

SPC@Enterprise

Software for statistical process control



(!) Benefits

- Efficient networking of a diverse range of devices and systems from Minebea Intec and other vendors
- Fast process control due to powerful monitoring program
- Easily generate production or calibration statistics
- Simple data backup will return a lower risk of data loss



The software SPC@Enterprise combines classic filling quantity control with dynamic process control for a wide range of different systems, thereby efficiently supporting quality management of your production processes.

Networked production processes with SPC@Enterprise

- ① Centralised data management prevents redundancies: Master data are created centrally in SPC@Enterprise and are therefore available on all devices.
- ① Monitoring in real-time: Reduce your response times with individually configured alarms and all running production tests at a glance.
- ① Automatic transmission of the measured data to the database. All data are immediately available centrally for evaluation and output in production and calibration statistics.
- ① Central storage in the MS SQL database ensures high data security and various possibilities for system automation and coupling to ERP or MES systems.

Functionalities — Software

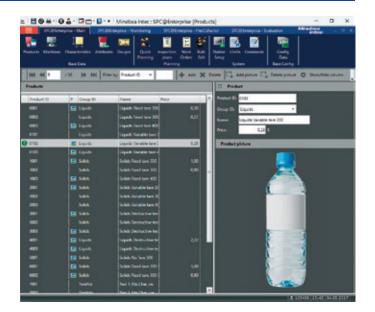


SPC@Enterprise main programme

- Innovative PC application for creating, managing and analysing master data and test data
- Unlimited installations possible, e.g. on user PCs in quality assurance, shift management or engineering
- The application can also be used as a versatile control unit on Windows® Tablets

Maintaining base data and planning inspections — main module

- Management of products, machines, features, attributes and test equipment
- Creation of inspection plans and inspection orders
- Statistical process control of all characteristics to be logged and assessed qualitatively, such as:
 - Filling quantities according to specific regional standards, including density and tare
 - SPC data (additional measured data outside of the scope of filling quantity control with individual limit values)
 - Attributes (visual, sensory or physical properties used for quality assessment)
- Quick-planning function for easy creation of test plans
- Global tare and density modifications
- Use of the standard limit value systems according to FPVO or creation of individual limit value systems
- Integrated image management, e.g. during PC data acquisition for product selection, attribute testing or in the user database



Languages

German, English, Italian, Spanish, Dutch, Polish, Czech, Hungarian

Use in regulated areas

- Option available with audit trail and electronic signatures 21CFR11-compliant
- Audit trail records all activities upon request electronic signatures are used for user authentication and activity tracking
- Data in the database are protected against corruption and cannot be changed
- Internationally certified
- Optional validation kit consisting of the test documentation (according to the GAMP recommendation) and IQ/OQ form sheets (language: English)

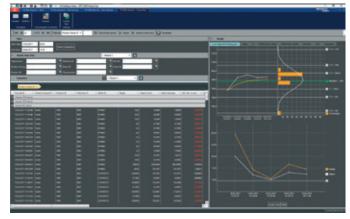
Production monitoring

- Display of the limit violations, alarms and faults logged by the system
- Production monitoring in real-time thanks to intuitive interface providing instant access to all important data, with filter options
- Automatically refresh displayed data at freely selectable intervals
- Customisable alarm setup and optional forwarding to freely selectable mailing list (via SMTP server)
- Overview of all current production lines in a practical tile view – clicking on a selected test attribute opens a detailed view with zoom function and histogram
- Display of the current equipment status, including the daily history of the checkweighers and metal detectors, logging of error notifications, transition between products and events
- Log and change comments on selected samples
- The mobile monitor for Windows® tablet PCs increases flexibility



Analysis

- Using the "Analysis" module, the stored data can be output in the form of statistics and sample reports
- Freely selectable statistics periods ensures that all analysis will automatically access all current and all archived data
- Statistical cumulations of all types (batch, hour, shift, etc.) available for all data
- All reports can be simulated on the screen, printed or exported (EXCEL, PDF or WORD)
- Reports can be saved for repeated applications
- Report layouts can be adapted to meet requirements
- Easy integration of your corporate name and logo
- Statistics can be created manually or automatically using the integrated print service
- Special evaluation of checkweigher intervals with production statistics and efficiency overview

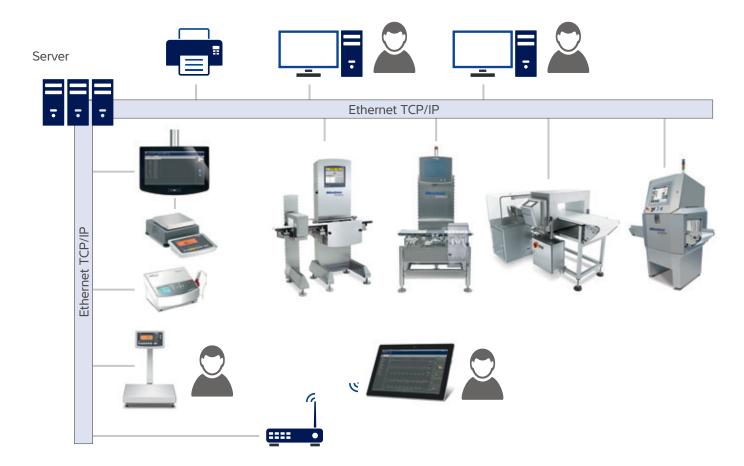




User management

- User management with multi-level user IDs
- Any number of users
- User-dependent operating language
- LDAP integration possible

System architecture of SPC@Enterprise

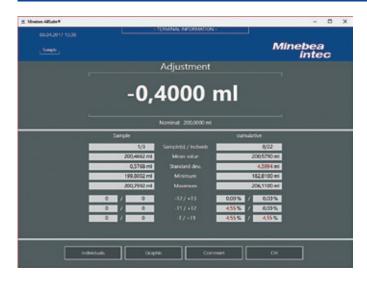


- Single-workstation solutions or networked systems with as many workstations as needed
- Server client architecture based on a MS SQL database direct linking of all clients to SQL database
- Background activities (e.g. device communication or printing) as a service
- Allows cross-site installation or system virtualisation (e.g. via terminal servers/thin clients such as Citrix or VMWare)
- Database capacity allows storage and retrieval of large amounts of data without performance loss full use of available SQL resources
- Designed to use a 64-bit architecture for optimal performance
- Data in the database are protected against corruption and cannot be changed

Coupling to ERP or MES systems as well as system automation

- SPC@Enterprise is based on MS SQL, providing the best prerequisites for versatile data matching with other IT systems
 e.g. in ERP (SAP/Microsoft Dynamics, etc.), MES, LIMS, BDE, OEE, SCADA, etc.
- Import master data and test data (file-based)
- Automatically import the current density from an external system (for example, LIMS) to update existing test plans via SQL View
- Customised export of statistically cumulated data and sample data (as SQL View, SQL table or CSV)

PC data acquisition - PC application for acquisition of weighing and measured data





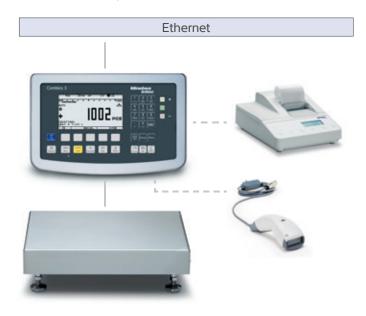
- Touch-optimised PC application to perform tests in production and the lab
- Select the product data and store the measured values via the software
- Connection of the scales/measuring devices to the PC via the serial interface or connection via TCP/IP,
 e.g. for operation on terminal servers
- Use of scales with alibi memory
- Connection of further serial measuring devices (residual oxygen measurements, torques, adjustment disc etc.) possible
- Overview of evaluation functions with graphic display allows quick response to errors
- Connecting barcode scanners for safe product selection
- Smart combination of attribute and SPC checks
- Filling head-related FPK and SPC tests possible
- Calculation of recorded values on the basis of individually prepared test formulas
- Windows® Tablets provide a flexible control unit



Connectivity

The following comprehensive connection options for measuring instruments are available in SPC@Enterprise:

Combics benchtop and floor scale connection



- Direct networking of Combics 3 Terminals via TCP/IP for bidirectional communication with the SPC@Enterprise database (requires Ethernet interface and Option H6)
 - Transmission of product data and test data to the device
 - Transmission of sample data, statistics to the database
- Filling head-related sample logging
- Recording attributive tests
- Update tare by weighing or manual entry
- Updating density by manual entry
- The user can be optionally prompted to update the tare and/or density before each sample or new batch
- Use of scales with alibi memory
- Optional barcode scanner ensures safe product selection
- Output of a dynamic adjustment recommendation as well as a statistical summary following each sample

Checkweigher connection

- Direct networking of checkweighers via TCP/IP for bidirectional communication with the SPC@Enterprise database (requires Ethernet interface and corresponding device option)
 - Transmission of product data and test data to the device
 - Transmission of interval statistics with individual values, as well as information on goods production and separated products and metal contaminants into the database
 - Transmission of equipment status, error notifications and events for central monitoring system in SPC@Enterprise
- Supports the equipment functions for Packaged Goods Regulation and classification with 3 and 5 classes, as well as adjustable specification of goods classes
- Compatible with the current generation of all Minebea Intec checkweighers and Combi devices (EWK 2000Plus, EWK 3000, Synus, Cosynus, Flexus)
- GARECO interface (Garvens/Mettler Toledo/OCS via TCP/IP) for connecting compatible external devices (compatibility check required)



Metal detectors Minebea Intec Vistus connection

- Direct networking of metal detectors Minebea Intec Vistus via TCP/IP two-way communication with the SPC@Enterprise database (requires Ethernet interface and relevant equipment option)
 - Transmission of product data and test data to the equipment
 - Transmission of metal detections and equipment tests with test specimens to the database
 - Transmission of equipment status, error notifications and events for central monitoring system in SPC@Enterprise



X-ray inspection systems connection

- Unidirectional connection of all Minebea Intec X-ray inspection systems via TCP/IP to SPC@Enterprise
 Database (requires Ethernet interface in the device and SPC@Enterprise FlexCollector)
- Interval logging of foreign body detections
- Documentation of equipment tests with test specimens



FlexCollector - universal interface

- External device connection also possible in the following test modes:
 - Filling quantity control (e.g., checkweighers or filling machines)
 - Attribute testing (e.g. foreign body detection or documentation of device tests)
 - Statistical process control (e.g. moisture meters, residual oxygen measurements, etc.)
- Requirement: Transmission of the required data as XML or ASCII protocols via TCP/IP (for serial devices, COM servers can be used as well)

System requirements		
Server	Operating system	Windows 2003, 2008, 2012 Server $^{\mathbb{IM}}$, Windows $7^{\mathbb{IM}}$, Windows $10^{\mathbb{IM}}$ (32 or 64 bit)
	SQL Server	Microsoft SQL Server 2005, 2008, 2008R2, 2012, 2014 or 2016 (preferably Standard or Enterprise Edition)
	.Net Framework	4.6
	Processor	Intel I5 comparable processor (5. Generation)
	Random access memory (RAM)	min. 8 GB RAM
	Hard drive space	min. 100 GB
Evaluation/operating computer	Operating system	Windows7™, Windows 8™ or Windows10™ (32 or 64 bit)
	.Net Framework	4.6
	Processor	Intel I5 comparable processor or larger
	Random access memory (RAM)	min. 4 GB RAM
	Hard drive space	min. 500 MB
Network	Ethernet	min. 100 Mbit/s

Order numbers			
Main module			
62S-SPC-0010	SPC@Enterprise QA software/main module Main module for network installation of SPC@Enterprise		
	Contains access to the main programme for maintaining master and test data, for system configuration as well as for evaluating sample data and statistics		
	If you desire additional accesses, please select 62S-SPC-0011		
62S-SPC-0020	SPC@Enterprise QA software/process monitor and dynamic sample display Extends the main module license 62S-SPC-0010 by the functions of process monitor and dynamic sample display for monitoring current test data with alarm function		
	If additional access is required, please select 62S-SPC-0021		
System extensions Extensions are only required once per system			
62S-SPC-1001	SPC@Enterprise QA software/Attribute Basic system extension Extends the basic module by the option for recording attributive tests via SPC@Enterprise PC data acquisition or Combics3 Terminal		
62S-SPC-1003	SPC@Enterprise QA software/SPC extension (statistical process control) Extends the basic module by the option for recording and calculation of additional measured data outside of the scope of filling quantity control		
62S-SPC-1005	SPC@Enterprise QA software/extension for dynamic checkweighing Extends the basic module by the option for connecting dynamic checkweighers to the system. Additional device licences are required		
62S-SPC-1006	SPC@Enterprise QA software/extension for metal detection technology Extends the basic module by the option for connecting metal detectors to the system. Additional device licences are required		
62S-SPC-1007	SPC@Enterprise QA software/extension 21 CFR Part 11 – Electronic signature and audit trail Extends the basic module by the functions "Electronic signature" and "Audit trail" for use in regulated areas		
	Audit trail records all activities upon request — electronic signatures are used for user authentication and tracking		
62S-SPC-1008	SPC@Enterprise QA software/extended planning with global tare/density modification Extends the basic module by the option for tare/density modifications to be carried out simultaneously for several product/machine combinations, instead of having to load each one individually. Helpful when filling the same initial product In different packaging variants and/or when using the same packaging for several products.		
62S-SPC-2008	SPC@Enterprise QA software/extension configurable data import/export Extends the basic module by the option for sharing data with other systems like ERP (SAP/Microsoft Dynamics), MES, LIMS, BDE, OEE, etc.		
	Customer-specific interface customizations are not included in this extension and will be charged separately.		
62S-SPC-2071	SPC@Enterprise QA software/extension MS Windows service for automatic density updating via the transfer of external software Extends the basic module by the option for automatic density updating from external software via an SQL View. Manual density updating in SPC@Enterprise is thereby eliminated		
Device licences Required for each additional device to be ported			
62S-SPC-2011	SPC@Enterprise QA software/device licence Ethernet polling for 1 Combics 3 Terminal		
62S-SPC-2051	SPC@Enterprise QA software/device licence for Sartonet software polling for 1 terminal scale FCQN/LAQN/isi30QN		
62S-SPC-2001	SPC@Enterprise QA software/device licence for PC data acquisition software, single licence for touchscreen or mouse operation running on MS Windows 7, 8 or 10		
62S-SPC-2021	SPC@Enterprise QA software/device licence for Ethernet communication to Minebea Intec checkweighers EWK 2000Plus, EWK 3000, Synus, Flexus, EWK 3000 Combi or Cosynus – single-user licence		
62S-SPC-2041	SPC@Enterprise QA software/device licence for FlexCollector for flexible data acquisition – licence for 1 terminal device		

(Other licence packages available if necessary)