



MedVision

**USER
MANUAL**

Simulator S.LPR

Virtual Simulator for Practical Skills

in Laparoscopy

LapVision STANDARD

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Introduction

The simulator is a training unit consisting of interconnected hardware and software elements. The simulator includes laparoscopic port imitators and laparoscopic instrument imitators, a computing device and visualization system.

The simulator is designed for studying the fundamentals and special features of laparoscopic interventions. Interventions are being performed in virtual but realistic anatomic environment, which ensures training without any risk to the health and life of a real patient.

This manual explains the design and operation of the simulator. A description of the operation and transportation conditions is provided subject to safety requirements. Any failure to comply with these conditions may result in equipment breakdown or personal injury.

Warning: The simulator medical equipment only imitates the real ones and must not be used outside the simulator's environment.



Simulator

1 Safety precautions

Before a session, carefully inspect the simulator and the power cable for tears, cracks, burned or scorched areas, etc. If any damage is found, wait until the failure is fixed.

In case of burning smell, smoke or sparks, immediately stop using the simulator and inform the person responsible for safe operation.

YOU MUST NOT:

- Spill liquids on the simulator.



Figure 1.1 Keep dry

- Dismantle the simulator.
 - Let the simulator fall, be hit or otherwise damaged.
 - Install the simulator on uneven, inclined, slippery or fragile surfaces.
 - Leave the simulator switched on if unused.
-

1 SAFETY PRECAUTIONS

Warning: The environment in the room where the simulator is located must not cause any condensation on electronic and mechanical components of the product.

Make sure simulator cables are not located in the aisle area and do not cause any danger when being moved during and after sessions.

2 Setting up

2.1 Setting up

The simulator is plugged into a standard power outlet of 220V/50Hz. To run the simulator, follow the steps below:

- Make sure that the power cords are not damaged and are connected to the power strip/sockets
- Start the simulator by pressing the power button on the side panel
- If the LED indicators of the monitors are not on, then try to turn them on manually by pressing the power button of each monitor
- After loading the Windows operating system, the simulator operating software runs automatically

Note: If the software has not started automatically, try starting the program through the shortcut on the desktop or restart the simulator by turning it off and on again.

If this does not help, contact the technical support.

2.2 Turning off

To turn off the simulator, follow the steps below:

- Remove the endoscope imitator from the port
- Press the power button on the side panel of the simulator
- Turn off the power switch (0/1) of the power strip (if used)

3 Laparoscopic instrument imitators

To perform simulation, a variety of surgical instrument imitators are used.

Instrument imitators are inserted into trocar simulators, i.e. laparoscopic instrument insertion ports. The exterior of the instrument control unit (handle) is presented below:



Figure 3.1 Instrument imitator control unit

Instrument imitators are wireless and battery powered. The wireless run time on a full charge is about 8 hours.

3.1 Instrument imitators operation

If the instrument imitator is not used for a certain time, the sleep mode is activated in the following cases:

- If the instrument imitator is not inserted into the port and is not being moved, the sleep mode is activated in 2 minutes.
- If the instrument imitator is inserted into the port and is not being moved, the sleep mode is activated in 10 minutes.

Each instrument imitator is equipped with an indicator (LED on the button) indicating its status in the course of normal operation:

- The indicator double blinks: the instrument imitator «sees» the base station, but is not inserted into the port.
- The indicator blinks fast (within 1-2 minutes after turning on): the instrument imitator is being calibrated.
- The indicator blinks fast: the instrument imitator is out of battery.

The instrument imitator wakes up from the sleep mode by a short press of the button. The instrument should blink with a long flash. As long as the instrument is sleeping, LED won't flash. To force the instrument imitator to turn off, press the button and hold it until the LED flashes three times.

3 LAPAROSCOPIC INSTRUMENT IMITATORS

There are two possible ways to change the instrument types in the program. If the collection of instruments includes a large number of instrument imitators with unique tips and handles, the change is made automatically by selecting the required instrument imitator from the collection. To do this, turn the instrument imitator on and insert it into the port. To turn the instrument imitator on, press the button on the control unit (handle).

If the collection includes 2-4 instrument imitators, to change them, do the following:

- Take the instrument imitator out of the port.
- Press the button on the control unit (handle) and find a list of instruments displayed on the screen. (Figure 3.2);
- By turning the wheel on the control unit (handle) of the instrument imitator, select the desired virtual instrument from the list and confirm the selection by pressing the button.
- Insert the instrument imitator into the port.

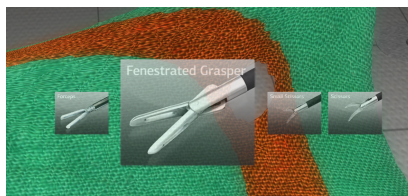


Figure 3.2 Instrument icons in the software

3.2 Instrument imitator charging

To charge an instrument imitator, connect it to the USB port using a special adapter cable (cables are supplied together with instrument imitators). You can charge the instrument imitator from a PC. If the LED is red, the instrument imitator is being charged. Charging time is about 2 hours. Each wireless instrument imitator has a 5V power socket.

3.3 Instrument freezing

In some exercises, an instrument imitator inserted into the trocar imitator can be «frozen» by pressing the «Freeze» button in the program located under or above the instrument icon or by using the button on the control unit (handle).

While the tool is «frozen», it will not respond to any instructions and movements of the instrument imitator in the port. To «unfreeze» a tool, press the «Unfreeze» button in the software or press the button on the control unit (handle) again (if the instrument imitator is inserted into the port).

Warning: always remove the instrument imitator before «unfreezing» it. Otherwise, it can cause perforation and tear of organ tissues, which is not recommended during the operation as it entails serious consequences for the health of the virtual patient and possible death.

3.4 Laparoscope imitator

The laparoscope imitator is shown in (Figure 3.3). There are three buttons on the control unit (handle). When the laparoscope imitator is not inserted into the port, the side buttons are used to change the angle of view (0, 30 or 45), and the central button is used to set the selected parameter.



Figure 3.3 The laparoscope imitator

If the laparoscope imitator is inserted into the port, then, using the central button, you can «freeze the camera», i.e. the image angle will not depend on the position of the laparoscope and the word «freeze» will appear in the upper left corner. When you press the button again, the laparoscope will «unfreeze».

Warning: Hold the laparoscope imitator by the control unit (handle) only so as not to block the LED located on the fiber. Otherwise, the image in the software may be lost.

3.5 Port imitators

Laparoscopic port imitators of the simulator serve for insertion of instrument imitators and are located in the section covered with a piece

3 LAPAROSCOPIC INSTRUMENT IMITATORS

of cloth with holes in it to accommodate the ports (Standard and Basic), and abdominal cavity of the human patient simulator (Hybrid). Ports can be equipped with a feedback system (except for the laparoscope imitator port) simulating the organs resistance towards the impact of laparoscopic instruments.

4 Exercise menu elements

4.1 Lower control panel

During an exercise, you can see the following buttons in the bottom right corner of the screen: «Virtual tips», «Video course», «Descriptions and instructions», «Video course», «Anatomical atlas».

«Descriptions and instructions» also contains «Ports placement», «Step by step instructions» and «Exercise description».

Clicking the «Virtual tips» button will activate performance hints, for example:

- in (Figure 4.1) the pointer directs to the ring, which is supposed to be put on the stick.

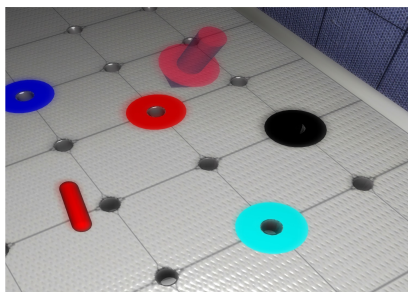


Figure 4.1 Virtual tips. Pointer

4 EXERCISE MENU ELEMENTS

- in (Figure 4.2) a semi-transparent needle shows the correct trajectory.

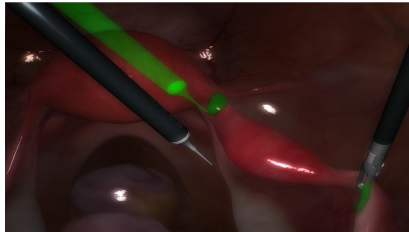


Figure 4.2 Virtual tips. Place of injection

- in (Figure 4.3) a blue line indicates dissection and coagulation areas.

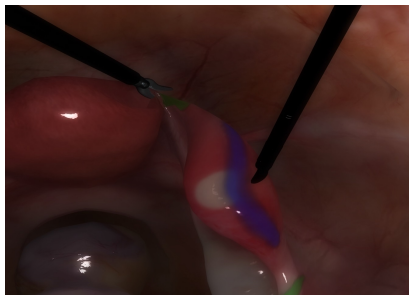


Figure 4.3 Virtual tips. Place of dissection

Each tip is also followed up with a text message on the top of the screen. To watch a video tutorial click the «Video Course» button.

Warning: Not all exercises have video courses available.

A new window will open inside the exercise. A video can be played, paused, moved forward or back. Tap on «Anatomical atlas» to open it (Figure 4.4).

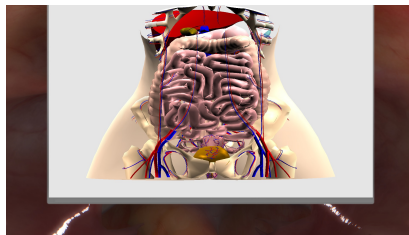


Figure 4.4 Anatomical atlas

The atlas allows viewing different areas of the anatomical environment, i.e. skeleton, lungs, colon, uterus, arteries and others.

4.2 General controls

Laparoscopic intervention controls. Electric surgical instruments are used when performing all surgical procedures and exercises designed to master fundamental laparoscopy skills. The control indicators and buttons are found on the bottom control panel.

- «Mode» indicator. There are two operation modes available: Electrodissection and Coagulation. The operation mode is set automatically and depends on the key pressed on the two-key

4 EXERCISE MENU ELEMENTS

pedal. The yellow key is used for electrodissection and the blue key is used for coagulation. As long as either of the keys is pressed you will hear a loud beep sound, the indicator of the active mode will be displayed on the control panel.

- «Electric tool changing» button. Click on this button to change the powered instrument. A powered instrument is marked with the lightning icon.
- Power buttons. Click «+» to increase electricity power and click «-» to decrease it.

4.3 Aspiration and irrigation unit controls

The aspiration and irrigation unit operation modes are controlled using the «Mode» button on the right from powered instruments buttons. There are two operation modes available: Aspiration and Irrigation. The current operation mode is displayed on the button. To change the operation mode, tap on the button Irrigation or Aspiration. The aspiration/irrigation mode activation method depends on the simulator type, i.e. clasp together scissors-shaped handles of the instruments or press the relevant button on the control unit (handle).

4.4 Harmonic scalpel controls

To use the harmonic scalpel, you need to set the lightning icon on the instrument icon using the powered instruments control buttons

and start electrodissection by pressing the electrodissection key on the pedal.

Remember, cutting is allowed only in certain areas different for every exercise. The cutting area is being highlighted by blue color, if hints have been activated (Figure 4.5).

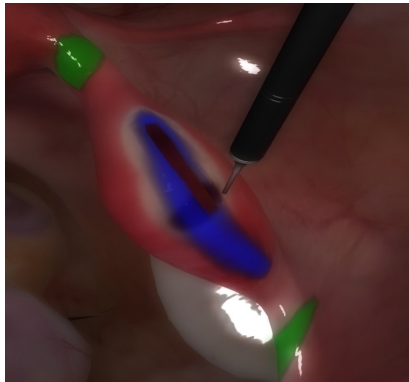


Figure 4.5 Cutting by line

Cutting in other areas, other than that marked blue, is not allowed by the software. But if careless actions during the operation entailed perforation and bleeding in any other area, it can be stopped by using electrocoagulation.

4 EXERCISE MENU ELEMENTS

4.5 Uterine manipulator controls

Gynecological operations use the same controls. Additionally, the uterine manipulator is used, which is found to the right from the powered instruments. To move the uterus press the buttons:

- Up (on the left)
- Left (on the left)
- Down (on the left)
- Right (on the left)
- Forward (on the right)
- Backward (on the right).

«Manipulator excretion» button is in charge of uterus removal in hysterectomy exercise. After cutting the uterus off press the button to complete the removal process.

4.6 Laparoscope imitator controls

The laparoscope imitator helps to display the operative field during the exercise. Use the side buttons on the control unit (handle) to set the angle of view (0, 30 or 45). The laparoscope imitator must be off the port. To set the selected angle, press the middle button.

While the laparoscope imitator is in the imitator trocar, it is possible to «freeze» it using the middle button, i.e. the image angle will not depend on the position of the laparoscope imitator. The word «freeze» will appear in the instrument icon in the upper left corner. Use of coagulation or electro-dissection during the exercise may cause camera view blurring, leading to visibility deterioration (Figure 4.6). It can be cleaned by wiping the camera tip on organs (set it against the organ in the software).

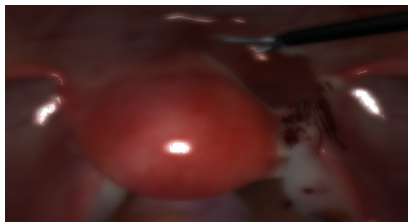


Figure 4.6 Blurring

4.7 Virtual port controls

Some simulations require using four ports, e.g. cholecystectomy and sigmoidectomy. Use the «Change to assistant port» button of the lower control panel (Figure 4.7).

4 EXERCISE MENU ELEMENTS

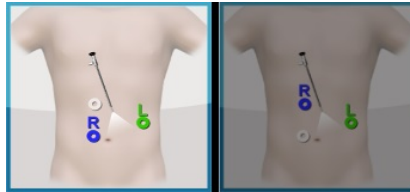


Figure 4.7 Virtual port change buttons

To switch between the ports, you need to remove the instrument from the left port and tap on the «Change to assistant port». After that the left port will start acting as an assistant port, and the button will change to «Change to left port». Now you can insert the instrument into the virtual port, perform traction during laparoscopic cholecystectomy, freeze the instrument in the port, pull out the instrument imitator from the port, press the button "Change to the left port" and continue working in the three-port mode. The assistant instrument remains in the position, in which it was left «frozen». Please, remember that when finishing the simulation: Switch back to the assistant port to remove all the instruments.

5 User accounts

When the simulator starts, the simulation program boots automatically and the start screen opens (Fig. 5.1). In the start screen menu there are two buttons available: Select User and Create New User.

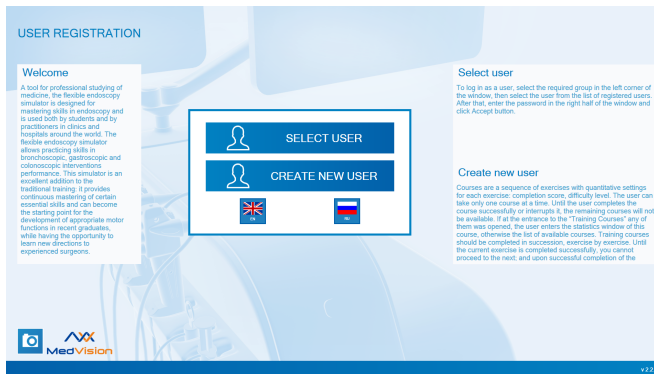


Figure 5.1 Start screen

5.1 Select user

To open the existing profile, click on «Select User».

Each user belongs to a specific group assigned during registration. The username is displayed only in the relevant group.

You can change the group in the Administrator mode.

5 USER ACCOUNTS

All existing groups are displayed on the left side of the authentication window (Fig. 5.2).

Click on the name of the group the user belongs to and select the user name from the list. Then enter the password in the appropriate box and click on Accept.

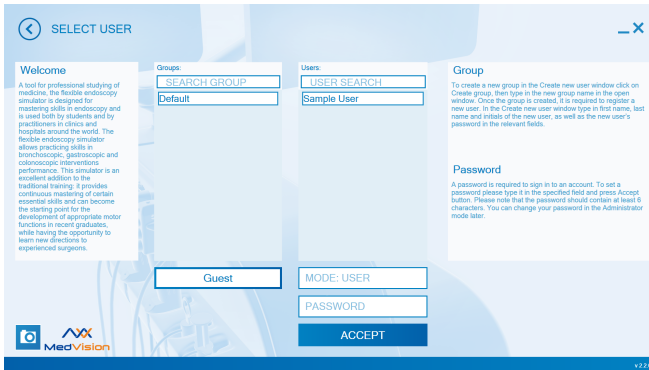


Figure 5.2 Authentication window

After completing the authentication the main menu of the simulator will open.

5.2 Create new user

To add a new user, tap on «Create New User» on the start screen (Fig. 5.1). The user can be included into the existing or into a newly

created group. In the latter case, you will first have to create a new group (see the "Creating a Group" section).

To include a user into the existing group, select the group from the list on the left side of the window. Then enter the desired profile name and password in the fields "Name" and "Password".

Tap on the Create New User button to finish the process.

5.3 Create a group

To create a new group, tap on Create a Group in the Create New User menu. In the pop-up window, enter the group name and tap on OK.

6 Exercises

Before initial use, you must do the following:

- Familiarize yourself with step-by-step instructions on operations and necessary procedures.
- Watch tutorial videos on operations run with the use of the simulator.
- Get started using virtual tips enabled.

Warning: Dissection is allowed in certain areas only, different for each exercise. The dissection area is being highlighted by blue color, if virtual tips have been activated (Figure 6.1).

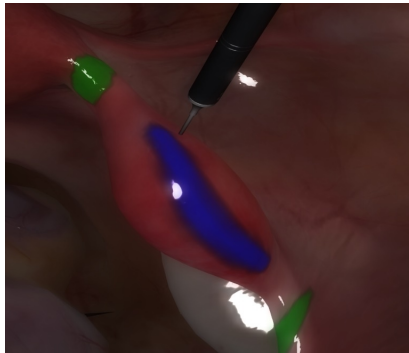


Figure 6.1 Dissection area

The simulator allows performing the following:

- training for the basics of control equipment
 - training for the basics of laparoscopic instruments
 - training for the use of laparoscopic equipment
 - practicing preoperative preparation skills
 - mastering laparoscope imitator controls with viewing angle (0°, 30°, 45°)
 - mastering 3-D coordination
 - training for clipping and grasp of vessels
 - mastering 3-D gripping, movement and rotation of objects
 - training for endoscopic scissors control
 - training for electrocoagulation skills
 - training for all surgical stages
 - control of acute operation complications
 - training for suturing and knotting
 - learning suturing equipment
 - watching real operations videos
 - 3-D virtual anatomical atlas.
-

6 EXERCISES

To access an exercise, select the study section in the Endosurgery menu. All exercises have three levels of complexity. To select the level of complexity, in the exercise description window, tap on the Set Difficult button at the bottom of the screen and select one of the levels offered, i.e. easy, normal or hard. Depending on the level of complexity, the following features of the exercise may change:

- Allowable duration of exercise
- Allowable blood loss limit
- Allowable total length of the left hand trajectory
- Allowable total length of the right hand trajectory
- Allowable total length of camera motion trajectory
- Allowable time of coagulation application
- Allowable time of the most long lasting coagulation

Tap on Next to go to the selected exercise. After that, a description of the exercises (selected in the left part of the window) will be displayed on the right side of the window.

7 End of exercise and exit

For sections «Basic skills in endoscopic surgery», «Certain important skills in laparoscopy», «Complex of training tasks on suturing and knotting» and «Special critical skills of suturing and knotting», you will automatically exit from the exercise after all stages of the exercise are successfully completed. For sections, «Skills in laparoscopic cholecystectomy», «Skills in gynecological surgery», «Execution of total hysterectomy» and «Execution of laparoscopic appendectomy», after the successful completion of all the stages, you must retract all the instrument imitators from the ports. After that the green «Finish» button will appear signaling that the exercise has been completed.

Even if the exercise has been successfully finished, the user must examine the cavity to detect any possible bleeding and aspire washing waters in the operation area. Every exercise can be manually ended by tapping on the Exit button.

8 Statistics

Statistics is individual for each user and is generated after finishing up the exercise.

To view statistics, you need to log in to the software Select User and select the Statistics in the main menu.

The following information on finished simulations will be displayed on the screen:

- date
- time
- exercise title
- score (Figure 8.1)

(from 0 to 100, where 100 is the best score).

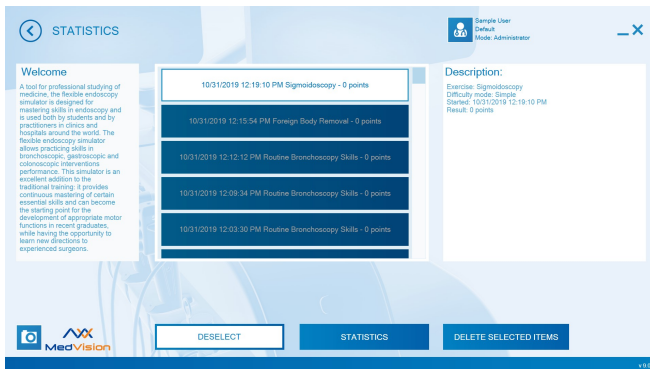


Figure 8.1 Statistics window

To view the results of a specific exercise, select the exercise from the general list and click on Statistics. In a new window, you will see the results of the selected exercise.

Statistics is also shown after the exercise has been finished or aborted. The window displays the current results.

9 Cleaning maintenance

- To clean the simulator body, use light-duty liquid soap or detergent.
- Soak a soft cloth in the selected light-duty liquid soap or detergent and carefully wipe dirt.
- Do not allow the liquid leak inside the simulator. To clean the monitor screen, use special cleaning cloth.
- Do not forget to perform regular dry and wet cleaning of the facility housing the simulator.
- If heating radiators are on in the facility make sure the simulator's body is not in its proximity.
- If you are not planning to use simulator for some time, turn off its power source.

Acknowledgement table

I have read and understood the manual:

Date	Name	Signature	Stamp