About the user manual

This user manual is applicable to Genetic Sequencer (DNBSEQ-G99). The manual version is 1.0 and the software version is V1.

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Figures in this manual are for illustrative purpose only. The content might be slightly different from the device, please refer to the device purchased.

Revision history

	Date	Version
Initial relaese		1.0

Contents

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01

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.

General safety

DANGER

- Ensure that the device is operated under the conditions specified in this manual. Otherwise, it might result in incorrect experiment results, device malfunction, or even 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 described in this manual to ensure best performance. Otherwise, it might result in device malfunction or even personal injury.
- Do not operate the device in the presence of flammable or explosive liquids, vapors or gases. Otherwise, it might result in device damage, or even personal injury.
- Do not operate the device during maintenance or transportation.

WARNING

- Only the technical support authorized by the manufacturer or the qualified and trained personnel can unpack, install, move, debug and maintain the device. Incorrect operations 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. Otherwise, it might result in inaccurate experiment results. 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 disconnect the power cord when the device is on. Otherwise, it might result in device malfunction.
- Only the components provided by the manufacturer can be used for device maintenance. Unapproved components might degrade device performance or cause device malfunction.
- Do not reuse the disposable items, including the reagent cartridge and flow cell.
- Do not place samples or sample preparation cartridges on the device. Liquids might seep into the device, which might damage the device.

CAUTION

- 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, contact the technical support.
- The device has been verified before delivery. If serious deviation occurs during use, contact the technical support for calibration.
- The device is a clinical laboratory analysis device and it is intended to be used in in vitro diagnosis. Therefore, the doctor should make clinical judgments according to sequencing and other clinical results.

Electrical safety

DANGER

- Ensure that the device is properly grounded, and the grounding resistance meets the requirements. Failure to do so might result in inaccurate experiment results, electric leakage, or even electric shock.
- Do not remove the device cover and expose the inner components outside. Otherwise, it might cause electric shock.

WARNING

Do not use the device in close proximity to the sources of strong electromagnetic fields, such as unshielded sources of radiated emissions. Radiated signals might reduce the accuracy of the results.

CAUTION

- Before initial use of the device, assess the electromagnetic environment in which the device will be used.
- Ensure that the input voltage meets the device requirement.
- Ensure that the voltage of the power outlet in your laboratory or the UPS (if any) meets the voltage requirements before using the device. Failure to do so might damage the electrical components.
- Prepare the laboratory and power supply according to the instructions described in this manual.

Mechanical safety

DANGER

To avoid falling off and personal injury, place the device on a level surface that meets the load-bearing requirements and ensure that the device cannot be easily moved.

Components safety

WARNING

- Only the software that has 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.
- Do not uninstall the control software by yourself. If any problem occurs during software operation, contact the technical support.
- If the fuse blew, replace the fuse with the specified type. For details, contact the technical support.

CAUTION

Ensure that the peripheral devices meet the IEC/EN 62368-1 standards.

Biological safety

- Chemicals in reagents and waste might cause personal injury through contacting with the skin, eyes, and mucosa. Follow the safety standards of your laboratory and wear protective equipment (such as laboratory coat, protective glasses, mask, gloves, and shoe covers) when performing a sequencing.
- If you accidentally splash the reagents or waste liquids on the skin or into eyes, immediately flush the affected area with large amounts of water and get medical aid immediately.
- When disposing of the expired reagents, waste liquids, waste DNBs, and consumables, comply with local regulations.

WARNING

- Use and store the reagents according to the user manual of the reagent set. Failure to do so might negate the reagent effects and cause inaccurate results.
- Check the expiration date of all reagents before use. Do not use expired reagents. Otherwise, it might cause inaccurate results.

Symbols

Packaging

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

Symbol	Name	Description
	This way up	Indicates the correct upright position of the distribution package for transport and/or storage
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	Keep dry	Indicates a medical device that needs to be protected from moisture

Symbol	Name	Description
	Do not stack	Indicates that stacking of the transport package is not allowed and no load shall be placed on the transport package
	Do not roll	Indicates that the transport package shall not be rolled or turned over but shall remain in the upright position
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	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

The following table describes symbols on the device:

Symbol	Name	Description
	General warning sign	Signifies a general warning
	Warning; biological hazard	Warns of a hazard from a biological hazard
	Caution; hot surface	Indicates that the marked item might be hot and should not be touched without taking care
	Warning; dangerous voltage	Indicates hazards arising from dangerous voltages

Symbol	Name	Description
	Protective earth	Indicates the terminal of a protective earth (ground) electrode
	Warning; laser beam	Warns of a hazard from laser beam
	"ON" (power)	Indicates connection to the mains supply
	"OFF" (power)	Indicates disconnection from the mains supply
T10AH250V	Fuse specification	Indicates the fuse specification
USB 2.0 USB 3.0	USB port	Connects USB devices to the computer
WLAN	Network port	Connects the server to the network
COM	COM port	Clusters communication ports
HDMI	HDMI port	Debugs the device

Label

The following table describes symbols on the label:

Symbol	Name	Description
	*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 name and address of the medical device manufacturer
	Date of manufacture	Indicates the date when the medical device was manufactured
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.

Symbol	Name	Description
	Unique device identifier	Indicates a carrier that contains unique device identifier information
	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.
	CE mark of conformity	Indicates that this device conforms with the specified Council Directive.
	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.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Consult instructions for use	Indicates the need for the user to consult the instructions for use

User manual

The following table describes symbols that are used in this manual:

Symbol	Description
 DANGER	Indicates that the operator should operate the device by following the instructions. Otherwise, it will result in death or serious injury
 WARNING	Indicates that the operator should operate the device by following the instructions. Otherwise, it might result in death or serious injury
 CAUTION	Indicates that the operator should operate the device by following the instructions. Otherwise, it might result in minor or moderate injury

Symbol	Description
	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

02

Device overview

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

Intended use

The device utilizes combinatorial probe-anchor synthesis (cPAS) technology. It is clinically intended for sequencing the deoxyribonucleic acid (DNA) and the ribonucleic acid (RNA) from the human sample, to detect genetic changes that might result in disease or susceptibility. The device can be used only with the in vitro diagnostic reagents approved by the National Medical Products Administration, and with the accompanying software. It is not intended for whole genome or de novo sequencing.

Contraindication: None.

Working principle

The device adopts the advanced DNA Nano-ball (DNB) and the core technology of combinatorial probe-anchor synthesis (cPAS) and uses a regular arrayed flow cell with the special decorated surface. Each decorated site of the flow cell contains a single DNB, and the decorated site is evenly arranged on the flow cell, ensuring that the optical signal of different Nano-ball cannot be interrupted by each other. Therefore, the accuracy of signal process is improved.

The following figure demonstrates how to make DNBs:

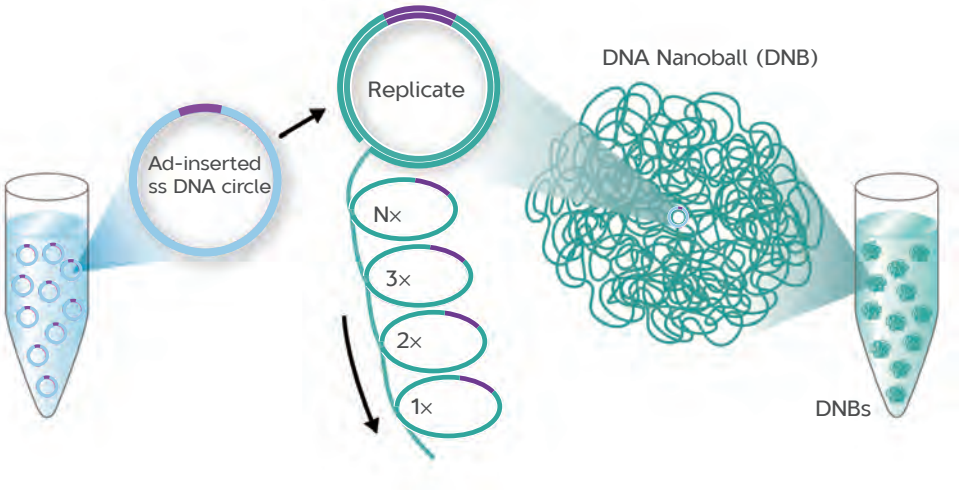

Figure 1 Making DNBs

The following figure demonstrates how to load DNBs:

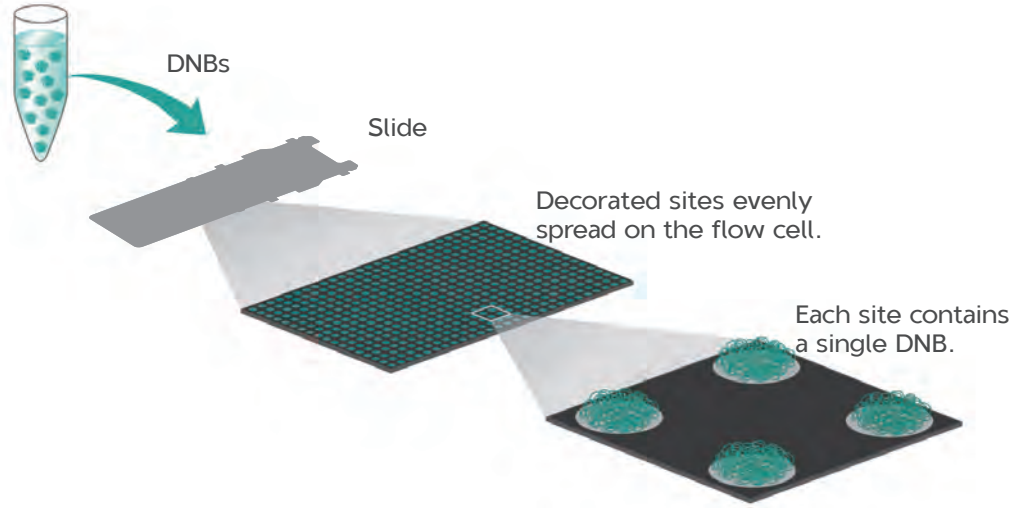

Figure 2 Loading DNBs

The DNB and sequencing reagent are pumped into the sequencing flow cell through the device's liquid system. Each DNB combines with the fluorescence group. The laser excites the fluorescence group to emit light, and the optical signals are acquired by the camera. Then the optical signals are processed and transferred to digital signals, the digital signal is transmitted to and processed by the computer, so as to acquire the nucleotide sequence of the DNB.

Structural composition

The device consists of the main unit and pre-installed control software (software version: V1). The main unit includes the main structure, host, optical system, XYZ-stage, flow cell stage, gasliquid system, electric control system, reagent storage system, power supply system, and display system.

The following table describes the function of each component:

Component	Description
Main structure	Provides the stable support for the main unit.
Host	Controls the device, collects, analyzes and stores data.
Optical system	Images the fluorescence signal on the flow cell.
XYZ-stage	Moves the flow cell and focuses automatically.
Flow cell stage	Connects the flow cell to fluidics lines and controls the temperature of the flow cell.

Component	Description
Gas-liquid system	Provides the gas-liquid support that is required for the biochemical reaction.
Electric control system	Controls the electric system.
Reagent compartment	Holds the reagent cartridge.
Power supply system	Provides the power supply for the device.
Display system	Provides the human-computer interaction interface.

Basic components

Front view

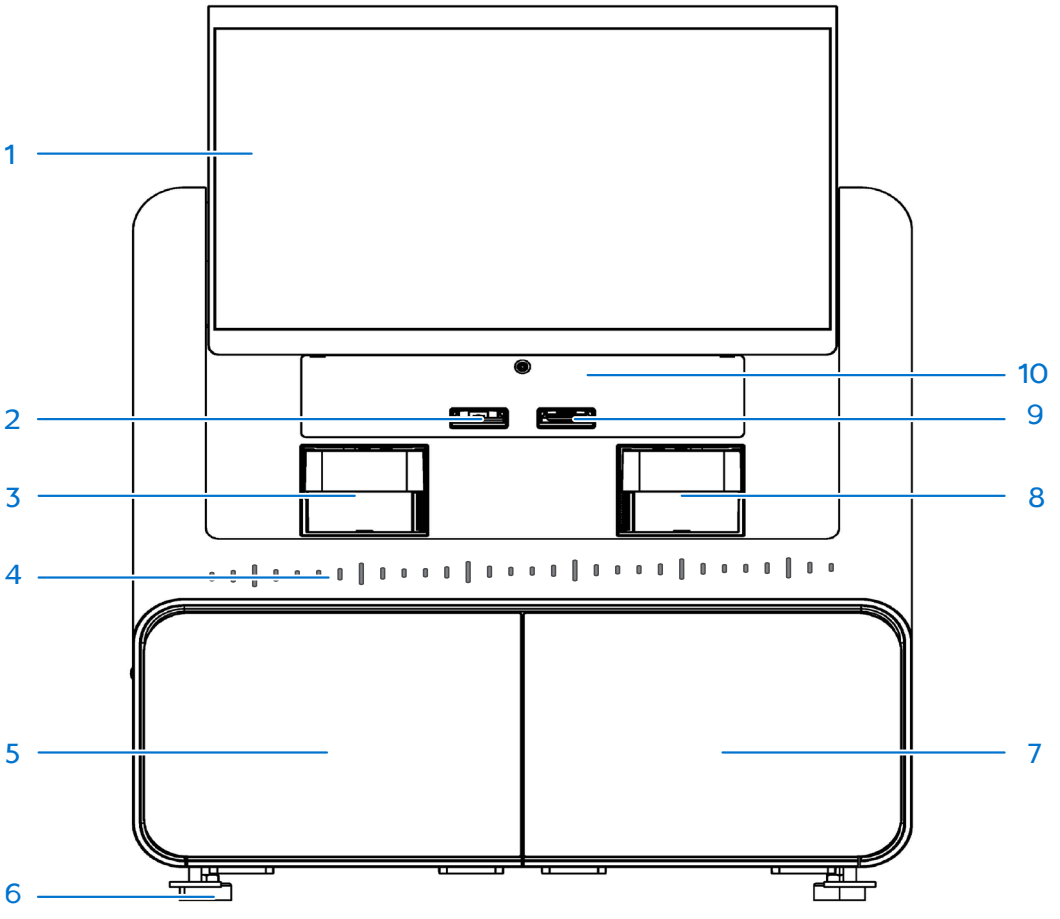

Figure 3 Front view

No.	Name	Description
1	Auto-sliding screen	• Facilitates on-screen operation and displays information. • shows the flow cell compartment door, the flow cell compartment, and the reagent cartridge when the auto-sliding screen is moved up.
2	Flow cell stage A	Holds and moves the flow cell A and controls the temperature of the flow cell A.

No.	Name	Description
3	Reagent compartment A	Holds the reagent cartridge.
4	Status indicator	Displays the current status of the device: • Green: the device is running. • Blue: the device is in standby status. • Yellow: a warning appears, but the device keeps running. • Red: an error occurs.
5	Waste container compartment door A	You can take out the waste container after the system automatically opens the compartment door A as the sequencing is completed.
6	Supporting feet	Supports the main unit to ensure stability.
7	Waste container compartment door B	You can take out the waste container after the system automatically opens the compartment door B as the sequencing is completed.
8	Reagent compartment B	Holds the reagent cartridge.
9	Flow cell stage B	Holds and moves the flow cell B and controls the temperature of the flow cell B.
10	Flow cell compartment door	You can use an Allen key to remove the M3 screw, and then open the flow cell compartment door to maintain the flow cell stage.

Back view

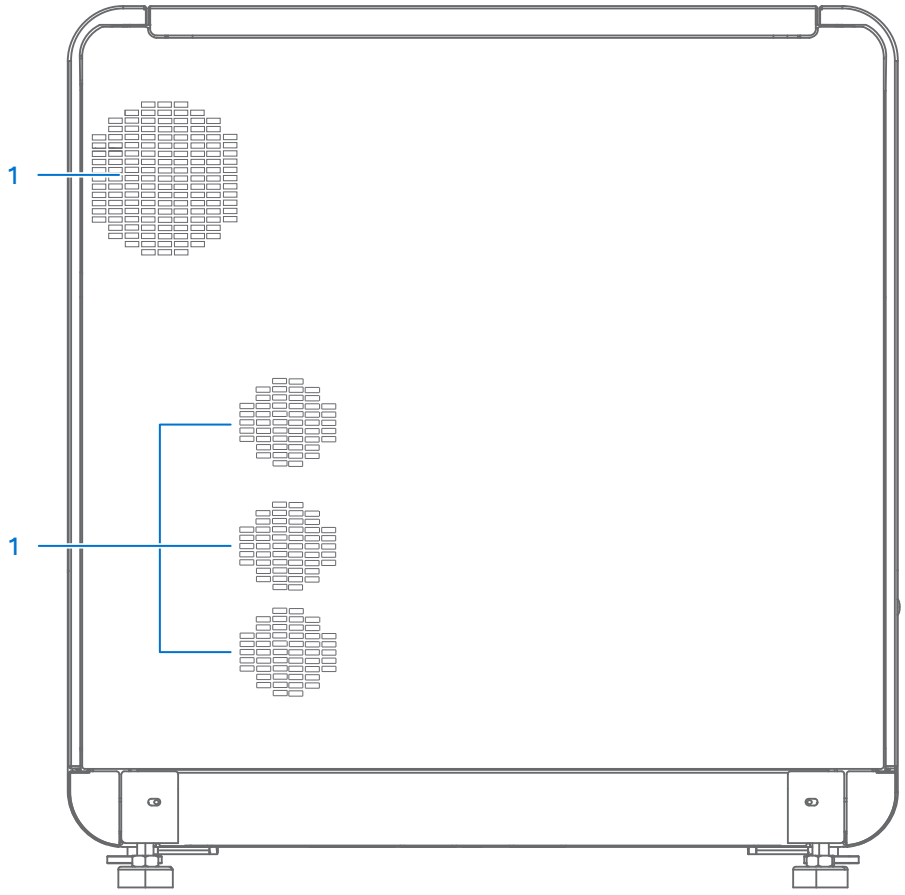

Figure 4 Back view

No.	Name	Description
1	Ventilation outlet	Ventilates the device.

Left view

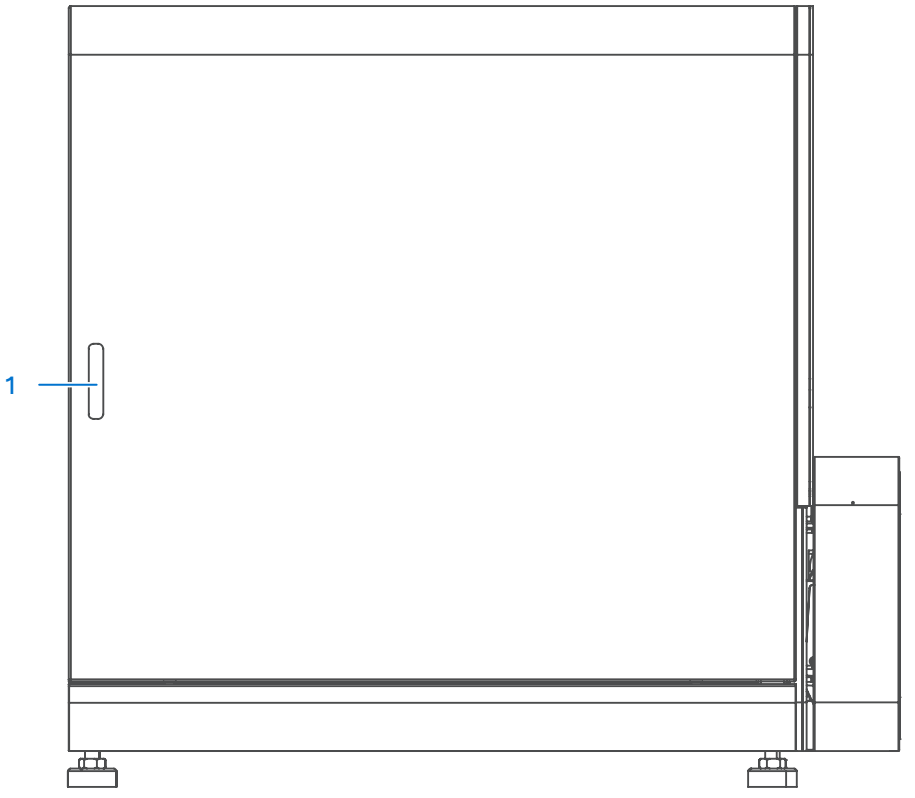

Figure 5 Left view

No.	Name	Description
1	Window	You can observe the status of the fluidics system.

Right view

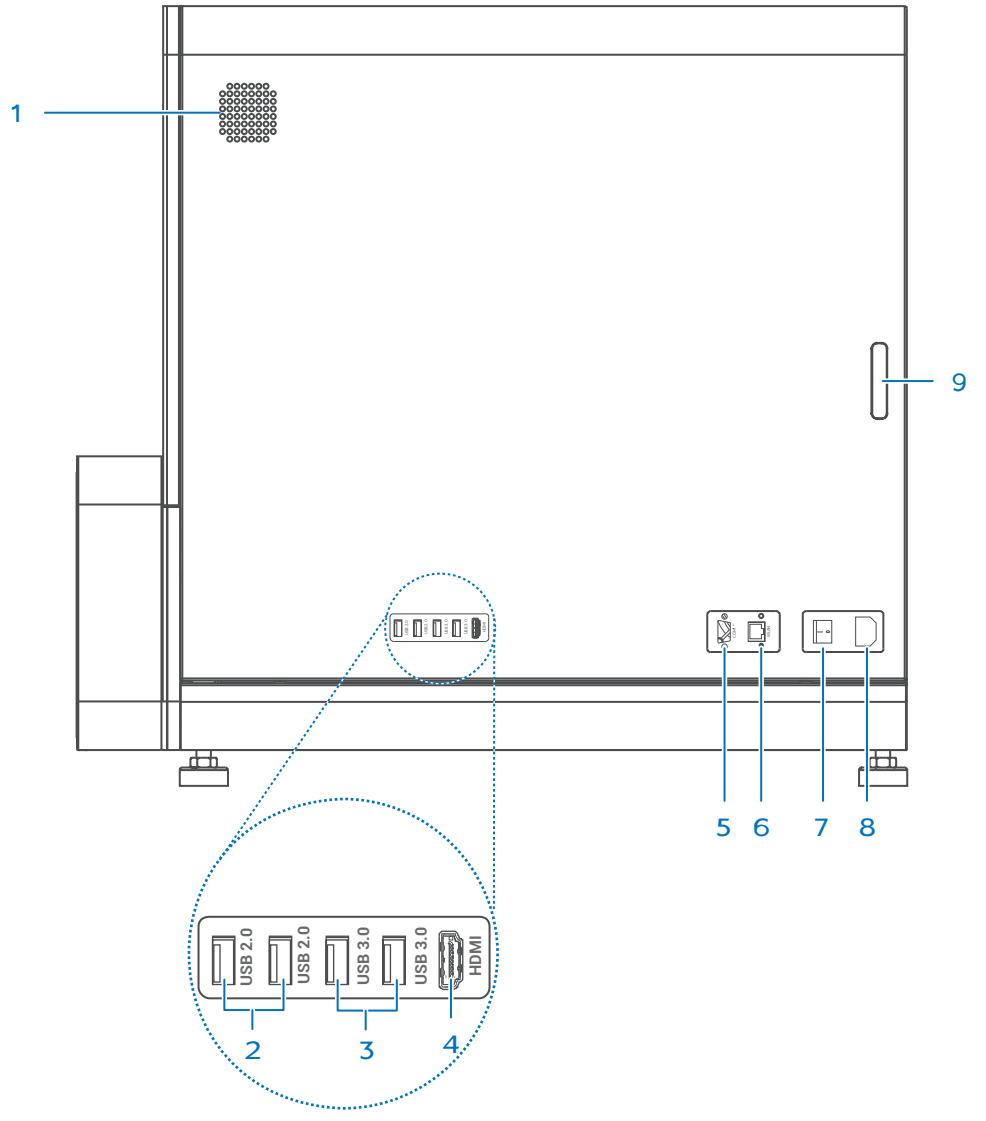

Figure 6 Right view

No.	Name	Description
1	Speaker	Emits sound to prompt the user.
2	USB port 2.0	Connects USB devices to the computer.
3	USB port 3.0	Connects USB to the server.
4	HDMI port	Debugs the device.
5	COM port	Clusters communication ports.

No.	Name	Description
6	Network port	Connects the server to the network.
7	Power switch	Powers on or off the device. • Switch to the | position to power on the device. • Switch to the ◯ position to power off the device.
8	Power port	Connects the power cord.
9	Window	You can observe the status of the fluidics system.

Control software

Overview

The system control software initiates the communication protocol through physical ports to coordinate with the hardware, control gas lines, fluidics lines, temperature, mechanical components, and optical components. The software detects the signal on the sequencing flow cell, transfers the photographic information to the base sequence files in standard format, and guides different users to perform different processes, such as maintenance and experimental protocols.

The following table describes the function of each functional module:

Item	Description
Check	Checks whether the components of the system are functional.
Sequence	Performs different types of sequencing processes.
Wash	Performs wash and maintenance for fluidics lines of the system.

Main interface

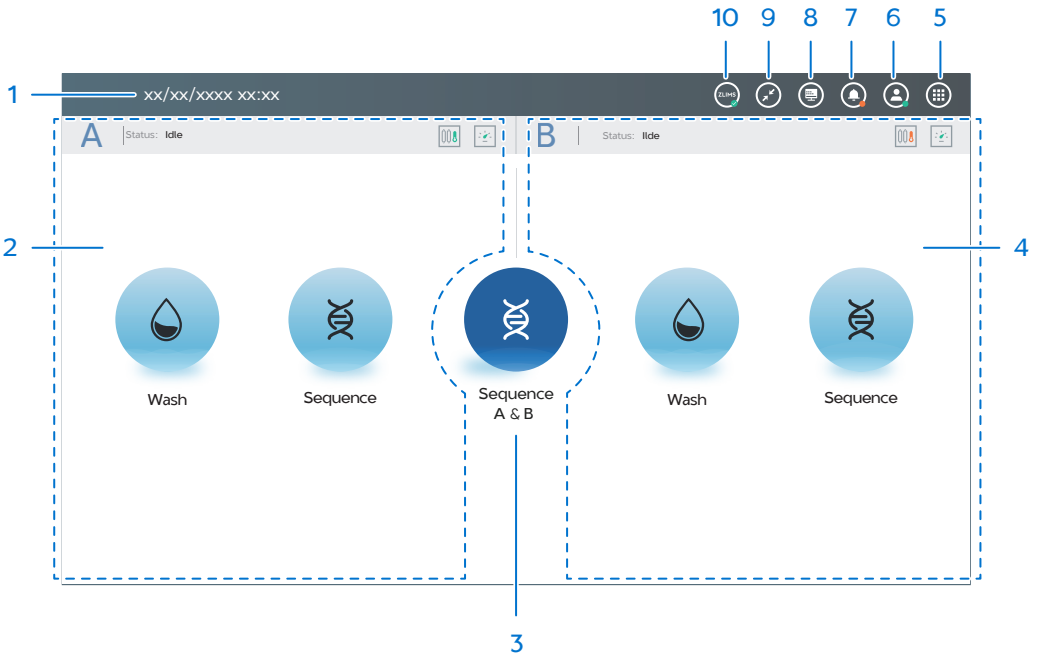

Figure 7 Main interface

The following table describes the function of each area or button in the main interface:

No.	Name	Description
1	Date and time area	Indicates the date and time.
2	Flow cell A operation area	Indicates the status of flow cell A and provides wash and sequence options.
3	**Sequence A&B**	Tap to simultaneously sequence flow cell A and B.
4	Flow cell B operation area	Indicates the status of flow cell A and provides wash and sequence options.
5	Menu button	Tap to view the logs, change settings, perform maintenance, lock screen, shut down or restart the system, or check the system information.
6	Login button	Tap to log in to the system.

No.	Name	Description
7	Prompt button	Tap to view the warnings, errors or other abnormal information. The prompt icon includes the following status: • No color marking: the device is running. • Yellow and flash: a warning appears. • Salmon pink and flash: the device is abnormal.
8	Sensor status indicator	Tap to check the status of sensors of the device.
9	Minimize	Tap to minimize the control software.
10	ZLIMS status	Displays the connection status of the device and the server that ZLIMS is installed on.

Operation area

Tips The icons include the following status:

- Green: the device is running.
- Salmon pink: the device is abnormal.

The following table describes the function of icons and buttons in the area:

Item	Description
A&B	Indicates flow cell A or flow cell B operation area.
Status	Displays the status of the selected operation area.
	Indicates the negative pressure of flow cell stage.
	Indicates the flow cell stage temperature.
Sequence	Tap to select sequencing recipe, and perform a sequencing by following the on-screen instructions. For details, refer to *Sequencing on Page 33*.
Wash	Tap to select the wash type, and perform the relevant operations by following the on-screen instructions. For details, refer to *Daily maintenance on Page 44*.

Status area

Tips The icons include the following status:

- Green: the device is running.
- Salmon pink: the device is abnormal.

The following table describes the function of icons in the area:

Item	Description
	The device runs independently, without being connected to the server on which the ZLIMS software is installed.
	Errors occur in connection with the server on which the ZLIMS software is installed.
	The device is connected normally to the server on which the ZLIMS software is installed.
	Basecall connection status.
	Images are being uploaded to the Basecall. Tips This icon is dynamic.
	The device temperature. The real-time value is displayed on the left.
	The device humidity. The real-time value is displayed on the left.

Log interface

Tap  to view the log in this interface.

The following table describes the function of controls in the interface:

Item	Description
Time	Tap to sort the logs time in an ascending or descending order.
Close	Tap to exit the log interface and return to the previous interface.
<	Tap to return to the previous page of logs.
X/X	Displays the current page and the total page of logs.
>	Tap to turn to the next page of logs.

System settings interface

Tap and select **Settings** to change system settings in this interface.

General settings

The following table describes the function of controls in the interface:

Item	Description
Data upload	Tap to upload the sequencing status or the data to the specified server. Restart the computer to apply the change of uploading the sequencing status.
Language	Tap to change the language of the software. Restart the computer to apply the changes.
Customize	Tap to change the wait time before the screen locks automatically. Move the slider to change the volume of the buzzer.
Close	Tap to exit the setting interface and return to the main interface.

Sequencing recipe settings

The following table describes the function of controls in the interface:

Item	Description
Create	Tap to customize a recipe.
Delete	Tap to delete the selected recipes.
Creation time	Tap to display the recipes according to the creation time.
Order	Tap ▲ or ▼ to adjust the order of displaying the recipes.
Close	Tap to exit the setting interface and return to the main interface.

Barcode settings

The following table describes the function of controls in the interface:

Item	Description
Template	Tap to down load the customized barcode template.
Import	Tap to import the Barcode files from external devices into the device.
Export	Tap to export the customized Barcode files.

Item	Description
Delete	Tap to delete the selected customized Barcode.
misMatch1	Displays the Barcode mismatch rate in the Barcode recipes.
misMatch2	Displays the DualBarcode mismatch rate in the Barcode recipes.
Import time	Tap to sort the Barcode files in an ascending or descending order according to the import time.
Order	Tap to adjust the order of the selected recipes.
Close	Tap to exit the setting interface and return to the main interface.

Maintenance interface

Tap and select **Maintenance** to maintain the system.

Tools

The following table describes the function of controls in the interface:

Item	Description
Check	Tap to initialize or check the device, without restarting the system.
Auto-sliding screen	Tap to move up and down the screen and maintain it.
Waste compartment door	Tap to open the selected waste compartment door. Close it manually as you finish the operation.
Verify stage flatness	Tap to verify whether the flow cell stage is flat, and take out the flow cell stage after verifying.
Close	Tap to exit the selected interface and return to the main interface.

Empty

The following table describes the function of controls in the interface:

Item	Description
Empty	Tap to empty the waste liquid in A/B fludics line into the waste container only when the waste container is in place.
Close	Tap to exit the setting interface and return to the main interface.

Shutdown or restart interface

You can shut down or restart the computer in this interface.

To open the shutdown or restart interface, tap and select **Shutdown** or **Restart**.

About interface

You can view the software version, serial number, other information of the device, and the manufacturer information in this interface.

To open the About interface, tap and select **About**.

03

Laboratory requirements

This chapter describes the requirements for the laboratory, the network, the power supply and so on.

Site requirements

DANGER

- Ensure that the laboratory floor is level and with a gradient of less than 1/200, and the weight capacity of the laboratory bench and the laboratory floor meets the requirements.
- Ensure that the laboratory is free of dust, corrosive and flammable gas, and heat and wind sources.
- We recommend that you use a clean laboratory with ISO Class 10 air cleanliness.

CAUTION

- Ensure that the laboratory is away from direct sunlight and is well ventilated. We recommend that you refer to the standard of a biosafety level (BSL) 2 laboratory.
- Ensure that enough space is provided for relevant configurations and peripheral devices.
- Ensure that enough space is provided around the device for ventilation, cable connection, power switch operation, and device operation and maintenance.

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

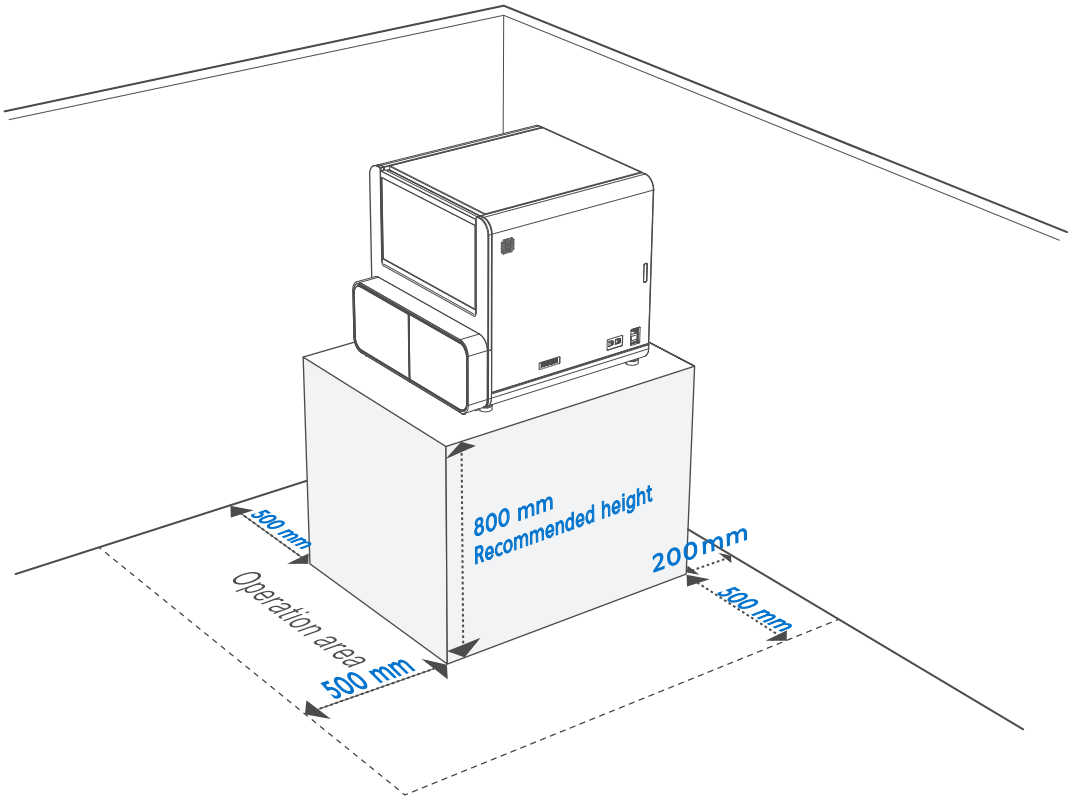

Figure 8 Site requirements

Network requirements

WARNING

- If necessary, contact the technical support to obtain or change the user name and password of the computer and the device.
- The control software provides two different types of user account. For detailed access authorization, contact the technical support. The rules for managing the device account are set by the agents who use the device. Please conform to the rules of your agents when using the device.
- 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.
- Do not uninstall the control software by yourself. If any problem occurs during software operation, contact the technical support.
- Considering the information security, we do not recommend that you connect the extranet to the device. If you need to upload the data to the server, contact the technical support in advance and ask the network administrators of your agents to configure the network so as to reduce the risk of network security.

CAUTION

- To protect the data, please change the password when you log in the device for the first time, and change the password regularly.
- To protect the data, we recommend that you connect the device to the server and enable the function of uploading the data to the server synchronously.
- The Logs system will not record the data deletion or revision through Windows. Please ensure that your data have been backed up before deletion or revision.

Table 1 Network requirements

Item		Description
Operating environments of the computer	Minimum configuration	Processor: Intel i9
	Software environments	Pre-installed software on the computer includes ▪ Microsoft Windows10 64-bit operating system ▪ Microsoft .Net Framework 4.6.1 and above ▪ Control software
	Network conditions	• Network architecture: C/S • Network type: local network • Network bandwidth: no less than 10 Gbit/s
Software security	We have installed the antivirus software. If you need to upgrade the antivirus software, contact the technical support in advance.	

Item	Description
Data and device port	• Network ports: connect to the network. • USB 3.0 port: connects USB devices to the computer. • USB 2.0 port: connects to external USB devices, such as the keyboard and mouse, or for future use.
Access control	User account types of the control software include standard user account and advanced user account. For detailed access authorization, contact the technical support.

Installing the device

CAUTION

- Only the technical support of the manufacturer or trained personnel under the guidance of the technical support 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 anti-shock and anti-tilt label is normal upon delivery. If any problem occurs, contact the technical support.
- To ensure that the performance of the device meets the specifications, the technical support will perform a standard sequencing before customer training and use.

The following table describes indicator status on the label:

Table 2 Indicator status

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

Preparing the power supply

WARNING

- 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.
- 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 the following table.
- Ensure that the grounding cable is connected in accordance with the relevant standard or under the guidance of the experienced electrician.
- Ensure that the power switch is in the off position before connecting to the power supply.
- Check whether the power socket matches the power cord. If not, check for available adapters.

CAUTION

To ensure a steady and uninterruptible power supply to the device during operation, we recommend the use of a separate UPS. For details about the UPS installation protocol, contact the technical support or the UPS supplier.

Table 3 Power specifications

Item	Description
Voltage and frequency range	100 V to 240 V~, 50/60 Hz
Rated power	1000 VA, the current the rated power supports is not less than 10 A.
Voltage fluctuation	± 10%
Transient over-voltage category	II
Grounding resistance	Less than 4 Ω

Preparing peripheral devices

Before using the device, prepare the following peripheral items:

Table 4 Peripheral device list

Device	Recommended supplier	Remarks
Ultra-pure water machine	General laboratory supplier	/
Frost-free freezers or refrigerators	General laboratory supplier	Temperature ranges (according to requirements): • 2 ℃ to 8 ℃ (36 ℉ to 46 ℉) • -18 ℃ to - 25 ℃ (-0.4 ℉ to -13 ℉)
Qubit 3.0 QC fluorometer	Thermo Fisher	/
Mini centrifuge	N/A	/
Vortex mixer	N/A	/
PCR	Bio-Rad	/
Pipettor	Eppendorf	/

Recommended consumables

WARNING

Tips are disposable consumables, do not reuse them.

Tips

You can use laboratory-grade water such as 18 Megohm (MΩ) water, Milli-Q water, Super-Q water, or similar molecular biology-grade water.

It is recommended to use following consumables:

Table 5 Recommended consumable list

Item	Recommended brand
Qubit ssDNA assay kit	Thermo Fisher
Sequencing flow cell	MGI
Sequencing cartridge	MGI
Washing flow cell	MGI

Item	Recommended brand
Washing cartridge	MGI
Waste container	MGI
Pure water container	MGI
Gas-liquid separation bottle	MGI
Air dust remover	MATIN
Boxed sterilization tip	AXYGEN
200 µL wide-bore tip	AXYGEN
Qubit assay tubes	Thermo Fisher
2 M NaOH	Aladdin
0.2 mL PCR 8-strip tube	AXYGEN
1.5 mL centrifuge tube	AXYGEN
Ice box	AXYGEN

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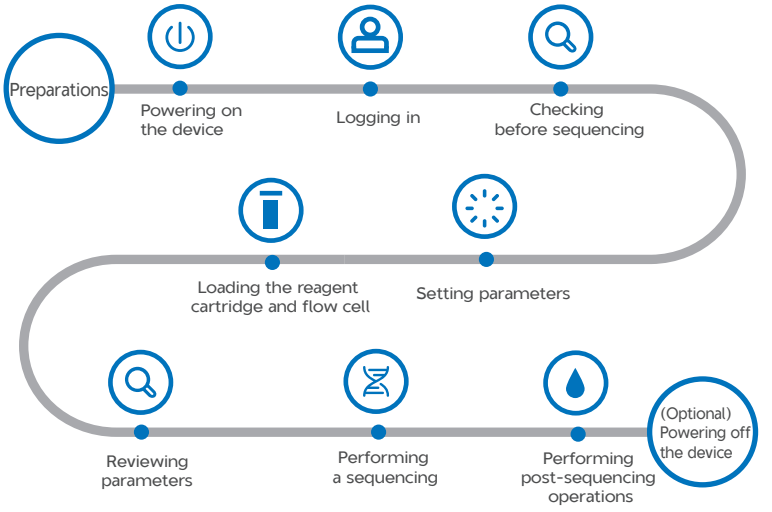
04

Sequencing

This chapter, with the sequence A as an example, describes the sequencing workflow and post-sequencing procedures. Read and follow the instructions before sequencing to ensure correct operations.

Workflow



- Chemicals in reagents and waste might cause personal injury through contacting with the skin, eyes, and mucosa. Follow the safety standards of your laboratory and wear protective equipment (such as laboratory coat, protective glasses, mask, gloves, and shoe covers) when performing a sequencing.
- If you accidentally splash the reagents or waste liquids on the skin or into eyes, immediately flush the affected area with large amounts of water and get medical aid immediately.
- When disposing of the expired reagents, waste liquids, waste DNBs, and consumables, comply with local regulations.

Preparations

Preparing samples

It is recommended to use the library preparation system of the manufacturer to prepare samples. For details, refer to the relevant reagent kit user manual.

Preparing the reagent cartridge and flow cell

CAUTION

- Use only the reagent cartridge and flow cell of the manufacturer for the sequencing process. You can purchase them as needed from the authorized sales representatives.
- If the sequencing reagent cartridge is not used immediately, store the cartridge at appropriate temperatures as required. Thaw the cartridge thoroughly before performing a sequencing.

Remove the sequencing reagent cartridge from storage and prepare it for sequencing. For details, refer to relevant reagent kit user manual.

Powering on the device

WARNING

- 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.
- Ensure that the power switch is in the off position before connecting to the power supply.
- Do not switch the account after you log in the computer. Otherwise, the authority of the system will be changed and the device might stop running.

CAUTION

- For the ports of the computer and how to use them, refer to the computer user manual.
- We recommend that you change the password after you firstly log in to the computer.
- To protect the information, we recommend that you set a long and complex password which should include the upper and lower case letters, numbers, and symbols, and that you change the password every three months.

Perform the following steps:

1. Ensure that the power switch is in the off position.
2. Connect the device to the power supply through power cord.
3. Turn the power switch of the device to the on position. After you power on the device, the log interface is displayed.
4. Select the user name, after you input the password, the device starts to check.
   - If the check is successful, the main interface is displayed.
   - If the check fails, perform the following steps:
     a. Tap , select **Logs** to check the self-test result in the logs.
     b. Solve the problem according to the on-screen instructions or the *Troubleshooting on Page 47*.

c. Tap , select **Maintenance** > **Tools** > **Check** > **Initialize & Check** as powering on the device, and repeat the steps mentioned above.

If the problem persists, contact the technical support.

Logging in

CAUTION You can perform the sequencing and wash procedures only after you log in to the control software.

Perform the following steps:

1. Tap in the main interface.
2. Select the user name and input the password.

Checking before sequencing

Perform the following steps:

1. Tap **Sequence** in the Flow cell A operation area, and the system will automatically open the waste container compartment door A.
2. Place the empty waste container in the waste container compartment by following the on-screen instructions.
3. Close the waste container compartment door. The device automatically starts checking.
   - If the check is successful, tap **Next** to enter the interface of setting parameters.
   - If the check fails, perform the following steps:
     a. Solve the problem by following the on-screen instructions.
     b. Tap **Previous**.
     c. Tap **Sequence** to restart the check.

     If the problem persists, contact the technical support.

Setting parameters

CAUTION Be careful to set the parameters. Once you go to the interface of loading the flow cell, you cannot return to the interface of setting parameters.

Perform the following steps:

1. Select the workflow type.
2. Input the DNB ID.
3. Select the recipe.
4. Select the Barcode.

   If you choose **Other**, you can tap to import the Barcode files.
5. In advanced settings, choose whether or not to split the Barcode files and whether or not to start the auto wash after sequencing. By default, the answer of both questions is **Yes**.
6. Tap **Next** and the auto-sliding screen will move up automatically.

Loading the reagent cartridge

CAUTION

Be careful to set the parameters. Once you go to the interface of loading the flow cell, you cannot return to the interface of loading the reagent cartridge.

Perform the following steps:

1. Prepare the reagent cartridges, including the sequencing cartridge and washing cartridge.

   For details about preparing the reagent cartridge, refer to the relevant reagent kit user manual.
2. Push the sequencing cartridge in the direction of the arrow A shown on the cartridge into the reagent compartment A until you hear a click.

CAUTION

Push the sequencing cartridge horizontally into the reagent compartment and avoid touching the needle in the upper part of the reagent compartment.

3. The system automatically identifies the ID of the reagent cartridges and shows it in the Reagent cartridge box.
   - If RFID scanning identifies the ID of the reagent cartridge, the system will automatically determine whether the reagent cartridge is the APP-C reagent cartridge, and choose **Yes** or **No** in the APP-C box.
   - If RFID scanning fails to identify the ID of the reagent cartridge, the system will choose **No**. At this moment, you need to manually choose **Yes** or **No** in the APP-C box.

Tips

The ID of the reagent cartridge consists of the 10-digit catalogue number and 11-character serial number. Ensure that the ID format is correct when you input ID manually. Otherwise, you will be prompted that the ID is incorrect and the procedure cannot continue.

4. Tap **Prime** and then **Yes** in the pop-up box.
5. The system automatically close the auto-sliding screen and starts prime. The prime takes at least 3 minutes.
6. Once the prime ends, the auto-sliding screen will move up automatically.

Loading the flow cell

WARNING If the flow cell accidentally drops to the floor and breaks, handle with care in case of personal injury.

CAUTION

- If the flow cell is not absorbed properly, wipe the flow cell stage and the back of the flow cell. Do not press the glass because it might bring particulate matters and fingerprints or damage the flow cell
- Do not move the flow cell once it is loaded. Otherwise, it might cause misalignment between the flow cell inlet and outlet and the gasket.

Perform the following steps:

1. Prepare the flow cell.

   For details about preparing the flow cell, refer to the relevant reagent kit user manual.
2. Ensure that the flow cell label is facing up and place the flow cell on the stage in the direction of the arrow shown on it.
3. The system will scan the flow cell ID automatically and shows it in the Flow cell ID box. If it fails to scan the flow cell ID, you can manually input it.
4. Tap **Next**, the auto-sliding screen will move down and show the interface of reviewing parameters.

Reviewing parameters

Carefully check each item in the review interface. Tap **Sequence**, and then select **Yes** in the pop-up box to start sequencing after you ensure that all items in the review interface are correct.

If necessary, tap **Previous** to revise the information.

Performing a sequencing

CAUTION

- Do not bump, move, vibrate, or impact the device during sequencing. Otherwise, sequencing results might be inaccurate.
- If malfunctions related to fluidics lines (for example, bubbles) occur during sequencing, solve the problems before you restart a sequencing.
- Pay special attention to the LED status bar or the on-screen instructions. If errors occur, troubleshoot the problem by following the instrcutions and this user manual. If errors still exist, contact the technical support.

The Sequencing interface displays real-time sequencing progress, you can operate the device if needed.

The following table describes the function of each item in the interface:

Item	Description
Estimated completion time	Shows the estimated time when sequencing completes.
Stage	Shows the current stage of sequencing,
QC type	You can select a QC value graph from the QC type list to assess the sequencing quality.
Flow cell ID	Shows the serial number of the flow cell that is sequencing.
	Tap it to pause sequencing, and tap it again to resume sequencing.
	Tap it and a confirmation dialog box appears. Select **Yes** to stop sequencing. CAUTION Be careful to tap this item because some stages of sequencing cannot be resumed once it pauses.
	Tap it to open the first base report after the first base photo is taken.

If the **Auto wash** is selected, the system will automatically perform a post-wash after each sequencing.

Performing the post-sequencing operations

Perform the following steps:

1. Tap **Finish**, the auto-sliding screen will move up and the waste compartment door will be open automatically.

2. Wash the waste container.

CAUTION

The waste container cannot be reused for more than one month, timely replace the waste container.

1) Take out the waste container from the waste container compartment and empty the waste into an appropriate container according to local regulations and your laboratory safety standards.
2) Add sufficient laboratory-grade water into the waste container, and gently shake the container until all inner walls are cleaned. If necessary, attach the lid back onto the waste container.

Tips

You can use laboratory-grade water such as 18 Megohm (MΩ) water, Milli-Q water, Super-Q water, or similar molecular biology-grade water.

3) Pour the waste into an appropriate waste container.
4) Clean the surface and opening of the waste container with a 75% alcohol wipe. Ensure that no waste remains in the container.
5) Place the waste container back into the waste container compartment and close the waste compartment door.

3. Take out the reagent cartridge and the flow cell.

Tips

Press the flow cell down or lift it up before removing it.

4. Clean the reagent compartment.

Tips

Mind the reagent needles in the upper part of the reagent compartment during cleaning.

Wipe the reagent compartment with a dust-free paper or a dust-free cloth moistened with the laboratory-grade water and keep it clean and dry.

5. Dispose of the waste according to local regulations and your laboratory safety standards.
6. Dispose of the flow cell and the reagent cartridge in accordance with the disposal standards of medical waste.
7. If the auto wash is not selected in advance, perform a maintenance wash within twelve hours.

   For details, refer to *Cleaning the fludics lines on Page 45*.
8. (Optional) Tap **Return home** to return to the login interface of the control software.

(Optional) Powering off the device

CAUTION

Power off the device and disconnect the power cord if you do not use the device for a long time.

Perform the following steps:

1. Tap  select **Shut down**. In the pop-up dialog box, select **Shut down**.
2. Turn the power switch to the  position.
3. Disconnect the power cord from the mains supply socket or UPS.

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05

Maintaining the device

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

DANGER

- Ensure that the power is off before cleaning or disinfecting. Failure to do so might cause personal injury.
- Do not spray the wash solutions or disinfectants into the device during cleaning or disinfecting. Failure to do so might damage the device.

WARNING

- It is not recommended to use other disinfectants or wash solutions except for those that are mentioned in this manual. Because other solutions are not verified for use and their effects to the device are unknown.
- If you have questions about the compatibility of wash solutions, contact the technical support.

Service plan

A free maintenance service is provided in the first year during the warranty period. For the purchase of additional services, contact the technical support.

Daily maintenance

WARNING Wear a laboratory coat, a mask, and gloves before performing the following steps.

Maintaining the power cord

Perform the following steps:

1. Check whether the power cord and cables are connected correctly and in good condition regularly. Contact the technical support if new cables are required.
2. Check whether the area around the power supply is dry without water.

Checking and cleaning the cooling fan

Perform the following steps:

1. Remove the dust on the holes of the cooling fan with a small brush. Ensure that the cooling fan can dissipate heat normally.
2. Check whether the cooling fan operates normally. If not, contact the technical support.

Cleaning the flow cell stage

Perform cleaning and maintenance for the flow cell stage before each use. Failure to do so might affect the attachment of flow cell to the chuck.

The tools that need to be prepared include: absolute alcohol, clean cloth, Eppendorf, dust remover, and Allen key.

WARNING Do not wipe the vacuum inlet and vacuum attachment slot to prevent absolute alcohol from entering the holes and damaging the device.

Perform the following steps:

1. Use an Allen key to remove the M3 screw, and then open the flow cell compartment door.
2. Check for dust, debris, damage, or particulate matters on the surface of the aluminum chuck of the flow cell stage. If any, use the dust remover to blow them away util all visible dust or other particulate matters are removed.
3. Wipe the aluminum chuck of the flow cell stage with a clean cloth moistened with absolute alcohol, and then let it air-dry.

Cleaning the fludics lines

You can perform a wash to remove the remaining reagents from the fluidics lines and flow cell stages, and avoid cross-contamination.

Select the appropriate wash type according to the use frequency of the device and the type of sequence. The following table contains requirements on wash solutions and frequencies.

Table 6 Wash requirements

Wash type	Wash solution	Frequency
Auto wash	Use the sequencing cartridges that contain the wash solutions.	Determine whether automatically wash the fludics lines after sequencing according to the real situaton.

Wash type	Wash solution	Frequency
Main tenance wash	Use the washing cartridge and add 7.5 mL of 0.1 M NaOH to the second hole of the washing cartridge.	• If you do not wash the fludics lines after previous sequencing, wash them before sequence. • Wash the fludics lines monthly. • The device is not in use for 7 days or longer. • Wash the fludics lines after you perform any device maintenance relevant to the fludics lines.

Tips
- For how to prepare the 0.1 M NaOH, refer to the relevant reagent kit user manual.
- No need to place a flow cell for washing.

Select the appropriate wash type according to the use frequency of the device and the type of sequence.

Perform the following steps:

1. Prepare the washing cartridge.

   For details about preparing the reagent cartridge, refer to the relevant reagent kit user manual.

CAUTION

Use only the washing reagent cartridges of the manufacturer for the maintenance. You can purchase them as needed from the authorized sales representatives.

2. Tap **Wash** in the main interface.
3. Follow the on-screen instructions to perform the washing.
4. Wash the waste container.
   1) Take out the waste container from the waste container compartment and empty the waste into an appropriate container according to local regulations and your laboratory safety standards.
   2) Add sufficient laboratory-grade water into the waste container and gently shake the container until all inner walls are cleaned. If necessary, attach the lid back onto the waste container.
   3) Pour the waste into an appropriate waste container.
   4) Clean the surface and opening of the waste container with a 75% alcohol wipe. Ensure that no waste remains in the container.
5. Place the waste container back into the waste container compartment and close the waste compartment door.
6. Dispose of the waste and waste container according to local regulations and safety standards of your laboratory.

Monthly maintaining

Clearing the history data in the disk

Check the disk space and timely back up the history data with the peripheral storage devices.

Maintaining the device

WARNING The dust-free cloth should keep moist only.

Perform the following steps:

1. Power off the device.
2. Wipe the surface and the auto-sliding screen of the device with a dust-free cloth moistened with 75% alcohol. Ensure that the surface is free of samples and reagents, blood, and saliva.

Annual maintenance

Contact the technical support to annually check and calibrate the laser power.

Maintaining the software

If necessary, contact the technical support to update and maintain the software.

Troubleshooting

If malfunction occurs during operation, the device beeps or a message is displayed on the screen. Follow the prompt to troubleshoot and solve the problem.

The following table lists some of the problems and possible solutions. If you need additional assistance, contact the technical support.

Table 7 Troubleshooting

Problem	Possible cause	Recommended action
After turning the power switch to ▌ position, I cannot turn on the device.	• The device is not connected to the mains supply or UPS • Fuses blew.	1. Check whether the device is connected to the mains supply or UPS. 2. Check whether the fuses blew. 3. If the problem persists, contact the technical support.
Error messages appear when the control software runs.	• The parameters are not set properly. • Errors occur when the software communicates with hardware.	1. Perform a check in the maintenance interface. Check the record of the hardware that fails the check. 2. Check error messages in the log, and solve the problem according to on-screen instructions. 3. Restart the device. 4. If the problem persists, contact the technical support.
Temperature error message and warning appears in the sequencing interface.	• The temperature exceeds the preset limits. • Temperature sensor error.	Record the warning and logs of this run and contact the technical support.

Transportation and storage

- Keep the device according to the environment requirements in this manual.
- 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. Or, if the device is confirmed that it still can work safely and effectively after maintenance, keep using the device.

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Specifications

CAUTION

- The maximum sound pressure level is measured based on the distance between the position where the device operator stands during normal operation and any position which is one meter from the device and has the maximum sound pressure level.
- Because the temperature and humidity fluctuations influence the accuracy of the experiment results, we recommend that you install an air conditioning system and a humidifier or dehumidifier in the laboratory to maintain the temperature and humidity.

Item	Description	
Category	Clinical examination and analytical instrument, Class III	
Laser classification of the device	Class 1 laser product	
EMC	Class A	
Power	Voltage	100 V to 240 V~
	Frequency	50/60 Hz
	Rated power	1000 VA
Dimensions	607 mm (L) × 680 mm (W) × 640 mm (H) (24 inches × 27 inches × 25 inches)	
Net weight	Approximately 140 kg (308 lb)	
Auto-sliding screen	Type	LCD
	Size	21.5 inches
	Resolution	1920 × 1080 pixels
Fuse specification	T10AH250V	
Maximum sound pressure level	75 dBA	
The lab bench bearing capacity	300 kg/m^2	

Item	Description	
Operating environment requirements	Temperature	15 ℃ to 30 ℃ (59 ℉ to 86 ℉)
	Relative humidity	20% RH to 80% RH, non-condensing
	Atmospheric pressure	70 kPa to 106 kPa
	Pollution degree	2
Transportation/ Storage environment requirements	Temperature	-20 ℃ to 50 ℃ (-4 ℉ to 122 ℉)
	Relative humidity	15% RH to 85% RH, non-condensing
	Atmospheric pressure	70 kPa to 106 kPa
Accompanying items	Refer to the packing list	

Compliance information

The device complies with the following standards:

Item	Standard
Electromagnetic Compatibility (EMC)	• 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 • IEC 61010-2-010:2019 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials • IEC 60825-1:2014 Safety of laser product part 1: equipment classification and requirements

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Performance specifications

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Manufacturer information

Medical device registration certificate number/Product technical requirement number	
Manufacturer	Wuhan MGI Tech Co., Ltd.
Address	Building 24, Stage 3.1, BioLake Accelerator, No.388, 2nd Gaoxin Road, East Lake High-Tech Development Zone, 430075, Wuhan, P.R.China
Production license number	
Technical support	Wuhan MGI Tech Co., Ltd.
Technical support E-mail	MGI-service@mgi-tech.com

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European representative information

Name	Shanghai International Holding Corp. GmbH (Europe)
Address	Eiffestrasse 80, 20537 Hamburg, Germany

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FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

To assure continued compliance, any changes or modifications not expressly approved by the party.

Responsible for compliance could void the user’s authority to operate this equipment. (Example- use only shielded interface cables when connecting to computer or peripheral devices).

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Radiation Exposure Statement:

The equipment complies with FCC Radiation exposure limits set forth for uncontrolled enviroment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body.

IC Statement

- English: This device complies with Part 15 of the FCC Rules [and contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS standard(s)]. Operation is subject to the following two conditions: (1)this device may not cause harmful interference, and (2)this device must accept any interference received, including interference that may cause undesired operation.

The digital apparatus complies with Canadian CAN ICES-3 (B)/NMB-3 (B).

-French: L'émetteur/récepteurexempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et DéveloppementéconomiqueCanada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

-(1) l'appareil ne doit pas produire de brouillage, et

-(2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

l'appareil numérique du ciem conforme canadien peut - 3 (b) / nmb - 3 (b).

This device meets the exemption from the routine evaluation limits in section 2.5 of RSS 102 and compliance with RSS 102 RF exposure, users can obtain Canadian information on RF exposure and compliance.

cet appareil est conforme à l'exemption des limites d'évaluation courante dans la section 2.5 du cnr - 102 et conformité avec rss 102 de l'exposition aux rf, les utilisateurs peuvent obtenir des données canadiennes sur l'exposition aux champs rf et la conformité.

This equipment complies with Canada radiation exposure limits set forth for an uncontrolled environment.

RF Exposure Statement

This equipment should be installed and operated with minimum distance 20cm between the radiator and your body.

Déclaration d'exposition aux radiofréquences

Lors de l'installation et de l'utilisation de cet appareil, la distance entre le radiateur et le corps doit être d'au moins 20 cm.

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