

naica® Analysis Pro v4.1

Release Note

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

Impacted product

naica® Analysis Pro (S30021) (part of the naica® system Pro software and the naica® system)

21 CFR Part 11

Purpose of the release note

The purpose of this document is to detail the implemented changes from the previous version v4.0.10.3 to version v4.1.34.3 for naica® Analysis Pro.

Implemented changes

Improvements of software features and PDF Report

Improvements	Modification list																																																																																																																																																																																																																																																										
Display of summary results table in PDF report	<p>In the PDF report generated with naica® Analysis Pro v4.0, the results were only displayed one after the other on sequential pages for each chamber individually. It was therefore difficult to get an overview of the results for all chambers at once.</p> <p>In the PDF report generated with naica® Analysis Pro v4.1, the results of all chambers are summarized in a single table as shown below:</p> <div data-bbox="365 1192 1526 1638" data-label="Table"> <p>Result Table</p> <table border="1"> <thead> <tr> <th></th> <th>Population</th> <th>Dilution Stock</th> <th>C (cp/μl)</th> <th>Number of positive droplets</th> <th>Number of negative droplets</th> <th>Separability Score</th> <th>C min (cp/μl)</th> <th>C max (cp/μl)</th> <th>Relative Uncertainty (%)</th> </tr> </thead> <tbody> <tr><td>S-0674824-1-A1</td><td>Blue Channel</td><td>1</td><td>8044.4</td><td>22934</td><td>153</td><td>3</td><td>7809.2</td><td>8320</td><td>3.2</td></tr> <tr><td>Sample 1</td><td>Green Channel</td><td>1</td><td>8433.9</td><td>22967</td><td>120</td><td>2.3</td><td>8170.6</td><td>8749.2</td><td>3.4</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>750.6</td><td>8630</td><td>14457</td><td>1.7</td><td>734.7</td><td>766.7</td><td>2.1</td></tr> <tr><td>S-0674824-1-B1</td><td>Blue Channel</td><td>1</td><td>815.7</td><td>7673</td><td>11571</td><td>6.2</td><td>797.4</td><td>834.3</td><td>2.3</td></tr> <tr><td>Sample 2</td><td>Green Channel</td><td>1</td><td>808.8</td><td>7623</td><td>11621</td><td>3.7</td><td>790.6</td><td>827.3</td><td>2.3</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>695</td><td>6768</td><td>12476</td><td>1.7</td><td>678.4</td><td>711.7</td><td>2.4</td></tr> <tr><td>S-0674824-1-C1</td><td>Blue Channel</td><td>1</td><td>298.4</td><td>3406</td><td>16654</td><td>6.9</td><td>288.4</td><td>308.5</td><td>3.4</td></tr> <tr><td>Sample 3</td><td>Green Channel</td><td>1</td><td>291.9</td><td>3338</td><td>16722</td><td>3.8</td><td>282</td><td>301.8</td><td>3.4</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>723.7</td><td>7286</td><td>12774</td><td>1.7</td><td>707</td><td>740.6</td><td>2.3</td></tr> <tr><td>S-0674824-1-D1</td><td>Blue Channel</td><td>1</td><td>8.4</td><td>109</td><td>20746</td><td>6.8</td><td>6.8</td><td>10</td><td>18.8</td></tr> <tr><td>Sample 4</td><td>Green Channel</td><td>1</td><td>9.6</td><td>124</td><td>20731</td><td>3.2</td><td>7.9</td><td>11.2</td><td>17.6</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>855.4</td><td>8622</td><td>12233</td><td>1.7</td><td>837.3</td><td>873.8</td><td>2.1</td></tr> <tr><td>S-0674814-2-A2</td><td>Blue Channel</td><td>1</td><td>0.7</td><td>10</td><td>21894</td><td>5.7</td><td>0.3</td><td>1.2</td><td>62</td></tr> <tr><td>Sample 5</td><td>Green Channel</td><td>1</td><td>27.2</td><td>368</td><td>21536</td><td>2.2</td><td>24.4</td><td>29.9</td><td>10.2</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>790.2</td><td>8522</td><td>13382</td><td>1.7</td><td>773.3</td><td>807.2</td><td>2.1</td></tr> <tr><td>S-0674814-2-B2</td><td>Blue Channel</td><td>1</td><td>0.2</td><td>3</td><td>20577</td><td>15.5</td><td>-0</td><td>0.5</td><td>113.2</td></tr> <tr><td>Sample 6</td><td>Green Channel</td><td>1</td><td>1.3</td><td>17</td><td>20563</td><td>2.2</td><td>0.7</td><td>2</td><td>47.5</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>733.9</td><td>7558</td><td>13022</td><td>1.7</td><td>717.3</td><td>750.7</td><td>2.3</td></tr> <tr><td>S-0674814-2-C2</td><td>Blue Channel</td><td>1</td><td>15862.3</td><td>19770</td><td>1</td><td>nan</td><td>14122.2</td><td>inf</td><td>inf</td></tr> <tr><td>Sample 7</td><td>Green Channel</td><td>1</td><td>14750.8</td><td>19769</td><td>2</td><td>4.3</td><td>13356.4</td><td>inf</td><td>inf</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>712.9</td><td>7096</td><td>12675</td><td>1.7</td><td>696.3</td><td>729.7</td><td>2.3</td></tr> <tr><td>S-0674814-2-D2</td><td>Blue Channel</td><td>1</td><td>3201</td><td>17613</td><td>2769</td><td>8.1</td><td>3146.4</td><td>3257.5</td><td>1.7</td></tr> <tr><td>Sample 8</td><td>Green Channel</td><td>1</td><td>3162.6</td><td>17546</td><td>2836</td><td>3.9</td><td>3108.8</td><td>3218.3</td><td>1.7</td></tr> <tr><td>Validity: Valid</td><td>Red Channel</td><td>1</td><td>701.8</td><td>7224</td><td>13158</td><td>1.7</td><td>685.5</td><td>718.1</td><td>2.3</td></tr> </tbody> </table> </div> <p>For details of all the information now included in the PDF report, please refer to section 5.3.3 in the latest the naica® system Pro software User Manual version (MKT-00150 Rev. 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Display of summary QC	<p>Unlike in naica® Analysis Pro v4.0, in Analysis Pro v4.1 the QC indicators are now exported in the PDF report in a single table for all chambers in the experiment. The addition of this table should help users to easily trace information relevant to the analysis of the experiment. The QC indicator table is displayed in the PDF report as shown below:</p>																																																																																																																																																																																																																																																										

indicators table in PDF report

Quality Indicators

ChamberID	Sample Name	Chamber Context	Image Sharpness		Nb Analyzable Droplets		Nb Saturated Objects		Global QC Chamber
			QC Flag	Score	QC Flag	Score	QC Flag	Score	
S-0674824-1-A1	Sample 1	n.a.	High	0.106094	High	23087	High	4	High
S-0674824-1-B1	Sample 2	n.a.	High	0.107518	High	19244	High	4	High
S-0674824-1-C1	Sample 3	n.a.	High	0.106920	High	20060	High	4	High
S-0674824-1-D1	Sample 4	n.a.	High	0.106513	High	20855	High	4	High
S-0674814-2-A2	Sample 5	n.a.	High	0.102723	High	21904	High	5	High
S-0674814-2-B2	Sample 6	n.a.	High	0.101853	High	20580	High	4	High
S-0674814-2-C2	Sample 7	n.a.	High	0.102124	High	19771	High	3	High
S-0674814-2-D2	Sample 8	n.a.	High	0.097852	High	20382	High	2	High

For details of all the information now included in the PDF report, please refer to section 5.3.3 in the latest the naica® system Pro software User Manual version (MKT-00150 Rev. C).

Display of chip layout in PDF report

Unlike in naica® Analysis Pro v4.0, in naica® Analysis Pro v4.1 the Chip Layout is represented in a table format in the PDF report generated. This includes the disposition of the chips (designated by the chip ID) in the reader and of the different samples on each chip. The addition of this information should help users to easily trace information relevant to the set-up of the experiment. The Chip Layout information is shown in the PDF report as shown below:

Chip Layout

Chip Holder 1

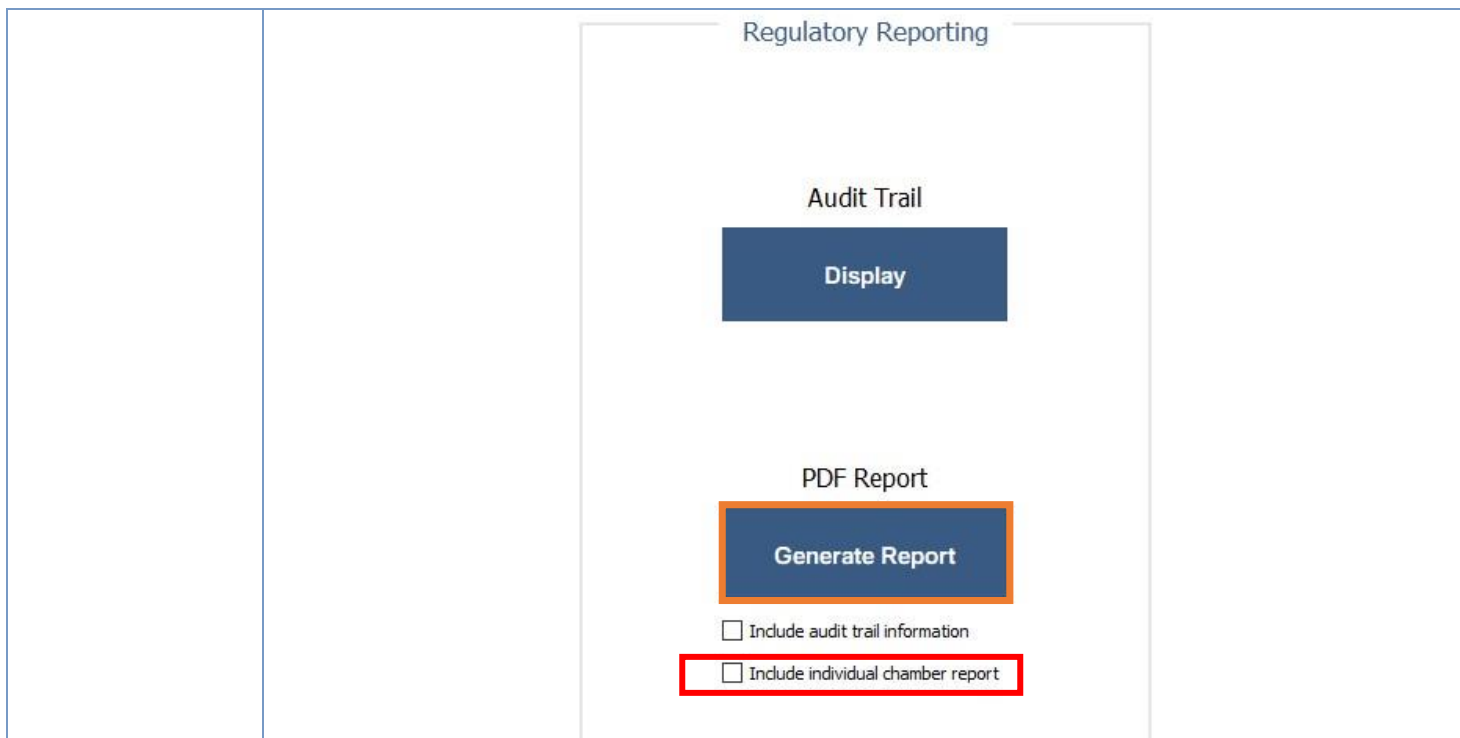
S-0674824-1		S-0674814-2		
A1		A2		A3
Sample 1		Sample 5		
B1		B2		B3
Sample 2		Sample 6		
C1		C2		C3
Sample 3		Sample 7		
D1		D2		D3
Sample 4		Sample 8		

NB: in this example, the third chip position is empty.

For details of all the information now included in the PDF report, please refer to section 5.3.3 in the latest the naica® system Pro software User Manual version (MKT-00150 Rev. C).

Feature addition: Optional inclusion of individual chamber report

When generating the PDF report with naica® Analysis Pro v4.1, the user can choose to include or not individual chamber reports (which includes the 2D plots associated with each chamber) in addition to the summary results table. The option can be selected by ticking the box “Include individual chamber report” below the “Generate Report” button as shown below:



For instructions on how to generate a PDF report, please refer to section 5.3.3 in the latest the naica® system Pro software User Manual version (MKT-00150 Rev. C).

<p>Feature addition: Multiple chamber validation</p>	<p>Unlike in naica® Analysis Pro v4.0, in Analysis Pro v4.1 it is possible to change the validity status of multiple samples at once.</p> <p>For instructions for sample validation, please refer to section 5.3 in the latest the naica® system Pro software User Manual version (MKT-00150 Rev. C).</p>
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<p>Improved chamber ID sorting</p>	<p>In naica® Analysis v4.1, in the table in “Edit experiment” and “Results” tab, when the user sorts the different chambers according to chamber ID, the chambers are sorted according to the order of the chambers on the chip (i.e. A1, B1, ... A2, B2, ...) instead of by alphanumeric order (i.e. A1,A2...etc).</p>
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<p>Additional improvements and modifications to PDF Report</p>	<ul style="list-style-type: none"> • Addition of “Experiment name” section at the beginning of the document • Rewording of “Details” into “User and software traceability information” • Rewording of “Signature” by “Signature operator, date and time” • Merge of “Operator” and “Scan date” information in a single line under designation “Scan operator, date and time” • Replacement of “Report generation time” by “Report generation operator, date and time” • Rewording of “Experiment Context” into “Experiment and analysis setup information” • Rewording of “total number of chambers” into “number of scanned chambers” • Rewording of “Focus” into “Instrument focus” • Rewording of “Zoning” into “Thresholding” to be consistent with the software user interface. • Removal of tray holder ID which always displays “n.a.” • Reordering of “Experiment and analysis setup information” into the following order: <ul style="list-style-type: none"> ○ Instrument type ○ Instrument SN ○ Instrument focus ○ Chip type ○ Scanning template
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- Number of analyzed chambers
- Number of analyzed samples
- Spill-over compensation matrix applied?
- Thresholding scope
- Thresholding type
- Removed “Channels” title as the table is now included in the “Experiment and analysis setup information” section
- Replaced “channels” by “scanned channels” in the channel table

- Rewording of “Author” into “Generated by” in the footer of the report.
- Addition of time information (in addition to date information) in the footer.

- Uniformization all traceability information using the format “name (datetime)”

For details of all the information now included in the PDF report, please refer to section 5.3.3 in the latest the naica® system Pro software User Manual version (MKT-00150 Rev. C).

An example of the PDF Report including all the modifications described above is shown below:



naica® Analysis Pro experiment report

Experiment name

Demo experiment

User and software traceability information

Signature operator, date and time	demo.user (2024-01-29T15:14:25+01:00)
Signature meaning	review
Scan operator, date and time	demo.user (2023-02-03T13:25:54Z)
Report generation operator, date and time	demo.user (2024-01-29T15:14:44+01:00)
naica® Analysis Pro software version	4.1.34.3
naicaReaderPro software version	4.0.10.3

Experiment and analysis setup information

Instrument type	Prism3
Instrument SN	0123
Instrument focus	1.3 mm
Chip type	sapphire
Scanning template	ScanningTemplate_Prism3_SapphireChip_naica-multiplex-PCR-MIX_Tagman v2.1
Number of analyzed chambers	8
Number of analyzed samples	8
Spill-over compensation matrix applied?	no
Thresholding scope	Common for all chambers
Thresholding type	Lines

Scanned channel	Fluorophore	Target	Exposure (ms)
Blue	FAM	Target A	65
Green	HEX	Target B	250
Red	Cy5	Target C	50

Chip Layout

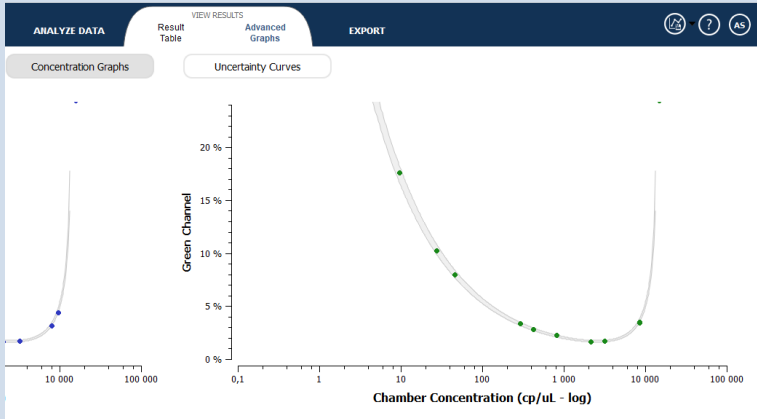
Chip Holder 1

S-0674824-1	S-0674814-2	
A1 Sample 1	A2 Sample 5	A3
B1 Sample 2	B2 Sample 6	B3
C1 Sample 3	C2 Sample 7	C3
D1 Sample 4	D2 Sample 8	D3

Modifications to the exported .csv or .xlsx file

Modification type	Modification list
Miscellaneous	<ul style="list-style-type: none"> Rewording of “Zoning” into “Thresholding” to be consistent with the software user interface

Bug corrections

Software feature	Bug description
Uncertainty curves	<p>Users can now visualize the “Uncertainty Curves” in “Advanced Graphs” tab even when the chamber concentrations in the experiment are spread across the limits of the dynamic range (software crash fixed).</p> 
Experiment signing	The chamber order is now maintained even when a user unsigned the experiment.
Scanning template registration in naica® Data Service	Scanning templates generated using the “I/O -> Save as a template (.ncx)” menu are now registered in naica® Data Service.
Scanning template name	The experiment name of a scanning template now corresponds to the file’s name (and no longer to the name of the file used to generate the scanning template).
Re-analysis	<p>When using the re-analysis function in naica® Analysis Pro, the regulatory information and audit trail is now fully propagated to the output file.</p> <p>For instructions on using the re-analysis function, please see the latest Crystal Miner software User Manual (MKT-00143 Rev B).</p>
Export data	Users with “Export Data” permission can export data in .xlsx and .csv format even if the experiment is not signed.
Edit experiment	Scanning parameters from Experiment Details in "Edit experiment" are no longer editable by user without "Create Template" permission in naica® Analysis Pro.

Miscellaneous

- The Rosace (Venn diagram) is now only displayed for 3-plex RGB experiments.
- Removal of visualization artifact in "Result table" when a pooling is removed.
- Fixed population selection and display after removing a polygon.
- Fixed software crash issues when loading a 3-plex experiment after a 6-plex experiment crashes the analysis software with the plot.
- Enabled export of an experiment when population names or sample names contain illicite Windows' path characters. Substitute illicit path characters in population names and sample names with '_' to allow the export.
- Fixed software crash when a population is removed.
- Added software icon in the "Add or remove programs" in Windows.
- Save all plot bounds ncr for all the plot pages (not just the first plot page).
- Fixed crash issue when an experiment is loaded on top of another experiment with a different channel range.
- Fixed typo in pop-up message "Please ensure that the input file is not corrupted.:"
- Fixed crash issue in View Result -> Advanced Graphs (bad narrow conversion).

List of known anomalies

For more details about the unresolved anomalies and, where applicable, the corresponding workarounds, please contact our customer support.

Technical support

For help and technical advice, please contact the Technical Support Department at Stilla Technologies.

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.fr.