

## **MKT-00227 revA**

### **Nio® Reader software v1.5**

#### 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®.

**Nio® Reader software v1.5**  
**Instructions for Download & Release Note**  
**MKT-00227 revA**

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 1.3.8.3 to version 1.5.10.3, 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 1.5.10.3

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.

## Table of Content

Product Name .....	1
Intended Use .....	1
Purpose of the Release Note and Instructions for Download .....	2
Resources .....	4
Download and Installation.....	4
Release Notes.....	5
Technical Support Contact Information.....	6

**Nio® Reader software v1.5**  
**Instructions for Download & Release Note**  
**MKT-00227 revA**

**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.

**Nio® Reader software v1.5**  
**Instructions for Download & Release Note**  
**MKT-00227 revA**

**Release Notes**

The section below provides an overview of the implemented changes, from the previous software version 1.3.8.3 to version 1.5.10.3, for Nio® Reader software.

The information is provided for:

- New software features
- Feature enhancements
- Bug fixes

New software features	Description
<b>Droplet Detection Algorithm</b>	<p>The Nio® Reader software version 1.5.10.3 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.</p> <p><b>! Warning!</b> To make sure that the new droplet detection algorithm is implemented, open and save the .nioprotocols that are created with the previous version using the latest Nio® Reader software version 1.5.10.3 in order to update the embedded droplet detection configuration. This update protocol is absolutely required to be taken account in the experiment files.</p>
<b>Protocol Edition</b>	Channel coherence is verified when loading .nca, .ncm, .ncp, during protocol creation.
<b>Mix compatibility</b>	<p>The Nio® Reader software version 1.5.10.3 is compatible with these following mixes:</p> <ul style="list-style-type: none"><li>• naica Multiplex ddPCR Mix</li><li>• naica ddPCR Mix</li><li>• QX700™ One-Step RT-ddPCR Kit for Probes</li><li>• QX700™ ddPCR™ EvaGreen® Supermix</li></ul> <p>qScript XLT 1-Step RT-qPCR ToughMix is not compatible with the Nio® Reader software version 1.5.10.3. It is still compatible with the previous version of Nio® Reader software 1.3.8.3</p>
<b>File download</b>	User may personalize a custom path as output path for .niodata when downloading run result directly or remotely

**Nio® Reader software v1.5**  
**Instructions for Download & Release Note**  
**MKT-00227 revA**

<b>Data size optimization</b>	The .niodata output file is lighter with The Nio® Reader software version 1.5.10.3 without compromising precision. Example: A niodata file with 6 channels and 48 chambers was 4 GB in size in version 1.4, compared to 1 GB in version 1.5.10.3.
-------------------------------	--

<b>Feature enhancements</b>	<b>Description</b>
<b>Installer</b>	UI/UX improvement for the installers
<b>Digital Experiments Page</b>	The “Chip Label” field has been removed from the DIGITAL EXPERIMENTS page.

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