

Instruction Manual

Automated Nucleic Acid Purification System

ePure



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Ecoli Dx, s.r.o.
Purkyňova 74/2
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Czech Republic



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Introduction

Thank you for purchasing the ePure system which is a fully automated, standalone robot that can purify nucleic acids within 30-45 minutes. With advanced magnetic bead separation technology, it enables you to obtain high-quality extraction results. Moreover, the most user-friendly interface makes users free from troublesome parameter settings and maintenance.

This guide contains important information regarding the safe use of the ePure system. Please read this manual carefully before you start to run the system for the first time, especially for Safety Information.

If there is any question about how to install or operate the system, please contact our certified distributors/agents or email our technical support center (ecolidx@ecolidx.com).

Manufacturer Info:

Manufacturer:	Ecoli Dx, s.r.o.
Address:	Purkyňova 74/2 11000 Praha 1 - Nové Město Czech Republic
	Tel: +420 325 209 912
Mail:	ecolidx@ecolidx.com
Product of Origin:	Czech Republic, EU

Safety Information

The meaning of safety precaution marks are as follows:

WARNING:

“WARNING” indicates a dangerous condition that may lead to death or serious injury.

BIOHAZARD:

This symbol indicates that certain precautions must be taken when working with potentially infectious material.

CAUTION:

This symbol indicates that non-compliance with instructions or procedures may lead to physical injury or even death or could cause damage to the instrument.

Important:

“Important” points an important note for appropriate usage, as well as prohibited actions.

Note:

“Note” indicates the procedures that should be obeyed and supplementary information for use.

HOT SURFACE:

This symbol labels potentially hot surfaces on the instrument.

IVD

This symbol shows this instrument is an “In vitro diagnostic”-certified medical device. For your safety and that of others, follow the guidelines provided in the following pages concerning the use of the ePure system.

Important Notice

- In the event of a malfunction of the device or a deterioration of its function, which may endanger its functionality, the device must not be used and an authorised service should be contacted immediately.
- Any serious adverse incident that occurred in connection with the device must be reported to the manufacturer of EcoliDx and to the competent authority of the Member State where the user is established.

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Limitations and Obligations

The information contained in this document may be changed or modified and is not for Ecoli Dx, spol. s.r.o. binding. The changes made will be reflected in the new edition of this publication.

Ecoli Dx, spol. s.r.o. assumes no responsibility for the use or faultlessness of a device that is not supplied directly by the manufacturer or an authorized distributor.



For safe recycling/disposal of the device and its accessories, contact your supplier. Please note that in the case of contaminated equipment, it is the user's responsibility to ensure that the product is decontaminated before its disposal and the user is obliged to provide a decontamination certificate to their supplier who will arrange for the disposal of the goods.

About Instrument

WARNING:

- Ignoring the following notations may lead to fire or electric shock.
 - In countries other than Taiwan, US and Canada, use a power cable that meets your country's standard or contact your local distributor.
 - Do not use the ePure system with the voltage other than the voltage specified on the device.
 - Do not use the ePure system with a damaged power plug or a loose socket.
 - If there is dust on the prongs of the power plug or on the plug socket, remove it with a dry cloth.
 - When you disconnect the plug from the outlet, be sure to hold the power plug itself. Do not pull the power cable.
 - For maintenance, disconnect the power plug from the outlet.
 - Do not touch the power plug when you hear the crash of thunder.
- Do not pour any liquid on the ePure system.
- Do not place any objects containing liquid on the ePure system. Doing so may cause device failure, fire, or electric shock.
- If the device starts to smoke or smells strange, immediately unplug the power cable.



CAUTION:

- Never attempt to remodel the ePure system without the manufacturer's permission. Doing so may cause fire or electric shock.
- Do not place or drop objects on the ePure system. Also refrain from bumping or knocking it, as doing so may cause a failure or malfunction of the ePure system.
- If any liquid materials are left inside the device, wipe it up with a soft paper tissue, etc. Otherwise, the ePure system may be damaged.

- Repairs to the ePure system should only be performed by such agencies as are specifically authorized by Ecoli.
- Only original Ecoli replacement parts should be used.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

About Reagent Kits



CAUTION:

- When handling any of the kits, refer to the respective handbook.
- Reagents in each kit should be handled by observing the safety information and precautions regarding the kit.
- Extraction should be performed in an appropriate laboratory or workplace.

Note:

- The kits are not supplied with the ePure system. Select the desired kit(s) and order it (them) separately.

ePure Magnetic Bead Purification Process



About Samples



BIOHAZARD:

- Always wear appropriate gloves, a mask, and safety goggles, etc. when handling any infectious samples.

About Infectious Wastes

- When handling or disposing of infectious materials, follow the laboratory guideline or the law regarding infectious waste to perform proper incineration, fusion, sterilization, and/or disinfection.
- When you use a third party company to dispose of wastes, outsource this work to an operator licensed to handle medical waste subject to special control, and give them the medical waste manifest at the same time.

Ecoli Service Center

- For technical problem and instrument maintenance please contact our service center:

Ecoli Dx, s.r.o.
Purkyňova 74/2
11000 Praha 1 - Nové Město
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ecolidx@ecolidx.com

1.0 Installation

1.1 Composition of the ePure system

Check that the following items are included in the package. Contact your local representative if you notice any missing part(s).

A. ePure X 1



B. EU Power Cord X 1



C. Sample Rack X 1



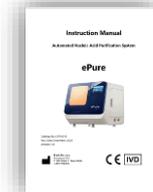
D. Barcode Reader X 1



D. microSD ADAPTER



E. User Manual X 1



Caution:

“TURN OFF POWER BEFORE INSERT AND PICK UP SD CARD”

To insert the Un-locked SD card in right direction

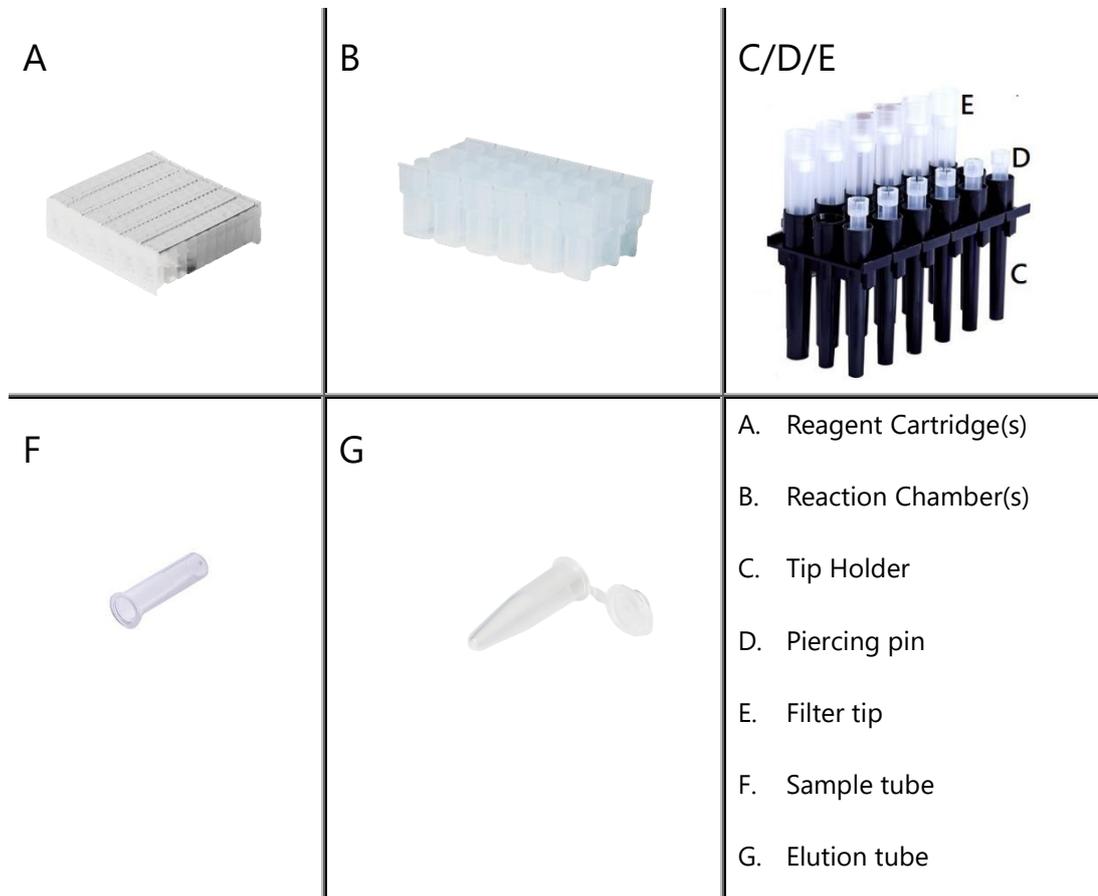
Please make sure all the components are free from damages as soon as you get the system. If any damage is found, please contact your local representative for instant support.



Note:

- Ecoli global warranty does not cover damages from transportation or improper operation.

1.2 Contents of Reagent Kits



Note:

- Reagent kits are to be purchased separately. Please contact your local agents or representatives to get further info.
- The contents of reagent kits will vary. Refer to the handbook of kits enclosed in reagent box for details.

1.3 Operating Environment / Condition

Use the ePure system in a location that meets the following conditions:



- The ePure system must be placed at a minimum distance of 5-10 cm from all sidewalls to allow good air circulation. The space for the allocation of the ePure system must remain 5-10 cm from instrument to sidewalls.
- A location where power supply is provided with safety.
- A location where the temperature ranges from 15 to 30°C and humidity ranges from 30% to 80% RH. (non condensing)
- A location that is flat and stable, with no vibration.
- A location away from direct sunlight. (Block the sunlight by closing curtains or blinds as necessary)
- A location which is well-ventilated and not dusty.
- A location where the temperature does not go up and down suddenly. (Warming a cold room suddenly or moving the ePure system from a room with low temperature to a warm room may cause condensation inside the device, resulting in abnormal extraction)
- A location where the temperature and humidity are kept within the specified range (far from water taps, water heaters, humidifiers, air-conditioners, and heaters)
- A location far from objects that generate strong magnetic fields. (motors, transformers, TV, audio speakers, magnets, etc.) (Bringing the ePure system close to any type of magnetic field may cause a malfunction)

Warning:

Do not use the ePure system in a location where it is wet or can be splashed with water. It may cause device failure, fire, or electric shock.

When relocating the ePure system, disconnect the plug from the outlet first. If the power cable is damaged, this may cause device failure, fire, injury, or electric shock.

 **Caution:**

Do not use the ePure system in an unstable place such as a slanted surface or a place subject to vibrations. It may cause injury or device failure.

Do not use the ePure system under direct sunlight or close to a heating device. It may shorten the life of the ePure system, or cause troubles.

Do not open the maintenance door while performing the experiment.

Do not open the front door while performing the experiment.

Operating Conditions

Items		Conditions
Temperature (°C)	During operation	15 – 30
	During downtime	0 – 55
Humidity % (RH)	During operation	30 – 80
	During downtime	10 – 80
Altitude, operating (m)		Less than 2000 m (1008 hPa)

1.4 Unpack the ePure system

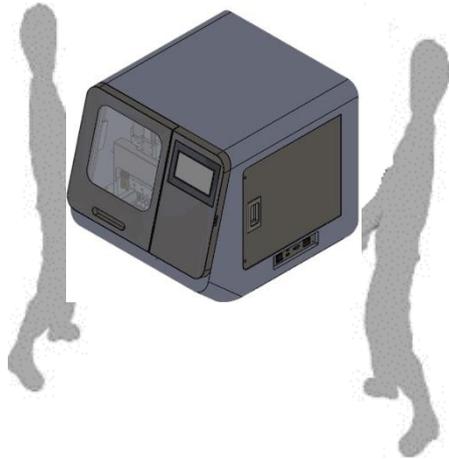
Open the packing box and take out the instrument and related accessories.

Important:

The ePure system weights approximately 71 kg. It should be lifted and moved by two persons.

Hold the moving handler of the instrument from two sides to move it out from

the box. Handlers are located under the device, on the chassis' bottom.



- Do not hold the outer covering.
- Do not hold the front panel.
- Do not hold the door.

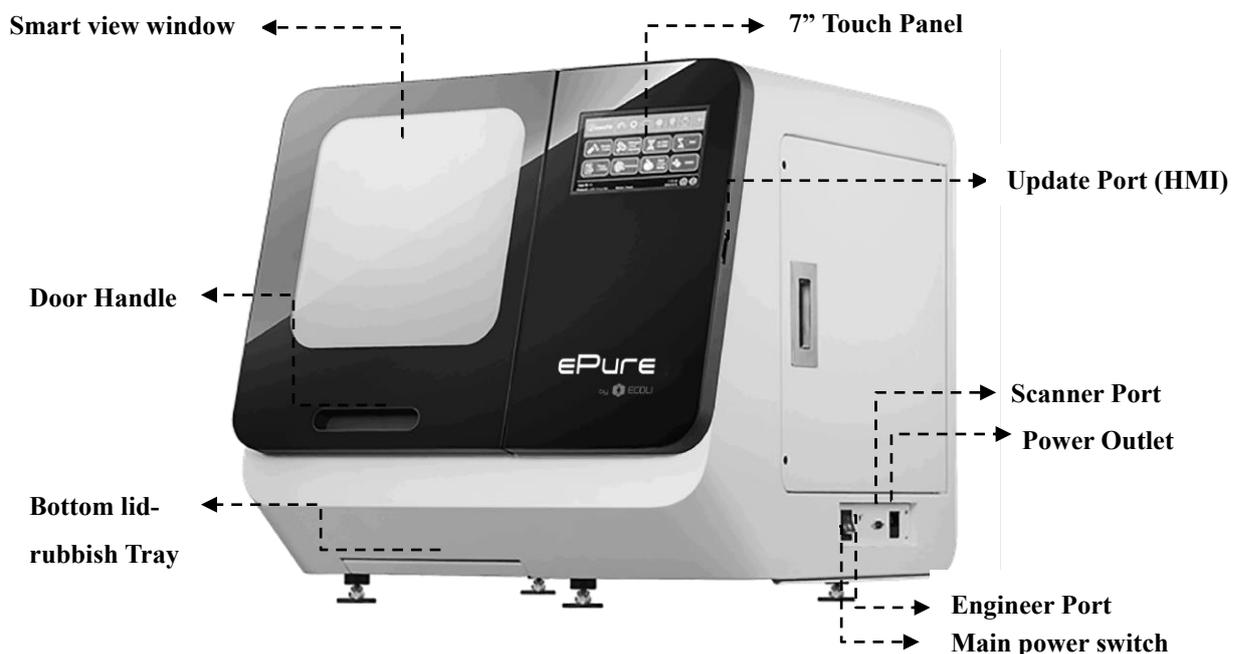
 **Caution:**

Improper ePure system movement handling will lead to instrument damages.

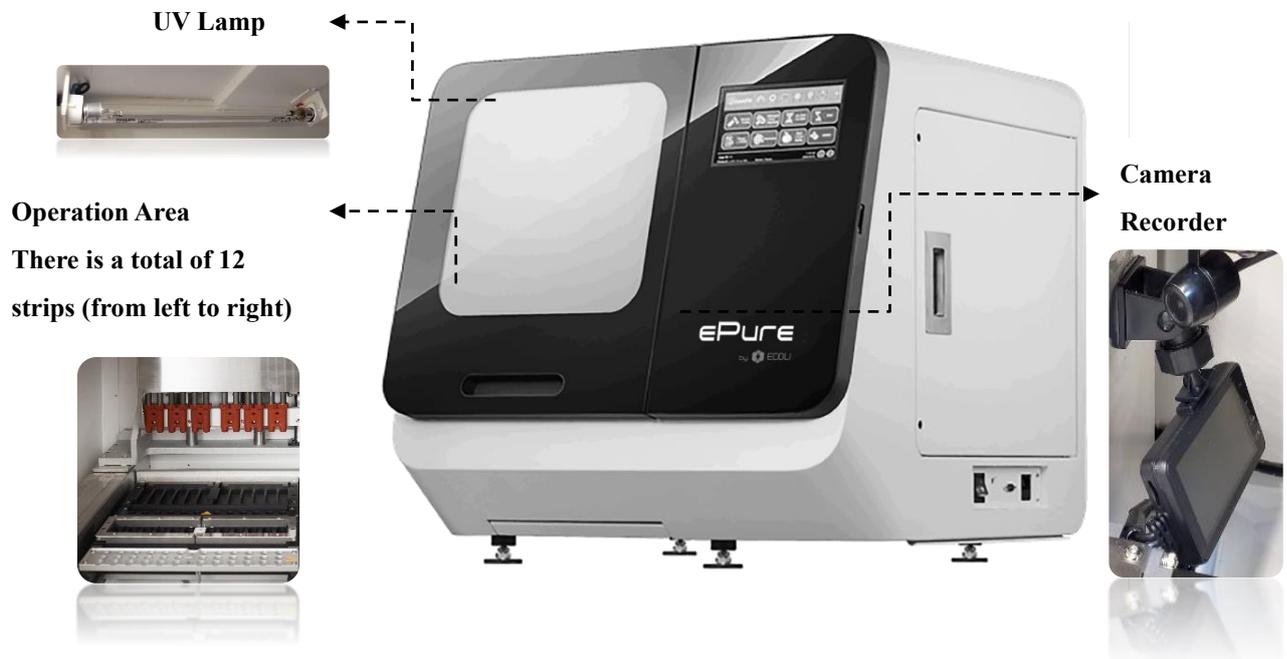
For correct and safe use of the ePure, install the device in a location close to the electrical outlet and that has enough space for installation and main switch operation .

1.5 Overall View

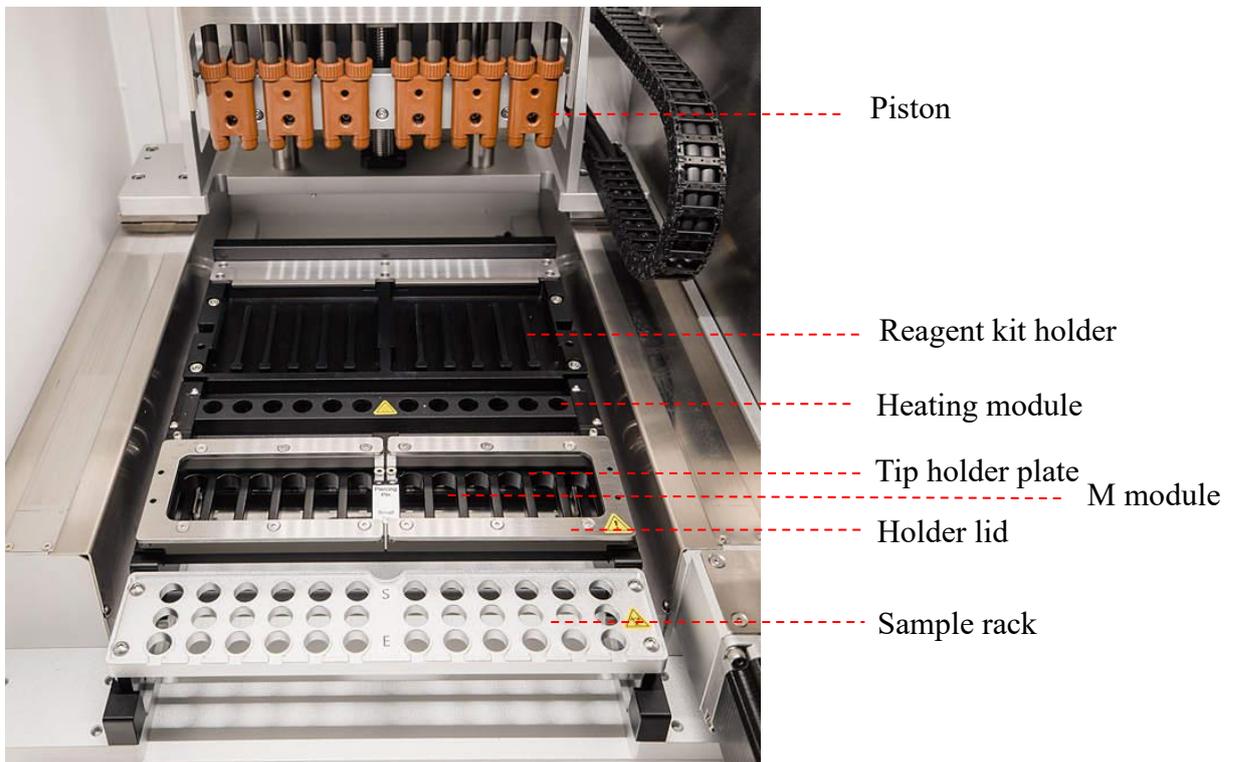
- Front view with Door closed



■ Front view with Door opened



■ Inside view



2.0 Getting Started



Biohazard:

Always wear appropriate gloves, a mask, and safety goggles during any biohazardous operation during the extraction process. Even when touching the device after any operation with a biohazard risk, wear appropriate gloves and a mask since the device may be contaminated.

Important:

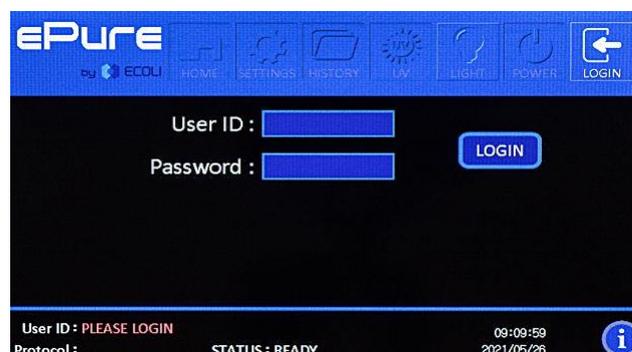
Before starting extraction, put on appropriate gloves, a mask, and safety goggles if required by the operation. During the operation, from sample preparation to extraction completion, be careful not to expose the samples to foreign contaminants such as sweat, saliva, etc.

2.1 Turning ON the power

Follow the steps below to release the fixed part inside the instrument

- i. Plugin the power cord to the instrument and connect to the electric outlet.
- ii. Connect the barcode reader to instrument. Turn the power ON and log in with User ID "1" without password (Display will delay startup to read the SD card)

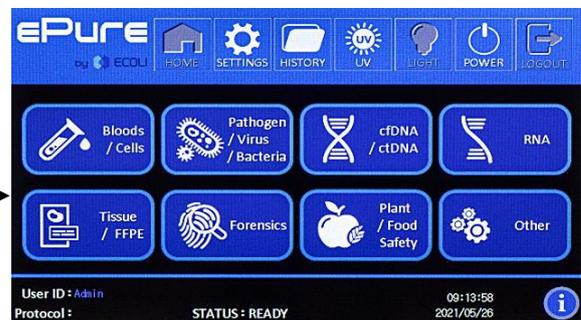
(Please refer to System Status for the operate information)



- iii. Set up the local time.
(Please refer to System Status for operating information)

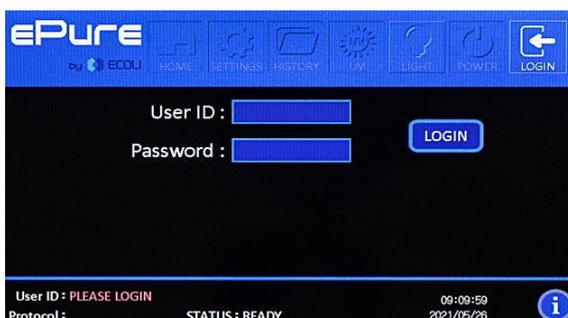


- iv. System will start to do the initialization and device will release transportation fixing parts automatically.



As an end user, log in with User ID "Admin" (as end user/top authority in the laboratory), password "ADMIN". You can set your Top authority "Admin" password to lock access to user to certain "Admin" options.

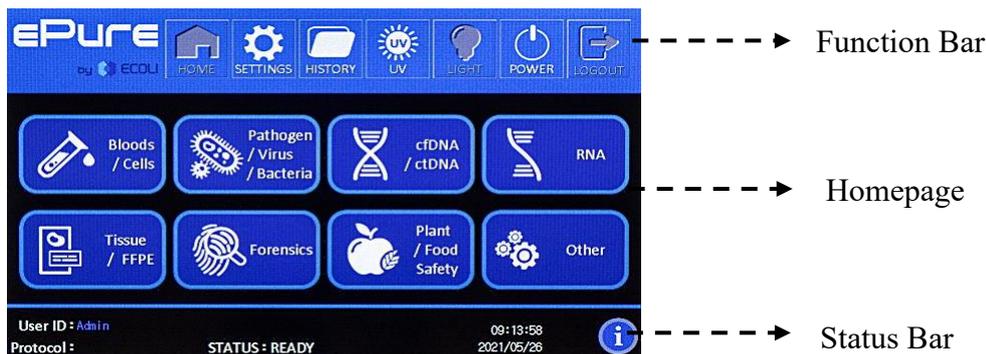
- v. Once logged in, you will be able to set up at least 10 other users with their own password.



Important:

Keep the shipping box and fixing block materials. They will be needed again when transporting the ePure system.

2.2 Touch Panel and User Interface



2.3 Preparation

The following preparations are required for extraction operation.

- Gloves
- Mask
- Safety Goggles
- ePure Kit



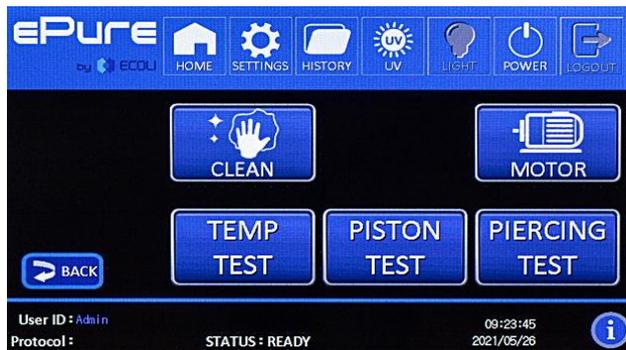
- For Sample preparation, please refer to the handbook of each kit.

2.4 Function Test

Enter to the settings "MOTOR" and check position of each axis (Y/Z/P/M)

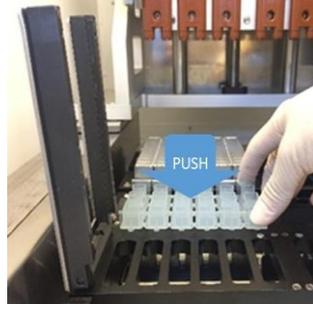
Select  then system will check the position automatically.

(Please refer to System Status for operating information)



2.5 Extraction

(1) Plastic consumable set up:



Insert the cartridges

Push down each cartridges

Insert Reaction Chambers

Insert Tip Holder

(ST cartridges with "click" sound)

(push down each wells)



Close the tip holder lids

Insert Piercing Pins

Insert Filter tips

Stick the barcode label



Insert Sample Tube

Insert Elution Tube

Load the sample(s)

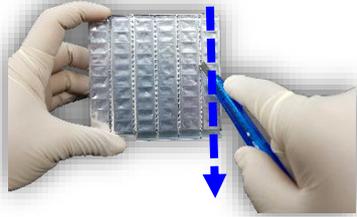
(On Sample Rack)

(On Sample Rack)

(To Sample Tube)

Note:

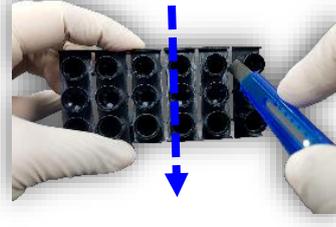
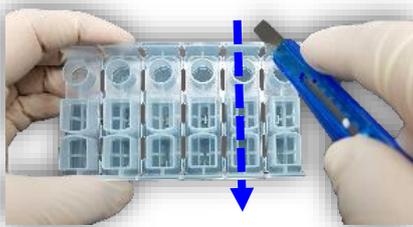
How to pull apart reagent cartridges strips: Slash open the dotted line with a cutter.



The position of piercing pins (on the right) and filter tips (on the left). The 2nd row in the middle should be EMPTY.



Use cutter or scissors **ONLY**, if you are intending to separate the **Tip Holder / Reaction Chamber strips**.

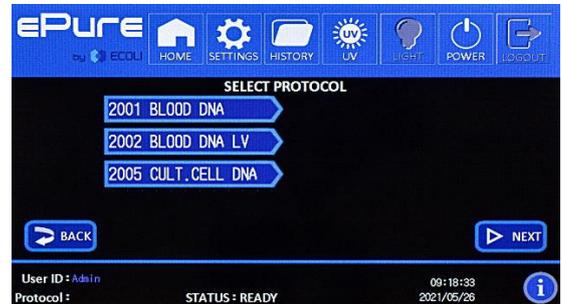


Important:

- Set Cartridges respecting the numbers order from left to right.
- Make sure that Cartridges are inserted into the Cartridge Tray tightly.
- You can load 1-12 strips on the tray depending on the number of samples you intend to process.

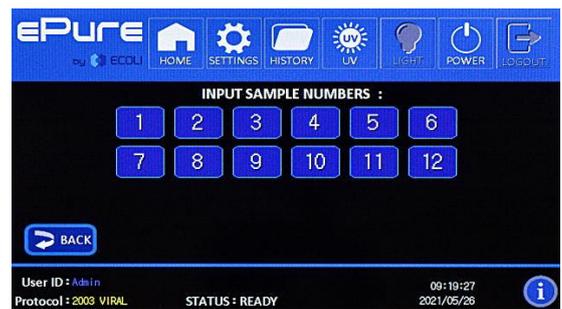
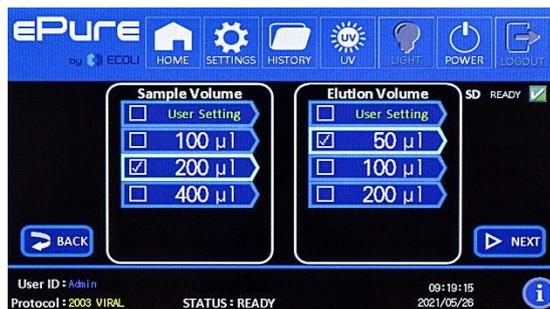
(2) Start Program:

(Please refer to System Status for operating information)



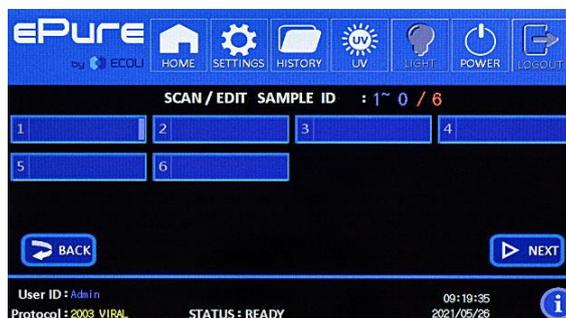
Select the desired targets from homepage

Select the Protocol then Press "NEXT"

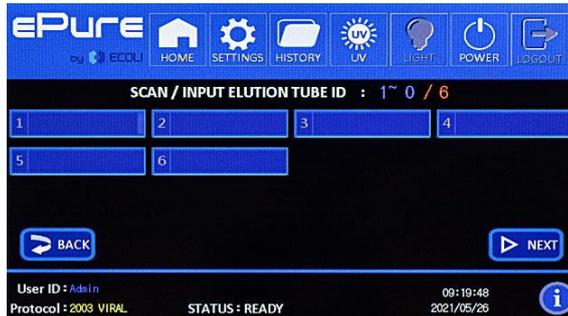


Select Sample and Elution Volume then Press "NEXT"

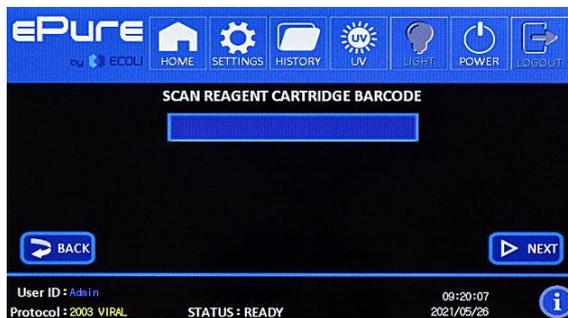
Select the Sample number then Press "NEXT"



Edit the Sample ID then Press "NEXT"



Edit the Elution ID then Press "NEXT"



Scan Reagent Cartridge Barcode then Press "NEXT"

Ecoli do not guarantee with expired kit performance. "Admin" & "Service" ID have to take responsibility for kit usage status.



System displays a consumable Checklist, Tick corresponding boxes then Press "NEXT". Note: The system will not allow user to go forward if not all consumable boxes are ticked. Add an Internal Control is optional.

Note:

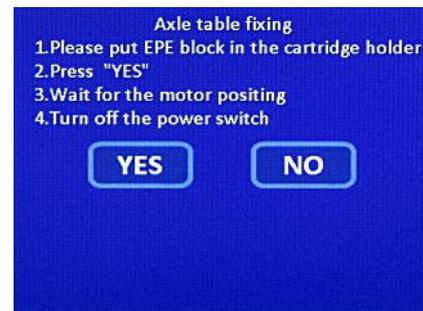
- To amend ID information: “DEL” wrong ID information → Scan right ID
- Pretreatments are essential for some sample types before loading to Sample Tube. Please refer to the handbook of reagent kits for details.
- Make sure the Sample Tray is placed correctly in the instrument
- Store the purified nucleic acids at 4°C for short-term storage or store at -70°C for long-term storage.

2.6 System fixing before transportation

(1) Enter to settings and select “Fixing”.

(Please refer to System Status for operating information)

(2) Put back the Fixing block at the Position of cartridge holder.



3.0 Cleaning & Maintaining the ePure

! Once the sample or the buffer splash, stop to clean as following information.

! **Caution:**

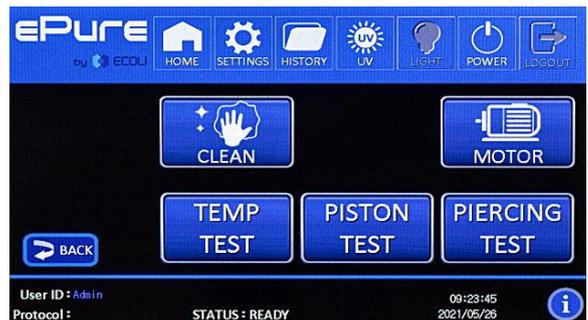
3.1 Cleaning of Rubbish Tray and M motor

To elevate M motor before cleaning of rubbish tray and M motor

(1) Enter to setting and select "Function Test"



(2) Select "CLEAN" to elevate M motor



(3) Cleaning of rubbish tray and M motor with mild detergent and rinse with deionized water. Allow the parts to dry before use. Clean and disinfect the platform surface by wiping with deionized water followed by 75% ethanol.

(4) To down M motor by click "FINISH" after cleaning



3.2 Routine and Preventive Maintenance

Two types of maintenance are to be performed on the ePure system instrument as listed in the table. For details on each type of maintenance, see below:

Schedule	Maintenance Type	Performed by
After each use	Routine <ul style="list-style-type: none"> ■ Cleaning of sample Tray, M module, piston and holder lid by 75% EtOH. ■ Cleaning of heating module and using cotton swab to check buffer residue in hold of heating module. 	User
Bi-weekly	<ul style="list-style-type: none"> ■ Check SD Memory space ■ Cleaning of instrument body (outside) ■ Cleaning of instrument body (inside) 	User
Two times a year or Annually	Preventive <ul style="list-style-type: none"> ■ Grease ball screws if required ■ Check motor movement ■ Check the air-tight status with piston units (using empty plastic wares and run) 	Service Engineer

Long-term shutdown

Remove the mains cable from the outlet. Protect the device from dirt and direct light.

UV Light 30min by default



- Clean the Sample Tray and M motor with mild detergent and rinse with deionized water. Allow the parts to dry before use. Clean and disinfect the platform surface by wiping with deionized water followed by 75% ethanol.
- Clean the instrument body by removing dust gently with a dry, soft cloth. If the outside of the ePure system is heavily soiled, or if any sample that may cause infection are adhering to the outside of the ePure system, wipe with a soft paper tissue, soaked with 75% ethanol.

4.0 Troubleshooting

Problem	Cause	Solution
Instrument Problems		
No power (the LCM Screen remains blank when the power is turned on)	AC power cord is not connected	Check AC power cord connections at both ends. Or Use the correct cords.
LCM Screen turns ON when the power is ON but the self-testing program does not run	Forget to remove the packing elements from the instrument	Turn off the instrument and remove the packing elements .
	Technical problem	Contact your local representative or agent.
Protocol stops after an initial start	Cartridge(s), Plastic wares (Reaction Chamber, Tip Holder, Filter tip, Sample Tube, Elute Tube) incorrectly loaded on the ePure system	Turn off the power and then turn it on again to stop the program. The system will move back to the initial state. Re-load them according to the instructions shown in this manual. Note: you cannot resume the protocol after stopping it, you may lose your samples.
Bubbles form during extraction	Miss adding sample or sample volume is lower than the recommended volume	Be sure to add the sample to tubes prior starting the protocol. To ensure proper mixing of reagents in the tip and prevent bubble formation during mixing, make sure the sample volume is at least the recommended volume listed in the handbook supplied with the ePure Reagent Kits.
	Motor movements may not be smooth, incorrect placement of plasticware or leakage from tips	Perform preventive maintenance annually to ensure proper motor movements.
Presence of buffer in the Cartridge Tray	Air leakage on the Filter tip	Swap the air-leaked Tip with a new one
Leakage from Filter tip Filter tips or uneven liquid handling between	Too much starting material or excess DNA in sample causing	Decrease the amount of starting material. Use the recommended amount of starting material as listed in the Reagent Kit manual (Handbook).

Filter tips	clumps or aggregates	
Blockage of tips and pipetting failure	Too much starting material or excess DNA in sample causing clumps or aggregates	Suggest using blood kit 1200 instead of blood kit 200 (if testing sample is blood).

DNA Quality Problems

Problem	Cause	Solution
Low DNA yield	Incomplete lysis	Decrease the amount of starting material used.
		Be sure to add Proteinase K during lysis, if included in the protocol.
		Make sure that the sample is completely immersed in the Lysis Buffer.
	Poor quality of starting material	Be sure to process the sample immediately after collection or store the sample at the appropriate temperature. The yield and the quality of DNA isolated depend on the starting material.
	Insufficient amount of magnetic beads added	During shipping, some magnetic bead solution may adhere to the sealing foil of the cartridge. To collect any bead solution from the foil, tap the cartridge to deposit the bead solution at the bottom of the well.
	Clogged Tips resulting in DNA loss	Ensure that the lysate does not contain any particulate material that can clog the tip sprout. If needed, centrifuge the sample prior to the ePure purification.
No DNA recovered	Magnetic beads stored or handled improperly	Store cartridge containing the beads at room temperature.
		Do not freeze the cartridge as the beads may be irreversibly damaged.
		Make sure that the beads are in solution at all times and do not dry. Dried beads are non-functional.
Eluate containing DNA is discolored	Magnetic beads present in the eluate	Remove any magnetic beads using a magnetic separator or centrifuge the sample in a microcentrifuge for 1 minute at maximum speed.
	DNA contaminated with heme	Minimize the amount of blood or blood-stained sample used ($\leq 20\mu\text{l}$ blood spot for forensics sample).
DNA is	Purified DNA was repeatedly	Aliquot purified DNA and store at 4°C (short-term) or -20°C

sheared or degraded	frozen and thawed	(long-term). Avoid repeated freezing and thawing.
	DNA contaminated with DNases	Maintain a sterile environment while working (i.e. wear gloves and use Dnase-free reagents).

5.0 Specifications

Model	ePure
Instrument Type:	Benchtop automated nucleic acid extractor
Sample Processing:	1 to 12 samples per batch
Sample Volume Handling:	100 – 2000 µL
Processing Time:	See purification kit manual for details
Heat Block Temperature:	60 °C to 70 °C (assuming the room temperature of ~25 °C)
Protocol Input:	Touch Panel
UV Light	30 minutes @ 250 nm
Built-in Features:	7" Touch Panel
Instrument Dimensions:	62.3 cm W x 63.5 cm D x 60.9 cm H
Weight:	71 kg
Input Power:	AC 100-240 V, 50/60 Hz, 350 VA
Operating Temperature:	15-30 °C
Operating Humidity:	30-80 %
Fuse:	F 5A 250 V

UPS Specification

On-Line, 1.5kVA/1200W, Battery energy (Watt-hours): 440 Wh

EMC

EN 61326-1:2013 (IEC 61326-1:2012), EN 61326-2-6:2013

Safety

IEC/EN61010-1, IEC/EN 61010-2-101

6.0 Warranty and Technical assistance

For more information about Ecoli Dx services go to our webpage.

Should you need any technical assistance and more information, please contact local distributor of Ecoli Dx products.

7.0 Accessories

Catalog number	Name
ZA01053-001	Sample rack (1.5ml Eppendorf tubes) 
ZA01004-002	Power Cord (Euro socket)
ZA01006-001	Bar code reader 
ZA01002-001	UV fluorescent lamp 

Revision history

Version	Date	Description
1.0	24/02/2021	Update of informations
1.1	16/05/2022	Addition of logo, Related products, important notices
1.2	14/07/2022	Added chapter 7.0 List of available accessories



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