Instruction Manual

Automated Nucleic Acid Purification System

BioMagPure 12



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Wellkang Limited Suite B, 29 Harley Street LONDON, W1G 9QR, U.K. www.CE-marking.eu RÓ

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INTRODUCTION

About BioMagPure 12

BioMagPure 12 Thank you for purchase of the BioMagPure 12 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 have 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 BioMagPure 12. Please read this manual carefully before you start to run the system at the first time, especially for Safety Information.

If there is any question about how to install or operate it, please contact our certified distributors / agents or email to our technical support center

Safety information

Safety	У	The meanings of safety precaution marks are as follows:
Warnin	ing	"WARNING" indicates a dangerous condition that may lead to death or serious injury.
Biohaz	azard	This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.
Cautio	ion <u>/</u>	This symbol is used to indicate that non-compliance with instructions or procedures may lead to physical injury or even death or could cause damage to the instrument.
Import	rtant	"Important" shows the important notes for usage, as well as prohibited actions.
Note		"Note" indicates the notes, procedures that should be obeyed and supplementary information for use.
Hot su	surface	This symbol is used to label potentially hot instrument surfaces.
IVD	IVD	This symbol is In vitro diagnostic medical device.

Important using notices

Notices	For your safety and that of others, follow the guidelines provided in the following pages concerning the use of the BioMagPure 12.		
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 BioMagPure 12 with voltage other than the voltage specified on the device. 		
	- Do not use the BioMagPure 12 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 BioMagPure 12.		
	Do not place any objects containing liquid on the BioMagPure 12. Doing so may cause a device failure, fire, or electric shock.		
	In the event the device overheats, starts to smoke or smells strange, immediately unplug the power cable.		
	Caution:		
	Never attempt to remodel the BioMagPure 12 without the manufacturer's permission. Doing so may cause fire or electric shock.		
	Do not place or drop objects on the BioMagPure 12. Also refrain from bumping or knocking it, as doing so may cause a failure or malfunction of the BioMagPure 12.		
	If any liquid materials are left inside the device, wipe it up a soft paper tissue, etc. Otherwise, the BioMagPure 12 may		

	be damaged.			
Important using	notices, continued			
About Instrument	Repairs to the BioMagPure 12 should only be performed by such agencies as are specifically authorized by the SIA BIOSAN.			
	 Only original the SIA BIOSAN 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 BioMagPure 12. Select the desired kit(s) and order it (them) separately.			
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 to dispose of it, outsource this work an operator licensed to handle medical waste subject to special control, and give them the manifest of the medical waste at the same time.			

Specifications

Product Specifications

Model	BioMagPure 12
Instrument Type:	Benchtop automated nucleic acid extractor
Sample Processing:	1 to 12 samples per batch
Sample Volume Handling:	100 – 2000uL
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:	Barcode Reader
Built-in Features:	LCD Display Screen
Instrument Dimensions:	47 cm W x 68 cm D x 51 cm H
Weight:	43 kg
Input Power:	AC 100-240 V, 240 VA, 50/60 Hz
Operating Temperature:	15-30°C
Operating Humidity:	30-80%
Fuse:	F3.15A 250V
Temperatures allowed during transportation/ storage/ packaging:	-25°C to +70°C
LV directive (73/23/EEC)	
EMC directive (89/336/EEC)	
EN61326-1	
EN60101-1, EN60101-2	

C F T C E E

EMC

Safety

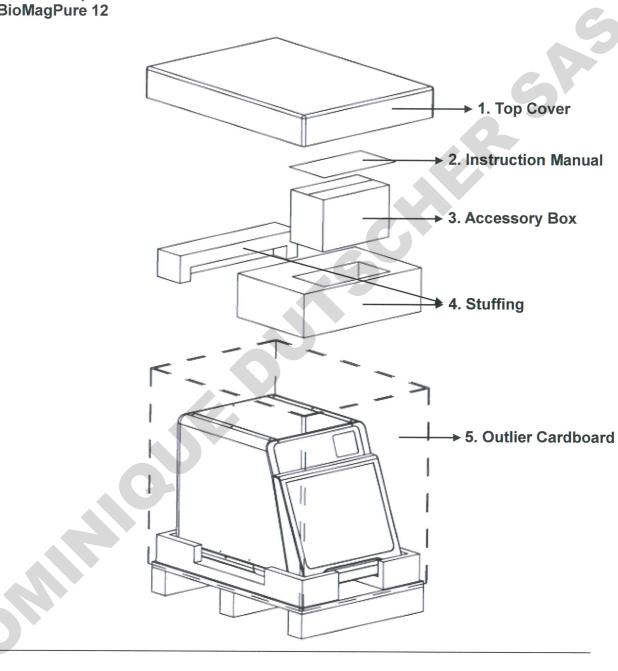
Purification process





Unpack the BioMagPure 12

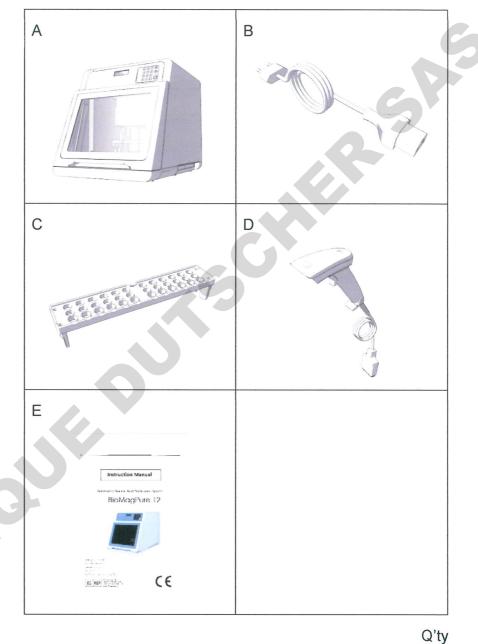
How to Unpack the BioMagPure 12



Composition of the BioMagPure 12

BioMagPure 12

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



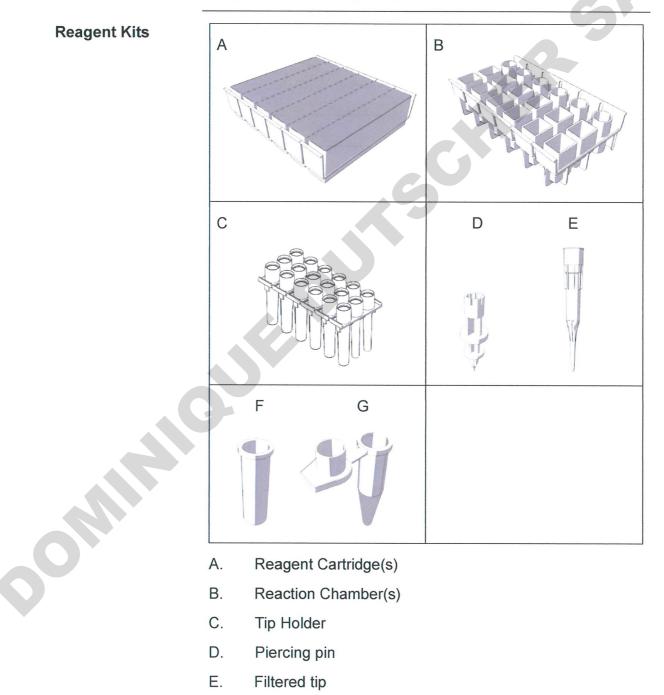
A. BioMagPure 12 Instrument	1
B. Power Cord	1
C. Sample Tube Rack	1
D. Barcode Reader	1
E. User's Manual	1

Composition of the BioMagPure 12, continued

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

Note:

Biosan's global warranty does not cover the damages from the transportation or improper operation.



Composition of the BioMagPure 12, continued

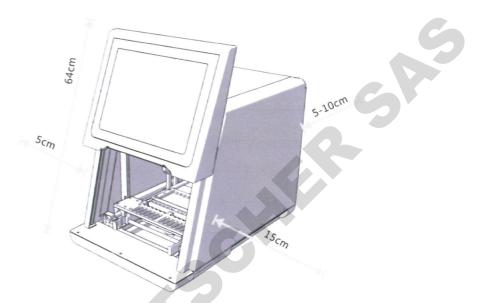
- F Sample tube
- G Elute tube

Note:

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

Operating Environment / Condition

BioMagPure 12 Operating Environment Use the BioMagPure 12 in a location that meets the following conditions:



- The space for the allocation of the BioMagPure 12 must be remained 5-10 cm from instrument to side walls.
- A location where power can be provided.
- A location where the temperature is 15 to 30°C, and humidity is 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 BioMagPure 12 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 which generate strong magnetic fields (motors, transformers, TV, audio speakers, magnets, etc.) (Bringing the BioMagPure 12 close to any type of magnetic field may cause a malfunction.)

Operating Environment / Condition, continued

Warning:

Do not use the BioMagPure 12 to a location where it is wet or can be splashed with water. It may cause a device failure, fire, or electric shock.

When relocating the BioMagPure 12, disconnect the plug from the outlet first. If the power cable is damaged, this may cause a device failure, fire, injury, or electric shock.



Do not use the BioMagPure 12 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 BioMagPure 12 in direct sunlight or close to a heating device. It may shorten the life of the BioMagPure 12, or cause a trouble.

BioMagPure 12 Operating Conditions

BioMagPure 12	Items		Conditions
Operating Conditions	Temperature (°C)	During operation	15 – 30
Conditions		During down time	0 – 55
	Humidity (RH)	During operation	30 - 80
		During down time	10 – 80
	Max. wet bulb	During operation	29 (non condensing)
	temperature (°C)	During down time	29 (non condensing)
	Temperature gradient (°C/hr)		12 or less
			(non condensing)
	Humidity gradient (RH/day)		30 or less
			(non condensing)
	Altitude, operating (m)	1600 or less

Initial setting

BioMagPure 12 Setting

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

Important:

The BioMagPure 12 has a weight of more than 45kgs. It should be lift and moved by two persons.

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

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

Caution:

Improper handling of the movement of the BioMagPure 12 will lead to instrument damages.

For correct and safe use of the BioMagPure 12, install it in a location that is close to electrical outlet and has enough space for installation and operation of the mains switch.

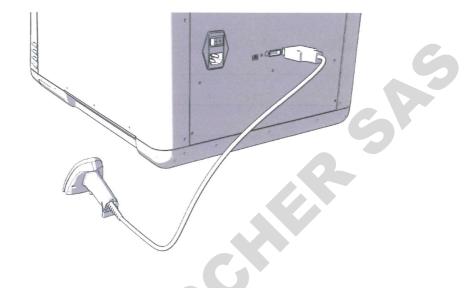
Important:

Keep the shipping box and stuffing materials. They will be needed again when transporting the BioMagPure 12.

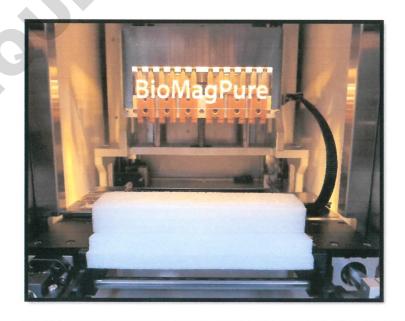
Initial setting, continued

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2. Connect Barcode Reader with the Instrument.



- **3.** How to remove the fixing stuff inside the instrument following the steps below
- i. Plug in the power cord to the instrument and connect to electric outlet
- ii. Turn the power switch on.
- iii. Press "START" button. The piston module will going up, and you can release the fixing stuff.



Notes for transporting / shipping

BioMagPure Transporting

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12 When transporting/shipping the BioMagPure 12 to a new location, perform the following tasks:

Warning:

- Before carrying the BioMagPure 12, disconnect the plug from the outlet. If the power cable is damaged, this may cause a device failure, fire, injury, or electric shock.
- When transporting/shipping the BioMagPure 12, be sure to perform the following tasks:

Remove all attached parts (Sample Rack, Barcode Reader) from the BioMagPure 12.

After completing the above tasks, pack the BioMagPure 12 in its original shipping box or some other equivalent box.

1. Instrument fixing stuff before Transport



(1) Press the button "0123"

(2) Press the button "3"

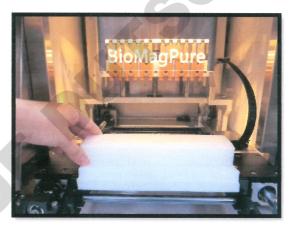


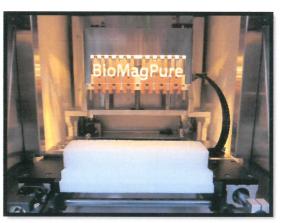
Notes for transporting / shipping, continued

(3) Press the button "3"



- (4) Open the sliding Door
- (5) Putting the Fixture on the Position of Tip Holder





(6) Close the sliding Door

Notes for transporting / shipping, continued

(7) Press Enter button

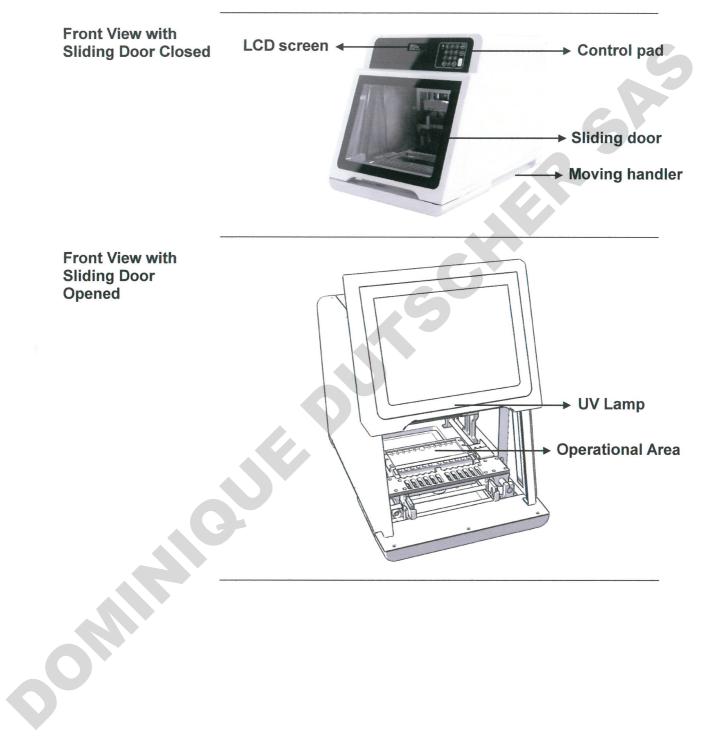


(8) Finish



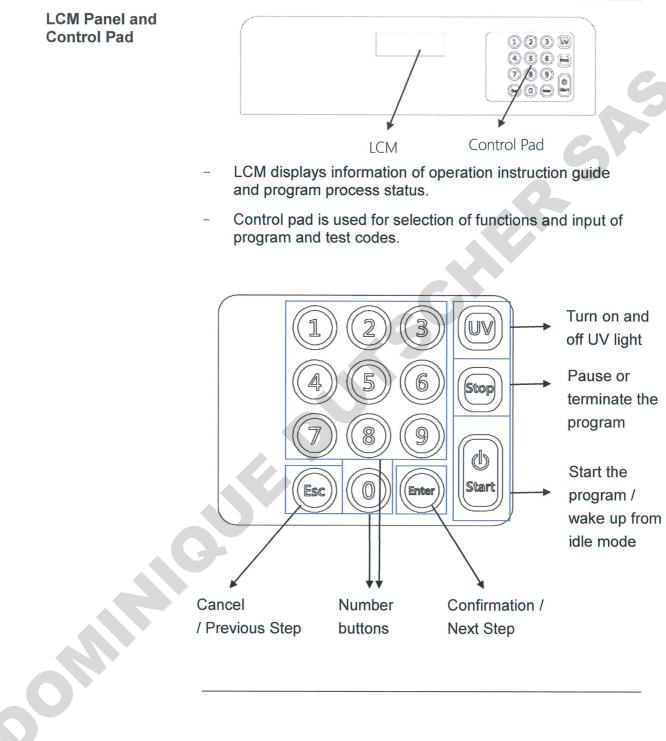
OVER VIEW

Front view



Front view, continued

LCM Panel and **Control Pad**



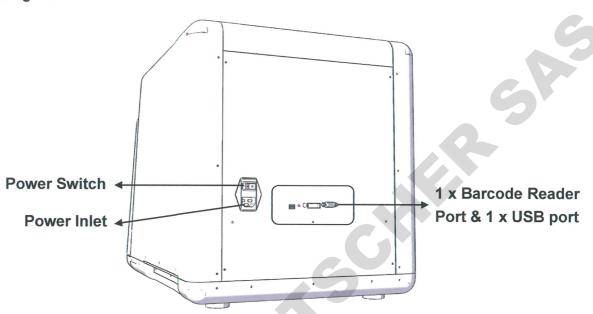
Inside view

Inside View of BioMagPure 12



Back view





Getting Started

Preparation

Accessories before Extraction



Biohazard:

Always wear appropriate gloves, a mask, and safety goggles during any biohazardous operations in 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. In the operation from preparing samples to extraction completion, be careful not to contaminate the samples with sweat, saliva, etc.

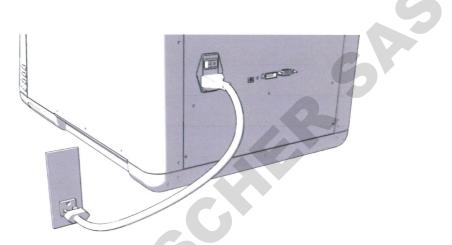
The following preparations are required for extraction operation.

- Items to be prepared (* : Provided with the Reagent Kits.)
 - Gloves
 - Mask
 - Safety Goggles
 - Reagent Cartridge*
 - Reaction Chamber*
 - Tip Holder*
 - Pestle (Option)*
 - Filtered tip*
 - Sample tube*
 - Elute tube*
 - Piercing Pin
- For the preparation of samples, refer to the handbook of each kit.

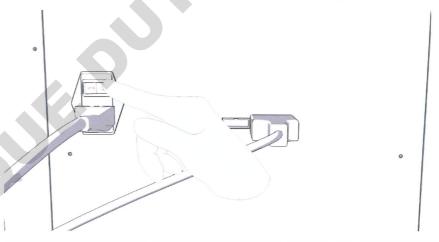
Operation

Turning On the Power

- (1) Make sure that the power cable are connected securely to the BioMagPure 12.
- (2) Connect the plug of the power cable to the outlet.



(3) Turn the power switch on and waiting for the LCM screen turn on and shows "BioMagPure 12 Stand-By".



Operation Procedure

(4) Press the "Start" button

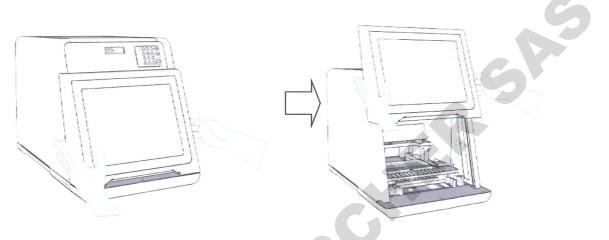
(The system will process self-testing, and then go to steady mode)

Note:

The system will block main functions before the completion of self-testing process.

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(5) Open the sliding door and remove the sample rack from the instrument.



Important:

Open and close the door with two hands, otherwise it may cause door damage.

(6) Load Reagent Cartridges, and all plastics disposables (Reaction Chamber, Tip Holder, Piercing Pin, Filtered Tip and Pestle (optionally supplied with some kit types)



Insert the cartridges

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How to pull apart reagent cartridges

Slash open the dotted line with nail and snap it with a little bit force.







Insert Reaction Chambers

Caution:

Please always perform the test with all plastic accessories installed, especially with Reaction Chambers; otherwise, this might cause serious damage to the instrument.



Insert Tip Holder





Insert Piercing Pin



Insert Filtered Tips

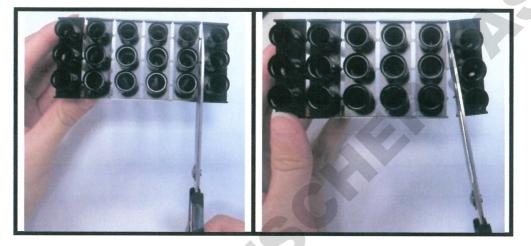
Note:

ONIN

1. The positions of piercing pin and filtered tip; the 2nd row should be "**EMPTY**".

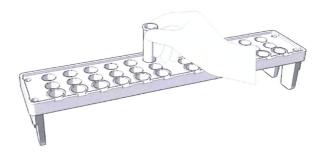


- 2. Load one Reagent Cartridge and one set of plastic disposable per sample.
- Use scissors ONLY, if you are intending to separate the tip holders.

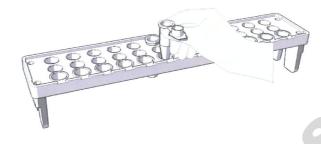


Important:

- Set Cartridges in the order of the number from left to right.
- Make sure that Cartridges are inserted in to the Cartridge Tray tightly.
- You can load 1-12 cartridges on the tray depending on the number of samples that you wish to process.
- (7) Load Sample Tube and Elute Tube to Sample Rack on the bench



Insert Sample Tube on to Sample Rack



Insert Elute Tube on to Sample Rack

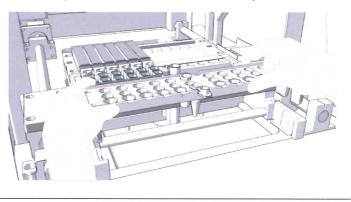
(8) Load the sample(s) to Sample Tube

Note:

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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 caps of Elute Tube are open as the figure shown above.
- (9) Place Sample Rack on the instrument platform



Note:

- Use two hands to handle the Sample Tray.
- Make sure the Sample Tray be placed correctly in the instrument
- (10) Close the Sliding Door and press Start button
- (11) Scan the protocol barcodes to select purification protocol, sample volume and elute volume



Note:

- There is one protocol barcode paper enclosed in the reagent kit box.
- Protocol's name, sample volume and elution volume will be shown on LCD screen after protocol barcode is scanned.
- (12) Follow the instructions displayed on LCM screen to double check the operating steps being completed before program running.
- (13) Push "Enter" to confirm. Instrument will start to run the protocol program automatically until whole processes are completed.

Note:

- It takes from 30 to 60 minutes to complete the extraction according to reagent types.
- (14) At the end of the run, the instrument beeps briefly and the LCM shows "Protocol Completed"

- (15) Open the instrument door
- (16) Remove the elute tubes containing the purified nucleic acid

Note:

Store the purified nucleic acids at 4° C for short-term storage or store at -70°C for long-term storage

- (17) Discard the used cartridges, all plastic consumables into biohazard waste. Do not reuse the cartridges
- (18) If you're not using the instrument, place the Sample Rack back to workplace, close the instrument door and push "Start" button for 2 seconds to get into "sleeping mode". And for longer time not using the instrument turn the power switch off.

After Extraction

Extraction Finish

(1) Take out the Elute Tubes (The extraction yields in them) **Note:**

You can apply quality checking or do downstream study or storage them as what you expect.

(2) Remove the Cartridges and plastic disposables from the diff. instrument and then dispose of them.

Cleaning and Maintenance

Cleaning and Maintenance

- **BioMagPure 12** Clean the Sample Tray 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 70% ethanol.
 - Clean the instrument body by removing dust gently with a dry, soft cloth. If the outside of the BioMagPure 12 is heavily soiled, or if any samples that may cause infection are adhered to the outside of the BioMagPure 12, wipe with a soft paper tissue, soaked with 0.5% sodium hypochlorite solution or ethanol.
- **BioMagPure Maintenance 12** Two types of maintenance are performed on the BioMagPure 12 Instrument as listed in the table. For details on each type of maintenance, see below:

	Maintenanc	е Туре	Performed by	Schedule
	Routine			
	(1)	Cleaning of	User	After each
		Sample Tray		use
	(2)	Cleaning of instrument body	User	Bi-weekly
		(outside)		
	(3)	Cleaning of	User	Bi-weekly
		instrument body (inside)		
	Preventive		Service	Ammunally
	Preventive		Engineer	Annually

Troubleshooting

Troubleshooting

BioMagPure 12 Troubleshooting

Instrument Problems			
Problem	Cause	Solution	
No power (the LCD 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.	
LCD Screen turns on when the power is on but the	Forget to remove the packing stuff from instrument	Turn off the instrument and remove the packing stuff.	
self-testing program does not run	Technical problem	Contact your local representative or agent	
Protocol stops after an initial start	Cartridge(s), Plastic wares (Reaction Chamber, Tip Holder, Filtered Tip Pestle, Sample Tube, Elute Tube) incorrectly loaded on the BioMagPure 12	Turn off the power and then turn it on again to stop the program. The system will move back to initial state. Re-load them according to the instructions shown in this manual. Note: you could not resume the protocol after stop and you may lose your samples	
	Problem with motion sensors	Turn off the power and remove all samples and plastic wares. Contact your local representatives	
Bubbles formed during extraction	Missed adding sample or sample volume is lower than the recommended volume	Be sure to add the sample to tubes prior to 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 BioMagPure Reagent Kits.	

Troubleshooting, continued

Instrument Problems		
Problem	Cause	Solution
Presence of buffer in the Cartridge Tray	Motor movements may not be smooth, incorrect placement of plastic wares, or leakage from tips	Perform preventive maintenance annually to ensure proper motor movements.
Leakage from Filtered Tips or uneven liquid handling between Filtered Tips	Air leakage on the Filtered Tip	Swap the air-leaked Tip with new one
Blockage of tips and pipetting failure	Too much starting material or excess DNA in sample causing clumps or aggregates	 Decrease the amount of starting material. Use the recommended amount of starting material as listed in the Reagent Kit manual (Handbook). Suggest using blood kit 1200 instead of blood kit 200 (if testing sample is blood)

DNA Quality Problems Troubleshooting

DNA Quality Problems			
Problem	Cause	Solution	
		To prevent bubble formation during mixing, make	
	Bubbles formed	sure the sample volume is at least the	
	during mixing steps	recommended volume listed	
DNA is		in the manual supplied with Reagent Kits.	
sheared or	Purified DNA	Aliquot purified DNA and store at 4°C (short-term)	
degraded	repeatedly frozen	or -20°C (long-term). Avoid repeated freezing and	
	and thawed	thawing.	
	DNA contaminated	Maintain a sterile environment while working (i.e.	
	with DNases	wear gloves and use Dnase-free reagents).	

Troubleshooting, continued

DNA Quality Problems			
Problem	Cause	Solution	
		Decrease the amount of starting material used.	
		Be sure to add Proteinase K during lysis, if	
	Incomplete lysis	included in the protocol.	
		Make sure that the sample is completely	
		immersed in the Lysis Buffer.	
		Be sure to process sample immediately after	
	Poor quality of	collection or store the sample at appropriate	
	starting material	temperature. The yield and the quality of DNA	
Low DNA		isolated depend on the starting material.	
yield		During shipping, some magnetic bead solution	
	Insufficient amount	may adhere to the sealing foil of the cartridge. To	
	of magnetic beads	collect any bead solution from the foil, tap the	
	added	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	
		BioMagPure purification.	
		Store cartridge containing the beads at room	
		temperature.	
No DNA	Magnetic beads	Do not freeze the cartridge as the beads may be	
recovered	stored or handled	irreparably damaged.	
	improperly	Make sure that the beads are in solution at all	
		times and do	
		not dry. Dried beads are non-functional.	
		Remove any magnetic beads using a magnetic	
Elute containing DNA	Magnetic beads present in the elute	separator or	
		centrifuge the sample in a micro-centrifuge for 1	
		minute at maximum speed.	
is discolored	DNA contaminated	Minimize the amount of blood or blood-stained	
	with heme	sample used (≤ 20 µl blood spot for forensics	
		sample).	

Specifications

	BioMagPure 12
Instrument Type:	Benchtop automated nucleic acid extractor
Sample Processing:	1 to 12 samples per batch
Sample Volume Handling:	100 –2000uL
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:	Barcode Reader
UV Light	30 minutes @ 250 nm
Built-in Features:	LCM Display Screen
Instrument Dimensions:	48 cm W x 70 cm D x 52 cm H
Weight:	43 kg
Input Power:	AC 100-240 V, 240 VA, 50/60 Hz
Operating Temperature:	15-30°C
Operating Humidity:	30-80%
Fuse:	F3.15A 250V
Temperatures allowed during	-25°C to +70°C
transportation/ storage/ packaging:	
transportation/ storage/ packaging:	