



TFP

Pharmaceutical clean room terminal filters

TROX GmbH
Heinrich-Trox-Platz
47504 Neukirchen-Vluyn, Germany
Germany
Phone: +49 (0) 2845 2020
Fax: +49 (0) 2845 202265
E-mail: trox@trox.de
Internet: <http://www.trox-technik.com>

Product overview

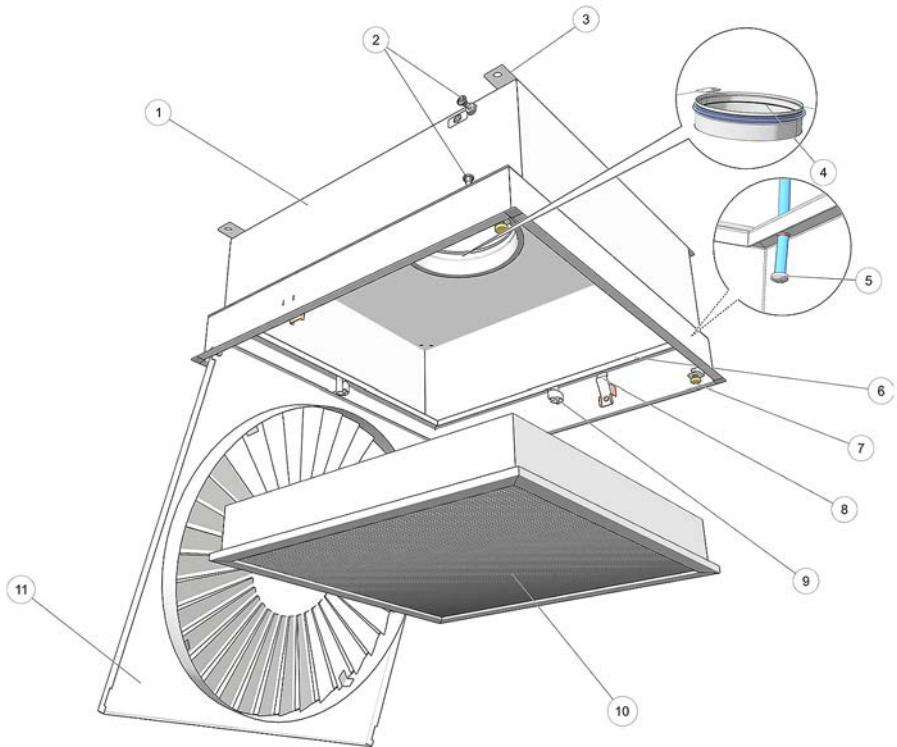


Fig. 1: Schematic illustration, e. g. TFP-TC-S

- | | | | |
|---|--------------------------------------------|---|-----------------|
| ① | Casing | ⑦ | Magnet (x2) |
| ② | Differential pressure measuring point (x2) | ⑧ | Springs (x2) |
| ③ | Suspension (x4) | ⑨ | Turn clip® (x4) |
| ④ | Spigot with lip seal | ⑩ | Filter |
| ⑤ | Internal measuring tube | ⑪ | Diffuser face |
| ⑥ | Seal blade | | |

Important notes

Information on the installation manual

This manual enables operating or service personnel to correctly install the product described below and to use it safely and efficiently.

It is essential that these individuals read and fully understand this manual before starting any work. The basic prerequisite for safe working is to comply with the safety notes and all instructions in this manual.

The local regulations for health and safety at work and general safety regulations also apply.

Correct use

The type TFP pharmaceutical clean room terminal filter for ceiling installation is used as a final filter for the separation of suspended particles and for air distribution. Sample applications include medicine, biology, pharmaceuticals, and sensitive technical areas.

The TFP can be used in the supply air and extract air of ventilation and air conditioning systems. They are suitable for the fitting of Mini Pleat filter panels for the separation of suspended particles, to ensure critical air cleanliness and meet demanding hygiene requirements.

It is important that you comply with any national hygiene regulations when you install, commission or use the pharmaceutical clean room terminal filter.

Incorrect use



WARNING!

Danger due to incorrect use!

Incorrect use of the unit can lead to dangerous situations.

Never use the unit:

- in areas with potentially explosive atmospheres
- in humid rooms
- in rooms with aggressive or dust-laden air

Limitation of liability

The information in this manual has been compiled with reference to the applicable standards and guidelines, the state of the art, and our expertise and experience of many years.

The manufacturer does not accept any liability for damages resulting from:

- Non-compliance with this manual
- Incorrect use
- Operation or handling by untrained individuals
- Unauthorised modifications
- Technical changes
- Use of non-approved replacement parts

The actual scope of delivery may differ from the information in this manual for bespoke constructions, additional order options or as a result of recent technical changes.

The obligations agreed in the order, the general terms and conditions, the manufacturer's terms of delivery, and the legal regulations in effect at the time the contract is signed shall apply.

We reserve the right to make technical changes.

Defects liability

For details regarding defects liability please refer to Section VI, Warranty Claims, of the Delivery and Payment Terms of TROX GmbH.

The Delivery and Payment Terms of TROX GmbH are available at www.troxtechnik.com.

Qualified staff

HVAC technician

HVAC technicians are individuals who have sufficient professional or technical training in the field they are working in to enable them to carry out their assigned duties at the level of responsibility allocated to them and in compliance with the relevant guidelines, safety regulations and instructions. HVAC technicians are individuals who have in-depth knowledge and skills related to HVAC systems; they are also responsible for the professional completion of the work under consideration.

HVAC technicians are individuals who have sufficient professional or technical training, knowledge and actual experience to enable them to work on HVAC systems, understand any potential hazards related to the work under consideration, and recognise and avoid any risks involved.

Properly trained person

Properly trained persons are trained individuals who understand any potential hazards related to the work under consideration, and who recognise and avoid any risks involved. Training is provided by the HVAC contractor when the system is handed over.

Properly trained persons are responsible for cleaning the unit, and for carrying out functional tests, regular checks and smaller adjustments.

Personal protective equipment

Personal protective equipment must be worn for any work in order to reduce health or safety hazards to the minimum.

The appropriate protective equipment for a job must be worn for as long as the job takes.

Industrial safety helmet



Industrial safety helmets protect the head from falling objects, suspended loads, and the effects of striking the head against stationary objects.

Light respiratory protection



Light respiratory protection is used to provide protection from harmful dusts.

Protective gloves



Protective gloves protect hands from friction, abrasions, punctures, deep cuts, and direct contact with hot surfaces.

Safety shoes



Safety shoes protect the feet from crushing, falling parts and prevent slipping on a slippery floor.

Supply package, transport and storage

Pharmaceutical clean room terminal filter supply package

- TFP housing
- Diffuser face
- Filter element (optional)

Transport

CAUTION!

Danger of injury from sharp edges, sharp corners and thin sheet metal parts!

Sharp edges, sharp corners and thin sheet metal parts may cause cuts or grazes.

- Be careful when carrying out any work.
- Wear protective gloves, safety shoes and a hard hat.

Use only lifting and transport gear designed for the required load. Always secure the load against tipping and falling.

Upon delivery, carefully remove the packaging and check the unit for transport damage and completeness.

Storage

Please note:

- Store the unit only in its original packaging
- Protect the unit from the effects of weather
- Protect the unit from humidity, dust and contamination
- Storage temperature: 14 °F to 122 °F.
- Relative humidity: 95 % max., no condensation

Assembly

General information

Personnel:

- HVAC technician

Protective equipment:

- Industrial safety helmet
- Protective gloves
- Safety shoes

DANGER!

Danger of death from the fall of suspended loads!

- Only use fixing materials designed for the required load.
- Use all hanging brackets supplied.
- Stand clear of suspended loads, unless properly secured.
- Check secure fixing after installation.

- Fix the unit only to load-bearing ceilings.
- Load suspension systems only with the weight of the unit. Adjacent components and connecting ducts must be supported separately.
- Do not unpack the diffuser face and any filter element until you are ready to install them.

NOTICE!

Possible malfunction due to a damaged casing

If the casing has been damaged, unfiltered (contaminated) air may leak.

Do not drill any holes into the casing.

Only work in pairs; preferably use a lift.

- ▶ To prevent damage to the diffuser face, remove it before assembling the filter casing, ↪ *'Removing the diffuser face'* on page 8

Fixing the unit to the ceiling

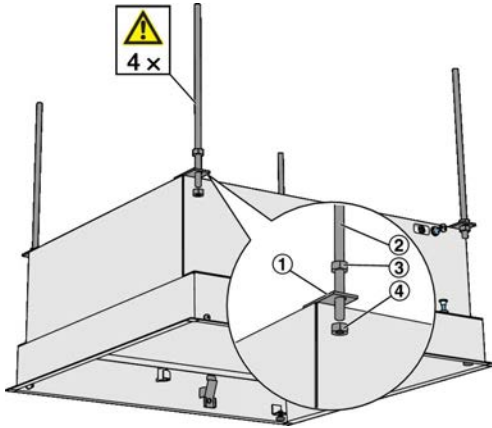


Fig. 2: Fixing

- Suspension lug with drilled hole \varnothing 0.5 in
- Threaded rod
- Lock nut
- Nut

If possible, install the device before fixing the ceiling tiles; if this is not possible, remove the adjacent ceiling tiles.

The TFP can weigh up to 53 lbs, depending on the construction variant. Use only approved and adequately sized suspension systems. Fixing material is not included in the supply package.

1. ▶ Fix any suspension elements, e.g. threaded rods (Fig. 2/2), to the ceiling.
2. ▶ Start by suspending the TFP casing on three suspension lugs (Fig. 2/1); ensure that the casing is horizontal, fix the nuts accordingly (Fig. 2/4), then use the locknuts (Fig. 2/3) to secure the suspended casing.

Loads imposed on the casing may impair the function of the unit. Be sure to install the unit without torsion.

3. ▶ Fix the fourth threaded rod without changing the position of the TFP casing and secure it with a locknut.

Fixing to the suspended ceiling

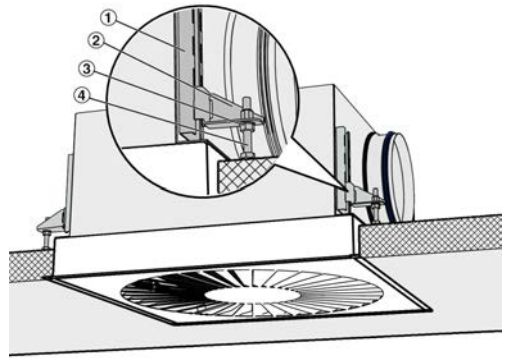


Fig. 3: Fixing to the load-bearing suspended ceiling

- ① C rail
- ② Support angle section
- ③ Lock nut
- ④ Adjusting screw

Depending on the construction variant, the TFP can weigh up to 53 lbs. It may only be fixed to structures with sufficient weight-bearing capacity.

Only work in pairs; preferably use a lift.

1. ▶ Insert the support angle section supplied as accessories (Fig. 3/2) into the C rails (Fig. 3/1) and adjust the height to the local conditions.
2. ▶ Fit the TFP casing to the suspended ceiling and attach to the load-bearing structure.
3. ▶ Then carry out the fine-adjustment using the adjusting screws (Fig. 3/4) and secure with the locknuts (Fig. 3/3).



If there is a lengthy break between installation and commissioning, cover all openings of the casing (e.g. with plastic) to protect the interior and avoid cumbersome cleaning procedures at the time of commissioning.

Connecting the ductwork

Type TFP pharmaceutical clean room terminal filters are available with different spigots:

- Top entry circular spigot
- Side entry circular spigot
- Side entry circular spigot, removable

TFPs with circular spigots are fitted with a lip seal and fit onto circular ducts to EN 1506 or EN 13180.

Connect the duct in such a way that the connection is tight.

To protect the filter once installed as much as possible from excessive contamination, proceed as follows when you install the ventilation system:

- Keep the ducts clean when you install them.
- If you have to interrupt the installation procedure, protect all openings from the ingress of dust.
- If necessary, clean the ducts before you commission the ventilation system.

Commissioning

General information

Before you start commissioning:

- Check that the filter casings are correctly seated.
- Remove protective film, if any.
- Ensure that all filter casings are clean and free from residues and foreign matter.
- Prime the ventilation and air conditioning system for 24 hours before you insert the filter element.

Volume flow rate balancing

To adjust the ventilation and air conditioning system, you first have to carry out volume flow rate balancing for each pharmaceutical clean room terminal filter. Volume flow rate balancing is required before initial commissioning.

Inserting filters

- Do not unpack filter elements until you are ready to install them.
 - Do not touch the filter, hold it by the filter frame only.
 - Check filter elements for any damage; replace damaged filter elements.
 - Insert only suitable Mini Pleat filter elements with a flat seal or fluid seal.
1. ▶ Before inserting the filter, wipe the filter casing and the sealing surfaces to disinfect them.

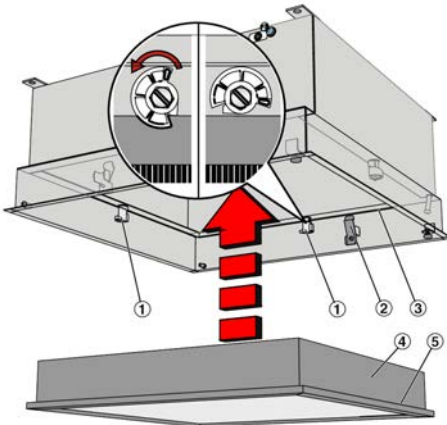


Fig. 4: Inserting filters

2. ▶ Open the turn clips (Fig. 4/1) by turning them anti-clockwise.

3. ▶

! NOTICE!

Do not damage the filter.

Handle the filter with care and hold it by the filter frame only.

Insert the filter (Fig. 4/4) with the seal (Fig. 4/5) upwards into the filter casing until it clicks into place at the springs (Fig. 4/2).

4. ▶ Tighten the turn clips (x4) crosswise in a clockwise direction as far as they will go. For this, use the key provided or a commercially available Allen key (SW10).

⇒ This presses the filter seal (Fig. 4/5) on to the seal blade (Fig. 4/3).

5. ▶ Once you have inserted the filter element, check that there are no leaks, ☞ *'Leakage test on an installed filter'* on page 9.
6. ▶ Installing the diffuser face, ☞ *'Installing the diffuser face'* on page 7.

Installing the diffuser face

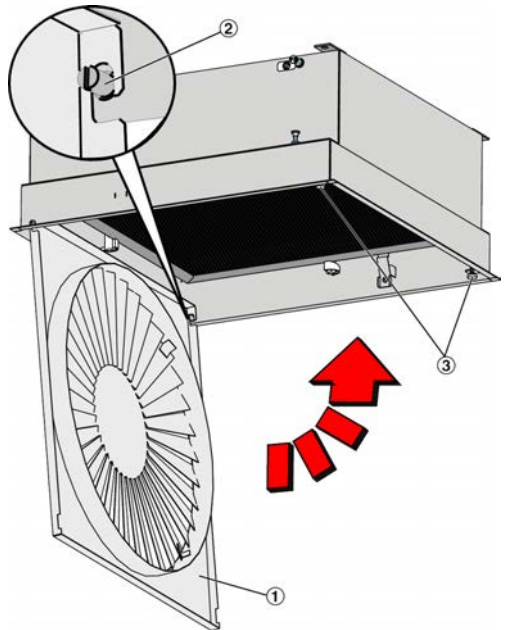


Fig. 5: Installing the diffuser face

1. ▶ Mount the diffuser face (Fig. 5/1) on to the two bolts (Fig. 5/2).
2. ▶ Swivel up the diffuser face until it is held by the magnets (Fig. 5/3).

! CAUTION!

Risk of injury from a falling diffuser face!

Ensure that the diffuser face is correctly seated and secured.

Maintenance

Maintenance applies mainly to the filter element. Check the filter regularly and replace it, if necessary.

The service life of a filter depends mainly on how polluted the air is. Check the filter in intervals that are short enough such that you can anticipate any defects or problems before they actually occur.

Replace the filter immediately if any of the following is true:

- The defined final differential pressure has been reached.
- Hygiene problems (micro-organisms, fungal spores, odours, etc.)
- Filter defects (particle count has been exceeded)
- The maximum filter usage time has been reached (8 years, to VDI 3803, part 4).



You may replace a filter even before the defined final differential pressure has been reached if it is more economic.

Removing the diffuser face

Some maintenance jobs, such as sealing integrity testing, leakage testing, filter changes or cleaning, require you to remove the diffuser face.

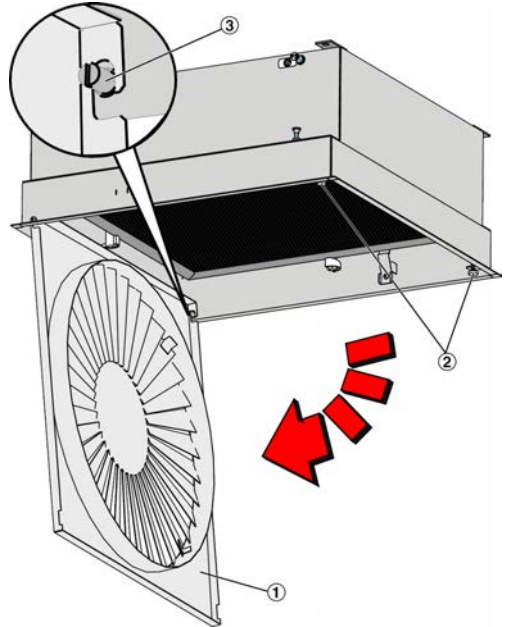


Fig. 6: Removing the diffuser face

1. ▶ Loosen the diffuser face (Fig. 6/1) from the magnets (Fig. 6/2) and swivel downwards. Press the diffuser face upwards slightly and lift away from the bolts (Fig. 6/3).
2. ▶ Place the diffuser face on a protective surface, e. g. on cardboard.

Leakage test on an installed filter

A functional test of the filter system is required to ensure that there are no leaks and that the filter element is without any defects (no small holes on the filter frame or on the seal, no leaks at the filter frame).

1. ▶ Remove the diffuser face, ☞ 'Removing the diffuser face' on page 8.

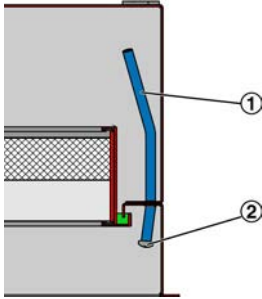


Fig. 7: Measuring tube

- Measuring tube $\varnothing 0.3 \times 0.1$ in
 - Cheese head screw M 0.2 \times 0.4 in
2. ▶ Open the measuring tube by removing the cheese head screw.
 3. ▶ Measure the particle concentration on the upstream side to ISO 14644-3 B6.
 4. ▶ Measure the particle concentration on the downstream side to ISO 14644-3 B6.
If there is a leak, seal it; then test for leakages again.
 5. ▶ Close the measuring tube by inserting the cheese head screw.
 6. ▶ Re-install the diffuser face.

Differential pressure measurement

The initial differential pressure for TROX filters is given on the label on the filter frame.

There are two ways to measure the differential pressure:

Permanent measurement: Continuous differential pressure measurement and monitoring of the final differential pressure. This is done with a static differential pressure measuring device (Fig. 8/1), e. g. with TROX measuring devices MD-UT, MD-APC or MD-DPC, using the pressure measurement points at the side or at the top of the casing (Fig. 8/2).

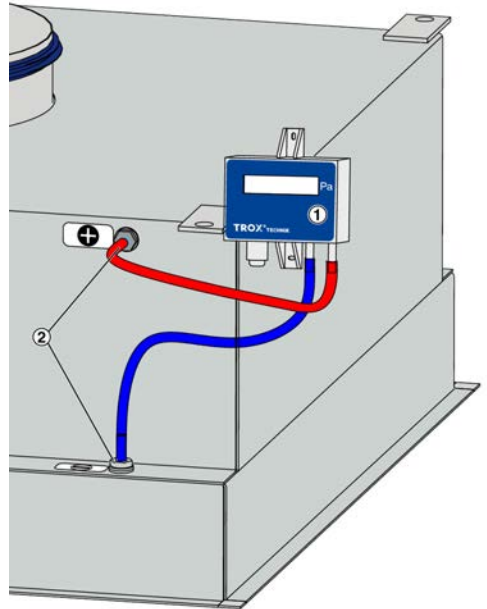


Fig. 8: TROX MD-DPC connection

Connecting a stationary measuring device

Plus (+) - to the 'Plus' measurement point (+)

Minus (-) - to the 'Minus' measurement point (-)

Temporary measurement: Temporary differential pressure measurement with a mobile measurement device connected to the internal measuring tube (Fig. 7/2). For this measurement you have to remove the diffuser face, ☞ 8.

Connecting a mobile measuring device

- Plus (+) - to the internal measuring tube (Fig. 7/2)
- Minus (–) - Don't connect; the differential pressure is measured against the room pressure.

Changing the filter

Personnel:

- Properly trained person

Protective equipment:

- Industrial safety helmet
- Light respiratory protection
- Protective gloves

Before you start changing filters, switch off the air conditioning system, or close the shut-off damper for the corresponding air stream (if any).

1. ▶ Remove the diffuser face, ↺ 'Removing the diffuser face' on page 8.

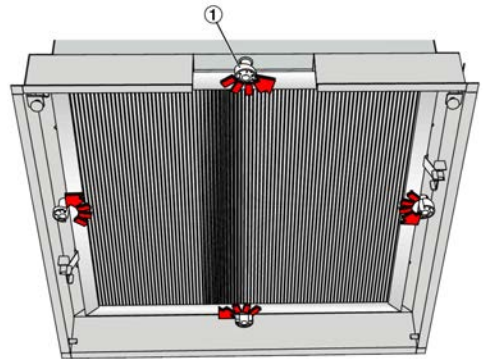


Fig. 9: Open the turn clips.

2. ▶ Open the turn clips (x4 Fig. 9/1) in an anti-clockwise direction. To do this, use the key provided or a commercially available Allen key (SW10).

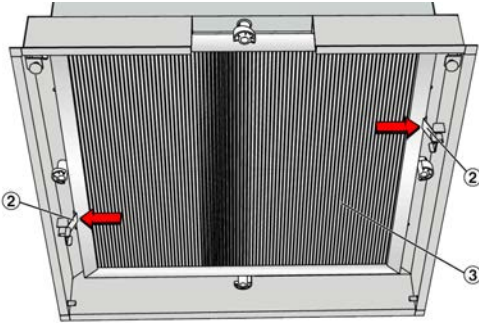


Fig. 10: Removing filters

3. ▶ Press the springs (Fig. 10/2) to loosen the filter (Fig. 10/3) and remove from the casing.
4. ▶ Dispose of the contaminated filter properly, see information on disposal ☞ 'Disposal' on page 11.
5. ▶ If the filter casing is dirty, clean and disinfect it ☞ 'Cleaning the filter casing' on page 11.
6. ▶ Insert a new filter element and fix the diffuser face again, see ☞ Chapter 6 'Commissioning' on page 6.

Disposal



ENVIRONMENT!

Risk of harm to the environment due to the incorrect handling of hazardous materials and substances.

Filters and cleaning materials that have been contaminated with bacterial, toxic or radioactive particles are considered hazardous waste and have to be disposed of by an authorised business in compliance with local regulations.

Disposing of filter elements with household waste is allowed only in the following cases:

- For unused filter elements
- For filter elements that have been exposed only to atmospheric outdoor air

Ordering replacement filters

To ensure permanent protection from particulate matter and other pollutants we recommend using only original TROX filters.

Original TROX filters carry a sticker on the frame with both the use before date and information on how to order replacements.



To avoid downtime of the ventilation and air conditioning system, we recommend you to always have the required filters in stock.

To order filters go to: www.troxtechnik.com

Cleaning the filter casing

Personnel:

- Properly trained person

Protective equipment:

- Light respiratory protection

It is usually not possible to regularly clean and disinfect the ductwork between the second filter stage and the filter casing, and neither is it required for hygienic reasons. As a prerequisite, however, you have to keep the ducts clean during installation.

It is then sufficient to clean and disinfect (wipe) the filter casing and the diffuser face; this has to be done for the first time just before the ventilation and air conditioning system is switched on for the first time.

The casing may be cleaned with a damp cloth. Sticky dirt or contamination may be removed with a commercial, non-aggressive cleaning agent. Cleaning agents that contain chlorine must not be used.

Once you have completed cleaning, disinfect the filter casing and any connecting rooms.

