lead to fire hazards, electrocution and injuries. Please contact your local distributor or Kyoto Kagaku Co., Ltd when repair is required.

- Unplug the power cord when the simulator is not in use.
  - This will prevent electrocution or fire hazards that may cause burns and damages.

- Keep the manikin, its machinery and power cord away from water or detergent.
  - Wet system can lead to fire hazards and/or electrocution.

- Keep flammable materials away from the product.
  - Such materials can lead to fire hazards and damages to the simulator.

- When unplugging the power cord, hold by the plug and pull.
  - Unplugging by the cord may lead to damages to the cord itself, fire hazards or electrocution.

- Do not bend, twist or damage the power cord.
  - This is to avoid to fire hazards and electrocution.
### Cautions

<table>
<thead>
<tr>
<th>Cautions</th>
<th>Cautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Do not apply excessive force or pressure onto the simulator. Forceful application or removal of the intestine and skin sheets may lead to damages.</td>
<td>● Do not install other software onto the computer; it may lead to system malfunctions.</td>
</tr>
<tr>
<td>● Do not mark the manikin with a pen or leave printed materials in direct contact with the surface. The ink marks on the torso cover, and intestine/ skin sheets are not removable.</td>
<td>● 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.</td>
</tr>
<tr>
<td>● Discoloration of the surface may occur over time. Natural discoloration does not affect the function of the simulator.</td>
<td>● Ensure to shut down the computer first. Then turn off the electricity power switch and unplug the power cord. Misuse may lead to damages.</td>
</tr>
<tr>
<td>● Store the simulator away from direct sunlight. Store it in room temperature, away from heat and moisture to prevent discoloration or other damages.</td>
<td>● Transport the simulator with caution. Hold the simulator by the handle when transporting. Do not hold the simulator by the screen, pole or the torso model. Carry with 2 or more people to transfer it from one level to another.</td>
</tr>
<tr>
<td>● Clean the simulator with water or mild detergent. Clean the torso cover with water or mild detergent and coat with baby powder. Be careful not to apply water or detergent on the internal machinery.</td>
<td>● 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.</td>
</tr>
<tr>
<td>● 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.</td>
<td></td>
</tr>
</tbody>
</table>

- 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: 2,000 meters above sea-level
- Environmental conditions: 5 degreesC. to 40 degreesC.
- 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 2.5 kg on the side trays.
### Before use

#### Set includes

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Laparoscopic Evaluation Simulator</td>
<td>1 unit</td>
</tr>
<tr>
<td>- main unit</td>
<td></td>
</tr>
<tr>
<td>- 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)</td>
<td></td>
</tr>
<tr>
<td>b. Printer</td>
<td>1 unit</td>
</tr>
<tr>
<td>c. Keyboard</td>
<td>1 unit</td>
</tr>
<tr>
<td>d. Trocar</td>
<td>2 units</td>
</tr>
<tr>
<td>e. Intestine sheet (muscle layer)</td>
<td>30 sheets</td>
</tr>
<tr>
<td>f. Intestine sheet (mucosal layer)</td>
<td>30 sheets</td>
</tr>
<tr>
<td>- <em>Intestinal sheets come with case</em></td>
<td></td>
</tr>
<tr>
<td>g. Skin sheet for suturing</td>
<td>40 sheets</td>
</tr>
<tr>
<td>h. Needle storage case</td>
<td>1 unit</td>
</tr>
<tr>
<td>- Instruction manual</td>
<td></td>
</tr>
</tbody>
</table>

### 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**
### Before use

**Set up and additional instruction**

#### 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.
Before use

Set up and additional instruction

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.
Before use

Control parts, buttons and functions

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.

<table>
<thead>
<tr>
<th>Wireless connection distance: Approx. 10m around non-magnetic material (ie. Wooden desks), approx. 3m around magnetic material (ie. Steel desks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power: Alkaline AAA batteries, manganese AAA batteries, nickel metal-hydride AAA batteries</td>
</tr>
<tr>
<td>Estimated battery life: Approximately 1 month *Test results of manufacturer</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Power icon:</th>
<th>Setting icon:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exits the simulator software and returns to the desktop screen.</td>
<td>Edits system settings</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Home icon:</th>
<th>Data icon:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Returns to the evaluation top page</td>
<td>Displays recorded data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Help icon:</th>
<th>Print icon:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displays the help menu</td>
<td>Print the displayed screen</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Skills to be assessed</th>
<th>Assessment criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic suturing</td>
<td>5 assessment criteria</td>
</tr>
<tr>
<td>- 3 simple interrupted stitches</td>
<td></td>
</tr>
<tr>
<td>Instrument tying</td>
<td></td>
</tr>
</tbody>
</table>

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

**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.

<table>
<thead>
<tr>
<th>Skills to be assessed</th>
<th>Assessment criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suturing</td>
<td>6 assessment criteria</td>
</tr>
<tr>
<td>- 3 simple interrupted stitches</td>
<td></td>
</tr>
<tr>
<td>Instrument tying</td>
<td></td>
</tr>
</tbody>
</table>

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

**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.

<table>
<thead>
<tr>
<th>Skills to be assessed</th>
<th>Measurement criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic use of laparoscopic forceps</td>
<td>Completion time</td>
</tr>
</tbody>
</table>

*Training kit is not included in the set

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Caution: 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.

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

Laparoscopic intestinal suture: Perform suturing

1 Perform suturing

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

   [Image of desktop screen with "Intestinal suture" option highlighted]

   * 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
   a. 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".
   b. 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.

   [Image of table top with intestine sheets and rotating block]

   If the rotating block stops during 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.
Training

Laparoscopic intestinal suture: Perform suturing

1. **Perform suturing**

   c. Assemble the intestine sheets
      1. Peel off the transparent protective film from the mucosal layer (red sheet with black back side).
      2. Put the muscle layer (light peach color sheet) over the mucosal layer so that base sides of two sheets come together. Align the opening in the center.
      3. Peel off the transparent protective film from the muscle layer.

   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](image)

   **Caution**
   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.

   ![Note](image)

   **Note**
   Set the intestine sheets light colored side up.

   ![Suture base](image)

   *Place the back side on the bottom.*
Training

Laparoscopic intestinal suture:
Perform suturing

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.]

![Focusing: twist the lens.]

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

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.]

Caution: "Save movie" check box need to be checked before the session. Otherwise the session cannot be saved.
6. Begin and end a training session

To begin a training session, select the "Start". This will activate the 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.
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.

**Caution**
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.)

- **Brightness Control**
  - dim
  - normal
  - bright

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. 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)

Caution

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.
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)

Caution
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.

- Laparoscopic suturing - 3 simple interrupted stitches
- Instrument tying

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

Caution

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**
  - **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 14.5 Kpa.

Note

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

Laparoscopic intestinal suture: Assessment method

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.
Training

Skin suture: Perform suturing

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

   ![Top page screenshot]

   * 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
   a. As shown on the top page screen, lift the torso cover up. Prepare one piece of skin sheet and select "Start".
   b. 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.

   ![Skin sheet setup]

   If the rotating block stops during rotation, adjust by pushing it to its correct side.

   ![Caution]

   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.
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.

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.

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

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

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

Focusing: twist the lens.
Training
Skin suture: Perform suturing

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.

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

   Replacement parts
   11230-020
   NUROLO™ 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.

   Caution
   “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.
6. Begin and end a training session

a. 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".

b. 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.

c. 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.

Cut off redundant thread from the knots.

The rotating block with the skin sheet will turn to the image evaluation side.
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 stiches are not detected automatically. Select "Retry" to return to the evaluation option menu. Select "Stop" to return to the top menu, without saving data.
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.

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. 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.

Caution
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.
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

Caution
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
  2. Force on tissue
  3. Suture tension
  4. Distance between stitches
  5. Equidistance from the wound edge
  6. Wound Dehiscence

Weight coefficient \( \omega_T, FoT, JuT, DbS, EqD, WoD \) : Weighting Coefficients

(Reference)
"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.
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.

\[ I_T = 1 - \frac{T - M_{\text{Dr}}}{M_{\text{Dr}} - M_{\text{MUnskill}}} \]

where \( T \) is time in seconds, \( M_{\text{Dr}} \) is the average of the surgeon group’s data, and \( M_{\text{MUnskill}} \) is the average of the unskilled group’s data.

Unskilled Person Surgeon

| Time [s] | 384 | 122 |
| Time (Normalize) | 0.05 | 0.95 |

Fig.1.1 Completion time

Fig.1.2 Force on tissue

The data of the force applied on the tissue during the suturing operation is normalized according to “the smaller, the better” principle.

\[ F_T = \int (|x| + |y| + |z| + |t| + |p|) \, dt \]

\[ I_{F_T} = 1 - \frac{F_T - M_{\text{Dr}}}{M_{\text{Dr}} - M_{\text{MUnskill}}} \]

where \( F_T \) is the force on the tissue, \( M_{\text{Dr}} \) is the average of the surgeon group’s data, and \( M_{\text{MUnskill}} \) is the average of the unskilled group’s data.

Fig.1.3 Suture tension

Fig.1.4 Distance between stitches

The center point of the suture is determined, and distances are then calculated. The smaller the difference between \( d_1 \) and \( d_2 \) will yield higher score.

\[ \sigma = \frac{1}{N} \sum_{i=1}^{N} (d_i - \bar{d})^2 \]

\[ I_{\sigma} = 1 - \frac{\sigma - M_{\text{Dr}}}{M_{\text{Dr}} - M_{\text{MUnskill}}} \]

where \( \sigma \) is the distance between sutures, \( M_{\text{Dr}} \) is the average of the surgeon group’s data, and \( M_{\text{MUnskill}} \) is the average of the unskilled group’s data.

Fig.1.5 Suture tension

Less deformation of the skin sheet will lead to higher results.

Fig.1.6 Distance between sutures

The smaller the difference between \( d_1 \) and \( d_2 \) will yield higher score.
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 $I_{WoD} = 0.746$

Fig 1.5 Equidistance from wound edge

Fig 1.6 Wound dehiscence
1. **Perform training**

   1. Display the top page

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

      ![Image of top page](image1)

      *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.

      ![Image of forceps training setup](image2)

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

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

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

Focusing: twist the lens.

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.

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

Laparoscopic forceps training: Perform training / Review and save the result

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.

![Image of forceps training](image1.png)

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**Note**

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.

![Image of saving results](image2.png)

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**Caution**

Symbols such as `/` or `*` 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)

Caution

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

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.

Note: Keyword for search can be partial.
4. The evaluation results will be displayed as seen below. Select the "Play" button to replay the saved movie.

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.

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.

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.
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.

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Caution: Only screens with the Print icon can be printed.
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.
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.
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

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.

Caution
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.
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.
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 button left of the screen and shut down the computer. Turn the main power switch off and unplug the power cord.

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.