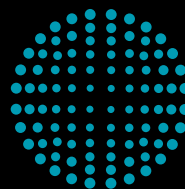


CONTAINMENT GUARD



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CONTAINMENT GUARD

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Efficient development of safe containment solutions for tableting

Increasing demands for user and environmental protection, avoiding cross-contamination, growing technical complexity of systems: the expanding usage of highly-potent and toxic substances means greater responsibility for pharmaceutical manufacturers.

Whether researching pharmaceutical companies or manufacturers of generic products / contract manufacturers – those hoping to take advantage of the opportunities for growth associated with these new, highly-potent substances are in need of safe and efficient containment solutions. But that's not all. Increasingly protective measures are necessary for many drugs previously manufactured without any special precautions. Low-dust production systems are the new minimum standard.

Despite comprehensive guidelines and increased specifications by the regulatory authorities, exact standards for individual production steps are still lacking in practice, which is why Fette Compacting is taking an initial step in the area of tableting. The Containment Guard is the first quality certificate establishing and documenting the retention efficiency of containment tableting systems prior to the subsequent risk assessment carried out by the operator.

The Containment Guard is both a test process and the basis for technical development of containment solutions in tableting. Furthermore, extensive services, training and consulting are available which are specifically tailored to the requirements of production under containment conditions. Users benefit from safe, simple and swiftly available solutions along the entire life cycle of the plant.

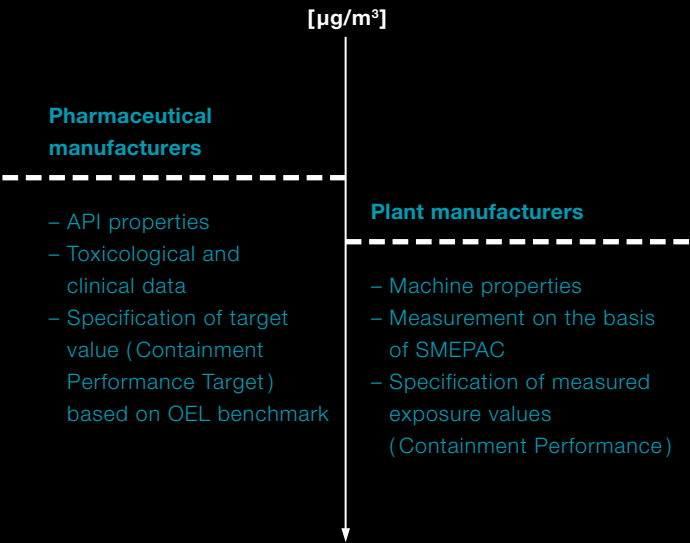
The Containment Guard is the comprehensive solution offered by Fette Compacting for efficient production of tablets under containment conditions. It is based on a modular system comprising services from the areas of Technology, Service and Competence in accordance with the Efficiency Guide.

A new standard for measuring the containment performance of tableting systems

Standard process: limit values as a basis for system design

A containment system design is always based on the toxicological assessment of the substances to be processed by the pharmaceutical manufacturer. This assessment is used to derive maximum permissible limit values. For this, the manufacturers use models such as Occupational Exposure Limit (OEL) or Permitted Daily Exposure (PDE). The specified limit values subsequently provide the reference point for the risk assessment when commissioning the complete system using the Standardized Measurement of Equipment Particulate Airborne Concentration Directive (SMEPAC). It offers a suitable framework for assessing the containment qualities of systems in general. The Containment Guard complements the SMEPAC Directive with additional practical aspects in order to make a reproducible evaluation possible for containment tableting systems:

- Position of measuring probes
- Location of operators
- Number of samples
- Machine operating conditions
- System reactions to errors or faults
- Calculation of the overall system output including process equipment



Usual classification of API (OEB)

Very high pharmacological and toxic effect

< 0.1

< 1

High pharmacological and toxic effect

0.1-1

1-10

Average pharmacological and toxic effect

1-10

10-100

Low pharmacological and toxic effect

10-100

100-1,000

Very low pharmacological and toxic effect

100-1,000

1,000-10,000

No pharmacological and toxic effect

1,000-5,000

10,000-50,000

OEL $\mu\text{g}/\text{m}^3$

ADE $\mu\text{g}/\text{day}$



Containment Guard: more accurate measurement, less expense

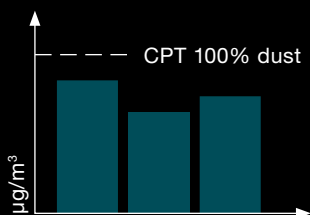
The Containment Guard from Fette Compacting adds additional cycles to the existing process. The measuring criteria correspond to the SMEPAC guidelines. The Containment Guard, however, always involves the total installation, including the process and safety equipment. The structure and flow of the test procedure is standardized. Fette Compacting performs the test in a test room at the Competence Centre in Schwarzenbek.

After testing, the equipment receives a Containment Guard certificate. The Containment Guard stages are based on the OEB levels of the containment pyramid. The total dust volume (100% dust) is used as the basis for calculating the Containment Guard level. In cases where the granulation contains less than 100% of the active ingredient, the Containment Guard classification changes accordingly.

Possible methods for determining the containment requirement

Consideration based on the total amount of dust

The Containment Performance Target (CPT) based on 100% dust is known.

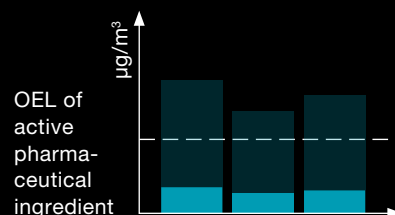


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Consideration based on a normal tableting mixture consisting of active pharmaceutical ingredient and excipient

The active pharmaceutical ingredient content (drug load) and limit value if the active pharmaceutical ingredients (OEL) are known.



Comprehensive solutions for safe and efficient tableting

The Containment Guard marks the efficiency of the comprehensive solutions offered by containment tableting systems. The technical basis is formed by a modular system based on the FE and i Series offered by Fette Compacting. Apart from tablet presses, this also includes the process and safety equipment as well as services and consulting specially tailored to containment requirements.



Competence

This offer covers consulting during design of the plant prior to project planning, the user training as well as the consulting and training during ongoing operation.



Technology

The containment systems from Fette Compacting offer efficient solutions for conventional and Wash-In-Place (WiP) cleaning, along with modular standard platforms for every requirement: from low-dust production up to high containment plant with integrated safety process equipment.



Service

Apart from the standardized Containment Guard test method, commissioning of the plant and maintenance therefore are also included in the service offering.

COMPETENCE

TECHNOLOGY

SERVICE

Consulting



Tablet press



Conventional
cleaning



Wash in Place

SMEPAC



Engineering



Safety Equipment



Filtration



Airmanagement



WiP Center

Commissioning



Training



Process Equipment



Deduster +
Metal check



IPC Unit



Isolator

Maintenance



Example Containment Guard: FE Series – Standard for low-dust tableting



The FE55 and FE75 tablet presses represent the standard platforms offered by Fette Compacting for low-dust production. Fitted with an optional containment package and the associated process equipment, they form the basis. The tableting process is fully automated in the FE Series – smooth containment from filling the machine through tablet ejection. The machines are accessible from all sides thanks to gloveports, enabling operators to carry out work inside the tablet press both swiftly and safely without breaching containment. The containment package for the FE55 and FE75 also includes:

- Flat valve for a safe product feed
- Hermetically-sealed and automatically-locking window flaps
- Rapid Transfer Port (RTP) access points for removing or introducing components
- Low-dust tablet discharge chute
- Hepa-filter H13
- Hand-held vacuum hose for preliminary manual cleaning
- Interface for containment deduster, metal check device and IPC unit (In-Process Control)
- A special safety concept and safety-oriented pressure monitoring





FE75 in bi-layer production with containment package and corresponding process equipment



Liner system as the connecting element between the individual system components



Single-use containment valves for connection to the tablet containers

Example Containment Guard: solutions with optimized cleaning technology



When processing highly-potent and toxic pharmaceutical substances, the use of Wash-in-Place (WiP) systems significantly reduces the strain on machine operators in cleaning. Product changes are faster which means considerably reduced machine downtime.

To ensure that product residue in the press room can be easily removed, the i Series containment presses are, in addition to a fully automated WiP system, fitted with a manual wash gun and vacuum wand. A Rapid Transfer Port (RTP) can also be added, through which tools can be introduced and removed.





↑ Previous cleaning of process room without breaching containment.



Example Containment Guard: tableting systems for maximum safety requirements



The isolator technology from Fette Compacting is the basis for Containment Guard systems. Encapsulated tableting solutions offer maximum safety in production and optimal protection for operating personnel.

The isolators can be fitted with various options such as:

- vertical deduster
- metal check device
- IPC-Checkmaster (In-Process-Control)

Using the integrated gloveports and RTP access points, operators can easily carry out all work inside the machine and isolator. The individual steps associated with tablet compression and in-process control can be monitored at the HMI. The same applies for air purification which operators can monitor via a software-controlled Airmanagement system that includes a negative pressure emergency system. In combination with a WiP Center from Fette Compacting, tablet presses can be automatically cleaned in no time.





↑ Installation example of a 2090i WiP with isolator technology for the process equipment and the patented Airmanagement system by Fette Compacting

← Removing a punch

Example Containment Guard test method: a new standard for assessing the containment performance by tableting systems

The Containment Guard certification takes place in Fette Compacting's Competence Center in Schwarzenbek. When the tests have been completed, Fette Compacting hands over the tablet press and the test results to the customer. These form the basis for the operators' risk assessment, as well as reduce the ongoing expense once the tablet press is brought into operation.

This approach allows us to consider all the system components as a whole, particularly the process and safety equipment by suppliers, as well as the patented Airmanagement system by Fette Compacting. The users receive a solution that is technically and economically customized to their needs. They invest in optimal cost effectiveness and a sustainable and long-lasting solution.

Fette Compacting makes containment efficient.

→ Double rotary tablet press FE75 with containment package, process equipment and the patented Pmax® segment technology for up to 1.6 million tablets per hour





Exposure measurements: seven steps to the Containment Guard level

Exposure measurements developed on the basis of the APCPPE good practice guide from the ISPE are a central element of the Containment Guard. This standardized method measures the concentration of particles that escape from the equipment. The APCPPE guide applies to different types of equipment, and therefore cannot fully capture the specific requirements of a containment tableting system. The Containment Guard goes one step further: On top of the measurement specifications used so far, such as the defined probe-taking process, or the selection of the test substance, it adds further methods, in order to realistically simulate all the production conditions encountered in tablet production.

For example, where the measuring probe or the operator is located during the measurement procedure, how many tablet samples are withdrawn for quality control in the Checkmaster, or which operating states and malfunctions of the tablet press are possible, are important for exposure measurements in tablet production. The Containment Guard tests all of these in seven measurement scenarios (cycles). The measurement results are reflected in the Containment Guard level.



Cycle 1: Zero measurement

The background level of the test substance in the measurement room is determined at the beginning of the measurement procedure. The subsequent test cycles can be more effectively classified with this information for reference.



2

Cycle 2: Production

The operator sets up the tablet press and begins operation. The machine runs normally for half an hour in order to measure the retention performance during ongoing production. Typical processes, such as the withdrawal of sample tablets for quality control, are also tested in this cycle.

Cycle 3: Introduction and removal of components

The operator transfers the punches and tools into the machine through the Rapid Transfer Port (RTP). He then uses the gloveports to change the punches. The tools are taken out of the tablet press again at the end of the cycle.



3



Cycle 4: Fault test

The fault test simulates a power failure. The tablet press and the filter unit are first run in regular operation for five minutes, and are then switched off. The emergency system takes over the Airmanagement system from this point on. The measurement then takes another 25 minutes.



Cycle 5: Cleaning the interior

The operator reaches into the interior of the machine through the gloveports, and cleans the interior of the tablet press room as well as the isolator, in relevant cases. Depending on the press, a manual washing gun is also passed through the port, and the components are cleaned again manually. The washing program then starts. The machine's window flaps remain closed the whole time.

Cycle 6: Removing process equipment

The upward deduster and the Checkmaster are disengaged. There are two measurement scenarios for this step: tablet presses with isolator and tablet presses with washable process equipment. This step is omitted if a machine with an isolator is measured, and the process proceeds from cycle 5 straight to cycle 7.



Cycle 7: Removing the Fill-O-Matic

The operator opens the window flaps and dismantles the Fill-O-Matic and the punches. The tablet press is wiped out wet.

To achieve measurement results with the maximum accuracy, the cycle runs are repeated three times for every tablet press to be measured.

Top: Surface samples (SWAB test) are also taken from defined areas at the beginning and end of a run

Right: Illustration of a measuring probe



Containment solutions

Pharmaceutical manufacturers are increasingly using highly-active and toxic substances which continuously increases the requirements on the protection of operators, products, and the environment. For this reason, Fette Compacting offers perfect-fit system solutions for tablet production under containment conditions.

The standard platform for dust-tight production is represented by the FE55 and FE75 tablet presses with an optional containment package as well as the F10i in containment design. The machines in the tried-and-tested i Series in WiP and containment designs are available for higher containment requirements.

In order to process highly-toxic substances efficiently, the process equipment is integrated in the isolator in containment and WiP tablet presses. Automated cleaning of the tablet presses relieves the operator and reduces machine downtimes.

Standardized safety

All solutions comply with the comprehensive safety philosophy pursued by Fette Compacting in which containment is part of the process cycle.

These include the following standards:

- No dust released during production and preparation for cleaning
- No contact with toxic products
- Water- and dust-tight press room
- Manual preliminary cleaning
- Maximum safety in the workplace
- Protection of operators throughout the entire production process

Containment Guard

The Containment Guard is the world's first quality seal marking the efficiency of containment tableting equipment. Using a standardized test method, Fette Compacting establishes the retention performance of all machines involved and then passes on the results to the customer. These data form the basis for subsequent risk assessments by the operator and significantly reduce the effort associated with measurements after installation.

Furthermore, Fette Compacting offers comprehensive services and consulting specifically coordinated to the Containment Guard. Users benefit from safe, simple, and swiftly available solutions along the entire life cycle of the plant as a whole.



Isolator technology offered by Fette Compacting ensures maximum safety for operating personnel while processing highly-toxic products.



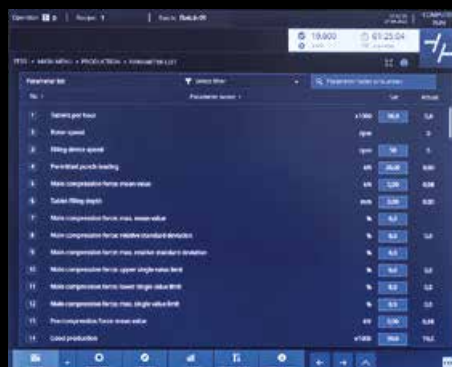
2090i containment WiP with isolator technology for process equipment.

Everything at a glance: FE Series software

In modern containment plants, the tablet press operating system is attributed a decisive function for operator safety. The software in the FE Series monitors the relevant safety components, regulates access to containment controls, and informs operators of faults and imminent dangers.

Advantages at a glance:

- Maximum safety through operator level monitoring
- Restricted access to containment controls (for authorized users only)
- Individual monitoring system for each glove port
- Audit trails for all operator entries
- Sensor for monitoring under-pressure
- Fail-safe locking of each of the four window flaps
- Display of switchable extraction unit
- Acoustic and optical safety information in the event of a leak



Extra safety: FE Series



Dimensions	1,306 × 1,306 × 2,048 mm excl. control cabinet
Weight	Tablet press 3,700 – 3,900 kg, operator terminal 100 kg, control cabinet 250 kg



Dimensions	1,463 × 1,463 × 2,046 mm excl. control cabinet
Weight	Tablet press 5,500 kg, operator terminal 100 kg, control cabinet 350 kg

Extra safety: FE Series

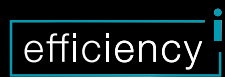
In order to guarantee maximum operator safety when operating the tablet presses in the FE Series, Fette Compacting has equipped the FE55 and FE75 with a containment option. From filling the machine through to tablet removal, the fully-automated tableting process prevents an interruption to containment at all times.

Glove ports from all sides and rapid transfer ports (RTP) ensure that manual interventions do not interrupt the containment process. Automatic monitoring stops the tablet press in the event of unsafe access. Glove ports and window flaps are integrated in the safety control system where they are also monitored. The possibility of unintended use is practically excluded.

Advantages at a glance:

- Flap valve for safe product feed
- Hermetically-sealed and lockable window flaps
- Dust-tight press room design
- Real-time monitoring for press room under-pressure
- RTP access points for removing components or tablet samples
- Ergonomic glove ports with safety sensor
- Dust-tight tablet discharge
- Suspended particulate material H13 hepa-filter
- Vacuum system for preliminary cleaning via manual extraction hose
- Special software security concept using HMI

Dust-tight and more: new i Series



The tablet presses in the new i Series are eminently suitable for small, medium, and large production volumes, attaching particular importance to operator protection. For this reason, the new i generation already features a consistently dust-tight design even in standard versions, from the press room to the connections between the machine and process equipment. They can also be upgraded with appropriate containment for products with active or highly-active substances.

Tableting is fully automated so that containment does not need to be interrupted during any production phase. Rapid transfer ports (RTP) permit the introduction and removal of material, tools, and punches. Glove ports in the window flaps guarantee manual access from all sides and also facilitate cleaning.

At the same time, the interior enclosure parts to be cleaned have been considerably reduced. Dust-tight connections between the press room and process equipment, coupled with intelligently-installed cables and lines, permit risk-free cleaning at all times.

Advantages at a glance:

- Dust-tight, cleaning-optimized press room
- Sensor-monitored window flaps with double barrier system
- Manual, fail-safe locking of window flaps
- RTP access points for introducing and removing material and tools
- HMI-based control of all containment parameters
- Individual monitoring system for each glove port
- Real-time monitoring for press room under-pressure
- Restricted access to containment controls (for authorized users only)
- Audit trails for all operator entries
- Acoustic and optical safety information in the event of a leak

Dust-tight and more: new i Series

efficiency



Dimensions	925 x 1,112 x 1,875 mm *
Weight	Tablet press approx. 2,100 kg **, operating terminal 90 kg

* Dimensions can deviate depending on the option
** Weight can deviate depending on the options chosen



F10i featuring containment

Dust-tight and more: new i Series

efficiency 

F20i



Dimensions	1,220 × 1,220 × 2,022 mm *
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Weight	Tablet press 3,300–3,500 kg **, operating terminal 90 kg
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* Dimensions can deviate depending on the option

** Weight can deviate depending on the options chosen



F20i featuring containment

Dust-tight and more: new i Series

efficiency 

F30i



Dimensions	1,394 × 1,394 × 2,030 mm *
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Weight	Tablet press 4,600 kg, operating terminal 90 kg
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* Dimensions can deviate depending on the option



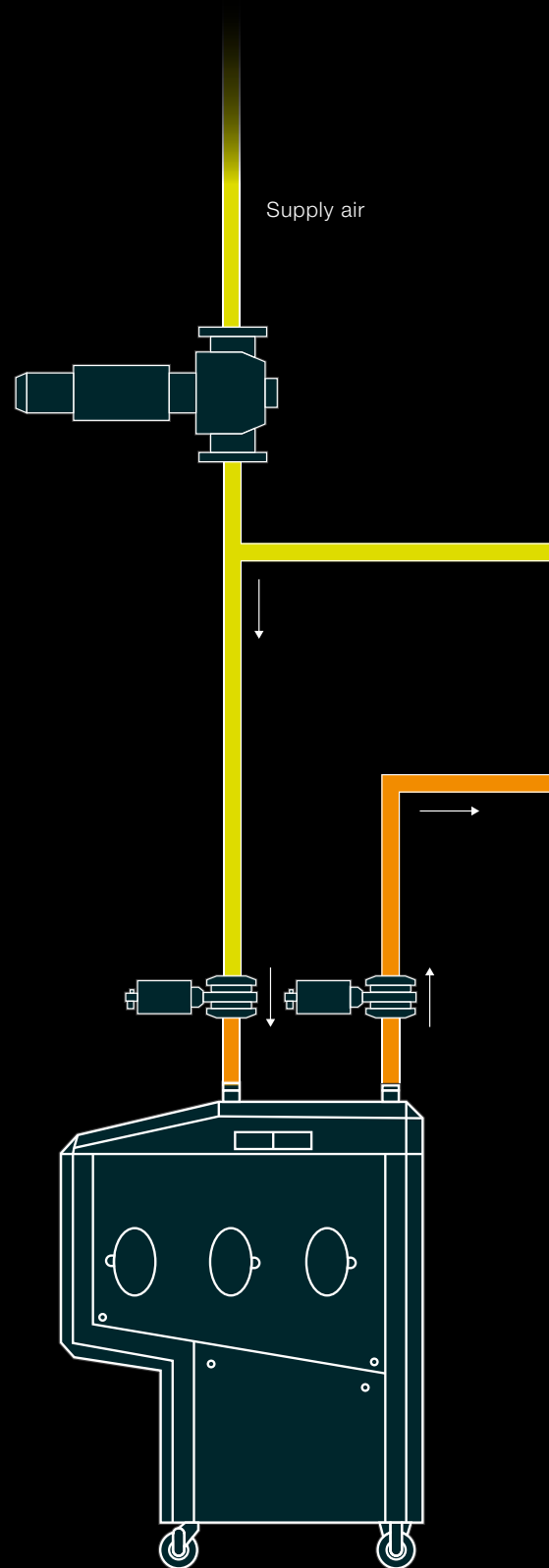
F30i featuring containment

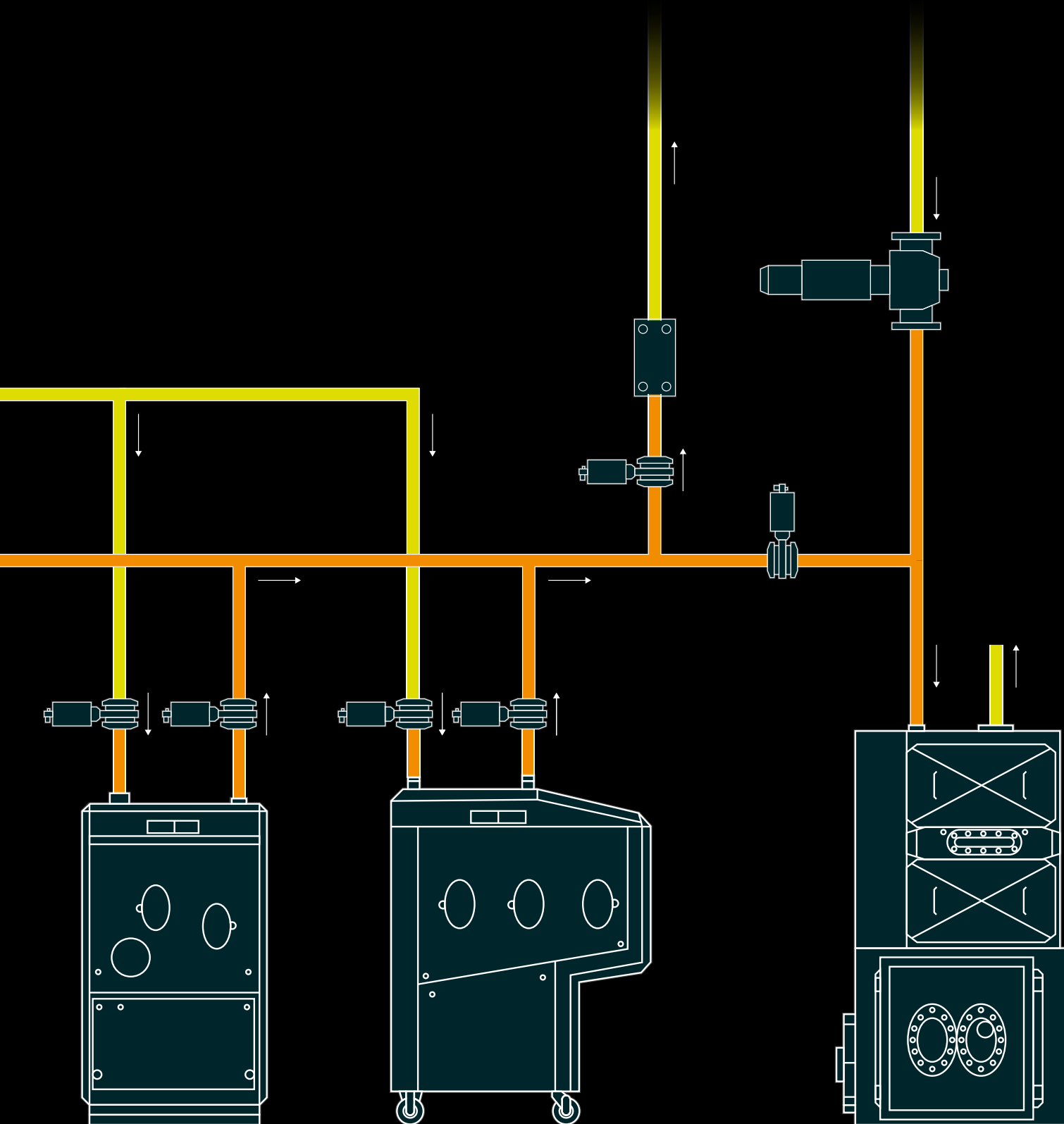
Airmanagement

One essential factor for high-containment solutions entails Airmanagement in the plant as a whole. For this reason, Fette Compacting has developed its patented Airmanagement system which controls the entire ventilation technology and the plant filter system.

Airmanagement combines hardware and software to form an innovative overall solution which meets maximum safety requirements. In the event of a production fault, Airmanagement has an under-pressure emergency system which prevents contamination of the production area even if the entire control system fails.

Airmanagement is integrated in the tablet press system controls. From here, Airmanagement is controlled, monitored, and documented for the entire plant. This offers a high degree of perfectly-coordinated safety for the entire production under containment conditions.





Safety at all levels: Airmanagement and WiP Center

Airmanagement features

Full Airmanagement control

Airmanagement ensures constant, adjustable under-pressure in the machine and periphery. Optional measuring adapters permit monitoring of flow rate and flow speed.

Easy control

Full operation via the machine terminal. Modifiable nominal values are stored in the tablet press parameter management.

Fast troubleshooting

Error messages are shown with diagnostic text.

Extensive data exchange

Via a modern interface, Airmanagement and filter systems exchange relevant parameters.

Automatic under-pressure monitoring

Pressure sensors monitor the current pressure values in the tablet press and isolator. Overpressure and under-pressure are monitored for adherence to limit values.

Clearly-defined maximum values

Monitoring of the limit values takes consideration of fluctuations in pressure which are attributable to operation. Warning and switch-off limits guarantee two-fold safety.

Safety during faults

When the pressure limits set are fallen short of or exceeded, the pneumatic emergency system is activated. Even in the event of full failure of the control system, this prevents contamination of the production area.

Dismantling and cleaning

Valves in a clamp design permit easy dismantling and cleaning of the system.

WiP Center features

Automatic cleaning

The WiP Center is a stationary cleaning unit for automatic control of the cleaning process from the tablet press to peripherals. The Wash-in-Place concept serves toward preliminary cleaning and binds airborne dust particles with water molecules.

Self-drainage

The WiP Center's pipes and valve blocks are installed at an incline of three degrees to permit self-drainage of the system.

Intelligent injection

The WiP Center avails of modern injection pumps with stepper motor technology and multi-color touch display. Injection of cleaning agents is pre-defined and can be set via the HMI.

Pragmatic design

The input and output block of the WiP Center is flush with the rear panel of the enclosure. Installation is facilitated by a labeled connector panel for all electrical and air connections.

High-quality material

The system's control box and the collection basins for solvents are made from high-quality stainless steel.

Modern connection

The WiP is connected to the tablet press controls via the industrial ethernet Profinet standard.

Easy recalibration

User-friendly design facilitates dismantling of the system for re-calibration of the pressure and temperature sensor.



Well-conceived cleaning: 1090i WiP and 2090i WiP

1090i WiP



2090i WiP



Dimensions	960 × 960 × 2,034 mm
Weight	Tablet press 2,100–2,400 kg, operator terminal 100 kg, control cabinet 350 kg

Dimensions	1,220 × 1,220 × 2,022 mm
Weight	Tablet press 3,400–3,600 kg, operator terminal 100 kg, control cabinet 350 kg

The WiP and containment designs of the 1090i and 2090i are single rotary tablet presses with segment technology, washable press room, and highly-developed containment. Thanks to contamination-free material input and output as well as zero-emissions cleaning, they easily process smaller to medium-sized batches of active and highly-active substances.

Swift conversion of the machine is possible with and without turret change. Thanks to a unique clamping system, the segmented turret, including all segments, as well as the upper and lower punches, can be removed in no time. This minimizes cleaning times and accelerates format or product changes which, in turn, results in significantly shorter machine downtime and higher overall output.

Each die table package is designed for using guided punches. The punches are protected by the punch-saving system. The 1090i WiP containment unit can also be equipped with a die turret as an option for the smallest quantities and galenic tests.

The 1090i and 2090i are operated via a separate terminal with a 15" touchscreen. The modern software ensures fully computer-controlled monitoring of the machines and permits unattended production in 24-hour mode.

Advantages at a glance:

- Water- and dust-tight, cleaning-optimized press room
- Fully exchangeable turret (incl. punches, dies, and segments)
- Automatic turret clamping and release
- Fully-automated production (incl. injection locking and Fill-O-Matic drainage)
- Format change in no time, even in the case of toxic products
- Maximum output through short downtime and 24-hour production
- Collection basin made of stainless steel with inclination and automatic drainage valve
- Smooth, easy-clean outer casing

Maximum performance: the 3090i WiP



Dimensions	1,390 × 1,390 × 2,024 mm
Weight	Tablet press 4,700 – 5,000 kg, operator terminal 100 kg, control cabinet 350 kg

The 3090i double rotary tablet press with WiP and containment features is the optimal solution for medium to very large batches of active and highly-active products. The plant is optimized for flexible high-performance production. Fast product and format change is easily possible.

An automatic turret clamping system and maintenance-free servo motors for adjusting the compression rollers are firm components of the 3090i in WiP and containment design. Integrated glove ports and RTP access points facilitate working inside the machine.

The individual processing steps can be monitored via HMI. The same applies for air purification which is regulated by the software-controlled Airmanagement system. Airmanagement also features an under-pressure emergency system which prevents contamination of the production area in the event of a fault. The WiP Center makes it possible to clean compression suites automatically in no time.

Advantages at a glance:

- Glove ports for safe access to the entire interior under containment conditions
- Safety sensors in all glove ports
- RTP access points for introducing and removing material and tools
- Automatic turret clamping system
- Pre- and main compression rollers of equal size
- Maintenance-free servo motors for adjusting the compression rollers
- All compression stations feature the same design

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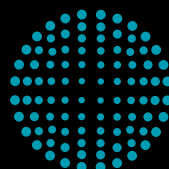
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