

Cybersecurity Information

XW™-100

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.

The XW-100 requires an internet connection and because of this we understand the need for information regarding cybersecurity.

During operation, the XW-100 system requires access to the Sysmex Network Communications System (SNCS) server via a broad band internet connection. For cybersecurity reasons Sysmex recommends the XW-100 be connected to the internet via a firewall protected local area network (LAN) with appropriate anti-malware software installed on the network. In order to connect to the SNCS server, the firewall must be configured to allow Dynamic Host Configuration Protocol (DHCP) and outbound communication via port 443 Secure Socket Layer (SSL) access to the URL address pochi-sncs-ws.sysmex.com.



1. Why does the XW-100 require an internet connection?

- a. Internet connection is required when the device needs to validate reagent and QC lot numbers, expiration dates, and QC ranges. If no internet connection is available, operators will be unable to validate QC, and will therefore be locked out of operation until the connection is restored.

2. What are the site requirements for XW-100 functionality?

- a. Power (110V) and one ethernet (RJ45) network connection is needed.
- b. An IP address provided by DHCP
- c. Access to the internet over port 443.

3. What does the XW-100 connect to?

Sysmex secure SNCS server exclusively.

4. Is the communication between the XW-100 and Sysmex secure?

Yes. The communication between the XW-100 and Sysmex is secured over SSL/TLS with 128-bit encryption

5. What data is sent by XW-100 to Sysmex?

The information sent from XW-100 to Sysmex consists of reagent Lot information and control values. No PHI is sent.

6. Can the XW-100 send or receive data from the LIS or other local data sources?

No, the XW-100 can only connect to SNCS. The XW-100 cannot interface to a Laboratory Information System or any other internal customer systems.

7. What data is stored on the XW-100?

Data related to the last 100 samples run on the XW-100 are stored on the device. This contains no PHI and it is over written as new samples are run on a first in first out basis.

8. How does the XW-100 prevent unauthorized user access?

The XW-100 is only able to be accessed by users standing in front of the device. It is expected that the XW-100 will be kept in a secure office or lab setting.

9. How do users login to the XW-100?

There are no user logins. The XW-100 does not utilize user accounts.

10. How does the XW-100 prevent unauthorized network access?

The XW-100 is unable to be accessed from the outside over the network. All communication with the XW-100 is initiated by the XW-100 and only to one SNCS IP for data checking purposes. There are no active services on the device to connect to.

11. Does the XW-100 support a web interface or application?

No, the XW-100 does not support a webserver or any type of web-based application.

12. How does the XW-100 prevent users from accessing unauthorized internet or intranet locations?

The XW-100 does not support any type of web browser, email or other application which could connect to an internet or intranet site. The XW-100 can only connect to the SNCS site for specific automated, SNCS data checking purposes.

13. How does the XW-100 prevent unauthorized files being saved to the device such as malware?

The XW-100 has no direct logical or electronic means of user access via files cannot be copied into place.

14. How does the XW-100 prevent unauthorized devices like USB drives from connecting?

There are no USB ports. There is no optical drive (CD/DVD ROM) or means of connecting an optical drive.

15. What antivirus software does the XW-100 run?

The XW-100 is a secure system with no user access to the file system or other ability to load malware or viruses onto the system.

16. What are the specifications of the XW-100?

The XW-100 is an integrated medical device with embedded logic and processing functionality.

17. What operating system does the XW-100 run?

The XW-100 runs a proprietary version of embedded Linux compiled specifically for the instrument.

18. What safeguards does Sysmex have in place to protect me?

- a. The operating system and internal services are inaccessible except through the provided user interface.
- b. The XW can only communicate with the SNCS system
- c. The XW initiates all communication
- d. All communication is encrypted.