

Date Issued: 23 August 2022

Action Type: IFU Manual Update

Detail on Affected Device:

Device Name	Product Number
Nexus IB10 Analyzer	IVR-IB59
Nexus IB10 Analyzer User Manual v7.0	022-00063, Rev. B

Based on a recent assessment and investigation, we have determined the information as outlined in the Nexus IB10 Analyzer User Manual on the use of the USB memory stick for Backup of Patient, QC and EQC results might be misleading related to its function. Data can be saved onto a USB memory stick, however, to protect patient privacy, the data is encrypted and cannot be retrieved. This feature was designed to comply with security controls that are in place as part of the software programming design.

In line with the requirements and implementation of the *In Vitro* Diagnostic Device Regulations (IVDR) Nexus Dx aim to provide the most accurate and up-to-date information on our Instructions for Use (IFU). For this reason, the Nexus IB10 Analyzer User Manual (part number 022-00063) is updated to remove the function of the USB memory stick for Backup of Patient, QC and EQC results.

This Technical Bulletin will be posted on the Nexus Dx website www.nexus-dx.com.

For any questions or inquiries regarding the Nexus IB10 Analyzer, please contact SpingoTec Customer Support at customer.support@sphingotec.com or (tel) + 49 (0)330 220 56 5 – 0.