



info@bocascientific.com (781) 686-1631 www.bocascientific.com

# Miracle-AutoXT

### Nucleic Acid Extraction System



Automated Nucleic Acid Extraction System, as an in vitro diagnosis(IVD) purpose

File no.	IBT-QMS-INT50104(R00)
Date	2017. 06. 01
Version	Rev 0.0

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This user manual introduces Miracle-AutoXT System instrument and protocol. It contains the specification for Miracle-AutoXT System.

Before using the Miracle-AutoXT System, it is essential that you read this user manual carefully especially for Safety Information.



### Section 0. Introduction





### 1. Product Intended Use

The Miracle-AutoXT System instrument is intended for use, in combination with the series of Miracle-AutoXT Extraction kits, as an in vitro diagnostic (IVD) purpose to perform automated isolation of nucleic acid from samples.

Miracle-AutoXT system is not intended for use as part of a specific in vitro diagnostic test. It is intended for professional use only. Diagnostic results obtained using the nucleic acids purified with this system must be interpreted in conjunction with other clinical or laboratory data.

The automated steps performed by Miracle-AutoXT System instrument include:

- Sample lysis and washing
- Binding of nucleic acids to magnetic beads
- Elution of the product

### 2. Product Description

Miracle-AutoXT System instrument is an automated nucleic acid purification system based on magnetic bead separation technology. For DNA/RNA isolation process, 96 well plate or individual strip containing magnetic beads should be set up into the instrument and then the instrument will perform the process for lysis, washing and elution automatically. This automated extraction system enables you to extract high quality of nucleic acids from samples by using magnetic force of Miracle-AutoXT magnetic rod in the system.

### 3. Product Characteristics

- System control and test implementation through LCD touch screen (No PC or tablet needed)
- UV light to aid in sanitizing the instrument
- Easy-to-use system (application of optimal protocols for DNA, RNA extraction)
- Preprogramed protocol for nucleic acid purification
- High efficiency of nucleic acids purification
- Minimize the hands on time
- Up to 32 samples in a single run

### 4. Miracle-AutoXT System Specification

- Processing time: 15-20 minutes
- Number of samples: up to 32
- Standard configuration: 100 ul elution volume
- Weight: 24 kg (52.9lb)
- Dimensions (W x D x H): 340 x 420 x 345mm (13.9 x 16.5 x 13.6 inches



## Section I. Miracle-AutoXT System Requirement





The system requirements are applied in general condition at room temperature (25°C) if there is any other specific notice or indication.

### Safety voltage

Please make sure that the range of voltage is as follow.

•	Input voltage	110-240V
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• Power requirements 50-60Hz, 2.5A

### Environmental requirements

٠	Temperature	Operation	10 ~ 40°C
		Storage	10 ~ 50°C
•	Humidity	Operation	10 ~ 80% RH, Noncondensed
		Storage	10 ~ 80% RH, Noncondensed
•	Maximum altitude	2000m	

• Use indoor



## Section II. Product Components





Please check and inspect the package carefully to make sure that all components Miracle-AutoXT System instrument are included prior to use



Miracle-AutoXT Nucleic Acid Extraction System

Power cable & Instruction for use

Figure 1. Components of Miracle-AutoXT System instrument



### Section III. Precautions







### Please make sure to read the precautions for correct use of the product.

- Do not use the Miracle-AutoXT System instrument with voltage(110~240V±10%, 50~60Hz) other than the voltage specified on the device.
- Do not use the Miracle-AutoXT System instrument with a damaged power supply or loose socket.
- Please keep the instrument on a flattened surface and provide minimum of a feet at every side of the device for air circulation.
- Strong impact on the instrument may cause severe damage and thus malfunction.
- Do not connect multiple devices to a single wall outlet. The load may cause an overload and fire.
- Miracle-AutoXT System vibrates when activated. Do not place any device that might be affected by vibration.
- Do not place any device that produce vibration or heat besides Miracle-AutoXT System.
- Do not install and/or store the device in dusty place
- Do not install and/or store the device near heat sources.
- Do not install and/or store the device near water or moist place
- Do not attempt to change or modify the instrument without iNtRON permission.
- Do not try to connect the power plug with wet hands.
- This automated nucleic acid purification system is exclusively optimized to use in combination with the Miracle-AutoXT Extraction reagents. Do not attempt to use any other brand of the kit or reagents.
- Please make sure that pre-filled % well plate or pre-filled individual strip is set correct position onto the heating plate.
- Do not disassemble unit. It may cause fire, electrical shock and malfunction. The warranty shall not be guaranteed if disassembled.



- Do not use this instrument with any purpose other than its intended use.
- Do not pour any liquid on the Miracle-AutoXT System instrument.
- Do not place near other vibration sensitive instruments.
- The front door must be closed during the operation of instrument.
- Do not operate the instrument in the place near flammable gases or liquids.
- Dispose UV bulb in accordance with country, federal, state and local regulations since it contains mercury.
- Disconnect the power before cleaning or performing routine maintenance.
- There is a possibility to be exposed by UV rays due to the UV lamp of instrument. Do not turn on the UV lamp unless completely close the front door.
- Ensure strips and plates have been securely inserted in their correct positions and orientation. Failure to do so may result in damage to the instrument.
- Before operation the system, check magnetic rod position.
- Use the switch in order to shut off the power supply.
- Do not operate the system if malfunction is expected.
- LCD screen is a touch panel. Slight and soft finger touch will activate the LCD screen. Sharp tools such as knife, Nail or pen may damage the LCD.
- This instrument is intended for use with human-derived samples. Use appropriate personal protective equipment (i.e-gloves, safety goggles, lab coat, etc.) for handling and disposing of biohazardous materials.
- · Keep hands clear of instrument platform as it moves in and out of the instrument.
- Keep the surface of instrument clean.
- When there is any sign of fire (Smoke, burning smell etc) during device operation or stand-by mode stop the operation immediately and disconnect the power cable from the unit, and then contact customer service or manufacturer.



- The device shall be sterilized with UV lamp at all time. Do not look or touch UV lamp directly. It may eyes or skin.
- If the device is stained by reagent, sample or dirt disinfects it with 70% Ethanol when the device is completely turned off.
- Heating Tray is heated automatically upon activation of the device. It may cause skin burn if touched with any part of body. Do not touch Heating Tray directly when the device is activated at any circumstance.
- Please discard used plate and strip in bio-hazard disposable container.
- If any part of body, especially eye is exposed to reagents directly wash with running water and go to hospital immediately.
- The Miracle-AutoXT System is not recyclable. Please contact customer service or manufacturer upon disposal of the device.



### Section IV. Installation





### 1. Unpacking Miracle-AutoXT System

Warring

LiliF Miracle-AutoXT 32 is operated by step motor which is movable. Therefore, it is fixed and delivered to prevent instrument damages.

Risk of personal injury and material damage Warring Ensure that the fixture must be removed before connecting the power

Cut and remove the any tapes or straps around the box to open the shipping box.

Check whether Miracle-AutoXT System is intact. If anything is damaged contact Technical service team. Do not use defected devices. The power supply should be switched off unless operational.

Remove the fixture



Risk of personal injury and material damage Ensure that the main power must be switched off before release the fixture

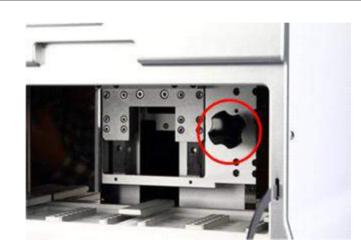


Figure 2. Remove the fixture

- 1 Two fixtures, one inside and one at the bottom, hold magnetic rod tight to prevent damage during shipment.
- 2 Open the cover and remove fixture marked red in Figure 2 above. If magnetic rods and 2 holder are located close to the fixture lift them one by one until you have enough space to turn the fixture.



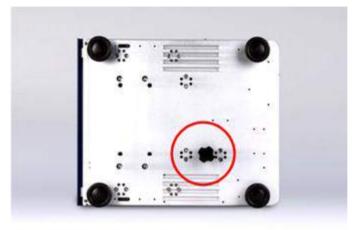


Figure 3. Remove the fixture (bottom view)



3

Warring

### Risk of material damage

If the device is operated without removing both fixtures it won't start with rattling sound. It may cause severe damage to the device, hence shall be removed completely before operation.

Remove another fixture located at the bottom of the device as marked in Figure 3 above. Be cautious not to damage the device.





4 Horizontalize the device using rubber feet as shown in Figure 4 above.

### 2. Installing Miracle-AutoXT System

Miracle-AutoXT System instrument is intended for indoor use only. Before installing Miracle-AutoXT System, install in a location that meets the following criteria:



- Locate on a sturdy, level surface
- Avoid dusty areas
- Do not place near generated heat
- Locate out of direct sunlight, away from heat sources
- Away from sources of vibration and electrical interference .
- Do not connect a large number of powers into an outlet. It can be a reason of fire. ٠
- Do not leave any things at front side of the instrument not to disturb the operation
- Do not use near flammable gases or liquids
- Locate a minimum clearance 10cm at the sides and rear of Miracle-AutoXT System

### 3. Hardware Overview

### External features

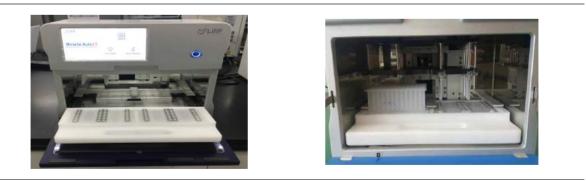


Front View

Rear View

Figure 5. External feature of Miracle-AutoXT System

#### Internal features



Internal View I

Internal View II

Figure 6. Internal feature of Miracle-AutoXT System

### 4. Switching on the Miracle-AutoXT System

After connecting the instrument to a power outlet, you can switch on the instrument. The power switch is located on the back of the instrument. (Figure 3)





Figure 7. On/Off Switch

For the extraction experiments, start and shut down button is used which is located next to the touchscreen of front side (on the upper right side).



Figure 8. Start/Shut down botton

Magnetic Rod automatically moves to its original position upon activation of the device



## Section V. Miracle-AutoXT System User Interface





### 1. User interface home screen

The start-up screen page is showed up on touchscreen and initializes the sensors after switching on the instrument.



Figure 9. Initializing screen window

If everything is completed and has no problems, then main home screen will be appeared as below.



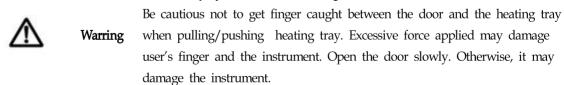
Figure 10. Home screen window

### 2. Plate set up (example, 96 plate well type)

The exclusive 96 well plate must be set by following the instructions

1 Open the front door and pull the heating tray to set % well plate for test

#### Risk of injury and material damage



2 Insert the plate on the hole of heating plate





Push the heating tray into the instrument for ready to operating. Ensure that the tray has been inserted to the end in order to avoid instrument damages.



#### Risk of material damage

**Warring** Ensure that the 96 well plate is located into the correct position of the heating tray.

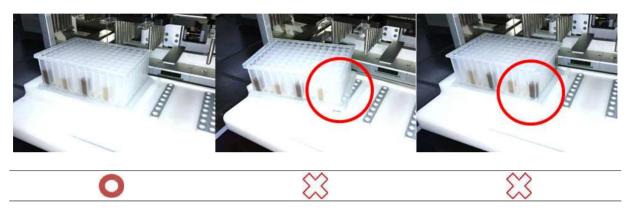


Figure 11. Correct and incorrect way of inserting plate on heating tray

If it is inserted incorrectly or upside down it may cause operating error and extraction may not work.

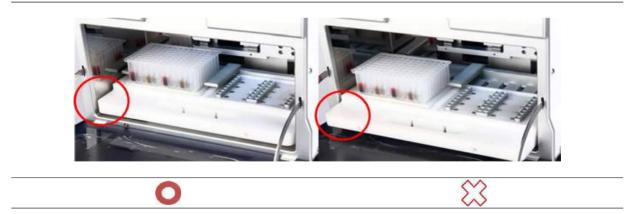


Figure 12. Correct and incorrect way of inserting plate on heating tray in the device



### 3. Strip set up

- 1 Load the strip to strip guide. To load properly, insert the strip to the end to strip guide.
- 2 Close the front door and ready to start.

		Risk of material damage
$\wedge$	TATa mina a	Ensure that the strip is inserted to the end of strip guide.
<u> </u>	Warring	Push strip until 'Click' sound is heard. Strip and/or magnetic rod may
		break and cause malfunction of the device if not pushed till the end.



Figure 13. Correct and incorrect way of inserting strip in the device

Strip shall be pushed until the end of the strip holder. Push strip until 'Click' sound is heard. Strip and/or magnetic rod may break and cause malfunction of the device if not pushed till the end.

Make sure to observe location of left-most strip with naked eyes when inserting into strip holder. Bottom end of strip shall be located above the first heating block at about half of height of the door.

### 4. Implementation of Miracle-AutoXT System

If the 96 well plate and strips are set on correctly, please follow the next step as below.

1 Press the 'Manu' button on touchscreen to select the extraction type.





Figure 14. Home screen & Menu selection

2 Select Press the 'Virus' button on touchscreen as Figure 15 below.

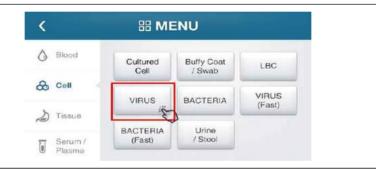


Figure 15. 'Virus' screen selection

3 Press the 'Start' button to perform the extraction.



Figure 16. Procedure screen

It will be started automatically and indicates the remaining time on the screen (Refer to Figure 16). After completion, it gives a beep. You can check the progress of step on window of touchscreen. Current process is indicated with blue color icon and remained process is presented with white icon.

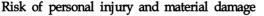
Time on the LCD screen does not run during magnetic rod positioning. There are approximately 3~4 minutes of magnetic rod positioning during the operation.



The instrument can be forcibly stopped by 'Pause' button.

The whole operation is initialized if home button on right top corner of LCD screen in Figure 16 is pressed; LCD screen returns to home and magnetic rod moves to its original position.

Opening the door during operation put it on hold and re-activated once closed.





4

WarringWorringWarringDo not put hand inside the device when it's operational at any circumstances. Insert and remove plate and strip only when the device is not operational. Do not touch any internal part of the device at any circumstances.

Alarm rings along with the display as Figure 17 below upon completion of extraction. Alarm and display last for 3 minutes. Alarm turns off and display switches to home screen after 3 minutes automatically. Home screen may appear if 'GO TO MAIN' button shown in Figure 17 below is pressed within 3 minutes.



Figure 17. Completion screen

### 5. UV lamp time setting

1 Press the 'UV setting' button to modify the running time of UV light.



Figure 18. Home screen & UV setting selection



- 2 UV lamp operation time can be set to 5 seconds from 5 seconds to 99 minutes, 55 seconds.
- 3 Use the top and bottom button to change the time setting.

Opening the door cancels UV disinfection and initialize the procedure. Minimum 5 minutes of UV disinfection is recommended.



Figure 19. UV setting screen



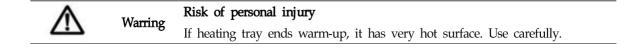
Warring Risk of personal injury UV light is harmful for human. Use carefully.

### 6. Preheating

Heating Tray starts warming up automatically upon activation of the device (Power on). If you start an operation, such as a photograph, LCD screen gives a warm-up period with warning signs and you can begin driving after all this time has elapsed.

Turn on the device 10 minutes before operation to preheat heating blocks. Turning on the device automatically preheats heating blocks.

- 1 If preheating system is unfunctional error code appears on LCD screen.
- 2 Preheated heating blocks is 80 °C maximum. Do not touch heating block when device is activated and for 15 minutes after deactivation.



### 7. Test mode

'Test mode' is to confirm proper activation of the device before regular operation. It is recommended to use 'Test Mode' after transportation, certain period of un-used time etc. Installation of strip and plate is



same or regular mode. 'Test Mode' also has pause and home button, literally to pause or to stop the test. Each step takes 20 seconds, hence much shorter than regular test mode and remaining time is displayed on LCD screen. Refer to figures 20 and 21 below.

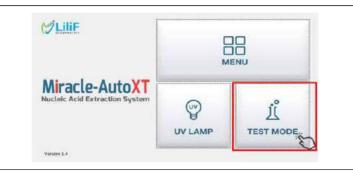


Figure 20. Home screen & Menu selection

<	TITLE
Lysis	Remaining Time
Washing 1	
Washing 2	
Washing 3	h ot ot
Elution	► START

Figure 21. Test mode procedure screen

### 8. Error code



### 9. Software update

New extraction kit would require new protocols; hence software update would be required. Contact local distributor for software update.



### 10. Other information

If power input is cut due to certain circumstances such as black out whole procedure gets initialized. It is highly recommended to restart the test with new kit otherwise data may be compromised.

- 1 Start fixing the device with fixtures 15 minutes after deactivation to avoid any skin burn from heated heating blocks.
- 2 Lift inner part of strip holder when needed (Ex. for transporting). Lifting outer part of strip holder may damage bolts that connect the device.
- 3 Do not screw fixtures too tight as it may cause malfunction of the device.



## Section VI. Troubleshooting





Problem	Possible caused and comments
	• Make sure to connect power cable to the instrument.
	• Check whether the instrument is plugged at 110~240V power
Instrument does not turn on.	outlet.
	• Contact local distributors or technical service team if problem
	continues.
Instrument is leaned	Adjust Rubber Feet to horizontalize the instrument
	• Check whether fixtures (Both inside and bottom side of the
	instrument) are completely removed. (refers to the section
The motor is not working after	'Installation')
switching on the instrument.	• Confirm absence of any foreign substances on sensor.
	Check that the front door has been closed.
	Contact local distributors or technical service team.
	In case of motor doesn't work,
	• Ensure that the power cord is plugged in.
	• Check the fuse connection next to the power cord.
Touchscreen doesn't display	• Contact the local distributors or technical service team.
anything after switching on	
the power button.	In case of motor works,
	• Touch LCD could be disconnected from the power or out of
	order.
	Contact local distributors or technical service team.
	• Make sure to connect power cable to the instrument and turn on
	the instrument.
LED light doesn't switch on	• Check whether the instrument is plugged at 110~240V power
LLD light doesn't buildh on	outlet.
	• Contact local distributors or technical service team if problem
	continues.
	Restart the instrument
Touch screen is not working	Contact local distributors or technical service team if problem
	continues.
	• Check whether plate and strip are inserted at the right position.
	Refer to 'Installation' for details.
	Confirm absence of any foreign substances on Heating Tray and
Can't locate Plate and strip at	strip holder.
the right position	• Check whether the plate and strip are deformed or bent.
are right position	Deformed or bent plate and strip may cause malfunction of the
	instrument.
• Conta	• Contact local distributors or technical service team if problem
	continues.



Problem	Possible caused and comments
	Check whether Heating Tray is inserted till the end.
Dear is not closed	• Confirm absence of any foreign substances between the door.
Door is not closed	• Contact local distributors or technical service team if problem
	continues.
	• The lifespan of UV lamp is about 4,000 hours and it should be
	changed.
UV light doesn't switch on	• UV lamp could be disconnected from the power or out of order.
ev light doesn't switch on	Check whether the door is closed.
	• Contact local distributors or technical service team if problem
	continues.
The instrument stops during	Check whether power source is connected properly.
operation	• Contact local distributors or technical service team if problem
	continues but LCD screen is turned on.
	• Check whether 'Whole blood' button in home screen is pressed.
	Improper extraction result may derive if processed by 'test' mode.
Device is not working properly	<ul> <li>Check whether plate and strip are properly placed.</li> </ul>
bevice is not working property	Make sure fixtures are completely removed.
	Contact local distributors or technical service team if probl
	continues.
	• Make sure Heating Tray is inserted till the end.
Heating blocks are not heated	• Contact local distributors or technical service team if problem
	continues.
	• If extraction is proceeded without strip bead will adhere on
Extraction without strip	magnetic rods, hence affects further tests. It is highly
-	recommended to replace magnetic rods. Contact local distributors
	<ul> <li>or technical service team for the replacement of magnetic rods.</li> <li>Review manuals for procedures and trouble shooting</li> </ul>
Unformulate outroption regult	neview manade for procedures and frouble shooting.
Unfavorable extraction result	Contact local distributors or technical service team if problem
	continues.
	ERROR
Error code 1	HEATER ERROR DETECTED
(Heater Error Detected)	Heater error detected. Turn off the device and restart it after
	30 minutes. Plase contect sevice center for technical support if the problem persists after rebooting.
	ERROR
Error code 2	OVERHEATING
(Over Heating Detected	DETECTED
(Over Training Delected	Overheat detected. Turn off the device and restart it after 30 minutes. Plase contect sevice center
	for technical support if the problem persists



Problem	Possible caused and comments	
E 1.2	ERROR	
Error code 3 (RS-232 Serial Error)	RS-232 SERIAL ERROR Communication error. Turn off the device and restart it after 30 minutes. Plase contect sevice center for technical support if the problem persists after rebooting.	
<u>.</u>	ERROR	
Error code 4 (Temperature Sensor Error)	TEMPERATURE SENSOR ERROR Turn off the device and restart it after 30 minutes. Plase contect sevice conter for technical support if the problem persists after rebooling.	
	ERROR	
Error code 5	UVLAMP ERROR Uvlamp is not work Plase contect sevice center for technical support if the problem persists after rebooting.	



## Section VII. Warranty





### Limited Warranty and Service Guidelines

Miracle-AutoXT System instrument is warranted by iNtRON Biotechnology, Inc. will be free from defects in materials and workmanship for a period of one year from the date of delivery.

iNtRON Biotechnology agrees, as its sole responsibility under this limited warranty, and upon prompt notice of a defect, to repair or replace any instrument discovered to be defective within the warranty period. Expendable items are not covered by this warranty.

Spare parts for the instrument will be available for five years from the delivery date. If a defect arises after the limited warranty period, shipping and handling charge may apply to any repair or exchange of the product undertaken by iNtRON Biotechnology.

### Exclusion and limitation

This warranty does not include repair or replacement necessitated by accident, neglect, misuse, unauthorized repair, flood, fire, earthquake or other external causes.

### Out of Warranty Service

Please review this User's manual and access the online support referred to in the manual accompanying this product before requesting warranty service.

If the equipment is still not functioning properly, Contact iNtRON or your local iNtRON Biotechnology representative. We will be happy to assist you by telephone or e-mail. You can send tech@intronbio.com

Repair service, if needed, will be billed at a flat rate to be agreed upon in advance. Your invoice will include shipping.



## Section VIII. Symbols





### Description of Symbols used

These symbols are the most common ones appearing on medical devices and their packing. They are explained in more detail in the British and European Standard ISO 15223-1:2012



Do not reuse



Use by Synonym for this: Expiry Date



Catalogue Number



Temperature Limitation



REP

EC

Manufactured by

Authorised Representative in European Union



Consult Instructions For Use



KEEP DRY



The risk of electrical shock



Biological hazard



In vitro diagnostic Medical device



Batch code Synonym for this are: Lot / Batch Number



Attention. See Instruction for use



Upper Limit of Temperature



Date of Manufacture



Contains sufficient for Tests

Keep Away From Sunlight

Waste electrical and electronic equipment directive



Hot surface

