

Part No.: H-020-000310-00

Sample Transfer Processing System

MGISTP-3000

User Manual

Version: 1.0

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About the user manual

This user manual is applicable to MGISTP-3000 Sample Transfer Processing System. The manual version is 1.0 and the software version is V1.

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Figures in this manual are all illustrations. The contents might be slightly different from the device, please refer to the device purchased.

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Safety

This chapter describes basic safety information about the device. Carefully read and understand the information before use to ensure correct operations, best performance, and personnel safety. Keep this manual at hand for reference at any time.

Conventions

The following table describes conventions that are used in the manual:

Item	Description
Warning	Indicates that the operator should operate the device by following the instructions. Otherwise, it might result in personal injury.
Caution	Indicates that the operator should operate the device by following the instructions. Otherwise, it might result in unsuccessful workflow running, device malfunction, or damage.
NOTE	Indicates that the operator should pay special attention to the note information, and operate the device by following the instructions.
	Indicates biological risk. The operator should operate the device by following the instructions.
Boldface	Indicates the printings and on-screen characters on the device.

General safety



- Ensure that the device is operated under the conditions specified in this manual. Otherwise, it might result in unsuccessful workflow running, device damage, or even cause personal injury.
- Ensure that the components of the device are completely installed before operation. Otherwise, it might result in personal injury.
- Maintain the device by following the instructions in Maintaining the device on Page 29 to ensure best performance. Otherwise, it might result in device malfunction or even personal injury.
- Ensure that the sleep mode is inactivated. The device will stop operating if sleep mode is enabled.
- Do not open the door when powering on the device for maintenance.
 Otherwise, it might cause personal injury.

• Ensure that the power supply is disconnected before cleaning the device.

Otherwise, it might cause personal injury.



Caution

- Only the technical support authorized by the manufacturer or the qualified and trained personnel can unpack, install, move, and maintain the device.
 Incorrect operation might cause inaccurate experiment results or damage to the device.
- Do not move the device after the technical support have installed and debugged the device. Incorrect operation will result in unsuccessful workflow running. If you require to re-position the device, contact the technical support.
- Only trained professionals such as doctors, technicians, or laboratory assistants can operate the device.
- Do not operate the device in the presence of flammable or explosive liquids, vapors or gases. Otherwise, it might result in device malfunction.
- Do not disconnect the power cord under the power-on status.
- Do not reuse the disposable items.
- Only the peripheral devices and consumables specified by the manufacturer can be used.
- If you have maintenance questions that are not mentioned in this manual, consult the technical support.
- Only the components provided by the manufacturer can be used for device maintenance. Unapproved components might damage the device or degrade performance.
- The device is verified before delivery. If serious deviation occurs during use, contact the technical support for calibration.

Electrical safety



Warning

- Before initial use of the device, assess the electromagnetic environment in which the device will be used.
- Do not use the device in close proximity to the sources of strong electromagnetic fields, such as unshielded sources of radiated emissions. Radiated signals can reduce the accuracy of the workflow.
- Ensure that the device is properly grounded, and the grounding resistance is less than 4 Ω . Failure to do so might result in unsuccessful workflow running or even electric shock.
- Do not remove the device cover and expose the inner component outside.
 Otherwise, it might cause electric shock.

• Only the power cord supplied by the manufacturer can be used.



- Prepare the laboratory and power supply according to *Getting started on Page 17*.
- Ensure that the input voltage meets the device requirement.

Mechanical safety



- To avoid personal injury, place the device on a level surface and ensure that the device cannot be easily moved.
- Do not stretch out your hands or head into the device during operation.
 Otherwise, it might cause personal injury.

Components safety



Warning

Only the software that have been provided by the manufacturer can be installed and used on the computer. Unknown software might interfere with normal device functions, or even cause data loss. If you need to install antivirus software, contact the technical support in advance.



Caution

- If the fuse blew, replace the fuse with the specified type. For details, contact the technical support.
- Do not uninstall the control software by yourself. If any problem occurs during software operation, contact the technical support.
- Ensure that the peripheral devices meet the IEC/EN 60950-1 standards.

Biological safety



Samples in the sample tubes might cause cross contamination through contact with the skin, eyes, and mucosa. Follow the safety standards of your laboratory and wear protective equipment (such as laboratory coat, and disposable bouffant cap, protective glasses, mask, gloves, and shoe covers).

- If you accidentally splash the sample on the skin or into eyes, immediately flush the affected area with large amounts of water and get medical aid immediately.
- Use a strong biological waste bag to avoid tips piercing the bag. Pierced bags might result in waste leakage and cross contamination.
- When disposing of the expired samples and consumables, comply with local regulations.

Symbols

Device

The following table describes symbols on the device:

Symbol	Name	Description
- 1	"ON" (power)	Indicates connection to the mains supply.
0	"OFF" (power)	Indicates disconnection from the mains supply.
	General warning sign	Signifies a general warning.
	Warning; biological hazard	Warns of a hazard from a biological hazard.
4	Warning; dangerous voltage	Indicates hazards arising from dangerous voltages.
	Protective earth	Indicates the terminal of a protective earth (ground) electrode.
A LONG	Warning; ultraviolet radiation	Taking care to avoid injury to eyes and skin when in the vicinity of ultraviolet radiation.
	Warning; crushing of hands	Taking care to avoid injury to hands when in the vicinity of equipment with closing mechanical parts.
T10AH250V	Fuse specification	Indicates the fuse specification of the device.

Symbol	Name	Description
POWER	Power for device	Power switch and power port of the device.
SCAN1	PCIe port	Used for communicating with the IO board and scanner.
SCAN2	PCIe port	Used for communicating with the IO board and scanner.
WLAN	Network port	Connects to the network.
CAN1	CAN1 port	Controls the motor.
CAN2	CAN2 port	Controls the motor.
10	IO port	Used for communicating with the IO board.

Label

The following table describes symbols on the label:

Symbol	Name	Description
IVD	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Manufacturer	Indicates the medical device manufacturer.
EC REP	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	Date of manufacture	Indicates the date when the medical device was manufactured.
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol	Name	Description
CE	CE Mark of Conformity	Indicates that this device conforms with the specified Council Directive.
Rolls	RoHS mark	Indicates that this device meets the requirements of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
[i]	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	WEEE symbol	Indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Packaging

The following table describes symbols on the packaging or on the label of the packaging:

Symbol	Name	Description
<u>†</u>	This way up	Indicates the correct upright position of the transport package for transport and/ or storage.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.

Symbol	Name	Description
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Do not stack	Indicates that stacking of the transport package is not allowed and no load shall be placed on the transport package.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
<u></u>	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Device overview

This chapter describes the intended use, working principle, and structural composition of the device.

Intended use

The device is used for processing and handling clinical samples and sample containers in pre- and post-analysis processes.

Working principle

The device supports functions of automated decapping and capping, automatic sample information input, negative pressure air exhaust, and sample tube to plate. Tubes with inactivated samples can directly be processed by one-click software operation, and then samples are transferred to the plates and all necessary information about the samples are recorded.

Structural composition

The device consists of the sample transfer modules and is connected with other necessary functional modules. It is used for fractionating the samples before detection and does not include the function of precise filling of reagents or samples before analysis by clinical detection and analysis instruments.

Basic components

Front view

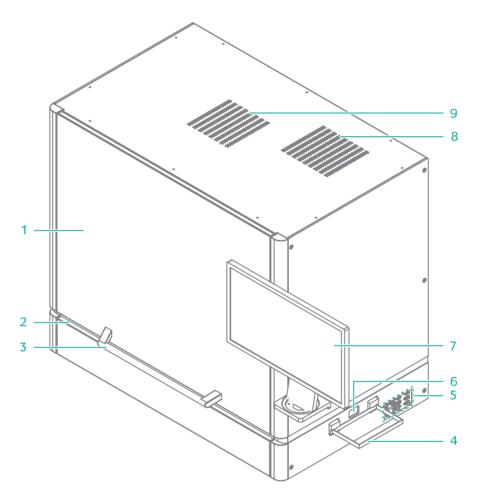


Figure 1 Front view

No.	Name	Description
1	Door	Used to access the deck and to observe the inside of the device during operation. The door is equipped with a sensor, and will automatically lock when the device is running.

No.	Name	Description
2	LED status bar	 Displays the current status of the device. Blue: the device is in standby status. Green: the device is running. Yellow: a warning appears. Red: a malfunction or an error occurs.
3	Door handle	Holds to open or close the door.
4	Fixing frame of the waste bag	Fixes the waste bag.
5	Port interface	Used for cable connections.
6	Waste tip outlet	Waste tips are discarded to the waste bag through this outlet.
7	Monitor	Facilitates the on-screen operation and displays information.
8	Air outlet	Ventilates the device. The inner air is filtered and discharged through this outlet.
9	Air inlet	The outer air is filtered and enters into the device through this inlet.

Right view

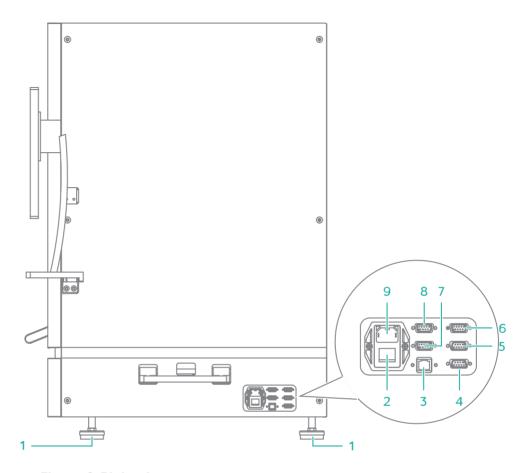


Figure 2 Right view

No.	Name	Description	
1	Supporting feet	Supports the main unit to ensure stability.	
		Powers on or off the device.	
2	Power switch	• Switch to the position to power on the device.	
		• Switch to the oposition to power off the device.	
3	Network port	Connects to the network of the computer and server.	
4	IO port	Used for communicating with the IO board.	
5	CAN2 port	Controls the motor.	

No.	Name	Description
6	CAN1 port	Controls the motor.
7	PCIe port	Used for communicating with the IO board and scanner.
8	PCIe port	Used for communicating with the IO board and scanner.
9	Power port	Connects the power cable. Fuses are installed in the port.

Top view of operation deck

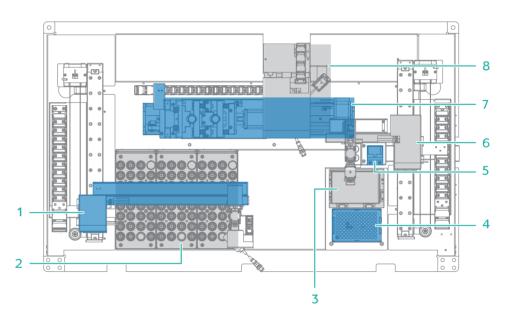


Figure 3 Top view of operation deck

No.	Name	Description
1	Robotic arm	Moves the gripper to the specified position.
2	Tube rack position	Places the tube rack.
3	Position 2	Places the consumables according to the fractionation requirement.
4	Position1	Places the consumables according to the fractionation requirement.
5	Tip-removing position	Waste tips are discarded in this position.

No.	Name	Description
6	Pipette	Loads and unloads disposable tips and processes samples.
7	Transfer module	Transfers tubes among components.
8	Decapping module	Uncap or cap the tube. The scanner scans the barcode affixed on the tube.

Control software

The control software realizes the timing action of the tube-to-plate through the built-in process engine. It has an efficient built-in plate process and one-to-one process for tube plate position, and can be flexibly extended according to actual needs. The system supports a variety of tube specifications and different sample transfer volumes. It has the following features: pure interface operation, one-click operating process, no complex scripts, visual workflow processing monitoring, real-time display of sample processing progress, and support for exporting barcodes for subsequent experiments.

The following table describes the function of each functional module:

Item	Description
Modularized operation	Performs one-step operations for modules, such as robotic arm, decapping module, scanning module, and pipette.
Workflow	Realizes standard automated sample transfer workflow.

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Getting started

This chapter describes laboratory preparations and experiment preparations.

Site requirements



- Caution Ensure that the laboratory floor is level and with a gradient of less than 1/200.
 - Ensure that the laboratory is free of dust, corrosive and flammable gas, and heat and wind sources.
 - Ensure that the laboratory is away from direct sunlight and well ventilated. We recommend that you refer to the standard of a biosafety level (BSL) 2 laboratory.
 - Ensure that enough space is provided around the device for ventilation, cable connection, and power switch operation.

The following figure indicates distances that are required for optimal operation and access.

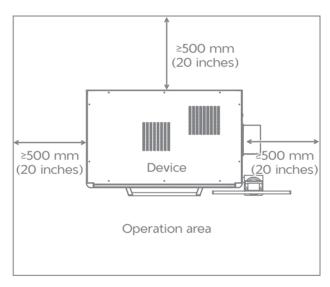


Figure 4 Space requirements

Network requirements

Operating environments of the computer

Minimum configuration

Processor: Intel Core i3

Software environments



Warning Only the software that has been provided by the manufacturer can be installed and used on the computer. Because unknown software might interfere with normal device functions, or even cause data loss. If you need to install antivirus software, contact the technical support in advance.

Pre-installed software on the computer includes:

- Microsoft Windows 10 64 bits operating system
- Microsoft .Net Framework 4.7 and above

Network conditions

Network architecture: C/S

Network type: local network

• Network bandwidth: no less than 1 Gbit/s

Software security

If you need to install antivirus software, contact the technical support in advance.

Data and device ports

- PCle port: connects to the CAN card, serial port card, and network card of the device and computer
- Network port: connects to the network
- USB port: connects to the keyboard, mouse, or for future use

Access control

Only the user authorized by the manufacturer can use the control software.

Inspecting the device



- Only the technical support of the manufacturer or trained personnel can unpack the device. Contact the technical support to unpack and install the device upon delivery. Failure to do so will void the warranty.
 - Ensure that the outer package is intact and the indicator status of the antishock and anti-tilt label is normal upon delivery. If any problem occurs, contact the technical support.

The device contains precise components. Therefore, anti-shock and anti-tilt labels are posted on the outer packaging to monitor any effects of transportation.

The following table describes indicator statuses on the label:

Table 1 Indicator status

Label	Indicator status	Description
Anti-shock	Remains unaffected	Indicates that the device is intact and no strong collision occurs during transportation, or the intensity does not exceed the limit.
label	Red	Indicates that the device might not be intact and a strong collision occurs during transportation and the intensity exceeds the limit.
Anti-tilt label	Remains unaffected	Indicates that no tilt occurs, or the gradient does not exceed the limit.
ATTIT-LITE (dDet	Red	Indicates that tilt occurs, and the gradient exceeds the limit.

Preparing the power supply



- To ensure a steady and uninterrupted power supply to the device during operation, we recommend the use of a separate UPS. For details about the UPS installation protocol, consult the UPS supplier.
 - The required power supply of the UPS should be no less than 1000 VA. Connect the power cord of the device to the output port of the UPS.
 - Ensure that the voltage meets the requirement to prevent poor performance of electronic components. Failure to do so might damage electronic components.

Item	Description
Voltage and frequency range	100 V - 240 V~, 50/60 Hz
Voltage fluctuation	±10%
Grounding resistance	<4 Ω
Rated power	600 VA
Transient over-voltage category	II

Installing the device

The device can be installed only by the technical support.

To ensure that the performance of the device meets the specifications, the technical support will perform a standard loading before customer training and use.

Powering on or off the device



- Ensure that the power switch is in the position before connecting to the power supply.
 - The mains supply socket should be a standard three-prong socket and its protective grounding terminal should be connected to the protective grounding cable of the power supply system. If the requirements above are not met, the device must be protectively grounded as described in *Preparing the power supply on Page 20*.
 - Ensure that the grounding cable is connected in accordance with the relevant standard or under the guidance of the experienced electrician.
 - We recommend that you use the power cord provided by the manufacturer to connect to the power supply, and the power cord can be only used with this device. Failure to do so might damage the power cord or device.
 - Do not replace the detachable power cord with inadequately rated cords (250V, 16A).

Powering on the device

NOTE For the connector location and use of the computer, refer to the user guide of the computer.

Perform the following steps:

- 1. Press the power buttons of the monitor and computer, and turn the power switch of the device to the position.
- 2. Enter password provided by the technical support to log in to the computer.

The desktop appears after login.

Powering off the device

Perform the following steps:

- 1. Click , click Yes in the dialog box, and wait to exit the software.
- 2. Click **Start** > **Power** > **Shutdown** to turn off the computer.
- 3. Turn the power switch of the device to the oposition.

Preparing consumables

Prepare the following items:

- Deep-well plate
- Tips
- Tube and tube rack

Preparing peripheral devices

Name	Specification	Recommended brand
Frost-free freezers or refrigerators	2 °C - 8 °C (36 °F -46 °F)	General laboratory supplier
Waste bag	The bag should be printed with biological risk symbol.	General laboratory supplier
Heat sealer	1	General laboratory supplier
Barcode printer	/	General laboratory supplier

Performing a workflow

This chapter describes the sample transfer workflow. Read and follow the instructions to ensure correct operations.

Workflow





Samples in the sample tubes might cause cross contamination through contact with the skin, eyes, and mucosa. Follow the safety standards of your laboratory and wear protective equipment (such as laboratory coat, and disposable bouffant cap, protective glasses, mask, gloves, and shoe covers).

Logging in to the control software

NOTE You can start an experiment only after you log in to the control software.

Perform the following steps:

- 1. Power on the device, and then power on the computer.
- 2. Log in to the computer with the password that is provided by the technical support.
- 3. Wait about 3 minutes, on the desktop, double-click the control software icon to launch the software.
- 4. Set the mode to Real.
- 5. Select **User** in the **Username** list, use the on-screen keyboard to input the password that is provided by the technical support, and click **Login**.

Initializing the device

Perform the following steps:

- 1. Close the door.
- 2. In the main interface, click **Boot**. The device starts initializing.

After a successful initialization, a prompt is displayed.

Preparing for a workflow

Installing consumables

Perform the following steps:

- 1. Open the door.
- 2. Place the tubes onto the tube rack, align the groove of the tube rack with the rail in the tube rack position, and push the tube rack forwards until it stops.
- 3. Prepare consumables.
 - 1) Place the left side of the tip plate into the groove of the tip box, and press the right side of the tip plate. Ensure the tip plate is securely fixed.



To avoid contamination, try not to touch the tips during placement.

- 2) Place the deep-well plate in the corresponding positions. Ensure that the direction of the numbers and letters on the deep-well plate is correct.
- 4. Fix the waste bag with biological risk symbol on the fixing frame of the waste bag.
- 5. Close the door.

Setting parameters

Perform the following steps:

- (Optional) Click the menu button and select User Settings to perform general settings, mode details settings or LIMS connection settings,
- 2. Click the menu button and select Workflow.

3. Set the parameters about the workflow, select the input and output positions, and select the quantity of the tips.

Starting a workflow



- Ensure that the door is closed before starting the experiment. Or follow the on-screen prompt to close the door.
 - Do not violently open the door during experiment, to avoid accidental skin contact with the sample on the tip of the moving pipette. Failure to do so might cause cross contamination or personal injury.
 - If the door is open, an interlock installed on the door will stop or pause the experiment. And you will be prompted that the door is open.
 - Pay special attention to the LED status bar, icons, and prompts. If errors occur, a message appears on the screen. Follow the prompt to troubleshoot and solve the problem. For information about the troubleshooting, refer to *Troubleshooting on Page 32*. If the problem persists, contact the technical support.

After parameter settings, click **Start** and reconfirm the workflow information. The workflow starts.

During experiment, you can do the following:

- Click Pause, the workflow is paused. The button changes to Resume. Click it to resume the workflow.
- Click **Stop** to end the process.

Post-processing



Samples in the sample tubes might cause cross contamination through contact with the skin, eyes, and mucosa. Follow the safety standards of your laboratory and wear protective equipment (such as laboratory coat, and disposable bouffant cap, protective glasses, mask, gloves, and shoe covers).

Processing abnormal tubes

When the sample tube processing fails, the sample tube is put back to the original position of the tube rack, and can be processed according to the interface prompts after the process ends.

Processing consumables

Perform the following steps:

- 1. Click **New Run** to clear the data of the current process and create a new process.
- 2. Affix the sealing film on the deep-well plate and take it out for the next experiment.
 - If not used temporarily, the deep-well plate can be stored in a refrigerator at 4 $^{\circ}\text{C}$.
- 3. Take out the tube rack, ensure that all sample tube caps are tightly sealed, and process the sample tubes as needed.
 - If the sample tube needs to be discarded, follow the medical waste disposal standards.
- 4. Take out the empty tip plate and discard it into a container designated by the laboratory.
 - If the tips are not used up, you can continue to use them next time. The software will also automatically calculate the remaining number of tips, prompting whether the tips are sufficient.
- 5. Check whether the waste bag is full.

If it is full, remove the waste bag and discard it into a laboratory-designated container.

Processing the device



Warning Do not violently open the door during clean. Otherwise, the eyes and skin will be directly exposed to ultraviolet rays, which might cause eye and skin injuries.

Perform the following steps:

- 1. Click the menu button, select **Clean**. Ensure that the operation deck is emptied, and select the check box.
- 2. Moisten a dust-free cloth with pure water, wipe the operation deck and pipette, and let them air-dry.
- 3. Moisten a dust-free cloth with 75% alcohol, wipe the operation deck and pipette, and let them air-dry.
- 4. Ensure that the door is closed, click **Start**, and confirm again.

After the clean is complete, a prompt appears.

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Maintaining the device

This chapter describes maintenance procedures of the device and its parts. Perform maintenance regularly to ensure that the device runs smoothly.

Cleaning and disinfecting the device



- We do not recommend that you use the disinfectants other than 75% alcohol. Because other disinfectants are not verified for use and their effects to the device are unknown.
 - If you have questions about the compatibility of disinfectants, contact the technical support.

Auto cleaning and disinfection

The device is equipped with air filter and UV lamps. You should perform cleaning and disinfection before and after each experiment, to ensure that the cleanliness of the interior of the device and to avoid cross contamination.

Post-experiment cleaning and disinfection

NOTE Ensure that the dust-free wipe is wet but leaves no droplets.

Performing cleaning

After each experiment, perform the following steps:

- 1. Wipe the surfaces of the device, operation deck, and pipette with a dust-free wipe moistened with Milli-Q water or pure water.
- 2. Let the device air-dry.

Performing disinfection

After each experiment, perform the following steps:

- 1. Wipe the surfaces of the device, operation deck, and pipette with a dust-free wipe moistened with 75% alcohol.
- 2. Select Clean in the menu and run the workflow.

Weekly disinfection

Every week, perform the following steps:

- 1. Wipe the surface of the device, handle of the door, and inner walls with a dust-free wipe moistened with 75% alcohol.
- 2. Wipe the preceding components with a dust-free wipe moistened with Milli-Q water.

- 3. Wipe the surfaces of the mouse and keyboard with a dust-free wipe moistened with 75% alcohol.
- 4. Select **Clean** in the menu and run the workflow.

Monthly disinfection

Every month, wipe the inner walls of each tube well on the operation deck with cotton swabs moistened with 75% alcohol.

Service plan

According to the service plan, regularly contact the technical support to perform preventive maintenance for the device.

The preventive maintenance includes (but not limited to) annually replacing the UV lamp and filter of the fan filter unit once, inspecting and maintaining the pipette, and lubricating the motor screw and guide rail sliders.

Maintaining the power supply

- When the device is not in use for seven days or longer, perform a maintenance wash, power off the device, and disconnect the power cord.
- Check whether the power cord and cables are connected correctly and in good condition before each use. Re-connect the cables if needed (ensure that the device is powered off), or contact the technical support if new cables are required.

Maintaining the software

After the receival of *Release Notification*, you can contact the technical support to update the software.

Troubleshooting

If malfunction occurs during operation, the device beeps or a message appears on the screen. Follow the on-screen prompt to troubleshoot and solve the problem. The following table lists some of the problems and possible solutions. If problems that are not mentioned in this manual arise, or if you need additional assistance, contact the technical support.

Table 2 Troubleshooting

Problem	Solution
After turning the power switch to the position, I still cannot power on the device.	 Check whether the power cord is connected. Check whether the power switch is turned to the position. Check whether the voltage of the mains supply outlet is within the required range. If the problem persists, contact the technical support.
Error occurs when I start the software.	 Check whether the power switch is turned to the position. Check whether the door is closed. Check whether the network cable of the device is connected securely. Restart the software and device. If the problem persists, contact the technical support.
Error messages are displayed during operation.	Save a screenshot of error messages, and contact the technical support.

Storage and transportation

- For information about the environmental requirements for storing the device, refer to *Specifications on Page 35*.
- If you want to move or transport the device, contact the technical support.

Disposal of the device

The service life of this device is seven years, which is determined by the simulated service life evaluation method. For the date of manufacture, refer to the label on the device. Perform the maintenance according to the requirements mentioned in this manual. Dispose of the end of life device according to local regulations.

Specifications

Item	Description
Dimension	1093 mm (W) * 1021 mm (H) * 685 mm (D) (43 inches * 40 inches * 27 inches)
Net weight	Approximately 190 kg (419 lb)
Voltage	100 V - 240 V~
Power Frequency	50/60 Hz
Rated power	600 VA
Monitor	Size: approximately 21.5 inchesResolution: 1920 × 1080 pixels
Fuse specification	T10AH250V
Maximum sound pressure level	75 dB
Degrees of protecti provided by enclosures Code)	
Operating environme requirements	 Temperature: 19 °C to 25 °C (66 °F to 77 °F) Relative humidity: 20% RH to 80% RH, non-condensing Atmospheric pressure: 80 kPa to 106 kPa Maximum altitude: 2000 m Pollution degree: 2 Indoor use
Storage/transportation environment requirements	 Temperature: -20 °C to 50 °C (-4 °F to 122 °F) Relative humidity: 15% RH to 85% RH, non-condensing Atmospheric pressure: 80 kPa to 106 kPa
Accompanying items	Refer to the packing list

Item	Description
Pipetting range	10 μL - 1000 μL
	• 10 μL: CV<5%, accuracy <±10%
Pipetting precision	• 10 µL: CV<2%, accuracy <±5%
	• 1000 μL: CV<1%, accuracy <±2%

Compliance information

The device complies with following standards:

Item	Standard
Electromagnetic compatibility	• IEC 61326-1:2012
	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
	• IEC 61326-2-6:2012
	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
Safety requirements	• IEC 61010-1:2010+AMD1:2016
	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
	• IEC 61010-2-101:2018
	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Manufacturer information

Manufacturer	Wuhan MGI Tech Co., Ltd.
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Technical support E-mail	MGI-service@mgi-tech.com

European representative information

Manufacturer	Shanghai International Holding Corp. GmbH (Europe)
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