ACaution

Do not mark on the product and other components with pen nor leave printed materials contacted on surface. Ink marks on the models cannot be removed.

MW56 Laparo Cube



Instruction Manual

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1.Introduction

Before use

Laparo Cube is designed to assess skills in laparoscopic intestinal suture.

Features

Laparoscopic intestinal suture skills are assessed by 5 evaluation criteria, each criteria is

assessed with a maximum of 5 points, for a total of 25 points.

- 1. Air pressure leakage (maximum of 5 points)
- 2. Full-thickness suture (maximum of 5 points)
- 3. Suture tension (maximum of 5 points)
- 4. Opening area (maximum of 5 points)
- 5. Completion time (maximum of 5 points)

Total of 25 points

1. Air pressure leakage and 2. Full-thickness suture are used to determine successful procedure.

Evaluation criteria for 1. Air pressure leakage, 3. Suture tension, 5. Completion time can be adjusted. You can create your own evaluation criteria based on acquired data.

The evaluation data and video of performed suture can be saved for review and serve as resource for effective self-learning.

Please a the Instruction carefully before use.

Do not use this simulator for any purpose other than training of healthcare professionals,

and read this instructions carefully. We are not responsible for any damage caused by use

that is not accepted by this instruction.

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.



To use this simulator, tools for endoscopic training such as a training box, monitor, needle holder, auxiliary forceps, etc. are required separately. (See P.6 for details)



2.Before use

2-1 DOs and DON'Ts

$\underline{\mathbb{A}}$ DOs and DON'Ts

DOs

•Operate the system under the designated circumstances

Power input: AC100V $\sim\!230V$ 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 a power source outside of the designated range may lead to fire.

•Safe disposition

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

•Use the authentic adapter and the cables

included in the set.

Use of different adapters or cables may lead to shock or fire. Also, do not use these components to other products.

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.
- Always hold the plug when unplugging. Do not pull the cable.
 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.

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 areas, 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 a 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 use the wireless LAN or Blue-tooth of the computer

It may lead to system malfunctions.

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

2.Before use

2-2 Set Includes

Set includes

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

















- $\textcircled{4} \mathsf{USB} \mathsf{Cable}$
- (5) AC Adapter
- 6 Suture Sheet (30 sheets)
- $\ensuremath{\overline{\mathcal{O}}}$ Instruction Manual



Types of laptop PC may vary depending on time of production, though it does not affect the operation of this simulator.



3-1 Setting

Connecting Laptop with Assessment Unit Connect laptop and assessment unit as shown below. ④ USB Cable 2 Laptop 1) Assessment Unit (5) AC adapter (AC100V~220V) (AC adapter from laptop) Outlet

Preparation the suture sheets

Peel off the transparent protective film from the sheet. Set the skin sheet to the holder.





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

3-1 Setting



Prepare the following tools for endoscopic training.

- ① training box, camera (1)
- \bigcirc monitor (1)
- ③ needle holder (1)
- ④ auxiliary forceps (1)
- (5) scissors forceps (1)
- 6 needle thread (3-0, knitting thread)

Put the holder into the training box.

Push the lever in to anchor with the suction cup.







Use the holder on a smooth surface.

3-1 Setting



 $\underline{\Lambda}_{Caution}$ Be sure to turn on the power of the assessment unit before launching the software.

S1

3-2 Suture

Suture Method

Suture the 4 layers with 3 (6) simple interrupted stitches.

Ligate 3 times for 1 stitch.

(* 3 stitches are set for assessment as initial state.)





Suture skills are assessed by 5 evaluation criteria, each criteria is assessed with a maximum of 5 points, for a total of 25 points.

| 1 Air pressure leakage " leaks from the suture " | (maximum of 5 points) |
|--------------------------------------------------------------------|-----------------------|
| 2 Full-thickness suture " whether sutures made through all layers" | (maximum of 5 points) |
| ③ Suture tension "force applied to the skin" | (maximum of 5 points) |
| ④ Opening area " remaining open wound" | (maximum of 5 points) |
| (5) Completion time "completion within adequate time" | (maximum of 5 points) |
| | Total of 25 points |

1. Air pressure leakage and 2. Full -thickness suture are used to determine successful procedure.

3-2 Suture



3-3 Skills Assessment

Skill assessment 1

After the suturing completed, move the suture sheet from the holder to the assessment unit. Pass the corner holes of the skin sheet through 2 pins at the top of the assessment unit.



3-3 Skills Assessment

Skill assessment 2



The screen will display the rear side view of the sutured intestine sheets. Select the ends of the thread on each suture.

When a suture is incomplete and the thread is not visible, move to the next suture.

When a stitch seen on the mucosal layer does not cross the wound, this stitch is incomplete as full layer suture. In that case, select the starting point and select "Skip".



Select "Finish" when selections are done. Select "Return" to undo the selections.

Once all three threads have been selected and the "Finish" button has selected the leak pressure screen will display.

leak pressure evaluation (the measurement will take approximately 5 seconds)



Once the measurement is complete, leak pressure and opening area will be shown. Select "Assessment Screen" to display the assessment results.

When the test needs to be repeated, in case such as air leakage from the gap of the lid, conduct a re-leak test.

Select "Re-Leak Test" to re test.

opening area enclosed by blue line



3-3 Skills Assessment



3-4 Evaluation Criteria





3-4 Evaluation Criteria

3 Suture tension



3. Suture tension

Automatically measured and evaluated based on the deformation of the suture sheet.

acceptable range

27~51%

deformation degree





30%





80%



13)

4

3-4 Evaluation Criteria

Opening area







1

3-5 About Assessment

Good/ Poor grading

There are 5 evaluation criteria, " air leak pressure" and "full -thickness suture" are used to determine successful procedure.

If both of the 2 criteria are under acceptable range, then it appears "Good" Either or the 2 criteria is out of acceptable range, then it appears "Poor"





* "Poor" sign can be hidden by changing the display setting. SeeP.30 for details.

- 1. Air pressure leakage
- Is the wound sutured without a leak? (maximum of 5 points)
- 2. Full-thickness suture
- Is suture completed through muscular layer to mucosal layer? (maximum of 5 points) 3. Suture tension
- Is ligature appropriate for suture? (maximum of 5 points)
- 4. Opening area
- How much opening area is there in the mucosal layer? (maximum of 5 points) 5. Completion time
- How long does it take for suturing procedure? (maximum of 5 points)

total of 25 points

Why Good/Poor grading with only 2 criteria?

The concept of this simulator is to let trainers perform suture of all

layers without leak.





4-1 Operation Icons



4-2 Save Data





4-3 Export Saved Data





| | Caution A USB | memory needs to b | | | | | | |
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4-4 Change Evaluation Criteria

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| | | Preset password : kyotokagaku |
| | Change Language Change Password | |
| 6 | C KNOTOKANAU Laptinoco.go: Suiture Simulator - Accessment System Setting Leak Pressize Suiture Tension Time Threshold 5 points | Criteria for Leak pressure, Suture tension, Completion time can be adjusted. (Switch between each evaluation items by tabs) Change the criteria value by moving the |
| | 2 points 97 m. | slide bar or directly entering a value. |
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| | 4 points (122) | 3 points |
| | 40 | 2 points 712 |
| | 3 points 27 v | 1 points 956 |
| | | |

4-4 Change Evaluation Criteria



4-5 Change Evaluation Criteria from Exported Data



Be sure to save only the data used for evaluation criteria. If other data is included, the evaluation criteria will be incorrect.

4-5 Change Evaluation Criteria from Exported Data



4-6 Change the Language (Japanese/English)

| 515) C. Introvenue Laparoscopic Sulture Simulator 設定 パスワード: [| -Assessment System | Select "Setting" icon, the scree will display a password entry screen for password changing. |
|------------------------------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------------------------|
| 言語変更 C: кото кыжи Laparoscopic Suture Simulator | パスワード変更 - Assessment System | Select "言語変更", |
| Setting Password: | Version 305.1 | all screen settings will be changed from Japanese to English. |
| Change Language | Change Password | Select "Change language" again, all screen settings will be changed from English to Japanese. |

4-7 Change the Password

| | Change passwords | |
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| | Laparoscopic Suture Simulator - Assessment Syst | em 🎯 🖬 🥐 🏠 😃 |
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| | Password: | |
| \frown | Change Language Change Password | |
| (S20) | C KNOTOKKAWU Laparoscopic Suture Simulator - Assessment System Setting Version : 305.1 | Enter your present and new passwords |
| | Current Password | and select Change. |
| | New Password: Retype Password: Change Cancel | Preset password : kyotokagaku |
| S17 | | |
| | Change is complete. | |
| | ОК | S15) Return to password entry screen. |
| Cautio | Keep the record of your changed password. Please contact your distributor or KYOTO KAGA (Refer to the back cover for contact informatio | AKU CO., LTD. in case you forget the password. n) |

| | Display "Poor" s | ign | |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
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| S15 | Сі котокломи Laparoscopic Suture Simulator - Assessment Sy Setting | stem ? 🐼 🕖 Verson : 3.0.5.1 | Select "Setting" icon, the screen will display a password entry screen for password changing. |
| | Password: | | Preset password : kyotokagaku |
| \frown | Change Language Char | ge Password | |
| (\$16) | Laparoscopic Suture Simulator - Assessment Sy Setting Leak Pressure Suture Tension Time Threshold 5 points 4 points 3 points | Sern ? ? 200 Verson : 30,5,1 208 ex. 145 ex. | Enter the password. |
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| | ⊠ Display Poor | When the check box "Display Poor" is cheo "Poor" will be display evaluation screen wh evaluation criteria are | of cked, red on the then the e not |
| | □ Display Poor | reached. Uncheck the "Display checkbox to , "Poor" not be displayed. | ✓ Poor" sign will |

4-9 Print Assessment Result





5.Q&A

5-2 How to Record Suture Video



5-2 How to Record Suture Video



6.Trouble Shooting

6-1 Different Image Displayed for Image Evaluation



6.Trouble shooting

6-1 Different Image Displayed for Image Evaluation

How to change camera selection Follow the procedure below to change the selecton of the camera.

1Close all running software.

2. While holding " 🚅 "key, press "X" key.



3. Below menu will be displayed. Select "Device Manager".



6.Trouble S shooting

6-1 Different Image Displayed for Image Evaluation



6.Trouble Shooting

6-2 Air Pressure Leakage Always Shows "0kPa"6-3 No Motor Noise During Leak Evaluation6-4 Leak Evaluation Takes Too Long

What to do if

- Air pressure leakage always shows "0 kPa"
- No motor noise during leak evaluation
- Leak evaluation takes too long

Cause: The assessment unit is not connected correctly to laptop

Follow the procedure below to check the connection between the assessment unit and laptop.

- 1. Verify the device connection. (P. 4)
- 2. Verify that the main power of the assessment unit is "ON". (P. 6)
- 3. Verify that the USB connection is displayed as "OK". (P. 8)
- 4. Start "Device Manager" and check if the assessment unit is recognized.

(See P. 37 for how to start "Device Manager".) Expand "Custom USB Devices" in "Device Manager" and check if there is "WinUSB Device".



 If there is no "WinUSB Device", you need to reinstall the device. If the problem is still not solved, the device may be defective. Please contact your distributor or KYOTO KAGAKU CO., LTD.

6.Trouble Shooting

6-5 Error Appears When Starting the Software

What to do when the error message saying "The object reference is not set in the object instance" appears while starting the software



Cause: camera in the assessment unit is not connected correctly to laptop

Follow the procedure below to check the connection between camera in the assessment unit

and the laptop

- 1. Verify the device connection. (P. 5) Also, restart the laptop and software.
- 2. Start "Device Manager" and check if the camera in the evaluation box is recognized.

(See P. 37 for how to start "Device Manager".)

Expand "Imaging Device" in "Device Manager" and check if there is "USB2.0 PC CAMERA".



3. If "USB 2.0 PC CAMERA" is still not found after reconnecting the device and restarting laptop, the device may be defective. Please contact your distributor or KYOTO KAGAKU CO., LTD.

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

KYOTO KAGAKU co., ltd

▲ Caution

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greatly appreciated.