

## Nio® Analyzer software v1.3

### 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 1.2.8.3 to version 1.3.12.3, 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 1.3.12.3

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 “User Manual” tab in the “Technical Resources” section of the website.

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

[https://www.stillatechnologies.com/downloads/Setup\\_NioInstaller\\_v1.3.8.3-45833.exe](https://www.stillatechnologies.com/downloads/Setup_NioInstaller_v1.3.8.3-45833.exe)

And

[https://www.stillatechnologies.com/downloads/Setup\\_NioAnalyzerInstaller\\_v1.3.12.3-46259.exe](https://www.stillatechnologies.com/downloads/Setup_NioAnalyzerInstaller_v1.3.12.3-46259.exe)

### Download and Installation

Visit [www.stillatechnologies.com](http://www.stillatechnologies.com)

Under “Learning & Resources” and select “**Support**”

Select “**Technical Resources**”

To access the restricted area please proceed by entering the user-specific credentials: the user specific credentials were provided during the initial installation of the Nio® Digital PCR instrument.

*If you do not have the required details to access the restricted “Technical Resources” section, please contact your regional support team.*

The installer files for Nio® Reader and Nio® Analyzer software are available for free under “SOFTWARE DOWNLOADS”

Select the Nio® Digital PCR specific software download page to download the respective download files:

[https://www.stillatechnologies.com/downloads/Setup\\_NioInstaller\\_v1.3.8.3-45833.exe](https://www.stillatechnologies.com/downloads/Setup_NioInstaller_v1.3.8.3-45833.exe)

And

[https://www.stillatechnologies.com/downloads/Setup\\_NioAnalyzerInstaller\\_v1.3.12.3-46259.exe](https://www.stillatechnologies.com/downloads/Setup_NioAnalyzerInstaller_v1.3.12.3-46259.exe)

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.

## Release Notes

The section below provides an overview of the implemented changes, from the previous software version 1.2.8.3 to version 1.3.12.3, for Nio® Analyzer software.

The information is provided for:

- New software features
- Feature enhancements
- Bug fixes

New software features	Description
New fields	<p>Pooling, Result graphs: Addition of the Uncertainty curve and the Concentration plots for a pool, on top of the pooled chambers.</p> <p>Addition of a "Language" item in File menu to switch between English and Chinese</p> <p>Addition of the Protocol ramp rate in the "View Protocols" pop-up window of the "Edit Experiment" tab, and the exported PDF report</p> <p>Allow the modification of min/max values per axis in the 3D dot-plot section</p> <p>Addition of the Post-Processing menu composed of the Set-up and Results table submenus, which allow computing Copy Number Variation, Gene Expression, Mutant Allelic Fraction and to analyze Linkage.</p> <p>Recording of the Post-Processing Set-up in the .nioresults file format</p> <p>Saving of the Post-Processing Set-up in the .nca configuration file</p> <p>Addition of the Post-Processing Set-up and Results in the exported data</p> <p><b>[Regulatory mode only]</b> Addition of the Post-Processing Set-up and Results in the PDF report and audit trail. Editing Post-Processing set-up is not permitted after the experiment has been signed.</p>
<b>[Regulatory mode only]</b> Individual User authentication	Change of the login method: the user must use the default and locked value to log in.

Feature enhancements	Description
<b>About page</b>	Replacement of the Trademark symbol by the registered symbol for the brand Nio®
<b>Channel color</b>	Renaming long-Shift channel to Purple channel

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<b>Windows version</b>	Software compatibility with both 64bit Windows 10 Pro and Windows 11 Pro
<b>General</b>	Increase of the disk capacity until saturation from 30Go to 40Go

<b>Bug fixes</b>	<b>Description</b>
1D dot Plot	Correction of the threshold size in 1D dot-plot .svg export image
[Regulatory mode only] <b>naica® Data Service</b>	An error message is displayed in Nio Analyzer Regulatory when naica® Data Service is unreachable

For a detailed list of known anomalies, please contact our customer support team.

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**Technical Support Contact Information**

Stilla Technologies

F-94800 Villejuif, FRANCE

Online Technical Support is also available at: [www.stillatechnologies.com/technical-support/](http://www.stillatechnologies.com/technical-support/)

For help and technical advice or any issue regarding Nio® Reader software and Nio® Analyzer software update contact us:

For all customers:

Monday to Friday, 9:30 AM - 6:30 PM Central European Time (CET).

Closed on French bank holidays.

Phone: (+33) 9 82 27 47 47

Email: [support-stilla@bio-rad.com](mailto:support-stilla@bio-rad.com)

Pat.: [www.stillatechnologies.com/patents](http://www.stillatechnologies.com/patents)

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