

NUCLEIC ACID PURIFICATION
PURE AND SIMPLE[®]



USER GUIDE

Ionic[®] Purification System

REV 3.0

PART #: 44001

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All product names, brands, and trademarks are properties of their respective owners.

Support

For technical information or advice, please contact Purigen Biosystems Support at any time.

Phone: 1-877-PURIGEN (787-4436)

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USA

EU WEEE Directive Compliance

The EU Waste Electrical and Electronic Equipment Directive implemented the EU WEEE Directive 2012/19/EU requiring Producers of electronic and electrical equipment (EEE) to manage and finance the collection, reuse, recycling and to appropriately treat WEEE products currently on the EU market. The goal of this directive is to minimize the volume of electrical and electronic waste disposal and to encourage re-use and recycling at the end of life.

If you have purchased Purigen Biosystems-branded electrical or electronic products in the EU and are intending to discard these products at the end of their useful life, please do not dispose of them at your municipal waste center. All electronic products bearing the WEEE Symbol shall alert our customers that Purigen Biosystems is making a return and collection system available to you, free of transportation and recycling costs, for proper disposal arrangements for these products.

Please contact Purigen Support (info above) to make arrangements for verification and the proper return of the equipment.

Safety Information

Regulatory

The Ionic Purification System is certified to the following standards:

- UL 61010-1, 3rd Edition (UL evaluation done only to 120V/60Hz)
- CAN/CSA C22.2 No. 61010-1-12, 3rd Edition
- Subpart B of Part 15 of FCC Rules for Class A digital devices
- ICES-003, Issue 6
- EN61326-1:2013
- EN61010-1:2010
- WEEE Directive 76/769/EC

Instrument Safety

Prior to using this instrument, all operators must complete the following:

- Thorough review of this manual with careful attention to all safety information
- Training on all safety guidelines established for the laboratory where the instrument will be used
- Training for the proper use and operation of an Ionic system
- Review of all safety materials including applicable Material Safety Data Sheet (MSDS) and SDS documents

Precautions are illustrated in the following way:



WARNING

Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.



CAUTION

Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.

Proper Use

Inappropriate use of the Ionic Purification System may cause personal injury or irreparable damage to the instrument.

- Only trained personnel should operate the Ionic system following Purigen Biosystems published methods.
- Only Ionic system qualified service engineers should service the Ionic system.
- Routine maintenance should be performed in accordance with "**Maintenance Procedures**" on page 34 of this guide.

Damage to the Ionic system caused by inappropriate use, neglect to perform required maintenance, or performing inappropriate maintenance may void warranty or require services not covered by standard service contract terms.

At all times, the following warnings apply:

- Do not move the instrument after it has been installed
- Do not unplug the instrument while it is in operation

- Do not spill liquids on any area of the instrument
- Do not use with flammable materials or in the presence of toxic fumes
- Do not attempt to manually move the system cover
- Use only with Purigen Biosystems Fluidic Chips and associated kits and protocols

Laboratory supervisors and/or facility managers must take the necessary precautions to ensure a safe workplace and appropriate training of personnel. All laboratory activities should be in accordance with all national, state, and local health and safety regulations. Care should be taken to ensure that instrument operators and laboratory personnel are not exposed to hazardous or infectious materials as defined by SDS (or MSDS), and other laboratory safety and regulatory documentation.

Electrical Safety

This instrument contains electrical components within its covers. Removal of any covers or panels while the instrument is connected to live power (plugged in) can expose live electrical current and create a danger to laboratory personnel.

Always observe the following recommendations:

- Only use the power cord provided to connect the instrument to a properly grounded power receptacle.
- Do not remove any covers, panels or attempt to access, adjust, or replace any internal components of the instrument.
- Avoid spilling any liquids on any component of the instrument.

Regularly monitor the instrument for unsafe electrical states and contact Purigen Biosystems Support immediately if an unsafe state is observed. Unsafe states can include any of the following:

- Power cord or power receptacle is visibly damaged
- Instrument covers are visibly damaged
- Large amounts of liquid cover any component of the instrument
- Instrument has been mishandled, dropped, or has been impacted by another object
- Instrument surfaces or covers appear to have been corroded or display chemical residue

Environment

The Ionic Purification System is designed to operate within the following environmental conditions:

TABLE 1: Operating environment specifications

Operating Environment	Specification
Temperature	Maintain a lab temperature of 15°C – 25°C; This temperature is the operating temperature of the instrument.
Humidity	Maintain a non-condensing relative humidity between 30-70%

Biological Safety

Specimens, samples, or reagents containing materials from humans should be considered potentially infectious. Use, storage, and disposal of such materials should be in accordance with all national, state, and local safety regulations. Always wear appropriate personal protective equipment as determined by the safety guidelines established for the laboratory where the instrument is being used.

Chemicals

Chemicals used in or in association with use of this instrument may be considered hazardous. Use, storage, and disposal of such materials should be in accordance with all national, state, and local safety regulations. Always wear appropriate personal protective equipment as determined by the safety guidelines established for the laboratory where the instrument is being used.

The Ionic system is not intended for use with flammable liquids or liquids that produce a toxic fume. Such liquids should not be used within any component of the instrument and the instrument should not be operated in the presence of such liquids without proper ventilation.

Waste Disposal

Used labware, Ionic system fluidic chips, and personal protective equipment that may have come in contact with hazardous or infectious materials should be collected and disposed of properly in accordance any safety guidelines established for the laboratory where the instrument is used and with national, state, and local health and safety regulations.

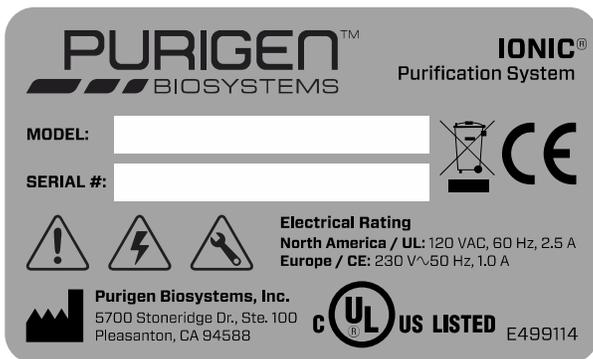
All reagents, including Ionic system kit reagents, should be disposed of in accordance with SDS (or MSDS) recommendations.

Mechanical Hazards

The cover of the Ionic system will extend and retract during normal operation. Contact with the cover while it is moving should be avoided.

Labels on the Ionic Purification System

Product Label



Warning Symbol	Definition
	Use Caution During Use Operation of this instrument should be performed by trained users following the guidance provided in documentation from Purigen Biosystems.
	Warning: Electrical Shock Hazard Disconnect power before servicing.
	No User Serviceable Parts Inside Maintenance requiring removal of the outer cover must be performed by an authorized Purigen Biosystems representative.

Introduction

The Ionic system is designed for use in research laboratories for the extraction and purification of nucleic acids from biological samples. The instrument uses a proprietary technology, isotachopheresis, to separate and aggregate nucleic acids without surface binding; to preserve the native state of the nucleic acid for high purity and quantity.

Please read this user guide in its entirety before using the Ionic system.

Carefully review all safety information, operation, and maintenance instructions. Proper use and maintenance of the instrument as well as observance of applicable safety guidelines is necessary to prevent damage to the instrument or harm to its users.

Product Use

The Ionic system is exclusively designed to be used with Purigen Biosystems Ionic Purification kits to perform fully automated extraction and purification of nucleic acids for scientific research applications. This system is intended to be used by trained professionals following all applicable safety guidelines in accordance with all applicable safety regulations. The Ionic system is for research use only.

Product Use Limitations

The Ionic system is not intended for use with reagent kits or methods other than Purigen Biosystems purification kits. The system is recommended for use only with samples defined within the product limitations of the Purigen Biosystems purification kit and method being used.

Purigen Fluidic chips are designed for laboratory use only and must be stored and handled properly to achieve the expected performance. Each chip should remain sealed inside a static dissipative bag and only opened prior to immediate use. Chips should be handled only while wearing gloves and gripped by the side skirts. Contact of any kind with the chip surface and features (wells, connection points) should be avoided except for the loading or removal of samples and reagents by pipette. Failure to follow this guidance can result in poor performance or run errors.

Instrument Features

- Easy-to-use and easy-to-maintain system operation
- Standardized sample preparation workflow
- Comprehensive technical support
- Touchscreen-guided operation
- Auto-generated reports and logs
- USB support for data transfer

Instrument Specifications

TABLE 2: Instrument specifications

Specification	Value
Weight	24.5 kg (54.0 lbs.)
Dimensions (W x D x H)	41.9 x 48.9 x 42.4 cm (16.5 x 19.3 x 16.7 inches)
Power requirements	North America: 120 VAC, 50/60Hz, 2.5 A with a NEMA 5-15 receptacle Europe: 230 V~50 Hz, 1.0 A (connectors vary by country)
Ventilation requirements	Minimum 5.09 cm (2 inches) around all sides
Usable temperature range	15 - 25°C (59-77°F), Indoor use only
Humidity	30-70% (non-condensing)

Fluidic Chip Specifications

Fluidic Chip Dimensions

TABLE 3: Fluidic chip dimensions

Description	Value
Height	14.53 mm
Width	85.48 mm
Length	127.76 mm

Fluidic Chip Volumes

TABLE 4: Fluidic chip volumes

Description	Value
Number of samples	Up to 8 samples per fluidic chip
Sample well volume	200 µL (typical)
Buffer well volume	Varies by protocol
Extraction well volume	> 50 µL

Fluidic Chip Storage and Handling

TABLE 5: Storage and handling specifications

Description	Value
Temperature	15 to 32 °C
Packaging	In sealed, static dissipative bag
Handling	With disposable gloves, avoiding contact with surface

Product Components

Ionic Purification System Instrument (Part Number: 44001)

Includes:

- 1 instrument (with leveling system)
- 1 power cable

Terms and Definitions

TABLE 6: Terms and Definitions

Term	Definition
Ionic Purification Kits	Kit containing the fluidic chip and reagents
Fluidic chip(s)	Ionic® Purification Chip(s)
Ionic Purification System instrument chip holder	Location where the chip rests in the instrument
Ionic Purification System instrument screen	Refers to the touchscreen on the instrument
Ionic Purification System	Umbrella term to cover instrument, technology, and consumables
Ionic system	Short name to specifically call out the instrument
Extraction well	Wells on the chip where the nucleic acid is collected
Sample well	Wells on chip where the sample is dispensed
“XYZ” buffer well	Wells on chip where buffers are dispensed
Dispense	Act of depositing a material into a well of the chip “Dispense lysate from previous step into...”
Aspirate	Act of removing any material that is not extract from the chip “Aspirate and dispose of any remaining...”
Collect	Act of removing extraction from the chip “Collect extracted sample from...”
Channel	Physical connection between a series of wells on the chip where isotachopheresis occurs for an individual sample

General Description

The revolutionary Ionic® Purification System from Purigen Biosystems uses isotachopheresis (ITP) to extract, purify, and concentrate nucleic acid from biological samples. Samples prepared by the system are pure, abundant, and ready in just 60 minutes.

System Overview

FIGURE 1: Instrument (front)



TABLE 7: Instrument parts (front)

Call Out	Instrument Component	Definition
1	Touchscreen	Operation of the Purigen Biosystems Ionic system is conducted entirely through the integrated touchscreen. Operators can select and initiate protocols as well as import sample information and export run data from the touchscreen. All error messages, help messages, and prompting will occur on the touchscreen during normal operation. The system software also includes integrated user management to track protocols and information by user.
2	Cover	The Ionic system utilizes an actuated cover during normal operation to control the environment and processing of samples on a Purigen Biosystems fluidic chip. The cover will automatically extend and retract in response to interaction with the instrument's touchscreen while progressing through a protocol or performing maintenance operations.
3	Chip holder	The chip holder within the instrument provides a location for the placement of a Purigen Biosystems fluidic chip. The holder is designed to prevent placement of a fluidic chip in an incorrect orientation.
4	USB port	Operators can insert a USB flash drive into the USB port at the front of the system to export data files for off-line analysis.
5	Leveling knobs (left, right)	The integrated leveling system is adjusted at the time of system install. Adjustment may be necessary to re-level the instrument after moving the instrument or if the position of the instrument has somehow changed after installation.

FIGURE 2: Instrument (back)



TABLE 8: Instrument parts (back)

Call Out	Instrument Component	Definition
1	Product label	See " Labels on the Ionic Purification System " on page 8 for a close-up image of the product label.
2	Exhaust fans	The exhaust fans located at the rear of the Purigen Biosystems Ionic Purification System maintain a safe operating temperature within the instrument. Refer to the Purigen Biosystems Ionic Purification System Site Preparation Guide or Specifications for recommendations on appropriate clearance to prevent obstructing the airflow from the fans.
3	Power receptacle	Used to connect the power cord included with the instrument to the power outlet.
4	RJ-45 port	Used for instrument service only.
5	Power switch	The power switch located at the rear of the system is used to power on and power off the instrument. Do not power off the instrument while the system software is running. To shut down the system software, see " Shutdown " on page 32.



TABLE 9: Ionic system LED display

LED Color	LED State	System State
Cyan	Slow flash	Idle
Green	Solid	Active
Red	Fast flash	Error
Green	Slow flash	Run complete

Installation Procedures



IMPORTANT

Do not unpack the instrument prior to installation. The system must be unpacked by or under the supervision of a Purigen Biosystems representative.

Purigen Biosystems offers both a traditional installation, performed at your site by a Purigen Biosystems representative, and a Virtual Installation and Training where a Purigen Biosystems representative will guide you through the installation and training over a series of remote web-based teleconferences.

To learn more about our Virtual Installation and Training program visit: <https://purigen.co/ionic-virtual-install>.



CAUTION

After your Purigen Biosystems representative has installed and prepared the instrument, do not relocate the instrument. Moving the instrument improperly can damage the instrument and compromise data integrity. If you want to relocate the instrument, contact your Purigen Biosystems representative.

Operating Procedures

Ionic Purification System Software

The system software is comprised of many screens. The main functions that a user would need are explained in the sections below.

- **"Using the Instrument"** on the next page
- **"Create or Select User Profile"** on the next page
- **"Defining Samples for a Purification Kit Run"** on page 18
 - **"USB Upload"** on page 19
 - **"User defaults"** on page 21
 - **"Manual Input"** on page 23
 - **"Review Results"** on page 25
- **"Settings"** on page 26
 - **"About Instrument"** on page 27
 - **"Manage Users"** on page 28
 - **"Maintenance & Service"** on page 35

The table below lists functions that are available in many of the system software screens.

TABLE 10: System software screen icons and buttons

Icon/Button	Name	Definition
	Cog icon	Loads the Setting screen
	Help icon	Loads the Help screen
	Shutdown icon	Used to shut down the system software
	Add User icon	Loads the Add User screen
	Clear icon	Clear the text in the User Name text box in the Create New User screen
	USB download icon	Initiates the USB download function
	Cancel button	Cancels the current operation, if applicable
	Back button	Returns the to the previous screen
	Next button	Moves to the next screen

Using the Instrument

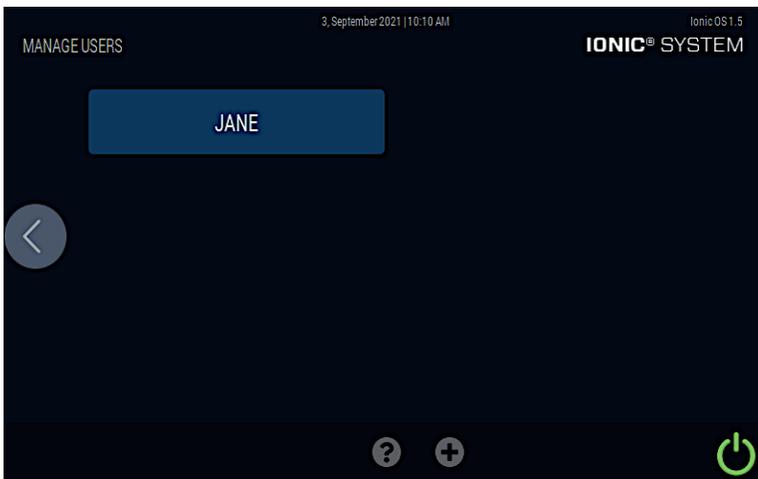
1. Ensure the instrument cover is free of any obstructions.
2. Turn on the system using the power switch at the rear of the instrument.
3. Press **Start** on the **Start** screen.

FIGURE 3: Start screen



Create or Select User Profile

1. If you have not already created a **User Profile**, create a profile by pressing  the button at the bottom of the touchscreen.



2. Use the touchscreen keyboard to enter the desired **User Name** and press **Save**.

FIGURE 5: Create New User screen



TABLE 11: Create a User screen

Call Out	Screen Component	Definition
1	User Name textbox	Use the touchscreen keyboard to type in a new user name
2	Cancel button	Click Cancel button to return to the Choose a User Screen without adding the user
3	Save button	Click Save button to add the new user
4	Help icon	Loads the Help screen



TIP

If you select the icon in the input area, the existing text is cleared.



NOTE

Once a **User Profile** is created, it is saved in the system software and can be selected from the menu in the future.

FIGURE 6: Choose a User screen



3. Select the user profile you just created or a previously created profile to go on to the next step.

Select an Ionic Purification Kit Protocol

After a user profile has been selected, a list of available purification kit protocols will be displayed.

Select the protocol you wish to run and follow the guidance on the touchscreen.

For detailed protocols available for each Ionic purification kit, please visit: <https://www.purigenbio.com/support/documentation..>

Defining Samples for a Purification Kit Run

1. In the Select a channel naming option screen, press USB Upload, Manual Input, or User defaults.



NOTE

If available, a barcode scanner can be used to scan the samples.

2. For additional details on USB Upload, see **"USB Upload"** below.
3. For additional details on User defaults, see **"User Defaults"** on page 22.
4. For additional details on Manual Input, see **"Manual Input"** on page 23.

USB Upload

1. In the **Select a channel naming option** screen, press **USB Upload**.

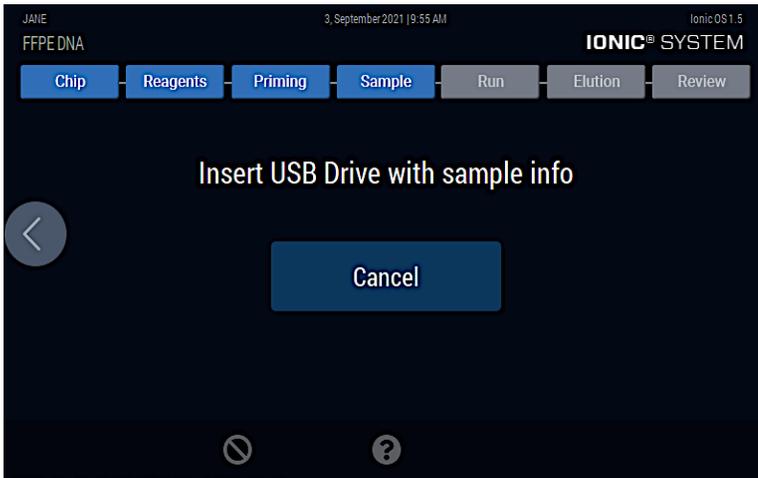


NOTE

If available, a barcode scanner can be used to scan the samples.

2. Insert a USB drive in the USB port located on the front bottom-right of the instrument.

FIGURE 7: Sample screen – **Step 2**

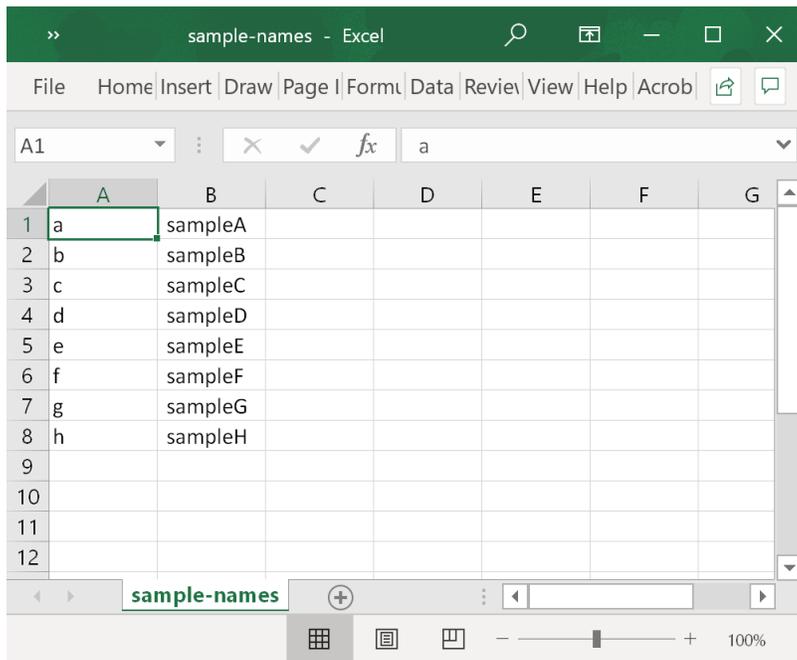


3. If there are valid sample CSV files on the USB drive and no errors loading the USB drive were encountered, a screen listing the sample files on the USB drive is shown. Select the sample file you would like to use.

FIGURE 8: Sample screen – **Step 3**



FIGURE 9: Sample-names.csv file contents



NOTE

The CSV input file should have two columns.

Column A: Should contain a lowercase or uppercase letter (a-h) to identify the channel.
Any other characters will cause an error.

Column B: Should contain the sample name which can be made up of numbers, letters, dashes, and underscores.
Any other characters will cause an error.

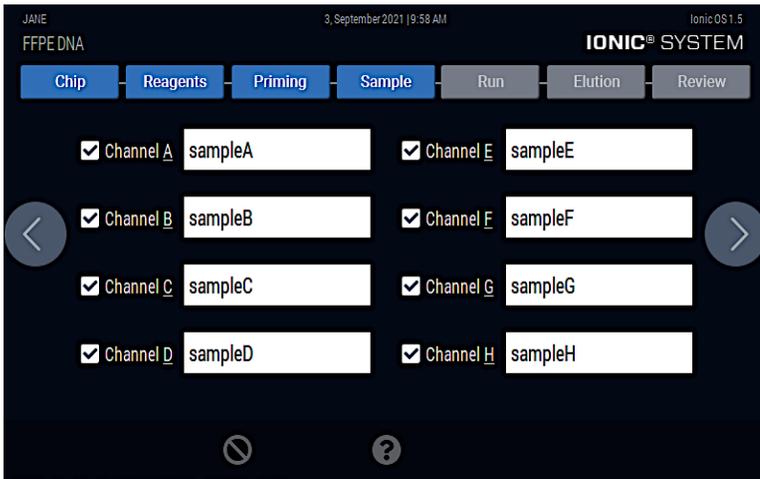
4. The first **Review** screen is displayed. Verify sample names and then press the arrow button on the right side of the screen to continue.



NOTE

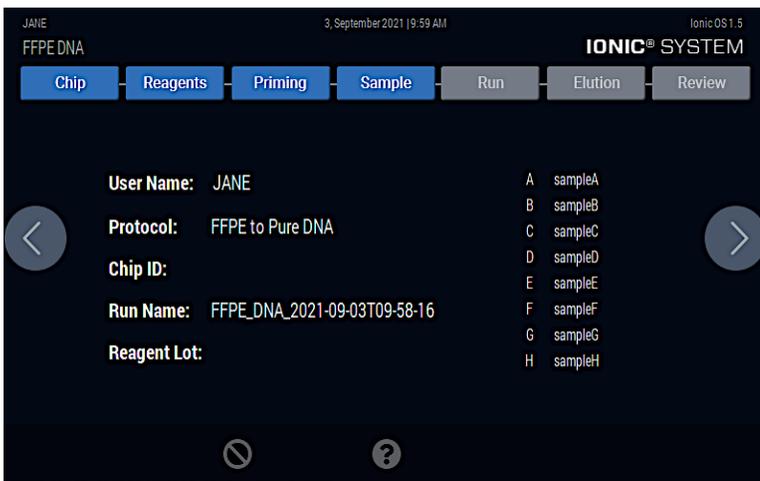
Deselect the checkbox next to a **Channel** if you will not be adding a sample to that **Channel** to disable it.

FIGURE 10: Sample screen – Step 4



- 5. The second **Review** screen is displayed. Verify sample names, input, and protocol, then press the arrow button on the right side of the screen to continue.

FIGURE 8: Sample screen – Step 5



User Defaults

The **User Defaults** option will automatically assign a generic name to each sample.

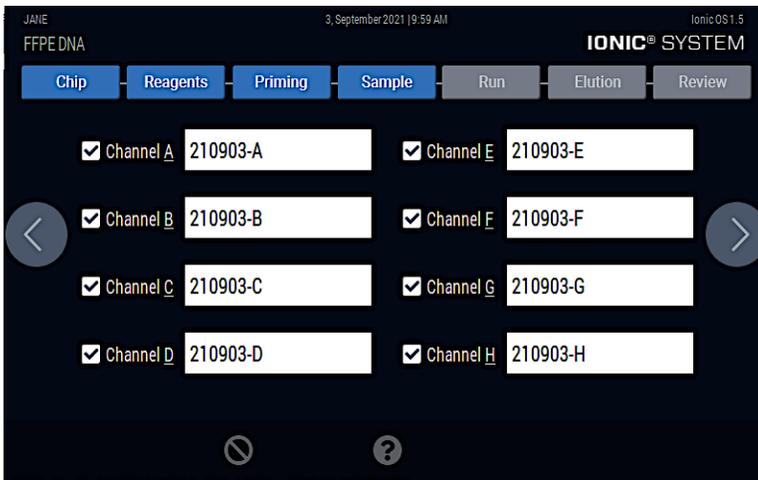
1. In the **Select a channel naming option** screen, press **User Defaults**.
2. The first **Review** screen is displayed. Verify sample names and then press the arrow button on the right side of the screen to continue.



NOTE

Deselect the checkbox next to a **Channel** if you will not be adding a sample to that **Channel** to disable it.

FIGURE 12: Sample Screen – Step 2



3. The second **Review** screen is displayed. Verify sample names and then press the arrow button on the right side of the screen to continue.

FIGURE 13: Sample Screen – Step 3



Manual Input

1. In the **Select a channel naming option** screen, press **Manual Input**.



NOTE

If available, a barcode scanner can be used to scan the samples.

2. Manually enter custom sample names and press the arrow button on the right side of the screen.

FIGURE 14: Sample Screen – Step 2



NOTE

Deselect the checkbox next to a **Channel** if you will not be adding a sample to that **Channel** to disable it.

3. The **Review** screen is displayed. Verify sample names and then press the arrow button on the right side of the screen to continue.

FIGURE 15: Sample Screen – Step 3



Review Results

1. Press the **USB Download** icon to save the run file in CSV format to a USB flash drive. The run file below was generated for the example we have been using to illustrate the run protocol function.



NOTE

Run file is encoded in UTF-8.

FIGURE 16: Sample Run File

	A	B	C	D	E
1	Column1	Column2	Column	Column	
2	Machine Name	Ionic Purification System			
3	Machine Serial Number	PXXXXXXX			
4	Machine IP Address	X.X.X.X			
5	Machine MAC Address	X.X.X.X.X.X			
6	GUI Version	X			
7					
8	User Name	JANE			
9	Run Name	FFPE_RNA_2020-07-21T18-13-03			
10	Protocol	FFPE to Pure RNA			
11	Reagent Lot				
12	Chip ID				
13	Timezone Info:	US/Pacific (PDT UTC-07:00)			
14	Run Start Time	07-21-2020 06:16:15 PM PDT			
15	Run End Time	07-21-2020 06:36:37 PM PDT			
16					
17	Lane	Sample ID	Enabled	Run	
18	A	10K_1	YES	PASS	
19	B	50K_2	YES	PASS	
20	C	50K_3	YES	PASS	
21	D	50K_4	YES	PASS	
22	E	50K_5	YES	PASS	
23	F	<Disabled>	NO	PASS	
24	G	<Disabled>	NO	PASS	
25	H	<Disabled>	NO	PASS	
26					

Settings

The **Settings** screen provides access to user management and maintenance functions. For more information on these functions, select the links below.

- **"About Instrument"** on the next page
- **"Manage Users"** on page 27
- **"Maintenance & Service"** on page 34

FIGURE 17: Settings Screen

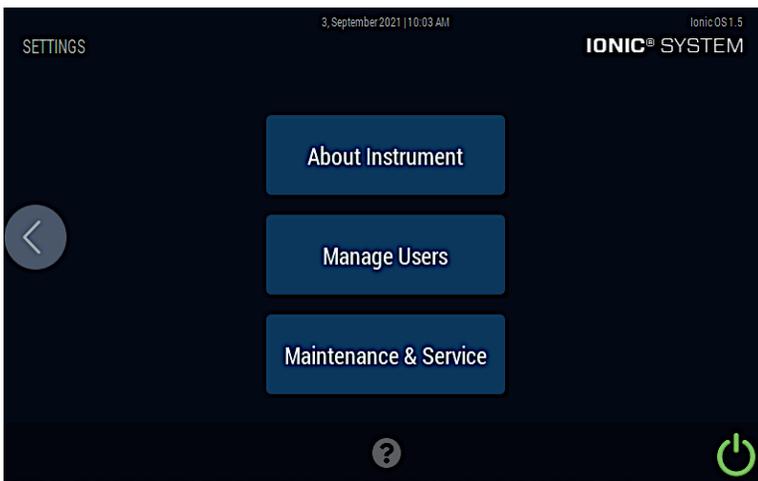


TABLE 12: Settings screen

Call Out	Screen Component	Definition
1	About Instrument button	Shows instrument model number, serial number, firmware version, and free disk space available.
2	Manage Users button	Lists all the active and inactive users. Active users accounts are shown at the top and inactive users are shown at the bottom
3	Maintenance & Service button	Loads the Settings screen which allows the user to perform a Self Test, Update System, Service Instrument, or list Instrument Statistics
4	Help icon	Loads the Help screen
5	Power icon	Used to power down the instrument

About Instrument

The **About** screen shows the instrument model number, serial number, firmware version, and free disk space available.

FIGURE 18: About screen



TABLE 13: About screen

Call Out	Screen Component	Definition
1	Instrument Configuration	Instrument configuration details such as name, model, serial number, IP address, MAC address, free disk space, firmware version, GUI version, build version, pure version, and hardware version
2	Copyright Notice button	Displays the Purigen Biosystems copyright
3	Open Source button	Displays a list of open source licenses used in development of the system software

Manage Users

The **Manage Users** screen is used to add users, deactivate users, and reactivate users. For more information on each of these functions, see the topics below.

- **"Add User"** on the next page
- **"Deactivate User"** on page 29
- **"Reactivate User"** on page 31

FIGURE 19: Manage Users screen

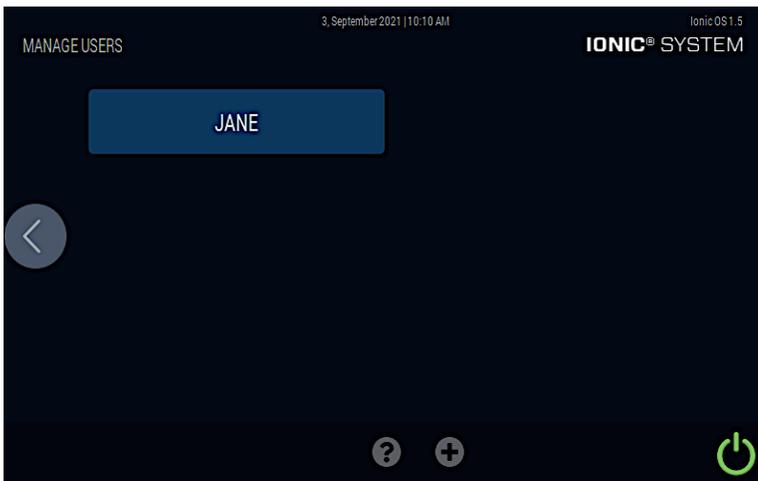


TABLE 14: Manage Users screen

Call Out	Screen Component	Definition
1	User Name button	Buttons for each user that was added to the system software. You can click on a user name button to edit a user name, view run total, view individual run data, and deactivate or reactivate users
2	Help icon	Loads the Help screen
3	Plus icon	Used to add a new user
4	Shutdown icon	Used to shut down the system software

Add User

Follow the steps below to add a user profile in the system software.

1. From the **Settings** screen, press the **Manage Users** button.
2. In the **Manage Users** screen, press  the button at the bottom of the touchscreen.
3. Use the touchscreen keyboard to enter the desired **User Name** and press **Save**. The new user is added and listed in the **Manage Users** screen.



TABLE 15: Create New User screen

Call Out	Screen Component	Definition
1	User Name textbox	Use the keyboard to type in a new user name
2	Cancel button	Click Cancel button to return to the Choose a User Screen without adding the user
3	Save button	Click Save button to add the new user
4	Help icon	Loads the Help screen



TIP

If you select the  icon in the input area, the existing text is cleared.



NOTE

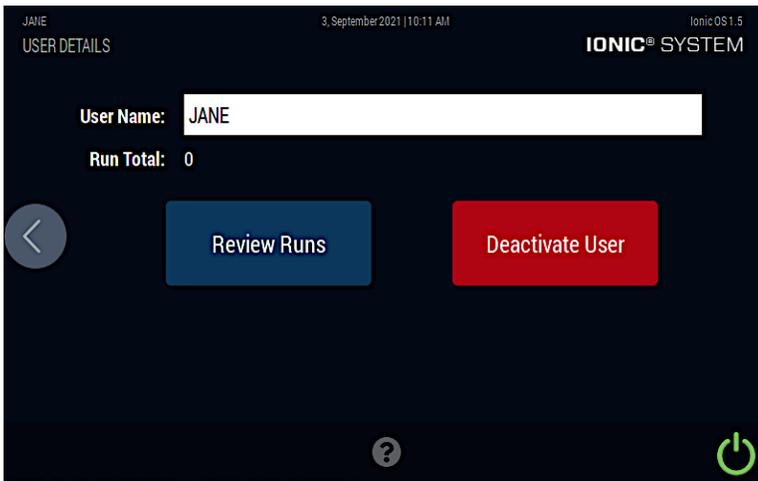
Once a User Profile is created, it is saved in the system software and can be selected from the menu in the future.

Deactivate User

Follow the steps below to deactivate a user profile in the system software.

1. From the **Settings** screen, press the **Manage Users** button.
2. In the **Manage Users** screen, select the user name you want to deactivate. The **User Details** screen is displayed.
3. Press **Review Runs** if you would like to review the runs for the user before deactivating the user.
4. Press the **Deactivate User** button.

FIGURE 21: User Details screen: Deactivate User – **Step 1**



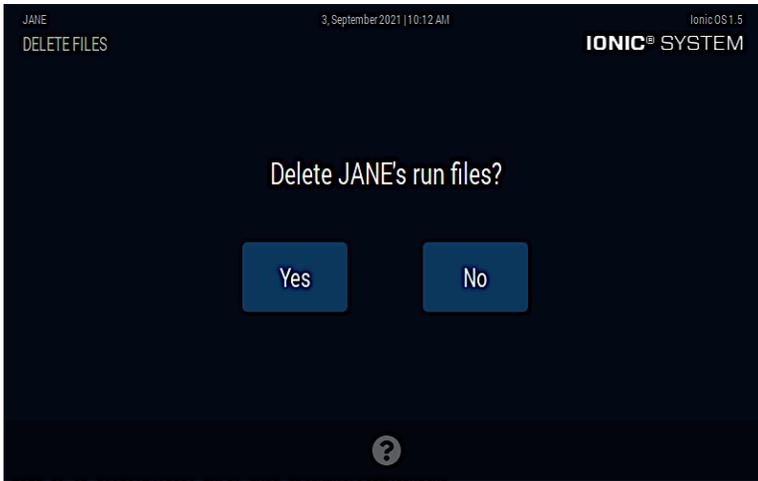
5. Press the **Yes** button to confirm if you want to deactivate the user name shown. Otherwise, select **No** to cancel and return to the previous screen.

FIGURE 22: User Details screen: Deactivate User – **Step 2**



- Press **Yes** to delete the run files for the user, or press **No** if you do not want to delete the run files.

FIGURE 23: User Details screen: Deactivate User – **Step 3**

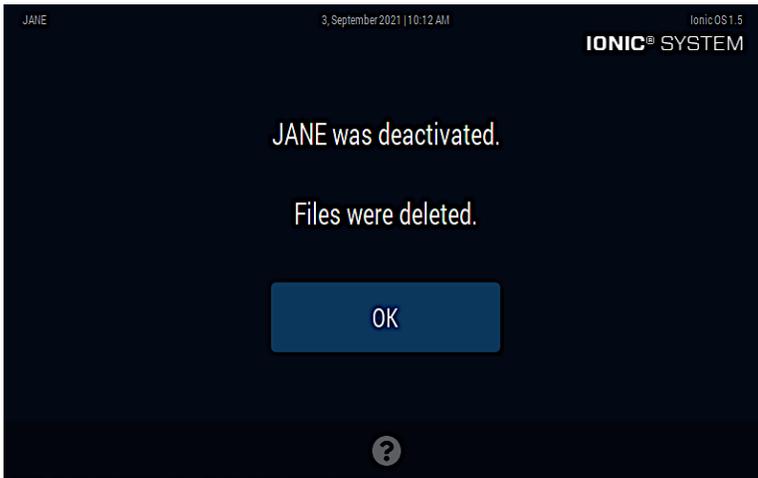


NOTE

If **Yes** is selected, the run files for this user will not be recovered even if the user profile is reactivated.

- Press **OK** to return to the **Mange Users** screen.

FIGURE 24: User Details screen: Deactivate User – **Step 4**

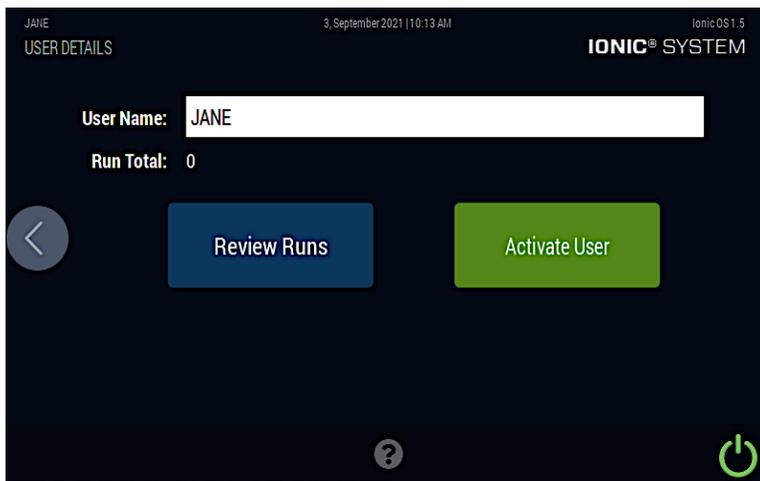


Reactivate User

Follow the steps below to reactivate a user profile in the system software.

1. From the **Settings** screen, press the **Manage Users** button.
2. In the **Manage Users** screen, select the user name you want to reactivate. The **User Details** screen is displayed.
3. Press **Review Runs** if you would like to review the runs for the user before reactivating the user.
4. Press the **Activate User** button. The **User Details** screen is closed and the **Manage Users** screen is displayed.

FIGURE 25: User Details screen: Activate User



Maintenance & Service

The **Maintenance & Service** screen is accessed from the **Settings** screen and enables the following maintenance functions.

FIGURE 26: Maintenance & Service screen



The links below provide more details on each of these maintenance functions.

- **"Self Test"** on page 42
- **"Open/Close Cover"** on page 43
- **"Save System Logs"** on page 44
- **"System Time Settings"** on page 46
- **"System Update"** on page 48
- **"Instrument Statistics"** on page 48
- **"Save Diagnostics"** on page 49
- **"Service"** on page 51

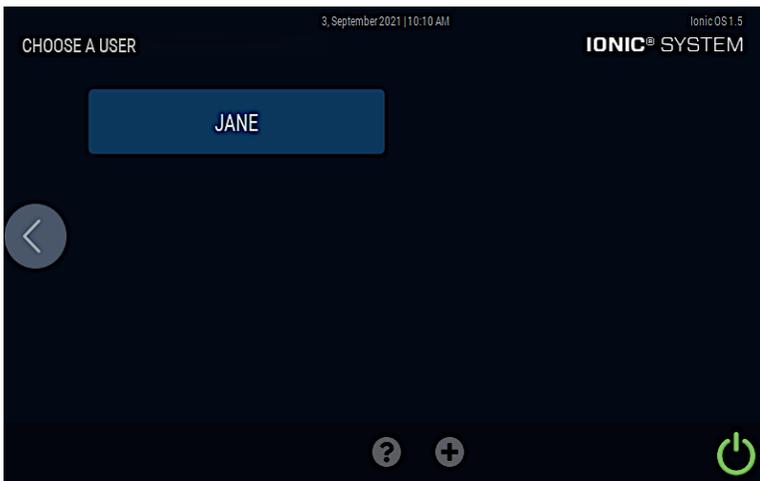
Shutdown



NOTE

The Shutdown button is accessible on several screens and shuts down the system software. The instrument must be powered off separately. If the Shutdown button is pressed while the instrument is in operation, all run progress and information may be lost.

1. Press the **Shutdown** icon on the bottom-right of the screen.



2. Press **No** to cancel and return to the previous screen.
3. Press **Yes** to shut down the system software. Another screen is displayed telling you that the system software is shutting down.



4. Wait for a black screen on the system software and then power off the instrument using the power switch at the back of the instrument.



IMPORTANT

If the instrument has successfully shut down the system software, the instrument touchscreen will be black.

Maintenance Procedures

Regular Maintenance

The Ionic Purification System has no user-serviceable parts and is designed to require minimal maintenance. Any parts requiring replacement, including the power cord, must be sourced directly from Purigen Biosystems. It is important to clean the instrument after every use. If samples or reagents have been spilled, it is important to clean the instrument immediately to avoid damage or contamination of samples.

**NOTE**

Wiping down the instrument after each use and keeping it clear of spills is different than the periodic maintenance of cleaning of the instrument. See "[Cleaning the Ionic Purification System](#)" on the next page for the maintenance related cleaning procedure.

**NOTE**

Always turn off and unplug the instrument before cleaning.

Periodic Maintenance Procedures

The following maintenance functions should be followed as needed:

- "[Cleaning the Ionic Purification System](#)" on the next page
- "[Decontaminating the Ionic Purification System](#)" on page 40
- "[Shipping the Instrument](#)" on page 51

Cleaning the Ionic Purification System

The Ionic System Cleaning Kit is designed for use with the Ionic® Purification System. The kit contains fluidic chips and cleaning solutions required to complete one system cleaning cycle.

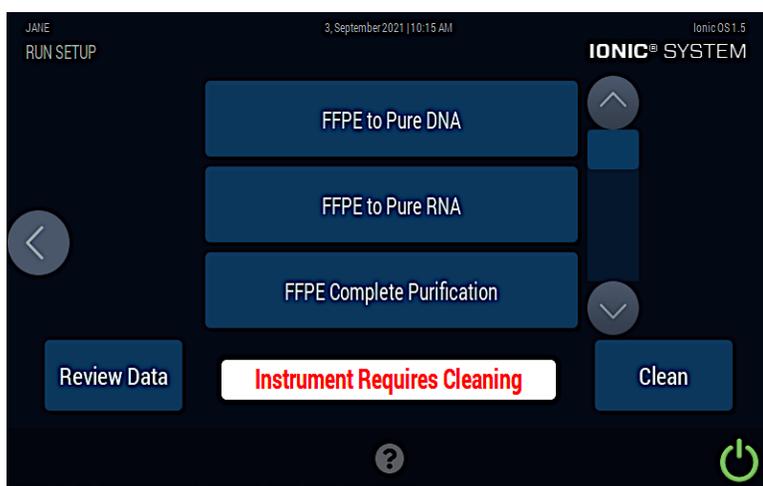


NOTE

A system cleaning cycle **should be performed once every 30 protocol runs**. If the system is used less frequently, a cleaning cycle should be performed every 90 days.

If more than 30 protocol runs have been completed without a cleaning, a warning will be displayed on the **Run Setup** screen.

FIGURE 27: Run Setup screen: Instrument Requires Cleaning



The number of runs remaining until the next cleaning cycle is required can be found in the **Instrument Statistics** screen in the **"Maintenance & Service"** on page 34 menu.

Ionic Purification System and associated consumables are intended for research use only. The table below lists the items included in the Ionic System Cleaning Kit.

TABLE 16: Cleaning Kit contents

Description	Quantity	Unit of Measure	Storage Requirements
Ionic System Cleaning Chip	2	Chip(s)	Room temperature
Cleaning Solution A	1	Bottle	Room temperature
Cleaning Solution B	1	Bottle	Room temperature
Cleaning Chip Seal	2	Seal(s)	Room temperature

In addition, you will need the following items:

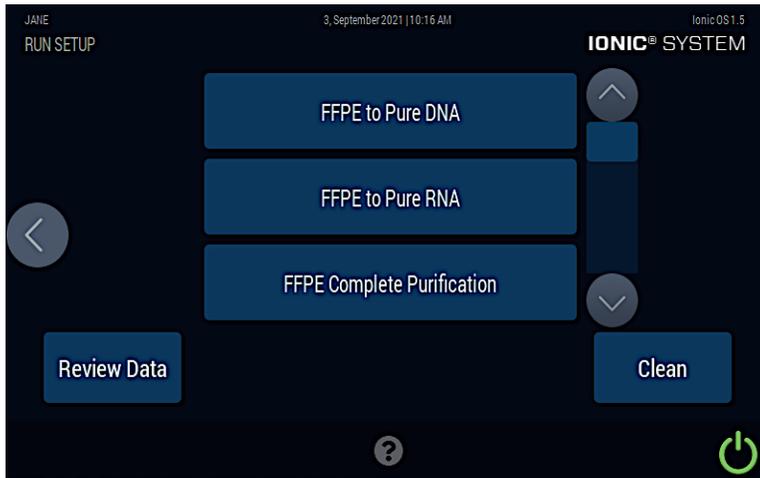
TABLE 17: User-supplied equipment

Name
P5000 Single Channel Pipette
P10000 Single Channel Pipette
Serologic (5 or 10 mL)

Procedure

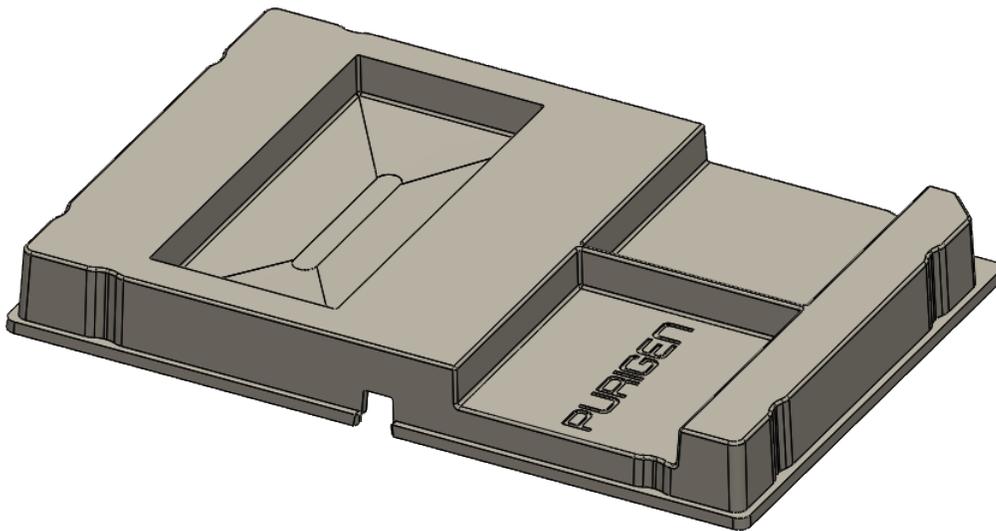
1. Using the system's touchscreen, select a valid user profile.
2. Press the **Clean** button and follow the instructions on the screen.

FIGURE 28: Run Setup screen



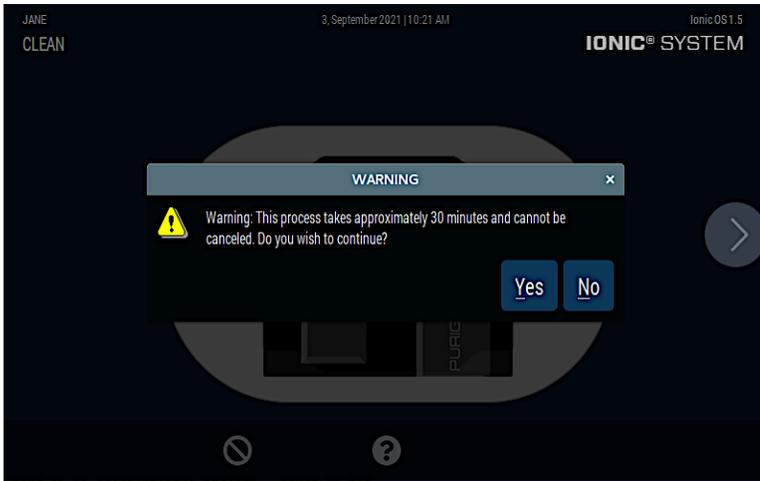
3. Place a Cleaning Chip on the chip platform.

FIGURE 29: Cleaning Chip



4. Press **Yes** to confirm you understand that the cleaning procedure cannot be canceled after this point.

FIGURE 30: Clean screen - **Step 2**



5. Pour 1 bottle of **Cleaning Solution A** into the large reservoir (*approximate volume 12 mL*).

FIGURE 31: Clean screen - **Step 3**



6. Press the arrow on the right side of the system's touchscreen to continue.
7. The Ionic Purification System cover will close and complete the first step of the electrode cleaning process.
8. After approximately 10 minutes, the first **Complete** screen is shown. Press the arrow on the right side of the system's touchscreen to open the instrument cover.

FIGURE 32: Clean screen - **Step 4**



9. Before removing the chip from the instrument, use a pipette to remove any remaining solution in the reservoir and cover the reservoir with the seal provided for disposal.

FIGURE 33: Clean screen - **Step 5**



10. Press the arrow on the right side of the system's touchscreen to continue.
11. Dispose of the chip, reservoir, and pipettes according to your lab safety guidelines.

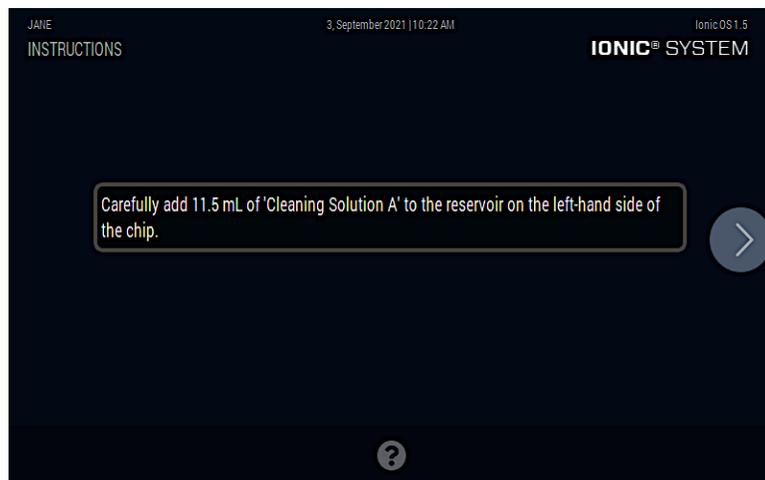
- Place second cleaning chip on the chip platform.

FIGURE 34: Clean screen - **Step 6**



- Press the arrow on the right side of the system's touchscreen to continue.
- Pour 1 bottle of **Cleaning Solution B** into the large reservoir (*approximate volume 12mL*).

FIGURE 35: Clean screen - **Step 7**



- Press the arrow on the right side of the system's touchscreen to continue.
- The Ionic Purification System cover will close and complete the second step of the electrode cleaning process.
- After approximately 10 minutes, the second **Complete** screen is shown. Press the arrow on the right side of the system's touchscreen to open the instrument cover.

FIGURE 36: Clean screen - **Step 8**

18. Before removing the chip from the instrument, use a pipette to remove any remaining solution in the reservoir and cover the reservoir with the seal provided for disposal.
19. Dispose of the chip, reservoir, and pipettes according to your lab safety guidelines.
20. Press the arrow button on the right side to return to the **Run Setup** screen.

Decontaminating the Ionic Purification System

If instrument contamination occurs, follow the guidelines below to decontaminate the instrument.

Interior

Ionic Purification System tray has been designed to catch and contain drips and small volume of liquid spills. Occasionally, use a soft lab towel to clean these areas with a 70% ethanol and 30% deionized water solution. When wiping down the instrument, apply the cleaning solution directly to a soft lab towel enough to slightly dampen it. Do not oversaturate the lab towel. Never add liquids directly onto any surface of the instrument.



NOTE

Do not use detergents, bleach, or acetone and other harsh solvents. Apply all standard safety practices when using cleaners and dispose of any generated waste in a responsible manner.

Exterior

The exterior of Ionic Purification System should always be kept clean and free of dust and debris that may affect its function and/or cooling efficiency. Generally, the exterior finish can be wiped down using a mixture of 70% ethanol and 30% deionized water applied to a slightly dampened lab towel. Do not oversaturate the lab towel. As an added precaution, it is recommended that the instrument be unplugged from the power source before beginning any cleaning process.



NOTE

Do not use bleach or acetone and other harsh solvents. Apply all standard safety practices when using cleaners and dispose of any generated waste in a responsible manner.

Other Maintenance Procedures

The following maintenance functions are accessed from the **Settings > Maintenance & Service** screen.

- **"Self Test"** below
- **"Open/Close Cover"** on page 43
- **"Save System Logs"** on page 44
- **"System Time Settings"** on page 46
- **"System Update"** on page 48
- **"Instrument Statistics"** on page 48
- **"Save Diagnostics"** on page 49
- **"Service"** on page 51

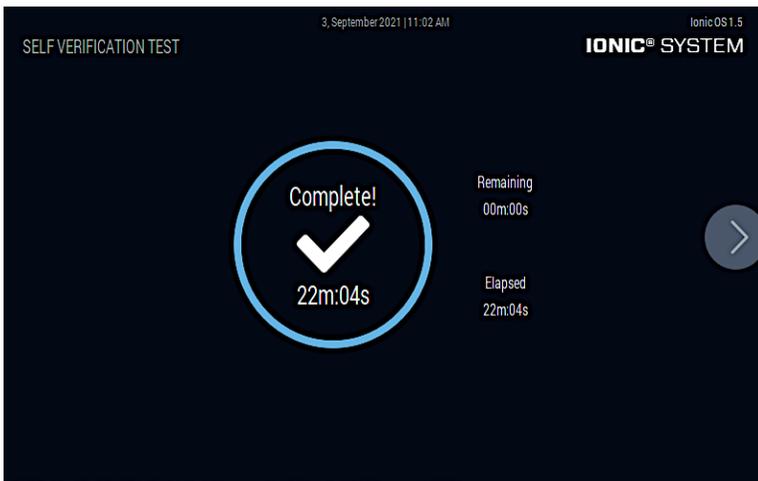
In addition, if you need to ship the instrument, follow the steps in the topic, **"Shipping the Instrument"** on page 51.

Self Test

The **Self Test** runs a set of automated diagnostics that checks many of the instrument functions. Once complete, a green check indicates the diagnostic tests passed and a red x indicates one or more diagnostic tests did not pass. If the self test results in a red x, the results should be emailed to support@purigenbio.com for interpretation.

1. From the Maintenance & Service menu, press **Self Test**.
2. The Ionic system begins performing a self test. Progress is indicated by the percent progress wheel on the screen. When the self test is complete, press the arrow button on the left-side of the touchscreen to return to the **Maintenance & Service** screen.

FIGURE 37: Self Verification Test screen



3. If the **Self Test** is not successful, follow the steps in "**Save System Logs**" on the next page to save the system log file to a USB flash drive and then email the log file to Purigen Biosystems support.

Open/Close Cover

The **Open/Close Cover** Maintenance screen is used to manually open or close the instrument cover.



IMPORTANT

Ensure the instrument cover is clear of all obstructions before manually opening or closing the cover.

1. Press the **Open/Close Cover** button view the **Open/Close** screen.

FIGURE 38: Open/Close Cover screen



TABLE 15: Open/Close Cover screen

Call Out	Screen Component	Definition
1	Open Cover button	A button to open the instrument cover
2	Close Cover button	A button to close the instrument cover
3	Help icon	Loads the Help screen

2. Press the **Open Cover** button to manually open the cover on the instrument or press **Close Cover** button to manually close the cover on the instrument.
3. Press the arrow button on the left side to return to the **Maintenance & Service** screen.

Save System Logs

The **Save System Logs** Maintenance screen is used to save system log files to a USB flash drive. The system log files can be used by Purigen Biosystems to diagnose problems with the instrument.



NOTE

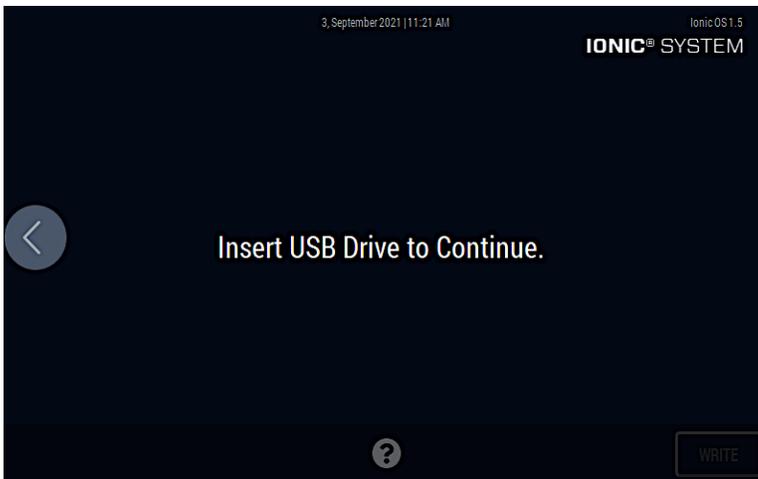
USB flash drive must be in a FAT32 format. It is recommended to have a minimum of 1GB of available space on the USB flash drive.

Some cases where this function should be used:

- If the run results are not as expected
- If the self test fails
- If Purigen Biosystems Support personnel request a system log

1. Press the **Save System Logs** button to save system log files to a USB device.

FIGURE 39: Save System Logs Screen - **Step 1**



2. Insert a USB drive into the USB slot located the bottom-right on the front of the instrument.
3. Once a valid USB drive is detected, the next screen is displayed. Press **Write** to begin the transfer.

FIGURE 40: Save System Logs Screen - **Step 2**



TABLE 19: Save System Logs screen

Call Out	Screen Component	Definition
1	Write button	A button to copy the system log to the USB drive inserted in the USB slot in the front of the instrument. The system log file is copied to the root directory of the USB drive
2	Help icon	Loads the Help screen

4. A status bar is displayed on the touchscreen.

 **NOTE**
The status bar may seem inactive for larger log files. Wait for the system log to be saved to the USB flash drive.

5. After the system log file is saved to the USB flash drive, press the button on the left side to return to the **Maintenance & Service** screen.

System Time Settings

The **System Time Settings** Maintenance screens are used to set the time zone, time zone offsets, date, and time for the instrument.

1. Select the UTC time zone offset for your location, if required.



NOTE

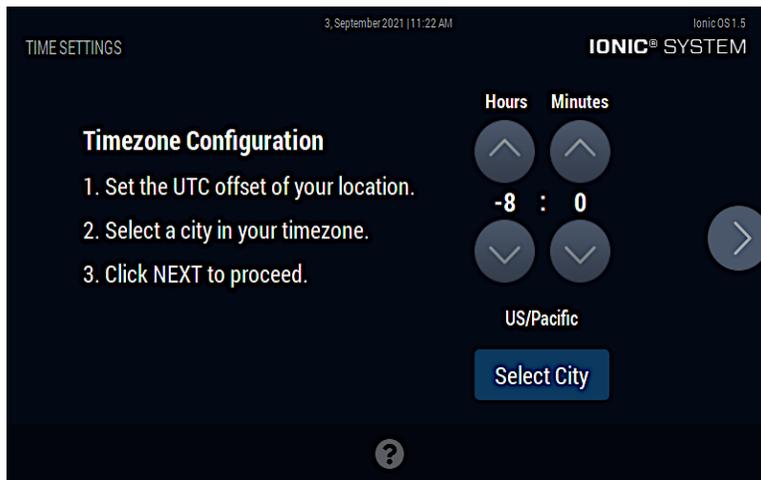
Default Continent/City is America/Los Angeles with a UTC offset of -8 (PST - Pacific Standard Time).



NOTE

Do not adjust the offset for daylight savings.

FIGURE 41: Time Settings screen

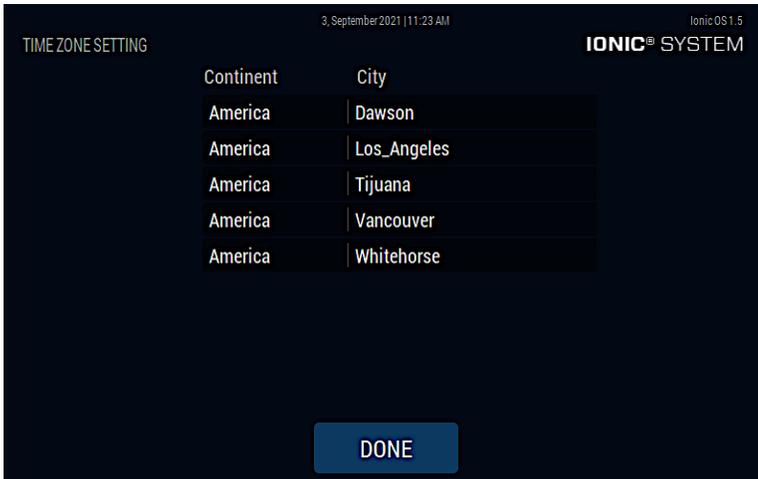


WARNING

If you select an invalid UTC offset, the Select City button is disabled. You must change the UTC offset to a valid offset to continue.

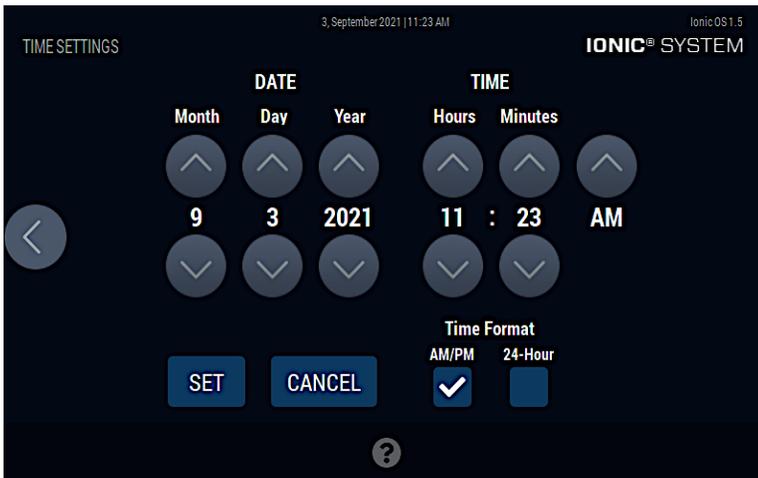
- Press the **Select City** button to select the city in your time zone. Once you have selected the city, please press **DONE** button.

FIGURE 42: Time Zone Setting screen



- Press the arrow on the right side to move to the **Time Settings** screen.

FIGURE 43: Time Settings screen



- Using the up and down arrows, select the month, day, year and time in hours and minutes.
- Select the **Time Format**.
- If all the settings are correct, press the **SET** button. The new time and date settings are applied to the instrument.

System Update

The **System Update** Maintenance screens are used to update the system software for the instrument.

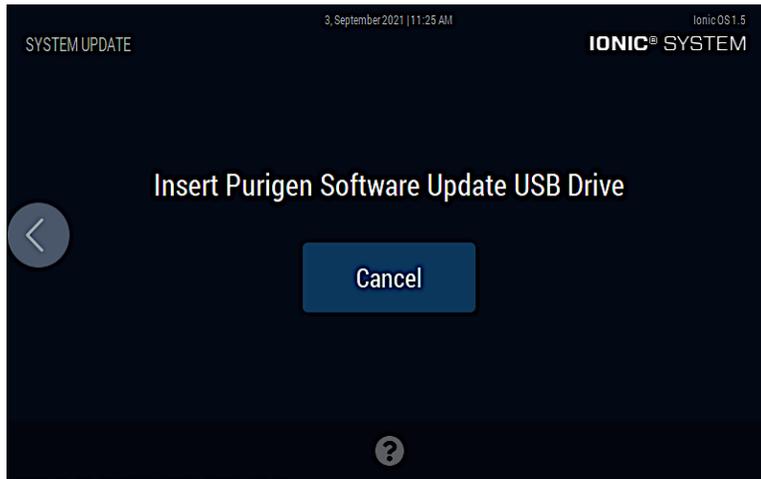


IMPORTANT

USB drive must be FAT32 formatted with at least 1 GB of free space.

1. Insert the USB drive in the instrument USB port located on the front right-side of the instrument.

FIGURE 44: System Update screen



2. The **System Update** screen displays the date and file name of the ISO system update file.



NOTE

Before starting the system update, you can press the arrow on the left side to return to the Maintenance & Support screen. Once the system update has started, it cannot be canceled.

3. Press the arrow button on the right to begin the system update.
4. The instrument will reboot once the system update has completed and proceed to the time settings window.

Instrument Statistics

The **Instrument Statistics** Maintenance screen is used to view instrument statistics listed below.

- **Runs Total** - Number of runs completed for the instrument
- **Sample Run Total** - Number of samples used from all the runs completed on the instrument
- **Run Time Total** - Total number of minutes for all the runs
- **Cell Runs** - Number of runs using the Cells protocol
- **Canceled Runs** - Number of runs canceled before completion
- **FFPE Runs** - Number of runs using the FFPE protocol

1. Press the **Instrument Stats** button to view instrument statistics.

FIGURE 45: Instrument Statistics screen



2. Press the button on the left side to return to the **Maintenance & Service** screen.

Save Diagnostics

The **Save Diagnostics** Maintenance screen is used to save instrument diagnostics to assist in troubleshooting. The saved log file should be sent to Purigen Biosystems. Please contact Purigen support to coordinate appropriate transfer of the log file.

If an error occurs or, if directed by Purigen Biosystems Support personnel, follow the steps below to save the instrument diagnostic log file.

1. From the **Maintenance & Service** menu, press **Save Diagnostics** to save the instrument diagnostic log file to a USB drive.



IMPORTANT

USB drive must be FAT32 formatted with at least 1 GB of free space.

FIGURE 46: Save Diagnostics screen - **Step 1**



2. Insert a USB drive into the USB slot located the bottom-right on the front of the instrument.
3. Once a valid USB drive is detected, the next screen is displayed. Press **Write** to begin the transfer.

Figure 47: Save Diagnostics screen - **Step 2**

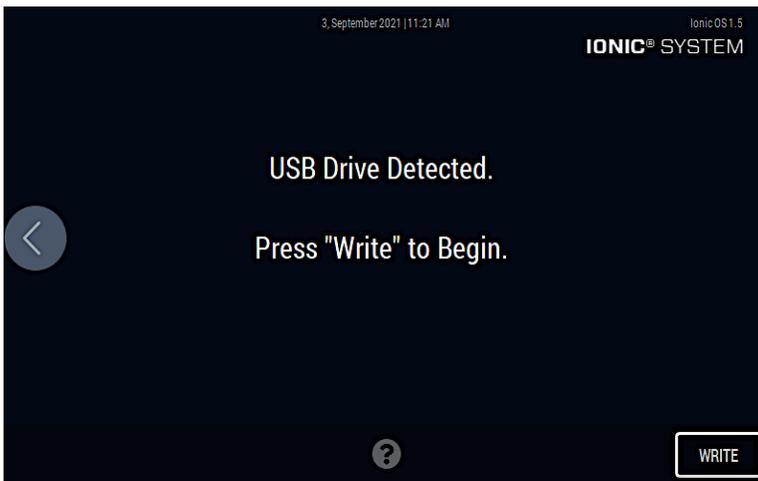


TABLE 20: Save Diagnostics screen

Call Out	Screen Component	Definition
1	Write button	A button to copy the system log to the USB drive inserted in the USB slot in the front of the instrument. The system log file is copied to the root directory of the USB drive
2	Help icon	Loads the Help screen

4. A countdown screen is displayed. This operation will take several minutes.
5. After the diagnostic log file is saved to the USB device, press the button on the left side to return to the **Maintenance & Service** screen.
6. Please contact Purigen support at support@purigenbio.com to coordinate appropriate transfer of file.

Shipping the Instrument

If you need to ship the instrument, the instrument cover should be in the open position.



NOTE

If you will be moving the instrument within the lab, you should move the instrument with the cover closed.

1. Follow the steps in the topic **"Open/Close Cover"** on page 43 to open the instrument cover.
2. Follow the steps in the topic **"Shutdown"** on page 33 to shutdown the instrument after the cover is open.

Troubleshooting

If you encounter any errors while running the instrument, follow the steps in **"Save Diagnostics"** on page 49 and then email the log file you saved to support@purigenbio.com. Purigen Biosystems support will contact you within 48 hours to follow up.