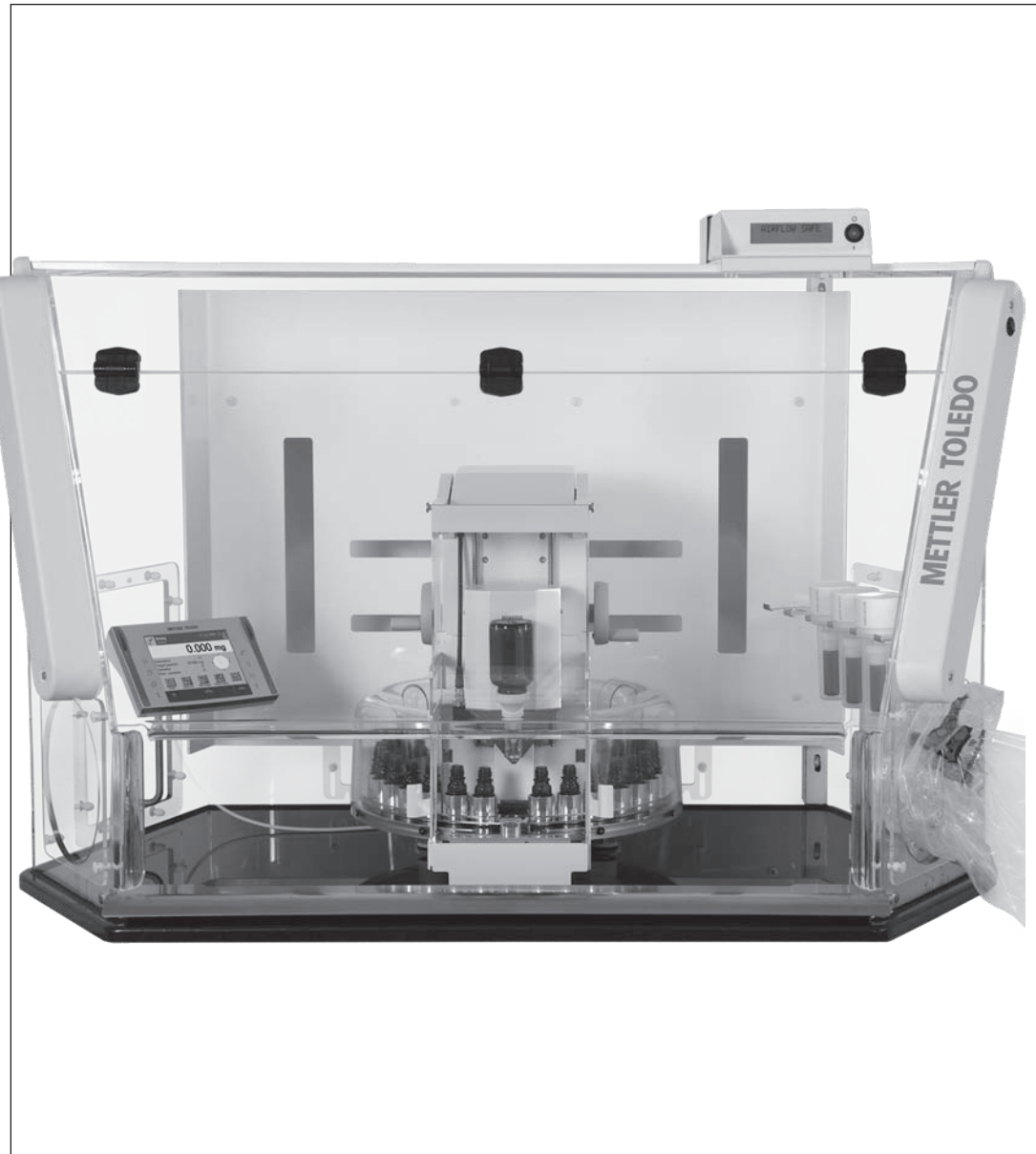


QSE2 Safety Enclosure System



METTLER TOLEDO

Contents

| | | |
|-----------|--|-----------|
| 1 | Intended Use | 4 |
| 1.1 | Standard Features of the QSE2 Instrument Include | 4 |
| 2 | Safety Information | 5 |
| 2.1 | Definition of Warnings and Symbols | 5 |
| 2.1 | Product Specific Safety Notes | 5 |
| 3 | Unpacking | 6 |
| 4 | General Operating Principles | 7 |
| 5 | Pre-Installation Guide | 8 |
| 6 | Dimensions | 9 |
| 6.1 | System Dimensions | 9 |
| 6.2 | Extract Fan Unit Dimensions | 9 |
| 7 | Fan Filtration System and Filter | 10 |
| 7.1 | Technical Data System | 12 |
| 7.2 | Installation of HEPA Filter | 13 |
| 8 | Alarm System | 14 |
| 8.1 | Description and Operation | 14 |
| 8.2 | Technical Data Alarm System | 17 |
| 9 | Installation and Calibration Guide | 18 |
| 9.1 | Installation | 18 |
| 9.2 | Alarm Calibration | 20 |
| 10 | System Maintenance | 23 |
| 10.1 | Maintenance Schedule | 23 |
| 10.2 | Cleaning Procedure | 24 |
| 10.3 | Safe Change Procedure for Bag-out HEPA Filters | 25 |
| 10.4 | Disposal | 30 |
| 11 | Troubleshooting | 31 |
| 12 | Accessories | 32 |
| 13 | EC Declaration of Conformity | 33 |

1 Intended Use

The Quantos Safety Enclosure QSE2 has been specifically designed to provide a safe operating environment for the Quantos Automated Powder Dosing System. The QSE2 system provides protection for the user from airborne contaminants present when using the Quantos system for the weighing of active drug compounds. The QSE2 also provides a work station environment that helps the operator operate the Quantos system more efficiently and comfortably.

The QSE2 safety enclosure system has been tested in accordance to internationally recognised ISPE guidelines (International Society for Pharmaceutical Engineers) and has a performance level for the handling of Active or Potent Pharmaceutical compounds.

The tested ECL (Exposure Control Limit) is less than 10 ng/m³ for the automated weighing of active drug powders over a wide range 100 mg – 1 g from a series of sample containers stored within the QSE2 enclosure.

1.1 Standard Features of the QSE2 Instrument Include

- Turbulence free weighing environment
- Simple to clean baffle system
- Printer / label access plate
- Keyboard support stand
- Reversible extract plenum
- Independent fan extraction system
- Safe change bag-out HEPA filtration
- Dual sensor airflow alarm
- Airflow data logging capability
- Integral black granite base
- Waste disposal chute

2 Safety Information

2.1 Definition of Warnings and Symbols

Signal Words

| | |
|------------------|--|
| CAUTION | for a hazardous situation with low risk, resulting in damaged to the device or the property or in losing of data or minor or medium injuries if not avoided. |
| Attention | (no symbol) for important information about the product. |
| Note | (no symbol) for useful information about the product. |

Symbols



General hazard



Electrical shock

Mandatory Signs



Wear protective eyewear



Wear protective clothing



Wear gloves

2.1 Product Specific Safety Notes



CAUTION

Damage of Device

- To prevent electrical shock, always unplug unit prior to installation. To reduce the risk of electrical shock, do not expose to liquid.

Read this instruction manual thoroughly and train all operators before attempting to place this unit into service. It is the customer's responsibility to understand the proper function and operational characteristics of this apparatus. Awareness of the stated cautions and warnings, and compliance within recommended operating procedures together with maintenance requirements are important for safe and satisfactory operation.

Customer satisfaction and safety are important to us. A complete understanding of this unit is necessary to ensure safe operation. All units must be certified to be operating within the requirements set by the customer's Health and Safety Department. The alarm should be calibrated and airflow set to meet your Health & Safe Department requirements.

If you have any questions about installations of this product, please call technical services for assistance.

Note

As a routine laboratory precaution, always wear protective eyewear, coat and gloves when operating apparatus.

Operating Conditions

| | |
|-------------|-------------|
| Temperature | 0 - 40 °C |
| Humidity | 20 - 75% rF |

3 Unpacking

This product is carefully packed and thoroughly inspected before leaving the factory.

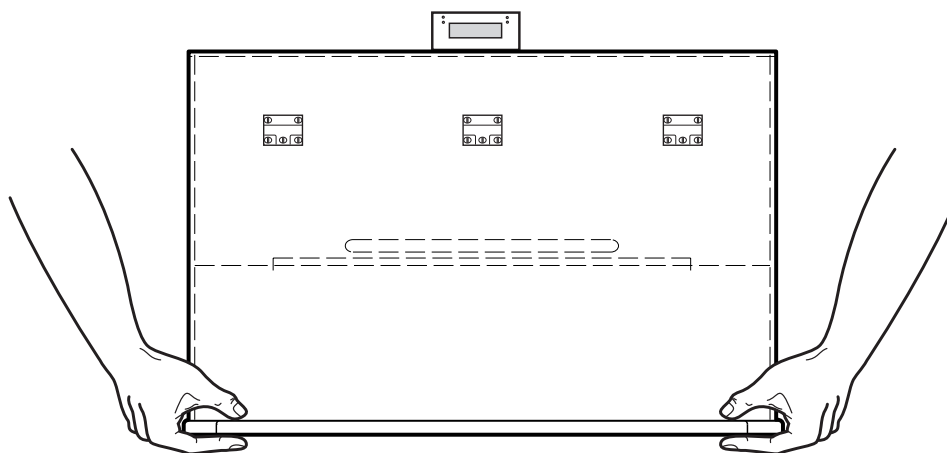
After unpacking the QSE2 System, check it immediately for any visible damage as a result of rough handling during shipment. It is a good idea to save the box and all parts of the packaging until you have successfully installed the weighing enclosure. Only the original packaging provides the best protection for shipment. If you need to return the enclosure to the manufacturer, be sure to unplug all connected cables before packing it to prevent damage.

Note

If the enclosure system has been used for handling active pharmaceutical drug product, a decontamination certificate will have to be provided with the returned unit.

Lift from BASE only!

Weight Enclosure = 90 kg, Weight Fan = 30 kg



4 General Operating Principles

The QSE2 Safety Enclosure is designed to protect the analyst from exposure to airborne contaminants during the weighing process. The design and use of this system is based around the following principles.

- Safety Engineering Controls
- Functional Design
- Ergonomic Design
- Good Operational Practices

PPE (Personal Protective Equipment) such as face masks will provide an analyst with a good degree of respiratory protection. The level of protection however is based on the correct use at all times and also on the analyst remembering to use the mask at all times. The aim of good **Safety Engineering Controls** is to engineer out the use of PPE and wherever possible to eliminate the human error factor, and provide a guaranteed level of safety.

A well designed Weighing Enclosure will vent any toxic contaminants via an approved filtration system and then either into a house exhaust system, or re-circulate back into the laboratory to save on energy. The user is protected by the Safety Enclosure's ability to maintain a constant and controlled flow of air away from the user and toward a dedicated filtration system. An airflow alarm system provides warning of air flow failure both visual and audible, essentially providing a fail safe system. A recessed base area provides protection from spillage. The assembled system is a single complete enclosure allowing access from one opening only, and being designed as a specific workstation will identify a dedicated area for potentially hazardous weighing operations. The system design is portable allowing the enclosure to be moved from one location to another as the laboratory functions change. The air handling requirements of the QSE2 System is relatively low (80 l/s) and of Constant Volume requirements meaning that it is simple to integrate into existing extract systems if required.

The **Functional Design** of the QSE2 Enclosure ensures that the Quantos Automated Powder Dosing System can operate effectively. Air flow is designed to be a smooth, horizontal laminar flow providing effective containment at low velocities (0.30 to 0.40 m/s). The exhaust plenum is removable and designed so that it can be orientated upwards or downwards which helps with installation requirements. The analyst can clean the exhaust plenum area easily without any additional protection. Extract and filtration is provided by a separate fan filtration system which remains remote in order to minimise vibration and to isolate the contaminated filter. The HEPA filtration system is a safe change bag-out system which provides effective filtration to recognised standards for up to 4 years.

A base airfoil located on the front opening section is designed to provide good airflow across the base of the enclosure. This section defines the cross over from a safe to hazardous area, and a clean location for the operator to use as an arm rest.

Ergonomic Design is an important function as the analyst naturally needs to lean towards the balance in order to be able to handle small quantities of drug compound. The sloping front design of the QSE2 system allows comfortable access and use, the internal height allows the system door mechanism to operate without restriction.

Good Operational Practices ensure that the QSE2 Enclosure system is used effectively and to its maximum potential. Disposal chutes allow contaminated material to be disposed of without first leaving the cabinet. The alarm system ensures that the system is not used when the equipment access door is open.

Performance testing of this system has been carried out using surrogate sampling techniques that test the systems control performance for the actual application in which it will be used.

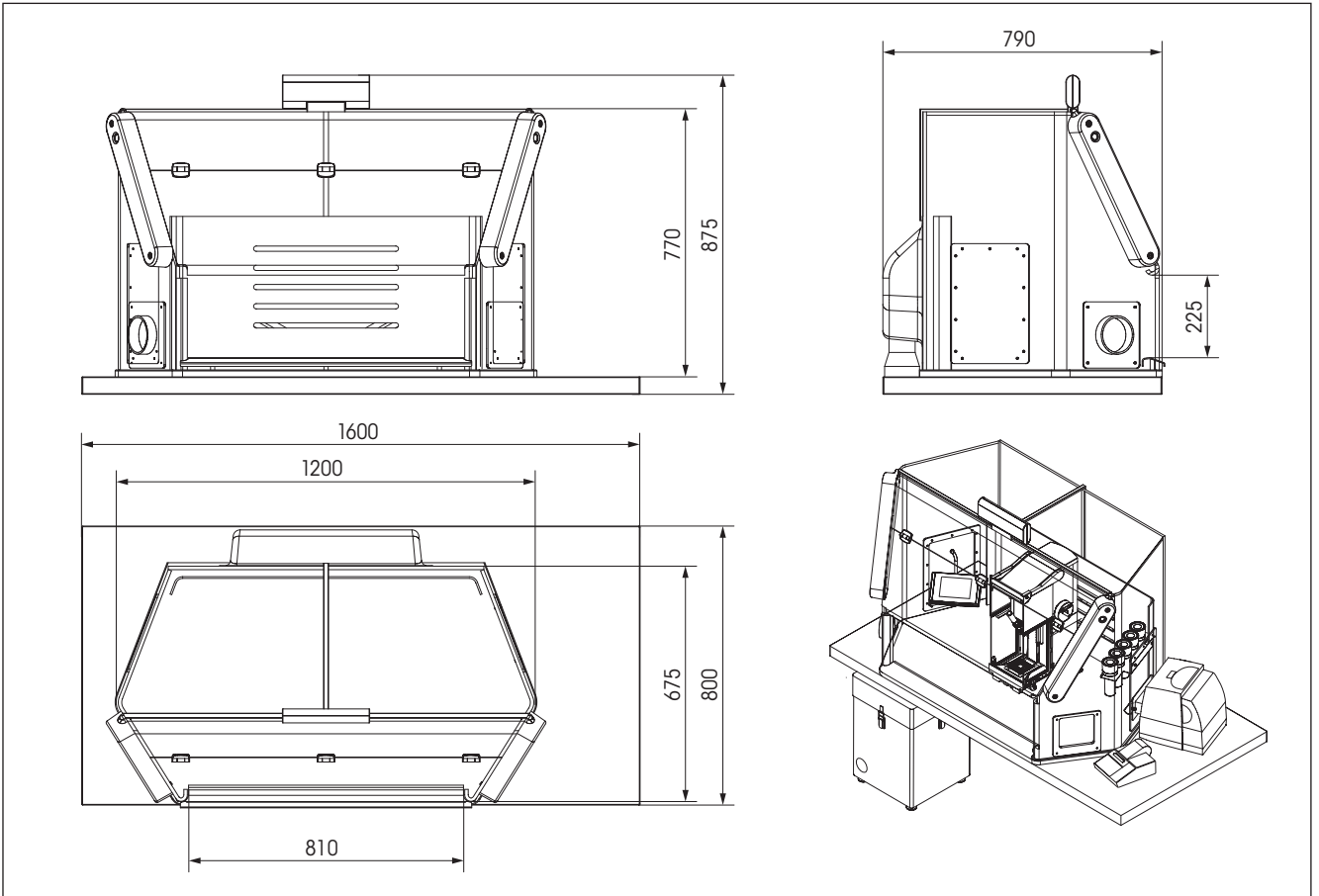
Safe weighing and sample handling training is recommended for analysts using this equipment so that the maximum possible protection levels are achieved.

5 Pre-Installation Guide

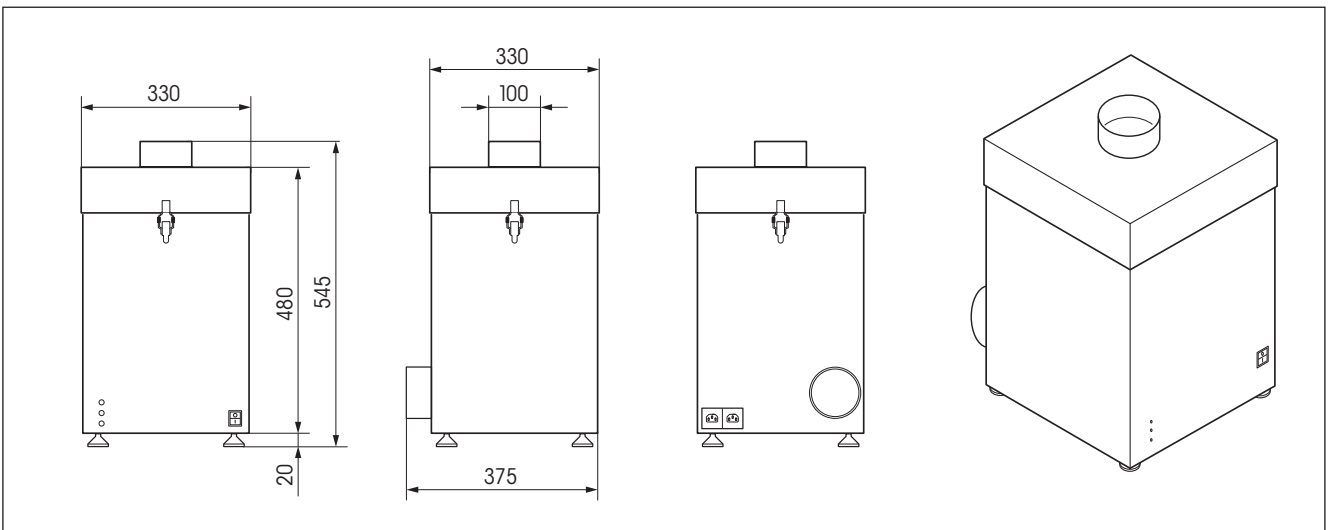
1. Remove the enclosure from the packing case ensuring to lift from the base and not the sides, inspect for any damage, scratches or breakage, which may have occurred in transit. If any problems or concerns are noted, please contact the shipping company immediately.
2. Clean, and if necessary, decontaminate the surface on which the enclosure will be installed. Every effort should be made to ensure that the area is as free of potential chemical, physical, or biological contamination as possible.
3. Ensure that the surface on which the enclosure is to be installed is well lit, level, smooth, and free from vibration. The front of the cabinet should be as close to the front of the balance table as is practical.
4. A comfortable chair with an upright back and adjustable height should be designated as part of the workstation area. Seat height should be adjusted so that lower arms are approximately at right angles (90 degrees) to upper arms when in the working position.
5. The enclosure system should be positioned on the bench so that the front lower airfoil is slightly forward of the front edge of the bench to allow good airflow to the velocity sensors.
6. The cabinet should not be placed in an area of strong room air currents or cross-drafts that are caused by ventilation systems or from an open window or corridor. These currents should be eliminated such that the airflow entering the workstation is not disturbed. Limiting elbows and bends and using the minimum duct lengths will result in more efficient use of your exhaust system. If the enclosure is to be connected to the in-house exhaust system, an adjustable damper (or gate valve) must be installed in the system in order to control the airflow to provide the required face velocity (0.30 - 0.45 m/s). This is especially important in balancing a system that has more than one enclosure installed in series.
7. Care must be taken when vapours, gases and particulate are being exhausted from an enclosure that is connected in series with ducts to the exhaust of another enclosure to ensure that the gases/fumes are chemically compatible.
8. If you have any questions about installations of this product, call for technical assistance.

6 Dimensions

6.1 System Dimensions



6.2 Extract Fan Unit Dimensions



7 Fan Filtration System and Filter



WARNING

Contamination Risk

- Adjustments in the fan filter unit volume rates may only be made by a1-safetech or specially authorized personnel as incorrect extract volume settings can lead to a contamination risk!
- The installation of the HEPA filter (High Efficiency Particulate Arrestor) must be carried out only by a1-safetech or specially authorized personnel
Improper installation can cause damage to the filter.
- Only the correct procedure ensures that the filter is properly installed and a subsequent filter changes can be carried out without contamination.
- Once installed and tested HEPA filters can not be removed without a risk of contamination.

a1-safetech fan filter units are designed to house filters used to trap airborne contaminants generated by handling processes with the ST enclosure ranges. Both HEPA for particulates and Activated Carbon filters for solvent vapors are available.

The fan filter unit is a box-shaped housing fitted with a centrifugal fan in the base. The air is drawn from the enclosure through the duct and filters (the fan motor is on the clean side) and exhausted through 100 mm diameter spigot on the back of the unit.

The air volume capacity is adjustable via a potentiometer mounted on the front of the fan unit from 30 to 360 m³/s. Once the volume extract is set, the fan motor will maintain the set speed ensuring CAV (constant air volume operation).

The fan filter unit is located away from the enclosure to minimize the risk of vibration, it should be mounted on a solid surface upright. Do not mount the fan filter unit upside down.

The ducting connection to the fan filter unit and enclosure housing should such that there is no risk of vibration transmission from the side walls of the duct to the enclosure.

Notes

Easy access for maintenance and filter changes must be guaranteed.

Yearly maintenance of Local Exhaust Ventilation Enclosures is a requirement of UK HSE guidelines HSG258.



WARNING

Contamination Risk

- Following installation, the HEPA filter is integrity tested using DOP (Dispersed Oil Particulate) by a1-safetech in accordance to EN1822. Once tested the complete enclosure system is certified.
- If no DOP test is carried out the integrity of the filter is not guaranteed and so also the functionality of the Safety Enclosure System and it could have a significant contamination risk exist.

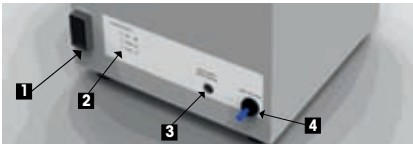


When installing the fan filter unit a1-safetech will calibrate the airflow and record in the IQ/OQ documentation.

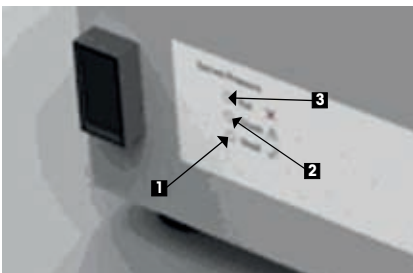
When in operation the power switch (1) is illuminated to show the fan is operating. Power supply to the fan can be made via the alarm/power module.

The user can see the fan pressure status (2) when in use.

More information on regular maintenance work can be found in the chapter (Maintenance and Troubleshooting).



| | |
|---|---|
| 1 | Power Switch |
| 2 | Status indicator |
| 3 | Potentiometer to adjust volume flow rate (service only) |
| 4 | Pressure Test Port (service only) |



The lights indicate the pressure status of the fan motor and HEPA filter:

| | |
|---|---|
| 1 | Green: The fan motor and filter are working properly |
| 2 | Yellow: Possible filter change or speed adjustment required – contact a1-service. |
| 3 | Red: Filter change or fan service required, do not use system. |

If the filter becomes fully loaded, the fan filter unit will not be able to maintain the required airflows and the alarm system will sound.

7.1 Technical Data System

Fan Filtration Unit

| Model | FAN-300-240 | FAN-300-110 |
|---------------------------------|--|---------------------------------------|
| Supplier: | a1-safetech | a1-safetech |
| Flow rate: | 360 m ³ /h 212 cfm | 360 m ³ /h 212 cfm |
| Fan Type: | Centrifugal | Centrifugal |
| Dimensions (W x D x H): | 330 x 375 x 520 mm 13" x 15" x 20" | 330 x 375 x 520 mm 13" x 15" x 20" |
| Weight (with Filter): | 23 kg 50 lbs | 23 kg 50 lbs |
| Power consumption: | 0.36 kW | 0.36 kW |
| Voltage: | 230 V/1-Ph./50 Hz | 115 V/1-Ph./50 Hz |
| Current, max. load: | 2 A | 3.5 A |
| Noise Level: | 49 dBA - 63 dBA | 49 dBA - 63 dBA |
| Environmental conditions | | |
| Temperature range: | +5 °C bis +40 °C | |
| Relative air humidity: | max. 80% at 31 °C, linearly decreasing to 50% at 40 °C | |

HEPA Filter

| Model | FILT-S-HEPA/300 | FILT-D-HEPA/300 |
|-------------------------|---------------------------------------|---------------------------------------|
| Filter Type: | HEPA Single Layer | HEPA Double Layer |
| Class: | H14 | H14 |
| Tested to: | EN 1822 | EN 1822 |
| Construction: | MDF Body, PVC Sleeve | MDF Body, PVC Sleeve |
| Dimensions (W x D x H): | 305 x 305 x 305 mm 12" x 12" x 12" | 305 x 305 x 305 mm 12" x 12" x 12" |
| Weight: | 7 kg 15 lbs | 7 kg 15 lbs |

7.2 Installation of HEPA Filter



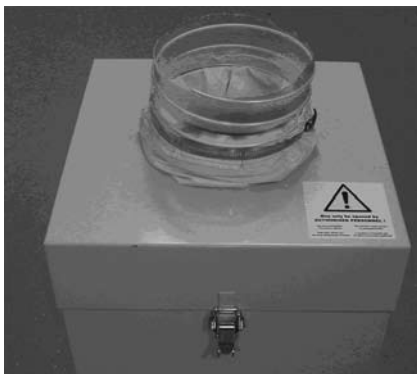
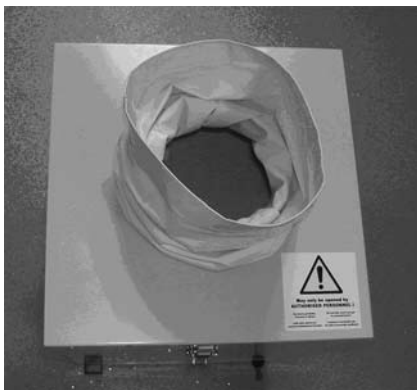
WARNING

- Improper installation can cause damage to the filter. Never touch the filter media.
- Only the correct procedure ensures that the filter is correctly fitted and a subsequent filter changes can be carried out without contamination.
- The HEPA filter, once installed correctly will be certified by a 1-safetech.

This procedure assumes that this is the installation of a new system. To change the filter on a used system, please follow the instructions in the chapter (Safe Change Procedure for Bag-out-HEPA Filters).

For the installation of a new system in a clean and safe area PPE is not required, unless the laboratory guidelines prescribe a specific PPE.

Proceed as follows:



1. Carefully unpack the filter, do not touch the filter media.
2. Remove the fan filter lid, and place the filter into the fan filter unit with the sleeve section facing upwards.
3. Replace the lid and pull the whole sleeve completely through the lid opening, and return over the inlet spigot. Push the sleeve over the spigot ensuring that the inner area of the sleeve is smooth against the sides of the inlet spigot so that airflow is not restricted.
4. Slide the intermediate DOP port onto the sleeve and spigot as far down as possible. Fit the excess sleeve material on the outer side of the duct/DOP collar and secure with a jubilee clamp against the duct so that the sleeve will unravel and form a protective tube between the duct and spigot when it is disconnected from the spigot.
5. Now, fit the duct hose onto the intermediate DOP port section and fasten with a hose clamp

8 Alarm System

8.1 Description and Operation



WARNING

Contamination Risk

- Calibration of the sensors and air flow rates should only be carried out by a1-safetech engineers or authorized personnel.
 - Incorrect flow and calibration settings can lead to unsafe flow conditions and to a risk of contamination.
 - Do not use the enclosure if the alarm is not operational.
-



The QSE system alarm has the ability to read from three separate sensors:

- Right and left sensors located under the base airfoil.
- Optional tube sensor which can be located in the exhaust duct.

As standard the alarm module comes with the two face velocity sensors which locate under the base airfoil and provide a measure of the actual face velocity at the opening of the enclosure.

The alarm module also acts as a power distribution unit which can supply power output for up to 2 fan filter modules, plus a roof mounted LED lamp option.

The QSE2 alarm is able to measure low airflow rates as it is site calibrated between 0.1 and 0.5 m/s. The two flow sensors act independently and provide a true status of flow conditions at the face of the enclosure.

The alarm power switch will also act as a system power switch enabling the user to turn on the alarm plus associated fan modules, and lamp.

On installation a1-safetech use a hot wire anemometer calibrated at low ranges to measure the airflow level at the enclosure opening.

The installation engineer will make speed adjustments on the fan filter unit to set the required airflow rates for calibration of the alarm system to the enclosure.

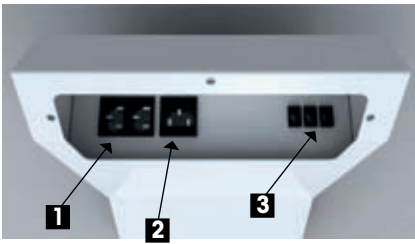
Following calibration the required face velocity is set and the alarm functions are tested.

The alarm system also has a data logging function which can be enabled if the user wishes to download data regarding flow alarm conditions. This function is enabled on installation if requested by the user.

Attention

The installation of the alarm system should be conducted only by a1-safetech or specially authorized personnel.

Incorrect installation, calibration and adjustment settings of the airflow will mean the system will not be operating correctly which can lead to unsafe conditions and contamination.



Connections to alarm system

Two power outputs (1) (for connection to fan filter units).

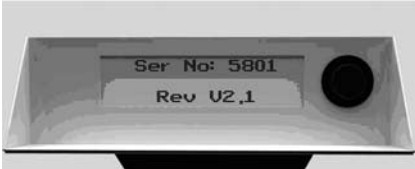
Power Inlet (2).

Sensor inputs (3).

The sensors are connected via a signal cable to the alarm system. The left sensor is inserted into the outer left and right socket sensor in the right socket. The middle plug is used for the duct sensor (optional).

In addition, two ports for the LED light units (not shown).

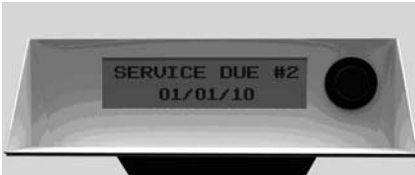
On power up the alarm serial number is briefly displayed along with the software version number.



If activated, the display will then show the total hours running time of the system for maintenance planning.



After this the service due date will be displayed.



If service is overdue the background will appear red.

Next Follows:

Stabilizing flow sensors, Please wait 20 s

A counter counts down whilst the sensors stabilize.

Sensor status is then displayed for example:

RHS Sensor OK (RHS = Right Hand Sensor)

If a fault is detected this will be displayed: For example:

Sensor Fault LHS (LHS = Left hand sensor)

If both face velocity sensors are active and functioning the alarm will check for the tube sensor option, if this is installed correctly, the display will read:

Tube sensor is in use

If not installed the display will show:

Tube sensor not in use

Note: The sensors must be connected before the alarm system is activated, otherwise, the sensors are not detected.

The alarm system has a data-logging feature to record the alarm conditions.

This feature is an option, and therefore set to off by default.

If required this is an engineer function to activate.

The last test checks the memory status when the data-logging function is active.

If the internal memory is greater than 80% full this will be displayed.

> 80% full

Once the memory is full the following warning appears:

Memory Full

If the data-logging feature is not enabled, this test is not executed.

Once all of the above tests and initializations have been successfully passed, the alarm system will continue in normal operating mode.

In operating mode, both sensors are checked every 100 ms. The results are averaged over 20 cycles, which corresponds to an update flow reading every 2 seconds.

If the mean flow value for both sensors is over the alarm set point (normally 0.3 m/s), then the display shows an **Airflow Safe** message against a green backlit display:

The **Airflow Safe** status indicates that the system is safe to use.

If the optional duct sensor is installed in the exhaust duct, then the calculated face velocity flow rate appears in the second row of the display:

Flow = xxxx

The value shown here is the calculated airflow taking into account the enclosure size. If no duct sensor is installed, the second line is left blank.

If the airflow falls below the alarm set point for more than 3 seconds, the display shows the following warning:

Airflow Caution

If the average flow rate for one of the two sensors falls below the alarm set point for longer than 15 seconds, then the screen will switch from green to red and the display will show which sensor caused the error. For example:

Low flow on RHS

In addition, an audible alarm will sound as follows: 1 second on, 5 seconds off

If the average falls for both sensors for longer than 10 seconds below the alarm point, then the backlight will be switched from green to red and the display will display:

Airflow Fail

The average flow rate for both sensors must go above the alarm set point for more than 3 seconds for the alarm to reset back to an **Airflow Safe** condition.

If a sensor fails or is removed, then the display indicates which sensor has failed. The backlit screen will change from green to red and the audible alarm will sound. This will remain in alarm condition until the fault is rectified or the defective sensor is replaced.

The sensor function can be tested as follows:

1. Cover the sensors located under the airfoil (one at a time in, then both together).
2. Open the door.
3. Turn off the fan filtration unit.

With all of these actions, the screen will change from green to orange and then to red. The display will show which sensor is affected. In addition, an audible alarm will sound every 5 seconds when one sensor is affected and a continuous tone will sound when both sensors are affected.



8.2 Technical Data Alarm System

Alarm

| | |
|--|--|
| Model | ST-ALARM-V2 |
| Supplier: | a1-safetech |
| Operating range: | 0.01 – 1m/s |
| Calibration range: | 0 – 1 m/s |
| Memory size: | 3800 events |
| Dimensions (W x D x H): | 180 x 350 x 57 mm |
| Weight: | 4 kg |
| Materials: | Mild Steel |
| Colour: | White Powder coat RAL 9016 |
| Display type: | LCD 16 x 2 Dual Farben Hintergrundbeleuchtung |
| Max Power consumption Alarm and lamp With 2 fans connected | 50 W 115 V: 560 W; 230 V: 530 W |
| Voltage range: | 115 V – 230 V |
| Frequency range: | 50/60 Hz |
| Max. current load: | 230 V: 5 A, 115 V: 10 A |
| Fuse ratings: | IEC fused connector 115 V operation = T10AH250V 230 V operation = T5AH250V Internal fuse = in line T2AH250V |
| Certifications: | UL, EC |
| Cleaning: | Can be cleaned with a damp cloth and non aggressive detergent |

Sensor

| | |
|-------------------------|---|
| Model | ST-AL/SENS/F-V2 Sensor |
| Dimensions (W x D x H): | 80 x 50 x 12 mm |
| Weight: | 50 g |
| Sensor: | GT-Stil NTC Thermistor Running temperature 105 –120 °C |

Datalogger

| | |
|-------------------------|--|
| Model | ST-AL/LOG Datalogger |
| Dimensions (W x D x H): | 80 x 120 x 25 mm |
| Weight: | 100 g |
| Power: | 5 VDC self powered via alarm module or PC |
| Memory size: | 8 x 512K EEPROM |

Software

| | |
|------------------|------------------------------|
| Model | ST-AL/SWR-V2 Software |
| PC Requirements: | Minimum Windows 95 |
| Connection: | USB |

9 Installation and Calibration Guide

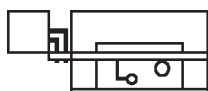
9.1 Installation

Alarm Assembly and Connection

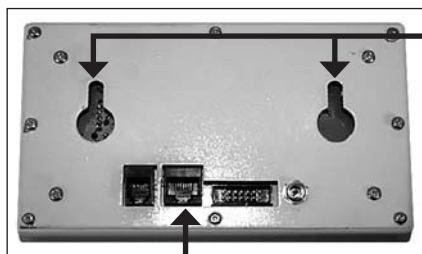


Sensor Assembly

The unit uses two types of ribbon cable: 10-way and 14-way. The two 10-way cables connect the flow sensors on the airfoil to the connection box. The 14-way cable connects the connection box to display unit (as shown). Also connected to the display unit is the power supply. This is where the data logger is connected.



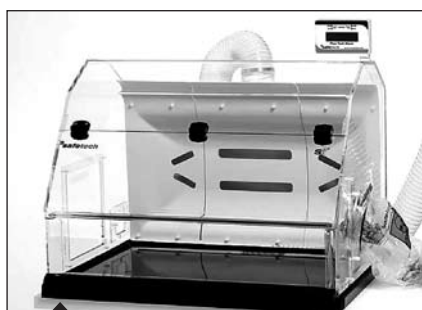
Sensor block and cables



Rear of Alarm Unit

Mounting slots

Data and power connection



Sensor Positions

Sensor positions under airfoil

Alarm Function

Both sensors are checked once every 100 ms. The results are averaged over 20 cycles, a period of 2 seconds.

If the flow of both sensors' average is greater than 0.3 m/s, then the display will read **Airflow Safe**.

Both the left- and right-hand green LEDs are illuminated, indicating a safe condition.

If the left or right-hand sensor's average is less than 0.3 m/s for more than 20 seconds the red alarm LED is illuminated.

The display will show which sensor triggered the alarm, i.e. **Low flow on RHS** (Right Hand Sensor). An audible alarm sounds at an interval of 1 second on, 5 seconds off.

If both sensors' average is < 0.3 m/s for more than 5 seconds, then the unit displays **Airflow Fail**. The red alarm LEDs are lit and the audible alarm sounds as above.

Once the unit has entered either of the above alarm states, then an average flow of > 0.3 m/s for more than 2 seconds needs to be achieved. When this occurs, the alarm condition will automatically be reset.

Sensor Fault

If during normal operation any of the sensors are removed or become faulty, the unit will display which sensor is faulty. The unit will flash both red alarm LEDs and sound an alternating audible. This will continue until the sensor causing the alarm is reactivated.

If the cause is due to a faulty sensor, then the sensor needs to be replaced. During this fault condition, the unit will not measure or log any flow data; however the alarm condition that has resulted in a fault will be logged.

Logging of Fault Conditions

A fault condition is logged along with date and time when:

- Any sensor registers a low flow condition
- Power is turned off and on
- Airflow failure is registered when both sensors record a low flow condition

Sensor Operation Check

The sensors can be checked by blocking the air flow or opening the cabinet door. Within 20 seconds an audible alarm will sound and an LED will indicate which sensor has failed.

9.2 Alarm Calibration

Plug the remote logging unit into the alarm unit, the logger will be powered via the alarm.

The remote logger will show the status of the internal memory before entering the main menu.



Menu Functions

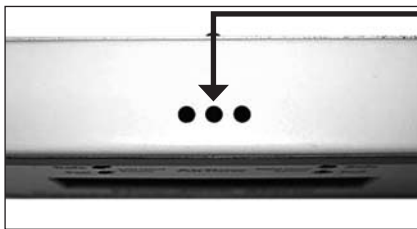
Navigation is by means of the [UP], [DOWN] and [ENTER] buttons. There are 9 main modes as follows:

- Set Up Sensors
- Disable Logging
- Enable Logging
- Set Cabinet
- Set Tube Diameter
- Memory to PC
- View Memory
- Download Data
- Set Time and Date

To enter the above modes, navigate with the [UP] and [DOWN] buttons until the mode is displayed and then press the [ENTER] button.

Set Up Sensors

Upon entering this mode, the remote logger display will read **Set L/R/T Pots** on the first line and **<= Escape** on its second line. The logger will display the left- and right-hand sensor flow readings on the first line and, if fitted, the tube sensor readings on the second line.



There are three potentiometer ("pot") adjusters on top of the alarm. The left potentiometer adjusts the left-hand sensor; the middle potentiometer, the tube sensor; and the right potentiometer, the right-hand sensor.

1. With the use of a **calibrated anemometer**, the sensors should be calibrated by adjusting the relevant trimming pots for each sensor so that they read the average face velocity near the location of each of the sensors.
2. Once the sensors have been calibrated, press the [ENTER] button to escape. This will return the remote unit back to the menu mode and the logger back to its main routine.

Disable Logging

When the logging function is disabled, the alarm unit will act as a standard flow alarm.

Enable Logging

This function allows the alarm unit to log the following conditions:

- Left hand sensor fail
- Right hand sensor fail
- System low flow
- System power on
- System power off

Downloading of this information is described in the section **Download Data**.

Set Cabinet

This function is not used on QSE2 Series Enclosures.

Set Tube Diameter

This function is not used on QSE2 Series Enclosures.

Memory to PC

This sends the information from the handheld datalogger to the PC for manipulation by the user. Further details shown in section **Download Data**.

View Memory

This shows the faults that have been logged on the alarm unit.



Download Data

Downloading data from alarm logger to remote logger:

1. When in **Download Data Mode** press the [**ENTER**] button. The unit will immediately try to download all stored events from the alarm logger unit to the remote logger.
2. If there are no events stored, the remote logger will display **No Data Stored**. The remote will return to the menu mode and the logger unit will return to its main routine.

If there is data to download, the alarm will display **Sending data to remote** and the remote will display **Receiving data**. Upon completion both units will display **Download complete** and all data will be automatically erased from the internal memory of the alarm logger in order to free up space. This is important to note because once the data has been erased from the main logger, it can not be retrieved again from this unit (it will be stored in the remote logger for PC download only).

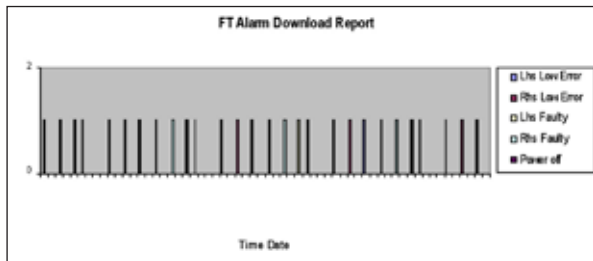
Downloading Data to PC

In order to download and record the data from the alarm logger the **AirFlow** data logging software supplied with the alarm unit must be loaded onto a PC.

Connection to the PC from the datalogger is via a 9 pin serial port cable for the data and USB cable for power.



1. This mode is used to send to a PC the data that has been loaded into the remote logger from the alarm logger.
2. After the download program has been launched on the target PC, press the [ENTER] button on the remote logger.
3. Remote display will show **Sending data now**. The PC will show a progress bar. When the transfer is complete the remote will display **Download to PC completed** and the PC will show **Download completed**.
4. The remote will then display **Clear Memory**, and ask you to select [Yes] or [No]. If you are happy that the transfer was successful, select [Yes] to clear the memory. Once you do this then the only record of the data is on the PC. If you select [No]; then the memory will remain on the remote. You can then use the remote to again download its memory contents to another PC if required.



Data from the download file can be used to produce dedicated reports highlighting specific events. The pictures shows screen display of the data logging software and a simple report chart highlighting airflow failures triggered over a short period of time.

Date and Time

If the time is correct, press the [UP] button for [Yes] and the unit will beep before returning to the menu mode. If the time is incorrect, press the [DOWN] button to enter the Set Up **Date and Time** mode.

1. The first step is to set the year. With the use of the [UP] and [DOWN] buttons, select the correct year, then press the enter key.
2. Next set the month, date, hour and minutes in a similar manner to above.
3. Once all of the settings are correct, the logger will beep and return to the menu mode.
4. The logger will display the new date and time on its top line and **Please Wait** on its second line. You should not try to enter a new menu until this has cleared (stopped displaying). Otherwise, a message **Comms failure** will be displayed on the remote.

10 System Maintenance

10.1 Maintenance Schedule

| | |
|-----------------------|--|
| Every 6 Months | Visual Inspection – Check |
| | • Physical damage to panels |
| | • Physical damage to base |
| | • Alarm connection points |
| | • Duct work damage |
| | • Duct connection to enclosure and fan |
| | • Base airfoil check |
| | • Door operation |
| | • Cable access plates |
| | • Plenum fasteners on back. |
| | • Disposal chute fixing. |
| | Operational Inspection – Check |
| | • Alarm operation |
| | • Smoke test (airflow check) |

| | |
|------------------------|---|
| Every 12 Months | Same tests protocol as 6 months plus |
| | • Alarm test and calibration |
| | • Filter integrity test (DOP Test) |
| | • Room pressure test |

Service

Regular servicing by a service technician prolongs its working life. Ask your METTLER TOLEDO dealer for details of servicing options.

10.2 Cleaning Procedure



CAUTION

Damage of Device

Do not use acetone or other strong solvents to clean the cabinet.

Cleaning

The cabinet should be kept clean at all times, proper use will mean that any spillages or contamination is disposed of in a safe manner and that the enclosure is left clean for the next analyst to use without the risk of cross contamination.

The base area of the cabinet is a black granite plate which has good resistance to cleaning chemicals and being black in colour will highlight the majority of (white) drug compounds.

Cleaning of the cabinet panels should be with weak or non solvent based solutions such as: Isopropanol, Ethanol, or soapy water.

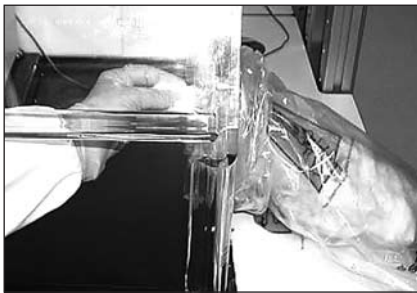
Safe Removal of Waste Disposal Bag

Attention

When removing a contaminated waste bag the operator must wear the following PPE (Personal Protective Equipment) as a minimum.



Wear double gloves for this procedure!



Waste chute disposal procedure



Prior to removal have ready inside of the enclosure:

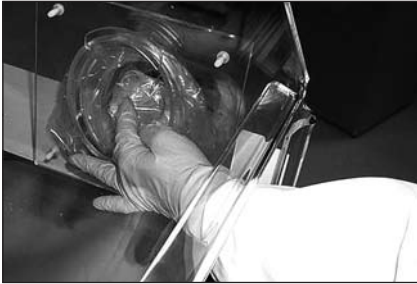
1. Replacement waste bag.
2. Elastic band to secure to disposal chute.
3. Remove and seal the internal bag.
4. Push the sealed bag into the outer bag.



5. Attach a new waste bag to the internal disposal chute section so that the bag faces into the enclosure.



6. Remove outer gloves and place inside the enclosure.
7. Remove the external bag and seal.
8. Attach a new waste bag and fix with elastic band.
9. Dispose of used waste bag.
10. Push the new internal bag through to the disposal chute and dispose of contaminated outer gloves.



Waste disposal procedure is now complete.

10.3 Safe Change Procedure for Bag-out HEPA Filters



CAUTION

Dynamic Risk Assessment

Before entering an area to carry out a HEPA filter change ensure the client has made you aware of any health and safety risks in the area and, or conduct a risk assessment to ensure the safety controls stated in this procedure will remain adequate.

You may be required to follow a client's safe change procedure. If this is the case, ensure training is provided.



CAUTION

Contamination Risk

Keep tools and equipment in bags to minimize contamination and clean after use.

Attention

When removing a contaminated HEPA filter the operator must wear the following PPE (Personal Protective Equipment) as a minimum.



Double gloves (Nitrile or Vinyl)



Disposable coverall with overshoes



P3 filtered air respirator

Filter replacement will be required when:

- An acceptable face velocity is no longer attainable
- The Filter Integrity has become compromised
- After a maximum of 4 years use

Prior to starting Change Out Procedure

1. Ensure that the fan filtration has been running for at least 2 hours since last being used for extracting a potentially contaminated atmosphere from a cabinet system.
2. Gently tap on the flexible ducting along its length just prior to the fan housing. This will ensure any loose residual powders attached to duct and at the immediate connection point are drawn into the filter. Leave to run for a further 10 minutes.

Filter Removal and Replacement Procedure

Attention

Full PPE to be worn, in case of system failure during change procedure!



Double gloves (Nitrile or Vinyl)



Disposable coverall with overshoes



P3 filtered air respirator



1. With the fan unit still running, slightly loosen the jubilee clip to allow the flexible duct to pull upward extending out the sleeve. Do **not** allow the sleeve to come away from the duct as this may result in escape of contaminants. Allow the sleeve to close and collapse by the vacuum produced by the fan extract.

Note

The inner of the extended sleeve should be significantly less contaminated than the duct and inner of the filter bag because it has very limited exposure to the contaminants passing through the duct into the filter bag.



2. Secure the bottom first, and then the top section of the sleeve with two cable ties. Allow at least 100 mm space between the ties.

3. Turn off the fan unit.

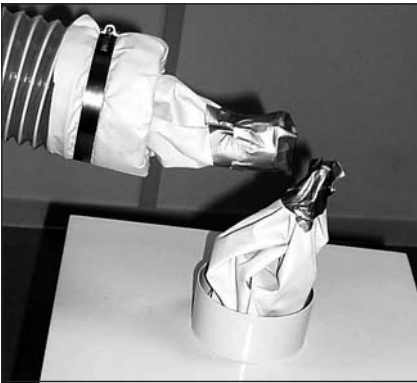
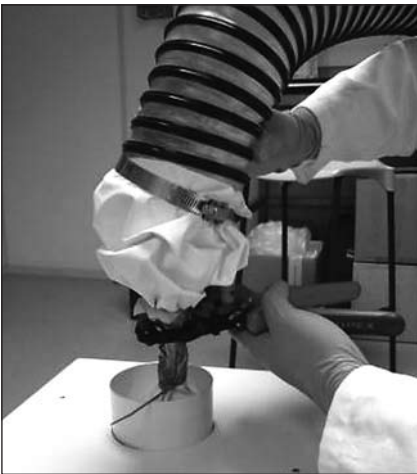
Tape securely between the 2 cable ties with heavy-duty duct tape.



Cut the taped bag sleeve at the mid point with the ratchet cutter.

Wipe the ratchet cutter and handle with a cleaning wipe to remove any contamination.

Dispose of the wipe in a hazardous waste bag.



Carefully place the duct with sealed filter sleeve cover to one side in a place where it will not be disturbed.



The fan unit lid can now be removed leaving the sealed filter assembly standing in the fan house cavity. The filter is now safe to remove.

- Wipe the top of the filter housing lid with a cleaning wipe and place to one side.
- Using the bag the new filter is supplied in lift the old filter out and zip tie the bag shut (the new filter should be put to one side).
- Place into a second hazard bag along with your top pair of gloves and seal with a zip tie.
- Place the double-bagged filter in the box the new filter came in, seal the box and label with the contents ready for disposal.

4. Place the new HEPA filter into the fan unit, replace clean lid, pull the sleeve material through and open out around the entrance to the filter.

Turn on the fan again ensuring that the bag-out sleeve is secure and not being drawn in by the filter.

Put a second pair of gloves on.



Position the flexible duct so the end of the duct is above the centre of the new filter.



Loosen the jubilee clip and using a hazardous waste bag, ease the sleeve and jubilee clip from the duct and seal. Place to one side.



CAUTION

Contamination Risk

This is the highest risk part of the filter change because the duct is open potentially exposing any hazardous contaminants inside.



Keeping the duct over the filter opening, slide the vent ducting over the sleeve and filter housing inlet. Once the ducting is in place over the sleeve there should be excess sleeve material showing which must be wrapped around the outside of the duct.



Around this sleeve material and onto the fan inlet spigot, fasten a jubilee clip with a flat head screwdriver to secure the ducting and sleeve in place.

Ensure the jubilee clip is secure.

Wipe the screwdriver with a clean wipe, dispose of the wipe in a hazardous waste bag.

The filter change is complete.

Now follow equipment clean up and PPE removal procedure.

Equipment Clean up after Filter Change

Prepare a hazardous waste bag for wipes and gloves.

Place bagged waste sleeve in another hazardous waste bag, seal and label with contents.

Dispose of second pair of gloves (into hazardous waste bag) and replace with clean gloves.

Wipe the outside of the duct for 1 m from the connection point with a cleaning wipe. Dispose of wipe in hazardous waste bag.

Wipe the top and sides of the filter housing with a cleaning wipe.

Dispose of wipe in hazardous waste bag.

Wipe any other tools used with a cleaning wipe. Dispose of wipe in hazardous waste bag.

PPE Removal

To remove a coverall suit or over coat:

Aseptically remove coverall suit.

Carefully work suit off shoulders without touching under clothes.

If necessary, reach behind and with fingertips and pull coverall from middle of back.

Pull arms from the inside out removing outer second pair of gloves as well.

Once at waist level and touching only the inside of the suit, work the suit to your ankles by rolling it down.

At this point, step out of the suit and remove coverall boots/overshoes.

Roll the suit up keeping the contaminated side inwards.

Place in a hazardous waste bag twice, seal and label.

Finally, remove re-useable respirator full-face mask and clean as per maintenance procedure.

Remove final pair of gloves and dispose in hazardous waste bag.

Final Waste Removal

Take additional hazardous waste bags, seal then place into a second hazardous waste bag, seal and label with contents.

Ensure all hazardous waste is collected, or made available for disposal.

Thoroughly wash hands, wrists and face.

10.4 Disposal



In conformance with the European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) this device may not be disposed of in domestic waste.

This also applies to countries outside the EU, per their specific requirements.

Please dispose of this product in accordance with local regulations at the collecting point specified for electrical and electronic equipment.

If you have any questions, please contact the responsible authority or the distributor from which you purchased this device.

Should this device be passed on to other parties (for private or professional use), the content of this regulation must also be related.

Thank you for your contribution to environmental protection.

11 Troubleshooting

| | |
|--|--|
| Alarm lights not on | <ul style="list-style-type: none">• Check power connections |
| Fan Switch not illuminated | <ul style="list-style-type: none">• Check power connections |
| Airflow Alarm Sounding Frequently | <ul style="list-style-type: none">• Check fan switched on• Check for obstructions near sensor• Check connections to sensors• Check airflow with smoke tubes• Check airflow with anemometer |
| Alarm Sounding Intermittently | <ul style="list-style-type: none">• Check for obstructions near sensors• Check airflow profile near enclosure for drafts from air conditioning units, doors etc.• Check room pressure relative to corridor• Measure airflow (ensure more than 0.35 m/s) |
| Alarm Display (data logger full) | <ul style="list-style-type: none">• Download data to clear memory |
| Face Velocity below 0.35 m/s | <ul style="list-style-type: none">• Check fan is switched on• Check for obstructions at fan exhaust• Check that ducting fitted correctly• Check Filter sleeve fitted correctly• Increase fan motor speed |

12 Accessories

| Designation | Part No. |
|-----------------------|----------|
| Label printer adapter | 11141294 |

13 EC Declaration of Conformity

Manufacture: **a1-envirosciences**
Brühlweg 1
CH-4132 Muttenz

Product: **QSE2 Enclosure System**
Models: **QSE2 230 V, QSE2 110 V**

The above named product conforms to the requirements of the following European Directives:

2006/95/EC Low Voltage Directive
2004/108/EC Electromagnetic Compatibility

Conformity with the requirements of the above directives is testified by adherence to the following harmonized standards:

EN 55014 Part 1 and Part 2Product Standard for Motor Operated Appliances
EN 61010-1: 2001 + EN 61010-2-040 : 2005Safety requirements for electrical equipment for measurement, control, and laboratory use

a1-envirosciences

23rd September 2011



Christian Weinmann

For and on behalf of a1-envirosciences

Brühlweg 1, CH-4132 Muttenz
Tel +44 (0)61 461 99 11, Fax +44 (0)61 461 99 22

Quantos Safety Enclosure QSE2 for the METTLER TOLEDO Quantos QB5 Automated Powder Dosing System

Control Performance Evaluation, SafeBridge Europe, Ltd.

Control performance of the Quantos safety enclosure QSE2, manufactured by a1-safetech, was evaluated by SafeBridge Europe, Limited in May 2008 during simulated weighing operations using the Quantos QB5 automated powder dosing system.

Simulated weighing operations using naproxen sodium as a surrogate active pharmaceutical ingredient, were undertaken by trained a1-safetech personnel in a demonstration laboratory under controlled conditions. Standardised weighing and cleaning procedures were used, which included safe handling techniques designed to achieve good control performance. A highly sensitive occupational hygiene measurement technique was used to detect releases of airborne naproxen sodium during the weighing and cleaning operations.

The control performance of the QSE2 was evaluated by applying the principles of EN 689¹ to three sets of measurements of airborne surrogate concentration outside the enclosure during use of the QB5 dosing system and was found to be 8 ng/m³.

Results of the measurements indicate potential control performance of the Quantos safety enclosure QSE2 under the test conditions used and represent control performance which could potentially be achieved in the workplace by trained operators applying safe handling techniques. Users of the Quantos safety enclosure QSE2 or any control device should undertake suitable control performance evaluation under the actual conditions of intended use.

SafeBridge recommends that powder handling enclosure systems such as the QSE2 be used in a suitable laboratory environment by trained operators. Operators may need to wear respiratory protective equipment which is appropriate for the task.

For full details of the study, please refer to SafeBridge Report prepared for a1-envirosciences (proposal 1.1B) dated July 2008.

¹EN 689, 1996 Workplace atmospheres — Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy

GWP® – Good Weighing Practice™

The global weighing guideline GWP® reduces risks associated with your weighing processes and helps to

- choose the appropriate balance
- reduce costs by optimizing testing procedures
- comply with the most common regulatory requirements

► www.mt.com/GWP

www.mt.com/quantos

For more information

Mettler-Toledo AG Laboratory & Weighing Technologies

CH-8606 Greifensee, Switzerland

Tel. +41 (0)44 944 22 11

Fax +41 (0)44 944 30 60

Internet: www.mt.com

Subject to technical changes.

© Mettler-Toledo AG 10/2011

11781243A en



* 1 1 7 8 1 2 4 3 *