

# WHAT'S NEXT?



**FETTE  
COMPACTING**



A member of  
Excellence United

FETTE COMPACTING MAGAZINE 2019



## EFFICIENCY<sup>i</sup>

New i Series: dust-proof and digital ready

## SHARED CONTAINMENT KNOWLEDGE

Containment Guard measurements

## CAPSULES AT FULL SPEED

FEC40 and FEC20 in practice

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DEAR READERS,

The question “What’s Next?” is more than a magazine title: it is also at the top of our agenda. We are taking a very close look at how pharmaceutical production is changing. What is the influence of digital technologies? Is data the new medicine and will “smart pharma” soon replace “big pharma”?

One thing is clear: the pharmaceutical world is currently undergoing a profound change, driven by immense cost and innovation pressure. Manufacturers want to be compatible with the Internet of Things (IoT). But not many have the luxury of reconfiguring the entire factory and revalidating every process.

We are pursuing a different strategy: retaining and expanding established methods and technologies to gradually turn the machine park into a digital platform. This is precisely what we have achieved with the i Series, our most-installed series of tablet presses worldwide. In this issue we present the revamped i Series with its entry-level model, the F10i, for the very first time. Find out how a machine can be turned into a production system – fully compatible with the existing environment.

Also read about the exciting answers to the question of “What’s Next?”: from capsule fillers, which break the output record, to pioneering containment measurements, and virtual reality training sessions as well as other highlights.

I hope you have an inspiring read!

Yours sincerely,  
Olaf J. Müller  
CEO LMT Group  
Division President Fette Compacting



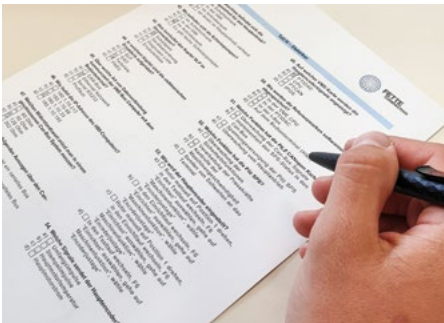
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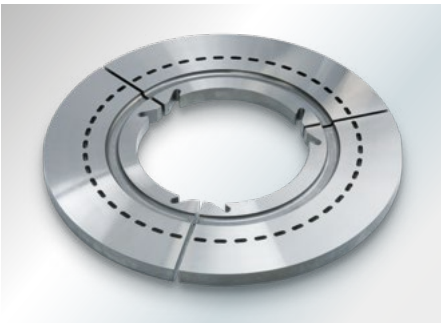
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**TECHNOLOGY** stands for everything we offer in production technology – from tablet presses and capsule filling machines through process equipment to tableting tools and format parts.

**SERVICE** covers all the services related to machines, process equipment and installations such as spare parts supply, plant modernization and technical field service department.

**COMPETENCE** is the overarching idea behind all our process-related services. This includes training, product trials, application and Performance Consulting as well as engineering.

Imprint

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# THE NEXT LEVEL OF EFFICIENCY

**Productive, flexible, unailing – this is what Fette Compacting's i Series has stood for over decades. This will remain the case in the future, too, but with far many more possibilities: the new i Series, which was launched in 2019 with the F10i single rotary press, offers numerous innovative features. It bridges the gap between an established technology and the digital future of pharmaceutical production.**

The tablet is the most successful form of administration in the history of medicine. This is not likely to change in the foreseeable future, as tablets enable a precise dose, are easy to administer, and are economical to manufacture. However, the requirements faced by pharmaceutical manufacturers are becoming increasingly complex, while the economic pressure continues to rise.

For manufacturers, this change can be an opportunity, if they can successfully transform production: from a cost factor to a value driver. This requires an integrated understanding of the process, which no longer targets individual machines but rather extends to the production system. The machine also has to change. It must expand to become a technological platform, which can flexibly align its components to different requirements. This allows pharmaceutical manufacturers to respond more quickly to changing product pipelines, new active substances, and other trends.

## **Innovation yes, validation effort no**

But, in pharmaceutical production this kind of reconfiguration has a snag: anyone who changes existing technologies and processes may have to re-validate everything. This involves a huge amount of effort and cost. The question therefore is how it is possible to successfully connect to innovative methods of production without this resulting in high revalidation costs.

Fette Compacting worked together with its customers to develop a solution in this area of conflicting requirements: "We painstakingly searched for an interface between established production and digital pharma of the future – and rethought our i Series," explains Jörg Gierds, Senior Product Manager at Fette Compacting. "The current i Series includes the high-performance machines 2090i and 3090i as well as the standard tablet presses 1200i, 2200i and 3200i. These single and double rotary presses provide a high output in the various production tasks with an installed base of several thousand machines worldwide. This is what we are now building on."

# efficiency<sup>i</sup>

## **Efficiency<sup>i</sup> – meeting of the machine generations**

As the next generation of the i Series, Fette Compacting developed a technological platform on which the electrical and mechanical components are based. What's special about this is that the components relevant for validation are largely retained. "The i Series therefore retains all of its features that make it so valuable to our customers," highlights Gierds. "With regard to the machine, Efficiency<sup>i</sup> means that the user can retain everything that makes their production successful today in the future – with even higher efficiency and more possibilities."

**»WITH REGARD TO THE MACHINE, EFFICIENCY<sup>i</sup> MEANS THAT THE USER CAN RETAIN EVERYTHING THAT MAKES THEIR PRODUCTION SUCCESSFUL TODAY IN THE FUTURE – WITH EVEN HIGHER EFFICIENCY AND WITH MORE POSSIBILITIES.«**

JÖRG GIERDS, SENIOR PRODUCT MANAGER AT FETTE COMPACTING





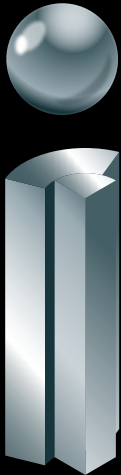
**1. Innovative:  
from dust-proof to containment**

The increased use of new pharmaceuticals, including highly potent active pharmaceutical ingredients (HPAPI) means that containment has become a key issue in production. It is already apparent that “dust-proof” will soon be the minimum standard for pharmaceutical machines. The new i Series already features a consistent dust-proof design in its most basic version. The new window flaps with double safety barrier systems also help ensure operator protection when using active substances. The press room is designed to optimize cleaning, as around 50 percent of all enclosure parts and components have been removed, thus reducing the surfaces to be cleaned by around 70 percent. The tablet discharge is a completely new feature; it is suitable for all standard formats and is entirely dust-proof. This improves the workplace quality and operator protection while product losses and cleaning effort are reduced to a minimum.

If containment is also required, a suitable solution can be swiftly found using the Containment Guard option. In this case, the emphasis is on “suitable”, as containment systems are often oversized so as not to endanger the project result. But the Containment Guard gives users a reliable basis for evaluating their individual containment based on precise exposure measurements (see pages 16–21).



Cleaning made easy: in the press room of the new i Series, around 50 percent of all enclosure parts have been removed, thus reducing the surfaces to be cleaned by around 70 percent.



**2. Integrative:  
system-compatible up to IoT and MES**

For several years the i Series has been distinguished by its cross-generation system compatibility. This is also the case for the machines in the new i Series. Practically all products with contact to the system assemblies remain unchanged despite its innovative design. „Not new, but better. This is the basic formula behind the features of the next generation,” says Gierds. “If relevant processes change in certain cases, Fette Compacting also has a solution: as part of our Lifetime Efficiency concept, we offer service packages specifically tailored to the i Series, which support users with revalidation.”

**»THE I SERIES IS NOW  
DIGITAL READY.«**

**JÖRG GIERDS, SENIOR PRODUCT MANAGER  
AT FETTE COMPACTING**

Thanks to the possible system integration, the new tablet presses fit perfectly into existing production environments. In other words, old and new machines can work efficiently next to one another. But the system concept extends even further into the future: the new i Series features technical connectivity for state-of-the-art production environments, up to “Pharmaceutical production 4.0”. This includes process equipment integrated via plug-and-play and open interfaces for connections to the Internet of Things (IoT) as well as for a manufacturing execution system (MES). The interfaces correspond to the standard for data exchange in industrial automation (Open Platform Communications Unified Architecture, OPCUA). “The i Series is now digital ready”, concludes Gierds.



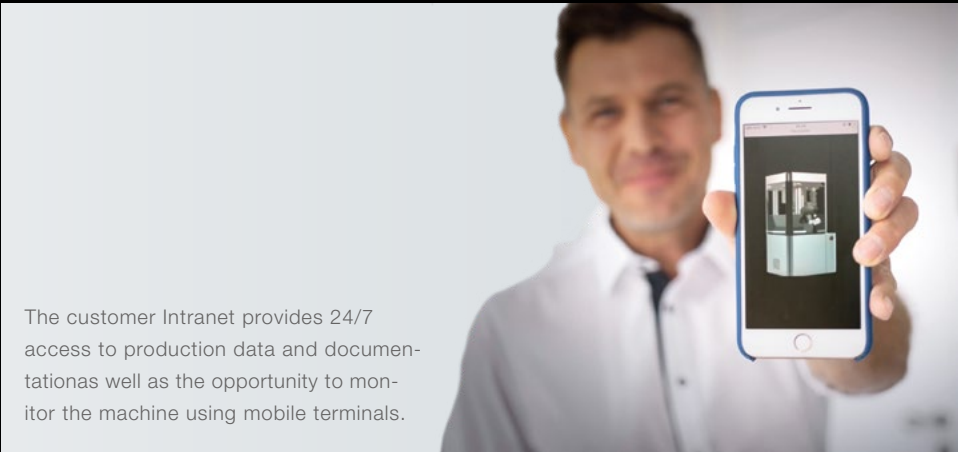
The new i Series features the technical connectivity for the latest production environments, including process equipment integrated via plug-and-play.



**3. Intelligent:**  
**SmartInterface and RFID**

SmartInterface by Fette Compacting is another step along the path to the data-based production of the future. The centerpiece is a server-based real time monitoring, which allows the user to monitor their production processes using mobile devices. “The user can download batch logs at any time and is always kept updated on the production parameters,” explains Gierds. “This allows the production manager to stay in full control of production from any location and they can schedule personnel more efficiently, by saving time during diagnostics for example.”

To increase process reliability even further and avoid tooling errors, the new i Series tablet presses feature an RFID option (radio-frequency identification). The contactless transceiver system allows process components to be automatically identified by the machine so that they can be compared against preset recipes. In addition, the new i Series is easy to scale so mechanical settings can be changed precisely in line with the recipes. For example, the tablet scraper can be reproducibly adjusted via an ax using a coding element. This facilitates operation, increases precision during removal and increases process stability.



The customer Intranet provides 24/7 access to production data and documentation as well as the opportunity to monitor the machine using mobile terminals.



**4. Intuitive:**  
**tactile HMI and workflow operation wizard**

An ultra-modern human machine interface (HMI) supports the user in the form of intuitive control, monitoring, and documentation of the machine and process equipment via a terminal. Tactile feedback, which generates a vibration and a sound when the operating keys are touched, provides added certainty when making entries. At the software level, a workflow operation wizard provides support in the safe and error-free implementation of standard operating procedures (SOPs). The wizard makes it even easier to operate the system. “These new tools ensure that operators have all parameters under control and that associated costly operating errors are a thing of the past,” says Gierds. Intuitive handling also includes highly simplified cleaning processes.



A workflow operation wizard facilitates the adjustment of the tablet press.

**The first machine: F10i for small batches**

As the first model of the new machine generation, the F10i was presented to the professional public in Schwarzenbek, Germany, in September 2019. The F10i is a flexible, efficient single rotary press for small batches – with or without HPAPIs. Producers can quickly adapt the tablet press to different requirements. Flexibility and versatility are also ensured by a handling arm, which supports the operator when changing the turrets, and a mechanical manual turret clamping system.

# FULL POWER FOR NUTRACEUTICAL ENCAPSULATION

»CONSUMERS HAVE BECOME BETTER INFORMED IN RECENT YEARS. THEY HAVE CONVERTED TO WHOLE FOODS, TO NATURAL, BIOLOGICALLY CERTIFIED INGREDIENTS AND PRODUCTS.«

Andrew Holtz, Maintenance Manager at Standard Process

Standard Process is a pioneer in the production of natural, whole food supplements. The US company is also a pioneer in the operation of a root-and-branch new capsule filling technology: the FEC40 from Fette Compacting. Through a field trial that sets the benchmark.

The market for nutritional supplements is growing fast. Market researchers estimate global annual sales to be around 133 billion US dollars. They expect growth of 7.5 percent a year until 2024. Vitamin-based supplements alone are expected to make up almost half of sales by the end of 2024.

This trend goes hand-in-hand with a change in consumer awareness. "Consumers have become better informed in recent years. They have converted to whole foods, to natural, biologically certified ingredients and products." So says Andrew Holtz, Maintenance Manager at Standard Process. "Customers nowadays expect high quality ingredients, and look for quality products and quality companies, companies who demonstrate respect for their employees and for the environment."



### Ingredients from the company's own organic farm

Standard Process, a US manufacturer of whole food supplements, has been using nutritious ingredients since 1929. The company's goal is to provide foods that are as close as possible to their natural form. That is why it grows more than 80 percent of the ingredients it uses. Its 420 hectare organic farm in Wisconsin harvests more than 2,500 tons of vegetables each year.

Holtz explains what happens after harvesting: "We process our crops immediately so as to minimize the loss of phytonutrients and retain the valuable nutrient complexes. Quality control of the processing, such as checking for microorganisms and gluten content, takes place continuously. Finally the ingredients are precisely mixed and made into tablets or capsules. We offer about 50 different preparations in capsule format, either as gelatin or HPMC capsules."

### The FEC40 overcomes limitations

To do justice in the same way to the high quality requirements and the growing demand for nutritional supplements, Standard Process

has been looking for an efficient capsule-filling technology since 2015. On the other hand, Fette Compacting has been looking for a field trial partner for its first capsule filling machine. Scott Anderson, Vice President Operations at Standard Process, looks back at the beginning: "One thing led to another, and we joined forces to take the highest-performance capsule filling machine in the industry, and to test it intensively under production conditions. We wanted to find out whether the limitations of our existing capsule filling machines could be overcome, including speed, flexibility, uptime and the ability to process demanding formulations."

The result, the FEC40 capsule filling machine, lived up to its promise: With a yield of up to 400,000 capsules per hour at 140 cycles per minute, the FEC40 has set new standards for efficiency. Thanks to the high output, production costs for each 1,000 capsules have fallen by up to 30 percent. In order to reach this dimension of performance, Fette Compacting's engineers have developed the first double sided capsule filling machine. Fette Compacting has carried the general technical concept of the FEC40 over to a second machine for medium batch sizes: the FEC20, the single sided version which has a yield of 200,000 capsules.





**Servo and torque drives instead of the synchronized cam driven system**

Anderson views the intelligent drive using servo and torque motors as a central advantage of the FEC technology: “The drive gives us enormous flexibility when setting up and refitting. All of our other capsule filling machines are controlled by cams, which makes adjustment extremely time-consuming, or even impossible. With the FEC40 on the other hand, every process step can be adjusted separately. To accelerate the set-up process, the parameters are saved with the formulation for every product. This means that downtimes are shortened from what used to be several hours down to a few minutes. On top of this, the operator can even make adjustments during operation, for example to maximize throughput.”

The TRI.EASY design of the FEC40 is tailored for optimum operation. It allows for a 360° approach, even when process equipment is connected, so that the stations can be accessed easily. “The edge that the FEC40 has over every other capsule filling machine, apart from the output, is above all the ease with which the tamping pin stations can be exchanged,” adds Anderson. “The operator can dismantle them and clean them outside the machine. This saves us any number of intermediate steps and adjustment work before the machine is ready to operate again.” A human machine interface (HMI) with a 19" touchscreen and integrated keyboard allows for intuitive user guidance. It ensures a total overview of the process and quality parameters at any time.

**From zero to 41 percent of all capsules**

For Standard Process the FEC40 is equipped with twelve stations, 24 capsules each. Anderson summarizes the final test phase: “During the first half of 2018 we manufactured a wide variety of products with a large range of flow and compressibility properties, in 0 and 00 capsule sizes. By the end of the year, the FEC40 had already taken over no less than 41 percent of our total capsule production. We have manufactured

»BY THE END OF THE YEAR, THE FEC40 HAD ALREADY TAKEN OVER NO LESS THAN 41 PERCENT OF OUR TOTAL CAPSULE PRODUCTION.«

Scott Anderson, Vice President Operations at Standard Process



25 different products on this machine. The batch size was the primary factor in the question of which products should run on this capsule filler. In the light of the FEC40's output, it made sense to process those of our products with the highest volumes on this machine at full power – with great success.”

Standard Process was impressed with more than just the machine itself. “Fette Compacting's services also include training for operators and maintenance staff, the availability of telephone support at any time from Fette Compacting America in Rockaway, New Jersey, and Fette Compacting in Germany, along with the online faultfinding through a direct, off-site login at the machine,” explains Anderson. “We particularly value their responsiveness. Very few vendors have partnered with Standard Process to provide the fast responsive service like Fette Compacting does.”



# EVERYTHING UNDER CONTROL

The Swiss LeeGroup GmbH has opted for the FEC20 capsule filling machine offered by Fette Compacting. For its numerous capsule products, this new company was on the lookout for a machine which enables a high degree of process control and short conversion times.

“The main difference between the FEC20 and other capsule filling machines is the fact that it permits full control of the production process,” claims Nathanael Lee, Division Manager Production at LeeGroup. His enthusiasm at the technical excellence of this machine is clearly obvious.

In early 2019, Lee ordered an FEC20 from Fette Compacting with the aim of commissioning it as soon as the following fall. Under the Lee-Sport brand name, LeeGroup develops, produces and sells a wide variety of special foodstuffs and nutrition supplements. Whether organic cocoa, linseed oil capsules or baobab fruit powder, the company’s online shop offers nutrition-conscious customers a range of everyday to exotic products.

**Rapid growth**  
The Swiss company currently sells 24 different protein powders in more than 20 flavors via its web shop. These are supplemented by around 70 different preparations in capsule and tablet form. “We introduce new products to our range every month. And the future will see us continuing to extend our range and maintain dynamic development,” adds Lee. This strategy has been a resounding success for the startup to date: since its establishment in 2012, revenue has doubled each year.

A decisive contribution to this rapid growth is made by the company’s capsule products. The range currently includes more than 30 different preparations sold as capsules. Some of them contain classic nutrition supplements such as calcium while others have more unusual ingredients like turmeric or green-lipped mussel. “Our wide range of various products means that we have frequent batch and product changes during capsule

production. As a result, speed is a very important factor,” explains Lee. “The special drive concept displayed by the FEC20 reduces the overall process time without any compromises on quality. Furthermore, machine setup is recipe-controlled which means that production can be recommenced without mechanical intervention.”

**Continued cooperation**  
As for the larger FEC40, the FEC20 enables the process steps associated with capsule filling to be controlled and monitored separately. The assemblies in capsule filling machines are usually controlled by mechanical coupling. The FEC Series, however, uses individually controllable servo and torque motors for each process step. This enables users to individually specify the optimal parameters for each partial step of the filling process which significantly improves the quality of capsules, output per time unit, and safety.



»OUR WIDE RANGE OF VARIOUS PRODUCTS MEANS THAT WE HAVE FREQUENT BATCH AND PRODUCT CHANGES DURING CAPSULE PRODUCTION. AS A RESULT, SPEED IS A VERY IMPORTANT FACTOR.«

Nathanael Lee, Division Manager Production at LeeGroup

In an effort to accelerate conversion of the machine, the FEC20 features a patented removal system for the tamping pin station. And the filling stations can be easily dismantled and cleaned outside the machine. Where additional pre-fitted filling stations are used, the FEC20 is ready for production within an extremely short period of time. This enables manufacturers such as LeeGroup to swiftly change dosing methods, products and batches, and immediately react to market demands.

Apart from the FEC20, LeeGroup does not yet have any other Fette Compacting machines in operation. But that could change very soon. “The technical advantages of the FEC20 and the very good support offered were decisive factors for opting for collaboration with Fette Compacting,” claims Lee. “We hope to continue this cooperation within the framework of other projects.”

**LeeGroup**  
The Swiss LeeGroup GmbH has been developing high-quality foodstuffs under the Lee-Sport brand name since 2012 which the company offers online as powder, capsules, tablets, bars or in the form of dried fruit. Under the motto of “Shape, Health, Performance”, Lee-Sport products are oriented toward health- and figure-conscious customers, sports fans, and the elderly. The organic quality of products has been confirmed by a certificate since 2015 and many preparations are also vegan. The startup has been extremely successful with this concept. As its products are gaining in popularity, storage and production have already been obliged to relocate on two occasions due to a lack of space.



Lee-Sport develops, produces and sells special foodstuffs and nutrition supplements.



# WHAT HAD TO BE SHOWN



Containment Guard is a seven-cycles method that determines the retention performance of a containment system using reproducible measuring techniques.



**In Containment Guard, Fette Compacting has developed a measuring system that reliably predicts the retention performance of a containment system. But does the laboratory data correspond accurately to the values from real tablet production? A comparison with containment measurements taken at a large pharmaceutical concern has provided exciting results.**

"In the beginning they were rather sceptical," said Dr.-Ing. Martin Schöler, Head of Engineering & Design at Fette Compacting. "Until now, pharmaceutical companies simply assumed that we machine manufacturers could not reliably predict the performance of a containment system. We've put an end to these concerns now."

Over the past few years, Schöler and Fette Compacting have developed the Containment Guard, a seven-cycles measuring system that determines the retention performance of containment tableting systems. Containment is a central topic for the pharmaceutical industry: year after year, manufacturers have been processing larger quantities of highly active ingredients like those used in cancer and hormone therapies. Operative protection is ensured through ever-better containment systems.

**Avoid unnecessary costs**

Being able to predict the containment performance of a plant before it starts operating would be truly valuable to pharmaceutical manufacturers: on the one hand the technology is expensive, and on the other hand the containment level of a new plant must be specified at a very early stage. That is not easy, because until now predicting the containment performance was very difficult. Factors such as the ambient surroundings or the operative play too big a part. Until now, it has only been through their own hazard measurements that manufacturers have discovered how much retention performance their new plant really offered. At that stage, however, the plant has already been installed.

Every investment is a high financial risk for the project manager: if a decision is taken to use too much containment, unnecessary costs arise. If the calculation is stricter, but is based on an unreliable assessment of the containment, a plant with inadequate performance may be the result. The machine must be laboriously upgraded if operatives are to be protected after all. Unnecessary costs arise again.





Containment Guard is the solution to this problem. It is with this system that Fette Compacting has developed a risk-based measuring method, in line with the criteria of the International Society for Pharmaceutical Engineering (ISPE), which determines the retention performance of the plant by means of reproducible measuring techniques. In contrast to the standard measurements taken in the past, Containment Guard follows a seven-cycles protocol. The method also takes fault scenarios into account, as well as steps that have in the past been ignored. „It used to be said that measurement data from different plants couldn’t be compared. We have, however, enabled this comparison through holding a large number of parameters constant,“ explained Schöler.

**Practical test passed**

To determine the containment performance, Fette Compacting assembles plants at the Competence Center in Schwarzenbek under laboratory conditions. But how reliable, really, are the values that are measured there? “Until now we could not compare our laboratory values with measurement data from the real world. That meant that we could not be certain whether pharmaceutical companies would come to the same result in their own risk evaluation,” explained Sven Hems, Manager Containment Systems at Fette Compacting.

In order to get clarity, Fette Compacting has been exchanging data for some time with its customers, comparing their data records with Fette Compacting own. The comparison with measurements taken at globally active pharmaceutical companies was a great success.

One company shared the data from measurements taken at the 2090i WiP tablet press, on which highly active ingredients have been processed for some years, with Fette Compacting. Martin Schöler was really pleased by the comparison with the Containment Guard values taken on the same machine constellation: “The data from the pharmaceutical company matched our own measurements extraordinarily well,” he explained. The agreement between the measurements shows that Fette Compacting has a very good understanding of the most important factors influencing containment – much better than is usual in the marketplace. “You could say that Containment Guard passed the practical test with honors,” added Schöler.

»THE AGREEMENT BETWEEN OUR CONTAINMENT GUARD MEASUREMENTS WITH THE VALUES FROM MAJOR PHARMACEUTICAL CONCERNS SHOWS THAT FETTE COMPACTING HAS A VERY GOOD UNDERSTANDING OF THE MOST IMPORTANT FACTORS INFLUENCING CONTAINMENT – MUCH BETTER THAN IS USUAL IN THE MARKETPLACE.«

Dr.-Ing. Martin Schöler, Head of Engineering & Design at Fette Compacting



**Shared knowledge**

Fette Compacting is at present also working together with other famous customers from the pharmaceutical sector in order to put the shared knowledge about good containment on a broad foundation. Hems explained that, “In general we are seeing high levels of interest in exchanging data.” The main reason for this is that the manufacturers themselves also profit from it: “With external data, responsible project managers can check their own measurements. It is also reassuring for them to know that in future they can rely on the machine manufacturer’s measurements.”

In full sympathy with the idea that shared knowledge gives everyone greater security, Fette Compacting will share its assembled containment know-how with the sector. To this end, the solid product specialists have prepared a manual that makes the way in which Containment Guard measurements operate available to the public. This manual explains the details of the seven-cycle measuring technique, and provides a professionally-based insight into the current state of knowledge surrounding the topic of containment. “For us, this is the first step to an entirely new understanding of containment, one that will benefit the whole of the sector,” says Schöler. “Right now we are laying the foundations that in future will earn us even more trust on containment issues.”



# KNOWLEDGE CREATES SECURITY



Sven Hems, Manager Containment Systems  
by Fette Compacting



Dr.-Ing. Martin Schöler, Head of Engineering &  
Design by Fette Compacting

**Mr. Hems, Fette Compacting works closely with customers to match the Containment Guard measurements with the containment performance in real, productive operation. What has been your experience of that?**

Hems: Nothing but good so far. In the course of our cooperative work with pharmaceutical companies, we have noticed a great readiness to exchange data on the containment topic. We have held a lot of productive discussions, and we expect further companies to share their measurement results with us. Everybody in the pharmaceutical world is interested in know-how and in data exchange. For a long time now, pharmaceutical companies have exchanged data in other fields such as tableting, equipment, working processes, and worker safety. Until recently, there simply hadn't been very much about containment that could be shared.

**Dr. Schöler, what knowledge has Fette Compacting gained as a result of the work on Containment Guard and the exchange of data with pharmaceutical companies?**

Schöler: We have been able to confirm our assumption that transfer processes are crucial factors in the retention performance of a client. What this means in practice is that the fewer interfaces there are between the individual process steps, the less active ingredient escapes from the machine. The docking and undocking of containers is always fault-prone, since people are, as in the past, still performing this job manually. And even when no mistakes are made, it is necessarily the case that there is at least some exposure. The more docking and undocking goes on in the course of the process, the more active material is released.

Hems: Something else we learned is that to assess the retention performance properly we have to avoid only fixating on the individual components of a containment plant. It is important to consider the system as a whole. The air management for example – that is to say the control of the supply of air to the entire plant – plays a central part. We therefore look at this factor as we develop our containment installations.

**What benefits do customers reap if they work together with Fette Compacting on the containment topic?**

Schöler: Every bit of new knowledge about containment improves working safety in the long term. And this knowledge grows with every exchange of data. Being able to have one's own measurements reflected as an external partner is very helpful. The principle of two pairs of eyes reinforces the confidence in having measured correctly, and that no surprises are lurking. The majority of companies are, for this reason, very ready to share their data with us.

Hems: From granulation through to the final packaging, pharmaceutical companies have an overview of the entire process, but we have a more detailed insight when it comes to the partial process of tableting. We know all the possibilities and the risks for the containment of a tablet press. That is the reason why we know exactly how we need to measure an installation if we are going to achieve meaningful results.

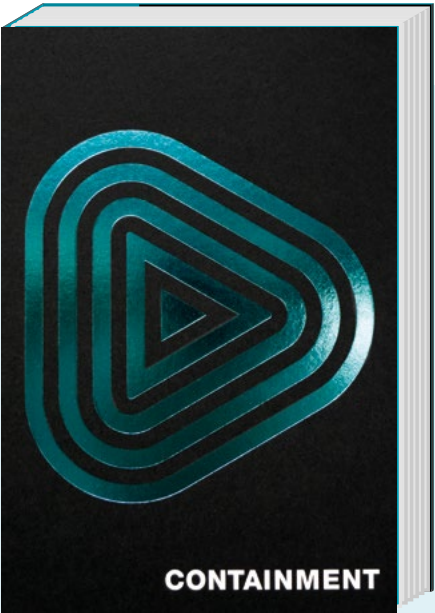
**What is the outlook for Containment Guard going forward?**

Schöler: By developing a standardized measuring method we have significantly extended our understanding of good containment and the underlying processes. We want to share this knowledge with the whole of the industry. That is why we have put together a guideline in our manual about containment, where we have made our method – and the knowledge we have gained so far – transparent and freely available. We see that is the first step to establishing Containment Guard as a standard for the whole sector, and to make our measuring methods public in the service of user protection.

**Containment manual**

In the Containment manual, Dr.-Ing. Martin Schöler from Fette Compacting summarizes his findings from his many years of work on the topic of containment. Given the constant tightening of operator protection requirements in the pharmaceutical industry, manufacturing plants increasingly have to be equipped with containment. This complex topic shares a special connection with mechanical engineering: theoretical knowledge of the physical relationships in the dispersion of substances combines with the ability to test this knowledge in practical trials.

The manual describes the fundamentals and the framework conditions of a systematic measurement procedure and outlines the process for recording a tableting system's relevant statuses. This system allows us to reliably determine a system's retention capacity.



# AVATAR “HELMUT” HELPS



**A significant cost factor in pharmaceutical production is incorrect operation, often caused by a lack of training or well-intentioned but incorrect actions when troubleshooting. Fette Compacting tackles these problems at their root – with the help of new digital tools. An initial training program in virtual reality is already ready for use: the preparation of an isolator for cleaning with avatar “Helmut”.**

“A machine is only as good as the people operating it,” stresses Britta von Selchow, Head of Digital Product Innovation at Fette Compacting. Around half of all errors in pharmaceutical production occur due to inadequately trained personnel. The resulting costs for companies reach up to the high six-figure range every year. Training sessions are therefore essential for efficient and reliable production.

Fette Compacting's newly developed digital instruments specifically target operator know-how. This starts with a virtual reality training offer: employees can practice the cleaning and tooling processes in production under containment conditions based on the example of a virtual isolator. “Customers can repeat the training as often as necessary without risk and other limitations,” explains von Selchow, “until all hand movements are learned and the process flows are internalized. During this period, the capacity of the actual machine remains available for production. The VR application even permits training sessions before a machine is installed.”

Avatar “Helmut” is there to provide assistance if you get stuck in the virtual cleaning training.



Employees clean the isolator in virtual glove ports. A checklist guides employees through the process.



**»IN MY SO FAR 47 YEARS AT FETTE COMPACTING I HAVE ANSWERED COUNTLESS PERSONAL QUESTIONS ON TABLET PRESSES. SO MY COLLEAGUE BRITTA VON SELCHOW ASKED ME IF I WOULD LIKE TO BE AVAILABLE VIRTUALLY AS AN AVATAR.«**  
**HELMUT BOMMROWITZ, MANAGER TECHNOLOGY CENTER AT FETTE COMPACTING**

**Learning with high scores and an avatar**

The virtual training process requires the use of a gaming notebook, VR goggles, and two controllers. The employee slips into the virtual glove ports and learns the cleaning process based on an interactive checklist. The brain perceives these actions as real. To increase the level of immersion even further, the developers even recorded the actual sounds for every activity and integrated these into the program. For instance, the operator hears the typical clicking when they close the glove port in virtual reality. A high score provides additional learning motivation: the highest scores are obtained by employees who remove a particularly high number of product residues at critical points in the isolator.

The test mode is another highlight, where employees can complete a test in the virtual world. Those who master certain tasks receive a certificate.

But employees are not just guided through the process by checklists and illuminated objects. “Helmut” is also there to help with the initial training. The avatar is based on a real person called Helmut Bommrowitz, Manager Technology Center and long-term Fette Compacting employee. “In my so far 47 years at Fette Compacting I have answered countless questions on the tablet presses,” reminisces Bommrowitz with a grin. “So my colleague Britta von Selchow asked me if I would like to be available virtually as an avatar.”

**Digital outlook: troubleshooting with a guide and augmented reality**

In addition to the VR training, Fette Compacting is working on other digital applications that are primarily intended to provide valuable assistance with troubleshooting. For example, this includes a digital step-by-step guide that provides troubleshooting instructions based on the error messages issued by the tablet press. In the event that even this instructed troubleshooting is not successful, in future, users will be able to count on real-time remote support with an augmented reality function. In the next issues of What's Next? we will report on this and other digital solutions from Fette Compacting.



A virtual high-containment tablet press with an isolator in the center that is accurate represented down to the last detail.



Employees practice the process step-by-step until all hand movements are learned and the process flows are internalized.



# TARGETED TRAINING

Since 2017 Fette Compacting has been offering training sessions that address the specific knowledge gaps of employees in pharmaceutical production. A questionnaire initially documents the current level of knowledge in relevant areas of competence. The results are used to prepare tailored training programs for individuals or teams. The case of a medium-sized pharmaceutical manufacturer shows: skill-based training enabled productivity to be increased in a short space of time.

A high-quality tablet press is distinguished by its ability to make precise adjustments. This allows the optimum result to be achieved when manufacturing demanding pharmaceutical products. Well-trained personnel are required to fully exploit this potential. “A Fette Compacting tablet press has over one hundred production parameters. But what good is that if only twenty of these are used effectively?” asks Tim Klingenhof, Head of Training at Fette Compacting.

Getting staff experienced in pharmaceutical production to teach new employees has the benefit that every new person receives individual training as soon as they join the company. But this also bears the risk that, besides the valuable experience, knowledge gaps and misconceptions are also passed on.

Not just for new employees

To support pharmaceutical manufacturers, Fette Compacting offers skill-based training courses, which identify and specifically address these kinds of knowledge gaps that are often passed down from employee to employee. A multiple-choice test initially determines the relevant knowledge in the areas of mechanics, electronics, and operation. The result shows the knowledge gaps that exist for individual employees as well as whether the entire team lacks certain competences.

The questions in the test vary in their degree of difficulty. Particularly easy and general questions should be able to be answered by all, while only a few people in a team need to be familiar with the difficult and specific contents. “What is inconvenient is if no one can answer a question. In this case, it is clear that there is some catching up to do,” explains Klingenhof.

The skill-based training is not just intended for new personnel. It can also be used as supplementary training or as a refresher, where it provides a good opportunity to increase the overall efficiency of production, or to provide specific operational training when switching to a new machine.

»A FETTE COMPACTING TABLET PRESS HAS OVER ONE HUNDRED PRODUCTION PARAMETERS. BUT WHAT GOOD IS THAT IF ONLY TWENTY OF THESE ARE USED EFFECTIVELY?«

TIM KLINGENHOF, HEAD OF TRAINING AT FETTE COMPACTING

Rather than having to work through a complete training course in an area, the multiple-choice test can be used to compile a customized program with the critical contents. This reduces the length of the training and ensures that topics in which people already feel comfortable are not repeated. Another benefit is that employees do not need to spend an unnecessary amount of time out of the production area for the training.

Higher production speed after targeted training sessions

The case of a medium-sized pharmaceutical manufacturer demonstrates the success of the skill-based training approach: the manufacturer recruited several individuals at the same time, who had previously had little experience in the pharmaceutical industry. This quickly led to lower tablet quality, higher product loss, and slower production.

To counter this, the manufacturer decided to provide direct training for the entire workforce. The results of the multiple-choice tests were used to pair up employees depending on the knowledge gaps and language skills. In total, Fette Compacting held seven individually designed tandem training sessions in German and English. This approach had the added benefit that only two people were ever missing from the production area at

any one time. “Measurements confirm that the product quality and product loss were able to be returned to the original values after the skill-based training sessions. What’s more, after the training sessions, the speed of production increased beyond the values recorded before the new appointments,” reports Klingenhof.



The multiple-choice test is the basis of the skill-based training sessions.



**Difficult question:**  
What is the function of parameter 66 “number of punches on the turret”?  
Answer: d) It defines the number of punches bores which are used to calculate the correct machine speed and output of the machine.

**Easy question:**  
What is the function of the cylindrical height adjustment?  
Answer: a) To change the tablet hardness

# THE POWER OF SEGMENTS

A revolution in tablet production: Fette Compacting patented segment technology in 2001. That's where the success story of segments started. Since then the technology has become globally one of the most successful and widespread innovations. It is no longer possible to imagine the production of branded drugs at the big pharmaceutical companies or at the makers of generic drugs without segments. And the success story goes on. Fette Compacting is continuously developing new offers, such as special geometries or materials. It's time to look back – and to take a general look at the latest developments in the segments field.

## Segment technology in numbers

Distribution:

40%

proportion of segments on machines sold globally

40%

increase in output (max.)

Performance:

50%

reduction of product loss (max.)

100%

dimensional accuracy compared to dies

300%

increase in service life through the use of carbide bushes

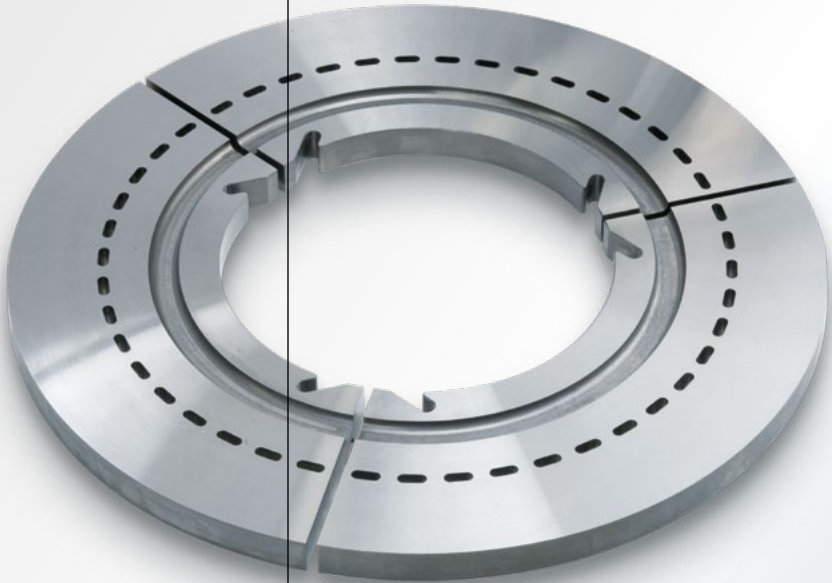
Time-saving:

80%

time saving for refitting

88%

reduction in manual operations for refitting

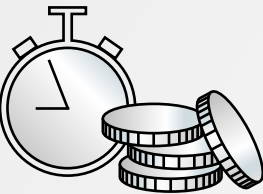


## The advantages of segment technology



### The clever way to higher output

Dies with multtip punches have long been one of the most important ways to increase output. Suddenly, another lever for an increase of up to 40 percent output appeared: segment technology. The trick was that the holes are made directly in the segments. This means that significantly more tablet stations can be integrated into a segment turret of the same size. Loss of product is also reduced, while production safety rises. There is no difficulty if the punches used before with dies continue in use with segments.



### Time is money

The segments replace both the conventional die table as well as the dies. But, in contrast to die tables, only two fastening bolts now have to be undone for a changeover. The refitting is also done with just a few manual operations, while production parameters and filling behavior remain unchanged. Cleaning is something else that is faster. As compared with the use of multtip punch, there is also no need for additional downtimes – such as the manual operations needed for exact alignment of the dies.

## Innovations in segment technology

### Segments for special geometries

Tablets that can be pressed particularly efficiently are usually round and flat, or are slightly convex. This allows for easy filling, dosing, pressing and for optimum yields. But special shapes for the tablet design are popular, and are often chosen for marketing reasons: They give tablets a unique feature and a recognition value. For some active materials, the dosing also affects the shape. Domed or spherical shapes are necessary if, for example, the tablets are to be coated. Over the years, Fette Compacting has also converted a large number of special geometries to segment technology, and has risen to the challenge of rising demand.

### Segments for special materials

Special materials are sometimes needed for pressing, depending on the nature of the powder and the granulate, particularly when abrasive or adhesive components are included. Fette Compacting has developed carbide inserts for segments for just such requirements. This lets users reduce abrasive wear and ensure optimum tablet quality. The service life of the segments is tripled through minimizing ring formation and erosion of the walls.

### TRI.EASY-Tool Box System for segments

Segments are compact components that can be handled securely, easily and quickly. The TRI.EASY-segment boxes here provide additional security for these valuable tools. The boxes offer a secure, easier method of storage for all sizes of segment, and, having a maximum weight of 15 kg, can be lifted easily. A plug-in system allows any size of segment to be used in just one box system. And there are also box systems for punches and dies.



### Innovation as a continuous process

As the inventor of segment technology, Fette Compacting has the highest level of experience with the system. Ongoing development and extension ensure that segments will also contribute to modern, efficient tablet production in the future.



# THE DOUBLE-LAYER WONDER



The user guidance of modern tablet presses is designed to be highly intuitive. In this connection, the TRI.EASY concept from Fette Compacting ensures an optimum combination of performance and simple operation. It therefore enables efficient tabletting. This means that the user does not need to have detailed familiarity with the complex underlying pressing process. This is crucially affected by large numbers of parameters and machine settings. The Performance Consultants at Fette Compacting are usually brought in when the process is not running optimally. They have succeeded in raising the output in the production of a double-layer tablet by 180 percent.

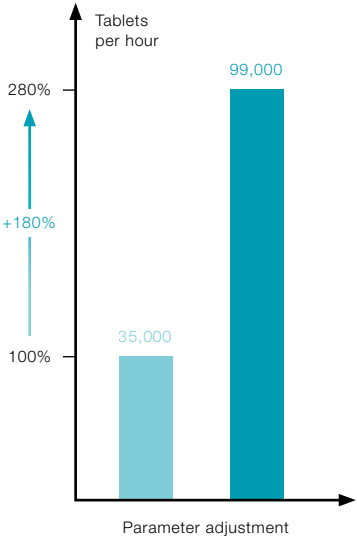
Jochen Gäth, Performance Consultant at Fette Compacting, remembers his last customer visit in Africa: “Actually I was only there to optimize the production of an anti-malaria product on a new FE75 tablet press.” But since he was in any case already on site, the Performance Consultant also took on the optimization of another machine. In the process of modernizing the production facility, the customer wanted to transfer the manufacture of a double-layer tablet to the FE75. It was therefore only logical to take a look at the existing parameters and settings.

**Special features of double-layer tablets**  
Double-layer tablets are most often used when two active ingredients cannot be brought together in one mixture. This can be the case, for example, if the actual medication should have a stomach-protecting agent added, or when a delayed release of active ingredient is needed. The machine was fitted out in

advance for this purpose, using two filling stations for the double-layer production. In addition, the first part of the tablet has received initial pressing before it is combined with the second component to make a sturdy double-layer tablet.

**A question of timing**  
“The timing and the control rate of the pressing force are central control parameters that affect the properties of the tablet and of the entire process at various locations,” explains Gäth. In the case of the double-layer tablet, a whole range of settings were less than optimum on the original machine (3090i). “It started with the outlet deflector delay which was set to a very high figure of ten seconds. It went on with the lead time of the Fill-O-Matic, which was five seconds, and a run-on time of ten seconds, which are not required for normal applications. The control lag was also not properly chosen. This can be used to set when the machine attempts to adjust to achieve the optimum pressing force,” continues Gäth.

All the values were first set to zero in order to find out which parameters were not optimum. It became clear that the control lag above all was critical for the process flow. The machine had made adjustments too soon and they were too much. An adjustment to the delay is often a central lever for optimizing a machine. After changing to a control lag of ten seconds, the process ran smoothly. The parameter adjustment alone achieved an increase of 17 percent in the output (from 35,000 to 41,000 tablets per hour).



Jochen Gäth, Performance Consultant at Fette Compacting

**From 35,000 to 99,000 tablets each hour**  
The experience gained on the 3090i provided a good basis for optimizing the process again on the FE75. The filling unit is responsible for filling the segment holes, and it was changing this that made the crucial difference. Gäth suggested that the filling cone system, available particularly on the FE Series, should be used. Depending on the tablet size, the flow rate of the material and the production speed, this brings about better filling properties, and has proven itself particularly useful for large tablets.

In this way it was possible to increase the output from 35,000 tablets per hour to 99,000 tablets per hour, without losing any quality. Gäth's summary of potential optimization was that, “A 180 percent increase in output is nothing rare. The fact is that if appropriate parameters or settings are not optimum, this often has fundamental effects.”

Tablet presses from Fette Compacting are aimed precisely at the needs of modern medication production, and offer the highest possible reliability and performance. The potential can be increased even further with the help of Performance Consultants. Their expertise provides more efficient production, increases the value creation, and allows the processes to be optimized continuously.



In the three-chamber Fill-O-Matic the product does not flow directly into the dies, but is moved through the chambers.

NEWS

Welcome to the first  
Pharmaceutical Circle!

WHAT'S  
NEXT?

AGILE PHARMACEUTICAL  
PRODUCTION  
From Vision to Action

The pharmaceutical industry is faced with major changes: a rapidly growing demand for medication, increasing regulatory requirements, advances in technology, such as continuous manufacturing, and much, much more. Times like these demand agile, forward-looking concepts and actions. What this specifically means will be discussed by renowned experts at the first “Pharmaceutical Circle” at Fette Compacting in Schwarzenbek. This novel event format offers the opportunity for a practical exchange of ideas and experiences with representatives from the world of pharmacy as well as other industries.

IS DATA THE NEW MEDICINE?

WHAT CAN THE PHARMACEUTICAL INDUSTRY LEARN  
FROM OTHER SECTORS?

WHAT ROLE DOES ORAL SOLID DOSAGE (OSD) PLAY  
IN A FUTURE OF PERSONALIZED MEDICINE?

1st Pharmaceutical Circle  
September 4 – 5, 2019  
Schwarzenbek/Hamburg

We will report on the results of the Pharmaceutical Circle.



Anniversary:  
15 years in Nanjing



In May 2019, Fette Compacting China threw open its doors: Experts from the international world of pharmacy met at the Customer Center to celebrate the location’s 15th anniversary in the metropolis of Nanjing. A highlight of the anniversary celebrations was the technology workshop at the new Competence Center, during which guests discussed new technologies and trends in pharmaceutical production.

Fette Compacting has been producing tablet presses in Nanjing and offering training since 2004. Besides the anniversary, the location also celebrated the delivery of the 700th locally produced tablet press. Dr. Andreas Risch, Managing Director of Fette Compacting China, highlighted the location’s continuous success: “The past 15 years have been an extraordinary story of economic growth as well as our coming and growing together as people.”

Award-winning  
responsibility



An opportunity to exchange ideas and show appreciation: for the past five years, the European Union Chamber of Commerce in China has handed out several awards to European companies operating in China every year. The non-profit organization issues the awards to acknowledge entrepreneurial commitment in the area of corporate social responsibility (CSR). The award ceremony is a chance to present CSR success stories, highlight trends and social practices in the industries and raise awareness of holistic sustainability.

Around one hundred representatives of companies, NGOs, social organizations, governments, media, and schools attended the most recent award ceremony at the Intercontinental Hotel in Nanjing. Fette Compacting China was amongst the companies to receive an award, winning the “MNC – Employee Development Award”. The award acknowledges the multinational company’s commitment to employee development.

FEC40 in South America



The largest international product and service providers in the production segment in the pharmaceutical industry came together at the pharmaceutical industry’s international exhibition FCE Pharma São Paulo, held between May 21 and 23, 2019. The FCE Pharma, with over 16,000 visitors, is the only event of this magnitude in South America. Every year, the exhibition is used to present trends and innovations in the areas related to the production chain, such as machinery, equipment, packaging, quality control, service, and digitalization.

This year, Fette Compacting America Latina (FCAL) presented the FEC40 capsule filling machine to the South American market. The FEC40 is ideal for large output quantities of up to 400,000 capsules per hour. Edilson Viola, Managing Director of FCAL, recognizes the value of the event and concludes: “The trade fair gave us the opportunity to get closer to the customer. In the three days, we had a vibrant exchange of information, insights, and experiences with many visitors.”



**Volker Reinsch**, Director Corporate Marketing  
& Communication, Schwarzenbek, Germany,  
**Jian Sun**, Senior Regional Sales Manager,  
Fette Compacting (China)

A perfectly normal

# business call

at Fette Compacting

To focus on a task completely while remaining open-minded and retaining a good sense of humor is not just possible – it is necessary to achieve efficiency and innovation. And at Fette Compacting, it is perfectly normal. Only by doing so can we achieve top performance. **More about us at [www.fette-compacting.com/careers](http://www.fette-compacting.com/careers)**



**FETTE  
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be efficient

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