



BEYOND A BETTER BOX™

XW™-100 AUTOMATED HEMATOLOGY ANALYZER
CLIA WAIVED
CLINICIAN'S QUICK GUIDE



XW-100 CLINICIAN'S INFORMATION

Introduction

The XW-100 Automated Hematology Analyzer (XW-100), is a quantitative automated hematology analyzer intended for *in vitro* diagnostic use to classify and enumerate the following parameters for venous whole blood anti-coagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#. It is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.

This Quick Guide is for use with the Sysmex XW-100. Your facility must:

- Have a CLIA Certificate of Waiver in order to perform waived tests.
- Meet all applicable state and local laboratory testing laws.
- Follow the manufacturer's instructions; please read the complete test procedure before performing a test.

Sample Flags and Possible Causes

Flag	Possible Causes
WBC	<ul style="list-style-type: none"> • Lyse resistant RBCs • Immature white blood cells • White blood cell agglutination • Platelet satellite phenomenon • Hyper segmented neutrophils • Cryoglobulins • Nucleated RBCs • Malaria parasites • Fragile white blood cells • Platelet aggregation • Elevated WBC count • Sample coagulation • Giant platelets • Aged sample • Fibrin • Proteins • Lipids
RBC	<ul style="list-style-type: none"> • Fragmented RBCs • Platelet aggregation • Cold agglutinin • Inclusion of white blood cells • Nucleated RBCs • In vitro hemolysis • Sample coagulation • Giant platelets • Microcytes • Anisocytosis • High WBC
PLT	<ul style="list-style-type: none"> • Platelet aggregation • Non-uniformity in platelet size • Cytoplasmic fragments of nucleated cells • Low platelet count • Fragmented RBCs • Cold agglutinins • Sample coagulation • Giant platelets • Microcytes • Cryoglobulins • Lipids
WBC Diff	<ul style="list-style-type: none"> • Lyse resistant RBCs • Increased mixed population • Decreased neutrophils • Immature granulocytes • High values for monocytes • High values for Eosinophils • High values for Basophils • Aged sample • CML

XW-100 CLINICIAN'S INFORMATION

Reference Ranges

	ALERT Low (not printed)	Low	Reference Range	High	ALERT High	
Adult (≥21 years of age)	WBC (x 10 ³ /μL)	< 3.0	3.0 - 3.8	3.9 - 10.4	10.5 - 50.0	> 50.0
	RBC (x 10 ⁶ /μL)		< 3.71	3.71 - 5.52	> 5.52	
	HGB (g/dL)	< 10.0	10.0 - 10.8	10.9 - 16.7	16.8 - 24.0	> 24.0
	HCT (%)	< 25.0	25.0 - 32.4	32.5 - 49.4	> 49.4	
	PLT (x 10 ³ /μL)	< 100.0	100.0 - 147.0	148.0 - 382.0	> 382.0	
	Neut # (x 10 ³ /μL)		< 2.2	2.2 - 7.1	> 7.1	
	Neut (%)		< 46.4	46.4 - 76.9	> 76.9	
	LYMPH # (x 10 ³ /μL)		< 0.9	0.9 - 3.4	> 3.4	
	LYMPH (%)		< 14.7	14.7 - 45.9	> 45.9	
	Other WBC # (x 10 ³ /μL)		< 0.2	0.2 - 1.2	> 1.2	
	Other WBC %		< 3.2	3.2 - 16.9	> 16.9	
	MCV (fL)		< 82.5	82.5 - 98.0	> 98.0	
	Adolescents (≥12 to <21 years of age)	WBC (x 10 ³ /μL)	< 3.0	3.0 - 4.7	4.8 - 10.8	10.9 - 50.0
RBC (x 10 ⁶ /μL)			< 4.20	4.20 - 6.10	> 6.10	
HGB (g/dL)		< 10.0	10.0 - 11.9	12.0 - 18.0	18.1 - 24.0	> 24.0
HCT (%)		< 25.0	25.0 - 36.9	37.0 - 52.0	> 52.0	
PLT (x 10 ³ /μL)		< 100.0	100.0 - 162.0	163.0 - 369.0	> 369.0	
Neut # (x 10 ³ /μL)			< 1.9	1.9 - 8.6	> 8.6	
Neut (%)			< 40.0	40.0 - 80.0	> 80.0	
LYMPH # (x 10 ³ /μL)			< 0.4	0.4 - 3.9	> 3.9	
LYMPH (%)			< 15.0	15.0 - 40.0	> 40.0	
Other WBC # (x 10 ³ /μL)				0.0 - 2.0	> 2.0	
Other WBC (%)				0.0 - 19.0	> 19.0	
MCV (fL)			< 80.0	80.0 - 99.0	> 99.0	
Pediatric (≥2 to <12 years of age)		WBC (x 10 ³ /μL)	< 3.0	3.0 - 4.7	4.8 - 13.5	13.6 - 50.0
	RBC (x 10 ⁶ /μL)		< 4.20	4.20 - 5.40	> 5.40	
	HGB (g/dL)	< 10.0	10.0 - 10.4	10.5 - 16.0	16.1 - 24.0	> 24.0
	HCT (%)	< 25.0	25.0 - 28.9	29.0 - 48.0	> 48.0	
	PLT (x 10 ³ /μL)	< 100.0	100.0 - 162.0	163.0 - 369.0	> 369.0	
	Neut # (x 10 ³ /μL)		< 1.9	1.9 - 8.6	> 8.6	
	Neut (%)		< 35.0	35.0 - 76.0	> 76.0	
	LYMPH # (x 10 ³ /μL)		< 1.0	1.0 - 7.3	> 7.3	
	LYMPH (%)		< 20.0	20.0 - 54.0	> 54.0	
	Other WBC # (x 10 ³ /μL)			0.0 - 2.3	> 2.3	
	Other WBC (%)			0.0 - 19.0	> 19.0	
	MCV (fL)		< 76.0	76.0 - 99.0	> 99.0	

XW-100 START-UP

Start-up

1. Choose a convenient work space:
 - Near an internet connection (provided Ethernet cable is 6.6 feet long) and a 3-prong power outlet (provided power cord is 6.6 feet long).
 - Ensure the space is level, dry, dust-free, and protected from splashing water.
 - Review EMC Information listed in this Quick Guide and the IFU.
 - Environmental conditions:
 - Ambient temperature: 15 - 25 °C or 59 - 77 °F
 - Relative humidity: 30% - 85%
2. Unpack the XW-100. Ensure that the Start-up Quick Guide is present and perform a parts check on the boxes that arrive with the analyzer:

Box 1: (open first)	Box 2:
<ul style="list-style-type: none">• Reagent Tray• Thermal Paper• Waste Bottle• Adapters (Green and White)• Clinician's Quick Guide• Operator's Quick Guide• Shutdown Quick Guide• Technical Specifications	<ul style="list-style-type: none">• Power Cord• Ethernet Cable• Barcode Reader and Cable• Reagent Tubing• COIL TUBE SS-10• Instructions for Use

3. Remove the XW-100 and Power Cord from Box 2.
4. Connect the Power Cord to the XW-100 by inserting it into the socket in the back.
5. Insert the Power Cord into a 3-prong outlet.
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SAFETY WARNINGS:

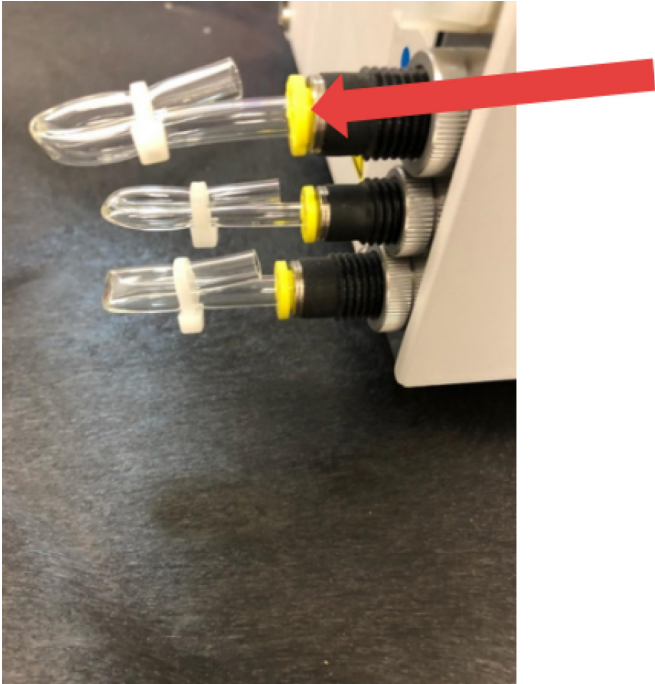
- The XW-100 weighs approximately 38 lbs.; **DO NOT** try to lift it without help.
- Install the instrument with the following clearance, for ventilation:
 - At least 6 inches at the front and sides.
 - At least 12 inches at the back.
- **DO NOT** place anything on, bend, kink, or pull the Power Cord.
- Improper grounding of the instrument can cause electrical shock.
- The printer head can get very hot. **DO NOT** touch! Only use paper recommended by Sysmex.



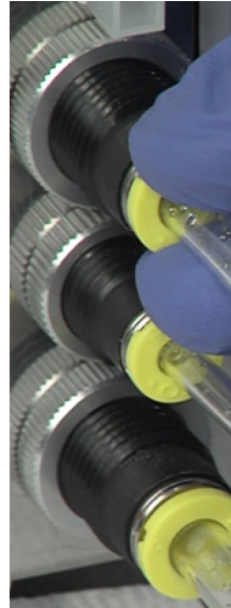
XW-100 START-UP

Start-up, continued from previous page

6. To remove the temporary tubes, locate yellow section of tubing connector on back of XW-100.



7. Push and hold yellow section of connector in, then pull out tubing to disconnect.



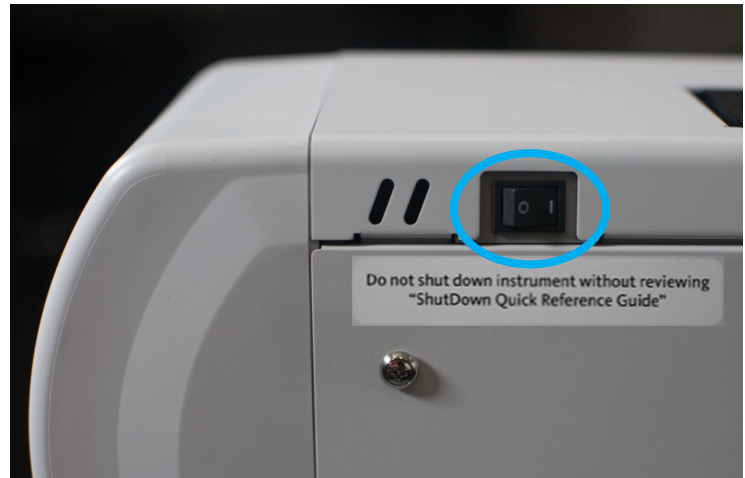
XW-100 START-UP

Start-up, continued from previous page

8. Insert the plug end of the Barcode Reader cord into the "BR" plug on the side of the XW-100.



9. Switch the Power button to the "I" position (as opposed to the "O" position), to turn on the XW-100.



10. Follow the instructions on the screen to complete the setup; when requested, insert the Ethernet Cable plug into the network socket.



11. During Initial Setup, the system will instruct the user to scan the barcode on the Quick Reference Guide. Use the barcode below to do so. If the Barcode Reader is working properly, the screen will react.



XW-100 GENERAL CARE

Daily Cleaning and Disinfecting

NOTE: The following must be cleaned and disinfected every day that patient samples are tested to prevent the spread of infection:

- XW-100 cover and display
 - Exterior of the sample chamber
 - White sample adapter used for testing
1. Put on personal protective equipment (PPE); disposable gloves, eye protection, and lab coat.
 2. Clean any soiling from the following with two new, separate Clorox® Wipes:
 - All surfaces of the adapter
 - All surfaces of the XW-100
 3. Allow the disinfected areas to sit for at least one minute. Then wipe down all areas with a towelette moistened with water.
 4. Dispose of all cleaning materials in a biohazard container. Allow surfaces to air dry prior to use.

Periodic Cleaning - Waste Container Cap

NOTE: The waste container cap must be cleaned and disinfected after each time the waste is emptied, or disposal cycle, to prevent the spread of infection.

1. Put on disposable gloves, eye protection, and lab coat.
2. Remove the waste cap, and empty or discard the waste container following your laboratory's rules for biohazardous waste material.
3. Place the waste cap on an empty waste container.
4. Wipe down all accessible areas on the waste cap thoroughly with a new Clorox® Wipe.



Periodic Cleaning - Adapters

NOTE: Clean if blood or QC material is spilled onto either adapter.

1. Put on disposable gloves, eye protection, and lab coat.
2. Remove the adapter from the XW-100.
3. With a new Clorox® Wipe, remove any blood or dirt from adapter.
4. Rinse the adapter with water and allow it to air dry prior to running additional samples.



Weekly Instrument Care

- Every 7 days, the XW-100 will instruct the user to perform weekly care using XW CELLCLEAN™ (comes in a single-use tube, and is ready to use)
- Weekly care may be scheduled at any time; press the [>] key on the "Ready" screen, then select [General Care].
- Once care is completed, the XW-100 provides a reminder at the same time, every 7 days thereafter.



XW-100 QUALITY CONTROL & STORAGE

Quality Control

Sysmex XW QC CHECK™ is a set of simulated whole blood samples. We run QC CHECK on the XW-100 to ensure the system is performing correctly.

- Sysmex will ship XW QC CHECK **every 28 days**. Upon arrival, unpack and store the container at room temperature.
- **DO NOT** freeze or expose the vials to excessive heat.
- The first vial is the "primary" vial to use each day testing is performed. The second vial is the "back-up" vial to use if the primary vial is broken, or if the XW-100 prompts for a new unused vial following a QC failure.
- There is sufficient quantity of XW QC CHECK to perform QC daily until the next lot arrives. When the new lot arrives, discontinue using the current lot and begin using the new lot **immediately**.
- The XW-100 requires the successful performance of all three levels of XW QC CHECK **every eight hours** when testing is being performed.
- When the screen displays "QC check is required," follow the on-screen instructions using the green adapter.

Storage Requirements

- All XW-100 reagents, XW CELLCLEAN™, and XW QC CHECK must be stored at room temperature (59° to 77° F or 15° to 25° C).
- Store XW CELLCLEAN in the box it was shipped in, until use.
- Keep the extra reagent, XW CELLCLEAN, and XW QC CHECK in a clean, dry location.
- The analyzer will not allow the use of reagents, XW CELLCLEAN, or XW QC CHECK that are past their expiration date, open container stability, or container cycle time.



XW QC CHECK Disposal Procedure

- This product must not be thrown away in regular garbage. Instead, throw away with infectious medical waste.
- Disposal by incineration is recommended. Requirements of applicable local regulations must be considered.



Specimen Storage

- It is recommended that samples be tested **immediately** following collection. However, samples may be stored at either room temperature or refrigerated and then run on the analyzer.
- Whole blood samples stored at room temperature (59° to 77° F or 15° to 25° C) are stable for up to 8 hours. Samples stored refrigerated (36° to 46° F or 2° to 8° C) are stable for up to 36 hours.
- Specimens that have been refrigerated must be warmed as instructed by the XW-100 before running. Any specimen that has been stored must be mixed thoroughly as instructed by the XW-100 prior to running.

XW-100 SAMPLE PROCESSING

Sample Preparation

The blood sample must:

- Be collected in an EDTA-K2 or K3 (purple top) vacuum tube as shown on the instrument's display screen.
- Be run within 8 hours of having been drawn, if stored at room temperature, or within 36 hours if refrigerated.
- Required sample volume: > 1 mL

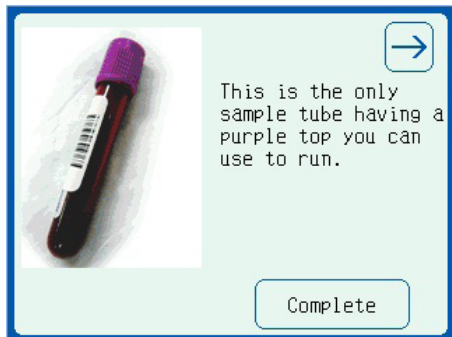
Instrument Preparation

- If the screen displays "QC Required," refer to the Quality Control section of this Quick Guide.
- If the screen displays "General Care Required," refer to the General Care section of this Quick Guide.

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XW-100 SAMPLE PROCESSING

Sample Processing



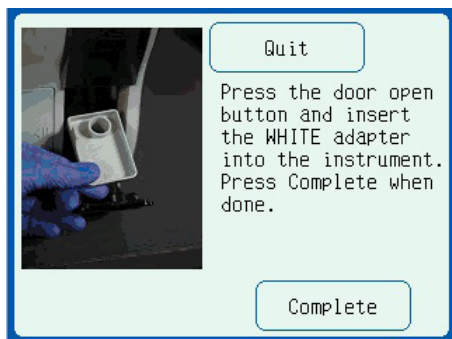
1. Confirm purple top blood collection tube is properly labeled.

NOTE:

This is the only sample tube with a purple top that may be used.

WARNING/LIMITATIONS:

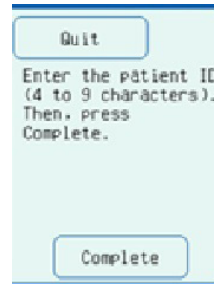
- Samples from children under 2 years of age must not be tested.



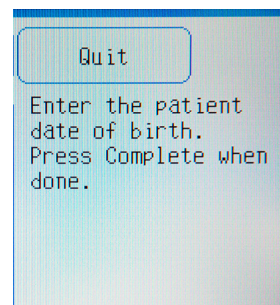
2. Insert the white adapter, when prompted.



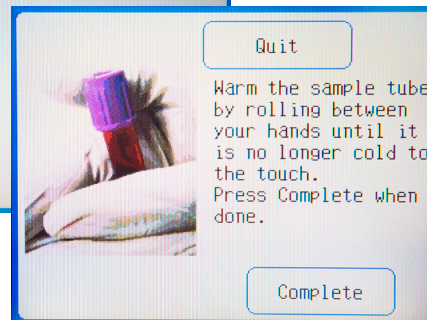
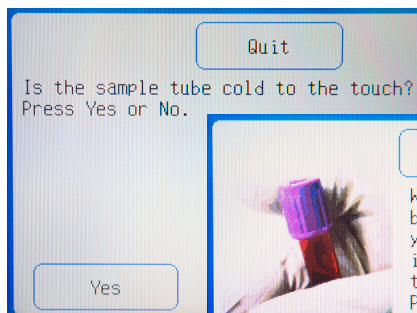
3. Enter the Operator ID.
4. Confirm the Operator ID.



5. Enter the Patient ID.
6. Confirm the Patient ID.



7. Enter the patient Date of Birth (DOB).
8. Confirm the patient DOB.

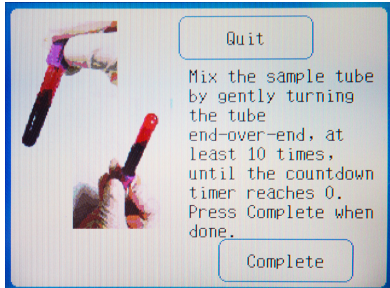


9. When asked if the collection tube is cold, touch [Yes] or [No]; if [Yes], follow the on-screen instructions to warm the collection tube.

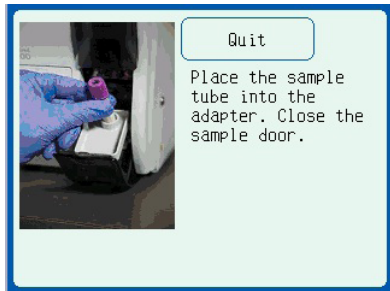
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XW-100 SAMPLE PROCESSING

Sample Processing, continued from previous page



10. Follow the on-screen instructions to mix the collection tube.



11. Insert the collection tube, then close the door.

Before inserting the tube:



After inserting the tube:



Review Results

IMPORTANT:

- Deliver the printed test results **promptly** to the person who ordered the test. All test results **must** be interpreted by a clinician.
- The thermal paper printout is **NOT** permanent; the operator must make a photocopy of the printout.
- If the operator is assigned the task of entering quantitative information into the electronic record, do so carefully and double check the information to limit transcription errors.

Processing the sample. This will take approximately 3 minutes. Please wait ...

Testing is complete. deliver the printout to the ordering Doctor, Nurse Practitioner or Physician Assistant. Press Continue to print the results.

Continue

12. Wait for the test cycle to complete.

XW-100 SYSTEM COMPONENTS



XW-100



Power Cord



Ethernet Cable



Waste Tubing



Barcode Reader



Reagent Tray



Green Adapter



White Adapter



Thermal Paper



Container Spout Kit
(XW pack D, XW pack L)



Waste Bottle



XW pack D



XW pack L



XW CELLCLEAN



XW QC CHECK

XW-100 SHUTDOWN

Shutdown

Shutdown of the XW-100 is not required. If your laboratory would like to shutdown the instrument, please refer to the instructions below.

1. Press the [↵] button in the upper right corner of the Main Screen; a second screen displays.
2. Press the [Move Instrument] button; this will cause the reagents to drain and the XW-100 to shut down.
3. Follow the on-screen instructions; you may be prompted to press the Power switch on the right side of the analyzer to complete Shutdown.

NOTE: Once shutdown has been performed:

1. The internet connection will need to be reestablished.
2. New reagents will need to be scanned to replace existing reagents.

XW-100 SAFETY INFORMATION

Waste Disposal

BIOLOGICAL RISKS:

After becoming waste at end-of-life, this instrument and its accessories are regarded as infectious. They are exempted from EU directive 2002/96/EC (Waste Electrical and Electronic Equipment Directive) and may **NOT** be collected by public recycling to prevent possible risk of infection of personnel working at those recycling facilities.

EMC Information

- This instrument complies with IEC 61326-1 (Class B, Group 1, Industrial environment)
- This equipment might be used in areas other than laboratories.
- EMI (Electromagnetic Interference): For this standard the requirements of class B are fulfilled.
- EMS (Electromagnetic Susceptibility): For this standard the minimum requirements with regards to susceptibility are fulfilled.
- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
- It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.
- If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- When XW-100 is installed, keep following distance between XW-100 and radio transmitter:

Radio transmitter	Maximum power (W)	Minimum separation distance (m)
Mobile phone Wireless LAN	0.2W~	0.9m~
Digital Convenience Radio	5W~	4.5m~

XW-100 SAFETY INFORMATION

Instrument Failure

If the instrument fails, contact your Technical Assistant Center (TAC). Please note the [ERROR CODE](#) to help the representative provide quick assistance.

1-800-779-7639

Equipment Operation and Ethernet Cable Connections

The connection of a non-shielded equipment interface cable to this equipment will invalidate the IEC Certification of this device and may cause interference levels which exceed the limits established by the IEC for this equipment. It is the responsibility of the user to obtain and use a shielded equipment interface cable with this device. Do not leave cables connected to unused interfaces. Changes or modifications not expressly approved by the manufacturer could void the warranty for the equipment.



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