

ADAM r WBC

Instruction Manual



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ADAM - rWBC Instruction Manual

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The information in this manual is described as accurately as possible.
Firmware and software changes and updates may change without prior consent or notification.

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Table of Contents

Introduction	
General description	4
Technology - Mechanical	5
Technology - Viability measurement	6
<hr/>	
Product description	
Packing list	7~8
Front view of the ADAM-rWBC	9
Rear view of the ADAM-rWBC	10
<hr/>	
System installation	
Environmental requirements	11
Power on and initial display	11-13
Icon functions	13
<hr/>	
General operation	
Preparing the test sample	14
Sample preparation and testing	15
Operating the ADAM-rWBC	16-17
Start input	18
Result analysis	18
Maintenance and cleaning	19
<hr/>	
Trouble shooting	20
Warranty	21
Technical specifications	22
Product list	23
Safety precautions	24-25
Safety symbols	26-27
Warnings	28
Technical support	29

Introduction

General description

ADAM-rWBC is an analyzing device that counts the number of residual leukocytes in a blood component for transfusion.

Targeting the leukocyte, the ADAM-rWBC uses fluorescent dye to perform cell dyeing and automated cell counting. Automated cell counting eliminates user bias or subjective interpretation that can be found when counting residual leukocytes using other methods.



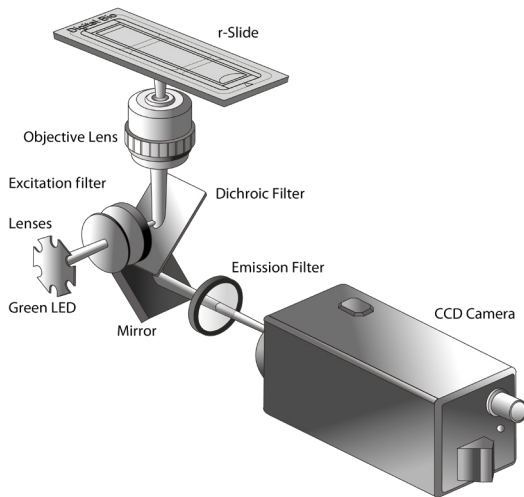
Introduction

Technology - Mechanical

White blood cell counting for residual leukocytes may be performed manually using a Nageotte chamber. Limitations to this method include (1) propensity for the staining of artifacts; (2) is only appropriate for use with very low cell counts, (3) the testing is time consuming and (4) interpretation may be subjective. Other devices that count residual leukocytes can be costly and very user technique dependent.

NanoEntek has developed the ADAM-rWBC, which is based on fluorescent microscopy techniques for counting cells. The ADAM-rWBC utilizes sensitive fluorescence dye staining, LED optics and CCD detection to make provide accurate and reliable leukocyte detection.

To use the ADAM-rWBC, a blood sample is mixed with a Propidium Iodide (PI) stain and directly pipetted onto a disposable plastic slide. The slide is then loaded onto a precision stage. The ADAM-rWBC system automatically focuses on the slide, and the cells that have been stained are scanned by a sensitive CCD camera. The image results are automatically processed and displayed on the instrument's LCD screen interface.



Introduction

Technology **- Viability** **measurement**

ADAM-rWBC is based on the staining of mammalian cell DNA using the fluorescent dye, Propidium Iodide (PI), a nucleic acid dye. When used with RNase, PI stains only cellular DNA. In the case of blood samples, white blood cells (with DNA-containing nuclei) are stained while platelets and red blood cells, (without nuclei) are not stained.

The ADAM-rWBC Kit consists of r-Solution and the disposable 1 test r-Slide. For absolute counting of residual leukocytes, appropriate sample preparation is needed. After mixing the sample with the r-Solution and loading into the r-Slide, the number of total leukocytes is automatically calculated and displayed on ADAM-rWBC.

Product description

Packing list

The ADAM-rWBC is shipped with the components listed in the table follow. Once you receive your instrument, please check that all items listed follow were shipped. If any items are missing or damaged, contact your local distributor or ivdst@nanoentek.com.

Item	Quantity
Main device	1
rWBC Kit (Starter kit with package insert)	1
Instruction manual	1
Power cord	1
Fuse	2
Installation CD	1
Barcode scanner	1
USB Cable	1
Software Manual	1
Quick Manual	1
Barcode scanner (Optional)	1
External video monitor (Optional)	1

Any damage incurred during transit must be filed with the carrier.



CAUTION :

Neglecting to remove any or all shipping brackets or foam inserts prior to operation may result in damage to the equipment.

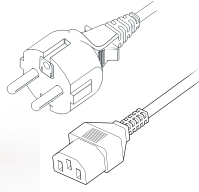
The shipping brackets or foam inserts must be reinstalled prior to shipping the unit to prevent damage to the equipment.

Packing list

Main device



Power cord



Fuse



ADAM-rWBC Kit

(Starter kit with package insert)



Installation CD



Instruction manual



ADAM-rWBC PC Software User Manual



Optional

External video monitor (Optional)



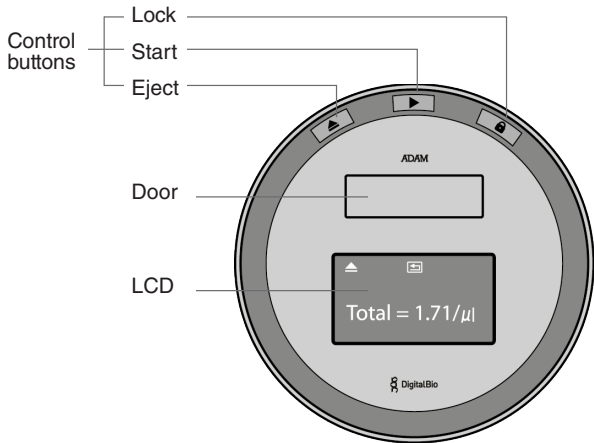
Optional

Barcode Scanner



Product description

Front view of the ADAM-rWBC



Control buttons

▲ Eject

▶ Start

🔒 Lock

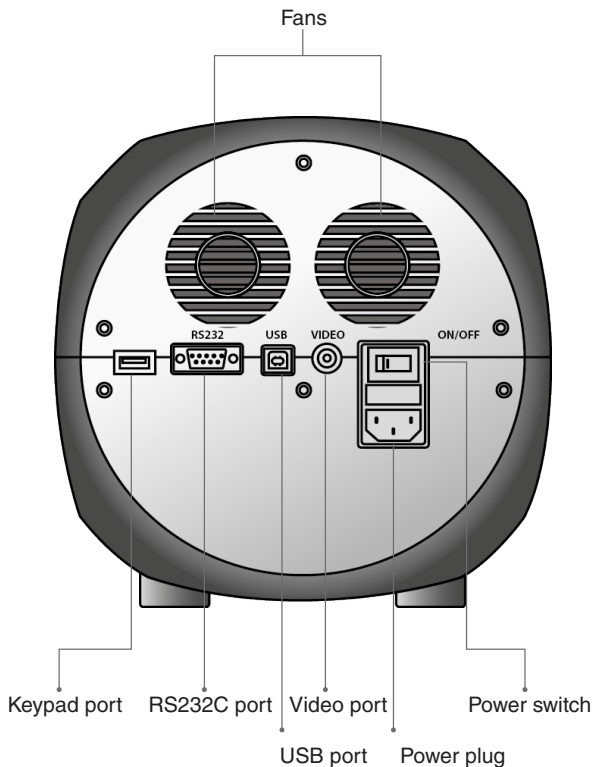
Door

LCD

- Ejects the slide from the ADAM-rWBC.
- Functions as load and unload.
- Performs all procedures of automatic counting.
- Protects the alignment of stage from external shock when the ADAM-rWBC is being moved.
- 🔒 **Lock ADAM-rWBC before turning it off or moving it.**
- Slide is inserted and ejected.
- Displays processes and results.

Product description

Rear view of the ADAM-rWBC



Fans	ADAM-rWBC's cooling
Power switch	ADAM-rWBC ON/OFF power
Power plug	Connects the ADAM-rWBC power cord to wall outlet
USB port	Port for connect to ADAM-rWBC PC software
RS232C port	Port for only QC and service
Keypad port	Port for only QC and service

System installation

Environmental requirements



CAUTION:

At low temperatures (≤ 10 °C), allow the device to warm up for 10 minutes at ambient temperature before use.

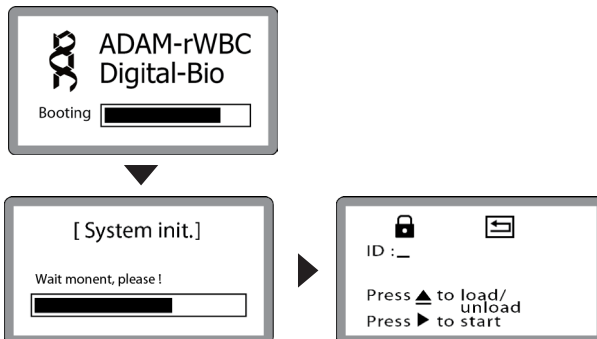
To ensure correct operation and stable performance, install the ADAM-rWBC in a location which meets the following conditions:

- Use at room temperature.
- Do not use in cold rooms.
- Not exposed to direct sunlight.
- Not subject to direct or continuous vibration.
- Not subject to intense magnetic or electromagnetic fields.
- Not installed in high humidity environments.
- Area free from corrosive gases or other corrosive substances.
- Area with very little dust or other airborne particles.
- Area with a 10 cm minimum space around the instrument for proper air flow.
- Do not place anything on top of ADAM-rWBC device.

Power on and initial display

- 1) Check the connection of the main device power cord.
- 2) Make sure that the main power switch is in the "I" (ON) position.
(On the rear side of the main device.)

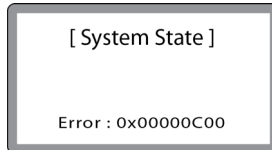
• When you turn on the ADAM-rWBC, it will go through self diagnostic tests. If you get an error message, please contact your local distributor or ivdst@nanoentek.com. If boot up is successful and no errors are detected, the home screens will be displayed as follow.



System installation

Power on and initial display

* Error Messages during booting



[System State] It appears when booting not working properly. Turn off main power and re-start device.

* Power switch is located back side of instrument.

If this message still appears after re-start, contact your local distributor or ivdst@nanoentek.com.

Error code	Cause
0x0000C00	Failure of X-axis sensor
0x00007000	Failure of Y-axis sensor
0x00008000	Failure of Z-axis sensor
0x06000000	Failure of locking module sensor

A screenshot of a system initialization error message. The text reads "[System init.]" at the top, followed by "Detect chip inside." and "Please check!". Below the text is a solid black horizontal bar. The entire message is enclosed in a rectangular border.

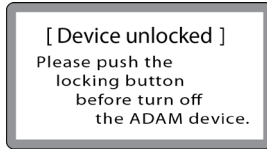
[System init.] If a r-Slide is detected during initial booting, this error message will be shown.
(Trouble shooting) 1. Remove the r-Slide 2. Power off/on 3. Redo initial booting again.

CAUTION:
When you turn off the device, please remove the r-Slide from the ADAM-rWBC.
This is the cause of malfunction.

If this message continues to display when no r-Slide is inserted, contact your local distributor or ivdst@nanoentek.com.

System installation

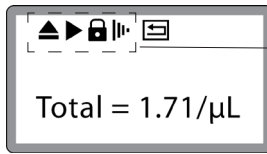
Power on and initial display







[Device unlocked] It appears when turning off the device without locking. Press the lock button before turn off the device.

If this message still appears after re-start, contact your local distributor or ivdst@nanoentek.com.

Icon functions



Display a status of the functions such as Eject, Start, Lock or Insert. (status of slide holder)

Icon	Features
	Shows when cell counting is started (After pressing the Start button).
	Shows the slide holder is ejected (After pressing the Eject button).
	Shows the slide holder is locked (After pressing the Lock button).
	Shows the slide holder is inserted (After pressing the Eject button with rWBC counting slide).

General operation

Preparing the test sample

Precision stage calibration

Each time the ADAM-rWBC is powered on, calibration of the precision stage is performed using the Standard beads provided in the ADAM-rWBC Kit. Calibration is successful if the test result is within range of the value on the vial.

Refer to the ADAM-rWBC Kit Package Insert for specific instructions.

- The ADAM-rWBC must be calibrated after each start up and at least once each day of use.
 1. Let beads equilibrate to room temperature before use (~10 minutes).
 2. Mix by shaking gently, including upside down.
 3. Load 100µL of the beads into the r-Slide. Let settle for 40-60 seconds.
 4. Insert bead loaded r-Slide into ADAM-rWBC main device and press '▶' to start.

For Leukocyte Reduced samples

Blood samples should be tested within **48 hours** after leukocyte reduction.

The blood sample is mixed, and an aliquot removed and diluted with r-Solution for staining. After staining, a sample is loaded into the r-Slide and left to settle. After settling, the r-Slide is inserted arrow end first, right side up, into the ADAM-rWBC and counted. Refer to the ADAM-rWBC kit Package Insert for specific instructions.



CAUTION:

- Avoid bubbles as they may negatively affect results.
- Do not re-use r-Slides. Re-use of r-Slides may result in errors in the result value.
- Do not use r-Solution, r-Slides or Standard beads after their expiration date.
- Store r-Solution at 2–8 °C when not in use. The expiration data is one year. Do not use after the expiration date shown on the label. Open r-Solution may be stored at 2–8°C and used for up to 6 months, but not past the expiration date.



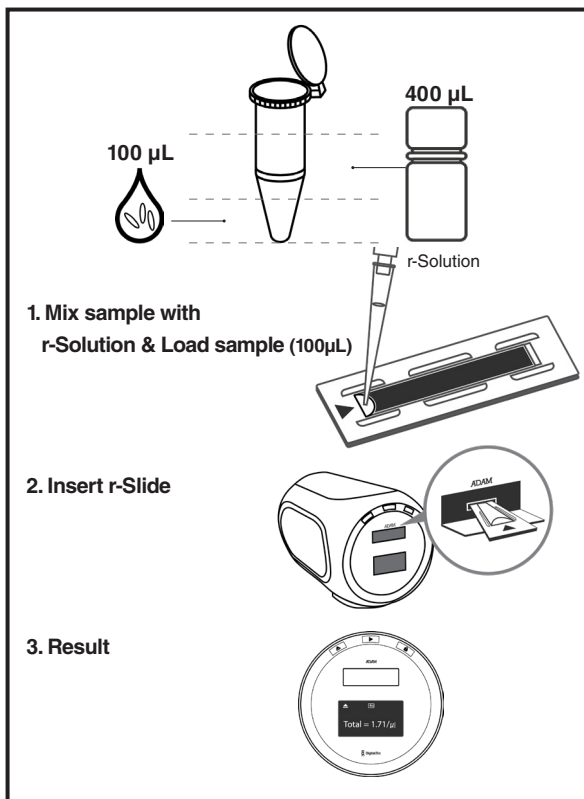
Warning:

The instrument will not detect incorrectly diluted samples. Also refer to ADAM-rWBC Kit Package Insert.

General operation

Sample preparation and testing

1. Leave the r-Kit at room temperature for 10 minutes before use.
2. Carefully dispense 100 μL of well-mixed RBC or platelet sample into a clean test tube.
3. Add 400 μL of reagent into the tube.
4. Mix the tube well (100 μL sample+400 μL reagent).
5. Load 100 μL mixed sample/reagent onto a r-Slide.
6. Wait 4~7 minutes for sample settling.
7. Insert r-Slide into ADAM instrument and press **▶** to start.
8. After approximately 3 minutes, the result, calculated as WBC per μL , will be displayed automatically.



General operation

Operating the ADAM-rWBC



Warning:

- **Sample loading error**

Load 100µL of sample into the r-Slide and ensure correct filling.

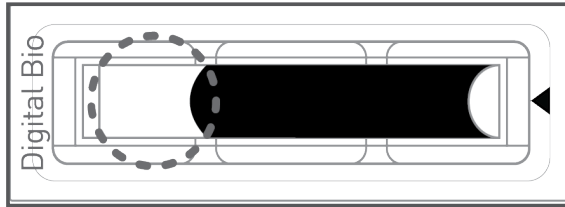
The instrument **will not detect** in low or high sample volumes.



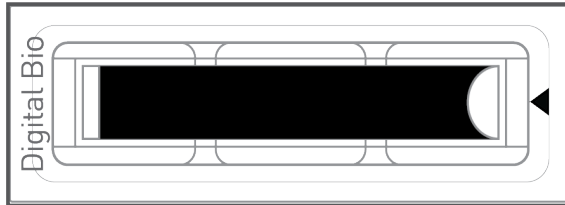
CAUTION:

- **Avoid bubbles as they may negatively affect results.**

Low volume



Correct volume

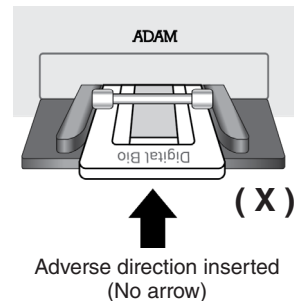
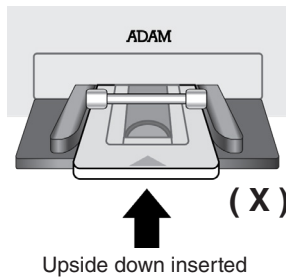
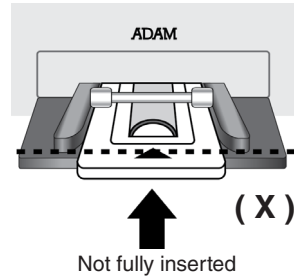
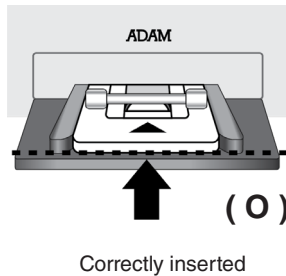
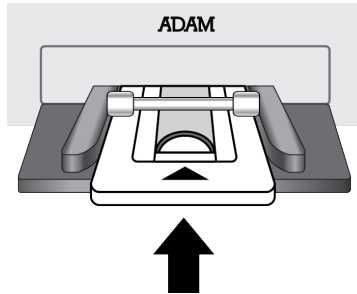


General operation

Operating the ADAM-rWBC

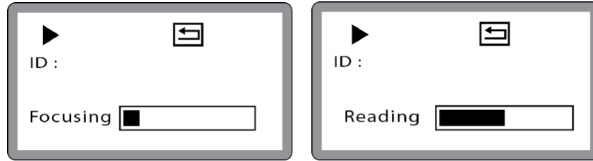


- r-Slide insert error
Completely insert r-Slides face up, in the direction of the arrow on the slide. The instrument will not detect if slides are inserted incorrectly.
See pictures below for proper insertion.



General operation

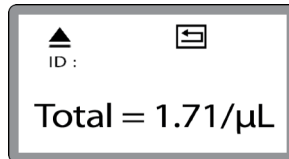
Start input



Starts the counting process by the Start button input.
Once the focusing process finished after calibration step,
ADAM-rWBC will skip the focusing process for the repeated experiments.

Captures the images from the valid r-Slide measuring area and ana-
lyzes the images in memory and performs the counting process.

Result analysis

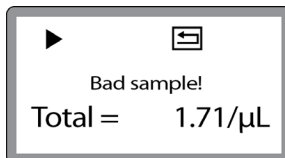


Number of total leucocytes

1.71/μL

The number of total leukocytes will be automatically calculated by the
ADAM-rWBC software.

• Error message during result analysis



[Bad sample!]

In the event that 1 cell image contains of more than 100 pixels includ-
ing dust or the number of error frame is more than 10 frames, this error
message will be displayed on the LCD screen. The error frame occurs
when the number of cells is more than 50 in one frame. Check the
sample contains dust or cell clumping and retest.

General operation

Maintenance and cleaning

ADAM-rWBC does not need regularly scheduled maintenance because ADAM-rWBC has no consumable materials to replace.

Frequent or before every testing, please clean the exposed outer surface of ADAM-rWBC using a soft cloth and isopropyl alcohol or deionized water.

Trouble shooting

Problem	Cause	Solution
ADAM-rWBC does not power up.	Power switch in off position	Check power switch on back of unit.
	No power from outlet	Check power source.
	Bad power cord	Replace or repurchase
Booting error message	[System state]	Refer to the 12 page
	[System init.]	Refer to the 12 page
	[Device unlocked]	Refer to the 13 page
Result error message	[Bad sample!]	Refer to the 18 page

Warranty

If any defects occur in the ADAM-rWBC during one(1) year warranty period, NanoEntek will repair or replace the defective parts at its discretion without charge. The following defects, however, are specifically excluded:

1. Defects caused by improper operation.
2. Repair or modification done by anyone other than NanoEntek or an authorized agent.
3. Damage caused by substituting alternative parts.
4. Use of fittings or spare parts supplied by anyone other than NanoEntek.
5. Damage caused by accident or misuse.
6. Damage caused by disaster.
7. Corrosion caused by improper solvent or sample.

For your protection, items being returned must be insured against possible damage or loss. NanoEntek cannot be responsible for damage incurred during shipment of a repair instrument. It is recommend that you save the original packing material in which the instrument was shipped. This warranty should be limited to the replacement of defective products.

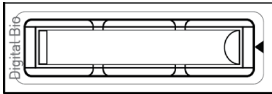
For any inquiry or request for repair service, contact ivdst@nanoentek.com or your local distributor.

Technical specifications



ADAM-rWBC

- Voltage : AC100-240V~, 50/60 Hz
- Current : max. 1.8 A, max 100 W
- Fuse : F3.15AL250V
- Objective lens : 4 X
- LED : 4W Green LED, IEC 62471:2006
- CCD camera : B/W CCD
- Filter : Excitation filter, Dichroic filter, Emission filter
- Weight : 9 Kg
- Size (WxLxH) : 220 x 375 x 250 mm
- Degree of protection : IPX0



r-Slide

- Measuring range : 1–100 cells / μ L
- Measuring time : 2.5–3 min /test
- Loading sample vol. : 100 μ L /r-Slide
- Measuring vol. : about 57 μ L /r-Slide



Solutions

- r-Solution: Propidium Iodide (PI)
- Standard bead solution

Operating environment condition

0 °C \leq Temperature \leq 40 °C
10 % \leq Humidity \leq 90 %
Altitude \leq 2,000 m

Transportation & storage environment condition

-30 °C \leq Temperature \leq 60 °C
10 % \leq Humidity \leq 90 %

Product list

Product	Cat. No.	Contents	Quantity
ADAM-rWBC	ADAM-rWBC	Main device	1
		Power cord	1
		Fuse	2
		Installation CD	1
		Instruction manual	1
		ADAM-rWBC PC Software	1
		User Manual	1
		External video monitor (Optional)	1
		Barcode Scanner (Optional)	1
		ADAM-rWBC Kit (50 tests)	RDS-50
RDR-50	r-Solution 25ml		1
ST-001	Standard Bead Solution 7ml		1
	Instruction manual		1

* Each component and power cord are available for purchase separately.
Please contact your local distributor or ivdst@nanoentek.com.

* This Instruction Manual can be downloaded from the NanoEntek website,
www.nanoentek.com.

Safety precautions

Review and follow the safety instructions below :

-
- If water or other material enters the instrument, the adaptor, or power inlet, disconnect the power cord and contact a service person. For operating environment, refer to Product Specifications.
-
- Do not touch the main plug or power cord with wet hands.
-
- Always ensure that the power supply input voltage matches the voltage available at your location.
-
- This instrument is air-cooled and its surfaces may become hot during operation. When installing, leave a space of more than 10 cm (4 inches) around the instrument and do not place any objects between the instrument and walls.
-
- Do not install an instrument on a slant or a place prone to vibrations, which induces the risk of malfunction or damage of the instrument.
-
- Never insert any objects into the air vents of the instrument as this can result in electric shock, personal injury, and equipment damage.
-
- Plug the power cord firmly into the wall outlet and AC adapter.
-
- To avoid potential shock hazard, make sure that the power cord is properly grounded.
-
- Be sure to position the instrument such that it is easy to disconnect.
-
- Turn off an instrument before unplugging the power cord and/or moving the instrument.
-
- If an instrument is dropped or broken, disconnect the power cord and contact a service person. The warrant will be void in case of disassembly.
-
- Use only authorized accessories (adaptor, power cord, and USB drive)

WARNING

Class A equipment is intended for use in an industrial environment. In the documentation for the user, a statement shall be included drawing attention to the fact that there may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.

Consignes de securite

Examinez et suivez les consignes de securite ci-dessous :

-
- Si de l'eau ou d'autres matières entrent dans l'instrument, l'adaptateur, ou l'entrée de la prise, débrancher le cordon d'alimentation et contacter un technicien de service. Pour l'environnement d'exploitation, se reporter aux Spécifications du Produit.
-
- Ne pas toucher la prise principale ou le cordon d'alimentation avec les mains mouillées.
-
- S'assurer toujours que la tension d'alimentation correspond à la tension disponible à votre localisation.
-
- Cet instrument est refroidi à l'air et ses surfaces peuvent devenir chaudes pendant le fonctionnement. Lors de l'installation, laisser un espace de plus de 10 cm (4 pouces) autour de l'instrument et ne placer aucun objet entre l'instrument et les murs.
-
- Ne pas installer d'instrument sur une pente ou un endroit sujet aux vibrations, qui entraînent un risque de défaillance ou de détérioration de l'instrument.
-
- Ne jamais insérer d'objets dans les événements d'air de l'instrument, car cela peut causer des chocs électriques, des blessures corporelles et des dommages de l'instrument.
-
- Mettre le cordon d'alimentation fermement dans la prise murale et l'adaptateur courant alternatif.
-
- Pour éviter tout risque de choc, s'assurer que le cordon d'alimentation est correctement mis à la terre.
-
- S'assurer de positionner l'instrument de telle sorte qu'il soit facile à débrancher.
-
- Éteindre l'instrument avant de débrancher le cordon d'alimentation et/ou de le déplacer.
-
- En cas de chute ou de rupture d'un instrument, débrancher le cordon d'alimentation et contacter un technicien de service. La garantie sera annulée en cas de démontage.
-
- Utiliser uniquement les accessoires autorisés (adaptateur, cordon d'alimentation et clé USB).



















AVERTISSEMENT

L'équipement de classe A est destiné à être utilisé dans un environnement industriel. Dans la documentation pour l'utilisateur, une déclaration doit être incluse pour attirer l'attention sur le fait qu'il peut y avoir des difficultés à assurer la compatibilité électromagnétique dans d'autres environnements, en raison de perturbations aussi bien conduites que radiées.














Safety symbols

The following symbols are found on the instrument and this document. Always use the equipment in the safest possible manner.

Symbol	Meaning
	Caution, warning, Consul accompanying documents
	Catalogue number/Reference number
	Consult Instructions for Use An electronic instructions for use (eIFU) indicator (website address) may accompany the symbol when used to indicate an instruction to consult an eIFU.
	ON (Power)
	Protective earth (Ground)
	CE marking
	UK Conformity Assessment
	Caution: BIOHAZARD Protective measures must be used in dealing with biologically hazardous materials such as carcinogenic reagents.
	USB Connection
	LED
	Serial number
	Manufacturer
	Date of Manufacturer
	In vitro diagnostic medical device
	Current direction, voltage and frequency
	Maximum current (ampere) and maximum performance (watt) for energy consumed per unit time

Safety symbols

The following symbols are found on the instrument and this document. Always use the equipment in the safest possible manner.

Symbol	Meaning
	Meets FCC requirements per 21 CFR Part 15 This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference in which case the user will be required to correct the interference at his own expense.
	For prescription use only CAUTION: Federal (The U.S.) law restricts this device to sale by or on order of a physician.
	This product conforms to UL 61010-1, CAN/CSA C22.2 No.61010-1 "Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part I: General Requirements." Instruments bearing the TUV symbol are certified by TUV Product Services to be in conformance with the applicable safety standard for the US and Canada.
	Disposal of your old appliance <ol style="list-style-type: none"> 1. When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2012/19/EU. 2. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. 3. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. 4. For more detailed information about disposal of your old appliance, please contact local distributor, waste disposal service or call the number listed in the manual.
	<i>Keep dry</i> <i>Keep away from rain</i>
	Fragile, handle with care
	This way up
	General symbol for recover/recyclable
	US Corporation
	Authorized representative in the European Community
	Authorized representative in United Kingdom
	Authorized representative in Switzerland
	Authorized representative in Brazil

Warnings

- 1) After using device, please turn off main power.
If not, it can be cause of malfunction or reduce lifetime of device.
- 2) When turn off the device, be sure lock the device with Lock button.
If not, it can be cause of mechanical problem or error message when device is booting.

Item	Warning
Battery inside device	Risk of explosion if battery is replaced incorrectly. This battery is not replaceable by user. Refer to an authorized service person.
Cover	Do not remove cover or disassemble case. There are no adjustable components inside the instrument. If a malfunction is found, refer to an authorized service person.
Manual	Do not attempt to service the equipment. This manual is only available in English. Failure to heed warnings may result in injury to service provider or operator.
Sample handling	Wear personal protective equipment during sampling and testing. Sample may contain infectious or bio-hazardous agents. Use of capped tubes and lint free wipes. Lint free wipes to be used one time and discarded.
Waste	After using r-Slides, appropriately dispose as bio-hazardous waste. Do not reuse r-Slides.

Technical support

Visit the our Website at www.nanoentek.com for :



- Technical resources, including manuals, FAQs, etc.
- Technical support contact information
- Additional product information and special offers.

For more information or technical assistance, please call or email.



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