



Miracle-AutoXT

Nucleic Acid Extraction System



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

| | |
|----------|-----------------------|
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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
- Power requirements 50-60Hz, 2.5A

Environmental requirements

- 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 96 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

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



Warning

Risk of personal injury and material damage

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



Warning

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 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)



Warning

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.

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



Figure 4. Adjust horizontality by turning the rubber feet (bottom view)

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

2. Installing Miracle-AutoXT System

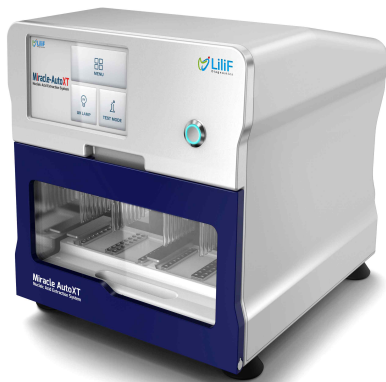
Miracle-AutoXT System instrument is intended for indoor use only.

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.
- 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 button

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 96 well plate for test



Warning

Risk of injury and material damage

Be cautious not to get finger caught between the door and the heating tray when pulling/pushing heating tray. Excessive force applied may damage user's finger and the instrument. Open the door slowly. Otherwise, it may damage the instrument.

- 2 Insert the plate on the hole of heating plate

- 3 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.



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

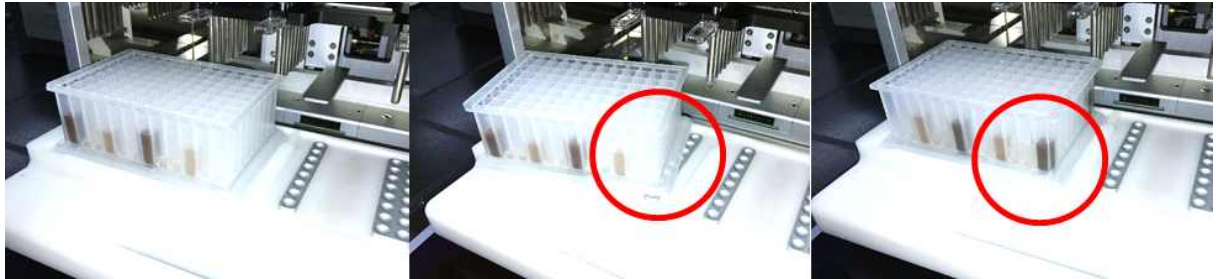


Figure 11. Correct and incorrect way of inserting plate on heating tray

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.



Warning

Risk of material damage

Ensure that the strip is inserted to the end of strip guide.
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.

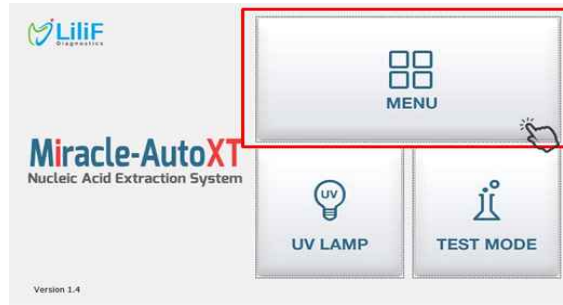


Figure 14. Home screen & Menu selection

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

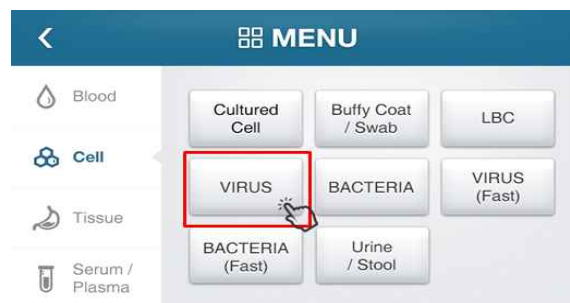


Figure 15. 'Virus' screen selection

- 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.



Warning

Risk of personal injury and material damage

Do 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.

- 4 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.

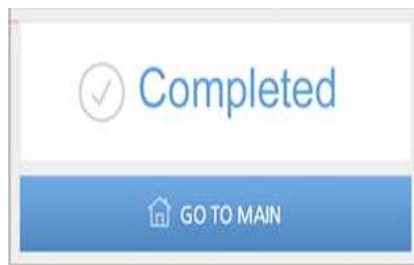


Figure 17. Completion screen

5. UV lamp time setting

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

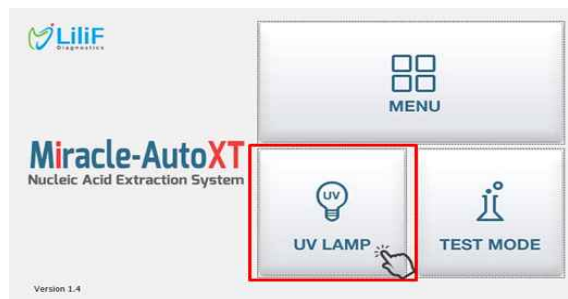


Figure 18. Home screen & UV setting selection



- 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



Warning

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.



Warning

Risk of personal injury

If heating tray ends warm-up, it has very hot surface. Use carefully.

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.

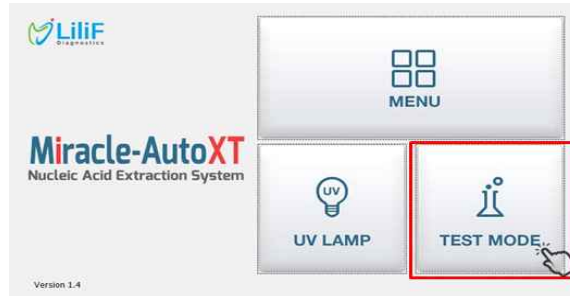




Figure 20. Home screen & Menu selection



Figure 21. Test mode procedure screen

8. Error code

| | | Warning | |
|-----------|-------------|---|--|
| Warning 1 | Door open |  | DOOR OPEN The front door is open. Please close the door to continue the process. |
| Warning 2 | Pre-Heating |  | PRE-HEATING Pre-heating. Please wait. It will move on the next screen automatically upon completion of pre-heating. |

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 |
|---|---|
| Instrument does not turn on. | <ul style="list-style-type: none"> • Make sure to connect power cable to the instrument. • Check whether the instrument is plugged at 110~240V power outlet. • Contact local distributors or technical service team if problem continues. |
| Instrument is leaned | <ul style="list-style-type: none"> • Adjust Rubber Feet to horizontalize the instrument |
| The motor is not working after switching on the instrument. | <ul style="list-style-type: none"> • Check whether fixtures (Both inside and bottom side of the instrument) are completely removed. (refers to the section 'Installation') • Confirm absence of any foreign substances on sensor. • Check that the front door has been closed. • Contact local distributors or technical service team. |
| Touchscreen doesn't display anything after switching on the power button. | <p>In case of motor doesn't work,</p> <ul style="list-style-type: none"> • Ensure that the power cord is plugged in. • Check the fuse connection next to the power cord. • Contact the local distributors or technical service team. <p>In case of motor works,</p> <ul style="list-style-type: none"> • Touch LCD could be disconnected from the power or out of order. • Contact local distributors or technical service team. |
| LED light doesn't switch on | <ul style="list-style-type: none"> • Make sure to connect power cable to the instrument and turn on the instrument. • Check whether the instrument is plugged at 110~240V power outlet. • Contact local distributors or technical service team if problem continues. |
| Touch screen is not working | <ul style="list-style-type: none"> • Restart the instrument • Contact local distributors or technical service team if problem continues. |
| Can't locate Plate and strip at the right position | <ul style="list-style-type: none"> • 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 strip holder. • Check whether the plate and strip are deformed or bent. Deformed or bent plate and strip may cause malfunction of the instrument. • Contact local distributors or technical service team if problem continues. |



| Problem | Possible caused and comments |
|---|--|
| Door is not closed | <ul style="list-style-type: none"> • Check whether Heating Tray is inserted till the end. • Confirm absence of any foreign substances between the door. • Contact local distributors or technical service team if problem continues. |
| UV light doesn't switch on | <ul style="list-style-type: none"> • The lifespan of UV lamp is about 4,000 hours and it should be changed. • UV lamp could be disconnected from the power or out of order. • Check whether the door is closed. • Contact local distributors or technical service team if problem continues. |
| The instrument stops during operation | <ul style="list-style-type: none"> • Check whether power source is connected properly. • Contact local distributors or technical service team if problem continues but LCD screen is turned on. |
| Device is not working properly | <ul style="list-style-type: none"> • Check whether 'Whole blood' button in home screen is pressed. Improper extraction result may derive if processed by 'test' mode. • Check whether plate and strip are properly placed. • Make sure fixtures are completely removed. • Contact local distributors or technical service team if problem continues. |
| Heating blocks are not heated | <ul style="list-style-type: none"> • Make sure Heating Tray is inserted till the end. • Contact local distributors or technical service team if problem continues. |
| Extraction without strip | <ul style="list-style-type: none"> • If extraction is proceeded without strip bead will adhere on magnetic rods, hence affects further tests. It is highly recommended to replace magnetic rods. Contact local distributors or technical service team for the replacement of magnetic rods. |
| Unfavorable extraction result | <ul style="list-style-type: none"> • Review manuals for procedures and trouble shooting. • Contact local distributors or technical service team if problem continues. |
| Error code 1 (Heater Error Detected) |  |
| Error code 2 (Over Heating Detected) |  |



| Problem | Possible caused and comments |
|--|--|
| Error code 3 (RS-232 Serial Error) | <p data-bbox="740 349 1187 389">ERROR</p>  <p data-bbox="890 427 1171 454">RS-232 SERIAL ERROR</p> <p data-bbox="890 456 1182 533">Communication error. Turn off the device and restart it after 30 minutes. Please contact service center for technical support if the problem persists after rebooting.</p> |
| Error code 4 (Temperature Sensor Error) | <p data-bbox="740 575 1187 616">ERROR</p>  <p data-bbox="890 636 1091 680">TEMPERATURE SENSOR ERROR</p> <p data-bbox="890 683 1182 761">Temperature sensor error. Turn off the device and restart it after 30 minutes. Please contact service center for technical support if the problem persists after rebooting.</p> |
| Error code 5 | <p data-bbox="740 801 1187 842">ERROR</p>  <p data-bbox="900 887 1107 909">UVLAMP ERROR</p> <p data-bbox="900 920 1182 985">Uvlamp is not work. Please contact service center for technical support if the problem persists after rebooting.</p> |



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 | | In vitro diagnostic Medical device |
| | Use by Synonym for this: Expiry Date | | Batch code Synonym for this are: Lot / Batch Number |
| | Catalogue Number | | Attention. See Instruction for use |
| | Temperature Limitation | | Upper Limit of Temperature |
| | Manufactured by | | Date of Manufacture |
| | Authorised Representative in European Union | | Contains sufficient for Tests |
| | Consult Instructions For Use | | Keep Away From Sunlight |
| | KEEP DRY | | Waste electrical and electronic equipment directive |
| | The risk of electrical shock | | Hot surface |
| | Biological hazard | | |