

MP Diagnostics
MPure-12 aNAP System

CE

Operation Manual



IMPORTANT - Please read this manual carefully before using the MPure-12 aNAP System

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Revision Date: 2019-03

MMF0131-ENG-2

REF EMC017



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INTRODUCTION

Thank you for purchase of the MPure-12 aNAP 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.

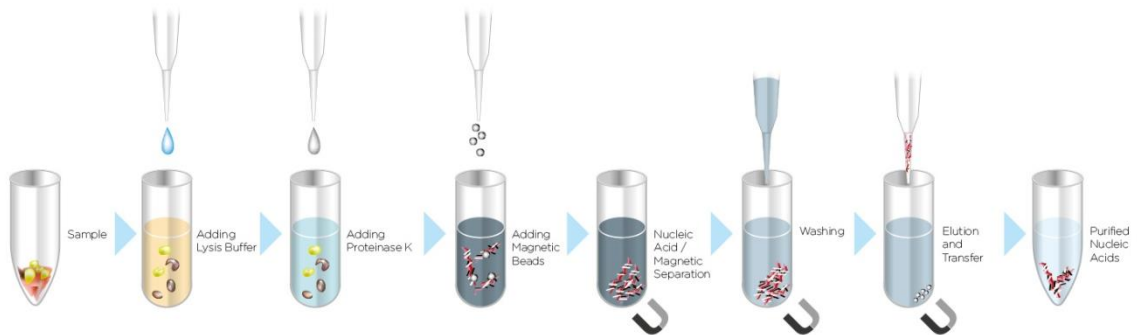
This guide contains important information regarding the safe use of the MPure-12 aNAP System. Please read this manual carefully before you start to run the system at the first time, especially for Safety Information.

If there is any question about how to install or operate it, please contact our certified distributors / agents or email to our technical support center (http://www.mpbio.com/tech_support.php).

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MPure Magnetic Bead Preparation Process



SAFETY INFORMATION

The meanings of safety precaution marks are as follows:

WARNING:

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



BIOHAZARD:

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



CAUTION:

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.

Important:

“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 SURFACE:

This symbol is used to label potentially hot instrument surfaces.

For your safety and that of others, follow the guidelines provided in the following pages concerning the use of the MPure-12 aNAP System.

About Instrument

WARNING:

- Ignoring the following notations may lead to fire or electric shock.
 - In countries other than US and Canada, use a power cable that meets your country’s standard, or contact your local distributor.
 - Do not use the MPure-12 aNAP System with voltage other than the voltage specified on the device.
 - Do not use the MPure-12 aNAP 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 MPure-12 aNAP System.
- Do not place any objects containing liquid on the MPure-12 aNAP 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.

**CAUTION:**

- Never attempt to remodel the MPure-12 aNAP System without the manufacturer's permission. Doing so may cause fire or electric shock.
- Do not place or drop objects on the MPure-12 aNAP System. Also refrain from bumping or knocking it, as doing so may cause a failure or malfunction of the MPure-12 aNAP System.
- If any liquid materials are left inside the device, wipe it up a soft paper tissue, etc. Otherwise, the MPure-12 aNAP System may be damaged.
- Repairs to the MPure-12 aNAP System should only be performed by such agencies as are specifically authorized by the MP Biomedicals Asia Pacific Pte Ltd
- Only original the MP Biomedicals Asia Pacific Pte Ltd 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.
- The power plug is served to disconnect the equipment. Do not placed the equipment in a position that will make it difficult to remove the power plug.

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 MPure-12 aNAP System. 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.

MP Biomedicals Service Center

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

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1 Installation

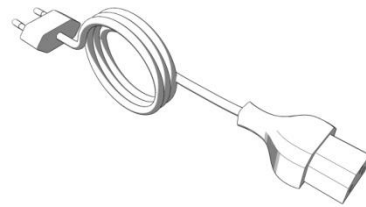
1.1 Composition of the MPure-12 aNAP System

Check that the following are included in the package. Contact your local representative if any parts are missing.

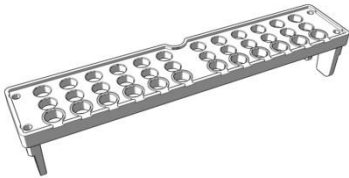
A



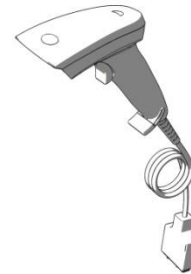
B



C



D



E



F



	Quantity
A. MPure-12 aNAP System	1
B. Power Cord	1
C. Sample Tube Rack	1
D. Barcode Reader	1
E. Operation Manual	1
F. M-axis Module	1*

* 1 as backup

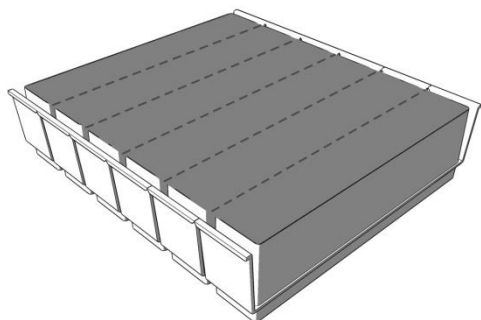
Please confirm that all the components are damage-free upon delivery. If any damage is found, please contact your local representative for immediate support.

Note:

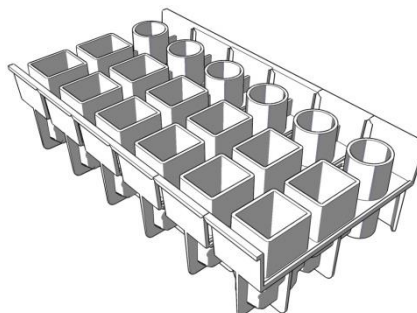
MP Bio's global warranty does not cover damage from transportation or improper operation.

1.2 Contents of Reagent Kits

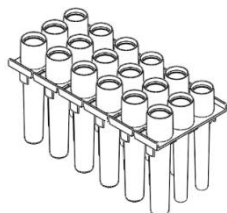
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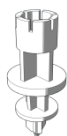
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D



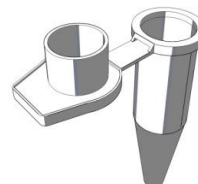
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F



G



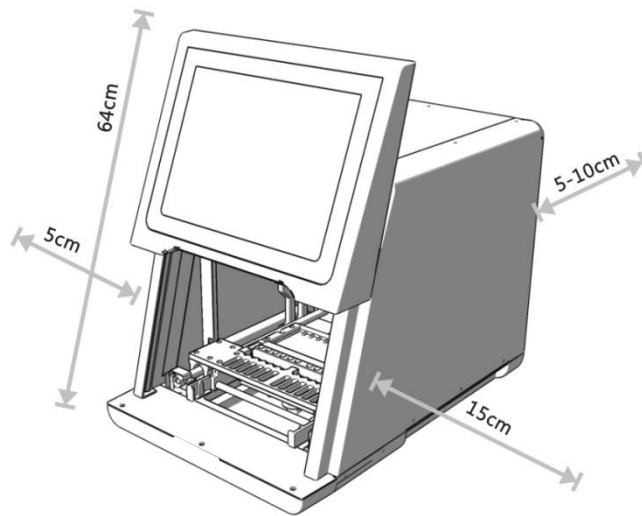
- A. Reagent Cartridge(s)
- B. Reaction Chamber(s)
- C. Tip Holder
- D. Piercing Pin
- E. Filtered Tip
- F. Sample Tube
- G. Elution Tube

Note:

- Reagent kits are purchased separately. Please contact your local representatives for further information.
- The contents of extraction kits will vary. Refer to the extraction kit IFU enclosed in the kit box for details.

1.3 Operating Environment / Condition

Use the MPure-12 aNAP System in a location that meets the following conditions:



- Install the MPure-12 aNAP System in a location that allows a minimum 5-10 cm clearance around the instrument base at all times to ensure proper ventilation.
- A location with power supplied.
- A location where the temperature is 10 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 with minimal sudden temperature fluctuation (Warming a cold room suddenly or moving the MPure-12 aNAP System from a room with low temperature to a warm room because it 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 away from strong magnetic fields generators (e.g. motors, transformers, TV, audio speakers, magnets, etc.) (Close proximity to any type of magnetic field may cause a malfunction.)

Warning:

Do not use the MPure-12 aNAP System to a location where it is wet or where water contact could occur. Device failure, fire, or electric shock could result.

When relocating the MPure-12 aNAP System, disconnect the power cable 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 MPure-12 aNAP 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 MPure-12 aNAP System in direct sunlight or close to a heating device. It may shorten the life of the MPure-12 aNAP System, or cause a trouble.

Operating Conditions

Items		Conditions
Temperature (°C)	During operation	10 – 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

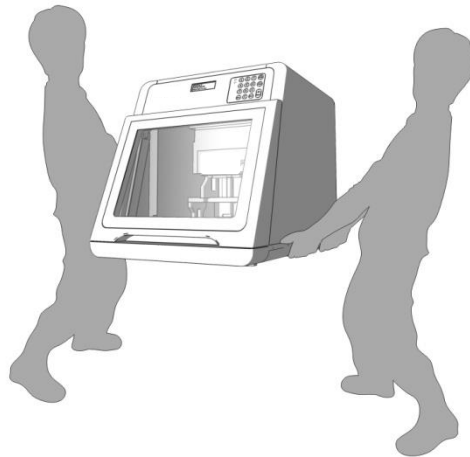
1.4 Unpack the MPure-12 aNAP System

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

Important:

The MPure-12 aNAP System weighs more than 45 kg. It should be lifted and moved by two persons, observing proper lifting techniques.

Hold the transport handler attached to 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 will result in damage to the MPure-12 aNAP System.

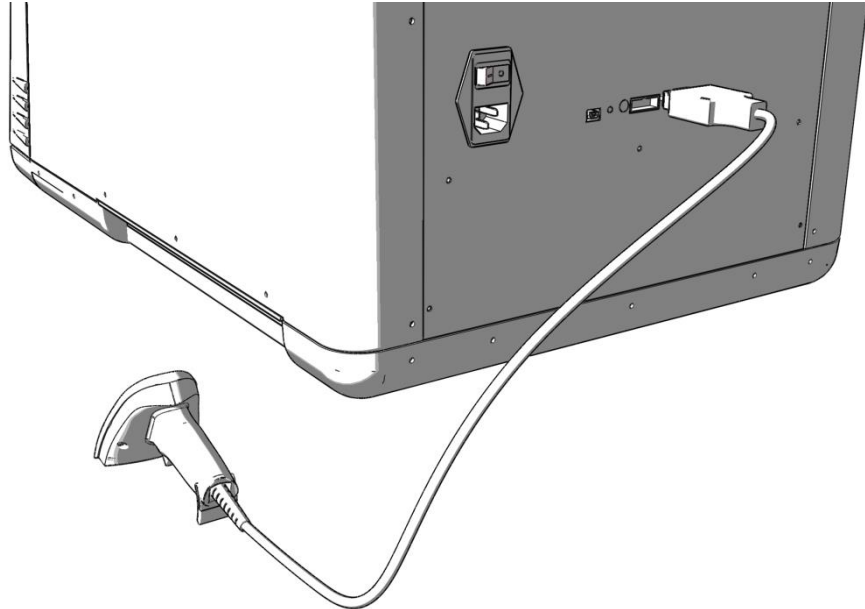
For correct and safe use of the MPure-12 aNAP System, install it in a location that is close

to electrical outlet and with enough space for installation and operation of the main switch.

Important:

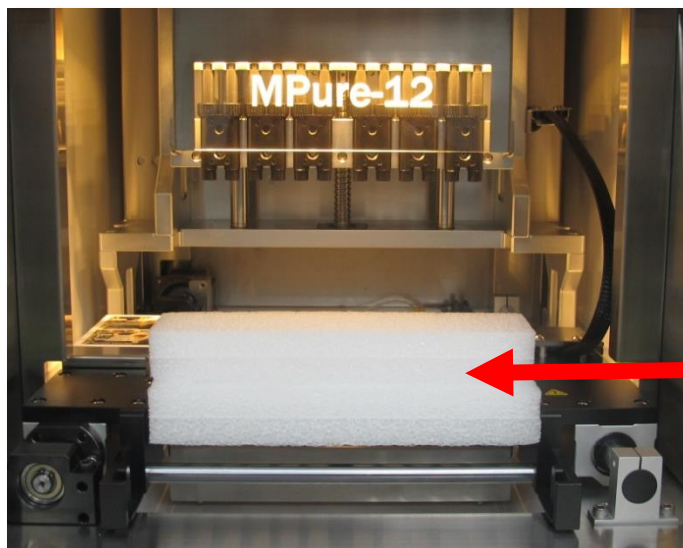
It is necessary to keep the shipping box and all packaging materials as they will be used for relocation of the MPure-12 aNAP System.

- (2) Connect Barcode Reader with the Instrument.



- (3) Remove the packing materials inside the instrument:

- i. Plug in the power cord to the instrument and connect to electric outlet
- ii. Turn the power switch on
- iii. Press 'START' button
- iv. The piston module will going up allowing for removal of interior packing materials



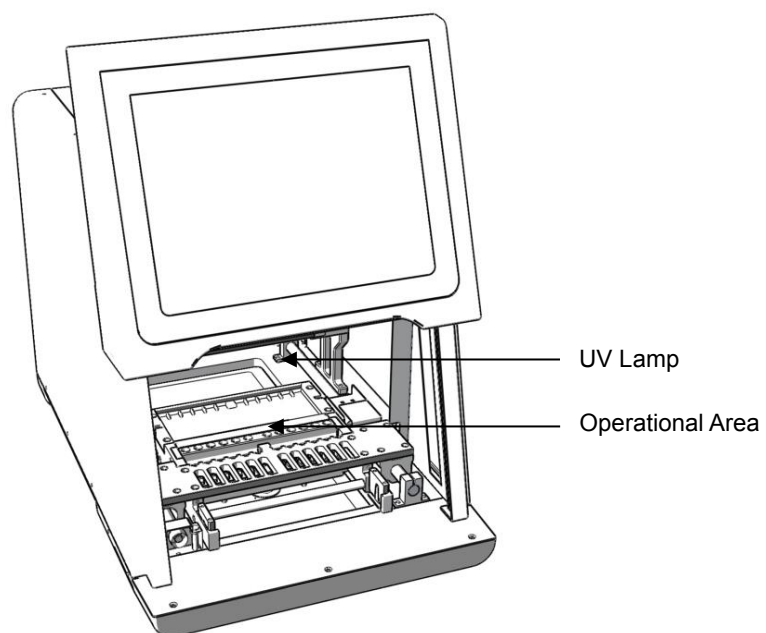
Remove foam packing materials

1.5 Overview

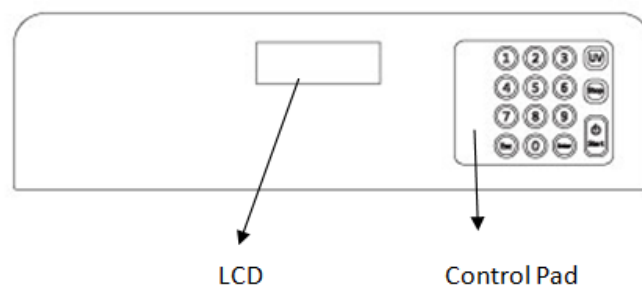
- Front view with Sliding Door closed



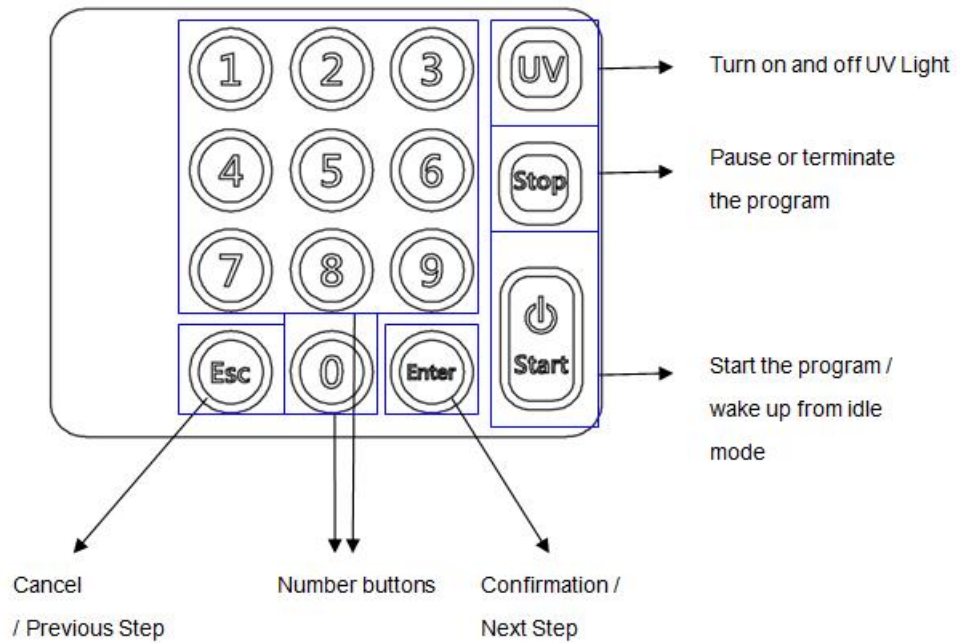
- Front view with Sliding Door opened



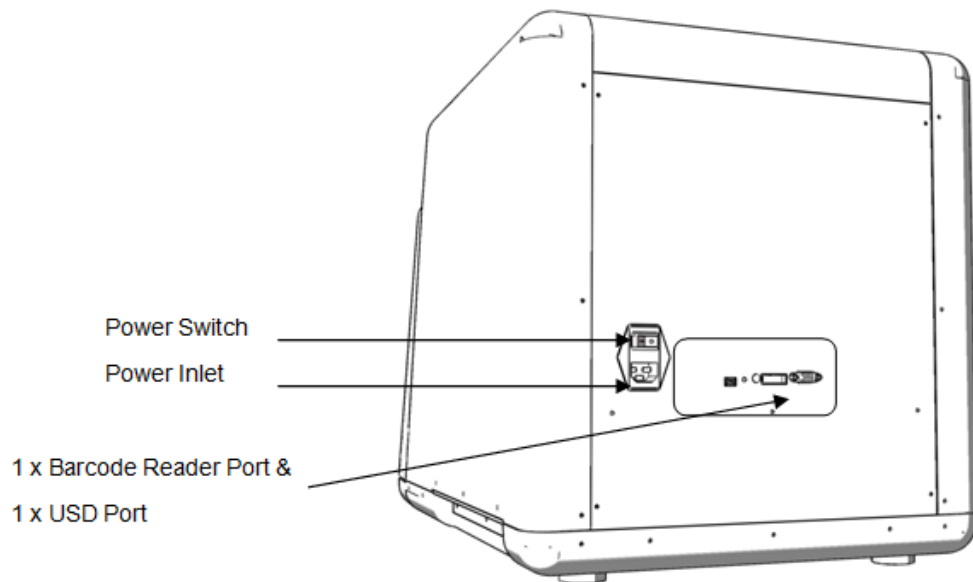
- LCD Panel and Control Pad



- LCD 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.



■ Back View



2 Operation



Biohazard:

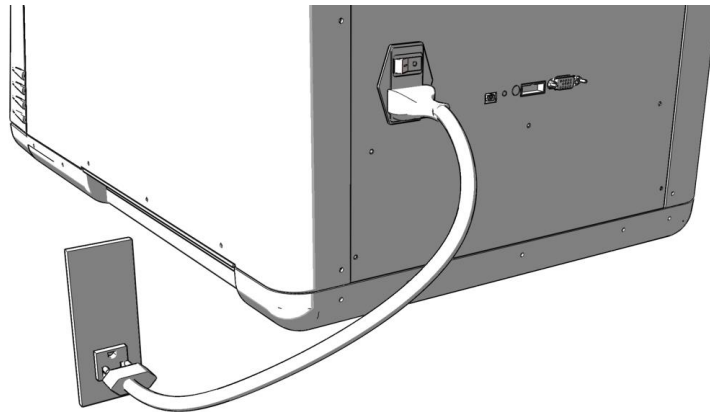
Always wear appropriate gloves, mask, and safety goggles during any biohazardous operations. After any operation with a potentially biohazardous sample, treat the device as contaminated and wear appropriate gloves and mask until the device is properly decontaminated.

Important:

Before starting an extraction, put on appropriate gloves, 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.

2.1 Turning on the power

- (1) Make sure that the power cable is connected securely to the MPure-12 aNAP System.
- (2) Connect the plug of the power cable to the electrical outlet.



2.2 Preparation

The following preparations are required for extraction operation.

- Items to be prepared
 - Gloves
 - Mask
 - Safety Goggles
 - Reagent Cartridge*
 - Reaction Chamber*
 - Tip Holder*

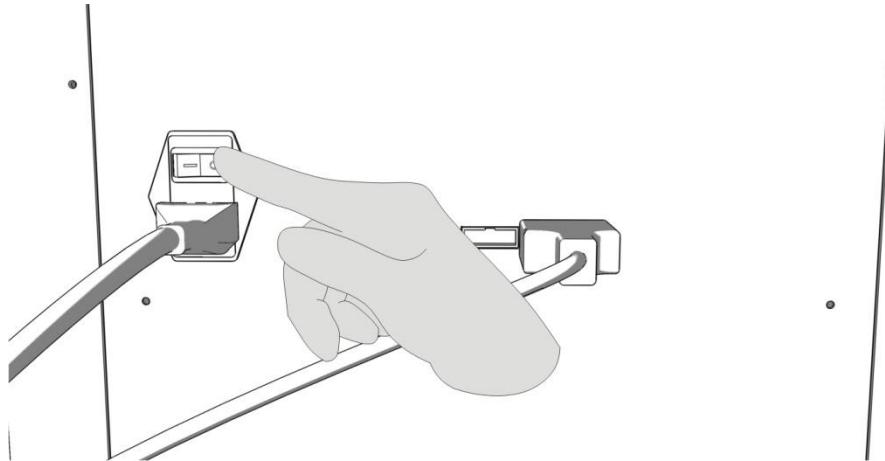
- Small Tip (Option)*
- Filtered Tip*
- Sample Tube*
- Elution Tube*
- Piercing Pin*

■ For the preparation of samples, refer to the IFU of each extraction kit.

*: Provided with the extraction kits.

2.3 Extraction

- (1) Turn the power switch on and waiting for the LCD screen turn on and shows “MPure-12 aNAP System Stand-By”.

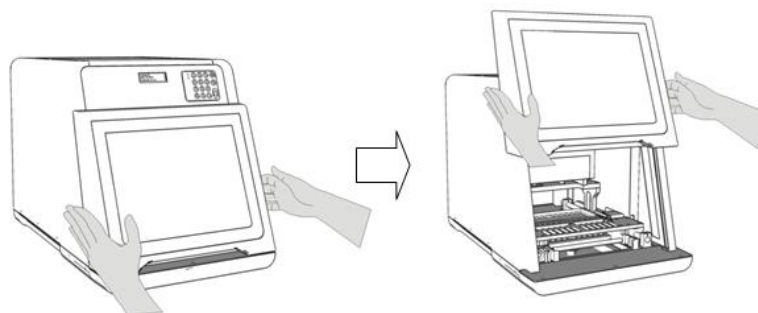


- (2) Press the “START” button

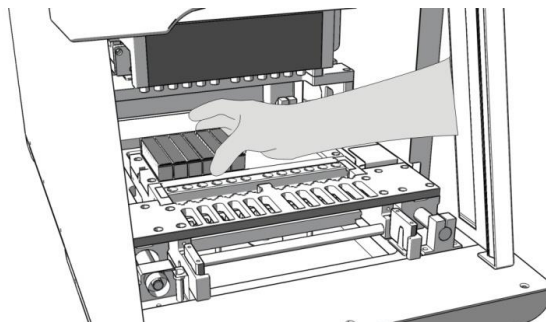
(The system will process self-testing, and then go to steady mode)

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

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



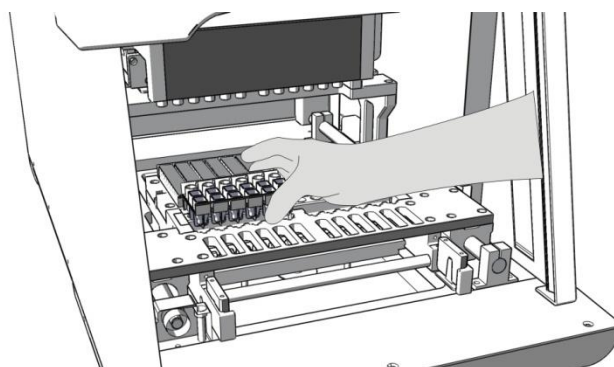
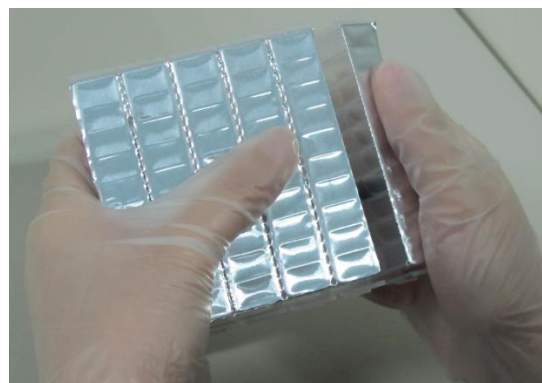
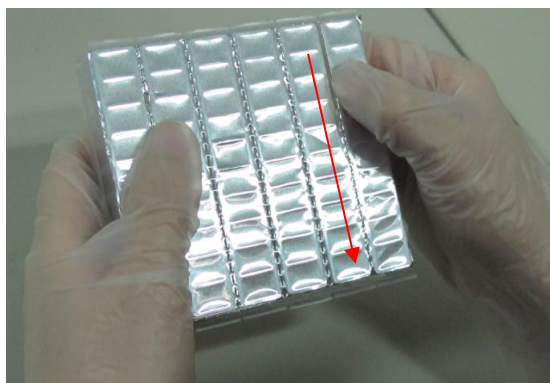
- (4) Load Reagent Cartridges, and all plastics disposables (Reaction Chamber, Tip Holder, Piercing Pin, Filtered Tip, Sample tube and Elute Tube).



Insert the cartridges

■ **How to pull apart reagent cartridges**

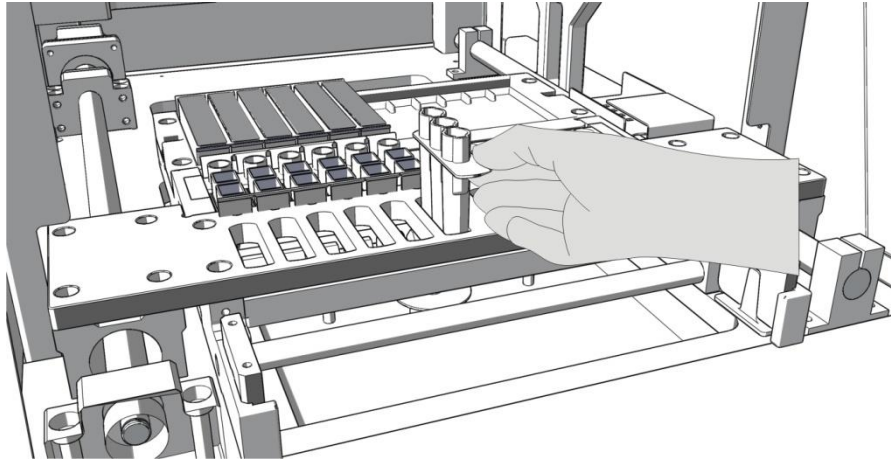
- Score the foil perforation line with finger nail and snap apart using light force.



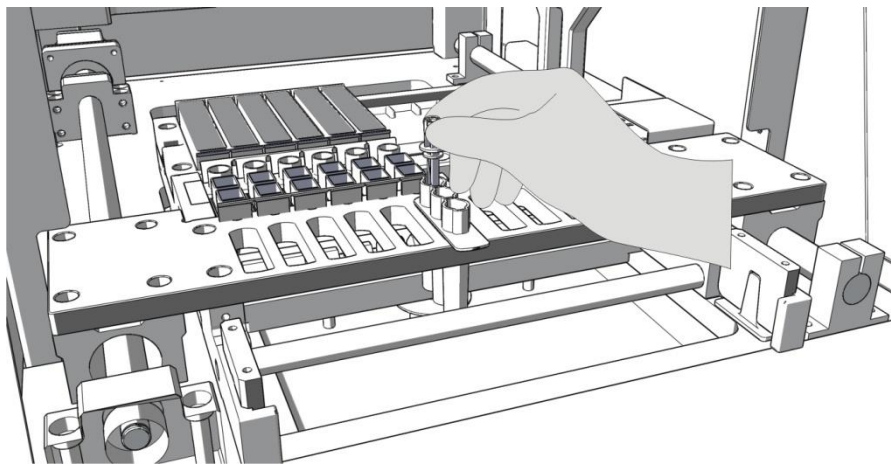
Insert Reaction Chambers



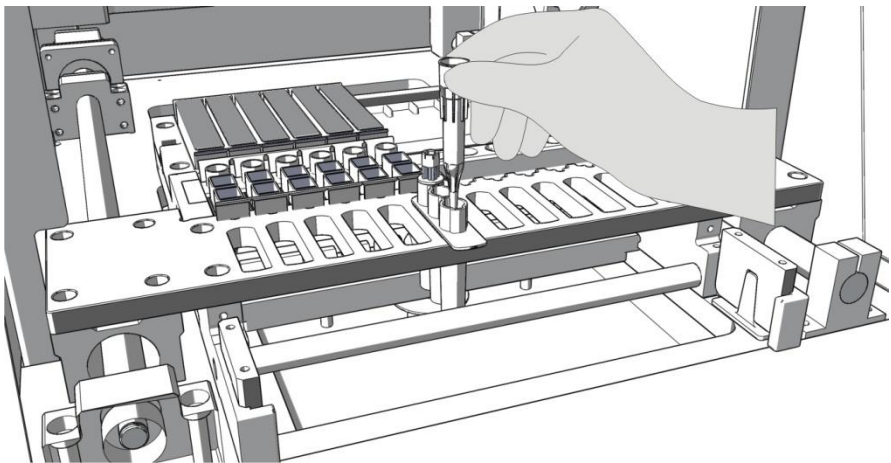
Caution: Please always perform the test with all plastic accessories installed, especially with **Reaction Chambers**; otherwise this might cause serious damage to the instrument.



Insert Tip Holder



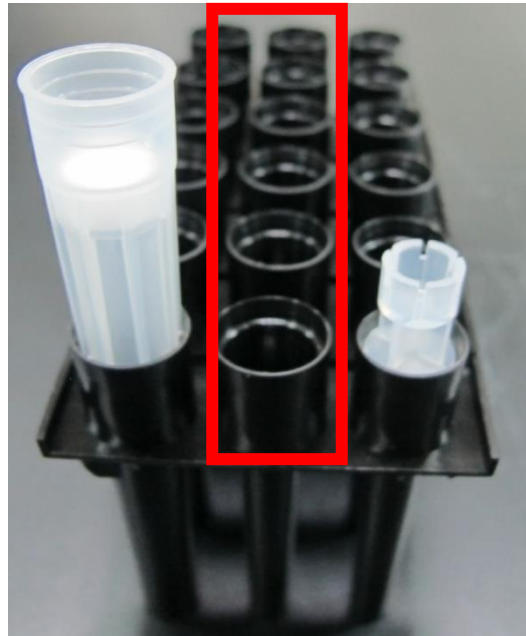
Insert Piercing Pins



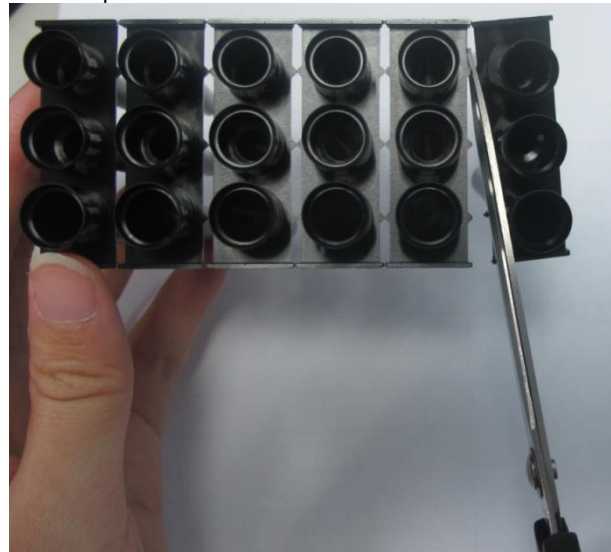
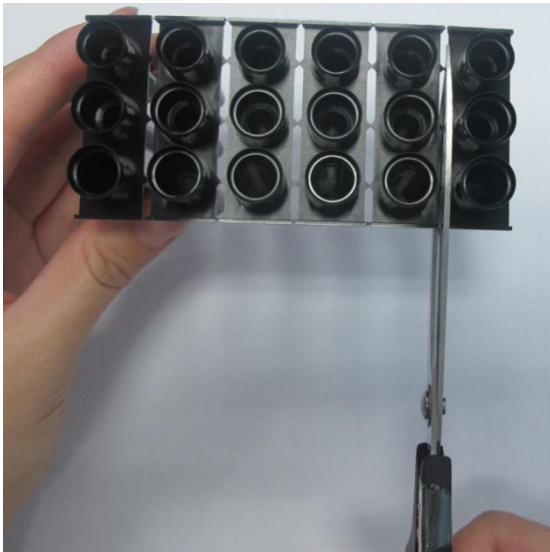
Insert Filtered Tips

Note:

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



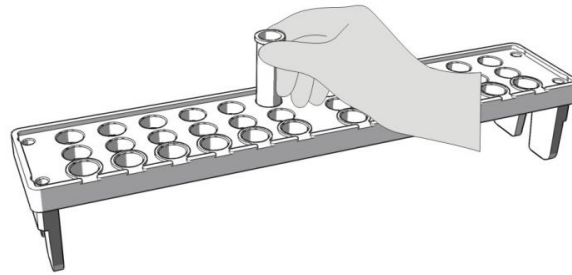
2. Load one Reagent Cartridge and one set of plastic disposable per sample.
3. ! Use scissors ONLY to separate the tip holders.



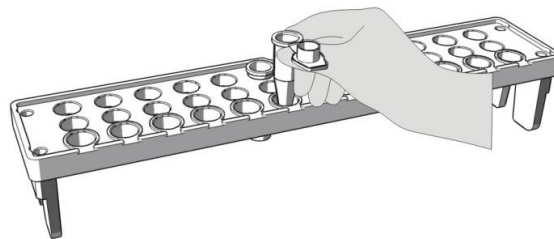
Important:

- Set Cartridges in order of the numbered lanes from left to right.
- Make sure that Cartridges are inserted into the Cartridge Tray tightly.
- Load 1-12 cartridges on the tray depending on the desired number of samples.

- (5) Load Sample Tube and Elution Tube onto the Sample Rack on the bench

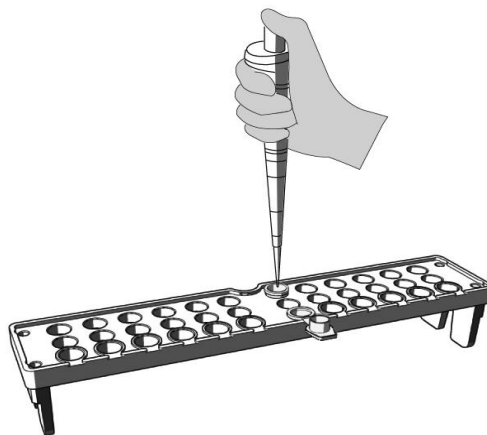


Insert Sample Tube on to Sample Rack



Insert Elution Tube on to Sample Rack

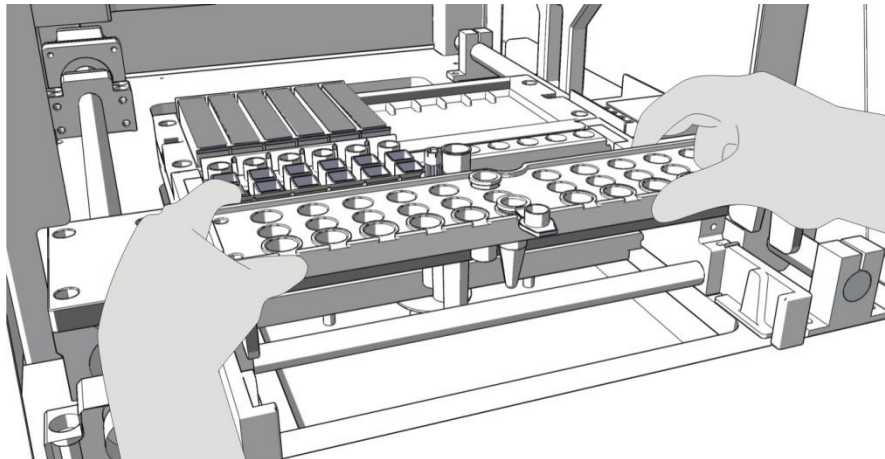
- (6) Load the sample(s) to Sample Tube



Note:

- Pretreatments are essential for some sample types before loading to Sample Tube. Please refer to the extraction kit IFU for details.
- Make sure the caps of Elution Tube are open facing the front of the device (See figure above).

- (7) Place Sample Rack on the instrument platform

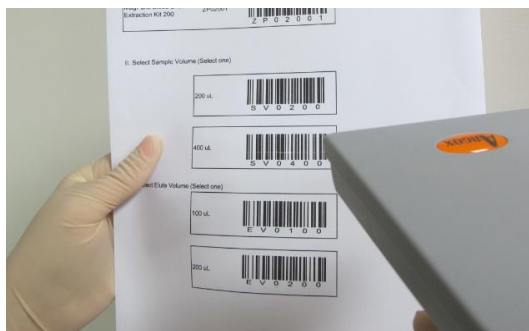


Note:

- Use two hands to handle the Sample Rack.
- Make sure the Sample Rack is placed correctly in the instrument.

- (8) Close the Sliding Door

- (9) Scan the protocol barcodes to select purification protocol, sample volume and elution volume with the barcode scanner.



Note:

- There is one protocol barcode paper enclosed in each extraction kit box.
- Protocol's name, sample volume and elution volume will be shown on LCD screen after protocol barcode is scanned.

- (10) Follow the instructions displayed on LCD screen to confirm the operating steps are completed and accurate before starting the program.

- (11) Press "Enter" to confirm. Instrument will start and run the program automatically until the entire process is completed.

Note:

- It takes from 30 to 45 minutes to complete the extraction depending upon the extraction kit types.

- (12) At the end of the run, the instrument beeps briefly and the LCD displays "Protocol Completed"

- (13) Open the instrument door

- (14) Cap and remove the Elution tubes containing the purified nucleic acid

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

- (15) Discard the used cartridges, all plastic consumables into biohazard waste. Do not reuse the cartridges
- (16) Upon completion of a program, place the Sample Rack back into the platform stage, close the instrument door and press “START” button for 2 seconds to activate instrument “sleeping mode”.

For longer idle periods, turn the power switch off.

2.4 Post Extraction Procedures

- (1) Take out the Elution Tubes (contains purified end-product)

Note:

- i. Purified nucleic acids are now ready for storage, quality or yield determination, or for downstream analysis.
- (2) Remove the Cartridges and plastic disposables from the instrument and then dispose using proper procedures.

3 Cleaning & Maintaining the MPure-12 aNAP System

Two types of maintenance are required for the MPure-12 aNAP System and are listed in the table below:

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

- Clean the Sample Rack using a 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 and remove dust gently with a dry, soft, lint-free cloth. If the outside of the MPure-12 aNAP System is heavily soiled, or if any hazardous samples contact the outside of the MPure-12 aNAP System, disinfect using a soft paper tissue, soaked with 0.5% sodium hypochlorite solution or ethanol.

4 Troubleshooting

Problem	Cause	Solution
Instrument Problems		
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 devices and wall outlet. Confirm that the correct cord is in place.
LCD Screen turns on when the power is on but the self-testing program does not run	Failure to remove the packing materials from the instrument	Turn off the instrument and remove the packing materials.
	Technical problem	Contact your local representative.
Protocol stops after an initial start	Cartridge(s), Plasticwares (Reaction Chamber, Tip Holder, Filtered Tip, Sample Tube, Elution Tube) incorrectly loaded on the MPure-12 aNAP System	Turn off the power and then turn it on again to stop the program. The system will move back to the home position. Re-position disposables 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 plasticwares. Contact your local representatives.
Bubbles formed during extraction	Failure to add sample or sample volume is lower than the recommended volume	Confirm addition of 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 MPure Extraction Kit IFU.
Presence of buffer in the Cartridge Tray	Motor movements may not be smooth, incorrect placement of plasticware, 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	Replace tip with new one.
Blockage of tips and pipetting failure	Too much starting material or excess DNA in sample causing clumps or aggregates	<ol style="list-style-type: none"> 1. Decrease the amount of starting material. Use the recommended amount of starting material as listed in the MPure Extraction Kit IFU. 2. Suggest using MPure Blood Kit 1200 instead of MPure Blood Kit 200 (if test 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 upon the quality of the starting material.
	Insufficient amount of magnetic beads added	During shipping, some magnetic bead solution may adhere to the sealing foil of the cartridge. Lightly tap the cartridge on the benchtop to deposit the bead solution in 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 MPure 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 irreparably 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 (≤ 20 μ l blood spot for forensics sample).
DNA is sheared or degraded	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 MPure Extraction Kit IFU.
	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).

5 Specifications

Model	MPure-12 aNAP System
Instrument Type:	Benchtop automated nucleic acid extractor
Software version	J-140307-3
Sample Processing:	1 to 12 samples per batch
Sample Volume Handling:	100 – 1200 µL
Processing Time:	See MPure Extraction Kit IFU 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:	10-40°C
Operating Humidity:	30-80%
Fuse:	F3.15A 250V
Temperatures allowed during transportation/ storage/ packaging:	-25°C to +70°C

CE

LV directive (73/23/EEC)

EMC directive (89/336/EEC)

IVD Directive (98/79/EC)

EMC

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

Safety

- IEC/EN 61010-1:2001
- IEC/EN 6010-2-101:2002

APPENDIX

Replacement/ Optional Parts

Item	Qty
Barcode Reader	1
Power Cord	1
Sample Rack	1
Filtered Tip	50
Piercing Pin	50
Sample Tube	50
Elution Tube	50

Product Guarantees

- I. The guarantee period shall be one year from the delivery of the product.
- II. Any part which fails to function properly under normal use, provided that all warnings and cautions in this operation manual are observed, during the guarantee period will be repaired by the **MP Biomedicals Asia Pacific Pte Ltd** free of charge.
- III. If the problem is due to the causes listed below, some charge may be applied for the repair even within the guarantee period.
 - Any failures due to improper use or that are affected by other devices except for those approved by the **MP Biomedicals Asia Pacific Pte Ltd**.
 - Any malfunctions or damages during transportation or due to dropping of the product by a user.

About Services

Before seeking for device repairs, refer to “Troubleshooting” to check user initiated solutions. If the problems cannot be solved, contact your local representative, or the relative customer support.

Notes for Transporting / Shipping the MPure-12 aNAP System

When transporting/shipping the MPure-12 aNAP System to a new location, perform the following tasks:

Warning:

- Before lifting the MPure-12 aNAP System, 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 MPure-12 aNAP System, be sure to perform the following tasks:

Remove all attached parts (Sample Rack, Barcode Reader, Power Cable) from the

MPure-12 aNAP System.

- After completing the above tasks, pack the MPure-12 aNAP System in its original shipping box.

Instrument packing materials Installation before Transport

- (1) Press the button "0123"



- (2) Press the button "3"



- (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



(7) Press Enter button



(8) Finish

