magLEAD 12gC Instruction for Use

Version 2
Dec 2023

C E IVD

Index

Doc. No.: P30001PE0101-09

1.Information for the User

Congratulations on purchasing the magLEAD 12gC instrument, which features Precision System Science's worldwide patented Magtration® technology utilizing magnetic particles.

This Instructions for Use provides information necessary for the safe and effective use of the instrument. Please read this manual thoroughly to familiarize yourself with the device and its settings before you use it.

・Do not operate the instrument without understanding the instructions described in this manual.

・Always keep this manual near the instrument in case you need a quick reference.

Please inform us, Precision System Science Co., Ltd., or a distributor, if this manual is lost or damaged.

The following items are included in the instrument package.

Items	Qty.	Remarks
1. magLEAD 12gC main body	1	
2. Power cable AC125V	1	
3. Power cable AC250V	1	
4. Reagent cartridge rack	1	
5. Tip/tube rack	1	
6. Silicon grease	1	
7. D-rings	12	
8. Fuse (3.15A, 250V)	2	For power switch
9. Package insert	1	
10. Package checklist	1	

Optional items (Not included)

11. Handheld barcode reader	1	
12. magLEAD Communicator (CD)	1	PC software
13. Communication cable	1	
14. USB-RS232 converter	1	

Disposables (Not included)
F4430_magLEAD Consumable kit

1.	magLEAD Tip and Sheath set	52	DN 100N, Sheath DN 100N
2.	Micro tube	100	
3.	Screw cap	100	

Reagents (Not included)

Code	Name
E1300	MagDEA Dx SV

IC card (Not included)

Code	Name
I7712	MagDEA Dx SV 200 12gC
I7812	MagDEA Dx SV 400 12gC

For other RUO products, please see the PSS homepage.

Please notice to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established, in case where any serious incident has occurred in relation to the device.

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2.Information for Safe Usage

Most problems arise from incorrect usage of the instrument and from not following the safety instructions. Please read this manual thoroughly so you can understand and familiarize yourself with measures for preventing problems in instrument operation.
If the instrument is used in a manner not specified by the manufacturer, the protective features of the equipment may be impaired.

About the Symbols

This manual uses various symbols to help you easily understand important information regarding safe operation of the instrument. Their meanings are described below.

Symbol	Description
⚠ **Warning**	Indicates the need for the user to consult the instructions for use. When the instructions for use and patient information are located within the same electronic instructions for use, a manufacture may choose to use this symbol to indicate both.
⚠ **Caution**	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
⚠	Caution label for hot surface To warn of a hot surface.
⚠	Caution label for crushing of hands To warn of a closing motion of mechanical parts of equipment.
⚠	Caution label for biological hazard To warn of a biological hazard.
⚠	Caution label (e.g. of UV Lamp) To signify a general warning
🏭	Manufacturer Indicates the medical device manufacturer.
EC REP	Authorized representative in the European community / European Union Indicate the authorized representative in the European community / European Union.
IVD	In vitro diagnostic medical devices Indicates a medical device that is intended to be used as an in vitro diagnostic medical device. magLEAD 12gC is not considered as a medical device (IVD) in the United States of America, and it is not registered with the FDA.

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$C \epsilon$	CE mark for Europe Regulation (EU) 2017/746 (IVD Directive) This instrument has been tested and complies with the following standards: Base Standard(s): I EC 61010-1:2010/AMD1:2016/COR1:2016 /COR1:2019 Additional Standards: UL 61010-2-010 Ed.4, Published June 27, 2019, CSA 22.2 No. 61010-2-010:19, Published November 2019, IEC 61010-2-010 (2019) Ed.4, UL61010-2-101 Ed. 3, Published July 31, 2019, CAN/CSA C22.2 No. 61010-2-101:19, Published August 2019, IEC 61010-2-101 (2018) Ed.3, IEC 62471: 2006

About the symbol of label

The symbols on the labels for devices other than those listed above are described below.

SN	Serial number Indicate the manufacturer's serial number so that a specific medical device can be identified.
JP YYYYMMDD	Country of manufacture "Japan" To identify the country of manufacture of products. The date of manufacture.
UDI	Unique device identifier Indicates a carrier that contains unique device identifier information.
c(UL)us LISTED	UL listing mark for Canada and the USA This instrument has been tested and complies with the following standards: Base Standard(s): UL 61010-1, 3rd Edition, May 11, 2012, Revised July 19, 2019, CAN/CSA-C22.2 No. 61010-1(2012-05), 3rd Edition, with revisions through 2018-11 Additional Standards: UL 61010-2-010 Ed.4, Published June 27, 2019, CSA 22.2 No. 61010-2-010:19, Published November 2019, IEC 61010-2-010 (2019) Ed.4, UL61010-2-101 Ed. 3, Published July 31, 2019, CAN/CSA C22.2 No. 61010-2-101:19, Published August 2019, IEC 61010-2-101 (2018) Ed.3, IEC 62471: 2006
(waste bin symbol)	This product complies with the WEEE Directive (2002/96/EC) marking requirement. This marking indicates that you must not discard this electrical/electronic product in domestic household waste.

Other's symbol

	⚠	This symbol indicates a caution message (including danger and warning). The mark inside the triangle specifies the type of caution (the example on the left illustrates electric shock).
	🚫	This symbol indicates actions that you should not perform. Details are illustrated inside the symbol or near the symbol.
	⊖	This symbol is used to restrict operations or to illustrate what action should be performed. Details are illustrated inside the symbol (the example on the left shows unplugging of an AC plug from the wall outlet).

⚠ **Caution**

- Do not use kits other than the MagDEA Dx reagent kits.

- Follow corresponding instructions for use of the MagDEA Dx reagent to use.

- Do not use this instrument in a strong electric field or magnetic field.

- Use of this instrument in a dry environment may cause erroneous results due to damage from static discharge.

⚠ Warning

The following precautionary instructions are included to ensure safe operation of the magLEAD 12gC instrument. Please always keep this manual near the instrument or operator. Failure to comply with the instructions in this manual may pose dangerous risk to the user and will void the manufacturer's warranty.
If problems occur with the instrument, immediately turn off the main power switch and unplug the power cable. Then contact PSS.

Installation

- Be sure that no water or liquid gets inside the instrument. This could cause fire or electric shock.

  🚫 **Prohibited acts**

- Do not attempt to disassemble, modify, or repair the instrument yourself. This may cause instrument failure or electric shock to you. Contact PSS for instrument repair or maintenance.

  🚫 **Prohibited acts**

Emergency Situations

- In case of an instrument emergency, such as extraordinary heat, smoking, abnormal smell, etc., immediately unplug the power cable from the wall outlet to avoid fire or electric shock. Contact PSS for repair.

  Unplug AC power

- If foreign material or water splashes onto the instrument or gets inside the instrument, immediately unplug the power cable from the wall outlet to avoid fire or electric shock. Contact PSS.

  Unplug AC power

- If the power cable is damaged (e.g., the core wire is exposed or broken), immediately unplug the power cable from the wall outlet to avoid fire or electric shock. Contact PSS.

  Unplug AC power

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⚠ Caution

- Avoid installing the instrument in the locations indicated below. This may cause instrument damage or malfunction.

  -Locations exposed to direct sunshine

  -Locations with high vibrations, humidity, or dust

  -Locations with strong electric or magnetic fields

  -Locations where liquid or oil could splash onto the instrument

  -Locations with flammable gas, corrosive gas, or high heat sources.

Prohibited acts

- The instrument will be installed by field service personnel authorized by PSS.
  Contact us if you need to move the instrument.

Prohibited acts

Storage

- Unplug the power cable from the wall outlet if the instrument will not be used for an extended period of time.

Unplug AC power

Precautions for Instrument Operation

- There is a possibility of biohazard exposure while operating the instrument. Wear appropriate personal protective equipment such as a mask, goggles, and gloves.

- Pay close attention when handling biohazardous samples.

- When operating the instrument under low temperature conditions, keep the instrument power on.

- Make sure that no foreign materials get into the instrument from outside.

- Do not scratch or press the operation panel with knives or other sharp items.

- Pay close attention when working around the piercing unit to prevent injury to yourself.

- Handheld barcode reader uses LEDs. Do not look directly at the LED.

- The fuse should only be replaced by field service personnel authorized by PSS. Contact us for fuse replacement.

About the Warranty Period

- 12 months after installation, regardless of the instrument usage.

- This warranty excludes problems that occur due to inadequate storage, inadequate usage or operation, or repair, modification, or maintenance of the instrument by people who are not authorized by PSS, even within the warranty period.

About Disposal

- Contact PSS if you need to dispose of the instrument.

3.Specifications

3.1.Intended Use

magLEAD 12gC employs PSS's original Magtration® technology to perform automated isolation and purification of nucleic acids (DNA, RNA) from biological samples using magnetic particles as preparation for in vitro diagnostic testing using genes.

magLEAD 12gC is intended to be used only in combination with the MagDEA Dx reagent kits for this instrument only for the applications described in the product's instructions for use. The system is intended for use by professional users, such as technicians and physicians trained in molecular biological techniques and the operation of the magLEAD 12gC.

3.2. Features

➢ Full automation of nucleic acid extraction/purification by Magtration® technology
➢ Compact body that occupies minimal space
➢ High speed, simultaneous processing of up to 12 samples by 12 nozzles
➢ Special disposable tips and reaction cartridges for ease-of-operation

3.3. Performance

➢ Instrument type: Desktop
➢ Throughput: Samples・・・1 - 12 samples/batch
　　　　　　　　　　　 Processing time・・・About 30 min/1 - 12 samples
➢ Temperature control function: Heat Block・・・40 to 90 deg. C

➢ Processing volume: 25 - 1000ul
➢ Dispensing accuracy: 25 - 50ul・・・・+/-10%
   (Aspiration accuracy)   50 - 1000ul・・・+/-3%

　　※Accuracy with distilled water at room temperature 20 - 25 deg. C
➢ Protocol: IC Card

Note
• Processing time depends on the protocol in use.

3.4. Size, Weight, and Power Requirements

➢ Size: W500×D535×H574mm
➢ Weight: About 55 kg (121 lbs.)
➢ Power requirement: AC100 - 240V +/- 10%, 50/60Hz, 300VA

⚠ **Caution**

• Do not share a power source with other instruments.
• Do not place next to other instruments that cause noises or power fluctuation.
• Connect the power cable to the wall outlet with a grounded line.
• Connect to protective earth.

3.5. Storage Conditions
➢ Temperature: +5 ~ +40 deg. C
➢ Relative humidity: 15 ~ 75 % ※Non-condensing
➢ Barometric pressure: More than 70kPa (min)

3.6. Transport Conditions
➢ Temperature: - 25 ~ + 60 deg. C
➢ Relative humidity: 15 ~ 75% ※Non-condensing
➢ Barometric pressure: More than 70kPa (min)

3.7. Environmental Requirements and Instrument life
➢ Overvoltage category: Ⅱ
   Transient overvoltage: 2500 V
➢ Pollution degree: 2
➢ Installation site: Indoor use only
➢ Temperature: +15 ~ +30 deg. C
➢ Relative humidity: 15 - 75% ※Non-condensing
➢ Altitude: Up to 2,000 m above the sea level
➢ Space: Maintain sufficient distances from the walls as indicated below for ventilation, maintenance work, etc. Also maintain more than 200 mm free space above the instrument.
➢ Product life: 5 years (4 runs/day, 250 day/year) with proper maintenance.

Environmental Requirements
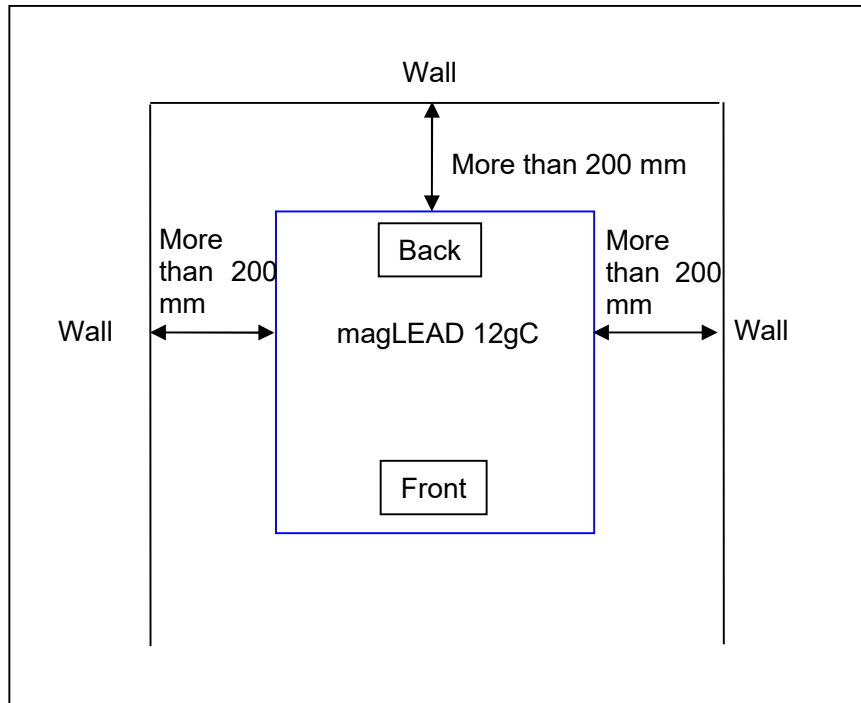
⚠ Caution

- Place the instrument on a horizontal surface that can support the instrument weight.

- Place the instrument on a horizontal surface.

- Do not place the instrument in locations exposed to direct sunlight or vibrations.

- When operating the instrument in a cold chamber or cold room, keep the instrument power on to avoid condensation.

3.8. About the Caution Labels Inside the Instrument

3.8.1. Caution label for hot surface
Place attached: Heat block and inner wall of the cover
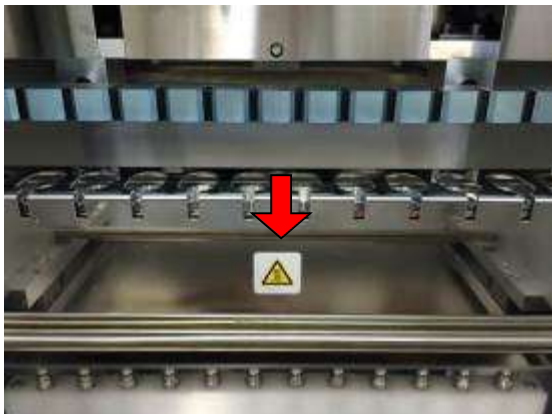
⚠ Caution

- The area where this label is attached becomes hot during operation. Be sure not to touch this area.

3.8.2. Caution label for crushing of hands
Place attached: Magtration® Unit

⚠ Caution

- The area where this label is attached can potentially pinch your hand or fingers in the driving mechanism of the open/close operation. Take care not to be pinched.

3.8.3. Caution label for biological hazard
Place attached: Inner wall of the instrument cover

⚠ **Caution**

- The area where this label is attached (inside cover) has the potential of biohazard contamination from samples or extracted/purified products. Take care not to expose yourself to potential contamination.

- Note that it is not possible to completely eliminate biohazard risk from samples or extracted/purified products while operating this instrument. Wear a mask, goggles, and gloves for your own safety as described in this manual.

- Pay close attention when handling highly hazardous samples.

3.8.4. Caution label for UV Lamp
Place attached: Top of the instrument cover
CAUTION UV emitted from this product.
IEC62471   Risk Group 2
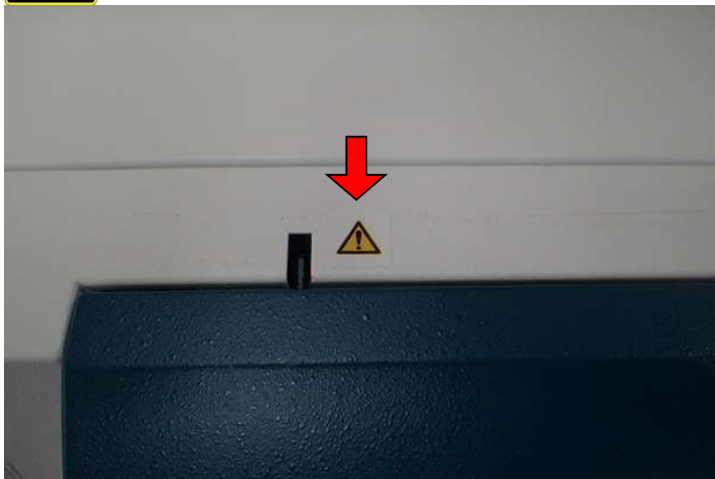
⚠ **Caution**

- The magLEAD 12gC contains a UV lamp. Avoid looking directly at the UV light. Do not expose your skin to UV light.

4.System Components
4.1. Front View

*1 Power Status LED (green)	
*2 Alarm Status LED (red)	
Display	
Operation Panel	
IC Card Inlet	
Door	
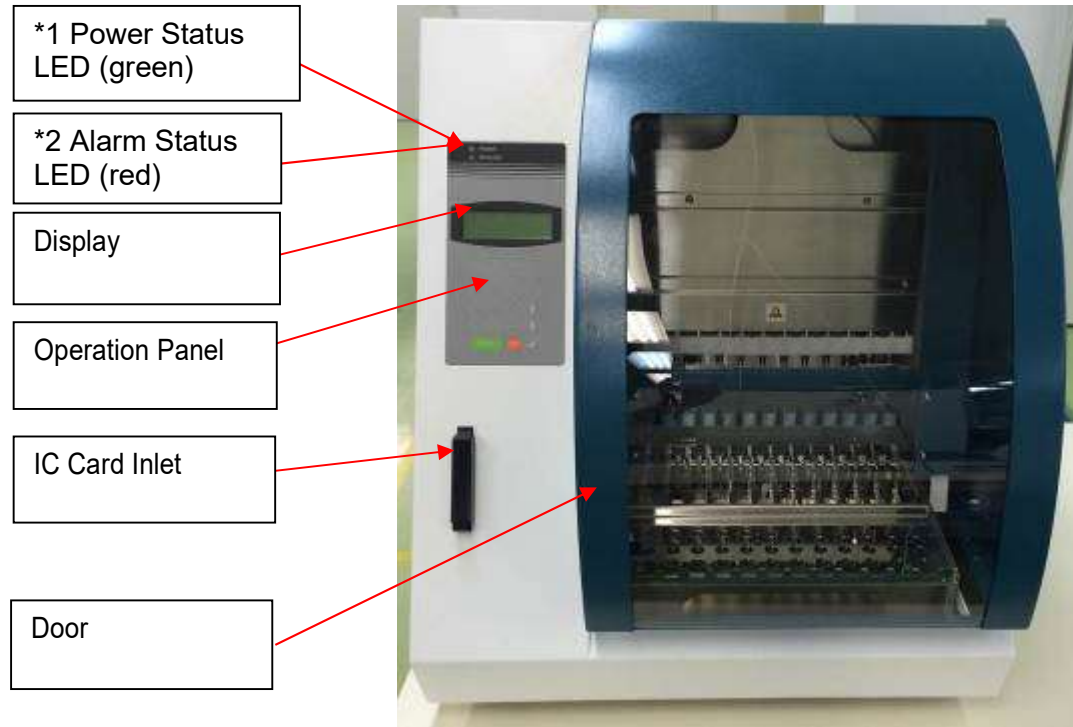
*1: Green LED: Lit when powered on

*2: Red LED: Blinks if an error occurred

4.2. Side and Rear View

The power switch is located on the left side of the instrument.
The fuse box and connectors are located on the back of the instrument.

Power Switch

Fuse box

RS232C Connector for PC

Power Cable Connector

Connector for Handheld Barcode Reader
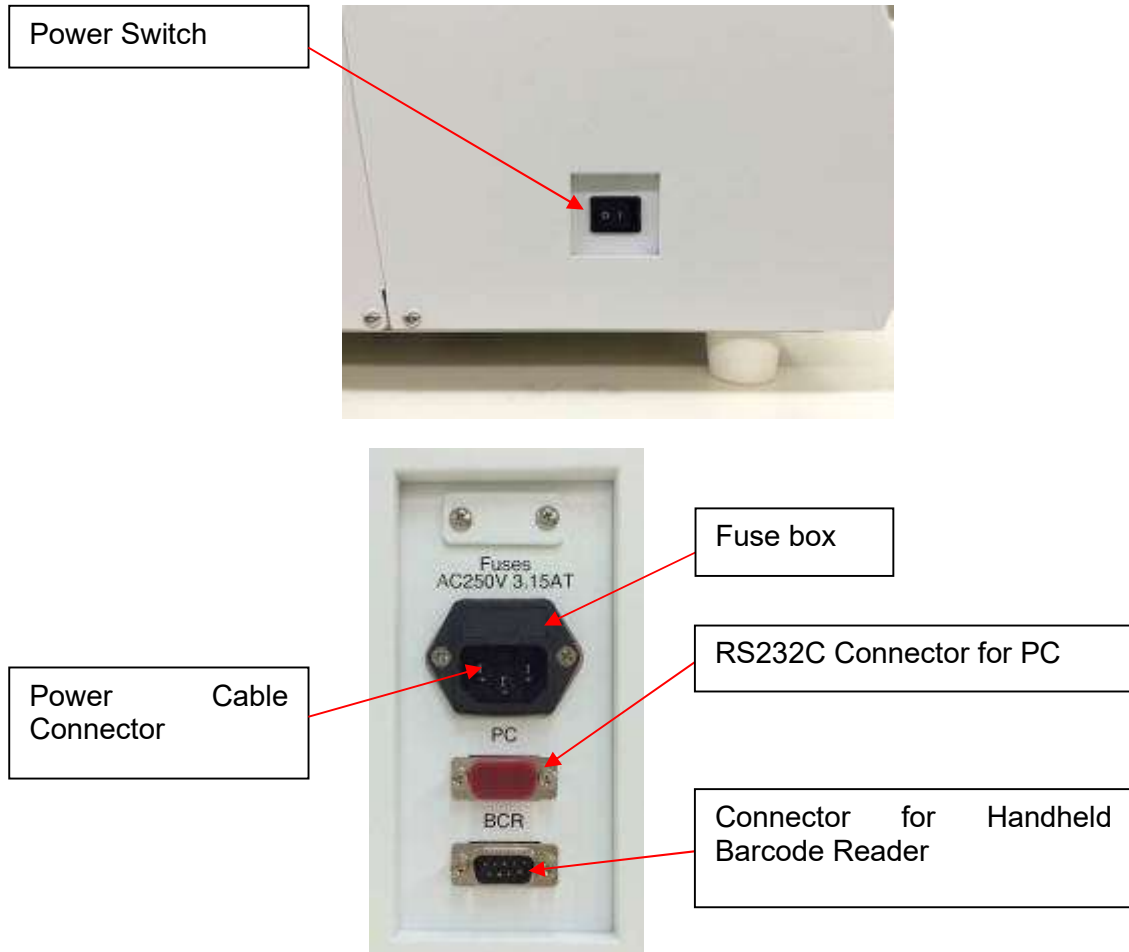
Note

- Replacement of the fuse shall only be made by field service personnel authorized by PSS. Contact us for fuse replacement.

4.3.Internal Components

The Magtration® unit and stage unit are located inside the instrument.

UV lamp Unit

Syringe Unit

Magnets

Reagent Cartridges

Tip Sets
(magLEAD Tip and Sheath set)

Sample Tubes

Elution Tubes
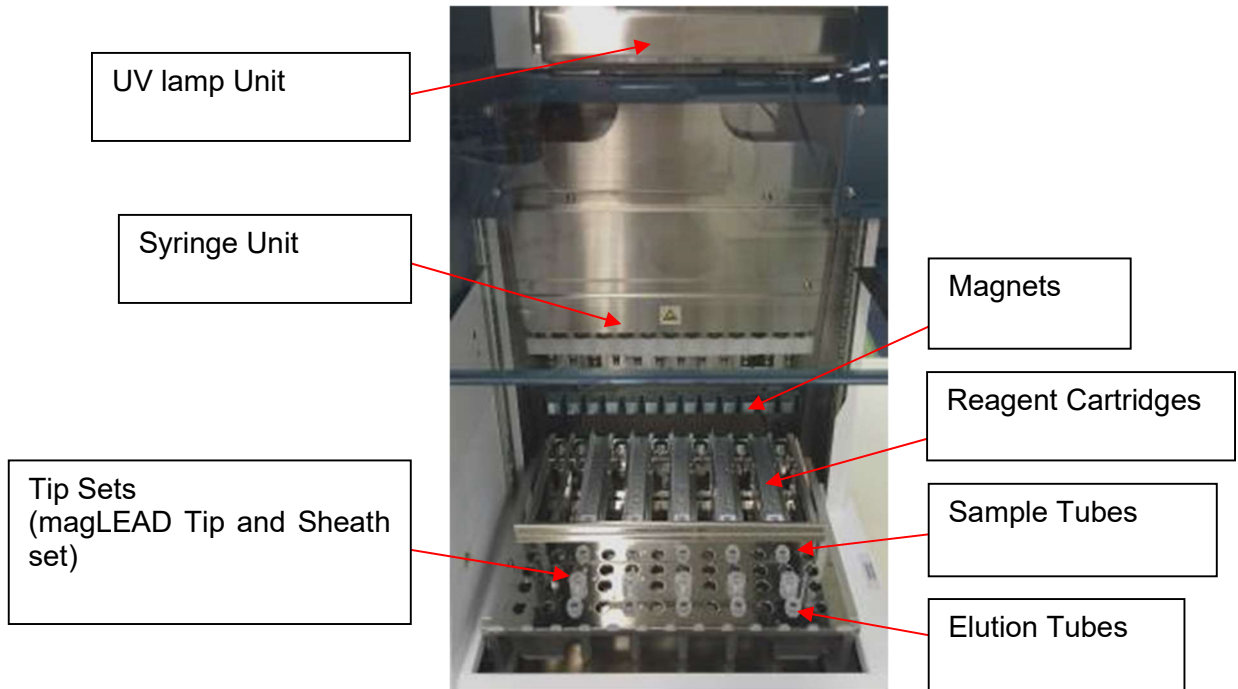
1. **Magtration® Unit**
   - ➢ Syringe Unit: Twelve nozzles for simultaneous processing of up to 12 samples with accurate and rapid aspiration and dispensing.

   - ➢ Magnets: Twelve magnets aligned with 12 tips for simultaneous separation of magnetic particles from up to 12 samples.

2. **Stage Unit**
   - ➢ Reagent Cartridges: Simple placement of special disposable cartridges pre-filled with reagents minimizes cross-contamination.
     The back two positions (wells) in the cartridge are used for heating.

   - ➢ Tip Sets: Positions for tips (DN100N tips) in the tip sheath. One or two tips or tip sheath (Sheath DN100) are used per sample depending on the protocol. Refer the instructions provided in the package insert for the reagent kit.

   - ➢ Elution Tubes: Positions for Micro tube.

   - ➢ Sample Tubes: Positions for Micro tube.

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5.Installation

5.1. Setup procedure

    1. Remove the instrument from the shipping crate.

⚠ Warning

- The instrument will be installed by field service personnel authorized by PSS. Contact us if you need to move the instrument.

    2. Remove the protective films attached to the instrument.

    3. Open the instrument door.

    4. Push the pipettor head upward.

5. Remove the bubble wrap, Y-axis fixing bracket, and silica gel bag.
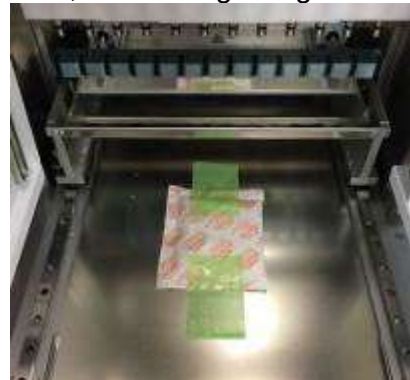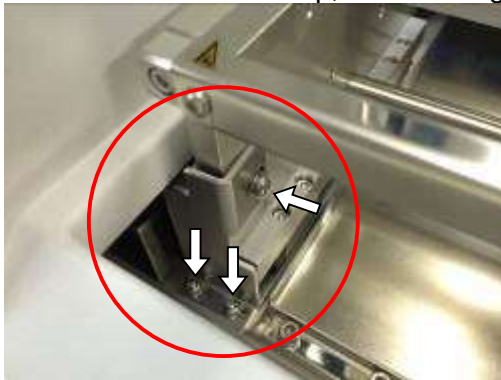
6. Connect the power cable and the handheld barcode reader that came with the instrument. Connect the power cable to the wall outlet.

Power Cable

RS232C Connector for PC

Connector for Handheld Barcode Reader
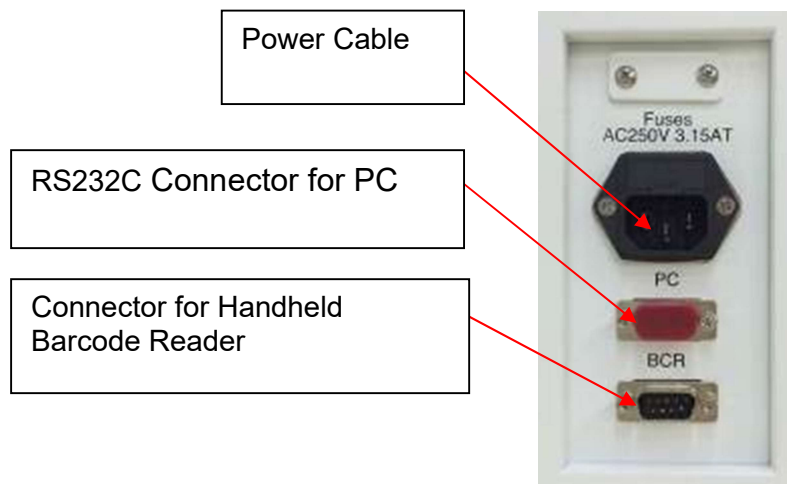
⚠ **Caution**

- Do not use any power cable other than the one provided to avoid risk of fire or temporary blackout.

7. Confirm that the power switch is turned off. Following the images below, open the inlet cover and insert the IC Card. Make sure that the picture side is on the left and the triangle mark ▽ faces down when inserting the card. After inserting the card, turn on the power using the switch on the left side of the unit.
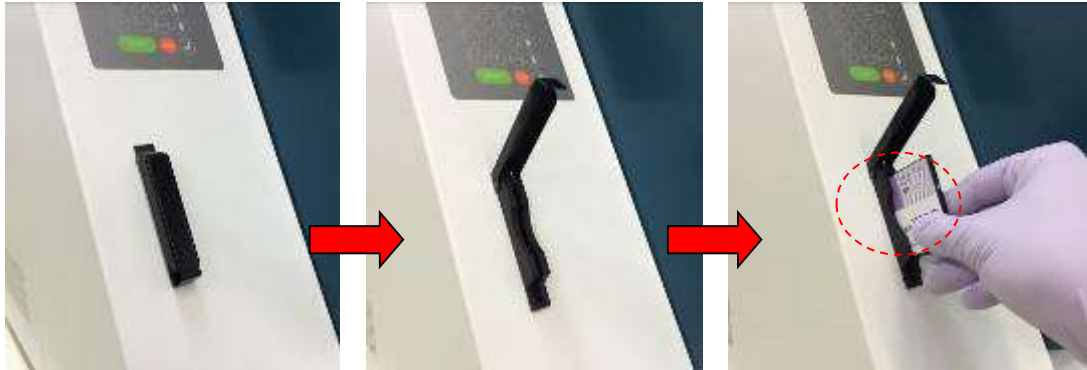
➢ **Removing IC Card**
   Before removing the IC card, make sure that the power is switched off.
   Press the bottom as shown below and pull out the card.
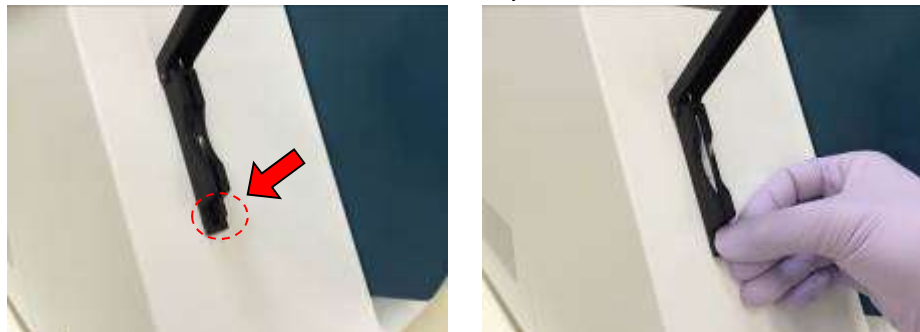
⚠ **Caution**

- Ensure that the power is turned OFF when inserting or removing the IC card. The card and/or the instrument may become damaged if the card is inserted or removed while the power is on.
- Handle the IC Card with care as it can be damaged by impact, exposure to water or dust
- If the IC Card is not inserted properly, the LCD may not display correctly.
   Ensure that the IC Card is inserted properly.

8. Make sure that the instrument completes the homing operation of all axes after it is powered on.

9. Installation is complete.

⚠ Caution

- When transporting the instrument, be sure to fix the syringe unit and stage using cushions and screws to avoid any damage to the instrument.

5.2. Configuration and setting up the instrument

5.2.1. Setting the installation date

The first time the magLEAD 12gC is switched on, the installation date must be entered. This date will be recorded in the report file described below.
In addition, the instrument uses this installation date for determining when to display the weekly and annual maintenance reminders.

```
SERV: SETUP SYSTEM
Installation date
DD MM YYYY
Key:Up, Dn, SHIFT, ENT
```

Set the day, month, and year. Press "SHIFT" and the down arrow to move the cursor to the right, from DD (day) to MM (month) to YYYY (year).
Press "SHIFT" and the up arrow to move the cursor to the left, from YYYY to MM to DD.
Press the up arrow or down arrow to increase or decrease the value of the selected field.
After setting the date, store the setting by pressing "ENT".
Press "ESC" to leave the date unchanged.
If you accidentally set the wrong date, call Precision System Science.

5.2.2. Setting the serial port

Set the serial port to use a PC as the output device for the report file (Section 5.2, 11, 12).

5.2.3. Setting time and date

The magLEAD 12gC has an integrated clock and date tracker.
Check the time and date and reset if necessary.
(Section 9.3.1 and 9.3.2)

5.2.4. Setting the preventive maintenance reminder

The magLEAD 12gC reminds you when the annual maintenance is due.
You can set the reminder to alert you annually or semiannually.
(Section 9.3.4).

5.2.5. Installing the barcode reader (optional)

The barcode reader is powered through the data cable.

Unpack the barcode reader. Connect the cable to the barcode reader.

Connect the barcode data cable to the instrument.
The connector is located at the rear of the instrument, labeled "Barcode Reader".
Make sure that the connector is secured with the two screws provided.
Switch on the magLEAD 12gC instrument.

The data communication between the barcode reader and the instrument uses a RS232 interface.

5.3. Installing the PC software (optional)

The magLEAD 12gC software "magLEAD Communicator" must be installed on the PC.
This software is required for receiving report files from instrument and storing instrument data on the PC hard disk.

5.3.1. System requirements

- ■ Operating system: Windows 10, Windows 7 or Windows 8
- ■ USB-Port: USB 1.1 or higher
- ■ Microsoft.NET Framework V1.1 (freely available for download at www.microsoft.com) installed on the PC

The instructions in Sections 5.3.2 and 5.3.3 refer to the Windows 10 operating system.
Specifications for Windows 8 are similar,
but the appearance and some parameters may vary.

5.3.2. Installing the driver of the USB-RS232 converter

Installing the driver

If the PC has no RS232 port, first install the driver of the USB–RS232 converter on the PC.
For detailed installation procedures, refer to the manual for the USB-RS232 converter.
Insert the CD and follow the instructions.

5.3.3. Mapping the COM port (For users of "Windows 10 Professional")
- ■ Right-click on the Windows button to open the "Device Manager".
  NOTE: The way to open the "Device Manager" differs depending on the OS you are using.
- ■ Open the "Device Manager".
  NOTE: The process to open the Device Manager varies according to the operating system version.
- ■ Expand "Ports" to show all available COM ports.
- ■ Connect the converter to an open USB port on the PC.
  The device manager should then automatically update the COM port list.
  Look for the COM port named "USB Serial Port".
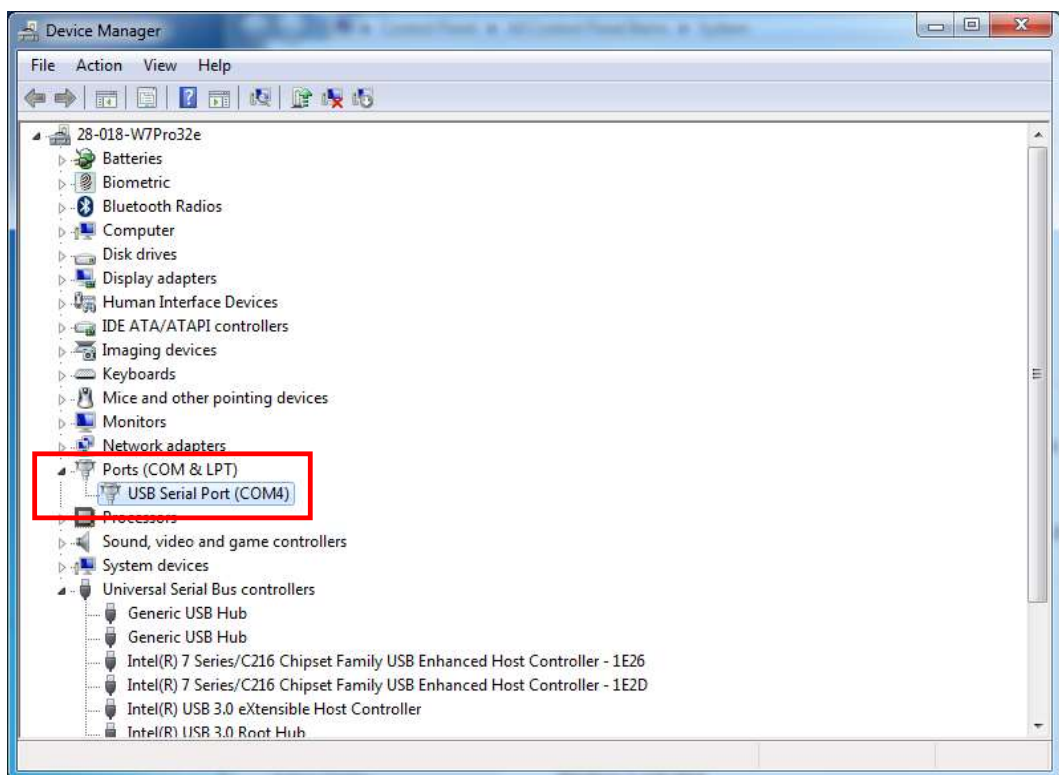
- ■ Right-click this COM port and select "Properties".
- ■ Click the "Port Setting" tab and select the "Advanced" button.

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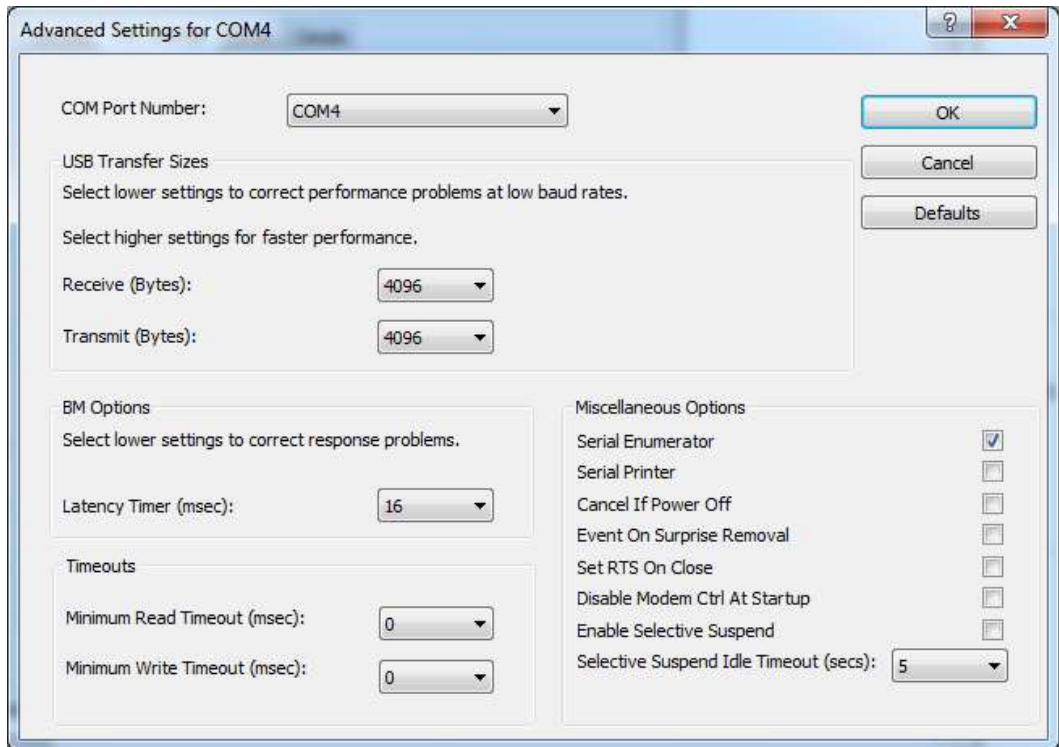
■ Change the dialog field "COM Port Number" to "COM1".
   The USB port is now mapped to COM port 1.
   Always use COM Port 1 when working with the magLEAD 12gC.

5.3.4. Installing the magLEAD Communicator
■ Insert the CD labeled "magLEAD Communicator" into the PC.
   Start "Setup.exe".
■ The installation wizard will guide you through the installation process.
■ After installation, open the magLEAD Communicator
   by double-clicking the magLEAD Communicator icon in the lower system bar.

The user interface of the "magLEAD Communicator" opens.
■ Select "Options" and open the "Serial port" window.
   Check the "COM1" box.
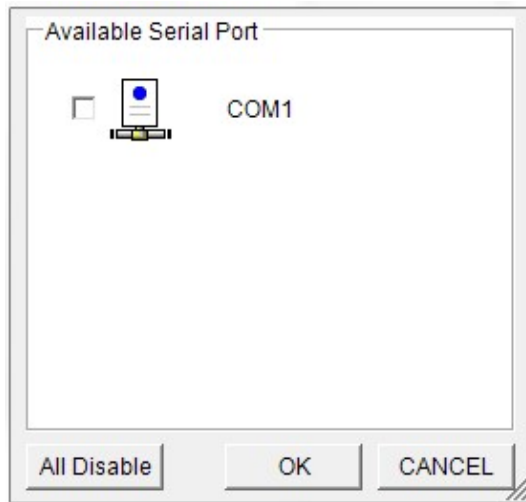
■ The magLEAD Communicator is now ready to receive data from the instrument.
■ To check the connectivity between the PC and magLEAD 12gC, follow the test described in Section 9.4.3.

6.System Components
6.1. Accessories

- Power Cable

| Power Cable for 250VAC | Power Cable for 125VAC |

- Silicon Grease, Fuses, and D-Rings

Silicon Grease

Fuse (3.15A)

D-Rings

- Reagent Cartridge Rack

- Tip/Tube Rack
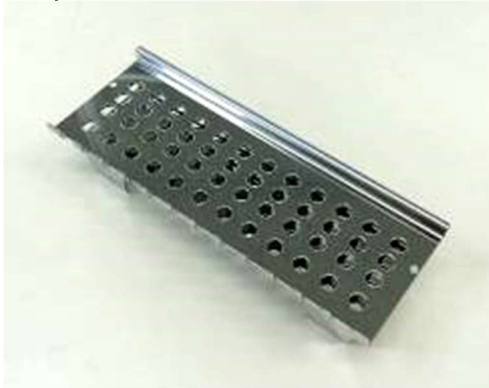
- Handheld Barcode Reader (optional)

Reference

Refer to the user manual for the barcode reader for details.

- magLEAD Communicator (PC Software, optional product)
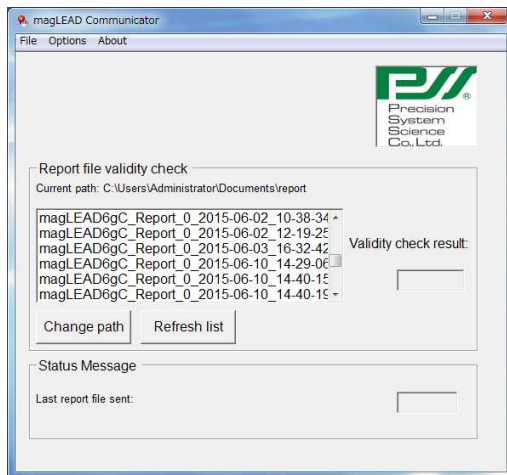
Reference

Please refer to "Installing the PC software (Chapter 5.3)" for details.

6.2. Disposables

magLEAD Tip and Sheath set

Micro tube・Screw cap

Reference
   Refer to the package insert of the disposables for details.

6.3. Reagents

Prefilled Reagent Cartridges

Reference
 Refer to the package insert of the reagent kit for details.

⚠ Caution

- Do not reuse any disposables to avoid contamination and/or instrument malfunction.

- Do not use disposables or reagents other than those specified to avoid instrument malfunction.

- Be sure to wear a mask, goggles, and gloves for your own safety when loading or discarding reagents, disposables, and samples.

- When discarding disposables, follow the regulations required by your facility and regional laws.

7.Directions for Use

7.1. Door operation

The door moves up to open and down to close. It is held by magnets at both the top and the bottom.

When opening or closing the door, be careful not to pinch your hand or fingers and be sure that the door is held in place by the magnets at the top or the bottom.
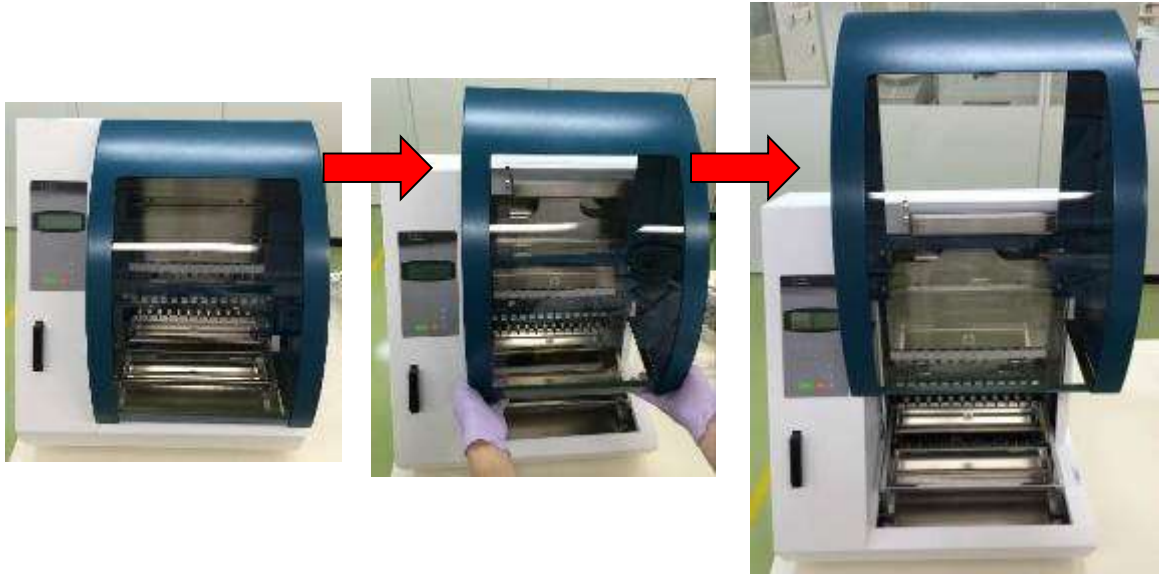
⚠ Caution

- The door may slide downward if it is not held by the magnet at the top. When opening the door, make sure lift the door fully that you hear a clicking sound at the upper end.

7.2. Inserting Reagent Cartridges into the Reagent Cartridge Rack

1. Hold the bar code side of the reagent cartridge as shown in the figure below. Slide the cartridge diagonally upward into the rack and slide it along the groove until it hits the stopper at the far end.
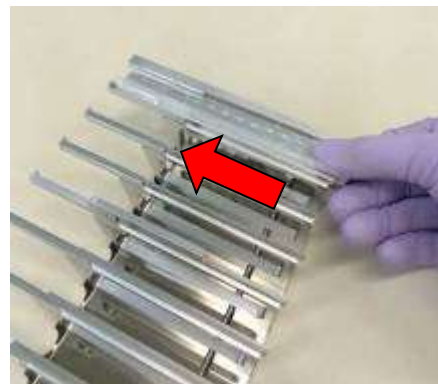
2. Place the reagent cartridge rack into the rack position on the stage.

Reference
Be sure that two farthest wells of the cartridge fit into the heating block.

⚠ **Caution**

- Operating the instrument operation with the Reagent Cartridges or the Reagent Cartridge Rack incorrectly positioned may result in instrument malfunction.

7.3. Inserting Sample Tubes

Place Micro tubes (without caps) containing the samples into the Tip/Tube Rack.

7.4. Inserting magLEAD Tip and Sheath sets

magLEAD Tip and Sheath set insert them into the holes of the Tip/Tube Rack.

7.5.Inserting Elution Tubes

Place the Micro tubes (for elution) into the Tip/Tube Rack.

⚠ Caution

- For details regarding the correct position and number of Tubes and maglEAD Tip and Sheath set, refer to the package insert of the reagent kit and consumable kit.

7.6. Inserting the Tip/Tube Rack

Place the tip/tube rack into the instrument. Refer to the pictures below for the placement direction of the rack. Please make sure that the tip/tube rack is correctly aligned with the location pins.

Back side of the instrument

Front side of the instrument
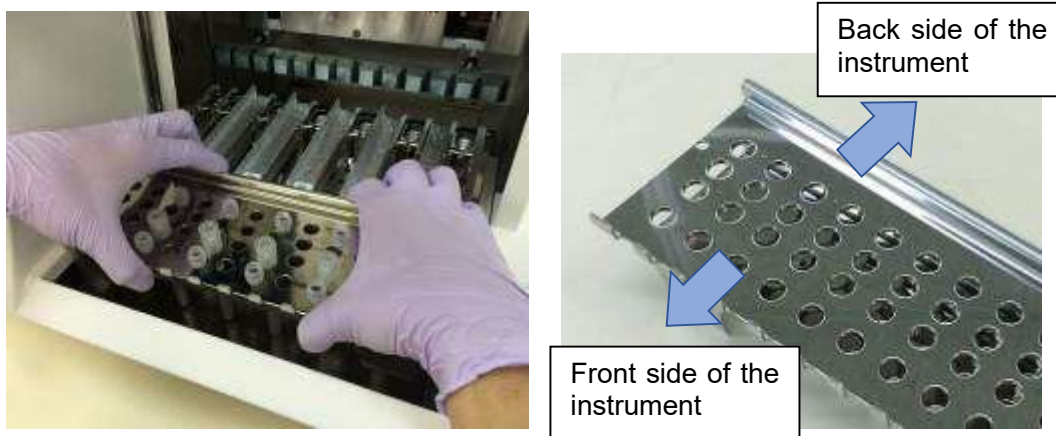
Insert the rack, making sure that the holes on the right side of the rack fit to the location pins on the stage.

⚠ **Caution**

- Operating the instrument with incorrectly positioned Tip Sets or Tip/Tube Rack may result in instrument malfunction.
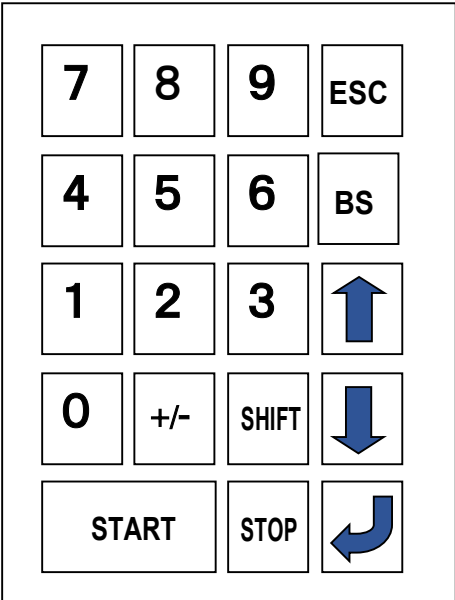
Note
When running a protocol with a small number of samples, use bilaterally symmetric positions in the Reagent Cartridge Rack and the Tip/Tube Rack, using central positions with high priority.

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8.Basic Operation
8.1. magLEAD 12gC Operation Panel

Operation Panel

7	8	9	ESC
4	5	6	BS
1	2	3	↑
0	+/-	SHIFT	↓
START	STOP	↵

Key	Description
0～9	Choosing a menu
ESC	Returns to previous menu
START	Runs protocol
STOP	Halts or aborts protocol
(Enter)	ENTER: Confirm or enter the next menu
SHIFT+Up/Dn	SHIFT + Up or Down arrow: Enter the installation date

※Keys other than those listed above may also be used.

8.2. Startup and Shutdown Procedure

8.2.1. Startup
1. Make sure the instrument is turned OFF. Insert the IC Card into the IC card inlet, ensuring that the card is in the correct orientation.
2. Turn on the instrument using the power switch on the left side of the instrument.
3. As shown below, the "Power On Screen" screen will appear on the display. All axes will be homed automatically during the system initialization.

⚠ Caution

- Be sure the power is OFF when inserting or removing the IC card. If the IC Card is inserted or removed while the instrument is powered on, the IC Card and/or the main unit may be damaged.

Power ON Screen

```
PSS magLEAD 12gC
Version X.X.X.X

Initializing…
```
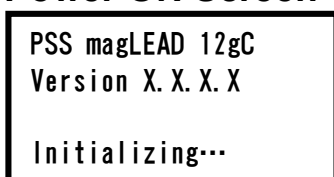
Following system initialization, the "MENU" Screen will appear. (Refer to section 8.3 for MENU Screen..)

MENU Screen

```
DD MM YYYY HH:MM
START:Run 1:UV
2:Man 3:Test 4:Setup
Key:START, 1, 2, 3, 4
```

From the MENU screen, press the "START" key to run a protocol.
Follow the instructions that appear on the screen for your specific protocol.
The UV Lamp Operation Screen will be displayed when the "1: UV" key is pressed (Refer to the section 9.2).
The Manual Screen will be displayed when the "2: Man" key is pressed (Refer to the section 9.1).
The Test Screen will be displayed when the "3: Test" key is pressed (Refer to the section 9.4).
The Setup Screen will be displayed when the "4: Setup" key is pressed (Refer to the section 9.3).

8.2.2. Shutdown
After completion of a protocol run, the MENU Screen will be displayed.
Confirm that the run has been fully completed. Turn the instrument power switch off.

8.3. Protocol Run Procedure

After inserting the protocol IC Card and switching on the magLEAD 12gC, follow the steps below to start a protocol.

1. From the MENU Screen, press the "START" key to run a protocol.
    Follow the instructions for your specific protocol as they appear on the screen.

MENU Screen

```
DD MM YYYY HH:MM
START:Run 1:UV
2:Man 3:Test 4:Setup
Key:START, 1, 2, 3, 4
```

2. Enter additional data, such as user ID, reagent cartridge QR code, and sample barcode so they can be included in the report file.

Note
The reagent name and lot number can be entered using the barcode reader.
The on-board calendar checks the reagent's expiration date. Therefore, ensure that the date has been set correctly. For details regarding setting the date, refer to sections 9.3.1 and 9.3.2.

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3. Open the instrument door, and set up the reagent cartridge and consumables according to the instructions shown on the display.
    For details, refer to the package insert of the reagent and consumables you are using.

4. Close the door and press the "START" key to start the protocol run.

5. After the protocol run has finished, remove the elution tubes, the used reagent cartridges and the plastic consumables.
    Discard the used reagent cartridge and plastic consumables according to your local safety regulations.

6. The magLEAD 12gC will automatically generate a report file, and send it to the PC.

    Note
        For generating and sending a report to the PC, confirm that the serial port has been set correctly. Refer to the section 9.3.3.

7. After the protocol run, you may choose to perform an optional UV decontamination run.

    ◆   If the "STOP" key is pressed during a run, the protocol will stop and provide the option to continue or to abort the run. If you select to abort the run, the protocol cannot be resumed. (Refer to Chapter 14.2 for further details.)

    ◆   Do not open the door when starting a run and during a protocol run.
        If the door is not closed correctly, the door locking mechanism will not function correctly, and a run cannot be started.

⚠ Caution

·   After confirming that the protocol run has been fully completed, open the door to remove the Elution tubes, the Tip/Tube Rack, and the Reagent Cartridge Rack.

·   Discard the used reagent cartridge and plastic consumables according to your local safety regulations.

9.Manual Operation

9.1. Manual Screen

Press the "2" key from the MENU Screen to display the Manual Screen. Press the ESC key from the Manual Screen to return to the MENU Screen.

```
DD MM YYYY HH:MM
START:Run 1:UV
2:Man 3:Test 4:Setup
Key:START, 1, 2, 3, 4
```

Manual Screen

```
MANUAL OPERATION
1:Home 2:Return Tip
3:Clean 4:Resend
Key:1, 2, 3, 4, ESC
```

9.1.1. Home Screen

Press the "1" key from the Manual Screen to display the Home Screen. From the Home Screen, you can select the homing operation of an individual axis or all axes.

```
MANUAL OPERATION
Home axis 0:ALL
1:Y 2:Z 3:P 4:M
Key:0, 1, 2, 3, 4, ESC
```

- ・"1" key: Homes the Y-Axis
- ・"2" key: Homes the Z-Axis
- ・"3" key: Homes the P-Axis
- ・"4" key: Homes the M-Axis
- ・"0" key: Home all Axes
- ・"ESC" key: Returns to the previous screen

The following screen appears.

```
MANUAL OPERATION
Home axis Axis
START:Run
Key:START, ESC
```

"Axis" indicates either the ALL, Y, Z, P, or M function.
Press "START" to perform the "home axis" operation or press "ESC" to return to the previous screen.
During this operation, the following screen will appear:

```
MANUAL OPERATION
home axis Axis


Executing...
```

9.1.2. Return Tip Screen
Press the "2" key from the Manual Screen to display the following screen:

```
MANUAL OPERATION
return tip
START:Run
Key:START, ESC
```

Press "START" to perform the Return Tip operation to return any tips that are attached to the Syringe unit into tip holders. Press "ESC" to return to the previous screen.

9.1.3. Cleaning Screen
Use the Clean operation to access the piercing unit for cleaning.
The door must initially be closed. Press "3" in the manual operation screen to select the "clean" operation. The following screen appears:

```
MANUAL OPERATION
Clean piercing unit
START:Run
Key:START, ESC
```

Press the "START" key to clean the Piercing Unit. After the key is pressed, the Piercing Unit will be lowered for cleaning, and the following screen appears:

```
MANUAL OPERATION
Open door and
clean piercing unit
ENT:Done
```

Open the door, and clean the piercing unit, using a paper or cloth moistened with water or 70% ethanol, depending on how dirty the piercing unit is.
After cleaning the piercing unit, close the door and press the "ENT" key.

⚠ Caution

- Wear a mask, goggles, and gloves for your safety when cleaning the piercing unit.

9.1.4. Resend Screen

If a report file cannot be sent to the PC, it will be temporarily stored on the magLEAD 12gC instrument. Up to 10 report files can be stored.
Use the "resend" function to manually transmit the report file(s) to the PC.
Press "4" in the manual operation screen to select the "resend" operation.
The following screen appears:

```
MANUAL OPERATION
resend report file
START:Run
Key:START, ESC
```

Press "START" to start the "resend" operation or press "ESC" to return to the previous screen.
While the operation is in progress, the following screen appears:

```
MANUAL OPERATION
resend report file

Executing...
```

If there are no report files temporarily stored on the instrument, the following screen appears:

```
MANUAL OPERATION
No report file to
be sent
Key:ESC
```

Press "ESC" to return to the manual operation screen.
If an error occurs during transmission, the following screen appears:

```
MANUAL OPERATION
Resend report file
failed
Key:ESC
```

Press "ESC" and check the connection between the instrument and the PC.
Make sure that the PC is turned on and that the magLEAD Communicator is installed and running on the PC.

9.2.UV Screen

At the end of a protocol run, a message will be displayed providing the option to start a UV decontamination run.
You can also manually start a UV decontamination run by switching on the UV lamp as described below.

Note

UV decontamination helps to reduce possible pathogen contamination of the magLEAD 12gC stage surfaces.
The efficiency of inactivation must be determined for each specific organism and depends on the layer thickness and sample type.
Precision System Science cannot guarantee complete eradication of specific pathogens.

9.2.1.Switching on the UV lamp

Make sure that the instrument door is closed. In the MENU Screen, press "1" to select the UV light function.

```
DD MM YYYY HH:MM
START:Run 1:UV
2:Man 3:Test 4:Setup
Key:START, 1, 2, 3, 4
```

The following screen appears:

```
Decontamination
Set Time: 30 min.


Key:0-9, ENT, ESC
```

Use the keys "0" through "9" to set the duration of the decontamination time.
The minimum time is 30 minutes, and the maximum time is 330 minutes.
The default is 30 minutes.
After setting a valid time, press the "ENT" key. The following screen appears:

```
Decontamination
Time: 30 min.
Run:START
Key:START, ESC
```

If you enter an invalid time (<30 min. or >330 min.),
the following screen will appear:

```
UV DECONTAMINATION
Number must be
between 30 and 330
Key:ESC
```

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After entering a valid time, press "START" to switch on the UV lamp.
The stage will move slowly back and forth under the UV light.
During the UV decontamination run, the following screen is shown:

```
DECONTAMINATION>Run
TotalTime:TT min.
LeftTime: LL min.
Key:STOP
```

"TT" indicates the total time (in minutes), and "LL" indicates
the amount of time remaining.
At the end of the run, the following screen appears:

```
DECONTAMINATION>Run
UV lamp cooling

Please stand by
```

For user safety, the UV lamp will cool for approximately 3 minutes, and the door
cannot be opened until the cooling time has elapsed.
After cooling, the "MENU Screen" appears.

9.2.2. Switching off the UV lamp
During a manual UV run, you can abort the run by pressing the "STOP" key.
The following screen appears:

```
Attention:
UV decontamination
not finished.
Continue:START/STOP
```

Press "STOP" again to abort the UV run.
Press "START" to continue the UV run.

9.2.3. Lifetime reminder of the UV lamp
The lifetime of the UV lamp is limited to 5000 cycles, corresponding to about 5000
decontamination runs of 30 minutes each.
The instrument will inform you when the UV lamp will expire by
displaying the following screen:

```
UV Lamp Reminder:
UV lamp expires soon
UV runs left: XXXX.
ENT=continue
```

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Starting at 50 cycles before the 5000-cycle limit, the instrument
will display this screen every time the instrument is switched on.
"XXXX" indicates the number of cycles remaining.
If this number is "0", the UV lamp must be replaced.
Contact Precision System Science or a distributor for UV lamp replacement.

9.3. Setup Screen

Press the "4" key from the MENU Screen to display the Setup Screen.
Press the "ESC" key from the Setup Screen to return to the MENU Screen.

```
DD MM YYYY HH:MM
START:Run 1:UV
2:Man 3:Test 4:Setup
Key:START, 1, 2, 3, 4
```

```
SYSTEM SETUP
1:Date       2:Time
3:Serial Port4:PM
Key:1, 2, 3, 4, ESC
```

9.3.1. Setting the date

Press "1" in the System Setup menu. The following screen appears:

```
SETUP: DATE
DD MM YYYY
Key:
Up, Dn, SHIFT, ENT, ESC
```

Set the day, month, and year. Press "SHIFT" and the down arrow to move
the cursor to the right, from DD (day) to MM (month) to YYYY (year).
Press "SHIFT" and the up arrow to move the cursor to the left, from YYYY to MM
to DD.
Press the up arrow or down arrow to increase or decrease the value
of the selected field.
After setting the date, store the setting by pressing "ENT".
Press "ESC" to leave the date unchanged.

9.3.2. Setting the time

Press "2" in the System Setup menu. The following screen appears:

```
┌─────────────────────────────┐
│ SETUP: TIME                 │
│ HH:MM                       │
│ Key:                        │
│ Up, Dn, SHIFT, ENT, ESC     │
└─────────────────────────────┘
```

Press "SHIFT" and the down arrow to move the cursor to the right, from HH (hours) to MM (minutes). Press "SHIFT" and the up arrow to move the cursor to the left, from MM to HH.
Press the up arrow or down arrow to increase or decrease the value of the selected field.
After setting the time, store the setting by pressing "ENT".
Alternatively, press "ESC" to leave the time unchanged.

9.3.3. Setting the serial port
This setting configures the serial port for using a PC as the output device for the report file.
Press "3" in the system setup menu to change the setting of the serial port.
The following screen appears:

```
┌─────────────────────────────┐
│ SETUP: SERIAL PORT          │
│ Current: CS                 │
│ Set:     NS                 │
│ Key:Up, Dn, ENT, ESC        │
└─────────────────────────────┘
```

"CS" (current setting) indicates the current setting of the serial port as "PC" or "Not Used".
Press the up arrow or the down arrow to change the "NS" (new setting) field to "PC" or "Not Used".
If "Not Used" is selected a report file will not be generated/sent to the PC.
Press "ENT" to store the new setting. Alternatively, press "ESC" to leave the current setting unchanged.

9.3.4. Setting the preventive maintenance reminder
Press "4" in the system setup menu to change the settings for the preventive maintenance reminder.
The following screen appears:

```
┌─────────────────────────────┐
│ SETUP: REMINDER             │
│ PM Interval                 │
│                             │
│ Key:Up, Dn, ENT, ESC        │
└─────────────────────────────┘
```

Press the up arrow or the down arrow to change the "Interval" field to "1/2 year" (semiannual) or "1 year" (annual).
After setting the new interval, store the setting by pressing "ENT".
Alternatively, press "ESC" to leave the current interval unchanged.

9.4.Test Screen

Open the Test Screen by pressing the "3" key from the MENU Screen.
Press the "ESC" key from the Test Screen to return to the MENU Screen.

```
DD MM YYYY HH:MM
START:Run 1:UV
2:Man 3:Test 4:Setup
Key:START, 1, 2, 3, 4
```

```
TEST
1:Axis     2:Temp
3:Serial  4:Version
Key:1, 2, 3, 4, ESC
```

9.4.1. Axis Test Screen

Open the Axis Test Screen by pressing the "1" key from the Test Screen.

```
TEST:AXIS
 insert disposables
START:Run
Key:1, 2, 3, 4, ESC
```

・ "Start" key: Press this key to check the operation of all axes. Use this function to determine where a problem occurred during a run. Place all required disposables onto the instrument before executing this test.
・ "ESC" key: Press this key to display the Test Screen.

9.4.2. Temp Test Screen

Open the Temp Test Screen by pressing "2" key from the Test Screen.

```
TEST: TEMPERATURE
set temp: SS.S C
START: Run
Key:Up, Dn, START, ESC
```

"SS.S" indicates the set temperature in degrees Celsius. Press the up arrow or the down arrow to increase or decrease the temperature. The upper limit is 99°C. Press "START" to start the heating process.
The following screen appears:

```
TEST: TEMPERATURE
Temp: ss.s C
actual: aa.a C
Key:ESC
```

"ss.s" indicates the set temperature, and "aa.a" indicates the
current temperature. "r" indicates the result, and displays "O" if
the temperature is within a given range or "X" if the
temperature is outside the given range.

9.4.3. Serial port test Screen
Press the "3" key in the Test Screen to display the Serial port test screen.

```
TEST: SERIAL PORT
1:PC
2:Bar code
Key:1, 2, ESC
```

PC

Press "1" in the serial port test screen to test the PC communication.
The following screen appears.

```
TEST: PC
Target:PC
START:Run
Key:START, ESC
```

Press "START" to send a test string to the PC. The following screen appears:

```
TEST: PC
Target:PC
Result: PASSED
Key:ESC
```

If the transmission is successful, the result will show "PASSED".
If not successful, it will show "FAILED".

Barcode reader

Press "2" in the serial port test screen to test the bar code reader.
The following screen appears:

```
TEST:



Key:ESC
```

Use the barcode reader to read a barcode.
When a new barcode is read, the previous barcode will be overwritten.
A beep sound indicates a successful barcode scan.
The following screen appears, showing up to 25 digits:

```
TEST:BBBBBBBBBBBBBBBB
BBBBBBBBBBBBBBBBBBBBBB
BBBBBBBBBBBBBBBBBBBBBB
Key:ESC
```

"B" indicates the individual digits of the bar code.

9.4.4. Version Screen

Open the Version screen by pressing the "4" key in the Test Screen.
The following screen appears:

```
TEST: VERSION
Firmware: VersionNo

Key:ESC
```

"VersionNo" indicates the current version of the firmware.
Press "ESC" to return to the test screen.

10. Barcode reader (optional)

The barcode reader is preset to read the following types of barcodes:

■ Code 39
■ Code 128
■ QR Code
■ Data Matrix

Press the button on the inner side of the barcode reader handle to read a barcode and focus red light toward the scanned barcode.
Hold the barcode reader in front of the barcode approximately 20 mm away.
(depending on a barcode size, type and quality)
A beep sound confirms that the barcode has been read.
The barcode will be displayed on the screen.

11. Report file

The magLEAD 12gC generates a report file during the protocol run.
This report file contains the fields described in the table below.

Note

For generating and sending a report, confirm that the serial port has been properly set up. Refer to section 9.3.3.

Up to 10 report files can be stored temporarily on the magLEAD 12gC instrument. When this maximum has been reached, the oldest report file must be deleted before additional reports can be saved.
The following screen appears:
(refer to section 8.3)

```
Caution: Memory full
Oldest report file
will be erased
1:Cont ESC:abort run
```

Press "1" to delete the oldest report file and continue the protocol run.
Alternatively, press "ESC" to abort the protocol run.

Contents of a report file

Parameter	Example output	Description
REPORT - FILE magLEAD 12gC:		Title of report file
Serial no. magLEAD 12gC:	12C1502A0001	Serial number stored on the magLEAD 12gC
User ID:	9267	User ID that was set during the protocol run. This can be a number or a name, scanned with the barcode reader, up to a maximum of 9 characters
Firmware version:	V1.0.0	Current firmware version
Installation date of instr.:	Jan 07, 2015	Installation date, which was set the first time the magLEAD 12gC was powered on. This date is stored permanently on the magLEAD 12gC.
Weekly maintenance done on:	Jan 14, 2015	When you accept the weekly maintenance reminder, the date is stored and is reported here.
Yearly maintenance done on:	Jan 07, 2015	When you accept the annual maintenance reminder, the date is stored and is reported here.
Date of last UV run:	Jan 16, 2015	Date of the last UV run recorded and stored.
Start of last UV run:	14:04	Start time of last UV run
End of last UV run:	14:34	End time of last UV run
Status of last UV run:	o.k.	Status of the last UV run; possible options: ■o.k. (normal finish) ■UV run aborted ■UV lamp expired
Protocol name:	MagDEA Dx SV 200mL 12gc	Protocol name stored on the magLEAD 12gC Card and copied into the report file
	Trace	Additional protocol name (specifies the protocol if there are multiple protocols on the magLEAD 12gC Card)
Date of run:	Jan 14, 2015	Time stamp for the date of the run according to the instrument's clock and calendar
Start of run:	15:13	Time stamp for the start of the run according to the instrument's clock and calendar
End of run:	15:43	Time stamp for the end of the run according to the instrument's clock and calendar
Status run:	o.k.	The status of the run; possible options: ■o.k. (normal finish) ■not o.k.

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		■aborted
Error code:	21	See section 15 for error codes
Sample input volume [μl]:	300	Sample input volume in microliters; depends on the protocol
Elution Volume [μl]:	50	Elution volume in microliters; depends on the protocol
Channel 1:		Information for channel 1 begins here
Sample ID:	8730	Sample ID, defined by the barcode system of the user. Maximum of 20 characters.
Reagent kit name:	MagDEA Dx SV	Reagent kit name defined by the barcode reading only.
Reagent lot number:	1151234567	Reagent lot number defined by the barcode reading only.
Reagent expiry date:	201602 (In this case, February, 2016)	Reagent expiration date. This information can only be entered through a barcode reading.
Assay kit ID:		N/A
Note:		N/A
Channel 2:		Information about channels 2–12 begins here (same format as above for channel 1).

12.magLEAD Communicator (optional)

magLEAD Communicator is a software program that runs on a PC.
The software receives the report file (refer to section 11) and stores it in a folder defined by the user.
After the PC has received the report file, you can use and process the file with a LIMS (Laboratory Information Management System) or other programs.

12.1.User interface

The main window shows the list of report files received.
Click the "Refresh list" button to update the list.
Select a file by single-clicking the file name.
The software(magLEAD communicator) will perform a checksum test on the file.
The result is shown under "Validity check result".
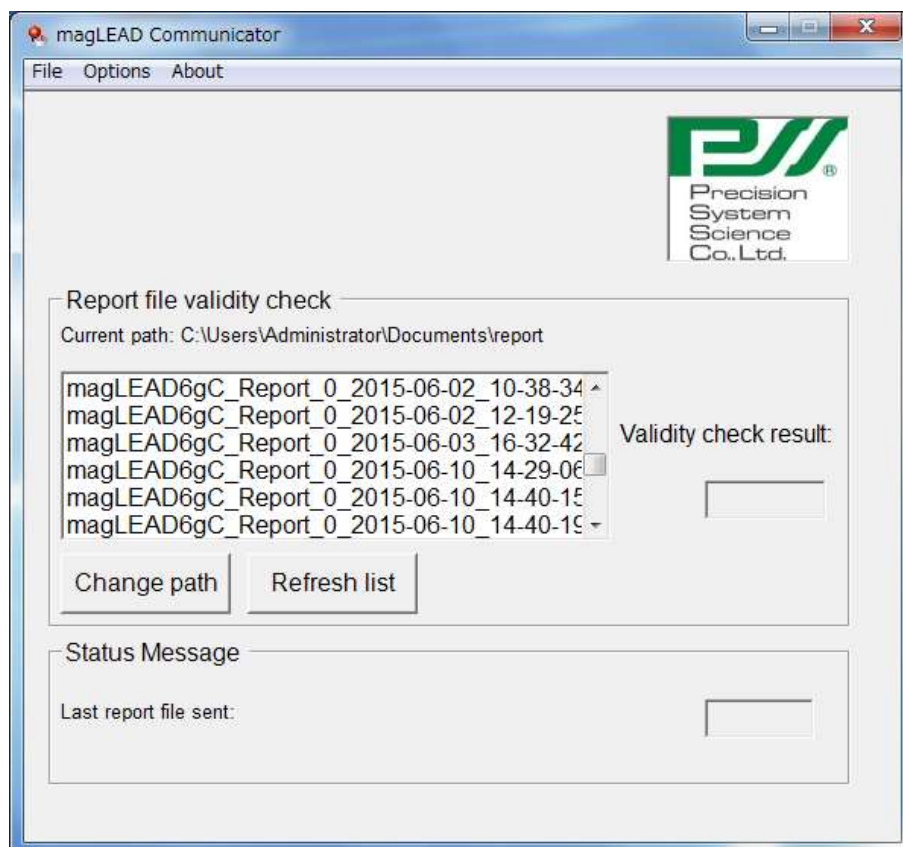
The report file name contains the following components:
■ Title (e.g., magLEAD12gC Report)
■ Serial number of the magLEAD
■ Date in format YYYY-MM-DD
■ Time in format HH-MM-SS
■ File extension *.csv (comma-separated value)

The date and time indicate when the report file was received by the PC.
The "Status Message" panel displays the name of the last
report file that was sent to the PC.

Select "File" to exit the graphical user interface.
Select "Options" to display the following window showing the
magLEAD 12gC serial ports:
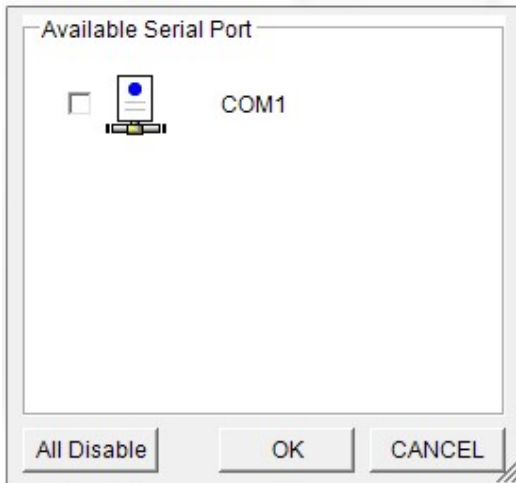
COM1 should already be selected.
You can check the serial settings by checking one of the boxes.
The following window opens:
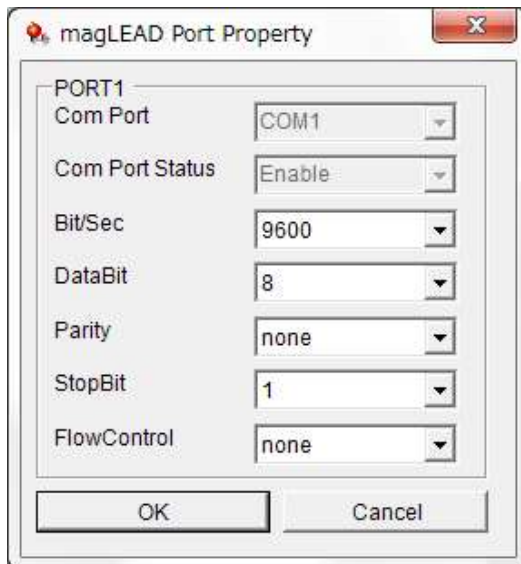
The following default settings are as shown in the image above:
baud rate of 9600 bits/s, 8 data bits, parity none, 1 stop bit, flow control none.

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Select "About" in the main window to show the version of the magLEAD Communicator.

magLEAD Communicator:
magLEAD Communicator Version 1.0.0.0
Copyright (C) 2014
PSS

O.K.

Click the "Change path" button in the main window to change the folder where the selected report file will be stored.
Browse and select the folder in the following window:

13.Maintenance

Maintenance items to be performed are listed below.

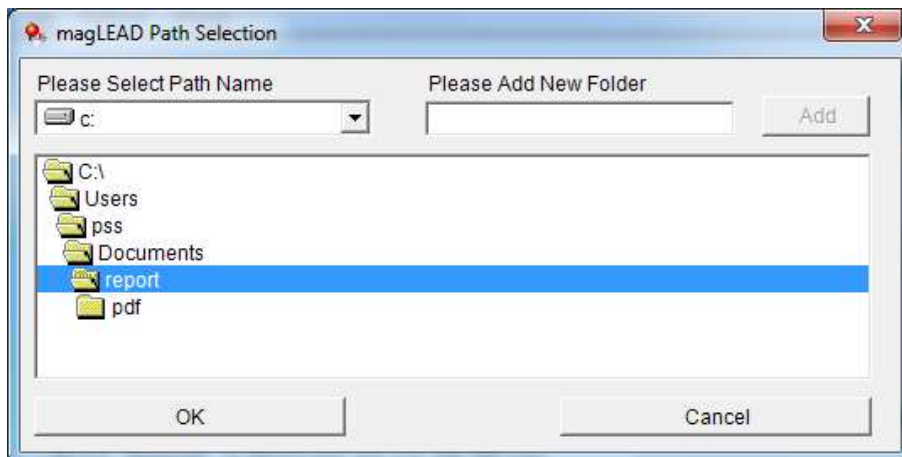| Item	Frequency	Done by
Cleaning of stage and racks	After every operation	User
Cleaning of nozzles and piercing unit	After every operation	User
Greasing of D-rings	Once every two weeks	User
Replacement of D-rings	Once every half year	Field service

⚠ Caution

- Note that it is not possible to completely eliminate biohazard risk from samples or extracted/purified products while operating this instrument. Wear a mask, goggles, and gloves for your own safety.
- Ensure that the instrument power is turned OFF when doing maintenance work.
- Pay close attention when cleaning areas on the instrument where caution labels are attached.

Note
- Maintenance work must be performed as indicated. Otherwise the results of extraction/purification runs cannot be guaranteed.
- Contact us for maintenance work that must be done by Field Service personnel.
- Clean up the stage, nozzles, piercing unit, and racks after each time the instrument is shut down.

13.1. Cleaning Procedure

➢ Areas to be cleaned:

- ・ Tip/Tube rack
- ・ Reagent cartridge rack
- ・ Nozzles
- ・ Piercing unit
- ・ All accessories and instrument interiors

➢ Cleaning Method:
- ・ Choose the cleaning solution according to the instrument's pollution status. Wipe the polluted areas using paper wipes, such as Kim Wipes®, moistened with the liquid.
  Wear a mask, goggles, and gloves when cleaning the instrument for your safety.
  Possible cleaning liquids:
  -Water
  -70% ethanol

- Do not use alcohol when cleaning the clear panel on the instrument door.
  Instead, use water for those parts.

- 70% ethanol is a flammable liquid. If you are using 70% ethanol, ensure that there are no flames nearby.

13.2. D-Ring Maintenance

To ensure complete connection and to prevent leakage, we recommend performing maintenance of the D-Rings once every two weeks.

1. Wearing gloves, wipe away old grease using a paper or cloth.

2. Slightly apply some silicon grease to your gloved finger.

3. Wipe the silicon grease onto the surfaces of the D-Rings (black rubber rings on the nozzles).

Tip Ejector

D-ring

Nozzle

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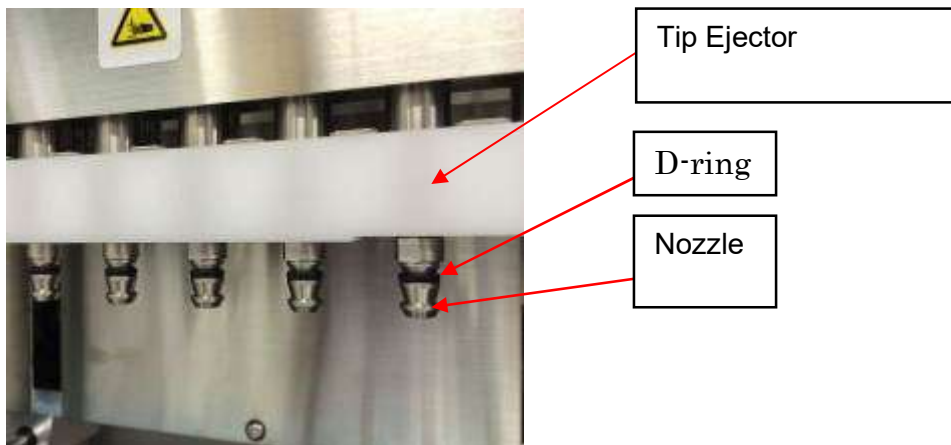
4. Wipe off any excess silicon grease from the edges of nozzles and the tip ejector using lint-free paper.

⚠ Caution

- Excess silicon grease can lead to instrument operation problems, such as improper tip removal.

14.Troubleshooting
14.1. Error Reported During Protocol Run

```
Error during process
 Code:XXX
   LineNo.= #####
Key:ESC to return
```

The above screen will be displayed, to indicate that an error occurred.
(Refer to Chapter 15 for Error Code List.)

1. If an error occurs during a protocol run, the above screen will be displayed. The red alarm LED will blink, an audible alarm will sound, and the instrument will stop operating.

2. The error code is displayed in the second line as "Code: XXX". Refer to the error code list, and take appropriate action as recommended.
Take note of the error code, because you will need to provide it when contacting us for technical support.

⚠ Caution

- "LineNo.= ####" indicates the line number of the protocol where the error occurred.

- A protocol run that was interrupted by an error cannot be resumed.

3. Press the "ESC" key after confirming the error to display the MENU Screen.

4. Press the "1" key in the MENU Screen to display the Manual Screen.

5. Press the "2" key in the Manual Screen to return the tips to the tip holders and to home all axes.

⚠ Caution

- If the instrument stops while there are tips on the nozzles, follow the steps described above.

- Keep the door closed when operating the instrument. Re-check that disposables have been positioned correctly.

6. After confirming that the instrument operation has been completed, press the "ESC" key to display MENU Screen.

- If, after taking appropriate actions, the same error occurs again when running the same protocol, contact us for technical support.

14.2. Suspending or Aborting a Protocol Run

It is possible to stop a protocol run while the run is in the data reading phase before <u>extraction phase</u> (e.g., sample tube barcode information). Follow the instructions below.

1. Press "STOP". The following screen appears:

```
===== PAUSE =====
START:Continue
STOP: Stop
Key:START, STOP
```

2. Press "STOP" again to abort the protocol, or press "START" to continue the protocol.

It is possible to abort a protocol run while the instrument is actively processing samples. Follow the instructions below.

1. Press "STOP". The following screen appears:

```
Do you really want to
abort the run ?

Key:START, STOP
```

Note that the protocol has not stopped yet.

2. Press "STOP" again to abort the protocol.
The protocol run will be invalid and will be marked accordingly in the report file.
The following screen appears:

```
DD MM YYYY HH:MM
START:Run 1:UV
2:Man 3:Test 4:Setup
Key:START, 1, 2, 3, 4
```

Alternatively, if you do not want to abort the protocol at this point, press the "START" key.
The protocol run will not be stopped and should not be affected.

3. After aborting a protocol, press "2" to display "Manual" in the display.
   Press "2" again to return the tips to the tip rack and to return the modules to their home positions.

⚠ **Caution**

- If the instrument stops while there are tips on the nozzles, follow the steps described above.

- Keep the door closed while operating the instrument. Re-check that disposables have been positioned correctly.

14.3. Frequently Reported Problems

Problem	Possible cause	Countermeasures to be taken
Back light of the display is not lit	AC power cable is not connected properly.	Check the AC power cable connection. Be sure to use the power cable that was supplied with the instrument. ※Do not use any power cable other than the one supplied with the instrument.
	Fuse is broken	Contact us if the fuse needs to be replaced.
Nothing appears on the display.	IC Card has not been inserted correctly.	Turn the instrument power off and re-insert the IC Card. Be sure that the IC Card is inserted correctly and completely.
Error code is displayed	Causes vary depending on the error code.	Record the error code displayed and take appropriate countermeasures, as described in the list of error codes. If the countermeasure does not eliminate the problem, contact us for technical support.
Protocol was started with incomplete placement of tips or tubes.	--	Be sure to confirm that reagents and disposables have been correctly placed, before starting a protocol run. If you want to add disposables after the protocol has already started, press "STOP" to abort the instrument operation. We strongly recommend that you restart the protocol run from the beginning after you have added the disposables. We are not responsible for incorrect results if you continue a protocol run from the point it was stopped after adding disposables. * If you open the front door after stopping the instrument, the power to the motors will be shut down as a safeguard, resulting in displacement of motor stopping positions.
Protocol run was stopped.	Front door was opened during the run.	Be sure not to open the door during a protocol run. If you need to stop the protocol run, press the "STOP" key. You can resume the run again. * If you open the front door after stopping the instrument, the power to the motors will be shut down as a safeguard, resulting in displacement of motor stopping positions. Therefore, results may not be correct if the run is resumed after opening the door.
Liquid leakage from the ends of the tips or large difference in liquid levels	Silicon grease on the D-rings has been lost or the D-rings are deteriorated.	Grease or replace the D-rings. We recommend that the D-rings are replaced by trained service personnel. *Pay close attention if you replace the D-rings yourself.

from one lane to the next.			

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15.Error Code List

Code No	Description	Countermeasure to be taken
10	Zero-returning failure due to an operation other than a protocol	contact us for assistance.
11	End-limit error due to an operation other than a protocol	contact us for assistance.
12	Z-axis zero-returning failure during a protocol run	contact us for assistance.
13	P-axis zero-returning failure during a protocol run	contact us for assistance.
14	M-axis zero-returning failure during a protocol run	contact us for assistance.
15	Y-axis zero-returning failure during a protocol run	contact us for assistance.
16	Z-axis end-limit error during a protocol run	contact us for assistance.
19	Y-axis end-limit error during a protocol run	contact us for assistance.
20	Z-axis time-out error during a protocol run	contact us for assistance.
21	P-axis time-out error during a protocol run	contact us for assistance.
22	M-axis time-out error during a protocol run	contact us for assistance.
23	Y-axis time-out error during a protocol run	contact us for assistance.
24	Door open error when starting an operation	Close the door and follow the operation in section 14.
25	Bottom sensor of pipettor head (Z-axis) activated during an operation	Check if something obstructed the motion of the corresponding unit. Remove any obstacles and try the homing operation of all axes, according to the description in section 14.
26	Communication error between the heating block and the temperature controller, or the card is not a magLEAD 12gC Card	Turn the instrument power off and wait about 10 seconds before turning the instrument power back on.
27	Communication error between motors and driver board.	
30	Protocol import error	contact us for assistance.
31	Door lock error during operation	contact us for assistance.
100	Protocol checksum error	contact us for assistance.
101	VP table checksum error	contact us for assistance.
110	System error	contact us for assistance.

- Most of the errors listed above occur as a result of improper positioning of disposables/accessories or from opening the door. Be sure to check these before restarting a protocol run.

- If you encounter error codes other than those listed above or if the error could not be solved by the countermeasure described, contact us with the specific error codes.

- The instrument specifications and appearance may be changed without prior notification.

16.Revision history
- Update regulations and standards
- Update "Intended Use"
- Change of product of life definition
- Change of description in terminology or chapter configuration

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