



Total pharma dedusting filter systems



PURE TRUST For your safe and reliable operations.



Intended use and description



ECR-10-1 (with Bag-in/Bag-out on filter ports)

The dedusting filter systems ('dust collectors') of the ECR series are the pinnacle of our decades of experience in the field of dedusting and filtration. They are designed for the filtration of process air or other gasses, predominantly in the pharmaceutical solid dosage manufacturing process (fluidized bed coating, tablet compression, drum coating, etc.) and similarly demanding processes with the formation of challenging dust in the chemical industry.

There are several areas where our ECR dust collectors excel that make them the first choice of users when it comes to selecting dust collection filter systems for processes with the most demanding operating parameters. These areas are:

- Containment
- Explosion safety
- ROTATRONIC Smart filter cleaning technology
- Efficient filtration

Containment

The ECR dust collectors have been developed from the ground up to meet the containment requirements of the pharmaceutical and chemical industries. They can cover a wide range of containment requirements during dust discharge (emptying the dust container) and filter element replacement. There are several solutions for each of these processes, from the highest performance to the most economical.

ECR dust collectors are today the prime example of products where state-of-the-art containment solutions meet ergonomic requirements. During the development process, we have implemented many ideas that came directly from end users – people who work with dust collectors every day in the production process. This was the most reliable way to perfect the design down to the smallest detail to ensure the best possible user experience even with the highest HSE requirements.



ECR-10-5 (connected to the central dust collection system)



Explosion detection sensor on ECR dust collector

R TATRONIC Smart filter

cleaning technology

Explosion safety

The second area in which ECR dust collectors excel is their inherent explosion protection. They can handle most potentially explosive media (dry dust or hybrid mixtures) without the need for an external autonomous explosion protection system. They offer the highest filtration efficiency and built-in explosion protection in a compact volume. All implemented explosion protection solutions have been extensively tested under the most vigorous conditions.

ROTATRONIC - Smart filter cleaning technology

The integral parts of the ROTATRONIC System are the ROTATRONIC Mechanics and the ROTATRONIC Control. Together, they guarantee efficient and optimized cleaning of the filter elements and a long service life of the ECR dust collectors.

The rotating cleaning nozzles of ROTATRONIC Mechanics ensure efficient cleaning of the filter media from very close distances, while the ROTATRONIC Control has two important functions. Firstly, it controls and optimizes the filter cleaning process, and secondly, it also functions as a central node to which all installed accessories and peripheral equipment are connected, allowing the user to monitor and control all aspects of the filtration process locally or remotely.

Efficient filtration

The last area that illustrates the advantages of ECR dedusting filter systems is their filtration efficiency. It is not only the high filtration grade that determines the efficiency, but there are other factors that are equally important. Combining the optimum filter medium with the other physical properties of ECR filter elements, such as optimal pleat geometry, compact design, large surface area, excellent cleanability, and inherent explosion protection, results in efficient and costeffective filtration.

With our extensive knowledge, we will always support you in the selection of filter media tailored to the application, regardless of its challenges.



FCR-10-4 (with individual dust containers and **ROTATRONIC Control electrical cabinet)**





Containment

One of the most important features of the ECR dedusting filter systems is their ability to be adapted to various containment-related requirements. In the pharmaceutical industry in particular, the toxicological effects and side effects of active substances are well known, and it was there where precise limit values for permissible emissions (OEL - Occupational Exposure Limit) in operational plant areas were defined for the first time. But also, in other branches of industry, such as the chemical industry, biotechnology, and other sectors, the awareness of occupational hygiene has increasingly gained ground.



The toxicological risks of exposure to compounds and substances can be illustrated using the pyramid diagram on the left. As permissible OEL values decrease, the solutions that provide an appropriate level of containment are becoming increasingly complex. Especially when the requirements approach the range of 10 μ g/m³ and below, it is technically very difficult to design a containment solution. At TRM Filter, we have taken up this challenge and developed an ECR dedusting filter system that reliably protects operators and keeps emissions consistently below these limits.

To validate the containment performance of ECR systems, we decided to obtain measurable, quantitative data for the containment solutions developed. We simulated the typical operating conditions during filter element replacement and dust extraction, and the third party performed APCPPE* tests (formerly known as 'SMEPAC') from ISPE's Good Practice Guide (GPG).

* Assessing the Particulate Containment Performance of Pharmaceutical Equipment



The results confirmed that our solutions provide a safe work environment for the end user (see below for more detailed information). But also, from an investor's perspective, ECR dedusting filter systems certainly have advantages. Often, to be on the safe side when handling substances in OEB 5 (Occupational Exposure Band), it is necessary to use cumbersome and expensive solutions (such as glovebox isolators). With ECR systems, additional protective layers are not necessary in most cases, but they can always be added if the requirement arises.

The strictest requirements for the containment, where the permissible emissions are almost unimaginably low, can only be achieved by focusing on the smallest details. To secure continuous operation of the dust collection system, regular emptying of the dust container and occasional replacement of the filter elements is necessary. To reduce the exposure time of operators and service personnel and to ensure that both activities are carried out safely, the containment provisions must be **intuitive** and **user-friendly**.

To ensure this, we have decided to listen to our customers and, as mentioned above, we have made many innovative improvements to the known principles and raised them to a higher level. The result is the best user experience when working with containment provisions that ensure health and safety in the workplace for the daily users of our ECR dedusting filter systems.



Primary filter replacement with protective bag

Filter replacement

This activity is less frequent, but more complex when containment must be considered. There are standard principles on the market, however, with our optimized design there are many advantages:

• Bag/in-Bag/out (BiBo)

The unique design of the BiBo sealing port eliminates the need to use any straps to secure the sealing o-rings. The filter replacement through protective bags on TRM Filter's dust collectors is faster and more intuitive than on any other on the market.

APCPPE measurements (from ISPE's GPG) have shown that the average emissions during filter replacement on the ECR system, using all prescribed procedures, are below $0.9 \ \mu g/m^3$.

• WIP (Wash In Place)

Washing the raw gas side surfaces and the filter itself before removing it from the dust collector provides the highest containment levels, as the light suspended particles in the air are wetted and immobilized. The geometry of the ECR ensures that only a few internal surfaces come into contact with the washing medium. This reduces the amount of wastewater and enables shorter drying times.

With washing process before filter replacement, emissions reach values of $0.3 \ \mu g/m^3$ and below.



ECR-10-1 (with continuous liner for safe dust extraction)

Dust discharge

This process is carried out regularly and must therefore be optimized to efficiently reduce the exposure of the person performing this activity. We offer several different solutions to ensure the safe handling of the to-be-disposed-of dust. The technical complexity of the options listed below is increasing, as is the degree of containment that can be achieved by an individual solution:

- dust container with bag,
- dust container with bag and lid,
- dust container with Bag-in/Bag-out and
- continuous liner (with optional glovebox).

The safest and most ergonomic solution is the integration of the central dust collection system (CDC), where the dust collected in the hopper is transported into the large-volume dust container. APCPPE measurements have shown that emission levels can be reduced to $0.5 \ \mu g/m^3$ when the CDC is combined with the continuous liner at the dust discharge.

Regardless of the knowledge about the toxicological effects of the substances in the process air, it is always advisable to have a coordinated approach when planning the process with integrated dedusting filters and containment requirements. This includes the entire circle of participants: operators, HSE specialists, engineering partners, equipment and dedusting filter suppliers.

With our knowledge, experience, and testing capabilities, we at TRM Filter can always offer strong support in this very important process.

BENEFITS

- Safe working environment for operators
- Reduced time of the exposure during dust discharge and filter replacement
- Shorter down times due to intuitive solutions

Explosion safety

Handling combustible dust often involves the risk of explosion, and dust collectors are not an exclusion. On the contrary, small particle sizes, especially in conjunction with flammable gases or vapors, actually increase it. Unfortunately, numerous historical events will confirm this.

For this reason, appropriate safety measures for dust collectors should be taken to reduce the risk of explosion and to ensure continuity of operation throughout the lifetime of the equipment. Based on the principles of explosion protection, ignition sources must be excluded from the process if the presence of a potentially explosive atmosphere cannot be controlled.

It is often not possible to ensure reliable safety by this approach only. In these cases, an additional constructional protection measure must be applied. There are many explosion protection solutions on the market, and most of them are so-called 'autonomous systems' appended to a dust collector, such as explosion suppression or venting. These systems can have various disadvantages, such as additional space requirements for installation, as well as requirements for the positioning of a dust collector, such as proximity to the outside wall or roof, etc. Especially in the case of explosion venting, there is also an additional health risk, as hazardous substances are ejected from the system in the event of an explosion. This is particularly relevant if very toxic materials or highly effective active pharmaceutical ingredients (HPAPIs) are used. All this imposes unwanted compromises during the design phase and can also have notable financial implications.

We at TRM Filter have decided to use our experience and knowledge to overcome these limitations of conventional dust collectors and have developed ECR dedusting filter systems with inherent explosion protection. This innovative design has enabled us to achieve the following benefits:

- Explosion protection with zero emissions of hazardous substances to the external environment,
- Compact size of the ECR unit without any influence on the filtration performance,
- Seamless integration of the explosion protection into the design, with minimal additional maintenance.

The implemented solution is designed according to state-of-the-art principles and allows the use of ECR with a wide range of materials and under process conditions as expected in the pharmaceutical and chemical industries. Furthermore, the design of the ECR and its safety fully comply with all relevant EU legislation, including the Machinery Directive (2006/42/EC) and ATEX Directive (2014/34/EU), as well as international standards and codes.

To validate and prove that the ECR dust collectors meet the strictest explosion safety requirements, we have subjected them to "live" explosion tests. Many tests were carried out at the **FSA** test site in Germany, using the knowledge and experience of this renowned notified body. With these tests we have shown that the ECR dust collector can be operated safely with:

- Dry organic or metallic combustible dust with Pmax ≤ 10 bar and K-value ≤ 640 bar·m/s,
- Hybrid mixtures with Pmax ≤ 10 bar and K-value ≤ 505 bar·m/s.

These Pmax and K values make the ECR safe for operation in most chemical, pharmaceutical, and other industrial environments. With the tests, we have also confirmed that the ECR's own butterfly inlet valve can be used for explosion isolation purpose in majority of applications. However, alternative explosion isolation systems such as quick-acting or floating valves can still be used with ECR if required by the customer, or due to demanding process conditions.



ECR unit during explosion tests at the FSA site in Germany



The heart of the inherent explosion protection: primary filter element of the ECR dedusting filter system – filter element and flame barrier in one unit.

BENEFITS

- Production plant designing process is simplified with ECR dust collectors
- Robust safety when used with dry organic and metallic dusts and hybrid mixtures
- Seamless integration of the explosion protection, with minimal additional maintenance

Inherent explosion protection - working principle

As already mentioned, the ECR dust collector is designed for operation without its own ignition sources. The probability of an explosion is therefore very low but cannot be completely excluded due to process-related ignition sources. These include electrostatic discharges, entrance of foreign bodies, exothermic decomposition of materials, and many others which cannot be controlled by TRM Filter.

Therefore, should an explosion occur, the ECR will protect personnel and prevent damage to property by applying the principles of inherent explosion protection. The principle of inherent explosion protection is effective in the next sequence (see also the pictures at the bottom of the page):



Ignition of dust or hybrid mixture occurs on the "raw gas" side of the ECR.

The pressure and temperature increase in the "raw gas" volume due to combustion. A specially designed geometry of the "raw gas" side ensures that only a limited overpressure can be achieved, which is significantly below the burst pressure of the dust collector housing. To prevent spreading of explosion to an upstream equipment, dust collector is isolated by means of an inlet butterfly valve or an autonomous explosion isolation system, where this is required based on application. Since the inlet valve or an explosion isolation system is closed, the explosion overpressure is vented through the primary filter element to the "clean gas side." Due to the special design of the filter element, the element acts as a flame barrier, quenching the flame completely. Thus, no flames reach the "clean gas side" and the downstream direction is completely protected against ignition and a subsequent explosion.

ROTATRONIC – Smart filter cleaning technology ROTATRONIC Control





Graphical user interface of the standard ROTATRONIC Control (the user interface of the ROTATRONIC Control LT offers an alphanumeric display)

SIMPLICITY

The intuitive ROTATRONIC user interface ensures the best overview of the operating parameters and the history log.

EFFICIENCY

Lower total cost of ownership through longer filter element life, lower energy consumption, less maintenance, and waste.

VERSATILITY

Thanks to numerous options, the ROTATRONIC Control can be connected to various central control systems (SCADA, BMS, etc.).

Total cost of ownership is an important factor in the selection of a dust collection system. To reduce the cost of replacing filter cartridges, it is essential to use dust collectors with integrated filter cleaning systems (using compressed air). They extend the life of the filter and prevent dust migration into the deeper layers of the filter media, thus maintaining pleat stability at its best performance.

Since many factors influence the optimal cleaning performance, we have developed the ROTATRONIC cleaning system. Its integral part is ROTATRONIC Control, a smart filter cleaning technology based on 6-sigma process optimization. The clogging tendency of the filter media and the development of the differential pressure across the filter cartridges are constantly monitored during the dust removal process. The setpoint is continuously adjusted and the filter media are always cleaned at the ideal level. Their behavior, including their ageing, becomes predictable.

In addition to optimizing the cleaning process, the ROTATRONIC Control also functions as a central node to which all installed accessories and peripheral equipment are connected. Monitoring and control of all aspects of the filtration process is made possible by a userfriendly graphic interface (touch screen), on which the essential parameters can also be displayed in diagram form. The ROTATRONIC Control offers numerous upgrade and connection options:

- A connection to the control systems of an individual production process or to the central system of a company (SCADA, BMS).
- The connection of additional sensors for monitoring and recording the following parameters: Emissions at the outlet of a filter, humidity, temperature, and airflow.
- A remote start option allows connection to other devices in the process.

ROTATRONIC – Smart filter cleaning technology ROTATRONIC Mechanics



The performance of dust collectors can be measured with different parameters. One of these is certainly cost efficiency, which is significantly influenced by the frequency of required filter replacements and the associated costs, i.e., downtime, logistics, labor, consumables, and waste management.

Several factors influence the service life of filter elements, from dust properties (variation in particle size, moisture, and adhesion properties of the dust, etc.) to the type of filter media and the design of the filter elements. However, the key factor is the efficiency of the filter cleaning process.

In addition to the innovative ROTATRONIC Control, we have also developed unique ROTATRONIC Mechanics which includes special rotating cleaning nozzles and the lifting mechanism.

The nozzles rotate during the filter cleaning process and are guided close to the clean air surface of the pleated filter element. In doing so, they direct compressed air over a short distance onto the filter medium. This enhances the cleaning effect of the compressed air and enables uniform and stable operation at reduced air pressure. The shape of the special cleaning nozzles in ECR dust collectors has been carefully designed to minimize internal pressure loss, ensure effective cleaning of the filter cartridge over its entire surface, and reduce the load on the filter medium.

During the filter cleaning process, the airflow through the ECR deducting filter system is stopped by the pneumatically-driven flap at the inlet. This maximizes the cleaning efficiency of the ROTATRONIC Mechanics system.

COST OPTIMIZATION

Superb cleaning performance of the ROTATRONIC Mechanics has a beneficial impact on various costs and procedures associated with the replacement of filter element.

REDUCED EXPOSURE

The less frequent filter replacement brings with it perhaps the most important advantage of the ROTATRONIC System, namely the reduced exposure time of service personnel. Both the ROTATRONIC Mechanics and the ROTATRONIC Control are among our main distinguishing features compared to the alternatives on the market.



Efficient filtration

The purpose of any dust filtration is to reduce the concentration of airborne particles in the process air. The result must be efficient filtration, but in industry the economic aspect is also important. The pressure drop across the filter media should be as low as possible and the time between filter replacements should not be too short. The level of pressure drop depends on the surface area and physical properties of the filter media. The service life of the filter element, in contrast, depends primarily on the process characteristics, dust load and dust properties (dry, moist, sticky, etc.). An important factor is also the ability of the filter to be efficiently cleaned and (at least for the most part) regenerated. To achieve this, the best filter media must be selected.

The electron microscope image below on the left shows a base polyester material that is often used in dust collectors. The filtration efficiency is achieved by material that is deposited on the surface and forms a so-called "cake layer." However, particles below a certain size penetrate deep into the filter medium and are retained there. Cleaning these types of filters with compressed air is a challenge.



Base filter media (100% polyester)



Polyester filter media with ePTFE membrane



One of the test benches for filter media validation

One of the best methods to prevent particles from penetrating deeply into the filter material is to laminate the base filter media with a special membrane made of expanded PTFE (ePTFE). The picture below on the right shows at the same magnification how extremely fine the structure of the filter surface is. The efficiency of cleaning with compressed air is considerably improved with this type of filter media.

Primary filter elements installed in ECR dedusting filter systems combine many advantages:

- Large surface area and high air throughput in a compact design,
- Filter media are typically laminated with ePTFE membranes,
- Their filtration efficiency can reach up to HEPA **H13** (**ISO 35 H** according to ISO 29463),
- Excellent cleanability in combination with our ROTATRONIC System.

There is another very important aspect of ECR primary filter elements! One of our goals in developing a "Total Pharma" dust collector was the inherent explosion protection of ECR dust collectors. Through a combination of design and specially developed filter media, the primary filter elements can act as an effective flame barrier in the unlikely event of an explosion. This unique combination is the cornerstone of ECR's multi-talented character.

Configurations

For your convenience, we have prepared five series of ECR dedusting filter systems with predefined configurations. However, there is a wide range of functionalities and options that can be added to each of them. The most important ones are listed in the table on the next page.

ECR Maximo

The ECR Maximo is designed for the dedusting of extremely hazardous HPAPIs (OEB ≥5). It is equipped with highly efficient containment provisions for dust extraction and filter replacement. To achieve the required degree of protection, the filtered dust is collected in the hopper and discharged into the continuous liner which is located in a flexible glove box, from which it is removed through a Bag-in/Bag-out port. The dust collected on the primary and secondary filter elements is also contained with Bag-in/Bag-out provisions.

ECR Optimo

ECR Optimo for the dedusting of highly hazardous dusts (OEB 4 & OEB 5) are intended to prevent carry-over from batch to batch. In the typical configuration of the ECR Optimo, dust is discharged into the continuous liner, while filter replacement is performed via the Bag-in/Bag-out port. Both solutions provide an excellent containment barrier.

ECR Practico

Containment solutions integrated in ECR Practico enable the processing of hazardous dusts (OEB 3) that may occur in closed intermediates handling processes in the pharmaceutical industry. The Bagin/Bag-out principle is used as standard for dust extraction and filter replacement. Unlike ECR Maximo and Optimo, ECR Practico is not equipped with filter integrity test ports by default.

ECR Novento

ECR Novento can be used for the dedusting of intermediates in open systems where dust poses medium health risk (OEB <3). The dust extraction system consists of the dust container with the bag with lid, while the primary and secondary filter elements are replaced via the Bag-in/ Bag-out port.

ECR Enduro

ECR Enduro is designed for applications where containment is not required. However, its cost-effective configuration offers the same unsurpassed filtration efficiency and user-friendly solutions as the other types in the ECR portfolio. If required, it can be configured to meet more demanding application requirements.

Continuous operation (on-line cleaning)

ECR dedusting filter systems operate fully continuously if at least two units are installed. In this case all filters work simultaneously most of the time. During the cleaning phase, however, one filtration chamber is taken off-line (closed inlet), while the other chambers work undisturbed. This principle is known as **on-line cleaning** and enables continuous operation of the dedusting process.

Options

	Enduro	Novento	Practico	Optimo	Maximo	
OEB Target Level	None	up to 3	3	4/5	≥5	
HOUSING MATERIAL						
Powder coated steel						
Stainless steel AISI 304	0	0	0	0		
Stainless steel AISI 316	0	0	0	0	0	
SURFACE FINISH*						
Sand blasted, pickled, and passivated	0	0	0	0	0	
Fine brushed Ra = 1, pickled, and passivated	0	0	0	0		
Polished Ra = 0.4 and passivated			0	0	0	
FILTER REPLACEMENT TECHNIQUES						
Open access						
Bag-in/Bag-out exchange	0					
WIP (primary filter - upstream)				0		
WIP (secondary filter - upstream)				0	0	
WIP (secondary filter - downstream)				0	0	
Dust hin with standard bag 50 l						
Bag with lid 50 l	0					
Safe change hag 25 l	0	0				
Continuous liner 25 l	0	0	0			
Central dust collection with pneumatic transport	0	0	0	0	0	
Manual butterfly	0			U		
Pherimatic butterfly	0	0	0			
Manual lifting /closing mechanism	•					
Phandal miting/closing mechanism	0	0	0			
Elevible glovebox isolator	•	U		0		
Pigid glovebox isolator				0	0	
WIP provision for glovebox				0	0	
				U		
	-				-	
$Z = St 2 \otimes MIE < Z = I$						
A - Hybrid mixturo	0	0	0	0	0	
	0	0	0	0	0	
Up to 110%						
	0	0	0	0	0	
Drogoss control interface	0		-		-	
Airflow control	0	0				
Airriow control	0	0	0	0	0	
CMD design	0	0	0	0	0	
GMP design	0		0		0	
	0	0	0			
Primary filter sealing test	0		<u>^</u>			
Secondary filter earling test	0	0	0			
			_		_	
	0	0				

Standard equipment

O Optional equipment

* Marked surface finishes refer to external surfaces. Interior surfaces are to be defined according to the respective application.

Configurational overview

OFF-LINE filter cleaning

AIRFLOW (up to) m ³ /h	2,000	4,000	6,000	8,000	10,000	12,000	14,000
Type ECR-10	ECR-10-1	ECR-10-2	ECR-10-3	ECR-10-4	ECR-10-5	ECR-10-6	ECR-10-7
Type ECR-20	-	ECR-20-1	-	ECR-20-2	-	ECR-20-3	-
	16,000	18,000	20,000	22,000	24,000	26,000	28,000
	ECR-10-8	ECR-10-9	ECR-10-10	ECR-10-11	ECR-10-12	ECR-10-13	-
	ECR-20-4	-	ECR-20-5	-	ECR-20-6	-	ECR-20-7

ON-LINE filter cleaning

AIRFLOW (up to) m ³ /h	2,000	4,000	6,000	8,000	10,000	12,000	14,000
Type ECR-10	ECR-10-2	ECR-10-3	ECR-10-4	ECR-10-5	ECR-10-6	ECR-10-7	ECR-10-8
Type ECR-20	-	ECR-20-2	-	ECR-20-3	-	ECR-20-4	-

16,000	18,000	20,000	22,000	24,000	26,000	28,000
ECR-10-9	ECR-10-10	ECR-10-11	ECR-10-12	ECR-10-13	ECR-10-14	-
ECR-20-5	-	ECR-20-6	-	ECR-20-7	-	ECR-20-8







ECR-10-2

ECR-10-5

ECR-10-8

Technical characteristics

	ECR-10	ECR-20	
Airflow	2,000 m³/h	4,000 m³/h	
No. of filter elements	1+1	1+1	
Primary filter type	ROTATRONIC cartridge	ROTATRONIC cartridge	
Filter area	15 m²	30 m²	
Primary filter efficiency	up to H13	up to H13	
Secondary filter type	filter cassette	filter cassette	
Secondary filter efficiency	H13/H14	H13/H14	
Unit height*	2,525 mm	2,885 mm	
Unit width*	840 mm	1,040 mm	
Unit depth*	840 mm	1,040 mm	
Unit mass*	550 kg	750 kg	
Inlet size (from back)	DN 200	DN 250	
Outlet size (standard position from back)	DN 200	DN 250	
Dust bin volume	50 L	50 L	
Process temperature	-10 / +40 °C	-10 / +40 °C	
Compressed air consumption	15 NL/h @ 1 cycle/h	30 NL/h @ 1 cycle/h	
Filter cleaning system	ROTATRONIC Mechanics ROTATRONIC Mech		
Compressed air pressure	6 bar	6 bar	

* Dimensions and mass are valid for the Novento configuration.





TRM Filter d.o.o. Litijska cesta 261 SI-1261 Ljubljana Dobrunje Slovenia

T +386 1 527 22 10 sales@trm-filter.com

www.trm-filter.com

TRM Filter provides trusted and reliable solutions to all aspects of pharmaceutical dedusting.

Our solutions are implemented by leading pharmaceutical companies.

ECR Total pharma dedusting filter systems ensure ultimate safety in process dedusting against explosions and for risk-based occupational hygiene.