CE IVD

ADAM rWBC

Instruction Manual

NanoEnTek

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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.

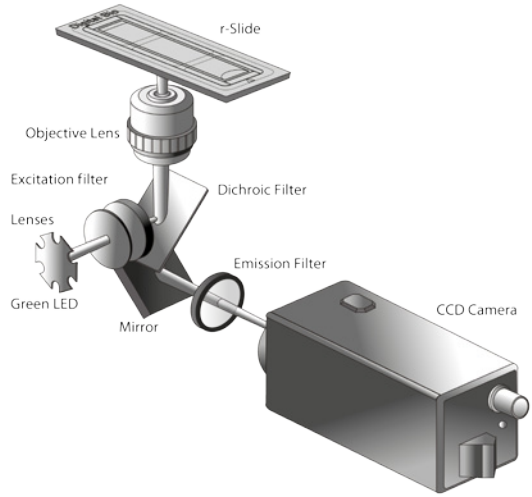
Introduction

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 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 sales@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
External video monitor	1
Barcode scanner	1

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

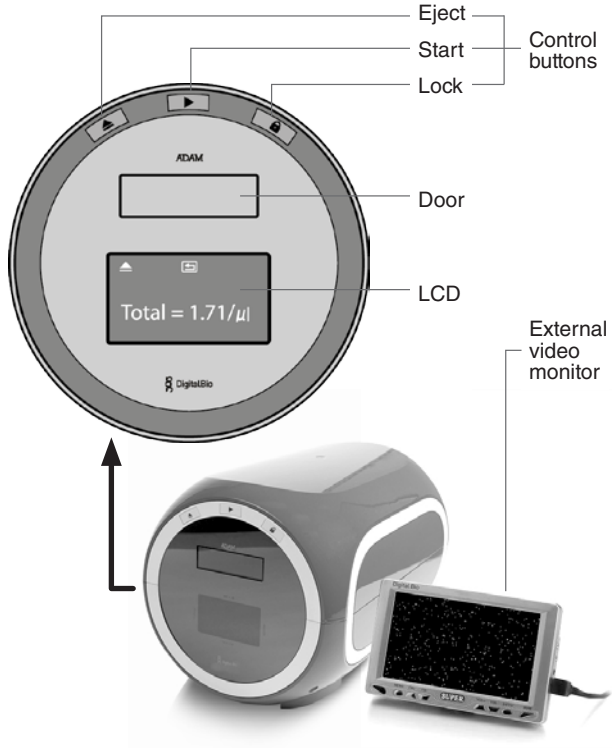
C A U T I O N :

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

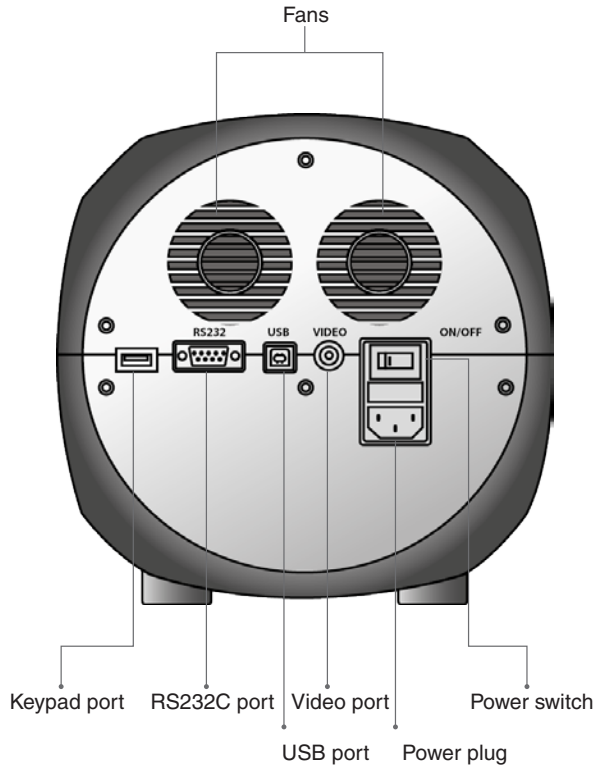
Front view of the ADAM-rWBC



Control buttons	
⏏ Eject	• Ejects the slide from the ADAM-rWBC. • Functions as load and unload.
▶ Start	• Performs all procedures of automatic counting.
🔒 Lock	• 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.**
Door	• Slide is inserted and ejected.
LCD	• Displays processes and results.
External video monitor	: Displays live image of ADAM-rWBC.

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
Video port	External video monitor port (Yellow port)
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.

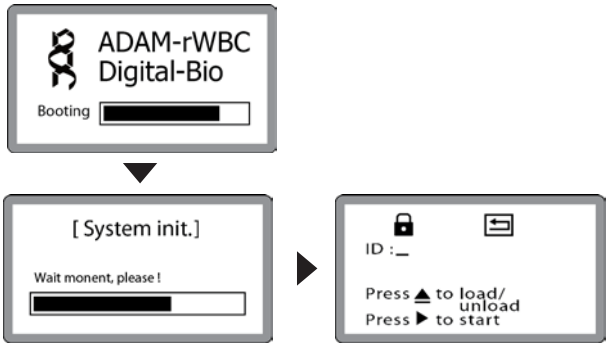
To ensure correct operation and stable performance,
install the ADAM-rWBC in a location which meets the following conditions:

- 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.)

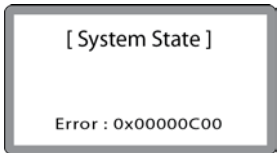
• When you turn on the ADAM-rWBC, it will go through self diagnostic tests. If you get an error message, please contact your local distributor or sales@nanoentek.com. If boot up is successful and no errors are detected, the home screens will be displayed as below.



System installation

Power on and initial display

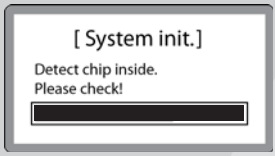
*** Error Messages during booting**



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

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

Error code	Cause
0x00000C00	Failure of X-axis sensor
0x00007000	Failure of Y-axis sensor
0x00008000	Failure of Z-axis sensor
0x06000000	Failure of locking module sensor



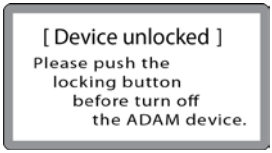
[System init.] If a r-Slide is detected during initial booting, this error message will be shown.
(Trouble shooting) 1. Remove the r-Slide 2. Power off/on 3. Redo initial booting again.

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-Side is inserted, contact your local distributor or sales@nanoentek.com.

System installation

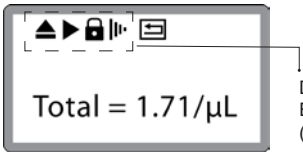
Power on and initial display



[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 sales@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 ±10% 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:

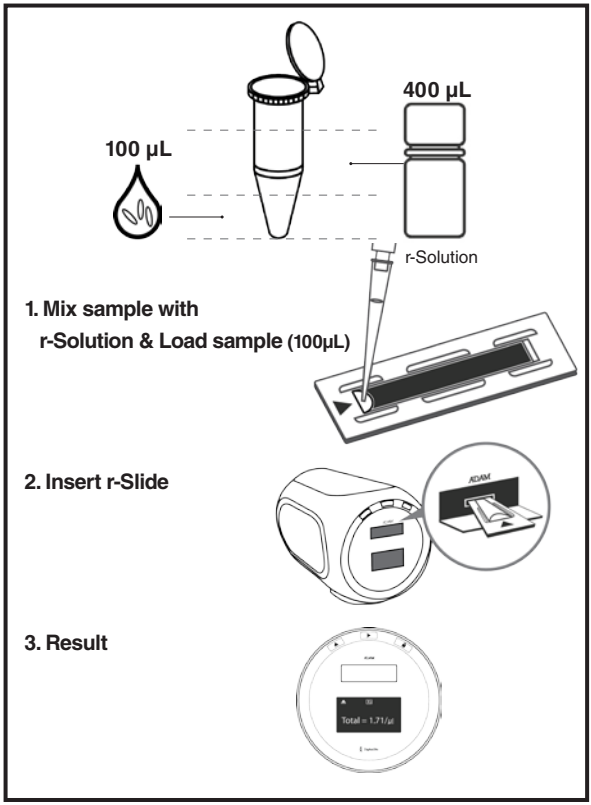
The instrument will not detect incorrectly diluted samples.

Also refer to ADAM-rWBC Kit Package Insert.

General operation

Sample preparation and testing

1. Take out r-Solution (reagent) from the refrigerator.
   Approximately 10 minutes before use, to allow equilibration to room temperature.
2. Carefully dispense 100 µL of well-mixed RBC, platelet or QC sample into a clean test tube.
3. Load 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**

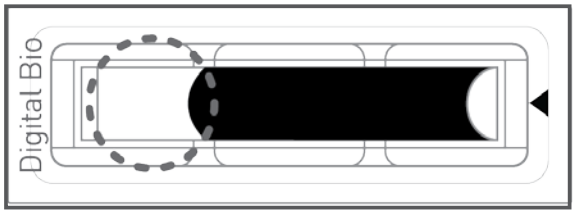
  Load 100µL of sample into the r-Slide and ensure correct filling.

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

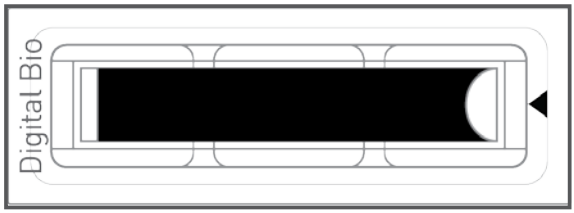
CAUTION:

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

Low volume



Correct volume



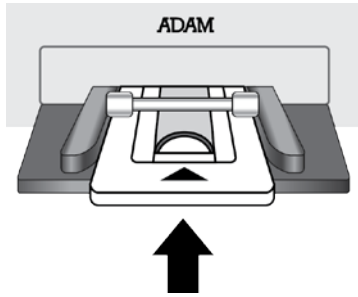
General operation

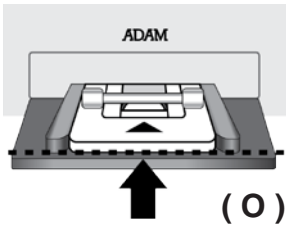
Operating the ADAM-rWBC

- r-Slide insert error

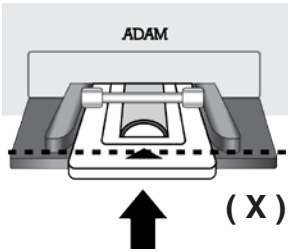
  Completely insert r-Slides face up, in the direction of the arrow on the slide. The instrument will not detect if slides are inserted incorrectly.

  See pictures below for proper insertion.

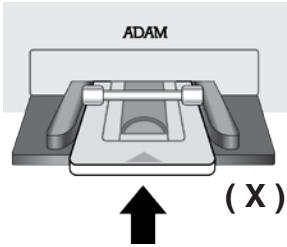




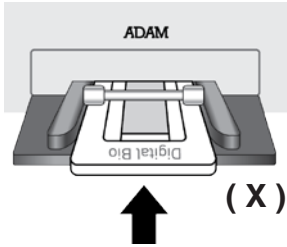
Correctly inserted



Not fully inserted



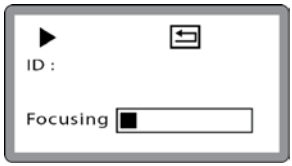
Upside down inserted

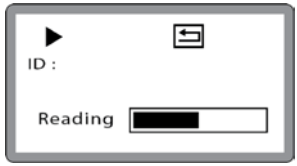


Adverse direction inserted
(No arrow)

General operation

Start input

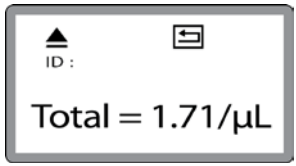




Starts the counting process by the Start button input.
Once the focusing process finished after calibration step,
ADAM-rWBC will skip the focusing process for the repeated experiments.

Captures the images from the valid r-Slide measuring area and analyzes 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 including 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.

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 11 page
	[System init.]	Refer to the 11 page
	[Device unlocked]	Refer to the 12 page
Result error message	[Bad sample!]	Refer to the 17 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.

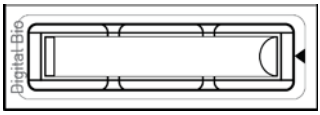
For your protection, items being returned must be insured against possible damage or loss. NanoEnTek cannot be responsible for damage incurred during shipment of a repair instrument. It is recommend that you save the original packing material in which the instrument was shipped. This warranty should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

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

Technical specifications

ADAM-rWBC

- Voltage : AC100~240 V, 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 (W×L×H) : 220 × 375 × 250 mm
- Degree of protection : IPX0

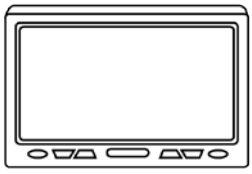


r-Slide

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

Solutions

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



Accessories

- External video monitor
  (Fuse: 250 VAC, 3 A; F3.15AL250V)
- Barcode scanner

Environment Condition

20 °C ≤ Temperature ≤ 35 °C

10 % ≤ Humidity ≤ 90 %

Altitude ≤ 2,000 m

Product list

Cat. No.	Product	Contents	Quantity
rWBC	ADAM-rWBC	Main device	1
AD1K-050	ADAM-rWBC Kit(50 tests)	50 pcs r-Slide	1
		r-Solution 25mL	1
		Standard bead solution 7mL	1
ADM-001	Accesories	7” LCD Monitor	1
-	Accesories	Barcode scanner	1

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

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

Safety precautions

Review and follow the safety instructions below :

· Always ensure that the power supply input voltage matches the voltage available at your location.

· To avoid the danger of electric shock, install the instrument per the environmental specifications located in “Technical Specifications”. If water or other material enters the instrument, the adaptor, or power inlet, disconnect the power cord and contact a service person.

· Do not touch the main plug or power cord with wet hands.

· This machine is air-cooled so its surfaces become hot during operation. During installation and use, leave more than 10 cm (4 inches) free around the device.

· Do not install the instrument on a slant or a place prone to vibrations or the risk of instrument malfunction or damage to the instrument will increase.

· Never insert any objects (especially metallic) into the air vents of the instrument as this could result in electrical shock, personal injury, and equipment damage.

· Always set the main switch on the power supply unit to OFF before connecting the power cord to the wall outlet.

· To avoid a potential shock hazard, always connect the grounding terminal of the instrument and that of the wall outlet properly. The power cord should be connected to a grounded, 3-conductor power outlet.

· Position the device so that there is sufficient length for the cables and their respective connections.

· Set the main switch to “ O ” (OFF), unplug the power cord, and lock the stage before moving.

· If the instrument is broken or dropped, disconnect the power cord and contact an authorized service person. Do not disassemble the instrument.

· Only use authorized accessories.

· Use this equipment only as specified in this manual and as specified in any documentation associated with its components. Use of the equipment in an unspecified manner may result in damage to the device or injury to the user.

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
	ON (Power)
	Protective earth (Ground)
	This instrument and consumables conforms to the Declaration of Conformity.
	Caution: BIOHAZARD Protective measures must be used in dealing with biologically hazardous materials such as carcinogenic reagents.
	USB Connection
	LED
	Disposal of your old appliance 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 your city office, waste disposal service or visit our web-site, www.nanoentek.com.

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 dissemble 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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ADAM - rWBC Instruction Manual

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E-mail : sales@nanoentek.com

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Documentation : **NESMU-ARC-001E(V.3.2)**

Revision history : V.0.0 Date: DEC 2009
V.1.0 Date: JAN 2010
V.1.5 Date: MAY 2010
V.2.0 Date: DEC 2010
V.2.5 Date: JULY 2011
V.3.0 Date: MAY 2011
V.3.1 Date: DEC 2013
V.3.2 Date: FEB 2014

ADAM-rWBC

NESMU-ARC-001E (V.3.2)

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