

KingFisher™ Apex Dx Purification Instrument

INSTRUCTIONS FOR USE | IVD

Catalog Number B5400900P

Document Part Number 100123011

Publication Number MAN0030020

Revision A.0



For In Vitro Diagnostic Use.



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Revision history: MAN0030020 A.0 (English)

Revision	Date	Description
A.0	13 October 2023	New document for KingFisher™ Apex Dx Purification Instrument for Australia.

The information in this guide is subject to change without notice.

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Product information

Product description

The Thermo Scientific™ KingFisher™ Apex Dx Purification Instrument is intended for automated transfer and processing of magnetic particles in a microplate format. The instrument utilizes magnetic heads covered with a disposable, specially designed tip comb, and plates. The instrument functions without any dispensing or aspiration parts or devices. Before the run, samples and reagents (including magnetic particles) are dispensed into the plate according to default, uneditable or uncustomizable *in vitro* diagnostic (IVD) protocols.

For the product information sheet on the magnetic heads or the quick reference card on instrument installation see the following documents:

- *KingFisher™ Apex Dx Heads Product Information Sheet* (Pub. No. MAN0029197)
- *KingFisher™ Apex Dx Purification Instrument Quick Reference* (Pub. Part No. 100109527)

Intended use

The KingFisher™ Apex Dx Purification Instrument is intended to automate the process of isolation and purification of nucleic acids, proteins and cells for *in vitro* diagnostics (IVD) procedures in combination with a dedicated purification kit. The instrument is intended for use by professional users, such as technicians and physicians trained in molecular biological techniques.

Ordering configurations

The KingFisher™ Apex Dx Purification Instrument is available to order in combination with one of four different magnetics heads as outlined in the following table. The following catalog numbers are used for customer ordering purposes only.

Details	Cat. no.	Cat. no. B5400910	Cat. no. B5400920	Cat. no. B5400930	Cat. no. B5400940
Instrument					
KingFisher™ Apex Dx Purification Instrument	B5400900P	1	1	1	1
Components of instrument					
UV lamp	N21447	2	2	2	2
3-mm flat-tip driver	MLS	1	1	1	1

(continued)

Details	Cat. no.	Cat. no. B5400910	Cat. no. B5400920	Cat. no. B5400930	Cat. no. B5400940
Heating blocks					
PCR Heating Block	24075910	1	—	—	—
96 Heating Block	24075920	1	1	1	—
96 Deep Well Heating Block	24075930	—	1	1	—
24 Deep Well Heating Block	24075940	—	—	—	1
Magnetic heads					
KingFisher™ Apex Dx 96 PCR Head	B24079910	1	—	—	—
KingFisher™ Apex Dx 96 Combi Head	B24079920	—	1	—	—
KingFisher™ Apex Dx 96 Deep Well Head	B24079930	—	—	1	—
KingFisher™ Apex Dx 24 Combi Head	B24079940	—	—	—	1

Product overview

Instrument overview

The KingFisher™ Apex Dx Purification Instrument consists of a touch screen control and a process chamber with lid to protect specimens and processing plates against environmental contamination.

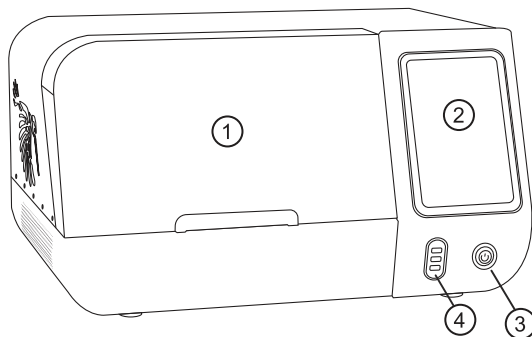


Figure 1 KingFisher™ Apex Dx Purification Instrument front view

- ① Front lid
- ② Touch screen
- ③ On/off button
- ④ USB port × 3 (Host)

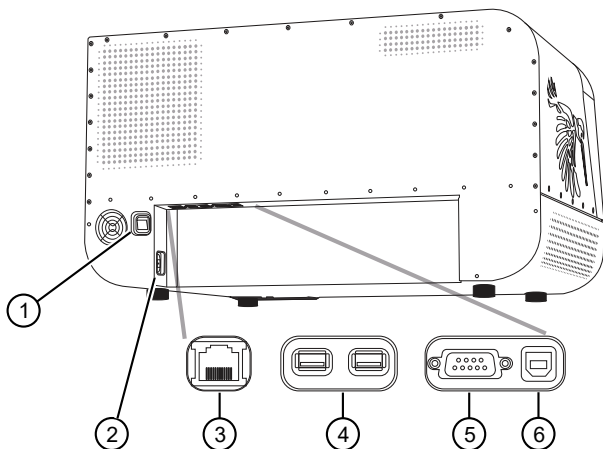


Figure 2 KingFisher™ Apex Dx Purification Instrument rear view

- ① Power switch
- ② Power inlet
- ③ Ethernet/LAN port
- ④ USB port (Host) × 2
- ⑤ RS-232 serial port
- ⑥ USB port (Device)

Internal layout

The process chamber of the KingFisher™ Apex Dx Purification Instrument consists of a turntable with eight plate stations. The loading position has an illuminated display, while the processing position is situated over the heating block and underneath the processing head. There are two heating block stations under the turntable (not shown on picture) that can be selected for applying to the processing position.

The processing head consists of two vertically moving platforms—the magnetic head holder, and the tip comb holder. The magnetic head holder is used to attach up to two magnetic heads composed of 24 or 96 magnetic rods, while the tip comb holder is used to hold plastic tip combs with 24 or 96 tips.

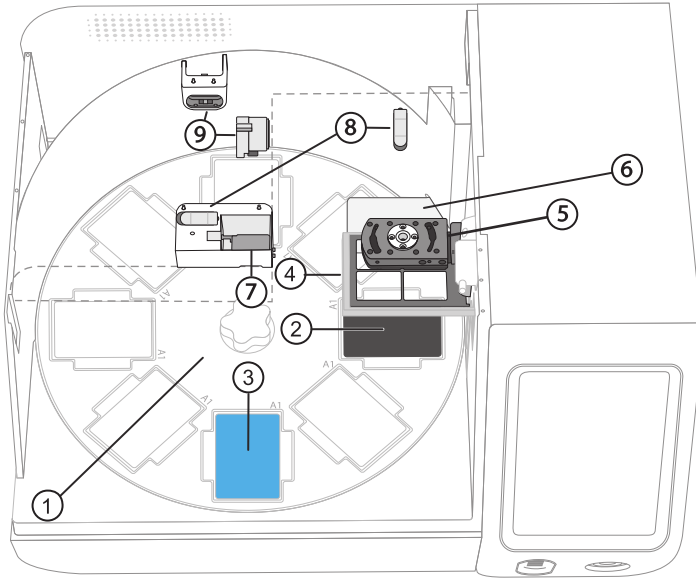






Figure 3 Process chamber layout

- ① Turntable with plate stations (1–8)
- ② Processing position
- ③ Loading position
- ④ Tip comb holder
- ⑤ Magnetic head holder
- ⑥ Shield plate
- ⑦ Barcode reader
- ⑧ UV light clip × 2
- ⑨ UV light socket × 2

User interface overview

Symbol	Function
Notifications screen (For more details, see “Home screen” on page 29)	
	Swipe down from the top of the touch screen Displays the following information: <ul style="list-style-type: none"> • Notifications • Internet status • Storage devices

(continued)

Symbol	Function
Menu screen (For more details, see “Menu screen” on page 30)	
	<p>Select Menu</p> <p>Gives access to the following items:</p> <ul style="list-style-type: none"> • Home • Run history • Import/Export • Settings • Instrument • User management
Settings screen (For more details, see “Settings screen” on page 30)	
	<p>Select Menu ▶ Settings</p> <p>Gives access to the following items:</p> <ul style="list-style-type: none"> • Localization • Protocols • Sound • Loading position display • Network share • About • Reset factory settings • Troubleshoot • View EULA
Instrument screen (For more details, see “Instrument screen” on page 35)	
	<p>Select Menu ▶ Settings</p> <p>Gives access to the following items:</p> <ul style="list-style-type: none"> • Tools • Magnets • Heating blocks

General login functionality description

The KingFisher™ Apex Dx Purification Instrument has a login functionality. The user can log in to the instrument locally or via Security, Auditing, and E-Signature (SAE) server (if Applied Biosystems™ Diomni™ Software and SAE integration is enabled). See “Enable Diomni™ Software and SAE integration” on page 26.

The instrument has two modes: research use only (RUO) and IVD. The purpose of this instructions for use is solely for IVD mode. The IVD mode is available when logged in locally or via SAE.



When the instrument is used by logging in locally, only locally available IVD protocols can be used and are not customizable.

When the instrument is used while logged in via SAE, the usage is limited to work with **Run** tasks created through Diomni™ Software. The IVD **Run** tasks are available in IVD mode. The user can switch between Local-Login and SAE-Login (if enabled).

Upon receiving the device

- Visually inspect the transport package, the instrument and the accessories for any damage incurred during transit.
- If the carton has been damaged in transit, it is particularly important that you retain it for inspection by the carrier in case there has also been damage to the instrument.
- Any damage claims must be filed with the carrier. Neither the manufacturer nor its agents can be held responsible for any damage incurred in transit. Upon receipt of the carrier's inspection report, arrangements will be made for repair or replacement.

Precautions for use



CAUTION! PHYSICAL INJURY HAZARD. Do not remove the instrument cover. There are no components inside the instrument that you can safely service yourself. If you suspect a problem, contact technical support.



CAUTION! PHYSICAL INJURY HAZARD. The instrument weighs 56 kg (123 lbs) and requires at least two people to lift. Use the proper precautions when lifting the instrument to avoid injury..



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the heating block temperature can reach 100°C. Allow it to cool to room temperature before handling.



CAUTION! Before using a cleaning or decontamination method other than those recommended by Thermo Fisher Scientific, confirm with Thermo Fisher Scientific that the proposed method will not damage the instrument. See “Decontaminate instrument” on page 44.

Magnetic heads



WARNING! This product contains very strong permanent magnets. People wearing a pacemaker or metallic prosthesis should not use this product. A pacemaker or prosthesis may be affected or damaged if it comes in close contact with a strong magnetic field.

There are four kinds of interchangeable magnetic heads with corresponding disposable plastic tip combs available for the instrument. The magnetic head holder has two positions that can be used to hold different types of magnetic heads.

IMPORTANT! Keep magnetic heads away from each other and other magnets at all times. Clashing of the magnets can cause serious damage to the magnets.

- Do not place the magnetic head on top of the instrument or on any metal surfaces.
- Do not use metal tools when handling magnetic heads.
- Do not place the magnetic head in close proximity to magnetic tapes, computer discs or other magnetic storage systems, such as credit cards, as damage can occur due to the strong magnetic field of the magnetic heads.
- Do not place the magnetic heads near a PC display, as this may cause damage to the display.
- When not in use, keep the magnetic heads in their respective storage boxes.
- For details on changing a magnetic head, see “Change heat block/magnetic head” on page 23.

Guidelines for unpacking the instrument

- To prevent condensation, the instrument should be left in its protective, antistatic plastic wrapping until the ambient temperature has been reached.
- Retain the original packaging and packing material for future transportation. The packaging is designed to assure safe transport and minimize transit damage. Use of alternative packaging materials may invalidate the warranty. Also retain all instrument-related documentation provided by the manufacturer for future use.

First time instrument setup

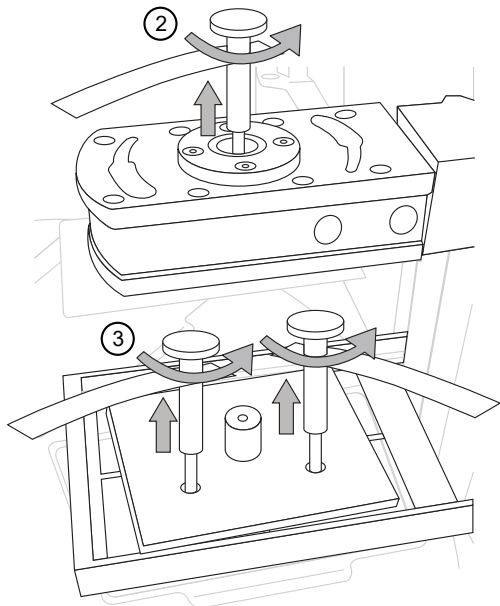
The initial installation and initial operational check (IQ/OQ) must be performed by FSEs. Content should be retained for the instances where there is an emergency by the end user.

1. Connect the power supply cable to the power inlet.

The instrument operates at voltages of 100–240 VAC and the frequency range of 50/60 Hz. Ensure that the local supply voltage in the laboratory conforms to that specified on the type label on the back of the instrument

2. Remove the transport lock screw from the magnet holder.

3. Remove the transport lock screws from the transport lock plate over the tip comb holder.

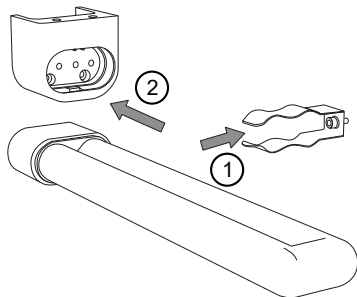


4. Remove the upper transport lock plate, then lift the tip comb holder and remove the lower transport lock plate.

Do not discard the parts of the transport lock. The lock is required in case of future transportation of the instrument (see “Store transport lock” on page 43).

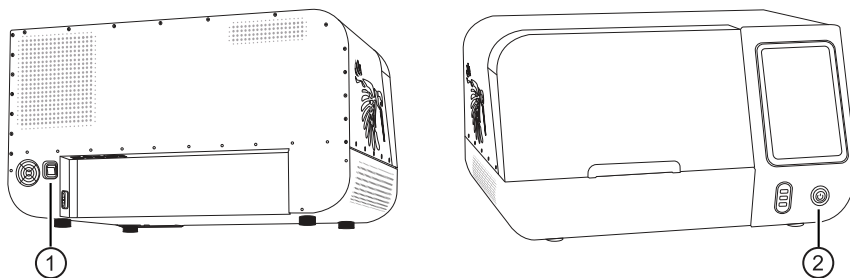
Install the UV light bulbs

1. Insert the UV light bulb into the light clip.
2. Slide the light bulb back and into the light socket.



Power on the instrument

1. Turn on the power switch at the rear of the instrument.
2. Press the on/off button to turn on the instrument.



Log in to KingFisher™ Apex Dx Purification Instrument for first time as administrator

1. At initial login, create username and password for administrator.

Note: Create a username and password that contains at least six characters, and may contain upper- and lower-case letters, numbers, and special characters. Not all characters are supported.

IMPORTANT! Only the administrator can create and modify the other user roles.

2. Read the license agreement, then select accept.
3. Choose region.
4. Set date, time, and other selectable options

IMPORTANT! The time set here will be applied in the logging and reporting functions.

5. On the Mode selection screen, select IVD mode.

Note: After IVD mode is selected, a new window should open.

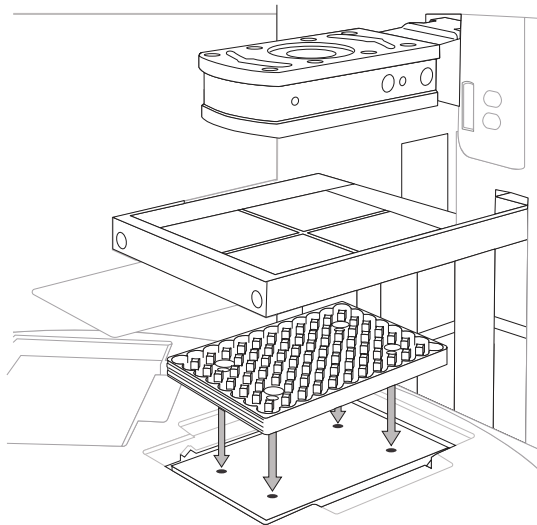
Install heating block

1. Select **Menu ▶ Instrument**.
2. In the Heating blocks section, select **Insert** for the position (1 or 2). The system will present the heating block station to allow the user to install the heating block.
3. Scan the heating block to be installed by facing the heating block barcode sticker approximately 8–10 cm from the barcode reader inside the process chamber.

Note: Alternatively, select the heating block to be installed manually from the list shown on the screen menu.

4. Place the heating block on the heating block station. Fit the pins on the block into the slots of the station. Press the block down until it clicks properly into position.

Note: Select **Information** for details on heating block installation.



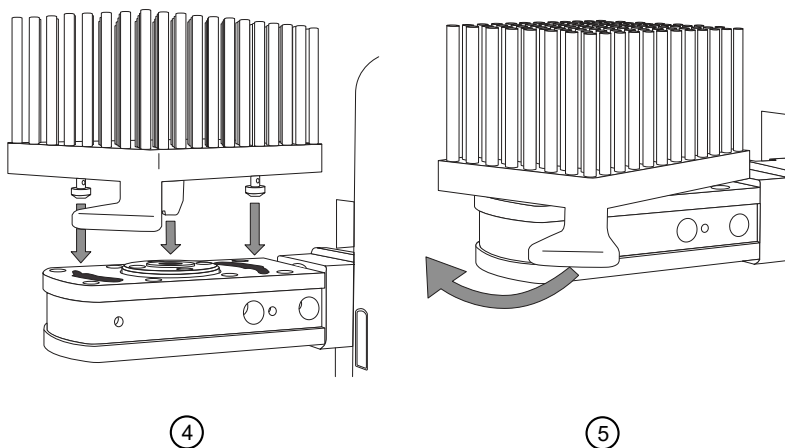
5. Select ✓.

Install magnetic head

1. Select **Menu ▶ Instrument**.
2. Select **Insert** for the position (1 or 2) to install the magnet.
3. Scan the magnetic head to be installed with the barcode reader or perform manual selection with the menu.
4. Place the magnetic head onto the holder. Fit the pins on the head into the slots in the holder.

5. Turn the handle to lock the magnet in place.

Note: Select **Information** for details on magnetic head installation.



6. Select ✓.

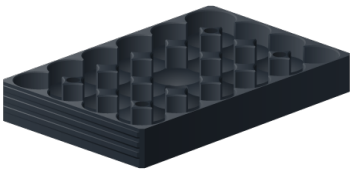
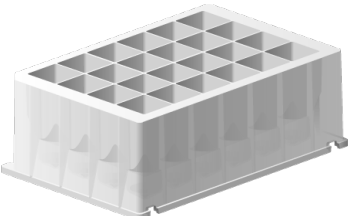
Instrument components and plastic compatibility

Heating block and compatible plate

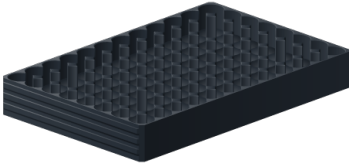
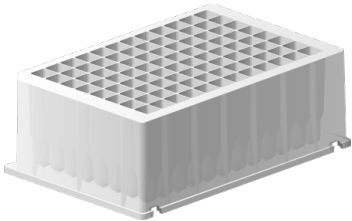
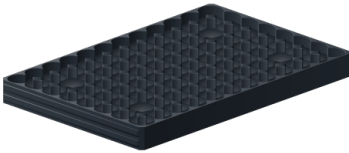
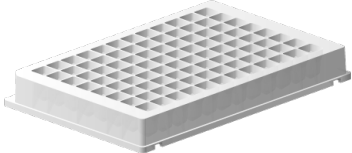
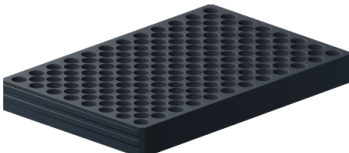

The instrument uses specially designed barcoded plates for optimal processing. Use of other types of plates may damage the instrument and compromise the warranty, as well as result in below optimal performance.

The heating blocks are specifically designed for the plates listed in the following table to ensure even heating during sample processing.

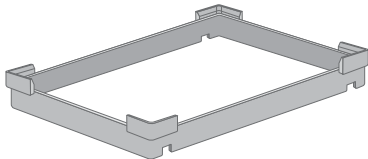
For details on changing a heating block, see “Change heat block/magnetic head” on page 23.

Heating block	Plate
	
KingFisher™ Apex 24 Deep Well Heating Block, barcoded (Cat. No. 24075940)	KingFisher™ 24 Deep Well Plate, barcoded (30 µL to 5 mL ^[1] , Cat. No. 95040470B)

(continued)

Heating block	Plate
	
<p>KingFisher™ Apex 96 Deep Well Heating Block, barcoded (Cat. No. 24075930)</p>	<p>KingFisher™ 96 Deep-Well Plate, barcoded (15–1000 μL ^[1], Cat. No. 95040450B)</p>
	
<p>KingFisher™ Apex 96 KF Heating Block, barcoded (Cat. No. 24075920)</p>	<p>KingFisher™ 96-Well Microplate, barcoded (15–200 μL ^[1], Cat. No. 97002540B)</p>
	
<p>KingFisher™ Apex PCR Heating Block, barcoded (Cat. No. 24075910)</p>	<p>PCR plate (10–80 μL ^[1]), skirted (Cat. No. AB2396 ^[2])</p>

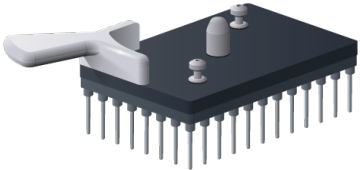
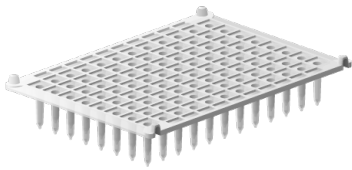
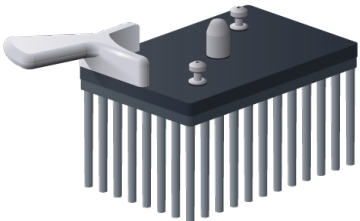
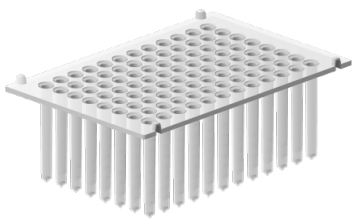
(continued)

Heating block	Plate
Adapter	
	
KingFisher™ Apex 96 PCR Semiskirted Plate Adapter (Cat. No. N21446) or semi-skirted (Cat. No. AB2496) ^[1]	

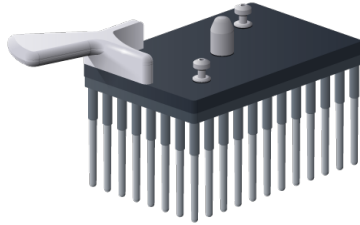
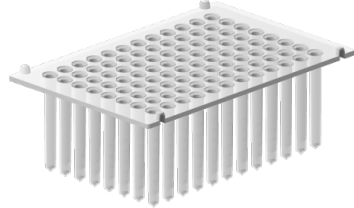
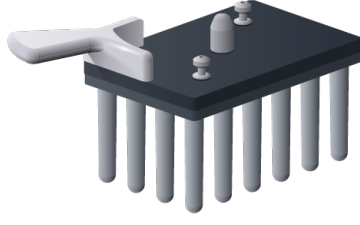
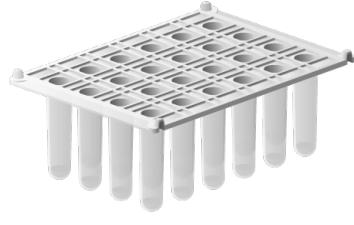
^[1] The fill volume depends on the type of tip comb being used.

^[2] Recommended PCR plate

Magnetic head

Magnetic head	Tip comb
	
KingFisher™ Apex Dx 96 PCR Head, barcoded (Cat. No. B24079910)	KingFisher™ 96 PCR Tip Comb, barcoded (Cat. No. 97002560)
	
KingFisher™ Apex Dx 96 Deep Well Head, barcoded (Cat. No. B24079930)	KingFisher™ 96 Tip Comb for Deep Well Magnets, barcoded (Cat. No. 97002534B)

(continued)

Magnetic head	Tip comb
	
<p>KingFisher™ Apex Dx 96 Combi Head, barcoded (Cat. No. B24079920)</p>	<p>KingFisher™ 96 Combi Tip Comb, barcoded (Cat. No. 97002570)</p>
	
<p>KingFisher™ Apex Dx 24 Combi Head, barcoded (Cat. No. B24079940)</p>	<p>KingFisher™ 24 Deep Well Tip Comb, barcoded (Cat. No. 95040470B) (also KingFisher™ 24 Combi Tip Comb, barcoded)</p>

Tip comb and plate compatibility

Tip comb	Compatible plates
<p>KingFisher™ 96 Tip Comb for Deep Well Magnets (Cat. No. 97002534B)</p>	<p>KingFisher™ 96 Deep Well plate (Cat. No. 95040450B) KingFisher™ 96-Well Microplate (Cat. No. 97002540B)</p>
<p>KingFisher™ 96 Combi Tip Comb (Cat. No. 97002570)</p>	<p>KingFisher™ 96 Deep Well plate (Cat. No. 95040450B) KingFisher™ 96-Well Microplate (Cat. No. 97002540B)</p>
<p>KingFisher™ 24 Deep Well Tip Comb (Cat. No. 97002610B)</p>	<p>KingFisher™ 24 Deep Well plate (Cat. No. 95040470B)</p>
<p>KingFisher™ 24 Combi Tip Comb (Cat. No. 97002580)</p>	<p>KingFisher™ 24 Deep Well plate (Cat. No. 95040470B)</p>
<p>KingFisher™ 96 PCR Tip Comb (Cat. No. 97002560)</p>	<p>PCR plate, skirted (Cat. No. AB2396) PCR plate, semi-skirted (Cat. No. AB2496) KingFisher™ 96-well Microplate (Cat. No. 97002540)</p>

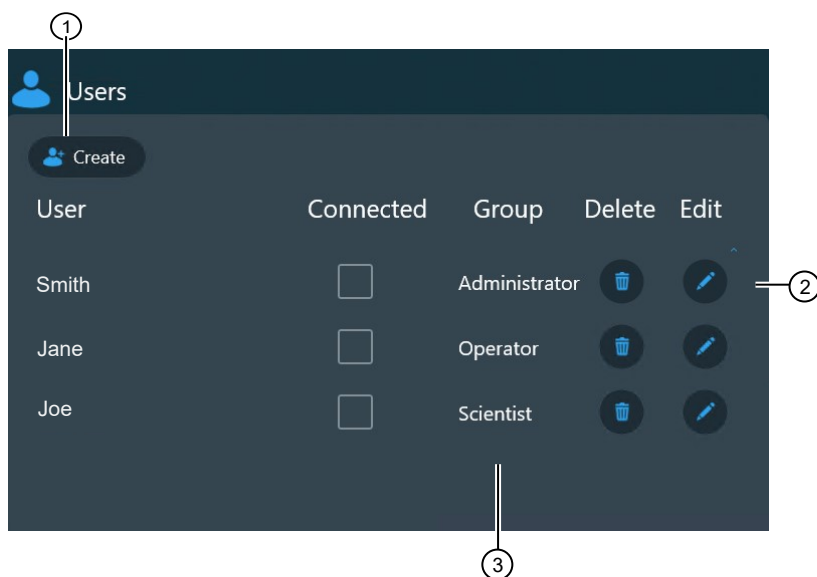
Change password

1. Select **User Settings** from Menu.
2. Click the **Change the password** tab.
3. Enter your current password, then enter the new password twice.
4. Click **Confirm** or exit without changing the password.

Create, edit, or delete users

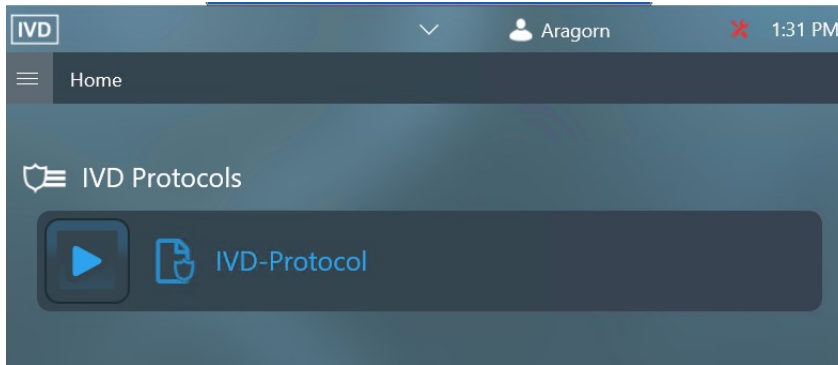
To create a new user, you must be logged in as Administrator.

1. Click **Create** tab and select the user role from a drop-down menu.
2. To delete or edit the user, click the trashcan or pencil icons.
3. The **Groups** window shows the privileges of the three user groups. Click the Administrator, Operator, or Scientist icon to view the privileges for each group (see “Users and roles” on page 26).




Access IVD protocol and load to instrument memory

The available protocols appear as a list under **IVD Protocols** heading.

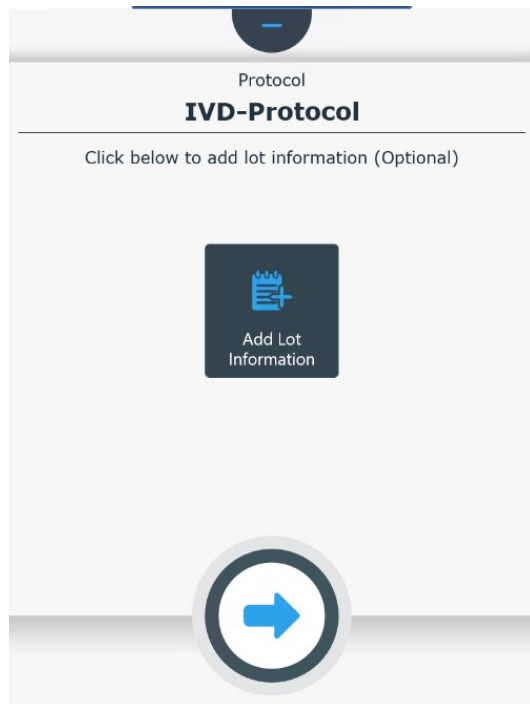


Run purification kit

1. Prepare reagents and samples and place them in the appropriate plates according to the instructions for your kit of choice.
2. Select a protocol from IVD Protocol list and press  on the **Home** screen.

Note: A new window will open.




3. Click **Add Lot information** to select and insert a Tip Plate.



4. (Optional) Enter lot information for reagents in the **Description** field.

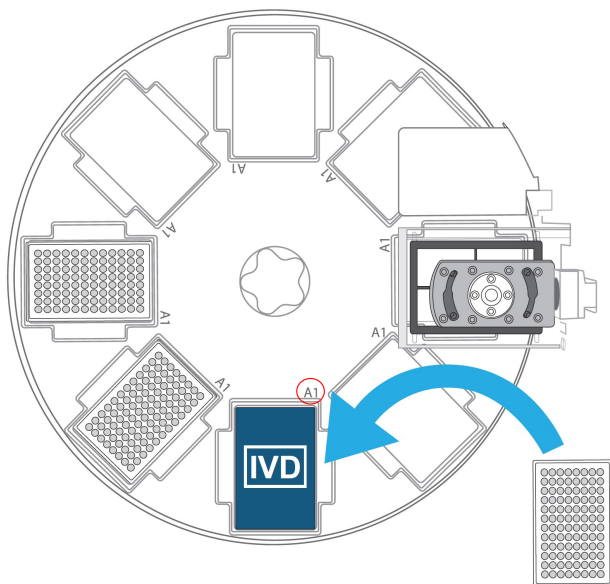
Note: All data entered at this step will appear in the run report.

5. (Optional):

- Select  to hide (if protocol run has been started) or cancel (if protocol run has not yet been started) protocol run, then return to the selection screen.
- Select  to cancel the run once it has been started.
- Select  to end the run completely.

6. Load the appropriate plates into the instrument on the lighted loading position as prompted by the instructions displayed on the touch screen.

IMPORTANT! When loading plates, ensure that the A1 position of plate aligns with the A1 position indicated on the plate stations of the turntable in the instrument.



7. After each requested plate is loaded into the instrument, press **Next**.
8. If a barcode of the plate is not detected, manually select the plate.

Note: The run starts automatically after all the required plates are placed in the instrument.


9. Close the front lid to protect the instrument against environmental contamination.
10. Wait for the instrument to complete the IVD protocol.

Note: The instrument will prompt the user to unload the plates.

11. Open the front lid and unload the processing plates from the turntable following the instructions provided by the instrument.

12. (Optional) Review the run report (see “Run history overview” on page 37).
13. (Optional) Export the report to a USB memory device (see “Export run report” on page 37).
14. (Optional) Use the UV lamp to decontaminate the process chamber.

Abort run

Icon	Function
	Abort a protocol that is in progress.

Turn off the instrument

1. On the Home screen, select **User Settings**, then click **Logout** to log off from the instrument.
2. Return to the Local-Login screen.
3. Press the power switch to turn off the instrument.

Change heat block/magnetic head

Heat blocks and magnetic heads can be changed depending upon the needs of the protocol. Access the **Instrument** screen (see “Instrument screen” on page 35) to unload an existing heat block/magnetic head, and install a different heat block/magnetic head in their place.

Unload heating block

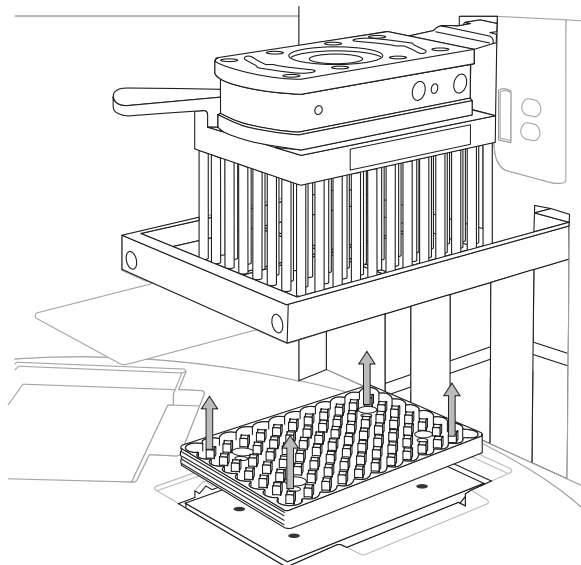
1. Select **Menu ▶ Instrument**.
2. Select **Unload** for the position (1 or 2) you want to remove the heating block from.



WARNING! The heating block surface may be hot during operation. Use caution to avoid risk of burns.

3. Lift the heating block up to remove it from the heating platform.

Note: Select **Information** for details on heating block removal.



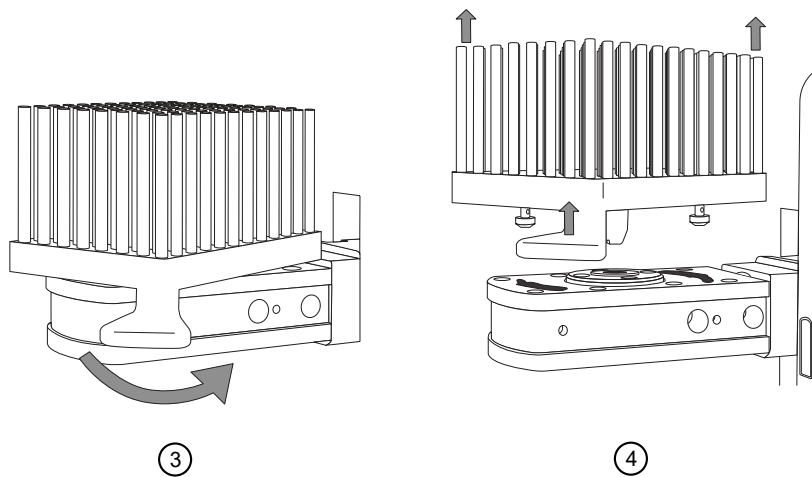
4. Select ✓.

Unload magnetic head

1. Select **Menu** ▶ **Instrument**.
2. Select **Unload** for the position (1 or 2) you want to remove the magnet from.
3. Turn the handle to release the magnet.

- Lift the magnetic head from the holder.

Note: Select **Information** for details on magnetic head removal.



- Select ✓.



Software applications

About the user interface

The KingFisher™ Apex Dx Purification Instrument has a login functionality. You can log in to the instrument locally or via SAE server (if Applied Biosystems™ Diomni™ Software and SAE integration is enabled).

When the instrument is used after logged in locally, the user (with scientist or administrator privileges) can run and import IVD protocols. It is not possible to create or modify IVD protocols.

When IVD mode is used after logged in through SAE (Diomni™ Software and SAE connected), the usage is limited to working with IVD **Run** tasks initiated through Diomni™ Software.

Users and roles

There are three different user roles, each with different rights in the KingFisher™ Apex Dx Purification Instrument:

- **Administrator:** The administrator has no limitations for instrument use. The administrator can create, modify, and delete other roles. The administrator can change the network share and software settings.
- **Scientist:** The scientist can run and view protocols. The scientist can't edit shared network settings or reset the factory defaults (e.g. change instrument name or modify users).
- **Operator:** The operator can run, view the protocols and reports, and can export a troubleshooting package. The operator cannot delete run reports or protocols, access the Import/Export view, or edit the settings.

The IVD mode only allows users to run IVD protocols and view reports.

Diomni™ and SAE integration

This setting is disabled by default.

You must be logged in as local administrator to RUO mode to enable Diomni™/GSD-SAE integration.

Enable Diomni™ Software and SAE integration

1. Contact local IT to define a network path to a shared folder (base directory).
2. Enter the network path to the field.

Note: Network share cannot be used at the same time Diomni™ integration is enabled.

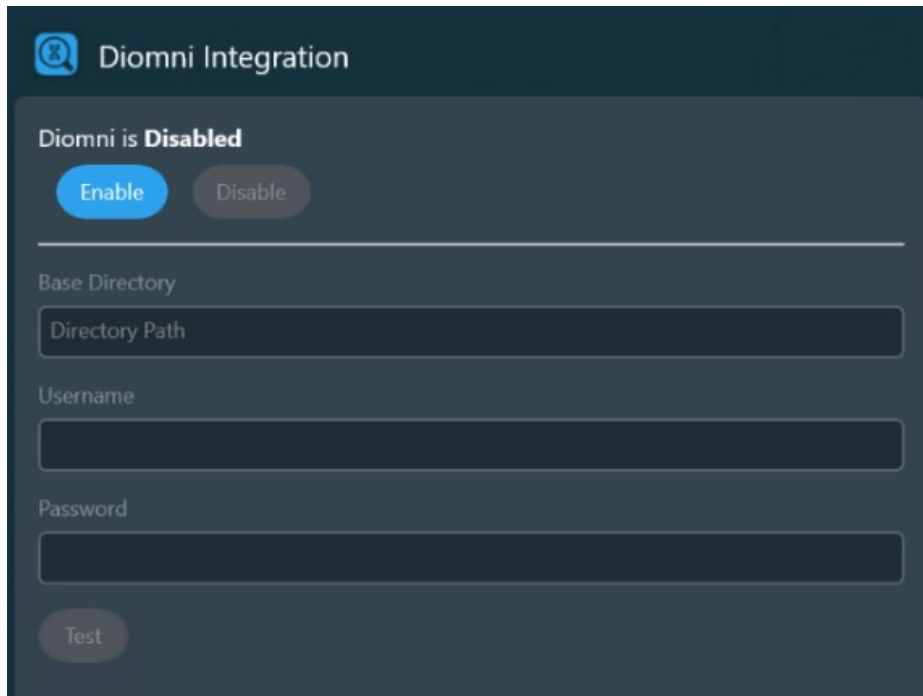
3. If required, enter the SMB username and password for accessing base directory.

4. Click **Test** to initiate verification that the instrument has the required permissions to the base folder.

Note: If any test ends in an error, the verification fails. An error report is displayed.

5. If the shared folder test is successful, then the following settings are available for GSD-SAE:
 - SAE server IP address
 - SAE server TCP port number

Note: The settings are not available by default.



The screenshot shows a dark-themed settings window titled "Diomni Integration". At the top, it says "Diomni is Disabled" with two buttons: "Enable" (highlighted in blue) and "Disable" (greyed out). Below this is a section for "Base Directory" with a text input field containing "Directory Path". Underneath are two more text input fields labeled "Username" and "Password". At the bottom left, there is a "Test" button.

Test SAE server settings

1. Click **Test SAE** to test the SAE server settings.
2. If the tests are successful, the **Apply** button is enabled.

Note: If an error occurs during the SAE server settings test, an error report is displayed.

3. Click **Apply**.

Note: A prompt window with a notification text appears: "Please note. You will be logged out in order to apply SAE settings."

- Click **OK** to confirm. Click **Cancel** to modify the settings.

Note: After the confirmation you are logged out and cannot modify the settings

IVD mode (local)

When the IVD mode is selected, it is possible only to run IVD protocols, it is not possible to create new protocols.

All protocols must be imported to the instrument using the **Import / Export** function. Note that the protocols are saved in the base directory.

The **scientist user** can run protocols, view the run history, import / export protocols, and change some basic settings.

The operator user cannot use the **Import / Export** function.

Switch instrument mode

The instrument mode can be switched in the **User Settings** tab.

- Click your own user profile tab, located below **Settings** in the Toolbar column.
- Click the **Switch mode** tab to return to **Select modes** screen.

Overview of user interface controls

Home screen

The **Home screen** on the KingFisher™ Apex Dx Purification Instrument instrument is used to select or run protocols.

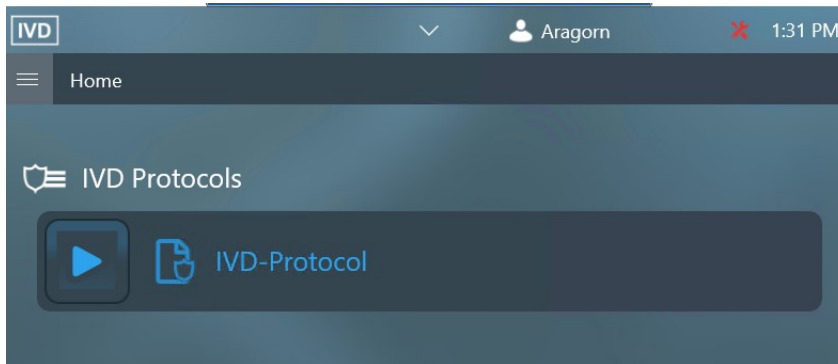
When the IVD mode is selected, it is possible only to run IVD protocols, it is not possible to create new protocols. All protocols must be imported to the instrument using the Import / Export function. Note that the protocols are saved in the base directory.

In the IVD **Home** screen, the following are available for the user with administrator role:

- Run history
- Import / Export
- Instrument
- Settings
- User profile

The user with scientist role can run protocols, view the run history, import, and export protocols, and change some basic settings.

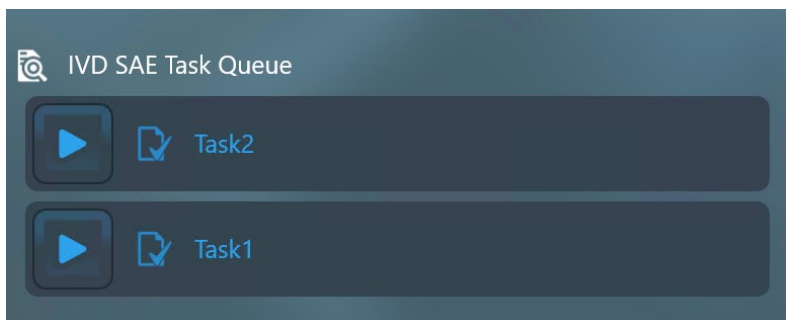
The user with operator role cannot use the **Import / Export** function.



Run protocol from Home screen

The **Home** screen shows the IVD SAE Task Queue.

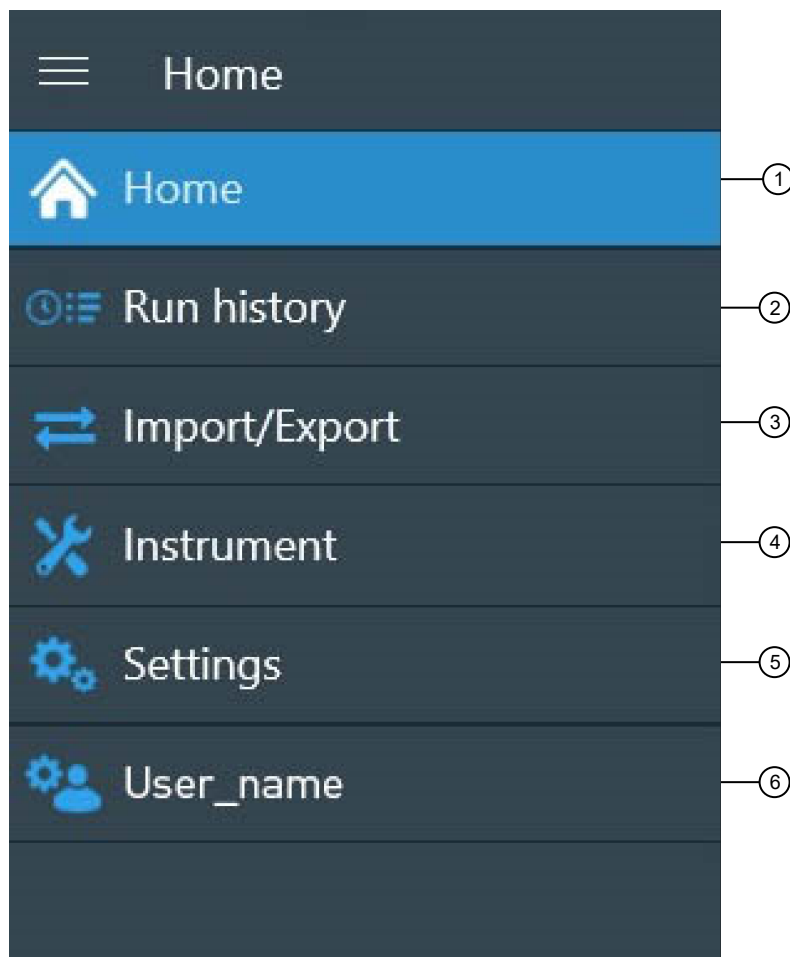
Select a task from the task queue list to run a protocol.



Menu screen

The **Menu screen** is the primary means of navigation between screens for the different applications on the instrument.

Use the **Menu screen** to exit from, or return to a screen.



- ① Return to **Home screen**.
- ② Access **Run history screen**
- ③ Access **Import/Export screen**
- ④ Access **Instrument screen**
- ⑤ Access **Settings screen**
- ⑥ Access **User name screen**

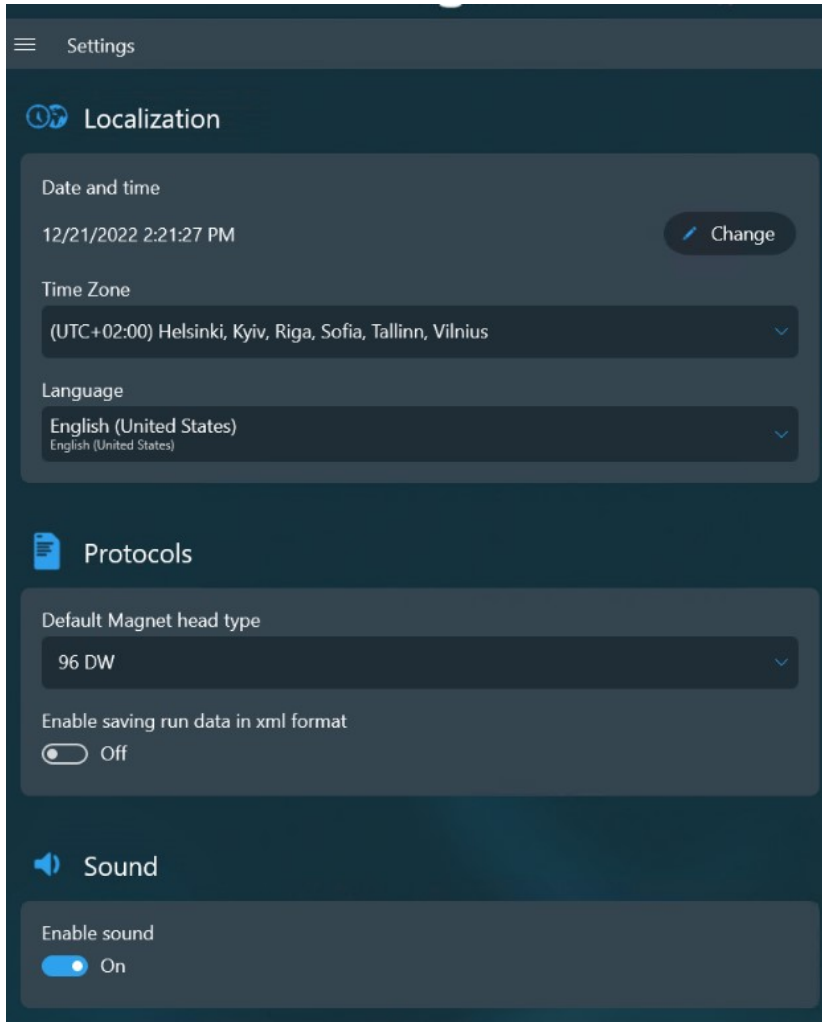
Settings screen

The **administrator user** and **scientist user** can modify these settings in the **Settings screen**:



- Date and time
- Language
- Select the default magnet head type
- Enable/Disable saving run data in xml format

- Sound on/off
- Setting the logout time in minutes


Localization settings



Set date and time

1. Select  **(Change)** under **Date and time**
2. Scroll through the numerical menus to select the time and date.
3. Select .

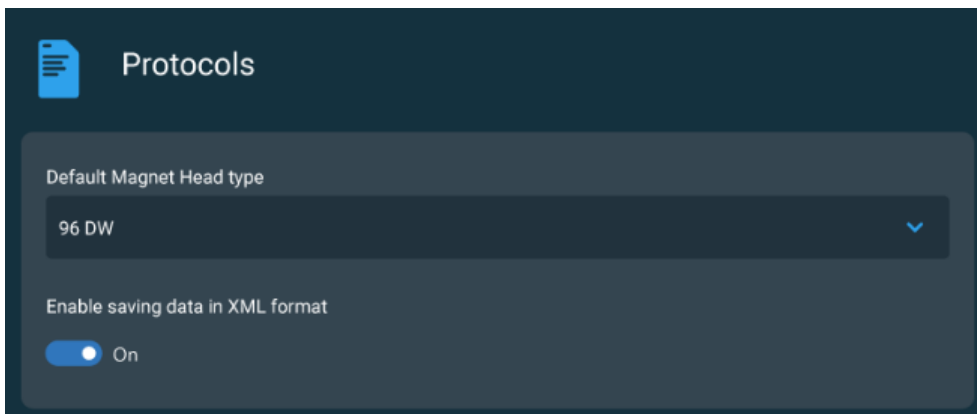
Set time zone

1. Select the **Time zone** field to open the drop down menu.
2. Scroll to the desired time zone.
3. Select .

Set language

1. Select the **Language** field to open the drop down menu.
2. Select the desired language.
3. Select ✓.

Protocol settings



Set default magnetic head type

1. Select the **Default magnet head type** field to open the drop down menu.
2. Select the desired magnetic head (96 DW, 96 Combi, 24 Combi, 96 PCR).
3. Select ✓.

Enable saving run data in extensible markup language (XML) format

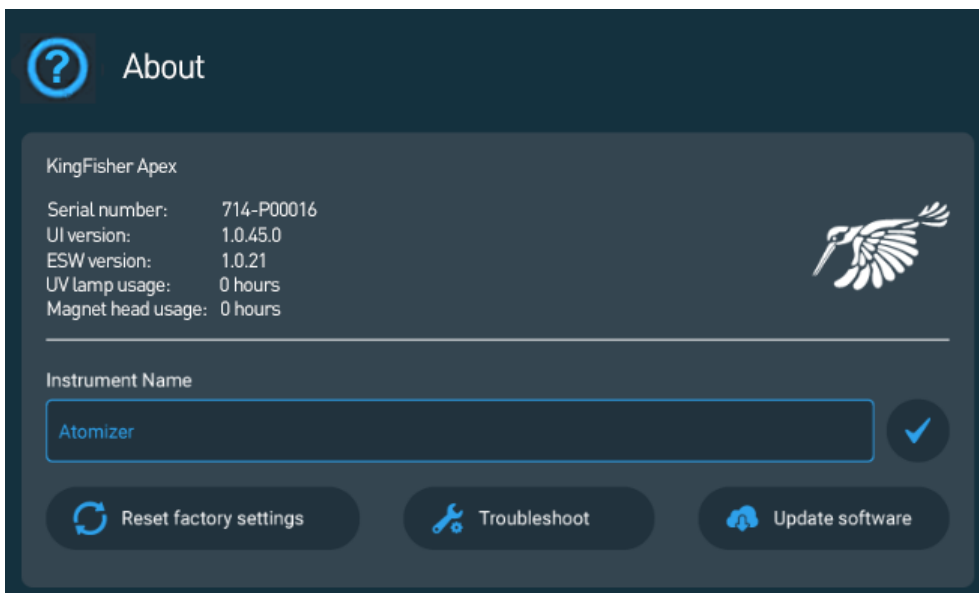
When enabled, a report in structured xml format is saved in addition to the portable document format (PDF) report. The structured XML format can be used for purposes such as LIMS integration.

Switch the toggle to allow run data to be saved in XML format.

Sound settings



About



About (?) displays instrument information, including instrument serial number, software versions, and usage information.




All users can change the instrument settings.

Set instrument name



1. Select the **Instrument name** field to access the keyboard.
2. Enter a name for the instrument.
3. Select ✓.

Reset factory settings

Performing a reset will restore all setting parameters to the factory defaults. All Connect user and instrument links are removed, but locally stored protocols and run reports are retained.

1. Select  **Reset factory settings**.
2. Select  to reset, or  to cancel.

Download instrument data to troubleshoot

1. Select  **Troubleshoot**.
2. Place a USB memory device into a USB device port.
3. Select  to download data.

View end-user license agreement (EULA)

Select **View EULA** to see licensing information for use of the instrument operating software.

User settings

The **operator user** cannot change any settings.

The **scientist user** can change the following settings:

- Date, time, and language
- Enable / disable saving run data in xml format
- Sound on / off
- Loading position display on / off

All users can export troubleshooting package. The instrument prompts to insert USB memory into the device before proceeding with troubleshooting.

Only the **administrator user** can change the Diomni integration settings.

Instrument screen

The **Instrument screen** is the main control panel for manual operation of the instrument.



- ① Move the turntable counterclockwise.
- ② Move the turntable clockwise.
- ③ Perform check to ensure that tip combs are properly aligned with magnetic head.
- ④ Manually release tip comb from magnetic head.
- ⑤ Enable installation of transport lock.
- ⑥ Turn UV light on/off.
- ⑦ Unload magnetic head (See “Unload magnetic head” on page 24).
- ⑧ Insert magnetic head (See “Install magnetic head” on page 15).
- ⑨ Unload heating block (See “Unload heating block” on page 23).
- ⑩ Insert heating block (See “Install heating block” on page 15).

Protocol overview

A protocol is a set of instructions that the instrument uses to perform a sample processing procedure. The protocol is a collection of information regarding the layout of with reagent data and procedure steps done in a session as well as the instrument used. This information is also used to create a run report (see “Run history overview” on page 37).

The IVD protocol appears as a file with a .kfdx file extension. IVD protocols can be only viewed but not modified.

Import/Export overview

The **Import/Export** function is used to import protocols to, and export protocols from the instrument using a USB memory device.

This function can be used to create copies of instrument protocols for data backup purposes.

IMPORTANT! Please contact Technical Support for Thermo Fisher-developed IVD reagents and protocols.

Please contact Technical Support to secure a protocol compatible with IVD mode.

Import protocol from a USB memory device

1. Insert a USB memory device containing your protocol into a USB port on the instrument.
2. Select the protocol that you want to import to the instrument.
3. Select **↑** to import the protocol.

Note: For automation interface use of a protocol, it needs to be enabled. Click protocol in protocol list to enable use.

Export protocol to a USB memory device

1. Insert a USB memory device into a USB port on the instrument.
2. Select the protocol that you want to export from the instrument.
3. Select **↓** to export the protocol.

Run history overview


The **Run history** tab shows the recent protocol runs, also the protocols that were aborted or stopped because of an error occurred.

When a protocol is executed, a run report with run-specific information is created. User provided run information must be entered before protocol execution, and includes such information as sample data and consumable lot numbers.



After the protocol has been executed, you can view the run log. The report also contains information on individual steps and the plate layout.

You can save the exported report in xml or pdf format.

Export run report

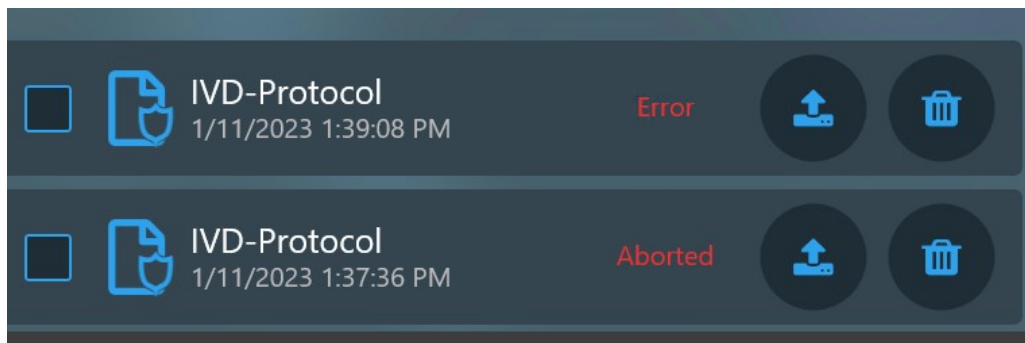
1. Insert a USB memory device into a USB port on the instrument.
2. Click  to run a report export.

Delete run report

1. Select the row containing run report that you want to delete.
2. Select  to delete the protocol.
3. Select  to confirm deletion.

Search runs

1. You can search runs by name by typing the name in the search window
2. You can add or remove a tick box by clicking on the sign next to the search field.



Telemetry data

Statistical data is collected so that the instrument can be developed to better serve the actual needs of the users. The collected data is not connected to single users, and users do not have access to the statistical data.

When the instrument is connected to the cloud, all the statistical data that has been collected until that time is sent to Thermo Fisher Scientific.

To prevent the sending of statistical data, go to **Settings ▶ Thermo Fisher Cloud** and set **Upload telemetry data to cloud** to off.

Note: Other data might be collected by Thermo Fisher Scientific, as stated in its Terms of Use.

When the instrument is connected to Connect, the following data is collected.

- Executed protocol count with after cooling [integer]
- Executed protocol heat block configuration
 - single block count [integer]
 - dual block count [integer]
- Executed protocol magnet configuration
 - single magnet count [integer]
 - dual magnet count [integer]
- Executed protocol application type (count of each type [integer])
- Plate usage count [integer]
 - 96 well standard plates
 - 96 well deep well plates
 - 24 well deep well plates
 - AB2396 or AB2496 PCR plates
 - PCR plates with frame
 - 24 storage tubes
 - 96 storage tubes
- Tip comb usage count [integer]
 - 96 tip comb for deep well magnets
 - 24 tip comb for deep well magnets
 - 96 KF tip comb
 - 96 combi tip comb
 - 24 combi tip comb
 - 96 PCR tip comb
- Export count of run report files [integer]
 - to USB
 - to network share
 - to Connect

- Export count of protocol files [integer]
 - to USB
 - to network share
 - to Connect
- Import count of protocol files [integer]
 - from USB
 - from network share
 - from personal Connect storage
 - from Protocol Library
- Power on count [integer]
- Selected language [string]
- Connection type [none | wired | wireless | both]
- Magnet head mileage [timespan]
- UV-lamp usage hours [timespan]
- Interrupted protocol recovery accepted count [int]
- Interrupted protocol recovery rejected count [int]



Troubleshooting

Troubleshooting guide

Table 1 Actions taken against error messages and warnings

Code	Error message	Action
4	Head position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
5	Magnets position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
6	Turntable position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
7	Turntable nest counting mismatch when rotating	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
8	Heater unit 1 position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
9	Heater unit 2 position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
10	Heater track position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
11	Tip motor 1 position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
12	Tip motor 2 position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
13	Flip position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
14	Tip shield position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
15	Lock position error	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
21	Protocol memory is full	Remove some protocols from the device and try again.
36	Cannot do head cycles from unknown starting position	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.

Table 1 Actions taken against error messages and warnings *(continued)*

Code	Error message	Action
37	Cannot drive current heater from unknown sledge position	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
42	Tips are not installed	Make sure that tips are loaded as guided.
43	Magnetic head is missing	Make sure that correct Magnetic head is installed.
44	Tips are not expected to be installed	Remove tip if it is attached to instrument.
55	Motor logic can't resolve how to drive the motors	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
59	Lamp current not detected	Make sure that lamps are correctly in place. If repeated, change the lamp.
60	Plate mixing sensor has detected a collision with tip head	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
62	Instrument configuration does not match to detected parts	Make sure that heating blocks and magnetic heads are installed correctly.
63	Head and magnets collision detected	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
64	Heater 1 Too high temperature measurement offset	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
65	Heater 1 Temperature measurement failed	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
66	Heater 1 Temperature is not changing	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
67	Heater 1 Heater not working	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
68	Heater 2 Temperature measurement failed	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
69	Heater 2 Temperature is not changing	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
70	Heater 2 not working	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
71	Magnets are not expected to be installed	Make sure that magnetic heads are installed correctly.
72	Heaters ambient temperature not measured yet	Switch the instrument OFF and ON, then try again. If the error appears during initialization or is otherwise repeated, contact service.
73	Wrong tip comb.	Check that right tip comb used.

Table 1 Actions taken against error messages and warnings *(continued)*

Code	Error message	Action
74	Cover opened during UV decontamination.	Start UV decontamination again after closing the door.
–	Any other error	Record error number and contact authorized technical service.



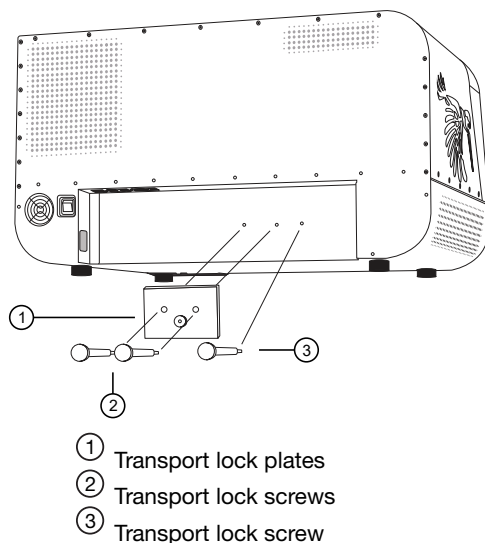
Maintenance

Regular and preventive maintenance

- Keep the instrument free of dust and liquid spills.
- Immediately wipe away spilled saline solutions, solvents, acids or alkaline solutions from outer surfaces to prevent damage.
- Use a mild sterilizing solution to clean any surfaces are contaminated with biohazardous material.
- Clean the outside of the instrument and the turntable with clean low-pressure compressed air or a cloth dampened with water or a mild detergent when necessary.
- Clean the display areas with a mild laboratory detergent.
- Plastic covers and surfaces can be cleaned with a mild laboratory detergent or alcohol.
- Periodically clean the instrument case with a soft cloth dampened in a warm, mild detergent solution to maintain its appearance.
- Painted surfaces can be cleaned with most laboratory detergents. Dilute the cleaning agent as recommended by the manufacturer. Do not expose the surfaces to concentrated acids or concentrated alcohols for prolonged periods of time as damage may occur.
- Abrasive cleaning agents are not recommended, because they can damage the paint finish.

Store transport lock

Use the transport lock screws to secure the transport lock to the rear of the instrument.



Magnetic head maintenance

If necessary, wipe the magnetic rods using a soft cloth or tissue paper soaked in a mild detergent solution (SDS), soap solution, or alcohol.

Decontamination procedure



WARNING! The decontamination procedure should be performed by authorized trained personnel in a well-ventilated room wearing disposable gloves, protective glasses and clothing.

If you have spilled infectious agents, carry out the decontamination procedure.

Perform decontamination in accordance with normal laboratory procedures. Any decontamination instructions provided with the reagents used should be followed.

It is strongly recommended to perform the complete decontamination procedure before relocating the instrument from one laboratory to another. The complete decontamination procedure is required if the instrument is being sent out for service.

After performing this decontamination procedure, enclose a signed and dated Certificate of Decontamination both inside the transport package and attached to the outside of the package.

Example of decontaminants:

- Ethanol 70%
- Virkon™ solution 1–3%
- Glutaraldehyde solution 4%
- Chloramine T
- Microcide SQ™ 1:64
- Decon™ 90 min. 4%

Decontaminate instrument



WARNING! The instrument weighs 56 kg (123 lb) and requires 2–3 people for moving. Moving the instrument alone may result in serious injury.

1. Prepare the decontaminant: 200 mL 4% glutaraldehyde solution (or another agent recommended by your safety officer).
2. Empty the turntable.
3. Switch OFF the power and disconnect the power supply cable.
4. Disinfect the outside of the instrument using a cloth dampened with 70% ethanol.
5. Place the instrument in a large plastic bag.

6. Place a cloth soaked in the prepared solution into the bag. Ensure that the cloth does not make contact with the instrument.
7. Close the bag firmly and leave the instrument in the bag for at least 24 hours.
8. Remove the instrument from the bag.
9. Clean the instrument using a mild detergent.
10. Remove any stains using 70% ethanol.

UV decontamination procedure

The UV lamps can be used to decontaminate the process chamber. If the front lid is opened, the UV lamps shut down.

UV radiation is useful in decontamination because of its ability to inactivate biological molecules. The instrument is equipped with two UV lamps that can be used to treat the interior of the instrument with UV light to help with decontamination after cleaning.

IMPORTANT! UV treatment is not a substitute for cleaning. For cleaning instructions, see “Decontaminate instrument” on page 44.

UV treat process chamber


1. Go to **Menu ▶ Instrument ▶ Tools ▶ UV light**.
2. Set the decontamination time.
The default is 1 h. The maximum time setting is 23 h 59 min.
3. Select **OK**.

Note: To abort the procedure, select **X** or open the front lid. To restart the procedure, select **OK**.

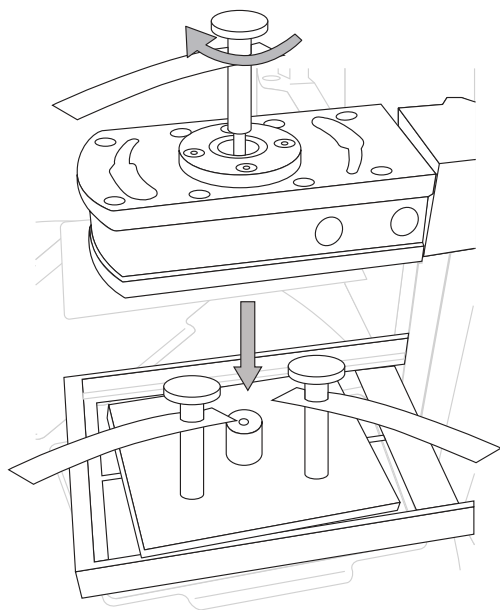
Prepare instrument for transport

If it becomes necessary to relocate or ship the instrument, install the transport lock to secure tip comb holder and magnetic head holder.

Refit the transport lock

1. Select  **Transport locking** to move the magnetic holder to the correct position.
2. Turn the power off.
3. Place the lower transport lock plate on top of the heating platform.
4. Lower the tip comb holder to the lower transport lock plate.

5. Place the upper transport lock plate over the tip comb holder and fasten the screws to hold the plates together.
6. Lower the magnetic head holder to the upper transport lock plate and fasten the magnetic head holder to the transport lock with the screw.





Specifications

Physical dimensions

Parameter	Instrument ^[1]	Transport package
Width	79 cm (31 in)	99 cm (39 in)
Depth	59 cm (23 in)	77.5 cm (30.5 in)
Height	45 cm (18 in)	83.5 cm (33 in)
Weight	56 kg (123 lb)	58 kg (128 lbs) ^[2]

^[1] Addition of +/-0.5 cm tolerance to the Width, Depth, and Height of the instrument dimensions.

^[2] Weight including instrument.

Instrument specifications

Technical specifications	
Operating conditions (indoor use only)	Ambient temperature range should be between 4°C (39°F) and 35°C (95°F) Ambient humidity should be no more than 80% at temperatures up to 31°C (88°F) decreasing linearly to 50% relative humidity at 35°C (95°F)
Transportation conditions	-29°C to 60°C, Humidity 30%–85%, packed in transport packaging
Storage conditions	-29°C to 38°C, Humidity 30%–85%, packed in transport packaging
Mains power supply	100–240±10% VAC, 50/60 Hz (nominal), automatic voltage detection
Overvoltage category	Installation categories II
Power consumption	280 VA maximum
Heat dissipation	545 BTU maximum
Data connectivity	USB (Device) for PC, LAN or USB Wi-Fi adapter for network, RS-232 for automation
Display/Touch screen	10" touch display
Instrument memory	~30 GB
Normal use	10 runs/day, 250 days/year (using 40 min protocols on medium speed setting at room temperature)
Ultraviolet light	2 UV lamps 18 W (can be set to run for up to 23h 59 min)



(continued)

Technical specifications	
Internal barcode reader	1D
Altitude	Located between sea level and 2,000 m (6,500 ft) above sea level
Pollution degree	Pollution Degree II – Install the instrument in an environment with only non-conductive pollutants (e.g., dust particles or wood chips). Typical environments with a Pollution Degree II rating are laboratories and sales or commercial areas.

Performance specifications

Table 2 Performance specifications

Performance specifications	
Maximum specimens per run	96
Magnet rods	24- or 96-well format in one frame Four options as interchangeable KingFisher™ Apex Dx Heads
Plate types (polypropylene – disposable, barcoded)	24- or 96-well plates: <ul style="list-style-type: none"> KingFisher™ 24 deep well plate (30 µL to 5 mL ^[1]) KingFisher™ 96 deep well plate (15–1000 µL ^[1]) KingFisher™ 96 plate (15–200 µL^[1]) PCR plate (10–80 µL^[1], AB2396 and AB2496)
Tip combs (polypropylene – disposable, barcoded)	24- or 96-well format in one frame <ul style="list-style-type: none"> KingFisher™ 96 Combi Tip Comb KingFisher™ 24 Combi Tip Comb KingFisher™ 96 PCR tip comb KingFisher™ 96 Deep Well Tip Comb KingFisher™ 96 Tip Comb for KingFisher™ 96 Magnets KingFisher™ 24 Deep Well Tip Comb
Collection efficiency of the particles (indoor use)	Minimum > 95% using KingFisher™ 96 deep well plate, KingFisher™ 96 tip comb for deep well magnets, neutral wash buffer containing detergent, 2,8 µm particles (Dynabeads™ magnetic beads) with 3 standard collections, instrument at room temperature
Magnetic particle size	approximately 1–2.8 µm



Table 2 Performance specifications (continued)

Performance specifications	
Heating/Cooling temperature range	From 4°C to 100°C, instrument at room temperature
Heating block accuracy	±2°C (min 4°C), ±2°C (max 80°C), ±3°C (min 81°C to 100°C), instrument at room temperature

^[1] Processing volume



Ordering information

Ordering configurations

IMPORTANT! The customer is responsible for validation of all consumables before use, and for compliance with regulatory requirements that pertain to the procedures and uses with the instrument.

Details	Cat. No.
Instrument	
KingFisher™ Apex Dx Purification Instrument	B5400900P
Magnetic heads	
KingFisher™ Apex Dx 96 PCR Head	B24079910
KingFisher™ Apex Dx 96 Combi Head	B24079920
KingFisher™ Apex Dx 96 Deep Well Head	B24079930
KingFisher™ Apex Dx 24 Combi Head	B24079940
Heating blocks^[1]	
PCR Heating Block	24075910
96 Heating Block	24075920
96 Deep Well Heating Block	24075930
24 Deep Well Heating Block	24075940
Plastics for 96-well plate and PCR plate formats	
KingFisher™ 96 PCR Tip Comb	97002560
KingFisher™ 96-Well Microplate, barcoded	97002540B
PCR Plate, 96-well, skirted	AB2396
PCR Plate, 96-well, semi-skirted	AB2496
KingFisher™ 96 Tip Comb for KingFisher™ Magnets, barcoded	97002524B
Plastics for 96 deep well format	
KingFisher™ 96 Combi Tip Comb	97002570
KingFisher™ 96 Deep Well Plate	95040450B

(continued)

Details	Cat. No.
KingFisher™ 96 Deep Well Plate, sterile	95040460B
KingFisher™ 96 Tip Comb for Deep Well Magnets	97002534B
KingFisher™ 96 Deep Well Tip Comb and Plate, sterile	97002820B
Plastics for 24 deep well format	
KingFisher™ 24 Combi Tip Comb	97002580
KingFisher™ 24 Deep Well Plate, barcoded	95040470B
KingFisher™ 24 Deep Well Plate, sterile barcoded	95040480B
KingFisher™ 24 Deep Well Tip Comb and Plate, barcoded	97002610B
KingFisher™ 24 Deep Well Tip Comb and Plate, sterile, barcoded	97002620B
Other consumables	
KingFisher™ 96 PCR Semiskirted Plate Adapter	N21446
UV Lamp	N21447

[1] General Lab Equipment



Safety



WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit thermofisher.com/support.

Safety compliance



WARNING! The instrument weighs 56 kg (123 lb) and requires 2–3 people for moving. Moving the instrument alone may result in serious injury.

The instrument design and manufacture complies with the following standards and requirements for safety, electromagnetic compatibility and Environmental WEEE.

Reference	Description
EU Directive 2014/35/EU	European Union “Low Voltage Directive”
EU Directive 2006/42/EC	European Union "Machinery Directive"
IEC 61010-1 EN 61010-1 UL 61010-1 CAN/CSA C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
IEC 61010-2-101	<i>Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials</i>















Symbols on this instrument

Symbols may be found on the instrument to warn against potential hazards or convey important safety information. In this document, the hazard symbol is used along with one of the following user attention words.






- **CAUTION!**—Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
- **WARNING!**—Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
- **DANGER!**—Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

Medical device symbols

The following table describes symbols that may be displayed on product labels. The symbols that are used on labels conform to standards *BS EN ISO 15223-1:2021* and *FDA 21 CFR 809.10 "Labeling for in vitro diagnostic products"*.

	IN VITRO DIAGNOSTIC MEDICAL DEVICE		MANUFACTURER
	CONSULT INSTRUCTIONS FOR USE		CATALOG NUMBER
	SERIAL NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		DATE OF MANUFACTURE
	CONTAINS		TEMPERATURE LIMIT
	UNIQUE DEVICE IDENTIFIER		INDICATES CONFORMITY WITH EUROPEAN UNION REQUIREMENTS
	INDICATES CONFORMITY WITH UNITED KINGDOM REQUIREMENTS		CAUTIOUS, STATIC MAGNETIC FIELD HAZARD

Standard safety symbols

Symbol and description	
	CAUTION! Risk of danger. Consult the manual for further safety information.
	CAUTION! Hot surface.
	CAUTION! Potential biohazard.
	CAUTION! Ultraviolet light.
	<p>WEEE (Waste Electrical and Electronic Equipment) symbol indicates that this product should not be disposed of in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of WEEE.</p> <p>This instrument meets European requirement WEEE Directive 2012/19/EU.</p>

Electromagnetic compatibility (EMC) standards

EMC compliance

Reference	Description
Directive 2014/30/EU	European Union “EMC Directive”
IEC 61326-1 Class B EN 61326-1 Class B The equipment is intended for use in a basic electromagnetic environment. Conducted emission: CISPR 11 Class B Radiated emission: CISPR 11 Class B	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
FCC Part 15 Subpart B (47 CFR)	U.S. Standard Radio Frequency Devices
IEC60601-1-2	Electromagnetic Compatibility (EMC) of Medical Devices Draft Guidance for Industry and Food and Drug Administration Staff)

Physical injury



CAUTION! Moving and Lifting Injury. Improper lifting can cause painful and permanent back injury.

Things to consider before lifting or moving the instrument or accessories:

- Depending on the weight, moving or lifting may require two or more persons.
- If you decide to lift or move the instrument after it has been installed, do not attempt to do so without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques.
- Ensure you have a secure, comfortable grip on the instrument or accessory.
- Make sure that the path from where the object is to where it is being moved is clear of obstructions.
- Do not lift an object and twist your torso at the same time. Keep your spine in a good neutral position while lifting with your legs.
- Participants should coordinate lift and move intentions with each other before lifting and carrying.
- For smaller packages, rather than lifting the object from the packing box, carefully tilt the box on its side and hold it stationary while someone else slides the contents out of the box.



CAUTION! Moving Parts. Moving parts can crush, pinch and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing.

Electrical safety

The following information on electrical safety must be observed, failing to follow these instruction may result in electric shock, fire and/or serious personal injury or death.

In the event of an equipment malfunction, it is the responsibility of the customer to report the need for service to Thermo Fisher Scientific or to one of the authorized agents. For service information, contact Technical Support (page 59).

Servicing of this device is to be performed by trained service personnel only.

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Prior to switching on the product, ensure that the nominal voltage setting on the product matches the nominal voltage of the AC supply network.
- This product should be connected to the power mains using a 3-wire (two conductors and ground) power cable and plug. Use this power cable with a properly grounded electrical outlet to avoid electrical shock.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.
- If extension cords or connector strips are implemented, they must be checked on a regular basis to ensure that they are safe to use.
- Never use the product if the power cable is damaged. Check the power cable on a regular basis to ensure that it is in proper operating condition. By taking appropriate safety measures and carefully laying the power cable, you can ensure that the cable will not be damaged and that no one can be hurt by, for example, tripping over the cable or suffering an electric shock.
- Do not insert the plug into sockets that are dusty or dirty. Insert the plug firmly and all the way into the socket. Otherwise, sparks that result in fire and/or injuries may occur.



- Do not overload any sockets, extension cords or connector strips; doing so can cause fire or electric shocks.
- To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.
- Ensure that the connections with information technology equipment, e.g., PCs or other industrial computers, comply with the IEC60950-1/EN60950-1 or IEC61010-1/EN 61010-1 standards that apply in each case.
- Use suitable overvoltage protection to ensure that no overvoltage (such as that caused by a bolt of lightning) can reach the product. Otherwise, the person operating the product will be exposed to the danger of an electric shock.
- The overvoltage protection should limit the magnitude of the overvoltage surge to 1 kV between the any of the power line and ground.
- Unless expressly permitted, never remove the cover or any part of the housing while the product is in operation. Doing so will expose circuits and components and can lead to injuries, fire or damage to the product.
- Any object that is not designed to be placed in the openings of the housing must not be used for this purpose. Doing so can cause short circuits inside the product and/or electric shocks, fire or injuries.

Chemical safety



WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.



WARNING! HAZARDOUS WASTE (from instruments). Waste produced by the instrument is potentially hazardous. Follow the guidelines noted in the preceding General Chemical Handling warning.

Biological hazard safety



WARNING! Potential Biohazard. Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.



WARNING! BIOHAZARD. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020
www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
www.who.int/publications/i/item/9789240011311

Serious incidents

Any serious incident that has occurred in relation to the device shall be reported to the sponsor and the relevant regulatory authority in which the user and/or the patient is established.



Documentation and support

Customer and technical support

Visit [thermofisher.com/support](https://www.thermofisher.com/support) for the latest service and support information.

- Worldwide contact telephone numbers
- Product support information
 - Product FAQs
 - Software, patches, and updates
 - Training for many applications and instruments
- Order and web support
- Product documentation
 - User guides, manuals, and protocols
 - Certificates of Analysis
 - Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.
