



BEYOND A BETTER BOX™

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



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

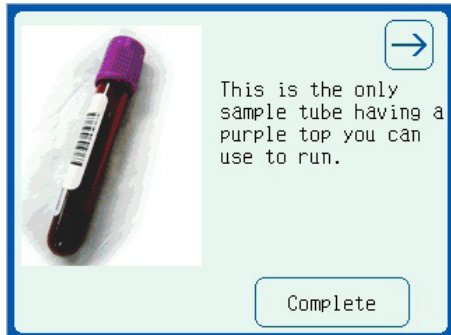
Instrument Preparation

- 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



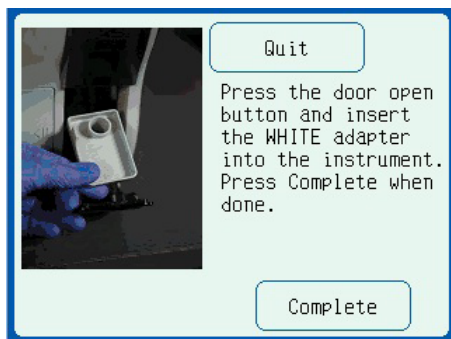
1. Confirm purple top blood collection tube is properly labeled.

NOTE:

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

WARNING/LIMITATIONS:

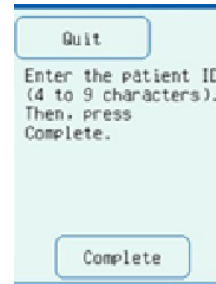
- Samples from children under 2 years of age must not be tested.



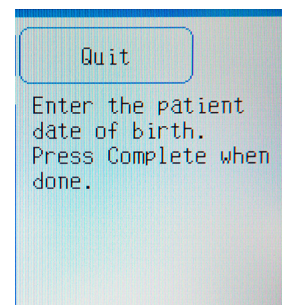
2. Insert the white adapter, when prompted.



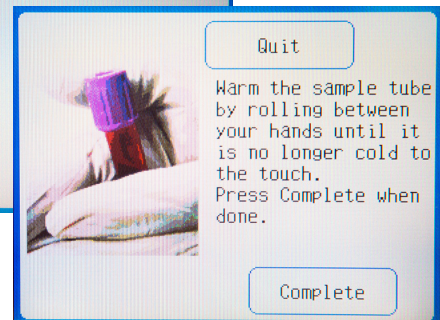
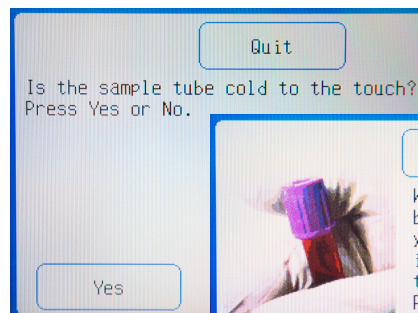
3. Enter the Operator ID.
4. Confirm the Operator ID.



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



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

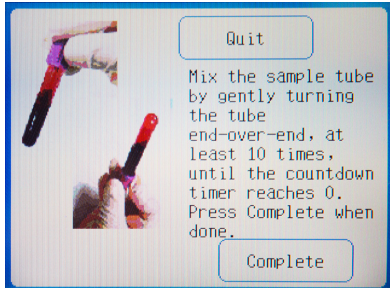


9. When asked if the collection tube is cold, touch [Yes] or [No]; if [Yes], follow the on-screen instructions to warm the collection tube.

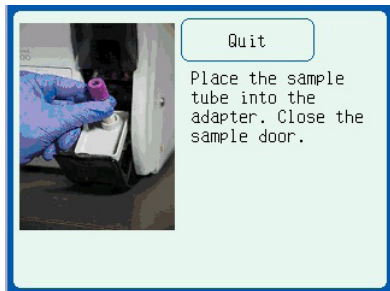
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XW-100 SAMPLE PROCESSING

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.

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.

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.

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 INSTRUMENT SHUTDOWN

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

NOTE: Once shutdown has been performed, the following will need to be completed upon start up:

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:

Once used, this instrument and its accessories are considered biohazardous. Do **NOT** dispose of the instrument, components, or waste in public trash containers. Please contact your Technical Assistant Center (TAC) for instructions on instrument, component, and waste disposal. 1-800-779-7639

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.

NOTES



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