

MKT-00226 revA

Nio® Analyzer software v1.5

Instructions for Download & Release Note

For Research Use Only. Not for use in diagnostic procedures.

Product Name

Nio® Analyzer software Standard mode (S50000) and Nio® Analyzer software Regulatory mode (S50021)

Intended Use

The Nio® Digital PCR for Crystal Digital PCR® is composed of the Nio® Digital PCR instrument, either in its Nio® E, Nio® or Nio® + configuration, which performs droplet generation and amplification, and enables imaging of the Droplet Crystal in up to 3 to 7 detection channels. The Nio® Reader software is used to control and set up Crystal Digital PCR® experiments on the Nio® Digital PCR.

The Nio® Analyzer software is used to extract data from the images acquired using the Nio® Digital PCR and to calculate the absolute concentrations of the targeted nucleic acids.

Both Nio® Reader software and Nio® Analyzer software are pre-installed on the Nio® Digital PCR.

Both Nio® software are available in two modes: Standards or Regulatory. The latter enables Nio® Digital PCR users (customers) to meet the Food and Drug Administration's regulations on good laboratory practices (GLP) as well as good manufacturing practices (GMP) in pharmaceutical as well as biotechnology industries. Nio® Analyzer software Regulatory provides the necessary features to permit the Nio® Digital PCR to operate, in compliance with Title 21 of the U.S. Code of Federal Regulations Part 11 (21 CFR Part 11), within a closed system. A closed system is defined as "an environment in which system access is controlled by the persons who are responsible for the content of electronic records that are on the system". The customers choose between Standard or Regulatory mode when installing or updating Nio® Analyzer software.

In Regulatory mode, Nio® Analyzer software operates in conjunction with naica® Data Service, the latter functions as the Nio® Digital PCR user account manager and ensures the compliance of all Nio® Digital PCR operations with respect to regulation 21 CFR Part 11. Please refer to the Nio® Digital PCR User Manual for detailed instructions of use of naica® Data Service.

Note: The security controls built into Nio® Analyzer software must be properly configured and administered by the Nio® Digital PCR administrator(s) in the customer's organization to be secure and in compliance with 21 CFR Part 11. Stilla® Technologies makes no claim that Nio® Analyzer software is 21 CFR Part 11 compliant in and of itself, nor does the company guarantee compliance for the user. The Nio® Digital PCR user organization must establish policies and standard operating procedures (SOPs) that work in conjunction with the tools provided by Stilla® Technologies to ensure compliance with 21 CFR Part 11.

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The Nio® Analyzer software is intended for use by professional users trained in molecular biological techniques and in the operation of the Nio® Digital PCR and Nio® Reader software.

The Nio® Analyzer software is part of the Nio® Digital PCR.

The Nio® Digital PCR is intended for Research Use Only. Not for use in diagnostic procedures.

Purpose of the Release Note and Instructions for Download

This document provides an overview of the implemented changes, from the previous software version 1.3.12.3 to version 1.5.8.3, for Nio® Analyzer software. Stilla Technologies recommends installing the software update to benefit from all the described bug fixes, feature improvements and new software features that are only available with version 1.5.8.3

This document provides a step-by-step guide to install the required Nio® Analyzer software update to run Crystal Digital PCR® experiments on the Nio® Digital PCR instruments.

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Resources

Please consult the latest version of the User Manual for the Nio® Digital PCR instruments available under the “Downloads” tab in the “Product Information” section of the website.

The installer files for Nio® Reader and Nio® Analyzer software are available for free to download at:

<https://www.bio-rad.com/fr-fr/product/nio-system?ID=9d6dac6d-4584-a142-2cce-f1b84b48e731>

Download and Installation

To update Nio® Reader and Nio® Analyzer software to the latest version, double click on the respective software product and proceed with the supported download instructions.

Please refer to the User Manual to get additional information about the installation workflow.

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Release Notes

The section below provides an overview of the implemented changes, from the previous software version 1.3.12.3 to version 1.5.8.3, for Nio® Analyzer software.

The information is provided for:

- New software features
- Feature enhancements
- Bug fixes

New software features	Description
Droplet Detection Algorithm	The Nio® Analyzer software version 1.5.8.3 contains a perfected droplet detection algorithm. This new version is able to estimate individual droplet size of each chamber and adapt the concentration calculation accordingly for data files produced with Nio Reader v1.5 configuration.

Feature enhancements	Description
User Interface	Addition of a waiting widget when applying post processing configuration instead of freezing.
Recomputation time optimization	Population data is only being recomputed when zone change have been applied

Bug fixes	Description
Setup	When merging two niodata files, the protocol is only visible on the first one (given that the two niodata files contain compatible nioprotocol details)
Compensation Matrix	Software no longer crashes when user sets negative-value for threshold
2D dot plot	Population selection eye icon is no longer hidden when a selection is active. Population selection in plots is reset after population removal. Upper/Lower bound RFU value is updated in settings pop-up after changing population Axis
3D dot plot	3D dotplot axis are now renamed according to dyes names
Population Editor	The name part in Population editor's zone list now scales with font to allow full visibility.

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Post-processing	Correction of dilution use in post processing results. For Linkage analysis: Display of information message about dilution factor use that is always =1
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For a detailed list of known anomalies, please contact our customer support team.

Technical Support Contact Information

For technical support inquiries:

- **United States:** support@bio-rad.com | 1-800-424-6723[AA1]
- **Austria / Germany / Switzerland:** cts-ce@bio-rad.com | 00 800 00 24 67 23
- **France:** sp-lsg@bio-rad.com | 00 800 00 24 67 23
- **Denmark:** techsupport.nordic@bio-rad.com | 00 800 00 24 67 23
- **United Kingdom:** lsgtechsupport.uk@bio-rad.com | 00 800 00 24 67 23
- **Belgium / Netherlands:** cts.benelux@bio-rad.com | 00 800 00 24 67 23