

Clarity

Validation kit

HW + SW

ENG

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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:

Instrument (blue text) marks the name of the window to which the text refers.

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 (when you already are in the topic describing the window).

WORK1 (capital) indicates the name of the file and/or directory.

ACTIVE (capital italics) marks the state of the station or its part.

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.

I 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 Virtual detector control module, which is able to send data into **Clarity** in exactly the same way as a real chromatographic instrument would do. This will ensure that digital signal is processed correctly after being received from detector. Virtual 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 Virtual Detector (VD) has to be installed otherwise OQ validation cannot be performed. During **Full** and **Typical** installation VD is installed automatically. During **Custom** installation select Virtual Detector option in the following tree: LC Control - Knauer modules - Detectors - Virtual detector.

1.1 System requirements

- **DataApex Clarity Chromatography Station** version **2.8** or higher is required for performing Operational Qualification.

Note: **Clarity** can be updated to last version free of charge. Latest updates are available on the www.dataapex.com website in the **Download** section.

Note: The **Clarity** version number can be found in the **About – Clarity** dialog invoked using the *Help – About* command.

- **Clarity SST module**, an optional part of **Clarity** software (p/n A22), is necessary for data evaluation.
- 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 Virtual 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 Virtual detector if the station does not have GC Control (p/n A23), LC Control (p/n A24) or CE Extension (p/n A31) purchased.
- Printer configured on the PC. Virtual PDF printer can be used instead of hardware printer.

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 will provide 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**.

1.2 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 Operational Qualification

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

2.1 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

2.2 List of used files

The OQ_VALIDATION folder in **Clarity** main folder contains the AD_CONVERTER and VIRTUAL_DETECTOR subfolders with all the sequences, methods, calibrations, SST and report style files.

2.2.1 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.

2.2.2 Calibration files

OQ_CAL.CAL used for linearity and ESTD tests

OQ_ISTD.CAL used for ISTD test

2.2.3 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.

2.2.4 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 header of the reports.

2.2.5 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).

2.2.6 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.

2.3 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 Virtual Detector will generate necessary dataset instead.

2.3.0.1 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

2.3.0.2 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	Limit	RT min	Area mV.s	Height mV	Amount
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 corresponds to this value.

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

2.3.0.3 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	Limit	RT min	Area mV.s	Height mV	Amount
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 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 analytic 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 crash 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*. Note it can also a virtual PDF printer, etc.

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.

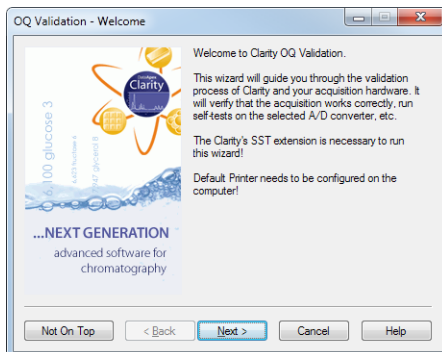


Fig 1: Welcome

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.

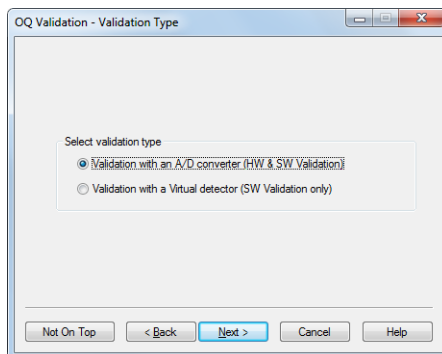


Fig 2: Validation Type

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).

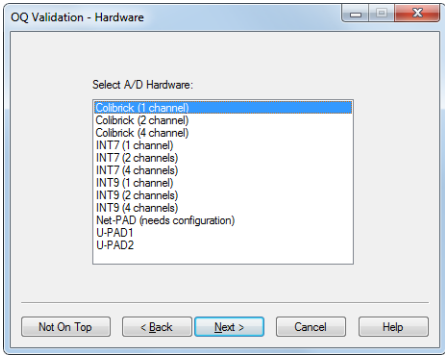


Fig 3: Hardware

Step 5 : Validator

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

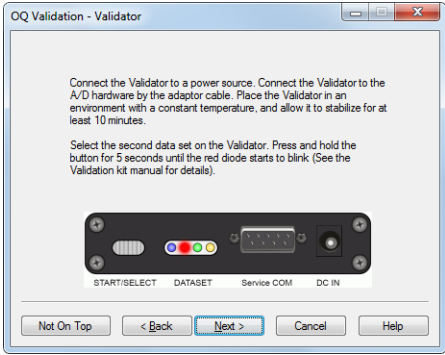


Fig 4: Validator

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.

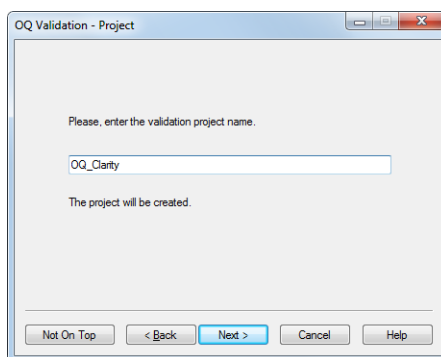


Fig 5: Project

Step 7 : Ready

This step summarizes all selected values.

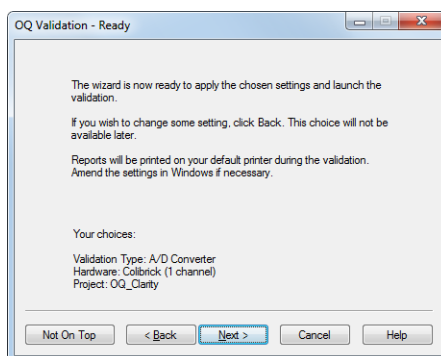


Fig 6: Ready

Step 8 : Running

This dialog indicates the progress of the entire validation process. During the validation, several windows will automatically be opened (*Instrument*, *Data Acquisition*, *Sequence*, *Chromatogram*). You can check actually 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.



Fig 7: 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.

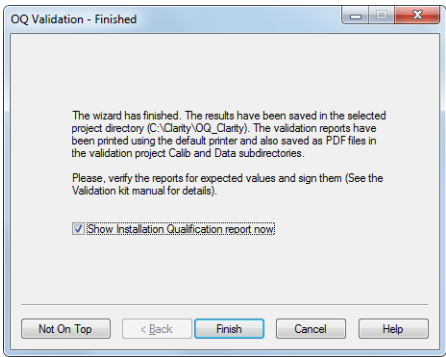


Fig 8: Finished

4 Validator

4.1 Description



Fig 9: 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 (potentially 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 10: 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.

4.2 Technical specification

4.2.1 Generated data parameters:

Signal Accuracy +/- 1 mV at 10 V Range
Signal Resolution +/- 10 μ V at 10 V Range
Signal Linearity -/+ 0,0015%
Time Accuracy 0,01% (stabilized state)

4.2.2 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.

4.2.3 Power supply

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

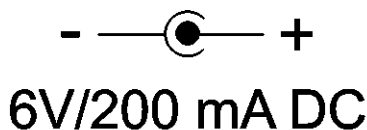


Fig 11: Power supply connector description

4.3 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.

4.4 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.

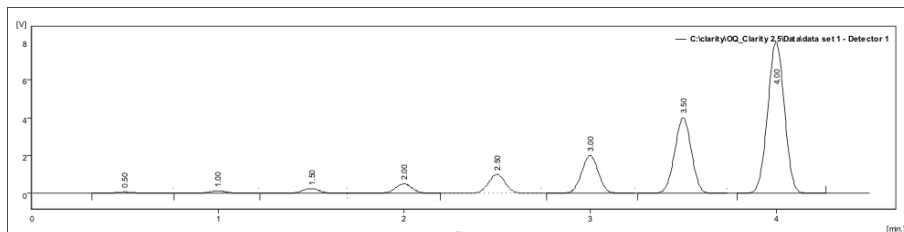
Calibration certificate is valid for a limited period of one year from the day of the calibration. Following its expiration, the **Validator** should be recalibrated at DataApex facility.

4.5 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.

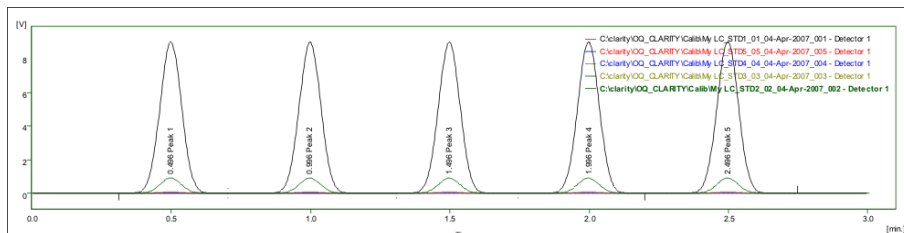
Note: The **Validator** can be supplied or re-programmed with different data sets upon request.

Chromatogram data set 1

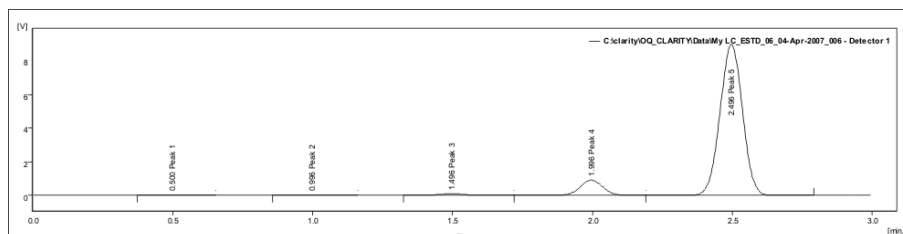


This chromatogram set is used for optional further testing. It consists of single chromatogram **eight gaussian peaks**, evenly spaced by 30 s and increasing in size by a factor of 2. The last peak height is 8000 mV and area is 50000 mV.s. The chromatogram length is 300 s, after this time it is repeated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

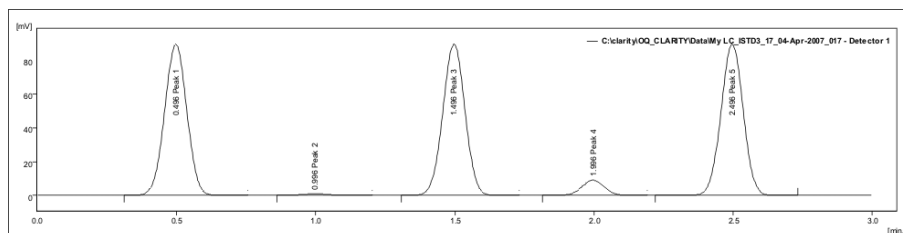
Chromatogram data set 2



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.



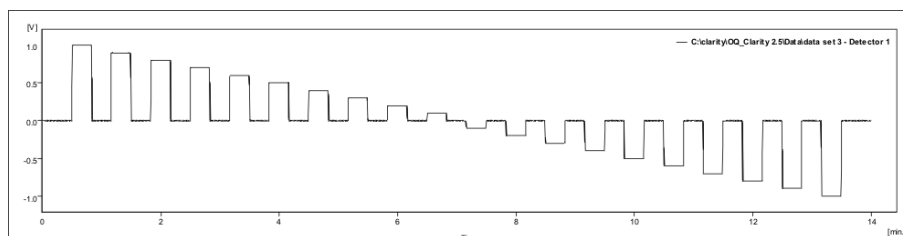
Next six identical chromatograms have **peaks increasing in size by factor of 10**, the last peak has height 9000 mV and area 50000 mV.s. They are used for ESTD calculation and reproducibility tests.



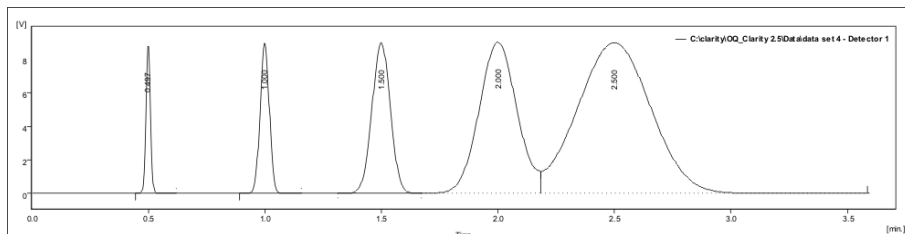
Last six chromatograms have peaks 1,3,5 of the same size: height 90 mV and area 500 mV.s, peak 2 has height 0.9 mV and area 5 mV.s and peak 4 has height 9 mV and area 50 mV.s. They are used for ISTD calculations and range consistency check.

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.

5 Options

5.1 Validation of systems without the SST module

Without the **Clarity SST module**, the measured chromatogram's results can be evaluated against the specifications provided in part **3.3**, using a suitable spreadsheet program (e.g. MS Excel). This option is not supported by **DataApex**.

5.2 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).

6 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.

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.

6 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

Certificates can be downloaded in high resolution from DataApex website (www.dataapex.com).



Validator Certificate 69/01

Validator S/N: 69
Validated: November 24, 2008
Validation Expiry: November 24, 2009

Validation performed using calibrated HP Digital Multimeter 34401A
S/N 3146A11899 (EZU Calibration list 200700140)

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:

A handwritten signature in black ink, appearing to read 'Jan Kuf', is written over a light blue horizontal line.

	<h1 style="font-size: 48px; margin: 0;">EMC</h1>	Ref. Certif. No. IECEE-EZU-07-0008-EMC
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IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE)	CB EMC TEST CERTIFICATE
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Product Name and address of the applicant Name and address of the manufacturer Name and address of the factory Ratings and principal characteristics Trademark (if any) Model / Type Ref. Additional information A sample of the product was tested and found to be in conformity with As shown in the Test Report Ref. No. which forms part of this Certificate 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	Validator DataApex spol. s r.o. Lety 24, 252 29 Dobřichovice, Czech Republic DataApex spol. s r.o. Lety 24, 252 29 Dobřichovice, Czech Republic DataApex s.r.o. Podhradská 1704/1, 155 00 Praha 5, Czech Republic 6 V DC, 500 mA (adapter: 230 V, 50 Hz, 50 mA) Validator <table style="width: 100%;"> <tr> <td style="text-align: center; width: 50%;">PUBLICATION</td> <td style="text-align: center; width: 50%;">EDITION</td> </tr> <tr> <td style="text-align: center;">CISPR 24 CISPR 22</td> <td style="text-align: center;">1997+Am.1:2001+Am.2:2002 2005</td> </tr> </table> 702864-01/01, 702864-01/02 of: 09.10.2007 <div style="text-align: center;">  </div>	PUBLICATION	EDITION	CISPR 24 CISPR 22	1997+Am.1:2001+Am.2:2002 2005
PUBLICATION	EDITION				
CISPR 24 CISPR 22	1997+Am.1:2001+Am.2:2002 2005				



list 1 z 2



Kalibrační list č. 200700140

Kalibrační list byl vydán Elektrotechnickým zkušebním ústavem, s.p., Pod Lisem 129, 171 02 Praha 8, Kalibrační laboratoří č. 2294, akreditovanou ČIA a pověřenou ÚNMZ jako středisko kalibrační služby s kalibrační značkou C 294.



Zákazník: DataApex s.r.o.
pan L. Šiška
Podohradská 1704/1
155 00 Praha 5

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

Datum přijetí: 5.9.2007

Datum provedení: 11.9.2007

Podmínky prostředí: Teplota $23\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, relativní vlhkost $45\% \pm 25\%$.

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.

Valentová
Měřila: Marta Valentová

V Praze dne 11.9.2007



Ing. Jan Černý
Ing. Jan Černý
technický vedoucí laboratoře

Kalibrační list nesmí být bez písemného souhlasu vydávající kalibrační 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. 200700140
naměřené hodnoty

list 2 z 2

Funkce	Rozsah	Konvenčně pravá hodnota	Indikace měřidla	Chyba měřidla	% meze dovolené chyby	Meze dovolené chyby (±)	Nejistota měření (±)
VDC-2W	120 mV	11,9968 mV	11,9960 mV	-0,88 uV	-22	4,08 uV	0,47 uV
VDC-2W	120 mV	59,9960 mV	59,9933 mV	-2,72 uV	-42	6,48 uV	0,86 uV
VDC-2W	120 mV	109,9980 mV	109,9927 mV	-5,3 uV	-59	9,0 uV	1,2 uV
VDC-2W	120 mV	-110,0015 mV	-109,9977 mV	3,8 uV	43	9,0 uV	1,2 uV
VDC-2W	1,2 V	0,119999 V	0,119999 V	-0,0001 mV	-1	0,0118 mV	0,0014 mV
VDC-2W	1,2 V	0,599999 V	0,600001 V	0,0019 mV	6	0,0310 mV	0,0045 mV
VDC-2W	1,2 V	1,099997 V	1,100000 V	0,0023 mV	4	0,0510 mV	0,0082 mV
VDC-2W	1,2 V	-1,099995 V	-1,100002 V	-0,0066 mV	-13	0,0510 mV	0,0082 mV
VDC-2W	12 V	1,20000 V	1,20000 V	0,005 mV	5	0,092 mV	0,010 mV
VDC-2W	12 V	3,60000 V	3,60002 V	0,020 mV	11	0,176 mV	0,028 mV
VDC-2W	12 V	5,99999 V	6,00002 V	0,038 mV	15	0,260 mV	0,045 mV
VDC-2W	12 V	8,39998 V	8,40003 V	0,055 mV	16	0,344 mV	0,063 mV
VDC-2W	12 V	10,99997 V	11,00004 V	0,067 mV	15	0,435 mV	0,083 mV
VDC-2W	12 V	-1,20000 V	-1,20001 V	-0,015 mV	-16	0,092 mV	0,010 mV
VDC-2W	12 V	-10,99998 V	-11,00008 V	-0,095 mV	-22	0,435 mV	0,083 mV
VDC-2W	120 V	12,0000 V	12,0000 V	0,04 mV	3	1,14 mV	0,10 mV
VDC-2W	120 V	59,9995 V	60,0003 V	0,79 mV	24	3,30 mV	0,72 mV
VDC-2W	120 V	109,9990 V	110,0004 V	1,4 mV	25	5,6 mV	1,3 mV
VDC-2W	120 V	-109,9991 V	-110,0008 V	-1,8 mV	-32	5,6 mV	1,3 mV
VDC-2W	1 kV	0,099999 kV	0,100000 kV	0,0012 V	8	0,0145 V	0,0013 V
VDC-2W	1 kV	0,499997 kV	0,499998 kV	0,0008 V	2	0,0325 V	0,0060 V
VDC-2W	1 kV	0,899993 kV	0,899995 kV	0,002 V	4	0,050 V	0,010 V
VDC-2W	1 kV	-0,899993 kV	-0,899997 kV	-0,004 V	-7	0,050 V	0,010 V

značení funkcí: VDC-2W stejnosměrné napětí

Meze dovolené chyby jsou stanoveny podle roční specifikace výrobce měřidla.

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



CERTIFICATE

The TÜV CERT Certification Body
of TÜV SÜD Management Service GmbH

certifies in accordance
with TÜV CERT procedures that



DataApex, spol. s r.o.
Podohradská 1
CZ- 155 00 Praha 5

has established and applies
a Quality Management System for

**Software development. Measurement engineering
and hardware development and production
including trade activities in these fields.**

An audit was performed, Report No. **70720554**

Proof has been furnished that the requirements
according to

ISO 9001: 2000

are fulfilled. The certificate is valid until **2010-01-17**

Certificate Registration No. **12 100 30406/01**



TGA-ZM-16-96

Munich, 2007-01-18



Management Service

A handwritten signature in black ink, appearing to read "M. Wogel".

TÜV CERT Certification Body
of TÜV SÜD Management Service GmbH
Ridlerstraße 65
D-80339 München

Certificate of Clarity station Validation

Certificate No.: 01/2012

User: Example Laboratories Ltd.

John Analyst, head of QA laboratory

Software: Clarity

Version: 4.0.3.871

S/N: 11-54321

A/D Board: Colibrick 2-channel, S/N: 1234

Computer: LAB01

Operating System: Windows 7

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: 1.1.2012

User:

John Analyst

Signature:

Date: 1.1.2012