

ADAM r WBC 2

Instruction Manual



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ADAM-rWBC2 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	4-6
General Description	4
Technology - Mechanical	5
Technology - residual Leukocytes Counting	6
Product Description	7-10
Packing List	7
Front View of ADAM-rWBC2	9
Rear View of ADAM-rWBC2	10
System Installation	11
Environmental Requirements	11
Power On and Initial Display	11
General Operation	13-21
Calibration	13
Sample Preparation and Testing	13
Run Sample	18
Result Analysis	19
Lock	20
Power off	20
Maintenance and Cleaning	21
Trouble Shooting	22
Warranty	23
Technical Specifications	24
Product List	25
Safety Precautions	26
Safety Symbols	28
Warnings	30
Technical Support	31

Introduction

General Description

ADAM-rWBC2 is an analyzing device that counts the number of residual leukocytes in a blood component for transfusion. Targeting the leukocyte, ADAM-rWBC2 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

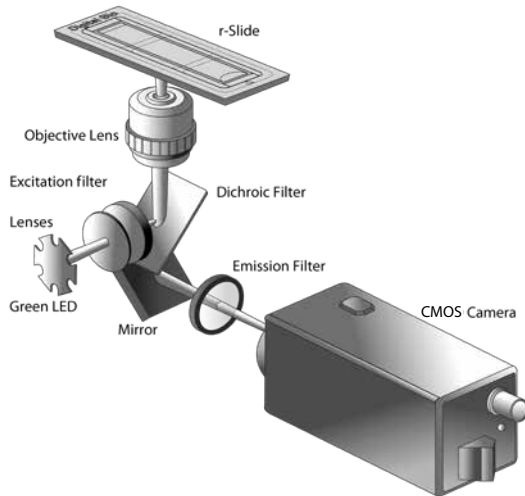
Technology

- 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 ADAM-rWBC2, which is based on fluorescent microscopy techniques for counting cells. ADAM-rWBC2 utilizes sensitive fluorescence dye staining, LED optics and CMOS detection to provide accurate and reliable leukocyte detection.

To use ADAM-rWBC2, 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. ADAM-rWBC2 system automatically focuses on the slide, and the cells that have been stained are scanned by a sensitive CMOS camera. The image results are automatically processed.



Introduction

Technology

- residual Leukocytes Counting

ADAM-rWBC2 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, 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-rWBC2.

Product Description

Packing List

ADAM-rWBC2 is shipped with the components listed in the table below. Once you receive your instrument, please check that all items listed below were shipped. If any items are missing or damaged, contact your local distributor or ivdst@nanoentek.com.

Item	Quantity
Main device	1
ADAM-rWBC Kit (Starter Kit with Package Insert)	1
Instruction manual	1
Adapter & Power cord	1
Installation USB	1
USB cable	1
Software Manual	1
Quick Manual	1
Barcode scanner (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.

Product Description

Packing list

Main device



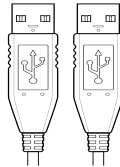
Adapter & Power cord



Installation USB



USB cable



ADAM-rWBC Kit

(Starter kit with package insert)

Cat. No. AD1K-050



Instruction manual



ADAM-rWBC2

PC Software User Manual



Quick manual



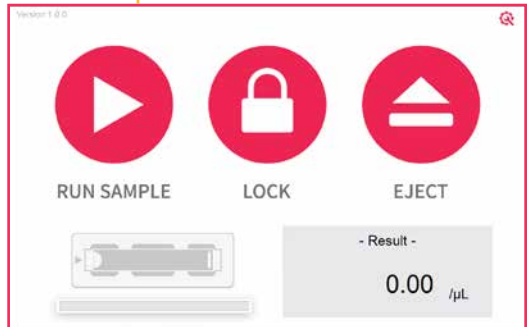
Optional




Barcode Scanner



Product Description

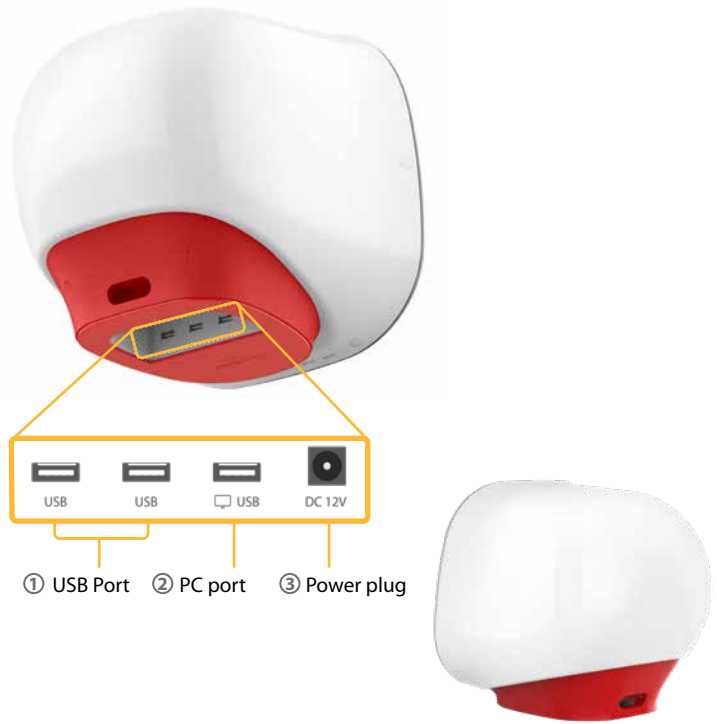
Front View of ADAM-rWBC2



Control buttons	Description
 EJECT	<ul style="list-style-type: none"> Ejects the slide holder from ADAM-rWBC2. Functions as unload.
 RUN SAMPLE	<ul style="list-style-type: none"> Performs all procedures of automatic counting.
 LOCK	<ul style="list-style-type: none"> Protects the alignment of stage from external shock when ADAM-rWBC2 is being moved. Lock ADAM-rWBC2 before turning it off or moving it.
Door	<ul style="list-style-type: none"> Slide holder is inserted and ejected
LCD	<ul style="list-style-type: none"> Display processes and results
Power	<ul style="list-style-type: none"> Power On/Off

Product Description

Rear View of ADAM-rWBC2



Port	Description
① USB Port	Port for software and firmware updates
② PC port	Connects USB cable to ADAM-rWBC2 and PC for using a software
③ Power Plug	Connects ADAM-rWBC2 power cord to wall outlet

System Installation

Environmental Requirements

⚠ CAUTION

At low temperatures ($\leq 10^{\circ}\text{C}$), allow the device to warm up for 10 minutes at ambient temperature before use.

To ensure correct operation and stable performance, install ADAM-rWBC2 in a location which meets the following conditions :

- Use at room temperature.
- Do not expose the device to direct sunlight.
- Do not subject the device to direct or continuous vibration.
- Do not subject the device to intense magnetic or electromagnetic fields.
- Do not install the device in high-humidity environment.
- Location of device should be free from corrosive gases or other corrosive substances.
- Ensure minimal contact with dust or other airborne particles.
- Allow for 10 cm (4 inches) minimum space around the device for proper airflow.
- Do not place any objects on the device.

Power On and Initial Display

1. Check the connection of ADAM-rWBC2 and power cord.
2. Press the power button for 2~3 seconds.

If you get an error message, please contact your local distributor or ivdst@nanoentek.com. If booting is successful and no errors are detected, the home screens will be displayed as below.



⚠ CAUTION

- *Do not tilt the device too much in the forward when connecting the power cord.*
 - *Do not move the device after connecting power cord.*
- When you connect the power cord to ADAM-rWBC2 even without power on the device, it will go through self diagnostic tests.*

System Installation

Power On and Initial Display

Error Messages during booting

[System State]



It appears when booting is not working properly.
Turn off main power and restart device.

If this message still appears after restarting,
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

General Operation

Calibration


Calibration test

Prior to use ADAM-rWBC2, calibration test MUST be performed. The calibration test should be performed to verify if optic and auxiliary structures of ADAM-rWBC2 are completely ready for the real sample test by using Standard bead solution provided in ADAM-rWBC kit.

The device is ready to use ONLY if the calibration result is within range as indicated on the individual Standard bead solution provided.

Refer to a package insert of ADAM-rWBC Kit for specific instruction of use.

The ADAM-rWBC2 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 rocking gently, including upside down.
3. Load 100 μ L of the beads into the r-Slide. Let settle for 40-60 seconds.
4. Insert loaded r-Slide into ADAM-rWBC2 main device and press RUN SAMPLE  to start.

Sample Preparation and Testing

Leukocyte-reduced samples

Samples should be tested within 48 hours after leukocyte reduction.

A sample is mixed with r-Solution for staining. After staining, the sample is loaded into r-Slide and left to be settled. After settling, r-Slide is inserted into ADAM-rWBC2 and counted. Refer to a package insert of ADAM-rWBC Kit for specific instruction of use.

CAUTION

- Avoid bubbles which may negatively affect the result.
- Do not reuse r-Slide. Reusing r-Slide may result in errors.
- Do not use expired r-Solution, r-Slide or Standard bead solution.
- Store r-Solution at 2~8°C. The expiration date is one year.
- Do not use after the expiration date shown on the label. Opened r-Solution may be stored at 2~8°C and used for up to 6 months, or until the expiration date.

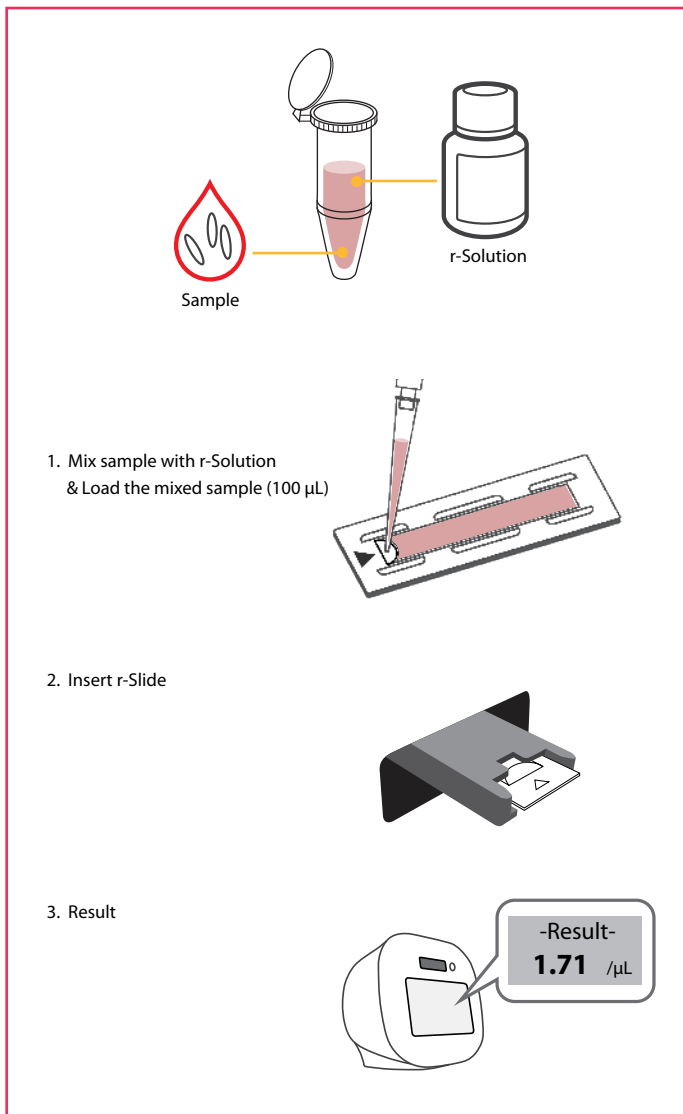
WARNING

The instrument does not detect incorrectly diluted samples.
Please refer to ADAM-rWBC Kit package insert.

General Operation

Sample Preparation and Testing

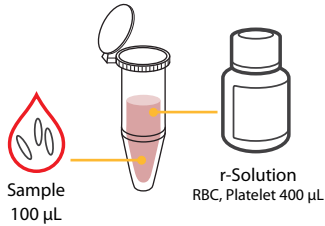
Please check the procedure of sample preparation and testing below.
For more detailed information, please refer to the next page.



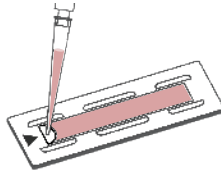
General Operation


Sample Preparation and Testing

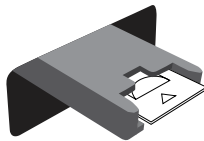
1. Leave the ADAM-rWBC Kit at room temperature for 10 minutes before use.
2. Carefully dispense 100 μL of well-mixed RBC or platelet sample into a clean test tube.
3. Add 400 μL of reagent into the tube.
4. Mix the tube well
 - RBC or Platelet : 100 μL sample + 400 μL reagent



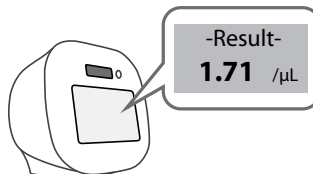
5. Load 100 μL mixed sample/reagent onto a r-Slide.



6. Wait 4~7 minutes for sample settling.
7. Insert r-Slide into ADAM instrument and press RUN SAMPLE  to start.



8. After approximately 1 minute, the result, calculated as WBC per μL , will be displayed automatically. It may take about 1 minute longer for auto focus at the initial test.



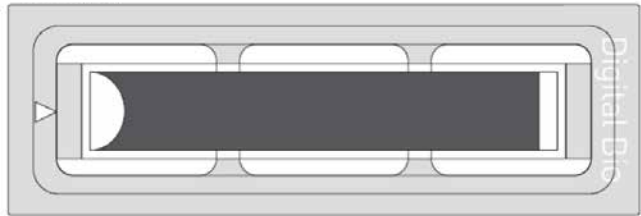
General Operation

Sample Preparation and Testing

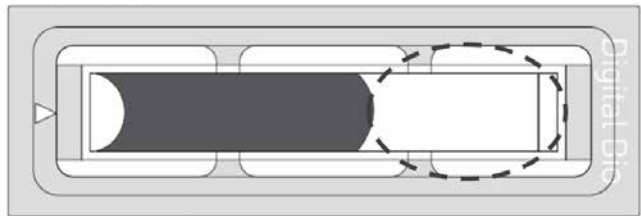
⚠ WARNING
[Sample loading error]
Be cautious of loading the correct volume (100 μ L) of the sample into r-Slide.
The instrument will not detect low or high sample volumes.

⚠ CAUTION
Avoid bubbles which may negatively affect the result.

Correct volume



Low volume



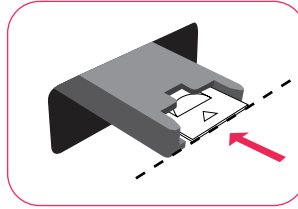
General Operation

Sample Preparation and Testing

⚠ WARNING

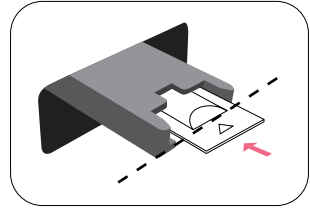
[r-Slide insert error]

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.



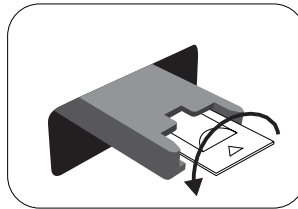
(O)

Correctly inserted



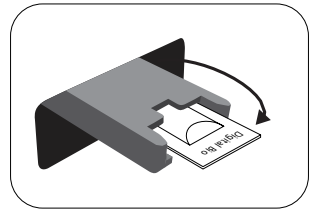
(X)

Not fully inserted



(X)

Upside down inserted



(X)


Wrong end inserted
(No arrow)

⚠ CAUTION

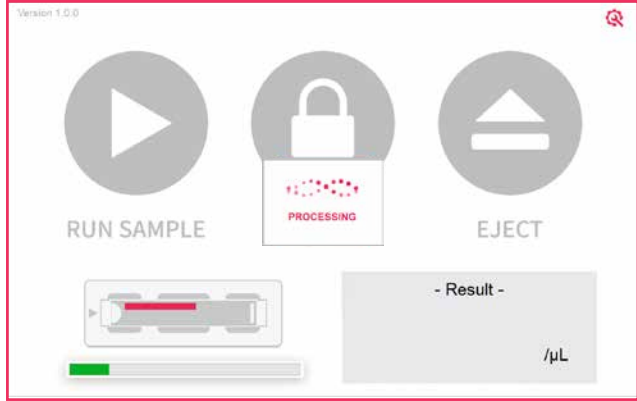
- Please insert or remove the r-slide when the slide holder is fully ejected.
- When the test is finished, please remove the r-slide from the slide holder.

General Operation

Run Sample

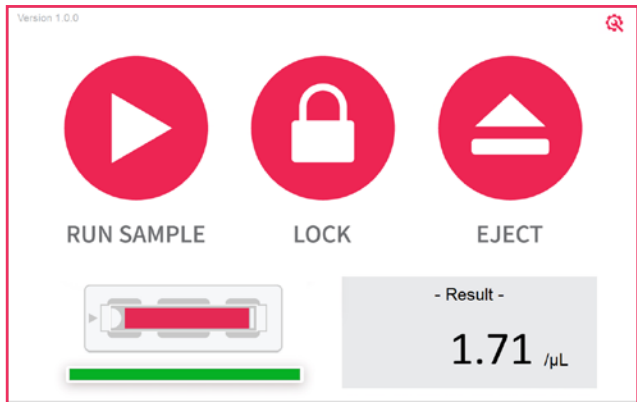
Start counting process by pressing RUN SAMPLE .

It may take about 1 minute longer for auto focus at the initial test.



Result Analysis

The total number of leukocytes will be displayed after being automatically calculated by ADAM-rWBC2 software.



Total Number of Leukocytes

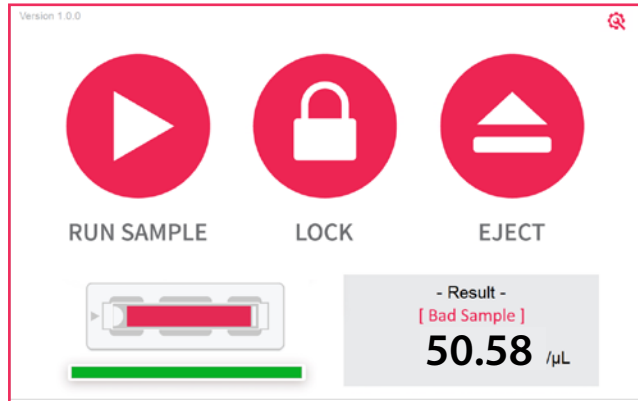
1.71/µL

General Operation

Result Analysis

Error Message


[Bad Sample]



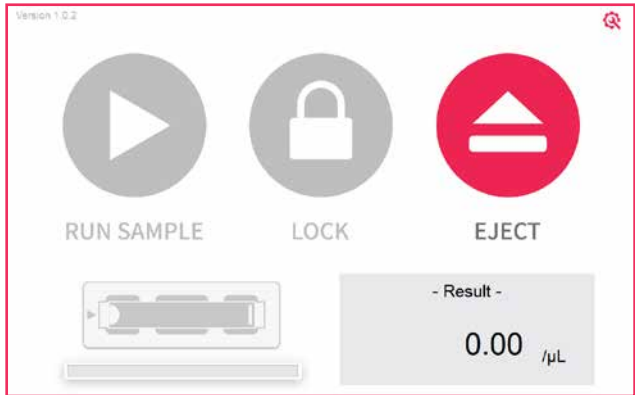
When 1 cell including dust consists of more than 100 pixels or the number of cells is more than 160 in 1 frame, this is considered as error frame. If these error frames are more than 5, then the error message [Bad Sample] will be displayed on the screen. Please check if the sample has any dust or cell clumping and retest.

General Operation

Lock

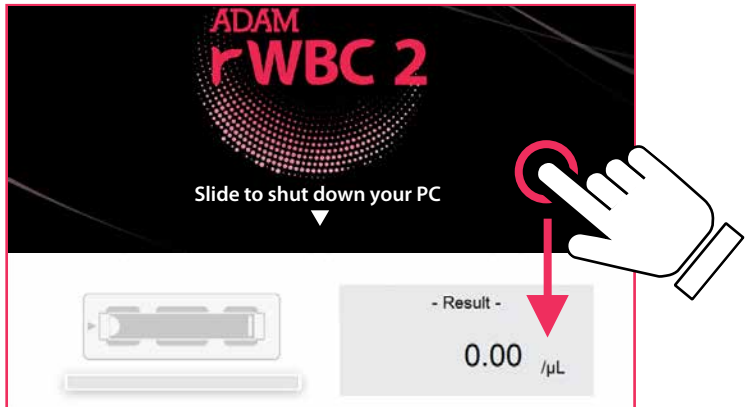
Press LOCK  before turning off the device.
If there is no operation for 1 minutes, the lock function will be activated automatically.

When the device is locked, the screen will be changed as shown below.



Power Off

If you press the power button for 2~3 seconds, then 'Slide to shut down your PC' message will appear. Slide down the screen to turn off the power.



General Operation

Maintenance and Cleaning

ADAM-rWBC2 does not need regularly scheduled maintenance because ADAM-rWBC2 has no consumable materials to replace.

Please clean the exposed surface of ADAM-rWBC2 frequently or before testing, using a soft cloth and isopropyl alcohol or deionized water.

Trouble Shooting

Problem	Cause	Solution
ADAM-rWBC2 does not power up	No power from outlet	Check power source.
	Bad power cord	Replace or Repurchase.
LED on the power button blinks and the screen does not turn on	Problem with Windows OS	Unplug the adapter and plug it back in to power on the device.
Booting error message	[System state]	Refer to the 11 page.
Result error message	[Bad sample!]	Refer to the 18 page.

Warranty

If any defects occur in the ADAM-rWBC2 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:

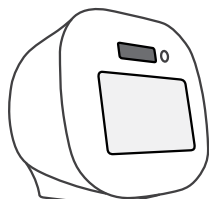
1. Defects caused by improper operation.
2. Repair or modification done by anyone other than NanoEntek or an authorized agent.
3. Damage caused by substituting alternative parts.
4. Use of fittings or spare parts supplied by anyone other than NanoEntek.
5. Damage caused by accident or misuse.
6. Damage 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 recommended 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-rWBC2



Measuring range	1~100 cells / μ L
Analysis time	< 1 min /test
Voltage	DC12V
Current	5A
Objective lens	4 X
LED	4W Green LED
Camera	CMOS camera
Filter	Excitation filter, Dichroic filter, Emission filter
Weight	7 Kg
Size (WxLxH)	227 × 276 × 270 mm
Degree of protection	IPX0

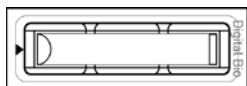
Operating environment condition

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

Transportation & storage environment condition

Temperature	-30 °C ≤ Temperature ≤ 60 °C
Humidity	10 % ≤ Humidity ≤ 90 %

ADAM-rWBC Kit



r-Slide

Loading sample vol.	100 μ L /r-Slide
Measuring vol.	about 57 μ L /r-Slide

Solutions

r-Solution	25 mL, Propidium Iodide (PI)
Standard bead solution	7 mL

Storage temperature

r-Slides	0 – 30 °C
r-Solution	2 – 8 °C
Standard bead solution	2 – 8 °C

Expiration date

r-Slides	2 years
r-Solution	1 year before open, 6 month after open
Standard bead solution	1 year before open, 6 month after open

Product List

Product	Cat. No.	Contents	Quantity
ADAM-rWBC2	ADAM-rWBC2	ADAM-rWBC2 Main device	1
		Instruction manual	1
		Adapter & Power cord	1
		Installation USB	1
		Barcode Scanner (Optional)	1
ADAM-rWBC Kit (50 tests)	RDS-50	r-Slide 50 pcs	1
	RDR-50	r-Solution 25mL	1
	ADST-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 sécurité

Examinez et suivez les consignes de sécurité 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.








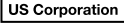
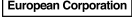


Safety Symbols

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

Symbol	Meaning
	Caution, warning, Consult accompanying documents
	Catalogue number/Reference number
 www.nanoentek.com/eifu.php	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.
	CE marking
	UK Conformity Assessment
	Power On /Off
	USB Connection
	LED
	Serial number
	Manufacturer
	Date of Manufacturer
	In vitro diagnostic medical device
	Electric input, Voltage, Current
	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.

Safety Symbols

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

Symbol	Meaning
	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
	European Corporation
	Authorized representative in the European Community
	Authorized representative in United Kingdom

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
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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