Sartorius ProMix for Windows
Manual Recipe System

- Recipe system for manual batching
- Systems for single and multiple locations
- Raw material batch reporting and verification
- Campaign and batch weighing (horizontal and vertical recipe execution)
- Calculation of set points for active components and equalizing materials
- Recalculation of set points after tolerance violation
- Simple connection of high-precision scales
- Transparent reporting of the entire recipe process
- Security access functions and audit trail in accordance with FDA 21 CFR Part 11
- Can be validated in compliance with GAMP/FDA 21CFR Part 11
- Connection to ERP systems is possible

The "Sartorius ProMix for Windows" recipe system is a powerful software package for manual weighing and recipe management. The system runs on a Windows PC, preferably an industrial PC (IPC), to which at least one weighing scale or platform is connected. The PC serves both as a weighing station, on which the user first selects the job orders and is then guided through the process, and for the management of raw material, recipe and production data.

Whilst offering a high degree of flexibility in terms of product variety, manufacturers in the food and cosmetics industries must also take account of high safety standards and legally regulated accountability.

EC Directives, IFS (International Food Standard) and GAMP (Good Automated Manufacturing Practice) demand traceability across all stages of the production process. At the same time, not only must the raw material batches be systematically traceable but the process steps and operators must also be fully identifiable.

Due to their high performance levels and great flexibility, Sartorius recipe management systems and scales offer the possibility to comply with the demand for more transparency and process safety, without a great deal of expenditure. All this – and a more efficient arrangement of the entire weighing process into the bargain.

Sartorius ProMix guarantees the exact execution of a recipe due to computer-supported, visually-aided operator management. This means that specified procedures are strictly adhered to and fully reported. In addition, the current status of the production process can be checked at any time. In this way, the consistency and high-quality of a product is assured. Deviations and particular events are specially recorded in the Audit Trail. As a result of these measures, continuous process transparency is achieved.

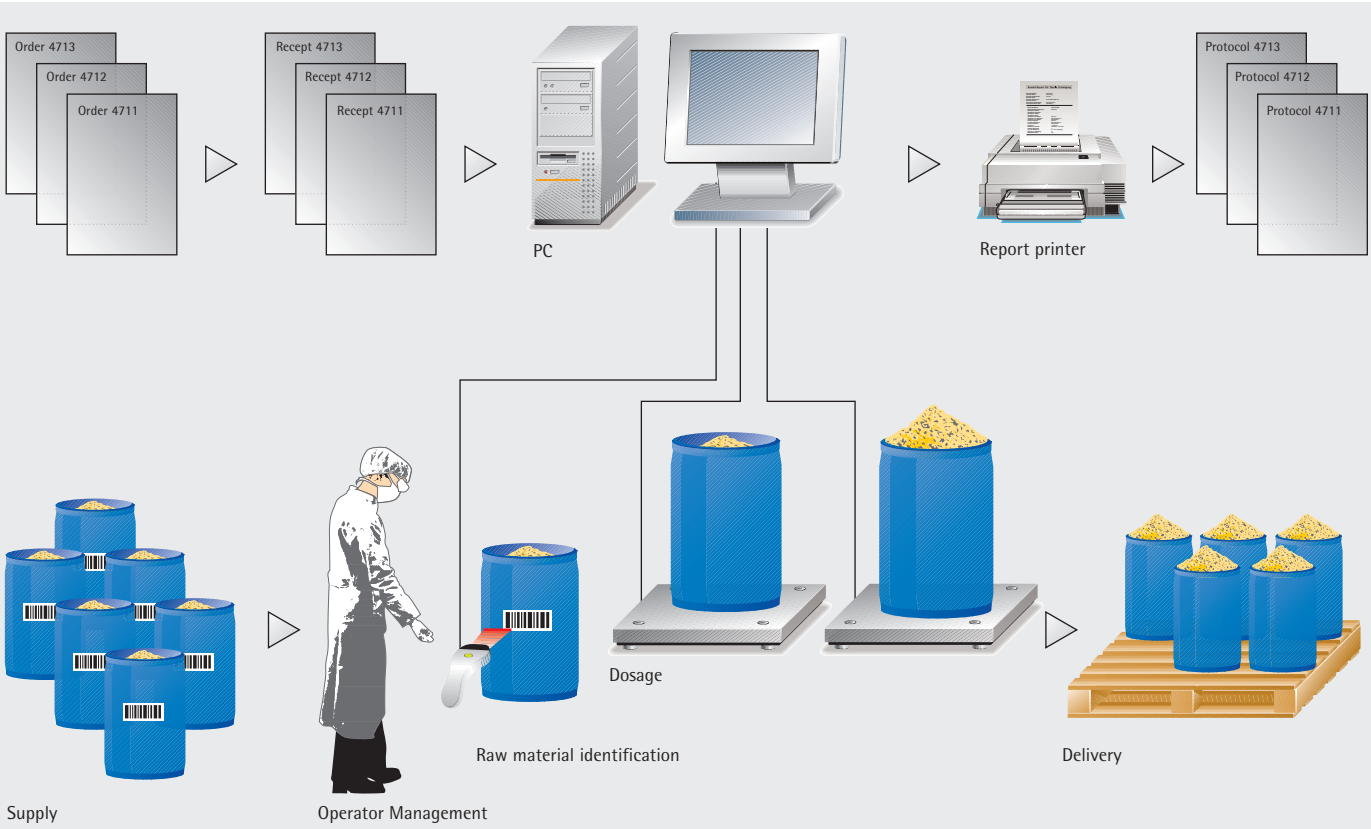
In combination with high-resolution Sartorius scales and weighing platforms, even the smallest quantities are batched precisely, enabling significant raw material cost savings to be obtained.

Automatic reporting simplifies many operator tasks with regard to documentation and shortens throughput times. Combined with the saving on raw material quantities this leads to a significant cost reduction.

Dependent on the structure of the overall system, the raw material data, recipes and production tasks can be taken care of by the PC at the weighing station and by an additional central computer.

Extremely simple installation, fast commissioning and easily understandable operation keep costs and expenditure low and manageable.

Sartorius ProMix was developed to satisfy the requirements for validation in compliance with GAMP and the legal specifications of the FDA (Food and Drug Administration, USA) in the cosmetics and pharmaceutical industries, and the demands of the IFS in the food industry.



System design
The ProMix recipe system runs on a Windows PC, to which scales or weighing platforms are connected via serial interfaces or USB ports. The system is operated on the PC. The operating concepts for the reception of materials and for the weighing station are designed to function with a touch-screen, which is recommended. The raw material batches can be read in with a scanner, to avoid time-consuming and erroneous data entry via the keyboard.

Batch labels are printed on a label printer on receipt of goods and weighing labels are printed after the weighing process has been completed. Job reports, recipes, batch inventory and other lists can be output to a report printer.

The software package
Sartorius ProMix consists of three modules: Goods reception, data management and weighing modules.

The goods reception module serves to identify and label incoming raw materials. Raw material batches can be temporarily blocked or released immediately. Stocks are updated in batch management.

Master data, dynamic data and the system configuration are managed in the data management module. This includes, for example, user data, suppliers, materials, recipes, goods received and raw material batches. Jobs are created and authorized here.

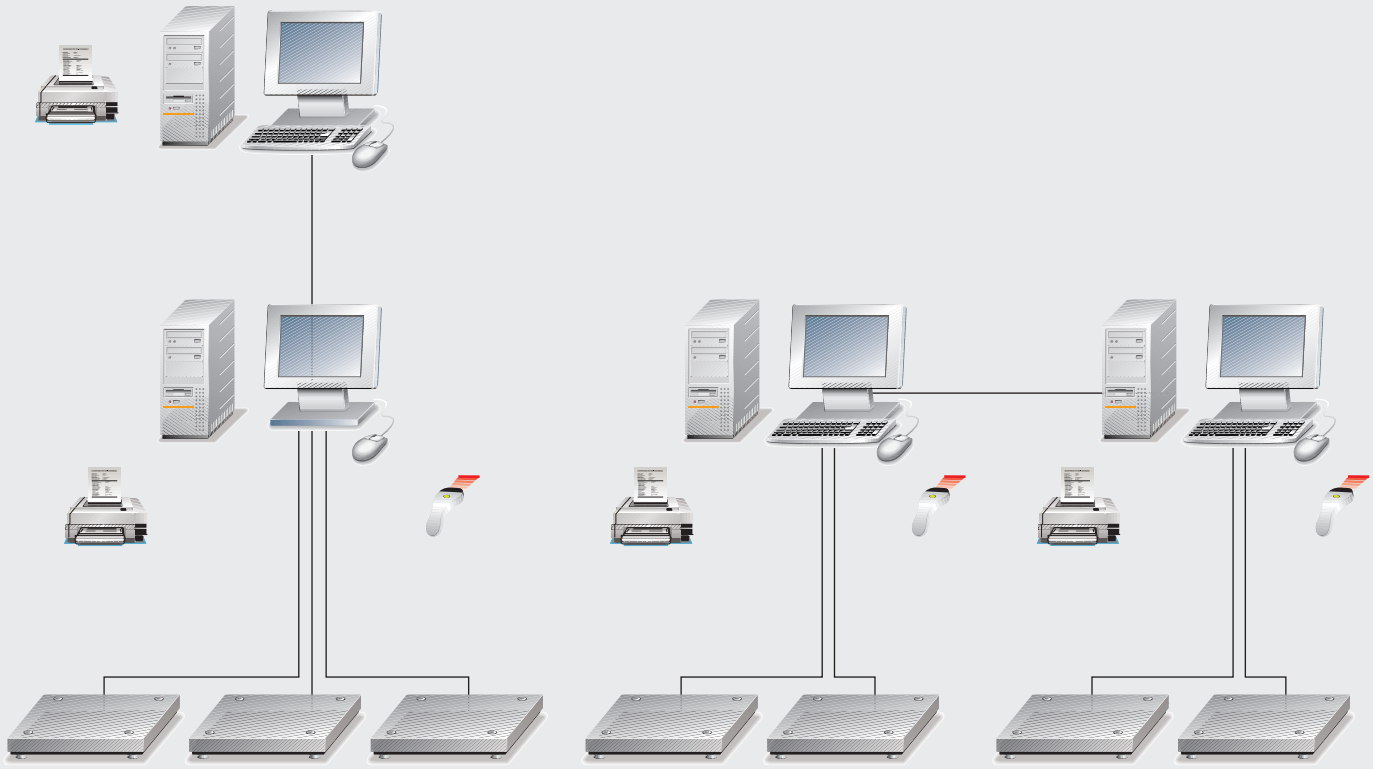
The weighing module guides the operator through the specified recipe steps. Weighing jobs can be selected and started. The scale is selected and the raw materials are identified and checked. The weighing process itself is supported visually with bargraphs and R+S-Symbols (pictograms).

Sartorius ProMix is supplied as a "Regulated" or "Non-Regulated" version. The "Regulated" version is for applications in the so-called "regulated industry", whose processes are validated. In this version, the "Audit Trail" and "Electronic Signature" functions are implemented, in addition to the "Non-Regulated" version.

The weighing process
In principle, there are two different procedures for executing recipes: individual batching, in which each raw material is weighed into a separate container, and mixed batching, in which all materials of a job are weighed into a single container. Before the weighing operative can process jobs, he or she must be authorized by means of a user name and password.

Execution can be vertical, i.e. in accordance with the specified recipe sequence, or horizontal, i.e. raw material campaigns are carried out. In principle, recipe lines can be freely selected. Information or instructions can be displayed before or after each individual weighing process.

Special actions, or actions deviating from standard procedures, must be confirmed with an electronic signature. This applies to part weighing, for example, where insufficient raw material is available for an individual batch. These processes are reported in the Audit Trail.



Single User Version with extra Database Server

Extendable Multiuser System

Special recipe functions
Recipes can be divided and processed over several weighing stations (recipe splitting). Recipe set-points can be calculated in accordance to the active component content of the current raw material batch. The set-points for equalizing materials are adjusted automatically.

Recalculation
If a tolerance threshold is exceeded in the case of a mixed batch, this creates a problem in that the excess raw material cannot simply be removed, as in the case of individual batching. In order to prevent incorrect batching and waste, all set-points are automatically extrapolated in proportion, such that the mixture is restored to specification following renewed batching. Of course, this function can be deactivated for validated processes in regulated applications.

Material tracing
The raw material batches used are identified, checked and reported. Two different methods can be used for tracing batches. Firstly, all batches used in a job can be searched for; secondly, all jobs in which a raw material batch was used can be listed.

System architectures
Sartorius ProMix can be used in a variety of ways and in a variety of applications. It can be applied as a compact, single location solution, in which all the software modules described above are installed on a single computer. On the single location version it is also possible to relocate the database to an extra database server.

If raw materials are weighed at several weighing stations, or if materials and recipes are to be managed at another office work location, a suitable multi-location system can be implemented with the Client/Server versions.

Any number of scales can be connected to the individual weighing stations, typically via serial interfaces. Sartorius digital scales and weighing platforms can be connected as standard. However, drivers are also available for scales from other suppliers.

When operators change work locations, the operating language is set automatically according to the user who is logged on. In this way, operators who speak different languages can work on the same system without problems, even if work locations are changed frequently.

Flexible data connection
It is possible to connect to MES and ERP-Systems, such as SAP, via a variety of import and export functions. In this way, raw aterial data, recipes, jobs and reports can be exchanged automatically. Thus, ProMix can be integrated into an existing information processing system.

Convincing advantages
Sartorius ProMix guarantees that process steps are executed exactly and in accordance with specified procedures. In addition, a high level of recipe security is achieved by means of the precise and efficient batching of the smallest quantities. This combines simultaneously with raw material savings and the avoidance of waste, particularly when recalculation is used.

A high level of transparency is achieved for the entire process with the aid of comprehensive reporting. Diverse functionality ensures that the requirements are met for the validation of an application.

Sartorius ProMix achieves a new dimension in operational and process security and provides profitable efficiency in manual recipe processing.

Technical Data

ProMix System
- Single and multiple location systems
- Extra database server can be used
- Operating at the Server-PC is not possible without a client
- PC weighing station with any desired quantity of scales is possible
- Drivers for Sartorius scales and weighing platforms including xBPI and SBI protocol
- Drivers available for scales by other suppliers, against extra price: e.g. Bizerba, MT, Precisa, Berkel, Soehnle. If required, please enquire about the driver for the specific make and model of scale
- Scanner, serial connection: e.g. Sartorius YBR02D09
- Printer: "Windows Printer"
- For labels: Sartorius YDP12IS
- IPC: Sartorius 15TSHD
- Firebird SQL database (license free)
- Oracle database on enquiry

Weighing functions
- Elective execution of recipe lines
- Vertical (batch weighing)
- Horizontal (campaign weighing)
- Scale change
- Raw material batch change
- Set-point value calculation according to the active component content
- Calculation of equalizing materials
- Part weighing: Division of weighing into various raw material batches
- Interruption of weighing
- Instructions
- R+S–Symbols (pictograms)

Recipe functions
- Manufacturing specifications
- Recipe version management
- Recipe splitting to various weighing stations
- Recalculation: Correction of setpoints proportionally over the whole recipe on over-batching

"Regulated Version"
Additional functions:
- Audit Trail
- Audit Report
- Electronic signature with password control per 21 CFR Part 11
- Calibration Report
- Gradation Chart

Material management
- Goods reception/receipt of raw materials
- Batch release/block
- Inventory management
- Batch verification (FIFO, ED)
- Batch traceability in respect of batch and job

Job planning
- Recipe
- Job creation
- Job list

Reports
- Job/Weighing report
- Evidence of use
- Stocks
- Production quantities
- Audit report
- Creation of label layout – on enquiry
- Label printing:
  - automatically after weighing
  - on request

User management
- User groups
- Individual user rights:
  - Module-related
  - Function-related
  - Actions (Edit, Delete,...)
- Password rules

Languages
- English
- German
- Other languages can be implemented
- Online Help in English and German

Minimum PC specification
- Windows 2000 SP5 or Windows XP with SP1
- Pentium III, 700MHz
- 256MB RAM
- 20GB hard disk
- 12" monitor, 15" recommended
- Graphics: Touch-screen for weighing station: 800 x 600,
- For data management and for the single location version: minimum: 1024 x 768
- 2 x RS232 COM ports or via USB adapter
- LPT port or USB for printer
- USB port for Hardware Key
- Ethernet interface
- Keyboard connection

Order information

Type	Description	Order number
PR8301/00	Sartorius ProMix for Windows – CD ROM Demo-Version	9405 383 01001
PR8301/10	Sartorius ProMix for Windows – Single location version "Non-Regulated" CD ROM and License	9405 383 01101
PR8301/20	Sartorius ProMix for Windows – Server for multiple location version "Non-Regulated" CD ROM and License	9405 383 01201
PR8301/21	Sartorius ProMix for Windows – Client for multiple location version "Non-Regulated" License	9405 383 01211
PR8302/10	Sartorius ProMix for Windows – Single location version "Regulated" CD ROM and License	9405 383 02101
PR8302/20	Sartorius ProMix for Windows – Server for multiple location version "Regulated" CD ROM and License	9405 383 02201
PR8302/21	Sartorius ProMix for Windows – Client for multiple location version "Regulated" License	9405 383 02211

Key
R+S: Risk and Safety; FIFO: First In First Out; ED: Expiry Date;
MES: Manufacturing Execution System; ERP: Enterprise Resource and Planning

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Sartorius Hamburg GmbH
Meiendorfer Straße 205
22145 Hamburg, Germany
Tel. +49.40.67 960 303
Fax +49.40.67 960 383
www.sartorius.com