

# Data Integration Solution

A laboratory middleware for central device data handling in production, development and research





# Sm@rtLine Data Cockpit

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## Research



## Development



## Manufacturing

**Sm@rtLine Data Cockpit** is a unique software middleware which enables the use of sensors and analyzers for the collection, review and approval of trial results. SDC is available in the following modes:

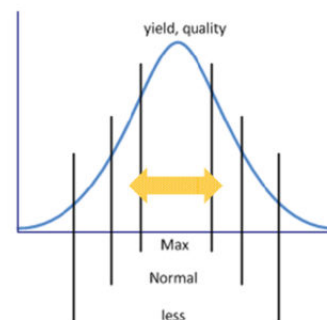
- SDC-LS provides a comprehensive user interface for operators in the laboratory
- SDC-PS collects data from the process control systems

## Closes the gap between LIMS, MES, DCS and the laboratory

SDC is placed between the sensors and the analyzers for the BIO-API processes and the interface to LIMS (laboratory information management system), MES (manufacturing execution system) or DCS (distributed control system) systems. SDC provides standardized, flexible interfaces for these systems which deliver calculated and evaluated data.

## Improves your quality

SDC supports your implementation of PAT/ QbD [Process Analytical Technology/ Quality by Design). These concepts strive to ensure a predefined product quality by implementing measures to improve understanding of the manufacturing process by using real-time measuring for all attributes. SDC supports these requirements by providing data transparency reliability and traceability instead of manual measurement, where accuracy of data and precisely timed sampling cannot be guaranteed.



## Increases your knowledge

The technician is no longer required to manually start and read measurements from the devices, but rather the measurements for these devices are reported centrally on the SDC server. SDC allows you to measure faster and more frequently and save the evaluated data in a central system. From this data, you can form a golden batch and compare your measurement and calibration curves together with multiple analyzers in a graph.

## Reduces your costs

SDC incorporates validated interfaces which have been approved by Roche. This reduces your cost for validation and integration of the analyzers as well as reducing costs for the validation of the data handling. Overall, your costs are optimized through the improved data quality, your reaction time improves, production is streamlined and yield can be increased.



# One hub system for your success



SDC, as the most used middleware in the pharma industry, connects your instruments in the laboratory with your preferred software for higher-level systems, and at the same time automatizes manual processes with a bidirectional data flow.

It increases not only efficiency and data quality but reduces the overall risk of data errors at every level of your production.





# Main features

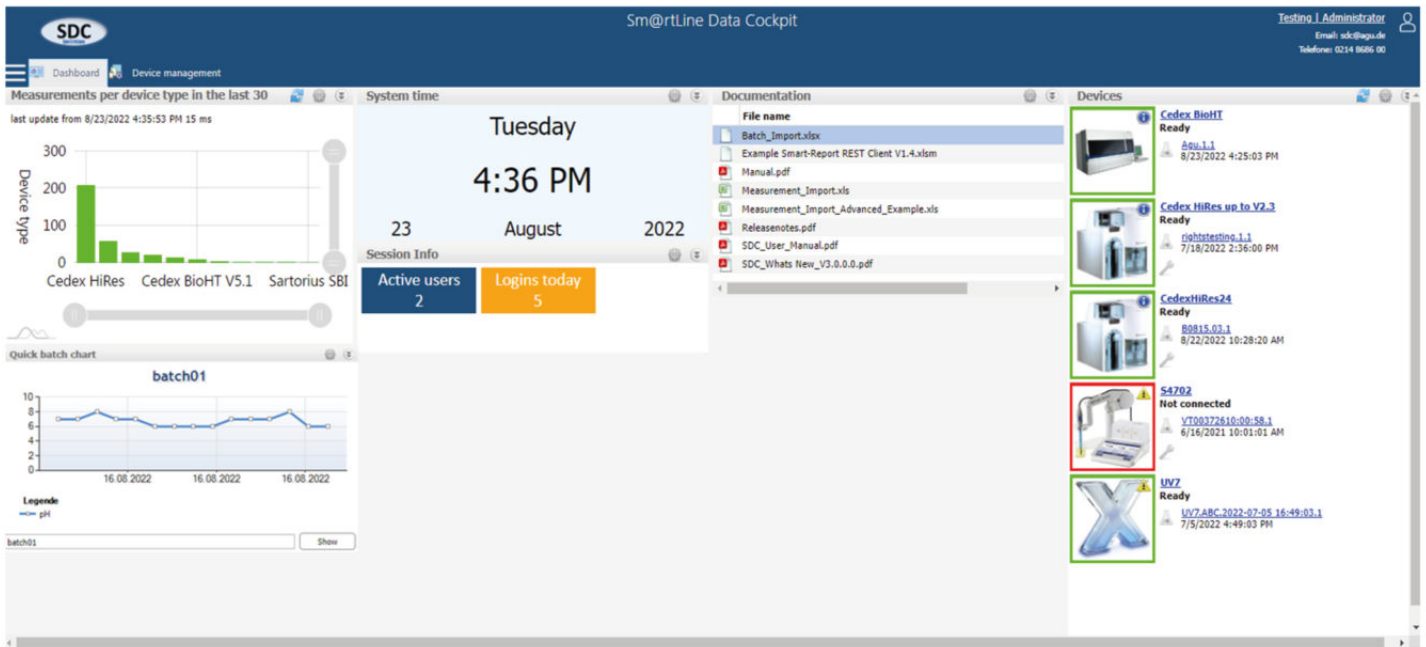
- SDC is a middleware between LIMS, MES and DCS systems and the laboratory areas of “research”, “development” and “production”.
- SDC provides a centralized master data management of devices, samplings, samples and users.
- SDC gives you the ability to combine a multitude of analyzers and sensors to form one system.
- SDC is a web-based platform that can be used from every client without special installation.
- SDC includes management of user-rights, which guarantees safe access to data.
- SDC is able to control analyzers so that the operator is using one consistent GUI while performing his or her tasks.
- Create, start and evaluate the analyzer measurements in a central system. The approved results can be uploaded to a foreign system (e.g., LIMS, ELN, MES or DCS)
- SDC offers the functionality of generating measurement results based on the data retrieved from the instruments. Available calculation methods include averaging and trypsinization.
- SDC gives you the ability to compare development and production (e.g. interface calibration data) comprehensively
- SDC can be connected to upper level systems
  - ChemLIMS persistent
  - SQL\*LIMS LabVantage
  - DasGip Technology
  - Labware
  - Sartorius MFCS/Win
  - IDBS E-WorkBook ELN (dev.)

## SDC is a scalable and configurable solution

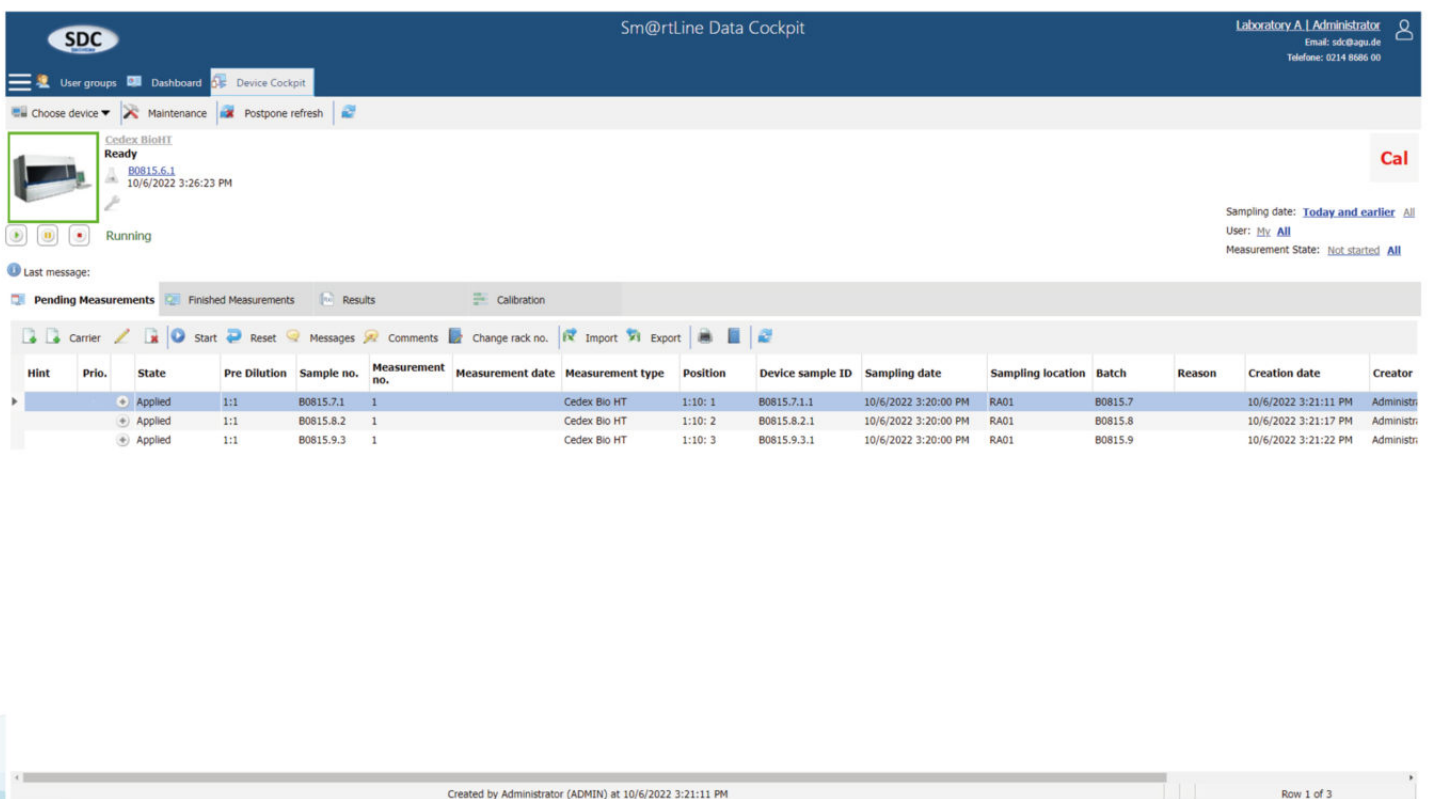


# User interface

SDC is a web based, easy-to-learn software solution. Great importance was placed on developing an intuitive operating concept and a perfect overview. The department-oriented dashboard provides the individual operators with simplified view of the analyzers that are important to them.



The consistency of operation is apparent in the recurring buttons and graphical elements for all analyzers. Information is displayed uniformly, creating data transparency.



SDC-Sandpit Demo System

Division 1.1 Administrator

Choose device Maintenance Logbook Postpone refresh

Advanced Instruments OsmoPro

Ready 202309.5 9/20/2023 4:44:41 PM

Running

Last message:

Pending Measurements Finished Measurements Results Calibration

Hint	State	Pre Dilution	Sample no.	Measurement no.	Measurement date	Measurement type	Position	Device sample ID	Sampling date	Sampling location	Batch	Reason	Creation date
	Finished	1:1	202309.5	1	9/20/2023 4:44:41 PM	Advanced Instruments OsmoPro Default		202309.5.1	9/20/2023 4:43:00 PM	RA01	202309		9/20/2023 4:44:13 PM
	Finished	1:1	202309.4	1	9/20/2023 4:44:38 PM	Advanced Instruments OsmoPro Default		202309.4.1	9/20/2023 4:43:00 PM	RA01	202309		9/20/2023 4:44:09 PM
	Finished	1:1	202309.3	1	9/20/2023 4:44:36 PM	Advanced Instruments OsmoPro Default		202309.3.1	9/20/2023 4:43:00 PM	RA01	202309		9/20/2023 4:44:08 PM
	Finished	1:1	202309.2	1	9/20/2023 4:44:34 PM	Advanced Instruments OsmoPro Default		202309.2.1	9/20/2023 4:43:00 PM	RA01	202309		9/20/2023 4:44:05 PM
	Finished	1:1	202309.1	1	9/20/2023 4:44:31 PM	Advanced Instruments OsmoPro Default		202309.1.1	9/20/2023 4:43:00 PM	RA01	202309		9/20/2023 4:43:59 PM

Double clicking a measurement entry shows details including images, if available

SDC-Sandpit Demo System

Division 1.1 Administrator

Choose device Maintenance Logbook Postpone refresh

Advanced Instruments OsmoTECH PRO

Ready 202309.6 9/20/2023 4:48:46 PM

Running

Last message:

Pending Measurements Finished Measurements Results Calibration

Hint	State	Pre Dilution	Sample no.	Measurement no.	Measurement date	Measurement type	Position	Device sample ID	Sampling date	Sampling location	Batch	Reason	Creation date
	Finished	1:1	202309.9	1	9/20/2023 4:48:46 PM	Advanced Instruments OsmoTECH PRO default	4	202309.9.1	9/20/2023 4:48:00 PM	RA01	202309		9/20/2023 4:48:25 PM
	Finished	1:1	202309.8	1	9/20/2023 4:48:44 PM	Advanced Instruments OsmoTECH PRO default	3	202309.8.1	9/20/2023 4:48:00 PM	RA01	202309		9/20/2023 4:48:21 PM
	Finished	1:1	202309.7	1	9/20/2023 4:48:42 PM	Advanced Instruments OsmoTECH PRO default	2	202309.7.1	9/20/2023 4:48:00 PM	RA01	202309		9/20/2023 4:48:19 PM
	Finished	1:1	202309.6	1	9/20/2023 4:48:40 PM	Advanced Instruments OsmoTECH PRO default	1	202309.6.1	9/20/2023 4:48:00 PM	RA01	202309		9/20/2023 4:48:18 PM

Finished measurements can be viewed under the corresponding tab

SDC-Sandpit - General

Details of the measurement 202309.10.1

General

Measurement no.: 202309.10.1 Status: Finished

Description: Measurement type: Collex HRes V2.4 Single

Reason: Type: Measurement

Comment: Created by: Administrator (ADMIN)

Position: 3 Created on: 9/20/2023 4:54:52 PM

External ID: Priority: Dilution: 1:1 Change dilution

Repetition measurement:

Description	Short name	Parameter	Result	Unit	Setpoint	Status	Info
Avg Area	AvgAreaOut	0	115.41	$\mu\text{m}^2$	0.00	OK	Device valu
Avg Compactness	AvgCompactnessOut	0	1.79		0.00	OK	Device valu
Avg Perimeter	AvgPerimeterOut	0	52.57	Pixel	0.00	OK	Device valu
Avg Segmentation Area	AvgSegAreaOut	0	454.78	Pixel <sup>2</sup>	0.00	OK	Device valu
CellType	CellType	Std. Size	Std. Size		0.00	OK	Device valu
Dead Cell Count	DeadCellCountOut	0	36		0.00	OK	Device valu
is SST measurement	SSTMeasurementOut	0	0		0.00	OK	Device valu
Measurement Invalid	MeasInvalidOut	0	0		0.00	OK	Device valu

Imag01 Imag02 Imag03 Imag04 Imag05 Imag06

Close

Created by Administrator (ADMIN) at 9/20/2023 4:54:52 PM Changed by System (System) at 9/20/2023 4:55:05 PM Row 1 of 1, 1 selected

The grid table gives a quick overview of samples, their corresponding IDs and more

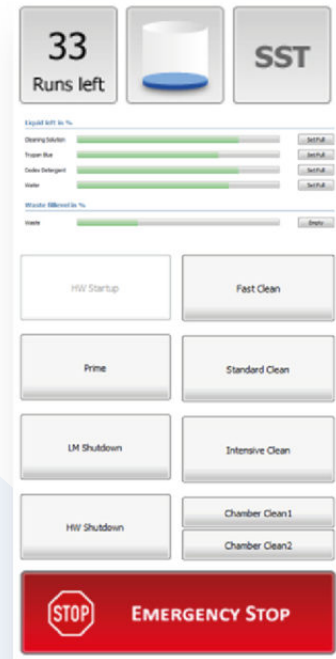


# Extended interface functions for the Cedex® HiRes Analyzer

SDC supports the operators and laboratory personnel when performing tasks in the areas of maintenance management, lifecycle management and consumption management.

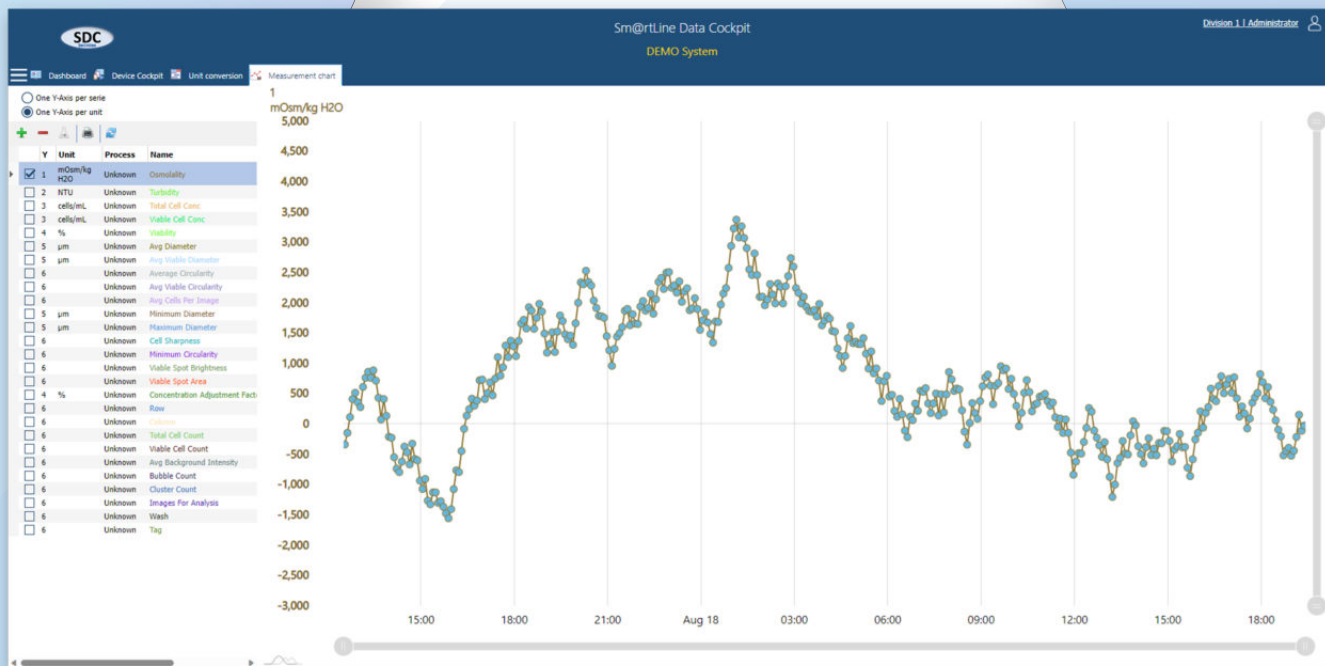
The interface to the Cedex® HiRes Analyzer offers multiple functions which can be performed directly from SDC.

- Liquid management (resetting liquid and waste levels)
- Hardware control (cleaning and emergency stop)
- Cedex® database storage optimization
- SST: performing System Suitability Tests
- Display of the runs-left counter



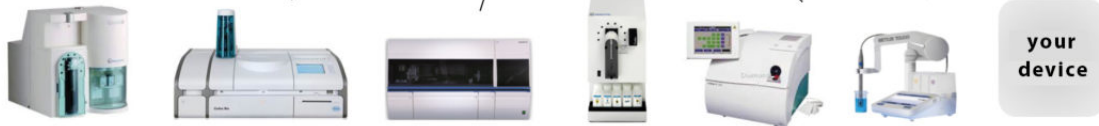
## Batch results compilation

The compilation and depiction of the measurement results of a batch makes SDC an efficient tool. Batch results can be compared and exported to Excel for additional evaluation.



LIMS ELN MES DCS

Lost time,  
less accuracy  
and wasted resources



Manual

no data integration

Digital

data integration

SDC simplifies the processes, increases flexibility and secures data quality. The implementation of SDC to connect the analyzer level to a higher system saves substantial costs because it is only necessary to take one interface into consideration

LIMS ELN MES DCS

With every analyzer you integrate, the advantage increases.

**SmartLine Data Cockpit**  
21 CFR Part 11 compliance



Lab 1

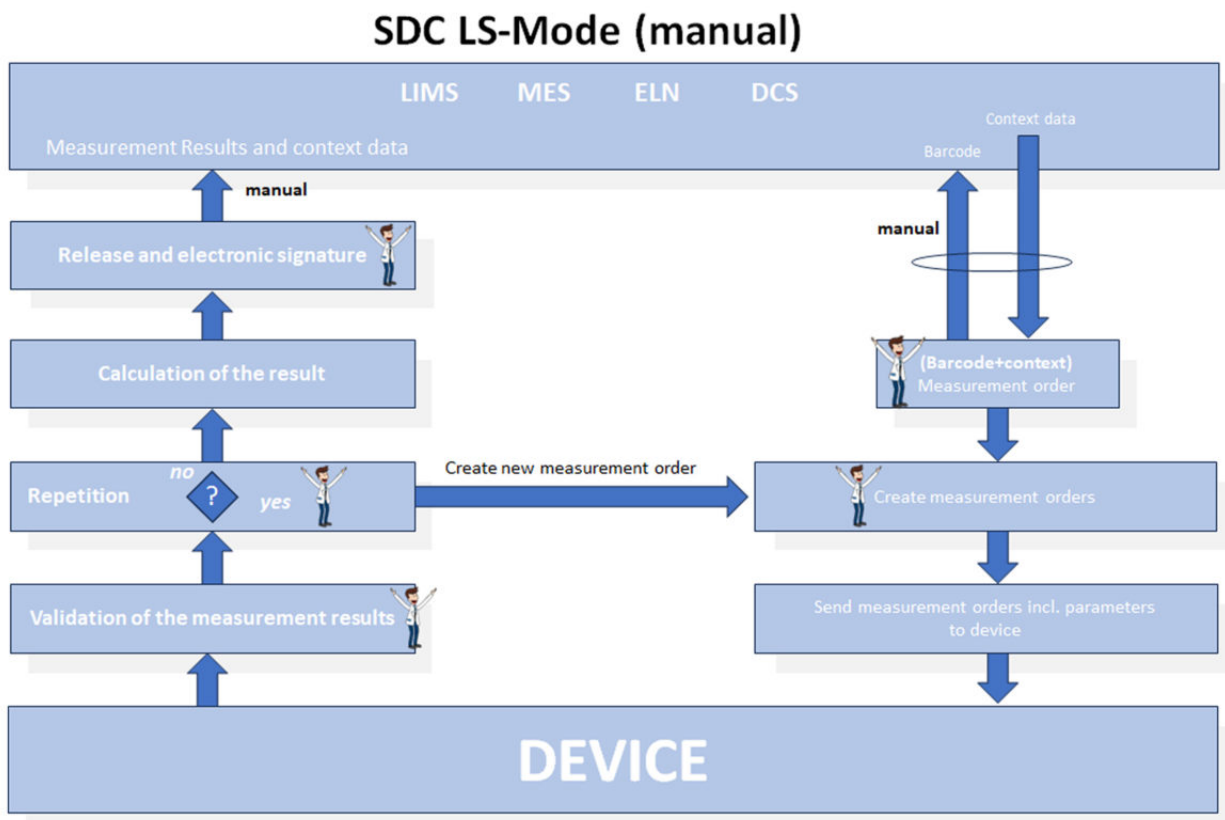
Lab 2

Lab n



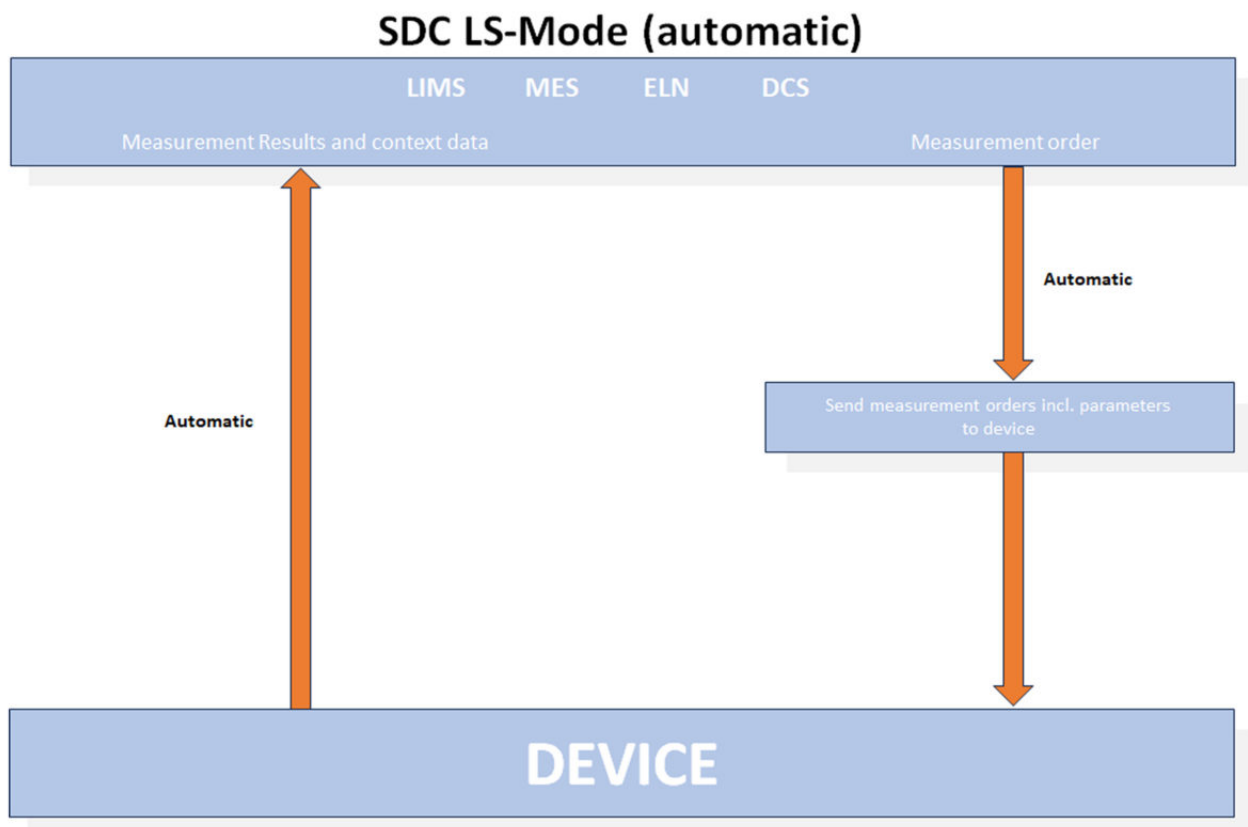
# SDC-LS [Laboratory System Mode]

- ❑ The implementation of SDC makes it possible to combine SDC-LS and SDC-PS in one environment
- ❑ Central user interface for all analyzers to support the operator in the laboratories.
- ❑ The operator can request the context data from the master system using the sample number, enter measurement jobs and send these to the analyzer. If the analyzer supports the remote control, the measurement jobs can be started using SDC.
- ❑ Measurement results are received from the analyzers and the measurement jobs and results are archived.
- ❑ The operator can evaluate, calculate and release the measurement results
- ❑ The released measurement results are transferred to the master system.





- in automatic mode SDC-LS creates measurement orders by itself
- these measurement orders will be sent to the device with the parameters
- results will be automatically transferred back to SDC



# SDC-PS [process system]

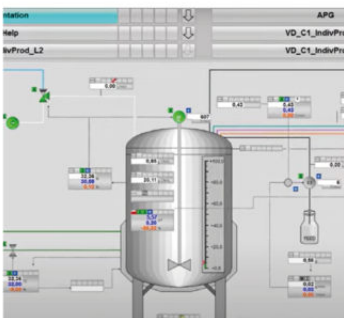
SDC-PS makes it possible to assign sensor data from the BIO API process to the sample-oriented data. Like all other data, the sensor data can be graphically depicted, exported and made available in the interfaces.

- SDC- PS includes all functions of SDC-LS systems
- It is possible to combine SDC-PS and LS systems
- SDC-PS enables the continuous reading of measurements from sensors which are implemented in the process control or other systems. Together with the intermittent, sample-oriented analyzer values, these values can be displayed, saved as a batch and compared.

## Process System



*Closed Loop*



**DCS**



**SDC**

## With SDC, it is possible to connect the following systems:

### Analyzers

Advanced Instruments - Model 2020  
Advanced Instruments - Model 3320 Micro-Osmometer  
Advanced Instruments - Model A20  
Advanced Instruments - Model 3250  
Advanced Instruments - Model OsmoPro  
Advanced Instruments - Model OsmoTech  
Advanced Instruments - Model OsmoTech Pro  
Advanced Instruments - Model OsmoTech HT  
Advanced Instruments - Model OsmoTech XT  
BeckmanCoulter - Vi-Cell Blu  
BeckmanCoulter - Vi-Cell XR  
C Technologies, Inc. - SoloVPE  
CAS - CI 153 CLiMET partical counter  
Chemometec - NucleoCounter NC-202  
Gonotec - Osmomat 030 RS/D  
Gonotec - Osmomat 3000  
Gonotec - Osmomat auto  
Hach Lange - DR 2800 photo meter  
Hach Lange - DR 3800 photo meter  
Hach Lange - TL2350  
Heidolph - Overhead Stirrer Hei-TORQUE  
Knick - Portavo 907 pH, conductivity, O2  
Mettler Toledo - Compact Titration G20 / G20 S  
Mettler Toledo - Compact Titration V20 / V30 / C20 / C30  
Mettler Toledo - D4 / D5 / D6 / R4 / R5 / RX4 / RX5  
Mettler Toledo - DM40 / DM45 / DM50 / RM40 / RM50  
Mettler Toledo - DX40 / DX45 / DX50 / RX40 / RX50  
Mettler Toledo - Excellence balances XP / XS / XPE / XSE - LabX  
Mettler Toledo - Excellence balances XPR / XSR - LabX  
Mettler Toledo - MP70 / MP80 / MP90  
Mettler Toledo - Quantos automatic dosing systems: XP/XS/XPE  
Mettler Toledo - SevenExcellence  
Mettler Toledo - Titration Excellence T5 / T7 / T9  
Mettler Toledo - Titration Excellence T50 / T70 / T90  
Mettler Toledo - UV7/UV5/UV5Nano/UV5Bio  
Nova Biomedical - BioProfile FLEX  
Nova Biomedical - BioProfile FLEX 2  
Nova Biomedical - BioProfile pHox  
Pall - Palltronic® Flowstar IV  
Perkin Elmer - Lambda 25 Spectrometer  
Radiometer - ABL 805  
Rapid Micro Biosystems - Growth Direct

Roche Diagnostics - Cedex Bio  
Roche Diagnostics - Cedex Bio HT  
Roche Diagnostics - Cedex HiRes  
Roche Diagnostics - cobas b 123  
Roche Diagnostics - cobas b 221  
Roche Diagnostics - cobas e 411  
Sartorius - ambr 15  
Sartorius ambr 250  
Sartorius - Sartocheck 5 Plus  
Sartorius - Scales  
Siemens - RAPIDLab 1200  
Siemens - RAPIDLab 248  
Siemens - RAPIDLab 348  
Siemens - RAPIDLab 348 EX  
Siemens - RAPIDPoint 500  
TECAN - EVO  
TECAN - Fluent  
TECAN - Infinite M200

### Bioreactor systems

Sartorius ambr® 15  
Sartorius ambr® 250  
Sartorius BioPAT® MFCS/win  
DASGIP  
Finesse TruBio

### ELN/LIMS systems

Labware LIMS  
Persistent LIMS  
LABVANTAGE LIMS  
IDBS E-WorkBook ELN

### Historian systems

OSIsoft-PI  
Generic OPC DA

**You can view the current list of supported instruments here:**

<https://www.agu.de/de/SDC/AnalyzersDevices>



**Your analyzer isn't listed?**

**No problem. SDC's development framework makes the integration of new interfaces a snap.**

**Contact us with your lab requirements.**

[sdc@agu.de](mailto:sdc@agu.de)



## Manager Benefits

**01 Cost:** SDC reduces cost by minimizing manual data processing and offering a unified validated interface for devices.

**02 Reliability of data:** SDC shortens measurement times, which leads to more frequent data and therefore to more knowledge about correlations between critical parameters. Reproducible and automated cell culture analysis improves the reliability of data.

**03 Transparency and traceability:** SDC makes a comprehensive correlation of analyzer and sensor measurements in research, development and production possible and creates transparency and traceability.

**04 Central database:** The central database provides a unique point of information. Data analysis occurs within ONE database and not in many different databases.

Efficient data evaluation occurs in ONE system for flexible data analysis and reporting.

**05 Global visibility:** Global data collection increases the visibility of different processes. Global task-sharing is facilitated.

**06 Data availability:** SDC delivers the data simply and transparently. The operator saves valuable time on the preparation of measurements and data transfer.

**07 Calibration data:** Calibration data during a product lifecycle (research, development and production) can be compared and contrasted regardless of the device used.

## User Benefits

**01 Sample handling:** Measurements can be repeated easily and they can be prepared while the analyzers are still working. It is possible to monitor measurement progress from anywhere within the company's network, including status observation of devices and calculation of time remaining. The measuring procedures of the analyzers are controlled without further user action.

**02 Data evaluation/ calculation:** Individual measurement results of the analyzers and sensors can be evaluated and calculated into a single result (e.g., mean value, trypsinization). Measurement results can be evaluated/ calculated according to batch ID and then displayed graphically in a "time cultivation chart". The integrated batch comparison enables comparison with the golden batch.

**03 Intuitive system:** SDC's modern and intuitive operating concept is grounded in practical experience, resulting in wide acceptance and minimizing need for on-the-job training.

**04 Validation effort:** SDC reduces the validation efforts tremendously by replacing the manual transaction and processing of data by the user.

**05 GMP conforming data handling:** Paperless data handling of measurements and data transfer to foreign systems (LIMS, MES, ERP) occurs with electronic signatures and change logs in consideration of 21 CFR Part 11. This ensures the data integrity of all measurements and further parameters. The operator can transfer data for special reports or evaluations easily to Excel.

## IT Benefits

**01 Cost:** SDC reduces cost by minimizing manual data processing and offering a unified validated interface for devices.

**02 Remote solution:** SDC can be used as a remote solution for facilities regardless of location. Due to its integrated web technology, SDC can be used within the complete network centrally or remotely. Due to modern web technology, no additional installation work is necessary at the client site.

**03 Interfaces:** SDC has an open interface concept that enables the connection of LIMS, MES, and ERP through XML, SQL and OPC.

**04 New analyzer:** The adapter concept for the connection of analyzers and sensors allows for a continual expansion of the system.

**05 Administration:** User administration (user- and rights- management) can be linked to the active directory.

**06 Backup:** SDC supports the central data backup of results and images.

**07 Setup:** A setup oriented toward master data enables conformity and expandability.

**08 IT concept:** SDC is a fully developed .NET technology with an Ajax GUI framework and MVP architecture.

## Production Benefits

**01 Real time:** Real-time data leads to a more accurate process adjustment. Real-time monitoring increases process understanding.

**02 Ready for automation:** SDC creates the basis for future automated processes. The development data can be compared to the production data and all process information (sensors and analyzers) can be viewed on a common timeline. The golden batch can be formed through real-time monitoring for "Closing the Loop" (QbD = Quality by Design)

**03 Boost of quality and yield:** More effective and faster processing time of trials makes more frequent measuring possible, optimizes process monitoring and boosts both quality and yield.

**04 Consolidation:** With SDC, the user can consolidate all sensors and analyzers used in fermentation research, development and production into a single system. This method makes the work easier and safer.

**05 Fulfill GMP requirements:** SDC supports your implementation of PATH / QbD (Process Analytical Technology / Quality by Design) by providing data transparency, reliability and traceability instead of manual measurement, where accuracy of data and precisely timed sampling cannot be guaranteed.

## How to get in contact with us:



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## Our partners:

