

Nio® Reader software v1.3

Instructions for Download & Release Note

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

Product Name

Nio® Reader software Standard mode (S40000) and Nio® Reader software Regulatory mode (S40021)

Intended Use

The Nio® Reader software functions as the user interface to set up all experiment parameters (amplification, image acquisition) on the Nio® Digital PCR for a single automated Crystal Digital PCR® workflow. Nio® Reader software is 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 industry.

Nio® Reader 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® Reader software.

The Nio® Reader software:

- Allows defining the analytical context of the experiments. Experiments can be set up on-demand or dedicated experimental templates can be created for recurring experimental setups.
- Controls the Nio® Digital PCR instrument for the acquisition of the fluorescence images.
- Applies pre-analysis treatments to the acquired images and provides a first quality control in preparation for the detailed downstream experiment analysis performed by the Nio® Analyzer software.
- In Regulatory mode, Nio® Reader 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. In Regulatory mode, locked standard experiments can be generated for routine use.

Note: The security controls built into Nio® Reader 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® Reader 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.

Nio® Reader software, Nio® Analyzer software and naica® Data Service are intended for use by laboratory personnel trained in the techniques of Crystal Digital PCR®.

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

The Nio® Digital PCR instruments are 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 1.2.9.3 to version 1.3.8.3, for Nio® Reader 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 1.3.8.3

This document provides a step-by-step guide to install the required Nio® Reader 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

And

https://www.stillatechnologies.com/downloads/Setup_NioAnalyzerInstaller_v1.3.12.3-46259.exe

Download and Installation

Visit 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

And

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 1.2.9.3 to version 1.3.8.3, for Nio® Reader software.

The information is provided for:

- New software features
- Feature enhancements
- Bug fixes

New software features	Description
Assay edition	A message displays information about the presence of a Post-Processing configuration embedded in the .nca file selected.
Shutdown	Addition of a popup window indicating to the user that shutdown cannot be performed while a run is ongoing Addition of a popup window when shutdown is triggered, followed by a success popup
View Results	Ability to automatically set the contrast for each channel individually. The settings of contrast and brightness remain when navigating from one channel to another
Split run	In the context of a split output niodata file, according to the assays or protocol used, addition of the timestamp in the different filename
Log files	Addition of the chip status update Addition of information on the instrument use history: creation of log files per run, per timestamp and addition of chip barcode logfile

Feature enhancements	Description
Installer	Setting of the right default address in installer when selecting “allow remote connections”
About page	Addition of the mentions: “International Design DM/238908” and “Chinese design patent No. ZL 2023 3 0731964.3” Replacement of the Trademark symbol by the registered symbol for the brand Nio®
Protocols	Renaming Long-Shift channel to Purple channel
Experiments	Allow dilution factor to reach 10 digits Limitation of auto naming feature to selected chambers

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	Systematic activation of the blue channel to ensure tile capture with enough overlap to take into account the mechanical play and stitching performance
Chip Plate Unloading	Addition of a popup window while a Chip Plate is unloading, indicating when the Chip Plate can be grabbed
Windows version	Software compatibility with both 64bit Windows 10 Pro and Windows 11 Pro
General	Increase of the disk capacity until saturation from 30Go to 40Go

Bug fixes	Description
Digital Experiment Page / Assay	The assayID only applied to an assay with sample
Plan&Start page / Chip plate availability	The color of the label indicating the availability of the chip plate in the lift is now visible in light mode.
View Results page / Contrast, Brightness	Contrast/Brightness are applied to the selected chamber:
Digital Experiment Page / View Assay	Adaptation of the pop-up window to display the correct long ncm/nca/ncp file name
Digital Experiment Page /Chamber naming	Auto naming button is disabled after chamber deactivation:
Image Processing	The mask is now correctly applied in the droplets image.

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/

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

Pat.: www.stillatechnologies.com/patents

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