Urgent Field Safety Notice

794400008

October 2022

XQ series: Incorrect WBC result output to the host computer

Product Name	XQ-320; XQ-520
Product Description	XQ-Series Automated Hematology Analyzer
Affected Serial No	all
Type of Action	Advice given by manufacturer regarding use of the IVD
FSCA-identifier	794400008

Dear valued customer,

This Field Safety Notice (FSN) is intended to provide information about a potential risk of incorrect white blood cell count (WBC) results that could lead to incorrect treatment.

IMPORTANT NOTE: This FSN applies only to analysers connected to host computers via serial connection and only when a legacy data transfer format (KX21N or XP series standard) is used!

To date, Sysmex has not received any incident report of misdiagnosis and mistreatment as a result of the malfunction described below.

Description of the situation:

During a new installation, Sysmex became aware of the risk of incorrect (false high) WBC results being output to LIS host computers connected to a Sysmex XQ-Series Automated Hematology Analyzer. Through investigations of the legal manufacturer Sysmex Corporation Japan, the malfunction could be reproduced and confirmed.

WBC value results transmitted from the analyser to a host computer are 10 times higher than the correct results displayed on the analyser screen.
This malfunction occurs only when you use a serial connection and a legacy data transfer format (KX21N or XP series standard) and is caused by the **[Serial connection]** and **[TCP/IP connection]** settings not matching. Due to a software bug, the host format setting selected for TCP/IP is used, even when a serial connection is used.
See example screenshots below:

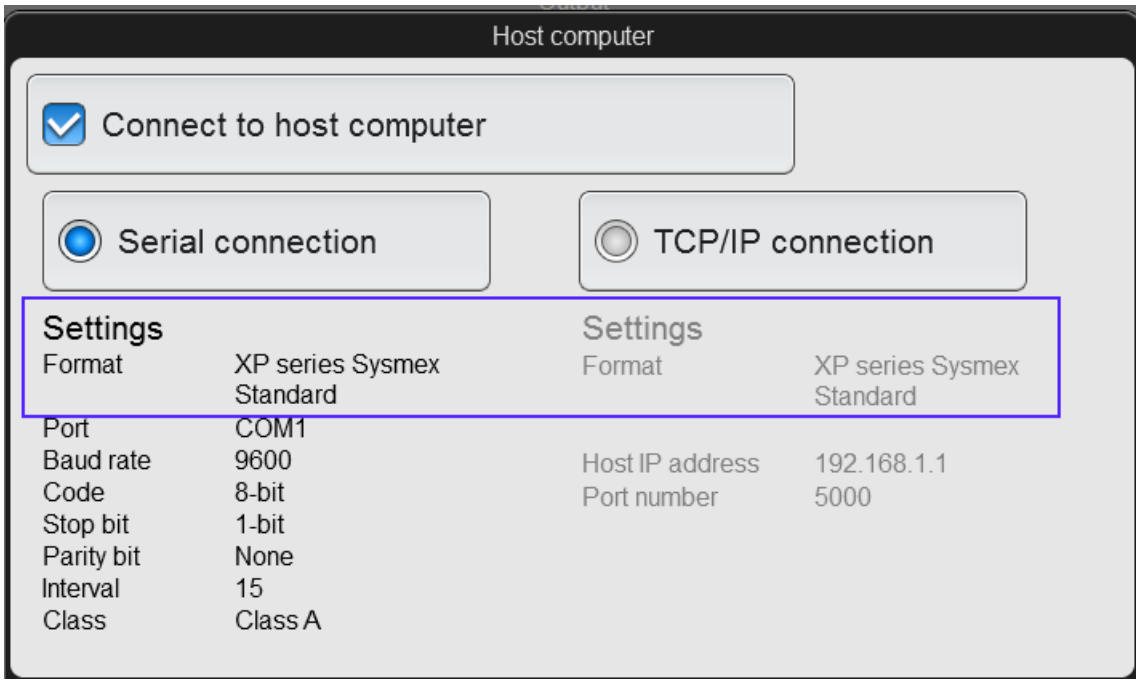

Figure 1: Example screenshot of the correct settings – the issue does **not** occur.

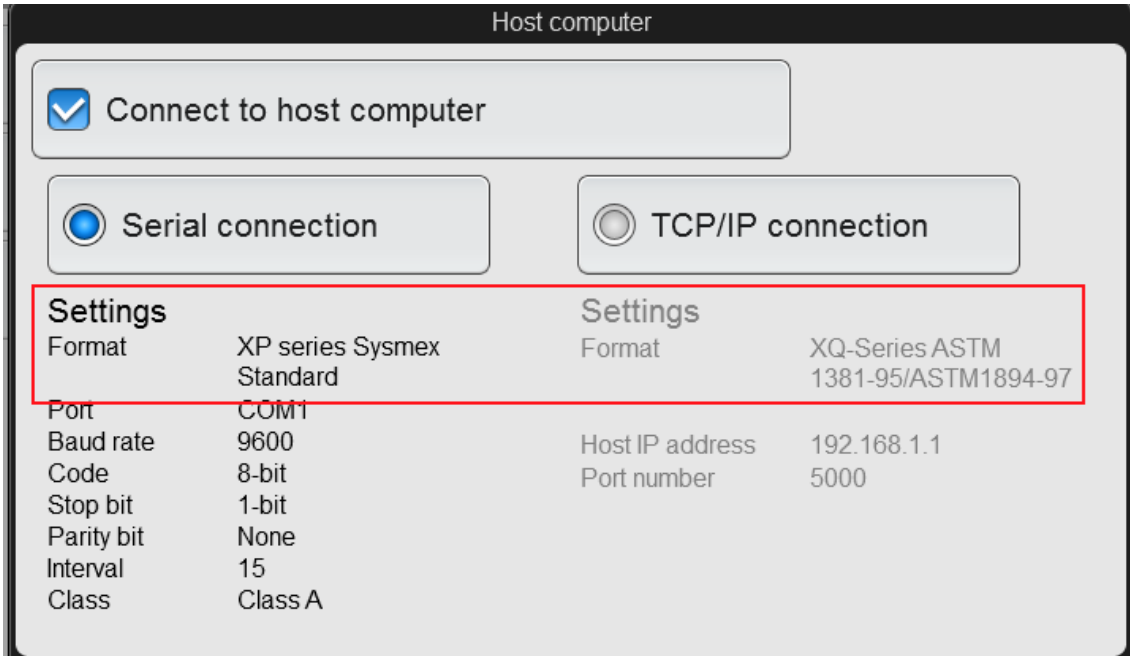

Figure 2: Example screenshot of affected settings – the issue does occur.

Risk to health:

When the issue occurs, all WBC results transmitted to a host computer are affected.
A risk to patient health is likely if pathologically low WBC results generated by the XQ analyser are transmitted to the host computer that are falsely high but physiologically normal:
(a) Leukopenia (and in most cases, neutropenia) may be misdiagnosed as normal leukocyte levels, leading to delay in detection, diagnosis, treatment of the underlying diseases and prophylaxis against infection.
(b) If low WBC levels (leukopenia) are misjudged as normal levels, the investigation of the causal diseases, the definite diagnosis, and the preventive measures against infection may be delayed, resulting in the progression of severe infections and leukaemias.

Actions to be taken by Sysmex:

1. Sysmex will update and release the XQ analyser software including correction of this issue around end of January 2023.

Actions to be taken by the user:

1. Confirm whether the WBC results in the analyser software and in the LIS on the host computer match.

2. If WBC results do not match, that is, if WBC results on the host computers are higher by a factor of 10, change the host computer setting. The data format of **[TCP/IP connection]** must be the same as the data format of [Serial connection].

   Example screenshot:

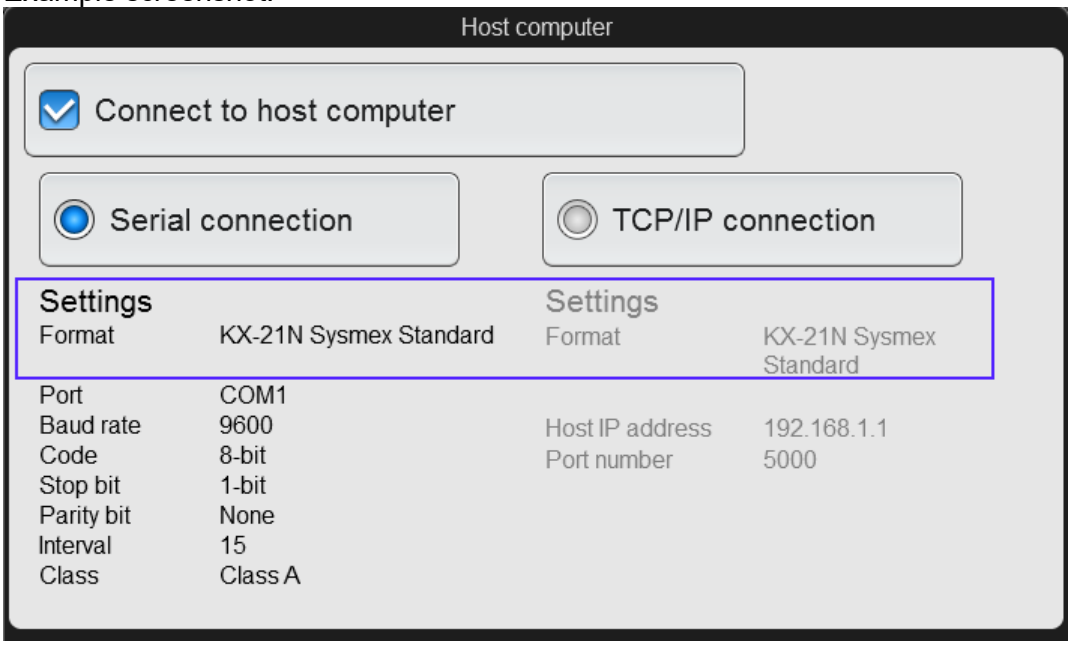

Figure 3: Example screenshot of the host computer settings with a matching [TCP/IP setting] and data format of [Serial connection].

3. Distribute this FSN to all responsible persons within your organisation and return the Acknowledgement of Receipt (AoR) with your signature by the end of November 2022 to your authorised local Sysmex representative.

4. Review the analysis results and perform re-testing as necessary if the malfunction has occured.

Communication of this Field Safety Notice:
Distribute this FSN to all responsible persons who need to be aware within your organisation.

To comply with regulatory requirements, we request that you complete the enclosed response form (AoR) and return it with your signature to your authorised local Sysmex representative by the end of November 2022.

We deeply apologise for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours

Sysmex Europe SE

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Person responsible for regulatory compliance

Customer's Acknowledgment of Receipt (AoR)

We hereby confirm the receipt of Field Safety Notice 794400008 issued in October 2022 concerning the Field Safety Corrective Action on

XQ series: Incorrect WBC result output to host computer.

We hereby also confirm that the described Immediate Action (Actions to be taken by the user) will be applied by us.

Analyser(s) and serial number(s) .....

Institution .....

Address .....

Responsible & authorised person .....

Signature .....

Date .....