

Automated Nucleic Acid Purification System

BioMagPure 12 Plus

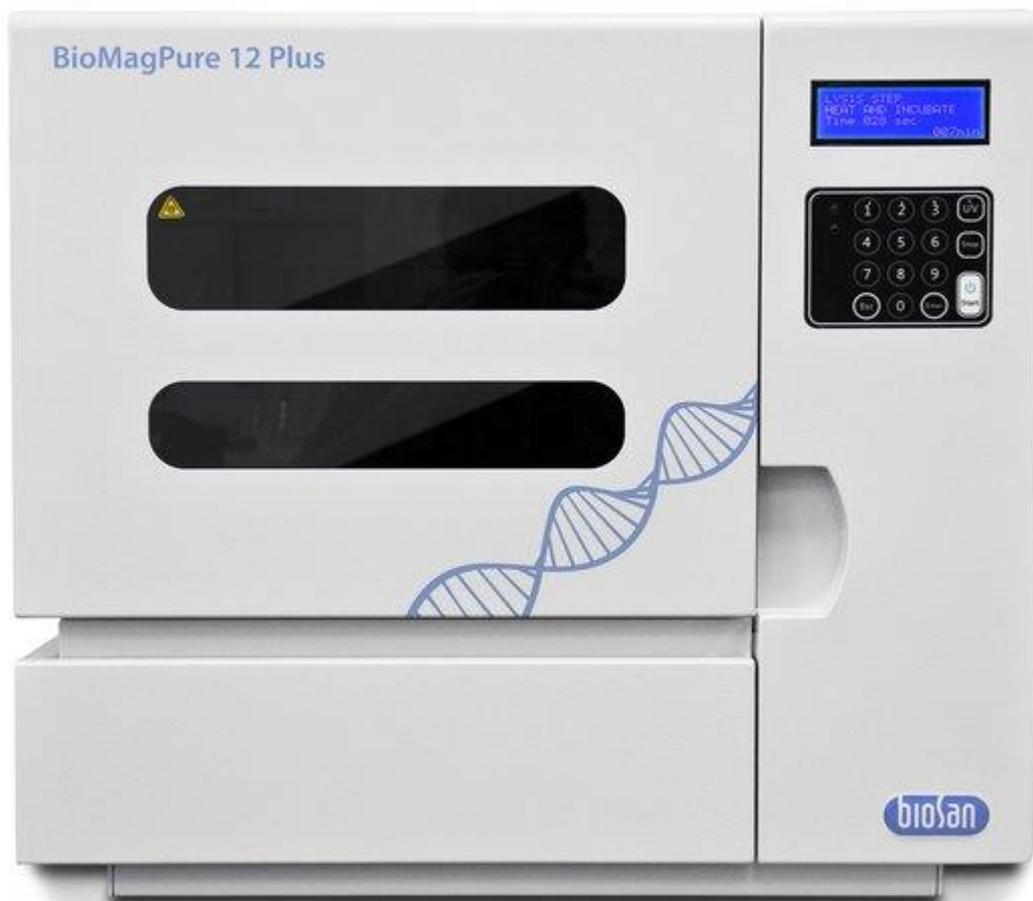


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1. Introduction

Thank you for purchase of the BioMagPure 12 Plus 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 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 Plus system. 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 centre (support@zinexts.com).

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BioMagPure Magnetic Bead Purification Process



2. Safety information

The meanings of safety precaution marks are as follows:



Warning! This indicates a dangerous condition that may lead to death or serious injury. Non-compliance with instructions or procedures may lead to physical injury or even death or could cause damage to the instrument.



Warning! Biohazard! This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.



Note. Shows the important notes for usage, as well as prohibited actions. It also indicates the notes, procedures that should be obeyed and supplementary information for use.



Warning! Hot surface! This symbol is used to label potentially hot instrument surfaces.



IVD This symbol is In vitro diagnostic medical device.

For your safety and that of others, follow the guidelines provided in the following pages concerning the use of the BioMagPure 12 Plus system.

2.1. 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 Plus system with voltage other than the voltage specified on the device.
- Do not use the BioMagPure 12 Plus 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 BioMagPure 12 Plus system.
- Do not place any objects containing liquid on the BioMagPure 12 Plus system. 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.
- Never attempt to remodel the BioMagPure 12 Plus system without the manufacturer's permission. Doing so may cause fire or electric shock.
- Do not place or drop objects on the BioMagPure 12 Plus system. Also, refrain from bumping or knocking it, as doing so may cause a failure or malfunction of the BioMagPure 12 Plus system.

- If any liquid materials are left inside the device, wipe it up a soft paper tissue, etc. Otherwise, the BioMagPure 12 Plus system may be damaged.
- Repairs to the BioMagPure 12 Plus system should only be performed by such agencies as are specifically authorized by the ZINEXTS LIFE SCIENCE CORPORATION.
- Only original the ZINEXTS LIFE SCIENCE CORPORATION 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.

2.2. About Reagent Kits

 **Warning!** 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 Plus system. Select the desired kit(s) and order it (them) separately.

2.3. About Samples

 **Warning! Biohazard!** Always wear appropriate gloves, a mask, and safety goggles etc. when handling any infectious samples.

2.4. 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.

2.5. Biosan Service Centre

For technical problem and instrument maintenance, <http://tw.dictionary.yahoo.com/dictionary?p=maintaince> please contact our service centre on our website www.biosan.lv or by e-mail, service@biosan.lv.

3. Installation

3.1. **Composition of the BioMagPure 12 Plus system.** Check that the following are included in the package. Contact your local representative if you notice any missing part(s).



A



B



C



D



E



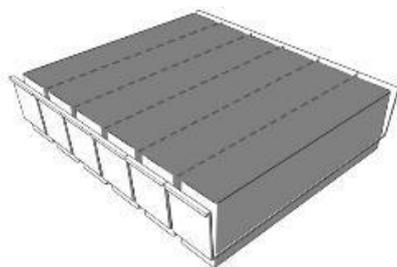
F

- A. BioMagPure Instrument..... 1
- B. Power Cable 1
- C. Sample Tube Rack..... 2
- D. Barcode Reader 1
- E. User's Manual 1
- F. M-axis Module 1

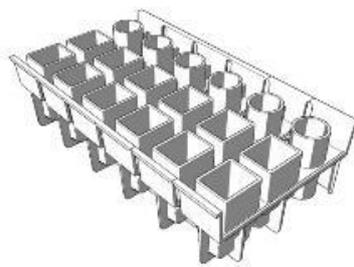
3.2. Please make all the components are free from damages as soon as you get the system. If any damage found, please contact your local representative for the instant support.

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

3.3. Contents of Reagent Kits



Reagent Cartridge(s)



Reaction Chamber(s)



Tip holder



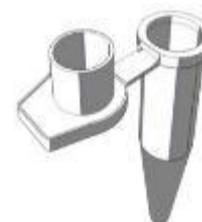
Piercer



Filtered tip



Sample tube



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.

3.4. Operating Environment / Condition. Use the BioMagPure 12 Plus system in a location that meets the following conditions:

- The space for the allocation of the BioMagPure 12 Plus system must be remained 5-10 cm from instrument to sidewalls.
- A location where power can be provided.
- A location where the temperature is 15 to 40°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 Plus 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, which generate strong magnetic fields such as motors, transformers, TV, audio speakers, magnets, etc. Bringing the BioMagPure 12 Plus system close to any type of magnetic field may cause a malfunction.

 **Warning!** Do not use the BioMagPure 12 Plus system 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 Plus system, disconnect the plug from the outlet first. If the power cable is damaged, this may cause a device failure, fire, injury, or electric shock.

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

Do not open the maintenance door while performing experiment.

Do not open the drawer while performing experiment.

3.5. Operating Conditions

Items		Conditions
Temperature (°C)	During operation	15 – 40
	During down time	0 – 55
Humidity (RH)	During operation	30 – 80
	During down time	10 – 80
Max. wet bulb temperature (°C)	During operation	29 (non condensing)
	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

3.6. Unpacking of the BioMagPure 12 Plus system

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

 **Note.** The BioMagPure 12 Plus system has a weight of more than 60 kg. 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 lift by the outer covering, front panel or the door.

 **Caution!** Improper handling of the movement of the BioMagPure 12 Plus system will lead to instrument damages.

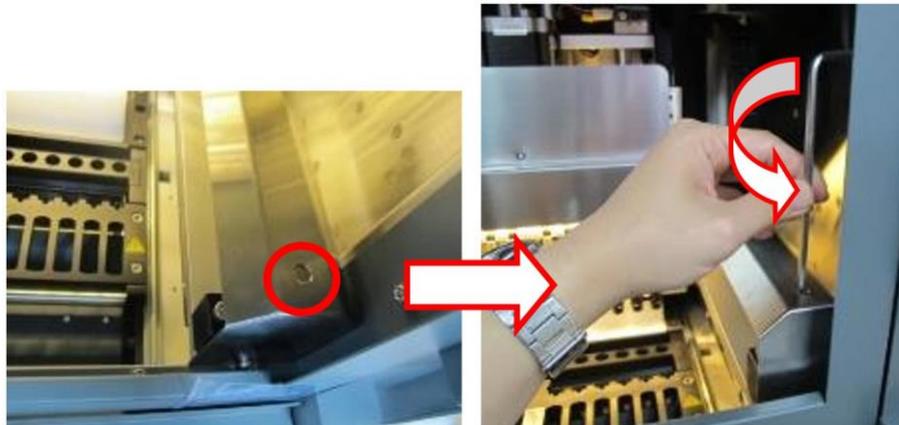
3.6.2. For correct and safe use of the BioMagPure 12 Plus, install it in a location that is close to electrical outlet and has enough space for installation and operation of the mains switch.

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

3.6.3. Connect Barcode Reader with the Instrument, see **3.7.**

3.6.4. Before turn on the power please make sure screw-out the screw which uses to lock the X-axis in the RIGHT inside of bar.

- Tool:(4MM hex tool)
- Direction: Counter clockwise at least 3 turns



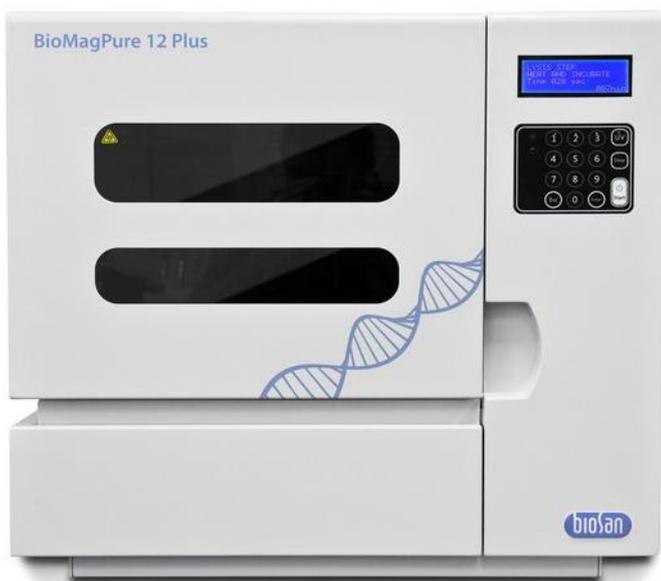
3.6.5. How to remove the transportation insert inside the instrument following the steps below,

3.6.5.1 Plug in the power cable to the instrument and connect to electric outlet

3.6.5.2 Turn the power switch on.

3.6.5.3 Press “START” button. The piston module will going up, and you can release the transportation insert.

3.7. Overall View



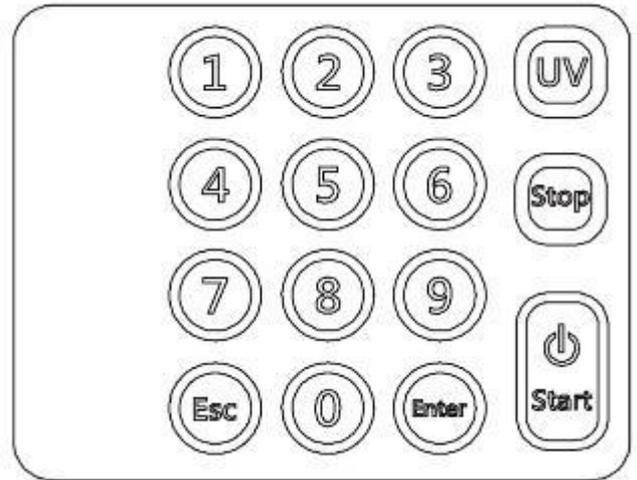
Front view with Door closed



Front view with Door opened



LCM Panel and Control Pad



Control pad, close view

- LCM displays information of operation instruction guide and program process status.
- Control pad is used for selection of functions and input of program and test codes.



Rear panel

4. Getting started



Caution! 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.



Note. 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.

4.1. Turning on the power. Make sure that the power cable are connected securely to the BioMagPure 12 Plus system. Connect the plug of the power cable to the outlet.

4.2. Preparation. User must prepare individual protection, such as gloves, masks and safety goggles. For the preparation of samples, refer to the handbook of each kit. Following items are provided with reagent kits: reagent cartridge, reaction chamber, tip holder, small tip (optional), filtered tip, sample tube, elute tube, piercing pin.

4.3. Extraction.

4.3.1. Turn the power switch on and waiting for the LCM screen turn on and shows “BioMagPure 12 Plus System Stand-By”.

4.3.2. 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.

4.3.3. Open the drawer and remove the sample rack from the instrument.

4.3.4. Load Reagent Cartridges, and all plastics disposables (Reaction Chamber, Tip Holder, Piercing Pin, Filtered Tip and Sample Tube and Elute Tube. (Optionally supplied with some kit types). To pull apart reagent cartridges, slash open the dotted line with cutter.



Divide the cartridges



Insert the cartridges



Insert Reaction Chambers



Insert Tip Holder



Insert Piercing Pins

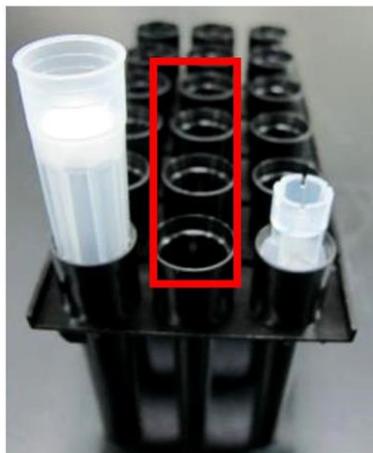


Insert Filtered Tips



Note.

The positions of piercing pin and filtered tip are displayed below, leave middle row empty!



4.3.5. Load one Reagent Cartridge and one set of plastic disposable per sample. 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.

4.3.6. Load Sample Tube and Elute Tube to Sample Rack on the bench



Sample tube



Elute tube

4.3.7. Load the sample(s) to Sample Tube. Place Sample Rack on the instrument platform.



Distribute samples



Place sample and elute rack



Note.

Pre-treatments 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.

Use two hands to handle the Sample Tray.

Make sure the Sample Tray be placed correctly in the instrument

4.3.8. Close the Drawer.

4.3.9. 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 LCM screen after protocol barcode is scanned.

4.3.10. Follow the instructions displayed on LCM screen to double check the operating steps being completed before program running.

4.3.11. Push “Enter” to confirm. Instrument will start to run the protocol program automatically until whole processes are completed.

 **Note.** It will take times to complete the extraction according to reagent types.

4.3.12. At the end of the run, the instrument beeps briefly and the LCM shows “Protocol Completed”.

4.3.13. Open the drawer.

4.3.14. 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.

4.3.15. Discard the used cartridges, all plastic consumables into biohazard waste. Do not reuse the cartridges.

4.3.16. If you are 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”. In addition, for longer time not using the instrument turn the power switch off.

4.4. After Extraction Operation

4.4.1. 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.

4.4.2. Remove the Cartridges and plastic disposables from the instrument and then dispose of them.

5. Cleaning and maintenance

5.1. Two types of maintenance are performed on the BioMagPure 12 Plus system Instrument as listed in the table. For details on each type of maintenance, see below:

Maintenance Type	Performed by	Schedule
Cleaning of Sample Tray	User	After each use
Cleaning of instrument body (outside)		Bi-weekly
Cleaning of instrument body (inside)		
Preventive	Service Engineer	Annually

5.2. 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 75% ethanol.

5.3. Clean the instrument body by removing dust gently with a dry, soft cloth. If the outside of the BioMagPure 12 Plus system is heavily soiled, or if any samples that may cause infection are adhered to the outside of the BioMagPure 12 Plus system, wipe with a soft paper tissue, soaked with 0.5% sodium hypochlorite solution or ethanol.

6. Troubleshooting

Problem	Cause	Solution
Instrument Problems		
No power (the LCM Screen remains blank when the power is turned on)	AC power cable is not connected	Check AC power cable connections at both ends. Alternatively, Use the correct cables.
LCM Screen turns on when the power is on but the self-testing program does not run	Forget to remove the packing stuff from instrument	Turn off the instrument and remove the packing stuff.
	Technical problem	Contact your local representative or agent
Protocol stops after an initial start	Cartridge(s), Plastic wares (Reaction Chamber, Tip Holder, Filtered Tip, Sample Tube, Elute Tube) incorrectly loaded on the BioMagPure 12 Plus system	Turn off the power and then turn it on again to stop the program. The system will move back to initial state. Reload 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.
Presence of buffer in the Cartridge Tray	Motor movements may not be smooth, incorrect placement of plastic ware, 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

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 sample immediately after collection or store the sample at 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.
No DNA recovered	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.
		Do not freeze the cartridge as the beads may be irreparably damaged.
Elute containing DNA is discoloured	Magnetic beads stored or handled improperly	Make sure that the beads are in solution at all times and do not dry. Dried beads are non-functional.
	Magnetic beads present in the elute	Remove any magnetic beads using a magnetic separator or centrifuge the sample in a micro centrifuge for 1 minute at maximum speed.
DNA is sheared or degraded	DNA contaminated with heme	Minimize the amount of blood or bloodstained sample used ($\leq 20\mu\text{l}$ blood spot for forensics sample).
	Bubbles formed during mixing steps	To prevent bubble formation during mixing, make sure the sample volume is at least the recommended volume listed in the manual supplied with Reagent Kits.
	Purified DNA repeatedly frozen and thawed	Aliquot purified DNA and store at 4°C (short-term) or -20°C (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).

7. Specifications

The unit is designed for operation in cold rooms and closed laboratory rooms at ambient temperature from +15°C to +40°C in a non-condensing atmosphere and maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C.

Biosan is committed to a continuous programme of improvement and reserves the right to alter design and specifications of the equipment without additional notice.

Sample processing	1 to 12 samples per batch
Sample volume handling	100 – 1200µL
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
Display	LCD Screen
Instrument dimensions	56 cm W x 51 cm D x 59 cm H
Weight	60 kg
Input power	AC 100-240 V, 240 VA, 50/60 Hz
Fuse	F3.15A 250V

7.1. Applicable standards:

LV directive (73/23/EEC)

EMC directive (89/336/EEC) EN61326-1

Safety EN61010-1, EN61010-2-101

8. Replacement/Optional Parts

Item	Q'ty	Parts No.
Barcode Reader	1	A01001
Power Cable	1	A01002
Sample Rack	1	A01003
Filtered Tip	50	A02001
Piercing Pin	50	A02004
Sample Tube	50	A02002
Elute Tube	50	A02003

9. Product Guarantees

- 9.1. The warranty period shall be one year from the delivery of the product.
- 9.2. Any part, which fails to function properly under normal use, if all warnings and cautions in this manual are observed, during the warranty period will be repaired by the Manufacturer.
- 9.3. If the problem is due to the causes listed below, some charge may be applied for the repair even within the warranty period.
 - 9.3.1. Any failures due to improper use or that are affected by other devices except for those approved by the Manufacturer.
 - 9.3.2. Any malfunctions or damages during transportation or due to dropping of the product by a user.

10. About services

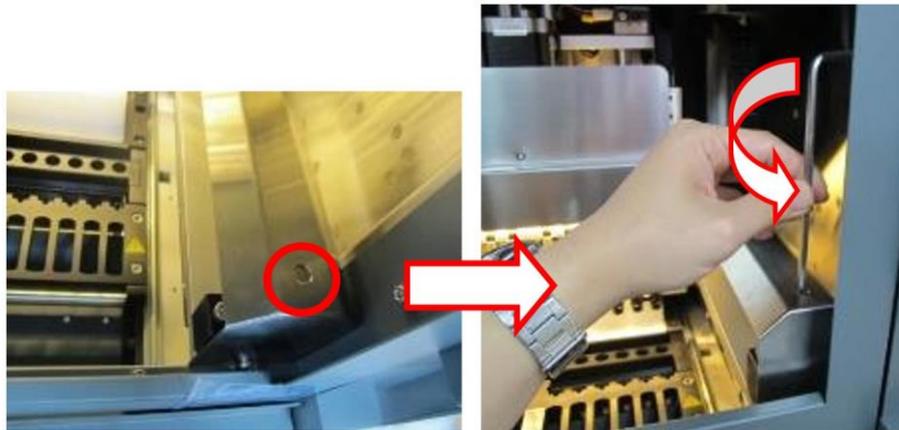
- 10.1. Before you ask for device repairs, refer to “4 Troubleshooting” to check the problems. If the problems cannot be solved, contact your local representative, or the relative customer support.

11. Notes for Transporting/Shipping

- 11.1. Before carrying the BioMagPure 12 Plus system, disconnect the plug from the outlet. If the power cable is damaged, this may cause a device failure, fire, injury, or electric shock.
- 11.2. Remove all attached parts (Sample Rack, Barcode Reader) from the BioMagPure 12 Plus system.
- 11.3. After completing the above tasks, pack the BioMagPure 12 Plus system in its original shipping box or some other equivalent box.

12. Instrument transportation insert before transport

- 12.1. Press 0 to enter the menu
- 12.2. Press 2 for engineering menu
- 12.3. Press 3 to choose FIXING
- 12.4. Open the front door of the unit. Put the transportation insert on the cartridge plate and close the door.
- 12.5. Lock the X-axis with 4 mm hex tool as shown below



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