DataApex
Clarity™
CHROMATOGRAPHY SOFTWARE

VALIDATION KIT

Clarity Software + Hardware ENG

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Contents

To facilitate the orientation in the **Validation kit** manual and **Clarity** chromatography station, different fonts are used throughout the manual. Meanings of these fonts are:

Open File (italics) describes the commands and names of fields in **Clarity**, parameters that can be entered into them or a window or dialog name.
WORK1 (capitals) indicates the name of the file and/or directory.
ACTIVE (capital italics) marks the state of the station or its part.
Chromatogram (blue underlined) marks clickable links referring to related chapters.

The bold text is sometimes also used for important parts of the text and the name of the **Clarity** station. Moreover, some sections are written in format other than normal text. These sections are formatted as follows:

Note: Notifies the reader of relevant information.

Caution: Warns the user of possibly dangerous or very important information.

Marks the problem statement or trouble question.

Description: Presents more detailed information on the problem, describes its causes, etc.

Solution: Marks the response to the question, presents a procedure how to remove it.

1 Brief Description

The quality of analytical data is an issue that has been gaining increased attention in many laboratories these days. One of the requirements for ensuring the reliability of generated results is the validation of all instrumentation and procedures that are used to acquire data.

1.0.1 Levels of Qualification

For chromatography datastations, usually three levels of validation (qualification) are relevant:

Installation Qualification (IQ): a procedure confirming that the datastation was successfully installed and that the installation contains all needed files of the correct version. Installation qualification is an integral part of the **Clarity** Chromatography datastation installation procedure and could be performed at any time.

Operational Qualification (OQ): a procedure confirming that the datastation is performing according to manufacturer's specifications. In Clarity, OQ Validation Wizard serves this purpose. Chromatography data are acquired and analyzed with prepared procedures and the acquired results are compared with expected values. **System Suitability Test (SST)** module is required for this type of qualification. For performing OQ on systems without digital acquisition of signal, a **Validator** precise peak generator is also required.

Performance Qualification: a procedure confirming that the analytical system is fit for a given type of analysis. Usually, the overall system performance is tested by this procedure with respect to the requirements of the desired application. **Clarity** datastation offers many tools in the **System Suitability Test (SST)** module to efficiently evaluate the system performance.

1.0.2 Operational Qualification of Clarity datastation.

This manual describes the **Operational Qualification** of **Clarity** datastations.

It is possible to perform Operational Qualification in two different ways :

1. Validation with an A/D converter

Colibrick, INT7, INT9, U-PAD, U-PAD2 or Net-PAD A/D converter and a Validator peak generator (a part of Validation Kit , p/n CVK) are required for this type of validation. The Validator will generate signal which is received by A/D converter and acquired dataset is compared with expected values. This way of validation will prove the entire acquisition chain from analog signal input to result calculation.

2. Validation with a Virtual detector

For systems with digital acquisition this is the only feasible way of validation. The input of signal is simulated via OQ detector (a control module developed specifically for the purpose of OQ Validation), which is able to send data into **Clarity** in exactly the same way as a real chromatography instrument would do. This will ensure that digital signal is processed correctly after being received from detector. OQ detector is a part of **Clarity** software, so no extra hardware is needed for this type of validation.

Performing of the validation procedure is facilitated by OQ Validation Wizard, which automatically opens the prearranged sequence and all the methods needed, sets all the parameters, launches measurement and saves and prints the results. The installation of the wizard is optional (although turned on in the Typical installation), and it is always possible to install it separately into exiting installation of **Clarity**.

Caution: In case of "Validation with a virtual detector", control module OQ detector has to be installed otherwise OQ validation cannot be performed. During **Full** and **Typical** installation of OQ detector is installed automatically. During **Custom** installation select Universal Drivers option - OQ detector is part of it.

1.1 System requirements

- **DataApex Clarity Chromatography Station** version **2.8** or higher is required for performing Operational Qualification.
- **Clarity SST module**, an optional part of **Clarity** software (p/n A22), is necessary for validation.
- A **Validator** is needed for hardware validation of systems equipped with **Colibrick, INT7, INT9, U-PAD, U-PAD2 or Net-PAD** A/D converters. For systems with digital data acquisition it is possible to perform validation of software only by using OQ detector (a part of standard **Clarity** installation). It is not possible to perform the validation of **Clarity** station which is used with an A/D converter by the use of OQ detector if the station does not have GC Control (p/n A23) or LC Control (p/n A24).
- Printer configured on the PC. Virtual PDF printer can be used instead of hardware printer.

Caution: Virtual printer that does not require manual intervention (like inputting file name) is necessary, therefore, standard Microsoft print to pdf is not sufficient.

1.1.1 Competency to perform Validation

The OQ is primarily intended for trained service personnel who have experience performing validations of chromatography systems with **Clarity** datastations. However, it can also be used by experienced users for in-house validation. The operator must be familiar with **Clarity** datastation operations.

DataApex provides a **certificate** to service personnel who are trained in the use of the **Validation kit**. This certificate entitles the bearer to perform validations on behalf of **DataApex**.

1.1.2 Validity of Validation

The validity of the performed validation is dependent on type of performed Operational Qualification.

1. Validation with an A/D converter

The validation of systems equipped with **Colibrick, INT7, INT9, U-PAD, U-PAD2 or Net-PAD** A/D converter is valid one year.

2. Validation with a Virtual detector

The validation of systems without A/D converter where a digital acquisition and control of chromatography systems is used can be adjusted to meet requirements of the organization but the maximum validity of this type of validation is two years.

1.2 Clarity Validation Kit Content

The **Clarity Validation Kit** consists of:

- **Validator** version 2
- **Clarity** Validation Kit Manual
- AC power adapter
- Cable for connecting the Validator to Colibrick, INT7, INT9,U-PAD, U-PAD2 or Net-PAD converters or to the Terminal Board.
- Terminal board
- Validator Certificate

2 Installation Qualification

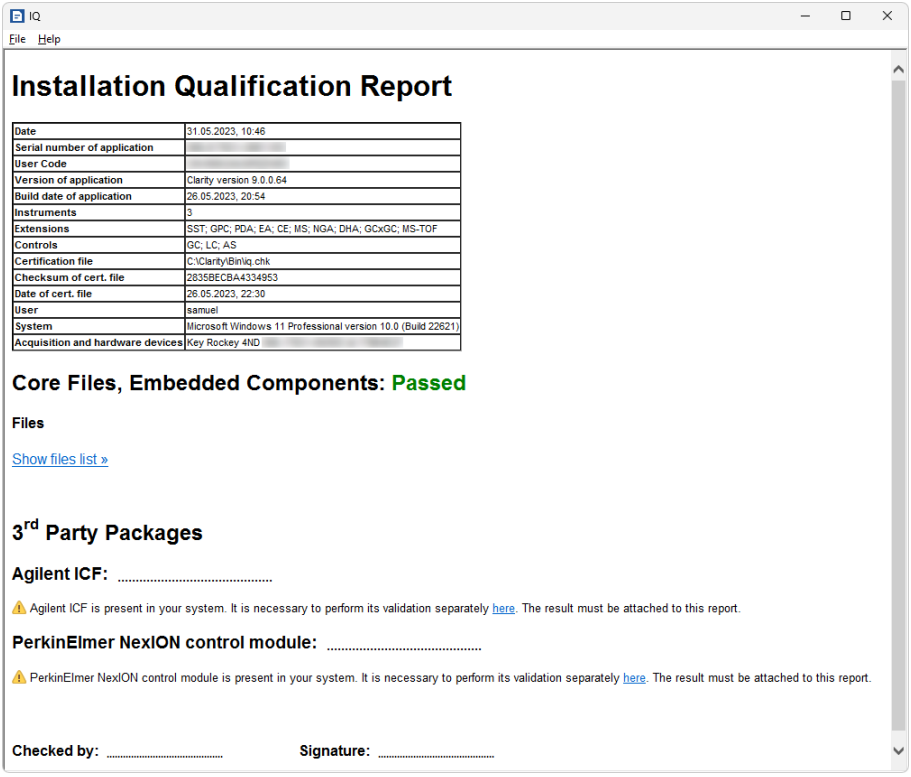
Installation Qualification (IQ) is a procedure confirming that the datastation was successfully installed and that the installation contains all needed files of the correct version. Installation qualification is an integral part of the **Clarity** Chromatography datastation installation procedure and could be performed at any time.

2.1 Evaluation of installation qualification

When IQ utility finishes the test it displays an *Installation Qualification Report* which can be evaluated. It is possible to obtain a few result types. If there are any problems detected, it is possible to locate problematic file in the expanded file list and take relevant countermeasure. An example of blank of *Installation Qualification Report* is available in the chapter **"Appendices"** on pg. **34**..

It is recommended to print final IQ report after Clarity was started at least once, since some information is only loaded after the first start. Any *3rd Party Package* must have its own IQ done separately, it can be started by clicking *here* in respective sections.

If IQ failed for any reason, first proposed solution is to reinstall Clarity. If this does not help please contact support.


IQ

File Help

Installation Qualification Report

Date	31.05.2023, 10:46
Serial number of application	
User Code	
Version of application	Clarity version 9.0.0.64
Build date of application	26.05.2023, 20:54
Instruments	3
Extensions	SST; GPC; PDA; EA; CE; MS; NGA; DHA; GCxGC; MS-TOF
Controls	GC; LC; AS
Certification file	C:\ClarityIBin\iq.chk
Checksum of cert. file	2835BECBA4334953
Date of cert. file	26.05.2023, 22:30
User	samuel
System	Microsoft Windows 11 Professional version 10.0 (Build 22621)
Acquisition and hardware devices	Key Rockey 4ND

Core Files, Embedded Components: Passed

Files

Show files list »

3rd Party Packages

Agilent ICF: .....

Agilent ICF is present in your system. It is necessary to perform its validation separately here. The result must be attached to this report.

PerkinElmer NexION control module: .....

PerkinElmer NexION control module is present in your system. It is necessary to perform its validation separately here. The result must be attached to this report.

Checked by: ..... **Signature:** .....

Fig. 1: Installation Qualification - report

3 Operational Qualification

Operational Qualification is a procedure confirming that the datastation is performing according to manufacturer's specifications. The OQ Validation Wizard provides the solution. With a precise peak generator (Validator) or OQ detector, simulated chromatography data is acquired and analyzed using prepared procedures and the acquired results are compared with expected values.

3.1 Parameters tested during Operation Qualification:

- Retention time precision and accuracy
- Voltage (peak height) measurement precision and accuracy
- Area determination precision and accuracy
- Calibration and calculations – ESTD and ISTD methods
- Consistency of acquisition ranges

3.2 List of used files

The OQ_VALIDATION folder, located in the BIN subdirectory of the Clarity installation (C:\CLARITY\ by default), contains the AD_CONVERTER and VIRTUAL_DETECTOR subfolders with all the sequences, methods, calibrations, SST and report style files.

3.2.1 Methods

- OQ_CAL.MET method for constructing calibration curve and a linearity test.
- OQ_ESTD.MET method for checking the reproducibility and accuracy of measured data and ESTD calculation.
- OQ_ISTD1.MET – OQ_ISTD3.MET methods for checking the ISTD calculation and consistency of measuring ranges.

3.2.2 Calibration files

OQ_CAL.CAL used for linearity and ESTD tests

OQ_ISTD.CAL used for ISTD test

3.2.3 SST files

OQ_ESTD.SST and OQ_ISTD.SST

Files used for comparing acquired data with expected values. Those files are located in the OQ_CLARITY project directory.

3.2.4 Report styles

OQ_LINEARITY.STY, OQ_ESTD.STY, OQ_ISTD.STY

Report styles used for printing the Validation Protocol. Fields for entering validation results, and signatures are provided in the footer of the reports.

3.2.5 Sequence

OQ_SEQ.SEQ

The passive sequence will automatically perform all measurements and print the Calibration linearity test report (the *Print Results* checkbox in the PostRun Setting dialog must be checked).

3.2.6 Desktop file

DATA.DSK

A desktop file with the user settings needed for the OQ validation procedure. The settings include and will automatically open the project, the sequence and set the postrun, SST table and other options.

3.3 Validation procedure description

During the **Operational Qualification** procedure, a series of chromatograms, which are specified by the OQ_ SEQ.SEQ sequence, will be acquired and evaluated. Chromatogram data set 2 generated by the **Validator** will be used in case of validation with an A/D converter. When only software validation is performed, integrated OQ detector will generate necessary dataset instead.

3.3.0.1 Calibration Curve Linearity

The linearity of a calibration curve will be tested by constructing a calibration curve for peak 1-5.

Using the *Chromatogram data set 2*, first five chromatograms will be acquired.

The OQ_CAL.CAL calibration file will be recalibrated using the acquired data. FINALLY, THE CALIBRATION CURVE REPORT WILL BE PRINTED FROM THE SEQUENCE USING THE OQ_LINEARITY.STY REPORT STYLE.

The evaluated parameters are:

Parameter	Expected value
Calibration curve slope	500 +/- 2
Calibration curve intercept	0,0 +/- 0,5
Correlation factor	min 0,999999

3.3.0.2 Reproducibility and Precision, ESTD calculation

The remaining six chromatograms for ESTD and six chromatograms for ISTD calculations will then be acquired.

The results for ESTD chromatograms will be compared using the OQ_ESTD.SST system suitability method and a report will be printed using the OQ_ESTD.STY report style.

The evaluated parameters for ESTD are:

Peak	Limit	RT min	Area mV.s	Height mV	Amount
PEAK 1	Lower	0,49	4,5	0,85	0,009
	Upper	0,51	5,5	0,95	0,011
	RSD%	1,5	2	2	2
PEAK 3	Lower	1,49	495	89,0	0,99
	Upper	1,51	505	91,0	1,01
	RSD%	0,4	0,1	0,1	0,1
PEAK 5	Lower	2,49	49800	8950	99,95
	Upper	2,51	50200	9050	100,05
	RSD%	0,2	0,01	0,1	0,01

This step, besides testing the precision and reproducibility of retention time, area and peak height, also tests the ESTD calculation and report.

Using **UPAD** or **INT7** A/D boards, the minimum distinguishable time step in starting an analysis at 10 Hz sample rate is *0,003 min* and the ***RSD%*** limits for retention time coresponds to this value.

The limits set for the Peak 1 peak reflect the detection near the determination limit.

3.3.0.3 Acquisition ranges, ISTD calculation

The results for ISTD chromatograms will be compared using the OQ_ISTD.SST system suitability method and a report will be printed using the OQ_ISTD.STY report style.

After finishing the sequence:

- collected files will be manually opened by the user in the Chromatogram window (*Overlay mode* must be *ON*) and then
- compared against the OQ_ ISTD.SST system suitability method that contains defined limits for expected values.
- Finally, a report will be printed using the OQ_ISTD.STY report style.

The evaluated parameters for ISTD are:

Peak	Limit	RT min	Area mV.s	Height mV	Amount
PEAK 2	Lower	0,99	4,5	0,85	0,950
	Upper	1,01	5,5	0,95	1,050
	RSD%	0,60	2,00	2,00	2,00
PEAK 4	Lower	1,99	49,5	8,9	9,950
	Upper	2,01	50,5	9,1	10,0500
	RSD%	0,30	0,75	0,75	0,50
PEAK 5	Lower	2,49	495	89,0	99,500
	Upper	2,51	505	91,0	100,500
	RSD%	0,20	0,75	0,75	0,20

The limits reflect the processing of a low-level signal at different ranges. This results in a difference in noise levels.

3.4 Evaluation of validation procedure

When validation procedure is finished it is necessary to check all results. These results are propagated into three independent reports which are printed and also stored next to chromatograms created during validation procedure.

3.4.0.1 Calibration linearity test

When first part of validation sequence is finished there is created first report called *Clarity linearity test* which summarizes results for calibration curves of peaks 1 - 5. It is necessary to check whether *Slope, Offset* and *Correlation Factor* values for all five calibration curves are within limits. Upper part of report contains results from current validation procedure, expected values and their limits are listed in bottom part. Image below highlights these sections. It is necessary to check all five calibration curves and all of their values have be within limits in order to be possible to claim that *Calibration linearity test* passed.

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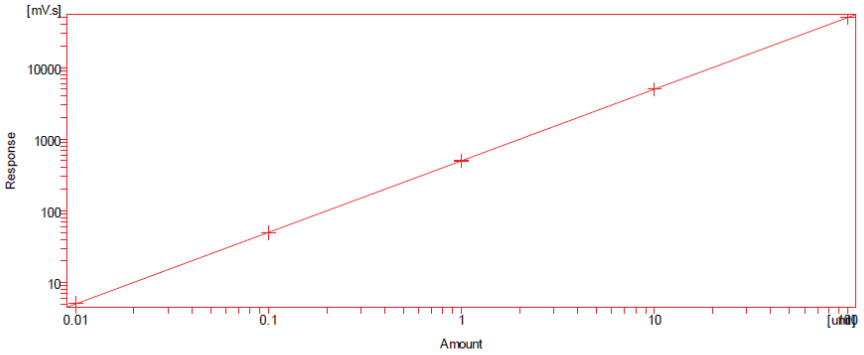
Clarity - Operational Qualification

Calibration linearity test

Peak 1 - Signal 1 - 0.497 min

Peak Type	: Ordnr
Search Window	: Abs
Left Window	: 0.200 min
Right Window	: 0.200 min
Peak Selection	: Nearest
Response Base	: Area
Is ISTD	: None
Use ISTD	: None
Curve Fit Type	: Linear
Origin	: Ignore Origin
Weighting Method	: 1/Response
Linearisation X	: None
Linearisation Y	: None
Correction Factor	: 1.0000
Calculate By	:
Correlation Factor	: 1
Residuum	: 0.00143 [mV.s]
Equation	: Y = 500.05653*X - 0.03684

	Response	Amount	Resp. Factor	Rec No.	Used
1	50007.9706	100.0000	0.0020	1/1	☒
2	4998.8362	10.0000	0.0020	1/1	☒
3	499.4035	1.0000	0.0020	1/1	☒
4	49.9108	0.1000	0.0020	1/1	☒
5	4.9771	0.0100	0.0020	1/1	☒
6	0.0000	0.0000	0.0000	1/1	☒
7	0.0000	0.0000	0.0000	1/1	☒
8	0.0000	0.0000	0.0000	1/1	☒
9	0.0000	0.0000	0.0000	1/1	☒
10	0.0000	0.0000	0.0000	1/1	☒
11	0.0000	0.0000	0.0000	1/1	☒
12	0.0000	0.0000	0.0000	1/1	☒
13	0.0000	0.0000	0.0000	1/1	☒
14	0.0000	0.0000	0.0000	1/1	☒
15	0.0000	0.0000	0.0000	1/1	☒
16	0.0000	0.0000	0.0000	1/1	☒
17	0.0000	0.0000	0.0000	1/1	☒
18	0.0000	0.0000	0.0000	1/1	☒
19	0.0000	0.0000	0.0000	1/1	☒
20	0.0000	0.0000	0.0000	1/1	☒
BL	0.0000	Blank	0.0000	0/0	☐



Expected values for Subst.Equation: Y = Slope *X + Offset

Slope	500	+/- 2
Offset	0,0	+/- 0,5
Correlation	> 0,999999	

TEST Result: Passed [ ] Signature: _____

Fig. 2: Calibration linearity test - report

3.4.0.2 Reproducibility and Precision, ESTD calculation

When second part of validation sequence is finished there is created second report called *ESTD calculation test* which summarizes results for reproducibility and precision for peaks 1, 3 and 5. It is necessary to check SST tables - *Overall SST Result* table and individual *SST Result Component "Peak X"* tables for peaks 1, 3 and 5. *Overall SST Result* table lists overall results for all three evaluated peaks. *Peak 2* and *Peak 4* are excluded from evaluation thus their results are intentionally missing.

SST Result Component tables have to consist of precisely six chromatograms (not more nor fewer) and all six chromatograms have to contain *ESTD* abbreviation in their names.

All the tables have to filled in with green signs only in order to be able to claim that *ESTD calculation test* passed. Presence of a single red sign in any of all tables causes *Overall SST Result* to fail.

Clarity - Operational Qualification

ESTD calculation test

SST Components Table

- Overall SST Result

	Used	OK	Component Name	Retention Time
1	☒	✓	Peak 1	0,500
2	☐		Peak 2	1,000
3	☒	✓	Peak 3	1,500
4	☐		Peak 4	2,000
5	☒	✓	Peak 5	2,499

SST Parameters Table

- SST Result for Component "Peak 1", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	0,490	4,500	0,850	0,009
		Upper Limit	0,510	5,500	0,950	0,011
		%RSD Limit	1,50	2,00	2,00	2,00
		Mean	0,497	5,060	0,892	0,010
		RSD [%]	0,50	1,49	0,95	1,48
		Parameter Result	✓	✓	✓	✓
✓	☒	DataIOQ_Validation_VD_ESTD11_06.12.2019 4_13_16	0,500	5,105	0,898	0,010
✓	☒	DataIOQ_Validation_VD_ESTD06_06.12.2019 3_58_08	0,497	5,058	0,897	0,010
✓	☒	DataIOQ_Validation_VD_ESTD07_06.12.2019 4_01_11	0,500	4,912	0,877	0,010
✓	☒	DataIOQ_Validation_VD_ESTD08_06.12.2019 4_04_12	0,497	5,111	0,898	0,010
✓	☒	DataIOQ_Validation_VD_ESTD09_06.12.2019 4_07_13	0,497	5,102	0,897	0,010
✓	☒	DataIOQ_Validation_VD_ESTD10_06.12.2019 4_10_14	0,493	5,071	0,888	0,010

SST Parameters Table

- SST Result for Component "Peak 3", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	1,490	495,000	89,000	0,990
		Upper Limit	1,510	505,000	91,000	1,010
		%RSD Limit	0,40	0,10	0,10	0,10
		Mean	1,498	499,432	89,788	0,999
		RSD [%]	0,11	0,02	0,01	0,02
		Parameter Result	✓	✓	✓	✓
✓	☒	DataIOQ_Validation_VD_ESTD11_06.12.2019 4_13_16	1,497	499,502	89,791	0,999
✓	☒	DataIOQ_Validation_VD_ESTD06_06.12.2019 3_58_08	1,497	499,386	89,785	0,999
✓	☒	DataIOQ_Validation_VD_ESTD07_06.12.2019 4_01_11	1,497	499,344	89,796	0,999
✓	☒	DataIOQ_Validation_VD_ESTD08_06.12.2019 4_04_12	1,500	499,561	89,787	0,999
✓	☒	DataIOQ_Validation_VD_ESTD09_06.12.2019 4_07_13	1,500	499,469	89,784	0,999
✓	☒	DataIOQ_Validation_VD_ESTD10_06.12.2019 4_10_14	1,497	499,329	89,785	0,999

TEST Result: Passed [ ] Signature: _____

Fig. 3: ESTD calculation test - report

3.4.0.3 Acquisition ranges, ISTD calculation

When last part of validation sequence is finished there is created last report called *ESTD calculation test* which summarizes results for acquisition ranges for peaks 1, 3 and 5. It is necessary to check SST tables - *Overall SST Result* table and individual *SST Result Component "Peak X"* tables for peaks 1, 3 and 5. *Overall SST Result* table lists overall results for all three evaluated peaks. *Peak 2* and *Peak 4* are excluded from evaluation thus their results are intentionally missing.

SST Result Component tables have to consist of precisely six chromatograms (not more nor fewer) and all six chromatograms have to contain *ISTD* abbreviation in their names.

Clarity - Operational Qualification

ISTD calculation test

SST Components Table

- Overall SST Result

	Used	OK	Component Name	Retention Time
1	☐		Peak 1	0,500
2	☒	✓	Peak 2	1,000
3	☐		Peak 3	1,500
4	☒	✓	Peak 4	2,000
5	☒	✓	Peak 5	2,500

SST Parameters Table

- SST Result for Component "Peak 2", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	0,990	4,500	0,850	0,950
		Upper Limit	1,010	5,500	0,950	1,050
		%RSD Limit	0,60	2,00	2,00	2,00
		Mean	0,997	4,999	0,899	1,000
		RSD [%]	0,00	0,92	0,58	0,88
		Parameter Result	✓	✓	✓	✓
✓	☒	DataIOQ_Validation_VD_ISTD17_06.12.2019 4_31_28	0,997	4,965	0,895	0,994
✓	☒	DataIOQ_Validation_VD_ISTD12_06.12.2019 4_16_18	0,997	5,069	0,905	1,013
✓	☒	DataIOQ_Validation_VD_ISTD13_06.12.2019 4_19_20	0,997	5,045	0,907	1,009
✓	☒	DataIOQ_Validation_VD_ISTD14_06.12.2019 4_22_22	0,997	4,973	0,896	0,994
✓	☒	DataIOQ_Validation_VD_ISTD15_06.12.2019 4_25_24	0,997	4,984	0,897	0,996
✓	☒	DataIOQ_Validation_VD_ISTD16_06.12.2019 4_28_26	0,997	4,959	0,895	0,993

SST Parameters Table

- SST Result for Component "Peak 4", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	1,990	49,500	8,900	9,950
		Upper Limit	2,010	50,500	9,100	10,050
		%RSD Limit	0,30	0,75	0,75	0,50
		Mean	1,999	49,998	8,986	10,000
		RSD [%]	0,07	0,16	0,12	0,12
		Parameter Result	✓	✓	✓	✓
✓	☒	DataIOQ_Validation_VD_ISTD17_06.12.2019 4_31_28	2,000	49,914	8,973	9,993
✓	☒	DataIOQ_Validation_VD_ISTD12_06.12.2019 4_16_18	2,000	50,129	8,995	10,022
✓	☒	DataIOQ_Validation_VD_ISTD13_06.12.2019 4_19_20	2,000	50,041	8,996	10,003
✓	☒	DataIOQ_Validation_VD_ISTD14_06.12.2019 4_22_22	1,997	49,991	8,987	9,992
✓	☒	DataIOQ_Validation_VD_ISTD15_06.12.2019 4_25_24	2,000	50,001	8,989	9,994
✓	☒	DataIOQ_Validation_VD_ISTD16_06.12.2019 4_28_26	2,000	49,914	8,973	9,993

TEST Result: Passed [ ] Signature: _____

Fig. 4: ISTD calculation test - report

When entire validation process is finished, all three reports are printed, checked and evaluated as passed they be combined with passed *IQ report* and *Certificate of Clarity station validation*.. An example of possible certificate is available in the chapter **"Appendices"** on pg. **34**.. This chapter also contains blank examples of reports for all three reports.

4 OQ Validation Wizard

OQ Validation Wizard is an easy way to perform Operational Qualification (OQ) in Clarity, both with A/D converter card in PC or with digital acquisition equipped chromatograph. It consists of several steps, in which you can select a type of validation, A/D hardware used and validation project filename. This chapter provides a step-by-step description of the entire procedure. Output of the OQ is a printed report, which is one of prerequisites necessary for quality assurance audit of analytical laboratories.

Step 1 : Launching the wizard

Launch the wizard with *OQ Validation Wizard* item in Windows Start menu *(Start – Programs – Clarity – OQ Validation Wizard)*.

Caution: Even though it is allowed to launch OQ Validation Wizard without **Clarity** SST Extension installed, OQ will fail after finishing first few chromatograms as some files necessary for data evaluation will be missing.

Caution: Remember to configure a *Default Printer* in *Windows Printer Settings*. It can be also a virtual PDF printer, but avoid Microsoft Print to PDF printer or similar printers requiring user response. It may cause crash at the end of validation.

Step 2 : Welcome

Informational dialog, just press *Next* to continue. Please note that this dialog will stay on top of your desktop during entire process of validation. In case this is not convenient for you it is possible to turn this feature off by using the *Not On Top* button.

Fig. 5: Welcome

Step 3 : Validation Type

In this step you can select type of validation.

Choose :

- "Validation with an A/D converter" to perform Operational Qualification with external Validator connected to A/D converter card (Colibrick, INT7, INT9, U-PAD, U-PAD2 or Net-PAD). External Validator is a part of Clarity Validation kit (P/N Val2).
- "Validation with a Virtual detector" if you are using digital acquisition of detector signal (without hardware A/D card in your computer). In this case, entire OQ proceeds on software level without any additional hardware needed and wizard will thereby skip over following Step 4 and Step 5.

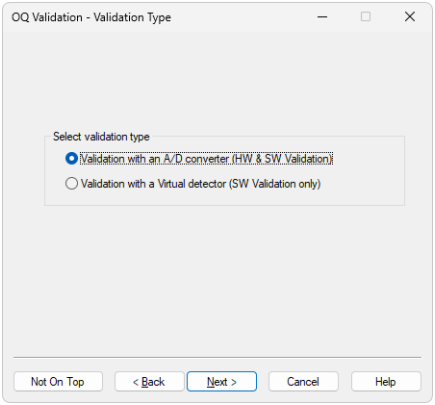


Fig. 6: Validation Type

Step 4 : Hardware

Select an item according to an A/D converter installed on your station. With Net-PAD selected one must specify network location of particular Net-PAD device (see Net-PAD Setup).

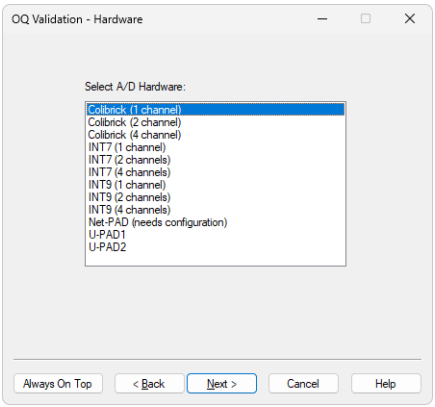


Fig. 7: Hardware

Step 5 : Validator

Setting up the Validator. Follow the instructions in the dialog.

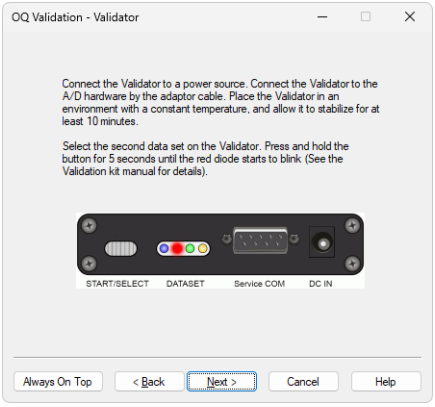


Fig. 8: Validator

Step 6 : Project

Enter the name of validation project. It is recommended to choose a project name carefully for the convenience of its future finding and checking.

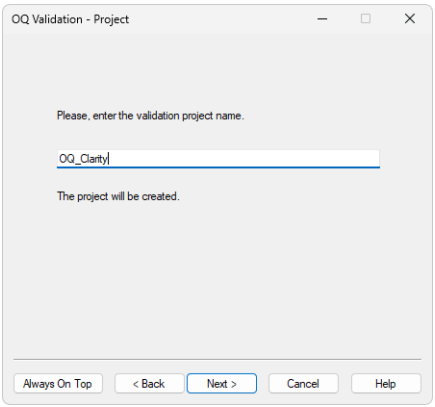


Fig. 9: New Project

If the name of an already existing project is entered, you cannot proceed unless the option to allow overwriting is checked. If you proceed with this option and sufficient user rights, the original project will be entirely overwritten by the OQ, including any methods, sequences, calibrations, and chromatograms.

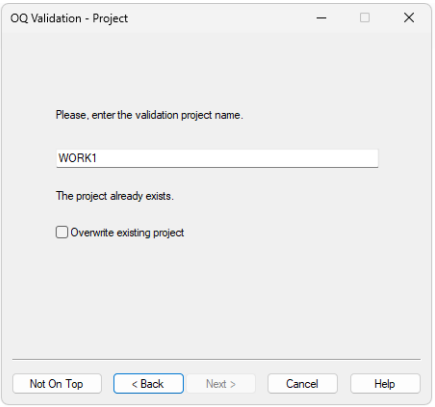


Fig. 10: Existing Project

Step 7 : Ready

This step summarizes all selected values.

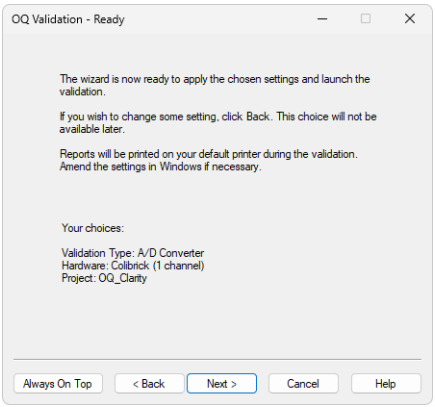


Fig. 11: Ready

Step 8 : Running

This dialog indicates the progress of the entire validation process. During the validation, after you confirm the *Login Dialog*, several windows will automatically be opened (*Instrument, Data Acquisition, Sequence, Chromatogram*). You can check the currently measured chromatograms in ***Data Acquisition*** window and supervise the entire process in the ***Sequence*** window. It is strongly recommended not to interfere with the process of validation and not to set anything in **Clarity** during the entire validation. During the process, it is also recommended not to perform other tasks that are demanding on your CPU.

Caution: If the first login attempt was unsuccessfull, the validaton procedure in Clarity will not start. It is recommended to close Clarity and relaunch the OQ Validation Wizard.

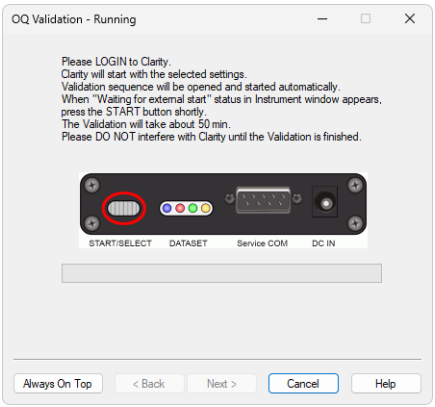


Fig. 12: Running

Step 9 : Finished

This dialog acknowledges that the validation has finished. You can select the Installation Qualification Report to be displayed immediately. Otherwise it can be opened and printed later.

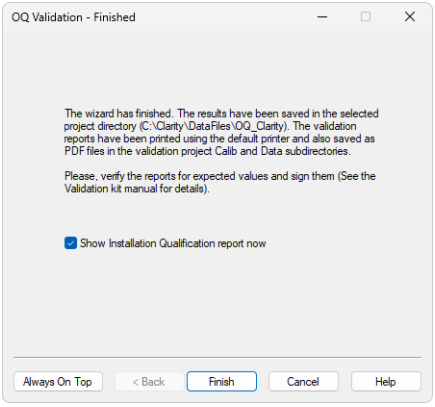


Fig. 13: Finished

5 Validator

5.1 Description

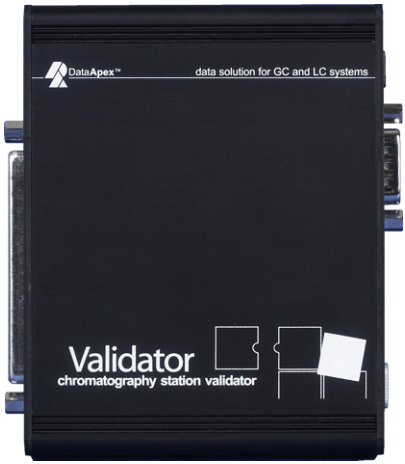


Fig. 14: Validator - front view

The **Validator** is a precise analog signal generator device. The data is stored in the FLASH EEPROM memory in digital form and is converted to analog data using a 1-bit D/A pulse width modulator. This converter guarantees full monotonicity, good linearity and no missing datapoints. The signal resolution is *20bit*.

The Validator 37-pin connector corresponds to the wiring of the **DataApex Colibrick, INT7, INT9,U-PAD, U-PAD2 or Net-PAD** A/D converters and is suitable for direct connection.

The **Validator** analog signal output is in parallel connected to all (potentionally four) analog inputs of the A/D boards. The LOW and AGND pins are shortened together in the Validator.

The **DI1 to DI4** digital inputs (connected to the A/D board **OUT1 – OUT4** digital outputs) allow for external triggering of data generation.

The **DO1 – DO4** digital outputs (connected to the A/D board **IN1 - IN4** digital inputs) enable sending a starting impulse to the data acquisition device.

Note: The starting impulse is a part of chromatogram data set, in standard chromatogram data sets the starting impulse is generated only on the **DO1** digital output.

The **Validator** can be connected either directly to the DataApex A/D board 37-pin connector through the extension cable or through the terminal board to any other data acquisition device.

Four sets of chromatogram data are stored in Validator. The sets can be selected by holding the **START/SELECT** button for sufficient time (**longer than 5 seconds**). The selected set is indicated by one of the four indicating LEDs.

The four indicator LEDs reflect the state of the generator.

- Active LED indicates the data set selected
- Steady light = Generating a signal
- Blinking = Idle

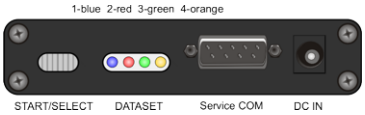


Fig. 15: Validator - Controls

The data generation can be started by pressing the **START/SELECT** button, or by changing the Validator *DI1* input level. The start impulse is generated to Validator *DO1* output.

5.2 Technical specification

5.2.1 Generated data parameters:

Signal Accuracy +/- 1 mV at 10 V Range

Signal Resolution +/- 10 uV at 10 V Range

Signal Linearity -/+ 0,0015%

Time Accuracy 0,01% (stabilized state)

5.2.2 Chromatogram data set options:

Chromatogram Size

4 data sets with maximum length 70 min at 10 Hz, can be connected together to one data set maximum length 290 min.

Sample Frequency

10, 25, 50, 100 Hz programmable in chromatogram data set.

Output Signal Range

10V, 1,25 V, 150 mV programmable in chromatogram data set.

Chromatogram Start

Change of the DO1 – DO4 digital output state is programmable in the chromatogram data set .

Data set generation start

The data set generation is started by releasing the START/SELECT button, or by changing the state of any of the DI1 – DI4 digital inputs from *HIGH* (open) to *LOW* (closed)

The impulse must be at least *10* ms long after 250 ms of steady state.

5.2.3 Power supply

The **Validator** is powered with **6V DC** from AC power adapter.

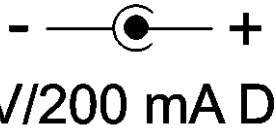


Fig. 16: Power supply connector description

5.3 Operation

When connected to a power supply, the **Validator** is ready to generate the data using the first data set.

Start generating manually by pressing the **START/SELECT** button, or by changing the state of the *DI1* digital input (connected to the **OUT1** digital output of the A/D board) from *High* to *Low*.

Stop generating manually by pressing the **START/SELECT** button again, or by changing the state of the **DI1** digital input from *High* to *Low*.

The selection of data set is performed by holding the **START/SELECT** button for 5 sec, the active indicating LED begins to change in 2 sec intervals.

By releasing the **START/SELECT** button the data set corresponding to the blinking LED is selected.

The actual chromatogram start is indicated by the impulse generated on the **DO1** contact. As it is a part of chromatogram data, it is slightly delayed to the release of the **START/SELECT** button or the starting impulse on the **DI1** contact. The data set may contain multiple start impulses, thus a series of chromatograms may be simulated from one chromatogram data set.

5.4 Validator Calibration

Each Validator is accompanied with a **Certificate of Calibration**. It states the **Validator** serial number, description of chromatograms in Flash EEPROM, model and serial number of the equipment used for calibration, date, name and signature of the person performing the calibration.

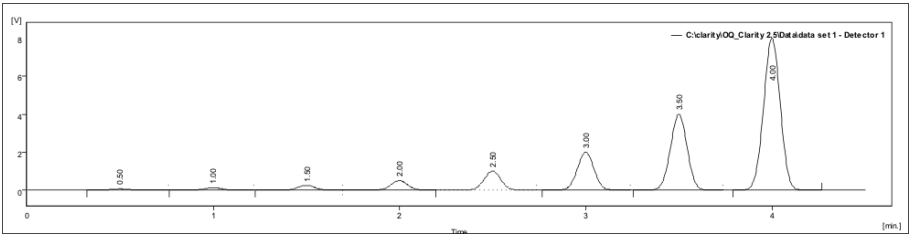
Calibration certificate is valid for a limited period of one year from the day of the calibration. Following its expiration, the **Validator** should be recalibrated at DataApex facility.

5.5 Description of chromatogram data sets

The data used for generating chromatograms are stored in a FLASH EEPROM memory. The programming of datasets requires special software and can be done through the RS232 serial port (Service COM) by the manufacturer.

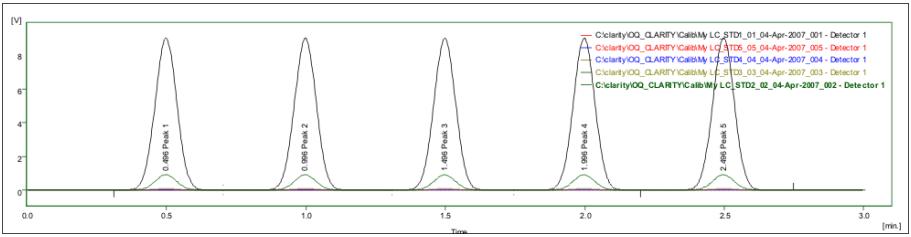
Note: The **Validator** can be supplied or re-programmed with different data sets upon request.

Chromatogram data set 1

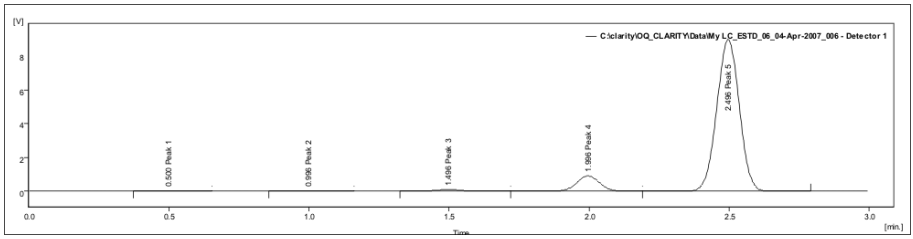


This chromatogram set is used for optional further testing. It consists of single chromatogram **eight gaussian peaks**, evenly spaced by 30 s and increasing in size by a factor of 2. The last peak height is 8000 mV and area is 50000 mV.s. The chromatogram length is 300 s, after this time it is repeated indefinitely.

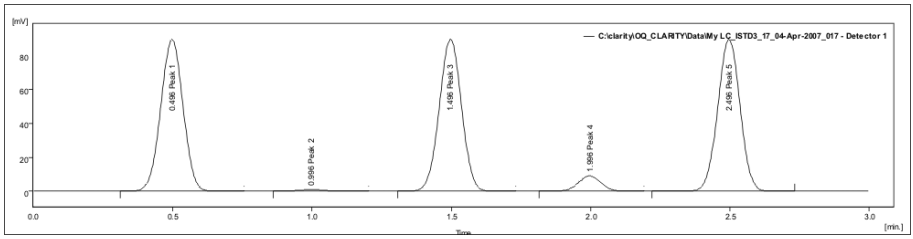
Chromatogram data set 2



This chromatogram set is used throughout the entire validation procedure. It consists of seventeen individual chromatograms, containing five **gaussian peaks**, evenly spaced by 30 sec. The individual chromatogram length is 180 s. First five chromatograms have peaks of the same size, decreasing by factor of 10 in each subsequent chromatogram. The first chromatogram has peak heights 9000 mV and areas 50000 mV.s. Those chromatograms serve for the generation of calibration file and linearity testing.



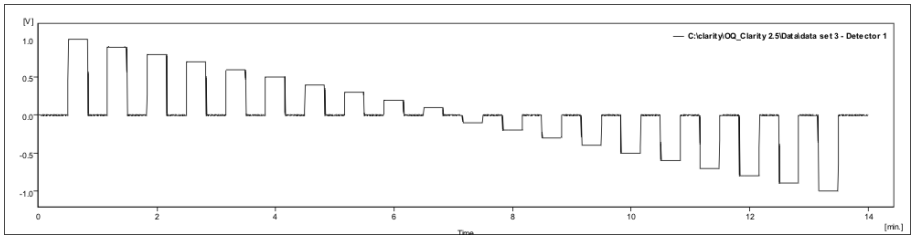
Next six identical chromatograms have **peaks increasing in size by factor of 10**, the last peak has height 9000 mV and area 50000 mV.s. They are used for ESTD calculation and reproducibility tests.



Last six chromatograms have peaks 1, 3, 5 of the same size: height 90 mV and area 500 mV.s, peak 2 has height 0,9 mV and area 5 mV.s and peak 4 has height 9 mV and area 50 mV.s. They are used for ISTD calculations and range consistency check.

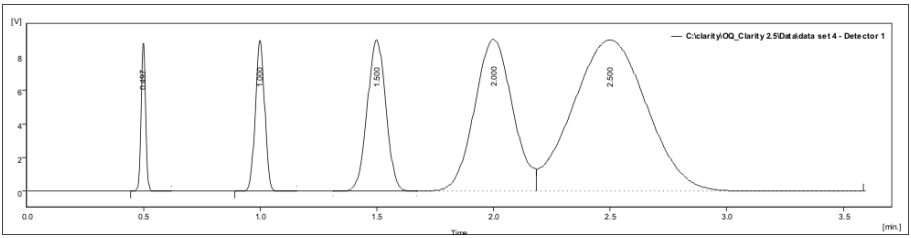
Note: The range is decreased to 150 mV to reduce noise, some pulses are generated during *Range* switching.

Chromatogram data set 3



This chromatogram is used for optional further testing. It consists of **twenty square peaks**. The heights decrease from 1 000 mV to –1000 mV in 100 mV steps. The total chromatogram length is 820 s, the peaks are spaced by 20 s and their width is 20 s. The **baseline** is at *0 mV*

Chromatogram data set 4



This chromatogram is used for optional further testing. It consists **of five gaussian peaks** of the same height, evenly spaced and increasing in width by a factor of 2. The later peaks are overlapping. The total **chromatogram length** is *200* s, the peaks are spaced by 30 s, the **baseline** is at *0 mV* and the first peak's height is 9000 mV. The first peak's area is 12 500 mV.s.

6 Options

6.1 How to validate Clarity Offline

For Operational Qualification of **Clarity Offline**, the SST module is required as well. To perform the validation, follow the outlined procedure:

1. Copy the OQ project folder from the *DataFiles* directory (and the corresponding .PRJ file from the *PROJECTS* subdirectory) of **Clarity** (online), where the OQ has been performed, into your **Clarity Offline** *DataFiles* (and *DataFiles/PROJECTS*) directory. Rename or move the previously generated PDF files containing OQ reports elsewhere.

Note: For the validation of **Clarity Offline**, it is convenient to use shared data storage so that copying of data is not necessary. For more information, refer to User Guide, chapter **Clarity** in Network.

2. From **Clarity Offline** *Bin\OQ_VALIDATION* directory, copy the DATA.DSK file to the *Cfg* directory.
3. Use the *Launch Manager* to run **Clarity Offline** with the copied DATA.DSK file.
4. Open Instrument and choose the copied OQ project.
5. Open *Sequence*. In the *Setup Columns* dialog accessible via *Edit - Setup columns...*, show the *Print to PDF* and *Run Program* columns.
6. In the *Sequence* window, uncheck all checkboxes in the *Run Program* column except for line 12. Uncheck the last checkbox in the *Print* and *Print to PDF* column. Save the sequence.

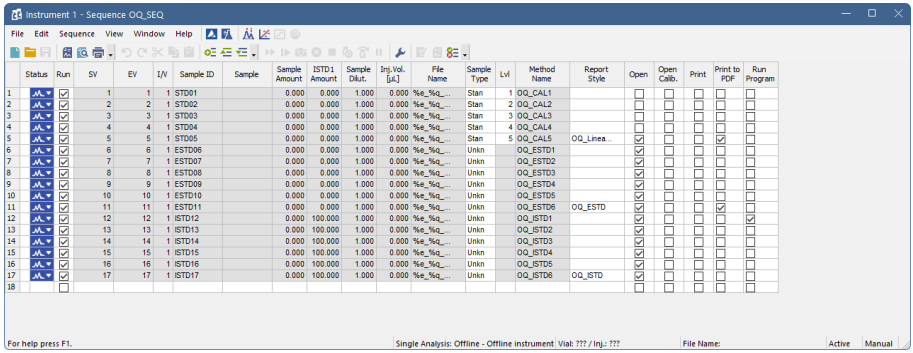


Fig. 17: OQ Offline - sequence settings

7. Open the *Chromatogram* window and close any opened chromatogram. In the *SST* top menu, click *SST Results*. Subsequently, open the OQ_ESTD.SST method via the *SST - Open...* option.
8. From the *Instrument* window, open the *Batch* dialog via *Analysis - Batch*. In the *File Type* combobox, filter only *Sequence Files* and select the OQ_SEQ file. In

the *Options* field, check the *Complete Processing* option. For both *Integration* and *Calibration*, select *Update*.

9. Now, click *Proceed*.

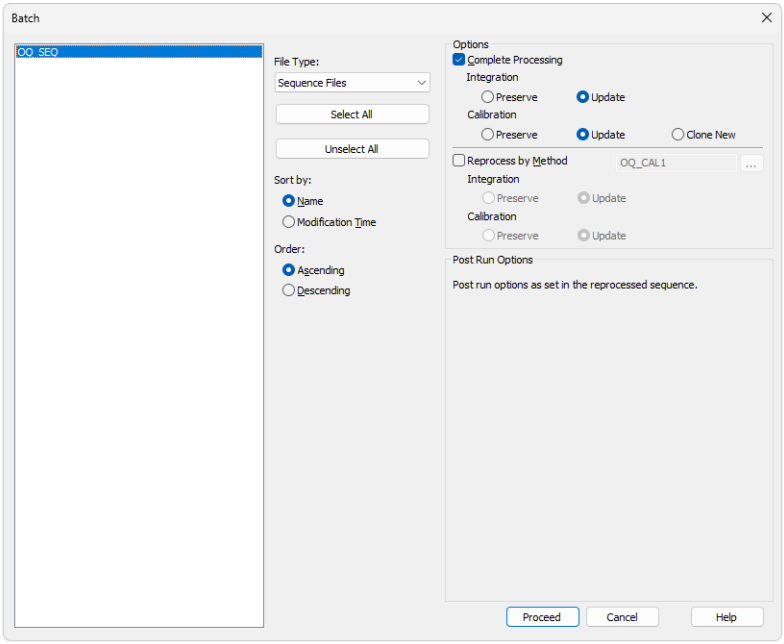


Fig. 18: OQ Offline - batch settings

10. In the *Chromatogram* window, open the *Report Setup* dialog. Via the *Open...* button, open the OQ_ISTD.STY report style. Print the final report.
11. You can now view the generated OQ reports. Note that the names of the new PDF files contain the dates of the original OQ of **Clarity** (online). Rename them if necessary.

6.2 Use with other data systems

A **Terminal Board** can be used for connecting the **Validator** through cables. This allows for the testing of the functionality of the leads or for operation with other data systems. The board has screw contacts for Analog signal OUT, Digital signal IN (External Start) and Digital signal OUT (Start OUT).

7 Troubleshooting

When the validated system does not meet the specified criteria, please check this chapter for possible causes and remedies.

The OQ_linearity calibration curve slope, (also peak area and height for ESTD test) are outside specified limits.

- The A/D board is not properly calibrated. The reported voltage differs from the actual value more than that which is allowed by manufacturer's specifications. As relative measurements by comparison of unknown samples to standards are commonly used in chromatography, this problem is usually not critical and the board can still be used. The problem will only be critical when an absolute evaluation based on tabulated response factors or a calibration from other systems will be used.

The RSD% limits for peak areas and heights are exceeded.

A/D board malfunction or external interferences can cause increased baseline noise.

- Inspect the baseline for possible spikes.
- If using the connection through cables, try directly connecting the **Validator** by the extension cable to the A/D board.

The RSD% and Absolute limits for RT are not met.

With **U-PAD**, on certain slow computers with **Windows 98** operating system, data can be lost in communication on the **USB** line during a processor overload.

- On such computers, avoid demanding disk operations such as disk backup, antivirus scanning, extensive printing during data acquisition.

ISTD or ESTD evaluation in SST module fails.

- Check that the correct SST method files are used. That is OQ_ISTD.SST method for evaluation of the ISTD chromatograms and OQ_ESTD.SST method for evaluation of ESTD chromatograms.
- Check that only the ESTD (or ISTD) chromatograms are loaded in the Chromatogram window.

ISTD or ESTD evaluation SST tables contain single chromatogram only.

- Check that the correct desktop file is used. There has to be used DATA.DSK desktop file.
- Check if *Overlay mode* is enabled. For correct evaluation of SST results *Overlay mode* has to be enabled. For more information about *Overlay mode* refer to Clarity Help.

The absolute limits for ESTD Amounts are exceeded.

This typically appears when the **Validator** was not stabilized enough before starting the sequence or when its temperature was changing (i.e. it was placed on some heat source like on top of a computer).

- Place the **Validator** in constant environment, let it stabilize and then repeat the validation.

8 Appendices

1. Certificate of calibration of the Validator (an example)
2. Certificate of electromagnetic compatibility of the Validator
3. Certificate of calibration of the metering device, used for factory calibration of a Validator
4. ISO 9001 certificate of DataApex company
5. Example of Certificate of Clarity station Validation, issued by the company who performs QA

Up-to-date certificates can be downloaded in from DataApex website or provided upon request. Certificates below are meant only as example.

Validator Certificate 95/04

Validator S/N: 95
Validated: March 13, 2018
Validation Expiry: March 13, 2019

Validation performed using calibrated HP Digital Multimeter 34401A
S/N 3146A11899 (EZU Calibration list 201700127)

CHROMATOGRAM DATA:

SET1: Single chromatogram eight gaussian peaks, evenly spaced by 30 s and increasing in size by a factor of 2. The last peak height is 8000 mV and area is 50000 mV.s. The chromatogram length is 300 s, after this time it is repeated indefinitely.

SET2: Seventeen individual chromatograms, containing five gaussian peaks, evenly spaced by 30 sec. The individual chromatogram length is 180 s. First five chromatograms have peaks of the same size, decreasing by factor of 10 in each subsequent chromatogram. The first chromatogram has peak heights 9000 mV and areas 50000 mV.s. Those chromatograms serve for the generation of calibration file and linearity testing. Next six identical chromatograms have peaks increasing in size by factor of 10; the last peak has height 9000 mV and area 50000 mV.s. Last six chromatograms have peaks 1, 3, 5 of the same size: height 90 mV and area 500 mV.s, peak 2 has height 0,9 mV and area 5 mV.s and peak 4 has height 9 mV and area 50 mV.s.

SET3: Twenty square peaks. The heights decrease from 1 000 mV to –1000 mV in 100 mV steps. The total chromatogram length is 820 s, the peaks are spaced by 20 s and their width is 20 s. The baseline is at 0 mV.

SET4: Five gaussian peaks of the same height, evenly spaced and increasing in width by a factor of 2 (two). The later peaks are overlapping. The total chromatogram length is 200 s, the peaks are spaced by 30 s, the baseline is at 0 mV and the first peak height is 9000 mV. The first peak area is 12 500 mV.s.

The Validator was calibrated and programmed with the above-described data sets. It was tested and it was found to comply with DataApex technical specifications.

Validation performed by: Authorized signature:

DataApex
www.dataapex.com

EMC

Ref. Certif. No.
IECEE-EZU-07-0008-EMC

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE)

CB EMC TEST CERTIFICATE

Product	Validator
Name and address of the applicant	DataApex spol. s r.o. Lety 24, 252 29 Dobřichovice, Czech Republic
Name and address of the manufacturer	DataApex spol. s r.o. Lety 24, 252 29 Dobřichovice, Czech Republic
Name and address of the factory	DataApex s.r.o. Podhradská 1704/1, 155 00 Praha 5, Czech Republic
Ratings and principal characteristics	6 V DC, 500 mA (adapter: 230 V, 50 Hz, 50 mA)
Trademark (if any)	
Model / Type Ref.	Validator
Additional information	

	PUBLICATION	EDITION
A sample of the product was tested and found to be in conformity with	CISPR 24 CISPR 22	1997+Am.1:2001+Am.2:2002 2005
As shown in the Test Report Ref. No. which forms part of this Certificate	702864-01/01, 702864-01/02 of: 09.10.2007	

This CB EMC Test Certificate is issued by the National Certification Body

Elektrotechnický zkušební ústav, s.p.
Pod Lisem 129, 171 02 Praha 8 – Troja
Czech Republic

Date: 6.12.2007

1 Signature: Pavel Kudrna
Certification and Inspection Manager

Issued 2003-05

CER/IECEE-EZU-07-0008-EMC

702864-01

list 1 z 2

ezú elektrotechnický zkušební ústav

Kalibrační list č. 201700127

K 2294

Elektrotechnický zkušební ústav, s.p., Pod Lisem 129, 171 02 Praha 8, Kalibrační laboratoř č. 2294, akreditovaná ČIA podle ČSN EN ISO/IEC 17025:2005

Zákazník: DataApex, spol. s r. o.
Petržílkova 2583/13
158 00 Praha 5 - Stodůlky

Kalibrované měřidlo: Digitální multimetr
Výrobce: Hewlett Packard
Typ: 34401A
Výrobní číslo: 3146A11899

Datum přijetí: 27.6.2017

Datum provedení: 14.7.2017

Podmínky prostředí: Teplota 23 °C ± 2 °C, relativní vlhkost 45 % ± 25 %.

Použité etalony: Multifunkční kalibrátor Datron 4700 v.č. 21121-14
Multimetr Wavetek 1281 v.č. 42742
Návaznost: Etalony jsou navázány na ČMI.

Použité metody: Metodika kalibrace MK8 - pouze stejnosměrné napětí

Výsledek kalibrace: Naměřené hodnoty jsou uvedeny na listu 2. Měřidlo bylo označeno štítkem s číslem tohoto kalibračního listu a s datem provedení kalibrace.

Nejistota měření: Uvedená rozšířená nejistota měření je součinem standardní nejistoty měření a koeficientu rozšíření k=2, což pro normální rozdělení odpovídá pravděpodobnosti pokrytí cca 95 %. Standardní nejistota měření byla určena v souladu s dokumentem EA 4/02.

elektrotechnický zkušební ústav ezú -1- kalibrační laboratoř

Měřil: Ing. Vladimír Choura

V Praze dne 24.7.2017

Ing. Jan Černý
technický vedoucí laboratoře

Kalibrační list nesmí být bez písemného souhlasu vydávající laboratoře dále rozmnožován jinak než celý. Naměřené hodnoty se týkají jen kalibrovaného měřidla. Na hodnoty označené jako neakreditované se akreditace ČIA nevztahuje.

Kalibrační list č. 201700127 *list 2 z 2*
naměřené hodnoty

Funkce	Rozsah	Konvenčně pravá hodnota	Indikace měřidla	Chyba měřidla	% meze dovolené chyby	Meze dovolené chyby (±)	Nejistota měření
VDC-2W	120 mV	11,9995 mV	11,9987 mV	-0,74 µV	-18	4,08 µV	0,46 µV
VDC-2W	120 mV	59,9985 mV	59,9966 mV	-1,92 µV	-30	6,48 µV	0,87 µV
VDC-2W	120 mV	109,9977 mV	109,9942 mV	-3,4 µV	-38	9,0 µV	1,2 µV
VDC-2W	120 mV	-109,9979 mV	-109,9963 mV	1,5 µV	17	9,0 µV	1,2 µV
VDC-2W	1,2 V	0,119997 V	0,119999 V	0,0017 mV	15	0,0118 mV	0,0015 mV
VDC-2W	1,2 V	0,599997 V	0,600001 V	0,0039 mV	12	0,0310 mV	0,0045 mV
VDC-2W	1,2 V	1,099993 V	1,100000 V	0,0068 mV	13	0,0510 mV	0,0082 mV
VDC-2W	1,2 V	-1,099989 V	-1,100003 V	-0,0134 mV	-26	0,0510 mV	0,0083 mV
VDC-2W	12 V	1,19999 V	1,20000 V	0,008 mV	8	0,092 mV	0,010 mV
VDC-2W	12 V	3,59998 V	3,60001 V	0,030 mV	17	0,176 mV	0,028 mV
VDC-2W	12 V	5,99996 V	6,00001 V	0,052 mV	20	0,260 mV	0,045 mV
VDC-2W	12 V	8,39994 V	8,40002 V	0,073 mV	21	0,344 mV	0,063 mV
VDC-2W	12 V	10,99993 V	11,00002 V	0,094 mV	21	0,435 mV	0,082 mV
VDC-2W	12 V	-1,19999 V	-1,20001 V	-0,024 mV	-25	0,092 mV	0,011 mV
VDC-2W	12 V	-10,99995 V	-11,00006 V	-0,116 mV	-27	0,435 mV	0,083 mV
VDC-2W	120 V	11,9999 V	12,0001 V	0,21 mV	18	1,14 mV	0,10 mV
VDC-2W	120 V	59,9997 V	60,0009 V	1,24 mV	38	3,30 mV	0,72 mV
VDC-2W	120 V	109,9996 V	110,0016 V	2,0 mV	37	5,6 mV	1,3 mV
VDC-2W	120 V	-109,9995 V	-110,0020 V	-2,6 mV	-46	5,6 mV	1,3 mV
VDC-2W	1 kV	0,099999 kV	0,100001 kV	0,0018 V	13	0,0145 V	0,0013 V
VDC-2W	1 kV	0,500001 kV	0,500006 kV	0,0051 V	16	0,0325 V	0,0060 V
VDC-2W	1 kV	0,900002 kV	0,900011 kV	0,010 V	19	0,051 V	0,010 V
VDC-2W	1 kV	-0,900001 kV	-0,900013 kV	-0,012 V	-23	0,051 V	0,010 V

značení funkcí: VDC-2W stejnosměrné napětí

Meze dovolené chyby jsou stanoveny podle roční specifikace výrobce měřidla.

Konec kalibračního listu.

Elektrotechnický zkušební ústav
Kalibrační laboratoř
Pod Lisem 129
171 02 Praha 8 - Troja

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

DataApex

DataApex, spol. s r.o.
Lety 24
252 29 Dobřichovice
Czech Republic

with the location

Petržílkova 2583/13
CZ - 158 00 Praha 5
Czech Republic

has established and applies
a Quality Management System for

Software development. Development and production of hardware and measurement instruments inclusive of trade activities in these fields.

An audit was performed, Order No. **704076499**.
Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2019-01-04** until **2022-01-03**.

Certificate Registration No.: **12 100 30406 TMS**.

Product Compliance Management
Munich, 2019-01-03

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstrasse 65 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

TÜV®

MZ/31.02/2018

Certificate of Clarity station Validation

Certificate No.: 01/2018
User: Example Laboratories Ltd.
John Analyst, head of QA laboratory
Software: Clarity
Version: 7.4.1.088
S/N: 11-54321
A/D Board: Colibrick 2-channel, S/N: 1234
Computer: LAB01
Operating System: Windows 7 Service Pack 1
Validator: Validator ver.2

The chromatography datastation specified above was properly installed and its functionality verified by procedure developed by the DataApex, Ltd. This certificate confirms, that the station is functional and performs according to the manufacturer's specifications. Part of this certificate are the *Installation Qualification Report* and properly checked and signed records of the *Calibration Linearity Test, ESTD Calculation Test* and *ISTD Calculation Test.*

The Validation was performed by qualified service engineer of Instrument Service Company.

Validation performed by: Peter Qualificator **Signature:** **Date: 01.01.2018**
Authorization number: XX123
Company name: AB Company

User: **John Analyst** **Signature:** **Date: 01.01.2018**

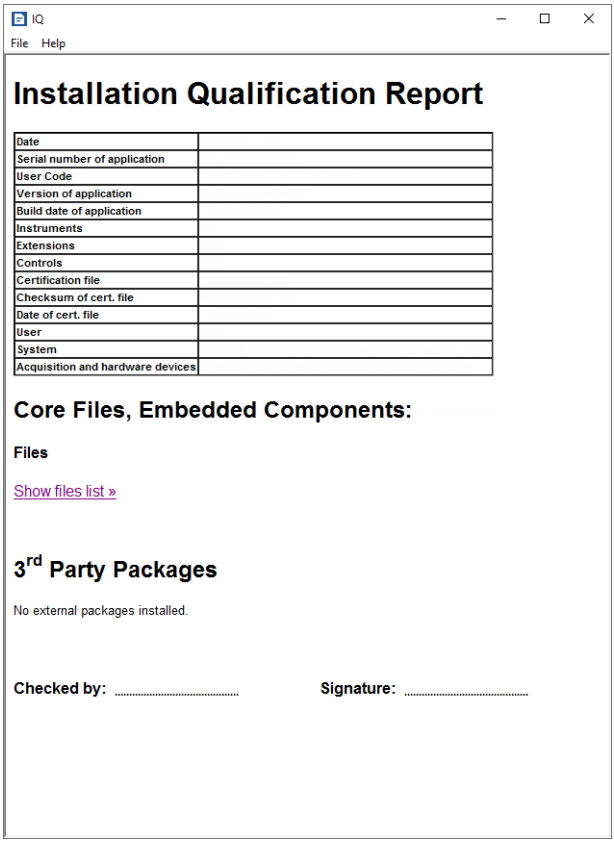


Fig. 19: Installation qualification blank report

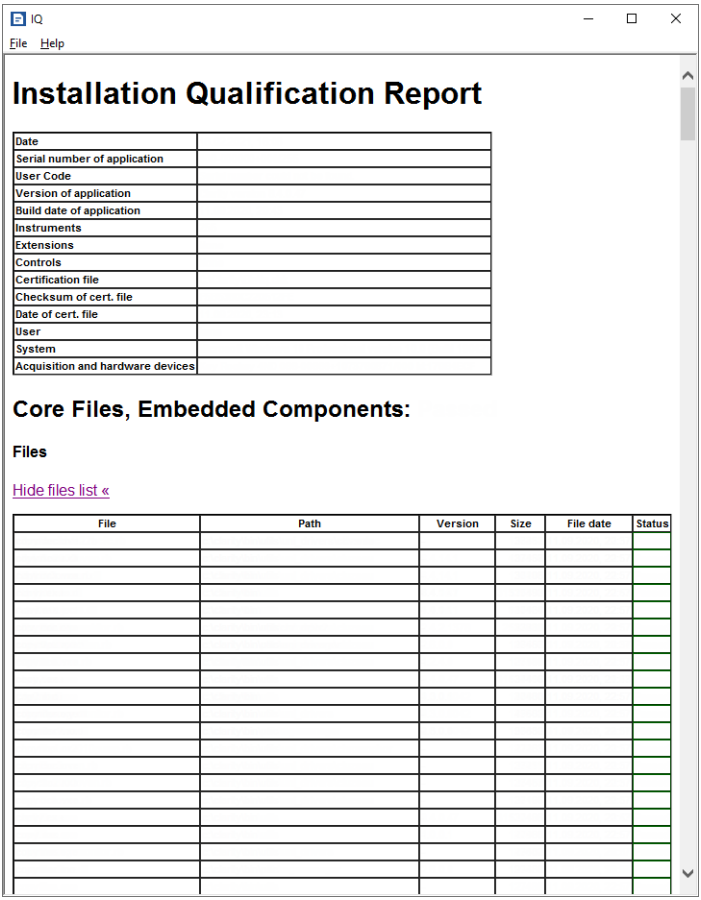


Fig. 20: Installation qualification blank report

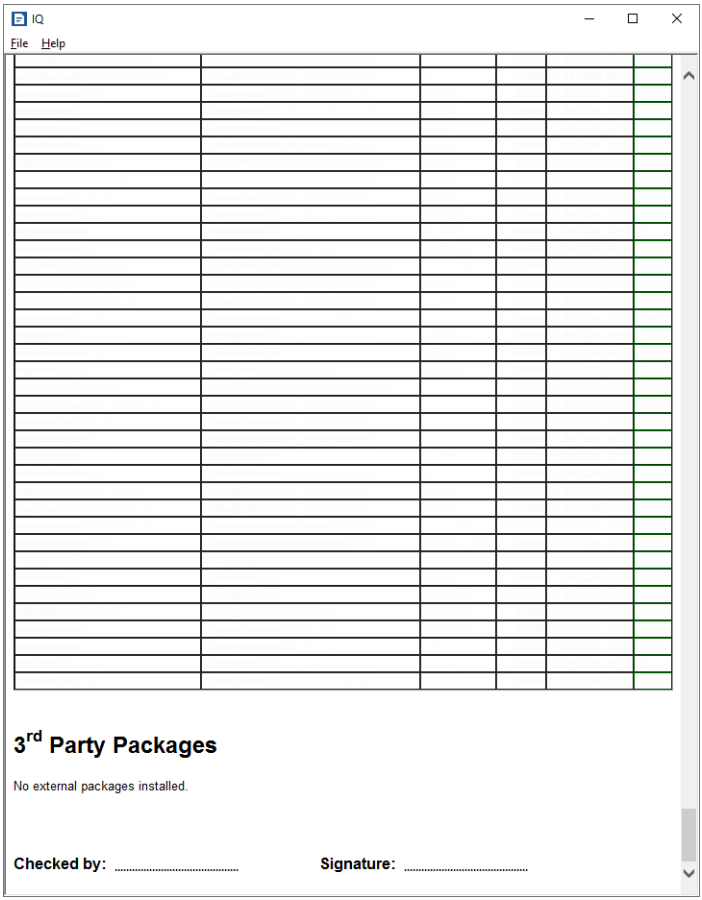


Fig. 21: Installation qualification blank report

Page of

Clarity - Operational Qualification

Calibration linearity test

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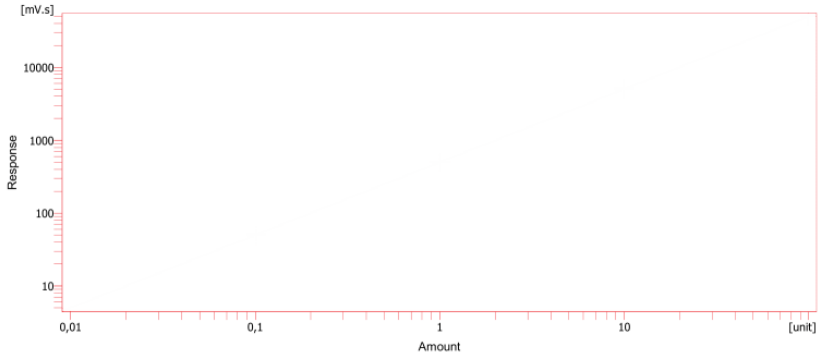
Peak - Signal 1 - min

Peak Type	:
Search Window	:
Left Window	:
Right Window	:
Peak Selection	:
Response Base	:
Is ISTD	:
Use ISTD	:
Curve Fit Type	:
Origin	:
Weighting Method	:
Linearisation X	:
Linearisation Y	:
Correction Factor	:
Calculate By	:
Correlation Factor	:
Residuum	:
Equation	:

	Response	Amount	Resp. Factor	Rec No.	Used
1					☐
2					☐
3					☐
4					☐
5					☐
6					☐
7					☐
8					☐
9					☐
10					☐
11					☐
12					☐
13					☐
14					☐
15					☐
16					☐
17					☐
18					☐
19					☐
20					☐
BL					☐

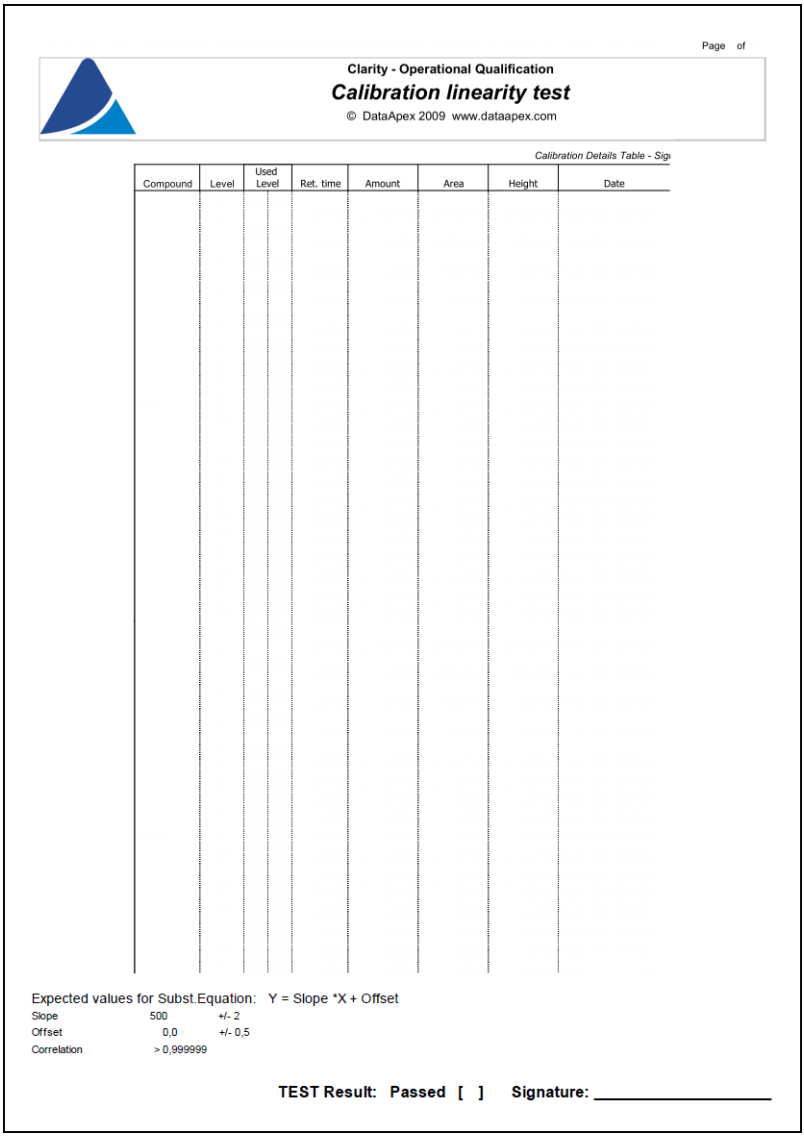


Expected values for Subst.Equation: Y = Slope *X + Offset

Slope	500	+/- 2
Offset	0,0	+/- 0,5
Correlation	> 0,999999	

TEST Result: Passed [ ] Signature: _____

Fig. 22: Calibration linearity blank report



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Clarity - Operational Qualification

Calibration linearity test

Calibration Details Table - Sig

Compound	Level	Used Level	Ret. time	Amount	Area	Height	Date

Expected values for Subst.Equation: Y = Slope *X + Offset

Slope	500	+/- 2
Offset	0,0	+/- 0,5
Correlation	> 0,999999	

TEST Result: Passed [ ] Signature: _____

Fig. 23: Calibration linearity blank report

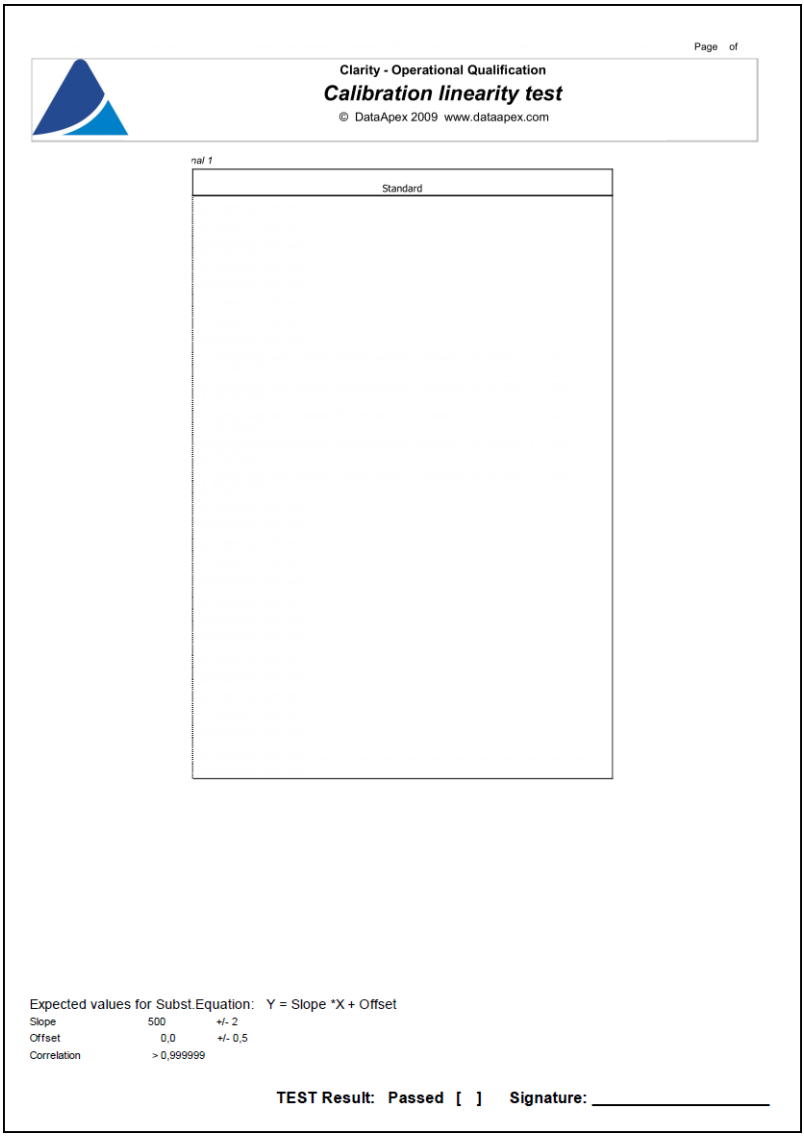
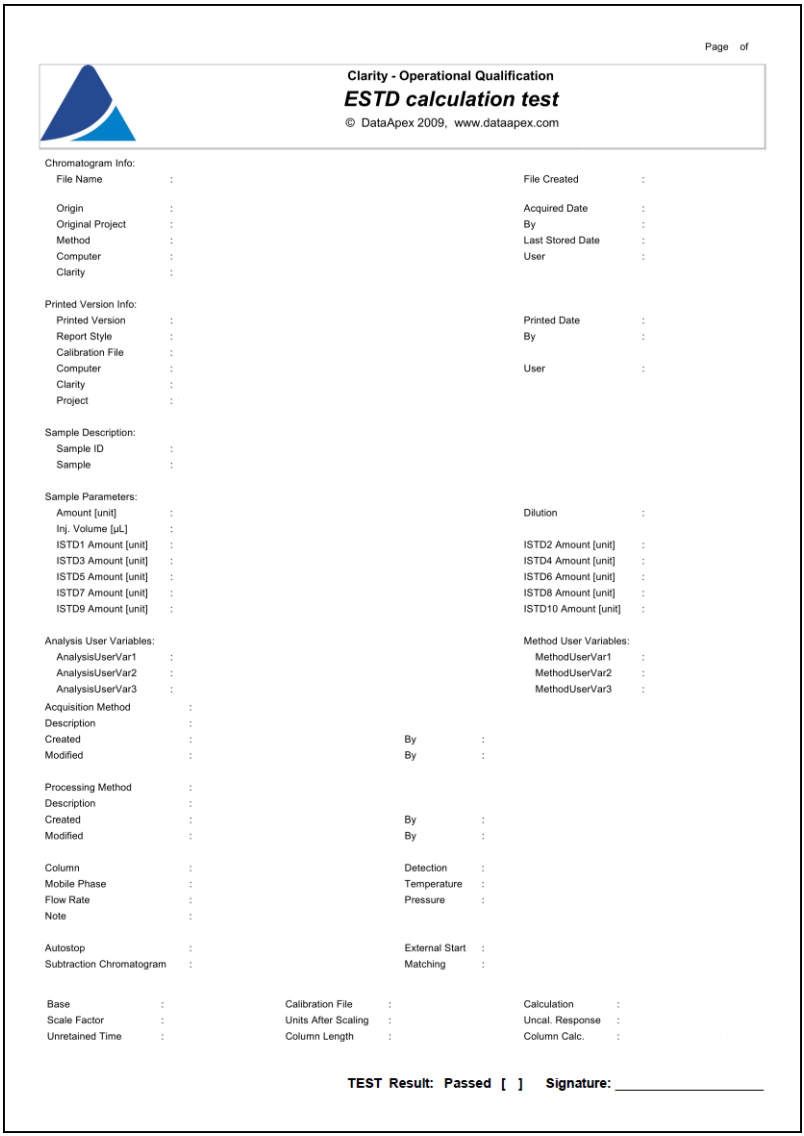


Fig. 24: Calibration linearity blank report



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Clarity - Operational Qualification

ESTD calculation test

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Chromatogram Info:
File Name : File Created :
Origin : Acquired Date :
Original Project : By :
Method : Last Stored Date :
Computer : User :
Clarity :

Printed Version Info:
Printed Version : Printed Date :
Report Style : By :
Calibration File :
Computer : User :
Clarity :
Project :

Sample Description:
Sample ID :
Sample :

Sample Parameters:
Amount [unit] : Dilution :
Inj. Volume [µL] :
ISTD1 Amount [unit] : ISTD2 Amount [unit] :
ISTD3 Amount [unit] : ISTD4 Amount [unit] :
ISTD5 Amount [unit] : ISTD6 Amount [unit] :
ISTD7 Amount [unit] : ISTD8 Amount [unit] :
ISTD9 Amount [unit] : ISTD10 Amount [unit] :

Analysis User Variables: Method User Variables:
AnalysisUserVar1 : MethodUserVar1 :
AnalysisUserVar2 : MethodUserVar2 :
AnalysisUserVar3 : MethodUserVar3 :

Acquisition Method :
Description :
Created : By :
Modified : By :

Processing Method :
Description :
Created : By :
Modified : By :

Column : Detection :
Mobile Phase : Temperature :
Flow Rate : Pressure :
Note :

Autostop : External Start :
Subtraction Chromatogram : Matching :

Base : Calibration File : Calculation :
Scale Factor : Units After Scaling : Uncal. Response :
Unretained Time : Column Length : Column Calc. :

TEST Result: Passed [ ] Signature: _____

Fig. 25: ESTD test blank report

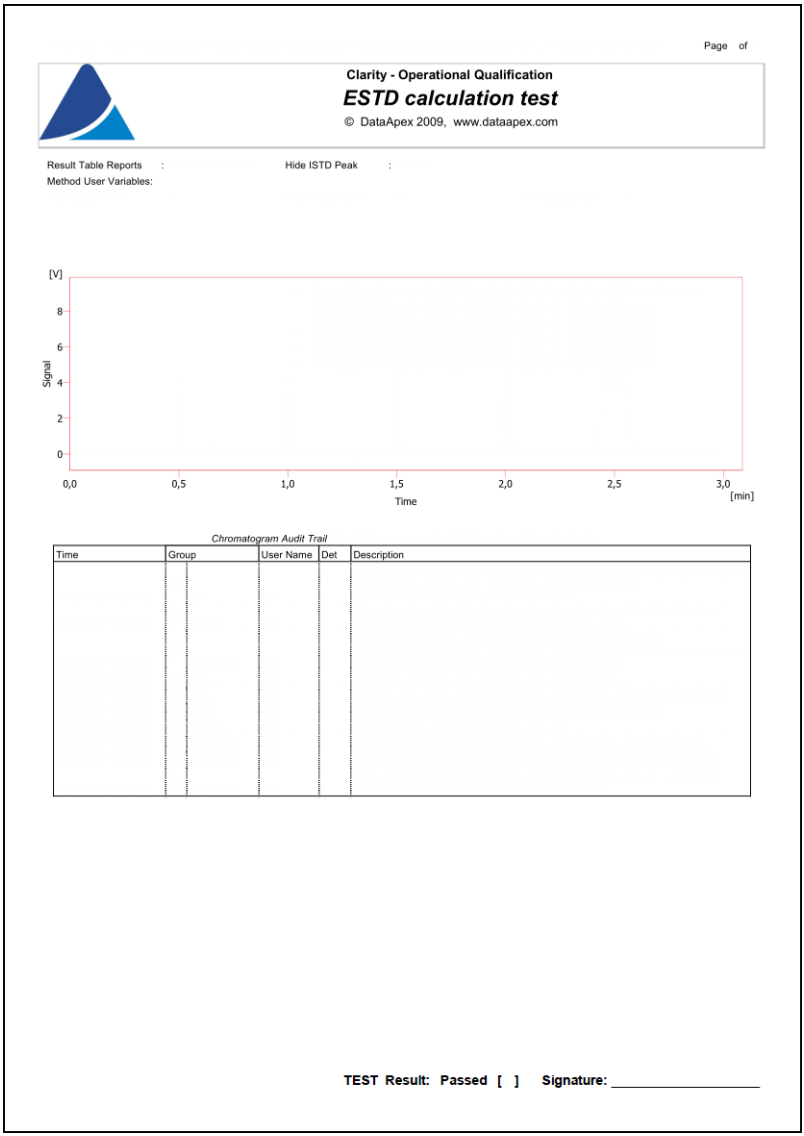
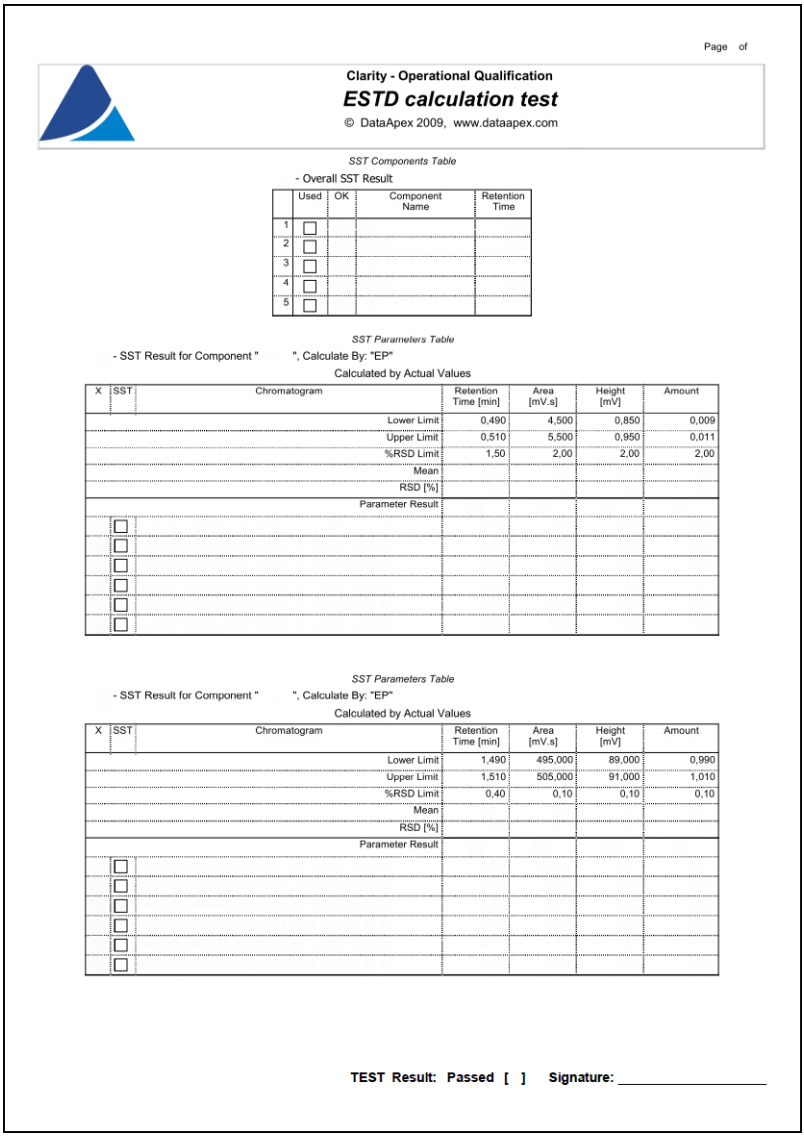


Fig. 26: ESTD test blank report



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Clarity - Operational Qualification

ESTD calculation test

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SST Components Table

- Overall SST Result

	Used	OK	Component Name	Retention Time
1	☐			
2	☐			
3	☐			
4	☐			
5	☐			

SST Parameters Table

- SST Result for Component " ", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	0,490	4,500	0,850	0,009
		Upper Limit	0,510	5,500	0,950	0,011
		%RSD Limit	1,50	2,00	2,00	2,00
		Mean				
		RSD [%]				
		Parameter Result				
	☐					
	☐					
	☐					
	☐					
	☐					
	☐					

SST Parameters Table

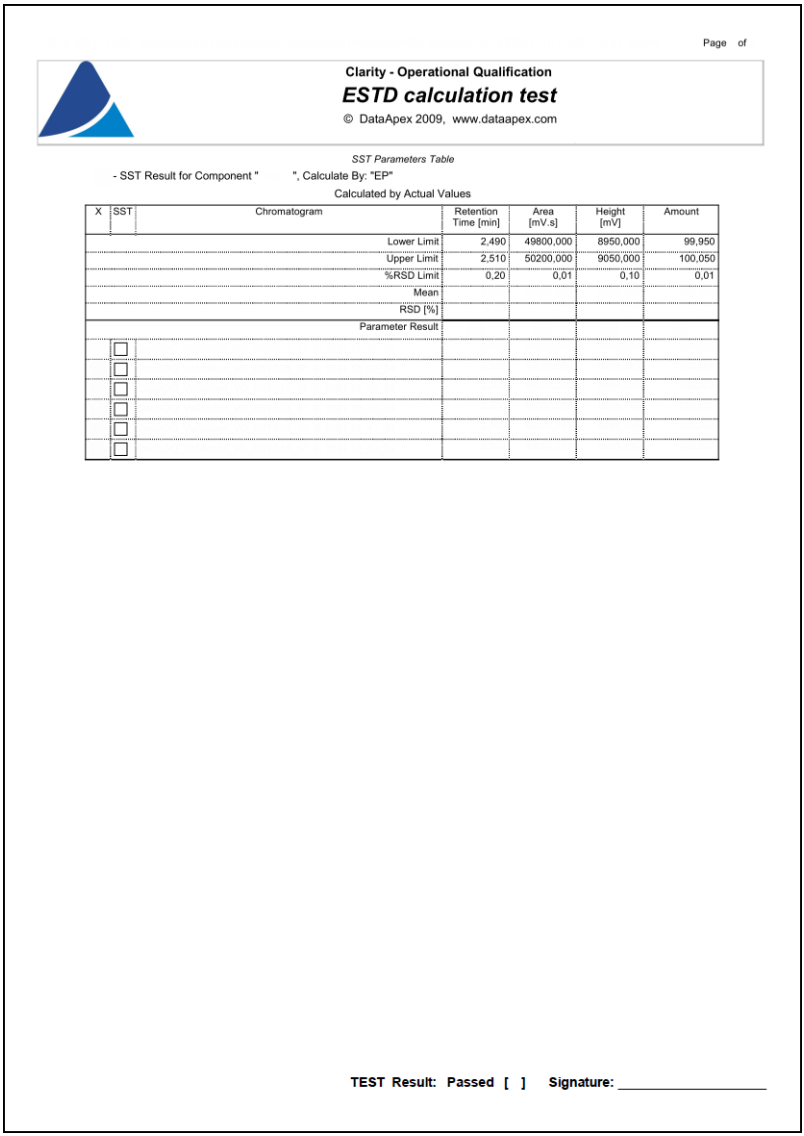
- SST Result for Component " ", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	1,490	495,000	89,000	0,990
		Upper Limit	1,510	505,000	91,000	1,010
		%RSD Limit	0,40	0,10	0,10	0,10
		Mean				
		RSD [%]				
		Parameter Result				
	☐					
	☐					
	☐					
	☐					
	☐					
	☐					

TEST Result: Passed [ ] Signature: _____

Fig. 27: ESTD test blank report



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Clarity - Operational Qualification

ESTD calculation test

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SST Parameters Table

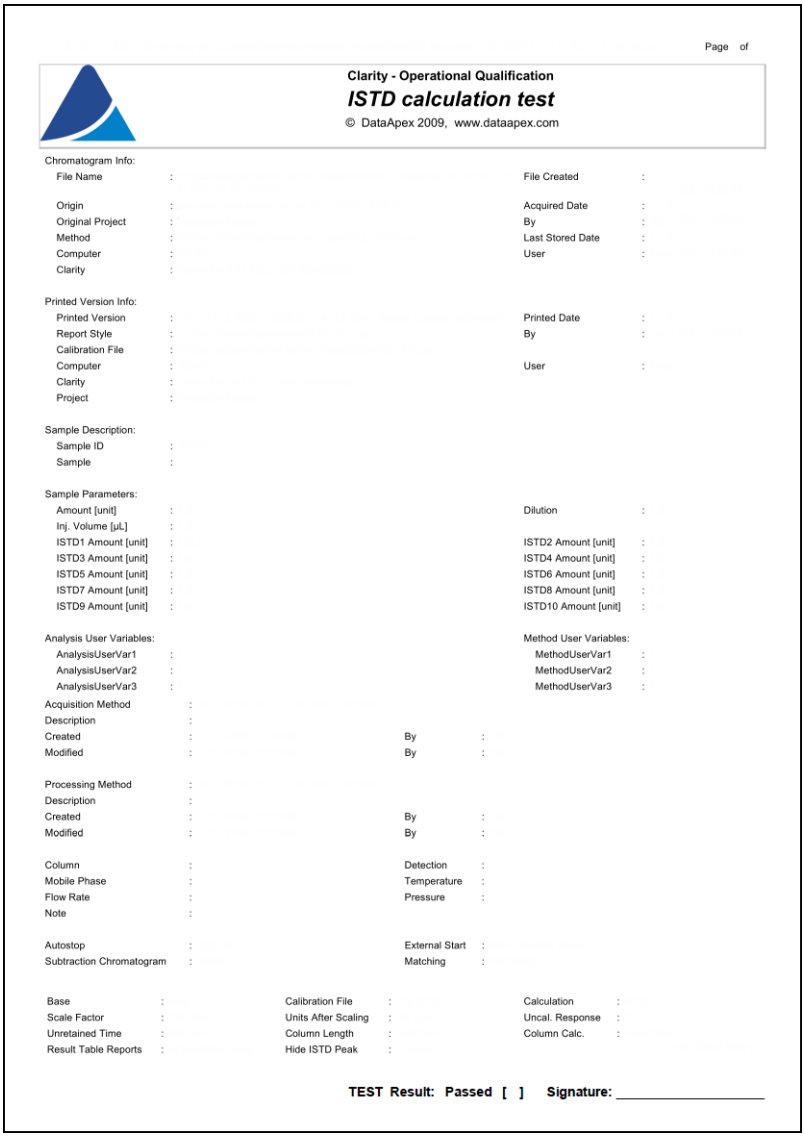
- SST Result for Component " ", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	2,490	49800,000	8950,000	99,950
		Upper Limit	2,510	50200,000	9050,000	100,050
		%RSD Limit	0,20	0,01	0,10	0,01
		Mean				
		RSD [%]				
		Parameter Result				
	☐					
	☐					
	☐					
	☐					
	☐					
	☐					

TEST Result: Passed [ ] Signature: _____

Fig. 28: ESTD test blank report



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Clarity - Operational Qualification

ISTD calculation test

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Chromatogram Info:
File Name : File Created :
Origin : Acquired Date :
Original Project : By :
Method : Last Stored Date :
Computer : User :
Clarity :

Printed Version Info:
Printed Version : Printed Date :
Report Style : By :
Calibration File :
Computer : User :
Clarity :
Project :

Sample Description:
Sample ID :
Sample :

Sample Parameters:
Amount [unit] : Dilution :
Inj. Volume [µL] :
ISTD1 Amount [unit] : ISTD2 Amount [unit] :
ISTD3 Amount [unit] : ISTD4 Amount [unit] :
ISTD5 Amount [unit] : ISTD6 Amount [unit] :
ISTD7 Amount [unit] : ISTD8 Amount [unit] :
ISTD9 Amount [unit] : ISTD10 Amount [unit] :

Analysis User Variables: Method User Variables:
AnalysisUserVar1 : MethodUserVar1 :
AnalysisUserVar2 : MethodUserVar2 :
AnalysisUserVar3 : MethodUserVar3 :

Acquisition Method :
Description :
Created : By :
Modified : By :

Processing Method :
Description :
Created : By :
Modified : By :

Column : Detection :
Mobile Phase : Temperature :
Flow Rate : Pressure :
Note :

Autostop : External Start :
Subtraction Chromatogram : Matching :

Base : Calibration File : Calculation :
Scale Factor : Units After Scaling : Uncal. Response :
Unretained Time : Column Length : Column Calc. :
Result Table Reports : Hide ISTD Peak :

TEST Result: Passed [ ] Signature: _____

Fig. 29: ISTD test blank report

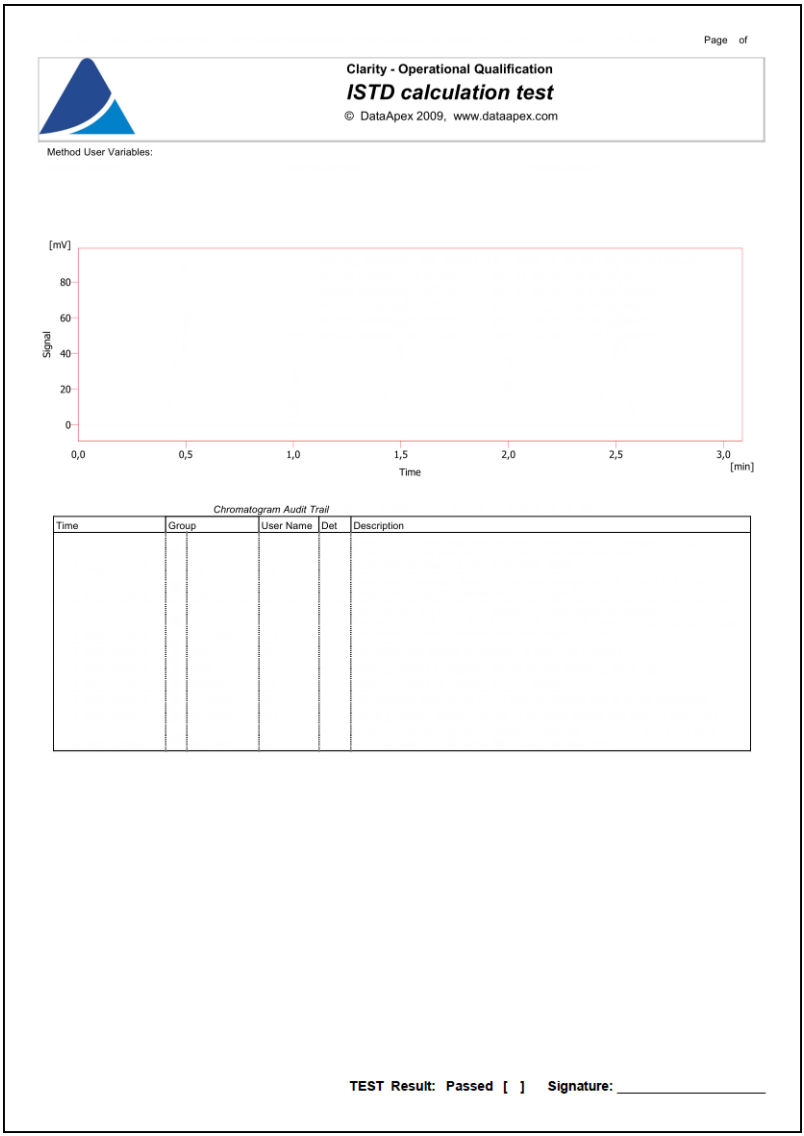

Fig. 30: ISTD test blank report

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Clarity - Operational Qualification

ISTD calculation test

SST Components Table

- Overall SST Result

	Used	OK	Component Name	Retention Time
1	☐			
2	☐			
3	☐			
4	☐			
5	☐			

SST Parameters Table

- SST Result for Component " ", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	0,990	4,500	0,850	0,950
		Upper Limit	1,010	5,500	0,950	1,050
		%RSD Limit	0,60	2,00	2,00	2,00
		Mean				
		RSD [%]				
		Parameter Result				
	☐					
	☐					
	☐					
	☐					
	☐					
	☐					

SST Parameters Table

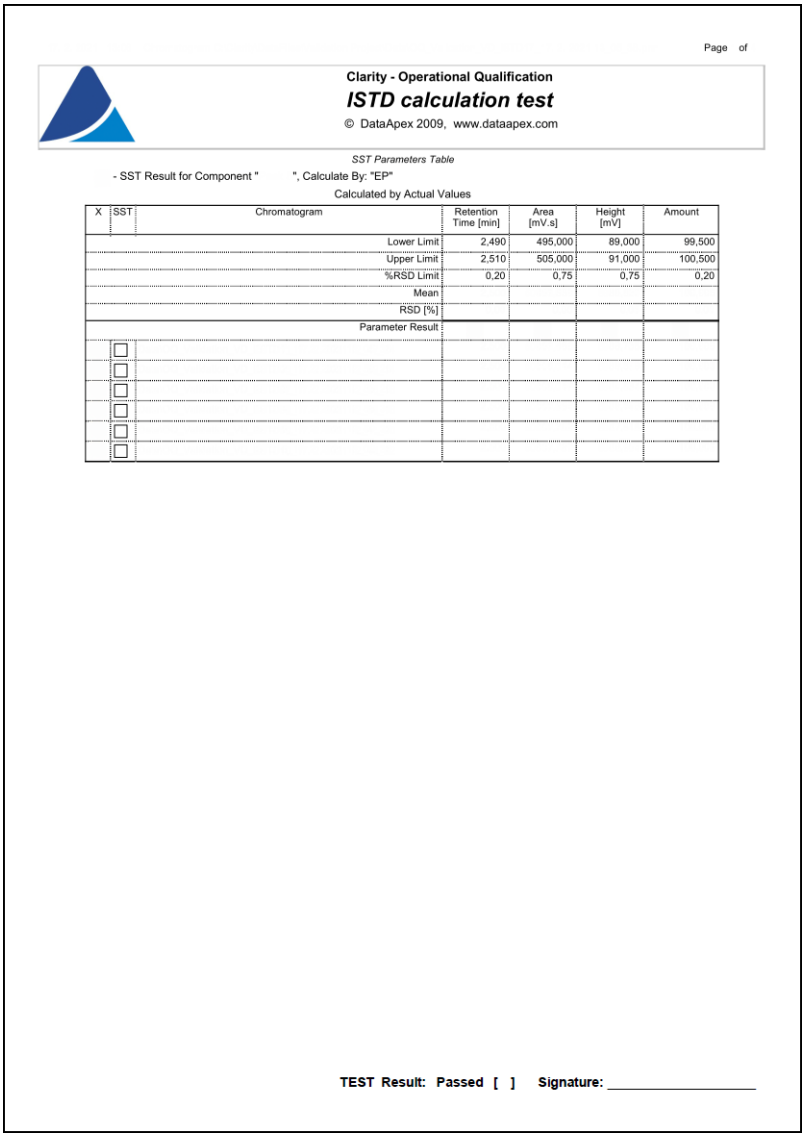
- SST Result for Component " ", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	1,990	49,500	8,900	9,950
		Upper Limit	2,010	50,500	9,100	10,050
		%RSD Limit	0,30	0,75	0,75	0,50
		Mean				
		RSD [%]				
		Parameter Result				
	☐					
	☐					
	☐					
	☐					
	☐					
	☐					

TEST Result: Passed [ ] Signature: _____

Fig. 31: ISTD test blank report



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Clarity - Operational Qualification

ISTD calculation test

SST Parameters Table

- SST Result for Component " ", Calculate By: "EP"

Calculated by Actual Values

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount
		Lower Limit	2,490	495,000	89,000	99,500
		Upper Limit	2,510	505,000	91,000	100,500
		%RSD Limit	0,20	0,75	0,75	0,20
		Mean				
		RSD [%]				
		Parameter Result				
	☐					
	☐					
	☐					
	☐					
	☐					
	☐					

TEST Result: Passed [ ] Signature: _____

Fig. 32: ISTD test blank report